

646551

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(to be filed before acceptance)

I/We Harold R. Patton
being authorised by MEDTRONIC, INC.
of 7000 Central Avenue N.E., Minneapolis, MN 55432 United States of America
the applicant in respect of an application for a patent for an invention entitled Implantable pulse generator
filed under Australian Application No. 13631/92, state the following:-

Part 1 - Must be completed for all applications.

The person(s) nominated for the grant of the patent: MEDTRONIC, INC.
~~is/are the actual inventor(s)~~
~~or~~
 has, for the following reasons, gained entitlement from the actual inventor(s):
The nominated person is the assignee of the invention
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Part 2 - Must be completed if the application is a Convention application.

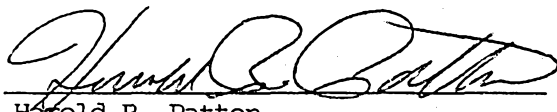
The person(s) nominated for the grant of the patent is/are:
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 entitled to rely on the basic application(s) listed on the patent request form by reason of the following:

The basic application(s) listed on the request form is/are the first application(s) made in a Convention country in respect of the invention.

Part 3 - must be completed if the application was made under the PCT and claims priority.

The person(s) nominated for the grant of the patent is/are:
~~the applicant(s) of the application(s) listed in the declaration under Article 8 of the PCT~~
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The nominated person is the assignee of the basic
application from the said actual inventor(s)

The basic application(s) listed in the declaration made under Article 8 of the PCT is/are the first application(s) made in a Convention country in respect of the invention.

Signed: 
Harold R. Patton
Vice President and Chief Patent Counsel

Date: August 16, 1993

Status: _____



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IMPLANTABLE PULSE GENERATOR
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- (56) Prior Art Documents
US 4254775
US 4182345
US 3822707
- (57) Claim

1. An implantable pulse generator, comprising:
a hermetically sealed housing containing a hybrid circuit
and a battery, said housing defining two generally planar
opposed major surfaces connected to one another by means of
a circumferential edge surface, such that said housing
displays a generally flattened configuration, said hybrid
circuit located general parallel to said major surfaces of
said housing; and

a connector module mounted to one of said major
surfaces of said housing, said connector module comprising a
plurality of connector receptacles and electrical connectors
associated with said receptacles, each of said electrical
connectors coupled to said hybrid circuit within said
housing by means of a feedthrough pin extending through a
feedthrough, said feedthrough pins extending through said
housing perpendicular to said major surfaces and to said
hybrid circuit.

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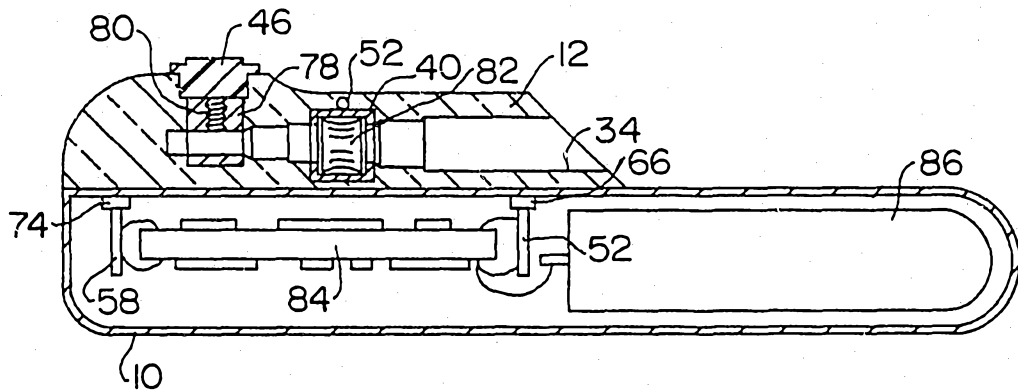
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(54) Title: IMPLANTABLE PULSE GENERATOR



(57) Abstract

An implantable pulse generator particularly adapted for implantation in the abdomen. The pulse generator displays a generally flattened configuration having two generally opposed major surfaces and a smaller, circumferential edge surface, and includes a plurality of electrical connectors (82) located in a connector module mounted to one of the major surfaces of the pulse generator. The housing (10) of the pulse generator contains a hybrid circuit (84) mounted generally parallel to the major surfaces of the pulse generator, connected to the electrical connectors (82) by means of feedthroughs (74, 66) passing through one of the major surfaces of the pulse generator, located adjacent to the edges of the hybrid circuit (84) and perpendicular thereto.

