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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 August 2017 (10.08.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/136619 A1

(51) International Patent Classification:
H04R 25/00 (2006.01) *A61F 11/00* (2006.01)
H04R 25/02 (2006.01) *A61F 11/04* (2006.01)

(21) International Application Number:
PCT/US2017/016338

(22) International Filing Date:
3 February 2017 (03.02.2017)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/291,559 5 February 2016 (05.02.2016) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, 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.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: VARIABLE TRANSDUCER FIXATION

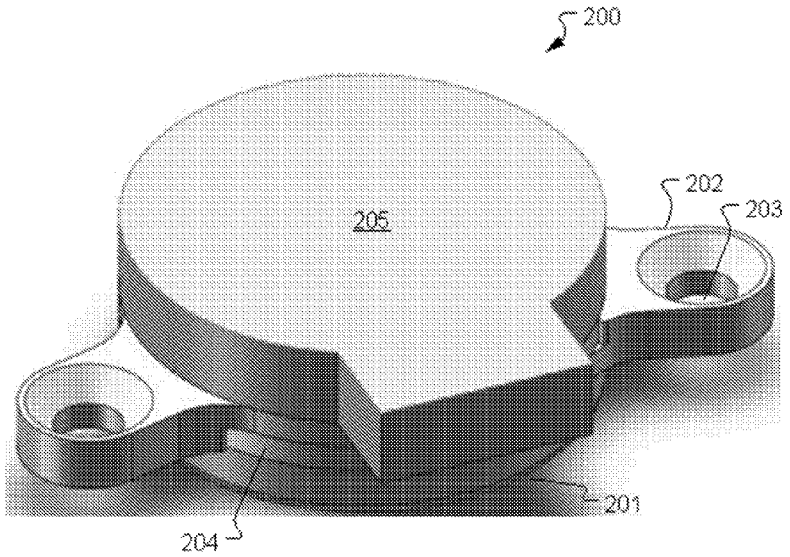

Fig. 2

(57) **Abstract**: An implantable bone conduction transducer arrangement includes a transducer housing having an outer surface with a side wall and opposing ends. A pair of fixation projections are connected to the transducer housing at one end. Each fixation projection includes a bone screw opening configured for insertion of a bone fixation screw to engage underlying skull bone. At least one fixation projection is configured to be independently moveable relative to the transducer housing to form an adjustable relative position between the fixation projections.

WO 2017/136619 A1

TITLE

Variable Transducer Fixation

[0001] This application claims priority from U.S. Provisional Patent Application 62/291,559, filed February 5, 2016, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to hearing implants, and more specifically to fixation of a bone conduction floating mass transducer to a patient's skull bone.

BACKGROUND ART

[0003] A normal ear transmits sounds as shown in Figure 1 through the outer ear **101** to the tympanic membrane (eardrum) **102**, which moves the ossicles of the middle ear **103** (malleus, incus, and stapes) that vibrate the oval window **106** and round window **107** membranes of the cochlea **104**. The cochlea **104** is a long narrow duct wound spirally about its axis for approximately two and a half turns. It includes an upper channel known as the scala vestibuli and a lower channel known as the scala tympani, which are connected by the cochlear duct. The cochlea **104** forms an upright spiraling cone with a center called the modiolar where the spiral ganglion cells of the cochlear nerve **105** reside. In response to received sounds transmitted by the middle ear **103**, the fluid-filled cochlea **104** functions as a transducer to generate electric pulses which are transmitted to the cochlear nerve **105**, and ultimately to the brain.

[0004] Hearing is impaired when there are problems in the ability to transduce external sounds into meaningful action potentials along the neural substrate of the cochlea **104**. To improve impaired hearing, hearing prostheses have been developed. For example, when the impairment is related to operation of the middle ear **103,** a conventional hearing aid or middle ear implant may be used to provide acoustic-mechanical stimulation to the auditory system in the form of amplified sound. Or when the impairment is associated with the cochlea **104**, a cochlear implant with an implanted stimulation electrode can electrically stimulate auditory nerve tissue with small currents delivered by multiple electrode contacts

distributed along the electrode.

