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(54) ALERT SYSTEM AND METHOD FOR AN IMPLANTABLE MEDICAL DEVICE

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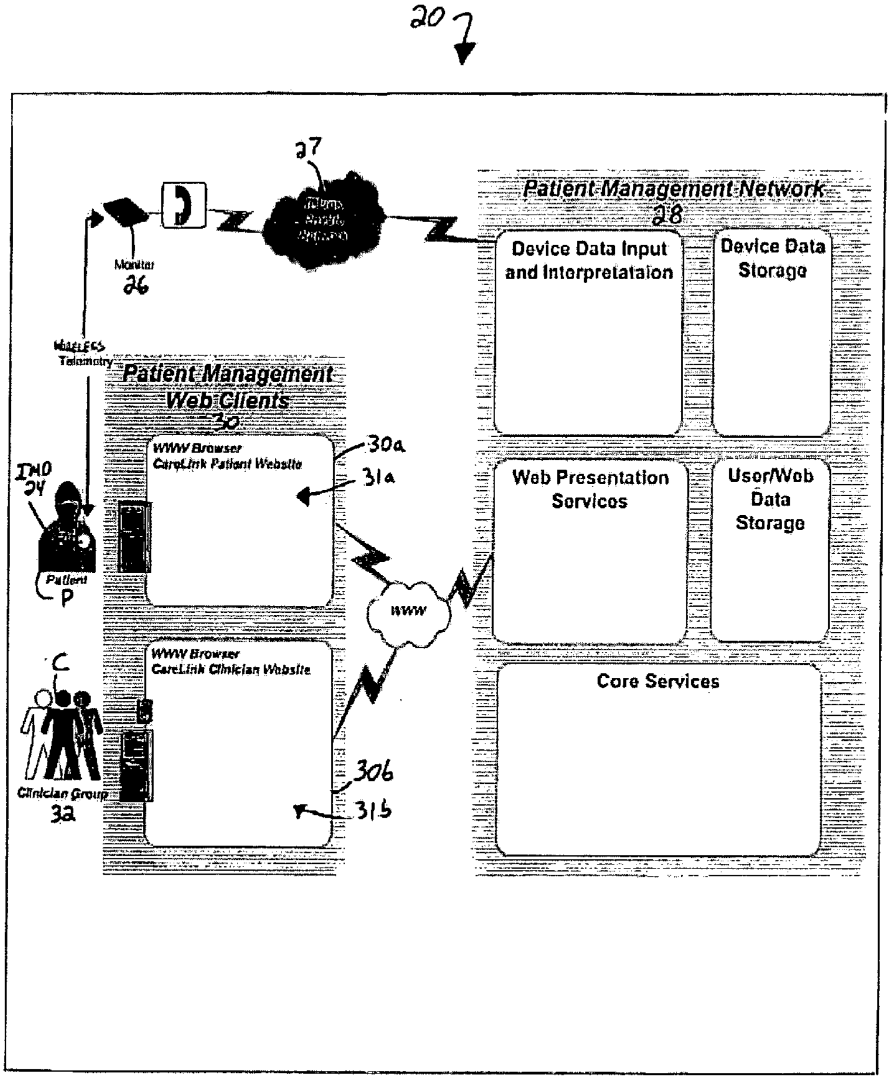
A61B 5/02 (2006.01)

(52) **U.S. Cl.** **340/573.1**; 128/903; 600/547; 600/485; 600/365

(57) **ABSTRACT**

An alert system and method for providing alerts indicating an occurrence and a termination of an event relating to a patient. An implantable medical device, implanted within a patient, detects the occurrence of the event. Next an alert signal is wirelessly transmitted from the implantable medical device to provide an alert indicating the occurrence of the event. The implantable medical device then monitors for the termination of the event. When the termination of the event is detected, the implantable medical device wirelessly transmits an end alert signal to provide an alert indicating the termination of the event.



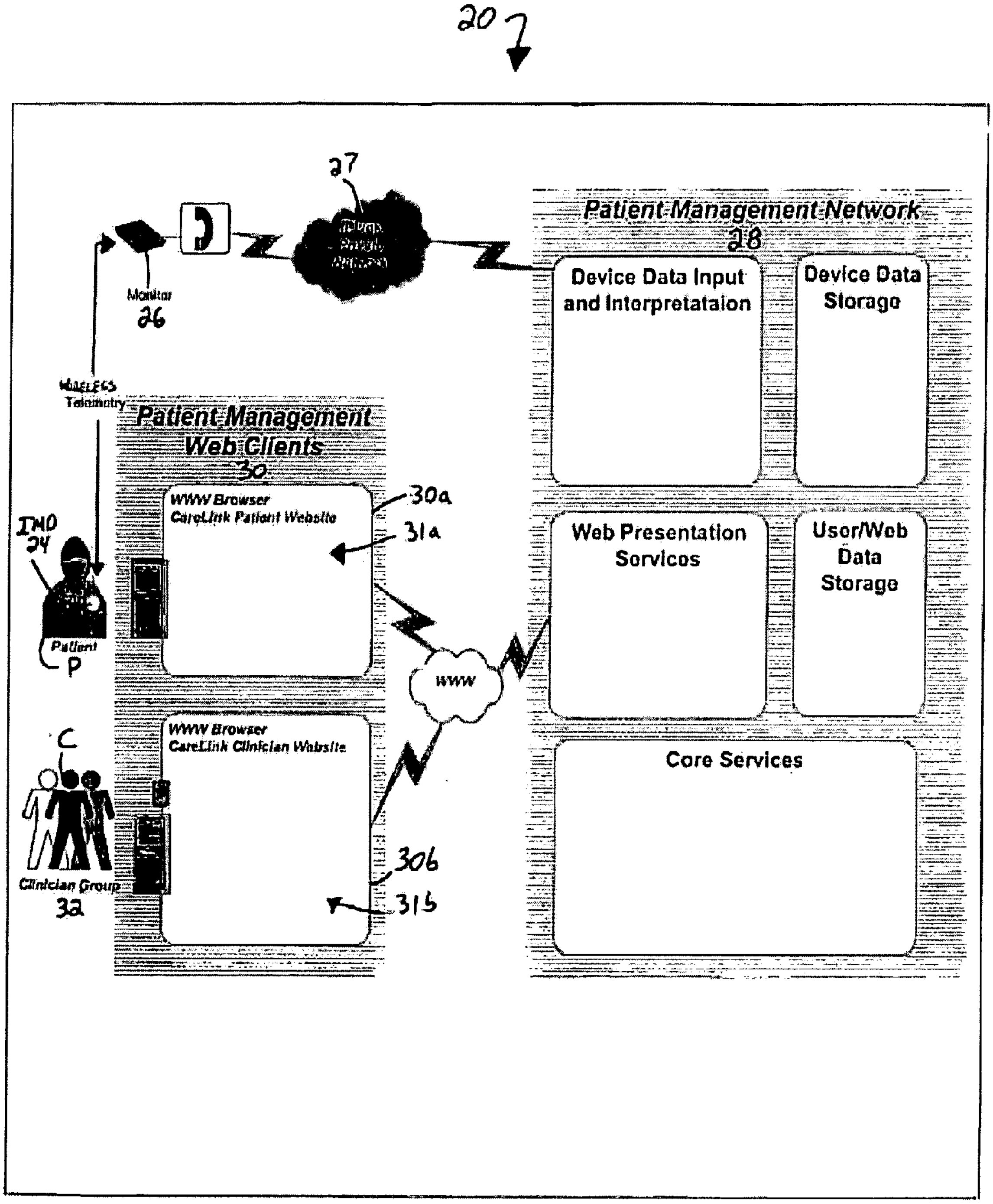

20
27
Patient Management Network
28
Device Data Input and Interpretataion
Device Data Storage
Monitor
26
Wireless Telemetry
Patient Management Web Clients
30
WWW Browser
CareLink Patient Website
30a
31a
IMD
24
Patient
P
Web Presentation Services
User/Web Data Storage
www
C
WWW Browser
CareLink Clinician Website
Core Services
30b
Clinician Group
32
31b

FIG. 1

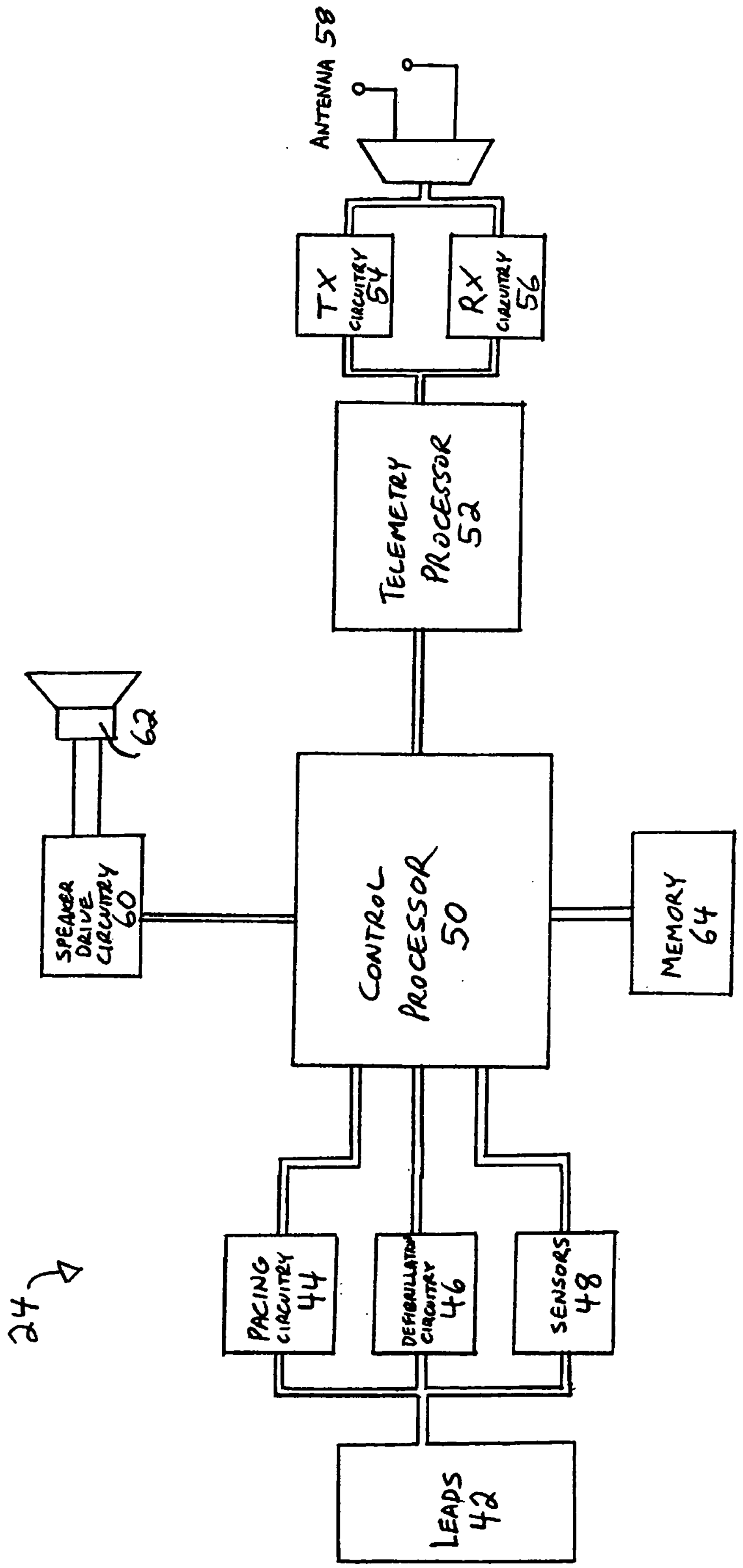

ANTENNA 58
TX CIRCUITRY 54
RX CIRCUITRY 56
TELEMETRY PROCESSOR 52
62
SPEAKER DRIVE CIRCUITRY 60
CONTROL PROCESSOR 50
MEMORY 64
PACING CIRCUITRY 44
DEFIBRILLATOR CIRCUITRY 46
SENSORS 48
LEADS 42
24

