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(54) **EMERGENCY ROOM TRIAGE SYSTEM**

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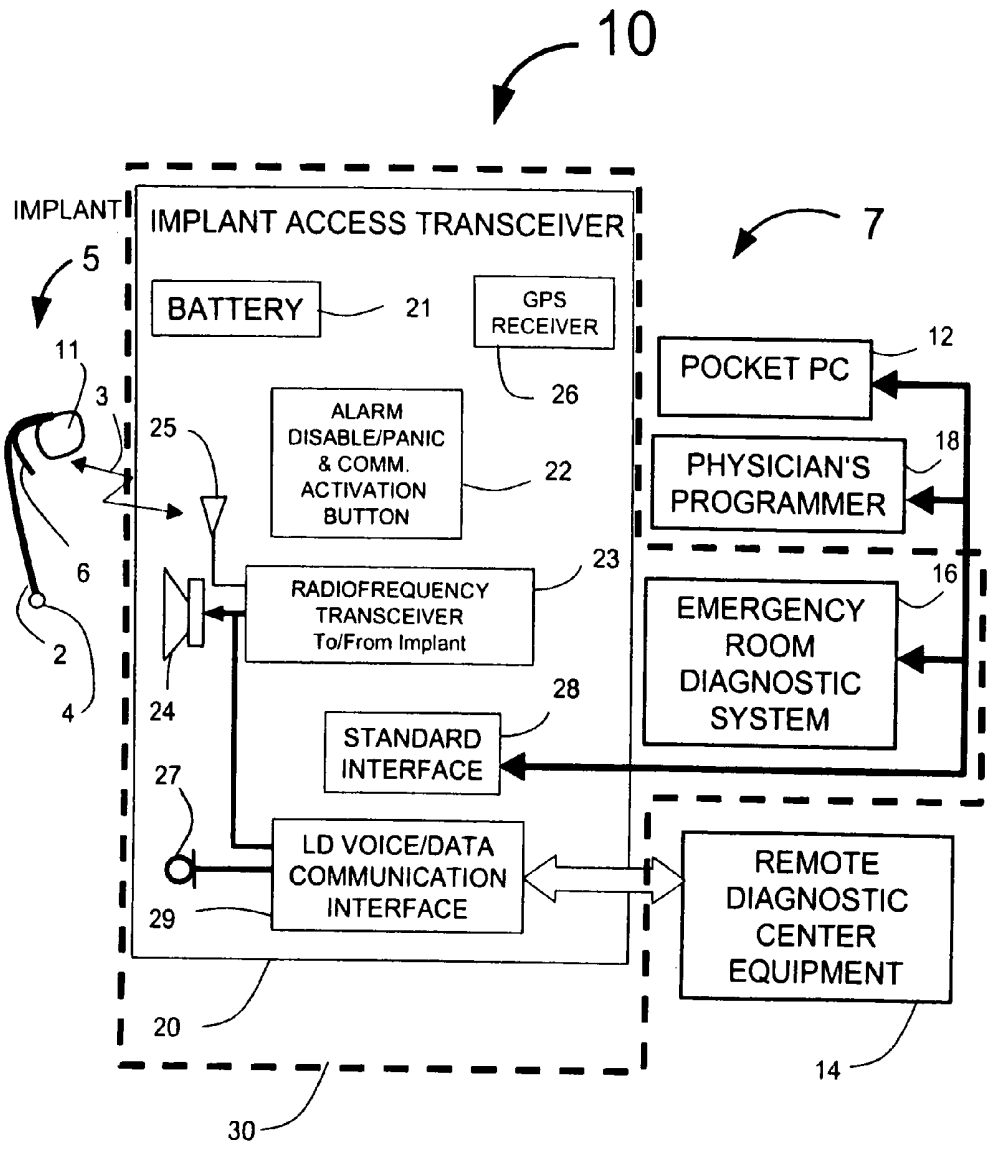
(57) **ABSTRACT**

A patient diagnostic emergency room triage system includes an implanted cardiac device which may be a cardiosaver, pacemaker or cardiac defibrillator for recording electrogram data associated with the detection of a cardiac event. A communication mechanism receives electrogram data from the implanted cardiac device and a visual display displays the electrogram data recorded by the implanted cardiac device. The visual display permits displaying electrogram data associated with an ST segment related cardiac event.



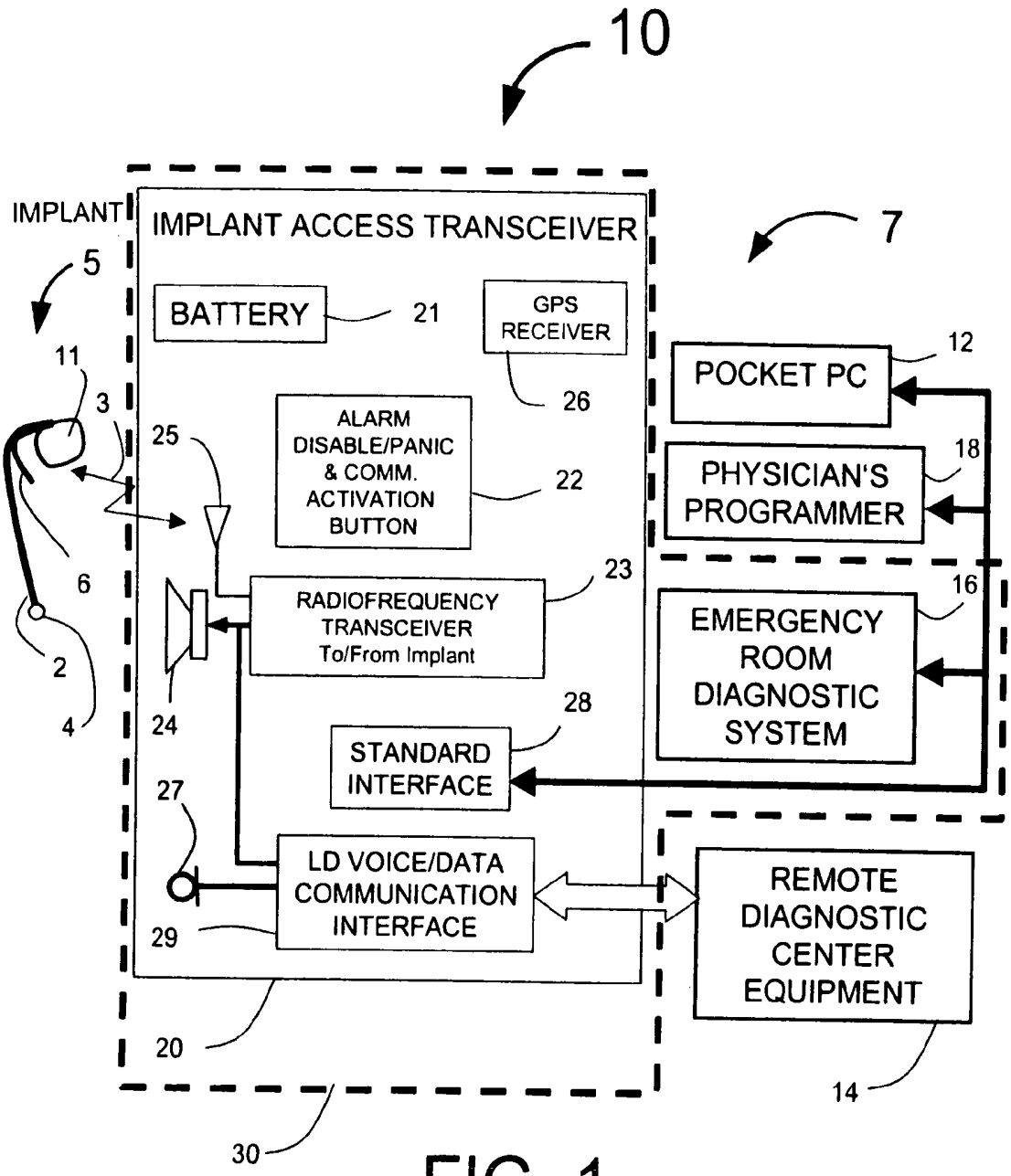

10
IMPLANT
5
IMPLANT ACCESS TRANSCEIVER
7
BATTERY
21
GPS RECEIVER
26
POCKET PC
12
PHYSICIAN'S PROGRAMMER
18
ALARM DISABLE/PANIC & COMM. ACTIVATION BUTTON
22
RADIOFREQUENCY TRANSCEIVER To/From Implant
23
EMERGENCY ROOM DIAGNOSTIC SYSTEM
16
STANDARD INTERFACE
28
LD VOICE/DATA COMMUNICATION INTERFACE
29
REMOTE DIAGNOSTIC CENTER EQUIPMENT
14
11
3
25
6
2
4
24
27
20
30

