EXHIBIT A

US007223235B2

(12) **United States Patent**
Brown

(10) **Patent No.: US 7,223,235 B2**
(45) **Date of Patent: *May 29, 2007**

(54) **SYSTEM AND METHOD FOR MONITORING BLOOD PRESSURE FROM A PERSON**

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(*) 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.: **11/221,807**

(22) Filed: **Sep. 9, 2005**

(65) **Prior Publication Data**

US 2006/0009705 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. 11, 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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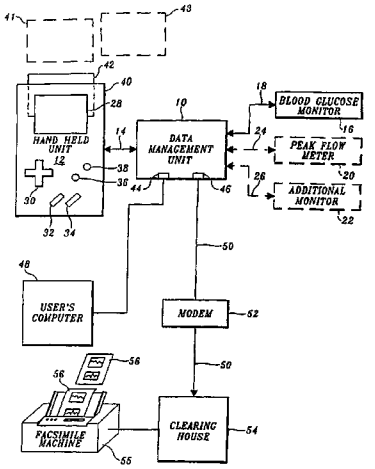
(57) **ABSTRACT**

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 conition and to communicate related data to the central server.

20 Claims, 6 Drawing Sheets



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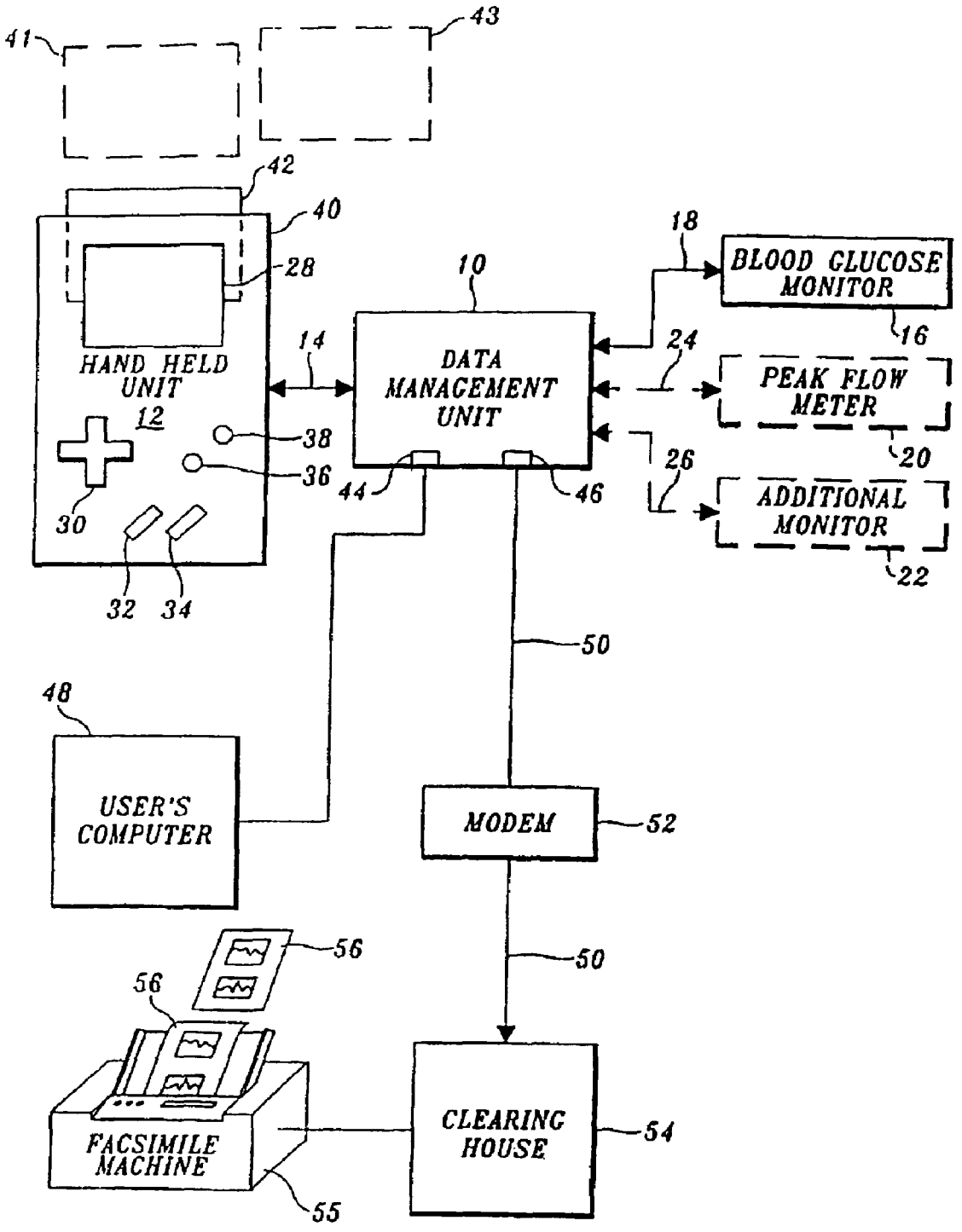
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BLOOD GLUCOSE MONITOR
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ADDITIONAL MONITOR
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CLEARING HOUSE
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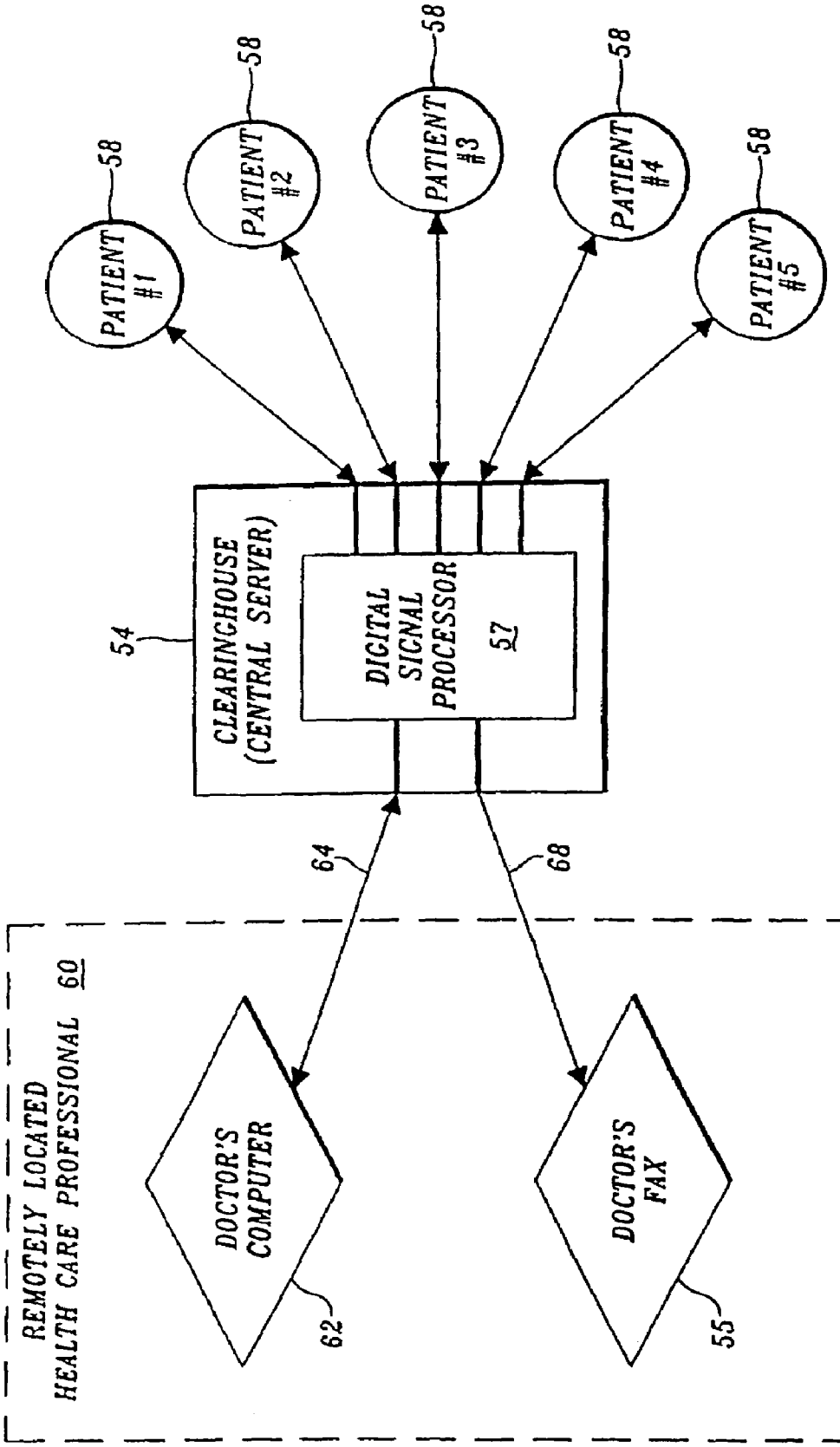
Fig. 1.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PATIENT #2
PATIENT #3
PATIENT #4
PATIENT #5
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DIGITAL SIGNAL PROCESSOR
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REMOTELY LOCATED HEALTH CARE PROFESSIONAL 60
DOCTOR'S COMPUTER
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DOCTOR'S FAX
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Fig. 2.

