PTO-1390 (01-17)
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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

Attorney Docket No.	
I618.118.103	
U.S. Application No. (if known, see 37 CFR 1.5)	

International Application No.	International Filing Date	Priority Date Claimed
PCT/US2016/022611	2016/03/16	2015/03/19

Title of Invention
STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

First Named Inventor
Darrell Wagner et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information.

1. ☑ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). NOTE: The express request under 35 U.S.C. 371(f) will not be effective unless the requirements under 35 U.S.C. 371(c)(1), (2), and (4) for payment of the basic national fee, copy of the International Application and English translation thereof (if required), and the oath or declaration of the inventor(s) have been received.
2. ☐ A copy of the International Application (35 U.S.C. 371(c)(2)) is attached hereto (not required if the International Application was previously communicated by the International Bureau or was filed in the United States Receiving Office (RO/US)).
3. An English language translation of the International Application (35 U.S.C. 371(c)(2))
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
4. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4))
   a. ☐ is attached.
   b. ☐ was previously filed in the international phase under PCT Rule 4.17(iv).

Items 5 to 8 below concern amendments made in the international phase.

PCT Article 19 and 34 amendments

5. ☐ Amendments to the claims under PCT Article 19 are attached (not required if communicated by the International Bureau) (35 U.S.C. 371(c)(3)).
6. ☐ English translation of the PCT Article 19 amendment is attached (35 U.S.C. 371(c)(3)).
7. ☐ English translation of annexes (Article 19 and/or 34 amendments only) of the International Preliminary Examination Report is attached (35 U.S.C. 371(c)(5)).

Cancellation of amendments made in the international phase

8a. ☐ Do not enter the amendment made in the international phase under PCT Article 19.

8b. ☐ Do not enter the amendment made in the international phase under PCT Article 34.

NOTE: A proper amendment made in English under Article 19 or 34 will be entered in the U.S. national phase application absent a clear instruction from applicant not to enter the amendment(s).

The following items 9 to 17 concern a document(s) or information included.

9. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
10. ☐ A preliminary amendment.
11. ☑ An Application Data Sheet under 37 CFR 1.76.
12. ☐ A substitute specification. NOTE: A substitute specification cannot include claims. See 37 CFR 1.125(b).
13. ☐ A power of attorney and/or change of address letter.
14. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.3 and 37 CFR 1.821-1.825.
15. ☐ Assignment papers *(cover sheet and document(s))*. Name of Assignee: _____
16. ☐ 37 CFR 3.73(c) Statement *(when there is an Assignee)*.

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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U.S. APPLN. No. (if known – see 37 CFR 1.5)	INTERNATIONAL APPLICATION No.	ATTORNEY DOCKET No.
	PCT/US2016/022611	I618.118.103

17. ☐ Other items or information:

The following fees have been submitted.	CALCULATIONS	PTO USE ONLY
18. ☑ Basic national fee (37 CFR 1.492(a)) **$280**	$ 280	
19. ☑ Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... **$0** All other situations **$720**	$ 720	
20. ☑ Search fee (37 CFR 1.492(b)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... **$0** Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... **$120** International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... **$480** All other situations **$600**	$ 480	
TOTAL OF 18, 19, and 20 =	$ 1480	
☐ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)). Fee for each additional 50 sheets of paper or fraction thereof **$400**		

Total Sheets	Extra Sheets	Number of each addition 50 or fraction thereof (round **up** to a whole number)	RATE	
- 100 =	/ 50 =		x **$400**	$
Surcharge of **$140.00** for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h))				$

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	20 - 20 =		x **$80**	$	
Independent claims	1 - 3 =		x **$420**	$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$780**	$	
Processing fee of **$140.00** for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). +				$	
TOTAL OF ABOVE CALCULATIONS =				$ 1480	
☐ **Applicant asserts small entity status.** See 37 CFR 1.27. Fees above are reduced by ½.					
☐ **Applicant certifies micro entity status.** See 37 CFR 1.29. Fees above are reduced by ¾. Applicant must attach form PTO/SB/15A or B or equivalent.					
TOTAL NATIONAL FEE =				$ 1480	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property. +				$	
TOTAL FEES ENCLOSED =				$ 1480	
				Amount to be refunded:	$
				Amount to be charged:	$ 1480

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0002

a. ☐ A check in the amount of $_____ to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $_____ to cover the above fees.

c. ☐ The Director is hereby authorized to charge additional fees which may be required, or credit any overpayment, to Deposit Account No. _____ as follows:

i. ☐ any required fee.

ii. ☐ any required fee except for excess claims fees required under 37 CFR 1.492(d) and (e) and multiple dependent claim fee required under 37 CFR 1.492(f).

d. ☑ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. The PTO-2038 should only be mailed or faxed to the USPTO. However, when paying the basic national fee, the PTO-2038 may NOT be faxed to the USPTO.

ADVISORY: If filing by EFS-Web, do **NOT** attach the PTO-2038 form as a PDF along with your EFS-Web submission. Please be advised that this is **not** recommended and by doing so your **credit card information may be displayed via PAIR**. To protect your information, it is recommended to pay fees online by using the electronic payment method.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File)Transition Applications

☑ This application (1) claims priority to or the benefit of an application filed before March 16, 2013, and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

NOTE 1: By providing this statement under 37 CFR 1.55 or 1.78, **this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA**.

NOTE 2: A U.S. national stage application may not claim priority to the international application of which it is the national phase. The filing date of a U.S. national stage application is the international filing date. See 35 U.S.C. 363.

Correspondence Address

☑ The address associated with Customer Number: 25281 **OR** ☐ Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone			
Email					

Signature	/Paul S. Grunzweig/	Date	2017-09-28
Name (Print/Type)	Paul S. Grunzweig	Registration No. (Attorney/Agent)	37143

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc Code: PET.PCT
Document Description: Petition for review by the PCT Legal Office

PTO/SB/64PCT (10-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FOR REVIVAL OF AN INTERNATIONAL APPLICATION FOR PATENT DESIGNATING THE U.S. ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(a) Page 1 of 2	Docket Number (Optional) I618.118.103

First named inventor: Darrell Wagner et al.

International (PCT) Application No.: PCT/US2016/022611 U.S. Application No. (if known): _____

Filed: March 16, 2016

Title: STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

Attention: PCT Legal Office
Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

The above-identified application became abandoned as to the United States because the fees and documents required by 35 U.S.C. 371(c) and 37 CFR 1.495 were not filed prior to the expiration of the time set in 37 CFR 1.495(b) or (c) (as applicable). The date of abandonment is the day after the date on which the 35 U.S.C. 371(c) requirements were due. See 37 CFR 1.495(c) and (h).

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION.

NOTE: A grantable petition requires the following items:

(1) Petition fee;
(2) Proper reply;
(3) Terminal disclaimer with disclaimer fee which is required for all international applications having an international filing date before June 8, 1995; and
(4) Statement that the entire delay was unintentional.

1. Petition fee

☐ Small entity fee $ _____ (37 CFR 1.17(m)). Applicant asserts small entity status. See 37 CFR 1.27.

☒ Undiscounted fee $ 1,700 (37 CFR 1.17(m)).

2. Proper reply

The proper reply (the missing requirement(s)) in the form of

371PatApplication:Despn,Dwgs,Clms,Fees (identify the type of reply):

☐ has been filed previously on _____.

☒ is enclosed herewith.

3. Terminal disclaimer with disclaimer fee

☒ Since this international application has an international filing date on or after June 8, 1995, no terminal disclaimer is required.

☐ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $ _____ for a small entity or $ _____ for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

This collection of information is required by 37 CFR 1.137(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: PET.PCT
Document Description: Petition for review by the PCT Legal Office

PTO/SB/64PCT (10-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PETITION FOR REVIVAL OF AN INTERNATIONAL APPLICATION FOR PATENT DESIGNATING THE U.S. ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(a)

4. STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(a) was unintentional. [NOTE: The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(a) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D)).]

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

/Paul S. Grunzweig/ — Signature
September 28, 2017 — Date

Paul S. Grunzweig — Typed or Printed Name
37,143 — Registration Number, if applicable

100 South Fifth Street, Ste. 2250 — Address
612-767-2504 — Telephone Number

Minneapolis, MN 55402 — Address

Enclosures:

- [X] Fee Payment
- [ ] Reply
- [ ] Terminal Disclaimer Form
- [ ] Additional sheet(s) containing statements establishing unintentional delay
- [X] Other (please identify): 371PatentApplication(includesDescription,Dwgs,Claims,FilingFees)

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

- [ ] Deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.
- [X] Transmitted to the United States Patent and Trademark Office by EFS-Web, or by facsimile to (571) 273-8300, on the date shown below.

September 28, 2017 — Date
/Paul S. Grunzweig/ — Signature

Paul S. Grunzweig — Typed or printed name of person signing certificate

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Darrell		Wagner	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
Maple Grove	MN	US

Mailing Address of Inventor:

Address 1	9700 63rd Ave. N.
Address 2	

City	State/Province	Postal Code	Country
Maple Grove	MN	55369	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Quan		Ni	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
Maple Grove	MN	US

Mailing Address of Inventor:

Address 1	9700 63rd Ave. N.
Address 2	

City	State/Province	Postal Code	Country
Maple Grove	MN	55369	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	John		Rondoni	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

PTO/AIA/14 (11-15)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

City	Maple Grove	State/Province	MN	Country of Residence	US

Mailing Address of Inventor:

Address 1	9700 63rd Ave. N.		
Address 2			
City	Maple Grove	State/Province	MN
Postal Code	55369	Country	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Dave		Dieken	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Maple Grove	State/Province	MN	Country of Residence	US

Mailing Address of Inventor:

Address 1	9700 63rd Ave. N.		
Address 2			
City	Maple Grove	State/Province	MN
Postal Code	55369	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	25281		
Email Address	USPTO.PATENTS@dbclaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING		
Attorney Docket Number	I618.118.103	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	13	Suggested Figure for Publication (if any)	

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	25281		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	a 371 of international	PCT/US2016/022611	2016-03-16

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2016/022611	Claims benefit of provisional	62135305	2015-03-19
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.			Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

			Remove
Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.			Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	INSPIRE MEDICAL SYSTEMS, INC.		
Mailing Address Information For Applicant:			
Address 1	9700 63rd Ave. N.		
Address 2			
City	Maple Grove	**State/Province**	MN
Country	US	Postal Code	55369
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☒

Organization Name	INSPIRE MEDICAL SYSTEMS, INC.

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1	9700 63rd Ave. N.		
Address 2			
City	Maple Grove	**State/Province**	MN
Country i	US	Postal Code	55369
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Paul S. Grunzweig/			Date (YYYY-MM-DD)	2017-09-28
First Name	Paul S.	Last Name	Grunzweig	Registration Number	37143

Additional Signature may be generated within this form by selecting the Add button. Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0016

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference I618118111	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2016/022611	International filing date *(day/month/year)* 16 March 2016 (16.03.2016)	Priority date *(day/month/year)* 19 March 2015 (19.03.2015)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant INSPIRE MEDICAL SYSTEMS, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 10 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 19 September 2017 (19.09.2017)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Lingfei Bai e-mail: pct.team2@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2016/022611	16.03.2016	19.03.2015

International Patent Classification (IPC) or both national classification and IPC
INV. A61N1/36 A61B5/08 A61B5/00

Applicant
INSPIRE MEDICAL SYSTEMS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Molina Silvestre, A Telephone No. +49 89 2399-0

Form PCT/ISA/237 (Cover Sheet) (January 2015)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2016/022611

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0019

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	5, 6, 11-13, 15-32, 35, 36, 38, 43, 45-128
	No:	Claims	1-4, 7-10, 14, 33, 34, 37, 39-42, 44
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-128
Industrial applicability (IA)	Yes:	Claims	1-128
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0020

1 **Re Item V**

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1.1 Reference is made to the following documents:

D1 US 7 340 302 B1 (FALKENBERG ERIC [US] ET AL) 4 March 2008 (2008-03-04)

D2 WO 97/50049 A1 (MEDTRONIC INC [US]) 31 December 1997 (1997-12-31)

D3 US 2010/174341 A1 (BOLEA STEPHEN L [US] ET AL) 8 July 2010 (2010-07-08)

1.2 The application does not meet the requirements of Article 6 PCT, because claims 11-14, 23, 35, 39, 43, 44, 48, 49, 51, 80, 83, 98, 99, 101-103, 108, 109, 113 are not clear.

1.2.1 Claim 11 is not clear because the term "the reference respiratory cycle" as used therein lacks an antecedent and is therefore undefined.

For the purposes of the present document claim 11 has therefore been interpreted as if clarified to refer to "a reference respiratory cycle" instead.

1.2.2 An analogous objection and interpretation applies in respect of each of claims 12-14, 23, 35, 39, 80, 83.

1.2.3 In addition, and independently, claim 39 is not clear because the following technical feature is unclear:

F39.1: "a therapy manager to evaluate the first stimulation protocol relative to the reference respiratory cycle"

In turn, F39.1 is unclear because it fails to define what it means, in terms of technical features of the claimed device, for an "evaluation" to be done "relative to a (...) cycle".

For the purposes of the present document claim 39 has therefore been interpreted as if this unclear technical feature did not further restrict the claimed subject-matter.

1.2.4 An analogous objection and interpretation applies in respect of each of claims 99, 113.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0021

1.2.5 Claim 43 is not clear because the term "the therapy manager" as used therein lacks an antecedent and is therefore undefined.

For the purposes of the present document claim 43 has therefore been interpreted as if clarified to be made dependent on claim 39, which provides for such an antecedent.

1.2.6 An analogous objection and interpretation applies in respect of claim 44.

1.2.7 In addition, and independently, claim 44 is not clear because each of the following technical features is unclear:

F44.1: "upon the sleep disordered breathing behavior meeting or exceeding a severity threshold"

F44.2: "until the detected sleep disordered breathing behavior is less than the severity threshold"

In turn, F44.1-2 are unclear because they to define how a "behavior" is to be compared to a "threshold" and because no generally-accepted meaning for such a comparison is known in the art.

For the purposes of the present document claim 39 has therefore been interpreted as if these unclear technical features did not further restrict the claimed subject-matter.

1.2.8 An analogous objection and interpretation applies in respect of each of claims 37, 48, 49, 51, 98, 101-103, 108, 109.

1.3 The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claim 1 is not new.

D1 discloses a device (fig. 1, 2 (100)) for treating sleep disordered breathing, comprising: a stimulation element (electrodes fig. 2 (200-216)) to stimulate an airway-patency-related nerve (phrenic nerve, see citations below), according to a first stimulation protocol (e.g. the one of fig. 3 (300)) not synchronized relative to sensed respiratory information and in which each stimulation cycle (stimulation delivery window, fig. 4 (404)) includes a stimulation period (each of the pulses, fig. 4 (406)) and a non-stimulation period (each of the pauses between the pulses, fig. 4 (406)) (D1, abstract; figures 1-4; column 1, lines 6-9; column 1, line 62 - column 2, line 10; column 2, lines 14-29; column 3, line 1 - column 4, line 18; column 4, line 47 - column 5, line 46; column 7, lines 5-40; column 8, line 37 - column 10, line 49).

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0022

1.4 It is noted for completeness that, in an alternative reading, each of the sets of pulses during a stimulation delivery window (fig. 4 (404)) of D1 constitutes a stimulation period as per claim 1, the interval between stimulation delivery windows constituting the corresponding non-stimulation period as per claim 1.

1.5 It is further noted for completeness that, in an alternative reading, each of the sets of pulses during a stimulation delivery window (fig. 4 (404)) of D1 constitutes a stimulation period as per claim 1, any arbitrary interval without phrenic nerve stimulation after the stimulation delivery window constituting the corresponding non-stimulation period as per claim 1.

1.6 It is further noted for completeness that, in an alternative reading, each of the further stimulation protocols disclosed in D1 (fig. 9, 10 (900, 1000)) of D1 constitutes a stimulation protocol as per claim 1.

1.7 The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of claim 71 does not involve an inventive step.

D1 discloses a device (fig. 1, 2 (100)) including a processing resource (fig. 1, 2 (220)) to execute machine-readable instructions to an airway-patency-related nerve (phrenic nerve, see citations below), according to a first stimulation protocol (e.g. the one of fig. 3 (300)) not synchronized relative to sensed respiratory information and in which each stimulation cycle (stimulation delivery window, fig. 4 (404)) includes a stimulation period (each of the pulses, fig. 4 (406)) and a non-stimulation period (each of the pauses between the pulses, fig. 4 (406)) (D1, abstract; figures 1-4; column 1, lines 6-9; column 1, line 62 - column 2, line 10; column 2, lines 14-29; column 3, line 1 - column 4, line 18; column 4, line 47 - column 5, line 46; column 7, lines 5-40; column 8, line 37 - column 10, line 49).

The subject-matter of claim 71 differs from the device of D1 in that the instructions are stored in a non-transitory medium. That constitutes however an obvious solution to the problem of filling the gap in D1 with respect to the type of memory (non-volatile or volatile) that is used to store the instructions executed by the disclosed processor.

1.8 Dependent claims 2-70, 72-128 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step.

1.8.1 In respect of each of claims 1-4, 7-10, 14, 33, 34, 37, 39-42, 44 this is because its subject-matter is anticipated by the disclosure of D1 (see D1 citations above).

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In respect of claim 3 it is noted that the duration of a pulse as per D1 constitutes a treatment period as claimed. In respect of claim 4 it is noted that any length of time shorter than a stimulation delivery window constitutes an inspiratory reference as claimed. In respect of claim 10 it is noted that the duration of a pulse as per D1 constitutes a stimulation period, the duration of the stimulation delivery window a stimulation cycle as claimed. In respect of claim 23 it is noted that the duration of a stimulation delivery window as per D1 constitutes a stimulation period as per D1. In respect of claims 33, 34 reference is made to the disclosed physiological sensors (fig. 2 (270)) and, independently, to the disclosed sleep apnea detector (fig. 2 (238)).

1.8.2 In respect of each of claims 5, 6, 11-13, 15-29, this is because its subject-matter constitutes an obvious solution to the problem of filling the gap in D1 with respect to either the minimum number of stimulation deliver windows issued in a row (claims 5, 6) or to the specific relationship between stimulation cycles and stimulation periods (claims 11-13, 15-29). This applies in particular in view of the generality of the terms used in the claims and the corresponding observations under 1.4 and 1.5 above.

1.8.3 In respect of each of claims 30, 31, this is because its subject-matter constitutes an obvious solution to the problem of designing an alternative electrode for the disclosed nerve stimulation of the device of D1 (given that such cuff electrodes are commonly used in the art for this purpose).

1.8.4 In respect of claim 32, this is because its subject-matter constitutes an obvious solution to the problem of filling the gap in D1 with respect to the type of memory (non-volatile or volatile) that is used to store the instructions executed by the disclosed processor.

1.8.5 In respect of each of claims 35-38, this is because its subject-matter constitutes an obvious solution to the problem of designing an alternative respiration sensing mechanism for the device of D1 (given that such sensing mechanisms are also well known in the art).

1.8.6 In respect of each of claims 43, 45-52, this is because its subject-matter constitutes an obvious solution to the problem of designing an alternative therapy scheme for the device of D1 (given that such therapy schemes having several modes, including continuous stimulation, are also well known in the art, see e.g. D2 or D3).

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1.8.7 In respect of each of claims 53-70, this is because its subject-matter constitutes an obvious solution to the problem of designing an alternative therapy scheme for the device of D1 (given that also such therapy schemes with both synchronous and non-synchronous modes are also well known in the art, see e.g. D2 or D3).

1.8.8 In respect of each of claims 72-74, 76-79, 98-100 this is because the features of the respective claim that go beyond those of claim 71 are also anticipated by D1 (see D1 citations under 1.7 above). Each of these claims therefore differ from the disclosure of D1 in the use of a non-transitory medium, which is obvious as discussed under 1.7 above.

1.8.9 In respect of claim 75, 80-96, 113-115 this is because its subject-matter constitutes an obvious solution to the additional independent problem of filling the gap in D1 with respect to either the minimum number of stimulation deliver windows issued in a row (claim 75) or to the specific relationship between stimulation cycles and stimulation periods (claims 80-87). This applies in particular in view of the generality of the terms used in the claims and the corresponding observations under 1.4 and 1.5 above.

1.8.10 In respect of each of claims 97, this is because its subject-matter constitutes an obvious solution to the additional independent problem of designing an alternative respiration sensing mechanism for the device of D1 (given that such sensing mechanisms are also well known in the art).

1.8.11 In respect of each of claims 101-104 this is because its subject-matter constitutes an obvious solution to the additional, independent problem of designing an alternative therapy scheme for the device of D1 (given that such therapy schemes having several modes, including continuous stimulation, are also well known in the art, see e.g. D2 or D3).

1.8.12 In respect of each of claims 105-112, 116-128 this is because its subject-matter constitutes an obvious solution to the additional independent problem of designing an alternative therapy scheme for the device of D1 (given that also such therapy schemes with both synchronous and non-synchronous modes are also well known in the art, see e.g. D2 or D3).

2 **Re Item VII**

Certain defects in the international application

2.1 The features of claims 1-128 are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

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2.2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1-D3 is not mentioned in the description, nor are these documents identified therein.

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0026

PCT REQUEST

Original (for **SUBMISSION**)

0	**For receiving Office use only**	
0-1	International Application No.	PCT/US16/22611
0-2	International Filing Date	16 MAR 2016 (16.03.16)
0-3	Name of receiving Office and "PCT International Application"	RO/US
0-4	**Form PCT/RO/101 PCT Request**	
0-4-1	Prepared Using	PCT-SAFE [EFS-Web mode] Version 3.51.070.246 MT/FOP 20151001/0.20.5.23
0-5	**Petition** The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	**Receiving Office (specified by the applicant)**	United States Patent and Trademark Office (USPTO) (RO/US)
0-7	**Applicant's or agent's file reference**	I618118111
I	**Title of Invention**	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING
II	**Applicant**	
II-1	This person is	Applicant only
II-2	Applicant for	All designated States
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II-9	Facsimile No.	612-573-2005
II-10	e-mail	pct@dbclaw.com
II-10(a)	E-mail authorization The receiving Office, the International Searching Authority, the International Bureau and the International Preliminary Examining Authority are authorized to use this e-mail address, if the Office or Authority so wishes, to send notifications issued in respect of this international application:	as advance copies followed by paper notifications

III-1	**Applicant and/or inventor**	
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	The person identified below is hereby/ has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	Agent
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IV-1-4	Facsimile No.	612-573-2005
IV-1-5	e-mail	pct@dbclaw.com
IV-1-5(a)	E-mail authorization The receiving Office, the International Searching Authority, the International Bureau and the International Preliminary Examining Authority are authorized to use this e-mail address, if the Office or Authority so wishes, to send notifications issued in respect of this international application	as advance copies followed by paper notifications
IV-1-6	Agent's registration No.	37,143
IV-2	**Additional agent(s)**	additional agent(s) with same address as first named agent
IV-2-1	Name(s)	LUND, Scott (41,166)
V	**DESIGNATIONS**	
V-1	**The filing of this request constitutes under Rule 4.9(a), the designation of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.**	
VI-1	**Priority claim of earlier national application**	
VI-1-1	Filing date	19 March 2015 (19.03.2015)
VI-1-2	Number	62/135,305
VI-1-3	Country or Member of WTO	US
VI-2	**Incorporation by reference :**	
	where an element of the international application referred to in Article 11(1)(iii)(d) or (e) or a part of the description, claims or drawings referred to in Rule 20.5(a) is not otherwise contained in this international application but is completely contained in an earlier application whose priority is claimed on the date on which one or more elements referred to in Article 11(1)(iii) were first received by the receiving Office, that element or part is, subject to confirmation under Rule 20.6, incorporated by reference in this international application for the purposes of Rule 20.6.	

PCT REQUEST

Original (for **SUBMISSION**)

VII-1	**International Searching Authority Chosen**	European Patent Office (EPO) (ISA/EP)	
VIII	**Declarations**	Number of declarations	
VIII-1	Declaration as to the identity of the inventor	–	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	–	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	–	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	–	
VIII-5	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	–	
IX	**Check list**	Number of sheets	Electronic file(s) attached
IX-1	Request (including declaration sheets)	5	✓
IX-2	Description	65	–
IX-3	Claims	23	–
IX-4	Abstract	1	✓
IX-5	Drawings	13	–
IX-7	TOTAL	107	
	Accompanying Items	Paper document(s) attached	Electronic file(s) attached
IX-8	Fee calculation sheet	✓	–
IX-20	**Figure of the drawings which should accompany the abstract**	12	
IX-21	**Language of filing of the international application**	English	
X-1	**Signature of applicant, agent or common representative**	/Paul S. Grunzweig, Reg. No. 37,143/ 16-03-2016	
X-1-1	Name (LAST, First)	GRUNZWEIG, Paul S.	
X-1-3	Capacity (if such capacity is not obvious from reading the request)		

PCT REQUEST

Original (for **SUBMISSION**)

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10-1	**Date of actual receipt of the purported international application**	16 MAR 2016 (16.03.16)
10-2	**Drawings:**	
10-2-1	Received	
10-2-2	Not received	
10-3	**Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application**	
10-4	**Date of timely receipt of the required corrections under PCT Article 11(2)**	
10-5	**International Searching Authority**	ISA/EP
10-6	**Transmittal of search copy delayed until search fee is paid**	

FOR INTERNATIONAL BUREAU USE ONLY

11-1	**Date of receipt of the record copy by the International Bureau**	

Information on Search Strategy - Pilot phase (see OJ 2015, A86)
The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number
PCT/US2016/022611

TITLE: STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

APPLICANT: INSPIRE MEDICAL SYSTEMS, INC.

IPC CLASSIFICATION: A61N1/36, A61B5/08, A61B5/00

EXAMINER: Molina Silvestre, A

CONSULTED DATABASES: WPI, NPL

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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, 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, KN, KP, KR, 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.

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(54) Title: STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

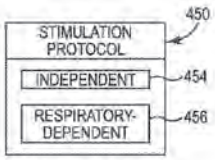


Fig. 12

(57) Abstract: A device for treating sleep disordered breathing includes a stimulation element to stimulate an airway-patency-related nerve.

WHAT IS CLAIMED IS:

1. A device for treating sleep disordered breathing, comprising:

a stimulation element to stimulate an airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to sensed respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period.

2. The device of claim 1, wherein the stimulation is implemented via an implanted electrode and the device includes an implantable pulse generator in which the stimulation element is at least partially stored.

3. The device of claim 1, wherein a total duration of stimulation via the first stimulation protocol during a treatment period is greater than 30 percent of the total duration of the treatment period.

4. The device of claim 3, wherein each stimulation period includes continuous stimulation and has a minimum duration equal to or greater than an inspiratory reference.

5. The device of claim 4, wherein the inspiratory reference corresponds to a duration of an inspiratory phase of a reference respiratory cycle.

6. The device of claim 5, wherein each stimulation period of the stimulation cycle has a duration greater than a duration of the inspiratory reference followed by the non-stimulation period having a duration less than the duration of the stimulation period.

7. The device of claim 1, wherein the duration of the stimulation period is at least 25 percent of a duration of the stimulation cycle.

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8. The device of claim 1, wherein the duration of the stimulation period is at least 50 percent of a duration of the stimulation cycle.

9. The device of claim 1, wherein the duration of the stimulation period is at least 80 percent of the duration of the stimulation cycle.

10. The device of claim 1, wherein the duration of the stimulation period is less than 80 percent of a duration of the stimulation cycle.

11. The device of claim 1, wherein the duration of the stimulation period is at least 25 percent of a duration of the reference respiratory cycle.

12. The device of claim 1, wherein the duration of the stimulation period is at least 50 percent of a duration of the reference respiratory cycle.

13. The device of claim 1, wherein the duration of the stimulation period is at least 80 percent of the duration of the reference respiratory cycle.

14. The device of claim 1, wherein the duration of the stimulation period is less than 80 percent of a duration of the reference respiratory cycle.

15. The device of claim 6 wherein the duration of the stimulation cycle is less than the duration of the reference respiratory cycle, and a duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of 3.

16. The device of claim 15, wherein the stimulation period and the non-stimulation period are in a proportion of 4 to 1.

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17. The device of claim 6, wherein the duration of the stimulation cycle is greater than the duration of the reference respiratory cycle.

18. The device of claim 17, wherein the stimulation period and the non-stimulation period are in a proportion of at least 1.5 to 1.

19. The device of claim 17, wherein the stimulation period and the non-stimulation period are in a proportion of at least 3 to 1.

20. The device of claim 6, wherein the duration of the stimulation cycle is equal to the duration of the reference respiratory cycle, and wherein the duration of the reference respiratory cycle differs from a duration of a real time respiratory cycle by an amount exceeding a duration variability criteria.

21. The device of claim 20, wherein the stimulation period and the non-stimulation period are in a proportion of 4 to 1.

22. The device of claim 6, wherein each stimulation cycle includes:
at least two different duration continuous stimulation periods; and
at least two different duration non-stimulation periods.

23. The device of claim 3, wherein each stimulation period includes continuous stimulation and a duration of the stimulation cycle is substantially less than a duration of the reference respiratory cycle.

24. The device of claim 23, wherein the duration of the stimulation cycle less than 50 percent of the duration of the reference respiratory cycle.

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25. The device of claim 23, wherein the duration of the stimulation cycle less than 20 percent of the duration of the reference respiratory cycle.

26. The device of claim 23, wherein a duration of each stimulation period of the respective stimulation cycles is substantially less than a duration of an inspiratory phase of the reference respiratory cycle.

27. The device of claim 26, wherein a sum of the duration of at least two stimulation cycles is less than or equal to the duration of an inspiratory phase of the reference respiratory cycle.

28. The device of claim 27, wherein a duration of a non-stimulation period of each stimulation cycle is substantially less than the duration of the stimulation period of each stimulation cycle.

29. The device of claim 28, wherein for each stimulation cycle, the stimulation period and the non-stimulation period are in a proportion of 4 to 1.

30. The device of claim 1, comprising:

a cuff electrode including a single operative contact group of at least two electrodes through which the stimulation is deliverable non-selectively to the airway-patency-related nerve.

31. The device of claim 1, comprising:

a cuff electrode including at least one operative contact group through which the stimulation is deliverable non-selectively to the airway-patency-related nerve.

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32. The device of claim 1, comprising a non-volatile computer readable medium to store instructions, executable on a processor, to implement the first stimulation element and to perform the first stimulation protocol.

33. A device for treating sleep disordered breathing comprising:

a stimulation element to stimulate an airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to sensed respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period; and

a sensing element to obtain respiratory information.

34. The device of claim 33, wherein the sensing element is to obtain the respiratory information via sensing respiratory-related behavior.

35. The device of claim 33, wherein sensing respiratory-related behavior includes at least periodically sensing a respiratory waveform without synchronization to stimulation.

36. The device of claim 35, wherein the stimulation element includes a function selector to automatically select, for the first stimulation protocol, between:

a first function to apply a repeating stimulation cycle having a duration different than a duration of the reference respiratory cycle, when the duration of the respiratory cycles in the sensed respiratory information is less variable than a respiratory duration variability criteria ; and

a second function to apply a repeating stimulation cycle having a duration matching the duration of the respiratory cycle reference, when the duration of respiratory cycles in the sensed respiratory information is more variable than the respiratory duration variability criteria.

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37. The device of claim 33, wherein the stimulation element is activated for stimulation upon the sensing element identifying sleep disordered breathing behavior meeting or exceeding a severity threshold and is deactivated upon the sensing element identifying that the sleep disordered breathing behavior is less than the severity threshold.

38. The device of claim 37, wherein the sensing element is configured to be in an inactive state by default and is periodically, temporarily activated to sense respiratory information to perform at least one of:

evaluating effectiveness of therapy according to at least the detected sleep disordered breathing relative to the severity threshold; and

calibrating the reference respiratory cycle relative to the sensed respiratory information.

39. The device of claim 33, comprising:

a therapy manager to evaluate the first stimulation protocol relative to the reference respiratory cycle based on the obtained respiratory information.

40. The device of claim 39, wherein in response to the evaluation, the therapy manager modifies at least one of the reference respiratory cycle and the first stimulation protocol, wherein modifying the first stimulation protocol includes at least one of:

adjusting features of the first stimulation protocol; and

substituting a different stimulation protocol for the first stimulation protocol.

41. The device of claim 39, wherein the therapy manager includes a stimulation protocol manager including an array of selectable stimulation protocols, including the first stimulation protocol, and

wherein the stimulation protocol manager further includes a rotation parameter to automatically cause the first stimulation element to apply at least some of the respective stimulation protocols on a rotating basis.

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42. The device of claim 41, wherein the therapy manager evaluates the selectable stimulation protocols for therapeutic effectiveness and selects at least one stimulation protocol to be applied on a non-rotating basis.

43. The device of claim 37, wherein the therapy manager evaluates the sensed respiratory information, and upon a determination that the first stimulation protocol fails to result in the detected sleep disordered breathing behavior being less than the severity threshold or that the sensed respiratory information fails to meet a sensor signal quality criteria, the therapy manager converts operation of the first stimulation element from the first stimulation protocol to a second stimulation protocol in which stimulation is applied continuously for at least two respiratory cycles or until the detected sleep disordered breathing behavior is less than the severity threshold.

44. The device of claim 33, comprising:

wherein the therapy manager is configured to detect sleep disordered breathing behavior from respiratory information sensed via the sensing element, and upon the sleep disordered breathing behavior meeting or exceeding a severity threshold, the therapy manager causes operation to convert from the first stimulation protocol into a second stimulation protocol for a second predetermined period of time or until the detected sleep disordered breathing behavior is less than the severity threshold.

45. The device of claim 44, wherein the detected sleep disordered breathing behavior is less than the severity threshold when the detected sleep disordered breathing behavior is absent for three consecutive respiratory cycles as sensed via the sensing element.

46. The device of claim 44, wherein the second stimulation protocol provides continuous stimulation.

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47. The device of claim 44, wherein the second stimulation protocol provides non-continuous stimulation.

48. The device of claim 39, wherein the stimulation element is activated in a first mode for stimulation upon the sensing element identifying sleep disordered breathing behavior meeting or exceeding a severity threshold and is deactivated upon the sensing element identifying that the sleep disordered breathing behavior is less than the severity threshold, and wherein upon a determination that detected sleep disordered breathing behavior meets or exceeds the severity threshold , the therapy manager terminates operation in the first stimulation mode and initiates operation in a third mode in which continuous stimulation is applied.

49. The device of claim 48, wherein the third mode is applied, before reverting to the first mode, until at least one of:

the detected sleep disordered breathing behavior is less than the severity threshold;

the detected sleep disordered breathing behavior is absent for three consecutive respiratory cycles as sensed via the sensing element; and

the continuous stimulation has been applied for a predetermined maximum period.

50. The device of claim 49, wherein the predetermined maximum period is 120 seconds.

51. The device of claim 48, wherein upon a determination that detected sleep disordered breathing behavior meets or exceeds the severity threshold, the therapy manager terminates operation in the first mode and initiates operation in a third mode including a stimulation protocol of a continuous stimulation period and a non-stimulation period in a proportion of at least 3 to 1 wherein the continuous stimulation period has a duration equal to or greater than a duration of at least four respiratory cycles..

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52. The device of claim 48, wherein in the first mode, the therapy manager causes stimulation at a first amplitude level and wherein, during at least a portion of operation in the third mode, the therapy manager causes stimulation at a second amplitude level substantially greater than the first amplitude level.

53. A device for treating sleep disordered breathing comprising:

a stimulation element to stimulate an airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to sensed respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period;

a sensing element to receive respiratory information; and

a therapy manager to provide convertible operation between:

a first stimulation mode implementing the first stimulation protocol; and

a second stimulation mode of stimulating the airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform.

54. The device of claim 53, wherein the therapy manager causes:

operation in the first mode for at least a first predetermined period of time;

converts operation into the second mode upon at least one parameter of the sensed respiratory waveform meeting a sensor signal quality criteria; and

reverts operation into the first mode for at least the first predetermined period of time upon the at least one parameter of the sensed respiratory waveform failing to meet the sensor signal quality criteria.

55. The device of claim 54, wherein conversion between the first and second modes is automatic.

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56. The device of claim 54, wherein conversion between the first and second modes is manual during operator titration of a therapy regimen implemented via the first stimulation element.

57. The device of claim 53, wherein the therapy manager includes a default mode selector to enable selection of either the first mode or the second mode as a default mode of operation, and wherein when the first mode is user-selected as the default mode, the therapy manager causes:

operation in the first mode for at least a first predetermined period of time;

converts operation into the second mode upon at least one parameter of the sensed respiratory waveform meeting a sensor signal quality criteria; and

reverts operation into the first mode for at least the first predetermined period of time upon the at least one parameter of the sensed respiratory waveform failing to meet the sensor signal quality criteria.

58. The device of claim 53, wherein the therapy manager includes a default mode selector to enable selection of either the first mode or the second mode as a default mode of operation, and wherein when the second mode is user-selected as the default mode, the therapy manager causes:

operation in the second mode;

converts operation into the first mode, for at least a first predetermined period of time, upon at least one parameter of the sensed respiratory waveform failing to meet a sensor signal quality criteria; and

reverts operation into the second mode upon the at least one parameter of the sensed respiratory waveform meeting the sensor signal quality criteria.

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59. The device of claim 53, wherein the first stimulation mode is a non-testing mode.

60. The device of claim 53, wherein the therapy manager is configured to selectively maintain full-time operation in the first stimulation mode and to deactivate the sensing element during the full-time operation in the first stimulation mode.

61. The device of claim 53, wherein upon a determination that detected sleep disordered breathing behavior meets or exceeds the severity threshold, the therapy manager terminates operation in the respective first and second stimulation modes and initiates operation in a third mode in which continuous stimulation is applied.

62. The device of claim 61, wherein the third mode is applied, before reverting to the first mode, until at least one of:

the detected sleep disordered breathing behavior is less than the severity threshold; and

the detected sleep disordered breathing behavior is absent for three consecutive respiratory cycles as sensed via the sensing element;
and

the continuous stimulation has been applied for a predetermined maximum period.

63. The device of claim 62, wherein the predetermined maximum period is 120 seconds.

64. The device of claim 53, wherein upon a determination that detected sleep disordered breathing behavior meets or exceeds the severity threshold, the therapy manager terminates operation in the respective first and second stimulation modes and initiates operation in a third mode including a stimulation protocol of a continuous stimulation period and a non-stimulation period in a proportion of at least 3 to 1 wherein the continuous stimulation period has a duration equal to or greater than a duration of at least four respiratory cycles.

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65. The device of claim 61, wherein in the first and second modes, the therapy manager causes stimulation at a first amplitude level and wherein, during at least a portion of operation in the third mode, the therapy manager causes stimulation at a second amplitude level substantially greater than the first amplitude level.

66. The device of claim 53, wherein the characteristic of the respiratory waveform is at least one of inspiration, a transition between expiratory pause and inspiration, a transition between inspiration and a first portion of expiration, peak inspiration, peak expiration, and expiratory pause.

67. The system of claim 53, wherein the at least one parameter of the respiratory waveform is at least one of:

a peak-to-peak amplitude;

a respiratory rate;

an duty cycle associated with at least one of inspiration, expiration, and expiratory pause; and

a statistical stability of at least one of the peak-to-peak amplitude, the respiratory rate, and the inspiratory duty cycle.

68. The device of claim 53, wherein the therapy manager causes:

operation in the second mode;

converts operation into the first mode, for at least a first predetermined period of time, upon at least one parameter of the sensed respiratory waveform failing to meet a sensor signal quality criteria; and

reverts operation into the second mode upon the at least one parameter of the sensed respiratory waveform meeting the sensor signal quality criteria.

69. The device of claim 68, wherein conversion between the first and second modes is automatic.

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70. The device of claim 68, wherein conversion between the first and second modes is manual during operator titration of a therapy regimen implemented via the first stimulation element.

71. A device including a processing resource to execute machine-readable instructions, stored in a non-transitory medium, to:

stimulate an airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to sensed respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period.

72. The device of claim 71, comprising:

an implantable electrode; and

a pulse generator in which the non-transitory medium is housed and which is in electrical communication with the implantable electrode.

73. The device of claim 71, wherein a total duration of stimulation during a treatment period is greater than 30 percent of the total duration of the treatment period.

74. The device of claim 73,wherein each stimulation period includes continuous stimulation and has a minimum duration equal to or greater than a duration of an inspiratory phase of a reference respiratory cycle.

75. The device of claim 74, wherein each stimulation cycle of the first stimulation protocol includes each stimulation period having a duration greater than the duration of the inspiratory phase followed by the non-stimulation period having a duration less than the duration of the stimulation period.

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76. The device of claim 71, wherein the duration of the stimulation period is at least 25 percent of a duration of the stimulation cycle.

77. The device of claim 71, wherein the duration of the stimulation period is at least 50 percent of a duration of the stimulation cycle.

78. The device of claim 71, wherein the duration of the stimulation period is at least 80 percent of the duration of the stimulation cycle.

79. The device of claim 71, wherein the duration of the stimulation period is less than 80 percent of a duration of the stimulation cycle.

80. The device of claim 71, wherein the duration of the stimulation period is at least 25 percent of a duration of the reference respiratory cycle.

81. The device of claim 75, wherein the duration of the stimulation period of the stimulation cycle is at least 50 percent of the duration of the reference respiratory cycle.

82. The device of claim 75, wherein the duration of the stimulation period of the stimulation cycle is at least 80 percent of the duration of the reference respiratory cycle.

83. The device of claim 71, wherein the duration of the stimulation period is less than 80 percent of a duration of the reference respiratory cycle.

84. The device of claim 75 wherein the duration of the stimulation cycle is less than the duration of the reference respiratory cycle, and a duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of 3.

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85. The device of claim 84, wherein the stimulation period and the non-stimulation period are in a proportion of 4 to 1.

86. The device of claim 75, wherein the duration of the stimulation cycle is greater than the duration of the reference respiratory cycle.

87. The device of claim 86, wherein the stimulation period and the non-stimulation period are in a proportion of at least one of:

at least 1.5 to 1; and

at least 3 to 1.

88. The device of claim 75, wherein the duration of the stimulation cycle is equal to the duration of the reference respiratory cycle, and wherein the duration of the reference respiratory cycle differs from a duration of a real time respiratory cycle by an amount exceeding a respiratory duration variability criteria.

89. The device of claim 71, wherein each stimulation cycle includes:

at least two different duration continuous stimulation periods; and

at least two different duration non-stimulation periods.

90. The device of claim 89, wherein each stimulation period includes continuous stimulation and a duration of the stimulation cycle is substantially less than a duration of the reference respiratory cycle.

91. The device of claim 90, wherein the duration of the stimulation cycle less than 50 percent of the duration of the reference respiratory cycle.

92. The device of claim 90, wherein the duration of the stimulation cycle less than 20 percent of the duration of the reference respiratory cycle.

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93. The device of claim 90, wherein a duration of each stimulation period of the respective stimulation cycles is substantially less than a duration of an inspiratory phase of the reference respiratory cycle.

94. The device of claim 93, wherein a sum of the duration of at least two stimulation cycles is less than or equal to the duration of an inspiratory phase of the reference respiratory cycle.

95. The device of claim 94, wherein a duration of a non-stimulation period of each stimulation cycle is substantially less than the duration of the stimulation period of each stimulation cycle.

96. The device of claim 95, wherein for each stimulation cycle, the stimulation period and the non-stimulation period are in a proportion of 4 to 1.50.

97. The device of claim 71, the instructions to automatically select, for the first stimulation protocol, between:

a first function to apply a repeating stimulation cycle having a duration different than a duration of the reference respiratory cycle, when the duration of the respiratory cycles in the sensed respiratory information is less variable than a respiratory duration variability criteria; and

a second function to apply a repeating stimulation cycle having a duration matching the duration of the respiratory cycle reference, when the duration of respiratory cycles in the sensed respiratory information is more variable than the respiratory duration variability criteria.

98. The device of claim 71, the instructions to activate stimulation of the airway-patency-related nerve upon identification of sleep disordered breathing behavior meeting or

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exceeding a severity threshold and to deactivate stimulation upon identification that the sleep disordered breathing behavior is less than the severity threshold.

99. The device of claim 71, the instructions to implement a therapy manager to evaluate the first stimulation protocol relative to the reference respiratory cycle based on sensed respiratory information.

100. The device of claim 99, the instructions to implement the therapy manager via a stimulation protocol manager including an array of selectable stimulation protocols, including the first stimulation protocol, and

wherein the stimulation protocol manager further includes a rotation parameter to automatically cause the first stimulation element to apply at least some of the respective stimulation protocols on a rotating basis.

101. The device of claim 99, the instructions to implement the therapy manager to evaluate the sensed respiratory information and upon a determination that at least one of the first stimulation protocol failing to result in the detected sleep disordered breathing behavior being less than the severity threshold or that the sensed respiratory information is unstable, the therapy manager converts operation of the first stimulation element from the first stimulation protocol to stimulation protocol in which stimulation is applied continuously for at least two respiratory cycles or until the detected sleep disordered breathing behavior is less than the severity threshold.

102. The device of claim 101, the instructions to implement the second stimulation protocol stimulation to be applied continuously for at least four respiratory cycles or until the detected sleep disordered breathing behavior is less than the severity threshold.

103. The device of claim 99, the instructions to implement the therapy manager to detect sleep disordered breathing behavior from respiratory information sensed via the sensing

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element, and upon the sleep disordered breathing behavior meeting or exceeding a severity threshold, the therapy manager causes operation to convert from the first stimulation protocol into a second stimulation protocol for a second predetermined period of time or until the detected sleep disordered breathing behavior is less than the severity threshold.

104. The device of claim 103, the instructions to implement the second stimulation protocol to provide continuous stimulation.

105. The device of claim 99, the instructions to implement the therapy manager to provide automatic convertible operation between:

the first stimulation mode to implement the first stimulation protocol; and

a second stimulation mode of stimulating the airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform,

wherein the therapy manager causes:

operation in the first mode for at least a first predetermined period of time;

converts operation into the second mode upon at least one parameter of the sensed respiratory waveform meeting a sensor signal quality criteria; and

reverts operation into the first mode for at least the first predetermined period of time upon the at least one parameter of the sensed respiratory waveform failing to meet the sensor signal quality criteria.

106. The device of claim 105, the instructions to implement the first stimulation mode as a non-testing mode.

107. The device of claim 105, the instructions to implement the therapy manager to selectively maintain full-time operation in the first stimulation mode and to deactivate the sensing element during the full-time operation in the first stimulation mode.

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108. The device of claim 105, the instructions to implement the therapy manager to, upon a determination that detected sleep disordered breathing behavior meets or exceeds the severity threshold, terminate operation in the respective first and second stimulation modes and initiates operation in a third mode in which continuous stimulation is applied.

109. The device of claim 108, the instructions to implement the third mode, before reverting to the first mode, until at least one of:

the detected sleep disordered breathing behavior is less than the severity threshold; and

the detected sleep disordered breathing behavior is absent for three consecutive respiratory cycles as sensed via the sensing element.

110. The device of claim 108, the instructions to implement the therapy manager, in the first and second modes, to cause stimulation at a first amplitude level and wherein, during at least a portion of operation in the third mode, the therapy manager causes stimulation at a second amplitude level substantially greater than the first amplitude level.

111. The device of claim 105, the instructions to define the characteristic of the respiratory waveform is at least one of inspiration, a transition between expiratory pause and inspiration, a transition between inspiration and a first portion of expiration, peak inspiration, peak expiration, and expiratory pause.

112. The device of claim 105, the instructions to define herein the at least one parameter of the respiratory waveform as at least one of:

a peak-to-peak amplitude;

a respiratory rate;

an inspiratory duty cycle; and

a statistical stability of at least one of the peak-to-peak amplitude, the respiratory rate, and the inspiratory duty cycle.

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113. The device of claim 75, the instructions to implement a therapy manager to evaluate the first stimulation protocol relative to the reference respiratory cycle based on sensed respiratory information and based on the evaluation, to determine parameters of the stimulation cycle.

114. The device of claim 113, the instructions to define the sensed respiratory information to includes at least respiratory rate and a percentage of the respiratory rate defined by an inspiratory phase.

115. The device of claim 113, the instructions to define the parameters of the stimulation cycle include at least a duration of the stimulation cycle, a relative proportion of a stimulation period and a non-stimulation period of the stimulation cycle, and a number of stimulation periods and non-stimulation periods of the stimulation cycle.

116. The device of claim 71, the instructions to implement convertible operation between:

a first stimulation mode implementing the first stimulation protocol; and

a second stimulation mode of stimulating the airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform.

117. The device of claim 116, the instructions to implement the convertible operation as:

operation in the first mode for at least a first predetermined period of time;

converting operation into the second mode upon at least one parameter of the sensed respiratory waveform meeting a sensor signal quality criteria; and

reverting operation into the first mode for at least the first predetermined period of time upon the at least one parameter of the sensed respiratory waveform failing to meet the sensor signal quality criteria.

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118. The device of claim 116, the instructions to implement the conversion between the first and second modes to be automatic.

119. The device of claim 116, the instructions to implement the conversion between the first and second modes to be manual during operator titration of a therapy regimen implemented via the first stimulation element.

120. The device of claim 116, the instructions to enable selection of the first mode or the second mode as a default mode of operation, and the instructions to implement, when the first mode is user-selected as the default mode, convertible operation as:

operation in the first mode for at least a first predetermined period of time;

converts operation into the second mode upon at least one parameter of the sensed respiratory waveform meeting a sensor signal quality criteria; and

reverts operation into the first mode for at least the first predetermined period of time upon the at least one parameter of the sensedrespiratory waveform failing to meet the sensor signal quality criteria.

121. The device of claim 116, the instructions to enable selection of the first mode or the second mode as a default mode of operation, and the instructions to implement, when the second mode is user-selected as the default mode, convertible operation as:

operation in the second mode;

converts operation into the first mode, for at least a first predetermined period of time, upon at least one parameter of the sensed respiratory waveform failing to meet a sensor signal quality criteria; and

reverts operation into the second mode upon the at least one parameter of the sensed respiratory waveform meeting the sensor signal quality criteria.

122. A device including a processing resource to execute machine-readable instructions, stored in a non-transitory medium, to:

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provide convertible operation between:

a first mode to stimulate an airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to sensed respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period; and

a second stimulation mode of stimulating the airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform.

123. The device of claim 122, the instructions to implement the convertible operation as:

operation in the first mode for at least a first predetermined period of time; and

converting operation in the second mode upon at least one parameter of the sensed respiratory waveform meeting a sensor signal quality criteria.

124. The device of claim 123, the instructions to implement the convertible operation as:

reverting operation into the first mode for at least the first predetermined period of time upon the at least one parameter of the sensed respiratory waveform failing to meet the sensor signal quality criteria.

125. The device of claim 122, the instructions to implement the conversion between the first and second modes to be automatic.

126. The device of claim 122, the instructions to implement the conversion between the first and second modes to be manual during operator titration of a therapy regimen implemented via the first stimulation element.

127. The device of claim 122, the instructions to enable selection of the first mode or the second mode as a default mode of operation, and the instructions to implement, when the first mode is user-selected as the default mode, convertible operation as:

operation in the first mode for at least a first predetermined period of time;

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converts operation into the second mode upon at least one parameter of the sensed respiratory waveform meeting a sensor signal quality criteria; and

reverts operation into the first mode for at least the first predetermined period of time upon the at least one parameter of the sensedrespiratory waveform failing to meet the sensor signal quality criteria.

128. The device of claim 122, the instructions to enable selection of the first mode or the second mode as a default mode of operation, and the instructions to implement, when the second mode is user-selected as the default mode, convertible operation as:

operation in the second mode;

converts operation into the first mode, for at least a first predetermined period of time, upon at least one parameter of the sensed respiratory waveform failing to meet a sensor signal quality criteria; and

reverts operation into the second mode upon the at least one parameter of the sensed respiratory waveform meeting the sensor signal quality criteria.

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Fig. 1A

Fig. 1B

Fig. 2A

Fig. 2B

Fig. 2C

Fig. 2E

Fig. 2D

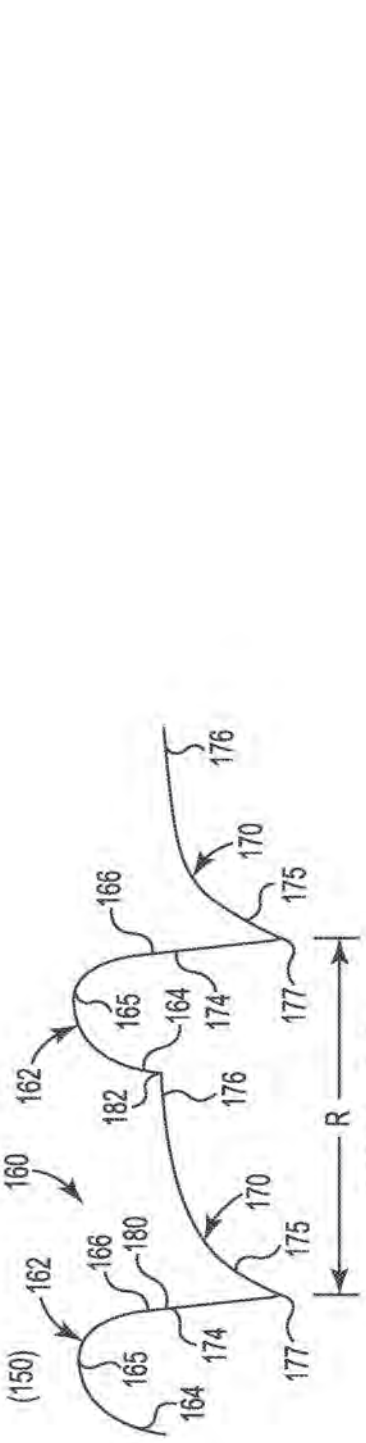

160
162
166
180
(150)
165
164
174
177
170
175
176
182
R

Fig. 3A

201
209
(4:1) < R
R
202
204A
204B
204C
204D
204E
204F
204G
204H
162
170
t
212A
212B
212C
212D
212E
212F
212G
212H
212I
212J
214
216
210
218A
218B
218C
218D
218E
218F
218G
218H
218I

Fig. 3B

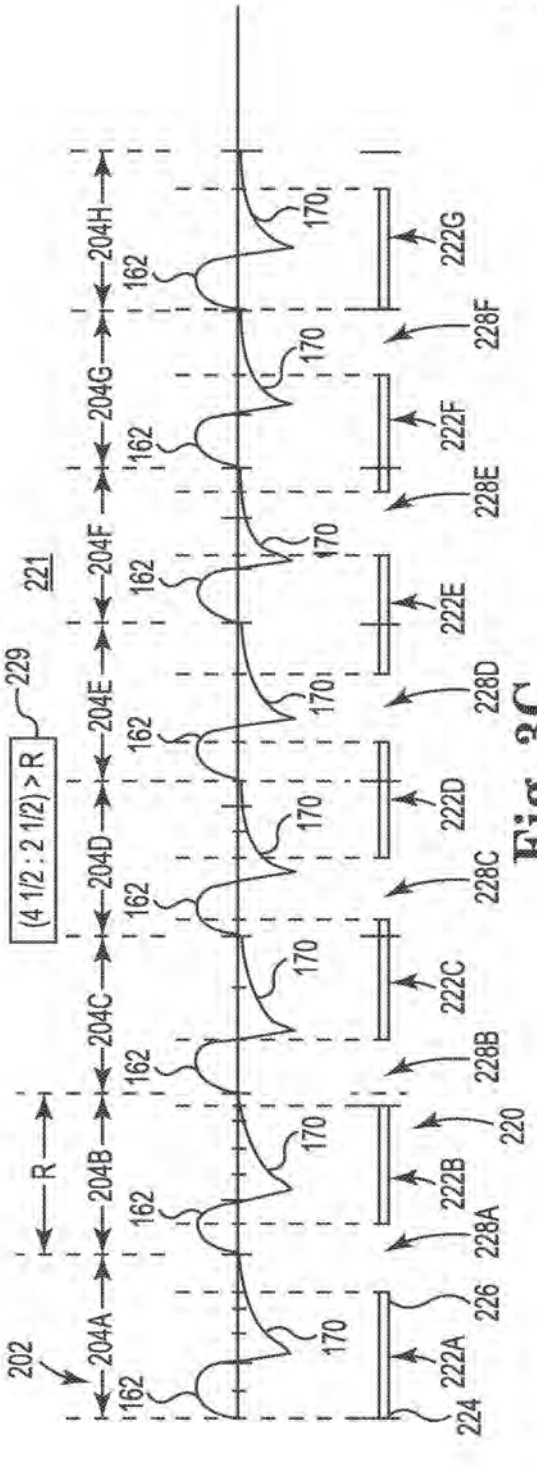

202
204A
204B
R
204C
204D
204E
204F
204G
204H
(4 1/2 : 2 1/2) > R
229
221
162
170
222A
222B
222C
222D
222E
222F
222G
224
226
228A
228B
228C
228D
228E
228F
220

Fig. 3C

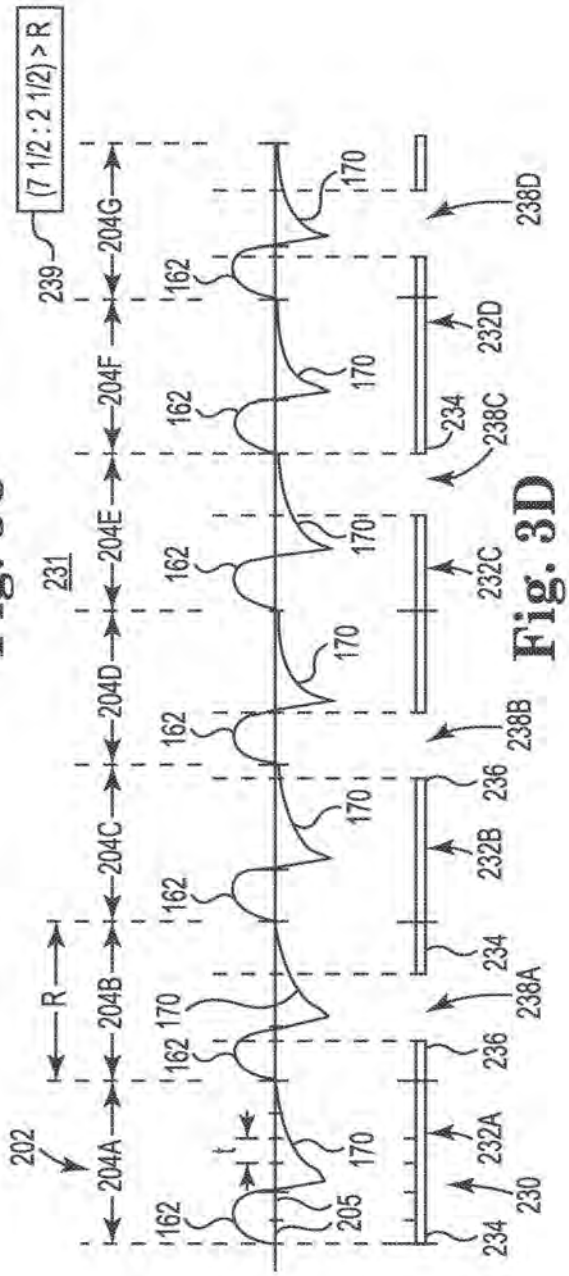

202
204A
204B
R
204C
204D
204E
204F
204G
(7 1/2 : 2 1/2) > R
239
231
162
170
205
t
230
232A
232B
232C
232D
234
236
238A
238B
238C
238D

Fig. 3D

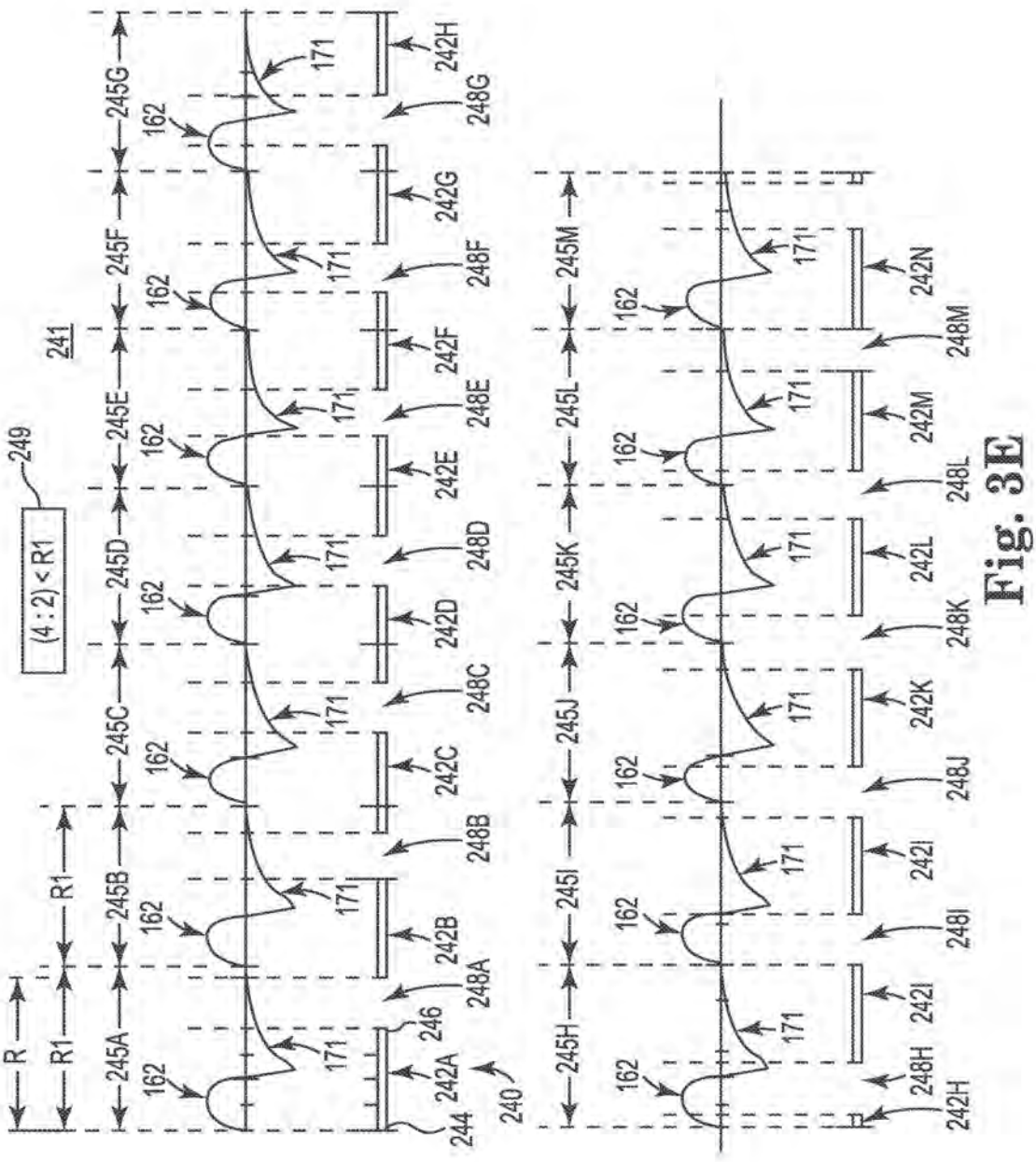

R
R1
R1
245A
245B
245C
245D
245E
245F
245G
245H
245I
245J
245K
245L
245M
241
249
(4 : 2) < R1
162
171
240
244
246
242A
242B
242C
242D
242E
242F
242G
242H
242I
242K
242L
242M
242N
248A
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248C
248D
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248F
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248J
248K
248L
248M

