



US006083156A

United States Patent [19]
Lisiecki

[11] Patent Number: 6,083,156
[45] Date of Patent: Jul. 4, 2000

[54] PORTABLE INTEGRATED PHYSIOLOGICAL MONITORING SYSTEM

[75] Inventor: Ronald S. Lisiecki, 815 E. Yale Ave.
#C, Salt Lake City, Utah 84105-1330

[73] Assignee: Ronald S. Lisiecki, Salt Lake City,
Utah

[21] Appl. No.: 09/192,714

[22] Filed: Nov. 16, 1998

[51] Int. Cl.⁷ A61B 5/0205

[52] U.S. Cl. 600/301

[58] Field of Search 600/300, 301,
600/503, 509, 534, 544

[56] References Cited

U.S. PATENT DOCUMENTS

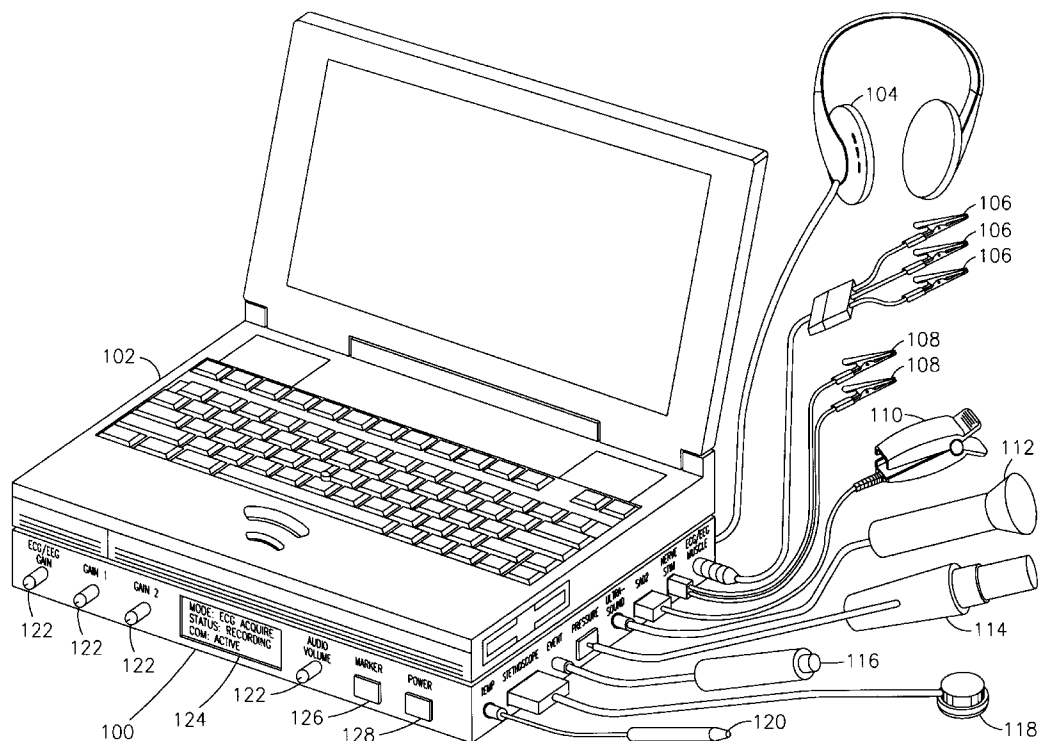
4,686,998	8/1987	Robbins	128/670
4,827,943	5/1989	Bornn	128/668
4,860,759	8/1989	Kahn	128/668
4,889,131	12/1989	Salem	128/671
4,974,607	12/1990	Miwa	128/904
5,012,411	4/1991	PolICASTRO	364/413.06
5,238,001	8/1993	Gallant	128/700
5,257,627	11/1993	Rapoport	128/661.07
5,263,491	11/1993	Thornton	128/774
5,275,159	1/1994	Griebel	128/633
5,339,821	8/1994	Fujimoto	128/700
5,375,604	12/1994	Kelly	128/671
5,417,222	5/1995	Dempsey	128/696

Primary Examiner—Max Hindenburg
Attorney, Agent, or Firm—Garron M. Hobson

[57] ABSTRACT

A portable, integrated physiological monitoring system is described for use in clinical outpatient environments. This system consists of a plethora of sensors and auxiliary devices, an electronics unit (100) that interfaces to the sensors and devices, and a portable personal computer (102). Electrodes (106) are provided to acquisition electrocardiographic, electroencephalographic, and neuromuscular signals. Electrodes (108) are provided to stimulate neural and muscular tissue. A finger pulse oximeter (110), an M-mode ultrasonic transducer (112), an airflow sensor (114), a temperature probe (120), a patient event switch (116), and an electronic stethoscope (118) are provided. A portable personal computer (102) interfaces to the electronics unit (100) via a standard parallel printer port interface (258) to allow communication of commands and information to/from the electronics unit (100). Control and display of the information gathered from the electronics unit (100) is accomplished via an application program executing on the portable personal computer (102). Sharing of common data acquisition hardware along with preliminary processing of information gathered is accomplished within the electronics unit (100). The entire system is battery operated and portable. This system, because of its architecture, offers significant cost advantages as well as unique modes of operation that cannot be achieved from the individual physiological parameter measurement devices alone. The system allows for the integration of acquisitioned information from the sensors into a patient's database stored on the portable personal computer.

