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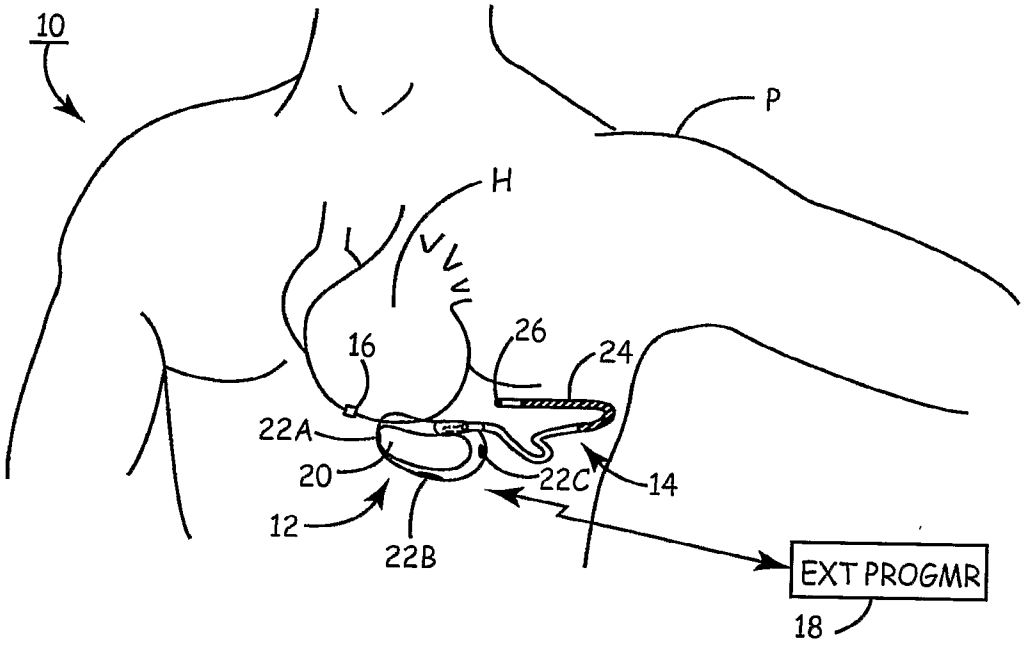
(54) Title: SUBCUTANEOUS ICD WITH SEPARATE CARDIAC RHYTHM SENSOR



(57) Abstract: A cardiac rhythm sensor positioned on or close to the heart senses electrical or mechanical activity and transmits a cardiac rhythm signal wirelessly to a subcutaneous ICD. Arrhythmia detection and delivery of therapy are performed by the SubQ ICD based upon the cardiac rhythm signal received from the sensor.

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SUBCUTANEOUS ICD WITH SEPARATE CARDIAC RHYTHM SENSOR

BACKGROUND OF THE INVENTION

The present invention relates to implantable medical devices. In particular, the invention relates to a subcutaneous implantable cardioverter defibrillator (SubQ ICD) which receives a rhythm signal wirelessly from an implantable cardiac rhythm sensor positioned on or close to the epicardium.

Implantable cardioverter defibrillators are used to deliver high energy cardioversion or defibrillation shocks to a patient's heart when atrial or ventricular fibrillation is detected. Cardioversion shocks are typically delivered in synchrony with a detected R-wave when fibrillation detection criteria are met. Defibrillation shocks are typically delivered when fibrillation criteria are met, and the R-wave cannot be discerned from signals sensed by the ICD.

Currently, ICD's use endocardial or epicardial leads which extend from the ICD housing through the venous system to the heart. Electrodes positioned in or adjacent to the heart by the leads are used for pacing and sensing functions. Cardioversion and defibrillation shocks are generally applied between a coil electrode carried by one of the leads and the ICD housing, which acts as an active can electrode.

A SubQ ICD differs from the more commonly used ICD's in that the housing is typically smaller and is implanted subcutaneously. The SubQ ICD does not require leads to be placed in the bloodstream. Instead, the SubQ ICD makes use of one or more electrodes on the housing, together with a subcutaneous lead that carries a defibrillation coil electrode and a sensing electrode.