Fig. 3E

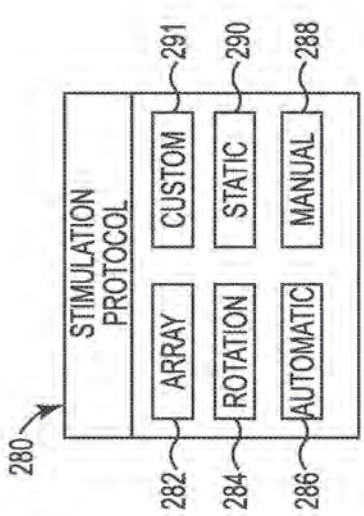


Fig. 5

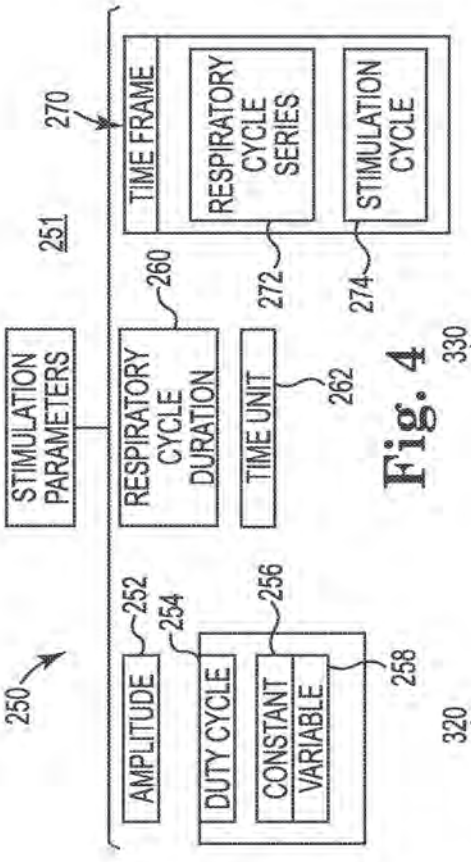


Fig. 4

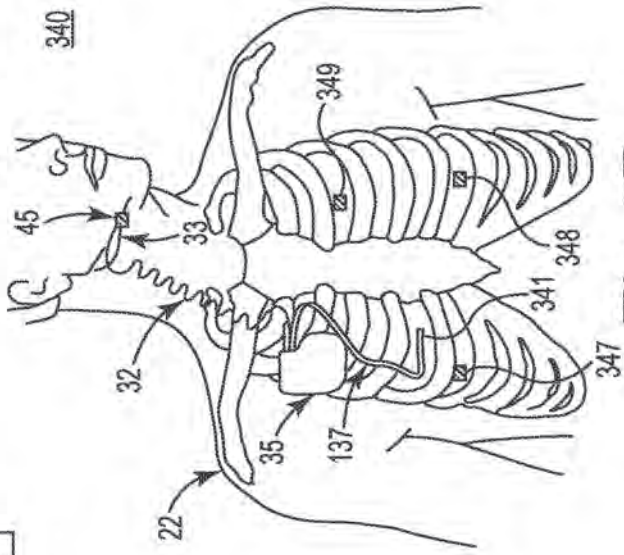


Fig. 7B

Fig. 6

Fig. 7A

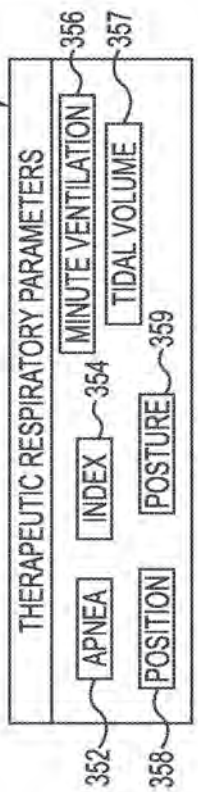


Fig. 8

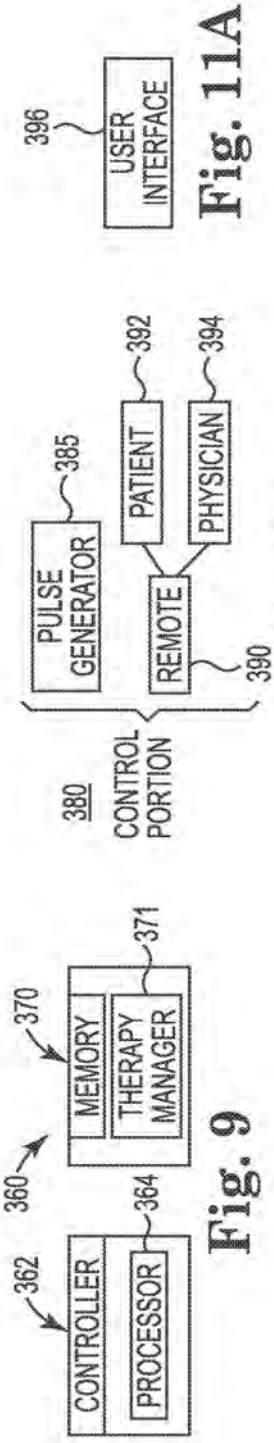


Fig. 9

Fig. 10

Fig. 11A

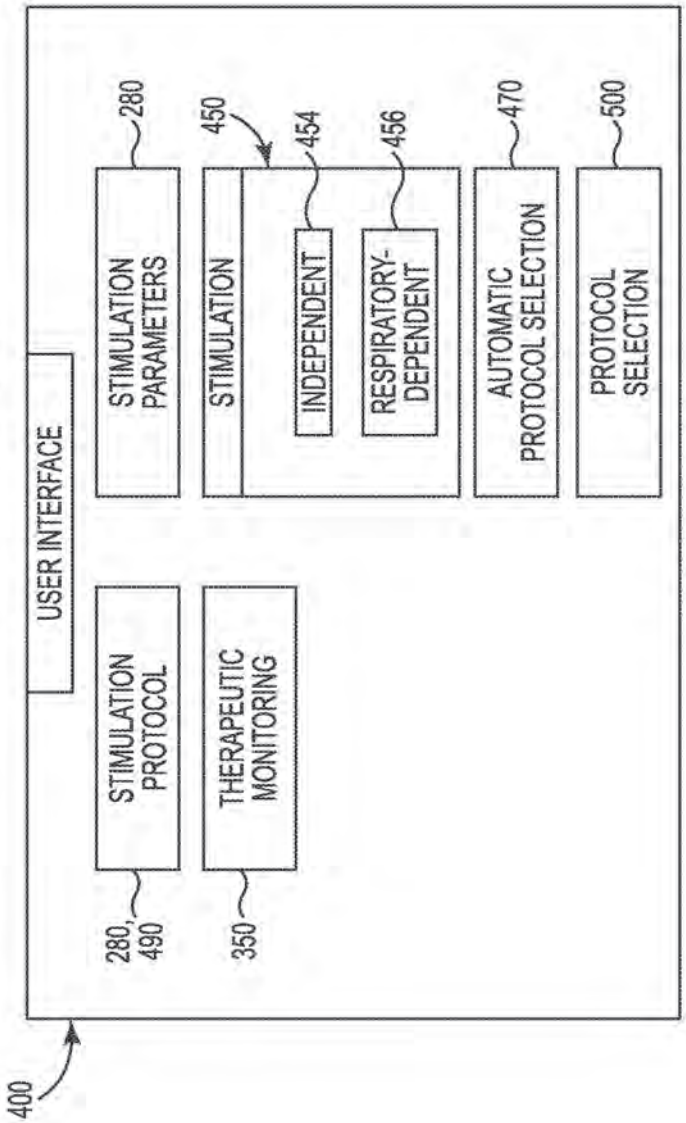


Fig. 11B

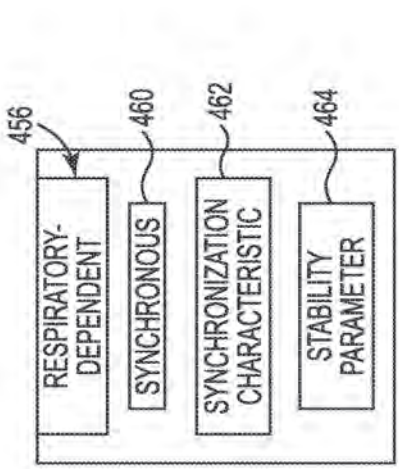


Fig. 13

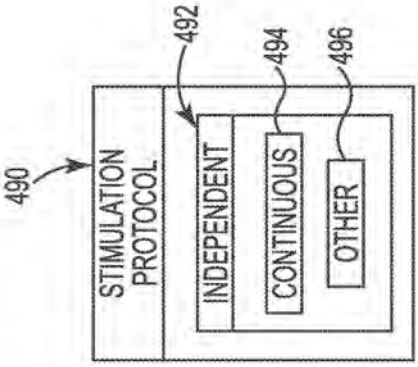


Fig. 15A

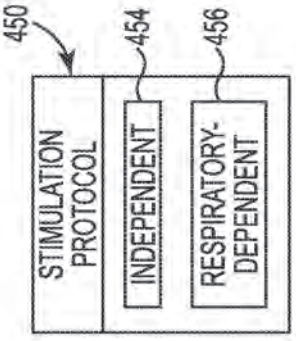


Fig. 12

Fig. 14

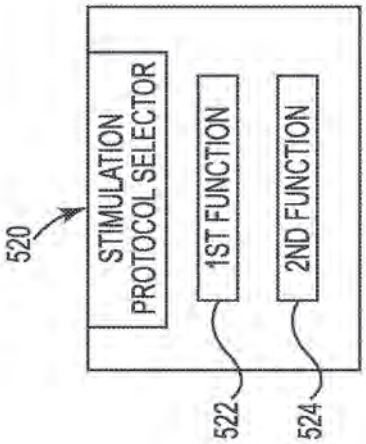


Fig. 15C

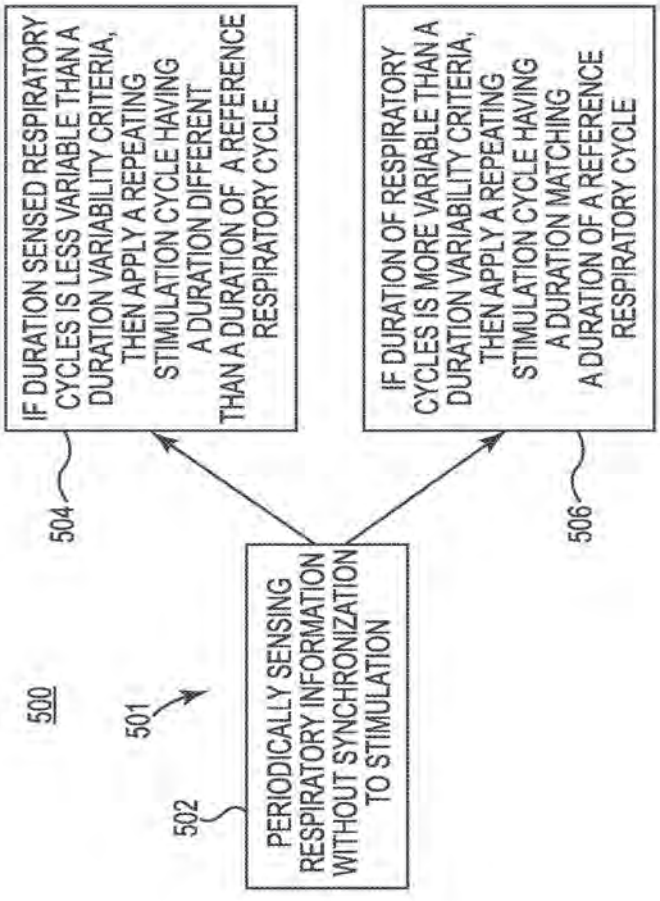


Fig. 15B

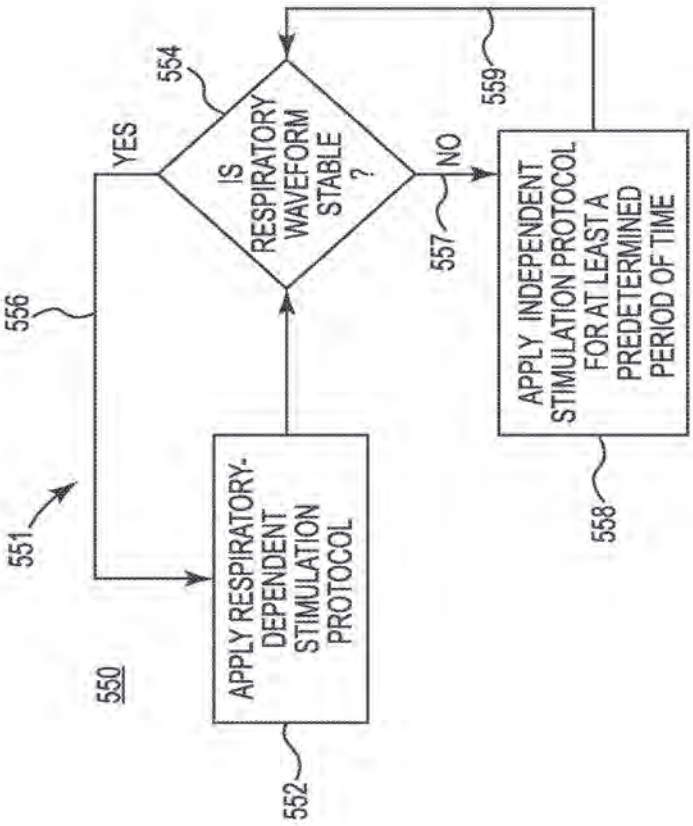

550
551
552
554
556
557
558
559
APPLY RESPIRATORY-DEPENDENT STIMULATION PROTOCOL
IS RESPIRATORY WAVEFORM STABLE ?
YES
NO
APPLY INDEPENDENT STIMULATION PROTOCOL FOR AT LEAST A PREDETERMINED PERIOD OF TIME

Fig. 15D

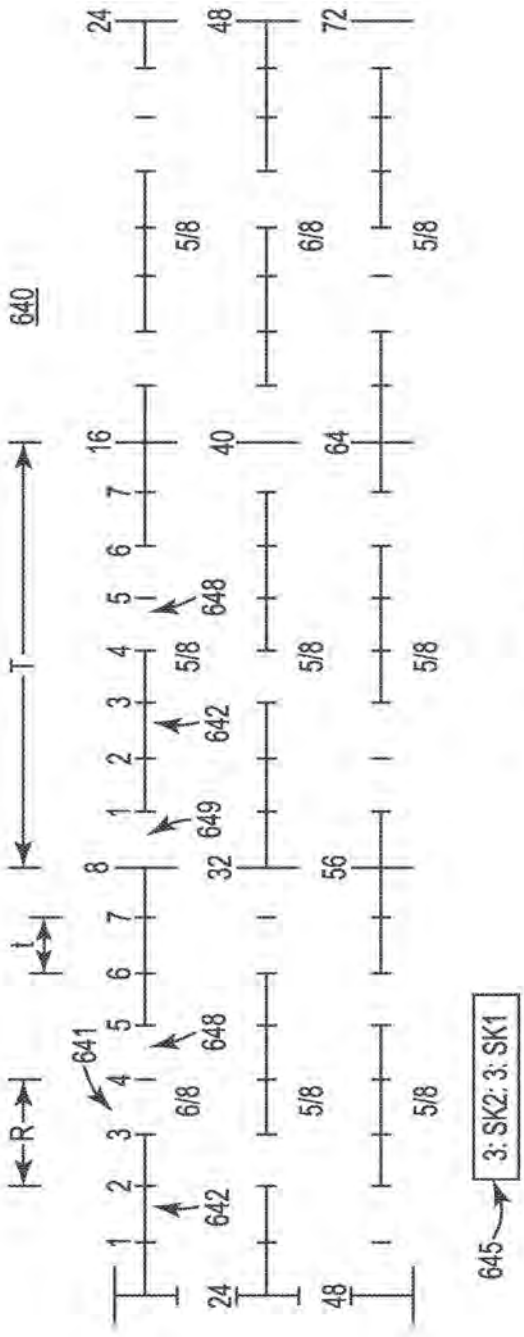


Fig. 16A

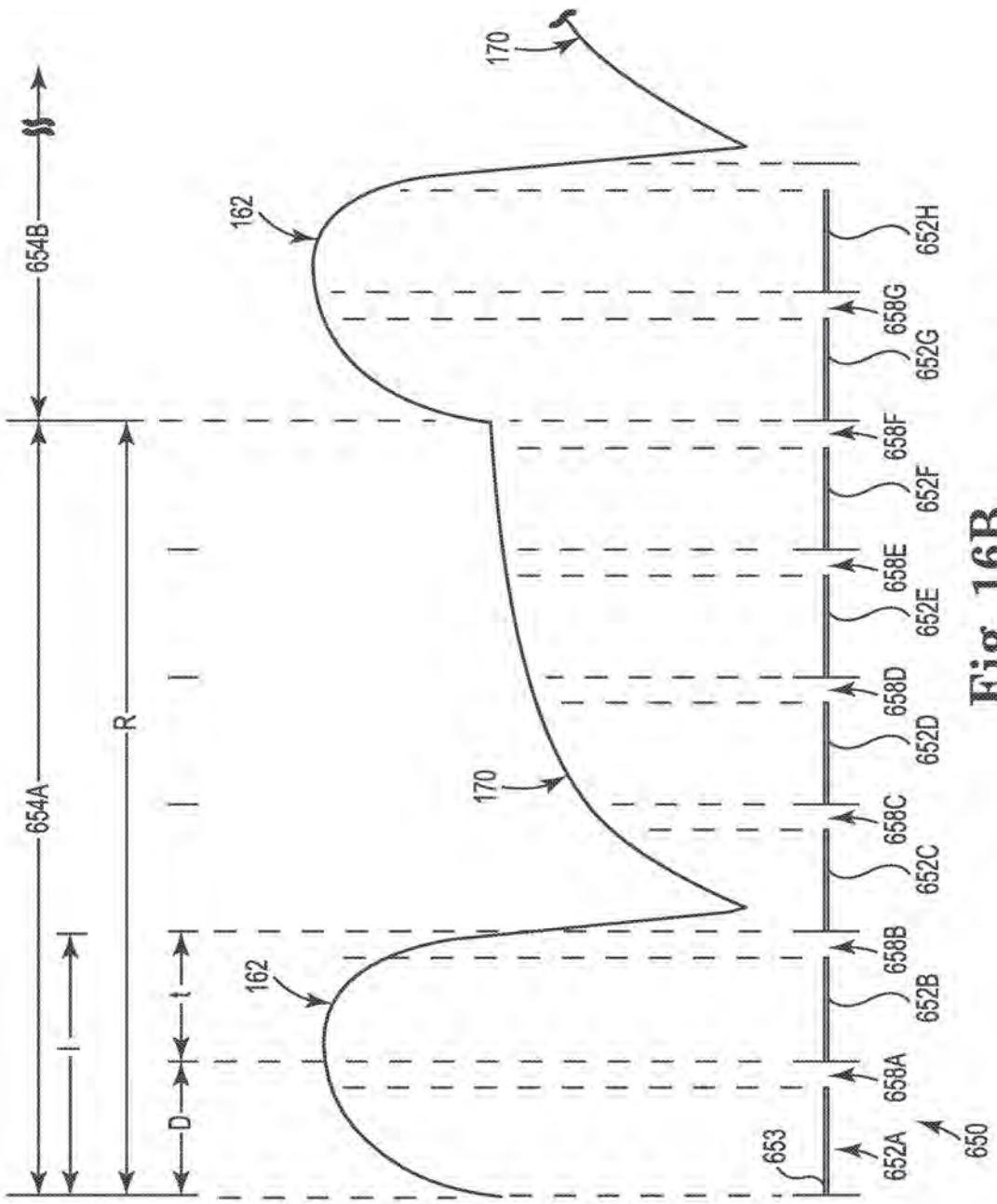

170
162
654B
652H
658G
652G
658F
652F
658E
652E
658D
652D
658C
652C
658B
652B
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652A
653
650
654A
R
l
t
D
170
162

Fig. 16B

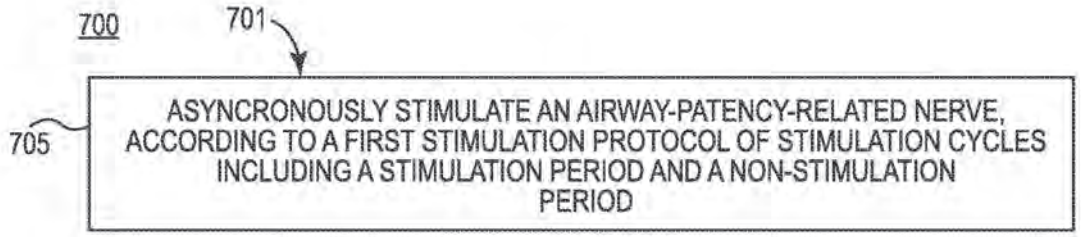


Fig. 17A

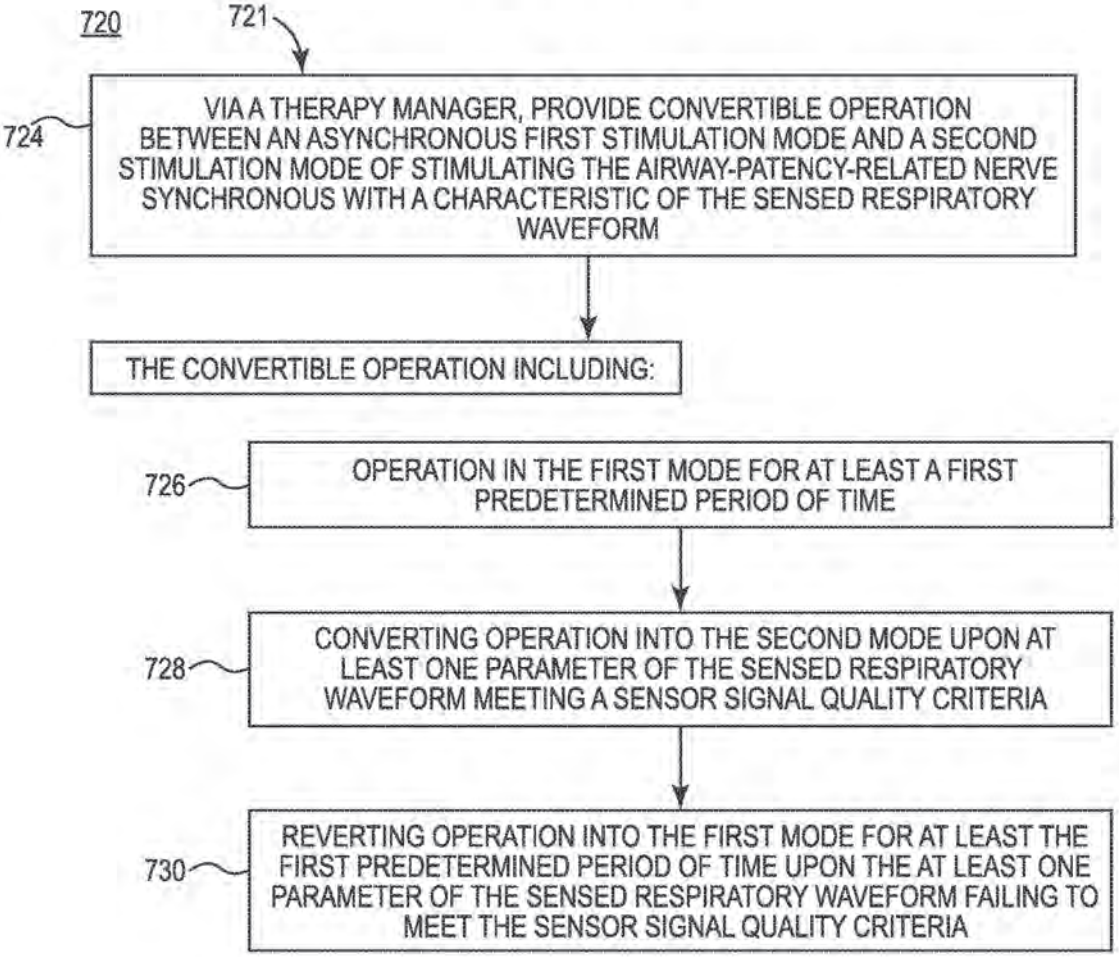


Fig. 17B

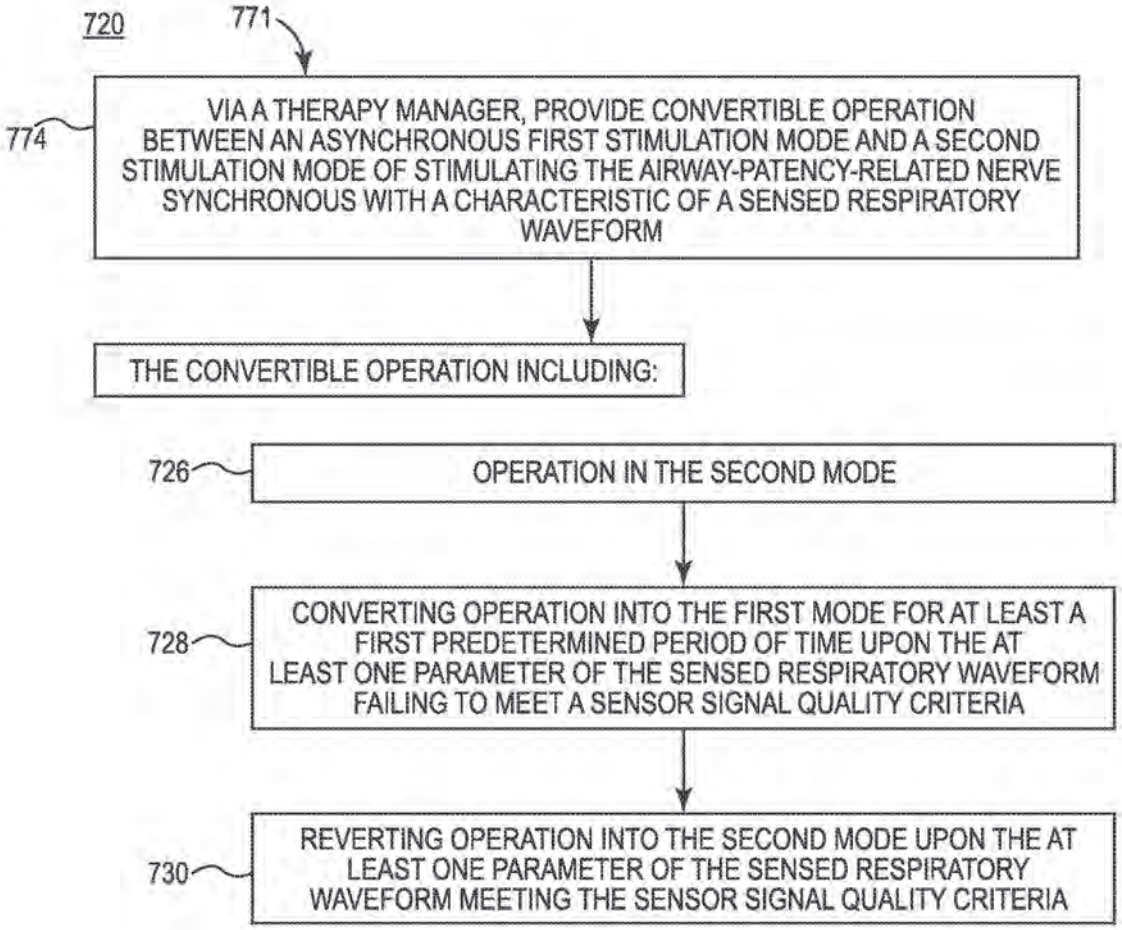


Fig. 17C

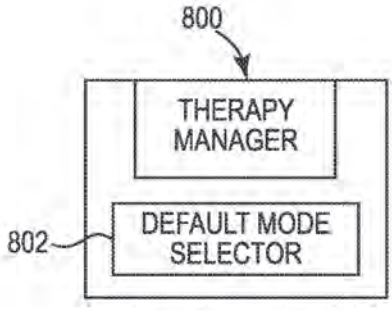


Fig. 18

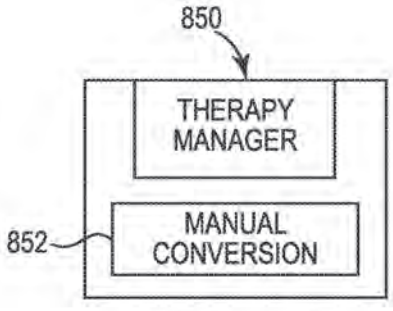


Fig. 19

STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

Cross-Reference to Related Applications

[0001] This PCT Patent Application claims benefit from U.S. Provisional Patent Application 62/135,305, filed March 19, 2015, incorporated by reference herein.

Background

[0002] Targeted electrical stimulation of a nerve shows great promise in a number of therapies. In one example, such stimulation of a hypoglossal nerve is known to alleviate obstructive sleep apnea by helping to maintain and/or restore upper airway patency.

Brief Description of the Drawings

[0003] Figure 1A is a block diagram schematically illustrating a stimulation element, according to one example of the present disclosure.

[0004] Figure 1B is a block diagram schematically illustrating a therapy manager, according to one example of the present disclosure.

[0005] Figure 2A is a diagram schematically illustrating an at least partially implantable stimulation system relative to a patient, according to an example of the present disclosure.

[0006] Figure 2B is a block diagram schematically illustrating an implantable pulse generator, according to one example of the present disclosure.

[0007] Figure 2C is a block diagram schematically illustrating a control portion for the at least partially implantable stimulation system, according to one example of the present disclosure.

[0008] Figure 2D is block diagram schematically illustrating a stimulation system, according to one example of the present disclosure.

[0009] Figure 2E is top view schematically illustrating a stimulation electrode, according to one example of the present disclosure.

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[0010] Figure 3A is a diagram schematically illustrating a respiratory cycle in one example breathing pattern, according to one example of the present disclosure.

[0011] Figure 3B is a diagram schematically illustrating a series of reference respiratory cycles juxtaposed relative to a stimulation protocol, according to one example of the present disclosure.

[0012] Figure 3C is a diagram schematically illustrating a series of reference respiratory cycles juxtaposed relative to a stimulation protocol, according to one example of the present disclosure.

[0013] Figure 3D is a diagram schematically illustrating a series of reference respiratory cycles juxtaposed relative to a stimulation protocol, according to one example of the present disclosure.

[0014] Figure 3E is a diagram schematically illustrating a series of reference respiratory cycles juxtaposed relative to a stimulation protocol, according to one example of the present disclosure.

[0015] Figure 4 is a block diagram schematically illustrating a plurality of stimulation parameters, according to one example of the present disclosure.

[0016] Figure 5 is a block diagram schematically illustrating a stimulation protocol element, according to one example of the present disclosure.

[0017] Figure 6 is a block diagram schematically illustrating power source components of the at least partially implantable stimulation system, according to one example of the present disclosure.

[0018] Figure 7A is a block diagram schematically illustrating a sensing element of the at least partially implantable stimulation system, according to one example of the present disclosure.

[0019] Figure 7B is a diagram schematically illustrating an at least partially implantable stimulation system relative to a patient and including sensing elements, according to an example of the present disclosure.

[0020] Figure 8 is a block diagram schematically illustrating therapeutic respiratory parameters, according to one example of the present disclosure.

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[0021] Figure 9 is a block diagram schematically illustrating a control portion of an at least partially implantable stimulation system, according to one example of the present disclosure.

[0022] Figure 10 is a block diagram schematically illustrating aspects of a control portion, according to one example of the present disclosure.

[0023] Figure 11A is a block diagram schematically illustrating a user interface, according to one example of the present disclosure.

[0024] Figure 11B is a block diagram schematically illustrating a user interface, according to one example of the present disclosure.

[0025] Figure 12 is a block diagram schematically illustrating a stimulation protocol element, according to one example of the present disclosure.

[0026] Figure 13 is a block diagram schematically illustrating a respiratory-dependent stimulation element, according to one example of the present disclosure. Figure 14 is a diagram schematically illustrating at least some aspects of stimulation protocol selection, according to one example of the present disclosure.

[0027] Figure 15A is a block diagram schematically illustrating a stimulation protocol element, according to one example of the present disclosure.

[0028] Figure 15B is a diagram schematically illustrating at least some aspects of stimulation protocol selection, according to one example of the present disclosure.

[0029] Figure 15C is a block diagram schematically illustrating a stimulation protocol selector, according to one example of the present disclosure.

[0030] Figure 15D is a diagram schematically illustrating at least some aspects of stimulation protocol selection, according to one example of the present disclosure.

[0031] Figure 16A is a diagram schematically illustrating a stimulation protocol, according to one example of the present disclosure.

[0032] Figure 16B is a diagram schematically illustrating a stimulation protocol, according to one example of the present disclosure.

[0033] Figure 17A is a flow diagram schematically illustrating a method of nerve stimulation, according to one example of the present disclosure.

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[0034] Figure 17B is a flow diagram schematically illustrating a method of nerve stimulation, according to one example of the present disclosure.

[0035] Figure 17C is a flow diagram schematically illustrating a method of nerve stimulation, according to one example of the present disclosure.

[0036] Figure 18 is a block diagram schematically illustrating a therapy manager, according to one example of the present disclosure.

[0037] Figure 19 is a block diagram schematically illustrating a therapy manager, according to one example of the present disclosure.

Detailed Description

[0038] In the following Detailed Description, reference is made to the accompanying drawings, which form a part hereof, and in which is shown by way of illustration specific examples in which the invention may be practiced. In this regard, directional terminology, such as "top," "bottom," "front," "back," "leading," "trailing," etc., is used with reference to the orientation of the Figure(s) being described. Because components of examples can be positioned in a number of different orientations, the directional terminology is used for purposes of illustration and is in no way limiting. It is to be understood that other examples may be utilized and structural or logical changes may be made without departing from the scope of the present disclosure. The following detailed description, therefore, is not to be taken in a limiting sense.

[0039] At least some examples of the present disclosure are directed to methods of treating obstructive sleep apnea via applying nerve stimulation. By doing so, upper airway patency may be maintained and/or increased while preventing or minimizing collapse of the upper airway. At the same time, by using targeted stimulation, one can limit the overall volume of stimulation applied to a given nerve or set of nerves.

[0040] In some examples, nerve stimulation is applied during a treatment period. In some examples, a treatment period corresponds to the patient engaging in sleeping behavior, and during which sleep disordered breathing is to be avoided. The treatment period can be

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manually initiated by the patient or automatically initiated by a device that applies the nerve stimulation.

[0041] In some examples, an at least partially implantable stimulation system for treating sleep disordered breathing includes an independent stimulation element to stimulate an airway-patency-related nerve without synchronization relative to characteristics of respiratory wave form. Accordingly, in some examples, the independent stimulation element forms part of a system that omits any sensing elements. In some examples, the stimulation element comprises a stimulation engine to determine and administer a stimulation protocol. In some examples, the stimulation element further includes and/or acts in cooperation with a pulse generator and stimulation electrode to deliver the stimulation to a target nerve. In such examples, the pulse generator includes the stimulation engine or the stimulation engine is in communication with the pulse generator. In some examples, the pulse generator is implantable and in some examples, the pulse generator is external to the patient's body. In some examples, the stimulation element is in communication with a therapy manager or is incorporated within a therapy manager. In some examples, the therapy manager is in communication with the pulse generator and/or incorporated within the pulse generator. In some examples, at least some components, functions, elements, etc. of the therapy manager are incorporated within a physician programmer external to the patient or a patient remote external to the patient.

[0042] In some examples, the at least partially implantable stimulation system includes sensing element(s) to receive and/or obtain respiratory information but that information is not employed to trigger stimulation by synchronizing the stimulation relative to characteristics of the sensed respiratory waveform. Rather, in these examples, the sensed respiratory information is used to detect and evaluate sleep disordered breathing behavior. When the detected behavior meets or exceeds a severity threshold, the therapy manager generally activates stimulation via the independent stimulation element. In some examples, the severity threshold is based on at least a frequency and/or an intensity of apneic events. In some instances, the severity threshold also may be expressed as an obstructive sleep apnea (OSA) burden, i.e. a quantity and/or intensity of apneas which are occurring. In some

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examples, the severity threshold or OSA burden is expressed as an Apnea-Hypopnea Index (AHI). However, despite the respiratory sensing occurring in these examples, the stimulation is performed via a protocol that remains independent of the particular characteristics of a real-time sensed respiratory waveform. In other words, individual stimulation periods are not triggered and/or synchronized relative to respiratory characteristics, such as the inspiratory phase.

[0043] In some examples, the independent stimulation element is configured to asynchronously stimulate an airway-patency-related nerve, according to a first stimulation protocol independent of sensed respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period. In some instances, the first stimulation protocol is referred to as being independent because the first stimulation protocol is not synchronized relative to sensed respiratory information. In some instances, the independence of the first stimulation protocol also may be referred to as being an asynchronous stimulation protocol because the first stimulation protocol is not synchronized relative to the sensed respiratory information.

[0044] In some examples, each stimulation period within a stimulation cycle includes continuous stimulation. In some examples, continuous stimulation refers to a train of stimulation pulses which occur in a relatively short time frame. For instance, in some examples, continuous stimulation corresponds to at least a finite number (e.g. 5, 10, etc.) of stimulation pulses per second. In some examples, continuous stimulation corresponds to at least 20 stimulation pulses per second. In some examples, continuous stimulation corresponds to at least 30 stimulation pulses per second. In some examples, the number of stimulation pulses per second is selectable by an operator via a control portion (e.g. 56 in Figure 2C).

[0045] In some examples, during the above-described continuous stimulation, each stimulation pulse within a train of stimulation pulses includes a primary stimulation pulse followed by a separate recharge pulse, which is in turn followed by a non-stimulation phase before the next primary stimulation pulse.

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[0046] In some examples, the stimulation period has a minimum duration equal to or greater than an inspiratory reference. In some examples, the inspiratory reference corresponds to a duration of an inspiratory phase of a reference respiratory cycle. In some examples, each stimulation cycle of the first stimulation protocol includes the stimulation period having a duration greater than a duration of the inspiratory reference followed by the non-stimulation period, which has a duration less than the duration of the stimulation period.

[0047] In some examples, the reference respiratory cycle is defined by a historical patient-specific average respiratory cycle for stable respiration. In some examples, the reference respiratory cycle is defined by a multi-patient average respiratory cycle for stable respiration.

[0048] Because the overall duration of the stimulation cycle (both stimulation period and non-stimulation period) intentionally does not match the duration (R) of the reference respiratory cycle in at least some examples, the stimulation protocol ensures that each successive stimulation period within the series of stimulation cycles will fall along a different portion of each of the successive reference respiratory cycles. Accordingly, even though the stimulation is not synchronized relative to a characteristic (e.g. inspiration) of reference respiratory waveform (which includes the series of reference respiratory cycles), no matter where the stimulation protocol is started relative to the ongoing pattern of reference respiratory cycles, the stimulation period of each stimulation cycle will overlap with at least a portion of the inspiratory phase of the respective reference respiratory cycles for a significant majority of the treatment period. Accordingly, even if the stimulation protocol happens to be initiated at a time that the non-stimulation period of the initial stimulation cycle at least partially overlaps with the inspiratory phase of a reference respiratory cycle, the stimulation periods of the successive stimulation cycles will at least partially overlap the inspiratory phase of the next reference respiratory cycles. Moreover, at least some of the later successive stimulation periods will significantly overlap (e.g. overlap at least a majority of the inspiratory phase) the inspiratory phase of the at least some of the respective successive reference respiratory cycles. In some instances, such significant overlap may include a complete overlap of the inspiratory phase.

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[0049] Via this arrangement, it becomes feasible to stimulate an airway-related-nerve to treat sleep disordered breathing either without any sensing elements at all or with minimal use of sensing elements. In this sense, the stimulation is performed asynchronously, i.e. without synchronization relative to sensed respiratory information. Among other benefits, this may reduce the cost of the stimulation system, may simplify its implantation, and may simplify operation of the stimulation system. Moreover, the presence of non-stimulation periods helps to minimize potential muscle fatigue that might otherwise be caused. Finally, providing asynchronous stimulation via the independent stimulation element may help to overcome situations in which sensor-based systems or synchronous systems are unable to achieve synchronization and/or the sensing signal become unstable (or is unavailable).

[0050] However, it will be understood that in some examples, an asynchronous independent stimulation protocol is implemented while still performing sensing respiratory information for non-synchronization purposes, such as evaluating stimulation therapy effectiveness and/or provide information to adjust parameters of the independent stimulation protocol.

[0051] In another aspect, providing stimulation asynchronously via the independent stimulation element may enable leveraging a greater number of different stimulation protocols because of fewer constraints on how the stimulation cycles of the stimulation protocols relate to characteristics of a respiratory waveform. Moreover, in some examples, the stimulation element applies nerve stimulation while rotating application through the plurality of different stimulation protocols, which in some instances provides a more robust therapy than using a single stimulation protocol. In some examples, this rotation also can be used to sort through the relative effectiveness of the different stimulation protocols and select the most effective stimulation protocol for a particular patient.

[0052] In some examples, an independent stimulation protocol is implemented in which the inspiratory phase of a majority of reference respiratory cycles are at least partially overlapped by a stimulation period, with more occurrences of such overlapping being preferred over fewer such occurrences. Similarly, in some examples, it is generally preferred to implement such an independent stimulation protocol via providing the sequence of

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stimulation periods to result in a greater degree of overlap with the inspiratory phase of the reference respiratory cycles rather than a lesser degree of overlap.

[0053] In some examples, the therapy manager includes a stimulation protocol element that provides convertible operation between the above-described independent (i.e. asynchronous) first stimulation mode and a synchronous second stimulation mode of stimulating the airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform. In this arrangement, the therapy manager causes: operation in the first stimulation mode for at least a first predetermined period of time; conversion of operation into the second stimulation mode upon at least one parameter of the sensed respiratory waveform meeting a sensor signal quality criteria; and reversion of operation into the first stimulation mode for at least the first predetermined period of time upon the at least one parameter of the sensed respiratory waveform failing to meet the sensor signal quality criteria. Accordingly, in one aspect, the first stimulation mode comprises the default mode of stimulation.

[0054] In some examples, the conversion between the first stimulation mode and the second stimulation mode is automatic. In some examples, the therapy manager includes a user selection function to enable user selection of either the first mode or the second mode as a default mode.

[0055] In some examples, the therapy manager includes an operator selection function to selectively cause conversion between the two different stimulation modes. In one aspect, such selective conversion can be implemented manually during operator titration of the therapeutic treatment as the operator adjusts parameters of the stimulation protocols for a particular patient.

[0056] In some examples the first predetermined period of time corresponds to a period sufficient to establish a steady state in which filtering is established, inspiration and expiration are being detected reliably, signal gain control is realized, etc. In some examples, the first predetermined period of time does not correspond to a test mode for evaluating the operational fitness of the stimulation system. Stated differently, activities occurring during the first predetermined period of time may sometimes be referred to as a non-test mode.

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[0057] Via this arrangement, the independent stimulation element first establishes a stable respiratory pattern. This arrangement therapeutically achieves airway patency while simultaneously increasing the likelihood of later successful synchronization of a respiratory-dependent stimulation protocol. In particular, because some examples dictate that stimulation is not implemented until or unless sleep disordered breathing behavior (above a severity threshold) is detected, the available respiratory signal will likely be a poor signal which attempt synchronization of a stimulation signal.

[0058] Accordingly, rather than attempt a likely problematic synchronization, at least some examples of the present disclosure first establish independent nerve stimulation that does not depend on synchronization. This independent stimulation, in turn, helps to establish a stable respiratory pattern or signal, which then in turn, significantly increases the success of later synchronizing a respiratory-dependent stimulation protocol relative to the respiratory signal. Once a robust synchronization is established, then the system is well positioned to maintain a stable respiratory period using less overall stimulation by stimulating on a synchronized basis in which stimulation is limited to generally coinciding with an inspiratory phase (or other characteristic of the sensed respiratory waveform).

[0059] Of course, in the event the sensed respiratory signal changes in a way that hinders synchronization and/or delivery of effective therapeutic stimulation, then in at least some examples, the therapy manager will cause operation to revert to the independent stimulation mode.

[0060] With this arrangement, the independent stimulation mode enables initially applying a higher intensity stimulation to establish and ensure a stable respiratory pattern, which in turn, increases the likelihood of being able to later establish and maintain a lower intensity stimulation via the synchronized, respiratory-dependent stimulation mode. In this way, it is expected that overall muscle fatigue is minimized because of the likelihood of the synchronization mode successfully operating for a longer period of time than if the independent stimulation mode were not applied first.

[0061] Accordingly, in some examples, an independent stimulation element is implemented alone to treat sleep disordered breathing. However, in some examples, treatment is

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accomplished via a complementary combination of an independent (i.e. asynchronous) stimulation mode and a synchronous stimulation mode.

[0062] As noted above, in some examples, a stimulation protocol element may provide convertible operation between the above-described independent (i.e. asynchronous) first stimulation mode and a synchronous second stimulation mode of stimulating the airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform. However, in one example arrangement, the therapy manager causes: operation in the second stimulation mode and conversion of operation into the first stimulation mode upon at least one parameter of the sensed respiratory waveform failing to meet a sensor signal quality criteria. Later, reversion of operation into the second stimulation mode is made upon the at least one parameter of the sensed respiratory waveform meeting the sensor signal quality criteria. Accordingly, in one aspect, the second stimulation mode comprises the default mode of stimulation.

[0063] These examples, and other examples, are further described in association with at least Figures 1-19.

[0064] Figure 1A is block diagram schematically illustrating a stimulation element 12, according to one example of the present disclosure. In some examples stimulation element 12 directs and controls nerve stimulation to treat obstructive sleep apnea. In some examples, stimulation element 12 includes an independent stimulation function 14, which in general terms, applies electrical stimulation via a stimulation protocol to an airway-patency-related nerve to treat upper airway obstructions. In some examples, such airway-patency-related nerves include at least the protrusor branches of the hypoglossal nerve.

[0065] In some examples, the independent stimulation function 14 operates to stimulate an airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to sensed respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period. Accordingly, in some examples, via the independent stimulation function 14, nerve stimulation is applied independent of characteristics of sensed respiratory information. In other words, once the independent stimulation function 14 has been activated, the initiation and termination of individual nerve

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stimulation periods is not synchronized relative to a characteristic, such as onset of the inspiratory phase of the patient respiratory cycle and/or other characteristics. In at least this context, operation of independent stimulation function 14 (Fig. 1A) may be referred to as an asynchronous stimulation function or mode.

[0066] In some examples, once a treatment period begins, such as when the patient is engaging in sleeping behavior (and during which sleep disordered breathing is to be avoided), the nerve stimulation function 14 is always in an "on" or active mode, and therefore stimulation cycles are applied to the nerve. In such examples, activation or deactivation of the independent stimulation function 14 is independent of whether or not apneas are occurring. For instance, the general activation and/or deactivation of the independent stimulation function 14 can be controlled according to a selectable time schedule, such as a predetermined start time (e.g. 10 p.m.) and predetermined end time (e.g. 6 a.m.).

[0067] Figure 1B is a block diagram schematically illustrating a therapy manager 16, according to one example of the present disclosure. In general terms, therapy manager 16 directs a therapeutic regimen for controlling sleep disordered breathing such as, but not limited to, obstructive sleep apnea. The therapy manager 16 operates as part of, or in cooperation with, an at least partially implantable nerve stimulation system. In some examples, therapy manager 16 forms at least part of a control portion such as, but not limited to, control portion 360 as later described in association with at least Figures 9-10, and as such, in some examples, therapy manager 16 includes at least some of substantially the same features and attributes as therapy manager 371 described in association with at least Figure 9.

[0068] In some examples, therapy manager 16 is in communication with and/or incorporates at least some aspects of stimulation element 12. In some examples, the therapy manager has access to physiologic sensing information via sensing elements (e.g. at least Figs. 7A-7B). In such examples, general activation and/or general deactivation of the independent stimulation function 14 is controlled according to a likelihood of sleep behavior, which is determined according to at least body position, body posture, body motion, and/or body

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activity parameters, which can be sensed via an accelerometer or other sensing elements. In some examples, determining likelihood of sleep behavior is supplemented via additional sensed physiologic information, including but not limited to sensed respiratory information.

[0069] In some of the examples in which the therapy manager 16 has access to sensed physiologic information (at least Figs. 7A-8), once a treatment period begins, the nerve stimulation function 14 is not generally activated and/or deactivated to stimulate a nerve until prompted to do so based on respiratory behavior criteria (e.g. whether apneas are likely or are occurring, etc.). This determination is separate from, and independent of, timing or synchronizing individual stimulation periods relative to particular characteristics (e.g., inspiration, expiration, etc.) of sensed respiratory information. Accordingly, in these examples, whether or not a patient receives any stimulation at all is governed by whether or not the patient experiences a sufficient quantity, frequency, or intensity of apneas.

[0070] In other words, in some examples, therapy manager 16 operates to apply stimulation when the patient is experiencing apneas or likely to experience apneas. In this way, nerve stimulation is limited to an as needed basis, thereby conserving energy of the stimulation system 20 and reducing potential muscle fatigue. As to the particular strength of the stimulation signal and whether it is applied in view of the relative severity of the sleep disordered respiratory behavior, at least some examples of automatic adjustment of a level of stimulation therapy is described in at least Christopherson, METHOD OF TREATING SLEEP DISORDERED BREATHING, published on October 27, 2011 as US 2011-0264164.

[0071] In some examples, the detection of flow limitations and/or associated apneas, as well as the detection of the beginning and end of the respective inspiratory and expiratory phases of the respiratory cycle, is performed according to, or in cooperation with, known methods and devices for doing so. Some non-limiting examples of such devices and methods to recognize and detect the various features and patterns associated with respiratory effort and flow limitations include, but are not limited to: PCT Publication WO/2010/059839, titled A METHOD OF TREATING SLEEP APNEA, published on May 27, 2010; Christopherson U.S. Patent 5,944,680, titled RESPIRATORY EFFORT DETECTION METHOD AND

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APPARATUS; and Testerman U.S. Patent 5,522,862, titled METHOD AND APPARATUS FOR TREATING OBSTRUCTIVE SLEEP APNEA.

[0072] In some examples, the stimulation element 12 comprises a stimulation engine to determine and administer a stimulation protocol. In some examples, the stimulation element 12 further includes and/or acts in cooperation with a pulse generator and stimulation electrode to deliver the stimulation to a target nerve, such as later described in association with at least Figures 2A-2D and 7B. In such examples, the pulse generator includes the stimulation engine or the stimulation engine is in communication with the pulse generator.

[0073] In some examples, the therapy manager 16 is in communication with the pulse generator and/or incorporated within the pulse generator. In some examples, at least some components, functions, elements, etc. of the therapy manager 16 are incorporated within a physician programmer external to the patient or a patient remote external to the patient.

[0074] Details regarding particular stimulation protocols implemented via the independent stimulation function 14 are later described in association with at least Figures 3B-3E. In particular, at least some details are provided regarding how asynchronous stimulation may increase therapeutic effectiveness in treating sleep disordered breathing.

[0075] Figure 2A is a schematic diagram of an at least partially implantable stimulation system 20, according to an example of the present disclosure. In general terms, the stimulation element 12 of Figure 1A (and/or therapy manager 16 of Figure 1B) is incorporated within and/or operates in association with stimulation system 20 to deliver stimulation.

[0076] As illustrated in Figure 2A, in one example system 20 includes an implantable pulse generator (IPG) 35 and a stimulation lead 32 electrically coupled with the IPG 35 via a connector (not shown) positioned within a connection port of the IPG 35. In some examples, the IPG 35 is surgically positioned within a pectoral region of a patient 22. The lead 32 includes a stimulation electrode portion 45 and extends from the IPG 35 so that the stimulation electrode portion 45 is positioned in contact with a desired nerve, such as an airway-patency-related nerve 33 of the patient 10, to enable stimulation of the nerve 33, as described below in detail. In some examples, the stimulation electrode portion 45 comprises

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a self-sizing cuff such as described in U.S. 8,340,785 to Bonde et al. In some examples, in association with electrode 45, lead 32 includes at least some of the features and attributes described in U.S. Patent Publication 20110160827 to Bonde et al. In some examples, lead 32 includes features and attributes at least consistent for use in an implantable stimulation system as described in U.S. Patent No. 6,572,543 to Christopherson et al.

[0077] As later described more fully in association with at least Figs. 9-10, in some examples the therapy manager 16 controls the IPG 35, and is implemented externally of the IPG 35, entirely within the IPG 35, or partially within the IPG 35.

[0078] In some examples, stimulation electrode portion 45 comprises a cuff electrode including a single operative contact group of at least two electrodes through which the stimulation is deliverable non-selectively to the airway-patency-related nerve. Figure 2E is a top view schematically illustrating one example of such an electrode 50 including a single operative contact group of at least two electrodes 52. In some examples, the stimulation electrode portion 45 comprises a cuff electrode including at least one operative contact group through which the stimulation is deliverable non-selectively to the airway-patency-related nerve. Accordingly, more than one operative contact group of electrodes can be incorporated in a single cuff electrode. In some examples, the stimulation electrode portion 45 can include multiple, separate cuff electrodes with each having at least one operative contact group of electrodes.

[0079] In some examples, the stimulation system for treating obstructive sleep apnea is a totally implantable system which provides therapeutic solutions for patients diagnosed with obstructive sleep apnea. However, in some examples, one or more components of the system are not implanted in a body of the patient, thereby providing an at least partially implantable system. A few non-limiting examples of such non-implanted components include an external processing unit and/or an external power source, as later noted in association with at least Figure 6.

[0080] In some examples, the at least partially implantable stimulation system 20 does not include any sensing elements. Accordingly, to the extent that the system 20 and its therapy manager 16 apply stimulation protocols to treat respiratory behavior, any patient-specific

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respiratory information would be received and/or obtained prior to, and/or during, implantation of the system 20. Alternatively, a temporary external sensing system could be employed to periodically calibrate and/or evaluate therapeutic efficacy of the at least partially implantable stimulation system 20 operating according to an independent stimulation function 14 (Fig. 1A).

[0081] At least some examples of the sensor-less stimulation system 20 use significantly less power than some sensor-based systems and are easier to implant. Moreover, in such examples, the system 20 is significantly easier to construct and/or operate because the sensors, certain sensing-related circuitry, and certain operational programming can be omitted.

[0082] However, it will be understood that in some examples, the stimulation system 20 includes sensing elements, at least in the manner later described in association with at least Figures 7A-7B. In at least some of these examples, the sensing elements are used to evaluate therapy and particular stimulation protocols but are not used to synchronize stimulation relative to characteristics of the sensed respiratory waveforms.

[0083] Figure 2B is block diagram of an implantable pulse generator (IPG) 50, according to one example of the present disclosure. In some examples, IPG 50 includes at least some of substantially the same features and attributes as IPG 35 (Fig. 2A). However, in some examples, IPG 50 includes at least some features and attributes different than those in IPG 35 (Fig. 2A). As such, in some examples, IPG 50 can take different forms and be implanted in locations other than those shown in Figure 2A (and also Figure 7B).

[0084] With further reference to Figure 2B, in some examples the implantable pulse generator 50 includes a stimulation element 52 and a communication element 54. The stimulation element 52 generates and applies a neuro-stimulation signal via electrode(s) (such as stimulation electrode(s) 45 in Fig. 2A) according to a treatment regimen programmed by a physician and/or in cooperation with therapy manager 16. In some examples, stimulation element 52 comprises at least some of substantially the same features and attributes as stimulation element 12 as previously described in association with Figure 1A.

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[0085] The communication element 54 provides a communication pathway to enable transmission of data, power, and/or controls signals both to and from the implanted portions of the system 20 relative to the external portions of the system 20. For instance, in some examples, the communication element 54 is configured to report activities of the IPG 50 (including sensed physiologic data, stimulation history, number of apneas detected, etc.) and is configured to receive initial or further programming of the IPG 50 from an external source, such as a patient programmer, clinician programmer, etc. as later noted in association with at least Figure 10. In some examples, the communication element 54 utilizes a radiofrequency (RF) telemetry link or other wireless communication protocols.

[0086] In some examples, the implantable pulse generator 50 includes a control portion or at least part of a control portion such as control portion 56 shown in Figure 2C. In general terms, control portion 56 directs operation of the pulse generator 50 and the at least partially implantable stimulation system. Further details regarding such a control portion 56 are described later in association with at least Figures 9-10. Moreover, in some examples, control portion 56 is operable in association with a user interface, such as described later in association with at least Figures 11A-11B.

[0087] Figure 2D is a block diagram 70 schematically illustrating an at least partially implantable stimulation system 80, according to an example of the present disclosure. In some examples, system 80 includes at least some of substantially the same features and attributes as system 20 (Fig. 2A), pulse generator 50 (Fig. 2B), and control portion 56 (Fig. 2C), except for system 80 having some portions in a non-pectoral location and located in close proximity to a target nerve to be stimulated, as further illustrated in association with at least Figure 2D.

[0088] In some examples, system 80 is a sensor-less system in a manner substantially similar to the above-described system 20. In other words, as at least partially implanted in the patient's body, system 80 omits a sensor.

[0089] As shown in Figure 2D, in some examples system 80 includes a nerve-coupling electrode portion 82 and a pulse generator 84. In some examples, the nerve-coupling electrode portion 82 comprises an element which is at least electrically coupled relative to a

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target nerve 72 suitable to maintain or restore airway patency, such as but not limited to, the hypoglossal nerve.

[0090] In some examples, the electrode portion 82 comprises a cuff, such as one of the stimulation electrode portions 45 described in association with Figure 2A in which the electrode portion is both mechanically and electrically coupled relative to the nerve 72. However, in some examples, the nerve-coupling electrode portion 82 comprises a cuff-less structure that is both mechanically and electrically coupled relative to the nerve 72.

[0091] In some examples, the nerve-coupling electrode portion 82 is not mechanically coupled to the nerve 72, but is mechanically coupled or secured in a location in close proximity to the nerve 72 and that enables electrically coupling of the electrode portion 82 relative to the nerve 72. In one instance, such examples include the electrode portion 82 being delivered to the target nerve 72 via a percutaneous access delivery. In one instance, such examples include the electrode portion 82 being delivered to the target nerve 72 via a transvenous delivery method in which the electrode portion 82 is delivered on a lead maneuvered within and through the vasculature of the patient.

[0092] In some examples, in a manner consistent with the previously described pulse generator 50 (Fig. 2B) pulse generator 84 includes a stimulation element 52 and a communication element 54. In some examples, pulse generator 84 includes solely internal components 90, which are internally within the body below the skin/tissue. However, in some examples, pulse generator 84 includes a combination of some internal components 90 and some external components 92, which are external to the body being above or outside the skin/tissue.

[0093] In some examples, via communication element 54 (Fig. 2B), system 80 includes a wired communication path 94 and/or a wireless communication path 96 between the pulse generator 84 and the nerve-coupling electrode portion 82, as shown in Fig. 2D. In some examples, either or both such communication pathways 94, 96 are also employable for communication between internal and external components 90, 92 of a pulse generator 84.

[0094] In some examples, in order to utilize and/or evaluate sensed respiratory information, the therapy manager 16 uses a reference point, such as a normal breathing pattern 150, as

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shown in Figure 3A. Of course, variances may exist from patient-to-patient so it will be understood that the normal breathing pattern 150 is a representative example provided for illustrative purposes and is not intended to strictly define a breathing pattern that is universally normal for all patients. With this in mind, in some examples, the system 20 uses the particular breathing pattern of a specific patient (to which the method is applied) as the reference point to utilize and/or evaluate sensed respiratory information.

[0095] In the example of normal breathing pattern 150 shown in Figure 3A, a respiratory cycle 160 includes an inspiratory phase 162 and an expiratory phase 170. The inspiratory phase 162 includes an initial portion 164, intermediate portion 165, and end portion 166 while expiratory phase 170 includes an initial portion 174, intermediate portion 175, end portion 176, and an expiratory peak 177. A first transition 180 occurs at a junction between the end inspiratory portion 166 and the initial expiratory portion 174 while a second transition 182 occurs at a junction between the end expiratory portion 176 and the initial inspiratory portion 164. In some instances, end expiratory portion 176 includes and/or is referred to as an expiratory pause that occurs just prior to onset of the initial inspiratory portion 164.

[0096] Figure 3B is a diagram 200 schematically illustrating a stimulation protocol 210 implemented via independent stimulation function 14 (Fig. 1A), according to one example of the present disclosure. In some examples, after initializing the system according to the known/applicable respiratory cycle for that patient and after general activation of the independent stimulation function 14, the initiation, operation, and termination of the stimulation protocol 210 operates without regard to sensed respiratory information. In one aspect, Figure 3B illustrates a respiratory pattern 202 including a series of reference respiratory cycles 204A-204H, with each cycle having substantially the same features and attributes as the respiratory cycle 160. Accordingly, each reference respiratory cycle 204A-204H has a duration R.

[0097] In one aspect, the pattern 202 represents a stable respiratory pattern that occurs during normal daytime breathing and/or that results from application of stimulation protocol 210.

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[0098] In some examples, because stimulation via the stimulation protocol 210 is not synchronized relative to characteristics of actively-sensed respiratory cycles (such as via real-time measure of respiratory effort), the stimulation protocol 210 operates based on a reference respiratory cycle. In some examples, the reference respiratory cycle includes at least one of a historical patient-specific average respiratory cycle for stable respiration and a multi-patient average respiratory cycle for stable respiration. This historical and/or predictive information is employed in at least some examples in which the therapy manager 16 (Fig. 1B) is not actively sensing respiratory waveforms during operation of the at least partially implantable stimulation system 20.

[0099] As shown in Figure 3B, stimulation protocol 210 includes a series of separate stimulation periods (e.g. pulses) 212A-212J spaced apart by a non-stimulation periods 218A-281I, each of which are interposed between an adjacent pair of stimulation periods. For instance, non-stimulation period 218B is interposed between stimulation periods 212B, 212C. In one aspect, each stimulation period (212A-212I) has a first end 214 and an opposite second end 216.

[00100] In some examples, in order to demonstrate the manner in which the stimulation protocol 210 is juxtaposed relative to the respiratory pattern 202, Figure 3B further illustrates each respiratory cycle being apportioned into a discrete number (e.g. 3, 4, 5, 6, 7, 8, etc.) time units, with each time unit having a duration t. In the example shown in Figure 3B, each respiratory cycle has a duration R and is divided into six time units t.

[00101] In some examples, the duration R is patient specific and is based on a long term average duration of a respiratory cycle. In some examples, the duration R is not patient specific and is based on an average duration of a respiratory cycle for many different patients. In some examples, duration R is about 3 to about 6 seconds. In some examples, via therapy manager 16, the duration R can be adjusted to a preferred duration. In some examples, the therapy manager 16 uses the patient-specific information regarding durations.

[00102] However, in some examples, where such information is not available or is problematic, the therapy manager 16 uses multi-patient information. For instance, for at least some patient populations a duration of an entire respiratory period is about 3 to 6

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seconds, which corresponds to a general respiratory rate of about 10-18 breaths/minute. Moreover, generally speaking inspiration (e.g. an inspiratory phase) is a minority of the entire respiratory period which includes inspiration, expiration, and expiratory pause.

[00103] In at least some patient populations, an apnea and/or hypopnea has a minimum duration of about 10 seconds, which corresponds to a minimum duration about 2-3 breaths.

[00104] In some examples, an apnea may be avoided via implementation of a stimulation protocol which avoids missing (either completely missing or significantly missing) stimulation for more than one breath (e.g. one inspiratory phase).

[00105] With further reference to Figure 3B, as represented by the legend 209, the stimulation protocol 210 operates according to a stimulation cycle in which the duration of the stimulation cycle is less than the duration (R) of the reference respiratory cycle. In some examples, the duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of 3. In some examples, as shown by legend 209, the stimulation period and the non-stimulation period are in a proportion of 4 to 1. In such examples, each stimulation cycle includes a continuous stimulation period of 4 time units followed by a non-stimulation period of 1 time units, with this stimulation cycle being repeated continuously when nerve stimulation is generally activated. The total duration of the stimulation cycle (e.g. 4 time units of stimulation and 1 time unit of non-stimulation) is 5 time units, which is less than the duration R of the respiratory period, which is 6 time units in this example. In one aspect, this example arrangement in which the stimulation period is in much greater proportion to the non-stimulation period may benefit some patients by minimizing tongue rubbing by minimizing the frequency or total volume of tongue motion incident to tongue protrusion intentionally caused by the stimulation therapy to restore airway patency.

[00106] In Figure 3B, the first end 214 of stimulation period 212A is shown as coinciding with the beginning of an inspiratory phase 162 of the respiratory cycle 204A. However, it will be understood that the beginning 214 of the stimulation period 212A is not synchronized relative to the inspiratory phase 162. Rather, the beginning 214 of stimulation period 212A is shown as coinciding with the beginning of inspiratory phase 162 for illustrative simplicity in juxtaposing the stimulation protocol 210 relative to the respiratory cycles 204A-204H.

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Accordingly, it will be understood that when stimulation (according to stimulation protocol 210) is initiated during a treatment period, the beginning of the stimulation period 212A may coincide with a different portion of the respiratory cycle (e.g. 204A) than shown in Figure 3B.

[00107] With further reference to the stimulation protocol 210 in Figure 3B, in one aspect, each respective non-stimulation period 218A-218I has a duration less than a duration of each respective stimulation periods 212A-212J. In one aspect, the duration of the stimulation period 212A is less than a duration (R) of the reference respiratory cycle 204A. In one aspect, the relative duration of the respective stimulation periods (e.g. 212A) and non-stimulation periods (e.g. 218A) causes each successive stimulation period (e.g. 212B) to begin at a different place along a successive respiratory cycle, such that the stimulation pattern is independent of (i.e. not synchronized relative to) the characteristics of the respiratory cycle. For instance, it can be seen from Figure 3B that the first end 214 of stimulation period 212D coincides with a portion of the expiratory phase 170 of respiratory cycle 204C while the first end 214 of stimulation period 212E coincides with a portion of inspiratory phase 162 of the successive respiratory cycle 204D.

[00108] As shown in Figure 3B, each of the respective stimulation periods 212A, 212B, 212C overlaps the entire inspiratory phase 162 of the respective respiratory cycles 204A-204C while stimulation period 212D at least partially overlaps the inspiratory phase 162 of respiratory cycle 204D.

