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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/348,852	06/16/2021	Darrell Wagner	I618.118.105	5390

25281 7590 12/26/2023

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
12/26/2023	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

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0001

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APPLICATION NO.	ISSUE DATE	PATENT NO.
17/348,852	26-Dec-2023	11850424

DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
MINNEAPOLIS, MN 55402

EGRANT NOTIFICATION

Your electronic patent grant (eGrant) is now available, which can be accessed via Patent Center at https://patentcenter.uspto.gov

The electronic patent grant is the official patent grant under 35 U.S.C. 153. For more information, please visit https://www.uspto.gov/electronicgrants

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/348,852	12/26/2023	11850424	I618.118.105	5390

25281 7590 12/06/2023

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. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at https://patentcenter.uspto.gov/. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at https://certifiedcopycenter.uspto.gov/index.html. The Certified Copy Center may be reached at (800)972-6382.

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 120 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 Center (https://patentcenter.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 Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0003

INVENTOR(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional inventors):

Darrell Wagner, Ham Lake, MN;
Quan Ni, Shoreview, MN;
John Rondoni, Plymouth, MN;
David Dieken, Minneapolis, MN;

APPLICANT(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional applicants):

INSPIRE MEDICAL SYSTEMS, INC., Golden Valley, 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.

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NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0004

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17348852
	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	29	20110288609		2011-11-24	Tehrani	
	30	20120192874		2012-08-02	Bolea	
Change(s) applied to document, /S.D./ 11/15/2023	31	20120253249		~~2011-10-04~~ 10/2012	Wilson	
	32	20080161878		2008-07-03	Tehrani	
	33	20080154330		2008-06-26	Tehrani	
	34	20150039045		2015-02-05	Ni et al.	
	35	20160193468		2016-07-07	Rondoni et al.	
	36	20160022204		2016-01-28	Mostov	
	37	20160354602		2016-12-08	Keenan	
	38	20160354603		2016-12-08	Keenan	
	39	20160354608		2016-12-08	Keenan	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

Exhibit 1002
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	Attorney Docket Number	I618.118.105

	4	20020156507		2002-10-24	Lindenthaler	
Change(s) applied to document, /S.D./ 11/15/2023	5	20030093128		~~2005-05-15~~ 05/2003	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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	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	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. /S.D./ 11/15/2023	170	6509164		~~2003-03-24~~ 01/2003	~~Jensen et al.~~ Guirguis	
	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./

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/348,852	**11/14/2023 01:54:34 PM Z ET**	**I618.118.105**

Title of Invention

STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5390	FILED BY	Justina Perez
PATENT CENTER #	63234195	FILING DATE	06/16/2021
CUSTOMER #	25281	FIRST NAMED INVENTOR	Darrell Wagner
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Paul Grunzweig

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-11-14IssueFee.pdf	1	Issue Fee Payment (PTO-85B)	1615 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-11-14IssueFee.pdf	1174F56A855DCBF7CAD915611A4A4A0B11F6CEDA570BF12E1 CC09C016CAE1D9138DEB82F780A652C3AE5DDAEE8EA832B5 238985C3E9A6455977DC4325CE0FEE9

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as

described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for 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

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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.

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/348,852	**11/14/2023 01:54:34 PM Z ET**	**I618.118.105**

Title of Invention

STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5390	FILED BY	Justina Perez
PATENT CENTER #	63234195	AUTHORIZED BY	Paul Grunzweig
CUSTOMER #	25281	FILING DATE	06/16/2021
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Darrell Wagner

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 1115	**E2023ADD56055533**	**Justina Perez**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1501	UTILITY ISSUE FEE	1200.00	1	1200.00
			TOTAL AMOUNT:	**$1,200.00**

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

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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
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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 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

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25281 7590 11/13/2023
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

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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)
November 14, 2023	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/348,852	06/16/2021	Darrell Wagner	I618.118.105	5390

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	$1200	$0.00	$0.00	$1200	02/13/2024

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/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 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: INSPIRE MEDICAL SYSTEMS, INC.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): 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)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via Patent Center or 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
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.

☐ Applicant asserting small entity status. See 37 CFR 1.27
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.

☐ Applicant changing to regular undiscounted fee 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 November 14, 2023

Typed or printed name Paul S. Grunzweig Registration No. 37143

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0012

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NOTICE OF ALLOWANCE AND FEE(S) DUE

25281 7590 11/13/2023

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: 11/13/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/348,852	06/16/2021	Darrell Wagner	I618.118.105	5390

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nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	02/13/2024

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 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted 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. 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.

PTOL-85 (Rev. 02/11)

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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(Typed or printed name)
(Signature)
(Date)

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1_____
2_____
3_____

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(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

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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.

❑ Applicant asserting small entity status. See 37 CFR 1.27
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.

❑ Applicant changing to regular undiscounted fee 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.
0014

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 NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/348,852	06/16/2021	Darrell Wagner	I618.118.105	5390

25281 7590 11/13/2023

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: 11/13/2023

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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0015

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. 17/348,852	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 10/1/2023.
   ☐ 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 PTO-2323.

/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.
0017

Continuation of 3. The allowed claim(s) is/are: 1-2,4-15,17-20 and 22-24

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 9-28, filed 10/1/2023, with respect to claims 1-2, 4-15, 17-20, 22-24 have been fully considered and are persuasive. The rejection of claims 1-2, 4-15, 17-20, 22-24 has been withdrawn.

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

4. Claim 18 is amended to change dependency to depend on claim 1 since claim 16 is cancelled:

"18. The device of claim 1[[6]], wherein a duration of a respective one of the stimulation periods exceeds the duration of a respective one of the non-stimulation periods by a factor of 3."

5. The Specification par. [0001] is amended as follows:

"This application is a continuation of utility application Serial Number 17/012,481,filed on September 04, 2020, now US Patent 11,806,526, which is a continuation of utility application Serial Number 15/562,714, filed September 28, 2017, now U.S. Patent 10,898,709, issued on January 26, 2021, which is a 371 National Phase Application of PCT Patent Application No. PCT/US20 16/022611, filed March 16, 2016, entitled STIMULATION FOR TREATING SLEEP DISORDERED BREATHING, which claims benefit from U.S. Provisional Patent Application 62/135,305, filed March 19, 2015, all of which are herein incorporated by reference."

Allowable Subject Matter

6. Claims 1-2, 4-15, 17-20, 22-24 are allowed.

Reasons for Allowance

7. The following is an examiner's statement of reasons for allowance: claims 1-2, 4-15, 17-20, 22-24 are allowable over the prior art because the Examiner found that none of the cited prior art discloses an implantable electrode and/or an IPG for stimulating a hypoglossal nerve… and wherein a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period, wherein the duration of each respective stimulation period is based on a reference respiration-related parameter, and wherein the means for stimulating comprises an implantable electrode and/or an implantable pulse generator electrically connectable to the implantable electrode in combination with the rest of the claimed elements.

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

8. 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 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 published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, 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. 17/348,852	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-20120158091-A1	06-2012	TEHRANI; Amir J.	A61N1/3601	607/42
*	B	US-20110112601-A1	05-2011	MEADOWS; Paul M.	A61N1/37223	607/42
*	C	US-20140228905-A1	08-2014	BOLEA; Stephen L.	A61F5/566	607/42
*	D	US-20140194793-A1	07-2014	Nakata; Robert Haruo	G01S13/87	601/48
*	E	US-20100174341-A1	07-2010	Bolea; Stephen L.	A61B5/4818	607/42
*	F	US-20120192874-A1	08-2012	BOLEA; Stephen L.	A61N1/37235	128/202.16
*	G	US-20100094379-A1	04-2010	Meadows; Paul M.	A61N1/37264	607/48
*	H	US-20060167523-A1	07-2006	Tehrani; Amir J.	A61B5/395	607/42
	I					
	J					
	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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/348,852	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61N1/3601,3611,3614,36146,36171	12/07/2022	ML
G16H20/40	12/07/2022	ML
A61B5/0816,0826,113,4818,4848,686,0205	12/07/2022	ML

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
607	42	12/07/2022	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 and prior art search on pe2e search	12/07/2022	ML
updated search on pe2e search	07/07/2023	ML
updated search on pe2e search	10/27/2023	ML

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
	see pe2e search history for intereference search	10/27/2023	ML

/MICHAEL J LAU/ Examiner, Art Unit 3792	

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0023

AFCP 2.0 Decision	Application No.	Applicant(s)	
	17/348,852	Wagner et al.	
	Examiner	Art Unit	AIA (FITF) Status
	MICHAEL J LAU	3792	Yes

This is in response to the After Final Consideration Pilot request filed 01 October 2023.

1. **Improper Request** – The AFCP 2.0 request is improper for the following reason(s) and the after final amendment submitted with the request will be treated under pre-pilot procedure.

   ☐ An AFCP 2.0 request form PTO/SB/434 (or equivalent document) was not submitted.

   ☐ A non-broadening amendment to at least one independent claim was not submitted.

   ☐ The request is not the first proper AFCP 2.0 request submitted in response to the most recent final rejection.

   ☐ Other: _____

2. **Proper Request**

   A. After final amendment submitted with the request will not be treated under AFCP 2.0.
   The after final amendment cannot be reviewed and a search conducted within the guidelines of the pilot program.

   ☐ The after final amendment will be treated under pre-pilot procedure.

   B. Updated search and/or completed additional consideration.
   The examiner performed an updated search and/or completed additional consideration of the after final amendment within the time authorized for the pilot program. The result(s) of the updated search and/or completed additional consideration are:

   ☑ 1. All of the rejections in the most recent final Office action are overcome and a Notice of Allowance is issued herewith.

   ☐ 2. The after final amendment would not overcome all of the rejections in the most recent final Office action . See attached interview summary for further details.

   ☐ 3. The after final amendment was reviewed, and it raises a new issue(s). See attached interview summary for further details.

   ☐ 4. The after final amendment raises new issues, but would overcome all of the rejections in the most recent final Office action. A decision on determining allowability could not be made within the guidelines of the pilot. See attached interview summary for further details, including any newly discovered prior art.

   ☐ 5. Other: _____

   Examiner Note: Please attach an interview summary when necessary as described above.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0024

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/348,852	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	12/07/2022	07/07/2023	10/27/2023						
1	1	✓	✓	=						
2	2	✓	✓	=						
	3	✓	✓	-						
3	4	✓	✓	=						
4	5	✓	✓	=						
5	6	✓	✓	=						
6	7	✓	✓	=						
7	8	✓	✓	=						
8	9	✓	✓	=						
18	10	✓	✓	=						
19	11	✓	✓	=						
9	12	✓	✓	=						
20	13	✓	✓	=						
10	14	✓	✓	=						
11	15	✓	✓	=						
	16	✓	✓	-						
12	17	✓	✓	=						
13	18	✓	✓	=						
14	19	✓	✓	=						
15	20	✓	✓	=						
	21	✓	✓	-						
16	22	✓	✓	=						
17	23			=						
21	24			=						

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0025

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/348,852	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
G16H	/	20	/	40		I	2018-01-01
A61B	/	5	/	0816		I	2013-01-01
A61B	/	5	/	113		I	2013-01-01
A61N	/	1	/	36146		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	28 October 2023	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	21	
/CARL H LAYNO/ Supervisory Patent Examiner, Art Unit 3792	30 October 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office — Part of Paper No.: 20231027

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0026

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/348,852	Wagner et al.
	Examiner	**Art Unit**
	MICHAEL J LAU	3792

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61N	/	1	/	36

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

/MICHAEL J LAU/ Examiner, Art Unit 3792 (Assistant Examiner)	28 October 2023 (Date)	**Total Claims Allowed:** 21	
/CARL H LAYNO/ Supervisory Patent Examiner, Art Unit 3792 (Primary Examiner)	30 October 2023 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

U.S. Patent and Trademark Office — Part of Paper No.: 20231027

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0027

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/348,852	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	1	19	11	16	22										
2	2	9	12	17	23										
3	4	20	13	21	24										
4	5	10	14												
5	6	11	15												
6	7	12	17												
7	8	13	18												
8	9	14	19												
18	10	15	20												

/MICHAEL J LAU/ Examiner, Art Unit 3792	28 October 2023	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	21	
/CARL H LAYNO/ Supervisory Patent Examiner, Art Unit 3792	30 October 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office

Part of Paper No.: 20231027

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0028

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	250	("20120232611" OR "20140188185" OR "5277193" OR "9737708" OR "20010010010" OR "20020010495" OR "20020049479" OR "20020156507" OR "20030093128" OR "20030114905" OR "20030163059" OR "20030195571" OR "20030216789" OR "20030224895" OR "20040015204" OR "20040073272" OR "20040111139" OR "20040215288" OR "20040230278" OR "20040254612" OR "20050004628" OR "20050010265" OR "20050042589" OR "20050043765" OR "20050043772" OR "20050074741" OR "20050076908" OR "20050080348" OR "20050080461" OR "20050081847" OR "20050085865" OR "20050085866" OR "20050085868" OR "20050085869" OR "20050085874" OR "20050101833" OR "20050113710" OR "20050115561" OR "20050145246" OR "20050148897" OR "20050165457" OR "20050182457" OR "20050209513" OR "20050209643" OR "20050222503" OR "20050234523" OR "20050251216" OR "20050261747" OR "20050267380" OR "20050277844" OR "20050277999" OR "20050278000" OR "20060052836" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/12/05 02:35 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0029

		"20060058852" OR "20060064029" OR "20060079802" OR "20060095088" OR "20060103407" OR "20060135886" OR "20060142815" OR "20060155341" OR "20060167523" OR "20060212096" OR "20060224209" OR "20060241708" OR "20060247729" OR "20060259079" OR "20060264777" OR "20060266369" OR "20060271137" OR "20060276701" OR "20060293720" OR "20060293723" OR "20070021785" OR "20070027482" OR "20070038265" OR "20070150022" OR "20070233204" OR "20070255379" OR "20080009685" OR "20080039904" OR "20080046055" OR "20080064977" OR "20080103545" OR "20080103570" OR "20080109046" OR "20080109048" OR "20080132802" OR "20080154330" OR "20080161878" OR "20080294060" OR "20090024047" OR "20090062882" OR "20090112116" OR "20090118787" OR "20090216293" OR "20090234427" OR "20090287279" OR "20090308395" OR "20090326408" OR "20100010566" OR "20100016749" OR "20100094379" OR "20100125310" OR "20100125314" OR "20100125315" OR "20100137931" OR "20100152553" OR "20100174341" OR "20100198103" OR "20100198289" OR					

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0030

		"20100228133" OR "20100228310" OR "20100228317" OR "20100241195" OR "20100262210" OR "20110060380" OR "20110093032" OR "20110093036" OR "20110112601" OR "20110152706" OR "20110152965" OR "20110160794" OR "20110172733" OR "20110264164" OR "20110288609" OR "20120192874" OR "20120253249" OR "20120290036" OR "20130253627" OR "20140135868" OR "20140228905" OR "20140364919" OR "20150039045" OR "20150328451" OR "20160022204" OR "20160193468" OR "20160354602" OR "20160354603" OR "20160354608" OR "20170368337" OR "4379462" OR "4567892" OR "4630614" OR "4813431" OR "4830008" OR "5123425" OR "5133354" OR "5134995" OR "5148802" OR "5158080" OR "5167229" OR "5174287" OR "5178156" OR "5190053" OR "5203343" OR "5211173" OR "5215082" OR "5233983" OR "5239995" OR "5245995" OR "5265624" OR "5281219" OR "5300094" OR "5335657" OR "5344438" OR "5351394" OR "5385144" OR "5388578" OR					

		"5398682" OR "5458137" OR "5483969" OR "5485851" OR "5522862" OR "5524632" OR "5540731" OR "5540732" OR "5540733" OR "5540734" OR "5546952" OR "5549655" OR "5588439" OR "5591216" OR "5605151" OR "5645053" OR "5671733" OR "5797852" OR "5823187" OR "5843135" OR "5895360" OR "5904141" OR "5919221" OR "5944680" OR "5999846" OR "6015389" OR "6021352" OR "6025624" OR "6041780" OR "6099479" OR "6120441" OR "6125290" OR "6125291" OR "6126611" OR "6132384" OR "6134459" OR "6144866" OR "6175767" OR "6181961" OR "6198952" OR "6223064" OR "6240316" OR "6248080" OR "6249703" OR "6251126" OR "6269269" OR "6307481" OR "6309350" OR "6314324" OR "6342039" OR "6345202" OR "6361494" OR "6393325" OR "6449507" OR "6450957" OR "6456866" OR "6509164" OR "6522928" OR					

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0032

		"6532388" OR "6572543" OR "6574507" OR "6587725" OR "6609016" OR "6609032" OR "6629527" OR "6641542" OR "6645143" OR "6647289" OR "6651652" OR "6654634" OR "6665560" OR "6666830" OR "6689068" OR "6703939" OR "6718208" OR "6719708" OR "6731976" OR "6731984" OR "6735471" OR "6752765" OR "6770022").pn.					
L2	113	("6773404" OR "6805667" OR "6811538" OR "6842647" OR "6881192" OR "6890306" OR "6893405" OR "6904320" OR "6907293" OR "6928324" OR "6935335" OR "6936011" OR "6964641" OR "6978171" OR "6988498" OR "7025730" OR "7041049" OR "7054692" OR "7077810" OR "7081095" OR "7082331" OR "7082336" OR "7087053" OR "7117036" OR "7128717" OR "7145461" OR "7149573" OR "7155278" OR "7160252" OR "7160255" OR "7167743" OR "7174215" OR "7186220" OR "7187978" OR "7189204" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/12/05 02:35 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0033

		"7195594" OR "7200440" OR "7206635" OR "7212862" OR "7214197" OR "7252640" OR "7269457" OR "7269459" OR "7277749" OR "7330760" OR "7336996" OR "7340302" OR "7351208" OR "7366572" OR "7371220" OR "7387608" OR "7395113" OR "7396333" OR "7398115" OR "7422015" OR "7438686" OR "7447545" OR "7453928" OR "7454250" OR "7468040" OR "7469697" OR "7473227" OR "7491181" OR "7510531" OR "7526341" OR "7542803" OR "7572225" OR "7590455" OR "7591265" OR "7596413" OR "7603170" OR "7610094" OR "7634315" OR "7644714" OR "7662105" OR "7672728" OR "7678061" OR "7680538" OR "7702385" OR "7717848" OR "7720541" OR "7725195" OR "7734340" OR "7734350" OR "7742819" OR "7747323" OR "7751880" OR "7775993" OR "7783353" OR "7792583" OR "7809442" OR "7818063" OR "7853322" OR					

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0034

		"7881798" OR "7908013" OR "7917230" OR "7942822" OR "7957797" OR "7957809" OR "7979128" OR "8016776" OR "8021299" OR "8150531" OR "8160711" OR "8160712" OR "8175720" OR "8233987" OR "8265759" OR "8280513" OR "8718776" OR "8731678" OR "8781587" OR "9895540").pn.					
L3	16120	A61N1/3601,3611,3614,36146,36171.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 12:12 PM
L4	42004	G16H20/40.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 12:13 PM
L5	121858	A61B5/0816,0826,113,4818,4848,686,0205.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA,	OR	ON	ON	2022/12/06 12:13 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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			EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L6	1065	607/42.ccls.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 12:16 PM
L7	172754	L3 OR L4 OR L5 OR L6	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 01:11 PM
L8	520	L7 AND "20150319"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO;	OR	ON	ON	2022/12/06 01:17 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0036

			JPO; DERWENT; IBM_TDB)				
L9	124110	L7 AND @pd>"20150319"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 01:47 PM
L10	2640	L7 AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 02:56 PM
L11	1670	L7 AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 02:59 PM
L12	578	L7 AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ SAME (regular$ OR periodic$)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	OR	ON	ON	2022/12/06 03:00 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0037

			IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L13	804	L7 AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 03:00 PM
L14	398	L7 AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) SAME (sample$ OR base$line OR normal OR template$)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 03:01 PM
L15	118	(L3 OR L4 OR L5 OR L6) AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) SAME (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 03:02 PM

L16	188	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) SAME (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 05:28 PM
L17	205	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$ OR upper ADJ air$way) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) SAME (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 05:28 PM
L18	180	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$ OR upper ADJ air$way) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 06:50 PM
L19	88	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$ OR upper ADJ air$way) WITH stimulat$ AND stimulat$ WITH (regular$ OR	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL,	OR	ON	ON	2022/12/06 06:51 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0039

		periodic$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L20	86	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (nerve$ OR hypo$glossal OR patenc$ OR upper ADJ air$way) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 06:51 PM
L21	60	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:03 PM
L22	64	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:20 PM
L23	48	(L3 OR L4 OR L5 OR L6) AND	(US-PGPUB; USPAT; USOCR; FIT (AP, AT,	OR	ON	ON	2022/12/06 07:21 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0040

		@pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$) SAME (breath$ OR respirat$) near3 (sample$ OR base$line OR normal OR template$) SAME stimulat$	AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L24	1	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$) SAME (breath$ OR respirat$) near3 (sample$ OR base$line OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:21 PM
L25	215	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:22 PM
L26	62	"5636129"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE,	OR	ON	ON	2022/12/06 07:23 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0041

			SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L27	197	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:24 PM
L28	243	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$ OR interval$)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:25 PM
L29	151	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$ OR interval$) SAME puls$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:26 PM
L30	2	("20140228905").pn.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU,	OR	ON	ON	2022/12/07 04:20 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0042

			CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L31	62	((("INSPIRE") near3 ("MEDICAL") near3 ("SYSTEMS") near3 ("INC"))).AS,AANM.	(USPAT)	OR	ON	ON	2022/12/07 04:21 PM
L32	567	((("WAGNER") near3 ("Darrell")) OR (("NI") near3 ("Quan")) OR (("RONDONI") near3 ("John")) OR (("DIEKEN") near3 ("David"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/12/07 04:24 PM
L33	9	("20140194793"|"20200147376"|"5146918").PN.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/05 02:58 PM
L34	154	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$ OR interval$ OR schedul$) SAME puls$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/06 06:47 PM
L35	163	(L3 OR L4 OR L5 OR	(US-PGPUB; USPAT;	OR	ON	ON	2023/07/06

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0043

		L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$ OR interval$ OR schedul$ OR independent) SAME puls$	USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				06:47 PM
L36	50	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (asynchron$ OR schedul$ OR independent) SAME puls$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 12:20 AM
L37	58	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (a$1synchron$ OR schedul$ OR independent OR manual) SAME puls$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 12:44 AM
L38	177	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (a$1synchron$ OR schedul$ OR	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL,	OR	ON	ON	2023/07/07 12:44 AM

Exhibit 1002
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0044

		independent OR manual) WITH (stimulat$ OR puls$)	PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L39	186	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (a$1synchron$ OR schedul$ OR independent OR manual OR fixed)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 12:56 AM
L40	88	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (a$1synchron$ OR schedul$ OR independent OR manual OR fixed) AND (reference OR sample) WITH respirat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/26 01:07 PM
L41	35	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (a$1synchron$ OR schedul$ OR independent OR manual OR fixed) AND (reference OR sample) WITH respirat$ WITH (duration OR period OR length OR segment)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/10/26 01:10 PM

PE2E SEARCH - Search History (Interference)

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0045

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N1	25	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (a$1synchron$ OR schedul$ OR independent OR manual OR fixed) AND (reference OR sample) WITH respirat$ WITH (duration OR period OR length OR segment)	(US-PGPUB; USPAT)	OR	ON	ON	2023/10/27 11:44 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1st Named Inventor: Darrell Wagner et al.	Examiner: LAU, Michael J.
Serial No.: 17/348,852	Group Art Unit: 3792
Filed: June 16, 2021	Docket No.: I618.118.105
	Conf. No.: 5390

Title: STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

AFTER FINAL AND RESPONSE

Mail Stop **AF**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the Final Office Action dated July 14, 2023, please enter and consider the following:

Amendments to the **Claims** begin on page 2; and

Remarks begin on page 9.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees due to Deposit Account No. 500471.