The absence of endocardial or epicardial electrodes make rhythm and arrhythmia sensing more challenging with the SubQ ICD. Sensing of atrial activation is limited since the atria represent a small muscle mass, and the atrial signals are not sufficiently detectable thoracically. Muscle movement, respiration, and other physiological signal sources and environmental noises also can affect the ability to sense ECG signals and detect arrhythmias with a SubQ ICD.

BRIEF SUMMARY OF THE INVENTION

An implantable cardioverter defibrillator system includes a SubQ ICD and a separate cardiac rhythm sensor that is positioned on or close to the heart. The cardiac rhythm sensor senses electrical or mechanical activity of the heart and transmits a signal wirelessly to the SubQ ICD. The SubQ ICD uses the signal from the cardiac rhythm sensor for arrhythmia detection and delivery of therapy.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts a SubQ ICD and a separate cardiac rhythm sensor implanted in a patient.

FIGS. 2A and 2B are front and top views of the SubQ ICD and associated subcutaneous lead.

FIG. 3 is a perspective view of one embodiment of the cardiac rhythm sensor.

FIG. 4 is an electrical block diagram of the cardiac rhythm sensor.

FIG. 5 is an electrical block diagram of the SubQ ICD.

DETAILED DESCRIPTION

FIG. 1 shows implantable cardioverter defibrillator (ICD) system 10, which includes SubQ ICD 12, subcutaneous sensing and cardioversion/defibrillation therapy delivery lead 14, cardiac rhythm sensor 16, and external programmer 18.

Housing or canister 20 of SubQ ICD 12 is subcutaneously implanted outside the ribcage of patient P, anterior to the cardiac notch, and carries three subcutaneous electrodes 22A-22C. Lead 14 extends from housing 20 and is tunneled subcutaneously laterally and posterially to the patient's back at a location adjacent to a portion of a latissimus dorsi mucle. Electrode coil 24 and sensing electrode 26 are located at the distal end of lead 14. Heart H is disposed between the SubQ ICD housing 20 and distal electrode coil 24 of lead 14.

SubQ ICD 12 contains signal processing and therapy delivery circuitry to detect bradycardia and tachycardia conditions and to apply appropriate pacing and defibrillation shocking pulses to heart H. The pacing pulses are applied using electrodes 22A-22C. The shocking pulses are applied between coil electrode 24 and electrically conductive housing

or can electrode 20 of SubQ ICD 12. Communication between SubQ ICD 12 and external programmer 18 is provided by an RF communication link.

Sensing of cardiac activity is performed by cardiac rhythm sensor 16, which is a small device separate from SubQ ICD 12 and which is positioned on or close to the epicardium of heart H using a minimally invasive approach. Sensor 16, which carries its own power source, is capable of sensing either electrical or mechanical activity of heart H, and then transmitting a cardiac rhythm signal representing the sensed activity to SubQ ICD 12 and lead 14. The transmitted cardiac rhythm signal from sensor 16 is received by SubQ ICD 12 using electrodes 22A-22C, or by lead 14 together with one of electrodes 22A-22C. SubQ ICD 12 uses the received cardiac rhythm signal to analyze cardiac activity and make therapy decisions.

FIGS. 2A and 2B are front and top views of SubQ ICD 12. Housing 20 is an ovoid with a substantially kidney-shaped profile. The ovoid shape of housing 20 promotes ease of subcutaneous implant and minimizes patient discomfort during normal body movement and flexing of the thoracic musculature. Housing 20 contains the electronic circuitry of SubQ ICD 12. Header 28 and connector 30 provide an electrical connection between distal electrode coil 20 and distal sensing electrode 22 on lead 14 and the circuitry within housing 20.

Subcutaneous lead 14 includes distal defibrillation coil electrode 24, distal sensing electrode 26, insulated flexible lead body 32 and proximal connector pin 34. Distal sensing electrode 26 is sized appropriately to match the sensing impedance of electrodes 22A-22C.

Electrodes 22A-22C are welded into place on the flattened periphery of canister 20 and are connected to electronic circuitry inside canister 20. Electrodes 22A-22C may be constructed of flat plates, or alternatively, spiral electrodes (as described in U.S. Patent No. 6,512,940) and mounted in a non-conductive surround shroud (as described in U.S. Patent Nos. 6,522,915 and 6,622,046). Electrodes 22A-22C shown in FIG. 2 are positioned on housing 20 to form orthogonal signal vectors.

