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(54) APPARATUS AND METHOD FOR REMOTE TROUBLESHOOTING, MAINTENANCE AND UPGRADE OF IMPLANTABLE DEVICE SYSTEMS

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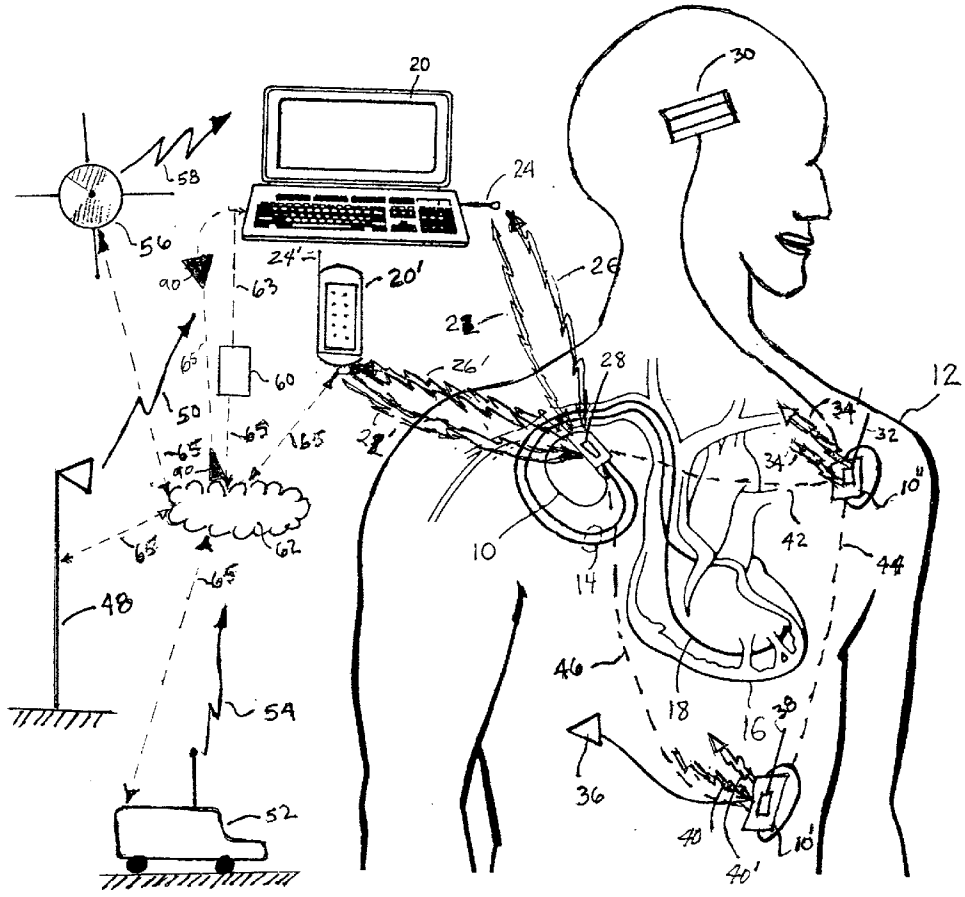
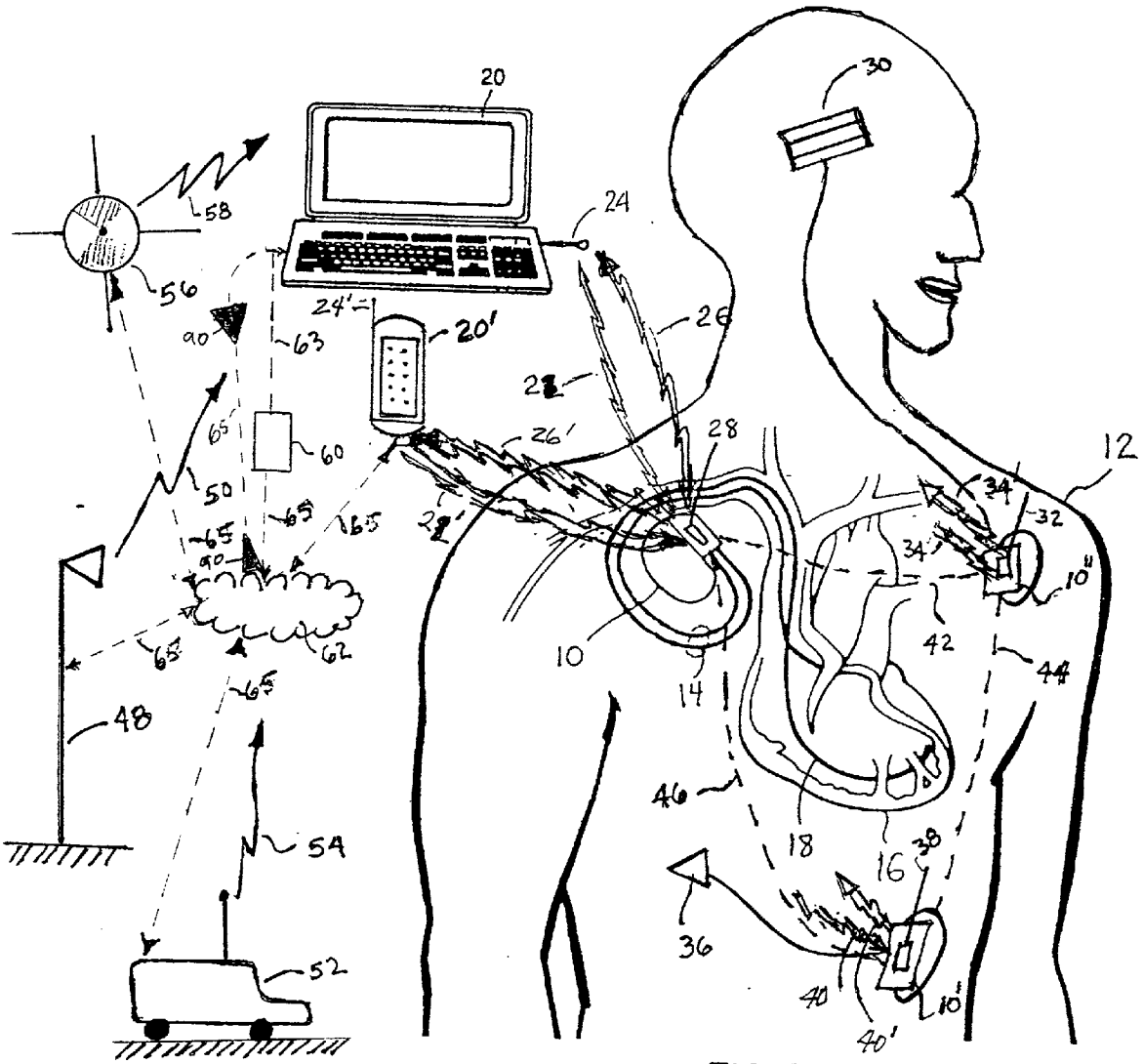
(57) ABSTRACT

A programmer operating in association with a diverse number of implantable medical devices (IMDs) is in a bi-directional operable data, voice and video communications with a remote web-based expert data center. The programmer is in telemetric wireless communications with the IMDs. The data center is equipped to manage the operational and functional aspects of the programmer remotely thus importing expertise to the patient environment. Specifically the communications scheme is scalable and adaptable to enable high-speed interactions between the programmer and the remote center across various communications media. The remote center is able to remotely assess, monitor, evaluate for failure or conduct other performance checks on the programmer to implement a remote solution to those problems. Specifically, by utilizing the robust communication scheme integrated with the remote web-based expert data center, the system enables a real-time deployment of executable software commands to manage the programmer by remotely monitoring, updating software, performing remote repairs or replacement of components and alerting operators to significant problems before they become critical to the optimal performance and reliability of the programmer.




20
30
24
58
56
24'
20'
26
90
63
22
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26'
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12
50
65
65
22'
34
32
34'
10"
65
90
42
10
62
44
14
65
48
46
18
16
38
54
36
52
40
10'
40'