FIG. 2

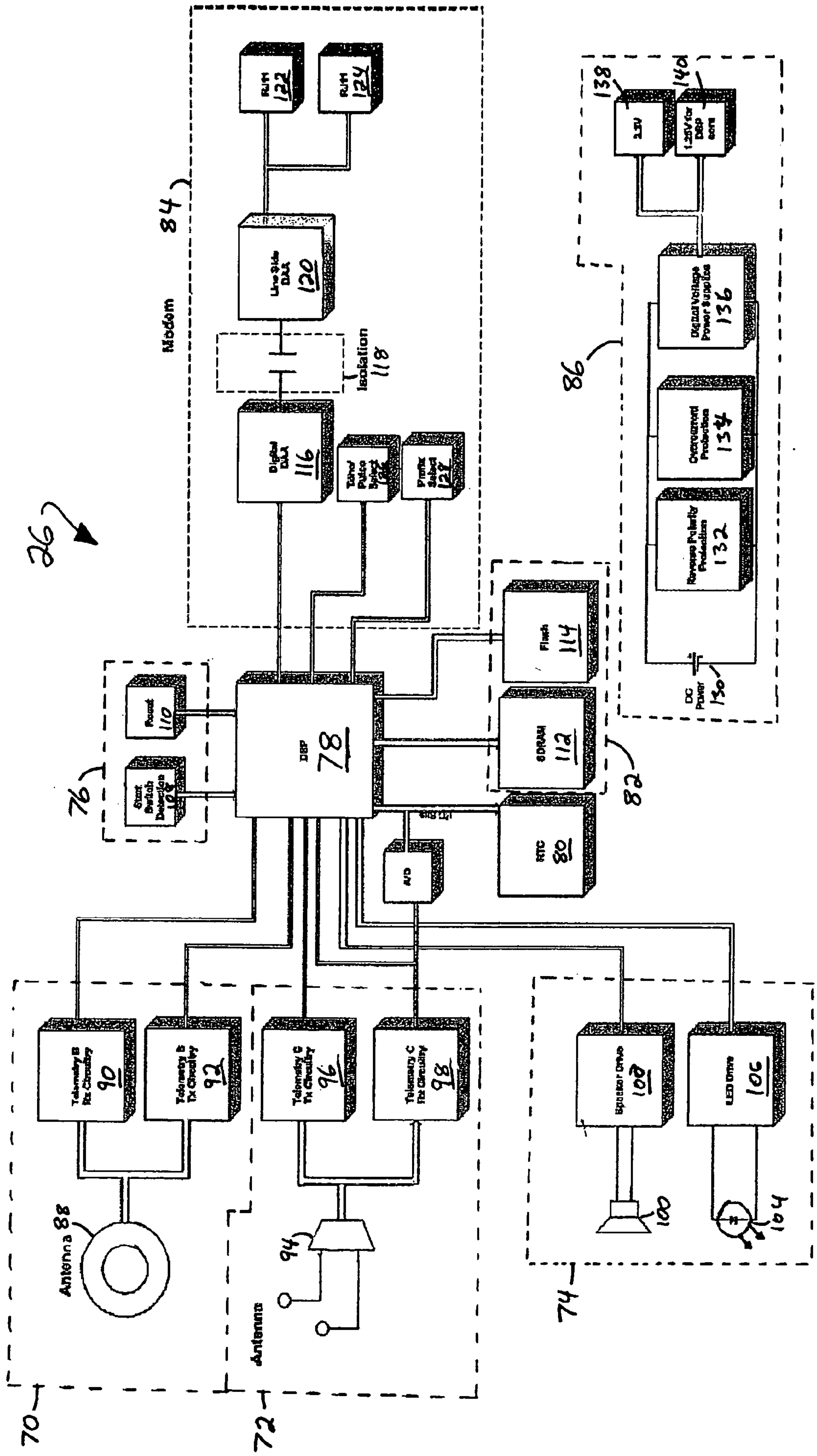

26
Modem
84
Isolation 118
86
DSP 78
Flash 114
SDRAM 112
RTC 80
A/D
76
82
Antenna 88
70
72
74

FIG. 3

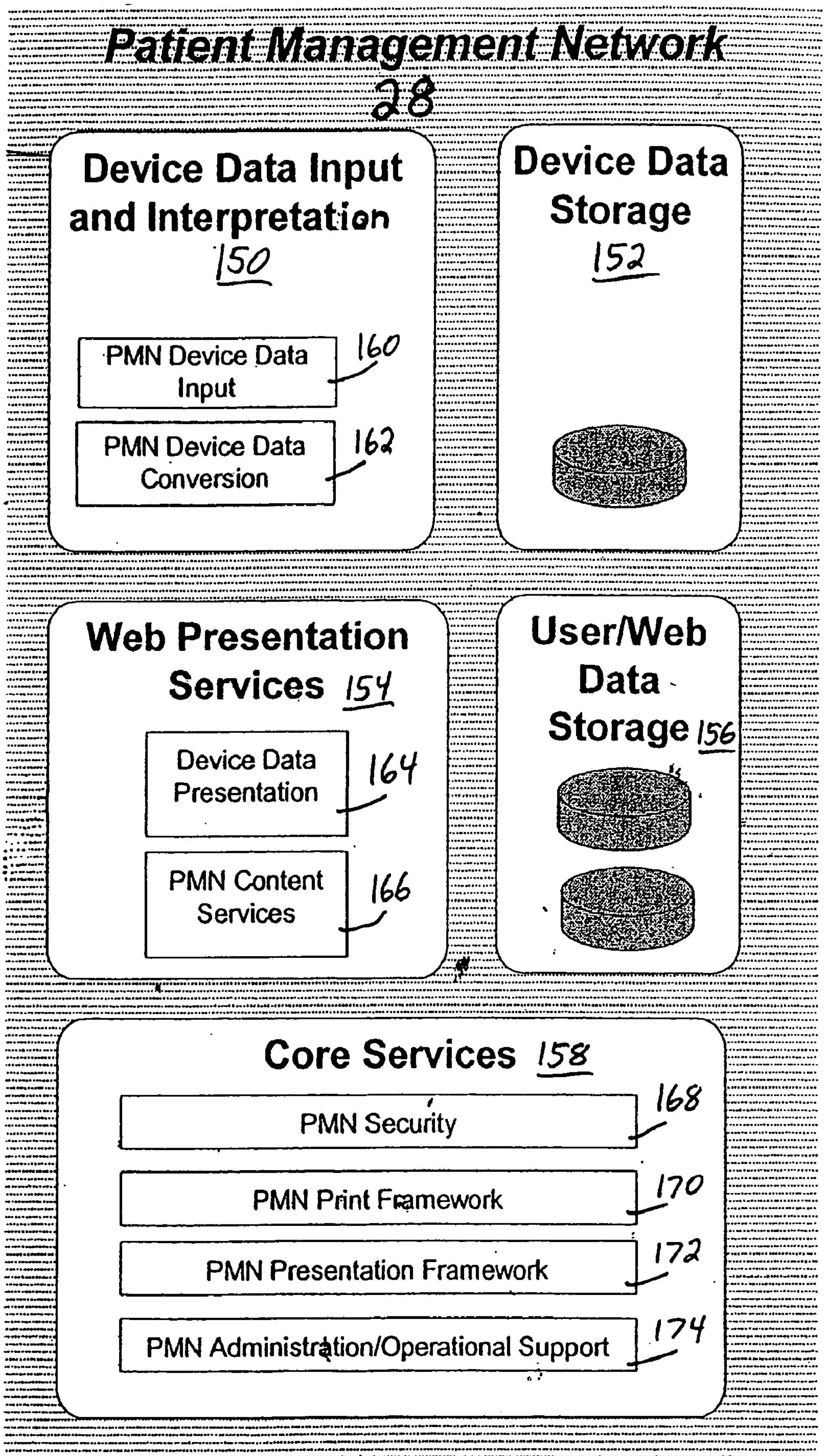

Patient Management Network
28
Device Data Input and Interpretation
150
PMN Device Data Input
160
PMN Device Data Conversion
162
Device Data Storage
152
Web Presentation Services
154
Device Data Presentation
164
PMN Content Services
166
User/Web Data Storage
156
Core Services
158
PMN Security
168
PMN Print Framework
170
PMN Presentation Framework
172
PMN Administration/Operational Support
174

FIG. 4

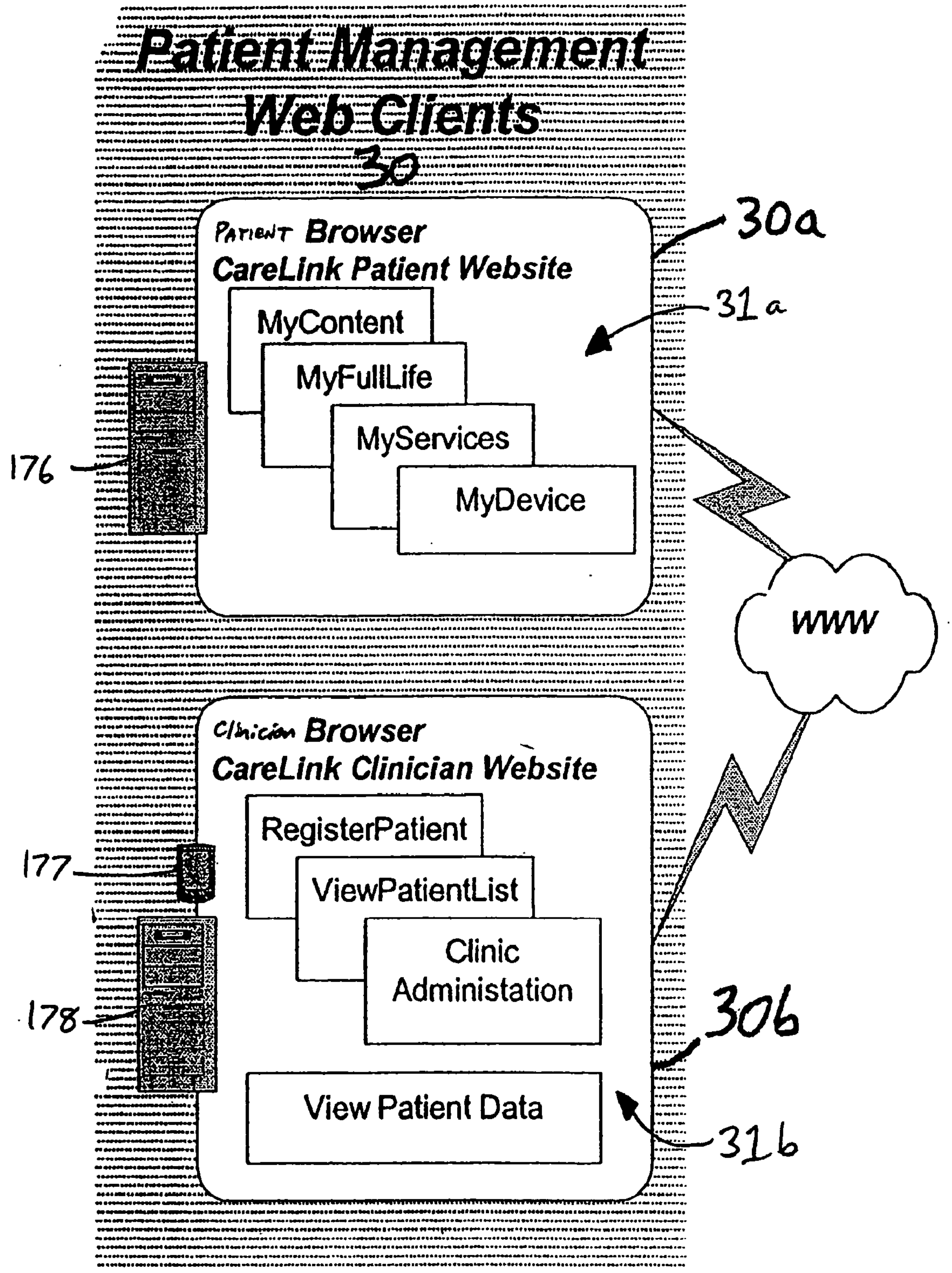

Patient Management
Web Clients
30
30a
PATIENT Browser
CareLink Patient Website
31a
MyContent
MyFullLife
MyServices
MyDevice
176
WWW
Clinician Browser
CareLink Clinician Website
RegisterPatient
ViewPatientList
Clinic
Administation
177
178
30b
View Patient Data
31b

FIG. 5

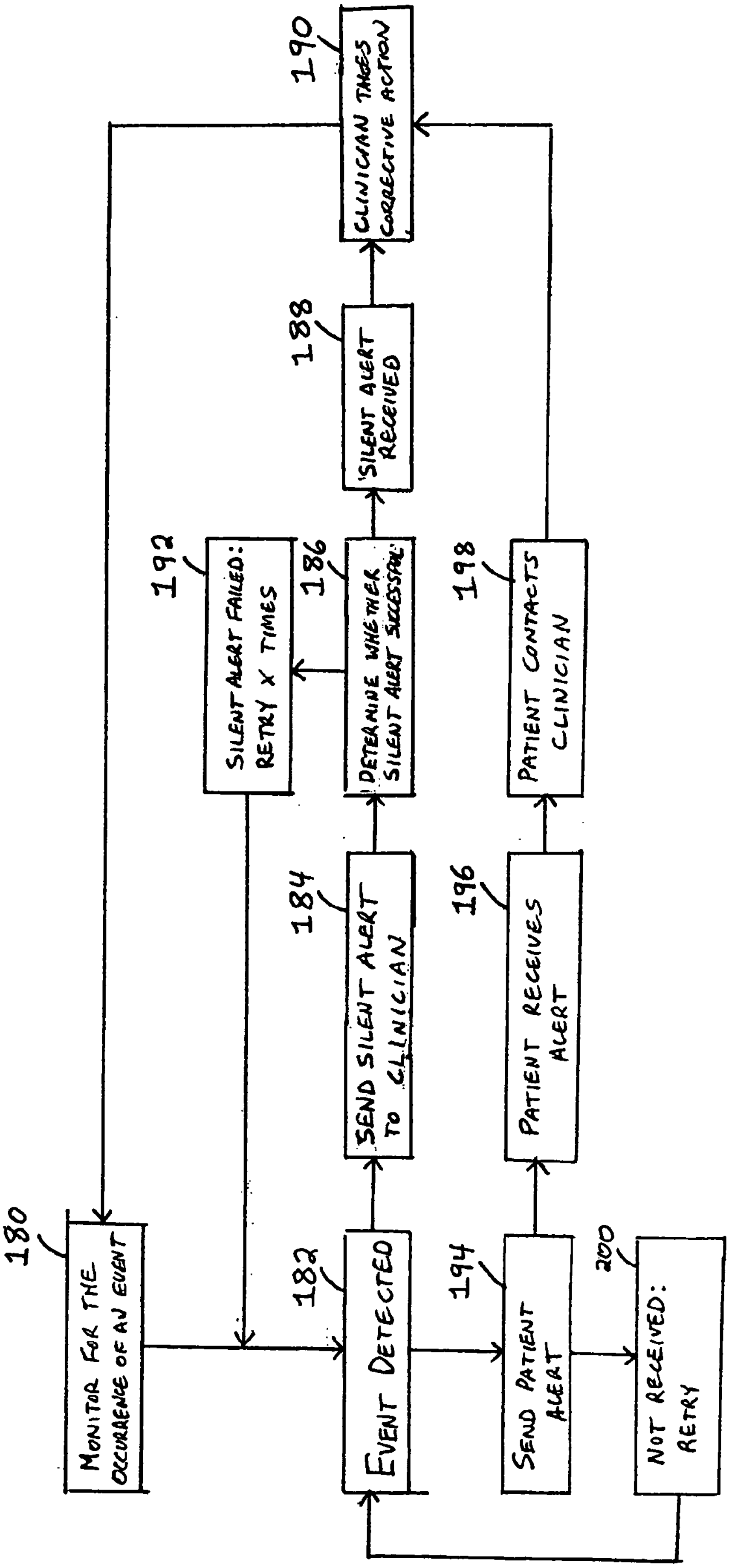

180
MONITOR FOR THE OCCURRENCE OF AN EVENT
182
EVENT DETECTED
184
SEND SILENT ALERT TO CLINICIAN
186
DETERMINE WHETHER SILENT ALERT SUCCESSFUL
188
SILENT ALERT RECEIVED
190
CLINICIAN TAKES CORRECTIVE ACTION
192
SILENT ALERT FAILED: RETRY X TIMES
194
SEND PATIENT ALERT
196
PATIENT RECEIVES ALERT
198
PATIENT CONTACTS CLINICIAN
200
NOT RECEIVED: RETRY