[00109] Because the overall duration of the stimulation cycle (both stimulation period and non-stimulation period) does not match the duration (R) of the reference respiratory cycle, the stimulation protocol 210 ensures that each successive stimulation period within the series of stimulation cycles will fall along a different portion of the successive respiratory cycles. Accordingly, even though the stimulation is not synchronized relative to a characteristic (e.g. inspiration) of the respiratory waveform, no matter where the stimulation protocol 210 is started relative to a series of respiratory cycles, the stimulation periods will overlap with at least a portion of the inspiratory phase of the respective reference respiratory cycles for a significant majority of the treatment period. Accordingly, even if the stimulation protocol

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210 happens to be initiated at a time that the non-stimulation period (e.g. 218D, 218E) at least partially overlaps with the inspiratory phase 162 of a respiratory cycle (e.g. 204D, 204E), the succeeding stimulation periods 212F, 212G, etc. at least partially overlaps the inspiratory phase 162 of the next respiratory cycle 204F, 204G, etc., with these later successive stimulation periods significantly overlapping (e.g. stimulation period 212F, which overlaps by at least a majority) or even completely overlapping (e.g. stimulation period 212G) the inspiratory phase 162 of the respective successive respiratory cycles (e.g. 204F, 204G).

[00110] In one aspect, in stimulation protocol 210 the duration of each stimulation period (e.g. 212A-212J) is less than a duration (R) of the reference respiratory cycles (204A-204H) but greater than a duration of the inspiratory phase 162 of an individual respiratory cycle (e.g. 204A).

[00111] In one aspect, a duty cycle for the stimulation cycle varies on a respiratory cycle-by-respiratory cycle basis. For instance, during respiratory cycles 204A, 204B, 204C, 204D, 204F, 204G, 204H the duty cycle is 5 time units of continuous stimulation and 1 time unit of non-stimulation, which equals about 83%. However, during respiratory cycle 204E, the duty cycle is 4 time units of continuous stimulation and 2 time units of non-stimulation, which equals about 67%. Every 5 respiratory cycles , the series of stimulation cycles repeats itself, as illustrated at respiratory cycle 204F, at which the first end 214 of the stimulation period 212G once again coincides with the beginning of the inspiratory phase 162 of the respiratory cycle 204F in a manner similar to respiratory cycle 204A. Accordingly, in one aspect, the long term duty cycle over an indefinite number of respiratory cycles (or average duty cycle over a sufficient number of time frames) is about 80%.

[00112] In some examples, via stimulation protocol 210, no sequence of four respiratory cycles occurs without a stimulation period significantly overlapping the inspiratory phase 162 (e.g. overlapping at least majority of the inspiratory phase 162) of respiratory cycles in Figure 3B. This criteria is based on the longest period of time, in at least some examples, that a patient can go without a breath while avoiding a respiratory-event related arousal and/or to maintain near normal blood oxygenation.

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[00113] In some examples, via stimulation element 12 (Fig. 1A) and/or therapy manager 16 (Fig. 1B) a clinician can implement a stimulation protocol in which a quantity (e.g. 2, 3, 4) is selected by the operator regarding how many respiratory cycles can pass without a significantly overlapping stimulation period, according to a predetermined amount of time and/or a predetermined number of respiratory cycles for a particular patient.

[00114] It will be understood that each inspiratory phase 162 of each respiratory cycle (204A-204H) is shown in its ideal form in Figure 3B, and that in some instances where the inspiratory phase 162 at least partially coincides with one of the respective non-stimulation periods (e.g. 218D), the inspiratory phase may sometimes have an irregular shape compared to the idealized shape shown in Figure 3B.

[00115] Accordingly, via stimulation protocol 210, the independent stimulation function 14 of stimulation element 12 (Fig. 1A) employs asynchronous nerve stimulation to achieve stable respiration despite potential sleep disordered breathing.

[00116] With the example of pattern 202 and stimulation protocol 210 as a foundation, it will be understood that in some examples, a stimulation protocol is adopted in which the duration of the stimulation period of each stimulation cycle is at least 50 percent of the duration of the reference respiratory cycle. In at least some contexts, this arrangement may ensure that the probability of entirely missing inspiration in an asynchronous stimulation protocol is less than 50%, such that a majority of the treatment period, stimulation will be delivered during at least a portion of inspiration, which may be sufficient to minimize or prevent sleep disordered breathing (e.g. apneas).

[00117] In some examples, a stimulation protocol is adopted in which the duration of the stimulation period of each stimulation cycle is 80 percent of the duration of the reference respiratory cycle. For instance, such an arrangement might be employed in some example patients having severe obstructive sleep apnea in which an inspiration can be missed for no more than 1 of 5 breaths. When applied asynchronously, such a duty cycle may likely ensure effective treatment (assuming other stimulation parameters are effective) while still allowing the protrusor muscles to rest sufficiently.

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[00118] While not depicted in Figure 3B, in some examples, a stimulation protocol is adopted in which the duration of the stimulation period of each stimulation cycle is at least 25 percent of the duration of the reference respiratory cycle. When employed in an asynchronous arrangement, such an arrangement will likely ensure that at least one stimulation period significantly overlaps with the inspiratory phase at least one breath (e.g. one respiratory cycle) out of every three breaths (i.e. three respiratory cycles). For some patients which exhibit less severe apneas, this arrangement can be sufficient to prevent obstructive events.

[00119] Figure 3C is a diagram 221 schematically illustrating a stimulation protocol 220 implemented via independent stimulation function 14 (Fig. 1A), according to one example of the present disclosure. In one example, diagram 221 includes at least some of substantially the same features and attributes as diagram 201, except for having a different stimulation protocol 220.

[00120] Moreover, as represented by the legend 229, the stimulation protocol 220 operates according to a stimulation cycle in which the duration of the stimulation cycle is greater than the duration (R) of the reference respiratory cycle. In some examples, the duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of at least 1.5. As represented via legend 229, in some examples stimulation protocol 220 includes a stimulation cycle including a stimulation period of 4 ½ time units and a non-stimulation period of 2 ½ time units, with the overall stimulation cycle of 7 time units having a duration greater than the duration R of the respiratory cycle (e.g. 204A) of 6 time units.

[00121] In a manner substantially the same as previously noted for stimulation protocol 210, even though stimulation protocol 220 is not synchronized relative to a characteristic (e.g. inspiration) of the respiratory waveform, no matter where the stimulation protocol 220 is started relative to a series of respiratory cycles, the stimulation periods will overlap with at least a portion of the inspiratory phase of the respective reference respiratory cycles for a significant majority of the treatment period. For instance, even if the stimulation protocol happens to be initiated at a time that the non-stimulation period 228B generally coincides with the inspiratory phase 162 of a respiratory cycle 204C, the succeeding stimulation period

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222C at least partially overlaps the inspiratory phase 162 of the next respiratory cycle 204D, and with later successive stimulation periods significantly overlapping (e.g. stimulation period 222D, exhibiting at least a majority overlap) or completely overlapping (e.g. stimulation period 222E) the inspiratory phase 162 of the respective successive respiratory cycles (e.g. 204E, 204F).

[00122] In some examples, a stimulation protocol is applied in which a total duration of stimulation via the first stimulation protocol during a treatment period is greater than 30 percent of the total duration of the treatment period.

[00123] In one aspect, in stimulation protocol 220 the duration of each stimulation period (e.g. 222A-222G) is less than a duration (R) of the respiratory cycles 204A-204H) but greater than a duration of the inspiratory phase 162 of an individual respiratory cycle (e.g. 204A).

[00124] In one aspect, a duty cycle exhibited by the repeating stimulation cycle varies on a respiratory cycle-by-respiratory cycle basis. For instance, during respiratory cycles 204D, 204E, 204F, 204G the stimulation duty cycle is 3 ½ time units of continuous stimulation and 2 ½ time units of non-stimulation, which equals about 58%. However, during respiratory cycles 204A and 204B the stimulation duty cycle is 4 ½ time units of continuous stimulation and 1 ½ time units of non-stimulation, which equals about 75%. Meanwhile, during respiratory cycles 204C, the duty cycle is 4 time units of continuous stimulation and 2 time units of non-stimulation, which equals about 67%. Every 8 respiratory cycles, the series of stimulation cycles repeats itself, as illustrated at respiratory cycle 204H, at which the first end 224 of the stimulation period 222G once again coincides with the beginning of the inspiratory phase 162 of the respiratory cycle 204H in a manner similar to respiratory cycle 204A. Accordingly, in one aspect, the long term or average duty cycle over a long period of time is about 64%.

[00125] In some examples, via stimulation protocol 220 no more than four respiratory cycles occur without a stimulation period significantly overlapping (e.g. at least a majority of the) inspiratory phase 162 of respiratory cycles in Figure 3C.

[00126] Figure 3D is a diagram 231 schematically illustrating a stimulation protocol 230 implemented via independent stimulation function 14 (Fig. 1A), according to one example

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of the present disclosure. In one example, diagram 231 includes at least some of substantially the same features and attributes as diagram 201 (Fig. 3B) or diagram 221 (Fig. 3C), except for having a different stimulation protocol 230.

[00127] Moreover, as represented by the legend 239, the stimulation protocol 220 operates according to a stimulation cycle in which the duration of the stimulation cycle is greater than the duration (R) of the reference respiratory cycle. In some examples, the duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of at least 3. As represented via legend 239 in Figure 3D, in some examples stimulation protocol 230 includes a stimulation cycle including a continuous stimulation period of 7 ½ time units and a non-stimulation period of 2 ½ time units, with the overall stimulation cycle of 10 time units having a duration greater than the duration R of the respiratory cycle (e.g. 204A) of 6 time units.

[00128] In a manner substantially the same as previously noted for stimulation protocols 210, 220, even though stimulation protocol 230 is not synchronized relative to a characteristic (e.g. inspiration) of the respiratory waveform, no matter where the stimulation protocol 230 is started relative to a series of respiratory cycles, the stimulation periods will overlap with at least a portion of the inspiratory phase of the respective respiratory cycles for a significant majority of the treatment period. Accordingly, even if the stimulation protocol happens to be initiated at a time that the non-stimulation period 238B generally coincides with the inspiratory phase 162 of a respiratory cycle 204D, the succeeding stimulation period 232C at least partially overlaps the inspiratory phase 162 of the next respiratory cycle 204E.

[00129] In one aspect, in stimulation protocol 230 the duration of each stimulation period (e.g. 232A-232D) is greater than a duration (R) of the respiratory cycles 204A-204G) and greater than a duration of the inspiratory phase 162 of an individual respiratory cycle (e.g. 204A).

[00130] In one aspect, a duty cycle exhibited by the repeating stimulation cycle varies on a respiratory cycle-by-respiratory cycle basis. For instance, during respiratory cycle 204A, the duty cycle is 6 time units of continuous stimulation, which equals 100%. However,

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during respiratory cycles 204B and 204E the stimulation duty cycle is 3 ½ time units of continuous stimulation and 2 ½ time units of non-stimulation, which equals about 58%. Meanwhile, during respiratory cycle 204C, the duty cycle is 5 1/2 time units of continuous stimulation and 1/2 time units of non-stimulation, which equals about 92 percent. Meanwhile, during respiratory cycle 204D, the duty cycle is 4 time units of continuous stimulation and 2 time units of non-stimulation, which equals about 66 percent.

[00131] Every 5 respiratory cycles, the series of stimulation cycles repeats itself, as illustrated at respiratory cycle 204F, at which the first end 234 of the stimulation period 232D once again coincides with the beginning of the inspiratory phase 162 of the respiratory cycle 204F in a manner similar to respiratory cycle 204A.

[00132] In one aspect, the long term (i.e. average) duty cycle over a sufficient number of respiratory cycles is about 75 percent.

[00133] In one aspect, this stimulation protocol provides an occasional 100% duty cycle (e.g. stimulation period 232D) to ensure that an inspiratory phase will be not missed during a stimulation period, while the overall average duty cycle is 75 percent. In some examples, such stimulation protocols are suitable for a patient in which the pattern of the respiratory waveform varies considerably but where effective therapy can be achieved without using continuous stimulation.

[00134] In some examples via stimulation protocol 230 no sequence of four respiratory cycles occurs without a stimulation period at least significantly overlapping the inspiratory phase 162 of respiratory cycles in Figure 3D.

[00135] Figure 3E is a diagram 241 schematically illustrating a stimulation protocol 240 implemented via independent stimulation function 14 (Fig. 1A), according to one example of the present disclosure. In one example, diagram 241 includes at least some of substantially the same features and attributes as diagram 201, except for having a different stimulation protocol 240.

[00136] As represented via legend 249 in Figure 3E, stimulation protocol 240 includes a stimulation cycle including a continuous stimulation period of 4 time units and a non-stimulation period of 2 time units, with the overall stimulation cycle of 6 time units having

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a duration generally matching the duration R of the reference respiratory cycle (e.g. 204A) of 6 time units. As in the prior examples associated with Figures 3A-3E, the stimulation protocol 240 is independent, i.e. not synchronized relative to sensing of respiratory information.

[00137] In some patients the duration (R) of their respiratory cycle may vary slightly over time as the respiratory cycle might shorten or lengthen. Diagram 241 schematically illustrates just one example in which the reference respiratory cycle represents a situation in which the duration of the respiratory cycle lengthens to R1 due to lengthening of the expiratory phase 171 of the respiratory cycles of the patient. It will be understood that other characteristics, parameters, features of the respiratory cycle often change as well, but these changes are not depicted in Figure 3E for illustrative simplicity and clarity.

[00138] It will be further understood that such changes may develop gradually over time and that Figure 3E provides a snapshot of one such change after it has already at least partially developed. Moreover, because this arrangement of independent stimulation operates without synchronization relative to sensed respiratory information, Figure 3E schematically represents at least some aspects regarding how stimulation protocol 240 may provide therapeutic effectiveness in this situation of lengthening respiratory cycles (or shortened respiratory cycles) as represented by the reference respiratory cycles 204A-245M in Figure 3E.

[00139] Accordingly, in this example, the stimulation cycle repeats itself in what otherwise would be exactly matching each reference respiratory cycle, but the elongated duration of the reference respiratory cycle causes the stimulation cycle to no longer coincide with various portions of the respiratory cycle.

[00140] It will be understood, of course, as previously noted elsewhere that at the time the stimulation protocol is initiated and while not shown in Figure 3E, the first end 244 of the initial stimulation period 242A may not necessarily coincide with the beginning of an inspiratory phase 162 of a respiratory cycle 245A.

[00141] In some examples, even though stimulation protocol 240 is not synchronized relative to a characteristic (e.g. inspiration) of the respiratory waveform, no matter where the

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stimulation protocol 240 is started relative to a series of respiratory cycles, the stimulation periods will overlap with at least a portion of the inspiratory phase of the respective respiratory cycles for a significant majority of the treatment period. Accordingly, even if the stimulation protocol happens to be initiated at a time that the non-stimulation period 248H 248I, 248J generally coincides with the inspiratory phase 162 of a respiratory cycle 245H, 245I, 245J, at least some subsequent stimulation periods 242L, 242M, 242N significantly overlap (at least a majority overlap) the inspiratory phase 162 of the next respiratory cycles 245K, 245L, 245M. As further seen in Figure 3E, other example stimulation periods also significantly overlap (e.g. stimulation period 242F) the inspiratory phase 162 of the corresponding respective respiratory cycle 245F.

[00142] In some examples, the stimulation periods 242A-242E, 242N completely overlap the inspiratory phase 162 of the respective respiratory cycles (e.g. 245A-245E, 245M). However, it will be understood that in some examples, such complete overlap with the inspiratory phase of some respiratory cycles may not be exhibited, and a significant overlap would suffice to achieve adequate airway patency.

[00143] In one aspect, in stimulation protocol 240, the duration of each stimulation period (e.g. 242A-242M) is less than a duration (R) of the respiratory cycles (245A-245M) but greater than a duration of the inspiratory phase 162 of an individual respiratory cycle (e.g. 245A).

[00144] In one aspect, the duty cycle associated with the stimulation cycle varies on a respiratory cycle-by-respiratory cycle basis. For instance, during respiratory cycles 245A, 245B, 245C, 245D, 245E, 245F, 245G, 245H, 245M the duty cycle is 4 1/2 time units of continuous stimulation and 2 time units of non-stimulation, which equals about 75 percent. However, during respiratory cycles 245I, 245J, 245K, 245L the duty cycle is 4 time units of continuous stimulation and 2 ½ time units of non-stimulation, which equals about 62 percent.

[00145] For at least the time that a particular duration (R1) of the elongated respiratory cycle persists (as represented by reference respiratory cycles), every 12 respiratory cycles, the series of stimulation cycles repeats itself, as illustrated at respiratory cycle 245M, at which the first end 244 of the stimulation period 242N once again coincides with the

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beginning of the inspiratory phase 162 of the respiratory cycle 245M in a manner similar to respiratory cycle 245A.

[00146] In one aspect, the long term, average stimulation duty cycle over a sufficient period of time is about 67 percent.

[00147] Accordingly, in some examples, via stimulation protocol 240 no sequence of four respiratory cycles occurs without a stimulation period at least partially overlapping or even significantly overlapping the inspiratory phase 162 of respiratory cycles in Figure 3E.

[00148] It will be further understood that the various stimulation protocols described and illustrated in association with at least Figures 3B-3E are implemented via the at least partially implantable stimulation system 20 as described in association with at least Figures 1-14. However, in some examples, the various stimulation protocols described and illustrated in association with at least Figures 3B-3E are implemented via at least some components, elements, systems etc. other than those described in association with Figures 1-14.

[00149] While the independent stimulation function 14 (Fig. 1A) does not use sensed respiratory information to trigger each stimulation period or synchronize each stimulation period, in some examples the independent stimulation mode 14 uses sensed respiratory information to track how a stimulation protocol is matching up relative to the characteristics of the sensed respiratory waveform. Accordingly, upon elongation or shortening of the sensed respiratory cycles, the therapy manager 16 (including independent stimulation function 14) can choose to maintain or modify which stimulation protocol is being applied in order to ensure that the desired amount and timing of stimulation is being applied. In addition, or as an alternative, the therapy manager 16 uses the sensed respiratory information to adjust or calibrate features of the reference respiratory cycle associated with a particular stimulation protocol.

[00150] In some examples, operation of the therapy manager 16 (as part of an at least partially implantable stimulation system 20) is not limited to the specific stimulation protocols described in association with at least Figures 3B-3E, as other stimulation protocols can be implemented with longer or shorter stimulation periods and with longer or shorter non-stimulation periods.

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[00151] In some examples the independent stimulation function 14 (Fig. 1A) includes a complex stimulation cycle in which at least two different length stimulation periods is employed and/or at least two different length non-stimulation periods is employed. As one non-limiting example to illustrate the principle, one stimulation protocol could include a first continuous stimulation period of three time units, a first non-stimulation period of two time units, a second continuous stimulation period of three time units, followed by a second non-stimulation period of one time unit. The example later described in association with Figure 16A illustrate some aspects of these features.

[00152] In some examples, and as illustrated in the diagrams of Figures 3B-3E, the stimulation cycles are not centered relative to a characteristic or feature of a respiratory waveform. In other words, the respective continuous stimulation periods or non-stimulation periods (in the example stimulation protocols) are not fixed or tied to a particular landmark or fiducial of the respiratory waveform. Accordingly, the respective continuous stimulation periods and non-stimulation periods within stimulation cycles (of a particular stimulation protocol) vary regarding which portion of a respiratory cycle (of a series of respiratory cycles) with which they coincide.

[00153] In some examples, the independent stimulation function 14 provides a stimulation protocol having a duty cycle of 80 percent, where a 100 percent duty cycle would correspond to continuous stimulation over a full respiratory cycle. In one example, a first portion of the duty cycle comprises a continuous stimulation period and a second portion of the duty cycle comprises a continuous non-stimulation period immediately following the first portion. In a non-limiting example in which a respiratory cycle has a duration of 5 seconds, the duty cycle includes applying continuous stimulation for 4 seconds immediately followed by continuous non-stimulation for 1 second, with the duty cycle being repeated.

[00154] Figure 4 is a block diagram 251 schematically illustrating a plurality of stimulation parameters 250, according to one example of the present disclosure. In general terms, these stimulation parameters may be employed as part of implementing one of the stimulation protocols described in association with Figures 3B-3E and/or as part of general operation of stimulation element 12 (Fig. 1A) and/or therapy manager 16 (Fig. 1B). In one example, a

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single parameter is implemented, while in some examples, several of these parameters may be implemented. When several parameters are implemented, they are implemented separately but contemporaneously in some examples and in other examples, they are implemented in combination.

[00155] As shown in Figure 4, these stimulation parameters 250 include amplitude parameter 252, a duty cycle parameter 254, a respiratory cycle duration parameter 260, a time unit parameter 262, and a time frame parameter 270. The amplitude parameter 252 controls an amplitude of the stimulation signal, which can be selected for a particular stimulation protocol.

[00156] In some examples, the duty cycle parameter 254 tracks and/or controls a duty cycle of stimulation. In some examples, the stimulation duty cycle is expressed relative to a duration (R) of one respiratory cycle (per parameter 260) in the manner previously described regarding the stimulations protocols previously described in association with at least Figures 3B-3E. The duty cycle parameter 254 comprises a constant function 256 and a variable function 258. The constant function 256 implements a duty cycle in which the stimulation duty cycle is identical relative to each respiratory cycle, while the variable function 258 implements a duty cycle in which the stimulation duty cycle varies relative to at least some respiratory cycles within a series of respiratory cycles.

[00157] As previously described in association with at least Figures 3B-3E, in some examples, the stimulation duty cycle is implemented according to a series of stimulation cycles in which each stimulation cycle includes at least one continuous stimulation period and at least one non-stimulation period. At least some stimulation protocols includes stimulation cycles in which the duration of the stimulation period(s) differs relative to the duration of the non-stimulation period(s) through a series of stimulation cycles such that an average duty cycle can be calculated.

[00158] Accordingly, the various stimulation protocols provide some duty cycles that vary from one respiratory cycle to the next, while simultaneously providing an overall or average duty cycle. By selecting a particular stimulation cycle, specific duty cycles are implemented

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on a respiratory-cycle by respiratory-cycle basis and an overall or average duty cycle is achieved.

[00159] In some examples, a respiratory cycle duration parameter 260 identifies a duration of a patient-specific average respiratory cycle during reasonably stable respiration (e.g. normal breathing) or a duration of a multi-patient average respiratory cycle during reasonably stable respiration. In some examples, the patient-specific average respiratory cycle is determined according to recent sensed respiration information while in some examples, the patient-specific average respiratory cycle is determined according to long term data gathered for that patient during reasonably stable respiration (e.g. normal breathing).

[00160] In some examples, the respiratory cycle duration parameter 260 tracks a duration of the sensed respiratory cycles of a patient and determines an average.

[00161] In some examples, the time unit parameter 262 tracks and controls a number of time units by which a stimulation cycle operates. In some examples, the time unit parameter 262 implements time units as a multiple of some natural time unit associated with a respiratory waveform. For instance, in some examples such as the stimulation protocols described and illustrated in association with Figures 3B-3E, the time unit parameter 262 equates six time units with a duration of a respiratory cycle, and in which an inspiratory phase comprises one-third of the entire respiratory cycle. However, it will be understood that in some examples, the time units (per parameter 262) are unit-less. For instance, suppose the respiratory period has a duration R of five seconds, and a convention has been adopted that the respiratory cycle is divisible into six time units. Then, the six time units would be distributed across the five second duration of the respiratory cycle.

[00162] In some examples, the time unit parameter 262 implements time units which are entirely arbitrary relative to one or more natural time units associated with a respiratory waveform. For instance, in some examples such as the stimulation protocol described and illustrated in association with Figure 16A, the time unit parameter 262 equates eight time units with a duration of a respiratory cycle, and in which an inspiratory phase comprises one-third of the entire respiratory cycle.

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[00163] In some examples, the time frame parameter 270 in Figure 4 identifies a respiratory cycle series parameter 272 and a stimulation cycle parameter 274. The respiratory cycle series parameter 272 identifies and tracks the number of respiratory cycles that occur before a particular portion of a particular stimulation cycle (274) would coincide again with a particular portion of a respiratory cycle. For example, it was previously noted in association with at least Figure 3C that the stimulation protocol 220 operated based on a time frame of seven respiratory cycles such that a sequence of seven respiratory cycles would occur before a beginning of a stimulation period of a stimulation cycle would coincide with a beginning of an inspiratory phase of the repeating respiratory cycle. While the stimulation protocols associated with independent stimulation function 14 (Fig. 1A) are not synchronized relative to characteristics (e.g. inspiratory phase) of a sensed respiratory waveform, the time frame parameter 270 enables tracking and adjusting how a given stimulation protocol is juxtaposed relative to sensed patient respiratory behavior.

[00164] Figure 5 is a block diagram of a stimulation protocol element 280, according to one example of the present disclosure. As shown in Figure 5, the stimulation protocol element 280 comprises an array parameter 282, a rotation parameter 284, an automatic parameter 286, a manual parameter 288, a static parameter 290, and a custom parameter 291.

[00165] In some examples, stimulation protocol element 280 includes at least some of substantially the same features and attributes as stimulation protocol element 12, as previously described in association with at least Figures 1-4. In particular, as previously noted, in some examples the independent stimulation function 14 (Fig. 1A) provides at least one stimulation protocol suitable for delivering electrical stimulation to a nerve of a patient, such as one of the stimulation protocols as previously described and illustrated in association with Figures 3B-3E.

[00166] With this in mind, array parameter 282 of stimulation protocol element 280 provides an array of stimulation protocols that can be applied, such as but not limited to those illustrated in association with Figures 3B-3E.

[00167] In some examples, via a rotation parameter 284, the stimulation protocol 280 enables delivering therapeutic nerve stimulation to a patient while rotating through different

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stimulation protocols available via array parameter 282. In some examples, such rotation enables identifying a stimulation protocol that works best for a particular patient on a particular day or on a long term basis. However, in some examples, rotation through different stimulation protocols is maintained for a particular day or on a long term basis to provide a large degree of variability in the overall stimulation pattern to thereby provide a robust therapy regimen when a patient's respiratory behavior is consistently erratic and/or when sensing of a patient's respiratory behavior is consistently problematic.

[00168] In some examples, in cooperation with an automatic parameter 286, the rotation parameter 284 automatically rotates through the different stimulation protocols to achieve goals set by therapy manager 16 (Fig. 1B). In some examples, via automatic parameter 286, the therapy manager 16 (Fig. 1B) automatically selects at least one stimulation protocol suitable for a particular patient. In some examples, the automatic selection of which stimulation protocol(s) is best suited for a particular patient is based on a sensed respiratory waveform of the patient.

[00169] In some examples, via a static parameter 290 shown in Figure 5, therapy manager 16 (Fig. 1B) enables selecting and then maintaining a single stimulation protocol indefinitely until and unless a user or operator selects a different stimulation protocol or parameters affecting the selected stimulation protocol. In some examples, if a particularly effective stimulation protocol is identified during operation of the rotation parameter 284, the therapy manager 16 (Fig. 1B) deactivates automatic rotation of the stimulation protocols and operates that single, "particularly effective" stimulation protocol, per the static parameter 290.

[00170] In some examples, stimulation protocol element 280 includes custom parameter 291, which enables adjusting a selected stimulation protocol or making a custom stimulation protocol by selecting a duration of respiratory cycle, duration of stimulation period(s), duration of non-stimulation periods, duration of stimulation cycle, and/or other parameters identified in the plurality of stimulation parameters 250 (Fig. 4).

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[00171] In some examples, the range of stimulation protocols available to a patient via stimulation protocol element 280 are selected and/or bounded according to the discretion of a physician or physician programmer.

[00172] Figure 6 is a block diagram of a power element 320, according to one example of the present disclosure. In one example, power element 320 represents IPG 35, 50 (Figs. 2A-2B) as having an external power source 322 and/or an on-board power source 324.

[00173] In some examples, an at least partially implantable stimulation system (according to examples of the present disclosure) operates in cooperation with and/or incorporates sensing functionality. With this in mind, in some examples, such systems include a sensing element 330, according to one example of the present disclosure, as shown in Figure 7A. The sensing element receives and/or obtains respiratory information.

[00174] In some examples, the sensing element 330 includes an on-board sensing element 332, which is physically incorporated into IPG 35 (Fig. 2A) or IPG 50 (Fig. 2B) in some manner such that communication between the on-board sensing element 332 and other elements of the IPG 35, 50 will occur within the case or housing of the IPG. In some examples, the on-board sensing element 332 includes internal components, such as an accelerometer and in some examples, the on-board sensing element 332 includes surface components, such as the external surface of the case or housing of the IPG 35, 50 acting as a sensing element alone or in combination with other sensing elements.

[00175] In some examples, the sensing element 330 includes an implanted sensing input 334 to receive signals from a sensor implanted within the body physically separate from the IPG 35, 50, with the sensing input 334 in communication with and/or connected to the IPG 35, 50 via wired or wireless communication pathways.

[00176] In some examples, the sensing element 330 includes an external sensing input 336 to receive signals from a sensor external to the patient's body, with the sensing input 336 in communication with the IPG 35, 50 via wireless communication pathways.

[00177] In some examples, sensing element 330 does not comprise a physically-embodied sensor but rather a sensing input to receive information sensed via sensors separate from,

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and independent of, sensing element 330 with such sensors in communication with sensing element 330.

[00178] In some examples, sensing element 330 can comprise both a sensing input and a physically-embodied sensor.

[00179] Via these various sensing elements and inputs, the sensing element 330 receives and tracks signals from at least one physiologic sensor in order to gather information pertinent to treating sleep disordered breathing. In some examples, this information includes respiratory information such as, but not limited to, determining a respiratory state of a patient, whether or not the patient is asleep or awake, and other respiratory-associated indicators, etc. In some examples, the type of sensed physiologic information received by, and/or the type of physiologic sensors embodied within, one of the sensing elements/inputs 332, 334, 336 (Fig. 7A) include, but are not limited to, a pressure sensing, blood oxygenation sensing, acoustic sensing, posture sensing, motion/activity sensing, differential pressure sensing, electrocardiogram (ECG) sensing, or impedance sensing. Via such sensing modalities, the system can measure thoracic impedance, respiratory pressure, diaphragm-based parameters, electrocardiac monitoring, airflow monitoring, snoring, etc. Gathering of this respiratory information, including information regarding respiratory-related behaviors, may be implemented via either a single sensor or any combination of various physiologic sensors that can provide a reliable and accurate signal. In some examples, these various measures of respiratory-related behavior can be considered alone or together in combination to indicate respiratory effort, which is at least one type of respiratory information receivable and/or obtainable by the sensing element.

[00180] In some examples, the therapy manager 16 (Fig. 1B) maintains the sensing components of the sensing element 330 in a default, dormant mode (i.e. off or low power) and periodically activates one or more of the available sensing element(s) to gather patient data. After gathering the data, the sensing elements are deactivated, thereby resuming their dormant mode. In some examples, the gathered patient data is used to evaluate the effectiveness of the therapy, such as the number, intensity, and/or frequency of apneas

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occurring. After such data gathering, the therapy manager 16 (Fig. 1B) deactivates the sensing element(s), thereby returning them to a dormant mode.

[00181] In some examples, the gathered patient data is used to measure the respiratory period to verify its duration and to determine or verify the relative durations (or absolute duration) of the inspiratory and expiratory phases. This information is used to assess a current stimulation protocol and potentially determine whether adjustments to the stimulation protocol are warranted or whether a different stimulation protocol should be employed. For instance, in some examples, the gathered patient data from the temporarily activated sensing elements is used to calibrate the reference respiratory cycle associated with implementation of a particular stimulation protocol.

[00182] Figure 7B is a schematic diagram of an at least partially implantable stimulation system 340, according to an example of the present disclosure. In one example, the system 340 includes at least some of substantially the same features and attributes as system 20 (previously described in association with at least Fig. 2A), except further including sensing functionality via at least one sensing element to sense respiratory information. In some examples, this sensing functionality is implemented via sensing element 330 (Fig. 7A).

[00183] In some examples, the system 340 comprises an additional lead 137 including at least one sensor portion 341 (electrically coupled to the IPG 35 and extending from the IPG 35) positioned in the patient 22 for sensing respiratory information, such as respiratory effort, respiratory pressure, etc. In some examples, this information includes identifying and tracking characteristics and parameters of sensed respiratory waveforms.

[00184] In some examples, the sensor portion 341 is a pressure sensor. In one example, the pressure sensor detects pressure in the thorax of the patient. In some examples, the sensed pressure could be a combination of thoracic pressure and cardiac pressure (e.g., blood flow). Via sensor portion 341, therapy manager 16 (Fig. 1B) is configured to analyze this pressure sensing information to identify, track, and evaluate the respiratory patterns of the patient.

[00185] In some examples, the respiratory sensor portion 341 comprises a bio-impedance sensor or forms one of a pair of bio-impedance sensors. In some examples, the respiratory sensor portion 341 is located in regions other than the pectoral region. In some examples,

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the sensor portion 341 is used to sense impedance in cooperation with other electrodes (e.g. a stimulation electrode) or with an electrically conductive exterior housing of the IPG 35, 50 (Figs. 2A-2B, 7B). In some examples, as shown in Figure 7B, additional sensors 347, 348, 349 are distributed about the chest area for measuring a trans-thoracic bio-impedance signal, an electrocardiogram (ECG) signal, or other respiratory-associated signals. In some examples, sensor portion 341 is omitted and sensors 347, 348, 349 are implemented.

[00186] In some examples, the system 340 for treating obstructive sleep apnea is a totally implantable system which provides therapeutic solutions for patients diagnosed with obstructive sleep apnea. However, as identified in various examples, in some examples, the system is partially implantable with some components (e.g. power source, sensing elements, or control circuitry) being at least partially or completely external to the patient's body.

[00187] In some examples, the previously-described at least partially implantable system 80 (Fig. 2D) includes at least some of substantially the same features described and illustrated in association with Figs. 4-7B, except for system 80 having a non-pectoral location and those attributes specific to system 80 as described in association with Figure 2D.

[00188] In some examples, the respiratory information and/or other physiologic information gathered via the sensing element 330 (Fig. 7A) and associated sensor schemes (Fig. 7B) is used to identify, track, evaluate, etc. various therapeutic parameters. Accordingly, in some examples the at least partially implantable stimulation system includes a therapeutic monitoring element 350, which as shown in Figure 8, includes a plurality of therapeutic parameters. In some examples, these parameters include identifying, tracking, and evaluating apnea events per parameter 352 and/or computing and tracking an apnea severity index 354, such as AHI or other index. The index parameter 354 determines a frequency, intensity, duration, etc. of detected apneas to indicate the relative severity of sleep disordered breathing for the patient.

[00189] In some examples, one therapeutic parameter of monitoring element 350 includes a minute ventilation parameter 356 to track minute ventilation of the patient before, during, or after a therapy regimen. In some examples, one therapeutic parameter of monitoring

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element 350 includes a tidal volume parameter 357 to track the tidal volume of a patient before, during, or after a therapy regimen.

[00190] In some examples, one therapeutic parameter of monitoring element 350 includes a body position parameter 358. In some examples, one therapeutic parameter of monitoring element 350 includes a posture parameter 359. Together or separately, the body position parameter 358 and posture parameter 359 determine and track a body position of the patient and posture of the patient. Among other uses, such information can be used to activate or deactivate a therapy, to select a therapeutic regimen (e.g. stimulation protocol), and/or to adjust a therapeutic regimen. It will be understood that these example parameters are not exhaustive and can be employed separately from each other or in various combinations.

[00191] In some examples, this information obtained via any one or several parameters 352, 354, 356, 357, 358, 359 of the therapeutic monitoring element 350 is used to initiate, terminate, select, and/or adjust stimulation applied via the IPG 35, 50 and stimulation electrode 45. For instance, upon determining that the number and/or intensity of apneic events has met or exceeded a severity threshold, the therapy manager 16 (Fig. 1B) can utilize control portion 56 (Fig. 2C) to initiate application of stimulation to the airway-patency related nerves to open the airway and thereby reduce the associated sleep disordered breathing behavior. However, it will be understood that in at least some examples, this arrangement does not include causing (or depend on) the stimulation signal to become synchronized relative to a characteristic (e.g. inspiratory phase, expiratory phase, etc.) of the respiratory waveform. Rather, as noted in association with at least Figure 1A, in the examples described thus far in association with Figures 1-8, such stimulation is applied independent of such synchronization.

[00192] In some examples, the therapeutic parameters element 350 may be employed to select one of a plurality of stimulation protocols and/or to evaluate the therapeutic effectiveness of a particular stimulation protocol(s) for a particular patient for a given period of time or on a long term basis.

[00193] In at least this context and/or other contexts in at least some examples of the present disclosure, therapeutic effectiveness may correspond to alleviating sleep disordered

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breathing, which in some instances is measurable via a severity threshold, such as an apnea-hypopnea index (AHI) and/or other scoring mechanisms. In some examples, the therapeutic effectiveness may also be measured or evaluated relative to sensor signal quality, such as via sensor signal quality criteria as described in at least some of the examples of the present disclosure.

[00194] Figure 9 is a block diagram schematically illustrating a control portion 360, according to one example of the present disclosure. In some examples, control portion 360 includes a controller 362 and memory 370. In some examples, therapy manager 371 is stored in memory 370, and in some examples, therapy manager 371 includes at least some of substantially the same features and attributes as therapy manager 16 (Fig. 1B), as previously described in association with at least Figures 1-8.

[00195] In general terms, controller 362 of control portion 360 comprises at least one processor 364 and associated memories that are in communication with memory 370 to generate control signals to direct operation of at least some components of the systems and components described throughout the present disclosure. In some examples, these generated control signals include, but are not limited to, employing therapy manager 371 to manage operation of the stimulation system to control sleep disordered breathing. In some examples, a control portion 360 is present in the IPG 35, 50, 84 (Figs. 2A, 2B, 2D) as control portion 56 (Fig. 2C) and/or is accessible to the IPG 35, 50, 84. In some examples, at least some aspects of stimulation element 12 (Fig. 1A) are at least partially implemented via control portion 360 and/or in communication with control portion 360, with at least some aspects of stimulation element 12 being storable in memory 370 with or as part of therapy manager 371.

[00196] In particular, in response to or based upon commands received via a user interface 396, 400 (Figs. 11A, 11B) and/or machine readable instructions (including software), controller 362 generates control signals to implement a nerve stimulation protocol to control sleep disordered breathing, in accordance with at least some of the previously described examples and/or later described examples of the present disclosure. In some examples, controller 362 is embodied in a general purpose computer while in other examples, controller

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362 is embodied in at least some of the components described throughout the present disclosure, such as IPG 35, 50, 84 or external components operatively coupled to implantable pulse generator 35, 50, 84. For purposes of this application, in reference to the controller 362, the term "processor" shall mean a presently developed or future developed processor (or processing resources) that executes sequences of machine readable instructions contained in a memory. In some examples, execution of the sequences of machine readable instructions, such as those provided via therapy manager 371 stored in memory 370 of control portion 360, cause the processor to perform actions, such as operating controller 362 to implement stimulation protocols as generally described in (or consistent with) at least some examples of the present disclosure. The machine readable instructions may be loaded in a random access memory (RAM) for execution by the processor from their stored location in a read only memory (ROM), a mass storage device, or some other persistent storage (e.g., non-transitory tangible medium or non-volatile tangible medium), as represented by memory 370. In some examples, memory 370 comprises a computer readable tangible medium providing non-volatile storage of the machine readable instructions executable by a process of controller 362. In other examples, hard wired circuitry may be used in place of or in combination with machine readable instructions to implement the functions described. For example, controller 362 may be embodied as part of at least one application-specific integrated circuit (ASIC). In at least some examples, the controller 362 is not limited to any specific combination of hardware circuitry and machine readable instructions , nor limited to any particular source for the machine readable instructions executed by the controller 362.

[00197] In some examples, user interface 396 shown in Figure 11A comprises a user interface or other display that provides for the simultaneous display, activation, and/or operation of at least some of the various components, functions, features, and of stimulation element 12 (Fig. 1A), therapy manager 16 (Fig. 1B), control portion 360 (Fig. 9), IPG 35, 50, 84 (Figs. 2A, 2B, 2D), and related elements, as described throughout the present disclosure. In some examples, at least some portions or aspects of the user interface 396 are provided via a graphical user interface (GUI) and may include an input and a display.

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[00198] In some examples, user interface 396 includes at least some of the components illustrated in user interface 400 schematically depicted in Figure 11B.

[00199] As shown in Figure 11B, user interface 400 includes at least some of the various components, functions, elements, and features as described and illustrated in association with at least stimulation protocol elements 280 (Fig. 5), 490 (Fig. 15A), therapeutic monitoring element 350 (Fig. 8), stimulation parameters 250 (Fig. 4), stimulation protocol element 450 (including independent function 454, respiratory-dependent function 456 in Fig. 12), automatic protocol selector 470 (Fig. 14), and stimulation protocol selection 500 (Fig. 15B).

[00200] Figure 10 is a diagram 380 schematically illustrating a manner in which the control portion 360 is implemented, according to one example of the present disclosure. In some examples, control portion 360 is entirely implemented within or by an implantable pulse generator 385, which has at least some of substantially the same features and attributes as pulse generator (IPG) 35, 50, 84 as previously described in association with at least Figures 1-9. In some examples, control portion 360 is entirely implemented within or by a remote control 390 (e.g. a programmer) external to the patient's body, such as a patient control 392 and/or a physician control 394. In some examples, the control portion 360 is partially implemented in the pulse generator 385 and partially implemented in the remote control 390 (at least one of patient control 392 and physician control 394).

[00201] In some examples, in association with control portion 360, user interface (396 in Fig. 11A; 400 in Fig. 11B) is implemented in remote control 390.

[00202] Figure 12 is a block diagram of a stimulation protocol element 450, according to one example of the present disclosure. As shown in Figure 12, stimulation protocol element 450 includes an independent stimulation function 454 and a respiratory-dependent function 456. In some examples, the independent stimulation function 454 includes at least some of substantially the same features as independent stimulation function 14 associated with stimulation element 12 (Fig. 1A) and/or therapy manager 16 (Fig. 1B) as part of an at least partially implantable stimulation system, as previously described in association with Figures

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1-11B. Meanwhile, Figure 13 is a block diagram of a respiration-dependent function 456, according to one example of the present disclosure.

[00203] After describing the features and attributes associated with the respiration-dependent stimulation function 456, at least some examples regarding the relationship and relative operation of the independent stimulation function 454 and respiratory-dependent stimulation function 456 will be addressed.

[00204] As shown in Figure 13, in some examples, the respiratory-dependent function 456 includes a synchronous parameter 460, a synchronization characteristic parameter 462, and a stability parameter 464.

[00205] In some examples, via the synchronous parameter 460, respiratory-dependent function 456 implements a stimulation protocol in which each individual nerve stimulation period (within a treatment period) is triggered by and/or synchronized relative to a synchronization characteristic of the patient's respiratory waveform. For instance, in some examples, respiratory-dependent function 456 causes individual stimulation periods to occur substantially simultaneous with the inspiratory phase (e.g. 162 in Fig. 3B) of the patient's respiratory cycle (e.g. 204A in Fig. 3B) such that stimulation is considered to be synchronous with inspiration.

[00206] In some examples, per synchronization characteristic parameter 462, one can select (or a therapy manager can automatically select) the characteristic to which stimulation will be synchronized. In some examples, via parameter 462 respiratory-dependent stimulation function 456 causes nerve stimulation periods to be synchronized relative to a junction or transition between expiratory pause and the onset of inspiration. In some examples, via parameter 462, nerve stimulation periods are synchronized relative to a junction or transition between inspiration and the onset (i.e. beginning) of expiration. In some examples, the characteristic to which stimulation will be synchronized can be peak inspiration, peak expiration, or expiratory pause.

[00207] In some examples, stability parameter 464 of respiratory-dependent stimulation function 456 (Fig. 13) tracks and determines at least one parameter of a sensed respiratory waveform to determine the relative stability of the respiratory waveform (e.g. sensor signal

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quality) to provide a reliable, accurate indication of respiratory behavior to the therapy manager (371 in Figure 9). Without a reasonably stable respiratory waveform, the respiratory-dependent function 456 cannot be implemented. In such a situation, the independent stimulation function 454 is implemented until the control portion 360 determines via stability parameter 464 that a reasonably stable respiratory waveform is available (e.g. the sensor signal has sufficient quality) and by which stimulation can be triggered and/or synchronized relative to a characteristic of the respiratory waveform.

[00208] Via the stability parameter 464, the control portion 56 of Fig. 2C (control portion 360 in Fig. 9) determines whether the respiratory waveform is stable enough (e.g. sensor signal quality is sufficient) to support synchronizing stimulation relative to characteristics (e.g. inspiratory phase) of the respiratory waveform. In some examples, the stability parameter 464 identifies and tracks parameters such as a peak-to-peak amplitude, a respiratory rate, sensor signal frequency content, signal morphology, and a duty cycle associated with at least one of inspiration, expiration, and expiratory pause, or various combinations of these parameters. In some examples, the at least one parameter comprises a statistical stability of these identified parameters. In some examples, a determination of such statistical stability may be performed relative to a known good state for the patient or a moving baseline of known good state for the patient. In some examples, a known good state corresponds to a period of respiration free from obstructive sleep apnea. In some examples, the determination of statistical stability may be performed relative to an independent threshold of statistical goodness.

[00209] In some examples, the inspiratory duty cycle is defined as the ratio of inspiration duration to the duration of respiratory period.

[00210] In some examples, the above-noted waveform signal stability or quality parameter may be evaluated after sufficient gain is applied to the signal to enable analysis. For instance, if the peak to peak amplitude is low and sensor signal quality is low, then signal gain can be increased to determine if signal quality analysis can be performed. In some examples, a sensed signal can be subject to a process in which a sensor obtains a physiologic signal, to which gain is applied prior to quality analysis, and then potentially used for synchronization

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of a stimulation protocol relative to the sensed respiratory waveform. In some examples, an automatic gain control mechanism is employed and queried to determine if the gain is stable so the signal may be reliably analyzed.

[00211] In some examples, via therapy manager 16, 371 (Figs. 1B, 9), the respiratory-dependent stimulation function 456 can be disabled so that therapy is selectively applied entirely via the independent stimulation function 14 (Fig. 2A), 454 (Fig. 12). Of course, in some examples as previously described, the respiratory-dependent stimulation function 456 is not even present with the independent stimulation function 14, 454 being the sole mechanism to apply nerve stimulation.

[00212] Figure 14 is a diagram 470 schematically illustrating a relationship between, and automatically selection between, the independent stimulation protocol 454 (Fig. 12) and the respiration-dependent stimulation protocol 456 (Fig. 12), according to one example of the present disclosure. In some examples, at least some aspects of stimulation protocol selection in diagram 470 can be embodied as a method while in some examples, at least some aspects of stimulation protocol selection in diagram 470 can be embodied as operational aspects of a stimulation protocol manager of a therapy manager, as described in association with at least Figures11B-13.

[00213] In some examples, operation of the at least partially implantable stimulation system is implemented via providing cooperation or complementary deployment of the respective stimulation protocols 454, 456. In some examples, an independent stimulation protocol 454 is applied for a predetermined period of time, as shown at 472 in Figure 14. The predetermined period of time corresponds at least to an amount of time for a stable respiration period to be established, which may be ensured based on the independent stimulation of the airway-patency-related nerve. In some examples the first predetermined period of time corresponds to a period sufficient to establish a steady state in which filtering is established, inspiration and expiration are being detected reliably, signal gain control is realized, etc.

[00214] In some examples, operation of the first independent stimulation protocol during at least the first predetermined period of time is not a test mode, such as a mode that may

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otherwise be dedicated to diagnosing or evaluating the operational fitness of the stimulation system. Rather, the first independent stimulation protocol operates for at least the predetermined period of time to apply therapeutic stimulation to achieve a stable respiratory behavior and a stable respiratory waveform.

[00215] In some examples, by applying stimulation protocol(s) via the independent stimulation, a stable respiratory waveform is achieved, thereby increasing the likelihood of being able to transition to operation in the respiratory-dependent stimulation at 478 than if independent stimulation at 472 were not deployed prior to the activation of the respiratory-dependent function at 478.

[00216] With further reference to Figure 14, based on monitoring of the sensed respiratory waveform, at repeating intervals, at 474 it is queried whether the respiratory waveform is sufficiently stable to support activation of the respiratory-dependent stimulation . If the answer to the query at 474 is NO, then pathway 476 directs continued operation of independent stimulation at 472. However, if the answer to the query at 474 is YES, then pathway 477 directs initiation of operation of respiratory-dependent stimulation at 478 of Figure 14. During operation of respiratory-dependent stimulation at 478, the query at 474 is periodically implemented. If the answer to the query (at 474) is NO, then operation in respiratory-dependent stimulation n (456 in Fig. 12) at 478 in Figure 14 is terminated as operation is returned (i.e. reverts) via pathway 476 to independent stimulation at 472 in Figure 14 for at least the predetermined period of time.

[00217] For at least the current example, it will be understood that, in the event that no stable respiratory waveform is established, the operation would remain in independent stimulation at 472 without converting to operation in respiratory-dependent stimulation 478.

[00218] In some examples, the query at 474 is performed generally continuously by monitoring parameters indicative of respiratory signal sensing quality (i.e. sensor signal quality criteria), such as but not limited to, peak to peak amplitude, inspiratory duty cycle, respiratory rate, etc. Upon one or more of these parameters failing to meet the sensor signal quality criteria, then the answer to the query (at 474) would be registered as NO. Upon meeting the sensor signal quality criteria, the answer to the query at 474 is YES

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[00219] In some examples, meeting the signal quality criteria (e.g. answer to query is YES) can be defined via a first parameter as an average peak-to-peak respiratory amplitude above a threshold, where the average is computed from the previous two respiratory cycles. In some examples, meeting the signal quality criteria (e.g. answer to query is YES) can be defined via a second parameter as a peak-to-peak respiratory amplitude variability below a threshold, where the threshold is referenced to an average computed over the previous 60 seconds. In some examples, meeting the signal quality criteria (e.g. answer to query is YES) can be defined via a third parameter as a respiratory duration variability below a threshold, where threshold is reference to an average computed of the previous 60 seconds. In some examples, meeting the signal quality criteria (e.g. answer to query is YES) can be defined via a fourth parameter as an average inspiratory phase duration above a threshold, where the average is computed of the previous two respiratory cycles. In some examples, meeting the signal quality criteria (e.g. answer to query is YES) can be defined via various combinations of the respective first, second, third, and fourth parameters, including but not limited to, a combination of all four parameters. It will be understood that the sensor signal quality criteria and/or meeting the sensor signal quality criteria is not exclusively defined by the respective four parameters.

[00220] Figure 15A is block diagram of a stimulation protocol element 490, according to one example of the present disclosure. In some examples, stimulation protocol element 490 includes at least some of substantially the same features and attributes as stimulation protocol element 450 as previously described in association with at least Figures 12-14, while further including at least the features shown in Figure 15A.

[00221] As shown in Figure 15A, stimulation protocol element 490 includes an override function 492 to take abrupt and sustained action to achieve a stable respiratory pattern. For instance, in some examples, persistent sleep disordered breathing is observed, which includes a series of unresolvable/intractable respiratory events (e.g. persistent apnea) that occur despite stimulation via either the independent stimulation function 454 or the respiratory-dependent function 456. In some examples, the override function 492 is activated when a stable respiratory pattern has not been detected for a predetermined period of time,

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such as 5 or 10 minutes. In some examples, the predetermined period of time is less than 5 minutes, such as when some number (e.g. 3 apneas) of apneas are detected prior to reaching 5 minutes.

[00222] Upon activation of the override function 492, therapy that was being implemented via the independent stimulation function 454 or via the respiratory-dependent function 456 is terminated or converted over to operation via a continuous stimulation function 494 (Fig. 15A) in which nerve stimulation is applied continuously (a 100 % duty cycle) for a predetermined period of time. As previously described, in some examples, continuous stimulation refers to a train of stimulation pulses which occur in a relatively short time frame. For instance, in some examples, continuous stimulation corresponds to at least a finite number (e.g. 5, 10, etc.) of stimulation pulses per second. In some examples, continuous stimulation corresponds to at least 20 stimulation pulses per second. In some examples, continuous stimulation corresponds to at least 30 stimulation pulses per second. In some examples, the number of stimulation pulses per second is selectable by an operator via a control portion (e.g. 56 in Figure 2C). In some examples, during such continuous stimulation, each stimulation pulse within a train of stimulation pulses includes a primary stimulation pulse followed by a separate recharge pulse, which is in turn followed by a non-stimulation phase before the next primary stimulation pulse.

[00223] In some examples, the override function 492 is implemented via an "other" function, in which nerve stimulation is applied that is not continuous but which has an intensity and duration substantially greater than implemented via the stimulation protocols of one of the independent stimulation function 454 (Fig. 12) or the respiratory-dependent function 456 (Fig. 12).

[00224] In some examples, operation via the override function 492 is maintained until at least one of a time limit, and/or the therapy manager detecting (via the sensed respiratory waveform) at least one respiratory cycle exhibiting an absence of sleep disordered breathing behavior as measured by a number of respiratory cycles and/or a severity threshold (in one example). In some examples, the time limit is 100 seconds, such as about 20 breaths. However, in some examples, the time limit can be much lower, such as 30 to 40 seconds. In

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some examples, the continuous stimulation is applied until detected sleep disordered breathing is absent for at least three consecutive respiratory cycles, i.e. a successful inspiration occurs for at least three consecutive respiratory cycles or some operator-selectable quantity (e.g. 2, 4) of consecutive respiratory cycles for a particular patient.

[00225] In some examples, the continuous stimulation is applied up to a predetermined maximum period. In some examples, the predetermined maximum period is at least 120 seconds. In some examples, the predetermined maximum period is selectable by an operator and can have values greater or less than 120 seconds, such as 130 seconds, 110 seconds, 90 seconds, etc. In general terms, the predetermined maximum period corresponds to an expired time by which fatigue of the stimulated muscle is complete or nearly complete.

[00226] In some examples, upon a determination that detected sleep disordered breathing behavior meets or exceeds the severity threshold, the therapy manager terminates operation in the respective independent and respiratory-dependent stimulation modes and initiates operation in a third mode including a stimulation protocol of a stimulation period and a non-stimulation period in a proportion of at least 3 to 1 wherein the stimulation period has a duration equal to or greater than a duration of at least four respiratory cycles.

[00227] In some examples, the duration of the stimulation period is about 30 seconds and the duration of the non-stimulation period is about 10 seconds. In some examples, the duration of the stimulation period is about 30 seconds and the duration of the non-stimulation period is about 5 seconds.

[00228] Upon determination that a stable respiratory period has been established, operation in the override function 492 terminates and operation is resumed via the independent stimulation function 454 (Fig. 12) consistent with the functionality previously described in association with at least Figs. 12-14.

[00229] Figure 15B is a diagram 500 schematically illustrating aspects of selecting a stimulation protocol, according to one example of the present disclosure. In some examples, at least some aspects of selecting a stimulation protocol as expressed in diagram 500 can be embodied as a method while in some examples, at least some aspects of selecting a stimulation protocol as expressed in diagram 550 can be embodied as operational aspects of

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a stimulation protocol management associated with a therapy manager 16 as described in association with at least Figures 1-15A.

[00230] As shown at 502, respiratory information can be periodically sensed during a treatment period and without synchronization to stimulation. In other words, in at least some instances, this periodic sensing is not related to and/or does not result in synchronizing stimulation to sensed respiratory information. Rather, such periodic sensing can be used to enhance and/or evaluate the effectiveness of the stimulation, among other uses for such periodically sensed respiratory information.

[00231] As shown at 504 in Figure 15B, if the duration of the sensed respiratory cycles (among a sample of respiratory cycles) is less variable from cycle-to-cycle than a duration variability criteria, then a stimulation protocol is adopted in which a repeating stimulation cycle is applied and which has a duration different than a duration of the reference respiratory cycle for this patient. This arrangement introduces an intentional stagger or offset between the duration of the stimulation cycle and the duration of respiratory cycle, which may ensure overlap of at least some stimulation periods (of the stimulation cycles) with the actual inspiratory phases of the respiratory cycles of the patient a majority of the time.

[00232] In some examples, the duration variability criteria establishes a measure of the variability of a duration of sensed respiratory cycles. The variability can be measured by a frequency of changes in the duration during an observation period and/or a magnitude of change in such durations during the observation period. Further details regarding the observation period are identified below.

[00233] In some examples, the duration variability criteria is based on several factors, including but not limited to, a duration of a typical stable respiratory period (e.g. 3-6 seconds, depending on the patient), the minimum duration of an apnea (e.g. 10 seconds), and/or an observation period (e.g. 5 minutes) following a change in stimulation parameters. In some examples, the observation period can more than 5 minutes while in some examples, the observation period can be less than 5 minutes, such as when some number (e.g. 3 apneas) of apneas are detected prior to reaching 5 minutes. In some examples, the duration variability

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criteria is further based on a standard deviation of respiratory periods of less than 1 second and a sample period of at least 4 minutes.

[00234] With further reference to 504 in Figure 15B, in some examples, this arrangement is implemented via stimulation protocol 210 in Figure 3B in which a respiratory waveform is represented via a series 202 of respiratory cycles 204A-204H. Moreover, in this example, the duration of the stimulation cycle (4 stimulation periods plus 1 non-stimulation period) is less than a duration (R) of the reference respiratory cycles, such that the repeating stimulation cycle has a duration different than a duration (R) of the reference respiratory cycle.

[00235] This arrangement ensures that no matter when the stimulation protocol is generally activated, no more than a finite number (e.g. 2, 3, 4) of respiratory cycles would occur without a stimulation period significantly coinciding with an inspiratory phase 162 of the respective respiratory phases. This phenomenon occurs, at least in part, because of a sufficiently large difference between the duration of the stimulation cycle and the duration of the respiratory cycle, and in view of the relative proportion of the stimulation period to the non-stimulation period.

[00236] In some examples, other example stimulation protocols are used for implementation. For instance, example stimulation protocols 220, 230 as described in association with at least Figures 3C, 3D can be used. It is noted that stimulation protocols 220, 230 include stimulation cycles having a duration greater than a duration (R) of the reference respiratory cycle as shown in the respective legends 229, 239 of Figures 3C, 3D, respectively.

[00237] As shown at 506 in Figure 15B, if the duration of the sensed respiratory cycle (of a sensed sample of respiratory cycles) is more variable than the duration variability criteria noted above, then a repeating stimulation cycle is applied and which has a duration generally matching a duration of a reference respiratory cycle. In this instance, the natural variability of the duration of the patient's respiratory cycle can be used to introduce a stagger or offset relative to the duration of the stimulation cycle, which may ensure an overlap of at least some stimulation periods relative to at least some of the inspiratory phases of the patient's live respiratory cycles at least a majority of the time.

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[00238] In some examples, the reference respiratory cycle is defined by a patient-specific average respiratory cycle obtained at an earlier point in time. In some examples, the reference respiratory cycle is defined by a multi-patient specific average respiratory cycle obtained from a database.

[00239] In some examples, this arrangement is implemented via stimulation protocol 240 in Figure 3E in which a respiratory waveform is represented via a series 244 of respiratory cycles 245A-245M. Accordingly, Figure 3E models the situation in which the duration (R1) of the respiratory cycles has varied (relative to the duration R of its base/stable respiratory cycle) by more than a threshold. In some examples, the threshold includes R changing (increasing or decreasing) in duration by 5 percent. In this instance the duration R1 represents about an 8 percent change from the duration R because the respiratory cycles 245A-245M have a duration R1 of 6 ½ time units whereas duration R is equal to 6 time units. It will be understood, of course, that other numeric values that are more or less than 5 percent can be used as the threshold.

[00240] While Figure 3E exhibits a duration R1 which remains constant at least for the illustrated series of respiratory cycles, it will be understood that duration R1 may have a different value (e.g. longer or shorter) in subsequent respiratory cycles and/or that duration R1 may have had different values (e.g. longer or shorter) in preceding respiratory cycles. Accordingly, at least with respect to the method of Figure 15B, duration R1 should not be viewed as being indefinitely static, but rather as having a particular value at one snapshot in time.

[00241] It will be further understood that variations in the duration of the respiratory cycle may be exhibited as decreases (instead of increases) and that variations in the duration of the respiratory cycle are not permanent but may last some finite number of respiratory cycles before reverting to a baseline or changing to yet another non-R duration.

[00242] In the example of Figure 3E, the duration of the stimulation cycle (4 stimulation periods plus 2 non-stimulation periods) is less than a duration (R1) of the respiratory cycles but with the duration of the stimulation cycles being equal to the duration (R) of the reference respiratory cycle (which is based on a historical baseline in at least some examples).

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[00243] With this arrangement, because the duration (R1) of the sampled respiratory cycle (obtained via periodic sensing) has varied relative to a reference duration R, the therapy manager 16 utilizes a stimulation cycle having a duration to match the duration of the reference respiratory cycle, which in turn introduces the above-mentioned intentional stagger or offset.

[00244] This arrangement ensures that no matter when the stimulation protocol is generally activated, no more than a finite number of respiratory cycles would occur without a stimulation period significantly coinciding with an inspiratory phase of the respective respiratory phases. This phenomenon occurs, at least in part, because of a sufficiently large difference between the duration of the stimulation cycle and the duration of the respiratory cycle, and in view of the relative proportion of the stimulation period to the non-stimulation period.

[00245] Accordingly, as represented at block 506, when the duration of the periodically sensed respiratory cycle varies more than a duration variability criteria, the therapy manager ensures an appropriate level of stimulation coinciding with the inspiratory phases of the respiratory cycles by intentionally not adjusting the duration of the stimulation cycle to match the modified duration R1 exhibited by the periodically sensed respiratory cycles.

[00246] While Figure 3E exhibits a duration R1 which remains constant at least for the illustrated series of respiratory cycles, it will be understood that duration R1 may have a different value (e.g. longer or shorter) in subsequent respiratory cycles and/or that duration R1 may have had different values (e.g. longer or shorter) in at least some preceding respiratory cycles. Accordingly, at least with respect to the method of Figure 15B, duration R1 should not be viewed as being indefinitely static, but rather as having a particular value at one snapshot in time.

[00247] Figure 15C is a block diagram schematically illustrating a stimulation protocol selector element 520, according to one example of the present disclosure. In some examples, the stimulation protocol selector element 520 includes, and enables, selection between a first function 522 and a second function 524. In some examples, a selection via element 520 between first function 520 and second function 522 can be implemented in association with

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the aspects of block 502 in Figure 15B. In some examples, first function 520 can be implemented via at least some of the aspects of stimulation selection as described in association with block 504 in Figure 15B while second function 522 can be implemented via at least some of the aspects of stimulation selection as described in association with block 506 in Figure 15B.

[00248] Figure 15D is a diagram 550 schematically illustrating a relationship between, and automatically selection between, the independent stimulation protocol 454 (Fig. 12) and the respiration-dependent stimulation protocol 456 (Fig. 12), according to one example of the present disclosure. In some examples, at least some aspects of stimulation protocol selection 551 in diagram 550 can be embodied as a method while in some examples, at least some aspects of stimulation protocol selection in diagram 550 can be embodied as operational aspects of a stimulation protocol manager of a therapy manager, as described in association with at least Figures11B-13.

[00249] In some examples, operation of the at least partially implantable stimulation system is implemented via providing cooperation or complementary deployment of the respective stimulation protocols 454, 456 (at least Figs. 11B-13). Accordingly, as shown at 552 in Figure 15D, operation starts in a respiratory-dependent stimulation protocol.

[00250] With further reference to Figure 15D, based on monitoring of the sensed respiratory waveform, at repeating intervals, at 554 it is queried whether the respiratory waveform is sufficiently stable to support continued operation of respiratory-dependent stimulation at 552. If the answer to the query at 554 is YES, then pathway 556 affirms continued operation of respiratory-dependent stimulation at 552. However, if the answer to the query at 554 is NO, then pathway 557 directs initiation of operation of independent stimulation at 558 of Figure 15D for at least a predetermined period of time. The first predetermined period of time is defined in substantially the same manner as previously described in association with at least Figure 14, and the operation of the independent stimulation function at 558 is not a test mode. Rather, the independent stimulation (at 558) operates for at least the predetermined period of time to apply therapeutic stimulation to achieve a stable respiratory behavior and a stable respiratory waveform.

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[00251] Upon operation of independent stimulation at 558 for at least the predetermined period of time, the query at 554 is periodically implemented. If the answer to the query (at 554) is YES, then operation in independent stimulation at 558 in Figure 15D is terminated as operation is returned via pathway 556 to respiratory-dependent stimulation at 552 in Figure 15D. For at least the current example, it will be understood that, in the event that no stable respiratory waveform is established, the operation would remain in the independent stimulation at 558 without reverting operation into respiratory-dependent stimulation at 552.

[00252] In some examples, the query at 554 is performed by monitoring parameters indicative of respiratory signal sensing quality (i.e. sensor signal quality criteria), such as but not limited to, peak to peak amplitude, inspiratory duty cycle, respiratory rate, etc.

[00253] Figure 16A is diagram 640 schematically illustrating a nerve stimulation protocol 641, according to one example of the present disclosure.

[00254] In one aspect, diagram 640 omits a representative respiratory waveform relative to the stimulation protocol because, in at least some examples, operation according to independent stimulation function 14 (Fig. 1A) occurs regardless of whether a sensed respiratory waveform is available or reasonably stable. Accordingly, diagram 640 illustrates stimulation periods relative to predetermined time periods instead of relative to inspiratory and expiratory phases of a normal respiratory pattern, as further described and illustrated below.

