



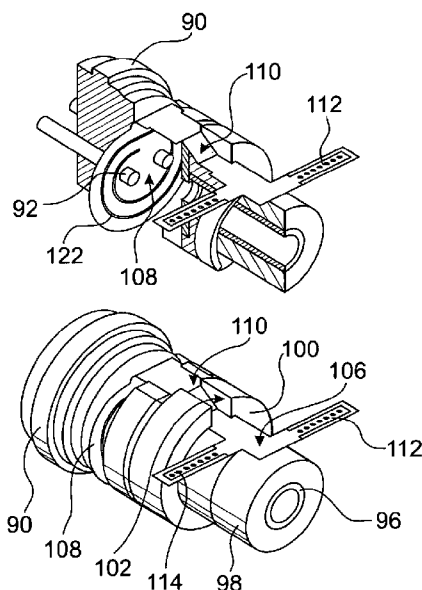
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CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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(54) **Title:** IMPLANTABLE ACTUATOR OF A HEARING AID**FIG. 6**

(57) **Abstract:** The invention relates to an implantable actuator of an at least partially implantable hearing instrument, comprising a housing (62), a mobile assembly (66) and a driver assembly (64) located within the housing, wherein the mobile assembly is for being coupled to a middle ear or inner ear component of a patient's hearing for vibrating that hearing component in order to stimulate the patient's hearing, wherein the driver assembly comprises a coil assembly (68) and cooperates with the mobile assembly to form an electro-magnetic motor, wherein the housing comprises a feedthrough assembly (90) including at least two feedthrough pins (92) having one end connected to a lead assembly (18) extending outside the housing, the actuator further comprising a flexible printed circuit board (PCB) (104) extending between the coil assembly and the feedthrough assembly for electrically connecting coil wires (98) to the other end of the respective feedthrough pin.

Implantable actuator of a hearing aid

The invention relates to an implantable actuator of an at least partially implantable hearing instrument, the actuator comprising a housing, a mobile assembly and a driver assembly located within the housing and comprising a coil cooperating with the mobile assembly to form an electromagnetic motor, wherein the mobile assembly is coupled to a middle ear or inner ear component of a patient's hearing for vibrating that hearing component in order to stimulate the patient's hearing.

WO 2006/058368 A1 relates to a partially implantable hearing instrument comprising an implantable electromagnetic actuator comprising a coil fixed within a tubular actuator housing for driving a magnetic part of the mobile assembly which, at the opposite end, comprises an artificial incus. The coil wires pass through a groove in the coil core and are welded to feedthrough pins which form part of a feedthrough assembly which seals the housing at one end. In an actuator of such type, the coil wires may be damaged by interaction with sharp edges of the coil core and/or a short circuit may be created by contact of the coil wires with the housing.

US 6,107,718, US 3,600,801 and US 3,602,814 relate to random-wound electrical coils of electromagnetic motors.

US 2005/0169627 A1 relates to an electromagnetic motor of a photo objective, wherein a coil is electrically connected via a flexible printed circuit board (PCB). US 2010/0188778 A1 relates to a hard disk drive comprising a coil which is electrically connected via a flexible PCB. WO 98/54705 A1 relates to a disk player comprising a coil which is electrically connected via a flexible PCB.

It is an object of the invention to provide for an implantable actuator of a hearing instrument which can be assembled in a reliable and efficient manner. It is also an object of the invention to provide for a corresponding manufacturing method.

According to the invention, these objects are achieved by an actuator as defined in claim 1 and a method as defined in claim 21, respectively.

The invention is beneficial in that, by using a flexible PCB for connecting the coil wires to the feedthrough pins, reliable assembly of the actuator can be achieved, since thereby the wire connection between the coil and the feedthrough pins is replaced by a more robust connection via the flexible PCB. In addition, the manufacturing process can be simplified, since, for example, no silicone coating of the coil wire path is necessary, since the PCB already provides for such insulation/protection functionality.

Preferred embodiments of the invention are defined in the dependent claims.

Hereinafter, an example of the invention will be illustrated by reference to the attached drawings, wherein:

10 Fig. 1 is a schematic cross-sectional view of an example of a hearing instrument using an implantable actuator according to the invention after implantation;

Fig. 2 is a block diagram of the system of Fig. 1;

Fig. 3 is a perspective view of an example of an actuator according to the invention prior to implantation;

15 Fig. 4 is a longitudinal sectional view of the actuator of Fig. 3, shown together with an explosive view of components of the actuator;

Fig. 5 is a longitudinal sectional view (upper part) and a side view (lower part) of the feedthrough assembly and the coil assembly of the actuator of Fig. 4 after assembly;

Fig. 6 is a corresponding perspective view of the components of Fig. 5;

20 Fig. 7 is a perspective view of the flexible PCB used in the actuator of Figs. 4 to 6 prior to assembly;

Fig. 8 is a schematic representation of manufacturing steps of the coil assembly of Figs. 5 and 6; and

25 Fig. 9 is a side view of the coil assembly and the feedthrough assembly of Fig. 5 illustrating of how the coil assembly is connected to the feedthrough assembly.

Fig. 1 shows a cross-sectional view of the mastoid region, the middle ear and the inner ear of a patient after implantation of an actuator of an example of a hearing aid according to the invention, wherein the hearing aid is shown only schematically. The system comprises an external unit 10, which is worn outside the patient's body at the patient's head, and an implantable unit 12, which is implanted under the patient's skin 14, usually in an artificial bed created in the user's mastoid. The implantable unit 12 is connected via a lead assembly 18 to an actuator 20. While in Fig. 1 an electromechanical actuator coupled to an ossicle 22 via a coupling rod 24 is shown, the actuator 20 also may be an electromechanical actuator coupled directly to the cochlear wall, e.g. an artificial incus is coupled to a stapes prosthesis moving through the oval window.

The external unit 10 is fixed at the patient's skin 14 in a position opposite to the implantable unit 12, for example, by magnetic forces created between a magnetic fixation arrangement 26 provided in the external unit 10 and a cooperating magnetic fixation arrangement 28 provided in the implantable unit 12, respectively.

An example of a block diagram of the system of Fig. 1 is shown in Fig. 2. The external unit 10 includes a microphone arrangement 28, which typically comprises at least two spaced-apart microphones 30 and 32 for capturing audio signals from ambient sound, which audio signals are supplied to an audio signal processing unit 34, wherein they undergo, for example, acoustic beam forming. The processed audio signals are supplied to a transmission unit 36 connected to a transmission antenna 38 in order to enable transcutaneous transmission of the processed audio signals via an inductive link 40 to the implantable unit 12 which comprises a receiver antenna 42 connected to a receiver unit 44 for receiving the transmitted audio signals. The received audio signals are supplied to a driver unit 48 which drives the actuator 20.

The external unit 10 also comprises a power supply 50 which may be a replaceable or rechargeable battery, a power transmission unit 52 and a power transmission antenna 54 for transmitting power to the implantable unit 12 via a wireless power link 56. The implantable unit 12 comprises a power receiving antenna 58 and a power receiving unit 60 for powering the implanted electronic components with power received via the power link 56.

Preferably, the audio signal antennas 38, 42 are separated from the power antennas 54, 58 in order to optimize both the audio signal link 40 and the power link 56. However, if a particularly simple design is desired, the antennas 38 and 54 and the antennas 42 and 58 could be physically formed by a single antenna, respectively.

5 According to Figs. 3 and 4 the actuator 20 comprises a housing 62, a driver assembly 64 located within the housing 62 and a mobile assembly 66 driven by the driver assembly 64 and extending beyond the housing 62. The housing 62 comprises a tubular portion 61 having an one open end closed by a membrane 78 and another open end closed by a feedthrough assembly 90. The driver assembly 64 comprises a coil assembly 68 surrounded in part by a
10 shell 70. The actuator 20 also comprises a lower magnet assembly 72 and an upper magnet assembly 74 which are surrounded by an annealed iron tube 76. The distal side of the housing 62 is closed by a membrane 78.

The mobile assembly 66 comprises a first, proximal portion 80 including an armature 82 and a second, distal portion 84. The first portion 80 is made of a magnetic material, for example a
15 permenorm alloy, and comprises a rod-like part 81 which extends axially within the coil 68. The armature 82 is located at the distal end of the rod-like part 81 between the lower magnet assembly 72 and the upper magnet assembly 74. The armature 82 has a flange-like shape and is located adjacent to the second portion 84 which extends through a hermetically sealed opening 86 in the membrane 78 beyond the housing 62. The driver assembly 64 and the first
20 portion 80 of the mobile assembly 66 thereby form an electromagnetic motor which imparts an axially reciprocating movement to the first portion 80. The second portion 84 has a rod-like shape and is made of a biocompatible material, such as titanium, and, at its distal end, may comprise an artificial incus 88 which is to be coupled to a stapes prosthesis (not shown in Fig. 3). The coil assembly 68 is electrically connected to the feedthrough assembly 90 made of
25 ceramic material and comprising two feedthrough pins 92.

Thus, by supplying a current/voltage to the coil 58 corresponding to the processed audio signals received from the external unit 10 the hearing of the patient can be stimulated according to the sound captured by the external unit 10.

The general structure of the actuator 20 may be similar to that described in WO 2006/058368 A1, apart from the specific structures of the coil assembly and the electrical connection of the coil assembly to the feedthrough assembly, as described hereinafter.

5 The coil assembly 68 comprises a coil core 94 which preferably is made of a single piece by a precision turning process from, for example, a permenorm material (nickel-iron alloy) and comprises a shaft portion 96 for carrying the coil wire windings 98 and a gap portion 100 which has a larger diameter than the shaft portion 96 which serves as a gap/spacer element and which is axially spaced-apart from the windings 98. The gap portion 100 of the coil
10 core 94 comprises an axially extending groove 102 provided in the peripheral surface thereof. In order to maximize the magnetic properties of the coil core 94 it may be annealed. The coil windings 98 preferably are formed by randomly winding the coil wires directly onto the shaft portion 96 of the coil core 94.

A flexible PCB 104 (see in particular Fig. 7, not shown in Fig. 4) is used for electrically
15 connecting the coil wires to the feedthrough pins 92. The flexible PCB 104 comprises a coil portion 106 at one end, a feedthrough portion 108 at the other end and a bending portion 110 extending in-between and connecting the coil portion 106 and the feedthrough portion 108. The coil portion 106 comprises a first portion 112 to which a first coil wire is to be welded, a second portion 114 to which a second coil wire is to be welded and an axially extending
20 central portion 116, with the first and second portions 112, 114 extending in opposite peripheral/lateral directions from the central portion 116 and with the first and second portions 112, 114 being axially offset relative to each other. The coil wires may be welded to track holes 111 provided in the first and second portions 112, 114.

The feedthrough portion 108 is provided with a pair of through-holes 118, with each through-
25 hole 118 being provided for receiving one of the feedthrough pins 92. The through-holes 118 are located in a central portion 120 of the feedthrough portion 108. Further, the feedthrough portion 108 is provided with a spiral slot 122 for increasing the flexibility of the feedthrough portion 108.

The bending portion 110 is provided for enabling bending of the feedthrough portion 108 relative to the coil portion 106 by preferably at least 90 degrees, and more preferably at least 180 degrees.

After manufacturing of the coil assembly 68 (step 3 in Fig. 8) the flexible PCB 104 is attached to the coil assembly 68 (step 4 in Fig. 8), wherein the PCB 104 is oriented in the axial direction of the coil assembly 68, wherein the coil portion 106 is fixed to the coil wire windings 98 by gluing and wherein part of the bending portion 110 is fixed within the groove 102 of the coil core 94 by gluing, i.e. the PCB 104 is fixed at the coil assembly 68 via an adhesive layer (not shown in the Figures). The coil wires are welded to the first and second portion 112, 114 of the coil portion 106 of the PCB 104 prior to fixing the PCB 104 to the coil assembly 68. In the final position, the first and second portion 112, 114 of the coil portion 106 of the PCB 104 are bent to follow the curvature of the peripheral surface of the coil windings 98.

As can be seen in the left part of Fig. 9, the bending portion 110 may be pre-shaped in such a manner that the feedthrough portion 108 is bent by about 90 degrees in such a manner that the feedthrough portion 108 is oriented substantially perpendicular to the axial direction of the coil assembly 68.

After the PCB 104 has been fixed to the coil assembly 68, the resulting assembly is inserted into the tubular housing portion 61 through an open end of the housing portion 61 in such a manner that the feedthrough portion 108 of the PCB 104 is located at the open end of the housing portion 61. In order to connect the feedthrough portion 108 to the feedthrough pins 92 of the feedthrough assembly 90, the feedthrough portion 108 is bent by about 180° from the position shown in the left part of Fig. 9, so that the interior (i.e. actuator side) end of the feedthrough pins 92 can be inserted into the through-holes 118, while the feedthrough assembly 90 is located outside the housing portion 61 in a lateral position with regard to the housing portion 61 (see right part of Fig. 9). In this position the feedthrough pins 92 are connected to the through-holes 118 via laser welding. Thereafter, the feedthrough portion 108 of the PCB 104, together with the feedthrough assembly 90, is bent back again by 180° into the original position (see Figs. 5 and 6), so that the feedthrough assembly 90 can be attached

to the housing portion 61 for closing/sealing the open end of the housing portion 61 (see right part of Fig. 4).

Both in the position shown in the left part of Fig. 9 and the position shown in the right part of Fig. 9 the feedthrough portion 108 of the PCB 104 is bent by about 90° with regard to the coil portion 16 of the PCB 104, however, in opposite directions.

As shown for example in Figs. 4, 5 and 6, the coil assembly 68 also comprises a bearing spacer element 95 adjacent to the gap portion 100, a spring bearing 97 for the rod-like part 81 of the mobile assembly 66 adjacent to the spacer element 95, and a cover spacer element 99 adjacent to the spring bearing 97.

By manufacturing the coil core as a single piece, manufacturing can be simplified compared to a two-part press fitting process.

Compared to stratified winding process, a random coil winding process is much more flexible and, if a wire is cut during the process, it is possible to stop the winding and recuperate the coil core for another process. By winding the coil wires directly onto the coil core, damages to the coil assembly resulting from an insertion of the coil core into the coil wire windings can be avoided.

By welding first the coil connecting wires to the flexible PCB prior to fixing the PCB at the groove of the coil core, the risk of damages to the electrical connection between the coil windings and the feedthrough pins can be significantly reduced compared to the case where the coil connecting wires are directly welded to the feedthrough pins, since the flexible PCB is much more robust than coil connecting wires. Further, the use of the flexible PCB, which has electrically insulated tracks, avoids any electrical contact between coil connecting wires and the actuator housing.

Since a laser welding process is much more accurate (with regard to soldering quantity, temperature repartition and process repeatability) than manual welding, the quality and reliability of the electrical connection between the coil assembly and the feedthrough pins can be significantly improved. Also, the use of the flexible PCB connecting spots, compared to the use of wires, contributes to such improvement of the electrical connection quality.

Thus, with the process of the invention, the risk of actuator failure can be considerably reduced. In addition, the manual soldering steps could be integrated in the coil assembly suppliers' manufacturing process so that the assembly process is simplified and product reliability can be enhanced while costs can be reduced. In particular, the total manufacturing
5 process time may be reduced significantly.

Claims

1. An implantable actuator of an at least partially implantable hearing instrument, comprising a housing (62), a mobile assembly (66) and a driver assembly (64) located within the housing, wherein the mobile assembly is for being coupled to a middle ear or inner ear component of a patient's hearing for vibrating that hearing component in order to stimulate the patient's hearing, wherein the driver assembly comprises a coil assembly (68) and cooperates with the mobile assembly to form an electro-magnetic motor, wherein the housing comprises a feedthrough assembly (90) including at least two feedthrough pins (92) having one end connected to a lead assembly (18) extending outside the housing, the actuator further comprising a flexible printed circuit board (PCB) (104) extending between the coil assembly and the feedthrough assembly for electrically connecting coil wires (98) to the other end of the respective feedthrough pin.
2. The actuator of claim 1, wherein the coil assembly (68) is for imparting reciprocating movement to the mobile assembly (66).
3. The actuator of claim 2, wherein the flexible PCB (104) comprises a coil portion (106) to which the coil wires (98) are welded, a feedthrough portion (108) to which the feedthrough pins (92) are welded and a bending portion (110) extending axially between the coil portion and the feedthrough portion of the PCB.
4. The actuator of claim 3, wherein the coil portion (106) of the PCB (104) is fixed at a peripheral surface of the coil assembly (68) via an adhesive layer.
5. The actuator of claim 4, wherein the coil portion (106) of the PCB (104) is laterally bent to follow the curvature of the peripheral surface of the coil assembly (68).
6. The actuator of claim 5, wherein the coil portion (106) of the PCB (104) comprises a first portion (112) to which a first one of the coil wires (98) is welded, a second portion (114) to which a second one of the coil wires is welded and an axially extending central portion (116), with the first and second portion extending in opposite peripheral directions from the central portion of the coil portion of the PCB.

7. The actuator of claim 6, wherein the first and second portions (112, 114) of the coil portion (106) of the PCB (104) are axially offset relative to each other.
8. The actuator of one of claims 6 and 7, wherein the coil wires (98) are welded to track holes (111) of the coil portion (106) of the PCB (104).
9. The actuator of one of claims 3 to 8, wherein the feedthrough portion (108) of the PCB (104) comprises a through-hole (118) for each of the feedthrough pins (92), with each through-hole receiving the feedthrough pin, and wherein the feedthrough pins are welded to the respective through-hole.
10. The actuator of claim 9, wherein the through-holes (118) are located in a central portion (120) of the feedthrough portion (108) of the PCB (104).
11. The actuator of claim 10, wherein the feedthrough portion (108) of the PCB (104) is provided with a spiral slot (122).
12. The actuator of one of the preceding claims, wherein the bending portion (110) of the PCB (104) is bent in manner so that the feedthrough portion (108) of the PCB (104) extends substantially perpendicular with regard to an axial direction of the coil assembly (68).
13. The actuator of claim 12, wherein the bending portion (110) of the PCB (104) is adapted to be bent by at least 90 degrees, preferably by at least 180 degrees.
14. The actuator of one of claims 12 and 13, wherein the bending portion (110) of the PCB (104) extends through an axially extending groove (102) provided in the peripheral surface of a gap portion (100) of a coil core (94) of the coil assembly (68) which extends axially beyond the coil wire windings (98) and has an enlarged radial dimension compared to a shaft portion (96) of the coil core carrying the coil wire windings.
15. The actuator of claim 14, wherein the bending portion (110) of the PCB (104) is fixed within the coil core groove (102) via an adhesive.

16. The actuator of one of the preceding claims, wherein the housing (62) comprises a tubular portion (61), and wherein the feedthrough assembly (90) comprises a disc-like ceramic part through which the feedthrough pins (92) extend in an axial direction and which is provided for closing one end of the tubular portion.
17. The actuator of one of the preceding claims, wherein the coil core (94) of the coil assembly (68) is made as a single piece.
18. The actuator of one of the preceding claims, wherein the coil assembly comprises random wound coil wires (98) on the coil core (94).
19. The actuator of one of the preceding claims, wherein the mobile assembly (66) comprises a first portion made of a magnetic material and extending axially within the coil assembly and a second portion extending beyond the housing (62) for being coupled to said hearing component.
20. The actuator of claim 19, wherein the second portion of the mobile assembly comprises or is connected to an artificial incus (88) adapted for coupling with a stapes prosthesis.
21. A method of manufacturing the implantable actuator (20) of one of the preceding claims, comprising: manufacturing the coil assembly (68) by producing a coil core (94) and winding the coil wires (98) onto the coil core, connecting the coil wires to the PCB (104), fixing the PCB at the coil assembly, inserting the coil assembly and the PCB through an open end of the housing (61, 62) into the housing, connecting the feedthrough pins (92) to the PCB, and closing the open end of the housing by attaching the feedthrough assembly to the housing.
22. The method of claim 21, wherein the coil wires (98) are connected to the PCB (104) by welding.
23. The method of one of claims 21 and 22, wherein the PCB (104) is fixed at the coil assembly (68) by gluing.
24. The method of one of claims 21 to 23, wherein the PCB (104) comprises a coil portion (106) to which the coil wires (98) are welded, a feedthrough portion (108) to which the

feedthrough pins (92) are welded and a bending portion (110) extending axially between the coil portion and the feedthrough portion of the PCB, wherein, after inserting the coil assembly and the PCB into the housing (62), a free end of the PCB forming the feedthrough portion of the PCB is bent with regard to the coil portion of the PCB in such a manner that the feedthrough pins can be connected to the feedthrough portion of the PCB while the feedthrough assembly (90) is located outside the housing, and wherein the feedthrough portion of the PCB, together with the feedthrough assembly connected to the the feedthrough portion, is bent back with regard to the coil portion of the PCB in a manner so that the feedthrough assembly can be attached to the housing for closing the open end of the housing.

25. The method of claim 24, wherein the feedthrough portion (108) of the PCB (104) is bent by about 90 degrees with regard to the coil portion (106) of the PCB for connecting the feedthrough pins (92) to the feedthrough portion of the PCB.
26. The method of one of claims 24 and 25, wherein the feedthrough portion (108) of the PCB (104) is bent by about 90 degrees with regard to the coil portion (106) of the PCB for attaching the feedthrough assembly (90) to the housing (61, 62) for closing the open end of the housing.
27. The method of one of claims 21 to 26, wherein the feedthrough pins (92) are fixed to the PCB (104) by laser welding.
28. The method of one of claims 21 to 27, wherein the coil core (94) is produced as a single piece by a turning process.
29. The method of one of claims 21 to 28, wherein the coil core (94) is annealed in order to maximize its magnetic properties.
30. The method of one of claims 21 to 29, wherein the coil assembly (68) is manufactured by random winding of the coil wires onto the coil core (94).

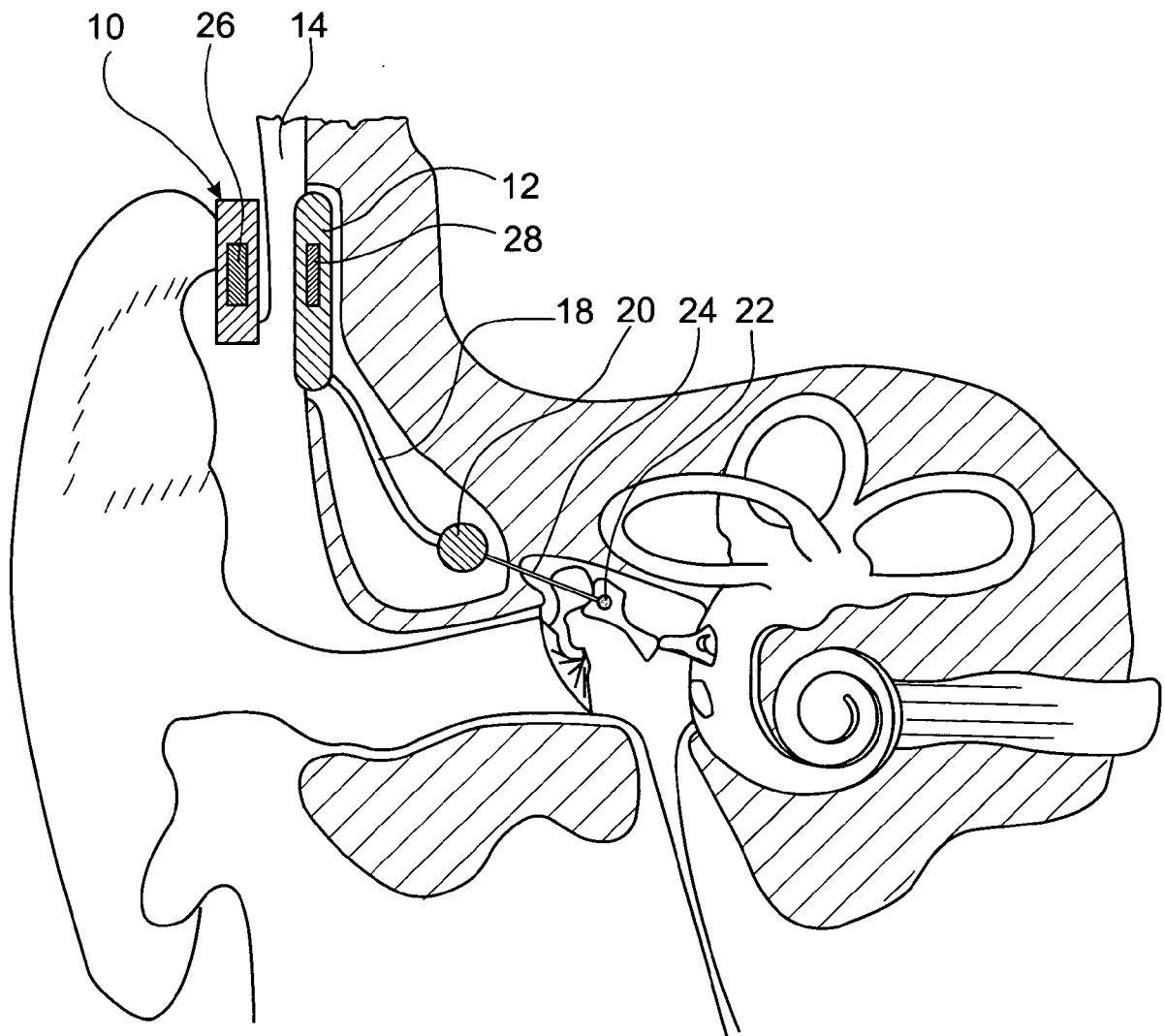


FIG. 1

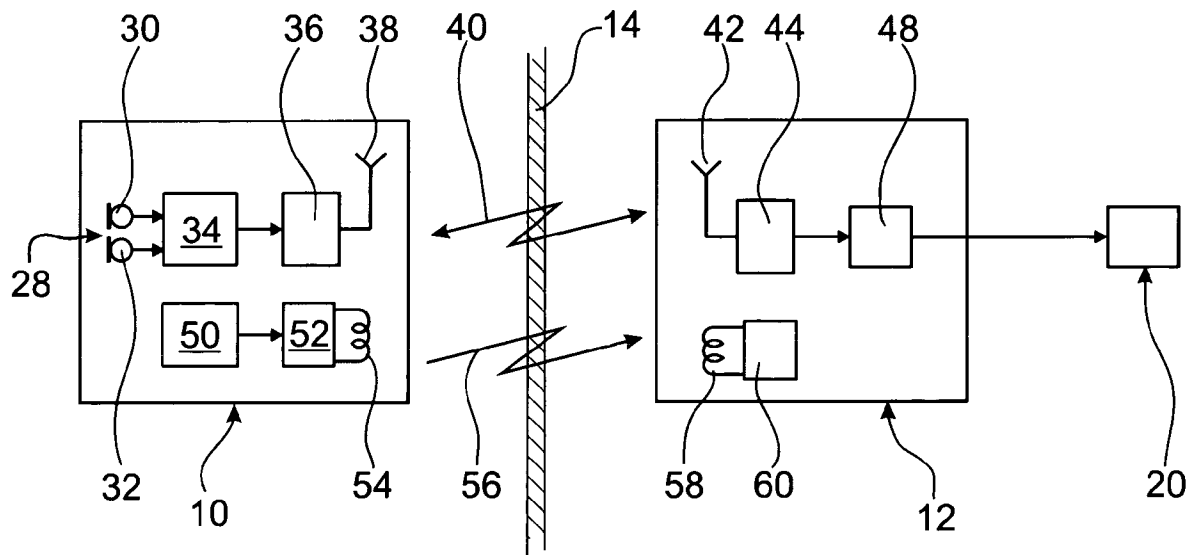


FIG. 2

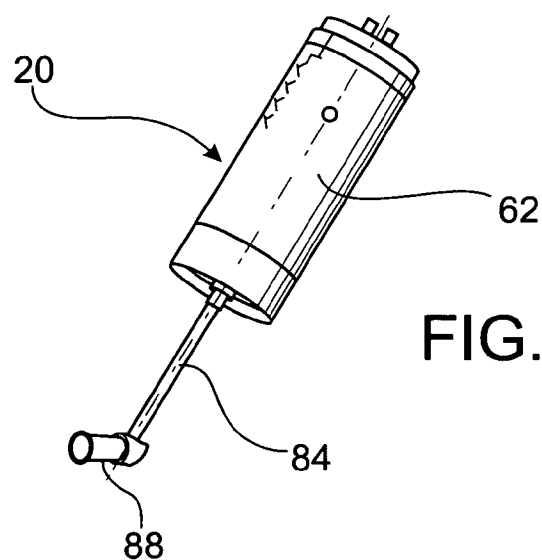


FIG. 3

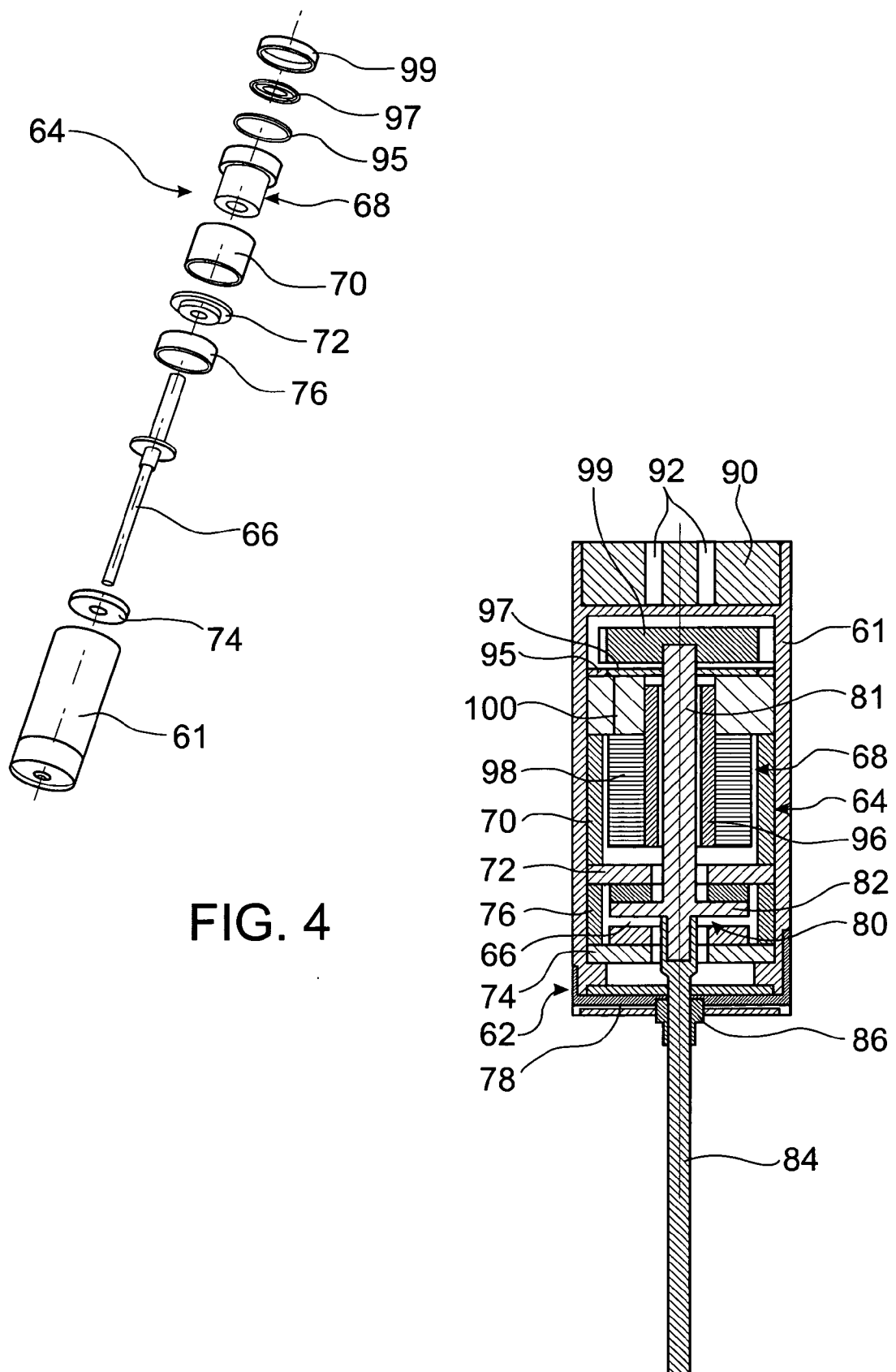


FIG. 4

FIG. 5

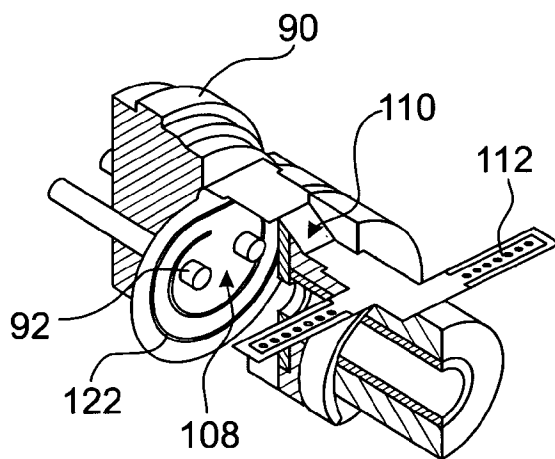
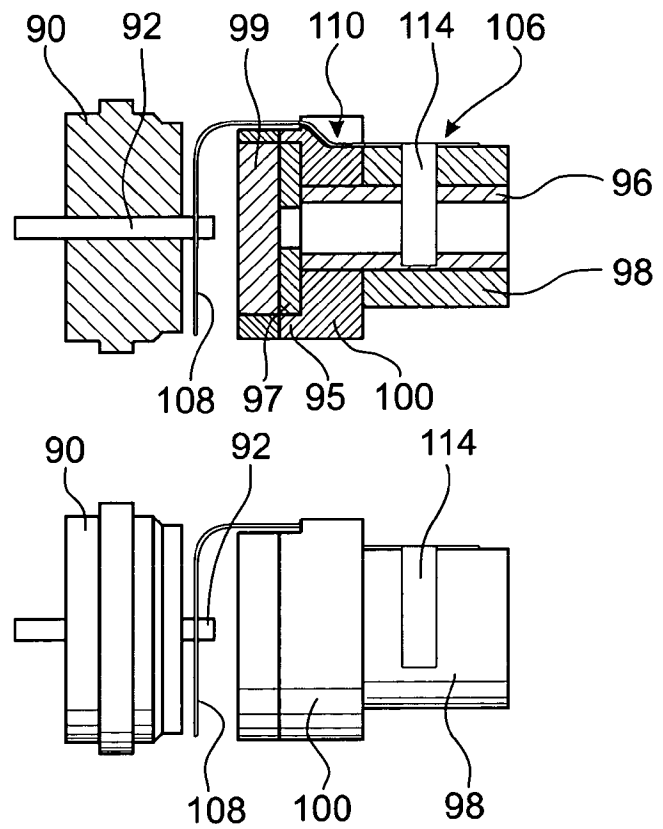
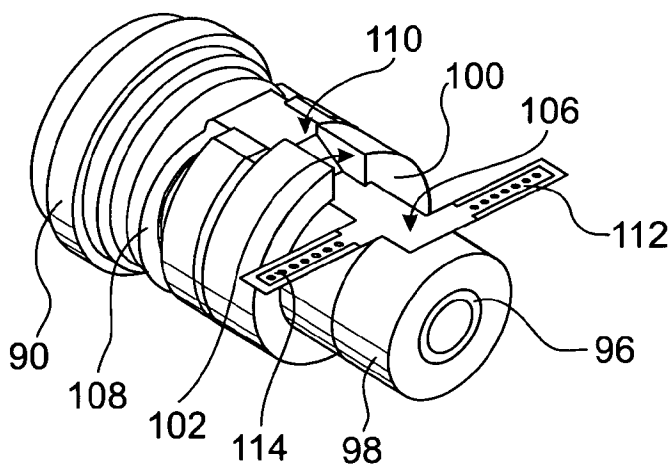


FIG. 6



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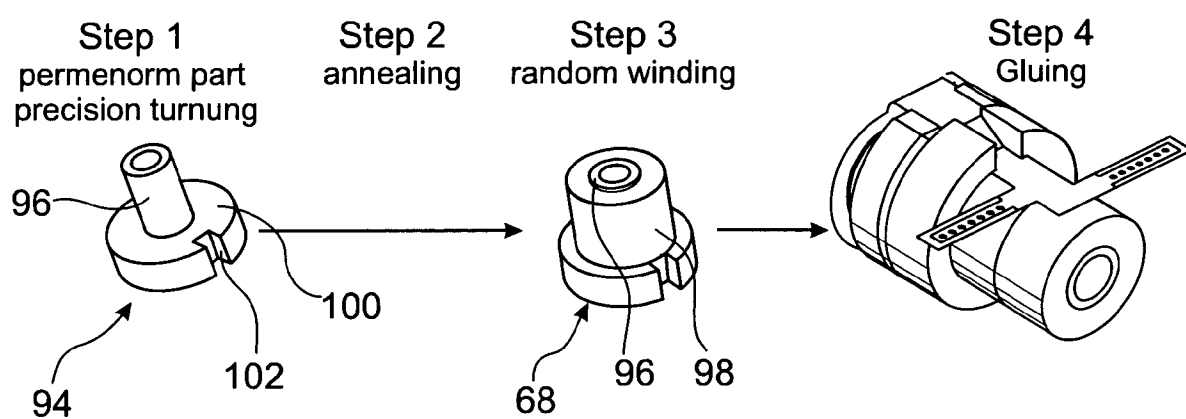
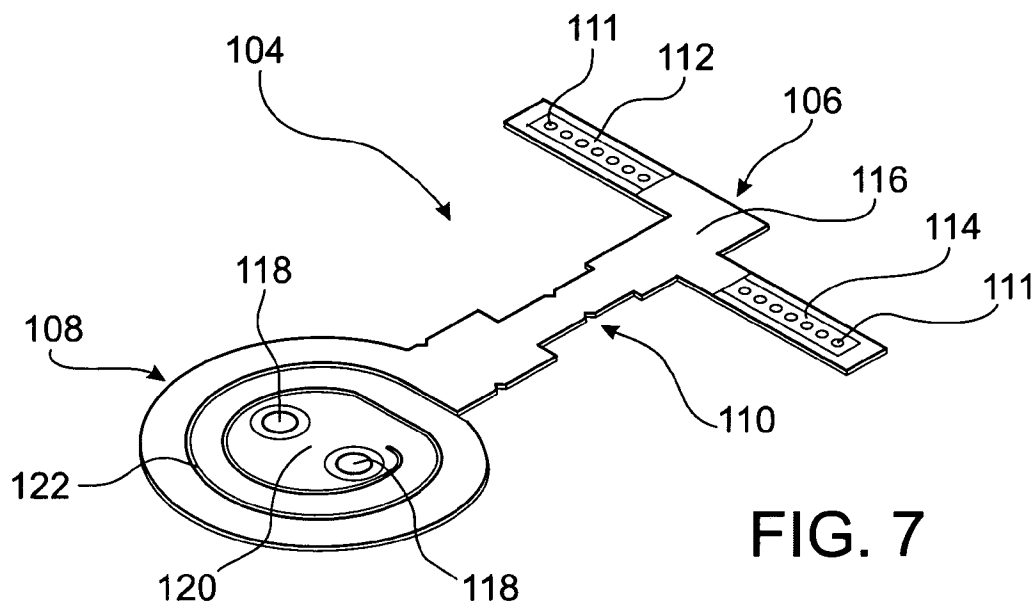


FIG. 8

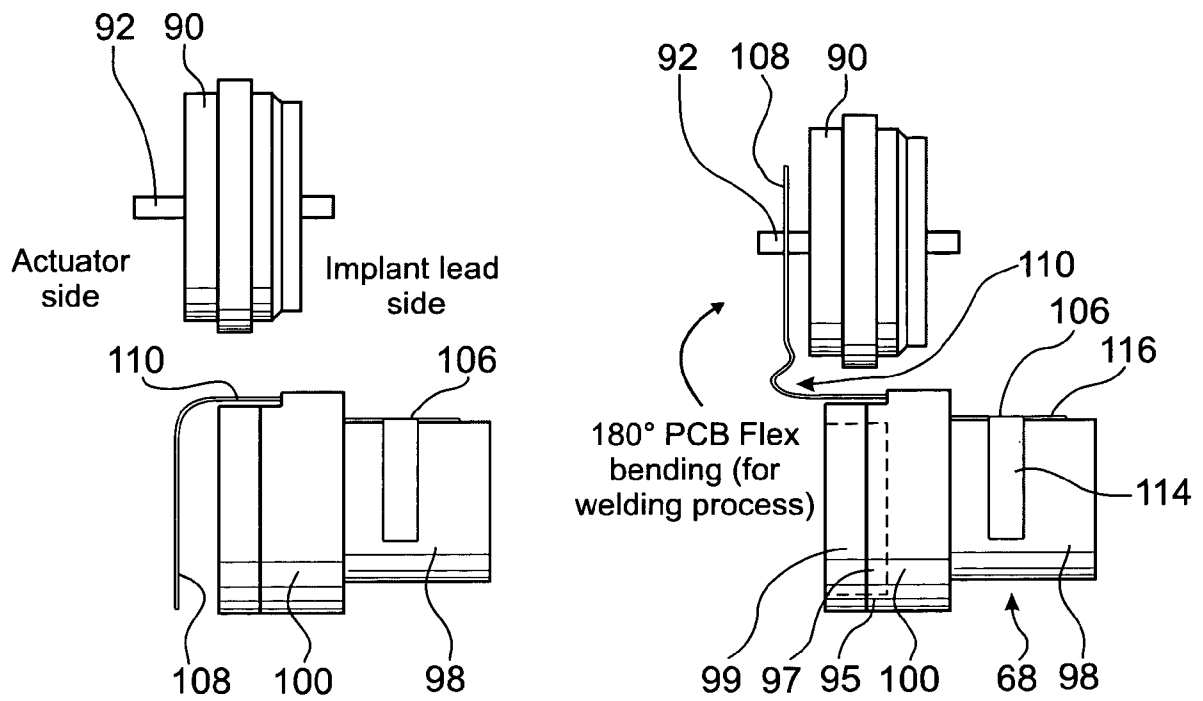


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2011/058294

A. CLASSIFICATION OF SUBJECT MATTER

INV. H04R25/00

ADD.

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)

A61F H04R G11B H01R G03B H05K

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 practicable, 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.
Y	WO 2010/102342 A1 (COCHLEAR LTD [AU]; VAN GERWEN PETER BART JOS [BE]) 16 September 2010 (2010-09-16) the whole document	1,2
Y	WO 98/54705 A1 (DAEWOO ELECTRONICS CO LTD [KR]) 3 December 1998 (1998-12-03) cited in the application the whole document	1,2
Y	US 2002/076071 A1 (SINGLE PETER [AU]) 20 June 2002 (2002-06-20) paragraph [0070]	1
A	US 2010/188778 A1 (CASTAGNA JOSEPH T [US]) 29 July 2010 (2010-07-29) cited in the application the whole document	1,21
	----- -/-	



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

19 September 2012

Date of mailing of the international search report

28/09/2012

Name and mailing address of the ISA/

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Timms, Olegs

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2011/058294

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 2005/169627 A1 (KAWAUCHI TAKAHIRO [JP]) 4 August 2005 (2005-08-04) cited in the application paragraph [0033] -----	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2011/058294

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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