

EXHIBIT A



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**

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(*) 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**

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,390,238 A 2/1995 Kirk et al.
5,434,611 A 7/1995 Tamura
5,441,047 A 8/1995 David et al.

5,596,994 A * 1/1997 Bro 128/905
5,868,669 A * 2/1999 Iliff 600/300
6,001,065 A * 12/1999 DeVito 600/544
6,050,940 A * 4/2000 Braun et al. 128/920

FOREIGN PATENT DOCUMENTS

EP 0251520 1/1988
EP 0320749 6/1989
WO 9520199 7/1995
WO 9708605 3/1997

OTHER PUBLICATIONS

Reis, H, *Telemedicine: transmitting Expertise to the point of care*, Toward an Electronic Patient Record '97, Nashville, TN, Apr. 27-May 3, 1997, pp. 248-256, v. 3.

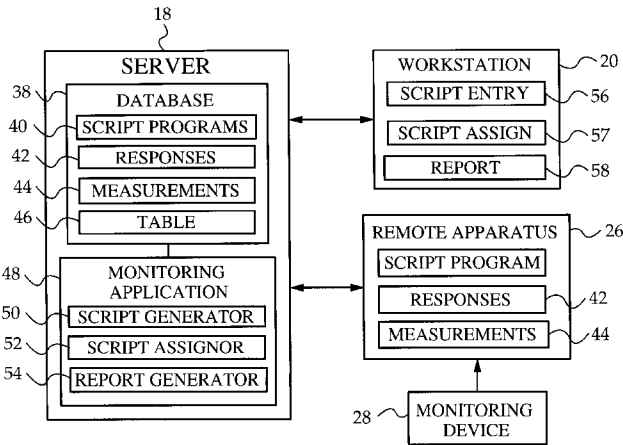
* cited by examiner

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(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