IMPLANTABLE PULSE GENERATOR

BACKGROUND OF THE INVENTION

This invention relates generally to medical electrical
5 stimulators, more particularly to muscle stimulators for
functional electrical stimulation, and most particularly to
implantable electrical stimulators for stimulation of muscle
employed as a myocardial substitute.

U.S. Patent No. 4,735,205 issued to Chachques et al
10 discloses method and apparatus for employing the latissimus
dorsi muscle to assist cardiac function. This patent is
incorporated herein by reference in its entirety. In the
method disclosed in this patent, the latissimus dorsi muscle
is surgically resected, divided into two parts to cover the
15 surface of the heart, and inserted into the thoracic cavity
by means of a resection of the second rib. After or before
positioning the muscle, stimulating electrodes are threaded
into the muscle at desired locations to affect contraction
of the muscle. Stimulating pulses are provided by an
20 implanted pulse generator, preferably implanted
subcutaneously in the abdomen. A pulse generator
appropriate for such use is disclosed in U.S. Patent No.
4,411,268 issued to Cox. Timing of contractions of the
latissimus dorsi muscle is controlled by the stimulator,
25 which senses natural contractions of the heart, and
stimulates the latissimus dorsi muscle to contract in
synchrony therewith. Sensing of heart activity, and
stimulation of heart contractions in the absence of
underlying heart activity is accomplished by means of an
30 additional electrical lead, coupling the heart to the pulse
generator.

The pulse generator disclosed in the above cited
patent, like most implantable pulse generators, has a
generally flattened external configuration with two major,
35 generally planar surfaces and a circumferential edge

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surface. Mounted to the circumferential edge surface is a connector block which includes receptacles for each of the three illustrated stimulation leads. This pulse generator is implanted with its major surfaces generally parallel to the skin.

SUMMARY OF THE INVENTION

When implanting a pulse generator in the abdominal region, a relatively limited area is available for implant of the device. As such, the length and width of the pulse generator (length and width of the major surfaces of the pulse generator) are more critical than the thickness of the pulse generator. As additional leads are added to the system illustrated in the Chachques et al patent, either to accomplish sequential stimulation of different muscle portions or to accomplish dual chamber pacing and sensing of the heart, the volume of the connector block increases proportionately. For practical reasons, implantable pulse generators have now evolved to the point where they almost all uniformly take the form of a hermetically sealed metal enclosure, with a molded connector module attached thereto. Connection between the circuitry and battery within the hermetic enclosure and the connector module is typically accomplished by means of feedthroughs.

The inventors of the present application have determined that by relocation of the molded connector module assembly to the major surface of the hermetic enclosure, from the edge surface, a pulse generator is produced that is more readily implanted in the abdominal region, and which can easily accommodate a multiplicity of stimulation and sensing leads. In addition, the inventors have determined that the configuration of the stimulator disclosed herein provides advantages in construction of the stimulator and in connecting the circuitry therein to the electrical

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connectors within the connector module. These advantages are also of benefit in pulse generators intended for pectoral implant. Feedthroughs are located in two spaced rows along one major surface of the hermetic enclosure, with the circuitry located between the rows of feedthroughs. This is particularly desirable where double sided hybrid circuitry is located, in that it allows for simple interconnection of either side of the hybrid to the feedthrough pins, without the necessity of bending and routing elongated feedthrough pins, as would be required if the connector module were located along an edge surface of the hermetic enclosure. Provision of the feedthrough pins perpendicular to the plane of the hybrid circuitry and arrayed along two edges of the hybrid circuitry simplifies the interconnection of the hybrid circuitry to the electrical connectors within the connector module and provides increased flexibility in hybrid circuit layouts.

