



- (51) **International Patent Classification:**
A61N 1/05 (2006.01) *A61N 1/36* (2006.01)
- (21) **International Application Number:**
PCT/US2011/065038
- (22) **International Filing Date:**
15 December 2011 (15.12.2011)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/423,714 16 December 2010 (16.12.2010) US
- (71) **Applicant (for all designated States except US):** MED-EL
ELEKTROMEDIZINISCHE GERAETE GMBH
[AT/US]; Fuerstenweg 77, A-6020 Innsbruck (AT).
- (72) **Inventor; and**
- (75) **Inventor/Applicant (for US only):** JOLLY, Claude
[FR/AT]; Karl-innerebner Str. 95a C4, A-6020 Innsbruck
(AT).
- (74) **Agents:** SUNSTEIN, Bruce D. et al.; Sunstein Kann
Murphy & Timbers LLP, 125 Summer Street, Boston, MA
02110 (US).
- (81) **Designated States (unless otherwise indicated, for every
kind of national protection available):** AE, AG, AL, AM,

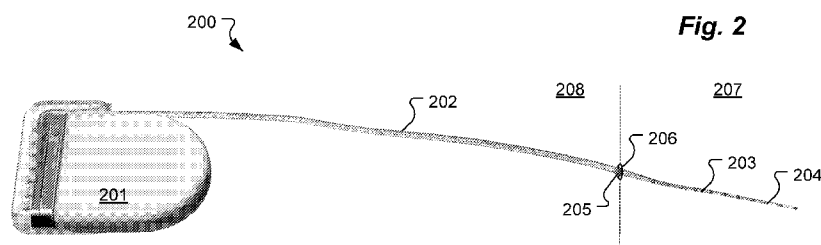
AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR,
KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, 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, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, 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, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments (Rule 48.2(h))

(54) **Title:** COCHLEAR IMPLANT WITH COCHLEOSTOMY GROUND



(57) **Abstract:** A cochlear implant electrode arrangement is described. An electrode lead is connected to an implantable stimulator and contains electrode wires for carrying stimulation signals from the implantable stimulator. An electrode array penetrates through a cochleostomy opening into a patient cochlea for immersion in cochlear fluid within the cochlea. The electrode array has electrode contacts for delivering the stimulation signals to adjacent neural tissue. A cochleostomy ground contact at the cochleostomy opening separates the electrode lead and the electrode array and provides a return current path for the stimulation signals. There may also be a stimulator ground contact on an outer surface of the implantable stimulator that provides a second return current path for the stimulation signals.



TITLE

Cochlear Implant with Cochleostomy Ground

[0001] This application claims priority from U.S. Provisional Patent Application 61/423,714, filed December 16, 2010; which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present invention relates to a ground electrode arrangement for a cochlear implant system.

BACKGROUND ART

[0003] A normal ear transmits sounds as shown in Figure 1 through the outer ear **101** to the tympanic membrane **102**, which moves the bones of the middle ear **103** that vibrate the oval window opening 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 acoustic nerve **113** 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 **113**, 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, auditory prostheses have been developed. For example, when the impairment is related to operation of the middle ear **103**, a conventional hearing aid 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] Figure 1 also shows some components of a typical cochlear implant system which includes an external microphone that provides an audio signal input to an external signal processor **111** where various signal processing schemes can be implemented. The processed signal is then converted into a digital data format, such as a sequence of data frames, for transmission into an implanted stimulator **108**. Besides receiving the processed audio information, the implanted stimulator **108** may also perform additional signal processing such as error correction, pulse formation, etc., and produces stimulation signals (based on the extracted audio information) that is sent through an electrode lead **109** to an implanted electrode array **112**. Typically, this electrode array **112** includes multiple electrode contacts **110** on its surface that deliver the stimulation signals to adjacent neural tissue of the cochlea **104** which the brain of the patient interprets as sound. The individual electrode contacts **110** may be activated sequentially, or simultaneously in one or more groups of electrode contacts **110**.

[0006] The electrical stimulation signals are usually in a monopolar mode between one active electrode contact **110** within the cochlea **104** and a distant extra-cochlear ground contact for the return current. For example, the ground contact may be on the extra-cochlear electrode lead **109** itself, or on a separate branch member. The surface area of the ground contact is usually much larger than that of an individual electrode contact **110** in order to minimize charge density and distribute the return current over a larger area.