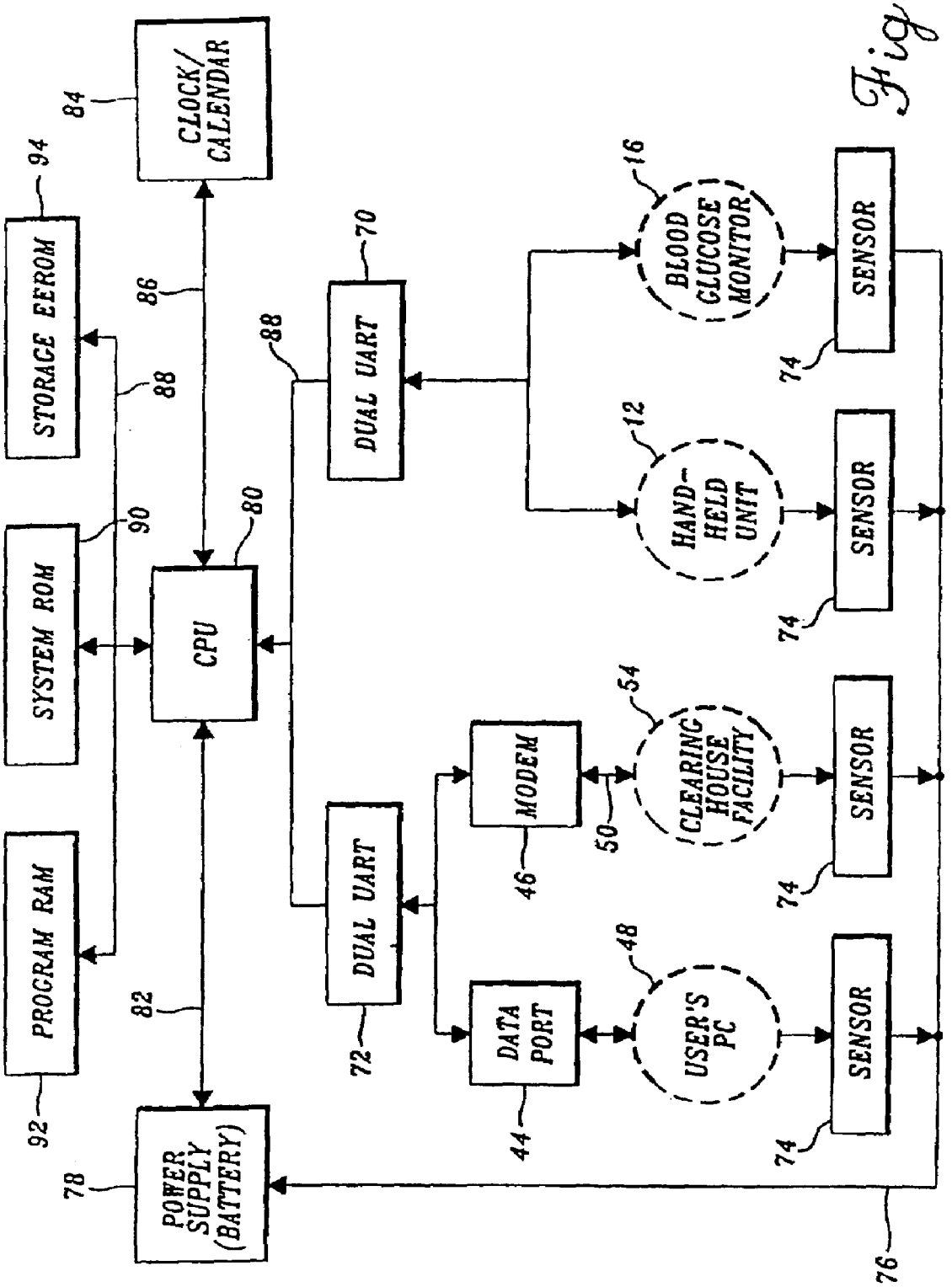
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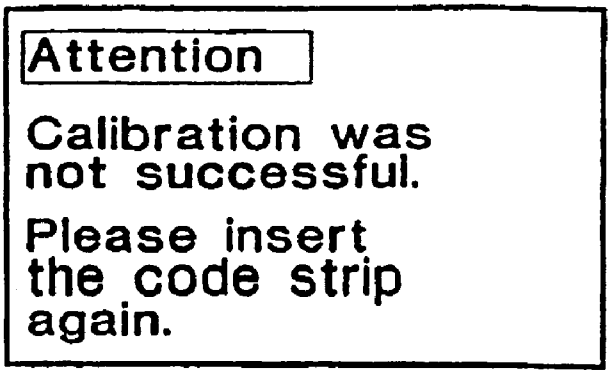
Fig. 3.

