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APPLICATION NO.	FILING DATE	FILING DATE FIRST NAMED INVENTOR		CONFIRMATION NO.
18/647,929	04/26/2024 David Townley		NEURE-008/07US 35242/159	9882
21710 BROWN RUD	7590 09/24/202 NICK LLP	EXAMINER		
ONE FINANCI BOSTON, MA	IAL CENTER	BOCK, ABIGAIL MARIE		
2001011,1111	V <b>-</b> 111		ART UNIT	PAPER NUMBER
			3794	
			NOTIFICATION DATE	DELIVERY MODE
			09/24/2024	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):

ip@brownrudnick.com usactions@brownrudnick.com

APPLICATION NO.	ISSUE DATE	PATENT NO.	
18/647,929	24-Sep-2024	12096974	

BROWN RUDNICK LLP ONE FINANCIAL CENTER BOSTON, MA 02111

# **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



#### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NUMBER 18/647,929

FILING OR 371(C) DATE 04/26/2024

FIRST NAMED APPLICANT
David Townley

ATTY. DOCKET NO./TITLE
NEURE-008/07US 35242/159

**CONFIRMATION NO. 9882** 

21710 BROWN RUDNICK LLP ONE FINANCIAL CENTER BOSTON, MA 02111 PUBLICATION NOTICE

Date Mailed: 09/05/2024

Title:SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE

Publication No.US-2024-0293175-A1 Publication Date:09/05/2024

#### 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 viewed using the USPTO's publicly available Searchable Databases via the Patent Public Search tool at www.uspto.gov. The direct link to access the Patent Public Search tool is currently https://ppubs.uspto.gov/pubwebapp/static/pages/ppubsbasic.html.

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 Patent Center, the USPTO's electronic patent application filing and management system. The direct link to access this status information is currently https://patentcenter.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of Patent Center.

Further assistance in electronically accessing the publication, or about Patent Center, 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

page 1 of 1

## 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 ww.uspto.go

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/647,929	09/24/2024	12096974	NEURE-008/07US 35242/159	9882

21710

09/04/2024

BROWN RUDNICK LLP ONE FINANCIAL CENTER BOSTON, MA 02111

7590

#### **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 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent 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.

IR103 (Rev. 10/09)

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

David Townley, County Clare, IRELAND;

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

Neurent Medical Limited, Oranmore, IRELAND;

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 <u>SelectUSA.gov</u>.





# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION # 18/647,929 RECEIPT DATE / TIME

08/28/2024 03:21:13 PM Z ET

ATTORNEY DOCKET #

NEURE-008/07US 35242/159

#### Title of Invention

SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE

# **Application Information**

APPLICATION TYPE Utility - Nonprovisional Application PATENT #

under 35 USC 111(a)

**CONFIRMATION #** 9882 FILED BY Matthew York

66962868

FILING DATE 04/26/2024

CUSTOMER # 21710

FIRST NAMED

David Townley

**INVENTOR** 

CORRESPONDENCE **ADDRESS** 

PATENT CENTER #

**AUTHORIZED BY** 

#### **Documents**

# **TOTAL DOCUMENTS: 1**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
NEURE-008- 07US_Misc_Paper.pdf	1	Miscellaneous Incoming Letter	93 KB

# **Digest**

DOCUMENT

#### **MESSAGE DIGEST(SHA-512)**

NEURE-008-

07US Misc Paper.pdf

68F62B3FCDE0EC4AD48F5AB00EFAD110D469332E11111E42 F60F84668078E30A2C95B5163EB09D635FB5DAE724009067A

A4B04765418399EA78F6320FEB5C512

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.

Attorney Docket No.: NEURE-008/07US 35242/159

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Neurent Medical ART UNIT: 3794

Limited

SERIAL NUMBER: 18/647,929 CONF. NO.: 9882

FILING DATE: April 26, 2024 EXAMINER: Bock, Abigail Marie

TITLE: SYSTEMS AND METHODS FOR THERAPEUTIC NASAL

TREATMENT USING HANDHELD DEVICE

FILED ELECTRONICALLY

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

#### **MISCELLANEOUS PAPER**

Applicant notes that, *In Aerin Medical Inc. et al v. Neurent Medical Inc. et al*, DDE-1-23-cv-00756, Neurent Medical Inc. asserts that claims of related Patent No. 11,998,262 are infringed by the use of Aerin's RhinAer® System, including at least the Stylus Model FG1393 and Console Model FG226 ("RhinAer System") for improving a patient's sleep by treating at least one of rhinitis, congestion, and rhinorrhea within a sino-nasal cavity of a patient. On August 5, Aerin Medical Inc. moved to Dismiss the patent from the case. (DDE-1-23-cv-00756, DI 089-091.).

If there are any questions regarding this paper, the Examiner is invited and encouraged to contact Applicant's undersigned representative.

Dated: August 28, 2024 Respectfully submitted,
BROWN RUDNICK LLP

BROWN RUDNICK LLP
One Financial Center
Boston, MA 02111
Tel: (617) 856-8200

/Matthew P. York/
Matthew P. York, Reg. No. 66,470
Attorney for Applicant

Fax: (617) 856-8201 Email: myork@brownrudnick.com

65426932 v1

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

( Not for submission under 37 CFR 1.99)

		•		
Application Number		18647929		
Filing Date		2024-04-26		
First Named Inventor David		Townley		
Art Unit		N/A		
Examiner Name Not Y		et Assigned		
Attorney Docket Number		NEURE-008/07US 35242/159		

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		50	20120078377	A1	2012-03-29	Gonzales et al.	
•		51	20120191003		2012-07-26	Robert Garabedian	
•		52	20120259326	A1	2012-10-11	Brannan et al.	
•		53	20120323214	A1	2012-12-20	Shantha	
-		54	20120323227	A1	2012-12-20	Wolf et al.	
-		55	20120323232	A1	2012-12-20	Wolf et al.	
-		56	20130018367	A1	2013-01-17	Wu et al.	
-		57	20130123778	A1	2013-05-16	RICHARDSON et al.	
-		58	20130158475	A1	2013-06-20	Xia et al.	
-		59	20130165916	A1	2013-06-27	MATHUR et al.	
C	nange(s) a		20130172877		2013-07-04	Subramaníam et al.  Beston Scientific Scimed, Inc.	
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#### PART B-FEE(S) TRANSMITTAL

Complete and send By mail, send to:	Mail Sto Commis P.O. Box	p ISSUE FEE sioner for Pate	ents	fee(s), by mail	or fax, o	r via the U	SPTO patent	t electronic fili By fax, sen		(571) 273-2885
All further correspond correspondence addre issue fee payment, ar	is form should be dence will be mai ess; and/or (b) in ny desired contin	used for trans led to the curre dicating a sep uing applicati	mitting the ISS ent corresponde arate "FEE AI on should pre	ence address as ir DDRESS" for ma ferably be filed p	ndicated un sintenance prior to pa	less correcte fee notificat	ed below or dir ions. <b>Because</b>	ected otherwise i	in Block 1, l t issuance n	leted where appropriate, by (a) specifying a new nay occur shortly after ndency.
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)  Brown Rudnick LLP One Financial Center Boston, Massachusetts 02111				ss)	Fee(s) Trapapers. Enhance its over I hereby States Posaddressed USPTO v	ansmittal. This ach additional p wn certificate of Cer certify that this stal Service wit to the Mail Stop ia the USPTO on the date below	certificate cannot paper, such as an mailing or transm- tificate of Mailing Fee(s) Transmitte h sufficient postage p ISSUE FEE addi- patent electronic f	be used for a assignment of ission. g or Transmi al is being de ge for first cl ress above, or	domestic mailings of the any other accompanying or formal drawing, must ission exposited with the United lass mail in an envelope r being transmitted to the or by facsimile to (571)  (Typed or printed name)	
								elle Aiello/		(Signature)
								st 6, 2024		(Date)
APPLICATION NO	FILIN	G DATE	FIRST	NAMED INVENT	OR	A7	TTORNEY DOO	KET NO	CC	ONFIRMATION NO
18/647,929	04/26	6/2024	Da	vid Townley		NEURI	E-008/07US	S 35242/159		9882
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nonprovisional	SMALL	\$480.0	00	\$0.00		\$0.	.00	\$480.0	00	11/06/2024
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DUCK, A	Jigan Mane		37:	7 <del>1</del>		- 00	0-041000		J	
1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363)  Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.  "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-09 or more recent) attached. Use of a Customer Number is required.  2. For printing on the patent (1) The names of up to 3 registered atternatively (2) The name of a single firegistered attorney or a registered attorney or a registered patent attorney is the patent of the pat					of up to 3 real alternatively  f a single fin  tomey or agulatent attorne	gistered paten , m (having as a ent) and the n ys or agents. I	t attorneys or a member a names of up to 2	<ol> <li>Brown Ru</li> <li>Adam M.</li> <li>3.</li> </ol>		P
3. ASSIGNEE NA	ME AND RESII	DENCE DATA	TO BE PRIN	TED ON THE PA	ATENT (pr	int or type)				
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Please check the approp					u):	Individual	X Corporation	on or other private	e group entity	Government
4a. Fees Submitted: 4b. Method of Payment		oly any previous		vn above):			٦			
	nent via the USPT		0 ,	_	osed check		_	payment by credi		i form PTO-2038)
	hereby authorized			y deficiency, or cr	edit any ove	erpayment to	Deposit Accoun	t No50-03	369	
	tifying micro en	tity status. Se	e 37 CFR 1.29	payment in t	the micro en	ntity amount	will not be acce	pted at the risk of	application a	A and 15B), issue fee bandonment. s box will be taken as
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NOTE: This form must	be signed in acco	rdance with 37	7 CFR 1.31 and			gnature requ	irements and co	ertifications.		
				I. Schoen/		<u> </u>	Date		5 2024	
Authorized Signa								C		50.57/
Typed or printed	name		Adam M	I. Schoen			Reg	istration No.		58,576
PTOL-85 Part B (11-2	3) Approved for	use through (	03/31/2026	OMB 0651-0	033 U	.S. Patent a	nd Trademark	Office; U.S. DE	EPARTMEN	T OF COMMERCE

PTOL-85 Part B (11-23) Approved for use through 03/31/2026





# **ELECTRONIC PAYMENT RECEIPT**

**APPLICATION #** 18/647,929 RECEIPT DATE / TIME

08/06/2024 02:45:17 PM Z ET

ATTORNEY DOCKET #

NEURE-008/07US 35242/159

#### Title of Invention

SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE

# **Application Information**

APPLICATION TYPE Utility - Nonprovisional Application PATENT #

under 35 USC 111(a)

**CONFIRMATION #** 9882 FILED BY

Michelle Aiello

PATENT CENTER # 66671716 **AUTHORIZED BY** 

Adam Schoen

CUSTOMER # 21710

FILING DATE

04/26/2024

CORRESPONDENCE **ADDRESS**  FIRST NAMED

**David Townley INVENTOR** 

# **Payment Information**

**PAYMENT METHOD** DA / 500369

**PAYMENT TRANSACTION ID** E202486E46337233

**PAYMENT AUTHORIZED BY** Michelle Aiello

FEE CODE **DESCRIPTION**  ITEM PRICE(\$)

**QUANTITY** 

**ITEM TOTAL(\$)** 

2501

UTILITY ISSUE FEE

480.00

1

480.00

**TOTAL** AMOUNT:

\$480.00

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#### 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.

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**APPLICATION #** 18/647,929 RECEIPT DATE / TIME

08/06/2024 02:45:17 PM Z ET

ATTORNEY DOCKET #

NEURE-008/07US 35242/159

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**CONFIRMATION #** 9882 FILED BY

Michelle Aiello

PATENT CENTER # 66671716 FILING DATE 04/26/2024

CUSTOMER # 21710

FIRST NAMED **INVENTOR** 

**David Townley** 

CORRESPONDENCE **ADDRESS** 

**AUTHORIZED BY** 

Adam Schoen

#### **Documents**

# **TOTAL DOCUMENTS: 1**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)	
35242_159US - NEURE-008- 07US-Issue-Fee- Transmittal.pdf	1	Issue Fee Payment (PTO-85B)	138 KB	

## **Digest**

#### DOCUMENT

## MESSAGE DIGEST(SHA-512)

35242 159US - NEURE-008-07US-Issue-Fee-Transmittal.pdf BF5461A0B063C0A1E2B16FE92318DDE641098A32CEF704449 D47AB6AE7936DDA1EAA18C92D33B89CE3D9B08A6AEFA0CE 47574D199ACD6E1EE0EF0F1889E30DE7

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#### 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

## NOTICE OF ALLOWANCE AND FEE(S) DUE

7590
RUDNICK LLP
NCIAL CENTER
MA 02111

08/06/2024

EXAMINER

BOCK, ABIGAIL MARIE

ART UNIT PAPER NUMBER

3794

DATE MAILED: 08/06/2024

35242/159

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/647 929	04/26/2024	David Townley	NEURE-008/07US	9882

TITLE OF INVENTION: SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	11/06/2024

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.

#### PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450					By fax, see	nd to: (571)-273-2885	
	Alexandria, Virgin	nia 22313-1450					
All further corresponder correspondence address	nce will be mailed to the ; and/or (b) indicating a se	current correspondence a eparate "FEE ADDRESS"	address as indicated unle ' for maintenance fee not filed prior to payment	ess corrected below of this issue fee in o	or directed otherwise in B electronic patent issuance rder not to jeopardize co		
	ONDENCE ADDRESS (Note		e of address) Fe	ee(s) Transmittal. The opers. Each additionate ove its own certificate	nis certificate cannot be us al paper, such as an assign e of mailing or transmission		
BROWN RUE ONE FINANCI BOSTON, MA	AL CENTER	/2024	Si ac U	hereby certify that that that es Postal Service of Idressed to the Mail S	with sufficient postage for Stop ISSUE FEE address al O patent electronic filing	ransmission  being deposited with the United  r first class mail in an envelope  bove, or being transmitted to the  system or by facsimile to (571)	
						(Typed or printed name)	
			F			(Signature) (Date)	
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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTO	OR	ATTORNEY DOCKET NO	O. CONFIRMATION NO.	
18/647,929	04/26/2024	ı	David Townley		NEURE-008/07US	9882	
TITLE OF INVENTION	J: SYSTEMS AND MET	HODS FOR THERAPEU	JTIC NASAL TREATM	ENT USING HAND	OHELD DĚや代刊 59		
APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DU	E PREV. PAID ISSU	JE FEE TOTAL FEE(S) I	DUE DATE DUE	
nonprovisional	SMALL	\$480	\$0.00	\$0.00	\$480	11/06/2024	
EXAM	MINER	ART UNIT	CLASS-SUBCLASS				
BOCK, ABIO	GAIL MARIE	3794	606-041000				
CFR 1.363).  Change of correst Address form PTO/A  "Fee Address" inc	condence address or indication condence address (or Cha JA/122 or PTO/SB/122) : dication (or "Fee Address' 7; Rev 03-02 or more rec	nge of Correspondence attached.	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.				
	AND RESIDENCE DATA	A TO BE PRINTED ON	THE PATENT (print or	type)			
PLEASE NOTE: Unl recorded, or filed for (A) NAME OF ASSI	recordation, as set forth i	ed below, no assignee dat n 37 CFR 3.11 and 37 CF	a will appear on the pate FR 3.81(a). Completion (B) RESIDENCE: (CI.	of this form is NOT	a substitute for filing an as	ment must have been previously ssignment.	
Please check the appropr	riate assignee category or	categories (will not be pr	rinted on the patent) :	Individual 🖵 Corp	oration or other private gro	oup entity 🖵 Government	
4a. Fees submitted:	☐Issue Fee ☐Pub	lication Fee (if required)			· · · · · · · · · · · · · · · · · · ·		
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_	nt via the USPTO patent	= -	■ Enclosed check		nic payment by credit card		
☐ The Director is he	ereby authorized to charge	e the required fee(s), any	deficiency, or credit any	overpayment to Dep	osit Account No		
5. Change in Entity Status (from status indicated above) Applicant certifying micro entity status. See 37 CFR 1.29 Applicant asserting small entity status. See 37 CFR 1.27 Applicant changing to regular undiscounted fee status.  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.  NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.							
NOTE: This form must	be signed in accordance w	vith 37 CFR 1.31 and 1.3	3. See 37 CFR 1.4 for sig	gnature requirements	and certifications.		
Authorized Signature	Authorized Signature Date						
Typed or printed nam	ne			Registration I	No		
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## UNITED STATES PATENT AND TRADEMARK OFFICE



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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/647,929	18/647,929 04/26/2024 David Townley	David Townley	NEURE-008/07US	9882
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BOSTON, MA 02	111		ART UNIT	PAPER NUMBER
			3794	
			DATE MAILED: 08/06/202	4

#### 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.

#### **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. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).

https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

- 1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
- 2) a federal, state, local, or international agency, in response to its request;
- 3) a contractor of the USPTO having need for the information in order to perform a contract;
- 4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
- 5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
- a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
- 7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
- 8) 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));
- 9) the Office of Personnel Management (OPM) for personnel research purposes; and

10)the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

	Application No. 18/647,929	Applicant(s) Townley, Dav	
Notice of Allowability	Examiner Abigail M Bock	Art Unit 3794	AIA (FITF) Status Yes
The MAILING DATE of this communication apperall claims being allowable, PROSECUTION ON THE MERITS IS (herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIC of the Office or upon petition by the applicant. See 37 CFR 1.313 at 1.	pars on the cover sheet with the co OR REMAINS) CLOSED in this apport other appropriate communication GHTS. This application is subject to and MPEP 1308.	orrespondence lication. If not i will be mailed i	e address included in due course. THIS
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 rest restriction requirement and election have been incorporated		he interview or	1; the
3. The allowed claim(s) is/are 1-20. As a result of the allowed Highway program at a participating intellectual property offic http://www.uspto.gov/patents/init_events/pph/index.jsp	ce for the corresponding application.	. For more info	
4. Acknowledgment is made of a claim for foreign priority unde	er 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 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority do International Bureau (PCT Rule 17.2(a)).  * Certified copies not received:  Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  5. CORRECTED DRAWINGS (as "replacement sheets") must including changes required by the attached Examiner's Paper No./Mail Date	e been received in Application Nocuments have been received in this  of this communication to file a reply ENT of this application.  be submitted.	national stage	
Identifying indicia such as the application number (see 37 CFR 1 sheet. Replacement sheet(s) should be labeled as such in the heat		ngs in the front	(not the back) of each
6. DEPOSIT OF and/or INFORMATION about the deposit of B attached Examiner's comment regarding REQUIREMENT F			:he
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 Amend 6. ☑ Examiner's Statem 7. ☐ Other		
/ABIGAIL BOCK/ Examiner, Art Unit 3794	/LINDA C DVORAK/ Supervisory Patent Ex	aminer, Art l	 Unit 3794

U.S. Patent and Trademark Office PTOL-37 (Rev. 08-13)

Notice of Allowability

Part of Paper No./Mail Date 20240724

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Art Unit: 3794

**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.

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.

Terminal Disclaimer

The terminal disclaimer filed on 07/15/2024 disclaiming the terminal portion of any patent

granted on this application which would extend beyond the expiration date of U.S. Patent No.

11,998,262 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance:

Upon further consideration of the prior art, the claimed invention is neither taught nor

suggested in part nor in whole. Specifically, the prior art does not teach "A method for treating at least

one of rhinitis, congestion, and rhinorrhea within a sino-nasal cavity of a patient, the method

comprising: advancing a multi-electrode end effector into the sino-nasal cavity of the patient, wherein

the multi-electrode end effector is operably associated with a shaft of a treatment device and

configured for delivering energy to one or more target sites within the sino-nasal cavity of the patient,

wherein the multi-electrode end effector comprises a first electrode that is spaced apart from a second

electrode along a length of the multi-electrode end effector, wherein each of the first and second

electrodes comprise an active state and an inactive state and comprise a respective location on the

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multi-electrode end effector, wherein at least one portion of the multi-electrode end effector comprises a diameter that is larger than a diameter of the shaft, and wherein: the first electrode is exposed from a surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the first electrode extending in a first outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a first location within the nasal cavity; and the second electrode is exposed from the surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the second electrode extending in a second outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a second location within the nasal cavity; and delivering energy, via the first and second electrodes, to one or more target sites within a sino-nasal cavity of the patient to disrupt multiple neural signals to mucus producing and/or mucosal engorgement elements, thereby reducing production of mucus and/or mucosal engorgement within a nose of the patient and reducing or eliminating one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea to improve nasal breathability of the patient." The most pertinent piece of prior art, Townley (U.S. Patent No. 11,998,262), no longer constitutes as prior art in view of the terminal disclosure filed 07/15/2024. Therefore, it is the Examiner's position that the claimed invention is in condition for allowance.

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

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M Bock whose telephone number is (571)272-8856. The examiner can normally be reached M-F 7:30am - 5:00pm.

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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, Linda Dvorak can be reached on 5712724764. 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/docxfor 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.

/ABIGAIL BOCK/ Examiner, Art Unit 3794 /LINDA C DVORAK/ Supervisory Patent Examiner, Art Unit 3794

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	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	18/647,929	Townley, David
	Examiner	Art Unit
	Abigail M Bock	3794

CPC							
Symbol			Туре	Version			
A61B	/ 18	/ 148	F	2013-01-01			
A61B	/ 2018	/ 00434	A	2013-01-01			
A61B	/ 2018	/ 00583	A	2013-01-01			
A61B	1 2018	/ 1467	A	2013-01-01			
A61B	/ 2018	/ 00327	A	2013-01-01			

CPC Combination Sets				
Symbol	Туре	Set	Ranking	Version

/ABIGAIL BOCK/ Examiner, Art Unit 3794	24 July 2024	Total Claim	s Allowed:
(Assistant Examiner)	(Date)	20	)
/LINDA C DVORAK/ Supervisory Patent Examiner, Art Unit 3794	25 July 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	4

U.S. Patent and Trademark Office

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	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	18/647,929	Townley, David
	Examiner	Art Unit
	Abigail M Bock	3794

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NON-CLAIMED			
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US ORIGINAL CLASSIFICATION				
CLASS SUBCLASS				

CROSS REFERENCE	ES(S)				
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				

/ABIGAIL BOCK/ Examiner, Art Unit 3794	24 July 2024	Total Claim	s Allowed:
(Assistant Examiner)	(Date)	20	)
/LINDA C DVORAK/ Supervisory Patent Examiner, Art Unit 3794	25 July 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	4

U.S. Patent and Trademark Office

Part of Paper No.: 20240724

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	18/647,929	Townley, David
	Examiner	Art Unit
	Abigail M Bock	3794

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/ABIGAIL BOCK/ Examiner, Art Unit 3794	24 July 2024	Total Claim	s Allowed:
(Assistant Examiner)	(Date)	20	)
/LINDA C DVORAK/ Supervisory Patent Examiner, Art Unit 3794	25 July 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	4

U.S. Patent and Trademark Office

Part of Paper No.: 20240724

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	18/647,929	Townley, David
	Examiner	Art Unit
	Abigail M Bock	3794

CPC - Searched*				
Symbol	Date	Examiner		
A61B18/148 A61B2018/00327 A612018/00434 A61B2018/00583 A61B2018/1467	07/03/2024	АВ		
A61B18/148 A61B2018/00327 A612018/00434 A61B2018/00583 A61B2018/1467	07/24/2024	AB		

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*					
Class	Subclass	Date	Examiner		

<sup>\*</sup> 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 assignee name search performed in PALM/DAV	07/03/2024	АВ		
Limited text and CPC search performed in PE2E Search - see attached search history	07/03/2024	АВ		
Limited text and CPC search performed in PE2E Search - see attached search history	07/24/2024	АВ		

/ABIGAIL BOCK/ Examiner, Art Unit 3794	

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	Application/Control No.	Applicant(s)/Patent Under Reexamination
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	Examiner	Art Unit
	Abigail M Bock	3794

Interference Search				
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner	
А	A61B18/148 A61B2018/00327 A612018/00434 A61B2018/00583 A61B2018/1467	07/24/2024	АВ	

/ABIGAIL BOCK/ Examiner, Art Unit 3794	

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Index of Claims	18/647,929	Townley, David
	Examiner	Art Unit
	Abigail M Bock	3794

✓	Rejected	-	Cancelled
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N	Non-Elected
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U.S. Patent and Trademark Office Part of Paper No.: 20240724

# PE2E SEARCH - Search History (Prior Art)

	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1 66	((("TOWNLEY") near3 ("David"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/06/17 09:32 AM
L2 41	((("NEURENT") near3 ("MEDICAL") near3 ("LIMITED"))).AS,AAN M.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/17 09:32 AM
L3 154	(US-20020068930-\$   US-20020072742-\$   US-20020177765-\$   US-20030016085-\$   US-20030212394-\$   US-20050080409-\$   US-20050171536-\$   US-20050171574-\$   US-20050171582-\$   US-20050171583-\$   US-20050171583-\$   US-20050187546-\$   US-20050288730-\$   US-20050288730-\$   US-20050288730-\$   US-20060036237-\$   US-20060036237-\$   US-20060016620-\$   US-20060166375-\$   US-20060116599-\$   US-20060149226-\$   US-20060149226-\$   US-20060036237-\$   US-20060149226-\$   US-20060149226-\$   US-20070031341-\$   US-20070032786-\$   US-20070032786-\$   US-20070033194-\$   US-20070033194-\$   US-20070033194-\$   US-20070033194-\$   US-20070033194-\$   US-20070233191-\$   US-20070233191-\$   US-20070233191-\$   US-20070287994-\$   US-20070287994-\$   US-20070287994-\$   US-20070287994-\$   US-20070287994-\$   US-20070287994-\$   US-20070287994-\$   US-20070299433-\$   US-20070287994-\$   US-20070299433-\$   US-20090306644-\$   US-20090306644-\$   US-20090306644-\$   US-20100049187-\$   US-20100049187-\$   US-20100049187-\$   US-20100049187-\$   US-201000305715-\$	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/17 09:32 AM

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	8460181-B2 OR US-			
	8463359-B2 OR US-			
	8512324-B2 OR US-			
	8747401-B2 OR US-			
	8920414-B2 OR US-			
	8936594-B2 OR US-			
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	9101384-B2 OR US- 8996137-B2 OR US-			
	9179973-B2 OR US-			
	9233245-B2 OR US-			

L14	60	((WO-2010077980-A1 OR WO-2009154456- A1 OR WO- 2007008954-A2 OR WO-9410921-A1).did. AND EPAB.dbnm.) L8 AND (L1 OR L2)	(US-PGPUB; l	JSPAT)	OR	ON	ON	2024/07/02 02:23 PM
		A1).did. AND FTDB.dbnm.) OR ((JP- 2012143573-A OR JP- 2001120565-A).did. AND JPAB.dbnm.) OR						
		A2 OR JP-2001526077- A OR JP-2001120565- A OR WO-0117450-A1 OR WO-9410921-						
		WO-2009154456-A1 OR JP-2009538641-A OR JP-2007537784-A5 OR JP-2007537784-A OR WO-2007008954-						
		OR WO-2015013252- A1 OR JP-2009538641- A5 OR WO- 2010077980-A1 OR						
		2016134264-A1 OR EP-2929852-A1 OR WO-2015048806-A2 OR JP-2015507964-A						
		2021205231-A1 OR WO-2018087601-A1 OR WO-2016183337- A2 OR WO-						
		DWPI.dbnm.) OR ((WO-2021260435-A1 OR WO-2021205230- A1 OR WO-						
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PE2E SEARCH - Search History (Interference)

Ref#	Hits	Search Query	DBs	Default Operator		British Equivalents	Time Stamp
N2	60	L14	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/15 10:00 AM

# **Bibliographic Data**

Application No: 18/647,92	,9		
Foreign Priority claimed:	<b>O</b> Yes	<b>⊙</b> No	
35 USC 119 (a-d) conditions met:	Yes	<b>☑</b> No	☐ Met After Allowance
Verified and Acknowledged:	/ABIGAIL B	OCK/	
	Examiner's Signature	gnature	Initials
Title:		ND METHODS FOR T USING HANDHEL	THERAPEUTIC NASAL D DEVICE

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
04/26/2024	606	3794	NEURE-008/07US 35242/159
RULE			

### **APPLICANTS**

Neurent Medical Limited, Oranmore, IRELAND

#### **INVENTORS**

David Townley,

#### **CONTINUING DATA**

This application is a CON of 18411476 01/12/2024 PAT 11998262 18411476 is a CON of 17225560 04/08/2021 PAT 11883091

17225560 has PRO of 63007584 04/09/2020

#### FOREIGN APPLICATIONS

#### IF REQUIRED, FOREIGN LICENSE GRANTED\*\*

05/24/2024

\*\* SMALL ENTITY \*\*

STATE OR COUNTRY

#### **ADDRESS**

BROWN RUDNICK LLP ONE FINANCIAL CENTER BOSTON, MA 02111 UNITED STATES

#### FILING FEE RECEIVED

\$2,400



#### 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, Vriginia 22313-1450 www.uspio.gov

APPLICATION NUMBER 18/647,929

FILING OR 371(C) DATE 04/26/2024

FIRST NAMED APPLICANT David Townley

ATTY. DOCKET NO./TITLE NEURE-008/07US 35242/159

**CONFIRMATION NO. 9882** 

21710 **BROWN RUDNICK LLP** ONE FINANCIAL CENTER BOSTON, MA 02111



Date Mailed: 07/16/2024

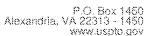
#### NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/26/2024.

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.

/lqchau/	





## ELECTRONIC ACKNOWLEDGEMENT RECEIPT

**APPLICATION #** 18/647,929 RECEIPT DATE / TIME

07/15/2024 01:33:09 PM Z ET

ATTORNEY DOCKET # NEURE-008/07US 35242/159

#### Title of Invention

SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE

## **Application Information**

APPLICATION TYPE Utility - Nonprovisional Application under 35 USC 111(a)

PATENT# -

CONFIRMATION #

9882

FILED BY Matthew York

PATENT CENTER # 66363983

FILING DATE 04/26/2024

CUSTOMER# 21710

**INVENTOR** 

FIRST NAMED David Townley

CORRESPONDENCE ADDRESS

AUTHORIZED BY -

#### **Documents**

# **TOTAL DOCUMENTS: 1**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
NEURE-008- 07US_Response_to_OA.pdf	6	Amendment/Request for Reconsideration-After Non- Final Rejection	105 KB

# **Digest**

DOCUMENT	MESSAGE DIGEST(SHA-512)
NEURE-008- 07US Response to OA.pdf	1EAC76704C0B47E8D1C74AF77C4ABF696477BD4F5D59E8E3 A1B2F5644F524B5579613A65374B1D701046CD4F44A9F94791
or od_nesponse_to_ompan	4F71C3AD2D9B2367B28171F9D578CB

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

APPLICANT: Neurent Medical Limited ART UNIT: 3794

SERIAL NUMBER: 18/647,929 CONFIRMATION NO.: 9882

FILING DATE: April 26, 2024 EXAMINER: Abigail Marie Bock

TITLE: SYSTEMS AND METHODS FOR THERAPEUTIC NASAL

TREATMENT USING HANDHELD DEVICE

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

#### **RESPONSE TO OFFICE ACTION**

This paper is in response to the non-final Office Action mailed July 10, 2024 from the United States Patent and Trademark Office.

Applicant believes that no fees are due with this response, but authorizes the Office to charge any required fees due to Deposit Account 500369 to make this response timely and have it considered.

Listing of the Claims begin on page 2.

Remarks begin on page 6.

Attorney Docket No.: NEURE-008/07US 35242/159 Application No. 18/647,929

#### **Listing of the Claims:**

No amendments to the claims are made herein.

1. (Original) A method for treating at least one of rhinitis, congestion, and rhinorrhea within a sino-nasal cavity of a patient, the method comprising:

advancing a multi-electrode end effector into the sino-nasal cavity of the patient, wherein the multi-electrode end effector is operably associated with a shaft of a treatment device and configured for delivering energy to one or more target sites within the sino-nasal cavity of the patient, wherein the multi-electrode end effector comprises a first electrode that is spaced apart from a second electrode along a length of the multi-electrode end effector, wherein each of the first and second electrodes comprise an active state and an inactive state and comprise a respective location on the multi-electrode end effector, wherein at least one portion of the multi-electrode end effector comprises a diameter that is larger than a diameter of the shaft, and wherein:

the first electrode is exposed from a surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the first electrode extending in a first outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a first location within the nasal cavity; and

the second electrode is exposed from the surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the second electrode extending in a second outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a second location within the nasal cavity; and

delivering energy, via the first and second electrodes, to one or more target sites within a sino-nasal cavity of the patient to disrupt multiple neural signals to mucus producing and/or mucosal engorgement elements, thereby reducing production of mucus and/or mucosal engorgement within a nose of the patient and reducing or eliminating one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea to improve nasal breathability of the patient.

Application No. 18/647,929

2. (Original) The method of claim 1, wherein radiofrequency (RF) energy is delivered from the

first and second electrodes to tissue at the one or more target sites and is controlled via a console

unit operably associated with the treatment device and multi-electrode end effector.

3. (Original) The method of claim 2, wherein the console unit is configured to receive feedback

from at least one temperature sensor arranged relative to the first and second electrodes and

configured to sense temperature at an interface between tissue and the first and second

electrodes, wherein the console unit is configured to control energy output from the first and

second electrodes based, at least in part, on the feedback in order to maintain a predetermined

temperature of tissue at the one or more target sites.

4. (Original) The method of claim 3, wherein the console unit is configured to receive one or

more temperature readings from the at least one temperature sensor and process the readings to

determine a level of RF energy to be delivered by the first and second electrodes that is sufficient

to maintain a temperature of tissue at the one or more target sites below a predetermined

threshold.

5. (Original) The method of claim 4, wherein the console unit comprises a hardware processor

coupled to non-transitory, computer-readable memory containing instructions executable by the

processor to cause the console unit to automatically control and adjust RF energy output from the

first and second electrodes based, at least in part, on a predetermined elapsed time period and a

predetermined threshold maximum temperature during delivery of RF energy to ensure that

application of said RF energy results in the desired effect of reduced engorgement of the tissue at

the target site for a given treatment application.

6. (Original) The method of claim 5, the predetermined elapsed time period is from about 1

second to about 20 seconds.

7. (Original) The method of claim 6, wherein the predetermined elapsed time period is from

about 10 seconds to about 12 seconds.

Page 3 of 6

Application No. 18/647,929

8. (Original) The method of claim 5, wherein the predetermined threshold maximum temperature

is less than 90°C.

9. (Original) The method of claim 5, wherein the predetermined threshold maximum temperature

is greater than 37°C and less than 90°C.

10. (Original) The method of claim 4, wherein the console unit is configured to monitor

temperature of tissue at the one or more target sites during delivery of RF energy thereto based

on temperature readings from the at least one temperature sensor and further monitor an elapsed

time during delivery of RF energy to tissue at the one or more target sites.

11. (Original) The method of claim 4, wherein the console unit is configured to provide, via a

display, feedback information to an operator during a given treatment application, wherein said

feedback information comprises at least an elapsed time during delivery of RF energy to tissue at

the one or more target sites.

12. (Original) The method of claim 11, wherein the display is a touchscreen monitor.

13. (Original) The method of claim 2, wherein the console unit is operably coupled to an energy

generator configured to generate RF energy to be delivered by the first and second electrodes.

14. (Original) The method of claim 13, wherein the RF energy comprises at least bipolar RF

energy.

15. (Original) The method of claim 1, wherein the multi-electrode end effector comprises at least

four electrodes,

wherein the at least four electrodes are oriented at an angle less than 90 degrees relative

to the shaft for the delivery of radiofrequency (RF) energy,

wherein the shaft is a substantially rigid shaft with a hollow cavity,

wherein the shaft comprises an outer sheath and hypotube,

Page 4 of 6

Application No. 18/647,929

wherein the first electrode and second electrode is operably coupled to a console unit via

wires disposed in the hollow cavity of the substantially rigid shaft, and

wherein RF energy is delivered from the first and second electrodes to tissue at the one or

more target sites and is controlled via the console unit operably associated with the treatment

device and multi-electrode end effector.

16. (Original) The method of claim 15, wherein the multi-electrode end effector comprises at

least six electrodes, and

wherein the at least six electrodes are oriented at an angle less than 90 degrees relative to

the shaft for the delivery of RF energy.

17. (Original) The method of claim 15, wherein the multi-electrode end effector comprises at

least eight electrodes, and

wherein the at least eight electrodes are oriented at an angle less than 90 degrees relative

to the shaft for the delivery of RF energy.

18. (Original) The method of claim 1, wherein the multi-electrode end effector comprises at least

one temperature sensor arranged relative to first and second electrode.

19. (Original) The method of claim 18, wherein the at least one temperature sensor is configured

to sense temperature of tissue at the one or more target sites.

20. (Original) The method of claim 1, wherein the one or more target sites comprises an inferior

turbinate within the nasal cavity and the tissue comprises submucosal tissue associated with the

inferior turbinate.

Page 5 of 6

Attorney Docket No.: NEURE-008/07US 35242/159 Application No. 18/647,929

**REMARKS** 

No amendments to the claims are made herein. Accordingly, claims 1-20 remain pending.

**Double Patenting** 

The Office Action states at page 4 that claims 1-20 are rejected on the ground of

nonstatutory double patenting over claims 1-20 of U.S. Patent No. 11,998,262.

The double patenting rejection is rendered moot with the filing of a terminal disclaimer

submitted and approved on July 15, 2024 between the instant application and U.S. Patent No.