[0005] U.S. Patent 8,246,532 (incorporated herein by reference in its entirety) described a type of implantable hearing prosthesis system which uses bone conduction to deliver an audio signal to the cochlea for sound perception in persons with conductive or mixed conductive/sensorineural hearing loss. An implanted floating mass transducer (FMT) is affixed to the temporal bone. A body worn audio processor, typically behind the ear, receives via microphones the audio signals and transforms it into an electrical audio signal. In response to an externally generated electrical audio signal, the FMT couples a mechanical stimulation signal to the temporal bone for delivery by bone conduction to the cochlea for perception as a sound signal. A certain amount of electronic circuitry must also be implanted with the FMT to provide power to the implanted device and at least some signal processing which is needed for converting the external electrical signal into the mechanical stimulation signal and mechanically driving the FMT.

[0006] To generate the mechanical vibration forces needed in a bone conduction transducer, an oscillating mass is used, which also has corresponding space requirements. In addition, the connection of a bone conduction transducer to the cranial bone must be very stable, since relatively large forces must be transferred to the skull bone. Typically this involves osseointegration of certain implant features.

[0007] Most existing bone conduction implants use two standard bone screws to attach the transducer to the patient's skull bone. This screw fixation arrangement requires sufficient space, additional parts, and sometimes can involve additional bone drilling (needing a longer surgical procedure). In addition, it is important that the geometry of the screw holes be correct, and that the structure and geometry of skull bone be appropriate.

[0008] A proper site for the implanted transducer has to be provided on the cranial bone during the implant surgery. On the outward-facing side of the implant, tension created on the skin by protruding structures is the limiting factor. On the inward-facing side of the implant are anatomical structures within the skull bone (blood vessels, nerves, etc.) and the dura mater of the brain. Each surgery involves a balancing between the burden to the

skin over the transducer together with the desire to drill out as little as possible of the underlying skull bone.

[0009] The choice of placement location for the transducer and the corresponding drilling depth is limited. Current commercial products do not provide for a variable/adjustable implant means of fixation. For example, fixation of the Bonebridge transducers sold by Vibrant Med-El are designed so that the screw connection to the skull bones of the entire transducer must be opposite each other. These require a comprehensive pre-operative examination and sometimes intra-operative surgical adjustments are necessary. In addition, the depth and positioning of the bone connection screws in the skull bone depends upon specific patient anatomical factors as well as the designated screw receptacle holes provided on the body of the implant housing. The BCI lifts provided with the Bonebridge transducer allow partial sinking of the device into the skull bone, which reduces the depth of bone removal that is needed.

[0010] U.S. Patent 8,241,201 describes various bone conduction transducer arrangements including an embodiment with a non-screw fixation mechanism where an adaptor made of biocompatible material is placed between the bottom of the transducer housing and the underlying bone. WO 2014138149 describes various different fixation features on the outer perimeter of a cochlear implant housing. U.S. Patent 8,909,348 also shows a cochlear implant with stabilizing projections on its outer perimeter. U.S. Patent 7,937,156 shows another cochlear implant housing with various osseointegrating projections.

SUMMARY

[0011] Embodiments of the present invention are directed to an implantable bone conduction transducer arrangement. A transducer housing has an outer surface with a side wall and opposing ends. A pair of fixation projections are connected to the transducer housing at one end. Each fixation projection includes a bone screw opening configured for insertion of a bone fixation screw to engage underlying skull bone. At least one fixation projection is configured to be independently moveable relative to the transducer housing to form an adjustable relative position between the fixation projections.

[0012] In specific embodiments, there may also be a pair of projection rings, each projection ring including one of the fixation projections. In such an embodiment, the projection rings are connected to the generally cylindrical shaped transducer housing with a central cylindrical axis at the side wall and at least one projection ring is configured to be rotatable relative to the transducer housing about the cylindrical axis so that an adjustable relative arc exists between the fixation projections. Both fixation projections may be configured to be independently rotatable relative to the transducer housing about the cylindrical axis.

[0013] Each fixation projection may further include a locking tab configured to slide away from the bone screw opening when a bone screw is inserted into the bone screw opening and engage against the outer surface of the transducer housing to resist movement of the transducer housing relative to the fixation projection. Each such locking tab may include a spring element configured for controlling engaging force of the locking tab against the outer surface of the transducer housing. And each locking tab may further include one or more handling tabs configured for engaging a surgical tool for squeezing the spring element to allow removal of the transducer housing from at least one fixation projection or ring and bone screws.

[0014] The fixation projections may be connected at an inner end of the transducer housing configured to fit against underlying skull bone, or at an outer end of the transducer housing furthest away from underlying skull bone. The transducer housing may be configured to be disconnectable from the fixation projections or rings without removing the bone fixation screws. The fixation projections or rings may be covered with a surface treatment for promoting osseointegration of the fixation projections with adjacent skull bone. And the transducer housing may specifically have a generally rectangular or cylindrical shape with a center cylindrical axis and opposing cylindrical ends.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Figure 1 shows anatomical structures of a typical human ear.

