EXHIBIT A

US005997476A

United States Patent [19]

Brown

[11] Patent Number: 5,997,476

[45] Date of Patent: Dec. 7, 1999

[54] **NETWORKED SYSTEM FOR INTERACTIVE COMMUNICATION AND REMOTE MONITORING OF INDIVIDUALS**

[75] Inventor: **Stephen J. Brown**, Mountain View, Calif.

[73] Assignee: **Health Hero Network, Inc.**, Mountain View, Calif.

[21] Appl. No.: **08/946,341**

[22] Filed: **Oct. 7, 1997**

Related U.S. Application Data

[63] Continuation of application No. 08/847,009, Apr. 30, 1997, Pat. No. 5,897,493

[60] Provisional application No. 60/041,746, Mar. 28, 1997, and provisional application No. 60/041,751, Mar. 28, 1997.

[51] **Int. Cl.**[6] **A61N 5/00**

[52] **U.S. Cl.** **600/300**; 600/301; 128/920; 705/2; 705/3

[58] **Field of Search** 600/300, 301; 379/93; 705/2, 3; 128/904, 905, 920–925, 897–898

[56] **References Cited**

U.S. PATENT DOCUMENTS

5,299,121	3/1994	Brill et al.	600/301
5,390,238	2/1995	Kirk et al.	379/93
5,410,471	4/1995	Alyfuku et al.	600/300
5,434,611	7/1995	Tamura	348/8
5,441,047	8/1995	David et al.	128/670
5,544,649	8/1996	David et al.	600/301
5,619,991	4/1997	Sloane	600/300

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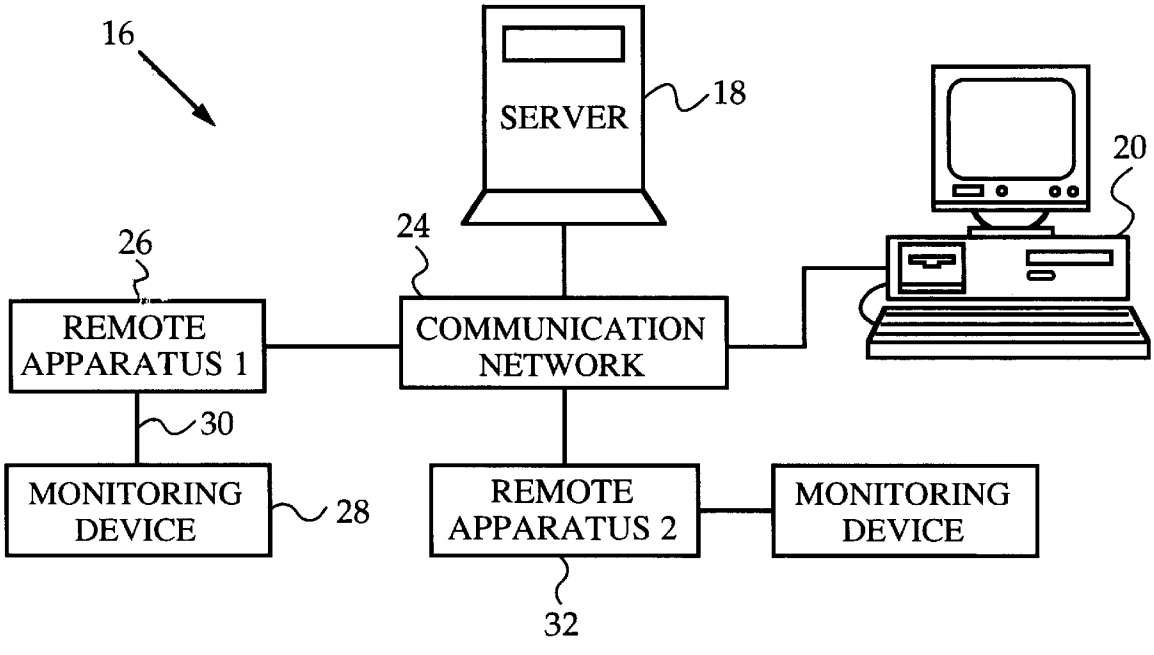
0251520	1/1988	European Pat. Off.	15/42
0320749	6/1989	European Pat. Off.	15/42
9520199	7/1995	WIPO .	
9708605	3/1997	WIPO .	

Primary Examiner—Cary O'Connor
Assistant Examiner—Michael Astorino
Attorney, Agent, or Firm—Lumen Intellectual Property Services

[57] **ABSTRACT**

The invention presents a networked system for communicating information to an individual and for remotely monitoring the individual. The system includes a server and a remote interface for entering in the server a set of queries to be answered by the individual. The server is preferably a web server and the remote interface is preferably a personal computer or remote terminal connected to the server via the Internet. The system also includes a remotely programmable apparatus connected to the server via a communication network, preferably the Internet. The apparatus interacts with the individual in accordance with a script program received from the server. The server includes a script generator for generating the script program from the set of queries entered through the remote interface. The script program is received and executed by the apparatus to communicate the queries to the individual, to receive responses to the queries, and to transmit the responses from the apparatus to the server.

50 Claims, 15 Drawing Sheets



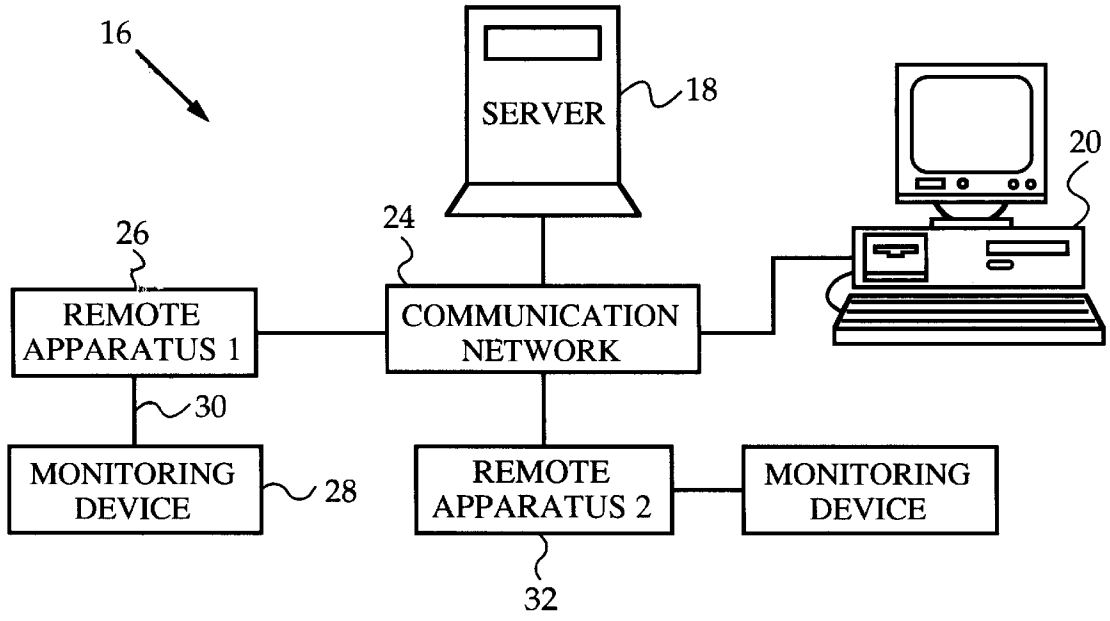

16
SERVER
18
20
24
26
REMOTE APPARATUS 1
COMMUNICATION NETWORK
30
MONITORING DEVICE
28
REMOTE APPARATUS 2
MONITORING DEVICE
32

FIG. 1

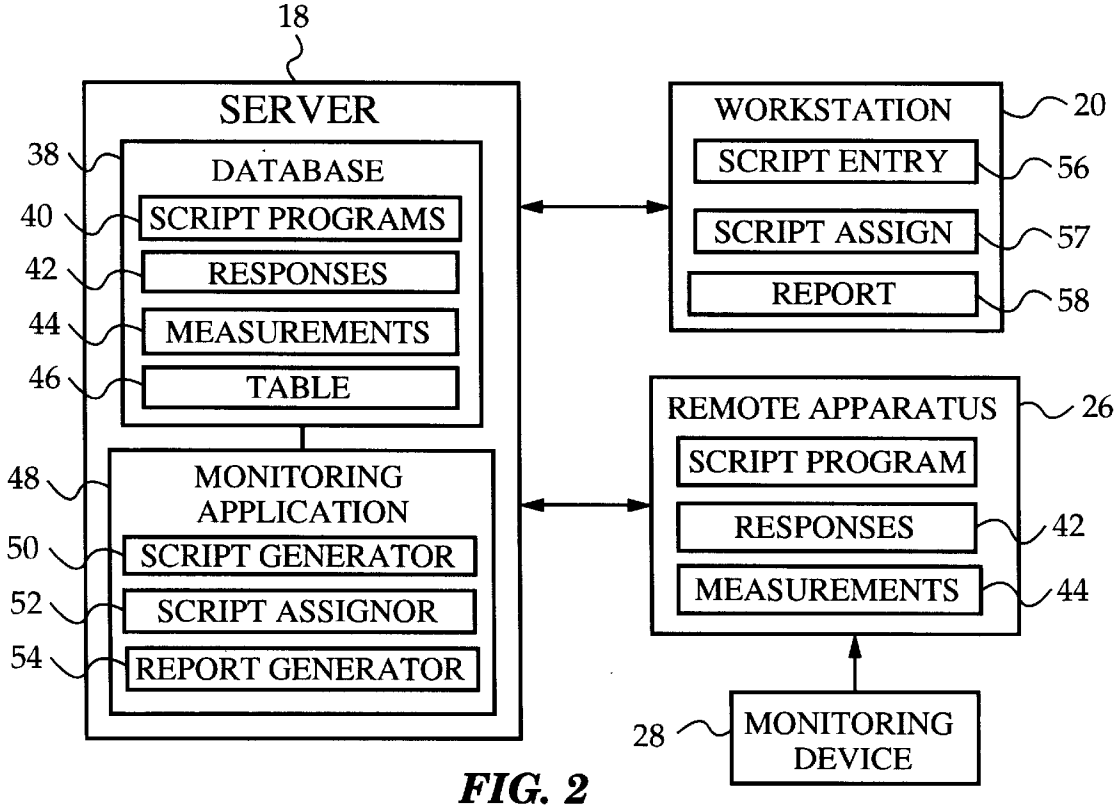

18
SERVER
38
DATABASE
40
SCRIPT PROGRAMS
42
RESPONSES
44
MEASUREMENTS
46
TABLE
48
MONITORING APPLICATION
50
SCRIPT GENERATOR
52
SCRIPT ASSIGNOR
54
REPORT GENERATOR
WORKSTATION
20
SCRIPT ENTRY
56
SCRIPT ASSIGN
57
REPORT
58
REMOTE APPARATUS
26
SCRIPT PROGRAM
RESPONSES
42
MEASUREMENTS
44
28
MONITORING DEVICE

FIG. 2

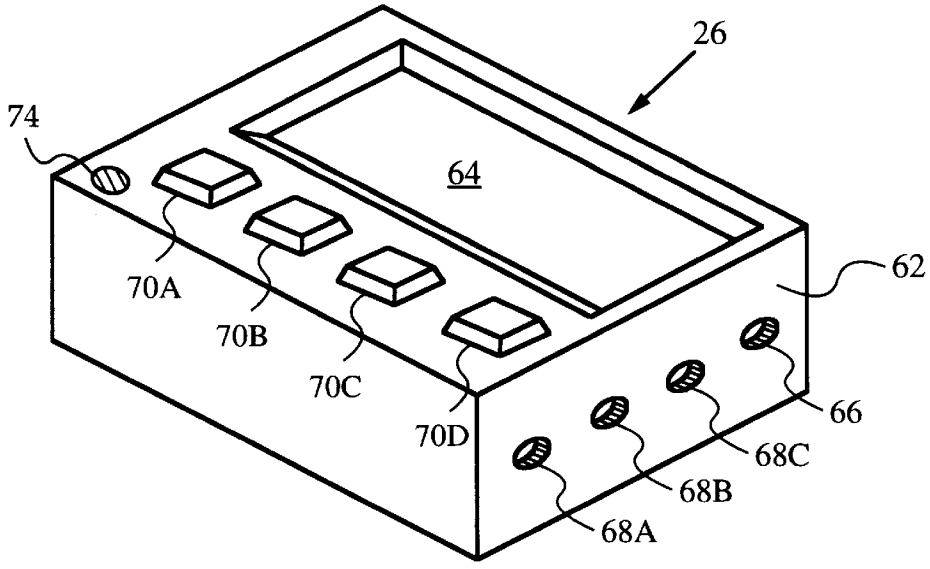

26
74
64
70A
70B
70C
70D
62
66
68C
68B
68A

FIG. 3

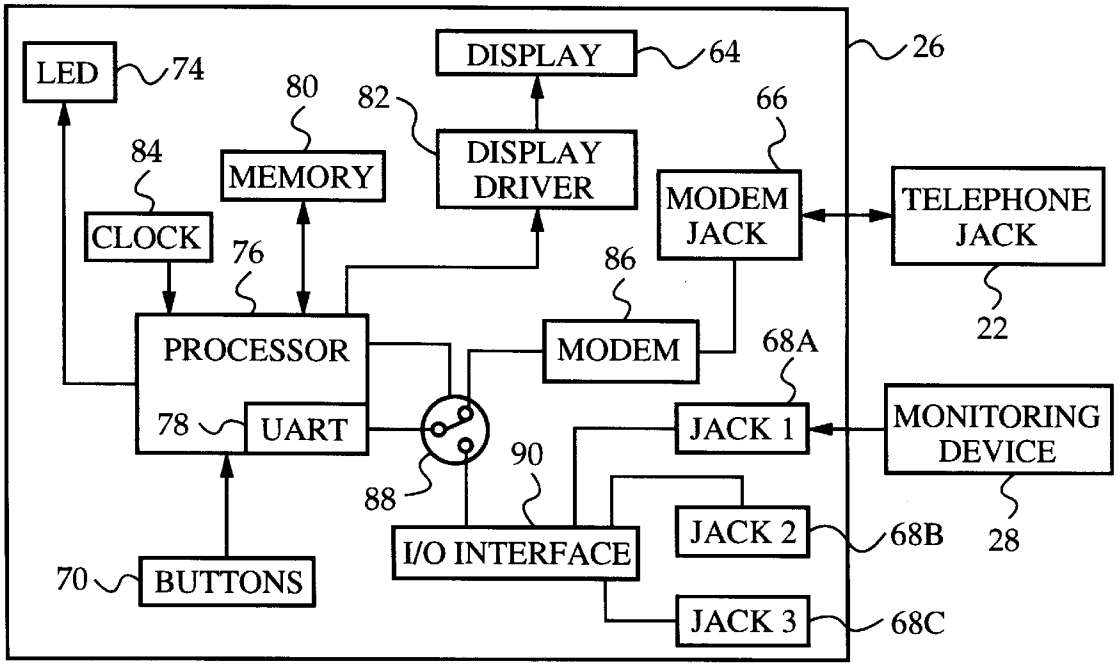

LED
74
DISPLAY
64
26
80
82
66
84
MEMORY
DISPLAY DRIVER
MODEM JACK
TELEPHONE JACK
CLOCK
76
86
22
PROCESSOR
MODEM
68A
78
UART
JACK 1
MONITORING DEVICE
90
88
JACK 2
68B
28
I/O INTERFACE
70
BUTTONS
JACK 3
68C

FIG. 4

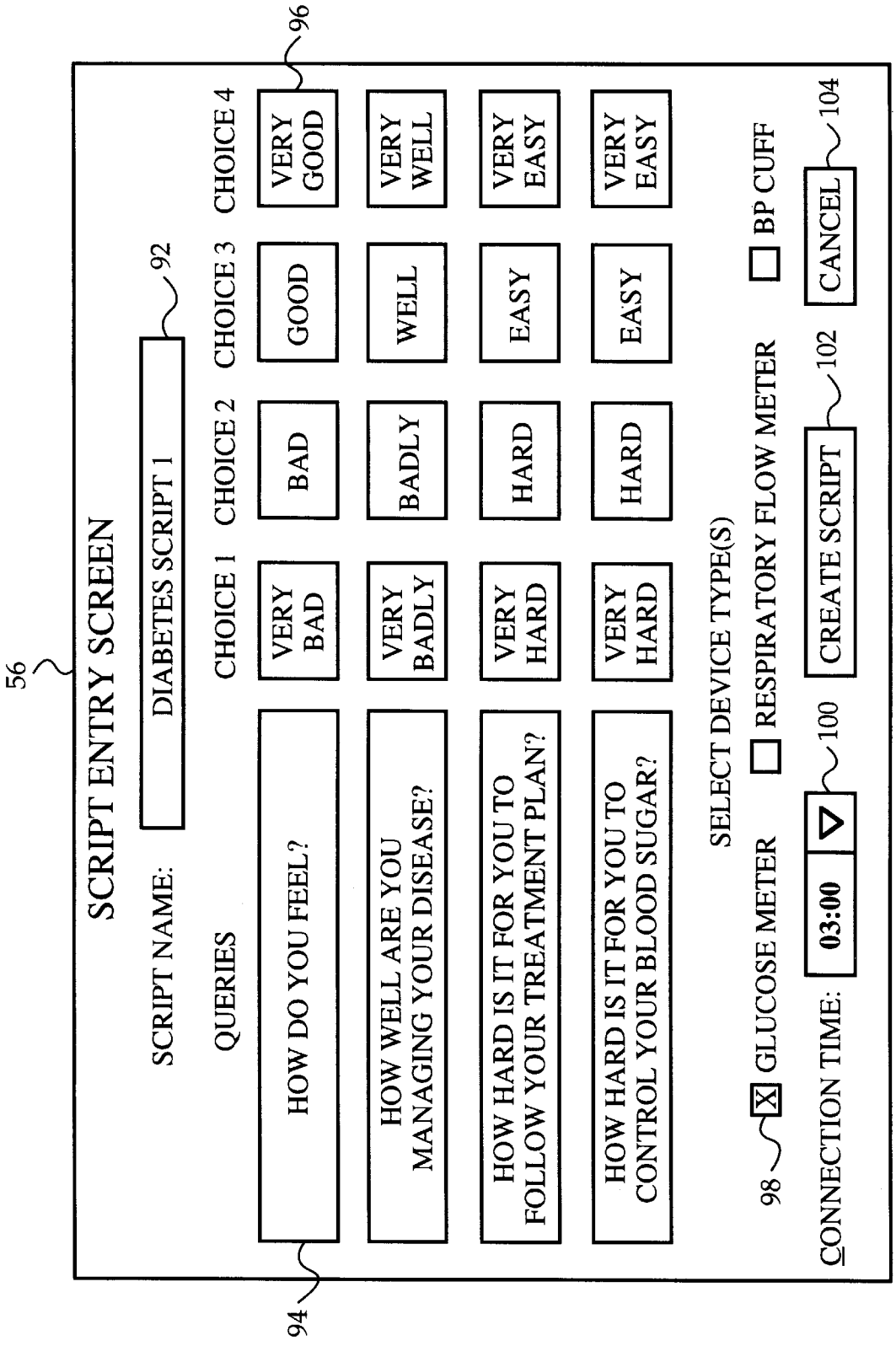

56
SCRIPT ENTRY SCREEN
SCRIPT NAME:
DIABETES SCRIPT 1
92
QUERIES
CHOICE 1
CHOICE 2
CHOICE 3
CHOICE 4
96
HOW DO YOU FEEL?
VERY BAD
BAD
GOOD
VERY GOOD
HOW WELL ARE YOU MANAGING YOUR DISEASE?
VERY BADLY
BADLY
WELL
VERY WELL
HOW HARD IS IT FOR YOU TO FOLLOW YOUR TREATMENT PLAN?
VERY HARD
HARD
EASY
VERY EASY
HOW HARD IS IT FOR YOU TO CONTROL YOUR BLOOD SUGAR?
VERY HARD
HARD
EASY
VERY EASY
94
SELECT DEVICE TYPE(S)
98
GLUCOSE METER
RESPIRATORY FLOW METER
BP CUFF
CONNECTION TIME:
03:00
100
CREATE SCRIPT
102
CANCEL
104

FIG. 5

```
NUMBER: 9001 {LF}

LED: 1 {LF}

ZAP: {LF}

CLS: {LF}

DISPLAY: ANSWER QUERIES NOW?
         PRESS ANY BUTTON TO START {LF}
WAIT: {LF}

CLS: {LF}

DISPLAY: HOW DO YOU FEEL?

              VERY                VERY
               BAD   BAD   GOOD  GOOD {LF}
INPUT: OOOO {LF}

CLS: {LF}

DISPLAY: HOW WELL ARE YOU
         MANAGING YOUR DISEASE?
         VERY                     VERY
         WELL   BADLY  WELL  WELL {LF}
INPUT: OOOO {LF}

CLS: {LF}

DISPLAY: HOW HARD IS IT FOR YOU TO
         FOLLOW YOUR TREATMENT PLAN?
         VERY                VERY
         HARD   HARD  EASY  EASY {LF}
INPUT: OOOO {LF}

CLS: {LF}

DISPLAY: HOW HARD IS IT FOR YOU TO
         CONTROL YOUR BLOOD SUGAR?
         VERY                VERY
         HARD   HARD  EASY  EASY {LF}
```

FIG. 6A

INPUT: OOOO {LF}

CLS: {LF}

DISPLAY: CONNECT GLUCOSE METER
AND PRESS ANY BUTTON
WHEN FINISHED {LF}

WAIT: {LF}

CLS: {LF}

DISPLAY: COLLECTING MEASUREMENTS {LF}

COLLECT: GLUCOSE_METER {LF}

CLS: {LF}

DISPLAY: CONNECT APPARATUS TO
TELEPHONE JACK AND
PRESS ANY BUTTON
WHEN FINISHED {LF}

WAIT: {LF}

LED: 0 {LF}

CLS: {LF}

DELAY: 03:00 {LF}

DISPLAY: CONNECTING TO SERVER {LF}

CONNECT: {LF}

{EOF}

FIG. 6B

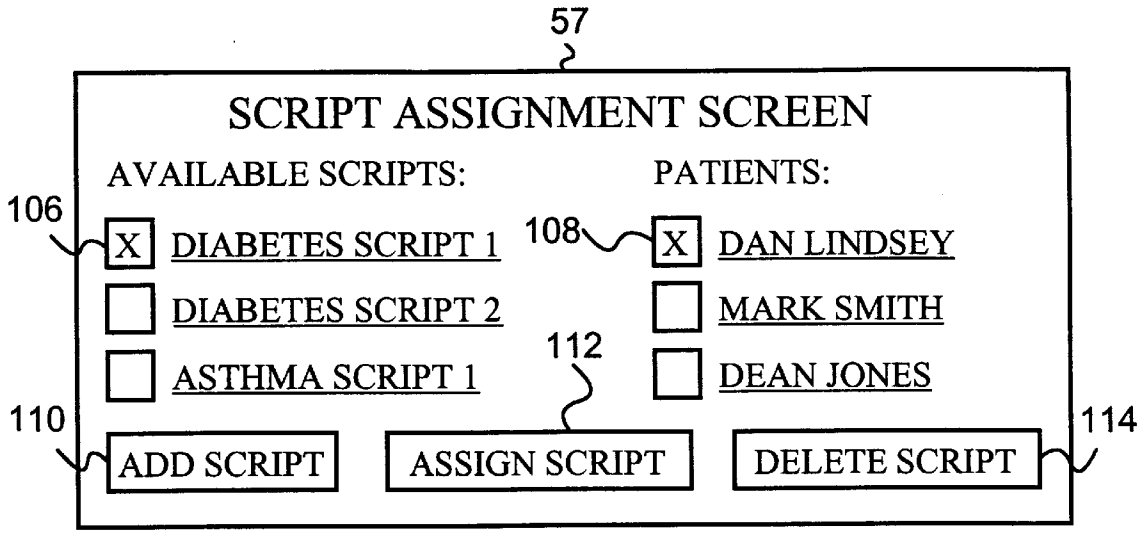


FIG. 7

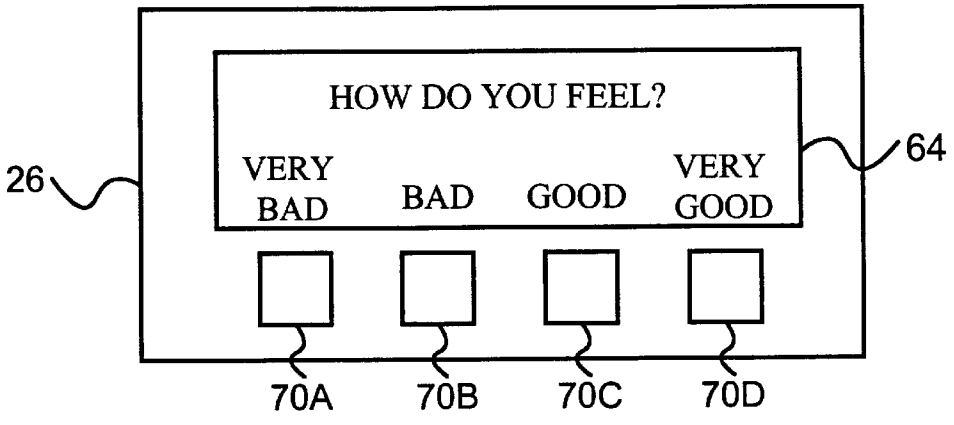


FIG. 8

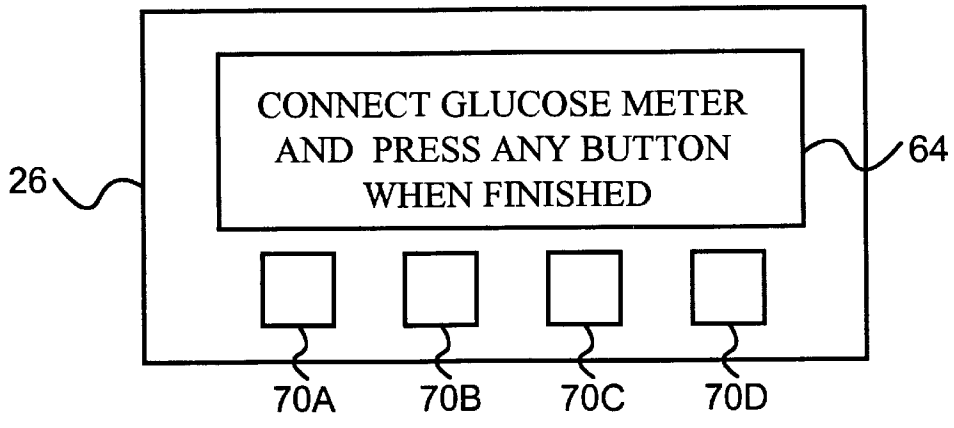


FIG. 9

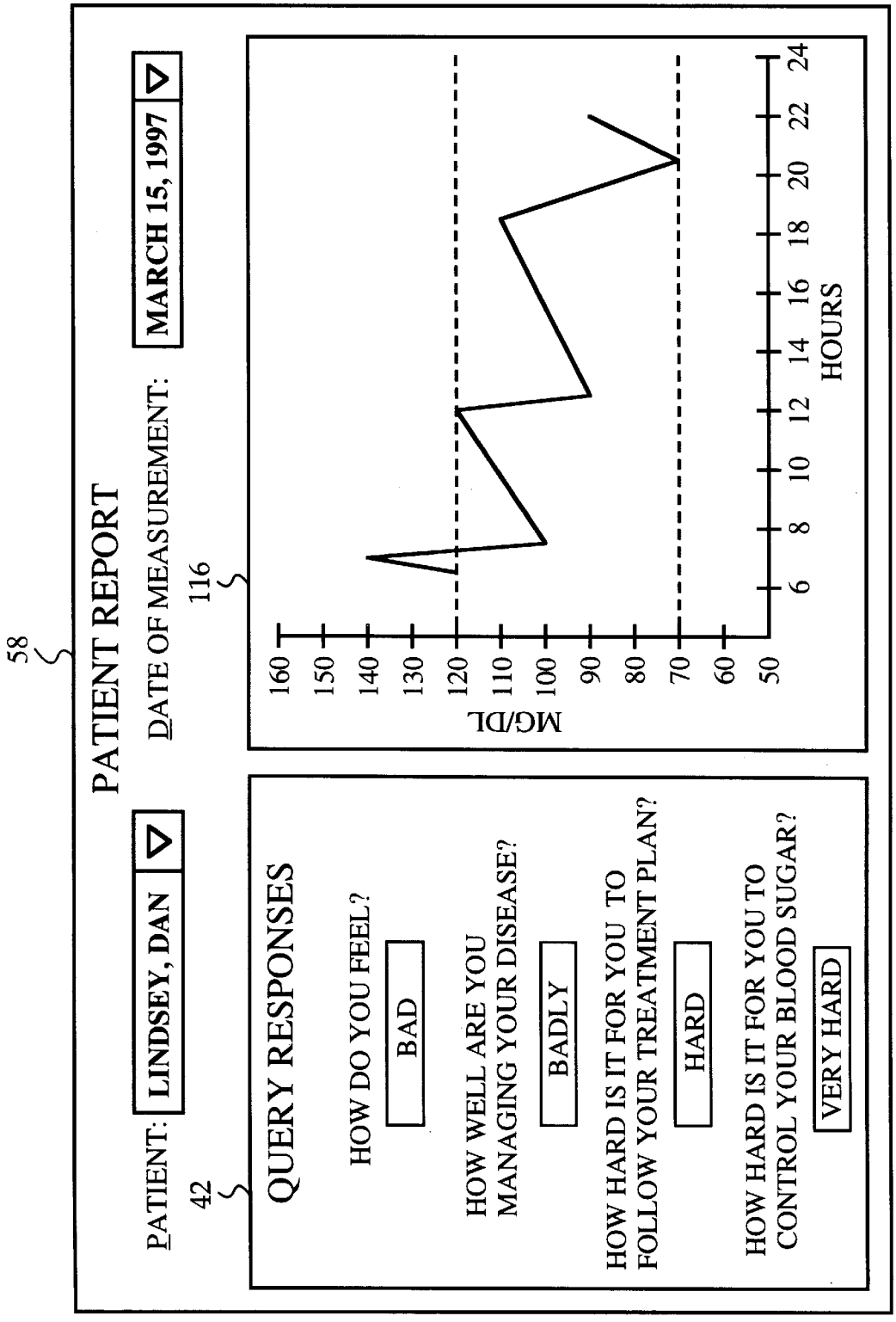

58
PATIENT REPORT
PATIENT: LINDSEY, DAN
DATE OF MEASUREMENT: MARCH 15, 1997
42
116
QUERY RESPONSES
HOW DO YOU FEEL?
BAD
HOW WELL ARE YOU MANAGING YOUR DISEASE?
BADLY
HOW HARD IS IT FOR YOU TO FOLLOW YOUR TREATMENT PLAN?
HARD
HOW HARD IS IT FOR YOU TO CONTROL YOUR BLOOD SUGAR?
VERY HARD
MG/DL
160
150
140
130
120
110
100
90
80
70
60
50
6
8
10
12
14
16
18
20
22
24
HOURS

FIG. 10

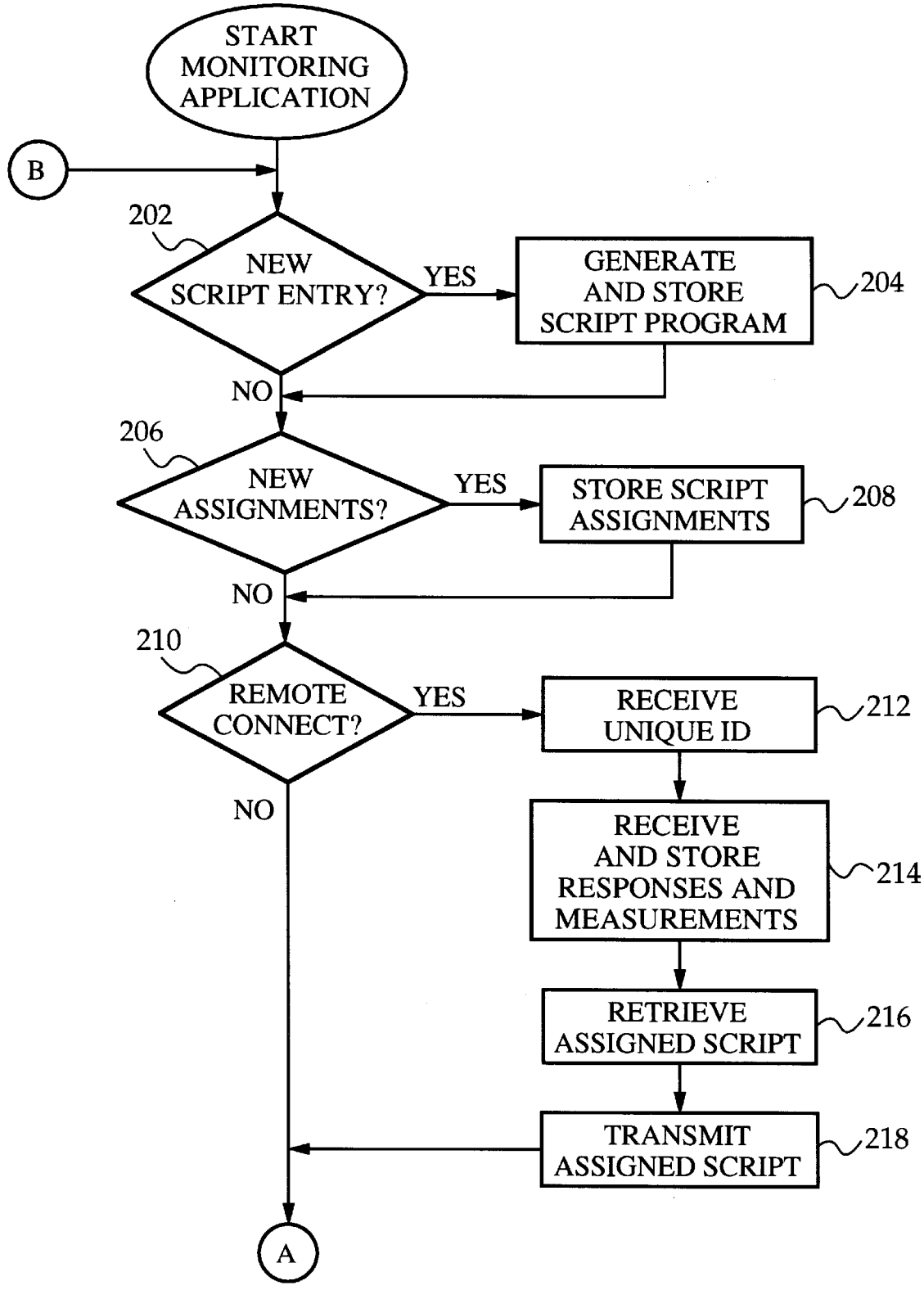

START MONITORING APPLICATION
B
202
NEW SCRIPT ENTRY?
YES
GENERATE AND STORE SCRIPT PROGRAM
204
NO
206
NEW ASSIGNMENTS?
YES
STORE SCRIPT ASSIGNMENTS
208
NO
210
REMOTE CONNECT?
YES
RECEIVE UNIQUE ID
212
NO
RECEIVE AND STORE RESPONSES AND MEASUREMENTS
214
RETRIEVE ASSIGNED SCRIPT
216
TRANSMIT ASSIGNED SCRIPT
218
A

FIG. 11A

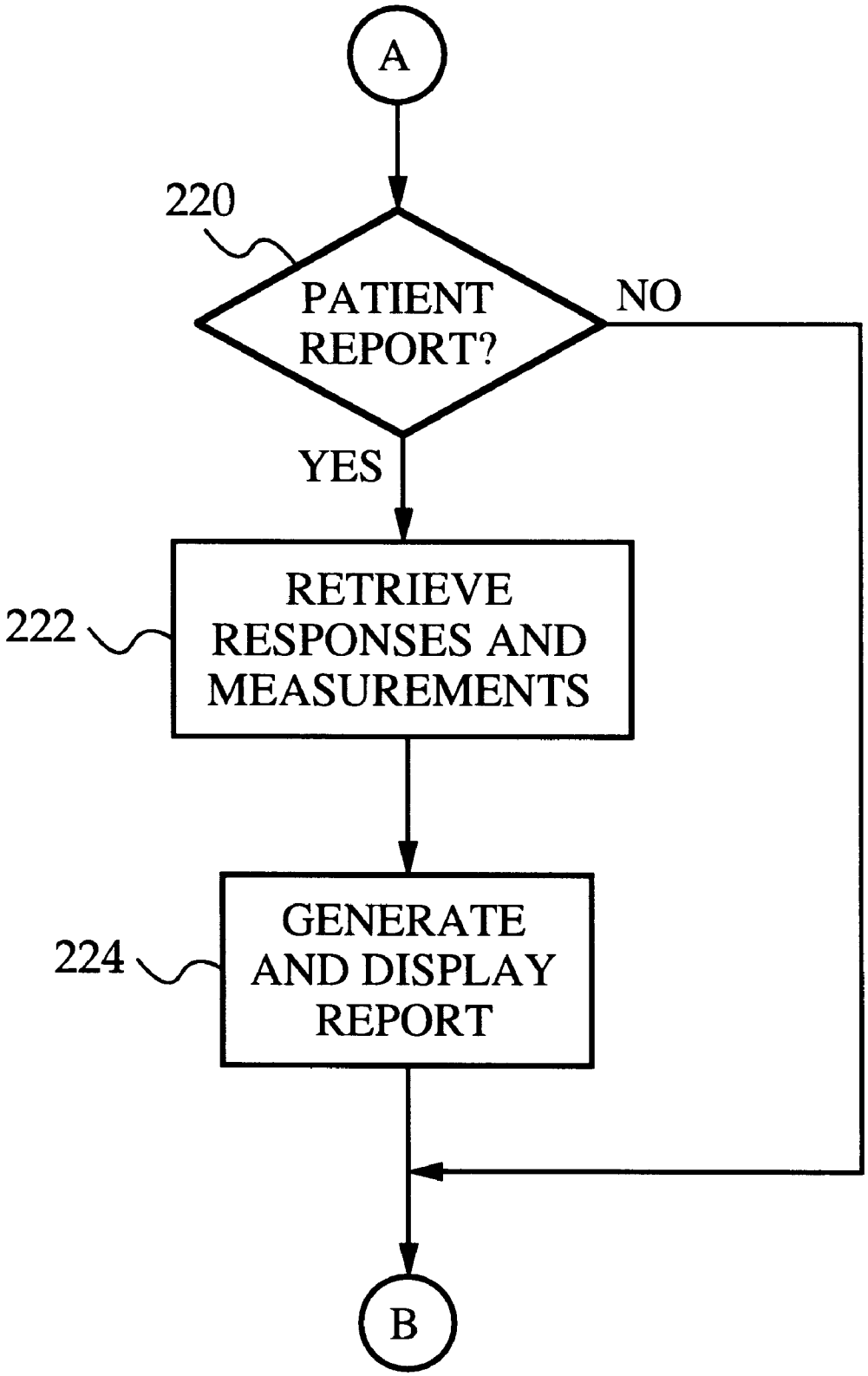

A
220
PATIENT REPORT?
NO
YES
222
RETRIEVE RESPONSES AND MEASUREMENTS
224
GENERATE AND DISPLAY REPORT
B

FIG. 11B

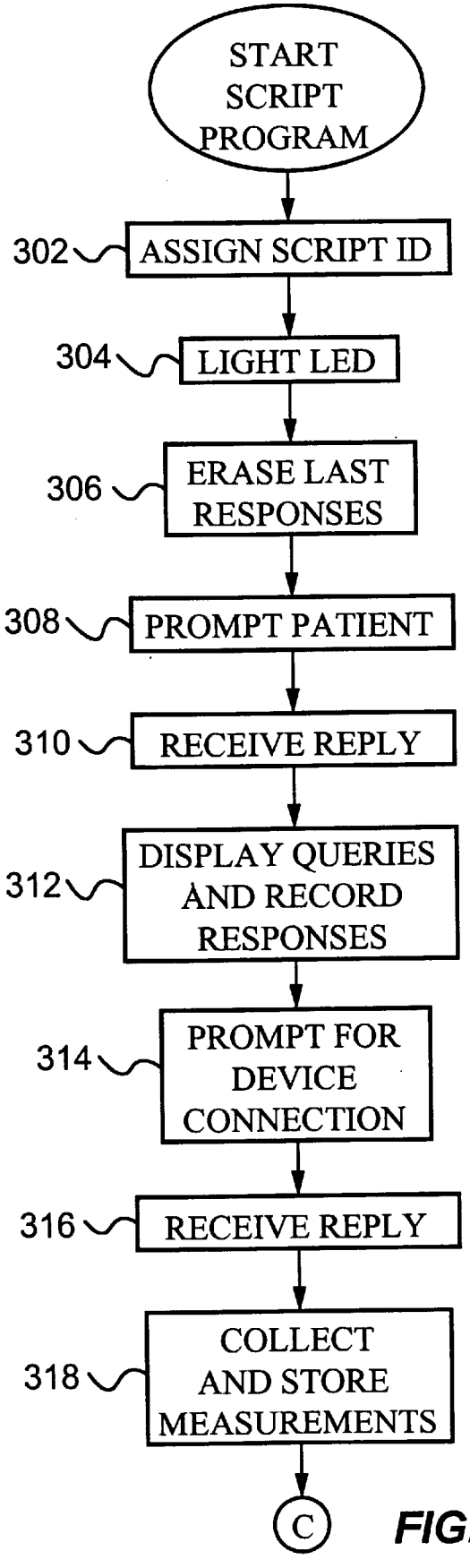

START SCRIPT PROGRAM
302
ASSIGN SCRIPT ID
304
LIGHT LED
306
ERASE LAST RESPONSES
308
PROMPT PATIENT
310
RECEIVE REPLY
312
DISPLAY QUERIES AND RECORD RESPONSES
314
PROMPT FOR DEVICE CONNECTION
316
RECEIVE REPLY
318
COLLECT AND STORE MEASUREMENTS
C

FIG. 12A

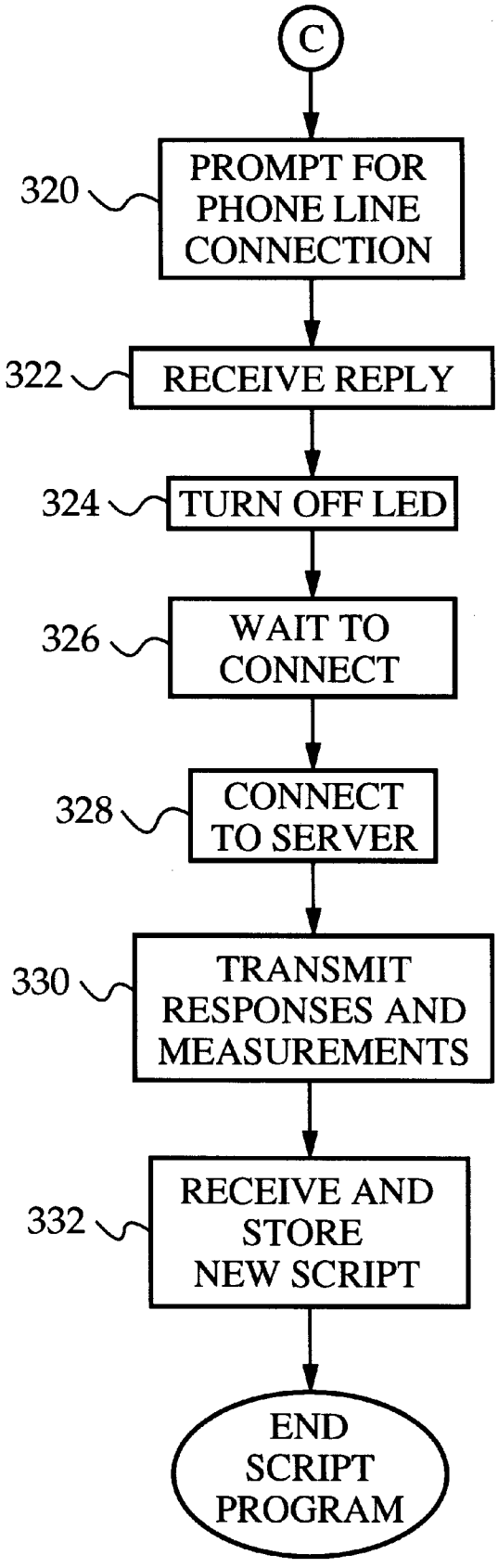

C
320
PROMPT FOR PHONE LINE CONNECTION
322
RECEIVE REPLY
324
TURN OFF LED
326
WAIT TO CONNECT
328
CONNECT TO SERVER
330
TRANSMIT RESPONSES AND MEASUREMENTS
332
RECEIVE AND STORE NEW SCRIPT
END SCRIPT PROGRAM

FIG. 12B

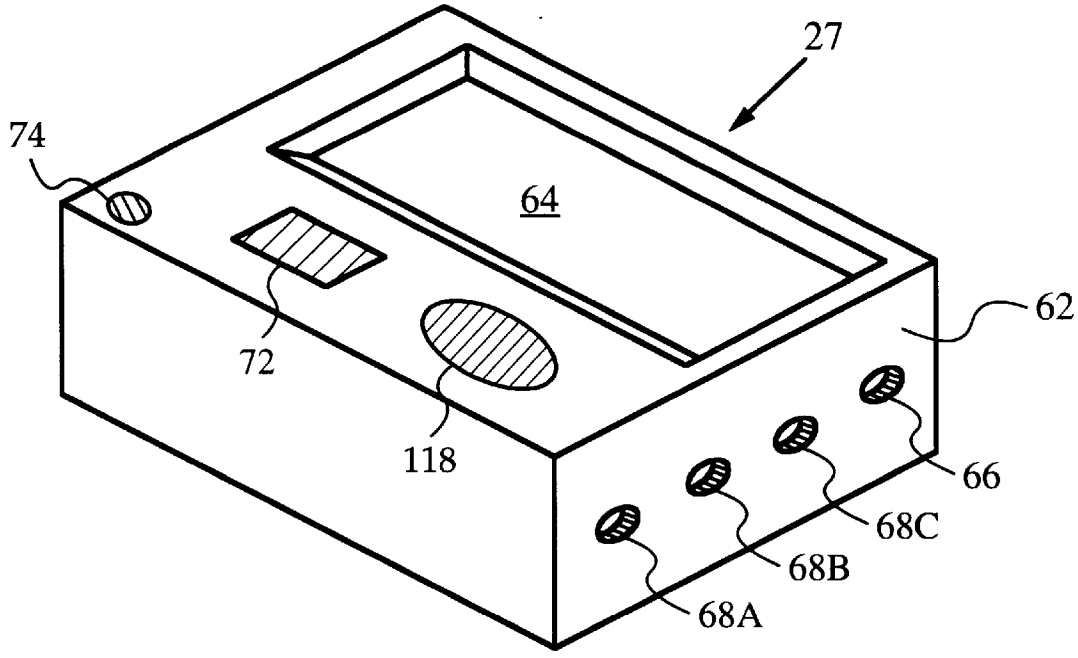

27
74
64
62
72
118
66
68C
68B
68A

FIG. 13

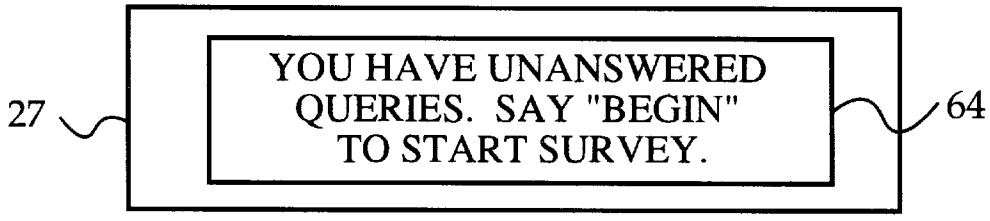

YOU HAVE UNANSWERED QUERIES. SAY "BEGIN" TO START SURVEY.
27
64

FIG. 14

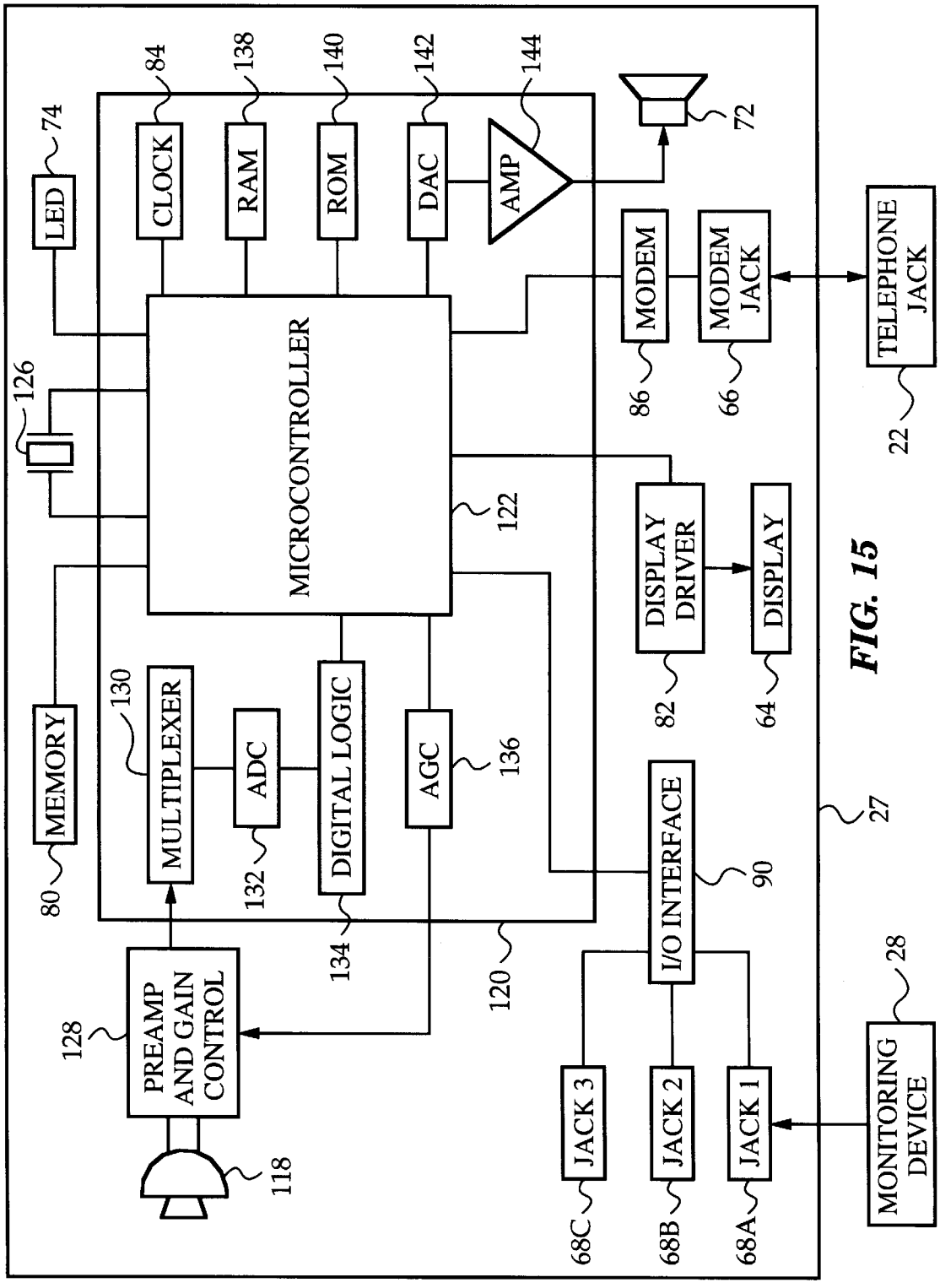

LED
74
CLOCK
84
RAM
138
ROM
140
DAC
142
AMP
144
72
MODEM
86
MODEM JACK
66
TELEPHONE JACK
22
126
MICROCONTROLLER
122
DISPLAY DRIVER
82
DISPLAY
64
MEMORY
80
MULTIPLEXER
130
ADC
132
DIGITAL LOGIC
134
AGC
136
I/O INTERFACE
90
27
PREAMP AND GAIN CONTROL
128
118
120
JACK 3
68C
JACK 2
68B
JACK 1
68A
MONITORING DEVICE
28

FIG. 15

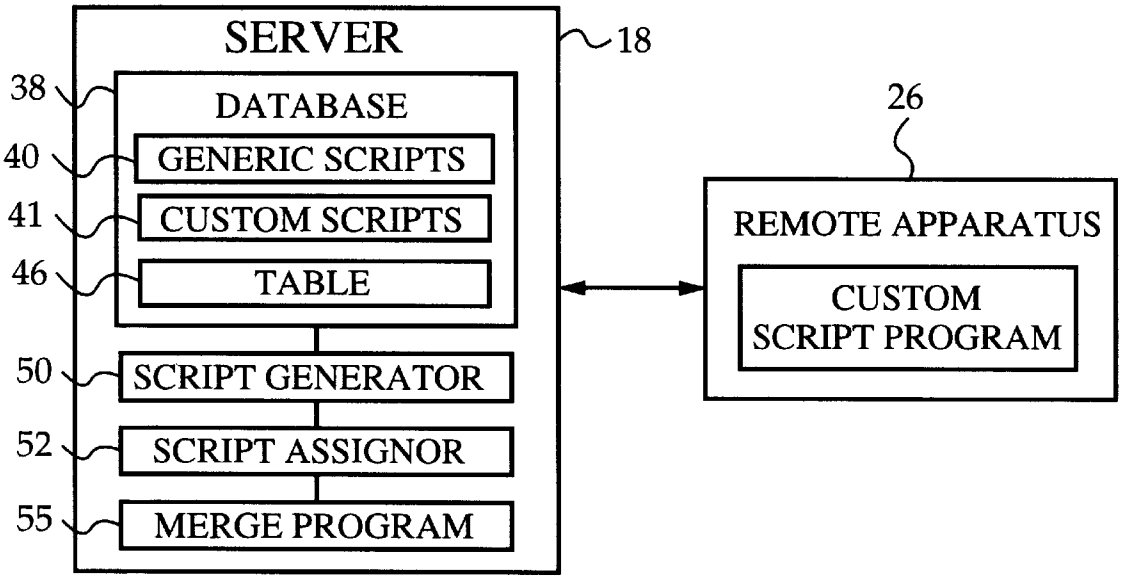


FIG. 16

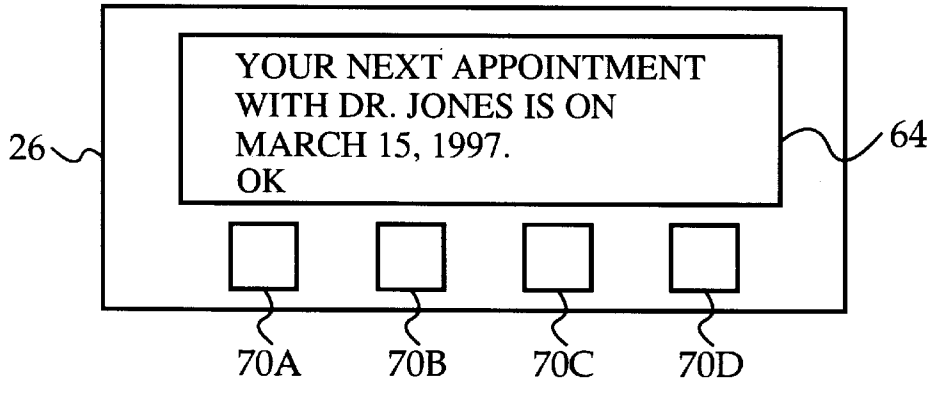


FIG. 17

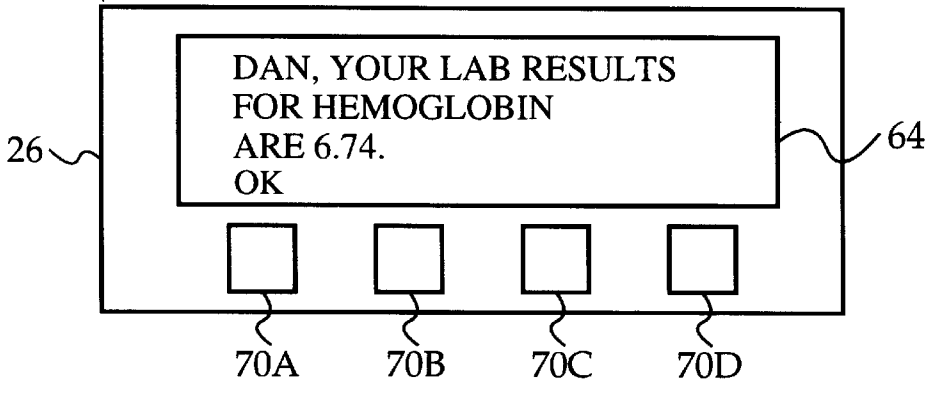


FIG. 18

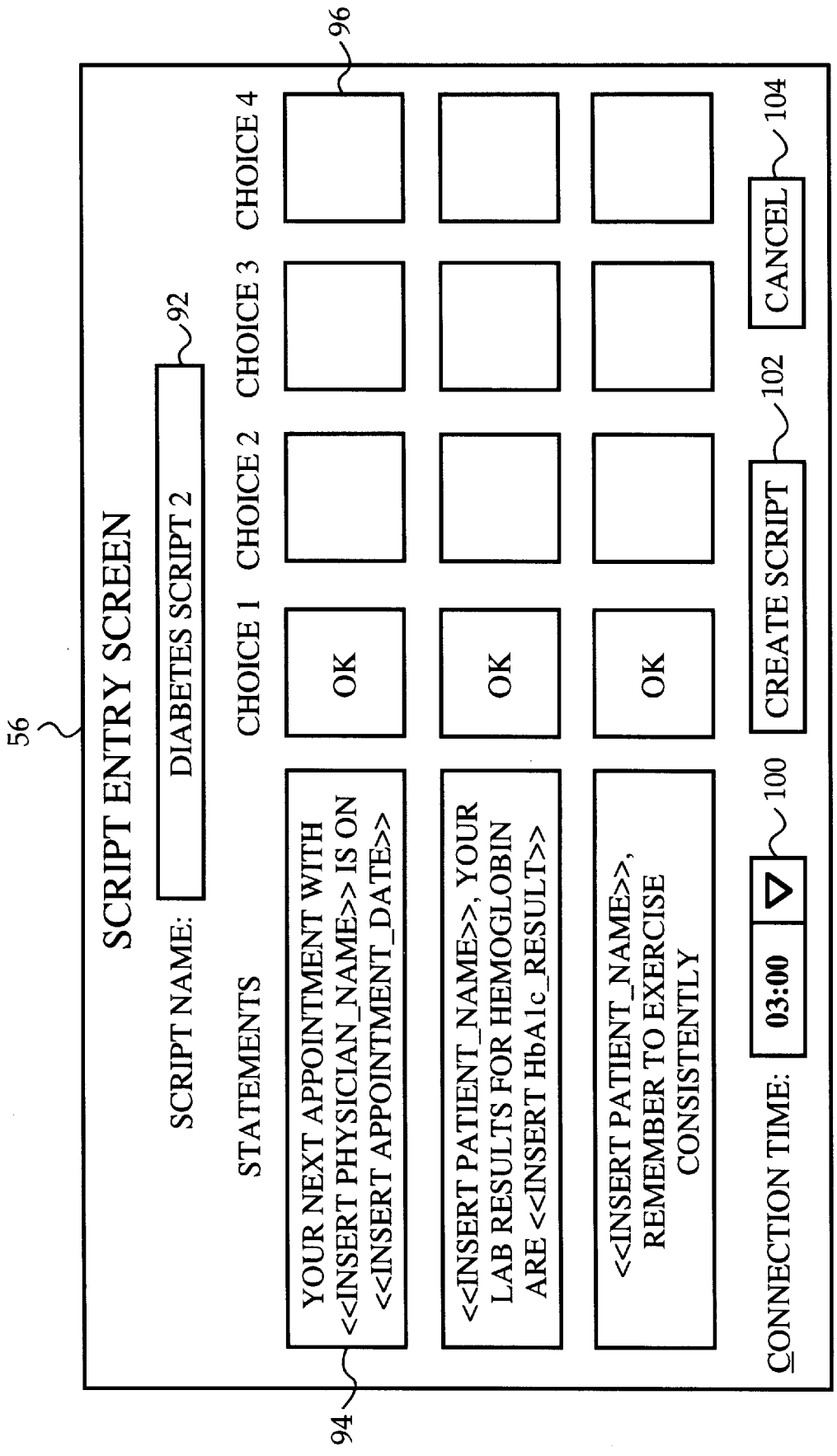

56
SCRIPT ENTRY SCREEN
SCRIPT NAME:
DIABETES SCRIPT 2
92
STATEMENTS
CHOICE 1
CHOICE 2
CHOICE 3
CHOICE 4
96
YOUR NEXT APPOINTMENT WITH <<INSERT PHYSICIAN_NAME>> IS ON <<INSERT APPOINTMENT_DATE>>
OK
<<INSERT PATIENT_NAME>>, YOUR LAB RESULTS FOR HEMOGLOBIN ARE <<INSERT HbA1c_RESULT>>
OK
<<INSERT PATIENT_NAME>>, REMEMBER TO EXERCISE CONSISTENTLY
OK
94
CONNECTION TIME:
03:00
100
CREATE SCRIPT
102
CANCEL
104

FIG. 19

NETWORKED SYSTEM FOR INTERACTIVE COMMUNICATION AND REMOTE MONITORING OF INDIVIDUALS

RELATED APPLICATION INFORMATION

This application is a continuation in part of application Ser. No. 08/847,009 filed Apr. 30, 1997 now U.S. Pat. No. 5,897,493. This application also claims priority from provisional application Ser. No. 60/041,746 filed Mar. 28, 1997 and from provisional application Ser. No. 60/041,751 filed Mar. 28, 1997. This application also claims priority from an application with Ser. No. 09/201,323 entitled "Leveraging Interactions with a Community of Individuals", filed Nov. 30, 1998 and from an application with Ser. No. 09/274,433 entitled "Client-Initiated Leveraged Interaction with Providers", filed Mar. 22, 1999. All of the above named applications are hereby incorporated by reference.

FIELD OF THE INVENTION

The present invention relates generally to communication systems for remote monitoring of individuals, and in particular to a networked system for remotely monitoring individuals and for communicating information to the individuals through the use of script programs.

BACKGROUND OF THE INVENTION

In the United States alone, over 100 million people have chronic health conditions, accounting for an estimated $700 billion in annual medical costs. In an effort to control these medical costs, many healthcare providers have initiated outpatient or home healthcare programs for their patients. The potential benefits of these programs are particularly great for chronically ill patients who must treat their diseases on a daily basis. However, the success of these programs is dependent upon the ability of the healthcare providers to monitor the patients remotely to avert medical problems before they become complicated and costly. Unfortunately, no convenient and cost effective monitoring system exists for the patients who have the greatest need for monitoring, the poor and the elderly.

Prior attempts to monitor patients remotely have included the use of personal computers and modems to establish communication between patients and healthcare providers. However, computers are too expensive to give away and the patients who already own computers are only a small fraction of the total population. Further, the patients who own computers are typically young, well educated, and have good healthcare coverage. Thus, these patients do not have the greatest unmet medical needs. The patients who have the greatest unmet medical needs are the poor and elderly who do not own computers or who are unfamiliar with their use.

Similar attempts to establish communication between patients and healthcare providers have included the use of the Internet and internet terminals. Although internet terminals are somewhat less costly than personal computers, they are still too expensive to give away to patients. Moreover, monthly on-line access charges are prohibitive for poor patients.

Other attempts to monitor patients remotely have included the use of medical monitoring devices with built-in modems. Examples of such monitoring devices include blood glucose meters, respiratory flow meters, and heart rate monitors. Unfortunately, these monitoring devices are only designed to collect physiological data from the patients. They do not allow flexible and dynamic querying of the patients for other

information, such as quality of life measures or psychosocial variables of illness.

Prior attempts to monitor patients remotely have also included the use of interactive telephone or video response systems. Such interactive systems are disclosed in U.S. Pat. No. 5,39.0,238 issued to Kirk et al. on Feb. 14, 1995, U.S. Pat. No. 5,434,611 issued to Tamura on Jul. 18, 1995, and U.S. Pat. No. 5,441,047 issued to David et al. on Aug. 15, 1995. One disadvantage of these systems is that they either require a patient to call in to a central facility to be monitored or require the central facility to call the patient according to a rigid monitoring schedule.

If the patients are required to call the central facility, only the compliant patients will actually call regularly to be monitored. Non-compliant patients will typically wait until an emergency situation develops before contacting their healthcare provider, thus defeating the purpose of the monitoring system. If the central facility calls each patient according to a monitoring schedule, it is intrusive to the patient's life and resistance to the monitoring grows over time.

Another disadvantage of these conventional interactive response systems is that they are prohibitively expensive for poor patients. Further, it is difficult to identify each patient uniquely using these systems. Moreover, these systems are generally incapable of collecting medical data from monitoring devices, such as blood glucose meters, respiratory flow meters, or heart rate monitors.

OBJECTS AND ADVANTAGES OF THE INVENTION

In view of the above, it is an object of the present invention to provide a simple and inexpensive system for remotely monitoring patients and for communicating information to the patients. It is another object of the invention to provide a system which allows flexible and dynamic querying of the patients. It is a further object of the invention to provide a system which combines querying of patients with medical device monitoring in the same monitoring session. Another object of the invention is to provide a monitoring system which incurs lower communications charges than those incurred by conventional monitoring systems. A further object of the invention is to provide a monitoring system which may be used at any time convenient for a patient.

These and other objects and advantages will become more apparent after consideration of the ensuing description and the accompanying drawings.

SUMMARY

The invention presents a networked system for remotely monitoring an individual and for communicating information to the individual. The system includes a server and a remote interface for entering in the server a set of queries to be answered by the individual. The server is preferably a world wide web server and the remote interface is preferably a personal computer or network terminal connected to the web server via the Internet. The system also includes a remotely programmable apparatus for interacting with the individual. The apparatus is connected to the server via a communication network, preferably the Internet. The apparatus interacts with the individual in accordance with a script program received from the server.

The server includes a script generator for generating the script program from the queries entered through the remote

interface. The script program is executable by the apparatus to communicate the queries to the individual, to receive responses to the queries, and to transmit the responses from the apparatus to the server. The server also includes a database connected to the script generator for storing the script program and the responses to the queries.

The apparatus has a communication device, such as a modem, for receiving the script program from the server and for transmitting the responses to the server. The apparatus also has a user interface for communicating the queries to the individual and for receiving the responses to the queries. In the preferred embodiment, the user interface includes a display for displaying the queries and user input buttons for entering the responses to the queries. In an alternative embodiment, the user interface includes a speech synthesizer for audibly communicating the queries and a speech recognizer for receiving spoken responses to the queries.

The apparatus also includes a memory for storing the script program and the responses to the queries. The apparatus further includes a microprocessor connected to the communication device, the user interface, and the memory. The microprocessor executes the script program to communicate the queries to the individual, to receive the responses to the queries, and to transmit the responses to the server through the communication network.

In the preferred embodiment, the system also includes at least one monitoring device for producing measurements of a physiological condition of the individual and for transmitting the measurements to the apparatus. The apparatus further includes a device interface connected to the microprocessor for receiving the measurements from the monitoring device. The measurements are stored in the memory and transmitted to the server with the responses to the queries. The server also preferably includes a report generator connected to the database for generating a report of the measurements and responses. The report is displayed on the remote interface.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram of a networked system according to a preferred embodiment of the invention.

FIG. **2** is a block diagram illustrating the interaction of the components of the system of FIG. **1**.

FIG. **3** is a perspective view of a remotely programmable apparatus of the system of FIG. **1**.

FIG. **4** is a block diagram illustrating the components of the apparatus of FIG. **3**.

FIG. **5** is a script entry screen according to the preferred embodiment of the invention.

FIG. **6**A is a listing of a sample script program according to the preferred embodiment of the invention.

FIG. **6**B is a continuation of the listing of FIG. **6**A.

FIG. **7** is a script assignment screen according to the preferred embodiment of the invention.

FIG. **8** is a sample query appearing on a display of the apparatus of FIG. **3**.

FIG. **9** is a sample prompt appearing on the display of the apparatus of FIG. **3**.

FIG. **10** is a sample report displayed on a workstation of the system of FIG. **1**.

FIG. **11**A is a flow chart illustrating the steps included in a monitoring application executed by the server of FIG. **1** according to the preferred embodiment of the invention.

FIG. **11**B is a continuation of the flow chart of FIG. **11**A.

FIG. **12**A is a flow chart illustrating the steps included in the script program of FIGS. **6**A–**6**B.

FIG. **12**B is a continuation of the flow chart of FIG. **12**A.

FIG. **13** is a perspective view of a remotely programmable apparatus according to a second embodiment of the invention.

FIG. **14** is a sample prompt appearing on a display of the apparatus of FIG. **13**.

FIG. **15** is a block diagram illustrating the components of the apparatus of FIG. **13**.

FIG. **16** is a schematic block diagram illustrating the interaction of the server of FIG. **1** with the apparatus of FIG. **3** according to a third embodiment of the invention.

FIG. **17** is a first sample message appearing on the display of the apparatus of FIG. **3**.

FIG. **18** is a second sample message appearing on the display of the apparatus of FIG. **3**.

FIG. **19** is a script entry screen according to the third embodiment of the invention.

DETAILED DESCRIPTION

The invention presents a system and method for remotely monitoring individuals and for communicating information to the individuals. In a preferred embodiment of the invention, the individuals are patients and the system is used to collect data relating to the health status of the patients. However, it is to be understood that the invention is not limited to remote monitoring of patients. The system and method of the invention may be used for any type of remote monitoring application. The invention may also be implemented as an automated messaging system for communicating information to individuals, as will be discussed in an alternative embodiment below.

A preferred embodiment of the invention is illustrated in FIGS. **1**–**12**. Referring to FIG. **1**, a networked system **16** includes a server **18** and a workstation **20** connected to server **18** through a communication network **24**. Server **18** is preferably a world wide web server and communication network **24** is preferably the Internet. It will be apparent to one skilled in the art that server **18** may comprise a single stand-alone computer or multiple computers distributed throughout a network. Workstation **20** is preferably a personal computer, remote terminal, or web TV unit connected to server **18** via the Internet. Workstation **20** functions as a remote interface for entering in server **18** messages and queries to be communicated to the patients.

System **16** also includes first and second remotely programmable apparatuses **26** and **32** for monitoring first and second patients, respectively. Each apparatus **26**/**32** is designed to interact with a patient in accordance with script programs received from server **18**. Each apparatus **26**/**32** is in communication with server **18** through communication network **24**, preferably the Internet. Alternatively, each apparatus **26**/**32** may be placed in communication with server **18** via wireless communication networks, cellular networks, telephone networks, or any other network which allows each apparatus **26**/**32** to exchange data with server **18**. For clarity of illustration, only two apparatuses **26** and **32** are shown in FIG. **1**. It is to be understood that system **16** may include any number of remotely programmable apparatuses for monitoring any number of patients.

In the preferred embodiment, each patient to be monitored is also provided with a monitoring device **28**. Monitoring device **28** is designed to produce measurements of a physiological condition of the patient, record the measurements,

and transmit the measurements to the patient's remotely programmable apparatus through a standard connection cable **30**. Examples of suitable monitoring devices **28** include blood glucose meters, respiratory flow meters, blood pressure cuffs, electronic weight scales, and pulse rate monitors. Such monitoring devices are well known in the art. The specific type of monitoring device **28** provided to each patient is dependent upon the patient's disease. For example, diabetes patients are provided with a blood glucose meter for measuring blood glucose concentrations, asthma patients are provided with respiratory flow meters for measuring peak flow rates, obesity patients are provided with weight scales, etc.

FIG. **2** shows server **18**, workstation **20**, and apparatus **26** in greater detail. Server **18** includes a database **38** for storing script programs **40**. Script programs **40** are executed by each apparatus e.g., **26**/**32**, to communicate queries and messages to a patient, receive responses **42** to the queries, collect monitoring device measurements **44**, and to transmit responses **42** and measurements **44** to server **18**. Database **38** is designed to store responses **42** and measurements **44**. Database **38** further includes a look-up table **46**. Table **46** contains a list of the patients to be monitored, and for each patient, a unique patient identification code and a respective pointer to the script program assigned to the patient. Each remotely programmable apparatus, e.g., **26**/**32**, is designed to execute assigned script programs **40** received from server **18**.

FIGS. **3**–**4** show the structure of each remotely programmable apparatus according to the preferred embodiment. For clarity, only remotely programmable apparatus **26** is shown since each remotely programmable apparatus of the preferred embodiment has substantially identical structure to apparatus **26**. Referring to FIG. **3**, apparatus **26** includes a housing **62**. Housing **62** is sufficiently compact to enable apparatus **26** to be hand-held and carried by a patient. Apparatus **26** also includes a display **64** for displaying queries and prompts to the patient. In the preferred embodiment, display **64** is a liquid crystal display (LCD).

Four user input buttons **70**A, **70**B, **70**C, and **70**D are located adjacent display **64**. User input buttons **70**A–D are for entering in apparatus **26** responses **42** to the queries and prompts. In the preferred embodiment, user input buttons **70**A–D are momentary contact push buttons. In alternative embodiments, user input buttons **70**A–D may be replaced by switches, keys, a touch sensitive display screen, or any other data input device.

Three monitoring device jacks **68**A, **68**B, and **68**C are located on a surface of housing **62**. Device jacks **68**A–C are for connecting apparatus **26** to a number of monitoring devices **28**, such as blood glucose meters, respiratory flow meters, or blood pressure cuffs, through respective connection cables **30** (not shown in FIG. **3**). Apparatus **26** also includes a modem jack **66** for connecting apparatus **26** to a telephone jack through a standard connection cord (not shown). Apparatus **26** further includes a visual indicator, such as a light emitting diode (LED) **74**. LED **74** is for visually notifying the patient that he or she has unanswered queries stored in apparatus **26**.

FIG. **4** is a schematic block diagram illustrating the components of apparatus **26** in greater detail. Apparatus **26** includes a microprocessor **76** and a memory **80** connected to microprocessor **76**. Memory **80** is preferably a non-volatile memory, such as a serial EEPROM. Memory **80** stores script programs **40** received from server **18**, measurements **44** received from monitoring device **28**, responses **42** to queries, and the patient's unique identification code. Microprocessor **76** also includes built-in read only memory (ROM) which stores firmware for controlling the operation of apparatus **26**. The firmware includes a script interpreter used by microprocessor **76** to execute script programs **40**. The script interpreter interprets script commands which are executed by microprocessor **76**. Specific techniques for interpreting and executing script commands in this manner are well known in the art.

Microprocessor **76** is preferably connected to memory **80** using a standard two-wire I^2C interface. Microprocessor **76** is also connected to user input buttons **70**, LED **74**, a clock **84**, and a display driver **82**. Clock **84** indicates the current date and time to microprocessor **76**. For clarity of illustration, clock **84** is shown as a separate component, but is preferably built into microprocessor **76**. Display driver **82** operates under the control of microprocessor **76** to display information on display **64**. Microprocessor **76** is preferably a PIC 16C65 processor which includes a universal asynchronous receiver transmitter (UART) **78**. UART **78** is for communicating with a modem **86** and a device interface **90**. A CMOS switch **88** under the control of microprocessor **76** alternately connects modem **86** and interface **90** to UART **78**.

Modem **86** is connected to a telephone jack **22** through modem jack **66**. Modem **86** is for exchanging data with server **18** through communication network **24**. The data includes script programs **40** which are received from server **18** as well as responses **42** to queries, device measurements **44**, script identification codes, and the patient's unique identification code which modem **86** transmits to server **18**. Modem **86** is preferably a complete 28.8 K modem commercially available from Cermetek, although any suitable modem may be used.

Device interface **90** is connected to device jacks **68**A, **68**B, and **68**C. Device interface **90** is for interfacing with a number of monitoring devices **28**, such as blood glucose meters, respiratory flow meters, blood pressure cuffs, weight scales, or pulse rate monitors, through device jacks **68**A–C. Device interface **90** operates under the control of microprocessor **76** to collect measurements **44** from monitoring devices **28** and to output the measurements to microprocessor **76** for storage in memory **80**. In the preferred embodiment, interface **90** is a standard RS232 interface. For simplicity of illustration, only one device interface **90** is shown in FIG. **4**. However, in alternative embodiments, apparatus **26** may include multiple device interfaces to accommodate monitoring devices which have different connection standards.

Referring again to FIG. **2**, server **18** includes a monitoring application **48**. Monitoring application **48** is a controlling software application executed by server **18** to perform the various functions described below. Application **48** includes a script generator **50**, a script assignor **52**, and a report generator **54**. Script generator **50** is designed to generate script programs **40** from script information entered through workstation **20**. The script information is entered through a script entry screen **56**. In the preferred embodiment, script entry screen **56** is implemented as a web page on server **18**. Workstation **20** includes a web browser for accessing the web page to enter the script information.

FIG. **5** illustrates script entry screen **56** as it appears on workstation **20**. Screen **56** includes a script name field **92** for specifying the name of a script program to be generated. Screen **56** also includes entry fields **94** for entering a set of queries to be answered by a patient. Each entry field **94** has

corresponding response choice fields **96** for entering response choices for the query. Screen **56** further includes check boxes **98** for selecting a desired monitoring device **28**, such as a blood glucose meter, respiratory flow meter, or blood pressure cuff, from which to collect measurements **44**.

Screen **56** additionally includes a connection time field **100** for specifying a prescribed connection time at which each apparatus **26** executing the script is to establish a subsequent communication link to server **18**. The connection time is preferably selected to be the time at which communication rates are the lowest, such as 3:00 AM. Screen **56** also includes a CREATE SCRIPT button **102** for instructing script generator **50** to generate a script program **40** from the information entered in screen **56**. Screen **56** further includes a CANCEL button **104** for canceling the information entered in screen **56**.

In the preferred embodiment, each script program **40** created by script generator **50** conforms to the standard file format used on UNIX systems. In the standard file format, each command is listed in the upper case and followed by a colon. Every line in the script program **40** is terminated by a linefeed character {LF}, and only one command is placed on each line. The last character in the script program **40** is a UNIX end of file character {EOF}. Table 1 shows an exemplary listing of script commands used in the preferred embodiment of the invention.

TABLE 1

SCRIPT COMMANDS

Command	Description
CLS: {LF}	Clear the display.
ZAP: {LF}	Erase from memory the last set of query responses recorded.
LED: b{LF}	Turn the LED on or off, where b is a binary digit of 0 or 1. An argument of 1 turns on the LED, and an argument of 0 turns off the LED.
DISPLAY: {chars} {LF}	Display the text following the DISPLAY command.
INPUT: mmmm{LF}	Record a button press. The m's represent a button mask pattern for each of the four input buttons. Each m contains an "X" for disallowed buttons or an "O" for allowed buttons. For example, INPUT: OXOX{LF} allows the user to press either button #1 or #3.
WAIT: {LF}	Wait for any one button to be pressed, then continue executing the script program.
COLLECT: device{LF}	Collect measurements from the monitoring device specified in the COLLECT command. The user is preferably prompted to connect the specified monitoring device to the apparatus and press a button to continue.
NUMBER: aaaa{LF}	Assign a script identification code to the script program. The script identification code from the most recently executed NUMBER statement is subsequently transmitted to the server along with the query responses and device measurements. The script identification code identifies to the server which script program was most recently executed by the remote apparatus.
DELAY: t{LF}	Wait until time t specified in the DELAY command, usually the prescribed connection time.
CONNECT: {LF}	Perform a connection routine to establish a communication link to the server, transmit the patient identification code, query responses, device measurements, and script identification code to the server, and receive and store a new script program. When the server instructs the apparatus to disconnect, the script interpreter is restarted, allowing the new script program to execute.

The script commands illustrated in Table 1 are representative of the preferred embodiment and are not intended to limit the scope of the invention. After consideration of the ensuing description, it will be apparent to one skilled in the art many other suitable scripting languages and sets of script commands may be used to implement the invention.

Script generator **50** preferably stores a script program template which it uses to create each script program **40**. To generate a script program **40**, script generator **50** inserts into the template the script information entered in screen **56**. For example, FIGS. **6**A–6B illustrate a sample script program **40** created by script generator **50** from the script information shown in FIG. **5**.

The script program **40** includes display commands to display the queries and response choices entered in fields **94** and **96**, respectively. The script program **40** also includes input commands to receive responses **42** to the queries. The script program **40** further includes a collect command to collect device measurements **44** from the monitoring device **28** specified in check boxes **98**. The script program **40** also includes commands to establish a subsequent communication link to server **18** at the connection time specified in field **100** FIG. **5**. The steps included in the script program **40** are also shown in the flow chart of FIGS. **12**A–12B and will be discussed in the operation section below.

Referring again to FIG. **2**, script assignor **52** is for assigning script programs **40** to the patients. Script programs **40** are assigned in accordance with script assignment information entered through workstation **20**. The script assignment information is entered through a script assignment screen **57**, which is preferably implemented as a web page on server **18**.

FIG. **7** illustrates a sample script assignment screen **57** as it appears on workstation **20**. Screen **57** includes check boxes **106** for selecting a script program **40** to be assigned, and check boxes **108** for selecting the patients to whom the script program is to be assigned. Screen **57** also includes an ASSIGN SCRIPT button **112** for entering the assignments. When button **112** is pressed, script assignor **52** creates and stores for each patient selected in check boxes **108** a respective pointer to the script program **40** selected in check boxes **106**. Each pointer is stored in the patient look-up table **46** of database **38**. Screen **57** further includes an ADD SCRIPT button **110** for accessing the script entry screen and a DELETE SCRIPT button **114** for deleting a script program **40**.

Referring again to FIG. **2**, report generator **54** is designed to generate a patient report **58** from responses **42** and device measurements **44** received in server **18**. Patient report **58** is displayed on workstation **20**. FIG. **10** shows a sample patient report **58** produced by report generator **54** for a selected patient. Patient report **58** includes a graph **116** of the device measurements **44** received from the patient, as well as a listing of responses **42** received from the patient. Specific techniques for writing a report generator program to display data in this manner are well known in the art.

