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(54) **EXTERNAL DATA PROCESSING DEVICE TO INTERFACE WITH AN AMBULATORY REPEATER AND METHOD THEREOF**

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(58) **Field of Classification Search** 600/300, 600/301; 128/903–905, 920
See application file for complete search history.

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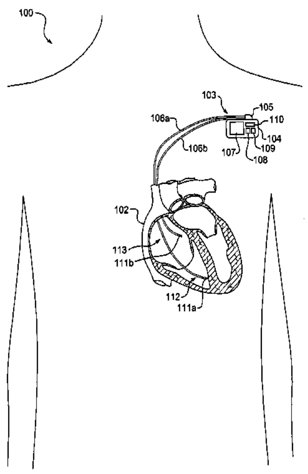
(57) **ABSTRACT**

An external data processing device to interface with an ambulatory repeater and method thereof is presented. An external data processing device is interfaced in far field telemetric communication with an ambulatory repeater. The external data processing device receives sensitive information preencrypted prior to implant under a cryptographic key uniquely assigned to an implantable medical device over a secure connection from the ambulatory repeater. Physiological measures retrieved from the implantable medical device by the ambulatory repeater are received by the external data processing device over a non-secure connection.

18 Claims, 11 Drawing Sheets



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Partial File History (from Sep. 24, 2010 to present) for co-pending U.S. Appl. No. 11/893,704, filed Aug. 17, 2007, entitled "An External Data Processing Device to Interface with an Ambulatory Repeater and Method Thereof" (18 pages).

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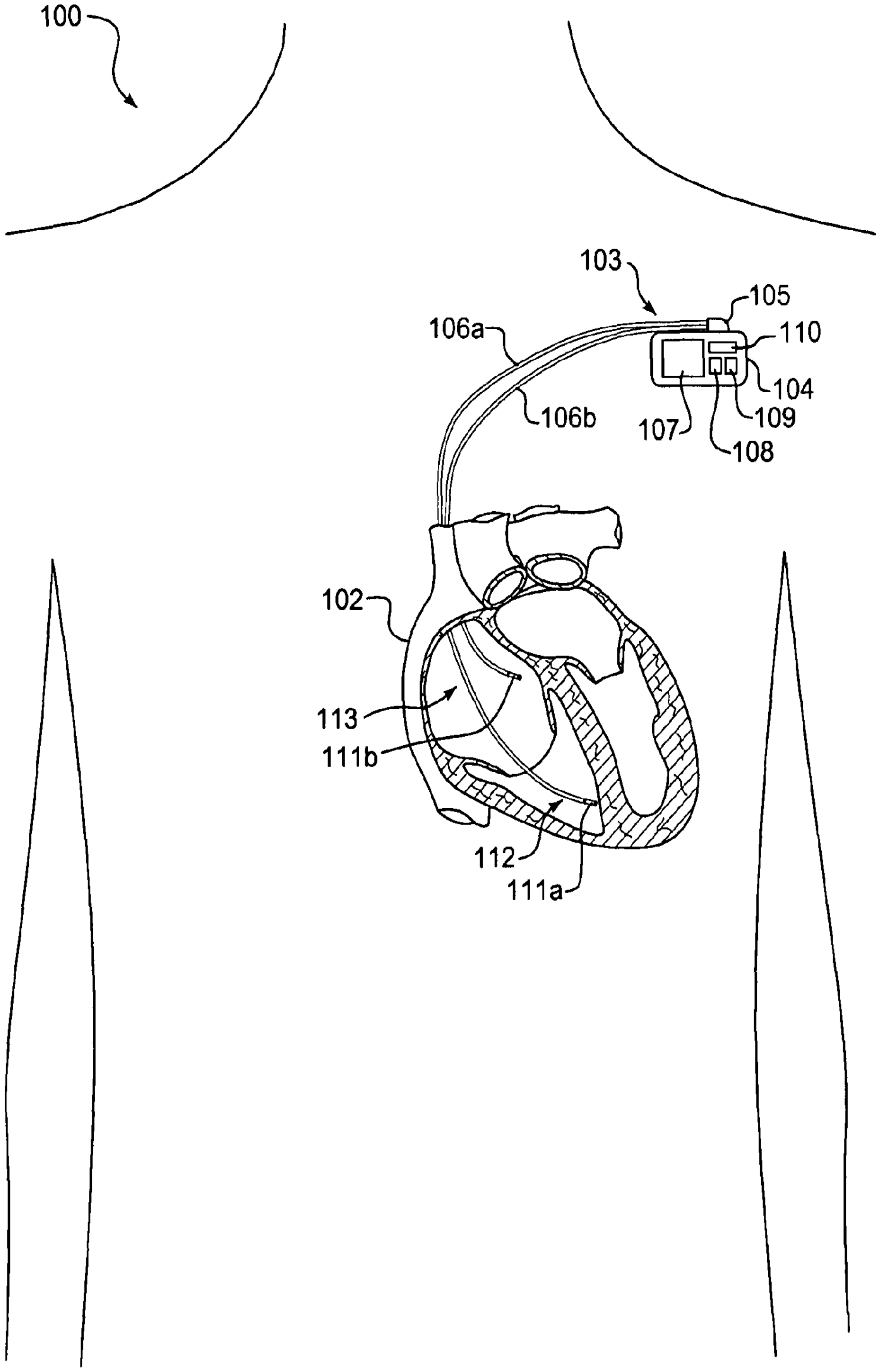
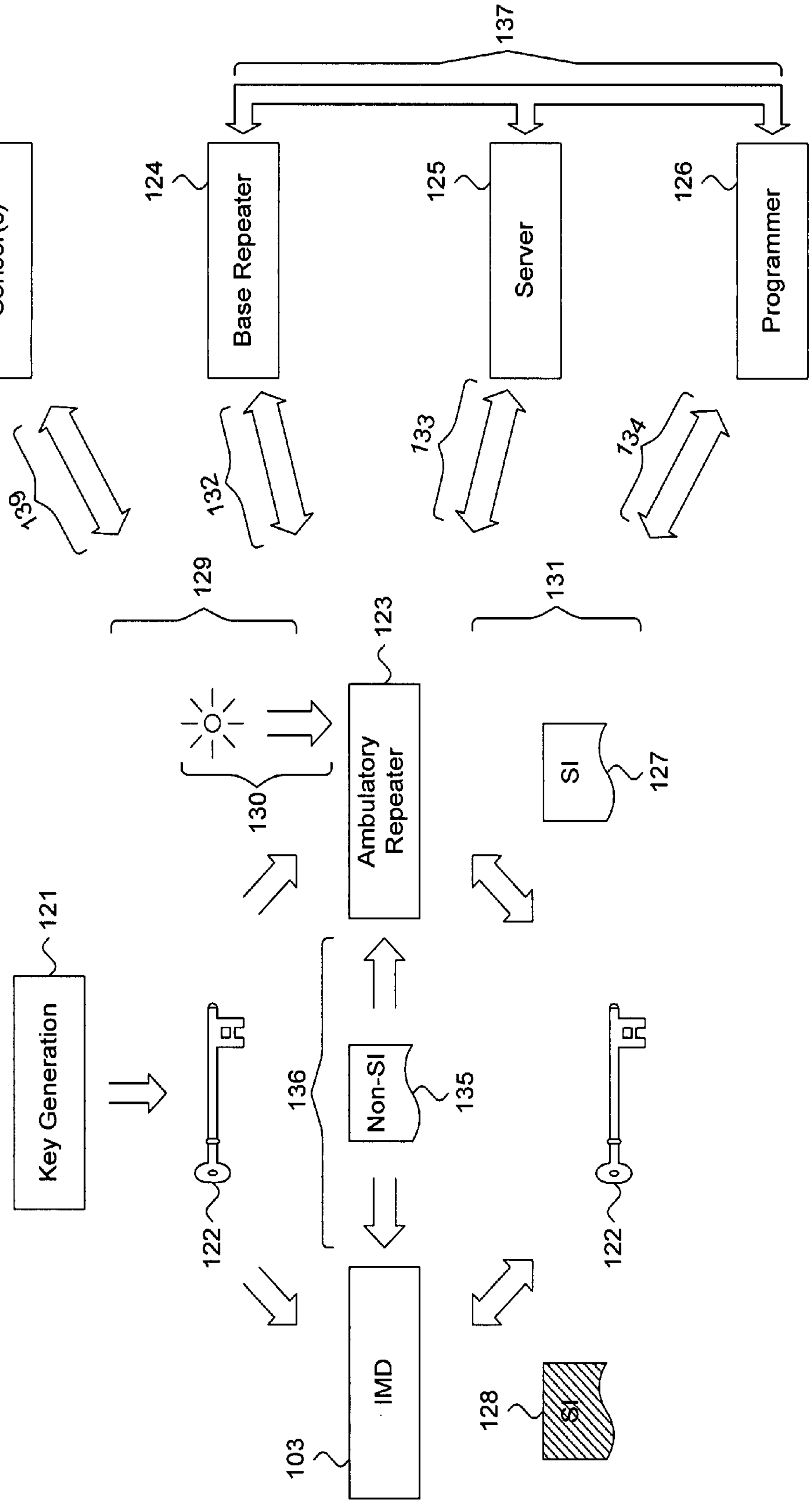
Fig. 1.





Sensor(s)
138
Base Repeater
124
Server
125
Programmer
126
137
139
132
133
134
129
131
130
Ambulatory Repeater
123
SI
127
Key Generation
121
122
Non-SI
135
136
IMD
103
SI
128
122

Fig. 2.
120

Fig. 3.