[0016] Figure 2 shows an elevated perspective view of an implantable bone conduction transducer arrangement according to an embodiment of the present invention.

[0017] Figures 3A-3C show another embodiment with locking tabs.

[0018] Figure 4 shows an example of a square shaped transducer housing.

DETAILED DESCRIPTION

[0019] Embodiments of the present invention are directed to arrangements for fixing a bone conduction transducer such as an FMT to an implanted patient's skull bone with an adjustable angle between the bone fixation screws, which allows the fixation of the bone conduction transducer to the skull bone to be individually adapted to the specific anatomy of the recipient patient.

[0020] Figure 2 shows an elevated perspective top view of an implantable bone conduction transducer arrangement which includes a generally cylindrical transducer housing **200** with a center cylindrical axis. Note that the transducer housing **200** has an outer surface that may include one or more eccentric projection lobes as is shown in Figure 2, which may be useful for example to accommodate the implant electronic circuits contained within the transducer housing **200**. The transducer housing **200** also has opposing cylindrical ends, inner end **201** and outer end **205**.

[0021] A pair of fixation projections **202** are connected to the transducer housing **200** at one cylindrical end. Each fixation projection **202** includes a bone screw opening **203** that is configured for insertion of a bone fixation screw to engage underlying skull bone. The fixation projections **202** are configured to be independently rotatable about the cylindrical axis of the transducer housing **200** so that an adjustable rotational arc exists between them. This has the advantage that an eccentric projection lobe form the transducer housing **200** may be positioned completely independent from the bone fixation screw. If is however understood, that only one fixation projection may be rotatable about the cylindrical axis of

the transducer housing **200**. In the specific embodiment shown in Figure 2, the fixation projections **202** are formed in independently rotatable projection rings **204** that rotate on the outer surface of the transducer housing **200** around the cylindrical axis so that an adjustable rotational arc exists between the fixation projections **202**. Each projection ring **204** has one of the fixation projections **202**. The projection rings **204** and their fixation projections **202** may be connected at the inner end **201** of the transducer housing **200** and configured to fit against underlying skull bone, or they may be located at the outer end **205** of the transducer housing **200** furthest away from underlying skull bone.

[0022] Figure 3A shows an elevated perspective view of another embodiment of a transducer housing **300** with an inner end **301** and an outer end **305**, in which the fixation projections **302** each include a locking tab **306,** shown in detail in Figures 3B and 3C. The locking tab **306** is configured to slide away along a sliding direction from the bone screw opening **303** when a bone screw is inserted into the bone screw opening **303** and engage its inner edge **307** against the outer surface of the transducer housing **300**. The locking tab **306** may have an edge receptacle notch or protrusion **308** that slidably engages into a corresponding edge receptacle protrusion or notch in the fixation projections **302** along the movement direction. For example, in the embodiment of the locking tab **306** shown in Fig. 3B, the inner edge **307** has a flat surface and opposing arranged a slider as part of the fixation projections **302** having a downward facing triangle shape, the edge of which fits into a corresponding edge receptacle notch on the outer surface of the transducer housing **300**. When the screw is inserted into the bone screw opening **303** and the locking tab **306** slides away, the inner edge **307** and opposing triangle shape move to each other and thereby clamp the transducer housing **300** in between so as to resist movement relative to the fixation projections **302**. In the embodiment shown in Fig. 3C, the inner edge **307** has an inner edge **307** that faces radially inward to engage on the outer surface of the transducer housing **300**. The transducer housing **300** may have a corresponding edge receptacle notch on the outer surface where the inner edge **307** may engage (not shown). In some embodiments, the structure and geometry of such edge receptacle notches may be adapted to allow adding the fixation projections **302** during the implantation surgery. Such providing of multiple edge receptacle notches on the outer surface of the transducer housing **300** would enable greater selection for the exact location of the fixation

projections **302**.

[0023] The locking tabs **306** may be made, for example, of moldable polymer material such as polyether ether ketone (PEEK), or of bio-compatible metal (e.g. titanium, MP35N). The fixation projection **302**, bone screw opening **303**, and locking tab **306** may be configured to allow the locking tab to simply snap into position within the bone screw opening **303** during assembly. The locking tab **306** may also include a spring element (not shown) that may help control the clamping force of the locking tab **306** against the outer surface of the transducer housing **300**.