20 Claims, 2 Drawing Sheets



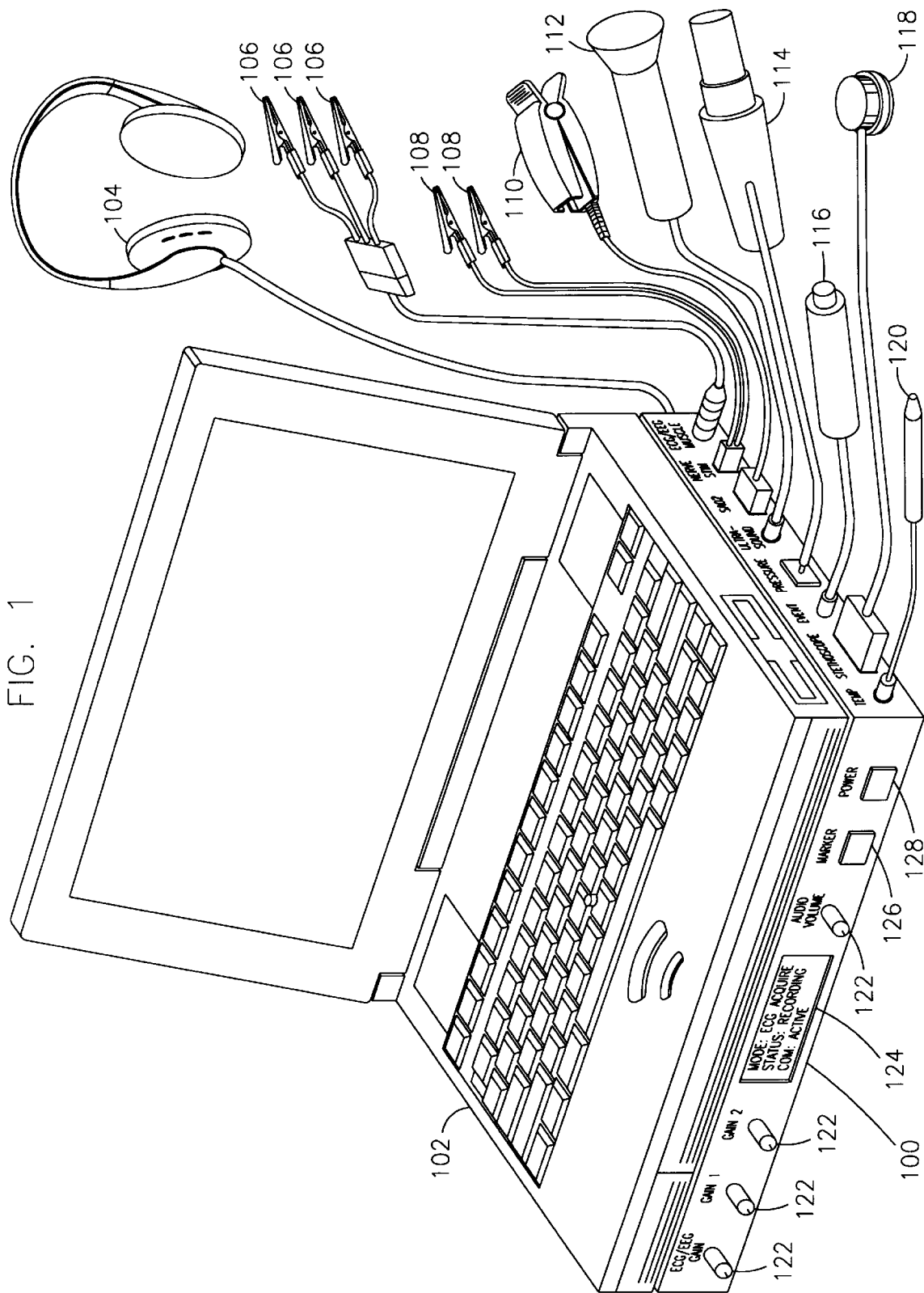
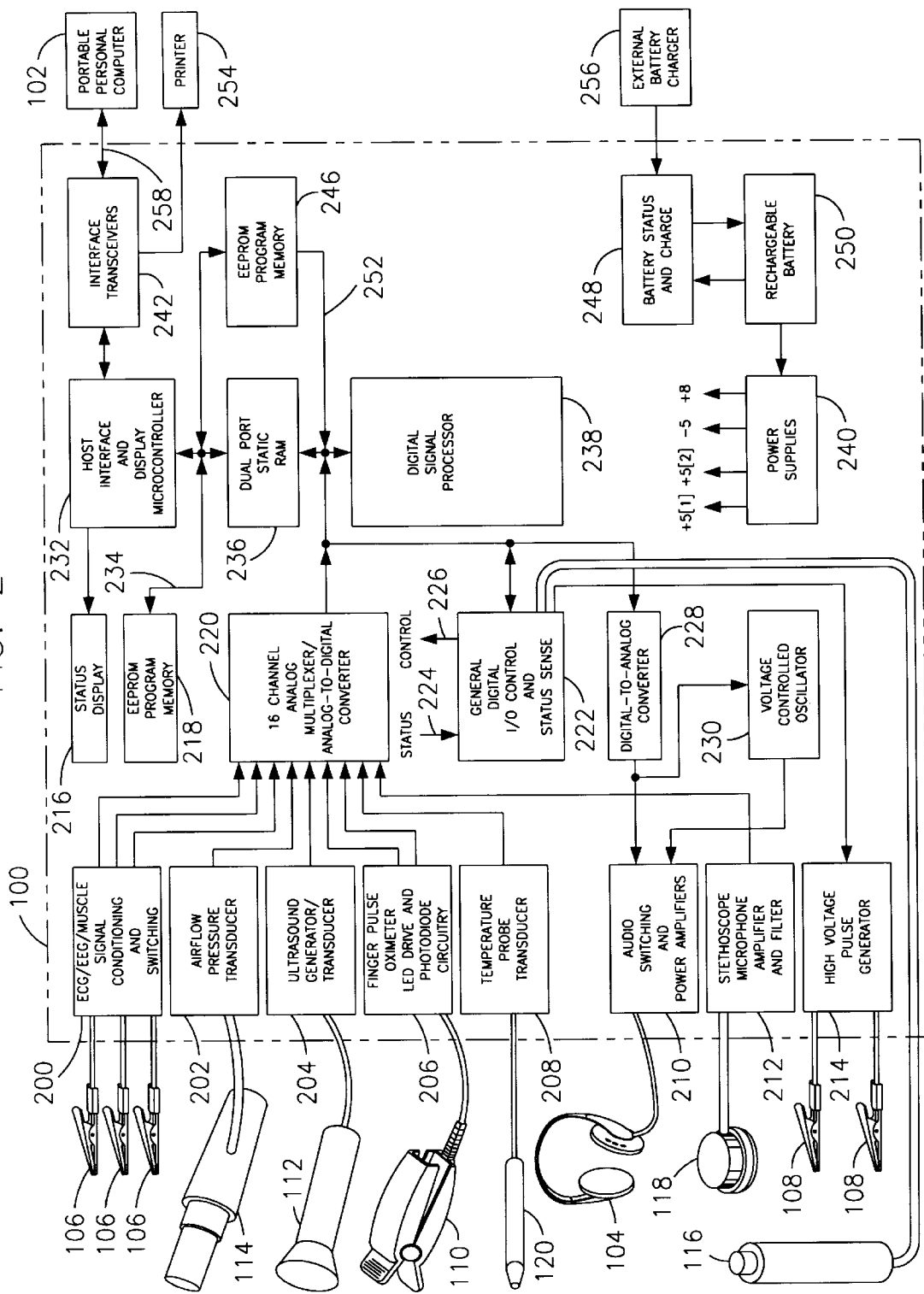


FIG. 2



PORTABLE INTEGRATED PHYSIOLOGICAL MONITORING SYSTEM

BACKGROUND

1. Field of Invention

This invention relates to portable systems capable of acquisition, displaying, and recording physiological information obtained from a human subject.