The operation of the preferred embodiment is illustrated in FIGS. **1**–**12**. FIG. **11**A is a flow chart illustrating steps included in the monitoring application executed by server **18**. FIG. **11**B is a continuation of the flow chart of FIG. **11**A. In step **202**, server **18** determines if new script information has been entered through script entry screen **56**. If new script information has not been entered, server **18** proceeds to step **206**. If new script information has been entered, server **18** proceeds to step **204**.

As shown in FIG. **5**, the script information includes a set of queries, and for each of the queries, corresponding response choices. The script information also includes a

selected monitoring device type from which to collect device measurements **44**. The script information further includes a prescribed connection time for each apparatus to establish a subsequent communication link to server **18**. The script information is generally entered in server **18** by a healthcare provider, such as the patients' physician or case manager. Of course, any person desiring to communicate with the patients may also be granted access to server **18** to create and assign script programs **40**. Further, it is to be understood that system **16** may include any number of remote interfaces for entering script generation and script assignment information in server **18**.

In step **204**, script generator **50** generates a script program from the information entered in screen **56**. The script program is stored in database **38**. Steps **202** and **204** are preferably repeated to generate multiple script programs, e.g. a script program for diabetes patients, a script program for asthma patients, etc. Each script program corresponds to a respective one of the sets of queries entered through script entry screen **56**. Following step **204**, server **18** proceeds to step **206**.

In step **206**, server **18** determines if new script assignment information has been entered through assignment screen **57**. If new script assignment information has not been entered, server **18** proceeds to step **210**. If new script assignment information has been entered, server **18** proceeds to step **208**. As shown in FIG. **7**, the script programs are assigned to each patient by selecting a script program through check boxes **106**, selecting the patients to whom the selected script program is to be assigned through check boxes **108**, and pressing the ASSIGN SCRIPT button **112**. When button **112** is pressed, script assignor **52** creates for each patient selected in check boxes **108** a respective pointer to the script program selected in check boxes **106**. In step **208**, each pointer is stored in look-up table **46** of database **38**. Following step **208**, server **18** proceeds to step **210**.

In step **210**, server **18** determines if any of the apparatuses are remotely connected to the server. Each patient to be monitored is preferably provided with his or her own remotely programmable apparatus which has the patient's unique identification code stored therein. Each patient is thus uniquely associated with a respective one of the apparatuses. If none of the apparatuses is connected, server **18** proceeds to step **220**.

If an apparatus is connected, server **18** receives from the apparatus the patient's unique identification code in step **212**. In step **214**, server **18** receives from the apparatus the query responses **42**, device measurements **44**, and script identification code recorded during execution of a previously assigned script program. The script identification code identifies to server **18** which script program was executed by the apparatus to record the query responses **42** and device measurements **44**. The responses, device measurements, and script identification code are stored in database **38**.

In step **216**, server **18** uses the patient identification code to retrieve from table **46** the pointer to the script program assigned to the patient. Server **18** then retrieves the assigned script program from database **38**. In step **218**, server **18** transmits the assigned script program to the patient's remotely programmable apparatus through communication network **24**. Following step **218**, server **18** proceeds to step **220**.

In step **220**, server **18** determines if a patient report request has been received from workstation **20**. If no report request has been received, server **18** returns to step **202**. If a report request has been received for a selected patient, server **18** retrieves from database **38** the measurements **44** and query responses **42** last received from the patient, step **222**. In step **224**, server **18** generates and displays patient report **58** on workstation **20**. As shown in FIG. **10**, report **58** includes the device measurements **44** and query responses **42** last received from the patient. Following step **224**, server **18** returns to step **202**.

FIGS. **12A–12B** illustrate the steps included in the script program executed by apparatus **26**. Before the script program is received, apparatus **26** is initially programmed with the patient's unique identification code and the script interpreter used by microprocessor **76** to execute the script program. The initial programming may be achieved during manufacture or during an initial connection to server **18**. Following initial programming, apparatus **26** receives from server **18** the script program assigned to the patient associated with apparatus **26**. The script program is received by modem **86** through a first communication link and stored in memory **80**.

In step **302**, microprocessor **76** assigns a script identification code to the script program and stores the script identification code in memory **80**. The script identification code is subsequently transmitted to server **18** along with the query responses **42** and device measurements **44** to identify to server **18** which script program was most recently executed by apparatus **26**. In step **304**, microprocessor **76** lights LED **74** to notify the patient that he or she has unanswered queries stored in apparatus **26**. LED **74** preferably remains lit until the queries are answered by the patient. In step **306**, microprocessor **76** erases from memory **80** the last set of query responses recorded.

In step **308**, microprocessor **76** prompts the patient by displaying on display **64** "ANSWER QUERIES NOW? PRESS ANY BUTTON TO START". In step **310**, microprocessor **76** waits until a reply to the prompt is received from the patient. When a reply is received, microprocessor **76** proceeds to step **312**. In step **312**, microprocessor **76** executes successive display and input commands to display the queries and response choices on display **64** and to receive responses to the queries.

FIG. **8** illustrates a sample query and its corresponding response choices as they appear on display **64** The response choices are positioned on display **64** such that each response choice is located proximate a respective one of input buttons **70A–D**. In the preferred embodiment, each response choice is displayed immediately above a respective input button **70A–D**. The patient presses the button **70A–D** corresponding to his or her response. Microprocessor **76** stores each response in memory **80**.

In steps **314–318**, microprocessor **76** executes commands to collect device measurements **44** from a selected monitoring device **28**. The script program specifies the selected monitoring device from which to collect the measurements. In step **314**, microprocessor **76** prompts the patient to connect the selected monitoring device **28**, for example a blood glucose meter, to one of device jacks **68A–C**. A sample prompt is shown in FIG. **9**. In step **316**, microprocessor **76** waits until a reply to the prompt is received from the patient. When a reply is received, microprocessor **76** proceeds to step **318**. Microprocessor **76** also connects UART **78** to interface **90** through switch **88**. In step **318**, microprocessor **76** collects device measurements **44** from monitoring device **28** through interface **90**. measurements **44** are stored in memory **80**.

In step **320**, microprocessor **76** prompts the patient to connect apparatus **26** to telephone jack **22** so that apparatus

26 may connect to server 18 at the prescribed connection time. In step 322, microprocessor 76 waits until a reply to the prompt is received from the patient. When a reply is received, microprocessor 76 turns off LED 74 in step 324. In step 326, microprocessor 76 waits until it is time to connect to server 18. Microprocessor 76 compares the connection time specified in the script program to the current time output by clock 84. When it is time to connect, microprocessor 76 connects UART 78 to modem 86 through switch 88.

In step 328, microprocessor 76 establishes a subsequent communication link between apparatus 26 and server 18 through modem 86 and communication network 24. If the connection fails for any reason, microprocessor 76 repeats step 328 to get a successful connection. In step 330, microprocessor 76 transmits the device measurements 44, query responses 42, script identification code, and patient identification code stored in memory 80 to server 18 through the subsequent communication link. In step 332, microprocessor 76 receives through modem 86 a new script program from server 18. The new script program is stored in memory 80 for subsequent execution by microprocessor 76. Following step 332, the script program ends.

One advantage of the monitoring system of the present invention is that it allows each patient to select a convenient time to respond to the queries, so that the monitoring system is not intrusive to the patient's schedule. A second advantage of the monitoring system is that it incurs very low communications charges because each remote apparatus connects to server 18 at times when communication rates are lowest. Moreover, the cost to manufacture each remote apparatus 26 is very low compared to personal computers or internet terminals, so that the monitoring system is highly affordable.

A third advantage of the monitoring system is that it allows each apparatus 26 to be programmed remotely through script programs 40. Patient surveys, connection times, display prompts, selected monitoring devices, patient customization, and other operational details of each apparatus 26 may be easily changed by transmitting a new script program 40 to apparatus 26. Moreover, each script program 40 may be easily created and assigned by remotely accessing server 18 through the Internet. Thus, the invention provides a powerful, convenient, and inexpensive system for remotely monitoring a large number of patients.

FIGS. 13–15 illustrate a second embodiment of the invention in which each remotely programmable apparatus has speech recognition and speech synthesis functionality. FIG. 13 shows a perspective view of remotely programmable apparatus 27 according to the second embodiment. Apparatus 27 includes a speaker 72 for audibly communicating queries and prompts to the patient. Apparatus 27 also includes a microphone 118 for receiving spoken responses to the queries and prompts. Apparatus 27 may optionally include a display 64 for displaying prompts to the patient, as shown in FIG. 14.

FIG. 15 is a schematic block diagram illustrating the components of apparatus 27 in greater detail. Apparatus 27 is similar in design to apparatus 26 of the preferred embodiment except that apparatus 27 includes an audio processor chip 120 in place of microprocessor 76. Audio processor chip 120 is preferably an RSC-164 chip commercially available from Sensory Circuits Inc. of 1735 N. First Street, San Jose, Calif. 95112.

Audio processor chip 120 has a microcontroller 122 for executing script programs received from server 18. A memory 80 is connected to microcontroller 122. Memory 80 stores the script programs and a script interpreter used by microcontroller 122 to execute the script programs. Memory 80 also stores measurements received from monitoring device 28, responses to the queries, script identification codes, and the patient's unique identification code.

Audio processor chip 120 also has built in speech synthesis functionality for synthesizing queries and prompts to a patient through speaker 72. For speech synthesis, chip 120 includes a digital to analog converter (DAC) 142 and an amplifier 144. DAC 142 and amplifier 144 drive speaker 72 under the control of microcontroller 122.

Audio processor chip 120 further has built in speech recognition functionality for recognizing responses spoken into microphone 118. Audio signals received through microphone 118 are converted to electrical signals and sent to a preamp and gain control circuit 128. Preamp and gain control circuit 128 is controlled by an automatic gain control circuit 136, which is in turn controlled by microcontroller 122. After being amplified by preamp 128, the electrical signals enter chip 120 and pass through a multiplexer 130 and an analog to digital converter (ADC) 132. The resulting digital signals pass through a digital logic circuit 134 and enter microcontroller 122 for speech recognition.

Audio processor chip 120 also includes a RAM 138 for short term memory storage and a ROM 140 which stores programs executed by microcontroller 122 to perform speech recognition and speech synthesis. Chip 120 operates at a clock speed determined by a crystal 126. Chip 120 also includes a clock 84 which provides the current date and time to microcontroller 122. As in the preferred embodiment, apparatus 27 includes an LED 74, display driver 82, modem 86, and device interface 90, all of which are connected to microcontroller 122.

The operation of the second embodiment is similar to the operation of the preferred embodiment except that queries, response choices, and prompts are audibly communicated to the patient through speaker 72 rather than being displayed to the patient on display 64. The operation of the second embodiment also differs from the operation of the preferred embodiment in that responses to the queries and prompts are received through microphone 118 rather than through user input buttons.

The script programs of the second embodiment are similar to the script program shown in FIGS. 6A–6B, except that each display command is replaced by a speech synthesis command and each input command is replaced by a speech recognition command. The speech synthesis commands are executed by microcontroller 122 to synthesize the queries, response choices, and prompts through speaker 72. The speech recognition commands are executed by microcontroller 122 to recognize responses spoken into microphone 118.

For example, to ask the patient how he or she feels and record a response, microcontroller 122 first executes a speech synthesis command to synthesize through speaker 72 "How do you feel? Please answer with one of the following responses: very bad, bad, good, or very good." Next, microcontroller 118 executes a speech recognition command to recognize the response spoken into microphone 118. The recognized response is stored in memory 80 and subsequently transmitted to the server. Other than the differences described, the operation and advantages of the second embodiment are the same as the operation and advantages of the preferred embodiment described above.

Although the first and second embodiments focus on querying individuals and collecting responses to the queries,

the system of the invention is not limited to querying applications. The system may also be used simply to communicate messages to the individuals. FIGS. **16–19** illustrate a third embodiment in which the system is used to perform this automated messaging function. In the third embodiment, each script program contains a set of statements to be communicated to an individual rather than a set of queries to be answered by the individual. Of course, it will be apparent to one skilled in the art that the script programs may optionally include both queries and statements.

The third embodiment also shows how the queries and statements may be customized to each individual by merging personal data with the script programs, much like a standard mail merge application. Referring to FIG. **16**, personal data relating to each individual is preferably stored in look-up table **46** of database **38**. By way of example, the data may include each individual's name, the name of each individual's physician, test results, appointment dates, or any other desired data. As in the preferred embodiment, database **38** also stores generic script programs **40** created by script generator **50**.

Server **18** includes a data merge program **55** for merging the data stored in table **46** with generic script programs **40**. Data merge program **55** is designed to retrieve selected data from table **46** and to insert the data into statements in generic script programs **40**, thus creating custom script programs **41**. Each custom script program **41** contains statements which are customized to an individual. For example, the statements may be customized with the individual's name, test results, etc. Examples of such customized statements are shown in FIGS. **17–18**.

The operation of the third embodiment is similar to the operation of the preferred embodiment except that the script programs are used to communicate messages to the individuals rather than to query the individuals. Each message is preferably a set of statements. Referring to FIG. **19**, the statements may be entered in server **18** through script entry screen **56**, just like the queries of the preferred embodiment.

Each statement preferably includes one or more insert commands specifying data from table **46** to be inserted into the statement. The insert commands instruct data merge program **55** to retrieve the specified data from database **38** and to insert the data into the statement. For example, the insert commands shown in FIG. **19** instruct data merge program **55** to insert a physician name, an appointment date, a patient name, and a test result into the statements. As in the preferred embodiment, each statement may also include one or more response choices which are entered in fields **96**.

Following entry of the statements and response choices, CREATE SCRIPT button **102** is pressed. When button **102** is pressed, script generator **50** generates a generic script program from the information entered in screen **56**. The generic script program is similar to the script program shown in FIGS. **6A–6B**, except that the display commands specify statements to be displayed rather than queries. Further, the statements include insert commands specifying data to be inserted into the script program. As in the preferred embodiment, multiple script programs are preferably generated, e.g. a generic script program for diabetes patients, a generic script program for asthma patients, etc. The generic script programs are stored in database **38**.

Following generation of the generic script programs, server **18** receives script assignment information entered through script assignment screen **57**. As shown in FIG. **7**, the script programs are assigned by first selecting one of the generic script programs through check boxes **106**, selecting individuals through check boxes **108**, and pressing the ASSIGN SCRIPT button **112**. When button **112** is pressed, data merge program **55** creates a custom script program **41** for each individual selected in check boxes **108**.

Each custom script program **41** is preferably created by using the selected generic script program as a template. For each individual selected, data merge program **55** retrieves from database **38** the data specified in the insert commands. Next, data merge program **55** inserts the data into the appropriate statements in the generic script program **40** to create a custom script program **41** for the individual. Each custom script program **41** is stored in database **38**.

As each custom script program **41** is generated for an individual, script assignor **52** assigns script program **41** to the individual. This is preferably accomplished by creating a pointer to the custom script program and storing the pointer with the individual's unique identification code in table **46**. When the individual's remotely programmable apparatus connects to server **18**, server **18** receives from remotely programmable apparatus **26** the individual's unique identification code. Server **18** uses the unique identification code to retrieve from table **46** the pointer to the custom script program assigned to the individual. Next, server **18** retrieves the assigned script program from database **38** and transmits the script program to the individual's remotely programmable apparatus **26** through communication network **24**.

The apparatus receives and executes the script program The execution of the script program is similar to the execution described in the preferred embodiment, except that statements are displayed to the individual rather than queries. FIGS. **17–18** illustrate two sample statements as they appear on display **64**. Each statement includes a response choice, preferably an acknowledgment such as "OK". After reading a statement, the individual presses the button **70**A–D corresponding to the response choice to proceed to the next statement. Alternatively, the script program may specify a period of time that each statement is to be displayed before proceeding to the next statement. The remaining operation of the third embodiment is analogous to the operation of the preferred embodiment described above.

Although it is presently preferred to generate a custom script program **41** for each individual as soon as script assignment information is received for the individual, it is also possible to wait until the individual's apparatus **26** connects to server **18** before generating custom script program **41**. This is accomplished by creating and storing a pointer to the generic script program **40** assigned to the individual, as previously described in the preferred embodiment. When the individual's apparatus **26** connects to server **18**, data merge program **55** creates a custom script program **41** for the individual from the generic script program **40** assigned to the individual. The custom script program **41** is then sent to the individual's apparatus **26** for execution.

SUMMARY, RAMIFICATIONS, AND SCOPE

Although the above description contains many specificities, these should not be construed as limitations on the scope of the invention but merely as illustrations of some of the presently preferred embodiments. Many other embodiments of the invention are possible. For example, the scripting language and script commands shown are representative of the preferred embodiment. It will be apparent to one skilled in the art many other scripting languages and specific script commands may be used to implement the invention.

Moreover, the invention is not limited to the specific applications described. The system and method of the invention have many other application both inside and outside the healthcare industry. For example, pharmaceutical manufacturers may apply the system in the clinical development and post marketing surveillance of new drugs, using the system as an interactive, on-line monitoring tool for collecting data on the efficacy, side effects, and quality of life impact of the drugs. Compared to the current use of labor intensive patient interviews, the system provides a fast, flexible, and cost effective alternative for monitoring the use and effects of the drugs.

The system may also be used by home healthcare companies to enhance the service levels provided to customers, e.g. panic systems, sleep surveillance, specific monitoring of disease conditions, etc. Alternatively, the system may be used to monitor and optimize the inventory of home stationed health supplies. As an example, the system may be connected to an appropriate measuring device to optimize timing of oxygen tank delivery to patients with chronic obstructive pulmonary disease (COPD).

The system and method of the invention also have many applications outside the healthcare industry. For example, the system may be used for remote education over the Internet, facilitating educational communication with children or adult trainees who lack access to sophisticated and expensive computer equipment. The system may also be used by law enforcement officers to perform on-line surveillance of individuals on probation or parole.

Further, the invention has numerous applications for gathering data from remotely located devices. For example, the system may be used to collect data from smart appliances, such as identification check systems. Alternatively, the system may be applied to the remote monitoring of facilities, including safety and security monitoring, or to environmental monitoring, including pollution control and pipeline monitoring. Many other suitable applications of the invention will be apparent to one skilled in the art.

Therefore, the scope of the invention should be determined not by the examples given, but by the appended claims and their legal equivalents.

What is claimed is:

1. A system for remotely monitoring an individual, the system comprising:

a) a server;

b) remote interface means for entering in the server a set of queries to be answered by the individual; and

c) a remotely programmable apparatus for interacting with the individual, the remotely programmable apparatus being in communication with the server via a communication network;

wherein the server comprises:

i) script generating means for generating a script program from the set of queries, the script program being executable by the remotely programmable apparatus to communicate the set of queries to the individual, to receive responses to the set of queries, and to transmit the responses from the remotely programmable apparatus to the server; and

ii) database means connected to the script generating means, the database means for storing the script program and the responses to the set of queries;

and wherein the remotely programmable apparatus comprises:

i) communication means for receiving the script program from the server and for transmitting the responses to the server;

ii) user interface means for communicating the set of queries to the individual and for receiving the responses to the set of queries;

iii) memory means for storing the script program and the responses to the set of queries; and

iv) processor means connected to the communication means, the user interface means, and the memory means for executing the script program to communicate the set of queries to the individual, to receive the responses to the set of queries, and to transmit the responses to the server.

2. The system of claim **1**, wherein the server comprises a web server having a web page for entry of the set of queries, and wherein the remote interface means is connected to the web server via the Internet.

3. The system of claim **1**, wherein the user interface means comprises a display for displaying the queries, and user input buttons for entering the responses.

4. The system of claim **1**, wherein the user interface means includes a speech synthesis means for audibly communicating the set of queries to the individual.

5. The system of claim **1**, wherein the user interface means includes a speech recognition means for receiving spoken responses to the set of queries.

6. The system of claim **1**, further comprising at least one monitoring device for producing measurements of a physiological condition of the individual and for transmitting the measurements to the remotely programmable apparatus, wherein the remotely programmable apparatus further includes device interface means connected to the processor means for receiving the measurements from the monitoring device, the memory means includes means for storing the measurements, and the communication means includes means for transmitting the measurements to the server.

7. The system of claim **6**, wherein the device interface means includes means for interfacing with a plurality of monitoring devices, and the script program specifies a selected one of the plurality of monitoring devices from which to collect the measurements.

8. The system of claim **6**, wherein the server further comprises report means for displaying the responses and the measurements on the remote interface means.

9. The system of claim **1**, wherein the communication means includes means for establishing a first communication link to the server to receive the script program and means for establishing a subsequent communication link to the server to transmit the responses, and wherein the script program specifies a connection time at which to establish the subsequent communication link.

10. The system of claim **1**, wherein the remotely programmable apparatus further comprises notification means connected to the processor means, the notification means for notifying the individual that unanswered queries are stored in the remotely programmable apparatus.

11. The system of claim **10**, wherein the notification means comprises a visual indicator for visually notifying the individual.

12. The system of claim **10**, wherein the notification means comprises a display for displaying a prompt.

13. The system of claim **1**, further comprising a plurality of remotely programmable apparatuses in communication with the server, the plurality of remotely programmable apparatuses for remotely monitoring a corresponding plurality of individuals, wherein the database means includes means for storing a plurality of script programs, the remote interface means includes means for entering script assignment information, the server includes script assignment

means connected to the database means for assigning to each of the plurality of individuals at least one of the plurality of script programs in accordance with the script assignment information, and the database means further includes means for storing a list of the plurality of individuals, and for each of the plurality of individuals, a respective pointer to the at least one of the plurality of script programs assigned to each of the plurality of individuals.

14. A method for remotely monitoring an individual, the method comprising the following steps:

a) providing the individual with an apparatus having:

i) a communication means for exchanging data with a server through a communication network, wherein the data includes a script program executable by the apparatus to communicate queries to the individual, to receive responses to the queries, and to transmit the responses to the server;

ii) a memory means for storing the script program and the responses to the queries;

iii) a user interface means for communicating the queries to the individual and for receiving the responses to the queries; and

iv) a processor means connected to the communication means, the user interface means, and the memory means for executing the script program;

b) entering in the server the queries to be answered by the individual;

c) generating the script program from the queries;

d) transmitting the script program from the server to the apparatus through the communication network;

e) executing the script program in the apparatus to communicate the queries, to receive the responses, and to transmit the responses to the server; and

f) receiving and storing the responses in the server.

15. The method of claim **14**, wherein the server comprises a web server having a web page for entry of the queries, and wherein the queries are entered by accessing the web page through the Internet and entering the queries in the web page.

16. The method of claim **14**, wherein the apparatus further comprises a device interface connected to the processor means for receiving from a monitoring device measurements of a physiological condition of the individual, and wherein the method further comprises the steps of:

a) collecting the measurements in the apparatus through the device interface;

b) transmitting the measurements from the apparatus to the server; and

c) receiving and storing the measurements in the server.

17. The method of claim **16**, wherein the device interface includes means for interfacing with a plurality of monitoring devices, the script program specifies a selected one of the plurality of monitoring devices from which to collect the measurements, and the method further comprises the step of prompting the individual to connect the selected one of the plurality of monitoring devices to the device interface.

18. The method of claim **16**, further comprising the step of reporting on a remote interface the responses and measurements received in the server.

19. The method of claim **14**, wherein the script program is transmitted from the server to the apparatus through a first communication link, the responses to the queries are transmitted from the apparatus to the server through a subsequent communication link, and the script program specifies a connection time at which to establish the subsequent communication link.

20. The method of claim **14**, further comprising the step of notifying the individual when unanswered queries are stored in the apparatus.

21. The method of claim **20**, wherein the apparatus further comprises a visual indicator connected to the processor means and the step of notifying the individual comprises lighting the visual indicator.

22. The method of claim **20**, wherein the apparatus further comprises a display connected to the processor means and the step of notifying the individual comprises displaying a prompt on the display.

23. The method of claim **14**, wherein the user interface means comprises a display and input buttons, and wherein the queries are communicated through the display and the responses are received through the input buttons.

24. The method of claim **14**, wherein the user interface means includes a speech synthesizer, and wherein the queries are communicated through the speech synthesizer.

25. The method of claim **14**, wherein the user interface means includes a speech recognizer, and wherein the responses are received through the speech recognizer.

26. The method of claim **14**, further comprising the steps of:

a) providing a plurality of individuals with a corresponding plurality of apparatuses such that each of the plurality of individuals is associated with a respective one of the plurality of apparatuses;

b) entering in the server a plurality of sets of queries;

c) generating in the server a plurality of script programs such that each of the plurality of script programs corresponds to a respective one of the plurality of sets of queries;

d) assigning to each of the plurality of individuals at least one of the plurality of script programs;

e) storing in the server the plurality of script programs, a list of the plurality of individuals, and for each of the plurality of individuals, a respective pointer to the at least one of the plurality of script programs assigned to each of the plurality of individuals; and

f) transmitting to each of the plurality of apparatuses the at least one of the plurality of script programs assigned to each of the plurality of individuals associated with the respective one of the plurality of apparatuses.

27. The system of claim **1**, wherein the communication means comprises a modem.

28. The system of claim **1**, wherein the system is adapted to allow the individual to select a time at which to respond to the set of queries.

29. The system of claim **1**, wherein the server includes a merge program and a database, said database including a look-up table, said look-up table for storing personal data relating to the individual, and said merge program for merging the personal data with at least one generic script program to provide at least one custom script program.

30. The system of claim **29**, wherein the at least one custom script program contains information customized to the individual.

31. A system for communicating information to an individual, the system comprising:

a) a server;

b) a remote interface means connected to the server, the remote interface means for specifying a message to be communicated to the individual; and

c) a remotely programmable apparatus for communicating the message to the individual, the remotely programmable apparatus being networked to the server via a communication network;

wherein the server includes a script generating means for generating a script program executable by the remotely programmable apparatus to communicate the message to the individual;

and wherein the apparatus comprises:

i) communication means for receiving the script program from the server;

ii) memory means for storing the script program;

iii) user interface means for communicating the message to the individual; and

iv) processor means connected to the communication means, the user interface means, and the memory means for executing the script program.

32. The system of claim **31**, wherein the server further includes database means connected to the script generating means, the database means for storing data relating to the individual, and wherein the script generating means includes means for inserting the data into the script program to customize the message to the individual.

33. The system of claim **31**, wherein the server comprises a web server, and wherein the remote interface means is connected to the web server via the Internet.

34. The system of claim **31**, wherein the user interface means comprises a display for displaying the message to the individual.

35. The system of claim **31**, wherein the user interface means comprises a speech synthesis means for audibly communicating the message to the individual.

36. The system of claim **31**, wherein the communication means includes means for establishing a first communication link to the server to receive a first script program and means for establishing a subsequent communication link to the server to receive a new script program, and wherein the first script program specifies a connection time at which to establish the subsequent communication link.

37. The system of claim **31**, wherein the remotely programmable apparatus further includes notification means, the notification means connected to the processor means for notifying the individual that a new message has been received.

38. The system of claim **37**, wherein the notification means comprises a visual indicator for visually notifying the individual.

39. The system of claim **37**, wherein the notification means comprises a display for displaying a prompt.

40. The system of claim **31**, further comprising a plurality of remotely programmable apparatuses networked to the server for communicating information to a corresponding plurality of individuals, wherein the server includes database means for storing a plurality of script programs, the remote interface means includes means for entering in the server script assignment information, the server includes script assignment means connected to the database means for assigning to each of the plurality of individuals at least one of the plurality of script programs in accordance with the script assignment information, and the database means further includes means for storing a list of the plurality of individuals, and for each of the plurality of individuals, a respective pointer to the at least one of the plurality of script programs assigned to each of the plurality of individuals.

41. A method for communicating information to an individual, the method comprising the following steps:

a) providing the individual with an apparatus having:

i) a communication means for exchanging data with a server through a communication network, wherein the data includes a script program executable by the apparatus to communicate a message to the individual;

ii) a memory means for storing the script program;

iii) a user interface for communicating the message; and

iv) a processor means connected to the communication means, the memory means, and the user interface for executing the script program;

b) entering in the server the message to be communicated to the individual;

c) generating the script program in the server;

d) transmitting the script program from the server to the apparatus through the communication network; and

e) executing the script program in the apparatus to communicate the message to the individual.

42. The method of claim **41**, wherein the step of transmitting the script program from the server to the apparatus is preceded by the steps of: storing in the server data relating to the individual, and inserting the data into the script program to customize the message to the individual.

43. The method of claim **41**, wherein the server comprises a web server having a web page for entry of the message, and wherein the message is entered in the server by accessing the web page through the Internet and entering the message in the web page.

44. The method of claim **41**, wherein the script program is transmitted from the server to the apparatus through a first communication link, the script program specifies a connection time at which the apparatus is to establish a subsequent communication link to the server, and the method further comprises the steps of establishing the subsequent communication link at the specified connection time and receiving a new script program in the apparatus through the subsequent communication link.

45. The method of claim **41**, further comprising the step of notifying the individual when a new message has been received in the apparatus.

46. The method of claim **45**, wherein the apparatus further comprises a visual indicator connected to the processor means and the step of notifying the individual comprises lighting the visual indicator.

47. The method of claim **45**, wherein the apparatus further comprises a display connected to the processor means and the step of notifying the individual comprises displaying a prompt on the display.

48. The method of claim **41**, wherein the user interface comprises a display, and the message is communicated to the individual by displaying the message on the display.

49. The method of claim **41**, wherein the user interface comprises a speech synthesizer, and the message is communicated to the individual by audibly synthesizing the message through the speech synthesizer.

50. The method of claim **41**, further comprising the steps of:

a) providing a plurality of individuals with a corresponding plurality of apparatuses such that each of the plurality of individuals is associated with a respective one of the plurality of apparatuses;

b) generating in the server a plurality of script programs;

c) assigning to each of the plurality of individuals at least one of the plurality of script programs;

d) storing in the server the plurality of script programs, a list of the plurality of individuals, and for each of the plurality of individuals, a respective pointer to the at least one of the plurality of script programs assigned to each of the plurality of individuals; and

e) transmitting to each of the plurality of apparatuses the at least one of the plurality of script programs assigned to each of the plurality of individuals associated with the respective one of the plurality of apparatuses.

* * * * *

EXHIBIT B

US006334778B1

(12) **United States Patent**
Brown

(10) **Patent No.: US 6,334,778 B1**
(45) **Date of Patent: Jan. 1, 2002**

(54) **REMOTE PSYCHOLOGICAL DIAGNOSIS AND MONITORING SYSTEM**

(75) Inventor: **Stephen J. Brown**, Woodside, CA (US)

(73) Assignee: **Health Hero Network, Inc.**, Mountain View, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/271,188**

(22) Filed: **Mar. 17, 1999**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/127,404, filed on Jul. 31, 1998, which is a continuation of application No. 08/843,495, filed on Apr. 16, 1997, now Pat. No. 5,828,943, which is a continuation of application No. 08/682,385, filed on Jul. 17, 1996, now abandoned, which is a continuation of application No. 08/479,570, filed on Jun. 7, 1995, now abandoned, which is a continuation of application No. 08/233,674, filed on Apr. 26, 1994, now abandoned, said application No. 09/127,404, is a continuation-in-part of application No.08/946,341, filed on Oct. 7, 1997.

(60) Provisional application No. 60/041,746, filed on Mar. 28, 1997, and provisional application No. 60/041,751, filed on Mar. 28, 1997.

(51) **Int. Cl.**[7] **G09B 7/00**

(52) **U.S. Cl.** **434/258**; 273/429; 273/430; 273/431; 273/432; 273/440; 434/236; 434/335; 434/362; 705/2

(58) **Field of Search** 434/258, 236, 434/335, 362; 273/429, 430, 431, 432, 440, 441, 445; 705/1, 2, 3

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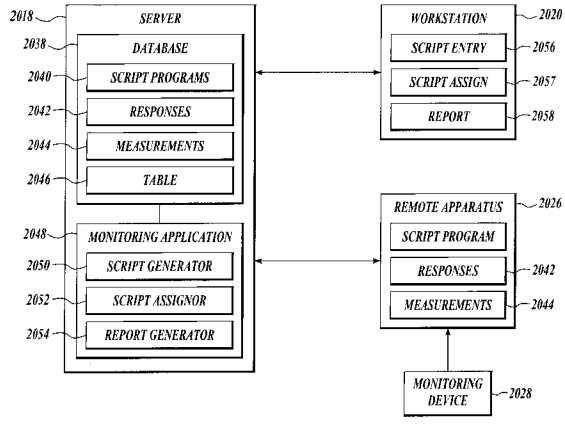
Primary Examiner—Stephen R. Tkacs
(74) *Attorney, Agent, or Firm*—Black Lowe & Graham PLLC

(57) **ABSTRACT**

A networked system for remotely assessing and monitoring psychological conditions. The system includes a server and a remote interface for entering in the server prompts, such as queries and instructions, to be responded to by the individual. The server is preferably a web server and the remote clinician interface is preferably a personal computer connected to the server via the Internet. The system also includes a remotely programmable patient apparatus connected to the server via a communication link, preferably the Internet. The patient apparatus interacts with the individual in accordance with a script received from the server. The server includes a script generator for generating the script from the set of prompts entered through the remote interface. The script is received and executed by the patient apparatus to communicate the prompts to the individual, to receive responses to the prompts, and to transmit the responses from the patient apparatus to the server. In accordance with the invention, the patient apparatus is programmed to prompt a patient to interactively operate one or more switches. Information recorded during an interactive diagnostic assessment procedure is analyzed to provide a health care professional with information that is helpful to determine whether clinical therapy and/or medication may be required. The preferred embodiment of the invention relates to diagnostic assessment of Attention Deficit Hyperactivity Disorder and Attention Deficit Disorder with a game-like video display being used to obtain a measure of various neuropsychologic indicia of attention.

66 Claims, 27 Drawing Sheets



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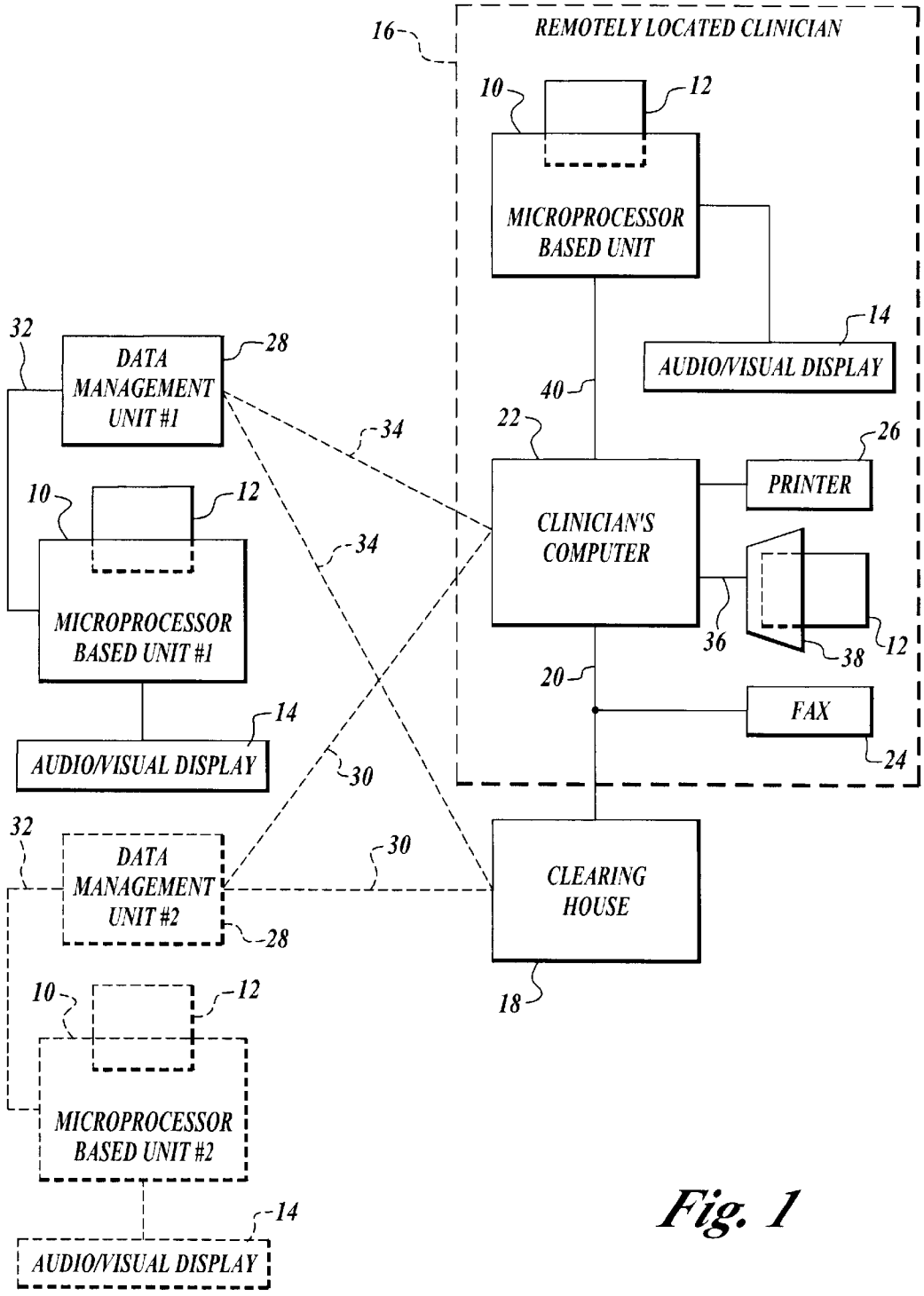
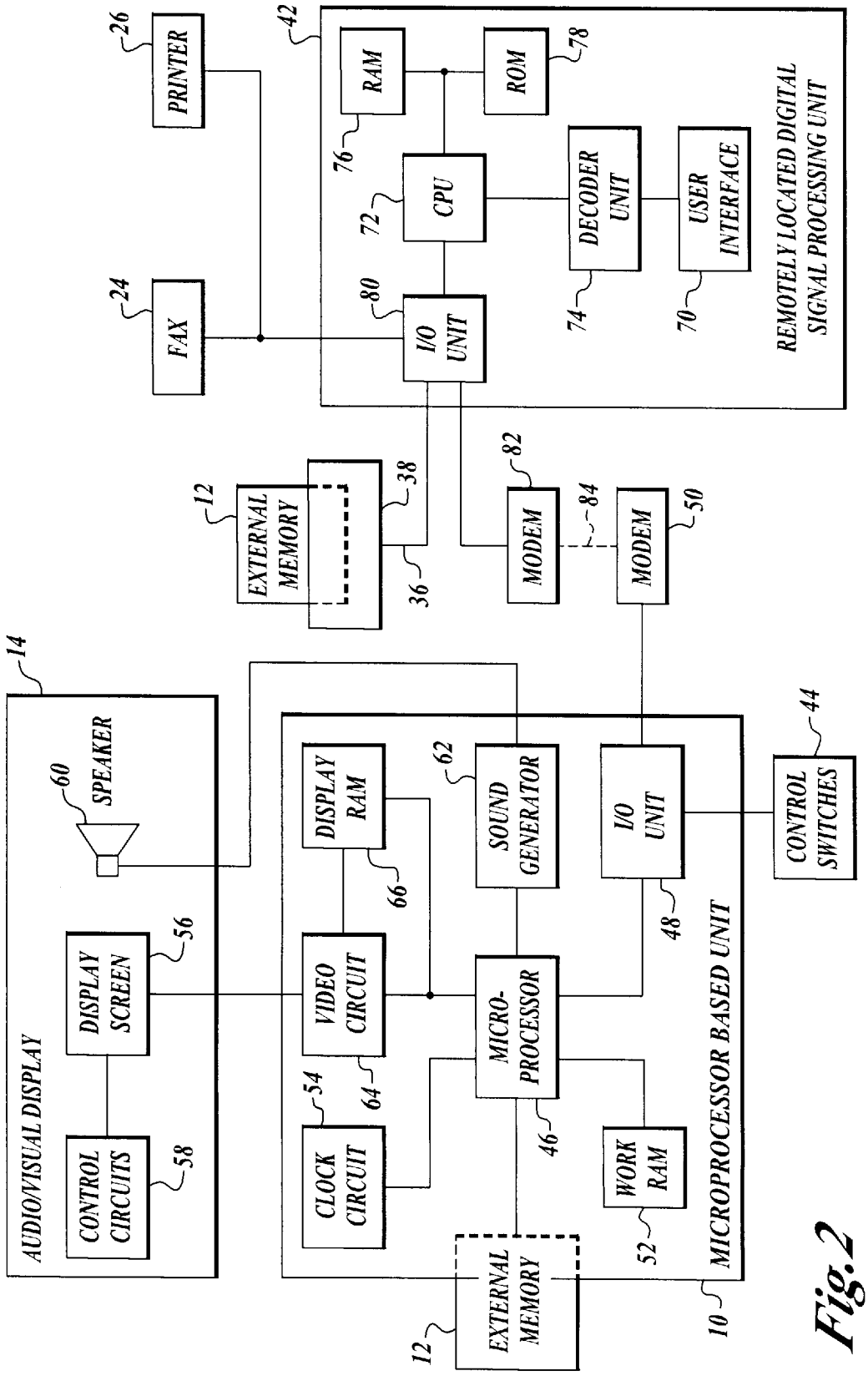

16
REMOTELY LOCATED CLINICIAN
10
12
MICROPROCESSOR BASED UNIT
14
AUDIO/VISUAL DISPLAY
40
22
CLINICIAN'S COMPUTER
26
PRINTER
36
38
12
20
FAX
24
32
DATA MANAGEMENT UNIT #1
28
34
10
12
MICROPROCESSOR BASED UNIT #1
34
14
AUDIO/VISUAL DISPLAY
30
32
DATA MANAGEMENT UNIT #2
30
28
CLEARING HOUSE
18
10
12
MICROPROCESSOR BASED UNIT #2
14
AUDIO/VISUAL DISPLAY

Fig. 1


PRINTER
26
FAX
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RAM
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ROM
78
CPU
72
DECODER UNIT
74
USER INTERFACE
70
I/O UNIT
80
REMOTELY LOCATED DIGITAL SIGNAL PROCESSING UNIT
EXTERNAL MEMORY
12
38
36
MODEM
82
84
MODEM
50
14
AUDIO/VISUAL DISPLAY
SPEAKER
60
DISPLAY SCREEN
56
CONTROL CIRCUITS
58
DISPLAY RAM
66
VIDEO CIRCUIT
64
CLOCK CIRCUIT
54
62
SOUND GENERATOR
MICRO-PROCESSOR
46
I/O UNIT
48
CONTROL SWITCHES
44
WORK RAM
52
MICROPROCESSOR BASED UNIT
10
EXTERNAL MEMORY
12

Fig. 2

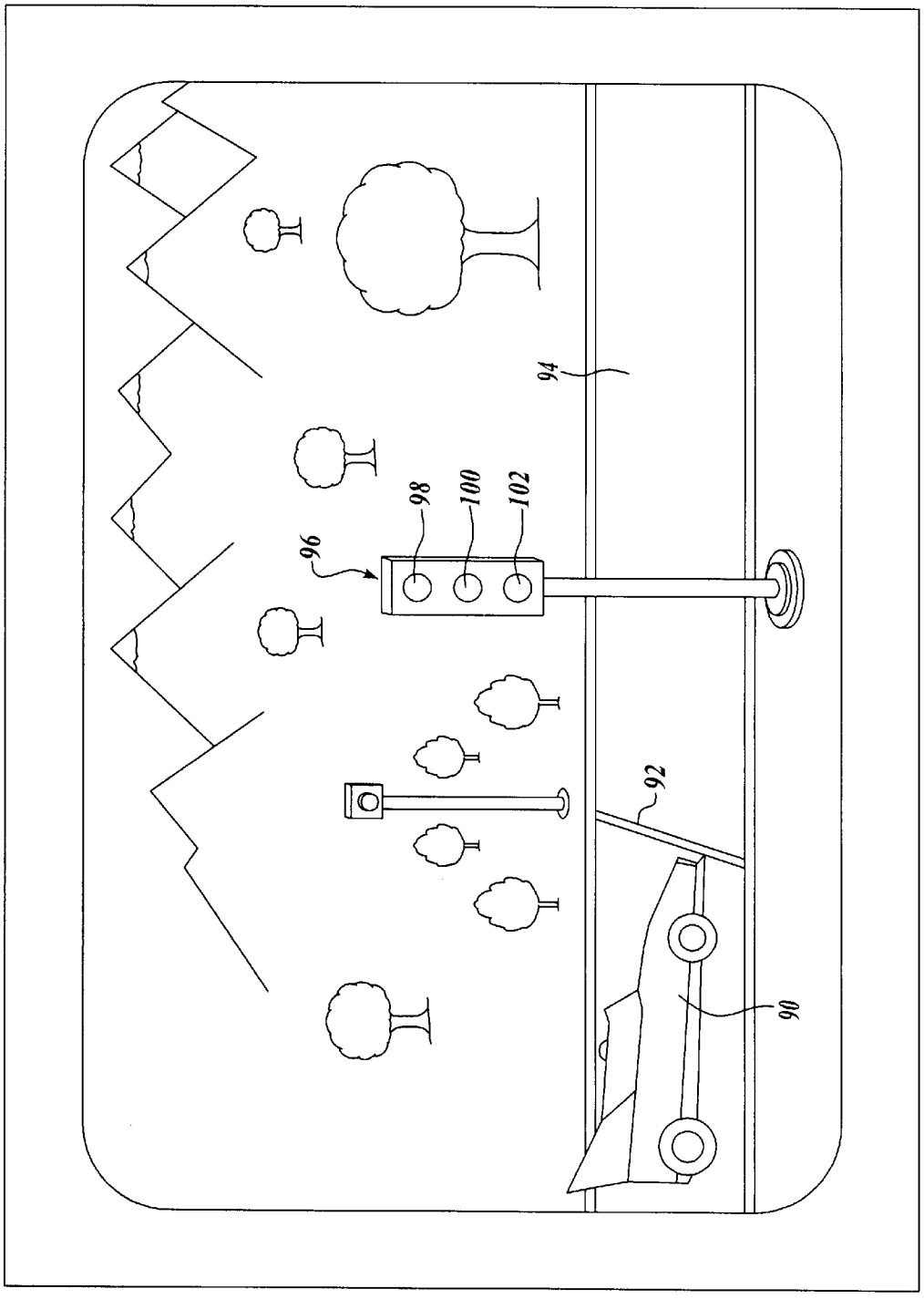

Fig. 3

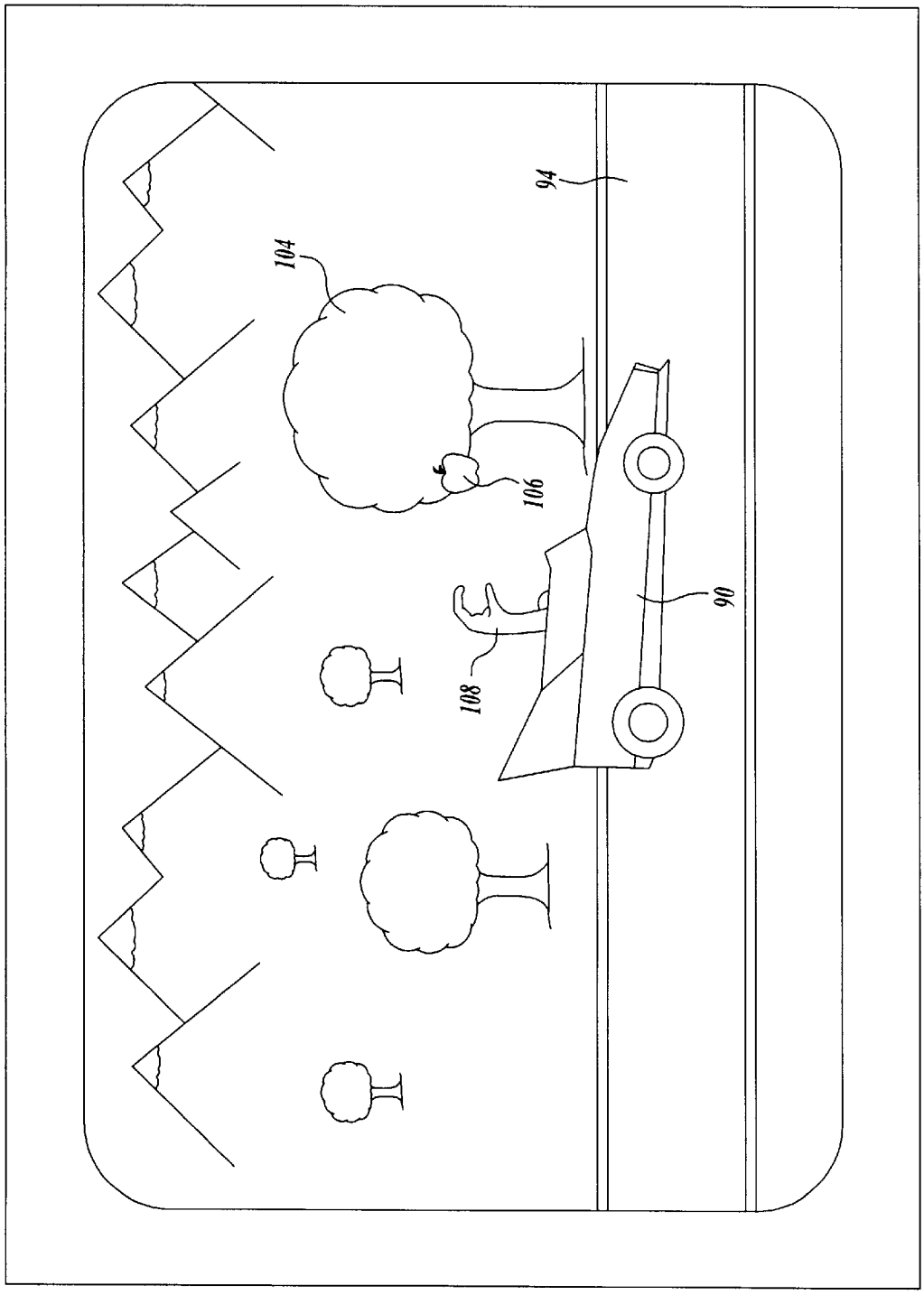

Fig. 4

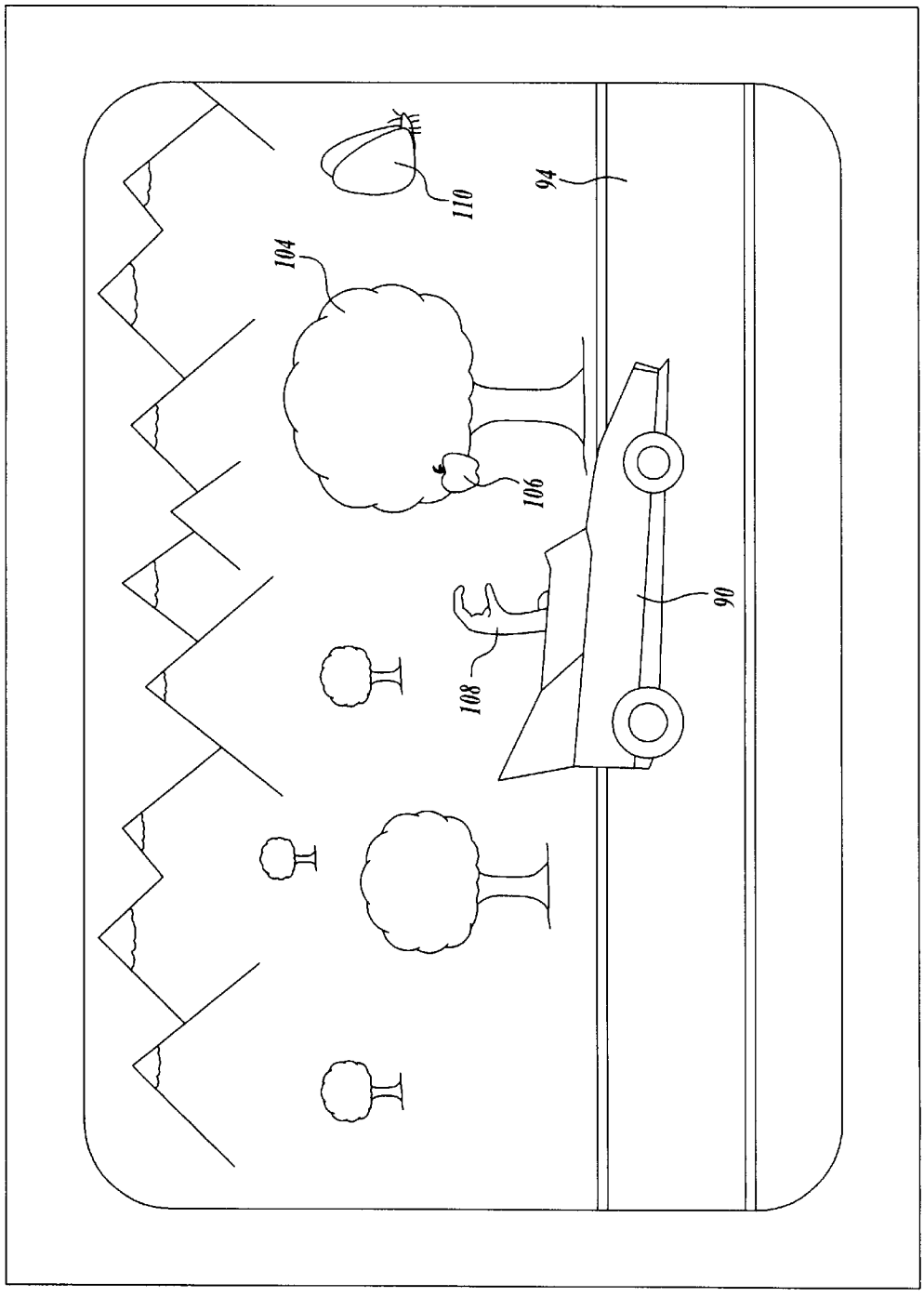

Fig. 5

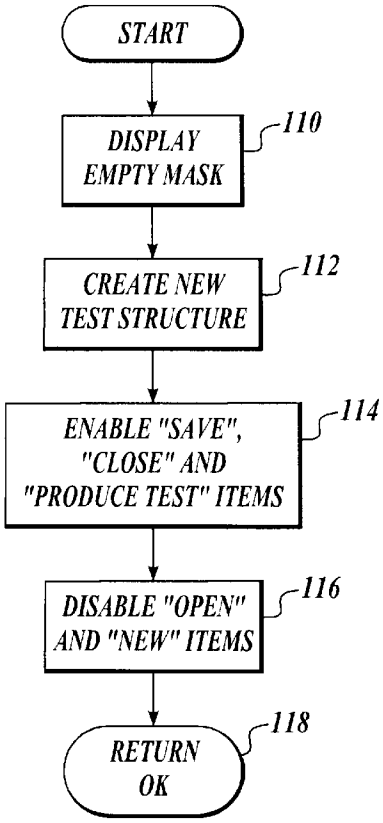
START
DISPLAY EMPTY MASK
110
CREATE NEW TEST STRUCTURE
112
ENABLE "SAVE", "CLOSE" AND "PRODUCE TEST" ITEMS
114
DISABLE "OPEN" AND "NEW" ITEMS
116
RETURN OK
118

Fig. 6

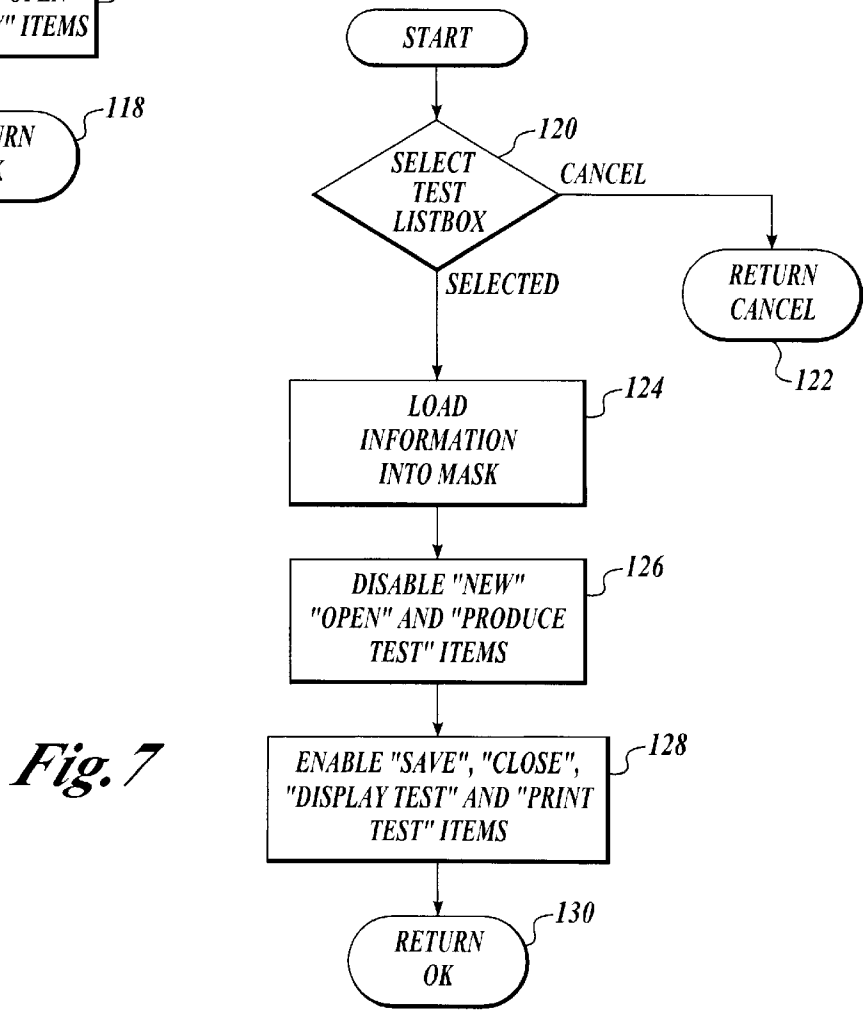
START
SELECT TEST LISTBOX
120
CANCEL
SELECTED
RETURN CANCEL
122
LOAD INFORMATION INTO MASK
124
DISABLE "NEW" "OPEN" AND "PRODUCE TEST" ITEMS
126
ENABLE "SAVE", "CLOSE", "DISPLAY TEST" AND "PRINT TEST" ITEMS
128
RETURN OK
130

Fig. 7

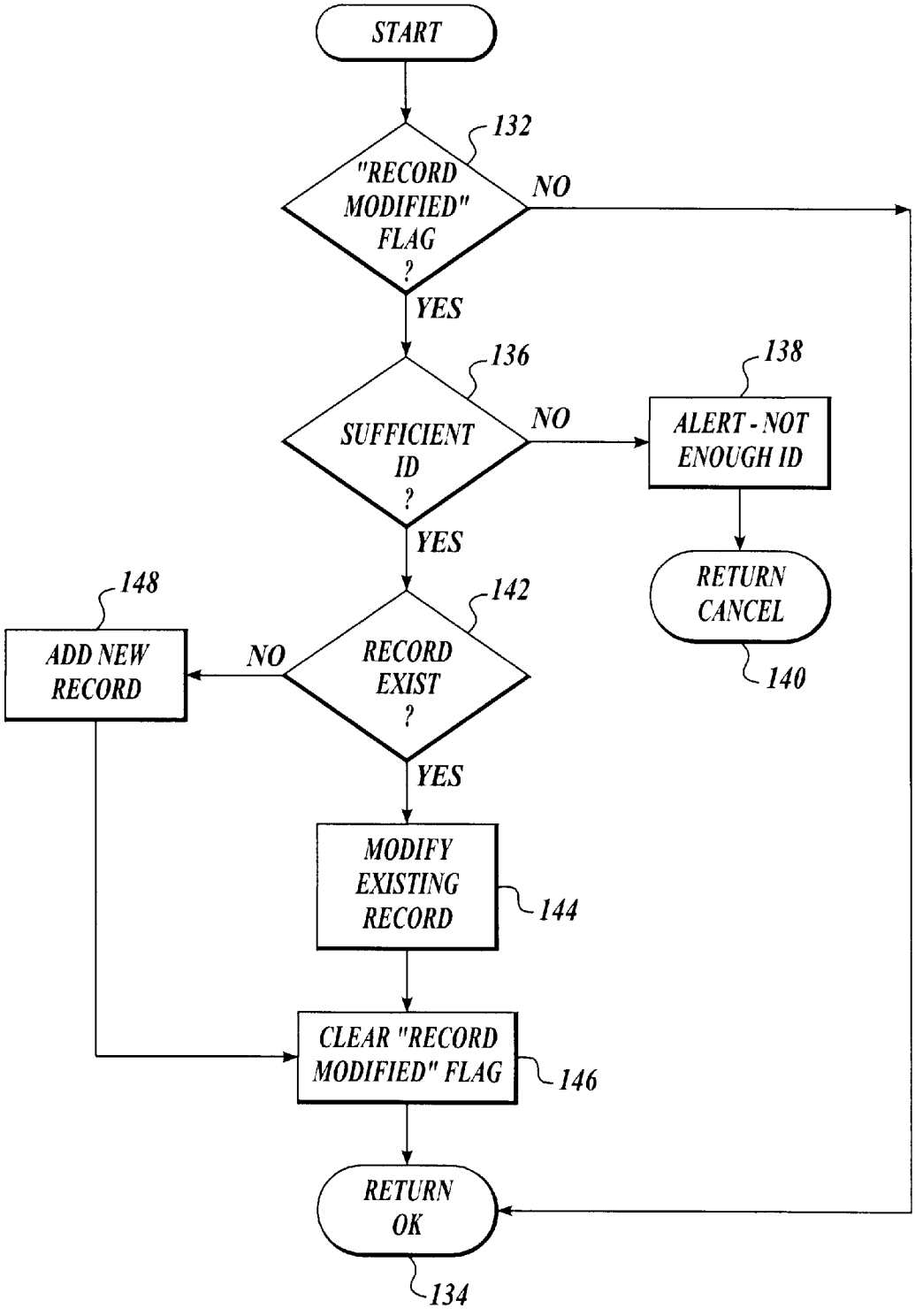
START
132
"RECORD MODIFIED" FLAG ?
NO
YES
136
SUFFICIENT ID ?
NO
138
ALERT - NOT ENOUGH ID
RETURN CANCEL
140
YES
148
ADD NEW RECORD
NO
142
RECORD EXIST ?
YES
MODIFY EXISTING RECORD
144
CLEAR "RECORD MODIFIED" FLAG
146
RETURN OK
134

Fig. 8

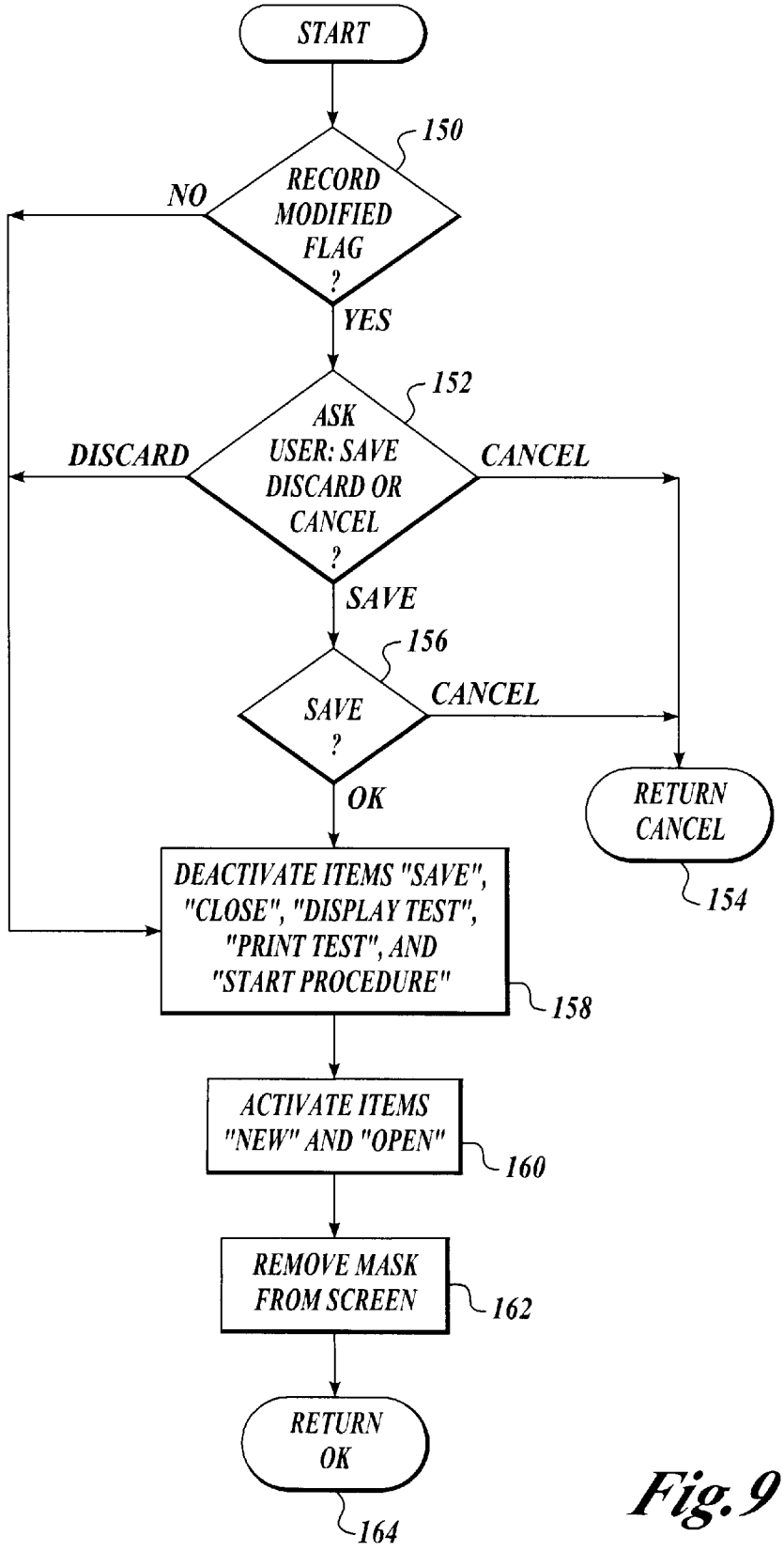
START
150
RECORD MODIFIED FLAG ?
NO
YES
152
ASK USER: SAVE DISCARD OR CANCEL ?
DISCARD
CANCEL
SAVE
156
SAVE ?
CANCEL
OK
RETURN CANCEL
154
DEACTIVATE ITEMS "SAVE", "CLOSE", "DISPLAY TEST", "PRINT TEST", AND "START PROCEDURE"
158
ACTIVATE ITEMS "NEW" AND "OPEN"
160
REMOVE MASK FROM SCREEN
162
RETURN OK
164

Fig. 9

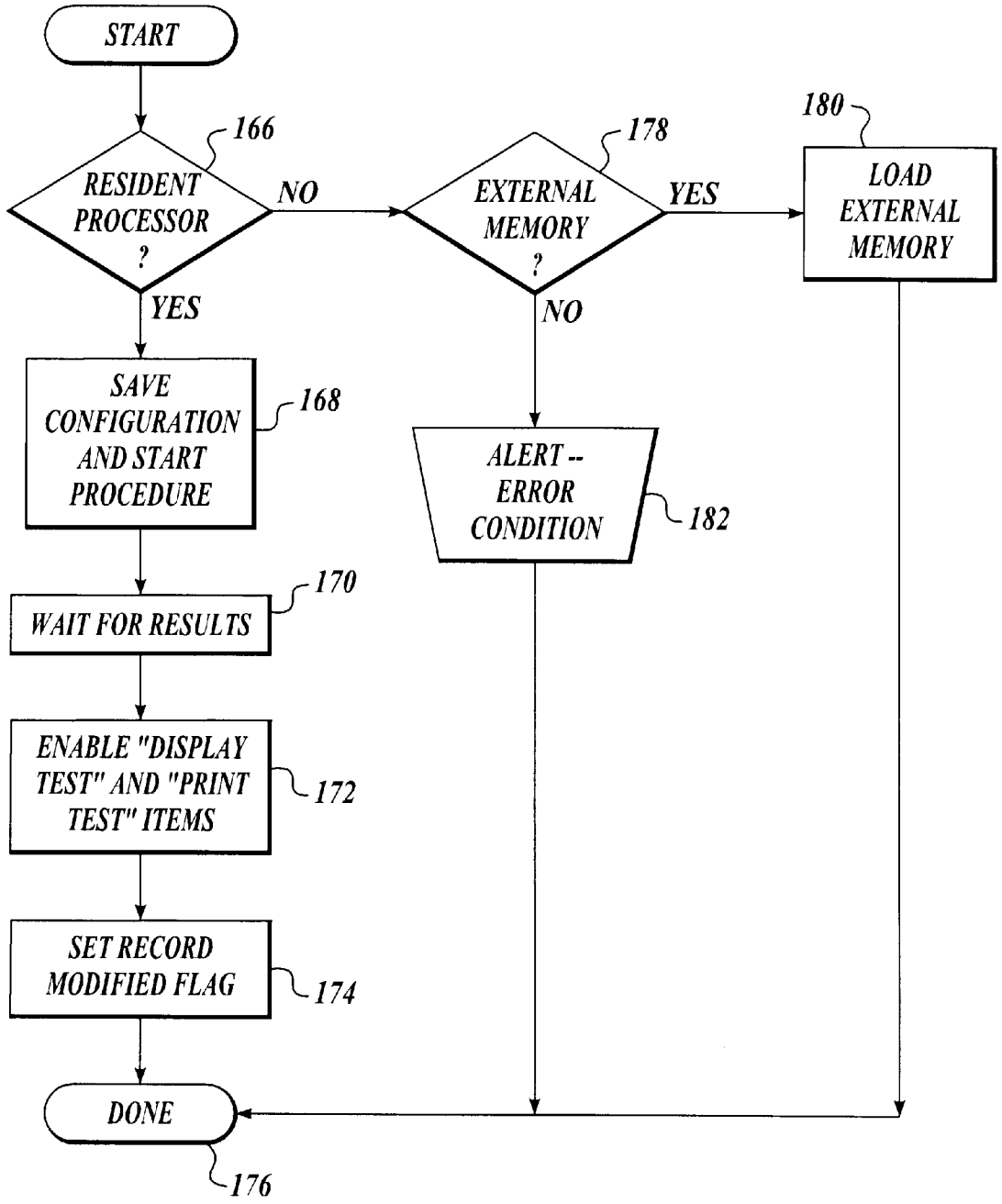
START
166
RESIDENT PROCESSOR ?
NO
YES
178
EXTERNAL MEMORY ?
YES
NO
180
LOAD EXTERNAL MEMORY
SAVE CONFIGURATION AND START PROCEDURE
168
ALERT -- ERROR CONDITION
182
WAIT FOR RESULTS
170
ENABLE "DISPLAY TEST" AND "PRINT TEST" ITEMS
172
SET RECORD MODIFIED FLAG
174
DONE
176

Fig. 10

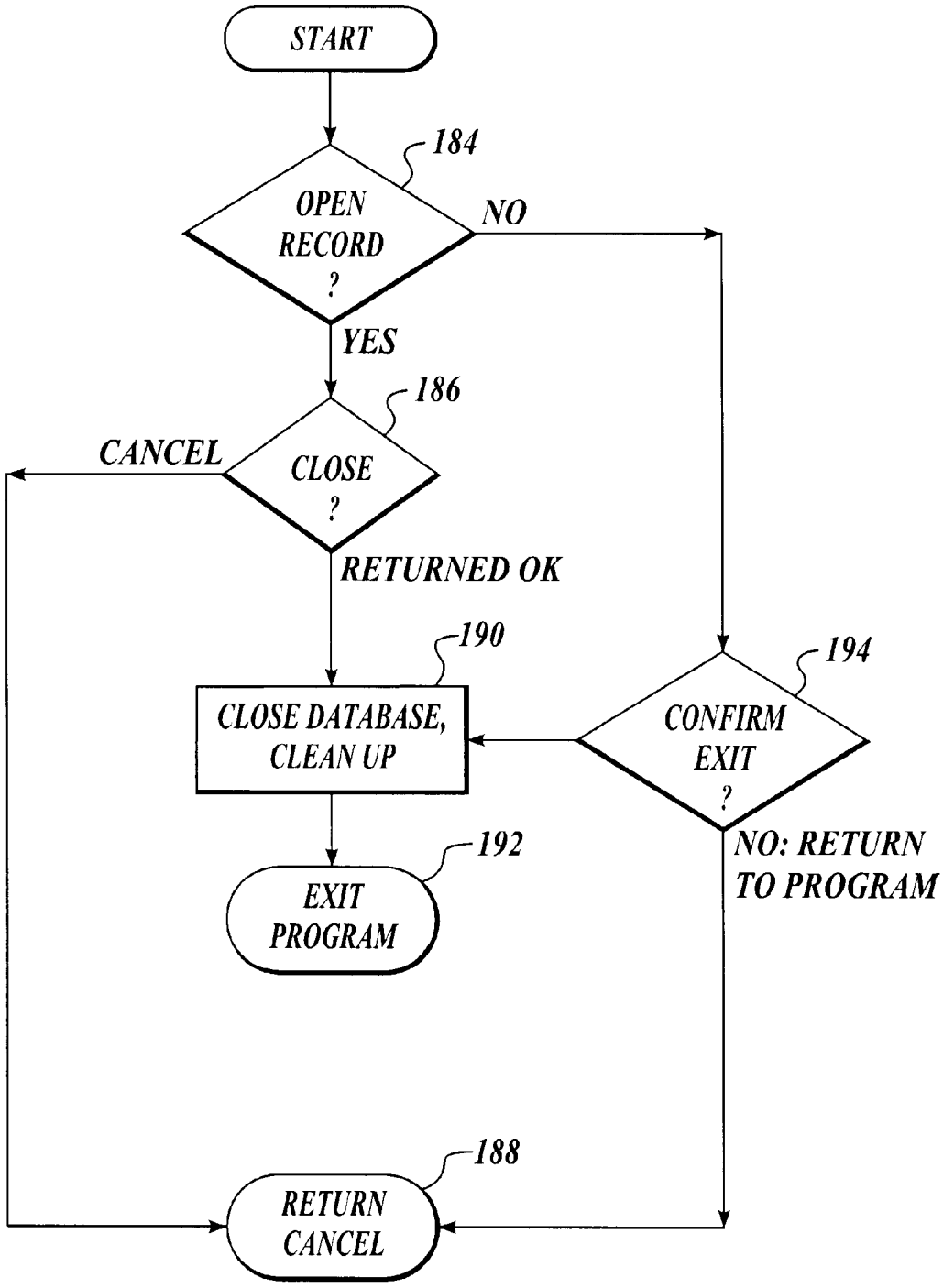
START
184
OPEN RECORD ?
NO
YES
186
CANCEL
CLOSE ?
RETURNED OK
190
194
CLOSE DATABASE, CLEAN UP
CONFIRM EXIT ?
192
NO: RETURN TO PROGRAM
EXIT PROGRAM
188
RETURN CANCEL

Fig. 11

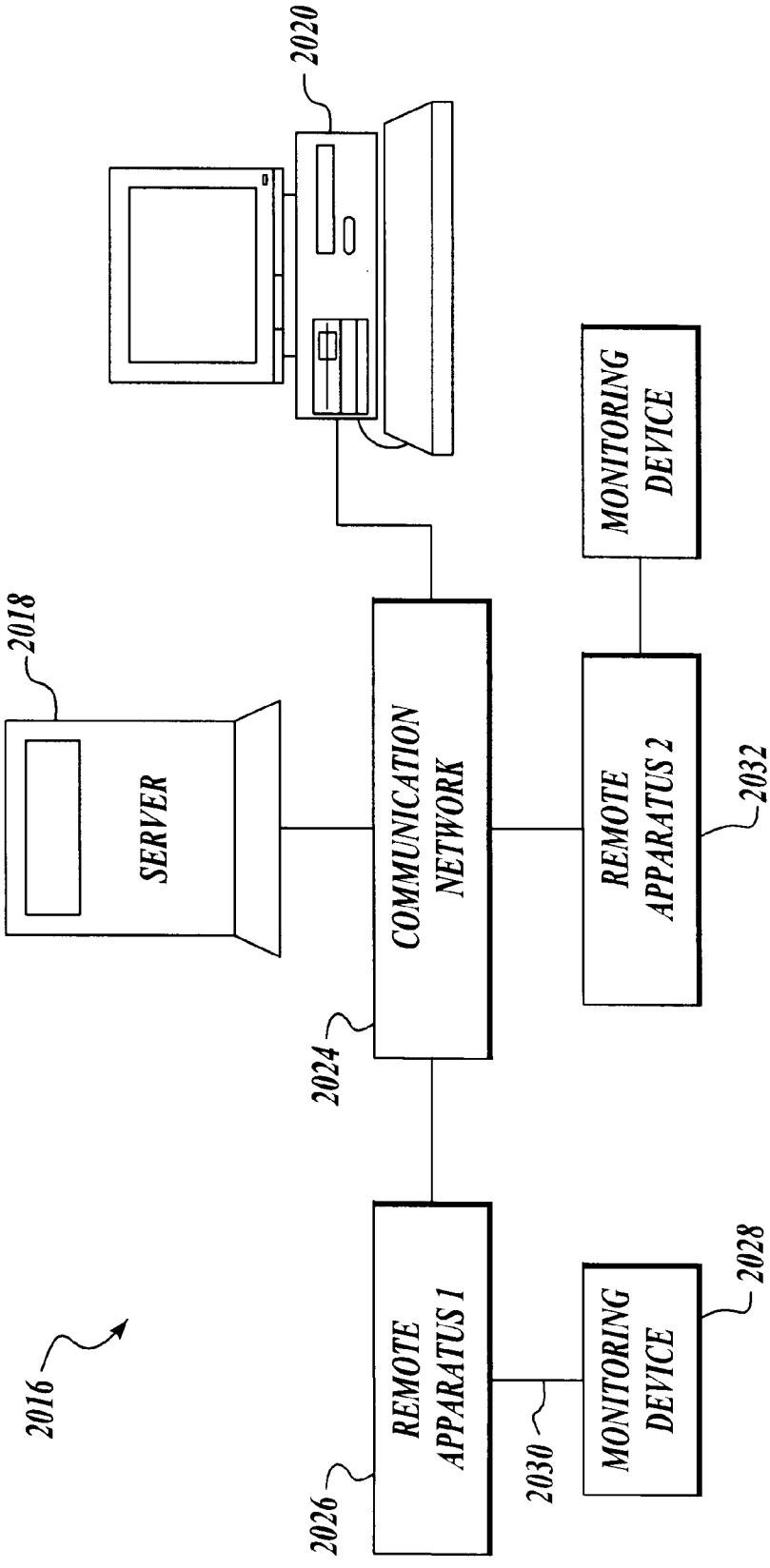
2020
MONITORING DEVICE
2018
SERVER
COMMUNICATION NETWORK
REMOTE APPARATUS 2
2032
2024
2016
REMOTE APPARATUS 1
MONITORING DEVICE
2028
2026
2030

Fig. 201

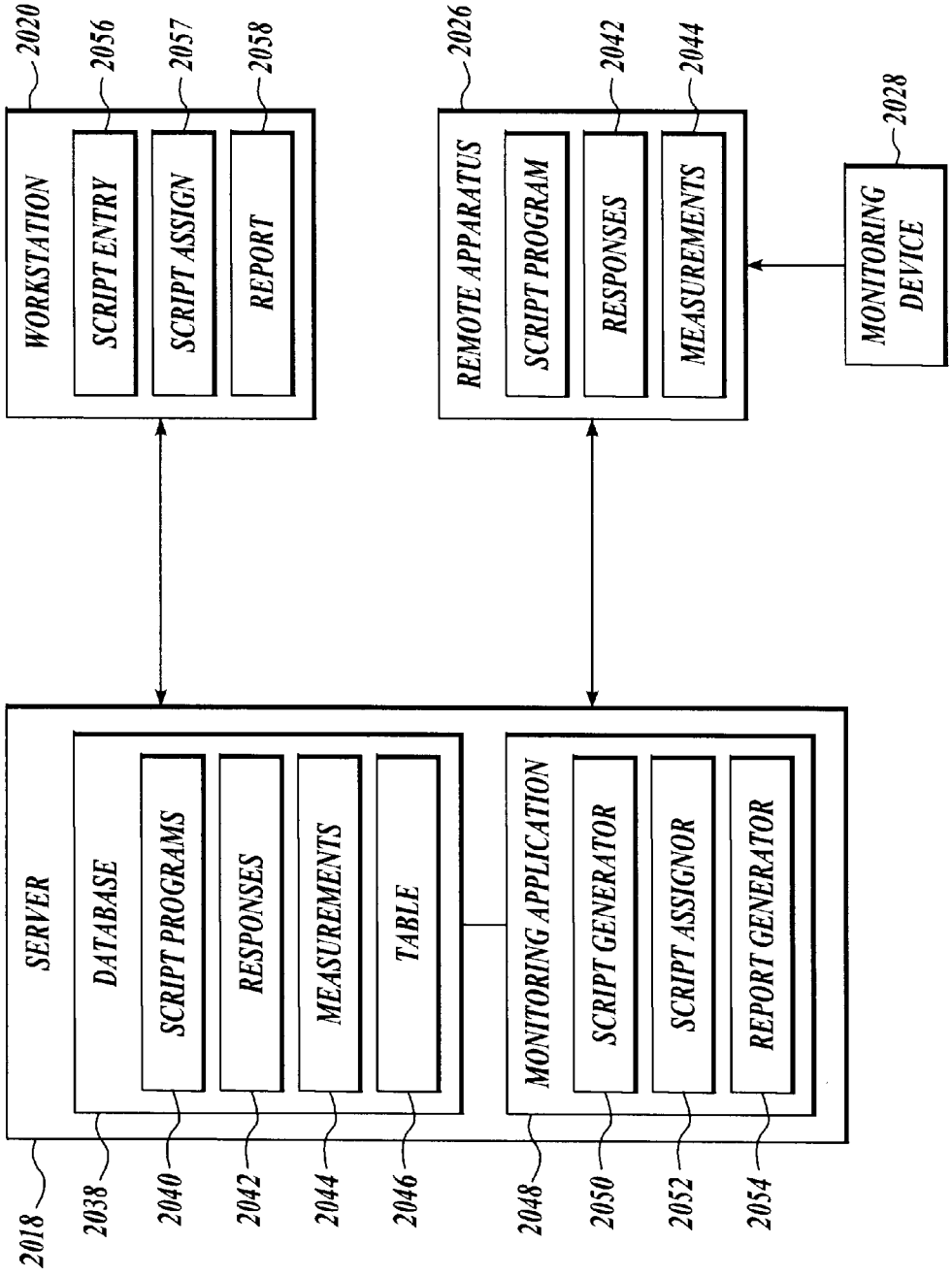
2020
2056
2057
2058
WORKSTATION
SCRIPT ENTRY
SCRIPT ASSIGN
REPORT
2026
2042
2044
REMOTE APPARATUS
SCRIPT PROGRAM
RESPONSES
MEASUREMENTS
2028
MONITORING DEVICE
SERVER
DATABASE
SCRIPT PROGRAMS
RESPONSES
MEASUREMENTS
TABLE
MONITORING APPLICATION
SCRIPT GENERATOR
SCRIPT ASSIGNOR
REPORT GENERATOR
2018
2038
2040
2042
2044
2046
2048
2050
2052
2054

