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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 December 2009 (10.12.2009)

PCT

(10) International Publication Number
WO 2009/146494 A1

(51) International Patent Classification:
H04R 25/00 (2006.01) *H04R 7/00* (2006.01)
A61F 2/18 (2006.01)

(21) International Application Number:
PCT/AU2009/000698

(22) International Filing Date:
4 June 2009 (04.06.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2008902843 4 June 2008 (04.06.2008) AU

(71) Applicant *(for all designated States except US)*: **COCHLEAR LIMITED** [AU/AU]; 14 Mars Road, Lane Cove, NSW 2066 (AU).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **CHAMBERS, John** [AU/AU]; 14 Mars Road, Lane Cove, NSW 2066 (AU).

(74) Agent: **F B RICE & CO**; Level 23, 44 Market Street, Sydney, NWS 2000 (AU).

(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, BR, BW, BY, BZ, 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, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, 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, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

WO 2009/146494 A1

(54) Title: IMPLANTABLE MICROPHONE DIAPHRAGM STRESS DECOUPLING SYSTEM

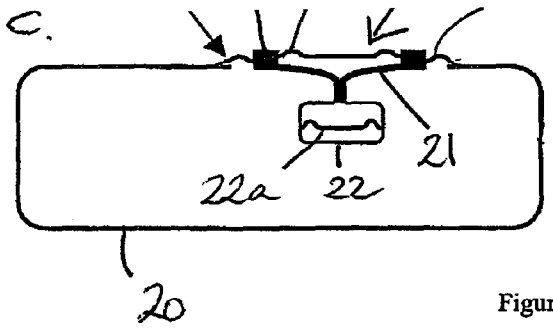

Figure 1

(57) Abstract: A diaphragm assembly (10) comprising a diaphragm (11) having a first surface (12), a second surface (13) opposed to the first surface (12) and a perimeter (14). A strengthening member (15) is disposed a distance inwardly from the perimeter (14) and divides the diaphragm (11) into an inner portion (16) and an outer portion (17). The strengthening member (15) has a rigidity relatively higher than the inner portion (16) and/or outer portion (17) of the diaphragm (11) and serves to at least substantially protect the assembly (10) from distortion that might arise, for example, from non¬ uniform mechanical stress or thermal expansion and contraction during manufacture and/or welding of the assembly (10) to a housing (20) and/or during the service life of an implantable prosthesis having such an assembly.

"Implantable microphone diaphragm stress decoupling system"

Cross-Reference to Related Applications

The present application claims priority from Australian Provisional Patent Application No 2008902843 filed on 4 June 2008, the content of which is incorporated herein by reference.

Field of the Invention

The present invention relates to a microphone assembly for an auditory prosthesis, including a microphone assembly suitable for use in a fully implantable hearing prosthesis, such as a cochlear implant.

Background of the Invention

While cochlear implants have typically relied upon use of both an external component, such as a speech processor unit, and an implantable component, such as a receiver/stimulator unit, fully implantable systems have been proposed. Such fully implantable systems have a number of potential advantages, including being usable in circumstances where a traditional system cannot be used.

Successful use of a fully implantable system does require devices that would normally be used on an external component to be implanted within a biocompatible housing. These devices potentially include a microphone and a power source.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention is a diaphragm assembly for hermetically sealing an opening in a housing of an implantable prosthesis, the assembly comprising:

a diaphragm having a first surface, a second surface opposed to said first surface and a perimeter; and

a strengthening member disposed a distance inwardly from said perimeter and dividing said diaphragm into an inner portion and an outer portion;

wherein said strengthening member has a rigidity relatively higher than said inner portion and/or said outer portion of the diaphragm.

According to a further aspect, the present invention is an implantable component of an auditory prosthesis, the implantable component comprising:

a housing having an opening;

a microphone disposed in said housing at least adjacent said opening; and

a diaphragm assembly hermetically sealing said opening, the assembly comprising:

a diaphragm having a first surface, a second surface opposed to said first surface and a perimeter; and

a strengthening member disposed a distance inwardly from said perimeter and dividing said diaphragm into an inner portion and an outer portion;

wherein said strengthening member has a rigidity relatively higher than said inner portion and/or said outer portion of the diaphragm.