[00255] As shown in Figure 16A, a nerve stimulation protocol 641 comprises stimulation segments 642 and non-stimulation segments 648, 649 (i.e. rest periods), which may occur within a time frame (T). In this arrangement, the time frame T comprises a series of eight time units with each time unit having a duration t, as shown in Figure 16A. In some examples, a combination of two consecutive time units have a duration R that generally corresponds to a duration of a respiratory cycle. In one aspect, the duration of one time unit (t) comprises one-half of duration R.

[00256] As shown in diagram 640, stimulation protocol 641 includes a repeating sequence of continuous stimulation segments 642 and non-stimulation segments 648, 649. Each stimulation segment 642 has a duration of 3 time units (t), each non-stimulation segment 648

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has a duration of two time units, and each non-stimulation segment 649 has a duration of one time unit. This pattern is represented by legend 645 as 3:SK2:3:SK1, where SK represents "skip" to indicate skipping stimulation.

[00257] As further shown by diagram 640, as this stimulation cycle pattern (3:SK 2:3:SK 1) is repeated through a series of time frames T (with each time frame T including 8 time units), one can identify the number of stimulation time units that occurs within each time frame T. For example, the first time frame includes 6 stimulation time units out of 8 total time units, followed by three time frames T including 5 stimulation time units out of 8 total time units, followed by two "six stimulation time unit" time frames T, and then three "five stimulation time unit" time frames T. With this in mind, one can express a pattern of the stimulation time units for the first twelve consecutive time frames as 6:5:5:5:6:6:5:5:5.

[00258] Via the stimulation protocol 641, a therapeutic nerve stimulation regimen is applied in which no period of four consecutive respiratory cycles will transpire without a stimulation period coinciding with an expected inspiratory phase of a respiratory cycle. In this stimulation protocol, the duration of stimulation periods exceeds the duration of non-stimulation periods.

[00259] Figure 16B is a diagram 651 schematically illustrating a stimulation protocol 650, according to one example of the present disclosure. In some examples, protocol 650 exhibits at least some of substantially the same features and attributes as the stimulation protocols, as previously described in association with at least Figs. 3B-3E. In general terms, via stimulation protocol 650, via stimulation element 12 (Fig. 1A) and/or therapy manager 16 (Fig. 1B) the independent stimulation function 14 implements asynchronous nerve stimulation which to promote stable respiration despite potential sleep disordered breathing.

[00260] As illustrated in Figure 16B, the stimulation protocol 650 operates according to stimulation cycles in which the duration (D) of each stimulation cycle is less than the duration (R) of the reference respiratory cycles 654A, 654B. Moreover, in some examples, the stimulation cycle has a duration (D) which is significantly less (at least half or less) than the duration (R) of the reference respiratory cycles 654A, 654B. In one of these examples, a duration (D) of the stimulation cycle is less than 30 percent of the duration (R) of the

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reference respiratory cycles 654A, 654B. In one of these examples, a duration (D) of the stimulation cycle is less than 20 percent of the duration (R) of the reference respiratory cycle 654A, 654B. In one such instance, as illustrated in Figure 16B, the duration (D) of the stimulation cycle is about 1 second, whereas the duration (R) of the reference respiratory cycle is about 6 seconds.

[00261] In some examples of implementing stimulation protocol 650, within a given stimulation cycle the stimulation period (e.g. 652A, 652B, etc.) and the non-stimulation period (e.g. 658A, 658B, etc.) are in a proportion of 4 to 1 to yield a stimulation duty cycle of 80 percent (for each stimulation cycle). In such examples, each stimulation cycle lasts about 1 time unit (t), including a continuous stimulation period of 4 "1/5" time units followed by a non-stimulation period of a single "1/5" time unit, with this stimulation cycle being repeated continuously when nerve stimulation via stimulation protocol 650 is implemented. Accordingly, in some examples, the duration of the entire stimulation cycle (e.g. 4 "1/5" time units of stimulation and a single "1/5" time unit of non-stimulation) is 1 time unit (t), which is significantly less than the duration R of the respiratory cycle, which is 6 time units in this example.

[00262] However, it will be understood that in some examples, the duration of the stimulation period need not coincide with a discrete number (e.g. 4) of fractional time units (e.g. "1/5" time units) and the duration of the non-stimulation period need not coincide with a discrete number (e.g. 1) of fractional time units (e.g. "1/5" time units).

[00263] In some examples, the duration (R) of the reference respiratory cycles (e.g. 654A, 654B, etc.) can be selected to be more or less than 6 time units (t), as shown in Fig. 16B. In some examples, the duration (D) of each stimulation cycle (including a stimulation period, such as 652A and a non-stimulation period, such as 658A) can be selected to be more or less than one time unit (t).

[00264] In Figure 16B, the first end 653 of stimulation period 652A is shown as coinciding with the beginning of an inspiratory phase 162 of the respiratory cycle 654A. However, it will be understood that the beginning 653 of the stimulation period 652A is not synchronized relative to the inspiratory phase 162. Rather, the beginning 653 of stimulation period 652A

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is shown as coinciding with the beginning of inspiratory phase 162 for illustrative simplicity in juxtaposing the stimulation protocol 650 relative to the reference respiratory cycles 654A, 654B, etc. Accordingly, it will be understood that when stimulation (according to stimulation protocol 650) is initiated during a treatment period, the beginning of the stimulation period 652A may coincide with a different portion of the reference respiratory cycle (e.g. 654A) than shown in Figure 16B.

[00265] As further shown in Figure 16B, in one aspect, each respective non-stimulation period (e.g. 658A, 658B, etc.) has a duration significantly less than (e.g. at least less than half) a duration of each respective stimulation period (e.g. 652A, 652B, etc.). In one aspect, the duration of each stimulation period (e.g. 652A, 652B, etc.) is also significantly less than (e.g. at least less than 30%) a duration (R) of the respective reference respiratory cycles (e.g. 654A, 654B, etc.). In some examples, in stimulation protocol 650, the duration (D) of each stimulation period (e.g. 652A, 652B, etc.) is significantly less than a duration (I) of the inspiratory phase 162 of an individual respiratory cycle (e.g. 654A) such that multiple, different stimulation periods occur during a single inspiratory phase 162. Accordingly, with this arrangement, several stimulation cycles will be repeated within a single reference respiratory cycle.

[00266] In some examples, the relatively short duration of the stimulation cycle causes a successive stimulation period (e.g. 652B) to begin at a different place within the inspiratory phase 162 of the reference respiratory cycle than prior stimulation period (e.g. 652A), such that the stimulation pattern is considered to be independent of (i.e. not synchronized relative to) the characteristics of the respiratory cycle. Rather, the asynchronous nature of stimulation protocol 650 is further exhibited via the stimulation periods 652C-652F occurring during the expiratory phase 170 of respiratory cycle 654A because the same stimulation cycle is repeated regardless of where the stimulation periods falls relative to different portions of the reference respiratory cycle.

[00267] Accordingly, even though the stimulation is not synchronized relative to a characteristic (e.g. inspiration) of the respiratory waveform, no matter where the stimulation protocol 650 is started relative to a series of respiratory cycles, the short duration (D) of the

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stimulation cycle (relative to the longer duration R of the respiratory cycle) ensures that at least a portion of two stimulation periods (e.g. 652A, 652B) will significantly overlap (at least a majority) the inspiratory phase 162 of the respective reference respiratory cycles throughout the portion of the treatment period during which stimulation protocol 650 is applied.

[00268] In some examples, via therapy manager 16 (Fig. 1B) a clinician can set a criteria how many respiratory cycles through which the stimulation protocol 650 will be applied before stimulation terminates and/or before a different stimulation protocol is implemented. In some examples, the criteria are based on a predetermined amount of time and/or a predetermined number of respiratory cycles for a particular patient.

[00269] It will be understood that each inspiratory phase 162 of each respiratory cycle (204A-204H) is shown in its ideal form in Figure 3B, and that in some instances where the inspiratory phase 162 at least partially coincides with one of the respective non-stimulation periods (e.g. 218D), the inspiratory phase may sometimes have an irregular shape compared to the idealized shape shown in Figure 3B.

[00270] Accordingly, via stimulation protocol 650, the independent stimulation function 14 of therapy manager 16 (Fig. 1B) employs asynchronous nerve stimulation to achieve stable respiration despite potential sleep disordered breathing.

[00271] In some examples, the stimulation protocol 650 (and similar protocols described above) is implemented via the "other" function 496 (Fig. 15A) of override function 492 to help overcome the type of persistent sleep-disordered breathing that does not become controlled via less intensive stimulation protocols. Accordingly, stimulation protocol 650 provides stimulation, which is not continuous but which has an intensity substantially greater than implemented via the stimulation protocols of one of the independent stimulation function 454 (Fig. 12) or the respiratory-dependent function 456 (Fig. 12), as previously illustrated in association with at least Figs. 3B-3E.

[00272] However, unlike a continuous stimulation pattern such as provided via continuous function 494 (Fig. 15A) of override function 492, stimulation protocol 650 regularly provides non-stimulation periods to enable the targeted nerve and/or muscle to rest

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somewhat among the stimulation periods, while still achieving an overall 80% stimulation duty cycle. In this arrangement, multiple stimulation periods can occur during each inspiratory phase of the repeating reference respiratory cycles such that no inspiratory phase occurs without stimulation occurring during at least a majority of any given inspiratory phase. In one aspect, such an arrangement may contribute to more favorable patient comfort or tolerance for the implementation of the "other" override function and/or contribute to diminishing any potential nerve or muscle fatigue.

[00273] In some examples, variations of stimulation protocol 650 are implemented in which the duration (D) of the stimulation cycle is significantly less than the duration (R) of the reference respiratory cycle, and the stimulation duty cycle is about 60 percent or 70 percent (instead of 80 percent). In such an arrangement, multiple stimulation periods can still occur during each inspiratory phase of the repeating reference respiratory cycles such that no inspiratory phase occurs without stimulation occurring during at least a majority of any given inspiratory phase, but with more non-stimulation available. In one aspect, such an arrangement may provide more comfort for some patients and/or potentially less muscle fatigue, as compared to the illustrated example stimulation protocol 650 having an 80% stimulation duty cycle (with relatively short duration stimulation cycles).

[00274] As with the other example stimulation protocols described herein, stimulation protocol 650 can be modified by an operator via the various parameters, functions, and components as previously described in association with at least Figures 4-5 can be selected and/or adjusted via a control portion (56 in Fig. 2C; 360 in Fig. 9; 380 in Fig. 10) in association with user interface (396 in Fig. 11A; 400 in Fig. 11B).

[00275] Figure 17A is a flow diagram 700 of a method 701 of nerve stimulation to treat sleep disordered breathing, according to one example of the present disclosure. In some examples, method 701 is performed using the components, elements, systems, etc. previously described and illustrated in association with Figures 1-16B. In some examples, method 701 is performed using components, elements, systems, etc. other than those previously described and illustrated in association with Figures 1-16B.

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[00276] As shown in Figure 17A, at 705 method 701 includes asynchronously stimulating an airway-patency-related nerve, according to a first stimulation protocol of stimulation cycles including a stimulation period and a non-stimulation period.

[00277] Figure 17B is a flow diagram 720 of a method 721 of nerve stimulation to treat sleep disordered breathing, according to one example of the present disclosure. In some examples, method 721 is performed using the components, elements, systems, etc. previously described and illustrated in association with Figures 1-16B. In some examples, method 721 is performed using components, elements, systems, etc. other than those previously described and illustrated in association with Figures 1-16B.

[00278] As shown in Figure 17B, in cooperation with the method 701 of Figure 17A, method 721 includes performing nerve stimulation via the therapy manager providing automatic convertible operation between the independent stimulation mode/function of Figure 17A and a second stimulation mode of stimulating the airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform, as shown at 724. With this arrangement, the therapy manager causes operation in the first mode for at least a first predetermined period of time (726) and converts operation into the second mode upon at least one parameter of the sensed respiratory waveform meeting a sensor signal quality criteria (728). Upon the at least one parameter of the sensed respiratory waveform failing to meet the sensor signal quality criteria (730), operation reverts into the first mode for at least the first predetermined period of time In this example, the first mode acts as the default mode of operation.

[00279] In some examples, the sensor signal quality criteria is indicative of the system's ability to actually deliver stimulation at the targeted portion of the respiratory period with a high degree of confidence. In some examples the system may define an obstructive event (e.g. apnea/hypopnea) as lasting at least 10 seconds, then the above-mentioned high degree of confidence would correspond to not missing the target portion of the respiratory period twice in consecutive respiratory cycles.

[00280] In some examples, the sensor signal quality criteria can be indicative of a patient's real-time condition either in the absence of or in the presence of stimulation. In some

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examples, the sensor signal quality criteria can be indicative of sensor noise, thereby indicating how well the sensor signal correlates with the patient's real-time condition.

[00281] However, in some examples, the second mode can act as the default mode of operation. Accordingly, as shown in Figure 17C, in cooperation with the method 701 of Figure 17A, method 771 includes performing nerve stimulation via the therapy manager providing convertible operation between the independent stimulation mode/function of Figure 17A and a second stimulation mode of stimulating the airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform, as shown at 774. With this arrangement, the therapy manager causes operation in the second mode (776), and upon at least one parameter of the sensed respiratory waveform failing to meet a sensor signal quality criteria, operation converts into the first mode for at least a first predetermined period of time (778). At 780, upon the at least one parameter of the sensed respiratory waveform meeting the sensor signal quality criteria, operation reverts back into the second mode.

[00282] In some examples, with respect to at least Figures 17B and 17C, the conversion between the first stimulation mode and the second stimulation mode is automatic.

[00283] With respect to selection of the first mode or the second mode in association with Figures 17B and 17C, in some examples a therapy manager 800 includes a default mode selector function 802 (as shown in Figure 18) to enable user selection of either the first mode or the second mode as a default mode. In some examples, the therapy manager 800 also comprises at least some of the features and attributes as therapy manager 16 (Fig. 1B) and other examples of a therapy manager, as previously described in association with at least Figures 1-17C.

[00284] With respect to selection of the first mode or the second mode in association with Figures 17B and 17C, in some examples a therapy manager 850 includes a manual conversion function 852 (as shown in Figure 19) to selectively cause conversion between the two different stimulation modes. In one aspect, such selective conversion can be implemented during operator titration of the therapeutic treatment as the operator adjusts parameters of the stimulation protocols for a particular patient. In some examples, the therapy manager 850 also comprises at least some of the features and attributes as therapy

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manager 16 (Fig. 1B) and other examples of a therapy manager, as previously described in association with at least Figures 1-17C. Accordingly, at least some examples of the present disclosure provide for a robust scheme to increase the effectiveness of nerve stimulation to treat sleep disordered breathing.

[00285] Although specific examples have been illustrated and described herein, it will be appreciated by those of ordinary skill in the art that a variety of alternate and/or equivalent implementations may be substituted for the specific examples shown and described without departing from the scope of the present disclosure. This application is intended to cover any adaptations or variations of the specific examples discussed herein.

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INTERNATIONAL PATENT LEGAL ADM.

DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
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MINNEAPOLIS MN 55402

In re Application of :
INSPIRE MEDICAL SYSTEMS, INC. :
Application No. 15/562,714 :
PCT No. PCT/US2016/022611 :
Int. Filing Date: 16 March 2016 :
Priority Date: 19 March 2015 :
Attorney Docket No. I618.118.103 :
For: STIMULATION FOR TREATING SLEEP :
DISORDERED BREATHING :

DECISION
ON PETITION

This is a decision on the petition under 37 CFR 1.137(a), filed 28 August 2017, to revive the above-identified application.

The petition is **GRANTED.**

The application became abandoned for failure to file the basic national fee and a copy of the international application pursuant to 37 CFR 1.495(b) by the expiry of 30 months from the priority date.

A grantable petition under 37 CFR 1.137(a) requires: (1) The reply required to the outstanding Office action or notice, unless previously filed; (2) The petition fee as set forth in § 1.17(m); (3) A statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to this paragraph was unintentional. The Director may require additional information where there is a question whether the delay was unintentional; and (4) any terminal disclaimer (and fee as set forth in § 1.20(d)) required pursuant to paragraph (d) of this section.

The instant petition has met the requirements of (1)-(4) above.

The present application is being forwarded to the Designated/Elected Office of the United States for further processing in accordance with this decision.

Telephone inquiries concerning this decision should be directed to the undersigned at (571) 272-3209.

/BethAnne Dayoan/

BethAnne Dayoan
PCT Legal Examiner
International Patent Legal Administration

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Darrell Wagner et al.	Examiner:	
Serial No.:	15/562,714	Group Art Unit:	
Filed:	September 28, 2017	Docket No.:	I618.118.103
Title:	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING		

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Sir/Madam:

This Preliminary Amendment modifies the National Phase Application filed September 28, 2017. Please amend the above-identified application as follows:

IN THE CLAIMS

Please cancel claims 1-20.

Please add claims 21-40.

1.-20. Cancel

21. (New) A device for treating sleep disordered breathing, comprising:

a stimulation element to stimulate an airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to sensed respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period.

22. (New) The device of claim 21, wherein the stimulation is implemented via an implanted electrode and the device includes a pulse generator comprising at least a portion of the stimulation element.

23. (New) The device of claim 21, wherein a total duration of stimulation via the first stimulation protocol during a treatment period is greater than 30 percent of the total duration of the treatment period.

24. (New) The device of claim 23, wherein each stimulation period includes continuous stimulation and has a minimum duration equal to or greater than an inspiratory reference.

25. (New) The device of claim 24, wherein the inspiratory reference corresponds to a duration of an inspiratory phase of a reference respiratory cycle.

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26. (New) The device of claim 25, wherein each stimulation period of the stimulation cycle has a duration greater than a duration of the inspiratory reference followed by the non-stimulation period having a duration less than the duration of the stimulation period.

27. (New) The device of claim 21, wherein the duration of the stimulation period is at least one of:

at least 25 percent of a duration of the stimulation cycle;

at least 50 percent of a duration of the stimulation cycle; and

at least 80 percent of a duration of the stimulation cycle.

28. (New) The device of claim 21, wherein the duration of the stimulation period is at least one of:

at least 25 percent of a duration of the reference respiratory cycle;.

at least 50 percent of a duration of the reference respiratory cycle; and

at least 80 percent of a duration of the reference respiratory cycle.

29. (New) The device of claim 26, wherein the duration of the stimulation cycle is less than the duration of the reference respiratory cycle, and a duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of 3.

30. (New) The device of claim 26, wherein the duration of the stimulation cycle is greater than the duration of the reference respiratory cycle.

31. (New) The device of claim 30, wherein the stimulation period and the non-stimulation period are in a proportion of at least 1.5 to 1.

32. (New) The device of claim 26, wherein the duration of the stimulation cycle is equal to the duration of the reference respiratory cycle, and wherein the duration of the reference

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respiratory cycle differs from a duration of a real time respiratory cycle by an amount exceeding a duration variability criteria.

33. (New) The device of claim 21, comprising:

a processor; and

a non-volatile computer readable medium storing instructions, executable on the processor, to implement the first stimulation element and to perform the first stimulation protocol.

34. (New) The device of claim 21, comprising:

a cuff electrode including at least one operative contact group through which the stimulation is deliverable non-selectively to the airway-patency-related nerve.

35. (New) A device for treating sleep disordered breathing comprising:

a stimulation element to stimulate an airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period; and

a sensing element to obtain respiratory information via at least periodically sensing a respiratory waveform without synchronization to stimulation,

wherein the stimulation element is activated for stimulation upon the sensing element identifying, via at least the respiratory information, sleep disordered breathing behavior which meets or exceeds a severity threshold and is deactivated upon the sensing element identifying, via at least the respiratory information, that the sleep disordered breathing behavior is less than the severity threshold.

36. (New) The device of claim 35, wherein the stimulation element includes a function selector to automatically select, for the first stimulation protocol, between:

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a first function to apply a repeating stimulation cycle having a duration different than a duration of the reference respiratory cycle, when the duration of the respiratory cycles in the sensed respiratory information is less variable than a respiratory duration variability criteria ; and

a second function to apply a repeating stimulation cycle having a duration matching the duration of the respiratory cycle reference, when the duration of respiratory cycles in the sensed respiratory information is more variable than the respiratory duration variability criteria.

37. (New) The device of claim 35, wherein the sensing element is configured to be in an inactive state by default and is periodically, temporarily activated to sense respiratory information to perform at least one of:

evaluating effectiveness of therapy according to at least the detected sleep disordered breathing relative to the severity threshold; and

calibrating the reference respiratory cycle relative to the sensed respiratory information.

38. (New) The device of claim 35, comprising:

a processor; and

a non-volatile memory storing instructions, executable via the processor, to:

evaluate the first stimulation protocol relative to the reference respiratory cycle based on the obtained respiratory information; and

modify, in response to the evaluation, at least one of the reference respiratory cycle and the first stimulation protocol, wherein modifying the first stimulation protocol includes at least one of:

adjusting features of the first stimulation protocol; and

substituting a different stimulation protocol for the first stimulation protocol.

39. (New) The device of claim 38, wherein the therapy manager is to evaluate the sensed respiratory information, and upon a determination that the first stimulation protocol fails to result in the detected sleep disordered breathing behavior being less than the severity threshold or that

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the sensed respiratory information fails to meet a sensor signal quality criteria, the therapy manager converts operation of the first stimulation element from the first stimulation protocol to a second stimulation protocol in which stimulation is applied continuously for at least two respiratory cycles or until the detected sleep disordered breathing behavior is less than the severity threshold.

40. (New) A device for treating sleep disordered breathing comprising:

a stimulation element to stimulate an airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period;

a sensing element to receive respiratory information; and

a control portion including:

a processor; and

a non-volatile memory storing instructions, executable via the processor, to:

provide convertible operation via a therapy manager between:

a first stimulation mode implementing the first stimulation protocol; and

a second stimulation mode of stimulating the airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform.

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REMARKS

Applicants have filed this Preliminary Amendment prior to examination. Accordingly, with the cancellation of claims 1-20 and by adding claims 21-40, claims 21-40 are pending in the application.

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CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 21-40 are in form for allowance and are not taught or suggested by the cited references.

Please consider this a Petition for Extension of Time for a sufficient number of months to enter these papers, if appropriate. At any time during the pendency of this application, please charge any additional fees or credit overpayment to Deposit Account No. 500471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Paul S. Grunzweig at Telephone No. (612) 767-2504, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

Darrell Wagner et al.,

By their attorneys,

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Date: January 17, 2018
PSG:cjk

/Paul S. Grunzweig/
Paul S. Grunzweig
Reg. No. 37,143

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner et al.
Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

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	1	20150039045		2015-02-05	Ni et al.	
	2	20160193468		2016-07-07	Rondoni et al.	

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	Attorney Docket Number	I618.118.103

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	1	Eisele Article – David W. Eisele, MD et al., "Tongue neuromuscular and direct hypoglossal nerve stimulation for obstructive sleep apnea," Otolaryngologic Clinics of North America, Otolayngol Clin N Am 36 (2003) 501-510 (10 pages).	
	2	Goodall Article – Eleanor V. Goodhall et al., "Position-Selective Activation of Peripheral Nerve Fibers with a Cuff Electrode," IEEE Transaction on Biomedical Engineering, Vol. 43, No. 8, August 1996, pages 851-856.	
	3	Naples Article – Gregory G. Naples et al., "A Spiral Nerve Cuff Electrode for Peripheral Nerve Stimulation," 8088 IEEE Transactions on Biomedical Engineering, 35. November 1988, No. 11, New York, NY, pages 905-915.	
	4	Oliven Article – Arie Oliven et al., "Upper airway response to electrical stimulation of the genioglossus in obstructive sleep apnea," Journal of Applied Physiology, Volume 95, pages 2023-2029, November 2003, www.jap.physiology.org on September 18, 2006. (8 pages)	
	5	Schwartz Article – Alan R. Schwartz MD et al., "Theraputic Electrical Stimulation of the Hypoglossal Nerve in Obstructive Sleep Apnea, Arch Otolaryngol HeadAnd Neck Surg., Vol. 127, Oct. 2001, pages 1216-1223. Copyright 2001 American Medical Association. (8 pages)	
	6	PARK, "Preoperative Percutaneous Cranial Nerve Mapping in Head and Neck Surgery," ARCH FACIAL PLAST SURG/VOL 5, Jan/Feb 2003, www.archfacial.compages 86-91.	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	First Named Inventor	Darrell Wagner et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2018-01-23
Name/Print	Paul S. Grunzweig	Registration Number	37143

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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0147

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4379462		1983-04-12	Borkan et al.	
	2	4567892		1986-02-04	Plicchi et al.	
	3	4630614		1986-12-23	Atlas	
	4	4813431		1989-03-21	Brown	
	5	4830008		1989-05-16	Meer	
	6	5133354		1992-07-28	Kallok	
	7	5134995		1992-08-04	Gruenke et al.	
	8	5148802		1992-09-22	Sanders et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Attorney Docket Number	I618.118.103

	9	5158080		1992-10-27	Kallok	
	10	5167229		1992-12-01	Peckham et al.	
	11	5174287		1992-12-29	Kallok et al.	
	12	5178156		1993-01-12	Takishima et al.	
	13	5203343		1993-04-20	Axe et al.	
	14	5211173		1993-05-18	Kallok et al.	
	15	5215082		1993-06-01	Kallok et al.	
	16	5233983		1993-08-10	Markowitz	
	17	5239995		1993-08-31	Estes et al.	
	18	5245995		1993-09-21	Sullivan et al.	
	19	5265624		1993-11-30	Bowman	

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	Filing Date	2017-09-28
	First Named Inventor	Darrell Wagner et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

	20	5281219		1994-01-25	Kallok	
	21	5300094		1994-04-05	Kallok et al.	
	22	5335657		1994-08-09	Terry, Jr. et al.	
	23	5344438		1994-09-06	Testerman et al.	
	24	5351394		1994-10-04	Weinberg	
	25	5385144		1995-01-31	Yamanishi et al.	
	26	5388578		1995-02-14	Yomtov et al.	
	27	5398682		1995-03-21	Lynn	
	28	5458137		1995-10-17	Axe et al.	
	29	5483969		1996-01-16	Testerman et al.	
	30	5485851		1996-01-26	Erickson	

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	31	5522862		1996-06-04	Testerman et al.	
	32	5524632		1996-06-11	Stein et al.	
	33	5540731		1996-07-30	Testerman	
	34	5540732		1996-07-30	Testerman	
	35	5540733		1996-07-30	Testerman et al.	
	36	5540734		1996-07-30	Zabara	
	37	5546952		1996-08-20	Erickson	
	38	5549655		1996-08-27	Erickson	
	39	5588439		1996-12-31	Hollub	
	40	5591216		1997-01-07	Testerman et al.	
	41	5605151		1997-02-25	Lynn	

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	42	5645053		1997-07-08	Remmers et al.	
	43	5671733		1997-09-30	Raviv et al.	
	44	5797852		1998-08-25	Karakasoglu et al.	
	45	5823187		1998-10-20	Estes et al.	
	46	5843135		1998-12-01	Weijand et al.	
	47	5895360		1999-04-20	Christopherson et al.	
	48	5904141		1999-05-18	Estes et al.	
	49	5919221		1999-07-06	Miesel	
	50	5944680		1999-08-31	Christopherson et al.	
	51	5999846		1999-12-07	Pardey et al.	
	52	6015389		2000-01-18	Brown	

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	53	6021352		2000-02-01	Christopherson et al.	
	54	6025624		2000-02-15	Figura	
	55	6041780		2000-03-28	Richard et al.	
	56	6099479		2000-08-08	Christopherson et al.	
	57	6120441		2000-09-19	Griebel	
	58	6125290		2000-09-26	Miesel	
	59	6125291		2000-09-26	Miesel et al.	
	60	6126611		2000-10-03	Bourgeouis et al.	
	61	6132384		2000-10-17	Christopherson et al.	
	62	6134459		2000-10-17	Roberts et al.	
	63	6144866		2000-11-07	Miesel et al	

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	64	6175767		2001-01-16	Doyle, Sr.	
	65	6181961		2001-01-30	Prass	
	66	6198952		2001-03-06	Miesel	
	67	6223064		2001-04-24	Lynn et al.	
	68	6240316		2001-05-29	Richmond et al.	
	69	6248080		2001-06-19	Miesel et al.	
	70	6249703		2001-06-19	Stanton et al.	
	71	6251126		2001-06-26	Ottenhoff et al.	
	72	6269269		2001-07-31	Ottenhoff et al.	
	73	6307481		2001-10-23	Lehrman et al.	
	74	6309350		2001-10-30	Van Tassel et al.	

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	75	6314324		2001-11-06	Lattner et al.	
	76	6342039		2002-01-29	Lynn et al.	
	77	6345202		2002-02-05	Richmond et al.	
	78	6361494		2002-03-26	Lindenthaler	
	79	6393325		2002-05-21	Mann et al.	
	80	6449507		2002-09-10	Hill et al.	
	81	6450957		2002-09-17	Yoshimi et al.	
	82	6456866		2002-09-24	Tyler et al.	
	83	6522928		2003-02-18	Whitehurst et al.	
	84	6532388		2003-03-11	Hill et al.	
	85	6572543		2003-06-03	Christopherson et al.	

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	86	6574507		2003-06-03	Bonnet	
	87	6587725		2003-07-01	Durand et al.	
	88	6609016		2003-08-19	Lynn	
	89	6609032		2003-08-19	Woods et al.	
	90	6629527		2003-10-07	Estes et al.	
	91	6641542		2003-11-04	Cho et al.	
	92	6645143		2003-11-03	Van Tassel et al.	
	93	6647289		2003-11-11	Prutchi	
	94	6651652		2003-11-25	Ward	
	95	6654634		2003-11-25	Prass	
	96	6665560		2003-12-16	Becker et al.	

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	97	6666830		2003-12-23	Lehrman et al.	
	98	6689068		2004-02-10	Hale et al.	
	99	6703939		2004-03-09	Lehrman et al.	
	100	6718208		2004-04-06	Hill et al.	
	101	6719708		2004-04-13	Jansen	
	102	6731976		2004-05-04	Penn et al.	
	103	6731984		2004-05-04	Cho et al.	
	104	6735471		2004-05-11	Hill et al.	
	105	6752765		2004-06-22	Jensen et al.	
	106	6770022		2004-08-03	Mechlenburg et al.	
	107	6773404		2004-08-10	Poezevera et al.	

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	108	6805667		2004-10-29	Christopherson et al.	
	109	6811538		2004-11-02	Westbrook et al.	
	110	6842647		2005-01-11	Griffith et al.	
	111	6881192		2005-04-19	Park	
	112	6890306		2005-05-10	Poezevera	
	113	6893405		2005-05-17	Kumar et al.	
	114	6904320		2005-06-07	Park et al.	
	115	6907293		2005-06-14	Grill et al.	
	116	6928324		2005-08-09	Park et al.	
	117	6935335		2005-08-30	Lehrman et al.	
	118	6936011		2005-08-30	Sheldon	

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	119	6964641		2005-11-15	Cho et al.	
	120	6978171		2005-12-20	Goetz et al.	
	121	6988498		2006-01-24	Berthon-Jones et al.	
	122	7025730		2006-04-11	Cho et al.	
	123	7041049		2006-05-09	Raniere	
	124	7054692		2006-05-30	Whitehurst et al.	
	125	7077810		2006-07-18	Lange et al.	
	126	7081095		2006-07-25	Lynn et al.	
	127	7082331		2006-07-25	Park et al.	
	128	7082336		2006-07-25	Ransbury et al.	
	129	7087053		2006-08-08	Vanney	

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	130	7117036		2006-10-03	Florio	
	131	7128717		2006-10-31	Thach et al.	
	132	7145461		2006-12-05	Lehrman et al.	
	133	7149573		2006-12-12	Wang	
	134	7155278		2006-12-26	King et al.	
	135	7160252		2007-01-09	Cho et al.	
	136	7160255		2007-01-09	Saadat	
	137	7167743		2007-01-23	Heruth et al.	
	138	7174215		2007-02-06	Bradley	
	139	7186220		2007-03-06	Stahmann et al.	
	140	7187978		2007-03-06	Malek et al.	

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	141	7189204		2007-03-13	Ni et al.	
	142	7195594		2007-03-27	Eigler et al.	
	143	7200440		2007-04-03	Kim et al.	
	144	7206635		2007-04-17	Cho et al.	
	145	7212862		2007-05-01	Park et al.	
	146	7214197		2007-05-08	Prass	
	147	7252640		2007-08-07	Ni et al.	
	148	7269457		2007-09-11	Shafer et al.	
	149	7269459		2007-09-11	Koh	
	150	7277749		2007-10-02	Gordon et al.	
	151	7330760		2008-02-12	Heruth et al.	

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	152	7336996		2008-02-26	Hartley et al.	
	153	7340302		2008-03-04	Falkenberg	
	154	7351208		2008-04-01	Brodnick et al.	
	155	7366572		2008-04-29	Heruth et al.	
	156	7371220		2008-05-13	Koh et al.	
	157	7387608		2008-06-17	Dunlop et al.	
	158	7395113		2008-07-01	Heruth et al.	
	159	7396333		2008-07-08	Stahmann et al.	
	160	7398115		2008-07-08	Lynn	
	161	7422015		2008-09-09	Delisle et al.	
	162	7438686		2008-10-21	Cho et al.	

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	163	7447545		2008-11-04	Heruth et al.	
	164	7454250		2008-11-18	Bjorling et al.	
	165	7453928		2008-12-09	Lee et al.	
	166	7468040		2008-12-23	Hartley et al.	
	167	7469697		2008-12-30	Lee et al.	
	168	7473227		2009-01-06	Hsu et al.	
	169	7491181		2009-02-17	Heruth et al.	
	170	6509164		2009-03-24	Jensen et al.	
	171	7510531		2009-03-31	Lee et al.	
	172	7526341		2009-04-29	Goetz et al.	
	173	7542803		2009-06-02	Heruth et al.	

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	174	7572225		2009-08-11	Stahmann et al.	
	175	7590455		2009-09-15	Heruth et al.	
	176	7591265		2009-09-22	Lee et al.	
	177	7596413		2009-09-29	Libbus et al.	
	178	7603170		2009-10-13	Hatlestad et al.	
	179	7610094		2009-10-27	Stahmann et al.	
	180	7634315		2009-12-15	Cholette	
	181	7644714		2010-01-12	Atkinson et al.	
	182	7662105		2010-02-16	Hatlestad	
	183	7672728		2010-03-02	Libbus et al.	
	184	7678061		2010-03-16	Lee et al.	

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	185	7680538		2010-03-16	Durand et al.	
	186	7702385		2010-04-20	Moffitt et al.	
	187	7717848		2010-05-18	Heruth et al.	
	188	7720541		2010-05-18	Stahmann et al.	
	189	7725195		2010-05-25	Lima et al.	
	190	7734340		2010-06-08	De Ridder	
	191	7734350		2010-06-08	Dubnov et al.	
	192	7742819		2010-06-22	Moffitt	
	193	7747323		2010-06-29	Libbus et al.	
	194	7751880		2010-07-06	Cholette	
	195	7775993		2010-08-17	Heruth et al.	

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	196	7783353		2010-08-24	Libbus et al.	
	197	7792583		2010-09-07	Miesel et al.	
	198	7809442		2010-10-05	Bolea et al.	
	199	7818063		2010-10-19	Wallace et al.	
	200	7853322		2010-12-14	Bourget et al.	
	201	7881798		2011-02-01	Miesel et al.	
	202	7908013		2011-03-15	Miesel et al.	
	203	7917230		2011-03-29	Bly	
	204	7942822		2011-05-17	Koh	
	205	7957809		2011-06-07	Bourget et al.	
	206	7957797		2011-06-07	Bourget et al.	

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	207	7979128		2011-07-12	Tehrani et al.	
	208	8016776		2011-09-13	Bourget et al.	
	209	8021299		2011-09-20	Miesel et al.	
	210	8150531		2012-04-03	Skelton	
	211	8160711		2012-04-17	Tehrani et al.	
	212	8175720		2012-05-08	Skelton et al.	

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	1	20010010010		2001-07-26	Richmond et al.	
	2	20020010495		2002-01-24	Freed et al.	
	3	20020049479		2002-04-25	Pitts	

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	4	20020156507		2002-10-24	Lindenthaler	
	5	20030093128		2005-05-15	Freed et al.	
	6	20030224895		2003-06-19	Gordon et al.	
	7	20030114905		2003-06-19	Kuzma	
	8	20030163059		2003-08-28	Poezevera et al.	
	9	20030195571		2003-10-16	Burnes et al.	
	10	20030216789		2003-11-20	Deem et al.	
	11	20040015204		2004-01-22	Whitehurst et al.	
	12	20040073272		2004-04-15	Knudson et al.	
	13	20040111139		2004-06-10	McCreery	
	14	20040215288		2004-10-28	Lee et al.	

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	15	20040230278		2004-11-18	Dahl et al.	
	16	20040254612		2004-12-16	Ezra	
	17	20050004628		2005-01-06	Goetz et al	
	18	20050010265		2005-01-13	Baru Fassio et al.	
	19	20050042589		2005-02-24	Hatlestad et al.	
	20	20050043765		2005-02-24	Williams et al.	
	21	20050043772		2005-02-24	Stahmann et al.	
	22	20050074741		2005-04-07	Lee et al.	
	23	20050076908		2005-04-14	Lee et al.	
	24	20050080348		2005-04-14	Stahmann et al.	
	25	20050080461		2005-04-14	Stahmann et al.	

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	26	20050081847		2005-04-21	Lee et al.	
	27	20050085865		2005-04-21	Tehrani	
	28	20050085866		2005-04-21	Tehrani	
	29	20050085868		2005-04-21	Tehrani et al.	
	30	20050085869		2005-04-21	Tehrani et al.	
	31	20050085874		2005-04-21	Davis et al.	
	32	20050101833		2005-05-12	Hsu et al.	
	33	20050113710		2005-05-26	Stahmann et al.	
	34	20050115561		2005-06-02	Stahmann et al.	
	35	20050145246		2005-07-07	Hartley et al.	
	36	20050165457		2005-07-28	Benser et al.	

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	37	20050182457		2005-08-18	Thrope et al.	
	38	20050209513		2005-09-22	Heruth et al.	
	39	20050209643		2005-09-22	Heruth et al.	
	40	20050222503		2005-10-06	Dunlop et al.	
	41	20050234523		2005-10-20	Levin et al.	
	42	20050251216		2005-11-10	Hill et al.	
	43	20050261747		2005-11-24	Schuler et al.	
	44	20050267380		2005-12-01	Poezevera	
	45	20050277844		2005-12-15	Strother et al.	
	46	20050277999		2005-12-15	Strother et al.	
	47	20050278000		2005-12-15	Strother et al.	

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	48	20060052836		2006-03-09	Kim et al.	
	49	20060058852		2006-03-16	Koh et al.	
	50	20060064029		2006-03-23	Arad (Abboud)	
	51	20060079802		2006-04-13	Jensen et al	
	52	20060095088		2006-05-04	De Ridder	
	53	20060103407		2006-05-18	Kakizawa et al.	
	54	20060135886		2006-06-22	Lippert et al.	
	55	20060142815		2006-09-29	Tehrani et al.	
	56	20060212096		2006-09-21	Stevenson	
	57	20060224209		2006-10-05	Meyer	
	58	20060241708		2006-10-26	Boute	

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	First Named Inventor	Darrell Wagner et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

	59	20060247729		2006-11-02	Tehrani et al.	
	60	20060259079		2006-11-16	King	
	61	20060264777		2006-11-23	Drew	
	62	20060266369		2006-11-30	Atkinson et al.	
	63	20060271137		2006-11-30	Stanton-Hicks	
	64	20060276701		2006-12-07	Ray	
	65	20060293720		2006-12-28	DiLorenzo	
	66	20060293723		2006-12-28	Whitehurst et al.	
	67	20070021785		2007-01-25	Inman et al.	
	68	20070027482		2007-02-01	Parnis et al.	
	69	20070038265		2007-02-15	Tcheng et al.	

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0173

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15562714
	Filing Date	2017-09-28
	First Named Inventor	Darrell Wagner et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

	70	20070150022		2007-06-28	Ujhazy et al.	
	71	20070233204		2007-10-04	Lima et al.	
	72	20070255379		2007-11-01	Williams et al.	
	73	20080009685		2008-01-10	Kim et al.	
	74	20080039904		2008-02-14	Bulkes et al.	
	75	20080046055		2008-02-21	Durand et al.	
	76	20080064977		2008-03-13	Kelleher et al.	
	77	20080103545		2008-05-01	Bolea et al.	
	78	20080103570		2008-05-01	Gerber	
	79	20080109046		2008-05-08	Lima et al.	
	80	20080109048		2008-05-08	Moffitt	

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0174

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15562714
	Filing Date	2017-09-28
	First Named Inventor	Darrell Wagner et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

	81	20080132802		2008-06-05	Ni et al.		
	82	20080294060		2008-11-27	Haro et al.		
	83	20090024047		2009-01-22	Shipley et al.		
	84	20090062882		2009-03-05	Zhang et al.		
	85	20090112116		2009-04-30	Lee et al.		
	86	20090118787		2009-05-07	Moffitt et al.		
	87	20090234427		2009-09-17	Chinn et al.		
	88	20090287279		2009-11-19	Parramon et al.		

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15562714
	Filing Date	2017-09-28
	First Named Inventor	Darrell Wagner et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

NON-PATENT LITERATURE DOCUMENTS			Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		

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EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15562714
	Filing Date	2017-09-28
	First Named Inventor	Darrell Wagner et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2018-01-23
Name/Print	Paul S. Grunzweig	Registration Number	37143

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0177

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0178

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner et al.
Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20090308395		2009-12-17	Lee et al.	
	2	20090326408		2009-12-31	Moon	
	3	20100010566		2010-01-14	Thacker et al.	
	4	20100016749		2010-01-21	Atsma et al.	
	5	20100094379		2010-04-15	Meadows	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

	6	20100125310		2010-05-20	Wilson et al.	
	7	20100125314		2010-05-20	Bradley et al.	
	8	20100125315		2010-05-20	Parramon et al.	
	9	20100137931		2010-06-03	Hopper et al.	
	10	20100152553		2010-06-17	Ujhazy et al.	
	11	20100174341		2010-07-08	Bolea et al.	
	12	20100198103		2010-08-05	Meadows et al.	
	13	20100198289		2010-08-05	Kameli et al.	
	14	20100228133		2010-09-09	Averina et al.	
	15	20100228317		2010-09-09	Libbus et al.	
	16	20100241195		2010-09-23	Meadows et al.	

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	Filing Date	2017-09-28
	First Named Inventor	Darrell Wagner et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

	17	20100262210		2010-10-14	Parramon et al.			
	18	20100174341		2010-07-08	Bolea et al.			
	19	20110093036		2011-04-21	Mashiach			
	20	20110112601		2011-05-12	Meadows et al.			
	21	20110152706		2011-06-23	Christopherson et al.			
	22	20110152965		2011-06-23	Mashiach et al.			
	23	20110160794		2011-06-30	Bolea et al.			
	24	20110264164		2011-10-27	Christopherson et al.			

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2010502276	JP		2010-01-28	Cardiac Pacemaker, Inc.		X

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15562714
	Filing Date	2017-09-28
	First Named Inventor	Darrell Wagner et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

	2	2011520526	JP		2011-07-21	Inspire Medical Systems, Inc.		☒
	3	199750049	WO		1997-12-31	Medtronic Inc.		☐
	4	2006047264	WO		2006-05-04	Advanced Neuromodulation Systems, Inc.		☐
	5	2006057734	WO		2006-06-01	Advanced Neuromodulation Systems, Inc.		☐
	6	2006102591	WO		2006-09-28	Vanderbilt University		☐
	7	2007068284	WO		2007-06-27	Synergio AG		☐
	8	2008048471	WO		2008-04-24	Apnex Medical, Inc.		☐
	9	2009048580	WO		2009-04-16	Imthera Medical, INc.		☐
	10	2009048581	WO		2009-04-16	Imthera Medical, Inc.		☐
	11	2009135138	WO		2009-11-05	Medtronic, Inc.		☐
	12	2009135140	WO		2009-11-05	Medtronic, Inc.		☐

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	First Named Inventor	Darrell Wagner et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

	13	2009140636	WO		2009-11-19	Inspire Medical Systems, Inc.		☐
	14	2010039853	WO		2010-04-08	Inspire medical Systems, Inc.		☐
	15	2010057286	WO		2010-05-27	Victhorn Human Bionics Inc.		☐
	16	2010059839	WO		2010-05-27	Inspire Medical Systems, Inc.		☐
	17	2010117810	WO		2010-10-14	Inspire Medical Systems, Inc.		☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1		

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Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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0183

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	First Named Inventor	Darrell Wagner et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

CERTIFICATION STATEMENT

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2018-01-23
Name/Print	Paul S. Grunzweig	Registration Number	37143

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Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0185

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET

Substitute for Form PTO-1360
(For use with Form PTO/SB/06)

Application Number	Filing Date
15562714	

Applicant(s) Darrell Wagner

* May be used for additional claims or amendments

CLAIMS	AS FILED		AFTER FIRST AMENDMENT		AFTER SECOND AMENDMENT		*					
	Indep	Depend	Indep	Depend	Indep	Depend		Indep	Depend	Indep	Depend	Indep	Depend
1	1						51		1				
2		1					52		1				
3		1					53	1					
4		1					54		1				
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MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET

Substitute for Form PTO-1360
(For use with Form PTO/SB/06)

Application Number	Filing Date
15562714	

Applicant(s): Darrell Wagner

* May be used for additional claims or amendments

CLAIMS	AS FILED		AFTER FIRST AMENDMENT		AFTER SECOND AMENDMENT	
	Indep	Depend	Indep	Depend	Indep	Depend
101		1				
102		1				
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Total Depend	123	↵	0	↵	0	↵
Total Claims	128		0		0	

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20160022204		2016-01-28	Mostov	
	2	20160354602		2016-12-08	Keenan	
	3	20160354603		2016-12-08	Keenan	
	4	20160354608		2016-12-08	Keenan	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

EFS Web 2.1.17

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15562714
	Filing Date	2017-09-28
	First Named Inventor	Darrell Wagner
	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1		

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15562714
	Filing Date	2017-09-28
	First Named Inventor	Darrell Wagner
	Art Unit	
	Examiner Name	
	Attorney Docket Number	I618.118.103

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2018-01-27
Name/Print	Paul S. Grunzweig	Registration Number	37,143

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0191

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Darrell Wagner et al.	Examiner:	
Serial No.:	15/562,714	Group Art Unit:	
Filed:	September 28, 2017	Docket No.:	I618.118.103
Title:	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING		

2nd PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Sir/Madam:

This Preliminary Amendment is responsive to the Notice of Insufficiency Under 37 CFR 1.492 and/or 1.495 (DO/EO/US) dated January 24, 2018. Please amend the above-identified application as follows:

IN THE CLAIMS

Please cancel claims 1-128.

Please add claims 129-148.

1-128. Canceled

129. (New) A device for treating sleep disordered breathing, comprising:

a stimulation element to stimulate an airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to sensed respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period.

130. (New) The device of claim 129, wherein the stimulation is implemented via an implanted electrode and the device includes a pulse generator comprising at least a portion of the stimulation element.

131. (New) The device of claim 129, wherein a total duration of stimulation via the first stimulation protocol during a treatment period is greater than 30 percent of the total duration of the treatment period.

132. (New) The device of claim 131, wherein each stimulation period includes continuous stimulation and has a minimum duration equal to or greater than an inspiratory reference.

133. (New) The device of claim 132, wherein the inspiratory reference corresponds to a duration of an inspiratory phase of a reference respiratory cycle.

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134. (New) The device of claim 133, wherein each stimulation period of the stimulation cycle has a duration greater than a duration of the inspiratory reference followed by the non-stimulation period having a duration less than the duration of the stimulation period.

135. (New) The device of claim 129, wherein the duration of the stimulation period is at least one of:

at least 25 percent of a duration of the stimulation cycle;

at least 50 percent of a duration of the stimulation cycle; and

at least 80 percent of a duration of the stimulation cycle.

136. (New) The device of claim 129, wherein the duration of the stimulation period is at least one of:

at least 25 percent of a duration of the reference respiratory cycle;.

at least 50 percent of a duration of the reference respiratory cycle; and

at least 80 percent of a duration of the reference respiratory cycle.

137. (New) The device of claim 134, wherein the duration of the stimulation cycle is less than the duration of the reference respiratory cycle, and a duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of 3.

138. (New) The device of claim 134, wherein the duration of the stimulation cycle is greater than the duration of the reference respiratory cycle.

139. (New) The device of claim 138, wherein the stimulation period and the non-stimulation period are in a proportion of at least 1.5 to 1.

140. (New) The device of claim 134, wherein the duration of the stimulation cycle is equal to the duration of the reference respiratory cycle, and wherein the duration of the reference

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respiratory cycle differs from a duration of a real time respiratory cycle by an amount exceeding a duration variability criteria.

141. (New) The device of claim 129, comprising:

a processor; and

a non-volatile computer readable medium storing instructions, executable on the processor, to implement the first stimulation element and to perform the first stimulation protocol.

142. (New) The device of claim 129, comprising:

a cuff electrode including at least one operative contact group through which the stimulation is deliverable non-selectively to the airway-patency-related nerve.

143. (New) A device for treating sleep disordered breathing comprising:

a stimulation element to stimulate an airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period; and

a sensing element to obtain respiratory information via at least periodically sensing a respiratory waveform without synchronization to stimulation,

wherein the stimulation element is activated for stimulation upon the sensing element identifying, via at least the respiratory information, sleep disordered breathing behavior which meets or exceeds a severity threshold and is deactivated upon the sensing element identifying, via at least the respiratory information, that the sleep disordered breathing behavior is less than the severity threshold.

144. (New) The device of claim 143, wherein the stimulation element includes a function selector to automatically select, for the first stimulation protocol, between:

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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a first function to apply a repeating stimulation cycle having a duration different than a duration of the reference respiratory cycle, when the duration of the respiratory cycles in the sensed respiratory information is less variable than a respiratory duration variability criteria ; and

a second function to apply a repeating stimulation cycle having a duration matching the duration of the respiratory cycle reference, when the duration of respiratory cycles in the sensed respiratory information is more variable than the respiratory duration variability criteria.

145. (New) The device of claim 143, wherein the sensing element is configured to be in an inactive state by default and is periodically, temporarily activated to sense respiratory information to perform at least one of:

evaluating effectiveness of therapy according to at least the detected sleep disordered breathing relative to the severity threshold; and

calibrating the reference respiratory cycle relative to the sensed respiratory information.

146. (New) The device of claim 143, comprising:

a processor; and

a non-volatile memory storing instructions, executable via the processor, to:

evaluate the first stimulation protocol relative to the reference respiratory cycle based on the obtained respiratory information; and

modify, in response to the evaluation, at least one of the reference respiratory cycle and the first stimulation protocol, wherein modifying the first stimulation protocol includes at least one of:

adjusting features of the first stimulation protocol; and

substituting a different stimulation protocol for the first stimulation protocol.

147. (New) The device of claim 146, wherein the therapy manager is to evaluate the sensed respiratory information, and upon a determination that the first stimulation protocol fails to result in the detected sleep disordered breathing behavior being less than the severity threshold or that

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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the sensed respiratory information fails to meet a sensor signal quality criteria, the therapy manager converts operation of the first stimulation element from the first stimulation protocol to a second stimulation protocol in which stimulation is applied continuously for at least two respiratory cycles or until the detected sleep disordered breathing behavior is less than the severity threshold.

148. (New) A device for treating sleep disordered breathing comprising:

a stimulation element to stimulate an airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period;

a sensing element to receive respiratory information; and

a control portion including:

a processor; and

a non-volatile memory storing instructions, executable via the processor, to:

provide convertible operation via a therapy manager between:

a first stimulation mode implementing the first stimulation protocol; and

a second stimulation mode of stimulating the airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0197

REMARKS

This Preliminary Amendment is responsive to the Notice of Insufficiency Under 37 CFR 1.492 and/or 1.495 (DO/EO/US) dated January 24, 2018. Applicants have filed this 2nd Preliminary Amendment prior to examination. Accordingly, with the cancellation of claims 1-128 and by adding claims 129-148, claims 129-148 are pending in the application.

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NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 129-148 are in form for allowance and are not taught or suggested by the cited references.

Please consider this a Petition for Extension of Time for a sufficient number of months to enter these papers, if appropriate. At any time during the pendency of this application, please charge any additional fees or credit overpayment to Deposit Account No. 500471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Paul S. Grunzweig at Telephone No. (612) 767-2504, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

Dicke, Billig & Czaja
Fifth Street Towers, Suite 2250
100 South Fifth Street
Minneapolis, MN 55402

Respectfully submitted,

Darrell Wagner et al.,

By their attorneys,

DICKE, BILLIG & CZAJA, PLLC
Fifth Street Towers, Suite 2250
100 South Fifth Street
Minneapolis, MN 55402
Telephone: (612) 573-2000
Facsimile: (612) 573-2005

Date: March 6, 2018
PSG:cjk

/Paul S. Grunzweig/
Paul S. Grunzweig
Reg. No. 37,143

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0199

Electronic Patent Application Fee Transmittal

Application Number:	15562714
Filing Date:	28-Sep-2017
Title of Invention:	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING
First Named Inventor/Applicant Name:	Darrell Wagner
Filer:	PAUL STEVEN GRUNZWEIG/Cindy Koski
Attorney Docket Number:	I618.118.103

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
OATH/DECL > 30 MOS FROM 371 COMMENCEMENT	1617	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**140**

Electronic Acknowledgement Receipt

EFS ID:	31971054
Application Number:	15562714
International Application Number:	
Confirmation Number:	3077
Title of Invention:	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING
First Named Inventor/Applicant Name:	Darrell Wagner
Customer Number:	25281
Filer:	PAUL STEVEN GRUNZWEIG/Cindy Koski
Filer Authorized By:	PAUL STEVEN GRUNZWEIG
Attorney Docket Number:	I618.118.103
Receipt Date:	06-MAR-2018
Filing Date:	28-SEP-2017
Time Stamp:	16:13:16
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$140
RAM confirmation Number	030718INTEFSW16143900
Deposit Account	500471
Authorized User	Cindy Koski

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37 CFR 1.17 (Patent application and reexamination processing fees)

37 CFR 1.19 (Document supply fees)

37 CFR 1.21 (Miscellaneous fees and charges)

37 CFR 1.492 (National application filing, search, and examination fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	2018-03-06Declaration.pdf	1719636 ca90...7ae8	no	5

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Information:

2		2018-03-06_2ndPreliminaryAmendment.pdf	41882 aaa67e8d947a55f461d77c64d77aba8d0cd9...5013a	yes	8

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Claims	2	6
Applicant Arguments/Remarks Made in an Amendment	7	8

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Information:

3	Fee Worksheet (SB06)	fee-info.pdf	30531 ...343c2	no	2

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket I618.118.103

PTO/AIA/01 (06-12)
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ☒ United States application or PCT international application number 15/562,714 filed on September 28, 2017.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Darrell Wagner Date (Optional): 7 Feb 2018

Signature: Darrell Wagner

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Docket I618.118.103

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 15/562,714 filed on September 28, 2017.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

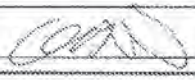
I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Quan Ni Date (Optional): 15 Feb 2018

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Docket I618.118.103

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ☒ United States application or PCT international application number 15/562,714 filed on September 28, 2017.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: John Rondoni Date (Optional): 26 Feb 2018

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Docket I618.118.103

PTO/AIA/01 (05-12)
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

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☐ The attached application, or

☒ United States application or PCT international application number 15/562,714 filed on September 28, 2017.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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LEGAL NAME OF INVENTOR

Inventor: David Dieken Date (Optional): 7 Feb 2018

Signature: [signature]

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/562,714

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	300
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A	520
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	760
TOTAL CLAIMS (37 CFR 1.16(i))	20 minus 20 =	*			OR	x 100 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*				x 460 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1580

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

Doc Code: PA..

Document Description: Power of Attorney

PTO/AIA/82A (07-12)

Approved for use through 11/30/2014. OMB 0651-0035

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B or equivalent) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5. If the Power of Attorney by Applicant form is not accompanied by this transmittal form or an equivalent, the Power of Attorney will not be recognized in the application.

Application Number	15/562,714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner et al.
Title	Stimulation for Treating Sleep Disordered Breathing
Art Unit	3766
Examiner Name	
Attorney Docket Number	I618.118.103

SIGNATURE of Applicant or Patent Practitioner

Signature	/Paul S. Grunzweig/	Date	2018-04-10
Name	Paul S. Grunzweig	Telephone	612-767-2504
Registration Number	37,143		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications.

■ *Total of 2 forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 25281

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Inspire Medical Systems, Inc., 9700 63rd Ave. North, Suite 200, Maple Grove, MN 55369

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	6 April 2016
Name	John Rondoni		
Title	Inspire Medical Systems, Inc. VP of product dvlp. QOS & Quality		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/562,714	09/28/2017	Darrell Wagner	I618.118.103

CONFIRMATION NO. 3077

25281
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

POA ACCEPTANCE LETTER

OC000000098739443

Date Mailed: 04/13/2018

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/10/2018.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/dgeln/

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/562,714	09/28/2017	Darrell Wagner	I618.118.103

CONFIRMATION NO. 3077

25281
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

PUBLICATION NOTICE



Title:STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

Publication No.US-2018-0117316-A1
Publication Date:05/03/2018

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/562,714	09/28/2017	Darrell Wagner	1618.118.103	3077

25281 7590 01/03/2019

DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

EXAMINER	
LAU, MICHAEL I	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
01/03/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBCLAW-Docket@dbclaw.com
USPTO.PATENTS@dbclaw.com
dmorris@dbclaw.com

Office Action Summary	Application No. 15/562,714	Applicant(s) Wagner et al.	
	Examiner MICHAEL J LAU	Art Unit 3792	AIA Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 06 March 2018.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b)☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 129-148 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 129-148 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 28 September 2017 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 479 in Fig. 14, 501 in Fig. 15B, and 559 in 15D. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 129-148 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

5. Regarding claims 129, 143, and 148, the claims are indefinite and confusing in that the stimulation and non-stimulation periods are not well defined.

6. Regarding claims 137 and 139, there are no upper limits to the ranges claimed.

7. Regarding claim 140, it is not clear what the distinction is between reference and real time respiratory cycles.

8. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 135 and 136 recite the broad recitation at least 25% of a duration, and the claims also recite at least 50% and 80% of a duration which is the narrower statement of the range/limitation.

9. Claims 130-134, 138, 141-142, 144-147 are dependent claims of 129 and 143, therefore are also rejected.

Claim Rejections - 35 USC § 103

10. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

11. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 129-141, and 143-148 are rejected under 35 U.S.C. 103 as being unpatentable over Falkenberg (US 7340302 B1), in view of Tehrani (US 8280513 B2).

14. Regarding claim 129, Falkenberg discloses a device for treating sleep disordered breathing (Fig. 1-2, 100), comprising: a stimulation element (electrodes Fig. 2, (200-216)) to stimulate an airway-patency-related nerve (Phrenic nerve, Abstract), according to a first stimulation protocol (Fig. 3, 300) not synchronized relative to sensed respiratory information and in which each stimulation cycle (Fig. 4,

window 404) includes a stimulation period and a non-stimulation period(Abstract, Fig. 1-4, Col. 1 Ln. 6-9, Col. 1, Ln. 62 – Col. 2, Ln. 10, Col. 2, Ln. 2, Ln. 14-29; Col. 3 Ln. 1 – Col. 4 Ln. 18; Col. 4, Ln. 19; Col. 4, Ln. 47 – Col. 5 Ln. 46; Col. 7 Ln. 5-40; Col. 8 Ln. 37-Col. 10 Ln. 49). Falkenberg does not disclose specifically disclose the interval between stimulation delivery windows correspond to non-stimulation periods.

15. Tehrani teaches on and off stimulation periods (Col. 17, Ln. 14-53).

16. It would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have combined the invention of Falkenberg with the on and off modes of stimulation as taught by Tehrani to provide an increased negative flow and increased positive pressure in the upper airway during exhalation (Col. 17, Ln. 17-20).

17. Regarding claim 130, the combined invention of Falkenberg and Tehrani discloses the stimulation is implemented via an implanted (Fig. 1, 100 and electrodes 104, 106, and 108) electrode and the device includes a pulse generator (Fig. 222) comprising at least a portion of the stimulation element (Col. 4, Ln 19-30).

18. Regarding claim 131, the combined invention of Falkenberg and Tehrani discloses a total duration of stimulation via the first simulation protocol during a treatment period is greater than 30 percent of the total duration of the treatment period (Col. 8, Ln. 8, Ln. 37- Col. 10, Ln 49, pulse width can be as long as treatment period).

19. Regarding claim 132, the combined invention of Falkenberg and Tehrani discloses each stimulation period includes continuous stimulation and has a minimum duration equal to or greater than an inspiratory reference (Tehrani, Fig.7A-10C, Col. 7, Ln. 63-Col. 34, Col. 17, Ln. 14-53). The examiner notes that any length of time shorter than a stimulation delivery window constitutes an inspiratory reference as claimed.

20. Regarding claim 133, the combined invention of Falkenberg and Tehrani discloses the inspiratory reference corresponds to a duration of an inspiratory phase of a reference respiratory cycle

(Falkenberg, Fig. 4, 404). The examiner notes that one of ordinary skill in the art can use the inspiratory reference as the duration of a patient's inspiration.

21. Regarding claim 134, the combined invention of Falkenberg and Tehrani discloses each stimulation period of the stimulation cycle has a duration greater than a duration of the inspiratory reference followed by the non-stimulation period having a duration less than the duration of the stimulation period (Falkenberg, Fig. 4, Col. 10, Ln. 4-40).

22. Regarding claim 135, the combined invention of Falkenberg and Tehrani discloses the duration of stimulation period is at least one of 25%/50%/80% of a duration of the stimulation cycle (Tehrani, Fig. 7A-10C, Col. 17, Ln. 14-53).

23. Regarding claim 136, the combined invention of Falkenberg and Tehrani discloses the duration of stimulation period is at least one of 25%/50%/80% of a duration of the reference respiratory cycle (Tehrani, Fig. 7A-10C, Col. 17, Ln. 14-53).

24. Regarding claim 137, the combined invention of Falkenberg and Tehrani discloses the duration of the stimulation cycle is less than the duration of the reference respiratory cycle, and a duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of 3 (Tehrani, Fig. 7A-10C, Col. 17, Ln. 14-53).

25. Regarding claim 138, the combined invention of Falkenberg and Tehrani discloses the duration of the stimulation cycle is greater than the duration of the reference respiratory cycle (Tehrani, Fig. 7A-10C, Col. 17, Ln. 14-53).

26. Regarding claim 139, the combined invention of Falkenberg and Tehrani discloses the stimulation period and the non-stimulation period are in a proportion of at least 1.5 to 1(Tehrani, Fig. 7A-10C, Col. 17, Ln. 14-53) (Falkenberg, Fig. 4, Col. 10, Ln. 4-40).

27. Regarding claim 140, the combined invention of Falkenberg and Tehrani discloses the duration of the stimulation cycle is equal to the duration of the reference respiratory cycle, and wherein the

duration of the reference respiratory cycle differs from a duration of a real time respiratory cycle by an amount exceeding a duration variability criteria (Tehrani, Fig. 7A-C, Col. 17, Ln. 14-29).

28. Regarding claim 141, the combined invention of Falkenberg and Tehrani discloses a processor (Falkenberg, Col. 4, Ln. 11-30) and non-volatile computer readable medium storing instructions (Falkenberg, Fig. 2, 220), executable on the processor, to implement the stimulation element and to perform the first stimulation protocol (Falkenberg, Col. 4, Ln. 11-30).

29. Regarding claim 143, the combined invention of Falkenberg and Tehrani discloses a device for treating sleep disordered breathing comprising (Falkenberg, Fig. 1-2, 100): a stimulation element (electrodes, Fig. 2, 200-216) to stimulate an airway-patency-related nerve, according to a first stimulation protocol (Fig. 3, 300) not synchronized relative to respiratory information and in which each stimulation cycle (Fig. 4, 404) includes a stimulation period and a non-stimulation period (Tehrani, Col. 17, Ln. 14-53); and a sensing element (Falkenberg, Col. 7, 20-34, 272) to obtain respiratory information via at least periodically sensing a respiratory waveform (Tehrani, Col. 12, Ln. 58-Col.13, Ln. 52) without synchronization to stimulation, wherein the stimulation element is activated for stimulation upon the sensing element identifying, via at least the respiratory information, sleep disordered breathing behavior which meets or exceeds a severity threshold and is deactivated upon the sensing element identifying, via at least the respiratory information, that the sleep disordered breathing behavior is less than the severity threshold (Tehrani, Fig. 1A-10C., Col. 12, Ln. 58 – Col. 13, Ln. 52).