Fig.4.



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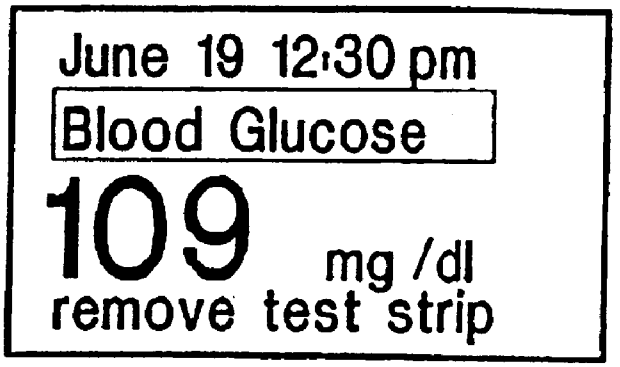

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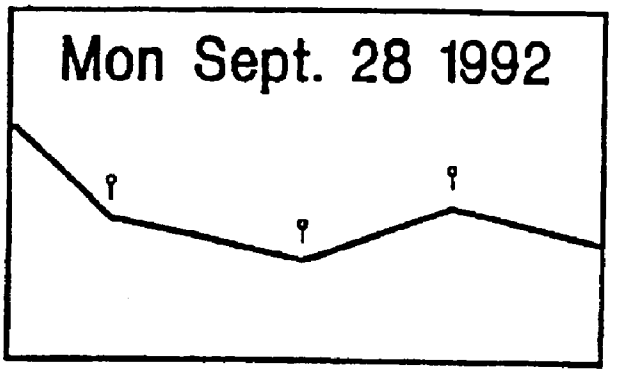

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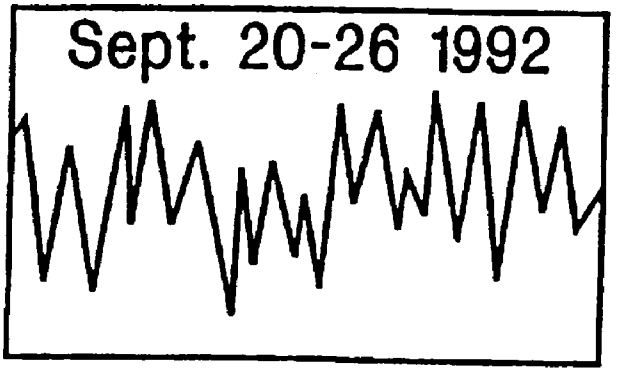

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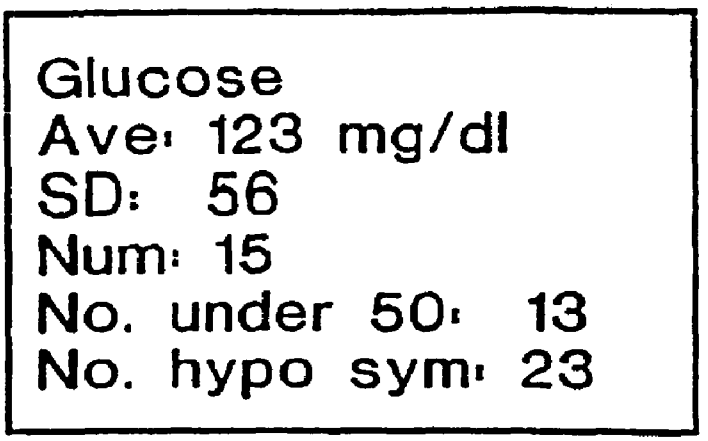

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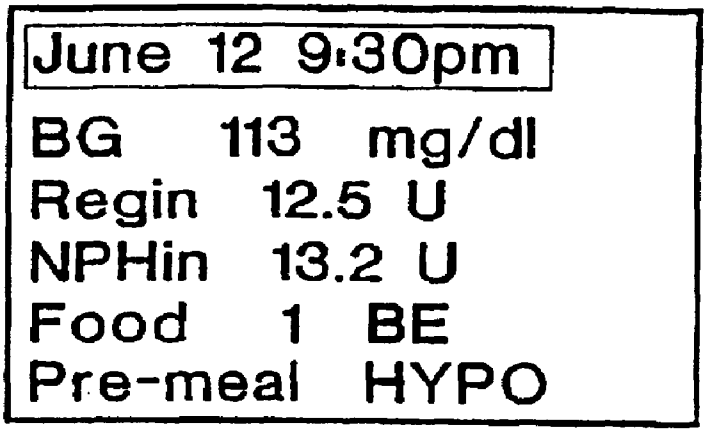
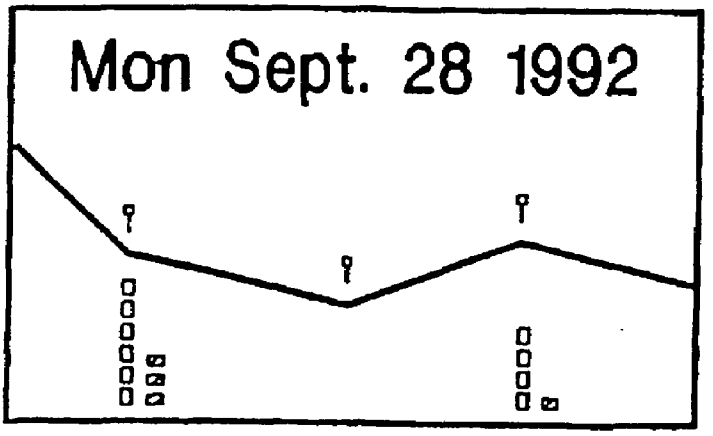