According to another aspect, the present invention is an implantable component of a prosthesis, the implantable component comprising:

a housing having an opening; and

a diaphragm assembly hermetically sealing said opening, the assembly comprising:

a diaphragm having a first surface, a second surface opposed to said first surface and a perimeter; and

a strengthening member disposed a distance inwardly from said perimeter and dividing said diaphragm into an inner portion and an outer portion;

wherein said strengthening member has a rigidity relatively higher than said inner portion and/or said outer portion of the diaphragm; and

a transducer mounted to the inner portion of said diaphragm.

In this further aspect, the prosthesis, housing, microphone, transducer and/or diaphragm assembly can have one, some or all of the features of these devices as described herein with reference to the drawings and/or the claims.

Brief Description of the Drawings

By way of example only, embodiments of the invention are now described with reference to the accompanying drawings, in which:

Fig. 1A is a simplified elevation view of one embodiment of a diaphragm assembly according to the present invention;

Fig. 1B is a plan view of another embodiment of the assembly;

Fig. 1C is a simplified view of yet another embodiment of an assembly mounted to an implantable housing;

Fig. 2 is a composite image of the assembly of Fig. 1A;

Fig. 3 is a perspective view of a housing having a diaphragm assembly mounted thereto;

Fig. 4A is a simplified elevation view of another embodiment of a diaphragm assembly according to the present invention;

Fig. 4B is a plan view of the embodiment of the assembly depicted in Fig. 4A;

Figs. 5 and 6 are simplified views of other embodiments of an assembly mounted to an implantable housing; and

Fig. 7 is a simplified view of yet another embodiment where the microphone of the prosthesis is replaced with a piezoelectric transducer.

Preferred Mode of Carrying out the Invention

One example of a prosthesis according to the present invention is a fully implantable cochlear implant. A fully implantable cochlear implant requires implantation of a relatively high quality microphone that will suitably meet the needs of the implantee to both hear and successfully engage in verbal communication.

Such a microphone needs to be mounted in a housing that is implantable within the implantee. This housing may also contain other componentry including a speech processor and stimulation circuitry to allow output of appropriate stimulation signals to an electrode assembly positioned within the cochlea of the implantee. The housing can be implantable in a recess of the temporal bone adjacent the ear of the implantee that is receiving the output of the implant system. The housing can be formed from a biocompatible material and/or have a biocompatible coating. The housing can be coated with a layer of silicone or parylene. While fully implantable, the housing may still need to, at least occasionally, communicate with an external component. As such, the implant will typically include an antenna coil for use as part of a bidirectional radio frequency magnetic induction link with an external antenna coil.

In addition to being biocompatible, the housing also needs to have a level of hermeticity, despite any openings that may be provided therein, to ensure preservation of the components within the housing while ensuring the safety of the implantee, potentially for the entire lifetime of the implantee.

In this regard, the microphone needs to be able to perform at a suitable level to meet the needs of the implantee while being mounted in a housing that must meet the requirements defined herein.

One example of a diaphragm assembly that is suitable to hermetically seal an opening in the housing of an implantable prosthesis is depicted as 10 in Figs. 1A and 2. The depicted assembly 10 comprises a diaphragm 11 having a first surface 12, a second surface 13 opposed to the first surface 12 and a circular perimeter 14. In addition to hermetically sealing the housing, the diaphragm is constructed and mounted so that

sound or fluid pressure vibrations can pass from a source exterior the housing through the housing.

While this embodiment has a circular perimeter, the diaphragm perimeter can be non-circular. Other potentially suitable perimeter shapes include polygons, squares, rectangles, and ellipses.

The assembly also comprises a strengthening member 15 that is disposed at an approximately constant distance inwardly from the perimeter 14. In the depicted embodiment, the strengthening member 15 is annular. Where the perimeter is non-circular, the strengthening member can be disposed at an approximately constant distance inwardly from whatever shape perimeter is utilised to form the diaphragm. For example, where the diaphragm has one or more straight edges, the strengthening member can be at least substantially or exactly parallel to the perimeter.