FIG. 3 shows an embodiment of cardiac rhythm sensor 16 which includes housing 40, ring electrode 42, tip electrode 44, fixation screw 46, and antenna 48. Ring electrode 42 and tip electrode 44 provide bipolar sensing of the electrogram (EGM) signal representing electrical activity of heart H. Fixation screw 46 holds sensor 16 in contact

with the epicardium or other tissue near heart H. Sensor 16 processes the EGM signal sensed by electrodes 42 and 44, amplifies the EGM signal, and transmits the amplified signal through electrode 50 at the distal end of antenna 48 to SubQ ICD 12 and lead 14. Signal processing circuitry within sensor 16 may analyze the EGM signal and either continuously transmit the EGM signal or transmit only if certain conditions, such as high or low heart rate conditions, are fulfilled or detected. The signal transmission between cardiac rhythm sensor 16 and SubQ ICD 12 may occur electrically through a large dipole electric field, via a radio frequency transmission by acoustic (e.g. ultrasonic) transmission, or by optical transmission. Either analog or digital transmission protocols can be used to transmit the cardiac rhythm signal from sensor 16 to SubQ ICD 12. Although antenna 48 is shown in FIG. 3 as extending from sensor 16, in other embodiments the antenna may be located on or within housing 40 of sensor 16.

FIG. 4 shows an electrical block diagram of cardiac rhythm sensor 16. Located within housing 40 are battery 52, signal processing circuitry 54, and transmitter 56. Battery 52 supplies the electrical energy required by signal processing circuitry 54 and transmitter 56. Signal processing circuitry 54 receives the EGM signal from ring electrode 42 and tip electrode 44. The EGM signal is filtered and amplified, and may also be analyzed by signal processing circuitry 54 to determine heart rate. Either analog or digital signal processing techniques may be used. Heart rate analysis of the EGM signal by signal processing circuitry 54 allows sensor 16 to transmit the cardiac rhythm signal only under conditions where therapy may be needed, rather than continuously. In the embodiment shown in FIG. 4, signal processing circuitry 54 provides the cardiac rhythm (EGM) signal and a transmit enable (XMIT) signal to transmitter 56 only when therapy may be needed.

In this embodiment, sensor 16 is sized to be implanted with a minimally invasive technique, such as with a trocar. The size of sensor 16 may be, for example, in the range of about 3 to about 10mm in length and about 5 to about 10mm in width or diameter. The small size of sensor 16 limits the battery size. Transmission of the cardiac rhythm signal only when a bradycardia or tachycardia condition exists, rather than continuous transmission of the signal, reduces the energy required by transmitter 56, and increases the battery life.

FIG. 5 is a block diagram of electronic circuitry 100 of SubQ ICD 12. Circuitry 100, which is located within housing 20, includes terminals 104A-104C, 106, 108 and 110; switch matrix 112; sense amplifier/noise cancellation circuitry 114; pacing/timing circuit 116; pacing pulse generator 118; microcomputer 120; control 122; supplemental sensor 124; low-voltage battery 126; power supply 128; high-voltage battery 130; high-voltage charging circuit 132; transformer 134; high-voltage capacitors 136; high-voltage output circuit 138; and telemetry circuit 140.

Electrodes 22A-22C are connected to terminals 104A-104C. Electrodes 22A-22C act as sensing electrodes (along with distal sense electrode 26) to supply the cardiac rhythm signals received from sensor 16 through switch matrix 112 to sense amplifier/noise cancellation circuit 114. Electrodes 22A-22C also act as pacing electrodes to deliver pacing pulses from pacing pulse generator 118 through switch matrix 112.

Terminal 106 is connected to distal sense electrode 26 of subcutaneous lead 14. The cardiac rhythm signal from sensor 16, as sensed by distal sense electrode 26 is routed from terminal 106 through switch matrix 112 to sense amplifier/noise cancellation circuit 114.

Terminals 108 and 110 are used to supply a high-voltage cardioversion or defibrillation shock from high-voltage output circuit 138. Terminal 108 is connected to distal coil electrode 24 of subcutaneous lead 18. Terminal 110 is connected to housing 20, which acts as a common or can electrode for cardioversion/defibrillation.

Sense amplifier/noise cancellation circuit 114 and pacer/device timing circuit 116 process the cardiac rhythm signal as sensed by electrodes 22A-22C and 26. The cardiac rhythm signal is amplified and bandpass filtered by preamplifiers, sampled and digitized by analog-to-digital converters, and stored in temporary buffers.

Bradycardia is determined by pacer/device timing circuit 116 based upon R waves sensed by sense amplifier/noise cancellation circuit 114. An escape interval timer within pacer/device timing circuit 116 or control 122 establishes an escape interval. Pace trigger signals are applied by pacer/device timing circuit 116 to pacing pulse generator 118 when the interval between successive R waves sensed is greater than the escape interval.

Detection of malignant tachyarrhythmia is determined in control circuit 122 as a function of the intervals between R wave sense event signals from pacer/device timing

circuit 116. This detection also makes use of signals from supplemental sensor(s) 124 as well as additional signal processing based upon the cardiac rhythm input signals.

Supplemental sensor(s) 124 may sense tissue color, tissue oxygenation, respiration, patient activity, or other parameters that can contribute to a decision to apply or withhold defibrillation therapy. Supplemental sensor(s) 124 can be located within housing 20, or may be located externally and carried by a lead to switch matrix 112.

Microcomputer 120 includes a microprocessor, RAM and ROM storage and associated control and timing circuitry. Detection criteria used for tachycardia detection may be downloaded from external programmer 18 through telemetry interface 140 and stored by microcomputer 120.

Low-voltage battery 126 and power supply 128 supply power to circuitry 100. In addition, power supply 128 charges the pacing output capacitors within pacing pulse generator 118. Low-voltage battery 126 can comprise one or two $LiCF_X$, $LiMnO_2$ or LiI_2 cells.

High-voltage required for cardioversion and defibrillation shocks is provided by high-voltage battery 130, high-voltage charging circuit 132, transformer 134, and high-voltage capacitors 136. High-voltage battery 130 can comprise one or two conventional LiSVO or $LiMnO_2$ cells.

When a malignant tachycardia is detected, high-voltage capacitors 136 are charged to a preprogrammed voltage level by charging circuit 132 based upon control signals from control circuit 122. Feedback signal Vcap from output circuit 138 allows control circuit 122 to determine when high-voltage capacitors 136 are charged. If the tachycardia persists, control signals from control 122 to high-voltage output signal 138 cause high-voltage capacitors 136 to be discharged through the body and heart H between distal coil electrode 26 and the can electrode formed by housing 12.

Telemetry interface circuit 140 allows SubQ ICD 10 to be programmed by external programmer 18 through a two-way telemetry link. Uplink telemetry allows device status and other diagnostic/event data to be sent to external programmer 18 and reviewed by the patient's physician. Downlink telemetry allows external programmer 18, under physician control, to program device functions and set detection and therapy parameters for a specific patient.

In another embodiment, cardiac rhythm sensor 16 includes an accelerometer for sensing mechanical movement of heart H. Sensor 16 is attached by fixation screw 16, but does not require ring electrode 42 and tip electrode 44.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An ICD system comprising:

a cardiac rhythm sensor for sensing cardiac activity and transmitting wirelessly a cardiac rhythm signal;

a lead carrying a defibrillation electrode; and

a SubQ ICD connected to the lead for providing electrical pulses to the defibrillation electrode upon detection of tachycardia based on the cardiac rhythm signal transmitted by the cardiac rhythm sensor.

2. The ICD system of claim 1, wherein the cardiac rhythm sensor comprises:
a plurality of electrodes for sensing an electrogram signal; and
signal processing circuitry for filtering and amplifying the electrogram signal.

3. The ICD system of claim 2, wherein the cardiac rhythm sensor further comprises:
a transmitter for transmitting the electrogram signal.

4. The ICD system of claim 3, wherein the cardiac rhythm sensor further comprises:
an antenna connected to the transmitter.

5. The ICD system of claim 3, wherein the signal processing circuitry selectively enables the transmitter based on analysis of the electrogram signal.

6. The ICD system of claim 1, wherein the cardiac rhythm sensor includes a motion sensing device for sensing mechanical activity of a heart.

7. The ICD system of claim 1, wherein the cardiac rhythm sensor is untethered.

8. The ICD system of claim 1, wherein the cardiac rhythm sensor is sized to be implanted with a minimally invasive procedure.