Fig. 10



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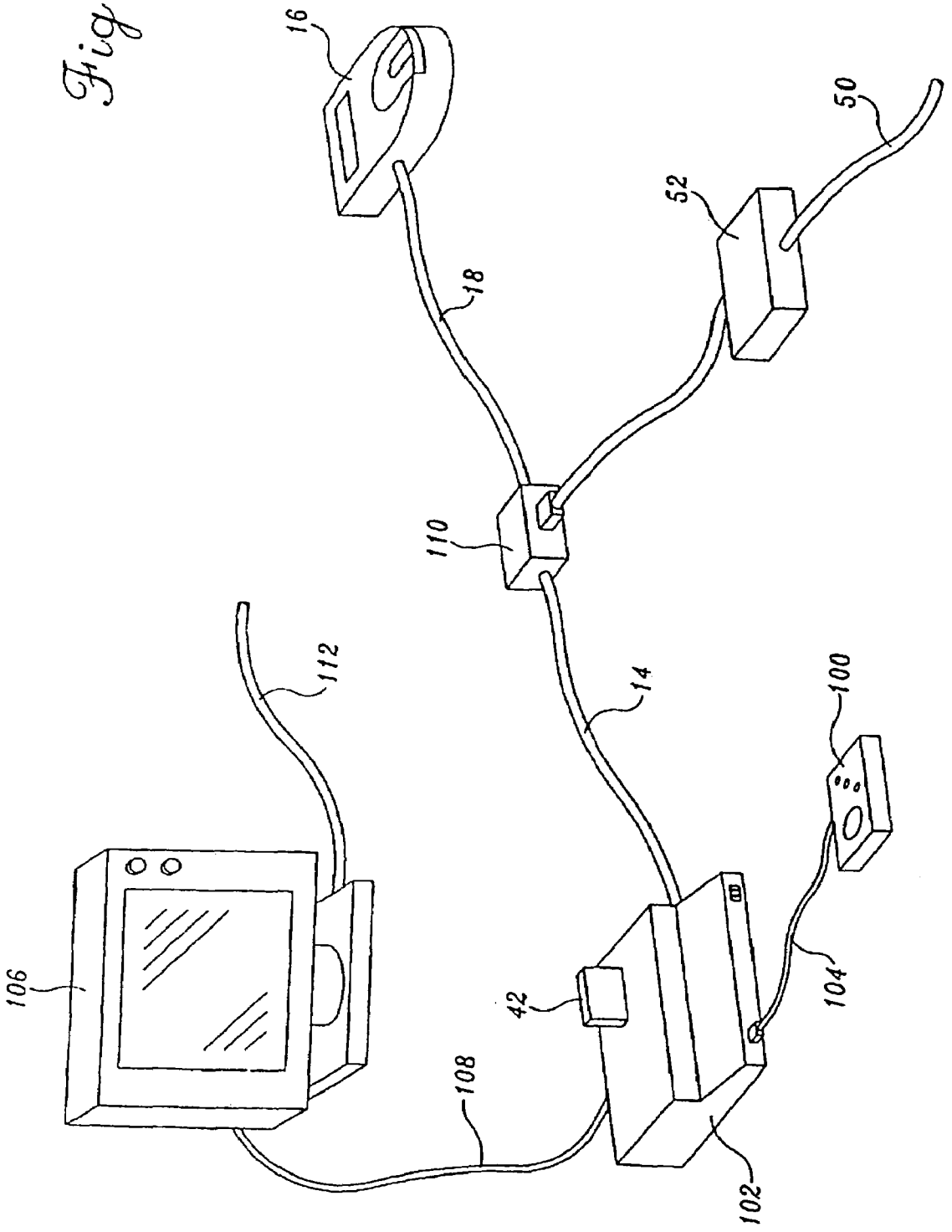


SYSTEM AND METHOD FOR MONITORING BLOOD PRESSURE FROM A PERSON

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 selectively 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 nec-

essary; 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 method for communicating with a person at a remote location, comprising the steps of:

(A) monitoring blood pressure information from said person using a subsystem;

(B) establishing a communication link between the subsystem and a central server;

(C) communicating said information from said subsystem to a server, wherein said subsystem is remotely located from said server;

(D) disconnecting the communication link;

(E) processing said blood pressure information in said server;

(F) communicating said processed information from said server to one or more computers, wherein said computers (i) are remotely located from said server and (ii) correspond to one or more users associated with said person;

(G) providing health-related information based on said processed information from at least one of said computers to the central server and storing the information in the server; and

(H) providing the information to the subsystem from the server when the next communication link is established.

2. The method of claim **1**, wherein said subsystem comprises:

(a) a data management unit having (i) a first interface configured to receive said information, (i) a second interface configured to transfer said information and (iii) a third interface configured to communicate with said server;

(b) a monitoring device configured to transfer said information directly to said first interface of said data management unit; and

(C) a display device configured to (i) receive said information from said second interface of said data management unit and (iii) display said information in a form suitable for viewing by said person.

3. The method of claim **1**, wherein said subsystem comprises video game device.

4. The method of claim **1**, further comprising the step of:

transferring at least one message corresponding to said person from at least one of said computers to said subsystem.

5. The method of claim **1**, further comprising the step of:

transferring one or more instructions corresponding to said person from at least one of said computers to said subsystem.

6. The method of claim **1**, further comprising the step of:

transferring at least one of (i) an educational content and (ii) a motivational content from at least one of said computers to said subsystem.

7. The method of claim **1**, further comprising the steps of:

providing at least one program from said server to said subsystem;

storing said program in a removable memory card in said subsystem; and

executing said stored program within said subsystem to collect said information.

8. A method of communicating with a person at a remote location, comprising the steps of:

(A) monitoring blood pressure information from said person using a subsystem;

(B) establishing a communication link between the subsystem and a central server;

(C) communicating said blood pressure information from said device to a server, wherein said subsystem is remotely located from said server;

(D) disconnecting the communications link;

(E) communicating said information unaltered from said server to one or more computers in response to a request for said information received at said server, wherein (i) said computers are remotely located from

said server and (ii) said computers correspond to one or more users associated with said person;

(F) processing said information in at least one of said computers;

(G) providing health-related information based on said processed information from at least one of said computers to the central server and storing the information in the server; and

(H) providing the information to the subsystem from the server when the next communication link is established.

9. The method of claim **8**, wherein step (A) comprises the sub-step of:

transferring said information from a monitoring device to a first interface of a data management unit; and wherein step (B) comprises the sub-step of:

communicating said information from said data management unit to both (i) said server and (ii) a display device corresponding to said person.

10. The method of claim **9**, further comprising the step of:

displaying said blood pressure information at said display device in a form suitable for viewing by said person.

11. The method of claim **8**, further comprising the step of:

communicating one or more instructions corresponding to said person from at least one of (i) said computers and (ii) said server to said subsystem.

12. The method of claim **8**, further comprising the step of:

communicating one or more messages corresponding to said person from at least one of (i) said computers and (ii) said server to said subsystem.

13. The method of claim **8**, further comprising the step of:

communicating at least one of (i) an educational content and (ii) a motivational content from at least one of said computers to said subsystem.