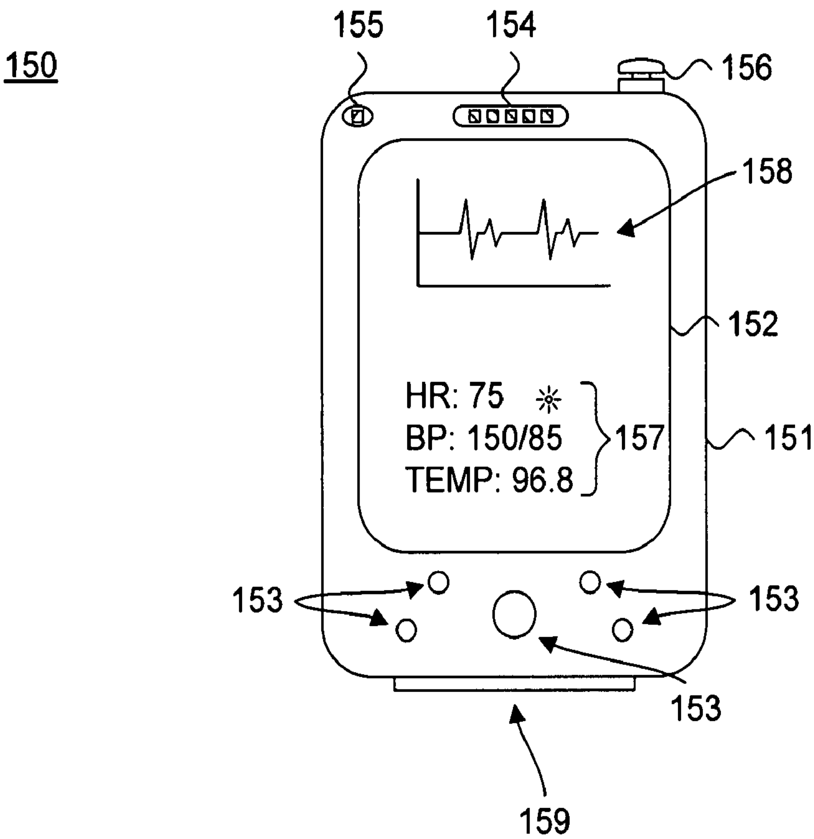

150
155
154
156
158
152
HR: 75
BP: 150/85
TEMP: 96.8
157
151
153
153
153
159

Fig. 4.

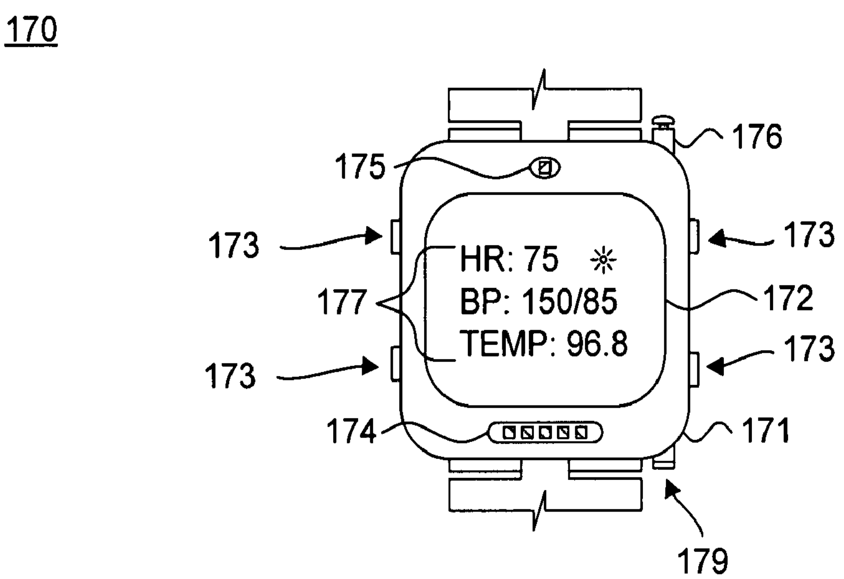

170
176
175
173
173
HR: 75
BP: 150/85
TEMP: 96.8
177
172
173
173
174
171
179

Fig. 5.

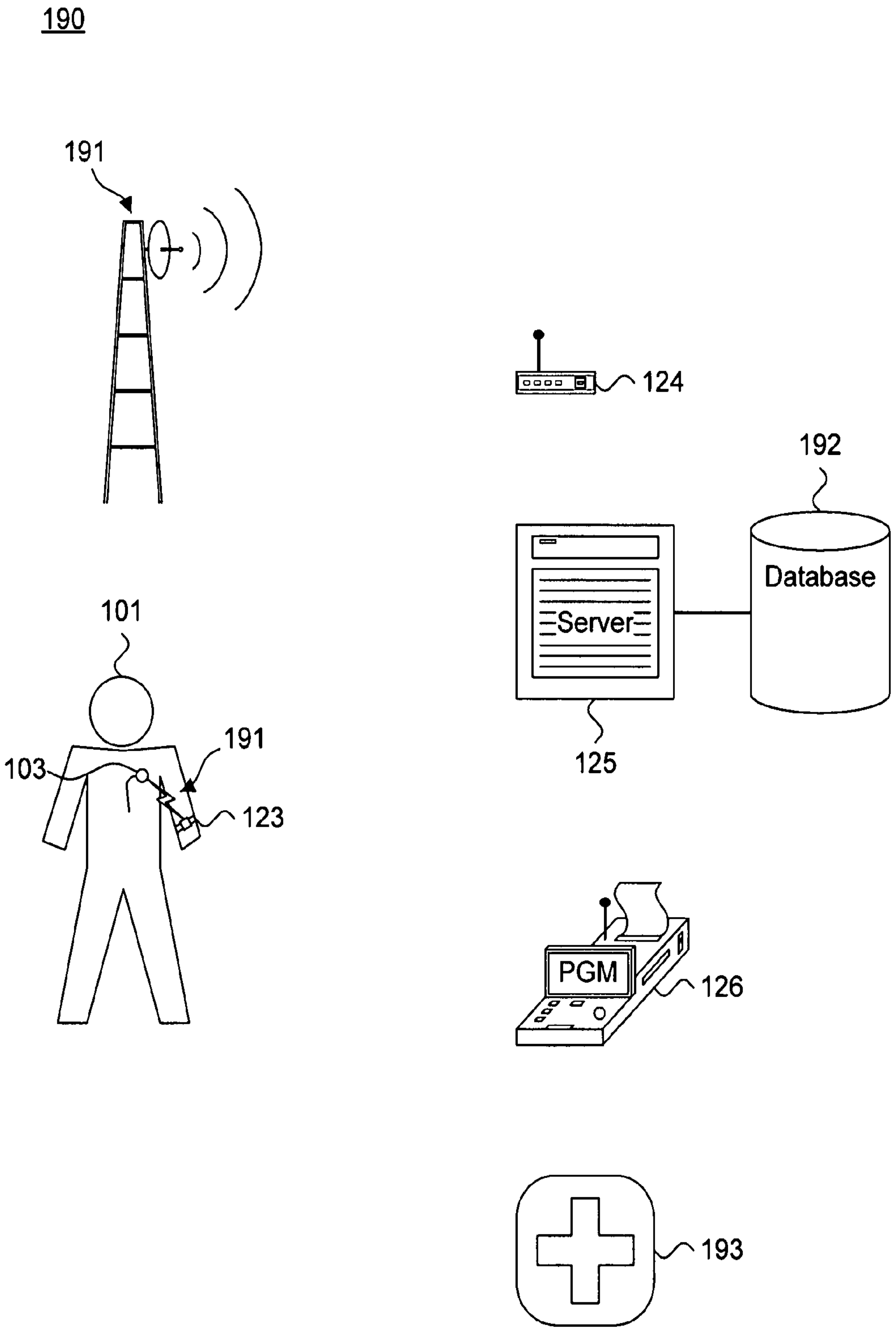

190
191
124
192
Database
Server
125
101
191
103
123
PGM
126
193

Fig. 6.

200

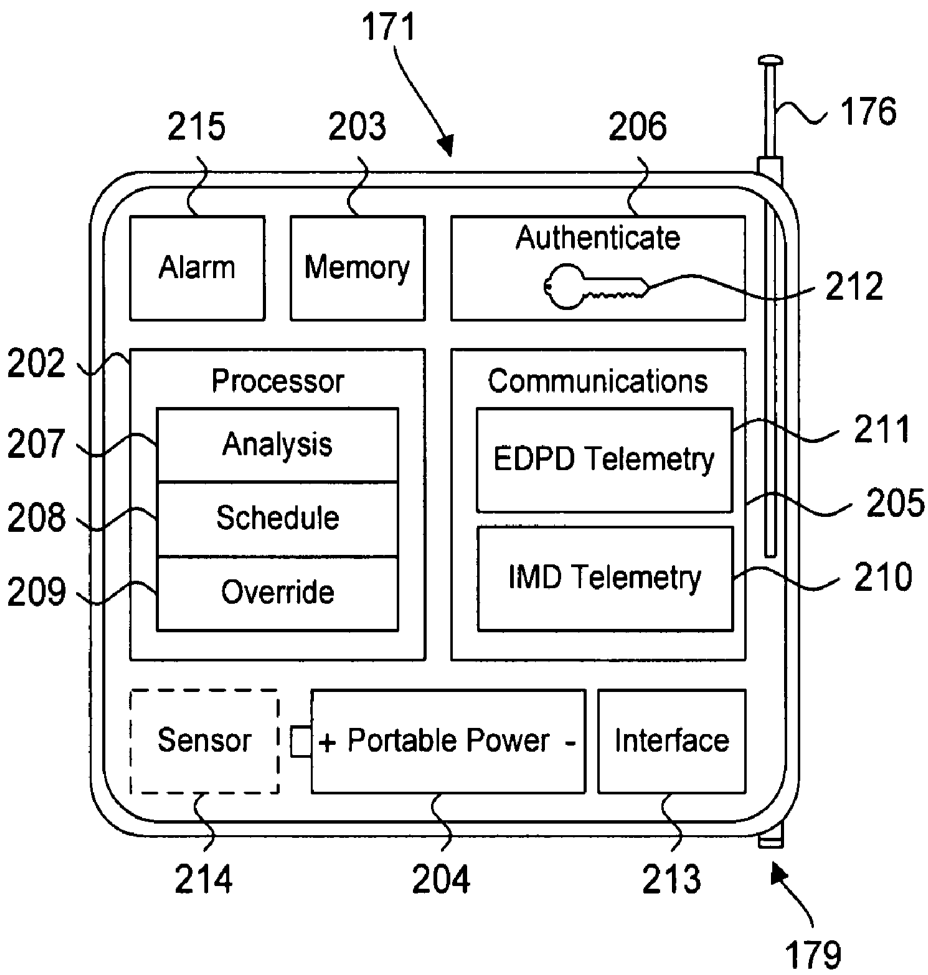

171
215
203
206
176
Alarm
Memory
Authenticate
212
202
Processor
Communications
207
Analysis
EDPD Telemetry
211
208
Schedule
205
209
Override
IMD Telemetry
210
Sensor
+ Portable Power -
Interface
214
204
213
179

Fig. 7.

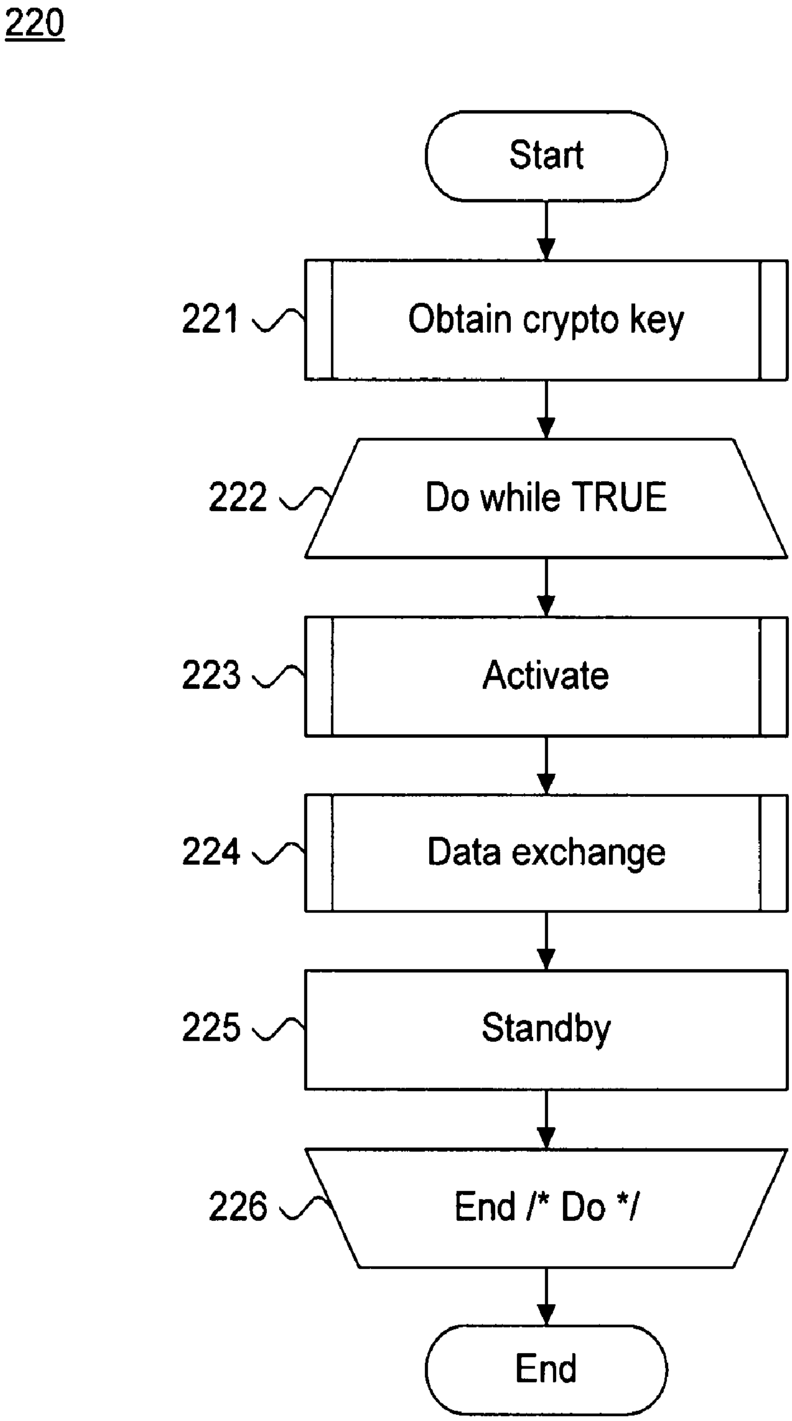

220
Start
221
Obtain crypto key
222
Do while TRUE
223
Activate
224
Data exchange
225
Standby
226
End /* Do */
End

Fig. 8.

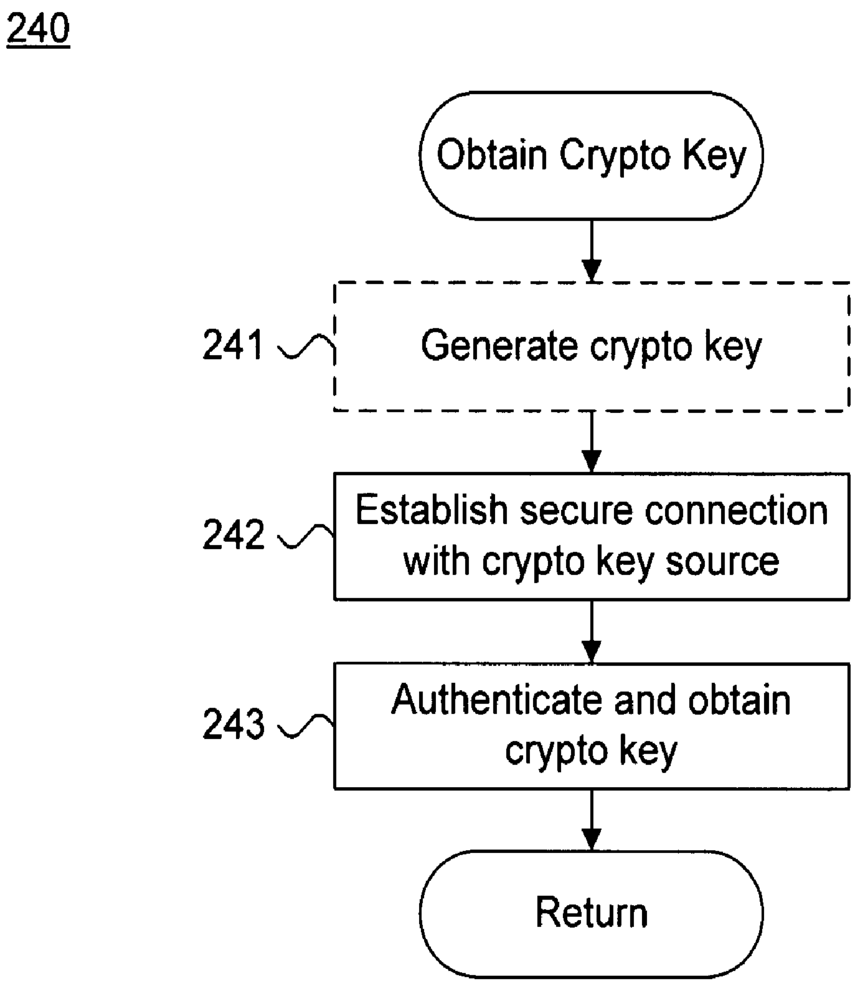

240
Obtain Crypto Key
241
Generate crypto key
242
Establish secure connection with crypto key source
243
Authenticate and obtain crypto key
Return

Fig. 9.

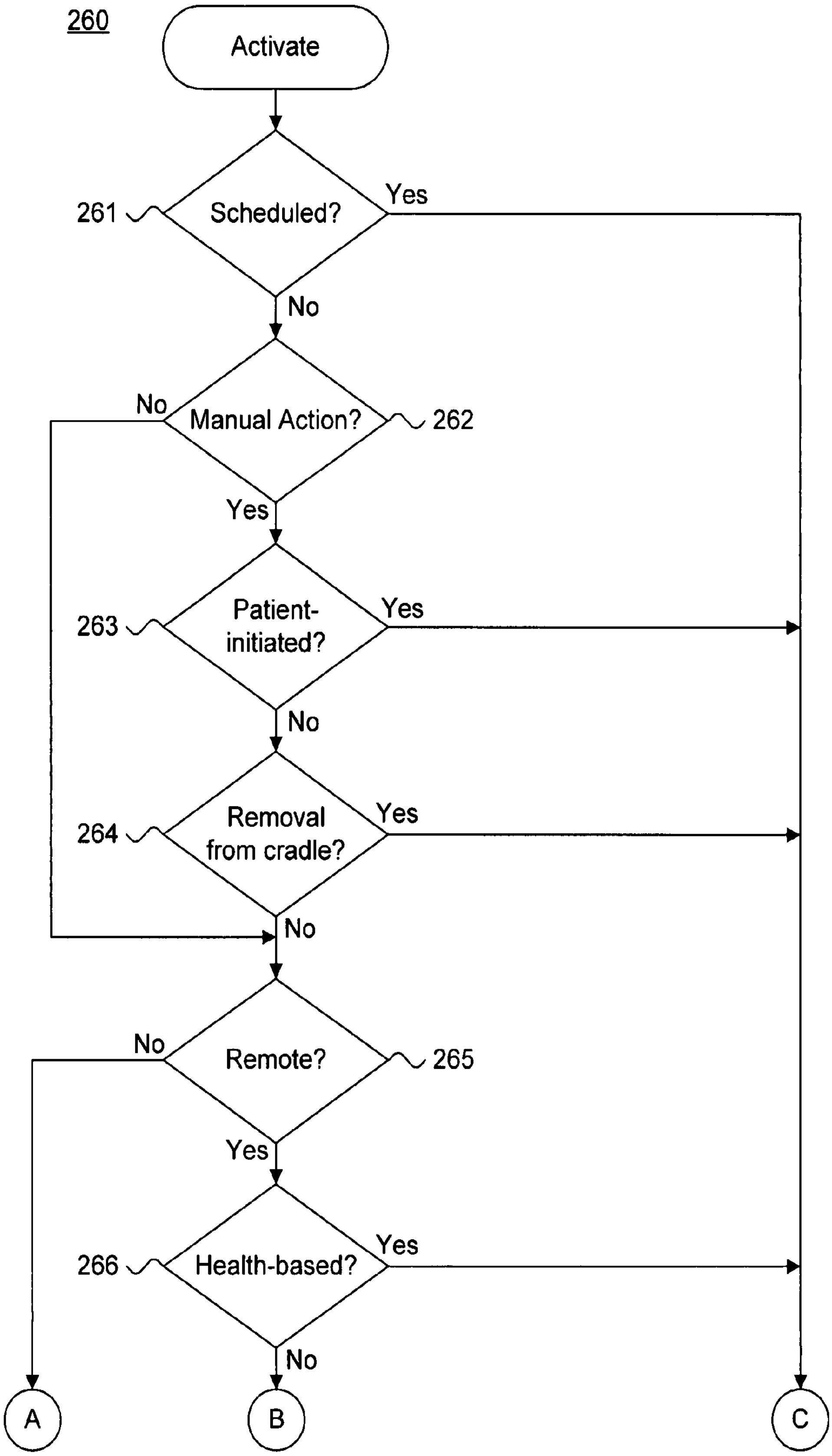

260
Activate
261
Scheduled?
Yes
No
No
Manual Action?
262
Yes
263
Patient-initiated?
Yes
No
264
Removal from cradle?
Yes
No
No
Remote?
265
Yes
266
Health-based?
Yes
No
A
B
C

Fig. 9 (Cont.).

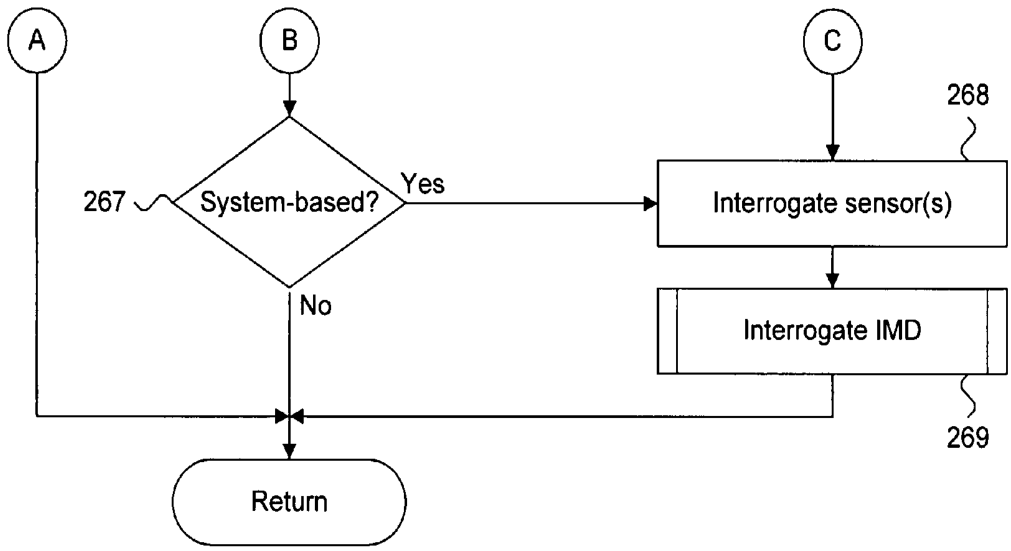

A
B
C
268
267
System-based?
Yes
Interrogate sensor(s)
No
Interrogate IMD
269
Return

Fig. 10.

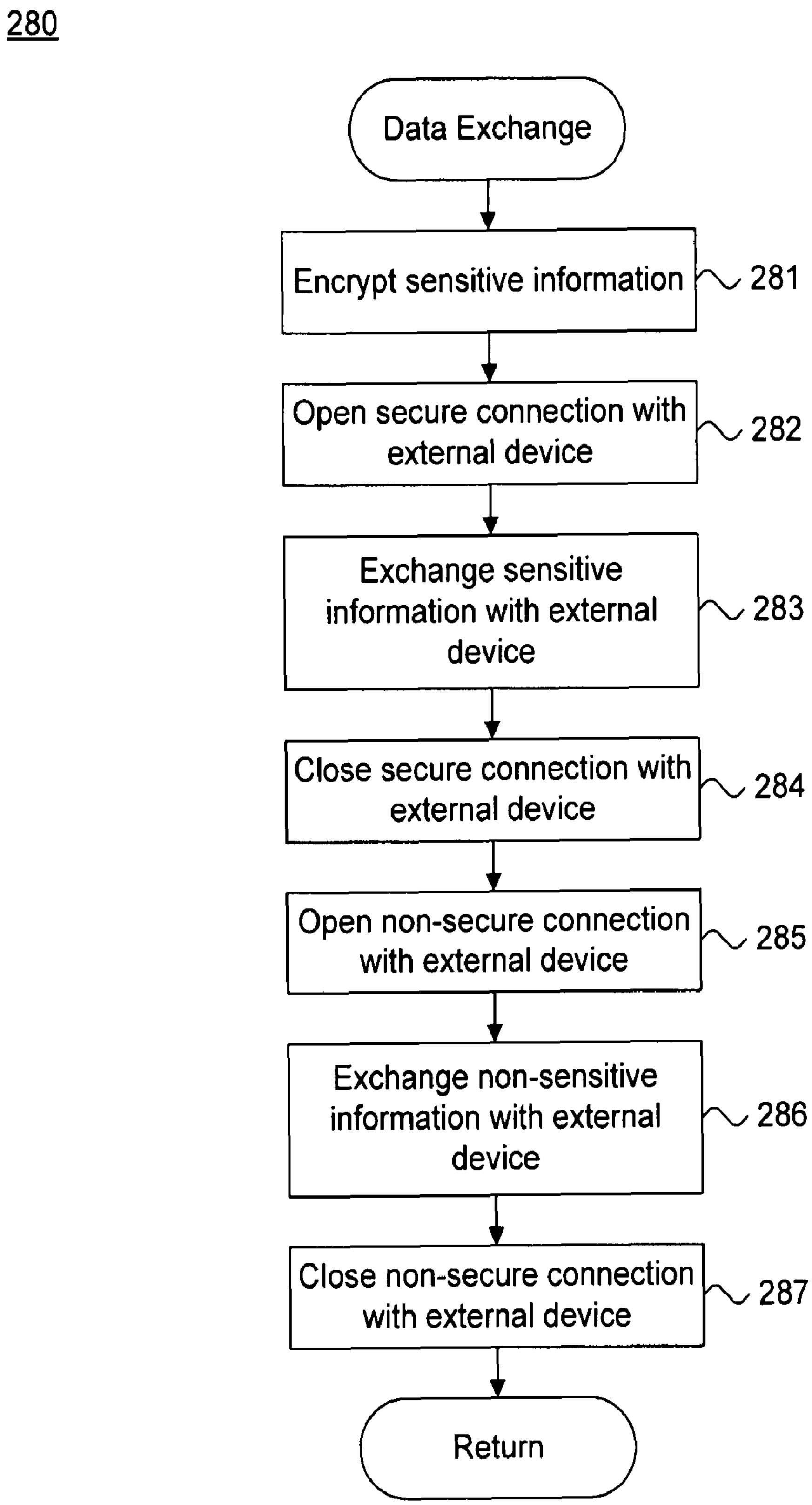
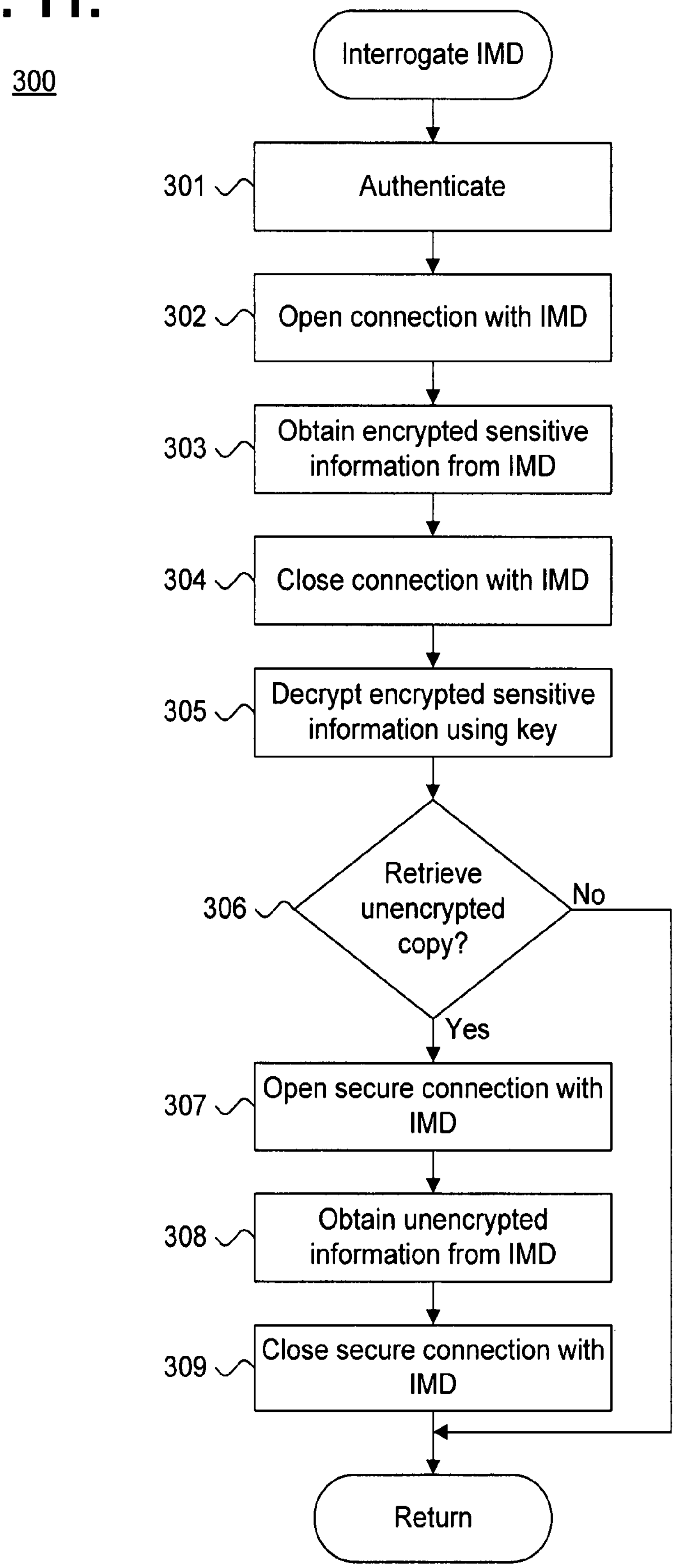

280
Data Exchange
Encrypt sensitive information
281
Open secure connection with external device
282
Exchange sensitive information with external device
283
Close secure connection with external device
284
Open non-secure connection with external device
285
Exchange non-sensitive information with external device
286
Close non-secure connection with external device
287
Return

Fig. 11.


300
Interrogate IMD
301
Authenticate
302
Open connection with IMD
303
Obtain encrypted sensitive information from IMD
304
Close connection with IMD
305
Decrypt encrypted sensitive information using key
306
Retrieve unencrypted copy?
No
Yes
307
Open secure connection with IMD
308
Obtain unencrypted information from IMD
309
Close secure connection with IMD
Return

EXTERNAL DATA PROCESSING DEVICE TO INTERFACE WITH AN AMBULATORY REPEATER AND METHOD THEREOF

CROSS-REFERENCE TO RELATED APPLICATION

This patent application is a continuation of U.S. patent application Ser. No. 11/113,206, filed Apr. 22, 2005, now U.S. Pat. No. 7,270,633, issued Sep. 18, 2007, the priority of filing date of which is claimed, and the disclosure of which is incorporated by reference.

FIELD OF THE INVENTION

The present invention relates in general to external data processing devices and, specifically, to an external data processing device to interface with an ambulatory repeater and method thereof.

BACKGROUND OF THE INVENTION

In general, implantable medical devices (IMDs) provide in situ therapy delivery, such as pacing, cardiac resynchronization, defibrillation, neural stimulation and drug delivery, and physiological monitoring and data collection. Once implanted, IMDs function autonomously by relying on pre-programmed operation and control over therapeutic and monitoring functions. IMDs can be interfaced to external devices, such as programmers, repeaters and similar devices, which can program, troubleshoot, and download telemetered data, typically through induction or similar forms of near-field telemetry.

