(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 April 2008 (03.04.2008)

PCT

(10) International Publication Number
WO 2008/039116 A1

(51) International Patent Classification:
A61B 5/0215 (2006.01) *H01L 41/083* (2006.01)
G01L 9/08 (2006.01)

(21) International Application Number:
PCT/SE2006/001101

(22) International Filing Date:
28 September 2006 (28.09.2006)

(25) Filing Language: English

(26) Publication Language: English

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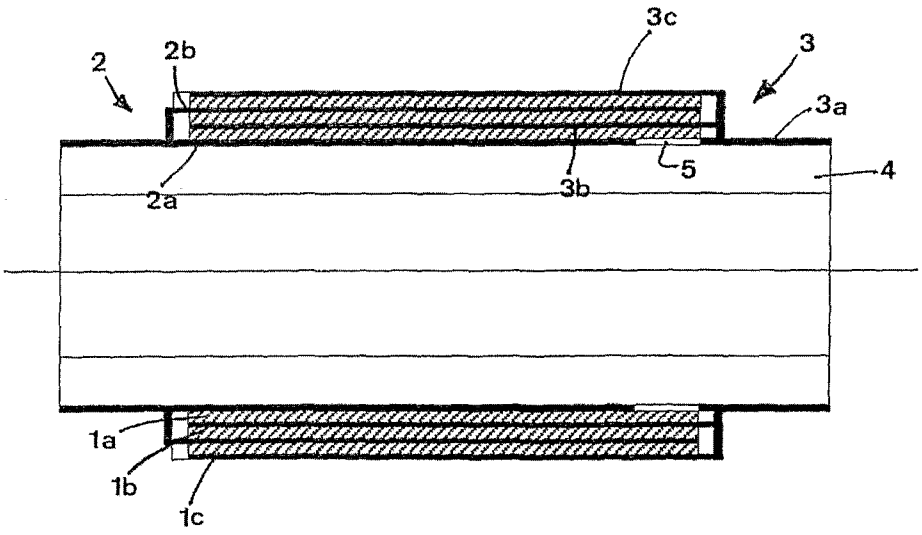
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

Published:
— *with international search report*

(54) **Title:** MEDICAL IMPLANTABLE PIEZOELECTRIC SENSOR AND METHOD FOR MANUFACTURING THE SAME



(57) **Abstract:** The invention relates to a medical implantable piezoelectric sensor comprising a piezoelectric layer and an electrode layer on each side of the piezoelectric layer. The piezoelectric sensor is formed of two or more piezoelectric layers (Ia-Ic) being arranged one over another and having separating layers, comprising electrode layers (2a-2b, 3a-3c) , between the piezoelectric layers. The invention also relates to a method for manufacturing such a piezoelectric sensor.

WO 2008/039116 A1

MEDICAL IMPLANTABLE PIEZOELECTRIC SENSOR AND METHOD FOR MANUFACTURING THE SAME

The present invention relates to a medical implantable piezoelectric sensor comprising a piezoelectric layer and an electrode layer on each side of the piezoelectric layer.

The invention also relates to a method for manufacturing of a medical implantable piezoelectric sensor.

Background of the invention

The development of medical implantable devices goes towards reduced dimensions. The reasons for this are e.g. that smaller devices are easier to insert and more comfortable for a person to use. Examples of such devices or equipment are implantable medical leads for pacemaker applications. However, it could also be other kinds of equipment, such as leads or devices for regulating and/or monitoring the function of any other arbitrary organ inside a human or animal body.

For monitoring pressure inside the body, e.g. blood pressure inside a heart or a blood vessel, it is common practice to use a piezoelectric element or sensor, which is inserted into the organ to be monitored. However, due to the reduction of the overall dimensions of the medical implantable devices, also the dimensions of the piezoelectric sensors have to be reduced. This may cause problems since the electrical charge generated by the piezoelectric sensor is directly proportional to the surface area of the piezoelectric material. In other words, the electric signals from the sensor will be reduced as the surface area of the piezoelectric material becomes smaller and this will put high demands on the electronic equipment to handle small signals and a small signal is also prone to interference and disturbance.