BRIEF DESCRIPTION OF THE DRAWINGS

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Fig. 1 is a side, plan view of a pulse generator according to the present invention.

Fig. 2 is a top, plan view of a pulse generator according to the present invention.

25 Fig. 3 is a side, cutaway view through the pulse generator illustrated in Figs. 1 and 2.

Fig. 4 is a drawing of the thoracic region of the human body, illustrating locations for implant of a pulse generator according to the present invention.

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DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 is a side, plan view of a pulse generator according to the present invention. The structure of the pulse generator illustrated can be divided into two major

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assemblies. Contained within the metal hermetic enclosure 10 is the battery and circuitry of the pulse generator. The enclosure 10, seen in this view from the side or edge, displays a generally flattened configuration with two large, 5 generally planar major surfaces 14 and 16 and a circumferential edge surface 18. In order to provide a more biocompatible configuration, the corners connecting the side and edge surfaces are generally rounded.

The second major assembly is the connector module 12, 10 which is molded from a transparent plastic, typically epoxy. Visible through the transparent epoxy is the structure associated with the outer most connector receptacle. The connector receptacle takes the form of a stepped cylindrical bore 20, which may correspond to the IS-1 or VS-1 in-line 15 connector configuration, generally described in the article "The Impact of Pending Technologies on a Universal Connector Standard", by Doring et al, published in PACE, Vol. 9, pp. 1186-1190, incorporated herein by reference in its entirety. This basic connector configuration is now widely in use 20 throughout the cardiac pacemaker industry and is well known to those of skill in the art. Visible through the transparent epoxy are two connectors 22 and 24. These connectors are coupled to the circuitry within hermetic enclosure 10 by means of feedthrough wires 26 and 28, which 25 pass through feedthroughs into the interior of hermetic enclosure 10. Connector 24 employs a crown contact, which is a louvered, cylindrical receptacle with curved, inwardly directed flat strips, illustrated in more detail in Fig. 3. Connector block 22 employs a set screw to make contact with 30 a cylindrical pin on the proximal end of the pacing or muscle stimulation lead. Access to the set screw is obtained by means of a pierceable grommet 30, of the type generally disclosed in U.S. Patent No. 3,908,668, issued to Bolduc. Connection of the feedthrough wires 26 and 28 to

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connector blocks 22 and 24 is made by means of a weld or other method of mechanical connection.

Fig. 2 is a top, plan view of the pulse generator illustrated in Fig. 1. In Fig. 2, it is apparent that the connector module is provided with four stepped cylindrical receptacles 20, 32, 34 and 36, each of which has associated therewith a crown contact connector 24, 38, 42, 44 for engaging the connector ring on the proximal end of a pacing or muscle stimulation electrode and a set screw connector block for engaging the connector pin of the corresponding leads. In this view, the connector blocks corresponding to connector block 22 in Fig. 1 are not readily visible as they are obscured by sealing grommets 30, 44, 46 and 48. The configuration of the receptacles 20, 32, 34, 36 may be identical. Alternatively, the receptacles may be differently dimensioned to prevent inadvertent insertion, for example, of a cardiac pacing lead into a receptacle intended for use with a muscle stimulating lead or vice versa.

In this view, it can be seen that each of the feedthrough wires 28, 50, 52, 54, 56, 58, 60 passes through a feedthrough into hermetic enclosure 10, allowing for contact with the circuitry located therein. Feedthroughs 62, 64, 66, 68, 70, 72, 74 and 76 are arranged generally along two parallel lines. As illustrated in Fig. 3 below, these two parallel lines are located on either side of the hybrid circuitry located within enclosure 10.

Fig. 3 is a side, cutaway view through the pulse generator illustrated in Figs. 1 and 2, through receptacle 34. In this view, set screw 80 is visible within connector block 78. Access to set screw 80 is obtained by piercing sealing grommet 46 with a screwdriver or hex wrench, as appropriate. Connector 82 is similarly visible within connector block 40.