FIG. 6

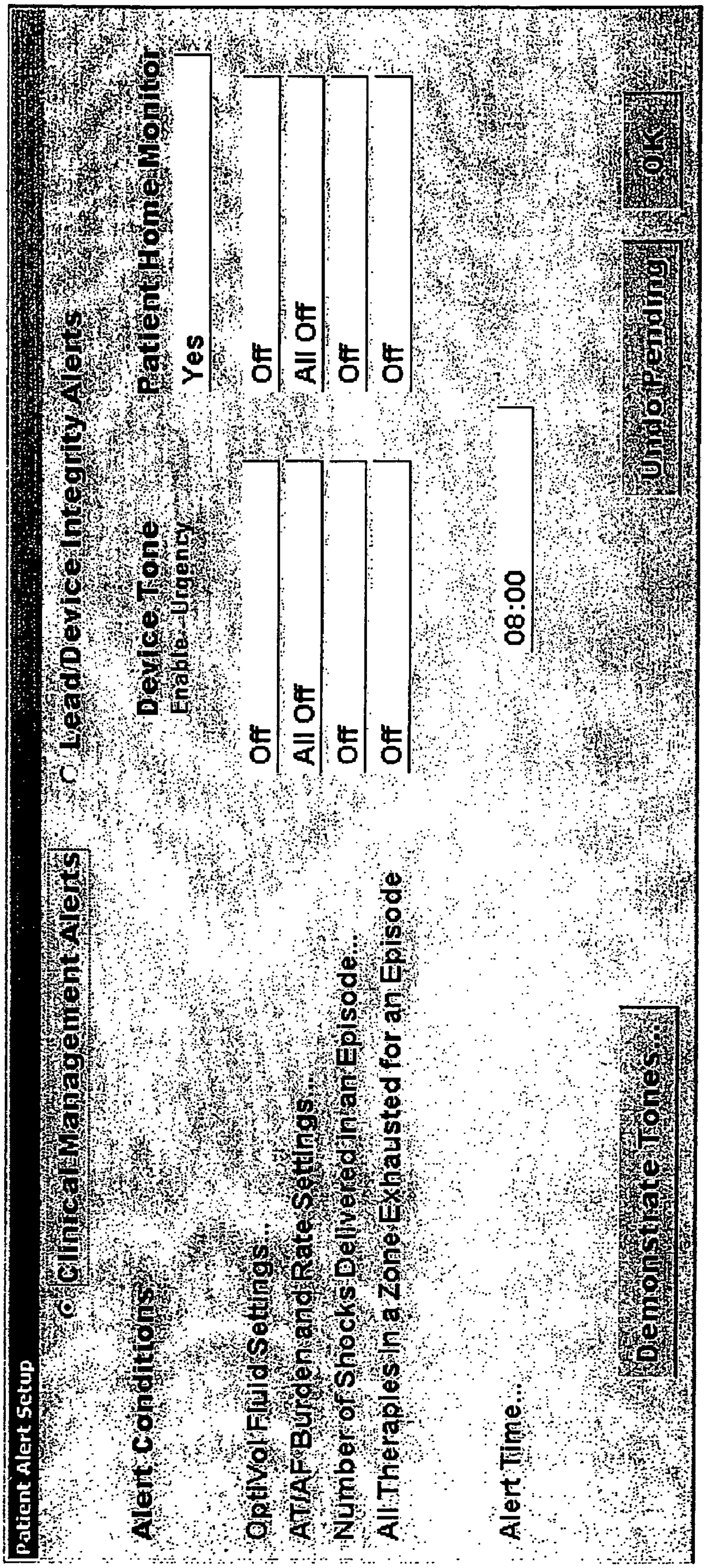

Patient Alert Setup
Clinical Management Alerts
Lead/Device Integrity Alerts
Alert Conditions
Device Tone
Enable Urgency
Patient Home Monitor
Yes
OptiVol Fluid Settings...
Off
Off
AT/AF Burden and Rate Settings...
All Off
All Off
Number of Shocks Delivered in an Episode...
Off
Off
All Therapies in a Zone Exhausted for an Episode
Off
Off
Alert Time...
08:00
Demonstrate Tones...
Undo Pending
OK

FIG. 7

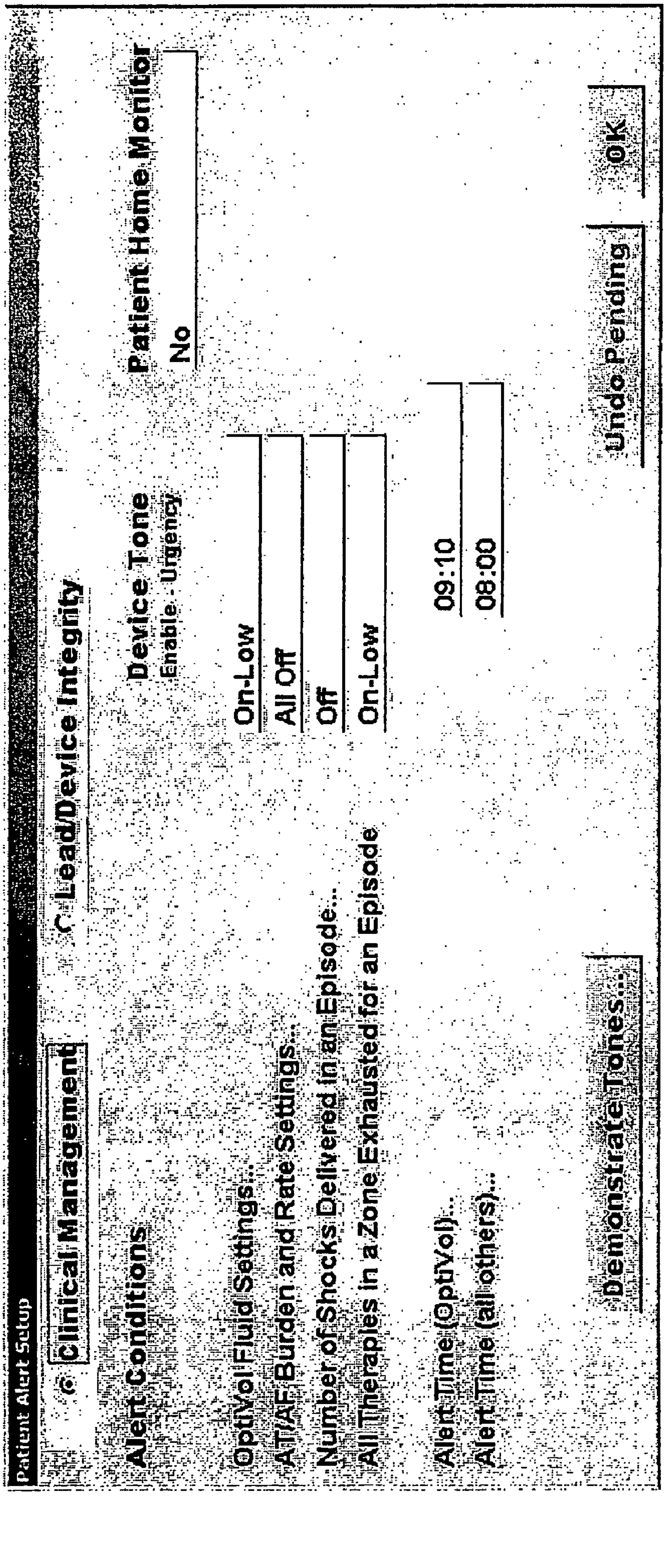

Patient Alert Setup
Clinical Management
Lead/Device Integrity
Alert Conditions
Device Tone
Enable - Urgency
Patient Home Monitor
No
OptiVol Fluid Settings...
On-Low
AT/AF Burden and Rate Settings...
All Off
Number of Shocks Delivered in an Episode...
Off
All Therapies in a Zone Exhausted for an Episode
On-Low
Alert Time (OptiVol)...
09:10
Alert Time (all others)...
08:00
Demonstrate Tones...
Undo Pending
OK

FIG. 8

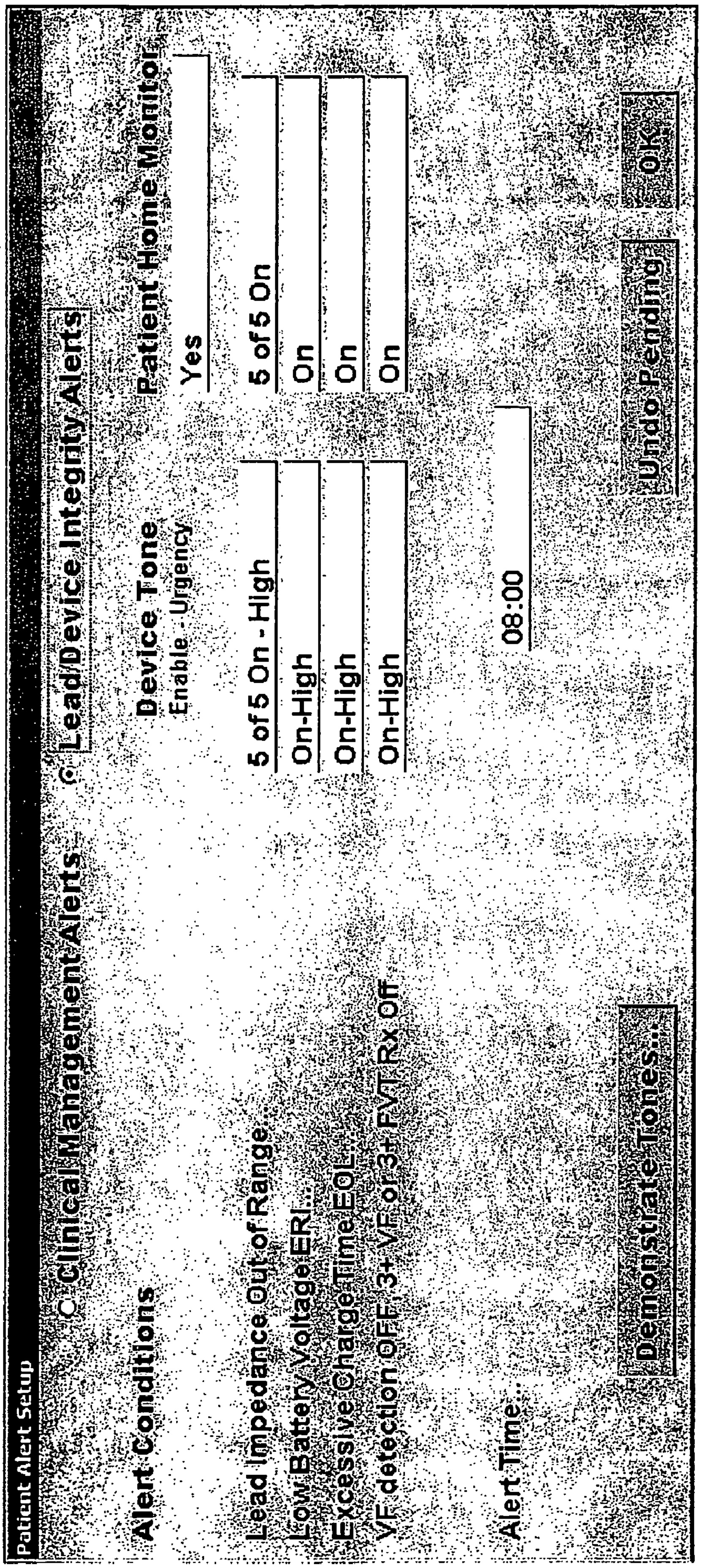

Patient Alert Setup
Clinical Management Alerts
Lead/Device Integrity Alerts
Alert Conditions
Device Tone
Enable - Urgency
Patient Home Monitor
Yes
Lead Impedance Out of Range...
5 of 5 On - High
5 of 5 On
Low Battery Voltage ERI...
On-High
On
Excessive Charge Time EOL...
On-High
On
VF detection OFF, 3+ VF or 3+ FVT Rx Off
On-High
On
Alert Time...
08:00
Demonstrate Tones...
Undo Pending
OK

FIG. 9

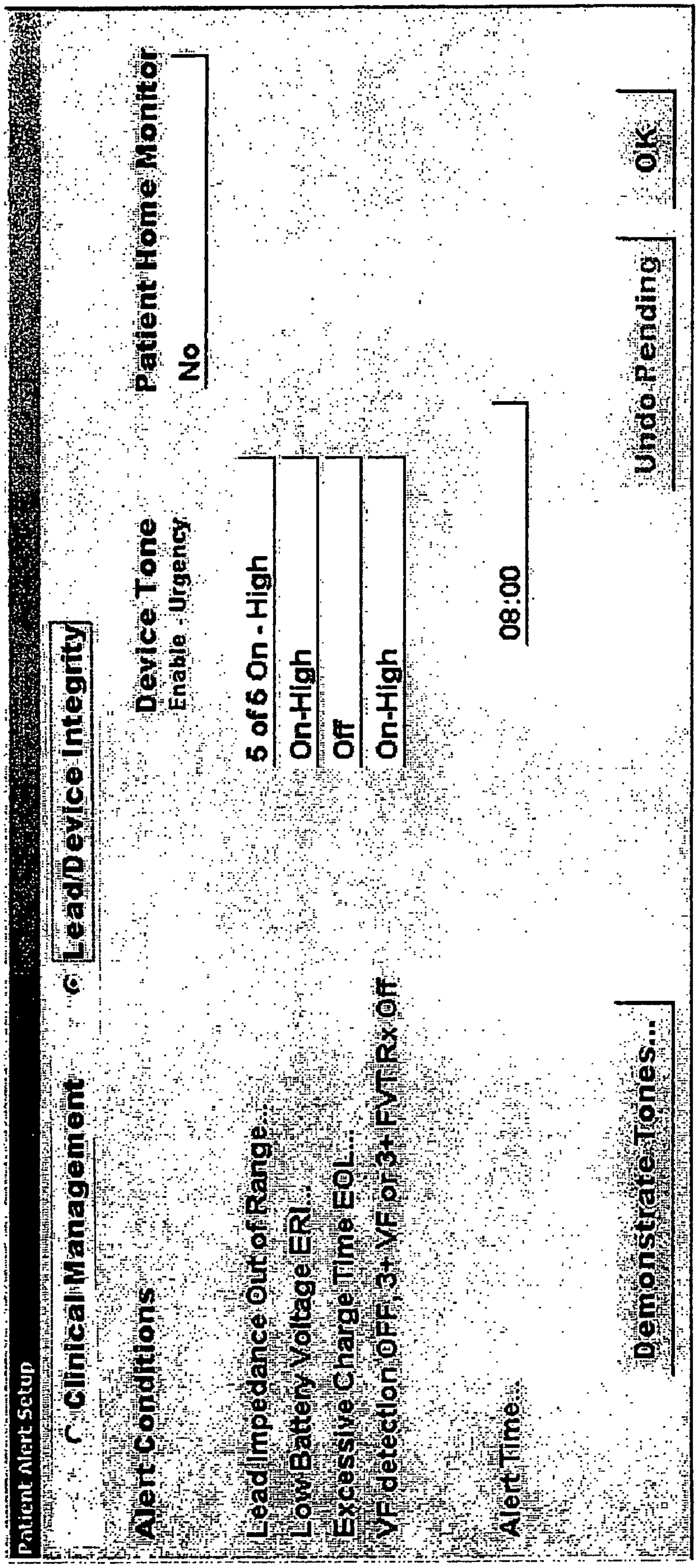

Patient Alert Setup
Clinical Management
Lead/Device Integrity
Alert Conditions
Device Tone
Enable - Urgency
Patient Home Monitor
No
Lead Impedance Out of Range...
5 of 6 On - High
Low Battery Voltage ERI...
On-High
Excessive Charge Time EOL...
Off
VF detection OFF, 3+ VF or 3+ FVT Rx Off
On-High
Alert Time...
08:00
Demonstrate Tones...
Undo Pending
OK