30. Regarding claim 144, the combined invention of Falkenberg and Tehrani discloses the stimulation element includes a function selector to automatically select (Tehrani, Col. 2, Ln. 30-Col. 3, Ln. 59), for the first stimulation protocol, between: a first function to apply a repeating stimulation cycle having a duration different than a duration of the reference respiratory cycle, when the duration of the respiratory cycles in the sensed respiratory information is less variable than a respiratory duration variability criteria ; and a second function to apply a repeating stimulation cycle having a duration

matching the duration of the respiratory cycle reference, when the duration of respiratory cycles in the sensed respiratory information is more variable than the respiratory duration variability criteria (Tehrani, Fig. 1A-10C, Col. 8, Ln. 4-56).

31. Regarding claim 145, the combined invention of Falkenberg and Tehrani discloses the sensing element is configured to be in an inactive state by default and is periodically, temporarily activated to sense respiratory information to perform at least one of: evaluating effectiveness of therapy according to at least the detected sleep disordered breathing relative to the severity threshold; and calibrating the reference respiratory cycle relative to the sensed respiratory information (Tehrani, Fig. 4-5C, Col. 2, Ln. 30- Col. 3, Ln. 59).

32. Regarding claim 146, the combined invention of Falkenberg and Tehrani discloses a non-volatile memory storing instructions (Falkenberg, Fig. 2, 220), executable via the processor (Falkenberg, Col. 4, Ln. 11-30), to: evaluate the first stimulation protocol relative to the reference respiratory cycle based on the obtained respiratory information; and modify, in response to the evaluation, at least one of the reference respiratory cycle and the first stimulation protocol, wherein modifying the first stimulation protocol includes at least one of: adjusting features of the first stimulation protocol; and substituting a different stimulation protocol for the first stimulation protocol (Tehrani, Fig. 4-5C, Col. 2, Ln. 30- Col. 3, Ln. 59, Col. 4, Ln. 41-46).

33. Regarding claim 147, the combined invention of Falkenberg and Tehrani discloses the therapy manager is to evaluate the sensed respiratory information, and upon a determination that the first stimulation protocol fails to result in the detected sleep disordered breathing behavior being less than the severity threshold or that the sensed respiratory information fails to meet a sensor signal quality criteria, the therapy manager converts operation of the first stimulation element from the first stimulation protocol to a second stimulation protocol in which stimulation is applied continuously for at

least two respiratory cycles or until the detected sleep disordered breathing behavior is less than the severity threshold (Tehrani, Fig. 1-10C, Col. 2, Ln. 30- Col. 3, Ln. 59).

34. Regarding claim 148, the combined invention of Falkenberg and Tehrani discloses a device for treating sleep disordered breathing (Falkenberg, Fig. 1-2, 100) comprising: a stimulation element (Fig. 2, 200-216) to stimulate an airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to respiratory information and in which each stimulation cycle includes a stimulation period and a non-stimulation period (Tehrani, Col. 17, Ln. 14-53); a sensing element to receive respiratory information (Falkenberg, Col. 7, 20-34, 272); and a control portion including: a processor (Falkenberg, Col. 4, Ln. 11-30); and a non-volatile memory storing instructions (Falkenberg, Fig. 2, 220), executable via the processor, to: provide convertible operation via a therapy manager between: a first stimulation mode implementing the first stimulation protocol; and a second stimulation mode of stimulating the airway-patency- related nerve synchronous with a characteristic of the sensed respiratory waveform (Tehrani, Fig. 4-5C, Col. 2, Ln. 30- Col. 3. Ln. 59, Col. 4, Ln. 41-46).

35. Claim 142 is rejected under 35 U.S.C. 103 as being unpatentable over Falkenberg (US 7340302 B1), in view of Tehrani (US 8280513 B2), further in view of Christopherson (US 5944680 A).

36. Regarding claim 142, the combined invention of Falkenberg and Tehrani discloses the device of claim 129, but does not disclose a cuff electrode including at least one operative contact group through which the stimulation is deliverable non-selectively to the airway-patency-related nerve.

37. Christopherson discloses placing a cuff electrode placed around the hypoglossal nerve (Col. 7, Ln. 25-44)

38. It would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have combined the invention of Falkenberg and Tehrani with the cuff electrode

of Christopherson to avoid increased respiratory effort by stimulating the muscles to keep the airway open during the inspiratory phase (Christopherson, Col. 7, Ln. 25-44).

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 9750049 A1, US 20100174341 A1, WO 2010059839 A2, US 20120290036 A1, US 20160354608 A1, US 20160022204 A1, US 20140364919 A1, US 20060247729 A1, US 20100198289, A1 US 8265759 B2, US 8233987 B2.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J LAU whose telephone number is (571)272-2317. The examiner can normally be reached on 8-5:30 PM.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Carl Layno** can be reached on **(571) 272-4949**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHAEL J LAU/
Examiner, Art Unit 3792

/CARL H LAYNO/
Supervisory Patent Examiner, Art Unit 3792

Notice of References Cited	Application/Control No. 15/562,714	Applicant(s)/Patent Under Reexamination Wagner et al.	
	Examiner MICHAEL J LAU	Art Unit 3792	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-7340302-B1	03-2008	Falkenberg; Eric	A61N1/3611	607/9
*	B	US-20100174341-A1	07-2010	Bolea; Stephen L.	A61N1/3601	607/42
*	C	US-5944680-A	08-1999	Christopherson; Mark A.	A61B5/03	128/897
*	D	US-20120290036-A1	11-2012	Karamanoglu; Mustafa	A61N1/3601	607/42
*	E	US-20160354608-A1	12-2016	KEENAN; DESMOND B.	A61N1/3611	1/1
*	F	US-20160022204-A1	01-2016	Mostov; Kirill	A61B5/0002	600/301
*	G	US-20140364919-A1	12-2014	Doan; Que T.	A61N1/36071	607/46
*	H	US-20060247729-A1	11-2006	Tehrani; Amir J.	A61N1/3601	607/42
*	I	US-20100198289-A1	08-2010	Kameli; Nader	A61B5/00	607/14
*	J	US-8280513-B2	10-2012	Tehrani; Amir J.	A61N1/3601	600/529
*	K	US-8265759-B2	09-2012	Tehrani; Amir J.	A61N1/3601	607/20
*	L	US-8233987-B2	07-2012	Gelfand; Mark	A61N1/3601	607/42
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N	WO-9750049-A1	12-1997	WO	HAMMARGREN JOHN W	A61B5/03
	O	WO-2010059839-A2	05-2010	WO	RONDONI JOHN	A61B5/0803
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/562,714	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/21/2018								
	129	✓								
	130	✓								
	131	✓								
	132	✓								
	133	✓								
	134	✓								
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	144	✓								
	145	✓								
	146	✓								
	147	✓								
	148	✓								

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0229

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/562,714	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

CPC - Searched*		
Symbol	Date	Examiner
A61B5/3601,0816,0826,113,4818,4848,686	12/21/2018	ML
A61B1/36135	12/21/2018	ML
A61N1/3611,36135,36146,36171	12/21/2018	ML
G06F19/3481	12/21/2018	ML

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
607	42, 72, 73	12/21/2018	ML

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Inventor search on PALM, Prior art search on east, consulted spe carl layno for search strategy	12/21/2018	ML

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/MICHAEL J LAU/ Examiner, Art Unit 3792	

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0230

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20160022204		2016-01-28	Mostov	
	2	20160354602		2016-12-08	Keenan	
	3	20160354603		2016-12-08	Keenan	
	4	20160354608		2016-12-08	Keenan	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

	1							

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/MICHAEL J LAU/	Date Considered	12/21/2018

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2018-01-27
Name/Print	Paul S. Grunzweig	Registration Number	37,143

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

Privacy Act Statement

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0234

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner et al.
Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20150039045		2015-02-05	Ni et al.	
	2	20160193468		2016-07-07	Rondoni et al.	

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Examiner Name	
Attorney Docket Number	I618.118.103

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	Eisele Article – David W. Eisele, MD et al., "Tongue neuromuscular and direct hypoglossal nerve stimulation for obstructive sleep apnea," Otolaryngologic Clinics of North America, Otolayngol Clin N Am 36 (2003) 501-510 (10 pages).	
	2	Goodall Article – Eleanor V. Goodhall et al., "Position-Selective Activation of Peripheral Nerve Fibers with a Cuff Electrode," IEEE Transaction on Biomedical Engineering, Vol. 43, No. 8, August 1996, pages 851-856.	
	3	Naples Article – Gregory G. Naples et al., "A Spiral Nerve Cuff Electrode for Peripheral Nerve Stimulation," 8088 IEEE Transactions on Biomedical Engineering, 35. November 1988, No. 11, New York, NY, pages 905-915.	
	4	Oliven Article – Arie Oliven et al., "Upper airway response to electrical stimulation of the genioglossus in obstructive sleep apnea," Journal of Applied Physiology, Volume 95, pages 2023-2029, November 2003, www.jap.physiology.org on September 18, 2006. (8 pages)	
	5	Schwartz Article – Alan R. Schwartz MD et al., "Theraputic Electrical Stimulation of the Hypoglossal Nerve in Obstructive Sleep Apnea, Arch Otolaryngol HeadAnd Neck Surg., Vol. 127, Oct. 2001, pages 1216-1223. Copyright 2001 American Medical Association. (8 pages)	
	6	PARK, "Preoperative Percutaneous Cranial Nerve Mapping in Head and Neck Surgery," ARCH FACIAL PLAST SURG/VOL 5, Jan/Feb 2003, www.archfacial.compages 86-91	

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EXAMINER SIGNATURE

Examiner Signature	/MICHAEL J LAU/	Date Considered	12/21/2018

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Name/Print	Paul S. Grunzweig	Registration Number	37143

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Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0238

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L10	15	(US-20100174341-$ or US-20120290036-$ or US-20160354608-$ or US-20160022204-$ or US-20140364919-$ or US-20060247729-$ or US-20100198289-$).did. or (US-7340302-$ or US-5944680-$ or US-8280513-$ or US-8265759-$ or US-8233987-$).did. or (WO-2010059839-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; FPRS; EPO	OR	ON	2018/12/21 09:27
L11	5	L10 and cuff	US-PGPUB; USPAT	OR	ON	2018/12/21 09:27
S1	1	"7340302".pn.	US-PGPUB; USPAT	OR	ON	2018/12/12 18:58
S2	5	"9750049".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/12 19:26
S3	2	"2010174341".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/12 19:38
S4	0	"2010174341".pn.	US-PGPUB; USPAT	OR	ON	2018/12/12 19:39
S5	1	"20100174341".pn.	US-PGPUB; USPAT	OR	ON	2018/12/12 19:39
S6	3	(US-20100174341-$).did. or (US-7340302-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; EPO	OR	ON	2018/12/13 13:33
S7	2	S6 and (pulse or duration or period)	US-PGPUB; USPAT	OR	ON	2018/12/13 13:33
S8	659	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:38
S9	10675	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:42
S10	0	A61B1/36135.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:42
S11	2915	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:44
S12	2915	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:44
S13	7232	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:44
S14	20277	S8 or S9 or S11 or S12 or S13	US-PGPUB;	OR	ON	2018/12/13

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0239

			USPAT			14:45
S15	11362	S14 and @pd<"20150319"	US-PGPUB; USPAT	OR	ON	2018/12/13 14:45
S16	66	(darrell near wagner).in.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:48
S17	6	(darrell near wagner).in. and sleep	US-PGPUB; USPAT	OR	ON	2018/12/13 14:51
S18	190	((darrell near wagner) or (ni near quan) or (rondini near john) or (dieken near dave)).in. and sleep	US-PGPUB; USPAT	OR	ON	2018/12/13 14:54
S19	161	((darrell near wagner) or (ni near quan) or (rondini near john) or (dieken near dave)).in. and sleep and @pd<"20150319"	US-PGPUB; USPAT	OR	ON	2018/12/13 14:59
S20	149	((darrell near wagner) or (ni near quan) or (rondini near john) or (dieken near dave)).in. and sleep and @pd<"20150319" and stimulat$3	US-PGPUB; USPAT	OR	ON	2018/12/13 15:24
S21	7	"2010059839".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/13 15:36
S22	5	"5944680".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/13 16:16
S23	293	S14 and @pd<"20150319" and pulse adj duration and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 16:56
S24	84	S14 and @pd<"20150319" and pulse adj (width or duration) same inspiration and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 16:56
S25	54	S14 and @pd<"20150319" and pulse adj (width or duration) same inspiration and sleep adj (apnea or aponea) and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 17:01
S26	4	A61B5/0826.cpc. and @pd<"20150319" and pulse adj (width or duration) same inspiration and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 17:07
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S28	235	("20010010010" | "20020010495" | "20020049479" | "20020156507" | "20030093128" | "20030114905" | "20030163059" | "20030195571" | "20030216789" | "20030224895" | "20040015204" | "20040073272" | "20040111139" | "20040215288" | "20040230278" | "20040254612" | "20050004628" | "20050010265" | "20050042589" | "20050043765" | "20050043772" | "20050074741" | "20050076908" | "20050080348" | "20050080461" | "20050081847" | "20050085865" | "20050085866" | "20050085868" | "20050085869" | "20050085874" | "20050101833" |	US-PGPUB; USPAT	OR	ON	2018/12/13 17:25

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0240

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		"5167229" | "5174287" | "5178156" | "5203343" | "5211173" | "5215082" | "5233983" |	
		"5239995" | "5245995" | "5265624" | "5281219" | "5300094" | "5335657" | "5344438" |	
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		"6307481" | "6309350" | "6314324" | "6342039" | "6345202" | "6361494" | "6393325" |	
		"6449507" | "6450957" | "6456866" | "6509164"		

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0241

		| "6522928" | "6532388" | "6572543" | "6574507" | "6587725" | "6609016" | "6609032" | "6629527" | "6641542" | "6645143" | "6647289" | "6651652" | "6654634" | "6665560" | "6666830" | "6689068" | "6703939" | "6718208" | "6719708" | "6731976" | "6731984" | "6735471" | "6752765" | "6770022" | "6773404" | "6805667" | "6811538" | "6842647" | "6881192" | "6890306" | "6893405" | "6904320" | "6907293" | "6928324" | "6935335" | "6936011" | "6964641" | "6978171" | "6988498").PN.				
S29	90	("7025730" | "7041049" | "7054692" | "7077810" | "7081095" | "7082331" | "7082336" | "7087053" | "7117036" | "7128717" | "7145461" | "7149573" | "7155278" | "7160252" | "7160255" | "7167743" | "7174215" | "7186220" | "7187978" | "7189204" | "7195594" | "7200440" | "7206635" | "7212862" | "7214197" | "7252640" | "7269457" | "7269459" | "7277749" | "7330760" | "7336996" | "7340302" | "7351208" | "7366572" | "7371220" | "7387608" | "7395113" | "7396333" | "7398115" | "7422015" | "7438686" | "7447545" | "7453928" | "7454250" | "7468040" | "7469697" | "7473227" | "7491181" | "7510531" | "7526341" | "7542803" | "7572225" | "7590455" | "7591265" | "7596413" | "7603170" | "7610094" | "7634315" | "7644714" | "7662105" | "7672728" | "7678061" | "7680538" | "7702385" | "7717848" | "7720541" | "7725195" | "7734340" | "7734350" | "7742819" | "7747323" | "7751880" | "7775993" | "7783353" | "7792583" | "7809442" | "7818063" | "7853322" | "7881798" | "7908013" | "7917230" | "7942822" | "7957797" | "7957809" | "7979128" | "8016776" | "8021299" | "8150531" | "8160711" | "8175720").PN.	US-PGPUB; USPAT	OR	ON	2018/12/13 17:25
S30	58	S28 and pulse adj (pulse or duration)	US-PGPUB; USPAT	OR	ON	2018/12/13 17:26
S31	8	S28 and pulse adj (pulse or duration) and '25%'	US-PGPUB; USPAT	OR	ON	2018/12/13 17:31
S32	47	S28 and pulse adj (duration or duration)	US-PGPUB; USPAT	OR	ON	2018/12/13 17:32
S33	104	S28 and pulse adj (width or duration)	US-PGPUB; USPAT	OR	ON	2018/12/13 17:32
S34	1	"5944680".pn. and pulse adj (width or duration)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/13 17:34
S35	1	("2015/0039045").URPN.	USPAT	OR	ON	2018/12/13 17:57
S36	4	A61B5/0826.cpc. and @pd<"20150319" and pulse adj (width or duration) same inspiration and implant and ramp	US-PGPUB; USPAT	OR	ON	2018/12/13 18:10
S37	0	A61B5/0826.cpc. and @pd<"20150319" and ramp with pulse adj (width or duration) same inspiration and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 18:10

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0242

S38	1	A61B5/0826.cpc. and @pd<"20150319" and ramp$3 same pulse adj (width or duration) same inspiration and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 18:11
S39	29	S14 and @pd<"20150319" and ramp with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:13
S40	0	S14 and @pd<"20150319" and full with ramp with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:13
S41	0	S14 and @pd<"20150319" and full same ramp with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:13
S42	0	S14 and @pd<"20150319" and full with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:15
S43	39	S14 and @pd<"20150319" and full same pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:15
S44	826	607/72,73.ccls.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:30
S45	532	607/72,73.ccls. and duration	US-PGPUB; USPAT	OR	ON	2018/12/20 10:30
S46	491	607/72,73.ccls. and @pd<"20150319" and duration	US-PGPUB; USPAT	OR	ON	2018/12/20 10:31
S47	51	607/72,73.ccls. and @pd<"20150319" and duration and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2018/12/20 10:32
S48	80	2006/0247729	US-PGPUB; USPAT	OR	ON	2018/12/20 10:45
S49	1	"20060247729".pn.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:45
S50	1	"20060247729".pn. and duration	US-PGPUB; USPAT	OR	ON	2018/12/20 10:48
S51	0	"2010098289".pn.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:59
S52	1	"20100198289".pn.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:59
S53	78	("2006/0247729").URPN.	USPAT	OR	ON	2018/12/20 11:27
S54	45	("2006/0247729").URPN. and @pd<"20150319"	USPAT	OR	ON	2018/12/20 11:27
S55	44	("2006/0247729").URPN. and @pd<"20150319" and (duration or width)	USPAT	OR	ON	2018/12/20 11:28

12/21/2018 11:30:18 AM
C:\Users\mlau2\Documents\EAST\Workspaces\15562714.wsp

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BIB DATA SHEET

CONFIRMATION NO. 3077

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
15/562,714	09/28/2017 RULE	607	3792	I618.118.103

APPLICANTS
INSPIRE MEDICAL SYSTEMS, INC., Maple Grove, MN;

INVENTORS
Darrell Wagner, Maple Grove, MN;
Quan Ni, Maple Grove, MN;
John Rondoni, Maple Grove, MN;
Dave Dieken, Maple Grove, MN;

**** CONTINUING DATA ***************************
This application is a 371 of PCT/US2016/022611 03/16/2016
which claims benefit of 62/135,305 03/19/2015

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****
01/22/2018

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /MICHAEL J LAU/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		MN	13	20	3

ADDRESS
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402
UNITED STATES OF AMERICA

TITLE
STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

FILING FEE RECEIVED	FEES: Authority has been given in Paper	☐ All Fees
1620	No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
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Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner et al.
Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

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	1	20090308395		2009-12-17	Lee et al.	
	2	20090326408		2009-12-31	Moon	
	3	20100010566		2010-01-14	Thacker et al.	
	4	20100016749		2010-01-21	Atsma et al.	
	5	20100094379		2010-04-15	Meadows	

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	6	20100125310		2010-05-20	Wilson et al.	
	7	20100125314		2010-05-20	Bradley et al.	
	8	20100125315		2010-05-20	Parramon et al.	
	9	20100137931		2010-06-03	Hopper et al.	
	10	20100152553		2010-06-17	Ujhazy et al.	
	11	20100174341		2010-07-08	Bolea et al.	
	12	20100198103		2010-08-05	Meadows et al.	
	13	20100198289		2010-08-05	Kameli et al.	
	14	20100228133		2010-09-09	Averina et al.	
	15	20100228317		2010-09-09	Libbus et al.	
	16	20100241195		2010-09-23	Meadows et al.	

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	17	20100262210		2010-10-14	Parramon et al.		
	18	20100174341		2010-07-08	Bolea et al.		
	19	20110093036		2011-04-21	Mashiach		
	20	20110112601		2011-05-12	Meadows et al.		
	21	20110152706		2011-06-23	Christopherson et al.		
	22	20110152965		2011-06-23	Mashiach et al.		
	23	20110160794		2011-06-30	Bolea et al.		
	24	20110264164		2011-10-27	Christopherson et al.		

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	1	2010502276	JP		2010-01-28	Cardiac Pacemaker, Inc.		X

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	2	2011520526	JP		2011-07-21	Inspire Medical Systems, Inc.		☒
	3	199750049	WO		1997-12-31	Medtronic Inc.		☐
	4	2006047264	WO		2006-05-04	Advanced Neuromodulation Systems, Inc.		☐
	5	2006057734	WO		2006-06-01	Advanced Neuromodulation Systems, Inc.		☐
	6	2006102591	WO		2006-09-28	Vanderbilt University		☐
	7	2007068284	WO		2007-06-27	Synergio AG		☐
	8	2008048471	WO		2008-04-24	Apnex Medical, Inc.		☐
	9	2009048580	WO		2009-04-16	Imthera Medical, INc.		☐
	10	2009048581	WO		2009-04-16	Imthera Medical, Inc.		☐
	11	2009135138	WO		2009-11-05	Medtronic, Inc.		☐
	12	2009135140	WO		2009-11-05	Medtronic, Inc.		☐

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	13	2009140636	WO		2009-11-19	Inspire Medical Systems, Inc.		☐
	14	2010039853	WO		2010-04-08	Inspire medical Systems, Inc.		☐
	15	2010057286	WO		2010-05-27	Victhom Human Bionics Inc.		☐
	16	2010059839	WO		2010-05-27	Inspire Medical Systems, Inc.		☐
	17	2010117810	WO		2010-10-14	Inspire Medical Systems, Inc.		☐

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Examiner Signature	/MICHAEL J LAU/	Date Considered	12/21/2018

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First Named Inventor	Darrell Wagner et al.
Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2018-01-23
Name/Print	Paul S. Grunzweig	Registration Number	37143

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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Attorney Docket Number	I618.118.103

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4379462		1983-04-12	Borkan et al.	
	2	4567892		1986-02-04	Plicchi et al.	
	3	4630614		1986-12-23	Atlas	
	4	4813431		1989-03-21	Brown	
	5	4830008		1989-05-16	Meer	
	6	5133354		1992-07-28	Kallok	
	7	5134995		1992-08-04	Gruenke et al.	
	8	5148802		1992-09-22	Sanders et al.	

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Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

	9	5158080		1992-10-27	Kallok	
	10	5167229		1992-12-01	Peckham et al.	
	11	5174287		1992-12-29	Kallok et al.	
	12	5178156		1993-01-12	Takishima et al.	
	13	5203343		1993-04-20	Axe et al.	
	14	5211173		1993-05-18	Kallok et al.	
	15	5215082		1993-06-01	Kallok et al.	
	16	5233983		1993-08-10	Markowitz	
	17	5239995		1993-08-31	Estes et al.	
	18	5245995		1993-09-21	Sullivan et al.	
	19	5265624		1993-11-30	Bowman	

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Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

	20	5281219		1994-01-25	Kallok	
	21	5300094		1994-04-05	Kallok et al.	
	22	5335657		1994-08-09	Terry, Jr. et al.	
	23	5344438		1994-09-06	Testerman et al.	
	24	5351394		1994-10-04	Weinberg	
	25	5385144		1995-01-31	Yamanishi et al.	
	26	5388578		1995-02-14	Yomtov et al.	
	27	5398682		1995-03-21	Lynn	
	28	5458137		1995-10-17	Axe et al.	
	29	5483969		1996-01-16	Testerman et al.	
	30	5485851		1996-01-26	Erickson	

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Attorney Docket Number	I618.118.103

	31	5522862		1996-06-04	Testerman et al.	
	32	5524632		1996-06-11	Stein et al.	
	33	5540731		1996-07-30	Testerman	
	34	5540732		1996-07-30	Testerman	
	35	5540733		1996-07-30	Testerman et al.	
	36	5540734		1996-07-30	Zabara	
	37	5546952		1996-08-20	Erickson	
	38	5549655		1996-08-27	Erickson	
	39	5588439		1996-12-31	Hollub	
	40	5591216		1997-01-07	Testerman et al.	
	41	5605151		1997-02-25	Lynn	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

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	42	5645053		1997-07-08	Remmers et al.	
	43	5671733		1997-09-30	Raviv et al.	
	44	5797852		1998-08-25	Karakasoglu et al.	
	45	5823187		1998-10-20	Estes et al.	
	46	5843135		1998-12-01	Weijand et al.	
	47	5895360		1999-04-20	Christopherson et al.	
	48	5904141		1999-05-18	Estes et al.	
	49	5919221		1999-07-06	Miesel	
	50	5944680		1999-08-31	Christopherson et al.	
	51	5999846		1999-12-07	Pardey et al.	
	52	6015389		2000-01-18	Brown	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

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	53	6021352		2000-02-01	Christopherson et al.	
	54	6025624		2000-02-15	Figura	
	55	6041780		2000-03-28	Richard et al.	
	56	6099479		2000-08-08	Christopherson et al.	
	57	6120441		2000-09-19	Griebel	
	58	6125290		2000-09-26	Miesel	
	59	6125291		2000-09-26	Miesel et al.	
	60	6126611		2000-10-03	Bourgeouis et al.	
	61	6132384		2000-10-17	Christopherson et al.	
	62	6134459		2000-10-17	Roberts et al.	
	63	6144866		2000-11-07	Miesel et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

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	64	6175767		2001-01-16	Doyle, Sr	
	65	6181961		2001-01-30	Prass	
	66	6198952		2001-03-06	Miesel	
	67	6223064		2001-04-24	Lynn et al.	
	68	6240316		2001-05-29	Richmond et al.	
	69	6248080		2001-06-19	Miesel et al.	
	70	6249703		2001-06-19	Stanton et al.	
	71	6251126		2001-06-26	Ottenhoff et al.	
	72	6269269		2001-07-31	Ottenhoff et al.	
	73	6307481		2001-10-23	Lehrman et al.	
	74	6309350		2001-10-30	Van Tassel et al.	

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	75	6314324		2001-11-06	Lattner et al.	
	76	6342039		2002-01-29	Lynn et al.	
	77	6345202		2002-02-05	Richmond et al.	
	78	6361494		2002-03-26	Lindenthaler	
	79	6393325		2002-05-21	Mann et al.	
	80	6449507		2002-09-10	Hill et al.	
	81	6450957		2002-09-17	Yoshimi et al.	
	82	6456866		2002-09-24	Tyler et al	
	83	6522928		2003-02-18	Whitehurst et al.	
	84	6532388		2003-03-11	Hill et al.	
	85	6572543		2003-06-03	Christopherson et al.	

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	86	6574507		2003-06-03	Bonnet	
	87	6587725		2003-07-01	Durand et al.	
	88	6609016		2003-08-19	Lynn	
	89	6609032		2003-08-19	Woods et al.	
	90	6629527		2003-10-07	Estes et al.	
	91	6641542		2003-11-04	Cho et al.	
	92	6645143		2003-11-03	Van Tassel et al.	
	93	6647289		2003-11-11	Prutchi	
	94	6651652		2003-11-25	Ward	
	95	6654634		2003-11-25	Prass	
	96	6665560		2003-12-16	Becker et al.	

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	97	6666830		2003-12-23	Lehrman et al.	
	98	6689068		2004-02-10	Hale et al.	
	99	6703939		2004-03-09	Lehrman et al.	
	100	6718208		2004-04-06	Hill et al.	
	101	6719708		2004-04-13	Jansen	
	102	6731976		2004-05-04	Penn et al.	
	103	6731984		2004-05-04	Cho et al.	
	104	6735471		2004-05-11	Hill et al.	
	105	6752765		2004-06-22	Jensen et al.	
	106	6770022		2004-08-03	Mechlenburg et al.	
	107	6773404		2004-08-10	Poezevera et al.	

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	108	6805667		2004-10-29	Christopherson et al.	
	109	6811538		2004-11-02	Westbrook et al.	
	110	6842647		2005-01-11	Griffith et al.	
	111	6881192		2005-04-19	Park	
	112	6890306		2005-05-10	Poezevera	
	113	6893405		2005-05-17	Kumar et al.	
	114	6904320		2005-06-07	Park et al.	
	115	6907293		2005-06-14	Grill et al.	
	116	6928324		2005-08-09	Park et al.	
	117	6935335		2005-08-30	Lehrman et al.	
	118	6936011		2005-08-30	Sheldon	

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	119	6964641		2005-11-15	Cho et al.	
	120	6978171		2005-12-20	Goetz et al.	
	121	6988498		2006-01-24	Berthon-Jones et al.	
	122	7025730		2006-04-11	Cho et al.	
	123	7041049		2006-05-09	Raniere	
	124	7054692		2006-05-30	Whitehurst et al.	
	125	7077810		2006-07-18	Lange et al.	
	126	7081095		2006-07-25	Lynn et al.	
	127	7082331		2006-07-25	Park et al.	
	128	7082336		2006-07-25	Ransbury et al.	
	129	7087053		2006-08-08	Vanney	

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	130	7117036		2006-10-03	Florio	
	131	7128717		2006-10-31	Thach et al.	
	132	7145461		2006-12-05	Lehrman et al.	
	133	7149573		2006-12-12	Wang	
	134	7155278		2006-12-26	King et al.	
	135	7160252		2007-01-09	Cho et al.	
	136	7160255		2007-01-09	Saadat	
	137	7167743		2007-01-23	Heruth et al.	
	138	7174215		2007-02-06	Bradley	
	139	7186220		2007-03-06	Stahmann et al.	
	140	7187978		2007-03-06	Malek et al.	

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	141	7189204		2007-03-13	Ni et al.	
	142	7195594		2007-03-27	Eigler et al.	
	143	7200440		2007-04-03	Kim et al.	
	144	7206635		2007-04-17	Cho et al.	
	145	7212862		2007-05-01	Park et al.	
	146	7214197		2007-05-08	Prass	
	147	7252640		2007-08-07	Ni et al.	
	148	7269457		2007-09-11	Shafer et al.	
	149	7269459		2007-09-11	Koh	
	150	7277749		2007-10-02	Gordon et al.	
	151	7330760		2008-02-12	Heruth et al.	

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	152	7336996		2008-02-26	Hartley et al.	
	153	7340302		2008-03-04	Falkenberg	
	154	7351208		2008-04-01	Brodnick et al.	
	155	7366572		2008-04-29	Heruth et al.	
	156	7371220		2008-05-13	Koh et al.	
	157	7387608		2008-06-17	Dunlop et al.	
	158	7395113		2008-07-01	Heruth et al.	
	159	7396333		2008-07-08	Stahmann et al.	
	160	7398115		2008-07-08	Lynn	
	161	7422015		2008-09-09	Delisle et al.	
	162	7438686		2008-10-21	Cho et al.	

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	163	7447545		2008-11-04	Heruth et al.	
	164	7454250		2008-11-18	Bjorling et al.	
	165	7453928		2008-12-09	Lee et al.	
	166	7468040		2008-12-23	Hartley et al.	
	167	7469697		2008-12-30	Lee et al.	
	168	7473227		2009-01-06	Hsu et al.	
	169	7491181		2009-02-17	Heruth et al.	
	170	6509164		2009-03-24	Jensen et al.	
	171	7510531		2009-03-31	Lee et al.	
	172	7526341		2009-04-29	Goetz et al.	
	173	7542803		2009-06-02	Heruth et al.	

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	174	7572225		2009-08-11	Stahmann et al.	
	175	7590455		2009-09-15	Heruth et al.	
	176	7591265		2009-09-22	Lee et al.	
	177	7596413		2009-09-29	Libbus et al.	
	178	7603170		2009-10-13	Hatlestad et al.	
	179	7610094		2009-10-27	Stahmann et al.	
	180	7634315		2009-12-15	Cholette	
	181	7644714		2010-01-12	Atkinson et al.	
	182	7662105		2010-02-16	Hatlestad	
	183	7672728		2010-03-02	Libbus et al.	
	184	7678061		2010-03-16	Lee et al.	

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	185	7680538		2010-03-16	Durand et al.	
	186	7702385		2010-04-20	Moffitt et al.	
	187	7717848		2010-05-18	Heruth et al.	
	188	7720541		2010-05-18	Stahmann et al.	
	189	7725195		2010-05-25	Lima et al.	
	190	7734340		2010-06-08	De Ridder	
	191	7734350		2010-06-08	Dubnov et al.	
	192	7742819		2010-06-22	Moffitt	
	193	7747323		2010-06-29	Libbus et al.	
	194	7751880		2010-07-06	Cholette	
	195	7775993		2010-08-17	Heruth et al.	

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	196	7783353		2010-08-24	Libbus et al.	
	197	7792583		2010-09-07	Miesel et al.	
	198	7809442		2010-10-05	Bolea et al.	
	199	7818063		2010-10-19	Wallace et al.	
	200	7853322		2010-12-14	Bourget et al.	
	201	7881798		2011-02-01	Miesel et al.	
	202	7908013		2011-03-15	Miesel et al.	
	203	7917230		2011-03-29	Bly	
	204	7942822		2011-05-17	Koh	
	205	7957809		2011-06-07	Bourget et al.	
	206	7957797		2011-06-07	Bourget et al.	

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	207	7979128		2011-07-12	Tehrani et al.	
	208	8016776		2011-09-13	Bourget et al.	
	209	8021299		2011-09-20	Miesel et al.	
	210	8150531		2012-04-03	Skelton	
	211	8160711		2012-04-17	Tehrani et al.	
	212	8175720		2012-05-08	Skelton et al.	

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	1	20010010010		2001-07-26	Richmond et al.	
	2	20020010495		2002-01-24	Freed et al.	
	3	20020049479		2002-04-25	Pitts	

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	4	20020156507		2002-10-24	Lindenthaler	
	5	20030093128		2005-05-15	Freed et al.	
	6	20030224895		2003-06-19	Gordon et al.	
	7	20030114905		2003-06-19	Kuzma	
	8	20030163059		2003-08-28	Poezevera et al.	
	9	20030195571		2003-10-16	Burnes et al.	
	10	20030216789		2003-11-20	Deem et al.	
	11	20040015204		2004-01-22	Whitehurst et al.	
	12	20040073272		2004-04-15	Knudson et al.	
	13	20040111139		2004-06-10	McCreery	
	14	20040215288		2004-10-28	Lee et al.	

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	15	20040230278		2004-11-18	Dahl et al.	
	16	20040254612		2004-12-16	Ezra	
	17	20050004628		2005-01-06	Goetz et al.	
	18	20050010265		2005-01-13	Baru Fassio et al.	
	19	20050042589		2005-02-24	Hatlestad et al.	
	20	20050043765		2005-02-24	Williams et al.	
	21	20050043772		2005-02-24	Stahmann et al.	
	22	20050074741		2005-04-07	Lee et al.	
	23	20050076908		2005-04-14	Lee et al.	
	24	20050080348		2005-04-14	Stahmann et al.	
	25	20050080461		2005-04-14	Stahmann et al.	

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	26	20050081847		2005-04-21	Lee et al.	
	27	20050085865		2005-04-21	Tehrani	
	28	20050085866		2005-04-21	Tehrani	
	29	20050085868		2005-04-21	Tehrani et al.	
	30	20050085869		2005-04-21	Tehrani et al.	
	31	20050085874		2005-04-21	Davis et al.	
	32	20050101833		2005-05-12	Hsu et al.	
	33	20050113710		2005-05-26	Stahmann et al.	
	34	20050115561		2005-06-02	Stahmann et al.	
	35	20050145246		2005-07-07	Hartley et al.	
	36	20050165457		2005-07-28	Benser et al.	

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	37	20050182457		2005-08-18	Thrope et al.	
	38	20050209513		2005-09-22	Heruth et al.	
	39	20050209643		2005-09-22	Heruth et al.	
	40	20050222503		2005-10-06	Dunlop et al.	
	41	20050234523		2005-10-20	Levin et al.	
	42	20050251216		2005-11-10	Hill et al.	
	43	20050261747		2005-11-24	Schuler et al.	
	44	20050267380		2005-12-01	Poezevera	
	45	20050277844		2005-12-15	Strother et al.	
	46	20050277999		2005-12-15	Strother et al.	
	47	20050278000		2005-12-15	Strother et al.	

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	48	20060052836		2006-03-09	Kim et al.	
	49	20060058852		2006-03-16	Koh et al.	
	50	20060064029		2006-03-23	Arad (Abboud)	
	51	20060079802		2006-04-13	Jensen et al.	
	52	20060095088		2006-05-04	De Ridder	
	53	20060103407		2006-05-18	Kakizawa et al.	
	54	20060135886		2006-06-22	Lippert et al.	
	55	20060142815		2006-09-29	Tehrani et al.	
	56	20060212096		2006-09-21	Stevenson	
	57	20060224209		2006-10-05	Meyer	
	58	20060241708		2006-10-26	Boute	

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	59	20060247729		2006-11-02	Tehrani et al.	
	60	20060259079		2006-11-16	King	
	61	20060264777		2006-11-23	Drew	
	62	20060266369		2006-11-30	Atkinson et al.	
	63	20060271137		2006-11-30	Stanton-Hicks	
	64	20060276701		2006-12-07	Ray	
	65	20060293720		2006-12-28	DiLorenzo	
	66	20060293723		2006-12-28	Whitehurst et al.	
	67	20070021785		2007-01-25	Inman et al.	
	68	20070027482		2007-02-01	Parnis et al.	
	69	20070038265		2007-02-15	Tcheng et al.	

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Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

	70	20070150022		2007-06-28	Ujhazy et al.	
	71	20070233204		2007-10-04	Lima et al.	
	72	20070255379		2007-11-01	Williams et al.	
	73	20080009685		2008-01-10	Kim et al.	
	74	20080039904		2008-02-14	Bulkes et al.	
	75	20080046055		2008-02-21	Durand et al.	
	76	20080064977		2008-03-13	Kelleher et al.	
	77	20080103545		2008-05-01	Bolea et al.	
	78	20080103570		2008-05-01	Gerber	
	79	20080109046		2008-05-08	Lima et al.	
	80	20080109048		2008-05-08	Moffitt	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner et al.
Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

	81	20080132802		2008-06-05	Ni et al.		
	82	20080294060		2008-11-27	Haro et al.		
	83	20090024047		2009-01-22	Shipley et al.		
	84	20090062882		2009-03-05	Zhang et al.		
	85	20090112116		2009-04-30	Lee et al.		
	86	20090118787		2009-05-07	Moffitt et al.		
	87	20090234427		2009-09-17	Chinn et al.		
	88	20090287279		2009-11-19	Parramon et al.		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	15562714
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EXAMINER SIGNATURE

Examiner Signature	/MICHAEL J LAU/	Date Considered	12/21/2018

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0280

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner et al.
Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2018-01-23
Name/Print	Paul S. Grunzweig	Registration Number	37143

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Darrell Wagner et al.	Examiner:	LAU, Michael J.
Serial No.:	15/562,714	Group Art Unit:	3792
Filed:	September 28, 2017	Docket No.:	I618.118.103
Title:	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING		

AMENDMENT AND RESPONSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Amendment and Response is in reply to the Non-Final Office Action mailed January 3, 2019. Please amend the above-identified patent application as follows:

REMARKS

The following remarks are made in response to the Non-Final Office Action mailed January 3, 2019, in which claims 129-148 were rejected. Claims 1-128 were cancelled previously. With this Response, claims 129-130, 132-138, 140, 142-145, and 147-148 have been amended. Claims 129-148 remain pending in the application and are presented for reconsideration and allowance.

Drawings

The drawings were objected to regarding several reference numerals.

Regarding reference numeral 479, Applicants have amended the specification (as provided in the IN THE SPECIFICATION section) to state "During operation of respiratory-dependent stimulation at **478**, the query at **474** is periodically implemented via pathway **479**."0 This amendment to Paragraph 0217 of "via pathway 479" is clearly supported by the illustration of arrow labeled 479 extending from block 478 to block 474 in FIG. 14, and supported by the explanation within the whole of Paragraph 0217 regarding the flow of action in FIG. 14.

Similarly, regarding reference numeral 559, Applicants have amended the specification (as provided in the IN THE SPECIFICATION section) to state: "Upon operation of independent stimulation at **558** for at least the predetermined period of time, the query at **554** is periodically implemented via pathway **559**." This amendment to Paragraph 252 of "via pathway 559" is clearly supported by the illustration of the arrow labeled 559 in FIG. 15D extending from block 558 to block 554, and supported by the explanation within the whole of Paragraph 252 regarding the flow of action in FIG. 15D.

Regarding reference numeral 501, Applicants have amended the specification (as provided in the IN THE SPECIFICATION section) to state "FIG. 15B is a diagram **500** schematically illustrating aspects of selecting a stimulation protocol **501**, according to one example of the present disclosure." This amendment to Paragraph 0230 Is clearly supported by the illustration of arrow labeled 501 pointing generally toward the blocks 502, 504, 506 and flow

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arrows between these blocks, and supported by the explanation within the whole of Paragraph 0230 regarding the flow of action depicted in FIG. 15B.

With these changes, Applicants respectfully request withdrawal of the objections to the drawings.

Claim Rejections under 35 U.S.C. § 112

Claims 129-148 stand rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite.

Claims 129, 143, and 148

Applicants respectfully traverse the rejection regarding the definiteness of the stimulation and non-stimulation periods in the claims because these terms are more than adequately supported by the specification and/or FIGS, and are disclosed in a manner by which one skilled in the art can reasonably determine their scope and meaning.

First, in Paragraph 044, Applicants' specification provides one example definition:

> In some examples, the independent stimulation element is configured to asynchronously stimulate an airway-patency-related nerve, according to a first stimulation protocol independent of sensed respiratory information and **in which each stimulation cycle includes a stimulation period and a non-stimulation period**. (emphasis added)

Moreover, in context with at least FIG. 3B, at least Paragraph 100 of Applicants' specification define the stimulation period and a non-stimulation period. In FIG. 3B, a series of stimulation cycles are shown, such as a first stimulation cycle having a stimulation period 212A and non-stimulation period 218A, a second stimulation cycle having a stimulation period 212B and non-stimulation period 218B, and so on. Applicants further note that, as disclosed in at least Paragraph 106, it is intentional (in some examples) that the duration of the stimulation cycle (a sum of a duration of stimulation period 212A and a duration of non-stimulation period 218A) does not match a duration (e.g. R) of a reference respiratory cycle (e.g. 204A) because the

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stimulation cycles (and particularly the stimulation period) is intentionally offset (e.g. staggered) relative to the respiratory cycles.

See also, for example, at least Paragraphs 47-49 in Applicants' specification.

In view of at least these portions of Applicants' specification and Figures, Applicants submit that the terms "stimulation period" and "non-stimulation period" are definite and more than adequately supported by the specification, Figures, and originally-filed claims.

Accordingly, withdrawal of the rejection of claims 129, 143, and 148 is respectfully requested.

Claims 137, 139

Regarding claims 137 and 139, Applicants submit that the numerical recitations in those claims are definite.

With regard to at least claim 137, as shown in at least FIG. 3B, the duration of the stimulation period and the duration of the non-stimulation period are in a proportion of at least 3 to 1. For example, as shown in FIG. 3B, the stimulation period 212A has a duration which is greater than (i.e. exceeds) a duration of the non-stimulation period 218A. A similar relationship holds for the successive stimulation cycles (212B, 218B; 212C, 218C; etc.) In comparing the duration of the stimulation period 212A and the duration of the non-stimulation period 218A in FIG. 3B, it would be apparent to one skilled in the art that the duration of the stimulation period 212A exceeds the duration of the non-stimulation period by a factor of at least 3, i.e. the duration of the stimulation period 212A and the duration of the non-stimulation period is in a proportion of at least 3:1. In fact, as shown in FIG. 3B, the duration of the stimulation period 212A exceeds the duration of the non-stimulation period by a factor of 4, i.e. the respective durations are in a proportion of 4:1 as shown by observing the duration of stimulation period 212A and of non-stimulation period 218A and as represented in legend 209.

See, for example, at least Paragraph 128.

Applicants submit that claim 139 is definite for at least some of substantially the same reasons as presented for claim 137. See, for example, at least Paragraph 121 which states at least

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"the duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of at least 1.5."

For at least these reasons, claims 137 and 139 are definite because, as supported by the specification, the scope and meaning of these claims would be clear to one skilled in the art.

Accordingly, withdrawal of the rejection of claims 137 and 139 is respectfully requested.

Claim 140

Regarding claim 140, Applicants submit that the distinction between a reference respiratory cycle and a real-time respiratory cycle is well-defined and apparent from in Applicants' specification and Figures. For example, as explained in Paragraph 0099 of Applicants' specification:

> In some examples, because stimulation via the stimulation protocol **210** is not synchronized relative to characteristics of **actively-sensed respiratory cycles (such as via real-time measure of respiratory effort)**, the stimulation protocol **210** operates based on a **reference respiratory cycle**. In some examples, the **reference respiratory cycle** includes at least one of a historical patient-specific average respiratory cycle for stable respiration and a multi-patient average respiratory cycle for stable respiration. This historical and/or predictive information is employed in at least some examples in which the therapy manager **16** (FIG. 1B) is not actively sensing respiratory waveforms during operation of the at least partially implantable stimulation system **20**. (Emphasis added)

In this passage, actively-sensed respiratory cycles provide one real-time measure of respiratory effort, and hence correspond to a real-time respiratory cycle. See, for example, Paragraph 043, which also refers to performing stimulation "via a protocol that remains independent of the particular characteristics of a real-time sensed respiratory waveform."

Conversely, as stated in Paragraph 0099, a "reference respiratory cycle" corresponds to "a historical patient-specific average respiratory cycle and/or multi-patient average respiratory cycle for stable respiration." See, for example, also Paragraph 0048.

Accordingly, in view of Applicants' specification and FIGS, the scope and/or meaning of the term "reference respiratory cycle" and "real-time respiratory cycle' would be clear to one skilled in the art.

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Accordingly, Applicants respectfully request withdrawal of the rejection regarding claim 140.

Claims 135-136

Applicants have amended claims 135-136 to specify a single numerical parameter, thereby obviating the rejection.

With these explanations and/or amendments, Applicants submit that the rejected claims are in compliance with Section 112. Accordingly, dependent claims 130-134, 138, 141-142, 144-147 (dependent claims of 129 and 143) are in compliance as well.

Claim Rejections under 35 U.S.C. § 103

Claims 129-141 and 143-148 stand rejected under 35 U.S.C. 103, as being unpatentable over Falkenberg (US 7,340,302) in view of Tehrani (US 8,280,513).

Falkenberg exhibits numerous deficiencies relative to Applicants' amended independent claim 129.

First, Applicants' independent claim 129 recites "a non-cardiac stimulation element to engage and to stimulate an upper-airway-patency-related nerve . . ."

In sharp contrast, Falkenberg discloses stimulation of a phrenic nerve, which innervates and causes contraction of the diaphragm. In further contrast to Applicants' claim 129, Falkenberg discloses use of a ventricular tip electrode 122 to stimulate the phrenic nerve. See, for example, at least Column 5, lines 16-19. Falkenberg also discloses additional cardiac locations, intravascular locations, etc., See, for example, at least Column 5, lines 21-32; Column 8, line 37-51.

In contrast to such intravascular and cardiac locations (as provided in Falkenberg) in which the electrode cannot engage the phrenic nerve, Applicants' independent claim 1 recites "a non-cardiac stimulation element to engage and to stimulate an upper-airway-patency-related nerve . . ."

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Second, the Office Action admits that Falkenberg does not disclose the interval between stimulation delivery windows correspond to non-stimulation periods. In this context, Applicants submit that Falkenberg exhibits additional deficiencies relative to Applicants' independent claim 129. In particular, with reference to at least the example stimulation delivery window (e.g. 404 in FIG. 4) mentioned in the Office Action, Falkenberg does not address or disclose the recitation in Applicants' independent claim 129 of "the first stimulation protocol comprises a series of repeating stimulation cycles in which each stimulation cycle includes a stimulation period and a non-stimulation period."

Instead, Falkenberg discloses at Column 9, line 53 to Column 10, line 3:

> FIG. 4 shows an exemplary pacing signal pattern **400** having several pacing pulses **402** and a phrenic nerve stimulation delivery window **404**. The pacing pulses **402** have a first voltage amplitude of VPP (e.g., 1-5 volts) that is sufficient to contract the left side of the heart without causing irritating phrenic nerve stimulation. The phrenic nerve stimulation delivery window **404** has a second voltage amplitude VPNSP-MAX (e.g., maximum amplitude of approximately 10 or more volts) that is greater than the pacing amplitude VPP. The phrenic nerve stimulation delivery window **404** occurs at or near the timing of the next pacing pulse and hence one or more stimulation pulses delivered within the delivery window **404** may also pace the heart in the desired cardiac rhythm. A higher voltage (e.g., VPNSP-MAX) phrenic nerve stimulation pulse delivered within the delivery window **404** can also stimulate the phrenic nerve to provoke respiration and thereby prevent or minimize sleep apnea episodes. (emphasis added)

Accordingly, in at least this passage to which the Office Action apparently refers regarding a "stimulation delivery window", Falkenberg does not even remotely address the scope and meaning of the recitation in Applicants' claim 129 of "a first stimulation protocol comprises a series of repeating stimulation cycles in which each stimulation cycle includes a stimulation period and a non-stimulation period."

In another passage, at Column 12 Falkenberg discloses:

> FIG. 10 shows an exemplary process or method **1000** that determines whether a patient is in expiration or inspiration and/or whether a patient is experiencing obstructive or central sleep apnea. At block **1002**, patient monitoring occurs. At block **1004**, a decision occurs that decides whether a patient is experiencing central sleep apnea. If the patient is not experiencing central sleep apnea, then the method **1000** continues at the patient

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> monitoring block **1002**. However, if the patient is experiencing central sleep apnea, then the method **1000** continues at block **1008** where another decision occurs. At block **1008**, a decision occurs that decides whether a patient is in an inspiration (or expiration) phase of a respiratory cycle. **If the patient is not in an inspiration phase, then the method 1000 continues at the patient monitoring block 1002. <u>However, if the patient is in an inspiration phase, then the method 1000 proceeds to block 1012 where phrenic nerve stimulation may occur</u>.** In general, if the conditions of blocks **1004** and **1008** are met, then delivery of one or more phrenic nerve stimulation pulses may occur. Of course, additional criteria may be used, such as, whether the patient's heart is outside of a vulnerable window (e.g., in a suitable delivery window, etc.). (emphasis added)
>
> Various exemplary devices, methods, systems, etc., optionally deliver a pulse train that has a duration that depends on respiration. For example, if a pulse train is delivered during inspiration, an extended duration (e.g., about 1 s) may be used in comparison to a pulse train delivered during expiration (e.g., about 0.5 s).

This arrangement in Falkenberg conflicts with and/or diverges from the recitation in Applicants' independent claim 1 of "a non-cardiac stimulation element to engage and to stimulate an <u>upper</u>-airway-patency-related nerve, <u>according to a first stimulation protocol **not synchronized relative to actively-sensed respiratory information**</u>." (emphasis added).

Moreover, additional passages of Falkenberg conflict with Applicants' independent claim 1. For example, Falkenberg discloses that "various exemplary devices, methods, systems, etc. prevent phrenic nerve stimulation during obstructive sleep apnea and/or during expiration", which appears to conflict with Applicants' independent claim 1 which is "a device for treating obstructive sleep apnea" and comprises "a non-cardiac stimulation element to engage and to stimulate an upper-airway-patency-related nerve . ."

Accordingly, Falkenberg exhibits numerous deficiencies relative to Applicants' independent claim 129 such that the Office Action fails to provide a prima facie case of unpatentability.

Applicants further submit that Tehrani fails to cure the above-demonstrated and Examiner-admitted deficiencies of Falkenberg. Among other deficiencies, Tehrani discloses stimulation of the phrenic nerve and/or diaphragm (e.g. Column 1, lines 47-49) and does not address stimulation of an upper-airway-patency-related nerve, as recited in Applicants'

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independent claim 129. In fact, Tehrani includes several instances which appear to teach avoidance of stimulation during obstructive apnea, such as in at least Column 4, lines 15-18; Column 2, lines 7-8; etc.

In sharp contrast, Applicants' independent claim 129 recites a device for treating obstructive sleep apnea comprising a non-cardiac stimulation element to engage and to stimulate an upper-airway-patency-related nerve. . ." Via this arrangement, stimulation is used to reduce obstructive sleep apnea, and may be used to prevent obstructive sleep apnea.

For at least these reasons, Applicants submit that Tehrani diverges from Applicants' independent claim 129 and/or fails to cure the deficiencies of Falkenberg relative to Applicants' independent claim 129.

Accordingly, even if one skilled in the art attempted to combine Tehrani with Falkenberg they would fail to arrive at Applicants' independent claim 129.

For at least these reasons, Applicants submit that the cited combination of Falkenberg and Tehrani fail to reasonably make obvious Applicants' independent claim 129, and therefore claim 129 is patentable over the cited combination. Claims 130-142 are patentable at least based on their dependency from independent claim 129.

Applicants submit that claim 131 (depending from independent 129) is further patentably distinguishable over the cited combination. While it is difficult to discern the particular citation within Tehrani which is used to support the rejection, Applicants traverse this rejection at least because the "treatment period" recited in Applicants' claim 131 defines a period such as sleep period (e.g. 10pm-6am in one example) during which the patient may exhibit obstructive sleep apnea (OSA) and therefore during which stimulation may be applied to prevent or minimize OSA during such sleep period.

In sharp contrast, the parenthetical comment ("pulse width can be as long as treatment period") stated in the Office Action (at Page 5, Section 18, lines 3-4) improperly conflicts with the scope and meaning of the term "treatment period" as provided in Applicants' specification.

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In view of the information regarding a treatment period in Applicants' specification, it is submitted that one skilled in the art would likely conclude that the assertion in the Office Action (that a pulse width of a stimulation signal would be as long as a sleeping period (e.g. 10 pm to 6 am during which treatment is provided, e.g. a treatment period) is unreasonable.

Moreover, in view of the comments above regarding the parenthetical assertion in the Office Action regarding the pulse width, it is unclear how the cited passage(s) purportedly meet the recitations of Applicants' claim 131.

For at least these reasons, Applicants submit that the Office Action has failed to establish a prima facie case of unpatentability of Applicants' claim 131.

Applicants submit that Applicants' claim 132 (depending from claim 131) is further patentably distinguishable over the cited combination. For at least some of substantially the same reasons previously presented, neither Falkenberg nor Tehrani discloses use of a "reference respiratory cycle" (as defined in Applicants' specification) and an arrangement in which each stimulation period includes continuous stimulation and has a minimum duration equal to or greater than an inspiratory reference of a reference respiratory cycle, as recited in claim 132.

For at least these reasons, Applicants submit that the cited combination of Falkenberg and Tehrani fail to reasonably make obvious Applicants' claim 132, and therefore claim 132 is patentable over the cited combination. Claims 133-134 are patentable at least based on their dependency from independent claim 129.

Applicants submit that Applicants' claim 134 is further patentably distinguishable over the cited combination. Claim 134 recites that each stimulation period of each respective stimulation cycle has a duration greater than a duration of the inspiratory reference of the reference respiratory cycle and the stimulation period is followed by the non-stimulation period of the respective stimulation cycle comprising a duration less than the duration of the stimulation period.

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Claim 134 is supported by at least FIG. 3B and Paragraphs 0108-111 of Applicants' specification. For instance, the first sentence of Paragraph 108 directly supports claim 134: "With further reference to the stimulation protocol 210 in FIG. 3B, in one aspect, each respective non-stimulation period 218A-218I has a duration less than a duration of each respective stimulation periods 212A-212J. In one aspect, the duration of the stimulation period 212A is less than a duration (R) of the reference respiratory cycle 204A."

As further explained in Paragraph 108 of Falkenberg, via this arrangement:

> In one aspect, the relative duration of the respective stimulation periods (e.g. 212A) and non-stimulation periods (e.g. 218A) causes each successive stimulation period (e.g. 212B) to begin at a different place along a successive respiratory cycle, such that the stimulation pattern is independent of (i.e. not synchronized relative to) the characteristics of the respiratory cycle. For instance, it can be seen from FIG. 3B that the first end 214 of stimulation period 212D coincides with a portion of the expiratory phase 170 of respiratory cycle 204C while the first end 214 of stimulation period 212E coincides with a portion of inspiratory phase 162 of the successive respiratory cycle 204D.

In Paragraph 0111, Falkenberg further explains that " in stimulation protocol 210 the duration of each stimulation period (e.g. 212A-212J) is less than a duration (R) of the reference respiratory cycles (204A-204H) but greater than a duration of the inspiratory phase 162 of an individual respiratory cycle (e.g. 204A).

As explained in Paragraph 109, via this arrangement:

> As shown in FIG. 3B, each of the respective stimulation periods 212A, 212B, 212C overlaps the entire inspiratory phase 162 of the respective respiratory cycles 204A- 204C while stimulation period 212D at least partially overlaps the inspiratory phase 162 of respiratory cycle 204D.

As further explained in Paragraph 110:

> Because the overall duration of the stimulation cycle (both stimulation period and non-stimulation period) does not match the duration (R) of the reference respiratory cycle, the stimulation protocol 210 ensures that each successive stimulation period within the series of stimulation cycles will fall along a different portion of the successive respiratory cycles. **Accordingly, even though the stimulation is not synchronized relative to a characteristic (e.g. inspiration)**

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> **of the respiratory waveform, no matter where the stimulation protocol 210 is started relative to a series of respiratory cycles, the stimulation periods will overlap with at least a portion of the inspiratory phase of the respective reference respiratory cycles for a significant majority of the treatment period.** Accordingly, even if the stimulation protocol 210 happens to be initiated at a time that the non- stimulation period (e.g. 218D, 218E) at least partially overlaps with the inspiratory phase 162 of a respiratory cycle (e.g. 204D, 204E), the succeeding stimulation periods 212F, 212G, etc. at least partially overlaps the inspiratory phase 162 of the next respiratory cycle 204F, 204G, etc., with these later successive stimulation periods significantly overlapping (e.g. stimulation period 212F, which overlaps by at least a majority) or even completely overlapping (e.g. stimulation period 212G) the inspiratory phase 162 of the respective successive respiratory cycles (e.g. 204F, 204G).

It would be clear to one skilled in the art that Falkenberg and Tehrani, whether alone or in combination, do not describe an arrangement like that recited in Applicants' dependent claim 134 and as supported by the specification and at least FIG. 3B. Among other aspects, such an arrangement provides for stimulation which may consistently occur in a manner highly likely to overlap with a significant majority of inspiratory phases of a patient's breathing, whether the patient's respiration is stable or not, even in the absence of sensing respiration.

For at least these reasons, Applicants submit that the cited combination of Falkenberg and Tehrani fail to reasonably make obvious Applicants' claim 134, and therefore claim 134 is patentable over the cited combination. Claims 137-140 are patentable at least based on their dependency from independent claim 134.

Moreover, Applicants submit that claim 137 (depending from claim 134) is further patentably distinguishable over the cited combination. For example, claim 137 is supported by at least the portion of the specification noted above and FIG. 3. As apparent from FIG. 3, the duration of the stimulation period (e.g. 212A) of a stimulation cycle exceeds the duration of the non-stimulation period (e.g. 218A) by a factor of at least 3. Upon repetition of this stimulation cycle, any given stimulation period would overlap with an inspiratory phase of a respiratory

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cycle, thereby ensuring upper-airway patency via such stimulation and achieving or maintaining stable respiration.

Falkenberg and Tehrani, alone or in combination, fail to provide such an arrangement as implemented via the recitations in Applicants' dependent claim 137.

For at least these reasons, Applicants submit that the cited combination of Falkenberg and Tehrani fail to reasonably make obvious Applicants' claim 137, and therefore claim 137 is patentable over the cited combination.

Moreover, Applicants submit that claim 138 is further patentably distinguishable over the cited combination for at least some of substantially the same reasons previously presented in favor of the patentability of Applicants' claims 134, 137, etc.

Applicants submit that claim 140 (dependent from claim 134, and other claims) is further patentably distinguishable over the cited combination.

Applicants submit that the Office Action fails to demonstrate how the information in the passages cited in Tehrani applies with particularity to the specific recitations in Applicants' claim 140, and to the claim as a whole, such that the Office Action does not apprise one precisely how the cited passage meets the each and every recitation in claim 140. Moreover, even if such demonstration were attempted, the cited passages of the references fail to address the recitations of Applicant's claim 140, as noted below. Therefore, the Office Action fails to demonstrate a prima facie case of unpatentability of Applicants' claim 140.

Nothing in the passages of Tehrani cited in the Office Action address the recitation in Applicants' claim 140 that "the duration of the stimulation cycle is equal to the duration of the reference respiratory cycle, and . . . the duration of the reference respiratory cycle differs from a duration of a real time respiratory cycle by an amount exceeding a duration variability criteria."

In addition to the Office Action failing to demonstrate the applicability of the passages of the cited references to the particular recitations, the passages of the applied references simply do not discuss these concepts and the manner in which they are arranged in claim 140.

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For at least these reasons, Applicants submit that the cited combination of Falkenberg and Tehrani fail to reasonably make obvious Applicants' claim 140.

Independent claim 143

Applicants respectfully submit that claim 143 is patentable for at least some of substantially the same reasons previously presented in favor of the patentability of independent claim 129.

For at least these reasons, Applicants submit that the cited combination of Falkenberg and Tehrani fail to reasonably make obvious Applicants' claim 143, which is therefore allowable. Clams 144-147 are patentable at least based on their dependency from independent claim 143 and/or because they are patentably distinct from independent claim 143.

Claim 144

Applicants submit that claim 144 (dependent from independent claim 143) is further patentably distinguishable over the cited combination.

Applicants submit that the Office Action fails to demonstrate how the information in the passages cited in Tehrani applies with particularity to the specific recitations in Applicants' claim 144, and to the claim as a whole, such that the Office Action does not apprise one precisely how the cited passage meets the each and every recitation in claim 144. Moreover, even if such demonstration were attempted, the cited passages of the references fail to address the recitations of Applicant's claim 144, as noted below. Therefore, the Office Action fails to demonstrate a prima facie case of unpatentability of Applicants' claim 144.

First, in the general context of causing a lung volume bias, functional residual capacity, and the like, the cited passages in Tehrani (e.g. Column 2, lines 31-39) relate to stimulating hemi-diaphragms, not to stimulating an upper-airway-patency-related nerve, such as hypoglossal nerve.

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Second, Tehrani addresses varying stimulation parameters but fails to even remotely address the specific elements and relationships noted below, and the manner in which they are recited, in Applicants' claim 144.

In particular, nothing in the passages of Tehrani cited in the Office Action address "a duration of a reference respiratory cycle" which is "different from" (in comparison) to 'a duration" of "a repeating stimulation cycle," in the manner recited in Applicants' claim 144. Moreover, nothing in the passages of Tehrani cited in the Office Action address application of the first function "when the duration of the respiratory cycles in the sensed respiratory information is less variable than a respiratory duration variability criteria," in the manner recited in Applicants' claim 144.

Moreover, nothing in the passages of Tehrani cited in the Office Action addresses "a second function" in which "a duration of a reference respiratory cycle" "matches" 'a duration" of "a repeating stimulation cycle," in the manner recited in Applicants' claim 144. Moreover, nothing in the passages of Tehrani cited in the Office Action address application of the second function "when the duration of the respiratory cycles in the sensed respiratory information is more variable than a respiratory duration variability criteria," in the manner recited in Applicants' claim 144.

Furthermore, nothing in the passages of Tehrani cited in the Office Action address "a function selector to automatically select, for the first stimulation protocol between the first function and the second function," in the manner recited in Applicants' claim 144.

For at least these reasons, Applicants submit that the cited combination of Falkenberg and Tehrani fail to reasonably make obvious Applicants' claim 144 and that the Office Action has failed to adequately state or explain a prima facie case of unpatentability regarding claim 144.

Claim 145

Applicants submit that claim 145 (dependent from independent claim 143) is further patentably distinguishable over the cited combination.

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Applicants submit that the Office Action fails to demonstrate how the information in the passages cited in Tehrani applies with particularity to the specific recitations in Applicants' claim 145, and to the claim as a whole, such that the Office Action does not apprise one precisely how the cited passage meets the each and every recitation in claim 145. Moreover, even if such demonstration were attempted, the cited passages of the references fail to address the recitations of Applicant's claim 145, as noted below. Therefore, the Office Action fails to demonstrate a prima facie case of unpatentability of Applicants' claim 145.

For instance, nothing in the passage of Tehrani cited in the Office Action addresses "the sensing element is configured to be in an inactive state by default and is periodically, temporarily activated to sense respiratory information," in the manner recited in Applicants' claim 145. In addition, nothing in the passage of Tehrani cited in the Office Action addresses the recitation in claim 145 " . . . activated to sense respiratory information to perform calibrating the reference respiratory cycle relative to the sensed respiratory information," in the manner recited in claim 145.

For at least these reasons, Applicants submit that the cited combination of Falkenberg and Tehrani fail to reasonably make obvious Applicants' claim 145.

Claim 147

Applicants submit that claim 147 (dependent from claim 146 and independent claim 143) is further patentably distinguishable over the cited combination.