Within hermetic enclosure 10, the hybrid circuitry 84 and the battery 86 are mounted. These are typically mounted by means of plastic spacers or retainers, which have been omitted in this view for the sake of clarity. Appropriate forms of such retainers or spacers are illustrated in U.S. Patent No. 4,314,562, issued to Ware, incorporated herein by reference. However, fabrication of appropriately sized and dimensioned plastic retainers will vary depending on the particular configuration of the hybrid circuitry and battery employed. In light of the teaching of the above cited patent, this is now believed to be a matter of routine engineering, readily accomplished by one of skill in the art.

For purposes of the present invention, it is the interrelation of hybrid circuitry 84 and the feedthrough pins 52 and 58 which is of primary importance. As illustrated, connection between the hybrid 84 and the connector pins 58 and 52 may be accomplished by either the upper or the lower side of the hybrid. Having feedthroughs extending along two opposed edges of the hybrid, allows for a substantial increase in flexibility with regard to layout of the printed circuit paths and connectors pads on the hybrid. In contrast to prior art hybrids, which would have only one edge located adjacent the feedthroughs, the present invention provides the ability to locate connector pads along two opposing edges. In addition, placing the connector pins perpendicular to the plane of the hybrid 84 allows for easy access to either the upper or lower side of the hybrid 84.

Placing the feedthrough wires perpendicular to the surface of the hybrid, arrayed along two opposing edges of the hybrid also minimizes the length of the jumper wires required to connect the hybrid to the connector pins, and eliminates any necessity to bend the feedthrough pins or otherwise route them within the hermetic enclosure 10. This

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is believed to substantially simplify the manufacture of the pulse generator.

Fig. 4 illustrates a view of the human thorax, illustrated in the areas of implant of the pulse generator. The pulse generator is preferably implanted within abdominal area 100, with the major surfaces 16 and 14 of the hermetic enclosure 10 generally parallel to the skin and to the underlying layers of muscle tissue. Because area 100 is relatively restricted, it is preferable that the outer dimensions of the pulse generator (length and width) do not exceed 7cm by 5cm. The pulse generator, in some cases, may be implanted in the pectoralis regions 102, 104.

While the above illustrated embodiment employs a pulse generator which has four lead receptacles, the basic design illustrated is readily adaptable to five or more connector receptacles. Indeed, as the number of desired connector receptacles increases, the value of the basic design configuration also increases. The present invention allows for large numbers of receptacles and associated connectors and feedthroughs with a minimum of increased complexity with regard to the manufacture of the pulse generator. While the above embodiment is particularly adapted for abdominal implant, in conjunction with a stimulator adapted to stimulate the latissimus dorsi muscle, wrapped around the heart, the basic design configuration is also believed applicable to other forms of implantable pulse generators where large numbers of connector lumens and associated connector blocks and feedthroughs are required to perform complicated stimulation and/or sensing functions.

Furthermore, while the disclosed embodiment employs jumper wires to connect the hybrid circuitry to the feedthroughs, it is anticipated that the invention might also be practiced using feedthrough wires passed through holes in the hybrid substrate and soldered or welded directly to the conductive paths on the hybrid. In such

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cases, the feedthrough pins might also interconnect the opposite sides of the hybrid. Of course, in this embodiment, the pins need not be limited to areas closely adjacent the edges of the hybrid. As an alternative to
5 welding or soldering, connection between the feedthrough pins and the hybrid circuit may be accomplished mechanically by means of crown contact or other known types of electrical connectors. As such, the above embodiment should be considered exemplary, rather than limiting, with regard to
10 the following claims.