FIG. 1

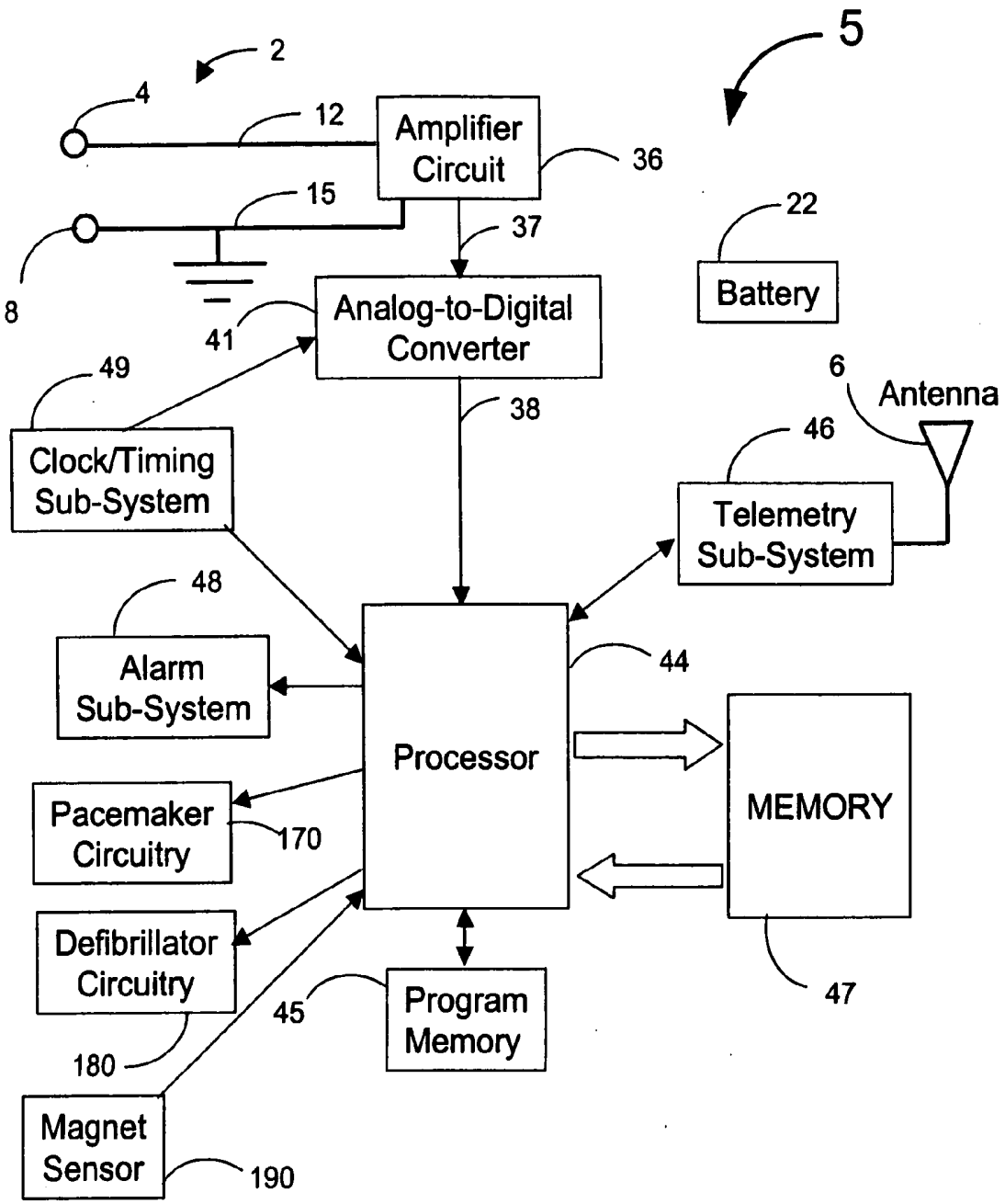

5
2
4
12
Amplifier Circuit
36
15
37
22
Battery
8
41
Analog-to-Digital Converter
49
6
Antenna
38
46
Clock/Timing Sub-System
Telemetry Sub-System
48
Alarm Sub-System
44
Processor
MEMORY
Pacemaker Circuitry
170
Defibrillator Circuitry
47
45
Program Memory
180
Magnet Sensor
190

FIG. 2

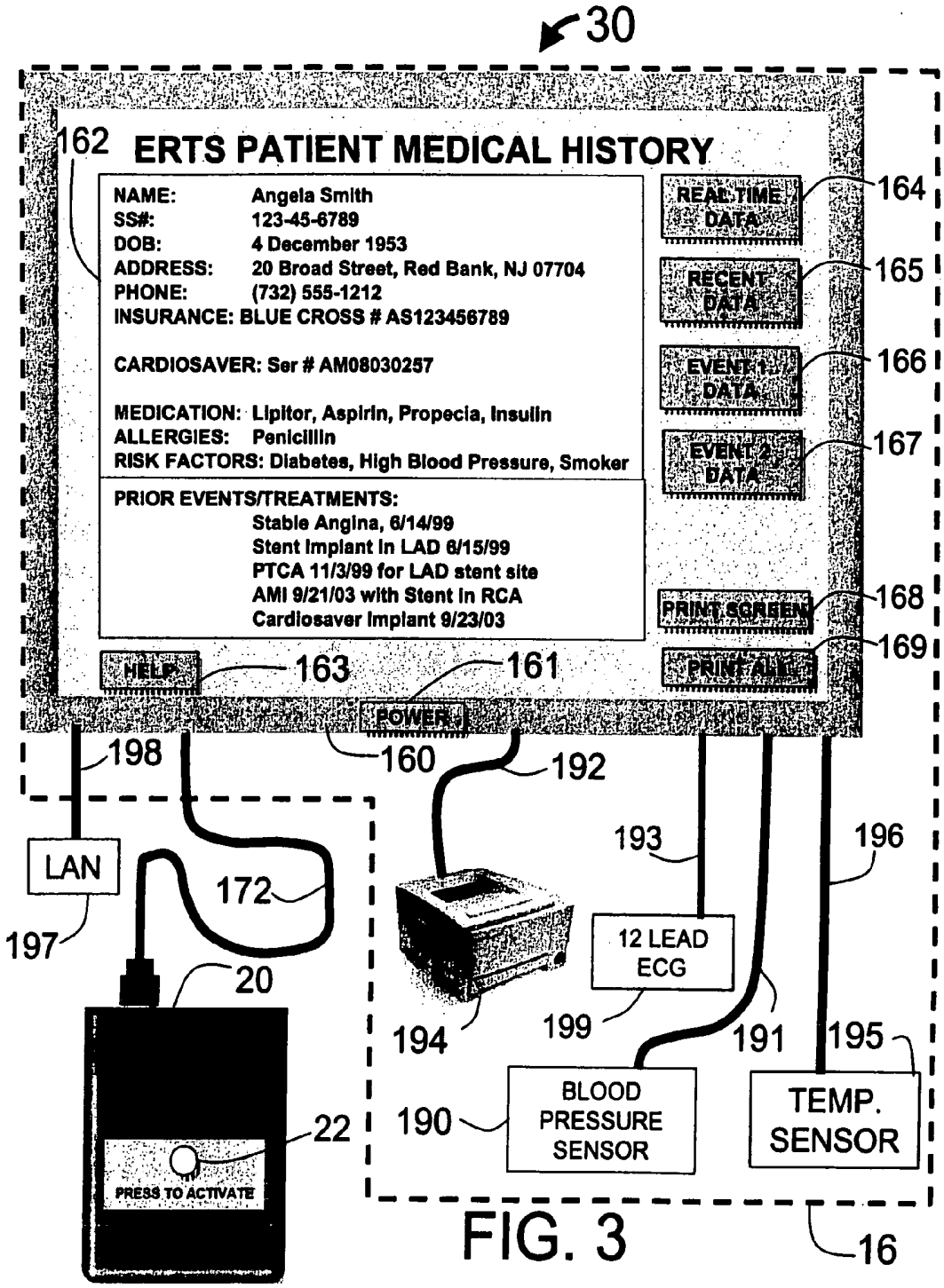

30
162
ERTS PATIENT MEDICAL HISTORY
NAME: Angela Smith
SS#: 123-45-6789
DOB: 4 December 1953
ADDRESS: 20 Broad Street, Red Bank, NJ 07704
PHONE: (732) 555-1212
INSURANCE: BLUE CROSS # AS123456789
CARDIOSAVER: Ser # AM08030257
MEDICATION: Lipitor, Aspirin, Propecia, Insulin
ALLERGIES: Penicillin
RISK FACTORS: Diabetes, High Blood Pressure, Smoker
PRIOR EVENTS/TREATMENTS:
Stable Angina, 6/14/99
Stent Implant in LAD 6/15/99
PTCA 11/3/99 for LAD stent site
AMI 9/21/03 with Stent in RCA
Cardiosaver Implant 9/23/03
REAL TIME DATA
RECENT DATA
EVENT 1 DATA
EVENT 2 DATA
PRINT SCREEN
PRINT ALL
HELP
POWER
164
165
166
167
168
169
163
161
160
198
192
193
196
LAN
197
172
20
194
199
12 LEAD ECG
191
195
190
BLOOD PRESSURE SENSOR
TEMP. SENSOR
22
PRESS TO ACTIVATE
16