FIG. 10

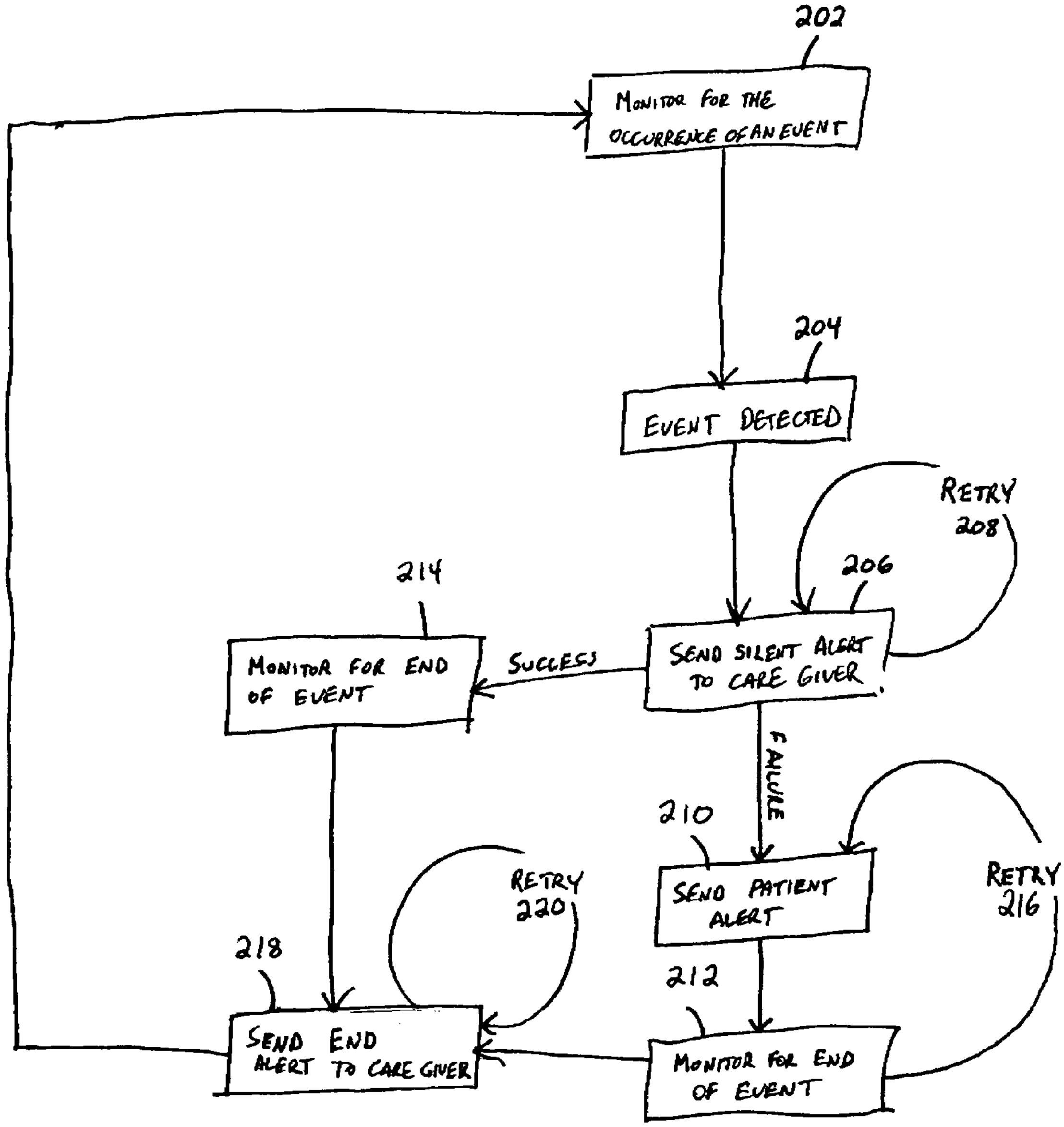

202
MONITOR FOR THE OCCURRENCE OF AN EVENT
204
EVENT DETECTED
RETRY 208
206
SEND SILENT ALERT TO CARE GIVER
SUCCESS
214
MONITOR FOR END OF EVENT
FAILURE
210
SEND PATIENT ALERT
RETRY 216
212
MONITOR FOR END OF EVENT
218
SEND END ALERT TO CARE GIVER
RETRY 220

FIG. 11

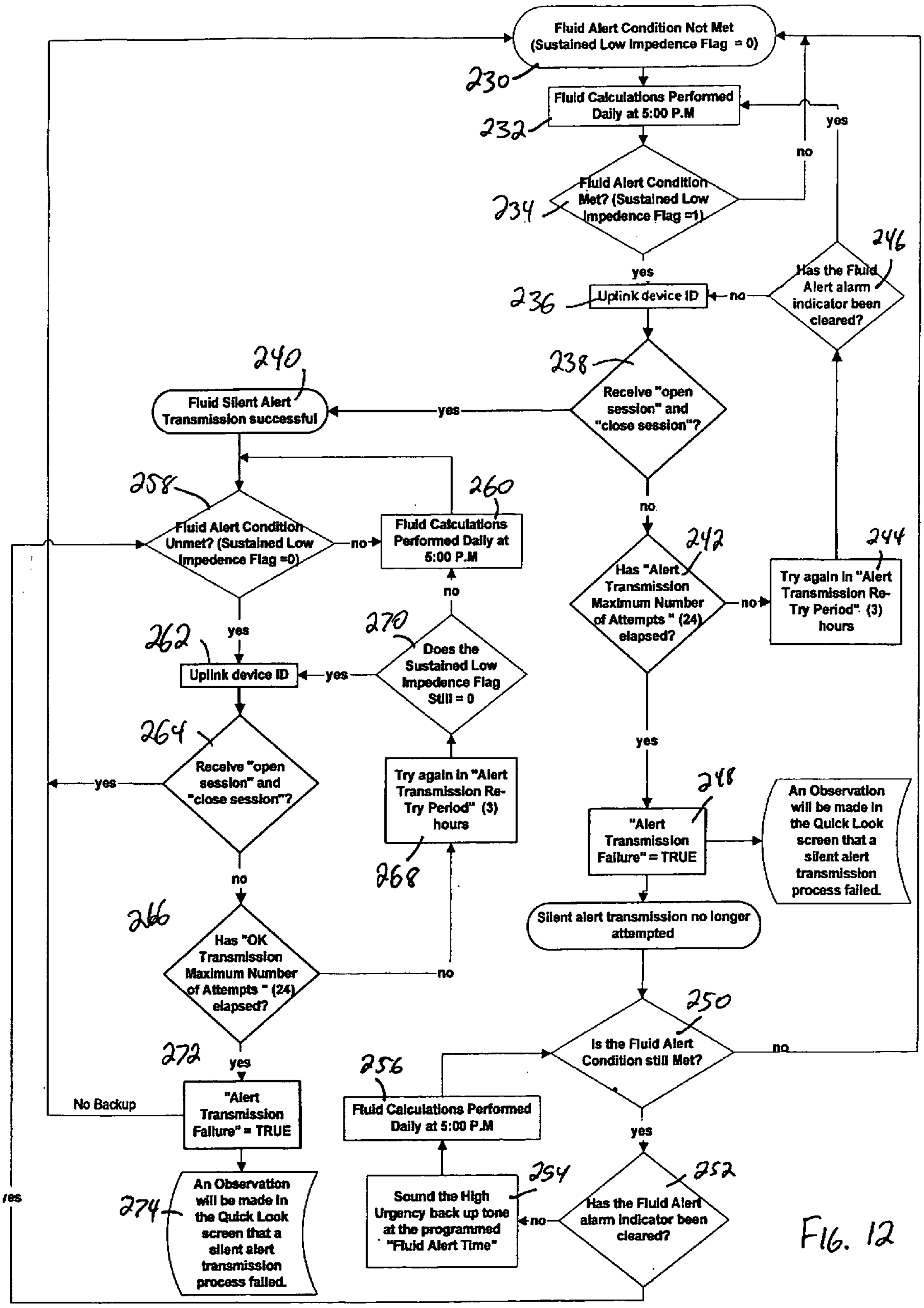

Fluid Alert Condition Not Met (Sustained Low Impedence Flag = 0)
230
Fluid Calculations Performed Daily at 5:00 P.M
232
Fluid Alert Condition Met? (Sustained Low Impedence Flag =1)
234
yes
no
Uplink device ID
236
Has the Fluid Alert alarm indicator been cleared?
246
Receive "open session" and "close session"?
238
Fluid Silent Alert Transmission successful
240
Fluid Alert Condition Unmet? (Sustained Low Impedence Flag =0)
258
Fluid Calculations Performed Daily at 5:00 P.M
260
Has "Alert Transmission Maximum Number of Attempts " (24) elapsed?
242
Try again in "Alert Transmission Re-Try Period" (3) hours
244
Uplink device ID
262
Does the Sustained Low Impedence Flag Still = 0
270
Receive "open session" and "close session"?
264
Try again in "Alert Transmission Re-Try Period" (3) hours
268
"Alert Transmission Failure" = TRUE
248
An Observation will be made in the Quick Look screen that a silent alert transmission process failed.
Silent alert transmission no longer attempted
Has "OK Transmission Maximum Number of Attempts " (24) elapsed?
266
Is the Fluid Alert Condition still Met?
250
Fluid Calculations Performed Daily at 5:00 P.M
256
"Alert Transmission Failure" = TRUE
272
No Backup
An Observation will be made in the Quick Look screen that a silent alert transmission process failed.
274
Sound the High Urgency back up tone at the programmed "Fluid Alert Time"
254
Has the Fluid Alert alarm indicator been cleared?
252

FIG. 12

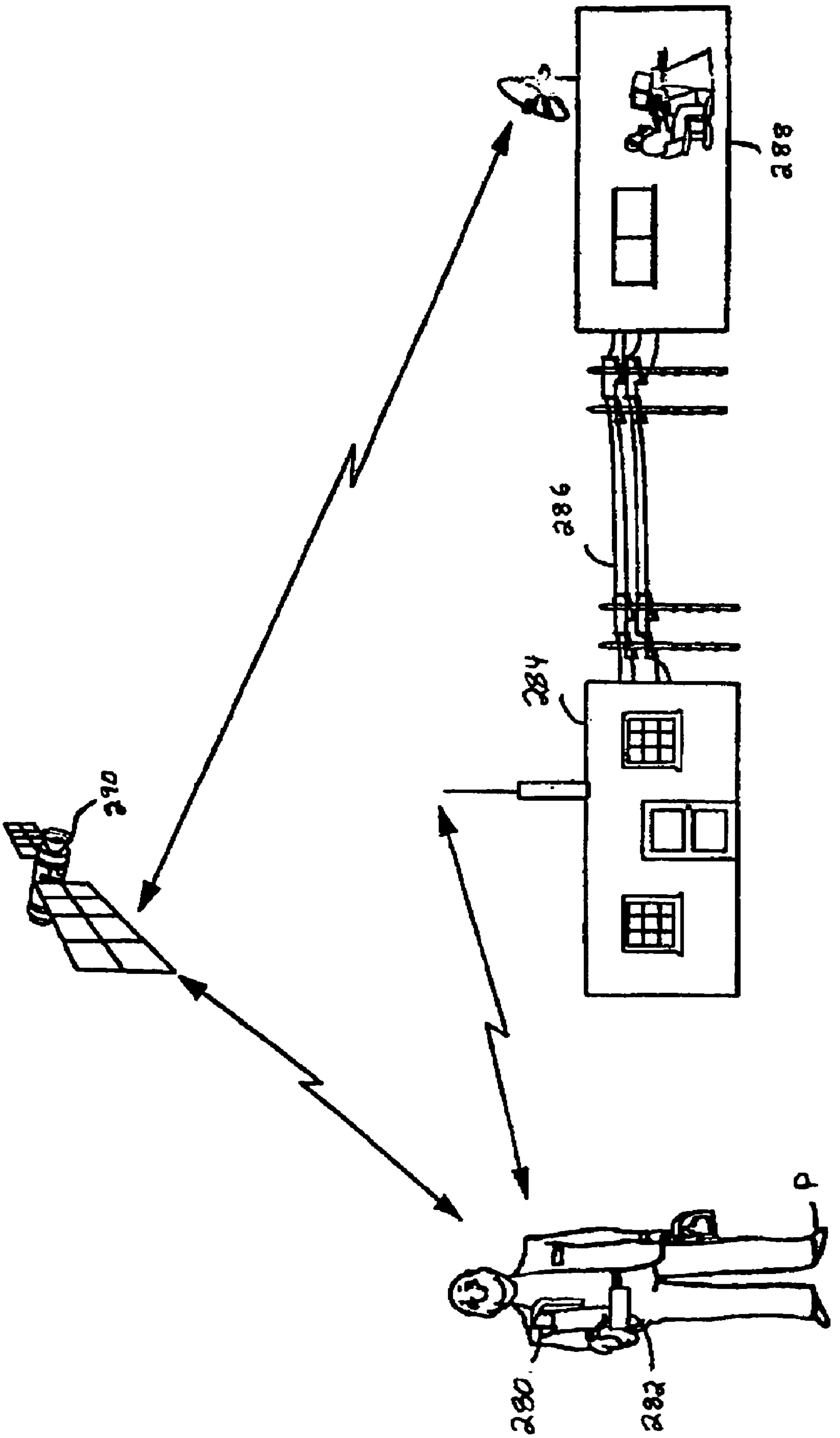


FIG. 13

ALERT SYSTEM AND METHOD FOR AN IMPLANTABLE MEDICAL DEVICE

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application claims the benefit of U.S. Provisional Application No. 60/589,250 filed Jul. 20, 2004 for "Alert System And Method For An Implantable Medical Device" by J. Willenbring, J. VanDanacker, P. Krause, J. Masoud, J. Ball, H. Vitense, S. McAdams, and D. Hooper.

INCORPORATION BY REFERENCE

[0002] U.S. Provisional Application No. 60/589,250 filed Jul. 20, 2004 for "Alert System And Method For An Implantable Medical Device" by J. Willenbring, J. VanDanacker, P. Krause, J. Masoud, J. Ball, H. Vitense, S. McAdams, and D. Hooper is hereby incorporated by reference in its entirety.

[0003] U.S. Non-Provisional application Ser. No. ______ (Atty. Dkt. P-20168.00) filed on even date for "Alert System And Method For An Implantable Medical Device" by J. Willenbring, J. VanDanacker, P. Krause, J. Masoud, J. Ball, H. Vitense, S. McAdams, and D. Hooper is hereby incorporated by reference in its entirety.