OK TO ENTER: /M.L./

10/27/2023

Bibliographic Data

Application No: 17/348,852

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /MICHAEL J LAU/ Examiner's Signature | Initials

Title: STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
06/16/2021	607	3792	I618.118.105
RULE			

APPLICANTS

INSPIRE MEDICAL SYSTEMS, INC., Golden Valley, MN, UNITED STATES

INVENTORS

Darrell Wagner, Ham Lake, MN, UNITED STATES

Quan Ni, Shoreview, MN, UNITED STATES

John Rondoni, Plymouth, MN, UNITED STATES

David Dieken, Minneapolis, MN, UNITED STATES

CONTINUING DATA

This application is a CON of 17012481 09/04/2020 PAT 11806526

17012481 is a CON of 15562714 09/28/2017 PAT 10898709

15562714 is a 371 of PCT/US2016/022611 03/16/2016

PCT/US2016/022611 has PRO of 62135305 03/19/2015

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

06/25/2021

STATE OR COUNTRY

UNITED STATES

ADDRESS

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MINNEAPOLIS, MN 55402

UNITED STATES

FILING FEE RECEIVED

$2,180

Doc Code: A.NE.AFCP
Document Description: After Final Consideration Pilot Program Request

PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0

Practitioner Docket No.:	Application No.:	Filing Date:
I618.118.105	17/348,852	June 16, 2021
First Named Inventor:	**Title:**	
Darrell Wagner	Stimulation for Treating Sleep Disordered Breathing	

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.

1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (*e.g.*, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c).
2. The above-identified application contains an outstanding final rejection.
3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect.
4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection.
5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response.
6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web).
7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.]
8. By filing this certification and request, applicant acknowledges the following:
   - Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0.
   - The examiner will verify that the AFCP 2.0 submission is compliant, *i.e.*, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions:
     - The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, *e.g.*, by mailing an advisory action.
     - If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview.
       - The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate.
       - If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116.

Signature	Date
/Paul S. Grunzweig/	September 30, 2023
Name (Print/Typed) Paul S. Grunzweig	Practitioner Registration No. 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. Submit multiple forms if more than one signature is required, see below*.*

☑ * Total of 1 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.

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/348,852	**10/01/2023 01:10:12 AM ET**	**I618.118.105**

Title of Invention

STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5390	FILED BY	Paul Grunzweig
PATENT CENTER #	62906512	FILING DATE	06/16/2021
CUSTOMER #	25281	FIRST NAMED INVENTOR	Darrell Wagner
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	-

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
2023-09-30AFCPRequest.pdf	2	After Final Consideration Program Request	236 KB
2023-09-30ResponseFOA.pdf	26	Response After Final Action	589 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2023-09-30AFCPRequest.pdf	0DE3468DFDE9F1C43798B8B7E32BA576BD078C3D04B45F84D4305F564B024F16F76757CB856F1340552D55A7B6972F7BD8

5B5769C2C946B1F209FF1D111B0C3D

2023-09-30ResponseFOA.pdf A992C08AA5E04C01DEDE10641B7DD73B7CA13D62184C0854
258C4A73A3BE82E0FDA87F826A93C6776D88998D10AC80261
A53F708F3366B6E4BA604F14D16EEF7

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for 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

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1st Named Inventor: Darrell Wagner et al.	Examiner: LAU, Michael J.
Serial No.: 17/348,852	Group Art Unit: 3792
Filed: June 16, 2021	Docket No.: I618.118.105
	Conf. No.: 5390

Title: STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

AFTER FINAL AND RESPONSE

Mail Stop **AF**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the Final Office Action dated July 14, 2023, please enter and consider the following:

Amendments to the **Claims** begin on page 2; and

Remarks begin on page 9.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees due to Deposit Account No. 500471.

IN THE CLAIMS

Please cancel claims 3, 16, and 21 without prejudice.

Please add new claims 23-24.

Please amend claims 1-2, 4, 6-8, 10-11, 13, and 17 as follows:

1. (Currently Amended) A device for treating obstructive sleep disordered breathing, comprising:

a ~~stimulation element to~~means for stimulating a hypoglossal ~~stimulate an upper airway patency related~~ nerve, according to a first stimulation therapy protocol including alternating periods of stimulation and non-stimulation in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation,

wherein a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period, wherein the duration of each respective stimulation period is based on a reference respiration-related parameter, and

wherein the means for stimulating comprises an implantable electrode and/or an implantable pulse generator electrically connectable to the implantable electrode.

2. (Currently Amended) The device of claim 1, wherein the timing of the stimulation periods being implemented without a sensing element for timing stimulation comprises the timing of the stimulation being implemented~~implement~~ without a sensing element for synchronization relative to sensed respiratory information.

3. (Canceled)

4. (Currently Amended) The device of claim 1 [[3]], wherein the reference respiration-related parameter comprises a reference breathing pattern.

5. (Original) The device of claim 4, wherein a duration of each respective stimulation period is greater than a duration of an inspiratory phase of the reference breathing pattern.

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0055

6. (Currently Amended) The device of claim 1 [[3]], wherein the reference respiration-related parameter is based on stable respiration.

7. (Currently Amended) The device of claim 1 [[3]], ~~wherein a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period,~~ wherein each stimulation period comprises continuous pulsed stimulation, and wherein a combined duration of each respective stimulation period and of each respective non-stimulation period is less than the reference respiration-related parameter, which comprises a duration of a reference breath.

8. (Currently Amended) The device of claim 1, wherein the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is no greater than a duration of a reference ~~breathing pattern~~breath.

9. (Original) The device of claim 1, wherein the duration of the respective stimulation periods remain uniform.

10. (Currently Amended) ~~A The~~ device for treating obstructive sleep disordered breathing ~~of claim 1~~, comprising:

means for stimulating a hypoglossal nerve, according to a first stimulation therapy protocol including alternating periods of stimulation and non-stimulation in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation, wherein a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period, wherein each stimulation period comprises continuous pulsed stimulation, and wherein the first stimulation therapy protocol is to deliver multiple stimulation periods within a duration of a reference breath of a reference breathing pattern, and wherein the means for stimulating comprises an implantable electrode and/or an implantable pulse generator electrically connectable to the implantable electrode.

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11. (Currently Amended) The device of claim 10, wherein the reference breathing pattern comprises at least one of:

a historical patient-specific reference breathing pattern; or[[~~and~~]]

a multiple patient reference breathing pattern.

12. (Previously Presented) The device of claim 1, wherein the first stimulation therapy protocol is to deliver multiple stimulation periods within a duration of an inspiratory phase of a reference breathing pattern.

13. (Currently Amended) A [[~~The~~]] device ~~of claim 1~~ for treating obstructive sleep disordered breathing, comprising:

means for stimulating a hypoglossal nerve, according to a first stimulation therapy protocol including alternating periods of stimulation and non-stimulation in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation, wherein a duration of each a respective ~~one of the~~ stimulation period ~~periods~~ is greater than a duration of each~~s~~ respective ~~one of the~~ non-stimulation period ~~periods~~, and wherein the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods comprises a duration of a stimulation cycle, which is greater than a duration of a reference breath of a reference breathing pattern, and wherein the means for stimulating comprises an implantable electrode and/or an implantable pulse generator electrically connectable to the implantable electrode.

14. (Original) The device of claim 1, wherein the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is less than 30 percent of duration of a reference breathing pattern.

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15. (Original) The device of claim 14, wherein the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is less than 20 percent of duration of the reference breathing pattern.

16. (Canceled)

17. (Currently Amended) The device of claim 1 [[16]], wherein a respective one of the stimulation periods and a respective one of the non-stimulation periods are in a proportion of at least 1.5 to 1.

18. (Original) The device of claim 16, wherein a duration of a respective one of the stimulation periods exceeds the duration of a respective one of the non-stimulation periods by a factor of 3.

19. (Original) The device of claim 1, wherein a respective one of the stimulation periods and a respective one of the non-stimulation periods comprises a stimulation cycle, and wherein a duration of the respective one of the stimulation periods comprises at least 80 percent of a duration of the stimulation cycle.

20. (Original) The device of claim 1, wherein each respective stimulation period comprises continuous pulsed stimulation.

21. (Canceled)

22. (Previously Presented) The device of claim 1, comprising:

a processor; and

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

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23. (New) The device of claim 1, wherein the reference breathing pattern comprises at least one of:

a historical patient-specific reference breathing pattern; or

a multiple patient reference breathing pattern.

24. (New) The device of claim 13, wherein the reference breathing pattern comprises at least one of:

a historical patient-specific reference breathing pattern; or

a multiple patient reference breathing pattern.

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REMARKS

The following remarks are made in response to the Final Office Action dated July 14, 2023, in which claims 1-22 were rejected. With this Response, claims 3, 6, and 21 have been canceled, claims 1-2, 4, 6-8, 10-11, 13, and 17 have been amended, and new claims 23-24 have been added. Claims 1-2, 4-5, 7-20, and 22-26 remain pending in the application and are presented for consideration and allowance.

Claim Rejections under 35 USC §103

As stated in the Office Action, claims 1-22 stand rejected under 35 USC §103 as being unpatentable over Bolea (US 2014/0228905) in view of Tehrani (US 2006/0167523).

Claims 3, 6, and 21 have been canceled.

At the outset, Applicants note that some of the rejections of claims 1-22 refer to Paragraphs within Tehrani (US 2006/0167523) while some of the rejections apparently refer to Paragraphs within Tehrani (US 2012/0158091) which is officially of record but not part of the formal rejection. In view of the mixing and matching of the two different Tehrani references, and in view of the interest of compact prosecution, Applicants have made their best attempt to reconcile discord within some of the rejections.

As admitted in the Office Action, Bolea fails to disclose a first stimulation therapy protocol .. in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation.

Applicants submit that Tehrani fails to cure the deficiencies of Bolea regarding Applicants' Claim 1. In particular, Applicants first note that any cited reference should be considered as a whole, including the portions which teach away from Applicants' claims and not just only the portions potentially favorable to a stated rejection.

With this in mind and with regard to Applicants' Claim 1, Applicants submit that formally cited Tehrani '523 fails to cure the deficiencies of Bolea.

First, ¶ 94 of Tehrani '523 (as cited in ¶ 8 of Office Action) conflicts with the recitation in Applicants' Claim 1 of:

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means for stimulating a hypoglossal nerve, according to a first stimulation therapy protocol including alternating periods of stimulation and non-stimulation in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation.

In particular, ¶ 94 of Tehrani '523 states:

> [0094] FIG. 4C illustrates tidal volume of a patient treated using a deep inspiration stimulator. The stimulator **detects the drop in tidal volume (breath 413) below a threshold level as described above with respect to FIGS. 4A-4B**. During the subsequent breath 414, stimulation 434 (schematically illustrated as an envelope of a burst of pulses) is provided by the stimulator to provide a deep inspiration breath 424 with the breath 414. The deep inspiration breath 424 comprises a breath that has a tidal volume greater than the tidal volume of a normal or intrinsic breath. After one or more deep inspiration breath stimulations, the tidal volume is expected to return to normal or close to normal, e.g. at breaths 425-429. **Synchronization is provided whereby the onset of inspiration is detected and stimulation is provided during the breath**. According to one variation, a tidal volume that is greater than or equal to a predetermined percentage of a normal inspiration is detected (e.g. 10% of tidal volume as described with respect to FIGS. 16A-16D). **Then when the onset of the next inspiration is detected, stimulation is provided**.. . (emphasis added).

As viewed by one skilled in the art, the above-highlighted passages of Tehrani '523 indicate that upon detection of onset of inspiration, stimulation is synchronized relative to inspiration. This situation directly conflicts with Applicants' Claim 1.

Moreover, it also would appear to one skilled in the art that detecting (e.g. sensing) tidal volume relative to a threshold also may be involved in a determination of whether to provide stimulation, which also would directly conflict Applicants' Claim 1.

Accordingly, at least this portion of ¶ 94 of Tehrani '523 directly conflicts with the recitation (in Applicants' Claim 1) of "timing of the stimulation periods is implemented without a sensing element for timing stimulation" because Tehrani clearly discloses detection (i.e. sensing), which must involve a detection element (i.e. sensing element), which is "used for timing stimulation."

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¶ 94 of Tehrani '523 continues with further information to address "additional periodic delivery of deep inspiration paced breaths" (e.g. synchronously or asynchronously). However, regardless of whether such additional periodic stimulation is implemented, the foregoing portion of ¶ 94 would make it clear to one skilled in the art that first stimulation is implemented synchronously with inspiration (and also may be depend on a value of a detected tidal volume relative to a threshold).

[Applicants note that ¶94 of the other Tehrani '091 merely refers to Fig. 16D (air flow) in a Brief Description of The Drawings and is apparently not applicable in this rejection]

Finally, ¶ 89 of Tehrani '523 generally introduces FIGS. 4A-4D, and therefore is applicable to ¶ 94. Among other things, ¶ 89 explains that "In accordance with a protocol, stimulation through one or more electrodes associated with the diaphragm or phrenic nerve is provided to cause the diaphragm to contract to cause a deep inspiration breath." Accordingly, it would be clear to one skilled in the art that ¶ 94 applies to stimulation of the phrenic nerve and/or diaphragm. Accordingly, ¶ 94 directly conflicts with the recitation in Applicants' Claim 1 of a "means for stimulating a hypoglossal nerve.."

While ¶ 59 of Tehrani '523 briefly mentions stimulation of a hypoglossal nerve, it would be clear to one skilled in the art that Tehrani '523 generally concerns stimulation of the phrenic nerve and/or diaphragm, with ¶ 8 of Tehrani '523 further mentioning that stimulation of a hypoglossal nerve is ineffective.

Accordingly, even if one skilled in the art attempted to combine Tehrani '523 and Bolea, they would fail to arrive at Applicants' Claim 1.

For these reasons alone, the cited combination of Bolea and Tehrani '523 fails to reasonably make obvious Applicants' Claim 1, and therefore, Applicants' Claim 1 is patentable over the cited combination.

However, Applicants submit that Claim 1 is further patentably distinguishable over the cited combination at least because the cited ¶ 94 of Tehrani '523 fails to meet the recitation in Applicants' Claim 1 of "wherein a duration of each respective stimulation period is greater than a

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duration of each respective non-stimulation period, wherein the duration of each respective stimulation period is based on a reference respiration-related parameter."

Moreover, because amended Applicants' Claim 1 incorporates the recitation of now canceled claim 3, Applicants will address the rejection of claim 3 as well.

At the outset it is worth clarifying that ¶11 of the Office Action apparently inadvertently switches away from Tehrani '523 and instead cites to the Tehrani '091 reference (e.g. ¶ 30, 46) because ¶ 30, 46 of the explicitly cited Tehrani '523 (e.g. boilerplate, Brief Description of FIGS. 13A,13B) do not correspond to the parenthetically quoted terminology ("ventilatory stability criteria") which does appear in Tehrani '091.

In making this inadvertent switch, the Office Action fails to state a prima facie case of unpatentability at least for failing to state a rationale for combining Tehrani '091 with Tehrani '523 and/or with Bolea and without accounting for the manner in which those references diverge from Applicants' claim 1 (and/or diverge from each other).

Nevertheless, Applicants submit that the cited portions of Tehrani '091 also fails to meet Applicants' Claim 1 by failing to cure the deficiencies of Bolea and/or Tehrani '523.

In particular, Applicants first note that ¶ 46 of Tehrani '091 describes (among other things) that "stimulation may also be triggered or timed to portions of a respiratory cycle." This passage, as viewed by one skilled in the art, would directly conflict with Applicants' Claim 1 ("means for stimulating a hypoglossal nerve, according to a first stimulation therapy protocol including alternating periods of stimulation and non-stimulation in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation") at least because of the extensive manner/instances in which Tehrani '091 discloses sensing (also disclosed as detecting, measuring, determining, detecting, ascertaining, etc.) information (e.g. respiratory), which is then used to trigger and/or provide timing for stimulation. See, for example, at least ¶ 42, 46, 105, 109-114, 119-122, 123-132, 140, 152-159, 161-162, 165-166, 171, 179, 180, 183-184, 186, 189, 196, 214-215 of Tehrani '091. With this in mind, ¶ 127 of Tehrani '091 provides just one example stating the relationship between such sensing and stimulation as: "The

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information ascertained from the sensed signals may be used to determine triggers for providing stimulation".

Moreover, ¶ 46 of Tehrani '091 discloses that "The durations [of stimulation] may be selected based on ventilatory stability criteria or respiration events **detected** (AHI or other **measure** of events, disorders or conditions) or other criteria related to a disease, disorder or condition." As viewed by one skilled in the art, the detection (or measuring) of respiratory information in relation to duration in this passage in Tehrani '091 would directly conflict with the recitation in Applicants' Claim 1 of:

> means for stimulating a hypoglossal nerve, according to a first stimulation therapy protocol including alternating periods of stimulation and non-stimulation in **which a timing of the stimulation periods is implemented without a sensing element for timing stimulation**.

Meanwhile, ¶ 30, 46 of the Tehrani '091 also fail to disclose:

> "wherein a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period, wherein the duration of each respective stimulation period is based on a reference respiration-related parameter . . .

In addition to the above Examiner-admitted deficiencies of Bolea and the above-demonstrated deficiencies of Tehrani '523 (and Tehrani '091), Applicants submit that Bolea is further deficient relative to amended Claim 1. Specifically, Applicants traverse the assertion in ¶11 of the Office Action (regarding claim 3) that ¶ 326 and ¶ 472-474 of Bolea meet the recitation that the "wherein the duration of each respective stimulation period is based on a reference respiration-related parameter."

In particular, Applicants submit that when the portion of Bolea (US 2014/0228905) cited in ¶11 of the Office Action (regarding claim 3), namely, ¶ 472-474 of Bolea, is taken in context with the full passage of ¶ 466-474 of Bolea (regarding FIGS. 64A-64D), the cited ¶ 472-474 of Bolea conflicts with at least the recitation "wherein the duration of each respective stimulation period is based on a reference respiration-related parameter" in Applicants' amended Claim 1.

¶ 472-474 of Bolea describes 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

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embodiments of preceding ¶ 466-471 of Bolea, which depend on stimulation timing synchronized relative to a detected peak of the respiration signal "Z."

In particular, ¶ 466-467 of Bolea 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 ¶ 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 ¶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 ¶472-474 of Bolea (cited in the Office Action regarding claim 3, now incorporated into Claim 1) 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."

In particular, at least some of those cited portions of Bolea (e.g. ¶473-474 with preceding ¶466-472) address a predictive algorithm which is synchronized relative to a **detected** peak of inspiration, which therefore does not relate to a "reference respiration-related parameter" in the manner recited in Applicants' amended Claim 1.

Accordingly, at least this cited portion of Bolea conflicts with at least the recitation "wherein the duration of each respective stimulation period is based on a reference respiration-related parameter" in Applicants' independent claim 1.

Applicants note that FIGS. 80A-80 and Paragraphs 489-499 of Bolea, also conflict with Applicants' independent claim 1 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 1.

Applicants also traverse the assertion of ¶ 326 of Bolea (cited in ¶11 of the Office Action regarding claim 3) against the recitation "the duration of each respective stimulation period is based on a reference respiration-related parameter", which is now incorporated into Applicants' amended Claim 1.

In particular, ¶ 326 of Bolea addresses a Patient PSG Titration Data block, which includes conventional polysomnographic (PSG) data obtained in a sleep study. ¶ 326 mentions "A *self-adjusting predictive algorithm utilizes a reference datum to which the algorithm can be adjusted,*" and then, among other things, describes that "**Onset** may be defined as onset of inspiration as measured by airflow or pressure sensor used in a sleep study" and mentions other onsets such as (but not limited to) Estimated Onset in the context of *enabling the predictive algorithm to be self-adjusting.*

Based on other preceding Paragraphs such as, for example, ¶ 296, 298, Bolea provides a "Description of Stimulus Trigger Algorithms." As stated in ¶ 296,

> As mentioned previously with reference to FIG. 39, **the neurostimulation system described herein may operate in a closed-loop process wherein the step of delivering stimulation 390 to the targeted nerve may be a function of a sensed feedback parameter (e.g., respiration).** For example, stimulation of the hypoglossal nerve may be triggered to occur during the inspiratory phase of respiration. In a health human subject, the hypoglossal nerve is triggered about 300 mS before inspiration. **Accordingly, a predictive algorithm may be used to predict the inspiratory phase** and deliver stimulation accordingly. FIG. 48 schematically illustrates a system 480 including devices, data and processes for implementing a self-adjusting predictive trigger algorithm. (emphasis added)

Unlike the closed loop system of Bolea which relies on a predictive algorithm, Applicants' independent claim 1 recites "a first stimulation therapy protocol" in which "a timing of the stimulation periods is implemented without a sensing element for timing stimulation."

Accordingly, Applicants' claim 1 addresses a duration of each respective stimulation period while, on the other hand, one skilled in the art likely would view Bolea (e.g. Paragraph 326)

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as addressing onsets to trigger stimulation, **predictively triggering** stimulation (versus duration), and the like.

For at least these additional reasons, the cited combination of Bolea and Tehrani '523 fails to reasonably make obvious Applicants' Claim 1, and therefore Claim 1 is patentable over the cited combination. Claims 2, 4-9, 12-15, 17-20, and 22 are patentable at least based on their dependency from Claim 1.

Dependent Claim 4

Applicants submit that claim 4 (depending from independent claim 1) is further patentably distinguishable over the cited combination of Bolea and Tehrani '523 (and Tehrani '091).

In particular, the recitation of claim 4 ("the reference respiration-related parameter comprises a reference breathing pattern") stands in sharp contrast to the portions of Bolea cited regarding base independent claim 1. In particular, at least some of those cited portions of Bolea (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 breathing pattern" in the manner recited in Applicants' claim 4 for "a first stimulation therapy protocol" in which "a timing of the stimulation periods is implemented without a sensing element for timing stimulation." (independent claim 1).

Meanwhile, Applicants also traverse the assertion of ¶ 498-500, 639 of Bolea (cited in ¶12 of the Office Action regarding claim 4) against the recitation "the reference respiration-related parameter comprises a reference breathing pattern."

Applicants also submit that FIGS. 80A-80 and ¶ 489-500 of Bolea also conflict with Applicants' independent claim 1 at least because such passages provide substantially similar information to the above-discussed ¶ 466-474 at least with respect to being conflicting relative to Applicants' independent claim 1.

Meanwhile, it is unclear exactly how the cited ¶ 639 of Bolea applies to Claim 4. ¶ 639 states:

> The patient may also undergo a vector-sweeping sleep study, wherein the programming system 2100 and **a respiratory signal (e.g., nasal cannula) are utilized**, 10520. During this study, the secondary vector may be changed at regular intervals to cycle through a

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> select group of vectors. **These vectors are compared to the primary vector to determine an optimal sensing vector to deliver therapy. Selection may be based on** maximum signal strength, consistent correlation to respiratory fiducials (e.g., offset of inspiration), and **maximum signal stability/reliability** across sleep stages, body positions, and disordered breathing events, for example. **A stable signal** has a minimum probability of signal inversion. **A reliable signal** has a minimum probability of signal loss, and may preferably have a minimum threshold of 0.1 to 0.5 Ohms peak-to-peak, for example. The optimal vector may be selected by incrementally scrolling through all or a preferred subset of possible vectors while **sampling the respiration signal** and comparing the signal against themselves or predefined thresholds. This scrolling technique may be performed manually (with inputs via the programmer system) or automatically (i.e., programmed). The sampling technique may also be performed manually (visual observation using programmer system) or automatically (i.e., programmed). (emphasis added)

As viewed by one skilled in the art, at least the highlighted portions of ¶ 639 of Bolea likely would be seen as indicating that ¶ 639 discloses a way to provide for a stable respiratory sensing signal on which stimulation can be based, with a nasal cannula being provided as one example sensing element. As seen in this manner, ¶ 639 conflicts with at least the recitations in Applicants' Claim 1 of "means for stimulating a hypoglossal nerve, according to a first stimulation therapy protocol including alternating periods of stimulation and non-stimulation **in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation**."

In view of the apparently expected use of a sensed respiratory signal per ¶ 639 of Bolea, it would be unclear to one skilled in the art how ¶ 639 of Bolea meets the recitation in Claim 1 of "a reference respiration-related parameter" and in claim 4 of "the reference respiration-related parameter comprises a reference breathing pattern."

Applicants also traverse the assertion in the ¶ 12 of the Office Action that ¶ 46, 140, 147 of Tehrani '091 meet the recitation of Applicants' claim 4. In this regard, Applicants further note the rejection of claim 4 does not provide a rationale, specific to the recitations of claim 4, for combining inadvertently cited Tehrani '091 with formally cited Tehrani '523 and/or Bolea. Moreover, Applicants submit that Tehrani ('523 or '091) fails to cure the above-demonstrated deficiencies of Bolea relative to at least Claim 4 (and/or independent Claim 1).