FIG. 3

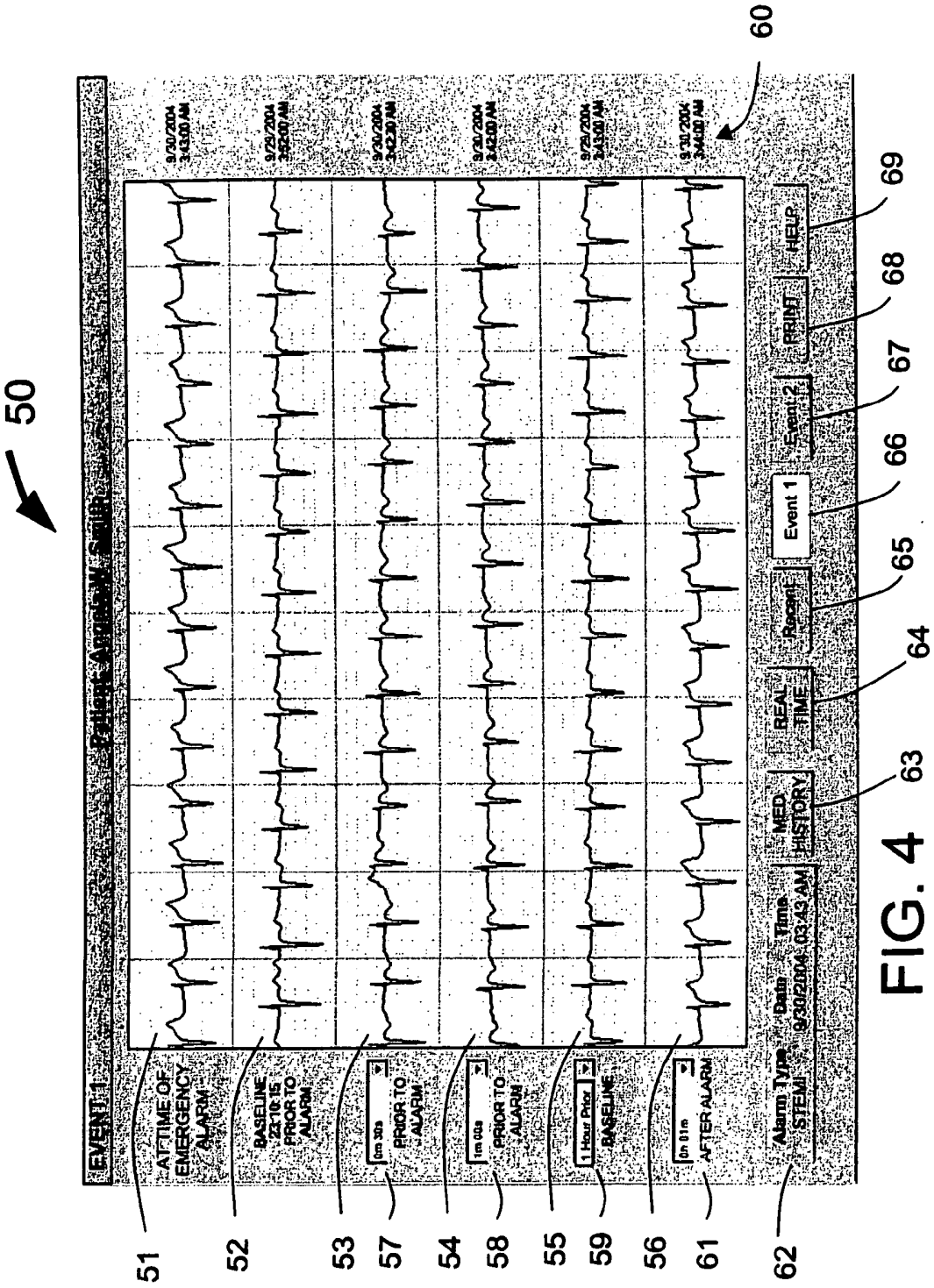

50
60
EVENT 1
AT TIME OF EMERGENCY ALARM
BASELINE 22 to 15 PRIOR TO ALARM
PRIOR TO ALARM
PRIOR TO ALARM
1 Hour Prior
BASELINE
AFTER ALARM
Alarm Type
STEMI
Date
9/30/2004
Time
03:43 AM
MED. HISTORY
REAL TIME
Recent
Event 1
Event 2
PRINT
HELP
51
52
53
57
54
58
55
59
56
61
62
63
64
65
66
67
68
69

FIG. 4

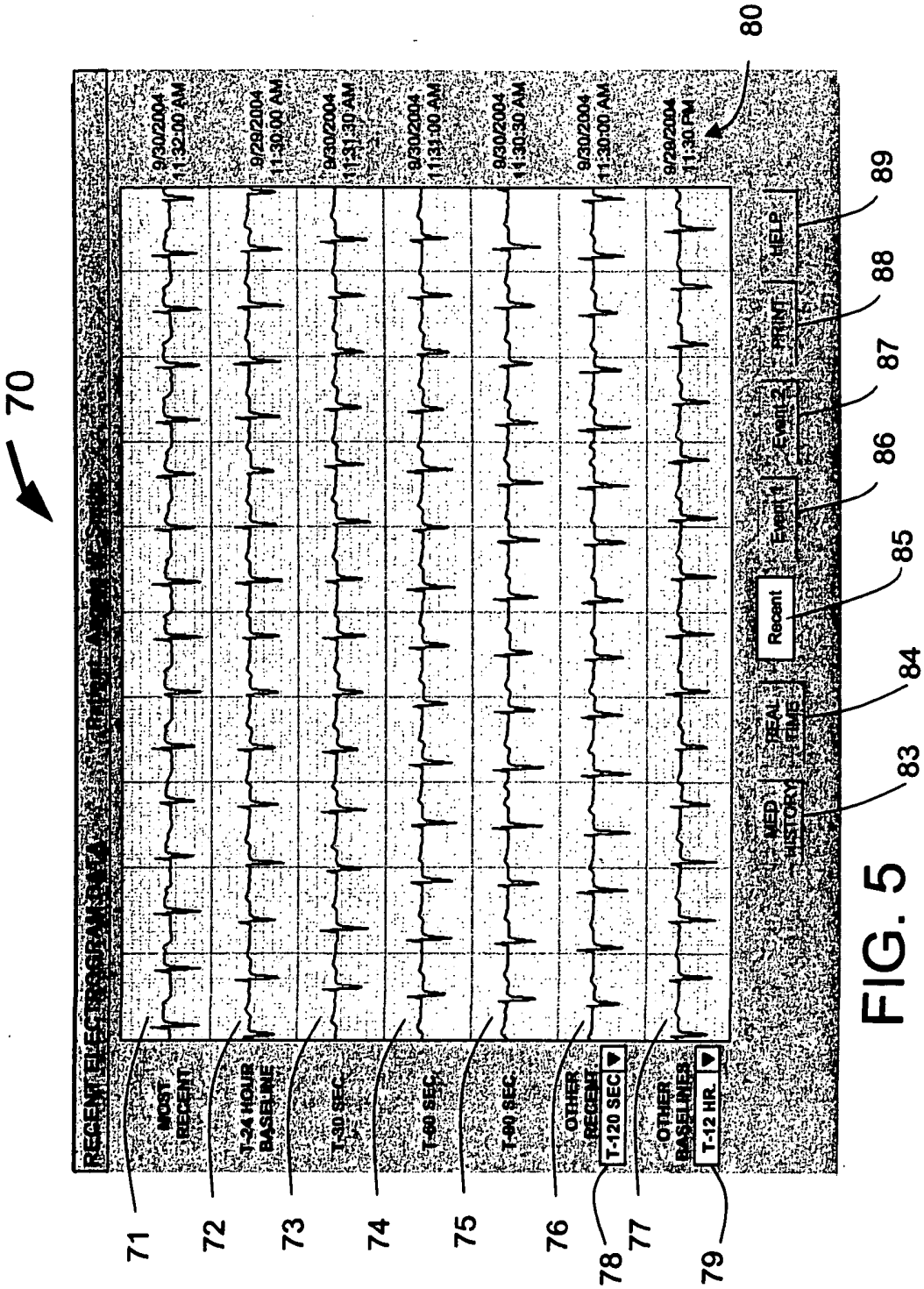

70
80
89
88
87
86
85
84
83
71
72
73
74
75
76
78
77
79
HELP
PRINT
Event 2
Event 1
Recent
REAL TIME
MED HISTORY
T-120 SEC
T-12 HR
MOST RECENT
T-24 HOUR BASELINE
T-30 SEC
T-60 SEC
T-90 SEC
OTHER RECENT
OTHER BASELINE