14. The method of claim **8**, further comprising the step of:

communicating at least one of (i) a medication dosage and (ii) a monitoring schedule from at least one of said computers to said subsystem.

15. A system comprising:

a subsystem configured to monitor blood pressure information from a person;

a server configured to (i) receive said information from said subsystem and (ii) process said information, wherein said subsystem is remotely located from said server; and

one or more computers configured to (i) receive said processed information and (ii) provide health-related information based on said processed information in a form viewable by one or more users associated with said person, wherein said computers are remotely located from said server;

where the subsystem is configured to intermittently establish a communications link to the central server and disconnect the link after a period of time; and

where the health-related information is stored in the central server at least until the next communications link is established.

16. The system of claim **15**, wherein said subsystem comprises:

a display device accessible by said person;

one or more monitoring devices, at least one of said monitoring devices being configured to measure said information; and

a data management unit (i) coupled to said display device through a first interface, (ii) coupled to said monitoring device through a second interface and (iii) configured to communicate with said server through a communication network coupled to a third interface.

17. The system of claim **15**, wherein said subsystem comprises a video game device.

18. The system of claim **15**, wherein at least one of (i) said computers and (ii) said server is further configured to communicate one or more messages corresponding to said person to said subsystem.

19. The system of claim **15**, wherein at least one of (i) said computers and (ii) said server is further configured to communicate at least one of (a) an educational content and (b) a motivational content to said subsystem.

20. The system of claim **15**, wherein at least one of (i) said computers and (ii) said server is further configured to communicate at least one of (a) a medication dosage and (b) a monitoring schedule corresponding to said person to said subsystem.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,223,235 B2
APPLICATION NO. : 11/221807
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 21, Claim 1, line 67, delete “central”

Column 22, Claim 1, line 2, replace “a” with --said--

Column 22, Claim 1, line 14, delete “central”

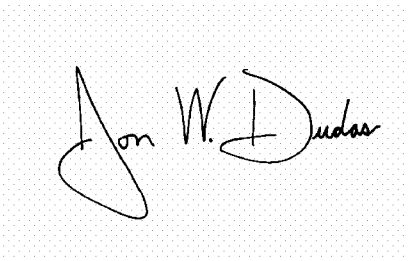
Column 22, Claim 8, line 61, replace “device” with --subsystem--.

Column 24, Claim 15, line 8, delete “central”.

Column 24, Claim 15, line 11, delete “central”.

Signed and Sealed this

Tenth Day of July, 2007



JON W. DUDAS
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,223,235 B2
APPLICATION NO. : 11/221807
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:

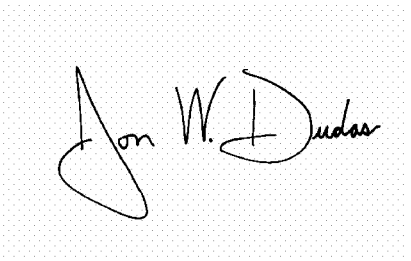
Column 22, Claim 8, line 59, delete “central”

Column 22, Claim 8, line 61, replace “a” with --said--

Column 23, Claim 8, line 7, delete “central”

Signed and Sealed this

Twenty-eighth Day of August, 2007



JON W. DUDAS
Director of the United States Patent and Trademark Office

EXHIBIT B

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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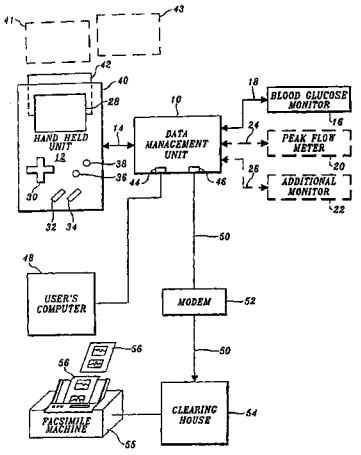
Primary Examiner—Robert L. Nasser
(74) *Attorney, Agent, or Firm*—Christopher P. Maiorana, PC