[0024] In specific embodiments, the transducer housing **200/300** may be configured to be disconnectable from one or both fixation projections **202/302** and/or the projection rings **204/304**. Thus, the locking tab **306** may include a pair of handling tabs that can be used to engage surgical forceps to squeeze the spring element of the locking tab **306** along the movement direction together to allow the inner edge **307** of the locking tab **306** to be pulled back from transducer housing **200/300** and allow for separate removal of the transducer housing **200/300** without removing the projection rings **204/304** and/or fixation projections **202/302** and the bone fixation screws.

[0025] And in some embodiments, the fixation projections **202/302** may be covered with a surface treatment for promoting osseointegration of the fixation projections **202/302** with adjacent skull bone. For example, the projection rings **204/304** may be made of titanium with a surface coating that promotes osseointegration of the projection rings **204/304** and the fixation projections **202/302** with the underlying skull bone. The outer surface of the remainder of the transducer housing **200/300** is uncoated, thereby avoiding osseointegration of the main body of the transducer housing **200/300**, and enabling its convenient disconnection during a second surgery; for example, to repair/replace the electronic circuits contained within.

[0026] Of course, the use of such fixation projections is not limited to transducer housings that specifically are more or less cylindrical. For example, Figure 4 shows an embodiment of a square shaped transducer housing **400**, and other specific shapes are

equally conceivable. In this specific example the outer surface of the transducer housing **400** has an edge receptacle notch on its side wall for slidable engaging the fixation projections **300**. The edge receptacle notch may have openings, here shown at the edges of the side walls to allow for insertion of fixation projections **300** into edge receptacle notch during surgery. This allows, for the example of the square shaped transducer housing **400**, to insert the fixation projections **300** during surgery onto the side wall where the bone screw fixation is best suited. Similarly the transducer housing **400** may be removable from the fixation projections **300** without removing bone fixation screws as described before and as long as the fixation projections **300** are slidable in parallel direction. Otherwise only those fixation projections **300** with non-parallel slidable direction may be removed by opening bone fixation screw first, the other fixation projections **300** may stay in place. It is however readily understood, that such openings may be equally used in other specific shapes, for example cylindrical shaped transducer housings **400**, that would enable greater selection of desired number of fixation projections and for exact location of the fixation projections **302**.

[0027] Although various exemplary embodiments of the invention have been disclosed, it should be apparent to those skilled in the art that various changes and modifications can be made which will achieve some of the advantages of the invention without departing from the true scope of the invention.

CLAIMS

What is claimed is:

1. An implantable bone conduction transducer arrangement comprising:

a transducer housing having an outer surface with a side wall and opposing ends;

a pair of fixation projections connected to the transducer housing at one end, each fixation projection including a bone screw opening configured for insertion of a bone fixation screw to engage underlying skull bone;

wherein at least one fixation projection is configured to be independently moveable relative to the transducer housing to form an adjustable relative position between the fixation projections.

2. The implantable bone conduction transducer arrangement according to claim 1, wherein each fixation projection includes a locking tab configured to slide away from the bone screw opening when a bone screw is inserted into the bone screw opening and engage against the outer surface of the transducer housing to resist movement of the transducer housing relative to the fixation projection.

3. The implantable bone conduction transducer arrangement according to claim 1 or 2, wherein each locking tab comprises a spring element configured for controlling engaging force of the locking tab against the outer surface of the transducer housing.

4. The implantable bone conduction transducer arrangement according to any of the foregoing claims, wherein each locking tab further comprises one or more handling tabs configured for engaging a surgical tool for squeezing the spring element to allow removal of the transducer housing from the at least one fixation projection and bone screws.

5. The implantable bone conduction transducer arrangement according to any of the foregoing claims, wherein the fixation projections are connected at an inner end of the transducer housing configured to fit against underlying skull bone.

6. The implantable bone conduction transducer arrangement according to any of the

foregoing claims, wherein the fixation projections are connected at an outer end of the transducer housing furthest away from underlying skull bone.

7. The implantable bone conduction transducer arrangement according to any of the foregoing claims, wherein the fixation projections are covered with a surface treatment for promoting osseointegration of the fixation projections with adjacent skull bone.

8. The implantable bone conduction transducer according to any of the foregoing claims, wherein the transducer housing has a generally rectangular shape.

9. The implantable bone conduction transducer according to any of the foregoing claims, wherein the transducer housing has a generally cylindrical shape with a center cylindrical axis and opposing cylindrical ends.