[0004] U.S. Non-Provisional application Ser. No. 10/727,008 filed Dec. 3, 2003 for "Method And Apparatus For Detecting Change In Intrathoracic Electrical Impedance" by Robert W. Stadler, et al. is hereby incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

[0005] The present invention relates to implantable medical devices, and more particularly to an alert system for an implantable medical device.

[0006] During the latter portion of the twentieth century, it became common to implant medical devices to provide therapy for a vast number of medical conditions. Such devices included electrical stimulation devices, pain control devices, and drug delivery systems. Additionally and as these devices became more complex, it became necessary to monitor both their operation and the patient's condition.

[0007] At the same time, patients with implantable medical devices (IMDs) have come to expect a fuller life post-implant. These expectations often include few, if any, restrictions on their lifestyle. Thus, patients expect a great degree of mobility while their medical condition is being monitored and/or treated by the IMD and their physician. Semi-annual or annual in-office checkups for the IMD and the patient limits the frequency of monitoring. Moreover, the patient feels that he or she must remain close to the care giver's clinic or the hospital where checkups take place. Further, emergency situations may sometimes occur which, in the mind of the elderly patient, demand a very close proximity to the attending care giver. Going to the clinic for frequent check-ups may impose a considerable burden on the patient as well as an overall increase in the cost of healthcare. Accordingly, some IMDs are equipped with a communication system that connects to an interface in such a manner that it is transparent to the patient and yet provides the medical data required by the care giver.

[0008] Until recently, data transmission systems within IMDs were only capable of transferring data over a very small distance. Recent advances in wireless telemetry systems, often utilizing radio frequency (RF) systems, have opened the door to a whole host of new technologies. These technologies are reducing the burden on patients to perform routine tasks and are allowing patients to live with greater freedom and fewer restrictions on their lifestyle. However, there still exist multiple ways in which wireless telemetry systems can be utilized to further enhance the freedom of patients and the quality of care that they receive.

[0009] Patient interaction is often required in prior IMDs at the occurrence of an event. For example, an alarm system creates an audible alarm to alert the patient to the occurrence of an event. The patient then must either initiate a transfer of data to the care giver over the telephone or like systems or must immediately contact a care giver who can assess the situation. A patient who is relying on the therapy of an IMD can become very distressed when an audible alarm in the IMD begins to sound. Conversely, an audible alarm may not be heard by the patient, depending on the patient's hearing and environment.

BRIEF SUMMARY OF THE INVENTION

[0010] The present invention relates to an alert system and method for informing and communicating to a preceptor (e.g. patient; care giver; or interested party) the occurrence and termination of an event related to a patient. The system generally includes an implantable medical device implanted within a patient. Specifically, the implantable medical device includes means for detecting the occurrence and termination of the event, and a means for transmitting an alert signal and an end alert signal.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] **FIG. 1** illustrates an embodiment of the alert system of the present invention.

[0012] **FIG. 2** is a block diagram of an IMD of the alert system of the present invention.

[0013] **FIG. 3** is a block diagram of a monitor of the alert system of the present invention.

[0014] **FIG. 4** is a block diagram of a patient management network of the alert system of the present invention.

[0015] **FIG. 5** is a block diagram of patient management web clients of the alert system of the present invention.

[0016] **FIG. 6** is an exemplary flow diagram illustrating a method of sending an alert signal from the IMD upon the occurrence of an event satisfying alert criteria.

[0017] **FIGS. 7 and 8** are exemplary screen shots of a user interface allowing the care giver to select clinical management alert settings.

[0018] **FIGS. 9 and 10** are exemplary screen shots of a user interface allowing the care giver to select lead/device integrity alert settings.

[0019] **FIG. 11** is an exemplary flow diagram illustrating a method of sending an alert signal when an event occurs and an all-clear signal when an event terminates.

[0020] **FIG. 12** is a more detailed embodiment utilizing an alert signal and an end alert signal.

[0021] **FIG. 13** shows an alternate communications system by which alert signals may be transmitted to a medical support network.

DETAILED DESCRIPTION

[0022] **FIG. 1** illustrates an embodiment of alert system **20** of the present invention, which communicates between patient P and care giver C. Alert system **20** includes implantable medical device ("IMD") **24** within patient P, monitor **26**, private network **27**, patient management network **28**, and patient management web clients **30** including patient browser **30***a* that is capable of displaying patient website **31***a* and care giver browser **30***b* that is capable of displaying care giver website **31***b*.

[0023] IMD **24** is, for example, a device such as a pacemaker or defibrillator that is implanted within patient P and is capable of providing cardiac therapies. These therapies may include providing pacing pulses or defibrillation shocks to the heart of patient P. IMD **24** also records useful data such as, for example, without limitation, data related to the condition of patient P, therapy delivery, device performance and functionality and periodically provides information to care giver C. IMD **24** also provides self-monitoring of the system operation (such as lead impedance data, high-voltage capacitor charge times, battery capacity, etc.). In addition, IMD **24** is capable of detecting the occurrence of an event that satisfies predefined alert criteria. The alert criteria may pertain to a clinically-relevant event or a result of self-diagnosis of the IMD that may be necessary, for example, to inform the patient or an interested person. Once an event has been detected that satisfies an alert criterion, IMD **24** is capable of providing a perceptible alert. A patient alert is a patient notification of a triggered alert criteria via an audible tone vibration, or other perceptible communication directed to the patient from IMD **24** or monitor **26**. A silent alert is a notification of a triggered alert criteria via alert system **20**, which is not perceptible to the patient.

[0024] Monitor **26** is an instrument, such as Medtronic's CareLink monitor, intended for use in a patient's home that is capable of receiving data from the patient's implanted device via telemetry and transmitting this information via phone lines or other communication platforms to private network **27** which transfers the data to patient management network **28**. Private network **27** is, for example, the IP Link service from MCI, which provides a private, secure, and reliable connection.

[0025] Patient management network **28** utilizes secure computer servers that collect, process and store data sent from monitor **26**. This information is available to patient P and care giver C through e.g., patient management web clients **30**. Patient management web clients **30** are computer systems with a browser capable of viewing web pages on the World Wide Web. At least two patient management web clients **30** are provided: a patient browser **30***a* and a care giver browser **30***b*. Patient P can access data and other information on patient website **31***a* via patient browser **30***a*. Care giver C can access data and other information on care giver website **31***b* via care giver browser **30***b*.

[0026] There are three follow-up scenarios in which care giver C can interact with IMD **24** to monitor the condition of patient P and IMD **24**: standard follow-up, remote follow-up, and ambulatory follow-up. Standard follow-up is a scheduled face-to-face interaction between patient P and care giver C in order to check the patient's health and the functioning of IMD **24**. Typically, the standard follow-up occurs every three to six months. Alert system **20** of the present invention reduces the number of standard follow-ups that need to take place. The remote follow-up is a scheduled electronic transmission of the data stored in IMD **24** to care giver C in order to check the health of patient P and the functioning of the patient's IMD **24**. Similar to the standard follow-up, the remote follow-up typically occurs every three to six months depending upon the patient's medical condition. The remote follow-up is enabled by use of monitor **26** and patient management network **28**. The ambulatory follow-up is an unscheduled and IMD-initiated electronic transmission of the data stored in IMD **24** to care giver C in order to alert care giver C to the occurrence of an event that satisfies the alert criteria and allow care giver C to check the health of patient P and the functioning of the patient's IMD **24**. It has been found that standard follow-ups are time consuming, and inconvenient for both patient P and care giver C. Ambulatory follow-ups, however, can be provided by alert system **20** of the present invention to provide many benefits.

[0027] Communication between the various components of alert system **20** will now be described. Either upon the detection of an event satisfying an alert criterion, or at a scheduled time, IMD **24** is interrogated by monitor **26** over a wireless telemetry system utilizing radio frequency (RF) signals. This interrogation provides data from IMD **24** to monitor **26**. Monitor **26** communicates the data to patient management network **28** over a standard telephone system from the home of patient P and through private network **27**. Data is then displayed to care giver C or patient P using patient management web clients **30** utilizing the standard world-wide web ("WWW") secured communication protocol (e.g. SSL).

[0028] **FIG. 2** is a block diagram of IMD **24** of alert system **20**. Although it is recognized that alert system **20** can be used with any type of implantable medical device, a specific example will now be provided in which IMD **24** is an implantable cardioverter defibrillator. IMD **24** includes leads **42**, pacing circuitry **44**, defibrillation circuitry **46**, sensors **48**, control processor **50**, telemetry processor **52**, transmitter circuitry **54**, receiver circuitry **56**, antenna **58**, speaker drive circuitry **60**, speaker **62**, and memory **64**. Control processor **50** is the primary controller for IMD **24** and thus control processor **50** controls the overall operation of IMD **24**.

[0029] Control processor **50** controls pacing circuitry **44** and defibrillation circuitry **46** to provide therapeutic electrical pulses to leads **42**. Leads **42** are preferably implanted within the heart of patient P and provide an electrically conductive path for the pulses to selected locations within the heart. In addition, leads **42** can be used by sensors **48** to detect cardiac signals in the heart. These cardiac signals are conducted through leads **42**, detected by sensors **48**, and then provided to control processor **50**. If desired, control processor **50** can save the signals in memory **64**, which is preferably a type of random access memory (RAM) or flash memory.

[0030] Control processor **50** is capable of analyzing the cardiac signals received from sensors **48** and determining whether an event has occurred which satisfies an alert criterion. In addition, control processor **50** is capable of monitoring the condition of IMD **24** to determine whether an event has occurred which satisfies an alert criterion. If control processor **50** determines that such an event has occurred, it then decides, based upon care giver selectable alert settings, what type of an alert should be provided. If the care giver selectable alert settings instruct control processor **50** to provide a patient alert, an alert signal is generated and sent to speaker drive circuitry **60**. Speaker drive circuitry **60** provides the necessary electrical signal to speaker **62** to create an audible sound which alerts patient P to the occurrence of the event.

[0031] Alternatively, if care giver selectable alert settings instruct control processor **50** to provide a silent alert, then control processor **50** instructs telemetry processor **52** to transmit a wireless telemetry signal. Telemetry processor **52** then controls transmitter circuitry **54** to create a radio frequency (RF) signal that is transmitted wirelessly over antenna **58**. This signal alerts monitor **26** (**FIG. 3**) that IMD **24** is initiating communication, provided that monitor **26** is within the telemetry range of IMD **24**. In this way, IMD **24** is capable of initiating communication with monitor **26** to inform monitor **26** of the occurrence of an event that satisfies the alert criteria. Further detail of the communication between IMD **24** and monitor **26** will be provided with reference to **FIG. 3**.

[0032] IMD **24** could be utilized to provide an alert signal in response to any detectable event as well as the absence of any detectable event. In one embodiment there are six types of events, the occurrence of which care giver C may choose to be notified of. The six types of events relate to therapy delivery, arrhythmias, heart failure, system integrity, cardiac ischemia, and edema.

[0033] Therapy delivery events occur when IMD **24** provides a therapy to patient P. These therapies may include electrical stimulation, defibrillation, drug delivery, or the delivery of other agents. The alert criterion may specify, for example, that an alert should be sent for all therapies, an initial therapy, an unsuccessful therapy, a successful therapy, an attempt at providing a therapy, a delayed or aborted therapy, only after a predetermined number of therapies, a defibrillation therapy that was not able to be delivered due to an unsuccessful attempt to charge its delivery capacitor, or a defibrillation therapy that was not successfully delivered due to a short circuit present in its delivery pathway. In addition, the alert criterion may specify, for example, that an alert should be sent for a change in percentage of pacing, a change in rate responsive therapy, a change in use of therapies, or a newly detected need for a therapy.

[0034] Arrhythmic events may include, for example, a new atrial or ventricular tachycardia, a new atrial or ventricular fibrillation, a non-sustained tachycardia, an atrioventricular nodal reentry tachycardia, a premature ventricular contraction, a detected episode with no therapy programmed, a change in duration of episodes, a frequency of episodes, a rate of arrhythmia, and a presence of rapid atrial conduction to ventricle, or when there is no intrinsic rhythm detected (asystole).

[0035] Heart failure events may include edema triggers, pressure data triggers (for example, data from an implantable hemodynamic monitor such as the Medtronic Chronicle® device), heart rate variability, activity, and nocturnal heart rate changes. Edema, for example, has been found to be a strong indicator of heart failure, and can be used to detect heart failure before any other symptoms are detectable by the patient. Intra-thoracic impedance relates the volume of fluid between a pair of electrodes and thus pulmonary edema (e.g., measuring the impedance between an electrode disposed within a chamber or major vessel (e.g., superior vena cava) of a heart and an surface electrode disposed in a housing, or "can," of IMD **24** or the conductive surface of the can itself. This impedance measurement can be used to detect the amount of fluid in the lungs, and the onset of pulmonary edema. The reader should note that while the term "transthoracic impedance" is used within this document, it should be interpreted as "intra-thoracic" or "inter-thoracic" impedance (e.g., impedance measured between in-dwelling electrodes disposed in or about the thoracic cavity of a subject). The impedance measurements may occur among one or more subcutaneous electrodes, endocardial electrodes, epicardial electrodes, pericardial electrodes and the like. Furthermore, while the generic term "edema" is oftentimes employed in this document, the term should be interpreted as relating more to pulmonary edema than to peripheral edema, although the onset of one form of edema can precipitate onset or increase in severity of the other form of edema.

[0036] System integrity events are events which indicate an abnormal functioning of IMD **24**. System integrity events may include a memory failure (such as with RAM), a power-on reset (POR), a charge circuit timeout, an elective replacement indicator (ERI), device hardware failure, EEPROM failure, device initialization failure, multiple microprocessor failure, capture threshold changes, sensing threshold changes, presence of far-field R wave oversensing, myopotentials, electromechanical interference (EMI), T-wave oversensing, pacemaker modes of VOO or DOO on for more than a predetermined amount of time, device detection off or therapy off, device has not had telemetry session in a predetermined amount of time, no superior vena cava lead when active can is off, and an excessive number of non-physiologic ventricular or atrial intervals.

[0037] An ischemia event is a deficiency of blood in tissue, usually due to functional constriction or actual obstruction of a blood vessel. An example of an ischemia event is cardiac/myocardial ischemia which is a deficiency of blood supply to areas of heart tissue.