In the depicted embodiments, the member 15 divides the diaphragm 11 non-equally into an inner portion 16 and an outer portion 17. In the depicted embodiment, the inner and outer portions 16, 17 have the same thickness. The diaphragm could be formed with the portions 16, 17 having different thicknesses. For example, the inner portion 16 can be thinner than the outer portion 17. In another embodiment, the inner portion can be thicker than the outer portion 17. The strengthening member has a rigidity that is relatively higher than the inner portion 16 and the outer portion 17, or at least one of the inner portion 16 or outer portion 17.

While Fig. 1A depicts the inner portion 16 and the outer portion 17 being in the same plane, the portions 16, 17 can be in different planes. One example of this is provided by Fig. 4A which depicts the inner portion 16 being disposed in a different, but parallel, plane to that of the outer portion 17.

The strengthening member 15 serves to effectively isolate the inner portion 16 from any forces differentially applied to the outer portion 17 during construction and/or mounting of the assembly 10 to an implantable housing 20, for example during welding of the perimeter 14 to the housing 20.

As depicted in Fig. 1A, the strengthening member 15 can extend outwardly from the first surface for a first height and the second surface for a different height. It will be

appreciated that the strengthening member 15 could extend from only one of the surfaces (for example, see the embodiments depicted in Figs 5 and 6). In another embodiment, and as depicted in Fig. 7, the strengthening member can extend outwardly from both the first surface and the second surface to heights that are substantially or exactly equal.

The strengthening member 15 can have a height that is greater than the thickness of the inner portion 16 and the outer portion 17 of the diaphragm 11. For example only, the height of the strengthening member 15 can be between about 5 and about 10 times greater than the thickness of inner portion 16 and/or the outer portion 17.

The outer portion 17 and/or inner portion 16 can have one or more annular corrugations. For example and as depicted in Figs. 1A and 4A, the outer portion 17 can have two concentric corrugations 18 and the inner portion a single corrugation 23. Figs 1C. 5, 6 and 7 depict alternative embodiments in which both the outer portion 17 and inner portion 16 each have a single corrugation (18, 23, respectively). Other combinations of numbers of corrugations on the outer portion 17 and inner portion 16 can be envisaged.

As depicted in Figs. 1B and 4B, at least part, and if desired all, of the first surface and/or the second surface of the outer portion 17 of the assembly 30 can be dimpled. It will be appreciated that the outer portion 17 could be both dimpled and corrugated.

This shaping of the outer portion 17, which may include various combinations of corrugations, folds, ridges and dimples etc, increases the relative compliance or planar elasticity of the outer portion 17 allowing it to flex, stretch or compress under the influence of mechanical force applied to or near to its perimeter. Mechanical force subsequently conveyed to the strengthening member 15 is thus dispersed to act upon a greater area of the strengthening member 15. The relative rigidity of the strengthening member 15 further disperses the applied forces that might otherwise act differentially upon the inner portion 16.

The shaping of the inner portion 16, particularly the provision of a optional corrugation 23, can serve to relatively enhance the acoustic properties of the inner portion 16 of the assembly 10.

The assembly 10 can be formed in one piece. In another embodiment, the assembly can be formed from two or more pieces. Where formed from two or more pieces, the pieces can be suitable joined or adhered to each other as required. Adhesive and/or metal bonding techniques and/or substances can be utilised to bring the pieces together.

The assembly can be formed from one material or two or more materials. In one embodiment, the assembly can be formed entirely from titanium or a titanium alloy. Other suitable biocompatible materials can be envisaged.

As depicted in Figs. 1C and 6, the strengthening member 15 of the assembly 40 can be connected or mechanically or acoustically coupled to a funnel-shaped microphone coupling 21 that is positioned within the housing 20. In these embodiments, the strengthening member 15 is connected to the microphone coupling 21 using a suitable relatively long-acting adhesive.

One example of an alternative arrangement for the mounting of a funnel-shaped microphone coupling 21 is depicted in Fig. 5. In this arrangement, the microphone coupling 21 is connected to the interior surface of the housing 20.

In the depicted embodiments, a microphone 22 is positioned at an inner end of the microphone coupling 21. The microphone 22 in turn can have an internal sound diaphragm 22a.

Of the depicted embodiments, it is currently envisaged that the embodiment depicted in Figs. 1C and 6 will be advantageously less sensitive to vibratory or accelerative forces that may be applied to the housing 20 as a whole.