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First, for reasons previously noted, ¶46 of Tehrani '523 fails to meet the recitations of Applicants' independent claim 1 regarding "means for stimulating a hypoglossal nerve, according to a first stimulation therapy protocol including alternating periods of stimulation and non-stimulation **in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation**", and for substantially similar reasons, ¶46 of Tehrani '523 also fails to address the recitation in Claim 1 of "a reference respiration-related parameter" and in claim 4 of "the reference respiration-related parameter comprises a reference breathing pattern."

Meanwhile, ¶ 140 of Tehrani '091 states:

> In accordance with another aspect of the invention, as described with respect to FIGS. 4A-4D, 6A-6C, 9A-9C and 10A-10C, 11A-11B, 12A-12B, 14A-14B, 18A-18C, 19A-19C, 20A-20D, 21A-21D, 22A-22C, 23A-23C, and/or 24A-24C, stimulation of the phrenic nerve or diaphragm is provided **during intrinsic breathing during or at the end of an intrinsic inspiration portion of a breathing cycle**. For purposes of the invention herein, the **intrinsic cycle may be detected near onset of inspiration**. Other portions of a breathing cycle may be identified for breathing stimulation. (emphasis added)

As seen in this manner, ¶ 140 conflicts with at least the recitations in Applicants' Claim 1 of "means for **stimulating a hypoglossal nerve**, according to a first stimulation therapy protocol including alternating periods of stimulation and non-stimulation **in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation**."

Moreover, in view of the apparently expected use of a sensed respiratory signal per ¶ 140 of Tehrani '091, it would be unclear to one skilled in the art how ¶ 140 of Tehrani '091 meets the recitation in Claim 1 of "a reference respiration-related parameter" and in claim 4 of "the reference respiration-related parameter comprises a reference breathing pattern."

¶ 140 of Tehrani '091 further states "Alternatively, the beginning of the breathing cycle or a portion of the breathing cycle may be **predicted**, e.g., based on a typical breathing pattern of an individual patient." As understood by one skilled by the art, this arrangement likely would be viewed as something akin to arrangement in Bolea in which a sensed signal provides a basis for predicting an aspect (e.g. "the beginning of the breathing cycle") of a breathing cycle on which stimulation may be triggered or otherwise timed. Accordingly, such an arrangement would

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conflict with the recitation in Applicants' claim 1 of "a first stimulation therapy protocol including alternating periods of stimulation and non-stimulation **in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation**."

Applicants also traverse the assertion of ¶ 147 of Tehrani '091 against Claim 4.

¶ 147 of Tehrani '091 states:

> In accordance with another aspect of the invention, as described with respect to FIGS. 9A-9C, 12A-12B, 13A-13B, and 14A-14B, stimulation of the phrenic nerve or diaphragm is provided to control breathing. According to one aspect of the invention, breathing is controlled either by inhibiting respiratory drive, entraining breathing or other mechanisms. Controlling breathing according to one variation comprises stimulating to control or manipulate the central respiratory drive. Controlling breathing may include taking over breathing to control one or more parameters of a stimulated breath. **Entraining breathing may include stimulating** at a rate greater than but close to, or equal to the **intrinsic respiratory rate** until the central pattern generator activates the respiration mechanisms, which includes those of the upper airway, in phase with the stimulation. As an alternative or in addition, inspiration duration may be increased with respect to the total respiration cycle or exhalation. . . . (emphasis added)

As viewed by one skilled in the art, ¶ 147 of Tehrani '091 likely would be viewed as disclosing the delivery of stimulation (e.g. of the phrenic nerve, diaphragm) based on sensed respiration information, from which the above-noted **intrinsic respiratory rate** would be determined. In this regard, ¶ 147 of Tehrani '091 directly conflicts with at least the recitations in Applicants' Claim 1 of "means for stimulating a hypoglossal nerve, according to a first stimulation therapy protocol including alternating periods of stimulation and non-stimulation **in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation**."

Moreover, in view of the apparently expected use of a sensed respiratory signal per ¶ 147 of Tehrani '091, it would be unclear to one skilled in the art how ¶ 147 of Tehrani '091 meets the recitation in Claim 1 of "a reference respiration-related parameter" and in claim 4 of "the reference respiration-related parameter comprises a reference breathing pattern."

For at least these reasons, the cited combination of Bolea and Tehrani '523 (and/or Tehrani '091) fails to reasonably make obvious Applicants' claim 4, and therefore Claim 4 is

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patentable over the cited combination. Claim 5 is patentable at least based on its dependency from Claim 1.

Dependent Claim 5

Applicants submit that claim 5 (depending from independent claim 1 and claim 4) is further patentably distinguishable over the cited combination of Bolea and Tehrani. In particular, Applicants' claim 5 recites that "a duration of each respective stimulation period is greater than a duration of an inspiratory phase of a reference respiratory cycle." (*At least some aspects of* the *term "inspiratory reference" are described in least Paragraph 46 of Applicants' specification.)* Applicants further note that the phrase "inspiratory phase" of the "reference respiratory cycle" as defined in Applicants' specification does **not** correspond to actively-sensed respiration. See, for example, at least ¶47 of Applicants' specification.

First, these recitations stand in sharp contrast to the portions of Bolea cited regarding base independent claim 1. In particular, at least some of those cited portions of Bolea (e.g. ¶ 473-474 with preceding ¶466-472) address a predictive algorithm which is synchronized relative to a **detected** peak of inspiration, which therefore does not relate to a "reference respiration-related parameter" in the manner recited in Applicants' claim 1 (and "reference breathing pattern" in claim 4) for "a first stimulation therapy protocol" in which "timing of the stimulation periods is implemented without a sensing element for timing stimulation" (independent claim 1).

Accordingly, for at least these reasons, the cited combination of Bolea and Tehrani ('523 and/or '091) fails to reasonably make obvious Applicants' claim 5 and/or otherwise significantly conflicts with Applicants' claim 5.

Dependent Claim 7

Claim 7 recites that "each stimulation period comprises continuous pulsed stimulation, and wherein a combined duration of each respective stimulation period and each respective non-stimulation periods is **less than the respiration-related parameter, which comprises** a duration of a reference breath."

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Applicants traverse the assertion that ¶ 129, 420, and 514-516 of Bolea meet Applicants' claim 7.

First, Applicants submit that Paragraphs ¶514-516 (cited in the Office Action), and particularly ¶ 515, of Bolea fails to meet the recitations of Applicants' independent claim 1. In particular, while ¶ 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 when a patient would be sleeping. 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.

Therefore, at least ¶ 515 of Bolea conflicts with the recitation of a "first stimulation therapy protocol" in base independent claim 1.

As a general matter, Applicants also submit that the above-addressed cited portions of Bolea (e.g. ¶472-474 with preceding ¶466-472) directly conflict with the recitation in Applicants' claim 7 that "a combined duration of a respective one of the stimulation periods and a respective one of the non-stimulation periods **is less than** a duration of the reference respiratory cycle." Via Applicant's claimed arrangement, the duration of the stimulation cycle (a stimulation period and a non-stimulation period) 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 a significant majority of the treatment period.*" See, for example, Applicants' specification in a least Paragraph 0049.

Applicants also traverse the assertion of ¶129 of Bolea (cited in the Office Action) against claim 7. ¶129 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

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addresses triggering the stimulation. ¶ 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 ¶129 meet the recitations of Applicants' claim 7.

Meanwhile, ¶ 420 of Bolea (cited 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," which likely would be viewed as including sensing respiration. Accordingly, Paragraph 420 of Bolea does not address a "**respiration-related parameter,** which comprises a duration of a **reference breath,**" which appears in the recitation "each stimulation period comprises continuous pulsed stimulation, and wherein a combined duration of each respective stimulation period and each respective non-stimulation periods is less than the **respiration-related parameter,** which comprises a duration of a **reference breath**." Moreover, any sensing of respiration would conflict with the recitation in base independent claim 1 of "a timing of the stimulation periods is implemented without a sensing element for timing stimulation."

Meanwhile, ¶ 420 of Bolea does not address the recitation in Applicants' base claim 1 of "a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period." Therefore, ¶ 420 of Bolea conflicts with claim 7 at least by conflicting with base claim 1.

Accordingly, Bolea fails to meet the recitations of Applicants' claim 7 and/or otherwise significantly conflicts with claim 7.

Applicants further submit that claim 7 is distinguishable from ¶ 46 of Tehrani '091 for at least the reasons previously presented in favor of the patentability of Applicants' claims 1, 4, and/or 5.

Meanwhile, the ¶ 178 of Tehrani '091 states:

> The stimulation described or shown herein may be comprised of several stimulation parameters. For example a burst of pulses may form a square pulse envelope or may ramp up or down in amplitude or a combination thereof. The frequencies may vary or may be

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> varied depending upon a desired result. In accordance with one embodiment, the burst (or pulse) frequency ranges between 5-500 Hz and more preferably between 20-50 Hz. However, other frequency ranges may be used as desired. Low level pulses or continuous stimulation may comprise stimulation at about 8 mA or less or may be determined on a case-by-case basis. However, other amplitudes and frequencies may be used as desired. The stimulation may be monophasic or may be biphasic. Stimulation may be provided in response to sensing respiration or other parameters. Alternatively, stimulation may be provided periodically or during specific times, for example during sleep, during sleep stage transitions, or during non-REM sleep.

As viewed by one skilled in the art, nothing in ¶ 178 addresses the recitation in Applicants' claim 7 that "each stimulation period comprises continuous pulsed stimulation, and wherein a combined duration of each respective stimulation period and each respective non-stimulation periods is **less than** the respiration-related parameter, which comprises a duration of a reference breath."

For at least these reasons, the cited combination of Bolea and Tehrani ('523 and/or '091) fails to reasonably make obvious Applicants' claim 7 and/or otherwise significantly conflicts with Applicants' claim 7.

Independent Claim 10

Independent Claim 10 is patentable over the cited combination of Bolea and Tehrani '523 for at least some of substantially the same reasons as previously presented in favor of the patentability of Applicants' independent claim 1 and dependent claims 4, 5, and 7. In addition, to reciting "a first stimulation **therapy** protocol including alternating stimulation periods and non-stimulation periods in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation" and reciting "wherein the duration of each respective stimulation period is based on a reference respiration-related parameter", independent claim 10 further recites that "wherein a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period, wherein each stimulation period comprises continuous pulsed stimulation, and **wherein the first stimulation therapy protocol is to deliver multiple stimulation periods within a duration of a reference breath of a reference breathing pattern.**"

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Per Applicants' specification, each stimulation period (within a stimulation cycle) comprises continuous pulsed stimulation such that each stimulation period comprises multiple pulses. See, for example, at least Paragraph 0044 of Applicants' specification which states:

> 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…..

First, as previously noted the reference to "Bolea and Tehrani" presumably refers to Tehrani '523 while the citation to FIG. 4D and ¶ 46 apparently refers to a different Tehrani '091, with no stated rationale regarding combination of the two different Tehranis relative to each other and/or relative to Bolea.

Second, the cited ¶ 470 of Bolea cannot be reasonably said to meet the above-noted recitation of independent Claim 10. In particular, ¶ 470 of Bolea relates to FIG. 64C, which clearly shows a single stimulation period occurring within a "predicted respiratory period" as would be viewed by one skilled in the art. As noted in ¶ 470 and as shown in FIG. 64C, "The stimulation period may start at 50%, for example, of the predicted time period." It would be further apparent to one skilled in the art that while the single stimulation period may comprise multiple stimulation pulses, the illustrated stimulation period is a single stimulation period in contrast to the single non-stimulation period coinciding with the remainder of the predicted respiratory period shown in FIG. 64C of Bolea.

For at least these reasons, Applicants respectfully submit that the cited arrangement in Bolea directly conflicts with the recitation in Applicants' Claim 10 of "wherein each stimulation period comprises continuous pulsed stimulation, and wherein the first stimulation therapy protocol is to deliver multiple stimulation periods within a duration of a reference breath of a reference breathing pattern."

Applicants also traverse the citation to FIG. 4D/ 46 of Tehrani '091.

In particular, as apparent to one skilled in the art, FIG. 4D (in relation to FIGS. 4A, 4B, or 4C) of Tehrani '091 illustrates a pacing pulse 434 (for stimulation of **phrenic nerve or diaphragm**)

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coinciding with a deep inspiration breath 424 and a single pacing pulse 439 coinciding with a deep inspiration breath 429, with numerous breaths 425, 426, 427, 428 occurring between breaths 424 and 429. No pacing pulse occurs during those breaths (425, 426, 427, 428). It is equally clear that during breaths (424, 429), just a single pacing pulse is delivered – not multiple stimulation periods as claimed by Applicants.

Accordingly, this arrangement in Tehrani '091 directly conflicts with the recitation in Applicants' Claim 10 of "wherein each stimulation period comprises continuous pulsed stimulation, and wherein the first stimulation therapy protocol is to deliver multiple stimulation periods within a duration of a reference breath of a reference breathing pattern."

Moreover, because of the different physiologic mechanisms, pathways, effects, etc. associated with phrenic or diaphragmatic stimulation, one skilled in the art likely would not view any such stimulation patterns as necessarily being applicable to hygoglossal nerve stimulation, as recited in independent claim 10.

Finally, Applicants submit that Claim 10 is patentable over ¶ 46 of Tehrani '091 for the reasons previously presented in favor of the patentability of claims 1, 4, 5, and 7.

Accordingly, for at least these reasons, the cited combination of Bolea and Tehrani ('523 or '091) fails to reasonably make obvious Applicants' independent claim 10 and/or otherwise significantly conflicts with independent claim 10. Therefore, Bolea fails to reasonably make obvious Applicants' independent claim 10. Claim 11 is patentable at least based on its dependency from independent claim 10.

Independent Claim 13

Independent Claim 13 is patentable over the cited combination of Bolea and Tehrani for at least some of substantially the same reasons as previously presented in favor of the patentability of Applicants' independent claim 1 and/or independent claim 10. In addition to reciting "a first stimulation **therapy** protocol including alternating stimulation periods and non-stimulation periods in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation," independent claim 13 further recites that "a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period, and wherein

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a combined duration of a respective one of the stimulation periods and a respective one of the non-stimulation periods comprises a duration of a stimulation cycle, which is greater than a duration of a reference breath of a reference breathing pattern.

Applicants claim 13 is patentable over ¶ 474 of Bolea for at least some of substantially the same reasons previously presented in favor of patentability of claims 1, 4, 5, 7 and 10, including distinguishing at least ¶ 472-474 of Bolea.

Meanwhile, ¶636 of Bolea states:

> When a stimulation level is estimated to be efficacious, it may be tested in AAAA mode for a fixed time (e.g., five minutes) after which stimulation may be turned off for a fixed time (e.g., five minutes). If stimulation noticeably reduced or eliminated respiratory events compared to no stimulation, the settings may be considered the goal setting.

Keeping in mind the recitation "a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period" in Applicants' claim 13, it would entirely unclear to one skilled in the art how or why ¶636 of Bolea purportedly meets the recitation "wherein a combined duration of a respective one of the stimulation periods and a respective one of the non-stimulation periods comprises a duration of a stimulation cycle, which is greater than a duration of a reference breath of a reference breathing pattern" in Applicants' Claim 13.

Moreover, as previously noted above, Bolea (e.g. at Paragraphs ¶492-499, FIGS. 80A-80C and elsewhere) discloses that 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 13 that "a combined duration of a respective one of the stimulation *periods* and a respective one of the non-stimulation *periods* comprises a duration of a stimulation *cycle,* which is greater than a duration of a reference breath." Via Applicant's claimed arrangement, the duration of the stimulation cycle does not match or coincide with the duration of the reference breath, such that upon the application of multiple stimulation cycles, the stimulation period will coincide with a different portion of each reference breath of a sequence of reference breaths. This arrangement may ensure that "*no matter where the stimulation protocol is started relative to the pattern of*

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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 a significant majority of the treatment period." See, for example, Applicants' specification in a least ¶ 49.

Moreover, as apparent to one skilled in the art, the cited FIG. 4D of Tehrani '091 discloses pacing pulse 434 and pacing pulse 439 with a non-stimulation period therebetween which has a duration substantially greater (e.g. 10 times) than the duration of either one of the pacing pulses 424, 429.

This arrangement of FIG. 4D in Tehrani '091 directly conflicts with the recitation in Applicants' claim 13 of "a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period."

For similar reasons, the arrangement in FIG. 6C of Tehrani '091 also directly conflicts with the above-noted recitation of Applicants' claim 13.

Accordingly, for at least these reasons, the cited combination of Bolea and Tehrani ('523 or '091) fails to reasonably make obvious Applicants' independent claim 13 and/or otherwise significantly conflicts with independent claim 13. Claim 24 is patentable at least based on its dependency from independent claim 13.

New Claims

Applicants respectfully request favorable consideration and allowance of claims 23-24.

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CONCLUSION

In view of the above, Applicants respectfully submit that pending claims 1-2, 4-5, 7-20, and 22-24 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-2, 4-5, 7-20, and 22-24 are respectfully requested.

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.

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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Fifth Street Towers, Suite 2250
100 South Fifth Street
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Respectfully submitted,

Date: 9/30/2023
PSG: jmp

/Paul S. Grunzweig/
Paul S. Grunzweig
Reg. No. 37143

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PTO/SB/06 (09-11)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/348,852	Filing Date 06/16/2021	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $480 =	
☐ 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).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	10/01/2023	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 21	Minus	** 22	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	PSS
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/FIKIRTE A GEREMEW/
*** 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 number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. 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 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. 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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/348,852	06/16/2021	Darrell Wagner	I618.118.105	5390

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EXAMINER	
LAU, MICHAEL J	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
07/14/2023	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

Office Action Summary	Application No. 17/348,852	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 3/14/2023.

☐ 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) 1-22 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) 1-22 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: _____.

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 6-18, filed 3/14/2023, with respect to the rejection(s) of claim(s) 1-22 under USC 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) in view of Tehrani (US 2006/0167523 A1)

Claim Rejections - 35 USC § 103

3. 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 (i.e., changing from AIA to pre-AIA) 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.

4. 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.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claim(s) 1-22 are rejected under 35 U.S.C. 103 as being unpatentable over Bolea (US 2014/0228905 A1) (cited previously) in view of Tehrani (US 2006/0167523 A1).

7. Regarding claim 1, The combined invention of Bolea and Tehrani discloses a device for treating obstructive sleep disordered breathing (eg. Abstract, Para. 2-4), comprising: a stimulation element (eg. Fig. 1, stimulation lead 60) to stimulate an upper airway patency-related nerve (eg. Abstract, Para. 127 and 361), according to a first stimulation protocol including alternating periods of stimulation and non-stimulation in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation in multiple embodiments (eg. Para. 473 and 514, using a fixed stimulation duty cycle). Bolea does not disclose a first stimulation therapy protocol…in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation.

8. Tehrani teaches a hypoglossal nerve stimulation system (eg. Fig. 1) that can stimulate asynchronously with intrinsic breathing to induce deep breaths (eg. Fig. 4D, Para. 94, and Claim 12)

9. It would have been obvious to one of ordinary skill before the effective filing date of the claimed invention to have modified the invention of Bolea to have an asynchronous stimulation delivery as taught by Tehrani to prevent a drop in tidal volume and reducing occurrence of obstructive respiratory events (eg. Tehrani, Para. 94).

10. Regarding claim 2, The combined invention of Bolea and Tehrani discloses the timing of the stimulation periods being implemented without a sensing element for timing stimulation comprises the timing of the stimulation being implement without a sensing element for synchronization relative to sensed respiratory information (eg. Bolea Para. 473-474 and 514).

11. Regarding claim 3, The combined invention of Bolea and Tehrani discloses a duration of each respective stimulation period is based on a reference respiration-related parameter (eg. Bolea, Para. 326 and 472-474) and (eg. Tehrani, Para. 30, Para. 46, duration selected on ventilatory stability criteria).

12. Regarding claim 4, The combined invention of Bolea and Tehrani discloses the reference respiration-related parameter comprises a reference breathing pattern (eg. Bolea Para. 498-500, 639) and (eg. Tehrani, Para. 46, 140, and 147).

13. Regarding claim 5, The combined invention of Bolea and Tehrani discloses a duration of each respective stimulation period is greater than a duration of an inspiratory phase of the reference breathing pattern (eg. Bolea Para. 472-474) and (eg. Tehrani, Para. 180).

14. Regarding claim 6, The combined invention of Bolea and Tehrani discloses the reference respiration-related parameter is based on stable respiration (eg. Para. 498-500, 639) and (eg. Tehrani, Para. 46).

15. Regarding claim 7, The combined invention of Bolea and Tehrani discloses a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period, wherein a combined duration of each respective stimulation period and of each respective non-stimulation period is less than the reference respiration-related parameter, which comprises a duration of a reference breath (eg. Para. 129, 420, period 514-516) and continuous pulsed stimulation (eg. Tehrani, Para. 46 and 178).

16. Regarding claim 8, The combined invention of Bolea and Tehrani discloses the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is no greater than a duration of a reference breathing pattern (eg. Bolea Para. 470, multiple pulses within a respiration cycle).

17. Regarding claim 9, The combined invention of Bolea and Tehrani discloses the duration of the respective stimulation periods remain uniform (Eg. Para. 501, can be uniform or non-uniform pulses).

18. Regarding claim 10, The combined invention of Bolea and Tehrani discloses the stimulation protocol is to deliver multiple stimulation periods within a duration of a reference breathing pattern (eg. Bolea Para. 470, multiple pulses within a respiration cycle) and the duration of each respective stimulation period is greater than a duration of each respective non-stimulation period wherein the stimulation period comprises continuous pulsed stimulation (eg. Tehrani, Fig. 4D multiple pulses within a breathing pattern segment and Para. 46).

19. Regarding claim 11, The combined invention of Bolea and Tehrani discloses the reference breathing pattern comprises at least one of: a historical patient-specific reference breathing pattern; and a multiple patient reference breathing pattern (eg. Bolea Para. 266, 296-298, and 494).

20. Regarding claim 12, The combined invention of Bolea and Tehrani discloses the stimulation protocol is to deliver multiple stimulation periods within a duration of an inspiratory phase of a reference breathing pattern (eg. Bolea Para. 420).

21. Regarding claim 13, The combined invention of Bolea and Tehrani discloses the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is greater than a duration of the reference breathing pattern (eg. Bolea, Para. 474, 499, and 636) and the duration of a respective one of the stimulation periods is greater than a duration of a respective one of the non-stimulation periods comprising a duration of a stimulation cycle (eg. Tehrani, Fig. 4D and 6C).

22. Regarding claim 14, The combined invention of Bolea and Tehrani discloses the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is less than 30 percent of duration of a reference breathing pattern (eg. Bolea Para. 420).

23. Regarding claim 15, The combined invention of Bolea and Tehrani discloses the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is less than 20 percent of duration of the reference breathing pattern (eg. Bolea Para. 420).

24. Regarding claim 16, The combined invention of Bolea and Tehrani discloses a duration of a respective one of the stimulation periods is greater than a duration of a respective one of the non-stimulation periods (eg. Bolea Para. 474 and 481).

25. Regarding claim 17, The combined invention of Bolea and Tehrani discloses a respective one of the stimulation periods and a respective one of the non-stimulation periods are in a proportion of at least 1.5 to 1 (eg. Bolea 474 and 481).

26. Regarding claim 18, The combined invention of Bolea and Tehrani discloses a duration of a respective one of the stimulation periods exceeds the duration of a respective one of the non-stimulation periods by a factor of 3 (eg. Bolea Para. 474 and 481, 69% duty cycle as a non-limiting example). The Examiner asserts that it would be obvious to try stimulation with a duty cycle of 75% as it is a very similar range to the non-limiting example disclosed in Bolea and it would be obvious to try under routine optimization since there is a finite number of solutions due to a duty cycle being between 0 and 100% (See MPEP 2144.05 I-II).

27. Regarding claim 19, The combined invention of Bolea and Tehrani discloses a respective one of the stimulation periods and a respective one of the non-stimulation periods comprises a stimulation cycle, and wherein a duration of the respective one of the stimulation periods comprises at least 80 percent of a duration of the stimulation cycle (same reason as claim 18 rejection).

28. Regarding claim 20, The combined invention of Bolea and Tehrani discloses each respective stimulation period comprises continuous pulsed stimulation (eg. Para. 302 and 354).