[0038] **FIG. 3** is a block diagram of monitor **26** of alert system **20** of the present invention. Monitor **26** includes short-range (e.g., programming head) communication system **70**, longer-range wireless communication system **72**, patient alerts **74**, control switches **76**, digital signal processor ("DSP") **78**, real-time clock ("RTC") **80**, memory **82**, modem **84**, and power supply **86**. Short-distance communication system **70** includes antenna **88**, receiver circuitry **90**, and transmitter circuitry **92**. Wireless communication system **72** includes wireless antenna **94**, wireless transmitter circuitry **96**, and wireless receiver circuitry **98**. Patient alerts include speaker **100**, speaker drive **102**, light-emitting diodes (LEDs) **104**, and LED drive **106**. Control switches **76** include start switch **108**, and reset **110**. Memory **82** includes SDRAM **112** and flash **114**. Modem **84** includes digital data access arrangement ("digital DAA") **116**, isolation **118**, line side DAA **120**, RJ11 ports **122** and **124**, tone/pulse select **126**, and prefix select **128**. Power supply **86** includes DC power **130**, reverse polarity protection **132**, overcurrent protection **134**, digital voltage power supplies **136**, and DC outputs **138** and **140**.

[0039] Monitor **26** is located within the home or in the vicinity of where patient P is present. In addition, multiple monitors could be located at different places to allow communications with IMD **24** through any one of the monitors. Monitor **26** is capable of longer-distance wireless communication with IMD **24** via wireless communication system **72**. Short-distance communication system **70** is also provided to enable communication with implantable medical devices which utilize the short-distance head-based communication systems.

[0040] Antenna **88** of short-distance communication system **70** is preferably a dual opposing coil RF read head which is used to transmit data during downlinks and receive data during uplinks. Short-distance receiver circuitry **90** amplifies, filters, and digitizes the received data signal before sending it to DSP **78**. Short-distance transmitter circuitry **92** receives logic level signals from DSP **78** and converts them to a higher current drive signal for RF read head antenna **88**. Transmitter circuitry **92** properly tunes the antenna to the appropriate frequency for transmission. Short-distance transmitter circuitry **92** is also capable of being disabled to isolate it from antenna **88** so that it does not affect the receive circuitry during receive mode.

[0041] Wireless communication system **72** provides the capability of communicating with IMD **24** using wireless telemetry with RF signals. Wireless antenna **94** includes two separate antennas to provide spatial diversity. It is tuned to a nominal wireless telemetry carrier frequency with sufficient bandwidth to accommodate the entire medical implant communication service ("MICS") 402-405 MHz band. Wireless transmitter circuitry **96** generates the RF downlink transmission to IMD **24** in the 403-405 MHz MICS band. Wireless receiver circuitry **98** receives and demodulates the RF uplink transmission to IMD **24** in the 402-405 MHz MICS band.

[0042] Patient alerts **74** include speaker **100** coupled to speaker drive **102** and LEDs **104** coupled to LED drive **106**. Speaker drive and LED drive are both controlled by DSP **78**. Speaker drive **102** and speaker **100** serve two functions: to generate tones to indicate an error or alert condition, and to make modem **84** audible. Speaker drive **102** multiplexes an audible tone from DSP **78** and the modem audio. Speaker drive **102** also has the ability to take a logic level signal as an input and drive the speaker at a high enough current to meet audio sound pressure level requirements. LEDs **104** are used as visual indicators to give status indications to patient P or (care giver C) during an interrogation and modem connection. LEDs **104** also alert patient P to power status and completion of uploaded data to the server. Light from LEDs **104** is transferred to a user interface overlay via injection molded optical light pipes. LED drive **106** accepts a logic signal from DSP **78** or digital DM **116** and drives LEDs **104** at a higher current. Switches **76** provide buttons which allow patient P to interact with monitor **26**. Switches **76** include start switch detection **108** and reset **110**. Start switch **108** allows patient P to instruct monitor **26** to begin an interrogation of IMD **24**. Reset **110** allows patient P to reset monitor **26** to factory defined settings.

[0043] DSP **78** is responsible for the majority of the functions of monitor **26**. It encodes and transmits data for both short-distance and wireless downlink transmissions, and decodes digitized data from the corresponding receiver circuitry **90** or **98** during uplink transmissions. DSP **78** is also used to implement a soft modem and directly interfaces with digital DAA **116** to send data out on a phone line. DSP **78** also runs the TCP/IP, PPP, and HTTP client software on top of the modem software. All user interface functions are handled by DSP **78** including control of patient alerts **74**, as well as reading the status of tone/pulse select switch **126** and prefix select switch **128**.

[0044] Real-time clock **80** is provided in monitor **26** to keep track of the time. Both IMD **24** and monitor **26** keep track of the time so that communication can take place at predetermined times. In order to save battery power in IMD **24**, the telemetry system of IMD **24** does not remain active at all times. Instead, IMD **24** and monitor **26** have predefined communication times during which routine communication can take place. However, as described above, alert system **20** also includes the capability of IMD **24** initiated communication at any time in which an event is detected which satisfies the alert criteria.

[0045] Memory **82** includes SDRAM **112** and flash **114**. SDRAM **112** is used to store interrogation data from IMD **24** as well as program code and other program-related data. Flash **114** is used to store program data and any parameters that need to be stored in non-volatile memory (e.g. phone numbers). DSP **78** boots from flash **114**.

[0046] Modem **84** includes digital DAA **116**, isolation **118**, line side DAA **120**, RJ-11 jacks **122** and **124**, tone/pulse select switch **126**, and prefix select switch **128**. Digital DAA **116** along with DSP **78** and line side interface **120** form a complete V.34 modem. As described above, DSP **78** is used to implement a soft modem and directly interfaces with digital DAA **116** to send data out on a phone line. DSP **78** also runs the TCP/IP, PPP, and HTTP client software on top of the modem software. DSP **78** also reads the status of tone/pulse select switch **126** and prefix select switch **128**. Tone/pulse select switch allows patient P to select whether dialing modem **84** should use tone or pulse dialing. Prefix select switch **128** allows patient P to select whether a prefix needs to be dialed to access an outside line, such as a number 9. Digital DAA **116** interfaces with DSP **78** through a serial interface and contains all of the control registers for modem **84** such as termination settings, clock phase-locked loop ("PLL") settings, etc. Digital DAA **116** also includes an audio output (not shown) that is coupled to speaker drive **102** that multiplexes the modem audio and the tones generated from DSP **78**. Line side DM **120** is connected directly to the phone line via RJ-11 jacks **122** and **124**. Line side DAA **120** generates DTMF signals that allow it to communicate over a telephone system to private network **27**, as well as providing several other necessary functions (overload protection, programmable terminations to generate an off-hook condition for various countries, 2 to 4 wire conversion, etc.). Modem **84** isolates the line side from the other components of monitor **26** through capacitive isolation barrier **118**.

[0047] Power supply **86** provides DC power to monitor **26**. Power supply **86** includes DC power source **130**, reverse polarity protection **132**, overcurrent protection **134**, digital voltage power supplies **136**, and DC outputs **138** and **140**. The function of power supply **86** should be easily understood by one skilled in the art and therefore will not be described in further detail.

[**0048**] Monitor **26** is a portable interrogation and data transfer tool used with IMD **24**. Monitor **26** offers the capabilities to patient P, care giver C, and service personnel of remote interrogations, data processing, reporting and follow-up to be performed when the patient is at home and the care giver is in the clinic or a location that has web-enabled capability. This remote feature allows for reduced travel and waiting time, providing prompt care to patients and better efficiencies to care givers. It also enables care givers to better manage patients and still maintain the quality of care that is warranted in the marketplace. Furthermore, monitor **26** allows field representatives to increase their productivity, provide equal or better service to existing and new customers worldwide, and control costs for providing the services. The increased productivity is obtained by reducing the time required for manufacturer-assisted follow-up. Monitor **26** performs four primary functions: it interrogates IMD **24** and stores the data, it collaborates with patient management network **28** to confirm the establishment of a connection with patient management network **28**, it performs any required file translation functions necessary for data transfer, and it executes the data file transfer and then collaborates with patient management network **28** to confirm that the data file transfer was successful. Although the preferred embodiment of the present invention utilizes monitor **26**, it is recognized that other devices could also be used to perform the function of monitor **26**. Examples of such devices include a telemetry transponder/repeater, a cell phone, or a Bluetooth-enabled or WiFi-enabled communication device.

[**0049**] Now that the structure of IMD **24** and monitor **26** have been described, the communications between IMD **24** and monitor **26** will be described. As explained above, care giver C and IMD **24** interact for standard follow-up, remote follow-up, and ambulatory follow-up. Of these, a remote follow-up and an ambulatory follow-up utilize monitor **26** as one of the communication links between IMD **24** and care giver C. An ambulatory follow-up occurs only when IMD **24** detects the occurrence of an event that satisfies the alert criteria and must be communicated to care giver C. A remote follow-up, on the other hand, is scheduled and expected by both IMD **24** and monitor **26**, and therefore is initiated by monitor **26**. This procedure also satisfies current FCC regulations for implantable medical device operating in the MICS band to initiate communications only if a "medical implant event" occurs. (Title 47 of the Code of Federal Regulations, Part 95.628.) The FCC has further defined the event as an occurrence that necessitates data exchange in order to maintain patient safety.

[**0050**] In any event, once communication has been established, monitor **26** performs an interrogation of IMD **24**. Control processor **50** of IMD **24** reads the desired data from memory **64** and then provides it to telemetry processor **52**. Telemetry processor **52** and transmitter circuitry **54** transform the data to an RF signal that is wirelessly transmitted by antenna **58** to monitor **26**. Monitor **26** receives the wireless transmission of data through antenna **94** and wireless receiver circuitry **98**. Receiver circuitry **98** then provides the data to DSP **78** which stores the data in SDRAM **112**. After all desired data has been received, the communication between monitor **26** and IMD **24** is closed.

[**0051**] **FIG. 4** is a block diagram of patient management network **28** of alert system **20** of the present invention. Patient management network **28** ("PMN") includes device data input and interpretation **150**, device data storage **152**, web presentation services **154**, user/web data storage **156**, and core services **158**. Device data input and interpretation **150** includes PMN device data input **160** and PMN device data conversion **162**. Web presentation services **154** include device data presentation **164** and PMN content services **166**. Core services **158** include PMN security **168**, PMN print framework **170**, PMN presentation framework **172**, and PMN administration/operational support **174**.

[**0052**] Patient management network **28** utilizes a series of secure computer servers that collect, process and store data sent from monitor **26**. This data is then made available to patient P and care giver C through Internet accessible websites that are personalized for their particular needs. The patient and care giver websites will be described in further detail with reference to **FIG. 5**.

[**0053**] After monitor **26** has completed a full interrogation of IMD **24**, it then transfers the data over a telephone line to private network **27**. One example of private network **27** is MCI's IP Link private network. Private network **27** allows monitor **26** to remotely access patient management network **28** over a private, secure, and reliable connection utilizing the hypertext transfer protocol ("HTTP"). Patient management network, which consists of a series of secure computer servers, receives the data from monitor **26** (over the private network) and into device data input and interpretation **150**, and more specifically through PMN device data input **160** which preferably includes a dedicated router. The data is then processed by PMN device data conversion **162** and stored in device data storage **152**. For example, further processing is performed by web presentation services **154** to turn the raw device data into viewable portable document format ("PDF") documents, graphs, tables, etc. and also to create client and patient personalized websites which are accessed by patient browser **30***a* and care giver browser **30***b*. This data is then stored in user/web data storage **156**. Additionally, core services **158** are performed by patient management system **28** to provide PMN security **168**, PMN framework **170**, PMN presentation framework **172**, and PMN administration/operational support **174**.

[**0054**] **FIG. 5** is a block diagram of patient management web clients **30** of alert system **20** of the present invention. Patient management web clients **30** include patient computer **176** running patient browser **30***a*, and care giver's personal digital assistant ("PDA") **177** or care giver computer **178** both capable of running care giver browser **30***b*. Patient browser **30***a* is used by patient P to access the patient website **31***a* from patient management network **28** through the world-wide web. Care giver browser **30***b* is used by care giver C to access the care giver website **31***b*.

[**0055**] Patient and care giver websites **31***a* and **31***b* are both generated by patient management network **28**. Patient website **31***a* includes: general information modules (not related to the patient's IMD data) concerning the patient's device and their disease; general ("wire feed") news items or articles containing information on medical topics of interest; psychosocial support modules designed to meet the needs of specific patient groups; access to a personalized "storefront" of products designed to meet the patient's needs; a virtual on-line community of "friends and family" that can share information and experiences with the patient; and views of IMD **24** data supplied from the device data level. Care giver website **31***b* includes the following capabilities: creation and maintenance of a patient list with various features for customization on a patient-specific basis; customized updates on products, clinical trials and research in addition to the provision of general ("wire-feed") news items or articles containing information on medical topics of interest; a route for care givers to access technical services; views of stored IMD data and alerts supplied from the device data level; and means for posting information on the site that their patients can read.

[0056] Now that the structure of alert system **20** has been described, further detail will be provided as to the operation of alert system **20** of the present invention.

[0057] **FIG. 6** is an exemplary flow diagram illustrating a method of sending an alert signal from IMD **24** upon the occurrence of an event satisfying the alert criteria. The method is intended only as an exemplary embodiment. IMD **24** begins by monitoring for the occurrence of an event (step **180**). Once an event is detected (step **182**), the system decides who should first be notified of the occurrence of the event based upon predefined alert criteria. This step is preferably performed by IMD **24**, but may also be performed by monitor **26** or patient management network **28**. If IMD **24** decides to attempt a silent alert to care giver C (step **184**), IMD **24** wirelessly transmits an alert signal to monitor **26**. If monitor **26** receives the alert signal, monitor **26** performs a full interrogation of IMD **24**, as defined above, and closes the session. Monitor **26** then transfers the data to patient management network **28**, which informs the care giver of the occurrence of the event. The system then determines whether the silent alert was successfully communicated to the care giver (step **186**).

[0058] Various methods of determining the success of the silent alert may be used. For example, monitor **26** can provide a verification signal to IMD **24** after monitor **26** has successfully transferred the data to patient management network **28**, care giver C can provide a verification signal to patient management network **28** which is then sent through alert system **20** to IMD **24**, or success can be defined as a successful transfer of data from IMD **24** to monitor **26** which would require no verification signal. If alert system **20** determines that the silent alert has been received (step **188**), it knows that care giver C will take the necessary corrective action (step **190**). If alert system **20** determines that the silent alert has failed (step **192**) (for example, if no verification signal is received in a predetermined amount of time), then IMD **24** assumes that the alert was not successfully communicated to care giver **30**. As a result, IMD **24** repeats the attempted transmission a predetermined number of times (steps **182**, **184**, **186**, and **192**). Since the most frequent cause of a failed transmission is that IMD **24** is not in range of monitor **26**, it is preferable to wait for a specified amount of time, such as three hours, before retrying the transmission. For example, IMD **24** will continue attempting communication every three hours for up to three days for a total of twenty four times.

[0059] If repeated attempts to transmit the alert signal are unsuccessful, IMD **24** will then switch to the backup alarm. In the exemplary embodiment, the backup alarm is the patient alert that includes speaker drive **60** and speaker **62**. Thus, after repeated unsuccessful attempts to wirelessly transmit the alert signal (steps **182**, **184**, **186**, and **192**), an alert signal is sent to the patient alert (step **194**). Once the patient has received the alert signal (**196**), patient P contacts care giver C (step **198**) to inform him or her of the occurrence of an event. In an exemplary embodiment, alert system **20** will continue to provide the patient alert periodically until alert system **20** verifies that the patient alert has been received. To do so, alert system **20** detects when a full interrogation of IMD **24** has been taken place, and recognizes at that point that the patient alert has been received and that care giver C will take the appropriate corrective action (step **190**).

[0060] In alternate embodiments, the patient alert may also be triggered by other situations in which the wireless transmission is considered a failure, such as: when the alert signal is not received by monitor **26**, when the interrogation of IMD **24** by monitor **26** does not complete, when patient management network **28** does not receive the interrogated data, when the care giver does not acknowledge an alert after being informed by patient management network **28**, or when the care giver does not log in to care giver website **31***b* via care giver browser **30***b* and check the patient's data after being alerted by patient management network **28**.

[0061] The present invention inherently includes software control (i.e., instructions performed by at least one computer processor) and, as applicable, the methods herein that are susceptible of being stored on a computer readable medium or being sent as control signals to affect a technical result are expressly disclosed and claimed herein.

[0062] Alert system **20** of the present invention provides a user interface in which care giver C can set the care giver selectable alert settings of alert system **20** to perform as desired. These settings define the alert criteria that are used by IMD **24** (or patient management network **28**) to determine whether or not an alert should be sent, and whether a silent alert of a patient alert should be sent. Thus, alert system **20** provides care giver C with a user interface in which he or she can select which events should initiate a silent alert, a patient alert, both alerts, or no alert at all. Table 1 is an exemplary list of care giver selectable alert conditions. It includes the alert name, a description of the alert, and the programmable condition parameters available for that alert.

TABLE 1

Care Giver Selectable Alert Conditions

ALERT NAME	DESCRIPTION	PROGRAMMABLE CONDITION PARAMETERS
Lead Impedance Out of Range	A measured lead impedance trend value has exceeded the acceptable range set for the lead.	Independently enabled for each lead: If enabled, Minimum and Maximum Impedances.
Low Battery Voltage	The elective-replacement-indicator (ERI) battery voltage condition occurs for three consecutive days, excluding days when high voltage charges took place.	Enable/disable

TABLE 1-continued

Care Giver Selectable Alert Conditions

ALERT NAME	DESCRIPTION	PROGRAMMABLE CONDITION PARAMETERS
Excessive Charge Time	Charging performance of device has met ERI indicator for charge time.	Enable/disable
VT/VF Therapies Exhausted	A ventricular tachyarrhythmia occurred which required delivery of all enabled therapies for the zone and failed to terminate the arrhythmia.	Enable/disable
Number of Ventric-ular CV or Defibril-lation Shocks	The programmable number of shocks, or more, were delivered for a single VT/VF episode.	Enable/Disable and Number of Shocks
VF Therapy Disabled	The device is not in session and six hours have elapsed since the last programming and one or more of the following conditions still exist: VF detection has been disabled, or more than two VF Therapies have been disabled, or FVT is enabled to 'via VF' and more than two FVT therapies have been disabled.	Enable (High Urgency Only)/ Disable
High Threshold	The measured threshold for the chamber is at 5 V for 1 day.	Independently Enabled for each paced chamber
AT/AF Burden	The cumulative time that the patient has been in AT/AF in a given day (since midnight) has exceeded the acceptable duration as set by the care giver.	Enable/Disable: Time in AT/AF Threshold
Fast V Rate during AT/AF	The patient has a mean ventricular rate while in AT/AF that has exceeded the acceptable rate threshold, and AT/AF has occurred for a minimum, cumulative duration as selected by the care giver (may be a different duration than AT/AF Burden duration). Determined on a per day basis.	Enable/Disable: Ventricular Rate while in AT/AF Threshold and Min. Time in AT/AF Threshold
Thoracic Fluid Overload Alert	The fluid index exceeded the threshold, indicating possible thoracic fluid accumulation in the patient.	Enable/Disable, Threshold, Alert Time

[0063] Alert system **20** not only allows care giver C to enable or disable the alert conditions, but also allows care giver C to select the response to each condition. If care giver C selects the alert mode to be "audible," the alert method is set as a patient alert. If care giver C selects the alert mode to be "silent," the alert method will be a silent alert. Finally, if the user selects the alert mode to be "audible+silent," both methods of notification will be used.

[0064] Additionally, a number of abnormalities always produce a notification and cannot be disabled by care giver C. These relate to catastrophic conditions requiring immediate follow-up and are shown in Table 2.

TABLE 2

Non-Programmable Alert Conditions

ALERT NAME	DESCRIPTION	PROGRAMMABLE CONDITION PARAMETERS
Power-On Reset (POR)	A POR has occurred	No selectable parameters
CPU Lockout	The device has entered the CPU Lockout state	No selectable parameters
Charge Time-out	An attempt to charge the high voltage therapy capacitors has aborted due to a time-out	No selectable parameters
Incorrectly Configured Defibrillation System	The case electrode is disabled as a high voltage therapy electrode and there is no acceptable impedance for a defibrillation pathway	No selectable parameters
Permanent Asynchronous Mode	The programmed pacing mode was asynchronous at midnight of the device clock, and still asynchronous at the alert alarm time	No selectable parameters

[0065] **FIGS. 7-10** are exemplary screen shots of user interface **210** allowing care giver C to select care giver selectable alert settings. **FIGS. 7 and 8** show clinical management alert settings and **FIGS. 9 and 10** show lead/device integrity alert settings. **FIG. 7** shows the dual-column clinical management alert settings that are available when "Patient Home Monitor" is set to "Yes" (enabled). **FIG. 8** shows the single-column clinical management alert settings that are available when "Patient Home Monitor" is set to "No" (disabled). Similarly, **FIGS. 9 and 10** show the lead/device integrity alert settings that are available when "Patient Home Monitor" is set to "Yes" or "No". User interface **210** provides a plurality of menus and sub-menus through which care giver C can select the desired alert settings. User interface **210** may be provided to care giver C in a number of different embodiments. In a first exemplary embodiment, user interface **210** is provided on a programmer for IMD **24**. A programmer for an implantable medical device is well known in the art and typically includes a computer-like system having a display and input devices such as a keyboard. The programmer also includes a communication device such as an RF head or a wireless telemetry system which allows the programmer to program IMD **24**. In this embodiment, user interface **210** is displayed on the display of the programmer, such that care giver C is able to select the desired alert settings. After care giver C has selected the desired settings, the programmer programs the settings into IMD **24**.

[0066] In a second exemplary embodiment, user interface **210** is provided by patient management system **28**. In this embodiment, user interface **210** is displayed to care giver C as a part of care giver website **31***b*. Care giver C is able to select the desired alert settings through care giver website **31***b* and then save them to patient management network **28**. Patient management network **28** then initiates communication through private network **27**, and monitor **26** to IMD **24** where the care giver selectable alert settings are stored in IMD **24**.

[0067] To select the desired settings, care giver C first selects the type of settings that he or she wishes to set:

Clinical Management Alerts (**FIGS. 7 and 8**) or Lead/Device Integrity Alerts (**FIGS. 9 and 10**). Clinical Management Alerts relate to events involving the condition of patient P, while Lead/Device Integrity Alerts relate to events involving the condition of IMD **24** and attached leads.

[0068] The user interface provides the option of enabling or disabling care giver-selectable settings for the interaction between IMD **24** and monitor **26** altogether. This feature accommodates those patients that do not have a monitor. Care giver C selects whether monitor **26** should be enabled or disabled by selecting the "Patient Home Monitor" field and selecting "Yes" or "No." If care giver C selects "Yes" then care giver-selectable silent alert options are enabled (**FIGS. 7 and 9**). If care giver C selects "No" then all silent alert options are disabled (**FIGS. 8 and 10**).

[0069] The desired settings are then selected from the menu and sub-menus as desired. For example, if care giver C wants to be alerted to an atrial tachycardia within patient P that exceeds a certain duration or exceeds a certain rate, care giver C would select the option that reads "AT/AF Burden and Rate Settings . . . " Care giver C would then be provided with a sub-menu in which he or she could select the type of alert desired, the urgency of the alert, and the duration or heart rate at which the alert would trigger. In addition, care giver C is also able to select the specific time of the day in which a patient alert ("device tone") is provided by selecting "Alert Time . . . " Alert settings for Lead/Device Integrity Alerts are similarly chosen through the menus as shown in **FIGS. 9 and 10** and additional sub-menus.

[0070] **FIG. 11** is an exemplary flow diagram illustrating a method of sending an alert signal when an event occurs and an end alert signal when an event terminates. This method of providing alert signals allows a care giver to be notified not only of when an event begins, but also when that same event comes to an end.

[0071] The process of detecting an event and sending an alert signal remains the same as that previously described. IMD **24** monitors for the occurrence of an event (step **202**). Once an event is detected (step **204**), IMD **24** transmits a silent alert to the care giver (step **206**). If the silent alert is unsuccessful, IMD **24** retries the transmission a predetermined number of tries (step **208**). If the silent alert is still unsuccessful, IMD **24** activates the patient alert (step **210**).

[0072] At this point, either the silent alert has been sent to care giver C, or the patient alert has been provided to alert patient P. IMD **24** then continues monitoring this event to detect the end of the event (steps **212** or **214**). Meanwhile, if a patient alert was provided (step **210**), this alert can be repeated periodically (step **216**) to ensure that patient P has become aware of the occurrence of the event. When the end of the event is detected, IMD **24** transmits an end alert signal (step **218**) in the same way that the alert signal was previously transmitted. If the transmission of the end alert signal is unsuccessful, IMD **24** retries the transmission (step **220**). When the end alert signal is successfully transmitted, care giver C is notified that the event has terminated, in the same way that care giver C was notified of the occurrence of the event.

[0073] In an embodiment of the present invention, sensors **48** of IMD **24** (shown in **FIG. 2**) include a transthoracic impedance sensor. The transthoracic impedance sensor is used to measure the impedance between a lead in a chamber of the heart and the can of IMD **24**. This impedance measurement can be used to detect the amount of fluid in the lungs, and the onset of edema. Edema has been found to be a strong indicator of heart failure, and can be used to detect heart failure before any other symptoms are detectable by the patient. Once edema has been detected, care giver C may choose to make use of one of a number of possible therapies. These therapies may include electrical stimulation from IMD **24** or medications.

[0074] The onset of edema can be detected by measuring the transthoracic impedance and comparing this to a threshold value or a normal range of values. The threshold value can be selected by a user, or set dynamically by IMD **24**. The dynamic settings are provided by monitoring the patient over a period of time and determining the normal fluctuations in transthoracic impedance. The normal range, or a minimum threshold value is then calculated.

[0075] In any event, IMD **24** continues to monitor the transthoracic impedance, to determine whether the therapy is successful. If the therapy is successful, IMD **24** will detect a decrease in the transthoracic impedance, which indicates that the amount of fluid in the lungs has been reduced. Once the impedance measurement is reduced below a predetermined threshold value, IMD **24** provides end alert signal to the physician to inform the physician that the therapy has been successful.

[0076] **FIG. 12** shows a more detailed embodiment utilizing an alert signal and an end alert signal. This embodiment is described with reference to a transthoracic impedance sensor to detect the onset and termination of edema. However, it is recognized that the embodiment is equally useful and applicable for sensing any other detectable event. For example, care givers will likely find the present invention particularly useful for monitoring events in which the time between onset and termination of the event is a relatively long period of time, such as one day or more. Detectable events such as reduced transthoracic impedance, out of range blood pressure, glucose level excursions, neurological events, empty reservoir in a drug infusion device, out of range electrolytes or protein levels are all examples of detectable events in which a physician will not only want to know when the event occurs, but also when the event terminates, often as a result of drugs or other therapies, or interaction from the patient or a care giver. It is also recognized that mathematical calculations may be performed on any, or a combination of, sensed levels or events, the result of these calculations being compared to a threshold value or range of values to determine whether an event has occurred or terminated.

[0077] The method begins with the fluid alert condition not met (step **230**). At this point a sustained low impedance flag in IMD **24** is set to "0" to indicate that the transthoracic impedance is above a threshold value. Fluid calculations are then performed periodically (step **232**). For example, the fluid calculations may be performed daily at a predetermined time such as 5:00 p.m. Alternatively, in order to account for daily fluctuations in transthoracic impedance these measurements may be taken periodically throughout the day, for example twenty measurements may be spread out through the day between a period of noon until 5:00 p.m.

[0078] At the end of the period the measurements are compared to a threshold value set by care giver C. If the transthoracic impedance is below the predetermined threshold value the sustained low impedance flag is set to "1" to indicate that the fluid alert condition has been met (step **234**). If the transthoracic impedance is not below the predetermined threshold value the sustained low impedance flag stays set at "0" and IMD **24** continues to monitor the patient for future occurrences. If the fluid alert condition has been met (step **234**), IMD **24** then begins the process of sending a silent alert. This process begins with IMD **24** uplinking its device identification code (ID) to monitor **26** (step **236**). The device ID may also include a medical event uplink code to indicate to monitor **26** that a medical event has occurred. The device ID informs monitor **26** that IMD wishes to communicate with it. Alternatively, a communication session can be scheduled in advance such that monitor **26** initiates the communication between IMD **24** and monitor **26**. In any event, monitor **26** performs a full interrogation of IMD **24** by transmitting an open session command, receiving device data including data about the occurrence of the event, and then transmitting a close session command (step **238**). If both the open session and close session commands are received by IMD **24**, IMD **24** recognizes that the silent alert transmission was successful (step **240**).

[0079] In another embodiment of the invention, IMD **24** includes a successful session bit. The successful session bit is turned ON (set to "1") after monitor **26** successfully transmits the alert. When monitor **26** successfully transmits the alert, monitor **26** initiates communication with IMD **24** to program the successful session bit ON to inform IMD **24** that the alert has been successfully transmitted.

[0080] If IMD **24** did not receive both the open session and close session commands (step **238**) (or if the successful session bit in IMD **24** has not been programmed ON by monitor **26**), IMD **24** begins the silent alert retry process (steps **242-246** , and **236-238**) in which IMD **24** retries transmission periodically (for example every three hours) for maximum number of attempts (such as twenty-four) or a maximum amount of time (such as three days). If the retry process is unsuccessful for a predetermined maximum number of attempts (step **242**) IMD **24** recognizes that the silent alert transmission failed (step **248**). As a result, IMD **24** stores an observation note that will inform care giver C, upon the next follow-up, that a silent alert was attempted and was unsuccessful.