Accordingly, there exists a need for a piezoelectric sensor, which can give an adequate signal level and still be miniaturized to fit the equipment to be implanted.

Summary of the invention

It is an object of the invention to overcome the drawbacks of prior art piezoelectric sensors and provide a piezoelectric sensor, which can be miniaturized and still provide an adequate signal level. At least this object can be achieved by a piezoelectric sensor according to claim 1.

The invention also relates to a method for manufacturing a piezoelectric sensor, having essentially the same object as above. At least this object can be achieved by a method according to claim 12.

The invention is thus based on the understanding that the above object may be achieved by a piezoelectric sensor having two or more piezoelectric layers placed one over another and separated by separating layers comprising electrode layers between the piezoelectric layers. By arranging the piezoelectric sensor in two or more layers, it is possible to increase the sensor area, without significantly increasing the overall sensor dimensions. This can be achieved by utilizing a film technique to build up the sensor. For example, the sensor film thickness including a piezoelectric layer and metallization, i.e. electrode layers, can by modern film technique, be limited to less than 10 micrometers. Preferably, the sensor can be built up by depositing the layers onto each other in which case the layers can be made very thin and the manufacturing costs will be very low. Accordingly, this invention provides techniques to build smaller sensors, which in many cases is necessary to be able to reduce the overall dimensions of the medical implantable device, such as a lead.

While in most cases there is preferred to use as thin film layers as possible, e.g. less than 10

micrometers, it is of course also conceivable to use film layers having a larger thickness. E.g. in many cases there would be possible to use film layers of up to 100 micrometers without any particular disadvantage.

Within this general inventive idea, the sensor can be formed in many different ways. For example, each piezoelectric layer can be provided with separate electrode layers on each side of the piezoelectric layer, in which case the piezoelectric layers can be separated by an insulating layer between adjacent electrode layers. However, in a preferred embodiment, the piezoelectric layers are electrically connected in parallel to each other. This can easily be achieved by arranging only one electrode layer between two successive piezoelectric layers and to connect successive electrode layers to different electrical potential and every second electrode layer to the same electrical potential. In this way it is possible to dispense with any insulating layers between electrode layers associated with adjacent piezoelectric layers, which is advantageous in terms of reduced thickness and costs for material and depositing or any other manufacturing step.

A further advantage with a multilayer piezoelectric sensor connected in parallel, is that it easily can be made electrically shielded. If namely, the lower electrode layer of the lower piezoelectric layer and the upper electrode layer of the upper piezoelectric layer are interconnected and attached to ground potential, the sensor will be shielded. However, this requires that the sensor contains an even number of layers. The shielding will protect the sensor from external electrical fields, which is advantageous in terms of reduced interference from other signals. With conventional sensors it is very difficult or even impossible to accomplish an electrical shielding to a reasonable cost without deteriorating the performance of the sensor or increasing the overall dimensions.

In a method for manufacturing a multilayer piezoelectric sensor connected in parallel, a first piezoelectric layer is provided, having a first and second electrode layer on each side. Next, a second piezoelectric layer is deposited on top of the second electrode layer and subsequently a third electrode layer is deposited on top of the second piezoelectric layer. A possible third and further piezoelectric layer is then deposited in the same way until the desired number of layers have been obtained. This will result in a twofold, threefold...etc, increase of the sensor area, and hence of the sensor signal, at the minor cost of less than 100 micrometers and preferably less than 10 micrometers increase in total film thickness for each layer.

The sensor can be separately built up and subsequently mounted, e.g. by adhesive bonding, on the medical implantable equipment. However, preferably it is built up on some kind of substrate, e.g. a rigid plate or directly onto some portion of the medical implantable equipment, for enhanced strength and ease of manufacturing. In a hereinafter shown and more in detail described embodiment, the sensor is built up on the outside of a tubular element such that the sensor itself will have a tubular form, preferably cylindrical.

The invention offers a possibility to increase the piezoelectric area, while at the same time reduce the overall dimensions of the sensor. One advantage associated with a larger sensor area, is that the output impedance of the sensor is lowered due to increasing capacitance. The higher the capacitance the more electrical leakage can be tolerated in e.g. a pacemaker lead. A higher capacitance will also protect the sensor from damage due to defibrillator shocks. Furthermore, since the sensor will become much smaller, the risk of physical damage during production and in clinical use, will be smaller than for a conventional sensor.

Brief description of the drawings

The invention will now be described by way of example with reference to the accompanying drawings, in which:

Fig 1 is a perspective view of a first embodiment of the invention;

Fig 2 is a perspective view of a second embodiment of the invention;

Fig 3 is a cut perspective view of a third embodiment of the invention; and

Fig 4 is a longitudinal section through the embodiment according to fig 3.

Detailed description of embodiments of the invention

Reference is first made to fig 1, in which is illustrated, in a perspective view in an enlarged scale, a plate formed piezoelectric sensor, according to the invention, having two piezoelectric layers. The sensor comprises two piezoelectric layers 1a, 1b of which one 1b is located over the other 1a. The sensor also comprises two electrical electrodes, namely one first electrode 2 and one second electrode 3. The first electrode 2 comprises two electrode layers 2a and 2b and encloses the sensor on three of the outer surfaces, namely a lower and an upper surface as well as a side surface. The second electrode 3 is positioned on a side surface on the other of the sensor side surfaces and comprises one electrode layer 3a, which is located between the piezoelectric layers 1a and 1b. The electrodes 2 and 3 is completely electrically separated from each other such that when the sensor is exposed to pressure, the electrodes will obtain different electrical potential, which can be measured by means of any suitable device.

A similar piezoelectric sensor is illustrated in fig 2. However, here the sensor comprises four piezoelectric layers 1a-1d. For this reason, the electrode 2 is provided with one additional electrode layer 2c located

between the piezoelectric layers 1b and 1c. Also the electrode 3 is provided with one additional electrode layer 3b located between the piezoelectric layers 1c and 1d. As with the sensor according to fig 1, this sensor is electrically shielded in that the electrode 2 encloses the sensor on three outer surfaces by means of the electrode layers 2a and 2b and on a side surface, wherein the electrode 2 preferably is connected to ground potential during operation.

In fig 3 and 4 is illustrated an alternative embodiment of the invention in a cut perspective view and a longitudinal section, respectively. In this embodiment, the sensor is applied onto a substrate in form of a cylindrical tube 4. The tube 4 can preferably constitute a part of a medical implantable lead, e.g. a so called header tube arranged in a distal end of a pacemaker lead. Here the number of piezoelectric layers 1a-1c are three and they are arranged around the circumference of the tube. In fig 4 the detailed arrangement of the sensor is illustrated. As can be seen, both the first electrode 2 and the second electrode 3 has one layer, 2a and 3a respectively, applied onto the outside surface of the tube 4. However, these two layers are not in electrical contact with each other. Instead a gap 5 is provided between the two layers and the tube is made of an electrically non-conducting material. Moreover, the electrode 3 comprises one electrode layer 3c on the outer piezoelectric layer 1c of the sensor as well as one electrode layer 3b between the piezoelectric layers 1a and 1b. The electrode layer 2a of the electrode 2 is located between the tube 4 and the first piezoelectric layer 1a and extended under almost the entire length of the piezoelectric layer 1a except in the area of the gap 5. In addition, the electrode 2 has one more electrode layer 2b located between the piezoelectric layers 1b and 1c.

The embodiment according to fig 3 and 4, offers a rigid and robust sensor structure with a very large total sensor area, which preferably can be made to add less than 20 micrometer increase of the tube diameter for each piezoelectric layer. One difference with this embodiment by comparison with the embodiments according to fig 1 and 2, is that this embodiment is not electrically shielded. This is due to the fact that in this embodiment there is no common electrode enclosing the sensor on the lower as well as the upper surface, which could be connected to e.g. ground potential. However, it would be a simple task to accomplish a shielding also here, e.g. by arranging one more piezoelectric layer covered by an electrode layer from the electrode 2.

CLAIMS

1. Medical implantable piezoelectric sensor comprising a piezoelectric layer and an electrode layer on each side of the piezoelectric layer, c h a r a c t e r i z e d in that the piezoelectric sensor is formed of two or more piezoelectric layers (1a-1c) being arranged one over another and having separating layers, comprising electrode layers (2a-2c, 3a-3c), between the piezoelectric layers.

2. Medical implantable piezoelectric sensor according to claim 1, c h a r a c t e r i z e d in that each piezoelectric layer including electrode layers, adds less than 100 micrometers in total thickness to the sensor.

3. Medical implantable piezoelectric sensor according to claim 1, c h a r a c t e r i z e d in that each piezoelectric layer including electrode layers, adds less than 10 micrometers in total thickness to the sensor.

4. Medical implantable piezoelectric sensor according to any of the preceding claims, c h a r a c t e r i z e d in that the piezoelectric layers being electrically connected in parallel.

5. Medical implantable piezoelectric sensor according to claim 4, c h a r a c t e r i z e d in that successive electrode layers have different electrical potential.

6. Medical implantable piezoelectric sensor according to any of the preceding claims, c h a r a c t e r i z e d in that the piezoelectric layers are arranged in a tubular form.

7. Medical implantable piezoelectric sensor according to claim 6, c h a r a c t e r i z e d in that the tubular piezoelectric layers are arranged on a tubular substrate (4).

8. Medical implantable piezoelectric sensor according to claim 7, c h a r a c t e r i z e d in that the tubular substrate (4) as well as the tubular piezoelectric layers have a cylindrical shape.

9. Medical implantable piezoelectric sensor according to any of the claims 1-5, c h a r a c t e r i - z e d in that the piezoelectric layers are arranged in a flat form.

10. Medical implantable piezoelectric sensor according to claim 9, c h a r a c t e r i z e d in that the tubular piezoelectric layers are arranged on a flat substrate.

11. Medical implantable piezoelectric sensor according to any of the preceding claims, c h a r a - c t e r i z e d in that a common electrode layer (2) covers the piezoelectric sensor on a lower as well as an upper surface and is connectible to ground potential to obtain electrical shielding of the sensor.

12. Method for manufacturing a medical implantable piezoelectric sensor, comprising the steps of:
providing a piezoelectric film or sheet; and
arranging at least two piezoelectric layers (1a-1d) of films or sheets one over another with separating layers, comprising electrode layers (2a-2c, 3a-3c), between the piezoelectric layers.

13. Method according to claim 12, comprising the further step of:
applying successive layers by means of depositing.

14. Method according to claim 12 or 13, comprising the further step of:
electrically connecting the piezoelectric layers in parallel.

15. Method according to claim 14, comprising the further step of:
electrically connecting successive electrodes to different electrical potential.

16. Method according to any of the preceding claims 12-15, comprising the further step of:
applying a common electrode layer (2) around the sensor which is connectible to ground potential to obtain electrical shielding of the sensor.

17. Method according to any of the preceding claims 12-16, comprising the further step of:
arranging the piezoelectric layers on a tubular substrate (4).

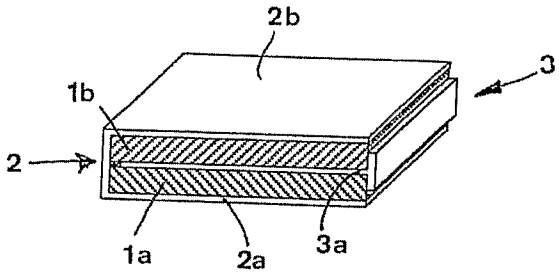


Fig 1

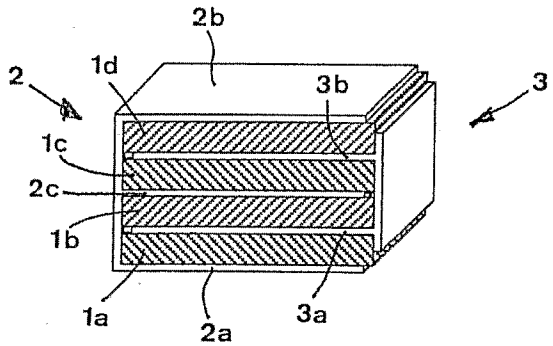


Fig 2

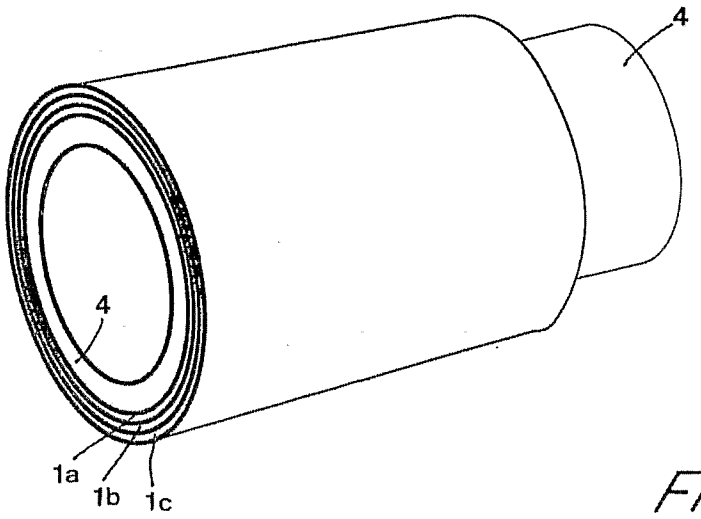


Fig 3

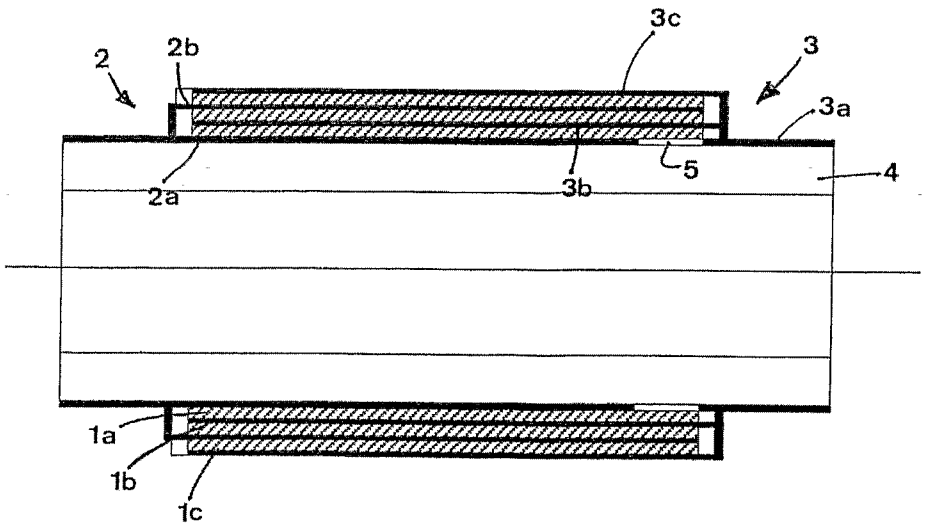


Fig 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2006/001101

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet
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)

IPC: A61B, A61N, H01L, G01L

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

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6585763 B1 (KEILMAN ET AL), 1 July 2003 (01.07.2003), page 21, line 25 - line 52, figure 14	1-17
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X	US 20010026111 A1 (DORON ET AL), 4 October 2001 (04.10.2001), figure 9, paragraph (0095)	1,12
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Y	WO 02341130 A1 (ST,JUDE MEDICAL AB), 2 May 2002 (02.05.2002), page 1, line 3 - line 9; page 5, line 29 - page 6, line 6, figure 2	1-17
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[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
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"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
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Date of the actual completion of the international search	Date of mailing of the international search report
10 May 2007	14 -05- 2007
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Henrik Eriksson / JA A Telephone No. +46 8 782 25 00

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2006/001101

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 20030114966 A1 (UENO ET AL), 26 June 2003 (26.06.2003), figures 1,2, paragraphs (0019)-(0021),(0024)-(0027),(0029) -- --------	1-17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2006/001101

International patent classification (IPC)

A61B 5/0215 (2006.01)
G01L 9/08 (2006.01)
H01L 41/083 (2006.01)

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Paper copies can be ordered at a cost of 50 SEK per copy from PRV InterPat (telephone number 08-782 28 85).

Cited literature, if any, will be enclosed in paper form.

INTERNATIONAL SEARCH REPORT
Information on patent family members

31/03/2007

International application No.
PCT/SE2006/001101

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