Telemetered data download typically occurs during follow-up, which requires an in-clinic visit by the patient once every three to twelve months, or as necessary. Following interrogation of the IMD, the telemetered data can be analyzed to evaluate patient health status. Although clinical follow-up is mandatory, the frequency and type of follow-up are dependent upon several factors, including projected battery life, type, mode and programming of IMD, stability of pacing and sensing, the need for programming changes, underlying rhythm or cardiac condition, travel logistics, and the availability of alternative follow-up methods, such as transtelephonic monitoring, for example, the CareLink Monitor, offered by Medtronic, Inc., Minneapolis, Minn.; Housecall Plus Remote Patient Monitoring System, offered by St. Jude Medical, Inc., St. Paul, Minn.; and BIOTRONIK Home Monitoring Service, offered by BIOTRONIK GmbH & Co. KG, Berlin, Germany.

Telemetered data generally includes information on all programmed device parameters, as well as real time or measured and recorded data on the operation of the IMD available at the time of interrogation. In addition, telemetered data can include parametric and physiological information on the output circuit, battery parameters, sensor activities for rate adaptive IMDs, event markers, cumulative totals of sensed and paced events, and transmission of electrograms. Derived measures include battery depletion, which can be gauged by the downloaded battery voltage and impedance levels, and lead integrity, which is reflected by pacing impedance. Event markers depict pacing and sensing simultaneously recorded with electrograms to indicate how the IMD interprets specifically paced or sensed events with timing intervals. Other types of telemetered data are possible.

Clinical follow-up is conventionally performed using a programmer under the direction of trained healthcare professionals. The programmer is typically interfaced to an IMD through inductive near field telemetry. Fundamentally, IMDs are passive devices that report on operational and behavioral patient status, including the occurrence of significant events, only when interrogated by an external device. As a result, the programmer-based follow-up sessions generally provide the sole opportunity for the IMD to report any significant event occurrences observed since the last follow-up session. Moreover, the latency in reporting significant event occurrences becomes dependent upon the timing of the clinical follow-up sessions for non-closely followed patients. Thus, in some circumstances, delays in downloading telemetered data can result in lost data or chronic cardiac conditions recognized too late.

Recently, far field telemetry using radio frequency (RF) carrier signals has provided an alternative means for interfacing programmers and similar external devices to IMDs, such as described in commonly-assigned U.S. Pat. No. 6,456,256, issued Sep. 24, 2002, to Amudson et al.; U.S. Pat. No. 6,574, 510, to Von Arx et al., issued Jun. 3, 2003; and U.S. Pat. No. 6,614,406, issued Sep. 2, 2003, to Amudson et al., disclosures of which are incorporated by reference. Far field telemetry has a higher data rate, which results in shorter downloading times, and the patient experiences greater freedom of movement while the IMD is being accessed. Nevertheless, despite the higher data rate, the IMD remains a passive device that only reports significant event occurrences when interrogated using an RF-capable programmer.

Similarly, dedicated monitoring devices, known as repeaters, have become available to patients to provide monitoring and IMD follow-up in an at-home setting similar to transtelephonic monitoring. Each repeater is specifically matched to an IMD. Once a day or as required, the patient uses the repeater to actively poll the IMD through induction or far field telemetry. Alternatively, some repeaters can be passively polled. During each session, any significant events occurrences are reported, although programming of the IMD is generally not allowed for safety reasons. As well, repeaters download recorded telemetered data. Despite the improved frequency and speed of telemetered data downloads, the latency to report significant event occurrences can be as long as a full day. The patient must also be physically proximal to the repeater during interrogation in the same fashion as a programmer. In addition, repeaters, by virtue of being stationary devices, are unable to capture patient physiological and behavioral data while the patient is engaged in normal everyday activities or at any other time upon the initiation of the patient or by a remote patient management system.

Furthermore, the use of RF telemetry in IMDs potentially raises serious privacy and safety concerns. Sensitive information, such as patient-identifiable health information (PHI), exchanged between an IMD and the programmer or repeater should be safeguarded to protect against compromise. Recently enacted medical information privacy laws, including the Health Insurance Portability and Accountability Act (HIPAA) and the European Privacy Directive underscore the importance of safeguarding a patient's privacy and safety and require the protection of all patient-identifiable health information (PHI). Under HIPAA, PHI is defined as individually identifiable health information, including identifiable demographic and other information relating to the past, present or future physical or mental health or condition of an individual, or the provision or payment of health care to an individual that is created or received by a health care provider, health plan, employer or health care clearinghouse. Other types of sensitive information in addition to or in lieu of PHI could also be protectable.

The sweeping scope of medical information privacy laws, such as HIPAA, may affect patient privacy on IMDs with longer transmission ranges, such as provided through RF telemetry, and other unsecured data interfaces providing sensitive information exchange under conditions that could allow eavesdropping, interception or interference. Sensitive information should be encrypted prior to long range transmission. Currently available data authentication techniques for IMDs can satisfactorily safeguard sensitive information. These techniques generally require cryptographic keys, which are needed by both a sender and recipient to respectively encrypt and decrypt sensitive information transmitted during a data exchange session. Cryptographic keys can be used to authenticate commands, check data integrity and, optionally, encrypt sensitive information, including any PHI, during a data exchange session. Preferably, the cryptographic key is unique to each IMD. However, authentication can only provide adequate patient data security if the identification of the cryptographic key from the IMD to the programmer or repeater is also properly safeguarded.

Therefore, there is a need for an approach to providing an ambulatory solution to retrieving physiological and parametric telemetered data from IMDs. Preferably, such an approach would provide authenticated and secure communication with IMDs and include configurable activation settings.

SUMMARY OF THE INVENTION

One embodiment provides a system and method for providing an external data processing device to interface with an ambulatory repeater. The external data processing device is interfaced in far field telemetric communication with an ambulatory repeater. The external data processing device receives sensitive information preencrypted prior to implant under a cryptographic key uniquely assigned to an implantable medical device over a secure connection from the ambulatory repeater. Physiological measures retrieved from the implantable medical device by the ambulatory repeater are received by the external data processing device over a non-secure connection.

A further embodiment provides an ambulatory repeater for use in automated patient care and method thereof. A sensor directly monitors a patient and records physiological measures on an ad hoc basis. The sensor interfaces with an implantable medical device and periodically retrieves physiological measures from the implantable medical device. Sensitive information is preencrypted and stored on the implantable medical device prior to implant under a cryptographic key uniquely assigned to the implantable medical device. The ambulatory repeater retrieves the cryptographic key and authorization to access the sensitive information and physiological measures on the implantable medical device is authenticated from an external data processing device. The ambulatory repeater is interfaced to the implantable medical device by wireless telemetry and to the external data processing device through wireless communication. The ambulatory repeater exchanges the sensitive information and physiological measures with the external data processing device.

Still other embodiments of the present invention will become readily apparent to those skilled in the art from the following detailed description, wherein are described embodiments of the invention by way of illustrating the best mode contemplated for carrying out the invention. As will be realized, the invention is capable of other and different embodiments and its several details are capable of modifications in various obvious respects, all without departing from the spirit and the scope of the present invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram showing, by way of example, an implantable medical device.

FIG. **2** is a process flow diagram showing interfacing with the implantable medical device of FIG. **1** using an ambulatory repeater.

FIG. **3** is a functional block diagram showing, by way of example, an ambulatory repeater in handheld form factor, in accordance with one embodiment.

FIG. **4** is a functional block diagram showing, by way of example, an ambulatory repeater in wearable form factor, in accordance with a further embodiment.

FIG. **5** is a functional block diagram showing, by way of example, systems for securely communicating using an ambulatory repeater, in accordance with one embodiment.

FIG. **6** is a functional block diagram showing, by way of example, the internal components of the ambulatory repeater in the wearable form factor of FIG. **4**.

FIG. **7** is a flow diagram showing a method for providing automated patient care using an ambulatory repeater, in accordance with one embodiment.

FIG. **8** is a flow diagram showing a routine for obtaining a cryptographic key for use in the method of FIG. **7**.

FIG. **9** is a flow diagram showing a routine for activating an ambulatory repeater for use in the method of FIG. **7**.

FIG. **10** is a flow diagram showing a routine for performing a secure data exchange for use in the method of FIG. **7**.

FIG. **11** is a flow diagram showing a routine for interrogating an IMD for use in the method of FIG. **7**.

DETAILED DESCRIPTION

Implantable Medical Device

FIG. **1** is a block diagram showing, by way of example, an implantable medical device (IMD) **103**. The IMD **103**, such as a pacemaker, implantable cardiac defibrillator (ICD) or similar device, is surgically implanted in the chest or abdomen of a patient to provide in situ therapy, such as pacing, cardiac resynchronization, defibrillation, neural stimulation and drug delivery, and physiological data monitoring. Examples of cardiac pacemakers suitable for use in the described embodiment include the Pulsar Max II, Discovery, and Discovery II pacing systems and the Contak Renewal cardiac resynchronization therapy defibrillator, sold by Guidant Corporation, St. Paul, Minn.

The IMD **103** includes a case **104** and terminal block **105** coupled to a set of leads **106***a*-*b*. The leads **106***a*-*b* are implanted transvenously for endocardial placement. The IMD **103** is in direct electrical communication with the heart **102** through electrodes **111***a*-*b* positioned on the distal tips of each lead **106***a*-*b*. By way of example, the set of leads **106***a*-*b* can include a right ventricular electrode **111***a*, preferably placed in the right ventricular apex **112** of the heart **102**, and a right atrial electrode **111***b*, preferably placed in the right atrial chamber **113** of the heart **102**. The set of leads **106***a*-*b* can also include a right ventricular electrode **114***a* and a right atrial electrode **114***b* to enable the IMD **103** to directly collect physiological measures, preferably through millivolt measurements.

The IMD **103** includes a case **104** and terminal block **105** coupled to a set of leads **106***a*-*b*. The IMD case **104** houses hermitically-sealed components, including a battery **107**, control circuitry **108**, memory **109**, and telemetry circuitry **110**. The battery **107** provides a finite, power source. The control circuitry **108** controls therapy delivery and monitoring, including the delivery of electrical impulses to the heart **102** and sensing of spontaneous electrical activity. The memory **109** includes a memory store in which the physiological signals sensed by the control circuitry **108** can be temporarily stored, pending telemetered data download.

The telemetry circuitry **110** provides an interface between the IMD **103** and an external device, such as a programmer conventional or ambulatory repeater, or similar device. For near field data exchange, the IMD **103** communicates with a programmer or conventional or ambulatory repeater (not shown) through inductive telemetry signals exchanged through a wand placed over the location of the IMD **103**. Programming or interrogating instructions are sent to the IMD **103** and the stored physiological signals are downloaded into the programmer or repeater. For far field data exchange, the IMD **103** communicates with an external device capable of far field telemetry, such as a radio frequency (RF) programmer, conventional or ambulatory repeater, or other wireless computing device, as further described below with reference to FIG. **2**. Other types of data interfaces are possible, as would be appreciated by one skilled in the art.

Other configurations and arrangements of leads and electrodes can also be used. Furthermore, although described with reference to IMDs for providing cardiac monitoring and therapy delivery, suitable IMDs also include other types of implantable therapeutic and monitoring devices in addition to or in lieu of cardiac monitoring and therapy delivery IMDs, including IMDs for providing neural stimulation, drug delivery, and physiological monitoring and collection.

Process Flow

FIG. **2** is a process flow diagram **120** showing interfacing with the IMD **103** of FIG. **1** using an ambulatory repeater **123**. The ambulatory repeater **123** provides a portable means for securely transacting a data exchange session with the IMD **103** and, in turn, at least one of a conventional or "base" repeater **124**, server **125**, or programmer **126**, as further described below with reference to FIG. **5**. Unlike a base repeater **124**, the ambulatory repeater **123** can collect patient health information as frequently or infrequently as needed and, due to being immediately proximate to the patient, can measure the activity level of the patient during normal everyday activities, rather than only at home or in a clinical setting.

Interfacing **120** with the IMD **103** includes key generation **121**, authentication **129**, activation **130**, protected data storage and retrieval **131**, unprotected data storage and retrieval **136**, and optional data exchanges **132**, **133**, **134** with the base repeater **124**, server **125**, and programmer **126**. Key generation **121** creates a cryptographic key **122**, which is used to encrypt and decrypt any sensitive information exchanged with the IMD **103**, such as during protected data storage and retrieval **131** using long range telemetry or over any other unsecured interface. The cryptographic key **122** can be statically generated and persistently stored, dynamically generated and persistently stored, dynamically generated and non-persistently stored as a session cryptographic key **122**, or a combination of the foregoing. Persistently-stored cryptographic keys **122** are maintained in a fixed secure key repository, such as a programmer, patient designator, secure database, token, base repeater **124**, ambulatory repeater **123**, and on the IMD **103** itself. Statically generated and persistently-stored cryptographic keys are stored in the IMD **103** prior to implantation, such as during the manufacturing process. Dynamically generated and persistently-stored cryptographic keys are generated dynamically, such as by the ambulatory repeater **123** for subsequent download to the IMD **103** using short range telemetry following implantation. Dynamically generated and non-persistently-stored session cryptographic keys are also generated dynamically and shared with the IMD **103**, but are not persistently stored and are used for a single patient data exchange. Each cryptographic key **122** is uniquely assigned to the IMD **103**. In one embodiment, the cryptographic key **103** has a length of 128 bits, is symmetric or is both 128-bits long and symmetric. Other cryptographic key lengths and symmetries are possible.

Authentication **129** provides an opportunity to securely obtain the cryptographic key **122** uniquely assigned to the IMD **103**. In one embodiment, the IMD **103** interfaces with an external source, such as the ambulatory repeater **123** or other wireless computing device, to either receive or share the cryptographic key **122** assigned to the IMD **103**, such as described in commonly-assigned U.S. Pat. No. 7,838,828, issued Nov. 9, 2010, the disclosure of which is incorporated by reference. In a further embodiment, the ambulatory repeater **123** retrieves the cryptographic key **122** from the IMD **103** using secure, short range telemetry, such as inductive telemetry, as further described below with reference to FIG. **5**.

In a further embodiment, the cryptographic key **122** is entrusted to a third party, such as hospital or emergency services, as a form of key escrow. Under normal circumstances, the cryptographic key **122** will not be released unless the requestor performs proper authentication **129**. However, the cryptographic key **122** could be released under specifically-defined circumstances, such as a bona fide medical emergency, to a third party to facilitate access to patient health information in the IMD **103**, ambulatory repeater **123**, base repeater **124**, server **125**, programmer **126**, or other such authenticated device.

Following authentication **126**, the ambulatory repeater **123** can be used to securely transact data exchange sessions with the IMD **103**. Each data exchange session is secure in that the patient health information being exchanged is safely protected from compromise and interception by encryption prior to being transmitted. Thus, the communication channel can be unsecured, as the data itself remains protected. As the ambulatory repeater **123** remains physically proximal to the patient, secure data exchange sessions are performed either as on demand or per a schedule, as further described below with reference to FIGS. **6** and **9**. Briefly, activation **130** can occur due to a patient-initiated interrogation, on demand or at scheduled times. A patient-initiated interrogation is triggered by a manual overwrite of the ambulatory repeater **123** by the patient when the patient, for instance, feels ill, or otherwise inclined to take a reading of data values. On demand interrogation occurs due to a remote or local event, such as remote activation request from the server **125**. Such a remote activation may be issued by a remote activation module that issues a data transfer trigger over the ambulatory repeater interface to the ambulatory repeater **123**. Scheduled interrogation is specified by a healthcare provider and remains in effect until a new schedule is downloaded.

Upon activation **130**, protected data storage and retrieval **131** and unprotected data storage and retrieval **136** are performed. During protected data storage and retrieval **131**, sensitive information **127** (SI), particularly PHI, is provided to and retrieved from the IMD **103**, as further described below. During unprotected data storage and retrieval **136**, non-sensitive information (non-SI) **135** is retrieved from and sent to the IMD **103** directly via the ambulatory repeater **123**. Protected data storage and retrieval **131** and unprotected data storage and retrieval **136** can occur simultaneously during the same data exchange session. In a further embodiment, the SI **127** provided to the IMD **103** can include programming instructions for the IMD **103**.

In one embodiment, the bulk of the patient health information retrieved from the IMD **103** is non-SI **135**. SI **127** is generally limited to only patient-identifiable health information, which typically does not change on a regular basis. The non-SI **135** loosely falls into two categories of data. First, physiological data relates directly to the biological and biochemical processes of the body, such as salinity, pulse, blood pressure, glucose level, sweat, and so forth. Second, behavioral data relates to physical activities performed by the patient either during the course of a normal day or in response to a specific request or exercise regimen, such as sitting, standing, lying supine, and so forth. Other types of patient health measures are possible.

During protected data storage and retrieval **131**, SI **127**, particularly PHI, can be received into the ambulatory repeater **123** from one or more sensors **128** and from a patient or clinician, respectively via the base repeater **124** and server **125** or programmer **126**. Part or all of the sensitive information **127** is preferably preencrypted using the cryptographic key **122**, including any PHI, which can be stored on the IMD **103** as static data for retrieval by health care providers and for use by the IMD **103**, such as described in commonly-assigned U.S. Pat. No. 7,475,245, issued Jan. 6, 2009, the disclosure of which is incorporated by reference. If the sensitive information needs to be retrieved, the ambulatory repeater **123** obtains the cryptographic key **122**, if necessary, through authentication **126** and retrieves the encrypted information **128** from the IMD **103** for subsequent decryption using the cryptographic key **122**. In one embodiment, the sensitive information **127**, including any PHI, is encrypted using a standard encryption protocol, such as the Advanced Encryption Standard protocol (AES). Other authentication and encryption techniques and protocols, as well as other functions relating to the use of the cryptographic key **122** are possible, including the authentication and encryption techniques and protocols described in commonly-assigned U.S. Pat. No. 7,155,290, issued Dec. 26, 2006, the disclosure of which is incorporated by reference.

Ambulatory repeater-to-sensor data exchanges **139** enable the ambulatory repeater **123** to receive patient health information from the sensors **138**, including external sensors, such as a weight scale, blood pressure monitor, electrocardiograph, Holter monitor, or similar device. In a further embodiment, one or more of the sensors **138** can be integrated directly into the ambulatory repeater **123**, as further described below with reference to FIG. **6**.

The non-SI **135** and SI **127** is exchanged with at least one of three external data processing devices, which include the base repeater **124**, server **125**, and programmer **126**. In addition, the ambulatory repeater **123** is communicatively interfaced to at least one external sensor to directly measure patient health information, as further described below beginning with reference to FIG. **5**. Ambulatory repeater-to-base repeater data exchanges **132** enable the ambulatory repeater **123** to function as a highly portable extension of the base repeater **124**. Unlike the base repeater **124**, the ambulatory repeater **123** includes a power supply that enables secure interfacing with the IMD **103** while the patient is mobile and away from the base repeater **124** and can interrogate the IMD **103** at any time regardless of the patient's activity level.

Ambulatory repeater-to-server data exchanges **133** enable the server **125** to directly access the IMD **103** via the ambulatory repeater **123** through remote activation, such as in emergency and non-emergency situations and in those situation, in which the base repeater **125** is otherwise unavailable.

Ambulatory repeater-to-programmer data exchanges **134** supplement the information ordinarily obtained during a clinical follow-up session using the programmer **126**. The ambulatory repeater **123** interfaces to and supplements the retrieved telemetered data with stored data values that were obtained by the ambulatory repeater **123** on a substantially continuous basis.

In addition, patient health information can be shared directly **137** between the base repeater **124**, server **125**, and programmer **126**. Other types of external data processing devices are possible, including personal computers and other ambulatory repeaters.

Ambulatory Repeater in Handheld Form Factor

FIG. **3** is a functional block diagram **150** showing, by way of example, an ambulatory repeater **123** in handheld form factor **151**, in accordance with one embodiment. The handheld form factor **151** enables the ambulatory repeater **123** to be carried by the patient and can be implemented as either a stand-alone device or integrated into a microprocessor-equipped device, such as a personal data assistant, cellular telephone or pager. Other types of handheld form factors are possible.

The handheld form factor **151** includes a display **152** for graphically displaying indications and information **157**, a plurality of patient-operable controls **153**, a speaker **154**, and a microphone **155** for providing an interactive user interface. The handheld form factor **151** is preferably interfaced to the IMD **103** through RF telemetry and to the base repeater **124**, server **125**, and programmer **126** through either RF telemetry, cellular telephone connectivity or other forms of wireless communications, as facilitated by antenna **156**. The display **152** and speaker **154** provide visual and audio indicators while the controls **153** and microphone **155** enable patient feedback. In addition, one or more external sensors (not shown) are interfaced or, in a further embodiment, intergraded into the handheld form factor **151** for directly monitoring patient health information whenever required.

The types of indications and information **157** that can be provided to the patient non-exclusively include:

(1) Health measurements
(2) Active or passive pulse generator or health information monitoring
(3) Data transmission in-process indication
(4) Alert condition detection
(5) Impending therapy
(6) Ambulatory repeater memory usage
(7) Ambulatory repeater battery charge

In addition to securely exchanging data with the IMD **103**, the ambulatory repeater **123** can perform a level of analysis of the downloaded teletemered data and, in a further embodiment, provide a further visual indication **158** to the patient for informational purposes.

The handheld form factor **151** can also include a physical interface **159** that allows the device to be physically connected or "docked" to an external data processing device, such as the base repeater **124**, for high speed non-wireless data exchange and to recharge the power supply integral to the handheld form factor **151**. The ambulatory repeater **123** can continue to securely communicate with the IMD **103**, even when "docked", to continue remote communication and collection of telemetered data.

Ambulatory Repeater in Wearable Form Factor

FIG. **4** is a functional block diagram **170** showing, by way of example, an ambulatory repeater **123** in wearable form factor **171**, in accordance with a further embodiment. The wearable form factor **171** enables the ambulatory repeater **123** to be worn by the patient and can be implemented as either a stand-alone device or integrated into a microprocessor-equipped device, such as a watch or belt. Other types of wearable form factors are possible.

Similar to the handheld form factor **151**, the wearable form factor **171** includes a display **172** for graphically displaying indications and information **177**, a plurality of patient-operable controls **173**, a speaker **174**, and a microphone **175** for providing an interactive user interface. The wearable form factor **171** is preferably interfaced to the IMD **103** through RF telemetry and to the base repeater **124**, server **125**, and programmer **126** through either RF telemetry, cellular telephone connectivity or other forms of wireless communications, as facilitated by antenna **176**. The display **172** and speaker **174** provide visual and audio indicators while the controls **173** and microphone **175** enable patient feedback. In addition, one or more external sensors (not shown) are interfaced or, in a further embodiment, intergraded into the wearable form factor **171** for directly monitoring patient health information whenever required. The wearable form factor **171** also includes a physical interface **179** that allows the device to be physically connected or "docked" to an external data processing device.

Ambulatory Repeater System Overview

FIG. **5** is a functional block diagram **190** showing, by way of example, systems for securely communicating using an ambulatory repeater **123**, in accordance with one embodiment. By way of example, an ambulatory repeater **123** in a wearable form factor **171** is shown, although the ambulatory repeater **123** could also be provided in the handheld form factor **151**. The ambulatory repeater **123** securely interfaces to the IMD **103** over a secure data communication interface **191**, such as described above with reference to FIG. **2**. The ambulatory repeater interrogates the IMD **103** due to a patient-initiated interrogation, on demand, or at scheduled times. Patient-initiated interrogations are triggered by the patient through a manual overwrite of the ambulatory repeater **123**. In one embodiment, the patient is limited in the number of times that a patient-initiated interrogation can be performed during a given time period. However, in a further embodiment, a healthcare provider can override the limit on patient-initiated interrogations as required. On demand interrogations occur in response to a remote or local event, such as a health-based event sensed by the ambulatory repeater **123**. Scheduled interrogations occur on a substantially regular basis, such as hourly or at any other healthcare provider-defined interval. The schedule is uploaded to the ambulatory repeater **123** using an upload module on the processor and remains in effect until specifically replaced by a new schedule. The ambulatory repeater **123** can also be activated by indirect patient action, such as removing the device from a "docking station."

Once activated, parametric and behavioral data collected and recorded by the IMD **103** from the external sensors are monitored by the ambulatory repeater **123** in a fashion similar to the base repeater **124**. However, the power supply enables the ambulatory repeater **123** to operate separately and independently from external power sources, thereby allowing the patient to remain mobile. The ambulatory repeater **123** also provides the collateral benefits of functioning as an automatic data back-up repository for the base repeater **124** and alleviates patient fears of a lack of monitoring when away from the base repeater **124**. In a further embodiment, the parametric and behavioral data is gathered and analyzed by either the ambulatory repeater **123** or an external data processing device, such as repeater **124**, server **125** or programmer **126**, and provided for review by a healthcare provider. Alternatively, the analysis can be performed through automated means. A set of new IMD parameters can be generated and provided to the ambulatory repeater **123** for subsequent reprogramming of the IMD **103**. The data is processed using a processing module on the processor operative on the physiological measures.

Periodically or as required, the ambulatory repeater **123** interfaces to one or more of the base repeater **124**, server **125**, and programmer **126** to exchange data retrieved from the IMD **103**. In one embodiment, the ambulatory repeater **123** interfaces via a cellular network **191** or other form of wireless communications. The base repeater **124**, comprising a monitoring module, is a dedicated monitoring device specifically matched to the IMD **103**. The base repeater **124** relies on external power source and can interface to the IMD **103** either through inductive or RF telemetry. The base repeater **124** further interfaces to the ambulatory repeater **123** either through a physical or wireless connection, as further described above.

The server **125** maintains a database **192** for storing patient records. The patient records can include physiological quantitative and quality of life qualitative measures for an individual patient collected and processed in conjunction with, by way of example, an implantable medical device, such a pacemaker, implantable cardiac defibrillator (ICD) or similar device; a sensor **138**, such as a weight scale, blood pressure monitor, electrocardiograph, Holter monitor or similar device; or through conventional medical testing and evaluation. In addition, the stored physiological and quality of life measures can be evaluated and matched by the server **123** against one or more medical conditions, such as described in related, commonly-owned U.S. Pat. No. 6,336,903, to Bardy, issued Jan. 8, 2002; U.S. Pat. No. 6,368,284, to Bardy, issued Apr. 9, 2002; U.S. Pat. No. 6,398,728, to Bardy, issued Jun. 2, 2002; U.S. Pat. No. 6,411,840, to Bardy, issued Jun. 25, 2002; and U.S. Pat. No. 6,440,066, to Bardy, issued Aug. 27, 2002, the disclosures of which are incorporated by reference.

The programmer **126** provides conventional clinical follow-up of the IMD **103** under the direction of trained healthcare professionals. In one embodiment, the ambulatory repeater **123** interfaces via a cellular network **191** or other form of wireless communications. Other types of external data processing devices and interfacing means are possible.

In a further embodiment, the ambulatory repeater **123** interfaces to emergency services **193**, which posses a copy of the cryptographic key **122** (shown in FIG. **2**) held in a key escrow. Under ordinary circumstances, patient health information is exchanged exclusively between the ambulatory repeater **123** and authenticated external data processing devices, such as the base repeater **124**, server **125**, and programmer **126**. However, in a bona fide emergency situation, the emergency services **193** can use the cryptographic key **122** to access the patient health information in the ambulatory repeater **123** and IMD **103**, as well as the repeater **124**, server **125**, and programmer **126**. Other forms of key escrow are possible.

Ambulatory Repeater Internal Components

FIG. **6** is a functional block diagram **190** showing, by way of example, the internal components of the ambulatory repeater **123** in the wearable form factor **171** of FIG. **4**. By way of example, the ambulatory repeater **123** includes a processor **202**, memory **203**, authentication module **212**, communications module **205**, physical interface **213**, optional integrated sensor **214**, and alarm **215**. Each of the components is powered by a power supply **204**, such as a rechargeable or replaceable battery. The internal components are provided in a housing **201** with provision for the antenna **176** and physical interface **179**.

The processor **202** enables the ambulatory repeater **123** to control the authentication and secure transfer of both non-sensitive and sensitive information between the IMD **103**, one or more external sensors (not shown), and one or more of the base repeater **124**, server **125**, and programmer **126**. The processor **202** also operates the ambulatory repeater **123** based on functionality embodied in an analysis module **207**, schedule module **208** and overwrite module **209**. The analysis module **207** controls the translation, interpretation and display of patient health information. The schedule module **208** controls the periodic interfacing of the ambulatory repeater **123** to the IMD **103** and external data processing device. The overwrite module **209** controls the patient-initiated interrogation. Other control modules are possible.

The communications module **205** includes an IMD telemetry module **210** and external data processing device (EDPD) telemetry module **211** for respectively interfacing to the IMD **103** and external data processing device, such as the base repeater **124**, server **125**, and programmer **126**. Preferably, the ambulatory repeater **123** interfaces to the IMD **103** and external sensors through inductive RF telemetry, Bluetooth, or other form of secure wireless interface, while the ambulatory repeater **123** interfaces to external data processing device preferably through RF telemetry or via cellular network or other form of wireless interface. The authentication module **206** is used to securely authenticate and encrypt and decrypt sensitive information using a retrieved cryptographic key **212**. The memory **203** includes a memory store, in which the physiological and parametric data retrieved from the IMD **103** are transiently stored pending for transfer to the external data processing device and, in a further embodiment, download to the IMD **103**. The physical interface **213** controls the direct physical connecting of the ambulatory repeater **123** to an external data processing device or supplemental accessory, such as a recharging "doc" or other similar device. The optional integrated sensor **214** directly monitors patient health information, such as patient activity level. Lastly, the alarm **215** provides a physical feedback alert to the patient, such as through a visual, tactual or audible warning, for example, flashing light, vibration, or alarm tone, respectively. Other internal components are possible, including a physical non-wireless interface and removable memory components.

Ambulatory Repeater Method Overview

FIG. **7** is a flow diagram showing a method **220** for providing automated patient care using an ambulatory repeater **123**, in accordance with one embodiment. The purpose of this method is to periodically activate and securely exchange information with the IMD **103**, one or more sensors **138**, and an external data processing device that includes one or more of a base repeater **124**, server **125**, and programmer **126**. The method **220** is described as a sequence of process operations or steps, which can be executed, for instance, by an ambulatory repeater **123**.

The method begins by obtaining the cryptographic key **122** (block **221**), as further described below with reference to FIG. **8**. The method then iteratively processes data exchange sessions (blocks **222-226**) as follows. First, the ambulatory repeater **123** is activated (block **223**), which includes securely interrogating the IMD **103**, as further described below with reference to FIG. **9**. Next, the ambulatory repeater **123** performs a data exchange session with one or more of the external data processing devices, including the base repeater **124**, server **125**, and programmer **126**, as further described below with reference to FIG. **10**. Following completion of the data exchange session, the ambulatory repeater **123** returns to a stand-by mode (block **225**). Processing continues (block **226**) while the ambulatory repeater **123** remains in a powered-on state.

Obtaining a Cryptographic Key

FIG. **8** is a flow diagram showing a routine **240** for obtaining a cryptographic key **122** for use in the method **220** of FIG. **7**. The purpose of this routine is to securely receive the cryptographic key uniquely assigned to the IMD **103** into the ambulatory repeater **123**.

Initially, the cryptographic key **122** is optionally generated (block **241**). Depending upon the system, the cryptographic key **122** could be generated dynamically by the base repeater **124** or programmer **126** for subsequent download to the IMD **103** using short range telemetry following implantation. Similarly, the cryptographic key **122** could be generated during the manufacturing process and persistently stored in the IMD **103** prior to implantation. Alternatively, the cryptographic key **122** could be dynamically generated by the IMD **103**.

Next, a secure connection is established with the source of the cryptographic key **122** (block **242**). The form of the secure connection is dependent upon the type of key source. For instance, if the key source is the IMD **103**, the secure connection could be established through inductive or secure RF telemetric link via the base repeater **124** or programmer **126**. If the key source is the base repeater **124**, a secure connection could be established through the dedicated hardwired connection. In one embodiment, the secure connection is established using a secure connection module over which sensitive information preencrypted prior to implant under a cryptographic key uniquely assigned to an implantable medical device is received from an ambulatory repeater.

Finally, the cryptographic key **122** is authenticated and obtained (block **243**) by storing the cryptographic key **122** into the authentication module **206**.

Ambulatory Repeater Activation

FIG. **9** is a flow diagram showing a routine **260** for activating an ambulatory repeater **123** for use in the method **220** of FIG. **7**. The purpose of the routine is to activate the ambulatory repeater **123** prior to interrogating the sensors **138** and IMD **103**.

The ambulatory repeater **123** can be activated as scheduled (block **261**) or through manual action directly or indirectly by the patient (block **262**) or remotely, such as by the server **125** (block **265**).

Manual activation typically involves either a direct patient-initiated interrogation (block **263**), such as operating a manual override control, or indirect action, such as removing the ambulatory repeater **123** from a "docking" cradle (block **264**). Similarly, remote activation involves either health-based data transfer triggers (block **266**) or system-based data transfer triggers (block **267**). A health-based data transfer is triggered when a prescribed or defined health status or alert condition is detected. A system-based data transfer trigger occurs typically due to a device-specific circumstance, such as data storage nearing maximum capacity. Other forms of manual and remote ambulatory repeater activations are possible. Upon activation, the sensors **138** and IMD **103** are interrogated (blocks **268** and **269**), as further described below with reference to FIG. **11**.

Secure Data Exchange

FIG. **10** is a flow diagram showing a routine **280** for performing a secure data exchange for use in the method **220** of FIG. **7**. The purpose of this routine is to exchange data between the ambulatory repeater **123** and one or more external data processing device, such as the base repeater **124**, server **125**, and programmer **126**.

Initially, any sensitive information **127** is encrypted (block **281**) using, for instance, the cryptographic key **122** that is uniquely assigned to the IMD **103**, or other cryptographic key (not shown) upon which the ambulatory repeater **123** and external data processing device have previously agreed. A secure connection is opened with the external data processing device (block **282**) and the sensitive information is exchanged (block **283**). The connection is "secure" in that the sensitive information is only exchanged in an encrypted or similar form protecting the sensitive information from compromise and interception by unauthorized parties. In the described embodiment, the secure connection is served through a Web-based data communications infrastructure, such as Web-Sphere software, licensed by IBM Corporation, Armonk, N.Y. Other types of data communications infrastructures can be used. Upon the competition of the exchange of sensitive information, the secure connection with external data processing device is closed (block **284**) and a non-secure connection is open (block **285**). Similarly, non-sensitive information is exchanged (block **286**) and the non-secure connection is closed (block **287**). The non-sensitive information can be sent in parallel to the sensitive information and can also be sent over the secure connection. However, the sensitive information cannot be sent over the non-secure connection. In one embodiment, the non-secure connection is established using a non-secure connection module over which physiological measures retrieved from the implantable medical device are received from the ambulatory repeater.

IMD Interrogation

FIG. **11** is a flow diagram showing a routine **300** for interrogating an IMD **103** for use in the method **220** of FIG. **7**. The purpose of this routine is to retrieve encrypted sensitive information **128**, including any PHI, from the IMD **103** and to decrypt the encrypted sensitive information **128** using the cryptographic key **122** uniquely assigned to the IMD **103**.

Initially, the ambulatory repeater **123** authenticates with the IMD **103** (block **301**). A connection is established between the IMD **103** and the ambulatory repeater **123** (block **302**) via an RF connection. Encrypted sensitive information **127**, including any PHI, is retrieved from the IMD **103** (block **303**) and the connection between the IMD **103** and the ambulatory repeater **123** is closed (block **304**). The encrypted sensitive information **128** is then decrypted using the cryptographic key **122** (block **305**).

While the invention has been particularly shown and described as referenced to the embodiments thereof, those skilled in the art will understand that the foregoing and other changes in form and detail may be made therein without departing from the spirit and scope of the invention.

What is claimed is:

1. A method for retrieving information from an implantable medical device, comprising:

activating an ambulatory repeater;

securely obtaining a cryptographic key uniquely assigned to an implantable device from the implantable device to the ambulatory repeater;

interrogating the implantable medical device with the ambulatory repeater to access patient health information, wherein the patient health information comprise sensitive information and physiological measures;

securely receiving sensitive information from the implantable medical device with the ambulatory repeater, wherein the sensitive information is preencrypted under the cryptographic key;

non-securely receiving physiological measures retrieved from the implantable medical device via the ambulatory repeater;

interfacing a base repeater with the ambulatory repeater through far field telemetric communication;

opening a secure connection between the ambulatory repeater and the base repeater;

securely exchanging the sensitive information from the ambulatory repeater with the base repeater;

closing the secure connection between the ambulatory repeater and the base repeater; and

transmitting the patient health information from the base repeater to a server.

2. The method according to claim **1**, further comprising one of:

providing a dedicated monitoring module matched to the implantable medical device;

storing the physiological measures, the processor further comprising a processing module operative on the physiological measures; and

providing a clinical interrogation interface to a plurality of implantable medical devices.

3. The method according to claim **1**, further comprising:

issuing a data transfer trigger over the ambulatory repeater interface to the ambulatory repeater.

4. The method according to claim **3**, wherein the data transfer trigger comprises a system-based data transfer trigger occurring in response to a device-specific circumstance.

5. The method according to claim **3**, wherein the data transfer trigger comprises a health-based data transfer trigger occurring in response to at least one of a detected prescribed health status and a detected alert condition.

6. The method according to claim **1**, further comprising:

scheduling interrogations of the implantable medical device by the ambulatory repeater; and

uploading the schedule to the ambulatory repeater.

7. The method according to claim **1**, wherein the far field telemetry is selected from at least one of radio frequency telemetry and cellular telemetry.

8. The method according to claim **1**, wherein the physiological measures comprises at least one of physiological and behavioral data.

9. The method according to claim **1**, further comprising:

opening a non-secure connection between the ambulatory repeater and the base repeater;

exchanging the sensitive information from the ambulatory repeater with the base repeater; and

closing the non-secure connection between the ambulatory repeater and the base repeater.

10. The method according to claim **9**, wherein non-sensitive information is sent in parallel to the sensitive information.

11. An ambulatory repeater system for providing automated patient care, comprising:

a sensor to directly monitor a patient and to record physiological measures on an ad hoc basis;

an implantable medical device comprising:

a sensor interface;

a memory comprising:

physiological measures periodically retrieved over the sensor interface;

a secure key repository for maintaining one or more cryptographic keys; and

stored sensitive information; and

an ambulatory repeater, comprising:

a processor comprising:

an authentication module to authenticate authorization from an external data processing device to interrogate the implantable medical device and to securely obtain the one or more cryptographic keys uniquely assigned to the implantable medical device from the secure key repository of the implantable medical device;

a telemetry transceiver to interface to the implantable medical device through wireless telemetry upon securing authorization and to obtain the sensitive information and physiological measures; and

a communications module to decrypt the sensitive information using the cryptographic key and to facilitate exchange of the sensitive information and the physiological measures with an external data processing device;

wherein the ambulatory repeater is selected from the group consisting of a wearable form factor and a handheld form factor.

12. The ambulatory repeater apparatus according to claim **11**, wherein the sensor is one of external to and integrated directly into the ambulatory repeater.

13. The ambulatory repeater apparatus according to claim **11**, wherein the sensor interface operates over at least one of inductive telemetry and radio frequency telemetry.

14. The ambulatory repeater apparatus according to claim **11**, wherein the sensor is selected from at least one of weight scale, blood pressure monitor, electrocardiograph, and Holter monitor.

15. A method for providing automated patient care using an ambulatory repeater apparatus, comprising:

directly monitoring a patient via a sensor and recording physiological measures on an ad hoc basis;

providing an implantable medical device, comprising:

interfacing to the sensor and periodically retrieving the physiological measures; and

storing sensitive information preencrypted prior to implant under a cryptographic key uniquely assigned; and

providing an ambulatory repeater, comprising:

authenticating authorization from an external data processing device to interrogate the implantable medical device;

securely obtaining the cryptographic key from the implantable medical device;

interfacing to the implantable medical device through wireless telemetry upon securing the authorization;

obtaining the sensitive information and the physiological measures from the implantable medical device;

decrypting the sensitive information using the cryptographic key; and

exchanging the secure information and the physiological measures with an external data processing device;

wherein the ambulatory repeater is selected from the group consisting of a wearable form factor and a handheld form factor.

16. The method according to claim **15**, wherein the sensor is one of external to and integrated directly into the ambulatory repeater.

17. The A method according to claim **15**, wherein the interfacing of the implantable medical device and the sensor operates over at least one of inductive telemetry and radio frequency telemetry.

18. The A method according to claim **15**, wherein the sensor is selected from at least one of weight scale, blood pressure monitor, electrocardiograph, and Holter monitor.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,955,258 B2
APPLICATION NO. : 11/901520
DATED : June 7, 2011
INVENTOR(S) : Donald L. Goscha et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page, Related U.S. Application Data, Item (62): "Division" should read --Continuation--

Col. 16, line 26, claim 17: "The A method" should read "The method"

Col. 16, line 30, claim 18: "The A method" should read "The method"

Signed and Sealed this
Eighth Day of November, 2011

David J. Kappos
Director of the United States Patent and Trademark Office

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摘要(译)

提出了一种与移动转发器连接的外部数据处理设备及其方法。外部数据处理设备在远场遥测通信中与移动中继器连接。外部数据处理设备在植入之前接收在加密密钥下预先加密的敏感信息，该密码密钥通过来自移动转发器的安全连接唯一地分配给可植入医疗设备。由移动中继器从可植入医疗设备检索的生理措施由外部数据处理设备通过非安全连接接收。