11,998,262. Accordingly, Applicant respectfully requests that the double patenting rejection be

withdrawn.

Applicant respectfully submits that the pending claims are in condition for allowance,

which is respectfully requested. If there are any questions regarding these remarks, the

Examiners are invited and encouraged to contact Applicant's representatives at the telephone

number provided.

Dated: July 15, 2024

Brown Rudnick LLP

One Financial Center

Boston, MA 02111

Tel: 617-856-8152

Fax: 617-856-8201

Respectfully submitted,

**BROWN RUDNICK LLP** 

/Matthew P. York/

Matthew P. York, Reg. No. 66,470

Attorney for Applicant

Email: myork@brownrudnick.com

65402320 v1-035242/0159

Page 6 of 6



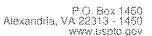
Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313 - 1450 www.uspto.gov

# **APPROVAL LETTER**

18/647,929	04/26/2024	David Townley
Title of Invention		APEUTIC NASAL TREATMENT USING HANDHELD DEVICE
Electronic terminal	disclaimer filed on 07	<sup>7</sup> /15/2024
₩ Approved		

Approved / Disapproved by: Electronic Terminal Disclaimer automatically approved

This patent is subject to a Terminal Disclaimer





## ELECTRONIC ACKNOWLEDGEMENT RECEIPT

**APPLICATION #** 18/647,929 RECEIPT DATE / TIME

07/15/2024 01:18:19 PM Z ET

ATTORNEY DOCKET # NEURE-008/07US 35242/159

#### Title of Invention

SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE

## **Application Information**

APPLICATION TYPE Utility - Nonprovisional Application under 35 USC 111(a)

PATENT# -

CONFIRMATION # 9882 FILED BY Matthew York

PATENT CENTER # 66363608

FILING DATE 04/26/2024

CUSTOMER# 21710

FIRST NAMED

David Townley

**INVENTOR** 

CORRESPONDENCE ADDRESS

AUTHORIZED BY -

#### **Documents**

# **TOTAL DOCUMENTS: 2**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
petition-request.pdf	3	Terminal Disclaimer-Filed (Electronic)	48 KB
grantLetter.pdf	1	Terminal Disclaimer-Electronic- Approved	19 KB

# **Digest**

DOCUMENT	MESSAGE DIGEST(SHA-512)
petition-request.pdf	955C4B84342F509EA14D47CD4F18E7611AD40DDC54C41231D
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	F6E53276C13EA66F1D2F3935974591
grantLetter.pdf	717D5729747686C44057919D5A87ECF3FF9C6CC630AFDF6B6 EB460C60E885A924A1EC1C4D55BB46007316116EF4613E839F D9B32494D8A0014DA21CC32515EC0

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.



P.O. 9ox 1450 Alexandria, VA 22313 - 1460 www.uspto.gov

# TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT

**APPLICATION #** 18647929

FILING DATE 04/26/2024

FIRST NAMED INVENTOR

David Townley

ATTORNEY DOCKET #
NEURE-008/07US 35242/159

#### Title of Invention

SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE



Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action



This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent interest	
Neurent Medical Limited	100%	
Total	100%	

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)

Application #	Filing Date	

as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the

instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

Patent #		
11998262		

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:

- expires for failure to pay a maintenance fee;
- · is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- \* is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.



Terminal disclaimer fee under 37 CFR 1.20(d) Included with Electronic Terminal Disclaimer request.

Applicant claims the following entity status:

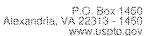
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I hereby declare that all statements made herein of my own knowledge are true and that all statemnts made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I certify, in accordance with 37 CFR 1.4(d)(4) that I am: An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Signature	Name	Registration #
/Matthew P. York/	Matthew York	86470

<sup>\*</sup> Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP 324.





#### ELECTRONIC PAYMENT RECEIPT

**APPLICATION #** 18/647,929 RECEIPT DATE / TIME

07/15/2024 01:18:19 PM Z ET

ATTORNEY DOCKET # NEURE-008/07US 35242/159

#### Title of Invention

SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE

#### **Application Information**

APPLICATION TYPE Utility - Nonprovisional Application

under 35 USC 111(a)

CONFIRMATION # 9882

FILED BY Matthew York

PATENT #

PATENT CENTER # 66363608

AUTHORIZED BY -

CUSTOMER# 21710

FILING DATE 04/26/2024

CORRESPONDENCE **ADDRESS** 

INVENTOR

FIRST NAMED David Townley

#### **Payment Information**

**PAYMENT METHOD** DA / 500369

**PAYMENT TRANSACTION ID** E20247ED19028620

**PAYMENT AUTHORIZED BY** Matthew York

FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
2814	STATUTORY DISCLAIMER, INCLUDING TERMINAL DISCLAIMER	170.00	1	170.00
			TOTAL	\$170.00

AMOUNT:

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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PTO/SB/06 (09-11)

Approved for use through 1/31/2014. OMB 0651-0032

U.S. Patent and Trademark Office; it displays a reliable 1/3 and 1/3 and

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

						Application	n or Docket Number 8/647,929	Filing Date 04/26/2024	To be Mailed	
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	(37 CFR 1.16(a), (b), o	or (c))		N/A		N/A		N/A		
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* It th	ne difference in co	olumn 1 is	less th	an zero,	enter "0" in colu	umn 2.		TOTAL		
					APPLICAT	TION AS AME	NDED - PA	ART II		
		(Colum CLAIMS	n 1)		(Column 2) HIGHEST	(Column 3	3)			
AMENDMENT	07/15/2024	REMAINI AFTER AMENDA			NUMBER PREVIOUSLY PAID FOR	PRESENT EX	(TRA	RATE (\$)	ADDIT	IONAL FEE (\$)
≅	Total (37 CFR 1.16(i))	* 20		Minus	** 20	= 0		x \$40 =		0
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	5,7						•	TOTAL ADD'L FE	≣	0
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F		CLAIM REMAIN AFTE AMENDI	IING R		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EX	(TRA	RATE (\$)	ADDIT	IONAL FEE (\$)
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-	Application S	Size Fee (	37 CFF	R 1.16(s	))	•				
₹						IT CLAIM (37 CF	-R	1		
	· · - U//							TOTAL ADD'L FE	<b> </b>	
* If t	he entry in column	1 is less tha	ın the eı	ntry in col	umn 2, write "0" in	column 3.		LIE	-	
	the "Highest Number						<b>"</b> .	/JAMES ELLIC	DTT/	
	f the "Highest Numb		_							
The	"Highest Number P	reviously P	aid For"	(Total or	Independent) is th	ne highest number	found in the a	appropriate box in colu	nn 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.

#### 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.
18/647,929	04/26/2024	David Townley	NEURE-008/07US 35242/159	9882
21710 BROWN RUD	7590 07/10/202 NICK LLP	4	EXAM	IINER
ONE FINANCI BOSTON, MA	IAL CENTER		BOCK, ABIO	GAIL MARIE
2001011,1111	V <b>=</b> 111		ART UNIT	PAPER NUMBER
			3794	
			NOTIFICATION DATE	DELIVERY MODE
			07/10/2024	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):

ip@brownrudnick.com usactions@brownrudnick.com

	Application No.Applicant(s)18/647,929Townley, David						
Office Action Summary	Examiner	Art Unit	AIA (FITF) Status				
	Abigail M Bock	3794	Yes				
The MAILING DATE of this communication app	_	orrespondenc	o addrass				
Period for Reply	ears on the cover sheet with the co	orrespondence	e address				
A SHORTENED STATUTORY PERIOD FOR REPLY DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	ely filed after SIX (6 the mailing date of D (35 U.S.C. § 133)	6) MONTHS from the mailing this communication.				
Status							
1)	.130(b) was/were filed on	ent set forth c to this action prosecution	as to the merits is				
Disposition of Claims*							
5) Claim(s) 1-20 is/are pending in the app 5a) Of the above claim(s) is/are withdred 6) Claim(s) is/are allowed. 7) Claim(s) 1-20 is/are rejected. 8) Claim(s) is/are objected to. 9) Claim(s) are subject to restriction at a lift any claims have been determined allowable, you may be eliminated allowable in the corresponding aphttp://www.uspto.gov/patents/init_events/pph/index.jsp or send	awn from consideration.  nd/or election requirement gible to benefit from the <b>Patent Pros</b> pplication. For more information, plea	se see	<b>vay</b> program at a				
Application Papers							
10) ☐ The specification is objected to by the Examir	ner.						
11) ✓ The drawing(s) filed on 04/26/2024 is/are: a)  Applicant may not request that any objection to the di  Replacement drawing sheet(s) including the correction	rawing(s) be held in abeyance. See 3	7 CFR 1.85(a).					
Priority under 35 U.S.C. § 119 12) ☐ Acknowledgment is made of a claim for foreige Certified copies:	gn priority under 35 U.S.C. § 11	9(a)-(d) or (f)	).				
a)□ All b)□ Some** c)□ None of t	he:						
<ol> <li>Certified copies of the priority document</li> </ol>	nents have been received.						
<ol><li>Certified copies of the priority document</li></ol>	nents have been received in Ap	plication No.	·				
<ol> <li>Copies of the certified copies of the application from the International But</li> </ol>		eceived in th	is National Stage				
** See the attached detailed Office action for a list of the certific	ed copies not received.						
Attachment(s)							
1) V Notice of References Cited (PTO-892)	3) Interview Summary	(PTO-413)					
Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/S Paper No(s)/Mail Date	Paper No(s)/Mail D						

U.S. Patent and Trademark Office PTOL-326 (Rev. 11-13) Application/Control Number: 18/647,929 Page 2

Art Unit: 3794

**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.

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.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 05/01/2024 and 06/18/2024 was filed

after the mailing date of the application on 04/26/2024. The submission is in compliance with the

provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the

examiner.

**Double Patenting** 

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded

in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise

extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple

assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not

identical, but at least one examined application claim is not patentably distinct from the reference

claim(s) because the examined application claim is either anticipated by, or would have been obvious

over, the reference claim(s). See, e.g., Inre Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); Inre

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed.

IPR2025-01126

Application/Control Number: 18/647,929

Art Unit: 3794

Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 et seq. for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The filing of a terminal disclaimer by itself is not a complete reply to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The actual filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/apply/applying-online/eterminal-disclaimer.

Page 3

Application/Control Number: 18/647,929 Page 4

Art Unit: 3794

Claims 1-20 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 11,998,262. Although the claims at issue are not identical, they are not patentably distinct from each other because the similarity between the claims. The current application does not differ from the patented material presented in U.S. Patent No. 11,998,262 because both applications share the same structural limitations and use cases described. Specifically, both applications describe a method for improving a patient's sleep through the use of a multi-end effector that includes a first electrode and second electrode with active and inactive states, wherein the first electrode is exposed from a surface and separate from the second electrode, where both electrodes target sites within the sino-nasal cavity and deliver energy thereto. The Examiner notes that U.S. Patent No. 11,998,262 does not describe the limitation "wherein at least one portion of the multi-end effector comprises a diameter that is larger than a diameter of the shaft" found in the instant application. However, it is the Examiner's position that increasing (or decreasing) the diameter of the multielectrode effector does not offer any inventive or non-predictable features to the claimed invention and is simply a matter of design choice that produces predictable results. Pending a statement of criticality, it would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to increase (or decrease) the diameter of the multi-electrode effector as a matter of design choice and produces predictable results. For at least this reason, it is the Examiner's position that there is no patentable distinction between the two applications. Appropriate correction is required.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M Bock whose telephone number is (571)272-8856. The examiner can normally be reached M-F 7:30am - 5:00pm.

Application/Control Number: 18/647,929

Art Unit: 3794

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,

Linda Dvorak can be reached on 5712724764. 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/docxfor information about filing in DOCXformat. 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.

/ABIGAIL BOCK/

Examiner, Art Unit 3794

/LINDA C DVORAK/

Supervisory Patent Examiner, Art Unit

Page 5

3794

		Notice of Deferen	Notice of References Cited					Applicant(s)/Patent Under Reexamination Townley, David Art Unit		
		Notice of Helerefice	es Chea		Examiner Abigail M Bo	ck	Page 1 of 1			
			1	U.S. PATI	ENT DOCUM	ENTS		1		
*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD		Nar	ne		CPC Classification	US Classification	
*	Α	US-11998262-B1	2024-06-04	Townle	ey; David			A61B18/148	1/1	
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\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in YYYY-MM-DD format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office PTO-892 (Rev. 11-2023)

Χ

Notice of References Cited

Part of Paper No. 20240703

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Index of Claims	18/647,929	Townley, David
	Examiner	Art Unit
	Abigail M Bock	3794

1	Rejected	-	Cancelled	N	Non-Elected	Α	Appeal
=	Allowed	÷	Restricted	I	Interference	0	Objected

Claims renumbered in the same order as presented by applicant         □ CPA         □ T.D.         □ R.1.47           CLAIM           Final         Original 07/03/2024         □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □		CLAIMS										
Final Original 07/03/2024  1	☐ Clair	☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.4										
1	CL.	AIM					DATE					
2	Final	Original	07/03/2024									
3		1	✓									
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U.S. Patent and Trademark Office Part of Paper No.: 20240703

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	18/647,929	Townley, David
	Examiner	Art Unit
	Abigail M Bock	3794

CPC - Searched*		
Symbol	Date	Examiner
A61B18/148 A61B2018/00327 A612018/00434 A61B2018/00583 A61B2018/1467	07/03/2024	AB
CPC Combination Sets - Searched*		
Symbol	Date	Examiner
US Classification - Searched*	_	_

US Classification - Searched*									
Class	Subclass	Date	Examiner						

 $<sup>^{\</sup>star}$  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 assignee name search performed in PALM/DAV	07/03/2024	AB					
Limited text and CPC search performed in PE2E Search - see attached search history	07/03/2024	AB					

Interference Search						
US Class/CPC Symbol	PC US Subclass/CPC Group Date Examin					

/ABIGAIL BOCK/	
Examiner, Art Unit 3794	
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U.S. Patent and Trademark Office

Part of Paper No.: 20240703

Page 1 of 1

Receipt date: 06/18/2024 18/647,929 - GAU: 3794

Docket No.: NEURE-008/07US

Examiner: Not Yet Assigned

35242/159 (PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Neurent Medical Limited

Application No.: 18/647,929 Confirmation No.: 9882

Filed: April 26, 2024 Art Unit: Not Yet Assigned

For: SYSTEMS AND METHODS FOR

THERAPEUTIC NASAL TREATMENT USING

HANDHELD DEVICE

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

#### **INFORMATION DISCLOSURE STATEMENT (IDS)**

Pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98, the attention of the United States Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of the above-identified application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Copies of the references listed below are attached:

Non-Patent Literature or Other Documents
Aerin Medical FDA 510(k) Summary - 510(k) Number K150637, dated October
23, 2015 (8 pages)
Aerin Medical FDA 510(k) Summary - 510(k) Number K161994, dated August
19, 2016 (6 pages)
Aerin Medical FDA 510(k) Summary - 510(k) Number K162810, dated
December 9, 2016 (7 pages)
Aerin Medical FDA 510(k) Summary - 510(k) Number K172529, dated
November 2, 2017 (7 pages)
Aerin Medical FDA 510(k) Summary - 510(k) Number K192471, dated
September 9, 2019 (7 pages)
Aerin Medical FDA 510(k) Summary - 510(k) Number K200300, dated March
13, 2020 (6 pages)

65386915

Receipt date: 06/18/2024 18/647,929 - GAU: 3794

Application No.: 18/647,929 2 Docket No.: NEURE-008/07US 35242/159

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98, and the Examiner is respectfully requested to consider the listed references.

Applicant further submits that submission of the information provided in the attached PTO/SB/08 does not constitute any admission that such information is considered prior art or satisfies the requirements to be a prior art publication.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0369, under Order No. NEURE-008/07US from which the undersigned is authorized to draw.

Dated: June 18, 2024 Respectfully submitted,

Electronic signature: /Matthew P. York/
Matthew P. York
Registration No.: 66,470
BROWN RUDNICK LLP
Brown Rudnick LLP
One Financial Center
Boston, Massachusetts 02111
(617) 856-8200
Attorney for Applicant

CONSIDERED: /A.M.B./ /ABIGAIL BOCK/ 07/03/2024 Receipt date: 05/01/2024 18/647,929 - GAU: 3794

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

Mation Disclosure Statement (IDS) Filed

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	Application Number		18647929
INFORMATION DIGGL COURT	Filing Date		2024-04-26
INFORMATION DISCLOSURE	First Named Inventor David Townley		Townley
(Not for submission under 37 CFR 1.99)	Art Unit		N/A
(Not for Submission under or of K 1.55)	Examiner Name	Not Yet Assigned	
	Attorney Docket Numb	er	NEURE-008/07US 35242/159

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Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	874178		1907-12-17	LEE DE FOREST	
	2	3117571		1964-01-14	FRY et al.	
	3	3538919		1970-11-10	MEYER ROBERT G	
	4	3941121		1976-03-02	Olinger et al.	
	5	3987795		1976-10-26	Morrison, Charles F.	
	6	4271848		1981-06-09	Turner et al.	
	7	4411266		1983-10-25	Cosman, Eric R.	
	8	4898169		1990-02-06	Norman et al.	

Application Number		18647929
Filing Date		2024-04-26
First Named Inventor David		Townley
Art Unit		N/A
Examiner Name Not Y		et Assigned
Attorney Docket Number		NEURE-008/07US 35242/159

9	5184625	1993-02-09	Cottone, Jr. et al.	
10	5395383	1995-03-07	Adams et al.	
11	5456662	1995-10-10	Edwards et al.	
12	5562720	1996-10-08	Stern et al.	
13	5575788	1996-11-19	Baker et al.	
14	5588429	1996-12-31	Isaacson et al.	
15	5697536	1997-12-16	Eggers et al.	
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17	5746224	1998-05-05	Edwards	
18	5766605	1998-06-16	Sanders et al.	
19	5800429	1998-09-01	Edwards, Stuart D.	

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Application Number		18647929
Filing Date		2024-04-26
First Named Inventor	David	Townley
Art Unit		N/A
Examiner Name Not Y		et Assigned
Attorney Docket Number		NEURE-008/07US 35242/159

20	5823197	1998-10-20	Edwards	
21	5827277	1998-10-27	Edwards	
22	5836947	1998-11-17	Fleischman et al.	
23	5843026	1998-12-01	Edwards et al.	
24	6033397	2000-03-07	Laufer et al.	
25	6045532	2000-04-04	Eggers et al.	
26	6053172	2000-04-25	Hovda et al.	
27	6063079	2000-05-16	Hovda et al.	
28	6106518	2000-08-22	Wittenberger et al.	
29	6139527	2000-10-31	Laufer et al.	
30	6142991	2000-11-07	Schatzberger, Shaike	

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Application Number		18647929	
Filing Date		2024-04-26	
First Named Inventor	David	Townley	
Art Unit		N/A	
Examiner Name Not Y		et Assigned	
Attorney Docket Number		NEURE-008/07US 35242/159	

31	6273886	2001-08-14	Edwards et al.	
32	6332880	2001-12-25	Yang et al.	
33	6352533	2002-03-05	Ellman et al.	
34	6517534	2003-02-11	McGovern et al.	
35	6517535	2003-02-11	Edwards, Stuart D.	
36	6520185	2003-02-18	Bommannan et al.	
37	6529756	2003-03-04	Phan et al.	
38	6594518	2003-07-15	Benaron et al.	
39	6595988	2003-07-22	Wittenberger et al.	
40	6626899	2003-09-30	Houser et al.	
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Application Number		18647929
Filing Date		2024-04-26
First Named Inventor	David	Townley
Art Unit		N/A
Examiner Name Not Y		et Assigned
Attorney Docket Number		NEURE-008/07US 35242/159

42	6669689	2003-12-30	Lehmann et al.	
43	6685648	2004-02-03	Flaherty et al.	
44	6746474	2004-06-08	Saadat	
45	7195629	2007-03-27	Behl et al.	
46	7232458	2007-06-19	Saadat	
47	7285119	2007-10-23	Stewart et al.	
48	7500985	2009-03-10	Saadat	
49	7524318	2009-04-28	Young et al.	
50	7608275	2009-10-27	Deem et al.	
51	7654997	2010-02-02	Makower et al.	
52	7655243	2010-02-02	Deem et al.	

		· ,
Application Number		18647929
Filing Date		2024-04-26
First Named Inventor David		Townley
Art Unit		N/A
Examiner Name Not Y		et Assigned
Attorney Docket Number		NEURE-008/07US 35242/159

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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

Application Number		18647929			
Filing Date		2024-04-26			
First Named Inventor David		Townley			
Art Unit		N/A			
Examiner Name	Not Y	et Assigned			
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Receipt date: 05/01/2024 18/647,929 - GAU: 3794

	Application Number		18647929
INFORMATION BIOOLOGUEE	Filing Date		2024-04-26
INFORMATION DISCLOSURE	First Named Inventor	David	Townley
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		N/A
(Not for Submission under or of K 1.00)	Examiner Name	Not Y	et Assigned
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#### PE2E SEARCH - Search History (Prior Art)

Ref# Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1 66	(((("TOWNLEY") near3 ("David"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/06/17 09:32 AM
L2 41	((("NEURENT") near3 ("MEDICAL") near3 ("LIMITED"))).AS,AAN M.	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/17 09:32 AM
L3 154	(US-20020068930-\$   US-20020072742-\$   US-20020072742-\$   US-20030016085-\$   US-20030016085-\$   US-20050080409-\$   US-20050171536-\$   US-20050171574-\$   US-20050171582-\$   US-20050171583-\$   US-20050187546-\$   US-20050240147-\$   US-20050288730-\$   US-20060036237-\$   US-20060036237-\$   US-20060010620-\$   US-20060106375-\$   US-20060149226-\$   US-20060149226-\$   US-20060247683-\$   US-20070031341-\$   US-20070031341-\$   US-20070031341-\$   US-20070031341-\$   US-20070083195-\$   US-20070129760-\$   US-20070129760-\$   US-20070233191-\$   US-20070233191-\$   US-20070287994-\$   US-20070287994-\$   US-2008021369-\$   US-2008021369-\$   US-20090318914-\$   US-20100049187-\$   US-20100057048-\$   US-20100057048	(US-PGPUB; USPAT)	OR	ON	ON	2024/06/17 09:32 AM

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PE2E SEARCH - Search History (Interference)

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There are no Interference searches to show.

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Receipt date: 06/18/2024 18/647,929 - GAU: 3794

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)

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Mation Disclosure Statement (IDS) Filed

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	Application Number		18647929	
INFORMATION BIOOLOGUES	Filing Date		2024-04-26	
INFORMATION DISCLOSURE	First Named Inventor	David	Townley	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		N/A	
(Notion submission under or of K 1.55)	Examiner Name	Not Y	et Assigned	
	Attorney Docket Number		NEURE-008/07US 35242/159	

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

Application Number		18647929		
Filing Date		2024-04-26		
First Named Inventor David		d Townley		
Art Unit		N/A		
Examiner Name Not You		et Assigned		
Attorney Docket Number		NEURE-008/07US 35242/159		

	1	Aerin	Medical FDA 510(k) Summary - 510(k) Number K150637, dated Octo	ober 23, 2015 (8 pag	ges)		
	2	Aerin	Medical FDA 510(k) Summary - 510(k) Number K161994, dated Augu	ust 19, 2016 (6 pag	es)		
	3	Aerin Medical FDA 510(k) Summary - 510(k) Number K162810, dated December 9, 2016 (7 pages)					
	4 Aerin Medical FDA 510(k) Summary - 510(k) Number K172529, dated November 2, 2017 (7 pages)						
	5	Aerin Medical FDA 510(k) Summary - 510(k) Number K192471, dated September 9, 2019 (7 pages)					
	6	Aerin	Medical FDA 510(k) Summary - 510(k) Number K200300, dated Marc	ch 13, 2020 (6 page	s)		
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			EXAMINER SIGNATURE				
Examiner	Examiner Signature   /ABIGAIL BOCK/   Date Considered   07/03/2024						
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<sup>1</sup> See Kind Codes of USPTO Patent Documents at <a href="https://www.USPTO.GOV">www.USPTO.GOV</a> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.							

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Application Number		18647929		
Filing Date		2024-04-26		
First Named Inventor David		Townley		
Art Unit		N/A		
Examiner Name Not Y		et Assigned		
Attorney Docket Number		NEURE-008/07US 35242/159		

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	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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Sig	nature	/Matthew P. York/	Date (YYYY-MM-DD)	2024-06-18		
Nar	Name/Print Matthew P. York Registration Number 66,470					
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# **Bibliographic Data**

Application No: 18/647,92	29		
Foreign Priority claimed:	<b>O</b> Yes	<b>●</b> No	
35 USC 119 (a-d) conditions met:	Yes	□No	☐Met After Allowance
Verified and Acknowledged:	/ABIGAIL B	OCK/	
	Examiner's Signature	gnature	Initials
Title:		ND METHODS FOR T USING HANDHEL	THERAPEUTIC NASAL LD DEVICE

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
04/26/2024	606	3794	NEURE-008/07US 35242/159
RULE			

#### **APPLICANTS**

Neurent Medical Limited, Oranmore, IRELAND

#### **INVENTORS**

David Townley,

#### **CONTINUING DATA**

This application is a CON of 18411476 01/12/2024 PAT 11998262 18411476 is a CON of 17225560 04/08/2021 PAT 11883091

17225560 has PRO of 63007584 04/09/2020

#### FOREIGN APPLICATIONS

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Application Numbe	er	18/647,929					
Filing Date	***************************************	April 26, 2024	000000000000000000000000000000000000000				
First Named Invent	tor	David Townley					
Title	SAL TREATMENT						
Art Unit 3794							
Examiner Name		Not Yet Assigned					
Attorney Docket No	umber	NEURE-008/07US 35242/159					
SIGNATUF	RE of Ap	oplicant or Patent Practitioner					
Signature	/Mattl	new P. York/	Date (Optional)				
Name	Matthew	P. York	Registration Number	66470			
Title (if Applicant is a juristic entity)	nt is a						
Applicant Name (if Appl			or algorithm rogulis	amenta and partifications of			
more than one applican		in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) fiple forms.	or signature requir	ements and certifications. If			
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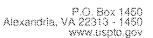
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	y revoke all pr kes below.	evious powers of attorney given in th	ne application	identified in <u>either</u>	the attached transmittal letter or
***************************************		Application Number	Fil	ling Date	
	I hereby appoint to transact all the attached to OR I hereby appoint all business in	The boxes above may be left blank if in int the Patent Practitioner(s) associated we business in the United States Patent and ransmittal letter (form PTO/AIA/82A) or ic int Practitioner(s) named in the attached the United States Patent and Trademark imittal letter (form PTO/AIA/82A) or ident	with the followin  i Trademark Off dentified above:  list (form PTO/A k Office connect	ng Customer Number fice connected there 21710 AIA/82C) as my/our a sted therewith for the	as my/our attorney(s) or agent(s), and with for the application referenced in attorney(s) or agent(s), and to transact patent application referenced in the
	e recognize o	r change the correspondence add above to:	ress for the a	application identi	fied in the attached transmittal
	OR The address a	associated with the above-mentioned Cus	stomer Number		
	OR Firm or				
	Individual Nan	ne			
Address	······				
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l am the	Applicant (if th	e Applicant is a juristic entity, list the App	olicant name in t	the box):	
Neu	urent Me	edical Limited			
	Inventor or Jo	int Inventor (title not required below)			
	Legal Represe	entative of a Deceased or Legally Incapa	citated Inventor	title not required be	elow)
$\checkmark$	Assignee or P	erson to Whom the Inventor is Under an	Obligation to As	ssign (provide signe	r's title if applicant is a juristic entity)
		Otherwise Shows Sufficient Proprietary in is concurrently being filed with this docur			
		SIGNATURE	of Applicant fo	or Patent	
The	undersigned (wh	iose title is supplied below) is authorized to	act on behalf of	·····	here the applicant is a juristic entity).
Sign	ature	Dod G		Date (Optional)	1 June 2020
Nam	e	David Townley		******************************	
Title	************************	Chief Technology Officer (CTO), Ne			
		his form must be signed by the applicant in nore than one applicant, use multiple forms		th 37 CFR 1.33. See 3	37 CFR 1.4 for signature requirements
Tota	l 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.





# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

**APPLICATION #** 18/647,929 RECEIPT DATE / TIME

06/26/2024 12:00:01 PM Z ET

ATTORNEY DOCKET # NEURE-008/07US 35242/159

#### Title of Invention

SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE

## **Application Information**

APPLICATION TYPE Utility - Nonprovisional Application under 35 USC 111(a)

PATENT# -

CONFIRMATION #

9882

FILED BY Matthew York

PATENT CENTER # 66126003

FILING DATE 04/26/2024

CUSTOMER# 21710

FIRST NAMED INVENTOR

David Townley

CORRESPONDENCE ADDRESS

AUTHORIZED BY -

#### **Documents**

# **TOTAL DOCUMENTS: 1**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
NEURE-008-07US_POA.pdf	2	Power of Attorney	336 KB

# **Digest**

DOCUMENT	MESSAGE DIGEST(SHA-512)
NEURE-008-07US_POA.pdf	0B21625D50C96641BC3C6986D0A605E4DC2172A1A5FFA79C3 E770C0BB58F2AF6DE88C40264F749A70EFB5D56846B014C07 0931B27C464ACE27141FC545B4D3CF

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.

# 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.
18/647,929	04/26/2024	David Townley	NEURE-008/07US 35242/159	9882
21710 BROWN RUD	7590 06/20/202 NICK LLP	4	EXAM	IINER
ONE FINANCI BOSTON, MA	IAL CENTER		CENTRAL	, DOCKET
2001011,1111	V <b>-</b> 111		ART UNIT	PAPER NUMBER
			3794	
			NOTIFICATION DATE	DELIVERY MODE
			06/20/2024	FLECTRONIC

### 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):

ip@brownrudnick.com usactions@brownrudnick.com

			Application No. 18/647,929	Applicant(s) Townley, David			
		n Granting Request for ed Examination (Track I)	Examiner CHERYL P GIBSON BAYLOR	Art Unit OPET	AIA (FITF) Status Yes		
1.		PUEST FILED <u>26 April 2024</u> IS <b>GF</b> e-identified application has met th ☑ for an original nonprovisiona ☐ for an application undergoing	ne requirements for prioriti. I application (Track I).				
2.	accorded	re-identified application will und special status throughout its entir	e course of prosecution u	ntil one of the foll	lowing occurs:		
	A.	filing a <u>petition for extension o</u>		_			
	B.	filing an amendment to amend independent claims, more that					
	C.	filing a request for continued e	xamination ;				
	D.	filing a notice of appeal;	filing a notice of appeal;				
	E.	filing a request for suspension o	filing a request for suspension of action;				
	F.	mailing of a notice of allowance;					
	G.	mailing of a final Office action;					
	Н.	completion of examination as de	efined in 37 CFR 41.102;	or			
	l.	abandonment of the application.					
	•	e inquiries with regard to this deci 3213. In his/her absence, calls m					
		_ GIBSON BAYLOR/ I Specialist, OPET					

U.S. Patent and Trademark Office PTO-2298 (Rev. 02-2012)

	Application Number		18647929	
INFORMATION BIOOLOGUEE	Filing Date		2024-04-26	
INFORMATION DISCLOSURE	First Named Inventor David		d Townley	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		N/A	
(Not for Submission under or of K 1.00)	Examiner Name	Not Y	et Assigned	
	Attorney Docket Number		NEURE-008/07US 35242/159	

	U.S.PATENTS Remove									
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue D	ate	of cited Document				
	1									
If you wisl	n to add	d additional U.S. Paten	t citatio	n inform	ation pl	ease click the	Add button.		Add	
U.S.PATENT APPLICATION PUBLICATIONS Remove										
Examiner Initial*	Cite N	o Publication Number	Kind Code <sup>1</sup>	Publica Date	tion	of cited Document		Pages,Columns,Lines where Relevant Passages or Releva Figures Appear		
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Examiner Initial*			Country Code <sup>2</sup> i	1	Kind Code <sup>4</sup>	Publication Date	Name of Patented Applicant of cited Document	e or	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T5
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Examiner Initials*	Examiner Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item						T5			

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

Application Number		18647929		
Filing Date		2024-04-26		
First Named Inventor David		Townley		
Art Unit		N/A		
Examiner Name Not You		et Assigned		
Attorney Docket Number		NEURE-008/07US 35242/159		

	1	Aerin	Medical FDA 510(k) Summary - 510(k) Number K150637, dated October 23, 2015 (8 pages)					
	2	Aerin	Medical FDA 510(k) Summary - 510(k) Number K161994, dated August 19, 2016 (6 pages)					
	3	Aerin	Aerin Medical FDA 510(k) Summary - 510(k) Number K162810, dated December 9, 2016 (7 pages)					
	4	Aerin	Aerin Medical FDA 510(k) Summary - 510(k) Number K172529, dated November 2, 2017 (7 pages)					
	5	Aerin	Aerin Medical FDA 510(k) Summary - 510(k) Number K192471, dated September 9, 2019 (7 pages)					
	6	Aerin Medical FDA 510(k) Summary - 510(k) Number K200300, dated March 13, 2020 (6 pages)						
If you wisl	h to ac	dd add	litional non-patent literature document citation information please click the Add button Add					
			EXAMINER SIGNATURE					
Examiner	Signa	ture	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.							
Standard ST  4 Kind of doo	See Kind Codes of USPTO Patent Documents at <a href="https://www.USPTO.GOV">www.USPTO.GOV</a> or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> 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) Filling Date 2024-04-26 First Named Inventor Art Unit N/A Examiner Name Net Yet Assigned

Application Number		18647929		
Filing Date		2024-04-26		
First Named Inventor	David	Townley		
Art Unit		N/A		
Examiner Name	Not Yet Assigned			
Attorney Docket Number		NEURE-008/07US 35242/159		

	CERTIFICATION STATEMENT							
Plea	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								
	foreign patent of after making rea any individual d	information contained in the information diffice in a counterpart foreign application, an sonable inquiry, no item of information contaesignated in 37 CFR 1.56(c) more than thr 37 CFR 1.97(e)(2).	id, to the knowledge of th ained in the information di	e person signing the certification sclosure statement was known to				
	See attached ce	rtification statement.						
	The fee set forth	in 37 CFR 1.17 (p) has been submitted here	ewith.					
X	A certification sta	atement is not submitted herewith.						
	ignature of the ap n of the signature.	SIGNA plicant or representative is required in accord		8. Please see CFR 1.4(d) for the				
Sigr	nature	/Matthew P. York/	Date (YYYY-MM-DD)	2024-06-18				
Nan	ne/Print	Matthew P. York	Registration Number	66,470				
pub	lic which is to file	rmation is required by 37 CFR 1.97 and 1.98 (and by the USPTO to process) an application is estimated to take 1 hour to complete, inclu	on. Confidentiality is gover	med by 35 U.S.C. 122 and 37 CFR				

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,** 

EFS Web 2.1.18

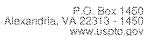
VA 22313-1450.

#### **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.





# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

**APPLICATION #** 18/647,929 RECEIPT DATE / TIME

06/18/2024 04:26:43 PM Z ET

ATTORNEY DOCKET # NEURE-008/07US 35242/159

#### Title of Invention

SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE

## **Application Information**

APPLICATION TYPE Utility - Nonprovisional Application

under 35 USC 111(a)

PATENT# -

CONFIRMATION # 9882

FILED BY Kelley Warren

PATENT CENTER # 66016892

FILING DATE 04/26/2024

CUSTOMER# 21710

FIRST NAMED David Townley

**INVENTOR** 

CORRESPONDENCE ADDRESS

AUTHORIZED BY Matthew York

#### **Documents**

# **TOTAL DOCUMENTS: 8**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
35242_159US - Information Disclosure Statement IDS.pdf	2	Transmittal Letter	24 KB
35242_159US - Information Disclosure Statement Fillable PDF.pdf	4	Information Disclosure Statement (IDS) Form (SB08)	1234 KB
35242_21US - Aerin- Medical_FDA-510 k - Summary_K150637-NPL.pdf	8	Non Patent Literature	337 KB
35242_21US - Aerin- Medical_FDA-510 k - Summary_K161994-NPL.pdf	6	Non Patent Literature	432 KB

			Page 2 of 3
35242_21US - Aerin- Medical_FDA-510 k - Summary_K162810-NPL.pdf	7	Non Patent Literature	245 KB
35242_21US - Aerin- Medical_FDA-510 k - Summary_K172529-NPL.pdf	7	Non Patent Literature	167 KB
35242_21US - Aerin- Medical_FDA-510 k - Summary_K192471-NPL.pdf	7	Non Patent Literature	2340 KB
35242_21US - Aerin- Medical_FDA-510 k - Summary_K200300-NPL.pdf	6	Non Patent Literature	512 KB

# Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
35242_159US - Information Disclosure Statement IDS.pdf	ABDDD91E132C7EDFFFECA85313BDD4B1EA8E914EB420340F 960DE45FC00D2888A585206371A63915078AFE7174685C0249 E10A759C7B95FC3D74D19D22C15911
35242_159US - Information	E8CBED0B0282318A272CE3FA4066718E3E5DC6FB2A83F4065
Disclosure Statement Fillable	41ACD32AEAC786B7800686AF7B5CD51A950512A6E040AF721
PDF.pdf	1479CB8198BD361974443B090F9AF1
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Summary_K161994-NPL.pdf	4443ACBDAEDEC03B015B22CEF7627
35242_21US - Aerin-	96973421DD55E85CFE14993EB23625B44E62EAB287049BF340
Medical_FDA-510 k -	320082F59DBB90F5357CC1AF7F0E3CFD00767D72DEE8C64E

Summary_K162810-NPL.pdf	BF02888E1E18D27BD9E4F843E715A7
35242_21US - Aerin-	723F389578B3639E08F5A0EA6A9E2F6DA4C4187BEC87117DE
Medical_FDA-510 k -	E8ECC263819E73FA83F0276CAEFB972DC9E2491CC8CDE864
Summary_K172529-NPL.pdf	882EEC4C5CC90B8F5E61474878E8098
35242_21US - Aerin-	B4EA01DB8DCAB669A280137E1D37070561ACE0B9AC325FF62
Medical_FDA-510 k -	D081E5BC60890DD12F1DA88B4B2255837C636FAAC6DF28DA
Summary_K192471-NPL.pdf	A19A3792DF20202AEA08D3428ECBB43
35242_21US - Aerin-	49E49E363BCA114D6BC54F8D05F940AC8D7E07E67F22CC899
Medical_FDA-510 k -	3AE3E1101F542BF08C696F88B6A51A9552C9283A7B07DFC15
Summary_K200300-NPL.pdf	E06A7E904834C3C47F14D7145D2678

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

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#### New International Application Filed with the USPTO as a Receiving Office

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Docket No.: NEURE-008/07US

Examiner: Not Yet Assigned

35242/159 (PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Neurent Medical Limited

Application No.: 18/647,929 Confirmation No.: 9882

Filed: April 26, 2024 Art Unit: Not Yet Assigned

For: SYSTEMS AND METHODS FOR

THERAPEUTIC NASAL TREATMENT USING

HANDHELD DEVICE

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

#### **INFORMATION DISCLOSURE STATEMENT (IDS)**

Pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98, the attention of the United States Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of the above-identified application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Copies of the references listed below are attached:

Non-Patent Literature or Other Documents
Aerin Medical FDA 510(k) Summary - 510(k) Number K150637, dated October
23, 2015 (8 pages)
Aerin Medical FDA 510(k) Summary - 510(k) Number K161994, dated August
19, 2016 (6 pages)
Aerin Medical FDA 510(k) Summary - 510(k) Number K162810, dated
December 9, 2016 (7 pages)
Aerin Medical FDA 510(k) Summary - 510(k) Number K172529, dated
November 2, 2017 (7 pages)
Aerin Medical FDA 510(k) Summary - 510(k) Number K192471, dated
September 9, 2019 (7 pages)
Aerin Medical FDA 510(k) Summary - 510(k) Number K200300, dated March
13, 2020 (6 pages)

65386915

Application No.: 18/647,929

It is submitted that the Information Disclosure Statement is in compliance with

37 C.F.R. § 1.98, and the Examiner is respectfully requested to consider the listed references.

Applicant further submits that submission of the information provided in the attached

PTO/SB/08 does not constitute any admission that such information is considered prior art or

satisfies the requirements to be a prior art publication.

Applicant believes no fee is due with this response. However, if a fee is due, please

charge our Deposit Account No. 50-0369, under Order No. NEURE-008/07US from which the

undersigned is authorized to draw.

Dated: June 18, 2024

Respectfully submitted,

Electronic signature: /Matthew P. York/

Matthew P. York

Registration No.: 66,470

BROWN RUDNICK LLP

Brown Rudnick LLP

One Financial Center Boston, Massachusetts 02111

(617) 856-8200

Attorney for Applicant



21710

#### 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

I	APPLICATION	FILING or	GRP ART				
l	NUMBER	371(c) DATE	UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
	18/647,929	04/26/2024		664	NEURE-008/07US 35242/159	20	1

18/647,929 04/26/2024

**BROWN RUDNICK LLP** ONE FINANCIAL CENTER BOSTON, MA 02111

**CONFIRMATION NO. 9882** 

**FILING RECEIPT** 

Date Mailed: 05/29/2024

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.

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Inventor(s)

David Townley, County Clare, IRELAND;

Applicant(s)

Neurent Medical Limited, Oranmore, IRELAND;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 18/411,476 01/12/2024 PAT 11,998,262 which is a CON of 17/225,560 04/08/2021 PAT 11,883,091 which claims benefit of 63/007,584 04/09/2020

Foreign Applications for which priority is claimed (You may be eligible to benefit from the Patent Prosecution Highway program at the USPTO. Please see <a href="http://www.uspto.gov">http://www.uspto.gov</a> 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

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page 1 of 3

If Required, Foreign Filing License Granted: 05/24/2024

The country code and number of your priority application, to be used for filing abroad under the Paris Convention,

is **US 18/647,929** 

**Projected Publication Date:** 09/05/2024

Non-Publication Request: No Early Publication Request: No

\*\* SMALL ENTITY \*\*

Title

SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD

DEVICE

**Preliminary Class** 

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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	PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875  Application or Docket Number 18/647,929										
	APPLICATION AS FILED - PART I  (Column 1) (Column 2) SMALL ENTITY OR SMALL ENTITY										
	FOR	NUMBE	R FILE	NUMBE	R EXTRA		RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)
	IC FEE FR 1.16(a), (b), or (c))	N	/ <b>A</b>	١	I/A		N/A	64	1	N/A	
	RCH FEE FR 1.16(k), (i), or (m))	N	/A	١	I/A		N/A	280		N/A	
	MINATION FEE FR 1.16(o), (p), or (q))	N	/ <b>A</b>	١	I/A		N/A	320		N/A	
	AL CLAIMS FR 1.16(i))	20	minus	20 = *	0	×	=	0	OR		
	PENDENT CLAI FR 1.16(h))	MS 1	minus	3 = *		×	=	0	1		
APF FEE	PLICATION SIZ	\$310 (\$15 50 sheets	paper, th 5 for sma or fraction	and drawings e e application sizall entity) for each on thereof. See CFR 1.16(s).	ze fee due is ch additional			0			
MUL	TIPLE DEPENDE	ENT CLAIM PRE	SENT (3	7 CFR 1.16(j))				0	1		
* If t	he difference in co	olumn 1 is less th	an zero,	enter "0" in colun	nn 2.	_	TOTAL	664		TOTAL	
	ADDI I	CATION AS A	MENID	ED - DART II	ı		'		•	'	
	7.11 2.13	(Column 1)		(Column 2)	(Column 3)		SMALL	ENTITY	OR	OTHEF SMALL	
NT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
ME	Total (37 CFR 1.16(i))	•	Minus	**	=	×	=		OR	X =	
AMENDMENT	Independent (37 CFR 1.16(h))	*	Minus	***	=	×	=		OR	x =	
AM	Application Size Fe	ee (37 CFR 1.16(s))			•				1		
	FIRST PRESENTA	ATION OF MULTIPL	E DEPEN	DENT CLAIM (37 C	FR 1.16(j))				OR		
							TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
		(Column 1)		(Column 2)	(Column 3)						
NT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
ME	Total (37 CFR 1.16(i))	*	Minus	**	=	×	=		OR	x =	
AMENDMENT	Independent (37 CFR 1.16(h))	•	Minus	***	=	×	=		OR	x =	
AME		e (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))											
						۱ –	TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
*	* If the "Highest N * If the "Highest N	olumn 1 is less th Number Previous umber Previously I ber Previously Paid	y Paid For	or" IN THIS SPACE IS	CE is less than s less than 3, en	1 20, nter ":	3. enter "20". 3".	in column 1.	J	7,50 - 1 - 1	



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#### Kathi Vidal

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

**Derrick Brent** 

Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office





# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

**APPLICATION #** 18/647,929 RECEIPT DATE / TIME

05/01/2024 04:56:09 PM Z ET

ATTORNEY DOCKET # NEURE-008/07US 35242/159

#### Title of Invention

SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE

## **Application Information**

APPLICATION TYPE Utility - Nonprovisional Application

under 35 USC 111(a)

PATENT# -

CONFIRMATION # 9882 FILED BY Kelley Warren

PATENT CENTER # 65313984

FILING DATE -

CUSTOMER# 21710

FIRST NAMED **INVENTOR** 

David Townley

CORRESPONDENCE ADDRESS

AUTHORIZED BY Matthew York

## **Documents**

# **TOTAL DOCUMENTS: 2**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
35242_159_Information_Disclosure_Statement.pdf	2	Transmittal Letter	113 KB
35242_159_Information_Discl osure_Statement_Fillable_PD F.pdf	35	Information Disclosure Statement (IDS) Form (SB08)	1243 KB

# **Digest**

DOCUMENT	MESSAGE DIGEST(SHA-512)
35242 159 Information Disclos	FC431168BD59ABBD5FF9CBFF37D57841636537C4380DFA0FB

ure_Statement.pdf	EC80686129F1D05ABD6BC963EB4DCAE1A99F88EFFECC91DF 0C21BA2F3E17DBFF6DEE4168EF647C5
35242_159_Information_Disclos	2892A3608BC287404E68BC36381CCC92EE16E9CDA2CD5023
ure_Statement_Fillable_PDF.pd	E3F09DBD1E3DF9081E5091D30E05054B99CB52FE9AD63AAA
f	7125176789F7EC78030136D8BE5D9DE8

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#### New International Application Filed with the USPTO as a Receiving Office

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	Application Number		18647929	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Filing Date		2024-04-26	
	First Named Inventor David		d Townley	
	Art Unit		N/A	
	Examiner Name	Not Yet Assigned		
	Attorney Docket Number		NEURE-008/07US 35242/159	

	U.S.PATENTS					Remove
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	874178		1907-12-17	LEE DE FOREST	
	2	3117571		1964-01-14	FRY et al.	
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	7	4411266		1983-10-25	Cosman, Eric R.	
	8	4898169		1990-02-06	Norman et al.	

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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First Named Inventor David		Townley	
Art Unit		N/A	
Examiner Name	Not Yet Assigned		
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22	5836947	1998-11-17	Fleischman et al.	
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30	6142991	2000-11-07	Schatzberger, Shaike	

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Examiner Name	Not Yet Assigned		
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Examiner Name	Not Y	et Assigned	
Attorney Docket Number		NEURE-008/07US 35242/159	

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Examiner Name	Not Y	et Assigned	
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Attorney Docket Number		NEURE-008/07US 35242/159	

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

Application Number		18647929
Filing Date		2024-04-26
First Named Inventor David		Townley
Art Unit		N/A
Examiner Name Not Y		et Assigned
Attorney Docket Number		NEURE-008/07US 35242/159

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If you wisl	h to ac	d additional non-patent literature document citation information please click the Add button Add						
		EXAMINER SIGNATURE						
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Filing Date First Named Inventor Art Unit

Application Number		18647929
Filing Date		2024-04-26
First Named Inventor David		Townley
Art Unit		N/A
Examiner Name Not Y		et Assigned
Attorney Docket Number		NEURE-008/07US 35242/159

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Docket No.: NEURE-008/07US

Examiner: Not Yet Assigned

35242/159 (PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Neurent Medical Limited

Application No.: 18/647,929 Confirmation No.: 9882

Filed: April 26, 2024 Art Unit: Not Yet Assigned

For: SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT

USING HANDHELD DEVICE

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

#### **INFORMATION DISCLOSURE STATEMENT (IDS)**

Pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98, the attention of the United States Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of the above-identified application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

In accordance with 37 C.F.R. § 1.98(d)(1) the references are not supplied because they were previously cited by or submitted to the Office in prior application numbers 18/411476 filed January 12, 2024 and 17/225560 filed April 8, 2021 and relied on in the above-identified application for an earlier effective filing date under 35 U.S.C. § 120.

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98, and the Examiner is respectfully requested to consider the listed references.

65348533

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0369, under Order No. NEURE-008/07US from which the undersigned is authorized to draw.

Dated: May 1, 2024 Respectfully submitted,

Electronic signature: /Matthew P. York/
Matthew P. York
Registration No.: 66,470
BROWN RUDNICK LLP
Brown Rudnick LLP
One Financial Center
Boston, Massachusetts 02111
(617) 856-8200
Attorney for Applicant

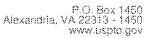
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#### DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN **APPLICATION DATA SHEET (37 CFR 1.76)**

Title of Invention	SYSTEMS AND METHODS FOR IMPROVING SLEEP WITH THE TREATMENT	RAPEUTIC NASAL
As the belo	elow named inventor, I hereby declare that:	
This declar		
	United States application or PCT international application number 17/225	5,560
The above-	e-identified application was made or authorized to be made by me.	
I believe tha	that I am the original inventor or an original joint inventor of a claimed invention in the applica	ation.
	acknowledge that any willful false statement made in this declaration is punishable under 18 imprisonment of not more than five (5) years, or both.	U.S.C. 1001
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APPLICATION # 18/647,929 RECEIPT DATE / TIME

04/26/2024 05:08:10 PM Z ET

ATTORNEY DOCKET #
NEURE-008/07US 35242/159

#### Title of Invention

SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE

#### **Application Information**

APPLICATION TYPE Utility - Nonprovisional Application under 35 USC 111(a)

PATENT #

CONFIRMATION # 9882

FILED BY Michelle Alello

PATENT CENTER # 65267075

AUTHORIZED BY Adam Schoen

CUSTOMER# 21710

FILING DATE -

CORRESPONDENCE **ADDRESS** 

INVENTOR

FIRST NAMED David Townley

#### **Payment Information**

**PAYMENT METHOD** DA / 500369

**PAYMENT TRANSACTION ID** E20244PH09187756

**PAYMENT AUTHORIZED BY** Michelle Aiello

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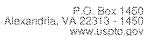
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# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

**APPLICATION #** 18/647,929 RECEIPT DATE / TIME

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ATTORNEY DOCKET # NEURE-008/07US 35242/159

### Title of Invention

SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE

## **Application Information**

APPLICATION TYPE Utility - Nonprovisional Application

under 35 USC 111(a)

PATENT# -

CONFIRMATION # 9882

FILED BY Michelle Aiello

PATENT CENTER # 65267075

FILING DATE -

CUSTOMER# 21710

FIRST NAMED **INVENTOR** 

David Townley

AUTHORIZED BY Adam Schoen

CORRESPONDENCE ADDRESS

#### **Documents**

# **TOTAL DOCUMENTS: 6**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
NEURE-008- 07US_Track_One.pdf	1	Track One Request	120 KB
NEURE-008-07US_ADS.pdf	8	Application Data Sheet	2174 KB
NEURE-008- 07US_Inventor_Dec.pdf	1	Oath or Declaration filed	133 KB
NEURE-008- 07US_Figures.pdf	23	Drawings-only black and white line drawings	6117 KB
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# SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE

#### **Cross-reference to Related Applications**

This application is a continuation of U.S. Patent Application No. 18/411,476, filed January 12, 2024, which is a continuation of U.S. Patent Application No. 17/225,560, filed April 8, 2021 (now issued as U.S. Patent No. 11,883,091), which claims the benefit of, and priority to, U.S. Provisional Patent Application No. 63/007,584, filed April 9, 2020, the contents of each of which are hereby incorporated by reference in their entireties.

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#### Field of the Invention

The invention generally relates to systems and methods for improving sleep by treating at least one of rhinitis, congestion, and/or rhinorrhea to thereby reduce or eliminate symptoms associated therewith, including, but not limited to, nasal congestion, coughing, sneezing, and nasal or throat irritation and itching.

#### **Background**

Many people suffer from breathing issues as a result of various health-related problems. For example, rhinitis is an inflammatory disease of the nose and is reported to affect up to 40% of the population. It is the fifth most common chronic disease in the United States. Allergic rhinitis accounts for up to 65% of all rhinitis patients. Allergic rhinitis is an immune response to an exposure to allergens, such as airborne plant pollens, pet dander or dust. As non-allergic rhinitis is not an immune response, its symptoms are not normally seasonal and are often more persistent.

The most common and impactful symptoms of rhinitis (both allergic and non-allergic) include a runny nose, coughing, sneezing, nasal and/or throat irritation and itching, and overall general congestion of the nasal passage. As a result, sleep problems are very common in individuals suffering from rhinitis, as such symptoms impact a person's ability to either fall asleep or remain asleep for adequate periods of time. In addition, sleep problems are linked with fatigue and daytime sleepiness, as well as decreased productivity at work or school, impaired learning and memory, depression, and a reduced quality of life.

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For example, most individuals suffering from rhinitis are unable to breathe efficiently through their nose due to restricted nasal passages, and are prone to breathe through their mouth. Studies have established that nocturnal mouth breathing is a primary cause of loud snoring, which is a precursor to sleep apnea, and sleep apnea is a precursor to heart attacks. Due to the lack of proper oxygenation, the ability to deliver fully oxygenated blood to the cells is also greatly reduced. In contrast, proper nose breathing delivers fully oxygenated blood to the body, reduces hypertension and stress, and promotes cardiovascular health. Thus, proper nose breathing is essential for one's wellbeing.

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Conventional nose breathing aids may provide relief from restricted breathing, but such relief is temporary. For example, traditional aids include nasal sprays, and various types of nasal dilators, sinus cones, nasal strips, and springs to hold nasal passages open. The disadvantage of most nose mounted dilators, particularly those mounted within the nasal cavity, is that while most of them dilate the nasal passages, the product itself becomes a new obstruction, and is most noticeable during exhalation. Upon exhalation, the user will experience the deflection of hoi breath against the apparatus. Consequently, this apparatus can become bothersome, and will generally not be worn for extended periods of time, thereby forfeiting the benefits of enhanced nose breathing.

Similarly, while allergen avoidance and pharmacotherapy are relatively effective in the majority of mild cases of rhinitis, such medications need to be taken on a long-term basis, incurring costs and side effects and often have suboptimal efficacy. For example, pharmaceutical agents prescribed for rhinosinusitis have limited efficacy and undesirable side effects, such as sedation, irritation, impairment to taste, sore throat, dry nose, and other side effects.

There are two modern surgical options: the delivery of thermal energy to the inflamed soft tissue, resulting in scarring and temporary volumetric reduction of the tissue to improve nasal airflow; and microdebrider resection of the inflamed soft tissue, resulting in the removal of tissue to improve nasal airflow. Both options address congestion as opposed to rhinorrhea and have risks ranging from bleeding and scarring to the use of general anesthetic. Accordingly, current surgical options fail to adequately address the various conditions and the associated symptoms causing breathing issues.

#### **Summary**

The invention recognizes that a problem with current aids and surgical procedures is that such products and procedures are either temporary or are not accurate and cause significant collateral damage in order to treat rhinitis and further fail to adequately treat the underlying symptoms and thus further fail to address sleeping problems.

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The invention solves that problem by providing treatment devices having a combination of unique components, including an elongate body (which may be in the form of a shaft or sheath, or other elongate body), a retractable and expandable multi-segment end effector, and handle, that, as a whole, provide a high level of precise control and feedback to an operator during a procedure. In particular, the elongate body is configured to not only aid an operator in the positioning and delivery of the multi-segment end effector to a desired target site within the nasal cavity, but further includes an electrode array provided along a length thereof that is configured to deliver energy to specific target sites within the nasal passage and nasal cavity, in conjunction with neuromodulation provided by the multi-segment end effector. The multi-segment end effector is configured to complement anatomy at multiple different locations within the nasal cavity. The handle is configured with multiple ergonomic and functional features that improve device use and feedback, such as independent control of deployment of the end effector and energy delivery and a shape associated with the architecture of the end effector in the deployed configuration. The handle may also include one or more markings that provide a user with a spatial orientation of the end effector while the end effector is in a nasal cavity.

In that manner, the present invention provides devices that are capable of highly conforming to anatomical variations within a nasal passage and nasal cavity while providing unprecedented control and guidance to an operator so that an operator can perform an accurate, minimally invasive, and localized application of energy to one or more target sites within the nasal passage and nasal cavity to cause multi-point interruption of neural signal without causing collateral damage or disruption to other neural structures.

Unlike other surgical treatments for rhinitis, the devices of the invention are minimally invasive. Accordingly, a procedure can be performed in an office environment under local anesthetic. The multi-segment end-effector allows for targeting the autonomic supply to the nasal turbinates and will have a positive impact on both allergic and non-allergic rhinitis. Using this approach, it is expected that devices of the invention will be able to provide long-term

symptom relief (e.g., years instead of months). Since the treatment is accurate with minimal collateral damage to the surrounding tissue, patients will begin to feel symptom relief immediately following the treatment. It is fully expected that patients will be removed from their pharmacotherapies following this therapy.

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The systems and methods of the present invention include a handheld device comprising a retractable and expandable multi-segment end effector that, once delivered to the one more target sites within the nasal cavity, can expand to a specific shape and/or size corresponding to anatomical structures within the nasal cavity and associated with the target sites. In particular, the end effector includes at least a first flexible segment and a second flexible segment, each of which includes a specific geometry when in a deployed configuration to complement anatomy of respective locations within the nasal cavity. Once deployed, the first and second segments contact and conform to a shape of the respective locations, including conforming to and complementing shapes of one or more anatomical structures at the respective locations. In turn, the first and second segments become accurately positioned within the nasal cavity to subsequently deliver, via one or more electrodes, precise and focused application of RF thermal energy to the one or more target sites to thereby therapeutically modulate associated neural structures. More specifically, the first and second segments have shapes and sizes when in the expanded configuration that are specifically designed to place portions of the first and second segments, and thus one or more electrodes associated therewith, into contact with target sites within nasal cavity associated with postganglionic parasympathetic fibers that innervate the nasal mucosa.

The handheld device further includes an elongate body operably associated with the end effector and a handle operably associated with the elongate body. The elongate body may be in the form of a shaft or sheath (or other elongate body operably associated with or coupled to the end effector). The elongate body may include a pre-defined shape (i.e., bent or angled at a specific orientation) so as to assist the surgeon (or other medical professional) for placement of the end effector at the target sites. The elongate body further includes one or more electrodes provided on one or respective portions along a length thereof and can be used to deliver energy to tissue adjacent to, or in contact with, such portions of the elongate body. For example, in some embodiments, the elongate body may reside with a portion of the nasal cavity proximate to the inferior turbinate upon advancing and deploying the multi-segment end effector in the

desired location (i.e., a target site associated with a sphenopalatine foramen within the nasal cavity of the patient). Accordingly, in addition to delivering energy from the electrodes of the multi-segment end effector, the surgeon may also activate and deliver energy from electrodes associated with the elongate body to tissue associated with the inferior turbinate. Such energy may be delivered at a level sufficient to reduce engorgement of tissue associated with the inferior turbinate to thereby increase volumetric flow through a nasal passage of the patient and improve a patient's ability to breathe.

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Accordingly, the treatment device of the present invention recognizes the desire or need to treat larger areas within the nasal cavity or passage that are located outside of a treatment zone associated with the end effector. For example, when performing surgical procedures using current rhinitis treatment devices, the surgeon must reposition an end effector when attempting to treat multiple areas within the nasal cavity, particularly those areas that are located outside of any given treatment zone. The need to reposition the end effector multiple times during a given procedure can lead to inaccuracy when delivering energy, resulting in unintended collateral damage, and further increases the time in which it takes to complete a given procedure. The treatment device of the present invention recognizes and addresses this problem by providing an elongate body including one or more electrodes thereon, in addition to a multi-segment end effector operably associated with the elongate body and including separate electrodes thereon. Accordingly, the elongate body serves to not only aid in positioning and delivering the end effector to a desired target site (to which the end effector may deliver energy), but the elongate body can also deliver energy to a target site that is separate and remote from the end effector. Such a design improves the efficiency with which a given procedure can be accomplished, particularly those procedures requiring treatment to multiple, separate areas within the nasal cavity or passage.

The handle includes an ergonomically-designed grip portion which provides ambidextrous use for both left and right handed use and conforms to hand anthropometrics to allow for at least one of an overhand grip style and an underhand grip style during use in a procedure. The handle further includes multiple user-operated mechanisms, including at least a first mechanism for deployment of the end effector from the retracted configuration to the expanded deployed configuration and a second mechanism for controlling of energy output by the end effector. The user inputs for the first and second mechanisms are positioned a sufficient

distance to one another to allow for simultaneous one-handed operation of both user inputs during a procedure. Accordingly, the handle accommodates various styles of grip and provides a degree of comfort for the surgeon, thereby further improving execution of the procedure and overall outcome. Furthermore, the handle and/or the elongate body may include markings (e.g., text, symbols, color-coding insignia, etc.) that provide a surgeon with a spatial orientation of the end effector while the end effector is in a nasal cavity. In particular, multiple markings may be provided on the handle and/or elongate body and provide a visual indication of the spatial orientation of one or more portions of the first segment and second segment of the end effector when in the deployed configurations. Thus, during initial placement of the end effector, when in a retracted configuration and enclosed within the elongate body, a surgeon can rely on the markings on the handle and/or elongate body as a visual indication of the spatial orientation of the end effector (e.g., linear, axial, and/or depth position) prior to deployment to thereby ensure that, once deployed, the end effector, including both the first and second segments, are positioned in the intended locations within the nasal cavity.

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Accordingly, the handheld device of the present invention provides a surgeon with a user-friendly, non-invasive, and precise means for treating rhinorrhea and other symptoms of rhinosinusitis, notably nasal congestion, coughing, sneezing, and nasal and throat irritation, to thereby improve a patient's sleep (i.e., improve a patient's nasal breathability to increase chances of successfully falling asleep and remaining asleep for adequate periods of time). By improving one's sleep, the systems and methods of the present invention can further improve one's overall quality of life by reducing the subsequent issues commonly associated with poor sleep, such as fatigue and daytime sleepiness, as well as decreased productivity at work or school, impaired learning and memory, and depression.

The handheld device provides for the precise and focused application of energy to the intended target sites for therapeutic modulation of the intended structures, including, but not limited to, engorged sub-mucosal tissue as well as neural structures without causing collateral and unintended damage or disruption to other structures. In particular, by targeting only those specific structures associated with such conditions, notably tissue responsible for providing engorgement of certain structures (i.e., inferior and middle turbinates) and postganglionic parasympathetic nerves innervating nasal mucosa, thereby reducing engorgement of inferior turbinate tissue to thereby increase volumetric flow through a nasal passage of the patient as well

as disrupting the parasympathetic nerve supply and interrupting parasympathetic tone. The device further allows for treatment of multiple areas within the nasal passage and/or nasal cavity that would normally require repositioning of an end effector due to their separated locations. In particular, inclusion of an elongate body with a dedicated set of electrodes, in addition to the multi-segment end effector with its own set of electrodes, allows for two separate target sites to receive treatment simultaneously, thereby reducing the need to reposition the end effector. Accordingly, such treatment is effective at treating rhinosinusitis conditions while greatly reducing the risk of causing lateral damage or disruption to other tissues, including other nerve fibers, thereby reducing the likelihood of unintended complications and side effects.

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One aspect of the invention provides a method for improving a patient's sleep by treating at least one of rhinitis, congestion, and rhinorrhea within a sino-nasal cavity of the patient. The method includes delivering energy to one or more target sites within a sino-nasal cavity of the patient to disrupt multiple neural signals to, and/or result in local hypoxia of, mucus producing and/or mucosal engorgement elements, thereby reducing production of mucus and/or mucosal engorgement within a nose of the patient and reducing or eliminate one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea to improve nasal breathability of the patient. The one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea are selected from the group consisting of nasal congestion, coughing, sneezing, and nasal or throat irritation and itching.

In some embodiments, the step of delivering energy results in ablation of targeted tissue at one or more locations to thereby disrupt the multiple neural signals to the mucus producing and/or mucosal engorgement elements within the nose. For example, the targeted tissue may be associated with one or more target sites proximate or inferior to a sphenopalatine foramen. The energy may be delivered at a level sufficient to therapeutically modulate postganglionic parasympathetic nerves innervating nasal mucosa at foramina and or microforamina of a palatine bone of the patient. As a result, the energy delivered may cause multiple points of interruption of neural branches extending through foramina and microforamina of palatine bone.

In some embodiments, the step of delivering energy results in ablation of targeted tissue at one or more locations to thereby result in local hypoxia of the mucus producing and/or mucosal engorgement elements within the nose. For example, in some embodiments, the ablation of targeted tissue may cause thrombus formation within one or more blood vessels

associated with mucus producing and/or mucosal engorgement elements within the nose. As such, the resulting local hypoxia of the mucus producing and/or mucosal engorgement elements may result in decreased mucosal engorgement to thereby increase volumetric flow through a nasal passage of the patient.

In some embodiments, the ablation is thermal ablation. The thermal ablation may include cyro-ablation, for example. In other embodiments, the ablation may be caused by delivery of radiofrequency (RF) energy.

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In some embodiments, the ablation may be caused by a treatment device comprising a handle, an elongate body extending therefrom, and a retractable and expandable end effector operably associated with the elongate body. Accordingly, during a procedure, the method may include advancing the end effector into the sino-nasal cavity under image guidance. The handle may generally control transformation of the end effector from a retracted state to an expanded state. The end effector may include a plurality of energy delivery elements provided thereon, such as electrodes, for example.

When in the expanded state, the end effector may generally position one or more of the plurality of energy delivery elements relative to the one or more target sites. In some embodiments, the end effector includes a proximal segment that is spaced apart from a separate distal segment. In some embodiments, the proximal segment may include a first set of flexible support elements arranged in a deployed configuration to fit around at least a portion of a middle turbinate at an anterior position relative to a lateral attachment and a posterior-inferior edge of the middle turbinate and position one or more energy delivery elements into contact with one or more respective tissue locations associated with the middle turbinate and the distal segment may include a second set of flexible support elements configured in a deployed configuration to position one or more energy delivery elements into contact with one or more respective tissue locations in a cavity at a posterior position relative to the lateral attachment and posterior-inferior edge of the middle turbinate.

In some embodiments, the elongate body may include a shaft to which the end effector is coupled. The shaft includes an outer sheath surrounding a hypotube or metallic member, wherein at least one of the outer sheath and hypotube and metallic member includes the one or more energy delivering elements provided thereon. Yet still, in other embodiments, the elongate body may include one or more of a plurality of support elements forming at least a portion of the

end effector. The energy delivering elements of the elongate body may be configured to deliver energy at one or more target sites associated with an inferior or middle turbinate within the sinonasal cavity of the patient at a level sufficient to reduce engorgement of tissue associated therewith to thereby increase volumetric flow through a nasal passage of the patient.

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#### **Brief Description of the Drawings**

FIGS. 1A and 1B are diagrammatic illustrations of a therapeutic neuromodulation system for treating a condition within a nasal cavity using a handheld device according to some embodiments of the present disclosure.

- FIG. 2 is a diagrammatic illustration of the console coupled to the handheld neuromodulation device consistent with the present disclosure, further illustrating a multi-segment end effector of the handheld device for delivering energy, via proximal and distal segments, to tissue at the one or more target sites within the nasal cavity.
  - FIG. 3A is a cut-away side view illustrating the anatomy of a lateral nasal wall.
  - FIG. 3B is an enlarged side view of the nerves of the lateral nasal wall of FIG. 1A.
- FIG. 3C is a front view of a left palatine bone illustrating geometry of microforamina in the left palatine bone.
- FIG. 4 is a side view of one embodiment of a handheld device for providing therapeutic nasal neuromodulation consistent with the present disclosure.
- FIG. 5A is an enlarged, perspective view of the multi-segment end effector illustrating the first (proximal) segment and second (distal) segment.
  - FIG. 5B is an exploded, perspective view of the multi-segment end effector.
  - FIG. 5C is an enlarged, top view of the multi-segment end effector.
  - FIG. 5D is an enlarged, side view of the multi-segment end effector.
- FIG. 5E is an enlarged, front (proximal facing) view of the first (proximal) segment of the multi-segment end effector.
  - FIG. 5F is an enlarged, front (proximal facing) view of the second (distal) segment of the multi-segment end effector.
- FIG. 6 is a perspective view, partly in section, of a portion of a support element illustrating an exposed conductive wire serving as an energy delivery element or electrode element.

- FIG. 7 is a cross-sectional view of a portion of the shaft of the handheld device taken along lines 7-7 of FIG. 4.
- FIG. 7A is a side view of the shaft and multi-segment end effector extending from a distal end thereof, further illustrating a plurality of electrodes provided on separate respective portions of the shaft.
- FIG. 7B is a sectional view of the shaft illustrating one embodiment in which a plurality of electrodes are embedded within the outer sheath of the shaft.
- FIG. 7C is a sectional view of the shaft illustrating another embodiment in which a plurality of electrodes are provided on the hypotube and associated portions of the outer sheath are absent or removed to thereby expose the underlying electrodes on the hypotube.
- FIG. 7D is a perspective view of a length of the shaft illustrating exposed portions of the outer sheath to reveal the underlying electrodes provided on the hypotube.
- FIG. 7E is a sectional view of the shaft illustrating another embodiment in which a plurality of electrodes are provided on one or more support elements extending through the hypotube, portions of which form the end effector.
- FIG. 7F is an enlarged, perspective view of the multi-segment end effector extending from the shaft and illustrating the plurality of electrodes provided on the support elements.
- FIG. 7G is a cross-sectional view of the shaft illustrating exemplary portions of the shaft that are retractable and expandable.
- FIG. 8 is a side view of the handle of the handheld device.

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- FIG. 9 is a side view of the handle illustrating internal components enclosed within.
- FIG. 10 is a side view of the handle illustrating multiple markings on a portion of the handle for providing a user with a spatial orientation of the end effector while the end effector is in a nasal cavity.
- FIG. 11 is a perspective view of the shaft illustrating multiple markings on a distal portion thereof for providing a user with a spatial orientation of the end effector while the end effector is in a nasal cavity.
  - FIG. 12 is a partial cut-away side views illustrating one approach for delivering a shaft and an associated end effector to respective target sites within a nasal region in accordance with embodiments of the present disclosure.

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FIG. 13 is a flow diagram illustrating one embodiment of a method for treating a condition within a nasal cavity of a patient.

- FIG. 14 is a flow diagram illustrating another embodiment of a method for treating a condition within a nasal cavity of a patient.
- 5 FIG. 15 is a flow diagram illustrating another embodiment of a method for treating a condition within a nasal cavity of a patient.
  - FIG. 16 is a flow diagram illustrating another embodiment of a method for treating a condition within a sino-nasal cavity of a patient.
- FIG. 17 is a flow diagram illustrating an embodiment of a method for improving a patient's sleep by treating at least one of rhinitis, congestion, and rhinorrhea within a sino-nasal cavity of the patient.

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#### **Detailed Description**

There are various conditions related to the nasal cavity which may impact breathing and other functions of the nose. One of the more common conditions is rhinitis, which is defined as inflammation of the membranes lining the nose. The symptoms of rhinitis include nasal blockage, obstruction, congestion, nasal discharge (e.g., rhinorrhea and/or posterior nasal drip), facial pain, facial pressure, and/or reduction or complete loss of smell and/or taste. Sinusitis is another common condition, which involves an inflammation or swelling of the tissue lining the sinuses, and results in similar symptoms as rhinitis, and may further lead to infection if left untreated or if it persists for prolonged periods of time. Rhinitis and sinusitis are frequently associated with one another, as sinusitis is often preceded by rhinitis. Accordingly, the term rhinosinusitis is often used to describe both conditions.

As a result of such symptoms, many who suffer from rhinosinusitis also have sleeping difficulties (i.e., difficulty falling asleep and/or remaining asleep). Sleep is a vital component of a person's overall health and well-being. Studies have shown that sleep problems are linked with fatigue and daytime sleepiness, as well as decreased productivity at work or school, impaired learning and memory, depression, and a reduced quality of life.

Depending on the duration and type of systems, rhinosinusitis can fall within different subtypes, including allergic rhinitis, non-allergic rhinitis, chronic rhinitis, acute rhinitis, recurrent rhinitis, chronic sinusitis, acute sinusitis, recurrent sinusitis, and medical resistant rhinitis and/or

sinusitis, in addition to combinations of one or more of the preceding conditions. It should be noted that an acute rhinosinusitis condition is one in which symptoms last for less than twelve weeks, whereas a chronic rhinosinusitis condition refers to symptoms lasting longer than twelve weeks.

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A recurrent rhinosinusitis condition refers to four or more episodes of an acute rhinosinusitis condition within a twelve-month period, with resolution of symptoms between each episode. There are numerous environmental and biological causes of rhinosinusitis. Non-allergic rhinosinusitis, for example, can be caused by environmental irritants, medications, foods, hormonal changes, and/or nasal septum deviation. Triggers of allergic rhinitis can include exposure to seasonal allergens, perennial allergens that occur any time of year, and/or occupational allergens. Accordingly, rhinosinusitis affects millions of people and is a leading cause for patients to seek medical care.

The invention recognizes that a problem with current aids and surgical procedures is that such products and procedures are either temporary or are not accurate and cause significant collateral damage in order to treat rhinitis and further fail to adequately treat the underlying symptoms and thus further fail to address sleeping problems.

The invention solves that problem by providing treatment devices having a combination of unique components, including an elongate body (which may be in the form of a shaft or sheath, or other elongate body), a retractable and expandable multi-segment end effector, and handle, that, as a whole, provide a high level of precise control and feedback to an operator during a procedure. In particular, the elongate body is configured to not only aid an operator in the positioning and delivery of the multi-segment end effector to a desired target site within the nasal cavity, but further includes an electrode array provided along a length thereof that is configured to deliver energy to specific target sites within the nasal passage and nasal cavity, in conjunction with neuromodulation provided by the multi-segment end effector. The multi-segment end effector is configured to complement anatomy at multiple different locations within the nasal cavity. The handle is configured with multiple ergonomic and functional features that improve device use and feedback, such as independent control of deployment of the end effector and energy delivery and a shape associated with the architecture of the end effector in the deployed configuration. The handle may also include one or more markings that provide a user with a spatial orientation of the end effector while the end effector is in a nasal cavity.

In that manner, the present invention provides devices that are capable of highly conforming to anatomical variations within a nasal passage and nasal cavity while providing unprecedented control and guidance to an operator so that an operator can perform an accurate, minimally invasive, and localized application of energy to one or more target sites within the nasal passage and nasal cavity to cause multi-point interruption of neural signal without causing collateral damage or disruption to other neural structures.

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Unlike other surgical treatments for rhinitis, the devices of the invention are minimally invasive. Accordingly, a procedure can be performed in an office environment under local anesthetic. The multi-segment end-effector allows for targeting the autonomic supply to the nasal turbinates and will have a positive impact on both allergic and non-allergic rhinitis. Using this approach, it is expected that devices of the invention will be able to provide long-term symptom relief (e.g., years instead of months). Since the treatment is accurate with minimal collateral damage to the surrounding tissue, patients will begin to feel symptom relief immediately following the treatment. It is fully expected that patients will be removed from their pharmacotherapies following this therapy.

The treatment devices of the present invention provides a surgeon with a user-friendly, non-invasive, and precise means for treating rhinorrhea and other symptoms of rhinosinusitis, notably nasal congestion, coughing, sneezing, and nasal and throat irritation, to thereby improve a patient's sleep (i.e., improve a patient's nasal breathability to increase chances of successfully falling asleep and remaining asleep for adequate periods of time). By improving one's sleep, the systems and methods of the present invention can further improve one's overall quality of life by reducing the subsequent issues commonly associated with poor sleep, such as fatigue and daytime sleepiness, as well as decreased productivity at work or school, impaired learning and memory, and depression.

The treatment devices provide for the precise and focused application of energy to the intended target sites for therapeutic modulation of the intended structures, including, but not limited to, engorged sub-mucosal tissue as well as neural structures without causing collateral and unintended damage or disruption to other structures. In particular, by targeting only those specific structures associated with such conditions, notably tissue responsible for providing engorgement of certain structures (i.e., inferior and middle turbinates) and postganglionic parasympathetic nerves innervating nasal mucosa, thereby reducing engorgement of inferior

turbinate tissue to thereby increase volumetric flow through a nasal passage of the patient as well as disrupting the parasympathetic nerve supply and interrupting parasympathetic tone. The device further allows for treatment of multiple areas within the nasal passage and/or nasal cavity that would normally require repositioning of an end effector due to their separated locations. In particular, inclusion of an elongate body with a dedicated set of electrodes, in addition to the multi-segment end effector with its own set of electrodes, allows for two separate target sites to receive treatment simultaneously, thereby reducing the need to reposition the end effector. Accordingly, such treatment is effective at treating rhinosinusitis conditions while greatly reducing the risk of causing lateral damage or disruption to other tissues, including other nerve fibers, thereby reducing the likelihood of unintended complications and side effects.

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For example, the systems and methods of the present invention include a handheld device comprising a retractable and expandable multi-segment end effector that, once delivered to the one more target sites within the nasal cavity, can expand to a specific shape and/or size corresponding to anatomical structures within the nasal cavity and associated with the target sites. In particular, the end effector includes at least a first flexible segment and a second flexible segment, each of which includes a specific geometry when in a deployed configuration to complement anatomy of respective locations within the nasal cavity. Once deployed, the first and second segments contact and conform to a shape of the respective locations, including conforming to and complementing shapes of one or more anatomical structures at the respective locations. In turn, the first and second segments become accurately positioned within the nasal cavity to subsequently deliver, via one or more electrodes, precise and focused application of RF thermal energy to the one or more target sites to thereby therapeutically modulate associated neural structures. More specifically, the first and second segments have shapes and sizes when in the expanded configuration that are specifically designed to place portions of the first and second segments, and thus one or more electrodes associated therewith, into contact with target sites within nasal cavity associated with postganglionic parasympathetic fibers that innervate the nasal mucosa.

The handheld device further includes an elongate body operably associated with the end effector and a handle operably associated with the elongate body. The elongate body may be in the form of a shaft or sheath (or other elongate body operably associated with or coupled to the end effector). The elongate body may include a pre-defined shape (i.e., bent or angled at a

specific orientation) so as to assist the surgeon (or other medical professional) for placement of the end effector at the target sites. The elongate body further includes one or more electrodes provided on one or respective portions along a length thereof and can be used to deliver energy to tissue adjacent to, or in contact with, such portions of the elongate body. For example, in some embodiments, the elongate body may reside with a portion of the nasal cavity proximate to the inferior turbinate upon advancing and deploying the multi-segment end effector in the desired location (i.e., a target site associated with a sphenopalatine foramen within the nasal cavity of the patient). Accordingly, in addition to delivering energy from the electrodes of the multi-segment end effector, the surgeon may also activate and deliver energy from electrodes associated with the elongate body to tissue associated with the inferior turbinate. Such energy may be delivered at a level sufficient to reduce engorgement of tissue associated with the inferior turbinate to thereby increase volumetric flow through a nasal passage of the patient and improve a patient's ability to breathe.

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Accordingly, the treatment device of the present invention recognizes the desire or need to treat larger areas within the nasal cavity or passage that are located outside of a treatment zone associated with the end effector. For example, when performing surgical procedures using current rhinitis treatment devices, the surgeon must reposition an end effector when attempting to treat multiple areas within the nasal cavity, particularly those areas that are located outside of any given treatment zone. The need to reposition the end effector multiple times during a given procedure can lead to inaccuracy when delivering energy, resulting in unintended collateral damage, and further increases the time in which it takes to complete a given procedure. The treatment device of the present invention recognizes and addresses this problem by providing an elongate body including one or more electrodes thereon, in addition to a multi-segment end effector operably associated with the elongate body and including separate electrodes thereon. Accordingly, the elongate body serves to not only aid in positioning and delivering the end effector to a desired target site (to which the end effector may deliver energy), but the elongate body can also deliver energy to a target site that is separate and remote from the end effector. Such a design improves the efficiency with which a given procedure can be accomplished, particularly those procedures requiring treatment to multiple, separate areas within the nasal cavity or passage.

It should be noted that, although many of the embodiments are described with respect to

devices, systems, and methods for therapeutically modulating tissue (neural and/or non-neural tissue) in the nasal region for the treatment of rhinitis, congestion, and/or rhinorrhea, other applications and other embodiments in addition to those described herein are within the scope of the present disclosure. For example, at least some embodiments of the present disclosure may be useful for the treatment of other indications, such as the treatment of chronic sinusitis and epistaxis. In particular, the embodiments described herein may be configured to treat allergic rhinitis, non-allergic rhinitis, chronic rhinitis, acute rhinitis, chronic sinusitis, acute sinusitis, chronic rhinosinusitis, acute rhinosinusitis, and/or medical resistant rhinitis.

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It should further be noted that the devices described herein, most notably the elongate body (which may be in the form of a shaft, outer sheath, hypotube, or other elongate body that is operably associated with the end effector) may be included and incorporated in any of the treatment devices, systems, and methods illustrated and described in U.S. Publication Nos.: 2016/0331459; 2018/0133460; 2017/0231651; 2017/0252089; 2018/0177542; 2018/0177546; 2018/0185085; 2018/0228533; 2018/0317997; 2018/0344378; 2019/0076185; 2019/0175242; 2019/0201069; 2019/0231409; 2019/0282289; 2016/0354136; 2017/0231474; 2018/0078327; 2018/0103994; 2018/0125560; 2018/0153375; 2018/0317993; 2018/0344411; and 2019/0083157, as well as U.S. Patent Nos.: 8,936,594; 8,986,301; 9,072,597; 9,179,964; 9,179,967; 9,237,924; 9,415,194; 9,433,463; 9,452,010; 9,486,278; 9,526,571; 9,687,296; 9,788,886; 9,801,752; 9,888,957; 9,913,682; 9,943,361; 10,028,780; 10,265,115; 10,335,221; 10,376,300; 10,398,489; 10,456,185; 10,456,186; 10,485,603; 7,758,571; 9,687,288; 9,763,723; 9,763,743; 10,028,781; 10,159,538; 10,201,687; 10,307,200; and 10,448,985, the contents of each of which are incorporated by reference herein in their entireties.

FIGS. 1A and 1B are diagrammatic illustrations of a therapeutic neuromodulation system 100 for treating a condition within a nasal cavity using a handheld device 102 according to some embodiments of the present disclosure. The system 100 generally includes a neuromodulation device 102 and a neuromodulation console 104 to which the device 102 is to be connected. FIG. 2 is a diagrammatic illustration of the console 104 coupled to the handheld neuromodulation device 102. As illustrated, the neuromodulation device 102 is a handheld device, which includes a retractable and expandable multi-segment end effector 114, a shaft 116 operably associated with the end effector 114 and a handle 118 operably associated with the shaft 116. The end effector 114 is configured to be advanced into the nasal cavity of a patient 12 and positioned at a

location associated with one or more target sites to undergo therapeutic neuromodulation treatment. It should be noted that the terms "end effector" and "therapeutic assembly" may be used interchangeably throughout this disclosure.

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For example, a surgeon or other medical professional performing a procedure can utilize the handle 118 to manipulate and advance the shaft 116 within the nasal cavity, wherein the shaft 116 is configured to locate at least a distal portion thereof intraluminally at a treatment or target site within a nasal region. The one or more target sites may generally be associated with postganglionic parasympathetic fibers that innervate the nasal mucosa. The target site may be a region, volume, or area in which the target nerves are located and may differ in size and shape depending upon the anatomy of the patient. Once positioned, the end effector 114 may be deployed and subsequently deliver energy to the one or more target sites to thereby therapeutically modulating nerves of interest, particularly nerves associated with a rhinosinusitis condition so as to treat such condition. For example, the end effector 114 may include at least one energy delivery element, such as an electrode, configured to the apeutically modulate the postganglionic parasympathetic nerves. For example, one or more electrodes may be provided by one or more portions of the end-effector 114, wherein the electrodes may be configured to apply electromagnetic neuromodulation energy (e.g., radiofrequency (RF) energy) to target sites. In other embodiments, the end effector 114 may include other energy delivery elements configured to provide therapeutic neuromodulation using various other modalities, such as cryotherapeutic cooling, ultrasound energy (e.g., high intensity focused ultrasound ("HIFU") energy), microwave energy (e.g., via a microwave antenna), direct heating, high and/or low power laser energy, mechanical vibration, and/or optical power.

In some embodiments, the end effector 114 may include one or more sensors (not shown), such as one or more temperature sensors (e.g., thermocouples, thermistors, etc.), impedance sensors, and/or other sensors. The sensors and/or the electrodes may be connected to one or more wires extending through the shaft 116 and configured to transmit signals to and from the sensors and/or convey energy to the electrodes.

As shown, the device 102 is operatively coupled to the console 104 via a wired connection, such as cable 120. It should be noted, however, that the device 102 and console 104 may be operatively coupled to one another via a wireless connection. The console 104 is configured to provide various functions for the neuromodulation device 102, which may include,

but is not limited to, controlling, monitoring, supplying, and/or otherwise supporting operation of the neuromodulation device 102. For example, when the neuromodulation device 102 is configured for electrode-based, heat-element-based, and/or transducer-based treatment, the console 104 may include an energy generator 106 configured to generate RF energy (e.g., monopolar, bipolar, or multi-polar RF energy), pulsed electrical energy, microwave energy, optical energy, ultrasound energy (e.g., intraluminally-delivered ultrasound and/or HIFU), direct heat energy, radiation (e.g., infrared, visible, and/or gamma radiation), and/or another suitable type of energy.

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In some embodiments, the console 104 may include a controller 107 communicatively coupled to the neuromodulation device 102. However, in the embodiments described herein, the controller 107 may generally be carried by and provided within the handle 118 of the neuromodulation device 102. The controller 107 is configured to initiate, terminate, and/or adjust operation of one or more electrodes provided by the end effector 114 directly and/or via the console 104. For example, the controller 107 can be configured to execute an automated control algorithm and/or to receive control instructions from an operator (e.g., surgeon or other medical professional or clinician). For example, the controller 107 and/or other components of the console 104 (e.g., processors, memory, etc.) can include a computer-readable medium carrying instructions, which when executed by the controller 107, causes the device 102 to perform certain functions (e.g., apply energy in a specific manner, detect impedance, detect temperature, detect nerve locations or anatomical structures, etc.). A memory includes one or more of various hardware devices for volatile and non-volatile storage, and can include both read-only and writable memory. For example, a memory can comprise random access memory (RAM), CPU registers, read-only memory (ROM), and writable non-volatile memory, such as flash memory, hard drives, floppy disks, CDs, DVDs, magnetic storage devices, tape drives, device buffers, and so forth. A memory is not a propagating signal divorced from underlying hardware; a memory is thus non-transitory.

The console 104 may further be configured to provide feedback to an operator before, during, and/or after a treatment procedure via evaluation/feedback algorithms 110. For example, the evaluation/feedback algorithms 110 can be configured to provide information associated with the temperature of the tissue at the treatment site, the location of nerves at the treatment site, and/or the effect of the therapeutic neuromodulation on the nerves at the treatment site. In

certain embodiments, the evaluation/feedback algorithm 110 can include features to confirm efficacy of the treatment and/or enhance the desired performance of the system 100. For example, the evaluation/feedback algorithm 110, in conjunction with the controller 107, can be configured to monitor temperature at the treatment site during therapy and automatically shut off the energy delivery when the temperature reaches a predetermined maximum (e.g., when applying RF energy) or predetermined minimum (e.g., when applying cryotherapy). In other embodiments, the evaluation/feedback algorithm 110, in conjunction with the controller 107, can be configured to automatically terminate treatment after a predetermined maximum time, a predetermined maximum impedance rise of the targeted tissue (i.e., in comparison to a baseline impedance measurement), a predetermined maximum impedance of the targeted tissue), and/or other threshold values for biomarkers associated with autonomic function. This and other information associated with the operation of the system 100 can be communicated to the operator via a graphical user interface (GUI) 112 provided via a display on the console 104 and/or a separate display (not shown) communicatively coupled to the console 104, such as a tablet or monitor. The GUI 112 may generally provide operational instructions for the procedure, such as directing the operator to select which nasal cavity to treat, indicating when the device 102 is primed and ready to perform treatment, and further providing status of therapy during the procedure, including indicating when the treatment is complete.

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For example, in some embodiments, the end effector 114and/or other portions of the system 100 can be configured to detect various parameters of the heterogeneous tissue at the target site to determine the anatomy at the target site (e.g., tissue types, tissue locations, vasculature, bone structures, foramen, sinuses, etc.), locate nerves and/or other structures, and allow for neural mapping. For example, the end effector 114 may be configured to detect impedance, dielectric properties, temperature, and/or other properties that indicate the presence of neural fibers in the target region. As shown in FIG. 1, the console 104 may further include a monitoring system 108 configured to receive detected electrical and/or thermal measurements of tissue at the target site taken by the end effector 114, specifically sensed by appropriate sensors (e.g., temperature sensors and/or impedance sensors), and process this information to identify the presence of nerves, the location of nerves, and/or neural activity at the target site. The nerve monitoring system 108 can be operably coupled to the electrodes and/or other features of the end effector 102 via signal wires (e.g., copper wires) that extend through the cable 120 and through

the length of the shaft 116. In other embodiments, the end effector 114 can be communicatively coupled to the nerve monitoring system 108 using other suitable communication means.

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The nerve monitoring system 108 can determine neural locations and activity before therapeutic neuromodulation to determine precise treatment regions corresponding to the positions of the desired nerves, during treatment to determine the effect of the therapeutic neuromodulation, and/or after treatment to evaluate whether the therapeutic neuromodulation treated the target nerves to a desired degree. This information can be used to make various determinations related to the nerves proximate to the target site, such as whether the target site is suitable for neuromodulation. In addition, the nerve monitoring system 108 can also compare the detected neural locations and/or activity before and after therapeutic neuromodulation, and compare the change in neural activity to a predetermined threshold to assess whether the application of therapeutic neuromodulation was effective across the treatment site. For example, the nerve monitoring system 108 can further determine electroneurogram (ENG) signals based on recordings of electrical activity of neurons taken by the end effector 114 before and after therapeutic neuromodulation. Statistically meaningful (e.g., measurable or noticeable) decreases in the ENG signal(s) taken after neuromodulation can serve as an indicator that the nerves were sufficiently ablated. Additional features and functions of the nerve monitoring system 108, as well as other functions of the various components of the console 104, including the evaluation/feedback algorithms 110 for providing real-time feedback capabilities for ensuring optimal therapy for a given treatment is administered, are described in at least U.S. Publication No. 2016/0331459 and U.S. Publication No. 2018/0133460, the contents of each of which are incorporated by reference herein in their entireties.

As will be described in greater detail herein, the neuromodulation device 102 provides access to target sites deep within the nasal region, such as at the immediate entrance of parasympathetic fibers into the nasal cavity to therapeutically modulate autonomic activity within the nasal cavity. In certain embodiments, for example, the neuromodulation device 102 can position the end effector 114 into contact with target sites within nasal cavity associated with postganglionic parasympathetic fibers that innervate the nasal mucosa.

FIG. 3A is a cut-away side view illustrating the anatomy of a lateral nasal wall and FIG. 3B is an enlarged side view of the nerves of the lateral nasal wall of FIG. 1A. The sphenopalatine foramen (SPF) is an opening or conduit defined by the palatine bone and the

sphenoid bone through which the sphenopalatine vessels and the posterior superior nasal nerves travel into the nasal cavity. More specifically, the orbital and sphenoidal processes of the perpendicular plate of the palatine bone define the sphenopalatine notch, which is converted into the SPF by the articulation with the surface of the body of the sphenoid bone.

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The location of the SPF is highly variable within the posterior region of the lateral nasal cavity, which makes it difficult to visually locate the SPF. Typically, the SPF is located in the middle meatus (MM). However, anatomical variations also result in the SPF being located in the superior meatus (SM) or at the transition of the superior and middle meatuses. In certain individuals, for example, the inferior border of the SPF has been measured at about 19 mm above the horizontal plate of the palatine bone (i.e., the nasal sill), which is about 13 mm above the horizontal lamina of the inferior turbinate (IT) and the average distance from the nasal sill to the SPF is about 64.4 mm, resulting in an angle of approach from the nasal sill to the SPA of about 11.4°. However, studies to measure the precise location of the SPF are of limited practical application due to the wide variation of its location.

The anatomical variations of the SPF are expected to correspond to alterations of the autonomic and vascular pathways traversing into the nasal cavity. In general, it is thought that the posterior nasal nerves (also referred to as lateral posterior superior nasal nerves) branch from the pterygopalatine ganglion (PPG), which is also referred to as the sphenopalatine ganglion, through the SPF to enter the lateral nasal wall of the nasal cavity, and the sphenopalatine artery passes from the pterygopalatine fossa through the SPF on the lateral nasal wall. The sphenopalatine artery branches into two main portions: the posterior lateral nasal branch and the posterior septal branch. The main branch of the posterior lateral nasal artery travels inferiorly into the inferior turbinate IT (e.g., between about 1.0 mm and 1.5 mm from the posterior tip of the inferior turbinate IT), while another branch enters the middle turbinate MT and branches anteriorly and posteriorly.

Beyond the SPF, studies have shown that over 30% of human patients have one or more accessory foramen that also carries arteries and nerves into the nasal cavity. The accessory foramen are typically smaller than the SPF and positioned inferior to the SPF. For example, there can be one, two, three or more branches of the posterior nasal artery and posterior nasal nerves that extend through corresponding accessory foramen. The variability in location, size, and quantity associated with the accessory foramen and the associated branching arteries and

nerves that travel through the accessory foramen gives rise to a great deal of uncertainty regarding the positions of the vasculature and nerves of the sphenopalatine region. Furthermore, the natural anatomy extending from the SPF often includes deep inferior and/or superior grooves that carry neural and arterial pathways, which make it difficult to locate arterial and neural branches. For example the grooves can extend more than 5 mm long, more than 2 mm wide, and more than 1 mm deep, thereby creating a path significant enough to carry both arteries and nerves. The variations caused by the grooves and the accessory foramen in the sphenopalatine region make locating and accessing the arteries and nerves (positioned posterior to the arteries) extremely difficult for surgeons.

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Recent microanatomic dissection of the pterygopalatine fossa (PPF) have further evidenced the highly variable anatomy of the region surrounding the SPF, showing that a multiplicity of efferent rami that project from the pterygopalatine ganglion (PPG) to innervate the orbit and nasal mucosa via numerous groups of small nerve fascicles, rather than an individual postganglionic autonomic nerves (e.g., the posterior nasal nerve). Studies have shown that at least 87% of humans have microforamina and micro rami in the palatine bone.

FIG. 3C, for example, is a front view of a left palatine bone illustrating geometry of microforamina and micro rami in a left palatine bone. In FIG. 3C, the solid regions represent nerves traversing directly through the palatine bone, and the open circles represent nerves that were associated with distinct microforamina. As such, FIG. 3C illustrates that a medial portion of the palatine bone can include at least 25 accessory posterolateral nerves.

The respiratory portion of the nasal cavity mucosa is composed of a type of ciliated pseudostratified columnar epithelium with a basement membrane. Nasal secretions (e.g., mucus) are secreted by goblet cells, submucosal glands, and transudate from plasma. Nasal seromucous glands and blood vessels are highly regulated by parasympathetic innervation deriving from the vidian and other nerves. Parasympathetic (cholinergic) stimulation through acetylcholine and vasoactive intestinal peptide generally results in mucus production. Accordingly, the parasympathetic innervation of the mucosa is primarily responsible submucosal gland activation/hyper activation, venous engorgement (e.g., congestion), and increased blood flow to the blood vessels lining the nose. Accordingly, severing or modulating the parasympathetic pathways that innervate the mucosa are expected to reduce or eliminate the hyper activation of

the submucosal glands and engorgement of vessels that cause symptoms associated with rhinosinusitis and other indications.

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As previously described herein, postganglionic parasympathetic fibers that innervate the nasal mucosa (i.e., posterior superior nasal nerves) were thought to travel exclusively through the SPF as a sphenopalatine neurovascular bundle. The posterior nasal nerves are branches of the maxillary nerve that innervate the nasal cavity via a number of smaller medial and lateral branches extending through the mucosa of the superior and middle turbinates ST, MT (i.e., nasal conchae) and to the nasal septum. The nasopalatine nerve is generally the largest of the medial posterior superior nasal nerves, and it passes anteroinferiorly in a groove on the vomer to the floor of the nasal cavity. From here, the nasopalatine nerve passes through the incisive fossa of the hard palate and communicates with the greater palatine nerve to supply the mucosa of the hard palate. The posterior superior nasal nerves pass through the pterygopalatine ganglion PPG without synapsing and onto the maxillary nerve via its ganglionic branches.

Based on the understanding that the posterior nasal nerves exclusively traverse the SPF to innervate the nasal mucosa, surgeries have been performed to selectively sever the posterior nasal nerve as it exits the SPF. However, as discussed above, the sinonasal parasympathetic pathway actually comprises individual rami project from the pterygopalatine ganglion (PPG) to innervate the nasal mucosa via multiple small nerve fascicles (i.e., accessory posterolateral nerves), not a single branch extending through the SPF. These rami are transmitted through multiple fissures, accessory foramina, and microforamina throughout the palatine bone and may demonstrate anastomotic loops with both the SPF and other accessory nerves. Thus, if only the parasympathetic nerves traversing the SPF were severed, almost all patients (e.g., 90% of patients or more) would retain intact accessory secretomotor fibers to the posterolateral mucosa, which would result in the persistence of symptoms the neurectomy was meant to alieve.

Accordingly, embodiments of the present disclosure are configured to therapeutically modulate nerves at precise and focused treatment sites corresponding to the sites of rami extending through fissures, accessory foramina, and microforamina throughout the palatine bone (e.g., target region T shown in FIG. 3B). In certain embodiments, the targeted nerves are postganglionic parasympathetic nerves that go on to innervate the nasal mucosa. This selective neural treatment is also expected to decrease the rate of postoperative nasal crusting and dryness because it allows a clinician to titrate the degree of anterior denervation through judicious

sparing of the rami orbitonasal. Furthermore, embodiments of the present disclosure are also expected to maintain at least some sympathetic tone by preserving a portion of the sympathetic contributions from the deep petrosal nerve and internal maxillary periarterial plexus, leading to improved outcomes with respect to nasal obstruction. In addition, embodiments of the present disclosure are configured to target a multitude of parasympathetic neural entry locations (e.g., accessory foramen, fissures, and microforamina) to the nasal region to provide for a complete resection of all anastomotic loops, thereby reducing the rate of long-term re-innervation.

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FIG. 4 is a side view of one embodiment of a handheld device 102 for providing therapeutic nasal neuromodulation consistent with the present disclosure. As illustrated, the device 102 includes a multi-segment end effector 114 transformable between a retracted configuration and an expanded deployed configuration, a shaft 116 operably associated with the end effector 114, and a handle 118 operably associated with the shaft 116. The multi-segment end effector 114 includes at least a first segment 122 and a second segment 124 spaced apart from one another. The first segment 122 is generally positioned closer to a distal end of the shaft 116, and is thus sometimes referred to herein as the proximal segment 122, while the second segment 124 is generally positioned further from the distal end of the shaft 116 and is thus sometimes referred to herein as the distal segment 124. Each of the first and second segments 122 and 124 is transformable between a retracted configuration, which includes a low-profile delivery state to facilitate intraluminal delivery of the end effector 114 to a treatment site within the nasal region, and a deployed configuration, which includes an expanded state, as shown in FIG. 4 and further illustrated in FIGS. 5A-5F. The handle 118 includes at least a first mechanism 126 for deployment of the multi-segment end effector 114, notably the first and second segments 122, 124, from the retracted configuration to the deployed configuration and a second mechanism 128, separate from the first mechanism 124, for control of energy output by either of the first and second segments 122, 124 of the end effector 114, specifically electrodes or other energy elements provided by first and/or second segments 122, 124. The handheld device 102 may further include an auxiliary line 121, which may provide a fluid connection between a fluid source, for example, and the shaft 116 such that fluid may be provided to a target site via the distal end of the shaft 116. In some embodiments, the auxiliary line 121 may provide a connection between a vacuum source and the shaft 116, such that the device 102 may include suction capabilities (via the distal end of the shaft 116).

FIGS. 5A, 5B, 5C, 5D, 5E, and 5F are enlarged views of the multi-segment end effector 114, illustrating various views of the first and second segments 122, 124 in greater detail. FIG. 5A is an enlarged, perspective view of the multi-segment end effector 114. FIG. 5B is an exploded, perspective view of the multi-segment end effector 114. FIGS. 5C and 5D are enlarged, top and side views, respectively, of the multi-segment end effector 114. FIG. 5E is an enlarged, front (proximal facing) view of the first segment 122 of the multi-segment end effector 114. FIG. 5F is an enlarged, front (proximal facing) view of the second segment 124 of the multi-segment end effector 114.

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As illustrated, the first segment 122 includes at least a first set of flexible support elements, generally in the form of wires, arranged in a first configuration, and the second segment 124 includes a second set of flexible support elements, also in the form of wires, arranged in a second configuration. The first and second sets of flexible support elements include composite wires having conductive and elastic properties. For example, in some embodiments, the composite wires include a shape memory material, such as nitinol. The flexible support elements may further include a highly lubricious coating, which may allow for desirable electrical insulation properties as well as desirable low friction surface finish. Each of the first and second segments 122, 124 is transformable between a retracted configuration and an expanded deployed configuration such that the first and second sets of flexible support elements are configured to position one or more electrodes provided on the respective segments (see electrodes 136 in FIGS. 5E and 5F) into contact with one or more target sites when in the deployed configuration.

As shown, when in the expanded deployed configuration, the first set of support elements of the first segment 122 includes at least a first pair of struts 130a, 130b, each comprising a loop (or leaflet) shape and extending in an upward direction and a second pair of struts 132a, 132b, each comprising a loop (or leaflet) shape and extending in a downward direction, generally in an opposite direction relative to at least the first pair of struts 130a, 130b. It should be noted that the terms upward and downward are used to describe the orientation of the first and second segments 122, 124 relative to one another. More specifically, the first pair of struts 130a, 130b generally extend in an outward inclination in a first direction relative to a longitudinal axis of the multi-segment end effector 114 and are spaced apart from one another. Similarly, the second pair of struts 132a, 132b extend in an outward inclination in a second direction substantially

opposite the first direction relative to the longitudinal axis of the multi-segment end effector and spaced apart from one another.

The second set of support elements of the second segment 124, when in the expanded deployed configuration, includes a second set of struts 134(1), 134(2), 134(n) (approximately six struts), each comprising a loop shape extending outward to form an open-ended circumferential shape. As shown, the open-ended circumferential shape generally resembles a blooming flower, wherein each looped strut 134 may generally resemble a flower petal. It should be noted that the second set of struts 134 may include any number of individual struts and is not limited to six, as illustrated. For example, in some embodiments, the second segment 124 may include two, three, four, five, six, seven, eight, nine, ten, or more struts 134.

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The first and second segments 122, 124, specifically struts 130, 132, and 134 include one or more energy delivery elements, such as a plurality of electrodes 136. It should be noted that any individual strut may include any number of electrodes 136 and is not limited to one electrode, as shown. In the expanded state, the struts 130, 132, and 134 can position any number of electrodes 136 against tissue at a target site within the nasal region (e.g., proximate to the palatine bone inferior to the SPF). The electrodes 136 can apply bipolar or multi-polar radiofrequency (RF) energy to the target site to therapeutically modulate postganglionic parasympathetic nerves that innervate the nasal mucosa proximate to the target site. In various embodiments, the electrodes 136 can be configured to apply pulsed RF energy with a desired duty cycle (e.g., 1 second on/0.5 seconds off) to regulate the temperature increase in the target tissue.

The first and second segments 122, 124 and the associated struts 130, 132, and 134 can have sufficient rigidity to support the electrodes 136 and position or press the electrodes 136 against tissue at the target site. In addition, each of the expanded first and second segments 122, 124 can press against surrounding anatomical structures proximate to the target site (e.g., the turbinates, the palatine bone, etc.) and the individual struts 130, 132, 134 can at least partially conform to the shape of the adjacent anatomical structures to anchor the end effector 114 In addition, the expansion and conformability of the struts 130, 132, 134 can facilitate placing the electrodes 136 in contact with the surrounding tissue at the target site. The electrodes 136 can be made from platinum, iridium, gold, silver, stainless steel, platinum-iridium, cobalt chromium, iridium oxide, polyethylenedioxythiophene (PEDOT), titanium, titanium nitride, carbon, carbon

nanotubes, platinum grey, Drawn Filled Tubing (DFT) with a silver core, and/or other suitable materials for delivery RF energy to target tissue. In some embodiments, such as illustrated in FIG. 6, a strut may include an outer jacket surrounding a conductive wire, wherein portions of the outer jacket are selectively absent along a length of the strut, thereby exposing the underlying conductive wire so as to act as an energy delivering element (i.e., an electrode) and/or sensing element, as described in greater detail herein.

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In certain embodiments, each electrode 136 can be operated independently of the other electrodes 136. For example, each electrode can be individually activated and the polarity and amplitude of each electrode can be selected by an operator or a control algorithm (e.g., executed by the controller 107 previously described herein. The selective independent control of the electrodes 136 allows the end effector 114 to deliver RF energy to highly customized regions. For example, a select portion of the electrodes 136 can be activated to target neural fibers in a specific region while the other electrodes 136 remain inactive. In certain embodiments, for example, electrodes 136 may be activated across the portion of the second segment 124 that is adjacent to tissue at the target site, and the electrodes 136 that are not proximate to the target tissue can remain inactive to avoid applying energy to non-target tissue. Such configurations facilitate selective therapeutic modulation of nerves on the lateral nasal wall within one nostril without applying energy to structures in other portions of the nasal cavity.

The electrodes 136 are electrically coupled to an RF generator (e.g., the generator 106 of FIG. 1) via wires (not shown) that extend from the electrodes 136, through the shaft 116, and to the RF generator. When each of the electrodes 136 is independently controlled, each electrode 136 couples to a corresponding wire that extends through the shaft 116. In other embodiments, multiple electrodes 136 can be controlled together and, therefore, multiple electrodes 136 can be electrically coupled to the same wire extending through the shaft 116. As previously described, the RF generator and/or components operably coupled (e.g., a control module) thereto can include custom algorithms to control the activation of the electrodes 136. For example, the RF generator can deliver RF power at about 460-480 kHz (+ or - 5 kHz) to the electrodes 136, and do so while activating the electrodes 136 in a predetermined pattern selected based on the position of the end effector 114 relative to the treatment site and/or the identified locations of the target nerves. The RF generator is able to provide bipolar low power (10 watts with maximum

setting of 50 watts) RF energy delivery, and further provide multiplexing capabilities (across a maximum of 30 channels).

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Once deployed, the first and second segments 122, 124 contact and conform to a shape of the respective locations, including conforming to and complementing shapes of one or more anatomical structures at the respective locations. In turn, the first and second segments 122, 124 become accurately positioned within the nasal cavity to subsequently deliver, via one or more electrodes 136, precise and focused application of RF thermal energy to the one or more target sites to thereby therapeutically modulate associated neural structures. More specifically, the first and second segments 122, 124 have shapes and sizes when in the expanded configuration that are specifically designed to place portions of the first and second segments 122, 124, and thus one or more electrodes associated therewith 136, into contact with target sites within nasal cavity associated with postganglionic parasympathetic fibers that innervate the nasal mucosa.

For example, the first set of flexible support elements of the first segment 122 conforms to and complements a shape of a first anatomical structure at the first location when the first segment 122 is in the deployed configuration and the second set of flexible support elements of the second segment 124 conforms to and complements a shape of a second anatomical structure at the second location when the second segment is in the deployed configuration. The first and second anatomical structures may include, but are not limited to, inferior turbinate, middle turbinate, superior turbinate, inferior meatus, middle meatus, superior meatus, pterygopalatine region, pterygopalatine fossa, sphenopalatine foramen, accessory sphenopalatine foramen(ae), and sphenopalatine micro-foramen(ae).

In some embodiments, the first segment 122 of the multi-segment end effector 114 is configured in a deployed configuration to fit around at least a portion of a middle turbinate at an anterior position relative to the middle turbinate and the second segment 124 of the multi-segment end effector is configured in a deployed configuration to contact a plurality of tissue locations in a cavity at a posterior position relative to the middle turbinate.

For example, the first set of flexible support elements of the first segment (i.e., struts 130 and 132) conforms to and complements a shape of a lateral attachment and posterior-inferior edge of the middle turbinate when the first segment 122 is in the deployed configuration and the second set of flexible support elements (i.e., struts 134) of the second segment 124 contact a plurality of tissue locations in a cavity at a posterior position relative to the lateral attachment

and posterior-inferior edge of middle turbinate when the second segment 124 is in the deployed configuration. Accordingly, when in the deployed configuration, the first and second segments 122, 124 are configured to position one or more associated electrodes 136 at one or more target sites relative to either of the middle turbinate and the plurality of tissue locations in the cavity behind the middle turbinate. In turn, electrodes 136 are configured to deliver RF energy at a level sufficient to therapeutically modulate postganglionic parasympathetic nerves innervating nasal mucosa at an innervation pathway within the nasal cavity of the patient.

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As illustrated in FIG. 5E, the first segment 122 comprises a bilateral geometry. In particular, the first segment 122 includes two identical sides, including a first side formed of struts 130a, 132a and a second side formed of struts 130b, 132b. This bilateral geometry allows at least one of the two sides to conform to and accommodate an anatomical structure within the nasal cavity when the first segment 122 is in an expanded state. For example, when in the expanded state, the plurality of struts 130a, 132a contact multiple locations along multiple portions of the anatomical structure and electrodes provided by the struts are configured to emit energy at a level sufficient to create multiple micro-lesions in tissue of the anatomical structure that interrupt neural signals to mucus producing and/or mucosal engorgement elements. In particular, struts 130a, 132a conform to and complement a shape of a lateral attachment and posterior-inferior edge of the middle turbinate when the first segment 122 is in the deployed configuration, thereby allowing for both sides of the anatomical structure to receive energy from the electrodes. By having this independence between first and second side (i.e., right and left side) configurations, the first segment 122 is a true bilateral device. By providing a bilateral geometry, the multi-segment end effector 114 does not require a repeat use configuration to treat the other side of the anatomical structure, as both sides of the structure are accounted at the same time due to the bilateral geometry. The resultant micro-lesion pattern can be repeatable and is predictable in both macro element (depth, volume, shape parameter, surface area) and can be controlled to establish low to high effects of each, as well as micro elements (the thresholding of effects within the range of the macro envelope can be controlled), as well be described in greater detail herein. The systems of the present invention are further able to establish gradients within allowing for control over neural effects without having widespread effect to other cellular bodies, as will be described in greater detail herein.

FIG. 7 is a cross-sectional view of a portion of the shaft 116 of the handheld device taken along lines 7-7 of FIG. 4. As illustrated, the shaft 116 may be constructed from multiple components so as to have the ability to constrain the end effector 114 in the retracted configuration (i.e., the low-profile delivery state) when the end effector 114 is retracted within the shaft 116, and to further provide an atraumatic, low profile and durable means to deliver the end effector 114 to the target site. The shaft 116 includes coaxial tubes which travel from the handle 118 to a distal end of the shaft 116. The shaft 116 assembly is low profile to ensure transnasal delivery of therapy. The shaft 116 includes an outer sheath 138, surrounding a hypotube 140, which is further assembled over electrode wires 129 which surround an inner lumen 142. The outer sheath 138 serves as the interface between the anatomy and the device 102. The outer sheath 138 may generally include a low friction PTFE liner to minimize friction between the outer sheath 138 and the hypotube 140 during deployment and retraction. In particular, the outer sheath 138 may generally include an encapsulated braid along a length of the shaft 116 to provide flexibility while retaining kink resistance and further retaining column and/or tensile strength. For example, the outer sheath 138 may include a soft Pebax material, which is atraumatic and enables smooth delivery through the nasal passage. The outer sheath 138 may further include orientation/landmark markings on an exterior surface thereof, generally at the distal end, wherein the markings may provide a visual indication to an operator of the architecture and/or spatial orientation of first and/or second segments 122, 124 of the end effector 114 to assist in positioning and deployment of the end effector 114.

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The hypotube 140 is assembled over the electrode wires starting within the handle 118 and travelling to the proximal end of the end effector 114. The hypotube 140 generally acts to protect the wires during delivery and is malleable to enable flexibility without kinking to thereby improve trackability. The hypotube 140 provides stiffness and enables torqueability of the device 102 to ensure accurate placement of the end effector 114. The hypotube 140 also provides a low friction exterior surface which enables low forces when the outer sheath 138 moves relative to the hypotube 140 during deployment and retraction or constraint. The shaft 116 may be pre-shaped in such a manner so as to complement the nasal cavity. For example, the hypotube 140 may be annealed to create a bent shaft 116 with a pre-set curve. The hypotube 140 may include a stainless-steel tubing, for example, which interfaces with a liner in the outer sheath 138 for low friction movement.

The inner lumen 142 may generally provide a channel for fluid extraction during a treatment procedure. For example, the inner lumen 142 extends from the distal end of the shaft 116 through the hypotube 140 and to atmosphere via a fluid line (line 121 of FIG. 4). The inner lumen 142 materials are chosen to resist forces of external components acting thereon during a procedure.

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FIG. 7A is a side view of one embodiment of an elongate body and a multi-segment end effector extending from a distal end thereof, further illustrating a plurality of electrodes provided on separate respective portions of the elongate body. In the illustrated example, the elongate body may generally be in the form of the shaft 116, including one or more specific components of the shaft 116, as previously described herein. For example, the elongate body in the present example may include the outer sheath 138, such that one or more electrodes 137 are provided and positioned on separate respective portions of the outer sheath 138. FIG. 7B is a sectional view of the shaft 116 illustrating one embodiment in which a plurality of electrodes are embedded within the outer sheath 138. As further illustrated in FIG. 7B, the electrodes 137 may be provided along an entirety of the circumference of the outer sheath 138 (i.e., along substantially all sides of the outer sheath 138).

FIG. 7C is a sectional view of the shaft 116 illustrating another embodiment in which a plurality of electrodes 137 are provided on the hypotube 140 and associated portions of the outer sheath 138 are absent or removed to thereby expose the underlying electrodes 137 on the hypotube 140. FIG. 7D is a perspective view of a length of the shaft 116 illustrating exposed portions of the outer sheath 138 to reveal the underlying electrodes 137 provided on the hypotube 140. More specifically, portions of the outer sheath 138 may be selectively absent along a length thereof, thereby exposing any underlying electrodes 137 provided on the enclosed portion of the hypotube 140. Accordingly, in such an embodiment, the elongate body is in the form of the hypotube 140.

FIG. 7E is a sectional view of the shaft 116 illustrating another embodiment in which a plurality of electrodes 137 are provided on one or more support elements 129 extending through the hypotube 140, portions of which form the end effector 114. FIG. 7F is an enlarged, perspective view of the multi-segment end effector 114 extending from the shaft 116, specifically the hypotube 140 and illustrating the plurality of electrodes 137 provided on the support elements 129. For example, during deployment of the end effector 114 from the

retracted to expanded configurations, proximal portions of the support elements 129 that form the proximal and distal segments 122 and 124 may be further exposed to thereby further expose the electrodes 137 provided thereon. Accordingly, in such an embodiment, the elongate body is in the form of the assembly of support elements 129.

In some embodiments, respective portions of the elongate body may be transformable between a retracted configuration and an expanded configuration. For example, FIG. 7G is a cross-sectional view of the shaft 116, specifically the outer sheath 138, illustrating exemplary portions of the sheath 138 that may be retractable and expandable. When in the expanded configuration, each separate respective portion of the outer sheath 138 may be configured to position a separate associated one of the electrodes 137 into contact with a target tissue.

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Similar to electrodes 136, the electrodes 137 may be configured to apply electromagnetic neuromodulation energy (e.g., radiofrequency (RF) energy) to target sites. In other embodiments, the electrodes 137 may be configured to provide therapeutic neuromodulation using various other modalities, such as cryotherapeutic cooling, ultrasound energy (e.g., high intensity focused ultrasound ("HIFU") energy), microwave energy (e.g., via a microwave antenna), direct heating, high and/or low power laser energy, mechanical vibration, and/or optical power. Yet still, in other embodiments, the electrodes can apply bipolar or multi-polar radiofrequency (RF) energy to a target site to therapeutically modulate tissue at the target site, which may include ablation of the tissue. For example, in various embodiments, the electrodes 136 can be configured to apply pulsed RF energy with a desired duty cycle (e.g., 1 second on/0.5 seconds off) to regulate the temperature increase in the target tissue.

In certain embodiments, each electrode 137 can be operated independently of the other electrodes 137. For example, each electrode can be individually activated and the polarity and amplitude of each electrode can be selected by an operator or a control algorithm (e.g., executed by the controller 107 previously described herein. The selective independent control of the electrodes 137 allows respective portions of the shaft to deliver RF energy to highly customized regions. For example, a select portion of the electrodes 137 can be activated to target tissue in a specific portion of the inferior turbinate while the other electrodes 137 remain inactive.

The electrodes 137 are electrically coupled to an RF generator (e.g., the generator 106 of FIG. 1) via wires (not shown) that extend from the electrodes 137, through the shaft 116, and to the RF generator. When each of the electrodes 137 is independently controlled, each electrode

137 couples to a corresponding wire that extends through the shaft 116. In other embodiments, multiple electrodes 137 can be controlled together and, therefore, multiple electrodes 137 can be electrically coupled to the same wire extending through the shaft 116. As previously described, the RF generator and/or components operably coupled (e.g., a control module) thereto can include custom algorithms to control the activation of the electrodes 137. For example, the RF generator can deliver RF power at about 460-480 kHz (+ or - 5 kHz) to the electrodes 137, and do so while activating the electrodes 137 in a predetermined pattern selected based on the position of the shaft 116 relative to the treatment site and/or the identified locations of the target tissue. The RF generator is able to provide bipolar low power (10 watts with maximum setting of 50 watts) RF energy delivery, and further provide multiplexing capabilities (across a maximum of 30 channels).

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The electrodes 137 may be used to deliver energy to tissue adjacent to, or in contact with, such the respective portions of the shaft 116. For example, in some embodiments, the shaft 116 may generally reside with a portion of the nasal cavity proximate to the inferior turbinate upon advancing and deploying the multi-segment end effector 114 in the desired location (i.e., a target site associated with a sphenopalatine foramen within the nasal cavity of the patient). Accordingly, in addition to delivering energy from the electrodes 136 of the multi-segment end effector 114, the surgeon may also activate and deliver energy from electrodes 137 associated with a given component of the shaft 116 (i.e., outer sheath 138, hypotube 140, or assembly of support elements 129) to tissue associated with the inferior turbinate. Such energy may be delivered at a level sufficient to reduce engorgement of tissue associated with the inferior turbinate to thereby increase volumetric flow through the nasal passage of the patient and improve a patient's ability to breathe. For example, the energy may be delivered at a level sufficient to disrupt multiple neural signals to, or result in local hypoxia of, mucus producing and/or mucosal engorgement elements associated with the inferior turbinate. For example, delivery of energy may result in ablation of targeted tissue of the inferior turbinate. The ablation may be thermal ablation. The ablation may be caused by delivery of radiofrequency (RF) energy, for example.

Accordingly, in a given procedure, the surgeon may utilize the multi-segment end effector 114 to deliver energy (via electrodes 136) at a level sufficient to the apeutically modulate postganglionic parasympathetic nerves innervating nasal mucosa at microforamina of a

palatine bone of the patient and further utilize a component of the shaft 116 or other elongate body operably associated with the end effector 114 (i.e., outer sheath 138, hypotube 140, or assembly of support elements 129) to deliver energy (via electrodes 137) at a level sufficient to reduce engorgement of tissue associated with the inferior turbinate to thereby increase volumetric flow through the nasal passage of the patient. Such a combination of energy delivery to two specific targeted sites improves the manner in which at least one of rhinitis, congestion, and rhinorrhea are treated, thereby increasing the potential for reducing or completely eliminating symptoms associated therewith, including, but not limited to, coughing, sneezing, nasal or throat irritation and itching, and difficulty sleeping.

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FIG. 8 is a side view of the handle 118. FIG. 9 is a side view of the handle 118 illustrating internal components enclosed within. The handle 118 generally includes an ergonomically-designed grip portion which provides ambidextrous use for both left and right handed use and conforms to hand anthropometrics to allow for at least one of an overhand grip style and an underhand grip style during use in a procedure. For example, the handle 118 may include specific contours, including recesses 144, 146, and 148 which are designed to naturally receive one or more of an operator's fingers in either of an overhand grip or underhand grip style and provide a comfortable feel for the operator. For example, in an underhand grip, recess 144 may naturally receive an operator's index finger, recess 146 may naturally receive an operator's middle finger, and recess 148 may naturally receive an operator's ring and little (pinkie or pinky) fingers which wrap around the proximal protrusion 150 and the operator's thumb naturally rests on a top portion of the handle 118 in a location adjacent to the first mechanism 126. In an overhand grip, the operator's index finger may naturally rest on the top portion of the handle 118, adjacent to the first mechanism 126, while recess 144 may naturally receive the operator's middle finger, recess 146 may naturally receive a portion of the operator's middle and/or ring fingers, and recess 148 may naturally receive and rest within the space (sometimes referred to as the purlicue) between the operator's thumb and index finger.

As previously described, the handle includes multiple user-operated mechanisms, including at least a first mechanism 126 for deployment of the end effector 114 from the retracted configuration to the expanded deployed configuration and a second mechanism 128 for controlling of energy output by the end effector, notably energy delivery from one or more electrodes 136. As shown, the user inputs for the first and second mechanisms 126, 128 are

positioned a sufficient distance to one another to allow for simultaneous one-handed operation of both user inputs during a procedure. For example, user input for the first mechanism 126 is positioned on a top portion of the handle 118 adjacent the grip portion and user input for the second mechanism 128 is positioned on side portions of the handle 118 adjacent the grip portion.

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As such, in an underhand grip style, the operator's thumb rests on the top portion of the handle adjacent to the first mechanism 126 and at least their middle finger is positioned adjacent to the second mechanism 128, each of the first and second mechanisms 126, 128 accessible and able to be actuated. In an overhand grip system, the operator's index finger rests on the top portion of the handle adjacent to the first mechanism 126 and at least their thumb is positioned adjacent to the second mechanism 128, each of the first and second mechanisms 126, 128 accessible and able to be actuated. Accordingly, the handle accommodates various styles of grip and provides a degree of comfort for the surgeon, thereby further improving execution of the procedure and overall outcome.

Referring to FIG. 9, the various components provided within the handle 118 are illustrated. As shown, the first mechanism 126 may generally include a rack and pinion assembly providing movement of the end effector 114 between the retracted and deployed configurations in response to input from a user-operated controller. The rack and pinion assembly generally includes a set of gears 152 for receiving input from the user-operated controller and converting the input to linear motion of a rack member 154 operably associated with at least one of the shaft 116 and the end effector 114. The rack and pinion assembly comprises a gearing ratio sufficient to balance a stroke length and retraction and deployment forces, thereby improving control over the deployment of the end effector. As shown, the rack member 154 may be coupled to a portion of the shaft 116, for example, such that movement of the rack member 154 in a direction towards a proximal end of the handle 118 results in corresponding movement of the shaft 116 while the end effector 114 remains stationary, thereby exposing the end effector 114 and allowing the end effector 114 to transition from the constrained, retracted configuration to the expanded, deployed configuration. Similarly, upon movement of the rack member 154 in a direction towards a distal end of the handle 118 results in corresponding movement of the shaft 116 while the end effector 114 remains stationary, thereby enclosing the end effector 114 within the shaft 116. It should be noted that, in other embodiments, the rack member 154 may be directly coupled to a portion of the end effector 114

such that movement of the rack member 154 results in corresponding movement of the end effector 114 while the shaft 116 remains stationary, thereby transitioning the end effector 114 between the retracted and deployed configurations.

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The user-operated controller associated with the first mechanism 126 may include a slider mechanism operably associated with the rack and pinion rail assembly. Movement of the slider mechanism in a rearward direction towards a proximal end of the handle results in transitioning of the end effector 114 to the deployed configuration and movement of the slider mechanism in a forward direction towards a distal end of the handle results in transitioning of the end effector to the retracted configuration. In other embodiment, the user-operated controller associated with the first mechanism 126 may include a scroll wheel mechanism operably associated with the rack and pinion rail assembly. Rotation of the wheel in a rearward direction towards a proximal end of the handle results in transitioning of the end effector to the deployed configuration and rotation of the wheel in a forward direction towards a distal end of the handle results in transitioning of the end effector to the retracted configuration.

The user-operated controller associated with the first mechanism 126 may generally provide a high degree of precision and control over the deployment (and retraction) of the first and second segments 122, 124. For example, in some instances, the operator may wish to only deploy the second segment 124 during the procedure, while the first segment 122 remains in the retracted configuration. The user-operated controller allows for an operator to provide a sufficient degree of input (i.e., slide the slider mechanism or scroll the scroll wheel to a specific position) which results in only the second segment 124 transitioning from the retracted configuration to the deployed configuration (while the first segment 122 remains enclosed within the shaft 116 and in the retracted configuration). For example, in some embodiments, the end effector 114 may further include a detent feature, such as a catch or similar element, positioned between the first and second segments 122, 124 and configured to provide a surgeon with feedback, such as haptic or tactile feedback, during deployment of the end effector segments, alerting the surgeon when at least the second segment 124 is fully deployed. In particular, as the surgeon slides the slider mechanism or scrolls the scroll wheel during deployment of the second segment 124, the detect feature (provided between the first and second segments 122, 124) may then reach a portion of the shaft 116 and cause an increase in resistance on the slider mechanism or scroll wheel, thereby indicating to the surgeon that the second segment 124 has been deployed

and the first segment 122 remains in the retracted configuration. Accordingly, the surgeon can position and orient the second segment 124 as they desire without concern over the first segment 122 as it remains in the retracted configuration. In turn, one the second segment 124 is positioned at the desired target site, the surgeon may then deploy the first segment 122 to perform the procedure. Yet still, in some instances, only the second segment 124 may be used to perform a procedure (i.e., deliver energy to one or more target sites in contact with the second segment 124) and, as such, the first segment 122 may never be deployed.

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The second mechanism 128 may generally include a user-operated controller configured to be actuated between at least an active position and an inactive position to thereby control delivery of energy from the end effector 114, notable delivery of energy from the electrodes 136. The user-operated controller may be multi-modal in that the user-operated controller may be actuated between multiple positions providing different functions/modes. For example, upon a single user input (i.e., single press of button associated within controller), the second mechanism may provide a baseline apposition / sensing check function prior to modulation. Upon pressing and holding the controller button for a pre-defined period of time, the energy output from the end effector may be activated. Further, upon double-tapping the controller button, energy output is deactivated.

Furthermore, the handle and/or the shaft may include markings that provide a surgeon with a spatial orientation of the end effector while the end effector is in a nasal cavity. FIG. 10 is a side view of the handle 118 illustrating multiple markings on a distal end of the handle 118 and FIG. 11 is a perspective view of a portion of the shaft 116 illustrating multiple markings on a distal end thereof. In particular, multiple markings may be provided on the handle and/or shaft and provide a visual indication of the spatial orientation of one or more portions of the first segment and second segment of the end effector when in the deployed configurations. The markings may include, for example, text, symbols, color-coding insignia, or the like. Thus, during initial placement of the end effector, when in a retracted configuration and enclosed within the shaft, a surgeon can rely on the markings on the handle and/or shaft as a visual indication of the spatial orientation of the end effector (e.g., linear, axial, and/or depth position) prior to deployment to thereby ensure that, once deployed, the end effector, including both the first and second segments, are positioned in the intended locations within the nasal cavity.

For example, the handle and/or shaft may include markings associated with each of the first pair of struts 130a, 130b and each of the second pair of struts 132a, 132b, so as to provide an operator with a visual indication as to the resulting spatial orientation and architecture of at least the first segment 122 when initially navigating the nasal cavity and delivering the distal end of the shaft 116 to a target site, prior to deployment of the end effector 114. In other words, the markings provide an operator with an indication of the orientation of at least the first segment 122 of the end effector 114 prior to deploying the end effector 114, thereby ensuring accurate positioning at the desired location.

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FIG. 12 is a partial cut-away side view illustrating one approach for delivering an end effector 114 a target site within a nasal region in accordance with embodiments of the present disclosure. As shown, the distal portion of the shaft 116 extends into the nasal passage (NP), through the inferior meatus (IM) between the inferior turbinate (IT) and the nasal sill (NS), and around the posterior portion of the inferior turbinate (IT) where the end effector 114 is deployed at a treatment site. The treatment site can be located proximate to the access point or points of postganglionic parasympathetic nerves (e.g., branches of the posterior nasal nerve and/or other parasympathetic neural fibers that innervate the nasal mucosa) into the nasal cavity. In other embodiments, the target site can be elsewhere within the nasal cavity depending on the location of the target nerves.

In various embodiments, the distal portion of the shaft 116 may be guided into position at the target site via a guidewire (not shown) using an over-the-wire (OTW) or a rapid exchange (RX) technique. For example, the end effector 114 can include a channel for engaging the guidewire. Intraluminal delivery of the end effector 114 can include inserting the guide wire into an orifice in communication with the nasal cavity (e.g., the nasal passage or mouth), and moving the shaft 116 and/or the end effector 114 along the guide wire until the end effector 114 reaches a target site (e.g., inferior to the SPF).

Yet still, in further embodiments, the neuromodulation device 102 can be configured for delivery via a guide catheter or introducer sheath (not shown) with or without using a guide wire. The introducer sheath can first be inserted intraluminally to the target site in the nasal region, and the distal portion of the shaft 116 can then be inserted through the introducer sheath. At the target site, the end effector 114 can be deployed through a distal end opening of the introducer sheath or a side port of the introducer sheath. In certain embodiments, the introducer sheath can

include a straight portion and a pre-shaped portion with a fixed curve (e.g., a 5 mm curve, a 4 mm curve, a 3 mm curve, etc.) that can be deployed intraluminally to access the target site. In this embodiment, the introducer sheath may have a side port proximal to or along the pre-shaped curved portion through which the end effector 114 can be deployed. In other embodiments, the introducer sheath may be made from a rigid material, such as a metal material coated with an insulative or dielectric material. In this embodiment, the introducer sheath may be substantially straight and used to deliver the end effector 114 to the target site via a substantially straight pathway, such as through the middle meatus (MM) (FIG. 3A).

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Image guidance may be used to aid the surgeon's positioning and manipulation of the distal portion of the shaft 116, as well as the deployment and manipulation of the end effector 114, specifically the first and second segments 122 thereof. For example, an endoscope 100 and/or other visualization device can be positioned to visualize the target site, the positioning of the end effector 114 at the target site, and/or the end effector 114 during therapeutic neuromodulation. The endoscope 100 may be delivered proximate to the target site by extending through the nasal passage NP and through the middle meatus MM between the inferior and middle turbinates IT and MT. From the visualization location within the middle meatus MM, the endoscope 100 can be used to visualize the treatment site, surrounding regions of the nasal anatomy, and the end effector 114.

In some embodiments, the distal portion of the shaft 116 may be delivered via a working channel extending through an endoscope, and therefore the endoscope can provide direct in-line visualization of the target site and the end effector 114. In other embodiments, an endoscope is incorporated with the end effector 114 and/or the distal portion of the shaft 116 to provide in-line visualization of the end effector 114 and/or the surrounding nasal anatomy. In other embodiments, image guidance can be provided with various other guidance modalities, such as image filtering in the infrared (IR) spectrum to visualize the vasculature and/or other anatomical structures, computed tomography (CT), fluoroscopy, ultrasound, optical coherence tomography (OCT), and/or combinations thereof. Yet still, in some embodiments, image guidance components may be integrated with the neuromodulation device 102 to provide image guidance during positioning of the end effector 114.

Once positioned at the target site, the therapeutic modulation may be applied via the one or more electrodes 136 and/or other features of the end effector 114 to precise, localized regions

of tissue to induce one or more desired therapeutic neuromodulating effects to disrupt parasympathetic motor sensory function. The end effector 114 can selectively target postganglionic parasympathetic fibers that innervate the nasal mucosa at a target or treatment site proximate to or at their entrance into the nasal region. For example, the end effector 114 can be positioned to apply therapeutic neuromodulation at least proximate to the SPF (FIG. 3A) to therapeutically modulate nerves entering the nasal region via the SPF. The end effector 114 can also be positioned to inferior to the SPF to apply therapeutic neuromodulation energy across accessory foramen and microforamina (e.g., in the palatine bone) through which smaller medial and lateral branches of the posterior superior lateral nasal nerve enter the nasal region. The purposeful application of the energy at the target site may achieve therapeutic neuromodulation along all or at least a portion of posterior nasal neural fibers entering the nasal region. The therapeutic neuromodulating effects are generally a function of, at least in part, power, time, and contact between the energy delivery elements and the adjacent tissue. For example, in certain embodiments therapeutic neuromodulation of autonomic neural fibers are produced by applying RF energy at a power of about 2-20 W (e.g., 5 W, 7 W, 10 W, etc.) for a time period of about 1-20 sections (e.g., 5-10 seconds, 8-10 seconds, 10-12 seconds, etc.).

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The therapeutic neuromodulating effects may include partial or complete denervation via thermal ablation and/or non-ablative thermal alteration or damage (e.g., via sustained heating and/or resistive heating). Desired thermal heating effects may include raising the temperature of target neural fibers above a desired threshold to achieve non-ablative thermal alteration, or above a higher temperature to achieve ablative thermal alteration. For example, the target temperature may be above body temperature (e.g., approximately 37° C.) but less than about 90° C. (e.g., 70-75° C.) for non-ablative thermal alteration, or the target temperature may be about 100° C. or higher (e.g., 110° C., 120° C., etc.) for the ablative thermal alteration. Desired non-thermal neuromodulation effects may include altering the electrical signals transmitted in a nerve.

Sufficiently modulating at least a portion of the parasympathetic nerves is expected to slow or potentially block conduction of autonomic neural signals to the nasal mucosa to produce a prolonged or permanent reduction in nasal parasympathetic activity. This is expected to reduce or eliminate activation or hyperactivation of the submucosal glands and venous engorgement and, thereby, reduce or eliminate the symptoms of rhinosinusitis. Further, because the device 102 applies therapeutic neuromodulation to the multitude of branches of the posterior nasal

nerves rather than a single large branch of the posterior nasal nerve branch entering the nasal cavity at the SPF, the device 102 provides a more complete disruption of the parasympathetic neural pathway that affects the nasal mucosa and results in rhinosinusitis. Accordingly, the device 102 is expected to have enhanced therapeutic effects for the treatment of rhinosinusitis and reduced re-innervation of the treated mucosa.

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In other embodiments, the device 102 can be configured to therapeutically modulate nerves and/or other structures to treat different indications. For example, the device 102 can be used to therapeutically modulate nerves that innervate the para-nasal sinuses to treat chronic sinusitis. In further embodiments, the system 100 and the device 102 disclosed herein can be configured therapeutically modulate the vasculature within the nasal anatomy to treat other indications, such as epistaxis (i.e., excessive bleeding from the nose). For example, the system 100 and the device 102 devices described herein can be used to apply therapeutically effective energy to arteries (e.g., the sphenopalatine artery and its branches) as they enter the nasal cavity (e.g., via the SPF, accessory foramen, etc.) to partially or completely coagulate or ligate the arteries. In other embodiments, the system 100 and the device 102 can be configured to partially or completely coagulate or ligate veins and/or other vessels. For such embodiments in which the end effector 114 ligates or coagulates the vasculature, the system 100 and device 102 would be modified to deliver energy at significantly higher power (e.g., about 100 W) and/or longer times (e.g., 1 minute or longer) than would be required for therapeutic neuromodulation.

As further illustrated in FIG. 12, the shaft 116 may reside with a portion of the nasal cavity proximate to the IT upon advancing and deploying the multi-segment end effector 114 in the desired location (i.e., a target site associated with a sphenopalatine foramen within the nasal cavity of the patient). Accordingly, in addition to delivering energy from the electrodes 136 of the multi-segment end effector 114, the surgeon may also activate and deliver energy from electrodes 137 associated with the shaft 116 ((i.e., outer sheath 138, hypotube 140, or assembly of support elements 129) to tissue associated with the IT. Such energy may be delivered at a level sufficient to reduce engorgement of tissue associated with the IT to thereby increase volumetric flow through a nasal passage of the patient and improve a patient's ability to breathe.

FIG. 13 is a flow diagram illustrating one embodiment of a method 400 for treating a condition within a nasal cavity of a patient. The method 400 includes advancing a multi-segment end effector within the nasal cavity of the patient (operation 410) wherein the multi-segment end

effector includes a first segment spaced apart from a second segment. The multi-segment end effector is retractable and expandable such that, once delivered to the one more target sites within the nasal cavity, the first and second segments can expand to a specific shape and/or size corresponding to anatomical structures within the nasal cavity and associated with the target sites. The method 400 further includes deploying the first and second segments at respective first and second locations within the nasal cavity (operation 420). In particular, each of the first and second flexible segments includes a specific geometry when in a deployed configuration to complement anatomy of respective locations within the nasal cavity. Accordingly, once deployed, the first and second segments contact and conform to a shape of the respective locations, including conforming to and complementing shapes of one or more anatomical structures at the respective locations. The method 400 further includes delivering energy, via the first and second segments, to tissue at one or more target sites with respect to the first and second locations (operation 430). In particular, the first and second segments become accurately positioned within the nasal cavity to subsequently deliver, via one or more electrodes, precise and focused application of RF thermal energy to the one or more target sites to thereby therapeutically modulate associated neural structures. The first and second segments have shapes and sizes when in the expanded configuration that are specifically designed to place portions of the first and second segments, and thus one or more electrodes associated therewith, into contact with target sites within nasal cavity associated with postganglionic parasympathetic fibers that innervate the nasal mucosa.

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FIG. 14 is a flow diagram illustrating another embodiment of a method 500 for treating a condition within a nasal cavity of a patient. The method 500 includes providing a treatment device comprising an end effector transformable between a retracted configuration and an expanded deployed configuration, a shaft operably associated with the end effector, and a handle operably associated with the shaft (operation 510). The method 500 further includes advancing the end effector to one or more target sites within the nasal cavity of the patient (operation 520). The shaft may include a pre-defined shape (i.e., bent or angled at a specific orientation) so as to assist the operation for placement of the end effector at the target sites. The handle includes an ergonomically-designed grip portion which provides ambidextrous use for both left and right handed use and conforms to hand anthropometrics to allow for at least one of an overhand grip style and an underhand grip style during use in a procedure.

The handle and/or the shaft may include markings (e.g., text, symbols, color-coding insignia, etc.) that provide a surgeon with a spatial orientation of the end effector while the end effector is in a nasal cavity. In particular, multiple markings may be provided on the handle and/or shaft and provide a visual indication of the spatial orientation of one or more portions of the first segment and second segment of the end effector when in the deployed configurations. Thus, during initial placement of the end effector, when in a retracted configuration and enclosed within the shaft, a surgeon can rely on the markings on the handle and/or shaft as a visual indication of the spatial orientation of the end effector (e.g., linear, axial, and/or depth position) prior to deployment to thereby ensure that, once deployed, the end effector, including both the first and second segments, are positioned in the intended locations within the nasal cavity.

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The method 500 further includes deploying the end effector at the one or more target sites (operation 530) and delivering energy from the end effector to tissue at the one or more target sites (operation 540). The handle includes multiple user-operated mechanisms, including at least a first mechanism for deployment of the end effector from the retracted configuration to the expanded deployed configuration and a second mechanism for controlling of energy output by the end effector. The user inputs for the first and second mechanisms are positioned a sufficient distance to one another to allow for simultaneous one-handed operation of both user inputs during a procedure. Accordingly, the handle accommodates various styles of grip and provides a degree of comfort for the surgeon, thereby further improving execution of the procedure and overall outcome.

FIG. 15 is a flow diagram illustrating another embodiment of a method 600 for treating a condition within a nasal cavity of a patient. The method 600 includes providing a treatment device comprising a multi-segment end effector, including a proximal segment that is spaced apart from a distal segment, and a visual marker (operation 610). As previously described herein, the visual marker may be provided by a shaft, for example, operably associated with the multi-segment end effector. The visual marker may be in the form of text, symbols, color-coding insignia, or the like, that generally provides a user (i.e., a surgeon or other medical professional) with a visual indication of a spatial orientation of one or more portions of the proximal segment while the multi-segment end effector is in a nasal cavity.

The method 600 further includes advancing, under image guidance, the proximal segment and the distal segment through a nasal cavity of a patient and past a middle turbinate (operation

620) and deploying the distal segment from a retracted configuration to an expanded configuration (operation 630). The image guidance may be in the form of an endoscope and/or other visualization device that can be positioned to so as to provide visualization to the user of one or more locations within the nasal cavity and to further provide visualization of the multi-segment end effector and other portions of the treatment device (i.e., at least a distal portion of the shaft with a visual marker) during advancement into the nasal cavity to assist the user in placement of the multi-segment end effector.

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Upon deploying the distal segment to an expanded configuration, the method 600 further includes aligning, under the image guidance and with reference to the visual marker, the proximal segment with respect to the middle turbinate (operation 640). The visual marker may be provided on the shaft, for example, and provide a visual indication of the spatial orientation of one or more portions of the proximal segment when in the deployed configuration. For example, the deployed proximal segment may include a geometry to complement a shape of the middle turbinate. More specifically, the proximal segment may include a set of flexible support elements that conform to and complement a shape of the middle turbinate when the proximal segment is in the deployed expanded configuration. The visual marker, provided by the shaft, provides a visual indication of the spatial orientation of one or more portions of the proximal segment, including, for example, a spatial orientation of the set of flexible support elements when in a deployed expanded configuration. Accordingly, aligning the proximal segment with respect to the middle turbinate includes the user positioning, under the image guidance, the shaft and associated visual marker relative to the middle turbinate.

Thus, during initial placement of at least the proximal segment when it is in a retracted configuration, a surgeon can rely on the markings on the shaft as a visual indication of the spatial orientation (e.g., linear, axial, and/or depth position) of one or more portions of the proximal segment prior to its deployment, thereby ensuring that, once deployed, the proximal segment is positioned in the intended location within the nasal cavity.

The method 600 further includes deploying the proximal segment around the middle turbinate and advancing the deployed proximal segment toward the middle turbinate to establish contact and secure the proximal segment to the middle turbinate (operation 650). Again, the set of flexible support elements of the proximal segment are able to conform to and complement a shape of the middle turbinate when the proximal segment is in the deployed expanded

configuration, thereby ensuring that the deployed proximal segment is secured to the middle turbinate.

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It should be noted that the treatment device further includes a handle operably associated with the multi-segment end effector and the shaft. The handle generally includes a controller mechanism for providing independent, controlled deployment of each of the proximal and distal segments from a retracted configuration to an expanded configuration within the nasal cavity. In particular, in some embodiments, the controller mechanism includes a rack and pinion assembly providing movement of the at least one of the proximal and distal segments between the retracted configuration and expanded configuration in response to user input from an associated user-operated controller. The rack and pinion assembly may include, for example, a set of gears for receiving user input from the user-operated controller and converting the user input to linear motion of a rack member operably associated with the multi-segment end effector.

The controller mechanism may further include a detent feature positioned relative to the proximal and distal segments and configured to provide active feedback to a user indicative of deployment of at least one of the proximal and distal segments. The active feedback may be in the form haptic feedback provided by the controller mechanism. For example, the haptic feedback may include an increase or decrease in resistance associated with user input with the controller mechanism for corresponding movement of the at least one of the proximal and distal segments between retracted and expanded configurations, and/or configurations therebetween (i.e., a plurality of configurations between a fully retracted configuration and a fully expanded configuration). For example, upon deploying the distal segment, the controller mechanism, as a result of interaction with the detent, may provide haptic feedback, in the form of a vibration or other motion (e.g., click(s) or change in resistance), to the user via the user-operated controller. The haptic feedback may indicate to the user that the distal segment is fully deployed and any further input with the user-operated controller will result in deployment of the proximal segment. The controller mechanism may further provide specific haptic feedback during deployment of a given segment, such as deployment of the proximal segment. For example, the haptic feedback may be in the form of an increase or decrease in resistance upon the user-operated controller, for example, which corresponds to the degree to which the proximal segment is deployed.

In some embodiments, the controller mechanism may further include a friction-based feature configured to provide stable movement of at least one of the proximal and distal

segments between the retracted and expanded configurations and further provide active feedback to a user indicative of deployment of at least one of the proximal and distal segments. The friction-based feature may include, for example, a lock mechanism configured to provide constant friction between one or more portions of the rack and pinion assembly sufficient to maintain a position of at least one of the proximal and distal segments during deployment thereof.

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For example, the constant friction may be sufficient to hold either of the proximal or distal segments in a certain position as the segment transitions between retracted and expanded configurations regardless of whether the user maintains contact with the user-operated controller. In other words, a user does not need to maintain contact with the user-operated controller in order to ensure that the proximal or distal segment holds a certain position during deployment thereof. Rather, a user can simply interact with the user-operated controller to transition one of the proximal and distal segments to a desired configuration and the constant friction provided by the locking mechanism is sufficient to maintain the configuration of proximal or distal segment in the event that the user goes hands free (i.e., removes any contact with the user-operated controller). The constant friction is of a level sufficient to prevent undesired movement of the proximal or distal segments (i.e., unintended collapsing or expanding), while still allowing for a user to overcome such friction to move the proximal or distal segment to a desired configuration upon user input with the user-operated controller.

In some embodiments, the user-operated controller includes a slider mechanism operably associated with the rack and pinion rail assembly, wherein movement of the slider mechanism in a first direction results in transitioning of at least one of the proximal and distal segments to an expanded configuration and movement of the slider mechanism in a second opposite direction results in transitioning of at least one of the proximal and distal segments to the retracted configuration. In other embodiments, the user-operated controller includes a scroll wheel mechanism operably associated with the rack and pinion rail assembly, wherein rotation of the wheel in a first direction results in transitioning of at least one of the proximal and distal segments to an expanded configuration and rotation of the wheel in a second opposite direction results in transitioning of at least one of the proximal and distal segments to the retracted configuration. As such, during deployment of the proximal segment, the slider mechanism or

scroll wheel may provide increased resistance to a user as the user transitions the proximal segment from a fully retracted configuration to a fully deployed configuration.

Accordingly, during deployment of either of the distal and proximal segments, the controller mechanism provides active feedback to the user, wherein such active feedback can be indicative of which segment is being actively controlled and/or the extent of deployment of either of the distal or proximal segments, thereby improving user control over the deployment of either of the distal and proximal segments.

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Upon securing the proximal segment to the middle turbinate, the method 600 further includes delivering energy, via the proximal segment, to the middle turbinate to treat a condition (operation 660). The condition may include, but is not limited to, allergic rhinitis, non-allergic rhinitis, chronic rhinitis, acute rhinitis, chronic sinusitis, acute sinusitis, chronic rhinosinusitis, acute rhinosinusitis, and medical resistant rhinitis, and a combination thereof. In some embodiments, delivering energy from the proximal segment includes delivering radiofrequency (RF) energy, via one or more electrodes provided by the proximal segment, to tissue of the middle turbinate at one or more target sites, wherein the one or more target sites are associated with parasympathetic nerve supply. In some embodiments, RF energy is delivered, via the one or more electrodes provided by the proximal segment, at a level sufficient to therapeutically modulate postganglionic parasympathetic nerves innervating nasal mucosa at an innervation pathway within the nasal cavity of the patient.

FIG. 16 is a flow diagram illustrating another embodiment of a method 700 for treating a condition within a nasal cavity of a patient. The method 700 includes providing a treatment device comprising an elongate body including one or more of a first set of electrodes provided along a length thereof and a retractable and expandable end effector operably associated with the elongate body and including one or more of a second set of electrodes provided thereon (operation 710).

The method 700 further includes advancing the shaft and end effector through a nasal passage and into a nasal cavity of a patient (operation 720) at which point a length of the elongate body is positioned at a first target site and the end effector is positioned at a second target site separate from the first target site (operation 730). For example, in some embodiments, the procedure may involve extending the elongate body into the nasal passage (NP), through the inferior meatus (IM) between the inferior turbinate (IT) and the nasal sill (NS). In other

embodiments, the procedure may involve extending the elongate body into the nasal passage (NP), through the middle meatus (MM) between the inferior turbinate (IT) and the middle turbinate (MT). In each instance, a proximal segment (of the end effector) is arranged in a deployed configuration to fit around at least a portion of a middle turbinate at an anterior position relative to a lateral attachment and a posterior-inferior edge of the middle turbinate and a separate distal segment (of the end effector) is configured in a deployed configuration to contact a plurality of tissue locations in a cavity at a posterior position relative to the lateral attachment and posterior-inferior edge of the middle turbinate. Additionally, the elongate body resides in a location adjacent to the inferior turbinate (IT).

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The method 700 further includes delivering energy from the first and second sets of electrodes (associated with elongate body and end effector, respectively) to tissue at the first and second target sites, respectively (operation 740). In particular, a given procedure, the surgeon may utilize the multi-segment end effector to deliver energy (via electrodes) at a level sufficient to therapeutically modulate postganglionic parasympathetic nerves innervating nasal mucosa at microforamina of a palatine bone of the patient and further utilize the elongate body to deliver energy (via electrodes) at a level sufficient to reduce engorgement of tissue associated with the inferior turbinate to thereby increase volumetric flow through the nasal passage of the patient. Such a combination of energy delivery to two specific targeted sites improves the manner in which at least one of rhinitis, congestion, and rhinorrhea are treated, thereby increasing the potential for reducing or completely eliminating symptoms associated therewith, including, but not limited to, coughing, sneezing, nasal or throat irritation and itching, and difficulty sleeping.

Accordingly, the treatment device of the present invention recognizes the desire or need to treat larger areas within the nasal cavity or passage that are located outside of a treatment zone associated with the end effector. For example, when performing surgical procedures using current rhinitis treatment devices, the surgeon must reposition an end effector when attempting to treat multiple areas within the nasal cavity, particularly those areas that are located outside of any given treatment zone. The need to reposition the end effector multiple times during a given procedure can lead to inaccuracy when delivering energy, resulting in unintended collateral damage, and further increases the time in which it takes to complete a given procedure. The treatment device of the present invention recognizes and addresses this problem by providing an elongate body including one or more electrodes thereon, in addition to a multi-segment end

effector operably associated with the elongate body and including separate electrodes thereon. Accordingly, the elongate body serves to not only aid in positioning and delivering the end effector to a desired target site (to which the end effector may deliver energy), but the elongate body can also deliver energy to a target site that is separate and remote from the end effector. Such a design improves the efficiency with which a given procedure can be accomplished, particularly those procedures requiring treatment to multiple, separate areas within the nasal cavity or passage.

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FIG. 17 is a flow diagram illustrating an embodiment of a method 800 for improving a patient's sleep by treating at least one of rhinitis, congestion, and rhinorrhea within a sino-nasal cavity of the patient. As previously described, the most common and impactful symptoms of rhinosinusitis include a runny nose, coughing, sneezing, nasal and/or throat irritation and itching, and overall general congestion of the nasal passage. As a result, sleep problems are very common in individuals suffering from rhinitis, as such symptoms impact a person's ability to either fall asleep or remain asleep for adequate periods of time. In addition, sleep problems are linked with fatigue and daytime sleepiness, as well as decreased productivity at work or school, impaired learning and memory, depression, and a reduced quality of life.

The method 800 includes delivering energy to one or more target sites within a sino-nasal cavity of the patient to disrupt multiple neural signals to, and/or result in local hypoxia of, mucus producing and/or mucosal engorgement elements, thereby reducing production of mucus and/or mucosal engorgement within a nose of the patient and reducing or eliminate one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea to improve nasal breathability of the patient (operation 810). The one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea are selected from the group consisting of nasal congestion, coughing, sneezing, and nasal or throat irritation and itching.

In some embodiments, the step of delivering energy results in ablation of targeted tissue at one or more locations to thereby disrupt the multiple neural signals to the mucus producing and/or mucosal engorgement elements within the nose. For example, the targeted tissue may be associated with one or more target sites proximate or inferior to a sphenopalatine foramen. The energy may be delivered at a level sufficient to therapeutically modulate postganglionic parasympathetic nerves innervating nasal mucosa at foramina and or microforamina of a palatine

bone of the patient. As a result, the energy delivered may cause multiple points of interruption of neural branches extending through foramina and microforamina of palatine bone.

Additionally, or alternatively, the step of delivering energy may result in ablation of targeted tissue at one or more locations to thereby result in local hypoxia of the mucus producing and/or mucosal engorgement elements within the nose. For example, in some embodiments, the ablation of targeted tissue may cause thrombus formation within one or more blood vessels associated with mucus producing and/or mucosal engorgement elements within the nose. As such, the resulting local hypoxia of the mucus producing and/or mucosal engorgement elements may result in decreased mucosal engorgement to thereby increase volumetric flow through a nasal passage of the patient.

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It should be noted that the ablation may include thermal ablation, which may be in the form of cyro-ablation, for example. In other embodiments, the ablation may be caused by delivery of radiofrequency (RF) energy.

In some embodiments, the ablation may be caused by a treatment device comprising a handle, an elongate body extending therefrom, and a retractable and expandable end effector operably associated with the elongate body. Accordingly, during a procedure, the method may include advancing the end effector into the sino-nasal cavity and positioning the end effector at a target site(s). The handle may generally control transformation of the end effector from a retracted state to an expanded state. The end effector may include a plurality of energy delivery elements provided thereon, such as electrodes, for example.

When in the expanded state, the end effector may generally position one or more of the plurality of energy delivery elements relative to the one or more target sites. In some embodiments, the end effector includes a proximal segment that is spaced apart from a separate distal segment. In some embodiments, the proximal segment may include a first set of flexible support elements arranged in a deployed configuration to fit around at least a portion of a middle turbinate at an anterior position relative to a lateral attachment and a posterior-inferior edge of the middle turbinate and position one or more energy delivery elements into contact with one or more respective tissue locations associated with the middle turbinate and the distal segment may include a second set of flexible support elements configured in a deployed configuration to position one or more energy delivery elements into contact with one or more respective tissue

locations in a cavity at a posterior position relative to the lateral attachment and posterior-inferior edge of the middle turbinate.

In some embodiments, the elongate body may include a shaft to which the end effector is coupled. The shaft includes an outer sheath surrounding a hypotube or metallic member, wherein at least one of the outer sheath and hypotube and metallic member includes the one or more energy delivering elements provided thereon. Yet still, in other embodiments, the elongate body may include one or more of a plurality of support elements forming at least a portion of the end effector. The energy delivering elements of the elongate body may be configured to deliver energy at one or more target sites associated with an inferior or middle turbinate within the sinonasal cavity of the patient at a level sufficient to reduce engorgement of tissue associated therewith to thereby increase volumetric flow through a nasal passage of the patient.

## Neuromodulation Monitoring, Feedback, and Mapping Capabilities

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As previously described, the system 100 includes a console 104 to which the device 102 is to be connected. The console 104 is configured to provide various functions for the neuromodulation device 102, which may include, but is not limited to, controlling, monitoring, supplying, and/or otherwise supporting operation of the neuromodulation device 102. The console 104 can further be configured to generate a selected form and/or magnitude of energy for delivery to tissue or nerves at the target site via the end effector 114, and therefore the console 104 may have different configurations depending on the treatment modality of the device 102. For example, when device 102 is configured for electrode-based, heat-element-based, and/or transducer-based treatment, the console 104 includes an energy generator 106 configured to generate RF energy (e.g., monopolar, bipolar, or multi-polar RF energy), pulsed electrical energy, microwave energy, optical energy, ultrasound energy (e.g., intraluminally-delivered ultrasound and/or HIFU), direct heat energy, radiation (e.g., infrared, visible, and/or gamma radiation), and/or another suitable type of energy. When the device 102 is configured for cryotherapeutic treatment, the console 104 can include a refrigerant reservoir (not shown), and can be configured to supply the device 102 with refrigerant. Similarly, when the device 102 is configured for chemical-based treatment (e.g., drug infusion), the console 104 can include a

chemical reservoir (not shown) and can be configured to supply the device 102 with one or more chemicals.

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In some embodiments, the console 104 may include a controller 107 communicatively coupled to the neuromodulation device 102. However, in the embodiments described herein, the controller 107 may generally be carried by and provided within the handle 118 of the neuromodulation device 102. The controller 107 is configured to initiate, terminate, and/or adjust operation of one or more electrodes provided by the end effector 114 directly and/or via the console 104. For example, the controller 107 can be configured to execute an automated control algorithm and/or to receive control instructions from an operator (e.g., surgeon or other medical professional or clinician). For example, the controller 107 and/or other components of the console 104 (e.g., processors, memory, etc.) can include a computer-readable medium carrying instructions, which when executed by the controller 107, causes the device 102 to perform certain functions (e.g., apply energy in a specific manner, detect impedance, detect temperature, detect nerve locations or anatomical structures, perform nerve mapping, etc.). A memory includes one or more of various hardware devices for volatile and non-volatile storage, and can include both read-only and writable memory. For example, a memory can comprise random access memory (RAM), CPU registers, read-only memory (ROM), and writable nonvolatile memory, such as flash memory, hard drives, floppy disks, CDs, DVDs, magnetic storage devices, tape drives, device buffers, and so forth. A memory is not a propagating signal divorced from underlying hardware; a memory is thus non-transitory.

The console 104 may further be configured to provide feedback to an operator before, during, and/or after a treatment procedure via mapping/evaluation/feedback algorithms 110. For example, the mapping/evaluation/feedback algorithms 110 can be configured to provide information associated with the location of nerves at the treatment site, the location of other anatomical structures (e.g., vessels) at the treatment site, the temperature at the treatment site during monitoring and modulation, and/or the effect of the therapeutic neuromodulation on the nerves at the treatment site. In certain embodiments, the mapping/evaluation/feedback algorithm 110 can include features to confirm efficacy of the treatment and/or enhance the desired performance of the system 100. For example, the mapping/evaluation/feedback algorithm 110, in conjunction with the controller 107 and the end effector 114, can be configured to monitor neural activity and/or temperature at the treatment site during therapy and automatically shut off

the energy delivery when the neural activity and/or temperature reaches a predetermined threshold (e.g., a threshold reduction in neural activity, a threshold maximum temperature when applying RF energy, or a threshold minimum temperature when applying cryotherapy). In other embodiments, the mapping/evaluation/feedback algorithm 110, in conjunction with the controller 107, can be configured to automatically terminate treatment after a predetermined maximum time, a predetermined maximum impedance or resistance rise of the targeted tissue (i.e., in comparison to a baseline impedance measurement), a predetermined maximum impedance of the targeted tissue), and/or other threshold values for biomarkers associated with autonomic function. This and other information associated with the operation of the system 100 can be communicated to the operator via a display 112 (e.g., a monitor, touchscreen, user interface, etc.) on the console 104 and/or a separate display (not shown) communicatively coupled to the console 104.

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In various embodiments, the end effector 114 and/or other portions of the system 100 can be configured to detect various bioelectric-parameters of the tissue at the target site, and this information can be used by the mapping/evaluation/feedback algorithms 110 to determine the anatomy at the target site (e.g., tissue types, tissue locations, vasculature, bone structures, foramen, sinuses, etc.), locate neural structures, differentiate between different types of neural structures, map the anatomical and/or neural structure at the target site, and/or identify neuromodulation patterns of the end effector 114 with respect to the patient's anatomy. For example, the end effector 114 can be used to detect resistance, complex electrical impedance, dielectric properties, temperature, and/or other properties that indicate the presence of neural fibers and/or other anatomical structures in the target region. In certain embodiments, the end effector 114, together with the mapping/evaluation/feedback algorithms 110, can be used to determine resistance (rather than impedance) of the tissue (i.e., the load) to more accurately identify the characteristics of the tissue. The mapping/evaluation/feedback algorithms 110 can determine resistance of the tissue by detecting the actual power and current of the load (e.g., via the electrodes 136).

In some embodiments, the system 100 provides resistance measurements with a high degree of accuracy and a very high degree of precision, such as precision measurements to the hundredths of an Ohm (e.g.,  $0.01\Omega$ ) for the range of 1-50 $\Omega$ . The high degree of resistance detection accuracy provided by the system 100 allows for the detection sub-microscale

structures, including the firing of neural structures, differences between neural structures and other anatomical structures (e.g., blood vessels), and event different types of neural structures. This information can be analyzed by the mapping/evaluation/feedback algorithms and/or the controller 107 and communicated to the operator via a high resolution spatial grid (e.g., on the display 112) and/or other type of display to identify neural structures and other anatomy at the treatment site and/or indicate predicted neuromodulation regions based on the ablation pattern with respect to the mapped anatomy.

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As previously described, in certain embodiments, each electrode 136 can be operated independently of the other electrodes 136. For example, each electrode can be individually activated and the polarity and amplitude of each electrode can be selected by an operator or a control algorithm executed by the controller 107. The selective independent control of the electrodes 136 allows the end effector 114 to detect information and deliver RF energy to highly customized regions. For example, a select portion of the electrodes 136 can be activated to target specific neural fibers in a specific region while the other electrodes 136 remain inactive. In certain embodiments, for example, electrodes 136 may be activated across the portion of the second segment 124 that is adjacent to tissue at the target site, and the electrodes 136 that are not proximate to the target tissue can remain inactive to avoid applying energy to non-target tissue. In addition, the electrodes 136 can be individually activated to stimulate or therapeutically modulate certain regions in a specific pattern at different times (e.g., via multiplexing), which facilitates detection of anatomical parameters across a zone of interest and/or regulated therapeutic neuromodulation.

The electrodes 136 can be electrically coupled to the energy generator 106 via wires (not shown) that extend from the electrodes 136, through the shaft 116, and to the energy generator 106. When each of the electrodes 136 is independently controlled, each electrode 136 couples to a corresponding wire that extends through the shaft 116. This allows each electrode 136 to be independently activated for stimulation or neuromodulation to provide precise ablation patterns and/or individually detected via the console 104 to provide information specific to each electrode 136 for neural or anatomical detection and mapping. In other embodiments, multiple electrodes 136 can be controlled together and, therefore, multiple electrodes 136 can be electrically coupled to the same wire extending through the shaft 116. The energy generator 16 and/or components (e.g., a control module) operably coupled thereto can include custom algorithms to control the

activation of the electrodes 136. For example, the RF generator can deliver RF power at about 200-100 W to the electrodes 136, and do so while activating the electrodes 136 in a predetermined pattern selected based on the position of the end effector 114 relative to the treatment site and/or the identified locations of the target nerves. In other embodiments, the energy generator 106 delivers power at lower levels (e.g., less than 1 W, 1-5 W, 5-15 W, 15-50 W, 50-150 W, etc.) for stimulation and/or higher power levels. For example, the energy generator 106 can be configured to delivery stimulating energy pulses of 1-3 W via the electrodes 136 to stimulate specific targets in the tissue.

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As previously described, the end effector 114 can further include one or more temperature sensors disposed on the flexible first and second segments 122, 124 and/or other portions of the end effector 114 and electrically coupled to the console 104 via wires (not shown) that extend through the shaft 116. In various embodiments, the temperature sensors can be positioned proximate to the electrodes 136 to detect the temperature at the interface between tissue at the target site and the electrodes 136. In other embodiments, the temperature sensors can penetrate the tissue at the target site (e.g., a penetrating thermocouple) to detect the temperature at a depth within the tissue. The temperature measurements can provide the operator or the system with feedback regarding the effect of the therapeutic neuromodulation on the tissue. For example, in certain embodiments the operator may wish to prevent or reduce damage to the tissue at the treatment site (e.g., the nasal mucosa), and therefore the temperature sensors can be used to determine if the tissue temperature reaches a predetermined threshold for irreversible tissue damage. Once the threshold is reached, the application of therapeutic neuromodulation energy can be terminated to allow the tissue to remain intact and avoid significant tissue sloughing during wound healing. In certain embodiments, the energy delivery can automatically terminate based on the mapping/evaluation/feedback algorithm 110 stored on the console 104 operably coupled to the temperature sensors.

In certain embodiments, the system 100 can determine the locations and/or morphology of neural structures and/or other anatomical structures before therapy such that the therapeutic neuromodulation can be applied to precise regions including target neural structures, while avoiding negative effects on non-target structures, such as blood vessels. As described in further detail below, the system 100 can detect various bioelectrical parameters in an interest zone (e.g., within in the nasal cavity) to determine the location and morphology of various neural structures

(e.g., different types of neural structures, neuronal directionality, etc.) and/or other tissue (e.g., glandular structures, vessels, bony regions, etc.). In some embodiments, the system 100 is configured to measure bioelectric potential. To do so, one or more of the electrodes 136 is placed in contact with an epithelial surface at a region of interest (e.g., a treatment site). Electrical stimuli (e.g., constant or pulsed currents at one or more frequencies) are applied to the tissue by one or more electrodes 136 at or near the treatment site, and the voltage and/or current differences at various different frequencies between various pairs of electrodes 136 of the end effector 114 may be measured to produce a spectral profile or map of the detected bioelectric potential, which can be used to identify different types of tissues (e.g., vessels, neural structures, and/or other types of tissue) in the region of interest. For example, current (i.e., direct or alternating current) can be applied to a pair of electrodes 136 adjacent to each other and the resultant voltages and/or currents between other pairs of adjacent electrodes 136 are measured. It will be appreciated that the current injection electrodes 136 and measurement electrodes 136 need not be adjacent, and that modifying the spacing between the two current injection

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electrodes 136 can affect the depth of the recorded signals. For example, closely-spaced current injection electrodes 136 provided recorded signals associated with tissue deeper from the surface of the tissue than further spaced apart current injection electrodes 136 that provide recorded signals associated with tissue at shallower depths. Recordings from electrode pairs with different spacings may be merged to provide additional information on depth and localization of anatomical structures.

Further, complex impedance and/or resistance measurements of the tissue at the region of interest can be detected directly from current-voltage data provided by the bioelectric potential measurements while differing levels of frequency currents are applied to the tissue (e.g., via the end effector 114), and this information can be used to map the neural and anatomical structures by the use of frequency differentiation reconstruction. Applying the stimuli at different frequencies will target different stratified layers or cellular bodies or clusters. At high signal frequencies (e.g., electrical injection or stimulation), for example, cell membranes of the neural structures do not impede current flow, and the current passes directly through the cell membranes. In this case, the resultant measurement (e.g., impedance, resistance, capacitance, and/or induction) is a function of the intracellular and extracellular tissue and liquids. At low signal frequencies, the membranes impede current flow to provide different defining

characteristics of the tissues, such as the shapes of the cells or cell spacing. The stimulation frequencies can be in the megahertz range, in the kilohertz range (e.g., 400-500 kHz, 450-480 kHz, etc.), and/or other frequencies attuned to the tissue being stimulated and the characteristics of the device being used. The detected complex impedance or resistances levels from the zone of interest can be displayed to the user (e.g., via the display 112) to visualize certain structures based on the stimulus frequency.

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Further, the inherent morphology and composition of the anatomical structures in the nasal region react differently to different frequencies and, therefore, specific frequencies can be selected to identify very specific structures. For example, the morphology or composition of targeted structures for anatomical mapping may depend on whether the cells of tissue or other structure are membranonic, stratified, and/or annular. In various embodiments, the applied stimulation signals can have predetermined frequencies attuned to specific neural structures, such as the level of myelination and/or morphology of the myelination. For example, second axonal parasympathetic structures are poorly myelinated than sympathetic nerves or other structures and, therefore, will have a distinguishable response (e.g., complex impedance, resistance, etc.) with respect to a selected frequency than sympathetic nerves. Accordingly, applying signals with different frequencies to the target site can distinguish the targeted parasympathetic nerves from the non-targeted sensory nerves, and therefore provide highly specific target sites for neural mapping before or after therapy and/or neural evaluation post-therapy. In some embodiments, the neural and/or anatomical mapping includes measuring data at a region of interest with at least two different frequencies to identify certain anatomical structures such that the measurements are taken first based on a response to an injection signal having a first frequency and then again based on an injection signal having a second frequency different from the first. For example, there are two frequencies at which hypertrophied (i.e., disease-state characteristics) sub-mucosal targets have a different electrical conductivity or permittivity compared to "normal" (i.e., healthy) tissue. Complex conductivity may be determined based on one or more measured physiological parameters (e.g., complex impedance, resistance, dielectric measurements, dipole measurements, etc.) and/or observance of one or more confidently known attributes or signatures. Furthermore, the system 100 can also apply neuromodulation energy via the electrodes 136 at one or more predetermined frequencies attuned to a target neural structure to provide highly targeted ablation of the selected neural structure associated with the

frequency(ies). This highly targeted neuromodulation also reduces the collateral effects of neuromodulation therapy to non-target sites/structures (e.g., blood vessels) because the targeted signal (having a frequency tuned to a target neural structure) will not have the same modulating effects on the non-target structures.

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Accordingly, bioelectric properties, such as complex impedance and resistance, can be used by the system 100 before, during, and/or after neuromodulation therapy to guide one or more treatment parameters. For example, before, during, and/or after treatment, impedance or resistance measurements may be used to confirm and/or detect contact between one or more electrodes 136 and the adjacent tissue. The impedance or resistance measurements can also be used to detect whether the electrodes 136 are placed appropriately with respect to the targeted tissue type by determining whether the recorded spectra have a shape consistent with the expected tissue types and/or whether serially collected spectra were reproducible. In some embodiments, impedance or resistance measurements may be used to identify a boundary for the treatment zone (e.g., specific neural structures that are to be disrupted), anatomical landmarks, anatomical structures to avoid (e.g., vascular structures or neural structures that should not be disrupted), and other aspects of delivering energy to tissue.

The bioelectric information can be used to produce a spectral profile or map of the different anatomical features tissues at the target site, and the anatomical mapping can be visualized in a 3D or 2D image via the display 112 and/or other user interface to guide the selection of a suitable treatment site. This neural and anatomical mapping allows the system 100 to accurately detect and therapeutically modulate the postganglionic parasympathetic neural fibers that innervate the mucosa at the numerous neural entrance points into the nasal cavity. Further, because there are not any clear anatomical markers denoting the location of the SPF, accessory foramen, and microforamina, the neural mapping allows the operator to identify and therapeutically modulate nerves that would otherwise be unidentifiable without intricate dissection of the mucosa. In addition, anatomical mapping also allows the clinician to identify certain structures that the clinician may wish to avoid during therapeutic neural modulation (e.g., certain arteries). The neural and anatomical bioelectric properties detected by the system 100 can also be used during and after treatment to determine the real-time effect of the therapeutic neuromodulation on the treatment site. For example, the mapping/evaluation/feedback algorithms 110 can also compare the detected neural locations and/or activity before and after

therapeutic neuromodulation, and compare the change in neural activity to a predetermined threshold to assess whether the application of therapeutic neuromodulation was effective across the treatment site.

In various embodiments, the system 100 can also be configured to map the expected therapeutic modulation patterns of the electrodes 136 at specific temperatures and, in certain embodiments, take into account tissue properties based on the anatomical mapping of the target site. For example, the system 100 can be configured to map the ablation pattern of a specific electrode ablation pattern at the 45° C. isotherm, the 55° C. isotherm, the 65° C. isotherm, and/or other temperature/ranges (e.g., temperatures ranging from 45° C. to 70° C. or higher) depending on the target site and/or structure.

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The system 100 may provide, via the display 112, three-dimensional views of such projected ablation patterns of the electrodes 136 of the end effector 114. The ablation pattern mapping may define a region of influence that each electrode 136 has on the surrounding tissue. The region of influence may correspond to the region of tissue that would be exposed to therapeutically modulating energy based on a defined electrode activation pattern (i.e., one, two, three, four, or more electrodes on any given strut of the first and second segments 122, 124). In other words, the ablation pattern mapping can be used to illustrate the ablation pattern of any number of electrodes 136, any geometry of the electrode layout, and/or any ablation activation protocol (e.g., pulsed activation, multi-polar/sequential activation, etc.).

In some embodiments, the ablation pattern may be configured such that each electrode 136 has a region of influence surrounding only the individual electrode 136 (i.e., a "dot" pattern). In other embodiments, the ablation pattern may be such that two or more electrodes 136 may link together to form a sub-grouped regions of influence that define peanut-like or linear shapes between two or more electrodes 136. In further embodiments, the ablation pattern can result in a more expansive or contiguous pattern in which the region of influence extends along multiple electrodes 136 (e.g., along each strut). In still further embodiments, the ablation pattern may result in different regions of influence depending upon the electrode activation pattern, phase angle, target temperature, pulse duration, device structure, and/or other treatment parameters. The three-dimensional views of the ablation patterns can be output to the display 112 and/or other user interfaces to allow the clinician to visualize the changing regions of influence based on different durations of energy application, different electrode activation sequences (e.g.,

multiplexing), different pulse sequences, different temperature isotherms, and/or other treatment parameters. This information can be used to determine the appropriate ablation algorithm for a patient's specific anatomy. In other embodiments, the three-dimensional visualization of the regions of influence can be used to illustrate the regions from which the electrodes 136 detect data when measuring bioelectrical properties for anatomical mapping. In this embodiment, the three dimensional visualization can be used to determine which electrode activation pattern should be used to determine the desired properties (e.g., impedance, resistance, etc.) in the desired area. In certain embodiments, it may be better to use dot assessments, whereas in other embodiments it may be more appropriate to detect information from linear or larger contiguous regions.

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In some embodiments, the mapped ablation pattern is superimposed on the anatomical mapping to identify what structures (e.g., neural structures, vessels, etc.) will be therapeutically modulated or otherwise affected by the therapy. An image may be provided to the surgeon which includes a digital illustration of a predicted or planned neuromodulation zone in relation to previously identified anatomical structures in a zone of interest. For example, the illustration may show numerous neural structures and, based on the predicted neuromodulation zone, identifies which neural structures are expected to be therapeutically modulated. The expected therapeutically modulated neural structures may be shaded to differentiate them from the nonaffected neural structures. In other embodiments, the expected therapeutically modulated neural structures can be differentiated from the non-affected neural structures using different colors and/or other indicators. In further embodiments, the predicted neuromodulation zone and surrounding anatomy (based on anatomical mapping) can be shown in a three dimensional view (and/or include different visualization features (e.g., color-coding to identify certain anatomical structures, bioelectric properties of the target tissue, etc.). The combined predicted ablation pattern and anatomical mapping can be output to the display 112 and/or other user interfaces to allow the clinician to select the appropriate ablation algorithm for a patient's specific anatomy.

The imaging provided by the system 100 allows the clinician to visualize the ablation pattern before therapy and adjust the ablation pattern to target specific anatomical structures while avoiding others to prevent collateral effects. For example, the clinician can select a treatment pattern to avoid blood vessels, thereby reducing exposure of the vessel to the therapeutic neuromodulation energy. This reduces the risk of damaging or rupturing vessels and,

therefore, prevents immediate or latent bleeding. Further, the selective energy application provided by the neural mapping reduces collateral effects of the therapeutic neuromodulation, such as tissue sloughing off during wound healing (e.g., 1-3 weeks post ablation), thereby reducing the aspiration risk associated with the neuromodulation procedure.

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The system 100 can be further configured to apply neuromodulation energy (via the electrodes 136) at specific frequencies attuned to the target neural structure and, therefore, specifically target desired neural structures over non-target structures. For example, the specific neuromodulation frequencies can correspond to the frequencies identified as corresponding to the target structure during neural mapping. As described above, the inherent morphology and composition of the anatomical structures react differently to different frequencies. Thus, frequency-tuned neuromodulation energy tailored to a target structure does not have the same modulating effects on non-target structures. More specifically, applying the neuromodulation energy at the target-specific frequency causes ionic agitation in the target neural structure, leading to differentials in osmotic potentials of the targeted neural structures and dynamic changes in neuronal membronic potentials (resulting from the difference in intra-cellular and extra-cellular fluidic pressure). This causes degeneration, possibly resulting in vacuolar degeneration and, eventually, necrosis at the target neural structure, but is not expected to functionally affect at least some non-target structures (e.g., blood vessels). Accordingly, the system 100 can use the neural-structure specific frequencies to both (1) identify the locations of target neural structures to plan electrode ablation configurations (e.g., electrode geometry and/or activation pattern) that specifically focus the neuromodulation on the target neural structure; and (2) apply the neuromodulation energy at the characteristic neural frequencies to selectively ablate the neural structures responsive to the characteristic neural frequencies. For example, the end effector 114 of the system 100 may selectively stimulate and/or modulate parasympathetic fibers, sympathetic fibers, sensory fibers, alpha/beta/delta fibers, C-fibers, anoxic terminals of one or more of the foregoing, insulated over non-insulated fibers (regions with fibers), and/or other neural structures. In some embodiments, the system 100 may also selectively target specific cells or cellular regions during anatomical mapping and/or therapeutic modulation, such as smooth muscle cells, sub-mucosal glands, goblet cells, stratified cellular regions within the nasal mucosa. Therefore, the system 100 provides highly selective neuromodulation therapy specific

to targeted neural structures, and reduces the collateral effects of neuromodulation therapy to non-target structures (e.g., blood vessels).

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The present disclosure provides a method of anatomical mapping and therapeutic neuromodulation. The method includes expanding an end effector (i.e., end effector 114) at a zone of interest ("interest zone"), such as in a portion of the nasal cavity. For example, the end effector 114 can be expanded such that at least some of the electrodes 136 are placed in contact with mucosal tissue at the interest zone. The expanded device can then take bioelectric measurements via the electrodes 136 and/or other sensors to ensure that the desired electrodes are in proper contact with the tissue at the interest zone. In some embodiments, for example, the system 100 detects the impedance and/or resistance across pairs of the electrodes 136 to confirm that the desired electrodes have appropriate surface contact with the tissue and that all of the electrodes are 136 functioning properly.

The method continues by optionally applying an electrical stimulus to the tissue, and detecting bioelectric properties of the tissue to establish baseline norms of the tissue. For example, the method can include measuring resistance, complex impedance, current, voltage, nerve firing rate, neuromagnetic field, muscular activation, and/or other parameters that are indicative of the location and/or function of neural structures and/or other anatomical structures (e.g., glandular structures, blood vessels, etc.). In some embodiments, the electrodes 136 send one or more stimulation signals (e.g., pulsed signals or constant signals) to the interest zone to stimulate neural activity and initiate action potentials. The stimulation signal can have a frequency attuned to a specific target structure (e.g., a specific neural structure, a glandular structure, a vessel) that allows for identification of the location of the specific target structure. The specific frequency of the stimulation signal is a function of the host permeability and, therefore, applying the unique frequency alters the tissue attenuation and the depth into the tissue the RF energy will penetrate. For example, lower frequencies typically penetrate deeper into the tissue than higher frequencies.

Pairs of the non-stimulating electrodes 136 of the end effector 114 can then detect one or more bioelectric properties of the tissue that occur in response to the stimulus, such as impedance or resistance. For example, an array of electrodes (e.g., the electrodes 136) can be selectively paired together in a desired pattern (e.g., multiplexing the electrodes 136) to detect the bioelectric properties at desired depths and/or across desired regions to provide a high level of

spatial awareness at the interest zone. In certain embodiments, the electrodes 136 can be paired together in a time-sequenced manner according to an algorithm (e.g., provided by the mapping/evaluation/feedback algorithms 110). In various embodiments, stimuli can be injected into the tissue at two or more different frequencies, and the resultant bioelectric responses (e.g., action potentials) in response to each of the injected frequencies can be detected via various pairs of the electrodes 136. For example, an anatomical or neural mapping algorithm can cause the end effector 114 to deliver pulsed RF energy at specific frequencies between different pairs of the electrodes 136 and the resultant bioelectric response can be recorded in a time sequenced rotation until the desired interest zone is adequately mapped (i.e., "multiplexing"). For example, the end effector 114 can deliver stimulation energy at a first frequency via adjacent pairs of the electrodes 136 for a predetermined time period (e.g., 1-50 milliseconds), and the resultant bioelectric activity (e.g., resistance) can be detected via one or more other pairs of electrodes 136 (e.g., spaced apart from each other to reach varying depths within the tissue). The end effector 114 can then apply stimulation energy at a second frequency different from the first frequency, and the resultant bioelectric activity can be detected via the other electrodes. This can continue when the interest zone has been adequately mapped at the desired frequencies. As described in further detail below, in some embodiments the baseline tissue bioelectric properties (e.g., nerve firing rate) are detected using static detection methods (without the injection of a stimulation signal).

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After detecting the baseline bioelectric properties, the information can be used to map anatomical structures and/or functions at the interest zone. For example, the bioelectric properties detected by the electrodes 136 can be amazed via the mapping/evaluation/feedback algorithms 110, and an anatomical map can be output to a user via the display 112. In some embodiments, complex impedance, dielectric, or resistance measurements can be used to map parasympathetic nerves and, optionally, identify neural structures in a diseased state of hyperactivity. The bioelectric properties can also be used to map other non-target structures and the general anatomy, such as blood vessels, bone, and/or glandular structures. The anatomical locations can be provided to a user (e.g., on the display 112) as a two-dimensional map (e.g., illustrating relative intensities, illustrating specific sites of potential target structures) and/or as a three-dimensional image. This information can be used to differentiate structures on a submicron, cellular level and identify very specific target structures (e.g., hyperactive

parasympathetic nerves). The method can also predict the ablation patterns of the end effector 114 based on different electrode neuromodulation protocol and, optionally, superimpose the predicted neuromodulation patterns onto the mapped anatomy to indicate to the user which anatomical structures will be affected by a specific neuromodulation protocol. For example, when the predicted neuromodulation pattern is displayed in relation to the mapped anatomy, a clinician can determine whether target structures will be appropriately ablated and whether non-target structures (e.g., blood vessels) will be undesirably exposed to the therapeutic neuromodulation energy. Thus, the method can be used for planning neuromodulation therapy to locate very specific target structures, avoid non-target structures, and select electrode neuromodulation protocols.

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Once the target structure is located and a desired electrode neuromodulation protocol has been selected, the method continues by applying therapeutic neuromodulation to the target structure. The neuromodulation energy can be applied to the tissue in a highly targeted manner that forms micro-lesions to selectively modulate the target structure, while avoiding non-targeted blood vessels and allowing the surrounding tissue structure to remain healthy for effective wound healing. In some embodiments, the neuromodulation energy can be applied in a pulsed manner, allowing the tissue to cool between modulation pulses to ensure appropriate modulation without undesirably affecting non-target tissue. In some embodiments, the neuromodulation algorithm can deliver pulsed RF energy between different pairs of the electrodes 136 in a time sequenced rotation until neuromodulation is predicted to be complete (i.e., "multiplexing"). For example, the end effector 114 can deliver neuromodulation energy (e.g., having a power of 5-10 W (e.g., 7 W, 8 W, 9 W) and a current of about 50-100 mA) via adjacent pairs of the electrodes 136 until at least one of the following conditions is met: (a) load resistance reaches a predefined maximum resistance (e.g.,  $350\Omega$ ); (b) a thermocouple temperature associated with the electrode pair reaches a predefined maximum temperature (e.g., 80° C.); or (c) a predetermined time period has elapsed (e.g., 10 seconds). After the predetermined conditions are met, the end effector 114 can move to the next pair of electrodes in the sequence, and the neuromodulation algorithm can terminate when all of the load resistances of the individual pairs of electrodes is at or above a predetermined threshold (e.g.,  $100\Omega$ ). In various embodiments, the RF energy can be applied at a predetermined frequency (e.g., 450-500 kHz) and is expected to initiate ionic

agitation of the specific target structure, while avoiding functional disruption of non-target structures.

During and/or after neuromodulation therapy, the method continues by detecting and, optionally, mapping the post-therapy bioelectric properties of the target site. This can be performed in a similar manner as described above. The post-therapy evaluation can indicate if the target structures (e.g., hyperactive parasympathetic nerves) were adequately modulated or ablated. If the target structures are not adequately modulated (i.e., if neural activity is still detected in the target structure and/or the neural activity has not decreased), the method can continue by again applying therapeutic neuromodulation to the target. If the target structures were adequately ablated, the neuromodulation procedure can be completed.

## **Detection of Anatomical Structures and Function**

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Various embodiments of the present technology can include features that measure bioelectric, dielectric, and/or other properties of tissue at target sites to determine the presence,
location, and/or activity of neural structures and other anatomical structures and, optionally, map
the locations of the detected neural structures and/or other anatomical structures. For example,
the present technology can be used to detect glandular structures and, optionally, their
mucoserous functions and/or other functions. The present technology can also be configured to
detect vascular structures (e.g., arteries) and, optionally, their arterial functions, volumetric
pressures, and/or other functions. The mapping features discussed below can be incorporated
into any the system 100 and/or any other devices disclosed herein to provide an accurate
depiction of nerves at the target site.

Neural and/or anatomical detection can occur (a) before the application of a therapeutic neuromodulation energy to determine the presence or location of neural structures and other anatomical structures (e.g., blood vessels, glands, etc.) at the target site and/or record baseline levels of neural activity; (b) during therapeutic neuromodulation to determine the real-time effect of the energy application on the neural fibers at the treatment site; and/or (c) after therapeutic neuromodulation to confirm the efficacy of the treatment on the targeted structures (e.g., nerves glands, etc.). This allows for the identification of very specific anatomical structures (even to the micro-scale or cellular level) and, therefore, provides for highly targeted neuromodulation. This

enhances the efficacy and efficiency of the neuromodulation therapy. In addition, the anatomical mapping reduces the collateral effects of neuromodulation therapy to non-target sites.

Accordingly, the targeted neuromodulation inhibits damage or rupture of blood vessels (i.e., inhibits undesired bleeding) and collateral damage to tissue that may be of concern during wound healing (e.g., when damage tissue sloughs off of the wall of the nasal wall).

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In certain embodiments, the systems disclosed herein can use bioelectric measurements, such as impedance, resistance, voltage, current density, and/or other parameters (e.g., temperature) to determine the anatomy, in particular the neural, glandular, and vascular anatomy, at the target site. The bioelectric properties can be detected after the transmission of a stimulus (e.g., an electrical stimulus, such as RF energy delivered via the electrodes 136; i.e., "dynamic" detection) and/or without the transmission of a stimulus (i.e., "static" detection).

Dynamic measurements include various embodiments to excite and/or detect primary or secondary effects of neural activation and/or propagation. Such dynamic embodiments involve the heightened states of neural activation and propagation and use this dynamic measurement for nerve location and functional identification relative to the neighboring tissue types. For example, a method of dynamic detection can include: (1) delivering stimulation energy to a treatment site via a treatment device (e.g., the end effector 114) to excite parasympathetic nerves at the treatment site; (2) measuring one or more physiological parameters (e.g., resistance, impedance, etc.) at the treatment site via a measuring/sensing array of the treatment device (e.g., the electrodes 136); (4) based on the measurements, identifying the relative presence and position of parasympathetic nerves at the treatment site; and (5) delivering ablation energy to the identified parasympathetic nerves to block the detected para-sympathetic nerves.

Static measurements include various embodiments associated with specific native properties of the stratified or cellular composition at or near the treatment site. The static embodiments are directed to inherent biologic and electrical properties of tissue types at or near the treatment site, the stratified or cellular compositions at or near the treatment site, and contrasting both foregoing measurements with tissue types adjacent the treatment site (and that are not targeted for neuromodulation). This information can be used to localize specific targets (e.g., parasympathetic fibers) and non-targets (e.g., vessels, sensory nerves, etc.). For example, a method of static detection can include: (1) before ablation, utilizing a measuring/sensing array of a treatment device (e.g., the electrodes 136) to determine one or more baseline physiological

parameters; (2) geometrically identifying inherent tissue properties within a region of interest based on the measured physiological parameters (e.g., resistance, impedance, etc.); (3) delivering ablation energy to one or more nerves within the region of via treatment device interest; (4) during the delivery of the ablation energy, determining one or more mid-procedure physiological parameters via the measuring/sensing array; and (5) after the delivery of ablation energy, determining one or more post-procedure physiological parameters via the measurement/sensing array to determine the effectiveness of the delivery of the ablation energy on blocking the nerves that received the ablation energy.

After the initial static and/or dynamic detection of bioelectric properties, the location of anatomical features can be used to determine where the treatment site(s) should be with respect to various anatomical structures for therapeutically effective neuromodulation of the targeted parasympathetic nasal nerves. The bioelectric and other physiological properties described herein can be detected via electrodes (e.g., the electrodes 136 of the end effector 114), and the electrode pairings on a device (e.g., end effector 114) can be selected to obtain the bioelectric data at specific zones or regions and at specific depths of the targeted regions. The specific properties detected at or surrounding target neuromodulation sites and associated methods for obtaining these properties are described below. These specific detection and mapping methods discussed below are described with reference to the system 100, although the methods can be implemented on other suitable systems and devices that provide for anatomical identification, anatomical mapping and/or neuromodulation therapy.

## Neural Identification and Mapping

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In many neuromodulation procedures, it is beneficial to identify the portions of the nerves that fall within a zone and/or region of influence (referred to as the "interest zone") of the energy delivered by a neuromodulation device 102, as well as the relative three-dimensional position of the neural structures relative to the neuromodulation device 102. Characterizing the portions of the neural structures within the interest zone and/or determining the relative positions of the neural structures within the interest zone enables the clinician to (1) selectively activate target neural structures over non-target structures (e.g., blood vessels), and (2) sub-select specific targeted neural structures (e.g., parasympathetic nerves) over non-target neural structures (e.g.,

sensory nerves, subgroups of neural structures, neural structures having certain compositions or morphologies). The target structures (e.g., parasympathetic nerves) and non-target structures (e.g., blood vessels, sensory nerves, etc.) can be identified based on the inherent signatures of specific structures, which are defined by the unique morphological compositions of the structures and the bioelectrical properties associated with these morphological compositions. For example, unique, discrete frequencies can be associated with morphological compositions and, therefore, be used to identify certain structures. The target and non-target structures can also be identified based on relative bioelectrical activation of the structures to sub-select specific neuronal structures. Further, target and non-target structures can be identified by the differing detected responses of the structures to a tailored injected stimuli. For example, the systems described herein can detect the magnitude of response of structures and the difference in the responses of anatomical structures with respect to differing stimuli (e.g., stimuli injected at different frequencies).

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At least for purposes of this disclosure, a nerve can include the following portions that are defined based on their respective orientations relative to the interest zone: terminating neural structures (e.g., terminating axonal structures), branching neural structures (e.g., branching axonal structures), and travelling neural structures (e.g., travelling axonal structures). For example, terminating neural structures enter the zone but do not exit. As such, terminating neural structures are terminal points for neuronal signaling and activation. Branching neural structures are nerves that enter the interest zone and increase number of nerves exiting the interest zone. Branching neural structures are typically associated with a reduction in relative geometry of nerve bundle. Travelling neural structures are nerves that enter the interest zone and exit the zone with no substantially no change in geometry or numerical value.

The system 100 can be used to detect voltage, current, complex impedance, resistance, permittivity, and/or conductivity, which are tied to the compound action potentials of nerves, to determine and/or map the relative positions and proportionalities of nerves in the interest zone. Neuronal cross-sectional area ("CSA") is expected to be due to the increase in axonic structures. Each axon is a standard size. Larger nerves (in cross-sectional dimension) have a larger number of axons than nerves having smaller cross-sectional dimensions. The compound action responses from the larger nerves, in both static and dynamic assessments, are greater than smaller nerves. This is at least in part because the compound action potential is the cumulative

action response from each of the axons. When using static analysis, for example, the system 100 can directly measure and map impedance or resistance of nerves and, based on the determined impedance or resistance, determine the location of nerves and/or relative size of the nerves. In dynamic analysis, the system 100 can be used to apply a stimulus to the interest zone and detect the dynamic response of the neural structures to the stimulus. Using this information, the system 100 can determine and/or map impedance or resistance in the interest zone to provide information related to the neural positions or relative nerve sizes. Neural impedance mapping can be illustrated by showing the varying complex impedance levels at a specific location at differing cross-sectional depths. In other embodiments, neural impedance or resistance can be mapped in a three-dimensional display.

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Identifying the portions and/or relative positions of the nerves within the interest zone can inform and/or guide selection of one or more treatment parameters (e.g., electrode ablation patterns, electrode activation plans, etc.) of the system 100 for improving treatment efficiency and efficacy. For example, during neural monitoring and mapping, the system 100 can identify the directionality of the nerves based at least in part on the length of the neural structure extending along the interest zone, relative sizing of the neural structures, and/or the direction of the action potentials. This information can then be used by the system 100 or the clinician to automatically or manually adjust treatment parameters (e.g., selective electrode activation, bipolar and/or multipolar activation, and/or electrode positioning) to target specific nerves or regions of nerves. For example, the system 100 can selectively activate specific electrodes 136, electrode combinations (e.g., asymmetric or symmetric), and/or adjust the bi-polar or multi-polar electrode configuration. In some embodiments, the system 100 can adjust or select the waveform, phase angle, and/or other energy delivery parameters based on the nerve portion/position mapping and/or the nerve proportionality mapping. In some embodiments, structure and/or properties of the electrodes 136 themselves (e.g., material, surface roughening, coatings, cross-sectional area, perimeter, penetrating, penetration depth, surface-mounted, etc.) may be selected based on the nerve portion and proportionality mapping.

In various embodiments, treatment parameters and/or energy delivery parameters can be adjusted to target on-axis or near axis travelling neural structures and/or avoid the activation of traveling neural structures that are at least generally perpendicular to the end effector 114. Greater portions of the on-axis or near axis travelling neural structures are exposed and

susceptible to the neuromodulation energy provided by the end effector 114 than a perpendicular travelling neural structure, which may only be exposed to therapeutic energy at a discrete cross-section. Therefore, the end effector 114 is more likely to have a greater effect on the on-axis or near axis travelling neural structures. The identification of the neural structure positions (e.g., via complex impedance or resistance mapping) can also allow targeted energy delivery to travelling neural structures rather than branching neural structures (typically downstream of the travelling neural structures) because the travelling neural structures are closer to the nerve origin and, therefore, more of the nerve is affected by therapeutic neuromodulation, thereby resulting in a more efficient treatment and/or a higher efficacy of treatment. Similarly, the identification of neural structure positions can be used to target travelling and branching neural structures over terminal neural structures. In some embodiments, the treatment parameters can be adjusted based on the detected neural positions to provide a selective regional effect. For example, a clinician can target downstream portions of the neural structures if only wanting to influence partial effects on very specific anatomical structures or positions.

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In various embodiments, neural locations and/or relative positions of nerves can be determined by detecting the nerve-firing voltage and/or current over time. An array of the electrodes 136 can be positioned in contact with tissue at the interest zone, and the electrodes 136 can measure the voltage and/or current associated with nerve-firing. This information can optionally be mapped (e.g., on a display 112) to identify the location of nerves in a hyper state (i.e., excessive parasympathetic tone). Rhinitis is at least in part the result of over-firing nerves because this hyper state drives the hyper-mucosal production and hyper-mucosal secretion. Therefore, detection of nerve firing rate via voltage and current measurements can be used to locate the portions of the interest region that include hyper-parasympathetic neural function (i.e., nerves in the diseased state). This allows the clinician to locate specific nerves (i.e., nerves with excessive parasympathetic tone) before neuromodulation therapy, rather than simply targeting all parasympathetic nerves (including non-diseased state parasympathetic nerves) to ensure that the correct tissue is treated during neuromodulation therapy. Further, nerve firing rate can be detected during or after neuromodulation therapy so that the clinician can monitor changes in nerve firing rate to validate treatment efficacy. For example, recording decreases or elimination of nerve firing rate after neuromodulation therapy can indicate that the therapy was effective in therapeutically treating the hyper/diseased nerves.

In various embodiments, the system 100 can detect neural activity using dynamic activation by injecting a stimulus signal (i.e., a signal that temporarily activates nerves) via one or more of the electrodes 136 to induce an action potential, and other pairs of electrodes 136 can detect bioelectric properties of the neural response. Detecting neural structures using dynamic activation involves detecting the locations of action potentials within the interest zone by measuring the discharge rate in neurons and the associated processes. The ability to numerically measure, profile, map, and/or image fast neuronal depolarization for generating an accurate index of activity is a factor in measuring the rate of discharge in neurons and their processes. The action potential causes a rapid increase in the voltage across nerve fiber and the electrical impulse then spreads along the fiber. As an action potential occurs, the conductance of a neural cell membrane changes, becoming about 40 times larger than it is when the cell is at rest. During the action potential or neuronal depolarization, the membrane resistance diminishes by about 80 times, thereby allowing an applied current to enter the intracellular space as well. Over a population of neurons, this leads to a net decrease in the resistance during coherent neuronal activity, such as chronic para-sympathetic responses, as the intracellular space will provide additional conductive ions. The magnitude of such fast changes has been estimated to have local resistivity changes with recording near DC is 2.8-3.7% for peripheral nerve bundles (e.g., including the nerves in the nasal cavity).

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Detecting neural structures using dynamic activation includes detecting the locations of action potentials within the interest zone by measuring the discharge rate in neurons and the associated processes. The basis of each this discharge is the action potential, during which there is a depolarization of the neuronal membrane of up to 110 mV or more, lasting approximately 2 milliseconds, and due to the transfer of micromolar quantities of ions (e.g., sodium and potassium) across the cellular membrane. The complex impedance or resistance change due to the neuronal membrane falls from 1000 to 25  $\Omega$ cm. The introduction of a stimulus and subsequent measurement of the neural response can attenuate noise and improve signal to noise ratios to precisely focus on the response region to improve neural detection, measurement, and mapping.

In some embodiments, the difference in measurements of physiological parameters (e.g., complex impedance, resistance, voltage) over time, which can reduce errors, can be used to create a neural profiles, spectrums, or maps. For example, the sensitivity of the system 100 can

be improved because this process provides repeated averaging to a stimulus. As a result, the mapping function outputs can be a unit-less ratio between the reference and test collated data at a single frequency and/or multiple frequencies and/or multiple amplitudes. Additional considerations may include multiple frequency evaluation methods that consequently expand the parameter assessments, such as resistivity, admittivity, center frequency, or ratio of extra- to intracellular resistivity.

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In some embodiments, the system 100 may also be configured to indirectly measure the electrical activity of neural structures to quantify the metabolic recovery processes that accompany action potential activity and act to restore ionic gradients to normal. These are related to an accumulation of ions in the extracellular space. The indirect measurement of electrical activity can be approximately a thousand times larger (in the order of millimolar), and thus are easier to measure and can enhance the accuracy of the measured electrical properties used to generate the neural maps.

The system 100 can perform dynamic neural detection by detecting nerve-firing voltage and/or current and, optionally, nerve firing rate over time, in response to an external stimulation of the nerves. For example, an array of the electrodes 136 can be positioned in contact with tissue at the interest zone, one or more of the electrodes 136 can be activated to inject a signal into the tissue that stimulates the nerves, and other electrodes 136 of the electrode array can measure the neural voltage and/or current due to nerve firing in response to the stimulus. This information can optionally be mapped (e.g., on a display 112) to identify the location of nerves and, in certain embodiments, identify parasympathetic nerves in a hyper state (e.g., indicative of Rhinitis or other diseased state). The dynamic detection of neural activity (voltage, current, firing rate, etc.) can be performed before neuromodulation therapy to detect target nerve locations to select the target site and treatment parameters to ensure that the correct tissue is treated during neuromodulation therapy. Further, dynamic detection of neural activity can be performed during or after neuromodulation therapy to allow the clinician to monitor changes in neural activity to validate treatment efficacy. For example, recording decreases or elimination of neural activity after neuromodulation therapy can indicate that the therapy was effective in therapeutically treating the hyper/diseased nerves.

In some embodiments, a stimulating signal can be delivered to the vicinity of the targeted nerve via one or more penetrating electrodes (e.g., microneedles that penetrate tissue) associated

with the end effector 114 and/or a separate device. The stimulating signal generates an action potential, which causes smooth muscle cells or other cells to contract. The location and strength of this contraction can be detected via the penetrating electrode(s) and, thereby, indicate to the clinician the distance to the nerve and/or the location of the nerve relative to the stimulating needle electrode. In some embodiments, the stimulating electrical signal may have a voltage of typically 1-2 mA or greater and a pulse width of typically 100-200 microseconds or greater. Shorter pulses of stimulation result in better discrimination of the detected contraction, but may require more current. The greater the distance between the electrode and the targeted nerve, the more energy is required to stimulate. The stimulation and detection of contraction strength and/or location enables identification of how close or far the electrodes are from the nerve, and therefore can be used to localize the nerve spatially. In some embodiments, varying pulse widths may be used to measure the distance to the nerve. As the needle becomes closer to the nerve, the pulse duration required to elicit a response becomes less and less.

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To localize nerves via muscle contraction detection, the system 100 can vary pulse-width or amplitude to vary the energy (Energy=pulse-width\*amplitude) of the stimulus delivered to the tissue via the penetrating electrode(s). By varying the stimulus energy and monitoring muscle contraction via the penetrating electrodes and/or other type of sensor, the system 100 can estimate the distance to the nerve. If a large amount of energy is required to stimulate the nerve/contract the muscle, the stimulating/penetrating electrode is far from the nerve. As the stimulating/penetrating electrode, moves closer to the nerve, the amount of energy required to induce muscle contraction will drop. For example, an array of penetrating electrodes can be positioned in the tissue at the interest zone and one or more of the electrodes can be activated to apply stimulus at different energy levels until they induce muscle contraction. Using an iterative process, localize the nerve (e.g., via the mapping/evaluation/feedback algorithm 110).

In some embodiments, the system 100 can measure the muscular activation from the nerve stimulus (e.g., via the electrodes 136) to determine neural positioning for neural mapping, without the use of penetrating electrodes. In this embodiment, the treatment device targets the smooth muscle cells' varicosities surrounding the submucosal glands and the vascular supply, and then the compound muscle action potential. This can be used to summate voltage response from the individual muscle fiber action potentials. The shortest latency is the time from stimulus artifact to onset of the response. The corresponding amplitude is measured from baseline to

negative peak and measured in millivolts (mV). Nerve latencies (mean±SD) in adults typically range about 2-6 milliseconds, and more typically from about 3.4±0.8 to about 4.0±0.5 milliseconds. A comparative assessment may then be made which compares the outputs at each time interval (especially pre- and post-energy delivery) in addition to a group evaluation using the alternative nasal cavity. This is expected to provide an accurate assessment of the absolute value of the performance of the neural functioning because muscular action/activation may be used to infer neural action/activation and muscle action/activation is a secondary effect or by-product whilst the neural function is the absolute performance measure.

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In some embodiments, the system 100 can record a neuromagnetic field outside of the nerves to determine the internal current of the nerves without physical disruption of the nerve membrane. Without being bound by theory, the contribution to the magnetic field from the current inside the membrane is two orders of magnitude larger than that from the external current, and that the contribution from current within the membrane is substantially negligible. Electrical stimulation of the nerve in tandem with measurements of the magnetic compound action fields ("CAFs") can yield sequential positions of the current dipoles such that the location of the conduction change can be estimated (e.g., via the least-squares method). Visual representation (e.g., via the display 112) using magnetic contour maps can show normal or nonnormal neural characteristics (e.g., normal can be equated with a characteristic quadrupolar pattern propagating along the nerve), and therefore indicate which nerves are in a diseases, hyperactive state and suitable targets for neuromodulation.

During magnetic field detection, an array of the electrodes 136 can be positioned in contact with tissue at the interest zone and, optionally, one or more of the electrodes 136 can be activated to inject an electrical stimulus into the tissue. As the nerves in the interest zone fire (either in response to a stimulus or in the absence of it), the nerve generates a magnetic field (e.g., similar to a current carrying wire), and therefore changing magnetic fields are indicative of the nerve nerve-firing rate. The changing magnetic field caused by neural firing can induce a current detected by nearby sensor wire (e.g., the sensor 314) and/or wires associated with the nearby electrodes 136. By measuring this current, the magnetic field strength can be determined. The magnetic fields can optionally be mapped (e.g., on a display 112) to identify the location of nerves and select target nerves (nerves with excessive parasympathetic tone) before neuromodulation therapy to ensure that the desired nerves are treated during neuromodulation

therapy. Further, the magnetic field information can be used during or after neuromodulation therapy so that the clinician can monitor changes in nerve firing rate to validate treatment efficacy.

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In other embodiments, the neuromagnetic field is measured with a Hall Probe or other suitable device, which can be integrated into the end effector 114 and/or part of a separate device delivered to the interest zone. Alternatively, rather than measuring the voltage in the second wire, the changing magnetic field can be measured in the original wire (i.e. the nerve) using a Hall probe. A current going through the Hall probe will be deflected in the semi-conductor. This will cause a voltage difference between the top and bottom portions, which can be measured. In some aspects of this embodiments, three orthogonal planes are utilized.

In some embodiments, the system 100 can be used to induce electromotive force ("EMF") in a wire (i.e., a frequency-selective circuit, such as a tunable/LC circuit) that is tunable to resonant frequency of a nerve. In this embodiment, the nerve can be considered to be a current carrying wire, and the firing action potential is a changing voltage. This causes a changing current which, in turn, causes a changing magnetic flux (i.e., the magnetic field that is perpendicular to the wire). Under Faraday's Law of Induction/Faraday's Principle, the changing magnetic flux induces EMF (including a changing voltage) in a nearby sensor wire (e.g., integrated into the end effector 114, the sensor 314, and/or other structure), and the changing voltage can be measured via the system 100.

In further embodiments, the sensor wire (e.g., the sensor 314) is an inductor and, therefore, provides an increase of the magnetic linkage between the nerve (i.e., first wire) and the sensor wire (i.e., second wire), with more turns for increasing effect. (e.g., V2,rms=V1,rms (N2/N1)). Due to the changing magnetic field, a voltage is induced in the sensor wire, and this voltage can be measured and used to estimate current changes in the nerve. Certain materials can be selected to enhance the efficiency of the EMF detection. For example, the sensor wire can include a soft iron core or other high permeability material for the inductor.

During induced EMF detection, the end effector 114 and/or other device including a sensor wire is positioned in contact with tissue at the interest zone and, optionally, one or more of the electrodes 136 can be activated to inject an electrical stimulus into the tissue. As the nerves in the interest zone fire (either in response to a stimulus or in the absence of it), the nerve generates a magnetic field (e.g., similar to a current carrying wire) that induces a current in the

sensor wire (e.g., the sensor 314). This information can be used to determine neural location and/or map the nerves (e.g., on a display 112) to identify the location of nerves and select target nerves (nerves with excessive parasympathetic tone) before neuromodulation therapy to ensure that the desired nerves are treated during neuromodulation therapy. EMF information can also be used during or after neuromodulation therapy so that the clinician can monitor changes in nerve firing rate to validate treatment efficacy.

In some embodiments, the system 100 can detect magnetic fields and/or EMF generated at a selected frequency that corresponds to a particular type of nerve. The frequency and, by extension, the associated nerve type of the detected signal can be selected based on an external resonant circuit. Resonance occurs on the external circuit when it is matched to the frequency of the magnetic field of the particular nerve type and that nerve is firing. In manner, the system 100 can be used to locate a particular sub-group/type of nerves.

In some embodiments, the system 100 can include a variable capacitor frequencyselective circuit to identify the location and/or map specific nerves (e.g., parasympathetic nerve, sensory nerve, nerve fiber type, nerve subgroup, etc.). The variable capacitor frequencyselective circuit can be defined by the sensor 314 and/or other feature of the end effector 114. Nerves have different resonant frequencies based on their function and structure. Accordingly, the system 100 can include a tunable LC circuit with a variable capacitor (C) and/or variable inductor (L) that can be selectively tuned to the resonant frequency of desired nerve types. This allows for the detection of neural activity only associated with the selected nerve type and its associated resonant frequency. Tuning can be achieved by moving the core in and out of the inductor. For example, tunable LC circuits can tune the inductor by: (i) changing the number of coils around the core; (ii) changing the cross-sectional area of the coils around the core; (iii) changing the length of the coil; and/or (iv) changing the permeability of the core material (e.g., changing from air to a core material). Systems including such a tunable LC circuit provide a high degree of dissemination and differentiation not only as to the activation of a nerve signal, but also with respect to the nerve type that is activated and the frequency at which the nerve is firing.

### 30 Anatomical Mapping

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In various embodiments, the system 100 is further configured to provide minimallyinvasive anatomical mapping that uses focused energy current/voltage stimuli from a spatially localized source (e.g., the electrodes 136) to cause a change in the conductivity of the of the tissue at the interest zone and detect resultant biopotential and/or bioelectrical measurements (e.g., via the electrodes 136). The current density in the tissue changes in response to changes of voltage applied by the electrodes 136, which creates a change in the electric current that can be measured with the end effector 114 and/or other portions of the system 100. The results of the bioelectrical and/or biopotential measurements can be used to predict or estimate relative absorption profilometry to predict or estimate the tissue structures in the interest zone. More specifically, each cellular construct has unique conductivity and absorption profiles that can be indicative of a type of tissue or structure, such as bone, soft tissue, vessels, nerves, types of nerves, and/or certain neural structures. For example, different frequencies decay differently through different types of tissue. Accordingly, by detecting the absorption current in a region, the system 100 can determine the underlying structure and, in some instances, to a submicroscale, cellular level that allows for highly specialized target localization and mapping. This highly specific target identification and mapping enhances the efficacy and efficiency of neuromodulation therapy, while also enhancing the safety profile of the system 100 to reduce collateral effects on non-target structures.

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To detect electrical and dielectric tissue properties (e.g., resistance, complex impedance, conductivity, and/or, permittivity as a function of frequency), the electrodes 136 and/or another electrode array is placed on tissue at an interest region, and an internal or external source (e.g., the generator 106) applies stimuli (current/voltage) to the tissue. The electrical properties of the tissue between the source and the receiver electrodes 136 are measured, as well as the current and/or voltage at the individual receiver electrodes 136. These individual measurements can then be converted into an electrical map/image/profile of the tissue and visualized for the user on the display 112 to identify anatomical features of interest and, in certain embodiments, the location of firing nerves. For example, the anatomical mapping can be provided as a color-coded or gray-scale three-dimensional or two-dimensional map showing differing intensities of certain bioelectric properties (e.g., resistance, impedance, etc.), or the information can be processed to map the actual anatomical structures for the clinician. This information can also be used during neuromodulation therapy to monitor treatment progression with respect to the anatomy, and after

neuromodulation therapy to validate successful treatment. In addition, the anatomical mapping provided by the bioelectrical and/or biopotential measurements can be used to track the changes to non-target tissue (e.g., vessels) due to neuromodulation therapy to avoid negative collateral effects. For example, a clinician can identify when the therapy begins to ligate a vessel and/or damage tissue, and modify the therapy to avoid bleeding, detrimental tissue ablation, and/or other negative collateral effects.

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Furthermore, the threshold frequency of electric current used to identify specific targets can subsequently be used when applying therapeutic neuromodulation energy. For example, the neuromodulation energy can be applied at the specific threshold frequencies of electric current that are target neuronal-specific and differentiated from other non-targets (e.g., blood vessels, non-target nerves, etc.). Applying ablation energy at the target-specific frequency results in an electric field that creates ionic agitation in the target neural structure, which leads to differentials in osmotic potentials of the targeted neural structures. These osmotic potential differentials cause dynamic changes in neuronal membronic potentials (resulting from the difference in intracellular and extra-cellular fluidic pressure) that lead to vacuolar degeneration of the targeted neural structures and, eventually, necrosis. Using the highly targeted threshold neuromodulation energy to initiate the degeneration allows the system 100 to delivery therapeutic neuromodulation to the specific target, while surrounding blood vessels and other non-target structures are functionally maintained.

In some embodiments, the system 100 can further be configured to detect bioelectrical properties of tissue by non-invasively recording resistance changes during neuronal depolarization to map neural activity with electrical impedance, resistance, bio-impedance, conductivity, permittivity, and/or other bioelectrical measurements. Without being bound by theory, when a nerve depolarizes, the cell membrane resistance decreases (e.g., by approximately 80×) so that current will pass through open ion channels and into the intracellular space. Otherwise the current remains in the extracellular space. For non-invasive resistance measurements, tissue can be stimulated by applying a current of less than 100 Hz, such as applying a constant current square wave at 1 Hz with an amplitude less than 25% (e.g., 10%) of the threshold for stimulating neuronal activity, and thereby preventing or reducing the likelihood that the current does not cross into the intracellular space or stimulating at 2 Hz. In either case,

the resistance and/or complex impedance is recorded by recording the voltage changes. A complex impedance or resistance map or profile of the area can then be generated.

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For impedance/conductivity/permittivity detection, the electrodes 136 and/or another electrode array are placed on tissue at an interest region, and an internal or external source (e.g., the generator 106) applies stimuli to the tissue, and the current and/or voltage at the individual receiver electrodes 136 is measured. The stimuli can be applied at different frequencies to isolate different types of nerves. These individual measurements can then be converted into an electrical map/image/profile of the tissue and visualized for the user on the display 112 to identify anatomical features of interest. The neural mapping can also be used during neuromodulation therapy to select specific nerves for therapy, monitor treatment progression with respect to the nerves and other anatomy, and validate successful treatment.

In some embodiments of the neural and/or anatomical detection methods described above, the procedure can include comparing the mid-procedure physiological parameter(s) to the baseline physiological parameter(s) and/or other, previously-acquired mid-procedure physiological parameter(s) (within the same energy delivery phase). Such a comparison can be used to analyze state changes in the treated tissue. The mid-procedure physiological parameter(s) may also be compared to one or more predetermined thresholds, for example, to indicate when to stop delivering treatment energy. In some embodiments of the present technology, the measured baseline, mid-, and post-procedure parameters include a complex impedance. In some embodiments of the present technology, the post-procedure physiological parameters are measured after a pre-determined time period to allow the dissipation of the electric field effects (ionic agitation and/or thermal thresholds), thus facilitating accurate assessment of the treatment.

In some embodiments, the anatomical mapping methods described above can be used to differentiate the depth of soft tissues within the nasal mucosa. The depth of mucosa on the turbinates is great whilst the depth off the turbinate is shallow and, therefore, identifying the tissue depth in the present technology also identifies positions within the nasal mucosa and where precisely to target. Further, by providing the micro-scale spatial impedance mapping of epithelial tissues as described above, the inherent unique signatures of stratified layers or cellular bodies can be used as identifying the region of interest. For example, different regions have

larger or small populations of specific structures, such as submucosal glands, so target regions can be identified via the identification of these structures.

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In some embodiments, the system 100 includes additional features that can be used to detect anatomical structures and map anatomical features. For example, the system 100 can include an ultrasound probe for identification of neural structures and/or other anatomical structures. Higher frequency ultrasound provides higher resolution, but less depth of penetration. Accordingly, the frequency can be varied to achieve the appropriate depth and resolution for neural/anatomical localization. Functional identification may rely on the spatial pulse length ("SPL") (wavelength multiplied by number of cycles in a pulse). Axial resolution (SPL/2) may also be determined to locate nerves.

In some embodiments, the system 100 can further be configured to emit stimuli with selective parameters that suppress rather than fully stimulate neural activity. for example, in embodiments where the strength-duration relationship for extracellular neural stimulation is selected and controlled, a state exists where the extracellular current can hyperpolarize cells, resulting in suppression rather than stimulation spiking behavior (i.e., a full action potential is not achieved). Both models of ion channels, HH and RGC, suggest that it is possible to hyperpolarize cells with appropriately designed burst extracellular stimuli, rather than extending the stimuli. This phenomenon could be used to suppress rather than stimulate neural activity during any of the embodiments of neural detection and/or modulation described herein.

In various embodiments, the system 100 could apply the anatomical mapping techniques disclosed herein to locate or detect the targeted vasculature and surrounding anatomy before, during, and/or after treatment.

Reference throughout this specification to "one embodiment" or "an embodiment" means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, appearances of the phrases "in one embodiment" or "in an embodiment" in various places throughout this specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments.

The terms and expressions which have been employed herein are used as terms of description and not of limitation, and there is no intention, in the use of such terms and expressions, of excluding any equivalents of the features shown and described (or portions

thereof), and it is recognized that various modifications are possible within the scope of the claims. Accordingly, the claims are intended to cover all such equivalents.

# Incorporation by Reference

References and citations to other documents, such as patents, patent applications, patent publications, journals, books, papers, web contents, have been made throughout this disclosure.

All such documents are hereby incorporated herein by reference in their entirety for all purposes.

# **Equivalents**

Various modifications of the invention and many further embodiments thereof, in addition to those shown and described herein, will become apparent to those skilled in the art from the full contents of this document, including references to the scientific and patent literature cited herein. The subject matter herein contains important information, exemplification and guidance that can be adapted to the practice of this invention in its various embodiments and equivalents thereof.

### <u>Claims</u>

What is claimed is:

1. A method for treating at least one of rhinitis, congestion, and rhinorrhea within a sino-nasal cavity of a patient, the method comprising:

advancing a multi-electrode end effector into the sino-nasal cavity of the patient, wherein the multi-electrode end effector is operably associated with a shaft of a treatment device and configured for delivering energy to one or more target sites within the sino-nasal cavity of the patient, wherein the multi-electrode end effector comprises a first electrode that is spaced apart from a second electrode along a length of the multi-electrode end effector, wherein each of the first and second electrodes comprise an active state and an inactive state and comprise a respective location on the multi-electrode end effector, wherein at least one portion of the multi-electrode end effector comprises a diameter that is larger than a diameter of the shaft, and wherein:

the first electrode is exposed from a surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the first electrode extending in a first outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a first location within the nasal cavity; and

the second electrode is exposed from the surface of the multi-electrode end effector and is positioned at a discrete portion thereon, the second electrode extending in a second outward direction relative to a longitudinal axis of the shaft to interact with anatomy at a second location within the nasal cavity; and

delivering energy, via the first and second electrodes, to one or more target sites within a sino-nasal cavity of the patient to disrupt multiple neural signals to mucus producing and/or mucosal engorgement elements, thereby reducing production of mucus and/or mucosal engorgement within a nose of the patient and reducing or eliminating one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea to improve nasal breathability of the patient.

2. The method of claim 1, wherein radiofrequency (RF) energy is delivered from the first and second electrodes to tissue at the one or more target sites and is controlled via a console unit

operably associated with the treatment device and multi-electrode end effector.

3. The method of claim 2, wherein the console unit is configured to receive feedback from at

least one temperature sensor arranged relative to the first and second electrodes and configured

to sense temperature at an interface between tissue and the first and second electrodes, wherein

the console unit is configured to control energy output from the first and second electrodes

based, at least in part, on the feedback in order to maintain a predetermined temperature of tissue

at the one or more target sites.

4. The method of claim 3, wherein the console unit is configured to receive one or more

temperature readings from the at least one temperature sensor and process the readings to

determine a level of RF energy to be delivered by the first and second electrodes that is sufficient

to maintain a temperature of tissue at the one or more target sites below a predetermined

threshold.

5. The method of claim 4, wherein the console unit comprises a hardware processor coupled to

non-transitory, computer-readable memory containing instructions executable by the processor to

cause the console unit to automatically control and adjust RF energy output from the first and

second electrodes based, at least in part, on a predetermined elapsed time period and a

predetermined threshold maximum temperature during delivery of RF energy to ensure that

application of said RF energy results in the desired effect of reduced engorgement of the tissue at

the target site for a given treatment application.

6. The method of claim 5, the predetermined elapsed time period is from about 1 second to about

20 seconds.

7. The method of claim 6, wherein the predetermined elapsed time period is from about 10

seconds to about 12 seconds.

8. The method of claim 5, wherein the predetermined threshold maximum temperature is less

than 90°C.

9. The method of claim 5, wherein the predetermined threshold maximum temperature is greater

than 37°C and less than 90°C.

10. The method of claim 4, wherein the console unit is configured to monitor temperature of

tissue at the one or more target sites during delivery of RF energy thereto based on temperature

readings from the at least one temperature sensor and further monitor an elapsed time during

delivery of RF energy to tissue at the one or more target sites.

11. The method of claim 4, wherein the console unit is configured to provide, via a display,

feedback information to an operator during a given treatment application, wherein said feedback

information comprises at least an elapsed time during delivery of RF energy to tissue at the one

or more target sites.

12. The method of claim 11, wherein the display is a touchscreen monitor.

13. The method of claim 2, wherein the console unit is operably coupled to an energy generator

configured to generate RF energy to be delivered by the first and second electrodes.

14. The method of claim 13, wherein the RF energy comprises at least bipolar RF energy.

15. The method of claim 1, wherein the multi-electrode end effector comprises at least four

electrodes,

wherein the at least four electrodes are oriented at an angle less than 90 degrees relative

to the shaft for the delivery of radiofrequency (RF) energy,

wherein the shaft is a substantially rigid shaft with a hollow cavity,

wherein the shaft comprises an outer sheath and hypotube,

wherein the first electrode and second electrode is operably coupled to a console unit via

wires disposed in the hollow cavity of the substantially rigid shaft, and

wherein RF energy is delivered from the first and second electrodes to tissue at the one or

more target sites and is controlled via the console unit operably associated with the treatment

device and multi-electrode end effector.

16. The method of claim 15, wherein the multi-electrode end effector comprises at least six

electrodes, and

wherein the at least six electrodes are oriented at an angle less than 90 degrees relative to

the shaft for the delivery of RF energy.

17. The method of claim 15, wherein the multi-electrode end effector comprises at least eight

electrodes, and

wherein the at least eight electrodes are oriented at an angle less than 90 degrees relative

to the shaft for the delivery of RF energy.

18. The method of claim 1, wherein the multi-electrode end effector comprises at least one

temperature sensor arranged relative to first and second electrode.

19. The method of claim 18, wherein the at least one temperature sensor is configured to sense

temperature of tissue at the one or more target sites.

20. The method of claim 1, wherein the one or more target sites comprises an inferior turbinate

within the nasal cavity and the tissue comprises submucosal tissue associated with the inferior

turbinate.

# **Abstract**

The invention generally relates to systems and methods for improving sleep by treating at least one of rhinitis, congestion, and/or rhinorrhea to thereby reduce or eliminate symptoms associated therewith, including, but not limited to, nasal congestion, coughing, sneezing, and nasal or throat irritation and itching.