(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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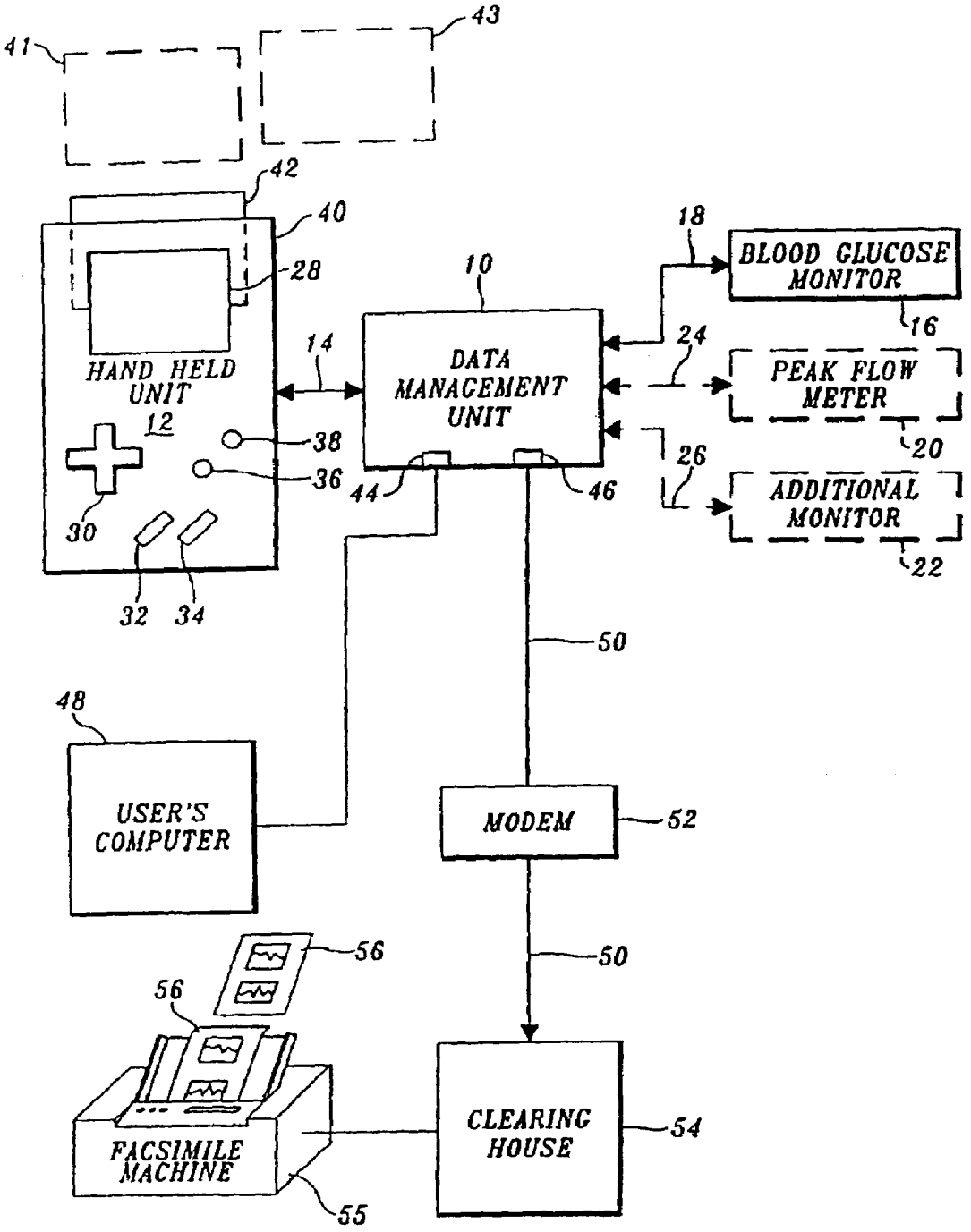
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43
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DATA MANAGEMENT UNIT
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46
18
BLOOD GLUCOSE MONITOR
16
24
PEAK FLOW METER
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ADDITIONAL MONITOR
22
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48
USER'S COMPUTER
MODEM
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FACSIMILE MACHINE
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CLEARING HOUSE
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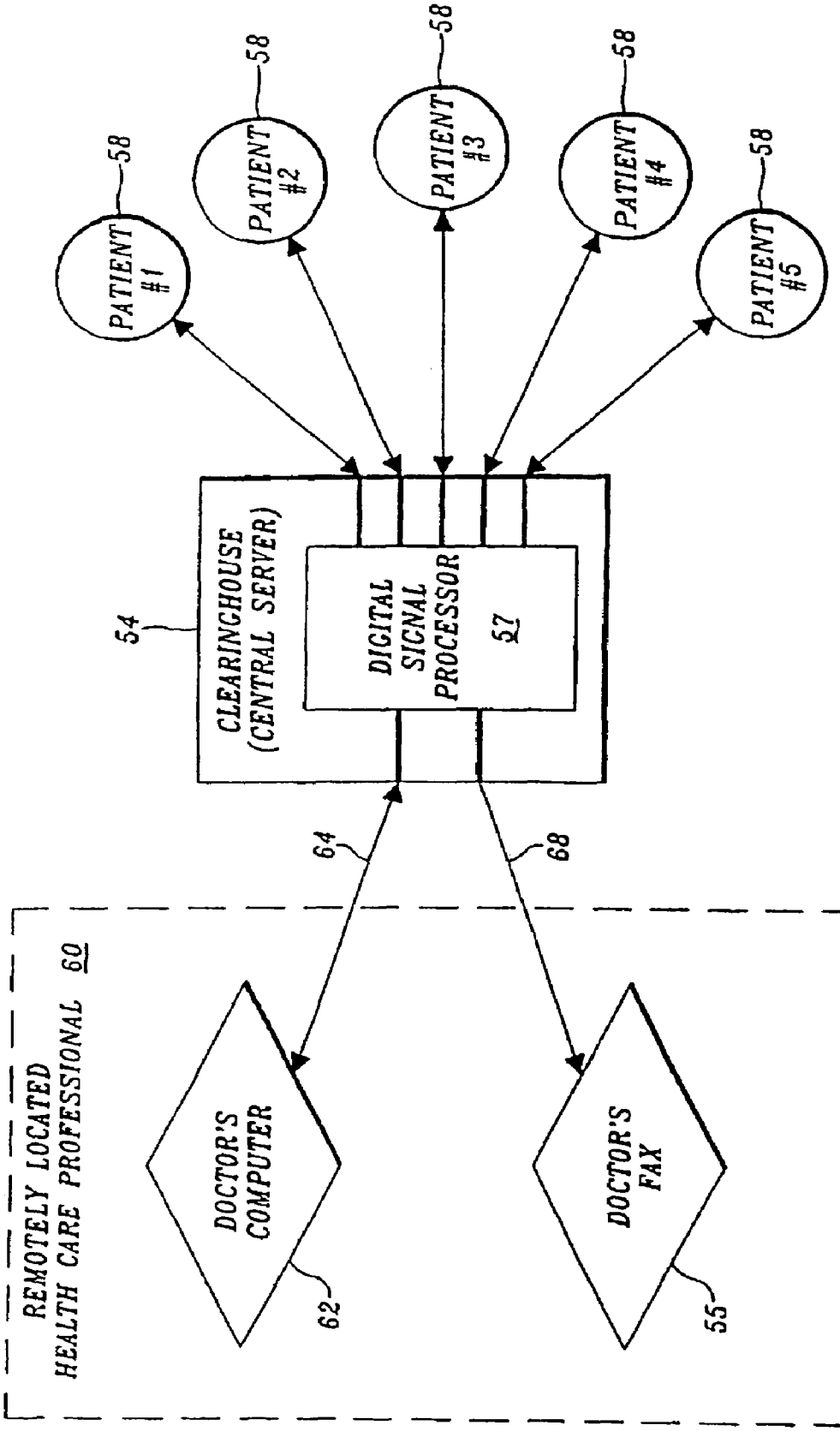
Fig. 1.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PATIENT #2
PATIENT #3
PATIENT #4
PATIENT #5
58
CLEARINGHOUSE (CENTRAL SERVER)
54
DIGITAL SIGNAL PROCESSOR
57
64
68
REMOTELY LOCATED HEALTH CARE PROFESSIONAL 60
DOCTOR'S COMPUTER
62
DOCTOR'S FAX
55

Fig. 2.