In conjunction with the above disclosure, we claim:

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CLAIMS

1. An implantable pulse generator, comprising:
5 a hermetically sealed housing containing a hybrid circuit
and a battery, said housing defining two generally planar
opposed major surfaces connected to one another by means of
a circumferential edge surface, such that said housing
displays a generally flattened configuration, said hybrid
10 circuit located general parallel to said major surfaces of
said housing; and
a connector module mounted to one of said major
surfaces of said housing, said connector module comprising a
plurality of connector receptacles and electrical connectors
15 associated with said receptacles, each of said electrical
connectors coupled to said hybrid circuit within said
housing by means of a feedthrough pin extending through a
feedthrough, said feedthrough pins extending through said
housing perpendicular to said major surfaces and to said
20 hybrid circuit.
2. An implantable pulse generator according to claim
1 wherein said feedthroughs and feedthrough pins are
arranged adjacent opposite edges of said hybrid circuit.
25
3. A pulse generator according to claim 1 or claim 2
wherein each of said receptacles has associated therewith at
least two of said electrical connectors.
- 30 4. A pulse generator according to claim 3 wherein
said feedthroughs are arranged generally along two parallel
lines, located adjacent opposite edges of said hybrid
circuit, and wherein each of said electrical connectors
associated with one of said receptacles is coupled to a

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feedthrough pin passing through a feedthrough in a different one of said two generally parallel lines of feedthroughs.

5 5. An implantable pulse generator according to claim 1 wherein said hybrid circuit is coupled to said feedthrough pins by means of jumper wires.

10 6. An implantable pulse generator according to claim 1 wherein said receptacles within said connector module are differentiated from one another by size whereby inadvertent misconnection of electrical leads with said pulse generator may be avoided.

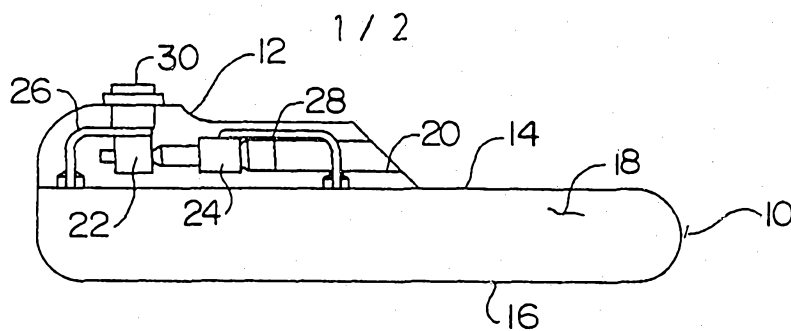


FIG. 1

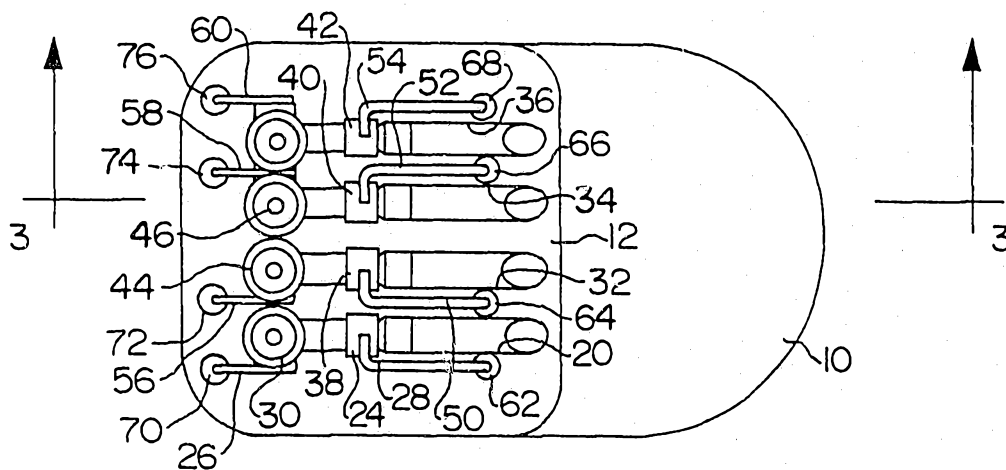


FIG. 2

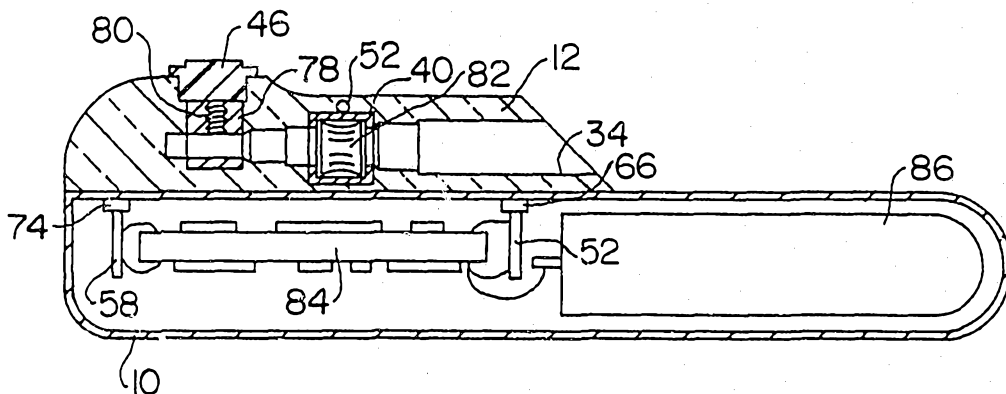


FIG. 3

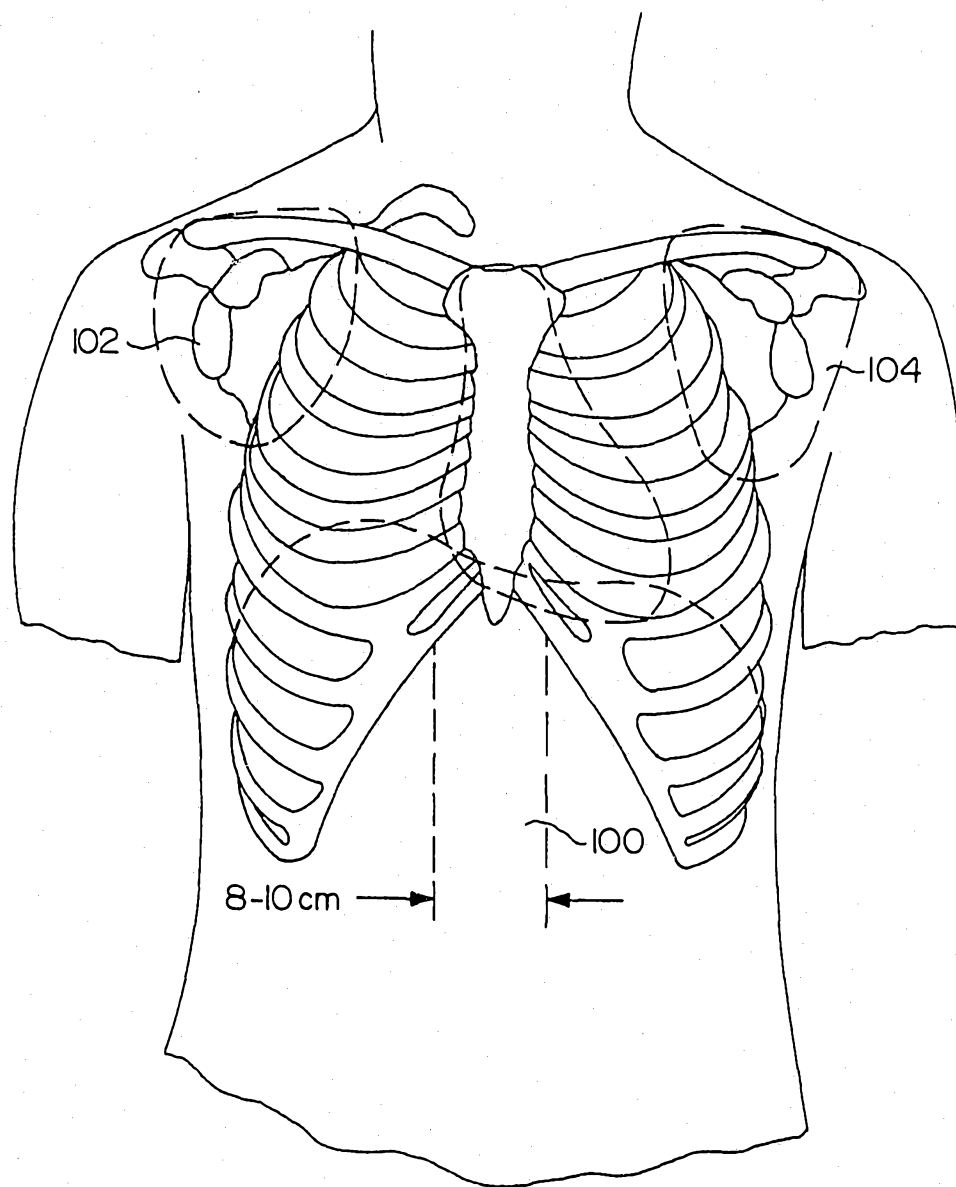


FIG. 4

INTERNATIONAL SEARCH REPORT

PCT/US 92/00036

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC ⁵ : A 61 N 1/375		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC ⁵	A 61 N	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	US, A, 4 182 345 (GROSE) 08 January 1980 (08.01.80), see abstract; fig. 1,2; column 2, lines 19-44; column 2, line 58 - column 3, line 42.	1, 2, 4
A	DE, A, 2 301 583 (CARDIAC PACE MAKERS) 25 October 1973 (25.10.73), see page 2, lines 22-34; page 3, lines 13-18,24-28; page 4, lines 18-23; page 5, lines 14-21,32-33; claim 1.	1, 4
A	DE, A1, 3 025 070 (MIROWSKI) 29 January 1981 (29.01.81), see page 14, lines 12-26; page 16, lines 21-29; page 17, lines 1-9; fig. 8.	1, 2
<p>* Special categories of cited documents: ¹⁴</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"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</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"Z" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
25 May 1992	23.06.92	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE		

ANHANG

ANNEX

ANNEXE

zum internationalen Recherchenbericht über die internationale Patentanmeldung Nr.

to the International Search Report to the International Patent Application No.

au rapport de recherche international relatif à la demande de brevet international n°

FCT/US92/00036 SAE 57063

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten internationalen Recherchenbericht angeführten Patendokumente angegeben. Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The Office is in no way liable for these particulars which are given merely for the purpose of information.

La présente annexe indique les membres de la famille de brevets relatifs aux documents de brevets cités dans le rapport de recherche international visée ci-dessus. Les renseignements fournis sont donnés à titre indicatif et n'engagent pas la responsabilité de l'Office.

Im Recherchenbericht angeführtes Patendokument Patent document cited in search report Document de brevet cité dans le rapport de recherche	Datum der Veröffentlichung Publication date Date de publication	Mitglied(er) der Patentfamilie Patent family member(s) Membre(s) de la famille de brevets	Datum der Veröffentlichung Publication date Date de publication
US A 4182345	08-01-80	AR A1 224125 AU A1 45228779 AU B2 521626 BR A 7902153 CA A1 1117606 DE A1 2913984 EP A2 4783 EP A3 4783 EP B1 4783 ES A1 479343 ES A5 479343 FR A1 2421600 FR B1 2421600 AR A1 217363 AU A1 45223779 AU B2 526122 BR A 7902152 CA A1 1121462 DE A1 2914034 EP A1 6281 ES A1 479225 ES A5 479225 FR A1 2422271 FR B1 2422271 US A 4226244 AU A1 45231779 AU B2 526950 CA A1 1118841 US A 4142532	30-10-81 18-10-79 22-04-82 04-12-79 02-02-82 18-10-79 17-10-79 31-10-79 10-02-82 16-06-79 12-07-79 02-11-79 10-02-84 14-03-80 28-02-80 16-12-82 04-12-79 06-04-82 18-10-79 09-01-80 01-12-79 27-12-79 02-11-79 10-11-83 07-10-80 18-10-79 10-02-83 23-02-82 06-03-79
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DE A1 3025070	29-01-81	CA A1 1161118 GB A1 2055296 GB B2 2055296 JP A2 56031761 NL A 8003840 US A 4254775	24-01-84 04-03-81 16-03-83 31-03-81 06-01-81 10-03-81