29. Regarding claim 21, The combined invention of Bolea and Tehrani discloses the stimulation element comprises a non- cardiac, implantable electrode (eg. Fig. 1, stimulation lead 60) and the device comprises an implantable pulse generator (eg. Bolea Fig. 1, implanted pulse generator 50) electrically connectable to the implantable electrode (eg. Bolea Fig. 1, Para. 127).

30. Regarding claim 22, The combined invention of Bolea and Tehrani discloses a processor; and a non-volatile computer readable medium storing instructions, executable on the processor, to implement the first stimulation protocol (eg. Bolea Para. 136).

Conclusion

31. 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.

32.

33. 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 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 published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like

assistance from a USPTO Customer Service Representative, 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. 17/348,852	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-20120158091-A1	06-2012	TEHRANI; Amir J.	A61N1/3601	607/42
*	B	US-20110112601-A1	05-2011	MEADOWS; Paul M.	A61N1/37223	607/42
*	C	US-20140228905-A1	08-2014	BOLEA; Stephen L.	A61F5/566	607/42
*	D	US-20140194793-A1	07-2014	Nakata; Robert Haruo	G01S13/825	601/48
*	E	US-20100174341-A1	07-2010	Bolea; Stephen L.	A61B5/4818	607/42
*	F	US-20120192874-A1	08-2012	BOLEA; Stephen L.	A61N1/37235	128/202.16
*	G	US-20100094379-A1	04-2010	Meadows; Paul M.	A61N1/37264	607/48
*	H	US-20060167523-A1	07-2006	Tehrani; Amir J.	A61N1/3601	607/42
	I					
	J					
	K					
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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.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/348,852	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	12/07/2022	07/07/2023							
	1	✓	✓							
	2	✓	✓							
	3	✓	✓							
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	20	✓	✓							
	21	✓	✓							
	22	✓	✓							

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/348,852	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61N1/3601,3611,3614,36146,36171	12/07/2022	ML
G16H20/40	12/07/2022	ML
A61B5/0816,0826,113,4818,4848,686,0205	12/07/2022	ML

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
607	42	12/07/2022	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 and prior art search on pe2e search	12/07/2022	ML
updated search on pe2e search	07/07/2023	ML

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**

/MICHAEL J LAU/ Examiner, Art Unit 3792	

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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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L13	804	L7 AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 03:00 PM
L14	398	L7 AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) SAME (sample$ OR base$line OR normal OR template$)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 03:01 PM
L15	118	(L3 OR L4 OR L5 OR L6) AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) SAME (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 03:02 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0102

L16	188	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) SAME (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 05:28 PM
L17	205	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$ OR upper ADJ air$way) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) SAME (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 05:28 PM
L18	180	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$ OR upper ADJ air$way) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 06:50 PM
L19	88	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$ OR upper ADJ air$way) WITH stimulat$ AND stimulat$ WITH (regular$ OR	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL,	OR	ON	ON	2022/12/06 06:51 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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		periodic$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L20	86	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (nerve$ OR hypo$glossal OR patenc$ OR upper ADJ air$way) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 06:51 PM
L21	60	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:03 PM
L22	64	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:20 PM
L23	48	(L3 OR L4 OR L5 OR L6) AND	(US-PGPUB; USPAT; USOCR; FIT (AP, AT,	OR	ON	ON	2022/12/06 07:21 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0104

		@pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$) SAME (breath$ OR respirat$) near3 (sample$ OR base$line OR normal OR template$) SAME stimulat$	AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L24	1	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$) SAME (breath$ OR respirat$) near3 (sample$ OR base$line OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:21 PM
L25	215	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:22 PM
L26	62	"5636129"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE,	OR	ON	ON	2022/12/06 07:23 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0105

			SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L27	197	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:24 PM
L28	243	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$ OR interval$)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:25 PM
L29	151	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$ OR interval$) SAME puls$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:26 PM
L30	2	("20140228905").pn.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU,	OR	ON	ON	2022/12/07 04:20 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0106

			CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L31	62	((("INSPIRE") near3 ("MEDICAL") near3 ("SYSTEMS") near3 ("INC"))).AS,AANM.	(USPAT)	OR	ON	ON	2022/12/07 04:21 PM
L32	567	((("WAGNER") near3 ("Darrell")) OR (("NI") near3 ("Quan")) OR (("RONDONI") near3 ("John")) OR (("DIEKEN") near3 ("David"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/12/07 04:24 PM
L33	9	("20140194793"|"20200147376"|"5146918").PN.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/05 02:58 PM
L34	154	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$ OR interval$ OR schedul$) SAME puls$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/06 06:47 PM
L35	163	(L3 OR L4 OR L5 OR	(US-PGPUB; USPAT;	OR	ON	ON	2023/07/06

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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		L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$ OR interval$ OR schedul$ OR independent) SAME puls$	USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				06:47 PM
L36	50	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (asynchron$ OR schedul$ OR independent) SAME puls$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 12:20 AM
L37	58	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (a$1synchron$ OR schedul$ OR independent OR manual) SAME puls$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 12:44 AM
L38	177	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (a$1synchron$ OR schedul$ OR	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL,	OR	ON	ON	2023/07/07 12:44 AM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0108

		independent OR manual) WITH (stimulat$ OR puls$)	PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L39	186	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (a$1synchron$ OR schedul$ OR independent OR manual OR fixed)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/07 12:56 AM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0109

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. 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	17348852
Filing Date	2021-06-16
First Named Inventor	Darrell Wagner et al.
Art Unit	3792
Examiner Name	Lau, Michael J.
Attorney Docket Number	I618.118.105

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	5146918		1992-09-15	Kallok 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	20200147376	A1	2020-05-14	Dieken et al.	
	2	20140194793	A	2014-07-10	Nakata et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17348852
	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	3792
	Examiner Name	Lau, Michael J.
	Attorney Docket Number	I618.118.105

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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EXAMINER SIGNATURE

Examiner Signature	/MICHAEL J LAU/	Date Considered	07/05/2023

*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	17348852
	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	3792
	Examiner Name	Lau, Michael J.
	Attorney Docket Number	I618.118.105

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)	2023-03-14
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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

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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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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1st Named Inventor: Darrell Wagner et al.	Examiner: LAU, Michael J.
Serial No.: 17/348,852	Group Art Unit: 3792
Filed: June 16, 2021	Docket No.: I618.118.105
	Conf. No.: 5390

Title: STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

AMENDMENT AND RESPONSE

Mail Stop **AMENDMENT**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In response to the Office Action dated December 14, 2022, please enter and consider the following:

Amendments to the **Claims** begin on page 2; and

Remarks begin on page 5.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees due to Deposit Account No. 500471.

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IN THE CLAIMS

Please amend claims 1, 7, 10, 13 and 22 as follows:

1. (Currently Amended) A device for treating obstructive sleep disordered breathing, comprising:

a stimulation element to stimulate an upper airway patency-related nerve, according to a first stimulation therapy protocol including alternating periods of stimulation and non-stimulation in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation.

2. (Original) The device of claim 1, wherein the timing of the stimulation periods being implemented without a sensing element for timing stimulation comprises the timing of the stimulation being implement without a sensing element for synchronization relative to sensed respiratory information.

3. (Original) The device of claim 1, wherein a duration of each respective stimulation period is based on a reference respiration-related parameter.

4. (Original) The device of claim 3, wherein the reference respiration-related parameter comprises a reference breathing pattern.

5. (Original) The device of claim 4, wherein a duration of each respective stimulation period is greater than a duration of an inspiratory phase of the reference breathing pattern.

6. (Original) The device of claim 3, wherein the reference respiration-related parameter is based on stable respiration.

7. (Currently Amended) The device of claim 3, wherein a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period, wherein each stimulation period comprises continuous pulsed stimulation, and wherein a combined duration of each respective stimulation period and of each respective non-stimulation period is less than the reference respiration-related parameter, which comprises a duration of a reference breath.

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8. (Original) The device of claim 1, wherein the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is no greater than a duration of a reference breathing pattern.

9. (Original) The device of claim 1, wherein the duration of the respective stimulation periods remain uniform.

10. (Currently Amended) The device of claim 1, wherein a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period, wherein each stimulation period comprises continuous pulsed stimulation, and wherein the first stimulation therapy protocol is to deliver multiple stimulation periods within a duration of a reference breathing pattern.

11. (Original) The device of claim 10, wherein the reference breathing pattern comprises at least one of: a historical patient-specific reference breathing pattern; and
a multiple patient reference breathing pattern.

12. (Currently Amended) The device of claim 1, wherein the first stimulation therapy protocol is to deliver multiple stimulation periods within a duration of an inspiratory phase of a reference breathing pattern.

13. (Currently Amended) The device of claim 1, wherein a duration of a respective one of the stimulation periods is greater than a duration of a respective one of the non-stimulation periods, and wherein the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods comprises a duration of a stimulation cycle, which is greater than a duration of [[~~the~~]]a reference breathing pattern.

14. (Original) The device of claim 1, wherein the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is less than 30 percent of duration of a reference breathing pattern.

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15. (Original) The device of claim 14, wherein the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is less than 20 percent of duration of the reference breathing pattern.

16. (Original) The device of claim 1, wherein a duration of a respective one of the stimulation periods is greater than a duration of a respective one of the non-stimulation periods.

17. (Original) The device of claim 16, wherein a respective one of the stimulation periods and a respective one of the non-stimulation periods are in a proportion of at least 1.5 to 1.

18. (Original) The device of claim 16, wherein a duration of a respective one of the stimulation periods exceeds the duration of a respective one of the non-stimulation periods by a factor of 3.

19. (Original) The device of claim 1, wherein a respective one of the stimulation periods and a respective one of the non-stimulation periods comprises a stimulation cycle, and wherein a duration of the respective one of the stimulation periods comprises at least 80 percent of a duration of the stimulation cycle.

20. (Original) The device of claim 1, wherein each respective stimulation period comprises continuous pulsed stimulation.

21. (Original) The device of claim 1, wherein the stimulation element comprises a non-cardiac, implantable electrode and the device comprises an implantable pulse generator electrically connectable to the implantable electrode.

22. (Currently Amended) The device of claim 1, comprising:

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a processor; and

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

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REMARKS

The following remarks are made in response to the Non-Final Office Action dated December 14, 2022, in which claims 1-22 were rejected. With this Response, claims 1, 7, 10, 12-13 and 22 have been amended. Claims 1-22 remain pending in the application and are presented for consideration and allowance.

Claim Rejections under 35 USC §103

Claims 1-22 stand rejected under 35 USC §103 as being unpatentable over multiple embodiments of Bolea (US 2014/0228905).

Independent Claim 1

Applicants respectfully traverse the rejection regarding independent claim 1. Applicants submit that the cited portion of Bolea (US 2014/0228905) in Paragraphs 470-474, when taken in context with the full passage of Paragraphs 466-474 regarding FIGS. 64A-64D, conflicts with at least the recitation "a stimulation element to stimulate an upper-airway-patency-related nerve, according to a **first stimulation therapy protocol** including alternating periods of stimulation and non-stimulation **in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation**" in Applicants' independent claim 1.

Paragraph 470-474 of Bolea, which were cited in the rejection of Applicants' independent claim 1, 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

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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 (including both fixed and adaptive 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."

Among other aspects within these Paragraphs 472-474, Paragraph 473 states in part:

> [0473] The stimulation duty cycle may be fixed or adaptive. In the fixed mode, the stimulation duty cycle is set using to programmer system 2100 to a fixed value. **This fixed value may be increased when the respiratory signal is lost**. In adaptive mode, the duty cycle is allowed to vary as a function of a characteristic of respiration . . . (emphasis added)

From at least the highlighted sentence, it would clear to one skilled in the art that the fixed mode applies to the foregoing synchronous stimulation protocol (e.g. Paragraphs 466-472) because one skilled in the art would understand Paragraph 473 to indicate that such fixed stimulation duty cycle was applied during synchronous stimulation (e.g. per the predictive algorithm) and that such fixed stimulation duty cycle "may be increased when the respiratory signal is lost" (e.g. temporarily as previously noted in Paragraph 471).

Accordingly, at least these cited portions of Bolea conflict with at least the recitation "a stimulation element to stimulate an upper-airway-patency-related nerve, according to a **first stimulation therapy protocol including alternating stimulation periods and non-stimulation periods in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation**" in Applicants' independent claim 1.

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Applicants note that FIGS. 80A-80 and Paragraphs 489-499 of Bolea, also conflict with Applicants' independent claim 1 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 1.

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' independent claim 1 and/or otherwise significantly conflicts with independent claim 1. Therefore, Bolea fails to reasonably make obvious Applicants' independent claim 1. Claims 2-22 are patentable at least based on their dependency from independent claim 1.

Applicants further submit that Paragraph 514 of Bolea cited in the Office Action fails to meet the recitations of Applicants' independent claim 1. Applicants further note that Paragraph 514 falls within a larger passage of Paragraphs 514-515 regarding stimulation. Paragraph 514 of Bolea states:

> Stimulation may also be delivered in two modes which are not inspiratory synchronous: manual stimulation and asynchronous (fixed) stimulation. Manual mode delivers stimulation at any frequency, pulse width, amplitude, pulse configuration, and/or duration (e.g., up to 12 seconds). In manual mode, **stimulation is delivered by manually entering a command via the programmer system to initiate delivery of a stimulation burst or bursts.** The stimulation continues until the burst duration expires or stimulation stop is commanded via the programmer system. Manually delivered stimulations may be delivered in any available pulse configuration. (emphasis added)

It would be apparent to one skilled in the art that this manual mode of stimulation would be impractical for delivering therapy to/for a patient during a treatment period, such as a nightly sleep period in a patient's home, at least because an individual other than the patient would have to present during the patient's sleep period, and attempt the daunting task of applying such manual stimulation in a therapeutically efficacious manner.

While Paragraphs 514-515 do refer to asynchronous stimulation, in providing details regarding asynchronous stimulation Paragraph 515 explains that "the asynchronous mode (fixed mode) may be used during daytime familiarization", which is not a **therapy** for sleep apnea when a patient would be sleeping. Bolea further explains:

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> 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), it would appear to one skilled in the art that the cited portions of Bolea do not address asynchronous stimulation as a "**first stimulation therapy protocol**" in the manner recited in Applicants' independent claim 1. Rather, for a therapy period in which the patient would be sleeping, these cited portions of Bolea would likely lead one skilled in the art to conclude that Bolea relies on "inspiratory synchronous" stimulation.

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' independent claim 1 and/or otherwise significantly conflicts with independent claim 1. Therefore, Bolea fails to reasonably make obvious Applicants' independent claim 1. Claims 2-22 are patentable at least based on their dependency from independent claim 1.

Dependent Claim 3

Dependent Claim 3 recites that "a duration of each respective stimulation period is based on a reference respiration-related parameter."

Applicants submit that claim 3 is patentable for at least some of substantially the same reasons as previously presented for base independent claim 1, and therefore, the recitations of Claim 3 also stand in sharp contrast to the portions of Bolea cited regarding base independent claim 1. In particular, at least some of those cited portions of Bolea (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 respiration-related parameter" in the manner recited in Applicants' claim 3. Accordingly, then the cited portions of Bolea necessarily do not relate to "a duration of each respective stimulation period is based on a reference respiration-related parameter" of Applicants' claim 3.

Meanwhile, the cited Paragraph 326 of Bolea (which was cited in the Office Action) relates to a Patient PSG Titration Data block. Paragraph 326 addresses a Patient PSG Titration Data block, which includes conventional polysomnographic (PSG) data obtained in a sleep study.

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Paragraph 326mentions "A *self-adjusting predictive algorithm utilizes a reference datum to which the algorithm can be adjusted,*" and then, among other things, describes that "**Onset** may be defined as onset of inspiration as measured by airflow or pressure sensor used in a sleep study" and mentions other onsets such as (but not limited to) Estimated Onset in the context of *enabling the predictive algorithm to be self-adjusting.*

Based on other preceding Paragraphs such as, for example, Paragraphs 296, 298, Bolea provides a "Description of Stimulus Trigger Algorithms." As stated in Paragraph 296,

> As mentioned previously with reference to FIG. 39, **the neurostimulation system described herein may operate in a closed-loop process wherein the step of delivering stimulation 390 to the targeted nerve may be a function of a sensed feedback parameter (e.g., respiration).** For example, stimulation of the hypoglossal nerve may be triggered to occur during the inspiratory phase of respiration. In a health human subject, the hypoglossal nerve is triggered about 300 mS before inspiration. **Accordingly, a predictive algorithm may be used to predict the inspiratory phase** and deliver stimulation accordingly. FIG. 48 schematically illustrates a system 480 including devices, data and processes for implementing a self-adjusting predictive trigger algorithm. (emphasis added)

Unlike the above-referenced closed loop system of Bolea which relies on a predictive algorithm per the cited passages, Applicants' base independent claim 1 recites "a first stimulation therapy protocol" in which "a timing of the stimulation periods is implemented without a sensing element for timing stimulation."

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' claim 3 and/or otherwise significantly conflicts with Applicants' claim 3. Therefore, Bolea fails to reasonably make obvious claim 3. Claims 4-7 are patentable at least based on their dependency from claim 3, and base independent claim 1.

Dependent Claim 4

Applicants submit that claim 4 (depending from independent claim 1 and claim 3) is further patentably distinguishable over Bolea. In particular, Applicants' claim 4 recites that "the reference respiration-related parameter comprises a reference breathing pattern."

Applicants submit that claim 4 is patentable for at least some of substantially the same reasons previously presented in favor of the patentability of independent claim 1, at least because Paragraphs 489-500 of Bolea (which were cited in the Office Action against claim 4) generally

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parallel Paragraphs 473-474 of Bolea, which Applicants addressed above in relation to independent claim 1.

Meanwhile, the Office Action fails to demonstrate how and/or why Paragraph 639 of Bolea meets the recitation in Applicants' claim 4. In sharp contrast to Applicants' claim 4 (including base independent claim 1 and intervening claim 3), Paragraph 639 of Bolea describes using a "vector-sweeping sleep study", using "a respiratory signal (e.g., nasal cannula)" to change a "secondary vector" "at regular intervals to cycle through a select group of vectors." Per Paragraph 639: "These vectors are compared to the primary vector **to determine an optimal sensing vector to deliver therapy.** Selection may be based on maximum signal strength, consistent correlation to respiratory fiducials (e.g., offset of inspiration), and maximum signal stability/reliability across sleep stages, body positions, and disordered breathing events, for example . . ." (emphasis added).

Accordingly, as viewed by one skilled in the art, the arrangement in Paragraph 639 of Bolea relates to determining a preferred sensing signal to deliver stimulation therapy, which stands in sharp contrast to the foregoing arguments and/or recitations relating to at least Applicants' independent claim 1 (and intervening claim 3) of "a first stimulation therapy protocol" "in which timing of the stimulation is implemented without a sensing element for timing stimulation."

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' claim 4 and/or otherwise significantly conflicts with Applicants' claim 4. Therefore, Bolea fails to reasonably make obvious claim 4. Claim 5 is patentable at least based on its dependency from claim 4, and base independent claim 1.

Dependent Claim 5

Applicants submit that claim 5 (depending from independent claim 1 and claims 3-4) is further patentably distinguishable over Bolea. Claim 5 recites that "a duration of each respective stimulation period is greater than a duration of an inspiratory phase of the reference breathing pattern." Applicants further note that the phrase "inspiratory phase" of the "reference breathing pattern" as supported in Applicants' specification does **not** correspond to actively-sensed respiration. See, for example, at least Paragraph 47 of Applicants' specification.

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These recitations of claim 5 stand in sharp contrast to the portions of Bolea cited regarding base independent claim 1. In particular, at least some of those cited portions of Bolea (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 breathing pattern" in the manner recited in Applicants' claim 5 for "a first stimulation therapy protocol" in which "timing is implemented without a sensing element for timing stimulation" (independent claim 1) and in which "a duration of each respective stimulation period is greater than a duration of an inspiratory phase of the reference breathing pattern."

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' claim 5 and/or otherwise significantly conflicts with Applicants' claim 5. Therefore, Bolea fails to reasonably make obvious claim 5.

Dependent Claim 7

Applicants submit that Applicants' claim 7 (depending from dependent claim 1) is further patentably distinguishable over Bolea. First, claim 7 depends indirectly from independent claim 1, and is therefore patentable over Bolea for at least the reasons explained above regarding independent claim 1, particularly including the arguments distinguishing over Paragraphs 514-516. Meanwhile, Claim 3 from which claim 7 depends, recites that "each respective stimulation period is based on a reference respiration-related parameter."

Applicants' claim 7 further recites that "a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period."

While Paragraph 420 of Bolea (cited in the Office Action against Applicants' claims) addresses ramping stimulation intensity, the number of pulses per second, amplitudes, and pulse width, Paragraph 420 concludes by stating that "Each of these ramp methods would require a predictive algorithm that would stimulate based on the previous inspiration cycle." For the reasons previously explained, this arrangement would involve use of a sensing element and therefore would directly conflict with the recitation in base independent claim 1 of "a first stimulation therapy protocol including alternating periods of stimulation and non-stimulation in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation.

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Moreover, Paragraph 420 fails to address additional recitation in claim 7 of "a combined duration of each respective stimulation period and of each respective non-stimulation period is **less than** the reference respiration-related parameter, which comprises a duration of a reference breath."

Paragraph 129 of Bolea does not appear to address the recitation of "a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period" and/or the recitation of "a combined duration of each respective stimulation period and of each respective non-stimulation period is less than the reference respiration-related parameter, which comprises a duration of a reference breath", in the manner recited in Applicants' claim 7 (and the claims from which it depends). Moreover, the Office Action fails to demonstrate how and/or why Paragraph 129 applies to claim 7 (and/or claims 1, 3).

Via Applicants' claimed arrangement, the duration of the stimulation cycle (a stimulation period and a non-stimulation period) does not match or coincide with the duration of the reference respiration-related parameter (which comprises a duration of a reference breath), such that upon the application of multiple stimulation cycles, the stimulation period will coincide with a different portion of each reference breath. 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 a significant majority of the treatment period.*" See, for example, Applicants' specification in a least Paragraph 0049.

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' claim 7 and/or otherwise significantly conflicts with claim 7. Therefore, Bolea fails to reasonably make obvious Applicants' claim 7.

<u>Dependent Claim 10</u>

Dependent Claim 10 is patentable over Bolea for at least some of substantially the same reasons as previously presented in favor of the patentability of Applicants' independent claim 1. In addition, to reciting "a first stimulation **therapy** protocol including alternating stimulation periods and non-stimulation periods in which a timing of the stimulation is implemented without

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a sensing element for timing stimulation," dependent claim 10 further recites that "wherein a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period, wherein each stimulation period comprises continuous pulsed stimulation, and **wherein the first stimulation therapy protocol is to deliver multiple stimulation periods within a duration of a reference breathing pattern.**"

Per Applicants' specification, each stimulation period (within a stimulation cycle) comprises continuous pulsed stimulation such that each stimulation period comprises multiple pulses. See, for example, at least Paragraph 0044 of Applicants' specification which states:

> 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…..

Therefore, Applicants submit that it is unreasonable in the Office Action to apparently assert equivalency between the term "multiple stimulation periods" and the term "multiple pulses", and in view of the recitation in Applicants' claim 10 of "wherein each stimulation period comprises continuous pulsed stimulation", the cited Paragraph 470 of Bolea cannot be reasonably said to meet this recitation.

For example, Paragraph 470 of Bolea (cited in the Office Action against Applicants' claim 17) refers to an example "stimulation period initiated (not centered) at a percentage (e.g. 50%) of the predicted respiratory period" (which is based on sensing, as previously explained). As shown in FIG. 64C, this example of Bolea includes a single stimulation period for a given respiratory cycle.

Accordingly, FIG. 64C of Bolea (on which Paragraph 470 is based) does not appear to even remotely address the recitation in Applicants' claim 10 of "wherein the first stimulation therapy protocol is to deliver multiple stimulation periods within a duration of a reference breathing pattern" and Paragraph 470 does not address the recitation in Applicants' claim 10 of "a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period."

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In addition to the above-mentioned previously presented arguments (and associated amendment of Claim 1) regarding Paragraphs 466-474 (with FIGS. 64A-64D) and 492-499 of Bolea (with FIGS. 80A-80C), as shown in FIG. 64C referenced by Paragraph 470 of Bolea, the duration of the predicted respiratory period appears to generally coincide with (e.g. matches) a duration of a combination of the stimulation period and the period of no-stimulation.