FIG. 1

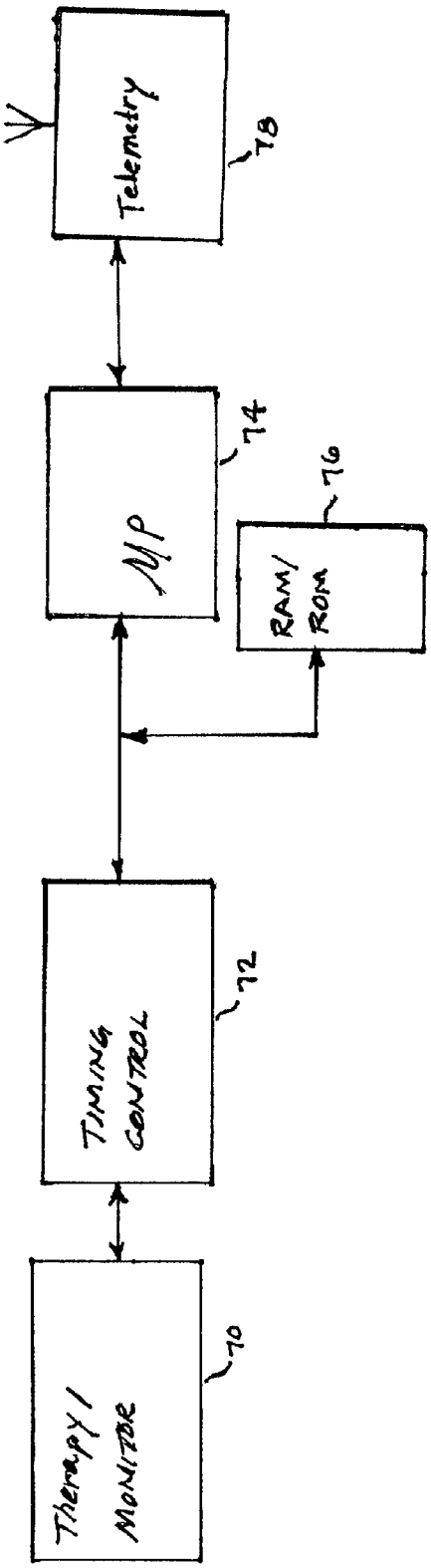


Fig - 2

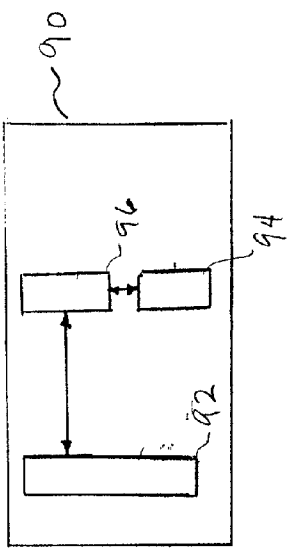


Fig - 3B

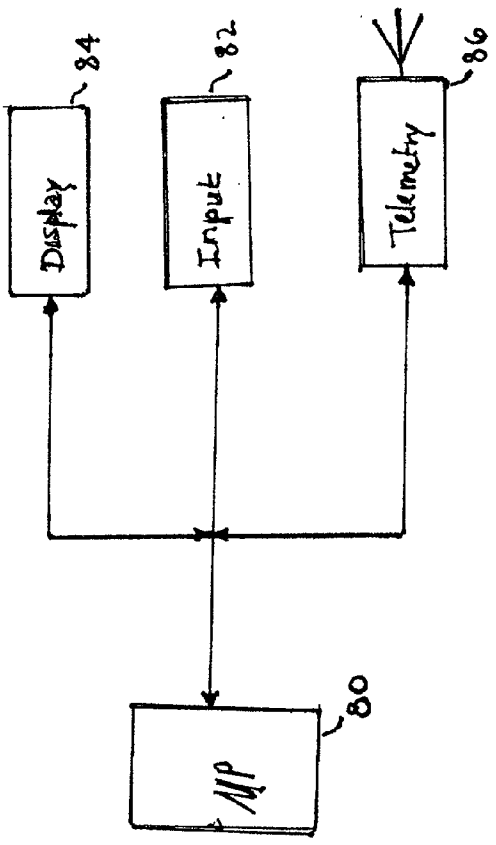


Fig - 3A

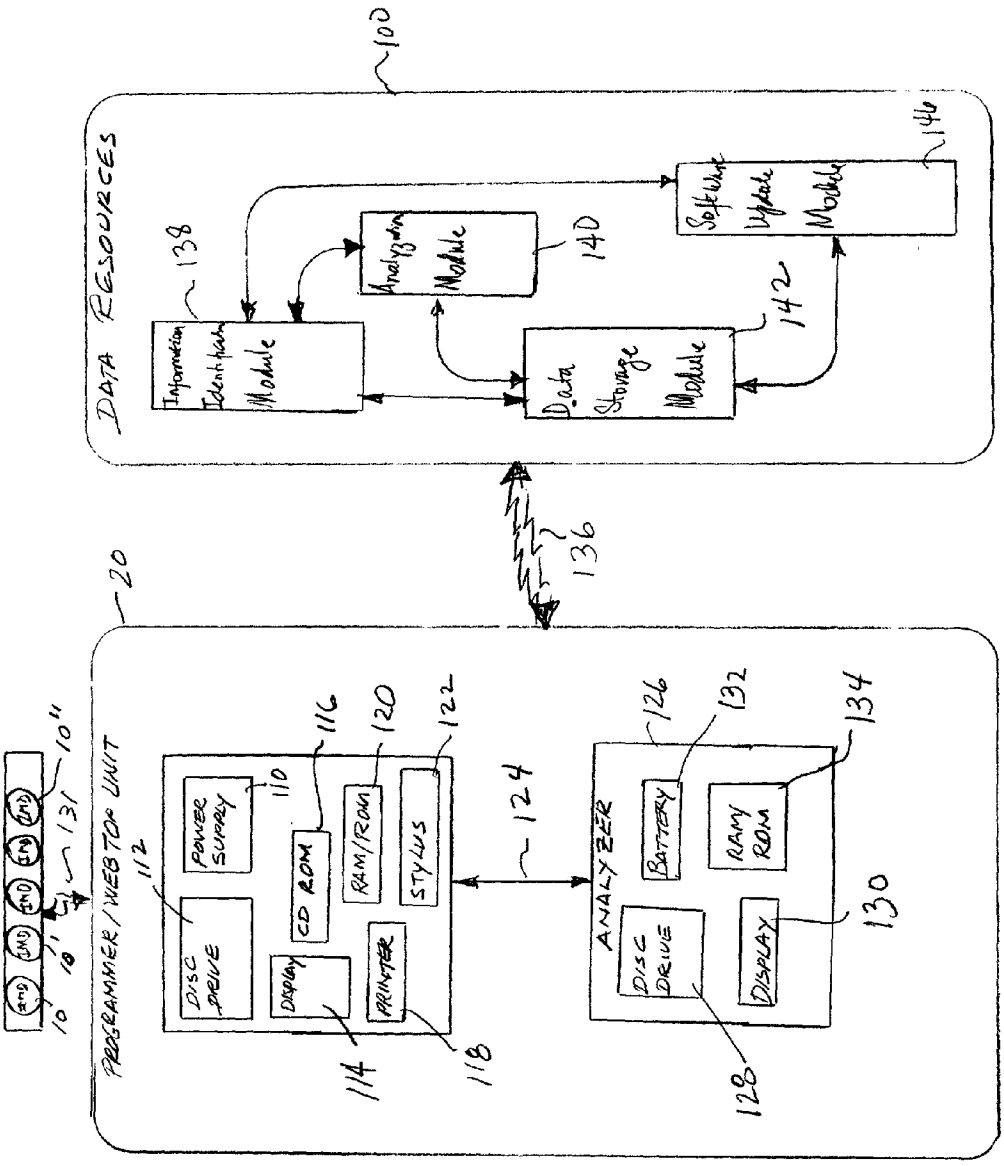

100
DATA RESOURCES
Information Identification Module
138
Analysis Module
140
Software Upgrade Module
142
Data Storage Module
136
20
PROGRAMMER / WEBTOP UNIT
POWER SUPPLY
110
DISC DRIVE
112
CD ROM
116
RAM/ROM
120
STYLUS
122
DISPLAY
114
PRINTER
118
124
ANALYZER
DISC DRIVE
128
BATTERY
126
132
DISPLAY
130
RAM/ROM
134
IMD
10
10'
10''
131

FIG-5

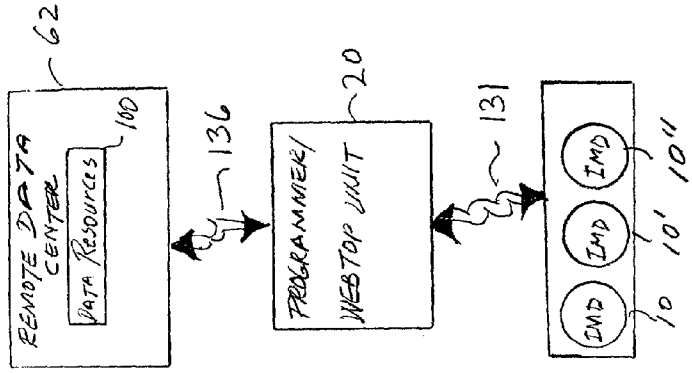

REMOTE DATA CENTER
62
DATA RESOURCES
100
136
PROGRAMMER/ WEBTOP UNIT
20
131
IMD
10
10'
10''

FIG-4

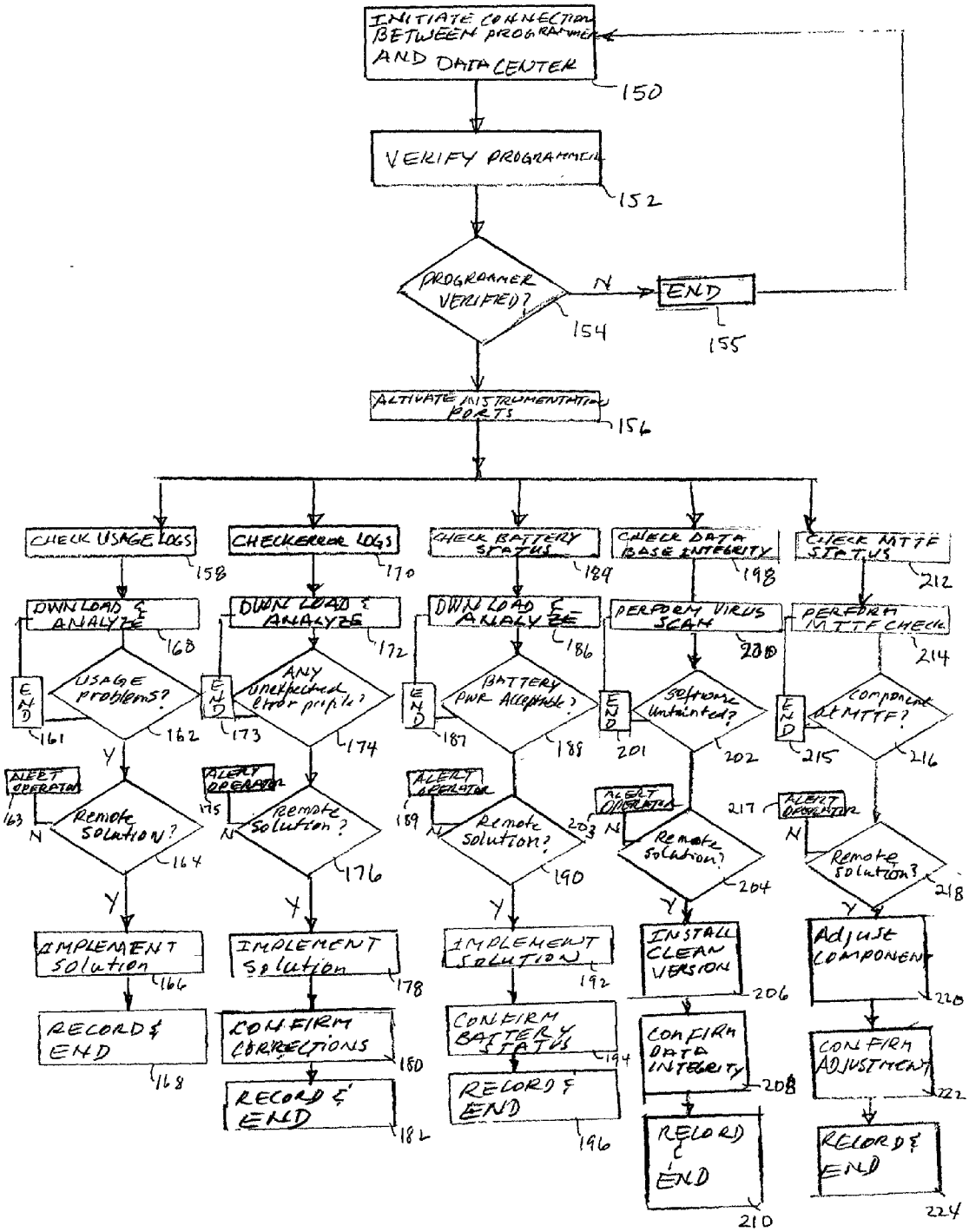
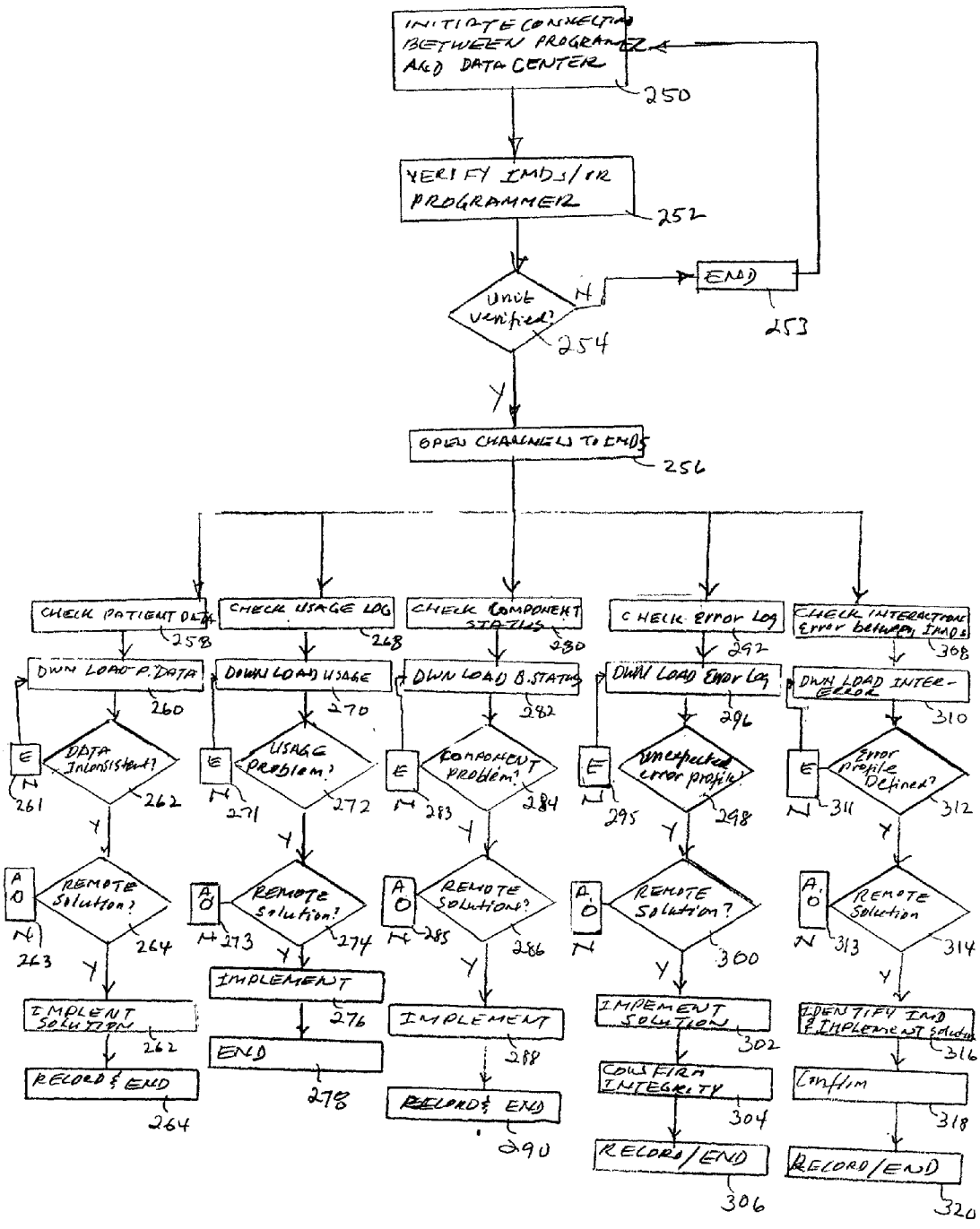