[0007] Sometimes in some cochlear implant patients, in addition to the desired auditory stimulation, one or more electrode contacts **110** may also create unwanted stimulation of the facial nerve. In some extreme cases, the stimulation to the facial nerve may occur on all the electrode contacts **110**. Facial nerve stimulation may occur when the patient fit programming to make the stimulation signals loud enough for optimal auditory perception exceeds the threshold for facial nerve stimulation. One possible reason for this may be because the bone of the cochlear may be sclerotic as in otosclerosis. Other possible reasons could include one or more bone thickness abnormalities of the bone that surrounds the cochlear fluids, or that the facial nerve may have an aberrant course around the exterior of the cochlear bone.

[0008] To date the problem has been solved by turning off individual electrode contacts **110** that undesirably stimulate the facial nerve. Another way that the problem has been approached is by using perimodiolar electrode contacts **110** that approach the modiolus and the nerve elements. When the electrode array **112** is displaced toward the inner wall of the cochlea **104**, the electrode contacts **110** are presumably at an adequate distance from the facial nerve.

SUMMARY

[0009] Embodiments of the present invention are directed to a cochlear implant electrode arrangement. An electrode lead is connected to an implantable stimulator and contains electrode wires for carrying stimulation signals from the implantable stimulator. An electrode array penetrates through a cochleostomy opening into a patient cochlea for immersion in cochlear fluid within the cochlea. The electrode array has electrode contacts for delivering the stimulation signals to adjacent neural tissue. A cochleostomy ground contact at the cochleostomy opening separates the electrode lead and the electrode array and provides a return current path for the stimulation signals.

[0010] In some embodiments, there may also be a stimulator ground contact on an outer surface of the implantable stimulator that provides a second return current path for the stimulation signals. The cochleostomy ground contact and the stimulator ground contact may be switchably selectable, for example, so that the cochleostomy ground contact provides the return current path for electrode contacts which affect the facial nerve, and the stimulator ground contact provides the return current path for all other electrode contacts.

[0011] In specific embodiments, the cochleostomy ground contact may span a length of the electrode from outside the cochleostomy opening to inside the cochleostomy opening. The cochleostomy ground contact may be larger than any of the electrode contacts.

[0012] Embodiments of the present invention also include a cochlear implant system having an electrode arrangement according to any of the above.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Figure 1 shows a section view of the anatomy of a human ear containing a typical cochlear implant (CI) system.

[0014] Figure 2 shows a CI system according to one embodiment of the present invention having a ground electrode at the cochleostomy window.

[0015] Figure 3 shows a CI system according to another embodiment of the present invention having one ground electrode at the cochleostomy window and another ground electrode on the stimulator housing.

DETAILED DESCRIPTION

[0016] Various embodiments of the present invention are directed to an electrode ground arrangement for cochlear implant systems that avoids facial nerve stimulation. Figure 2 shows a cochlear implant system **200** according to one embodiment of the present invention. An electrode lead **202** is connected to an implantable stimulator **201** and contains electrode wires for carrying stimulation signals from the implantable stimulator **201**. An electrode array **203** penetrates through a cochleostomy opening **206** into a patient cochlea **207** for immersion in cochlear fluid within the cochlea **207**. The electrode array **203** has electrode contacts **204** for delivering the stimulation signals to adjacent neural tissue. A cochleostomy ground contact **205** at the cochleostomy opening **206** separates the electrode lead **202** and the electrode array **203** and provides a return current path for the stimulation signals.

[0017] The cochleostomy ground contact **205** is much larger than the electrode contacts **204** and spans a length from the middle ear **208** outside the cochleostomy opening **206** to within the cochlea **207** inside the cochleostomy opening **206**. This situates the cochleostomy ground contact **205** close to or partially within the scala tympani fluid of the cochlea **207**, but still at some relative distance (e.g., 3-4 mm) from the first active electrode contact **204** at the base of the electrode array **203**. The return current return path is also more direct from the active electrode contact **204** to the cochleostomy ground contact **205** and has a tendency to remain confined within the conductive scala tympani

fluid without escaping through the abnormal surrounding bone connected to the facial nerve.

[0018] If we consider bipolar stimulation as referring to a signal applied between two adjacent electrode contacts on an equidistant array of contacts, then the stimulation mode in embodiments of the present invention is not bipolar, but rather quasi monopolar between the cochleostomy ground contact **205** and the first active electrode contact **204** at the base of the electrode array **203**, and then for the second active electrode contact **204** the stimulation mode is quasi monopolar +1, (one space between the first electrode contact and the second), then quasi monopolar +2, etc. At some distance from the cochleostomy ground contact **205** the electric field lines from the stimulation pulses stay the same.