FIG. 5

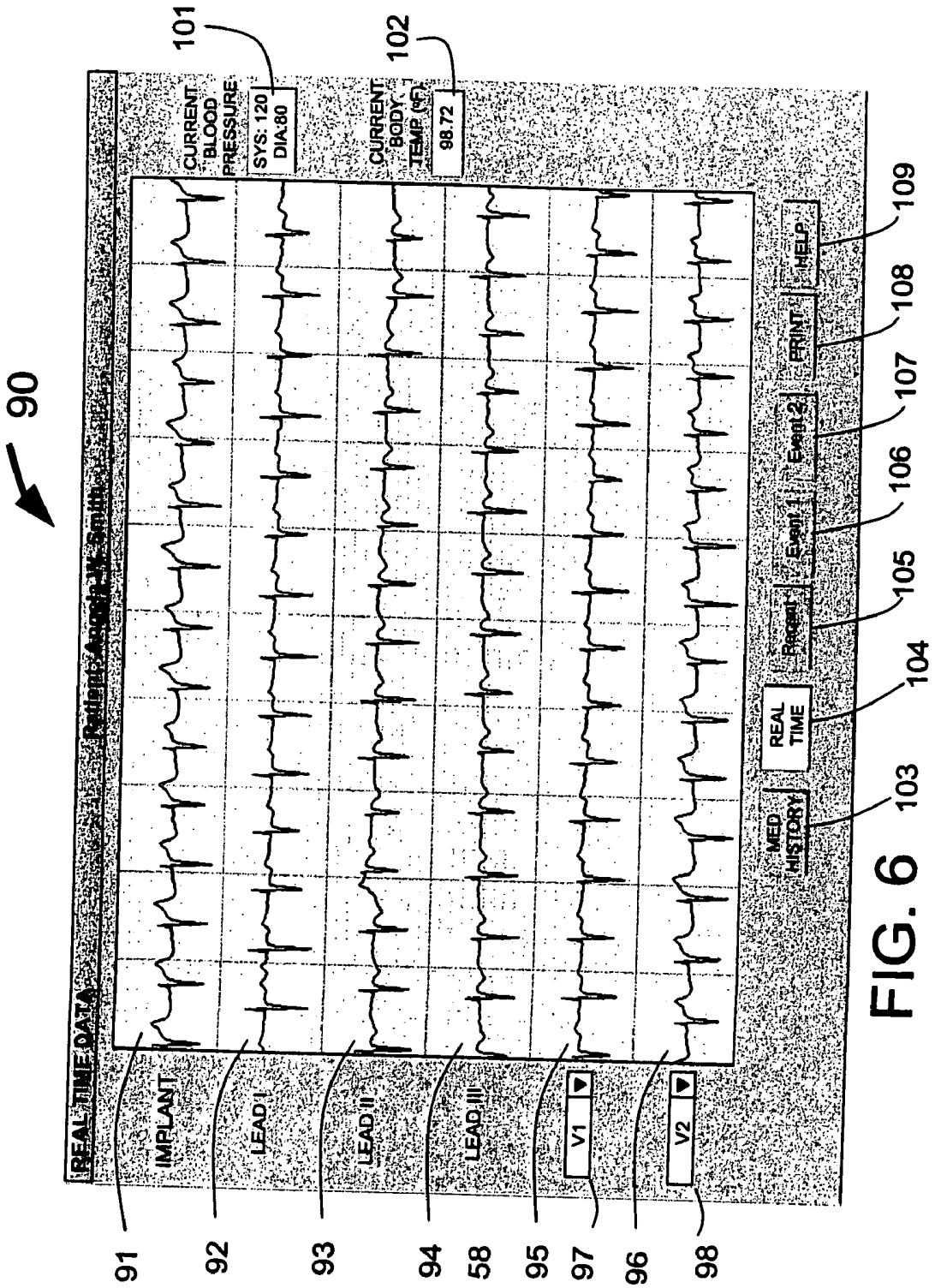

90
101
102
CURRENT BLOOD PRESSURE
SYS: 120
DIA:80
CURRENT BODY TEMP (°F)
98.72
REAL TIME DATA
IMPLANT
LEAD I
LEAD II
LEAD III
V1
V2
MED HISTORY
REAL TIME
Report
Expl 1
Expl 2
PRINT
HELP
91
92
93
94
58
95
97
96
98
103
104
105
106
107
108
109

FIG. 6

# EMERGENCY ROOM TRIAGE SYSTEM

## CROSS REFERENCE TO RELATED APPLICATION

[0001] This application is a Continuation-in-Part application of U.S. patent application Ser. No. 10/844,411, titled "Emergency Room Triage System," filed May 13, 2004, now pending.

## FIELD OF USE

[0002] This invention is in the field of systems, including devices with diagnostic capabilities implanted within a human patient.

## BACKGROUND OF THE INVENTION

[0003] Heart disease is the leading cause of death in the United States. A heart attack (also known as an acute myocardial infarction (AMI)) typically results from a thrombus (i.e., a blood clot) that obstructs blood flow in one or more coronary arteries. AMI is a common and life-threatening complication of coronary heart disease. Myocardial ischemia is caused by an insufficiency of oxygen to the heart muscle. Ischemia is typically provoked by physical activity or other causes of increased heart rate when one or more of the coronary arteries are narrowed by atherosclerosis. Patients will often (but not always) experience chest discomfort (angina) when the heart muscle is experiencing ischemia. Those with coronary atherosclerosis are at higher risk for AMI if the plaque becomes further obstructed by thrombus.

[0004] The two most significant problems faced in treating AMI are:

[0005] 1. The time delay from the onset of symptoms until arrival at a medical care facility. Currently in the United States this time delay is approximately 3 hours, and

[0006] 2. The additional time (often an hour or more) that it takes once the patient arrives at the medical care facility or emergency room until AMI is diagnosed and a therapy is provided.

[0007] Acute myocardial infarction and ischemia may be detected from a patient's electrocardiogram (ECG) by noting an ST segment voltage change and are therefore classified as ST segment related cardiac events. However, without knowing the patient's normal ECG pattern, detection from a standard 12-lead ECG can be unreliable. What is more, there is a significant time required to access a portable ECG machine, attach the leads to the patient, collect the ECG and then read and analyze the paper trace.

[0008] Fischell et al. in U.S. Pat. Nos. 6,112,116, 6,272,379 and 6,609,023 describe implantable systems and algorithms for detecting the onset of acute myocardial infarction and providing both treatment and alarming to the patient. These implantable systems include pacemakers, implantable cardiac defibrillators (ICDS) and purely diagnostic implants called cardiosavers. Fischell et al., in the above references, describes a physician's programmer as a laptop computer-like device designed to upload programming to the implant and download electrogram data collected by the implant. Also described is a hand-held computer designed to display alarm and baseline electrogram-related data. While these systems are designed to alert the patient to get him or her quickly to the emergency room, the Fischell et al. patents do not describe a means to quickly triage the patients in the emergency room to avoid the delays and inaccuracies currently found in the use of a 12-lead ECG to diagnose AMI.

[0009] Although often described as an electrocardiogram (ECG), the stored electrical signal from the heart as measured from electrodes within the body should be termed an "electrogram". The early detection of an acute myocardial infarction or exercise-induced myocardial ischemia caused by an increased heart rate or exertion is feasible using a system that can detect a change in a patient's electrogram. The portion of such a system that includes the means to detect a cardiac event is defined herein as a "cardiosaver," and the entire system including the cardiosaver and the external portions of the system is defined herein as a "guardian system."

[0010] While pacemaker and ICD programmers can download and display electrogram data, they are generally large complex machines, are not easily attached to a wall in an emergency room, and are not designed to automatically download and display ST-segment-related cardiac event electrogram data. In addition pacemakers and ICDs currently use high pass filtering that is unsuitable for use in the detection of ST segment elevation or depression. What is more, they do require extensive training to access downloaded electrogram data.

[0011] Furthermore, although the masculine pronouns "he" and "his" are used herein, it should be understood that the patient or the medical practitioner who treats the patient could be a man or a woman. Still further the term; "medical practitioner" shall be used herein to mean any person who might be involved in the medical treatment of a patient. Such a medical practitioner would include, but is not limited to, a medical doctor (e.g., a general practice physician, an internist or a cardiologist), a medical technician, a paramedic, a nurse or an electrogram analyst. A "cardiac event" can be ST segment related event such as an acute myocardial infarction or ischemia caused by effort (such as exercise). A cardiac event can also be arrhythmia. Examples of arrhythmia cardiac events include an elevated heart rate, bradycardia, tachycardia, atrial fibrillation, atrial flutter, ventricular fibrillation, and premature ventricular or atrial contractions (PVCs or PACs respectively).

[0012] For the purpose of this invention, the term "electrocardiogram" is defined to be the heart's electrical signals sensed by means of skin surface electrodes that are placed in a position to indicate the heart's electrical activity (depolarization and repolarization). An electrocardiogram segment refers to the recording of electrocardiogram data for either a specific length of time, such as 10 seconds, or a specific number of heart beats, such as 10 beats. For the purposes of this specification, the PQ segment of a patient's electrocardiogram is the typically flat segment of a beat of an electrocardiogram that occurs just before the R wave. A beat is defined as a sub-segment of an electrocardiogram segment containing exactly one R wave.

[0013] For the purpose of this invention, the term "electrogram" is defined to be the heart's electrical signals from one or more implanted electrode(s) that are placed in a position to indicate the heart's electrical activity (depolar-

ization and repolarization). An electrogram segment refers to the recording of electrogram data for either a specific length of time, such as 10 seconds, or a specific number of heart beats, such as 10 beats. For the purposes of this specification, the PQ segment of a patient's electrogram is the typically flat segment of an electrogram that occurs just before the R wave. For the purposes of this specification, the terms "detection" and "identification" of a cardiac event have the same meaning. A beat is defined as a sub-segment of an electrogram segment containing exactly one R wave.

