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(54) **Title:** APPARATUS AND METHODS FOR IMPLANT COUPLING INDICATION

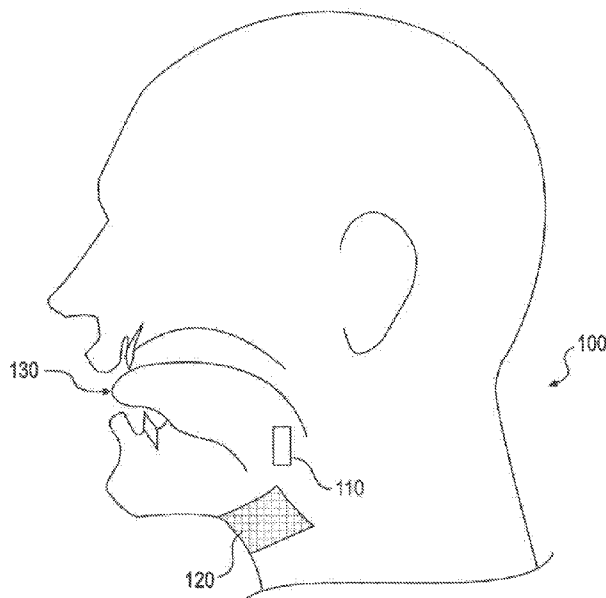


Fig. 2

(57) **Abstract:** A device is disclosed that includes an external unit configured to communicate with an implant unit beneath the skin of a subject and an indicator associated with the external unit. The indicator is configured to produce an indicator signal when the external unit is within a predetermined range of the implant unit. In addition, the indicator may be configured to vary the indicator signal according to a distance between the external unit and the implant unit. Furthermore, a method of locating an external unit with respect to an implant unit is disclosed that includes detecting a distance between the external unit and the implanted unit located beneath the skin of a subject, producing an indicator signal when the external unit is within a predetermined range of the implant unit, and varying the indicator signal as a function of a distance between the external unit and the implant unit.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB12/02357

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 5/08; A61N 1/00 (2013.01)

USPC - 607/116, 115, 42, 2, 1; 600/529, 300

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)

IPC(8): A61B 5/08; A61N 1/00 (2013.01)

USPC: 607/116, 115, 42, 2, 1; 600/529, 300

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)

MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); PubMed/MEDLINE; Google/GoogleScholar; IP.com: sleep, apnea, modulate, nerve, degree, coupling, indicator, mode, signal, alarm

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 7725195 B2 (LIMA, MG et al.) May 25, 2010; column 2, lines 33-35; column 4, lines 30-35; column 8, lines 62-67; column 11, lines 11-26, 44-48, column 12, lines 56-61	1, 2, 7-8 6, 9-10, 14
Y	WO 2011/077433 A1 (MASHIACH, A et al.) June 30, 2011; pages 9, 12-14, 18	1, 3-6, 9-14
Y	US 2010/0191136 A1 (WOLFORD, DK) July 29, 2010; abstract, paragraph [0033]	1, 3-5, 9-13
Y	US 2011/0065979 A1 (LEHRMAN, ML et al.) March 17, 2011; paragraphs [0071]-[0074]	3-5, 12-13

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB12/02357

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:

Group I: Claims 1-14 are directed toward a sleep apnea treatment device, comprising: an external unit configured for location on a neck of a subject to communicate with an implant unit implanted proximal to a tongue of a subject; and an indicator associated with the external unit, wherein the indicator is configured to produce an indicator signal when the external unit is within a predetermined range of the implant unit, and wherein the indicator is configured to vary the indicator signal according to a distance between the external unit and the implant unit.

Group II: Claims 15-25 are directed toward a device, comprising: an external unit configured to communicate with an implant unit beneath the skin of a subject; an indicator associated with the external unit; and at least one processor configured to: generate a primary signal on a primary antenna associated with the external unit, the primary signal being configured to cause a secondary signal on a secondary antenna associated with the implant unit; determine a degree of coupling between the primary antenna associated with the external unit and the secondary antenna associated with the implant unit; and cause the indicator to produce a signal when the degree of coupling exceeds a predetermined threshold.

***Continued on Supplemental 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 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.:
1-14

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.

Continuation of Box III

Group III: Claim 26 is directed toward a device, comprising: an external unit configured to communicate with an implant unit beneath the skin of a subject; and an indicator associated with the external unit, wherein the indicator is configured to produce an indicator signal when the external unit is within a predetermined range of the implant unit, and wherein the indicator is configured to vary the indicator signal according to a distance between the external unit and the implant unit.

Group IV: Claim 27 is directed toward a hypertension therapy device for affecting blood pressure, the hypertension therapy device comprising: a housing configured for location on a subject to communicate with an implant unit implanted proximate to at least one of the renal nerve, a baroreceptor, and a glossopharyngeal nerve; and an indicator associated with the housing, wherein the indicator is configured to produce an indicator signal when the housing is within a predetermined range of the implant unit, and wherein the indicator is configured to vary the indicator signal according to a distance between the housing and the implant unit.

Group V: Claim 28 is directed toward a head pain management device, comprising: a patch configured for placement on a side of a hairline opposite a substantially haired region of a subject; and an indicator associated with the patch, wherein the indicator is configured to produce an indicator signal when the patch is within a predetermined range of the implant unit, and wherein the indicator is configured to vary the indicator signal according to a distance between the patch and the implant unit.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I include a sleep apnea treatment device, comprising: an external unit configured for location on a neck of a subject to communicate with an implant unit implanted proximal to a tongue of a subject; and an indicator associated with the external unit, wherein the indicator is configured to produce an indicator signal when the external unit is within a predetermined range of the implant unit, and wherein the indicator is configured to vary the indicator signal according to a distance between the external unit and the implant unit, which are not present in Group II, Group II having special technical features including a device, comprising: an external unit configured to communicate with an implant unit beneath the skin of a subject; an indicator associated with the external unit; and at least one processor configured to: generate a primary signal on a primary antenna associated with the external unit, the primary signal being configured to cause a secondary signal on a secondary antenna associated with the implant unit; determine a degree of coupling between the primary antenna associated with the external unit and the secondary antenna associated with the implant unit; and cause the indicator to produce a signal when the degree of coupling exceeds a predetermined threshold, which are not present in Group III, Group III having special technical features including a device, comprising: an external unit configured to communicate with an implant unit beneath the skin of a subject; and an indicator associated with the external unit, wherein the indicator is configured to produce an indicator signal when the external unit is within a predetermined range of the implant unit, and wherein the indicator is configured to vary the indicator signal according to a distance between the external unit and the implant unit, which are not present in Group IV, Group IV having special technical features including a hypertension therapy device for affecting blood pressure, the hypertension therapy device comprising: a housing configured for location on a subject to communicate with an implant unit implanted proximate to at least one of the renal nerve, a baroreceptor, and a glossopharyngeal nerve; and an indicator associated with the housing, wherein the indicator is configured to produce an indicator signal when the housing is within a predetermined range of the implant unit, and wherein the indicator is configured to vary the indicator signal according to a distance between the housing and the implant unit, which are not present in Group V, Group V having special technical features including a head pain management device, comprising: a patch configured for placement on a side of a hairline opposite a substantially haired region of a subject; and an indicator associated with the patch, wherein the indicator is configured to produce an indicator signal when the patch is within a predetermined range of the implant unit, and wherein the indicator is configured to vary the indicator signal according to a distance between the patch and the implant unit.

Groups I-V share the technical features including device, comprising: an external unit configured for an external location of a subject to communicate with an implant unit implanted within a subject; and an indicator associated with the external unit, wherein the indicator is configured to produce an indicator signal when the external unit is within a predetermined range of the implant unit.

However, these shared technical features are previously disclosed by US 6,261,247 B1 to Ishikawa, et al. (hereinafter 'Ishikawa'). Ishikawa discloses a device (abstract), comprising: an external unit (Claim 1) configured for an external location of a subject to communicate with an implant unit implanted within a subject (abstract; Claims 1, 7); and an indicator associated with the external unit (abstract; alarm providing audible alerts), wherein the indicator is configured to produce an indicator signal when the external unit is within a predetermined range of the implant unit (abstract; column 5, lines 44-53; if the distance is less than some predetermined value set by the control panel 114, the CPU 112 can generate an alarm, such as a series of rapid beeps, using the audible alarm 120).

Since none of the special technical features of the Groups I-V inventions is found in more than one of the inventions, and since all of the shared technical features are previously disclosed by the Ishikawa reference, unity of invention is lacking.