Applicants submit that the Office Action fails to demonstrate how the information in the passages cited in Tehrani applies with particularity to the specific recitations in Applicants' claim 147, and to the claim as a whole, such that the Office Action does not apprise one precisely how the cited passage meets the each and every recitation in claim 147. Moreover, even if such demonstration were attempted, the cited passages of the references fail to address the recitations of Applicant's claim 147, as noted below. Therefore, the Office Action fails to demonstrate a prima facie case of unpatentability of Applicants' claim 147.

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Nothing in the passages of Tehrani (or Falkenberg) cited in the Office Action address the recitations of Applicants' claim 147 of "wherein the therapy manager is to evaluate the sensed respiratory information, and upon a determination that the first stimulation protocol fails to result in the detected sleep disordered breathing behavior being less than the severity threshold or that the sensed respiratory information fails to meet a sensor signal quality criteria, **the therapy manager is to convert operation of the first stimulation element from the first stimulation protocol to a second stimulation protocol in which stimulation is applied continuously for at least two respiratory cycles or until the detected sleep disordered breathing behavior is less than the severity threshold**." (emphasis added)

For at least these reasons, Applicants submit that the cited combination of Falkenberg and Tehrani fail to reasonably make obvious Applicants' claim 145 and/or submit that the Office Action has failed to establish a prima facie case of unpatentability regarding claim 145.

Independent Claim 148

First, Applicants submit that Applicants' independent claim 148 is patentable over the cited combination for at least some of substantially the same reasons previously presented in favor of the patentability of Applicants' independent claim 129 and claim 143.

Second, Applicants submit that claim 148 is further patentably distinguishable over the cited combination. In particular, Applicants' independent claim 148 further recites:

> a control portion including:
>
> a processor; and
>
> a non-volatile memory storing instructions, executable via the processor, to: provide convertible operation via a therapy manager between: a first stimulation mode implementing the first stimulation protocol; and a second stimulation mode of stimulating the upper-airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform.

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One passage (Col. 4, lines 41-46) of Tehrani cited in the Office Action mentions switching from a first type of stimulation to another type of stimulation, but otherwise fails to address specifics of the nature of the second ("another") type of stimulation. Accordingly, the cited passage fails to address the recitation in Applicants' independent claim 148 of "a second stimulation mode of stimulating the upper-airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform."

While the cited passage (e.g. at Column 2, line 30 to Column 3, line 59 of Tehrani) identifies a "closed loop" stimulation protocol (e.g. at Column 2, line 66) and also mentions that "sensing is used to periodically determine stimulation and response status", at least these aspects of Tehrani do not equate to "a second stimulation mode of stimulating the upper-airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform," as recited in Applicants' independent claim 148. Rather, the cited passage does not address "synchronous" stimulation, and does not do so particularly regarding "with a characteristic of the sensed respiratory waveform," as recited in Applicants' independent claim 148.

For at least these reasons, Applicants submit that the cited combination of Falkenberg and Tehrani fail to reasonably make obvious Applicants' claim 148.

Claim 142

Claim 142 stands rejected under 35 U.S.C. 103, as being unpatentable over Falkenberg in view of Tehrani, and further in view of Christopherson (US 5,944,680).

Applicants submit that Christopherson fails to cure the Examiner-admitted and the above-demonstrated deficiencies of the cited combination (of Falkenberg and Tehrani) regarding base independent claim 129 (from which claim 142 depends), and therefore claim 142 is patentable for at least some of substantially the same reasons as previously presented in favor of the patentability of Applicants' independent claim 129.

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CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 129-148 are in form for allowance and are not taught or suggested by the cited references.

Please consider this a Petition for Extension of Time for a sufficient number of months to enter these papers, if appropriate. At any time during the pendency of this application, please charge any additional fees or credit overpayment to Deposit Account No. 500471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Paul S. Grunzweig at Telephone No. (612) 767-2504, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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IN THE CLAIMS

Please amend claims 129-130, 132-138, 140, 142-145, and 147-148 as follows:

1-128. (Canceled)

129. (Currently Amended) A device for treating ~~sleep-disordered-breathing~~obstructive sleep apnea, comprising:

a non-cardiac stimulation element to engage and to stimulate an upper-airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to actively-sensed respiratory information, wherein the first stimulation protocol comprises a series of repeating stimulation cycles[[and]] in which each stimulation cycle includes a stimulation period and a non-stimulation period.

130. (Currently Amended) The device of claim 129, wherein the non-cardiac stimulation element comprises an implantable electrode ~~is implemented via an implanted electrode and the device includes~~ and a pulse generator electrically connected to the implantable electrode ~~comprising at least a portion of the stimulation element~~.

131. (Previously Presented) The device of claim 129, wherein a total duration of stimulation via the first stimulation protocol during a treatment period is greater than 30 percent of the total duration of the treatment period.

132. (Currently Amended) The device of claim 131, wherein each stimulation period includes continuous stimulation and has a minimum duration equal to or greater than an inspiratory reference of the reference respiratory cycle.

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133. (Currently Amended) The device of claim 132, wherein the inspiratory reference corresponds to a duration of an inspiratory phase of [[a]]the reference respiratory cycle.

134. (Currently Amended) The device of claim 133, wherein each stimulation period of [[~~the~~]]each respective stimulation cycle has a duration greater than a duration of the inspiratory reference of the reference respiratory cycle and the stimulation period is followed by the non-stimulation period of the respective stimulation cycle comprises ~~having~~ a duration less than the duration of the stimulation period.

135. (Currently Amended) The device of claim 129, wherein the duration of the stimulation period comprises ~~is at least one of:~~

~~at least 25 percent of a duration of the stimulation cycle;~~

at least 50 percent of a duration of the stimulation cycle~~; and~~

~~at least 80 percent of a duration of the stimulation cycle~~.

136. (Currently Amended) The device of claim 129, wherein the duration of the stimulation period comprises ~~is at least one of:~~

~~at least 25 percent of a duration of the reference respiratory cycle;~~

at least 50 percent of a duration of the reference respiratory cycle~~; and~~

~~at least 80 percent of a duration of the reference respiratory cycle~~.

137. (Currently Amended) The device of claim 134, wherein the duration of [[~~the~~]] each respective stimulation cycle is less than the duration of the reference respiratory cycle, and a duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of at least 3.

138. (Currently Amended) The device of claim 134, wherein the duration of [[~~the~~]]each respective stimulation cycle is greater than the duration of the reference respiratory cycle.

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139. (Previously Presented) The device of claim 138, wherein the stimulation period and the non-stimulation period are in a proportion of at least 1.5 to 1.

140. (Currently Amended) The device of claim 134, wherein the duration of [[~~the~~]]each respective stimulation cycle is equal to the duration of the reference respiratory cycle, and wherein the duration of the reference respiratory cycle differs from a duration of a real time respiratory cycle from actively-sensed respiration information by an amount exceeding a duration variability criteria.

141. (Previously Presented) The device of claim 129, comprising:

a processor; and

a non-volatile computer readable medium storing instructions, executable on the processor, to implement the first stimulation element and to perform the first stimulation protocol.

142. (Currently Amended) The device of claim ~~129~~130, ~~comprising~~

wherein the implantable electrode comprises a cuff electrode including at least one operative contact group through which the stimulation is deliverable non-selectively to the upper-airway-patency-related nerve.

143. (Currently Amended) A device for treating obstructive sleep apnea~~sleep disordered breathing~~ comprising:

a non-cardiac stimulation element to stimulate an upper-airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to respiratory information, wherein the first stimulation protocol comprises a series of repeating stimulation cycles [[and]] in which each stimulation cycle includes a stimulation period and a non-stimulation period and

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wherein each respective stimulation cycle comprises a duration related to a duration of a reference respiratory cycle.; and

a sensing element to obtain respiratory information via at least periodically sensing a respiratory waveform ~~without~~ unrelated to stimulation synchronization ~~to stimulation~~,

wherein the non-cardiac stimulation element is activated for stimulation upon the sensing element identifying, via at least the respiratory information, obstructive sleep apnea~~sleep disordered breathing~~ behavior which meets or exceeds a severity threshold and is deactivated upon the sensing element identifying, via at least the respiratory information, that the obstructive sleep apnea ~~sleep disordered breathing~~ behavior is less than the severity threshold.

144. (Currently Amended) The device of claim 143, wherein the stimulation element includes a function selector to automatically select, for the first stimulation protocol, between:

a first function to apply the stimulation in which each ~~a repeating~~ stimulation cycle has ~~having~~ a duration different ~~than a~~ from the duration of the reference respiratory cycle, when the duration of the respiratory cycles in the sensed respiratory information is less variable than a respiratory duration variability criteria ; and

a second function to apply the stimulation in which each ~~a repeating~~ stimulation cycle has ~~having~~ a duration matching the duration of the respiratory cycle reference, when the duration of respiratory cycles in the sensed respiratory information is more variable than the respiratory duration variability criteria.

145. (Currently Amended) The device of claim 143, wherein the sensing element is configured to be in an inactive state by default and is periodically, temporarily activated to sense respiratory information to perform ~~at least one of:~~

~~evaluating effectiveness of therapy according to at least the detected sleep disordered breathing relative to the severity threshold; and~~

calibrating the reference respiratory cycle relative to the sensed respiratory information.

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146. (Previously Presented) The device of claim 143, comprising:

a processor; and

a non-volatile memory storing instructions, executable via the processor, to:

evaluate the first stimulation protocol relative to the reference respiratory cycle based on the obtained respiratory information; and

modify, in response to the evaluation, at least one of the reference respiratory cycle and the first stimulation protocol, wherein modifying the first stimulation protocol includes at least one of:

adjusting features of the first stimulation protocol; and

substituting a different stimulation protocol for the first stimulation protocol.

147. (Currently Amended) The device of claim 146, wherein the therapy manager is to evaluate the sensed respiratory information, and upon a determination that the first stimulation protocol fails to result in the detected obstructive sleep apnea ~~disordered breathing~~ behavior being less than the severity threshold or that the sensed respiratory information fails to meet a sensor signal quality criteria, the therapy manager ~~converts~~is to convert operation of the first stimulation element from the first stimulation protocol to a second stimulation protocol in which stimulation is applied continuously for at least two respiratory cycles or until the detected obstructive sleep apnea ~~sleep disordered breathing~~ behavior is less than the severity threshold.

148. (Currently Amended) A device for treating obstructive sleep apnea ~~sleep disordered breathing~~ comprising:

a non-cardiac stimulation element to stimulate an upper-airway-patency-related nerve, according to a first stimulation protocol not synchronized relative to respiratory information, wherein the first stimulation protocol comprises a series of repeating stimulation cycles[[~~and~~]] in which each stimulation cycle includes a stimulation period and a non-stimulation period and wherein each respective stimulation cycle comprises a duration related to a duration of a reference respiratory cycle;

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a sensing element to receive respiratory information; and

a control portion including:

a processor; and

a non-volatile memory storing instructions, executable via the processor, to:

provide convertible operation via a therapy manager between:

a first stimulation mode implementing the first stimulation protocol; and

a second stimulation mode of stimulating the upper-airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform.

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IN THE SPECIFICATION

Please replace Paragraph 0217 with the following:

[0217] With further reference to FIG. 14, based on monitoring of the sensed respiratory waveform, at repeating intervals, at **474** it is queried whether the respiratory waveform is sufficiently stable to support activation of the respiratory-dependent stimulation. If the answer to the query at **474** is NO, then pathway **476** directs continued operation of independent stimulation at **472**. However, if the answer to the query at **474** is YES, then pathway **477** directs initiation of operation of respiratory-dependent stimulation at **478** of FIG. 14. During operation of respiratory-dependent stimulation at **478**, the query at **474** is periodically implemented via pathway **479**. If the answer to the query (at **474**) is NO, then operation in respiratory-dependent stimulation n (**456** in FIG. 12) at **478** in FIG. 14 is terminated as operation is returned (i.e. reverts) via pathway **476** to independent stimulation at **472** in FIG. 14 for at least the predetermined period of time.

Please replace Paragraph 0230 with the following:

[0230] FIG. 15B is a diagram **500** schematically illustrating aspects of selecting a stimulation protocol **501**, according to one example of the present disclosure. In some examples, at least some aspects of selecting a stimulation protocol as expressed in diagram **500** can be embodied as a method while in some examples, at least some aspects of selecting a stimulation protocol as expressed in diagram **500**~~**550**~~ can be embodied as operational aspects of a stimulation protocol management associated with a therapy manager **16** as described in association with at least FIGS. 1-15A.

Please replace Paragraph 0252 with the following:

[0252] Upon operation of independent stimulation at **558** for at least the predetermined period of time, the query at **554** is periodically implemented via pathway **559**. If the answer to the query (at **554**) is YES, then operation in independent stimulation at **558** in FIG. 15D is terminated as operation is returned via pathway **556** to respiratory-dependent stimulation at **552** in FIG. 15D. For at least the current example, it will be understood that, in the event that no stable respiratory waveform is established, the operation would remain in the independent stimulation at **558** without reverting operation into respiratory-dependent stimulation at **552**.

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

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	2	20110172733		2011-07-14	Lima et al.	
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	Filing Date	2017-09-28
	First Named Inventor	Darrell Wagner
	Art Unit	3792
	Examiner Name	Lau, Michael J.
	Attorney Docket Number	I618.118.103

	2	WO199749455	WO		1997-12-31	Medtronic, Inc.			
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15562714
	Filing Date	2017-09-28
	First Named Inventor	Darrell Wagner
	Art Unit	3792
	Examiner Name	Lau, Michael J.
	Attorney Docket Number	I618.118.103

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2019-08-28
Name/Print	Paul S. Grunzweig	Registration Number	37,143

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0312

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/562,714	09/28/2017	Darrell Wagner	1618.118.103	3077

25281 7590 08/29/2019

DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

EXAMINER	
LAU, MICHAEL I	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
08/29/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBCLAW-Docket@dbclaw.com
USPTO.PATENTS@dbclaw.com
dmorris@dbclaw.com

Office Action Summary	Application No. 15/562,714	Applicant(s) Wagner et al.	
	Examiner MICHAEL J LAU	Art Unit 3792	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 6/3/2019.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 129-148 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 129-148 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0314

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Response to Arguments

2. Applicant's arguments, see Pages 9-26, filed 6/3/2019, with respect to the rejection(s) of claim(s) 129-148 under USC 112 and 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bolea (US 2014/0228905 A1).

Claim Rejections - 35 USC § 112

3. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 132 and 147-148 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

5. Claim 132 recites the limitation "**the** reference respiratory cycle" in the end of claim 132 but is not mentioned in any of the preceding claims. There is insufficient antecedent basis for this limitation in the claim.

6. Claims 147 and 148 recite the limitation "**the** therapy manager" in beginning of claim 147 but is not mentioned in any of the preceding claims. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 129-130, 132-134, 137, 139-143, 148 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Bolea (US 2014/0228905 A1)

9. Regarding claim 129, Bolea discloses a device for treating obstructive sleep apnea (Para. 2), comprising a non-cardiac stimulation element to engage and to stimulate an upper airway patency related nerve (Bolea, Abstract), according to a first protocol not synchronized relative to actively sensed respiratory information, wherein the first stimulation protocol comprises a series of repeating stimulation cycles in which each stimulation cycle includes a stimulation period and a non-stimulation period (Para. 473-474, and 515 fixed mode with a duty cycle 41-69%).

10. Regarding claim 130, Bolea discloses the non-cardiac stimulation element having an implantable electrode (fig. 1, 60) and a pulse generator (Fig. 1, 50).

11. Regarding claim 132, Bolea discloses a continuous stimulation duration is greater than or equal to an inspiratory reference (Para. 129, 357, 420).

12. Regarding claim 133, Bolea discloses the inspiratory reference corresponds to a duration of the inspiratory phase (abstract, 129, 357, 420).

13. Regarding claim 134, Bolea discloses wherein the stimulation period of each respective stimulation cycle has a duration greater than the inspiratory reference of the reference cycle and the stimulation period is followed by the non-stimulation period of the respective stimulation cycle comprises a duration less than the duration of the stimulation period ((Para. 129, 357, 420).

14. Regarding claim 137, Bolea discloses the stimulation cycle is less than the duration of reference respiratory cycle and a duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of at least 3 (Bolea, Para. 492-499 and duty cycle of 69%). While the ratio is not 3:1, 69% is substantially similar with 75% to avoid overstimulation of the nerves. See MPEP 2144.05.

15. Regarding claim 139, Bolea discloses the stimulation period and nonstimulation period are in a proportion of at least 1.5:1 (Bolea, Para. 473-474, 492-499 duty cycle up to 69%).

16. Regarding claim 140, Bolea discloses each stimulation cycle is equal to the duration of the reference respiratory cycle, and wherein the duration of the reference respiratory cycle differs from a duration of a real time respiratory cycle from actively sensed respiration information by an amount exceeding a duration variability criteria (Bolea, Abstract, Para. 473-474, 492-499 using a preset fixed mode followed by an adaptive mode with prediction algorithm based on varying breath lengths).

17. Regarding claim 141, Bolea discloses processor and non-volatile computer readable medium storing instructions, executable on the processor, to implement the first stimulation element and to perform the first stimulation protocol (Para. 136, 462).

18. Regarding claim 142, Bolea discloses a cuff electrode including at least one operative contact group through which the stimulation is deliverable non-selectively to the upper airway patency related nerve (Fig. 3, Para. 134, cuff electrode 64).

19. Regarding claim 143, Bolea discloses a device for treating obstructive sleep apnea (Abstract, Para 2) comprising: a noncardiac stimulation element to stimulate an upper airway patency related nerve (Fig. 1, 50), according to a first stimulation protocol not synchronized relative to respiratory

information wherein the first stimulation protocol comprises a series of repeating stimulation cycles in which each stimulation cycle includes a stimulation period and a nonstimulation period and wherein each respective stimulation cycle incomprises related to a duration of a reference respiratory cycle (Para. 473-474 and 515 fixed mode stimulation); and a sensing element to obtain respiratory information via at least periodically sensing a respiratory waveform unrelated to stimulation synchronization (Fig. 1, 70), wherein the non-cardiac stimulation element is activated for stimulation upon the sensing element identifying, via at least the respiratory information, obstructive sleep apnea behavior which meets or exceeds a severity threshold (Para. 357 and 487) and is deactivated upon the sensing element identifying via at least the respiratory information that the obstructive sleep apnea behavior is less than the severity threshold (Abstract, Para. 492-499, 577 turns off below threshold).

20. Regarding claim 148, Bolea discloses device for treating obstructive sleep apnea (Para. 2) comprising: a non-cardiac stimulation element to stimulate an upper-airway-patency-related nerve (Fig. 2, 50), according to a first stimulation protocol not synchronized relative to respiratory information, wherein the first stimulation protocol comprises a series of repeating stimulation cycles, in which each stimulation cycle includes a stimulation period and a non-stimulation period and wherein each respective stimulation cycle comprises a duration related to a duration of a reference respiratory cycle (Para. 473-474, and 515 fixed mode); a sensing element to receive respiratory information (Fig.1, 70); and a processor (Para. 136); and provide convertible operation via a therapy manager between: a first stimulation mode implementing the first stimulation protocol; and a second stimulation mode of stimulating the upper-airway- patency-related nerve synchronous with a characteristic of the sensed respiratory waveform (Para. 355-357, 473-474, 492-499 adaptive mode).

Claim Rejections - 35 USC § 103

21. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

22. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

23. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

24. Claim 131 is rejected under 35 U.S.C. 103 as being unpatentable over Bolea (US 2014/0228905 A1), in view of Bashyam (US 2014/0228905 A1)

25. Regarding claim 131, Bolea discloses the invention of claim 129, but does not disclose a total duration of the first protocol stimulation greater than 30% of total duration of period.

26. Bashyam teaches a fixed mode stimulation of the hypoglossal nerve having a duration of 1 minute to 12 hours of a pre-defined pattern (Para. 71).

27. It would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have combined the invention of Bolea with the teachings of Bashyam to have a default mode while the patient is sleeping. While Bashyam does not specifically say the first mode has to be at least 30%, one of ordinary skill would be able to program the stimulation to run for the majority of a user's sleep duration.

28. Claims 135-136, 138, and 144-147 are rejected under 35 U.S.C. 103 as being unpatentable over Bolea (US 2014/0228905 A1) in view of Tehrani (US 8280513 B2).

29. Regarding claim 135 Bolea discloses the invention of 129, but does not disclose the duration of the stimulation period as at least 50% of the stimulation cycle.

30. Tehrani teaches stimulation of a phrenic nerve to treat sleep apnea by using a stimulation period being at least 50% of a duration of the reference respiratory cycle (Fig. 7A-10C, Col. 17, Ln. 14-53)

31. It would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have combined Bolea with the teachings of Tehrani to avoid fatigue/adaptation (Tehrani, Col. 2, Ln. 55-65).

32. Regarding claim 136, the combined invention of Bolea and Tehrani discloses the duration of the stimulation period is at least 50% of the reference respiratory cycle (Tehrani, Fig. 7A-10C, Col. 17, Ln. 14-53 and Bolea Para. 473-474 duty cycle).

33. Regarding claim 138, Bolea and Tehrani discloses each respective stimulation cycle is greater than the duration of the reference respiratory cycle (Tehrani, Fig. 7C)

34. Regarding claim 144, the combined invention of Bolea and Tehrani discloses the stimulation element includes a function selector to automatically select (Tehrani, Col. 2, Ln. 30- Col. 3, Ln. 59), for the first stimulation protocol, between: a first function to apply the stimulation in which each stimulation cycle has a duration different from the duration of the reference respiratory cycle, when the duration of the respiratory cycles in the sensed respiratory information is less variable than a respiratory duration variability criteria; and a second function to apply the stimulation in which each stimulation cycle has a duration matching the duration of the respiratory cycle reference, when the duration of respiratory cycles in the sensed respiratory information is more variable than the respiratory duration variability criteria (Tehrani, Fig. 1A-10C, Col. 8, Ln. 4-56).

35. Regarding claim 145, the combined invention of Bolea and Tehrani discloses the sensing element is configured to be in an inactive state by default and is periodically, temporarily activated to sense respiratory information to perform calibrating the reference respiratory cycle relative to the sensed respiratory information (Bolea, 473-474 and 492-499 and Tehrani, Fig. 4-5C, Col.2, Ln. 30-Col.3, Ln. 59).

36. Regarding claim 146, the combined invention of Bolea and Tehrani discloses a processor, and a non-volatile memory storing instructions executable via processor (Bolea, Para. 136, 462) to: evaluate the first stimulation protocol relative to the reference respiratory cycle based on the obtained respiratory information; and modify, in response to the evaluation, at least one of the reference respiratory cycle and the first stimulation protocol, wherein modifying the first stimulation protocol includes at least one of: adjusting features of the first stimulation protocol; and substituting a different stimulation protocol for the first stimulation protocol (Tehrani, Fig. 4-5C, Col. 2, Ln. 30-Col. 3, Ln. 49, Col. 4, Ln. 41-46) and (Bolea, Para. 473-474, 492-499).

37. Regarding claim 147, the combined invention of Bolea and Tehrani discloses a therapy manager (Processor, Bolea Para. 136) evaluates the sensed respiratory information, and upon a determination that the first stimulation protocol fails to result in the detected obstructive sleep apnea behavior being less than the severity threshold or that the sensed respiratory information fails to meet a sensor signal quality criteria, the therapy manager is to convert operation of the first stimulation element from the first stimulation protocol to a second stimulation protocol in which stimulation is applied continuously for at least two respiratory cycles or until the detected obstructive sleep apnea behavior is less than the severity threshold (Bolea, Para. 473-474, 492-499) and (tehrani, Fig. 1-10C, Col. 2, Ln. 30-Col. 3, Ln. 59).

Conclusion

38. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J LAU whose telephone number is (571)272-2317. The examiner can normally be reached on 8-5:30 PM.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Carl Layno** can be reached on **(571) 272-4949**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHAEL J LAU/
Examiner, Art Unit 3792

/CARL H LAYNO/
Supervisory Patent Examiner, Art Unit 3792

Notice of References Cited	Application/Control No. 15/562,714	Applicant(s)/Patent Under Reexamination Wagner et al.	
	Examiner MICHAEL J LAU	Art Unit 3792	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-7340302-B1	03-2008	Falkenberg; Eric	A61N1/3611	607/9
*	B	US-20100174341-A1	07-2010	Bolea; Stephen L.	A61N1/3601	607/42
*	C	US-5944680-A	08-1999	Christopherson; Mark A.	A61B5/03	128/897
*	D	US-20120290036-A1	11-2012	Karamanoglu; Mustafa	A61N1/3601	607/42
*	E	US-20160022204-A1	01-2016	Mostov; Kirill	A61B5/0002	600/301
*	F	US-20140364919-A1	12-2014	Doan; Que T.	A61N1/36071	607/46
*	G	US-20060247729-A1	11-2006	Tehrani; Amir J.	A61N1/3601	607/42
*	H	US-20100198289-A1	08-2010	Kameli; Nader	A61B5/00	607/14
*	I	US-8280513-B2	10-2012	Tehrani; Amir J.	A61N1/3601	600/529
*	J	US-8265759-B2	09-2012	Tehrani; Amir J.	A61N1/3601	607/20
*	K	US-8233987-B2	07-2012	Gelfand; Mark	A61N1/3601	607/42
*	L	US-20110093032-A1	04-2011	Boggs, II; Joseph W.	A61B5/415	607/42
*	M	US-20140135868-A1	05-2014	BASHYAM; JACOB BASHYAM	A61F5/566	607/42

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N	WO-9750049-A1	12-1997	WO	HAMMARGREN JOHN W	A61B5/03
	O	WO-2010059839-A2	05-2010	WO	RONDONI JOHN	A61B5/0803
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 15/562,714	Applicant(s)/Patent Under Reexamination Wagner et al.	
	Examiner MICHAEL J LAU	Art Unit 3792	Page 2 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20140228905-A1	08-2014	BOLEA; Stephen L.	A61N1/0556	607/42
	B					
	C					
	D					
	E					
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
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	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0325

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/562,714	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/21/2018	08/21/2019							
	129	✓	✓							
	130	✓	✓							
	131	✓	✓							
	132	✓	✓							
	133	✓	✓							
	134	✓	✓							
	135	✓	✓							
	136	✓	✓							
	137	✓	✓							
	138	✓	✓							
	139	✓	✓							
	140	✓	✓							
	141	✓	✓							
	142	✓	✓							
	143	✓	✓							
	144	✓	✓							
	145	✓	✓							
	146	✓	✓							
	147	✓	✓							
	148	✓	✓							

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0326

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/562,714	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

CPC - Searched*		
Symbol	Date	Examiner
A61B5/3601,0816,0826,113,4818,4848,686	12/21/2018	ML
A61B1/36135	12/21/2018	ML
A61N1/3611,36135,36146,36171	12/21/2018	ML
G06F19/3481	12/21/2018	ML

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
607	42, 72, 73	12/21/2018	ML

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Inventor search on PALM, Prior art search on east, consulted spe carl layno for search strategy	12/21/2018	ML
updated search on east	08/21/2019	ML

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/MICHAEL J LAU/ Examiner, Art Unit 3792	

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	"7340302".pn.	US-PGPUB; USPAT	OR	ON	2018/12/12 18:58
S2	5	"9750049".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/12 19:26
S3	2	"2010174341".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/12 19:38
S4	0	"2010174341".pn.	US-PGPUB; USPAT	OR	ON	2018/12/12 19:39
S5	1	"20100174341".pn.	US-PGPUB; USPAT	OR	ON	2018/12/12 19:39
S6	3	(US-20100174341-$).did. or (US-7340302-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; EPO	OR	ON	2018/12/13 13:33
S7	2	S6 and (pulse or duration or period)	US-PGPUB; USPAT	OR	ON	2018/12/13 13:33
S8	659	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:38
S9	10675	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:42
S10	0	A61B1/36135.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:42
S11	2915	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:44
S12	2915	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:44
S13	7232	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:44
S14	20277	S8 or S9 or S11 or S12 or S13	US-PGPUB; USPAT	OR	ON	2018/12/13 14:45
S15	11362	S14 and @pd<"20150319"	US-PGPUB; USPAT	OR	ON	2018/12/13 14:45
S16	66	(darrell near wagner).in.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:48
S17	6	(darrell near wagner).in. and sleep	US-PGPUB; USPAT	OR	ON	2018/12/13 14:51
S18	190	((darrell near wagner) or (ni near quan) or	US-PGPUB;	OR	ON	2018/12/13

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		(rondini near john) or (dieken near dave)).in. and sleep	USPAT			14:54
S19	161	((darrell near wagner) or (ni near quan) or (rondini near john) or (dieken near dave)).in. and sleep and @pd<"20150319"	US-PGPUB; USPAT	OR	ON	2018/12/13 14:59
S20	149	((darrell near wagner) or (ni near quan) or (rondini near john) or (dieken near dave)).in. and sleep and @pd<"20150319" and stimulat$3	US-PGPUB; USPAT	OR	ON	2018/12/13 15:24
S21	7	"2010059839".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/13 15:36
S22	5	"5944680".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/13 16:16
S23	293	S14 and @pd<"20150319" and pulse adj duration and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 16:56
S24	84	S14 and @pd<"20150319" and pulse adj (width or duration) same inspiration and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 16:56
S25	54	S14 and @pd<"20150319" and pulse adj (width or duration) same inspiration and sleep adj (apnea or aponea) and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 17:01
S26	4	A61B5/0826.cpc. and @pd<"20150319" and pulse adj (width or duration) same inspiration and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 17:07
S27	4	("20160022204" | "20160354602" | "20160354603" | "20160354608").PN.	US-PGPUB; USPAT	OR	ON	2018/12/13 17:24
S28	235	("20010010010" | "20020010495" | "20020049479" | "20020156507" | "20030093128" | "20030114905" | "20030163059" | "20030195571" | "20030216789" | "20030224895" | "20040015204" | "20040073272" | "20040111139" | "20040215288" | "20040230278" | "20040254612" | "20050004628" | "20050010265" | "20050042589" | "20050043765" | "20050043772" | "20050074741" | "20050076908" | "20050080348" | "20050080461" | "20050081847" | "20050085865" | "20050085866" | "20050085868" | "20050085869" | "20050085874" | "20050101833" | "20050113710" | "20050115561" | "20050145246" | "20050165457" | "20050182457" | "20050209513" | "20050209643" | "20050222503" | "20050234523" | "20050251216" | "20050261747" | "20050267380" | "20050277844" | "20050277999" | "20050278000" | "20060052836" | "20060058852" | "20060064029" |	US-PGPUB; USPAT	OR	ON	2018/12/13 17:25

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"20060079802" | "20060095088" |
"20060103407" | "20060135886" |
"20060142815" | "20060212096" |
"20060224209" | "20060241708" |
"20060247729" | "20060259079" |
"20060264777" | "20060266369" |
"20060271137" | "20060276701" |
"20060293720" | "20060293723" |
"20070021785" | "20070027482" |
"20070038265" | "20070150022" |
"20070233204" | "20070255379" |
"20080009685" | "20080039904" |
"20080046055" | "20080064977" |
"20080103545" | "20080103570" |
"20080109046" | "20080109048" |
"20080132802" | "20080294060" |
"20090024047" | "20090062882" |
"20090112116" | "20090118787" |
"20090234427" | "20090287279" |
"20090308395" | "20090326408" |
"20100010566" | "20100016749" |
"20100094379" | "20100125310" |
"20100125314" | "20100125315" |
"20100137931" | "20100152553" |
"20100174341" | "20100198103" |
"20100198289" | "20100228133" |
"20100228317" | "20100241195" |
"20100262210" | "20110093036" |
"20110112601" | "20110152706" |
"20110152965" | "20110160794" |
"20110264164" | "20150039045" |
"20160193468" | "4379462" | "4567892" |
"4630614" | "4813431" | "4830008" | "5133354"
| "5134995" | "5148802" | "5158080" |
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| "5211173" | "5215082" | "5233983" |
"5239995" | "5245995" | "5265624" | "5281219"
| "5300094" | "5335657" | "5344438" |
"5351394" | "5385144" | "5388578" | "5398682"
| "5458137" | "5483969" | "5485851" |
"5522862" | "5524632" | "5540731" | "5540732"
| "5540733" | "5540734" | "5546952" |
"5549655" | "5588439" | "5591216" | "5605151"
| "5645053" | "5671733" | "5797852" |
"5823187" | "5843135" | "5895360" | "5904141"
| "5919221" | "5944680" | "5999846" |
"6015389" | "6021352" | "6025624" | "6041780"
| "6099479" | "6120441" | "6125290" |
"6125291" | "6126611" | "6132384" | "6134459"
| "6144866" | "6175767" | "6181961" |
"6198952" | "6223064" | "6240316" | "6248080"
| "6249703" | "6251126" | "6269269" |
"6307481" | "6309350" | "6314324" | "6342039"
| "6345202" | "6361494" | "6393325" |
"6449507" | "6450957" | "6456866" | "6509164"
| "6522928" | "6532388" | "6572543" |
"6574507" | "6587725" | "6609016" | "6609032"
| "6629527" | "6641542" | "6645143" |
"6647289" | "6651652" | "6654634" | "6665560"
| "6666830" | "6689068" | "6703939" |
"6718208" | "6719708" | "6731976" | "6731984"
| "6735471" | "6752765" | "6770022" |
"6773404" | "6805667" | "6811538" | "6842647"
| "6881192" | "6890306" | "6893405" |

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		"6904320" | "6907293" | "6928324" | "6935335" | "6936011" | "6964641" | "6978171" | "6988498").PN.				
S29	90	("7025730" | "7041049" | "7054692" | "7077810" | "7081095" | "7082331" | "7082336" | "7087053" | "7117036" | "7128717" | "7145461" | "7149573" | "7155278" | "7160252" | "7160255" | "7167743" | "7174215" | "7186220" | "7187978" | "7189204" | "7195594" | "7200440" | "7206635" | "7212862" | "7214197" | "7252640" | "7269457" | "7269459" | "7277749" | "7330760" | "7336996" | "7340302" | "7351208" | "7366572" | "7371220" | "7387608" | "7395113" | "7396333" | "7398115" | "7422015" | "7438686" | "7447545" | "7453928" | "7454250" | "7468040" | "7469697" | "7473227" | "7491181" | "7510531" | "7526341" | "7542803" | "7572225" | "7590455" | "7591265" | "7596413" | "7603170" | "7610094" | "7634315" | "7644714" | "7662105" | "7672728" | "7678061" | "7680538" | "7702385" | "7717848" | "7720541" | "7725195" | "7734340" | "7734350" | "7742819" | "7747323" | "7751880" | "7775993" | "7783353" | "7792583" | "7809442" | "7818063" | "7853322" | "7881798" | "7908013" | "7917230" | "7942822" | "7957797" | "7957809" | "7979128" | "8016776" | "8021299" | "8150531" | "8160711" | "8175720").PN.	US-PGPUB; USPAT	OR	ON	2018/12/13 17:25
S30	58	S28 and pulse adj (pulse or duration)	US-PGPUB; USPAT	OR	ON	2018/12/13 17:26
S31	8	S28 and pulse adj (pulse or duration) and '25%'	US-PGPUB; USPAT	OR	ON	2018/12/13 17:31
S32	47	S28 and pulse adj (duration or duration)	US-PGPUB; USPAT	OR	ON	2018/12/13 17:32
S33	104	S28 and pulse adj (width or duration)	US-PGPUB; USPAT	OR	ON	2018/12/13 17:32
S34	1	"5944680".pn. and pulse adj (width or duration)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/13 17:34
S35	1	("2015/0039045").URPN.	USPAT	OR	ON	2018/12/13 17:57
S36	4	A61B5/0826.cpc. and @pd<"20150319" and pulse adj (width or duration) same inspiration and implant and ramp	US-PGPUB; USPAT	OR	ON	2018/12/13 18:10
S37	0	A61B5/0826.cpc. and @pd<"20150319" and ramp with pulse adj (width or duration) same inspiration and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 18:10
S38	1	A61B5/0826.cpc. and @pd<"20150319" and ramp$3 same pulse adj (width or duration) same inspiration and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 18:11
S39	29	S14 and @pd<"20150319" and ramp with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:13
S40	0	S14 and @pd<"20150319" and full with ramp with pulse adj (width or duration) and sleep adj	US-PGPUB; USPAT	OR	ON	2018/12/13 18:13

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		(apnea or aponea)				
S41	0	S14 and @pd<"20150319" and full same ramp with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:13
S42	0	S14 and @pd<"20150319" and full with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:15
S43	39	S14 and @pd<"20150319" and full same pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:15
S44	826	607/72,73.ccls.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:30
S45	532	607/72,73.ccls. and duration	US-PGPUB; USPAT	OR	ON	2018/12/20 10:30
S46	491	607/72,73.ccls. and @pd<"20150319" and duration	US-PGPUB; USPAT	OR	ON	2018/12/20 10:31
S47	51	607/72,73.ccls. and @pd<"20150319" and duration and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2018/12/20 10:32
S48	80	2006/0247729	US-PGPUB; USPAT	OR	ON	2018/12/20 10:45
S49	1	"20060247729".pn.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:45
S50	1	"20060247729".pn. and duration	US-PGPUB; USPAT	OR	ON	2018/12/20 10:48
S51	0	"2010098289".pn.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:59
S52	1	"20100198289".pn.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:59
S53	78	("2006/0247729").URPN.	USPAT	OR	ON	2018/12/20 11:27
S54	45	("2006/0247729").URPN. and @pd<"20150319"	USPAT	OR	ON	2018/12/20 11:27
S55	44	("2006/0247729").URPN. and @pd<"20150319" and (duration or width)	USPAT	OR	ON	2018/12/20 11:28
S56	15	(US-20100174341-$ or US-20120290036-$ or US-20160354608-$ or US-20160022204-$ or US-20140364919-$ or US-20060247729-$ or US-20100198289-$).did. or (US-7340302-$ or US-5944680-$ or US-8280513-$ or US-8265759-$ or US-8233987-$).did. or (WO-2010059839-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; FPRS; EPO	OR	ON	2018/12/21 09:27
S57	5	S56 and cuff	US-PGPUB; USPAT	OR	ON	2018/12/21 09:27
S58	15	(US-20100174341-$ or US-20120290036-$ or US-20160354608-$ or US-20160022204-$ or US-20140364919-$ or US-20060247729-$ or US-20100198289-$).did. or (US-7340302-$ or US-5944680-$ or US-8280513-$ or US-8265759-$ or US-8233987-$).did. or (WO-2010059839-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/19 15:36
S59	652	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse adj duration and sleep adj (apnea or apnoea)	US-PGPUB; USPAT	OR	ON	2019/08/19 15:37
S60	28	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse adj duration and sleep adj (apnea or apnoea) same repeat$4	US-PGPUB; USPAT	OR	ON	2019/08/19 15:40

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S61	17	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse adj duration and sleep adj (apnea or apnoea) same repeat$4 and hypoglossal	US-PGPUB; USPAT	OR	ON	2019/08/19 15:46
S62	1	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse adj duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal	US-PGPUB; USPAT	OR	ON	2019/08/19 15:49
S63	33	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal	US-PGPUB; USPAT	OR	ON	2019/08/19 15:55
S64	33	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and referenc$3	US-PGPUB; USPAT	OR	ON	2019/08/19 16:00
S65	0	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and referenc$3 adj respirat$4	US-PGPUB; USPAT	OR	ON	2019/08/19 16:01
S66	33	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and referenc$3	US-PGPUB; USPAT	OR	ON	2019/08/19 16:05
S67	26	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and active$3	US-PGPUB; USPAT	OR	ON	2019/08/19 16:05
S68	1	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and active$3 with sens$4	US-PGPUB; USPAT	OR	ON	2019/08/19 16:08
S69	30	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and (first and second)	US-PGPUB; USPAT	OR	ON	2019/08/19 16:38
S70	30	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and (first same second)	US-PGPUB; USPAT	OR	ON	2019/08/19 16:43
S71	18	(US-20100174341-$ or US-20120290036-$ or US-20160354608-$ or US-20160022204-$ or US-20140364919-$ or US-20060247729-$ or US-20100198289-$ or US-20110093032-$ or US-20140135868-$ or US-20140228905-$).did. or (US-7340302-$ or US-5944680-$ or US-8280513-$ or US-8265759-$ or US-8233987-$).did. or (WO-2010059839-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 08:16
S72	13	S71 and referenc$3	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 09:09
S73	13	S71 and synchron$	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 09:10
S74	12	S71 and mode$1	US-PGPUB; USPAT;	OR	OFF	2019/08/20 10:27

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			FPRS; EPO			
S75	7	S71 and fixed	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:46
S76	6	S71 and fixed same (duration$1 or length$1)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:46
S77	0	S71 and fixed same (duration$1 or length$1) same "%"	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:51
S78	0	S71 and fixed same (duration$1 or length$1) same ("%" or percent$4)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:52
S79	4	S71 and (duration$1 or length$1) same ("%" or percent$4)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:54
S80	4	S71 and (duration$1 or length$1) same ("%" or percent$4)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:54
S81	10	S71 and (fixed or repeat$4 or constant) same (duration$1 or length$1)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:55
S82	1	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and fixed same puls$3 same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal	US-PGPUB; USPAT	OR	ON	2019/08/20 10:56
S83	0	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and fixed same puls$3 same duration same repeat$4 and sleep adj (apnea or apnoea) same ("%" or percent$5)	US-PGPUB; USPAT	OR	ON	2019/08/20 10:57
S84	1	S71 and (minim$2) near3 (length$1 or duration$1)	US-PGPUB; USPAT	OR	ON	2019/08/20 11:21
S85	15	S71 and duration$1	US-PGPUB; USPAT	OR	ON	2019/08/20 11:21
S86	3	S71 and duration$1 same synchron$4	US-PGPUB; USPAT	OR	ON	2019/08/20 11:31
S87	11	S71 and synchron$4	US-PGPUB; USPAT	OR	ON	2019/08/20 11:34
S88	7	S71 and synchron$4 same inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 11:43
S89	10	S71 and (length$1 or duration$1) same inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 11:46
S90	18	(US-20100174341-$ or US-20120290036-$ or US-20160354608-$ or US-20160022204-$ or US-20140364919-$ or US-20060247729-$ or US-20100198289-$ or US-20110093032-$ or US-20140135868-$ or US-20140228905-$).did. or (US-7340302-$ or US-5944680-$ or US-8280513-$ or US-8265759-$ or US-8233987-$).did. or (WO-2010059839-$).did. or (WO-	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 15:06

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		9750049-$).did.				
S91	7	S90 and (length$1 or duration$1) same referenc$3	US-PGPUB; USPAT	OR	ON	2019/08/20 15:06
S92	5	S90 and duration$1 same referenc$3	US-PGPUB; USPAT	OR	ON	2019/08/20 15:09
S93	3	S90 and reference with inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 15:10
S94	7	S90 and reference same inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 15:14
S95	13	S90 and reference	US-PGPUB; USPAT	OR	ON	2019/08/20 15:35
S96	1	"8280513".pn.	US-PGPUB; USPAT	OR	ON	2019/08/20 15:54
S97	1	S96 and duty	US-PGPUB; USPAT	OR	ON	2019/08/20 16:37
S98	7	S90 and duty adj cycle$1	US-PGPUB; USPAT	OR	ON	2019/08/20 16:51
S99	4	S90 and duty adj cycle$1 and 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:52
S100	0	S90 and duty adj cycle$1 same 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:53
S101	142072	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:53
S102	139154	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with 75% same inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 16:54
S103	139153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with 75%1% same inspirat$4 and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 16:55
S104	139153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with 75%1% same inspirat$4 and nerve$1 and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:55
S105	139153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with "75%1%" same inspirat$4 and nerve$1 and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:55
S106	139153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with "75%1%" same inspirat$4 and nerve$1 same sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:55
S107	139153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" andduty adj cycle$1 with 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:56
S108	173	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:56
S109	33	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with 75% and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:57
S110	0	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with 75% same (inspirat$4 or respirat$4) and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:58
S111	161	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.)	US-PGPUB;	OR	ON	2019/08/20

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		and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) and sleep adj apnea	USPAT			16:59
S112	109	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 16:59
S113	66	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with $2% same (inspirat$4 or respirat$4) and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 17:01
S114	34	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with $2% same (inspirat$4 or respirat$4) same stimulat$4 and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 17:09
S115	13	S90 and (inspirat$4 or respirat$4) same stimulat$4 and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 17:13
S116	13	S90 and (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 17:14
S117	10	S90 and (inspirat$4 or respirat$4) same stimulat$4 same duration$1	US-PGPUB; USPAT	OR	ON	2019/08/20 17:25
S118	70	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4 and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/21 08:52
S119	660	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S120	12048	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S121	3221	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S122	3221	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S123	7298	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S124	21955	S119 or S120 or S121 or S122 or S123	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S125	11295	S124 and @pd<"20150319"	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S126	62	S125 and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4 and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S127	90	S125 and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 08:55
S128	61	S125 and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4 same duration	US-PGPUB; USPAT	OR	ON	2019/08/21 08:55
S129	90	S125 and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:10
S130	94	S125 and @pd<"20150319" and (duty adj cycle$1 or on$1time or on adj time) same (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:41
S131	392	S125 and @pd<"20150319" and duration$1 same (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:43

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S132	220	S125 and @pd<"20150319" and duration$1 with (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:43
S133	130	S125 and @pd<"20150319" and duration$1 with (inspirat$4 or respirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:43
S134	7	S125 and @pd<"20150319" and duration$1 with (inspirat$4 or respirat$4) with stimulat$4 same ratio	US-PGPUB; USPAT	OR	ON	2019/08/21 09:44
S135	169	S125 and @pd<"20150319" and duration$1 with inspirat$4 and respirat$4 with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:21
S136	97	S125 and @pd<"20150319" and duration$1 with inspirat$4 same respirat$4 with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:21
S137	1	S125 and @pd<"20150319" and overlap$4 with respirat$4 with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:30
S138	1	S125 and @pd<"20150319" and overlap$4 with respirat$4 with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:31
S139	5	S125 and @pd<"20150319" and overlap$4 with (respirat$4 or inspirat$4 or expirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:32
S140	14813	S125 and @pd<"20150319" and duration with (greater$1 or longer$1) (respirat$4 or inspirat$4 or expirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:33
S141	48	S125 and @pd<"20150319" and duration with (greater$1 or longer$1) with (respirat$4 or inspirat$4 or expirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:33
S142	8	S125 and @pd<"20150319" and puls$3 near3 (duration$1 or length$1 or width$2) with (greater$1 or longer$1) with (respirat$4 or inspirat$4 or expirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:42

EAST Search History (Interference)

<This search history is empty>

8/21/2019 2:45:07 PM
C:\Users\mlau2\Documents\EAST\Workspaces\15562714.wsp

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Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	15562714	Filing Date	2017-09-28	Docket Number (if applicable)	1618.118.103	Art Unit	3792
First Named Inventor	Darrell Wagner et al.			Examiner Name	Michael Lau		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☐ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 500471

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

X Patent Practitioner Signature

Applicant Signature

EFS - Web 2.1.15

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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Signature of Registered U.S. Patent Practitioner			
Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2020-01-29
Name	Paul S. Grunzweig	Registration Number	37143

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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EXPEDITED PROCEDURE
Examining Group Number 3792

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Darrell Wagner et al.	Examiner: LAU, Michael J.
Serial No.:	15/562,714	Group Art Unit: 3792
Filed:	September 28, 2017	Docket No.: I618.118.103
Title:	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

AMENDMENT AND RESPONSE UNDER 37 C.F.R. 1.116

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Amendment and Response is in reply to the Final Office Action mailed August 29, 2019. Please amend the above-identified patent application as follows:

IN THE CLAIMS

Please add new claims 149-150.

Please amend claims 129, 132, 134, 143-144, and 146-148 as follows

1-128. (Canceled)

129. (Currently Amended) A device for treating obstructive sleep apnea, comprising:

a non-cardiac stimulation element to engage and to stimulate an upper-airway-patency-related nerve, according to a first stimulation therapy protocol not synchronized relative to actively-sensed respiratory information, wherein the first stimulation therapy protocol comprises a series of repeating stimulation cycles in which each stimulation cycle includes a stimulation period and a non-stimulation period.

130. (Previously Presented) The device of claim 129, wherein the non-cardiac stimulation element comprises an implantable electrode and a pulse generator electrically connected to the implantable electrode.

131. (Previously Presented) The device of claim 129, wherein a total duration of stimulation via the first stimulation protocol during a treatment period is greater than 30 percent of the total duration of the treatment period.

132. (Currently Amended) The device of claim ~~131~~129, wherein each stimulation period includes continuous stimulation and has a minimum duration equal to or greater than an inspiratory reference of [[~~the~~]] a reference respiratory cycle, wherein the reference respiratory cycle comprises at least one of:

a historical patient-specific average respiratory cycle for stable respiration, and

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a multi-patient average respiratory cycle for stable respiration.

133. (Previously Presented) The device of claim 132, wherein the inspiratory reference corresponds to a duration of an inspiratory phase of the reference respiratory cycle.

134. (Currently Amended) The device of claim 133, wherein each stimulation period of each respective stimulation cycle has a duration greater than a duration of the inspiratory reference of the reference respiratory cycle and the stimulation period is followed by the non-stimulation period of the respective stimulation cycle ~~comprises~~comprising a duration less than the duration of the stimulation period.

135. (Previously Presented) The device of claim 129, wherein the duration of the stimulation period comprises

at least 50 percent of a duration of the stimulation cycle.

136. (Previously Presented) The device of claim 129, wherein the duration of the stimulation period comprises

at least 50 percent of a duration of the reference respiratory cycle.

137. (Previously Presented) The device of claim 134, wherein the duration of each respective stimulation cycle is less than the duration of the reference respiratory cycle, and a duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of at least 3.

138. (Previously Presented) The device of claim 134, wherein the duration of each respective stimulation cycle is greater than the duration of the reference respiratory cycle.

139. (Previously Presented) The device of claim 138, wherein the stimulation period and the non-stimulation period are in a proportion of at least 1.5 to 1.

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140. (Previously Presented) The device of claim 134, wherein the duration of each respective stimulation cycle is equal to the duration of the reference respiratory cycle, and wherein the duration of the reference respiratory cycle differs from a duration of a real time respiratory cycle from actively-sensed respiration information by an amount exceeding a duration variability criteria.

141. (Previously Presented) The device of claim 129, comprising:

a processor; and

a non-volatile computer readable medium storing instructions, executable on the processor, to implement the first stimulation element and to perform the first stimulation protocol.

142. (Previously Presented) The device of claim 130,

wherein the implantable electrode comprises a cuff electrode including at least one operative contact group through which the stimulation is deliverable non-selectively to the upper-airway-patency-related nerve.

143. (Currently Amended) A device for treating obstructive sleep apnea comprising:

a non-cardiac stimulation element to stimulate an upper-airway-patency-related nerve, according to a first stimulation therapy protocol not synchronized relative to respiratory information, wherein the first stimulation therapy protocol comprises a series of repeating stimulation cycles in which each stimulation cycle includes a stimulation period and a non-stimulation period and wherein each respective stimulation cycle comprises a duration related to a duration of a reference respiratory cycle[[.]]; and

a sensing element to obtain respiratory information via at least periodically sensing a respiratory waveform unrelated to stimulation synchronization,

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wherein the non-cardiac stimulation element is activated for stimulation upon the sensing element identifying, via at least the respiratory information, obstructive sleep apnea behavior which meets or exceeds a severity threshold and is deactivated upon the sensing element identifying, via at least the respiratory information, that the obstructive sleep apnea behavior is less than the severity threshold.

144. (Currently Amended) The device of claim 143, wherein the stimulation element includes a function selector to automatically select, for the first stimulation therapy protocol, between:

a first function to apply the stimulation in which each stimulation cycle has a duration different from the duration of the reference respiratory cycle, when the duration of the respiratory cycles in the sensed respiratory information is less variable than a respiratory duration variability criteria ; and

a second function to apply the stimulation in which each stimulation cycle has a duration matching the duration of the respiratory cycle reference, when the duration of respiratory cycles in the sensed respiratory information is more variable than the respiratory duration variability criteria.

145. (Previously Presented) The device of claim 143, wherein the sensing element is configured to be in an inactive state by default and is periodically, temporarily activated to sense respiratory information to perform calibrating the reference respiratory cycle relative to the sensed respiratory information.

146. (Currently Amended) The device of claim 143, comprising:

a processor; and

a non-volatile memory storing instructions, executable via the processor, to:

evaluate the first stimulation therapy protocol relative to the reference respiratory cycle based on the obtained respiratory information; and

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modify, in response to the evaluation, at least one of the reference respiratory cycle and the first stimulation therapy protocol, wherein modifying the first stimulation therapy protocol includes at least one of:

adjusting features of the first stimulation therapy protocol; and

substituting a different stimulation protocol for the first stimulation therapy protocol.

147. (Currently Amended) The device of claim 146, wherein the ~~therapy manager~~stored instructions, upon execution via the process, are [[~~is~~]]to evaluate the sensed respiratory information, and upon a determination that the first stimulation therapy protocol fails to result in the detected obstructive sleep apnea behavior being less than the severity threshold or that the sensed respiratory information fails to meet a sensor signal quality criteria, ~~the therapy manager is to convert~~ operation of the first stimulation element is converted from from the first stimulation therapy protocol to a second stimulation therapy protocol in which stimulation is applied continuously for at least two respiratory cycles or until the detected obstructive sleep apnea behavior is less than the severity threshold.

148. (Currently Amended) A device for treating obstructive sleep apnea comprising:

a non-cardiac stimulation element to stimulate an upper-airway-patency-related nerve, according to a first stimulation therapy protocol not synchronized relative to respiratory information, wherein the first stimulation therapy protocol comprises a series of repeating stimulation cycles in which each stimulation cycle includes a stimulation period and a non-stimulation period and wherein each respective stimulation cycle comprises a duration related to a duration of a reference respiratory cycle;

a sensing element to receive respiratory information; and

a control portion including:

a processor; and

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a non-volatile memory storing instructions, executable via the processor, to:

provide convertible operation via a therapy manager between:

a first stimulation mode implementing the first stimulation therapy protocol; and

a second stimulation mode of stimulating the upper-airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform.

149. (New) The device of claim 138, wherein the duration of the stimulation cycle is less than a duration of two consecutive reference respiratory cycles.

150. (New) The device of claim 129, wherein the stimulation period and the non-stimulation period are in a proportion of at least 1.5 to 1.

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REMARKS

The following remarks are made in response to the Final Office Action mailed August 29, 2019, in which claims 129-148 were rejected. Claims 1-128 were cancelled previously. With this Response, claims 129, 132, 134, 143-144, and 146-148 have been amended, and new claims 149-150 have been added. Claims 129-150 remain pending in the application and are presented for reconsideration and allowance.

Claim Rejections under 35 U.S.C. § 112

Claims 132 and 147-148 stand rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite.

Claim 132 has been amended to recite a reference respiratory cycle, thereby obviating the antecedent basis rejection.

Claim 147 has been amended to recite to remove the reference to "the therapy manager," thereby obviating the antecedent basis rejection. Claim 148 does not recite "the therapy manager," and therefore the antecedent basis rejection is moot as to claim 148.

For at least these reasons, Applicants respectfully request withdrawal of the Section 112 rejections.

Claim Rejections under 35 U.S.C. § 102

Claims 129-130, 132-134, 137, 139-143, 148 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Bolea (US 2014/0228905).

Applicants respectfully traverse this rejection regarding independent claim 129.

Applicants submit that the cited portion of Bolea in Paragraphs 473-474, taken in context with the full passage of Paragraphs 466-474 regarding FIGS. 64A-64D, conflicts with at least the recitation "a non-cardiac stimulation element to engage and to stimulate an upper-airway-patency-related nerve, according to a **first stimulation therapy protocol not synchronized relative to actively-sensed respiratory information**" in Applicants' independent claim 129.

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Paragraphs 472-474 of Bolea (cited in the rejection of Applicants' independent claim 129) describe aspects of various stimulation duty cycles. In doing so, it would be apparent to one skilled in the art that such stimulation duty cycles relate to the embodiments of preceding Paragraphs 466-471 of Bolea, which depend on stimulation timing synchronized relative to a detected peak of the respiration signal "Z."

In particular, Paragraphs 466-467 relate to a bio-impedance respiration signal and triggering stimulation based on a fiducial (e.g. begin-expiration) within this respiration signal, among other details. As noted in Paragraph 468 of Bolea, "an algorithm is used to predict respiratory period and determine stimulation trigger time. The predictive algorithm is contained in software and executed by a microprocessor resident in the INS circuitry 1130, thus enabling the INS 1100 to generate stimulation synchronous with inspiration." Example predictive algorithms are described in Paragraphs 469, 470 in association with FIGS. 64B, 64C. As further noted in Paragraph 471:

> A feature common to the predictive algorithms is illustrated in FIG. 64D. This feature provides a sequence of predicted respiratory periods in case the respiration impedance signal ("Z") is temporarily lost (e.g. due to change in respiratory effort). Until a subsequent respiratory peak is detected, stimulation parameters which are based on the measured respiratory period (e.g. stimulation period) are unchanged. **Thus, stimulation timing remains synchronous to the last detected peak.** (emphasis added)

With this in mind, as the following Paragraphs 472-474 of Bolea (cited in the Office Action) describe aspects of various stimulation duty cycles, it would be apparent to one skilled in the art that such stimulation duty cycles relate to the embodiments of Paragraphs 466-471, which depend on stimulation timing synchronized relative to a detected peak of the respiration signal "Z."

Accordingly, at least this cited portion of Bolea (relied in the rejection of Applicants' independent claim 129) conflicts with at least the recitation "a non-cardiac stimulation element to engage and to stimulate an upper-airway-patency-related nerve, according to a **first stimulation therapy protocol not synchronized relative to actively-sensed respiratory information**" in Applicants' independent claim 129.

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For at least this reason, Bolea fails to meet each and every recitation of Applicants' independent claim 129, and therefore fails to anticipate independent claim 129.

Applicants further submit that FIGS. 80A-80 and Paragraphs 489-499 of Bolea, which are cited elsewhere in the Office Action also conflict with Applicants' independent claim 129 at least because such passages (particularly Paragraph 496) provide substantially similar information to Paragraphs 466-471 at least with respect to being conflicting relative to Applicants' independent claim 129.

Applicants further submit that Paragraph 515 of Bolea (as cited in the Office Action) fails to meet the recitations of Applicants' independent claim 129. In particular, while Paragraph 514-515 does refer to asynchronous stimulation, this Paragraph 515 explains that "the asynchronous mode (fixed mode) may be used during daytime familiarization", which is not a therapy for sleep apnea. Bolea further explains:

> This mode may be used to **test** the benefits of asynchronous stimulation compared to inspiratory synchronous stimulation. Asynchronous stimulation may be initiated by programming the device to fixed mode and starting a therapy session. Fixed mode stimulation may be in any available pulse train configuration.

In view of the particular context in which asynchronous stimulation is described (e.g. daytime familiarization, testing), and given that other portions of Bolea do not appear to directly address such asynchronous stimulation, it would appear to one skilled in the art that Bolea does not address asynchronous stimulation as a "first stimulation therapy protocol" in the manner recited in Applicants' independent claim 129. Rather, Bolea relies on inspiratory synchronous stimulation, such as in at least the predictive algorithms as noted in the above-highlighted passages.

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' independent claim 129, and therefore fails to anticipate independent claim 129.

Claims 130, 132-134, 137, 139-142 are patentable at least based on their dependency from independent claim 129.

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Applicants submit that claim 132 (depending from independent claim 129) is further patentably distinguishable over Bolea. In particular, Applicants' claim 132 recites that "each stimulation period includes continuous stimulation and has a minimum duration equal to or greater than an inspiratory reference of a reference respiratory cycle, wherein the reference respiratory cycle comprises at least one of: a historical patient-specific average respiratory cycle for stable respiration; and a multi-patient average respiratory cycle for stable respiration.

These recitations stand in sharp contrast to the portions of Bolea cited regarding base independent claim 129. In particular, at least some of those cited portions (e.g. Paragraphs 473-474 with preceding Paragraphs 466-472) address a predictive algorithm which is synchronized relative to a detected peak of inspiration, which therefore does not relate to a "reference respiratory cycle" which comprises an "average respiratory cycle for stable respiration" (either a historical patient-specific average or a multi-patient average) in the manner recited in Applicants' claim 132.

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' claim 132, and therefore fails to anticipate claim 132.

Applicants submit that claim 134 (depending from dependent claim 133) is further patentably distinguishable over Bolea. In particular, Applicants' claim 134 recites "each stimulation period of each respective stimulation cycle has a duration greater than a duration of the inspiratory reference of the reference respiratory cycle" and further recites that "the stimulation period is followed by the non-stimulation period of the respective stimulation cycle comprising a duration less than the duration of the stimulation period."

Paragraph 420 of Bolea (cite in the Office Action) addresses ramping stimulation intensity, the number of pulses per second, amplitudes, and pulse width. The Paragraph concludes by stating that "Each of these ramp methods would require a predictive algorithm that would stimulate based on the previous inspiration cycle."

Accordingly, this Paragraph 420 does not even remotely address the recitation in Applicants' claim 134 of a duration of a stimulation period being greater than a "duration of the

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inspiratory reference of the reference respiratory cycle" and Paragraph 420 does not address the recitation in Applicants' claim 134 of the non-stimulation period (of a stimulation cycle) having a duration less a duration of the stimulation period.

Paragraph 357 of Bolea (cited in the Office Action) addresses measuring an inspiratory stage and related effort for comparison to a threshold, such as to identify a disordered breath if the inspiratory period is at least 40% of the entire respiratory period. However, this Paragraph 357 does not even remotely address a stimulation cycle as recited in claim 134, and more particularly, Paragraph 357 of Bolea does not address either the duration of a stimulation period or the duration of a non-stimulation period in the manner recited in Applicants' claim 134.

Among other things, Paragraph 129 of Bolea (cited in the Office Action) addresses that "the stimulus may be delivered for only a portion of the respiratory cycle, such as during inspiration which corresponds to negative pressure in the upper airway" and addresses triggering the stimulation. Paragraph 129 also cautions against overstimulation, while stating that "a 40% to 50% duty cycle may be safely tolerated, thus enabling limited over-stimulation." However, neither of these portions nor other portions of Paragraph 129 meet the recitations of claim 134.

The Abstract of Bolea (cited in the Office Action) states:

> A method of treating a patient, comprising: sensing a biological parameter indicative of respiration; analyzing the biological parameter to identify a respiratory cycle; identifying an inspiratory phase of the respiratory cycle; and delivering stimulation to a hypoglossal nerve of the patient, wherein stimulation is delivered if a duration of the inspiratory phase of the respiratory cycle is greater than a predetermined portion of a duration of the entire respiratory cycle.

However, this Abstract does not even remotely address a stimulation cycle as recited in claim 134, and more particularly, Paragraph 357 of Bolea does not address either the duration of a stimulation period or the duration of a non-stimulation period *in the manner recited* in Applicants' claim 134. Rather, the Abstract identifies merely that "stimulation is delivered **IF** a duration of the inspiratory phase of the respiratory cycle is greater than a predetermined portion of a duration of the entire respiratory cycle."

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Therefore, the Office Action has failed to state a prima facie case of unpatentability based on anticipation because, in citing Bolea, the Office Action has failed to meet each and every recitation of Applicants' claim 134, and therefore Bolea fails to anticipate claim 134.

Applicants submit that claim 137 (depending from dependent claim 134) is further patentably distinguishable over Bolea. First, claim 137 depends from at least claim 134, and is therefore patentable over Bolea for at least the reasons explained above regarding claim 134 and/or patentable for the reasons explained above regarding independent claim 129 and (additional intervening claims 132, 133). In particular, Applicants' claim 137 recites that "the duration of each respective stimulation cycle is less than the duration of the reference respiratory cycle, and a duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of at least 3.

Paragraphs 492-499 of Bolea (cited in the Office Action) appear in association with FIGS. 80A-80C. As shown in FIG. 80C and described in at least Paragraph 496, the duration of each (of several) predicted respiratory period coincides with (e.g. matches) a duration of a combination of a stimulation period and a period of no-stimulation.

This arrangement in Bolea directly conflicts with the recitation in Applicants' claim 137 that "the duration of each respective stimulation cycle is <u>less than</u> the duration of the reference respiratory cycle," wherein the base independent claim 129 (from which claim 137 indirectly depends) recites that "each stimulation cycle includes a stimulation period and a non-stimulation period." Via Applicant's claimed arrangement, the duration of the stimulation cycle does not match or coincide with the duration of the reference respiratory cycle, such that upon the application of multiple stimulation cycles, the stimulation period will coincide with a different portion of each reference respiratory cycle of a sequence of reference respiratory cycles. This arrangement may ensure that "no matter where the stimulation protocol is started relative to the pattern of ongoing reference respiratory cycles, the stimulation period of each stimulation cycle will overlap with at least a portion of the inspiratory phase of the reference respiratory cycles for

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a significant majority of the treatment period." See, for example, Applicants' specification at 0049.