2. Description of Prior Art

Medical clinicians often need to assess physiological information from a human subject in order to diagnose or monitor disease states. In clinical outpatient environments, the scope of this information widely ranges from cardiac information (i.e. ElectroCardioGrams [ECGs]) to pulmonary information (i.e. Pulmonary Function Tests [PFTs], pulse oximetry [S_aO_2]) to neurologic information (i.e. ElectroEncephaloGrams [EEGs], nerve conduction studies).

Current devices used to assess such physiological information are commonly available to clinicians and exist in numerous configurations. Typically, most of these configurations consist of a single device that assesses a single or related group of physiological parameters. This device is usually dedicated only to the acquisition of physiological information for one organ system of the human subject that is being tested. Typical examples of these devices include the electrocardiogram and the pulmonary function test. A few devices acquisition information from more than one organ system such as the PROPAQ System (U.S. Pat. No. 5,568,814 [1996]) manufactured by PROTOCOL Systems, Inc. which is capable of recording electrocardiograms, oxygen saturation, and blood pressure. These multiorgan, physiological monitoring systems are useful in portable/ambulatory situations where temporary monitoring of multiple physiologic parameters is required but, such systems lack utility in clinical outpatient environments where more parameters may be required to be assessed and where these parameters need to be integrated into the patients medical record.

Current devices are typically electrically powered from commercial power found in most office environments. Some devices are battery powered for portable operation such as the PROPAQ device mentioned above. The utility of portability of such devices is attained when the device is battery powered and many situations in a clinical outpatient environment benefit from this portability by having equipment that can be easily moved from one setting to another. An example of such utility is seen in today's portable finger pulse oximeters.

Current devices are limited in their ability to transmit their acquired information to locations where that information could be best utilized or stored. The predominant method of data storage is the hand-copying of the acquired information from the device to the patient's medical record (e.g. a blood pressure measurement or a finger oximeter measurement). Alternatively, the device may print either a strip or a page of paper which is retrieved and placed in the medical record. Both of these methods fail to "integrate" the information into the patient's medical record in a manner that is timely, that maximizes its utility there, and that minimizes losses of such acquired information.

The majority of devices used to collect physiological information from a human subject utilize electrical circuitry that must convert a transduced signal into a digital value (i.e. analog-to-digital conversion) which is then usually manipulated by a digital processing element (i.e. microprocessor, or

digital signal processor) into either displayable information, and/or a transmittable/storable element. Since the majority of devices utilize this method, it would seem reasonable if these devices could share their common conversion and manipulation elements by combining them into a common unit. This would offer significant cost advantages in the common unit as compared to the individual devices since redundant electrical hardware is shared among the signals to be transduced and manipulated.

Furthermore, alphanumeric as well as graphical information is commonly generated by these devices and is typically displayed on the front panel of such devices or is printed on paper medium. It would also be reasonable to share a common display device in a unit that would contain functions combining various measurement parameters so that a cost advantage could be obtained by sharing this common display device. This concept of sharing of the display device could also be extended to the sharing of a common printing device, again, achieving further cost advantages.

Additionally, certain medical conditions could be diagnosed in the clinical outpatient environment if multiple and/or continuous monitoring of certain physiological parameters could be performed. Examples of these conditions include sleep apnea, dysrhythmias, and certain neurological/psychiatric conditions. It would be advantageous to be able to monitor and record these parameters within the clinical outpatient environment, and diagnose/monitor these medical conditions in this environment rather than having to send the subject to specialized centers needed to diagnose/monitor these conditions. Having these capabilities within the clinical outpatient environment could offer expense savings to our healthcare system.

As more and more medical information is collected on a particular human subject over the course of his/her medical history, the need to centrally collect this information, organize it, store it, and transmit it to other locations becomes a more difficult task. Currently, in the clinical outpatient environment at least, these tasks are manually performed. There is a paucity of systems that efficiently organize and store such information. A need exists for a system that can accomplish the above tasks that utilizes a cost effective system.

Several types of monitoring systems that acquisition multiple physiologic parameters are currently employed within inpatient as well as outpatient clinical environments. Many of these, such as in U.S. Pat. No. 4,860,759 (1989), are intended only to continuously monitor and display certain groups of physiological parameters. Others, such as U.S. Pat. Nos. 5,263,491 (1993), 5,275,159 (1994), 5,238,001 (1993), and 5,339,821 (1994) continuously monitor and log certain groups of physiological parameters for future playback and analysis, but, do not display the information while it is being acquisitioned. Still, other systems such as described in U.S. Pat. Nos. 4,686,998 (1987), 4,827,943 (1989), 5,012,411 (1991), 4,974,607 (1990), 4,889,131 (1989), and 5,257,627 (1993) continuously monitor certain groups of physiological parameters and transmit the information to remote sites for decision making. None of the above systems describe a system to acquisition selected physiological parameters in a clinical outpatient environment and display this information on a viewing device, as well as incorporate the information into the medical record, and, interpret and store this information at the collection site.

Other physiological monitoring systems described in U.S. Pat. Nos. 5,375,604 (1994) and 5,417,222 (1995) are either portable, multichannel systems for monitoring only (i.e. not

intended to permanently record the data into a human subject's medical record) (the former patent) or bedside/intensive care type units with nonportable bedside sensors (the latter patent). Both of these devices are also intended to transmit information to a central station for analysis and logging of this information at this location, but not at the bedside.

A few other relatively new systems (of particular interest is the "NAS" system from BCI International; no patent found at this time) are ambulatory monitoring systems with a limited number of physiological parameters that can be monitored and whose parameters can only be viewed statically (i.e. the device does not provide continuous monitoring of the physiologic variable of interest). These devices utilize a personal computer to acquisition and display static parameters only. Integration of the information into the patient's medical record is not a capability of these types of systems.

Technological advances in personal computers, especially portable personal computers, now allow many systems access to processing capabilities not available in the past. Portable personal computers now have ample processing power to allow them to control external systems in a real-time fashion. These computers also allow a system to utilize their display and keyboard for very sophisticated user interaction as well as information displays. Furthermore, these computers offer very large temporary, as well as long-term storage capabilities, that allow for management of large databases of information. These systems also allow for simplified communication of information to/from remote computing facilities. Finally, these portable computers are battery powered and allow for remote processing/control of an application where commercial power is not available. The numerous capabilities of personal portable computers present a very cost effective method of controlling and interacting with external systems that has otherwise not been available in the past.

Although many patient physiological monitoring systems currently exist, most of these are not appropriate for the measurement and management of physiological parameters of human subjects in the clinical outpatient environment. This environment demands the ability to monitor more physiological parameters than current systems offer within one system. The acquisition of these parameters from human subjects needs to be integrated into the patient's medical record in a timely, efficient, and reliable manner. The acquisition process should have the capability of being performed without the use of commercial power and the equipment used should be easily portable between various environments. Because the various subsystems used to acquisition physiological parameters utilize similar electrical components, a system incorporating these various subsystems should take advantage of the sharing of these components in an effort to minimize the cost of the overall system. The physiological monitoring system described in this document incorporates the above concepts into an apparatus for monitoring physiological parameters that has very high utility and low cost in a clinical outpatient environment.

OVERVIEW OF THE INVENTION: OBJECTS AND ADVANTAGES

A portable, integrated physiological monitoring system is described for principal use in clinical outpatient environments. This physiological monitoring system consists of three principal elements: a) a plethora of physiological sensors and auxiliary devices, b) a chassis of electronic

components (electronics unit) that acquisitions information from the sensors and communicates this information to a portable personal computer, and c) a portable personal computer.

In the current embodiment of this physiological monitoring system, the plethora of sensors currently consists of a) electrodes for the acquisition of electrocardiographic, electroencephalographic and neuromuscular signals, b) electrodes to stimulate neural and muscular tissue, c) a finger pulse oximeter, d) an M-mode ultrasonic transducer, e) an airflow sensor, f) a handheld patient event switch, g) an electronic stethoscope, h) a temperature probe, and i) a pair of stereo headphones. It is envisioned that other sensors could easily be adapted to this system for acquisition of their respective signals/data.

The electronics unit consists of circuits that interface to the various external sensors, a rechargeable battery with charge status and charge control circuitry, a common analog-to-digital converter with a multiplexer, a digital signal processor to process the various streams of data coming from the sensors, memories to hold temporary data as well as permanent control instructions for the processors, a display/input/output microcontroller, a front panel status display, and an interface to the portable personal computer as well as to an external printer.

The portable personal computer resides on top of the electronics unit and interfaces to the unit via the parallel printer port of the portable personal computer. Commands from this portable personal computer are sent to the electronics unit via the parallel printer port interface to initiate and control acquisition of information from the sensors. Information collected from the electronics unit can be sent to the portable personal computer via the parallel printer port interface. The user interacts and controls the overall system operation from the keyboard and display of the portable personal computer. Information collected from the sensors can be displayed on the display of the portable personal computer in various formats. Real-time monitoring of continuous sensor information is possible. The hard disk drive of the personal computer can be utilized for long-term storage of acquisition information as well as for access and integration of information with the patient databases stored there. Communication with peripheral information systems may be accomplished through various standard communication pathways available on most portable personal computers. An external printer attached to the electronics unit allows for the ability of the system to print information from the portable personal computer while also being able to utilize the parallel printer port interface for control purposes.

Several objects and advantages of the present physiological monitoring systems are:

- (a) to provide a plethora of physiological sensors that are useful to the medical clinician in a clinical outpatient environment;
- (b) to share electronic elements (analog-to-digital converters and digital signal processors) that are common to the processing of information from the various attached sensors in a means that is conducive to the overall cost reduction of the device;
- (c) to utilize the various processing, display and user interface capabilities of the portable personal computer to control the operations of the device thereby minimizing components that would have had to be incorporated into the electronics of the device in order to effect the same capabilities;

5

- (d) to provide for the ability to monitor and display information continuously from sensors that provide real-time, continuous information;
- (e) to provide a portable, battery powered device, that is capable of being easily transported to various locations;
- (f) to provide a very low cost, common interface (i.e. the parallel printer port), between the device's electronics unit and the portable personal computer, for communication of commands and information between these devices;
- (g) to provide for the integration of acquisitioned information from the device's sensors with the patients medical records stored within the personal computer or stored in a remote facility;
- (h) to provide for the ability to acquisition multiple streams of continuous information from various sensors simultaneously in order to monitor/diagnose certain disease states;
- (i) to provide greater access to the monitoring of physiological parameters for healthcare providers that may not be able to acquire individual devices capable of monitoring these parameters due to their higher costs;
- Further objects will demonstrated from a consideration of the ensuing description and drawings.

DRAWING FIGURES

FIG. 1 shows a perspective view of the entire physiological monitoring system described in this patent which includes the sensors, the electronics unit, and the portable personal computer.

FIG. 2 shows a systems view of the electronics unit with attached sensors, portable personal computer, external printer and external battery charger.

Reference Numerals in Drawings

- 100** electronics unit
- 102** portable personal computer
- 104** stereo headphones
- 106** alligator clips for ECG/EEG/Muscle electrodes
- 108** alligator clips for nerve/muscle stimulator electrodes
- 110** finger pulse oximeter
- 112** M-mode, ultrasonic transducer
- 114** airflow sensor
- 116** patient event switch
- 118** electronic stethoscope
- 120** temperature probe
- 122** user adjustable gain controls
- 124** status display
- 126** user marker switch
- 128** power switch
- 200** ECG/EEG/Muscle signal conditioning and switching circuitry
- 202** airflow pressure transducer circuitry
- 204** ultrasound generator and transducer circuitry
- 206** finger pulse oximeter LED drive and photodiode circuitry
- 208** temperature probe transducer circuitry
- 210** audio switching and power amplifiers circuitry
- 212** stethoscope microphone amplifier and filter circuitry
- 214** high voltage pulse generator circuitry
- 216** status display circuitry
- 218** Electrically Erasable Programmable Read Only Memory (EEPROM) for host interface and display microcontroller

6

- 220** Sixteen channel analog multiplexer and analog-to-digital converter
- 222** general digital input/output and status sense circuitry
- 224** status signals from peripheral circuitry
- 226** control signals to peripheral circuitry
- 228** digital-to-analog converter
- 230** voltage controlled oscillator
- 232** host interface and display microcontroller
- 234** data, address, and control busses of host interface and display microcontroller
- 236** dual port static Random Access Memory (RAM)
- 238** digital signal processor
- 240** power supplies circuitry
- 242** interface transceivers circuitry
- 244** external printer interface
- 246** Electrically Erasable Programmable Read Only Memory (EEPROM) for digital signal processor
- 248** battery status and charge control circuitry
- 250** rechargeable battery
- 252** data, address, and control busses of digital signal processor
- 254** external printer
- 256** external battery charger
- 258** parallel printer port interface

DESCRIPTION OF INVENTION

A typical embodiment of the physiological monitoring system described in this patent is illustrated in FIG. 1. The principal physical components of this system are the set of attached sensors and auxiliary devices, an electronics unit **100**, and a portable personal computer **102**. Additional support components include an external printer **254** and battery charger **256** (shown in the systems diagram of FIG. 2).

Electronics unit **100** of the system consists of an enclosure that contains circuitry to support the acquisition and processing of signals obtained from the sensors. The front panel of this electronics unit contains user adjustable gain controls **122** used by the internal circuitry to set user adjusted gains. A status display **124** on the front panel will assist the user in assessing the unit's status however, the display of portable personal computer **102**, will be the principal display used in status reporting. A user marker switch **126** allows direct interaction with electronics unit **100** during some operations. A power switch **128** enables/disables power to the electronics unit. Various sensors and auxiliary devices attached to the side and back panel of electronics unit **100**. Portable personal computer **102** can be placed on top of electronics unit **100** for space savings or can be located adjacent to the unit. FIG. 2 also shows a parallel printer port interface **258** which allows for communication between electronics unit **100** and portable personal computer **102**. An external printer **254** attaches to electronics unit **100** at its rear panel.

A plethora of sensors and auxiliary devices attach to electronics unit **100** as shown in FIGS. 1 and 2. A pair of stereo headphones **104** allow the human subject to be presented various audio waveforms generated by electronics unit **100**. Alligator clips **106** consist of ten miniature alligator clips that attach to a human subject via disposable tab electrodes. FIGS. 1 and 2 show only three of these clips for illustrative purposes however, ten of them are required for acquisition of a 12-lead electrocardiogram. These clips can also be used for acquisition of electroencephalographic and

neuromuscular signals from a human subject. Alligator clips **108** consist of two miniature alligator clips that attach to a human subject via disposable tab electrodes. These clips apply high voltage pulses to the human subject for stimulation associated with nerve conduction studies. A finger pulse oximeter **110** is a standard oximeter that can be attached to a human subject's finger for acquisition of blood oxygen saturation signals via standard photometric techniques. An ultrasonic transducer **112** transmits and receives M-mode ultrasound to a human subject. An airflow sensor **114** enables measurement of airflow from a human subject during pulmonary function testing. A patient event switch **116** allows a human subject to interact with electronics unit **100** and indirectly with portable personal computer **102**. An electronic stethoscope **118** enables auscultation of heart and lung sounds from a human subject and allows for acquisition and recording of these sounds via electronics unit **100**. A temperature probe **120** enables temperature measurements of the human subject. Other sensors capable of physiological monitoring could be interfaced with electronics unit **100** but are not shown in this embodiment. These could include devices such as noninvasive blood pressure monitors.

FIG. 2 shows a systems diagram of the physiological monitoring system of this patent. Electrocardiographic, electroencephalographic and neuromuscular signals arrive at ECG/EEG/Muscle signal conditioning and switching circuitry **200** where they are amplified by gains set by either front panel user adjustable gain controls **122** or by commands sent from portable personal computer **102**. This circuitry also has preliminary signal filters for the arriving signals. The output of this circuitry consists of three separate analog signals which are presented to sixteen channel analog multiplexer and analog-to-digital converter **220** for conversion to digital signals. Groups of three signals are selected by control signals **226** arising from general digital input/output control and status sense circuitry **222** for the purpose of routing standard sets of electrocardiographic signals to sixteen channel analog multiplexer and analog-to-digital converter **220** for conversion to digital signals.

Pressure waveforms from airflow sensor **114** are applied to the pressure transducer within airflow pressure transducer circuitry **202**. The analog pressure signal from this circuitry is a function of the rate of airflow delivered to airflow sensor **114** from the human subject. After filtering the signal from this circuitry, the analog signal is presented to sixteen channel analog multiplexer and analog-to-digital converter **220** for conversion to digital signals.

M-mode, ultrasonic transducer **112** has its ultrasonic generator supplied by energy from ultrasound generator and transducer circuitry **204** which in turn is controlled by control signals **226** arising from general digital input/output control and status sense circuitry **222**. Reflected energy from the tissues in the human subject is transduced by M-mode, ultrasonic transducer **112** and the signal from this device is amplified and filtered by ultrasound generator and transducer circuitry **204**. The analog signal from this circuitry is presented to sixteen channel analog multiplexer and analog-to-digital converter **220** for conversion to digital signals.

Finger pulse oximeter **110** has its infrared and red light emitting diodes driven by finger pulse oximeter LED drive and photodiode circuitry **206** which in turn is controlled by control signals **226** arising from general digital input/output control and status sense circuitry **222**. Transmitted light waveforms from finger pulse oximeter's **110** photodiode are amplified and filtered by finger pulse oximeter LED drive and photodiode circuitry **206** and the two analog signals from this circuitry are presented to sixteen channel analog

multiplexer and analog-to-digital converter **220** for conversion to digital signals. Amplification of the light waveforms is selectively controlled by control signals **226** arising from general digital input/output control and status sense circuitry **222**.

The analog signal from temperature probe **120** is amplified and filtered by temperature probe transducer circuitry **208** and this signal is presented to sixteen channel analog multiplexer and analog-to-digital converter **220** for conversion to digital signals.

Stereo auditory signals are generated by audio switching and power amplifiers circuitry **210** and presented to stereo headphones **104** worn by the human subject. The source of these auditory signals can be from digital-to-analog converter **228** or from voltage controlled oscillator **230** whose frequency is controlled by the voltage output from digital-to-analog converter **228**. Voltage controlled oscillator **230** allows for simpler and purer generation of auditory test tones during audiometric testing of the human subject. Volume levels supplied to stereo headphones **104** can be controlled by either front panel user adjustable gain controls **122** or by digital control from digital signal processor **238** (pathway not explicitly shown in FIG. 2 for drawing clarity purposes) via a digital-to-analog converter within audio switching and power amplifiers circuitry **210**.

The analog signal from electronic stethoscope **118** is amplified and filtered by stethoscope microphone amplifier and filter circuitry **212** prior to it being sent to sixteen channel analog multiplexer and analog-to-digital converter **220** for conversion to digital signals. The gain of the amplifier can be controlled from front panel user adjustable gain controls **122**.

High voltage pulse generator circuitry **214** generates 70 Volt, 50 to 500 microsecond pulses to alligator clips **108** for use in nerve conduction studies as well as for use in Transcutaneous Electrical Nerve Stimulation (TENS) therapy. Control of these pulses occurs from control signals **226** derived from general digital input/output control and status sense circuitry **222**.

Patient event switch **116** routes human subject responses to general digital input/output control and status sense circuitry **222**.

Digital signal processor **238** executes control instructions from Electrically Erasable Programmable Read Only Memory (EEPROM) **246** and is the principal component effecting retrieval, preprocessing, and transmission of sensor data to portable personal computer **102** via host interface and display microcontroller **232**. Control instructions, information, and general control of digital signal processor **238** occur via signals from data, address, and control busses of the digital signal processor **252**. This processor has access to the digital words that are generated from sixteen channel analog multiplexer and analog-to-digital converter **220**. It also exerts general control over most of the circuitry in electronics unit **100** via general digital input/output control and status sense circuitry **222** through control signals **226**. Status signals **224** from the circuitry within electronics unit **100** are sensed by general digital input/output control and status sense circuitry **222** and are interrogated by digital signal processor **238**. Command and status semaphores from host interface and display microcontroller **232** are communicated to digital signal processor **238** via dual port static Random Access Memory (RAM) **236** and temporary data to and from digital signal processor **238** is also communicated through this RAM. Electrically Erasable and Programmable Read Only Memory (EEPROM) **246** used by digital signal

processor **238** for storage of control instructions, is also modifiable by host interface and display microcontroller **232**. Digital signal processor **238** is able to send data words to digital-to-analog converter **228** as well as the digital-to-analog converter located in the audio switching and power amplifiers circuitry **210**.

Host interface and display microcontroller **232** executes control instructions from Electrically Erasable and Programmable Read Only Memory (EEPROM) **218** and is principally responsible for receiving commands from portable personal computer **102** and communicating these commands to digital signal processor **238** via dual port static Random Access Memory (RAM) **236**. This processor also is responsible for communicating information generated by digital signal processor **238** to portable personal computer **102** and vice versa. Control instructions, information, and general control of host interface and display microcontroller **232** occur via signals from data, address, and control busses of the host interface and display microcontroller **234**. Host interface and display microcontroller **232** interfaces to parallel printer port interface **258** of portable personal computer **102** via interface transceivers circuitry **242**. Interface transceivers circuitry **242** has the capability of routing information to/from host interface and display microcontroller **232** to portable personal computer **102**, or can route information from portable personal computer **102** to external printer **254** via external printer interface **244** when printing is required by portable personal computer **102**. Host interface and display microcontroller **232** can execute control instructions from Electrically Erasable Programmable Read Only Memory (EEPROM) **246** that is normally used by digital signal processor **238** when it is necessary to reconfigure its own control instructions that are normally located in Electrically Erasable Programmable Read Only Memory (EEPROM) **218**. This microcontroller also controls status display circuitry **216** for the status display **124** on the front panel of electronics unit **100** to allow display of system status independent of portable personal computer **102**.

A rechargeable battery **250** provides the power for electronics unit **100** via power supplies circuitry **240**. This battery's charging control and status is monitored by a battery status and charge circuitry **248**. An external battery charger **256** provides power to battery status and charge circuitry **248** for the purpose of charging rechargeable battery **250** as well as providing power to electronic unit **100** when commercial power is available. Power supplies circuitry **240** generates the necessary voltages required by electronics unit **100**.

Operation of Invention

Four principal modes of operation can be invoked with this physiological monitoring system. Each of these modes will be described in detail below. It is the ability of the system to perform the third mode of operation that makes this system unique secondary to its architecture of objects and advantages stemming from this architecture.

The first mode of operation is the mode of monitoring a single physiological parameter from a human subject and displaying either a static value obtained, or continuously displaying values realtime. This mode is useful in monitoring temperature, electrocardiographic waveforms, electroencephalographic waveforms, neuromuscular waveforms, phonocardiographic waveforms, phonopulmonary waveforms, finger pulse oximetry, and adipose tissue measurements.

An example of the first mode of operation will be illustrated for the measurement of temperature from a human subject. The user in this case (i.e. the clinician) will attach

temperature probe **120** to the human subject in the area of interest. The user will invoke the continuous temperature monitoring mode from the application program that is executing on portable personal computer **102**. This program will communicate with electronics unit **100** via parallel printer port interface **258** and send electronics unit **100** a command that will instruct the unit to begin making temperature measurements from temperature probe **120**. The command will be interpreted initially by host interface and display microcontroller **232** which will subsequently task digital signal processor **238** to initiate temperature measurements from temperature probe **120** via temperature probe transducer circuitry **208**. Digital signal processor **238** will acquisition digital words from sixteen channel analog multiplexer and analog-to-digital converter **220** and hold these words within dual port static Random Access Memory (RAM) **236**. As these words fill this memory, host interface and display microcontroller **232** transmits these words back to portable personal computer **102** via parallel printer port interface **258** where the application program receives and displays these words in an appropriate format for the user. The user would be allowed to use various different modes of acquisition of temperature as allowed by the application program. For example, the rate of temperature sampling could be quite variable from one sample an hour to many thousands of samples per second. The capability of logging temperature samples to the hard disk drive of portable personal computer **102** could be another mode of the application program. In this example, one can easily see that portable personal computer **102** can allow for many different modes of capability of the entire physiological monitoring system via its ability to be programmed to fulfill these modes and without having to change the hardware of any part of the system. Portable personal computer **102** also allows for a multitude of display, storage, and user interaction options through its programmable features. Information gathered in a session such as this one involving temperature monitoring, could be integrated into the subject's database of medical information by having the application program interact with the database application via file systems.

A second mode of operation of this physiological monitoring system involves the acquisition of physiological parameters from a human subject whereby the subject and/or the user must physically interact with the system in order for the system to be able to acquisition the desired physiological parameter. Examples of this mode of operation are pulmonary function testing, audiological testing, nerve conduction studies, reaction time testing, memory sequence testing, ultrasonic measurements, and biofeedback sessions. In each of these examples, one physiological parameter is being measured by the system but, its measurement is dependent on the interaction with the human subject and/or user at specific time intervals during the testing.

An example of the second mode of operation will be illustrated using pulmonary function testing. The user in this case will utilize airflow sensor **114** to measure airflow rates and air volumes that are routinely measured in most pulmonary function tests. The user invokes the pulmonary function test mode from the application program that is executing on portable personal computer **102**. Unlike the previous mode described, this mode of testing must coordinate the testing with the user/human subject by signaling him/her from the display of personal portable computer **102** to begin taking a deep inspiration and then subsequently expiring as hard and quickly as he/she can. During this time, portable personal computer **102** will begin sending commands via parallel printer port interface **258** to electronics

unit **100** in a similar fashion to that described in the above temperature monitoring example. The difference here is that the application program will send sequential commands to electronics unit **100** in realtime, acquisitioning the airflow rates from airflow sensor **114** as the subject sequences through the steps of inspiration and expiration. Upon completion of the steps, the application program will calculate spirometric volumes based on the airflow information that it received during the test and generate test results on the display of portable personal computer **102** in the form of tables and graphs. This information can in turn, be integrated into the patient's database on the hard disk drive of portable personal computer **102**.

A third mode of operation of this physiological monitoring system involves the simultaneous acquisition of multiple physiological parameters with or without interaction between the user and/or human subject. Examples of this mode of operation are multiple sleep latency measurements that involve monitoring of electrocardiographic, electroencephalographic, and oxygen saturation parameters on a continuous basis as well as biological age measurements. A similar scheme to the two previous modes is used by the application program executing on portable personal computer **102** in issuing commands to electronics unit **100** and receiving sensor information from this unit.

The fourth mode of operation of this physiological monitoring system involves the transmission of commands from the application program executing on portable personal computer **102** to electronics unit **100** without feedback of any information back to the application program. An example of this mode is in the generation of pulses used in Transcutaneous Electrical Nerve Stimulation (TENS) therapy. In this example, pulse width commands are sent to electronics unit **100** similar to commands of the previously described modes to generate high voltage pulses in high voltage pulse generator circuitry **214**. These pulses are applied to the human subject but no physiological monitoring of any parameter is acquisitioned from the subject in this application.

Auxiliary, lower level operations of electronics unit **100** include the generation of status to status display **124** via status display circuitry **216** and, internal power generation from rechargeable battery **250** via power supplies circuitry **240**, as well as charge control of rechargeable battery **250** via battery status and charge circuitry **248** and external battery charger **256**. I will defer discussion of these subsystems of the electronics unit in this document as they do not impact on the novelty of operation of the overall physiological monitoring system and their theory of operation is easily deduced by the average layperson in this field.

SUMMARY, RAMIFICATIONS, AND SCOPE

Accordingly, the reader should be convinced from the above description and operations sections that the physiological monitoring system presented here is unique in its ability to perform many useful physiological monitoring tasks within a clinical outpatient environment in a manner that is cost effective in the components and their architecture that comprise this system. The versatility that is provided by its architecture in the various modes of operation that it can perform will offer many clinical outpatient environments capabilities that were not attainable prior to the conception of this system. Furthermore, this physiological monitoring system has additional advantages in that

it permits the system to not only be used portably within the clinical outpatient environment, but can have utility in remote environments such as nursing homes,

residences, auxiliary offices, harsh environments such as battlefields, public gatherings, and mobile situations; its architecture permits the easy addition of future devices to the electronics to allow for more parameter measurement capabilities without having to alter the overall architecture of the system;

its architecture also permits multiple combinations of physiological parameter gathering scenarios that may not yet be defined in current methods of disease diagnoses and monitoring;

it permits for future change of the portable personal computer to other computing/control elements since the functions of parameter gathering via the electronics are separated from the application program executing on the computing/control element;

it permits for an excellent bridge between office information systems in the clinical outpatient environment and more centralized systems that are continuing to evolve in the healthcare system.

Although the description above contains many specifications, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention. For example, although the interface between electronics unit **100** and portable personal computer **102** has been designated here as a parallel printer port interface, other interfaces such as an infrared interface or a high-speed serial interface would work equally well in this situation. These interfaces were not chosen for the preferred embodiment of this invention only because they are not as available on current versions of most portable personal computers. Also, there is no reason to believe that other computing elements besides the portable personal computer used in the preferred embodiment of this invention, can't be substituted for the portable personal computer used here. A desktop or palm computer could be used as the computing element instead of the portable personal computer. Finally, it should not be construed that this physiological monitoring system be used only in an clinical outpatient environment. It could have equal or greater utility in other environments also.

Thus the scope of the invention should be determined by the appended claims and their legal equivalents, rather than by the examples given.

I claim:

1. A portable, physiological monitoring system configured to monitor physiological parameters of a human subject, the system comprising:

- a portable personal computer including an applications program executable thereon to produce a command, and having a display, a user input, and a data storage configured to contain existing information related to the human subject;
- at least one physiological sensor, configured to be attached to the human subject to sense a physiological parameter of the human subject and to produce a signal representing the physiological parameter; and
- a portable electronics unit, separate from the portable personal computer, the at least one physiological sensor and the human subject, and having circuitry connected to the at least one physiological sensor and the portable personal computer, the circuitry being responsive to the command from the applications program to initiate acquisition of the signal from the at least one sensor, the circuitry being configured to manipulate the signal and send the signal to the portable personal computer; and
- the portable personal computer being configured to display the physiological parameter on the display, and

13

to store the physiological parameter in the data storage with the existing information related to the human subject.

2. The system of claim 1, wherein the portable personal computer is continuously connected to the electronics unit during operation; wherein the portable personal computer is configured to control the electronics unit in real-time; and wherein the portable personal computer is configured to display the physiological parameter on the display in real-time.

3. The system of claim 1, wherein the portable personal computer is removably disposed on top of the electronics unit to save space.

4. The system of claim 1, wherein the at least one physiological sensor includes multiple physiological sensors configured to sense multiple physiological parameters; and wherein the circuitry of the electronics unit includes conversion and manipulation circuitry common to the multiple physiological sensors.

5. The system of claim 1, wherein the electronics unit includes:

- a) a user adjustable gain control, connected to the circuitry, configured to allow a user to adjust gain;
- b) a user marker switch, connected to the circuitry, configured to allow the user direct interaction with the electronics unit; and
- c) a status display, connected to the circuitry, configured to display the status of the electronics unit.

6. The system of claim 1, wherein the portable personal computer, portable electronics unit, and at least one physiological sensor have at least three modes of operation, including:

- a) a first mode of operation in which the at least one physiological sensor is configured to sense a single physiological parameter, and the display of the portable personal computer is configured to display the parameter as either a static value or as continuous, real-time values;
- b) a second mode of operation in which the at least one physiological sensor is configured to sense a physiological parameter in conjunction with interaction by the human subject, and the portable personal computer is configured to signal the human subject to perform an act in conjunction with the physiological parameter; and
- c) a third mode of operation in which the at least one physiological sensor includes multiple physiological sensors configured to simultaneously sense multiple physiological parameters.

7. The system of claim 1, wherein the electronics unit is configured to generate electrical pulses which are applied to the human subject.

8. The system of claim 1, wherein the portable personal computer further has a parallel printer port; wherein the electronics unit and portable personal computer connect through the parallel printer port; further comprising an external printer connected to the electronics unit; and wherein the portable personal computer is configured to print information by sending the information through the parallel printer port, through the electronics unit, to the printer.

9. A portable, human subject, physiological monitoring system for clinical outpatient environments, the system comprising:

- a) at least one physiological sensor configured to be attached to the human subject, sense a physiological

14

parameter of the human subject, and produce a signal representing the physiological parameter;

b) a portable electronics unit, coupled to the at least one sensor and configured to be separate from the human subject, and having circuitry connected to the at least one sensor to acquire and process the signal from the at least one sensor; and

c) a portable personal computer, separate from and coupled to the electronics unit, to control the electronics unit in real-time and to receive information from the electronics unit, the portable personal computer having an application program executable thereon to produce a command to send to the electronics unit to initiate acquisition of the signal from the at least one sensor, and having:

- i) a display configured to display the information from the electronics unit;
- ii) an interface configured to receive user input; and
- iii) a data storage configured to contain existing information related to the human subject and to store information acquired such that existing and new information are integrated.

10. The system of claim 9, wherein the portable personal computer is removably disposed on top of the electronics unit to save space.

11. The system of claim 9, wherein the at least one physiological sensor includes multiple physiological sensors configured to sense multiple physiological parameters; and wherein the circuitry of the electronics unit includes conversion and manipulation circuitry common to the multiple physiological sensors.

12. The system of claim 9, wherein the circuitry of the electronics unit is configured to perform lower level operations, and the portable personal computer is configured to perform higher level operations.

13. The system of claim 9, wherein the electronics unit includes:

- a) a user adjustable gain control, connected to the circuitry, configured to allow a user to adjust gain;
- b) a user marker switch, connected to the circuitry, configured to allow the user direct interaction with the electronics unit; and
- c) a status display, connected to the circuitry, configured to display the status of the electronics unit.

14. The system of claim 9, wherein the portable personal computer, portable electronics unit, and at least one physiological sensor have at least four modes of operation, including:

- a) a first mode of operation in which the at least one physiological sensor is configured to sense a single physiological parameter, and the display of the portable personal computer is configured to display the parameter as either a static value or as continuous, real-time values;
- b) a second mode of operation in which the at least one physiological sensor is configured to sense a physiological parameter in conjunction with interaction by the human subject, and the portable personal computer is configured to signal the human subject through the display to perform an act in conjunction with the physiological parameter;
- c) a third mode of operation in which the at least one physiological sensor includes multiple physiological sensors configured to simultaneously sense multiple physiological parameters; and
- d) a fourth mode of operation in which the electronics unit is configured to generate electrical pulses which are applied to the human subject.

15

15. A method for obtaining, displaying and integrating human subject physiological information from a human subject, comprising the steps of:

- a) attaching a physiological sensor to the human subject;
- b) disposing a portable electronics unit adjacent the human subject, but separate from the human subject, and connecting the physiological sensor to the portable electronics unit;
- c) connecting a portable personal computer to the electronics unit;
- d) operating an application program executable on the portable personal computer to send a command to the electronics unit to initiate acquisition of the physiological parameter;
- e) sensing the physiological parameter and producing a signal using the physiological sensor;
- f) manipulating the signal using the electronics unit;
- g) communicating the sensed parameter to the portable personal computer; and
- h) displaying the parameter on a display of the portable personal computer; and storing the parameter in the data storage of the portable personal computer.

16. The method of claim 15, further comprising accessing existing information with respect to the human subject contained in the data storage of the portable personal computer.

17. The method of claim 15, further comprising removably disposing the portable personal computer on top of the electronics unit to save space.

18. The method of claim 15, further comprising:

- a) sensing multiple physiological parameters and producing multiple signals using multiple physiological sensors; and

16

b) manipulating the signals using common circuitry of the electronics unit.

19. The method of claim 15, further comprising

- a) manually adjusting the gain using a user adjustable gain control of the electronics unit;
- b) directly interacting with the electronics unit using a user marker switch; and
- c) displaying the status of the electronics unit using a status display of the electronics unit.

20. The method of claim 15, further comprising selectively operating the portable personal computer, electronics unit, and sensor in at least four modes of operation, including:

- a) a first mode of operation by sensing a single physiological parameter with the physiological sensor, and displaying the parameter as either a static value or as continuous, real-time values using a display of the portable personal computer;
- b) a second mode of operation by sensing a physiological parameter using the physiological sensor in conjunction with interaction by the human subject, and prompting the human subject to perform an act using the display of the portable personal computer;
- c) a third mode of operation by simultaneously sensing multiple physiological parameters using multiple physiological sensors; and
- d) a fourth mode of operation by generating electrical pulses using the electronics unit and applying the electrical pulses to the human subject.

* * * * *