[0019] Figure 3 shows an alternative cochlear implant system **200** according to another embodiment of the present invention having one cochleostomy ground contact **302** at the cochleostomy opening **206** and another stimulation ground contact **301** on the outer surface of the housing of the implantable stimulator **201** that provides a second return current path for the stimulation signals. The cochleostomy ground contact **302** and the stimulator ground contact **301** may be switchably selectable, for example, by system software so that the cochleostomy ground contact **302** provides the return current path for electrode contacts **204** which affect the facial nerve, and the stimulator ground contact **301** provides the return current path for all other electrode contacts **204**.

[0020] Thus with embodiments of the present invention, all the electrode contacts **204** can be used even if there is some initial stimulation of the facial nerve after the implanted system is turned on. For such adverse reactions, the implicated electrode contacts **204** can be paired with the cochleostomy ground contact **205** or **302** and there will be no unused regions without stimulation along the length of the electrode array **204**.

[0021] 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. A cochlear implant electrode arrangement comprising:
an electrode lead connected to an implantable stimulator and containing a plurality of electrode wires for carrying stimulation signals from the implantable stimulator and;
an electrode array penetrating through a cochleostomy opening into a patient cochlea for immersion in cochlear fluid within the cochlea, the electrode array having a plurality of electrode contacts for delivering the stimulation signals to adjacent neural tissue; and
a cochleostomy ground contact at the cochleostomy opening separating the electrode lead and the electrode array and providing a return current path for the stimulation signals.
2. An electrode arrangement according to claim 1, further comprising:
a stimulator ground contact on an outer surface of the implantable stimulator and
providing a second return current path for the stimulation signals.
3. An electrode arrangement according to claim 2, wherein the cochleostomy ground contact and the stimulator ground contact are switchably selectable.
4. An electrode arrangement according to claim 2, wherein the cochleostomy ground contact provides the return current path for electrode contacts which affect the facial nerve, and the stimulator ground contact provides the return current path for all other electrode contacts.
5. An electrode arrangement according to claim 1, wherein the cochleostomy ground contact spans a length of the electrode from outside the cochleostomy opening to inside the cochleostomy opening.
6. An electrode arrangement according to claim 1, wherein the cochleostomy ground

contact is larger than any of the electrode contacts.