In addition, the outer portion 17 can be appropriately welded to the housing 20 at or adjacent the perimeter 14 thereof.

Fig. 7 depicts a still further embodiment which does not rely on use of an internal microphone 22 and instead relies on use of a piezoelectric mechanical strain transducer 24. As depicted, the transducer 24 can be mounted to the second side 13 of the inner portion 16 of the diaphragm 11.

The diaphragm assembly 10 can be formed through use of one or more following techniques:

laser engraving, electron or ion beam welding, erosion or deposition techniques, electrical discharge machining, electrochemical machining, chemical deposition and pressure or impact forming.

The present invention provides a diaphragm assembly that is preferably at least substantially protected from distortion that might arise, for example, from non-uniform mechanical stress or thermal expansion and contraction during manufacture and/or welding of the assembly to the housing 20 and/or during the service life of the assembly, housing or prosthesis. Such distortion is undesirable as it can seriously degrade both the sensitivity and frequency response of the microphone or transducer used in an implantable prosthesis.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS:

1. A diaphragm assembly for hermetically sealing an opening in a housing of an implantable prosthesis, the assembly comprising:

a diaphragm having a first surface, a second surface opposed to said first surface and a perimeter; and

a strengthening member disposed a distance inwardly from said perimeter and dividing said diaphragm into an inner portion and an outer portion;

wherein said strengthening member has a rigidity relatively higher than said inner portion and/or said outer portion of the diaphragm.

2. The diaphragm assembly of claim 1 wherein the diaphragm assembly is formed in one piece or is formed from two or more pieces that are suitably joined and/or adhered to each other.

3. The diaphragm assembly of claim 1 or claim 2 wherein the strengthening member extends outwardly from the first surface and/or the second surface of the diaphragm.

4. The diaphragm assembly of claim 3 wherein the strengthening member has a height that is greater than the thickness of the inner portion and/or the outer portion of the diaphragm.

5. The diaphragm assembly of claim 4 wherein the height of the strengthening member is greater than the thickness of inner portion and/or the outer portion.

6. The diaphragm assembly of claim 4 or claim 5 wherein the thickness of the inner portion is about equal to the thickness of the outer portion.

7. The diaphragm assembly of any one of the preceding claims wherein the perimeter of the diaphragm is circular.

8. The diaphragm assembly of claim 7 wherein the strengthening member is disposed at an approximately constant distance inwardly from the perimeter.

9. The diaphragm assembly of claim 7 or claim 8 wherein the width of the outer portion is about the same around the perimeter of the diaphragm.

10. The diaphragm assembly of any one of the preceding claims wherein the outer portion is corrugated, folded, ridged or dimpled in a manner that imparts additional elasticity.

11. The diaphragm assembly of claim 10 wherein the outer portion has one or more annular corrugations.

12. The diaphragm assembly of claim 11 wherein the outer portion has two concentric corrugations.

13. The diaphragm assembly of any one of the preceding claims wherein the inner portion has one or more annular corrugations.

14. The diaphragm assembly of any one of the preceding claims wherein at least part of the first surface and/or the second surface of the outer portion is dimpled.

15. The diaphragm assembly of claim 14 wherein all of the first surface and/or the second surface of the outer portion is dimpled.

16. The diaphragm assembly of any one of the preceding claims wherein the inner and outer portions are at least substantially in the same plane.

17. The diaphragm assembly of any one of claims 1 to 15 wherein the inner and outer portions are in different planes.

18. The diaphragm assembly of claim 17 wherein the inner and outer portions are in at least substantially parallel planes.

19. The diaphragm assembly of any one of the preceding claims wherein the strengthening member has a rigidity relative higher than the inner portion and the outer potion of the diaphragm.

20. The diaphragm assembly of any one of the preceding claims wherein the strengthening member is connected or mechanically or acoustically coupled to a microphone coupling positioned within the housing of the implantable prosthesis.

21. The diaphragm assembly of claim 20 wherein the strengthening member is connectable to the microphone coupling using an adhesive.

22. The diaphragm assembly of claim 20 or claim 21 wherein the outer portion is weldable to the housing.

23. The diaphragm assembly of any one of claims 1 to 19 wherein a microphone coupling is connected to an inner surface of the housing.

