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(54) **MULTI-FUNCTION HEALTH MONITOR**

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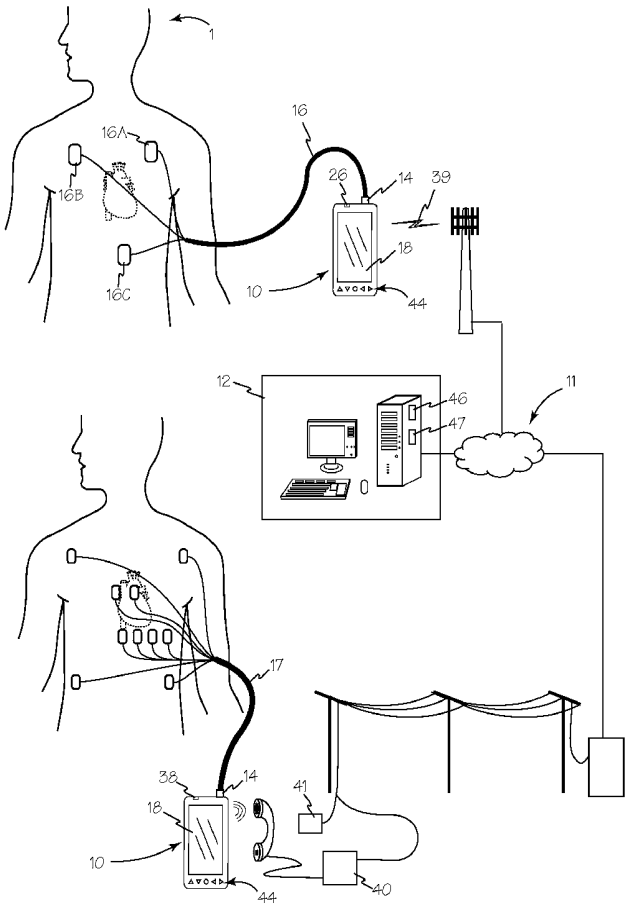
(57) **ABSTRACT**

A multi-function health monitor is capable of performing a resting 12-lead ECG test, an ECG stress test, a 24-hour holter monitor evaluation and or a 30-day MCT monitoring. Using only 3 electrodes, the multifunction health monitor derives 6 channels (Limb leads & Augmented leads) of data with the noise cancellation (ground) effect of a virtual dynamic RL electrode. An electrode resistivity measurement system quantifies and may compensate for increasing resistance the electrodes and the patient that results from the length of time the electrodes are installed on a patient. The multi-function health monitor can provide data analysis through the gate array as the data is acquired. Data may also be stored for remote analysis as well as for transmission to remote stations upon occurrence of one or more threshold events. Parameters for threshold events may be adjusted remotely to obviate the need for a patient to travel for system adjustment.



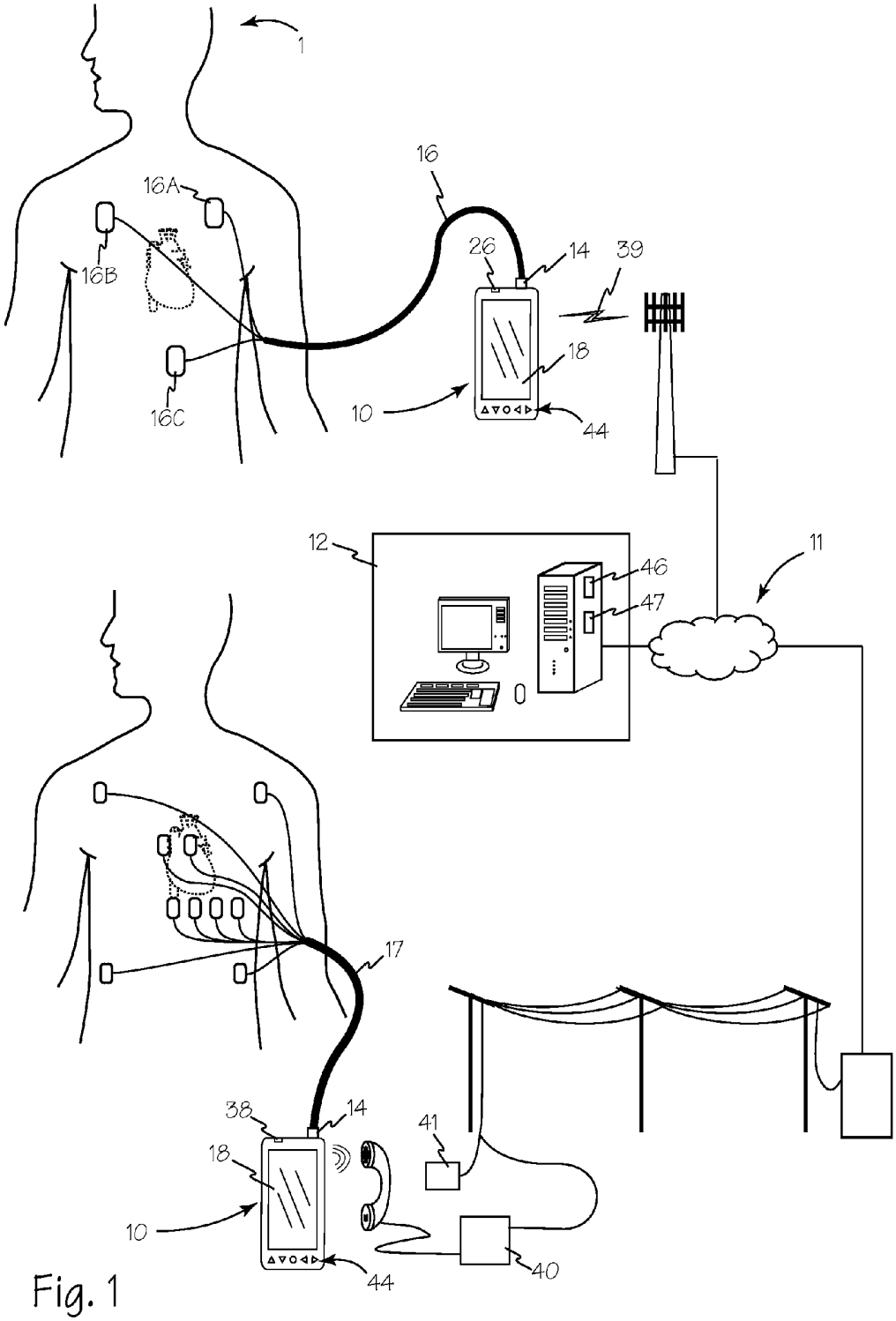


Fig. 1

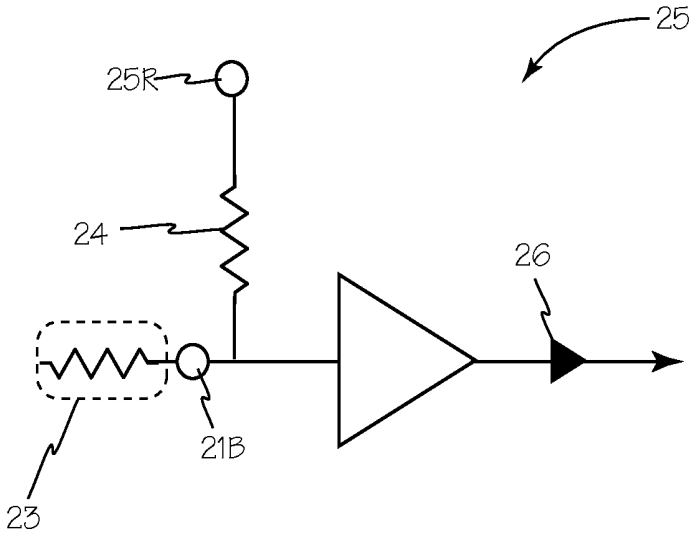

25
25R
24
26
21B
23

Fig. 2

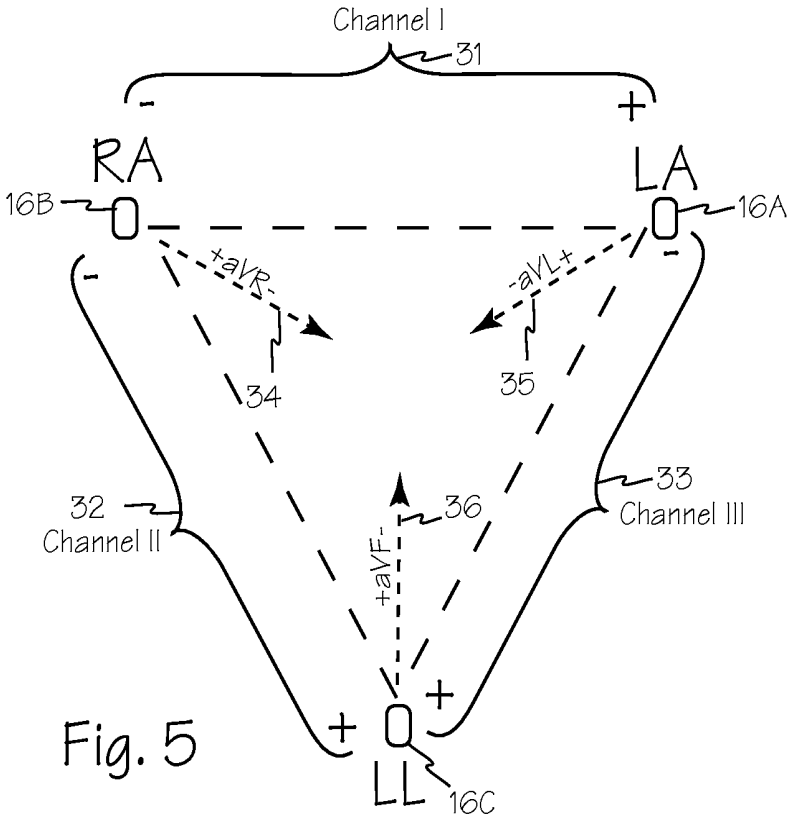

Channel I
31
RA
LA
16B
16A
+aVR-
-aVL+
34
35
32
Channel II
33
Channel III
36
+aVF-
LL
16C

Fig. 5

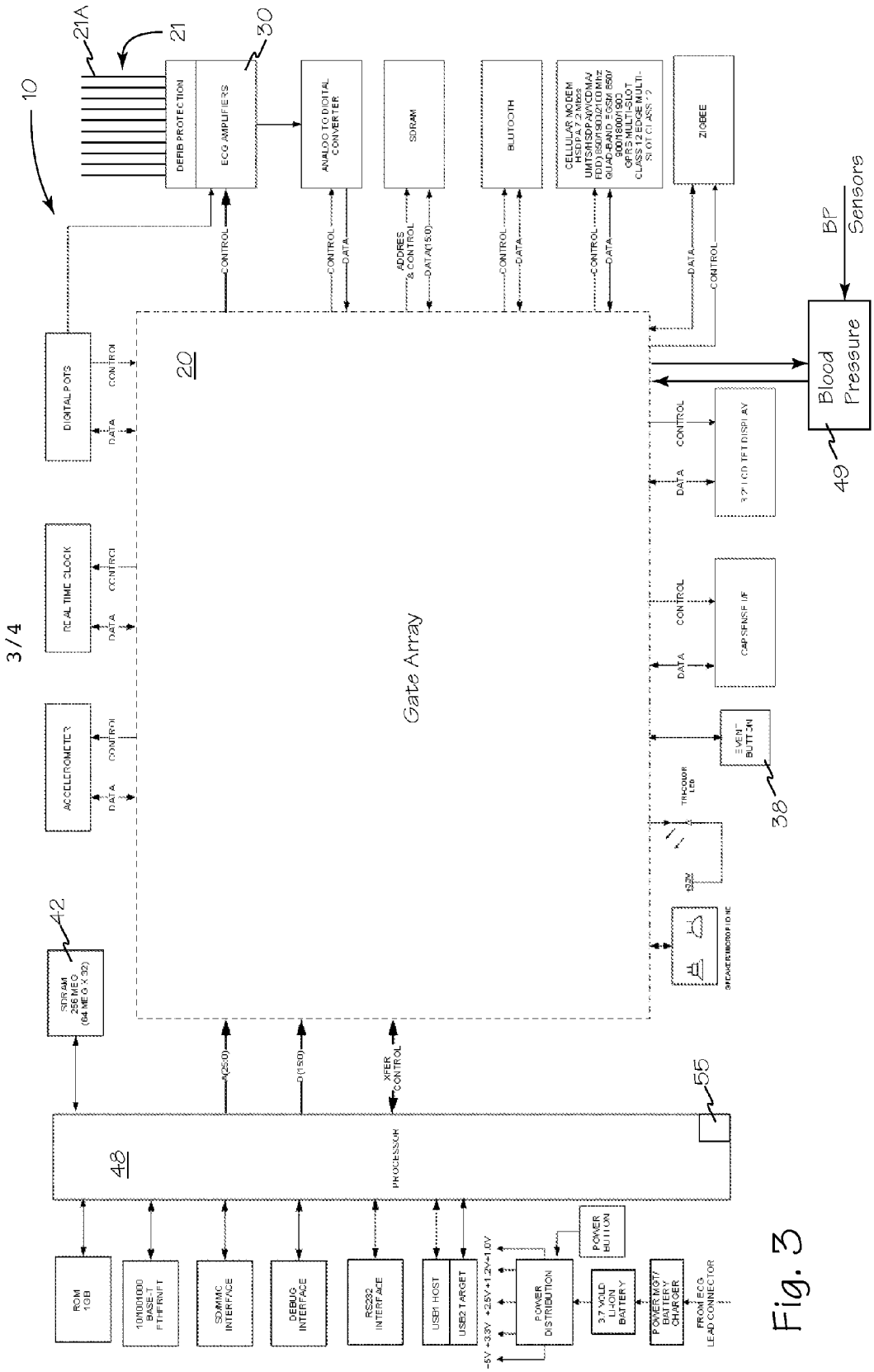

10
21A
21
30
DEFIB PROTECTION
ECG AMPLIFIERS
ANALOG TO DIGITAL CONVERTER
SDRAM
BLUETOOTH
CELLULAR MODEM
ZIGBEE
20
Gate Array
DIGITAL POTS
REAL TIME CLOCK
ACCELEROMETER
CONTROL
DATA
ADDRES & CONTROL
DATA(15:0)
Blood Pressure
BP Sensors
49
38
42
SDRAM 256 MEG (64 MEG X 32)
A(25:0)
D(15:0)
XFER CONTROL
48
PROCESSOR
55
ROM 1GB
SD/MMC INTERFACE
DEBUG INTERFACE
RS232 INTERFACE
USB1 HOST
USB2 TARGET
POWER DISTRIBUTION
POWER BUTTON
3.7 VOLT LI-ION BATTERY
POWER MGT/ BATTERY CHARGER
FROM ECG LEAD CONNECTOR