9. The ICD system of claim 1, wherein the cardiac rhythm sensor has a length of less than about 10mm and a width of less than about 10mm.

10. The ICD system of claim 1, wherein the cardiac rhythm sensor includes an attachment device for attaching the cardiac rhythm sensor to cardiac tissue.

11. An implantable cardiac rhythm sensor comprising:

a housing sized to permit implantation into contact with cardiac tissue using a minimally invasive implantation procedure;

a cardiac activity sensor carried by the housing;

signal processing circuitry within the housing for processing signals from the cardiac activity sensor to produce a cardiac rhythm signal; and

a transmitter for wirelessly transmitting the cardiac rhythm signal.

12. The implantable cardiac rhythm sensor of claim 11, wherein the cardiac activity sensor comprises a plurality of electrodes.

13. The implantable cardiac rhythm sensor of claim 11, wherein the cardiac activity sensor comprises a motion sensing device.

14. The implantable cardiac rhythm sensor of claim 11, wherein the signal processing circuitry selectively enables the transmitter based on analysis of the cardiac rhythm signal.

15. The implantable cardiac rhythm sensor of claim 11, wherein the housing has a length and a width of about 10mm or less.

16. The implantable cardiac rhythm sensor of claim 11, and further comprising:

an attachment device for securing the housing to cardiac tissue.

17. A system for delivering therapy to a heart, the system comprising:

an untethered implantable medical device sized to permit implantation into contact with cardiac tissue, the device comprising a plurality of electrodes for electrical coupling to the cardiac tissue; and

a therapy delivery device capable of wireless communication with the untethered implantable medical device.

18. The system of claim 17, wherein the untethered implantable medical device includes circuitry for producing a cardiac rhythm signal based, on electrical activity sensed by the plurality of electrodes, and for transmitting the cardiac rhythm signal to the therapy delivery device.

19. The system of claim 17, wherein the untethered implantable medical device includes a housing with a maximum dimension of 10mm or less.

20. The system of claim 19, wherein the untethered implantable medical device includes a battery and circuitry connected to the electrodes within the housing.

21. A method of providing therapy for cardiac arrhythmia, the method comprising:

injecting an untethered implantable medical device into contact with cardiac tissue;

wirelessly communicating between the untethered implantable medical device and a separate therapy delivery device when sensed cardiac activity indicates a need for delivery of therapy; and

delivering therapy in response to the wireless communicating.

22. The method of claim 21, wherein the implantable medical device includes a plurality of electrodes in contact with cardiac tissue.

23. The method of claim 21, wherein the untethered implantable medical device senses cardiac activity and wirelessly transmits a cardiac rhythm signal to the therapy delivery device.

24. The method of claim 23, wherein the untethered implantable medical device only transmits the cardiac rhythm signal when an analysis of the cardiac rhythm signal indicates presence of a bradycardia or tachycardia condition.

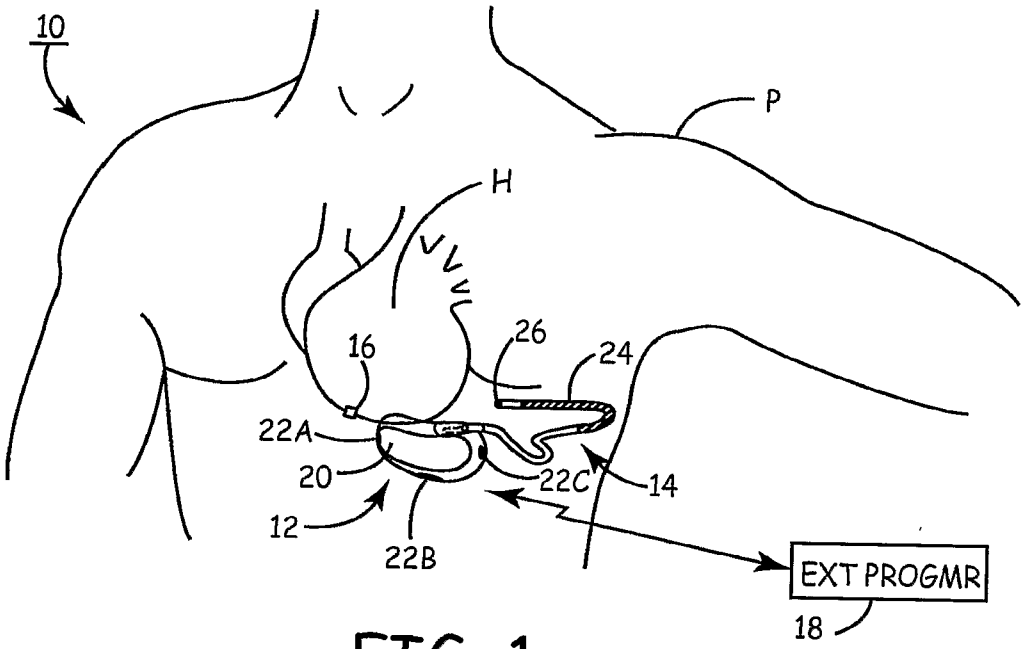

FIG. 1

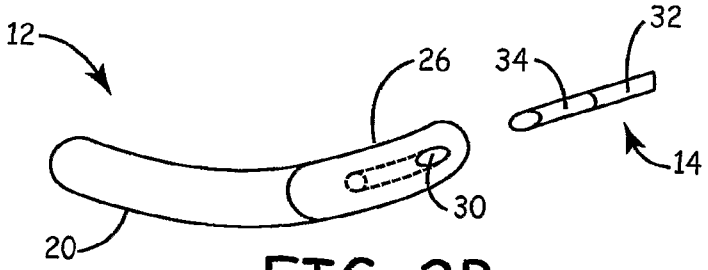

FIG. 2B

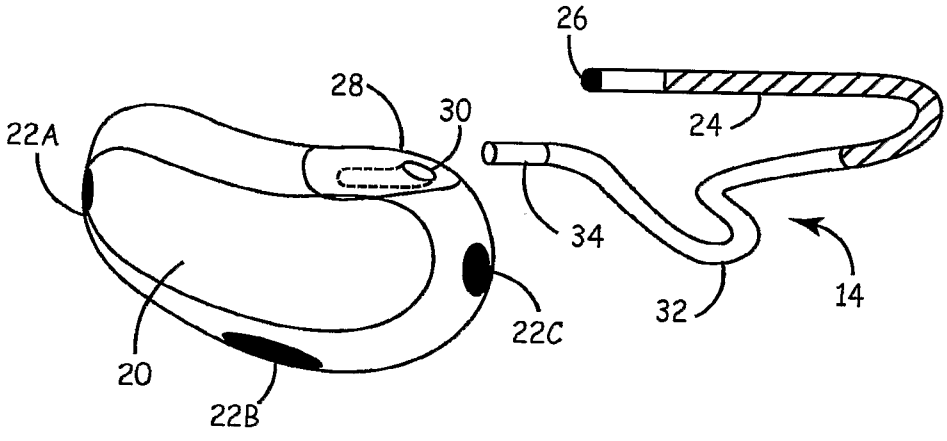

FIG. 2A

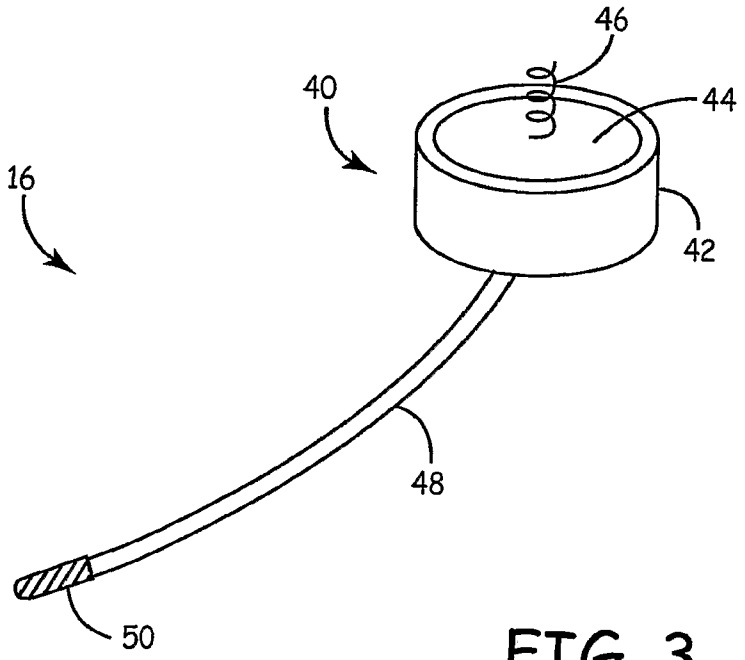
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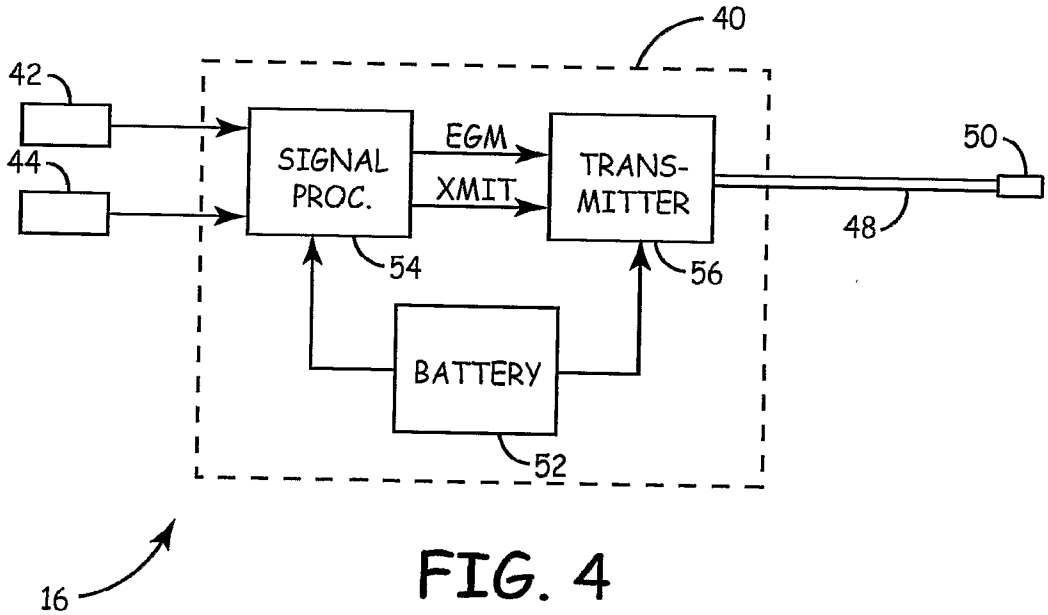
FIG. 3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BATTERY
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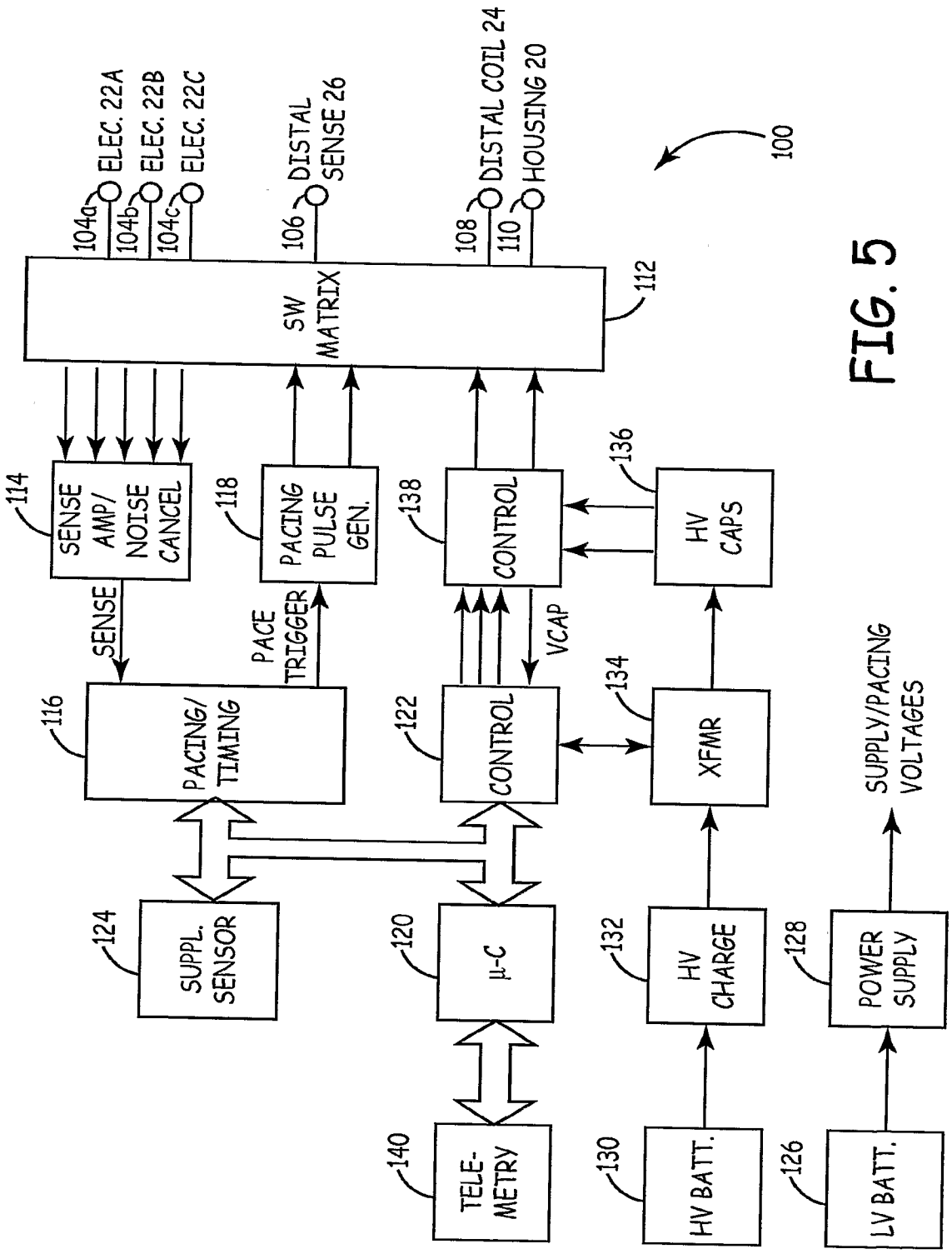
16

FIG. 4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ELEC. 22B
ELEC. 22C
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DISTAL COIL 24
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SW MATRIX
112
SENSE AMP/ NOISE CANCEL
114
PACING PULSE GEN.
118
CONTROL
138
HV CAPS
136
SENSE
PACE TRIGGER
VCAP
PACING/ TIMING
116
CONTROL
122
XFMR
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SUPPLY/PACING VOLTAGES
SUPPL. SENSOR
124
μ-C
120
HV CHARGE
132
POWER SUPPLY
128
TELE-METRY
140
HV BATT.
130
LV BATT.
126

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/060944

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/042 A61N1/372 A61N1/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/26840 A (MEDTRONIC INC [US]) 25 June 1998 (1998-06-25) pages 4-9; figures 1,2A,3A,3B	1-20
X	US 6 141 588 A (COX TIMOTHY J [US] ET AL) 31 October 2000 (2000-10-31) columns 8-13; figures 1,5,6	11-20

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 May 2007	01/06/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Aronsson, Fredrik

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 21-24

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Claims 21-24 refer to a surgical treatment due to the injection of a device into the body of a patient.
Claims 21-24 also refer to a therapeutic method of treatment practised on the human or animal body due to the step of delivering therapy.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/060944

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 21-24
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/060944

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9826840 A	25-06-1998	AU 5526798 A	15-07-1998
		US 5814089 A	29-09-1998
US 6141588 A	31-10-2000	NONE	

专利名称(译)	带独立心律传感器的皮下icd		
公开(公告)号	EP1978866A1	公开(公告)日	2008-10-15
申请号	EP2007762883	申请日	2007-01-24
[标]申请(专利权)人(译)	美敦力公司		
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发明人	STEGEMANN, BERTHOLD BRUNS, HANS-JUERGEN		
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优先权	11/343677 2006-01-31 US		
外部链接	Espacenet		

摘要(译)

位于心脏上或心脏附近的心律传感器感测电活动或机械活动，并将心律信号无线传输到皮下ICD。基于从传感器接收的心律信号，SubQ ICD执行心律失常检测和治疗的递送。