24. The diaphragm assembly of any one of claims 20 to 22 wherein the microphone coupling comprises a funnel-shaped member extending from the opening to an inner end.

25. The diaphragm assembly of claim 24 wherein a microphone is positioned at the inner end of the microphone coupling.

26. The diaphragm assembly of any one of claims 1 to 19 wherein a transducer is mounted to the inner portion of the diaphragm.

27. The diaphragm assembly of claim 26 wherein the transducer is mounted to the second surface of the inner portion of the diaphragm.

28. The diaphragm assembly of any one of the preceding claims wherein the prosthesis is an auditory prosthesis.

29. The diaphragm assembly of claim 28 wherein the auditory prosthesis is a cochlear implant.

30. The diaphragm assembly of any one of the preceding claims wherein the diaphragm assembly is formed from titanium or a titanium alloy.

31. The diaphragm assembly of any one of the preceding claims wherein the diaphragm assembly is formed through use of one or more following techniques:

laser engraving, electron or ion beam welding, erosion or deposition, electrical discharge machining, electrochemical machining, chemical deposition and pressure or impact forming.

32. An implantable component of an auditory prosthesis, the implantable component comprising:

a housing having an opening;

a microphone disposed in said housing at least adjacent said opening; and

a diaphragm assembly hermetically sealing said opening, the assembly comprising:

a diaphragm having a first surface, a second surface opposed to said first surface and a perimeter; and

a strengthening member disposed a distance inwardly from said perimeter and dividing said diaphragm into an inner portion and an outer portion;

wherein said strengthening member has a rigidity relatively higher than said inner portion and/or said outer portion of the diaphragm.

33. An implantable component of a prosthesis, the implantable component comprising:

a housing having an opening; and

a diaphragm assembly hermetically sealing said opening, the assembly comprising:

a diaphragm having a first surface, a second surface opposed to said first surface and a perimeter; and

a strengthening member disposed a distance inwardly from said perimeter and dividing said diaphragm into an inner portion and an outer portion;

wherein said strengthening member has a rigidity relatively higher than said inner portion and/or said outer portion of the diaphragm; and

a transducer mounted to the inner portion of said diaphragm.