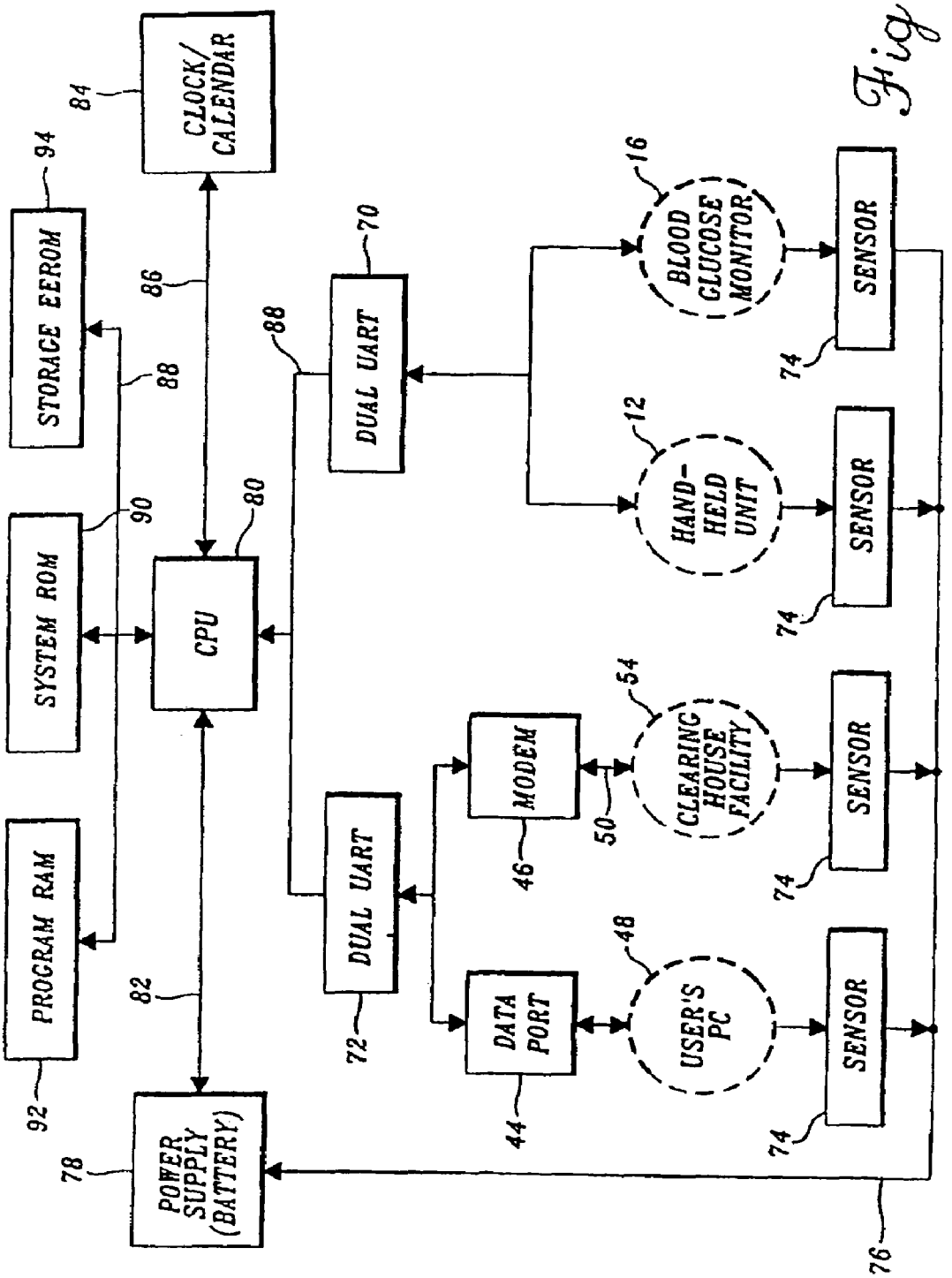

CLOCK/ CALENDAR
84
STORAGE EEROM
94
86
88
SYSTEM ROM
90
CPU
80
PROGRAM RAM
92
82
POWER SUPPLY (BATTERY)
78
DUAL UART
70
88
DUAL UART
72
MODEM
46
DATA PORT
44
BLOOD GLUCOSE MONITOR
16
HAND-HELD UNIT
12
CLEARING HOUSE FACILITY
54
50
USER'S PC
48
SENSOR
74
SENSOR
74
SENSOR
74
SENSOR
74
76

Fig. 3

Fig.4.

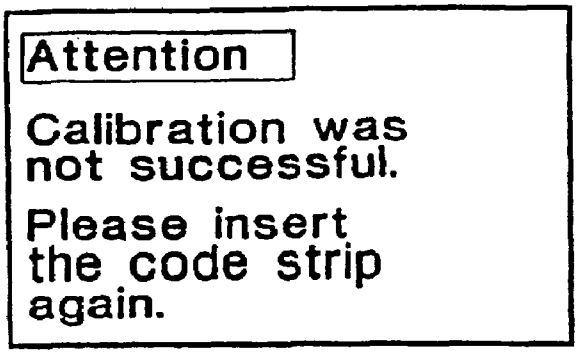


Fig.5.

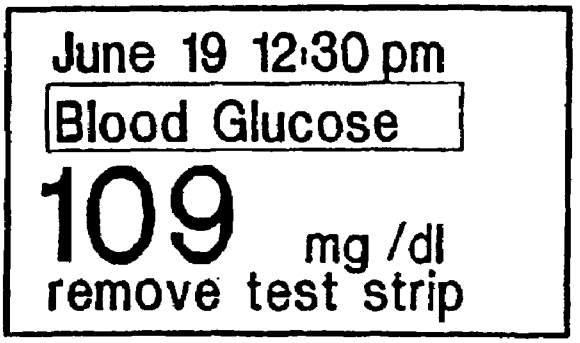


Fig.6.

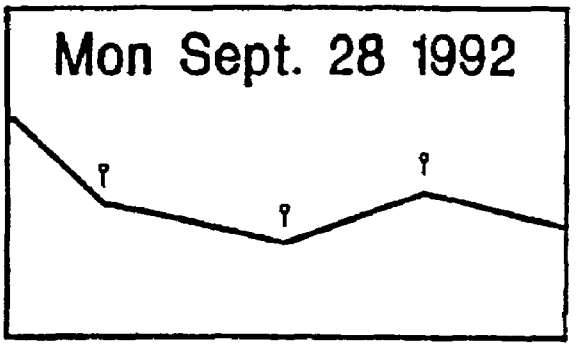


Fig.7.

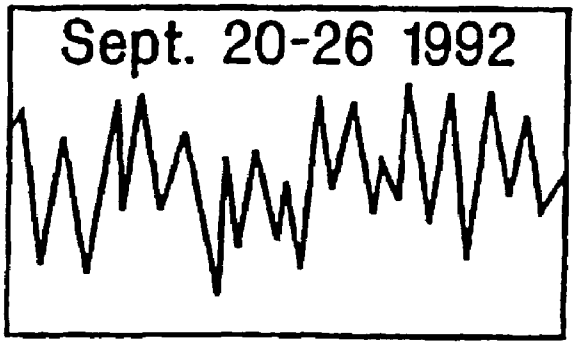


Fig. 8.