10. The implantable bone conduction transducer arrangement according to any of the foregoing claims, further comprising:

a pair of projection rings, each projection ring including one of the fixation projections, wherein the projection rings are connected to the transducer housing at the side wall and at least one is configured to be rotatable relative to the transducer housing about the cylindrical axis so that an adjustable relative arc exists between the fixation projections.

11. The implantable bone conduction transducer arrangement according to claim 10, wherein both fixation rings are configured to be independently rotatable relative to the transducer housing about the cylindrical axis.

12. The implantable bone conduction transducer arrangement according to claim 10, wherein the projection rings including the fixation projections are configured to be disconnectable from the transducer housing without removing the bone fixation screws.

13. An implantable bone conduction hearing prosthesis comprising an external body worn audio processor and a bone conduction implant including a transducer according to one of claims 1 to 12.

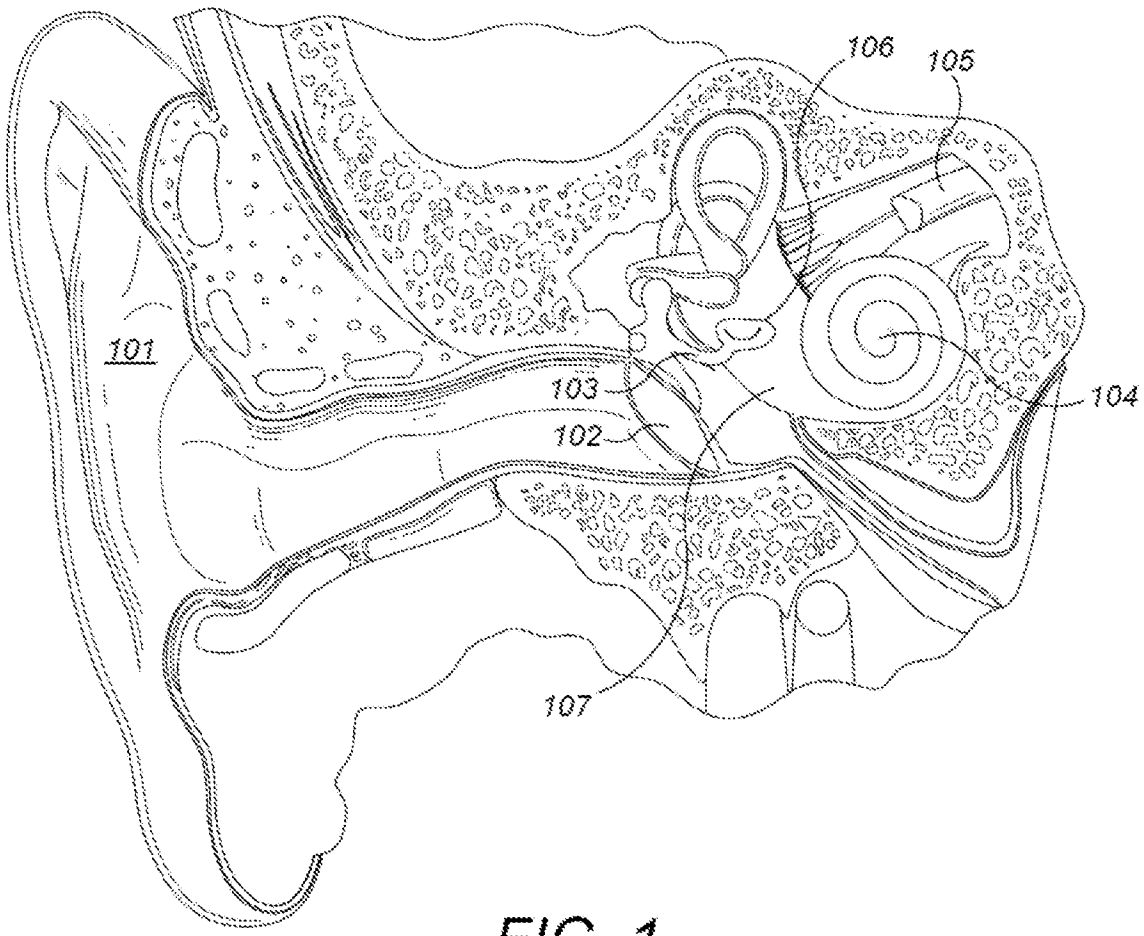

FIG. 1

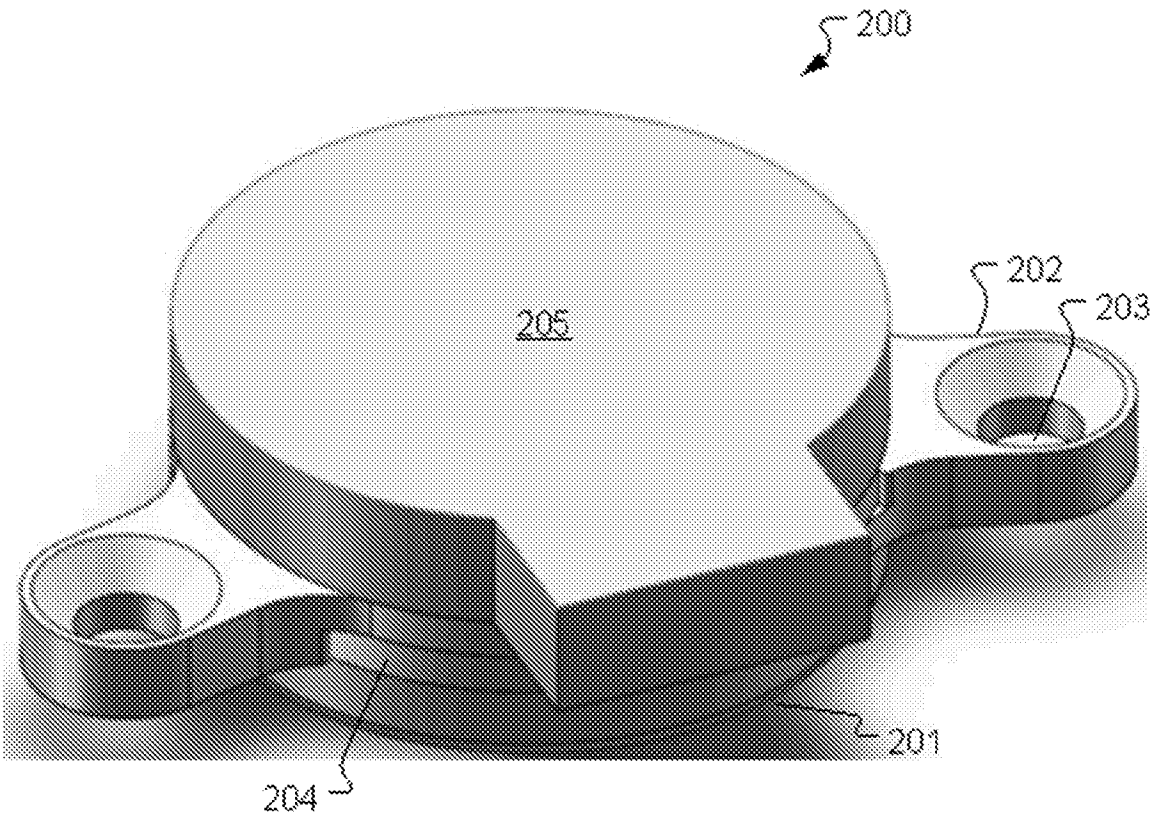

Fig. 2

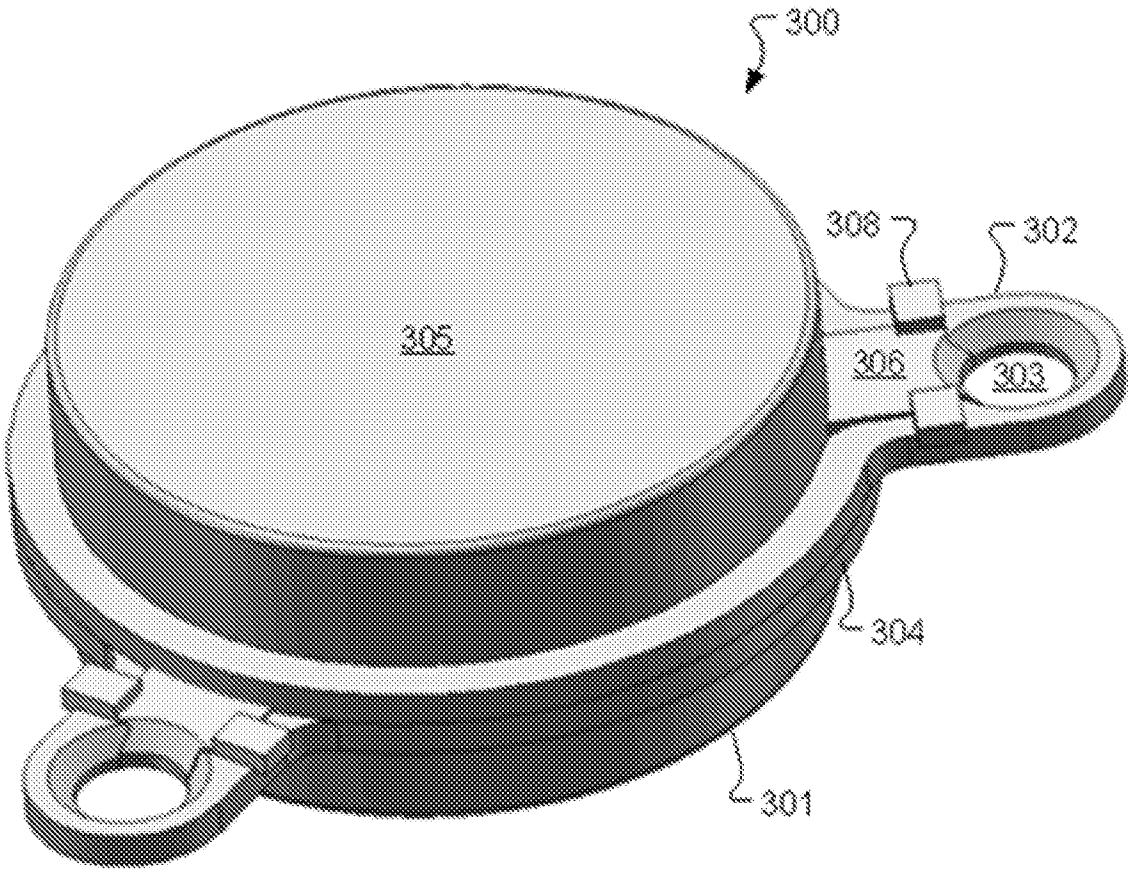

Fig. 3A

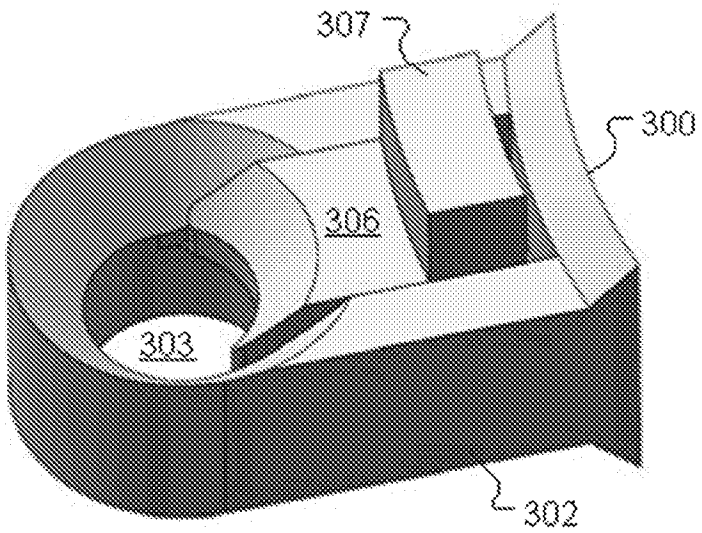

Fig. 3B

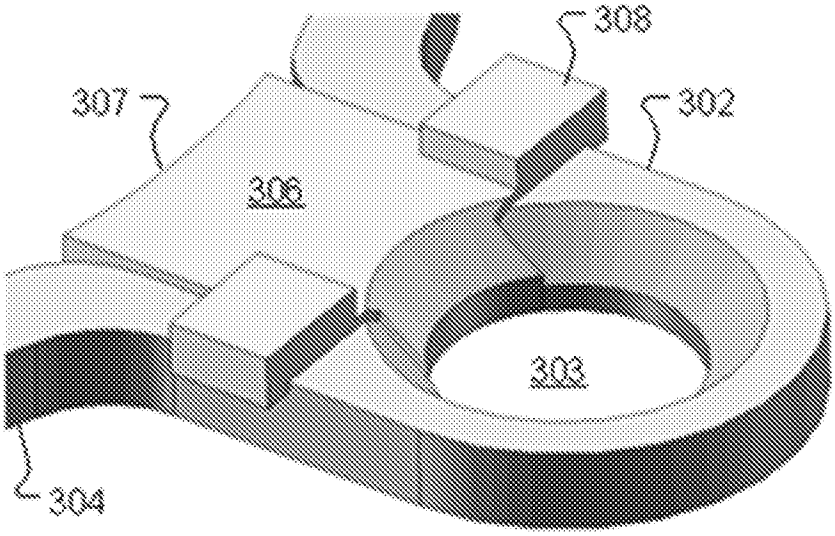

Fig. 3C

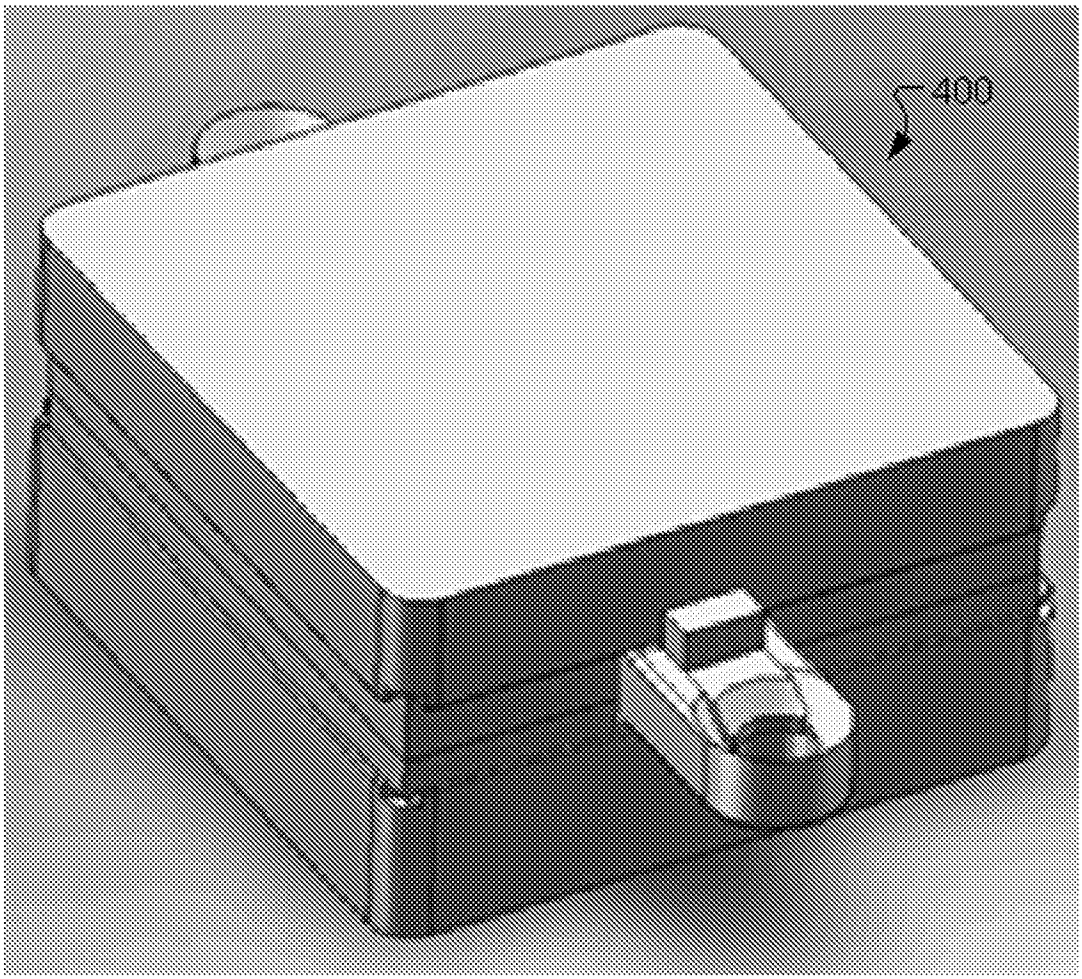

Fig. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US17/16338

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 5-13
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US17/16338

A. CLASSIFICATION OF SUBJECT MATTER
IPC - H04R 25/00, 25/02; A61F 11/00, 11/04 (2017.01)
CPC - H04R 25/604, 25/606; A61F 11/00, 11/04

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)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---- A	US 2013/0046131 A1 (BALL, G. et al.) February 21, 2013; figures 6a-6c; paragraphs [0035-0036]	1 --- 2-4
A	US 2014/0121452 A1 (Sophono, Inc.) May 1, 2014; figures 1a, 7c, 10a-10b; paragraphs [0033, 0052-0053]	2-4
A	US 2012/0271097 A1 (BALL, G. et al.) October 25, 2012; entire document	1-4

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 March 2017 (31.03.2017)	24 APR 2017
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774