[0014] Heart signal parameters are defined to be any measured or calculated value created during the processing of one or more beats of electrogram data. Heart signal parameters include PQ segment average value, ST segment average value, R wave peak value, ST deviation, ST shift, average signal strength, T wave peak height, T wave average value, T wave deviation, heart rate and R-R interval.

## SUMMARY OF THE INVENTION

[0015] The present invention is an emergency room triage system (ERTS) designed to facilitate rapid diagnosis of cardiac events including ST segment related cardiac events from patients with implanted cardiac devices.

[0016] The ERTS features of the present invention are applicable to cardiosavers, pacemakers and ICDs or any other implantable device having the capability to detect cardiac events. The cardiosaver is described by Fischell et al. in U.S. Pat. Nos. 6,112,116, 6,272,379 and 6,609,023 which are incorporated herein by reference. The ERTS is designed to display (and/or print) recorded electrogram data and other information downloaded from the implantable device to shorten the time from patient arrival to treatment.

[0017] Specifically, the present invention triage system includes a graphical user interface (GUI) designed to display real time and recorded electrogram data that have been downloaded from an implanted device. The recorded data include the following:

[0018] 1. Recent electrogram data recorded in the previous time period (e.g. 24 hours), and

[0019] 2. Event-related electrogram data stored following the detection by the implant of a cardiac event. Event-related electrogram data include the electrogram data whose analysis resulted in the detection and baseline electrogram data used for comparison by the detection algorithms in the implant.

[0020] 3. Trend statistical data such as histogram data that can be used to track ST segment levels over prolonged periods of time.

[0021] It is also envisioned that the cardiosaver, pacemaker, ICD and/or pacemaker/ICD combination device would have sensors for recoding of other physiological data including blood pressure, oxygen levels, blood sugar levels and temperature. Associated with such sensors, the ERTS would include the capability to display these additional data to facilitate diagnosis of the patient's condition.

[0022] Additionally, the ERTS might include external sensing instruments in the emergency room such as 12-lead electrocardiogram systems, blood pressure sensors and temperature sensors. In this way, the ERTS would begin to resemble the technology envisioned by the original STAR TREK series created by Gene Roddenberry where the sick bay diagnostic beds would display a wide range of physiological data for a recumbent patient.

[0023] It is envisioned that external sensing instruments and/or implant access transceiver **20** could be built into a diagnostic bed whereby contact with the patient and patient's implant **5** is made automatically when the patient lies down on the bed. It is also envisioned that the external sensing instruments could be embedded into patient clothes such as the hospital gown. Furthermore, it is envisioned that communication between the ERTS **30** and these external sensing instruments could be via a direct cable or a wireless connection using technologies such as Bluetooth, RF telemetry, and 802.11a-g.

[0024] The preferred embodiment of the present invention ERTS would be a touch-screen computer with an implant access transceiver that provides the RF communications link to the implant allowing implant data to be downloaded to and displayed by the touch-screen computer. The implant access transceiver may be built in or attached to the touch-screen computer. A preferred embodiment would have the implant access transceiver attached to the touch-screen computer with a connecting cable. The implant access transceiver would use long range and/or short range data communication. Purely short range data communication would be designed to work with pacemakers and ICDs having only short range telemetry where the implant access transceiver would be placed over the implant site.

[0025] Better still would be the use of long range telemetry as described by Fischell et al. in the above referenced patents. However, it may be more efficient to utilize a combination of short and long range data communication to increase the battery life of the implant. The combination of short and long range communication is the preferred embodiment of the present invention. For example, an emergency room might have the ERTS system attached to the wall next to a bed or chair or on a movable cart. An arriving patient would be put in the bed or chair, and the treating medical practitioner would place the implant access transceiver relatively close (typically within 6 inches) to the patient's implant and use the near field telemetry receiver of the implant to initiate long range data communication. The implant access transceiver could then be replaced in its location near the touch-screen computer (e.g. a cradle or a Velcro attachment). The download of data to the ERTS would then begin. Once the data are downloaded, the medical practitioner would use the GUI of the touch-screen computer (or digitizer stylus), to select the data to be displayed and could initiate printing of either the entire data set or the portion being displayed. Thus, another (optional) component of the ERTS would be a printer attached or wirelessly connected to the touch-screen computer using a standard protocol such as Bluetooth or 802.11 a, b or g.

[0026] Finally, it is always a challenge to emergency room medical practitioners to access a medical history for an incoming patient in an emergency situation. The capacity to store a patient's relevant medical history data within the implant memory and to display that history using the ERTS would also significantly reduce the time to treatment. Such medical history data could include current medications, allergies, medical insurance information, family history, prior cardiac events, etc.

[0027] As ERTS becomes widely used, it is envisioned that large numbers of patients without cardiac implants might receive a very small body-powered implant, such as those used for tracking endangered species, that would provide only the medical history data. In either case, being able to quickly display and print the patient's medical history data would also reduce the time to treatment as compared with having the patient or a family member fill out the appropriate forms.

[0028] An additional aspect of the present invention is a miniature data implant having the patient's medical history that works in conjunction with the ERTS. The data implant may be powered from the outside during data communication with the ERTS or by a power source within the patient's body including batteries, miniature fuel cells, kinetic power sources (e.g. as in a self winding watch), thermal power sources or solar power sources. It is envisioned that the miniature data implant might also contain the temperature and pressure sensors mentioned above.

[0029] Thus it is an object of this invention to have an emergency room triage system designed to automatically download and display electrogram data captured by an implanted medical device following establishment of data communication between the emergency room triage system and the implant.

[0030] Another object of this invention is to have an emergency room triage system with a touch-screen display or digitizer stylus/pen used to select the subset of electrogram data to be displayed.

[0031] Still another object of the present invention is to have an emergency room triage system having an attached implant access transceiver having only short range telemetry, both short and long range telemetry and only long range telemetry.

[0032] Still another object of the present invention is to have an emergency room triage system with an attached printer.

[0033] Yet another object of the present invention is to have an emergency room triage system that can display both recent electrogram data and cardiac-event-related electrogram data.

[0034] Yet another object of the present invention is to have an emergency room triage system that can display medical history downloaded from an implanted medical device.

[0035] Yet another object of the present invention is to have an emergency room triage system that can display histogram data downloaded from an implanted medical device.

[0036] Yet another object of the present invention is to have an emergency room triage system that will sense and display additional physiological data including, but not limited to, temperature, blood pressure, oxygen levels and blood sugar levels.

[0037] These and other objects and advantages of this invention will become obvious to a person of ordinary skill in this art upon reading of the detailed description of this invention including the associated drawings as presented herein.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0038] **FIG. 1** illustrates a Guardian system for the detection of a cardiac event and for warning the patient that a cardiac event is occurring.

[0039] **FIG. 2** is a block diagram of a cardiosaver system.

[0040] **FIG. 3** shows the components of the ERTS with the ERTS display showing the patient's medical history data.

[0041] **FIG. 4** is an example of the ERTS display of alarm related electrogram data downloaded from a cardiosaver.

[0042] **FIG. 5** is an example of the ERTS display of recent electrogram data downloaded from a cardiosaver.

[0043] **FIG. 6** is an example of the ERTS real time physiological data display.

## DETAILED DESCRIPTION OF THE INVENTION

[0044] **FIG. 1** illustrates one embodiment of the Guardian system **10** consisting of an implanted cardiosaver system **5** and external equipment **7**. The cardiosaver system **5** includes a cardiosaver **11**, an antenna **6** and an electrode **4** that is part of a lead **2**. The cardiosaver **11** includes electronic circuitry that can detect a cardiac event such as an acute myocardial infarction or arrhythmia and can warn the patient with an internal alarm signal when the event occurs. The cardiosaver **11** can store the patient's electrogram for later readout and can send and receive wireless signals **3** to and from the external equipment **7** via the antennas **6** and **25**. The wireless signals would typically use the FCC medical band (Medical Implant Communications Service) and can be implemented using a radiofrequency system such as the CC 1000 chipset from CHIPCOM as described by Fischell et al in U.S. patent application Ser. No. 10/994,466 which is incorporated herein by reference. The functioning of the cardiosaver system **5** will be explained in greater detail with the assistance of **FIG. 2**.

[0045] The cardiosaver system **5** has at least one lead **2** with at least one electrode **4**. In fact, the cardiosaver system **5** could utilize as few as one lead or as many as three, and each lead could have as few as one electrode or as many as eight electrodes. The lead **2** in **FIG. 1** would advantageously be placed through the patient's vascular system with the electrode **4** being placed into the apex of the right ventricle. For example, the lead **2** could be placed in the right ventricle or right atrium or the superior vena cava similar to the placement of leads for pacemakers and ICDs. The metal case of the cardiosaver **11** could serve as an indifferent electrode with the electrode **4** being the active electrode. Alternately, the lead **2** in **FIG. 1** could be placed through the patient's vascular system with the electrode **4** being placed into the apex of the left ventricle.

[0046] The lead **2** could advantageously be placed subcutaneously at any location where the electrode **4** would provide a good electrogram signal indicative of the electrical activity of the heart. Again for the lead **2**, the case of the cardiosaver **11** of the cardiosaver system **5** could be an indifferent electrode and the electrode **4** would be the active electrode. Although the Guardian system **10** described herein can readily operate with only two electrodes or with one electrode and the case of the cardiosaver being the other

electrode, it is envisioned that multiple electrodes used in monopolar or bipolar configurations could be used.