Moreover, as previously noted in association with at least claim 129, Applicants' arrangement "a first stimulation therapy protocol [is] not synchronized relative to actively-sensed respiratory information", which stands in sharp contrast to the arrangement in FIGS. 80A-80C (Paragraphs 492-499, particularly Paragraph 496) in which "the stimulation timing remains synchronous to the last detected peak" and in which the stimulation period is centered at 75% of the respiratory period from the last detected peak, as shown in FIG. 80B (Paragraph 495).

Finally, Applicants respectfully traverse the assertion in the Office Action regarding the comparison of the 69% to the recitation of "a factor of at least 3" because the duty cycle in Bolea of 69% is a maximum (e.g. not to exceed), whereas the recited ratio of at least 3:1 is a minimum. Therefore, contrary to the assertion in the Office Action the maximum quantity of 69% in Bolea cannot reasonably or fairly be equated to the recitation of a ratio of at least 3:1 in Applicants' claim 137.

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' claim 137, and therefore fails to anticipate claim 137.

Applicants submit that claim 139 (depending from dependent claim 129) is further patentably distinguishable over Bolea. First, claim 139 depends from at least claim 134, and is therefore patentable over Bolea for at least the reasons explained above regarding independent claim 129.

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' claim 139, and therefore fails to anticipate claim 139.

Applicants submit that claim 140 (depending from dependent claim 134) is further patentably distinguishable over Bolea. First, claim 140 depends from claim 134, and is therefore patentable over Bolea for at least the reasons explained above regarding claim 134 and/or

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patentable for the reasons explained above regarding independent claim 129 and (additional intervening claims 132, 133) from which both claims 134 and 140 depend.

Second, Applicants note that the portions of Bolea (e.g. at least FIGS. 64A-64D, FIGS. 80A-80D with Paragraphs 492-499) cited in the Office Action cannot be reasonably be asserted to meet the recitations of all three of Applicants' claim 137 ("the duration of each respective stimulation cycle is less than the duration of the reference respiratory cycle"), Applicants' claim 138 ("the duration of each respective stimulation cycle is greater than the duration of the reference respiratory cycle"), and Applicants' claim 140, which recites "the duration of each respective stimulation cycle is equal to the duration of the reference respiratory cycle."

Moreover, Applicants further submit that the assertion in the Office Action is not supportable by the cited portions of Bolea. In particular, Applicants' claim 140 recites that "the duration of the reference respiratory cycle differs from a duration of a real time respiratory cycle from actively-sensed respiration information by an amount exceeding a duration variability criteria."

For example, within the cited portions of Bolea, Paragraph 0496 states:

> A feature common to the predictive algorithms is illustrated in FIG. 80C. This feature provides a sequence of predicted respiratory periods in case the respiration impedance signal ("Z") is temporarily lost (e.g., due to change in respiratory effort). Until a subsequent respiratory peak is detected, stimulation parameters which are based on the measured respiratory period (e.g., stimulation period) are unchanged. Thus, stimulation timing remains synchronous to the last detected peak

By referencing the "respiration signal ("Z") is temporarily lost" and "Until a subsequent respiratory peak is detected", this passage of Bolea would clearly indicate to one skilled in the art the expectation in Bolea to normally perform stimulation synchronized to sensed respiration, which directly conflicts with base independent claim 129 ("first stimulation therapy protocol not synchronized relative to actively-sensed respiratory information") from which claim 140 depends indirectly.

Moreover, this passage in Paragraph 496 would further indicate to one skilled in the art that upon the respiratory signal being lost, no comparison (e.g. do the values differ ?) could

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reasonably be made between "a duration of a real time respiratory cycle of actively sensed respiration" and "the duration of the reference respiratory cycle" as recited in Applicants' claim 140. Accordingly, the arrangement in the cited portions of Bolea cannot reasonably meet the recitations of Applicants' claim 140.

With this in mind, this passage of Bolea fails to contemplate a "duration variability criteria" in the manner recited in Applicants' claim 140 by which it is determined to whether apply each respective stimulation cycle having a duration equal to the duration of the reference respiratory cycle. For example, see at least Paragraph 238 in Applicants' specification and at least 506 in FIG. 15B.

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' claim 140, and therefore fails to anticipate claim 140.

Applicants submit that independent claim 143 is patentable over Bolea for at least some of substantially the same reasons as previously presented in favor of the patentability of independent claim 129 and/or its dependent claims.

Moreover, Applicants submit that claim 143 is further patentably distinguishable over Bolea at least because independent claim 143 recites "a sensing element to obtain respiratory information via at least periodically sensing a respiratory waveform unrelated to stimulation synchronization" which stands in sharp contrast to the cited portions of Bolea use of a sensed respiratory signal used for synchronization (e.g. at least Paragraphs 471, 496 "stimulation timing remains synchronous to the last detected peak").

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' independent claim 140, and therefore fails to anticipate independent claim 140.

Applicants submit that independent claim 148 is patentable over Bolea for at least some of substantially the same reasons as previously presented in favor of the patentability of independent claim 129 and/or independent claim 143.

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Moreover, Applicants submit that claim 148 is further patentably distinguishable over Bolea at least because

For at least the reasons previously described in association with claim 129, Bolea (as cited in the Office Action) fails to provide for "a stimulation therapy protocol not synchronized to respiratory information" as recited in independent claim 148, and therefore Bolea also fails to disclose the recitation in Applicants' independent claim 148 for "instructions, executable via the processor, to: provide convertible operation via a therapy manager between:

a first stimulation mode implementing the first stimulation therapy protocol; and

a second stimulation mode of stimulating the upper-airway-patency-related nerve synchronous with a characteristic of the sensed respiratory waveform.

Moreover, the portions of Bolea cited regarding claim 148 also fails to disclose the "convertible operation" in the manner recited in Applicants' independent claim 148. In particular, cited Paragraphs such as Paragraph 498 of Bolea provide an adaptive mode, which can vary (e.g. different percentage) a duty cycle depending on a function of characteristic of respiration. However, it would appear to one skilled in the art that this discussion falls into the discussion relating to FIGS. 80A-80C, which includes Paragraph 496 of Bolea stating that even when a respiratory signal is lost, "stimulation timing remains synchronous to the last detected peak."

Accordingly, Bolea fails to disclose the "convertible operation" recited in Applicants' claim 148 at least because the cited portions of Bolea fails to disclose the first stimulation mode recited in Applicants' claim 148.

In view of the above, Applicants respectfully request withdrawal of the Section 102 rejections.

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Claim Rejections under 35 U.S.C. § 103

Claim 131 is rejected under 35 U.S.C. 103, as being unpatentable over Bolea in view of Bashyam (US 2014/0135868).

Applicants submit that the Bashyam fails to cure the above-demonstrated deficiencies of Bolea regarding Applicants' independent claim 129, and therefore the cited combination of Bolea and Bashyam fails to reasonably make obvious Applicants' independent claim 129, and its dependent claim 131.

For at least these reasons, Applicants submit that the cited combination of Bolea and Bashyam fail to reasonably make obvious Applicants' claim 131.

Claims 135-136, 138 and 144-147 are rejected under 35 U.S.C. 103 as being unpatentable over Bolea in view of Tehrani (US 8,280,513).

Applicants submit that Tehrani fails to cure the above-demonstrated deficiencies of Bolea regarding independent claim 129 (from which claims 135-136, 138 depend) such that claims 135-136 and 138 are patentable at least based on the reasons previously presented in favor of the patentability of independent claim 129.

Applicants submit that claim 138 (depending from dependent claim 134) is further patentable over the cited combination of Bolea and Tehrani.

Claim 138 recites "the duration of each respective stimulation cycle is greater than the duration of the reference respiratory cycle", while base independent claim 129 recites that the stimulation cycle comprises a stimulation period and a non-stimulation period.

Like Applicants' claim 137, in claim 138 the duration of each stimulation cycle does not match the duration of reference respiratory cycle, and therefore Applicants' claimed arrangement stands in sharp contrast to the arrangement in Bolea (e.g. cited FIGS. 64A-64C, 80A-80C) in which a duration of a stimulation cycle (stimulation period plus non-stimulation period) matches the duration of the predicted respiratory cycle.

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For possibly at least this reason and/or other reasons, the Office Action also effectively admits that Bolea does not anticipate Applicants' claim 138 because it cites to Tehrani to cure some deficiency of Bolea.

Moreover, claim 138 depends from intervening claim 134, and is therefore patentable over Bolea for at least the reasons explained above regarding claim 134 and/or patentable for the reasons explained above regarding independent claim 129 and (additional intervening claims 132, 133) from which both claims 134 and 138 depend.

For instance, regarding claim 134 (from which claim 138 depends), FIG. 7C of Tehrani (cited in the Office Action against claim 138) illustrates that a duration of a non-stimulation period (e.g. "OFF") is significantly greater than a duration of the stimulation period (e.g. "ON"), which directly conflicts with the recitation in Applicants' claim 134 (from which claim 138 depends) that "the non-stimulation period of the respective stimulation cycle compris[es] a duration less than the duration of the stimulation period." For this reason alone, Tehrani cannot cure the deficiencies of Bolea and/or meet the recitations of Applicants' claim 138.

Moreover, Tehrani fails to cure the deficiencies of Bolea regarding Applicants' claim 132 because Tehrani fails to meet the recitations of Applicants' claim 132, from which claims 134 and 138 depend, at least because Tehrani fails to address a reference respiratory cycle in the manner recited in Applicants' claim 132, with the term "reference respiratory cycle" appearing in claim 138.

In view of all these deficiencies of Bolea and/or Tehrani, as viewed by one skilled in the art, it is unclear how and/or why the cited portions of Tehrani (FIG. 7C) purportedly meet the recitations of claim 138 with Bolea.

With these deficiencies in mind, the rejection of claim 138 also fails to state a rationale of how and/or why one skilled in the art would seek to combine Tehrani with Bolea in view of the particular subject matter disclosed in Bolea and in Tehrani relative to the particular recitations of Applicants' claim 138 and the claim 134 from which claim 138 depends.

For at least these reasons, Applicants submit that the cited combination of Bolea and Tehrani fail to reasonably make obvious Applicants' claim 138.

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Applicants submit that Tehrani fails to cure the above-demonstrated deficiencies of Bolea regarding independent claim 143 (from which claims 144-147 depend) such that claims 144-147 are patentable at least based on the reasons previously presented in favor of the patentability of independent claims 129 and 143.

Regarding claim 144, Applicants submit that the Tehrani fails to cure the above-demonstrated deficiencies of Bolea regarding Applicants' independent claim 143, and therefore the cited combination of Bolea and Tehrani fails to reasonably make obvious Applicants' independent claim 143, and its dependent claim 144.

Tehrani is apparently cited because of an admitted deficiency of Bolea regarding Applicants' claim 144.

However, as viewed by one skilled in the art it is unclear how and/or why the cited portions of Tehrani (Col. 2, line 30 to Col. 3, line 59; Col. 8, lines 4-56; and all FIGS. 1A-10C) purportedly meet the recitations of claim 144, and it is unclear how and/or why the cited portion of Tehrani purportedly cures the deficiencies of Bolea because the Office Action has not mapped the substance of the cited portions of Tehrani (or Bolea) to each and every recitation of Applicant's claim 144.

For example, it would not be apparent to one skilled in the art how or which portion of Tehrani meets the recitation in Applicants' claim 144, with regard to the first function, "each stimulation cycle has a duration different from the duration of the reference respiratory cycle." In this regard, Applicants have previously demonstrated above that the cited portions of Bolea failed to address similar recitations in Applicants' claims 137 (e.g. duration less than) and/or 138 (e.g. duration greater than). Applicants also submit that the Office Action fails to meet the recitations of claim 144 for reasons similar to those presented in favor of patentability of Applicants' claim 140.

With these deficiencies in mind, the rejection of claim 144 also fails to state a rationale of how and/or why one skilled in the art would seek to combine Tehrani with Bolea in view of the

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particular subject matter disclosed in Bolea and in Tehrani relative to the particular recitations of Applicants' claim 144.

For at least these reasons, Applicants submit that the Office Action fails to state a prima facie case of unpatentability for Applicant's claim 145, and therefore, the cited combination of Bolea and Tehrani fails to reasonably make obvious Applicants' claim 145.

Regarding Applicants' claim 145, Applicants submit that the Tehrani fails to cure the above-demonstrated deficiencies of Bolea regarding Applicants' independent claim 143, and therefore the cited combination of Bolea and Tehrani fails to reasonably make obvious Applicants' independent claim 143, and its dependent claim 145.

Tehrani is apparently cited because of an admitted deficiency of Bolea regarding Applicants' claim 145.

For the reasons extensively presented above, the cited Paragraphs of Bolea (e.g. 473-474, 492-499) fail to meet the recitation "the sensing element is configured to be in an inactive state by default and is periodically, temporarily activated to sense respiration information to perform calibrating the reference respiratory cycle relative to the sensed respiratory information." In particular, while Paragraph 473 mentions situations in which "the respiratory signal is lost," these Paragraphs of Bolea apparently do not contemplate a sensing element (e.g. bio-impedance) being placed into "an inactive state by default" in the manner recited in Applicants' claim 145. Rather, as viewed by one skilled in the art, the default state in the cited portions of Bolea apparently is to perform bio-impedance sensing for respiratory information, which stands in sharp contrast to Applicants' claim 145.

Moreover, at least because the default state in Bolea would appear to one skilled in the art as using respiratory sensing, then Bolea likewise fails to meet the recitation in Applicants' claim 145 of the sensing element being configured to be "periodically, temporarily activated to sense respiratory information to perform calibrating the reference respiratory cycle relative to the sensed respiratory information.

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Tehrani fails to cure the deficiencies of Bolea. In particular, as viewed by one skilled in the art it is unclear how and/or why the cited portions of Tehrani (Col. 2, line 30 to Col. 3, line 59; FIGS 4-5C) purportedly meet the recitations of claim 145, and it is unclear how and/or why the cited portion of Tehrani purportedly cures the deficiencies of Bolea as the Office Action has not mapped the substance of the cited portions of Tehrani to each and every recitation of Applicant's claim 145.

With this in mind, the rejection of claim 145 also fails to state a rationale of how and/or why one skilled in the art would seek to combine Tehrani with Bolea in view of the particular subject matter disclosed in Bolea and in Tehrani relative to the particular recitations of Applicants' claim 145.

For at least these reasons, Applicants submit that the Office Action fails to state a prima facie case of unpatentability for Applicant's claim 145, and therefore, the cited combination of Bolea and Tehrani fails to reasonably make obvious Applicants' claim 145.

In view of the above, Applicants respectfully request withdrawal of the Section 103 rejections.

New Claims

New claim 149 depends from claim 138 and recites that the duration of the stimulation cycle is less than a duration of two consecutive reference respiratory cycles. Among other differences from Bolea and Tehrani, the recitations of claim 138 and its dependent claim 149 include "the duration of each respective stimulation cycle is greater than the duration of the reference respiratory cycle" and "the duration of the stimulation cycle is less than a duration of two consecutive reference respiratory cycles." These recitations directly conflict with the cited portion of Tehrani (e.g. FIG. 7C) which shows a stimulation cycle (stimulation period plus non-stimulation period), which has a duration of approximately nine respiratory cycles (e.g. FIG. 7A). Applicants also note that the cited combination of Bolea and Tehrani conflicts with Applicants' claim 134 from which claims 138 and 149 depend.

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New claim 150 depends from claim 129 and recites that the stimulation period and the non-stimulation period are in a proportion of at least 1.5 to 1.

Applicants respectfully request favorable consideration and allowance of new claims 149-150.

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CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 129-150 are in form for allowance and are not taught or suggested by the cited references.

Please consider this a Petition for Extension of Time for a sufficient number of months to enter these papers, if appropriate. At any time during the pendency of this application, please charge any additional fees or credit overpayment to Deposit Account No. 500471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Paul S. Grunzweig at Telephone No. (612) 767-2504, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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EXAMINER	
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ART UNIT	PAPER NUMBER
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NOTIFICATION DATE	DELIVERY MODE
04/02/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBCLAW-Docket@dbclaw.com
USPTO.PATENTS@dbclaw.com
dmorris@dbclaw.com

Office Action Summary	Application No. 15/562,714	Applicant(s) Wagner et al.	
	Examiner MICHAEL J LAU	Art Unit 3792	AIA (FITF) Status Yes

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 1/29/2020.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 129-150 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 129-133,135-136,141-148 and 150 is/are rejected.

8) ☑ Claim(s) 134,137-140 and 149 is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____

4) ☐ Other: _____

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0366

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/2020 has been entered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 129-130 and 141-142 are rejected under 35 U.S.C. 103 as being unpatentable over multiple embodiments of Christopherson (US 5944680 A1).

6. Regarding claim 129, Christopherson discloses a device for treating obstructive sleep apnea (eg. Col. 7, Ln. 25-45), comprising a non-cardiac stimulation element to engage and to stimulate an upper-airway patency-related nerve (eg. Col. 7, Ln. 25-64 upper airway nerves or hypoglossal nerve), in

multiple embodiments according to a first stimulation therapy protocol not synchronized relative to the actively-sensed respiratory information (Col. 30, Ln. 53 – Col. 31, Ln. 1-11, asynchronous stimulations when the respiration signals are too low), and the first stimulation therapy protocol comprises a series of repeating stimulation cycles in which each stimulation cycle includes a stimulation period and a non-stimulation period (eg. Fig. 16C, Col. 31-40, stimulation periods and refractory or non-stimulation periods).

7. It would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have combined the multiple embodiments of Christopherson to extend treatments to different types of apnea where the central nervous system cannot provides no drive to breathe by asynchronously giving stimulation pulse trains until respirations return (Christopherson, Col. 30, Ln. 53 – Col. 31, Ln. 1-11)

8. Regarding claim 130, Christopherson discloses the non-cardiac stimulation element comprises an implantable electrode and a pulse generator electrically connected to the implantable electrode (Fig. 5, system 50, Col. 7 Ln. 45-64).

9. Regarding claim 141, Christopherson discloses a processor and non-volatile computer readable medium storing instructions, executable on the processor to implement the first stimulation element and perform the first stimulation protocol (eg. Fig. 12A-B, Col. 5, Ln. 30-45).

10. Regarding claim 142, Christopherson discloses a cuff electrode placed around a hypoglossal nerve (Col. 7, Ln. 25-44).

11. Claim 131 is rejected under 35 U.S.C. 103 as being unpatentable over by Christopherson (US 5944680 A1) in view of Bashyam (US 2014/0228905 A1).

12. Regarding claim 131, Christopherson discloses the invention of claim 129, but does not disclose a total duration of the first protocol stimulation greater than 30% of total duration of period.

13. Bashyam teaches a fixed mode stimulation of the hypoglossal nerve having a duration of 1 minute to 12 hours of a pre-defined pattern (Para. 71).

14. It would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have combined the invention of Christopherson with the teachings of Bashyam to have a default mode while the patient is sleeping. While Bashyam does not specifically say the first mode has to be at least 30%, one of ordinary skill would be able to program the stimulation to run for the majority of a user's sleep duration.

15. Claims 132-133, 143, and 148 are rejected under 35 U.S.C. 103 as being unpatentable over by Christopherson (US 5944680 A1) in view of Bolea (US 2014/0228905 A1).

16. Regarding claim 132, Christopherson discloses the invention of 129 and a continuous stimulation (Col. 30, Ln. 53 - Col.31, Ln. 11) and tailoring stimulation refractory periods based on patient average (Col. 23, Ln. 43- Col. 24, Ln. 35, running average), but does not disclose each stimulation period has a minimum duration equal to or greater than an inspiratory reference of a reference respiratory cycle.

17. Bolea teaches applying stimuli with a duty cycle set for an average inspiratory duration at a frequency equal to an average respiratory cycle (eg. Para. 129) and tailoring stimulation periods based on historical data (eg. Para. 495).

18. It would have been obvious to one of ordinary skill in the art to have combined the invention of Christopherson with the stimulation period algorithm taught by Bolea to provide an appropriate stimulation for a patient when the weak respiration signal is identified by Christopherson.

19. Regarding claim 133, the combined invention of Christopherson and Bolea disclose the inspiratory reference corresponds to a duration of an inspiratory phase of the reference respiratory cycle (eg. Para. 129, independent average inspiratory duration, reference being an average).

20. Regarding claim 143, the combined invention of Christopherson and Bolea discloses a device for treating obstructive sleep apnea (Christopherson, eg. Col. 7, Ln. 25-45) comprising: a noncardiac stimulation element to stimulate an upper airway patency related nerve (Christopherson, eg. Col. 7, Ln. 25-64 upper airway nerves or hypoglossal nerve), according to a first stimulation protocol not synchronized relative to respiratory information wherein the first stimulation protocol comprises a series of repeating stimulation cycles in which each stimulation cycle includes a stimulation period and a nonstimulation period and wherein each respective stimulation cycle comprises related to a duration of a reference respiratory cycle (Christopherson, Col. 30, Ln. 53 – Col. 31, Ln. 1-11, asynchronous stimulations when the respiration signals are too low and Bolea, eg. Para. 473-474 and 515 fixed mode stimulation); and a sensing element to obtain respiratory information via at least periodically sensing a respiratory waveform unrelated to stimulation synchronization (Bolea, Fig. 1, 70), wherein the non-cardiac stimulation element is activated for stimulation upon the sensing element identifying, via at least the respiratory information, obstructive sleep apnea behavior which meets or exceeds a severity threshold (Bolea, Para. 357 and 487) and is deactivated upon the sensing element identifying via at least the respiratory information that the obstructive sleep apnea behavior is less than the severity threshold (Christopherson, Col. 30, Ln. 53 – Col. 31, Ln. 1-11, asynchronous stimulations when the respiration signals are too low and Bolea, Abstract, Para. 492-499, 577 turns off below threshold).

21. Regarding claim 148, the combined invention of Christopherson and Bolea discloses device for treating obstructive sleep apnea (Christopherson, eg. Col. 7, Ln. 25-45) comprising: a non-cardiac stimulation element to stimulate an upper-airway-patency-related nerve (Christopherson, eg. Col. 7, Ln. 25-64 upper airway nerves or hypoglossal nerve), according to a first stimulation protocol not synchronized relative to respiratory information, wherein the first stimulation protocol comprises a series of repeating stimulation cycles, in which each stimulation cycle includes a stimulation period and a non-stimulation period and wherein each respective stimulation cycle comprises a duration related to

a duration of a reference respiratory cycle (Bolea, Para. 473-474, and 515 fixed mode); a sensing element to receive respiratory information (Bolea, Fig.1, 70); and a processor (Para. 136); and provide convertible operation via a therapy manager between: a first stimulation mode implementing the first stimulation protocol; and a second stimulation mode of stimulating the upper-airway- patency-related nerve synchronous with a characteristic of the sensed respiratory waveform (Bolea, Para. 355-357, 473-474, 492-499 adaptive mode).

22. Claims 135-136 are rejected under 35 U.S.C. 103 as being unpatentable over by Christopherson (US 5944680 A1) in view of Tehrani (US 8280513 B2).

23. Regarding claims 135-136, Christopherson discloses the invention of claim 129 but not the 50 percent duration of the stimulation period being 50 percent of a duration of the stimulation cycle or reference respiratory cycle.

24. Tehrani teaches on and off stimulation periods (Col. 17, Ln. 1-20) with the duration being 25%/50%/80% of a duration of the stimulation and reference cycles (Tehrani, Fig. 7A-10C, Col. 17, Ln. 14-53).

25. It would have been obvious to combine the invention of Christopherson with the stimulation configuration taught by Tehrani to provide increased negative flow and increased positive pressure in the upper airway during exhalation (Tehrani, col. 17, Ln. 17-20).

26. Claims 144-147, and 150 are rejected under 35 U.S.C. 103 as being unpatentable over by Christopherson (US 5944680 A1) in view of Bolea (US 2014/0228905 A1), further in view of Tehrani (US 8280513 B2).

27. Regarding claim 144, the combined invention of Christopherson and Bolea discloses the invention of claim of 143, but does not disclose the stimulation element includes a function selector to

automatically select, for the first stimulation protocol, between: a first function to apply the stimulation in which each stimulation cycle has a duration different from the duration of the reference respiratory cycle, when the duration of the respiratory cycles in the sensed respiratory information is less variable than a respiratory duration variability criteria ; and a second function to apply the stimulation in which each stimulation cycle has a duration matching the duration of the respiratory cycle reference, when the duration of respiratory cycles in the sensed respiratory information is more variable than the respiratory duration variability criteria.

28. Tehrani teaches the stimulation element includes a function selector to automatically select (Tehrani, Col. 2, Ln. 30- Col. 3, Ln. 59), for the first stimulation protocol, between: a first function to apply the stimulation in which each stimulation cycle has a duration different from the duration of the reference respiratory cycle, when the duration of the respiratory cycles in the sensed respiratory information is less variable than a respiratory duration variability criteria; and a second function to apply the stimulation in which each stimulation cycle has a duration matching the duration of the respiratory cycle reference, when the duration of respiratory cycles in the sensed respiratory information is more variable than the respiratory duration variability criteria (Tehrani, Fig. 1A-10C, Col. 8, Ln. 4-56).

29. It would have been obvious to combine the invention of Christopherson and Bolea with the function selector taught by Tehrani to improve adjustability to parameters or protocol during device usage (eg. Col. 3, Ln. 16-54).

30. Regarding claim 145, the combined invention of Chrstopherson, Bolea, and Tehrani discloses the sensing element is configured to be in an inactive state by default and is periodically, temporarily activated to sense respiratory information to perform calibrating the reference respiratory cycle relative to the sensed respiratory information (Bolea, 473-474 and 492-499 and Tehrani, Fig. 4-5C, Col.2, Ln. 30-Col.3, Ln. 59).

31. Regarding claim 146, the combined invention of Christopherson, Bolea, and Tehrani discloses a processor, and a non-volatile memory storing instructions executable via processor (Bolea, Para. 136, 462) to: evaluate the first stimulation protocol relative to the reference respiratory cycle based on the obtained respiratory information; and modify, in response to the evaluation, at least one of the reference respiratory cycle and the first stimulation protocol, wherein modifying the first stimulation protocol includes at least one of: adjusting features of the first stimulation protocol; and substituting a different stimulation protocol for the first stimulation protocol (Tehrani, Fig. 4-5C, Col. 2, Ln. 30-Col. 3, Ln. 49, Col. 4, Ln. 41-46) and (Bolea, Para. 473-474, 492-499).

32. Regarding claim 147, the combined invention of Christopherson, Bolea and Tehrani discloses a therapy manager (Processor, Bolea Para. 136) evaluates the sensed respiratory information, and upon a determination that the first stimulation protocol fails to result in the detected obstructive sleep apnea behavior being less than the severity threshold or that the sensed respiratory information fails to meet a sensor signal quality criteria, the therapy manager is to convert operation of the first stimulation element from the first stimulation protocol to a second stimulation protocol in which stimulation is applied continuously for at least two respiratory cycles or until the detected obstructive sleep apnea behavior is less than the severity threshold (Bolea, Para. 473-474, 492-499) and (tehrani, Fig. 1-10C, Col. 2, Ln. 30-Col. 3, Ln. 59).

33. Regarding claim 150, the combined invention of Christopherson, Bolea, and Tehrani discloses the stimulation and non-stimulation period are in a proportion of at least 1.5 to 1 (Tehrani, Fig. 7A-10C, Col. 17, Ln. 14-53.

Allowable Subject Matter

34. Claims 134, 137-140, and 149 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J LAU whose telephone number is (571)272-2317. The examiner can normally be reached on 8-5:30 PM.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHAEL J LAU/
Examiner, Art Unit 3792

/CARL H LAYNO/
Supervisory Patent Examiner, Art Unit 3792

Notice of References Cited	Application/Control No. 15/562,714	Applicant(s)/Patent Under Reexamination Wagner et al.	
	Examiner MICHAEL J LAU	Art Unit 3792	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-7340302-B1	03-2008	Falkenberg; Eric	A61N1/3611	607/9
*	B	US-20100174341-A1	07-2010	Bolea; Stephen L.	A61N1/3601	607/42
*	C	US-5944680-A	08-1999	Christopherson; Mark A.	A61B5/03	128/897
*	D	US-20120290036-A1	11-2012	Karamanoglu; Mustafa	A61N1/3601	607/42
*	E	US-20160022204-A1	01-2016	Mostov; Kirill	A61B5/0002	600/301
*	F	US-20140364919-A1	12-2014	Doan; Que T.	A61N1/36071	607/46
*	G	US-20060247729-A1	11-2006	Tehrani; Amir J.	A61N1/3601	607/42
*	H	US-20100198289-A1	08-2010	Kameli; Nader	A61B5/00	607/14
*	I	US-8280513-B2	10-2012	Tehrani; Amir J.	A61N1/3601	600/529
*	J	US-8265759-B2	09-2012	Tehrani; Amir J.	A61N1/3601	607/20
*	K	US-8233987-B2	07-2012	Gelfand; Mark	A61N1/3601	607/42
*	L	US-20110093032-A1	04-2011	Boggs, II; Joseph W.	A61B5/415	607/42
*	M	US-20140135868-A1	05-2014	BASHYAM; JACOB BASHYAM	A61F5/566	607/42

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0376

Notice of References Cited	Application/Control No. 15/562,714	Applicant(s)/Patent Under Reexamination Wagner et al.	
	Examiner MICHAEL J LAU	Art Unit 3792	Page 2 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20140228905-A1	08-2014	BOLEA; Stephen L.	A61N1/0556	607/42
*	B	US-20110288609-A1	11-2011	TEHRANI; Amir J.	A61N1/3601	607/42
*	C	US-7809442-B2	10-2010	Bolea; Stephen L.	A61N1/3606	607/42
*	D	US-20120192874-A1	08-2012	BOLEA; Stephen L.	A61N1/36139	128/848
	E					
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
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	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0377

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/562,714	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

CPC - Searched*		
Symbol	Date	Examiner
A61B5/3601,0816,0826,113,4818,4848,686	12/21/2018	ML
A61B1/36135	12/21/2018	ML
A61N1/3611,36135,36146,36171	12/21/2018	ML
G06F19/3481	12/21/2018	ML

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
607	42, 72, 73	12/21/2018	ML

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Inventor search on PALM, Prior art search on east, consulted spe carl layno for search strategy	12/21/2018	ML
updated search on east	08/21/2019	ML
updated search on east	03/28/2020	ML

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/MICHAEL J LAU/ Examiner, Art Unit 3792	

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0378

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/562,714	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

/MICHAEL J LAU/ Examiner, Art Unit 3792	

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/562,714	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/21/2018	08/21/2019	03/28/2020						
	129	✓	✓	✓						
	130	✓	✓	✓						
	131	✓	✓	✓						
	132	✓	✓	✓						
	133	✓	✓	✓						
	134	✓	✓	O						
	135	✓	✓	✓						
	136	✓	✓	✓						
	137	✓	✓	O						
	138	✓	✓	O						
	139	✓	✓	O						
	140	✓	✓	O						
	141	✓	✓	✓						
	142	✓	✓	✓						
	143	✓	✓	✓						
	144	✓	✓	✓						
	145	✓	✓	✓						
	146	✓	✓	✓						
	147	✓	✓	✓						
	148	✓	✓	✓						
	149			O						
	150			✓						

Exhibit 1002
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0380

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	49	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (period or duration or width or pulse adj width) with (stimul$2 or stimulat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 14:43
L2	12	sleep adj apnea and @pd<"20150319" and (reference) with (respirat$ or breath$) with (period or duration or width or pulse adj width) with (stimul$2 or stimulat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 14:53
L3	0	sleep adj apnea and @pd<"20150319" and (reference) with (inspirat$) with (period or duration or width or pulse adj width) with (stimul$2 or stimulat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 14:53
L4	5	sleep adj apnea and @pd<"20150319" and (reference) with (inspirat$) with (stimul$2 or stimulat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 14:55
L5	47	sleep adj apnea and @pd<"20150319" and (reference or sample or average or mean or database) with (inspirat$) with (stimul$2 or stimulat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 15:20
L9	137	sleep adj apnea and @pd<"20150319" and (reference or sample or average or mean or database) same (inspirat$) same (stimul$2 or stimulat$) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 16:03
L10	662	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2020/03/28 16:08
L11	13235	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 16:08
L12	3475	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 16:08
L13	3475	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 16:08
L14	7461	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 16:08
L15	23481	L10 or L11 or L12 or L13 or L14	US-PGPUB; USPAT	OR	ON	2020/03/28 16:08
L16	158	L15 and @pd<"20150319" and (reference or sample or average or mean or database) same (inspirat$) same (stimul$2 or stimulat$) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 16:08
L17	80	L15 and @pd<"20150319" and (reference or sample or average or mean or database) with (inspirat$) same (stimul$2 or stimulat$) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 16:08
L18	154	L15 and @pd<"20150319" and (inspirat$) with (stimul$2 or stimulat$) with (length duration width or pulse adj width or pulse$1width or period) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 17:40

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L19	2695	L15 and @pd<"20150319" and (inspirat$) with (longer or greater) (stimul$2 or stimulat$) with (length duration width or pulse adj width or pulse$1width or period) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 17:42
L20	30	L15 and @pd<"20150319" and (inspirat$) with (longer or greater) with (stimul$2 or stimulat$) with (length duration width or pulse adj width or pulse$1width or period) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 17:42
L21	41	L15 and @pd<"20150319" and (inspirat$) with (longer or greater) with (stimul$2 or stimulat$ or pulse) with (length duration width or pulse adj width or pulse$1width or period) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 17:45
L22	38	sleep adj apnea and @pd<"20150319" and (inspirat$) with (longer or greater) with (stimul$2 or stimulat$ or pulse) with (length duration width or pulse adj width or pulse$1width or period) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 17:50
L24	55	@pd<"20150319" and (inspirat$ or inhal$) with (longer or greater) with (stimul$2 or stimulat$ or pulse) with (length duration width or pulse adj width or pulse$1width or period) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 18:00
L25	40	@pd<"20150319" and (inspirat$ or inhal$) with (longer or greater) with (stimul$2 or stimulat$ or pulse) with (length duration width or pulse adj width or pulse$1width or period) same (breath$3 or respirat$) and (hypogloss$ or upper adj airway)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 18:01
S1	1	"7340302".pn.	US-PGPUB; USPAT	OR	ON	2018/12/12 18:58
S2	5	"9750049".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/12 19:26
S3	2	"2010174341".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/12 19:38
S4	0	"2010174341".pn.	US-PGPUB; USPAT	OR	ON	2018/12/12 19:39
S5	1	"20100174341".pn.	US-PGPUB; USPAT	OR	ON	2018/12/12 19:39
S6	3	(US-20100174341-$).did. or (US-7340302-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; EPO	OR	ON	2018/12/13 13:33
S7	2	S6 and (pulse or duration or period)	US-PGPUB; USPAT	OR	ON	2018/12/13 13:33
S8	659	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:38

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S9	10675	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:42
S10	0	A61B1/36135.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:42
S11	2915	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:44
S12	2915	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:44
S13	7232	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:44
S14	20277	S8 or S9 or S11 or S12 or S13	US-PGPUB; USPAT	OR	ON	2018/12/13 14:45
S15	11362	S14 and @pd<"20150319"	US-PGPUB; USPAT	OR	ON	2018/12/13 14:45
S16	66	(darrell near wagner).in.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:48
S17	6	(darrell near wagner).in. and sleep	US-PGPUB; USPAT	OR	ON	2018/12/13 14:51
S18	190	((darrell near wagner) or (ni near quan) or (rondini near john) or (dieken near dave)).in. and sleep	US-PGPUB; USPAT	OR	ON	2018/12/13 14:54
S19	161	((darrell near wagner) or (ni near quan) or (rondini near john) or (dieken near dave)).in. and sleep and @pd<"20150319"	US-PGPUB; USPAT	OR	ON	2018/12/13 14:59
S20	149	((darrell near wagner) or (ni near quan) or (rondini near john) or (dieken near dave)).in. and sleep and @pd<"20150319" and stimulat$3	US-PGPUB; USPAT	OR	ON	2018/12/13 15:24
S21	7	"2010059839".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/13 15:36
S22	5	"5944680".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/13 16:16
S23	293	S14 and @pd<"20150319" and pulse adj duration and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 16:56
S24	84	S14 and @pd<"20150319" and pulse adj (width or duration) same inspiration and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 16:56
S25	54	S14 and @pd<"20150319" and pulse adj (width or duration) same inspiration and sleep adj (apnea or aponea) and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 17:01
S26	4	A61B5/0826.cpc. and @pd<"20150319" and pulse adj (width or duration) same inspiration and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 17:07
S27	4	("20160022204" | "20160354602" | "20160354603" | "20160354608").PN.	US-PGPUB; USPAT	OR	ON	2018/12/13 17:24
S28	235	("20010010010" | "20020010495" | "20020049479" | "20020156507" | "20030093128" | "20030114905" |	US-PGPUB; USPAT	OR	ON	2018/12/13 17:25

"20030163059" | "20030195571" |
"20030216789" | "20030224895" |
"20040015204" | "20040073272" |
"20040111139" | "20040215288" |
"20040230278" | "20040254612" |
"20050004628" | "20050010265" |
"20050042589" | "20050043765" |
"20050043772" | "20050074741" |
"20050076908" | "20050080348" |
"20050080461" | "20050081847" |
"20050085865" | "20050085866" |
"20050085868" | "20050085869" |
"20050085874" | "20050101833" |
"20050113710" | "20050115561" |
"20050145246" | "20050165457" |
"20050182457" | "20050209513" |
"20050209643" | "20050222503" |
"20050234523" | "20050251216" |
"20050261747" | "20050267380" |
"20050277844" | "20050277999" |
"20050278000" | "20060052836" |
"20060058852" | "20060064029" |
"20060079802" | "20060095088" |
"20060103407" | "20060135886" |
"20060142815" | "20060212096" |
"20060224209" | "20060241708" |
"20060247729" | "20060259079" |
"20060264777" | "20060266369" |
"20060271137" | "20060276701" |
"20060293720" | "20060293723" |
"20070021785" | "20070027482" |
"20070038265" | "20070150022" |
"20070233204" | "20070255379" |
"20080009685" | "20080039904" |
"20080046055" | "20080064977" |
"20080103545" | "20080103570" |
"20080109046" | "20080109048" |
"20080132802" | "20080294060" |
"20090024047" | "20090062882" |
"20090112116" | "20090118787" |
"20090234427" | "20090287279" |
"20090308395" | "20090326408" |
"20100010566" | "20100016749" |
"20100094379" | "20100125310" |
"20100125314" | "20100125315" |
"20100137931" | "20100152553" |
"20100174341" | "20100198103" |
"20100198289" | "20100228133" |
"20100228317" | "20100241195" |
"20100262210" | "20110093036" |
"20110112601" | "20110152706" |
"20110152965" | "20110160794" |
"20110264164" | "20150039045" |
"20160193468" | "4379462" | "4567892" |
"4630614" | "4813431" | "4830008" | "5133354"
| "5134995" | "5148802" | "5158080" |
"5167229" | "5174287" | "5178156" | "5203343"
| "5211173" | "5215082" | "5233983" |
"5239995" | "5245995" | "5265624" | "5281219"
| "5300094" | "5335657" | "5344438" |
"5351394" | "5385144" | "5388578" | "5398682"
| "5458137" | "5483969" | "5485851" |
"5522862" | "5524632" | "5540731" | "5540732"
| "5540733" | "5540734" | "5546952" |

		"5549655" | "5588439" | "5591216" | "5605151" | "5645053" | "5671733" | "5797852" | "5823187" | "5843135" | "5895360" | "5904141" | "5919221" | "5944680" | "5999846" | "6015389" | "6021352" | "6025624" | "6041780" | "6099479" | "6120441" | "6125290" | "6125291" | "6126611" | "6132384" | "6134459" | "6144866" | "6175767" | "6181961" | "6198952" | "6223064" | "6240316" | "6248080" | "6249703" | "6251126" | "6269269" | "6307481" | "6309350" | "6314324" | "6342039" | "6345202" | "6361494" | "6393325" | "6449507" | "6450957" | "6456866" | "6509164" | "6522928" | "6532388" | "6572543" | "6574507" | "6587725" | "6609016" | "6609032" | "6629527" | "6641542" | "6645143" | "6647289" | "6651652" | "6654634" | "6665560" | "6666830" | "6689068" | "6703939" | "6718208" | "6719708" | "6731976" | "6731984" | "6735471" | "6752765" | "6770022" | "6773404" | "6805667" | "6811538" | "6842647" | "6881192" | "6890306" | "6893405" | "6904320" | "6907293" | "6928324" | "6935335" | "6936011" | "6964641" | "6978171" | "6988498").PN.				
S29	90	("7025730" | "7041049" | "7054692" | "7077810" | "7081095" | "7082331" | "7082336" | "7087053" | "7117036" | "7128717" | "7145461" | "7149573" | "7155278" | "7160252" | "7160255" | "7167743" | "7174215" | "7186220" | "7187978" | "7189204" | "7195594" | "7200440" | "7206635" | "7212862" | "7214197" | "7252640" | "7269457" | "7269459" | "7277749" | "7330760" | "7336996" | "7340302" | "7351208" | "7366572" | "7371220" | "7387608" | "7395113" | "7396333" | "7398115" | "7422015" | "7438686" | "7447545" | "7453928" | "7454250" | "7468040" | "7469697" | "7473227" | "7491181" | "7510531" | "7526341" | "7542803" | "7572225" | "7590455" | "7591265" | "7596413" | "7603170" | "7610094" | "7634315" | "7644714" | "7662105" | "7672728" | "7678061" | "7680538" | "7702385" | "7717848" | "7720541" | "7725195" | "7734340" | "7734350" | "7742819" | "7747323" | "7751880" | "7775993" | "7783353" | "7792583" | "7809442" | "7818063" | "7853322" | "7881798" | "7908013" | "7917230" | "7942822" | "7957797" | "7957809" | "7979128" | "8016776" | "8021299" | "8150531" | "8160711" | "8175720").PN.	US-PGPUB; USPAT	OR	ON	2018/12/13 17:25
S30	58	S28 and pulse adj (pulse or duration)	US-PGPUB; USPAT	OR	ON	2018/12/13 17:26
S31	8	S28 and pulse adj (pulse or duration) and '25%'	US-PGPUB; USPAT	OR	ON	2018/12/13 17:31
S32	47	S28 and pulse adj (duration or duration)	US-PGPUB; USPAT	OR	ON	2018/12/13 17:32
S33	104	S28 and pulse adj (width or duration)	US-PGPUB; USPAT	OR	ON	2018/12/13 17:32
S34	1	"5944680".pn. and pulse adj (width or duration)	US-PGPUB; USPAT; USOCR;	OR	ON	2018/12/13 17:34

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			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S35	1	("2015/0039045").URPN.	USPAT	OR	ON	2018/12/13 17:57
S36	4	A61B5/0826.cpc. and @pd<"20150319" and pulse adj (width or duration) same inspiration and implant and ramp	US-PGPUB; USPAT	OR	ON	2018/12/13 18:10
S37	0	A61B5/0826.cpc. and @pd<"20150319" and ramp with pulse adj (width or duration) same inspiration and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 18:10
S38	1	A61B5/0826.cpc. and @pd<"20150319" and ramp$3 same pulse adj (width or duration) same inspiration and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 18:11
S39	29	S14 and @pd<"20150319" and ramp with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:13
S40	0	S14 and @pd<"20150319" and full with ramp with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:13
S41	0	S14 and @pd<"20150319" and full same ramp with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:13
S42	0	S14 and @pd<"20150319" and full with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:15
S43	39	S14 and @pd<"20150319" and full same pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:15
S44	826	607/72,73.ccls.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:30
S45	532	607/72,73.ccls. and duration	US-PGPUB; USPAT	OR	ON	2018/12/20 10:30
S46	491	607/72,73.ccls. and @pd<"20150319" and duration	US-PGPUB; USPAT	OR	ON	2018/12/20 10:31
S47	51	607/72,73.ccls. and @pd<"20150319" and duration and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2018/12/20 10:32
S48	80	2006/0247729	US-PGPUB; USPAT	OR	ON	2018/12/20 10:45
S49	1	"20060247729".pn.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:45
S50	1	"20060247729".pn. and duration	US-PGPUB; USPAT	OR	ON	2018/12/20 10:48
S51	0	"2010098289".pn.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:59
S52	1	"20100198289".pn.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:59
S53	78	("2006/0247729").URPN.	USPAT	OR	ON	2018/12/20 11:27
S54	45	("2006/0247729").URPN. and @pd<"20150319"	USPAT	OR	ON	2018/12/20 11:27
S55	44	("2006/0247729").URPN. and @pd<"20150319" and (duration or width)	USPAT	OR	ON	2018/12/20 11:28
S56	15	(US-20100174341-$ or US-20120290036-$ or US-20160354608-$ or US-20160022204-$ or US-	US-PGPUB; USPAT;	OR	ON	2018/12/21 09:27

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		20140364919-$ or US-20060247729-$ or US-20100198289-$).did. or (US-7340302-$ or US-5944680-$ or US-8280513-$ or US-8265759-$ or US-8233987-$).did. or (WO-2010059839-$).did. or (WO-9750049-$).did.	FPRS; EPO			
S57	5	S56 and cuff	US-PGPUB; USPAT	OR	ON	2018/12/21 09:27
S58	15	(US-20100174341-$ or US-20120290036-$ or US-20160354608-$ or US-20160022204-$ or US-20140364919-$ or US-20060247729-$ or US-20100198289-$).did. or (US-7340302-$ or US-5944680-$ or US-8280513-$ or US-8265759-$ or US-8233987-$).did. or (WO-2010059839-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/19 15:36
S59	652	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse adj duration and sleep adj (apnea or apnoea)	US-PGPUB; USPAT	OR	ON	2019/08/19 15:37
S60	28	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse adj duration and sleep adj (apnea or apnoea) same repeat$4	US-PGPUB; USPAT	OR	ON	2019/08/19 15:40
S61	17	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse adj duration and sleep adj (apnea or apnoea) same repeat$4 and hypoglossal	US-PGPUB; USPAT	OR	ON	2019/08/19 15:46
S62	1	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse adj duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal	US-PGPUB; USPAT	OR	ON	2019/08/19 15:49
S63	33	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal	US-PGPUB; USPAT	OR	ON	2019/08/19 15:55
S64	33	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and referenc$3	US-PGPUB; USPAT	OR	ON	2019/08/19 16:00
S65	0	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and referenc$3 adj respirat$4	US-PGPUB; USPAT	OR	ON	2019/08/19 16:01
S66	33	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and referenc$3	US-PGPUB; USPAT	OR	ON	2019/08/19 16:05
S67	26	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and active$3	US-PGPUB; USPAT	OR	ON	2019/08/19 16:05
S68	1	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and active$3 with sens$4	US-PGPUB; USPAT	OR	ON	2019/08/19 16:08
S69	30	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and (first and second)	US-PGPUB; USPAT	OR	ON	2019/08/19 16:38
S70	30	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea)	US-PGPUB; USPAT	OR	ON	2019/08/19 16:43

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		and hypoglossal and (first same second)				
S71	18	(US-20100174341-$ or US-20120290036-$ or US-20160354608-$ or US-20160022204-$ or US-20140364919-$ or US-20060247729-$ or US-20100198289-$ or US-20110093032-$ or US-20140135868-$ or US-20140228905-$).did. or (US-7340302-$ or US-5944680-$ or US-8280513-$ or US-8265759-$ or US-8233987-$).did. or (WO-2010059839-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 08:16
S72	13	S71 and referenc$3	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 09:09
S73	13	S71 and synchron$	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 09:10
S74	12	S71 and mode$1	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:27
S75	7	S71 and fixed	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:46
S76	6	S71 and fixed same (duration$1 or length$1)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:46
S77	0	S71 and fixed same (duration$1 or length$1) same "%"	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:51
S78	0	S71 and fixed same (duration$1 or length$1) same ("%" or percent$4)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:52
S79	4	S71 and (duration$1 or length$1) same ("%" or percent$4)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:54
S80	4	S71 and (duration$1 or length$1) same ("%" or percent$4)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:54
S81	10	S71 and (fixed or repeat$4 or constant) same (duration$1 or length$1)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:55
S82	1	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and fixed same puls$3 same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal	US-PGPUB; USPAT	OR	ON	2019/08/20 10:56
S83	0	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and fixed same puls$3 same duration same repeat$4 and sleep adj (apnea or apnoea) same ("%" or percent$5)	US-PGPUB; USPAT	OR	ON	2019/08/20 10:57
S84	1	S71 and (minim$2) near3 (length$1 or	US-PGPUB;	OR	ON	2019/08/20

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		duration$1)	USPAT			11:21
S85	15	S71 and duration$1	US-PGPUB; USPAT	OR	ON	2019/08/20 11:21
S86	3	S71 and duration$1 same synchron$4	US-PGPUB; USPAT	OR	ON	2019/08/20 11:31
S87	11	S71 and synchron$4	US-PGPUB; USPAT	OR	ON	2019/08/20 11:34
S88	7	S71 and synchron$4 same inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 11:43
S89	10	S71 and (length$1 or duration$1) same inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 11:46
S90	18	(US-20100174341-$ or US-20120290036-$ or US-20160354608-$ or US-20160022204-$ or US-20140364919-$ or US-20060247729-$ or US-20100198289-$ or US-20110093032-$ or US-20140135868-$ or US-20140228905-$).did. or (US-7340302-$ or US-5944680-$ or US-8280513-$ or US-8265759-$ or US-8233987-$).did. or (WO-2010059839-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 15:06
S91	7	S90 and (length$1 or duration$1) same referenc$3	US-PGPUB; USPAT	OR	ON	2019/08/20 15:06
S92	5	S90 and duration$1 same referenc$3	US-PGPUB; USPAT	OR	ON	2019/08/20 15:09
S93	3	S90 and reference with inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 15:10
S94	7	S90 and reference same inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 15:14
S95	13	S90 and reference	US-PGPUB; USPAT	OR	ON	2019/08/20 15:35
S96	1	"8280513".pn.	US-PGPUB; USPAT	OR	ON	2019/08/20 15:54
S97	1	S96 and duty	US-PGPUB; USPAT	OR	ON	2019/08/20 16:37
S98	7	S90 and duty adj cycle$1	US-PGPUB; USPAT	OR	ON	2019/08/20 16:51
S99	4	S90 and duty adj cycle$1 and 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:52
S100	0	S90 and duty adj cycle$1 same 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:53
S101	142072	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:53
S102	139154	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with 75% same inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 16:54
S103	139153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with 75%1% same inspirat$4 and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 16:55
S104	139153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with 75%1% same inspirat$4 and nerve$1 and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:55
S105	139153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with "75%1%" same inspirat$4 and nerve$1 and	US-PGPUB; USPAT	OR	ON	2019/08/20 16:55

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		sleep adj apnea				
S106	139153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with "75%1%" same inspirat$4 and nerve$1 same sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:55
S107	139153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" andduty adj cycle$1 with 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:56
S108	173	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:56
S109	33	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with 75% and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:57
S110	0	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with 75% same (inspirat$4 or respirat$4) and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:58
S111	161	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:59
S112	109	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 16:59
S113	66	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with $2% same (inspirat$4 or respirat$4) and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 17:01
S114	34	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with $2% same (inspirat$4 or respirat$4) same stimulat$4 and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 17:09
S115	13	S90 and (inspirat$4 or respirat$4) same stimulat$4 and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 17:13
S116	13	S90 and (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 17:14
S117	10	S90 and (inspirat$4 or respirat$4) same stimulat$4 same duration$1	US-PGPUB; USPAT	OR	ON	2019/08/20 17:25
S118	70	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4 and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/21 08:52
S119	660	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S120	12048	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S121	3221	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S122	3221	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S123	7298	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S124	21955	S119 or S120 or S121 or S122 or S123	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54

S125	11295	S124 and @pd<"20150319"	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S126	62	S125 and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4 and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S127	90	S125 and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 08:55
S128	61	S125 and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4 same duration	US-PGPUB; USPAT	OR	ON	2019/08/21 08:55
S129	90	S125 and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:10
S130	94	S125 and @pd<"20150319" and (duty adj cycle$1 or on$1time or on adj time) same (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:41
S131	392	S125 and @pd<"20150319" and duration$1 same (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:43
S132	220	S125 and @pd<"20150319" and duration$1 with (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:43
S133	130	S125 and @pd<"20150319" and duration$1 with (inspirat$4 or respirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:43
S134	7	S125 and @pd<"20150319" and duration$1 with (inspirat$4 or respirat$4) with stimulat$4 same ratio	US-PGPUB; USPAT	OR	ON	2019/08/21 09:44
S135	169	S125 and @pd<"20150319" and duration$1 with inspirat$4 and respirat$4 with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:21
S136	97	S125 and @pd<"20150319" and duration$1 with inspirat$4 same respirat$4 with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:21
S137	1	S125 and @pd<"20150319" and overlap$4 with respirat$4 with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:30
S138	1	S125 and @pd<"20150319" and overlap$4 with respirat$4 with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:31
S139	5	S125 and @pd<"20150319" and overlap$4 with (respirat$4 or inspirat$4 or expirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:32
S140	14813	S125 and @pd<"20150319" and duration with (greater$1 or longer$1) (respirat$4 or inspirat$4 or expirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:33
S141	48	S125 and @pd<"20150319" and duration with (greater$1 or longer$1) with (respirat$4 or inspirat$4 or expirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:33
S142	8	S125 and @pd<"20150319" and puls$3 near3 (duration$1 or length$1 or width$2) with (greater$1 or longer$1) with (respirat$4 or inspirat$4 or expirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:42
S143	2	"20060155341".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/03/26 19:45
S144	2	"20110172733".pn.	US-PGPUB; USPAT; USOCR;	OR	ON	2020/03/27 11:41

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S145	2	"20100228310".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/03/27 11:50
S146	662	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57
S147	13235	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57
S148	3475	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57
S149	3475	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57
S150	7461	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57
S151	23481	S146 or S147 or S148 or S149 or S150	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57
S152	921	S151 and @pd<"20150319" and a$1synchron$	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57
S153	111	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$)	US-PGPUB; USPAT	OR	ON	2020/03/27 11:59
S154	54	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$)	US-PGPUB; USPAT	OR	ON	2020/03/27 12:10
S155	33	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$	US-PGPUB; USPAT	OR	ON	2020/03/27 12:11
S156	24	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$ and stimulat$4 with reference	US-PGPUB; USPAT	OR	ON	2020/03/27 13:46
S157	24	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$ and stimulat$4 with reference and (duration or period)	US-PGPUB; USPAT	OR	ON	2020/03/27 14:29
S158	6	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$ and stimulat$4 with reference and (duration or period) and non$stimulat$	US-PGPUB; USPAT	OR	ON	2020/03/27 14:36
S159	24	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$ and stimulat$4 with reference and (duration or period) same (refractory or pulse)	US-PGPUB; USPAT	OR	ON	2020/03/27 14:51
S160	22	S151 and @pd<"20150319" and a$1synchron$	US-PGPUB;	OR	ON	2020/03/27

		with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$ and stimulat$4 with reference and duty adj cycle$1	USPAT			15:05
S161	22	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$ and duty adj cycle$1	US-PGPUB; USPAT	OR	ON	2020/03/27 15:11
S162	662	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S163	13235	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S164	3475	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S165	3475	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S166	7461	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S167	23481	S162 or S163 or S164 or S165 or S166	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S168	33	S167 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S169	662	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04
S170	13235	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04
S171	3475	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04
S172	3475	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04
S173	7461	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04
S174	23481	S169 or S170 or S171 or S172 or S173	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04
S175	16	S174 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$ and duty adj cycle	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04
S176	1	"5211173".pn.	US-PGPUB; USPAT	OR	ON	2020/03/28 00:07
S177	128	("4969467").PN. OR ("5211173").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/28 00:10
S178	83	S177 and (pulse adj width or pulse$1width or duration or period) with stimulat$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:12
S179	64	@pd<"20150319" and S177 and (pulse adj width or pulse$1width or duration or period) with stimulat$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:12
S180	16	@pd<"20150319" and S177 and (pulse adj width or pulse$1width or duration or period) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:14
S181	16	@pd<"20150319" and S177 and (pulse adj width or pulse$1width or duration or period or	US-PGPUB; USPAT;	OR	ON	2020/03/28 00:20

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		duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	USOCR			
S182	14	S174 and @pd<"20150319" and S177 and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:33
S183	612	S174 and @pd<"20150319" and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:35
S184	206	S174 and @pd<"20150319" and sleep adj apnea and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:39
S185	5105	S174 and @pd<"20150319" and sleep adj apnea and asynch$ (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:39
S186	45	S174 and @pd<"20150319" and sleep adj apnea and asynch$ and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:40
S187	28108	sleep adj apnea @pd<"20150319" and S177 and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 01:04
S188	16	sleep adj apnea and @pd<"20150319" and S177 and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 01:04
S189	522	sleep adj apnea and @pd<"20150319" and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 01:06
S190	65	sleep adj apnea and @pd<"20150319" and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 01:06
S191	1	"5944680".pn.	US-PGPUB; USPAT	OR	ON	2020/03/28 02:23
S192	1	"5944680".pn. and average same (period or duration or width)	US-PGPUB; USPAT	OR	ON	2020/03/28 02:23
S193	192	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:26
S194	115	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:26
S195	0	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) same histor$ with (duration or period or width) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:28
S196	39	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width) same (histor$ or profile or personal or patient or specific) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:29

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S197	39	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width) same (histor$ or profile or personal or patient or specific or population) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:34
S198	62	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width) same (histor$ or profile or personal or patient or specific or populationor data$1base) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:39
S199	51	S174 and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width) same (histor$ or profile or personal or patient or specific or populationor data$1base) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:40
S200	51	S174 and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width) same (histor$ or profile or personal or patient or specific or populationor data$1base multiple) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:52
S201	54	S174 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$)	US-PGPUB; USPAT	OR	ON	2020/03/28 02:55
S202	13	S174 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) same stimulat$	US-PGPUB; USPAT	OR	ON	2020/03/28 03:01
S203	13	S174 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) same stimulat$	US-PGPUB; USPAT	OR	ON	2020/03/28 03:22
S204	662	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2020/03/28 12:50
S205	13235	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 12:50
S206	3475	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 12:50
S207	3475	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 12:50
S208	7461	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 12:50
S209	23481	S204 or S205 or S206 or S207 or S208	US-PGPUB; USPAT	OR	ON	2020/03/28 12:50
S210	59	S209 and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width window) same (histor$ or profile or personal or patient or specific or populationor data$1base multiple) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 12:50

EAST Search History (Interference)

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C:\Users\mlau2\Documents\EAST\Workspaces\15562714.wsp

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0395

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0396

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20060155341		2006-07-13	Tehrani et al.	
	2	20110172733		2011-07-14	Lima et al.	
	3	20100228310		2010-09-09	Shuros et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	JPH11514557	JP		1999-12-14			

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

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First Named Inventor	Darrell Wagner
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Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

	2	WO199749455	WO		1997-12-31	Medtronic, Inc.		
	3	WO2013023218	WO		2013-02-14	Inspire Medical Systems, Inc.		

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NON-PATENT LITERATURE DOCUMENTS [Remove]

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Stanescu, "Expiratory flow limitation during sleep in heavy snorers" European Respiratory Journal, 1996, 9, 2116-2121	

If you wish to add additional non-patent literature document citation information please click the Add button [Add]

EXAMINER SIGNATURE

Examiner Signature	/MICHAEL J LAU/	Date Considered	03/28/2020

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Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2019-08-28
Name/Print	Paul S. Grunzweig	Registration Number	37,143

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8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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0400

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20080154330		2008-06-26	Tehrani et al.	
	2	20090216293		2009-08-27	Sasaki et al.	
	3	20150328451		2015-11-19	Kobayashi	
	4	20140228905	A1	2014-08-14	Bolea	
	5	20130253627	A1	2013-09-26	Meadows et al.	

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	First Named Inventor	Darrell Wagner
	Art Unit	3792
	Examiner Name	Lau, Michael J.
	Attorney Docket Number	I618.118.103

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2013509943	JP		2013-03-21	Imthera Medical, Inc.	[Equivalent US20130253627]	
	2	4960704	JP	B2	2008-08-07		[Equivalent US20090216293]	
	3	5636129	JP	B2	2015-12-07	TECHNO LINK CO LTD	[Equivalent US20150328451]	

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2020-04-21
Name/Print	Paul S. Grunzweig	Registration Number	37143

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Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0403

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U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8781587	B2	2014-07-15	Alt et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050148897	A1	2005-07-07	Cho et al.	
	2	20110060380	A1	2011-03-10	Gelfand et al.	

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	1	102548610	CN	A	2012-07-04	CARDIAC CONCEPTS INC	[Equivalent to US20110060380]	

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	1	J Sleep Res., "Hypoglossal nerve stimulation improves obstructive sleep apnea: 12-month outcomes" Journal, 2014, 23, 77-83.	☒
	2	The Laryngoscope, "Implanted Upper Airway Stimulation Device for Obstructive Sleep Apnea" Journal, 2012, 122, 1626-1633.	☒

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Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2020-05-06
Name/Print	Paul S. Grunzweig	Registration Number	37143

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Darrell Wagner et al.	Examiner:	LAU, Michael J.
Serial No.:	15/562,714	Group Art Unit:	3792
Filed:	September 28, 2017	Docket No.:	I618.118.103
Title:	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING		

AMENDMENT AND RESPONSE

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Amendment and Response is in reply to the Non Final Office Action mailed April 02, 2020. Please amend the above-identified patent application as follows:

IN THE CLAIMS

Please amend claims 129, 137-138, 140-141, 143-148 as follows:

1-128. (Canceled)

129. (Currently Amended) A device for treating obstructive sleep apnea, comprising:

a non-cardiac stimulation element to engage and to stimulate an upper-airway-patency-related nerve, according to a first stimulation therapy protocol not synchronized relative to actively-sensed respiratory information, wherein the first stimulation therapy protocol comprises a series of repeating stimulation cycles in which each stimulation cycle includes a stimulation period and a non-stimulation period,

wherein each stimulation period includes continuous stimulation and has a minimum duration equal to or greater than an inspiratory reference of a reference respiratory cycle, wherein the inspiratory reference corresponds to a duration of an inspiratory phase of the reference respiratory cycle, and wherein the reference respiratory cycle comprises at least one of:

a historical patient-specific average respiratory cycle for stable respiration; and

a multi-patient average respiratory cycle for stable respiration, and

wherein each stimulation period of each respective stimulation cycle has a duration greater than a duration of the inspiratory reference of the reference respiratory cycle and the stimulation period is followed by the non-stimulation period of the respective stimulation cycle comprising a duration less than the duration of the stimulation period.

130. (Previously Presented) The device of claim 129, wherein the non-cardiac stimulation element comprises an implantable electrode and a pulse generator electrically connected to the implantable electrode.

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131. (Previously Presented) The device of claim 129, wherein a total duration of stimulation via the first stimulation protocol during a treatment period is greater than 30 percent of the total duration of the treatment period.

132-134. (Canceled)

135. (Previously Presented) The device of claim 129, wherein the duration of the stimulation period comprises

at least 50 percent of a duration of the stimulation cycle.

136. (Previously Presented) The device of claim 129, wherein the duration of the stimulation period comprises

at least 50 percent of a duration of the reference respiratory cycle.

137. (Currently Amended) The device of claim 129[[~~134~~]], wherein the duration of each respective stimulation cycle is less than the duration of the reference respiratory cycle, and a duration of the stimulation period exceeds the duration of the non-stimulation period by a factor of at least 3.

138. (Currently Amended) The device of claim 129[[~~134~~]], wherein the duration of each respective stimulation cycle is greater than the duration of the reference respiratory cycle.

139. (Previously Presented) The device of claim 138, wherein the stimulation period and the non-stimulation period are in a proportion of at least 1.5 to 1.

140. (Currently Amended) The device of claim 129[[~~134~~]], wherein the duration of each respective stimulation cycle is equal to the duration of the reference respiratory cycle, and wherein the duration of the reference respiratory cycle differs from a duration of a real time

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respiratory cycle from actively-sensed respiration information by an amount exceeding a duration variability criteria.

141. (Currently Amended) The device of claim 129, comprising:

a processor; and

a non-volatile computer readable medium storing instructions, executable on the processor, to implement the ~~first~~non-cardiac stimulation element and to perform the first stimulation therapy protocol.

142. (Previously Presented) The device of claim 130,

wherein the implantable electrode comprises a cuff electrode including at least one operative contact group through which the stimulation is deliverable non-selectively to the upper-airway-patency-related nerve.

143. (Currently Amended) The[[A]] device of claim 129, ~~for treating obstructive sleep apnea~~ comprising:

~~a non-cardiac stimulation element to stimulate an upper-airway-patency-related nerve according to a first stimulation therapy protocol not synchronized relative to respiratory information, wherein the first stimulation therapy protocol comprises a series of repeating stimulation cycles in which each stimulation cycle includes a stimulation period and a non-stimulation period and ; and~~

a sensing element to ~~obtain respiratory information via~~ at least periodically actively sense ~~sensing a~~ respiratory ~~waveform~~ information to obtain the actively-sensed respiratory information unrelated to stimulation synchronization,

wherein the non-cardiac stimulation element is activated for stimulation upon the sensing element identifying, via at least the actively-sensed respiratory information, obstructive sleep apnea behavior which meets or exceeds a severity threshold and wherein the non-cardiac stimulation element is deactivated upon the sensing element identifying, via at least the actively-

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sensed respiratory information, that the obstructive sleep apnea behavior is less than the severity threshold.