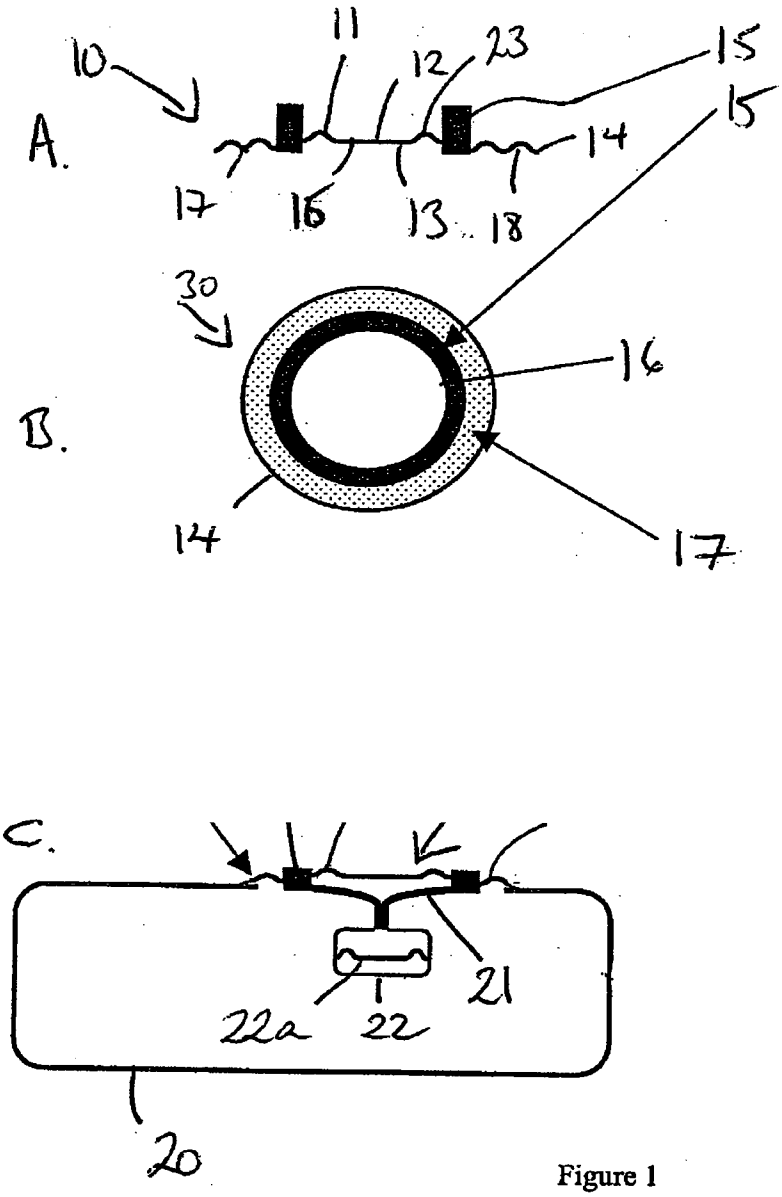

Figure 1

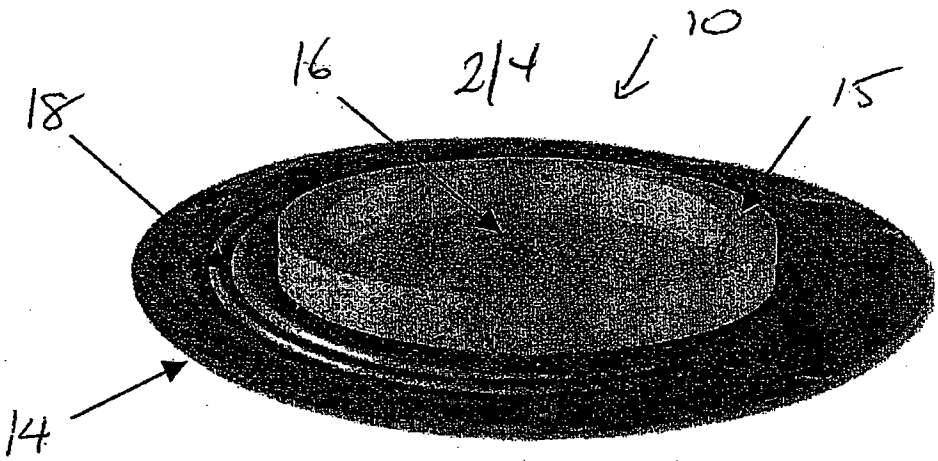

Figure 2

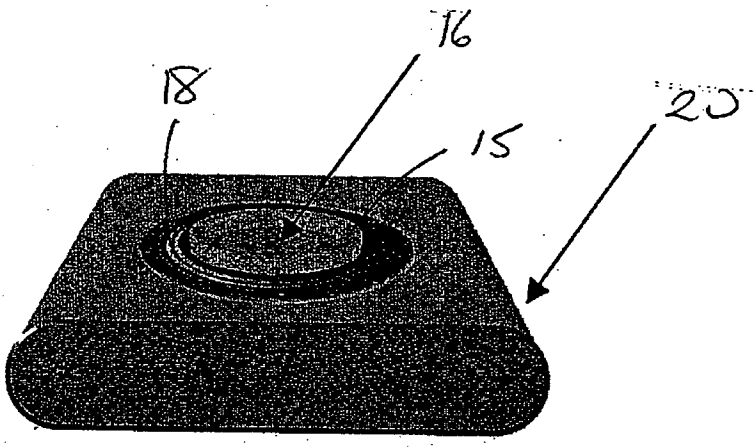

Figure 3

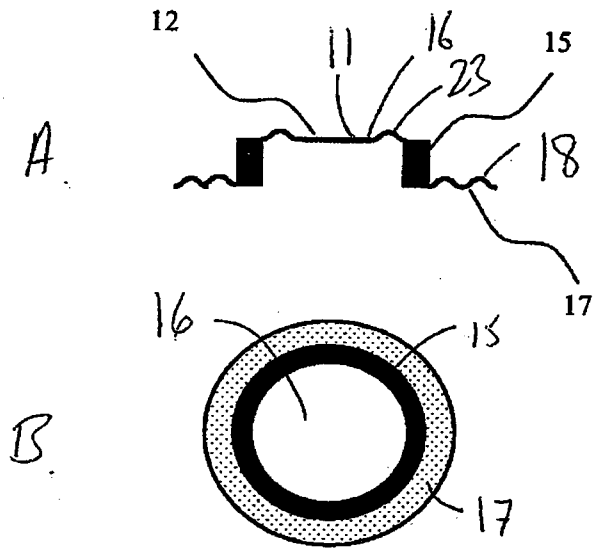

Fig. 4.