[0081] IMD **24** then provides a patient alert (steps **250-256**) to inform patient P that the fluid alert condition has been met. At this point IMD **24** verifies that the fluid alert condition is still met (step **250**) and verifies that the fluid alert alarm indicator has not been cleared (step **252**). If the fluid alert condition is not still met (step **250**) IMD **24** returns to monitoring patient P for a future event (step **230**). If IMD **24** determines that the fluid alert condition has still been met (step **250**) and that the fluid alert alarm indicator has not been cleared (step **252**), it then provides a patient alert such as a high urgency backup tone (step **254**). This alert may be provided immediately or at the programmed "fluid alert time." IMD **24** then continues with the patient alert retry process (steps **250-256**). The retry process will repeatedly perform fluid calculations (step **256**), determine whether the fluid alert condition is still met, whether the fluid alert alarm indicator has been cleared, and provide the patient alert if necessary.

[0082] After providing either a silent alert (step **240**) or a patient alert (steps **250-256**), IMD **24** begins monitoring for the end of the event. To do so, IMD **24** determines whether the fluid alert condition is unmet (in other words whether the sustained low impedance flag has returned to "0") (step **258**). If the event has not terminated, IMD **24** continues to monitor for the termination of the event by performing fluid calculations (step **260**) and determining whether the fluid alert condition has been unmet (step **258**). When the termination of the event is detected (such that the sustained low impedance flag is set to "0") IMD **24** begins the process of sending a silent end alert signal.

[0083] To transmit a silent end alert signal, IMD **24** uplinks its device ID (step **262**) to monitor **26**. Monitor **26** then recognizes that IMD **24** wishes to communicate with it and performs a full interrogation of IMD **24**. Alternatively, a communication session can be scheduled in advance, such that monitor **24** initiates the communication between IMD **24** and monitor **26**. In any event, monitor **26** transmits an open session command, receives the interrogation data including data about the end of the event, and transmits a close session command (step **264**). If IMD **24** receives both the open session and close session commands (or if the successful session bit has been programmed ON), IMD **24** recognizes that the silent end alert signal was successfully received and IMD **24** returns to monitoring for the occurrence of the next event (step **230**). If both the open session and close session commands are not received by IMD **24** (step **264**) (or the successful session bit has not been programmed ON), IMD **24** again begins a retry process (steps **262-270**) in which the transmission is retried periodically (such as every three hours) for a maximum number of attempts (such as twenty-four) or a maximum amount of time (such as three days). If the retry process (steps **262-270**) is unsuccessful, such that the silent end alert is not transmitted successfully, IMD **24** recognizes that the transmission of the silent end alert was not successful (step **272**). IMD **24** then makes an observation note for the care giver, such that a caregiver will be informed upon the next follow-up that the silent end alert transmission was attempted but was not successful (step **272**). IMD **24** then returns to monitoring for the occurrence of the next event (step **230**).

[0084] In an embodiment of the invention, monitor **26** includes an LED to provide a visual indicator to patient P of the occurrence of an event. The LED is turned on when monitor **26** receives the silent alert. After the event terminates, and monitor **26** receives the silent end alert signal, the LED is turned off to indicate that the event has terminated.

[0085] **FIG. 13** shows an alternate communications system by which alert signals may be transmitted to a medical support network. IMD **280** is shown as being an implantable medical device, but could alternately be external rather than implantable. External device **282** is portable and carried with patient P and communicates with IMD **280** by wireless signals. External device **282** communicates with communications link transceiver **284** by wireless signals. Transceiver **284**, in turn, communicates with medical support network **288** via telephone lines **286**. Any of a number of forms of communication of data may be used. External device **282** may also communicate with medical support network **288** via communications link satellite **290**. Once an alert is received by medical support network **288**, care giver C is notified.

[0086] Although alert system **20** of the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention. The inventors have contemplated many changes which will be readily understood by one skilled in the art. For example, the alert system includes a number of patient alert methods including a speaker in IMD **24** and a speaker and LED's in monitor **26**. Other known types of patient alerts may also be used including muscle stimulation, vibration, or olfactory stimulation (in an external device such as monitor **26**). Furthermore, multiple patient alerts may be provided such that care giver C can select the most desired alert for the particular event. Similarly, various means of alerting the care giver (or any other person) are contemplated. An alert may be provided to a device worn or nearby a care giver such as a telemetry enabled watch, home PC, public access transponder, WiFi/Bluetooth network, telephone, pager, cell phone, or displayed on a programmer during the next interrogation. Alternatively, the alert could be provided to a call center from monitor **26** or patient management network **28**, the call center having an operator who would contact the care giver. The alerts may include all information from the interrogation of IMD **24**, or it may be simply a message informing care giver C to check care giver website **31***b*. Furthermore, a silent alert may be provided to alert patient P of the occurrence of an event in the same way that a silent alert is provided to alert care giver C of the occurrence of an event.

[0087] The exemplary embodiments of the invention store the care giver-selectable alert settings in memory **64** of IMD **24**. It is recognized that the alert settings may also be stored in other locations such that other methods may be utilized. For example, care giver-selectable alert settings can be stored only on patient management network **28**. In this embodiment, IMD **24** would send an alert signal to monitor **26** upon the occurrence of any possible event. Monitor **26** would then transfer the alert to patient management network **28**. Patient management network **28** would then inform care giver C of the event only if the settings for that particular alert had been programmed ON. In another exemplary embodiment, the care giver-selectable alert settings are again stored on patient management network **28**. IMD **24** then provides an alert signal frequently (preferably more than one per day) and the patient management network **28** would inform care giver C only if an event were detected which matched an event that was programmed ON in the care giver-selectable alert settings. Although these embodiments reduce the amount of memory needed on IMD **24** (or increase the amount of memory available for other data storage), they also decrease the longevity of the battery of IMD **24** by requiring more frequent transmission of data.

[0088] Furthermore, the alert system **20** is capable of providing an alert when an event is detected by IMD **24**. It is recognized that this alert may be provided for any event which can be detected by IMD **24**, or any other device in the system, or a system in communication with any device in the system. The event may include an event internal to IMD **24** , within patient P, or external to patient P. Sensors capable of detecting the event may include any known sensor such as cardiac sensors, blood sensors, neurological sensors, a global positioning system receiver, microphones, magnetic sensors, pressure sensors, temperature sensors, impact sensors, electric or magnetic field sensors, vibration sensors, chemical sensors, light sensors, radiation sensors, etc. In addition, control processor **50** can be utilized to perform calculations, check for patterns, or otherwise process data and provide an alert based upon a predetermined criterion. Thus, it should be understood that the alert system of the present invention provides enormous possibilities for improving the safety of patients, increasing the quality of care that they receive, and increasing their quality of life.

1. An improved method of providing clinician- and/or patient-alerts indicating a termination of an event relating to a patient, wherein a prior detected occurrence of an event by an implantable medical device (IMD) wirelessly transmits an alert signal from the IMD indicating the occurrence of the event, said improved method comprising:

detecting the termination of a previously detected event with an IMD; and

wirelessly transmitting an end-alert signal from the IMD indicating the termination of the event.

2. A method according to claim 1, further comprising:

receiving the end-alert signal with a monitor;

transferring the end-alert signal from the monitor to a patient management network; and

communicating information regarding the event that occurred and terminated to at least one of a care giver, a hospital, a clinic, a clinician, the patient, said information comprising at least one of:

an event duration, an event type, a time the event started, a time the event ended, an aggregate event burden, a device intervention code, an activity sensor input for the patient.

3. A method according to claim 1, further comprising:

receiving the end-alert signal with a monitor;

transferring the end-alert signal from the monitor to a patient management network; and

communicating to at least one of a care giver, a hospital, a clinic, a clinician, the patient, that the event has terminated.

4. A method according to claim 1, wherein detecting the occurrence of the event comprises determining when a measured intra-thoracic impedance is less than a threshold value.

5. A method according to claim 4, wherein detecting the termination of the event comprises determining when a measured intra-thoracic impedance returns to a value greater than the threshold value.

6. A method according to claim 1, wherein detecting the occurrence of the event and detecting the termination of the event comprise periodically performing a physiologic measurement.

7. A method according to claim 6, wherein periodically performing the measurement comprises one of performing a measurement at a predetermined time and a predetermined date.

8. A method according to claim 7, wherein the measurement comprises an intra-thoracic impedance measurement.

9. A method according to claim 6, wherein periodically performing the measurement comprises performing a series of measurements during a predetermined range of times each day.

10. A method according to claim 9, wherein the measurement comprises an intra-thoracic impedance measurement.

11. A method according to claim 1, wherein wirelessly transmitting the end-alert signal comprises:

transmitting a device identification code;

receiving an open session command;

transmitting device data including data related to the event; and

receiving a close session command.

12. A method according to claim 11, wherein the device identification code further comprises a medical event uplink code.

13. A method according to claim 11, further comprising adjusting the status of a successful session bit of the IMD to inform the IMD that the wireless transmission of the alert signal was successful.

14. A method according to claim 1, wherein wirelessly transmitting an end-alert signal comprises:

transmitting a device identification code;

receiving an open session command;

transmitting device data including at least one of: a data set related to the end of the event, a temporal event-length, an event-type code; and

receiving a close-session command.

15. A method according to claim 1, wherein wirelessly transmitting an alert signal comprises:

transmitting a device identification code;

determining whether the device identification code was received, by monitoring for an open session command;

retrying the wireless transmission if the device identification code was not received;

transmitting device data if the device identification code was received;

determining whether the device data was received by monitoring for a close-session command;

retrying the wireless transmission if the device data was not received.

16. A method according to claim 15, wherein retrying the wireless transmission occurs after a delay.

17. A method according to claim 1, wherein wirelessly transmitting the end-alert signal comprises:

transmitting a device identification code;

determining whether the device identification code was received by monitoring for an open session command;

retrying the wireless transmission if the device identification code was not received;

transmitting device data if the device identification code was received;

determining whether the device data was received by monitoring for a close-session command;

retrying the wireless transmission if the device data was not received.

18. A method according to claim 17, wherein retrying the wireless transmission occurs after a delay.

19. A method according to claim 1, wherein the event relates to pulmonary edema excursion.

20. A method according to claim 1, wherein the event relates to a blood pressure excursion.

21. A method according to claim 1, wherein the event relates to a glucose level excursion.

22. A method according to claim 1, wherein the event relates to a neurological event.

23. A method according to claim 1, wherein the event relates to a low drug level in a drug infusion device.

24. A method according to claim 1, wherein the event relates to physiologic electrolyte concentrations.

25. A method according to claim 1, wherein the event relates to one of a protein level and a cardiac arrhythmia.

26. An improved alert system for alerting a care giver to an occurrence of an event detected by an implantable medical device, the alert system comprising:

means associated with the implantable medical device for detecting the occurrence and termination of a device- and/or physiologic-related event;

means associated with the implantable medical device for transmitting an alert signal after detection of the occurrence of the event and for transmitting an end-alert signal after detection of the termination of the event;

means for receiving the alert signal and for receiving the end-alert signal; and

means for communicating that the event has occurred, after receiving the alert signal, and for communicating that the event has terminated, after receiving the end-alert signal.

27. An alert system according to claim 26, further comprising a patient alert system for alerting the patient to the occurrence of the event.

28. An alert system according to claim 27, wherein the patient alert system is configured to begin alerting the patient to the occurrence of the event when the occurrence of the event is detected, and stops alerting the patient to the occurrence of the event when the end of the event is detected.

29. An alert system according to claim 27, wherein the patient alert system comprises a part of the implantable medical device.

30. An alert system according to claim 29, wherein the patient alert system comprises a viewable portion of a monitor.

31. An alert system according to claim 30, wherein the portion of the monitor comprises an LED that is turned on to indicate the occurrence of the event, and is turned off to indicate that the event has terminated.

32. An alert system according to claim 26, wherein the means for receiving the alert signal and for receiving the end alert signal comprises a monitor.

33. An alert system according to claim 26, wherein the means for receiving the alert signal and for receiving the end alert signal comprises a communications link transceiver.

34. An alert system according to claim 26, wherein the means for communicating to the care giver that the event has occurred and for communicating to the care giver that the event has terminated comprises a patient management network.

35. An alert system according to claim 26, wherein the means associated with the implantable medical device for detecting the occurrence and termination of the event comprises a thoracic impedance sensor.

36. An implantable medical device comprising:

a control processor for detecting a termination of a previously detected event and providing an end-alert signal; and

a telemetry system to wirelessly transmit the end-alert signal subsequent to the termination of the event.

37. An implantable medical device according to claim 36, further comprising detecting an initial occurrence of the event by determining when a measured value goes outside a normal range.

38. An implantable medical device according to claim 37, wherein detecting the termination of the event comprises determining when the measured value returns to within the normal range.

39. An implantable medical device according to claim 37, wherein the normal range is user selectable.

40. An implantable medical device according to claim 39, wherein the normal range is dynamically defined.

41. An implantable medical device according to claim 37, further comprising memory controlled by the control processor, the memory comprising a successful session bit to allow the implantable medical device to determine whether the wireless transmission of the alert signal has been successfully communicated.

42. A computer readable medium for storing instructions for a method operated under computer processor control, said method comprising an improved method of providing clinician- and/or patient-alerts indicating a termination of an event relating to a patient, wherein a prior detected occurrence of an event by an implantable medical device (IMD) wirelessly transmits an alert signal from the IMD indicating the occurrence of the event, said medium comprising:

instructions for detecting the termination of a previously detected event with an IMD; and

instructions for wirelessly transmitting an end-alert signal from the IMD indicating the termination of the event.

43. A medium according to claim 42, further comprising:

instructions for receiving the end-alert signal with a monitor;

instructions for transferring the end-alert signal from the monitor to a patient management network; and

instructions for communicating information regarding the event that occurred and terminated to at least one of a care giver, a hospital, a clinic, a clinician, the patient, said information comprising at least one of:

an event duration, an event type, a time the event started, a time the event ended, an aggregate event burden, a device intervention code, an activity sensor input for the patient.

44. A medium according to claim 42, further comprising:

instructions for receiving the end-alert signal with a monitor;

instructions for transferring the end-alert signal from the monitor to a patient management network; and

instructions for communicating that the event has terminated to at least one of a care giver, a hospital, a clinic, a clinician, the patient.

* * * * *

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摘要(译)

一种警报系统和方法，用于提供指示与患者有关的事件的发生和终止的警报。植入患者体内的植入式医疗设备检测事件的发生。接下来，从可植入医疗设备无线发送警报信号，以提供指示事件发生的警报。然后，可植入医疗设备监视事件的终止。当检测到事件的终止时，可植入医疗设备无线地发送结束警报信号以提供指示事件终止的警报。