[0047] **FIG. 1** also shows the external equipment **7** that consists of a physician's programmer **18**, a pocket PC **12**, the equipment **14** in a remote diagnostic center and the emergency room triage system **30** which includes an implant access transceiver **20** and the emergency room diagnostic system **16**. The external equipment **7** provides the means to interact with the cardiosaver system **5**. These interactions include programming the cardiosaver **11**, retrieving data collected by the cardiosaver system **5** and handling alarms generated by the cardiosaver **11**. It should be understood that the cardiosaver system **5** could operate with some but not all of the external equipment **7**.

[0048] The implant access transceiver **20** includes a battery **21**, an alarm disable/panic & communications activation button **22**, a radio frequency transceiver **23**, a speaker **24** an antenna **25**, and a standard interface **28** for providing wired or wireless communication with the pocket PC **12**, emergency room diagnostic system **16**, or physician's programmer **18**. The implant access transceiver **20** may also include an optional microphone **27** and GPS satellite receiver **26**. A long distance voice/data communications interface **29** provides connectivity to the remote diagnostic center equipment **14** through voice and data telecommunications networks. For example, the microphone **27** and speaker **24** could be used for wired or wireless telephone calls to and from a medical practitioner at a remote diagnostic center. A built-in modem as part of the interface **29** would allow data to be transmitted to and from the remote diagnostic center equipment **14** over a voice connection. Alternately, a data communications capability of the interface **29** could allow data to be sent or received through a wired or wireless data network. The implant access transceiver **20** may be a separate unit that can be carried by the patient and used by the patient's physician as the data interface to the cardiosaver system **5** or it may also be built into the pocket PC **12**, physician's programmer **18** or emergency room diagnostic system **16**.

[0049] The physician's programmer **18** shown in **FIG. 1** is to used to set and/or change the patient medical history data and operating parameters of the implanted cardiosaver system **5** and to read out data stored in the memory of the cardiosaver **11** such as stored electrogram segments as described by Fischell et al. in U.S. Pat. No. 6,609,023.

[0050] The pocket PC also described by Fischell et al. in U.S. Pat. No. 6,609,023 can provide the patient or physician the ability to check the status of the cardiosaver **11** and display a limited set of electrogram data downloaded from the cardiosaver **11**.

[0051] The emergency room diagnostic system **16** is a more sophisticated system than the pocket PC as it can download, display and print all of the data stored within the cardiosaver **11** and would, in its preferred embodiment, use a touch screen display to facilitate triage of patients arriving in an emergency room who have the cardiosaver system **5**. This should greatly reduce the time from arrival at the emergency room until treatment for cardiosaver system patients having a cardiac event. The combination of the implant access transceiver **20** and the emergency room diagnostic system **16** form the Emergency Room Triage System (ERTS) **30**. The ERTS **30** is preferably installed and located in a medical center that is located within one hour's driving time from the home and/or work of patients that have been implanted with the cardiosaver system **5**. Also, the ERTS **30** may be installed in medical centers in major metropolitan areas. The ERTS **30** is designed to reduce the time required for a patient arriving at an emergency medical facility to be rapidly processed and treated as compared to current methods that include the filling out of forms relating to medical history and insurance, finding a portable ECG machine, placing surface leads onto the patient, collecting 12-lead ECG data, and then reading the output of the 12-lead trace. For a patient with an implanted cardiosaver, the present invention includes a method of triage that includes the following steps:

[0052] 1. Have the patient sit or lie within **6** feet of the implant access transceiver **20** of the ERTS **30**.

[0053] 2. Activate the long range telemetry between the cardiosaver **5** and the implant access transceiver **20** (this would take a few seconds).

[0054] 3. Quickly download, from the cardiosaver to the ERTS, the stored patient medical history data that then can be displayed and/or printed in the hospital's preferred format.

[0055] 4. While the medical history is being displayed (and/or printed), the electrogram data stored within the cardiosaver is transmitted to the emergency room diagnostic system **16**, the data are then displayed by the ERTS **30** and/or printed on an attached printer **194** (see **FIG. 3**).

[0056] 5. Have a medical practitioner review the ST segment levels of the electrogram data displayed by the ERTS **30** or the print out from the printer **194** to confirm or deny the presence of an ST-segment-related cardiac event.

[0057] 6. If an ST-segment-related cardiac event is diagnosed, rapidly provide the best available treatment.

[0058] An implant access transceiver **20** might also be carried by the patient. If a cardiac event is detected by the cardiosaver system **5**, an internal alarm signal (typically a vibration or electrical tickle) is generated by the cardiosaver system **5** and an alarm message is sent by a wireless signal **3** to the patient's alarm transceiver **20** via the antennas **6** and **25**. When the alarm is received by the alarm transceiver **20**, an external alarm signal (typically a sequence of sounds) is generated by the external alarm transceiver **20** and played through the loudspeaker **24** to warn the patient that a cardiac event has occurred. Examples of such sounds include a periodic buzzing, a sequence of tones and/or a speech message that instructs the patient as to what actions should be taken. As described in U.S. Pat. No. 6,609,023, the cardiosaver system **5** may have at least two levels of patient alerting, where one level of alert is an emergency alarm which indicates that the patient should seek immediate medical attention. Furthermore, the alarm transceiver **20** can, depending upon the nature of the signal **3**, send an outgoing message to the remote diagnostic center equipment **14** to alert medical practitioners that a cardiosaver system alarm has occurred. The medical practitioners can then utilize the voice communications capabilities of the remote diagnostic center equipment **14** to call back the patient similar to the call that occurs to drivers through the

ONSTAR service when their car's air bags deploy in an accident. The optional GPS receiver **26** would allow the data sent to the remote diagnostic center equipment **14** to include patient location to facilitate the summoning of emergency medical services.

[**0059**] The preferred embodiment of the present invention includes long range data communications between the cardiosaver and ERTS **30** such that the communication will work at a distance separation between the antennas **6** and **25** of greater than 1 foot. This is compared with current pacemaker and ICD telemetry systems requiring the data access operate at separations of much less than one foot.

[**0060**] The button **22** will turn off both the internal alarm signal of the implant **5** and the external alarm signal sound being emitted from the loudspeaker **24**. An additional feature of the patient's transceiver **20** (i.e. one not connected into an ERTS or programmer), is that if no alarm is occurring, then pressing the alarm button **22** will place a voice and/or data call to the remote diagnostic center similar to the call that is placed when the ONSTAR button is pressed in a car equipped to access the ONSTAR service. Patient location information from the GPS receiver **26** and a subset of patient medical history and electrogram data may be sent as well to the medical practitioners at the remote diagnostic center. The remotely located medical practitioner could then analyze the electrogram data and call the patient back to offer advice as to whether this is an emergency situation or the situation could be routinely handled by the patient's personal physician at some later time.

[**0061**] The implant access transceiver **20** that is part of the ERTS could be the same design as the one carried by the patient; however, they might have different internal programming.

[**0062**] **FIG. 2** is a block diagram of the cardiosaver system **5**. The electrode **4** connects with wire **12** to the amplifier circuit **36** that is also connected by the wire **15** to the case **8** acting as an indifferent electrode. The lead **2** includes the electrode **4** together with the wire **12** for bringing an electrogram signal into the amplifier circuit **36**. The amplified electrogram signals **37** from the amplifier circuit **36** are converted to digital signals **38** by the analog-to-digital converter **41**. The digital electrogram signals **38** are then sent to the processor **44**. The processor **44** in conjunction with the memory **47** can process the digital signals **38** according to the programming instructions stored in the program memory **45**. This programming (i.e. software) enables the cardiosaver system **5** to detect the occurrence of an ST-segment-related cardiac event. An ST-segment-related cardiac event is a cardiac event that is indicated by a change in the shape or level of the ST segment and includes ST segment elevation that is typically indicative of an acute myocardial infarction or ST segment depression that is typically indicative of myocardial ischemia.

[**0063**] A clock/timing sub-system **49** provides the means for timing specific activities of the cardiosaver system **5** including the absolute or relative time stamping of detected cardiac events. The clock/timing sub-system **49** can also facilitate power savings by causing components of the cardiosaver system **5** to go into a low power stand-by mode in between times for electrogram signal collection and processing. Such cycled power savings techniques are often used in implantable pacemakers and defibrillators. In an alternative embodiment, the clock/timing sub-system can be provided by a program subroutine run by the central processing unit **44**. It is also envisioned that the processor **44** may include an integral or external First-In-First-Out (FIFO) buffer memory to allow saving of data from before the detection of a cardiac event. Techniques for detecting cardiac events by the processor **44** are described by Fischell et al. in U.S. Pat. No. 6,609,023.

[**0064**] An important aspect of the present invention is the filtering of the electrical signals sensed by the electrodes **4** and **8**. The preferred embodiment of the present invention cardiosaver **11** will include high pass and/or low pass filtering of the electrical signals in the amplifier circuit **36**. An alternative embodiment would introduce filtering in any or all of the following locations:

[**0065**] 1. a separate analog filter between the amplifier circuit **36** and analog-to-digital converter **41**,

[**0066**] 2. a separate digital filter circuit placed between the analog-to-digital converter **41** and the processor **44**,

[**0067**] 3. digital filtering performed by the processor **44** on the digital signals **38**.