Fig. 202

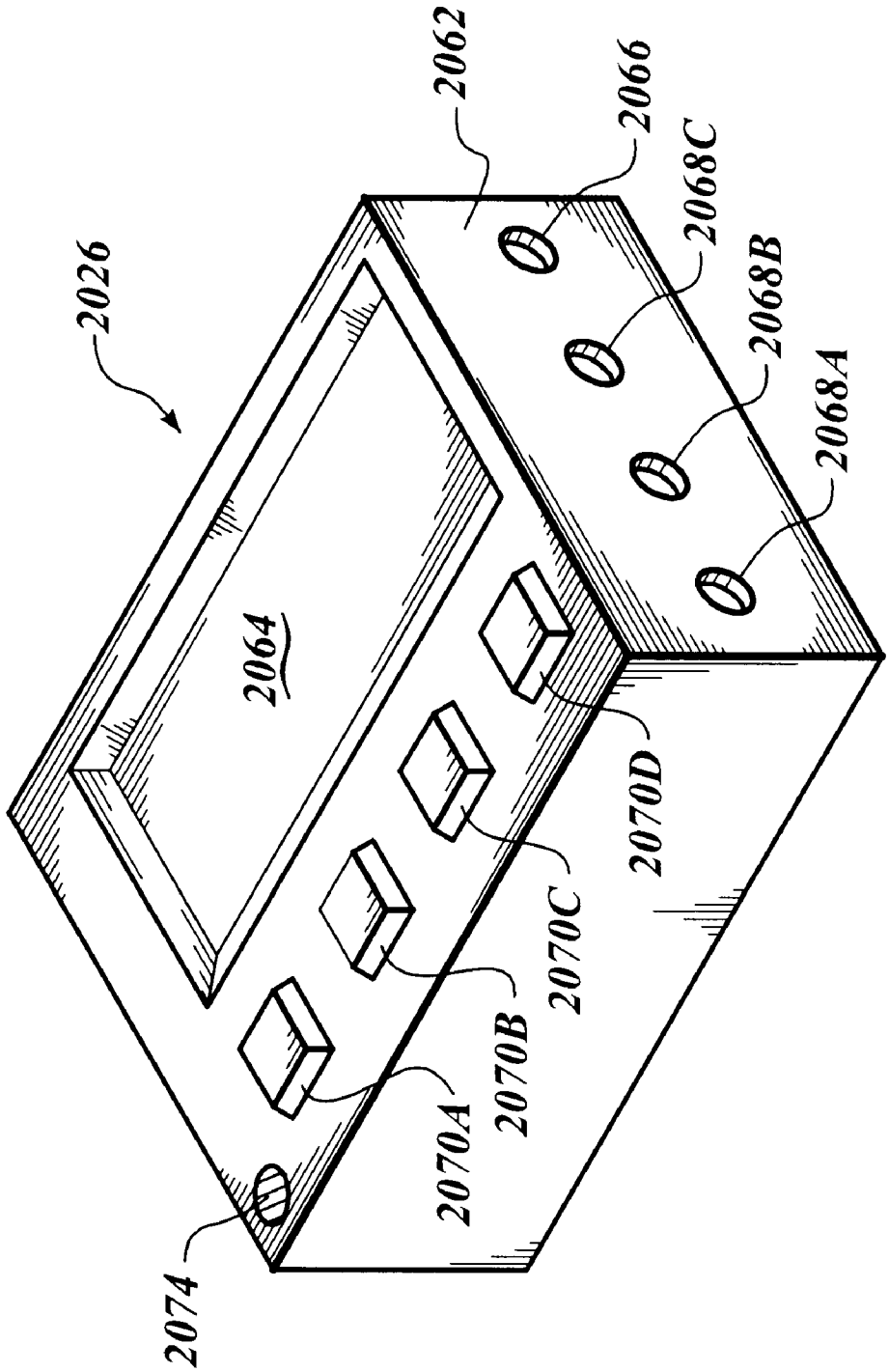
2062
2066
2068C
2068B
2068A
2026
2064
2070D
2070C
2070B
2070A
2074

Fig. 203

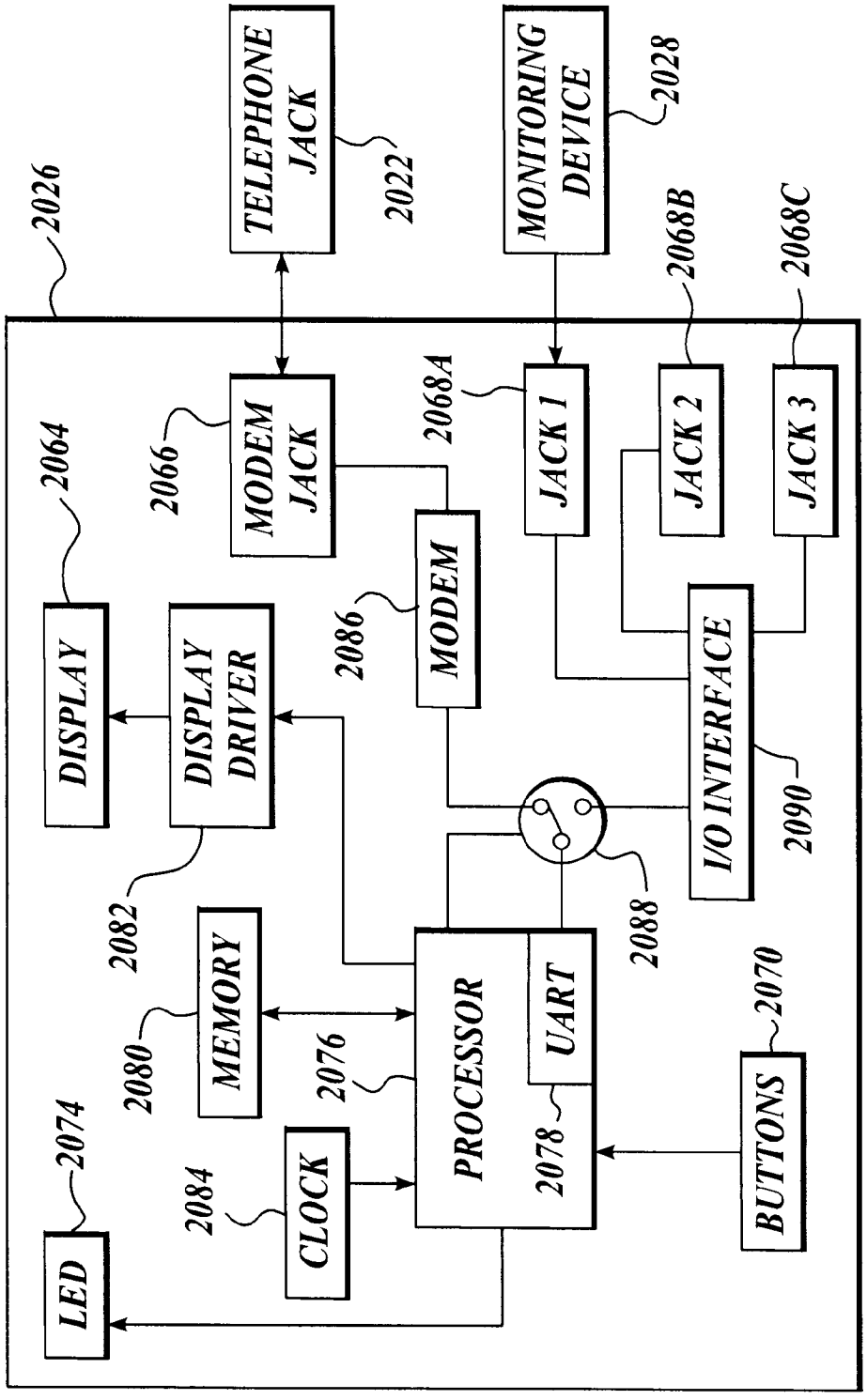
2026
TELEPHONE JACK
2022
MONITORING DEVICE
2028
2068B
2068C
2064
2066
MODEM JACK
2068A
JACK 1
JACK 2
JACK 3
DISPLAY
DISPLAY DRIVER
2086
MODEM
I/O INTERFACE
2090
2082
2088
2080
MEMORY
2076
PROCESSOR
UART
2070
2074
2084
CLOCK
2078
BUTTONS
LED

Fig. 204

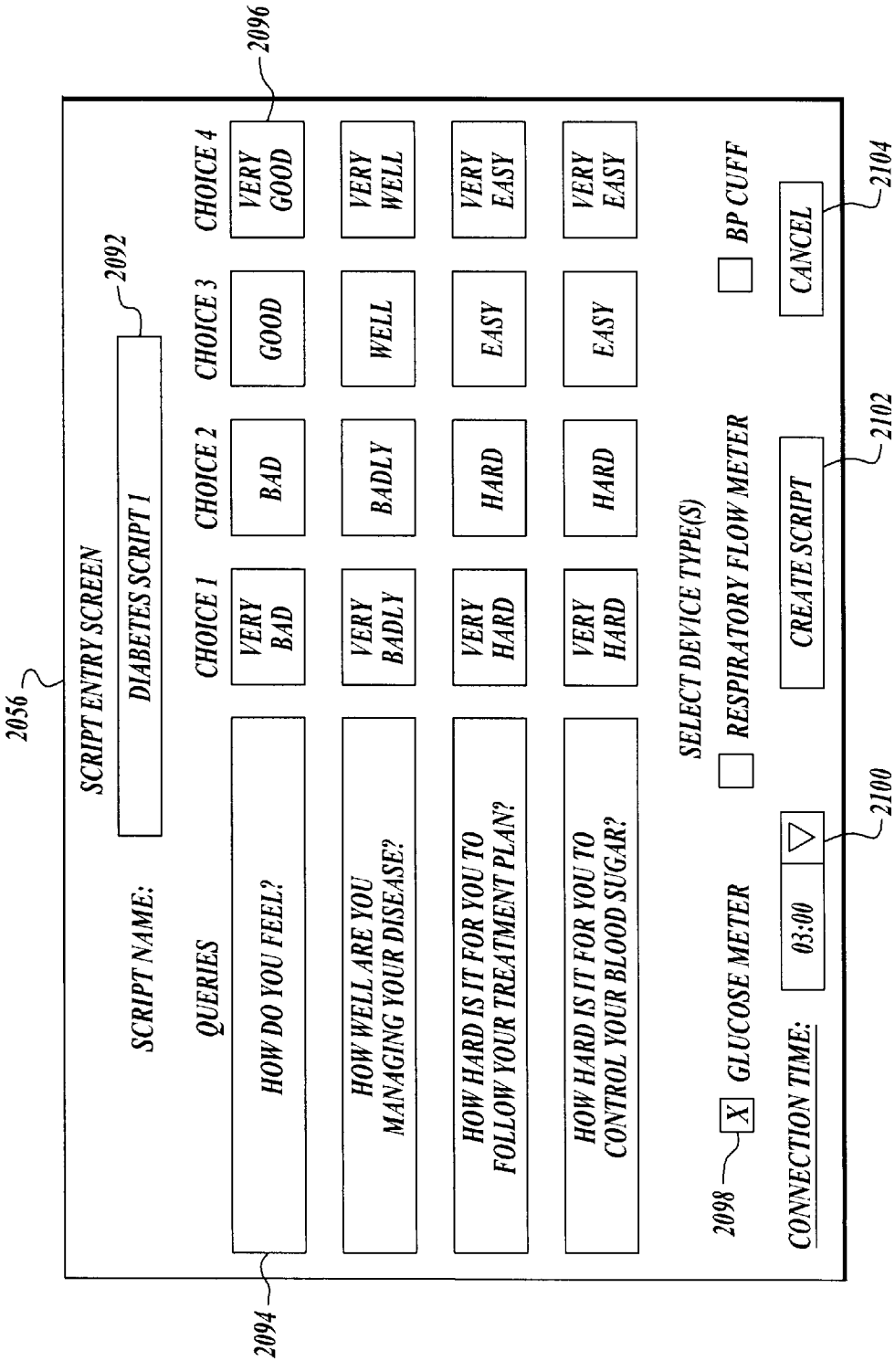
2056
SCRIPT ENTRY SCREEN
SCRIPT NAME:
DIABETES SCRIPT 1
2092
2096
QUERIES
CHOICE 1
CHOICE 2
CHOICE 3
CHOICE 4
HOW DO YOU FEEL?
VERY BAD
BAD
GOOD
VERY GOOD
HOW WELL ARE YOU MANAGING YOUR DISEASE?
VERY BADLY
BADLY
WELL
VERY WELL
HOW HARD IS IT FOR YOU TO FOLLOW YOUR TREATMENT PLAN?
VERY HARD
HARD
EASY
VERY EASY
HOW HARD IS IT FOR YOU TO CONTROL YOUR BLOOD SUGAR?
VERY HARD
HARD
EASY
VERY EASY
SELECT DEVICE TYPE(S)
2098
X GLUCOSE METER
RESPIRATORY FLOW METER
BP CUFF
CONNECTION TIME:
03:00
2100
CREATE SCRIPT
2102
CANCEL
2104
2094

Fig. 205

```
NUMBER: 9001 {LF}
LED: 1 {LF}
ZAP: {LF}
CLS: {LF}
DISPLAY: ANSWER QUERIES NOW?
                PRESS ANY BUTTON TO START {LF}
WAIT: {LF}
CLS: {LF}
DISPLAY: HOW DO YOU FEEL?
                VERY                    VERY
                BAD     BAD     GOOD    GOOD {LF}
INPUT: 0000 {LF}
CLS: {LF}
DISPLAY: HOW WELL ARE YOU
                MANAGING YOUR DISEASE?
                VERY                    VERY
                WELL    BADLY   WELL    WELL {LF}
INPUT: 0000 {LF}
CLS: {LF}
DISPLAY: HOW HARD IS IT FOR YOU TO
                FOLLOW YOUR TREATMENT PLAN?
                VERY                    VERY
                HARD    HARD    EASY    EASY {LF}
INPUT: 0000 {LF}
CLS: {LF}
DISPLAY: HOW HARD IS IT FOR YOU TO
                CONTROL YOUR BLOOD SUGAR?
                VERY                    VERY
                HARD    HARD    EASY    EASY {LF}
```

Fig. 206A

```
INPUT: 0000 {LF}
CLS: {LF}
DISPLAY: CONNECT GLUCOSE METER
                AND PRESS ANY BUTTON
                WHEN FINISHED {LF}
WAIT: {LF}
CLS: {LF}
DISPLAY: COLLECTING MEASUREMENTS {LF}
COLLECT: GLUCOSE_METER {LF}
CLS: {LF}
DISPLAY: CONNECT APPARATUS TO
                TELEPHONE JACK AND
                PRESS ANY BUTTON
                WHEN FINISHED {LF}
WAIT: {LF}
LED: 0 {LF}
CLS: {LF}
DELAY: 03:00 {LF}
DISPLAY: CONNECTING TO SERVER {LF}
CONNECT: {LF}
{EOF}
```

Fig. 206B

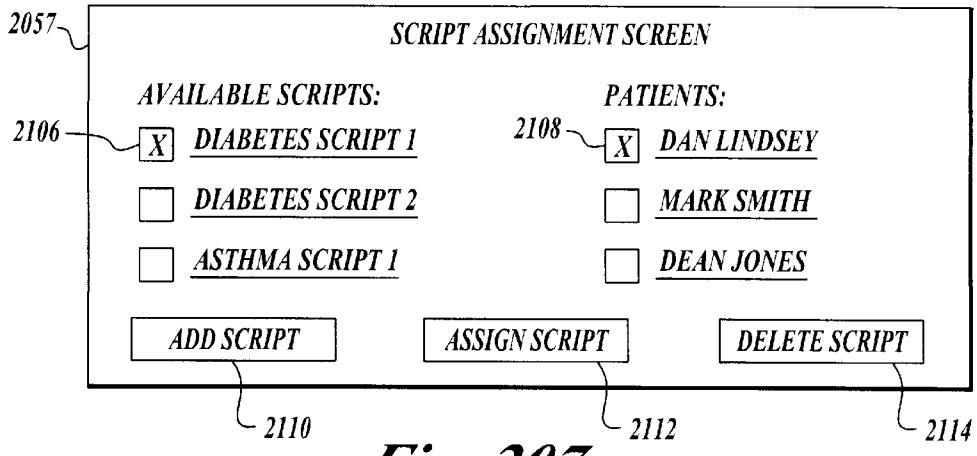

Fig. 207

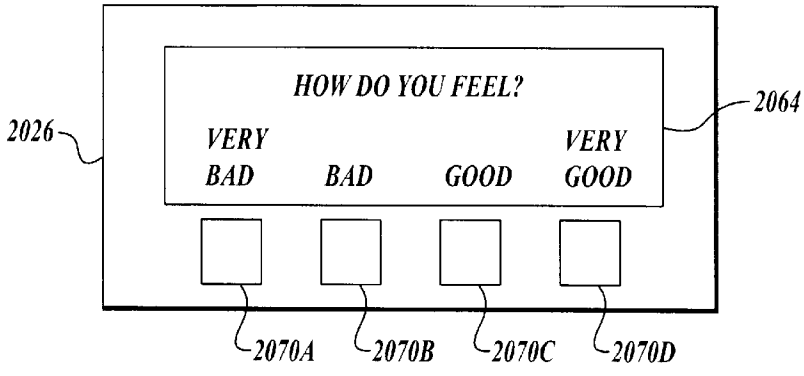

Fig. 208

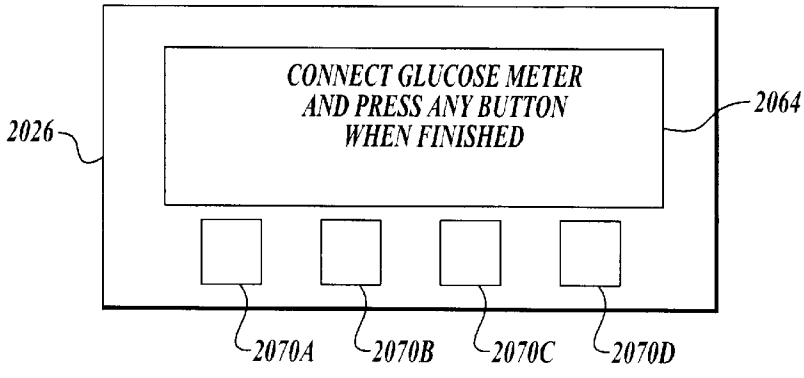

Fig. 209

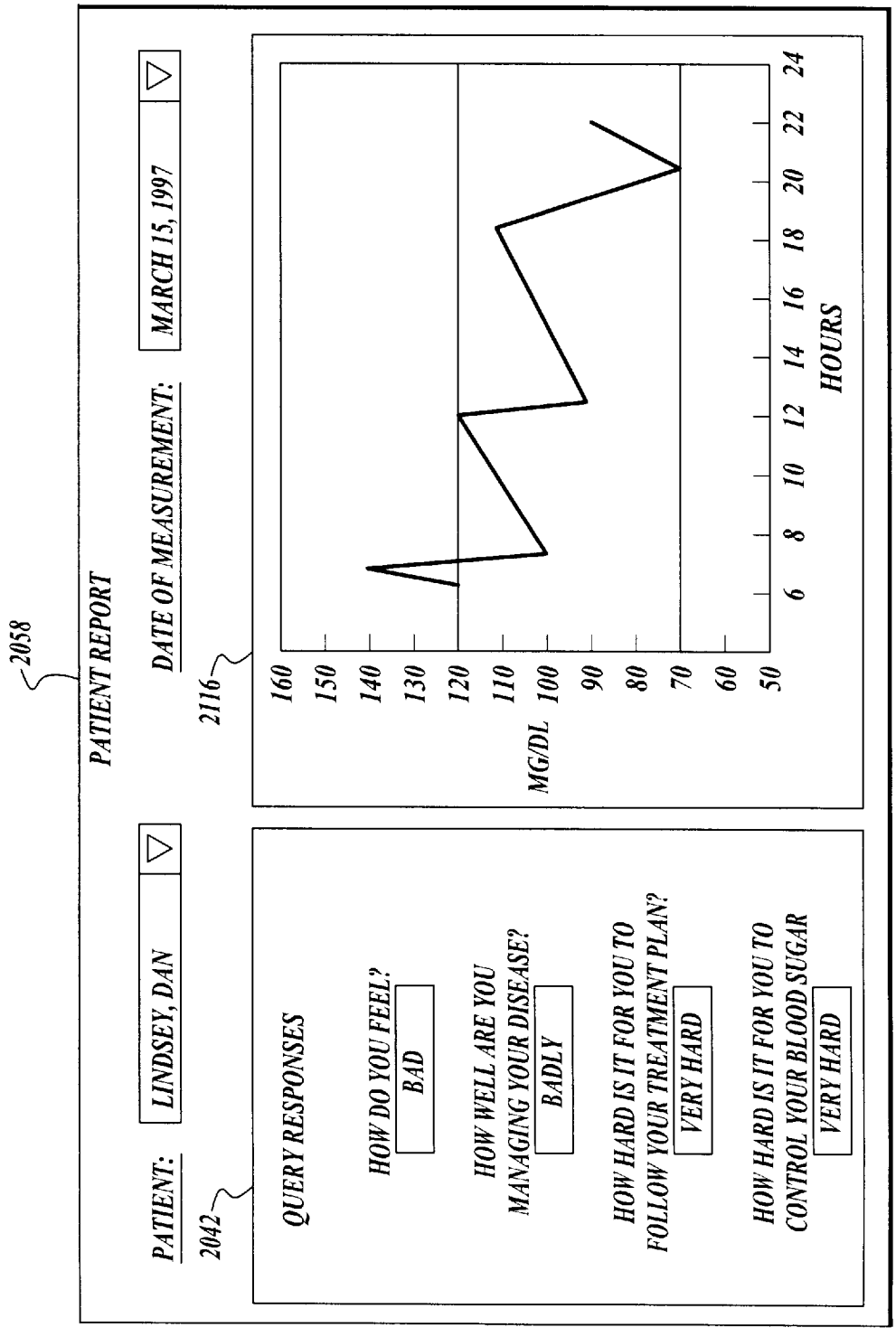
2058
PATIENT REPORT
PATIENT: LINDSEY, DAN
DATE OF MEASUREMENT: MARCH 15, 1997
2042
QUERY RESPONSES
HOW DO YOU FEEL? BAD
HOW WELL ARE YOU MANAGING YOUR DISEASE? BADLY
HOW HARD IS IT FOR YOU TO FOLLOW YOUR TREATMENT PLAN? VERY HARD
HOW HARD IS IT FOR YOU TO CONTROL YOUR BLOOD SUGAR VERY HARD
2116
MG/DL
160 150 140 130 120 110 100 90 80 70 60 50
HOURS
6 8 10 12 14 16 18 20 22 24

Fig. 210

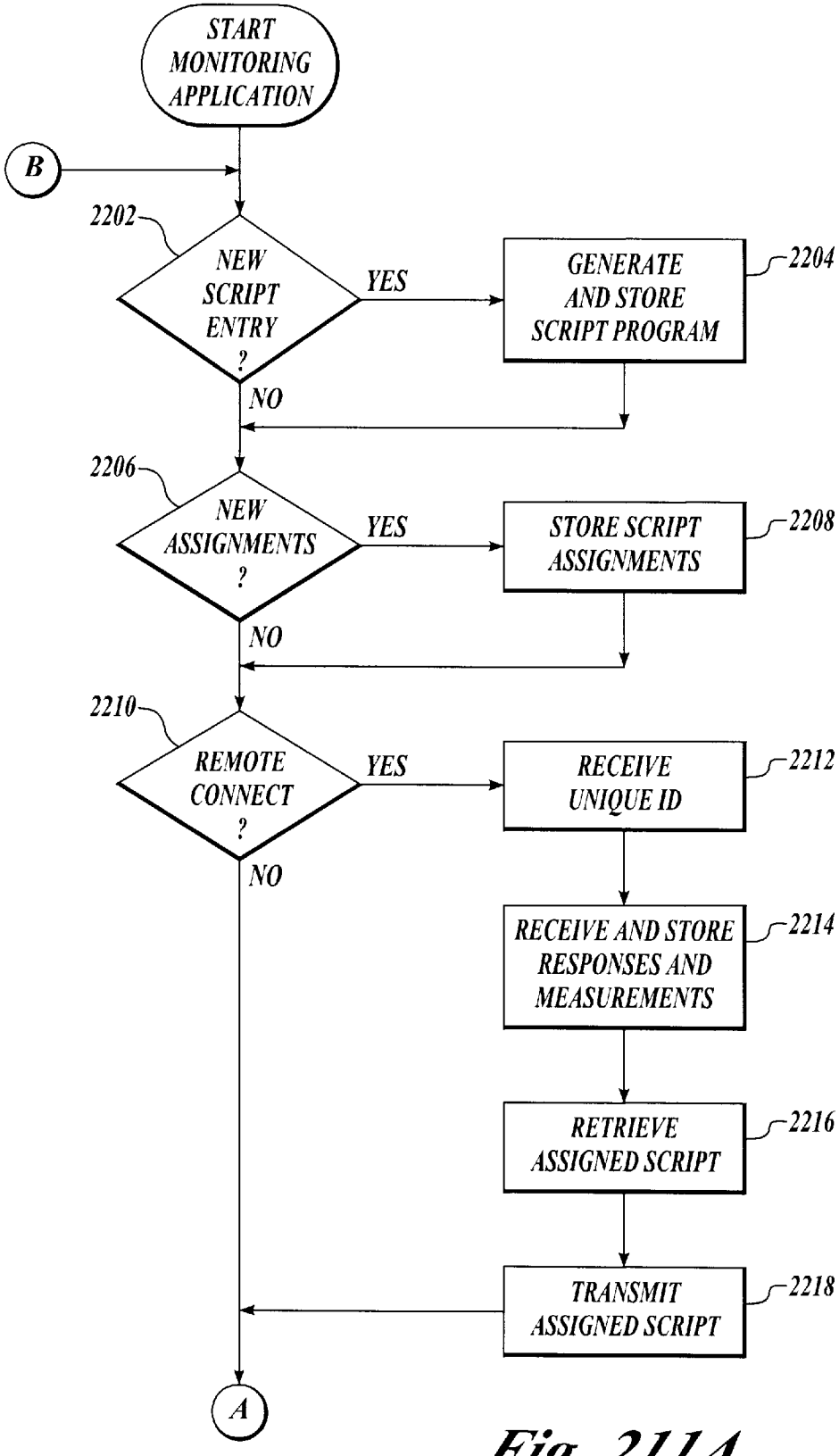
START MONITORING APPLICATION
B
2202
NEW SCRIPT ENTRY ?
YES
GENERATE AND STORE SCRIPT PROGRAM
2204
NO
2206
NEW ASSIGNMENTS ?
YES
STORE SCRIPT ASSIGNMENTS
2208
NO
2210
REMOTE CONNECT ?
YES
RECEIVE UNIQUE ID
2212
NO
RECEIVE AND STORE RESPONSES AND MEASUREMENTS
2214
RETRIEVE ASSIGNED SCRIPT
2216
TRANSMIT ASSIGNED SCRIPT
2218
A

Fig. 211A

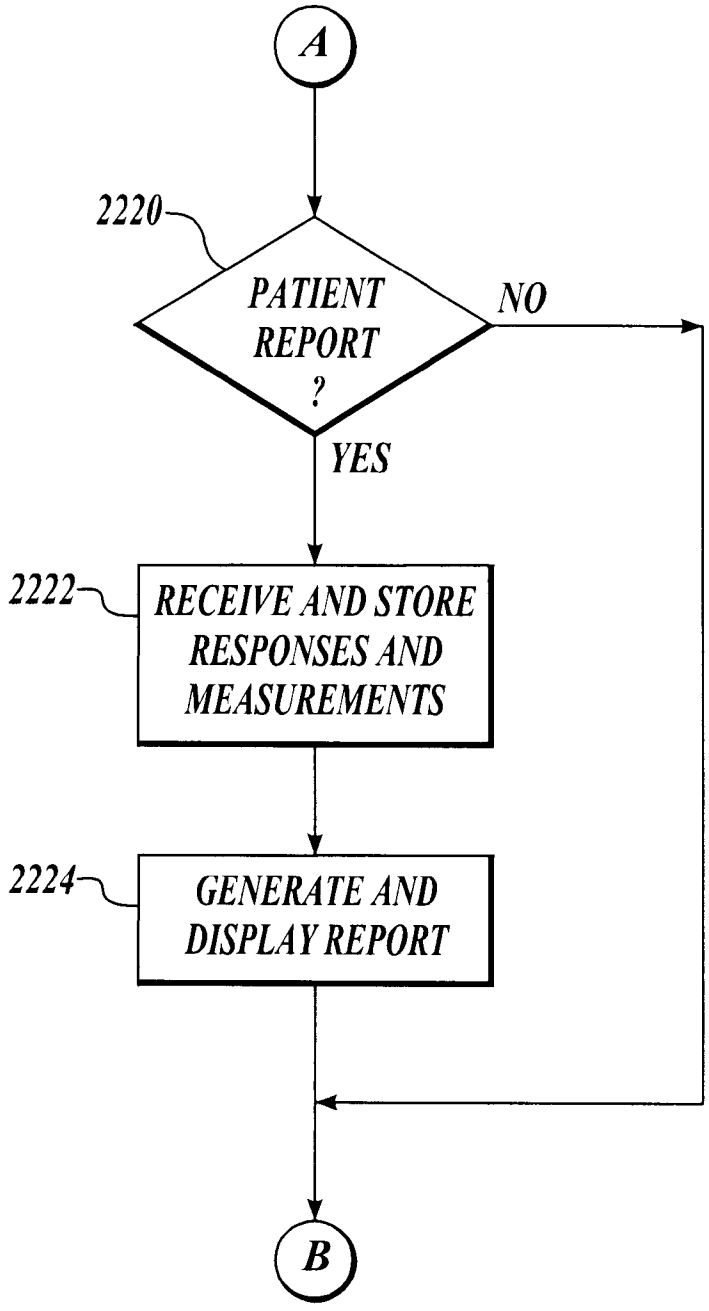
A
2220
PATIENT REPORT ?
NO
YES
2222
RECEIVE AND STORE RESPONSES AND MEASUREMENTS
2224
GENERATE AND DISPLAY REPORT
B

Fig. 211B

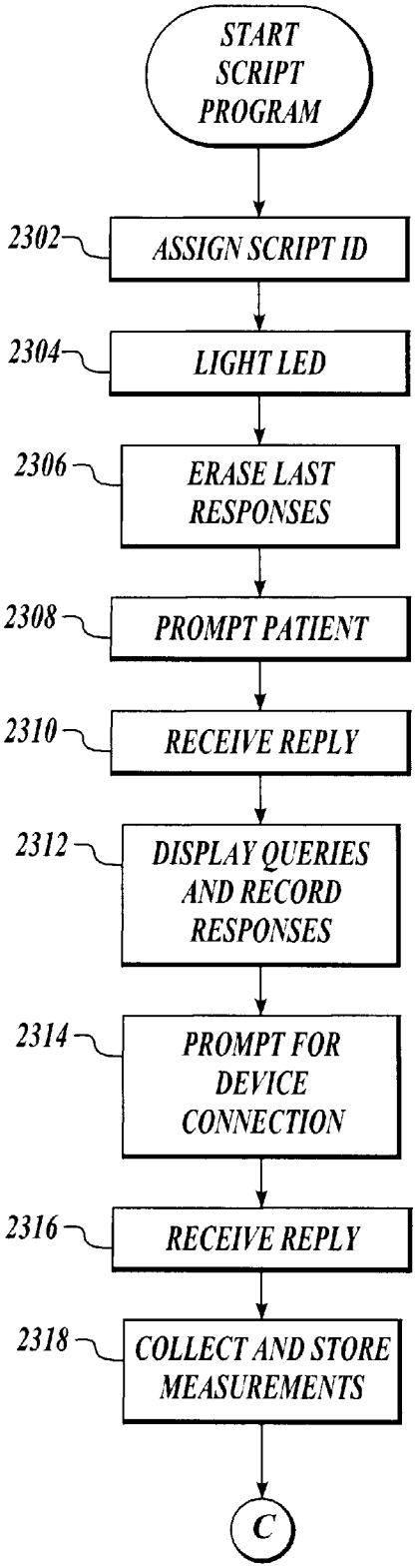
START SCRIPT PROGRAM
2302
ASSIGN SCRIPT ID
2304
LIGHT LED
2306
ERASE LAST RESPONSES
2308
PROMPT PATIENT
2310
RECEIVE REPLY
2312
DISPLAY QUERIES AND RECORD RESPONSES
2314
PROMPT FOR DEVICE CONNECTION
2316
RECEIVE REPLY
2318
COLLECT AND STORE MEASUREMENTS
C

Fig. 212A

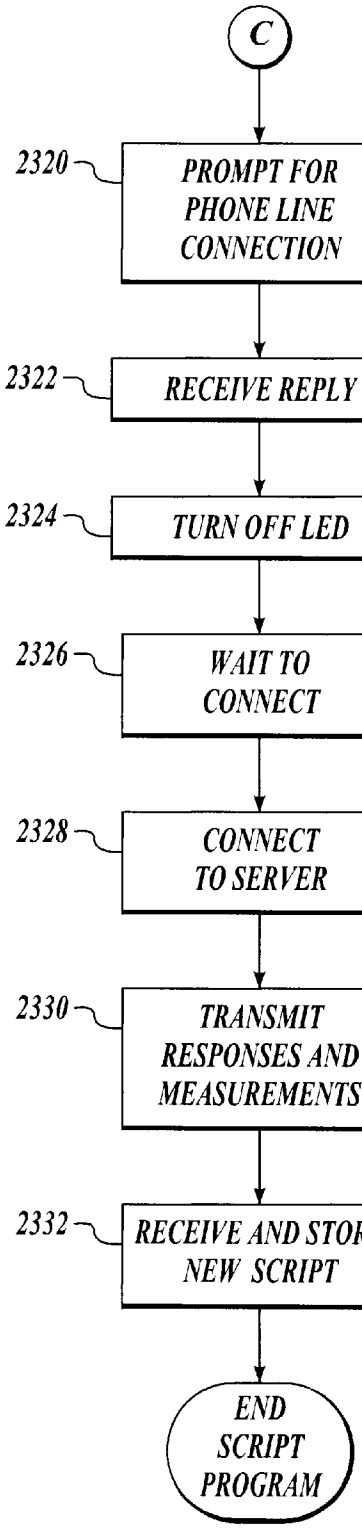
C
2320
PROMPT FOR PHONE LINE CONNECTION
2322
RECEIVE REPLY
2324
TURN OFF LED
2326
WAIT TO CONNECT
2328
CONNECT TO SERVER
2330
TRANSMIT RESPONSES AND MEASUREMENTS
2332
RECEIVE AND STORE NEW SCRIPT
END SCRIPT PROGRAM

Fig. 212B

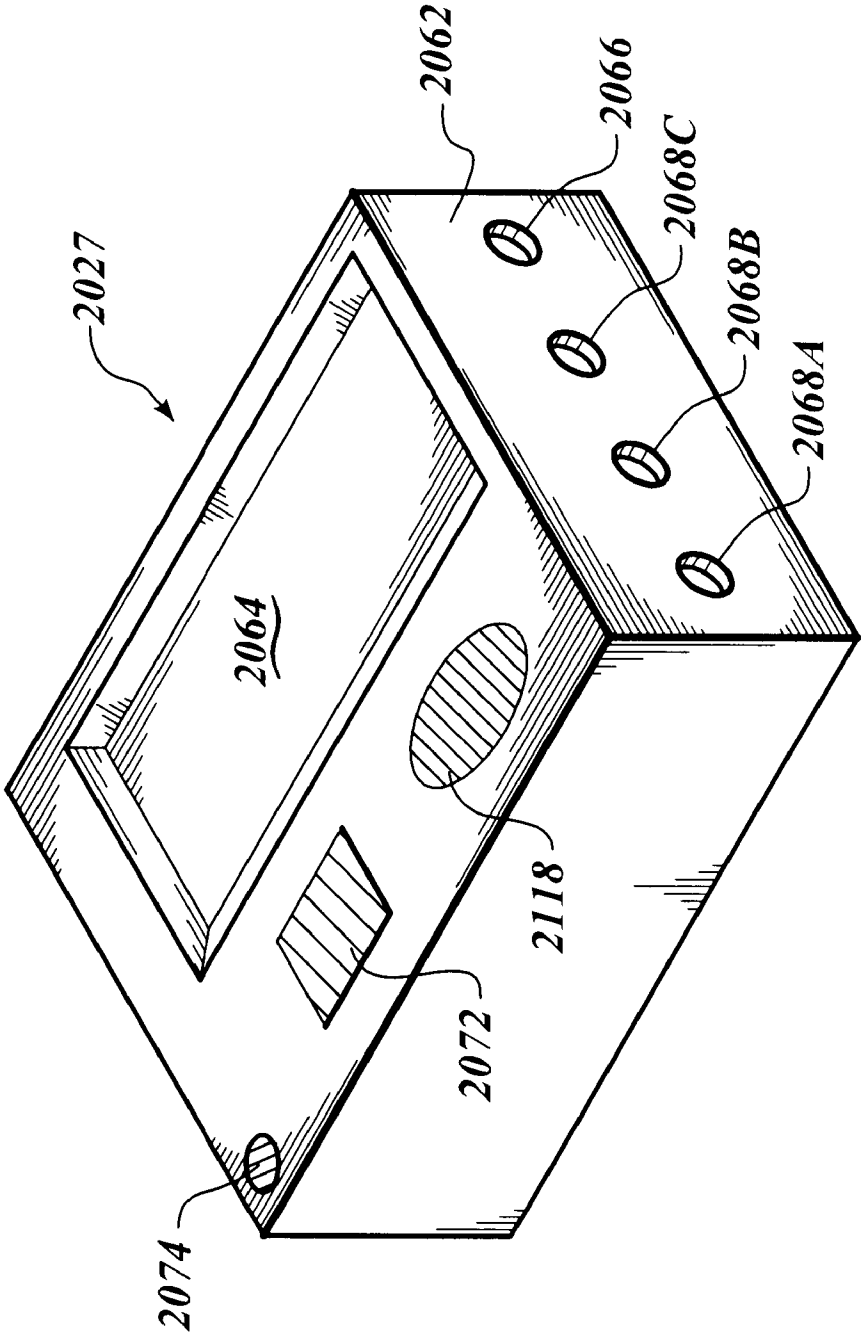

Fig. 213

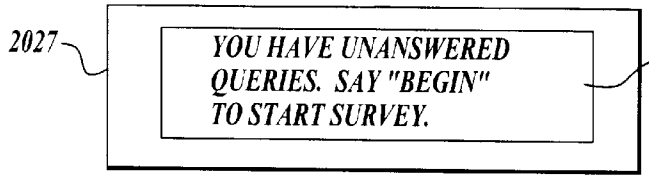

Fig. 214

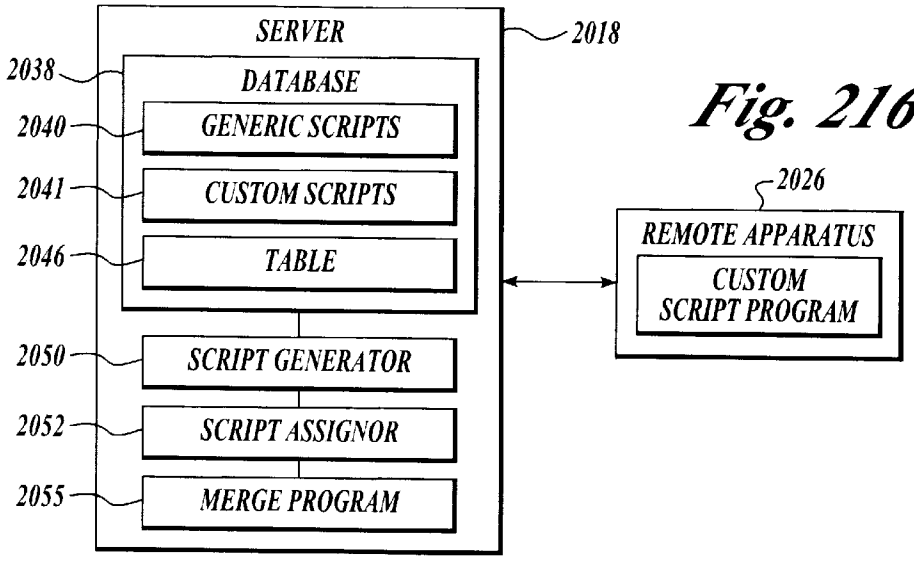

Fig. 216

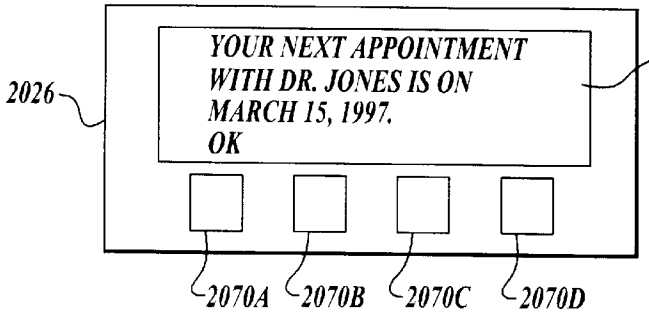

Fig. 217

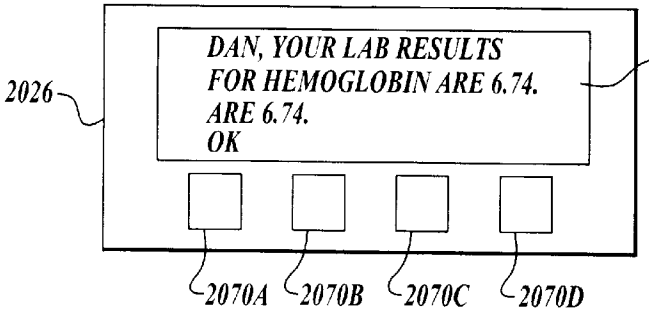

Fig. 218

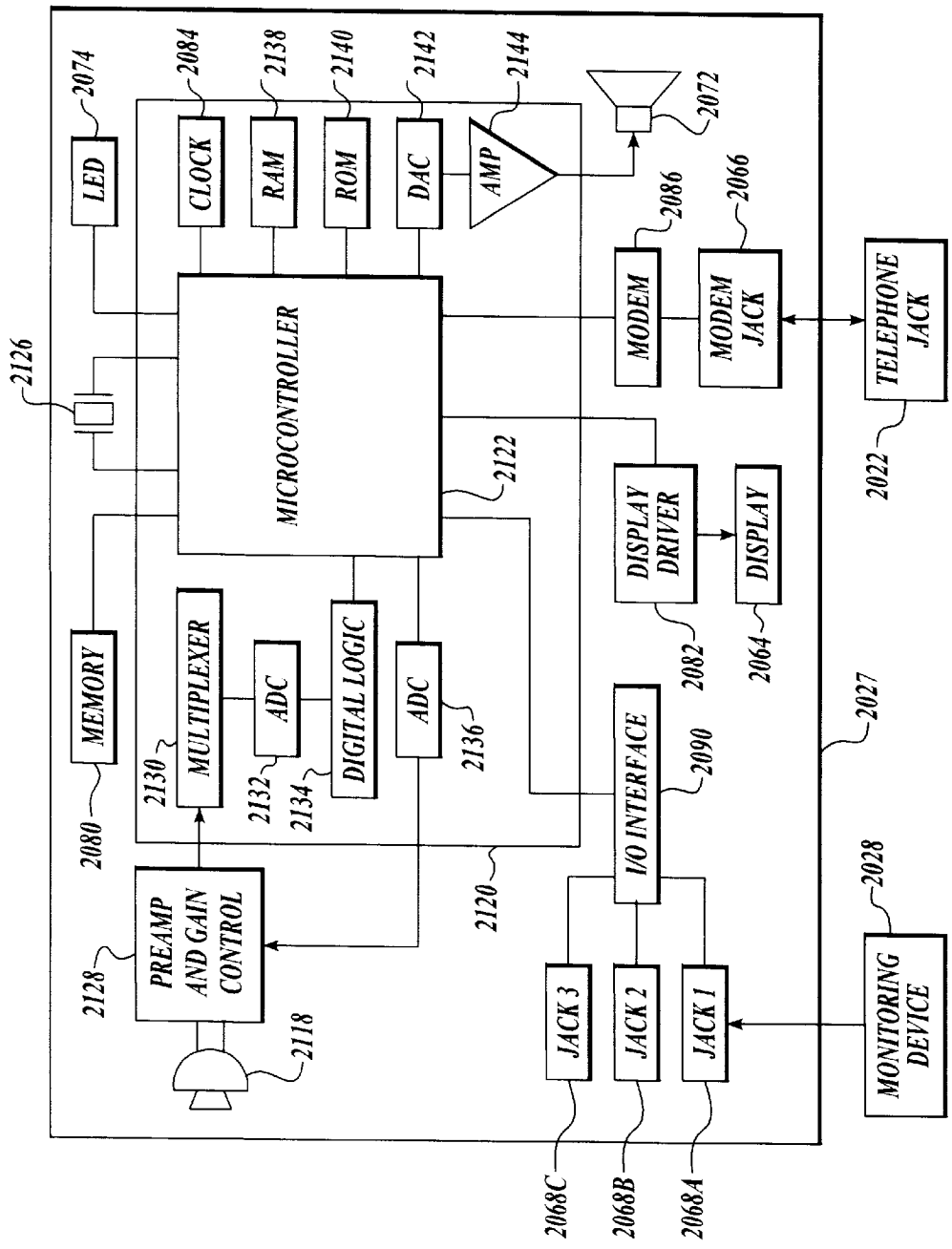
LED
2074
CLOCK
2084
RAM
2138
ROM
2140
DAC
2142
AMP
2144
2072
2126
MICROCONTROLLER
2122
MODEM
2086
MODEM JACK
2066
TELEPHONE JACK
2022
DISPLAY DRIVER
2082
DISPLAY
2064
MEMORY
2080
MULTIPLEXER
2130
ADC
2132
DIGITAL LOGIC
2134
ADC
2136
I/O INTERFACE
2090
2027
PREAMP AND GAIN CONTROL
2128
2118
2120
JACK 3
JACK 2
JACK 1
2028
MONITORING DEVICE
2068C
2068B
2068A

Fig. 215

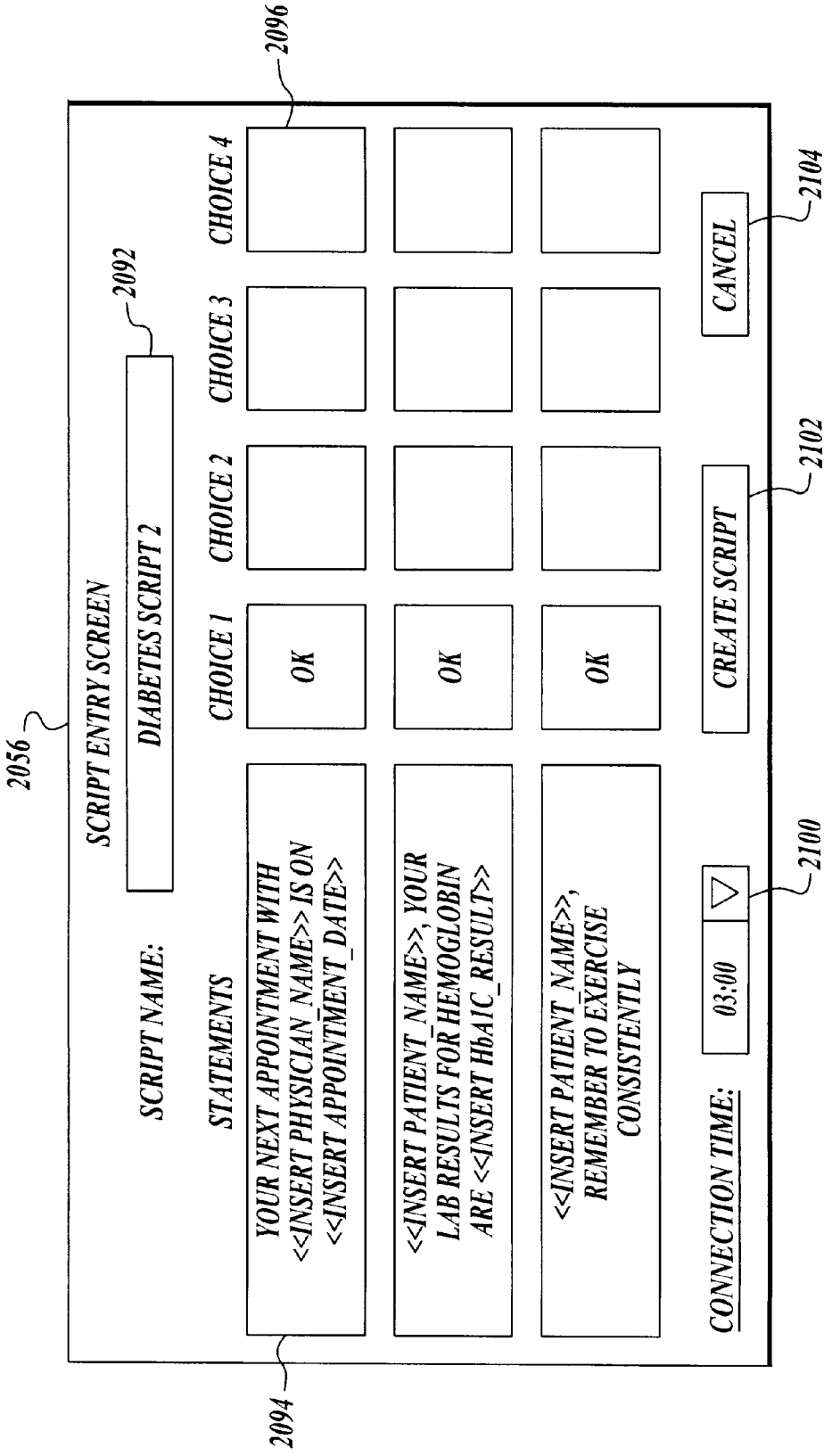
2056
SCRIPT ENTRY SCREEN
SCRIPT NAME:
DIABETES SCRIPT 2
2092
STATEMENTS
CHOICE 1
CHOICE 2
CHOICE 3
CHOICE 4
2096
YOUR NEXT APPOINTMENT WITH <<INSERT PHYSICIAN_NAME>> IS ON <<INSERT APPOINTMENT_DATE>>
OK
<<INSERT PATIENT_NAME>>, YOUR LAB RESULTS FOR HEMOGLOBIN ARE <<INSERT HbA1C_RESULT>>
OK
<<INSERT PATIENT_NAME>>, REMEMBER TO EXERCISE CONSISTENTLY
OK
CONNECTION TIME:
03:00
2100
CREATE SCRIPT
2102
CANCEL
2104
2094

Fig. 219

REMOTE PSYCHOLOGICAL DIAGNOSIS AND MONITORING SYSTEM

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application No. 09/127,404 filed Jul. 31, 1998, which is a continuation of U.S. patent application Ser. No. 08/843,495 which was filed Apr. 16, 1997 and issued on Oct. 27, 1998 as U.S. Pat. No. 5,828,943, and which is a file wrapper continuation of U.S. patent application Ser. No. 08/682,385 filed Jul. 17, 1996, now abandoned, which is a file wrapper continuation of U.S. patent application Ser. No. 08/479,570 filed Jun. 7, 1995, now abandoned, which is a file wrapper continuation of U.S. patent application Ser. No. 08/233,674 filed Apr. 26, 1994, now abandoned, priority from the filing date of which is hereby claimed under 35 U.S.C. §120, and all of which are hereby incorporated in their entirety by reference.

All the new subject matter in this continuation-in-part application comes from U.S. patent application Ser. No. 08/946,341, filed Oct. 7, 1997, which claims priority from provisional application No. 60/041,746 filed Mar. 28, 1997 and from provisional application No. 60/041,751 filed Mar. 28, 1997, priority from the filing date of which is hereby claimed under 35 U.S.C. §120, and all of which are incorporated herein by reference. For clarity, figure numbers and reference numerals from Ser. No. 08/946,341 have all been increased by a constant, respectively, in order to enable easier distinction as to the origin of the matter herein. Specifically, figure numbers have been increased by 200 and reference numerals by 2000.

FIELD OF THE INVENTION

This invention relates to apparatus and methods for diagnostic assessment of psychological conditions that enable a patient or user to collect important diagnostic measures of psychological conditions or behavior for transmittal to and analysis by a health care professional. The invention further relates generally to communication systems for remote monitoring of individuals, and in particular to a networked system for remotely monitoring individuals and for communicating information to the individuals through the use of script programs.

BACKGROUND OF THE INVENTION

The traditional method of diagnosing and assessing psychological conditions involves periodic clinical sessions in which a clinician attempts to obtain insights of a patient's condition by conducting interviews and, in some cases, conducting tests. This traditional method of psychological testing and evaluation is often very lengthy and, as a result, costly. Moreover, many psychological conditions and behavior patterns are not easily diagnosed during a series of routine clinical visits because the condition or behavior is situation-dependent and, thus, may not be observable in a clinical setting. Further, the manifestations or behavior patterns of certain disorders are heterogeneous in nature, which complicates identification and diagnosis. Specifically, where a high degree of heterogeneity is present, standardized and normalized diagnostic measures intended to identify a particular or preferred regimen of therapy often do not exist. Under such conditions, the identification and diagnosis of a psychological condition or behavior pattern becomes very subjective, often resulting in an even larger number of diagnostic clinical sessions and higher costs. Lower rates of diagnostic accuracy and efflcacy also result.

Many people suffering from psychological disorders are unable to obtain clinical assistance because of the high cost of diagnosis and treatment. Further, even where cost is not of a major deterrent, many people lose confidence in the clinical procedure and cease attending clinical sessions when diagnostic assessment becomes difficult and lengthy. Difficulties can be encountered even by patients that persevere. Between their periodic clinical visits, they usually are left on their own with no encouragement or treatment.

Advances in the various fields of electronics and telecommunications have had a significant impact on medical diagnostic and monitoring equipment, including the development of devices that can be used in the home or other non-clinical settings. Recent advancement with respect to self-care health monitoring of afflictions such as diabetes were set forth in my patent application Ser. No. 07/977,323, filed Nov. 17, 1992, entitled "MODULAR MICROPROCESSOR-BASED HEALTH MONITORING SYSTEM" now issued as U.S. Pat. No. 5,307,263.

Some experiments and trials have been conducted with respect to incorporating computers and similar electronic equipment in arrangements for psychological testing and assessment that is performed in a clinical setting. Very recently, some experiments and trials have been conducted in which a patient uses a microprocessor device such as a "palm-top computer" to record behavioral information between clinical sessions and, in some cases, for limited therapeutic purposes. However, adoption of modem microprocessor and communication technology to diagnosing, monitoring or treating psychological disorders has not progressed at the same rate as technological advances in areas of medicine that relate to physiological conditions.

There are numerous reasons why microprocessors and modem communication techniques have not been widely applied to devices for psychological diagnoses, evaluation or treatment. As previously mentioned, the behavior attendant many psychological disorders is situation dependent. Thus, to be useful, a device must be relatively small, relatively easy to use and unobtrusive so that a patient or subject can use the device in an appropriate environment and is comfortable with using the device in that environment. Cost and efflcacy are also important factors if use of the device is to result in a reduction in the professional time and other costs associated with diagnosis and treatment of various psychological conditions.

In order to provide a diagnostic tool that can be used in settings other than clinical sessions, other criteria should be met. For example, provision should be made for a clinician or other health care professional to easily acquire data gathered by the diagnostic tool and to analyze that data. Further, to achieve optimum utilization, the diagnostic tool should be extremely versatile, lending itself to adaptation to the assessment of various psychological conditions. Preferably, the device should be adaptable enough to allow a clinician to establish diagnostic routines suited for various species of the same general psychological disorder of even for a particular individual. Versatility sufflcient for use of the device in at least limited monitoring and therapeutic procedures is also desirable.

For all of the above reasons, a need exists for improved methods and apparatus for psychological evaluation and assessment. This is especially true with disorders such as depression, anxiety, schizophrenia, addiction, eating disorders, attention deficit disorders, attention deficit and hyperactivity disorder, and other psychological and behavioral problems which are highly stimulus-dependent (i.e.,

may be manifested primarily or only in situations that are difficult to synthesize in a clinical environment). The extreme heterogeneity of these psychological conditions has complicated diagnosis and treatment, a drawback that leaves many adults and children with chronic conditions that are handicaps both from the social and economic standpoint.

Providing reliable and accurate tests for diagnosing psychological disorders in children has been a substantial problem. In particular, prevalent childhood psychological disorders such as Attention Deficit Hyperactivity Disorder and Attention Deficit Disorder are difficult to assess because attention is a multi-construct neuropsychological process that includes sustained attention (vigilance) and selective attention (i.e., the ability to maintain attention in the presence of distractions and the ability to appropriately shift attention). Children with Attention Deficit Disorder and Attention Deficit and Hyperactivity Disorder are often impulsive, requiring a relatively high degree of motivation in order to complete tasks that employ cognitive skills appropriate to their particular age group. Moreover, current assessment tests for Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder are relatively subjective, and even when effectively administered, basically provide only an evaluation of whether a child exhibits a deficit in his or her ability to focus and maintain attention. That is, current tests have been successful only in identifying a large heterogeneous group that exhibit the basic symptoms of Attention Deficit Hyperactivity Disorder. Little success has been obtained relative to assessing the degree of neuropsychologic mechanism impairment. Thus, current diagnostic techniques do not identify homogeneous subgroups of children having Attention Deficit Hyperactivity Disorder, which is needed in order to prescribe and administer effective therapy.

Developing diagnostic and therapeutic tools for psychological assessment and treatment of children is especially challenging. To obtain essential, unbiased information for diagnosis of Attention Deficit Hyperactivity Disorder or Attention Deficit Disorder, a child being tested must be at ease and must be motivated since children with these disorders are easily distracted when faced with situations requiring continued attention and/or routine, relatively tedious tasks. Thus, if cognitive tests are employed, they must be appealing to younger children, but not leave older children bored and unmotivated to perform well. Otherwise, test results will be skewed and diagnosis made even more difficult.

In the United States alone, over 100 million people have chronic health conditions, accounting for an estimated $700 billion in annual medical costs. In an effort to control these medical costs, many healthcare providers have initiated outpatient or home healthcare programs for their patients. The potential benefits of these programs are particularly great for chronically ill patients who must treat their diseases on a daily basis. However, the success of these programs is dependent upon the ability of the healthcare providers to monitor the patients remotely to avert medical problems before they become complicated and costly. Unfortunately, no convenient and cost effective monitoring system exists for the patients who have the greatest need for monitoring, the poor and the elderly.

Prior attempts to monitor patients remotely have included the use of personal computers and modems to establish communication between patients and healthcare providers. However, computers are too expensive to give away and the patients who already own computers are only a small fraction of the total population. Further, the patients who own computers are typically young, well educated, and have good healthcare coverage. Thus, these patients do not have the greatest unmet medical needs. The patients who have the greatest unmet medical needs are the poor and elderly who do not own computers or who are unfamiliar with their use.

Similar attempts to establish communication between patients and healthcare providers have included the use of the Internet and Internet terminals. Although Internet terminals are somewhat less costly than personal computers, they are still too expensive to give away to patients. Moreover, monthly on-line access charges are prohibitive for poor patients.

Other attempts to monitor patients remotely have included the use of medical monitoring devices with built-in modems. Examples of such monitoring devices include blood glucose meters, respiratory flow meters, and heart rate monitors. Unfortunately, these monitoring devices are only designed to collect physiological data from the patients. They do not allow flexible and dynamic querying of the patients for other information, such as quality of life measures or psychosocial variables of illness.

Prior attempts to monitor patients remotely have also included the use of interactive telephone or video response systems. Such interactive systems are disclosed in U.S. Pat. Nos. 5,390,238 issued to Kirk et al. on Feb. 14, 1995; 5,434,611 issued to Tamura on Jul. 18, 1995; and 5,441,047 issued to David et al. on Aug. 15, 1995. One disadvantage of these systems is that they either require a patient to call in to a central facility to be monitored or require the central facility to call the patient according to a rigid monitoring schedule.

If the patients are required to call the central facility, only the compliant patients will actually call regularly to be monitored. Non-compliant patients will typically wait until an emergency situation develops before contacting their healthcare provider, thus defeating the purpose of the monitoring system. If the central facility calls each patient according to a monitoring schedule, it is intrusive to the patient's life and resistance to the monitoring grows over time.

Another disadvantage of these conventional interactive response systems is that they are prohibitively expensive for poor patients. Further, it is difficult to identify each patient uniquely using these systems. Moreover, these systems are generally incapable of collecting medical data from monitoring devices, such as blood glucose meters, respiratory flow meters, or heart rate monitors.

OBJECTS AND ADVANTAGES OF THE INVENTION

In view of the above, it is an object of the present invention to provide a simple and inexpensive system for remotely monitoring patients and for communicating information to the patients. It is another object of the invention to provide a system which allows flexible and dynamic querying of the patients. It is a further object of the invention to provide a system which combines querying of patients with medical device monitoring in the same monitoring session. Another object of the invention is to provide a monitoring system which incurs lower communications charges than those incurred by conventional monitoring systems. A further object of the invention is to provide a monitoring system which may be used at any time convenient for a patient.

These and other objects and advantages will become more apparent after consideration of the ensuing description and the accompanying drawings.

SUMMARY OF THE INVENTION

This invention addresses the previously discussed need for new and useful apparatus and methods for diagnostic assessment of psychological conditions, providing a valuable adjunct and supplementation to traditional clinical assessment. Apparatus arranged in accordance with the invention is extremely versatile, being suitable for use in diagnostic assessment of various psychological conditions and being especially well suited for assessment of conditions that affect children such as Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder. The invention also is extremely versatile in that it is suited for use in a clinical setting as well as use in remote locations such as the home, school, or workplace.

Basically, apparatus configured in accordance with the invention includes a programmable microprocessor unit that is responsive to program instructions that are supplied by an external source. In the disclosed embodiment, a receptacle is included in the programmable microprocessor-based unit for receiving an external ("removable/insertable") memory unit which includes a digital storage medium for storing program instructions that control operation of the programmable microprocessor-based unit. In other embodiments, the program instruction instructions can be transferred to memory circuits of the microprocessor-based unit by various digital data transmission systems and techniques.

The programmable microprocessor-based unit also includes circuitry for generating a video display in accordance with program instructions stored in an internal memory of the microprocessor-based unit and/or the digital storage medium of the external memory unit. In the operation of the invention, the displayed video signals interactively prompt a patient or user to operate one or more switches that are located on the microprocessor-based unit. Preferably, the programmable microprocessor-based unit also includes a sound generator operable for producing selected tones, single words or simple phrases of simulated speech, simple musical passages, and other sounds appropriate to the video display during the operation of the microprocessor-based unit.

In the currently preferred embodiments of the invention, the microprocessor-based unit is a compact video game system, with the program instructions being provided by an external memory unit that corresponds to a game cartridge. The invention can employ either a hand held video game such as the compact video game system manufactured by Nintendo of America Inc. under the trademark "GAME BOY," or less compact video game systems such as the "SUPER NES" video game, which also is marketed by Nintendo of America Inc. As is well known, hand held video games of the type mentioned are unitary devices that include a display screen and control switches for operating the video game. On the other hand, the larger video game systems operate in conjunction with a television set or video monitor and consist of a console unit, which receives a game cartridge, and one or more controllers, which include at least a portion of the switches for operating the video game system. Use of either type of video game system has several general advantages, including the widespread availability and low cost of such systems. Further, such systems provide an easy-to-use, unobtrusive device that can be used either in a clinical setting or other environment such as the home, school, or workplace. Moreover, the video display can be structured to provide motivation for a patient or user and, in at least some instances, the same or an additional program cartridge can provide appropriate educational or therapeutic video displays and processes.

Use of the video game system for the programmable microprocessor-based unit of the invention is especially advantageous with children because of the popularity and widespread acceptance of all types of video games. In accordance with the invention, video and audio sequences are preferably presented in game-like format with animation that is suitable for children or other selected age groups.

Regardless of whether a video game system is employed, the programmable microprocessor-based unit can be used to analyze the data obtained during a diagnostic assessment procedure. In some cases, a full analysis will be performed so that the information that is transmitted or returned to a clinician is in a final form. In other situations, partial (or even no) analysis of gathered diagnostic information is performed by the programmable microprocessor-based unit. In those situations, partial (or full) analysis is performed at the clinician's facility or, alternatively, at a facility that gathers information for analysis and subsequent relay to the clinician.

Systems that are arranged in accordance with the invention include two components in addition to the above-discussed programmable microprocessor-based unit: (1) a programmable digital signal processor; and, (2) a communication link for allowing signal transmission between the programmable microprocessor-based unit and the programmable digital signal processor. In some arrangements of the invention, the programmable digital signal processor is a personal computer that is located at the clinic or other facility of the health care professional. In these arrangements, the programmable microprocessor-based unit can be located at the clinician's facility with the communication link for coupling signals between the programmable microprocessor-based unit and the clinician's computer being an electrical cable that provides a RS232 communication link or some other digital signal transmission arrangement. However, a primary advantage of the invention is use of the microprocessor-based unit at a location that is remote from the clinician's facility (e.g., use between clinical sessions in an environment appropriate to assessment of the psychological condition of interest). At least two basic types of communication links allow assessment of the psychological condition to be made at a subject's home or other location that is remote from the clinician's facility.

First, an RS232 serial data port or other means for coupling digital signals to the central processing unit of the clinician's personal computer can be connected to a cable that is adapted for receiving an external memory unit (e.g., memory cartridge) that is used with the programmable microprocessor-based unit to gather assessment data. In such an arrangement, the external memory unit is interconnected with the clinician's computer to access stored signals that represent information gathered during a diagnostic assessment procedure that was performed earlier at a subject's home or other suitable location. In many situations, the clinician's computer will have been previously interconnected with the external memory unit to allow the clinician to establish stored program instructions that will implement a desired diagnostic assessment procedure when the patient or user operates the microprocessor-based unit in conjunction with the memory unit.

The second type of communication link that allows the diagnostic assessment procedure to be conducted at a location other than the clinician's facility involves the use of various types of signal transmission media. For example, the digital data signal processor (e.g., personal computer) employed by the clinician can include an external or internal modem for receiving and transmitting digital signals via the

various types of conventional telephone systems. Likewise, a modem and associated conventional data management circuitry can be either included in or interconnected with the microprocessor-based unit to allow information gathered during a diagnostic assessment procedure to be transmitted to the clinician for review and analysis. In some cases, it may also be advantageous to use the data transmission link for remote programming of the user's external memory unit, thereby permitting changes to be made in the diagnostic procedure of a particular patient or user without a visit to the clinician's office.

Transmission media other than a telephone system can be used for coupling signals between a clinician's digital data processing system and a remotely located programmable microprocessor-based unit that is used for diagnostic assessment of psychological conditions. For example, recently developed interactive audio/visual systems using coaxial cable or optical fiber can be employed as well as other types of digital networks that provide information services and communication between users. In some of these arrangements, the digital data signal processor need not be located at the clinician's facility. That is, the invention can be implemented so that the digital signal processor is a clearinghouse that in effect functions as a central server that is capable of functioning with a relatively large number of programmable microprocessor units and, in addition, capable of serving the needs of at least several clinicians. In these arrangements, the clearinghouse digital signal processor collects and stores diagnostic assessment information transmitted to the clearinghouse from any number of programmable microprocessor-based units. Information is then provided to the appropriate clinician or clinical facility by facsimile or data transmission techniques. Alternatively, the information can be printed and delivered to the appropriate clinician.

The disclosed embodiments of the invention are configured and programmed for diagnostic assessment of Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder. The currently preferred realizations of the disclosed embodiment allow a clinician to selectively configure sequences of tests ("tasks") that fall into the two basic categories: delay reaction tasks and performance-paced continuous performance tasks. During a delay reaction task, the programmable microprocessor-based unit operates to first generate an audible and/or visual warning signal to alert the user that the microprocessor-based unit will soon produce an audio, visual, or audiovisual target stimulus. When the target stimulus is produced, the user or patient responds by activating a switch or control of the microprocessor-used unit. Preferably, the time between the warning stimulus and the target stimulus within a predetermined range that is selected by the clinician, with each particular time delay being randomly selected through programmed operation of the microprocessor-based unit. For each delayed reaction task, a signal is generated indicating whether the user reacted to the target stimulus and, if so, the time that elapsed between generation of the target stimulus and the user's operation of the selected switch. Collecting and storing the user's reaction times for a sequence of delayed reaction tasks allows subsequent analysis by the system digital data processor to obtain information such as a record of reaction time versus time delay, the user's best (fastest) reaction time, the user's mean reaction time, and/or the standard deviation of reaction times. In some situations, it may also be advantageous to store the delayed reaction task information so that analysis can be performed that allows the detection of trends such as whether the user's reaction time generally increased or decreased as the sequence of delayed reaction tasks progressed. Such information may indicate an increase or decrease in attention level with time.

In the currently preferred realizations of the disclosed embodiment of the invention, the visual delayed reaction task includes the display of a car, the model of which selected by the user prior to initiation of the diagnostic procedure. The car is shown at a starting line with a traffic signal having a red, yellow, and green light being prominently displayed in the foreground. Initially, the red light is illuminated, a warning signal is then provided to the user by illuminating the yellow light and, when the microprocessor-selected time delay has elapsed, the green light is illuminated to provide the target stimuli. In the currently preferred realizations of the disclosed embodiments of the invention, the words "ready . . . set . . . go" are synthesized by the sound generator of the microprocessor-based unit.

During the continuous performance tasks, the system user observes the system display while target stimuli pass across it. The object is for the user to activate a switch or control of the microprocessor-based unit when target stimuli are at a predetermined location on the display. For example, in the currently preferred realizations of the disclosed embodiments of the invention, the previously mentioned car is displayed so that it appears to be passing by trees that are located along the side of a road. The target stimulus is a specified type of fruit (e.g., an orange, apple, lemon, or cluster of grapes) on the tree. The object is for the user to activate the switch or control of the microprocessor-based unit when a predetermined stimulus appears (e.g., an apple). When the switch or control is activated a hand and arm move upwardly from the car and, if the switch is timely activated, the fruit is captured. When the user correctly identifies and captures a target stimulus, the time interval between appearance of target stimuli is decreased by a predetermined amount. On the other hand, if the user does not properly respond to a target stimulus, the time interval between target stimuli is increased.

During the conduction of a sequence of continuous performance tasks, information is recorded to reflect the number of target stimuli correctly identified, the number of target stimuli missed, the number of responses to non-target stimuli, the number of correct, but delayed, responses, and the final interstimulus time interval.

Audio continuous performance tasks are also provided wherein the user is to respond to certain audio signals while ignoring others. For example, in the currently preferred realizations of the disclosed embodiments, the car shown on the system display unit is passing along a dark road with a small portion of the road passing under the car's headlights. A low frequency "radar beep" is sounded for each non-target stimulus, and a high frequency radar beep is sounded to represent the target stimulus. Although the display is relatively dark, the bases of the trees can be seen and when the user properly responds to a target stimulus, a hand swings upwardly from the car to catch the fruit.

The battery of tests provided by the currently preferred embodiments of the invention also include continuous performance tasks with various distractions. For example, in the above-discussed realization in which the user activates a switch or control of the microprocessor-based unit to catch a predetermined type of fruit as a car passes across the system display, moving objects such as hopping frogs, fluttering butterflies, and flying saucers are periodically and randomly displayed. In the audio continuous performance tasks, the distractions consist of synthesized speech such as

"Now!" or "Go!." During sequences of continuous performance tasks that include distractions, the number of distractions that cause user reaction are recorded as well as the information recorded during continuous performance task sequences that do not include distractions.

SUMMARY—I

The invention presents a networked system for remotely monitoring an individual and for communicating information to the individual. The system includes a server and a remote interface for entering in the server a set of queries to be answered by the individual. The server is preferably a world wide web server and the remote interface is preferably a personal computer or network terminal connected to the web server via the Internet. The system also includes a remotely programmable apparatus for interacting with the individual. The apparatus is connected to the server via a communication network, preferably the Internet. The apparatus interacts with the individual in accordance with a script program received from the server.

The server includes a script generator for generating the script program from the queries entered through the remote interface. The script program is executable by the apparatus to communicate the queries to the individual, to receive responses to the queries, and to transmit the responses from the apparatus to the server. The server also includes a database connected to the script generator for storing the script program and the responses to the queries.

The apparatus has a communication device, such as a modem, for receiving the script program from the server and for transmitting the responses to the server. The apparatus also has a user interface for communicating the queries to the individual and for receiving the responses to the queries. In the preferred embodiment, the user interface includes a display for displaying the queries and user input buttons for entering the responses to the queries. In an alternative embodiment, the user interface includes a speech synthesizer for audibly communicating the queries and a speech recognizer for receiving spoken responses to the queries.

The apparatus also includes a memory for storing the script program and the responses to the queries. The apparatus further includes a microprocessor connected to the communication device, the user interface, and the memory. The microprocessor executes the script program to communicate the queries to the individual, to receive the responses to the queries, and to transmit the responses to the server through the communication network.

In the preferred embodiment, the system also includes at least one monitoring device for producing measurements of a physiological condition of the individual and for transmitting the measurements to the apparatus. The apparatus further includes a device interface connected to the microprocessor for receiving the measurements from the monitoring device. The measurements are stored in the memory and transmitted to the server with the responses to the queries. The server also preferably includes a report generator connected to the database for generating a report of the measurements and responses. The report is displayed on the remote interface.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same becomes better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIG. **1** is a block diagram that illustrates a psychological diagnostic measurement system of this invention, depicting microprocessor-based patient units connected in signal communication with a clinician's computer system and/or a clearinghouse for collection and analysis of diagnostic data originating with a large number of patient units;

FIG. **2** is a block diagram illustrating in greater detail the basic structure of a microprocessor-based patient unit and a digital signal processor of a type that can be used within a clearinghouse or be used as a clinician's computer;

FIG. **3** illustrates a graphic display suitable for use when a microprocessor-based patient unit administers a delayed reaction tests in an embodiment of the invention that is configured for diagnostic measurements relating to Attention Deficit Hyperactivity Disorder or Attention Deficit Disorder;

FIG. **4** illustrates a graphic display suitable for use when a microprocessor-based patient unit administers continuous performance tests in an embodiment of the invention that is configured and programmed for diagnostic measurement relating to Attention Deficit Hyperactivity Disorder and Attention Deficit Disorder;

FIG. **5** illustrates a graphic display suitable for use when a microprocessor-based patient unit administers continuous performance tests that also include visual distractions in an embodiment of the invention that is configured and programmed for diagnostic measurement relative to Attention Deficit Hyperactivity Disorder and Attention Deficit Disorder; and

FIGS. **6–11** are sequence diagrams that illustrate operation of a clinician's computer during periods of time in which the computer is used to establish a battery of tests to be administered by the microprocessor-based unit; is used to supply program instructions to the microprocessor-based unit that will result in the desired psychological diagnostic testing; and, is used to retrieve diagnostic measurements obtained by the microprocessor-based unit during the administration of the diagnostic test.

FIG. **201** is a block diagram of a networked system according to a preferred embodiment of the invention;

FIG. **202** is a block diagram illustrating the interaction of the components of the system of FIG. **201**;

FIG. **203** is a perspective view of a remotely programmable apparatus of the system of FIG. **201**;

FIG. **204** is a block diagram illustrating the components of the apparatus of FIG. **203**;

FIG. **205** is a script entry screen according to the preferred embodiment of the invention;

FIG. **206**A is a listing of a sample script program according to the preferred embodiment of the invention;

FIG. **206**B is a continuation of the listing of FIG. **206**A;

FIG. **207** is a script assignment screen according to the preferred embodiment of the invention;

FIG. **208** is a sample query appearing on a display of the apparatus of FIG. **203**;

FIG. **209** is a sample prompt appearing on the display of the apparatus of FIG. **203**;

FIG. **210** is a sample report displayed on a workstation of the system of FIG. **201**;

FIG. **211**A is a flow chart illustrating the steps included in a monitoring application executed by the server of FIG. **201** according to the preferred embodiment of the invention;

FIG. **211**B is a continuation of the flow chart of FIG. **211**A;

FIG. **212**A is a flow chart illustrating the steps included in the script program of FIGS. **206**A–**206**B;

FIG. **212**B is a continuation of the flow chart of FIG. **212**A;

FIG. **213** is a perspective view of a remotely programmable apparatus according to a second embodiment of the invention;

FIG. **214** is a sample prompt appearing on a display of the apparatus of FIG. **213**;

FIG. **215** is a block diagram illustrating the components of the apparatus of FIG. **213**;

FIG. **216** is a schematic block diagram illustrating the interaction of the server of FIG. **201** with the apparatus of FIG. **203** according to a third embodiment of the invention;

FIG. **217** is a first sample message appearing on the display of the apparatus of FIG. **203**;

FIG. **218** is a second sample message appearing on the display of the apparatus of FIG. **203**; and

FIG. **219** is a script entry screen according to the third embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. **1** illustrates one embodiment of a diagnostic measurement system configured in accordance with the invention. The depicted embodiment includes a programmable microprocessor-based unit **10** that includes a receptacle for receiving an external memory unit **12**, which can be easily inserted and removed from microprocessor-based unit **10**. Removable memory unit **12** includes a digital storage medium for storing program instructions that control the operation of microprocessor-based unit **10** and, in addition, allows storage of diagnostic test information that is generated during operation of microprocessor-based unit **10** for diagnostic assessment of a psychological condition.

Various storage media known to those skilled in the art can be used as the digital storage medium of external memory unit **12**. For example, conventional read-only memory (ROM) can be employed for storage of program instructions that are not changed or altered when external memory **12** is reconfigured for a different patient or reconfigured for measurements relating to a different type of psychological condition. Optically scanned memory such as currently available compact disc memory can also be employed. In addition, various types of erasable read-only memory and random access memory (RAM) having a battery back-up can be used to provide a storage medium for program instructions that may be changed when external memory **12** is configured for use with a different patient or for the diagnostic assessment of the different psychological condition. Erasable read-only memory or battery backed-up RAM also can be used for storage of information gathered when microprocessor-based unit **10** is operated to gather diagnostic measurement information that relates to one or more psychological conditions. Moreover, in newly developing technologies such as audio/video interactive television and networks for digital communications program instructions can be transmitted to microprocessor-based unit **10** and stored in random access memory.

As is indicated in FIG. **1**, microprocessor-based unit **10** is interconnected with an audio/visual display unit **14**. During operation of the invention for diagnostic assessment of psychological conditions, microprocessor-based unit **10** generates audio and video signals that are presented to the patient or system user by audio/visual display unit **14**. The audio/visual presentation is controlled by program instructions that are either stored in external memory **12** or are otherwise supplied to microprocessor-based unit **10**. In the disclosed embodiments, the visual presentation is structured to elicit responses from the user of microprocessor-based unit **10** (e.g., a patient or research subject) that provide that diagnostic measures relating to a particular psychological condition. In that regard, the embodiments disclosed herein are arranged for diagnostic assessment of Attention Deficit Hyperactivity Disorder and Attention Deficit Disorder. Upon understanding the operation of the invention and the various manners in which it can be configured, it will be recognized that the invention can be used in the diagnoses of various other psychological conditions and behavior patterns, including anxiety disorders, depression, schizophrenia, addiction, and weight control/eating disorders.

A primary advantage of the invention is the ability to conduct a diagnostic assessment procedure in an environment other than the office of a clinician or other health care facility. This particular aspect of the invention can be important with respect to diagnosing psychological conditions that are highly situation-dependent. Further, since it is not necessary for a clinician to be present when a diagnostic assessment procedure is executed, the costs of diagnoses and treatment is reduced. For example, during a clinical session, a clinician can instruct a patient or subject in the use of the invention for diagnostic assessment of a particular psychological condition. The patient or user then uses microprocessor-based unit **10**, a suitably programmed external memory **12**, and an audio/visual display unit **14** between clinical sessions to gather appropriate diagnostic measurements while the subject is in suitable environmental surroundings (e.g., at home, school, or the workplace). Information gathered during the diagnostic assessment is then made available to the clinician for consideration and analysis.

There are two basic ways in which information that relates to the results of the diagnostic assessment can be conveyed to a clinician or other person who serves as an administrator for the conduction of the diagnostic assessment. These same techniques are employed for establishing the diagnostic procedure (i.e., storing suitable program instructions in external memory **12**). The first technique for transferring test results or programming microprocessor-based unit **10** (e.g., external memory unit **12**) involves data transmission between microprocessor-based unit **10** and a remotely located clinician's office (or other health care facility) or, alternatively, a remotely located facility that stores the information for subsequent analysis and transmission to the clinician. In the second technique, microprocessor-based unit **10** (or external memory unit **12**) is physically transferred between the site at which the diagnostic assessment is made and the clinician's facility or other remote location.