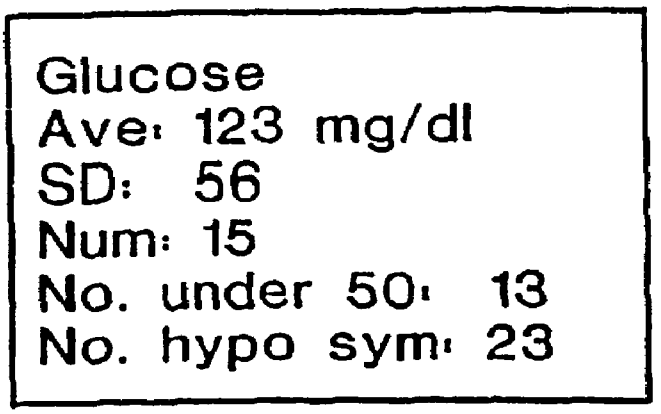


Fig. 9.

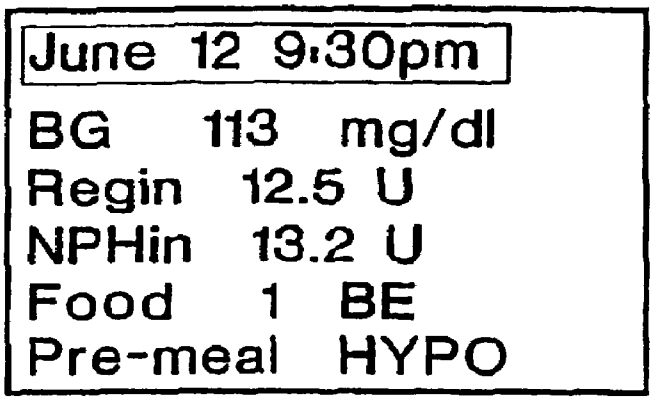


Fig. 10.

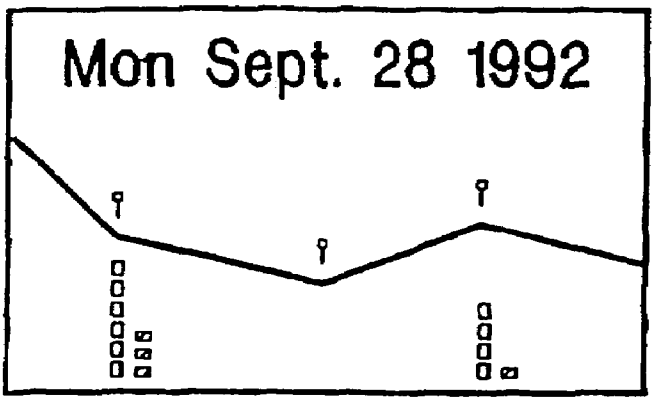
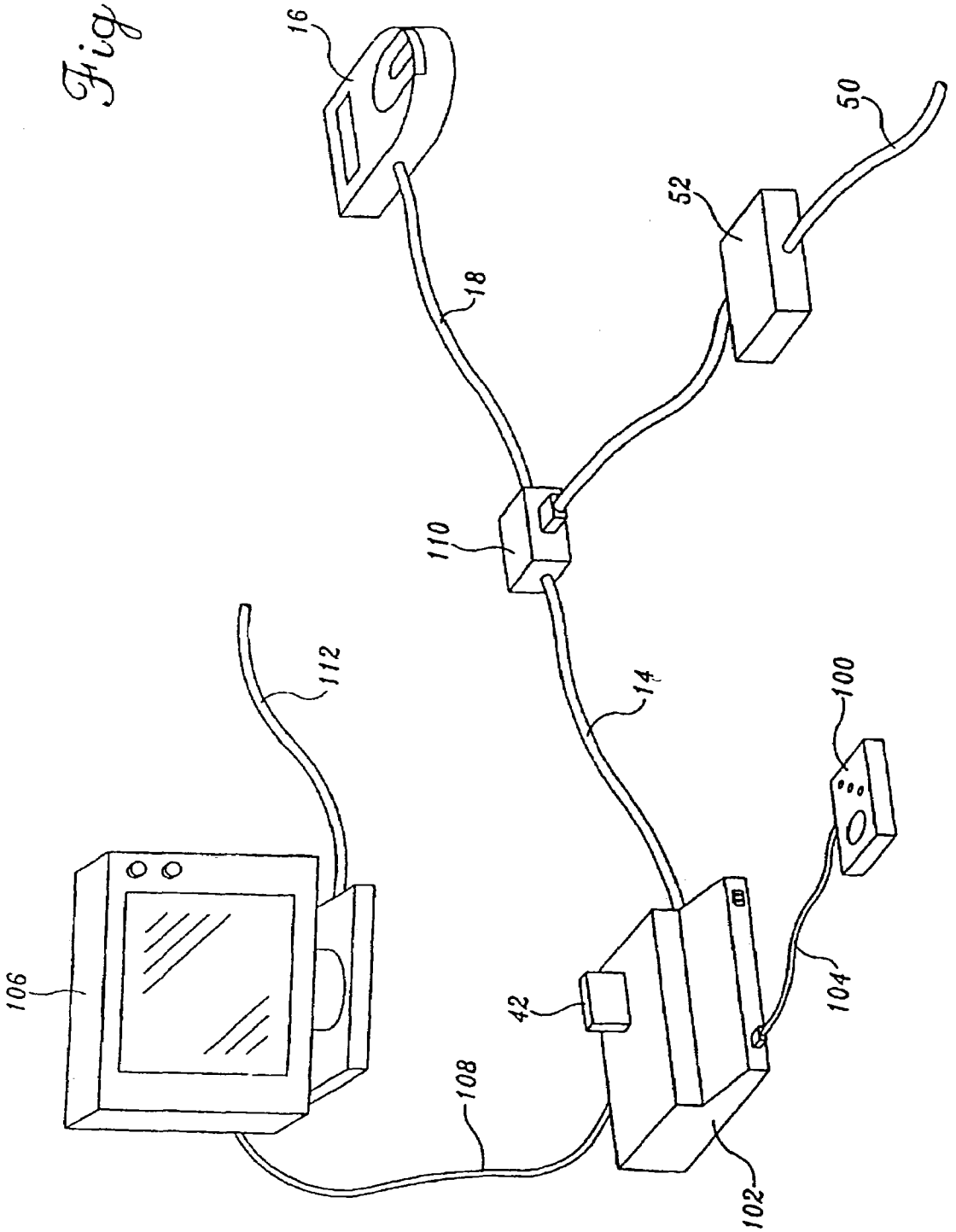


Fig. 11.



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--

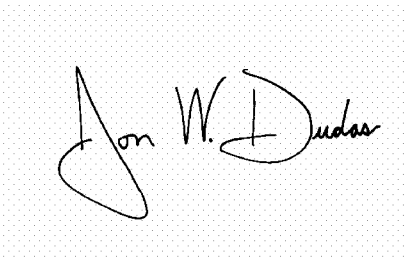
Column 24, Claim 22, line 2, replace "system" with --subsystem--

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