[**0068**] The memory **47** includes specific memory locations for patient data, electrogram segment, histogram/statistical data, and other relevant data storage.

[**0069**] It is envisioned that the cardiosaver system **5** could also contain pacemaker circuitry **170** and/or defibrillator circuitry **180** similar to the cardiosaver system described by Fischell et al. in U.S. Pat. No. 6,240,049.

[**0070**] The alarm sub-system **48** contains the circuitry and transducers to produce the internal alarm signals for the cardiosaver **11**. The internal alarm signal can be a mechanical vibration, a sound or a subcutaneous electrical tickle or shock.

[**0071**] The telemetry sub-system **46** with antenna **6** provides the cardiosaver **11** with the means for two-way wireless communication to and from the external equipment **7** of **FIG. 1**. It is also envisioned that short range telemetry such as that typically used in pacemakers and defibrillators could also be applied to the cardiosaver system **5**. It is also envisioned that standard wireless protocols such as Bluetooth and 802.11a or 802.11b might be used to allow communication with a wider group of peripheral devices.

[**0072**] A magnet sensor **190** may be incorporated into the cardiosaver system **5**. The primary purpose for a magnet sensor **190** is to keep the cardiosaver system **5** in an off condition until it is checked out just before it is implanted into a patient. This can prevent depletion of the battery life in the period between the times that the cardiosaver system **5** is packaged at the factory until the day it is implanted.

[**0073**] **FIG. 3** shows an example of components that can be included in the ERTS **30**. These components are the implant access transceiver **20** with activation button **22** and connection **172** and the emergency room diagnostic system **16**. The emergency room diagnostic system **16** includes the ERTS display **160** showing the patient's medical history data **162** and may also include a printer **194** with connection **192**, a blood pressure sensor **190** with connection **191**, a **12** lead electrocardiogram system **199** with connection **193**, and a temperature sensor **195** with connection **196**. The ERTS **30**

also may have a connection **198** to the hospital local area network **197** for sharing data from the ERTS **30** with other hospital systems. The connections **172**, **191**, **192**, **193**, **196** and **198** may be either physical wired cables or wireless data connections using infra-red or radiofrequency (RF) data transmission. If a wireless connection is used it would preferably use a standardized protocol such as IRDA for infra-red transmission and Bluetooth or 802.11 a, b, or g for RF transmission. The 12-lead electrocardiogram system **199** would typically have a standard PC interface such as the QRS card system from Pulse Biomedical that can connect into a USB or RS-232 serial port.

[**0074**] The blood pressure and temperature sensors **190** and **195** allow display of real time patient physical data on the display **160** as display boxes **101** and **102** respectively. It is envisioned that this could be combined with real time display of electrogram data as seen in **FIG. 6**. The example of the ERTS patient medical history data **162** as shown in **FIG. 3** includes the patient name, social security number, date of birth, address, phone, insurance, current medications, allergies, risk factors and a history of prior events and treatments. The ERTS **160** also includes a power button **161** to turn on and off the ERTS **30** and soft control buttons **164** through **167** to switch to the displays of real time data **164**, recent data **165**, or event data **166** and **167**. Soft control buttons are virtual buttons on the display that use the touch-screen or digitizer pen interface. **FIGS. 4, 5** and **6** show examples of ERTS displays activated by these buttons. The soft control buttons **168** and **169** are print buttons including a print screen button **168** that will print the data on the current screen, and a print all button **169** that will provide a full print out of all the patient data available in the ERTS **30**. When the ERTS **30** is turned on, it would typically show a start screen instructing the medical practitioner to place the implant access transceiver **20** near to the implant **5** of **FIG. 1** and depress the button **22**. This will initiate a data communications session with the implant **5** and initiate the transmission of data stored in the implant memory **47** of **FIG. 2** to the ERTS **30**. Once the transmission (that may take a few minutes) is complete, the ERTS display **160** would show the patient medical history **162** and the other control buttons seen in **FIG. 3**.

[**0075**] Although **FIG. 3** shows only two event data buttons **166** and **167**, it is envisioned that the ERTS **30** would typically show one button for each cardiac event whose data have been transmitted from the implant **5** to the ERTS **30** during the data communication session. The soft control button **163** provides built in instructions for use of the ERTS **30** and the functions of the display **160**. The display **160** would typically be a touch sensitive screen that can be used interacted with by use of a finger or stylus. An attached stylus might be best.

[**0076**] The preferred embodiment of the present invention envisions a Graphical User Interface (GUI) that includes the use of selection boxes with pop up menus (e.g., a windows start button) and soft control buttons (e.g. a windows X button that closes a window), well known in PC software. Such selection boxes and soft control buttons are typically selected using a touch-screen interface as in a PDA or tablet PC or a pointing device like a mouse, touchpad or trackball. However, because of the limited number of buttons needed for the ERTS **30**, it is envisioned that actual physical buttons could be utilized by the ERTS **30** instead of soft control buttons shown in **FIGS. 3, 4, 5** and **6**.

[**0077**] **FIG. 4** is an example of the ERTS display **50** initiated by the selection of soft control button **166** of **FIG. 3**. The display **50** shows the first cardiac event alarm-related electrogram data downloaded from the cardiosaver **5** of **FIG. 1**. The display **50** shows **6** electrogram segments **51** through **56** related to the emergency alarm that occurred at T=03:43 am as indicated by the segment time indications **60**. The electrogram segment **51** is the electrogram segment whose analysis by the cardiosaver system **5** triggered the detection of the cardiac event associated with an emergency alarm. The alarm information box **62** indicates that this detection was of the type STEMI (ST Elevation Myocardial Infarction) and also includes the date and time of the detection. Although the **FIG. 4** shows times with that have AM (or PM), a 24 hour time could also be used.

[**0078**] The electrogram segment **52** is the baseline electrogram segment from approximately 24 hours before the time of the alarm. As described by Fischell et al. in U.S. Pat. No. 6,240,049, The T minus 24 hour baseline electrogram segment is utilized by the cardiosaver system **5** ST shift detection algorithm for comparison with current electrogram data. The display **50** also includes the segments **53** through **56** that provide information on the patient's heart both before and after the cardiac event. The segments **53** and **54** are selectable to display any of the electrogram segments from the period just preceding the cardiac event. In this example **53** has been selected to display the T minus 0 minutes 30 seconds electrogram segment and **54** has been selected to display the T minus 1 minute 0 seconds. The selection boxes **57** and **58** typically accessed by the touch-screen interface allow the user to select other recorded electrogram segments from the time period just before the cardiac event. For example, the cardiosaver system **5** might record electrogram segments for 10 seconds every 30 seconds and always have in memory the last **8** electrogram segments. When a cardiac event is detected, these would be saved for later review as the segments **51**, **53** and **54**. Similarly, if for example the cardiosaver system **5** stores a baseline electrogram segment once per hour, then at the time of a detected cardiac event, these baseline segments would be saved for later review as the electrogram segment **52** (the T−24 hour baseline) and the other baseline segments **55** selectable by the box **59**. The cardiosaver system **5** also has the capability to record electrogram data for some period of time after the detection of a cardiac event. These post event electrogram data are shown as the electrogram segment **56** selectable by the selection box **61**. The display **50** would typically be a touch-sensitive screen that can be used interacted with by use of a finger or stylus. An attached stylus might be best.

[**0079**] The soft control buttons **63** through **69** provide access to the other functions and screens from the display **50**. Button **66** is highlighted on screen **50** to show that this is the display of Event 1. Button **63** will return to the patient medical history screen **160** of **FIG. 3**. Button **64** will access the real time electrogram display **90** shown in **FIG. 6**. Button **65** will provide access to the screen **70** of **FIG. 5**. Button **67** would provide access to the display of electrogram data for Event 2 downloaded from the cardiosaver **5** of **FIG. 1**. If more than 2 events have been downloaded from the cardiosaver system **5** of **FIG. 1** then it is envisioned that

there could be additional event display buttons (e.g. EVENT 3, EVENT 4 etc) or the event 2 button **67** could instead be labeled "OTHER EVENTS") that would enable an additional menu used to select the other event to be displayed. Button **68** will access print controls allowing the printing of either the data of the display **50** or all of the downloaded data also printed from the soft control button **169** of **FIG. 3**. The soft control button **69** provides built in instructions for use of the ERTS **30** and the functions of the display **50**.

[**0080**] **FIG. 5** is an example of the ERTS display **70** of recent electrogram data downloaded from the cardiosaver **5** of **FIG. 1**. The display **70** accessed by the soft control button **165** of **FIG. 3** or button **65** of **FIG. 4** shows the most recently collected electrogram data downloaded from the cardiosaver **5** of **FIG. 1**. The display **70** shows **7** electrogram segments **71** through **77**. The electrogram segment **71** is the last electrogram segment stored by the cardiosaver **5** just before the download process began. The actual date and time for each electrogram segment **71** through **77** are shown in the corresponding location in the data field **80**.