INITIATE CONNECTION BETWEEN PROGRAMMER AND DATA CENTER
150
VERIFY PROGRAMMER
152
PROGRAMMER VERIFIED?
154
N
END
155
ACTIVATE INSTRUMENTATION PORTS
156
CHECK USAGE LOGS
158
CHECK ERROR LOGS
170
CHECK BATTERY STATUS
184
CHECK DATA BASE INTEGRITY
198
CHECK MTTF STATUS
212
DOWNLOAD & ANALYZE
160
DOWNLOAD & ANALYZE
172
DOWNLOAD & ANALYZE
186
PERFORM VIRUS SCAN
200
PERFORM MTTF CHECK
214
END
161
USAGE PROBLEMS?
162
END
173
ANY UNEXPECTED ERROR PROBLEMS?
174
END
187
BATTERY PWR ACCEPTABLE?
188
END
201
SOFTWARE UNTAINTED?
202
END
215
COMPONENT AT MTTF?
216
ALERT OPERATOR
163
REMOTE SOLUTION?
164
Y
N
ALERT OPERATOR
175
REMOTE SOLUTION?
176
Y
N
ALERT OPERATOR
189
REMOTE SOLUTION?
190
Y
N
ALERT OPERATOR
203
REMOTE SOLUTION?
204
Y
N
ALERT OPERATOR
217
REMOTE SOLUTION?
218
Y
N
IMPLEMENT SOLUTION
166
IMPLEMENT SOLUTION
178
IMPLEMENT SOLUTION
192
INSTALL CLEAN VERSION
206
ADJUST COMPONENT
220
RECORD & END
168
CONFIRM CORRECTIONS
180
CONFIRM BATTERY STATUS
194
CONFIRM DATA INTEGRITY
208
CONFIRM ADJUSTMENT
222
RECORD & END
182
RECORD & END
196
RECORD & END
210
RECORD & END
224

Fig 6A


INITIATE CONNECTION BETWEEN PROGRAMMER AND DATA CENTER
250
VERIFY IMDs/OR PROGRAMMER
252
UNIT VERIFIED?
254
N
END
253
Y
OPEN CHANNELS TO IMDs
256
CHECK PATIENT DATA
258
CHECK USAGE LOG
268
CHECK COMPONENT STATUS
280
CHECK ERROR LOG
292
CHECK INTERACTION ERROR BETWEEN IMDs
308
DOWN LOAD P. DATA
260
DOWN LOAD USAGE
270
DOWN LOAD B. STATUS
282
DOWN LOAD ERROR LOG
296
DOWN LOAD INTER-ERROR
310
DATA INCONSISTENT?
262
USAGE PROBLEM?
272
COMPONENT PROBLEM?
284
UNEXPECTED ERROR PROFILE
298
ERROR PROFILE DEFINED?
312
REMOTE SOLUTION?
264
REMOTE SOLUTION?
274
REMOTE SOLUTION?
286
REMOTE SOLUTION?
300
REMOTE SOLUTION
314
IMPLEMENT SOLUTION
262
IMPLEMENT
276
IMPLEMENT
288
IMPLEMENT SOLUTION
302
IDENTIFY AND IMPLEMENT SOLUTION
316
RECORD & END
264
END
278
RECORD & END
290
CONFIRM INTEGRITY
304
CONFIRM
318
RECORD/END
306
RECORD/END
320

6B

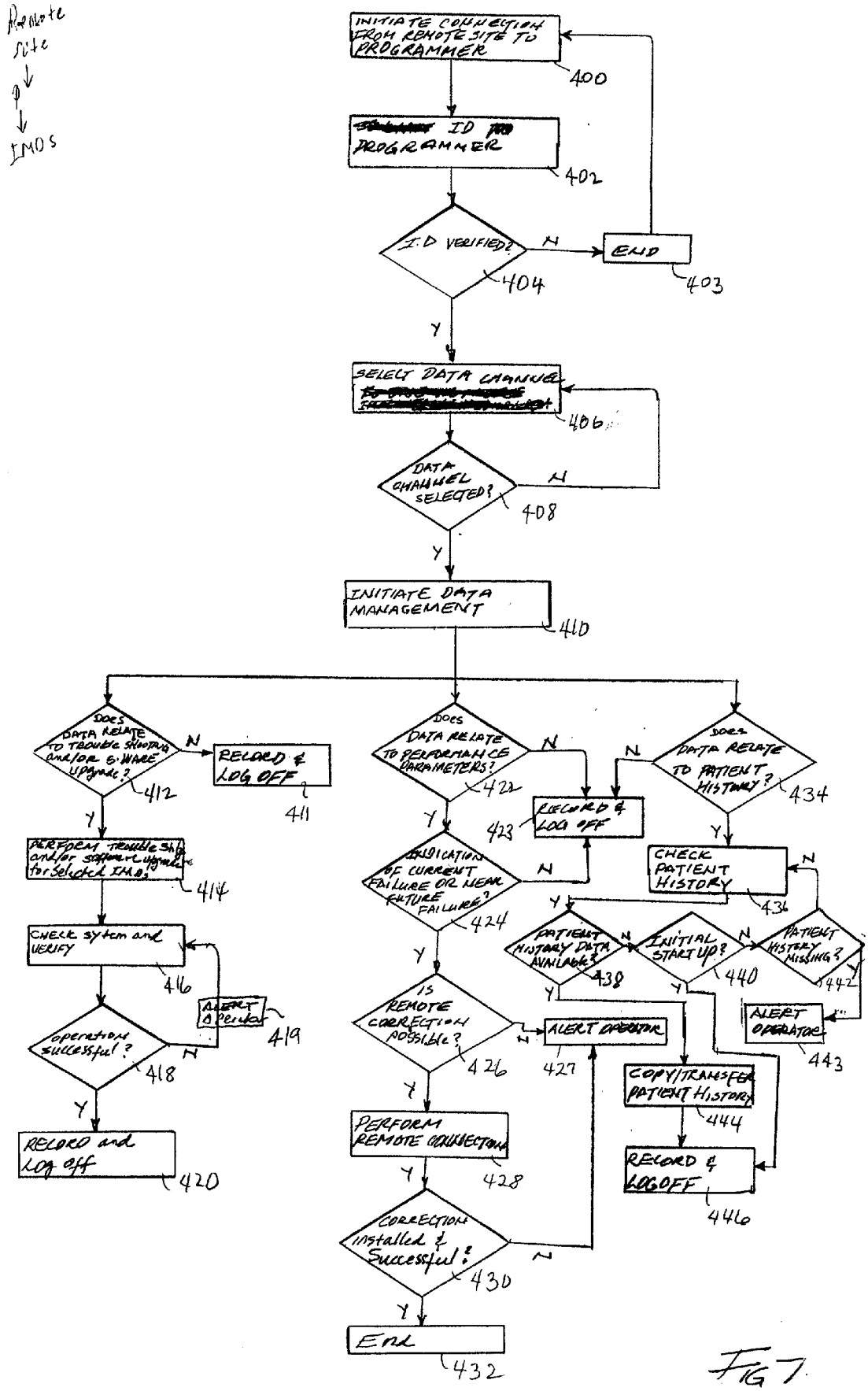

Remote site
IMDs
INITIATE CONNECTION FROM REMOTE SITE TO PROGRAMMER
400
ID PROGRAMMER
402
I.D VERIFIED?
404
N
END
403
Y
SELECT DATA CHANNEL
406
DATA CHANNEL SELECTED?
408
N
Y
INITIATE DATA MANAGEMENT
410
DOES DATA RELATE TO TROUBLE SHOOTING AND/OR S/WARE UPGRADE?
412
N
RECORD & LOG OFF
411
Y
PERFORM TROUBLE SHOOTING AND/OR SOFTWARE UPGRADE FOR SELECTED IMDs
414
CHECK SYTEM AND VERIFY
416
ALERT PROGRAMMER
419
OPERATION SUCCESSFUL?
418
N
Y
RECORD and LOG off
420
DOES DATA RELATE TO PERFORMANCE PARAMETERS?
422
N
RECORD & LOG OFF
423
Y
INDICATION OF CURRENT FAILURE OR NEAR FUTURE FAILURE?
424
N
Y
IS REMOTE CORRECTION POSSIBLE?
426
N
ALERT OPERATOR
427
Y
PERFORM REMOTE CORRECTION
428
CORRECTION INSTALLED & SUCCESSFUL?
430
N
Y
End
432
DOES DATA RELATE TO PATIENT HISTORY?
434
N
Y
CHECK PATIENT HISTORY
436
PATIENT HISTORY DATA AVAILABLE?
438
N
Y
INITIAL START UP?
440
N
Y
PATIENT HISTORY MISSING?
442
N
Y
ALERT OPERATOR
443
COPY/TRANSFER PATIENT HISTORY
444
RECORD & LOG OFF
446

FIG 7

APPARATUS AND METHOD FOR REMOTE TROUBLESHOOTING, MAINTENANCE AND UPGRADE OF IMPLANTABLE DEVICE SYSTEMS

THE FIELD OF THE INVENTION

[0001] The present invention relates generally to medical device systems. Specifically, the invention pertains to a remote bi-directional communications with one or more programmable devices, that are associated with implantable medical devices. More specifically, the invention relates to an integrated system and method of bi-directional telecommunications between a web-based expert data center and at least one programmer, utilizing various types of network platforms and architecture to implement, in the programmer, distance-based troubleshooting, maintenance, upgrade, information and administrative services thereby providing an economical and highly interactive system for therapy and clinical care.

BACKGROUND OF THE INVENTION

[0002] A technology-based health care system that fully integrates the technical and social aspects of patient care and therapy should be able to flawlessly connect the client with care providers irrespective of separation distance or location of the participants. While clinicians will continue to treat patients in accordance with accepted modern medical practice, developments in communications technology are making it ever more possible to provide medical services in a time and place independent manner.

[0003] Prior art methods of clinical services are generally limited to in-hospital operations. For example, if a physician needs to review the performance parameters of an implantable device in a patient, it is likely that the patient has to go to the clinic. Further, if the medical conditions of a patient with an implantable device warrant a continuous monitoring or adjustment of the device, the patient would have to stay in a hospital indefinitely. Such a continued treatment plan poses both economic and social problems. Under the exemplary scenario, as the segment of the population with implanted medical devices increases many more hospitals /clinics including service personnel will be needed to provide in-hospital service for the patients, thus escalating the cost of healthcare. Additionally the patients will be unduly restricted and inconvenienced by the need to either stay in the hospital or make very frequent visits to a clinic.

[0004] Yet another condition of the prior art practice requires that a patient visit a clinical center for occasional retrieval of data from the implanted device to assess the operations of the device and gather patient history for both clinical and research purposes. Such data is acquired by having the patient in a hospital /clinic to down load the stored data from the implantable medical device. Depending on the frequency of data collection this procedure may pose a serious difficulty and inconvenience for patients who live in rural areas or have limited mobility. Similarly, in the event a need arises to upgrade the software of an implantable medical device, the patient will be required to come into the clinic or hospital to have the upgrade installed.

[0005] A further limitation of the prior art relates to the management of multiple implantable devices in a single patient. Advances in modern patient therapy and treatment have made it possible to implant a number of devices in a patient. For example, implantable devices such as a defibrillator or a pacer, a neural implant, a drug pump, a separate physiologic monitor and various other implantable devices may be implanted in a single patient. To successfully manage the operations and assess the performance of each device in a patient with multi-implants requires a continuous update and monitoring of the devices. Further, it may be preferred to have an operable communication between the various implants to provide a coordinated clinical therapy to the patient. Thus, there is a need to monitor the performance of the implantable devices on a regular, if not a continuous, basis to ensure optimal patient care. In the absence of other alternatives, this imposes a great burden on the patient if a hospital or clinic is the only center where the necessary frequent follow up, evaluation and adjustment of the medical devices could be made. Moreover, even if feasible the situation would require the establishment of multiple service areas or clinic centers to provide adequate service to the burgeoning number of multi-implant patients worldwide. Accordingly, it is vital to have a programmer unit that would connect to a remote expert medical center to provide access to expert systems and import the expertise to a local environment. This approach would enable unencumbered access to the IMD or the patient.

[0006] The prior art provides various types of remote sensing and communications with an implanted medical device. One such system is, for example, disclosed in Funke, U.S. Pat. No. 4,987,897 issued Jan. 29, 1991. This patent discloses a system that is at least partially implanted into a living body with a minimum of two implanted devices interconnected by a communication transmission channel. The invention further discloses wireless communications between an external medical device/programmer and the implanted devices.

[0007] One of the limitations of the system disclosed in the Funke patent includes the lack of communication between the implanted devices, including the programmer, with a remote clinical station. If, for example, any assessment, monitoring or maintenance is required to be performed on the IMD the patient will have to go to the remote clinic station or the programmer device needs to be brought to the patient's location. More significantly, the operational worthiness and integrity of the programmer cannot be evaluated remotely thus making it unreliable over time as it interacts with the IMD.

[0008] Yet another example of sensing and communications system with a plurality of interactive implantable devices is disclosed by Stranberg in U.S. Pat. No. 4,886,064, issued Dec. 12, 1989. In this disclosure, body activity sensors, such as temperature, motion, respiration and /or blood oxygen sensors, are positioned in a patient's body outside a pacer capsule. The sensors wirelessly transmit body activity signals, which are processed by circuitry in the heart pacer. The heart pacing functions are influenced by the processed signals. The signal transmission is a two-way network and allows the sensors to receive control signals for altering the sensor characteristics.

[0009] One of the many limitations of Stranberg is the fact that although there is corporeal two-way communications between the implantable medical devices, and the functional response of the heart pacer is processed in the pacer after collecting input from the other sensors, the processor is not

remotely programmable. Specifically, the system does not lend itself to web-based communications to enable remote troubleshooting, maintenance and upgrade from outside the patient's body because the processor/programmer is internally located in the patient forming an integral part of the heart pacer.

[0010] Yet another prior art reference provides a multimodule medication delivery system as disclosed by Fischell in U.S. Pat. No. 4,494,950 issued Jan. 22, 1985. The disclosure relates to a system consisting a multiplicity of separate modules that collectively perform a useful biomedical purpose. The modules communicate with each other without the use of interconnecting wires. All the modules may be installed intracorporeal or mounted extracorporeal to the patient. In the alternate, some modules may be intracorporeal with others being extracorporeal. Signals are sent from one module to the other by electromagnetic waves. Physiologic sensor measurements sent from a first module cause a second module to perform some function in a closed loop manner. One extracorporeal module can provide electrical power to an intracorporeal module to operate a data transfer unit for transferring data to the external module.

[0011] The Fischell disclosure provides modular communication and cooperation between various medication delivery systems. However, the disclosure does not provide an external programmer with remote sensing, remote data management and maintenance of the modules. Further, the system does neither teach nor disclose an external programmer for telemetrically programming the modules.

[0012] Yet another example of remote monitoring of implanted cardioverter defibrillators is disclosed by Gessman in U.S. Pat. No. 5,321,618 issued. In this disclosure a remote apparatus is adapted to receive commands from and transmit data to a central monitoring facility over telephone communication channels. The remote apparatus includes equipment for acquiring a patient's ECG waveform and transmitting that waveform to the central facility over the telephone communications channels. The remote apparatus also includes a segment, responsive to a command received from the central monitoring facility, for enabling the emission of audio tone signals from the cardioverter defibrillator. The audio tones are detected and sent to the central monitoring facility via the telephone communication channel. The remote apparatus also includes patient alert devices, which are activated by commands received from the central monitoring facility over the telephone communication channel.

[0013] One of the many limitations of the apparatus and method disclosed in the Gessman patent is the fact that the segment, which may be construed to be equivalent to a programmer, is not remotely adjustable from the central monitoring device. The segment merely acts as a switching station between the remote apparatus and the central monitoring station.

[0014] An additional example of prior art practice includes a packet-based telemedicine system for communicating information between central monitoring stations and a remote patient monitoring station disclosed in Peifer, WO 99/14882 published Mar. 25, 1999. The disclosure relates to a packet-based telemedicine system for communicating video, voice and medical data between a central monitoring station and a patient that is remotely located with respect to the central monitoring station. The patient monitoring station obtains digital video, voice and medical measurement data from a patient and encapsulates the data in packets and sends the packets over a network to the central monitoring station. Since the information is encapsulated in packets, the information can be sent over multiple types or combination of network architectures, including a community access television (CATV) network, the public switched telephone network (PSTN), the integrated services digital network (ISDN), the Internet, a local area network (LAN), a wide area network (WAN), over a wireless communications network, or over asynchronous transfer mode (ATM) network. A separate transmission code is not required for each different type of transmission media.

[0015] One of the advantages of the Pfeifer invention is that it enables data of various forms to be formatted in a single packet irrespective of the origin or medium of transmission. However, the data transfer system lacks the capability to remotely debug the performance parameters of the medical interface device or the programmer. Further, Pfeifer does not disclose a method or structure by which the devices at the patient monitoring station may be remotely updated, maintained and tuned to enhance performance or correct errors and defects.

[0016] Another example of a telemetry system for implantable medical devices is disclosed in Duffin et al, U.S. Pat. No. 5,752,976, issued May 19, 1998, incorporated by reference herein in its entirety. Generally, the Duffin et al disclosure relates to a system and method for communicating with a medical device implanted in an ambulatory patient and for locating the patient in order to selectively monitor device function from a remote medical support network. The communications link between the medical support network and the patient communications control device may comprise a world wide satellite network, a cellular telephone network or other personal communications system.

[0017] Although the Duffin et al disclosure provides significant advances over the prior art, it does not teach a communications scheme in which a programmer is remotely debugged, maintained, upgraded or modified to ultimately enhance the support it provides to the implantable device with which it is associated. Specifically, the Duffin et al disclosure is limited to notifying remote medical support personnel or an operator about impending problems with an IMD and also enables constant monitoring of the patient's position worldwide using the GPS system. However, Duffin et al does not teach the remote programming scheme contemplated by the present invention.

[0018] In a related art, Thompson discloses a patient tracking system in a co-pending application entitled "Worldwide Patient Location and Data Telemetry System For Implantable Medical Devices", Ser. No. 09/045,272, filed on Mar. 20, 1998 which is incorporated by reference herein in its entirety. The disclosure provides additional features for patient tracking in a mobile environment worldwide via the GPS system. However, the remote programming concepts advanced by the present invention are not within the purview of the Thompson disclosure because there is no teaching of a web-based environment in which a programmer is remotely evaluated and monitored to effect functional and parametric tune up, upgrade and maintenance as needed.

[0019] Yet in another related art, Ferek-Petric discloses a system for communication with a medical device in a co-pending application, Ser. No. 09/348,506 which is incorporated by reference herein in its entirety. The disclosure relates to a system that enables remote communications with a medical device, such as a programmer. Particularly, the system enables remote communications to inform device experts about programmer status and problems, The experts will then provide guidance and support to the remotely to service personnel or operators located at the programmer. The system may include a medical device adapted to be implanted into a patient; a server PC communicating with the medical device; the server PC having means for receiving data transmitted across a dispersed data communication pathway, such as the Internet; and a client PC having means for receiving data transmitted across a dispersed communications pathway from the SPC. In certain configurations the server PC may have means for transmitting data across a dispersed data communication pathway (Internet) along a first channel and a second channel; and the client PC may have means for receiving data across a dispersed communication pathway from the server PC along a first channel and a second channel.

[0020] One of the significant teachings of Ferek Petric's disclosure, in the context of the present invention, includes the implementation of communication systems, associated with IMDs that are compatible with the Internet. Specifically the disclosure advances the art of remote communications between a medical device, such as a programmer, and experts located at a remote location using the Internet. As indicated hereinabove, the communications scheme is structured to primarily alert remote experts to existing or impending problems with the programming device so that prudent action, such as early maintenance or other remedial steps, may be timely exercised. Further, because of the early warning or advance knowledge of the problem, the remote expert would be well informed to provide remote advice or guidance to service personnel or operators at the programmer.

[0021] While Ferek's invention advances the art in communications systems relating to interacting with a programmer via a communication medium such as the Internet, the system does neither propose nor suggest remote programming, debugging and maintenance of a programmer without the intervention of a service person.

[0022] Accordingly it would be advantageous to provide a system in which a programmer could uplink to a remote expert data center to import enabling software for self-diagnosis, maintenance and upgrade of the programmer. Yet another desirable advantage would be to provide a system to implement the use of remote expert systems to manage a programmer on a real-time basis. A further desirable advantage would be to provide a communications scheme that is compatible with various communications media, to promote a fast uplink of a programmer to remote expert systems and specialized data resources. Yet another desirable advantage would be to provide a high speed communications scheme to enable the transmission of high fidelity sound, video and data to advance and implement efficient remote data management of a clinical/therapy system via a programmer thereby enhancing patient clinical care. As discussed herein below, the present invention provides these and other desirable advantages.

SUMMARY OF THE INVENTION

[0023] The present invention generally relates to a communications scheme in which a remote web-based expert data center interacts with a patient having one or more implantable medical devices (IMDs) via an associated external medical device, preferably a programmer, located in close proximity to the IMDs. Some of the most significant advantages of the invention include the use of various communications media between the remote web-based expert data center and the programmer to remotely exchange clinically significant information and ultimately effect real-time parametric and operational changes as needed.

[0024] In the context of the present invention, one of the many aspects of the invention includes a real-time access of a programmer to a remote web-based expert data center, via a communication network, which includes the Internet. The operative structure of the invention includes the remote web-based expert data center, in which an expert system is maintained, having a bi-directional real-time data, sound and video communications with the programmer via a broad range of communication link systems. The programmer is in turn in telemetric communications with the IMDs such that the IMDs may uplink to the programmer or the programmer may down link to the IMDs, as needed.

[0025] In yet another context of the invention, the critical components and embedded systems of the programmer are remotely maintained, debugged and/or evaluated to ensure proper functionality and performance by down linking expert systems and compatible software from the web-based expert data center.

[0026] In a further context of the invention, a programmer is remotely monitored, assessed and upgraded as needed by importing expert systems from a remote expert data center via a wireless or equivalent communications system. The operational and functional software of the embedded systems in the programmer may be remotely adjusted, upgraded or changed as apparent. Some of the software changes may ultimately be implemented in the IMDs as needed by down linking from the programmer to the IMDs.

[0027] Yet another context of the invention includes a communications scheme that provides a highly integrated and efficient method and structure of clinical information management in which various networks such as Community access Television, Local area Network (LAN), a wide area network (WAN) Integrated Services Digital Network (ISDN), the Public Switched telephone Network (PSTN), the Internet, a wireless network, an asynchronous transfer mode (ATM) network, a laser wave network, satellite, mobile and other similar networks are implemented to transfer voice, data and video between the remote data center and a programmer. In the preferred embodiment, wireless communications systems, a modem and laser wave systems are illustrated as examples only and should be viewed without limiting the invention to these types of communications alone. Further, in the interest of simplicity, the applicants refer to the various communications system, in relevant parts, as a communications system. However, it should be noted that the communication systems, in the context of this invention, are interchangeable and may relate to various schemes of cable, fiber optics, microwave, radio, laser and similar communications or any practical combinations thereof.

[0028] Some of the distinguishing features of the present invention include the use of a robust web-based expert data center to manage and tune the operational and functional parameters of a programmer in real-time. Specifically, the invention enables remote diagnosis, maintenance, upgrade, performance tracking, tuning and adjustment of a programmer from a remote location. Although the present invention focuses on the remote real-time monitoring and management of the programmer, some of the changes and upgrades made to the programmer could advantageously be transferred to the IMDs. This is partly because some of the performance parameters of the programmer are functionally parallel to those in the IMDs. Thus, one additional benefit of the present invention is an enhancement of the programmer may be implemented, on a proactive basis, in the IMDs by down linking from the programmer thereby upgrading the IMDs to promote the patient's well being.

[0029] Yet one of the other distinguishing features of the invention includes the use a highly flexible and adaptable communications scheme to promote continuous and real-time communications between a remote expert data center and a programmer associated with a plurality of IMDs. The IMDs are structured to share information intracorporeally and may interact with the programmer, as a unit. Specifically, the IMDs either jointly or severally can be interrogated to implement or extract clinical information as required. In other words, all of the IMDs may be accessed via one IMD or, in the alternate, each one of the IMDs may be accessed individually. The information collected in this manner may be transferred to the programmer by up linking the IMDs as needed.

[0030] Further, the present invention provides significant advantages over the prior art by enabling remote trouble-shooting, maintenance and software upgrade to the programmer. The communications scheme enables remote debugging and analysis on the programmer. In the event a component or software defect is noted, the system is able to check whether a 'remote-fix' is possible. If not, the system broadcasts an alert to an operator thus attending to the problem on a real-time basis. In the execution of this function the communications scheme of the present invention performs, inter alia, a review of usage logs, error logs, power and battery status, data base integrity and the mean time between failures status of all the significant and relevant components. Further, patient history, performance parameter integrity and software status are mined from the programmer's database and analyzed by an analyzer at the remote expert data center.

[0031] The invention provides significant compatibility and scalability to other web-based applications such as telemedicine and emerging web-based technologies such as tele-immersion. For example, the system may be adapted to webtop applications in which a webtop unit may be used to uplink the patient to a remote data center for non-critical information exchange between the IMDs and the remote expert data center. In these and other web-based similar applications the data collected, in the manner and substance of the present invention, may be used as a preliminary screening to identify the need for further intervention using the advanced web technologies.

BRIEF DESCRIPTION OF THE DRAWINGS

[0032] The present invention will be appreciated as the same becomes better understood by reference to the following detailed description of the preferred embodiment of the invention when considered in connection with the accompanying drawings, in which like numbered reference numbers designate like parts throughout the figures thereof, and wherein:

[0033] **FIG. 1** is a simplified schematic diagram of major uplink and downlink telemetry communications between a remote clinical station, a programmer and a plurality of implantable medical devices (IMDs);

[0034] **FIG. 2** is a block diagram representing the major components of an IMD;

[0035] **FIG. 3A** is a block diagram presenting the major components of a programmer or webtop unit;

[0036] **FIG. 3B** is a block diagram representing a laser transceiver for high speed transmission of voice, video and other data;

[0037] **FIG. 4** is a block diagram illustrating the organizational structure of the wireless communication system in accordance with the present invention;

[0038] **FIG. 5** is a block diagram illustrating further component details of the structure depicted in **FIG. 4**;

[0039] **FIGS. 6A and 6B** represent flow charts relating to a high level operational logic of the invention as it relates to functional elements of the components; and

[0040] **FIG. 7** represents flow charts relating to component hardware and database management logic for implementing remote maintenance and software upgrade as needed.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0041] **FIG. 1** is a simplified schematic of the major components of the present invention. Specifically, a bi-directional wireless communications system between programmer **20**, webtop unit **20'** and a number of implantable medical devices (IMDS) represented by IMD **10**, IMD **10'** and IMD **10"** is shown. The IMDs are implanted in patient **12** beneath the skin or muscle. The IMDs are electrically coupled to electrodes **18**, **30**, and **36** respectively in a manner known in the art. IMD **10** contains a microprocessor for timing, sensing and pacing functions consistent with preset programmed functions. Similarly, IMDs **10'** and **10"** are microprocessor-based to provide timing and sensing functions to execute the clinical functions for which they are employed. For example, IMD **10'** could provide neural stimulation to the brain via electrode **30** and IMD **10"** may function as a drug delivery system that is controlled by electrode **36**. The various functions of the IMDs are coordinated using wireless telemetry. Wireless links **42**, **44** and **46** jointly and severally couple IMDs **10**, **10'** and **10"** such that programmer **20** may transmit commands or data to any or all the of IMDs via one of telemetry antennas **28**, **32** and **38**. This structure provides a highly flexible and economical wireless communications system between the IMDS. Further, the structure provides a redundant communications system, which enables access to any one of a multiplicity of IMDs in the event of a malfunction of one or two of antennas **28**, **32** and **38**.

[0042] Programming commands or data are transmitted from programmer **20** to IMDs **10**, **10'** and **10"** via external

RF telemetry antenna **24**. Telemetry antenna **24** may be an RF head or equivalent. Antenna **24** may be located on programmer **20** externally on the case or housing. Telemetry antenna **24** is generally telescoping and may be adjustable on the case of programmer **20**. Both programmer **20** and webtop unit **20'** may be placed a few feet away from patient **12** and would still be within range to wirelessly communicate with telemetry antennas **28**, **32** and **38**.

[**0043**] The uplink to remote web-based expert data center **62**, hereinafter referred to as, interchangeably, "data center **62**", "expert data center **62**" or "web-based data center **62**" without limitations, is accomplished through programmer **20** or webtop unit **20'**. Accordingly programmer **20** and webtop unit **20'** function as an interface between IMDs **10**, **10'** and **10"** and data center **62**. One of the many distinguishing elements of the present invention includes the use of various scalable, reliable and high-speed wireless communication systems to bi-directionally transmit high fidelity digital/analog data between programmer **20** and data center **62**.

[**0044**] There are a variety of wireless mediums through which data communications could be established between programmer **20** or webtop unit **20'** and data center **62**. The communications link between Programmer **20** or webtop unit **20'** and data center **62** could be modem **60**, which is connected to programmer **20** on one side at line **63** and data center **62** at line **64** on the other side. In this case, data is transferred from data center **62** to programmer **20** via modem **60**. Alternate data transmission systems include, without limitations, stationary microwave and/or RF antennas **48** being wirelessly connected to programmer **20** via tunable frequency wave delineated by line **50**. Antenna **48** is in communications with data center **62** via wireless link **65**. Similarly, webtop unit **20'**, mobile vehicle **52** and satellite **56** are in communications with data center **62** via wireless link **65**. Further, mobile system **52** and satellite **56** are in wireless communications with programmer **20** or webtop unit **20'** via tunable frequency waves **54** and **58**, respectively.

[**0045**] In the preferred embodiment a Telnet system is used to wirelessly access data center **62**. Telnet emulates a client/server model and requires that the client run a dedicated software to access data center **62**. The Telnet scheme envisioned for use with the present invention includes various operating systems including UNIX, Macintosh, and all versions of Windows.

[**0046**] Functionally, an operator at programmer **20** or an operator at data center **62** would initiate remote contact. Programmer **20** is down linkable to IMDs via link antennas **28**, **32** and **38** to enable data reception and transmission. For example, an operator or a clinician at data center **62** may downlink to programmer **20** to perform a routine or a scheduled evaluation of programmer **20**. In this case the wireless communication is made via wireless link **65**. If a downlink is required from programmer **20** to IMD **10** for example, the downlink is effected using telemetry antenna **22**. In the alternate, if an uplink is initiated from patient **12** to programmer **20** the uplink is executed via wireless link **26**. As discussed herein below, each antenna from the IMDs can be used to uplink all or one of the IMDs to programmer **20**. For example, IMD **10"** which relates to neural implant **30** can be implemented to up-link, via wireless antenna **34** or wireless antenna **34'**, any one, two or more IMDs to programmer **20**. Preferably bluetooth chips, adopted to function within the body to outside the body and also adopted to provide low current drain, are embedded in order to provide wireless and seamless connections **42**, **44** and **46** between IMDs **10**, **10'** and **10"**. The communication scheme is designed to be broadband compatible and capable of simultaneously supporting multiple information sets and architecture, transmitting at relatively high speed, to provide data, sound and video services on demand.

[**0047**] **FIG. 2** illustrates typical components of an IMD, such as those contemplated by the present invention. Specifically, major operative structures common to all IMDs **10**, **10'** and **10"** are represented in a generic format. In the interest of brevity, IMD **10** relative to **FIG. 2** refers to all the other IMDs. Accordingly, IMD **10** is implanted in patient **12** beneath the patient's skin or muscle and is electrically coupled to heart **16** of patient **12** through pace/sense electrodes and lead conductor(s) of at least one cardiac pacing lead **18** in a manner known in the art. IMD **10** contains timing control **72** including operating system that may employ microprocessor **74** or a digital state machine for timing, sensing and pacing functions in accordance with a programmed operating mode. IMD **10** also contains sense amplifiers for detecting cardiac signals, patient activity sensors or other physiologic sensors for sensing the need for cardiac output, and pulse generating output circuits for delivering pacing pulses to at least one heart chamber of heart **16** under control of the operating system in a manner well known in the prior art. The operating system includes memory registers or RAM/ROM **76** for storing a variety of programmed-in operating mode and parameter values that are used by the operating system. The memory registers or RAM/ROM **76** may also be used for storing data compiled from sensed cardiac activity and/or relating to device operating history or sensed physiologic parameters for telemetry out on receipt of a retrieval or interrogation instruction. All of these functions and operations are well known in the art, and many are generally employed to store operating commands and data for controlling device operation and for later retrieval to diagnose device function or patient condition.

[**0048**] Programming commands or data are transmitted between IMD **10** RF telemetry antenna **28**, for example, and an external RF telemetry antenna **24** associated with programmer **20**. In this case, it is not necessary that the external RF telemetry antenna **24** be contained in a programmer RF head so that it can be located close to the patient's skin overlying IMD **10**. Instead, the external RF telemetry antenna **24** can be located on the case of programmer **20**. It should be noted that programmer **20** can be located some distance away from patient **12** and is locally placed proximate to the IMDs such that the communication between IMDs **10**, **10'** and **10"** and programmer **20** is telemetric. For example, programmer **20** and external RF telemetry antenna **24** may be on a stand a few meters or so away from patient **12**. Moreover, patient **12** may be active and could be exercising on a treadmill or the like during an uplink telemetry interrogation of real time ECG or other physiologic parameters. Programmer **20** may also be designed to universally program existing IMDs that employ RF telemetry antennas of the prior art and therefore also have a conventional programmer RF head and associated software for selective use therewith.

[**0049**] In an uplink communication between IMD **10** and programmer **20**, for example, telemetry transmission **22** is

activated to operate as a transmitter and external RF telemetry antenna **24** operates as a telemetry receiver. In this manner data and information may be transmitted from IMD **10** to programmer **20**. In the alternate, IMD **10** RF telemetry antenna **26** operates as a telemetry receiver antenna to downlink data and information from programmer **20**. Both RF telemetry antennas **22** and **26** are coupled to a transceiver comprising a transmitter and a receiver.

[**0050**] **FIG. 3A** is a simplified circuit block diagram of major functional components of programmer **20**. The external RF telemetry antenna **24** on programmer **20** is coupled to a telemetry transceiver **86** and antenna driver circuit board including a telemetry transmitter and telemetry receiver **34**. The telemetry transmitter and telemetry receiver are coupled to control circuitry and registers operated under the control of microcomputer **80**. Similarly, within IMD **10**, for example, the RF telemetry antenna **26** is coupled to a telemetry transceiver comprising a telemetry transmitter and telemetry receiver. The telemetry transmitter and telemetry receiver in IMD **10** are coupled to control circuitry and registers operated under the control of microcomputer **74**.

[**0051**] Further referring to **FIG. 3**A, programmer **20** is a personal computer type, microprocessor-based device incorporating a central processing unit, which may be, for example, an Intel Pentium microprocessor or the like. A system bus interconnects CPU **80** with a hard disk drive, storing operational programs and data, and with a graphics circuit and an interface controller module. A floppy disk drive or a CD ROM drive is also coupled to the bus and is accessible via a disk insertion slot within the housing of programmer **20**. Programmer **20** further comprises an interface module, which includes a digital circuit, a non-isolated analog circuit, and an isolated analog circuit. The digital circuit enables the interface module to communicate with interface controller module. Operation of the programmer in accordance with the present invention is controlled by microprocessor **80**.

[**0052**] In order for the physician or other caregiver or operator to communicate with the programmer **20**, a keyboard or input **82** coupled to CPU **80** is optionally provided. However the primary communications mode may be through graphics display screen of the well-known "touch sensitive" type controlled by a graphics circuit. A user of programmer **20** may interact therewith through the use of a stylus, also coupled to a graphics circuit, which is used to point to various locations on screen or display **84** which display menu choices for selection by the user or an alphanumeric keyboard for entering text or numbers and other symbols. Various touch-screen assemblies are known and commercially available. Display **84** and or the keyboard comprise means for entering command signals from the operator to initiate transmissions of downlink or uplink telemetry and to initiate and control telemetry sessions once a telemetry link with data center **62** or an implanted device has been established. Display screen **84** is also used to display patient related data and menu choices and data entry fields used in entering the data in accordance with the present invention as described below. Display screen **84** also displays a variety of screens of telemetered out data or real time data. Display screen **84** may also display plinked event signals as they are received and thereby serve as a means for enabling the operator to timely review link-history and status.

[**0053**] Programmer **20** further comprises an interface module, which includes digital circuit, non-isolated analog circuit, and isolated analog circuit. The digital circuit enables the interface module to communicate with the interface controller module. As indicated hereinabove, the operation of programmer **20**, in accordance with the present invention, is controlled by microprocessor **80**. Programmer **20** is preferably of the type that is disclosed in U.S. Pat. No. 5,345,362 to Winkler, which is incorporated by reference herein in its entirety.

[**0054**] Screen **84** may also display up-linked event signals when received and thereby serve as a means for enabling the operator of programmer **20** to correlate the receipt of uplink telemetry from an implanted device with the application of a response-provoking action to the patient's body as needed. Programmer **20** is also provided with a strip chart printer or the like coupled to interface controller module so that a hard copy of a patient's ECG, EGM, marker channel of graphics displayed on the display screen can be generated.

[**0055**] As will be appreciated by those of ordinary skill in the art, it is often desirable to provide a means for programmer **20** to adapt its mode of operation depending upon the type or generation of implanted medical device to be programmed and to be compliant with the wireless communications system through which data and information is transmitted between programmer **20** and data center **62**.

[**0056**] **FIG. 3B** is an illustration of the major components of Wave unit **90** utilizing laser technologies such as for example the WaveStar Optic Air Unit, manufactured by Lucent Technologies or equivalent. This embodiment may be implemented for large data transfer at high speed in applications involving several programmers. The unit includes laser **92**, transceiver **94** and amplifier **96**. A first wave unit **90** is installed at data center **62** and a second unit **90'** is located proximate to programmer **20** or webtop unit **20'**. Data transmission between remote data center **62** and programmer unit **20** is executed via wave units **90**. Typically, the first wave unit **90** accepts data and splits it into unique wavelength for transmission. The second wave unit **90'** recomposes the data back to its original form.

[**0057**] **FIG. 4** is a simplified block diagram illustrating the principal systems of the invention. The Remote expert system or data center **62** includes data resource **100**. As discussed hereinabove, data center **62** is preferably in wireless communications with programmer **20**. The medium of communications between programmer **20** and data center **62** may be selected from one or a combination of several cable and wireless systems discussed hereinabove. Further, programmer **20** is in wireless communications with a number of IMDs, such as shown in **FIG. 1**. Although three IMDs are shown for illustrative purposes, it should be noted that several IMDs may be implemented and the practice of the present invention does not limit the number of implants per se.

[**0058**] **FIG. 5** is a representation of the major functional components of Programmer **20**, data resources **100** and the wireless data communications **131** and **136**. Specifically, as discussed hereinabove, programmer **20** includes power supply **110**, disc drive **112**, display screen **114**, CD ROM **116**, printer **118**, RAM/ROM **120** and stylus **122**. Analyzer **126** is in bi-directional data communications with the other components of programmer **20** and includes disc drive **128**, display **130**, battery **132** and RAM/ROM **134**.

[0059] Programmer **20** is connected to remote data center **62** via bi-directional data communication link **136**. Data resource center forms the web-based data resources/expert system **100**. Accordingly, data resources system **100** is a sub-component of remote data center **62**, which includes information identification module **138**, analyzation module **140**, data storage module **142** and software update module **146**.

[0060] Referring to programmer **20** in more detail, when a physician or an operator needs to interact with programmer **20**, a keyboard coupled to Processor **80** is optionally employed. However the primary communication mode may be through graphics display screen of the well-known "touch sensitive" type controlled by graphics circuit. A user of programmer **20** may interact therewith through the use of a stylus **122**, also coupled to a graphics circuit, which is used to point to various locations on screen/display **114** to display menu choices for selection by the user or an alphanumeric keyboard for entering text or numbers and other symbols as shown in the above-incorporated '362 patent. Various touch-screen assemblies are known and commercially available. The display and or the keyboard of programmer **20**, preferably include means for entering command signals from the operator to initiate transmissions of downlink telemetry from IMDs and to initiate and control telemetry sessions once a telemetry link with one or more IMDs has been established. The graphics display /screen **114** is also used to display patient related data and menu choices and data entry fields used in entering the data in accordance with the present invention as described below. Graphics display/screen **114** also displays a variety of screens of telemetered out data or real time data. Programmer **20** is also provided with a strip chart printer **118** or the like coupled to interface controller module so that a hard copy of a patient's ECG, EGM, marker channel or similar graphics display can be generated. Further, Programmer **20**'s history relating to instrumentation and software status may be printed from printer **118**. Similarly, once an uplink is established between programmer **20** and any one of IMDs **10**, **10'** and **10"**, various patient history data and IMD performance data may be printed out. The IMDs contemplated by the present invention include a cardiac pacemaker, a defibrillator, a pacer-defibrillator, implantable monitor (Reveal), cardiac assist device, and similar implantable devices for cardiac rhythm and therapy. Further the IMD units contemplated by the present invention include electrical stimulators such as, but not limited to, a drug delivery system, a neural stimulator, a neural implant, a nerve or muscle stimulator or any other implant designed to provide physiologic assistance or clinical therapy.

[0061] Data resources **100** represents a high speed computer network system which is located in remote expert data center **62** having wireless bi-directional data, voice and video communications with programmer **20** via wireless communications link **136**. Generally data resources **100** are preferably located in a central location and are equipped with high-speed web-based computer networks. Preferably, the data resource center is manned 24-hours by operators and clinical personnel who are trained to provide a web-based remote service to programmer **20**. Additionally, as discussed hereinabove, data resources **100** provide remote monitoring, maintenance and upgrade of programmer **20**. The location of remote data center **62** and, consequently, the location of data resources **100** are dependent upon the sphere of service. In accordance with the present invention, data resource **100** may be located in a corporate headquarters or manufacturing plant of the company that manufactures programmer **20**. Wireless data communications link/connection **136** can be one of a variety of links or interfaces, such as a local area network (LAN), an internet connection, a telephone line connection, a satellite connection, a global positioning system (GPS) connection, a cellular connection, a laser wave generator system, any combination thereof, or equivalent data communications links.

[0062] As stated hereinabove, bi-directional wireless communications **136** acts as a direct conduit for information exchange between remote data center **62** and programmer **20**. Further, bi-directional wireless communications **136** provides an indirect link between remote data center and IMDs **10**, **10'** and **10"** via programmer **20**. In the context of this disclosure the word "data" when used in conjunction with bi-directional wireless communications also refers to sound, video and information transfer between the various centers.

[0063] Accordingly, once data communications is established, data resources **100** may assess, monitor or analyze various data and information relating to programmer **20** or its components. For example, data resource **100** can analyze the performance history of a specific component of programmer **20**. More specifically, data resource **100** can analyze usage statistical data, component status information or analyze error information of programmer **20**. If an error is discovered in programmer **20**, or any of its sub-components, preventative actions can be performed via bi-directional wireless data communications link/connection **124**.

[0064] During one of the wireless bi-directional communications sessions, contemplated by the invention, information identification module **138** receives identification information and historical data from one or more of the components of programmer **20**. These components may include analyzer **126**, or any sub-component thereof. Further, operational and instrumentation data relating to programmer **20** is collected and submitted for review by analyzation module **140**, at remote data center **62**. More particularly, information identification module **138** receives information identifying a particular medical component or sub-component through bar code information, a serial number, and/or a model number. Information identification module **138** also receives historical data such as the number of times the component has been turned on, the length of time of each session, the functions performed by the component during each session, and past errors or malfunctions of the component. This data is transferred from programmer **20** to data center **62** for analysis, documentation, evaluation and monitoring of the functional and operational parameters of programmer **20**. In the event a defect or malfunction is indicated by the data, remedial action will be taken as deemed appropriate based on the recommendation of the expert systems or technical support residing in data center **62**.

[0065] Data storage module **142** contains various information including industry-set or manufacturer's recommendation for mean time to failure standards relating to various components of programmer **20**. The software contained in module **142** keeps track of usage and mean time to failure information such that when programmer **20** is interrogated,

the information is readily available. This information is used to determine the maintenance, replacement or checkup of critical components in programmer **20**.

[**0066**] Analyzation module **140** compares the historical data, such as usage, idle time and near failure or actual failure events and similar other information of a component or sub-component with information in data storage module **142**. Analyzation module **140** further evaluates the historical and performance data, using the mean time to failure standards as a model. More specifically, analyzation module **140** compares usage information, instrument status information, and error information against preset performance and operations standards for the same or similar conditions. The preset standards are generally derived from analysis of prior similar components use and failure modes. Analyzation module **140** determines whether a present failure has occurred or a near-future failure is eminent. In either case, data resources **100** would attempt to correct the present and foreseeable failures or would initiate a course of action to rectify the situation.

[**0067**] For example, a software upgrade application from update software module **146** can be transmitted via data communications link/connection **136** and remotely installed in a specific component or sub-component of programmer **20**. An upgrade software application may correct a present or near-future failure if, for example, the failure mode of an imbedded system are known. In addition, remote data center **62** can interface with a component or sub-component directly of programmer **20** to suggest modifications or adjustments. Remote data center **62**, through its web-based expert and computer systems in data resources **100**, can also schedule a parts replacement order for a component in programmer **20**. Setting or broadcasting an urgent message to the operator over the web-based LAN or WAN system typically does this.

[**0068**] Further, as discussed hereinabove, programmer **20** has touch-sensitive display **114** capable of displaying communications information from data resources **100**. Therefore, urgent information relating to a critical component of programmer **20** may be communicated via display **114** to notify an operator of a component failure, a scheduled replacement activity or similar emergency maintenance issues. Finally, data center **62** can interface directly or indirectly with the components of programmer **20** to alert the operator to change/maintain a component. The replacement activity may occur on-site or may require the component be shipped to a centralized repair facility.

[**0069**] With the invention, the computers and software and other tools at data resources **100** residing in remote data center **62** can remotely analyze a diverse number of components and sub-components of programmer **20**. As discussed above, data center **62** is preferably a web-based high-speed computer network and includes other resources to enable remote troubleshooting, preventative maintenance, and upgrade of programmer **20**. Specifically, updated software can be provided to programmer **20** by exporting it via one of the communications media disclosed herein. Alternatively, a remote assessment and decision as to whether a component or sub-component of programmer **20** requires service can be made by remotely monitoring the component in question.

[**0070**] Referring now to **FIG. 6A, a** high-level software logic is provided illustrating the remote troubleshooting, maintenance and upgrade capabilities of the present invention. Specifically, the logic is initiated by requesting a connection between programmer **20** and remote data center **62** under logic step **150**. The logic proceeds to verify programmer **20** under logic step **152**. Subsequently, programmer **62** is verified for authenticity under decision step **154**. If no verification is obtained, by means of an identification or a password, the process is terminated under logic step **155**. If however, programmer **20** is verified, the logic proceeds to logic step **156** to activate instrument ports under logic step **156**. Subsequently, the software logic proceeds to check usage logs under logic step **158**. The usage logs indicate the duration and use of programmer **20**. Excessive or under usage may indicate operational or functional problems. Accordingly, the usage logs are downloaded under logic step **160** to remote data station **62** and directed to analyzer module **140** in data resources **100**, for analysis and evaluation. Subsequently, the usage log is checked for problems under decision step **162**. If no problems are indicted the session is terminated. However, if there is an identifiable problem, the logic proceeds to decision step **164** where the logic queries if a remote solution is possible for the problem. If a remote solution is not considered viable, the system broadcasts an immediate alert to the operator under logic step **163**. In the alternate, if the problem could be solved remotely, the logic proceeds to step **166** where a solution is implemented. The session then terminates under logic step **168**, after recording the event. Similarly, the logic may activate instrument port to check error logs under logic step **170** and execute the designated logic routine as represented in the chart. Further, ports to check battery or power status under logic step **184**, to check data base integrity under logic step **198** and to evaluate mean time between failure status under logic step **212** can be accessed and the relevant logic steps executed in the manner outlined in the chart of **FIG. 6A**. The software-specific procedure described hereinabove encapsulates some of the major aspects of the present invention. Specifically, the process and communications scheme between remote data station **62** and programmer **20** provide a unique system for remote software installation, upgrade, maintenance and monitoring on a continuous basis.

[**0071**] It should be noted that patient data and related information which is ultimately the basis upon which remote station **62** interacts with programmer **20** is obtained from IMDs **10**, **10'** and **10"**. Thus, for example, patient history that is collected from the memory bank of the IMDs by up linking to programmer **20** could be ultimately transferred to remote station **62** for evaluation and analysis.

[**0072**] Referring to **FIG. 6**B, the chart relates to another logic for an uplink episode between programmer **20** and data center **62**. Specifically the logic relates to data and components, data registers and software in programmer **20** which are interactive with IMDs **10**, **10'** and **10"**. The link is initiated under logic step **250**. Programmer **20** is verified under logic step **252**. The logic proceeds to decision step **254** to check if all the verification requirements have been met before access could be allowed. If access is not allowed, the logic to step **253** and the session is terminated. If the session is to continue, the logic proceeds to step **256** where the channels are open. The various channels include patient data under step **258**, usage log data under logic **268**, component status data under logic **280**, error log data under logic **292**

and IMDs interaction/inter-relation data under logic **308**. For illustrative purposes, the patient data branch of the logic is discussed herein below.

[**0073**] Under logic step **258** the patient data port is opened. This data is initially obtained by up linking any one of IMDs **10**, **10'** and **10"** to programmer **20** and transferring patient specific data stored in the IMDs. The data is generally uploaded and stored in programmer **20** on a regular or on as needed basis. Although, some of the patient data may be analyzed locally at programmer **20** level, the flow chart assumes that all patient data will be exported to remote data center **62** for analysis by analyzation module **140**. Thus, the logic proceeds to decision block **262** where inconsistency in the data is checked. In the event there are no recognizable data inconsistencies, the logic proceeds to step **261** and the session is terminated. However, if there are problems in the structure and /or makeup of the patient history data the logic proceeds to decision block **264** and would determine whether the problem could be solved remotely. If the problem is such that remote implementation of a fix is not possible, the logic proceeds to step **263** where an emergency flag is broadcast to an operator thus alerting the responsible party of the problem. In the alternate, if a solution could be implemented remotely, the logic proceeds to implement the solution under logic step **262**. Thereafter, the logic proceeds to step **264** where the operation is recorded, indicating a synopsis of the problem and the remedial measures undertaken. Subsequently, the session is terminated.

[**0074**] Similarly, as outlined in the remainder of the logic chart, usage log is checked under logic step **268**, component(s) status is evaluated under logic step **280**, error log is checked under logic step **292** and interaction/interface error, which may result from programmer **20** interacting with the IMDs, is checked under logic step **308**. In all these cases, in the event a problem with a component or an error with a data set is detected by data center **62**, a remote solution such as software upgrade via module **146** may be implemented or a component replacement notice may be posted.

[**0075**] **FIG. 7** relates to a high-level logic flow chart relating to data management of programmer **20** and a session relating to the evaluation/debugging of the data management system by remote expert data center **62**. Specifically, the system relates to debugging of software, evaluation of embedded systems by checking performance parameters of imbedded systems and analysis of database relating to patient history. The software logic is initiated by down linking data center **62** to programmer **20**, under logic step **400**. The programmer is identified under logic step **402**. Under decision block **404** programmer **20**'s identification is verified. If there is no confirmation of the identification, the session is terminated under logic step **403**. If programmer **20** is verified, however, the logic proceeds to initiate data management ports under logic step **410**. Consequently, the logic proceeds to decision step **412** to check if the session relates to trouble shooting or software upgrade issues. If not, the logic proceeds to logic step **411** and the session is terminated. In the alternate, if the issue deals with software upgrade and/or troubleshooting, the task is performed under logic step **414**. Next, the system is checked to verify the accuracy and completeness of the implemented remedy under logic step **416**. Consequently the system is checked to see if the implemented has resolved the problem under decision block **418**. If the problem remains unresolved the logic proceeds to check the system a few times and after a preset number of attempts broadcasts an alert to the operator under logic step **419**. If the operation is confirmed a success, the logic proceeds to step **420** where the event is recorded and the session terminated.

[**0076**] Similarly, if the data management issue relates to performance parameters, the logic proceeds to decision block **422**. If it is found that the issue is other than performance parameters, for example, of embedded systems in programmer **20**, the logic proceeds to step **423** and the session is terminated. The logic otherwise proceeds to decision block **424** to check if the evaluation session relates to current or near-future failure of imbedded systems or operational parameters thereof. If not the sessions ended at logic step **423**. If failure or near-future failure is the issue, however, the logic proceeds to decision step **426** to check if a remote correction is possible under logic step **426**. If a remote correction is not viable the logic proceeds to step **427** to issue/broadcast an alert to the operator. In the alternate, if a remote solution is possible, the correction is implemented under logic step **428**. Thereafter, the logic proceeds to decision step **430** where the correction is checked for accuracy and related factors. If the correction is found to be successful, the session is terminated under logic step **432**. However, if the problem remains unresolved, the logic proceeds to step **427** to issue/broadcast an alert to the operator.

[**0077**] Further, if the data management issue relates patient history, the program logic advances to decision step **434**. If the investigation does not relate to patient history, the program advances to stop **423** where the event is recorded and the session ended. If, however, the session relates to patient data, the logic advances to step **436** to check various types of patient history status under decision blocks **438**, **440** and **442** where the logic checks to see if the session relates to available patient history, initial startup or missing patent history, respectively. If patient history is available under decision step **438**, it is copied under step **44** and subsequently the event is recorded and the session terminated. In the alternate, if patient history is not available, the logic proceeds to decision step **44** to check if this is a condition of initial startup of either programmer **20** or initial installation of IMDs **10**, **10'** and **10"**. Clearly no prior history will be found in the database if the checkup for patient history is done in the early few hours of the implant. Accordingly under decision block **440** if it is found that the session is being undertaken during initial startup, the logic proceeds to step **446** where the event is recorded and the session terminated. In the alternate if the session is not performed during initial startup, the logic proceeds to decision step **442** where the system checks to see if patient history data is missing. If it is found that patient history data is not missing, the logic reverts back to step **436** to repeat the logic steps stated hereinabove. On the other hand, if patient history data is confirmed to be missing, the logic advances to step **443** to issue/broadcast an alert to the operator.

[**0078**] Accordingly, the present invention provides several advantages over the prior art. Specifically, the prior art does not teach a structure and/or method in which components of a programmer are remotely assessed, monitored or evaluated for failure or other performance defects to implement a remote solution to those problems. In summary, the present invention provides several advances over the prior

art some of which include: the utilization of a communication scheme integrated with a remote web-based expert data center **62** in which expert systems are remotely deployed to evaluate component usage, check error logs and frequency of failure, check power or battery status, monitor mean time to failure status of components/subcomponents, update software, evaluate data base integrity and check information management, perform remote or order on site repair and replacement of components and alert operators to any significant problems with programmer **20**.

[**0079**] Although specific embodiments of the invention have been set forth herein in some detail, it is understood that this has been done for the purposes of illustration only and is not to be taken as a limitation on the scope of the invention as defined in the appended claims. It is to be understood that various alterations, substitutions, and modifications may be made to the embodiment described herein without departing from the spirit and scope of the appended claims.

What is claimed is:

1. A bi-directional communications system integrated with a remote web-based expert data center wherein a medical programmer for an implantable medical device is plinked to the web-based expert center via the bi-directional communications system, the web-based expert data center in combination with the programmer comprising:

the remote web-based expert data center including high-speed computer resources;

the bi-directional communications system being in operable data communications with resources at the remote web-based expert data center; and

the programmer being in executable bi-directional data communications with the web-based expert data center wherein component/sub-component operations and data management of the programmer are monitored, evaluated and modified via commands executed on a remote basis by the high speed computer resources at the web-based expert data center.

2. The communications system of claim 1 wherein said bi-directional communications system includes one of a modem, Internet network, fiber optics, cable, laser transceivers, mobile systems, radio frequency and satellite communications.

3. The communications system of claim 1 wherein said interface includes one of a cellular phone, a palm pilot and a programming device.

4. The communications of claim 2 wherein said Internet network includes the internet structured to provide access to resources located in said remote web-based expert data center and further includes delivery portals.

5. The communications system of claim 2 wherein said mobile systems include a ground-vehicle-installed wireless communications systems having data communications with the remote web-based expert data center and the programmer.

6. The communications system of claim 3 wherein said palm pilot includes handheld computers and screen phones structured to function as webtops to provide access to the internet via one of said bi-directional wireless communications system.

7. The communications system of claim 2 wherein said bi-directional communications system further includes telemetry between the programmer and a plurality of implantable devices.

8. The communications system of claim 7 wherein the implantable device includes a multiplicity of implantable devices in various parts of a patient's body and having independent and common telemetric link to the interface.

9. The communications system of claim 8 wherein said common telemetry link includes communication between said multiplicity of implantable devices implemented at a location within one of the implanted devices.

10. The communications system of claim 2 wherein said laser transceivers are implemented to wirelessly transmit data received via optical wireless systems wherein the data is split, into specified wavelengths, using an amplifier, a laser and a receiver to wirelessly transmit the data to the remote clinic station.

11. The communications system of claim 2 wherein said modem includes a telephone connection including POTS, Switched **56**, ISDN and T1.

12. The communications system of claim 1 wherein said resources at the remote web-based data center include operators, clinicians and web-based high speed computers containing centralized data and information structured to provide distance-based clinical support to patients with implantable devices.

13. The communications system of claim 1 wherein said programmer includes a memory system to store data from the web-based data center for later transfer to the implantable device.

14. A wireless communications system wherein a web-based data center located in a remote information station is in wireless communications with a programmer or webtop unit wherein various clinical data and therapy are delivered through portals which are uploaded into at least one implantable medical device via the programmer or webtop unit, the programmer being disposed external to but within a telemetry range of the implanted medical device, the wireless communications system in combination with the programmer comprising:

The web-based data center utilizing Telnet protocol to provide bi-directional communications with the programmer;

the programmer having direct bi-directional communications with the at least one implantable medical devices; and

the at least one implantable medical device having telemetric wireless communications with the programmer.

15. The wireless system of claim 14 wherein the various clinical data and therapy delivered through the portals include executable commands implemented in the programmer to remotely perform maintenance on components and manage a data base.

16. The system of claim 15 wherein said maintenance on the components includes software upgrade on imbedded systems of the programmer.

17. The system of claim 15 wherein said database includes usage logs, patient data, error logs and performance parameter information.

18. The system of claim 14 wherein said webtop is implemented to transfer non-critical information from said web-based data center.

19. The system of claim of claim 15 wherein said database includes patient history that is transferred to the programmer by up linking the at least on implantable medical device.

20. The system of claim 17 wherein said usage logs includes an imbedded system implemented clock/timer data relating to the number of connections between the at least one implantable medical device and the programmer.

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