This example arrangement in Bolea directly conflicts with the recitation in Applicants' claim 10 that "the first stimulation therapy protocol is to deliver multiple stimulation periods within a duration of a reference breathing pattern." Via Applicant's claimed arrangement, the duration of the stimulation cycle does not match or coincide with the duration of the reference breathing pattern, such that upon the application of multiple stimulation cycles, the stimulation period will coincide with a different portion of each reference breathing pattern of a sequence of reference breathing patterns. 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 a significant majority of the treatment period.*" See, for example, Applicants' specification in a least Paragraph 0049.

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' dependent claim 10 and/or otherwise significantly conflicts with dependent claim 10. Therefore, Bolea fails to reasonably make obvious Applicants' dependent claim 10. Claim 11 is patentable at least based on its dependency from dependent claim 10.

Claim 13

In addition to base independent claim 1 reciting "a first stimulation **therapy** protocol including alternating stimulation periods and non-stimulation periods in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation," dependent claim 13 further recites that "a duration of a respective one of the stimulation periods is greater than a duration of a respective one of the non-stimulation periods, and wherein **a combined duration of a respective one of the stimulation periods and a respective one of the non-**

stimulation periods comprises a duration of a stimulation cycle, which is greater than a duration of a reference breathing pattern.

In addition to the above-mentioned previously presented arguments (and associated amendment of Claim 1), Applicants note that Paragraph 499 (of passage 492-499) of Bolea cited in the Office Action appears in association with FIGS. 80A-80C. As shown in FIG. 80C and described in at least Paragraph 496 of Bolea, 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 13 that "a combined duration of a respective one of the stimulation *periods* and a respective one of the non-stimulation *periods* comprises a duration of a stimulation *cycle*, which is greater than a duration of a reference breathing pattern." Via Applicant's claimed arrangement, the duration of the stimulation cycle does not match or coincide with the duration of the reference breathing pattern, such that upon the application of multiple stimulation cycles, the stimulation period will coincide with a different portion of each reference breathing pattern of a sequence of reference breathing patterns. 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 a significant majority of the treatment period.*" See, for example, Applicants' specification in a least Paragraph 0049.

With regard to the cited Paragraph 474, Applicants note that Paragraphs 466-474 of Bolea, also conflict with claim 13 (and Applicants' independent claim 1 as previously explained) at least because such passages provide substantially similar information to Paragraphs 489-499 at least with respect to being conflicting relative to Applicants' claim 13 and base independent claim 1.

Meanwhile, Paragraph 636 of Bolea (cited in the Office Action) states:

> When a stimulation level is estimated to be efficacious, it may be tested in AAAA mode for a fixed time (e.g., five minutes) after which stimulation may be turned off for a fixed time (e.g., five minutes). If stimulation noticeably reduced or eliminated respiratory events compared to no stimulation, the settings may be considered the goal setting.

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0129

Applicants submit that, on its face, Paragraph 636 fails to meet the recitations of Applicants' claim 13 (and base independent claim 1) and the Office Action fails to demonstrate how Paragraph 636 would meet the recitations of claim 13 (and base claim 1).

Accordingly, for at least these reasons, Bolea fails to meet each and every recitation of Applicants' claim 13 and/or otherwise significantly conflicts with claim 13. Therefore, Bolea fails to reasonably make obvious Applicants' claim 13.

In view of the above arguments and amendments, Applicants respectfully request withdrawal of the Section 103 rejection.

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CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-22 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-22 are respectfully requested.

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.

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,

Date: March 14, 2023
PSG: jmp

/Paul S. Grunzweig/
Paul S. Grunzweig
Reg. No. 37143

Exhibit 1002
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0131

Electronic Patent Application Fee Transmittal

Application Number:	17348852
Filing Date:	16-Jun-2021
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:	I618.118.105

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	260	260
		Total in USD ($)		**260**

Electronic Acknowledgement Receipt

EFS ID:	47680184
Application Number:	17348852
International Application Number:	
Confirmation Number:	5390
Title of Invention:	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING
First Named Inventor/Applicant Name:	Darrell Wagner
Customer Number:	25281
Filer:	PAUL STEVEN GRUNZWEIG/Justina Perez
Filer Authorized By:	PAUL STEVEN GRUNZWEIG
Attorney Docket Number:	I618.118.105
Receipt Date:	14-MAR-2023
Filing Date:	16-JUN-2021
Time Stamp:	16:16:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$260
RAM confirmation Number	E20233DG17349205
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	2023-03-14SIDS.pdf	1263366 03e96557d56238447833516399 8d88cfb7596894	no	4
Warnings:					
Information:					
2		2023-03-14ResponseNFOA.pdf	192491 9fba47dc6639b5babe372c7c1f093568746a4101	yes	18

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Request for Reconsideration-After Non-Final Rejection	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	18

Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	37962 1710b80e7116464cf789a7eeb96a7988d7d177f6	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1493819		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	17348852
	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	3792
	Examiner Name	Lau, Michael J.
	Attorney Docket Number	I618.118.105

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	5146918		1992-09-15	Kallok 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	20200147376	A1	2020-05-14	Dieken et al.	
	2	20140194793	A	2014-07-10	Nakata 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]
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	17348852
	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	3792
	Examiner Name	Lau, Michael J.
	Attorney Docket Number	I618.118.105

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	17348852
	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	3792
	Examiner Name	Lau, Michael J.
	Attorney Docket Number	I618.118.105

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)	2023-03-14
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.**

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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0140

PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/348,852	Filing Date 06/16/2021	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $480 =	
☐ 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).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	03/14/2023	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/ROZENIA HARMON/
*** 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 number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. 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 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. 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.

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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/348,852	06/16/2021	Darrell Wagner	I618.118.105	5390

25281 7590 12/14/2022

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
12/14/2022	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

Office Action Summary	Application No. 17/348,852	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 6/16/2021.

☐ 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) 1-22 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) 1-22 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 9/4/2020 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

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Rejections - 35 USC § 103

1. 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.

2. 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.

3. The factual inquiries 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.

4. Claim(s) 1-22 is/are rejected under 35 U.S.C. 103 as being unpatentable over multiple embodiments of Bolea (US 2014/0228905 A1).

5. Regarding claim 1, Bolea discloses a device for treating obstructive sleep disordered breathing (eg. Abstract, Para. 2-4), comprising: a stimulation element (eg. Fig. 1, stimulation lead 60) to stimulate an upper airway patency-related nerve (eg. Abstract, Para. 127 and 361), according to a first stimulation protocol including alternating periods of stimulation and non-stimulation in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation in multiple embodiments (eg. Para. 473 and 514, using a fixed stimulation duty cycle).

6. It would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have incorporated fixed duty cycles instead of adaptive such as Fig. 64C and Para. 470-474) to allow for stimulation to continue when a respiratory signal is lost (eg. Para. 473). Therefore, it is implied that the fixed cycle stimulation can be performed without using a sensing element for timing/synchronization purposes.

7. Regarding claim 2, Bolea discloses the timing of the stimulation periods being implemented without a sensing element for timing stimulation comprises the timing of the stimulation being implement without a sensing element for synchronization relative to sensed respiratory information (eg. Para. 473-474 and 514).

8. Regarding claim 3, Bolea discloses a duration of each respective stimulation period is based on a reference respiration-related parameter (eg. Para. 326 and 472-474).

9. Regarding claim 4, Bolea discloses the reference respiration-related parameter comprises a reference breathing pattern (eg. Para. 498-500, 639).

10. Regarding claim 5, Bolea discloses a duration of each respective stimulation period is greater than a duration of an inspiratory phase of the reference breathing pattern (eg. Para. 472-474).

11. Regarding claim 6, Bolea discloses the reference respiration-related parameter is based on stable respiration (eg. Para. 498-500, 639).

12. Regarding claim 7, Bolea discloses a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period, wherein a combined duration of each respective stimulation period and of each respective non-stimulation period is less than the reference respiration-related parameter, which comprises a duration of a reference breath (eg. Para. 129, 420, period 514-516).

13. Regarding claim 8, Bolea discloses the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is no greater than a duration of a reference breathing pattern (eg. Para. 470, multiple pulses within a respiration cycle).

14. Regarding claim 9, Bolea discloses the duration of the respective stimulation periods remain uniform (Eg. Para. 501, can be uniform or non-uniform pulses).

15. Regarding claim 10, Bolea discloses the stimulation protocol is to deliver multiple stimulation periods within a duration of a reference breathing pattern (eg. Para. 470, multiple pulses within a respiration cycle).

16. Regarding claim 11, Bolea discloses the reference breathing pattern comprises at least one of: a historical patient-specific reference breathing pattern; and a multiple patient reference breathing pattern (eg. Para. 266, 296-298, and 494).

17. Regarding claim 12, Bolea discloses the stimulation protocol is to deliver multiple stimulation periods within a duration of an inspiratory phase of a reference breathing pattern (eg. Para. 420).

18. Regarding claim 13, Bolea discloses the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is greater than a duration of the reference breathing pattern (eg. Para. 474, 499, and 636).

19. Regarding claim 14, Bolea discloses the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is less than 30 percent of duration of a reference breathing pattern (eg. Para. 420).

20. Regarding claim 15, Bolea discloses the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is less than 20 percent of duration of the reference breathing pattern (eg. Para. 420).

21. Regarding claim 16, Bolea discloses a duration of a respective one of the stimulation periods is greater than a duration of a respective one of the non-stimulation periods (eg. Para. 474 and 481).

22. Regarding claim 17, Bolea discloses a respective one of the stimulation periods and a respective one of the non-stimulation periods are in a proportion of at least 1.5 to 1 (eg. 474 and 481).

23. Regarding claim 18, Bolea discloses a duration of a respective one of the stimulation periods exceeds the duration of a respective one of the non-stimulation periods by a factor of 3 (eg. Para. 474 and 481, 69% duty cycle as a non-limiting example). The Examiner asserts that it would be obvious to try stimulation with a duty cycle of 75% as it is a very similar range to the non-limiting example disclosed in Bolea and it would be obvious to try under routine optimization since there is a finite number of solutions due to a duty cycle being between 0 and 100% (See MPEP 2144.05 I-II).

24. Regarding claim 19, Bolea discloses a respective one of the stimulation periods and a respective one of the non-stimulation periods comprises a stimulation cycle, and wherein a duration of the respective one of the stimulation periods comprises at least 80 percent of a duration of the stimulation cycle (same reason as claim 18 rejection).

25. Regarding claim 20, Bolea discloses each respective stimulation period comprises continuous pulsed stimulation (eg. Para. 302 and 354).

26. Regarding claim 21, Bolea discloses the stimulation element comprises a non- cardiac, implantable electrode (eg. Fig. 1, stimulation lead 60) and the device comprises an implantable pulse generator (eg. Fig. 1, implanted pulse generator 50) electrically connectable to the implantable electrode (eg. Fig. 1, Para. 127).

27. Regarding claim 22, Bolea discloses a processor; and a non-volatile computer readable medium storing instructions, executable on the processor, to implement the first stimulation protocol (eg. Para. 136).

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2011/0112601 A1 and US 2012/0158091 A1 which teach stimulating a hypoglossal nerve to help treat obstructive sleep apnea.

29. 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 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 published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHAEL J LAU/
Examiner, Art Unit 3792

/PAULA J STICE/
Primary Examiner, Art Unit 3792

Notice of References Cited	Application/Control No. 17/348,852	Applicant(s)/Patent Under Reexamination Wagner et al.	
	Examiner MICHAEL J LAU	Art Unit 3792	Page 1 of 1

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*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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/348,852	Wagner et al.
	Examiner	Art Unit
	MICHAEL J LAU	3792

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61N1/3601,3611,3614,36146,36171	12/07/2022	ML
G16H20/40	12/07/2022	ML
A61B5/0816,0826,113,4818,4848,686,0205	12/07/2022	ML

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
607	42	12/07/2022	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 and prior art search on pe2e search	12/07/2022	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.
0151

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/348,852	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	12/07/2022								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
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	20	✓								
	21	✓								
	22	✓								

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0152

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17348852
Filing Date	2021-06-16
First Named Inventor	Darrell Wagner et al.
Art Unit	N/A
Examiner Name	Unassigned
Attorney Docket Number	I618.118.105

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	151	7330760		2008-02-12	Heruth et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Darrell Wagner et al.
	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	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.	
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	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.	
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	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	163	7447545		2008-11-04	Heruth et al.	
	164	7454250		2008-11-18	Bjorling et al.	
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	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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	Attorney Docket Number	I618.118.105

	174	7572225		2009-08-11	Stahmann et al.	
	175	7590455		2009-09-15	Heruth et al.	
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	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.	
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	196	7783353		2010-08-24	Libbus et al.	
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	198	7809442		2010-10-05	Bolea et al.	
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	200	7853322		2010-12-14	Bourget et al.	
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	203	7917230		2011-03-29	Bly	
	204	7942822		2011-05-17	Koh	
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	211	8160711		2012-04-17	Tehrani 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	20010010010		2001-07-26	Richmond et al.	
	2	20020010495		2002-01-24	Freed et al.	
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	5	20030093128		2005-05-15	Freed et al.	
	6	20030224895		2003-06-19	Gordon et al.	
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	Attorney Docket Number	I618.118.105

	15	20040230278		2004-11-18	Dahl et al.	
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	23	20050076908		2005-04-14	Lee et al.	
	24	20050080348		2005-04-14	Stahmann et al.	
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	27	20050085865		2005-04-21	Tehrani	
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Exhibit 1002
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0176

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	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

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	50	20060064029		2006-03-23	Arad (Abboud)	
	51	20060079802		2006-04-13	Jensen et al.	
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	59	20060247729		2006-11-02	Tehrani et al.	
	60	20060259079		2006-11-16	King	
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	64	20060276701		2006-12-07	Ray	
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	Attorney Docket Number	I618.118.105

	70	20070150022		2007-06-28	Ujhazy et al.	
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	85	20090112116		2009-04-30	Lee et al.	
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	88	20090287279		2009-11-19	Parramon et al.	

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	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

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)	2021-10-22
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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L1	250	("20120232611" OR "20140188185" OR "5277193" OR "9737708" OR "20010010010" OR "20020010495" OR "20020049479" OR "20020156507" OR "20030093128" OR "20030114905" OR "20030163059" OR "20030195571" OR "20030216789" OR "20030224895" OR "20040015204" OR "20040073272" OR "20040111139" OR "20040215288" OR "20040230278" OR "20040254612" OR "20050004628" OR "20050010265" OR "20050042589" OR "20050043765" OR "20050043772" OR "20050074741" OR "20050076908" OR "20050080348" OR "20050080461" OR "20050081847" OR "20050085865" OR "20050085866" OR "20050085868" OR "20050085869" OR "20050085874" OR "20050101833" OR "20050113710" OR "20050115561" OR "20050145246" OR "20050148897" OR "20050165457" OR "20050182457" OR "20050209513" OR "20050209643" OR "20050222503" OR "20050234523" OR "20050251216" OR "20050261747" OR "20050267380" OR "20050277844" OR "20050277999" OR "20050278000" OR "20060052836" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/12/05 02:35 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0184

		"20060058852" OR "20060064029" OR "20060079802" OR "20060095088" OR "20060103407" OR "20060135886" OR "20060142815" OR "20060155341" OR "20060167523" OR "20060212096" OR "20060224209" OR "20060241708" OR "20060247729" OR "20060259079" OR "20060264777" OR "20060266369" OR "20060271137" OR "20060276701" OR "20060293720" OR "20060293723" OR "20070021785" OR "20070027482" OR "20070038265" OR "20070150022" OR "20070233204" OR "20070255379" OR "20080009685" OR "20080039904" OR "20080046055" OR "20080064977" OR "20080103545" OR "20080103570" OR "20080109046" OR "20080109048" OR "20080132802" OR "20080154330" OR "20080161878" OR "20080294060" OR "20090024047" OR "20090062882" OR "20090112116" OR "20090118787" OR "20090216293" OR "20090234427" OR "20090287279" OR "20090308395" OR "20090326408" OR "20100010566" OR "20100016749" OR "20100094379" OR "20100125310" OR "20100125314" OR "20100125315" OR "20100137931" OR "20100152553" OR "20100174341" OR "20100198103" OR "20100198289" OR					

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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		"20100228133" OR "20100228310" OR "20100228317" OR "20100241195" OR "20100262210" OR "20110060380" OR "20110093032" OR "20110093036" OR "20110112601" OR "20110152706" OR "20110152965" OR "20110160794" OR "20110172733" OR "20110264164" OR "20110288609" OR "20120192874" OR "20120253249" OR "20120290036" OR "20130253627" OR "20140135868" OR "20140228905" OR "20140364919" OR "20150039045" OR "20150328451" OR "20160022204" OR "20160193468" OR "20160354602" OR "20160354603" OR "20160354608" OR "20170368337" OR "4379462" OR "4567892" OR "4630614" OR "4813431" OR "4830008" OR "5123425" OR "5133354" OR "5134995" OR "5148802" OR "5158080" OR "5167229" OR "5174287" OR "5178156" OR "5190053" OR "5203343" OR "5211173" OR "5215082" OR "5233983" OR "5239995" OR "5245995" OR "5265624" OR "5281219" OR "5300094" OR "5335657" OR "5344438" OR "5351394" OR "5385144" OR "5388578" OR					

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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		"5398682" OR "5458137" OR "5483969" OR "5485851" OR "5522862" OR "5524632" OR "5540731" OR "5540732" OR "5540733" OR "5540734" OR "5546952" OR "5549655" OR "5588439" OR "5591216" OR "5605151" OR "5645053" OR "5671733" OR "5797852" OR "5823187" OR "5843135" OR "5895360" OR "5904141" OR "5919221" OR "5944680" OR "5999846" OR "6015389" OR "6021352" OR "6025624" OR "6041780" OR "6099479" OR "6120441" OR "6125290" OR "6125291" OR "6126611" OR "6132384" OR "6134459" OR "6144866" OR "6175767" OR "6181961" OR "6198952" OR "6223064" OR "6240316" OR "6248080" OR "6249703" OR "6251126" OR "6269269" OR "6307481" OR "6309350" OR "6314324" OR "6342039" OR "6345202" OR "6361494" OR "6393325" OR "6449507" OR "6450957" OR "6456866" OR "6509164" OR "6522928" OR					

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0187

		"6532388" OR "6572543" OR "6574507" OR "6587725" OR "6609016" OR "6609032" OR "6629527" OR "6641542" OR "6645143" OR "6647289" OR "6651652" OR "6654634" OR "6665560" OR "6666830" OR "6689068" OR "6703939" OR "6718208" OR "6719708" OR "6731976" OR "6731984" OR "6735471" OR "6752765" OR "6770022").pn.					
L2	113	("6773404" OR "6805667" OR "6811538" OR "6842647" OR "6881192" OR "6890306" OR "6893405" OR "6904320" OR "6907293" OR "6928324" OR "6935335" OR "6936011" OR "6964641" OR "6978171" OR "6988498" OR "7025730" OR "7041049" OR "7054692" OR "7077810" OR "7081095" OR "7082331" OR "7082336" OR "7087053" OR "7117036" OR "7128717" OR "7145461" OR "7149573" OR "7155278" OR "7160252" OR "7160255" OR "7167743" OR "7174215" OR "7186220" OR "7187978" OR "7189204" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/12/05 02:35 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0188

		"7195594" OR "7200440" OR "7206635" OR "7212862" OR "7214197" OR "7252640" OR "7269457" OR "7269459" OR "7277749" OR "7330760" OR "7336996" OR "7340302" OR "7351208" OR "7366572" OR "7371220" OR "7387608" OR "7395113" OR "7396333" OR "7398115" OR "7422015" OR "7438686" OR "7447545" OR "7453928" OR "7454250" OR "7468040" OR "7469697" OR "7473227" OR "7491181" OR "7510531" OR "7526341" OR "7542803" OR "7572225" OR "7590455" OR "7591265" OR "7596413" OR "7603170" OR "7610094" OR "7634315" OR "7644714" OR "7662105" OR "7672728" OR "7678061" OR "7680538" OR "7702385" OR "7717848" OR "7720541" OR "7725195" OR "7734340" OR "7734350" OR "7742819" OR "7747323" OR "7751880" OR "7775993" OR "7783353" OR "7792583" OR "7809442" OR "7818063" OR "7853322" OR					

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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		"7881798" OR "7908013" OR "7917230" OR "7942822" OR "7957797" OR "7957809" OR "7979128" OR "8016776" OR "8021299" OR "8150531" OR "8160711" OR "8160712" OR "8175720" OR "8233987" OR "8265759" OR "8280513" OR "8718776" OR "8731678" OR "8781587" OR "9895540").pn.					
L3	16120	A61N1/3601,3611,3614,36146,36171.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 12:12 PM
L4	42004	G16H20/40.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 12:13 PM
L5	121858	A61B5/0816,0826,113,4818,4848,686,0205.cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA,	OR	ON	ON	2022/12/06 12:13 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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			EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L6	1065	607/42.ccls.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 12:16 PM
L7	172754	L3 OR L4 OR L5 OR L6	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 01:11 PM
L8	520	L7 AND "20150319"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO;	OR	ON	ON	2022/12/06 01:17 PM

			JPO; DERWENT; IBM_TDB)				
L9	124110	L7 AND @pd>"20150319"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 01:47 PM
L10	2640	L7 AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 02:56 PM
L11	1670	L7 AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 02:59 PM
L12	578	L7 AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ SAME (regular$ OR periodic$)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	OR	ON	ON	2022/12/06 03:00 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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			IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L13	804	L7 AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 03:00 PM
L14	398	L7 AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) SAME (sample$ OR base$line OR normal OR template$)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 03:01 PM
L15	118	(L3 OR L4 OR L5 OR L6) AND @pd>"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) SAME (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 03:02 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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L16	188	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) SAME (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 05:28 PM
L17	205	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$ OR upper ADJ air$way) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) SAME (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 05:28 PM
L18	180	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$ OR upper ADJ air$way) WITH stimulat$ AND (regular$ OR periodic$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 06:50 PM
L19	88	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea AND (nerve$ OR hypo$glossal OR patenc$ OR upper ADJ air$way) WITH stimulat$ AND stimulat$ WITH (regular$ OR	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL,	OR	ON	ON	2022/12/06 06:51 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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		periodic$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L20	86	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (nerve$ OR hypo$glossal OR patenc$ OR upper ADJ air$way) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 06:51 PM
L21	60	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:03 PM
L22	64	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$) SAME (breath$ OR respirat$) WITH (sample$ OR base$line OR normal OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:20 PM
L23	48	(L3 OR L4 OR L5 OR L6) AND	(US-PGPUB; USPAT; USOCR; FIT (AP, AT,	OR	ON	ON	2022/12/06 07:21 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
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		@pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$) SAME (breath$ OR respirat$) near3 (sample$ OR base$line OR normal OR template$) SAME stimulat$	AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L24	1	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$) SAME (breath$ OR respirat$) near3 (sample$ OR base$line OR template$) SAME stimulat$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:21 PM
L25	215	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR patenc$ OR upper ADJ airway near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:22 PM
L26	62	"5636129"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE,	OR	ON	ON	2022/12/06 07:23 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0196

			SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L27	197	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:24 PM
L28	243	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$ OR interval$)	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:25 PM
L29	151	(L3 OR L4 OR L5 OR L6) AND @pd<"20150319" AND apnea SAME (hypo$glossal OR upper ADJ air$way$ near2 nerve) WITH stimulat$ AND stimulat$ WITH (regular$ OR periodic$ OR asynchron$ OR interval$) SAME puls$	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/12/06 07:26 PM
L30	2	("20140228905").pn.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU,	OR	ON	ON	2022/12/07 04:20 PM

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0197

			CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L31	62	((("INSPIRE") near3 ("MEDICAL") near3 ("SYSTEMS") near3 ("INC"))).AS,AANM.	(USPAT)	OR	ON	ON	2022/12/07 04:21 PM
L32	567	((("WAGNER") near3 ("Darrell")) OR (("NI") near3 ("Quan")) OR (("RONDONI") near3 ("John")) OR (("DIEKEN") near3 ("David"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/12/07 04:24 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0198

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	17348852
Filing Date	2021-06-16
First Named Inventor	Darrell Wagner et al.
Art Unit	N/A
Examiner Name	Unassigned
Attorney Docket Number	I618.118.105

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	5277193		1994-01-11	Takishima et al.	
	2	9737708	B2	2017-08-22	Kobayashi	

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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	20120232611	A1	2012-09-13	Sasaki et al.	
	2	20140188185	A1	2014-07-03	Tesfayesus 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	H0323870	JP	A	1991-01-31	CHEST CORP	[English Equivalent US 5277193]	

EFS Web 2.1.17

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

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	First Named Inventor	Darrell Wagner et al.
	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	2	2015217108	JP	A	2015-12-07	TECHNO LINK CO LTD	[English Equivalent US 9737708]	

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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		

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EXAMINER SIGNATURE

Examiner Signature	/MICHAEL J LAU/	Date Considered	12/07/2022

*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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	First Named Inventor	Darrell Wagner et al.
	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

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)	2022-06-28
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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CONFIRMATION NO. 5390

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
17/348,852	06/16/2021 RULE	607	3792	I618.118.105

APPLICANTS

INSPIRE MEDICAL SYSTEMS, INC., Golden Valley, MN;

INVENTORS

Darrell Wagner, Ham Lake, MN;
Quan Ni, Shoreview, MN;
John Rondoni, Plymouth, MN;
David Dieken, Minneapolis, MN;

**** CONTINUING DATA ***************************

This application is a CON of 17/012,481 09/04/2020
which is a CON of 15/562,714 09/28/2017 PAT 10898709
which 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 ****

06/25/2021

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
❑ Yes ☑ No	❑ Yes ☑ No	/MICHAEL J LAU/ Examiner's Signature	❑ Initials	MN	13	22	1

ADDRESS

DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402
UNITED STATES

TITLE

STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

FILING FEE RECEIVED	FEES: Authority has been given in Paper	
2180	No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	❑ All Fees ❑ 1.16 Fees (Filing) ❑ 1.17 Fees (Processing Ext. of time) ❑ 1.18 Fees (Issue) ❑ Other _____ ❑ Credit

BIB (Rev. 05/07).