With respect to the first information transfer technique, FIG. **1** schematically illustrates arrangement of the invention for remote exchange of data and information between a microprocessor-based unit **10** and either a remotely located clinician **16**, or a clearinghouse **18**. In such an arrangement, clearinghouse **18** includes one or more digital signal processors and associated peripheral equipment (e.g., printers, signal storage media, facsimile facilities) sufficient for gathering diagnostic measurement information from a relatively large number of microprocessor-based diagnostic tools (represented by microprocessor-based unit number 1 and microprocessor-based unit number 2 of FIG. **1**). A communication link **20** is shown in FIG. **1** between clearinghouse

18 and the clinician's remote location 16 to indicate transfer of information electronically or by other signal transmission means. Specifically, data and information can be transferred electronically between clearinghouse 18 and a clinician by various conventional data transmission systems, including those implemented through telephony, transmission of radio frequency signals, modulated coherent light, etc. As is indicated in FIG. 1, the signals sent by clearinghouse 18 to the clinician's facility 16 can be coupled to devices such as the clinician's computer 22 and/or the clinician's facsimile machine 24. Signals transmitted to the clinician's computer 22 can be stored with or without additional processing. In the same regard, analytical signal processing of the diagnostic assessment data gathered by microprocessor-based unit can be performed at various stages of information transmission between patient and clinician. For example, data processing can be performed in microprocessor-based unit 10, the clinician's computer 22, clearinghouse 18 and/or the hereinafter described data management unit 28. In any case, when the diagnostic information is transmitted to the clinician's facility, it can be displayed on a display unit of the clinician's computer 22 (not shown in FIG. 1); printed by a printer 26 that is connected to computer 22; or processed by other devices that are peripheral to the clinician's computer 22.

With continued reference to the embodiment of the invention shown in FIG. 1, signals representative of information gathered during a diagnostic assessment procedure (and other signals appropriate to system operation) are coupled to (or from) clearinghouse 18 and microprocessor-based diagnostic unit 10 via a data management unit 28 and a communication link 30. Like communication link 20, which provides signal transfer between clearinghouse 18 and the clinician's facility 16, communication link 30 can be of several different types. In some instances, communication link 30 will be a signal path established by a telephone system. Alternatively, RF signal transmission can be employed. Communication link 30 also can be established through the use of specialized digital networks, including recently developed interactive audio/video systems such as those operated in conjunction with cable television.

In the arrangement of FIG. 1, each depicted data management unit 28 is interconnected with its associated microprocessor-based unit 10 by a cable 32 that includes electrical conductors for carrying signals between the two units. In each arrangement of the invention, data management unit 28 provides the signal processing that is necessary for interfacing microprocessor-based unit 10 with communications link 30 and/or a communications link 34. Communications link 34 provides for transmission of signals between microprocessor-based unit 10 and the clinician's remote location 16 (e.g., coupling of signals to and from the clinician's computer 22). Like the previously discussed communication links 20 and 30, communication link 34 can be realized in a variety of ways.

Because of the wide range of communication links 30 and 34 that are available for practice of the invention, data management 28 will take on various forms and configurations. For example, in an arrangement of the invention in which communications link 30 and/or 34 is a signal path established by a conventional telephone system, data management unit 28 will include a modem and will operate to perform the signal processing necessary to transmit information to clearinghouse 18 and/or the clinician's remote location 16. In some arrangements of the invention, the signal processing required for modem data transmission will be implemented by a microprocessor unit that is incorporated in data management unit 28. In other situations, the microprocessor of microprocessor-based unit 10 can be employed to perform the signal processing necessary for modem signal transmission. Similarly, the hardware associated with modem transmission (e.g., telephone line connection) can be included in data management unit 28 or incorporated in microprocessor-based unit 10.

FIG. 1 also indicates one manner in which the invention can be employed for remote administration of diagnostic assessment of psychological conditions without the need for data management unit 28 and communication links 30 and 34. In particular, in the arrangement of FIG. 1, an external memory unit 12 can be inserted in a receptacle 38 that electrically connects external memory unit 12 to the clinician's computer 22 via a cable 36. With an external memory 12 connected in this manner, a clinician or other administrator of the diagnostic assessment to be performed can operate computer 22 to store program instructions appropriate for the diagnostic procedure in an external memory unit 12. The programmed external memory unit 12 can be given to a patient or subject at the end of a clinical session or transmitted to the patient or subject by other appropriate means. The patient or subject can subsequently insert the programmed external memory unit 12 in a microprocessor-based unit 10 that is located at the patient's home or some other location at which the diagnostic procedure will be executed. Signals representative of the diagnostic information gathered during the procedure are stored in external memory unit 12 when microprocessor unit 10 implements the diagnostic assessment procedure. External memory unit 12 is then returned to the clinician, inserted into receptacle 38 and the clinician's computer 22 is used to retrieve the diagnostic information stored in the external memory unit 12. In situations in which program instructions and diagnostic results are stored internally in microprocessor-based unit 10 (i.e., without use of an external memory unit 12), the entire microprocessor-based unit can be taken to the clinician's office. Information relating to diagnostic assessment results can then be unloaded to the clinician's computer 22 and, if desired, program instructions can be downloaded to the microprocessor-based unit 10 for administering further diagnostic assessment.

As also is shown in FIG. 1, in most applications of the invention, an additional microprocessor-based unit 10 and audio/visual display unit 14 will be located at the clinician's office or other facility. In the arrangement shown in FIG. 1, the additional microprocessor-based unit 10 is directly connected to the clinician's computer 22 by an electrical cable 40 to allow signal transmission between the microprocessor-based unit and computer 22. Providing a microprocessor-based unit 10 and audio/visual display unit 14 at the clinician's location allows a patient or subject to be instructed in the use of the system and also allows the administration of diagnostic assessment procedures at the clinician's facility, if desired.

FIG. 2 depicts a more detailed block diagram of a microprocessor-based unit 10 that can be employed in the practice of the invention and an associated audio/visual display unit 14. Also shown in FIG. 2 is a basic block diagram of a remotely located digital signal processing system 42 which typifies the arrangement of clearinghouse 18 and computer 22 of FIG. 1.

As is indicated in FIG. 2, signals supplied by one or more control switches 44 are coupled to a microprocessor 46 of microprocessor-based unit 10 via an input/output circuit 48. Also interconnected with input/output unit 48 of microprocessor-based unit 10 is an external modem 50,

which serves as data management unit **48** (FIG. **1**) for the depicted arrangement. Although not indicated in FIG. **2**, it will be understood by those skilled in the art that interconnections such as the connection shown between microprocessor **46** and input/output unit **48**, generally include a data, address, and control bus.

With continued reference to microprocessor-based unit **10** of FIG. **2**, the depicted microprocessor **46** is interconnected with the receptacle that receives an external memory unit **12** so that microprocessor **46** can access program instructions stored in external memory unit **12** and store diagnostic assessment results in external memory **12**. As previously mentioned, program instructions can be provided to a microprocessor-based unit **10** via a digital signal communications system, instead of an external memory unit **12**. In such arrangements, digital signals supplied by a system such as cable television or a digital communications can be coupled to microprocessor **46** via input/output unit **48** or other conventional signal processing arrangements.

In the arrangement of FIG. **2**, a random access memory **52** is interconnected with and is used by microprocessor **46** to implement a desired diagnostic assessment procedure and perform any desired analysis of the gathered diagnostic data. In addition, random access memory **52** can be used for storing program instructions that are supplied to an embodiment of the invention that does not employ an external memory unit **12** (i.e., an embodiment in which program instructions are supplied via a digital signal communications system). A clock circuit **54** is provided to allow microprocessor **46** to store date and time signals in situations in which date and time tags are to be included with the gathered diagnostic data. Although not specifically shown in FIG. **2**, microprocessor-based unit **10** generally includes an internal read-only memory for storing various program instructions and data that are not unique to a particular diagnostic assessment procedure or other application for the microprocessor-based unit **10**.

The audio/visual display unit **14** that is shown in FIG. **2** corresponds to a video monitor that includes a display screen **56**, control circuitry **58**, and a speaker **60**. In an arrangement of this type, microprocessor **46** of microprocessor-based unit **10** controls the operation of a sound generator **62** and video circuits **64** in accordance with the program instructions stored in external memory **12**. A display random access memory **66** is used to store and format video signals which are coupled to display screen **56** of audio/visual display unit **14**. Music, synthesized speech, and other sounds generated by sound generator **62** are coupled to speaker **60**. Control circuit **58** includes the circuitry necessary for adjusting volume and display quality as well as the circuitry for driving the display screen. In other arrangements, a television set may be used as audio/visual display unit **14**, with microprocessor-based unit **10** supplying an appropriate modulated RF signal or being connected to the television set video and audio inputs.

It will be recognized by those of ordinary skill in the art that a diagnostic tool that corresponds to microprocessor-based unit **10** of FIGS. **1** and **2** can be easily realized using conventional microprocessor design techniques and components. It also will be recognized that various commercially available devices can be adopted for use as a microprocessor-based unit **10** of this invention. In that regard, in the currently preferred embodiments of the invention, the microprocessor-based unit **10** is a compact video game system, with external memory unit **12** being configured to correspond to the type of game cartridge that is used with that particular video game system. In some arrangements of the invention, a hand held video game system such as the compact video game system marketed by Nintendo of America Inc. under the trademark "GAME BOY" can be used to realize, in unitary form, microprocessor-based unit **10**, audio/visual display unit **14**, and control switches **44** of the arrangement shown in FIG. **2**. In other applications of the invention, a less compact video game system such as the "SUPER NINTENDO ENTERTAINMENT SYSTEM" or "NES" video game is used. In those situations, control switches **44** correspond to the video game controller and audio/visual display unit **14** is a conventional television set or video monitor. The less compact video game systems often are advantageous because the external memory unit (game cartridge) has greater memory capacity than the corresponding memory of hand held units; the microprocessor has superior processing capability; and relatively high-quality sound and graphics can be achieved.

Regardless of the type employed, there are many advantages to using a video game system in the practice of the invention. Of prime importance, video game systems enjoy widespread popularity and, hence, low cost. In many cases, the user of a diagnostic assessment system that is constructed in accordance with the invention may already own or have access to a video game system. In addition, video game systems are simple to use. Therefore, little time is required for instructing a patient or other system user in how to operate the system for performance of a particular diagnostic assessment. Even further, adapting a video game system for use with the invention provides a convenient way for realizing diagnostic assessment procedures that are presented in game-like format with animation or other graphics that provide motivation for all age groups while gathering needed diagnostic data. The cumulative effect is achievement of an unobtrusive test and diagnosis arrangement that is acceptable to patients and other subjects and can be used in many environments.

Referring again to FIG. **2**, it can be recognized that the depicted remotely located digital signal processing unit **42** corresponds to a wide range of computational arrangements, including the clinician's computer **22** of FIG. **1** and the previously discussed, more complex, clearinghouse **18** of FIG. **1**. In the arrangement depicted in FIG. **2**, a user interface **70** is connected in signal communication with a central processor unit **72** via a decoder circuit **74**. Random access memory **76** and read-only memory **78** are accessed by central processor unit **72** of digital signal processing unit **42** during execution of the various programs and procedures used in carrying out the invention. An input/output unit **80** acts under the direction of central processor unit **72** to provide signals to a facsimile unit **24** and printer **26**. As also is indicated in FIG. **2**, signals can be provided to central processor unit **72** via input/output unit **80** by a modem **82**. In the arrangement shown, a communication link **84** interconnects modem **82** with modem **50** to thereby allow the depicted digital signal processing system to receive diagnostic test information from the depicted microprocessor-based unit **10**. As also is indicated, input/output unit **80** is connected to a receptacle **38**, which as was described relative to FIG. **1**, allows the digital data processing system to access storage addresses within an external memory unit **12** that is connected to receptacle **38**. As shall be described in more detail, an administration program that is executable by digital signal processing unit **42** includes a program module that allows program instructions to be stored in an external memory unit **12** to establish a desired diagnostic assessment procedure. Execution of another module of the

administration program by digital signal processing unit **42** allows the retrieval of diagnostic test data stored in external memory unit **12** when a diagnostic assessment procedure was conducted (i.e., when a patient or user executed a diagnostic procedure in accordance with the procedure).

The currently preferred embodiments of the invention utilize a microprocessor-based unit **10** that corresponds to the previously mentioned SUPER NINTENDO ENTERTAINMENT SYSTEM, with the invention being realized for diagnostic assessment of Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder. In the current realization of the invention, program instructions for a battery of separate tests that assess various aspects of a juvenile's attention are stored in external memory unit **12**. Two basic types of tests are employed: tests that include a series of delayed reaction tasks and tests that include a series of continuous performance tasks. In the delayed reaction tasks, programmable microprocessor-based unit **10** operates to generate an audible and/or visual warning signal to alert the user that the microprocessor-based unit soon will produce an audible and/or visual trigger stimulus. When the trigger stimulus is generated, the patient or user activates a designated switch or control of microprocessor-based unit **10** (e.g., a switch or control included in control switches **44** of FIG. **2**). In current practice, the clinician or other administrator of the diagnostic assessment procedure can select one or more audio delayed reaction tests and/one or more video delayed reaction tests when establishing a battery of tests for a particular patient or user. As shall be described relative to FIGS. **6–11**, the clinician establishes the battery of tests by executing a computer program, which also allows the clinician or administrator to establish the sequence in which various tests will be administered and, for each audio or visual delayed reaction test, select both the number of trigger stimuli to be generated and a time delay range. The time delay range establishes the upper and lower bounds of the delay between warning stimuli and trigger stimuli. The specific delay between a particular warning stimulus and its associated trigger stimulus is selected randomly by microprocessor-based unit **10** when the delayed reaction test is conducted.

Each time that microprocessor-based unit **10** generates a trigger stimulus, a timer (e.g., clock circuit **54** of FIG. **2**) is activated. If the patient or user does not activate the appropriate switch or control within a predetermined time interval, a digital signal is stored indicating a failure to respond. On the other hand, if the patient or user responds, a digital signal is stored indicating the user's reaction time (i.e., the time period between the occurrence of a trigger stimulus and the patient's reaction). Since a series of delayed reaction tasks is used in each audio or visual delayed reaction test, the stored data that are accumulated during the diagnostic assessment will allow later analysis to determine various measures that relate to the patient's degree of attention. For example, measures that can be important include the user's fastest reaction time, his or her mean reaction time, and the standard deviation of reaction times. In addition, the difference between the results for audio and visual delayed reaction tasks may also be considered. For example, young children tend to respond more quickly to audio trigger stimuli than video trigger stimuli. Thus, the relationship between the results of audio and video delayed reaction tests for a patient may provide some insight as to that patient's relative deficit or development of both auditory and visual attention skills.

In the currently preferred realizations of embodiments for use in diagnostic assessment of Attention Deficit Hyperactivity Disorder and Attention Deficit Disorder, external memory unit **12** is programmed to cause microprocessor unit **10** to generate a display of the type shown in simplified form in FIG. **4**. In the display of FIG. **4**, a car **90** is positioned at a starting line **92** on a roadway or racetrack **94**. A traffic signal **96**, having a red light **98**, an amber light **100**, and a green light **102**, is prominently displayed. As each visual delayed reaction task is generated, microprocessor-based unit **10** causes sequential illumination of red light **98**, amber light **100**, and green light **102**. Amber light **100** serves as the warning stimulus, with green light **102** providing a trigger stimulus after a randomly generated time delay that is within the time delay range that was established when the visual delayed reaction test being executed was established by the clinician or the administrator having control over the diagnostic testing.

During the audio delayed reaction tests, the three lights of traffic light **100** in FIG. **3** are extinguished and program instructions that are stored in external memory unit **12** result in generation of suitable audio warning and trigger stimuli by sound generator **62** of FIG. **2**. In arrangements having sufficient memory and sound generation capability, the words "ready . . . set . . . go" are used, with the time interval between "set" and "go" being a random value within the range of values selected when a clinician established the diagnostic procedure. Two tones that are clearly distinct from one another also can be used for the warning and trigger stimuli.

The currently preferred realizations of embodiments of the invention that are directed to diagnostic assessment of Attention Deficit Hyperactivity Disorder and Attention Deficit Disorder provide for both visual and audible continuous performance tests. In each test a sequence or series of events occurs for which the patient or user is to respond by activating a predetermined switch or control such as the control switches **44** in the arrangement of FIG. **2**. The continuous performance test used in the currently preferred embodiments of the invention are performance-paced in that the interstimulus stimulus interval (i.e., the time that elapses between consecutive stimuli) is reduced by a predetermined amount each time a correct response is made and is increased by the same or a different predetermined amount if an improper response occurs (i.e., the user responds to a non-target stimulus or fails to respond to a target stimulus).

The video display for the continuous performance tests of the currently preferred embodiments is indicated in FIG. **4**. In FIG. **4**, the car **90** that is used in the above-discussed delayed reaction tests is shown traveling along a roadway **94**. Periodically, the car **90** approaches a tree **104**, which is positioned along side roadway **94**. As car **90** approaches a tree **104**, various types of fruit (oranges, apples, lemons, and grapes) will appear, hanging downwardly from a branch of the tree. The object is for the patient or user to respond to a specified type of fruit only (e.g., apple **106** in FIG. **4**) by depressing a selected switch such as one of the switches of control switches **44** in FIG. **2**. When the appropriate switch is pressed, a hand and arm extend upwardly from car **90** to capture the fruit. As previously noted, with each correct response, the interstimulus interval is decreased (i.e., the car **90** appears to travel at a higher rate of speed) and with each incorrect response or failure to respond, the interstimulus interval is increased (car **90** appears to travel slower).

In the audio continuous performance tests of the referenced realizations of the invention, the display shows car **90** traveling at night, with only a portion of roadway **94** being illuminated by the car's headlights. Each time the car approaches a darkened tree **104**, a low-frequency radar-like

"beep" is heard if the tree does not bear the desired fruit (apple **106** in FIG. **4**). When the proper fruit is present, a high-pitched radar-like beep is emitted.

Embodiments of the invention for diagnostic assessment for Attention Deficit Hyperactivity Disorder and Attention Deficit Disorder can also include programming for conduction of continuous performance tests that include distractions. For example, as is shown in FIG. **5**, a fluttering butterfly **110** or other moving object such as a hopping frog or flying saucer can be generated in the peripheral region of the video display to provide a measure of the patient's degree of distractibility. During audio continuous performance tests synthesized voice signals such as "Now!" or "Go!" can be generated by microprocessor-based unit **10**. In situations in which synthesized voice is beyond the capability of the sound generator being used, the microprocessor-based unit **10** can supply various distractive sounds or noises.

When the battery of diagnostic assessments is established by a clinician, program instructions can be stored in external memory unit **12** (or otherwise provided to a microprocessor-based unit) to determine the number of continuous performance tests to be performed and the type of each test (i.e., video without distractions; video with distractions; audio without distractions; and, audio with distractions). The sequence of the tests, both with respect to one another and with respect to the previously discussed delayed reaction tests, is also determined by the clinician. For each continuous performance test, the clinician can select the total number of target and non-target stimuli to be presented; the test duration; and the minimum stimulus duration (which is typically set at around 100 milliseconds). Diagnostic measures that are recorded in external memory unit **12** during conduction of continuous performance tests include: the number of target stimuli correctly identified (i.e., captured); the number of target stimuli for which the user failed to react (missed stimuli); the number of non-target stimuli for which there was a response; the number of times the button or switch was activated after a stimulus passed (late hits); and the final interstimulus interval (and/or the minimum interstimulus interval attained during the test).

As was described relative to FIGS. **1** and **2**, program instructions for establishing the diagnostic assessment procedure (e.g., storing suitable program instructions in external memory **12**) and retrieval of signals representative of the diagnostic measures gathered during diagnostic testing (e.g., accessing information stored in external memory **12**) are performed by executing an administrator program with the clinician's computer (**22** in FIG. **1**; digital signal processing unit **42** in FIG. **2**). When the administrator program of the current realizations of the invention is executed, a main menu screen is displayed, allowing the clinician to select menu items that include: the opening of a new file (i.e., establishing a diagnostic assessment procedure for a new patient or subject); opening an existing file; saving a file (storing a diagnostic assessment configuration in memory of the clinician's computer); closing a file; and producing the diagnostic assessment procedure (i.e., storing the appropriate program instructions in an external memory **12** or, alternatively, initiating execution of a diagnostic assessment procedure with a microprocessor-based unit **10** that is directly connected to the clinician's computer (FIG. **2**).

The sequence of steps that is executed when a new file is opened during execution of the administrator program is shown in FIG. **6**. As is indicated at block **110**, the first step of opening a new file is the display of a "mask," i.e., a form that includes empty fields for insertion of information such as the name of the patient or subject, age, sex, grade or educational level, date on which the test is to be performed, name of attending physician or clinician; and the identity of the person establishing the diagnostic assessment procedure.

The next step of establishing a new file is indicated at block **112** and consists of creating the desired diagnostic assessment procedure. In this step, a set-up screen is displayed that allows the clinician or test administrator to establish a desired battery of the previously described audio and visual delayed reaction tests and the previously described audio and visual continued performance tests (both with and without distractions). The tests can be selected in any sequence and, if desired, a particular type of test can be repeated without intervening execution of a different type of test. Further, in the currently preferred realizations of the invention, a short training procedure is available for both delayed reaction testing and continuous performance testing. In most cases, the clinician or administrator will include one or both of the training procedures in the diagnostic assessment procedure.

The set-up screen also includes provision for the clinician or administrator to select the various previously mentioned delayed reaction test parameters and continuous performance test parameters. Specifically, the clinician can select the delay range that will determine the upper and lower limits of the random time delay between a warning stimulus and a trigger stimulus in the delayed reaction tests and can also set the number of trigger stimuli that will occur during each delayed reaction test. With respect to each continuous performance test, the set-up screen allows the clinician to set the duration of each test, the percentage of target stimuli (i.e., the mix of non-target and target stimuli), the amount by which the interstimulus interval decreases each time a patient or subject captures a target stimulus; the amount by which the interstimulus interval increases when the patient misses; and the type of target stimulus to be used (e.g., apples, grapes, lemons, or oranges).

Once the diagnostic assessment procedure has been established for a patient or subject, the sequence for establishing a new file causes the "save," "close," and "produce test" sequences of the administrator program to be enabled (indicated at block **114**) and disables the "open" and "new" sequences of the administrator program. As is indicated at block **118** in FIG. **7**, the sequence then returns to the menu screen. Since the "open" and "new" sequences have been disabled, those menu items are preferably at least partially blanked out or otherwise indicated as not being available for selection.

When the administrator program is initiated, the clinician can select the "open file" menu item as an alternative to the "new file" item. As is indicated in FIG. **7**, the sequence that is executed when the "open file" menu item is selected begins with the display with a list of existing files (e.g., patient names or identification numbers), which is indicated at block **120**. Also displayed is an option that allows the clinician or administrator to cancel the sequence for opening a file. If selected, the option for canceling the sequence returns the screen display to a display of the main menu (indicated at block **122**). On the other hand, if the clinician or administrator selects a particular patient, the information about the patient and the battery of tests and test parameters that was recorded during the new file procedure is displayed (indicated at block **124**). As is shown at block **126**, the administrator program then sequences to disable menu items that would otherwise allow the opening of a new or different. The menu item that allows the production of a diagnostic test routine (such as the loading of an external memory unit **12**

with program instructions) also is disabled. As is indicated at block **128**, menu items for saving a file, closing a file, and for displaying or printing test results that were stored when the diagnostic assessment procedure for that patient was conducted or enabled.

The system then returns to displaying the menu with the enabled menu items being displayed in a manner that distinguishes those menu items from the disabled menu items (indicated at block **130**).

The sequence that is executed when the administrator program is used to save a patient file is shown in FIG. **8** and begins with a determination of whether a "record modified" is set (block **132**). The record modified flag is a field in the data record for each patient and is set whenever that patients file is opened and modified by adding new information, or changing information that was previously entered. If the record modified flag is not set, the sequence shown in FIG. **8** is terminated and the system display returns to the selection menu (indicated at block **134**). On the other hand, if the record modified flag is set, a determination is made as to whether sufficient patient identification information is included in the patient file or record being processed (indicated at decision block **136**). In the event of insufficient identification a warning message is displayed (block **138**). The sequence for saving the file is canceled and the display returns to the main menu (indicated at block **140**).

When sufficient patient identification is included in the record being processed, the administrator program determines whether the record already exists (decision block **142**). As is shown at block **144**, an existing file is modified in accordance with information included in the file being saved. Next, the record modified flag is cleared (block **146**); and the system display is returned to the main menu (block **134**). However, if the file being processed does not already exist, a new record is stored in system memory (block **148**); the record modified flag is cleared (block **146**); and the system display is returned to the main menu (block **134**).

As is shown in FIG. **9**, the sequence by which the administrator program closes a previously opened patient record begins with a determination of whether the record modifier flag is set (indicated at decision block **150**). If the record has been modified, the clinician or administrator executing the program is prompted to specify whether the modified record should be saved, discarded, or whether the sequence to close the record should be canceled (indicated at block **152**). As is indicated at block **156**, if the modified record is to be saved, the above-discussed sequence for saving the record is executed.

A determination at decision block **150** that the record has not been modified causes deactivation of the menu items for saving a file or record, closing a file, and for displaying and printing test results. The menu item that allows storage of program instructions in an external memory **12** or the alternative administration of a diagnostic assessment procedure with a microprocessor-based unit **10** that is connected to the clinician's computer is also disabled (all indicated at block **158** in FIG. **9**). As is shown in FIG. **9**, these menu items also are disabled after saving a modified file (i.e., the completion of the operation indicated at block **156**) and, in addition, upon executing an instruction to discard a modified record (shown at block **152**). As is indicated at block **160**, once the specified menu items have been disabled, the menu items for establishing a new file and for opening an existing file are enabled (block **160**); the record is removed from the display screen (block **162**); and the main menu is displayed (block **164**).

The sequence that is executed during the administrator program to load desired program instructions into an external memory unit **12** or, alternatively, initiate a diagnostic assessment procedure with a microprocessor-based unit **10** that is electrically connected to the clinician's computer is shown in FIG. **10**. As is indicated at decision block **166**, the sequence begins with a determination of whether a microprocessor-based unit **10** is both connected to the clinician's computer and is turned on. If a microprocessor-based unit is both connected and active, the program instructions required to configure the microprocessor for the test specified in the currently open patient file are transferred to the microprocessor-based unit (block **168**). The sequence then remains in a "wait" state until the microprocessor **10** signals that the diagnostic test results are available (block **170**). Once the test results are available and stored in memory, the menu items for displaying test results and printing test results are enabled (block **172**); the previously discussed record modified flag is set (block **174**); and the system display returns to the main menu (block **176**).

When a microprocessor unit **10** that is electrically connected with the clinician's computer is not turned on (determined at block **166**), a determination is made at block **178** as to whether an external memory unit **12** is to be loaded with program instructions (e.g., whether an external memory unit **12** is present in receptacle **38** of the arrangements shown in FIGS. **1** and **2**). If an external memory unit **12** is not present, a message is displayed indicating that an error condition has been encountered (block **182**) and the administrator program sequences to the main menu screen (block **176**). If an external memory unit **12** is present, the program instructions for establishing a diagnostic assessment procedure for the open patient file are loaded into the external memory unit **12** for subsequent use by the patient.

Referring to FIG. **11**, the sequence by which the clinician or administrator exits the administrator program begins with the determination as to whether a patient file or record is open (decision block **184**). If an open patient file or record is detected, the sequence for closing the file that was discussed relative to FIG. **9** is executed (indicated at block **186**). If the sequence for closing the file is canceled prior to completion, the sequence for exiting the administrator program is canceled and the main menu is displayed (indicated at block **188**). Successful completion of the sequence for closing an open file results in execution of "housekeeping" routines that close the database that stores test results and, in addition, perform memory cleanup operations (indicated at block **190**); and the administrator program is removed from active memory (indicated at block **192**).

If no record is open when the exit sequence is executed (determined at block **184**), the clinician is prompted to confirm whether an exit from the administrator program is to be made (indicated at block **194**). If the exit command is verified, the database of test results is closed and memory cleanup accomplished (block **190**), with subsequent exit from the administrator program (block **192**). In the event exit is not to be made, the main menu is again displayed (block **188**).

While the preferred embodiment of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the spirit and scope of the invention. As previously mentioned, the invention can be embodied in various ways to provide a microprocessor-based unit with program instructions that cause the microprocessor-based unit to operate in a manner suitable for the assessment of various psychological conditions. For example, in assessing and treating habitual smok-

ing or addiction to nicotine, a microprocessor-based unit (e.g., video game system) can be programmed to present a game-like presentation that may or may not directly relate to smoking. Such a unit can be given to a user with instructions to "play" the game-like presentation each time the user has an urge to smoke over a predetermined period such as three weeks. At the end of the prescribed period, the clinician can access the stored information and based on computer assisted analysis of the retrieved data can determine the nature, frequency and severity of the user's habit or addiction, as well as the motivation or stimulus that triggers an urge to smoke. Based on that information, an informed decision can be reached as to whether the user of the system (e.g., patient) is likely to respond to behavioral therapy or whether chemical replacement therapy or a combination of the two therapies should be used. Various other addictions and behavioral patterns can be assessed in similar fashion.

As another example of the manner in which the invention can be embodied, a series of interactive assessment sessions for conditions such as depression or anxiety can be presented via interactive cable television to a wide audience. In such an arrangement, the patient or subject is enrolled in the sessions by a psychiatrist or other healthcare professional. The patient or user tunes the interactive television system to a predetermined channel at a predetermined time and enters a personal identification code via a microprocessor-based unit that is connected for receiving and sending signals via the interactive television system. Program instructions are then provided to the microprocessor-based unit via the interactive television system and the patient or user responds to various stimuli during the televised diagnostic assessment section. As is the case with other arrangements of the invention, the televised assessment session can be in a game-like format or other presentation that is unobtrusive. Diagnostic information gathered during the session can be provided to the clinician in one of the several ways discussed with respect to FIGS. **1** and **2**. By analyzing the diagnostic assessment data gathered during the interactive assessment sessions, the psychiatrist or other healthcare professional can make a better informed decision as to the need for clinical therapy and/or medication than can be made based only on traditional clinical sessions.

The invention further presents a system and method for remotely monitoring individuals and for communicating information to the individuals. In a preferred embodiment of the invention, the individuals are patients and the system is used to collect data relating to the health status of the patients. However, it is to be understood that the invention is not limited to remote patient monitoring. The system and method of the invention may be used for any type of remote monitoring application. The invention may also be implemented as an automated messaging system for communicating information to individuals, as will be discussed in an alternative embodiment below.

A preferred embodiment of the invention is illustrated in FIGS. **201**–**212**. Referring to FIG. **201**, a networked system **2016** includes a server **2018** and a workstation **2020** connected to server **2018** through a communication network **2024**. Server **2018** is preferably a world wide web server and communication network **2024** is preferably the Internet. It will be apparent to one skilled in the art that server **2018** may comprise a single stand-alone computer or multiple computers distributed throughout a network. Workstation **2020** is preferably a personal computer, remote terminal, or web TV unit connected to server **2018** via the Internet. Workstation **2020** functions as a remote interface for entering in server **2018** messages and queries to be communicated to the patients.

System **2016** also includes first and second remotely programmable apparatuses **2026** and **2032** for monitoring first and second patients, respectively. Each apparatus is designed to interact with a patient in accordance with script programs received from server **2018**. Each apparatus is in communication with server **2018** through communication network **2024**, preferably the Internet. Alternatively, each apparatus may be placed in communication with server **2018** via wireless communication networks, cellular networks, telephone networks, or any other network which allows each apparatus to exchange data with server **2018**. For clarity of illustration, only two apparatuses are shown in FIG. **201**. It is to be understood that system **2016** may include any number of apparatuses for monitoring any number of patients.

In the preferred embodiment, each patient to be monitored is also provided with a monitoring device **2028**. Monitoring device **2028** is designed to produce measurements of a physiological condition of the patient, record the measurements, and transmit the measurements to the patient's apparatus through a standard connection cable **2030**. Examples of suitable monitoring devices include blood glucose meters, respiratory flow meters, blood pressure cuffs, electronic weight scales, and pulse rate monitors. Such monitoring devices are well known in the art. The specific type of monitoring device provided to each patient is dependent upon the patient's disease. For example, diabetes patients are provided with a blood glucose meters for measuring blood glucose concentrations, asthma patients are provided with respiratory flow meters for measuring peak flow rates, obesity patients are provided with weight scales, etc.

FIG. **202** shows server **2018**, workstation **2020**, and apparatus **2026** in greater detail. Server **2018** includes a database **2038** for storing script programs **2040**. The script programs are executed by each apparatus to communicate queries and messages to a patient, receive responses **2042** to the queries, collect monitoring device measurements **2044**, and transmit responses **2042** and measurements **2044** to server **2018**. Database **2038** is designed to store the responses **2042** and measurements **2044**. Database **2038** further includes a look-up table **2046**. Table **2046** contains a list of the patients to be monitored, and for each patient, a unique patient identification code and a respective pointer to the script program assigned to the patient. Each remote apparatus is designed to execute assigned script programs which it receives from server **2018**.

FIGS. **203**–**204** show the structure of each apparatus according to the preferred embodiment. For clarity, only apparatus **2026** is shown since each apparatus of the preferred embodiment has substantially identical structure to apparatus **2026**. Referring to FIG. **203**, apparatus **2026** includes a housing **2062**. Housing **2062** is sufficiently compact to enable apparatus **2026** to be hand-held and carried by a patient. Apparatus **2026** also includes a display **2064** for displaying queries and prompts to the patient. In the preferred embodiment, display **2064** is a liquid crystal display (LCD).

Four user input buttons **2070**A, **2070**B, **2070**C, and **2070**D are located adjacent display **2064**. The user input buttons are for entering in apparatus **2026** responses to the queries and prompts. In the preferred embodiment, the user input buttons are momentary contact push buttons. In alternative embodiments, the user input buttons may be replaced by switches, keys, a touch sensitive display screen, or any other data input device.

Three monitoring device jacks **2068**A, **2068**B, and **2068**C are located on a surface of housing **2062**. The device jacks

are for connecting apparatus **2026** to a number of monitoring devices, such as blood glucose meters, respiratory flow meters, or blood pressure cuffs, through respective connection cables (not shown). Apparatus **2026** also includes a modem jack **2066** for connecting apparatus **2026** to a telephone jack through a standard connection cord (not shown). Apparatus **2026** further includes a visual indicator, such as a light emitting diode (LED) **2074**. LED **2074** is for visually notifying the patient that he or she has unanswered queries stored in apparatus **2026**.

FIG. **204** is a schematic block diagram illustrating the components of apparatus **2026** in greater detail. Apparatus **2026** includes a microprocessor **2076** and a memory **2080** connected to microprocessor **2076**. Memory **2080** is preferably a non-volatile memory, such as a serial EEPROM. Memory **2080** stores script programs received from the server, measurements received from monitoring device **2028**, responses to queries, and the patient's unique identification code. Microprocessor **2076** also includes built-in read only memory (TOM) which stores firmware for controlling the operation of apparatus **2026**. The firmware includes a script interpreter used by microprocessor **2076** to execute the script programs. The script interpreter interprets script commands which are executed by microprocessor **2076**. Specific techniques for interpreting and executing script commands in this manner are well known in the art.

Microprocessor **2076** is preferably connected to memory **2080** using a standard two-wire I^2C interface. Microprocessor **2076** is also connected to user input buttons **2070**, LED **2074**, a clock **2084**, and a display driver **2082**. Clock **2084** indicates the current date and time to microprocessor **2076**. For clarity of illustration, clock **2084** is shown as a separate component, but is preferably built into microprocessor **2076**. Display driver **2082** operates under the control of microprocessor **2076** to display information on display **2064**. Microprocessor **2076** is preferably a PIC 16C65 processor which includes a universal asynchronous receiver transmitter (UART) **2078**. UART **2078** is for communicating with a modem **2086** and a device interface **2090**. A CMOS switch **2088** under the control of microprocessor **2076** alternately connects modem **2086** and interface **2090** to UART **2078**.

Modem **2086** is connected to a telephone jack **2022** through modem jack **2066**. Modem **2086** is for exchanging data with server **2018** through communication network **2024**. The data includes script programs which are received from the server as well as responses to queries, device measurements, script identification codes, and the patient's unique identification code which modem **2086** transmits to the server. Modem **2086** is preferably a complete 28.8 K modem commercially available from Cermetek, although any suitable modem may be used.

Device interface **2090** is connected to device jacks **2068**A, **2068**B, and **2068**C. Device interface **2090** is for interfacing with a number of monitoring devices, such as blood glucose meters, respiratory flow meters, blood pressure cuffs, weight scales, or pulse rate monitors, through the device jacks. Device interface **2090** operates under the control of microprocessor **2076** to collect measurements from the monitoring devices and to output the measurements to microprocessor **2076** for storage in memory **2080**. In the preferred embodiment, interface **2090** is a standard RS232 interface. For simplicity of illustration, only one device interface is shown in FIG. **204**. However, in alternative embodiments, apparatus **2026** may include multiple device interfaces to accommodate monitoring devices which have different connection standards.

Referring again to FIG. **202**, server **2018** includes a monitoring application **2048**. Monitoring application **2048** is a controlling software application executed by server **2018** to perform the various functions described below. Application **2048** includes a script generator **2050**, a script assignor **2052**, and a report generator **2054**. Script generator **2050** is designed to generate script programs **2040** from script information entered through workstation **2020**. The script information is entered through a script entry screen **2056**. In the preferred embodiment, script entry screen **2056** is implemented as a web page on server **2018**. Workstation **2020** includes a web browser for accessing the web page to enter the script information.

FIG. **205** illustrates script entry screen **2056** as it appears on workstation **2020**. Screen **2056** includes a script name field **2092** for specifying the name of a script program to be generated. Screen **2056** also includes entry fields **2094** for entering a set of queries to be answered by a patient. Each entry field **2094** has corresponding response choice fields **2096** for entering response choices for the query. Screen **2056** further includes check boxes **2098** for selecting a desired monitoring device from which to collect measurements, such as a blood glucose meter, respiratory flow meter, or blood pressure cuff.

Screen **2056** additionally includes a connection time field **2100** for specifying a prescribed connection time at which each apparatus executing the script is to establish a subsequent communication link to the server. The connection time is preferably selected to be the time at which communication rates are the lowest, such as 3:00 AM. Screen **2056** also includes a CREATE SCRIPT button **2102** for instructing the script generator to generate a script program from the information entered in screen **2056**. Screen **2056** further includes a CANCEL button **2104** for canceling the information entered in screen **2056**.

In the preferred embodiment, each script program created by the script generator conforms to the standard file format used on UNIX systems. In the standard file format, each command is listed in the upper case and followed by a colon. Every line in the script program is terminated by a linefeed character {LF}, and only one command is placed on each line. The last character in the script program is a UNIX end of file character {EOF}. Table 1 shows an exemplary listing of script commands used in the preferred embodiment of the invention.

Command	Description
CLS: {LF}	Clear the display.
ZAP: {LF}	Erase from memory the last set of query responses recorded.
LED: b{LF}	Turn the LED on or off, where b is a binary digit of 0 or 1. An argument of 1 turns on the LED, and an argument of 0 turns off the LED.
DISPLAY: {chars}{LF}	Display the text following the DISPLAY command.
INPUT: mmmm{LF}	Record a button press. The m's represent a button mask pattern for each of the four input buttons. Each m contains an "X" for disallowed buttons or an "O" for allowed buttons. For example, INPUT: OXOX{LF} allows the user to press either button #1 or #3.
WAIT: {LF}	Wait for any one button to be pressed, then continue executing the script program.
COLLECT: device{LF}	Collect measurements from the monitoring device specified in the COLLECT command. The user is preferably prompted to connect the specified monitoring device to the apparatus and press a button to continue.
NUMBER: aaaa{LF}	Assign a script identification code to the script program. The script identification code from the most recently executed NUMBER statement is subsequently transmitted

-continued

Command	Description
	to the server along with the query responses and device measurements. The script identification code identifies to the server which script program was most recently executed by the remote apparatus.
DELAY: t{LF}	Wait until time t specified in the DELAY command, usually the prescribed connection time.
CONNECT: {LF}	Perform a connection routine to establish a communication link to the server, tramsmit the patient identification code, query responses, device measurements, and script identification code to the server, and receive and store a new script program. When the server instructs the apparatus to disconnect, the script interpreter is restarted, allowing the new script program to execute.

The script commands illustrated in Table 1 are representative of the preferred embodiment and are not intended to limit the scope of the invention. After consideration of the ensuing description, it will be apparent to one skilled in the art many other suitable scripting languages and sets of script commands may be used to implement the invention.

Script generator **2050** preferably stores a script program template which it uses to create each script program. To generate a script program, script generator **2050** inserts into the template the script information entered in screen **2056**. For example, FIGS. **206**A–**206**B illustrate a sample script program created by script generator **2050** from the script information shown in FIG. **205**.

The script program includes display commands to display the queries and response choices entered in fields **2094** and **2096**, respectively. The script program also includes input commands to receive responses to the queries. The script program further includes a collect command to collect device measurements from the monitoring device specified in check boxes **2098**. The script program also includes commands to establish a subsequent communication link to the server at the connection time specified in field **2100**. The steps included in the script program are also shown in the flow chart of FIGS. **212**A–**212**B and will be discussed in the operation section below.

Referring again to FIG. **202**, script assignor **2052** is for assigning script programs **2040** to the patients. Script programs **2040** are assigned in accordance with script assignment information entered through workstation **2020**. The script assignment information is entered through a script assignment screen **2057**, which is preferably implemented as a web page on server **2018**.

FIG. **207** illustrates a sample script assignment screen **2057** as it appears on workstation **2020**. Screen **2057** includes check boxes **2106** for selecting a script program to be assigned and check boxes **2108** for selecting the patients to whom the script program is to be assigned. Screen **2057** also includes an ASSIGN SCRIPT button **2112** for entering the assignments. When button **2112** is pressed, the script assignor creates and stores for each patient selected in check boxes **2108** a respective pointer to the script program selected in check boxes **2106**. Each pointer is stored in the patient look-up table of the database. Screen **2057** further includes an ADD SCRIPT button **2110** for accessing the script entry screen and a DELETE SCRIPT button **2114** for deleting a script program.

Referring again to FIG. **202**, report generator **2054** is designed to generate a patient report **2058** from the responses and device measurements received in server **2018**. Patient report **2058** is displayed on workstation **2020**. FIG. **210** shows a sample patient report **2058** produced by report generator **2054** for a selected patient. Patient report **2058** includes a graph **2116** of the device measurements received from the patient, as well as a listing of responses **2042** received from the patient. Specific techniques for writing a report generator program to display data in this manner are well known in the art.

The operation of the preferred embodiment is illustrated in FIGS. **211**–**212**. FIG. **211**A is a flow chart illustrating steps included in the monitoring application executed by server **2018**. FIG. **211**B is a continuation of the flow chart of FIG. **211**A. In step **2202**, server **2018** determines if new script information has been entered through script entry screen **2056**. If new script information has not been entered, server **2018** proceeds to step **2206**. If new script information has been entered, server **2018** proceeds to step **2204**.

As shown in FIG. **205**, the script information includes a set of queries, and for each of the queries, corresponding responses choices. The script information also includes a selected monitoring device type from which to collect device measurements. The script information further includes a prescribed connection time for each apparatus to establish a subsequent communication link to the server. The script information is generally entered in server **2018** by a healthcare provider, such as the patients' physician or case manager. Of course, any person desiring to communicate with the patients may also be granted access to server **2018** to create and assign script programs. Further, it is to be understood that the system may include any number of remote interfaces for entering script generation and script assignment information in server **2018**.

In step **2204**, script generator **2050** generates a script program from the information entered in screen **2056**. The script program is stored in database **2038**. Steps **2202** and **2204** are preferably repeated to generate multiple script programs, e.g. a script program for diabetes patients, a script program for asthma patients, etc. Each script program corresponds to a respective one of the sets of queries entered through script entry screen **2056**. Following step **2204**, server **2018** proceeds to step **2206**.

In step **2206**, server **2018** determines if new script assignment information has been entered through assignment screen **2057**. If new script assignment information has not been entered, server **2018** proceeds to step **2210**. If new script assignment information has been entered, server **2018** proceeds to step **2208**. As shown in FIG. **207**, the script programs are assigned to each patient by selecting a script program through check boxes **2106**, selecting the patients to whom the selected script program is to be assigned through check boxes **2108**, and pressing the ASSIGN SCRIPT button **2112**. When button **2112** is pressed, script assignor **2052** creates for each patient selected in check boxes **2108** a respective pointer to the script program selected in check boxes **2106**. In step **2208**, each pointer is stored in look-up table **2046** of database **2038**. Following step **2208**, server **2018** proceeds to step **2210**.

In step **2210**, server **2018** determines if any of the apparatuses are remotely connected to the server. Each patient to be monitored is preferably provided with his or her own apparatus which has the patient's unique identification code stored therein. Each patient is thus uniquely associated with a respective one of the apparatuses. If none of the apparatuses is connected, server **2018** proceeds to step **2220**.

If an apparatus is connected, server **2018** receives from the apparatus the patient's unique identification code in step

2212. In step 2214, server 2018 receives from the apparatus the query responses 2042, device measurements 2044, and script identification code recorded during execution of a previously assigned script program. The script identification code identifies to the server which script program was executed by the apparatus to record the query responses and device measurements. The responses, device measurements, and script identification code are stored in database 2038.

In step 2216, server 2018 uses the patient identification code to retrieve from table 2046 the pointer to the script program assigned to the patient. The server then retrieves the assigned script program from database 2038. In step 2218, server 2018 transmits the assigned script program to the patient's apparatus through communication network 2024. Following step 2218, server 2018 proceeds to step 2220.

In step 2220, server 2018 determines if a patient report request has been received from workstation 2020. If no report request has been received, server 2018 returns to step 2202. If a report request has been received for a selected patient, server 2018 retrieves from database 2038 the measurements and query responses last received from the patient, step 2222. In step 2224, server 2018 generates and displays patient report 2058 on workstation 2020. As shown in FIG. 210, report 2058 includes the device measurements and query responses last received from the patient. Following step 2224, the server returns to step 2202.

FIGS. 212A–212B illustrate the steps included in the script program executed by apparatus 2026. Before the script program is received, apparatus 2026 is initially programmed with the patient's unique identification code and the script interpreter used by microprocessor 2076 to execute the script program. The initial programming may be achieved during manufacture or during an initial connection to server 2018. Following initial programming, apparatus 2026 receives from server 2018 the script program assigned to the patient associated with apparatus 2026. The script program is received by modem 2086 through a first communication link and stored in memory 2080.

In step 2302, microprocessor 2076 assigns a script identification code to the script program and stores the script identification code in memory 2080. The script identification code is subsequently transmitted to the server along with the query responses and device measurements to identify to the server which script program was most recently executed by the apparatus. In step 2304, microprocessor 2076 lights LED 2074 to notify the patient that he or she has unanswered queries stored in apparatus 2026. LED 2074 preferably remains lit until the queries are answered by the patient. In step 2306, microprocessor 2076 erases from memory 2080 the last set of query responses recorded.

In step 2308, microprocessor 2076 prompts the patient by displaying on display 2064 "ANSWER QUERIES NOW? PRESS ANY BUTTON TO START". In step 2310, microprocessor 2076 waits until a reply to the prompt is received from the patient. When a reply is received, microprocessor 2076 proceeds to step 2312. In step 2312, microprocessor 2076 executes successive display and input commands to display the queries and response choices on display 2064 and to receive responses to the queries.

FIG. 208 illustrates a sample query and its corresponding response choices as they appear on display 2064. The response choices are positioned on display 2064 such that each response choice is located proximate a respective one of the input buttons. In the preferred embodiment, each response choice is displayed immediately above a respective input button. The patient presses the button corresponding to his or her response. Microprocessor 2076 stores each response in memory 2080.

In steps 2314–2318, microprocessor 2076 executes commands to collect device measurements from a selected monitoring device. The script program specifies the selected monitoring device from which to collect the measurements. In step 2314, microprocessor 2076 prompts the patient to connect the selected monitoring device, for example a blood glucose meter, to one of the device jacks. A sample prompt is shown in FIG. 209. In step 2316, microprocessor 2076 waits until a reply to the prompt is received from the patient. When a reply is received, microprocessor 2076 proceeds to step 2318. Microprocessor 2076 also connects UART 2078 to interface 2090 through switch 2088. In step 2318, microprocessor 2076 collects the device measurements from monitoring device 2028 through interface 2090. The measurements are stored in memory 2080.

In step 2320, microprocessor 2076 prompts the patient to connect apparatus 2026 to telephone jack 2022 so that apparatus 2026 may connect to server 2018 at the prescribed connection time. In step 2322, microprocessor 2076 waits until a reply to the prompt is received from the patient. When a reply is received, microprocessor 2076 turns off LED 2074 in step 2324. In step 2326, microprocessor 2076 waits until it is time to connect to server 2018. Microprocessor 2076 compares the connection time specified in the script program to the current time output by clock 2084. When it is time to connect, microprocessor 2076 connects UART 2078 to modem 2086 through switch 2088.

In step 2328, microprocessor 2076 establishes a subsequent communication link between apparatus 2026 and server 2018 through modem 2086 and communication network 2024. If the connection fails for any reason, microprocessor 2076 repeats step 2328 to get a successful connection. In step 2330, microprocessor 2076 transmits the device measurements, query responses, script identification code, and patient identification code stored in memory 2080 to server 2018 through the subsequent communication link. In step 2332, microprocessor 2076 receives through modem 2086 a new script program from server 2018. The new script program is stored in memory 2080 for subsequent execution by microprocessor 2076. Following step 2332, the script program ends.

One advantage of the monitoring system of the present invention is that it allows each patient to select a convenient time to respond to the queries, so that the monitoring system is not intrusive to the patient's schedule. A second advantage of the monitoring system is that it incurs very low communications charges because each remote apparatus connects to the server at times when communication rates are lowest. Moreover, the cost to manufacture each remote apparatus is very low compared to personal computers or Internet terminals, so that the monitoring system is highly affordable.

A third advantage of the monitoring system is that it allows each apparatus to be programmed remotely through script programs. Patient surveys, connection times, display prompts, selected monitoring devices, patient customization, and other operational details of each apparatus may be easily changed by transmitting a new script program to the apparatus. Moreover, each script program may be easily created and assigned by remotely accessing the server through the Internet. Thus, the invention provides a powerful, convenient, and inexpensive system for remotely monitoring a large number of patients.

FIGS. 213–215 illustrate a second embodiment of the invention in which each remotely programmable apparatus

has speech recognition and speech synthesis functionality. FIG. **213** shows a perspective view of an apparatus **2027** according to the second embodiment. Apparatus **2027** includes a speaker **2072** for audibly communicating queries and prompts to the patient. Apparatus **2027** also includes a microphone **2118** for receiving spoken responses to the queries and prompts. Apparatus **2027** may optionally include a display **2064** for displaying prompts to the patient, as shown in FIG. **214**.

FIG. **215** is a schematic block diagram illustrating the components of apparatus **2027** in greater detail. Apparatus **2027** is similar in design to the apparatus of the preferred embodiment except that apparatus **2027** includes an audio processor chip **2120** in place of microprocessor **2076**. Audio processor chip **2120** is preferably an RSC-164 chip commercially available from Sensory Circuits Inc. of 1735 N. First Street, San Jose, Calif. 95112.

Audio processor chip **2120** has a microcontroller **2122** for executing script programs received from the server. A memory **2080** is connected to microcontroller **2122**. Memory **2080** stores the script programs and a script interpreter used by microcontroller **2122** to execute the script programs. Memory **2080** also stores measurements received from monitoring device **2028**, responses to the queries, script identification codes, and the patient's unique identification code.

Audio processor chip **2120** also has built in speech synthesis functionality for synthesizing queries and prompts to a patient through speaker **2072**. For speech synthesis, chip **2120** includes a digital to analog converter (DAC) **2142** and an amplifier **2144**. DAC **2142** and amplifier **2144** drive speaker **2072** under the control of microcontroller **2122**.

Audio processor chip **2120** further has built in speech recognition functionality for recognizing responses spoken into microphone **2118**. Audio signals received through microphone **2118** are converted to electrical signals and sent to a preamp and gain control circuit **2128**. Preamp and gain control circuit **2128** is controlled by an automatic gain control circuit **2136**, which is in turn controlled by microcontroller **2122**. After being amplified by preamp **2128**, the electrical signals enter chip **2120** and pass through a multiplexer **2130** and an analog to digital converter (ADC) **2132**. The resulting digital signals pass through a digital logic circuit **2134** and enter microcontroller **2122** for speech recognition.

Audio processor chip **2120** also includes a RAM **2138** for short term memory storage and a ROM **2140** which stores programs executed by microcontroller **2122** to perform speech recognition and speech synthesis. Chip **2120** operates at a clock speed determined by a crystal **2126**. Chip **2120** also includes a clock **2084** which provides the current date and time to microcontroller **2122**. As in the preferred embodiment, apparatus **2027** includes an LED **2074**, display driver **2082**, modem **2086**, and device interface **2090**, all of which are connected to microcontroller **2122**.

The operation of the second embodiment is similar to the operation of the preferred embodiment except that queries, response choices, and prompts are audibly communicated to the patient through speaker **2072** rather than being displayed to the patient on display **2064**. The operation of the second embodiments also differs from the operation of the preferred embodiment in that responses to the queries and prompts are received through microphone **2118** rather than through user input buttons.

The script programs of the second embodiment are similar to the script program shown in FIGS. **206**A–**206**B, except that each display command is replaced by a speech synthesis command and each input command is replaced by a speech recognition command. The speech synthesis commands are executed by microcontroller **2122** to synthesize the queries, response choices, and prompts through speaker **2072**. The speech recognition commands are executed by microcontroller **2122** to recognize responses spoken into microphone **2118**.

For example, to ask the patient how he or she feels and record a response, microcontroller **2122** first executes a speech synthesis command to synthesize through speaker **2072** "How do you feel? Please answer with one of the following responses: very bad, bad, good, or very good." Next, microcontroller **2118** executes a speech recognition command to recognize the response spoken into microphone **2118**. The recognized response is stored in memory **2080** and subsequently transmitted to the server. Other than the differences described, the operation and advantages of the second embodiment are the same as the operation and advantages of the preferred embodiment described above.

Although the first and second embodiments focus on querying individuals and collecting responses to the queries, the system of the invention is not limited to querying applications. The system may also be used simply to communicate messages to the individuals. FIGS. **216**–**219** illustrate a third embodiment in which the system is used to perform this automated messaging function. In the third embodiment, each script program contains a set of statements to be communicated to an individual rather than a set of queries to be answered by the individual. Of course, it will be apparent to one skilled in the art that the script programs may optionally include both queries and statements.

The third embodiment also shows how the queries and statements may be customized to each individual by merging personal data with the script programs, much like a standard mail merge application. Referring to FIG. **216**, personal data relating to each individual is preferably stored in look-up table **2046** of database **2038**. By way of example, the data may include each individual's name, the name of each individual's physician, test results, appointment dates, or any other desired data. As in the preferred embodiment, database **2038** also stores generic script programs **2040** created by script generator **2050**.

Server **2018** includes a data merge program **2055** for merging the data stored in table **2046** with generic script programs **2040**. Data merge program **2055** is designed to retrieve selected data from table **2046** and to insert the data into statements in generic script programs **2040**, thus creating custom script programs **2041**. Each custom script program **2041** contains statements which are customized to an individual. For example, the statements may be customized with the individual's name, test results, etc. Examples of such customized statements are shown in FIGS. **217**–**218**.

The operation of the third embodiment is similar to the operation of the preferred embodiment except that the script programs are used to communicate messages to the individuals rather than to query the individuals. Each message is preferably a set of statements. Referring to FIG. **219**, the statements may be entered in the server through script entry screen **2056**, just like the queries of the preferred embodiment.

Each statement preferably includes one or more insert commands specifying data from table **2046** to be inserted into the statement. The insert commands instruct data merge program **2055** to retrieve the specified data from database **2038** and to insert the data into the statement. For example,

the insert commands shown in FIG. **219** instruct the data merge program to insert a physician name, an appointment date, a patient name, and a test result into the statements. As in the preferred embodiment, each statement may also include one or more response choices which are entered in fields **2096**.

Following entry of the statements and response choices, CREATE SCRIPT button **2102** is pressed. When button **2102** is pressed, script generator **2050** generates a generic script program from the information entered in screen **2056**. The generic script program is similar to the script program shown in FIGS. **206**A–**206**B, except that the display commands specify statements to be displayed rather than queries. Further, the statements include insert commands specifying data to be inserted into the script program. As in the preferred embodiment, multiple script programs are preferably generated, e.g. a generic script program for diabetes patients, a generic script program for asthma patients, etc. The generic script programs are stored in database **2038**.

Following generation of the generic script programs, server **2018** receives script assignment information entered through script assignment screen **2057**. As shown in FIG. **207**, the script programs are assigned by first selecting one of the generic script programs through check boxes **2106**, selecting individuals through check boxes **2108**, and pressing the ASSIGN SCRIPT button **2112**. When button **2112** is pressed, data merge program **2055** creates a custom script program for each individual selected in check boxes **2108**.

Each custom script program is preferably created by using the selected generic script program as a template. For each individual selected, data merge program **2055** retrieves from database **2038** the data specified in the insert commands. Next, data merge program **2055** inserts the data into the appropriate statements in the generic script program to create a custom script program for the individual. Each custom script program is stored in database **2038**.

As each custom script program is generated for an individual, script assignor **2052** assigns the script program to the individual. This is preferably accomplished by creating a pointer to the custom script program and storing the pointer with the individual's unique identification code in table **2046**. When the individual's remote apparatus connects to server **2018**, server **2018** receives from the apparatus the individual's unique identification code. Server **2018** uses the unique identification code to retrieve from table **2046** the pointer to the custom script program assigned to the individual. Next, server **2018** retrieves the assigned script program from database **2038** and transmits the script program to the individual's apparatus through communication network **2024**.

The apparatus receives and executes the script program. The execution of the script program is similar to the execution described in the preferred embodiment, except that statements are displayed to the individual rather than queries. FIGS. **217**–**218** illustrate two sample statements as they appear on display **2064**. Each statement includes a response choice, preferably an acknowledgment such as "OK". After reading a statement, the individual presses the button corresponding to the response choice to proceed to the next statement. Alternatively, the script program may specify a period of time that each statement is to be displayed before proceeding to the next statement. The remaining operation of the third embodiment is analogous to the operation of the preferred embodiment described above.

Although it is presently preferred to generate a custom script program for each individual as soon as script assignment information is received for the individual, it is also possible to wait until the individual's apparatus connects to the server before generating the custom script program. This is accomplished by creating and storing a pointer to the generic script program assigned to the individual, as previously described in the preferred embodiment. When the individual's apparatus connects to the server, data merge program **2055** creates a custom script program for the individual from the generic script program assigned to the individual. The custom script program is then sent to the individual's apparatus for execution.

SUMMARY, RAMIFICATIONS, AND SCOPE

Although the above description contains many specificities, these should not be construed as limitations on the scope of the invention but merely as illustrations of some of the presently preferred embodiments. Many other embodiments of the invention are possible. For example, the scripting language and script commands shown are representative of the preferred embodiment. It will be apparent to one skilled in the art many other scripting languages and specific script commands may be used to implement the invention.

Moreover, the invention is not limited to the specific applications described. The system and method of the invention have many other applications both inside and outside the healthcare industry. For example, pharmaceutical manufacturers may apply the system in the clinical development and post marketing surveillance of new drugs, using the system as an interactive, on-line monitoring tool for collecting data on the efficacy, side effects, and quality of life impact of the drugs. Compared to the current use of labor intensive patient interviews, the system provides a fast, flexible, and cost effective alternative for monitoring the use and effects of the drugs.

The system may also be used by home healthcare companies to enhance the service levels provided to customers, e.g., panic systems, sleep surveillance, specific monitoring of disease conditions, etc. Alternatively, the system may be used to monitor and optimize the inventory of home stationed health supplies. As an example, the system may be connected to an appropriate measuring device to optimize timing of oxygen tank delivery to patients with COPD.

The system and method of the invention also have many applications outside the healthcare industry. For example, the system may be used for remote education over the Internet, facilitating educational communication with children or adult trainees who lack access to sophisticated and expensive computer equipment. The system may also be used by law enforcement officers to perform on-line surveillance of individuals on probation or parole.

Further, the invention has numerous applications for gathering data from remotely located devices. For example, the system may be used to collect data from smart appliances, such as identification check systems. Alternatively, the system may be applied to the remote monitoring of facilities, including safety and security monitoring, or to environmental monitoring, including pollution control and pipeline monitoring. Many other suitable applications of the invention will be apparent to one skilled in the art.

In terms of relating the new matter from application Ser. No. 08/946,341 (and its parent applications) to the original matter in this case, it will be readily appreciated and understood by one of ordinary skill in the art that many of the terms in the original case are the functional equivalent

of, a particular embodiment of, and/or otherwise interchangeable with, terms in the detailed description which came from application Ser. No. 08/946,341. For example, in light of the foregoing description, and particularly comparing FIGS. **1** and **2** (from the original application) with FIGS. **201** and **202** (from application Ser. No. 08/946,341), it will be readily understood of ordinary skill that:

a) the remote clearinghouse **18** in FIG. **1** (and further identified as one part of an alternate embodiment of the remotely located digital signal processing unit **42** in FIG. **2**), is equivalent to and interchangeable with server **2018** of FIG. **201**, and vice versa;

b) in FIG. **1**, the arrangement comprising data management unit **28** connected via cable **32** to microprocessor based unit **10** and to audiovisual display **14**, is a particular embodiment of, and in that sense equivalent to and interchangeable with, the remote apparatus **1** (or remote apparatus **2**) of FIGS. **201** and **202**, and vice versa;

c) the arrangement comprising control switches **44** of FIG. **2** operated by the user in conjunction with or response to audiovisual display **14** (of FIG. **1** or **2**) is an example, or particular embodiment, of a monitoring device **2028** of FIG. **201**, and is in that sense equivalent to and interchangeable with monitoring device **2028**, and, in certain embodiments, vice versa;

d) the audiovisual display **14** of FIG. **1** or **2** is equivalent to and interchangeable with the display **2064** of FIG. **203**, and vice versa;

e) the four user input buttons **2070**A, **2070**B, **2070**C, and **2070**D, of FIG. **203** are examples of, or particular embodiments of, and are in that sense equivalent to and interchangeable with, the control switches **44** in FIG. **2**, which are connected to microprocessor based unit **10** in FIG. **2**;

f) the clinician's computer **22** in FIG. **1** is equivalent to and interchangeable with workstation **2020** of FIG. **201**, and vice versa;

g) the communication network **2024** in FIG. **201** are examples of, and/or particular embodiments of, and are in that sense equivalent to and interchangeable with, the arrangement of communications links **20**, **30** and **34** in FIG. **1**, and **84** in FIG. **2**, and vice versa;

h) the program instruction modules of the administrator program executed by the remotely located digital signal processing unit **42** in FIG. **2** are examples of, or particular embodiments of, and are in that sense equivalent to and interchangeable with, certain of the script programs **2040** executed by server **18** in FIG. **202**, and vice versa.

The foregoing list merely identifies examples, and is not an exhaustive list.

While the preferred embodiment of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the spirit and scope of the invention.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A system for assessment of a psychological condition of a patient comprising:

(A) a patient system including:

(1) a display for displaying an image to the patient;

(2) a patient processor unit including a patient processor, a switch operable for supplying an electrical signal that is detectable by the patient processor, and circuit means responsive to signals supplied by the patient processor for generating the image on the display; and

(3) a memory for storing program instructions for displaying an image on the display for provoking operation of the switch, and for changing the image in response to the operation of the switch by the patient;

(B) a clinician system located remotely from the patient system and including:

(1) a memory for storing administrator program instructions for establishing a diagnostic assessment procedure and for retrieving a diagnostic signal which results from the operation of the switch and which is representative of a diagnostic measure indicated by the diagnostic assessment procedure, wherein the administrator program instructions further comprise a script and the diagnostic assessment procedure includes executing the script for displaying queries on the display and retrieving the patient's responses to the queries; and

(2) a clinician processor for executing at least one of the administrator program instructions; and

(C) a communications link connectable in signal communication with the patient system and the clinician system for the exchange of signals between the patient system and the clinician system.

2. The system of claim **1** wherein the diagnostic assessment procedure established by the administrator program further comprises execution of the program instructions for administration of a diagnostic task selected from the group of tasks comprising:

a delayed reaction task with distractions;

a delayed reaction task without distractions;

a continuous performance task with distractions;

a continuous performance task without distractions.

3. The system of claim **1** wherein the administrator program further comprises program instructions for display of a main menu screen allowing a clinician using the clinician system to select a menu item from the group comprising:

opening of a new file for establishing the diagnostic assessment procedure for the patient;

opening an existing file for storing the diagnostic measure resulting from the diagnostic assessment procedure in the memory of the clinician's computer workstation;

opening an existing file for storing a particular configuration of the diagnostic assessment procedure in the memory of the clinician's computer workstation;

saving a file associated with a particular the patient;

closing a file;

producing the diagnostic assessment procedure;

storing the program instructions in the memory of the patient processor unit of the patient system; and

initiating execution of the diagnostic assessment procedure with the patient processor unit that is connected to the clinician's computer workstation.

4. The system of claim **1** wherein the clinician system is a clinician computer workstation.

5. The system of claim **1** wherein the clinician processor of the clinician system further comprises an input/output unit connected in signal communication with the clinician processor and connectable in signal communication with peripheral devices selected from the group comprising:

a printer for printing diagnostic measurement information generated from the diagnostic measure resulting from the diagnostic assessment procedure;

a facsimile machine for displaying diagnostic measurement information generated from the diagnostic measure resulting from the diagnostic assessment procedure;

a receptacle for receiving a removable and insertable external memory unit; and

a patient system located locally relative to the clinician processor and wherein the signal communication with the clinician processor is accomplished by a serial data cable.

6. The system of claim **5** wherein:

(A) the external memory unit connectable in signal communication with said input/output unit further comprises means for storage of the program instructions for controlling the operation of the patient processor unit and the diagnostic measurement information generated from the diagnostic measure resulting from the diagnostic assessment procedure; and

(B) the patient processor unit includes a receptacle for receiving the external memory unit.

7. The system of claim **1** wherein the clinician system further comprises a clearinghouse:

(A) for receiving the diagnostic signal resulting from the interactive operation of the switch of at least one of the patient processor units; and

(B) connectable in signal communication for data transmission with the clinician system.

8. The system of claim **7** wherein the administrator program instructions further comprise a script and the diagnostic assessment procedure includes executing the script for displaying queries on the display and retrieving the patient's responses to the queries.

9. The system of claim **8** wherein:

(A) the clearinghouse further comprises a server including a script generator capable of generating the script and a database means connected to the script generator for storing scripts created by the script generator; and

(B) the clinician system further comprises means for entering into the server the queries to be responded to by the patient, and for causing the script generator to generate the script.

10. The system of claim **9** wherein the clearinghouse further comprises means for receiving and storing a plurality of the diagnostic signals from a plurality of the patient processor units.

11. The system of claim **10** wherein the program instructions for retrieving a diagnostic signal representative of a diagnostic measure resulting from the diagnostic assessment procedure further include program instructions for transmitting the plurality of diagnostic signals stored in the clearinghouse to the clinician system.

12. The system of claim **1** further comprising analytical signal processing means for executing at least one instruction from a set of instructions that performs one or more analyses of the patient's interactive operation of the switch in response to the image on the display for provoking operation of the switch.

13. The system of claim **12** wherein the analytical signal processing means is the patient processor unit, and wherein:

(A) the program instructions further include at least one instruction from the set of instructions which perform the one or more analyses;

(B) the patient processor unit is further programmable for executing the at least one instruction;

(C) the memory of the patient processor unit further comprises an addressable memory for storage of the diagnostic signal and the at least one instruction for implementing the analyses; and

(D) the patient processor of the patient processor unit further comprises means for accessing the at least one instruction and processing the diagnostic signal stored in the addressable memory.

14. The system of claim **12** wherein the analytical signal processing means is the clinician processor of the remotely located clinician system, and wherein

(A) the administrator program instructions further include at least one instruction from the set of instructions which perform the one or more analyses;

(B) the clinician processor is further programmable for executing the at least one instruction;

(C) the memory of the clinician processor further comprises an addressable memory for storage of the diagnostic signal retrieved as a result of execution of the administrator program instructions and the at least one instruction for implementing the analyses; and

(D) the clinician processor further comprises means for accessing the at least one instruction and processing the diagnostic signal stored in the addressable memory.

15. The system of claim **12** wherein the analytical signal processing means is a clearinghouse; and wherein the clearinghouse:

(A) includes a memory for storing, and a processor for executing, program instructions for retrieving a diagnostic signal resulting from the operation of the switch and representative of a diagnostic measure indicated by the diagnostic assessment procedure; and is

(B) connectable in signal communication for data transmission with the clinician system.

16. The system of claim **12** wherein the analytical signal processing means further comprises a data management unit, said data management unit being programmable for executing the at least one instruction from the set of instructions which perform the one or more analyses; and including:

(A) an addressable memory for storage of the diagnostic signal;

(B) means for accessing the at least one instruction and processing the diagnostic signal stored in the addressable memory; and

(C) connecting means for connecting in signal communication with the patient processor unit for coupling and transmitting signals representative of the interactive operation of the switch from the patient processor unit to the data management unit.

17. A system for remotely assessing and monitoring the psychological condition of a patient, the system comprising:

(A) a server including:

(1) a script generator for generating a script from clinician information;

(2) a database coupled to the script generator for storing scripts created by the script generator;

(B) a clinician interface for:

(1) receiving entered clinician information;

(2) generating the script based upon the entered clinician information;

(C) a patient system comprising:

(1) a remotely programmable apparatus including:

a. a memory for storing the script;

b. a processor that is coupled to the memory for implementing the script;

(2) a user interface for displaying an output determined by the processor implementing the script;

(3) monitoring means for obtaining diagnostic signals representative of the psychiatric condition of the patient;

(4) circuitry for communicating signals between the remotely programmable apparatus, the user interface, and the monitoring means; and

(D) a communication link for providing communication between the patient system, the server and the clinician interface.

18. The system of claim **17** wherein the server comprises a web server for generating a web page for entry of the clinician information.

19. The system of claim **17** wherein the clinician information further comprises patient message information not intended to cause the script to elicit a response from the patient.

20. The system of claim **17** wherein the clinician information further comprises patient prompt information which is intended to cause the script to elicit a response from the patient.

21. The system of claim **20** wherein the patient prompt information is intended to cause the script to generate queries to be answered by the patient.

22. The system of claim **20** wherein the patient prompt information is intended to cause the script to generate instructions for the patient.

23. The system of claim **20** wherein:

(A) the remotely programmable apparatus provides the monitoring means for obtaining the diagnostic signals;

(B) the user interface is included within the remotely programmable apparatus;

(C) the memory for storing the script further includes memory for storing the diagnostic signals;

(D) the remotely programmable apparatus includes means for causing the diagnostic signals to be transmitted to the server via the communication link; and

(E) the clinician interface further comprises means for receiving the diagnostic signals from the server.

24. The system of claim **23** wherein:

(A) the remotely programmable apparatus further includes user input buttons operable for supplying an electrical signal that is detectable by the processor that is coupled to the memory;

(B) the user interface includes a display for displaying an image and presenting audible signals to the patient;

(C) the memory further comprises means for storing program instructions for generating the patient prompt information;

(D) the patient prompt information further comprises an animated sequence of images displayed on the display for provoking interactive operation of the user input buttons by the patient;

(E) the program instructions further cause changes to the animated sequence and generate the diagnostic signals in response to the patient's interactive operation of the user input buttons; and

(F) the communication provided by the communication link includes transmission of diagnostic signals from the patient system to the server and from the server to the clinician interface, and transmission of script from the server to the patient system.

25. The system of claim **24** wherein the animated sequence presents a diagnostic task selected from the group of tasks comprising:

a delayed reaction task with distractions;

a delayed reaction task without distractions;

a continuous performance task with distractions;

a continuous performance task without distractions.

26. The system of claim **20** wherein the monitoring means is a separate monitoring device that is connectable in signal communication with the remotely programmable apparatus of the patient system.

27. The system of claim **26** wherein the monitoring device further comprises:

(A) a display for displaying an image and presenting audible signals to the patient;

(B) a patient processor unit including:

(1) a patient processor;

(2) a switch operable for supplying an electrical signal that is detectable by the patient processor;

(3) circuitry responsive to signals supplied by the patient processor for generating a visual display on the display;

(4) a memory for storing program instructions for:

a. generating an animated sequence of images on the display for provoking interactive operation of the switch, and

b. changing the animated sequence and generating the diagnostic signal in response to interactive operation of the switch by the patient.

28. The system of claim **27** wherein the server comprises a web server for generating a web page for entry of the clinician information, and wherein the clinician interface is connected to the web server.

29. The system of claim **27** further comprising analytical signal processing means for executing at least one instruction from a set of instructions that performs one or more analyses of the patient's interactive operation of the switch of the patient processor unit in response to the animated sequence generated by the program instructions.

30. The system of claim **20** wherein the patient user interface includes a speech synthesis means for audibly communicating the patient prompt information to the patient; and wherein the patient prompt information includes a sequence of audio signals communicated by the speech synthesis means for provoking interactive operation of the user input buttons.

31. The system of claim **20** wherein the patient user interface includes a speech recognition means for receiving spoken responses to the patient prompt information.

32. The system of claim **20** wherein the patient user interface comprises a display for displaying the patient prompt information and user input buttons for entering the patient's responses; and wherein the patient prompt information includes an animated sequence of images on the display for provoking interactive operation of the user input buttons.

33. The system of claim **32** wherein the animated sequence presents a diagnostic task selected from the group of tasks comprising:

a delayed reaction task with distractions;

a delayed reaction task without distractions;

a continuous performance task with distractions;

a continuous performance task without distractions.

34. The system of claim **17** wherein the communication link includes means for establishing a first communication link to the server to receive the script and means for establishing a subsequent communication link to the server to transmit the responses, and wherein the script specifies a connection time at which to establish the subsequent communication link.

35. The system of claim 17 wherein the remotely programmable apparatus further includes notification means connected to the processor for notifying the patient that output of at least one of the scripts has not been communicated to the patient.

36. The system of claim 35 wherein the notification means is a visual indicator displayed by the user interface for visually notifying the patient.

37. The system of claim 35 wherein the notification means is an audible prompt displayed by the user interface for audibly notifying the patient.

38. The system of claim 17 further comprising a plurality of remotely programmable apparatuses in communication with the server for remotely monitoring a plurality of patients, wherein the database means includes means for storing a plurality of scripts, the clinician interface includes means for entering script assignment information, the server includes script assignment means for assigning to each of the patients at least one of the scripts from the database means in accordance with the script assignment information, and the database further includes means for storing a list of the patients, and for each of the patients, a respective pointer to the script assigned to the patient.

39. The system of claim 17 wherein the user interface of the patient system further comprises user input buttons and presents a diagnostic task selected from the group of tasks comprising:

a delayed reaction task with distractions;

a delayed reaction task without distractions;

a continuous performance task with distractions;

a continuous performance task without distractions.

40. The system of claim 17 wherein the monitoring means further comprises at least one monitoring device to gather the diagnostic signals representative of the psychological condition of the patient and to transmit the diagnostic signal to the remotely programmable apparatus, wherein the remotely programmable apparatus further includes a device interface means connected to the processor for receiving the diagnostic signals from the monitoring device, and wherein the memory for storing the script includes memory for storing the diagnostic signals, and the communication provided by the communication link includes transmission of the diagnostic signals to the server.

41. The system of claim 40 wherein the device interface means includes means for interfacing with a plurality of monitoring devices, and the script specifies a selected monitoring device from which to collect the diagnostic signals.

42. The system of claim 40 wherein the server further comprises report means for reporting the responses and the diagnostic signals to the clinician interface.

43. The system of claim 40 wherein the monitoring device further comprises:

(A) a display for displaying an image and presenting audible signals to the patient;

(B) a patient processor unit connectable in signal communication with the remotely programmable apparatus and including:

(1) a patient processor;

(2) a switch operable for supplying an electrical signal that is detectable by the patient processor;

(3) circuit means responsive to signals supplied by the patient processor for generating a visual display on the display;

(4) a memory for storing program instructions for:

a. generating an animated sequence of images on the display for provoking interactive operation of the switch, and

b. changing the animated sequence and generating the diagnostic signals in response to interactive operation of the switch by the patient;

(C) means for transmitting the diagnostic signals from the patient processor unit to the remotely programmable apparatus.

44. A method of assessing and monitoring the psychological condition of a patient comprising the method steps of:

(A) receiving a script at a patient apparatus;

(B) executing the script to generate a series of stimuli on a display;

(C) including within the series a stimulus for provoking interactive operation of a switch by the patient;

(D) executing an analytical signal processing instruction that analyses the patient's interactive operation of the switch in response to the series of stimuli;

(E) generating a diagnostic measure from the analysis of the interactive operation of the switch; and

(F) transmitting a diagnostic signal representative of the diagnostic measure to a clinician system located remotely from the patient by means of a communication link.

45. The method of claim 44 further comprising the method steps of:

(A) executing an administrator program instruction for prescribing a diagnostic assessment procedure for obtaining the diagnostic measure;

(B) retrieving the diagnostic signal representative of the diagnostic measure prescribed by the diagnostic assessment procedure via the communication link;

(C) storing the diagnostic signal in a memory coupled to the communication link.

46. The method of claim 44 wherein the display further includes a visual display, wherein the stimuli includes visual stimuli, and wherein the stimulus for provoking interactive operation of the switch is a visual stimulus.

47. The method of claim 44 wherein the display includes an audio display, wherein the stimuli includes auditory stimuli, and wherein the stimulus for provoking interactive operation of the switch is an auditory stimulus.

48. A method for remotely assessing and monitoring the psychological condition of a patient, the method comprising the following steps:

entering clinician information;

generating a script based on the clinician information

transmitting the script to a server, and from the server to a patient apparatus through a communication link;

executing the script at the patient apparatus for generating output for the patient, wherein the output generated by execution of the scripts comprises output of a type selected from the group comprising:

(A) messages for the patient's information which are not intended to elicit a patient reply to be transmitted to the server;

(B) queries intended to elicit a patient reply to be transmitted to the server;

(C) prescriptive instructions intended to cause the patient to perform a patient-administered diagnostic procedure and to communicate the results of the procedure to the server through the patient apparatus and the communication link.

49. The method of claim 48:

(A) wherein the step of entering the clinician information comprises a step selected from the group of steps comprising:

(1) entering script information for generation of the script through a script entry means;
(2) assigning a predefined script to a specific patient through a script assignment means;
(3) modifying a predefined script through the script entry means;
(4) creating a new script through the script entry means; and

(B) further comprising the step of providing means within the server for storing information selected from the following types of information:
(1) the script;
(2) the patient replies to the queries; and
(3) the results of the patient-administered diagnostic procedure.

50. The method of claim **49** wherein the server comprises a web server; wherein the script entry means and script assignment means further comprise a web page hosted on the web server, wherein the clinician information is entered by accessing the web page through the Internet and wherein the step of entering clinician information comprises the step of entering the clinician information in the web page.

51. The method of claim **49** further comprising the steps of:

providing a plurality of patients with a corresponding plurality of patient apparatuses such that each of the patients is associated with a respective one of the patient apparatuses,

entering in the server a plurality of sets of the clinician information;

generating in the server a plurality of scripts such that each of the scripts corresponds to a respective one of the sets of clinician information;

assigning to each of the patients at least one of the scripts;

storing in the server the scripts, a list of the patients, and for each of the patients, a respective pointer to the script assigned to the patient; and

transmitting to each of the patient apparatuses the script assigned to the patient associated with the patient apparatus.

52. The method of claim **48** wherein the patient apparatus includes a device interface for receiving the results from the patient-administered diagnostic procedure, and wherein the method further comprises the steps of: collecting the results in the patient apparatus through the device interface; transmitting the results from the patient apparatus to the server; and receiving and storing the results in the server.

53. The method of claim **52** wherein the device interface includes means for interfacing with a plurality of monitoring devices, the script specifies a selected monitoring device from which to collect the diagnostic signals, and the method further comprises the step of prompting the patient to connect the selected monitoring device to the device interface.

54. The method of claim **52** wherein the patient-administered diagnostic procedure comprises the method step of operating a monitoring device to generate the results, wherein the results further comprise diagnostic signals representative of diagnostic measurements of a psychological condition of a patient.

55. The method of claim **54** further comprising the step of reporting on a remote interface the diagnostic signals received in the server.

56. The method of claim **54** further comprising the method steps of:

(A) providing as the monitoring device a patient processor unit;

(B) providing for the patient processor unit:
(1) a patient processor,
(2) a switch operable for supplying an electrical signal that is detectable by the patient processor,
(3) circuit means responsive to signals supplied by the patient processor for generating a visual display on the display,
(4) a memory for storing program instructions;

(C) operating the monitoring device by executing the program instructions for performing the method steps of:
(1) generating an animated sequence of images on the display for provoking interactive operation of the switch, and
(2) causing operation of the patient processor and changing the animated sequence in response to interactive operation of the switch by the patient.

57. The method of claim **56** wherein the animated sequence of images presents a psychiatric diagnosis task selected from the group comprising:

a delayed reaction task with distractions;

a delayed reaction task without distractions;

a continuous performance task with distractions; and

a continuous performance task without distractions.

58. The method of claim **48** wherein the script is transmitted from the server to the patient apparatus through a first communication link, the responses to the script output presented to the patient are transmitted from the patient apparatus to the server through a subsequent communication link, the script specifies a connection time at which to establish the subsequent communication link.

59. The method of claim **48** wherein the patient apparatus includes a user interface; the user interface including a display and input buttons, and wherein the script output presented to the patient is communicated through the display and the patient responses to the output are received through the input buttons.

60. The method of claim **48** wherein the patient apparatus includes a user interface; the user interface including a speech synthesizer, and wherein the script output presented to the patient is communicated through the speech synthesizer.

61. The method of claim **48** wherein the patient apparatus includes a user interface; and wherein the user interface includes a speech recognizer for receiving the patient replies and the results of the procedure.

62. The method of claim **48** further comprising the steps of:

providing a plurality of patients with a plurality of patient apparatuses such that each of the patients is associated with a respective one of the patient apparatuses;

entering in the server a plurality of sets of the clinician information, generating in the server a plurality of scripts such that each of the scripts corresponds to a respective one of the sets of clinician information;

assigning to each of the patients at least one of the scripts;

storing in the server the scripts, a list of the patients, and for each of the patients, a respective pointer to the script assigned to the patient; and

transmitting to each of the patient apparatuses the script assigned to the patient associated with the patient apparatus.