144-147. (Canceled)

148. (Currently Amended) The [[A]] device ~~for treating obstructive sleep apnea~~of claim 129, comprising:

~~a non-cardiac stimulation element to stimulate an upper airway patency related nerve according to a first stimulation therapy protocol not synchronized relative to respiratory information, wherein the first stimulation therapy protocol comprises a series of repeating stimulation cycles in which each stimulation cycle includes a stimulation period and a non-stimulation period and wherein each respective stimulation cycle comprises a duration related to a duration of a reference respiratory cycle;~~

a sensing element to ~~receive~~obtain the actively-sensed respiratory information; and

a control portion including:

a processor; and

a non-volatile memory storing instructions, executable via the processor, to:

provide convertible operation via a therapy manager between:

a first stimulation mode implementing the first stimulation therapy protocol; and

a second stimulation mode of stimulating the upper-airway-patency-related nerve synchronous with a characteristic of the actively-sensed respiratory ~~waveform~~information.

149. (Previously Presented) The device of claim 138, wherein the duration of the stimulation cycle is less than a duration of two consecutive reference respiratory cycles.

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150. (Previously Presented) The device of claim 129, wherein the stimulation period and the non-stimulation period are in a proportion of at least 1.5 to 1.

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REMARKS

The following remarks are made in response to the Non Final Office Action mailed April 02, 2020, in which claims 129-133, 135-136, 141-148, and 150 were rejected and claims 134, 137-140, and 149 were indicated to be allowable objected to regarding form. With this Response, claims 129, 137-141, 143, and 148 have been amended and claims 132-134 and 144-147 have been cancelled. Claims 129-131, 135-143, and 148-150 remain pending in the application and are presented for reconsideration and allowance.

Allowable Subject Matter

Claims 134, 137-140, and 149 were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections under 35 U.S.C. § 103

Claims 129-130 and 141-142 stand rejected under 35 U.S.C. 103, as being unpatentable over multiple embodiments of Christopherson (US 5,944,680).

Applicants have amended base independent claim 129 to incorporate the recitations of claim 134 and the intervening claims 132-133, thereby obviating the rejection of independent claim 129. Claims 130 and 141-142 also are allowable at least based on their dependency from amended independent claim 129.

Claim 131 stands rejected under 35 U.S.C. 103 as being unpatentable per Christopherson in view of Bashyam (US 2014/0228905).

Claim 131 depends from base independent claim 129 in allowable form, thereby obviating the rejection.

Claims 132-133, 143, and 148 stand rejected under 35 U.S.C. 103 as being unpatentable per Christopherson in view of Bolea (US 2014/0228905).

Claims 132-133 have been canceled, with their subject matter having been incorporated into independent claim 129, thereby obviating the rejection.

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Both claims 143 and 148 have been amended in their dependency (now depending from independent claim 129) and their subject matter in a manner which obviates this rejection.

Claims 135-136 stand rejected under 35 U.S.C. 103 as being unpatentable per Christopherson in view of Tehrani (US 8280513).

Both claims 135 and 136 depend from allowable independent claim 129, thereby obviating this rejection.

Claims 144-147, and 150 stand rejected under 35 U.S.C. 103 as being unpatentable over by Christopherson in view of Bolea, further in view of Tehrani.

Claims 144-147 have been canceled, which thereby obviates this rejection as to those claims. Claim 150 depends from allowable independent claim 129, thereby obviating this rejection.

In view of the above, Applicants respectfully request withdrawal of the Section 103 rejections.

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CONCLUSION

In view of the above, Applicants respectfully submit that the pending claims 129-131, 135-143, and 148-150 are in form for allowance and are not taught or suggested by the cited references.

Please consider this a Petition for Extension of Time for a sufficient number of months to enter these papers, if appropriate. At any time during the pendency of this application, please charge any additional fees or credit overpayment to Deposit Account No. 500471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Paul S. Grunzweig at Telephone No. (612) 767-2504, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

Dicke, Billig & Czaja
Fifth Street Towers, Suite 2250
100 South Fifth Street
Minneapolis, MN 55402

Respectfully submitted,

Darrell Wagner et al.,

By their attorneys,

DICKE, BILLIG & CZAJA, PLLC
Fifth Street Towers, Suite 2250
100 South Fifth Street
Minneapolis, MN 55402
Telephone: (612) 573-2000
Facsimile: (612) 573-2005

Date: July 2, 2020

/ Paul S. Grunzweig/
Paul S. Grunzweig
Reg. No. 37,143

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NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0417

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5123425		1992-06-23	Shannon, Jr. et al.	
	2	5190053		1993-03-02	Meer	
	3	8160712	B1	2012-04-17	Freed	
	4	5591216		1997-01-07	Testerman et al.	
	5	8718776	B2	2014-05-06	Mashiach et al.	
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	Application Number	15562714
	Filing Date	2017-09-28
	First Named Inventor	Darrell Wagner
	Art Unit	3792
	Examiner Name	Lau, Michael J.
	Attorney Docket Number	I618.118.103

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Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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0419

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15562714
	Filing Date	2017-09-28
	First Named Inventor	Darrell Wagner
	Art Unit	3792
	Examiner Name	Lau, Michael J.
	Attorney Docket Number	I618.118.103

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2020-07-02
Name/Print	Paul S. Grunzweig	Registration Number	37143

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0421

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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NOTICE OF ALLOWANCE AND FEE(S) DUE

25281 7590 09/30/2020

DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

EXAMINER	
LAU, MICHAEL J	
ART UNIT	PAPER NUMBER
3792	

DATE MAILED: 09/30/2020

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/562,714	09/28/2017	Darrell Wagner	I618.118.103	3077

TITLE OF INVENTION: STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1000	$0.00	$0.00	$1000	12/30/2020

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

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0422

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

25281 7590 09/30/2020
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/562,714	09/28/2017	Darrell Wagner	I618.118.103	3077

TITLE OF INVENTION: STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1000	$0.00	$0.00	$1000	12/30/2020

EXAMINER	ART UNIT	CLASS-SUBCLASS
LAU, MICHAEL J	3792	607-042000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0423

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/562,714	09/28/2017	Darrell Wagner	I618.118.103	3077

25281 7590 09/30/2020

DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

EXAMINER	
LAU, MICHAEL J	

ART UNIT	PAPER NUMBER
3792	

DATE MAILED: 09/30/2020

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Exhibit 1002
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0424

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 15/562,714	Applicant(s) Wagner et al.	
	Examiner MICHAEL J LAU	Art Unit 3792	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 7/2/2020.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are See Continuation Sheet. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____.
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☑ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MICHAEL J LAU/ Examiner, Art Unit 3792	/CARL H LAYNO/ Supervisory Patent Examiner, Art Unit 3792

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0426

Continuation of 3. The allowed claim(s) is/are: 129-131,135-143 and 148-150

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Response to Arguments

2. Applicant's arguments, see Pages 9-11, filed 7/2/2020, with respect to USC 103 have been fully considered and are persuasive. The USC 103 rejection of 129-131, 135-143, 148-150 has been withdrawn.

Allowable Subject Matter

3. Claims 129-131, 135-143, and 148-150 allowed.

Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance: Claims 129-131, 135-143, and 148-150 are allowable over the prior art because the examiner found that none of the cited prior art taught stimulating at a duration equal to or greater an inspiratory reference of a reference respiratory cycle based on a historical patient-specific average or multi-patient average. The examiner notes close prior art Tehrani (US 2008/0161878 A1) discloses a stimulation time greater than one inspiration cycle but does not specify a non-stimulation period less than the duration of a stimulation period and applies these stimulations to the hemidiaphragms which are not upper airway nerves.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tehrani (US 2008/0151878 A1) and Kobayashi (US 2015/0328451 A1).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J LAU whose telephone number is (571)272-2317. The examiner can normally be reached on 8-5:30 PM.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHAEL J LAU/
Examiner, Art Unit 3792

/CARL H LAYNO/
Supervisory Patent Examiner, Art Unit 3792

Notice of References Cited	Application/Control No. 15/562,714	Applicant(s)/Patent Under Reexamination Wagner et al.	
	Examiner MICHAEL J LAU	Art Unit 3792	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-7340302-B1	03-2008	Falkenberg; Eric	A61N1/3611	607/9
*	B	US-20100174341-A1	07-2010	Bolea; Stephen L.	A61N1/0556	607/42
*	C	US-5944680-A	08-1999	Christopherson; Mark A.	A61B5/03	128/897
*	D	US-20120290036-A1	11-2012	Karamanoglu; Mustafa	A61B5/686	607/42
*	E	US-20160022204-A1	01-2016	Mostov; Kirill	A61B5/0002	600/301
*	F	US-20140364919-A1	12-2014	Doan; Que T.	A61N1/36164	607/46
*	G	US-20060247729-A1	11-2006	Tehrani; Amir J.	A61N1/3601	607/42
*	H	US-20100198289-A1	08-2010	Kameli; Nader	G06F19/3481	607/14
*	I	US-8280513-B2	10-2012	Tehrani; Amir J.	A61N1/3601	607/42
*	J	US-8265759-B2	09-2012	Tehrani; Amir J.	A61N1/3627	607/42
*	K	US-8233987-B2	07-2012	Gelfand; Mark	A61N1/36171	607/42
*	L	US-20110093032-A1	04-2011	Boggs, II; Joseph W.	A61N1/3611	607/42
*	M	US-20140135868-A1	05-2014	BASHYAM; JACOB BASHYAM	A61N1/3601	607/42

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 15/562,714	Applicant(s)/Patent Under Reexamination Wagner et al.	
	Examiner MICHAEL J LAU	Art Unit 3792	Page 2 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20140228905-A1	08-2014	BOLEA; Stephen L.	A61F5/56	607/42
*	B	US-20110288609-A1	11-2011	TEHRANI; Amir J.	A61N1/36031	607/42
*	C	US-7809442-B2	10-2010	Bolea; Stephen L.	A61N1/0558	607/42
*	D	US-20120192874-A1	08-2012	BOLEA; Stephen L.	A61N1/3601	128/848
*	E	US-20060167523-A1	07-2006	Tehrani; Amir J.	A61N1/3601	607/42
*	F	US-20120253249-A1	10-2012	Wilson; Willard	A61N1/3611	601/154
*	G	US-20090062882-A1	03-2009	Zhang; Yi	A61N1/3601	607/42
*	H	US-20080161878-A1	07-2008	Tehrani; Amir J.	A61N1/3601	607/42
*	I	US-20080154330-A1	06-2008	Tehrani; Amir J.	A61N1/3601	607/42
*	J	US-20150328451-A1	11-2015	Kobayashi; Tatsuyuki	A61N1/0492	607/42
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0431

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/562,714	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

CPC						
Symbol					Type	Version
A61N	/	1	/	3601	F	2013-01-01
A61B	/	5	/	0826	I	2013-01-01
A61B	/	5	/	4818	I	2013-01-01
A61B	/	5	/	4848	I	2013-01-01
A61N	/	1	/	3611	I	2013-01-01
A61B	/	5	/	686	I	2013-01-01
A61B	/	5	/	0816	I	2013-01-01
A61B	/	5	/	113	I	2013-01-01
A61N	/	1	/	36146	A	2013-01-01
G06F	/	19	/	3481	A	2013-01-01
A61N	/	1	/	3614	A	2017-08-01
A61B	/	5	/	0205	A	2013-01-01
A61N	/	1	/	36171	A	2013-01-01

CPC Combination Sets							
Symbol					Type	Set	Ranking	Version
	/		/					

/MICHAEL J LAU/ Examiner, Art Unit 3792	16 September 2020	Total Claims Allowed:	
(Assistant Examiner)	(Date)	15	
/CARL H LAYNO/ Supervisory Patent Examiner, Art Unit 3792	18 September 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1A,3B

U.S. Patent and Trademark Office — Part of Paper No.: 20200915

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0432

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/562,714	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61N	/	1	/	00

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

/MICHAEL J LAU/ Examiner, Art Unit 3792	16 September 2020	Total Claims Allowed:	
(Assistant Examiner)	(Date)	15	
/CARL H LAYNO/ Supervisory Patent Examiner, Art Unit 3792	18 September 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1A,3B

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0433

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/562,714	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	129	12	141												
2	130	3	142												
4	131	13	143												
5	135	14	148												
6	136	10	149												
7	137	15	150												
8	138														
9	139														
11	140														

/MICHAEL J LAU/ Examiner, Art Unit 3792	16 September 2020	Total Claims Allowed:	
(Assistant Examiner)	(Date)	15	
/CARL H LAYNO/ Supervisory Patent Examiner, Art Unit 3792	18 September 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1A,3B

U.S. Patent and Trademark Office Part of Paper No.: 20200915

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0434

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/562,714	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/21/2018	08/21/2019	03/28/2020	09/16/2020					
1	129	✓	✓	✓	=					
2	130	✓	✓	✓	=					
4	131	✓	✓	✓	=					
	132	✓	✓	✓	-					
	133	✓	✓	✓	-					
	134	✓	✓	O	-					
5	135	✓	✓	✓	=					
6	136	✓	✓	✓	=					
7	137	✓	✓	O	=					
8	138	✓	✓	O	=					
9	139	✓	✓	O	=					
11	140	✓	✓	O	=					
12	141	✓	✓	✓	=					
3	142	✓	✓	✓	=					
13	143	✓	✓	✓	=					
	144	✓	✓	✓	-					
	145	✓	✓	✓	-					
	146	✓	✓	✓	-					
	147	✓	✓	✓	-					
14	148	✓	✓	✓	=					
10	149			O	=					
15	150			✓	=					

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0435

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/562,714	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

CPC - Searched*		
Symbol	Date	Examiner
A61B5/3601,0816,0826,113,4818,4848,686	12/21/2018	ML
A61B1/36135	12/21/2018	ML
A61N1/3611,36135,36146,36171	12/21/2018	ML
G06F19/3481	12/21/2018	ML

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
607	42, 72, 73	12/21/2018	ML

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Inventor search on PALM, Prior art search on east, consulted spe carl layno for search strategy	12/21/2018	ML
updated search on east	08/21/2019	ML
updated search on east	03/28/2020	ML
updated search on east	09/16/2020	ML

/MICHAEL J LAU/ Examiner, Art Unit 3792	

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/562,714	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	see search history for interference search	09/16/2020	ML

/MICHAEL J LAU/ Examiner, Art Unit 3792	

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0437

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5123425		1992-06-23	Shannon, Jr. et al.	
	2	5190053		1993-03-02	Meer	
	3	8160712	B1	2012-04-17	Freed	
	4	5591216		1997-01-07	Testerman et al.	
	5	8718776	B2	2014-05-06	Mashiach et al.	
	6	9895540	B2	2018-02-20	Mashiach	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

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EXAMINER SIGNATURE

Examiner Signature	/MICHAEL J LAU/	Date Considered	09/16/2020

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

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Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2020-07-02
Name/Print	Paul S. Grunzweig	Registration Number	37143

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0441

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	660	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2020/09/16 18:10
L2	14,119	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2020/09/16 18:10
L3	3,408	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2020/09/16 18:10
L4	3,408	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2020/09/16 18:10
L5	7,380	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2020/09/16 18:10
L6	24,240	L1 or L2 or L3 or L4 or L5	US-PGPUB; USPAT	OR	ON	2020/09/16 18:10
L7	11	L6 and @pd<"20150319" and reference with inspirat$4 with (average or histor$ or profile)	US-PGPUB; USPAT	OR	ON	2020/09/16 18:10
S1	1	"7340302".pn.	US-PGPUB; USPAT	OR	ON	2018/12/12 18:58
S2	5	"9750049".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/12 19:26
S3	2	"2010174341".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2018/12/12 19:38

			; IBM_TDB			
S4	0	"2010174341".pn.	US-PGPUB; USPAT	OR	ON	2018/12/12 19:39
S5	1	"20100174341".pn.	US-PGPUB; USPAT	OR	ON	2018/12/12 19:39
S6	3	(US-20100174341-$).did. or (US-7340302-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; EPO	OR	ON	2018/12/13 13:33
S7	2	S6 and (pulse or duration or period)	US-PGPUB; USPAT	OR	ON	2018/12/13 13:33
S8	659	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:38
S9	10,675	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:42
S10	0	A61B1/36135.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:42
S11	2,915	A61N1/3611,36135,36146,36171.cpc.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:44
S12	2,915	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:44
S13	7,232	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:44
S14	20,277	S8 or S9 or S11 or S12 or S13	US-PGPUB; USPAT	OR	ON	2018/12/13 14:45
S15	11,362	S14 and @pd<"20150319"	US-PGPUB; USPAT	OR	ON	2018/12/13 14:45
S16	66	(darrell near wagner).in.	US-PGPUB; USPAT	OR	ON	2018/12/13 14:48
S17	6	(darrell near wagner).in. and sleep	US-PGPUB; USPAT	OR	ON	2018/12/13 14:51

S18	190	((darrell near wagner) or (ni near quan) or (rondini near john) or (dieken near dave)).in. and sleep	US-PGPUB; USPAT	OR	ON	2018/12/13 14:54
S19	161	((darrell near wagner) or (ni near quan) or (rondini near john) or (dieken near dave)).in. and sleep and @pd<"20150319"	US-PGPUB; USPAT	OR	ON	2018/12/13 14:59
S20	149	((darrell near wagner) or (ni near quan) or (rondini near john) or (dieken near dave)).in. and sleep and @pd<"20150319" and stimulat$3	US-PGPUB; USPAT	OR	ON	2018/12/13 15:24
S21	7	"2010059839".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/13 15:36
S22	5	"5944680".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/13 16:16
S23	293	S14 and @pd<"20150319" and pulse adj duration and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 16:56
S24	84	S14 and @pd<"20150319" and pulse adj (width or duration) same inspiration and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 16:56
S25	54	S14 and @pd<"20150319" and pulse adj (width or duration) same inspiration and sleep adj (apnea or aponea) and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 17:01
S26	4	A61B5/0826.cpc. and @pd<"20150319" and pulse adj (width or duration) same inspiration and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 17:07
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S28	235	("20010010010" | "20020010495" | "20020049479" | "20020156507" | "20030093128" | "20030114905" | "20030163059" | "20030195571" | "20030216789" | "20030224895" |	US-PGPUB; USPAT	OR	ON	2018/12/13 17:25

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S30	58	S28 and pulse adj (pulse or duration)	US-PGPUB; USPAT	OR	ON	2018/12/13 17:26
S31	8	S28 and pulse adj (pulse or duration) and '25%'	US-PGPUB; USPAT	OR	ON	2018/12/13 17:31
S32	47	S28 and pulse adj (duration or duration)	US-PGPUB; USPAT	OR	ON	2018/12/13 17:32
S33	104	S28 and pulse adj (width or duration)	US-PGPUB; USPAT	OR	ON	2018/12/13 17:32
S34	1	"5944680".pn. and pulse adj (width or duration)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2018/12/13 17:34
S35	1	("2015/0039045").URPN.	USPAT	OR	ON	2018/12/13 17:57
S36	4	A61B5/0826.cpc. and @pd<"20150319" and pulse adj (width or duration) same inspiration and implant and ramp	US-PGPUB; USPAT	OR	ON	2018/12/13 18:10
S37	0	A61B5/0826.cpc. and @pd<"20150319" and ramp with pulse adj (width or duration) same inspiration and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 18:10
S38	1	A61B5/0826.cpc. and @pd<"20150319" and ramp$3 same pulse adj (width or duration) same inspiration and implant	US-PGPUB; USPAT	OR	ON	2018/12/13 18:11

S39	29	S14 and @pd<"20150319" and ramp with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:13
S40	0	S14 and @pd<"20150319" and full with ramp with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:13
S41	0	S14 and @pd<"20150319" and full same ramp with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:13
S42	0	S14 and @pd<"20150319" and full with pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:15
S43	39	S14 and @pd<"20150319" and full same pulse adj (width or duration) and sleep adj (apnea or aponea)	US-PGPUB; USPAT	OR	ON	2018/12/13 18:15
S44	826	607/72,73.ccls.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:30
S45	532	607/72,73.ccls. and duration	US-PGPUB; USPAT	OR	ON	2018/12/20 10:30
S46	491	607/72,73.ccls. and @pd<"20150319" and duration	US-PGPUB; USPAT	OR	ON	2018/12/20 10:31
S47	51	607/72,73.ccls. and @pd<"20150319" and duration and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2018/12/20 10:32
S48	80	2006/0247729	US-PGPUB; USPAT	OR	ON	2018/12/20 10:45
S49	1	"20060247729".pn.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:45
S50	1	"20060247729".pn. and duration	US-PGPUB; USPAT	OR	ON	2018/12/20 10:48
S51	0	"2010098289".pn.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:59
S52	1	"20100198289".pn.	US-PGPUB; USPAT	OR	ON	2018/12/20 10:59
S53	78	("2006/0247729").URPN.	USPAT	OR	ON	2018/12/20 11:27
S54	45	("2006/0247729").URPN. and @pd<"20150319"	USPAT	OR	ON	2018/12/20 11:27

S55	44	("2006/0247729").URPN. and @pd<"20150319" and (duration or width)	USPAT	OR	ON	2018/12/20 11:28
S56	15	(US-20100174341-$ or US-20120290036-$ or US-20160354608-$ or US-20160022204-$ or US-20140364919-$ or US-20060247729-$ or US-20100198289-$).did. or (US-7340302-$ or US-5944680-$ or US-8280513-$ or US-8265759-$ or US-8233987-$).did. or (WO-2010059839-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; FPRS; EPO	OR	ON	2018/12/21 09:27
S57	5	S56 and cuff	US-PGPUB; USPAT	OR	ON	2018/12/21 09:27
S58	15	(US-20100174341-$ or US-20120290036-$ or US-20160354608-$ or US-20160022204-$ or US-20140364919-$ or US-20060247729-$ or US-20100198289-$).did. or (US-7340302-$ or US-5944680-$ or US-8280513-$ or US-8265759-$ or US-8233987-$).did. or (WO-2010059839-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/19 15:36
S59	652	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse adj duration and sleep adj (apnea or apnoea)	US-PGPUB; USPAT	OR	ON	2019/08/19 15:37
S60	28	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse adj duration and sleep adj (apnea or apnoea) same repeat$4	US-PGPUB; USPAT	OR	ON	2019/08/19 15:40
S61	17	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse adj duration and sleep adj (apnea or apnoea) same repeat$4 and hypoglossal	US-PGPUB; USPAT	OR	ON	2019/08/19 15:46
S62	1	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse adj duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal	US-PGPUB; USPAT	OR	ON	2019/08/19 15:49
S63	33	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal	US-PGPUB; USPAT	OR	ON	2019/08/19 15:55
S64	33	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and referenc$3	US-PGPUB; USPAT	OR	ON	2019/08/19 16:00
S65	0	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and	US-PGPUB; USPAT	OR	ON	2019/08/19 16:01

		sleep adj (apnea or apnoea) and hypoglossal and referenc$3 adj respirat$4				
S66	33	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and referenc$3	US-PGPUB; USPAT	OR	ON	2019/08/19 16:05
S67	26	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and active$3	US-PGPUB; USPAT	OR	ON	2019/08/19 16:05
S68	1	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and active$3 with sens$4	US-PGPUB; USPAT	OR	ON	2019/08/19 16:08
S69	30	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and (first and second)	US-PGPUB; USPAT	OR	ON	2019/08/19 16:38
S70	30	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and pulse same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal and (first same second)	US-PGPUB; USPAT	OR	ON	2019/08/19 16:43
S71	18	(US-20100174341-$ or US-20120290036-$ or US-20160354608-$ or US-20160022204-$ or US-20140364919-$ or US-20060247729-$ or US-20100198289-$ or US-20110093032-$ or US-20140135868-$ or US-20140228905-$).did. or (US-7340302-$ or US-5944680-$ or US-8280513-$ or US-8265759-$ or US-8233987-$).did. or (WO-2010059839-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 08:16
S72	13	S71 and referenc$3	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 09:09
S73	13	S71 and synchron$	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 09:10
S74	12	S71 and mode$1	US-PGPUB; USPAT;	OR	OFF	2019/08/20 10:27

			FPRS; EPO			
S75	7	S71 and fixed	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:46
S76	6	S71 and fixed same (duration$1 or length$1)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:46
S77	0	S71 and fixed same (duration$1 or length$1) same "%"	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:51
S78	0	S71 and fixed same (duration$1 or length$1) same ("%" or percent$4)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:52
S79	4	S71 and (duration$1 or length$1) same ("%" or percent$4)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:54
S80	4	S71 and (duration$1 or length$1) same ("%" or percent$4)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:54
S81	10	S71 and (fixed or repeat$4 or constant) same (duration$1 or length$1)	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 10:55
S82	1	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and fixed same puls$3 same duration same repeat$4 and sleep adj (apnea or apnoea) and hypoglossal	US-PGPUB; USPAT	OR	ON	2019/08/20 10:56
S83	0	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and fixed same puls$3 same duration same repeat$4 and sleep adj (apnea or apnoea) same ("%" or percent$5)	US-PGPUB; USPAT	OR	ON	2019/08/20 10:57

S84	1	S71 and (minim$2) near3 (length$1 or duration$1)	US-PGPUB; USPAT	OR	ON	2019/08/20 11:21
S85	15	S71 and duration$1	US-PGPUB; USPAT	OR	ON	2019/08/20 11:21
S86	3	S71 and duration$1 same synchron$4	US-PGPUB; USPAT	OR	ON	2019/08/20 11:31
S87	11	S71 and synchron$4	US-PGPUB; USPAT	OR	ON	2019/08/20 11:34
S88	7	S71 and synchron$4 same inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 11:43
S89	10	S71 and (length$1 or duration$1) same inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 11:46
S90	18	(US-20100174341-$ or US-20120290036-$ or US-20160354608-$ or US-20160022204-$ or US-20140364919-$ or US-20060247729-$ or US-20100198289-$ or US-20110093032-$ or US-20140135868-$ or US-20140228905-$).did. or (US-7340302-$ or US-5944680-$ or US-8280513-$ or US-8265759-$ or US-8233987-$).did. or (WO-2010059839-$).did. or (WO-9750049-$).did.	US-PGPUB; USPAT; FPRS; EPO	OR	OFF	2019/08/20 15:06
S91	7	S90 and (length$1 or duration$1) same referenc$3	US-PGPUB; USPAT	OR	ON	2019/08/20 15:06
S92	5	S90 and duration$1 same referenc$3	US-PGPUB; USPAT	OR	ON	2019/08/20 15:09
S93	3	S90 and reference with inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 15:10
S94	7	S90 and reference same inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 15:14
S95	13	S90 and reference	US-PGPUB; USPAT	OR	ON	2019/08/20 15:35
S96	1	"8280513".pn.	US-PGPUB; USPAT	OR	ON	2019/08/20 15:54

S97	1	S96 and duty	US-PGPUB; USPAT	OR	ON	2019/08/20 16:37
S98	7	S90 and duty adj cycle$1	US-PGPUB; USPAT	OR	ON	2019/08/20 16:51
S99	4	S90 and duty adj cycle$1 and 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:52
S100	0	S90 and duty adj cycle$1 same 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:53
S101	142,072	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:53
S102	139,154	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with 75% same inspirat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 16:54
S103	139,153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with 75%1% same inspirat$4 and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 16:55
S104	139,153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with 75%1% same inspirat$4 and nerve$1 and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:55
S105	139,153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with "75%1%" same inspirat$4 and nerve$1 and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:55
S106	139,153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" duty adj cycle$1 with "75%1%" same inspirat$4 and nerve$1 same sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:55
S107	139,153	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" andduty adj cycle$1 with 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:56
S108	173	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with 75%	US-PGPUB; USPAT	OR	ON	2019/08/20 16:56
S109	33	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with 75% and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:57
S110	0	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and	US-PGPUB; USPAT	OR	ON	2019/08/20 16:58

		duty adj cycle$1 with 75% same (inspirat$4 or respirat$4) and sleep adj apnea				
S111	161	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) and sleep adj apnea	US-PGPUB; USPAT	OR	ON	2019/08/20 16:59
S112	109	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 16:59
S113	66	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with $2% same (inspirat$4 or respirat$4) and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 17:01
S114	34	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 with $2% same (inspirat$4 or respirat$4) same stimulat$4 and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 17:09
S115	13	S90 and (inspirat$4 or respirat$4) same stimulat$4 and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/20 17:13
S116	13	S90 and (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/20 17:14
S117	10	S90 and (inspirat$4 or respirat$4) same stimulat$4 same duration$1	US-PGPUB; USPAT	OR	ON	2019/08/20 17:25
S118	70	(607/42.ccls. or A61N1/$.cpc. or A61B5/$.cpc.) and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4 and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/21 08:52
S119	660	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S120	12,048	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S121	3,221	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S122	3,221	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54

S123	7,298	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S124	21,955	S119 or S120 or S121 or S122 or S123	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S125	11,295	S124 and @pd<"20150319"	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S126	62	S125 and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4 and sleep adj apnea and nerve$1	US-PGPUB; USPAT	OR	ON	2019/08/21 08:54
S127	90	S125 and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 08:55
S128	61	S125 and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4 same duration	US-PGPUB; USPAT	OR	ON	2019/08/21 08:55
S129	90	S125 and @pd<"20150319" and duty adj cycle$1 same (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:10
S130	94	S125 and @pd<"20150319" and (duty adj cycle$1 or on$1time or on adj time) same (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:41
S131	392	S125 and @pd<"20150319" and duration$1 same (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:43
S132	220	S125 and @pd<"20150319" and duration$1 with (inspirat$4 or respirat$4) same stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:43
S133	130	S125 and @pd<"20150319" and duration$1 with (inspirat$4 or respirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 09:43
S134	7	S125 and @pd<"20150319" and duration$1 with (inspirat$4 or respirat$4) with stimulat$4 same ratio	US-PGPUB; USPAT	OR	ON	2019/08/21 09:44
S135	169	S125 and @pd<"20150319" and duration$1 with inspirat$4 and respirat$4 with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:21
S136	97	S125 and @pd<"20150319" and duration$1 with inspirat$4 same respirat$4 with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:21
S137	1	S125 and @pd<"20150319" and overlap$4 with respirat$4 with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:30

S138	1	S125 and @pd<"20150319" and overlap$4 with respirat$4 with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:31
S139	5	S125 and @pd<"20150319" and overlap$4 with (respirat$4 or inspirat$4 or expirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:32
S140	14,813	S125 and @pd<"20150319" and duration with (greater$1 or longer$1) (respirat$4 or inspirat$4 or expirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:33
S141	48	S125 and @pd<"20150319" and duration with (greater$1 or longer$1) with (respirat$4 or inspirat$4 or expirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:33
S142	8	S125 and @pd<"20150319" and puls$3 near3 (duration$1 or length$1 or width$2) with (greater$1 or longer$1) with (respirat$4 or inspirat$4 or expirat$4) with stimulat$4	US-PGPUB; USPAT	OR	ON	2019/08/21 10:42
S143	2	"20060155341".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/03/26 19:45
S144	2	"20110172733".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/03/27 11:41
S145	2	"20100228310".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/03/27 11:50
S146	662	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57
S147	13,235	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57

S148	3,475	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57
S149	3,475	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57
S150	7,461	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57
S151	23,481	S146 or S147 or S148 or S149 or S150	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57
S152	921	S151 and @pd<"20150319" and a$1synchron$	US-PGPUB; USPAT	OR	ON	2020/03/27 11:57
S153	111	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$)	US-PGPUB; USPAT	OR	ON	2020/03/27 11:59
S154	54	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$)	US-PGPUB; USPAT	OR	ON	2020/03/27 12:10
S155	33	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$	US-PGPUB; USPAT	OR	ON	2020/03/27 12:11
S156	24	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$ and stimulat$4 with reference	US-PGPUB; USPAT	OR	ON	2020/03/27 13:46
S157	24	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$ and stimulat$4 with reference and (duration or period)	US-PGPUB; USPAT	OR	ON	2020/03/27 14:29
S158	6	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$ and stimulat$4 with reference and (duration or period) and non$stimulat$	US-PGPUB; USPAT	OR	ON	2020/03/27 14:36
S159	24	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and	US-PGPUB; USPAT	OR	ON	2020/03/27 14:51

		implant$ and stimulat$4 with reference and (duration or period) same (refractory or pulse)				
S160	22	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$ and stimulat$4 with reference and duty adj cycle$1	US-PGPUB; USPAT	OR	ON	2020/03/27 15:05
S161	22	S151 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$ and duty adj cycle$1	US-PGPUB; USPAT	OR	ON	2020/03/27 15:11
S162	662	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S163	13,235	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S164	3,475	A61N1/3611,36135,36146,36171.cpc.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S165	3,475	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S166	7,461	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S167	23,481	S162 or S163 or S164 or S165 or S166	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S168	33	S167 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$	US-PGPUB; USPAT	OR	ON	2020/03/27 19:10
S169	662	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04
S170	13,235	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04
S171	3,475	A61N1/3611,36135,36146,36171.cpc.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04

S172	3,475	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04
S173	7,461	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04
S174	23,481	S169 or S170 or S171 or S172 or S173	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04
S175	16	S174 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) and implant$ and duty adj cycle	US-PGPUB; USPAT	OR	ON	2020/03/28 00:04
S176	1	"5211173".pn.	US-PGPUB; USPAT	OR	ON	2020/03/28 00:07
S177	128	("4969467").PN. OR ("5211173").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/28 00:10
S178	83	S177 and (pulse adj width or pulse$1width or duration or period) with stimulat$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:12
S179	64	@pd<"20150319" and S177 and (pulse adj width or pulse$1width or duration or period) with stimulat$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:12
S180	16	@pd<"20150319" and S177 and (pulse adj width or pulse$1width or duration or period) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:14
S181	16	@pd<"20150319" and S177 and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:20
S182	14	S174 and @pd<"20150319" and S177 and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:33
S183	612	S174 and @pd<"20150319" and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:35
S184	206	S174 and @pd<"20150319" and sleep adj apnea and (pulse adj width or pulse$1width	US-PGPUB;	OR	ON	2020/03/28 00:39

		or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	USPAT; USOCR			
S185	5,105	S174 and @pd<"20150319" and sleep adj apnea and asynch$ (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:39
S186	45	S174 and @pd<"20150319" and sleep adj apnea and asynch$ and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 00:40
S187	28,108	sleep adj apnea @pd<"20150319" and S177 and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 01:04
S188	16	sleep adj apnea and @pd<"20150319" and S177 and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 01:04
S189	522	sleep adj apnea and @pd<"20150319" and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 01:06
S190	65	sleep adj apnea and @pd<"20150319" and (pulse adj width or pulse$1width or duration or period or duty adj cycle) with stimulat$ same (micro$1seconds mu$1s) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 01:06
S191	1	"5944680".pn.	US-PGPUB; USPAT	OR	ON	2020/03/28 02:23
S192	1	"5944680".pn. and average same (period or duration or width)	US-PGPUB; USPAT	OR	ON	2020/03/28 02:23
S193	192	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:26
S194	115	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:26
S195	0	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) same histor$ with (duration or period or width) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:28

S196	39	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width) same (histor$ or profile or personal or patient or specific) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:29
S197	39	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width) same (histor$ or profile or personal or patient or specific or population) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:34
S198	62	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width) same (histor$ or profile or personal or patient or specific or populationor data$1base) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:39
S199	51	S174 and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width) same (histor$ or profile or personal or patient or specific or populationor data$1base) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:40
S200	51	S174 and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width) same (histor$ or profile or personal or patient or specific or populationor data$1base multiple) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 02:52
S201	54	S174 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$)	US-PGPUB; USPAT	OR	ON	2020/03/28 02:55
S202	13	S174 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) same stimulat$	US-PGPUB; USPAT	OR	ON	2020/03/28 03:01
S203	13	S174 and @pd<"20150319" and a$1synchron$ with (breath$ or respirat$) and (historic$ or history or profile or average) with (breath$ or respirat$) same stimulat$	US-PGPUB; USPAT	OR	ON	2020/03/28 03:22
S204	662	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2020/03/28 12:50
S205	13,235	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 12:50

S206	3,475	A61N1/3611,36135,36146,36171.cpc..cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 12:50
S207	3,475	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 12:50
S208	7,461	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 12:50
S209	23,481	S204 or S205 or S206 or S207 or S208	US-PGPUB; USPAT	OR	ON	2020/03/28 12:50
S210	59	S209 and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (duration or period or width window) same (histor$ or profile or personal or patient or specific or populationor data$1base multiple) and a$1sync$	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 12:50
S211	49	sleep adj apnea and @pd<"20150319" and (mean or average) with (respirat$ or breath$) with (period or duration or width or pulse adj width) with (stimul$2 or stimulat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 14:43
S212	12	sleep adj apnea and @pd<"20150319" and (reference) with (respirat$ or breath$) with (period or duration or width or pulse adj width) with (stimul$2 or stimulat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 14:53
S213	0	sleep adj apnea and @pd<"20150319" and (reference) with (inspirat$) with (period or duration or width or pulse adj width) with (stimul$2 or stimulat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 14:53
S214	5	sleep adj apnea and @pd<"20150319" and (reference) with (inspirat$) with (stimul$2 or stimulat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 14:55
S215	47	sleep adj apnea and @pd<"20150319" and (reference or sample or average or mean or database) with (inspirat$) with (stimul$2 or stimulat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 15:20
S216	137	sleep adj apnea and @pd<"20150319" and (reference or sample or average or mean or database) same (inspirat$) same (stimul$2 or stimulat$) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 16:03
S217	662	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2020/03/28 16:08

S218	13,235	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 16:08
S219	3,475	A61N1/3611,36135,36146,36171.cpc.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 16:08
S220	3,475	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 16:08
S221	7,461	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2020/03/28 16:08
S222	23,481	S217 or S218 or S219 or S220 or S221	US-PGPUB; USPAT	OR	ON	2020/03/28 16:08
S223	158	S222 and @pd<"20150319" and (reference or sample or average or mean or database) same (inspirat$) same (stimul$2 or stimulat$) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 16:08
S224	80	S222 and @pd<"20150319" and (reference or sample or average or mean or database) with (inspirat$) same (stimul$2 or stimulat$) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 16:08
S225	154	S222 and @pd<"20150319" and (inspirat$) with (stimul$2 or stimulat$) with (length duration width or pulse adj width or pulse$1width or period) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 17:40
S226	2,695	S222 and @pd<"20150319" and (inspirat$) with (longer or greater) (stimul$2 or stimulat$) with (length duration width or pulse adj width or pulse$1width or period) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 17:42
S227	30	S222 and @pd<"20150319" and (inspirat$) with (longer or greater) with (stimul$2 or stimulat$) with (length duration width or pulse adj width or pulse$1width or period) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 17:42
S228	41	S222 and @pd<"20150319" and (inspirat$) with (longer or greater) with (stimul$2 or stimulat$ or pulse) with (length duration width or pulse adj width or pulse$1width or period) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 17:45
S229	38	sleep adj apnea and @pd<"20150319" and (inspirat$) with (longer or greater) with (stimul$2 or stimulat$ or pulse) with (length duration width or pulse adj width or	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 17:50

		pulse$1width or period) same (breath$3 or respirat$)				
S230	55	@pd<"20150319" and (inspirat$ or inhal$) with (longer or greater) with (stimul$2 or stimulat$ or pulse) with (length duration width or pulse adj width or pulse$1width or period) same (breath$3 or respirat$)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 18:00
S231	40	@pd<"20150319" and (inspirat$ or inhal$) with (longer or greater) with (stimul$2 or stimulat$ or pulse) with (length duration width or pulse adj width or pulse$1width or period) same (breath$3 or respirat$) and (hypogloss$ or upper adj airway)	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/28 18:01
S232	660	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2020/09/15 13:09
S233	14,119	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2020/09/15 13:09
S234	3,408	A61N1/3611,36135,36146,36171.cpc.cpc.	US-PGPUB; USPAT	OR	ON	2020/09/15 13:09
S235	3,408	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2020/09/15 13:09
S236	7,380	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2020/09/15 13:09
S237	24,240	S232 or S233 or S234 or S235 or S236	US-PGPUB; USPAT	OR	ON	2020/09/15 13:09
S238	11,161	S237 and @pd<"20150319" reference adj respirat$4 and stimulat$4 with (period or duration or width) and phase	US-PGPUB; USPAT	OR	ON	2020/09/15 13:09
S239	11,159	S237 and @pd<"20150319" reference adj respirat$4 and stimulat$4 with (period or duration or width) same phase	US-PGPUB; USPAT	OR	ON	2020/09/15 13:10
S240	0	S237 and @pd<"20150319" and reference adj respirat$4 and stimulat$4 with (period or duration or width) same phase	US-PGPUB; USPAT	OR	ON	2020/09/15 13:12
S241	6	S237 and @pd<"20150319" and reference adj respirat$4 and stimulat$4 with (period or duration or width) and phase	US-PGPUB; USPAT	OR	ON	2020/09/15 13:12
S242	67	S237 and @pd<"20150319" and reference with respirat$4 and stimulat$4 with (period or duration or width) with inspirat$4	US-PGPUB; USPAT	OR	ON	2020/09/15 13:18

S243	67	S237 and @pd<"20150319" and reference with respirat$4 and stimulat$4 with (period or duration or width) with inspirat$4 and pulse$1	US-PGPUB; USPAT	OR	ON	2020/09/15 13:28
S244	67	S237 and @pd<"20150319" and reference with respirat$4 and stimulat$4 with (period or duration or width) with inspirat$4 and puls$3	US-PGPUB; USPAT	OR	ON	2020/09/15 13:28
S245	0	S237 and @pd<"20150319" and reference with respirat$4 with average and stimulat$4 with (period or duration or width) with inspirat$4 and puls$3	US-PGPUB; USPAT	OR	ON	2020/09/15 13:32
S246	24	S237 and @pd<"20150319" and respirat$4 with average and stimulat$4 with (period or duration or width) with inspirat$4 and puls$3	US-PGPUB; USPAT	OR	ON	2020/09/15 13:33
S247	1	(A61B5/$.cpc. or A61N1/36$.cpc. or G06F19/$.cpc.) and @pd<"20150319" and respirat$4 with average and stimulat$4 with (period or duration or width) with inspirat$4 with (greater or longer)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/09/15 15:08
S248	30	(A61B5/$.cpc. or A61N1/36$.cpc. or G06F19/$.cpc.) and @pd<"20150319" and stimulat$4 with (period or duration or width) with inspirat$4 with (greater or longer)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/09/15 15:35
S249	18	"20080154330".pn. or "20090216293".pn. or "20150328451".pn. or "20140228905".pn. or "20130253627".pn. or "8781587".pn. or "20050148897".pn. or "20110060380".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2020/09/15 18:10
S250	10	S249 and (duration or period or time)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2020/09/15 19:04

			; IBM_TDB			
S254	660	607/42.ccls.	US-PGPUB; USPAT	OR	ON	2020/09/16 13:01
S255	14,119	A61B5/3601,0816,0826,113,4818,4848,686.cpc.	US-PGPUB; USPAT	OR	ON	2020/09/16 13:01
S256	3,408	A61N1/3611,36135,36146,36171.cpc.cpc.	US-PGPUB; USPAT	OR	ON	2020/09/16 13:01
S257	3,408	A61N1/3611,36135,36146,36171.cpc.	US-PGPUB; USPAT	OR	ON	2020/09/16 13:01
S258	7,380	G06F19/3481.cpc.	US-PGPUB; USPAT	OR	ON	2020/09/16 13:01
S259	24,240	S254 or S255 or S256 or S257 or S258	US-PGPUB; USPAT	OR	ON	2020/09/16 13:01
S260	11,226	S259 and @pd<"20150319" reference with inspirat$4 with (average or histor$ or profile)	US-PGPUB; USPAT	OR	ON	2020/09/16 13:01

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L8	0	"S237" and @pd<"20150319" and respirat$4 with average and stimulat$4 with (period or duration or width) with inspirat$4 and puls$3	USPAT	OR	ON	2020/09/16 19:06
L9	0	"S237" and @pd<"20150319" and respirat$4 with average and stimulat$4 with (period or duration or width) with inspirat$4 and puls$3	US-PGPUB; USPAT	OR	ON	2020/09/16 19:06
L10	25	@pd<"20150319" and respirat$4 with average and stimulat$4 with (period or duration or width) with inspirat$4 and puls$3	US-PGPUB; USPAT	OR	ON	2020/09/16 19:30
L11	25	@pd<"20150319" and respirat$4 with average and stimulat$4 with (period or duration or width) with inspirat$4	US-PGPUB; USPAT	OR	ON	2020/09/16 19:31
L12	149	@pd<"20150319" and respirat$4 same stimulat$4 with (period or duration or width) with inspirat$4	US-PGPUB; USPAT	OR	ON	2020/09/16 19:31

S251	30	(A61B5/$.cpc. or A61N1/36$.cpc. or G06F19/$.cpc.) and @pd<"20150319" and stimulat$4 with (period or duration or width) with inspirat$4 with (greater or longer)	US-PGPUB; USPAT	OR	ON	2020/09/15 17:53
S252	14	(A61B5/$.cpc. or A61N1/36$.cpc. or G06F19/$.cpc.) and @pd<"20150319" and stimulat$4 with (period or duration or width) with inspirat$4 with (greater or longer) and average	US-PGPUB; USPAT	OR	ON	2020/09/15 17:54
S253	8	"20080154330".pn. or "20090216293".pn. or "20150328451".pn. or "20140228905".pn. or "20130253627".pn. or "8781587".pn. or "20050148897".pn. or "20110060380".pn.	US-PGPUB; USPAT	OR	ON	2020/09/15 18:03

9/16/2020 7:31:46 PM
C:\Users\mlau2\Documents\EAST\Workspaces\15562714.wsp

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8781587	B2	2014-07-15	Alt et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20050148897	A1	2005-07-07	Cho et al.	
	2	20110060380	A1	2011-03-10	Gelfand et al.	

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	1	102548610	CN	A	2012-07-04	CARDIAC CONCEPTS INC	[Equivalent to US20110060380]	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	J Sleep Res., "Hypoglossal nerve stimulation improves obstructive sleep apnea: 12-month outcomes" Journal, 2014, 23, 77-83.	☒
	2	The Laryngoscope, "Implanted Upper Airway Stimulation Device for Obstructive Sleep Apnea" Journal, 2012, 122, 1626-1633.	☒

If you wish to add additional non-patent literature document citation information please click the Add button [Add]

EXAMINER SIGNATURE

Examiner Signature	/MICHAEL J LAU/	Date Considered	09/16/2020

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

X That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2020-05-06
Name/Print	Paul S. Grunzweig	Registration Number	37143

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0471

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20080154330		2008-06-26	Tehrani et al.	
	2	20090216293		2009-08-27	Sasaki et al.	
	3	20150328451		2015-11-19	Kobayashi	
	4	20140228905	A1	2014-08-14	Bolea	
	5	20130253627	A1	2013-09-26	Meadows et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2013509943	JP		2013-03-21	Imthera Medical, Inc.	[Equivalent US20130253627]	
	2	4960704	JP	B2	2008-08-07		[Equivalent US20090216293]	
	3	5636129	JP	B2	2015-12-07	TECHNO LINK CO LTD	[Equivalent US20150328451]	

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NON-PATENT LITERATURE DOCUMENTS [Remove]

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		

If you wish to add additional non-patent literature document citation information please click the Add button [Add]

EXAMINER SIGNATURE

Examiner Signature	/MICHAEL J LAU/	Date Considered	09/16/2020

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.103

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

X That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Paul S. Grunzweig/	Date (YYYY-MM-DD)	2020-04-21
Name/Print	Paul S. Grunzweig	Registration Number	37143

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/562,714	09/28/2017	Darrell Wagner	I618.118.103	3077

7590 11/09/2020

DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

EXAMINER	
LAU, MICHAEL J	
ART UNIT	PAPER NUMBER
3792	
NOTIFICATION DATE	DELIVERY MODE
11/09/2020	ELECTRONIC

NOTICE REQUIRING INVENTOR'S OATH OR DECLARATION

☐ An inventor's oath or declaration in compliance with 37 CFR 1.63 or substitute statement in compliance with 37 CFR 1.64 executed by or with respect to each inventor has not yet been submitted.

The inventor's oath or declaration or substitute statement dated 03/06/18 is defective. The inventor's oath or declaration does not comply with 37 CFR 1.63 or the substitute statement does not comply with 37 CFR 1.64 because it:

☐ does not include a statement that the person executing the oath or declaration or substitute statement believes the named inventor or joint inventor to be the original inventor or an original joint inventor of a claimed invention in the application for which the oath or declaration is being submitted.

☐ does not state that the application was made or was authorized to be made by the person executing the oath or declaration or substitute statement.

☐ does not acknowledge that any willful false statement made in such oath or declaration or substitute statement is punishable under section 1001 of title 18 by fine or imprisonment of not more than 5 years, or both.

☑ does not identify the person executing the oath or declaration or substitute statement by his or her legal name.

☐ does not identify the application to which the oath or declaration or substitute statement is directed.

☑ Other: Inventor 4

The substitute statement dated _____ does not comply with 37 CFR 1.64 because it:

☐ does not identify the inventor with respect to whom the statement applies.

☐ does not identify the relationship to the non-signing inventor.

☐ does not identify the circumstances permitting execution of the statement.

☐ was signed by someone other than the applicant.

☐ Other: _____

An oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each inventor MUST be filed **no later than the date on which the issue fee is paid.** See 35 U.S.C. 115(f). Failure to timely comply will result in ABANDONMENT of this application. This period for reply is not extendable under 37 CFR 1.136(a).

Questions relating to this Notice should be directed to the Application Assistance Unit at 571-272-4200.

(571)-272-4200 or 1(888)-786-0101
Patent Publication Branch
Office of Data Management

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/562,714	09/28/2017	Darrell Wagner	I618.118.103

CONFIRMATION NO. 3077

25281
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

37 CFR 1.48(f)
ACKNOWLEDGEMENT LETTER

OC000000121360694

Date Mailed: 11/17/2020

IMPROPER SUBMISSION OF REQUEST UNDER 37 CFR 1.48(f)

The request under 37 CFR 1.48(f) (request to change inventorship) submitted on 11/11/2020 in the above-identified application is not accepted because:

- The request to correct inventorship under 37 CFR 1.48(f) is deficient because the fee set forth in 37 CFR 1.17(i) has not been submitted.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/hsarwari/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/562,714	09/28/2017	3792	1620	1618.118.103	20	3

CONFIRMATION NO. 3077

CORRECTED FILING RECEIPT

25281
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

OC000000121380624

Date Mailed: 11/17/2020

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Darrell Wagner, Ham Lake, MN;
Quan Ni, Golden Valley, MN;
John Rondoni, Plymouth, MN;
Dave Dieken, Minneapolis, MN;

Applicant(s)

INSPIRE MEDICAL SYSTEMS, INC., Golden Valley, MN;

Assignment For Published Patent Application

INSPIRE MEDICAL SYSTEMS, INC., Golden Valley, MN

Power of Attorney: The patent practitioners associated with Customer Number 25281

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US2016/022611 03/16/2016
which claims benefit of 62/135,305 03/19/2015

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0478

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

Preliminary Class

607

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0479

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

Doc Code: R48.REQ
Document Description: Request under Rule 48 correcting inventorship

PTO/AIA/40 (04-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST FOR CORRECTION IN A PATENT APPLICATION RELATING TO INVENTORSHIP OR AN INVENTOR NAME, OR ORDER OF NAMES, OTHER THAN IN A REISSUE APPLICATION (37 CFR 1.48)

Application Number	15/562,714
Filing Date	September 28, 2017
First Named Inventor	Darrell Wagner et al.
Art Unit	3792
Examiner Name	LAU, Michael J.
Practitioner Docket Number	I618.118.103

To: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Applicant hereby **requests that the inventorship be corrected or changed, or that the name of the inventor or a joint inventor, or the order of the names of joint inventors, be changed,** in the above-identified application. **Note:** 37 CFR 1.48 applies to any request to correct inventorship filed on or after September 16, 2012, regardless of the application filing date. **Do not submit this form after payment of the issue fee or if the application has been patented.** See 37 CFR 1.324 for correction of inventorship in a patent.

Please check the applicable box(es) below.

For a nonprovisional application:

☐ 1. This request is to correct or change the inventorship in a **nonprovisional** application (**under 37 CFR 1.48(a)**) and includes:

☐ An application data sheet (ADS) in accordance with 37 CFR 1.76(c) with the corrected or updated information shown with markings (*e.g.*, underlining for insertions, strikethrough for deletions). See the Manual of Patent Examining Procedure (MPEP) section 601.05(a) for information about filing an ADS in an application filed on/after September 16, 2012. For information about filing a Supplemental ADS in an application filed before September 16, 2012, see MPEP 601.05(b).

☐ The processing fee set forth in 37 CFR 1.17(i). $_____

☐ An inventor is being added. An inventor's oath or declaration by any actual inventor who has not yet executed an oath or declaration is required (see 37 CFR 1.48(b)). See MPEP 602.01(a) for information about an inventor's oath or declaration for an application filed on/after September 16, 2012 (*e.g.*, form **PTO/AIA/01**). For information about an inventor's oath or declaration for an application filed before September 16, 2012 (*e.g.*, form **PTO/SB/01**), see MPEP 602.01(b).

☐ This request is being filed after the first Office action on the merits has been given or mailed (see 37 CFR 1.48(c) and 1.17(d)). Check one of the following:

☐ This request to correct or change the inventorship is due solely to the cancellation of claims in the application.

OR

☐ The fee set forth in 37 CFR 1.17(d) is due (in addition to the fee set forth in 37 CFR 1.17(i)). $_____

This collection of information is required by 37 CFR 1.48. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/40 (04-18)
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REQUEST FOR CORRECTION IN A PATENT APPLICATION RELATING TO INVENTORSHIP OR AN INVENTOR NAME, OR ORDER OF NAMES, OTHER THAN IN A REISSUE APPLICATION (37 CFR 1.48)

■ 2. This request is to correct or update the name of the inventor or a joint inventor, or the order of names of joint inventors, in a **nonprovisional** application (**under 37 CFR 1.48(f)**) and includes:

■ An application data sheet in accordance with 37 CFR 1.76(c) identifying the complete inventive entity, including the corrected or updated name of the inventor, or the new order of names shown with markings (*e.g.*, underlining for insertions, strikethrough for deletions). See the MPEP 601.05(a) for information about filing an ADS in an application filed on/after September 16, 2012. For information about filing a Supplemental ADS in an application filed before September 16, 2012, see MPEP 601.05(b).

■ The processing fee set forth in 37 CFR 1.17(i). $ 140.00

For a provisional application:

☐ This request is to change or correct the inventorship, or correct or update the name of the inventor or a joint inventor, in a **provisional** application (**under 37 CFR 1.48(d)**) and includes:

☐ **Attached hereto** is a document that is signed by a party set forth in 37 CFR 1.33(b) and identifies each inventor by his or her legal name, in the preferred order. Note: the document may be an application data sheet in accordance with 37 CFR 1.76(c) that identifies the changes with markings (underlining for insertions, strikethrough for deletions).

☐ The processing fee set forth in 37 CFR 1.17(q). $ _____

Fee Payment Information:

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. _____.

■ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ Applicant*

■ attorney or agent of record
Registration number 37,143

☐ attorney or agent acting under 37 CFR 1.34
Registration number _____

Signature /Paul S. Grunzweig/

Typed or printed name Paul S. Grunzweig

Date November 25, 2020

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. *Juristic entities must be represented by a patent practitioner (See 37 CFR 1.31, applicable to any paper filed on or after September 16, 2012 that is presented on behalf of a juristic entity, regardless of application filing date). Submit multiple forms if more than one signature is required, see below**.

☐ ** Total of _____ forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	15562714
Filing Date:	28-Sep-2017
Title of Invention:	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING
First Named Inventor/Applicant Name:	Darrell Wagner
Filer:	PAUL STEVEN GRUNZWEIG/Justina Perez
Attorney Docket Number:	I618.118.103

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	140

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	15/562,714
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Darrell		Wagner	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Maple Grove Ham Lake	State/Province	MN	Country of Residence	US

Mailing Address of Inventor:

Address 1	9700 63rd Ave. N. 5500 Wayzata Boulevard		
Address 2	Suite 1600		
City	Maple Grove Golden Valley	State/Province	MN
Postal Code	55369 55416	Country i	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Quan		Ni	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Maple Grove Golden Valley	State/Province	MN	Country of Residence	US

Mailing Address of Inventor:

Address 1	9700 63rd Ave. N. 5500 Wayzata Boulevard		
Address 2	Suite 1600		
City	Maple Grove Golden Valley	State/Province	MN
Postal Code	55369 55416	Country i	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	John		Rondoni	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

City	Maple Grove Plymouth	State/Province	MN	Country of Residence	US

Mailing Address of Inventor:

Address 1	9700 63rd Ave. N. 5500 Wayzata Boulevard		
Address 2	Suite 1600		
City	Maple Grove Golden Valley	State/Province	MN
Postal Code	55369 55416	Country	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Dave David		Dieken	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Maple Grove Minneapolis	State/Province	MN	Country of Residence	US

Mailing Address of Inventor:

Address 1	9700 63rd Ave. N. 5500 Wayzata Boulevard		
Address 2	Suite 1600		
City	Maple Grove Golden Valley	State/Province	MN
Postal Code	55369 55416	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	25281		
Email Address	USPTO.PATENTS@dbclaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING		
Attorney Docket Number	I618.118.103	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	13	Suggested Figure for Publication (if any)	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	25281		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	a 371 of international	PCT/US2016/022611	2016-03-16

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

Prior Application Status	Expired	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2016/022611	Claims benefit of provisional	62135305	2015-03-19
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.			

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

			Remove
Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.			

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

(•) Assignee	( ) Legal Representative under 35 U.S.C. 117	( ) Joint Inventor
( ) Person to whom the inventor is obligated to assign.	( ) Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	INSPIRE MEDICAL SYSTEMS, INC.		
Mailing Address Information For Applicant:			
Address 1	~~9700 63rd Ave. N.~~ 5500 Wayzata Boulevard		
Address 2	Suite 1600		
City	~~Maple Grove~~ Golden Valley	**State/Province**	MN
Country	US	Postal Code	~~55369~~ 55416
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☒

Organization Name	INSPIRE MEDICAL SYSTEMS, INC.

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1	9700 63rd Ave. N. 5500 Wayzata Boulevard		
Address 2	Suite 1600		
City	Maple Grove Golden Valley	**State/Province**	MN
Country i	US	Postal Code	55369 55416
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Paul S. Grunzweig/			Date (YYYY-MM-DD)	2017-09-28
First Name	Paul S.	Last Name	Grunzweig	Registration Number	37143

Additional Signature may be generated within this form by selecting the Add button.

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.103
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

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Privacy Act Statement

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0494

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/562,714	09/28/2017	3792	1620	I618.118.103	20	3

CONFIRMATION NO. 3077

UPDATED FILING RECEIPT

25281
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

Date Mailed: 11/30/2020

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Darrell Wagner, Ham Lake, MN;
Quan Ni, Golden Valley, MN;
John Rondoni, Plymouth, MN;
David Dieken, Minneapolis, MN;

Applicant(s)

INSPIRE MEDICAL SYSTEMS, INC., Golden Valley, MN;

Assignment For Published Patent Application

INSPIRE MEDICAL SYSTEMS, INC., Golden Valley, MN

Power of Attorney: The patent practitioners associated with Customer Number 25281

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US2016/022611 03/16/2016
which claims benefit of 62/135,305 03/19/2015

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0495

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

Preliminary Class

607

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0496

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/562,714	09/28/2017	Darrell Wagner	I618.118.103

CONFIRMATION NO. 3077

25281
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

37 CFR 1.48(f)
ACKNOWLEDGEMENT LETTER

OC000000121635012

Date Mailed: 11/30/2020

NOTICE OF ACCEPTANCE OF REQUEST UNDER 37 CFR 1.48(f)

This is in response to the applicant's request under 37 CFR 1.48(f) submitted on 11/25/2020.

The request under 37 CFR 1.48(f) to correct the inventorship, to correct or update the name of an inventor, or to correct the order of names of joint inventors is accepted.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/mmasfaw/

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

25281 7590 09/30/2020
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

Paul S. Grunzweig	(Typed or printed name)
/Paul S. Grunzweig/	(Signature)
December 18, 2020	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/562,714	09/28/2017	Darrell Wagner	I618.118.103	3077

TITLE OF INVENTION: STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1000	$0.00	$0.00	$1000	12/30/2020

EXAMINER	ART UNIT	CLASS-SUBCLASS
LAU, MICHAEL J	3792	607-042000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Dicke, Billig & Czaja, PLLC
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE	(B) RESIDENCE: (CITY and STATE OR COUNTRY)
Inspire Medical Systems, Inc.	Golden Valley, MN

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 500471

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Paul S. Grunzweig/ Date December 18, 2020

Typed or printed name Paul S. Grunzweig Registration No. 37143

PTOL-85 Part B (08-18) Approved for use through 01/31/2020 OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0499

Change(s) applied to document,
/L.H./
11/2/2020

IN THE SPECIFICATION

Please replace Paragraph ~~0217~~ 00216 with the following:

[0217] With further reference to FIG. 14, based on monitoring of the sensed respiratory waveform, at repeating intervals, at **474** it is queried whether the respiratory waveform is sufficiently stable to support activation of the respiratory-dependent stimulation. If the answer to the query at **474** is NO, then pathway **476** directs continued operation of independent stimulation at **472**. However, if the answer to the query at **474** is YES, then pathway **477** directs initiation of operation of respiratory-dependent stimulation at **478** of FIG. 14. During operation of respiratory-dependent stimulation at **478**, the query at **474** is periodically implemented via pathway **479**. If the answer to the query (at **474**) is NO, then operation in respiratory-dependent stimulation n (**456** in FIG. 12) at **478** in FIG. 14 is terminated as operation is returned (i.e. reverts) via pathway **476** to independent stimulation at **472** in FIG. 14 for at least the predetermined period of time.

Please replace Paragraph ~~0230~~ 00229 with the following:

[0230] FIG. 15B is a diagram **500** schematically illustrating aspects of selecting a stimulation protocol **501**, according to one example of the present disclosure. In some examples, at least some aspects of selecting a stimulation protocol as expressed in diagram **500** can be embodied as a method while in some examples, at least some aspects of selecting a stimulation protocol as expressed in diagram **500**~~**550**~~ can be embodied as operational aspects of a stimulation protocol management associated with a therapy manager **16** as described in association with at least FIGS. 1-15A.

Please replace Paragraph ~~0252~~ 00251 with the following:

[0252] Upon operation of independent stimulation at **558** for at least the predetermined period of time, the query at **554** is periodically implemented via pathway **559**. If the answer to the query (at **554**) is YES, then operation in independent stimulation at **558** in FIG. 15D is terminated as operation is returned via pathway **556** to respiratory-dependent stimulation at **552** in FIG. 15D. For at least the current example, it will be understood that, in the event that no stable respiratory waveform is established, the operation would remain in the independent stimulation at **558** without reverting operation into respiratory-dependent stimulation at **552**.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0500

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner et al.
Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

	4	20020156507		2002-10-24	Lindenthaler	
Change(s) applied to document. /N.W.S/ 11/4/2020	5	20030093128		05/2003 ~~2005-05-15~~	Freed et al.	
	6	20030224895		2003-06-19	Gordon et al.	
	7	20030114905		2003-06-19	Kuzma	
	8	20030163059		2003-08-28	Poezevera et al.	
	9	20030195571		2003-10-16	Burnes et al.	
	10	20030216789		2003-11-20	Deem et al.	
	11	20040015204		2004-01-22	Whitehurst et al.	
	12	20040073272		2004-04-15	Knudson et al.	
	13	20040111139		2004-06-10	McCreery	
	14	20040215288		2004-10-28	Lee et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0501

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	15562714
Filing Date	2017-09-28
First Named Inventor	Darrell Wagner et al.
Art Unit	
Examiner Name	
Attorney Docket Number	I618.118.103

	163	7447545		2008-11-04	Heruth et al.	
	164	7454250		2008-11-18	Bjorling et al.	
	165	7453928		2008-12-09	Lee et al.	
	166	7468040		2008-12-23	Hartley et al.	
	167	7469697		2008-12-30	Lee et al.	
	168	7473227		2009-01-06	Hsu et al.	
	169	7491181		2009-02-17	Heruth et al.	
Change(s) applied to document. /N.W.S./ 11/4/2020	170	6509164		01/2003 ~~2009-03-24~~	Guirguis ~~Jensen et al.~~	
	171	7510531		2009-03-31	Lee et al.	
	172	7526341		2009-04-29	Goetz et al.	
	173	7542803		2009-06-02	Heruth et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0502

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Alexandria, Virginia 22313-1450
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/562,714	01/26/2021	10898709	I618.118.103	3077

25281 7590 01/06/2021

DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

INSPIRE MEDICAL SYSTEMS, INC., Golden Valley, MN;
Darrell Wagner, Ham Lake, MN;
Quan Ni, Golden Valley, MN;
John Rondoni, Plymouth, MN;
David Dieken, Minneapolis, MN;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.