Fig. 3

3/4

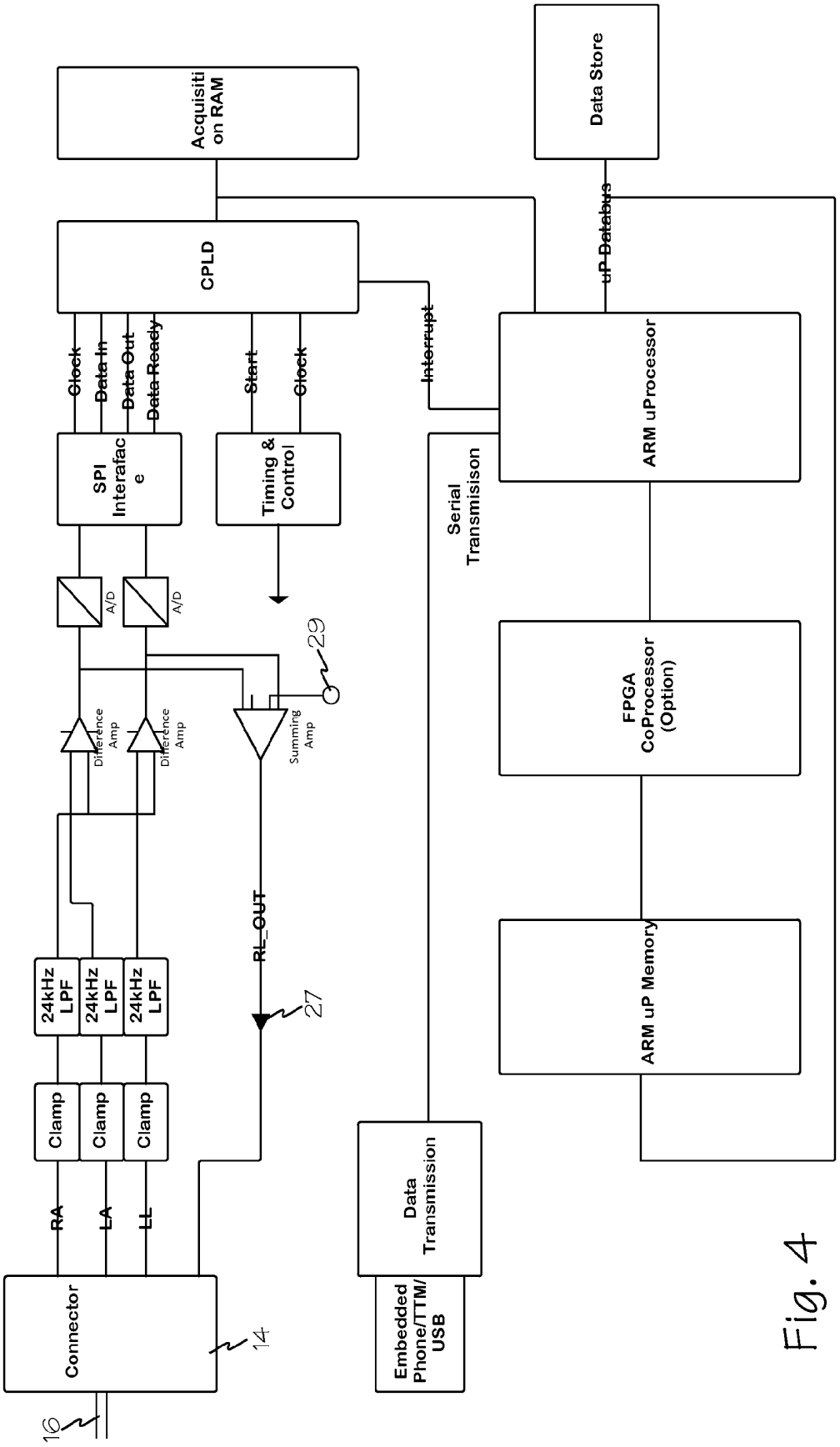

Acquisition RAM
Data Store
CPLD
uP Databus
Clock
Data In
Data Out
Data Ready
Start
Clock
Interrupt
SPI Interface
Timing & Control
ARM uProcessor
Serial Transmisison
A/D
A/D
29
Difference Amp
Difference Amp
Summing Amp
FPGA CoProcessor (Option)
RL_OUT
27
24kHz LPF
24kHz LPF
24kHz LPF
Clamp
Clamp
Clamp
ARM uP Memory
RA
LA
LL
Data Transmission
Connector
14
Embedded Phone/TTM/ USB
16

Fig. 4

MULTI-FUNCTION HEALTH MONITOR

RELATED APPLICATIONS

[0001] This application claims priority to copending U.S. Utility application Ser. No. 12/938,268 filed Nov. 2, 2010 which claims priority to U.S. Provisional patent application 61/257,388 filed Nov. 2, 2009.

FIELD OF THE INVENTIONS

[0002] The present invention relates generally to the field of portable health monitors and more specifically to battery operated multi-function ECG recorder/transmitters.

BACKGROUND OF THE INVENTIONS

[0003] If you or your doctor have concerns about the function of your heart or other similar organ you may embark on a multi-step evaluation that may include many different tests for example a resting 12-lead ECG test, an ECG stress test, a 24-hour holter monitor evaluation and or a 30-day MCOT monitoring. These tests and others utilize many different and specialized tools due to some of the conflicting requirements of the tests or the equipment. For example, some of the tests must be done in a doctor's office or a hospital or lab because of the cost and power consumption of the test tools and it would be unrealistic to conduct a 30-day MCOT analysis with the patient confined to the hospital, or worse, the doctors office.

[0004] Some of the evaluation tests are also challenging because of the limitations enforced by the ability of the medical system to derive adequate compensation for the work necessary. For example, an MCOT monitor analysis of a patient may be conducted for up to 30 days. The equipment to perform this monitoring and analysis must be portable, thus low-power, durable and accurate. The necessity of low-power and durable equipment forces the equipment designers to cut corners on real-time data analysis. As a result, many false positive events generate excessive data that requires expensive medical professional time to review. Thus the doctor ordering the test (and the insurance company looking over his shoulder) must be cognizant that the test, and the analysis of the resulting data could cost more that anyone will be paid to perform the test.

SUMMARY

[0005] A multi-function health monitor avoids the power hungry microprocessors that are becoming ubiquitous in favor of a gate array hardware implementation for data gathering, analysis and data encryption. The use of a gate array, complex programmable logic device (CPLD), for data processing minimizes power consumption while enabling fast processing as well as accommodating many functions with dissimilar analysis algorithms. The multi-function health monitor is capable of calculating six channels or leads of ECG data using only three electrodes connected to the patient. The lead switching technique calculates six channels of ECG data with the noise cancellation benefits of a right leg feed system. Use of only three electrodes makes the multi-function health monitor ideal for ambulatory data gathering and to enable better long term compliance by patients.

[0006] A multi-function health (MFH) monitor capable of performing a resting 12-lead ECG test, an ECG stress test, a 24-hour holter monitor evaluation and or a 30-day MCOT monitoring as well as providing both resting and ambulatory blood pressure monitoring would provide a tool for generating revenue through insurance payments for a single device that may be provided to patients through their doctors and or hospitals.

[0007] The MFH monitor can provide data analysis through the gate array as the data is acquired. Data may also be stored for remote analysis as well as for transmission to remote stations upon occurrence of one or more threshold events. Parameters for threshold events may be adjusted remotely to obviate the need for a patient to travel for system adjustment.

[0008] The design of the gate array and the data algorithms permits one or more sections of the gate array to be powered off when unused to prevent unnecessary power drain. The advanced data algorithms implemented in the hardware of the gate array permits a high level of sophisticated data processing by the remote ambulatory cardiac monitoring system as data is acquired to minimize false events and minimize the requirement for remote data analysis.

[0009] A lead resistivity measurement system quantifies and may also compensate for increasing resistance between an electrode and the patient that results from the length of time the electrodes are installed on a patient. This system can also detect and alert to an electrode disconnected.

[0010] These and other features and advantages will become further apparent from the detailed description and accompanying figures that follow. In the figures and description, numerals indicate the various features of the disclosure, like numerals referring to like features throughout both the drawings and the description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. **1** is a block diagram of multifunction health monitor systems with alternate electrode sets and the system network.

[0012] FIG. **2** is a schematic diagram of an electrode input.

[0013] FIG. **3** is a block diagram of the gate array controller and connected components of the remote ambulatory cardiac monitoring system of FIG. **1**.

[0014] FIG. **4** is a block diagram of the timing and data paths of a remote ambulatory cardiac monitoring system.

[0015] FIG. **5** is a block diagram for channel derivation from three electrodes.

DETAILED DESCRIPTION OF THE INVENTIONS

[0016] In electrocardiography, the word "lead" may refer to either the electrodes attached to the patient, or, properly, to the voltage or signal measured between two electrodes. To avoid confusion, "channel" is used to describe the voltage, signal or view from a positive electrode to a negative electrode across the heart.

[0017] Referring now to FIG. **1**, remote ambulatory cardiac monitoring system **1** is a multi-purpose ECG recorder, arrhythmia detector and alarm, capable of changing its functionality to meet the normal workflow of a Cardiologist office. For a patient of concern such as patient **1**, a cardiologist might first order a resting 12-channel ECG study. If the study is negative, then a 24-hour holter would be prescribed next. If the holter study is still negative then a mobile cardiac telemetry (MCT) study might be performed for up to 30 days.

[0018] Remote ambulatory cardiac monitoring system **1** can perform all of these functions as individual instruments

have done in the past and can change the way these tests are usually performed. A single instrument can save money and improve patient compliance particularly when going from a holter to a MCT recorder because a new apparatus is not necessary. Because of the built-in cellular modem technology, patient demographic and scheduling information can be "pushed" from an EMR or HIS system to device **1** over a network such as network **2**. Conversely, test results can automatically be sent back the electronic management system of to a 24 hour monitoring service such as remote monitoring service **3**. Monitoring system **1** is "smart" in that it automatically adapts to its intended purpose by detecting the ECG electrode set or other cable inserted into cable socket **5**. For example insertion of three electrode cable **7** will cause monitoring system **10** to initiate MCT mode. Insertion of ten electrode cable **8** will cause monitoring system **10** to initiate 12-lead EKG mode. Remote ambulatory cardiac monitoring system **1** also provides video tutorials and other information on display screen **9** related to electrode connection, specific to the modality and can also provide real-time ECG arrhythmia detection using its built-in hardware DSP engine in any mode: resting 12-lead; holter; or MCT.

[0019] Monitoring system **1** also integrates various ECG-specific functions that are well-suited for scalable electrocardiogram (ECG) applications. The device can also be used in high-performance, multichannel data acquisition system by powering down the ECG-specific circuitry in the controller.

[0020] Referring now to FIG. **3**, controller **11** has a highly programmable multiplexer that allows for temperature, supply, input short, and RLD measurements. Additionally, a multiplexer allows any of input electrode lines **12** such as electrode line **12**A to be programmed as the patient reference drive. The PGA gain can be chosen from one of seven settings (1, 2, 3, 4, 6, 8, and 12). The ADCs in the device offer data rates from 250 SPS to 32 kSPS. Communication to the device is accomplished using an SPI-compatible interface. The device provides four GPIO pins for general use. Multiple devices can be synchronized using the START pin.

[0021] The internal reference can be programmed to either 2.4V or 4V. The internal oscillator generates a 2.048 MHz clock. The versatile right leg drive (RLD) block allows the user to choose the average of any combination of electrode lines **12** to generate the patient drive signal for signal noise reduction.

[0022] Referring now to FIG. **2**, lead-off detection and electrode analysis can be accomplished either by using a pull-up/pull-down resistor or a current source/sink such as the voltage divider formed by electrode **14** and reference resistor **15** of electrode input channel **16**. A fixed voltage or current is applied at reference point **16**R and electrode **14** is connected at input point **12**B. As electrode **14** separates from the patient's skin and or the electrode adhesive decays, the resistance between electrode **14** and the patient will grow relative to reference resistor **15**. Controller **11** can quantify the change of electrode resistance and adjust signal gain to compensate until the electrode separates from the patient. Input signal **17** may be analyzed for the contribution of reference voltage or current at reference point **16**R and if signal **17** is entirely the reference voltage or current, a lead-off alarm is initiated.

[0023] Monitoring system **1** supports both hardware pace detection and software pace detection. The Wilson center terminal (WCT) block can be used to generate the WCT point of the standard 12-lead ECG.

[0024] Remote ambulatory cardiac monitoring system **1** is a multipurpose device designed with the ability to perform: a 3-channel (3-electrode) Mobile Cardiac Telemetry complete with Arrhythmia Detection and Alarm for up to 30 days; a 24-hour or longer 12-channel or 3-channel (5-electrode) ECG Holter study; and a resting 12-channel EKG. The device may be used for patient in home use with remote clinician data analysis as well as use within the office or home setting by a medical professional.

[0025] Remote cardiac monitor **1** includes:

[0026] 1) a single component ECG monitor with an integrated cellular modem and

[0027] 2) an interface to five independent cable configurations through a single connector. Monitor **1** automatically changes functionality when a specific cable with the same form factor is inserted with the following configurations:

[0028] 3-wire, ambulatory, snap electrode cable invokes a 1, 2, or 3-channel MCT mode (Lead I, II, III—no anterior views)

[0029] 10-wire, ambulatory, snap electrode cable invokes the Holter 12-channel mode

[0030] 5-wire, ambulatory, snap electrode cable invokes the Holter 3-channel mode by default (up to 7-leads are available with anterior views); If programmed to do so, the system can automatically switch to the MCT mode after 24- or more hours

[0031] 10-wire, resting (lengthened for full body), alligator clip electrode cable invokes the Resting 12-lead EKG mode (8-channels; Lead III, aVF, aVR, aVL derived)

[0032] 4-wire, USB cable invokes the PC communication service mode. Cable is interchangeable with ECG lead sets requiring disconnection from the body before connection to an external device can be made.

[0033] The built-in cellular modem technology pushes and pulls information to and from the device in a HIPAA compliant fashion using the cryptographic protocol; Transport Layer Security (TLS). Additional data integrity is performed by Error Correction Coding (ECC) and MD5 hash sums.

[0034] Monitor **1** houses a microprocessor for running the algorithm and an application specific integrated circuit (ASIC) as controller **11**, a rechargeable battery, real time ECG arrhythmia detection using built-in hardware DSP engine in any mode, ECG capture circuitry provided by the ASIC and the multiple components, GSM/GPRS/EGPRS/WCDMA/HSPA

[0035] Upon detection of an arrhythmic or patient-activated event through activation of patient, the ECG signal is transmitted wirelessly via the cellular network to a remote monitoring center for additional analysis and intervention by a clinician. When cellular service is unavailable, the event will be stored until such time the cellular network becomes available or the patient transmits the data using a land telephone line.

[0036] If in the resting 12-lead mode, the device can capture, display, and analyze 12 channels of ECG for up to 1,024 patients in diagnostic quality. The ECG can be streamed in real-time to a computer wirelessly via the 802.15.4 network transceiver to be displayed, printed, and stored. An embedded SQL database is used in monitor **1** for ECG storage and reporting in all modes—MCT, Holter, and resting 12-lead as well as storage of other data such as blood pressure data.

[0037] Conventional 3-lead electrode systems provide a single channel measurement with no redundancy. Referring

now to FIGS. **1** and **4**, the MCT mode of remote ambulatory cardiac monitoring system **1** is initiated by connection of cable **7** which uses three electrodes, electrodes **7**A, **7**B and **7**C, configured as RA (Right Arm), LA (Left Arm) and LL (Left Leg) to calculate Lead I (channel I), Lead II (channel II), or Lead III (channel III). Controller **11** dynamically substitutes RL (Right Leg) drive **18** for each electrode as it makes a measurement across the other two electrodes. This allows the system to function as if it were a four electrode system making use of the noise cancellation of the RL output. The RL drive also has an integrated constant current source **20** which can be momentarily switched on to make an impedance measurement of each connected electrode. This allows system to make an immediate lead-off or high impedance (HiZ) determination and use the remaining two electrodes to make a single lead measurement. Controller **11** can measure and calculate six separate data channels (Lead I, Lead II, Lead III, aVL, aVR, and aVF) with the effect of full AC noise cancellation via the RL drive provided to each of the three electrodes are connected. In the case of any electrode becoming disconnected, the system will still function as a single channel system.

[0038] RL drive **18** sums the ECG signals from two of the three electrodes, the LA, RA, and LL electrodes, and applies the combined signal 180 degrees out of phase and drives the resulting inverted signal, signal **18**, back into the patient for noise cancellation. In MCT mode, remote ambulatory cardiac monitoring system **1** only uses three electrodes such as electrodes **7**A, **7**B and **7**C, so the fourth electrode (RL) has to replace one of the limb lead electrodes dynamically. This done by electronically switching the LL input circuitry in ECG instrumentation amplifier **21**, shown in FIG. **4**, with the RL output drive circuitry. The LA-RA (channel I) measurement orientation is show in FIG. **5** as channel **22**. LL Electrode circuitry is replaced by the RL circuitry.

[0039] Controller **11** electronically switches the LA input circuitry in ECG instrumentation amplifier **21** with the RL output drive circuitry. The RA-LL (channel II) measurement orientation is shown in FIG. **5** as channel **23**. LA Electrode circuitry is replaced by the RL circuitry.

[0040] Controller **11** next electronically switches the RA input circuitry in the ECG instrumentation amplifier with the RL output drive circuitry. The LA-LL (channel III) measurement orientation is show in FIG. **5** as channel **24**. RA Electrode circuitry is replaced by the RL circuitry.

[0041] The RL drive circuitry sequentially connects from the LL to LA to RA so the Noise cancellation system functions without the fourth RL electrode being necessary. Once the data has been acquired for Lead I, channel **22**, and Lead II, channel **23** then Lead III, channel **24** can be derived or measured directly. This is possible because Einthoven's Law states that I+(−II)+III=0. The equation can also be written I+III=II. It is written this way (instead of I−II+III=0). Therefore Lead III is Lead II−Lead I. Now the derived channels, channels **25**, **26**, and **27** can be calculated:

[0042] channel **25**, aVR (Lead I+Lead II)/2

[0043] channel **26**, aVL Lead I−(Lead II/2)

[0044] channel **27**, aVF Lead II−(Lead I/2)

[0045] Lead III Lead II−Lead I

[0046] Using only 3 electrodes, electrodes **7**A, **7**B and **7**C it is possible to derive 6 channels (Limb leads & derived leads) of data with the noise cancellation (ground) effect of a virtual dynamic RL electrode.

[0047] All ECG signals will be analyzed real-time by the internal algorithm of controller **11**. Upon determination of an arrhythmic or patient-activated event such as by activation of event button **29**, composite ECG data **30** will be wirelessly transmitted to a remote Monitoring Center such as monitoring center **3** for additional analysis and intervention. If cellular transmission is not possible, the event will be stored for future cellular/TTM/base station transmission such as through conventional phone **31** or base station **32**.

[0048] Monitoring device **1** will be equipped with a service center lab changeable flash-based memory **33** in order to record the receiving signal coming from the sensor and to allow pre and post processing options through the use of this memory and a mobile database of ECG data and corresponding event markers. The database will facilitate query and retrieval of specific ECG based on event information, time and date, or other data as desired.

[0049] Remote ambulatory cardiac monitoring system **1** will automatically transmit the recorded ECG, via cellular technology, to a Remote Management System but will also allow patients to use a land line such as phone **31**, plugged into a base station such as base station **32** or held to the MCT Device in a standard Trans-telephonic way (TTM) as illustrated in FIG. **1**, to transmit the data in the case where cellular transmission is not possible.

[0050] Six elements generally influence physicians' decision on which provider to use for a particular ECG monitor:

[0051] Compliance: Ensure greatest amount of quality ECG for analysis

[0052] Higher Diagnostic Yield: Provide most clinically-relevant information

[0053] Technology: Reliable transmission, easy to use, less patient intervention

[0054] Reimbursement: highest reimbursement rates for Partner Physicians

[0055] Innovation and fashion: Best solution offered for arrhythmia detection and transmission, including continuous storage and monitoring. Engaging new technology

[0056] Device Overview

[0057] Remote ambulatory cardiac monitoring device **1** is a battery-powered, portable and ambulatory, multi-purpose ECG device capable of serving as (1) a resting 12-lead EKG (2) a multi-day Holter recorder and (3) a Mobile Cardiac Telemetry (MCT) device with real-time arrhythmia analysis and a cellular modem.

[0058] Cardiac monitoring device **1** is designed to be operated by both patients and medical professionals and has two user-interfaces to address each type of user. It can be operated through touch screen **9** and alternatively using 5-button keyboard **35** with complete functionality by either method.

[0059] Cardiac monitoring device **1** has four functional modes of operation: resting 12-lead EKG (medical professionally only); 1-5 day Holter recorder (patient and medical professional interfaces); 30 day MCT operation (patient, medical professional and service center interfaces); and a USB data transfer mode to download the data stored in memory to a personal computer for long term storage and to perform a more extensive analysis (medical professional only). The built-in cellular modem technology allows patient demographic and scheduling information to be "pushed" from an EMR or HIS system to cardiac monitoring device **1**.

Conversely, the results can automatically be sent back to same electronic management system to a 24-hour monitoring service facility.

[0060] Cardiac monitoring device **1** is "smart," automatically adapting to its intended purpose by detecting the ECG lead set inserted. It also provides embedded video tutorials on hook-up specific to the modality and can also provide real-time ECG arrhythmia detection using its built-in hardware DSP engine in any mode: resting 12-lead EKG; Holter; or MCOT.

[0061] 12-Lead EKG Mode:

[0062] Cardiac monitoring device **1** can function as a 12-lead EKG with a special 10-wire, alligator-clip, electrode cable lead set. It can be set in "Capture Only" mode or "Capture & Stream" mode.

[0063] "Capture Only" mode allows the operator to acquire data in monitor or diagnostic quality mode and store up to 1024 patients EKG on the device. The EKG can later be transmitted wirelessly or downloaded directly via USB to central cardiovascular system computer running receiving and analysis software **37**.

[0064] The system is intended as a mobile device which can be carried to the patient in a medical office or home environment. Each EKG is displayed on display **9** which may be any suitable touch screen display such as a 3.2" TFT color display in high-resolution and all 12 channels are able to be viewed. There is no EKG interpretive analysis in this mode.

[0065] If in the "Capture & Stream" mode, cardiac monitoring device **1** will operate as in "Capture Only" but also send the EKG wirelessly via 802.15.4 transceivers to the central cardiovascular system PC. Cardiac monitoring device **1** can deliver 3, 6, 12 EKG's, interpretive (continued) analysis and vector loops where the data may be viewed, printed, and stored. Additionally, the data is analyzed in the PC using automated ECG analysis and interpretation software library **38**.

[0066] Holter Mode:

[0067] Cardiac monitoring device **1** can function as a Holter with a 3-wire, 5-wire, or 10-wire, snap, ambulatory, electrode cable lead set. It can be set to convert to MCT (30 day ambulatory monitoring) mode automatically if the Holter is negative after 24 or 48 hours. It can be programmed to record 1, 2, 3, or 12 leads up to five days. There are two user-interfaces available: one designed for the medical professional (Tech Mode) which allows recording configurations to be set and; another for the patient (Patient Mode) with a simplified interface allowing events and symptoms to be annotated within the device. There is also a third user-interface where low-level system settings can be changed intended for system administrators (Admin Mode). Cardiac monitoring device **1** also contains hook-up diagrams and instructional videos to aid in assisting to properly prep and place the electrodes properly depending on the ECG lead set being used. Additionally, monitoring system **1** will perform an impedance test, as discussed above, of the electrode cable currently connected for validation of the electrode connection. The impedence test quantifies the resistance of each electrode connection and can compensate for degrading connections that occur over time and also provides the ability to detect an electrode off condition. After connection of the electrodes, all channels of ECG can be reviewed on display screen **9** by a medical professional.

[0068] The device screen is normally blank during recording but will show the time and date if a key is pressed along with a message stating "Recording". If "Event" button **29** is pressed, the device will present a drop-down menu for both symptoms and activities. The user may add menu items with the built-in virtual keyboard through touch screen display **9** if desired. The patient also has control over the screen brightness, speaker volume, and the LED indicator.

[0069] Furthermore, the patient is not permitted to turn off the device in holter mode. If the "Power" button is held in for more than five seconds, a special "Tech Mode" key prompt (EVENT-SELECT), only known to the medical technician, will need to be entered to complete the power down function.

[0070] The holter data is also processed and analyzed software library **38**.

[0071] MCT Mode:

[0072] Cardiac monitoring device **1** can also function as a MCT device with a 3-wire, snap electrode, ambulatory cable lead set such as cable **7** of FIG. **1**. There are two user-interfaces: one designed for the medical professional which allows recording configurations to be set (Tech Mode) and another for the patient with a simplified interface (Patient Mode) allowing events and symptoms to be annotated within the device and control over the screen brightness, speaker volume, and the LED indicator. There is also a third user-interface where low-level system settings can be changed intended for system administrators (Admin Mode) including patient enrollment, downloading all MCT data, and clearing all memory.

[0073] As in holter mode above, MCT mode also provides hook-up diagrams and instructional videos as well as performing an impedance test and. After the electrode connection in MCT mode, all channels can be reviewed on the screen. If a patient electrode connection is performed, no ECG is presented; only a good or bad electrode connection indication message.

[0074] Whenever monitoring device **1** is powered up, the patient enrollment is verified and must be confirmed before the device may be used.

[0075] The device screen is normally blank during recording but will show the time and date if a key is pressed along with a message stating "Recording". If event button **29** is pressed, device **1** will present a drop-down menu for both symptoms and activities. The user may add menu items with the built-in virtual keyboard if desired. The system will use the display screen, and LED indicator, and audible alarms to notify the user of any messages including a phone number to make a voice call to the 24-hour monitoring service facility. The service may also post messages for the patient.

[0076] Cardiac monitoring device **1** is programmed with preset triggers and alarms for sinus bradycardia [based ventricular rate], sinus tachycardia [based on ventricular rate], A-Fib, pauses, and heart-block. If triggers are made then the event is just stored in memory and downloaded at the end of the study. If an alarm is made, the event is sent to a 24-hour monitoring service facility via the cellular modem. The service facility may also adjust the triggers and alarms remotely.

[0077] Controller **11** is also configured to interact with software algorithm such as algorithm **46** to cross check each alarm trigger before initiating an alarm. Using the sequential connection to data channels discussed above, an alarm trigger from a data channel will be checked using one or more other data channels to verify the validity of the alarm trigger. The verification cross-check prevents false positive alarms.

[0078] In the case where there is no extended cellular coverage, there is a TTM method provided to send events by a conventional (wired) telephone which requires no disconnection of the ECG lead set.

[0079] Furthermore, the patient is not permitted to turn off the device unless the "Power" button is held in for more than five seconds; a software confirmation is made by the user to complete the power down function. This would normally be done to perform battery charging, to bathe or change electrodes.

[0080] USB Connection Mode:

[0081] The USB connection mode is performed by medical professionals to download data from the device or to program the internal settings including patient enrollment. Patients are not permitted to enter this mode.

[0082] HARDWARE Description

[0083] Referring now to FIG. **3**, the design of cardiac monitoring device **1** is based on microprocessor **39** such as an Atmel AT92SAM9G20 ARM **9** providing very low power consumption, (50 mA with all internal peripherals active) and a Field Programmable Gate Array (FPGA) controller **11**. Any suitable microprocessor and gate array may also be used.

[0084] Controller **11** controls the functionality of remote ambulatory cardiac monitoring device **1** at the lowest level. There are several modules within the system controller **11** and external to the controller. External components include: the ECG Amplifier, the Analog to Digital Converter, the Digital Pots for programming offset and gains to the ECG amplifier, 3.2" TFT color Display, a keyboard and touch screen interface for the display, a Real Time Clock, a Zigbee 802.15.4 interface, a Bluetooth interface, and Accelerometer interface, a Cell Phone interface, Cellular SIM card, SDHC flash memory, Power control circuit, Speaker, Microphone, RGB LED indicator, Event and Power Buttons, and microprocessor **39**.

[0085] Inside system controller **11** there are also a number of modules. They are the Data Acquisition Module, the Processor Decode module, the SDRAM controller module, the Digital Pot control module, the Hardware Watchdog module, the Video Control module, the Zigbee Control module, the Bluetooth Control module, the Accelerometer Control module and the Cell Phone Control module. Each of these modules has the appropriate Register sets to allow total control via microprocessor **39**.

[0086] Zigbee transceiver (802.15.4)

[0087] Bluetooth transceiver

[0088] Accelerometer

[0089] Cell phone/GPS

[0090] Video Controller

[0091] Touch panel interface.

[0092] ECG Data Acquisition

[0093] Battery monitor

[0094] Digital POTS interface

[0095] GPIO interface.

[0096] DSP core interface

[0097] 8051 secondary Microprocessor core

[0098] Speaker/Microphone interface

[0099] SDRAM

[0100] RGB LED registers & control

[0101] Keyboard button controller

[0102] System decoder

[0103] Resource State Machine & 8051 Arbiter

[0104] 8051 Local decoder & Timing Generator

[0105] System control & Status Registers

[0106] I2C Serial modules

[0107] DCM Clock Synthesis

[0108] Real-Time Clock controller

[0109] Byte swapper

[0110] Watch-Dog Timer Control

[0111] Refresh Controller

[0112] SRAM Controller

[0113] The selection of a suitable processor as microprocessor **39** is based on the integration of fast ROM and RAM memories and a wide range of peripherals. A suitable processor will embed a USB Device Port and a USB Host controller. It may also integrate several standard peripherals, such as the USART, SPI, TWI, Timer Counters, Synchronous Serial Controller, ADC and Multimedia Card Interface. Microprocessor **39** should include a maximum of six concurrent high bandwidth 32-bit busses, and it should also feature an external bus interface capable of interfacing with a wide range of memory devices.

[0114] System controller and hardware accelerator block is directly connected to the External Bus Interface of microprocessor **39**. Controller **11** is the interface controls all aspects of hardware not integrated into the processor. The following blocks are implemented internal to the controller, and all control and data transfers are via memory mapped I/O for setup, control, and processor data transfers.

[0115] Acquire Module. This module controls all aspects of the data acquisition functionality of the design. This module is responsible for the acquisition Channel List Control, Frequency of Scan, Transfer Interrupts, Interrupt Threshold Control, Analog To Digital SPI interface control, Conversion Control, and houses the buffering RAM that feeds the SDRAM Interface block.

[0116] Local Decoder. This module is responsible for the decoding of processor accesses to all Read/Write registers accessible to the local processor. It generates all timing and direction control to all modules within the CORE system controller.

[0117] Memory Controller. This module directly controls the local SDRAM in all aspects. The local refresh timer, SDRAM power down and power saving control, local DMA transfers between the Acquire block and the SDRAM, Processor access to the SDRAM, (both in random access and FIFO mode access), arbitration control between the DMA requests, Video data requests, and the local processor accesses, and all addresses generated to the SDRAM.

[0118] Local Watchdog Timer. This module is programmable for general purpose use in timing for whatever type of wakeup might be needed based on time.

[0119] Digital Pot Controller. This module controls all SPI accesses, Digital Pot selection, timing control, and registering of all processor accesses to and from the Digital pots.

[0120] Bluetooth Controller. This module interfaces to the Bluetooth hardware.

[0121] ZigBee Controller. This module interfaces to the ZigBee hardware.

[0122] Video Controller. This module controls the LCD accesses by the processor, the raster scan, video data access. All timing generation and sequencing is controlled from this module to present whatever graphics are required.

[0123] Touch Screen Interface. This module controls the capacitive virtual button interface that allows the user access to setup and control of the hardware.

[0124] Accelerometer Interface. This module is a direct processor access to the 3 axis accelerometer so the display screen orientation flips on position and detects patient position.

[0125] Operations

[0126] Remote ambulatory cardiac monitoring system **1** is a multi-purpose ECG recorder based on a modular approach. Each requirement of functionality of the design is isolated in its own module, and has a standard intercommunication architecture with other modules of functionality, and the local processor. At the highest level of description, there are several modules within gate array controller **11**, and external to the gate array. There are the ECG Amplifier, the Analog to Digital Converter, the Digital Pots for programming offset and gains to the ECG amplifier, a capacitive touch sense interface for a from panel, the front panel itself, a Real Time Clock, a Zigbee interface, a Bluetooth interface, and Accelerometer interface, a Cell Phone interface, and a processor interface are all external to the gate array. Gate array controller **11** controls all of these above mentioned modules that are external to the gate array.

[0127] Inside gate array, controller **11**, there are also a number of modules. They are the Data Acquisition Module, the Processor Decode module, the SDRAM controller module, the Digital Pot control module, the Hardware Watchdog module, the Video Control module, the Zigbee Control module, the Bluetooth Control module, the Accelerometer Control module and the Cell Phone Control module. Any other suitable control module may also be added for additional functionality such as blood pressure module **40** which captures blood pressure data using ambulatory blood pressure cable **41**. Each of these modules has the appropriate Register sets to allow total control via the local microprocessor.

[0128] The design of controller **11** is totally synchronous and supports a single software controllable clock rate. There are many different VHDL modules in this design.

[0129] Top Level Module (holter_top.vhd)

[0130] This is the top level VHDL module. It is a wrapper for all of the other modules listed above. This module is responsible for all port mapping of sub-modules. It also contains the system control register, the potentiometer select register, write/read strobe generation for I/O, The refresh timer, processor transaction flow control, and reset synchronization. All other modules to follow, are instantiated within this module.

[0131] Local Decode Module: (lcl_dec.vhd)

[0132] This module is responsible for the decoding local processor accesses to the FPGA. It is capable of up to 256 word only locations, (16 bits). The read/write strobe generation is done in the top level module to be used in conjunction with the output of this module. This decode is based on the activation of io_acc, signal by hardware, and the processor request for read or write. This module also decodes the address space for the SDRAM when CS7 is active. An SDRAM access is only decoded here, and not acted upon. The action is when the SDRAM module sees the decode of SDRAM space. The decodes are based on a simple 3 state machine.

[0133] 1. Idle_state: This is where the state machine spends most of its time until an access to the decode module is sensed. When in this state, the hardware is looking for an I/O access. This is done with a comparator. Once detected, the io_acc signal goes active to the state machine, and forces the state machine to put out the hold signal to the processor during the transition to the next state, decode1. It also latches the chip select lines, and the lower 9 down to 1 bits of address for decode1.

[0134] 2. Decode1: This state is entered one clock after the detection of the leading edge of an I/O access. Bits 9 down to 1, (8 bits) are then fed into a look-up table for decode, the proper decode enables are activated to the rest of the FPGA, and is unconditionally sent to the next state, decode2.

[0135] 3. Decode2: This state does an immediate release of the io_hold generated on transition from the idle state to decode1. The io_hold signal is also used by the top level module to form the trailing edge of a write strobe if it is a write transaction. During a read transaction, the read strobe is generated for the duration of decode. In either case, decode2 waits for the io_acc to clear as a result of the release of the io_hold signal. It then advances back to the starting point, idle state, as soon as the processor terminates the transaction. Transaction termination is based on the negation of all Chip Selects.

[0136] Data Acquisition Module: (acquire.vhd)

[0137] This module controls, (after programming), all aspects of the data acquisition sequence.

[0138] The major blocks within this module are:

[0139] 1. Scan Sequencer

[0140] 2. Programmable clock divider to program the acquisitions/sec

[0141] 3. Processor interface

[0142] 4. A2D SPI interface

[0143] 5. Pot Selection

[0144] 6. Wake Up Count Register

[0145] 7. Memory Threshold Register

[0146] 8. DMA Count Register.

[0147] 9. A2D Mux Address

[0148] 10. Calibration Voltage Select

[0149] 11. Input Select

[0150] 12. ADC Pot Select

[0151] 13. Wake Up Interrupt Generation

[0152] 14. A2D Converter control

[0153] 15. A2D SPI Data accesses

[0154] 16. Conversion Frequency

[0155] 17. DMA transfers to SDRAM requests

[0156] Scan Sequencer

[0157] The Scan Sequencer is made up of a 16×5 bit RAM that holds the following control:

[0158] 1. Channel to be converted, (bits 3:0)

[0159] 2. End Sequence Flag, (bit 4)

[0160] 3. Processor Multiplexer Address

[0161] 4. Data acquisition sequence address

[0162] After the processor loads the desired address into the Processor Multiplexer Address register, the required processor access location is setup. When a decode of the scan ram sequencer is decoded on a processor access, the value of the Processor Multiplexer Address is sent to the address inputs of the scan ram. The Data transaction (read/write), will take place to the channel location set up previously in the Processor Mux Address register. This location is one of 16 channels feeding the Analog to Digital Converter addressed by the Scan Ram.

[0163] The Scan Ram Sequencer is simply a four bit counter that increments after every scan. The address, (count), comes from the Scan Sequencer logic when running.

If location 0 of the scan ram wanted to scan channel **5**, then the processor would set up the Processor Mux Address register to 0, and write a 5 into that location. The scan list can be programmed to acquire any channel in any order to provide for maximum flexibility

[0164] This RAM is accessed in two different manners. Either the processor addresses it to read/write the RAM, (Holter_Run='0' and Mux_Ctl_Mode='1'), or the acquisition control state machine scan sequence register, (Holter_run='1').

[0165] When in the processor mode of access, the processor accesses this RAM as a Memory Mapped resource. When the local decoder decodes processor access to this RAM, the hardware passes the address in the processor multiplexer address register to the address inputs of the scan ram, along with the lower five bits of the system data bus, (sys_dat) to the data inputs of the RAM, on a write. During a read, the internal sys_data is tri-stated, and the contents of the RAM are put on bits (4:0) for a read access. Based on the read strobe, (rstrb), and write strobe, (wstrb), the data is either read from the RAM to bits (4:0) of the sys_data bus from the address specified in the processor multiplexer address, or a write to the same location from sys_data (4:0).

[0166] When running, (Holter_Run='1'), the address presented to the Scan RAM is from the data acquisition state machine, (scan_seq). These accesses are always reads. At the beginning of a convert cycle, just before the conversion command is given to the A2D converter, the address of the scan sequence is presented to the Scan RAM, and its contents are sent to the external analog multiplexer that feeds the input to the A2D converter. After this, on the next clock, the convert command is given. After the conversion, the scan sequence address is incremented with one exception. If bit 4 of the Scan RAM contents is '1' for the address given, after the conversion the scan sequencer is reset to "0000". This restarts the scan list. The Scan list length is programmable. To make the scan list 1 deep, (then it repeats itself), simply set BIT 4 of the data, (channel included in the data). BIT 4 of the output of the Scan Ram directly resets the counter addressing the scan ram. Therefore, bit 4 being set at location zero, will lock the counter at location 0 when running. For a scan list of 2, write BIT 4 of location 1 to a 1. This causes a counter reset when location 1 is accessed allowing the counter to cycle between locations 0 and 1. Writing a 1 to BIT 4 of location 0xF makes the Scan list 16 long. The scan list can be programmed to acquire any channel in any order to provide for maximum flexibility. For a scan list of 16, writing the same channel address in all locations would be logically the same as a single length list. All 16 locations would be accessed, but they would all have the same channel #. This is true for any sequence. This allows the setup to scan one channel more times than another during a scan run allowing individual channels to be acquired at different sampling rates.

[0167] Programmable Clock Divider to Program the Acquisitions/Sec

[0168] This is a 16 Bit register that counts 100 ns intervals. Loading this register with a 1 would cause an acquisition clock every 200 ns. This is an illegal number and this register should never be loaded with a value of less than the maximum speed of the A2D converter. Resolution is 100 ns. The slowest clock rate is 65535×100 nS, or 1 channel every 6.5546 mS per channel. A scan rate of 1 MHz, (1 channel every microsecond), would load a value of 9 to this register, (0x0009). Clock rate=N+1 (100 ns), where N=value of this register. A value of zero is illegal and will produce undetermined results.

[0169] Processor Interface

[0170] The Processor interface accepts decodes from the local decoder pertinent to this module of the design. This interface is based on the output of the local decoder module. When the local processor is making an access, the local decoder sends the appropriate decode signals to this interface. The following signals are pertinent to the update/access to the following blocks of this module:

[0171] 1. Clock Divider Register

[0172] 2. Acquisition Control Register, (described earlier).

[0173] 3. Scan RAM

[0174] 4. Processor MUX Address.

[0175] 5. Wake Up Count Register

[0176] 6. Memory Threshold Register

[0177] 7. DMA Count Register.

[0178] 8. A2D Data Path

[0179] 9. A2D FIFO Path

[0180] 10. SPI Data Path/Control

[0181] A2D SPI interface

[0182] The A2D SPI interface is for the purpose of all local processor to A2D protocol conversion and control. The A2D is an SPI based device that has a 16 bit transfer in either direction. There is a state machine to handle both sides of this interface. On one side of the state machine is the local processor. The local processor sets appropriate bits to the state machine for high level control, and for data writes and data reads. On the other side of the state machine is the A2D Converter SPI Interface. This part of the interface, (acquisition control and translation), is also fed by the Base Time Acquisition clock, (adc_clk), that is a direct derivative of the Programmable Clock Divider described above. Once the local processor asserts the holter_run bit, every adc_clk starts another conversion from the channel addressed from the Scan RAM. This can be confusing due to the fact that the Scan RAM both produces addresses and accepts them for look-up. The address in this discussion is the output of the Scan RAM. This is done with a multiple, (8 state), state machine.

[0183] IDLE: This is the state entered after a power up, a reset, or a completion of a conversion. While in this state, the state machine is looking at the holter_run bit. This bit is set on the next leading edge of a conversion clock, (adc_clk). At this time the SPI data out pin of the FPGA is driven high to do the CS mode of operation, this forces the busy bit active mode. The state machine then transitions to START_CNV.

[0184] START_CNV: During this state the adc_cnv clock is asserted. This instructs the A2D converter to convert the analog value presented at its input. There are 16 data bits in conversion transfer. The lower 16 bits are converted data and the 17th bit, (busy) is the MSB of the serial chain. Then the next state BUSY_W8 is entered.

[0185] BUSY_W8: Upon entering this state, the state machine waits for the data out of the SPI, (SD0 from the ADC) to go to a zero state. This signifies the negation of the busy signal from the previous convert pulse, (ADC_CNV). Once this is detected, the state machine negates A2D_SDI, and asserts the SPI_CLK signal, shifting out the busy bit. The state machine then transitions to the BUSY_SHIFT state.

[0186] BUSY_SHIFT: Upon entering this state, the state machine negates the SPI_CLK, and forms the trailing edge of the first SPI_CLK. There is one system clock skipped to allow for minimum pulse width of the ADC SPI interface. After this

delay, the state machine asserts the leading edge of the next pulse. We then transition the BUSY_SHIFT1 state.

[0187] BUSY_SHIFT1: This state, when entered skips one machine clock to not violate the minimum pulse width of the SPI_CLK. After this delay, SPI_CLK is negated and the state machine transitions to GET_DATA1.

[0188] GET_DATA1: This state, when entered again skips one machine clock to allow for setup time from the SPI_DATA pin, but at the same time negates the SPI_CLK. After this delay the internal shift count is incremented, and the data from the SPI is shifted into the LSB of the serial to parallel register, and at the same time, the MSB is shifted out to the SPI interface. The information shifted into the serial to parallel register is a function of the command. If the command is a read command, the register specified in the command is accessed. If it is a write command, the command word is written right back into the serial to parallel register as a function of the SPI interface of the A2D converter. On this same clock edge, the SPI_CLK is again asserted, and the transition to GET_DATA2 takes place.

[0189] GET_DATA2: Upon entering this state, the SPI_CLK is negated. On the same clock edge, the shift count is checked for 16. If the result is false, the state machine transitions back to GET_DATA1. If the count is 16, the load a2d fifo signal is activated, (LD_A2D_FIFO). This causes a shift of the parallel word just captured, and the state machine transitions to TERMINATE1.

[0190] TERMINATE1: This state negates the SPI_CLK signal and jumps to the IDLE state.

[0191] Algorithm Specifications

[0192] This section shall define the functional requirements of the system and sub-system of controller algorithm **20**A.

[0193] Sinus Pause:

[0194] A sinus pause will be documented whenever a predetermined period of time elapses without a QRS complex of any morphology. This algorithm will not discriminate between a Sinus Pause and Sinus Block as this interval timer will be based on R-Wave to R-Wave intervals. The programmable time period for a Sinus Pause is 1.5, 2.0, 2.5, 3.0, 3.5 or 4.0 seconds, with 2.0 seconds being the factory default setting. The detection of Sinus Pause can be turned on or off without affecting any of the other arrhythmia settings.

[0195] Bradycardia:

[0196] Bradycardia occurs when the patient's heart rate goes below a preset limit. The heart rate for calculating Bradycardia is based on a 6-beat rolling average, a 10-beat rolling average or a 16-beat rolling average that can be selected in the configuration software. The factory default setting is a 10-beat rolling average. The programmable heart rate settings for Bradycardia are 30, 35, 40, 45, 50, 55, 60, 65 and 70 beats per minute (BPM) with 40 BPM being the factory default setting. The detection of Bradycardia can be turned on and off without affecting any of the other arrhythmia configuration settings.

[0197] Bradycardia Time Offset:

[0198] Bradycardia within a patient can often go below the preset limit when sleeping. In order to accommodate for this phenomena, the heart rate for calculating Bradycardia can be lowered by 5, 10, 15, 20 beats per minute (BPM) with 10 BPM being the factory default. The selection for window set in Bradycardia will be utilized for this setting. The Bradycardia Time Offset can be turned on and off without affecting any of the other arrhythmia configuration settings and is OFF by default.

[0199] Tachycardia:

[0200] Tachycardia occurs when the patient's heart rate goes above a preset limit or in the event of 3 or more sequential Ventricular beats. The heart rate for calculating Tachycardia is based on a 6-beat rolling average, a 10-beat rolling average or a 16-beat rolling average that can be selected in the configuration software. The factory default setting is a 10-beat rolling average. The algorithm will calculate the rate for both Normal and Ventricular beat such that it will detect Sinus Tachycardia, Supraventricular Tachycardia and Ventricular Tachycardia. The programmable heart rate settings for Tachycardia are 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120, 125, 130, 135, 140, 145, 150, 155, 160, 165, 170, 175, 180, 185, 190, 195, and 200 beats per minute (BPM) with 100 BPM being the factory default setting. The detection of Tachycardia can be turned on and off without affecting any of the other arrhythmia configuration settings.

[0201] Atrial Fibrillation:

[0202] The AFib detection algorithm uses a probability density function (PDF) method based on a reconstructed attractor of R-R intervals. By constructing the PDF of distance between two points in the reconstructed phase space of R-R intervals of normal sinus rhythm (NSR) and atrial fibrillation (AF), the distributions of PDF of NSR and AF R-R intervals have significant differences. By taking advantage of their differences, a characteristic quantity parameter kn, which represents the sum of n points slope in filtered PDF curve, is used to detect both NSR and AF R-R intervals. AFib detection is based on dynamically created PDFs and is not dependent on reference PDFs from known published databases from MIT-BIH, AHA, etc. Those databases were, however, used in preliminary algorithm development to determine the optimal embedding dimension m, the characteristic quantity Kn, and the slope number used by the algorithm for optimal performance as described below.

[0203] Stage 10 consists of Phase Space Reconstruction. The R-R interval is just one observable variable from the multi-variable cardiac system. According to Takens' embedding theorem, the state of a dynamic system can be represented in a reconstructed phase space by time delay embedding. Taken's theorem guarantees that the dynamic characteristics of the real physiological) and the reconstructed system are the same. Therefore, it is possible to reconstruct the phase space of the original cardiac system from the R-R intervals while preserving the system dynamics. If x(i) is an element of the R-R intervals vector X, then a reconstructed vector Yi is introduced as

$$Yi=[x(i),x(i+\tau),\ldots,x(i+(m-1)\tau)] \quad \text{(Equation 1)}$$

where τ is the time delay and m is the embedding dimension. The reconstructed vector Yi represents a point in the m-dimensional phase space. By reconstructing the R-R intervals and investigating the structure of the reconstructed attractor, it is possible to provide more information and new diagnostic potential of the analyzed cardiac system. The phase space reconstruction consists of 5 dimensions (embedding dimension m=5) based on a 40 beat window ([40,5] phase-space array) to a 100 beat window ([100,5] phase space array). A 40-beat windows gives speed the priority (real-time applica-

tion) where moving towards a 100-beat window gives accuracy the priority (real-time application with DSP assist or PC-based system).

[0204] Stage **11** constructs the Probability density function. The basic idea behind the PDF method is to construct the correlation function C(r,m,τ). C(r,m,τ) describes the probability that the distance between arbitrary two points Yi and Yj in the phase space is shorter than distance r. C(r,m,τ) can be written as

$$C(r,m,\tau)=2/(N(N-1))\Sigma_{i=1}^{N-1}\Sigma_{j=i+1}^{N}\theta(r-\|Y_i-Y_j\|) \quad \text{(Equation 2)}$$

where N is the number of phase space points, symbol ||•|| represents the Euclidean distance, and θ(x) is the Heaviside unit-step function which is defined by

$$\theta(z)=\{1 Z\geq 0\}\{0 Z<0\} \quad \text{(Equation 3)}$$

Equations (1)-(3) are essential steps of the Grassberger and Procaccia (GP) method to calculate the correlation dimension. The determination of the correlation dimension from R-R intervals are commonly used for gaining information about the nature of the underlying cardiac dynamics. Since the correlation function C(r,m,τ) has a maximum of 1, minimum of 0 and is a continuous distribution function, we define the probability density function as

$$p(r,m,\tau)=dC(r,m,\tau)/dr$$

[0205] The PDF is now used for the analysis of the reconstructed attractor structure. A low pass filter (IIR Butterworth type, eight orders with cutoff frequency 1.5 Hz) is used to filter the high frequency fluctuating components of the PDF curves. After low pass filtering, PDF curves of short-time R-R intervals have a near Gaussian distribution.

[0206] Stage **12** calculates the Characteristic Quantity kn from the Receiver Operating Curve (ROC). rmin, rtop and rmax are defined as the abscissas of the starting point, the peak and the ending point of the filtered PDF curves, respectively. The values of rmin, rtop and rmax of NSR R-R intervals are smaller than those of AF R-R intervals. This is due to the fact that the neighboring NSR R-R intervals are more correlated, so points in the reconstructed phase space are more concentrated; whereas the neighboring AF R-R intervals are less correlated, so points in the reconstructed phase space are more dispersed. However, rmin, rtop and rmax are not good indexes for differentiating AF from NSR. Therefore, the slope information of the filtered PDF curves is used to improve the detection precision

$$k_n=[PDF]\_\text{filtered}/r\_\max(n)\times 100$$

rrmax is divided evenly into 100 segments and d is the length of each segment. PDFfiltered (n) is the value of the nth point in the filtered PDF curve. Naturally, the 0th point in the filtered PDF curve is 0. Therefore, kn denotes the sum of the slope of n points in the filtered PDF curve. The characteristic quantity kn fully takes advantage of the following characteristics of filtered PDF curves:

(1) most of the values of rmax of AF are bigger than those of NSR;

(2) most of the values of rtop of AF are bigger than those of NSR, which means filtered PDF curves of NSR rise much faster than those of AF;

(3) most of the values of rmin of AF are bigger than those of NSR, i.e., among the n points slope, AF has more small slope than NSR. All these characteristics make the value of kn of NSR bigger than that of AF as long as n is carefully selected.

Stage **13** uses Kn to determine whether the PDF represents values of NSR or AFib. If a 40 beat window is used then the number of points used to determine the slope is 20 and a threshold of 210 for Kn is used to determine whether the PDF value is characteristic of AFib of NSR. If a 100 beat window is used, the number of the slope points n is 10 and 78 is used for the threshold of Kn. The same concept applies to 60 and 80 beat windows.

[0207] Thus, while the preferred embodiments of the devices and methods have been described in reference to the environment in which they were developed, they are merely illustrative of the principles of the inventions. Other embodiments and configurations may be devised without departing from the spirit of the inventions and the scope of the appended claims.

We claim:

1. A remote ambulatory cardiac monitoring system comprising:

microprocessor for controlling interactions with external devices;

a hardware gate array for controlling acquisition of ECG signals and other data and analysis of data as it is acquired;

a cable connector operably connected to the microprocessor for engaging a plurality of different input/output cables, insertion of each of the plurality of input/output cables causes the microprocessor to initiate one of a plurality of different modes from the remote ambulatory cardiac monitoring system;

a plurality of electrodes secured to a patient, each electrode operably connected to at least one of the plurality of input/output cables for sensing ECG signals from a patient; and

means for quantifying resistance changes between each of the one or more of the plurality of electrodes and the patient during acquisition of the ECG signals.

2. The apparatus of claim **1** wherein the mode initiated by the connection of one of the plurality of different input/output cables is selected from the group of modes including:

12-lead EKG mode, Holter recorder mode, MCT mode, and USB data transfer mode.

3. The apparatus of claim **1** wherein the mode initiated by the connection of one of the plurality of different input/output cables is MCT mode.

4. The apparatus of claim **1** wherein the mode initiated by the connection of one of the plurality of different input/output cables is selected from the group of modes including:

12-lead EKG mode and Holter recorder mode.

5. The apparatus of claim **1** wherein the means for quantifying resistance changes is operable to detect when one or more of the plurality of electrodes is not secured to the patient and upon detection of one or more electrodes not secured, the means for quantifying resistance changes initiates an alarm signal.

6. The apparatus of claim **1** further comprising:

means for cross checking alarm triggers before initiating an alarm using one or more alternate data channels, where the one or more alternate data channels did not initiate the alarm trigger.

7. A mobile cardiac telemetry system comprising:

microprocessor for controlling interactions with external devices;

a hardware gate array for controlling acquisition and analysis of ECG signals and other data;

a cable connector operably connected to the microprocessor for engaging a plurality of different input/output cables, insertion of each of the plurality of input/output cables causes the microprocessor to initiate one of a plurality of different modes from the remote ambulatory cardiac monitoring system;

no more than three electrodes secured to a patient, each of the electrodes operably connected to one of the plurality of input/output cables for sensing ECG signals from a patient;

means for quantifying resistance changes between one or more of the electrodes and the patient during data acquisition; and

means for sequentially processing ECG signals from the electrodes to generate six channels of data and a noise cancellation signal to feed back to the electrodes.

* * * * *

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摘要(译)

多功能健康监护仪能够执行静息12导联心电图测试，心电图压力测试，24小时动态心电图监测评估和/或30天MCT监测。多功能健康监测器仅使用3个电极，通过虚拟动态RL电极的噪声消除（接地）效应获得6个通道（肢体引线和增强引线）数据。电极电阻率测量系统量化并且可以补偿由于电极安装在患者身上的时间长度而导致的电极和患者的电阻增加。当获取数据时，多功能健康监测器可以通过门阵列提供数据分析。还可以存储数据用于远程分析以及在发生一个或多个阈值事件时传输到远程站。可以远程调整阈值事件的参数，以避免患者前往系统调整的需要。