63. The method of claim **62** wherein the patient apparatus includes a device interface for receiving the results from the patient-administered diagnostic procedure, and wherein the

method further comprises the steps of: collecting the results in the patient apparatus through the device interface; transmitting the results from the patient apparatus to the server; and receiving and storing the results in the server.

64. The method of claim **63** wherein the patient-administered diagnostic procedure comprises the method step of operating a monitoring device to generate the results, wherein the results further comprise diagnostic signals representative of diagnostic measurements of a psychological condition of a patient.

65. The method of claim **64** wherein:

(A) the monitoring device further comprises a patient processor unit including:

(1) a patient processor,

(2) a switch operable for supplying an electrical signal that is detectable by the patient processor,

(3) circuitry responsive to signals supplied by the patient processor for generating a visual display on the display,

(4) a memory for storing program instructions; and

(B) the step of operating the monitoring device further comprises the method step of executing the program instructions for performing the method steps of:

(1) generating an animated sequence of images on the display for provoking interactive operation of the switch; and

(2) causing operation of the patient processor and changing the animated sequence in response to interactive operation of the switch by the patient.

66. The method of claim **65** wherein the animated sequence of images presents a psychiatric diagnosis task selected from the group comprising:

a delayed reaction task with distractions;

a delayed reaction task without distractions;

a continuous performance task with distractions;

a continuous performance task without distractions.

* * * * *

EXHIBIT C

US006368273B1

(12) **United States Patent**
Brown

(10) **Patent No.: US 6,368,273 B1**
(45) **Date of Patent: *Apr. 9, 2002**

(54) **NETWORKED SYSTEM FOR INTERACTIVE COMMUNICATION AND REMOTE MONITORING OF INDIVIDUALS**

(75) Inventor: **Stephen J. Brown**, Woodside, CA (US)

(73) Assignee: **Health Hero Network, Inc.**, Mountain View, CA (US)

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/300,856**

(22) Filed: **Apr. 28, 1999**

Related U.S. Application Data

(60) Division of application No. 08/946,341, filed on Oct. 7, 1997, now Pat. No. 5,997,476, which is a continuation-in-part of application No. 08/847,009, filed on Apr. 30, 1997, now Pat. No. 5,897,493.

(60) Provisional application No. 60/041,746, filed on May 28, 1997, and provisional application No. 60/041,751, filed on Mar. 28, 1997.

(51) **Int. Cl.**[7] **A61B 5/00**

(52) **U.S. Cl.** **600/300**; 705/3; 600/301; 128/904

(58) **Field of Search** 600/300–301, 600/529–538, 500–509, 481–486; 128/897–898, 904, 905, 920–925, 903

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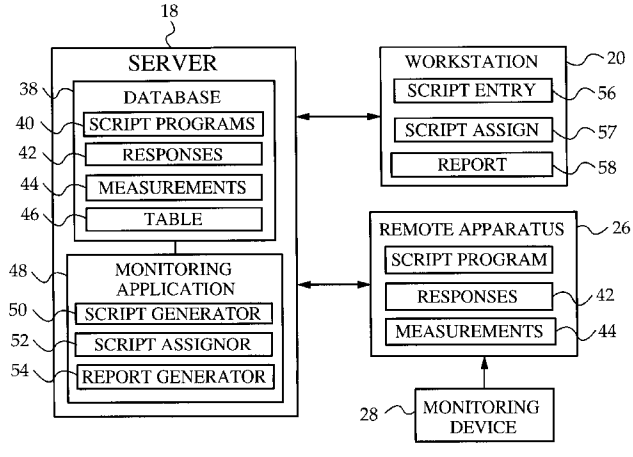
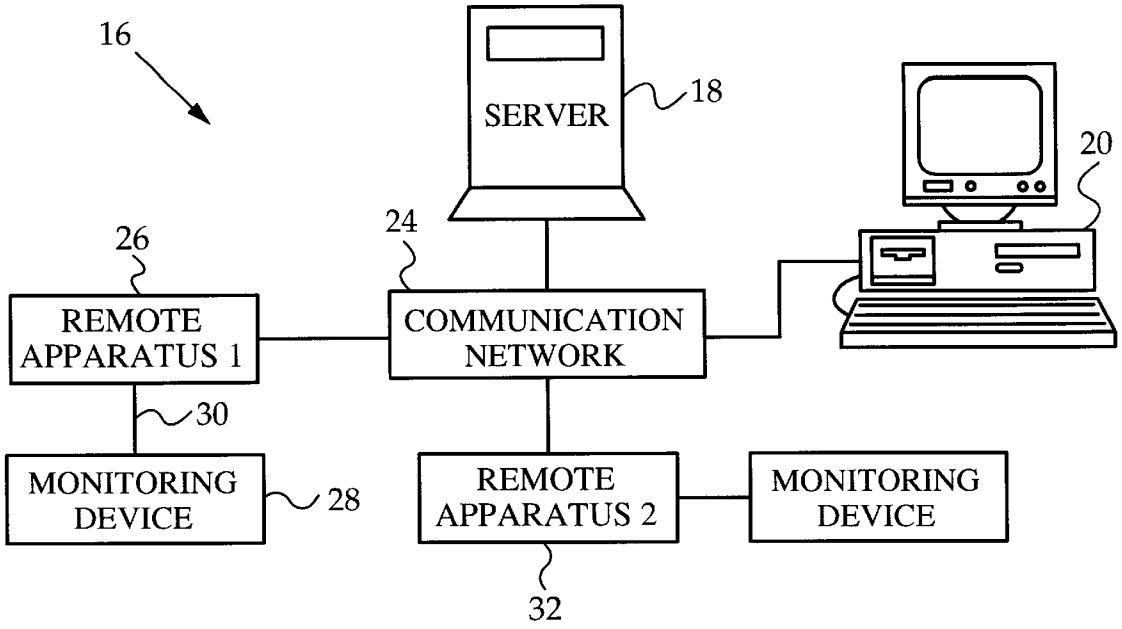
Primary Examiner—John P. Lacyk
Assistant Examiner—Michael Astorino
(74) *Attorney, Agent, or Firm*—Black Lowe & Graham, PLLC

(57) **ABSTRACT**

The invention presents a networked system for communicating information to an individual and for remotely monitoring the individual. The system includes a server and a remote interface for entering in the server a set of queries to be answered by the individual. The server is preferably a web server and the remote interface is preferably a personal computer or remote terminal connected to the server via the Internet. The system also includes a remotely programmable apparatus connected to the server via a communication network, preferably the Internet. The apparatus interacts with the individual in accordance with a script program received from the server. The server includes a script generator for generating the script program from the set of queries entered through the remote interface. The script program is received and executed by the apparatus to communicate the queries to the individual, to receive responses to the queries, and to transmit the responses from the apparatus to the server.

10 Claims, 15 Drawing Sheets

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SERVER
18
20
24
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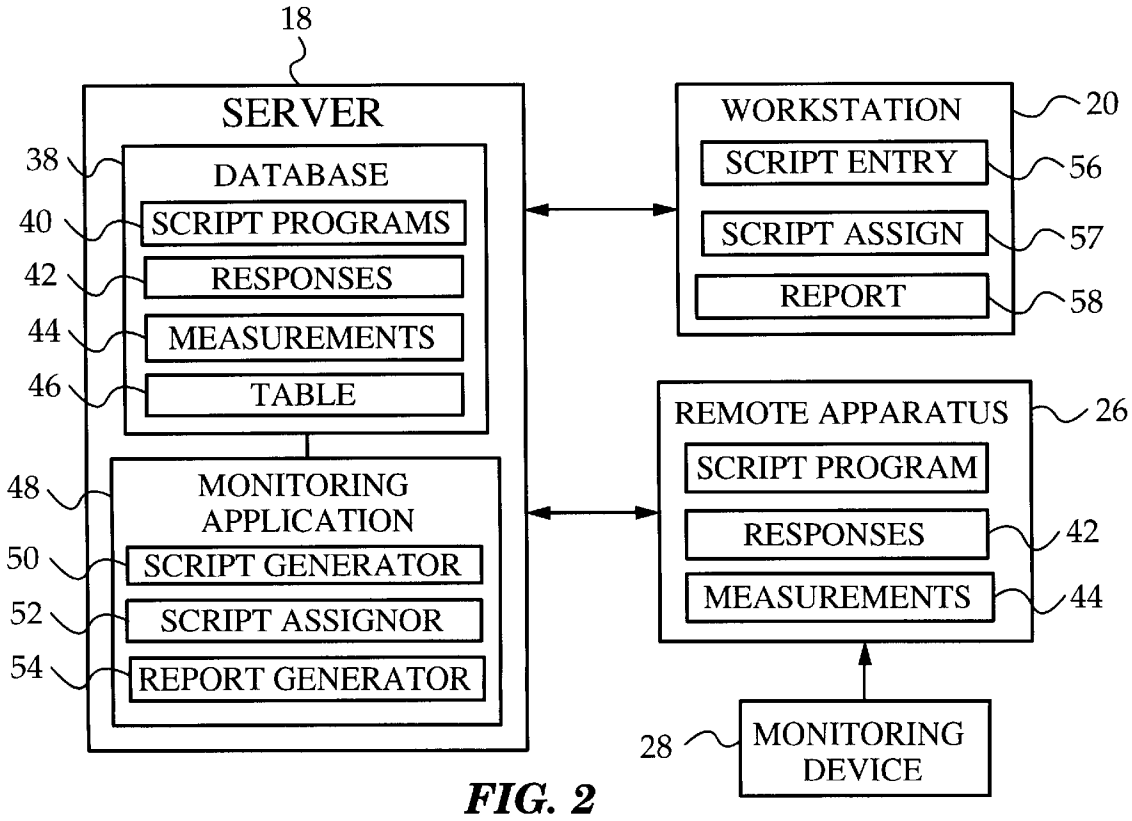
REMOTE APPARATUS 1
COMMUNICATION NETWORK
30
MONITORING DEVICE
28
REMOTE APPARATUS 2
MONITORING DEVICE
32

FIG. 1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SERVER
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DATABASE
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SCRIPT PROGRAMS
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RESPONSES
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MEASUREMENTS
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TABLE
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52
SCRIPT ASSIGNOR
54
REPORT GENERATOR
WORKSTATION
20
SCRIPT ENTRY
56
SCRIPT ASSIGN
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REPORT
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MEASUREMENTS
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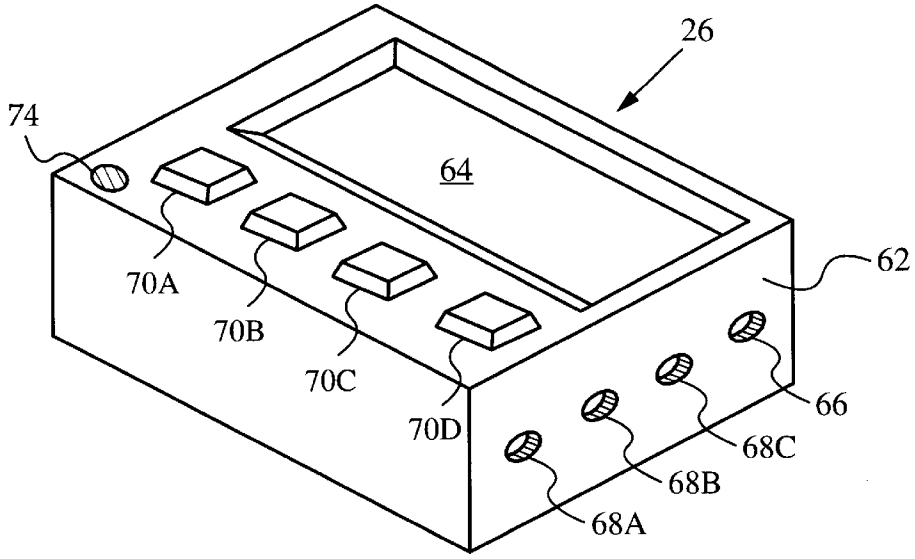
28
MONITORING DEVICE

FIG. 2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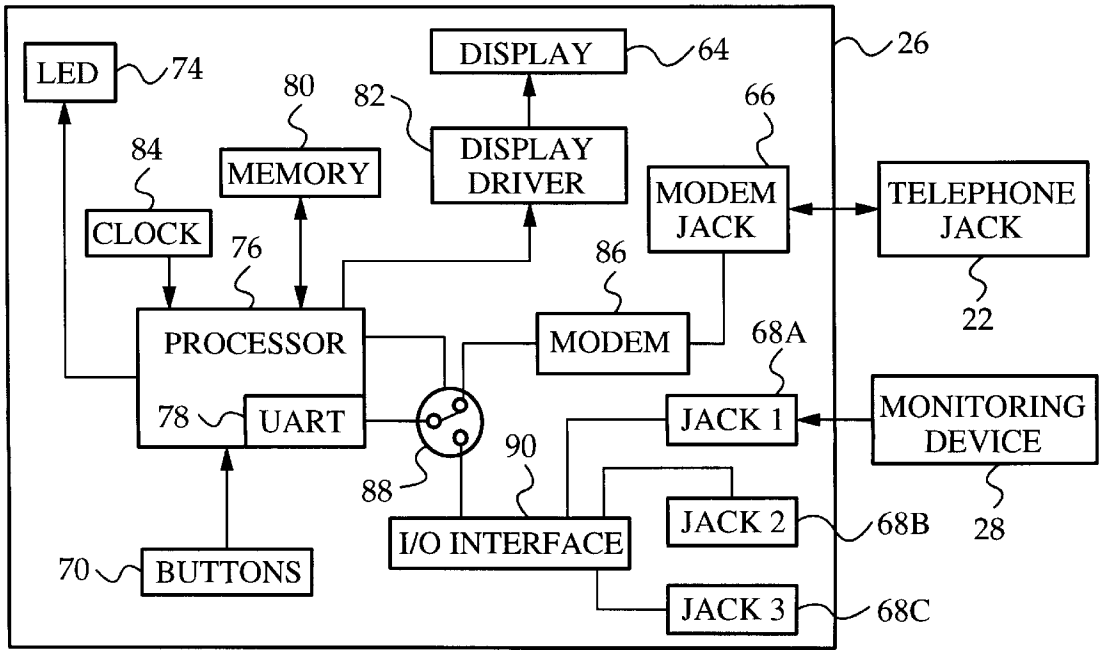
70B
70C
70D
66
68C
68B
68A

FIG. 3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DISPLAY
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26
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MEMORY
DISPLAY DRIVER
MODEM JACK
TELEPHONE JACK
CLOCK
76
86
22
PROCESSOR
MODEM
68A
78
UART
JACK 1
MONITORING DEVICE
90
88
JACK 2
68B
28
I/O INTERFACE
70
BUTTONS
JACK 3
68C

FIG. 4

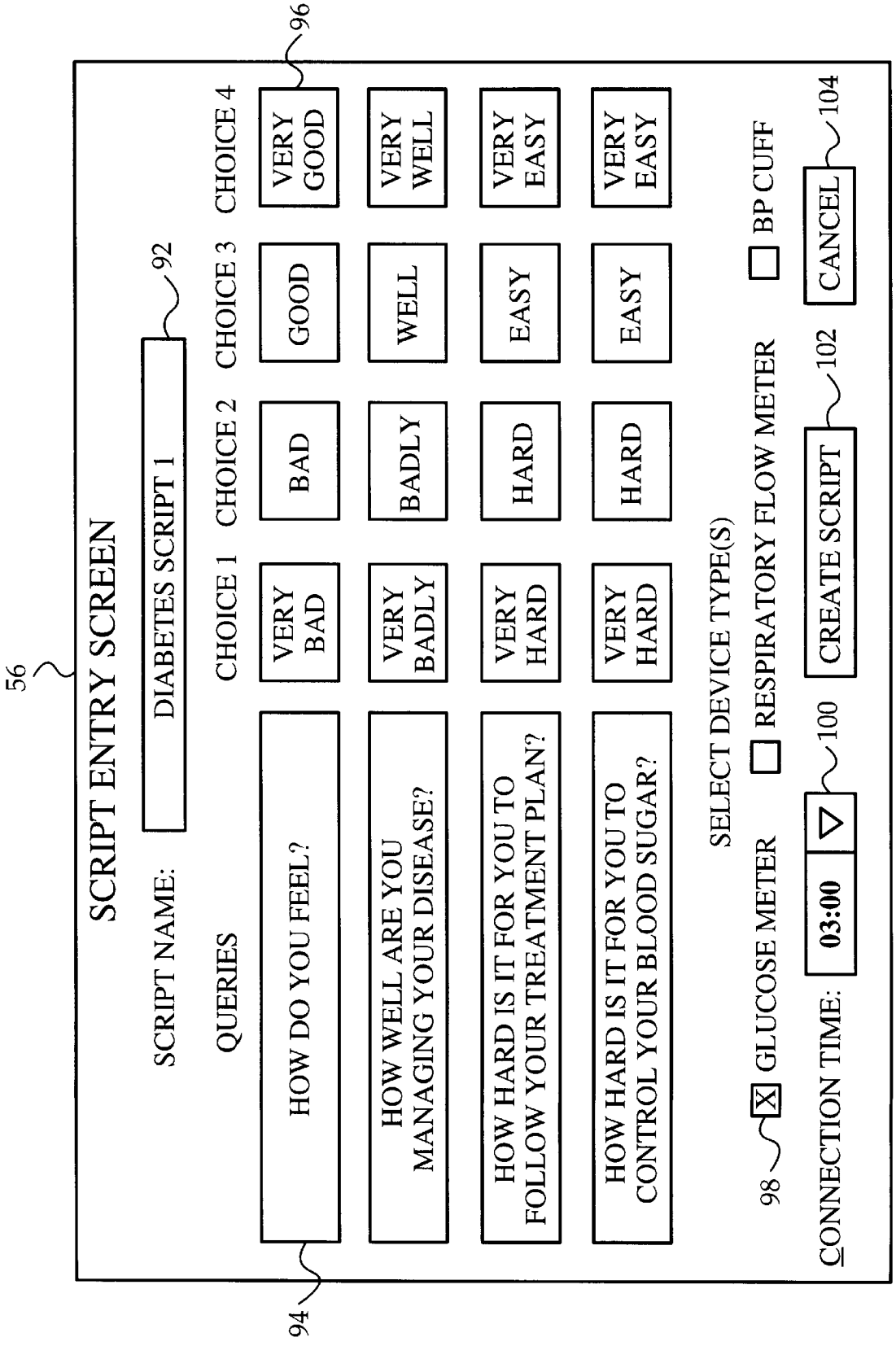

56
SCRIPT ENTRY SCREEN
SCRIPT NAME:
DIABETES SCRIPT 1
92
QUERIES
CHOICE 1
CHOICE 2
CHOICE 3
CHOICE 4
96
HOW DO YOU FEEL?
VERY BAD
BAD
GOOD
VERY GOOD
HOW WELL ARE YOU MANAGING YOUR DISEASE?
VERY BADLY
BADLY
WELL
VERY WELL
HOW HARD IS IT FOR YOU TO FOLLOW YOUR TREATMENT PLAN?
VERY HARD
HARD
EASY
VERY EASY
HOW HARD IS IT FOR YOU TO CONTROL YOUR BLOOD SUGAR?
VERY HARD
HARD
EASY
VERY EASY
94
SELECT DEVICE TYPE(S)
98
GLUCOSE METER
RESPIRATORY FLOW METER
BP CUFF
CONNECTION TIME:
03:00
100
CREATE SCRIPT
102
CANCEL
104

FIG. 5

```
NUMBER: 9001 {LF}

LED: 1 {LF}

ZAP: {LF}

CLS: {LF}

DISPLAY: ANSWER QUERIES NOW?
         PRESS ANY BUTTON TO START {LF}
WAIT: {LF}

CLS: {LF}

DISPLAY: HOW DO YOU FEEL?

         VERY                VERY
          BAD   BAD  GOOD   GOOD {LF}

INPUT: OOOO {LF}

CLS: {LF}

DISPLAY: HOW WELL ARE YOU
         MANAGING YOUR DISEASE?
         VERY                 VERY
         WELL  BADLY  WELL   WELL {LF}

INPUT: OOOO {LF}

CLS: {LF}

DISPLAY: HOW HARD IS IT FOR YOU TO
         FOLLOW YOUR TREATMENT PLAN?
         VERY                 VERY
         HARD  HARD  EASY   EASY {LF}

INPUT: OOOO {LF}

CLS: {LF}

DISPLAY: HOW HARD IS IT FOR YOU TO
         CONTROL YOUR BLOOD SUGAR?
         VERY                 VERY
         HARD  HARD  EASY   EASY {LF}
```

FIG. 6A

INPUT: OOOO {LF}

CLS: {LF}

DISPLAY: CONNECT GLUCOSE METER
AND PRESS ANY BUTTON
WHEN FINISHED {LF}

WAIT: {LF}

CLS: {LF}

DISPLAY: COLLECTING MEASUREMENTS {LF}

COLLECT: GLUCOSE_METER {LF}

CLS: {LF}

DISPLAY: CONNECT APPARATUS TO
TELEPHONE JACK AND
PRESS ANY BUTTON
WHEN FINISHED {LF}

WAIT: {LF}

LED: 0 {LF}

CLS: {LF}

DELAY: 03:00 {LF}

DISPLAY: CONNECTING TO SERVER {LF}

CONNECT: {LF}

{EOF}

FIG. 6B

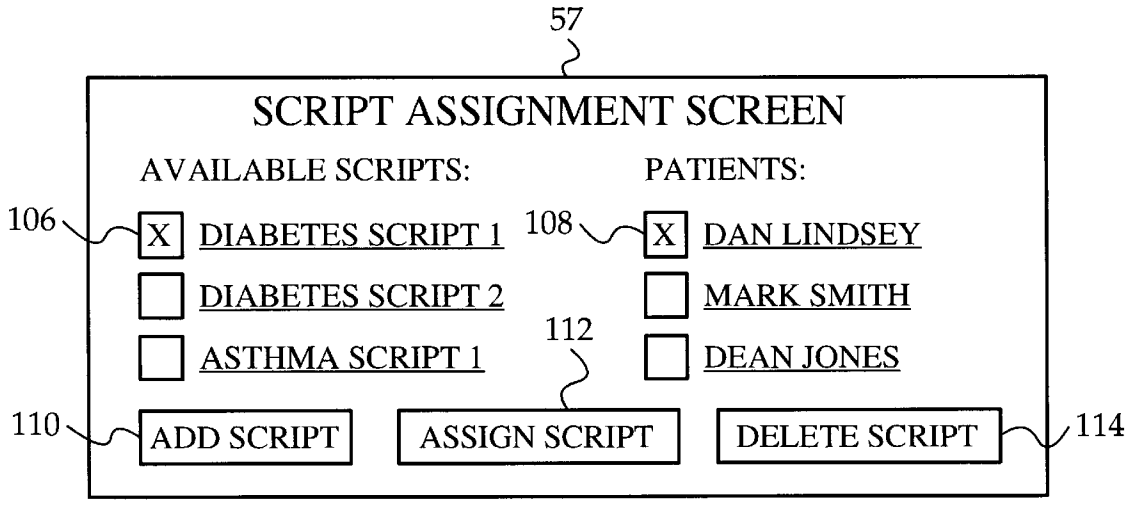


FIG. 7

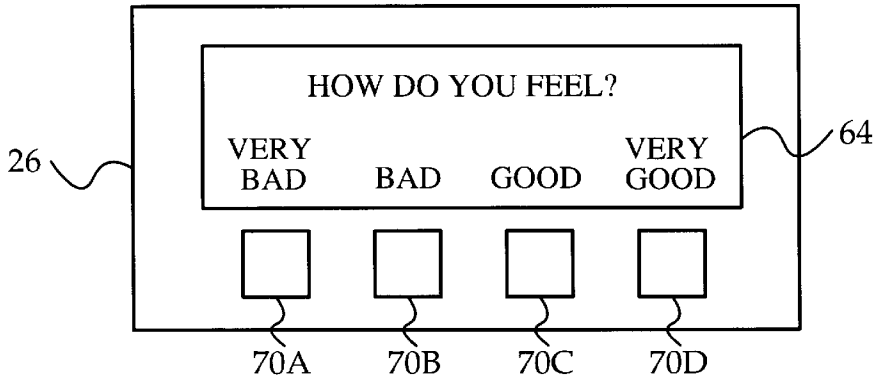


FIG. 8

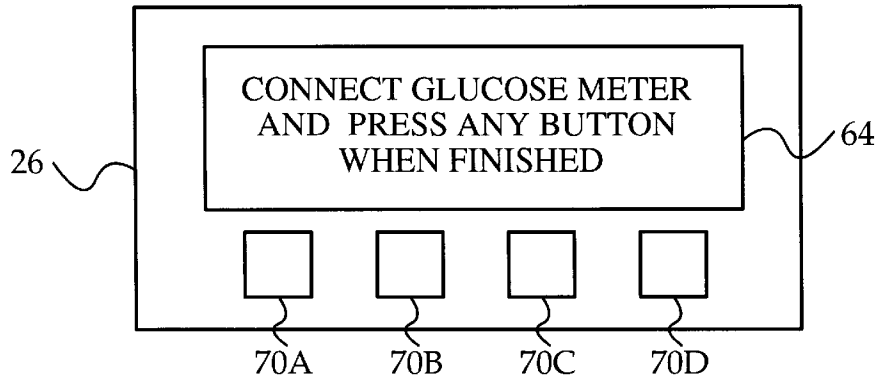


FIG. 9

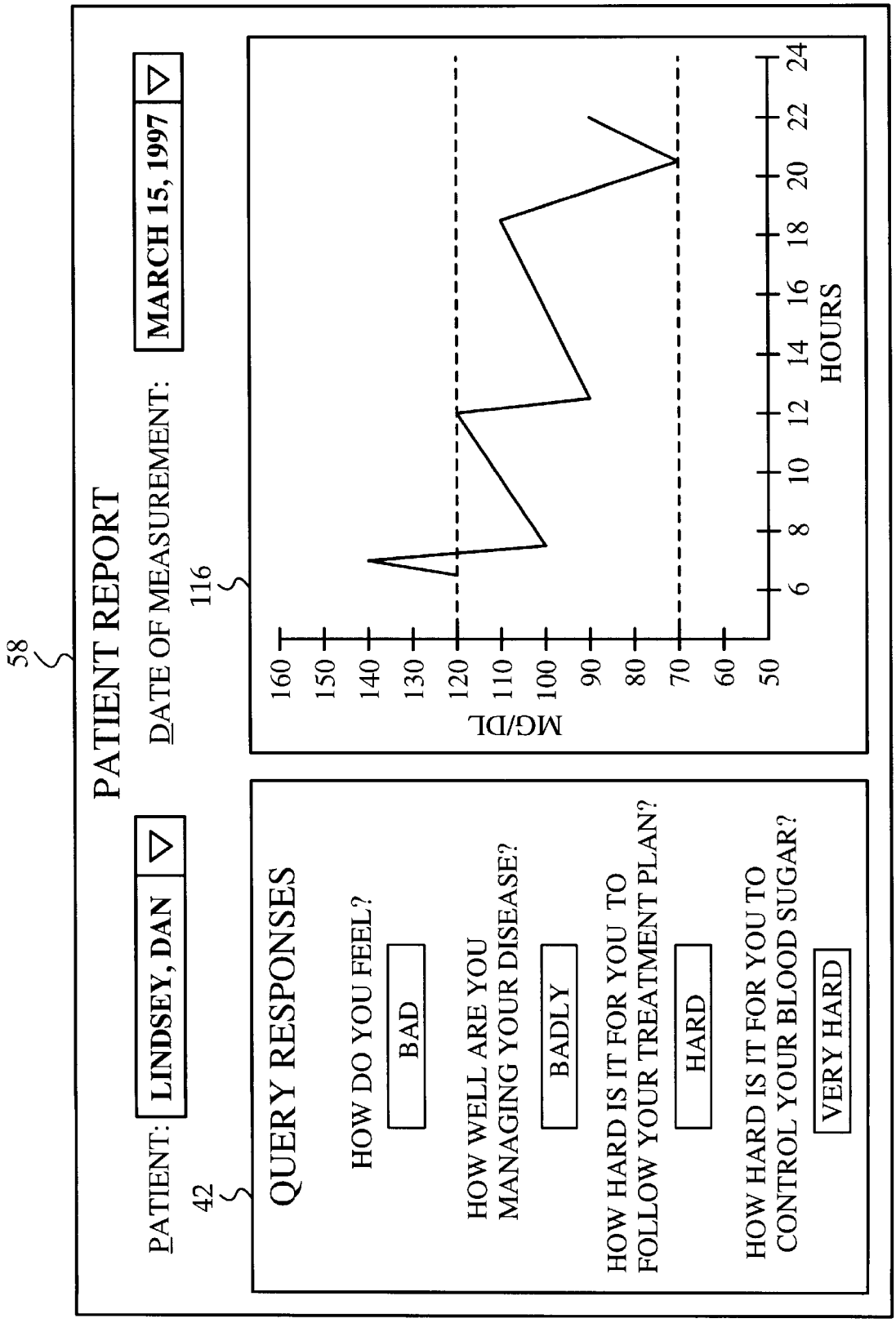

58
PATIENT REPORT
PATIENT: LINDSEY, DAN
DATE OF MEASUREMENT: MARCH 15, 1997
42
116
QUERY RESPONSES
HOW DO YOU FEEL?
BAD
HOW WELL ARE YOU MANAGING YOUR DISEASE?
BADLY
HOW HARD IS IT FOR YOU TO FOLLOW YOUR TREATMENT PLAN?
HARD
HOW HARD IS IT FOR YOU TO CONTROL YOUR BLOOD SUGAR?
VERY HARD
MG/DL
160
150
140
130
120
110
100
90
80
70
60
50
6
8
10
12
14
16
18
20
22
24
HOURS

FIG. 10

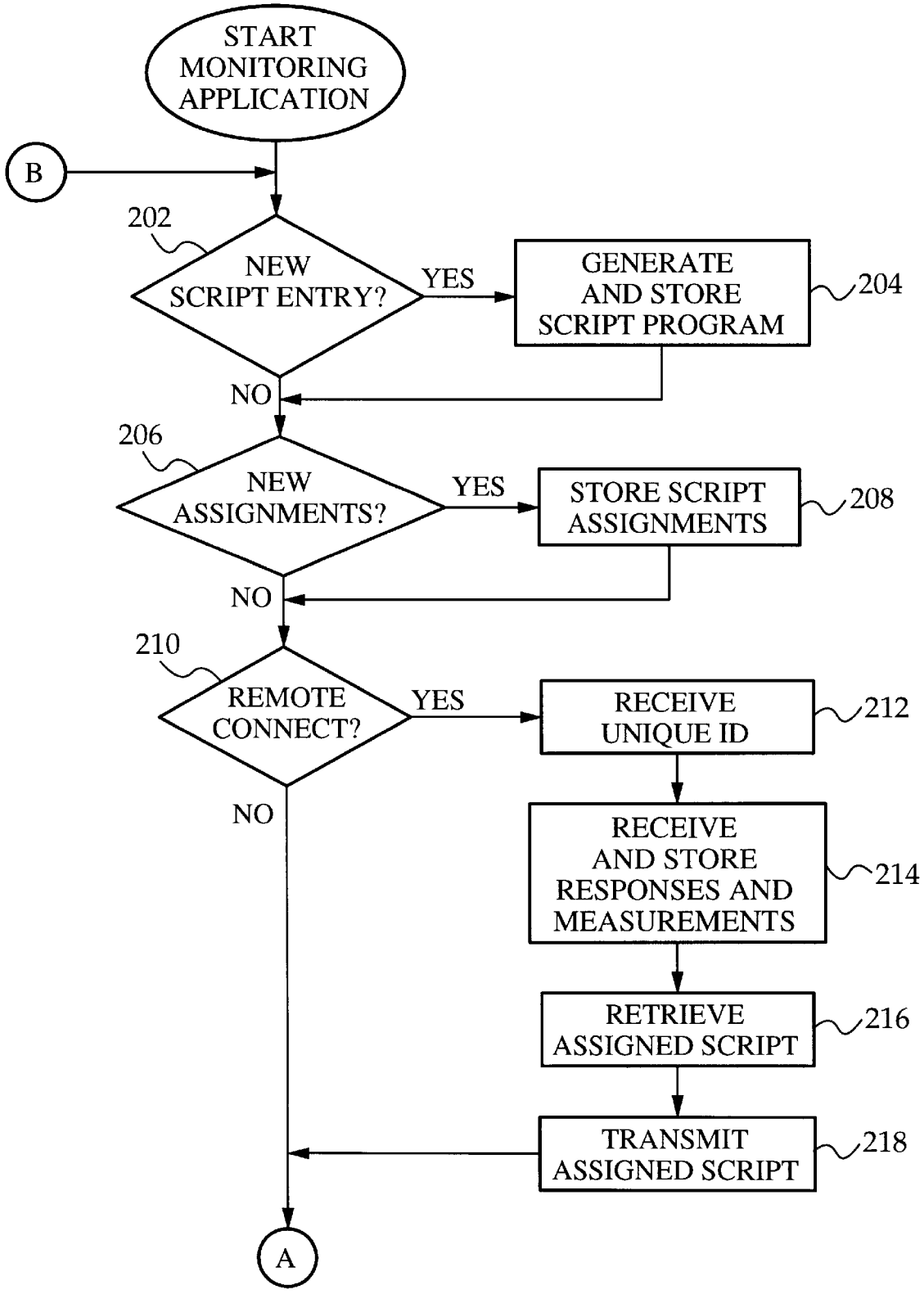

START MONITORING APPLICATION
B
202
NEW SCRIPT ENTRY?
YES
GENERATE AND STORE SCRIPT PROGRAM
204
NO
206
NEW ASSIGNMENTS?
YES
STORE SCRIPT ASSIGNMENTS
208
NO
210
REMOTE CONNECT?
YES
RECEIVE UNIQUE ID
212
NO
RECEIVE AND STORE RESPONSES AND MEASUREMENTS
214
RETRIEVE ASSIGNED SCRIPT
216
TRANSMIT ASSIGNED SCRIPT
218
A

FIG. 11A

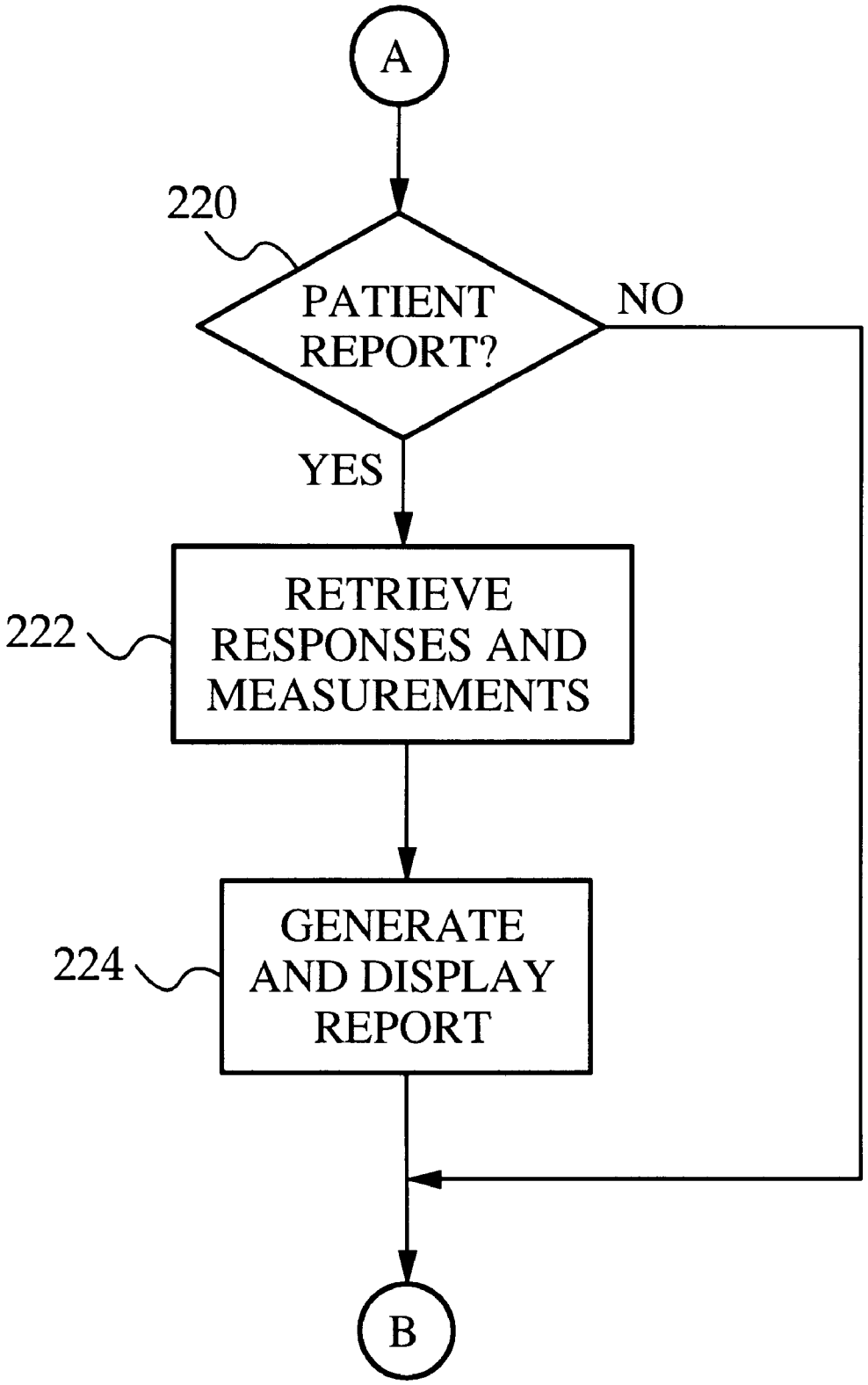

A
220
PATIENT REPORT?
NO
YES
222
RETRIEVE RESPONSES AND MEASUREMENTS
224
GENERATE AND DISPLAY REPORT
B

FIG. 11B

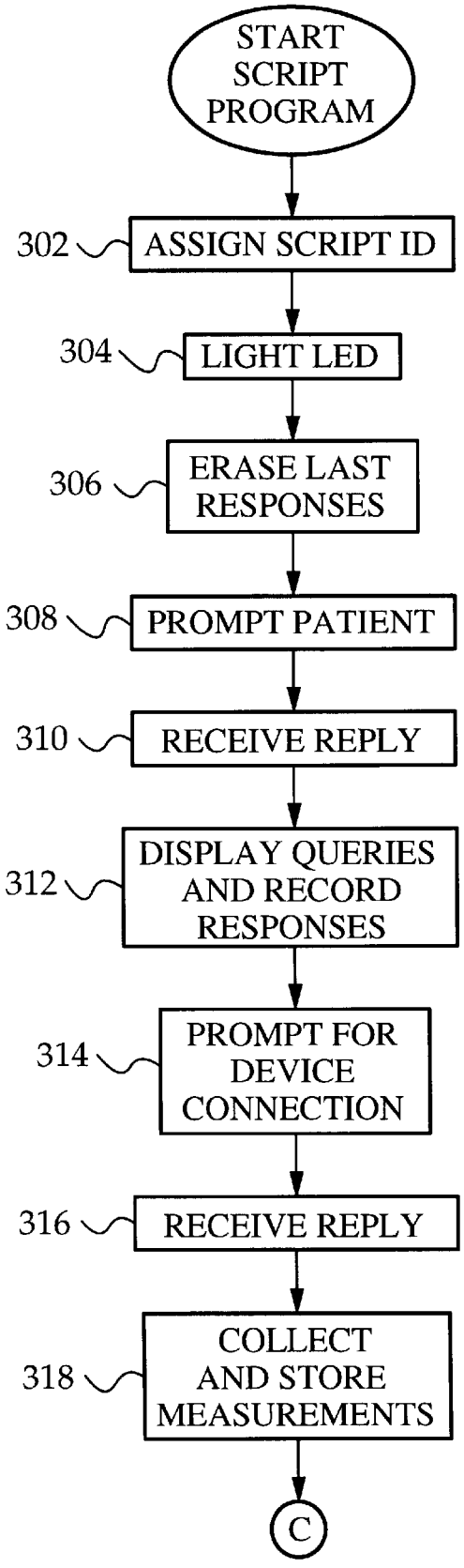

START SCRIPT PROGRAM
302
ASSIGN SCRIPT ID
304
LIGHT LED
306
ERASE LAST RESPONSES
308
PROMPT PATIENT
310
RECEIVE REPLY
312
DISPLAY QUERIES AND RECORD RESPONSES
314
PROMPT FOR DEVICE CONNECTION
316
RECEIVE REPLY
318
COLLECT AND STORE MEASUREMENTS
C

FIG. 12A

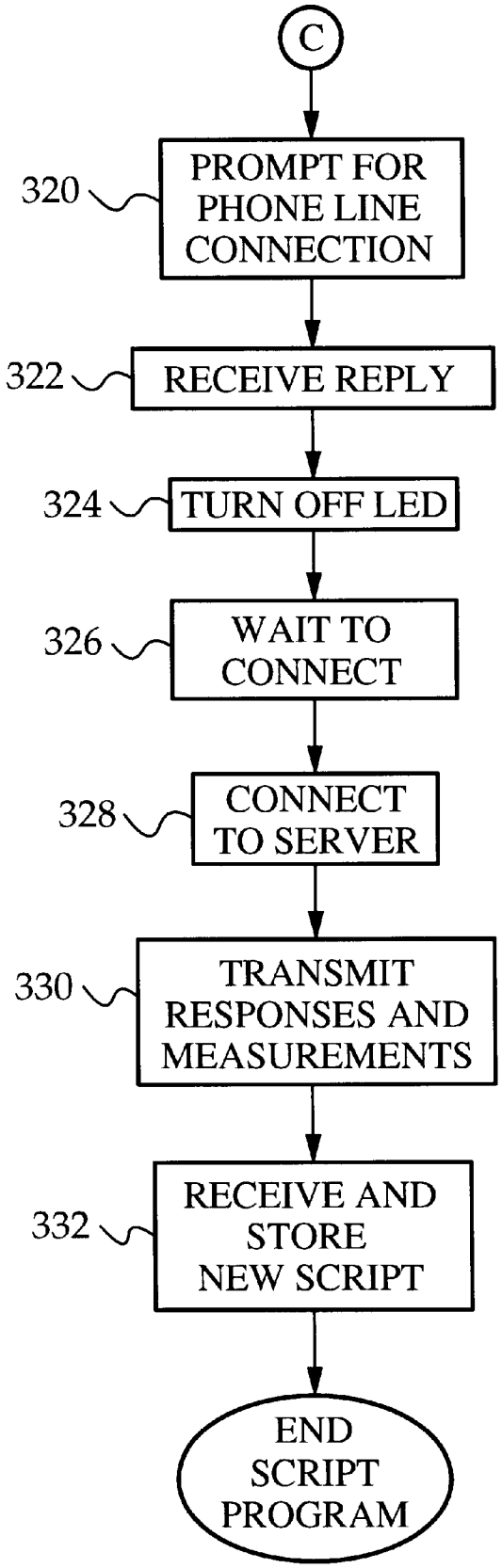

C
320
PROMPT FOR PHONE LINE CONNECTION
322
RECEIVE REPLY
324
TURN OFF LED
326
WAIT TO CONNECT
328
CONNECT TO SERVER
330
TRANSMIT RESPONSES AND MEASUREMENTS
332
RECEIVE AND STORE NEW SCRIPT
END SCRIPT PROGRAM

FIG. 12B

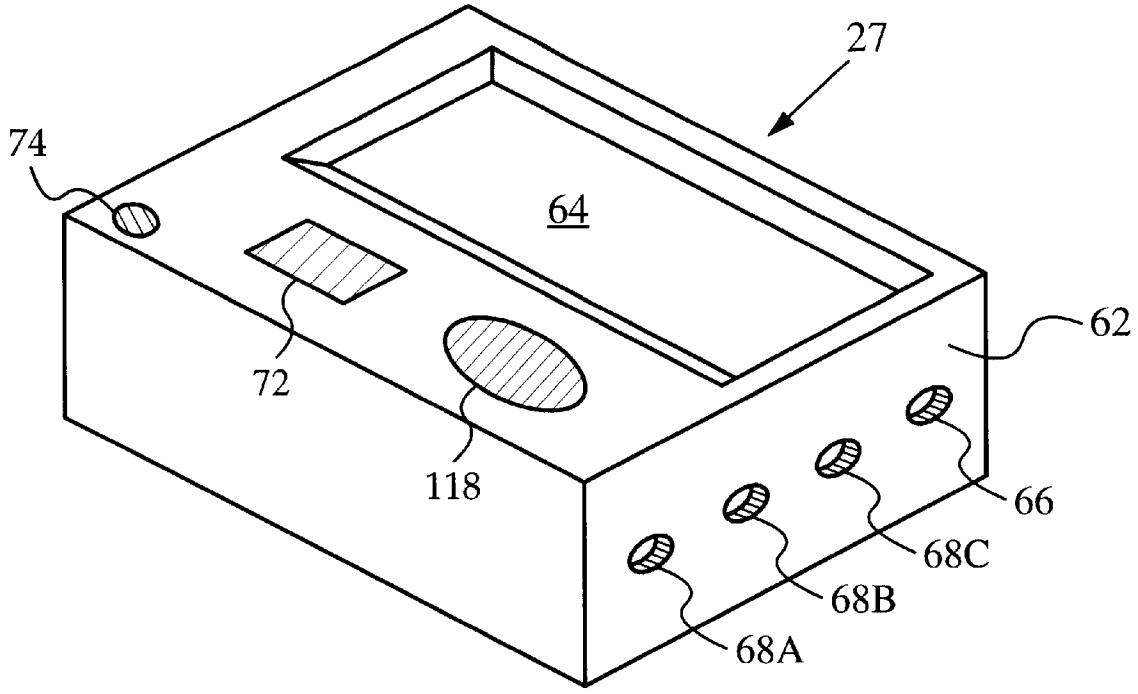

27
74
64
72
118
62
66
68C
68B
68A

FIG. 13

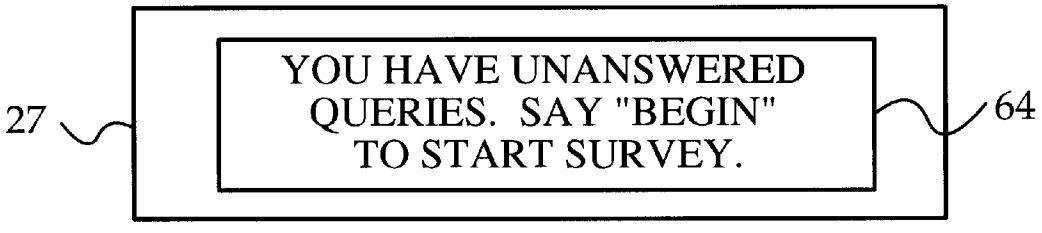

27
YOU HAVE UNANSWERED QUERIES. SAY "BEGIN" TO START SURVEY.
64

FIG. 14

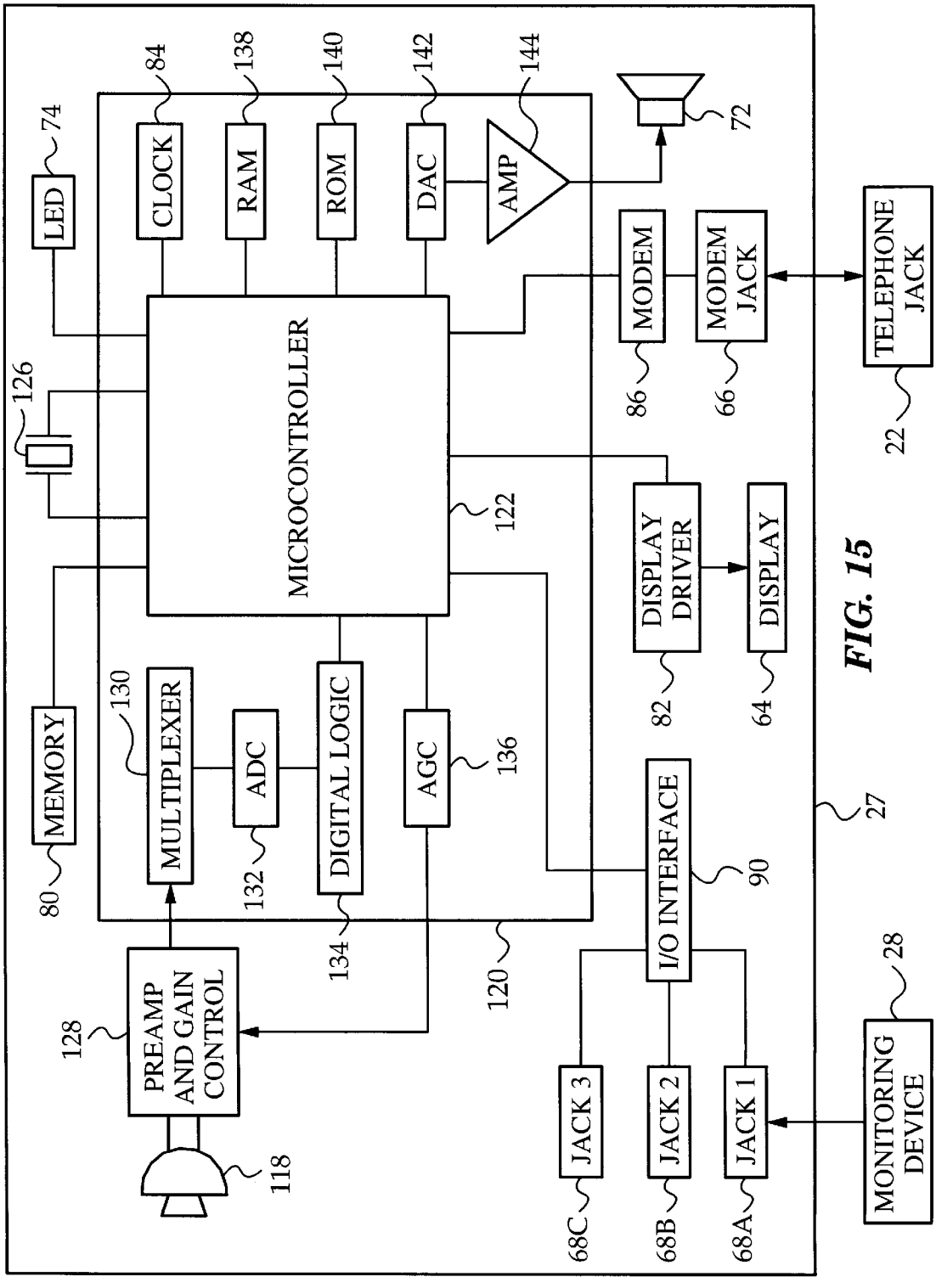

LED
74
CLOCK
84
RAM
138
ROM
140
DAC
142
AMP
144
72
MODEM
86
MODEM JACK
66
TELEPHONE JACK
22
126
MICROCONTROLLER
122
DISPLAY DRIVER
82
DISPLAY
64
MEMORY
80
MULTIPLEXER
130
ADC
132
DIGITAL LOGIC
134
AGC
136
I/O INTERFACE
90
27
PREAMP AND GAIN CONTROL
128
118
120
JACK 3
68C
JACK 2
68B
JACK 1
68A
MONITORING DEVICE
28

FIG. 15

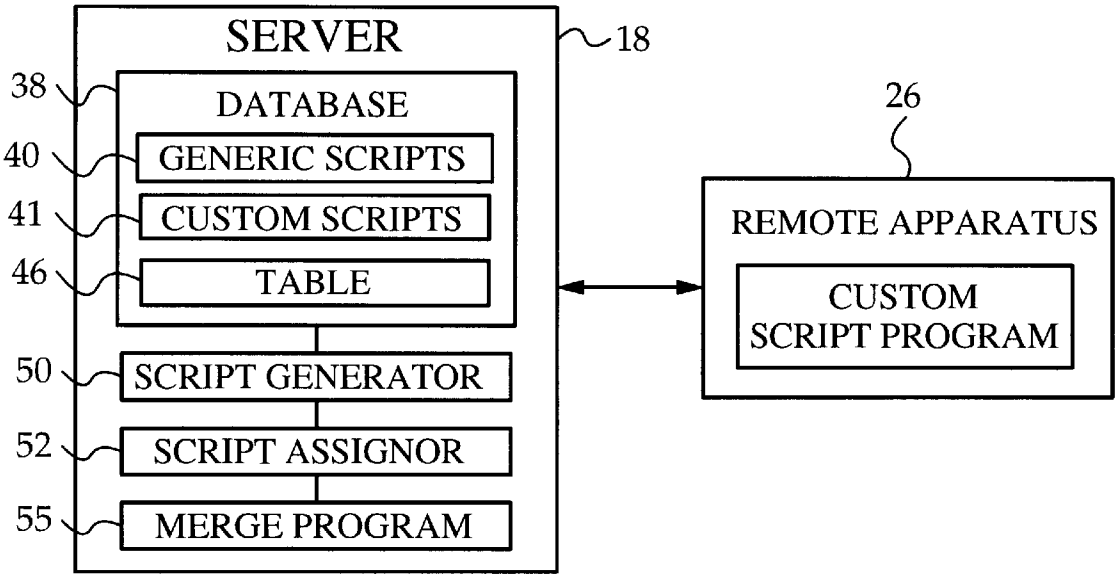


FIG. 16

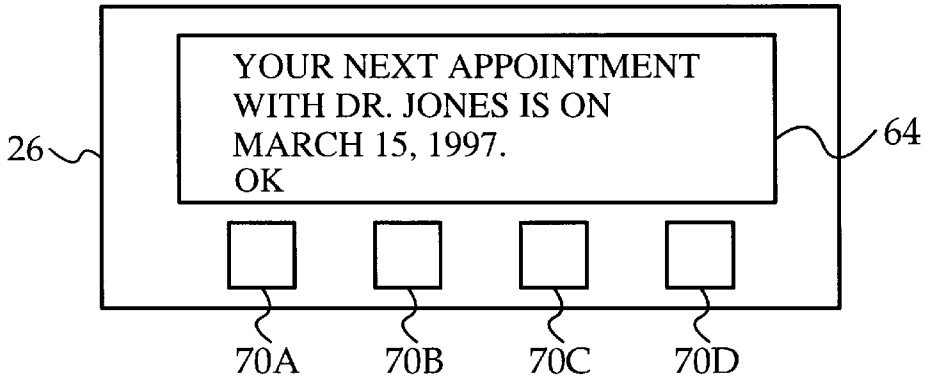


FIG. 17

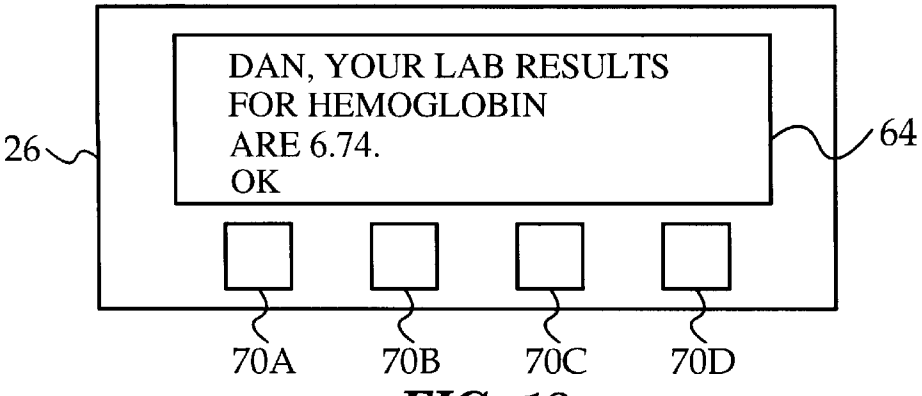


FIG. 18

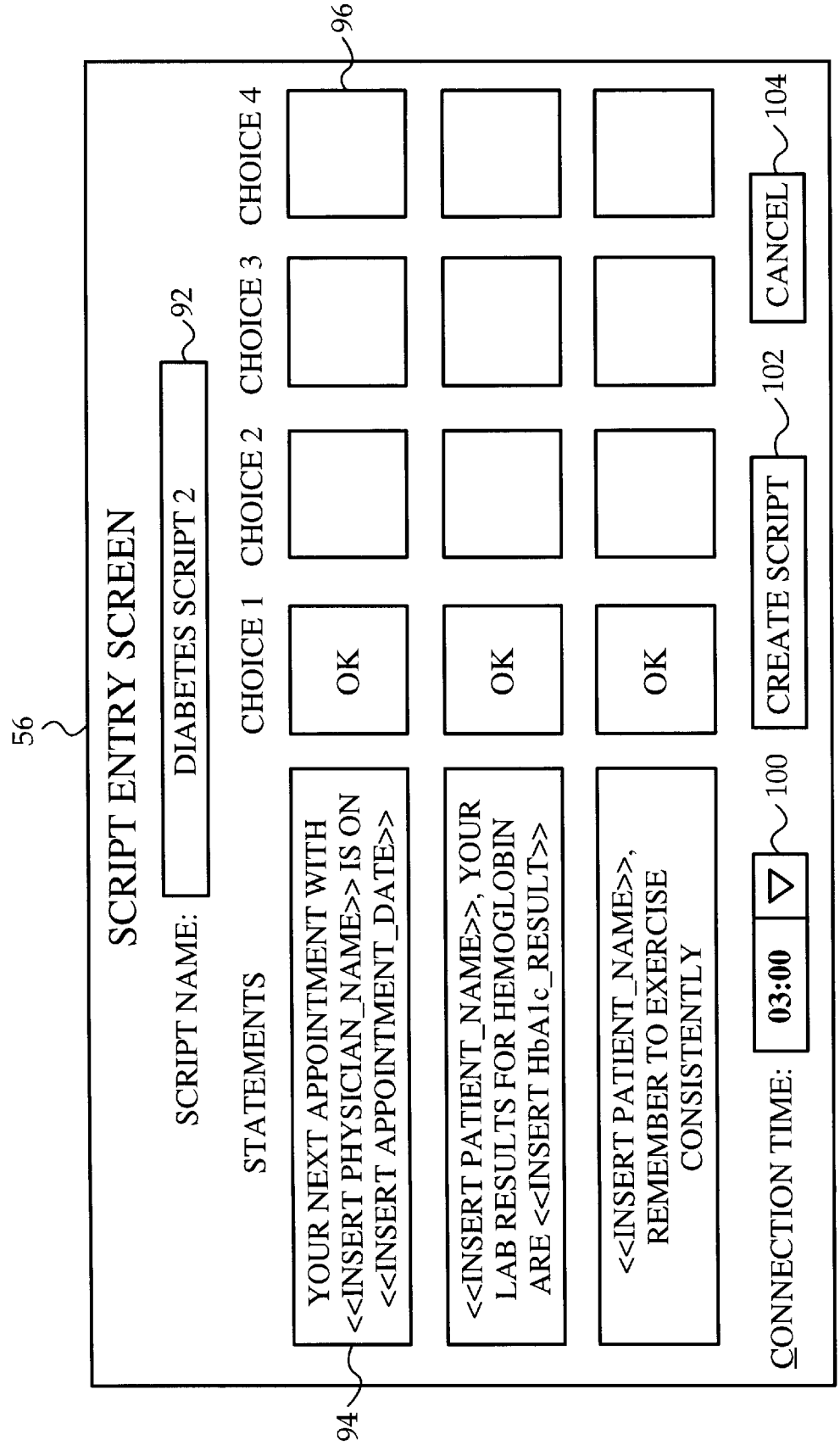

56
SCRIPT ENTRY SCREEN
SCRIPT NAME:
DIABETES SCRIPT 2
92
STATEMENTS
CHOICE 1
CHOICE 2
CHOICE 3
CHOICE 4
96
YOUR NEXT APPOINTMENT WITH <<INSERT PHYSICIAN_NAME>> IS ON <<INSERT APPOINTMENT_DATE>>
OK
<<INSERT PATIENT_NAME>>, YOUR LAB RESULTS FOR HEMOGLOBIN ARE <<INSERT HbA1c_RESULT>>
OK
<<INSERT PATIENT_NAME>>, REMEMBER TO EXERCISE CONSISTENTLY
OK
94
CONNECTION TIME:
03:00
100
CREATE SCRIPT
102
CANCEL
104

FIG. 19

NETWORKED SYSTEM FOR INTERACTIVE COMMUNICATION AND REMOTE MONITORING OF INDIVIDUALS

RELATED APPLICATION INFORMATION

This application is a divisional application of application Ser. No. 08/946,341 filed Oct. 7, 1997, now U.S. Pat. No. 5,997,476 which is a continuation-in-part of application Ser. No. 08/847,009 filed Apr. 30, 1997, now U.S. Pat. No. 5,897,493. This application also claims priority from provisional application Ser. No. 60/041,746 filed Mar. 28, 1997 and from provisional application Ser. No. 60/041,751 filed Mar. 28, 1997. This application also claims priority from application Ser. No. 09/201,323 entitled "Leveraging Interactions with a Community of Individuals", filed Nov. 30, 1998 and from application Ser. No. 09/274,433 entitled "Client-Initiated Leveraged Interaction with Providers", filed Mar. 22, 1999. All of the above named applications are hereby incorporated by reference.

FIELD OF THE INVENTION

The present invention relates generally to communication systems for remote monitoring of individuals, and in particular to a networked system for remotely monitoring individuals and for communicating information to the individuals through the use script programs.

BACKGROUND OF THE INVENTION

In the United States alone, over 100 million people have chronic health conditions, accounting for an estimated $700 billion in annual medical costs. In an effort to control these medical costs, many healthcare providers have initiated outpatient or home healthcare programs for their patients. The potential benefits of these programs are particularly great for chronically ill patients who must treat their diseases on a daily basis. However, the success of these programs is dependent upon the ability of the healthcare providers to monitor the patients remotely to avert medical problems before they become complicated and costly. Unfortunately, no convenient and cost effective monitoring system exists for the patients who have the greatest need for monitoring, the poor and the elderly.

Prior attempts to monitor patients remotely have included the use of personal computers and modems to establish communication between patients and healthcare providers. However, computers are too expensive to give away and the patients who already own computers are only a small fraction of the total population. Further, the patients who own computers are typically young, well educated, and have good healthcare coverage. Thus, these patients do not have the greatest unmet medical needs. The patients who have the greatest unmet medical needs are the poor and elderly who do not own computers or who are unfamiliar with their use.

Similar attempts to establish communication between patients and healthcare providers have included the use of the Internet and internet terminals. Although internet terminals are somewhat less costly than personal computers, they are still too expensive to give away to patients. Moreover, monthly on-line access charges are prohibitive for poor patients.

Other attempts to monitor patients remotely have included the use of medical monitoring devices with built-in modems. Examples of such monitoring devices include blood glucose meters, respiratory flow meters, and heart rate monitors. Unfortunately, these monitoring devices are only designed

to collect physiological data from the patients. They do not allow flexible and dynamic querying of the patients for other information, such as quality of life measures or psychosocial variables of illness.

Prior attempts to monitor patients remotely have also included the use of interactive telephone or video response systems. Such interactive systems are disclosed in U.S. Pat. Nos. 5,390,238 issued to Kirk et al. on Feb. 14, 1995, 5,434,611 issued to Tamura on Jul. 18, 1995, and 5,441,047 issued to David et al. on Aug. 15, 1995. One disadvantage of these systems is that they either require a patient to call in to a central facility to be monitored or require the central facility to call the patient according to a rigid monitoring schedule.

If the patients are required to call the central facility, only the compliant patients will actually call regularly to be monitored. Non-compliant patients will typically wait until an emergency situation develops before contacting their healthcare provider, thus defeating the purpose of the monitoring system. If the central facility calls each patient according to a monitoring schedule, it is intrusive to the patient's life and resistance to the monitoring grows over time.

Another disadvantage of these conventional interactive response system is that they are prohibitively expensive for poor patients. Further, it is difficult to identify each patient uniquely using these systems. Moreover, these systems are generally incapable of collecting medical data from monitoring devices, such as blood glucose meters, respiratory flow meters, or heart rate monitors.

OBJECTS AND ADVANTAGES OF THE INVENTION

In view of the above, it is an object of the present invention to provide a simple and inexpensive system for remotely monitoring patients and for communicating information to the patients. It is another object of the invention to provide a system which allows flexible and dynamic querying of the patients. It is a further object of the invention to provide a system which combines querying of patients with medical device monitoring in the same monitoring session. Another object of the invention is to provide a monitoring system which incurs lower communications charges than those incurred by conventional monitoring systems. A further object of the invention is to provide a monitoring system which may be used at any time convenient for a patient.

These and other objects and advantages will become more apparent after consideration of the ensuing description and the accompanying drawings.

SUMMARY

The invention presents a networked system for remotely monitoring an individual and for communicating information to the individual. The system includes a server and a remote interface for entering in the server a set of queries to be answered by the individual. The server is preferably a world wide web server and the remote interface is preferably a personal computer or network terminal connected to the web server via the Internet. The system also includes a remotely programmable apparatus for interacting with the individual. The apparatus is connected to the server via a communication network, preferably the Internet. The apparatus interacts with the individual in accordance with a script program received from the server.

The server includes a script generator for generating the script program from the queries entered through the remote

interface. The script program is executable by the apparatus to communicate the queries to the individual, to receive responses to the queries, and to transmit the responses from the apparatus to the server. The server also includes a database connected to the script generator for storing the script program and the responses to the queries.

The apparatus has a communication device, such as a modem, for receiving the script program from the server and for transmitting the responses to the server. The apparatus also has a user interface for communicating the queries to the individual and for receiving the responses to the queries. In the preferred embodiment, the user interface includes a display for displaying the queries and user input buttons for entering the responses to the queries. In an alternative embodiment, the user interface includes a speech synthesizer for audibly communicating the queries and a speech recognizer for receiving spoken responses to the queries.

The apparatus also includes a memory for storing the script program and the responses to the queries. The apparatus further includes a microprocessor connected to the communication device, the user interface, and the memory.

The microprocessor executes the script program to communicate the queries to the individual, to receive the responses to the queries, and to transmit the responses to the server through the communication network.

In the preferred embodiment, the system also includes at least one monitoring device for producing measurements of a physiological condition of the individual and for transmitting the measurements to the apparatus. The apparatus further includes a device interface connected to the microprocessor for receiving the measurements from the monitoring device. The measurements are stored in the memory and transmitted to the server with the responses to the queries. The server also preferably includes a report generator connected to the database for generating a report of the measurements and responses. The report is displayed on the remote interface.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram of a networked system according to a preferred embodiment of the invention.

FIG. **2** is a block diagram illustrating the interaction of the components of the system of FIG. **1**.

FIG. **3** is a perspective view of a remotely programmable apparatus of the system of FIG. **1**.

FIG. **4** is a block diagram illustrating the components of the apparatus of FIG. **3**.

FIG. **5** is a script entry screen according to the preferred embodiment of the invention.

FIG. **6**A is a listing of a sample script program according to the preferred embodiment of the invention.

FIG. **6**B is a continuation of the listing of FIG. **6**A.

FIG. **7** is a script assignment screen according to the preferred embodiment of the invention.

FIG. **8** is a sample query appearing on a display of the apparatus of FIG. **3**.

FIG. **9** is a sample prompt appearing on the display of the apparatus of FIG. **3**.

FIG. **10** is a sample report displayed on a workstation of the system of FIG. **1**.

FIG. **11**A is a flow chart illustrating the steps included in a monitoring application executed by the server of FIG. **1** according to the preferred embodiment of the invention.

FIG. **11**B is a continuation of the flow chart of FIG. **11**A.

FIG. **12**A is a flow chart illustrating the steps included in the script program of FIGS. **6**A–**6**B.

FIG. **12**B is a continuation of the flow chart of FIG. **12**A.

FIG. **13** is a perspective view of a remotely programmable apparatus according to a second embodiment of the invention.

FIG. **14** is a sample prompt appearing on a display of the apparatus of FIG. **13**.

FIG. **15** is a block diagram illustrating the components of the apparatus of FIG. **13**.

FIG. **16** is a schematic block diagram illustrating the interaction of the server of FIG. **1** with the apparatus of FIG. **3** according to a third embodiment of the invention.

FIG. **17** is a first sample message appearing on the display of the apparatus of FIG. **3**.

FIG. **18** is a second sample message appearing on the display of the apparatus of FIG. **3**.

FIG. **19** is a script entry screen according to the third embodiment of the invention.

DETAILED DESCRIPTION

The invention presents a system and method for remotely monitoring individuals and for communicating information to the individuals. In a preferred embodiment of the invention, the individuals are patients and the system is used to collect data relating to the health status of the patients. However, it is to be understood that the invention is not limited to remote patient monitoring. The system and method of the invention may be used for any type of remote monitoring application. The invention may also be implemented as an automated messaging system for communicating information to individuals, as will be discussed in an alternative embodiment below.

A preferred embodiment of the invention is illustrated in FIGS. **1**–**12**. Referring to FIG. **1**, a networked system **16** includes a server **18** and a workstation **20** connected to server **18** through a communication network **24**. Server **18** is preferably a world wide web server and communication network **24** is preferably the Internet. It will be apparent to one skilled in the art that server **18** may comprise a single stand-alone computer or multiple computers distributed throughout a network. Workstation **20** is preferably a personal computer, remote terminal, or web TV unit connected to server **18** via the Internet. Workstation **20** functions as a remote interface for entering in server **18** messages and queries to be communicated to the patients.

System **16** also includes first and second remotely programmable apparatuses **26** and **32** for monitoring first and second patients, respectively. Each apparatus is designed to interact with a patient in accordance with script programs received from server **18**. Each apparatus is in communication with server **18** through communication network **24**, preferably the Internet. Alternatively, each apparatus may be placed in communication with server **18** via wireless communication networks, cellular networks, telephone networks, or any other network which allows each apparatus to exchange data with server **18**. For clarity of illustration, only two apparatuses are shown in FIG. **1**. It is to be understood that system **16** may include any number of apparatuses for monitoring any number of patients.

In the preferred embodiment, each patient to be monitored is also provided with a monitoring device **28**. Monitoring device **28** is designed to produce measurements of a physiological condition of the patient, record the measurements, and transmit the measurements to the patient's apparatus

through a standard connection cable **30**. Examples of suitable monitoring devices include blood glucose meters, respiratory flow meters, blood pressure cuffs, electronic weight scales, and pulse rate monitors. Such monitoring devices are well known in the art. The specific type of monitoring device provided to each patient is dependent upon the patient's disease. For example, diabetes patients are provided with a blood glucose meters for measuring blood glucose concentrations, asthma patients are provided with respiratory flow meters for measuring peak flow rates, obesity patients are provided with weight scales, etc.

FIG. **2** shows server **18**, workstation **20**, and apparatus **26** in greater detail. Server **18** includes a database **38** for storing script programs **40**. The script programs are executed by each apparatus to communicate queries and messages to a patient, receive responses **42** to the queries, collect monitoring device measurements **44**, and transmit responses **42** and measurements **44** to server **18**. Database **38** is designed to store the responses **42** and measurements **44**. Database **38** further includes a look-up table **46**. Table **46** contains a list of the patients to be monitored, and for each patient, a unique patient identification code and a respective pointer to the script program assigned to the patient. Each remote apparatus is designed to execute assigned script programs which it receives from server **18**.

FIGS. **3**–**4** show the structure of each apparatus according to the preferred embodiment. For clarity, only apparatus **26** is shown since each apparatus of the preferred embodiment has substantially identical structure to apparatus **26**. Referring to FIG. **3**, apparatus **26** includes a housing **62**. Housing **62** is sufficiently compact to enable apparatus **26** to be hand-held and carried by a patient. Apparatus **26** also includes a display **64** for displaying queries and prompts to the patient. In the preferred embodiment, display **64** is a liquid crystal display (LCD).

Four user input buttons **70**A, **70**B, **70**C, and **70**D are located adjacent display **64**. The user input buttons are for entering in apparatus **26** responses to the queries and prompts. In the preferred embodiment, the user input buttons are momentary contact push buttons. In alternative embodiments, the user input buttons may be replaced by switches, keys, a touch sensitive display screen, or any other data input device.

Three monitoring device jacks **68**A, **68**B, and **68**C are located on a surface of housing **62**. The device jacks are for connecting apparatus **26** to a number of monitoring devices, such as blood glucose meters, respiratory flow meters, or blood pressure cuffs, through respective connection cables (not shown). Apparatus **26** also includes a modem jack **66** for connecting apparatus **26** to a telephone jack through a standard connection cord (not shown). Apparatus **26** further includes a visual indicator, such as a light emitting diode (LED) **74**. LED **74** is for visually notifying the patient that he or she has unanswered queries stored in apparatus **26**.

FIG. **4** is a schematic block diagram illustrating the components of apparatus **26** in greater detail. Apparatus **26** includes a microprocessor **76** and memory **80** connected to microprocessor **76**. Memory **80** is preferably a non-volatile memory, such as a serial EEPROM. Memory **80** stores script programs received from the server, measurements received from monitoring device **28**, responses to queries, and the patient's unique identification code. Microprocessor **76** also includes built-in read only memory (ROM) which stores firmware for controlling the operation of apparatus **26**. The firmware includes a script interpreter used by microprocessor **76** to execute the script programs. The script interpreter interprets script commands which are executed by microprocessor **76**. Specific techniques for interpreting and executing script commands in this manner are well known in the art.

Microprocessor **76** is preferably connected to memory **80** using a standard two-wire I^2C interface. Microprocessor **76** is also connected to user input buttons **70**, LED **74**, a clock **84**, and a display driver **82**. Clock **84** indicates the current date and time to microprocessor **76**. For clarity of illustration, clock **84** is shown as a separate component, but is preferably built into microprocessor **76**. Display driver **82** operates under the control of microprocessor **76** to display information on display **64**. Microprocessor **76** is preferably a PIC 16C65 processor which includes a universal asynchronous receiver transmitter (UART) **78**. UART **78** is for communicating with a modem **86** and a device interface **90**. A CMOS switch **88** under the control of microprocessor **76** alternately connects modem **86** and interface **90** to UART **78**.

Modem **86** is connected to a telephone jack **22** through modem jack **66**. Modem **86** is for exchanging data with server **18** through communication network **24**. The data includes script programs which are received from the server as well as responses to queries, device measurements, script identification codes, and the patient's unique identification code which modem **86** transmits to the server. Modem **86** is preferably a complete 28.8 K modem commercially available from Cermetek, although any suitable modem may be used.

Device interface **90** is connected to device jacks **68**A, **68**B, and **68**C. Device interface **90** is for interfacing with a number of monitoring devices, such as blood glucose meters, respiratory flow meters, blood pressure cuffs, weight scales, or pulse rate monitors, through the device jacks. Device interface **90** operates under the control of microprocessor **76** to collect measurements from the monitoring devices and to output the measurements to microprocessor **76** for storage in memory **80**. In the preferred embodiment, interface **90** is a standard RS232 interface. For simplicity of illustration, only one device interface is shown in FIG. **4**. However, in alternative embodiments, apparatus **26** may include multiple device interfaces to accommodate monitoring devices which have different connection standards.

Referring again to FIG. **2**, server **18** includes a monitoring application **48**. Monitoring application **48** is a controlling software application executed by server **18** to perform the various functions described below. Application **48** includes a script generator **50**, a script assignor **52**, and a report generator **54**. Script generator **50** is designed to generate script programs **40** from script information entered through workstation **20**. The script information is entered through a script entry screen **56**. In the preferred embodiment, script entry screen **56** is implemented as a web page on server **18**. Workstation **20** includes a web browser for accessing the web page to enter the script information.

FIG. **5** illustrates script entry screen **56** as it appears on workstation **20**. Screen **56** includes a script name field **92** for specifying the name of a script program to be generated. Screen **56** also includes entry fields **94** for entering a set of queries to be answered by a patient. Each entry field **94** has corresponding response choice fields **96** for entering response choices for the query. Screen **56** further includes check boxes **98** for selecting a desired monitoring device from which to collect measurements, such as a blood glucose meter, respiratory flow meter, or blood pressure cuff.

Screen **56** additionally includes a connection time field **100** for specifying a prescribed connection time at which

each apparatus executing the script is to establish a subsequent communication link to the server. The connection time is preferably selected to be the time at which communication rates are the lowest, such as 3:00 AM. Screen **56** also includes a CREATE SCRIPT button **102** for instructing the script generator to generate a script program from the information entered in screen **56**. Screen **56** further includes a CANCEL button **104** for canceling the information entered in screen **56**.

In the preferred embodiment, each script program created by the script generator conforms to the standard file format used on UNIX systems. In the standard file format, each command is listed in the upper case and followed by a colon. Every line in the script program is terminated by a linefeed character {LF} and only one command is placed on each line. The last character in the script program is a UNIX end of file character {EOF}. Table 1 shows an exemplary listing of script commands used in the preferred embodiment of the invention.

TABLE 1

SCRIPT COMMANDS

Command	Description
CLS: {LF}	Clear the display.
ZAP: {LF}	Erase from memory the last set of query responses recorded.
LED: b{LF}	Turn the LED on or off, where b is a binary digit of 0 or 1. An argument of 1 turns on the LED, and an argument of 0 turns off the LED.
DISPLAY: {chars} {LF}	Display the text following the DISPLAY command.
INPUT: mmmm{LF}	Record a button press. The m's represent a button mask pattern for each of the four input buttons. Each in contains an "X" for disallowed buttons or an "O" for allowed buttons. For example, INPUT: OXOX{LF} allows the user to press either button #1 or #3.
WAIT: {LF}	Wait for any one button to be pressed, then continue executing the script program.
COLLECT: device{LF}	Collect measurements from the monitoring device specified in the COLLECT command. The user is preferably prompted to connect the specified monitoring device to the apparatus and press a button to continue.
NUMBER: aaaa{LF}	Assign a script identification code to the script program. The script identification code from the most recently executed NUMBER statement is subsequently transmitted to the server along with the query responses and device measurements. The script identification code identifies to the server which script program was most recently executed by the remote apparatus.
DELAY: t {LF}	Wait until time t specified in the DELAY command, usually the prescribed connection time.
CONNECT: {LF}	Perform a connection routine to establish a communication link to the server, transmit the patient identification code, query responses, device measurements, and script identification code to the server, and receive and store a new script program. When the server instructs the apparatus to disconnect, the script interpreter is restarted, allowing the new script program to execute.

The script commands illustrated in Table 1 are representative of the preferred embodiment and are not intended to limit the scope of the invention. After consideration of the ensuing description, it will be apparent to one skilled in the art many other suitable scripting languages and sets of script commands may be used to implement the invention.

Script generator **50** preferably stores a script program template which it uses to create each script program. To generate a script program, script generator **50** inserts into the template the script information entered in screen **56**. For example, FIGS. **6**A–**6**B illustrate a sample script program created by script generator **50** from the script information shown in FIG. **5**.

The script program includes display commands to display the queries and response choices entered in fields **94** and **96**, respectively. The script program also includes input commands to receive responses to the queries. The script program further includes a collect command to collect device measurements from the monitoring device specified in check boxes **98**. The script program also includes commands to establish a subsequent communication link to the server at the connection time specified in field **100**. The steps included in the script program are also shown in the flow chart of FIGS. **12**A–**12**B and will be discussed in the operation selection below.

Referring again to FIG. **2**, script assignor **52** is for assigning script programs **40** to the patients. Script programs **40** are assigned in accordance with script assignment information entered through workstation **20**. The script assignment information is entered through a script assignment screen **57**, which is preferably implemented as a web page on server **18**.

FIG. **7** illustrates a sample script assignment screen **57** as it appears on workstation **20**. Screen **57** includes check boxes **106** for selecting a script program to be assigned and check boxes **108** for selecting the patients to whom the script program is to be assigned. Screen **57** also includes an ASSIGN SCRIPT button **112** for entering the assignments. When button **112** is pressed, the script assignor creates and stores for each patient selected in check boxes **108** a respective pointer to the script program selected in check boxes **106**. Each pointer is stored in the patient look-up table of the database. Screen **57** further includes an ADD SCRIPT button **110** for accessing the script entry screen and a DELETE SCRIPT button **114** for deleting a script program.

Referring again to FIG. **2**, report generator **54** is designed to generate a patient report **58** from the responses and device measurements received in server **18**. Patient report **58** is displayed on workstation **20**. FIG. **10** shows a sample patient report **58** produced by report generator **54** for a selected patient. Patient report **58** includes a graph **116** of the device measurements received from the patient, as well as a listing of responses **42** received from the patient. Specific techniques for writing a report generator program to display data in this manner are well known in the art.

The operation of the preferred embodiment is illustrated in FIGS. **1**–**12**. FIG. **11**A is a flow chart illustrating steps included in the monitoring application executed by server **18**. FIG. **11**B is a continuation of the flow chart of FIG. **11**A. In step **202**, server **18** determines if new script information has been entered through script entry screen **56**. If new script information has not been entered, server **18** proceeds to step **206**. If new script information has been entered, server **18** proceeds to step **204**.

As shown in FIG. **5**, the script information includes a set of queries, and for each of the queries, corresponding responses choices. The script information also includes a selected monitoring device type from which to collect device measurements. The script information further includes a prescribed connection time for each apparatus to

establish a subsequent communication link to the server. The script information is generally entered in server **18** by a healthcare provider, such as the patients' physician or case manager. Of course, any person desiring to communicate with the patients may also be granted access to server **18** to create and assign script programs. Further, it is to be understood that the system may include any number of remote interfaces for entering script generation and script assignment information in server **18**.

In step **204**, script generator **50** generates a script program from the information entered in screen **56**. The script program is stored in database **38**. Steps **202** and **204** are preferably repeated to generate multiple script programs, e.g. a script program for diabetes patients, a script program for asthma patients, etc. Each script program corresponds to a respective one of the sets of queries entered through script entry screen **56**. Following step **204**, server **18** proceeds to step **206**.

In step **206**, server **18** determines if new script assignment information has been entered through assignment screen **57**. If new script assignment information has not been entered, server **18** proceeds to step **210**. If new script assignment information has been entered, server **18** proceeds to step **208**. As shown in FIG. **7**, the script programs are assigned to each patient by selecting a script program through check boxes **106**, selecting the patients to whom the selected script program is to be assigned through check boxes **108**, and pressing the ASSIGN SCRIPT button **112**. When button **112** is pressed, script assignor **52** creates for each patient selected in check boxes **108** a respective pointer to the script program selected in check boxes **106**. In step **208**, each pointer is stored in look-up table **46** of database **38**. Following step **208**, server **18** proceeds to step **210**.