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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First Named Inventor	Darrell Wagner et al.
Art Unit	N/A
Examiner Name	Unassigned
Attorney Docket Number	I618.118.105

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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	8280513		2012-10-02	Tehrani	
	2	8265759		2012-09-11	Tehrani	
	3	8233987		2012-07-31	Gelfand	
	4	8781587		2014-07-15	Alt et al.	
	5	5123425		1992-06-23	Shannon, Jr. et al.	
	6	5190053		1993-03-02	Meer	
	7	8160712		2012-04-17	Freed	
	8	5591216		1997-01-07	Testerman et al.	

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	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	9	8718776		2014-05-06	Mashiach et al.	
	10	9895540		2018-02-20	Mashiach	
	11	8731678		2014-05-20	DeRidder	

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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	
	6	20100125310		2010-05-20	Wilson et al.	

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	Attorney Docket Number	I618.118.105

	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.	
	17	20100262210		2010-10-14	Parramon et al.	

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	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	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.	
	25	20120290036		2012-11-15	Karamanoglu	
	26	20140364919		2014-12-11	Doan	
	27	20110093032		2011-04-21	Boggs	
	28	20140135868		2014-05-15	Bashyam	

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	Attorney Docket Number	I618.118.105

	29	20110288609		2011-11-24	Tehrani	
	30	20120192874		2012-08-02	Bolea	
	31	20120253249		2014-10-04	Wilson	
	32	20080161878		2008-07-03	Tehrani	
	33	20080154330		2008-06-26	Tehrani	
	34	20150039045		2015-02-05	Ni et al.	
	35	20160193468		2016-07-07	Rondoni et al.	
	36	20160022204		2016-01-28	Mostov	
	37	20160354602		2016-12-08	Keenan	
	38	20160354603		2016-12-08	Keenan	
	39	20160354608		2016-12-08	Keenan	

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	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	40	20060155341		2006-07-13	Tehrani et al.	
	41	20110172733		2011-07-14	Lima et al.	
	42	20100228310		2010-09-09	Shuros et al.	
	43	20050148897		2005-07-07	Cho et al.	
	44	20110060380		2011-03-10	Gelfand et al.	
	45	20170368337		2017-12-28	Steier	
	46	20080154330		2008-06-26	Tehrani et al.	
	47	20090216293		2009-08-27	Sasaki et al.	
	48	20150328451		2015-11-19	Kobayashi	
	49	20140228905		2014-08-14	Bolea	
	50	20130253627		2013-09-26	Meadows et al.	

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	51	20060167523		2006-07-27	Tehrani et al.	

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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]
	1	2010502276	JP		2010-01-28	Cardiac Pacemaker, Inc.	[English Equivalent WO2008027297]	
	2	2011520526	JP		2011-07-21	Inspire Medical Systems, Inc.	[English Equivalent WO2009140636]	
	3	2009140636	WO		2010-03-11	Inspire Medical Systems, 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.		

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	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	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.		
	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.		
	18	H11514557	JP		1999-12-14		[English Equivalent WO9749455]	
	19	9749455	WO		1997-12-31	Medtronic, Inc.		

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	Attorney Docket Number	I618.118.105

	20	2013023218	WO		2013-02-14	Inspire Medical Systems, Inc.		
	21	102548610	CN		2012-07-04	CARDIAC CONCEPTS INC	[Equivalent to US20110060380]	
	22	2013509943	JP		2013-03-21	Imthera Medical, Inc.	[Equivalent US20130253627]	
	23	4960704	JP		2008-08-07		[Equivalent US20090216293]	
	24	5636129	JP		2015-12-07	TECHNO LINK CO LTD	[Equivalent US20150328451]	
	25	2008027297	WO		2008-06-05	CARDIAC PACEMAKERS INC		
	26	9750049	WO		1997-12-31	MEDTRONIC 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	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.	
	2	Eisele Article – David W. Eisele, MD et al., "Tongue neuromuscular and direct hypoglossal nerve stimulation for obstructive sleep apnea," Otolaryngologic Clinics of North America, Otolaryngol Clin N Am 36 (2003) 501-510 (10 pages).	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.L./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17348852
	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	3	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.	
	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.	
	7	Stanescu, "Expiratory flow limitation during sleep in heavy snorers" European Respiratory Journal, 1996, 9, 2116-2121.	
	8	J Sleep Res., "Hypoglossal nerve stimulation improves obstructive sleep apnea: 12-month outcomes" Journal, 2014, 23, 77-83.	
	9	The Laryngoscope, "Implanted Upper Airway Stimulation Device for Obstructive Sleep Apnea" Journal, 2012, 122, 1626-1633.	

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EXAMINER SIGNATURE

Examiner Signature	/MICHAEL J LAU/	Date Considered	12/07/2022

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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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17348852
	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

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)	2021-10-22
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.

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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).

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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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	17348852
Filing Date	2021-06-16
First Named Inventor	Darrell Wagner et al.
Art Unit	N/A
Examiner Name	Unassigned
Attorney Docket Number	I618.118.105

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	5277193		1994-01-11	Takishima et al.	
	2	9737708	B2	2017-08-22	Kobayashi	

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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	20120232611	A1	2012-09-13	Sasaki et al.	
	2	20140188185	A1	2014-07-03	Tesfayesus 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	H0323870	JP	A	1991-01-31	CHEST CORP	[English Equivalent US 5277193]	

EFS Web 2.1.17

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17348852
	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	2	2015217108	JP	A	2015-12-07	TECHNO LINK CO LTD	[English Equivalent US 9737708]	

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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		

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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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	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

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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)	2022-06-28
Name/Print	Paul S. Grunzweig	Registration Number	37143

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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.
0219

Electronic Acknowledgement Receipt

EFS ID:	46067735
Application Number:	17348852
International Application Number:	
Confirmation Number:	5390
Title of Invention:	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING
First Named Inventor/Applicant Name:	Darrell Wagner
Customer Number:	25281
Filer:	PAUL STEVEN GRUNZWEIG/Justina Perez
Filer Authorized By:	PAUL STEVEN GRUNZWEIG
Attorney Docket Number:	I618.118.105
Receipt Date:	28-JUN-2022
Filing Date:	16-JUN-2021
Time Stamp:	16:58:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	2022-06-28SIDS.pdf	612361 cdca29c49f06bc5ed3fa20c2abc33dbdce5b9cca	no	4

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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

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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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.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/348,852	06/16/2021	Darrell Wagner	I618.118.105

CONFIRMATION NO. 5390

25281
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

POA ACCEPTANCE LETTER

OC000000129376165

Date Mailed: 10/29/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/22/2021.

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**.

/sleutchit/

Doc Code: PA..
Document Description: Power of Attorney

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Application Number	17348852
Filing Date	2021-06-16
First Named Inventor	Darrell Wagner
Title	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING
Art Unit	N/A
Examiner Name	Unassigned
Attorney Docket Number	I618.118.105

SIGNATURE of Applicant or Patent Practitioner

Signature	/Paul S. Grunzweig/	Date (Optional)	2021-10-22
Name	Paul S. Grunzweig	Registration Number	37143
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ *Total of 2 forms are submitted.

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Document Description: Power of Attorney

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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.

☐ 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)
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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)	10 June 2021
Name	John Rondoni		
Title	Senior Vice President: Research, Development, & Ventures		

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.**

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

Docket I618.118.103

PTO/AIA/01 (05-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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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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PTO/AIA/01 (06-12)
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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.

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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.

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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.

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

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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 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 Acknowledgement Receipt

EFS ID:	44100045
Application Number:	17348852
International Application Number:	
Confirmation Number:	5390
Title of Invention:	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING
First Named Inventor/Applicant Name:	Darrell Wagner
Customer Number:	25281
Filer:	PAUL STEVEN GRUNZWEIG/Justina Perez
Filer Authorized By:	PAUL STEVEN GRUNZWEIG
Attorney Docket Number:	I618.118.105
Receipt Date:	22-OCT-2021
Filing Date:	16-JUN-2021
Time Stamp:	15:30:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	2021-10-22IDSSTMNT.pdf	102201 a22bea590760a171b6945e63c511e3a2765b70a0	no	2

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	2021-10-22IDS.pdf	618421 3c87447f6d6e5c4ba2a3637f1f018c19ae0ccf56	no	31
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	2021-10-22IDS2.pdf	615622 c379d9b0b981b618895fc3dc1654b72896c939e0	no	12
Warnings:					
Information:					
4	Power of Attorney	2021-10-22POA.pdf	1846912 5045951d089956cac01dc030b6db58c56468c69f	no	2
Warnings:					
Information:					
5	Oath or Declaration filed	2021-10-22Decl.pdf	3578137 0c254e51c9649ecf2beaba7c678768ee71a8ea3d	no	5
Warnings:					
Information:					
			Total Files Size (in bytes):	6761293	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

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

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	**Darrell Wagner et al.**	**Examiner: N/A**	
Serial No.:	**17/348,852**	**Group Art Unit: N/A**	
Filed:	**June 16, 2021**	**Docket: I618.118.105**	
Title:	**STIMULATION FOR TREATING SLEEP DISORDERED BREATHINGETHOD OF SENSING PRESSURE FOR AN IMPLANTABLE STIMULATION SYSTEM**		

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

INFORMATION DISCLOSURE STATEMENT

Dear Commissioner:

In compliance with the duty of disclosure under 37 CFR § 1.56, and in accordance with the practice under 37 CFR § 1.97 and § 1.98, the Examiner's attention is directed to the documents listed on the enclosed modified Form PTO-1449. No inference should be made that the cited references are in fact material, are in fact prior art, or that no better art exists. The cited patents are not in any order based on their pertinence.

This Information Disclosure Statement is also being filed in accordance with 37 CFR 1.98(d)(1). Since the pending application is a **Continuation of USSN 17/012,481**, copies of all foreign references and articles that were filed in the parent application are not submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No certification or fee is required (37 CFR §1.97(b)). By submitting these references, Applicant does not admit that the references are prior art to or material to this application, and reserves the right to establish that any reference is not prior art. Applicant does not represent that the references have been reviewed in detail; there may be details in the references of which Applicant is unaware. The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account 500471. It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Form PT0-1449 be returned indicating that such information has been considered.

Respectfully submitted,

Date: October 22, 2021

By: /Paul S. Grunzweig/
Name: Paul S. Grunzweig
Reg. No.: 37,143

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17348852
Filing Date	2021-06-16
First Named Inventor	Darrell Wagner et al.
Art Unit	N/A
Examiner Name	Unassigned
Attorney Docket Number	I618.118.105

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	8280513		2012-10-02	Tehrani	
	2	8265759		2012-09-11	Tehrani	
	3	8233987		2012-07-31	Gelfand	
	4	8781587		2014-07-15	Alt et al.	
	5	5123425		1992-06-23	Shannon, Jr. et al.	
	6	5190053		1993-03-02	Meer	
	7	8160712		2012-04-17	Freed	
	8	5591216		1997-01-07	Testerman et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17348852
	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	9	8718776		2014-05-06	Mashiach et al.	
	10	9895540		2018-02-20	Mashiach	
	11	8731678		2014-05-20	DeRidder	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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	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	
	6	20100125310		2010-05-20	Wilson et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	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.	
	17	20100262210		2010-10-14	Parramon et al.	

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	Application Number	17348852
	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	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.	
	25	20120290036		2012-11-15	Karamanoglu	
	26	20140364919		2014-12-11	Doan	
	27	20110093032		2011-04-21	Boggs	
	28	20140135868		2014-05-15	Bashyam	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17348852
	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

	29	20110288609		2011-11-24	Tehrani	
	30	20120192874		2012-08-02	Bolea	
	31	20120253249		2014-10-04	Wilson	
	32	20080161878		2008-07-03	Tehrani	
	33	20080154330		2008-06-26	Tehrani	
	34	20150039045		2015-02-05	Ni et al.	
	35	20160193468		2016-07-07	Rondoni et al.	
	36	20160022204		2016-01-28	Mostov	
	37	20160354602		2016-12-08	Keenan	
	38	20160354603		2016-12-08	Keenan	
	39	20160354608		2016-12-08	Keenan	

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0238

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17348852
	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	N/A
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Exhibit 1002
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0239

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	51	20060167523		2006-07-27	Tehrani 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.	[English Equivalent WO2008027297]	
	2	2011520526	JP		2011-07-21	Inspire Medical Systems, Inc.	[English Equivalent WO2009140636]	
	3	2009140636	WO		2010-03-11	Inspire Medical Systems, Inc.		
	4	2006047264	WO		2006-05-04	Advanced Neuromodulation Systems, Inc.		
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	18	H11514557	JP		1999-12-14		[English Equivalent WO9749455]	
	19	9749455	WO		1997-12-31	Medtronic, Inc.		

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	20	2013023218	WO		2013-02-14	Inspire Medical Systems, Inc.		
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	25	2008027297	WO		2008-06-05	CARDIAC PACEMAKERS INC		
	26	9750049	WO		1997-12-31	MEDTRONIC INC		

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	1	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.	
	2	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).	

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	Examiner Name	Unassigned
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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)	2021-10-22
Name/Print	Paul S. Grunzweig	Registration Number	37143

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0245

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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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	2	4567892		1986-02-04	Plicchi et al.	
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	Filing Date	2021-06-16
	First Named Inventor	Darrell Wagner et al.
	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

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	Art Unit	N/A
	Examiner Name	Unassigned
	Attorney Docket Number	I618.118.105

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	Examiner Name	Unassigned
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	Art Unit	N/A
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	Art Unit	N/A
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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)	2021-10-22
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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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/348,852	06/16/2021	Darrell Wagner	I618.118.105

CONFIRMATION NO. 5390

25281
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

PUBLICATION NOTICE

OC000000128959089

Title:STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

Publication No.US-2021-0308454-A1
Publication Date:10/07/2021

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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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
17/348,852	06/16/2021		2180	I618.118.105	22	1

CONFIRMATION NO. 5390

FILING RECEIPT

25281
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

OC000000128366428

Date Mailed: 06/29/2021

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, Shoreview, 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: None

Domestic Priority data as claimed by applicant

This application is a CON of 17/012,481 09/04/2020
which is a CON of 15/562,714 09/28/2017 PAT 10898709
which 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

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.

If Required, Foreign Filing License Granted: 06/25/2021
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/348,852**
Projected Publication Date: 10/07/2021
Non-Publication Request: No
Early Publication Request: No
Title

STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

Preliminary Class

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,

Exhibit 1002
NYXOAH, INC., et al. v. INSPIRE MEDICAL SYSTEMS, INC.
0279

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).

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.

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0281

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/348,852

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	320
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	700
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	800
TOTAL CLAIMS (37 CFR 1.16(i))	22 minus 20 =	* 2			OR	x 100 =	200
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*				x 480 =	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	2020

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.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/348,852	06/16/2021	Darrell Wagner	I618.118.105

CONFIRMATION NO. 5390

25281
DICKE, BILLIG & CZAJA
FIFTH STREET TOWERS
100 SOUTH FIFTH STREET, SUITE 2250
MINNEAPOLIS, MN 55402

INFORMAL NOTICE

OC000000126566427

Date Mailed: 06/29/2021

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file 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 actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Darrell Wagner
  Quan Ni
  John Rondoni
  David Dieken

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**.

/sleutchit/

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.105
	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
Ham Lake	MN	US

Mailing Address of Inventor:

Address 1	5500 Wayzata Blvd.
Address 2	Suite 1600

City	State/Province	Postal Code	Country
Golden Valley	MN	55416	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
Shoreview	MN	US

Mailing Address of Inventor:

Address 1	5500 Wayzata Blvd.
Address 2	Suite 1600

City	State/Province	Postal Code	Country
Golden Valley	MN	55416	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	I618.118.105
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

City	Plymouth	State/Province	MN	Country of Residence	US

Mailing Address of Inventor:

Address 1	5500 Wayzata Blvd.		
Address 2	Suite 1600		
City	Golden Valley	State/Province	MN
Postal Code	55416	Country	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	David		Dieken	

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

City	Minneapolis	State/Province	MN	Country of Residence	US

Mailing Address of Inventor:

Address 1	5500 Wayzata Blvd.		
Address 2	Suite 1600		
City	Golden Valley	State/Province	MN
Postal Code	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	I618.118.105	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	13	Suggested Figure for Publication (if any)	3B

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.105
	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)
	Continuation of	17/012481	2020-09-04

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.105
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17/012481	Continuation of	15/562714	2017-09-28	10898709	2021-01-26
Prior Application Status	Expired				Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
15/562714	a 371 of international	PCT/US2016/022611	2016-03-16		
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	62/135305	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.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.105
	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	I618.118.105
	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

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.105
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

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Signature	/Paul S. Grunzweig/			Date (YYYY-MM-DD)	2021-06-16
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	I618.118.105
	Application Number	
Title of Invention	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING	

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STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

Cross-Reference to Related Applications

[0001] This application is a continuation of utility application Serial Number 17/012,481, filed on September 04, 2020, which is a continuation of utility application Serial Number 15/562,714, filed September 28, 2017, now U.S. Patent 10,898,709, issued on January 26, 2021, which is a 371 National Phase Application of PCT Patent Application No. PCT/US2016/022611, filed March 16, 2016, entitled STIMULATION FOR TREATING SLEEP DISORDERED BREATHING, which claims benefit from U.S. Provisional Patent Application 62/135,305, filed March 19, 2015, all of which are herein incorporated by reference.

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.

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[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.

[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.

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[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.

[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.

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[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.

[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.

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[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 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

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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 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

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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.

[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,

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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.

[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.

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[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 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.

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[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.

[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

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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 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.

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[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 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

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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 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.

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[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 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.

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[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 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

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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 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).

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[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.

[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

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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 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

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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 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

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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.

[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.

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[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 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

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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. 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.

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[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 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

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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.

[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

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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.

[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

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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 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

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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 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

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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, 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.

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[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 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

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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 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

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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 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

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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.

[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.

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[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 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

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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 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

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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.

[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.

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[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 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

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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).

[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.

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[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, 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

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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 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.

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[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, 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

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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 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

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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 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

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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 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.

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[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.

[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.

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[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 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

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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 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.

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[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 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

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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 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.

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[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.

[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

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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, 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

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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 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.

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[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 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

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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 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

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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.

[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

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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).

[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

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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 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

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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.

[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.

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[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 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,

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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 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

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(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 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.

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[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 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.

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[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 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

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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.

[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

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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 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.

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[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 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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WHAT IS CLAIMED IS:

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

a stimulation element to stimulate an upper airway patency-related nerve, according to a first stimulation protocol including alternating periods of stimulation and non-stimulation in which a timing of the stimulation periods is implemented without a sensing element for timing stimulation.

2. The device of claim 1, wherein the timing of the stimulation periods being implemented without a sensing element for timing stimulation comprises the timing of the stimulation being implement without a sensing element for synchronization relative to sensed respiratory information.

3. The device of claim 1, wherein a duration of each respective stimulation period is based on a reference respiration-related parameter.

4. The device of claim 3, wherein the reference respiration-related parameter comprises a reference breathing pattern.

5. The device of claim 4, wherein a duration of each respective stimulation period is greater than a duration of an inspiratory phase of the reference breathing pattern.

6. The device of claim 3, wherein the reference respiration-related parameter is based on stable respiration.

7. The device of claim 3, wherein a duration of each respective stimulation period is greater than a duration of each respective non-stimulation period, wherein a combined duration of each respective stimulation period and of each respective non-stimulation period is less than the reference respiration-related parameter, which comprises a duration of a reference breath.

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8. The device of claim 1, wherein the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is no greater than a duration of a reference breathing pattern.

9. The device of claim 1, wherein the duration of the respective stimulation periods remain uniform.

10. The device of claim 1, wherein the stimulation protocol is to deliver multiple stimulation periods within a duration of a reference breathing pattern.

11. The device of claim 10, wherein the reference breathing pattern comprises at least one of:
a historical patient-specific reference breathing pattern; and
a multiple patient reference breathing pattern.

12. The device of claim 1, wherein the stimulation protocol is to deliver multiple stimulation periods within a duration of an inspiratory phase of a reference breathing pattern.

13. The device of claim 1, wherein the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is greater than a duration of the reference breathing pattern.

14. The device of claim 1, wherein the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is less than 30 percent of duration of a reference breathing pattern.

15. The device of claim 14, wherein the combined duration of a respective one of the stimulation periods and of a respective one of the non-stimulation periods is less than 20 percent of duration of the reference breathing pattern.

16. The device of claim 1, wherein a duration of a respective one of the stimulation periods is greater than a duration of a respective one of the non-stimulation periods.

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17. The device of claim 16, wherein a respective one of the stimulation periods and a respective one of the non-stimulation periods are in a proportion of at least 1.5 to 1.

18. The device of claim 16, wherein a duration of a respective one of the stimulation periods exceeds the duration of a respective one of the non-stimulation periods by a factor of 3.

19. The device of claim 1, wherein a respective one of the stimulation periods and a respective one of the non-stimulation periods comprises a stimulation cycle, and wherein a duration of the respective one of the stimulation periods comprises at least 80 percent of a duration of the stimulation cycle.

20. The device of claim 1, wherein each respective stimulation period comprises continuous pulsed stimulation.

21. The device of claim 1, wherein the stimulation element comprises a non-cardiac, implantable electrode and the device comprises an implantable pulse generator electrically connectable to the implantable electrode.

22. The device of claim 1, comprising:

a processor; and

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

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STIMULATION FOR TREATING SLEEP DISORDERED BREATHING

Abstract

A device for treating sleep disordered breathing includes a stimulation element to stimulate an airway patency related nerve.

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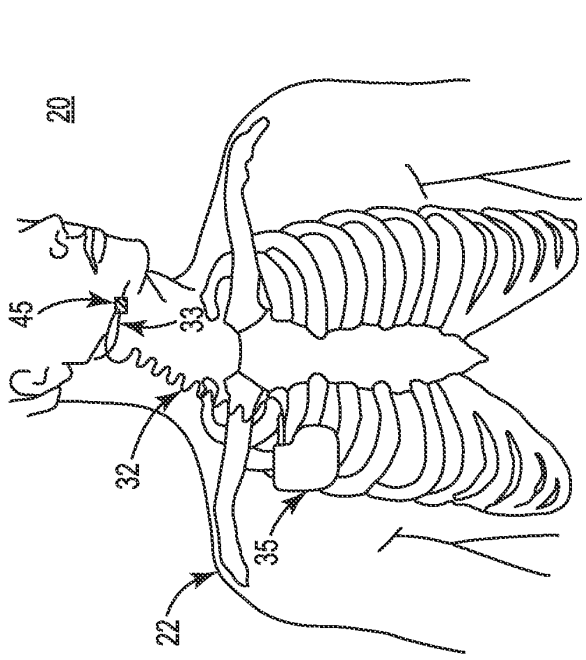


Fig. 2A

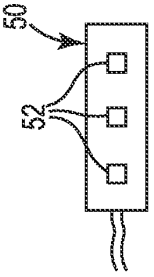


Fig. 2E

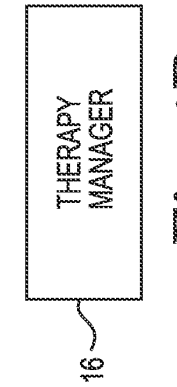


Fig. 1B

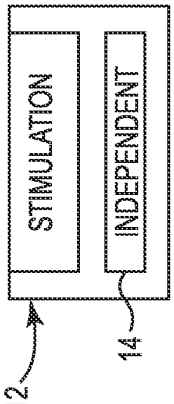


Fig. 1A

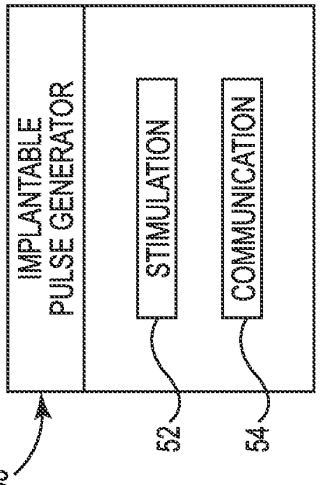


Fig. 2B



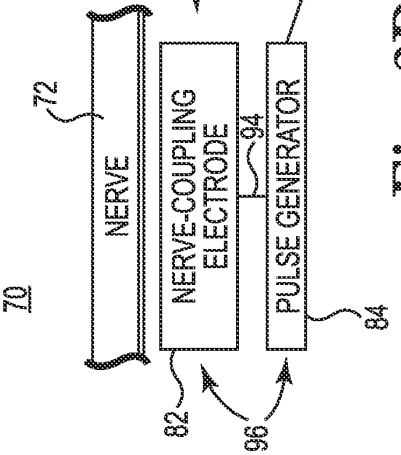


Fig. 2D

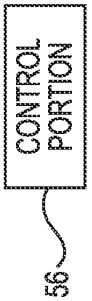


Fig. 2C

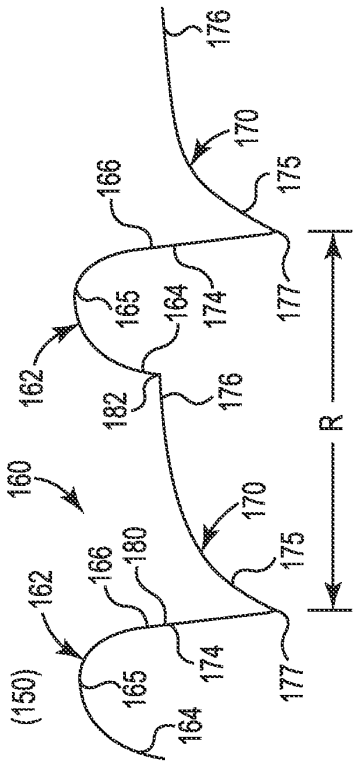

(150)
160
162
164
165
166
170
174
175
176
177
180
182
R

Fig. 3A

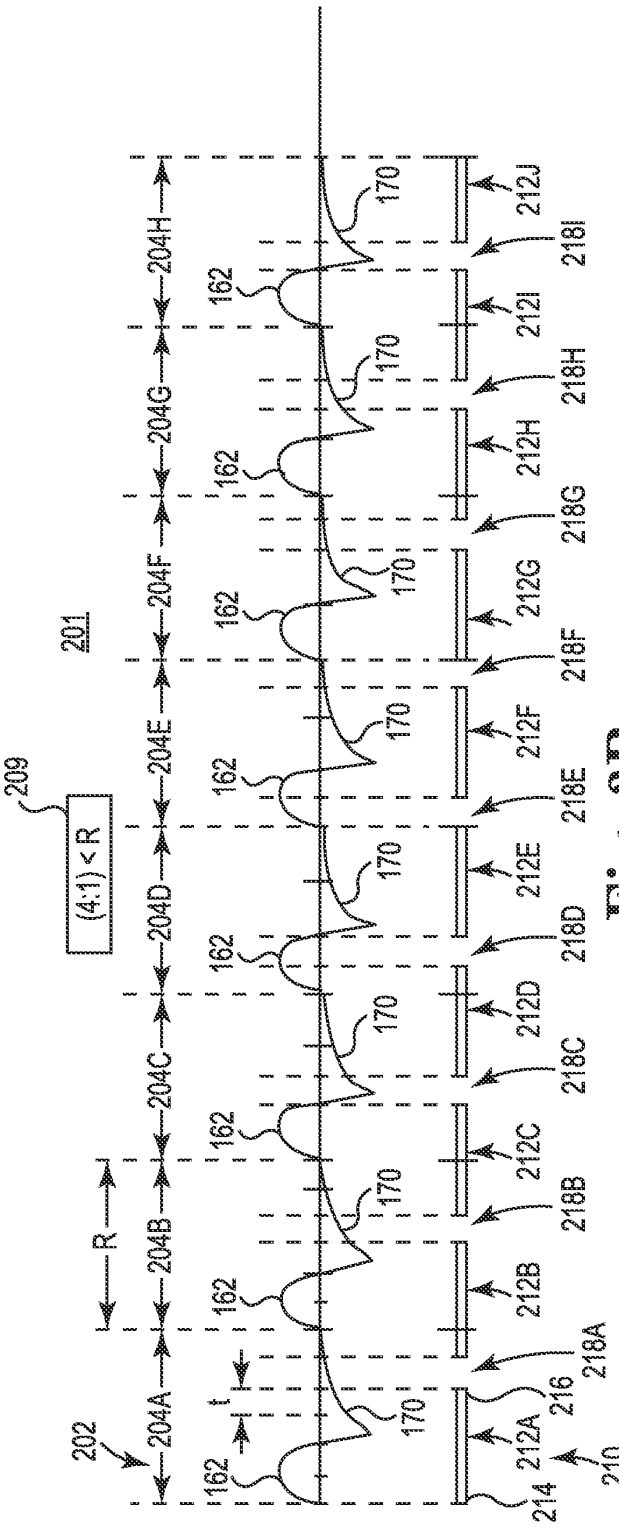

201
209
(4:1) < R
R
202
204A
204B
204C
204D
204E
204F
204G
204H
210
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212B
212C
212D
212E
212F
212G
212H
212I
212J
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218A
218B
218C
218D
218E
218F
218G
218H
218I
162
170

Fig. 3B

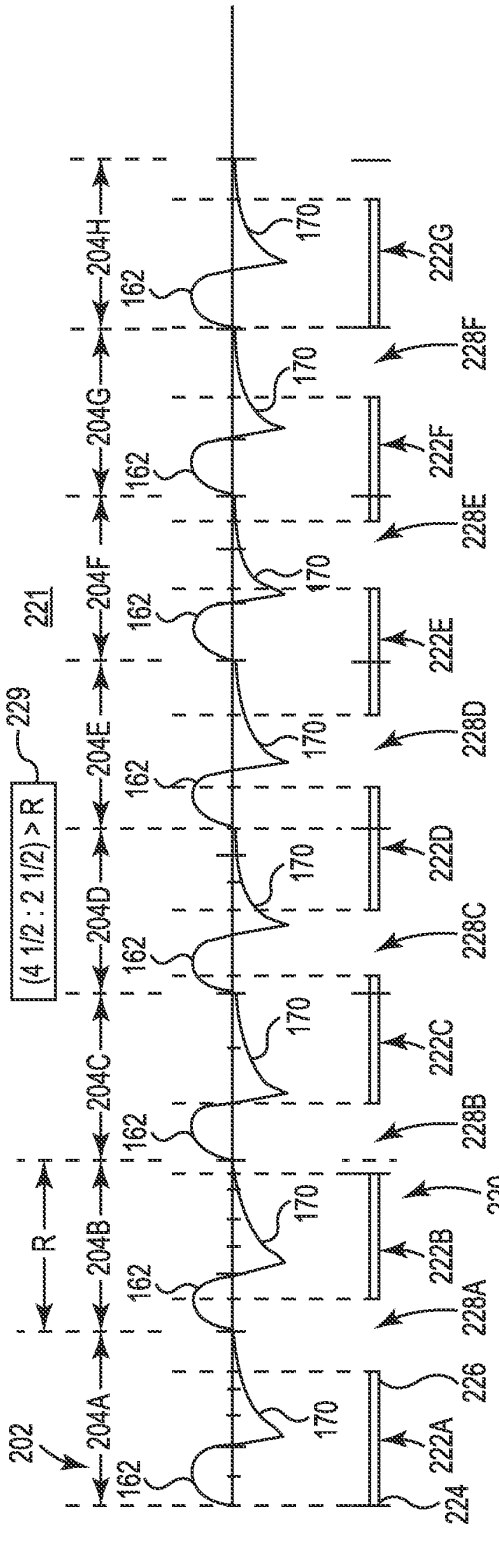

202
204A
204B
204C
204D
204E
204F
204G
204H
R
(4 1/2 : 2 1/2) > R
229
221
162
170
222A
222B
222C
222D
222E
222F
222G
224
226
228A
228B
228C
228D
228E
228F
220

Fig. 3C

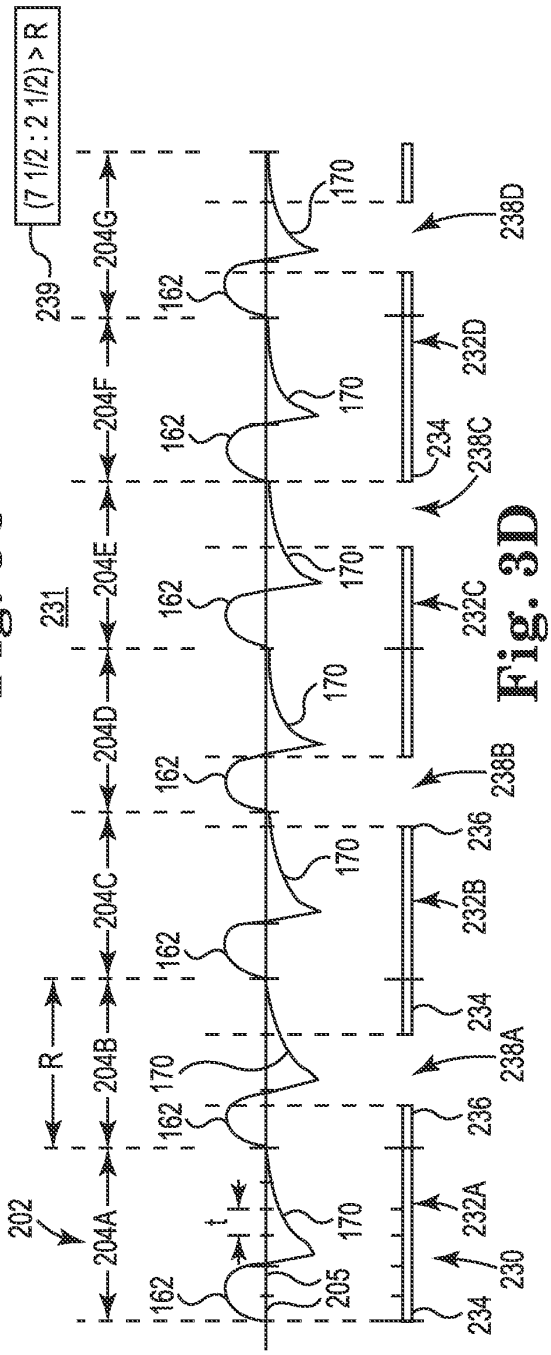

202
204A
204B
204C
204D
204E
204F
204G
R
(7 1/2 : 2 1/2) > R
239
231
162
170
t
205
230
232A
232B
232C
232D
234
236
238A
238B
238C
238D

Fig. 3D

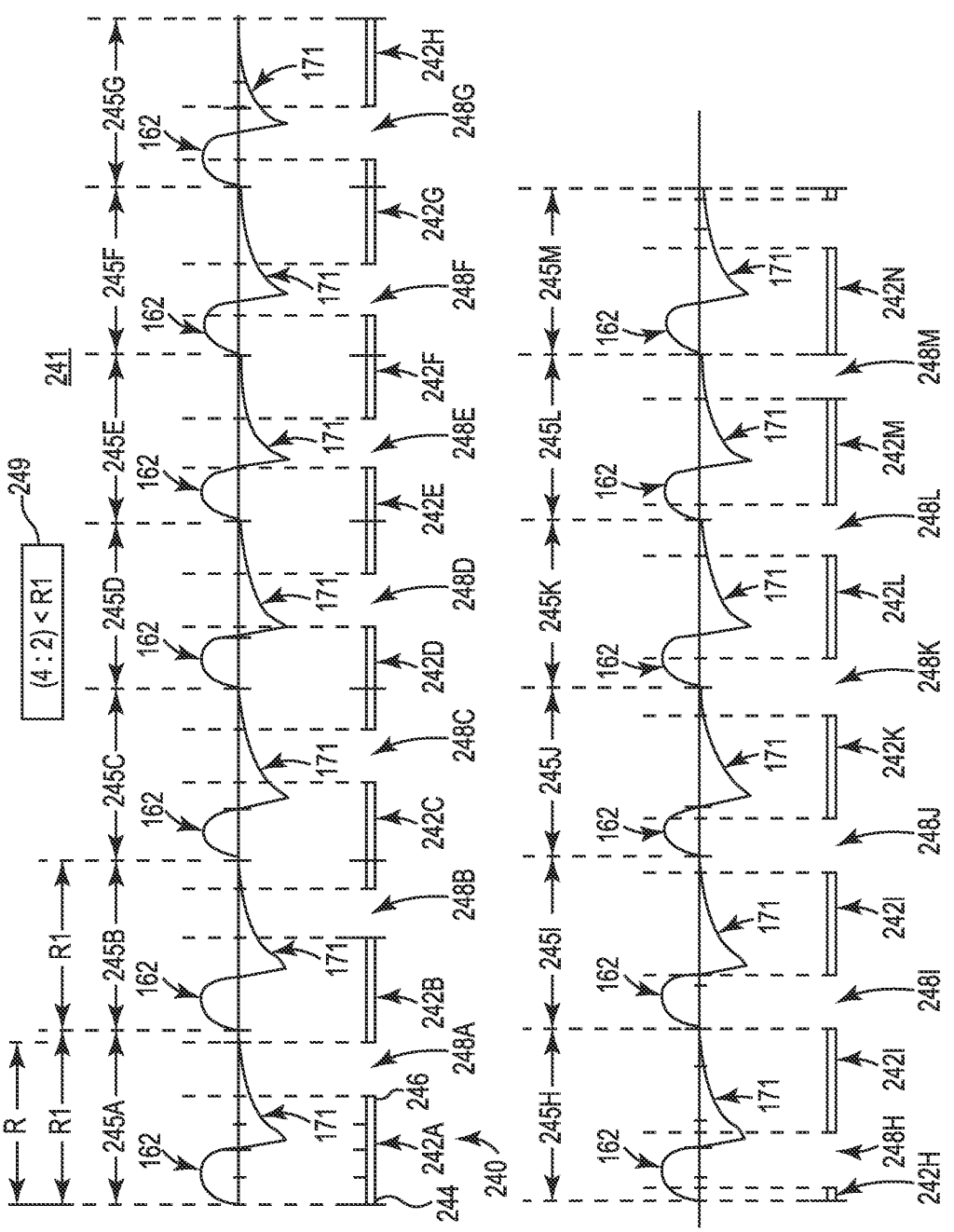

R
R1
R1
245A
245B
245C
245D
245E
245F
245G
241
249
(4 : 2) < R1
162
171
242A
242B
242C
242D
242E
242F
242G
242H
246
244
240
248A
248B
248C
248D
248E
248F
248G
245H
245I
245J
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242M
242N