7. A cochlear implant system having an electrode arrangement according to any of claims 1-5.

1/3

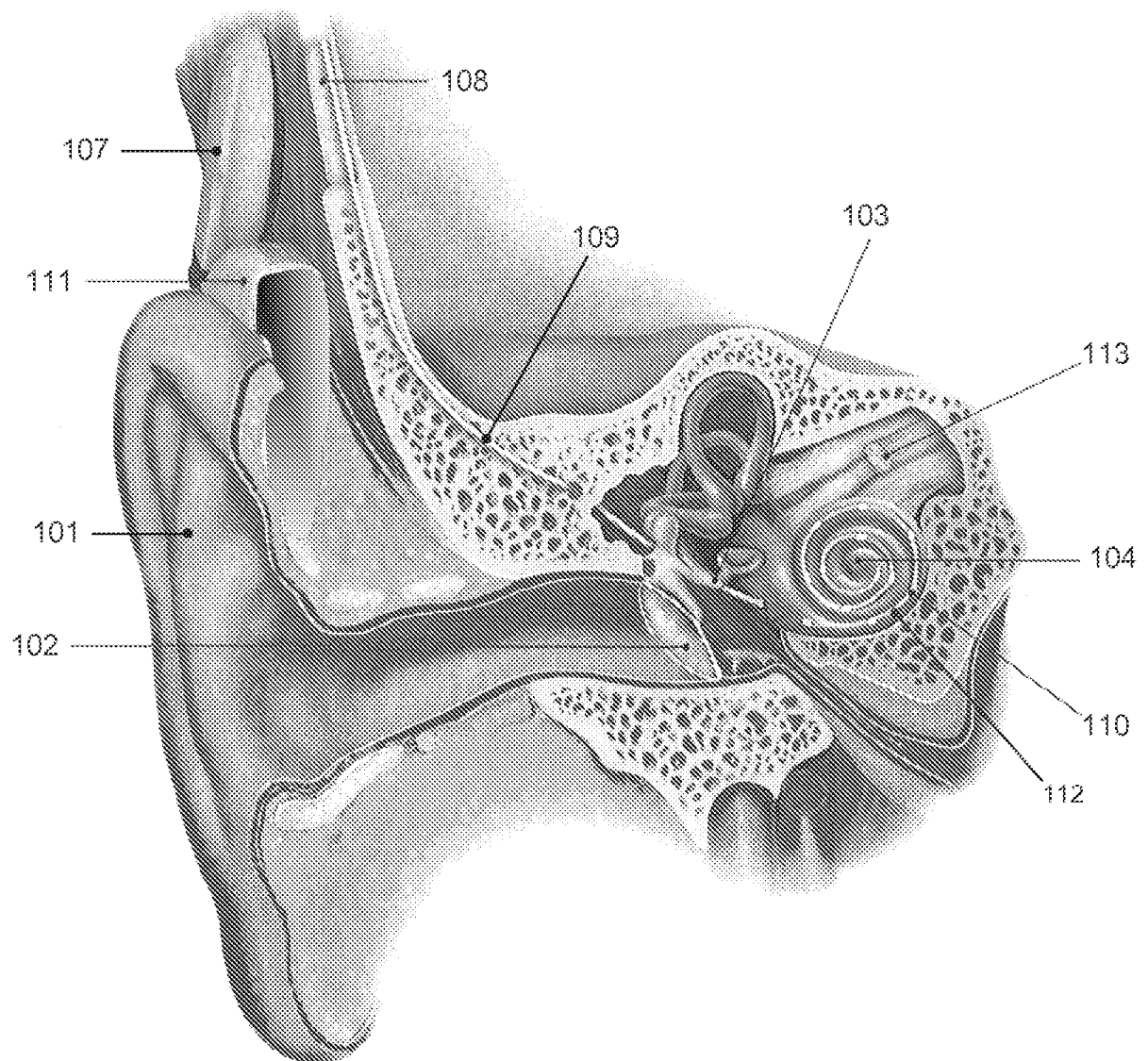


Fig. 1

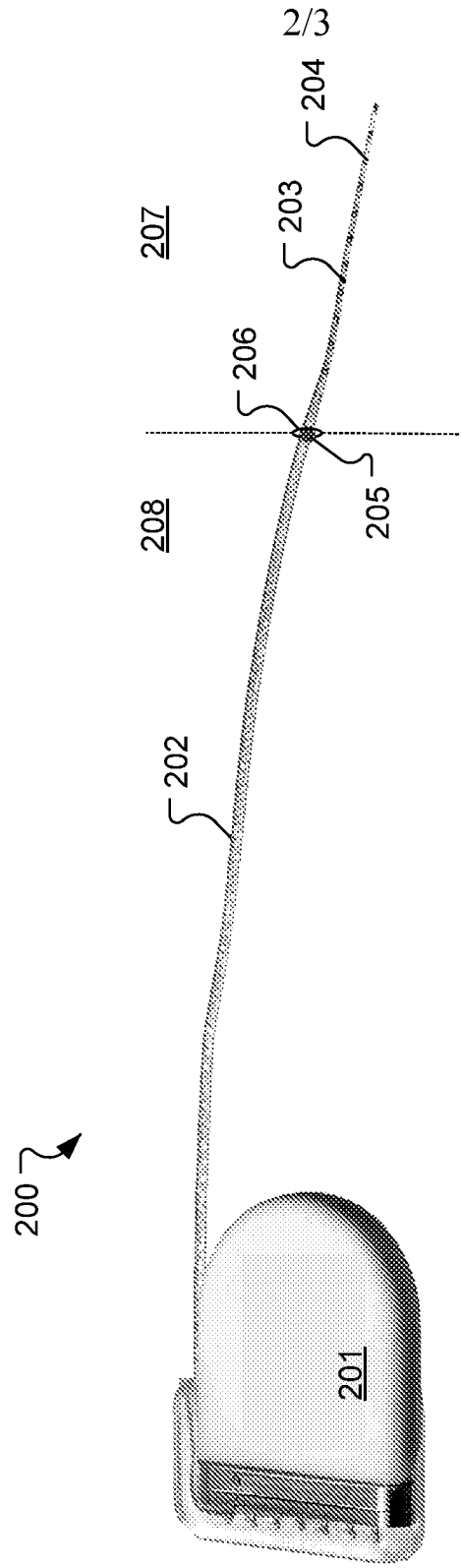


Fig. 2

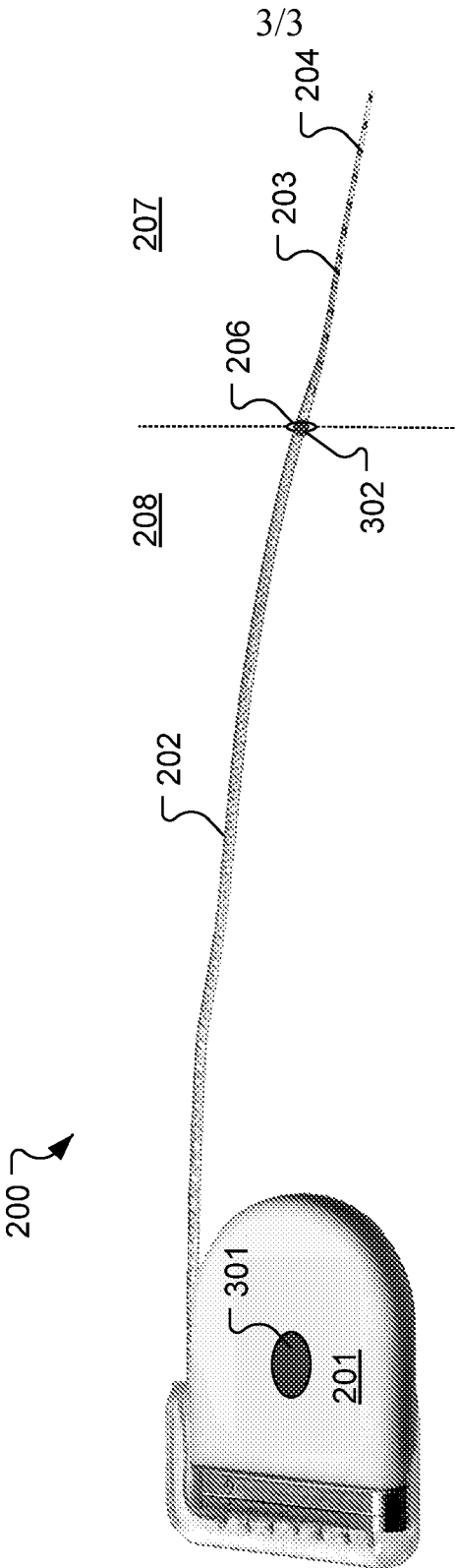


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/065038

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61N1/05
ADD. A61N1/36

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)

A61N

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.
X	US 2009/143848 A1 (GREENBERG ROBERT J [US] ET AL) 4 June 2009 (2009-06-04)	1,5-7
Y	paragraphs [0005] - [0006], [0012], [0043] - [0045], [0055] - [0056]; figures 3-4	2-4
A	----- US 6 112 124 A (LOEB GERALD E [CA]) 29 August 2000 (2000-08-29) the whole document	1,5-7
A	----- US 2005/216073 A1 (JOLLY CLAUDE [AT] ET AL) 29 September 2005 (2005-09-29) the whole document ----- -/--	1,5-7

☒ 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

8 May 2012

Date of mailing of the international search report

14/05/2012

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Smit, Jos

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/065038

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 6 889 094 B1 (KUZMA JANUSZ A [US] ET AL) 3 May 2005 (2005-05-03) column 8, line 13 - column 9, line 13; figure 10 column 3, lines 17-34 -----	2
Y	US 7 194 314 B1 (RICHTER CLAUS-PETER [US] ET AL) 20 March 2007 (2007-03-20) column 17, lines 11-47 column 6, lines 57-62; figure 4 -----	3,4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/065038

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.:
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:

see additional sheet

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 an 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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1, 5-7

Cochlear implant electrode arrangement comprising an electrode lead, an electrode array and a cochleostomy ground contact, and a system having such an electrode arrangement; and

2. claims: 1-4, 7

Cochlear implant electrode arrangement comprising an electrode lead, an electrode array, a cochleostomy ground contact and a stimulator ground contact, both ground contacts being switchably selectable, and a system having such an electrode arrangement.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2011/065038

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009143848	A1	04-06-2009	AU 2008323691 A1 14-05-2009
			EP 2224999 A2 08-09-2010
			US 2009143848 A1 04-06-2009
			WO 2009062114 A2 14-05-2009
US 6112124	A	29-08-2000	NONE
US 2005216073	A1	29-09-2005	NONE
US 6889094	B1	03-05-2005	NONE
US 7194314	B1	20-03-2007	NONE