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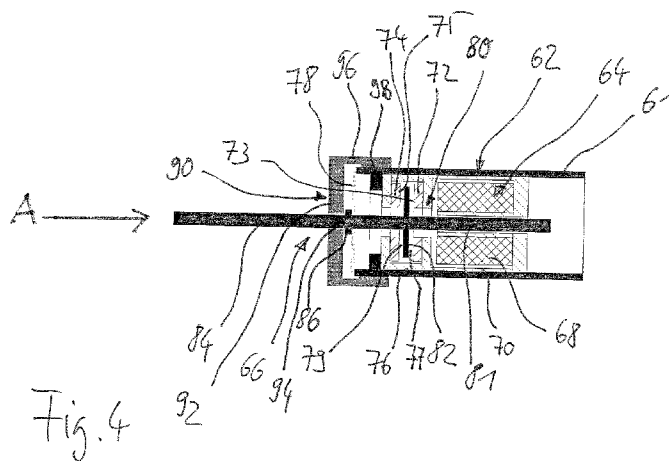
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(54) Title: IMPLANTABLE ACTUATOR OF A HEARING INSTRUMENT



(57) **Abstract:** The invention relates to an implantable actuator of an at least partially implantable hearing instrument (10, 12), comprising a housing (62), a mobile assembly (66) and a driver assembly (64), wherein the mobile assembly comprises a base portion (80) coupled to the driver assembly in a manner so as to be driven by the driver assembly to an axially reciprocating movement and an output coupling portion (84) adjacent to the base portion for being coupled to a middle ear or inner ear component (22) of a patient's hearing for vibrating that hearing component in order to stimulate the patient's hearing, wherein the driver assembly and the base portion of the mobile assembly are located within the housing, wherein the housing comprises an opening closed by a membrane (78) supporting the output coupling portion, wherein the actuator further comprises a displacement limiting assembly (90) engaging with the output coupling portion so as to limit the axial and/or radial displacement of the output coupling portion at the membrane in order to protect the membrane from plastic deformation caused by the movement of the output coupling portion, and wherein the displacement limiting assembly is designed to be detachably fixed at the housing in a manner that the displacement limiting assembly can be removed prior or after implantation of the actuator.

Implantable actuator of a hearing instrument

The invention relates to an implantable actuator of an at least partial implantable hearing instrument, the actuator comprising a housing, a driver assembly located in the housing and a mobile assembly which is driven by the driver assembly and which is to be coupled to a middle or inner ear component of a patient's hearing for vibrating said component in order to stimulate the patient's hearing.

WO 2006/058368 A1 relates to an implantable hearing instrument actuator comprising a tubular housing closed at one end by a membrane which is provided with a ring fixed to a shaft portion of a mobile assembly comprising an armature element extending radially from the shaft portion and being driven by a coil fixed within the housing. The armature element is biased to a predetermined position within a biasing field gap between axially spaced apart pole faces of two permanent magnets, with the pole faces been arranged opposite to each other with regard to the axial direction. The shaft portion extending through the membrane forms a coupling rod with an artificial incus at its end.

Such implantable actuators usually contain non-biocompatible materials which must be housed in a hermetic housing to protect them from the human body (and vice versa). Typically, such implantable housing is made of metal, such as titanium, and the sealing membrane is welded to the housing in order to provide a hermitically sealed housing. In order to be compliant, such membrane has to be very thin and consequently is fragile and prone to plastic deformation which, in turn, may result in loss of performance or damages of the actuator, including possible breach of hermeticity.

It is an object of the invention to provide for an implantable actuator of a hearing instrument which is protected at least to some extent from mechanical damage which may result from handling of the actuator prior or during implantation.

According to the invention, this object is achieved by an actuator as defined in claims 1 and 10, respectively.

The invention is beneficial in that, by providing the actuator with a displacement limiting assembly engaging with the output coupling portion of the actuator in a manner so as to limit

the axial and/or radial displacement of the output coupling portion at the membrane, the membrane of the actuator may be protected from displacements resulting in a plastic deformation of the membrane. Thus damage of the membrane during manufacturing and/or during implantation can be avoided, thereby enhancing product yield and reducing costs
5 resulting from damaged actuators. In particular, the need for explantation of damaged actuators may be eliminated. Also, handling of such protected actuators may be simplified in view of the more robust nature of such protected actuators (typically, the fragility of the membrane leads to high costs in the manufacturing process, because great care must be taken (complex tooling, additional inspection steps, more careful and therefore longer handling and
10 processing times, etc.)), thereby reducing costs.

The solution according to claim 1, providing for a removable version of the displacement limiting assembly, is particularly beneficial in that a certain protection of the membrane can be imparted to the actuator during the critical phases, namely during manufacturing and/or during or prior to implantation, while, due to the detachable nature of the displacement
15 limiting element, it can be removed after implantation of the actuator, so that the structure of the actuator as such requires no changes and hence is not compromised.

The solution according to claim 10, providing the driver assembly and/or the housing with the displacement limiting assembly, is particularly beneficial in that the protection provided to the membrane is present not only during manufacturing and/or implantation, but remains also
20 after implantation.

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

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

Fig. 1 is a schematic cross sectional view of an example of a hearing instrument using
25 a 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;

Fig: 4 is a sectional view of an example of an actuator according to the invention;

Fig. 5 is a view of the actuator of Fig. 4 seen in the direction labeled "A" in Fig. 4;
5 and

Figs. 6 and 7 are views like Fig. 5, wherein alternative examples of an actuator according to the invention are shown.

Fig. 1 shows a cross-sectional view of the mastoid region, the middle ear and the inner ear of a
10 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
15 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
20 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
25 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.

- 5 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.
- 10 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.

- According to the example shown in Figs. 3 and 4, the actuator 20 comprises a housing 62, a
15 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 open end closed by a membrane 78 which is preferably made of titanium. The driver assembly 64 comprises a coil assembly 68 surrounded in part by a shell 70. The actuator 20 also comprises a lower magnet assembly 72 having a pole face 73 and an
20 upper magnet assembly 74 having a pole face 75. The magnet assemblies 72, 74 are kept spaced apart in the axial direction by an annealed iron tube 76. The pole faces 73, 75 are arranged axially spaced apart and opposed to each other for forming an axially extending biasing gap, with a magnetic biasing field extending between the pole faces 73, 75.

- The mobile assembly 66 comprises a proximal base portion 80 including an armature 82 and a
25 distal output coupling portion 84. The base portion 80 is made of a magnetic material, for example a permenorm alloy, and comprises a rod-like shaft portion 81 which extends axially within the coil 68. The armature 82 is located at the distal end of the shaft portion 81 between the pole face 73 of the lower magnet assembly 72 and the pole face 75 of the upper magnet assembly 74, thereby forming a first and second working gap 77, 79. The armature 82 is

mechanically biased (e.g. by spring bearing (not shown) at the proximal end of the shaft portion 81) to a predetermined axial position between the pole faces 73, 75. The armature 82 has a flange-like shape and is located adjacent to the output coupling portion 84 which extends through a hermetically sealed central opening in the membrane 78 beyond the housing 62. The membrane 78 is provided with a titanium ring 86 at its center, with the output coupling portion 84 extending through the ring 86 and being fixed at the ring, typically by welding.

The driver assembly 64 and the base portion 80 of the mobile assembly 66 form an electromagnetic motor which imparts an axially reciprocating movement to the base portion 80. The output coupling 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).

Thus, by supplying a current/voltage to the coil 68 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 of Fig. 4 may be similar to that described in WO 2006/058368 A1, apart from the displacement limitation features described hereinafter.

In the example shown in Fig. 4, the actuator 20 also is provided with a cup-like element 90 comprising a bottom portion 92 with an opening 94, through which the coupling portion 84 extends, and a wall portion 96 which surrounds a peripheral region, i.e. an outer surface region, of the tubular portion 61 of the housing 62 in a manner so as to engage with that peripheral surface region of the tubular portion 61 in a detachable manner. In the example of Fig. 4, the wall portion 96 comprises an elevated engagement portion 98 for touching peripheral region of the tubular portion 61 of the housing 62 in a ring-like manner. The cup-like element 90 is designed to engage with the housing 62 by elastic forces provided by the elasticity of the cup-like element 90. The cup-like element 90 can either be made of the same family of material (such as CP1, CP2, or Ti-6-4) as the body of the actuator, or of biocompatible and decontaminable plastic materials (such as PEEK, PVC, or PE). The cup-

like element 90 is designed to become detached from the housing 62 when appropriate axial forces are applied to the cup-like element 90.

In the example of Fig. 4, the opening 94 of the element 90 is a bore designed to limit radial movement of the coupling portion 84. Preferably, radial displacement limitation should prevent the membrane 78 from deformation due to an exaggerated bending of the coupling portion 84 of the mobile assembly 66 occurring after any fall, shock or lateral force exceeding 200mN. In addition, the bottom portion 92 of the element 90 acts as a stopper element for limiting axial movement of the ring 86 of the mobile assembly 66 in the direction away from the housing 62.

Thereby the element 90 acts as a displacement limiting assembly for the coupling portion 84 of the mobile assembly 66 with regard to the radial direction and one of the two axial directions. Preferably, the element 90 is designed such that the axial movement of the coupling portion 84 is limited to not more than 70 μm .

The element 90 serves to protect the membrane 78 from being damaged or deteriorated by plastic deformation resulting from excessive axial or radial displacement of the coupling portion 84, which may occur when manually handling actuator 20.

The element 90 may be attached to the housing 62 after manufacturing of the actuator 20 (or it may be attached even already during parts of the manufacturing process, such as welding of the artificial incus 88 to the coupling portion 84 and/or assembly of the actuator 20 with the implantable unit 12) and it may remain attached to the housing 62 until implantation of the actuator 20 has been terminated, thereby protecting the membrane 78 from damages resulting from improper handling of the actuator 20 - and in particular of the coupling portion 84 - during manufacturing and/or prior to or during implantation steps (unpacking of the actuator, stapedectomy, placement and fixation of the actuator within the body, etc).

As shown in Fig. 5, the opening 94 in the bottom portion 92 of the element 90 may comprise a slot 95 extending radially from the edge 97 of the bottom portion 92 to the centre of the bottom portion for allowing the coupling portion 84 to be inserted into the opening 94 from the edge 97, thereby facilitating attachment of the element 90 to the housing 62.

While Figs. 4 and 5 show an example removable displacement limitation assembly, an alternative protection of the membrane 78 is shown in Fig. 6, wherein the element 90 has been omitted in favor of a permanent built-in axial displacement limitation of the mobile assembly 66. According to such embodiments of the invention, the actuator 20 comprises at least one
5 fixed displacement limitation assembly engaging with a radially extending part of the mobile assembly 66 in a manner so as to limit the maximal axial displacement of the mobile assembly 66 to not more than 70 μm .

In the example of Fig. 6, the displacement limitation assembly is formed by non-magnetic layers 102, 104 provided on the pole faces 73 and 75, respectively, of the magnet assemblies
10 72, 74, which act as stopper elements for the armature element 82 of the mobile assembly 66. Preferably, the non-magnetic layers 102, 104 are made of an elastic material, such as a plastics material.

A further example of the principle to provide for a built-in displacement limitation of the mobile assembly 66, and hence the membrane 78, is shown in Fig. 7, wherein the distal end of
15 the housing 62 is provided with a displacement limitation assembly 106 comprising a plate-like element 108 fixed to or forming part of the housing 62, which is located at the "outer" side of the membrane 78 (i.e. at that side of the membrane 78 which faces away from the driver assembly 64) and which comprises an opening 110 through which the coupling portion 84 extends. The displacement limitation assembly 106 is designed such that the region of the
20 plate-like element 108 around the opening 110 limits the axial movement of the ring 86 of the coupling portion 84 in the direction away from the housing 62. In addition, the opening 110, which preferably is a bore, is designed to limit the radial displacement of the coupling portion 84.

In the example shown in Fig. 7, the coupling portion 84 is provided with a second ring 112
25 which is fixed to the inner side (i.e. that side facing the driver assembly 64) of a second membrane 114 oriented parallel to the (first) membrane 78 and forming the outer side of the displacement limitation assembly 106 and the housing 62 (i.e. the membrane 114 forms the distal end of the housing 62). The second ring 112 is axially spaced apart from the (first) ring 86 in such a manner that the plate-like element 108 is located between the rings 86 and 112.
30 The plate-like element 108 is designed to limit the axial movement of the second ring 112 in

the direction towards the housing 62, thereby providing for a limitation of the axial movement of the coupling portion 84 in both axial directions.

Claims

1. An implantable actuator of an at least partially implantable hearing instrument (10, 12), comprising a housing (62), a mobile assembly (66) and a driver assembly (64),

wherein the mobile assembly comprises a base portion (80) coupled to the driver assembly in a manner so as to be driven by the driver assembly to an axially reciprocating movement and an output coupling portion (84) adjacent to the base portion for being coupled to a middle ear or inner ear component (22) of a patient's hearing for vibrating that hearing component in order to stimulate the patient's hearing,

wherein the driver assembly and the base portion of the mobile assembly are located within the housing, wherein the housing comprises an opening closed by a membrane (78) supporting the output coupling portion,

wherein the actuator further comprises a displacement limiting assembly (90) engaging with the output coupling portion so as to limit the axial and/or radial displacement of the output coupling portion at the membrane in order to protect the membrane from plastic deformation caused by the movement of the output coupling portion, and wherein the displacement limiting assembly is designed to be detachably fixed at the housing in a manner that the displacement limiting assembly can be removed prior or after implantation of the actuator.
2. The actuator of claim 1, wherein the displacement limiting assembly is cup-like element (90) comprising a bottom portion (92) with an opening (94), through which the coupling portion (84) of the mobile assembly (66) extends, and a wall portion (96) for surrounding a peripheral region (61) of the housing (62) in manner so as to engage with that peripheral region of the housing in a detachable manner.
3. The actuator of claim 2, wherein said opening of the displacement limiting assembly (90) is a bore (94) designed to limit radial movement of the coupling portion (84) of the mobile assembly (66).
4. The actuator of one of claims 2 and 3, wherein said opening (94) of the displacement limiting assembly (90) comprises a slot (95) extending radially from the edge (97) of the bottom portion (92) to the center of the bottom portion.

5. The actuator of one of claims 2 to 4, wherein the wall portion (96) comprises an elevated engagement portion (98) for touching the peripheral region (61) of the housing (62) in a ring-like manner.
6. The actuator of one of claims 2 to 5, wherein the displacement limiting assembly (90) is designed to engage with housing (62) by elastic forces.
7. The actuator of one of claims 2 to 6, wherein displacement limiting assembly (90) is designed to become detached from the housing (62) when axial forces are applied to the displacement limiting assembly.
8. The actuator of one of claims 2 to 7, wherein a central part of the membrane (78) is provided at its outer side with a ring (86), which ring is fixed to the coupling portion (84) of the mobile assembly (66), with the coupling portion passing through the ring, and wherein the displacement limiting assembly is designed such that the bottom portion (92) is to act as a stopper element regarding axial movement of the ring in the direction away from the housing.
9. The actuator of one of the preceding claims, wherein the displacement limiting assembly (90) can either be made of the same family of material, such as CP1, CP2 or Ti-6-4 as the body of the actuator, or of biocompatible and decontaminable plastic materials, such as PEEK, PVC or PE.
10. An implantable actuator of an at least partially implantable hearing instrument, comprising a housing (62), a mobile assembly (66) and a driver assembly (64),
wherein the mobile assembly comprises a base portion (80) coupled to the driver assembly in a manner so as to be driven by the driver assembly to an axially reciprocating movement and an output coupling portion (84) adjacent to the base portion for being coupled to a middle ear or inner ear component (22) of a patient's hearing for vibrating that hearing component in order to stimulate the patient's hearing,
wherein the driver assembly and the base portion of the mobile assembly are located within the housing, wherein the housing comprises an opening closed by a membrane (78) supporting the output coupling portion,

wherein the driver assembly and/or the housing comprises a displacement limiting assembly (73, 75, 102, 104, 106) engaging with a radially extending part (82, 86, 112) of the mobile assembly in a manner to limit the maximal axial displacement of the mobile assembly to not more than 70 μm .

11. The actuator of claim 10, wherein the displacement limiting assembly (73, 75, 102, 104) comprises at least one non-magnetic layer (102, 104) engaging with said radially extending part (82) of the mobile assembly (66) in a manner to limit said maximal axial displacement of the mobile assembly.
12. The actuator of claim 11, wherein said at least one non-magnetic layer (102, 104) is made of a plastic material.
13. The actuator of claim 12, wherein the base portion (80) of the mobile assembly (66) comprises an armature element (82) made of magnetically permeable material, wherein the armature element extends radially with regard to and is carried by a shaft portion (81) of the base portion, with the armature element forming said radially extending part of the mobile assembly, and wherein the driver assembly (64) comprises a stationary coil (68) for driving the armature element.
14. The actuator of claim 13, wherein the driver assembly (64) comprises a first permanent magnet assembly (72) having a first pole face (73) and a second permanent magnet assembly (74) having a second pole face (75), wherein the two pole faces are arranged axially spaced apart and opposed to each other for forming an axially extending biasing gap with a biasing field region in-between the two pole faces, with the armature element (82) being biased to a predetermined position with the biasing gap, thereby forming a first working gap (77) between the armature element und the first pole face and a second working gap (79) between the armature element und the second pole face.
15. The actuator of claim 14, wherein the pole faces (73, 75) are arranged to limit the axial movement of the armature element (82).
16. The actuator of claim 15, wherein the pole faces (73, 75) form the displacement limiting assembly and are provided with said non-magnetic layers (102, 104).

17. The actuator of one of claims 14 to 16, wherein the armature element (82) is biased by the membrane (78) and by a spring bearing supporting at one end of the shaft portion (81) of the base portion (80).
18. The actuator of one of claims 13 to 17, wherein the coil (68) surrounds part of the shaft portion (81) of the base portion (80) of the mobile assembly (66).
19. The actuator of one of claims 13 to 18, wherein the armature element (82) is located axially between the membrane (78) and the coil (68).
20. The actuator of claim 10, wherein a central region of the membrane (78) is provided at its outer side with a ring (86), which ring is fixed to the coupling portion (84) of the mobile assembly (66) as said radially extending part of the mobile assembly, with the coupling portion passing through the ring, wherein the displacement limiting assembly (106) comprises a plate-like element (108) fixed to or forming part of the housing, wherein the plate-like element is located at the outer side of the membrane and is provided with an opening (110), with the coupling portion extending through said opening, and is designed such that the region of the plate-like element around the opening limits the axial movement of the ring in the direction away from the housing (62).
21. The actuator of claim 21, wherein said ring (86) is a first ring and said membrane (78) is a first membrane, wherein the coupling portion (84) of the mobile assembly (66) is provided with a second ring (112) axially spaced apart from said first ring and fixed to the inner side of a second membrane (114) oriented parallel to said first membrane and forming the outer side of the plate-like element (108), wherein the plate-like element is located between the second ring and the first ring, and wherein the plate-like element is designed to limit the axial movement of the second ring in the direction towards the housing (62).
22. The actuator of claim 22, wherein said opening (110) is a bore which is designed to limit the radial displacement of the coupling portion (4) of the mobile assembly (66).
23. The actuator of one of claims 9 and 21, wherein at least one of the ring(s) (86, 112) and the membrane(s) (78, 114) is made of titanium.

24. The actuator of one of the preceding claims, wherein the housing (62) has a substantially tubular shape.

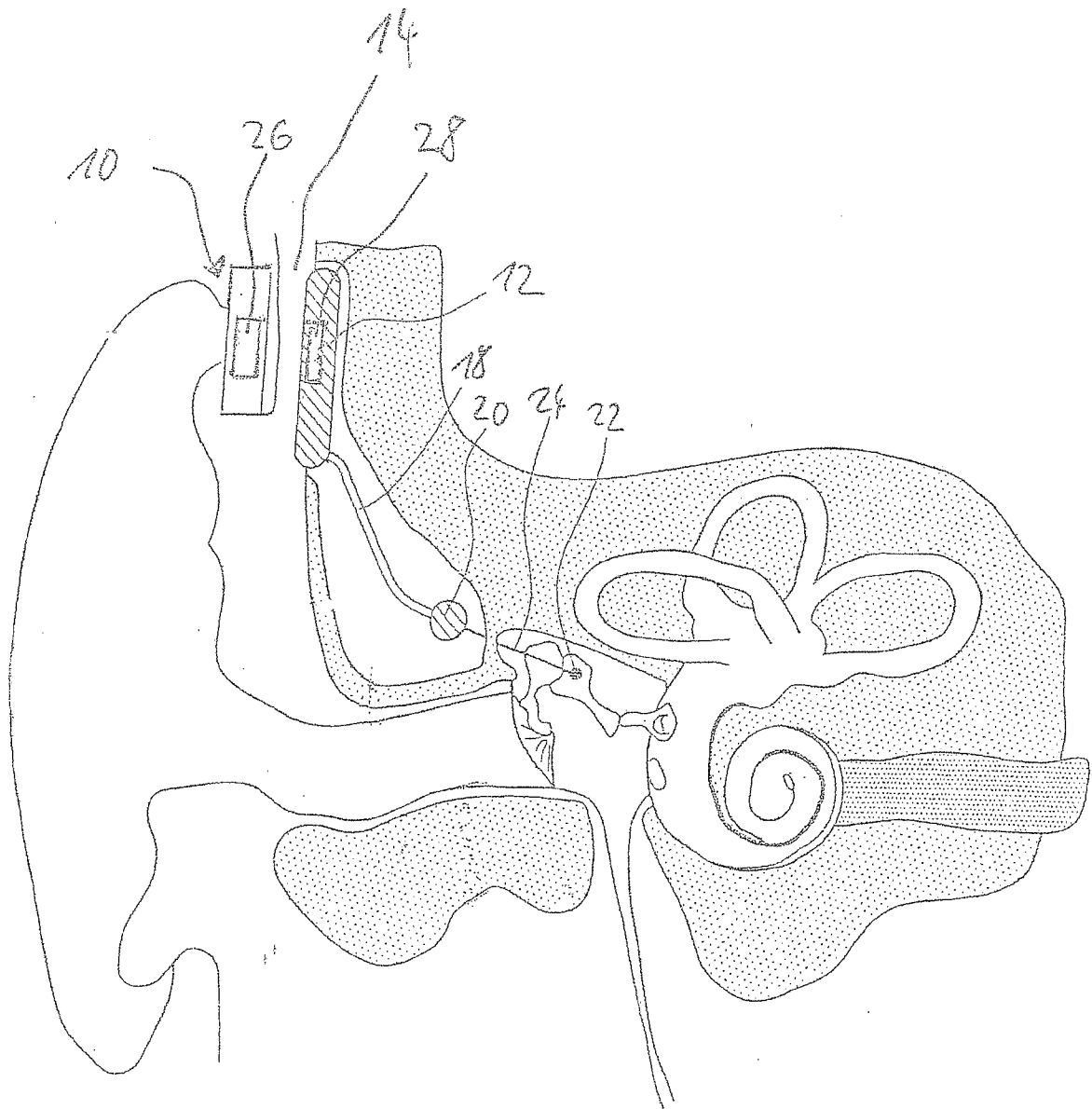


Fig. 1

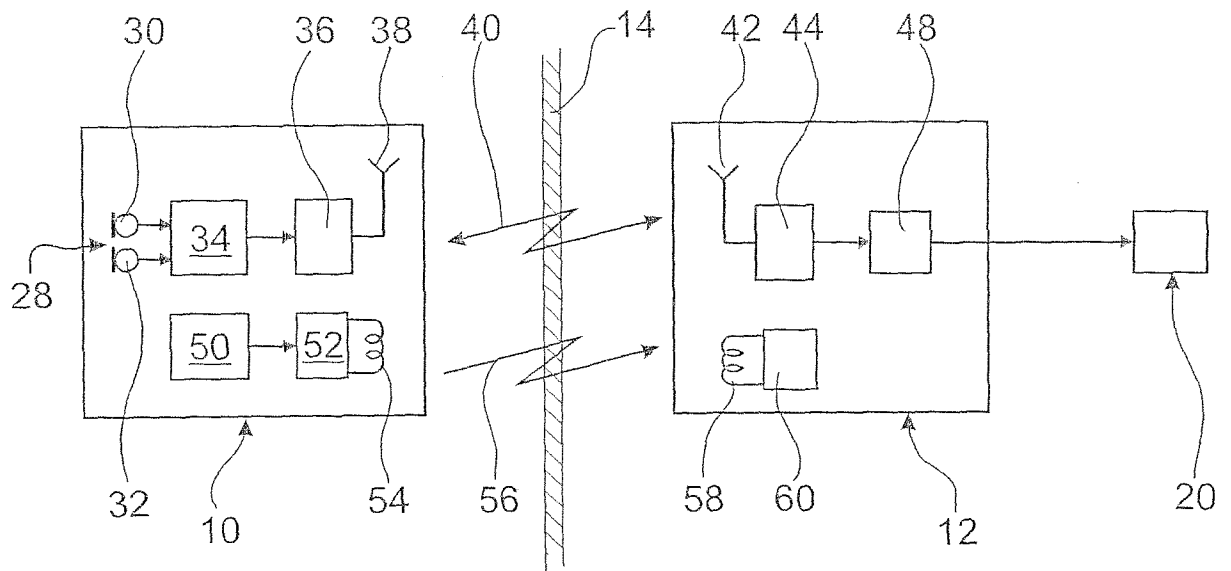
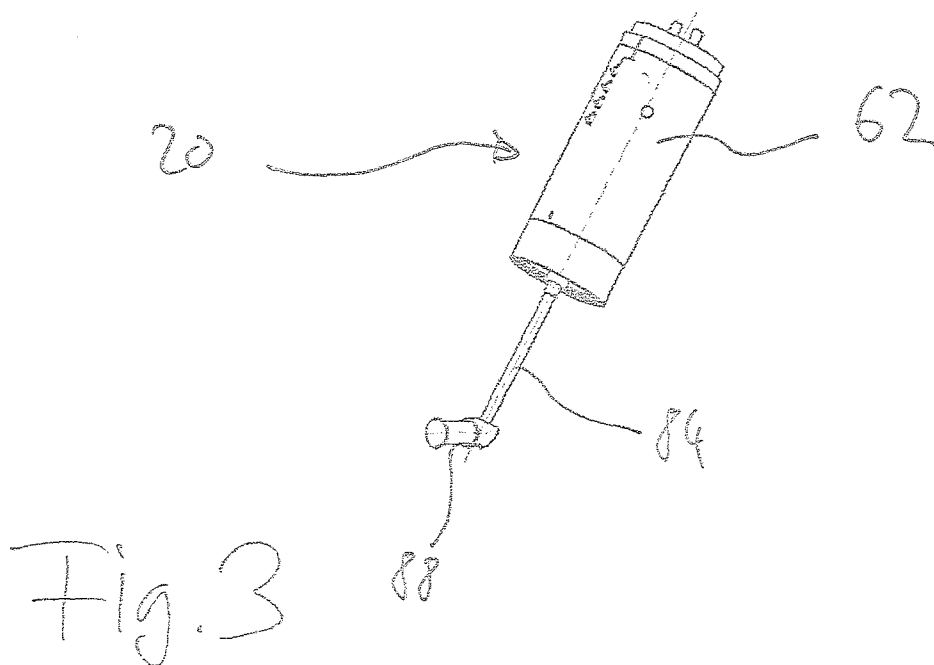
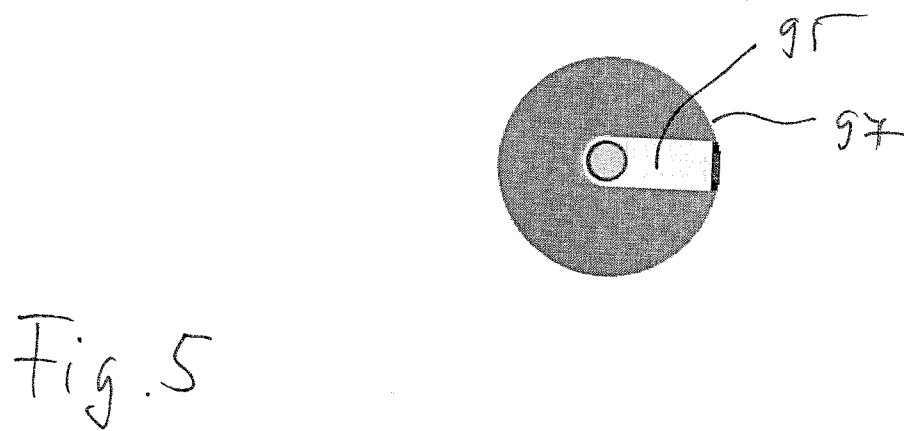
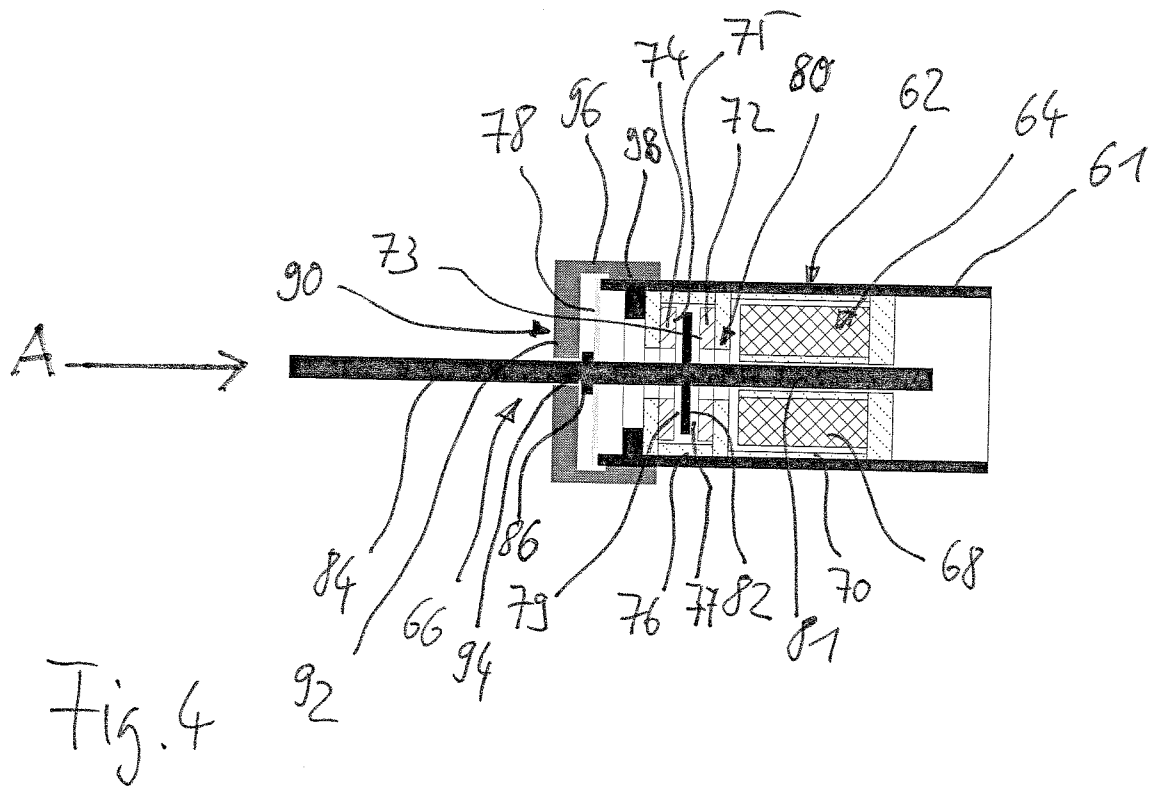


FIG. 2





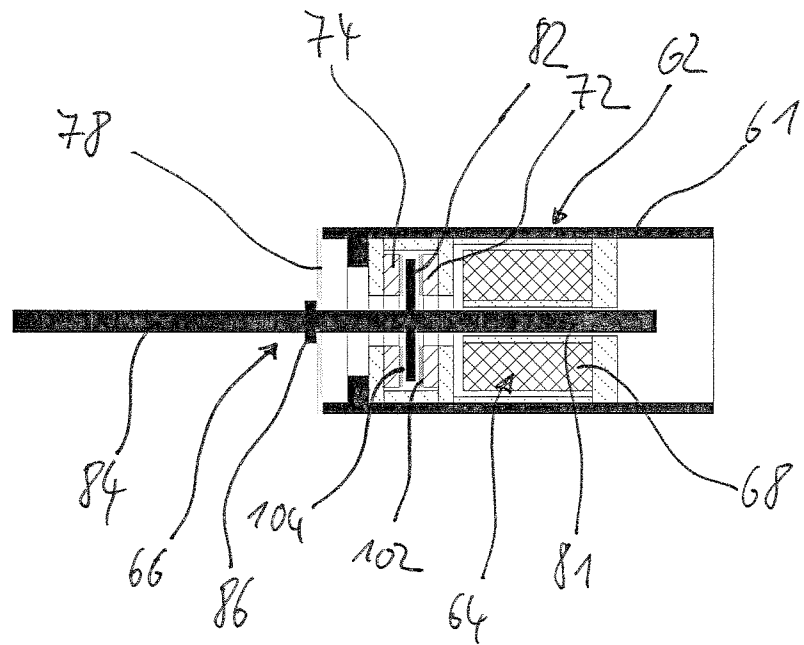


Fig. 6

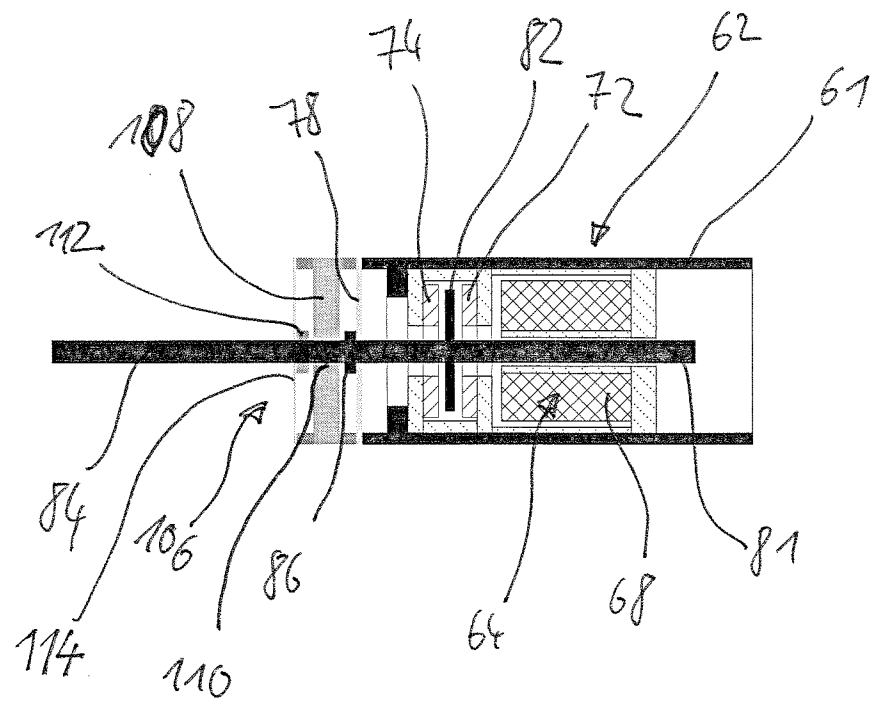


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/063394

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)
H04R

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, COMPENDEX, INSPEC, PAJ, IBM-TDB, 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 2010/133706 A2 (ADVANCED BIONICS AG [CH]; CLAIR PIERRE-YVES [FR]; IMBERT CHRISTIAN [CH]) 25 November 2010 (2010-11-25)	1-7,9
A	page 5, line 10 - page 9, line 28 figures 1-4,10,11	8,10-24
X	WO 2006/058368 A1 (COCHLEAR ACOUSTICS LTD [AU]; BERNHARD HANS [CH]; FONTANNAZ JOEL [CH];) 8 June 2006 (2006-06-08)	10-19,24
A	page 7, line 3 - page 9, line 29 figures 1-4	1-9, 20-23
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Further documents are listed in the continuation of Box C.



See patent family annex.

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INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2011/063394

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 2005/228213 A1 (SCHNEIDER ROBERT E [US] ET AL SCHNEIDER ROBERT EDWIN [US] ET AL) 13 October 2005 (2005-10-13) page 2, paragraph 12 page 5, paragraph 61 - page 7, paragraph 69 figures 1-7 -----	10 1-9, 11-24

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2011/063394

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