In step **210**, server **18** determines if any of the apparatuses are remotely connected to the server. Each patient to be monitored is preferably provided with his or her own apparatus which has the patient's unique identification code stored therein. Each patient is thus uniquely associated with a respective one of the apparatuses. If none of the apparatuses is connected, server **18** proceeds to step **220**.

If an apparatus is connected, server **18** receives from the apparatus the patient's unique identification code in step **212**. In step **214**, server **18** receives from the apparatus the query responses **42**, device measurements **44**, and script identification code recorded during execution of a previously assigned script program. The script identification code identifies to the server which script program was executed by the apparatus to record the query responses and device measurements. The responses, device measurements, and script identification code are stored in database **38**.

In step **216**, server **18** uses the patient identification code to retrieve from table **46** the pointer to the script program assigned to the patient. The server then retrieves the assigned script program from database **38**. In step **218**, server **18** transmits the assigned script program to the patient's apparatus through communication network **24**. Following step **218**, server **18** proceeds to step **220**.

In step **220**, server **18** determines if a patient report request has been received from workstation **20**. If no report request has been received, server **18** returns to step **202**. If a report request has been received for a selected patient, server **18** retrieves from database **38** the measurements and query responses last received from the patient, step **222**. In step **224**, server **18** generates and displays patient report **58** on workstation **20**. As shown in FIG. **10**, report **58** includes the device measurements and query responses last received from the patient. Following step **224**, the server returns to step **202**.

FIGS. **12A–12B** illustrate the steps included in the script program executed by apparatus **26**. Before the script program is received, apparatus **26** is initially programmed with the patient's unique identification code and the script interpreter used by microprocessor **76** to execute the script program. The initial programming may be achieved during manufacture or during an initial connection to server **18**. Following initial programming, apparatus **26** receives from server **18** the script program assigned to the patient associated with apparatus **26**. The script program is received by modem **86** through a first communication link and stored in memory **80**.

In step **302**, microprocessor **76** assigns a script identification code to the script program and stores the script identification code in memory **80**. The script identification code is subsequently transmitted to the server along with the query responses and device measurements to identify to the server which script program was most recently executed by the apparatus. In step **304**, microprocessor **76** lights LED **74** to notify the patient that he or she has unanswered queries stored in apparatus **26**. LED **74** preferably remains lit until the queries are answered by the patient.

In step **306**, microprocessor **76** erases from memory **80** the last set of query responses recorded.

In step **308**, microprocessor **76** prompts the patient by displaying on display **64** "ANSWER QUERIES NOW? PRESS ANY BUTTON TO START". In step **310**, microprocessor **76** waits until a reply to the prompt is received from the patient. When a reply is received, microprocessor **76** proceeds to step **312**. In step **312**, microprocessor **76** executes successive display and input commands to display the queries and response choices on display **64** and to receive responses to the queries.

FIG. **8** illustrate a sample query and its corresponding response choices as they appear on display **64**. The response choices are positioned on display **64** such that each response choice is located proximate a respective one of the input buttons. In the preferred embodiment, each response choice is displayed immediately above a respective input button. The patient presses the button corresponding to his or her response. Microprocessor **76** stores each response in memory **80**.

In steps **314–318**, microprocessor **76** executes commands to collect device measurements from a selected monitoring device. The script program specifies the selected monitoring device from which to collect the measurements. In step **314**, microprocessor **76** prompts the patient to connect the selected monitoring device, for example a blood glucose meter, to one of the device jacks. A sample prompt is shown in FIG. **9**. In step **316**, microprocessor **76** waits until a reply to the prompt is received from the patient. When a reply is received, microprocessor **76** proceeds to step **318**. Microprocessor **76** also connects UART **78** to interface **90** through switch **88**. In step **318**, microprocessor **76** collects the device measurements from monitoring device **28** through interface **90**. The measurements are stored in memory **80**.

In step **320**, microprocessor **76** prompts the patient to connect apparatus **26** to the telephone jack **22** so that apparatus **26** may connect to server **18** at the prescribed connection time. In step **322**, microprocessor **76** waits until a reply to the prompt is received from the patient. When a reply is received, microprocessor **76** turns off LED **74** in step **324**. In step **326**, microprocessor **76** waits until it is time to connect to server **18**. Microprocessor **76** compares the connection time specified in the script program to the current time output by clock **84**. When it is time to connect, microprocessor **76** connects UART **78** to modem **86** through switch **88**.

In step **328**, microprocessor **76** establishes a subsequent communication link between apparatus **26** and server **18** through modem **86** and communication network **24**. If the connection fails for any reason, microprocessor **76** repeats step **328** to get a successful connection. In step **330**, microprocessor **76** transmits the device measurements, query responses, script identification code, and patient identification code stored in memory **80** to server **18** through the subsequent communication link. In step **332**, microprocessor **76** receives through modem **86** a new script program from server **18**. The new script program is stored in memory **80** for subsequent execution by microprocessor **76**. Following step **332**, the script program ends.

One advantage of the monitoring system of the present invention is that it allows each patient to select a convenient time to respond to the queries, so that the monitoring system is not intrusive to the patient's schedule. A second advantage of the monitoring system is that it incurs very low communications charges because each remote apparatus connects to the server at times when communication rates are lowest. Moreover, the cost to manufacture each remote apparatus is very low compared to personal computers or internet terminals, so that the monitoring system is highly affordable.

A third advantage of the monitoring system is that it allows each apparatus to be programmed remotely through script programs. Patient surveys, connection times, display prompts, selected monitoring devices, patient customization, and other operational details of each apparatus may be easily changed by transmitting a new script program to the apparatus. Moreover, each script program may be easily created and assigned by remotely accessing the server through the Internet. Thus, the invention provides a powerful, convenient, and inexpensive system for remotely monitoring a large number of patients.

FIGS. **13–15** illustrate a second embodiment of the invention in which each remotely programmable apparatus has speech recognition and speech synthesis functionality. FIG. **13** shows a perspective view of an apparatus **27** according to the second embodiment. Apparatus **27** includes a speaker **72** for audibly communicating queries and prompts to the patient. Apparatus **27** also includes a microphone **118** for receiving spoken responses to the queries and prompts. Apparatus **27** may optionally include a display **64** for displaying prompts to the patient, as shown in FIG. **14**.

FIG. **15** is a schematic block diagram illustrating the components of apparatus **27** in greater detail. Apparatus **27** is similar in design to the apparatus of the preferred embodiment except that apparatus **27** includes an audio processor chip **120** in place of microprocessor **76**. Audio processor chip **120** is preferably an RSC-164 chip commercially available from Sensory Circuits Inc. of 1735 N. First Street, San Jose, Calif. 95112.

Audio processor chip **120** has a microcontroller **122** for executing script programs received from the server. A memory **80** is connected to microcontroller **122**. Memory **80** stores the script programs and a script interpreter used by microcontroller **122** to execute the script programs. Memory **80** also stores measurements received from monitoring device **28**, responses to the queries, script identification codes, and the patient's unique identification code.

Audio processor chip **120** also has built in speech synthesis functionality for synthesizing queries and prompts to a patient through speaker **72**. For speech synthesis, chip **120** includes a digital to analog converter (DAC) **142** and an amplifier **144**. DAC **142** and amplifier **144** drive speaker **72** under the control of microcontroller **122**.

Audio processor chip **120** further has built in speech recognition functionality for recognizing responses spoken into microphone **118**. Audio signals received through microphone **118** are converted to electrical signals and sent to a preamp and gain control circuit **128**. Preamp and gain control circuit **128** is controlled by an automatic gain control circuit **136**, which is in turn controlled by microcontroller **122**. After being amplified by preamp **128**, the electrical signals enter chip **120** and pass through a multiplexer **130** and an analog to digital converter (ADC) **132**. The resulting digital signals pass through a digital logic circuit **134** and enter microcontroller **122** for speech recognition.

Audio processor chip **120** also includes a RAM **138** for short term memory storage and a ROM **140** which stores programs executed by microcontroller **122** to perform speech recognition and speech synthesis. Chip **120** operates at a clock speed determined by a crystal **126**. Chip **120** also includes a clock **84** which provides the current date and time to microcontroller **122**. As in the preferred embodiment, apparatus **27** includes an LED **74**, display driver **82**, modem **86**, and device interface **90**, all of which are connected to microcontroller **122**.

The operation of the second embodiment is similar to the operation of the preferred embodiment except that queries, response choices, and prompts are audibly communicated to the patient through speaker **72** rather than being displayed to the patient on display **64**. The operation of the second embodiments also differs from the operation of the preferred embodiment in that responses to the queries and prompts are received through microphone **118** rather than through user input buttons.

The script programs of the second embodiment are similar to the script program shown in FIGS. **6A–6B**, except that each display command is replaced by a speech synthesis command and each input command is replaced by a speech recognition command. The speech synthesis commands are executed by microcontroller **122** to synthesize the queries, response choices, and prompts through speaker **72**. The speech recognition commands are executed by microcontroller **122** to recognize responses spoken into microphone **118**.

For example, to ask the patient how he or she feels and record a response, microcontroller **122** first executes a speech synthesis command to synthesize through speaker **72** "How do you feel? Please answer with one of the following responses: very bad, bad, good, or very good." Next, microcontroller **118** executes a speech recognition command to recognize the response spoken into microphone **118**. The recognized response is stored in memory **80** and subsequently transmitted to the server. Other than the differences described, the operation and advantages of the second embodiment are the same as the operation and advantages of the preferred embodiment described above.

Although the first and second embodiments focus on querying individuals and collecting responses to the queries, the system of the invention is not limited to querying applications. The system may also be used simply to communicate messages to the individuals. FIGS. **16–19** illustrate a third embodiment in which the system is used to perform this automated messaging function. In the third embodiment, each script program contains a set of statements to be communicated to an individual rather than a set of queries to be answered by the individual. Of course, it will be apparent to one skilled in the art that the script programs may optionally include both queries and statements.

The third embodiment also shows how the queries and statements may be customized to each individual by merg-

ing personal data with the script programs, much like a standard mail merge application. Referring to FIG. **16**, personal data relating to each individual is preferably stored in look-up table **46** of database **38**. By way of example, the data may include each individual's name, the name of each individual's physician, test results, appointment dates, of any other desired data. As in the preferred embodiment, database **38** also stores generic script programs **40** created by script generator **50**.

Server **18** includes a data merge program **55** for merging the data stored in table **46** with generic script programs **40**. Data merge program **55** is designed to retrieve selected data from table **46** and to insert the data into statements in generic script programs **40**, thus creating custom script programs **41**. Each custom script program **41** contains statements which are customized to an individual. For example, the statements may be customized with the individual's name, test results, etc. Examples of such customized statements are shown in FIGS. **17–18**.

The operation of the third embodiment is similar to the operation of the preferred embodiment except that the script programs are used to communicate messages to the individuals rather than to query the individuals. Each message is preferably a set of statements. Referring to FIG. **19**, the statements may be entered in the server through script entry screen **56**, just like the queries of the preferred embodiment.

Each statement preferably includes one or more insert commands specifying data from table **46** to be inserted into the statement. The insert commands instruct data merge program **55** to retrieve the specified data from database **38** and to insert the data into the statement. For example, the insert commands shown in FIG. **19** instruct the data merge program to insert a physician name, an appointment date, a patient name, and a test result into the statements. As in the preferred embodiment, each statement may also include one or more response choices which are entered in fields **96**.

Following entry of the statements and response choices, CREATE SCRIPT button **102** is pressed. When button **102** is pressed, script generator **50** generates a generic script program from the information entered in screen **56**. The generic script program is similar to the script program shown in FIGS. **6A–6B**, except that the display commands specify statements to be displayed rather than queries. Further, the statements include insert commands specifying data to be inserted into the script program. As in the preferred embodiment, multiple script programs are preferably generated, e.g. a generic script program for diabetes patients, a generic script program for asthma patients, etc. The generic script programs are stored in database **38**.

Following generation of the generic script programs, server **18** receives script assignment information entered through script assignment screen **57**. As shown in FIG. **7**, the script programs are assigned by first selecting one of the generic script programs through check boxes **106**, selecting individuals through check boxes **108**, and pressing the ASSIGN SCRIPT button **112**. When button **112** is pressed, data merge program **55** creates a custom script program for each individual selected in check boxes **108**.

Each custom script program is preferably created by using the selected generic script program as a template. For each individual selected, data merge program **55** retrieves from database **38** the data specified in the insert commands. Next, data merge program **55** inserts the data into the appropriate statements in the generic script program to create a custom script program for the individual. Each custom script program is stored in database **38**.

As each customs script program is generated for an individual, script assignor **52** assigns the script program to the individual. This is preferably accomplished by creating a pointer to the custom script program and storing the pointer with the individual's unique identification code in table **46**. When the individual's remote apparatus connects to server **18**, server **18** receives from the apparatus the individual's unique identification code. Server **18** uses the unique identification code to retrieve from table **46** the pointer to the custom script program assigned to the individual. Next, server **18** retrieves the assigned script program from database **38** and transmits the script program to the individual's apparatus through communication network **24**.

The apparatus receives and executes the script program. The execution of the script program is similar to the execution described in the preferred embodiment, except that statements are displayed to the individual rather than queries. FIGS. **17–18** illustrate two sample statements as they appear on display **64**. Each statement includes a response choice, preferably an acknowledgment such as "OK". After reading a statement, the individual presses the button corresponding to the response choice to proceed to the next statement. Alternatively, the script program may specify a period of time that each statement is to be displayed before proceeding to the next statement. The remaining operation of the third embodiment is analogous to the operation of the preferred embodiment described above.

Although it is presently preferred to generate a custom script program for each individual as soon as script assignment information is received for the individual, it is also possible to wait until the individual's apparatus connects to the server before generating the custom script program. This is accomplished by creating and storing a pointer to the generic script program assigned to the individual, as previously described in the preferred embodiment. When the individual's apparatus connects to the server, data merge program **55** creates a custom script program for the individual from the generic script program assigned to the individual. The custom script program is then sent to the individual's apparatus for execution.

SUMMARY, RAMIFICATIONS, AND SCOPE

Although the above description contains many specificities, these should not be construed as limitations on the scope of the invention but merely as illustrations of some of the presently preferred embodiments. Many other embodiments of the invention are possible. For example, the scripting language and script commands shown are representative of the preferred embodiment. It will be apparent to one skilled in the art many other scripting languages and specific script commands may be used to implement the invention.

Moreover, the invention is not limited to the specific applications described. The system and method of the invention have many other application both inside and outside the healthcare industry. For example, pharmaceutical manufacturers may apply the system in the clinical development and post marketing surveillance of new drugs, using the system as an interactive, on-line monitoring tool for collecting data on the efficacy, side effects, and quality of life impact of the drugs. Compared to the current use of labor intensive patient interviews, the system provides a fast, flexible, and cost effective alternative for monitoring the use and effects of the drugs.

The system may also be used by home healthcare companies to enhance the service levels provided to customers,

e.g. panic systems, sleep surveillance, specific monitoring of disease conditions, etc. Alternatively, the system may be used to monitor and optimize the inventory of home stationed health supplies. As an example, the system may be connected to an appropriate measuring device to optimize timing of oxygen tank delivery to patients with COPD.

The system and method of the invention also have many applications outside the healthcare industry. For example, the system may be used for remote education over the

Internet, facilitating educational communication with children or adult trainees who lack access to sophisticated and expensive computer equipment. The system may also be used by law enforcement officers to perform on-line surveillance of individuals on probation or parole.

Further, the invention has numerous applications for gathering data from remotely located devices. For example, the system may be used to collect data from smart appliances, such as identification check systems. Alternatively, the system may be applied to the remote monitoring of facilities, including safety and security monitoring, or to environmental monitoring, including pollution control and pipeline monitoring. Many other suitable applications of the invention will be apparent to one skilled in the art.

Therefore, the scope of the invention should be determined not by the examples given, but by the appended claims and their legal equivalents.

What is claimed is:

1. A system of communicating information to an individual, comprising:

a) remote computer workstation configured for specifying information to be communicated to the individual;

b) a server connected to said remote computer workstation via a first communication network, said server including a script program generator for generating a script program according to the specified information;

c) a remotely programmable apparatus networked to said server via a second communication network, said remotely programmable apparatus including:

i) communication devices for receiving said script program from said server;

ii) user interface; and

iii) processor device for executing said script program, wherein said executing script program conveys the information to the individual using the user interface and receives input from the individual in response to the conveyed information through the user interface, said processor device being connected to said communication device and to said user interface; and

d) at least one monitoring device in communication with said remotely programmable apparatus, said at least one monitoring device for providing at least one measurement of a physiological parameter of the individual.

2. The system of claim **1**, wherein said communications device comprises a modem.

3. The system of claim **1**, wherein said measurement is transmitted to said remote computer workstation via said server.

4. The system of claim **1**, wherein said at least one monitoring device is connected to said remotely programmable apparatus via a cable.

5. The system of claim **1**, wherein said at least one monitoring device is selected from the group consisting of a blood glucose meter, a respiratory flow meter, a blood pressure cuff, an electronic weight scale, and a pulse monitor.

6. The system of claim **1**, wherein the information to be communicated is a message.

7. The system of claim **1**, wherein the information to be communicated is a set of queries to be answered by the individual.

8. The system of claim **1**, wherein said remotely programmable apparatus comprises at least one monitoring device jack for operably linking at least one monitoring device to said remotely programmable apparatus.

9. The system of claim **1**, wherein said remotely programmable apparatus is located at the residence of an individual to be monitored, and said remote computer workstation is located at a location remote from the residence of the individual to be monitored.

10. The system of claim **1**, where the first and second communication networks are the same network.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,368,273 B1
APPLICATION NO. : 09/300856
DATED : April 9, 2002
INVENTOR(S) : Stephen J. Brown

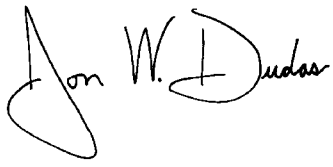
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 15, claim 1, line 40, replace "devices" with --device--.

Column 16, claim 2, line 13, replace "communications" with --communication--.

Signed and Sealed this

Twenty-fifth Day of December, 2007



JON W. DUDAS
Director of the United States Patent and Trademark Office

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(12) EX PARTE REEXAMINATION CERTIFICATE (7559th)

United States Patent
Brown

(10) **Number: US 6,368,273 C1**
(45) **Certificate Issued: Jun. 15, 2010**

(54) **NETWORKED SYSTEM FOR INTERACTIVE COMMUNICATION AND REMOTE MONITORING OF INDIVIDUALS**

(75) Inventor: **Stephen J. Brown**, Woodside, CA (US)

(73) Assignee: **Health Hero Network**, Mountain View, CA (US)

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Reexamination Certificate for:
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Certificate of Correction issued Dec. 25, 2007.

Related U.S. Application Data

(60) Division of application No. 08/946,341, filed on Oct. 7, 1997, now Pat. No. 5,997,476, which is a continuation-in-part of application No. 08/847,009, filed on Apr. 30, 1997, now Pat. No. 5,897,493.

(60) Provisional application No. 60/041,746, filed on Mar. 28, 1997, and provisional application No. 60/041,751, filed on Mar. 28, 1997.

(51) **Int. Cl.**
A61B 5/00 (2006.01)

(52) **U.S. Cl.** **600/300**; 705/3; 600/301; 128/904

(58) **Field of Classification Search** ..... None
See application file for complete search history.

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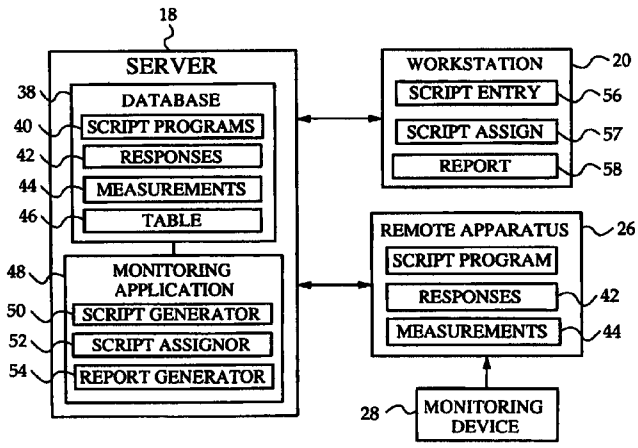
Primary Examiner—Jeffrey R. Jastrzab

(57) **ABSTRACT**

The invention presents a networked system for communicating information to an individual and for remotely monitoring the individual. The system includes a server and a remote interface for entering in the server a set of queries to be answered by the individual. The server is preferably a web server and the remote interface is preferably a personal computer or remote terminal connected to the server via the Internet. The system also includes a remotely programmable apparatus connected to the server via a communication network, preferably the Internet. The apparatus interacts with the individual in accordance with a script program received from the server. The server includes a script generator for generating the script program from the set of queries entered through the remote interface. The script program is received and executed by the apparatus to communicate the queries to the individual, to receive responses to the queries, and to transmit the responses from the apparatus to the server.



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EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

Claims **1** and **2** are determined to be patentable as amended.

Claims **3-10**, dependent on an amended claim, are determined to be patentable.

1. A system of communicating information to an individual, comprising:

a) *a* remote computer workstation configured for specifying information to be communicated to the individual *in a format readable by a health care provider, wherein said specified information is entered by said health care provider using an interface*;

b) a server connected to said remote computer workstation via a first communication network, said server including a script program generator for generating a script program *in a computer readable format* according to the specified information;

c) a remotely programmable apparatus networked to said server via a second communication network, said remotely programmable apparatus including:

i) *a* communication **[**devices**]** *interface* for receiving said script program from said server;

ii) *a memory for storing said script program;*

iii) *a* user interface; and

[iii**]***iv*) *a* processor device for executing said script program *from said memory*, wherein said executing script program conveys **[**the information to**]** *output data readable by* the individual using the user interface and receives *and stores* input from the individual in response to the *output data* conveyed **[**information**]** through the user interface, said processor device being connected to said communication **[**device**]** *interface* and to said user interface; and

d) at least one monitoring device in communication with said remotely programmable apparatus, said at least one monitoring device for providing at least one measurement of a physiological parameter of the individual.

2. The system of claim **1**, wherein said **[**communications device**]** *communication interface* comprises a modem.

* * * * *

EXHIBIT D

US006968375B1

(12) **United States Patent**
Brown

(10) **Patent No.: US 6,968,375 B1**
(45) **Date of Patent: *Nov. 22, 2005**

(54) **NETWORKED SYSTEM FOR INTERACTIVE COMMUNICATION AND REMOTE MONITORING OF INDIVIDUALS**

(75) Inventor: **Stephen J. Brown**, Woodside, CA (US)

(73) Assignee: **Health Hero Network, Inc.**, Mountain View, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 860 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/658,209**

(22) Filed: **Sep. 8, 2000**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/300,856, filed on Apr. 28, 1999, now Pat. No. 6,368,273, which is a division of application No. 08/946,341, filed on Oct. 7, 1997, now Pat. No. 5,997,476, which is a continuation-in-part of application No. 08/847,009, filed on Apr. 30, 1997, now Pat. No. 5,897,493.

(60) Provisional application No. 60/041,746, filed on Mar. 28, 1997, and provisional application No. 60/041,751, filed on Mar. 28, 1997.

(51) **Int. Cl.**[7] **G06F 15/173**

(52) **U.S. Cl.** **709/224**; 709/217; 709/203; 705/3; 600/301

(58) **Field of Search** 709/224, 203, 709/217; 705/3, 2; 600/301, 300; 379/106.2

(56) **References Cited**

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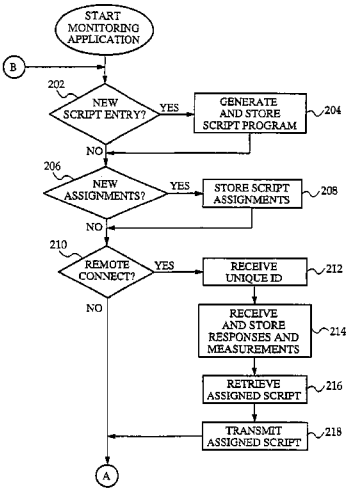
Primary Examiner—Ario Etienne
Assistant Examiner—Abdullahi E. Salad
(74) *Attorney, Agent, or Firm*—Morgan, Lewis & Bockius LLP; Craig P. Opperman

(57) **ABSTRACT**

A system for remotely monitoring an individual. The system includes a server system for generating a script program from a set of queries. The script program is executable by a remote apparatus that displays information and/or a set of queries to the individual through a user interface. Responses to the queries that are entered through the user interface together with individual identification information are sent from the remote apparatus to the server system across a communication network. The server system also includes an automated answering service for providing a series of questions from a stored set of questions for an individual at the remote apparatus to respond to, storing responses to each provided question in the series of questions and providing a service based on the individual's response to the questions.

67 Claims, 19 Drawing Sheets



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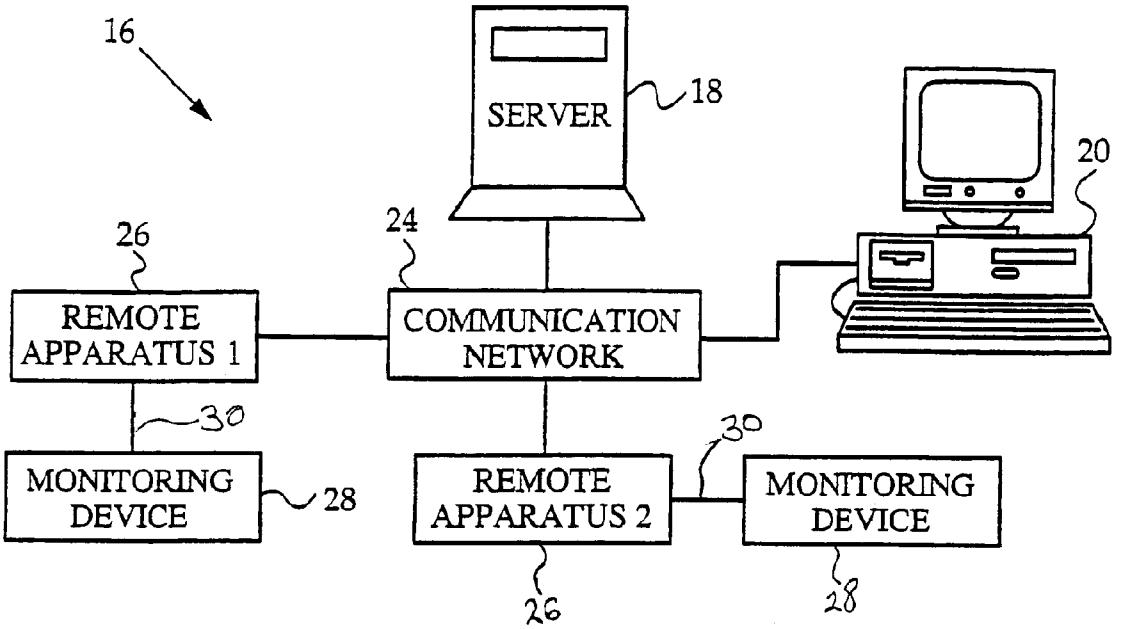

16
SERVER
18
20
24
26
REMOTE APPARATUS 1
COMMUNICATION NETWORK
30
MONITORING DEVICE
28
REMOTE APPARATUS 2
30
MONITORING DEVICE
26
28

FIG. 1

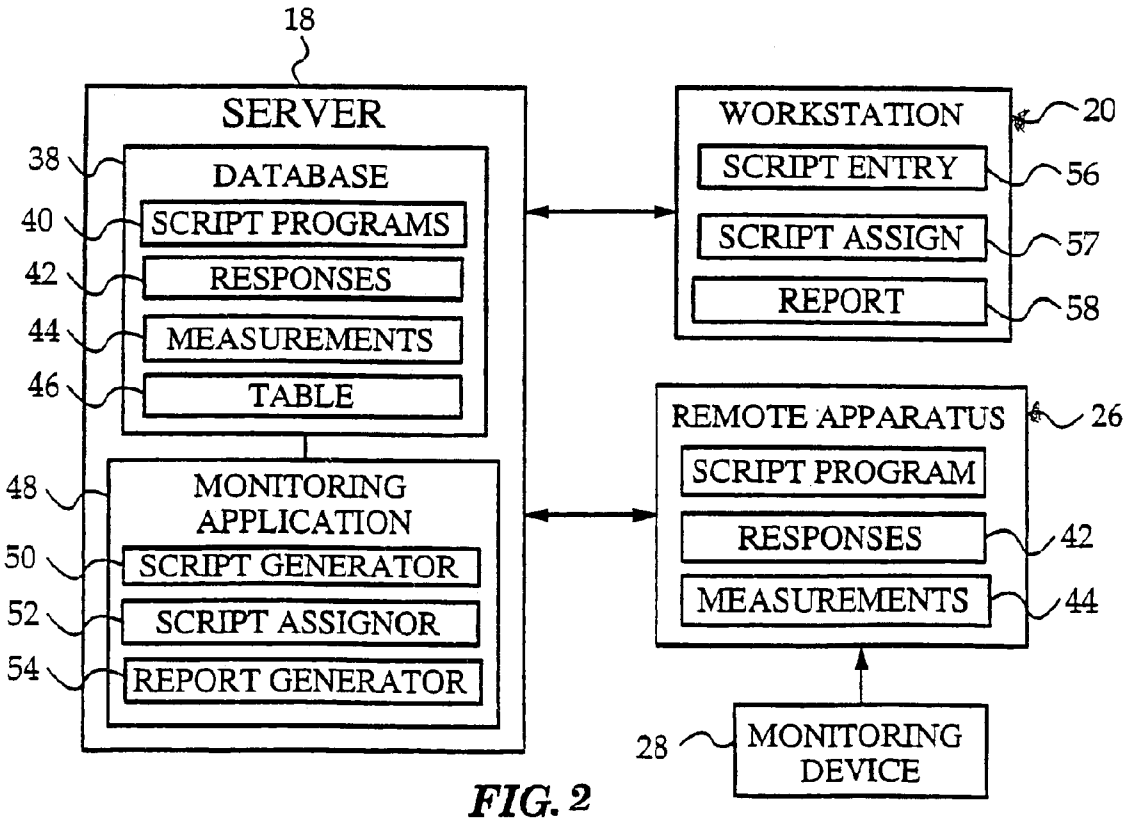

18
SERVER
38
DATABASE
40
SCRIPT PROGRAMS
42
RESPONSES
44
MEASUREMENTS
46
TABLE
48
MONITORING APPLICATION
50
SCRIPT GENERATOR
52
SCRIPT ASSIGNOR
54
REPORT GENERATOR
WORKSTATION
20
SCRIPT ENTRY
56
SCRIPT ASSIGN
57
REPORT
58
REMOTE APPARATUS
26
SCRIPT PROGRAM
RESPONSES
42
MEASUREMENTS
44
28
MONITORING DEVICE

FIG. 2

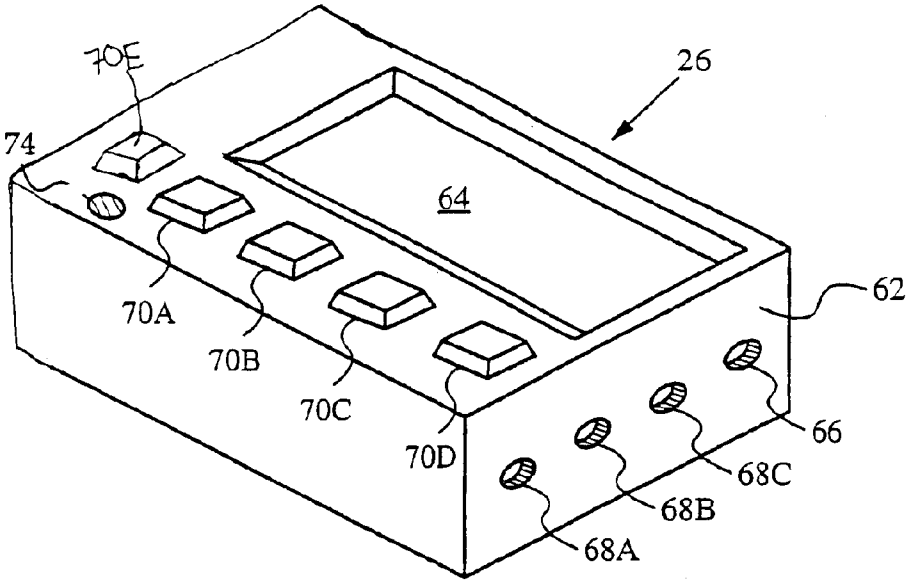

70E
26
74
64
62
70A
70B
70C
70D
66
68C
68B
68A

FIG. 3

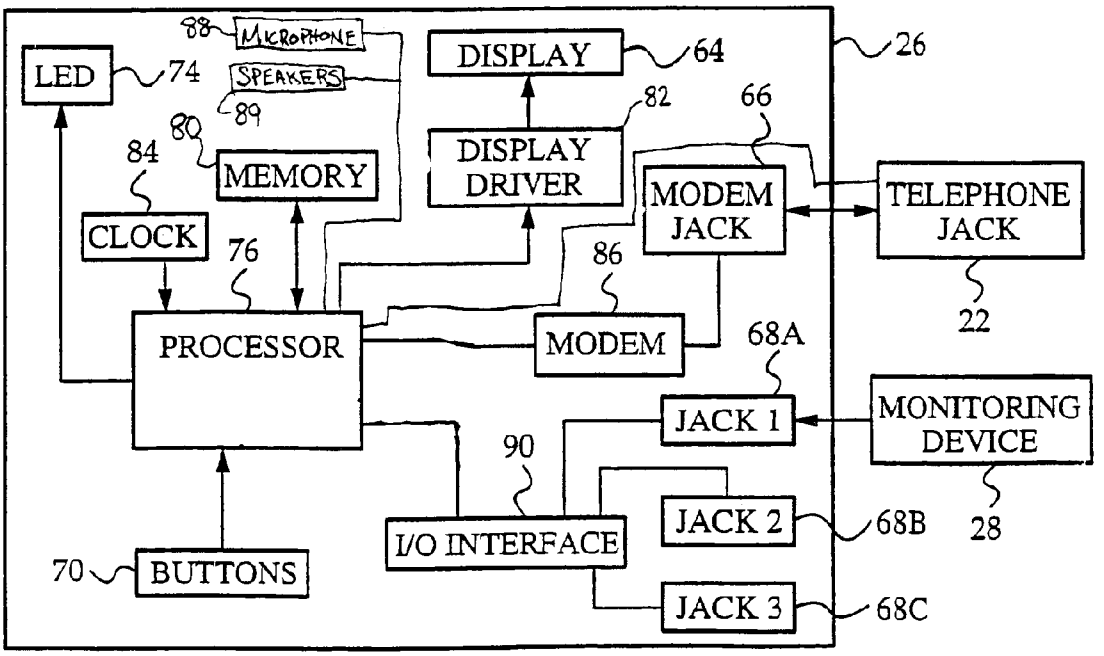

88
MICROPHONE
LED
74
SPEAKERS
89
DISPLAY
64
26
82
66
80
84
MEMORY
DISPLAY DRIVER
MODEM JACK
TELEPHONE JACK
CLOCK
76
86
22
PROCESSOR
MODEM
68A
JACK 1
MONITORING DEVICE
90
JACK 2
68B
28
I/O INTERFACE
70
BUTTONS
JACK 3
68C

FIG. 4

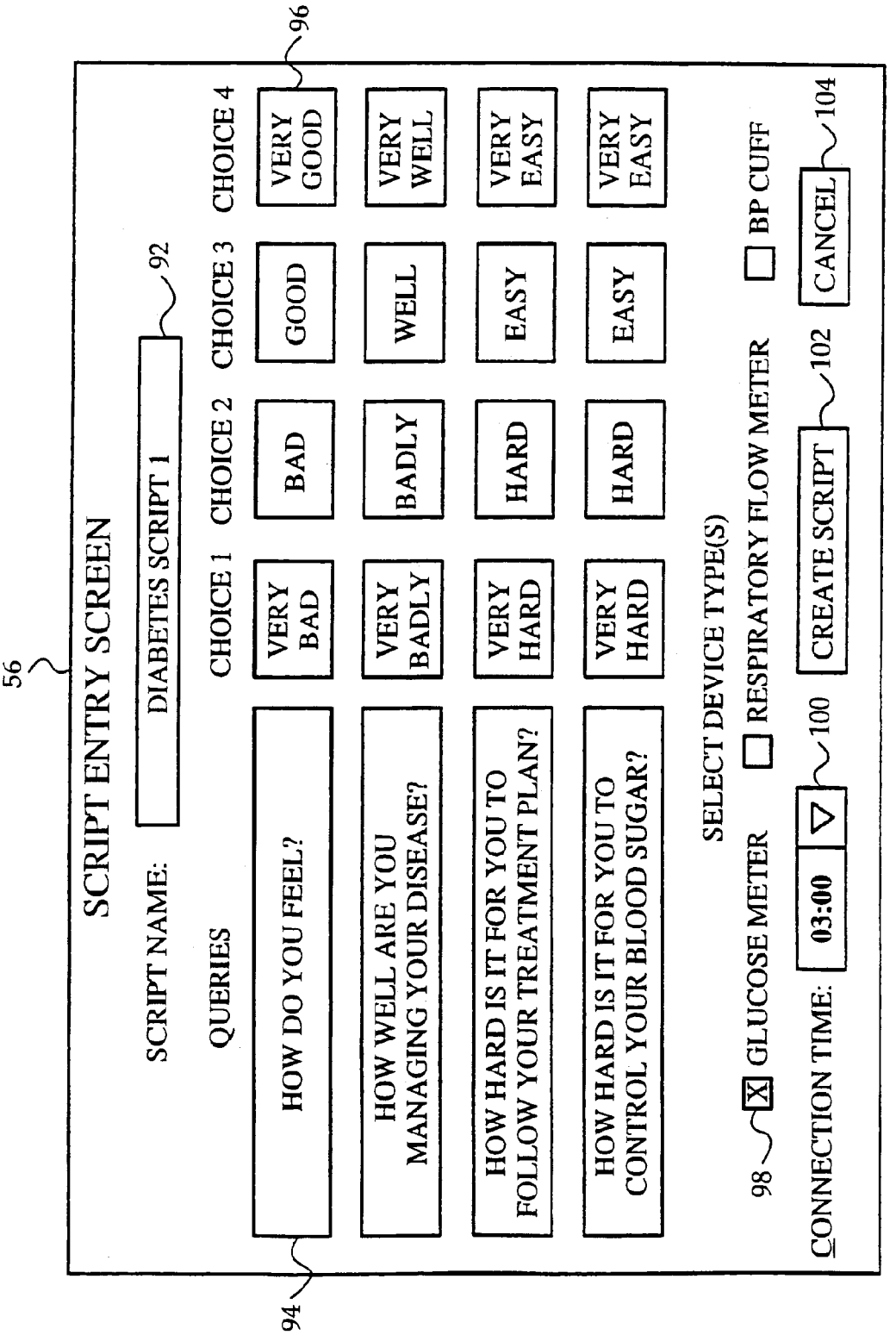

56
SCRIPT ENTRY SCREEN
SCRIPT NAME:
DIABETES SCRIPT 1
92
QUERIES
CHOICE 1
CHOICE 2
CHOICE 3
CHOICE 4
96
HOW DO YOU FEEL?
VERY BAD
BAD
GOOD
VERY GOOD
HOW WELL ARE YOU MANAGING YOUR DISEASE?
VERY BADLY
BADLY
WELL
VERY WELL
HOW HARD IS IT FOR YOU TO FOLLOW YOUR TREATMENT PLAN?
VERY HARD
HARD
EASY
VERY EASY
HOW HARD IS IT FOR YOU TO CONTROL YOUR BLOOD SUGAR?
VERY HARD
HARD
EASY
VERY EASY
94
SELECT DEVICE TYPE(S)
98
GLUCOSE METER
RESPIRATORY FLOW METER
BP CUFF
CONNECTION TIME:
03:00
100
CREATE SCRIPT
102
CANCEL
104

FIG. 5

```
NUMBER: 9001 {LF}                                          40
LED: 1 {LF}
ZAP: {LF}
CLS: {LF}
93  DISPLAY: ANSWER QUERIES NOW?
             PRESS ANY BUTTON TO START {LF}
    WAIT: {LF}
    CLS: {LF}
    DISPLAY: HOW DO YOU FEEL?

                  VERY                VERY
                   BAD   BAD   GOOD   GOOD {LF}
95  INPUT: OOOO {LF}
    CLS: {LF}
    DISPLAY: HOW WELL ARE YOU
             MANAGING YOUR DISEASE?
             VERY                      VERY
             WELL   BADLY  WELL        WELL {LF}
    INPUT: OOOO {LF}
    CLS: {LF}
    DISPLAY: HOW HARD IS IT FOR YOU TO
             FOLLOW YOUR TREATMENT PLAN?
             VERY                    VERY
             HARD   HARD   EASY      EASY {LF}
    INPUT: OOOO {LF}
    CLS: {LF}
    DISPLAY: HOW HARD IS IT FOR YOU TO
             CONTROL YOUR BLOOD SUGAR?
             VERY                    VERY
             HARD   HARD   EASY      EASY {LF}
```

FIG. 6A

INPUT: OOOO {LF}

CLS: {LF}

DISPLAY: CONNECT GLUCOSE METER
AND PRESS ANY BUTTON
WHEN FINISHED {LF}

WAIT: {LF}

CLS: {LF}

DISPLAY: COLLECTING MEASUREMENTS {LF}

97 ~ COLLECT: GLUCOSE_METER {LF}

CLS: {LF}

DISPLAY: CONNECT APPARATUS TO
TELEPHONE JACK AND
PRESS ANY BUTTON
WHEN FINISHED {LF}

WAIT: {LF}

LED: 0 {LF}

CLS: {LF}

DELAY: 03:00 {LF}

DISPLAY: CONNECTING TO SERVER {LF}

CONNECT: {LF}

{EOF}

FIG. 6B

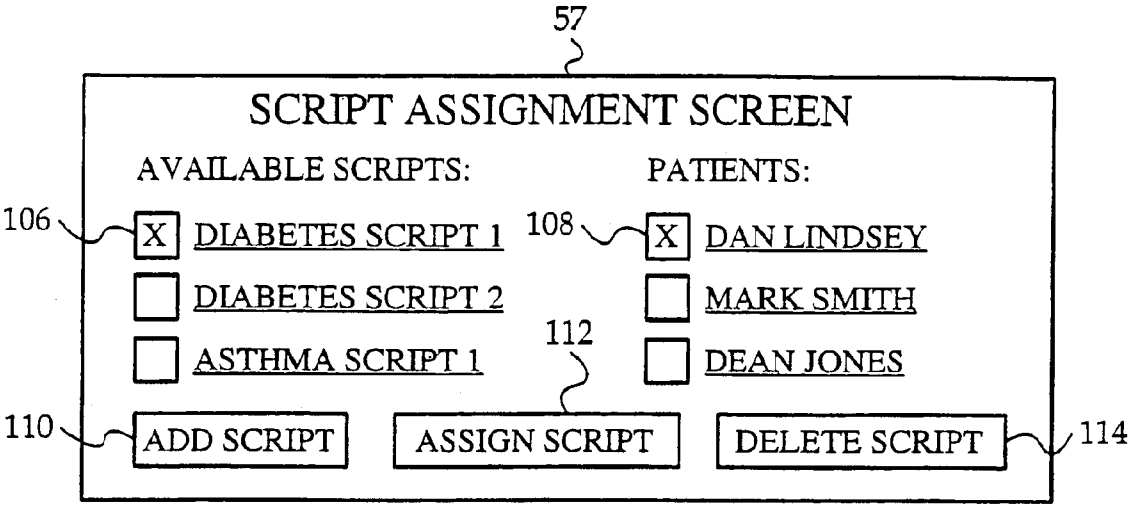


FIG. 7

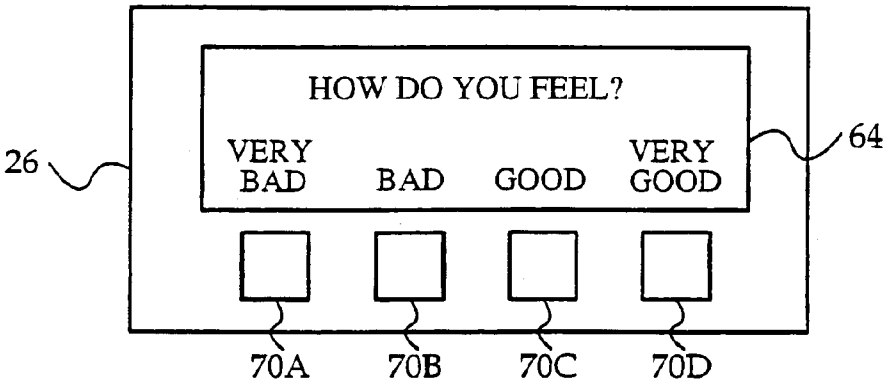


FIG. 8

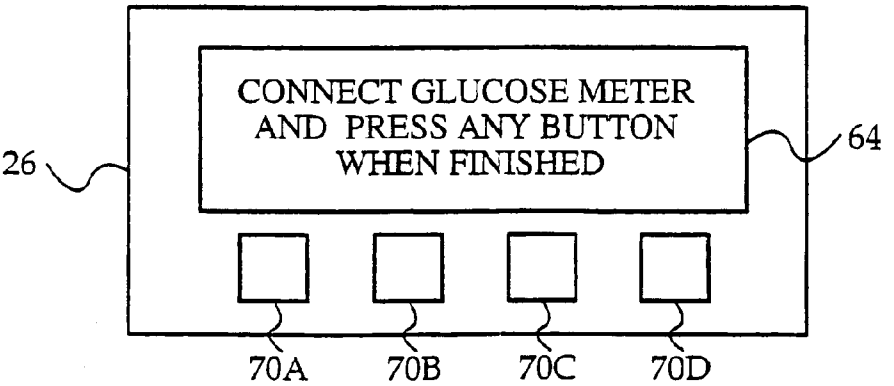


FIG. 9

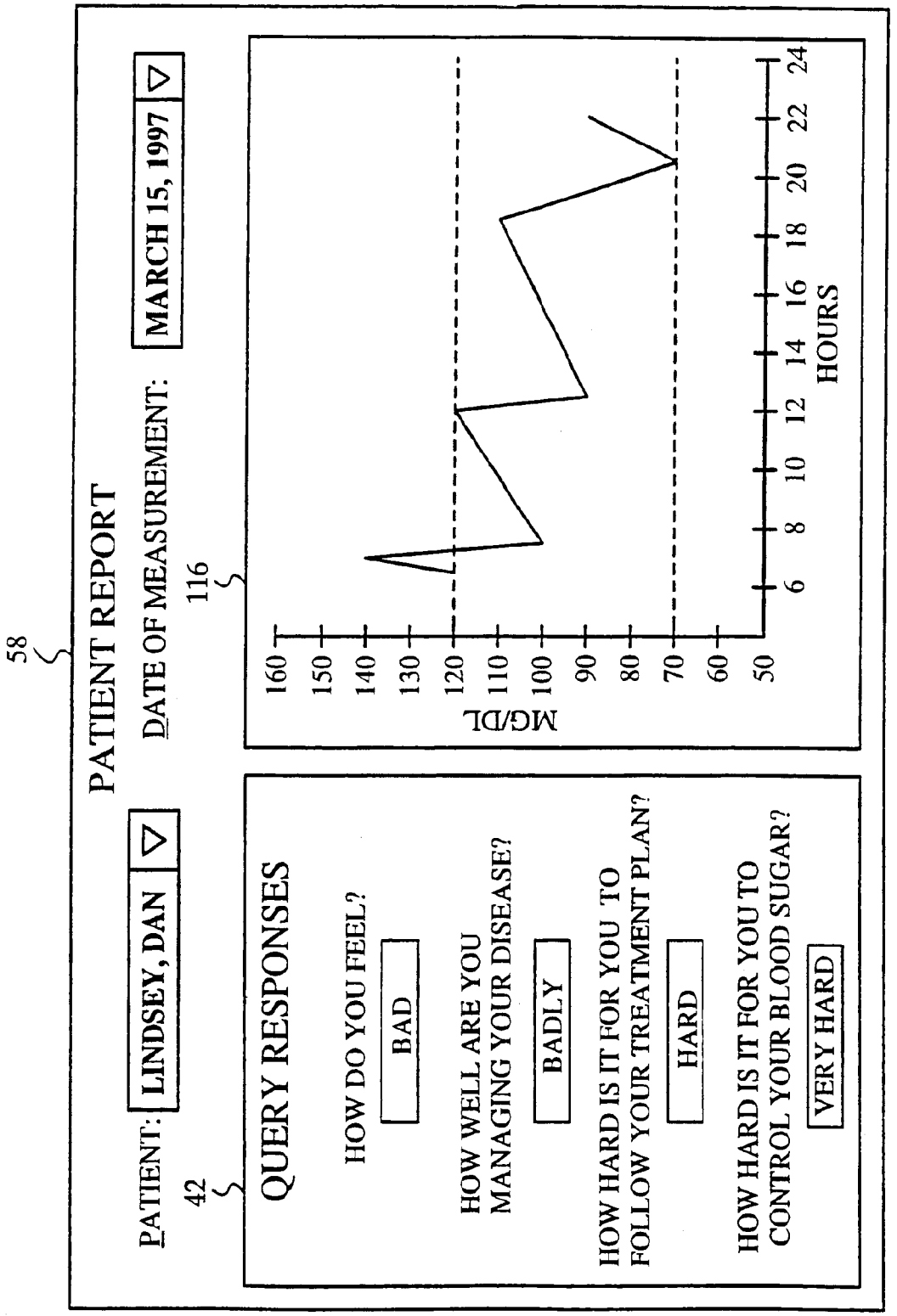

58
PATIENT REPORT
PATIENT: LINDSEY, DAN
DATE OF MEASUREMENT: MARCH 15, 1997
42
116
QUERY RESPONSES
HOW DO YOU FEEL?
BAD
HOW WELL ARE YOU MANAGING YOUR DISEASE?
BADLY
HOW HARD IS IT FOR YOU TO FOLLOW YOUR TREATMENT PLAN?
HARD
HOW HARD IS IT FOR YOU TO CONTROL YOUR BLOOD SUGAR?
VERY HARD
MG/DL
160
150
140
130
120
110
100
90
80
70
60
50
6
8
10
12
14
16
18
20
22
24
HOURS

FIG. 10

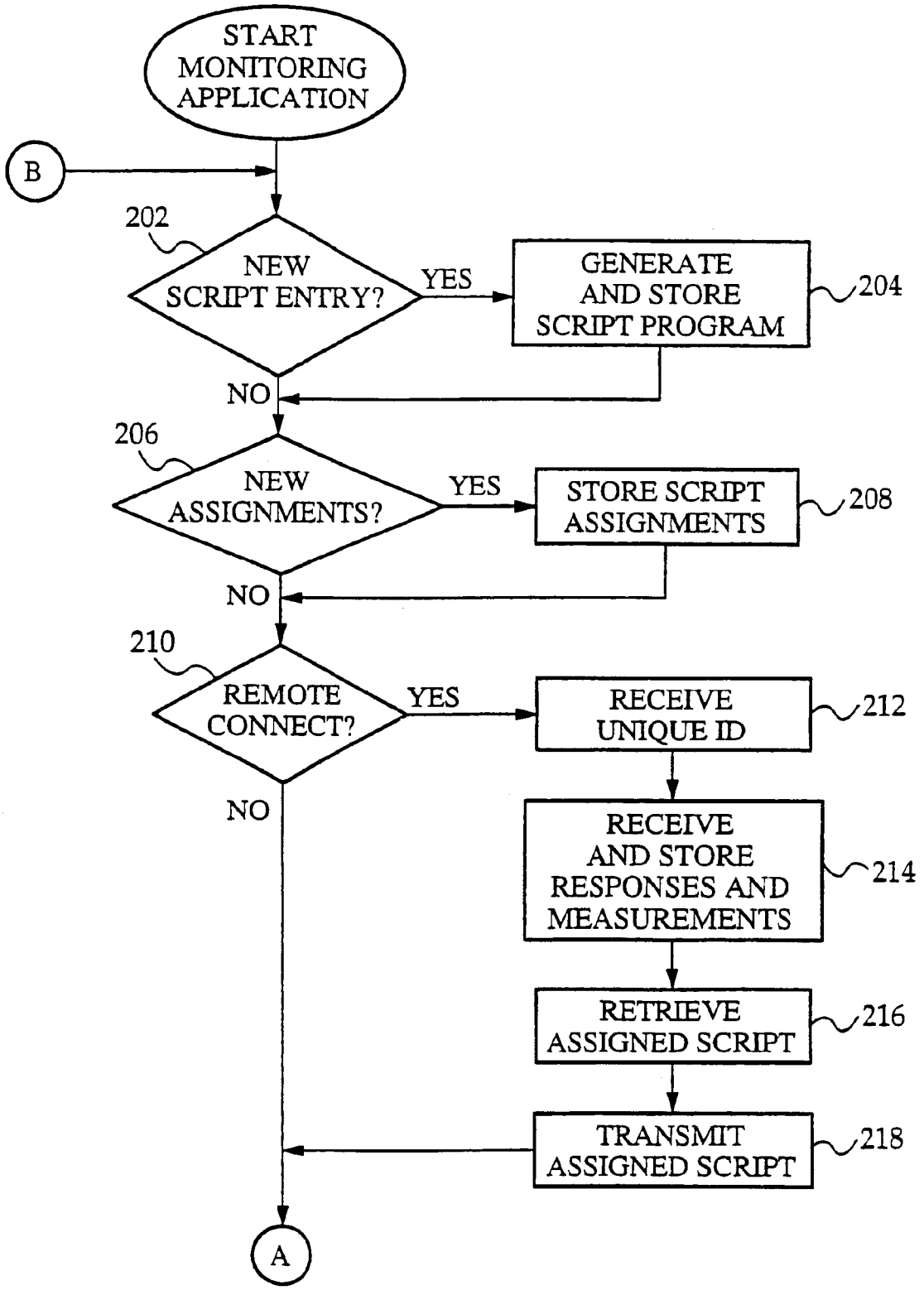

START MONITORING APPLICATION
B
202
NEW SCRIPT ENTRY?
YES
GENERATE AND STORE SCRIPT PROGRAM
204
NO
206
NEW ASSIGNMENTS?
YES
STORE SCRIPT ASSIGNMENTS
208
NO
210
REMOTE CONNECT?
YES
RECEIVE UNIQUE ID
212
NO
RECEIVE AND STORE RESPONSES AND MEASUREMENTS
214
RETRIEVE ASSIGNED SCRIPT
216
TRANSMIT ASSIGNED SCRIPT
218
A

FIG. 11A

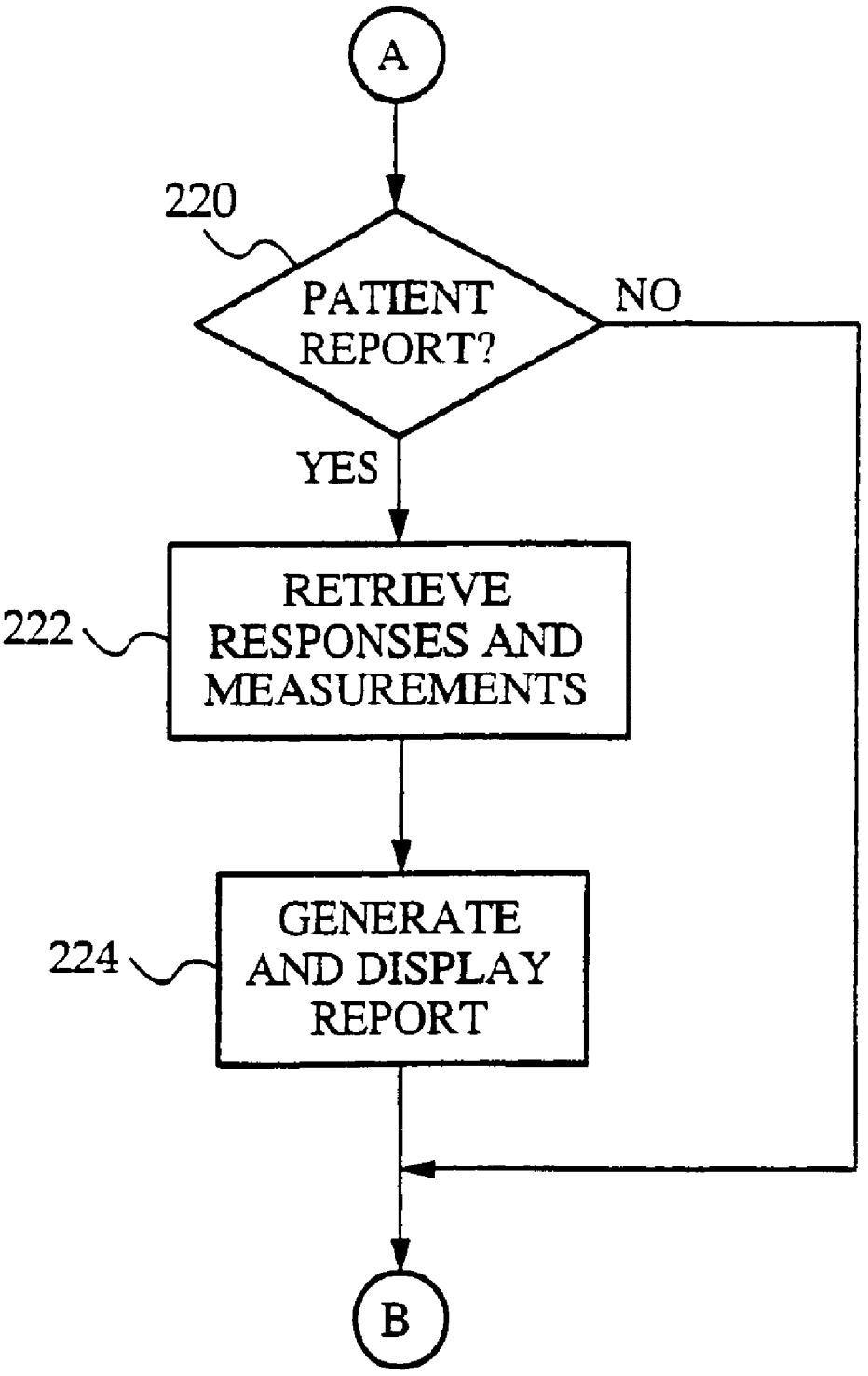

A
220
PATIENT REPORT?
NO
YES
222
RETRIEVE RESPONSES AND MEASUREMENTS
224
GENERATE AND DISPLAY REPORT
B

FIG. 11B

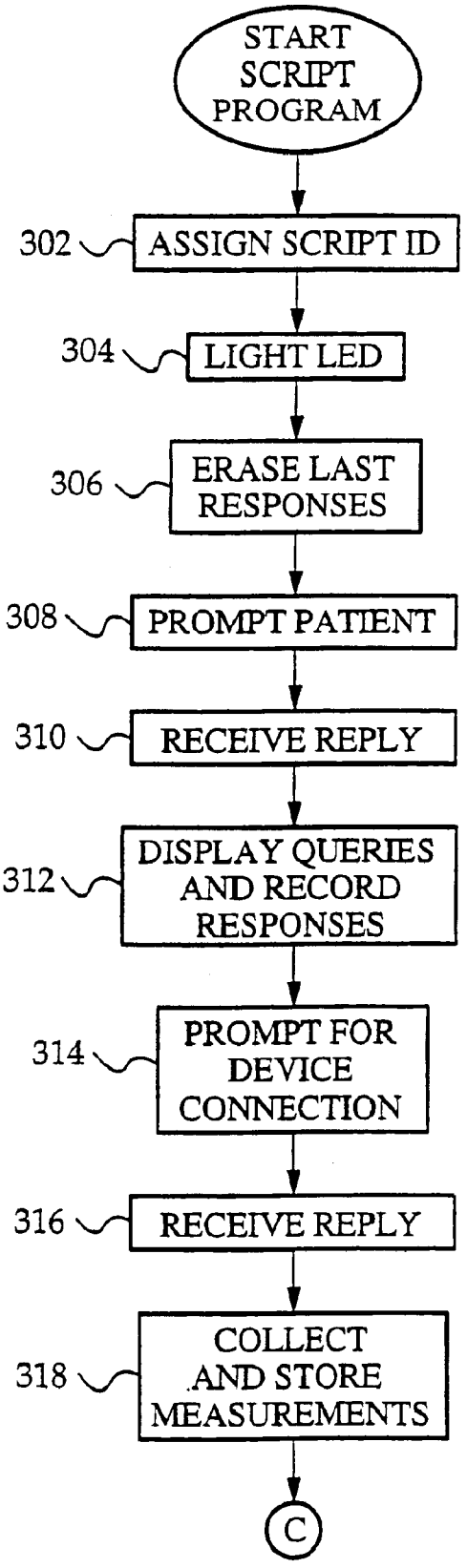

START SCRIPT PROGRAM
302
ASSIGN SCRIPT ID
304
LIGHT LED
306
ERASE LAST RESPONSES
308
PROMPT PATIENT
310
RECEIVE REPLY
312
DISPLAY QUERIES AND RECORD RESPONSES
314
PROMPT FOR DEVICE CONNECTION
316
RECEIVE REPLY
318
COLLECT AND STORE MEASUREMENTS
C

FIG. 12A

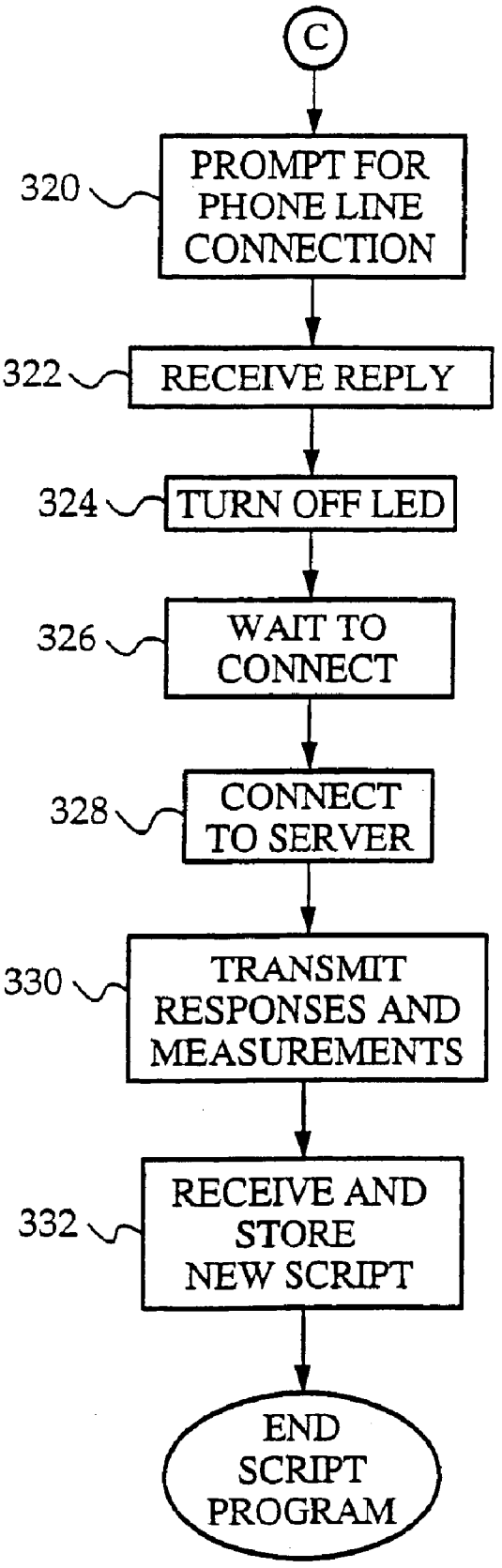

C
320
PROMPT FOR PHONE LINE CONNECTION
322
RECEIVE REPLY
324
TURN OFF LED
326
WAIT TO CONNECT
328
CONNECT TO SERVER
330
TRANSMIT RESPONSES AND MEASUREMENTS
332
RECEIVE AND STORE NEW SCRIPT
END SCRIPT PROGRAM

FIG. 12B

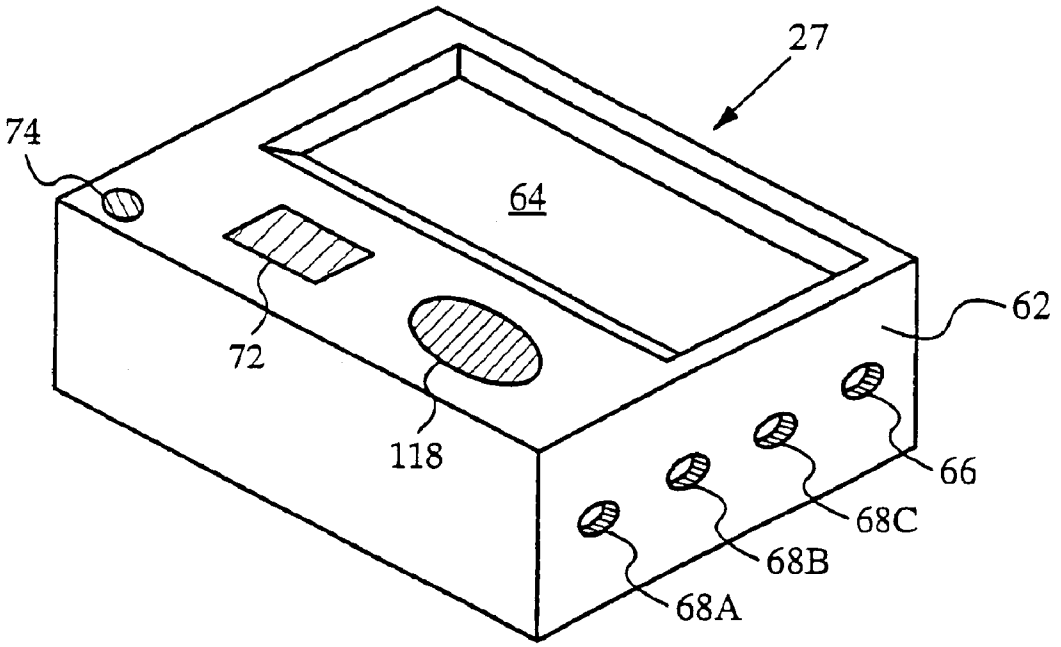

27
74
64
72
118
62
66
68C
68B
68A

FIG. 13

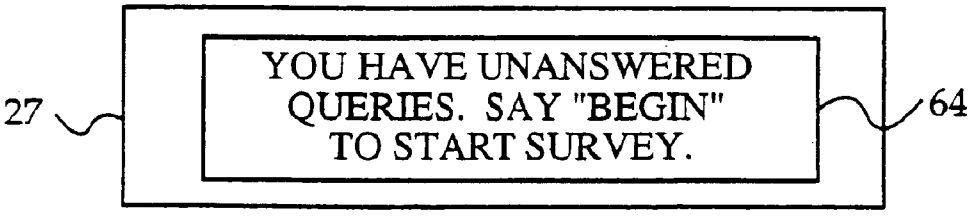

YOU HAVE UNANSWERED QUERIES. SAY "BEGIN" TO START SURVEY.
27
64

FIG. 14

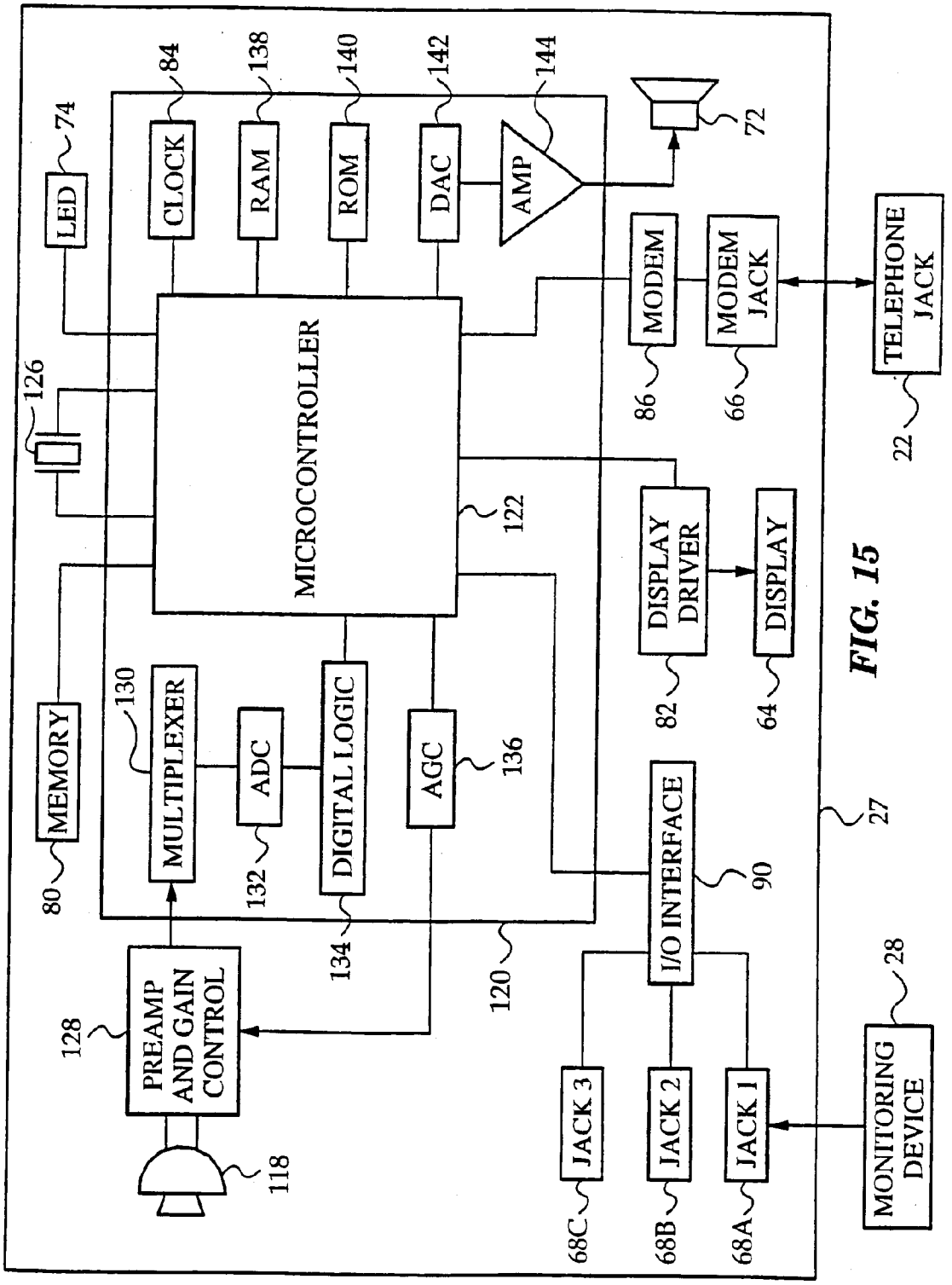

MICROCONTROLLER
LED
74
CLOCK
84
RAM
138
ROM
140
DAC
142
AMP
144
72
126
MODEM
86
MODEM JACK
66
TELEPHONE JACK
22
122
DISPLAY DRIVER
82
DISPLAY
64
MEMORY
80
MULTIPLEXER
130
ADC
132
DIGITAL LOGIC
134
AGC
136
I/O INTERFACE
90
27
PREAMP AND GAIN CONTROL
128
118
120
JACK 3
68C
JACK 2
68B
JACK 1
68A
MONITORING DEVICE
28

FIG. 15

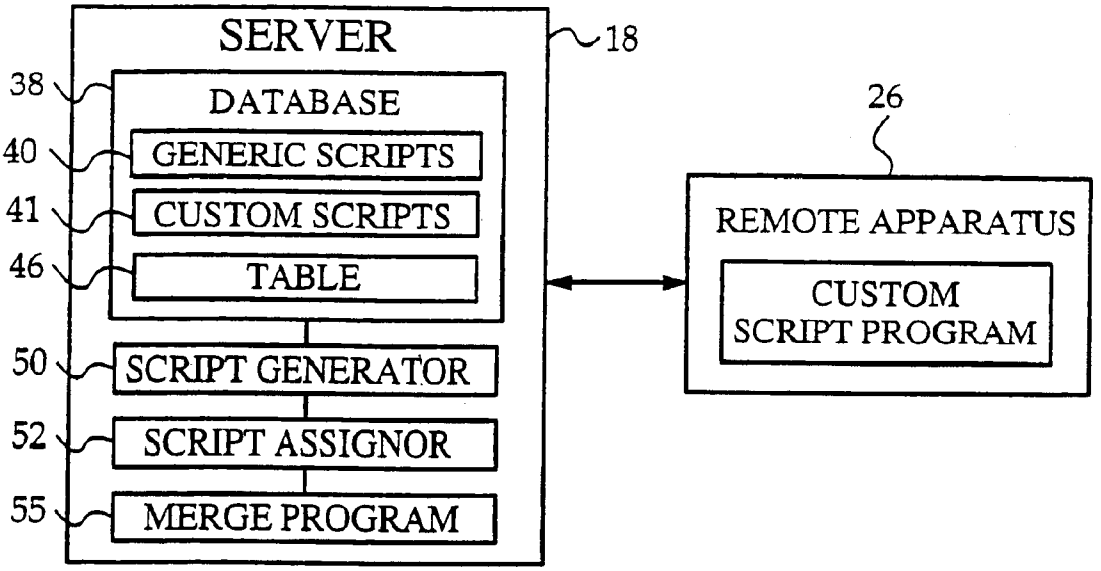


FIG. 16

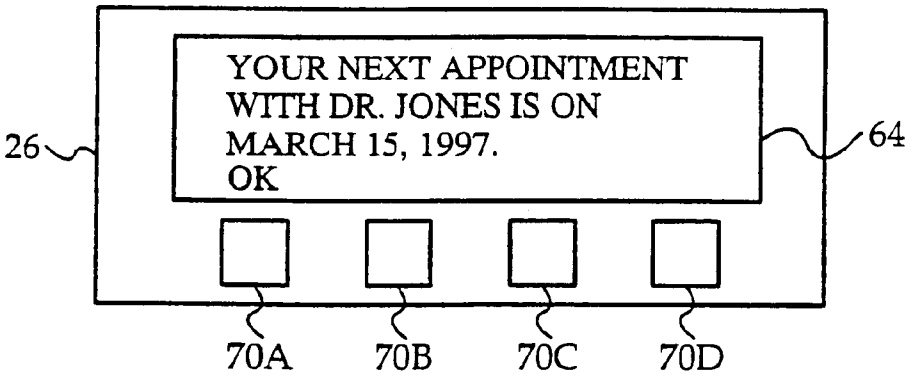


FIG. 17

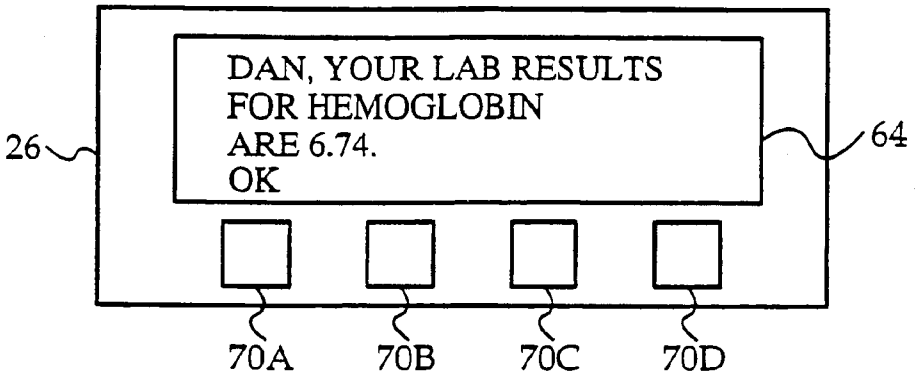


FIG. 18

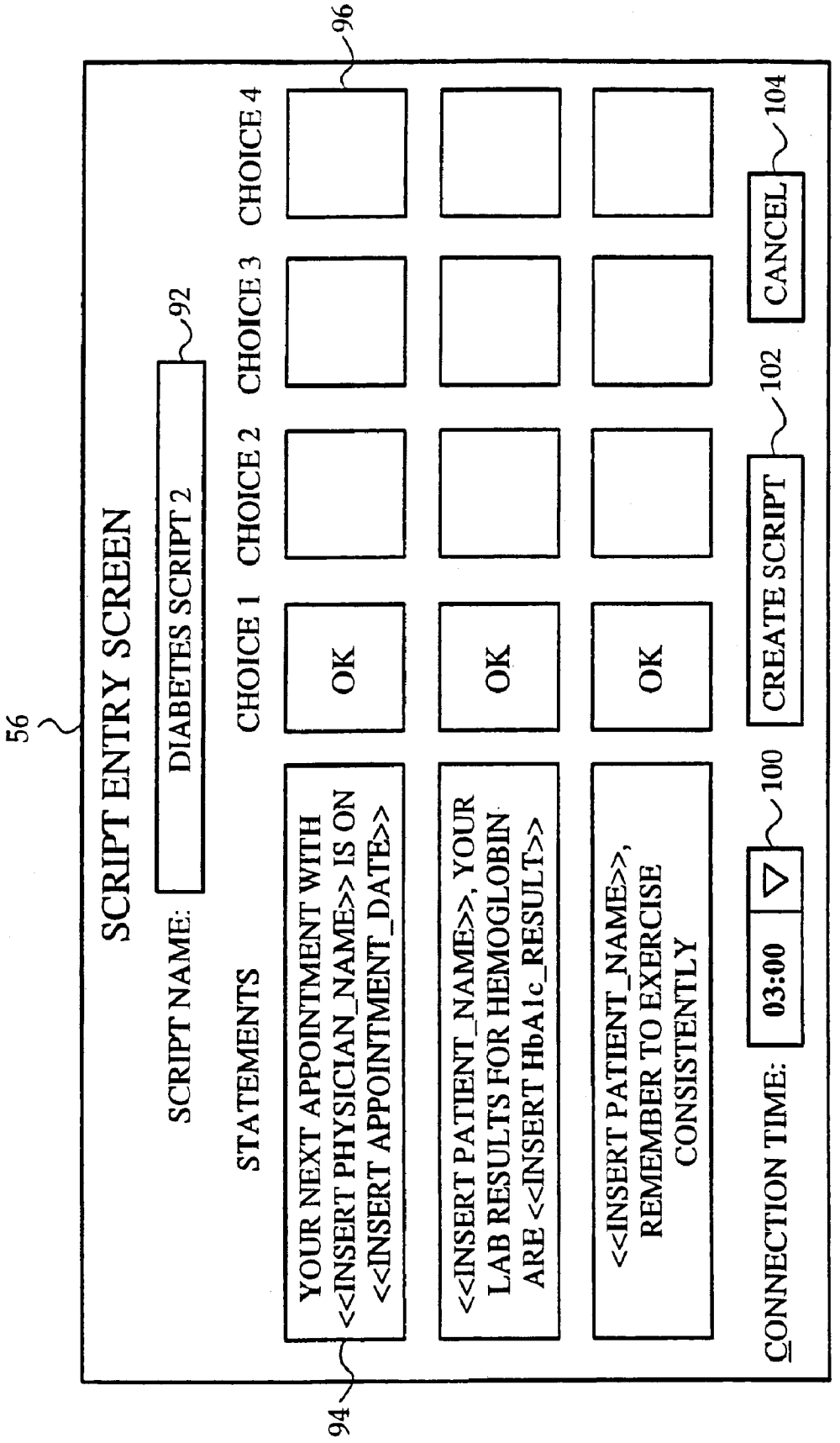

56
SCRIPT ENTRY SCREEN
SCRIPT NAME:
DIABETES SCRIPT 2
92
STATEMENTS
CHOICE 1
CHOICE 2
CHOICE 3
CHOICE 4
96
YOUR NEXT APPOINTMENT WITH <<INSERT PHYSICIAN_NAME>> IS ON <<INSERT APPOINTMENT_DATE>>
OK
<<INSERT PATIENT_NAME>>, YOUR LAB RESULTS FOR HEMOGLOBIN ARE <<INSERT HbA1c_RESULT>>
OK
<<INSERT PATIENT_NAME>>, REMEMBER TO EXERCISE CONSISTENTLY
OK
94
CONNECTION TIME:
03:00
100
CREATE SCRIPT
102
CANCEL
104

FIG. 19

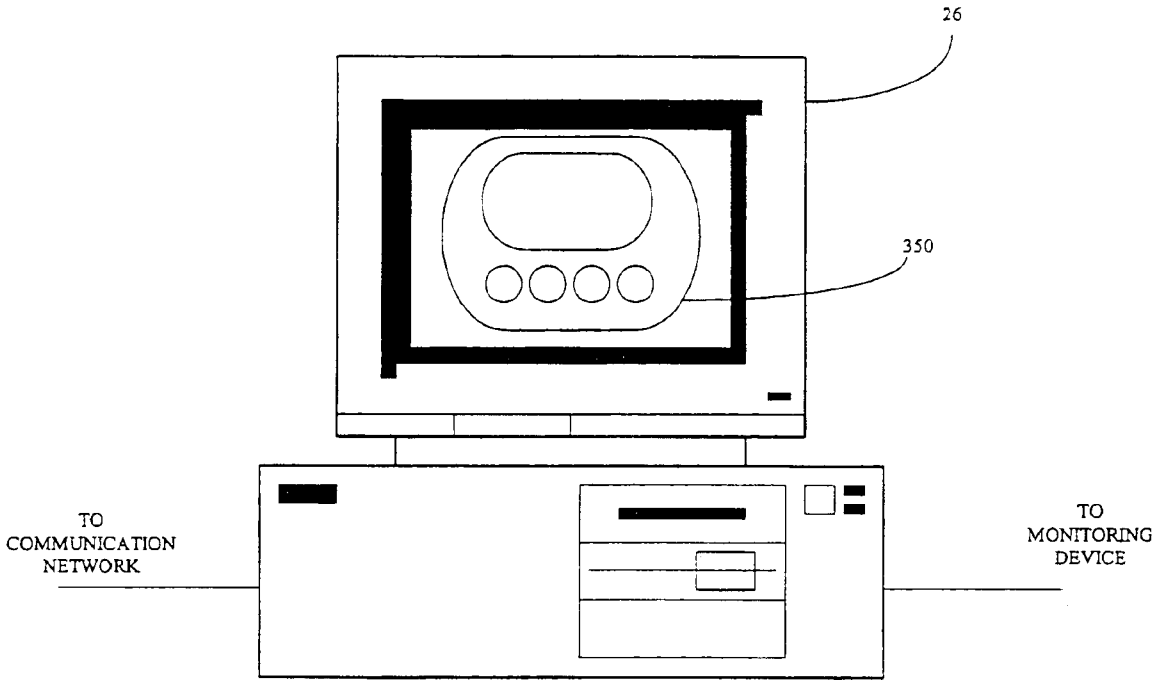


FIG. 20.

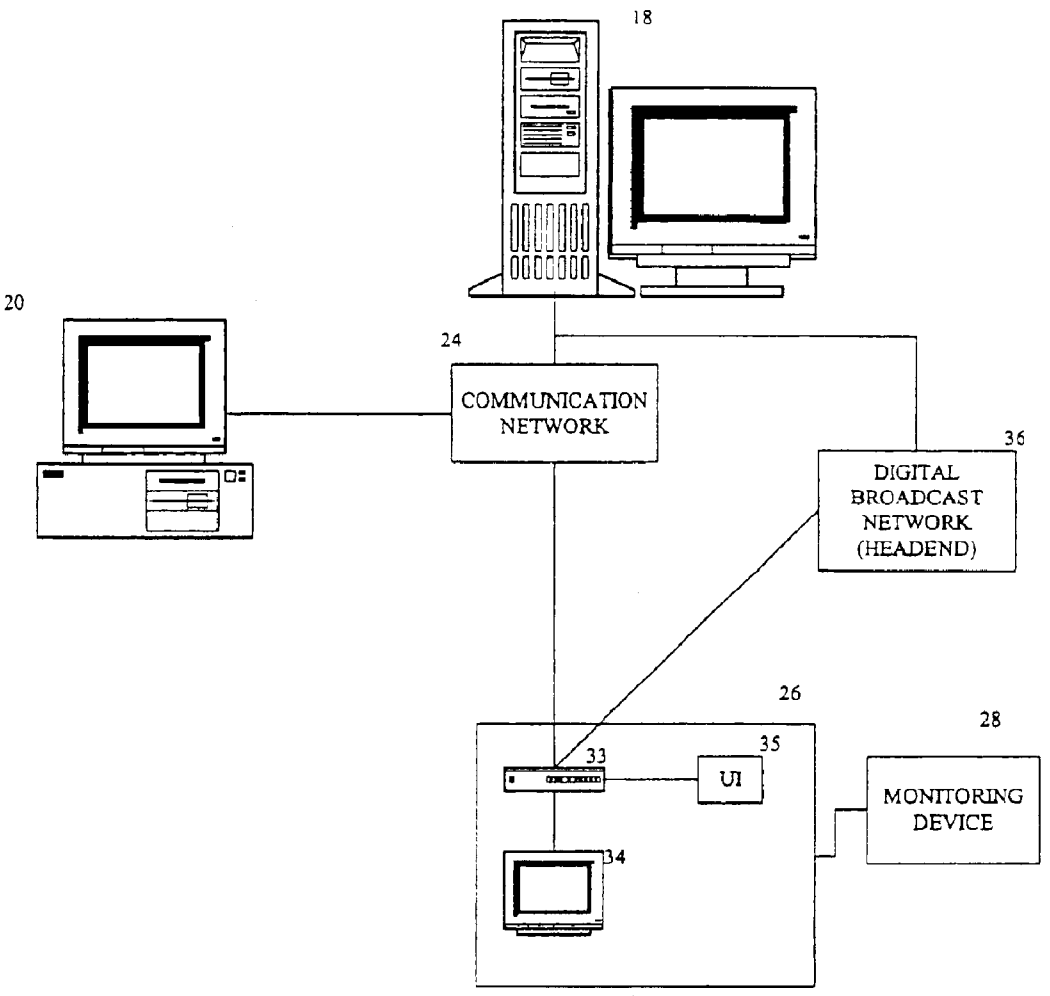

18
20
24
COMMUNICATION NETWORK
36
DIGITAL BROADCAST NETWORK (HEADEND)
26
28
33
35
UI
MONITORING DEVICE
34

FIG. 21.

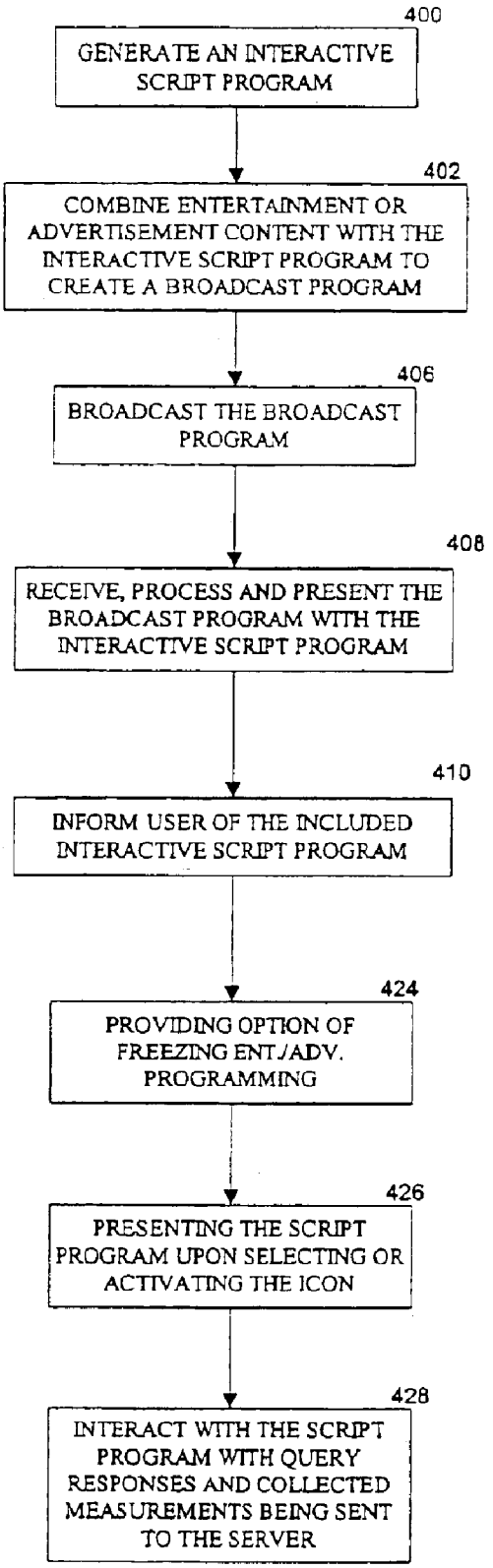

400
GENERATE AN INTERACTIVE SCRIPT PROGRAM
402
COMBINE ENTERTAINMENT OR ADVERTISEMENT CONTENT WITH THE INTERACTIVE SCRIPT PROGRAM TO CREATE A BROADCAST PROGRAM
406
BROADCAST THE BROADCAST PROGRAM
408
RECEIVE, PROCESS AND PRESENT THE BROADCAST PROGRAM WITH THE INTERACTIVE SCRIPT PROGRAM
410
INFORM USER OF THE INCLUDED INTERACTIVE SCRIPT PROGRAM
424
PROVIDING OPTION OF FREEZING ENT./ADV. PROGRAMMING
426
PRESENTING THE SCRIPT PROGRAM UPON SELECTING OR ACTIVATING THE ICON
428
INTERACT WITH THE SCRIPT PROGRAM WITH QUERY RESPONSES AND COLLECTED MEASUREMENTS BEING SENT TO THE SERVER

FIG. 22.

FIG. 23.

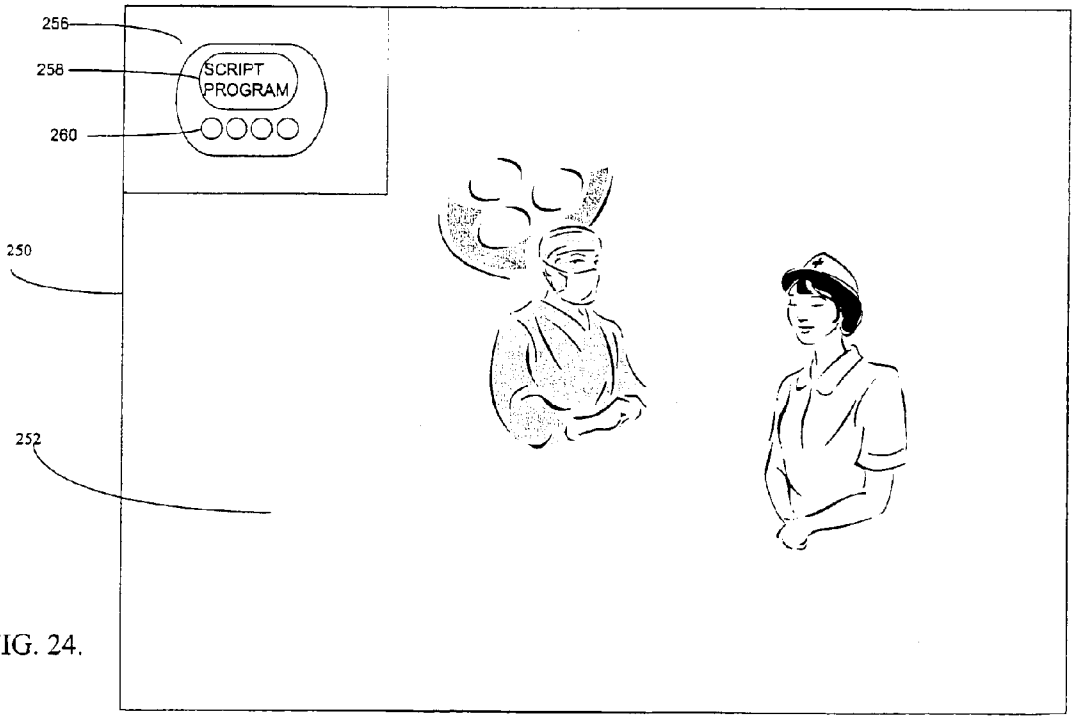


FIG. 24.

NETWORKED SYSTEM FOR INTERACTIVE COMMUNICATION AND REMOTE MONITORING OF INDIVIDUALS

PRIORITY CLAIM

This application is a continuation-in-part of U.S. application Ser. No. 09/300,856, filed Apr. 28, 1999, now U.S. Pat. No. 6,368,273, issued Apr. 9, 2002, which application is a divisional of U.S. application Ser. No. 08/946,341, filed Oct. 7, 1997, now U.S. Pat. No. 5,997,476, issued Dec. 7, 1999, which application is a continuation-in-part of U.S. application Ser. No. 08/847,009, filed Apr. 30, 1997, now U.S. Pat. No. 5,897,493, issued Apr. 27, 1999, which application claims priority from U.S. Provisional Application No. 60/041,746, filed Mar. 28, 1997 and from U.S. Provisional Application No. 60/041,751, filed Mar. 28, 1997.

RELATED APPLICATIONS

This application is also related to U.S. application Ser. No. 09/531,237 filed on Mar. 22, 2000, now abandoned, which is a continuation-in-part of U.S. Pat. No. 6,368,273 filed on Apr. 28, 1999 and issued on Apr. 9, 2002 which is a divisional of U.S. Pat. No. 5,997,476 filed on Oct. 7, 1997 and issued on Dec. 07, 1999, which is a continuation-in-part of U.S. Pat. No. 5,897,493 filed on Apr. 30, 1997 and issued on Apr. 27, 1999. This application is also related to U.S. Pat. No. 6,270,455 filed on Nov. 30, 1998 and issued on Aug. 7, 2001, which is a continuation-in-part of U.S. Pat. No. 5,997,476 filed on Oct. 7, 1997 and issued on Dec. 07, 1999.

This application is also related to U.S. application Ser. No. 09/665,442 filed on Sep. 19, 2000 which is a continuation-in-part of U.S. Pat. No. 6,381,577 filed on Mar. 2, 2000 and issued on Apr. 30, 2002 which is related to U.S. Pat. No. 6,101,478 filed on Nov. 21, 1997 and issued on Aug. 8, 2000 which is a continuation-in-part of U.S. Pat. No. 5,897,493 filed on Apr. 30, 1997 and issued Apr. 27, 1999.

This application is also related to U.S. application Ser. No. 09/378,188 filed on Aug. 20, 1999, now abandoned, which relates to U.S. Pat. No. 6,101,478 filed on Nov. 21, 1997 and issued Aug. 8, 2000. U.S. application Ser. No. 09/378,188 is also related to U.S. Pat. No. 5,985,559 filed on May 3, 1997 and issued Nov. 16, 1999, which is a continuation-in-part of U.S. Pat. No. 5,897,493 filed on Apr. 30, 1997 and issued on Apr. 27, 1999.

This application also relates to U.S. Pat. No. 6,248,065 filed on Jan. 19, 1999 and issued on Jun. 19, 2001, which is a divisional application of U.S. Pat. No. 5,897,493 filed on Apr. 30,1997 and issued on Apr. 27, 1999.

This application is also related to U.S. application Ser. No. 10/279,749 filed on Oct. 23, 2002 which is related to U.S. application Ser. No. 10/233,296 filed on Aug. 30, 2002 which is related to U.S. application Ser. No. 09/713,922 filed on Aug. 15, 2000 which is a continuation-in-part of U.S. Pat. No. 6,381,577 filed on Mar. 2, 2000 and issued on Apr. 30, 2002.

This application is also related to U.S. application Ser. No. 10/233,296 filed on Aug. 30, 2002.

This application is also related to U.S. application Ser. No. 09/422,046 filed on Oct. 20, 1999 which claims priority from U.S. Pat. No. 6,168,563 filed on Mar. 27, 1999 and issued on Jan. 2, 2001, which is a continuation-in-part of U.S. Pat. No. 5,899,855 filed on Jun. 7, 1995 and issued on May 5, 1999.

FIELD OF THE INVENTION

The present invention relates generally to communication systems for remote monitoring of individuals, and in particular to a networked system for remotely monitoring individuals and for communicating information to the individuals through the use of script programs.

BACKGROUND OF THE INVENTION

In the United States alone; over 100 million people have chronic health conditions, accounting for an estimated $700 billion in annual medical costs. In an effort to control these medical costs, many healthcare providers have initiated outpatient or home healthcare programs for their patients. The potential benefits of these programs are particularly great for chronically ill patients who must treat their diseases on a daily basis. However, the success of these programs is dependent upon the ability of the healthcare providers to monitor the patients remotely to avert medical problems before they become complicated and costly. Further, success requires compliance with the program, which is often dependent on providing messages or other reminders to patients so that they will stay with the program. Unfortunately, no convenient and cost effective monitoring system exists to accomplish these objectives. While these problems are particularly acute for the poor and the elderly, all demographic groups could significantly benefit from remote communication and monitoring systems.

Prior attempts to monitor patients remotely have included the use of personal computers and modems to establish communication between patients and healthcare providers, either directly or via an Internet site. However, computers are too expensive to give away and the patients who already own computers are only a fraction of the total population.

Other attempts to monitor patients remotely have included the use of medical monitoring devices with built-in modems. Examples of such monitoring devices include blood glucose meters, respiratory flow meters, and heart rate monitors. While these devices can be quite successful, their multimedia capabilities arc often limited. In addition, many patients simply may prefer to interact with a device they are more familiar with, such as a television.

Prior attempts to monitor patients remotely have also included the use of interactive telephone or video response systems. Such interactive systems are disclosed in U.S. Pat. No. 5,39.0,238 issued to Kirk et al. on Feb. 14, 1995, U.S. Pat. No. 5,434,611 issued to Tamura on Jul. 18, 1995, and U.S. Pat. No. 5,441,047 issued to David et al. on Aug. 15, 1995. One disadvantage of these systems is that they either require a patient to call in to a central facility to be monitored or require the central facility to call the patient according to a rigid monitoring schedule.

If the patients are required to call the central facility, only the compliant patients will actually call regularly to be monitored. Non-compliant patients will typically wait until an emergency situation develops before contacting their healthcare provider, thus defeating the purpose of the monitoring system. If the central facility calls each patient according to a monitoring schedule, it is intrusive to the patient's life and resistance to the monitoring grows over time. Further, it is difficult to identify each patient uniquely using these systems. Moreover, these systems are generally incapable of collecting medical data from monitoring devices, such as blood glucose meters, respiratory flow meters, or heart rate monitors.

As such, there exists a need for a simple and inexpensive system for remotely monitoring patients and for easily communicating information to the patients. There is also a need to encourage patient's compliance with a prescribed treatment plan.

SUMMARY

The present invention provides a system for remotely interacting with an individual. The system includes a server, a remote interface device for assigning in the server a set of queries to be answered by the individual, a remotely programmable apparatus for interacting with the individual and a broadcaster in communication with the server and the remotely programmable apparatus.

By using the entertainment medium of interactive television with its ability to receive a large bandwidth of data, the present invention can more easily communicate interactive entertaining/educational information to potential and existing patients. The interactive nature of the received data makes it easy for a user to access interactive programs related to corresponding entertainment/advertisement content or related to user adherence to a predefined regimen.

In accordance with another aspect of the present invention, an answering service sends a series of questions as voice communication from a stored set of questions to the remote apparatus for the individual to respond to, when the voice communication button is activated. The answering service stores responses to each provided question in the series of questions and provides a service based on the individual's response to the questions. The provided service is communication with a health care professional or a service provider. Also, the answering service includes a speech recognition component for receiving spoken responses to the series of questions and a speech synthesis component for making the set of queries into a series of questions.

In accordance with yet another aspect of the present invention, the remotely programmable apparatus includes an appliance component for providing appliance functionality. The appliance component is an alarm clock, a kitchen appliance, or an entertainment device.

In accordance with still another aspect of the present invention, the remotely programmable apparatus includes a monitoring component for producing measurements of a physiological condition of the individual.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same becomes better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIG. **1** is a block diagram of networked system formed in accordance with a first embodiment of the present invention;

FIG. **2** is a block diagram illustrating the interaction of the components of the system of FIG. **1**;

FIG. **3** is a perspective view of a remotely programmable apparatus of the system of FIG. **1**;

FIG. **4** is a block diagram illustrating the components of the apparatus of FIG. **3**;

FIG. **5** is a script entry screen according to the preferred embodiment of the invention;

FIG. **6**A is a listing of a sample script program according to the preferred embodiment of the invention;

FIG. **6**B is a continuation of the listing of FIG. **6**A;

FIG. **7** is a script assignment screen according to the preferred embodiment of the invention

FIG. **8** is a sample query appearing on the apparatus of FIGS. **1**A–D;

FIG. **9** is a sample prompt appearing on the display of the apparatus of FIG. **3**;

FIG. **10** is a sample report displayed on a workstation of the system of FIGS. **1**A–D;

FIG. **11**A is a flow chart illustrating the steps included in a monitoring application executed by the server of FIGS. **1**A–D according to the present invention;

FIG. **11**B is a continuation of the flow chart of FIG. **11**A

FIG. **12**A is a flow chart illustrating the steps included in the script program of FIGS. **6**A–**6**B;

FIG. **12**B is a continuation of the flow chart of FIG. **12**;

FIG. **13** is a perspective view of a remotely programmable apparatus according to an embodiment of the present invention;

FIG. **14** is a sample prompt appearing on a display of the apparatus of FIG. **13**;

FIG. **15** is a block diagram illustrating the components of the apparatus of FIG. **13**;

FIG. **16** is a schematic block diagram illustrating the interaction of the server of FIGS. **1**A–D with the apparatus of FIG. **3** according to another embodiment of the present invention;

FIG. **17** is a first sample message appearing on the display of the apparatus of FIG. **3**;

FIG. **18** is a second sample message appearing on the display of the apparatus of FIG. **3**;

FIG. **19** is a script entry screen according to an embodiment of the present invention;

FIGS. **20** and **21** are block diagrams of alternate embodiments of the present invention;

FIG. **22** is a flow chart illustrating the process performed by the system of FIGS. **21**; and

FIGS. **23** and **24** are example broadcast programming presentations with an included script program.

DETAILED DESCRIPTION

The present invention provides a system and method for remotely monitoring individuals and for increasing individual use of health programs. In a first embodiment of the invention, the individuals are patients and the system is used to collect data relating to the health status of the patients. However, it is to be understood that the invention is not limited to remote monitoring of patients. The system and method of the invention may be used for any type of remote monitoring and program adherence application. The invention may also be implemented as an automated messaging system for communicating information to individuals, as will be discussed in an alternative embodiment below.

A first embodiment of the invention is illustrated in FIGS. **1**A and **2**–**12**. Referring to FIG. **1**, a networked system **16** includes a server **18** and a workstation **20** connected to the **30** server **18** through a communication network **24**. The server **18** is preferably a world wide web server and the communication network **24** is preferably the Internet. It will be apparent to one skilled in the art that the server **18** may comprise a single stand-alone computer or multiple computers distributed throughout a network. The workstation **20** is preferably a personal computer, remote terminal, or web TV unit connected to the server **18** via the Internet. The workstation **20** functions as a remote interface for entering in the server **18** messages and queries to be communicated to the patients.

The system **16** also includes multiple remotely programmable apparatus, such as first and second apparatuses **26** for monitoring multiple patients. Each apparatus **26** is designed to interact with a patient in accordance with script programs

received from the server **18**. Each apparatus **26** is in communication with the server **18** through the communication network **24**, preferably the Internet. Alternatively, each apparatus **26** may be placed in communication with the server **18** via wireless communication networks, cellular networks, telephone networks, satellite networks or any other network which allows each apparatus **26** to exchange data with the server **18**. It is to be understood that the system **16** may include any number of remotely programmable apparatuses for monitoring any number of patients.

In the preferred embodiment, each patient to be monitored is also provided with a monitoring device **28**. The monitoring device **28** is designed to produce measurements of a physiological condition of the patient, record the measurements, and transmit the measurements to the patient's remotely programmable apparatus through a standard connection cable **30**. Examples of suitable monitoring devices **28** include blood glucose meters, respiratory flow meters, blood pressure cuffs, electronic weight scales, and pulse rate monitors. Such monitoring devices are well known in the art. The specific type of monitoring device **28** provided to each patient is dependent upon the patient's disease or health treatment needs. For example, diabetes patients are provided with a blood glucose meter for measuring blood glucose concentrations, asthma patients are provided with respiratory flow meters for measuring peak flow rates, obesity patients are provided with weight scales, etc.

FIG. **2** shows the server **18**, the workstation **20**, and the apparatus **26** in greater detail. The server **18** includes a database **38** for storing programs **40**. The script programs **40** are executed by each apparatus **26**, to communicate queries and messages to a patient, receive responses **42** to the queries, collect monitoring device measurements **44**, and to transmit responses **42** and measurements **44** to the server **18**. The database **38** is designed to store responses **42** and measurements **44**. The database **38** further includes a look-up table **46**. The table **46** contains a list of the patients to be monitored, and for each patient, a unique patient identification code and a respective pointer to one or more script programs **40** assigned to the patient. Each remotely programmable apparatus **26** is designed to execute assigned script programs **40** received from the server **18**. The script programs **40** may include queries, reminder messages, informational statements, useful quotations, or other information of benefit to the patient. See Appendix A for example script programs.

FIGS. **3–4** show the structure of a remotely programmable apparatus **26** according to the preferred embodiment. Referring to FIG. **3**, the apparatus **26** includes a housing **62**. The housing **62** is sufficiently compact to enable the apparatus **26** to be hand-held and carried by a patient. The apparatus **26** also includes a display **64** for displaying queries and prompts to the patient. In the preferred embodiment, the display **64** is a liquid crystal display (LCD).

The apparatus **26** includes five user input buttons **70**A, **70**B, **70**C, **70**D and **70**E that are located on the same side of the apparatus **26** as the display **64**. The user input buttons **70**A–D are for entering in the apparatus **26** responses **42** to the queries and prompts. In the preferred embodiment, the user input buttons **70**A–D are momentary contact push buttons. In alternative embodiments, user input buttons **70**A–D may be replaced by switches, keys, a touch sensitive display screen, or any other data input device.

The user input button **70**E is a emergency or other services button and is preferably red, but may be of any size, shape, or color that draws special visual or tactile attention to the user. The services provided by the user input button **70**E are described in more detail below.

Three monitoring device jacks **68**A, **68**B, and **68**C are located on a surface of housing **62**. The device jacks **68**A–C are for connecting the apparatus **26** to a number of monitoring devices **28**, such as blood glucose meters, respiratory flow meters, or blood pressure cuffs (not shown in FIG. **3**). The apparatus **26** also includes a modem jack **66** for connecting the apparatus **26** to a telephone jack through a standard connection cord (not shown). The apparatus **26** further includes a visual indicator, such as a light emitting diode (LED) **74**. The LED **74** is for visually notifying the patient that he or she has unanswered queries stored in the apparatus **26**.

FIG. **4** is a schematic block diagram illustrating the components of the apparatus **26** in greater detail. The apparatus **26** includes a microprocessor **76** and a memory **80** connected to the microprocessor **76**. The memory **80** is preferably a non-volatile memory, such as a serial EEPROM. The memory **80** stores script programs **40** received from the server **18**, measurements **44** received from the monitoring device **28**, responses **42** to queries. The microprocessor **76** also includes built-in read only memory (ROM), which stores firmware for controlling the operation of the apparatus **26**. The firmware includes a script interpreter used by the microprocessor **76** to execute the script programs **40**. The script interpreter interprets script commands, which are executed by the microprocessor **76**. Specific techniques for interpreting and executing script commands in this manner are well known in the art.

The microprocessor **76** is preferably connected to memory **80** using a standard two-wire interface. The microprocessor **76** is also connected to the user input buttons **70**, the LED **74**, a clock **84**, and a display driver **82**. The clock **84** indicates the current date and time to the microprocessor **76**. For clarity of illustration, clock **84** is shown as a separate component, but is preferably built into the microprocessor **76**. The display driver **82** operates under the control of the microprocessor **76** to display information on the display **64**. The microprocessor **76** is preferably a PIC 16C65 processor. The modem **86** is connected to a telephone jack **22** through the modem jack **66**. The modem **86** is for exchanging data between the server **18** and the processor **76** through the communication network **24**. The data includes the script programs **40** which are received from the server **18** as well as the responses **42** to queries, the device measurements **44**, the script identification codes, and the patient's unique identification code, which the modem **86** transmits to the server **18**. The modem **86** is preferably a complete 28.8 K modem commercially available from Cermetek, although any suitable modem may be used. The processor **76** also includes a component that connects to the telephone jack **22** and a microphone **88** and a speaker **89**, thereby allowing telephone calls to be processed.

The device interface **90** is connected to the device jacks **68**A, **68**B, and **68**C. The device interface **90** is for interfacing with a number of monitoring devices **28**, such as blood glucose meters, respiratory flow meters, blood pressure cuffs, weight scales, or pulse rate monitors; through device jacks **68**A–C.

The device interface **90** operates under the control of the microprocessor **76** to collect measurements **44** from the monitoring devices **28** and to output the measurements to the microprocessor **76** for storage in the memory **80**. In the preferred embodiment, the interface **90** is a standard RS232

interface. For simplicity of illustration, only one device interface **90** is shown in FIG. **4**. However, in alternative embodiments, the apparatus **26** may include multiple device interfaces to accommodate monitoring devices that have different connection standards.

Referring again to FIG. **2**, the server **18** includes a monitoring application **48**. The monitoring application **48** is a controlling software application executed by the server **18** to perform the various functions described below. The application **48** includes a script generator **50**, a script assignor **52**, and a report generator **54**. The script generator **50** is designed to generate the script programs **40** from script information entered through the workstation **20**. The script information is entered through a script entry screen **56**. In the preferred embodiment, script entry screen **56** is implemented as a web page on the server **18**. The workstation **20** includes a web browser for accessing the web page to enter the script information.

FIG. **5** illustrates the script entry screen **56** as it appears on the workstation **20**. The screen **56** includes a script name field **92** for specifying the name of a script program to be generated. The screen **56** also includes entry fields **94** for entering a set of queries to be answered by a patient. Each entry field **94** has corresponding response choice fields **96** for entering response choices for the query. The screen **56** further includes check boxes **98** for selecting a desired monitoring device **28**, such as a blood glucose meter, respiratory flow meter, or blood pressure cuff, from which to collect measurements **44**.

The screen **56** additionally includes a connection time field **100** for specifying a prescribed connection time at which each apparatus **26** executing the script is to establish a subsequent communication link to the server **18**. The connection time is preferably selected to be the time at which communication rates are the lowest, such as 3:00 AM. The screen **56** also includes a CREATE SCRIPT button **102** for instructing script generator **50** to generate a script program **40** from the information entered in screen **56**. The screen **56** further includes a CANCEL button **104** for canceling the information entered in screen **56**.

In the preferred embodiment, each script program **40** created by script generator **50** conforms to the standard file format used on UNIX systems. In the standard file format, each command is listed in the upper case and followed by a colon. Every line in the script program **40** is terminated by a linefeed character {LF}, and only one command is placed on each line. The last character in the script program **40** is a UNIX end of file character {EOF}. Table 1 shows an exemplary listing of script commands used in the preferred embodiment of the invention.

TABLE 1

SCRIPT COMMANDS	Command Description
CLS: {LF}	Clear the display.
ZAP: {LF}	Erase from memory the last set of query responses recorded.
LED: b{LF}	Turn the LED on or off, where b is a binary digit of 0 or 1. An argument of 1 turns on t0he LED, and an argument of 0 turns off the LED.
DISPLAY: {chars} {LF}	Display the text following the DISPLAY command.
INPUT: mmmm{LF}	Record a button press. The m's represent a button mask pattern for each of the four input buttons. Each m contains an "X" for disallowed buttons or an "O" for allowed buttons. For example, INPUT: OXOX{LF} allows the user to press either button #1 or #3.

TABLE 1-continued

SCRIPT COMMANDS	Command Description
WAIT: {LF}	Wait for any one button to be pressed, then continue executing the script program.
COLLECT: device{LF}	Collect measurements from the monitoring device specified in the COLLECT command. The user is preferably prompted to connect the specified monitoring device to the apparatus and press a button to continue.
NUMBER: aaaa{LF}	Assign a script identification code to the script program. The script identification code from the most recently executed NUMBER statement is subsequently transmitted to the server along with the query responses and device measurements. The script identification code identifies to the server which script program was most recently executed by the remote apparatus.
DELAY: t{LF}	Wait until time t specified in the DELAY command, usually the prescribed connection time.
CONNECT: {LF}	Perform a connection routine to establish a communication link to the server, transmit the patient identification code, query responses, device measurements, and script identification code to the server, and receive and store a new script program. When the server instructs the apparatus to disconnect, the script interpreter is restarted, allowing the new script program to execute.

The script commands illustrated in Table 1 are representative of the preferred embodiment and are not intended to limit the scope of the invention. After consideration of the ensuing description, it will be apparent to one skilled in the art many other suitable scripting languages and sets of script commands may be used to implement the invention.

The script generator **50** preferably stores a script program template which it uses to create each script program **40**. To generate a script program **40**, the script generator **50** inserts into the template the script information entered in the screen **56**. For example, FIGS. **6**A–**6**B illustrate a sample script program **40** created by the script generator **50** from the script information shown in FIG. **5**.

The script program **40** includes display commands to display the queries and response choices entered in fields **94** and **96**, respectively. The script program **40** also includes input commands to receive responses **42** to the queries. The script program **40** further includes a collect command to collect device measurements **44** from the monitoring device **28** specified in the check boxes **98**. The script program **40** also includes commands to establish a subsequent communication link to the server **18** at the connection time specified in field **100** FIG. **5**. The steps included in the script program **40** are also shown in the flow chart of FIGS. **12**A–**12**B and will be discussed in the operation section below.

Referring again to FIG. **2**, the script assignor **52** is used to assign script programs **40** to the patients. The script programs **40** are assigned in accordance with script assignment information entered through workstation **20**. The script assignment information is entered through a script assignment screen **57**, which is preferably implemented as a web page on the server **18**.

FIG. **7** illustrates a sample script assignment screen **57** as it appears on workstation **20**. The screen **57** includes check boxes **106** for selecting a script program **40** to be assigned, and check boxes **108** for selecting the patients to whom the script program is to be assigned. The screen **57** also includes an ASSIGN SCRIPT button **112** for entering the assignments. When button **112** is pressed, the script assignor **52** creates and stores for each patient selected in check boxes **108** a respective pointer to the script program **40** selected in

the check boxes **106**. Each pointer is stored in the patient look-up table **46** of the database **38**. The screen **57** further includes an ADD SCRIPT button **110** for accessing the script entry screen and a DELETE SCRIPT button **114** for deleting a script program **40**.

Referring again to FIG. **2**, the report generator **54** is designed to generate a patient report **58** from the responses **42** and the device measurements **44** received in the server **18**. The patient report **58** is displayed on the workstation **20**. FIG. **10** shows a sample patient report **58** produced by the report generator **54** for a selected patient. The patient report **58** includes a graph **116** of the device measurements **44** received from the patient, as well as a listing of the responses **42** received from the patient. Specific techniques for writing a report generator program to display data in this manner are well known in the art.

The operation of the preferred embodiment is illustrated in FIGS. **1–12**. FIG. **11**A is a flow chart illustrating steps included in the monitoring application executed by the server **18**. FIG. **11**B is a continuation of the flow chart of FIG. **11**A. In step **202**, the server **18** determines if new script information has been entered through the script entry screen **56**. If new script information has not been entered, the server **18** proceeds to step **206**. If new script information has been entered, the server **18** proceeds to step **204**.

As shown in FIG. **5**, the script information includes a set of queries, and for each of the queries, corresponding response choices. The script information also includes a selected monitoring device type from which to collect device measurements **44**. The script information further includes a prescribed connection time for each apparatus to establish a subsequent communication link to the server **18**. The script information is generally entered in the server **18** by a healthcare provider, such as the patients' physician or case manager. Of course, any person desiring to communicate with the patients may also be granted access to the server **18** to create and assign script programs **40**. Further, it is to be understood that system **16** may include any number of remote interfaces for entering script generation and script assignment information in the server **18**.

In step **204**, the script generator **50** generates a script program from the information entered in the screen **56**. The script program is stored in the database **38**. Steps **202** and **204** are preferably repeated to generate multiple script programs, e.g. a script program for diabetes patients, a script program for asthma patients, etc. Each script program corresponds to a respective one of the sets of queries entered through the script entry screen **56**. Following step **204**, the server **18** proceeds to step **206**.

In step **206**, the server **18** determines if new script assignment information has been entered through the assignment screen **57**. If new script assignment information has not been entered, the server **18** proceeds to step **210**. If new script assignment information has been entered, the server **18** proceeds to step **208**. As shown in FIG. **7**, the script programs are assigned to each patient by selecting a script program through check boxes **106**, selecting the patients to whom the selected script program is to be assigned through check boxes **108**, and pressing the ASSIGN SCRIPT button **112**. When button **112** is pressed, the script assignor **52** creates for each patient selected in the check boxes **108** a respective pointer to the script program selected in the check boxes **106**. In step **208**, each pointer is stored in the look-up table **46** of the database **38**. Following step **208**, the server **18** proceeds to step **210**.

In step **210**, the server **18** determines if any of the apparatuses are remotely connected to the server. Each patient to be monitored is preferably provided with his or her own remotely programmable apparatus, which has the patient's unique identification code, stored therein. Each patient is thus uniquely associated with a respective one of the apparatuses. If none of the apparatuses is connected, the server **18** proceeds to step **220**. If an apparatus is connected, the server **18** receives from the apparatus the patient's unique identification code in step **212**. In step **214**, the server **18** receives from the apparatus **26** the query responses **42**, device measurements **44**, and script identification code recorded during execution of a previously assigned script program. The script identification code identifies to the server **18** which script program was executed by the apparatus to record the query responses **42** and device measurements **44**. The responses, device measurements, and script identification code are stored in the database **38**.

In step **216**, the server **18** uses the patient identification code to retrieve from the table **46** the pointer to the script program assigned to the patient. The server **18** then retrieves the assigned script program from the database **38**. In step **218**, the server **18** transmits the assigned script program to the patient's remotely programmable apparatus through the communication network **24**. Following step **218**, the server **18** proceeds to step **220**.

In step **220**, the server **18** determines if a patient report request has been received from the workstation **20**. If no report request has been received, the server **18** returns to step **202**. If a report request has been received for a selected patient, the server **18** retrieves from the database **38** the measurements **44** and query responses **42** last received from the patient, step **222**. In step **224**, the server **18** generates and displays the patient report **58** on the the workstation **20**. As shown in FIG. **10**, the report **58** includes the device measurements **44** and query responses **42** last received from the patient. Following step **224**, the server **18** returns to step **202**.

FIGS. **12**A–**12**B illustrate the steps included in the script program executed by the apparatus **26**. Before the script program is received, the apparatus **26** is initially programmed with the patient's unique identification code and the script interpreter used by microprocessor **76** to execute the script program. The initial programming may be achieved during manufacture or during an initial connection to the server **18**. Following initial programming, the apparatus **26** receives from the server **18** the script program assigned to the patient associated with the apparatus **26**. The script program is received by the modem **86** through a first communication link and stored in the memory **80**.

In step **302**, microprocessor **76** assigns a script identification code to the script program and stores the script identification code in the memory **80**. The script identification code is subsequently transmitted to the server **18** along with the query responses **42** and the device measurements **44** to identify to the server **18** which script program was most recently executed by apparatus **26**. In step **304**, the microprocessor **76** lights LED **74** to notify the patient that he or she has unanswered queries stored in the apparatus **26**. The LED **74** preferably remains lit until the patient answers the queries. In step **306**, the microprocessor **76** erases from the memory **80** the last set of query responses recorded.

In step **308**, the microprocessor **76** prompts the patient by displaying on the display **64** "ANSWER QUERIES NOW? PRESS ANY BUTTON TO START". In step **310**, the microprocessor **76** waits until a reply to the prompt is received from the patient. When a reply is received, the microprocessor **76** proceeds to step **312**. In step **312**, the

microprocessor **76** executes successive display and input commands to display the queries and response choices on the display **64** and to receive responses to the queries.

FIG. **8** illustrates a sample query and its corresponding response choices as they appear on the display **64** The response choices are positioned on the display **64** such that each response choice is located proximate a respective one of input buttons **70**A–D. In the preferred embodiment, each response choice is displayed immediately above a respective input button **70**A–D. The patient presses the button **70**A–D corresponding to his or her response. The microprocessor **76** stores each response in the memory **80**.

In steps **314–318**, the microprocessor **76** executes commands to collect the device measurements **44** from a selected the monitoring device **28**. The script program specifies the selected monitoring device from which to collect the measurements. In step **314**, the microprocessor **76** prompts the patient to connect the selected monitoring device **28**, for example a blood glucose meter, to one of device jacks **68**A–C. A sample prompt is shown in FIG. **9**. In step **316**, the microprocessor **76** waits until a reply to the prompt is received from the patient. When a reply is received, the microprocessor **76** proceeds to step **318**. In step **318**, the microprocessor **76** collects device measurements **44** from the monitoring device **28** through the interface **90**. The measurements **44** are stored in the memory **80**.

In step **320**, the microprocessor **76** prompts the patient to connect the apparatus **26** to the telephone jack **22** so that the apparatus **26** may connect to the server **18** at the prescribed connection time. In step **322**, the microprocessor **76** waits until a reply to the prompt is received from the patient. When a reply is received, the microprocessor **76** turns off the LED **74** in step **324**. In step **326**, the microprocessor **76** waits until it is time to connect to the server **18**. The microprocessor **76** compares the connection time specified in the script program to the current time output by the clock **84**.

In step **328**, the microprocessor **76** establishes a subsequent communication link between the apparatus **26** and the server **18** through the modem **86** and the communication network **24**. If the connection fails for any reason, the microprocessor **76** repeats step **328** to get a successful connection. In step **330**, the microprocessor **76** transmits the device measurements **44**, query responses **42**, script identification code, and patient identification code stored in the memory **80** to the server **18** through the subsequent communication link. In step **332**, the microprocessor **76** receives through the communication network **24** a new script program from the server **18**. The new script program is stored in the memory **80** for subsequent execution by the microprocessor **76**. Following step **332**, the script program ends.

One advantage of the monitoring system of the present invention is that it allows each patient to select a convenient time to respond to the queries, so that the monitoring system is not intrusive to the patient's schedule. A second advantage of the monitoring system is that it incurs very low communications charges because each remote apparatus connects to the server **18** at times when communication rates are lowest. Moreover, the cost to manufacture each remote the apparatus **26** is very low compared to personal computers or internet terminals, so that the monitoring system is highly affordable.

A third advantage of the monitoring system is that it allows each apparatus **26** to be programmed remotely through script programs **40**. Patient surveys, connection times, display prompts, selected monitoring devices, patient customization, and other operational details of each apparatus **26** may be easily changed by transmitting a new script program **40** to apparatus **26**. Moreover, each script program **40** may be easily created and assigned by remotely accessing the server **18** through the Internet. Thus, the invention provides a powerful, convenient, and inexpensive system for remotely monitoring a large number of patients.

FIGS. **13–15** illustrate a second embodiment of the invention in which each remotely programmable apparatus includes all of the functionality of the first embodiment described above while also including speech recognition and speech synthesis functionality. FIG. **13** shows a perspective view of the remotely programmable apparatus **27** according to the second embodiment. The apparatus **27** includes a speaker **72** for audibly communicating queries and prompts to the patient. The apparatus **27** also includes a microphone **118** for receiving spoken responses to the queries and prompts. The apparatus **27** may optionally include a display **64** for displaying prompts to the patient, as shown in FIG. **14**.

FIG. **15** is a schematic block diagram illustrating the components of the apparatus **27** in greater detail. The apparatus **27** is similar in design to the apparatus **26** of the preferred embodiment except that the apparatus **27** includes an audio processor chip **120** in place of the microprocessor **76**. The audio processor chip **120** is preferably an RSC-164 chip commercially available from Sensory Circuits Inc. of 1735 N. First Street, San Jose, Calif. 95112.

The audio processor chip **120** has a microcontroller **122** for executing script programs received from the server **18**. A memory **80** is connected to the microcontroller **122**. Memory **80** stores the script programs and a script interpreter used by the microcontroller **122** to execute the script programs. The memory **80** also stores measurements received from the monitoring device **28**, responses to the queries, script identification codes, and the patient's unique identification code.

The audio processor chip **120** also has built in speech synthesis functionality for synthesizing queries and prompts to a patient through the speaker **72**. For speech synthesis, the chip **120** includes a digital to analog converter (DAC) **142** and an amplifier **144**. The DAC **142** and the amplifier **144** drive the speaker **72** under the control of the microcontroller **122**.

The audio processor chip **120** further has built in speech recognition functionality for recognizing responses spoken into the microphone **118**. Audio signals received through the microphone **118** are converted to electrical signals and sent to a preamp and gain control circuit **128**. The preamp and gain control circuit **128** is controlled by an automatic gain control circuit **136**, which is in turn controlled by the microcontroller **122**. After being amplified by the preamp **128**, the electrical signals enter the chip **120** and pass through a multiplexer **130** and an analog to digital converter (ADC) **132**. The resulting digital signals pass through a digital logic circuit **134** and enter microcontroller **122** for speech recognition.

The audio processor chip **120** also includes a RAM **138** for short-term memory storage and a ROM **140**, which stores programs executed by the microcontroller **122** to perform speech recognition and speech synthesis. The chip **120** operates at a clock speed determined by a crystal **126**. The chip **120** also includes a clock **84** that provides the current date and time to the microcontroller **122**. As in the preferred embodiment, the apparatus **27** includes an LED **74**, display driver **82**, modem **86**, and device interface **90**, all of which are connected to the microcontroller **122**.

The operation of the second embodiment is similar to the operation of the preferred embodiment except that queries, response choices, and prompts are audibly communicated to the patient through the speaker **72** rather than being displayed to the patient on the display **64**. The operation of the second embodiment also differs from the operation of the preferred embodiment in that responses to the queries and prompts are received through the microphone **118** rather than through user input buttons.

The script programs of the second embodiment are similar to the script program shown in FIGS. **6A–6B**, except that each display command is replaced by a speech synthesis command and each input command is replaced by a speech recognition command. The speech synthesis commands are executed by the microcontroller **122** to synthesize the queries, response choices, and prompts through speaker **72**. The speech recognition commands are executed by the microcontroller **122** to recognize responses spoken into microphone **118**.

For example, to ask the patient how he or she feels and record a response, the microcontroller **122** first executes a speech synthesis command to synthesize through the speaker **72** "How do you feel? Please answer with one of the following responses: very bad, bad, good, or very good." Next, the microcontrollcr **122** executes a speech recognition command to recognize the response spoken into the microphone **118**. The recognized response is stored in the memory **80** and subsequently transmitted to the server. Other than the differences described, the operation and advantages of the second embodiment are the same as the operation and advantages of the preferred embodiment described above.

Although the first and second embodiments focus on querying individuals and collecting responses to the queries, the system of the invention is not limited to querying applications. The system may also be used simply to communicate messages to the individuals. FIGS. **16–19** illustrate a third embodiment in which the system is used to perform this automated messaging function. In the third embodiment, each script program contains a set of statements to be communicated to an individual rather than a set of queries to be answered by the individual. Of course, it will be apparent to one skilled in the art that the script programs may optionally include both queries and statements.

The third embodiment also shows how the queries and statements may be customized to each individual by merging personal data with the script programs, much like a standard mail merge application. As mentioned above, the individual may be identified for selection of individualized information either through an individual identification code associated with the remote apparatus **26** and stored in memory **80**. Referring to FIG. **16**, personal data relating to each individual is preferably stored in the look-up table **46** of the database **38**. By way of example, the data may include each individual's name, the name of each individual's physician, test results, appointment dates, or any other desired data. As in the preferred embodiment, the database **38** also stores generic script programs **40** created by the script generator **50**.

The server **18** includes a data merge program **55** for merging the data stored in table **46** with generic script programs **40**. The data merge program **55** is designed to retrieve selected data from table **46** and to insert the data into statements in generic script programs **40**, thus creating custom script programs **41**. Each custom script program **41** contains statements that are customized to an individual. For example, the statements may be customized with the individual's name, test results, etc. Examples of such customized statements are shown in FIGS. **17–18**.

The operation of the third embodiment is similar to the operation of the preferred embodiment except that the script programs are used to communicate messages to the individuals rather than to query the individuals. Each message is preferably a set of statements. Referring to FIG. **19**, the statements may be entered in the server **18** through the script entry screen **56**, just like the queries of the preferred embodiment.

Each statement preferably includes one or more insert commands specifying data from table **46** to be inserted into the statement. The insert commands instruct the data merge program **55** to retrieve the specified data from the database **38** and to insert the data into the statement. For example, the insert commands shown in FIG. **19** instruct the data merge program **55** to insert a physician name, an appointment date, a patient name, and a test result into the statements. As in the preferred embodiment, each statement may also include one or more response choices, which are entered in fields **96**.

Following entry of the statements and response choices, CREATE SCRIPT button **102** is pressed. When the button **102** is pressed, the script generator **50** generates a generic script program from the information entered in the screen **56**. The generic script program is similar to the script program shown in FIGS. **6A–6B**, except that the display commands specify statements to be displayed rather than queries. Further, the statements include insert commands specifying data to be inserted into the script program. As in the preferred embodiment, multiple script programs are preferably generated, e.g. a generic script program for diabetes patients, a generic script program for asthma patients, etc. The generic script programs are stored in the database **38**.

Following generation of the generic script programs, the server **18** receives script assignment information entered through the script assignment screen **57**. As shown in FIG. **7**, the script programs are assigned by first selecting one of the generic script programs through the check boxes **106**, selecting individuals through the check boxes **108**, and pressing the ASSIGN SCRIPT button **112**. When the button **112** is pressed, the data merge program **55** creates a custom script program **41** for each individual selected in check boxes **108**.

Each custom script program **41** is preferably created by using the selected generic script program as a template. For each individual selected, the data merge program **55** retrieves from the database **38** the data specified in the insert commands. Next, the data merge program **55** inserts the data into the appropriate statements in the generic script program **40** to create a custom script program **41** for the individual. Each custom script program **41** is stored in the database **38**.

As each custom script program **41** is generated for an individual, the script assignor **52** assigns the script program **41** to the individual. This is preferably accomplished by creating a pointer to the custom script program and storing the pointer with the individual's unique identification code in the table **46**. When the individual's remotely programmable apparatus connects to the server **18**, the server **18** receives from the remotely programmable apparatus **26** the individual's unique identification code. The server **18** uses the unique identification code to retrieve from the table **46** the pointer to the custom script program assigned to the individual. Next, the server **18** retrieves the assigned script program from the database **38** and transmits the script program to the individual's remotely programmable apparatus **26** through the communication network **24**.

The apparatus receives and executes the script program. The execution of the script program is similar to the execution described in the preferred embodiment, except that statements are displayed to the individual rather than queries. FIGS. **17–18** illustrate two sample statements as they appear on the display **64**. Each statement includes a response choice, preferably an acknowledgment such as "OK". After reading a statement, the individual presses the button **70**A–D corresponding to the response choice to proceed to the next statement. Alternatively, the script program may specify a period of time that each statement is to be displayed before proceeding to the next statement. The remaining operation of the third embodiment is analogous to the operation of the preferred embodiment described above.

Although it is presently preferred to generate a custom script program **41** for each individual as soon as script assignment information is received for the individual, it is also possible to wait until the individual's apparatus **26** connects to the server **18** before generating the custom script program **41**. This is accomplished by creating and storing a pointer to the generic script program **40** assigned to the individual, as previously described in the preferred embodiment. When the individual's apparatus **26** connects to the server **18**, the data merge program **55** creates a custom script program **41** for the individual from the generic script program **40** assigned to the individual. The custom script program **41** is then sent to the individual's apparatus **26** for execution.

Alternate Embodiments

In an alternate embodiment, when the user or patient (the terms user and patient are used interactively) activates the user input button **70**E (hereinafter the red button) a command signal is sent to the processor **76**. The processor **76** dial a preset phone number according to the command signal. The preset phone number is that of an answering service at the server **18** or at a workstation **20**. The answering service identifies the patient or user associated with the remote apparatus **26** that generated the call based on an identifier sent with the call and user information stored in memory in the database (similar to caller ID). The system (server **18** or workstation **20**) that receives the call then retrieves patient information with previous patient/user responses stored at the server's database **38**, within memory at the workstation **20**, or at some other remotely located storage site. The retrieved patient information is displayed to a live person who is in telephonic communication with the patient. This allows the patient to be placed in immediate contact with a person who has displayed before them the patient's personal health information or other patient historical information. The person receiving the call provides effective communication with the patient, because of the ability to view pertinent information.

In an alternate embodiment, an automated answering service is the recipient of the call made by the remote apparatus **26**. The automated answering service asks a series of questions according to the retrieved patient information in order to triage the patient toward different actions depending upon the situation. The patient information also includes previous patient interactions with the automated answering service.

The system receiving the call process patient responses according to the content associated with the question asked. Content is one of the following categories: symptoms; behavior; knowledge. The categories include such things as requests for service or product orders. In one example, the automated answering service asks "do you have difficulty breathing? press the red button if you are." If the patient then presses the red button, the call is forwarded to a case manager or a nurse on call.

In another example, red button selection is associated with a request for service. When the red button is pressed, the automated answering service asks "do you need someone to change your bed? press the red button if yes." If the patient presses the red button, a home care agency coordinating ancillary daily activity services is notified or is forwarded the call. Other service companies, such as transport companies or concierge service companies, are other possible recipients of forwarded calls depending what actions are available to the patients.

The automated answering service is dynamically adaptable based on previous interactions with the automated answering service. For example, the past couple of times the patient activated the red button and answered the question(s), the patient was connected to an emergency health care worker. If the worker determined through review questions of the patient's present condition, maybe information generated by the monitoring device sent over the network **24** to a workstation operated by the worker, and retrieved patient information that no emergency existed, the worker records this situation into the patient's records. If the patient's record includes a number of false alarms that exceed a predetermined limit over a period of time, the automated answering service reprograms itself so that the next time the patient activates the red button the patient is directly connected to a live person that is designated for non-emergency patient interaction or to other questions that direct the patient to the person designated for non-emergency patient interaction. This frees-up emergency healthcare workers from dealing with someone who has a history of not needing their expertise.

FIGS. **20** and **21** illustrate alternate embodiments of the invention illustrated in FIG. **1**. In FIG. **20**, the remote apparatus **26** is a personal computer including a processor and a user interface, e.g. display, keyboard, mouse, or other input and output devices (not all shown), that receives the script program, processes the script program and presents the script program for user interaction. For example, the script program requires that the personal computer present an image of a stand-alone remote apparatus **350**, such as the Health Buddy™ produced by Health Hero Network, Inc., on the display. The user then interacts with the displayed image of the stand-alone remote apparatus by operating the user interface(s) of the personal computer to select displayed responses. The displayed image of the stand-alone remote apparatus presents a virtual image with the same functionality as the apparatuses **26** and **27**, as described above in FIGS. **3** and **13**. It can be appreciated to those of ordinary skill in the art that the system of FIG. **20** provides all or part of the functionality of the apparatuses shown in FIGS. **3** and **13**, but does it on a personal computer.

FIG. **21** includes all the components of the FIG. **1** and a digital television network **36** in communication with the server **18** and the remote apparatus **26**. The remote apparatus **26** of FIG. **21** is an interactive television system that includes a processing unit **33**, such as a satellite broadcast receiving, set-top processor with OpenTV signal processing software, a display **34**, such as a television set, and a user interface **35**, such as a remote control.

The remote apparatus **26**, through the processing unit **33**, is coupled to the communication network **24**, the digital television network **36** and the monitoring device **28**.

The processing unit **33** includes a CPU, memory and embedded software for receiving and processing both digital entertainment and advertisement content and digital script

programs. Also, the processing unit **33** allows the user to view the entertainment and advertisement content, such as television programming, and interact with (i.e. respond to) the script programs. The script program(s) sent from the server **18** are viewable on the display **34** as they would appear on the display **64** of apparatus **26** or are viewed on a portion of the display **34**. For example, the question with options shown in FIG. **8** would appear on the display **34**. The user makes a selection of one of the choices by using the user interface **35**, i.e. giving voice commands that are processed by a voice recognition system, controlling and activating a cursor, etc. Example methods of making a selection are to control a cursor icon on the display screen of the display **34** and activate the cursor icon when it is co-located with one of the choices, to assign different keyboard keys are designated as a different one of the displayed choices. Another method is to have the user interface include voice actuation software for processing user voice commands that request selection of a desired choice.

With respect to this invention, a "broadcast" includes any form of delivering the content from a source to many viewers, including transmission over the airwaves or via cable, the Internet, a closed-circuit network, or other means of communication. A "broadcast" does not require multiple persons to watch at once, but rather can include multiple individual and independent viewings, such as in the form of video on demand or access to web pages. Moreover, the term "broadcast" may include a single tailored transmission from a source to a single intended viewer. Accordingly, while a "broadcast" may include a transmission from one point to multiple recipients, it is not limited to that case. Likewise, with respect to this invention, a "broadcast" is "transmitted" in any of the above forms.

The processing unit **33** is a multimedia processor that receives transmitted broadcast programs from a digital broadcast network **36** via a communication link, such as a satellite or cable link. The processing unit **33** also transmits as well as receives data via the communication network **24**. In addition, the multimedia processor has expansion ports to support additional user interface and other devices, such as keyboards, joysticks, trackballs, and to accept add-on circuits for enhanced sound, video, or processing performance.

FIG. **22** is an example for illustrative purposes only of a method for increasing user use of script programs by allowing the user to quickly access the script program during viewing of an entertainment or advertisement program in an interactive TV system. FIG. **22** illustrates a process performed by the system shown in FIG. **21**. At block **400**, the server **18** generates an interactive script program. In an alternate embodiment, the script program is fully or partially created at another remotely coupled computer, such as workstation **20**, and added to multimedia content, then the script program and multimedia content is sent to the server **18** In one embodiment, the script program is specialized for a specific user according to a health care professional request or to a predefined health regimen based on user profile information. In an alternate embodiment the script program is generated in relation to entertainment or advertisement content that it will later be broadcasted with. Next, at block **402**, the generated script program is combined with digital produced entertainment or advertisement content, i.e. a multimedia presentation, to create digital broadcast programming. The digital broadcast programming is then broadcasted or transmitted over the chosen communication link, block **406**. At block **408**, the processing unit **33** receives and processes the digital broadcast programming then presents the entertainment or advertisement content and the script program. The processing unit **33** as directed by software instructions previously imbedded in the processing unit **33**, included with the digital broadcast programming or a combination of both processes the digital broadcast programming by determining its content and how that content is to be presented on the display **34**. For example, the processing unit **33** determines if the script program is to be referenced by an icon over the entertainment content or displayed on a portion of the display with the entertainment content. As part of the presentation from block **408** the user is informed of any script program included in the broadcast programming, block **410**. Then, at block **426**, the user is presented with the script program after the user selects or activates the indication, e.g. an icon. Lastly, at block **428**, the user interacts with the script program by responding to any queries and inputting any requested measurements or other responses. The interaction with the script program is similar to that described above for the system of FIG. **1**. In another embodiment, the script program is presented in conjunction with the entertainment or advertisement content without requiring the user to select or activate an indicator.

FIGS. **23** and **24** are example images presented on the displays **34** in the system illustrated in FIG. **22**. FIG. **23** illustrates a screen shot of a broadcast program **250** that includes entertainment content **252**, such as a video program on heart surgery, and an icon **254**. The icon **254** indicates that a script program is available for the viewer. In order for the viewer to access the script program, the viewer selects the icon **254**. The program broadcasted from the broadcast network **24** may have included an entire script program or just a portion of a script program. If the entire script program were included with the broadcast, selection of the icon **254** would begin execution of the script program that was received. However, if only a portion of the script program was received and, for example, that portion only required that the icon **254** be displayed with the entertainment content **252**, selection of the icon **254** sends a signal through a back channel, i.e. the link to the communication network **24**, to the server **18**. The sent signal is a request for the rest of or just more of the script program to be sent to the apparatus **26** either through broadcast network **36** or communication network **24**.

FIG. **23** illustrates a screen shot of a broadcast program **250** that includes entertainment content **252** and a section that presents a script program image **256**. In this example the viewer can interact with the script program image **256** while simultaneously viewing the entertainment content **252**. As in FIG. **22** above, the script program may be fully or partially received and processed by the processing unit **33**. And again, if it has only been partially received, viewer interaction at a predetermined spot in the displayed interaction process automatically initiates a request through the back channel to the server **18** for the rest of the script program.

Because the broadcast program **250** is a digital broadcast, it can be readily appreciated by those of ordinary skill in the art of digital interactive television, that the entertainment content may be paused until viewer completion of the script program. The script program which can be sent with an initial broadcast program or during presentation of a previously delivered broadcast program that is being presented on the display may also include instructions to pause the entertainment content until viewer completion of the script program at which time the entertainment program resumes. For example, the viewer's/patient's doctor creates a message at the workstation **20** requesting that the patient as soon as possible send blood pressure measurement readings. This message is generated as a new script program at the server

18. The server **18** then sends the new script program to the broadcast network **36**. The broadcast network **36** includes hardware and/or software mechanisms for saving the new script program for inclusion with the next patient requested entertainment or advertisement content to be sent to the patient in the case where the patient is not presently viewing a broadcast from the broadcast network **36** or for just broadcasting the script program alone. If the patient is presently viewing entertainment or advertisement content received from the broadcast network **36**, the new script program is received, processed and presented to the patient by the apparatus **26**. The received new script program may include instructions to pause the presently viewed entertainment or advertisement content.

If the script program is specified for a particular patient, the server **18** or broadcast network **36** encodes the script program for that patient. The apparatus of that patient includes a decoding component within the processing unit **33** for decoding the encoded script program received with the broadcast program. For example, the script program includes a weight history chart of the patient. The present invention wants only the patient corresponding to this weight history chart to have viewing access. Therefore, it is encoded for transmission and encoded only by the corresponding patient's apparatus **26**.

It can be appreciated to one of ordinary skill in the art that this decision, as with the other flow diagram decisions, can be an inherent decision in the processing of the received entertainment/advertisement programming and script program.

The embodiments of FIGS. **20** and **21** may also be implemented without any entertainment or advertisement content and perform the functions as to those that illustrated and described for FIG. **1**.

The script programs or entertainment/advertisement programming can be designed for education and training of users. For example, the script program or information content could show a user, such as a patient, how to effectively use a medical treatment device. Also, the script program or information content could describe to users, such as doctors, nurses or anyone other professional, different treatment styles, plans or new medication.

A wide variety of information may be collected, delivered and analyzed in accordance with the present invention. For example, abandoned U.S. patent application Ser. No. 09/378,188 which is a continuation of U.S. Pat. No. 5,985,559, and unassigned U.S. patent application which is a continuation of U.S. patent application Ser. No. 09/041,809 (the text of which are hereby incorporated by reference) discusses information related to disease causes, treatments, and cures. Script programs include a set of queries for requesting data on lifestyle, environment, behavior, drug compliance, drug response over time, and other aspects. This data is then analyzed to identify trends and establish subgroups with similar responses.

Individuals' behavioral and environmental information in conjunction with their gene sequence information is analyzed to find drug candidates and drug targets. Individuals previously designated as having a high risk for developing a particular disease are each given an apparatus **26**. Queries related to the individuals' behavior and environment are included in a script program sent from a server **18** to the apparatus **26** or from a server **18** to the apparatus **26** through a broadcast network **36**. The individuals' responses are sent back to the server **18**. The process of collecting individuals' information can take place over a long period of time to ensure accurate data and to allow researchers to observe progression of the disease. A data mining program on the server analyzes the individuals' behavioral and environmental information, as well as their gene sequence information. Differences in gene sequence information, or in behavioral and environmental factors between individuals who show a severe disease phenotype and those who show a mild severe disease phenotype can then be distinguished and used to develop new drug candidates, targets, or general treatments.

Genetic testing allows an individual to determine whether or not he or she has a predisposition to a certain disease. The degree of expressivity of a certain disease will be determined in part by an individual's environment and lifestyle. The environment and lifestyle information is retrieved from responses to queries sent from the server **18** to the apparatus **26** or from the server **18** to the apparatus **26** through the broadcast network **36**. The present invention interprets a patient's gene sequence information and his or her environment and lifestyle to come up with a personalized prognosis. This procedure can be repeated many times over the course of a disease state to monitor a patient's condition. In addition, disease-causing pathogens can also have their genes sequenced. Using these sequences in combination with information about a patient's environment and lifestyle, the present invention comes up with a personalized treatment plan, ideally to eliminate the pathogen. It is also possible to use the procedure described above to monitor the course of the disease-state produced by a pathogen. Finally, a genotype-to-phenotype map or database can be constructed for developing better treatments and aiding in research.

Although the above description contains many specificities, these should not be construed as limitations on the scope of the invention but merely as illustrations of some of the presently preferred embodiments. Many other embodiments of the invention are possible. For example, the scripting language and script commands shown are representative of the preferred embodiment. It will be apparent to one skilled in the art many other scripting languages and specific script commands may be used to implement the invention.

Moreover, the invention is not limited to the specific applications described. The system and method of the invention have many other applications both inside and outside the healthcare industry. For example, pharmaceutical manufacturers may apply the system in the clinical development and post marketing surveillance of new drugs, using the system as an interactive, on-line monitoring tool for collecting data on the efficacy, side effects, and quality of life impact of the drugs. Compared to the current use of labor-intensive patient interviews, the system provides a fast, flexible, and cost effective alternative for monitoring the use and effects of the drugs.

The system may also be used by home healthcare companies to enhance the service levels provided to customers, e.g. panic systems, sleep surveillance, specific monitoring of disease conditions, etc. Alternatively, the system may be used to monitor and optimize the inventory of home-stationed health supplies. As an example, the system may be connected to an appropriate measuring device to optimize timing of oxygen tank delivery to patients with chronic obstructive pulmonary disease (COPD).

The system and method of the invention also have many applications outside the healthcare industry. For example, the system may be used for remote education over the Internet, facilitating educational communication with children or adult trainees who lack access to sophisticated and expensive computer equipment. The system may also be

used by law enforcement officers to perform on-line surveillance of individuals on probation or parole.

In an alternate embodiment, the software and hardware components of any one of the remote apparatuses **26** or **27** are incorporated directly into a monitoring device. This allows a patient to only have to interact with one device for their entire health monitoring needs.

Further, the invention has numerous applications for gathering data from remotely located devices. For example, the system may be used to collect data from smart appliances, such as identification check systems. Examples of appliances that are used as smart appliances are refrigerator, telephone, stove, clock radio, VCR, or any other electrical or non-electrical device including the monitoring device **28**. The smart appliance includes some or all of the components of the remote apparatuses **26** or **27** as illustrated in FIGS. **4** and **15**. The smart appliance with the necessary hardware or software components provides all the interactive capabilities described and shown for remote apparatuses **26** or **27**, see FIGS. **8–12**, **14**, **17** and **18**. In one embodiment, the assigned scripts are in the form of a recorded voice that is sent over the communication network (e.g. voice over IP) to the appliance or remote apparatus. Also, the user responds to the voice scripts through activation of buttons according to instructions in the voice scripts or by verbally responding to the voice scripts. The verbal responses by the user are sent to the server or workstation over the communication network (e.g. voice over IP). The server or workstation includes a voice recognition component for interpreting the user's verbal responses, records the response and determines the next question or request (verbal or otherwise) to be sent to the user according to the responses. Live voice communication is also possible between the remote apparatus and the server or workstation over the communication network.

Also, the monitoring device includes a communication component for allowing the monitoring device to send data directly to the server **18**. The server **18** then sends the monitoring device data to the patient's smart appliance for display to the patient. In an alternate additional setup, the monitoring device sends the data to the smart apparatus.

Alternatively, the system may be applied to the remote monitoring of facilities, including safety and security monitoring, or to environmental monitoring, including pollution control and pipeline monitoring. Many other suitable applications of the invention will be apparent to one skilled in the art.

Therefore, the scope of the invention should be determined not by the examples given, and their legal equivalents.

What is claimed is:

1. A system for remotely monitoring an individual, the system comprising:

(a) a remote apparatus for interacting with the individual;

(b) a server system including

(i) a script generator for generating a script program from a set of health related queries, the script program being executable at the remote apparatus to communicate the set of queries to the individual; and

(ii) a database for storing the the queries, the responses to the queries, and details of the individual;

wherein the remote apparatus includes:

(i) a communication component for receiving the script program from the server and for transmitting the responses to the server;

(ii) a user interface having an audio transducer for audibly notifying the individual and a display, and

a processor connected to the user interface for executing the script program to cause presentation on the display of queries to the individual.

2. The system of claim **1**, wherein the system is configured to receive script information from a health care provider.

3. The system of claim **2**, wherein the system is configured for audibly notifying the individual when unanswered queries are stored at the remote apparatus.

4. The system of claim **1**, wherein the system is configured to transmit the script program to the remote apparatus during a first communication link, and a response to at least one query at the central computer through a subsequent communication link.

5. The system of claim **1**, wherein the system is configured to transmit at least one script program to the remote apparatus and to receive a response to at least one query wherein the system is configured to transmit at least one script to the remote apparatus and to receive a response to at least one query in the same on-line session in the same on-line session.

6. A method for remotely monitoring an individual comprising:

generating a script program from a set of queries

sending the generated script program to a remote apparatus,

executing the script program at the apparatus to cause communication of at least one of the set of health related queries to the individual;

receiving responses to at least one of the communicated queries from the individual;

transmitting the received responses to a central system; and

storing the transmitted responses and details of the individual at the server system.

7. The method of claim **6**, further comprising providing health related service to the individual.

8. The method of claim **6**, further comprising audibly notifying the individual when unanswered queries are stored at the remote apparatus.

9. An apparatus for remotely monitoring an individual, apparatus comprising:

a communication component for receiving a script program from a server wherein the script program represents a set of health related queries;

a user interface including display and an audio transducer for audibly notifying the individual; and

a processor for executing the script program to cause communication of at least one of the set of queries to the individual

wherein the apparatus is configured to

receive responses to the set of queries from the individual and to transmit the responses to the server; and

for connection to a monitoring device.

10. The apparatus of claim **9**, wherein the monitoring device is one of the set of monitoring devices consisting of a blood glucose meter, a peak flow meter, and an EKG and wherein the apparatus is configured to receive at least one reading from at least one of the monitoring devices and to transmit the reading to the central computer.

11. The apparatus of claim **9**, wherein the wherein the apparatus further comprises input buttons configured for use by the individual being queried to enter the responses to queries displayed on the display.

12. The apparatus of claim **9**, further comprising a script interpreter that can be programmed during a connection with a central computer.

13. The apparatus of claim 9, wherein the apparatus is configured to receive the script program from a central computer system during a first communication link, and transmit a response to at least one query to the central computer system through a subsequent communication link.

14. The apparatus of claim 9, wherein the apparatus is configured to receive the script program from a central computer system and to transmit a response to at least one query in the same on-line session.

15. A system for remotely querying an individual, the system comprising:

a. a central computer;

b. a script generator configured to generate at least one script;

c. a remote apparatus associated with the individual to be queried;

d. a communication link

i. over which communication can be established between the central computer and the remote apparatus and

ii. over which the generated script can be transmitted to the remote apparatus;

e. a display associated with the individual to be queried; and

f. a script interpreter configured

i. to interpret a script communicated over the communications link and

ii. to cause display of at least one query related to a health condition of the individual on the display.

16. The system of claim 15 further comprising at least one workstation

a. in communication with the central computer, and

b. configured for entering a set of queries to be answered by the individual.

17. The system of claim 15, wherein the display includes at least one response choice for at least one of the queries.

18. The system of claim 17, wherein the script includes at least one program for execution at the remote apparatus.

19. The system of claim 18, wherein the script program further includes display commands to cause display of a plurality of queries and at least one response choice for at least one of the queries.

20. The system of claim 19, wherein the script program further includes a connection command to establish the communication with the central computer at a prescribed connection time and to transmit the at least one response to at least one query to the central computer over the communication link.

21. The system of claim 19, further comprising

a. a plurality of remote apparatuses each configured for remotely querying a corresponding associated individual,

wherein the system is configured to

assign to each of the apparatuses at least one script program and

to transmit to each of the apparatuses any script program assigned to the apparatus.

22. The system of claim 21, wherein

a the central computer includes a plurality of sets of queries and corresponding response choices and

b. the script generator is configured to generate a plurality of script programs from the sets of queries and response choices.

23. The system of claim 22, wherein each of the script programs corresponds to a respective one of the sets of queries and response choices.

24. The system of claim 18, wherein the script interpreter is programmable during a connection with the central computer.

25. The system of claim 18, wherein the system further comprises at least one database for storing

a. script programs,

b. a list of the individuals, and

c. a respective pointer to the script program assigned to each individual.

26. The system of claim 25, wherein the database includes a look-up table.

27. The system of claim 26, wherein the system is configured to

a. receive an identification code associated with an individual,

b. use the received identification code to retrieve from the look-up table the pointer to the script assigned to the individual, and

c. cause the retrieved script to be transmitted to the relevant individual apparatus.

28. The system of claim 17, wherein

a. the remote apparatus is configured to receive responses to at least one of the queries and

b. the system is configured to cause the responses to be transmitted to the central computer.

29. The system of claim 17, wherein the system is configured to transmit

a. the script to the remote apparatus during a first communication link, and

b. a response to at least one query to the central computer through a subsequent communication link.

30. The system of claim 17, wherein the system is configured to transmit at least one script to the remote apparatus and to receive a response to at least one query in the same on-line session.

31. The system of claim 17, wherein the apparatus includes input buttons configured for use by the individual being queried to enter the responses to queries displayed on the display.

32. The system of claim 17, further comprising a plurality of remote apparatuses each configured for remotely querying a corresponding associated individual.

33. The system of claim 32, wherein the system is configured to assign to each of the individuals at least one script.

34. The system of claim 17, further comprising at least one of the set of monitoring devices consisting of

a. a blood glucose meter,

b. a peak flow meter, and

c. an EKG

and wherein the system is configured to receive at least one reading from at least one of the monitoring devices and to transmit the reading to the central computer.

35. The system of claim 17, further comprising at least one of an audio transducer and an LED for notification to the individual to be monitored.

36. The system of claim 17, wherein the system is configured to use the at least one script to generate a survey.

37. A method for remotely querying an individual, the method comprising:

generating at least one script;

establishing a communications link between a central computer and a remote apparatus;

transmitting the generated script to the remote apparatus via the communication link;

interpreting the script communicated over the communications link; and

causing the display of at least one query related to a health condition of the individual on the display, the display being associated with the individual.

38. The method of claim **37**, further comprising configuring at least one workstation for entering a set of queries to be answered by the individual, the workstation being operatively in communication with the central computer.

39. The method of claim **37**, wherein the display includes at least one response choice for at least one of the queries.

40. The method stem of claim **39**, wherein the script includes at least one program for execution at the remote apparatus.

41. The method of claim **40**, wherein the script program further includes display commands to cause display of a plurality of queries and at least one response choice for at least one of the queries.

42. The method of claim **41**, wherein the script program further includes a connection command to establish the communication with the central computer at a prescribed connection time and to transmit the at least one response to at least one query to the central computer over the communication link.

43. The method of claim **39**, further comprising:

receiving responses to at least one of the queries at the remote apparatus; and

causing the responses to be transmitted to the central computer.

44. The method of claim **40**, which comprises programming the script interpreter during a connection with the central computer.

45. The method of claim **41**, further comprising

remotely querying a corresponding associated individual via a plurality of remote apparatuses;

assigning to each of the apparatuses at least one script program; and

transmitting to each of the apparatuses any script program assigned to the apparatus.

46. The method of claim **45**, further comprising:

providing at the central computer a plurality of sets of queries and corresponding response choices; and

generating a plurality of script programs from the sets of queries and response choices.

47. The method of claim **46**, wherein each of the script programs corresponds to a respective one of the sets of queries and response choices.

48. The method of claim **39**, further comprising:

transmitting the script to the remote apparatus during a first communication link; and

responding to at least one query to the central computer through a subsequent communication link.

49. The method of claim **39**, further comprising:

transmitting at least one script to the remote apparatus; and

receiving a response to at least one query in the same on-line session.

50. The method of claim **39**, which includes entering responses to queries displayed on the display using input buttons configured for use by the individual being queried.

51. The method of claim **39**, further comprising remotely querying a corresponding associated individual associated with one of a plurality of remote apparatuses.

52. The method of claim **51**, further comprising assigning to each of the individuals at least one script.

53. The method of claim **39**, further comprising storing in at least one database:

a. script programs,

b. a list of the individuals, and

c. a respective pointer to the script program assigned to each individual.

54. The method of claim **53**, wherein the database includes a look-up table.

55. The method of claim **54**, further comprising:

receiving an identification code associated with an individual,

using the received identification code to retrieve from the look-up table the pointer to the script assigned to the individual; and

causing the retrieved script to be transmitted to the relevant individual apparatus.

56. The method of claim **39**, further comprising monitoring using at least one of the set of monitoring devices consisting of:

a blood glucose meter,

a peak flow meter, and

an EKG

and wherein the method further comprises receiving at least one reading from at least one of the monitoring devices and transmitting the reading to the central computer.

57. The method of claim **39**, further comprising notifying the individual to be monitored using at least one of an audio transducer and an LED.

58. The method of claim **39**, further comprising using the at least one script to generate a survey.

59. Remote apparatus for use in the method of claim **37**.

60. A central computer for use in the method of claim **37**.

61. A computer program product for executing a set of instructions that, when executed by computer device, cause the computer device to:

generate at least one script;

establish a communications link between a central computer and a remote apparatus;

transmit the generated script to the remote apparatus via the communication link;

interpret the script communicated over the communications link; and

cause the display of at least one query related to a health condition of an individual on the display, the display being associated with the individual.

62. The computer program product of claim **61**, which configures at least one workstation for entering a set of queries to be answered by the individual, the workstation being operatively in communication with the central computer.

63. The computer program product of claim **61**, which configures the display to include at least one response choice for at least one of the queries.

64. The computer program product stem of claim **63**, wherein the script includes at least one program for execution at the remote apparatus.

65. The computer program product of claim **64**, wherein the script program further includes display commands to cause display of at least one of a plurality of queries and at least one response choice for at least one of the queries.

66. The computer program product of claim **65**, wherein the script program further includes a connection command to establish the communications link with the central computer at a prescribed connection time and to transmit the at least one response to at least one query to the central computer over the communication link.

67. A system for remotely querying an individual, the system comprising:

means for generating at least one script;

means for establishing a communications link between a central computer and a remote apparatus;

means for transmitting the generated script to the remote apparatus via the communication link;

means for interpreting the script communicated over the communications link; and

means for causing the display of at least one query related to a health condition of the individual on the display, the display being associated with the individual.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,968,375 B1
APPLICATION NO. : 09/658209
DATED : November 22, 2005
INVENTOR(S) : Stephen J. Brown

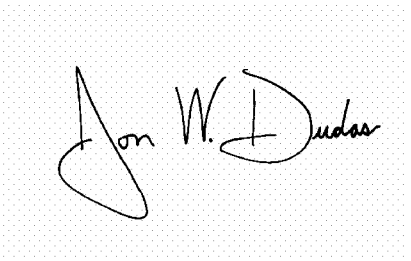
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 5, line 46, delete "Appendix A" and insert -- Figure 6 --.

Column 21, line 57, delete "the" (second occurrence).

Signed and Sealed this

Seventeenth Day of April, 2007



JON W. DUDAS
Director of the United States Patent and Trademark Office

EXHIBIT E

US007223236B2

(12) **United States Patent**
Brown

(10) **Patent No.: US 7,223,236 B2**
(45) **Date of Patent: *May 29, 2007**

(54) **SYSTEM AND METHOD FOR MONITORING USER-RELATED DATA FROM A PERSON**

(75) Inventor: **Stephen James Brown**, Mountain View, CA (US)

(73) Assignee: **Health Hero Network, Inc.**, Redwood City, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **11/221,873**

(22) Filed: **Sep. 9, 2005**

(65) **Prior Publication Data**

US 2006/0009706 A1 Jan. 12, 2006

Related U.S. Application Data

(60) Division of application No. 10/605,547, filed on Oct. 7, 2003, which is a continuation of application No. 09/237,194, filed on Jan. 26, 1999, which is a continuation of application No. 08/481,925, filed on Jun. 7, 1995, now Pat. No. 5,899,855, which is a continuation of application No. 08/233,397, filed on Apr. 26, 1994, now abandoned, which is a continuation-in-part of application No. 07/977,323, filed on Nov. 17, 1992, now Pat. No. 5,307,263.

(51) **Int. Cl.**
A61B 5/00 (2006.01)
G06Q 10/00 (2006.01)
G06Q 50/00 (2006.01)

(52) **U.S. Cl.** **600/300**; 128/903; 705/2

(58) **Field of Classification Search** 600/300–301; 128/903–904

See application file for complete search history.

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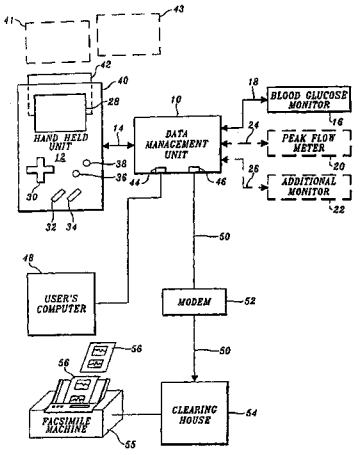
Primary Examiner—Robert L. Nasser
(74) *Attorney, Agent, or Firm*—Christopher P. Maiorana, PC

(57) **ABSTRACT**

Monitoring airflow from a person is accomplished by using a central server arranged to receive and communicate data together with at least one microprocessor-based subsystem. The subsystem includes a microprocessor, a display and a memory. It presents information to the person on the display and processes a digital signal representing airflow from the person. Airflow-related data is communicated to the central server and, in turn, is communicated to at least one health care professional computer. The system can be used to realize systems for self-care monitoring and control of afflictions and physical conditions, such as chronic respiratory afflictions. The system can also be used together with other monitoring devices, such as glucose, blood pressure, pulse and temperature monitors, to monitor the person's condition and to communicate related data to the central server.

26 Claims, 6 Drawing Sheets



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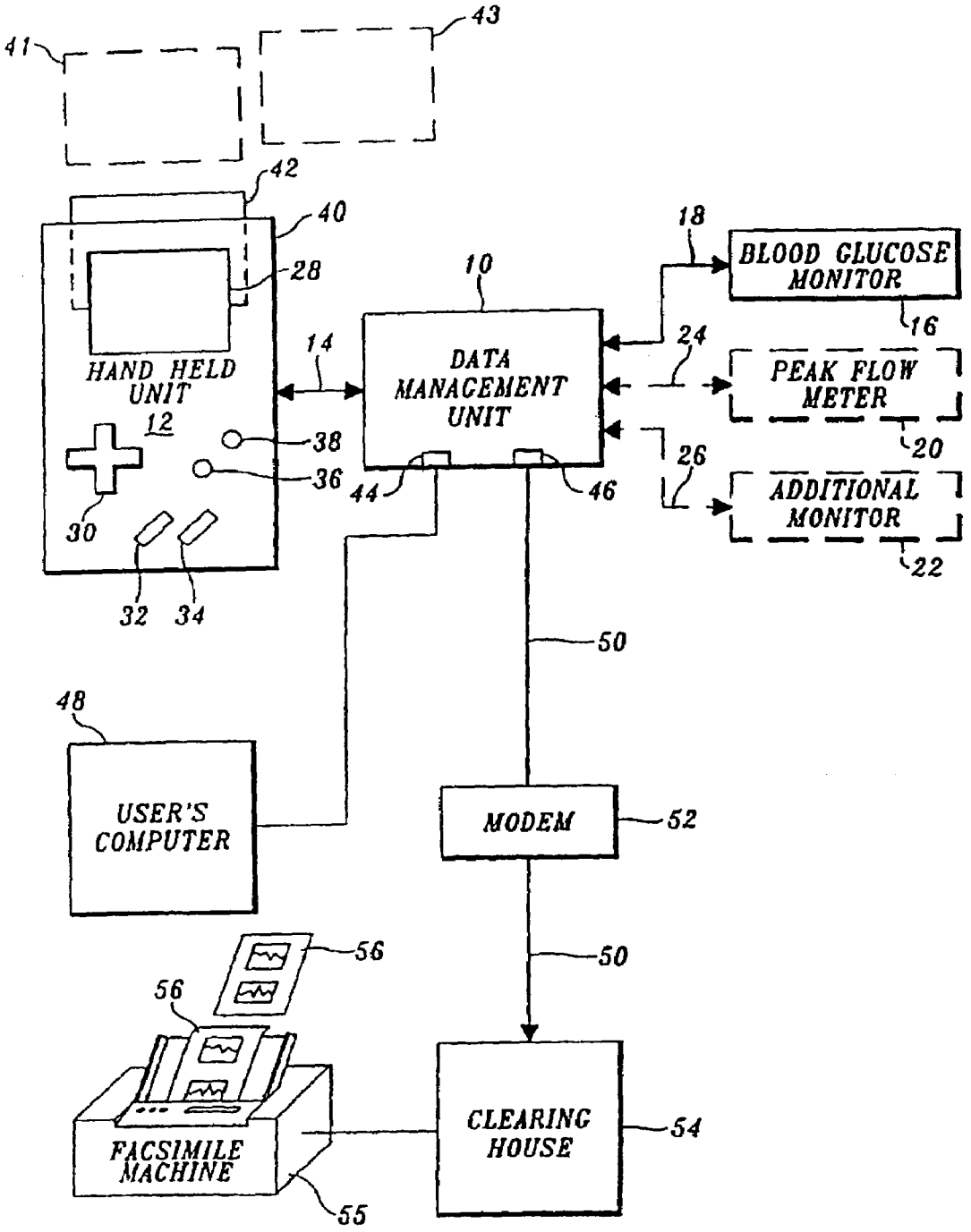
41
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28
HAND HELD UNIT
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DATA MANAGEMENT UNIT
44
46
18
BLOOD GLUCOSE MONITOR
16
24
PEAK FLOW METER
20
26
ADDITIONAL MONITOR
22
50
48
USER'S COMPUTER
MODEM
52
56
56
50
FACSIMILE MACHINE
55
CLEARING HOUSE
54

Fig. 1.

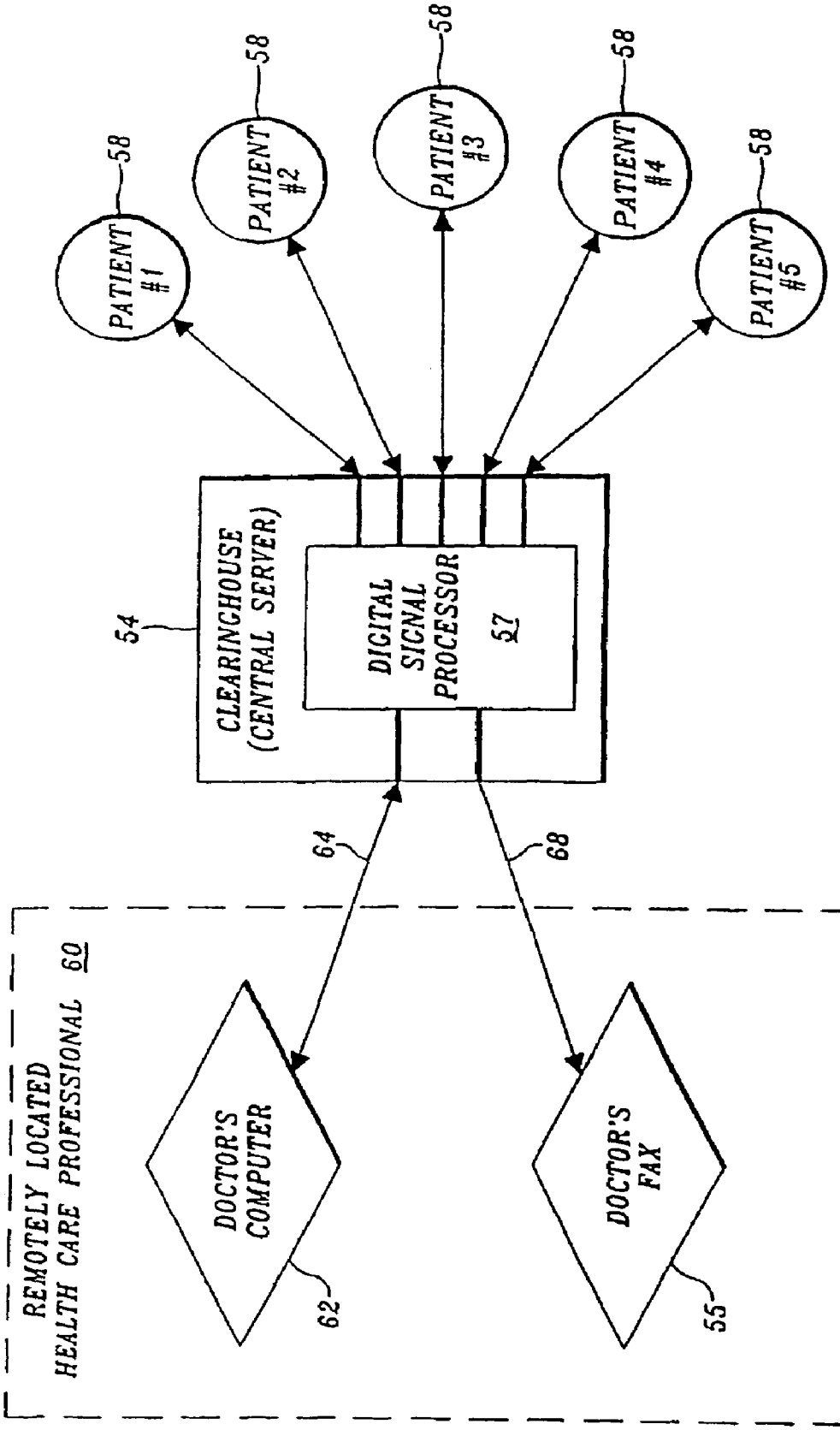
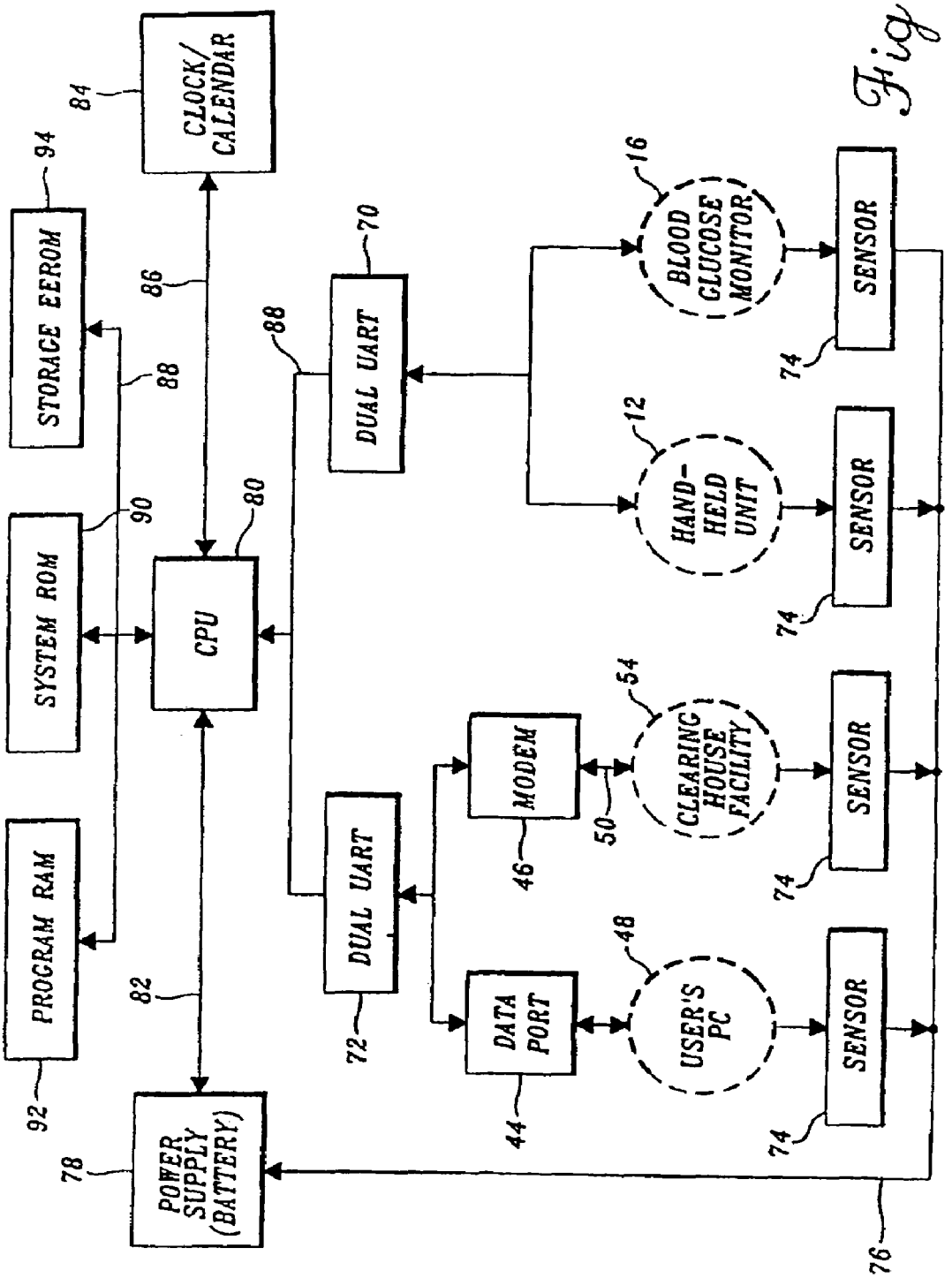

PATIENT #1
PATIENT #2
PATIENT #3
PATIENT #4
PATIENT #5
58
CLEARINGHOUSE (CENTRAL SERVER)
54
DIGITAL SIGNAL PROCESSOR
57
64
68
REMOTELY LOCATED HEALTH CARE PROFESSIONAL 60
DOCTOR'S COMPUTER
62
DOCTOR'S FAX
55

Fig. 2.


CLOCK/ CALENDAR
84
94
STORAGE EEROM
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SYSTEM ROM
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CPU
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PROGRAM RAM
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POWER SUPPLY (BATTERY)
78
DUAL UART
70
88
DUAL UART
72
MODEM
46
DATA PORT
44
BLOOD GLUCOSE MONITOR
16
HAND-HELD UNIT
12
CLEARING HOUSE FACILITY
54
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USER'S PC
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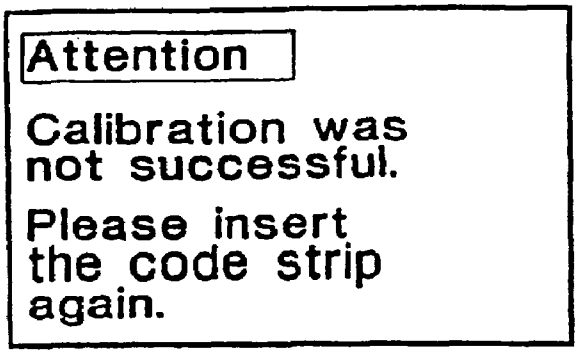
Fig. 3

Fig.4.



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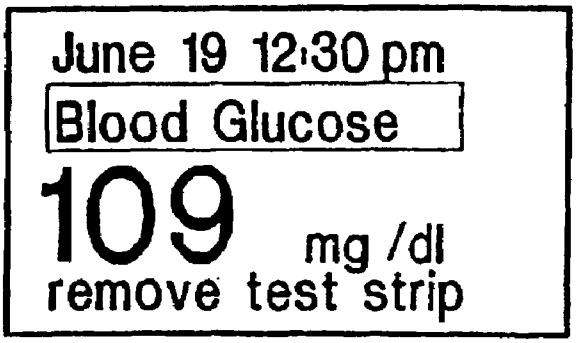

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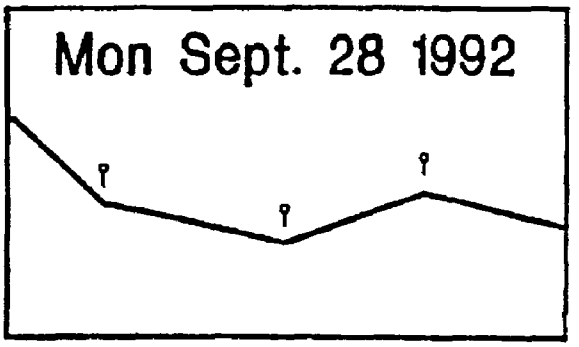

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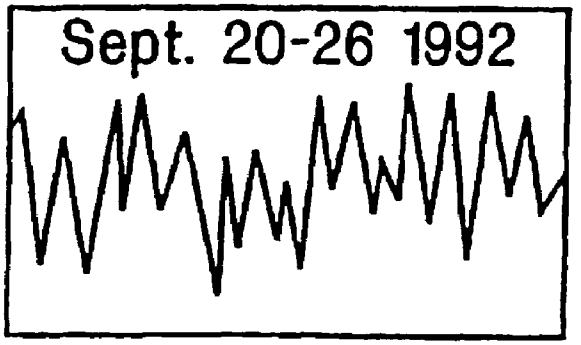

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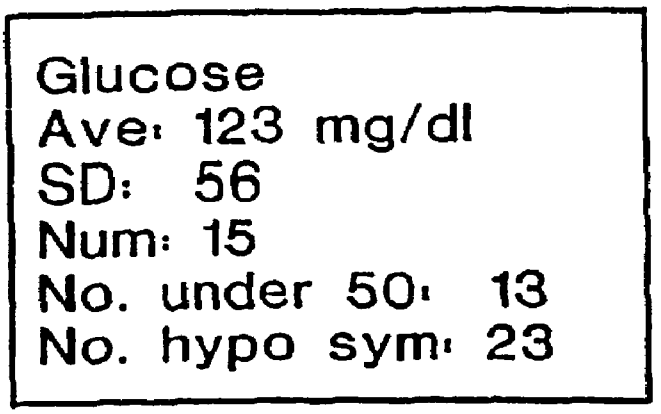


Fig. 9.

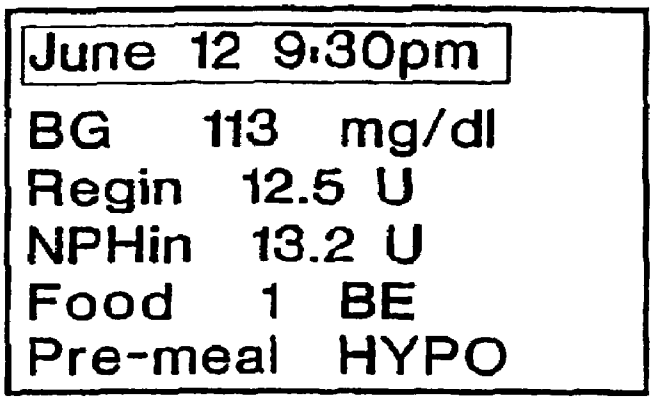


Fig. 10.

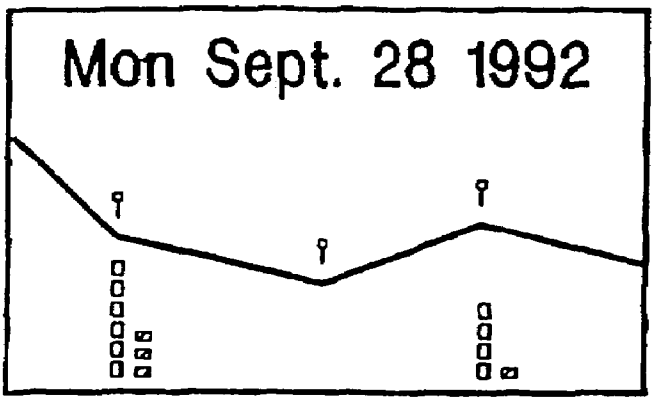
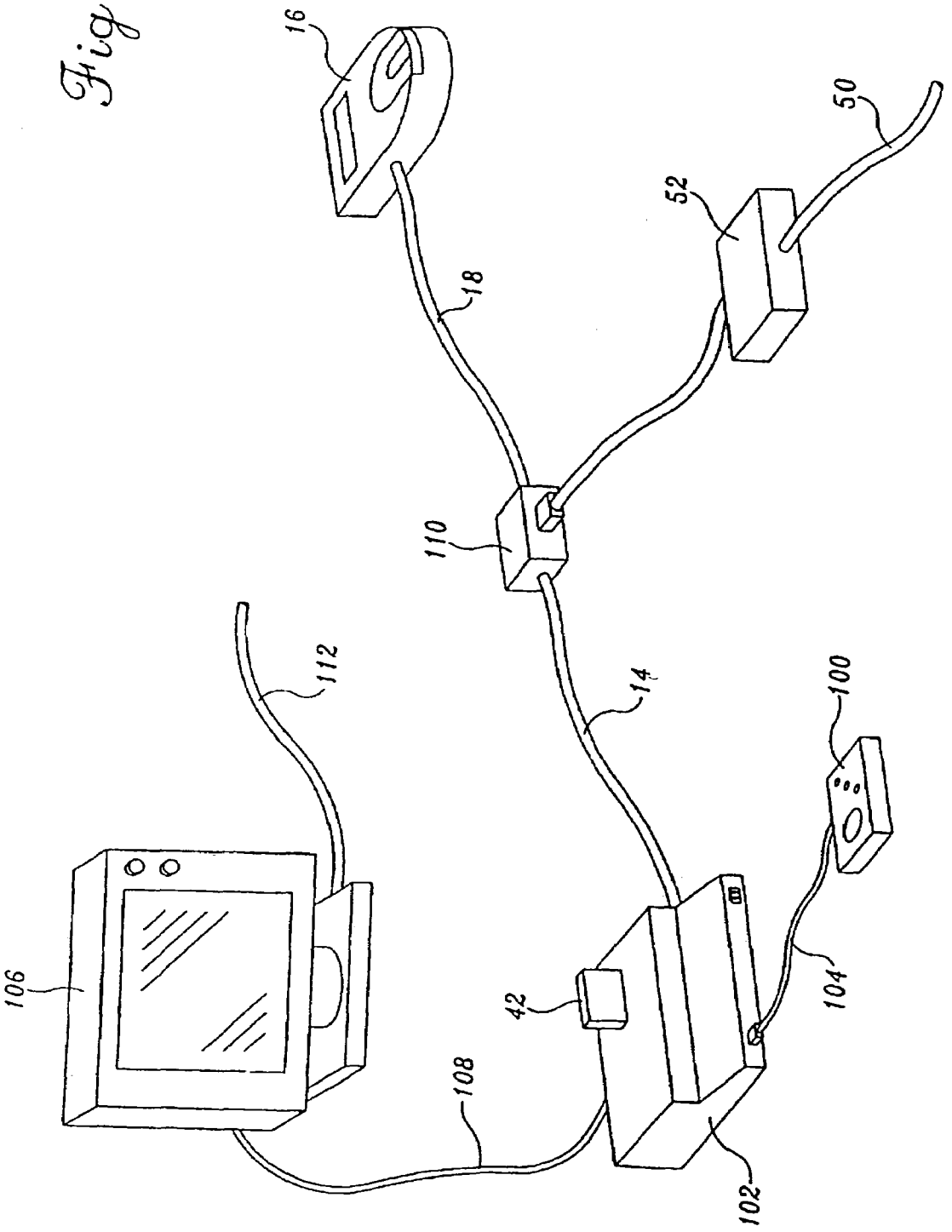


Fig. 11.



SYSTEM AND METHOD FOR MONITORING USER-RELATED DATA FROM A PERSON

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional of application Ser. No. 10/605,547 filed on Oct. 7, 2003, currently pending, which is a Continuation of application Ser. No. 09/237,194, filed on Jan. 26, 1999, currently pending, which is a Continuation of application Ser. No. 08/481,925, filed on Jun. 7, 1995, now U.S. Pat. No. 5,899,855, which is a Continuation of application Ser. No. 08/233,397, filed on Apr. 26, 1994, now abandoned, which is a Continuation-in-Part of application Ser. No. 07/977,323, filed Nov. 11, 1992, now U.S. Pat. No. 5,307,263. The contents of these applications are incorporated by reference herein, in their entirety.

BACKGROUND OF INVENTION

Controlling or curing conditions of ill health generally involves both establishing a therapeutic program and monitoring the progress of the afflicted person. Based on that progress, decisions can be made as to altering therapy to achieve a cure or maintain the affliction or condition at a controlled level. Successfully treating certain health conditions calls for rather frequent monitoring and a relatively high degree of patient participation. For example, in order to establish and maintain a regimen for successful diabetes care, a diabetic should monitor his or her blood glucose level and record that information along with the date and time at which the monitoring took place. Since diet, exercise, and medication all affect blood glucose levels, a diabetic often must record data relating to those items of information along with blood glucose level so that the diabetic may more closely monitor his or her condition and, in addition, can provide information of value to the healthcare provider in determining both progress of the patient and detecting any need to change the patient's therapy program.

Advances in the field of electronics over the past several years have brought about significant changes in medical diagnostic and monitoring equipment, including arrangements for self-care monitoring of various chronic conditions. With respect to the control and monitoring of diabetes, relatively inexpensive and relatively easy-to-use blood glucose monitoring systems have become available that provide reliable information that allows a diabetic and his or her healthcare professional to establish, monitor and adjust a treatment plan (diet, exercise, and medication). More specifically, microprocessor-based blood glucose monitoring systems are being marketed which sense the glucose level of a blood sample that is applied to a reagent-impregnated region of a test strip that is inserted in the glucose monitor. When the monitoring sequence is complete, the blood glucose level is displayed by, for example, a liquid crystal display (LCD) unit.

Typically, currently available self-care blood glucose monitoring units include a calendar/clock circuit and a memory circuit that allows a number of blood glucose test results to be stored along with the date and time at which the monitoring occurred. The stored test results (blood glucose level and associated time and date) can be sequentially recalled for review by the blood glucose monitor user or a health professional by sequentially actuating a push button or other control provided on the monitor. In some commercially available devices, the average of the blood glucose results that are stored in the monitor (or the average of the

results for a predetermined period of time, e.g., fourteen days) also is displayed during the recall sequence. Further, some self-care blood glucose monitors allow the user to tag the test result with an "event code" that can be used to organize the test results into categories. For example, a user might use a specific event code to identify test results obtained at particular times of the day, a different event code to identify a blood glucose reading obtained after a period of exercise, two additional event codes to identify blood glucose readings taken during hypoglycemia symptoms and hyperglycemia symptoms, etc. When event codes are provided and used, the event code typically is displayed with each recalled blood glucose test result.

Microprocessor-based blood glucose monitoring systems have advantages other than the capability of obtaining reliable blood glucose test results and storing a number of the results for later recall and review. By using low power microprocessor and memory circuits and powering the units with small, high capacity batteries (e.g., a single alkaline battery), extremely compact and light designs have been achieved that allow taking the blood glucose monitoring system to work, school, or anywhere else the user might go with people encountered by the user not becoming aware of the monitoring system. In addition, most microprocessor-based self-care blood glucose monitoring systems have a memory capacity that allows the system to be programmed by the manufacturer so that the monitor displays a sequence of instructions during any necessary calibration or system tests and during the blood glucose test sequence itself. In addition, the system monitors various system conditions during a blood glucose test (e.g., whether a test strip is properly inserted in the monitor and whether a sufficient amount of blood has been applied to the reagent impregnated portion of the strip) and if an error is detected generates an appropriate display (e.g., "retest"). A data port may be provided that allows test results stored in the memory of the microprocessor-based blood glucose monitoring system to be transferred to a data port (e.g., RS-232 connection) of a personal computer or other such device for subsequent analysis.

Microprocessor-based blood glucose monitoring systems are a significant advance over previously available self-care systems such as those requiring a diabetic to apply a blood sample to reagent activated portions of a test strip; wipe the blood sample from the test strip after a predetermined period of time; and, after a second predetermined period of time, determine blood glucose level by comparing the color of the reagent activated regions of the test strip with a color chart supplied by the test strip manufacturer. Despite what has been achieved, numerous drawbacks and disadvantages still exist. For example, establishing and maintaining diabetic healthcare often requires the diabetic to record additional data pertaining to medication, food intake, and exercise. However, the event codes of currently available microprocessor blood glucose monitoring systems provide only limited capability for tagging and tracking blood glucose test results according to food intake and other relevant factors. For example, the event codes of currently available monitoring systems only allow the user to classify stored blood glucose readings in a manner that indicates blood glucose tests taken immediately after a heavy, light or normal meal. This method of recording information not only requires subjective judgment by the system user, but will not suffice in a situation in which successfully controlling the user's diabetes requires the recording and tracking of relatively

accurate information relating to food intake, exercise, or medication (e.g., insulin dosage). An otherwise significant advantage of currently available blood glucose monitoring systems is lost when blood glucose test results must be recorded and tracked with quantitative information relating to medication, food intake, or exercise. Specifically, the system user must record the required information along with a time and date tagged blood glucose test result by, for example, writing the information in a log book.

The use of event codes to establish subcategories of blood glucose test results has an additional disadvantage or drawback. In particular, although alphanumeric display devices are typically used in currently available microprocessor-based blood glucose monitoring systems, the display units are limited to a single line of information having on the order of six characters. Moreover, since the systems include no provision for the user to enter alphanumeric information, any event codes that are used must be indicated on the display in a generic manner, e.g., displayed as "EVENT 1", EVENT 2" etc. This limitation makes the system more difficult to use because the diabetic must either memorize his or her assignment of event codes or maintain a list that defines the event codes. The limited amount of data that can be displayed at any one time presents additional drawbacks and disadvantages. First, instructions and diagnostics that are displayed to the user when calibrating the system and using the system to obtain a blood glucose reading must be displayed a line at a time and in many cases, the information must be displayed in a cryptic manner.

The above-discussed display limitations and other aspects of currently available blood glucose monitoring systems is disadvantageous in yet another way. Little statistical information can be made available to the user. For example, in diabetic healthcare maintenance, changes or fluctuations that occur in blood glucose levels during a day, a week, or longer period can provide valuable information to a diabetic and/or his or her healthcare professional. As previously mentioned, currently available systems do not allow associating blood glucose test results with attendant quantitative information relating to medication, food intake, or other factors such as exercise that affect a person's blood glucose level at any particular point in time. Thus, currently available blood glucose monitoring systems have little or no capability for the generating and display of trend information that may be of significant value to a diabetic or the diabetic's healthcare professional.

Some currently available blood glucose monitoring systems provide a data port that can be interconnected with and transfer data to a personal computer (e.g., via an RS-232 connection). With such a system and a suitable programmed computer, the user can generate and display trend information or other data that may be useful in administering his or her treatment plan. Moreover, in such systems, data also can be transferred from the blood glucose monitoring system to a healthcare professional's computer either directly or remotely by telephone if both the blood glucose monitoring system (or computer) to which the data has been downloaded and the healthcare professional's computer are equipped with modems. Although such a data transfer provision allows a healthcare professional to analyze blood glucose data collected by a diabetic, this aspect of currently available blood glucose monitoring systems has not found widespread application. First, the downloading and subsequent analysis feature can only be used by system users that have ready access to a computer that is programmed with appropriate software and, in addition, have both the knowledge required to use the software (and the inclination to do so). This same problem exists with respect to data transfer to (and subsequent analysis by) a healthcare professional. Moreover, various manufacturers of systems that currently provide a data transfer feature do not use the same data format. Therefore, if a healthcare professional wishes to analyze data supplied by a number of different blood glucose monitoring systems, he or she must possess software for each of the systems and must learn to conduct the desired analyses with each software system.

The above-discussed disadvantages and drawbacks of microprocessor-based self-care health monitoring systems take on even greater significance with respect to children afflicted with diabetes, asthma and other chronic illnesses. In particular, a child's need for medication and other therapy changes as the child grows. Current microprocessor-based self-care health monitoring systems generally do not provide information that is timely and complete enough for a healthcare professional to recognize and avert problems before relatively severe symptoms develop. Too often, a need for a change in medication and/or other changes in therapeutic regimen is not detected until the child's condition worsens to the point that emergency room care is required.

Further, currently available microprocessor-based health monitoring systems have not been designed with children in mind. As previously mentioned, such devices are not configured for sufficient ease of use in situations in which it is desirable or necessary to record and track quantitative information that affects the physical condition of the system user (e.g., medication dosage administered by a diabetic and food intake). Children above the age at which they are generally capable of obtaining blood samples and administering insulin or other medication generally can learn to use at least the basic blood glucose monitoring features of currently available microprocessor-based blood glucose monitoring systems. However, the currently available monitoring systems provide nothing in the way of motivation for a child to use the device and, in addition, include little or nothing that educates the child about his or her condition or treatment progress.

The lack of provision for the entering of alphanumeric data also can be a disadvantage. For example, currently available blood glucose monitoring systems do not allow the user or the healthcare professional to enter information into the system such as medication dosage and other instructions or data that is relevant to the user's self-care health program.

The above-discussed disadvantages and drawbacks of currently available microprocessor-based blood glucose monitoring systems also have been impediments to adopting the basic technology of the system for other healthcare situations in which establishing and maintaining an effective regimen for cure or control is dependent upon (or at least facilitated by) periodically monitoring a condition and recording that condition along with time and date tags and other information necessary or helpful in establishing and maintaining a healthcare program.

SUMMARY OF INVENTION

This invention provides a new and useful system for healthcare maintenance in which the invention either serves as a peripheral device to (or incorporates) a small handheld microprocessor-based unit of the type that includes a display screen, buttons or keys that allow a user to control the operation of the device and a program cartridge or other arrangement that can be inserted in the device to adapt the device to a particular application or function. The invention in effect converts the handheld microprocessor device into a

healthcare monitoring system that has significant advantages over systems such as the currently available blood glucose monitoring systems. To perform this conversion, the invention includes a microprocessor-based healthcare data management unit, a program cartridge and a monitoring unit. When inserted in the handheld microprocessor unit, the program cartridge provides the software necessary (program instructions) to program the handheld microprocessor unit for operation with the microprocessor-based data management unit. Signal communication between the data management unit and the handheld microprocessor unit is established by an interface cable. A second interface cable can be used to establish signal communication between the data management unit and the monitoring unit or, alternatively, the monitoring unit can be constructed as a plug-in unit having an electrical connector that mates with a connector mounted within a region that is configured for receiving the monitoring unit.

In operation, the control buttons or keys of the handheld microprocessor-based unit are used to select the operating mode for both the data management unit and the handheld microprocessor-based unit. In response to signals generated by the control buttons or keys, the data management unit generates signals that are coupled to the handheld microprocessor unit and, under control of the program instructions contained in the program cartridge, establish an appropriate screen display on the handheld microprocessor-based unit display. In selecting system operating mode and other operations, the control buttons are used to position a cursor or other indicator in a manner that allows the system user to easily select a desired operating mode or function and provide any other required operator input. In the disclosed detailed embodiment of the invention several modes of operation are made available.

In the currently preferred embodiments of the invention, the handheld microprocessor unit is a compact video game system such as the system manufactured by Nintendo of America Inc. under the trademark "GAME BOY." Use of a compact video game system has several general advantages, including the widespread availability and low cost of such systems. Further, such systems include switch arrangements that are easily adapted for use in the invention and the display units of such systems are of a size and resolution that can advantageously be employed in the practice of the invention. In addition, such systems allow educational or motivational material to be displayed to the system user, with the material being included in the program cartridge that provides the monitor system software or, alternatively, in a separate program cartridge.

The use of a compact video game system for the handheld microprocessor-based unit of the invention is especially advantageous with respect to children. Specifically, the compact video game systems of the type that can be employed in the practice of the invention are well known and well accepted by children. Such devices are easily operated by a child and most children are well accustomed to using the devices in the context of playing video games. Motivational and educational material relating to the use of the invention can be presented in game-like or animated format to further enhance acceptance and use of the invention by children that require self-care health monitoring.

A microprocessor-based health monitoring system that is configured in accordance with the invention provides additional advantages for both the user and a healthcare professional. In accordance with one aspect of the invention, standardized reports are provided to a physician or other healthcare provider by means of facsimile transmission. To accomplish this, the data management unit of the currently preferred embodiments of the invention include a modem which allows test results and other data stored in system memory to be transmitted to a remote clearinghouse via a telephone connection. Data processing arrangements included in the clearinghouse perform any required additional data processing; format the standardized reports; and, transmit the reports to the facsimile machine of the appropriate healthcare professional.

The clearinghouse also can fill an additional communication need, allowing information such as changes in medication dosage or other information such as modification in the user's monitoring schedule to be electronically sent to a system user. In arrangements that incorporate this particular aspect of the invention, information can be sent to the user via a telephone connection and the data management unit modem when a specific inquiry is initiated by the user, or when the user establishes a telephone connection with the clearinghouse for other purposes such as providing data for standardized reports.

The clearinghouse-facsimile aspect of the invention is important because it allows a healthcare professional to receive timely information about patient condition and progress without requiring a visit by the patient (system user) and without requiring analysis or processing of test data by the healthcare professional. In this regard, the healthcare professional need not possess or even know how to use a computer and/or the software conventionally employed for analysis of blood glucose and other health monitoring data and information.

The invention also includes provision for data analysis and memory storage of information provided by the user and/or the healthcare professional. In particular, the data management units of the currently preferred embodiments of the invention include a data port such as an RS-232 connection that allows the system user or healthcare professional to establish signal communication between the data management unit and a personal computer or other data processing arrangement. Blood glucose test data or other information can then be downloaded for analysis and record keeping purposes. Alternatively, information such as changes in the user's treatment and monitoring regimen can be entered into system memory. Moreover, if desired, remote communication between the data management unit and the healthcare professional's computer can be established using the clearinghouse as an element of the communications link. That is, in the currently preferred arrangements of the invention a healthcare professional has the option of using a personal computer that communicates with the clearinghouse via a modem and telephone line for purposes of transmitting instructions and information to a selected user of the system and/or obtaining user test data and information for subsequent analysis.

The invention can be embodied in forms other than those described above. For example, although small handheld microprocessor units such as a handheld video game system or handheld microprocessor units of the type often referred to as "palm-computers provide many advantages, there are situations in which other compact microprocessor units can advantageously be used. Among the various types of units that can be employed are using compact video game systems of the type that employ a program cartridge, but uses a television set or video monitor instead of a display unit that is integrated into the previously described handheld microprocessor units.

Those skilled in the art also will recognize that the above-described microprocessor-implemented functions

and operations can be apportioned between one or more microprocessors in a manner that differs from the above-described arrangement. For example, in some situations, the programmable microprocessor unit and the program cartridge used in practicing the invention may provide memory and signal processing capability that is sufficient for practicing the invention. In such situations, the microprocessor of the microprocessor-based data management unit of the above embodiments in effect is moved into the video game system, palm-computer or programmable microprocessor device. In such an arrangement, the data management unit can be realized as a relatively simple interface unit that includes little or no signal processing capability. Depending upon the situation at hand, the interface unit may or may not include a telephone modem and/or an RS-232 connection (or other data port) for interconnecting the healthcare system with a computer or other equipment. In other situations, the functions and operations associated with processing of the monitored health care data may be performed by a microprocessor that is added to or already present in the monitoring device that is used to monitor blood glucose or other condition.

Because the invention can be embodied to establish systems having different levels of complexity, the invention satisfies a wide range of self-care health monitoring applications. The arrangements that include a modem (or other signal transmission facility) and sufficient signal processing capability can be employed in situations in which reports are electronically transmitted to a healthcare professional either in hard copy (facsimile) form or in a signal format that can be received by and stored in the healthcare professional's computer. On the other hand, less complex (and, hence, less costly) embodiments of the invention are available for use in which transfer of system information need not be made by means of telephonic data transfer or other remote transmission methods. In these less complex embodiments, transfer of data to a healthcare professional can still be accomplished. Specifically, if the program cartridge includes a battery and suitable program instructions, monitored healthcare data can be stored in the program cartridge during use of the system as a healthcare monitor. The data cartridge can then be provided to the healthcare professional and inserted in a programmable microprocessor-based unit that is the same as or similar to that which was used in the healthcare monitoring system. The healthcare professional can then review the data, and record it for later use, and/or can use the data in performing various analyses. If desired, the microprocessor-based unit used by the healthcare professional can be programmed and arranged to allow information to be stored in the cartridge for return to and retrieval by the user of the healthcare monitoring system. The stored information can include messages (e.g., instructions for changes in medication dosage) and/or program instructions for reconfiguring the program included in the cartridge so as to effect changes in the treatment regimen, the analyses or reports to be generated by the healthcare monitoring system, or less important aspects such as graphical presentation presented during the operation of the healthcare system.

BRIEF DESCRIPTION OF DRAWINGS

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same becomes better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIG. **1** is a block diagram that illustrates a healthcare monitoring system arranged in accordance with the invention;

FIG. **2** diagrammatically illustrates monitoring systems constructed in accordance with the invention connected in signal communication with a remotely located computing facility which includes provision for making the data supplied by the monitoring system of the invention available to a designated healthcare professional and/or for providing data and instructions to the system user;

FIG. **3** is a block diagram diagrammatically depicting the structural arrangement of the system data management unit and its interconnection with other components of the system shown in FIG. **1**.

FIGS. **4-10** depict typical system screen displays of data and information that can be provided by the arrangements shown in FIGS. **1-3**; and

FIG. **11** diagrammatically illustrates an alternative healthcare monitoring system that is arranged in accordance with the invention.

DETAILED DESCRIPTION

FIG. **1** depicts a self-care health monitoring system arranged in accordance with the invention. In the arrangement shown in FIG. **1** a data management unit **10** is electrically interconnected with a handheld microprocessor-based unit **12** via a cable **14**. In the depicted arrangement, data management unit **10** also is electrically interconnected with a blood glucose monitor **16** of the type capable of sensing blood glucose level and producing an electrical signal representative thereof. Although FIG. **1** illustrates blood glucose monitor **16** as being connected to data management unit **10** by a cable **18**, it may be preferable to construct blood glucose monitor **16** as a plug-in unit that is placed in a recess or other suitable opening or slot in data management unit **10**. Regardless of the manner in which blood glucose monitor **16** is interconnected with data management unit **10**, both that interconnection and cable **14** are configured for serial data communication between the interconnected devices.

Also shown in FIG. **1** are two additional monitoring devices **20** and **22**, which are electrically connected for serial data communication with data management unit **10** via cables **24** and **26**, respectively. Monitoring units **20** and **22** of FIG. **1** represent devices other than blood glucose monitor **16** that can be used to configure the invention for self-care health monitoring applications other than (or in addition to) diabetes care. For example, as is indicated in FIG. **1** the monitoring device **20** can be a peak-flow meter that provides a digital signal representative of the airflow that results when a person suffering from asthma or another chronic respiratory affliction expels a breath of air through the meter. As is indicated by monitor **22** of FIG. **1** various other devices can be provided for monitoring conditions such as blood pressure, pulse, and body temperature to thereby realize systems for self-care monitoring and control of conditions such as hypertension, certain heart conditions and various other afflictions and physical conditions. Upon understanding the hereinafter discussed aspects and features of the invention it will be recognized that the invention is easily implemented for these and other types of healthcare monitoring. In particular, monitors used in the practice of the invention can be arranged in a variety of ways as long as the data to be recorded or otherwise employed by handheld microprocessor unit and/or data management unit **10** is provided in serial format in synchronization with clock signals provided by

data management unit **10**. As is the case with blood glucose monitor **16**, the additional monitors can be configured as plug-in units that are directly received by data management unit **10**, or can be connected to data management unit **10** with cables (as shown in FIG. **1**).

As is shown in FIG. **1**, handheld microprocessor unit **12** includes a display screen **28** and a plurality of switches or keys (**30**, **32**, **34**, **36**, and **38** in FIG. **1**) which are mounted on a housing **40**. Located in the interior of housing **40**, but not shown in FIG. **1** are a microprocessor, memory circuits, and circuitry that interfaces switches **30**, **32**, **34**, **36**, and **38** with the microprocessor. Stored in the memory of program handheld microprocessor unit **12** is a set of program instructions that establishes a data protocol that allows handheld microprocessor unit **12** to perform digital data signal processing and generate desired data or graphics for display on display unit **28** when a program cartridge **42** is inserted in a slot or other receptacle in housing **40**. That is, program cartridge **42** of FIG. **1** includes read-only memory units (or other memory means such as battery-powered random access memory) which store program instructions and data that adapt handheld microprocessor **12** for operation in a blood glucose monitoring system. More specifically, when the instructions and data of program cartridge **42** are combined with program instructions and data included in the internal memory circuits of handheld microprocessor unit **12** handheld microprocessor unit **12** is programmed for processing and displaying blood glucose information in the manner described below and additional monitors **22** to provide health monitoring for asthma and various other previously mentioned chronic conditions. In each case, the plurality of switches or keys (**30**, **32**, **34**, **36** and **38** in FIG. **1**) are selectively operated to provide signals that result in pictorial and/or alphanumeric information being displayed by display unit **42**.

Various devices are known that meet the above-set forth description of handheld microprocessor unit **12**. For example, compact devices are available in which the plurality of keys allows alphanumeric entry and internal memory is provided for storing information such as names, addresses, phone numbers, and an appointment calendar. Small program cartridges or cards can be inserted in these devices to program the device for various purposes such as the playing of games, spreadsheet application, and foreign language translation sufficient for use in travel. More recently, less compact products that have more extensive computational capability and are generally called "palm top computers" have been introduced into the marketplace. These devices also can include provision for programming the device by means of an insertable program card or cartridge.

The currently preferred embodiments of the invention are configured and arranged to operate in conjunction with yet another type of handheld microprocessor unit. Specifically, in the currently preferred embodiments of the invention, program cartridge **42** is electrically and physically compatible with commercially available compact video game systems, such as the system manufactured by Nintendo of America Inc. under the trademark "GAME BOY." Configuring data management unit **10** and program cartridge **42** for operation with a handheld video game system has several advantages. For example, the display unit of such a device provides display resolution that allows the invention to display both multi-line alphanumeric information and graphical data. In this regard, the 160×144 pixel dot matrix-type liquid crystal display screen currently used in the above-referenced compact video game systems provides sufficient resolution for at least six lines of alphanumeric text, as well as allowing graphical representation of statistical data such as graphical representation of blood glucose test results for a day, a week, or longer.

Another advantage of realizing handheld microprocessor unit **12** in the form of a compact video game system is the relatively simple, yet versatile arrangement of switches that is provided by such a device. For example, as is indicated in FIG. **1** a compact video game system includes a control pad that allows an object displayed on display unit **42** to be moved in a selected direction (i.e., up-down or left-right). As also is indicated in FIG. **1**, compact video game systems typically provide two pair of distinctly-shaped push button switches. In the arrangement shown in FIG. **1**, a pair of spaced-apart circular push button switches (**36** and **38**) and a pair of elongate switches (**32** and **34**) are provided. The functions performed by the two pairs of switches is dependent upon the program instructions contained in each program cartridge **42**.

Yet another advantage of utilizing a compact video game system for handheld microprocessor-based unit **12** of FIG. **1** is the widespread popularity and low cost of such units. In this regard, manufacture and sale of a data management unit blood glucose monitor **16** and program cartridge **42** that operate in conjunction with a compact microprocessor-based video allows the self-care health monitoring system of FIG. **1** to be manufactured and sold at a lower cost than could be realized in an arrangement in which handheld unit **12** is designed and manufactured solely for use in the system of FIG. **1**.

An even further advantage of using a compact video game system for handheld microprocessor **12** is that such video game systems include means for easily establishing the electrical interconnection provided by cable **14** in FIG. **1**. In particular, such compact video game systems include a connector mounted to the game unit housing (**40** in FIG. **1**) and a cable that can be connected between the connectors of two video game units to allow interactive operation of the two interconnected units (i.e., to allow contemporaneous game play by two players or competition between players as they individually play identical but separate games). In the preferred embodiments of the invention, the "two-player" cable supplied with the compact video game unit being used as handheld microprocessor unit **12** is used as cable **14** to establish serial data communication between the handheld microprocessor unit **12** (compact video game system) and data management unit **10**. In these preferred embodiments, the program instructions stored on the memory of data management unit **10** and program cartridge **42** respectively program data management unit **10** and the compact video game system (i.e., handheld microprocessor unit **12**) for interactive operation in which switches **30**, **32**, **34**, **36** and **38** are used to control the operation of data management unit **10** (e.g., to select a particular operational mode such as performance of a blood glucose test or the display of statistical test data and, in addition, to control operation such as selection of an option during operation of the system in a particular operational mode). In each operational mode, data management unit **10** processes data in accordance with program instructions stored in the memory circuits of data management unit **10**. Depending upon the operational mode selected by the user, data is supplied to data management unit **10** by blood glucose monitor **16** by additional monitors (**20** and **22** in FIG. **1**) or any interconnected computers or data processing facility (such as the hereinafter described user's computer **48** and clearinghouse **54** of FIG. **1**) During such operation, mode switches **30**, **32**, **34**, **36** and **38** are selec-

tively activated so that signals are selectively coupled to the video game system (handheld microprocessor unit **12**) and processed in accordance with program instructions stored in program cartridge **42**. The signal processing performed by handheld microprocessor unit **12** results in the display of alphanumeric, symbolic, or graphic information on the video game display screen (i.e., display unit **28** in FIG. **1**) which allow the user to control system operation and obtain desired test results and other information.

Although the above-discussed advantages apply to use of the invention by all age groups, employing a compact video game system in the practice of the invention is of special significance in monitoring a child's blood glucose or other health parameters. Children and young adults are familiar with compact video game systems. Thus, children will accept a health monitoring system incorporating a compact video game system more readily than a traditional system, even an embodiment of the invention that uses a different type of handheld microprocessor unit. Moreover, an embodiment of the invention that functions in conjunction with a compact video game system can be arranged to motivate children to monitor themselves more closely than they might otherwise by incorporating game-like features and/or animation in system instruction and test result displays. Similarly, the program instructions can be included in program cartridges **41**, **42** and **43** (or additional cartridges) that allow children to select game-like displays that help educate the child about his or her condition and the need for monitoring.

With continued reference to FIG. **1**, data management unit **10** of the currently preferred embodiments of the invention includes a data port **44** that allows communication between data management unit **10** and a personal computer **48** (or other programmable data processor). In the currently preferred embodiments of the invention, data port **44** is an RS-232 connection that allows serial data communication between data management unit **10** and personal computer **48**. In the practice of the invention, personal computer **48** can be used to supplement data management unit **10** by, for example, performing more complex analyses of blood glucose and other data that has been supplied to and stored in the memory circuits of data management unit **10**. With respect to embodiments of the invention configured for use by a child, personal computer **48** can be used by a parent or guardian to review and analyze the child's progress and to produce printed records for subsequent review by a healthcare professional. Alternatively, personal computer **48** can be used to supply data to data management unit **10** that is not conveniently supplied by using handheld microprocessor switches **30**, **32**, **34**, **36** and **38** as an operator interface to the system shown in FIG. **1**. For example, some embodiments of the invention may employ a substantial amount of alphanumeric information that must be entered by the system user. Although it is possible to enter such data by using switches **30**, **32**, **34**, **36**, and **38** in conjunction with menus and selection screens displayed on display screen **28** of FIG. **1** it may be more advantageous to use a device such as personal computer **48** for entry of such data. However, if personal computer **48** is used in this manner, some trade-off of system features may be required because data management unit **10** must be temporarily interconnected with personal computer **48** during these operations. That is, some loss of system mobility might result because a suitably programmed personal computer would be needed at each location at which data entry or analysis is to occur.

As is indicated in FIG. **1**, data management unit **10** of the currently preferred embodiments of the invention also includes a modem that allows data communication between data management unit **10** and a remote computing facility identified in FIG. **1** as clearinghouse **54** via a conventional telephone line (indicated by reference numeral **50** in FIG. **1**) and a modem **52** that interconnects clearinghouse **54** and telephone line **50**. As shall be described in more detail, clearinghouse **54** computing facility **54** facilitates communication between a user of the system shown in FIG. **1** and his or her healthcare professional and can provide additional services such as updating system software. As is indicated by facsimile machine **55** of FIG. **1***a* primary function of clearinghouse **54** is providing the healthcare professional with standardized reports **56**, which indicate both the current condition and condition trends of the system user. Although a single facsimile machine **55** is shown in FIG. **1**, it will be recognized that numerous healthcare professionals (and hence facsimile machine **55**) can be connected in signal communication with a clearinghouse **54**.

Regardless of whether a compact video game system, another type of commercially available handheld microprocessor-based unit, or a specially designed unit is used, the preferred embodiments of FIG. **1** provide a self-care blood glucose monitoring system in which program cartridge (a) handheld microprocessor unit **12** for displaying instructions for performing the blood glucose test sequence and associated calibration and test procedures; (b) handheld microprocessor unit **12** for displaying (graphically or alphanumerically) statistical data such as blood glucose test results taken during a specific period of time (e.g., a day, week, etc.); (c) handheld microprocessor unit **12** for supplying control signals and signals representative of food intake or other useful information to data management unit **10**; (d) handheld microprocessor unit **12** for simultaneous graphical display of blood glucose levels with information such as food intake; and, (e) handheld microprocessor unit **12** for displaying information or instructions from a healthcare professional that are coupled to data management unit **10** from a clearinghouse **54**. The manner in which the arrangement of FIG. **1** implements the above-mentioned functions and others can be better understood with reference to FIGS. **2** and **3**.

Referring first to FIG. **2**, clearinghouse **54** receives data from a plurality of self-care microprocessor-based healthcare systems of the type shown in FIG. **1**, with the individual self-care health monitoring systems being indicated in FIG. **2** by reference numeral **58**. Preferably, the data supplied to clearinghouse **54** by each individual self-care health monitoring system **58** consists of "raw data," i.e., test results and related data that was stored in memory circuits of data management unit **10**, without further processing by data management unit **10**. For example, with respect to the arrangement shown in FIG. **1**, blood glucose test results and associated data such as food intake information, medication dosage and other such conditions are transmitted to clearinghouse **54** and stored with a digitally encoded signal that identifies both the source of the information (i.e., the system user or patient) and those having access to the stored information (i.e., the system user's doctor or other healthcare professional).

As shall be recognized upon understanding the manner in which it operates, clearinghouse **54** can be considered to be a central server for the various system users (**58** in FIG. **2**) and each healthcare professional **60**. In that regard, clearinghouse **54** includes conventionally arranged and interconnected digital processing equipment (represented in FIG. **2** by digital signal processor **57**) which receives digitally encoded information from a user **58** or healthcare professional processes the information as required; stores the

information (processed or unprocessed) in memory if necessary; and, transmits the information to an intended recipient (i.e., user **58** or healthcare professional **60**).

In FIG. **2** rectangular outline **60** represents one of numerous remotely located healthcare professionals who can utilize clearinghouse **54** and the arrangement described relative to FIG. **1** in monitoring and controlling patient healthcare programs. Shown within outline **60** is a computer **62** (e.g., personal computer), which is coupled to clearinghouse **54** by means of a modem (not shown in FIG. **2**) and a telephone line **64**. Also shown in FIG. **2** is the previously mentioned facsimile machine **55**, which is coupled to clearinghouse **54** by means of a second telephone line **68**. Using the interface unit of computer **62** (e.g., a keyboard or pointing device such as a mouse), the healthcare professional can establish data communication between computer **62** and clearinghouse **54** via telephone line **64**. Once data communication is established between computer **62** and clearinghouse **54** patient information can be obtained from clearinghouse **54** in a manner similar to the manner in which subscribers to various database services access and obtain information. In particular, the healthcare professional can transmit an authorization code to clearinghouse **54** that identifies the healthcare professional as an authorized user of the clearinghouse and, in addition, can transmit a signal representing the patient for which healthcare information is being sought. As is the case with conventional database services and other arrangements, the identifying data is keyed into computer **62** by means of a conventional keyboard (not shown in FIG. **2**) in response to prompts that are generated at clearinghouse **54** for display by the display unit of computer **62** (not shown in FIG. **2**).

Depending upon the hardware and software arrangement of clearinghouse **54** and selections made by the healthcare professional via computer **62** patient information can be provided to the healthcare professional in different ways. For example, computer **62** can be operated to access data in the form that it is stored in the memory circuits of clearinghouse **54** (i.e., raw data that has not been processed or altered by the computational or data processing arrangements of clearinghouse **54**). Such data can be processed, analyzed, printed and/or displayed by computer **62** using commercially available or custom software. On the other hand, various types of analyses may be performed by clearinghouse **54** with the results of the analyses being transmitted to the remotely located healthcare professional **60**. For example, clearinghouse **54** can process and analyze data in a manner identical to the processing and analysis provided by the self-care monitoring system of FIG. **1**. With respect to such processing and any other analysis and processing provided by clearinghouse **54** results expressed in alphanumeric format can be sent to computer **62** via telephone line **64** and the modem associated with computer **62** with conventional techniques being used for displaying and/or printing the alphanumeric material for subsequent reference.

The arrangement of FIG. **2** also allows the healthcare professional to send messages and/or instructions to each patient via computer **62** telephone line **64** and clearinghouse **54**. In particular, clearinghouse **54** can be programmed to generate a menu that is displayed by computer **62** and allows the healthcare professional to select a mode of operation in which information is to be sent to clearinghouse **54** for subsequent transmission to a user of the system described relative to FIG. **1**. This same menu (or related submenus) can be used by the healthcare professional to select one or more modes of operation of the above-described type in which either unmodified patient data or the results of data that has been analyzed by clearinghouse **54** is provided to the healthcare provider via computer **62** and/or facsimile machine **55**.

In the currently contemplated arrangements, operation of the arrangement of FIG. **2** to provide the user of the invention with messages or instructions such as changes in medication or other aspects of the healthcare program is similar to the operation that allows the healthcare professional to access data sent by a patient, i.e., transmitted to clearinghouse **54** by a data management unit **10** of FIG. **1**. The process differs in that the healthcare professional enters the desired message or instruction via the keyboard or other interface unit of computer **62**. Once the data is entered and transmitted to clearinghouse **54** it is stored for subsequent transmission to the user for whom the information or instruction is intended.

With respect to transmitting stored messages or instructions to a user of the invention, at least two techniques are available. The first technique is based upon the manner in which operational modes are selected in the practice of the invention. Specifically, in the currently preferred embodiments of the invention, program instructions that are stored in data management unit **10** and program cartridge **42** cause the system of FIG. **1** to generate menu screens which are displayed by display unit **28** of handheld microprocessor unit **12**. The menu screens allow the system user to select the basic mode in which the system of FIG. **1** is to operate and, in addition, allow the user to select operational subcategories within the selected mode of operation. Various techniques are known to those skilled in the art for displaying and selecting menu items. For example, in the practice of this invention, one or more main menus can be generated and displayed which allow the system user to select operational modes that may include: (a) a monitor mode (e.g., monitoring of blood glucose level); (b) a display mode (e.g., displaying previously obtained blood glucose test results or other relevant information); (c) an input mode (e.g., a mode for entering data such as providing information that relates to the healthcare regimen, medication dosage, food intake, etc.); and, (d) a communications mode (for establishing a communication link between data management unit **10** and personal computer **48** of FIG. **1** or between data management unit **10** and a remote computing facility such as clearinghouse **54** of FIG. **2**.

In embodiments of the invention that employ a compact video game system for handheld microprocessor unit **12** the selection of menu screens and the selection of menu screen items preferably is accomplished in substantially the same manner as menu screens and menu items are selected during the playing of a video game. For example, the program instructions stored in data management unit **10** and program cartridge **42** of the arrangement of FIG. **1** can be established so that a predetermined one of the compact video game switches (e.g., switch **32** in FIG. **1**) allows the system user to select a desired main menu in the event that multiple main menus are employed. When the desired main menu is displayed, operation by the user of control pad **30** allows a cursor or other indicator that is displayed on the menu to be positioned adjacent to or over the menu item to be selected. Activation of a switch (e.g., switch **36** of the depicted handheld microprocessor unit causes the handheld microprocessor unit **12**) and/or data management unit **10** to initiate the selected operational mode or, if selection of operational submodes is required, causes handheld microprocessor unit **12** to display a submenu.

In view of the above-described manner in which menus and submenus are selected and displayed, it can be recog-

nized that the arrangement of FIG. **1** can be configured and arranged to display a menu or submenu item that allows the user to obtain and display messages or instructions that have been provided by a healthcare professional and stored in clearinghouse **54**. For example, a submenu that is generated upon selection of the previously mentioned communications mode can include submenu items that allow the user to select various communication modes, including a mode in which serial data communication is established between data management unit **10** and clearinghouse **54** and data management unit **10** transmits a message status request to clearinghouse **54**. When this technique is used, the data processing system of clearinghouse **54** is programmed to search the clearinghouse memory to determine whether a message exists for the user making the request. Any messages stored in memory for that user are then transmitted to the user and processed for display on display unit **28** of handheld microprocessor unit **12**. If no messages exist, clearinghouse **54** transmits a signal that causes display unit **28** to indicate "no messages." In this arrangement, clearinghouse **54** preferably is programmed to store a signal indicating that a stored message has been transmitted to the intended recipient (user). Storing such a signal allows the healthcare professional to determine that messages sent to clearinghouse **54** for forwarding to a patient have been transmitted to that patient. In addition, the program instructions stored in data management unit **10** of FIG. **1** preferably allow the system user to designate whether received messages and instructions are to be stored in the memory of data management unit **10** for subsequent retrieval or review. In addition, in some instances it may be desirable to program clearinghouse **54** and data management unit **10** so that the healthcare professional can designate (i.e., flag) information such as changes in medication that will be prominently displayed to the user (e.g., accompanied by a blinking indicator) and stored in the memory of data management unit **10** regardless of whether the system user designates the information for storage.

A second technique that can be used for forwarding messages or instructions to a user does not require the system user to select a menu item requesting transmission by clearinghouse **54** of messages that have been stored for forwarding to that user. In particular, clearinghouse **54** can be programmed to operate in a manner that either automatically transmits stored messages for that user when the user operates the system of FIG. **1** to send information to the clearinghouse or programmed to operate in a manner that informs the user that messages are available and allows the user to access the messages when he or she chooses to do so.

Practicing the invention in an environment in which the healthcare professional uses a personal computer in some or all of the above-discussed ways can be very advantageous. On the other hand, the invention also provides healthcare professionals timely information about system users without the need for a computer (**62** in FIG. **2**) or any equipment other than a conventional facsimile machine (**55** in FIGS. **1** and **2**) Specifically, information provided to clearinghouse **54** by a system user **58** can be sent to a healthcare professional **60** via telephone line **68** and facsimile machine **55** with the information being formatted as a standardized graphic or textual report (**56** in FIG. **1**) Formatting a standardized report **56** (i.e., analyzing and processing data supplied by blood glucose monitor **16** or other system monitor or sensor) can be effected either by data management unit **10** or within the clearinghouse facility **54**. Moreover, various standardized reports can be provided (e.g., the textual and graphic displays discussed below relating to FIGS. **6-10**) Preferably, the signal processing arrangement included in clearinghouse **54** allows each healthcare professional **60** to select which of several standardized reports will be routinely transmitted to the healthcare professionals' facsimile machine **55** and, to do so on a patient-by-patient (user-by-user) basis.

FIG. **3** illustrates the manner in which data management unit **10** is arranged and interconnected with other system components for effecting the above-described operational aspects of the invention and additional aspects that are described relative to FIGS. **4-10**. As is symbolically indicated in FIG. **3**, handheld microprocessor unit **12** and blood glucose monitor **16** are connected to a dual universal asynchronous receiver transmitter **70** (e.g., by cables **14** and **18** of FIG. **1**, respectively). As also is indicated in FIG. **3** when a system user connects a personal computer **48** (or other programmable digital signal processor) to data port **44** signal communication is established between personal computer **48** and a second dual universal asynchronous receiver transmitter **72** of data management unit **10**. Additionally, dual universal asynchronous receiver transmitter **72** is coupled to modem **46** so that data communication can be established between data management unit **10** and a remote clearinghouse **54** of FIGS. **1** and **2**.

Currently preferred embodiments of data management unit **10** include a plurality of signal sensors **74**, with an individual signal sensor being associated with each device that is (or may be) interconnected with data management unit **10**. As previously discussed and as is indicated in FIG. **3**, these devices include handheld microprocessor unit **12**, blood glucose monitor **16**, personal computer **48**, remote computing facility **54**, and, in addition, peak-flow meter **20** or other additional monitoring devices **22**. Each signal sensor **74** that is included in data management unit **10** is electrically connected for receiving a signal that will be present when the device with which that particular signal sensor is associated is connected to data management unit **10** and, in addition, is energized (e.g., turned on). For example, in previously mentioned embodiments of the invention in which data port **44** is an RS-232 connection, the signal sensor **74** that is associated with personal computer **48** can be connected to an RS-232 terminal that is supplied power when a personal computer is connected to data port **44** and the personal computer is turned on. In a similar manner, the signal sensor **74** that is associated with clearinghouse **54** can be connected to modem **46** so that the signal sensor **74** receives an electrical signal when modem **46** is interconnected to a remote computing facility (e.g., clearinghouse **54** of FIG. **2**) via a telephone line **50**.

In the arrangement of FIG. **3**, each signal sensor **74** is a low power switch circuit (e.g., a metal-oxide semiconductor field-effect transistor circuit), which automatically energizes data management unit **10** whenever any one (or more) of the devices associated with signal sensors **74** is connected to data management unit **10** and is energized. Thus, as is indicated in FIG. **3** by signal path **76** ach signal sensor is **74** interconnected with power supply **78** which supplies operating current to the circuitry of data management unit **10** and typically consists of one or more small batteries (e.g., three AAA alkaline cells). The microprocessor and other conventional circuitry that enables data management unit **10** to process system signals in accordance with stored program instructions is indicated in FIG. **3** by central processing unit (CPU) **80**. As is indicated in FIG. **3** by interconnection **82** between CPU **80** and battery **78**. CPU **80** receives operating current from power supply **78** with power being provided only when one or more of the signal sensors **74** are activated in the previously described manner. A clock/calendar circuit

84 is connected to CPU (80 via signal path 86 in FIG. 3) to allow time and date tagging of blood glucose tests and other information. Although not specifically shown in FIG. 3, operating power is supplied to clock/calendar 84 at all times.

In operation, CPU 80 receives and sends signals via a data bus (indicated by signal path 88 in FIG. 3) which interconnects CPU 80 with dual universal asynchronous receiver transmitters 70 and 72. The data bus 88 also interconnects CPU 80 with memory circuits which, in the depicted embodiment, include a system read-only memory (ROM) 90 a program random access memory (RAM) 92 and an electronically erasable read-only memory (EEROM) 94. System ROM 90 stores program instructions and any data required in order to program data management unit 10 so that data management unit 10 and a handheld microprocessor unit 12 that is programmed with a suitable program cartridge 42 provide the previously discussed system operation and, in addition, system operation of the type described relative to FIGS. 4-10. During operation of the system, program RAM 92 provides memory space that allows CPU 80 to carry out various operations that are required for sequencing and controlling the operation of the system of FIG. 1. In addition, RAM 92 can provide memory space that allows external programs (e.g., programs provided by clearinghouse 54 to be stored and executed. EEROM 94 allows blood glucose test results and other data information to be stored and preserved until the information is no longer needed (i.e., until purposely erased by operating the system to provide an appropriate erase signal to EEROM 94).

FIGS. 4-10 illustrate typical screen displays that are generated by the arrangement of the invention described relative to FIGS. 1-3. Reference will first be made to FIGS. 4 and 5 which exemplify screen displays that are associated with operation of the invention in the blood glucose monitoring mode. Specifically, in the currently preferred embodiments of the invention, blood glucose monitor 16 operates in conjunction with data management unit 10 and handheld microprocessor unit 12 to: (a) a test or calibration sequence in which tests are performed to confirm that the system is operating properly; and, (b) the blood glucose test sequence in which blood glucose meter 16 senses the user's blood glucose level. Suitable calibration procedures for blood glucose monitors are known in the art. For example, blood glucose monitors often are supplied with a "code strip," that is inserted in the monitor and results in a predetermined value being displayed and stored in memory at the conclusion of the code strip calibration procedure. When such a code strip calibration procedure is used in the practice of the invention, the procedure is selected from one of the system menus. For example, if the system main menu includes a "monitor" menu item, a submenu displaying system calibration options and an option for initiating the blood glucose test may be displayed when the monitor menu item is selected. When a code strip option is available and selected, a sequence of instructions is generated and displayed by display screen 28 of handheld microprocessor unit 12 to prompt the user to insert the code strip and perform all other required operations. At the conclusion of the code strip calibration sequence, display unit 28 of handheld microprocessor unit 12 displays a message indicating whether or not the calibration procedure has been successfully completed. For example, FIG. 4 illustrates a screen display that informs the system user that the calibration procedure was not successful and that the code strip should be inserted again (i.e., the calibration procedure is to be repeated). As is indicated in FIG. 4, display screens that indicate a potential malfunction of the system include a prominent message such as the "Attention" notation included in the screen display of FIG. 4.

As previously indicated, the blood glucose test sequence that is employed in the currently preferred embodiment of the invention is of the type in which a test strip is inserted in a receptacle that is formed in the blood glucose monitor. A drop of the user's blood is then applied to the test strip and a blood glucose sensing sequence is initiated. When the blood glucose sensing sequence is complete, the user's blood glucose level is displayed.

In the practice of the invention, program instructions stored in data management unit 10 (e.g., system ROM 90 of FIG. 3) and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 cause the system to display step-by-step monitoring instructions to the system user and, in addition, preferably result in display of diagnostic messages if the test sequence does not proceed in a normal fashion. Although currently available self-contained microprocessor-based blood glucose monitors also display test instruction and diagnostic messages, the invention provides greater message capacity and allows multi-line instructions and diagnostic messages that are displayed in easily understood language rather than cryptic error codes and abbreviated phraseology that is displayed one line or less at a time. For example, as is shown in FIG. 5 the complete results of a blood glucose test (date, time of day, and blood glucose level in milligrams per deciliter) can be concurrently displayed by display screen 28 of handheld microprocessor unit 12 along with an instruction to remove the test strip from blood glucose monitor 16. As previously mentioned, when the blood glucose test is complete, the time and date tagged blood glucose test result is stored in the memory circuits of data management unit 10 (e.g., stored in EEPROM 94 of FIG. 3)

The arrangement shown and described relative to FIGS. 1-3 also is advantageous in that data relating to food intake, concurrent medication dosage and other conditions easily can be entered into the system and stored with the time and date tagged blood glucose test result for later review and analysis by the user and/or his or her healthcare professional. Specifically, a menu generated by the system at the beginning or end of the blood glucose monitoring sequence can include items such as "hypoglycemic" and "hyperglycemic," which can be selected using the switches of handheld microprocessor unit 12 (e.g., operation of control pad 30 and switch 36 in FIG. 1) to indicate the user was experiencing hypoglycemic or hyperglycemic symptoms at the time of monitoring blood glucose level. Food intake can be quantitatively entered in terms of "Bread Exchange" units or other suitable terms by, for example, selecting a food intake menu item and using a submenu display and the switches of handheld microprocessors 2 to select and enter the appropriate information. A similar menu item—submenu selection process also can be used to enter medication data such as the type of insulin used at the time of the glucose monitoring sequence and the dosage.

As was previously mentioned, program instructions stored in data management unit 10 and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 enable the system to display statistical and trend information either in a graphic or alphanumeric format. As is the case relative to controlling other operational aspects of the system, menu screens are provided that allow the system user to select the information that is to be displayed. For example, in the previously discussed embodiments in which a system menu includes a "display" menu item, selection of

the menu item results in the display of one or more submenus that list available display options. For example, in the currently preferred embodiments, the user can select graphic display of blood glucose test results over a specific period of time, such as one day, or a particular week. Such selection results in displays of the type shown in FIGS. **6** and **7** respectively. When blood glucose test results for a single day are displayed (FIG. **6**) the day of the week and date can be displayed along with a graphic representation of changes in blood glucose level between the times at which test results were obtained. In the display of FIG. **6**, small icons identify points on the graphic representation that correspond to the blood glucose test results (actual samples). Although not shown in FIG. **6**, coordinate values for blood glucose level and time of day can be displayed if desired. When the user chooses to display a weekly trend graph (FIG. **7**) the display generated by the system is similar to the display of a daily graph, having the time period displayed in conjunction with a graph that consists of lines interconnecting points that correspond to the blood glucose test results.

The screen display shown in FIG. **8** is representative of statistical data that can be determined by the system of FIG. **1** (using conventional computation techniques) and displayed in alphanumeric format. As previously mentioned, such statistical data and information in various other textual and graphic formats can be provided to a healthcare professional (**60** in FIG. **2**) in the form of a standardized report **56** (FIG. **1**) that is sent by clearinghouse **54** to facsimile machine **55**. In the exemplary screen display of FIG. **8**, statistical data for blood glucose levels over a period of time (e.g., one week) or, alternatively, for a specified number of monitoring tests is provided. In the exemplary display of FIG. **8** the system (data management unit **10** or clearinghouse **54**) also calculates and displays (or prints) the average blood glucose level and the standard deviation. Displayed also is the number of blood glucose test results that were analyzed to obtain the average and the standard deviation; the number of test results under a predetermined level (50 milligrams per deciliter in FIG. **8**) and the number of blood glucose tests that were conducted while the user was experiencing hypoglycemic symptoms. As previously noted, in the preferred embodiments of the invention, a screen display that is generated during the blood glucose monitoring sequence allows the user to identify the blood sample being tested as one taken while experiencing hyperglycemic or hypoglycemic symptoms and, in addition, allows the user to specify other relevant information such as food intake and medication information.

The currently preferred embodiments of the invention also allow the user to select a display menu item that enables the user to sequentially address, in chronological order, the record of each blood glucose test. As is indicated in FIG. **9**, each record presented to the system user includes the date and time at which the test was conducted, the blood glucose level, and any other information that the user provided. For example, the screen display of FIG. **9** indicates that the user employed handheld microprocessor unit **12** as an interface to enter data indicating use of 12.5 units of regular insulin; 13.2 units of "NPH" insulin; food intake of one bread exchange unit; and pre-meal hypoglycemic symptoms.

Use of data management unit **10** in conjunction with handheld microprocessor unit **12** also allows display (or subsequent generation of a standardized report showing blood glucose test results along with food intake and/or medication information. For example, shown in FIG. **10** is a daily graph in which blood glucose level is displayed in the manner described relative to FIG. **6**. Related food intake and medication dosage is indicated directly below contemporaneous blood glucose levels by vertical bar graphs.

It will be recognized by those skilled in the art that the above-described screen displays and system operation can readily be attained with conventional programming techniques of the type typically used in programming microprocessor arrangements. It also will be recognized by those skilled in the art that various other types of screen displays can be generated and, in addition, that numerous other changes can be made in the embodiments described herein without departing from the scope and the spirit of the invention.

It will also be recognized by those skilled in the art that the invention can be embodied in forms other than the embodiments described relative to FIGS. **1-10**. For example, the invention can employ compact video game systems that are configured differently than the previously discussed handheld video game systems and palm-top computers. More specifically, as is shown in FIG. **11** a self-care health monitoring system arranged in accordance with the invention can employ a compact video game system of the type that includes one or more controllers **100** that are interconnected to a game console **102** via cable **104**. As is indicated in FIG. **11**, game console **102** is connected to a video monitor or television **106** by means of a cable **108**. Although differing in physical configuration, controller **100**, game console **102** and the television or video monitor **106** collectively function in the same manner as the handheld microprocessor **12** of FIG. **1**. In that regard, a program cartridge **42** is inserted into a receptacle contained in game console **102** with program cartridge **42** including stored program instructions for controlling microprocessor circuitry that is located inside game console **102**. Controller **100** includes a control pad or other device functionally equivalent to control pad **30** of FIG. **1** and switches that functionally correspond to switches **32-38** of FIG. **1**.

Regardless of whether the invention is embodied with a handheld microprocessor unit (FIG. **1**) or an arrangement such as the compact video game system (FIG. **11**) in some cases it is both possible and advantageous to apportion the signal processing functions and operations differently than was described relative to FIGS. **1-10**. For example, in some situations, the microprocessor-based unit that is programmed by a card or cartridge (e.g., handheld unit **12** of FIG. **1** or compact video game console **102** of FIG. **1**) includes memory and signal processing capability that allows the microprocessor to perform all or most of the functions and operations attributed to data management unit **10** of the embodiments discussed relative to FIGS. **1-10**. That is, the digitally encoded signal supplied by blood glucose monitor **16** (or one of the other monitors **20** and **22** of FIG. **1**) can be directly coupled to the microprocessor included in game console **102** of FIG. **11** or handheld microprocessor **12** of FIG. **1**. In such an arrangement, the data management unit is a relatively simple signal interface (e.g., interface unit **110** of FIG. **11**) the primary purpose of which is carrying signals between the blood glucose monitor **16** (or other monitor) and the microprocessor of game console **102** (FIG. **11**) or handheld unit (FIG. **1**). In some situations, the interface unit may consist primarily or entirely of a conventional cable arrangement such as a cable for interconnection between RS232 data ports or other conventional connection arrangements. On the other hand, as is shown in FIG. **11**, signal interface **110** can either internally include or be connected to a modem **52**, which receives and transmits signals via a telephone line **50** in the manner described relative to FIGS. **1** and **2**.

It also should be noted that all or a portion of the functions and operations attributed to data management unit **10** of FIG. **1** can be performed by microprocessor circuitry located in blood glucose monitor **16** (or other monitor that is used with the system). For example, a number of commercially available blood glucose monitors include a clock/calendar circuit of the type described relative to FIG. **3** and, in addition, include microprocessor circuitry for generating visual display signals and signals representative of both current and past values of monitored blood glucose level. Conventional programming and design techniques can be employed to adapt such commercially available units for the performance of the various functions and operations attributed in the above discussion of FIGS. **1-11** to data management unit **10** and/or the microprocessors of handheld unit and compact video console **102**. In arrangements in which the blood glucose monitor (or other system monitor) includes a microprocessor that is programmed to provide signal processing in the above-described manner, the invention can use a signal interface unit **110** of the above type. That is, depending upon the amount of signal processing effected by the monitoring unit (e.g., blood glucose monitor **16**) and the amount of signal processing performed by the microprocessor of video game console **102** (or handheld unit the signal interface required ranges from a conventional cable (e.g., interconnection of RS232 ports) to an arrangement in which signal interface **110** is arranged for signal communication with an internal or external modem (e.g., modem **52** of FIG. **11**) or an arrangement in which signal interface provides only a portion of the signal processing described relative to FIGS. **1-10**.

The invention also is capable of transmitting information to a remote location (e.g., clearinghouse **54** and/or a remotely located healthcare professional) by means other than conventional telephone lines. For example, a modem (**52** in FIGS. **1** and **11**) that is configured for use with a cellular telephone system can be employed to transmit the signals provided by the healthcare monitoring system to a remote location via modulated RF transmission. Moreover, the invention can be employed with various digital networks such as recently developed interactive voice, video and data systems such as television systems in which a television and user interface apparatus is interactively coupled to a remote location via coaxial or fiber optic cable and other transmission media (indicated in FIG. **11** by cable **112** which is connected to television or video monitor **106**). In such an arrangement, compact video game controller **100** and the microprocessor of video game console **102** can be programmed to provide the user interface functions required for transmission and reception of signals via the interactive system. Alternatively, the signals provided by video game console **102** (or handheld unit **12** if FIG. **1**) can be supplied to the user interface of the interactive system (not shown in FIG. **11**) in a format that is compatible with the interactive system and allows the system user interface to be used to control signal transmission between the healthcare system and a remote facility such as clearinghouse **54**, FIGS. **1** and **2**.

The invention claimed is:

1. A physiological data monitoring system comprising:

(a) at least one central server arranged to receive and communicate data;

(b) at least one microprocessor-based subsystem

(i) including at least one microprocessor, a display and a memory,

(ii) configured to present information on the display and provide a digital signal representative of physiological data from a person, and

(iii) arranged to establish a communication link to the central server, facilitate a communication of the physiological data on the communication link to the central server and disconnect the communication link after the communication of the physiological data has finished; and

(c) at least one health care professional computer in signal communication with the central server to receive health-related information based on the physiological data received from the microprocessor-based subsystem, wherein the central server stores additional data received from the health care professional computer and provides the additional data to the microprocessor-based subsystem to run after the communication link has been established by the microprocessor-based subsystem, the additional data including instructions to the person effecting a change in a treatment regimen based on earlier physiological data.

2. The system of claim **1**, wherein the microprocessor-based subsystem further includes

(a) a data management unit adapted for digital data signal processing; and

(b) a monitoring device that can transmit data to be received directly by the data management unit or that can be connected to data management unit.

3. The system of claim **2**, wherein at least one monitoring device is (a) configured to monitor at least one person's condition; and (b) connected to facilitate communication of data related to the monitored condition to the central server.

4. The system of claim **3**, wherein at least one monitoring device includes one or more of the set consisting of

(a) a blood glucose monitor;

(b) a blood pressure monitor;

(c) a pulse monitor; and

(d) a body temperature monitor.

5. The system of claim **1**, wherein the at least one microprocessor, the display and the memory is in a handheld device.

6. The system of claim **1**, wherein the microprocessor-based subsystem displays pictorial information.

7. The system of claim **1**, wherein the microprocessor-based subsystem displays animated information.

8. The system of claim **1**, the microprocessor-based subsystem further includes at least one of an insertable program card or cartridge.

9. The system of claim **8**, wherein instructions in the program card or cartridge are configured to facilitate the monitoring.

10. The system of claim **1**, further including at least one personal computer connected for use by the person.

11. The system of claim **1**, wherein the system is configured to use the physiological data to process a report.

12. The system of claim **11**, wherein the report includes graphs and/or icons.

13. The system of claim **11**, wherein the report includes information for a period of time.

14. The system of claim **1**, wherein the information includes at least one message.

15. The system of claim **14**, wherein the message is transmitted to a specific person.

16. The system of claim **1**, wherein the information includes step-by-step instructions.

17. The system of claim **1**, wherein the information is educational or motivational.

18. The system of claim 1, wherein the presentation of information can be controlled using at least one menu.

19. The system of claim 1, wherein the system is configured to enable the additional data to be provided for storage in the memory.

20. The system of claim 19, further comprising at least one of an insertable program card or cartridge and wherein at least part of the additional data is stored on the card or on a cartridge.

21. A physiological data monitoring system comprising:

(a) at least one central server arranged to receive and communicate data;

(b) at least one microprocessor-based subsystem

(i) including at least one microprocessor, a display and a memory,

(ii) configured to present information on the display and provide a digital signal representative of physiological data from a person, and

(iii) arranged to establish a communication link to the central server, facilitate a communication of the physiological data on the communication link to the central server and disconnect the communication link after the communication of the physiological data has finished; and

(c) at least one health care professional computer in signal communication with the central server to receive health-related information based on the physiological data received from the microprocessor-based subsystem, wherein the central server is configured to send data to the microprocessor-based subsystem in response to receiving a request from the microprocessor-based subsystem after the communication link has been established by the microprocessor-based subsystem,

where the central server stores additional data received from the health care professional computer and provides the additional data to the microprocessor-based subsystem after the communication link has been established by the microprocessor-based subsystem.

22. A physiological data monitoring system comprising:

(a) at least one central server arranged to receive and communicate data;

(b) at least one microprocessor-based subsystem

(i) including at least one microprocessor, a display and a memory,

(ii) configured to present information on the display and provide a digital signal representative of physiological data from a person, and

(iii) arranged to establish a communication link to the central server, facilitate a communication of the physiological data on the communication link to the central server and disconnect the communication link after the communication of the physiological data has finished, wherein the central server is configured to (i) wait for the microprocessor-based system to turn on and establish the communication link (ii) automatically send one or more messages viewable by the person to the microprocessor-based system before the communication link is disconnected, and (iii) notify the person of the messages; and

(c) at least one health care professional apparatus adapted to receive communication from the central server to receive health-related information based on the physiological data received from the microprocessor-based subsystem and to send data to the central server;

where the central server stores additional data received from the health care professional computer and provides the additional data to the microprocessor-based subsystem after the communication link has been established by the microprocessor-based subsystem.

23. The apparatus according to claim 22, wherein the health care professional apparatus is configured to automatically receive fax reports about health related information.

24. The apparatus according to claim 22, wherein the health care professional apparatus selects from standardized reports related to the health related information.

25. A user-related data monitoring system comprising:

(a) at least one central server arranged to receive and communicate data;

(b) at least one microprocessor-based subsystem

(i) including at least one microprocessor, a display and a memory,

(ii) configured to present information on the display and provide a digital signal representative of user-related data from a person; and

(iii) arranged to establish a communication link to the central server, facilitate a communication of the user-related data on the communication link to the central server and disconnect the communication link after the communication of the physiological data has finished, wherein the server provides test and calibration sequences for the microprocessor-based subsystem after the communication link has been established by the microprocessor-based subsystem; and

(c) at least one health care professional computer in signal communication with the central server to receive health-related information based on the user-related data received from the microprocessor-based subsystem and to supply data to the central server;

where the central server stores additional data received from the health care professional computer and provides the additional data to the microprocessor-based subsystem to run after the communication link has been established by the microprocessor-based subsystem.

26. The apparatus according to claim 25, wherein the microprocessor-based subsystem allows additional menus to be viewed allowing additional interactivity when the microprocessor-based subsystem is in the test and calibration sequence.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,223,236 B2
APPLICATION NO. : 11/221873
DATED : May 29, 2007
INVENTOR(S) : Stephen J. Brown

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 23, Claim 22, line 56, replace “system” with --subsystem--

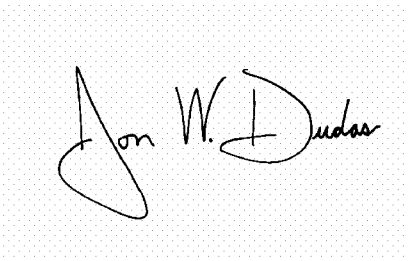
Column 24, Claim 22, line 2, replace “system” with --subsystem--

Column 24, Claim 22, line 11, replace “computer” with --apparatus--

Column 24, Claim 25, line 34, replace “physiological” with --user-related--.

Signed and Sealed this

Tenth Day of July, 2007



JON W. DUDAS
Director of the United States Patent and Trademark Office