Doc Code: TRACK1.REQ

Document Description: TrackOne Request

PTO/AIA/424 (11-23)

	CERTIFICATION AND REQUEST F UNDER 37 CFR 1.		AMINATION	
First Named Inventor:	David Townley	Nonprovisional Application Number (if known):	Not Yet Assigned	
Title of Invention:	SYSTEMS AND METHODS FOR THERAPEUTIC N	IASAL TREATMENT USING HAN	DHELD DEVICE	
	T HEREBY CERTIFIES THE FOLLOWING A E-IDENTIFIED APPLICATION.	AND REQUESTS PRIORITIZ	ZED EXAMINATION FOR	
37 CF that fe exami	he processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 7 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because nat fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any equired excess claims fees or application size fee must be paid for the application.			
indepe	derstand that the application may not contain, or be amended to contain, more than four pendent claims, more than thirty total claims, or any multiple dependent claims, and that any est for an extension of time will cause an outstanding Track I request to be dismissed.			
3. The a <sub>l</sub>	oplicable box is checked below:			
I. X	I. Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)			
Ìńis c	e application is an original nonprovisiona ertification and request is being filed with system. OR			
	(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.			
inven	recuted inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each tor, <u>or</u> the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is with the application.			
II.	Request for Continued Examination	<u>n - Prioritized Examinati</u>	ion under § 1.102(e)(2)	
ii. If the a patent iii. The a a natio i∨. This c	uest for continued examination has been application is a utility application, this cer electronic filing system. oplication is an original nonprovisional utonal stage entry under 35 U.S.C. 371. ertification and request is being tiled prior	tification and request is be	eing filed via USPTO - 35 U.S.C. 111(a), or is	
∨. No pri	request for continued examination. or request for continued examination has 37 CFR 1.102(e)(2).	s been granted prioritized	examination status	
Signature	/Adam M. Schoen/	Date	April 26, 2024	
Name (Print/Typed)	Adam M. Schoen	Practitioner Registration N	umber 58,576	
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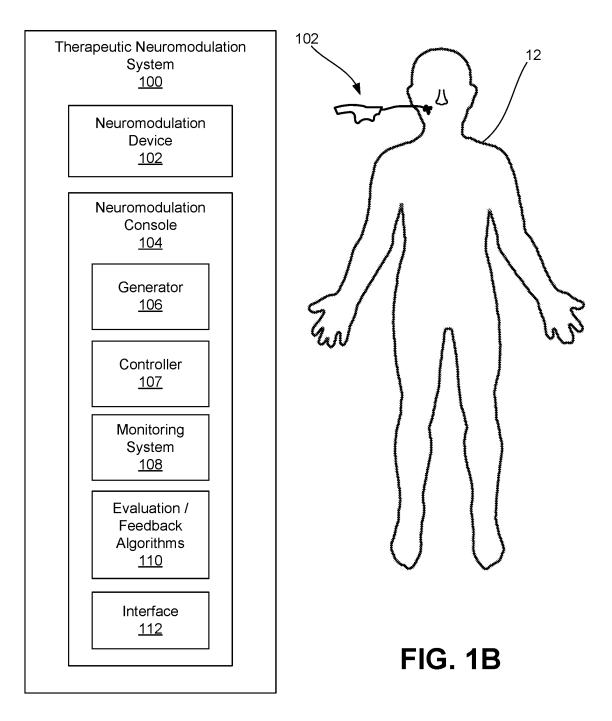


FIG. 1A

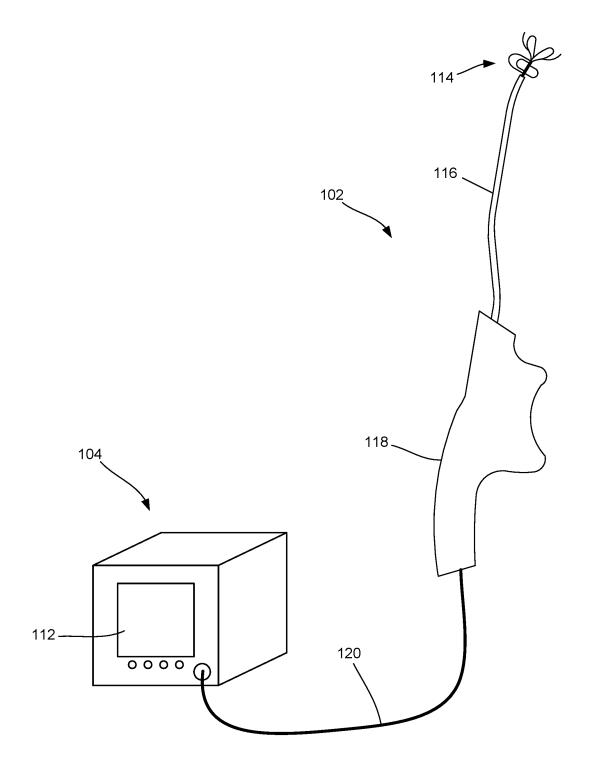


FIG. 2

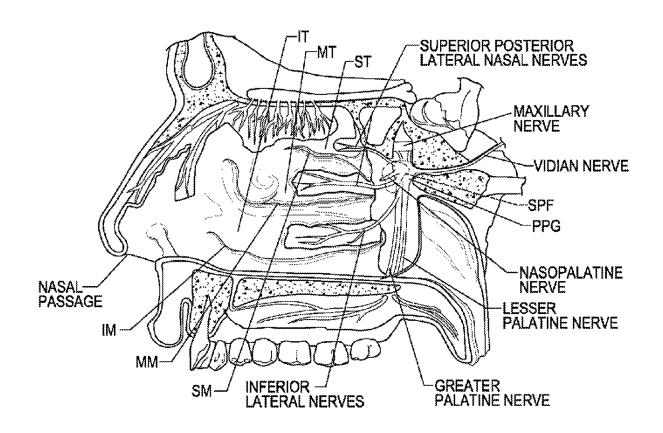


FIG. 3A

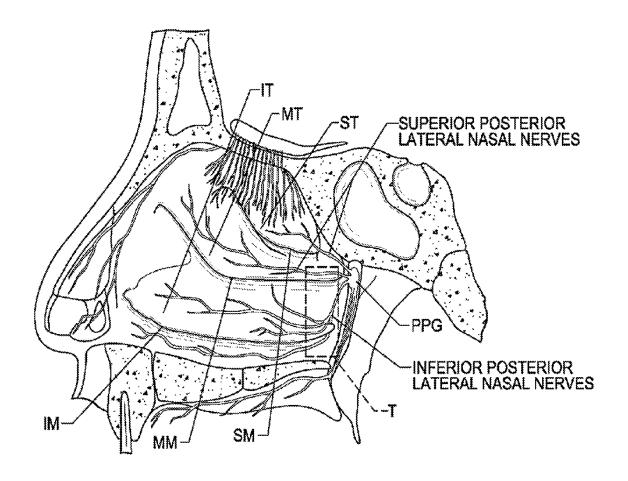


FIG. 3B

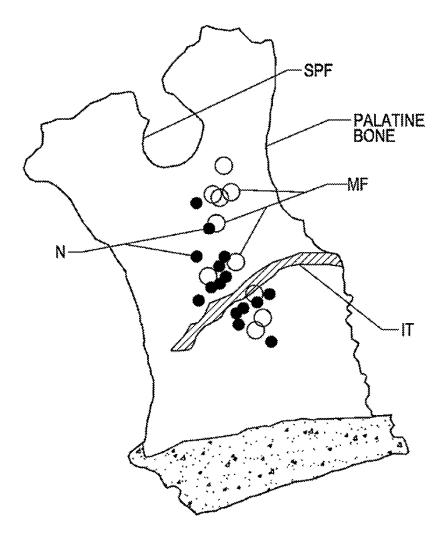
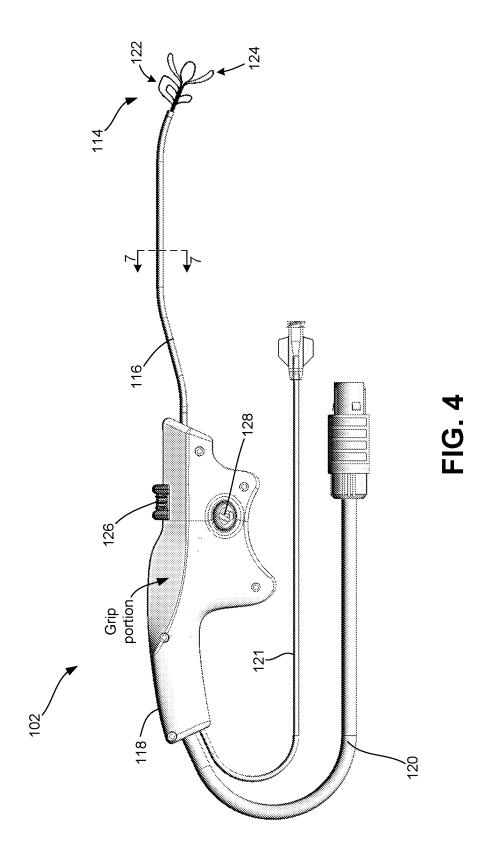


FIG. 3C



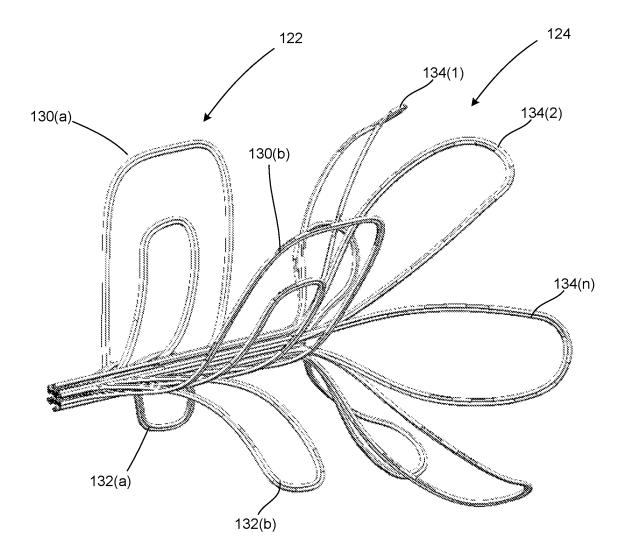
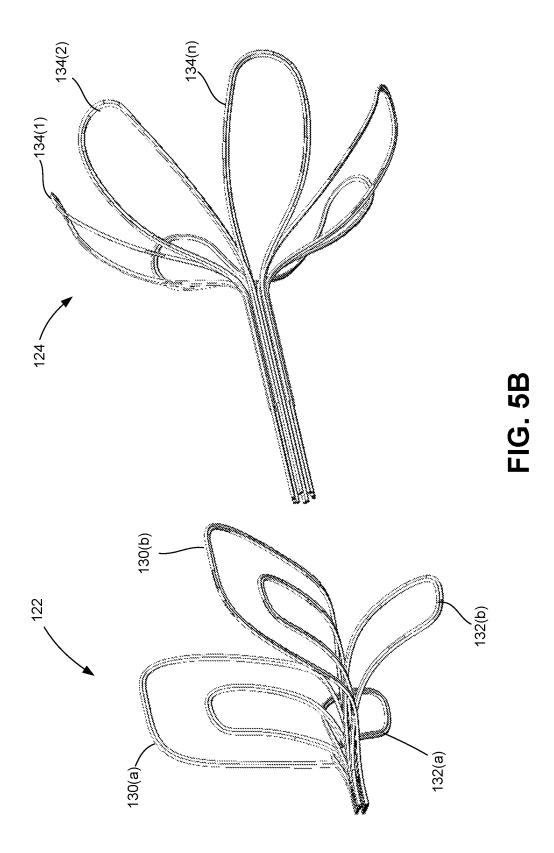


FIG. 5A



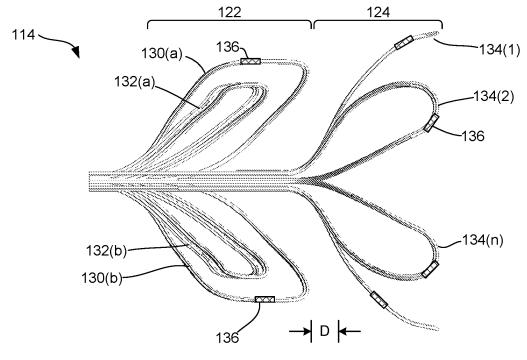


FIG. 5C

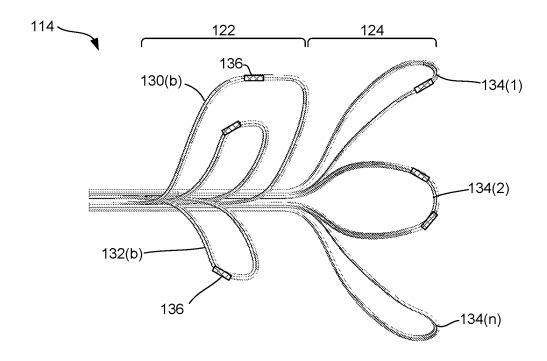


FIG. 5D

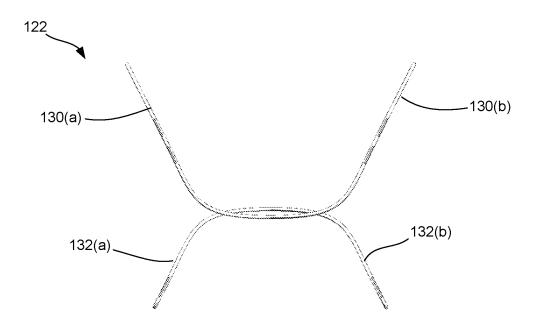


FIG. 5E

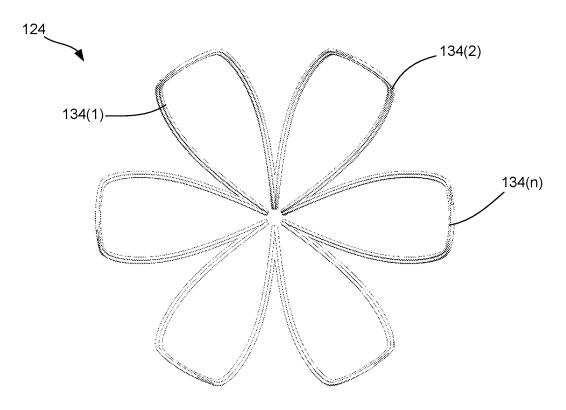


FIG. 5F

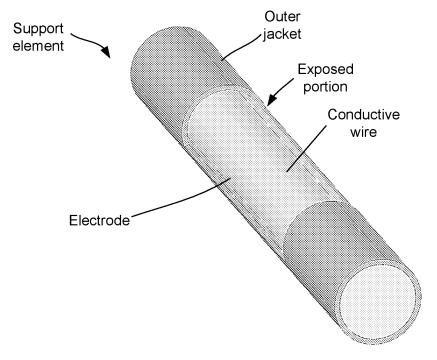
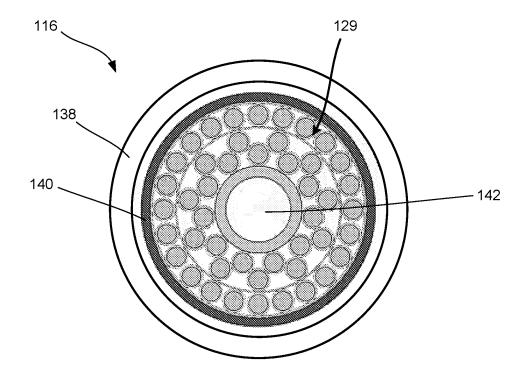
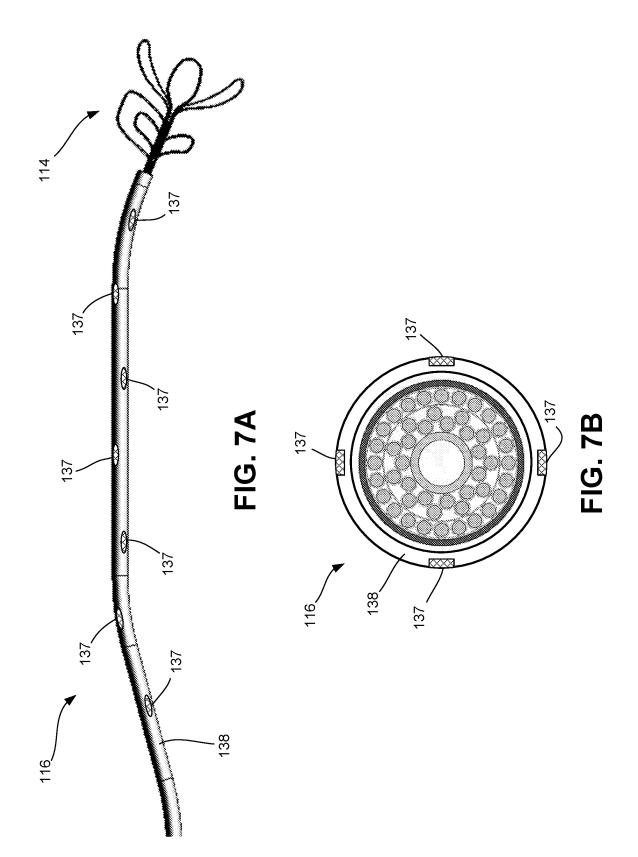


FIG. 6



**FIG. 7** 



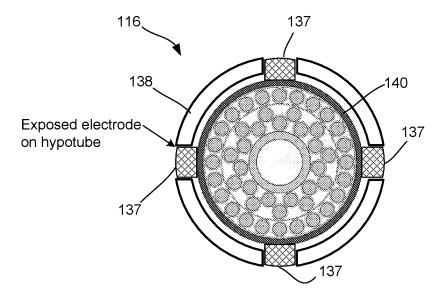
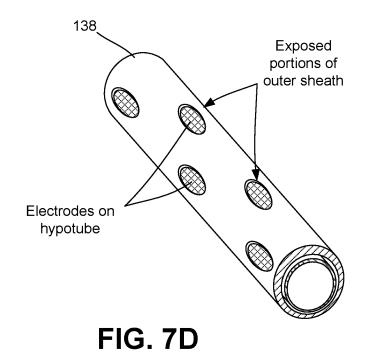
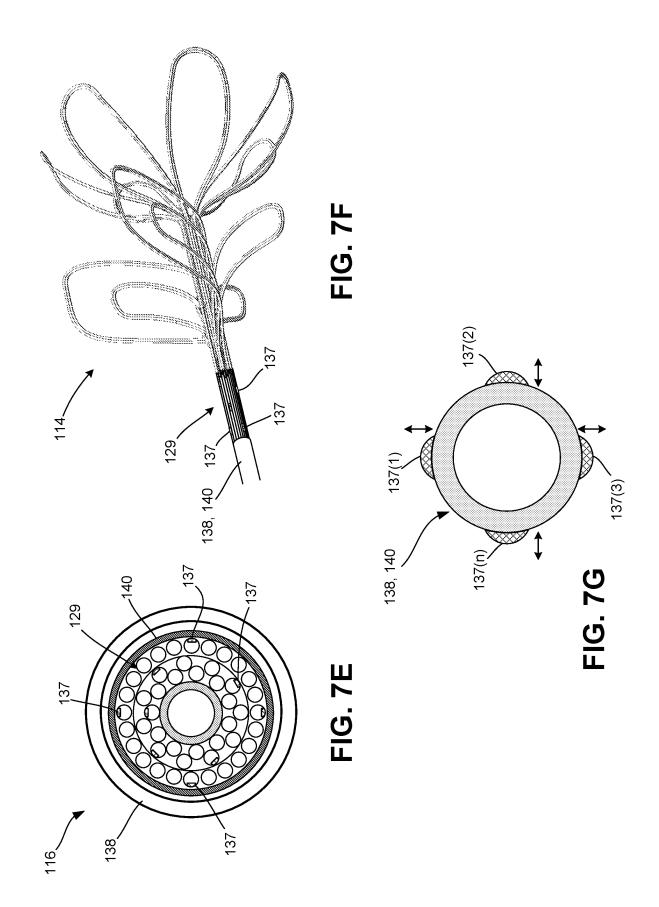
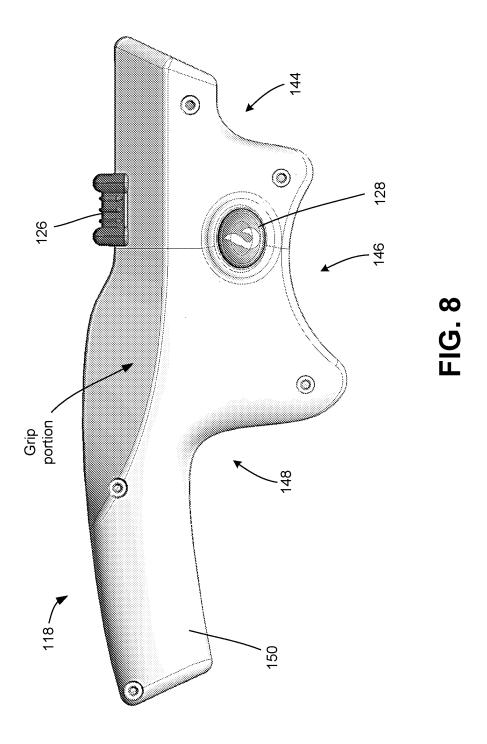
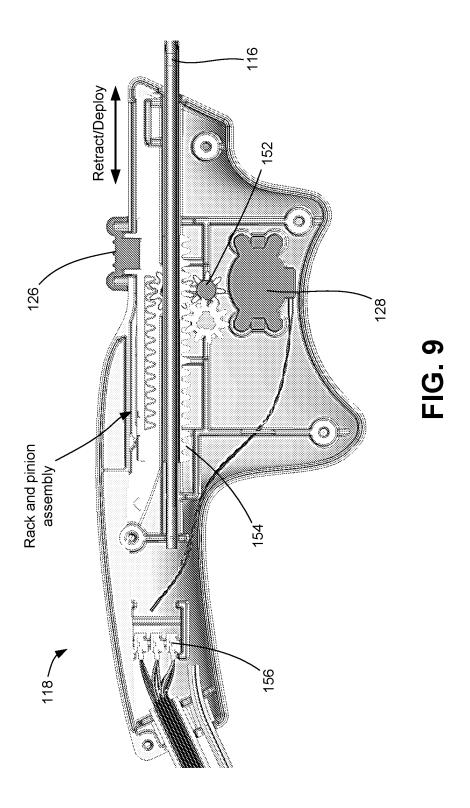


FIG. 7C









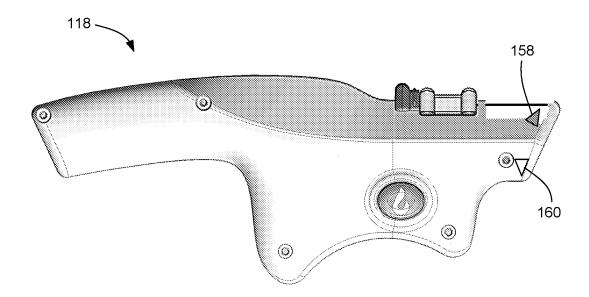
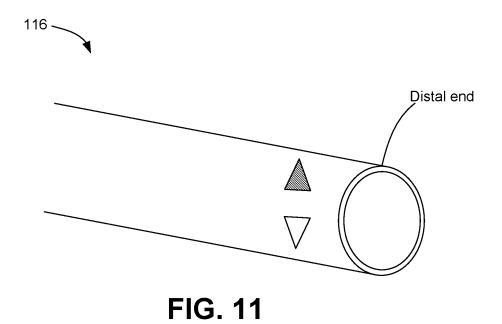


FIG. 10



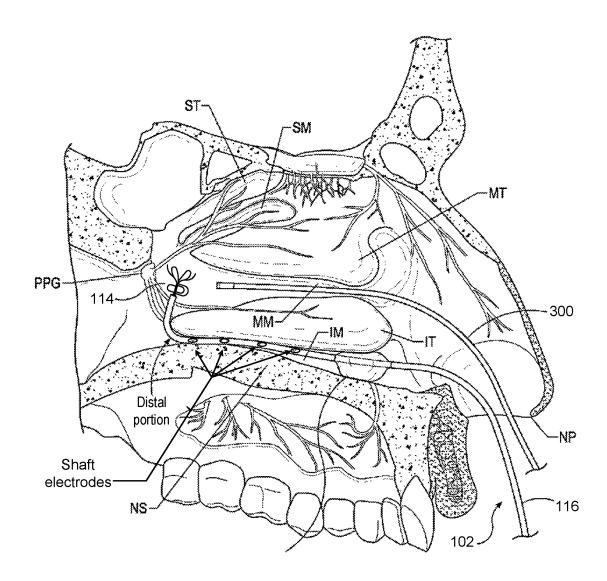


FIG. 12

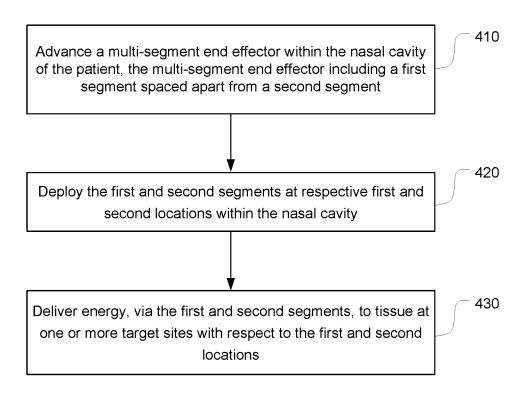
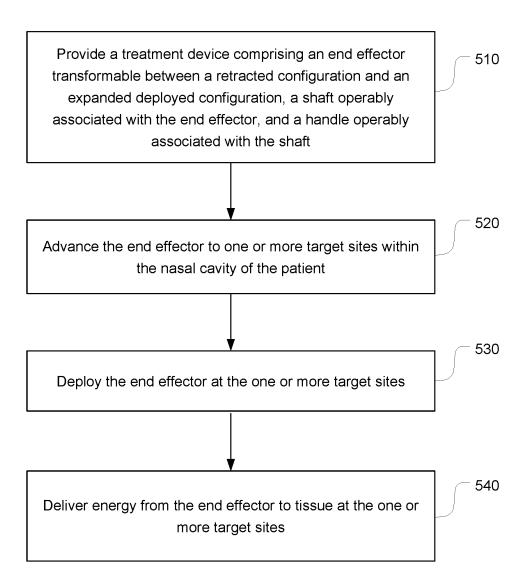


FIG. 13



**FIG. 14** 

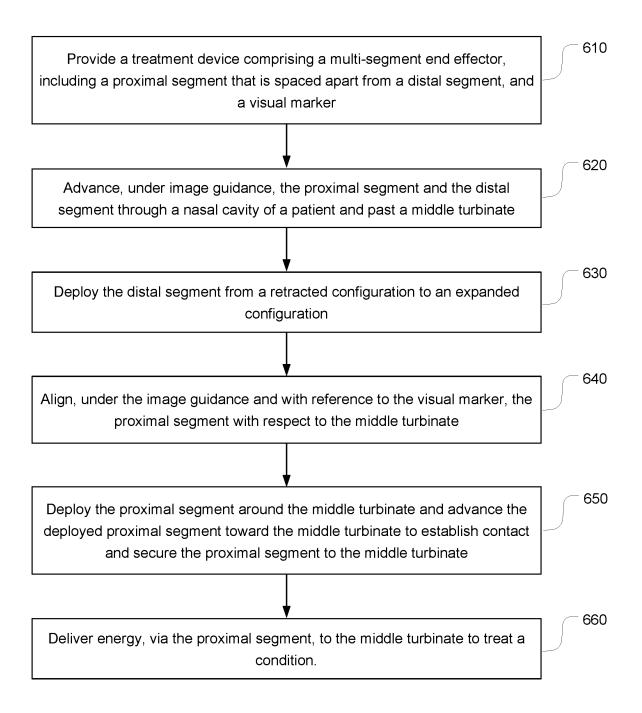
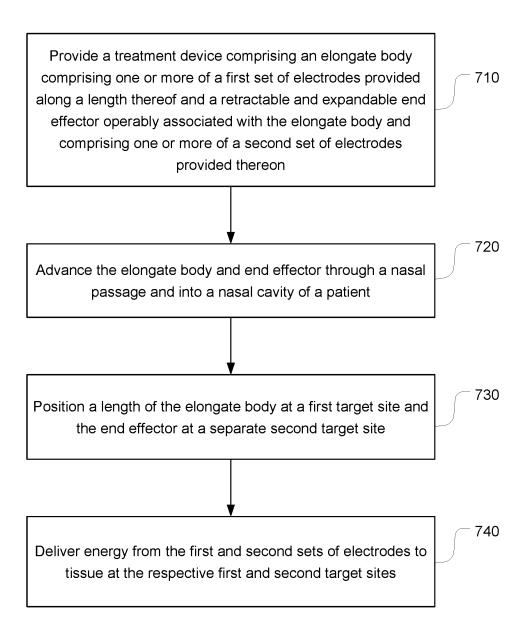


FIG. 15



**FIG. 16** 

Deliver energy to one or more target sites within a sino-nasal cavity of the patient to disrupt multiple neural signals to, and/ or result in local hypoxia of, mucus producing and/or mucosal engorgement elements, thereby reducing production of mucus and/or mucosal engorgement within a nose of the patient and reducing or eliminate one or more symptoms associated with at least one of rhinitis, congestion, and rhinorrhea to improve nasal breathability of the patient.

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# **FIG. 17**

Application Data Sheet 37 CFR 1.76			<sub>'6</sub>	Attorney I	Docket	ket Number NEURE-008/07US 35242/159		59			
			<u> </u>	Application	n Num	ber					
Title of	Invention	SYSTE	MS AND METHOD	)S F(	OR THERAI	PEUTIC	NASAL TR	REATMEN	NT USING HANDHEL	.D DEVIC	E
bibliogra This doc	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.										
Secre	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.)										
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Invent	or 1								Remove		
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	David							Townle	ey		
Resid	ence Informa	ation (S	Select One)	US F	Residency	•	Non US Re	sidency	Active US Milita	ary Servic	е
City	County Clare			С	ountry of F	Resider	nce <sup>i</sup>		IE		
Mailing	Address of I	Invento	or:								
Addres	ss 1		Latoon North, New	vmar	ket-on-Ferg	us					
Addres	ss 2										
City	County	y Clare					State/Prov	vince			
Postal	Code					Coun	itryi	IE			
			sted - Additiona by selecting the <b>A</b>			ormatio	n blocks	may be	Add		
Corre	sponden	ce In	formation:								
			ımber or comple ee 37 CFR 1.33(a		he Corres	ponde	nce Inforn	nation s	ection below.		
☐ An	Address is	being <sub> </sub>	provided for the	cor	responde	nce Inf	formation	of this a	application.		
Custor	mer Number		21710								
Email	Address		ip@brownrudnick	.com	n				Add Email	Remove	Email
Appli	ication In	form	ation:								
Title of	f the Invention	on	SYSTEMS AND DEVICE	MET	HODS FOR	THER	APEUTIC N	IASAL TR	REATMENT USING H	IANDHEL	D
Attorn	ey Docket N	umber		IS 35	5242/159		Small Ent	tity State	us Claimed 🔀		
Applic	ation Type		Nonprovisional			•					
Subjec	ct Matter		Utility								
Total N	Number of Di	rawing	Sheets (if any)		23		Suggest	ed Figui	re for Publication	(if any)	1A

Application Da	ta Sha	ot 27 CED 1 76	Attorney D	Docket Number   NEURE-008		8/07US 35242/159			
Application Da	ila Sile	et 37 CFR 1.76	Application	n Number					
Title of Invention	SYSTE	MS AND METHODS F	OR THERAP	EUTIC NASAL TR	EATMENT U	ISING HANDHELD DEVICE			
Filing By Refe	erenc	e:							
application papers inclu	iding a sp	ecification and any draw	ings are being	filed. Any domestic	benefit or fo	(a). Do not complete this section if reign priority information must be reign 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 o filed application	f the prev	iously Filing da	te (YYYY-MM-[	DD)	Intelle	ectual Property Authority or Country			
Publication I	nform	nation:							
Request Early	Publica	tion (Fee required a	t time of Rec	uest 37 CFR 1.2	<u>.</u> 19)				
publication at	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:								
this information in the Either enter Custom	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	. O us	Patent Practitione	r O Li	mited Recognition (37 CFR 11.9)			
Customer Number	- 2	21710			•				
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 Nur	nber	Continuity	Туре	Prior Applicati	Filing or 371(c) Date (YYYY-MM-DD)				

18/411476

Continuation of

2024-01-12

Application Data Sheet 37 CFR 1.76				Attorney Docket Number			NEURE-008/07US 35242/159		
Application	Application Bata chocker of K 1.70				Application Number				
Title of Invention	SYSTE	FOR THERAPE	EUTIC NASAL TR	REAT	MENT U	SING HANDHE	_D DEVICE		
		1						-	
Prior Application	on Status	Patented						Remo	ve
Application Cont		tinuity Type	Pr	ior Application Number	Filing Date (YYYY-MM-DD)		Patent Number		Issue Date (YYYY-MM-DD)
18/411476	Continua	Continuation of		25560	2021-04-08		11883091		2024-01-30
Prior Application Status		Expired					Remo	ve	
Application Number		Continuity Type		Туре	Prior Application Number		Filing or 371(c) Date (YYYY-MM-DD)		
17/225560 Claims benefit of pro			visional	63/007584 2020-04-09					
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the <b>Add</b> button.									

# **Foreign Priority Information:**

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)<sup>i</sup> 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 <sup>i</sup>	Filing Date (YYYY-MM-DD)	Access Code <sup>i</sup> (if applicable)
Additional Foreign Priority  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
Ш	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.

Application Da	ta Sheet 37 CED 1 76	Attorney Docket Number	NEURE-008/07US 35242/159			
Application Data Sheet 37 CFR 1.76		Application Number				
Title of Invention	SYSTEMS AND METHODS F	YSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE				

#### **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 <u>must opt-out</u> 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. <u>Search Results from U.S. Application to EPO</u> Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby <u>grants the USPTO authority</u> 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 <u>DOES NOT</u> 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 <u>DOES NOT</u> 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.

Application Da	ita Sheet 37 CFR 1.76	Attorney Docket Number	NEURE-008/07US 35242/159	
Application ba	ita Sheet 37 Of It 1.70	Application Number		
Title of Invention	SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE			

# **Applicant Information:**

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.							
Applicant 1				Remove			
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.							
<ul><li>Assignee</li></ul>		C Legal Representative ur	nder 35 U.S.C. 117	O Joint Inventor			
Person to whom the inv	entor is oblig	ated to assign.	Person who sho	ows sufficient proprietary interest			
If applicant is the legal re	epresentativ	ve, indicate the authority to	file the patent applicati	tion, the inventor is:			
Name of the Deceased	or Legally I	ncapacitated Inventor:		1			
If the Applicant is an O	rganization	check here.					
Organization Name	Neurent M	edical Limited					
Mailing Address Infor	mation Fo	r Applicant:					
Address 1	No. 1	No. 1 Oran Point					
Address 2	Main S	Main Street					
City	Orann	nore, Galway	State/Province				
Country <sup>j</sup> ∣E			Postal Code				
Phone Number			Fax Number				
Email Address				•			
Additional Applicant Data may be generated within this form by selecting the Add button.							

# **Assignee Information including Non-Applicant Assignee Information:**

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

PTO/AIA/14 (01-22)
Approved for use through 05/31/2024. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application	on Data	Shoo	t 37 CFR 1.76	Attorney Doc	ket Number	NEURE	NEURE-008/07US 35242/159			
Application	Jii Dala		CO1 OI IX 1.70	Application Number						
Title of Inver	ntion S	SYSTEM	S AND METHODS FO	OR THERAPEL	JTIC NASAL <sup>-</sup>	TREATMEN	IT USING HANI	OHELD DEVICE		
<b>A</b>										
Assignee	1									
application pub	Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application bublication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.									
								emove		
If the Assign	nee or No	n-Applic	cant Assignee is an	Organization	check here.					
Prefix		Giv	en Name	Middle Nam	me Family N		ame	Suffix		
Mailing Addr	ress Info	rmation	For Assignee inc	luding Non-A	Applicant As	ssignee:				
Address 1										
Address 2										
City					State/Prov	vince				
Country					Postal Code					
Phone Numl	ber			Fax Number						
Email Addre	ess									
Additional As selecting the			pplicant Assignee [	Data may be g	enerated wi	thin this fo	rm by	Add		
Signature	e:						DOCOCO	Remove		
NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the <a href="INITIAL">INITIAL</a> filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).  This Application Data Sheet <a href="must">must</a> be signed by a patent practitioner if one or more of the applicants is a juristic entity (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, <a href="must">all</a> joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of <a href="must">all</a> joint inventor-applicants.  See 37 CFR 1.4(d) for the manner of making signatures and certifications.										
Signature //Adam M. Schoen/					Date (YYYY-MM			D) 2024-04-26		
First Name	Adam		Last Name	Schoen		Regist	ration Number	f 58,576		
Additional S	Additional Signature may be generated within this form by selecting the Add button.									

Application Da	nta Sheet 37 CFR 1.76	Attorney Docket Number	NEURE-008/07US 35242/159		
Application ba	ita Sheet 37 Of K 1.70	Application Number			
Title of Invention	SYSTEMS AND METHODS FOR THERAPEUTIC NASAL TREATMENT USING HANDHELD DEVICE				

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

#### **Privacy Act Statement**

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

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

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

# **Placeholder Sheet for Supplemental Content**

Application Number: 18647929 Document Date: 04/26/2024

The presence of this form indicates that the following document type was received in electronic format on the date identified above. This document is stored separately from the typical case contents which are stored in image format.

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded and no paper documents or physical media exist.

### Drawing

At the time of document entry (noted above):

- USPTO employees may access this supplemental content via Docket Application Viewer (DAV) or Supplemental Content Viewer (SCV).
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Form Revision Date: March 1, 2024

#### SCORE Placeholder Sheet for IFW Content

Application Number: 18647929 Document Date: 04/26/2024

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

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- External customers may access SCORE content via PAIR using the Supplemental Content tab.

Form Revision Date: March 1, 2019