[**0081**] The electrogram segment **72** is the baseline electrogram segment from approximately 24 hours before the collection of the electrogram segment **71**. The segments **73**, **74** and **75** show the other electrogram segments from the two minutes just preceding the download. In this case they show the T minus **30** seconds, T minus 60 seconds and T minus 90 seconds, where T is the time of collection for the most recent electrogram segment **71**. The selection boxes **78** and **79** allow the user to select other recorded electrogram segments from the time period before the download. For example, the selection box **78** could select fairly recent electrogram data (e.g. T minus 120 seconds) and would typically have a pop up menu with available choices. The selection box **79** could be used to select the display of other hourly baseline electrogram data recordings (e.g. T minus 12 hours).

[**0082**] The display **70** would typically be a touch sensitive screen that can be used interacted with by use of a finger or stylus. An attached stylus might be best.

[**0083**] The soft control buttons **83** through **89** provide access to the other functions and screens from the display **70**. Button **85** is highlighted on screen **70** to show that this is the display of recently collected electrogram data. Button **83** will return to the patient medical history screen **160** of **FIG. 3**. Button **84** will provide access to the real time electrogram data display screen **90** shown in **FIG. 6**. Button **86** will provide access to the screen **50** of **FIG. 4**. Button **87** would provide access to the display of electrogram data for Event 2 downloaded from the cardiosaver **5** of **FIG. 1**. If more than 2 events have been downloaded from the cardiosaver system **5** of **FIG. 1** then it is envisioned that there could be additional event display buttons (e.g. EVENT 3, EVENT 4 etc) or the event 2 button **87** could instead be labeled "OTHER EVENTS") that would enable an additional menu used to select the other event to be displayed. Button **88** will access print controls allowing the printing of either the data of the display **70** or all of the downloaded data also printed from the soft control button **169** of **FIG. 3**. The soft control button **89** provides built in instructions for use of the ERTS **30** and the functions of the display **70**.

[**0084**] **FIG. 6** is an example of the ERTS display **90** of real time electrogram data transmitted by the implant **5** of **FIG. 1** and electrocardiogram data received from the 12-lead system **199** of **FIG. 3**. The display **90** is accessed by the soft control button **164** of **FIG. 3**, button **64** of **FIG. 4** or button **84** of **FIG. 5**. The display **90** shows real time heart signal data both from the implant **5** of **FIG. 1** and/or the 12-lead system **199** of **FIG. 3**. The display **90** shows **6** electrogram/electrocardiogram signals **91** through **96**. The electrogram segment **91** is the real time display of electrogram data transmitted from the cardiosaver **5**.

[**0085**] The electrocardiogram signals **92** through **96** come from the 12-lead system **199**. In this example, the signals **92**, **93** and **94** are the standard 12-lead displays of LEADS I, II and III respectively. The signals **95** and **96** chosen by selection boxes **97** and **98** are other 12-lead signal displays (e.g. V**1**, V**2** etc.).

[**0086**] The display **90** would typically be a touch-sensitive screen that can be interacted with by use of a finger or stylus. An attached stylus might be best.

[**0087**] The soft control buttons **103** through **109** provide access to the other functions and screens from the display **90**. Button **104** is highlighted on screen **90** to show that this is the display of real time data. Button **103** will return to the patient medical history screen **160** of **FIG. 3**. Button **105** will provide access to the recent electrogram data display screen **70** shown in **FIG. 5**. Button **106** will provide access to the screen **50** of **FIG. 4**. Button **107** would provide access to the display of electrogram data for Event 2 downloaded from the cardiosaver **5** of **FIG. 1**. Button **108** will access print controls allowing the printing of either the data of the display **90** or all of the downloaded data also printed from the soft control button **169** of **FIG. 3**. The soft control button **109** provides built in instructions for use of the ERTS **30** and the functions of the display **90**. It is also envisioned that all of the processing techniques described herein for the implantable cardiosaver **5** of **FIG. 1** are applicable to a guardian system configuration using skin surface electrodes and a non-implanted cardiosaver. If a non-implanted cardiosaver using skin surface electrodes is used then the term electrogram would be replaced by the term electrocardiogram.

[**0088**] Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that, within the scope of the appended claims, the invention can be practiced otherwise than as specifically described herein.

What is claimed is:

**1**. A system for diagnosis of a patient having an implanted cardiac device, the system including:

an implanted cardiac device including means for detecting a cardiac event, means for alerting the patient that the cardiac event has occurred, means for storing electrogram data associated with the cardiac event, and communication means for wirelessly transmitting the electrogram data from the implanted cardiac device to an emergency room triage system, wherein

the emergency room triage system includes communication means to wirelessly receive electrogram data from the implanted cardiac device and means for displaying the electrogram data associated with the cardiac event where the patient has been alerted.

2. The system of claim 1, wherein said implanted cardiac device includes pacemaker circuitry.

3. The system of claim 1, wherein said implanted cardiac device includes cardiac defibrillator circuitry.

4. The system of claim 1, wherein the cardiac event is a heart attack.

5. The system of claim 1, wherein the cardiac event is a detected heart arrhythmia.

6. The system of claim 1 wherein the cardiac device includes means to store regular electrogram data that is not associated with any cardiac event and the emergency room triage system includes means to display the regular electrogram data.

7. The system of claim 1, further including means for displaying ongoing electrogram data transmitted in real time from the implanted cardiac device.

8. The system of claim 1, wherein the means for displaying electrogram data includes a computer display screen.

9. The system of claim 1, wherein the means for displaying electrogram data includes a printer.

10. The system of claim 1 wherein the range of the communication means is greater than 1 foot.

11. The system of claim 1 wherein the emergency room triage system includes means to display the type of cardiac event associated with the displayed electrogram data.

12. The system of claim 1, wherein said implanted cardiac device has at least two levels of patient alerting, at least one of the at least two levels being an emergency alarm which indicates that the patient should seek immediate medical attention.

13. The system of claim 12, wherein the cardiac device will first transmit electrogram data associated with the emergency alarm before it transmits any other electrogram data to the emergency room triage system.

14. The system of claim 1 wherein the implanted cardiac device means for alerting the patient includes internal alarm means that produces an internal alarm signal from the implanted device to notify the patient when the implanted device detects the cardiac event.

15. The system of claim 14, wherein the internal alarm signal is a vibration.

16. The system of claim 14, wherein the internal alarm signal is a sound.

17. The system of claim 14, wherein the internal alarm signal is an electrical tickle.

18. The system of claim 14 wherein the implanted cardiac device means for alerting the patient includes external alarm means that produces an external alarm signal from the implanted device to notify the patient when the implanted device detects the cardiac event.

19. The system of claim 18, wherein the external alarm signal is a sound.

20. The system of claim 18, wherein the external alarm signal is a visual display.

21. The system of claim 1 wherein the implanted cardiac device means for alerting the patient includes external alarm means that produces an external alarm signal from the implanted device to notify the patient when the implanted device detects the cardiac event.

22. The system of claim 21, wherein the external alarm signal is a sound.

23. The system of claim 21, wherein the external alarm signal is a visual display.

24. The system of claim 1, wherein the communication means for transmitting the electrogram data from the implanted cardiac device is configured to transmit over the Federal Communications Commission Medical Implant Communications Service band.

25. A method for diagnosing a cardiac event in a human patient, the method comprising the steps of:

a. implanting a cardiosaver, the cardiosaver including the capabilities to detect at least one type of cardiac event, the cardiosaver also including means to alert the patient when the at least one type of cardiac event is detected;

b. installing an emergency room triage system in at least one medical center, the emergency room triage system including means to receive electrogram data wirelessly transmitted from the cardiosaver after the patient arrives at the medical center;

c. training medical practitioners at the medical center having the installed emergency room triage system as to the operation of the emergency room triage system so that the medical practitioners can view the electrogram data from the cardiosaver and provide appropriate medical treatment for the cardiac event that triggered the patient alert.

26. The method of claim 25 where the medical center is located within one hour's driving time from the patient's home.

27. The method of claim 25 where the medical center is located within one hour's driving time of the patient's place of work.

28. The method of claim 25 where the emergency room triage system is installed in at least one medical center in a major metropolitan area.

29. An emergency room triage system for diagnosis of a patient having an implanted cardiac device, the system including: means for receiving an alert from the implanted cardiac device, the alert indicating that a cardiac event has occurred, first communication means for receiving electrogram data from the implanted cardiac device, the electrogram data being associated with the cardiac event; means for displaying said electrogram data, and second communication means for sending instructions to the patient.

30. The system of claim 29, wherein said implanted cardiac device includes pacemaker circuitry.

31. The system of claim 29, wherein said implanted cardiac device includes cardiac defibrillator circuitry

32. The system of claim 29, wherein the cardiac event is a heart attack.

33. The system of claim 29 wherein the cardiac event is an ST segment shift t.

34. The system of claim 29, wherein the cardiac event is an arrhythmia.

35. The system of claim 29 wherein the cardiac device includes third communication means for receiving instructions from the second communication means for sending instructions to the patient.

36. The system of claim 29, wherein the means for displaying electrogram data comprise a computer display screen.

37. The system of claim 29, wherein the means for displaying electrogram data comprise a printer.

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摘要(译)

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