Fig. 3E

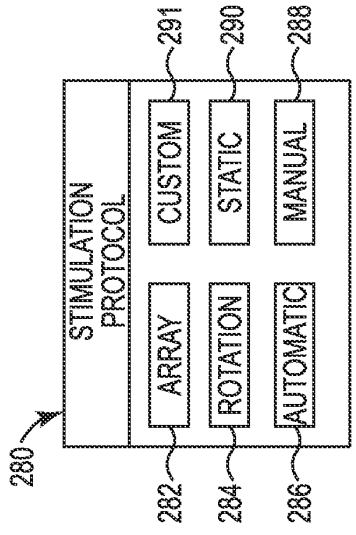


Fig. 5

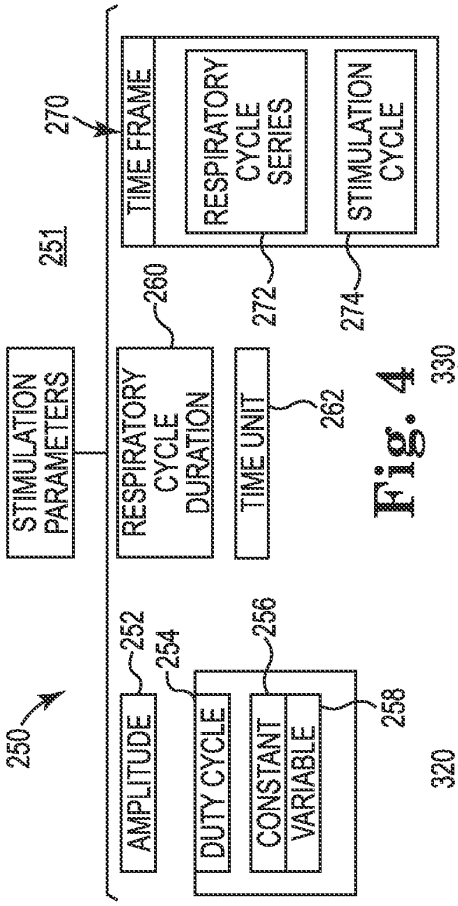


Fig. 4

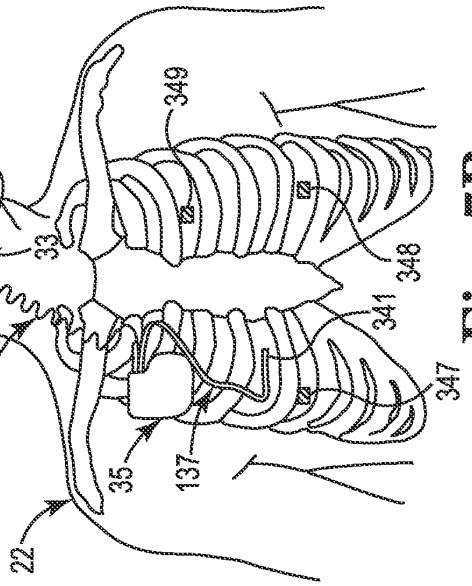


Fig. 7B

Fig. 6

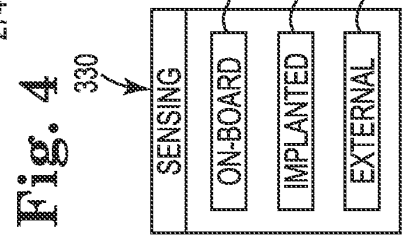


Fig. 7A

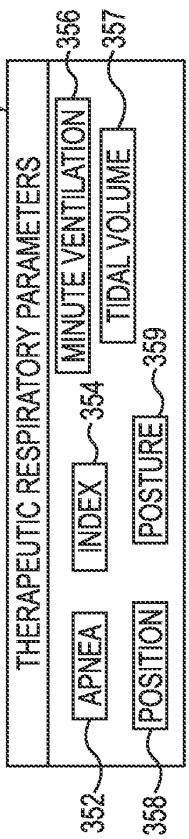


Fig. 8

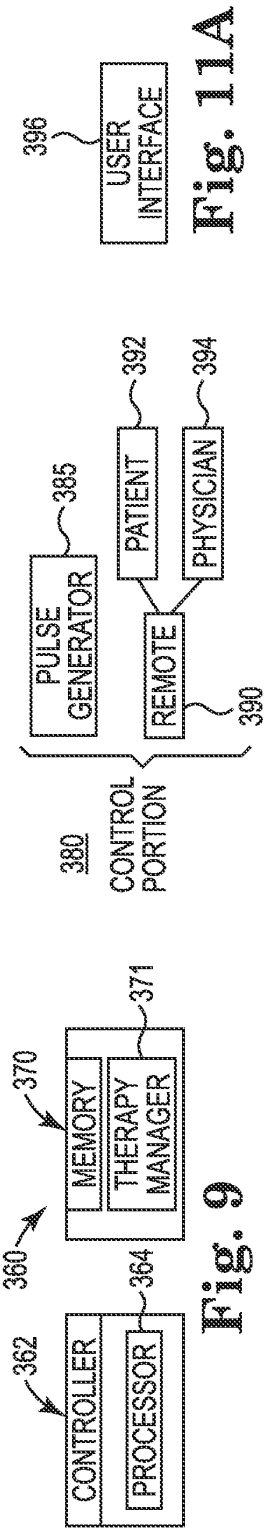


Fig. 9

Fig. 10

Fig. 11A

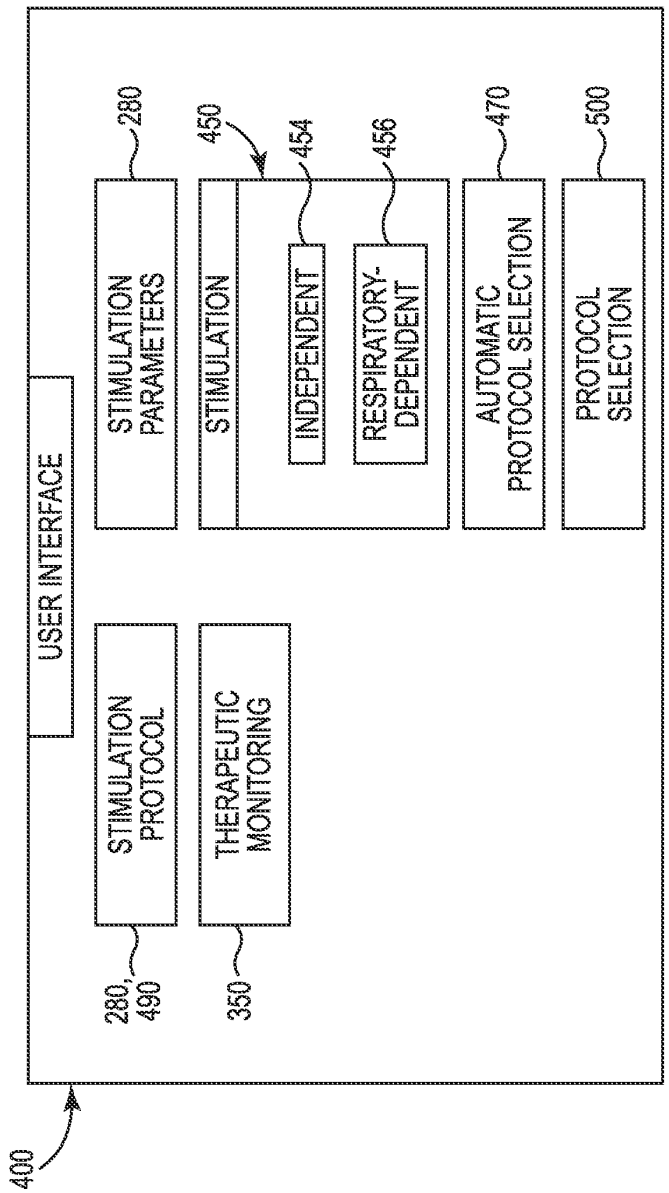


Fig. 11B

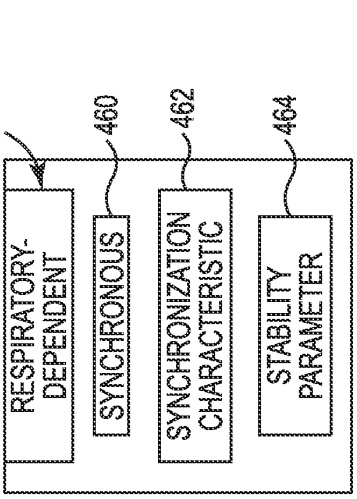


Fig. 13

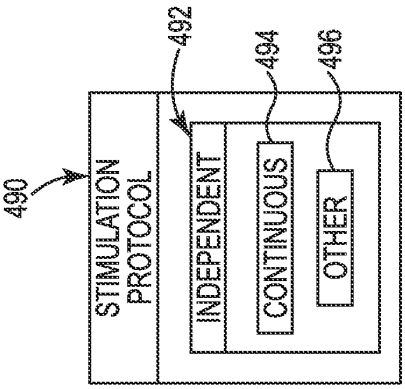


Fig. 15A

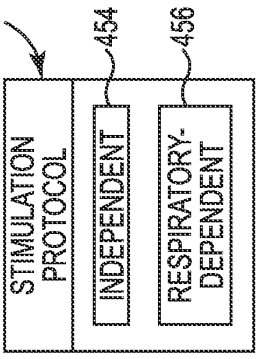


Fig. 12

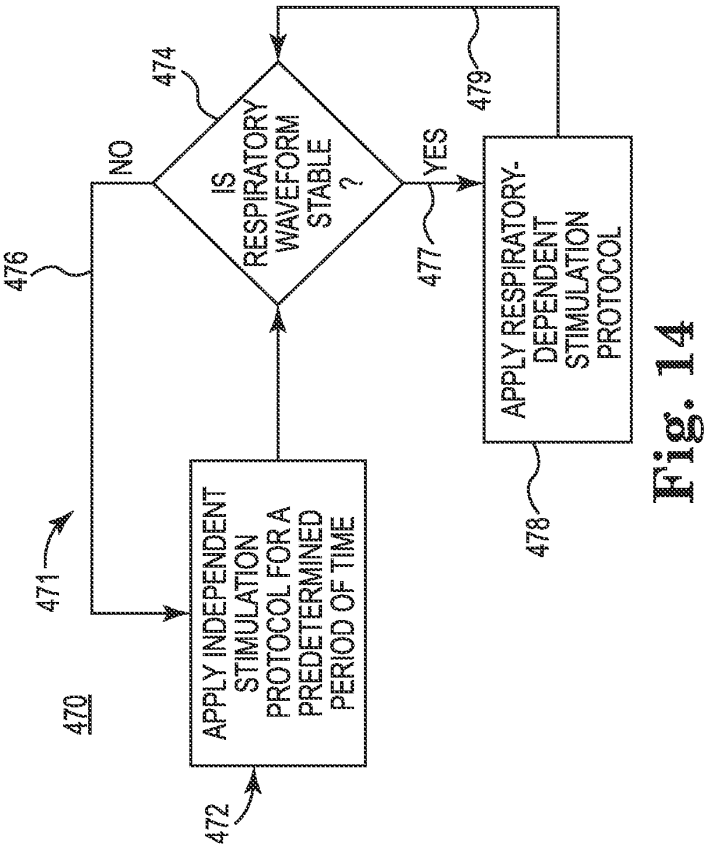


Fig. 14

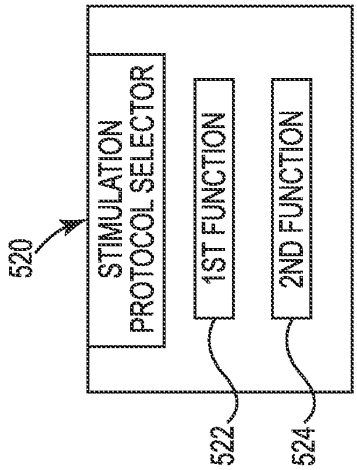


Fig. 15C

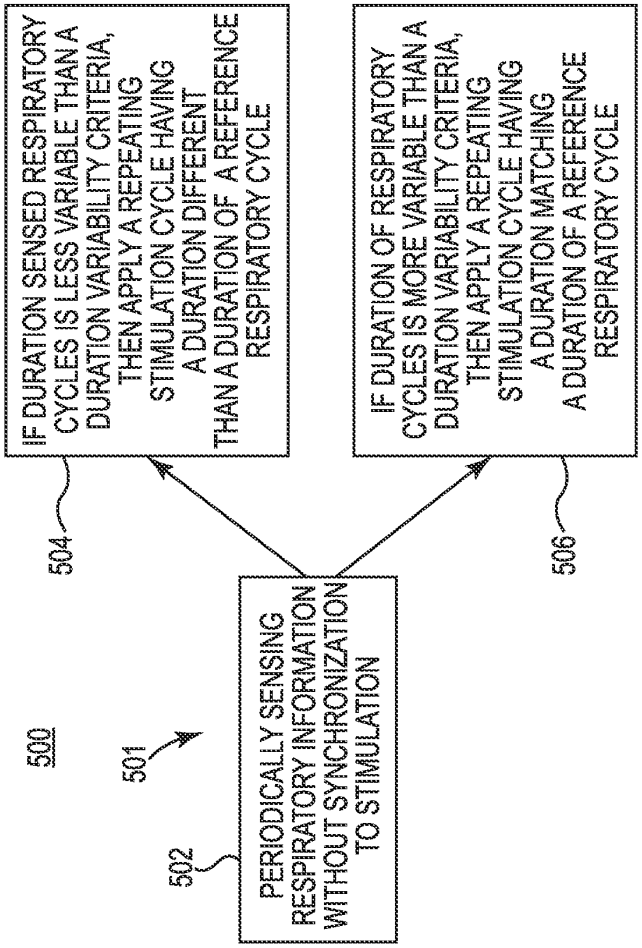


Fig. 15B

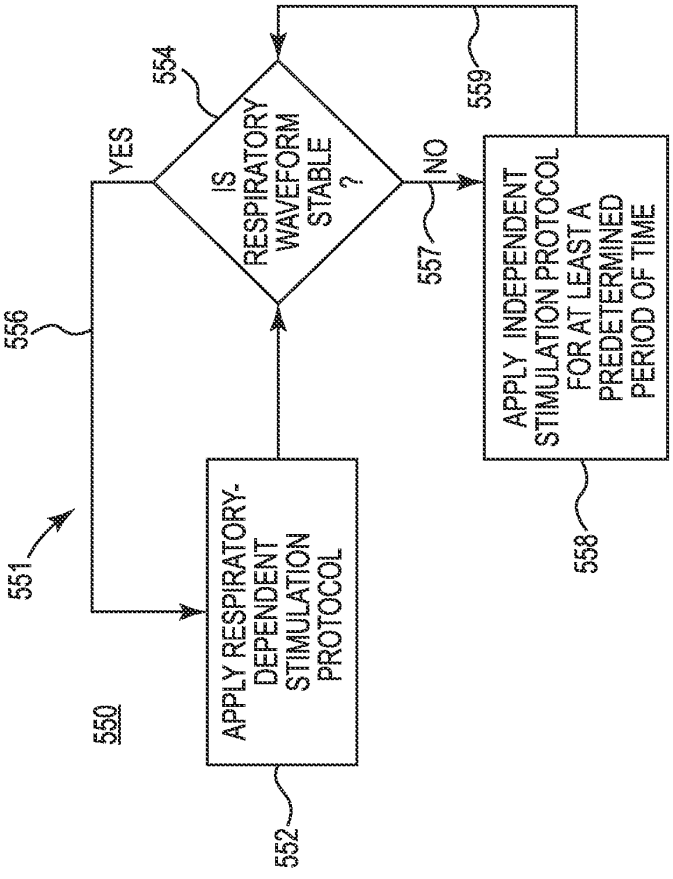

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APPLY RESPIRATORY-DEPENDENT STIMULATION PROTOCOL
IS RESPIRATORY WAVEFORM STABLE ?
YES
NO
APPLY INDEPENDENT STIMULATION PROTOCOL FOR AT LEAST A PREDETERMINED PERIOD OF TIME

Fig. 15D

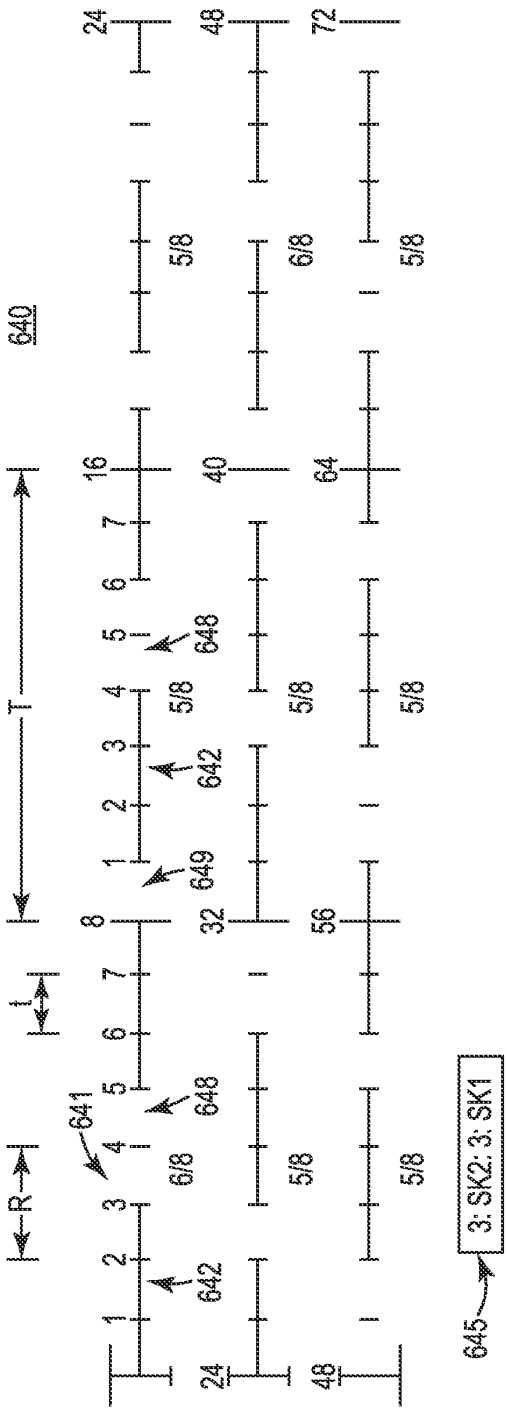

640
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641
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649
645
3: SK2; 3: SK1
6/8
5/8
1
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8
16
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32
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56
64
72

Fig. 16A

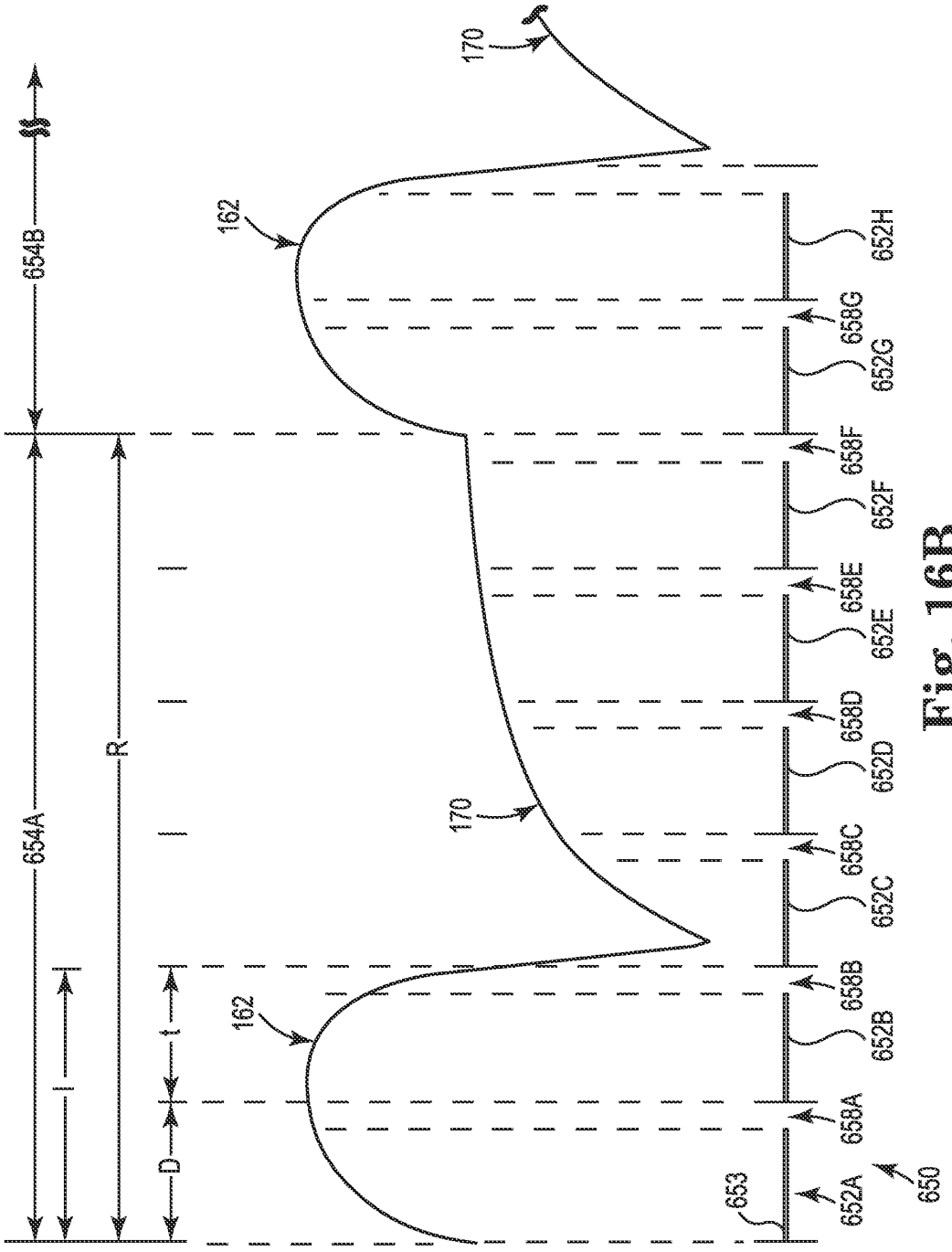

654A
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162
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652G
652H
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658D
658E
658F
658G

Fig. 16B

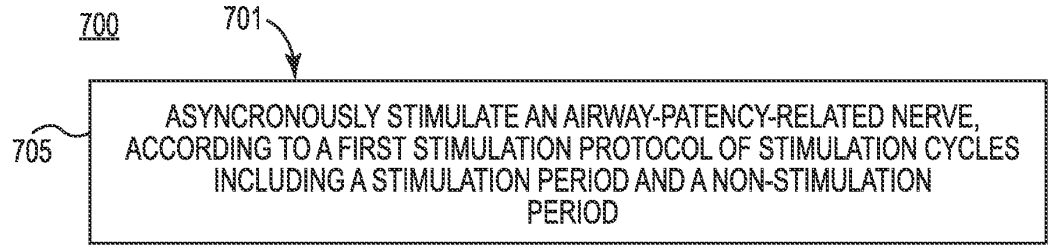


Fig. 17A

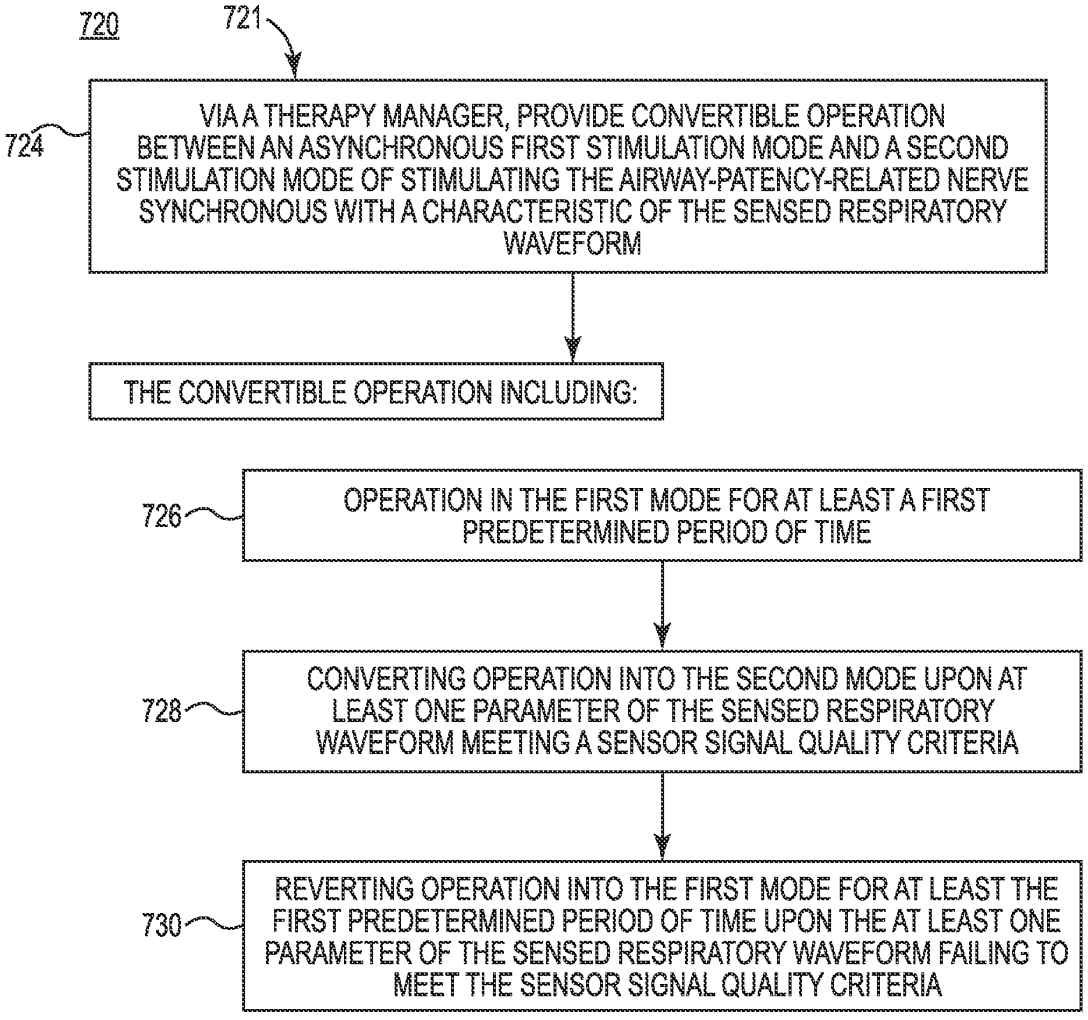


Fig. 17B

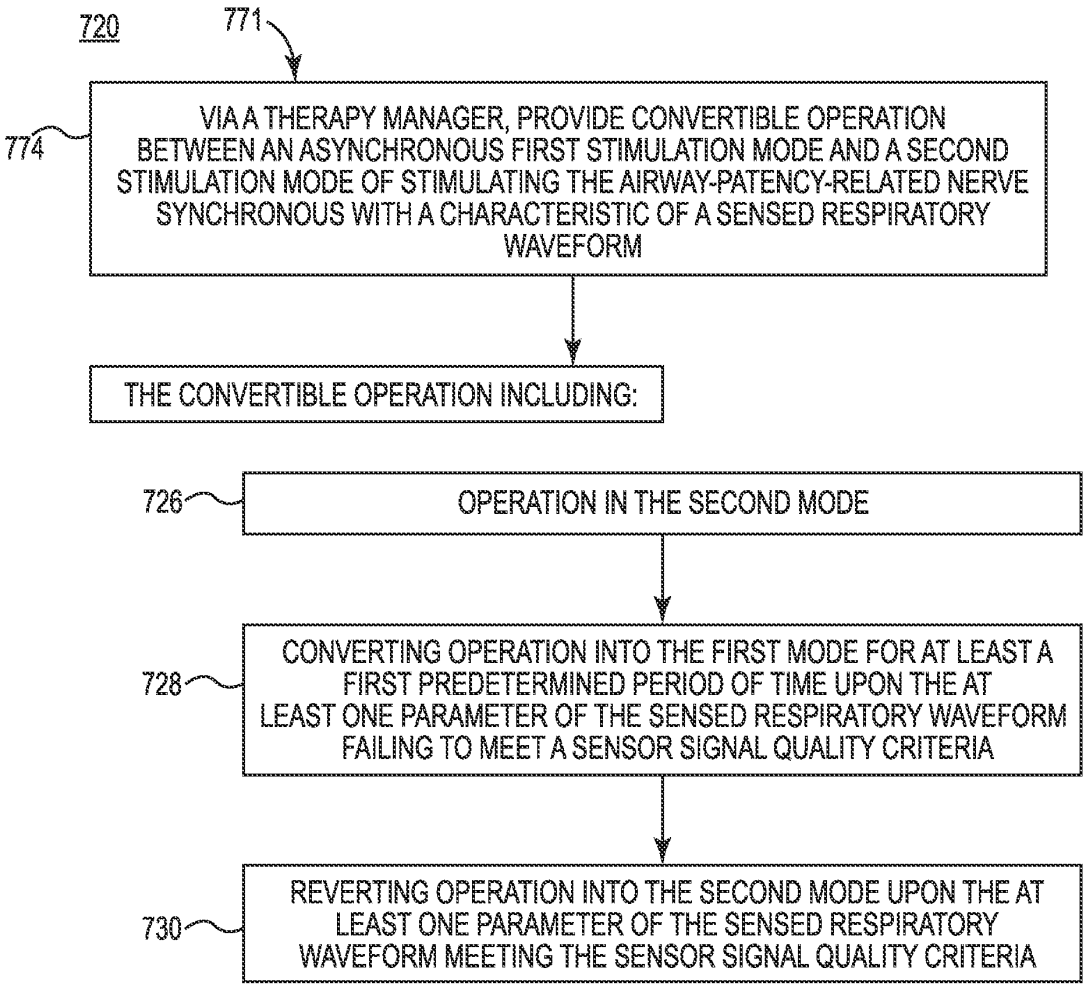


Fig. 17C

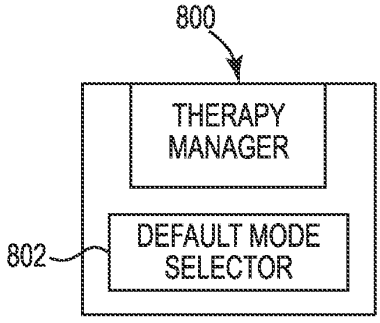


Fig. 18

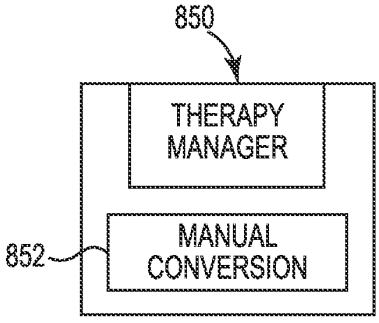


Fig. 19

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
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:	I618.118.105

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	320	320
UTILITY SEARCH FEE	1111	1	700	700
UTILITY EXAMINATION FEE	1311	1	800	800
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	2	100	200
Miscellaneous-Filing:				
LATE FILING FEE FOR OATH OR DECLARATION	1051	1	160	160

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**2180**

Electronic Acknowledgement Receipt

EFS ID:	42998377
Application Number:	17348852
International Application Number:	
Confirmation Number:	5390
Title of Invention:	STIMULATION FOR TREATING SLEEP DISORDERED BREATHING
First Named Inventor/Applicant Name:	Darrell Wagner
Customer Number:	25281
Filer:	PAUL STEVEN GRUNZWEIG/Justina Perez
Filer Authorized By:	PAUL STEVEN GRUNZWEIG
Attorney Docket Number:	I618.118.105
Receipt Date:	16-JUN-2021
Filing Date:	
Time Stamp:	09:37:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$2180
RAM confirmation Number	E20216F037521606
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	2021-06-16ADS.pdf	1823547 fbfb948233ec0e249bbbafe5db6a8ffd817f49a9	no	9
Warnings:					
Information:					
2		2021-06-16CONAppln.pdf	282311 c6e25c6cc3cf0c2b51494d393de1346aaf06a7d5	yes	69

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	65
Claims	66	68
Abstract	69	69

Warnings:					
Information:					
3	Drawings-only black and white line drawings	2021-06-16FIGS.pdf	1167502 30e4e36d96d10f83208258bd1ea2bf8a0116c6c5	no	13
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	38149 7fcaab1521d172aa8a8c5c8ea6feb34741cfcc85	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	3311509		

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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

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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.