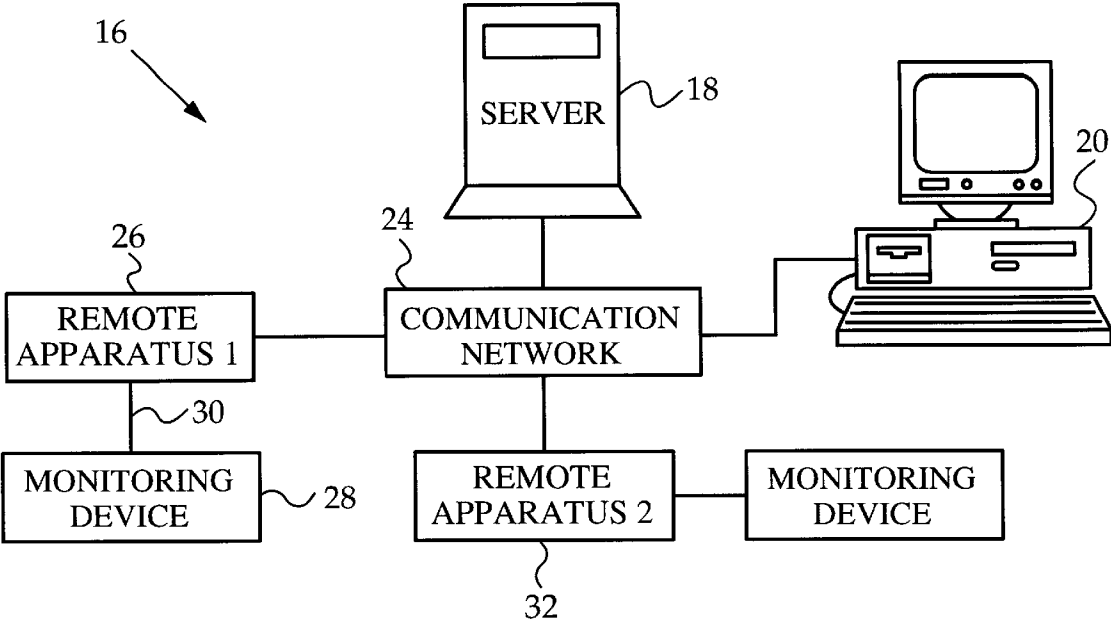


FIG. 1

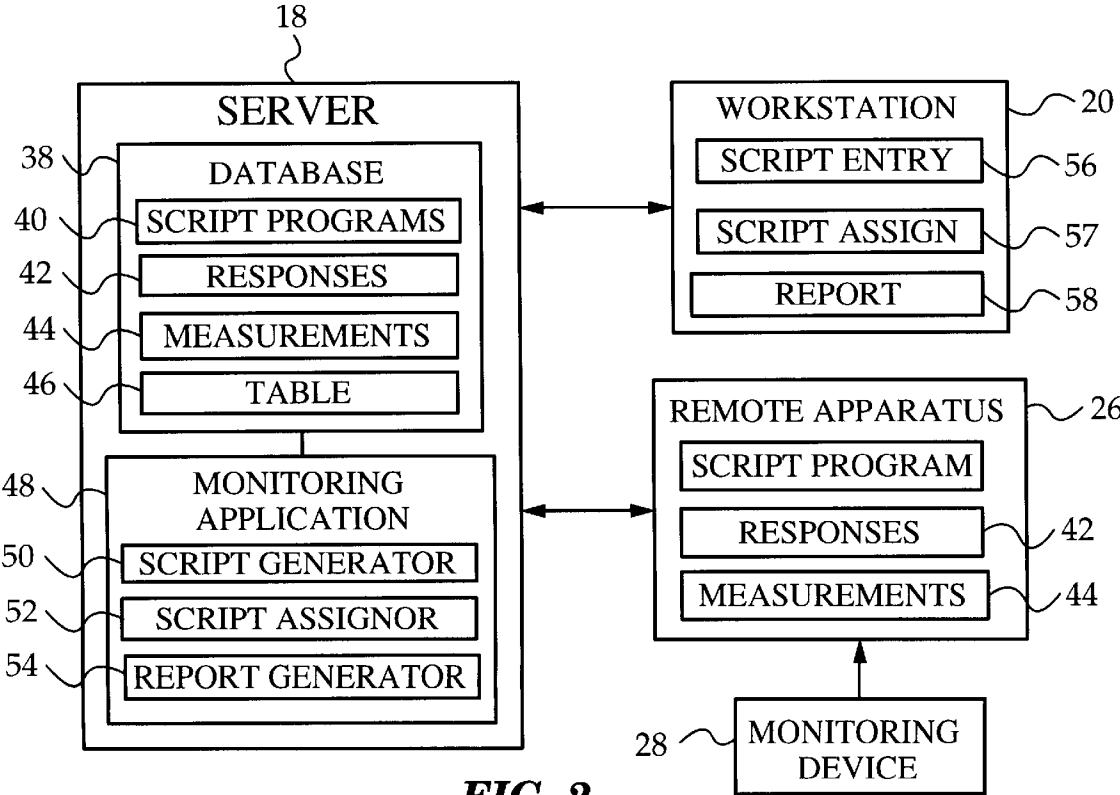


FIG. 2

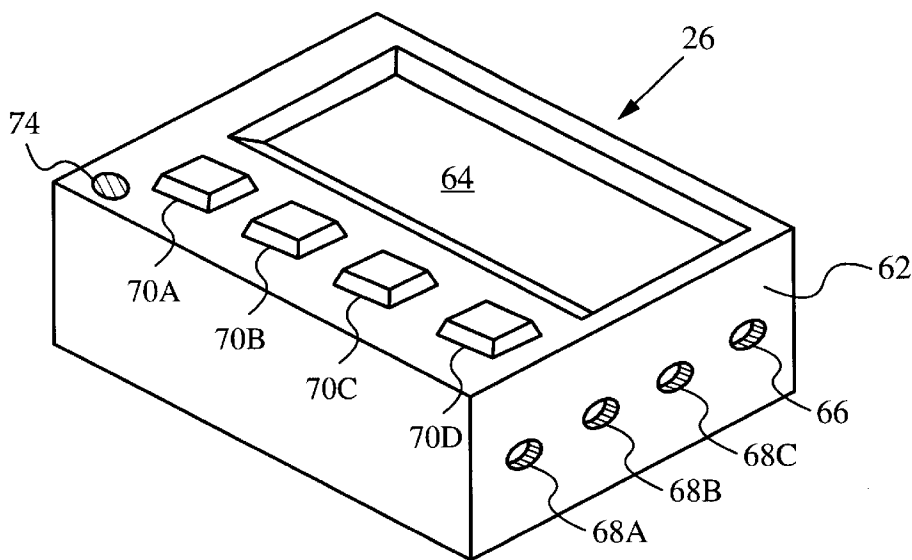


FIG. 3

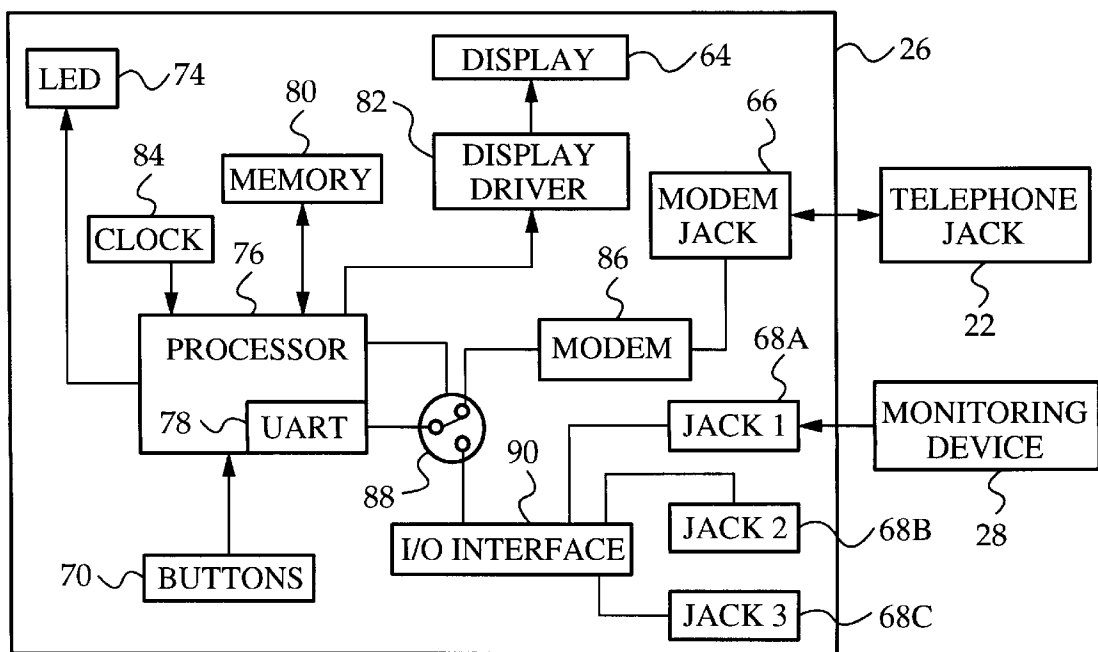


FIG. 4

56

SCRIPT ENTRY SCREEN

SCRIPT NAME:

DIABETES SCRIPT 1

92

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

94

96

SELECT DEVICE TYPE(S)

98

☒ GLUCOSE METER

☐ RESPIRATORY FLOW METER

☐ BP CUFF

CONNECTION TIME:

03:00

▽

100

102

CREATE SCRIPT

104

CANCEL

FIG. 5

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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

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SCRIPT ASSIGNMENT SCREEN

AVAILABLE SCRIPTS:	PATIENTS:
<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; width: 30px; height: 30px; margin-right: 5px; text-align: center; line-height: 30px;">X</div> <div>DIABETES SCRIPT 1</div> </div> <div style="display: flex; align-items: center; margin-top: 5px;"> <div style="border: 1px solid black; width: 30px; height: 30px; margin-right: 5px;"></div> <div>DIABETES SCRIPT 2</div> </div> <div style="display: flex; align-items: center; margin-top: 5px;"> <div style="border: 1px solid black; width: 30px; height: 30px; margin-right: 5px;"></div> <div>ASTHMA SCRIPT 1</div> </div>	<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; width: 30px; height: 30px; margin-right: 5px; text-align: center; line-height: 30px;">X</div> <div>DAN LINDSEY</div> </div> <div style="display: flex; align-items: center; margin-top: 5px;"> <div style="border: 1px solid black; width: 30px; height: 30px; margin-right: 5px;"></div> <div>MARK SMITH</div> </div> <div style="display: flex; align-items: center; margin-top: 5px;"> <div style="border: 1px solid black; width: 30px; height: 30px; margin-right: 5px;"></div> <div>DEAN JONES</div> </div>
<div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="border: 1px solid black; padding: 5px 10px;">ADD SCRIPT</div> <div style="border: 1px solid black; padding: 5px 10px;">ASSIGN SCRIPT</div> <div style="border: 1px solid black; padding: 5px 10px;">DELETE SCRIPT</div> </div>	

110 112 114

FIG. 7

HOW DO YOU FEEL?

VERY BAD	BAD	GOOD	VERY GOOD

70A 70B 70C 70D

FIG. 8

**CONNECT GLUCOSE METER
AND PRESS ANY BUTTON
WHEN FINISHED**

--	--	--	--

70A 70B 70C 70D

FIG. 9

58

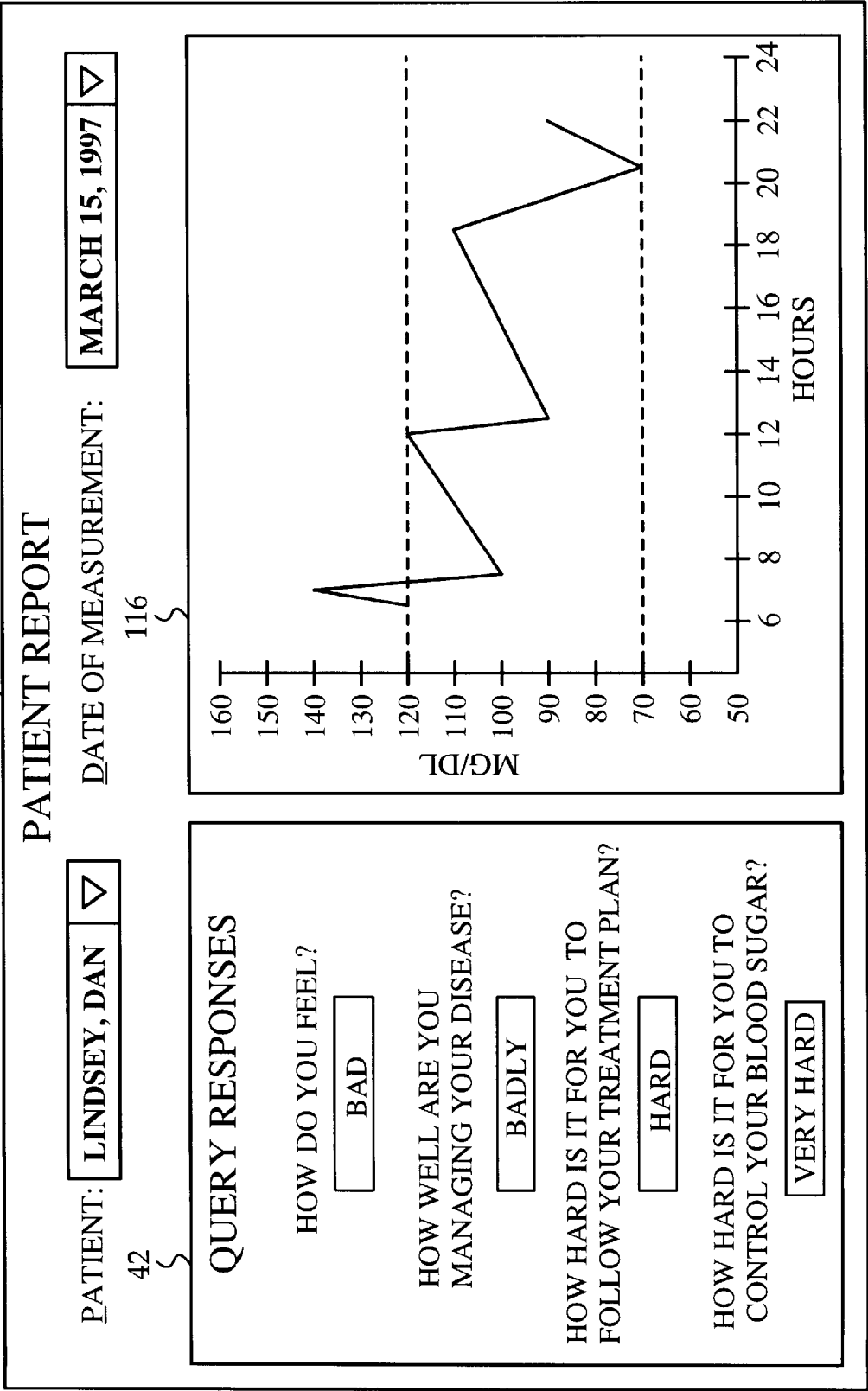
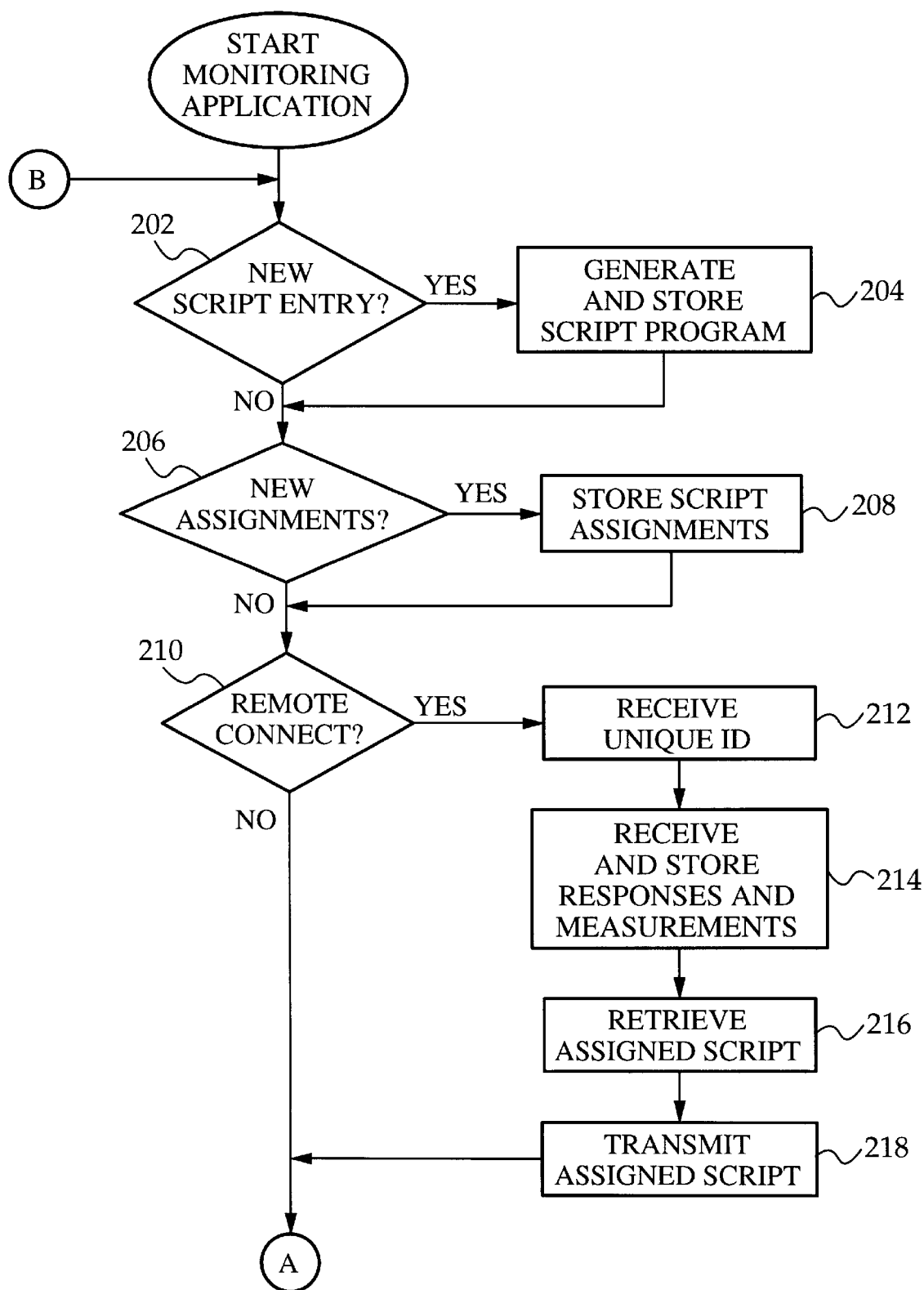
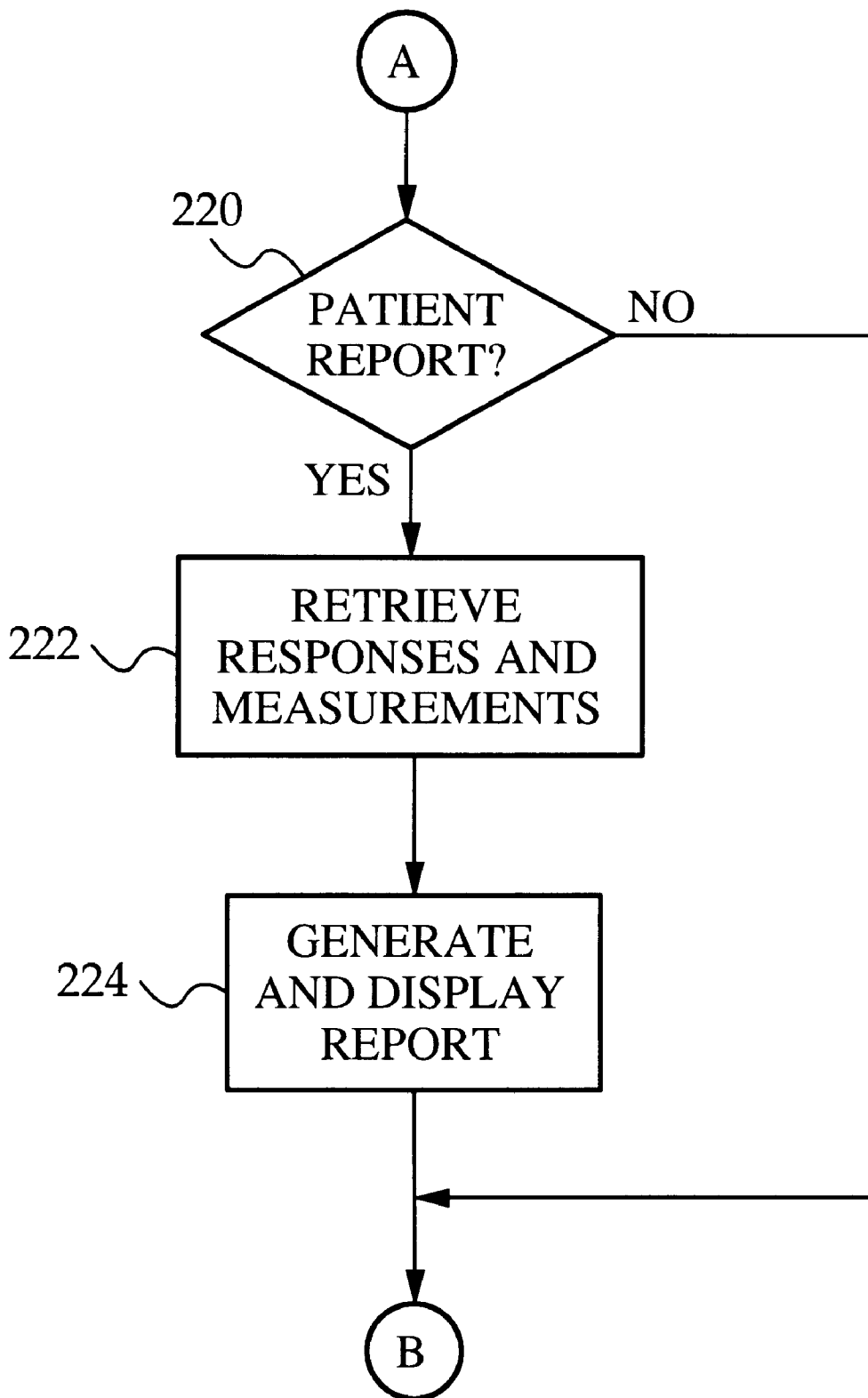
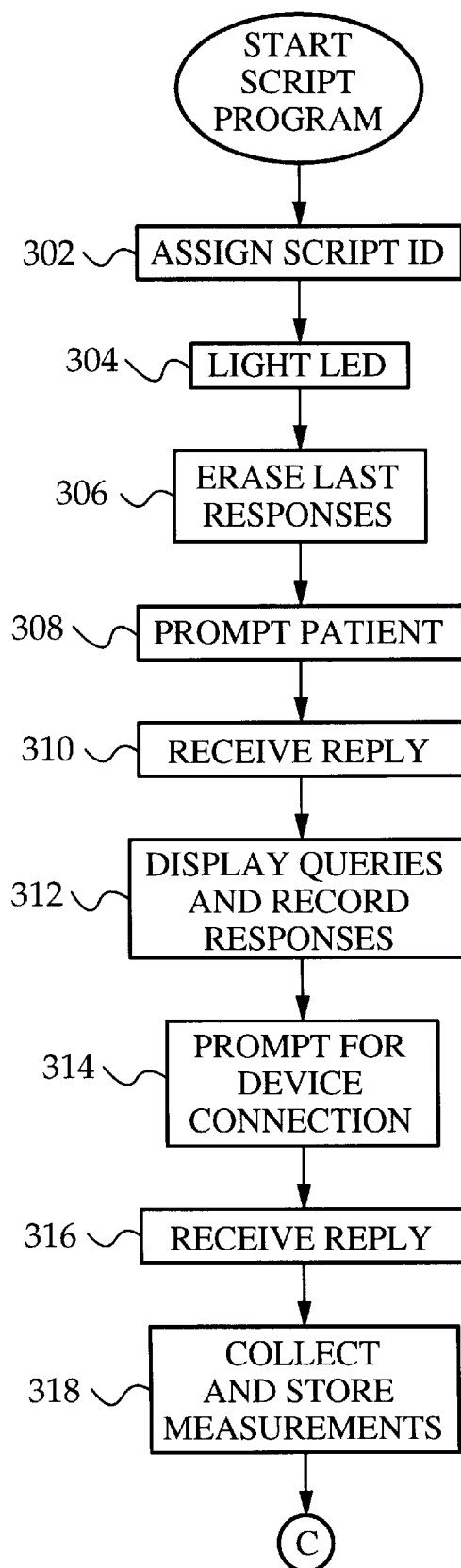
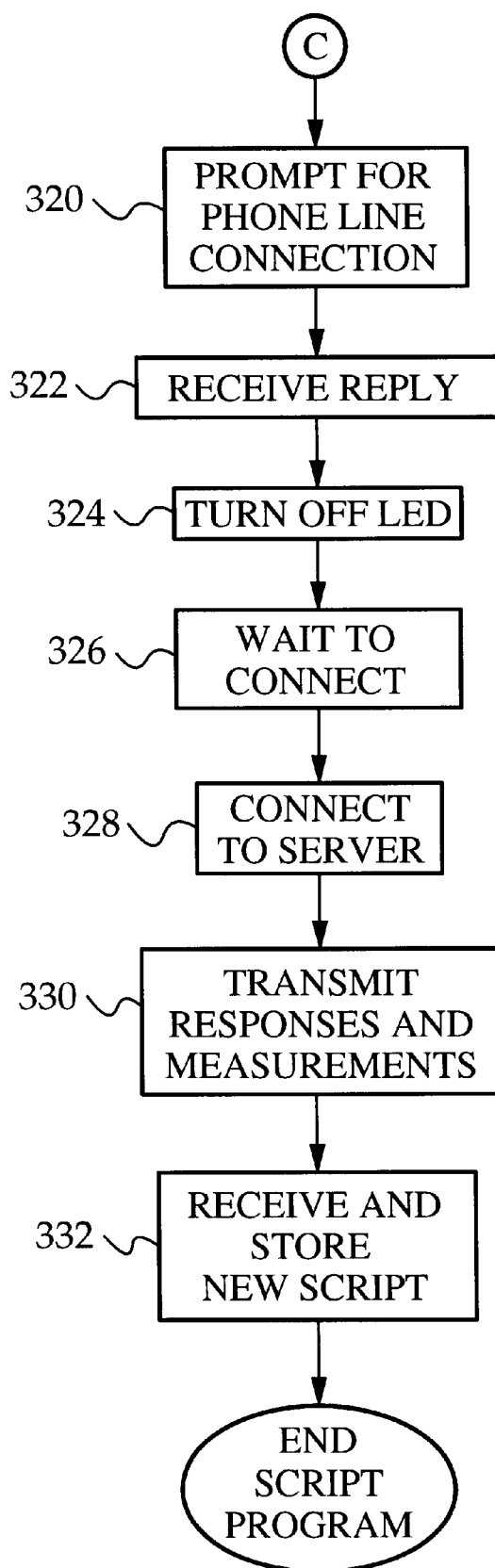


FIG. 10

**FIG. 11A**

**FIG. 11B**

**FIG. 12A**

**FIG. 12B**

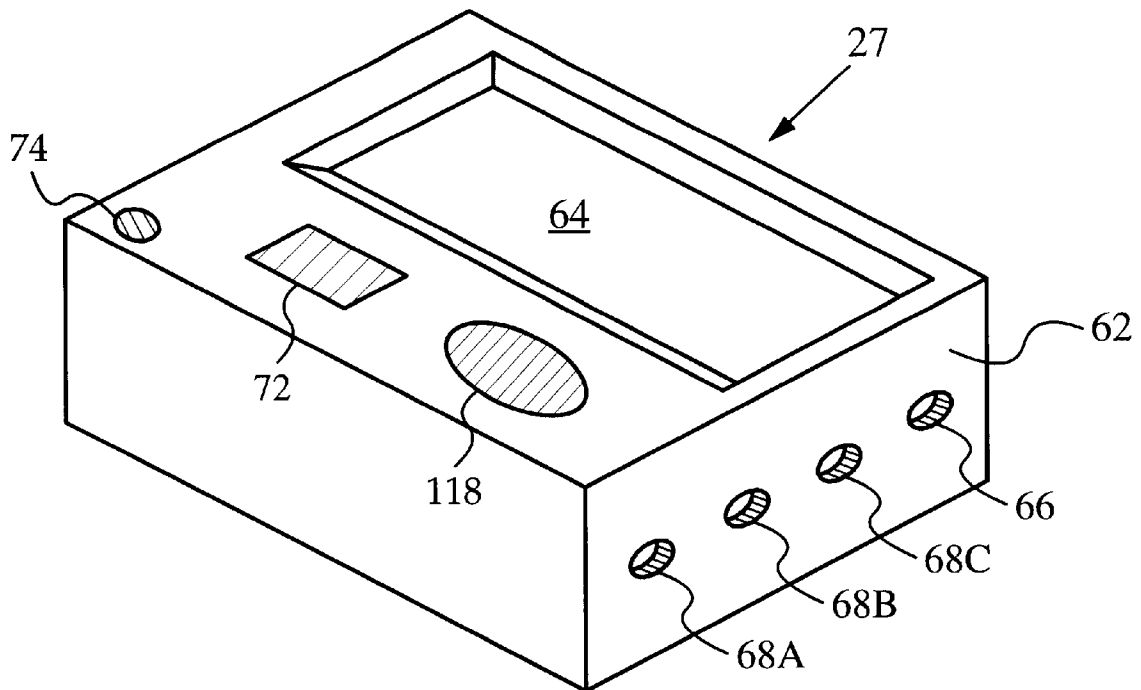


FIG. 13

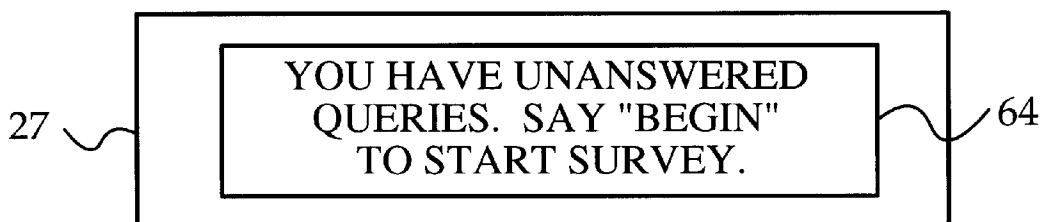
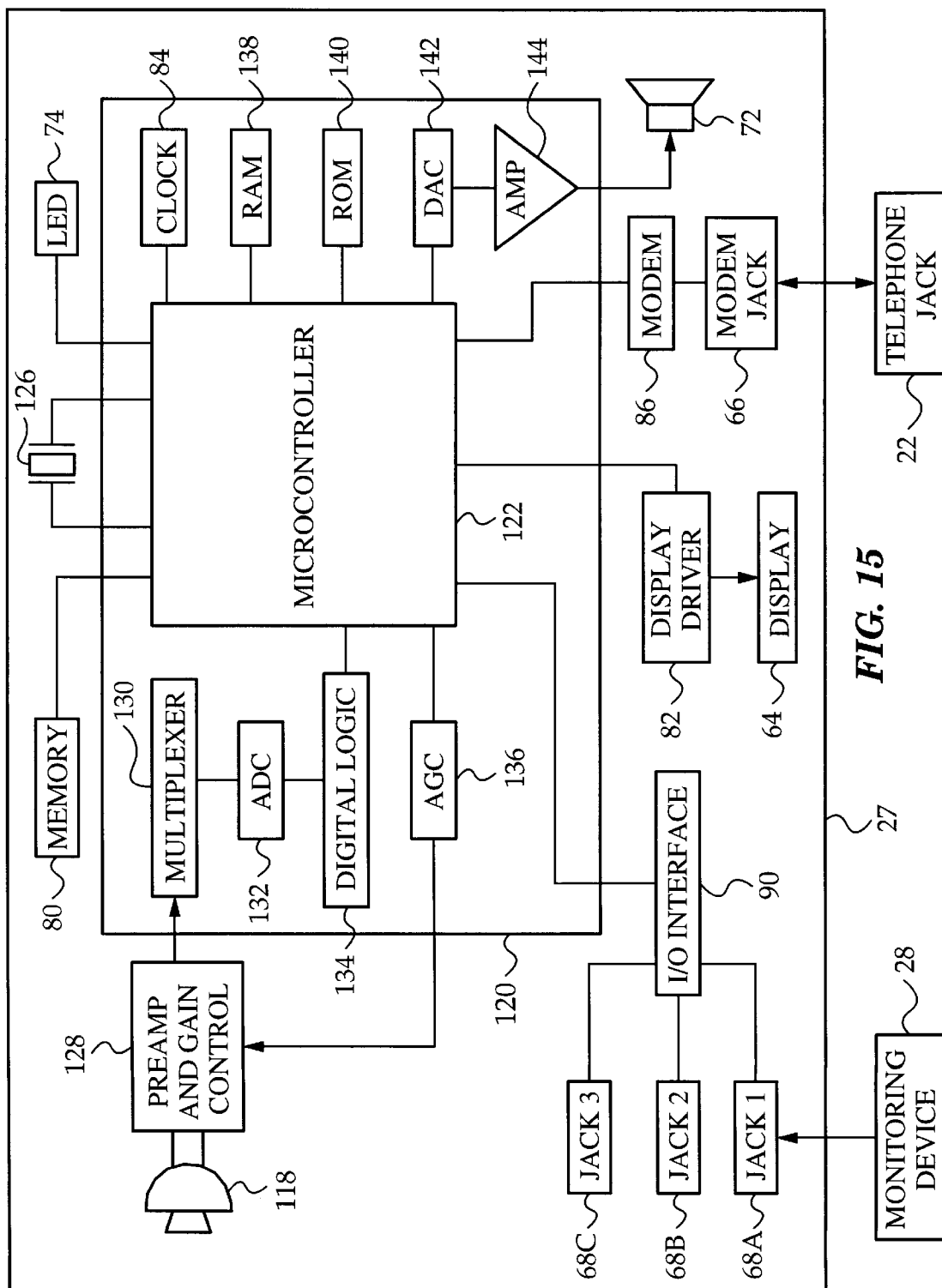
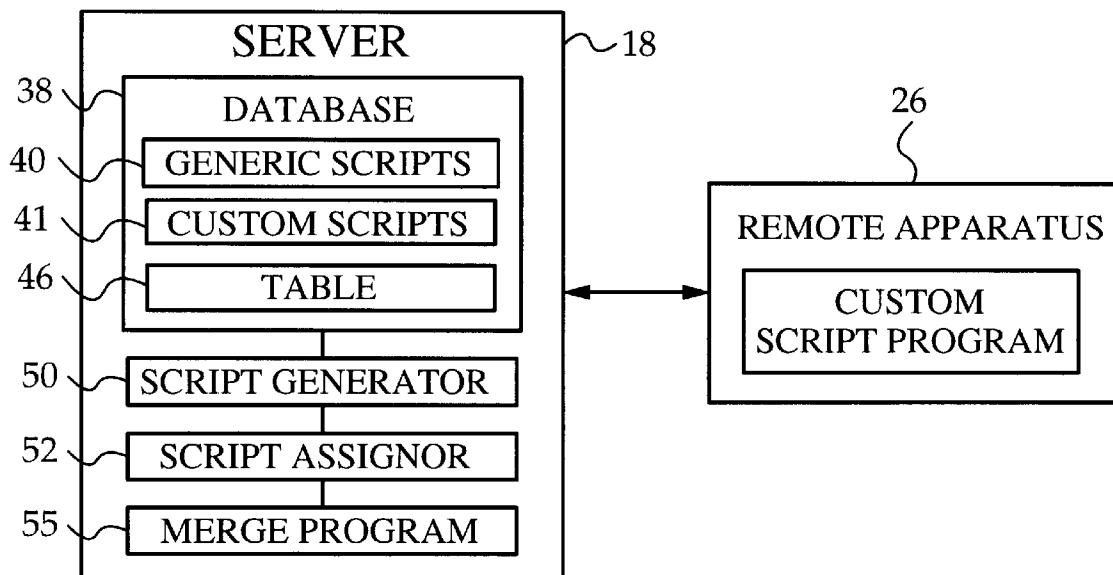
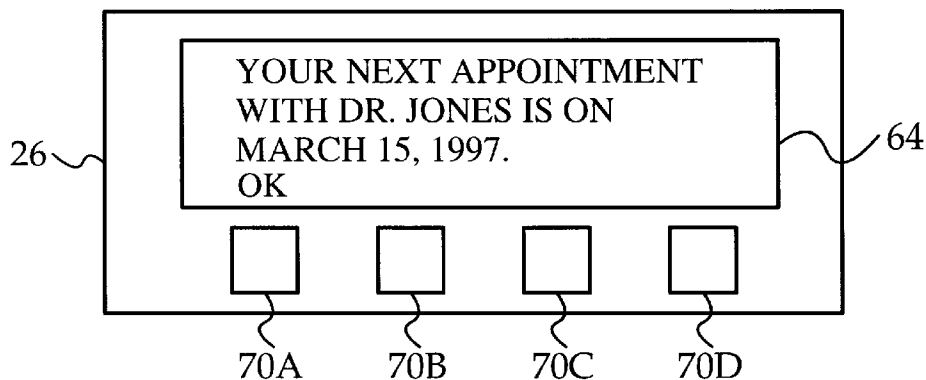
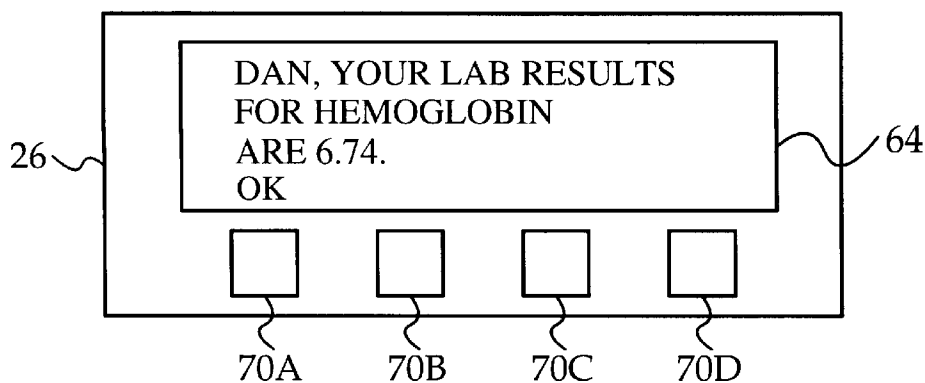


FIG. 14



**FIG. 16****FIG. 17****FIG. 18**

56

SCRIPT ENTRY SCREEN

SCRIPT NAME:

DIABETES SCRIPT 2

92

STATEMENTS

94

	CHOICE 1	CHOICE 2	CHOICE 3	CHOICE 4
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			

96

CONNECTION TIME:

03:00

▽

100

102

104

CREATE SCRIPT

CANCEL

FIG. 19

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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

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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.

5 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.

15 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.

20 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.

45 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.

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

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

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

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

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

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

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

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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 **70A**, **70B**, **70C**, and **70D** 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 **68A**, **68B**, and **68C** 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

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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 I²C 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 **68A**, **68B**, and **68C**. 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. 6A–6B 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. 12A–12B 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. 11A is a flow chart illustrating steps included in the monitoring application executed by server 18. FIG. 11B is a continuation of the flow chart of FIG. 11A. 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

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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.

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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.

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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.

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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 merg-

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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.

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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,

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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 station-
ed 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. 5

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. 10

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. 20

Therefore, the scope of the invention should be determined not by the examples given, but by the appended claims and their legal equivalents. 25

What is claimed is:

1. A system of communicating information to an individual, comprising: 30

- 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; 35
- c) a remotely programmable apparatus networked to said server via a second communication network, said remotely programmable apparatus including: 40
 - i) communication devices for receiving said script program from said server;
 - ii) user interface; and

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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. 15

4. The system of claim 1, wherein said at least one monitoring device is connected to said remotely programmable apparatus via a cable. 20

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. 25

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. 30

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. 40

10. The system of claim 1, where the first and second communication networks are the same network.

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