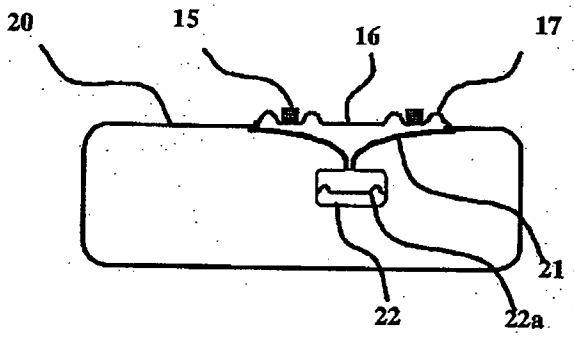

Figure 5

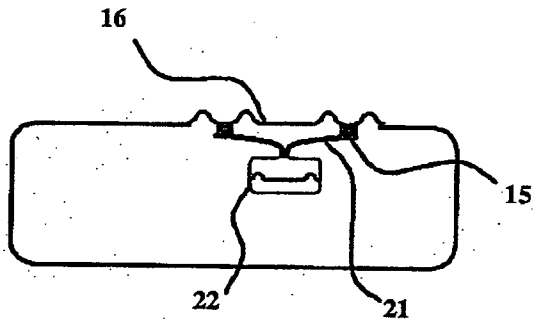

Figure 6

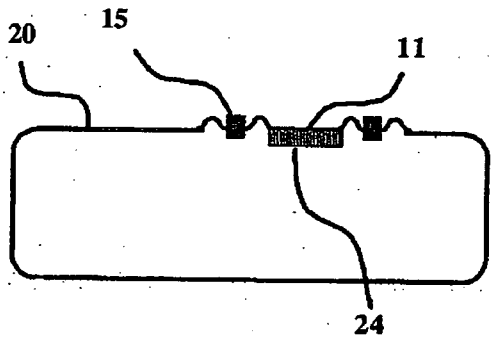

Figure 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2009/000698

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

H04R 25/00 (2006.01) ***A61F 2/18*** (2006.01) ***H04R 7/00*** (2006.01)

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)

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)
EPODOC, WPI: IPC- A61F 2/-, 11/- or H04R 7/- and Keywords- (auditory, prosthesis, strengthen, diaphragm, seal) and like terms
Google Patents: Keywords- (diaphragm, hermetically, seal, microphone, implant, stiff) in various combinations

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4969900 A (FLEISCHER, 13 November 1990) See Abstract, Figures 8-10, column 5 lines 15-22	1-19, 26-33
X	US 5881158 A (LESINSKI et al., 9 March 1999) See Abstract, Figure 2C, column 5 lines 16-17	1-19, 26-33
A	US 6093144 A (JAEGER et al., 25 July 2000) See whole document	

[X] Further documents are listed in the continuation of Box C [X] 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
22 July 2009	24 JUL 2009
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer **EMMA FRANCIS** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : +61 3 9935 9631

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2009/000698

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5859916 A (BALL et al., 12 January 1999) See whole document	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2009/000698

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

Patent Document Cited in Search Report		Patent Family Member					
US	4969900	DE	3707161	EP	0281047	JP	63283636
US	5881158	AU	30108/97	CA	2256389	CA	2479822
		EP	0963683	EP	1596629	KR	20000016084
		US	6381336	WO	1997/044987		
US	6093144	AU	18118/99	EP	1060638	US	6422991
		US	6626822	US	7322930	US	2004/0039245
		US	2008/0167516	WO	1999/031933		
US	5859916	AU	37263/97	WO	1998/003035		

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX