


PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 14/458,644	
APPLICATION AS FILED - PART I							
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(i))	31	minus 20 = 11				x 80 =	880
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	minus 3 =				x 420 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
			TOTAL			TOTAL	2480
* If the difference in column 1 is less than zero, enter "0" in column 2.							
APPLICATION AS AMENDED - PART II							
AMENDMENT A	(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	30	Minus **	31	x	=	
	Independent (37 CFR 1.16(h))	3	Minus ***	3	x	=	
	Application Size Fee (37 CFR 1.16(s))						
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
				TOTAL ADD'L FEE			
AMENDMENT B	(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus **		x	=	
	Independent (37 CFR 1.16(h))		Minus ***		x	=	
	Application Size Fee (37 CFR 1.16(s))						
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
				TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.							

UTILITY PATENT APPLICATION TRANSMITTAL <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	Attorney Docket No.	036213.US.08-32865-216897
	First Named Inventor	Dieter MANSTEIN
	Title	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE P
	Express Mail Label No.	

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
10. ACCOMPANYING APPLICATION PAPERS	10. <input checked="" type="checkbox"/> Assignment Papers (cover sheet & document(s)) Name of Assignee <u>The General Hospital Corporation</u>
1. <input type="checkbox"/> Fee Transmittal Form (PTO/SB/17 or equivalent)	11. <input checked="" type="checkbox"/> 37 CFR 3.73(c) Statement (when there is an assignee) <input checked="" type="checkbox"/> Power of Attorney
2. <input type="checkbox"/> Applicant asserts small entity status. See 37 CFR 1.27	12. <input type="checkbox"/> English Translation Document (if applicable)
3. <input type="checkbox"/> Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.	13. <input checked="" type="checkbox"/> Information Disclosure Statement (PTO/SB/08 or PTO-1449) <input type="checkbox"/> Copies of citations attached
4. <input checked="" type="checkbox"/> Specification [Total Pages <u>22</u>] Both the claims and abstract must start on a new page. (See MPEP § 608.01(a) for information on the preferred arrangement)	14. <input checked="" type="checkbox"/> Preliminary Amendment
5. <input checked="" type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets <u>4</u>]	15. <input type="checkbox"/> Return Receipt Postcard (MPEP § 503) (Should be specifically itemized)
6. <input type="checkbox"/> Inventor's Oath or Declaration [Total Pages <u>1</u>] (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))	16. <input type="checkbox"/> Certified Copy of Priority Document(s) (if foreign priority is claimed)
a. <input checked="" type="checkbox"/> Newly executed (original or copy) b. <input type="checkbox"/> A copy from a prior application (37 CFR 1.63(d))	17. <input type="checkbox"/> Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
7. <input checked="" type="checkbox"/> Application Data Sheet * See note below. See 37 CFR 1.76 (PTO/AIA/14 or equivalent)	18. <input checked="" type="checkbox"/> Other: Certification and Request for Prioritized Examination Under 37 C.F.R. § 1.102(e). _____ _____ _____
8. CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) <input type="checkbox"/> Landscape Table on CD	
9. Nucleotide and/or Amino Acid Sequence Submission (if applicable, items a. – c. are required)	
a. <input type="checkbox"/> Computer Readable Form (CRF) b. <input type="checkbox"/> Specification Sequence Listing on: i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or ii. <input type="checkbox"/> Paper c. <input type="checkbox"/> Statements verifying identity of above copies	

***Note:** (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
 (2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS				
<input checked="" type="checkbox"/> The address associated with Customer Number: <u>120944</u> OR <input type="checkbox"/> Correspondence address below				
Name				
Address				
City	State	Zip Code		
Country	Telephone	Email		
Signature			Date	August 13, 2014
Name (Print/Type)	Gary Abelev		Registration No. (Attorney/Agent)	40479

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. 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.

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 Data Sheet 37 CFR 1.76		Attorney Docket Number	036213.US.08-32865-216897
		Application Number	
Title of Invention	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING		
<p>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.</p> <p>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.</p>			

Secrecy Order 37 CFR 5.2

<input type="checkbox"/> Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
--

Inventor Information:

Inventor 1					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	DIETER		MANSTEIN			
Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service						
City	Coral Gables	State/Province	FL	Country of Residence	US	
Mailing Address of Inventor:						
Address 1		287 Carabela Court				
Address 2						
City	Coral Gables	State/Province	FL			
Postal Code	33143	Country	US			
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.						
Add						

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
<input type="checkbox"/> An Address is being provided for the correspondence information of this application.			
Customer Number	120944		
Email Address	PTONY@andrewskurth.com	Add Email	Remove Email

Application Information:

Title of the Invention	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING		
Attorney Docket Number	036213.US.08-32865-216897	Small Entity Status Claimed	<input type="checkbox"/>
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	4	Suggested Figure for Publication (if any)	

Filing By Reference :

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	036213.US.08-32865-216897
		Application Number	
Title of Invention	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING		

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

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

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

Publication Information:

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

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

Representative Information:

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

Please Select One:	<input checked="" type="radio"/> Customer Number	<input type="radio"/> US Patent Practitioner	<input type="radio"/> Limited Recognition (37 CFR 11.9)
Customer Number	120944		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this 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 blank.

Prior Application Status	Pending	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
	Continuation of	12914201	2010-10-28		
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12914201	Division of	11098030	2005-04-01	7824394	2010-11-02
Prior Application Status	Expired	Remove			

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	036213.US.08-32865-216897
		Application Number	
Title of Invention	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Claims benefit of provisional	60558476	2004-04-01
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			

Foreign Priority Information:

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

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

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

<p>This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.</p> <p><input type="checkbox"/> 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.</p>
--

Authorization to Permit Access:

<input checked="" type="checkbox"/> Authorization to Permit Access to the Instant Application by the Participating Offices
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	036213.US.08-32865-216897
		Application Number	
Title of Invention	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING		

If 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 World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.				
Applicant 1				
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.				
<input type="button" value="Clear"/>				
<input type="radio"/> Assignee		<input type="radio"/> Legal Representative under 35 U.S.C. 117		<input type="radio"/> Joint Inventor
<input type="radio"/> Person to whom the inventor is obligated to assign.			<input type="radio"/> Person who shows sufficient proprietary interest	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:				
Name of the Deceased or Legally Incapacitated Inventor : <input type="text"/>				
If the Applicant is an Organization check here. <input type="checkbox"/>				
Prefix	Given Name	Middle Name	Family Name	Suffix

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	036213.US.08-32865-216897
		Application Number	
Title of Invention	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING		


Mailing Address Information For Applicant:			
Address 1			
Address 2			
City		State/Province	
Country		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.

Assignee 1			
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.			
If the Assignee or Non-Applicant Assignee is an Organization check here. <input checked="" type="checkbox"/>			
Organization Name	The General Hospital Corporation		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1		55 Fruit Street	
Address 2			
City	Boston	State/Province	MA
Country ⁱ	US	Postal Code	02114
Phone Number		Fax Number	
Email Address			
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.			

Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications.		
Signature		Date (YYYY-MM-DD) 2014-08-13

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	036213.US.08-32865-216897		
		Application Number			
Title of Invention	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING				
First Name	Gary	Last Name	Abelev	Registration Number	40479
Additional Signature may be generated within this form by selecting the Add button.					

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.**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Dieter MANSTEIN

Serial No. : To be assigned (Continuation of Serial No. 12/914,201)

Filed : Filed herewith (August 13, 2014)

For : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING

Examiner : To be assigned

Art Unit : To be assigned

Confirmation No. : To be assigned

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

Commissioner:

PRELIMINARY AMENDMENT

Please amend the above-identified patent application, as follows:

IN THE SPECIFICATION:

On page 1, lines 4-6, please amend the specification, as follows:

RELATED APPLICATIONS

The present application is a continuation of U.S. Application No. 12/914,201, filed on October 28, 2010, which is a division of U.S. Application No. 11/098,030, filed on April 1, 2005, now issued as U.S. Patent No. 7,824,394. This application also claims priority to U.S. Provisional Application Serial No. 60/558,476 filed on April 1, 2004. The entire disclosures of such applications are incorporated herein by reference.

IN THE CLAIMS:

Please cancel originally-filed claims 1-15 without prejudice, and add new claims 16-46, as provided below. The listing of the claims as pending in this application is provided on separate sheets as follows:

Claims 1-15 (Cancelled).

16. (New) A tissue treatment apparatus, comprising:
- a housing configured to support a plurality of needles attached to a base, the needles having tips configured for an insertion into a dermal layer of skin;
 - and
 - a control module configured to regulate delivery of radio frequency (RF) energy from an RF energy source to at least a portion of the plurality of needles, wherein the control module is further configured to cause RF energy to be delivered via the needles to cause a pattern of fractional damage to be produced in the dermal layer surrounding the needles when inserted therein, wherein the control module is configured to regulate the delivery of the RF energy to cause at least one of:
 - (i) a formation of a new collagen structure in the skin, or
 - (ii) a pattern of regions of thermal damage within the dermal layer, wherein at least two adjacent regions of the thermal damage have a undamaged region therebetween.
17. (New) The apparatus of claim 16, wherein the control module is further configured to regulate the RF energy to cause the formation of the new collagen structure in the skin.

18. (New) The apparatus of claim 17, wherein the control module is further configured to control the RF energy to cause the pattern of regions of thermal damage within the dermal layer.
19. (New) The apparatus of claim 17, wherein the control module is further configured to regulate energy delivery such that skin ablation is substantially prevented.
20. (New) The apparatus of claim 17, wherein the needles are associated with each other in groups of bipolar pairs, and wherein the control module is further configured to regulate energy delivery to the bipolar pairs in order to cause areas of non-ablative damage within the dermal layer, wherein each area of non-ablative damage is associated with the bipolar pair of the plurality of needles.
21. (New) The apparatus of claim 20, wherein the areas of non-ablative damage are elongated regions, each provided between each bipolar pair of the plurality of needles.
22. (New) The apparatus of claim 17, wherein at least one of the needles is a monopolar needle.
23. (New) The apparatus of claim 16, wherein the control module is further configured to deliver up to 8W of power to each needle.

24. (New) The apparatus of claim 16, wherein the plurality of needles are arranged on the base in a substantially rectangular array.
25. (New) The apparatus of claim 16, wherein the control module is further configured to allow a user to select treatment parameters including duration and intensity of treatment.
26. (New) The apparatus of claim 16, wherein the control module is further configured to enable a user to select application-specific settings for the energy source, to thereby cause the energy source to vary a duration, intensity, and sequence of energy transmitted to the needles based on the selected settings.
27. (New) The apparatus of claim 16, wherein at least two of the plurality of needles have differing lengths.
28. (New) The apparatus of claim 16, further comprising a cooling arrangement configured to cool a skin surface to reduce pain of a subject when at least one of the needles penetrates the surface.
29. (New) The apparatus of claim 16, further comprising a vibrator configured to vibrate the plurality of needles.

30. (New) The apparatus of claim 16, wherein a diameter of at least one of the needles is between about 500 μ m and 1000 μ m.
31. (New) The apparatus of claim 16, wherein the plurality of needles have an average spacing therebetween of between about 1 mm and 2 mm, and wherein the plurality of needles are spaced in a non-uniform manner.
32. (New) The apparatus of claim 16, wherein one or more of the plurality of needles are hollow, and are configured to deliver a local analgesic to the tissue surrounding a tip of the one or more of the plurality of needles.
33. (New) The apparatus of claims 16, further comprising an electronic detection device configured to electrically communicate with at least one of the plurality of needles, wherein the electronic detection device is further configured to detect a presence of a nerve near a tip of at least one of the needles.
34. (New) The apparatus of claim 16, further comprising the energy source providing RF energy.
35. (New) A tissue treatment apparatus, comprising:
a plurality of needles;
a base supporting the plurality of needles with tips configured for an insertion into a dermal layer of skin, the base being configured for a connection to a

housing connecting the plurality of needles to a control module, the control module being configured to regulate delivery of radio frequency (RF) energy from an RF energy source to at least a portion of the plurality of needles, wherein the control module is further configured to cause RF energy to be delivered via the needles to cause a pattern of fractional damage to be produced in the dermal layer surrounding the plurality of needles when inserted therein,

wherein the control module is configured to regulate the delivery of the RF energy to cause at least one of:

- (i) a formation of a new collagen structure in the skin, or
- (ii) a pattern of regions of thermal damage within the dermal layer, wherein at least two adjacent regions of the thermal damage have a undamaged region therebetween.

36. (New) The apparatus of claim 35, wherein the base is configured to act as a stop, such that when the base is brought into contact with the skin, tips of the needles reside in the skin at a predetermined depth.
37. (New) The apparatus of claim 35, wherein the base includes a surface shaped to contour to a curved region of the skin.
38. (New) The apparatus of claim 35, wherein the base includes a substantially planar skin-contacting surface.

39. (New) The apparatus of claim 35, further comprising a cooling arrangement provided on or in the base, or connected thereto.
40. (New) The apparatus of claim 35, wherein at least one of the plurality of needles is hollow and configured to deliver a local analgesic to tissue surrounding a needle tip.
41. (New) The apparatus of claim 35, wherein the plurality of needles are arranged in a substantially rectangular array.
42. (New) The apparatus of claim 35, wherein at least two of the plurality of needles have differing lengths.
43. (New) The apparatus of claim 35, wherein the plurality of needles are supported by the base in a manner so as to cause the needles to be vibrated by a vibration device.
44. (New) The apparatus of claim 35, wherein a diameter of at least one of the plurality of needles is between about 500 μ m and 1000 μ m.
45. (New) The apparatus of claim 35, wherein the plurality of needles have an average spacing of between about 1 mm and 2 mm.

46. (New) A tissue treatment apparatus, comprising:
- a housing configured to support a plurality of needles attached to a base, the needles having tips configured for an insertion into a dermal layer of skin;
 - a control module configured to regulate delivery of radio frequency (RF) energy from an RF energy source to at least a portion of the plurality of needles, wherein the control module is further configured to cause RF energy to be delivered via the needles to cause a pattern of fractional damage to be produced in the dermal layer surrounding the needles; and
 - a vibration arrangement configured to vibrate the plurality of needles.

REMARKS

This Preliminary Amendment amends the originally-filed specification of the above-referenced U.S. application to indicate that it is a continuation application of application Serial No. 12/914,201, which is a divisional application of U.S. Patent Application Serial No. 11/098,030 filed on April 1, 2005 that issued as U.S. Patent No. 7,824,394, and that the present application claims priority from all these applications.


Further, originally-filed claims 1-15 were cancelled above, without prejudice. New claims 16-46 have been added herein above. Accordingly, claims 16-46 are now under consideration in the above-identified application. The cancellation of claims 1-15, and the addition of new claims 16-46 as identified above comply with 37 C.F.R. § 1.121. Applicants further respectfully assert that the addition of new claims 16-46 do not add new matter to the application.

Applicant asserts that the present invention is new, non-obvious, and useful. Prompt consideration and allowance of the pending claims are respectfully requested.

Respectfully submitted,

Dated: August 13, 2014

By:


Gary Abelev
Patent Office Reg. No. 40,479

ANDREWS KURTH L.L.P.
540 Lexington Avenue
New York, New York 10017

Attorney(s) for Applicant(s)
(212) 850-2881

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Dieter MANSTEIN

Serial No. : To be assigned (Continuation of Serial No. 12/914,201)

Filed : Filed herewith (August 13, 2014)

For : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING

Examiner : To be assigned

Art Unit : To be assigned

Confirmation No. : To be assigned

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

INFORMATION DISCLOSURE STATEMENT

Dear Sirs:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached Form PTO/SB/08a, and respectfully request that the listed documents be considered by the Examiner and made of record in the above-captioned application. Copies of the references listed on the Form PTO/SB/08a are not enclosed since the references have already been submitted in connection with Application Serial No. 12/914,201, the parent application of the present application.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are

material or constitute "prior art." If the Examiner applies the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

This submission is being filed with the initial filing of the application. Therefore, Applicants do not believe that any fee is due in connection with the submission of this paper. However, if any fee is due, or if any overpayment has been made, the Commissioner is authorized to charge any such fee or credit any overpayment, to our Deposit Account No. 50-2849.

Respectfully submitted,

Dated: August 13, 2014

By:



Gary Abelev
Patent Office Reg. No. 40,479

ANDREWS KURTH L.L.P.
540 Lexington Avenue
New York, New York 10017

Attorney(s) for Applicant(s)
(212) 850-2881

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	To be assigned
				Filing Date	Herewith (August 13, 2014)
				First Named Inventor	Dieter Manstein
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	1	of	5	Attorney Docket No: 036213.US.08-32865-216897	

US PATENT DOCUMENTS					
Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2002/0120260	August 29, 2002	Morris et al.	
		3505993	April 1970	Lewes et al.	
		4985027	January 1991	Dressel	
		5000752	March 1991	Hoskin et al.	
		5102410	April 1992	Dressel	
		5312395	May 1994	Tan et al.	
		5458596	October 1995	Lax et al.	
		5569242	October 1996	Lax et al.	
		5582184	December 1996	Erickson et al.	
		5599342	February 1997	Hsia et al.	
		5660836	August 1997	Knowlton	
		5697281	December 1997	Eggers et al.	
		5697909	December 1997	Eggers et al.	
		5755753	May 1998	Knowlton	
		5807385	September 1998	Keller	
		5814040	September 1998	Nelson et al.	
		5861002	January 1999	Desai	
		5871524	February 1999	Knowlton	
		5919219	July 1999	Knowlton	
		5984011	September 1999	Knowlton	
		5954710	September 1999	Paolini et al.	
		5976129	November 1999	Desai	
		6048352	April 2000	Douglas et al.	
		6106516	August 2000	Massengill	
		6120519	August 2000	Weber et al	
		6206873	March 2001	Paolini et al.	
		6241753	June 2001	Knowlton	
		6277116	August 2001	Utely et al.	
		6311090	October 2001	Knowlton	
		6334856	January 2002	Allen et al.	
		6350276	February 2002	Knowlton	
		6355054	March 2002	Neuberger	
		6377854	April 2002	Knowlton	
		6377855	April 2002	Knowlton	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. † Applicant's unique citation designation number (optional) ‡ Applicant is to place a check mark here if English language Translation is attached

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US PATENT DOCUMENTS					
Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		6381497	April 2002	Knowlton	
		6381498	April 2002	Knowlton	
		6387380	May 2002	Knowlton	
		6405090	June 2002	Knowlton	
		6413255	July 2002	Stern	
		6416531	July 2002	Chen	
		6418232	July 2002	Avrahami	
		6425912	July 2002	Knowlton	
		6427089	July 2002	Knowlton	
		6430446	August 2002	Knowlton	
		6438424	August 2002	Knowlton	
		6453202	September 2002	Knowlton	
		6461378	October 2002	Knowlton	
		6470216	October 2002	Knowlton	
		6482204	Nov 2002	Lax et al.	
		6503231	Jan 2003	Prausnitz et al.	
		6562054	May 2003	Weber et al.	
		6597946	July 2003	Avrahami et al.	
		6605079	Aug 2003	Shanks et al.	
		6605080	Aug 2003	Altshuler et al.	
		6611706	Aug 2003	Altshuler et al.	
		6615079	Sep 2003	Avrahami	
		6708060	March 2004	Avrahami	
		6711435	March 2004	Avrahami	
		6723092	April 2004	Brown et al	
		6743211	June 2004	Prausnitz et al.	
		6749624	June 2004	Knowlton	
		6766202	July 2004	Underwood et al	
		6997923	Feb 2006	Anderson et al.	
		7006874	Feb 2006	Knowlton	
		7008421	March 2006	Daniel et al.	
		7022121	April 2006	Stern et al.	
		7025765	April 2006	Balbierz et al.	
		7060061	June 2006	Altshuler et al.	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

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Sheet	3	of	5	Attorney Docket No: 036213.US.08-32865-216897	

US PATENT DOCUMENTS					
Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		7115123	Oct 2006	Knowlton et al.	
		7141049	Nov 2006	Stern et al.	
		7189230	March 2007	Knowlton	
		7217265	May 2007	Hennings et al.	
		7223264	May 2007	Daniel et al.	
		7278991	Oct 2007	Morris et al.	
		7331953	Feb 2008	Manstein et al.	
		7422586	Sept 2008	Morris et al.	
		2002/0115991	Aug 2002	Edwards	
		2002/0120263	Aug 2002	Brown et al.	
		2002/0128641	Sep 2002	Underwood et al.	
		2002/0138049	Sep 2002	Allen et al.	
		2002/0161357	Oct 2002	Anderson et al.	
		20030130655	July 2003	Woloszko et al.	
		20030212394	Nov 2003	Pearson et al.	
		20030216719	Nov 2003	Debenedictis et al.	
		20040048842	March 2004	McMillan	
		20040073277	April 2004	Geronemus et al.	
		20040267335	Nov 2004	Tulip et al.	
		20050049582	March 2005	Debenedictis et al.	
		20050087198	April 2005	Bruno-Raimondi et al.	
		20050137662	June 2005	Morris et al.	
		20050209564	Sep 2005	Bonner et al.	
		20050209565	Sep 2005	Yuzhakov et al.	
		20050222555	Oct 2005	Manstein et al.	
		20050222565	Oct 2005	Manstein et al.	
		2006/0004306	Jan 2006	Altshuler et al.	
		2006/0004347	Jan 2006	Altshuler et al.	
		20060009750	Jan 2006	Altshuler et al.	
		20060020309	Jan 2006	Altshuler et al.	
		20060058712	March 2006	Altshuler et al.	
		20060122668	June 2006	Anderson et al.	
		20060206110	Sep 2006	Knowlton et al	
		20060224148	Oct 2006	Cho et al.	

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Substitute Disclosure Statement Form (PTO-1449)

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				Filing Date	Herewith (August 13, 2014)
				First Named Inventor	Dieter Manstein
				Art Unit	To be assigned
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Sheet	4	of	5	Attorney Docket No: 036213.US.08-32865-216897	

US PATENT DOCUMENTS					
Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		20060253112	Nov 2006	Suarez et al.	
		20060293722	Dec 2006	Slatkine et al.	
		20070010811	Jan 2007	Stern et al.	
		20070073367	March 2007	Jones et al.	
		20070173799	July 2007	Hsia	
		20070198003	Aug 2007	Domankevitz et al.	
		20070208340	Sep 2007	Ganz et al.	
		20080125775	May 2008	Morris	
		20080221649	Sep 2008	Echague et al.	
		20090124958	05/14/2009	L. Kasey	
		20080082090	04/03/2008	D. Manstein	
		20080312647	12/18/2008	P. Knopp	
		20070106143	05/10/2007	J. Flaherty	
		6,277,116	08/21/2001	D. Utely	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
		WO 2005/007001	January 27, 2005	Resect Medical, Inc.		
		WO 1999/04710	February 4, 1999	Cosman, Eric, et al.		
		DE 19929713	January 2001			
		EP0226336	June 1987			
		WO0048644	Aug 2000			
		WO 0132073	May 2001			
		WO02/060523	Aug 2002			
		WO03005919	Jan 2003			
		WO2004086947	Oct 2004			
		WO2005096979	Oct 2005			
		WO2005096980	Oct 2005			

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Substitute Disclosure Statement Form (PTO-1449)

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Substitute for form 1449A/PTO					
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	To be assigned
				Filing Date	Herewith (August 13, 2014)
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				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	5	of	5	Attorney Docket No: 036213.US.08-32865-216897	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Urmev et al. "Percutaneous Electrode Guidance: A Noninvasive Technique for Prelocation of Peripheral Nerves to Facilitate Peripheral Plexus or Nerve Block", Regional Anesthesia and Pain Medicine, vol. 27, no. 3, 2002, pp. 261-267.	
		Copy of International Search Report mailed September 17, 2008 for International Application No. PCT/US2008/061682	
		Harrington, James A. "A Review of IR Transmitting, Hollow Waveguides", Fiber and Integrated Optics, 19:211-217 (2000).	
		Khan et al. "Intradermally Focused Infrared Laser Pulses: Thermal Effects at Defined Tissue Depths", Lasers in Surgery and Medicine, 36:270-280 (2005).	
		Manstein et al. "Fractional Photothermolysis: A New Concept for Cutaneous Remodeling Using Microscopic Patterns of Thermal Injury", Lasers in Surgery and Medicine, 34:426-438 (2004).	
		Medical Fiber Optic Components, Schott, Germany, 20 pages (May 2003).	
		Smartlipo: Laser Lipolysis With Pulsed Nd:YAG Laser Brochure, DEKA M.E.L.A. s.r.l., Italy, 2 pages.	
		TRI-ACTIVE Brochure, DEKA M.E.L.A. s.r.l., Italy, 4 pages.	
		Copy of International Search Report mailed on February 1, 2011 for International Patent Application No. PCT/US2010/037950	
		Copy of International Written Opinion mailed on February 1, 2011 for International Patent Application No. PCT/US2010/037950	

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2871551

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POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:



Practitioners associated with Customer Number:

120944

OR



Practitioner(s) named below (If more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignments documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:



The address associated with Customer Number:

120944

OR

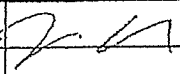
<input type="checkbox"/> Firm or Individual Name		
Address		
City		
Country		
Telephone		Email

Assignee Name and Address: The General Hospital Corporation
55 Fruit Street
Boston, Massachusetts 02114

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of the practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	1/24/12
Name	Richard Stevens		Telephone
Title	Director, IP Management Group Genentech Ventures & Licensing		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

2587

PTO/SB/06 (08-04)

Approved for use through 07/31/2008. OMB 0651-0031

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

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

STATEMENT UNDER 37 CFR 3.73(b)Applicant/Patent Owner: Dieter MansteinApplication No./Patent No.: 11/098,030 Filed/Issue Date: April 1, 2005Entitled: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

The General Hospital Corp. a Corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or2. ☐ an assignee of less than the entire right, title and interest.The extent (by percentage) of its ownership interest is _____ %
in the patent application/patent identified above by virtue of either:A. [] An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 032739, Frame 0147, or for which a copy thereof is attached.

OR

B. [] A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

[] Additional documents in the chain of title are listed on a supplemental sheet.

[x] Copies of assignments or other documents in the chain of title are attached.

(NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

April 14, 2006
DateKELIS BETESS
Typed or printed name[Signature]
SignatureLICENSING MGR
Title

This collection of information is required by 37 CFR 3.73(b). 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 1460, Alexandria, VA 22313-1460.

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

ASSIGNMENT

WHEREAS, I,

DIETER MANSTEIN

1 Longfellow Place

2624

Boston, Massachusetts 02114

Citizenship: Germany and the United States of America

have made an invention entitled "METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING," as set forth and described in the non-provisional patent application which was filed with the U.S. Patent and Trademark Office on April 1, 2005, and assigned Serial No. 11/098,030; and

WHEREAS, THE GENERAL HOSPITAL CORPORATION, a Corporation of Massachusetts, having an office for the transaction of business at 55 Fruit Street, Boston, Massachusetts 02114, is desirous of acquiring our entire right, title and interest in and to said invention and any improvements thereon, and in and to the said application for Letters Patent therefor, and any Letters Patent which may be obtained therefor;

NOW, THEREFORE, TO ALL WHOM IT MAY CONCERN, BE IT KNOWN, that WE, the said DIETER MANSTEIN for and in consideration of the sum of One Dollar (\$1.00), lawful money of the United States, to us in hand paid by said THE GENERAL HOSPITAL CORPORATION, and other valuable considerations unto us me moving from said THE GENERAL HOSPITAL CORPORATION, at or before the sealing and delivery of these presents, the receipt of which is hereby acknowledged, have sold, assigned, transferred and conveyed and by these presents do sell, assign, transfer and convey, unto said THE GENERAL HOSPITAL CORPORATION, its successors and assigns, the entire right, title and interest in and to the said invention entitled "METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING," as set forth and described in the non-provisional patent application which was filed with the U.S. Patent and Trademark Office on April 1, 2005, and assigned Serial No. 11/098,030, and any and all improvements thereon, and in and to said application and any application claiming priority therefrom, and any non-provisional application, division, continuation or continuation-in-part thereof, and in and to any Letters Patent of the United States which may be issued on any of said applications, and any reissues thereof, and in and to any and all applications for Letters Patent filed in foreign countries for said invention or improvements, including all priority rights under the Paris Convention, and any and all Letters Patent which may be granted in foreign countries therefor, TO HAVE AND TO HOLD THE SAME to the full end of the term or terms for which any and all said Letters Patent may be granted;

AND I, the said DIETER MANSTEIN do hereby authorize and request the Commissioner of Patents and Trademarks to issue the said Letters Patent of the United States to said THE GENERAL HOSPITAL CORPORATION, as the assignee of the entire right, title and interest in and to the same, for the sole use and benefit of said THE GENERAL HOSPITAL CORPORATION, its successors and assigns;

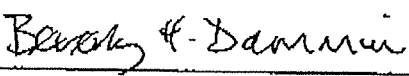
AND I, the said DIETER MANSTEIN for the considerations aforesaid, do hereby covenant and agree to and with said THE GENERAL HOSPITAL CORPORATION, its successors and assigns, that we have the full power to make this assignment, and that the rights assigned are not encumbered by any grant, license or right heretofore given, and that we, our executors or administrators, shall and will do all lawful acts and things and make, execute and deliver without further compensation, any and all other instruments in writing, further applications, papers, affidavits, powers of attorney, assignments, and other documents which, in the opinion of counsel for said THE GENERAL HOSPITAL CORPORATION, its successors and assigns, may be required or necessary to more effectively secure to and vest in said THE GENERAL HOSPITAL CORPORATION, its successors and assigns, the entire right, title and interest in and to said invention and improvements, applications, Letters Patent, rights, benefits, privileges and advantages hereby sold, assigned, transferred and conveyed, and that we will sign any applications for reissue which may be desired by the owner of the patent or patents which may be issued for the said invention or improvements.

IN WITNESS WHEREOF, WE, the said DIETER MANSTEIN, have hereunto
set our hands and seals on the date below written.


DIETER MANSTEIN

STATE OF MA)
COUNTY OF Suffolk) ss.:

BE IT KNOWN, that on this 14th day of April, 2006, before me
personally came DIETER MANSTEIN, to me known and known to me to be the person
mentioned in and who executed the foregoing assignment, and he acknowledged to me
that he executed the same as his free act and deed for the use and purposes therein
mentioned.


Notary Public

Beverly H. Dammin, Notary Public
Commonwealth of Massachusetts
My Commission Expires 6/30/2006



4816-4948-35201

TITLE OF THE INVENTION

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE
RESHAPING

RELATED APPLICATION

5 This application claims priority to U.S. Provisional Application Serial No.
60/558,476, filed on April 1, 2004.

INCORPORATION BY REFERENCE

10 The foregoing applications, and all documents cited therein or during their
prosecution (“appln cited documents”) and all documents cited or referenced in the appln
cited documents, and all documents cited or referenced herein (“herein cited documents”),
and all documents cited or referenced in herein cited documents, together with any
manufacturer’s instructions, descriptions, product specifications, and product sheets for any
products mentioned herein or in any document incorporated by reference herein, are hereby
incorporated herein by reference, and may be employed in the practice of the invention.

15 FIELD OF THE INVENTION

 The present invention is directed to an improved method for treatment of skin and
other tissues. More specifically, it is directed to a method of fractional wounding using
arrays of needles to damage selected regions of the skin or subdermal tissue and thereby
promote beneficial results including skin tightening and tissue remodeling.

20 BACKGROUND OF THE INVENTION

 Skin is primarily made of two layers. The outer layer, or epidermis, has a depth of
approximately 100 μm . The inner layer, or dermis, has depth of approximately 3000 μm from
the outer surface of the skin and is primarily composed of a network of fibrous protein known
as collagen.

25 There is an increasing demand for repair of skin defects, which can be induced by
aging, sun exposure, dermatological diseases, traumatic effects, and the like. Aging skin
tends to lose its elasticity, leading to increased formation of wrinkles and sagging. Other
causes of undesirable wrinkles in skin include excessive weight loss and pregnancy. There
are several well-known surgical approaches to improving the appearance of skin that involve
30 incisions being made in the skin followed by the removal of some tissue and rejoining of the
remaining tissue. These surgical approaches include facelifts, brow lifts, breast lifts, and
“tummy tucks.” Such approaches have many negative side effects including scar formation,
35 long healing times, displacement of skin from its original location relative to the underlying
bone structure, and nonuniform skin tightening.

Many treatments have been developed that use electromagnetic radiation to improve skin defects by inducing a thermal injury to the skin, which results in a complex wound healing response of the skin. This leads to a biological repair of the injured skin and may be accompanied by other desirable effects. Various techniques providing this objective have been introduced in recent years. The different techniques can be generally categorized in two groups of treatment modalities: ablative laser skin resurfacing ("LSR") and non-ablative collagen remodeling ("NCR"). The first group of treatment modalities, LSR, includes causing fairly extensive thermal damage to the epidermis and/or dermis, while the second group, NCR, is designed to avoid thermal damage of the epidermis.

LSR is considered to be an effective laser treatment for repairing skin. In a typical LSR procedure, shown schematically in Fig. 1, a region of the epidermis 100 and a corresponding region of the dermis 110 beneath it are thermally damaged to promote wound healing. Electromagnetic energy 120 is directed towards a region of skin, ablating the skin and removing both epidermal and dermal tissue in region 130. LSR with pulsed CO₂ or Er:YAG lasers, which may be referred to in the art as laser resurfacing or ablative resurfacing, is considered to be an effective treatment option for signs of photo aged skin, chronically aged skin, scars, superficial pigmented lesions, stretch marks, and superficial skin lesions. However, patients may experience major drawbacks after each LSR treatment, including edema, oozing, and burning discomfort during first fourteen (14) days after treatment. These major drawbacks can be unacceptable for many patients. A further problem with LSR procedures is that the procedures are relatively painful and therefore generally require an application of a significant amount of analgesia. While LSR of relatively small areas can be performed under local anesthesia provided by injection of an anesthetic, LSR of relatively large areas is frequently performed under general anesthesia or after nerve blockade by multiple injections of anesthetic.

A limitation of LSR is that ablative resurfacing in areas other than the face generally have a greater risk of scarring because the recovery from skin injury within these areas is not very effective. Further, LSR techniques are better suited for correction of pigmentation defects and small lesions than for reducing or eliminating wrinkles.

In an attempt to overcome the problems associated with LSR procedures, several types of NCR techniques has emerged. These techniques are variously referred to in the art as non-ablative resurfacing, non-ablative subsurfacing, or non-ablative skin remodeling. NCR techniques generally utilize non-ablative lasers, flashlamps, or radio frequency current to damage dermal tissue while sparing damage to the epidermal tissue. The concept behind

NCR techniques is that thermal damage of the dermal tissue is thought to induce collagen shrinkage, leading to tightening of the skin above, and stimulation of wound healing which results in biological repair and formation of new dermal collagen. This type of wound healing can result in a decrease of structural damage related to photoaging. Avoidance of epidermal damage in NCR techniques decreases the severity and duration of treatment-related side effects. In particular, post-procedural oozing, crusting, pigmentary changes and incidence of infections due to prolonged loss of the epidermal barrier function can usually be avoided by using NCR techniques.

In the NCR method of skin treatment, illustrated schematically in Fig. 2, selective portions of dermal tissue 135 within the dermal layer 110 are heated to induce wound healing without damaging the epidermis 100 above. Selective dermal damage that leaves the epidermis undamaged can be achieved by cooling the surface of the skin and focusing electromagnetic energy 120, which may be a laser beam, onto dermal region 135 using lens 125. Other strategies are also applied using nonablative lasers to achieve damage to the dermis while sparing the epidermis in NCR treatment methods. Nonablative lasers used in NCR procedures generally have a deeper dermal penetration depth as compared to ablative lasers used in LSR procedures. Wavelengths in the near infrared spectrum can be used. These wavelengths cause the non-ablative laser to have a deeper penetration depth than the very superficially-absorbed ablative Er:YAG and CO₂ lasers. Examples of NCR techniques and apparatus are disclosed by Anderson et al. in U.S. Patent Publication No. 2002/0161357.

While it has been demonstrated that these NCR techniques can assist in avoiding epidermal damage, one of the major drawbacks of these techniques is their limited efficacies. The improvement of photoaged skin or scars after the treatment with NCR techniques is significantly smaller than the improvements found when LSR ablative techniques are utilized. Even after multiple treatments, the clinical improvement is often far below the patient's expectations. In addition, clinical improvement is usually several months delayed after a series of treatment procedures. NCR is moderately effective for wrinkle removal and is generally not effective for dyschromia. One advantage of NCR is that it does not have the undesirable side effects that are characteristic of the LSR treatment, such as the risk of scarring or infection.

Another limitation of NCR procedures relates to the breadth of acceptable treatment parameters for safe and effective treatment of dermatological disorders. The NCR procedures generally rely on an optimum coordination of laser energy and cooling parameters, which can result in an unwanted temperature profile within the skin leading to

either no therapeutic effect or scar formation due to the overheating of a relatively large volume of the tissue.

Another approach to skin tightening and wrinkle removal involves the application of radio frequency ("RF") electrical current to dermal tissue via a cooled electrode at the surface of the skin. Application of RF current in this noninvasive manner results in a heated region developed below the electrode that damages a relatively large volume of the dermis, and epidermal damage is minimized by the active cooling of the surface electrode during treatment. This treatment approach can be painful, and can lead to short-term swelling of the treated area. Also, because of the relatively large volume of tissue treated and the need to balance application of RF current with surface cooling, this RF tissue remodeling approach does not permit fine control of damage patterns and subsequent skin tightening. This type of RF technique is monopolar, relying on a remote grounding of the patient to complete the current flow from the single electrode. The current in monopolar applications must flow through the patient's body to the remote ground, which can lead to unwanted electrical stimulation of other parts of the body. In contrast, bipolar instruments conduct the current between two relatively nearby electrodes through a more localized pathway.

In view of the shortcomings of the above methods of dermatological treatment and tissue remodeling, there is a need to provide a procedure and apparatus that combine safe and effective treatment for tissue remodeling, skin tightening, and wrinkle removal with minimal side effects, such as intra-procedural discomfort, post-procedural discomfort, lengthy healing time, and post-procedural infection.

Citation or identification of any document in this application is not an admission that such document is available as prior art to the present invention.

SUMMARY OF THE INVENTION

It is therefore one of the objects of the present invention to provide an apparatus and method that combines safe and effective treatment for an improvement of dermatological disorders with minimum side effects. Another object of the present invention is to provide an apparatus and method that promotes skin tightening and wrinkle removal by creation of a pattern of small localized regions of thermal damage within the dermis. Still another object of the present invention is to provide a method and apparatus for skin tightening or other forms of tissue remodeling by using an array of electrode needles to controllably deliver electrical or thermal energy to predetermined locations within the dermis or other tissue.

These and other objects can be achieved with an exemplary embodiment of the apparatus and method according to the present invention, in which portions of a target area of

tissue are be subjected electromagnetic radiation, such as radio frequency pulses, or thermal energy. Electromagnetic radiation is directed to portions of a target area within the skin or deeper tissue using minimally invasive methods, causing fractional wounding of the portions of the target area. The electromagnetic radiation may be generated by an electromagnetic radiation source, which is configured to deliver heat, radio frequency pulses, electrical current, or the like to a plurality of target areas.

In yet another exemplary embodiment according to the present invention, an electromagnetic radiation source is configured to generate electromagnetic radiation, and a delivery device comprising an array of needles, coupled to the electromagnetic radiation source, is configured to penetrate the skin to a desired depth to deliver the electromagnetic radiation directly to a plurality of target areas.

One method in accordance with the present invention comprises inserting an array of needles into a region of skin to a predetermined depth. Radio frequency pulses of electrical current are then applied to one or more of the needles, which can function as electrodes in monopolar or bipolar modes to create regions of thermal damage and/or necrosis in the tissue surrounding the tips of the needles.

In an alternate aspect of the invention, one or more of the needles in the array may be hollow and used to deliver small amounts of analgesic or anesthetic into the region of skin being treated. These hollow needles may be interspersed among the electrode needles in the array, and they may also function as electrodes.

In another embodiment of the invention, the electrode needles may also be connected to a second source of electrical current in the milliamperage range. Detection of a nerve close to any of the inserted needles of the array is achieved by sequential application of small currents to the needles in the array and observation of any visible motor response. If a nerve is detected, the nearby needle or needles can be deactivated during the subsequent application of RF current to other electrode needles in the array to avoid damaging the nerve.

In yet another embodiment of the invention, the methods and apparatus described herein can be used to heat portions of cartilage, such as that located in the nose, using a minimally invasive technique, allowing reshaping of the pliant heated cartilage to a desired form.

A further understanding of the nature and advantages of the present invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The following detailed description, given by way of example, but not intended to limit the invention solely to the specific embodiments described, may best be understood in conjunction with the accompanying drawings, in which:

Fig. 1 is a schematic drawing of a cross section of a tissue treated using the ASR method.

Fig. 2 is a schematic drawing of a cross section of a tissue treated using the NSR method.

Fig. 3 is a schematic illustration of an apparatus for conducting tissue reshaping using electromagnetic energy according to one embodiment of the present invention.

Fig. 4 is a schematic illustration of portions of an apparatus for conducting tissue reshaping according to one embodiment of the present invention.

Throughout the drawings, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components, or portions of the illustrated embodiments. Moreover, while the present invention will now be described in detail with reference to the Figures, it is done so in connection with the illustrative embodiments and is not limited by the particular embodiments illustrated in the Figures.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to methods and apparatus for improvement of skin defects including, but not limited to, wrinkles, stretch marks, and cellulite. In one embodiment, skin tightening or tissue remodeling is accomplished by creating a distribution of regions of necrosis, fibrosis, or other damage in the tissue being treated. The tissue damage is achieved by delivering localized concentrations of electrical current that is converted into heat in the vicinity of the tips of the electrode needles. Inducing regions of local thermal damage within the dermis results in an immediate shrinking of collagen, leading to beneficial skin tightening response. Additionally, the thermal damage tends to stimulate the formation of new collagen, which makes the local skin tissue fuller and gradually leads to additional skin tightening and reduction of wrinkles.

In an exemplary embodiment of the present invention, tissue treatment apparatus 300 shown in Fig. 3 may be used to create regions of damage within the tissue being treated. The tissue reshaping apparatus may comprise a plurality of needles 350 attached to a base 310. The base is attached to housing 340 or formed as a part of the housing. A source of RF current 320 is electrically connected to each of the needles 350. A control module 330 permits variation of the characteristics of the RF electrical current, which can be supplied

individually to one or more of the needles. Optionally, energy source 320 and/or control module 330 may be located outside of the housing.

In one exemplary embodiment, the energy source 320 is a radio frequency (RF) device capable of outputting signals having frequencies in a desired range. In another exemplary embodiment, the energy source is capable of outputting an AC or DC electric current. The control module 330 provides application-specific settings to the energy source 320. The energy source 320 receives these settings, and generates a current directed to and from specified needles for selectable or predetermined durations, intensities, and sequences based on these settings.

In yet another embodiment of the present invention, a spacer substrate 315 containing a pattern of small holes through which the array of needles protrudes may optionally be provided between the base 310 and the surface of the skin 306. This spacer substrate may be used to provide mechanical stability to the needles. Optionally, this substrate may be movably attached to the base 310 or housing 340 and adjustable with respect to base 310, supporting the array of needles to control the depth of the needles protruding from the lower surface 316 of spacer substrate 315, and thus controlling the depth to which the needles are inserted into the skin.

In practicing a method in accordance with the present invention, the sharp distal ends of needles 350 pierce the surface 306 of skin tissue 305 and are inserted into the tissue until the bottom surface 316 of spacer substrate 315 (or the bottom surface 311 of base 310 if a spacer substrate 315 is not used) contacts the surface 306 of the skin 305. This configuration permits reliable insertion of the array of needles to a predetermined depth within the tissue being treated. Control module 330 is then configured to deliver controlled amounts of RF current to one or more needles 350.

Base 310 and/or spacer substrate 315, if used, can be planar or they may have a bottom surface that is contoured to follow the shape of the region of tissue being treated. This permits penetration of the needle array to a uniform depth within the targeted tissue even if the surface of the skin is not planar, e.g., along the eye sockets.

In another embodiment, base 310 and/or a spacer substrate 315, if used, may be cooled by any suitable means (such as by embedded conduits containing circulating coolant or by a Peltier device) to cool the surface of the skin when the needle array penetrates the skin to reduce or eliminate pain. The surface region of the skin being treated and/or the needles themselves may also be precooled by separate means, including convective or conductive means, prior to penetration of the skin by the array of needles.

In a preferred embodiment of the present invention, the shafts of conductive needles 350 are electrically insulated except for the portion of the needle near the tip. In the apparatus of Fig. 3, application of RF current to the needles 350 causes heating in the exposed tip region, inducing thermal damage regions 370 around the tip of each needle.

Thermal damage regions 370 result from operation of the apparatus in monopolar configuration, in which a remote grounding electrode, not shown in Fig. 3, is attached to a remote part of the patient's body to complete the circuit of electricity conveyed to needles 350 by energy source 320. In this monopolar configuration, RF current causes heating of the tip regions of the needles 350, generating thermal damage in tissue regions 370 adjacent to the needle tips that are approximately spherical or slightly elongated in shape.

In one embodiment of the invention, current may be delivered simultaneously to all needles in the array to produce a pattern of thermal damage around the tip of each needle. In alternative embodiments, control module 330 and energy source 320 can be configured to supply electrical current to individual needles, to specific groups of needles within the array, or to any combination of individual needles in any desired temporal sequence. Providing current to different needles at different times during treatment (instead of heating all needles in the array at once) may help to avoid potential local electrical or thermal interactions among needles that can lead to excessive local damage.

In yet another embodiment of the present invention one or more vibrating means, such as a piezoelectric transducer or a small motor with an eccentric weight fixed to the shaft, may be mechanically coupled to housing 340 and/or base 310 that supports the array of needles 350. Vibrations conductively induced in needles 350 by such vibrating means can facilitate the piercing of the skin by the needle tips and subsequent insertion of the needles into the tissue. The vibrating means can have an amplitude of vibration in the range of about 50-500 μm or, more preferably, between about 100-200 μm . The frequency of the induced vibrations can be from about 10 hz to about 10 khz, more preferably from about 500 hz to about 2 khz, and even more preferably about 1 khz. The particular vibration parameters chosen may depend on the size and material of the needles, the number of needles in the array, and the average spacing of the needles. The vibrating means may further comprise an optional controller capable of adjusting the amplitude and/or frequency of the vibrations.

Additional details and embodiments of the present invention are shown in Figure 4. Conductive needles 410 and 415 are shown attached to base 310. Insulation 420 covers the shaft of needles 410 and 415 protruding from base 310 except for the region near the lower tip, and electrically insulates each conductive needle shaft from surrounding tissue 305.

Electrical conductors 430 and 431, which may be wires or the like, extend from an upper portion of needles 410 and 415 respectively, and are connected to the energy source (not shown here). Suitable insulating materials for insulation 420 include, but are not limited to, Teflon®, polymers, glasses, and other nonconductive coatings. A particular material may be chosen as an insulator to facilitate penetration and insertion of needles 410 and 415 into tissue 305.

Needles 410 and 415 are shown operating in bipolar mode in another embodiment of the present invention. Needle 410 is a positive electrode delivering RF or other current to the tip region of the needle from the energy source via conductor 430. Needle 415 functions as a grounding electrode that is connected to the ground of the energy source via conductor 431. In this configuration the applied current will travel through the tissue between the tips of needles 410 and 415, generating an elongated region of thermal damage 425 around and between the tips of the two needles.

An elongated region of damaged tissue 425 can be created between any two adjacent or nearby needles in the array through proper configuration of control module 330 and energy source 320. In an embodiment of the present invention, elongated damage regions 425 are formed between several pairs of needles within the array of needles to form a desired damage pattern in the tissue 305. The regions of thermal damage 325 created in bipolar operation of the apparatus may be formed simultaneously or, alternatively, sequentially, using any combinations of proximate needles in the array to form each region. A wide variety of thermal damage patterns can be created using a single array of needles through appropriate configuration of energy source 320 and control module 330 to deliver predetermined amounts of current between selected pairs of needles. This apparatus thus allows for the creation of complex damage patterns within the tissue 305 that may be macroscopically elongated in preferred directions to produce anisotropic shrinkage and reshaping.

In practicing the methods and apparatus of the present invention, the needles can have a width of about 500-1000 μm or preferably about 700-800 μm . Needles less than 500 μm in diameter may also be used if they are mechanically strong enough. Needles thicker than about 1000 μm in diameter may be undesirable because of the difficulty in forcing larger needles to penetrate the skin and because of the increased propensity for pain and scarring. The length of the needles extending into the skin will depend on the targeted depth for damaging the tissue. A typical depth for targeting collagen in the dermis is about about 1500-2000 μm , although shallower or deeper distances may be preferred for different treatments

2 and regions of the body being treated. Needles within a single array may protrude by
different lengths from the base 310 or spacer substrate 315. This will cause the tips of the
needles to be positioned at different depths within the tissue being treated, and allow creation
of damaged tissue at more than one depth. This variation in needle depth can achieve
5 formation of damaged tissue over a larger volume within the tissue being treated.

10 The needle arrays may have any geometry appropriate for the desired treatment being
performed. The spacing between adjacent needles is preferably greater than about 1mm
apart, and may be as large as about 2 cm. The spacing between needles in an array need not
be uniform, and can be closer in areas where a greater amount of damage or more precise
control of damage in the target area of tissue is desired. In one embodiment, the array of
needles may comprise pairs of needles separated from adjacent pairs by larger distances.
This geometry may be well-suited for inducing damage in bipolar mode between pairs of
needles. Needles may also be arranged in a regular or near-regular square or triangular array.
In any array geometry, the pattern of damage and resultant tissue reshaping may be controlled
15 with some precision by adjusting the intensity and duration of power transmitted to single
needles or pairs of needles.

20 The amount of energy directed to a given needle will vary depending on the tissue
being treated and the desired extent of thermal damage to induce. For typical needle spacings
noted above, the energy source should be configured to deliver about 1-100 mJ per needle or
pair of needles in the array. It may be preferable to initially use lower amounts of energy and
perform two or more treatments over the same target area to better control the damage patterns
and extent of reshaping.

25 In yet another embodiment of the present invention, one or more of the needles in the
array may be hollow, such as needle 440 in Fig. 4. Center channel 450 may be used to
deliver a local analgesic such as lidocaine 2% solution from a source (not shown) located
within or above base 310 into the tissue 305 to reduce or eliminate pain caused by the thermal
damage process.

30 In yet another embodiment of the present invention, hollow needle 440 is
bifunctional, capable of conducting RF current or other energy via conductor 432 and also
capable of delivering a local analgesic or the like through center channel 450. Similar to
needles 410 and 415, bifunctional needle 440 has insulation 445 covering the shaft extending
from base 310 except for the region near the lower tip. Analgesic may be supplied to the
tissue either before or during application of RF or other current to the needle 450.

In one embodiment of the invention, one or more of the needles in the array may be bifunctional like needle 440. Alternatively, one or more needles may be hollow and optionally nonconductive, suitable only for delivering a local analgesic or the like. The array of needles used for a given application may comprise any combination of solid electrodes, bifunctional needles, or hollow nonconductive needles. For example, one type of needle array may comprise pairs of electrode needles operating in bipolar mode, with a hollow needle located between each pair. In this configuration, the hollow needle can deliver analgesic to the tissue between the tips of the electrode needles prior to applying current to the electrodes and causing thermal damage in the numbed tissue.

In yet another embodiment of the present invention, one or more of the needles in the array may be further connected to an electronic detection apparatus and perform the additional function of a probe to detect the presence of a nerve near the tip. The electronic detection apparatus may comprise a source of electrical current in the milliampere range and control means to send small currents on the order of a milliamp to specific needles in the array. Detection of a nerve close to any of the inserted needles of the array is performed by sequential application of small currents to the needles in the array and observation of any visible motor response. If a nerve is detected, control module 330 can be configured to deactivate the needle or needles close to the nerve during the subsequent treatment to avoid damaging the nerve. A nerve detection method based on principles similar to those described herein is disclosed by Urmey et al. in *Regional Anesthesia and Pain Medicine* 27:3 (May-June) 2002, pp. 261-267.

In still another embodiment, one or more of the needles may be hollow, and a light fiber or light guide is inserted into the hollow needle such that one end of it extends to or slightly protrudes from the needle tip. The other end of the light fiber or light guide in communication with a source of optical energy. Optical energy supplied to the tip of the light guide or light fiber may then be used to heat the tip, which then heats the surrounding tissue, i.e., the target area, to cause fractional wounding at the needle tip. An array of needles used in accordance with the present invention may comprise a mix of electrode needles and light-guide needles. Alternatively, each needle may carry a light guide and all of the energy used to cause thermal damage may be generated by the optical energy source instead of using RF or other electrical current. A portion of the light guide or light fiber, such as the portion at the tip of the needle, may be configured to absorb energy and facilitate conversion of the optical energy to heat. In these embodiments, the optical energy source may comprise, but is not limited to, a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG

laser, an argon-ion laser, a He-Ne laser, a carbon dioxide laser, an excimer laser, or a ruby laser. The optical energy conveyed by a light guide or light fiber may optionally be continuous or pulsed.

Treatments performed in accordance with the present invention may be used to target collagen in the dermis. This can lead to immediate tightening of the skin and reduction of wrinkles overlying the damaged tissue arising from contraction of the heated collagen. Over time, the thermal damage also promotes the formation of new collagen, which serves to smooth out the skin even more.

An alternative application of the methods of the present invention may be to reduce or eliminate the appearance of cellulite. To achieve this, the arrays of needles are configured to target the dermis and optionally the upper layer of subcutaneous fat directly. Creating dispersed patterns of small thermally-damaged regions in these layers can tighten the networked collagen structure and suppress the protrusion of the subcutaneous fat into the dermal tissue that causes cellulite.

Yet another application of the methods and apparatus of the present invention is to reshape cartilage. It is known that cartilage softens upon heating, and heating it to about 70 degrees C can soften the cartilage sufficiently to permit reshaping that persists upon cooling. Currently, specialized lasers are used to heat and soften cartilage in the nasal passages for reshaping. Using the methods and apparatus described herein, cartilage can be targeted by an array of needles and heated in a suitably gradual way, using lower power densities and longer times, to provide relatively uniform heating. Shaping of the cartilage is thus possible using a minimally invasive technique that can be used where laser heating may not be feasible.

Any of the thermal damaging and tissue reshaping methods practiced in accordance with the present invention may be performed in a single treatment, or by multiple treatments performed either consecutively during one session or at longer intervals over multiple sessions. Individual or multiple treatments of a given region of tissue can be used to achieve the appropriate thermal damage and desired cosmetic effects.

The invention is further described by the following numbered paragraphs:

1. A tissue reshaping apparatus comprising:
 - a plurality of needles attached to a base, wherein the base is attached to a housing or part of the housing;
 - an energy source in communication with one or more of the needles; and
 - optionally comprising a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.

2. The apparatus of paragraph 1 wherein one or more of the needles are electrically conductive and the energy source is configured to supply RF current individually to one or more of the needles.

3. The apparatus of paragraph 2 wherein the energy source and/or control module is located outside of the housing.

4. The apparatus of any one of paragraphs 1 to 3 wherein the energy source is a radio frequency (RF) device capable of outputting signals having frequencies in a desired range.

5. The apparatus of any one of paragraphs 1 to 4 wherein the energy source is capable of outputting an AC or DC electric current.

6. The apparatus of any one of paragraphs 1 to 5 wherein the control module provides application-specific settings to the energy source, and wherein the energy source receives the settings, and generates a current directed to and optionally from specified needles for selectable or predetermined durations, intensities, and sequences based on the settings.

7. The apparatus of any one of paragraphs 1 to 6 wherein the needles comprise sharp distal ends capable of piercing the surface of skin tissue and penetrating into the tissue until the lower side of the base contacts the surface of the skin.

8. The apparatus of any one of paragraphs 1 to 7 wherein the control module is configured to deliver controlled amounts of RF current to one or more of the needles.

9. The apparatus of any one of paragraphs 1 to 8 further comprising a spacer substrate comprising a pattern of small holes through which the plurality of needles protrudes.

10. The apparatus of paragraph 9 wherein the substrate is movably attached to the base or the housing and wherein the position of the substrate is adjustable relative to that of the base to control the depth of the needles protruding from the lower surface of the spacer substrate.

11. The apparatus of any one of paragraphs 1 to 10 wherein the base and/or optionally, the spacer substrate, is planar or has a lower surface that is contoured to follow the shape of the region of tissue being treated.

12. The apparatus of any one of paragraphs 1 to 11 wherein the base and/or a spacer substrate further comprises cooling means configured to cool a skin surface to reduce or eliminate pain when the plurality of needles penetrates the skin surface.

13. The apparatus of paragraph 12 wherein said cooling comprises embedded conduits containing circulating coolant or a Peltier device.

14. The apparatus of any one of paragraphs 1 to 13 wherein said apparatus is configured to deliver RF energy to one or more needles in a monopolar configuration.

15. The apparatus of any one of paragraphs 1 to 13 wherein said apparatus is configured to deliver RF energy to one or more needles in a bipolar configuration.

16. The apparatus of any one of paragraphs 1 to 15 further comprising a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft.

17. The apparatus paragraph 16 wherein the vibrational frequency of said vibrating means is between about 10 hz to about 10 khz, between about 500 hz to about 2 khz, or is about 1 khz.

18. The apparatus paragraph 17 wherein the vibrational amplitude of said vibrating means is between about 50-500 μm or between about 100-200 μm .

19. The apparatus of any one of paragraphs 1 to 18 wherein the energy source and the control module are configured to deliver energy to a plurality of pairs of needles in bipolar mode..

20. The apparatus of any one of paragraphs 1 to 19 wherein the diameter of the needles is between about 500-1000 μm or between about 700-800 μm .

21. The apparatus of any one of paragraphs 1 to 20 wherein the average spacing of needles is between about 1 mm and 2 cm, and wherein the needles optionally are not uniformly spaced.

22. The apparatus of any one of paragraphs 1 to 21 wherein one or more of the needles are hollow and are configured to deliver a local analgesic to the tissue surrounding the tip of the needle.

23. The apparatus of any of paragraphs 1 to 22 further comprising an electronic detection device in electrical communication with one or more of the needles that is configured to detect the presence of a nerve near the tip of one or more of the needles.

24. The apparatus of paragraph 23 wherein the detection device is in communication with the control module and the control module is configured to prevent the energy source from supplying energy to any needle if a nerve has been detected near that needle.

25. The apparatus of any of paragraphs 1 to 24 further comprising a source of optical energy and one or more hollow needles containing light fibers or light guides, wherein

the apparatus is configured to deliver a controlled amount of electromagnetic energy through the light fiber or light guide and into the tissue surrounding the tip of the hollow needle.

26. The apparatus of paragraph 25 wherein the optical energy source comprises a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG laser, an argon-ion laser, a He-Ne laser, a carbon dioxide laser, an excimer laser, or a ruby laser, and wherein the electromagnetic energy conveyed by the light guide or light fiber is continuous or pulsed.

27. A method of treating skin comprising the steps of:
providing a plurality of needles attached to a base;
providing an energy source in communication with one or more of the needles;
inserting the needles into the skin to a predetermined depth; and
supplying energy to more than one of the needles to induce a pattern of damage in the tissue surrounding the needles.

28. The method of paragraph 27 further comprising:
providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.

29. The method of paragraph 28 further comprising:
providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin.

30. The method of paragraph 29 wherein the energy is RF current and the needles are insulated except near their tips.

31. The method of paragraph 30 further comprising:
providing a detection device in communication with one or more of the needles;
supplying low current to one or more of the needles sequentially to detect the presence of a nerve near the needles; and
preventing the energy source from supplying energy to any needle if a nerve has been detected near that needle.

32. The method of paragraph 27 further comprising:
providing one or more hollow needles attached to the base and injecting an analgesic through the hollow needles into the surrounding tissue after the needles are inserted into the skin.

33. The method of paragraph 29 further comprising:
providing hollow needles containing light fibers or light guides in communication with the energy source, wherein the energy source is a source of optical

energy;

supplying energy to the light fibers or light guides to induce thermal damage in a portion of the tissue surrounding the hollow needles.

* * *

Having thus described in detail preferred embodiments of the present invention, it is to be understood that the invention defined by the above paragraphs is not to be limited to particular details set forth in the above description as many apparent variations thereof are possible without departing from the spirit or scope of the present invention.

WHAT IS CLAIMED IS:

1. A tissue reshaping apparatus comprising:
a plurality of needles attached to a base, wherein the base is attached to a housing or part of the housing;
an energy source in communication with one or more of the needles; and
optionally comprising a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source.
2. The apparatus of claim 1 wherein one or more of the needles are electrically conductive and the energy source is configured to supply RF current individually to one or more of the needles or
wherein one or more of the needles are electrically conductive and the energy source is configured to supply RF current individually to one or more of the needles and
wherein the energy source and/or control module is located outside of the housing.
3. The apparatus of claim 1 wherein the energy source is a radio frequency (RF) device capable of outputting signals having frequencies in a desired range or
wherein the energy source is capable of outputting an AC or DC electric current.
4. The apparatus of claim 1 wherein the control module provides application-specific settings to the energy source, and wherein the energy source receives the settings, and generates a current directed to and optionally from specified needles for selectable or predetermined durations, intensities, and sequences based on the settings.
5. The apparatus of claim 1 wherein the needles comprise sharp distal ends capable of piercing the surface of skin tissue and penetrating into the tissue until the lower side of the base contacts the surface of the skin.
6. The apparatus of claim 1 wherein the control module is configured to deliver controlled amounts of RF current to one or more of the needles.
7. The apparatus of claim 1 wherein the apparatus further comprises a spacer substrate comprising a pattern of small holes through which the plurality of needles protrudes or
wherein the apparatus further comprises a spacer substrate comprising a pattern of small holes through which the plurality of needles protrudes and
wherein the substrate is movably attached to the base or the housing and wherein the position of the substrate is adjustable relative to that of the base to control the depth of the needles protruding from the lower surface of the spacer substrate.

8. The apparatus of claim 1 wherein the base and/or optionally, the spacer substrate, is planar or has a lower surface that is contoured to follow the shape of the region of tissue being treated or

wherein the base and/or a spacer substrate further comprises cooling means configured to cool a skin surface to reduce or eliminats pain when the plurality of needles penetrates the skin surface or

wherein the base and/or a spacer substrate further comprises cooling means configured to cool a skin surface to reduce or eliminats pain when the plurality of needles penetrates the skin surface and

wherein said cooling comprises embedded conduits containing circulating coolant or a Peltier device.

9. The apparatus of claim 1 wherein said apparatus is configured to deliver RF energy to one or more needles in a monopolar configuration or

wherein said apparatus is configured to deliver RF energy to one or more needles in a bipolar configuration.

10. The apparatus of claim 1 wherein the apparatus further comprises a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft or

wherein the apparatus further comprises a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft and

wherein the vibrational frequency of said vibrating means is between about 10 hz to about 10 khz, between about 500 hz to about 2 khz, or is about 1 khz or

wherein the apparatus further comprises a vibrational means in communication with the base, where said vibrational means comprises a piezoelectric device or a motor having an eccentric weight fixed to its shaft and

wherein the vibrational frequency of said vibrating means is between about 10 hz to about 10 khz, between about 500 hz to about 2 khz, or is about 1 khz and

wherein the vibrational amplitude of said vibrating means is between about 50-500 μm or between about 100-200 μm .

11. The apparatus of claim 1 wherein the energy source and the control module are configured to deliver energy to a plurality of pairs of needles in bipolar mode..

12. The apparatus of claim 1 wherein the diameter of the needles is between about 500-1000 μm or between about 700-800 μm or

wherein the average spacing of needles is between about 1 mm and 2 cm, and wherein the needles optionally are not uniformly spaced.

13. The apparatus of claim 1 wherein one or more of the needles are hollow and are configured to deliver a local analgesic to the tissue surrounding the tip of the needle.

14. The apparatus of claim 1 wherein the apparatus further comprises an electronic detection device in electrical communication with one or more of the needles that is configured to detect the presence of a nerve near the tip of one or more of the needles or

wherein the apparatus further comprises an electronic detection device in electrical communication with one or more of the needles that is configured to detect the presence of a nerve near the tip of one or more of the needles and

wherein the detection device is in communication with the control module and the control module is configured to prevent the energy source from supplying energy to any needle if a nerve has been detected near that needle.

15. The apparatus of claim 1 wherein the apparatus further comprises a source of optical energy and one or more hollow needles containing light fibers or light guides, wherein the apparatus is configured to deliver a controlled amount of electromagnetic energy through the light fiber or light guide and into the tissue surrounding the tip of the hollow needle or

wherein the apparatus further comprises a source of optical energy and one or more hollow needles containing light fibers or light guides, wherein the apparatus is configured to deliver a controlled amount of electromagnetic energy through the light fiber or light guide and into the tissue surrounding the tip of the hollow needle and

wherein the optical energy source comprises a diode laser, a diode-pumped solid state laser, an Er:YAG laser, a Nd:YAG laser, an argon-ion laser, a He-Ne laser, a carbon dioxide laser, an excimer laser, or a ruby laser, and wherein the electromagnetic energy conveyed by the light guide or light fiber is continuous or pulsed.

16. A method of treating skin comprising the steps of:
providing a plurality of needles attached to a base;
providing an energy source in communication with one or more of the needles;
inserting the needles into the skin to a predetermined depth; and
supplying energy to more than one of the needles to induce a pattern of damage in the tissue surrounding the needles.

17. The method of claim 16 further comprising:
providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source or
providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source and
providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin or
providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source and
providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin and wherein the energy is RF current and the needles are insulated except near their tips or
providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source and
providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin and wherein the energy is RF current and the needles are insulated except near their tips and
providing a detection device in communication with one or more of the needles;
supplying low current to one or more of the needles sequentially to detect the presence of a nerve near the needles; and
preventing the energy source from supplying energy to any needle if a nerve has been detected near that needle.

18. The method of claim 16 further comprising:
providing one or more hollow needles attached to the base and injecting an analgesic through the hollow needles into the surrounding tissue after the needles are inserting into the skin.

19. The method of claim 16 further comprising:
providing a control module, wherein the control module permits variation of the characteristics of energy supplied by the energy source and
providing cooling means to cool the surface of the skin, and optionally the plurality of needles, before inserting the needles into the skin and
providing hollow needles containing light fibers or light guides in communication with the energy source, wherein the energy source is a source of optical

energy;

supplying energy to the light fibers or light guides to induce thermal damage in a portion of the tissue surrounding the hollow needles.

ABSTRACT OF THE DISCLOSURE

The present invention provides improved methods and apparatus for skin treatment and tissue remodeling. The apparatus includes an array of needles that penetrate the skin and serve as electrodes to deliver radio frequency current or other electrical or optical energy into
5 the tissue being treated, causing thermal damage in controlled patterns. The damaged regions promote beneficial results such as uniform skin tightening by stimulation of wound healing and collagen growth.

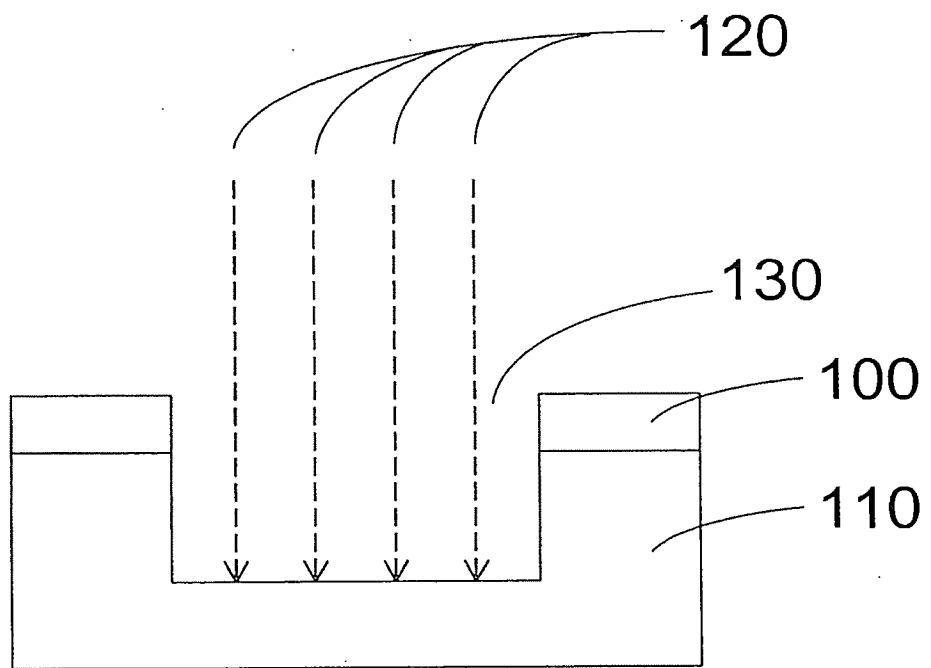


FIG. 1

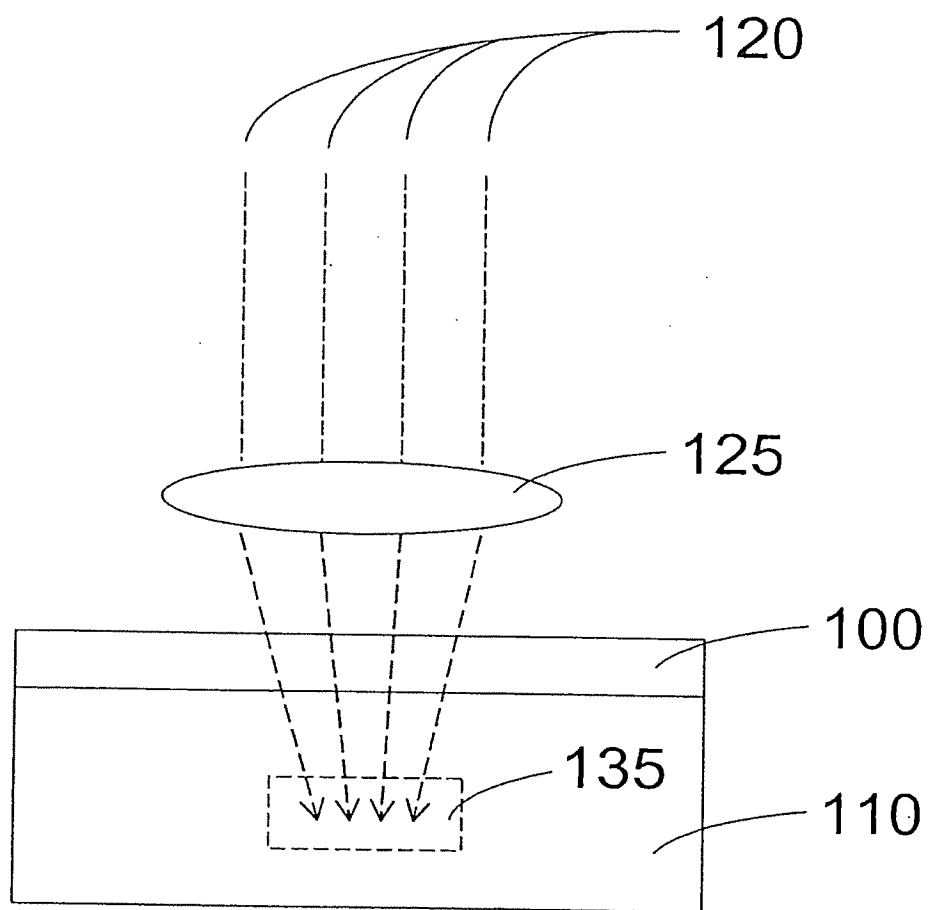


FIG. 2

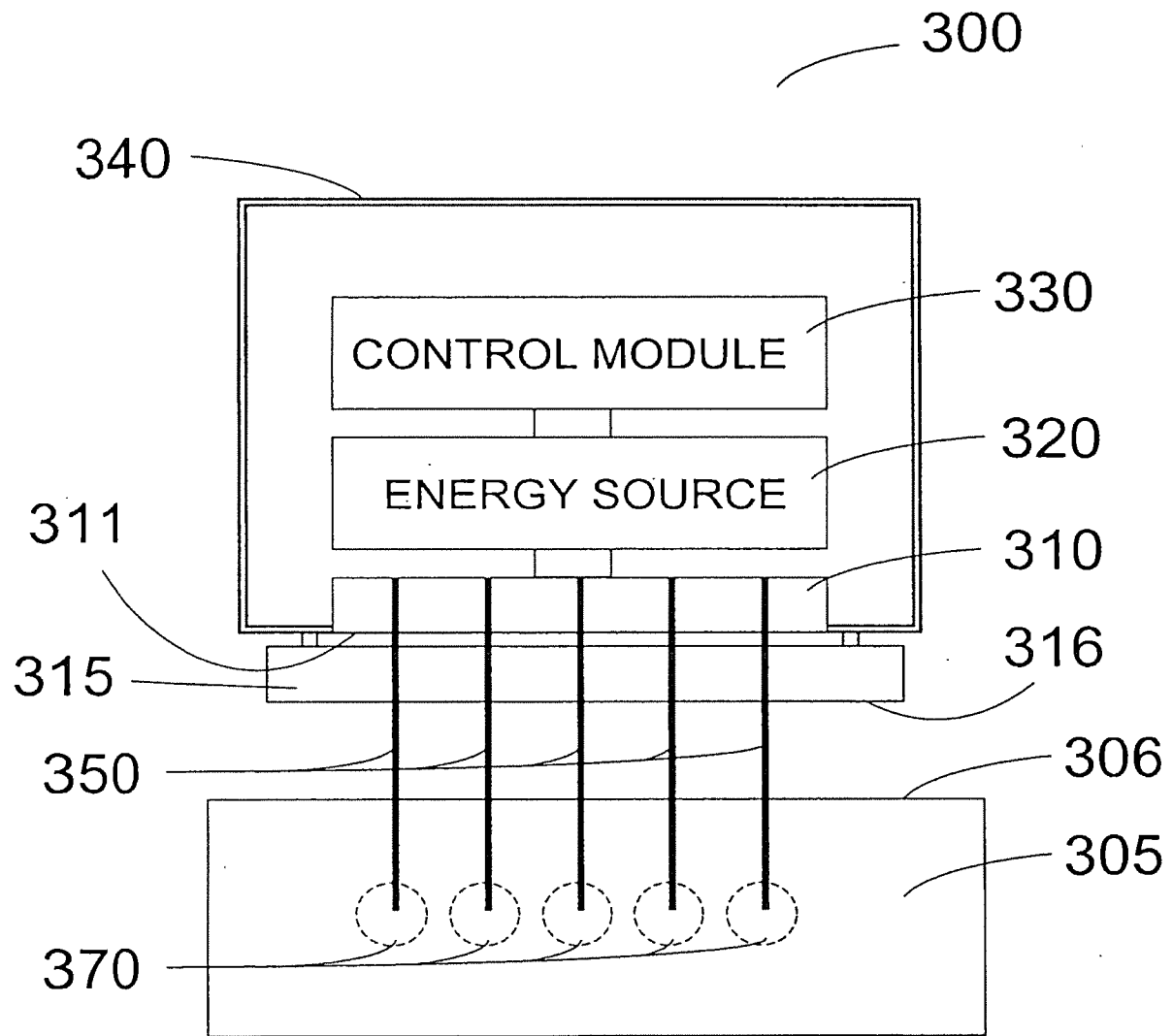


FIG. 3

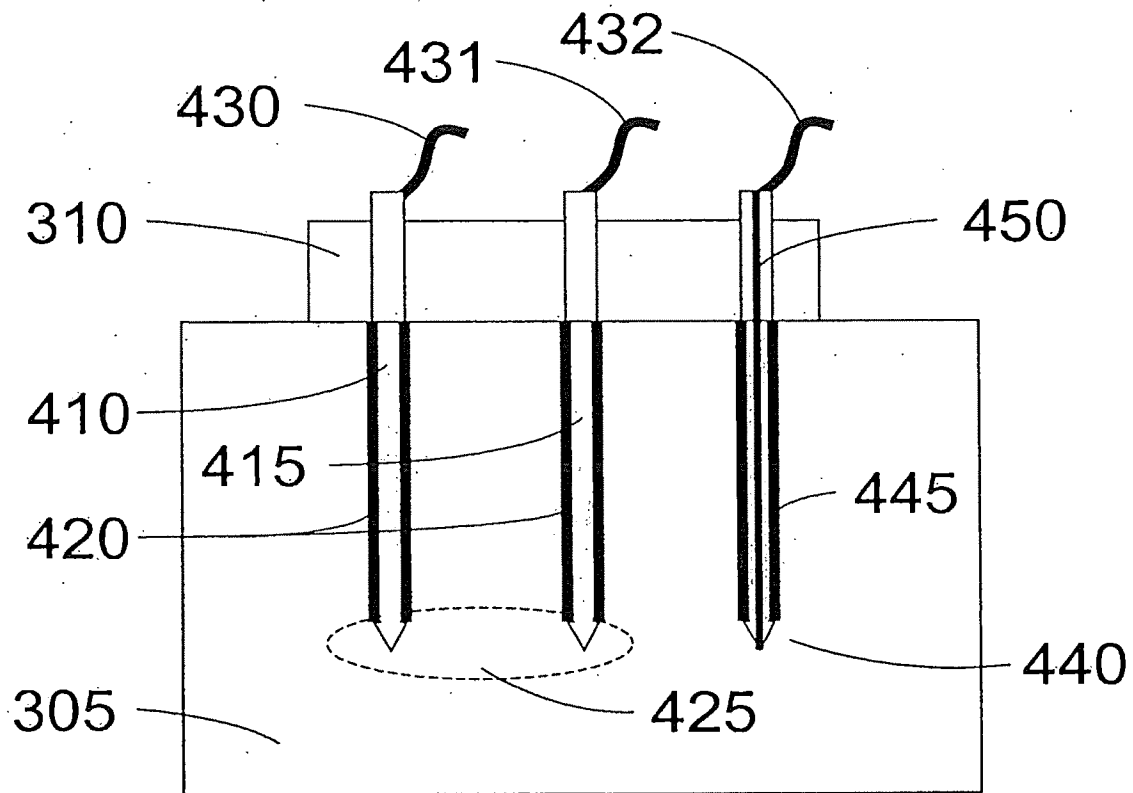


FIG. 4

Electronic Patent Application Fee Transmittal

Application Number:				
Filing Date:				
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING			
First Named Inventor/Applicant Name:	Dieter Manstein			
Filer:	Gary Abelev/Kim Dufault			
Attorney Docket Number:	036213.US.08-32865-216897			
Filed as Large Entity				
Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Utility application filing	1011	1	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720
Request for Prioritized Examination	1817	1	4000	4000
Pages:				
Claims:				
Claims in Excess of 20	1202	11	80	880
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Publ. Fee- Early, Voluntary, or Normal	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				6620

Electronic Acknowledgement Receipt

EFS ID:	19855257
Application Number:	14458644
International Application Number:	
Confirmation Number:	1016
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	120944
Filer:	Gary Abelev/Kim Dufault
Filer Authorized By:	Gary Abelev
Attorney Docket Number:	036213.US.08-32865-216897
Receipt Date:	13-AUG-2014
Filing Date:	
Time Stamp:	14:50:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$6620
RAM confirmation Number	1088
Deposit Account	502849
Authorized User	ABELEV, GARY

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		32865-216897.pdf	222440	yes	7
			305eb24f43f939baefff1d85b250a9ea68cebda9		
	Multipart Description/PDF files in .zip description				
	Document Description	Start	End		
	Transmittal of New Application	1	1		
	Application Data Sheet	2	7		
Warnings:					
Information:					
2	Preliminary Amendment	32865-216897PA.pdf	86623	no	12
			02823bf9b54f905870ec2ff66e0e634d53c0ff4d6		
Warnings:					
Information:					
3		32865-216897IDS.pdf	201942	yes	7
			60f2b134ad95de1dd087ec41e344b056112e0ce4		
	Multipart Description/PDF files in .zip description				
	Document Description	Start	End		
	Miscellaneous Incoming Letter	1	2		
	Information Disclosure Statement (IDS) Form (SB08)	3	7		
Warnings:					
Information:					
4		32865-216897Misc.pdf	287361	yes	7
			499d60104a2588e415c764a13607e3cc9d2a4d6b		
	Multipart Description/PDF files in .zip description				
	Document Description	Start	End		
	TrackOne Request	1	1		
	Oath or Declaration filed	2	2		

	Power of Attorney		3	3	
	Assignee showing of ownership per 37 CFR 3.73.		4	4	
	Miscellaneous Incoming Letter		5	7	
Warnings:					
Information:					
5		32865-216897Spec.pdf	503259 e6e2c234d6483d98ccf9395edde00f800b5cde92	yes	26
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	16	
	Claims		17	21	
	Abstract		22	22	
	Drawings-only black and white line drawings		23	26	
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	41777 a2aea4e13a1cfe5d8504cf390df2d4e079288438	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1343402		

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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 a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

**CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION
UNDER 37 CFR 1.102(e) (Page 1 of 1)**

First Named Inventor:	Dieter MANSTEIN	Nonprovisional Application Number (if known):	60/558,476
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.


1. The processing fee set forth in 37 CFR 1.17(i)(1), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. The basic filing fee, search fee, examination fee, and any required excess claims and application size fees are filed with the request or have been already been paid.
2. The application contains or is amended to contain no more than four independent claims and no more than thirty total claims, and no multiple dependent claims.
3. The applicable box is checked below:

I. ☒ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

- i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.
---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.
- ii. The executed inventor's oath or declaration is filed with the application. (37 CFR 1.63 and 1.64)

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

- i. A request for continued examination has been filed with, or prior to, this form.
- ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
- iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
- iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
- v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature 	Date August 13, 2014
Name (Print/Typed) Gary Abelev	Practitioner Registration Number 40479
Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*	
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.	

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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	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
-----------------------	---

As the below named inventor, I hereby declare that:

This declaration
is directed to:☒

The attached application, or


☐United States application or PCT international application number _____
filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001
by fine or imprisonment of not more than five (5) years, or both.**WARNING:**

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

LEGAL NAME OF INVENTORInventor: DIETER MANSTEINDate (Optional): 5/2/14Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/458,644	Filing Date 08/13/2014	<input type="checkbox"/> To be Mailed
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ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	08/13/2014	CLAIMS REMAINING AFTER AMENDMENT	Minus	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 31	Minus	** 31	= 0	X \$80 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X \$420 =	0
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))						
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
TOTAL ADD'L FEE						0	

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	Minus	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

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LIE
/ROLITA WIMBUSH/

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/458,644	Filing Date 08/13/2014	<input type="checkbox"/> To be Mailed
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ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO**APPLICATION AS FILED – PART I**

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	08/13/2014	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 31	Minus	** 31	= 0	X \$80 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	X \$420 =	0
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))						
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	X \$ =	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number
14/458,644

APPLICATION AS FILED - PART I

(Column 1)		(Column 2)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720
TOTAL CLAIMS (37 CFR 1.16(j))	31	minus 20 = * 11			OR	x 80 =	880
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	minus 3 = *				x 420 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
			TOTAL			TOTAL	2480

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED - PART II

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

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

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.



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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
14/458,644	08/13/2014	3769	2480	036213.US.08-32865-216897	31	3

CONFIRMATION NO. 1016

120944

Andrews Kurth LLP

Attention: Intellectual Property - Patent Docket

450 Lexington Avenue

New York, NY 10017

FILING RECEIPT



OC000000070328769

Date Mailed: 08/25/2014

Receipt is acknowledged of this non-provisional 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 APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Dieter Manstein, Coral Gables, FL;

Applicant(s)

Dieter Manstein, Coral Gables, FL;

Assignment For Published Patent Application

The General Hospital Corporation, Boston, MA

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 12/914,201 10/28/2010
which is a DIV of 11/098,030 04/01/2005 PAT 7824394

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 08/21/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/458,644**

Projected Publication Date: 12/04/2014

Non-Publication Request: No

Early Publication Request: No
Title

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

Preliminary Class

606

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

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

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The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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NOT GRANTED

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/458,644	08/13/2014	Dieter Manstein	036213.US.08-32865-216897

CONFIRMATION NO. 1016

IMPROPER CFR REQUEST



120944
Andrews Kurth LLP
Attention: Intellectual Property - Patent Docket
450 Lexington Avenue
New York, NY 10017

Date Mailed: 08/25/2014

RESPONSE TO REQUEST FOR CORRECTED FILING RECEIPT

Continuity, Priority Claims, Petitions, and Non-Publication Requests

In response to your request for a corrected Filing Receipt, the Office is unable to comply with your request because:

Improper Benefit Claim(s) to Prior-Filed Provisional Application(s)

The benefit claim(s) to prior-filed provisional application(s) is improper because the instant application was not filed within twelve (12) months from the filing date of the provisional application, and there is no indication of an intermediate nonprovisional or international application designating the United States that is directly claiming the benefit of the provisional application and filed within 12 months of the filing date of the provisional application. Applicant should review each benefit claim submitted and, if appropriate, provide the proper reference to the prior-filed applications (including an indication of any intermediate application that is directly claiming the benefit of the provisional application and filed with 12 months of the filing date of the provisional application) as required by 37 CFR 1.78.

Alternatively, if the instant application (or intermediate application) was filed within 14 months of the prior provisional application, applicant may file a petition (in the instant application or the intermediate application, as appropriate) to restore the benefit of the provisional application if the delay in filing the instant application (or intermediate application) within the 12 month time period was unintentional. See 37 CFR 1.78 for the requirements of a petition to restore the benefit of the provisional application.

For applications filed on or after September 16, 2012, applicant must submit a corrected application data sheet (ADS) to include a specific reference.

Timeliness: The required reference for each benefit claim must be filed during the pendency of the instant application and within the later of: (1) four months from the actual filing date of the instant application, or the national stage commencement date if the instant application is a national stage application under 35 U.S.C. 371; or (2) sixteen months from the filing date of the prior-filed application. Failure to timely file the required reference is considered a waiver of any benefit claim, unless a grantable petition to accept an unintentionally delayed claim under 37 CFR 1.78, the petition fee set forth in 37 CFR 1.17(m), and the required reference are filed.

/aabransyos/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/458,644	08/13/2014	Dieter Manstein	036213.US.08-32865-216897

CONFIRMATION NO. 1016
IMPROPER CPOA LETTER

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Date Mailed: 08/25/2014

NOTICE REGARDING POWER OF ATTORNEY

This is in response to the power of attorney filed 08/13/2014. The power of attorney in this application is not accepted for the reason(s) listed below:

- The power of attorney has not been accepted because the party who is giving power has not been identified. Power of attorney may only be signed by the applicant for patent (37 CFR 1.42) or the patent owner. A party who is not the applicant must become the applicant in accordance with 37 CFR 1.46(c) and appoint any power of attorney in compliance with 37 CFR 3.71 and 3.73. For a reissue application, reexamination proceeding, or supplemental examination proceeding, a patent owner who was not the applicant under 37 CFR 1.46 must appoint any power of attorney in compliance with 37 CFR 3.71 and 3.73. See 37 CFR 1.32(b)(4).

/wtsige/

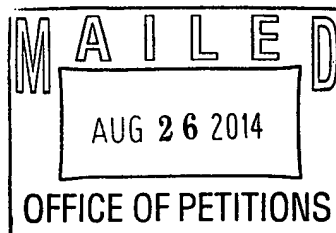
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Doc Code: TRACK1.DENY

**Decision Dismissing Request for
Prioritized Examination (Track I)**

Application No.: 14/458,644

1. THE REQUEST FILED August 13, 2014 IS **DISMISSED** BECAUSE:
- A. ☐ The application is not a utility application under 35 U.S.C. 111(a) filed by EFS-Web or a plant application under 35 U.S.C. 111(a) filed by paper:
- i. ☐ The application is a utility application that was not filed by EFS-Web.
- ii. ☐ The application is neither a utility application nor a plant application, but rather is a _____, which is excluded from the Track I program.
- B. ☐ The request was not filed with the application or on the same date the application was filed.
- C. ☐ One or more of the following fees were not filed with the application or on the same date the application was filed:
- i. ☐ Basic filing fee, as set forth in 37 CFR 1.16(a), or for a plant application, 37 CFR 1.16(c).
- ii. ☐ Search fee, as set forth in 37 CFR 1.16(k), or for a plant application, 37 CFR 1.16(m).
- iii. ☐ Examination fee, as set forth in 37 CFR 1.16(o), or for a plant application, 37 CFR 1.16(q).
- iv. ☐ Publication fee, as set forth in 37 CFR 1.18(d).
- v. ☐ Track I processing fee, as set forth in 37 CFR 1.17(i).
- vi. ☐ Track I prioritized examination fee, as set forth in 37 CFR 1.17(c).
- D. ☐ The executed inventor's oath or declaration, or an application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) was not filed with the application or on the same date the application was filed.
- E. ☒ The application contains or has been amended to contain:
- i. ☐ More than four independent claims.
- ii. ☒ More than thirty total claims.
- iii. ☐ One or more multiple dependent claims.
- F. ☐ The Track I program has exceeded its limit of 10,000 requests for the current fiscal year.
- G. ☐ Other: _____

2. CONCLUSION

☒ **ALL of the above defect(s) consist only of one or more of items E (i-iii). Applicant is hereby accorded a non-extendable ONE MONTH time period from the mailing date of this Decision to (1) correct the subject defect(s) and (2) file a petition under 37 CFR 1.181 requesting reconsideration of prioritized examination. If no such petition is timely filed, the application will not undergo prioritized examination.**

-OR-

☐ **The application will not undergo prioritized examination, because the request was not accompanied by all of the required items.**

Telephone inquiries with regard to this decision should be directed to Brian W. Brown at 571-272-5338.

/Brian W. Brown/
[Signature]

Petitions Examiner, Office of Petitions
(Title)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Dieter MANSTEIN
Serial No. : 14/458,644
Filed : August 13, 2014
For : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Examiner : To be assigned
Art Unit : To be assigned
Confirmation No. : 1016

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

Commissioner:

ANOTHER PRELIMINARY AMENDMENT

Please amend the above-identified patent application, as follows:

IN THE CLAIMS:

Please cancel claim 27, as provided below. The listing of the claims as pending in this application is provided on separate sheets as follows:

Claims 1-15 (Cancelled).

16. (Previously Presented) A tissue treatment apparatus, comprising:
- a housing configured to support a plurality of needles attached to a base, the needles having tips configured for an insertion into a dermal layer of skin;
 - and
 - a control module configured to regulate delivery of radio frequency (RF) energy from an RF energy source to at least a portion of the plurality of needles, wherein the control module is further configured to cause RF energy to be delivered via the needles to cause a pattern of fractional damage to be produced in the dermal layer surrounding the needles when inserted therein, wherein the control module is configured to regulate the delivery of the RF energy to cause at least one of:
 - (i) a formation of a new collagen structure in the skin, or
 - (ii) a pattern of regions of thermal damage within the dermal layer, wherein at least two adjacent regions of the thermal damage have a undamaged region therebetween.
17. (Previously Presented) The apparatus of claim 16, wherein the control module is further configured to regulate the RF energy to cause the formation of the new collagen structure in the skin.

18. (Previously Presented) The apparatus of claim 17, wherein the control module is further configured to control the RF energy to cause the pattern of regions of thermal damage within the dermal layer.
19. (Previously Presented) The apparatus of claim 17, wherein the control module is further configured to regulate energy delivery such that skin ablation is substantially prevented.
20. (Previously Presented) The apparatus of claim 17, wherein the needles are associated with each other in groups of bipolar pairs, and wherein the control module is further configured to regulate energy delivery to the bipolar pairs in order to cause areas of non-ablative damage within the dermal layer, wherein each area of non-ablative damage is associated with the bipolar pair of the plurality of needles.
21. (Previously Presented) The apparatus of claim 20, wherein the areas of non-ablative damage are elongated regions, each provided between each bipolar pair of the plurality of needles.
22. (Previously Presented) The apparatus of claim 17, wherein at least one of the needles is a mono-polar needle.

23. (Previously Presented) The apparatus of claim 16, wherein the control module is further configured to deliver up to 8W of power to each needle.
24. (Previously Presented) The apparatus of claim 16, wherein the plurality of needles are arranged on the base in a substantially rectangular array.
25. (Previously Presented) The apparatus of claim 16, wherein the control module is further configured to allow a user to select treatment parameters including duration and intensity of treatment.
26. (Previously Presented) The apparatus of claim 16, wherein the control module is further configured to enable a user to select application-specific settings for the energy source, to thereby cause the energy source to vary a duration, intensity, and sequence of energy transmitted to the needles based on the selected settings.
27. (Cancelled).
28. (Previously Presented) The apparatus of claim 16, further comprising a cooling arrangement configured to cool a skin surface to reduce pain of a subject when at least one of the needles penetrates the surface.

29. (Previously Presented) The apparatus of claim 16, further comprising a vibrator configured to vibrate the plurality of needles.
30. (Previously Presented) The apparatus of claim 16, wherein a diameter of at least one of the needles is between about 500 μ m and 1000 μ m.
31. (Previously Presented) The apparatus of claim 16, wherein the plurality of needles have an average spacing therebetween of between about 1 mm and 2 mm, and wherein the plurality of needles are spaced in a non-uniform manner.
32. (Previously Presented) The apparatus of claim 16, wherein one or more of the plurality of needles are hollow, and are configured to deliver a local analgesic to the tissue surrounding a tip of the one or more of the plurality of needles.
33. (Previously Presented) The apparatus of claims 16, further comprising an electronic detection device configured to electrically communicate with at least one of the plurality of needles, wherein the electronic detection device is further configured to detect a presence of a nerve near a tip of at least one of the needles.
34. (Previously Presented) The apparatus of claim 16, further comprising the energy source providing RF energy.

35. (Previously Presented) A tissue treatment apparatus, comprising:
- a plurality of needles;
 - a base supporting the plurality of needles with tips configured for an insertion into a dermal layer of skin, the base being configured for a connection to a housing connecting the plurality of needles to a control module, the control module being configured to regulate delivery of radio frequency (RF) energy from an RF energy source to at least a portion of the plurality of needles, wherein the control module is further configured to cause RF energy to be delivered via the needles to cause a pattern of fractional damage to be produced in the dermal layer surrounding the plurality of needles when inserted therein,
- wherein the control module is configured to regulate the delivery of the RF energy to cause at least one of:
- (i) a formation of a new collagen structure in the skin, or
 - (ii) a pattern of regions of thermal damage within the dermal layer, wherein at least two adjacent regions of the thermal damage have a undamaged region therebetween.
36. (Previously Presented) The apparatus of claim 35, wherein the base is configured to act as a stop, such that when the base is brought into contact with the skin, tips of the needles reside in the skin at a predetermined depth.

37. (Previously Presented) The apparatus of claim 35, wherein the base includes a surface shaped to contour to a curved region of the skin.
38. (Previously Presented) The apparatus of claim 35, wherein the base includes a substantially planar skin-contacting surface.
39. (Previously Presented) The apparatus of claim 35, further comprising a cooling arrangement provided on or in the base, or connected thereto.
40. (Previously Presented) The apparatus of claim 35, wherein at least one of the plurality of needles is hollow and configured to deliver a local analgesic to tissue surrounding a needle tip.
41. (Previously Presented) The apparatus of claim 35, wherein the plurality of needles are arranged in a substantially rectangular array.
42. (Previously Presented) The apparatus of claim 35, wherein at least two of the plurality of needles have differing lengths.
43. (Previously Presented) The apparatus of claim 35, wherein the plurality of needles are supported by the base in a manner so as to cause the needles to be vibrated by a vibration device.

44. (Previously Presented) The apparatus of claim 35, wherein a diameter of at least one of the plurality of needles is between about 500 μ m and 1000 μ m.
45. (Previously Presented) The apparatus of claim 35, wherein the plurality of needles have an average spacing of between about 1 mm and 2 mm.
46. (Previously Presented) A tissue treatment apparatus, comprising:
a housing configured to support a plurality of needles attached to a base, the needles having tips configured for an insertion into a dermal layer of skin;
a control module configured to regulate delivery of radio frequency (RF) energy from an RF energy source to at least a portion of the plurality of needles, wherein the control module is further configured to cause RF energy to be delivered via the needles to cause a pattern of fractional damage to be produced in the dermal layer surrounding the needles; and
a vibration arrangement configured to vibrate the plurality of needles.

REMARKS

This further Preliminary Amendment cancels previously-submitted claim 27, without prejudice. Further, originally-filed claims 1-15 were previously cancelled, without prejudice. Accordingly, claims 16-26 and 28-46 are now under consideration in the above-identified application. The cancellation of claim 27 as identified above complies with 37 C.F.R. § 1.121.

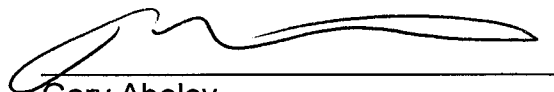
The cancellation of claim 27 has been made in response to and obviate the reasons provided in the Decision Dismissing Request for Prioritized Examination (Track I), i.e., to have 30 or less claims in the application. With such cancellation, only 30 claims are now presented in the present application. Thus, the Request for Prioritized Examination (Track I) should be granted.

Applicant asserts that the present invention is new, non-obvious, and useful. Prompt consideration and allowance of the pending claims are respectfully requested.

Respectfully submitted,

Dated: September 17, 2014

By:



Gary Abelev
Patent Office Reg. No. 40,479

ANDREWS KURTH L.L.P.
540 Lexington Avenue
New York, New York 10017

Attorney(s) for Applicant(s)
(212) 850-2881

Electronic Acknowledgement Receipt

EFS ID:	20165133
Application Number:	14458644
International Application Number:	
Confirmation Number:	1016
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	120944
Filer:	Gary Abelev/Kim Dufault
Filer Authorized By:	Gary Abelev
Attorney Docket Number:	036213.US.08-32865-216897
Receipt Date:	17-SEP-2014
Filing Date:	13-AUG-2014
Time Stamp:	15:00:05
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
------------------------	----

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		32865-216897.pdf	71507 1e256aa9937bd6ca3c63ff0e6d17937dbf3dda97	yes	11

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Miscellaneous Incoming Letter	1	2
	Preliminary Amendment	3	11
Warnings:			
Information:			
Total Files Size (in bytes):		71507	
<p>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.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> 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.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> 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>			

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Dieter MANSTEIN
Serial No. : 14/458,644
Filed : August 13, 2014
For : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Examiner : To be assigned
Art Unit : To be assigned
Confirmation No. : 1016

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

Commissioner:

**RESPONSE TO DECISION DISMISSING
REQUEST FOR PRIORITIZED EXAMINATION (TRACK 1)**

In response to the Decision Dismissing Request for Prioritized Examination (Track 1) mailed on August 26, 2014, submitted herewith is another Preliminary Amendment. This further Preliminary Amendment cancels previously-submitted claim 27, without prejudice. The cancellation of claim 27 complies with 37 C.F.R. § 1.121, which will obviate the reasons provided in the Decision Dismissing Request for Prioritized Examination (Track I), i.e., to have 30 or less claims in the application. Thus, for at least such reasons, it is respectfully asserted that the Request for Prioritized Examination (Track I) be granted.

Applicant does not believe that any fee is due in connection with the submission of this paper. However, if any fee is due, or if any overpayment has been made, the Commissioner is authorized to charge any such fee or credit any overpayment, to Andrews Kurth LLP Deposit Account No. 50-2849.

Respectfully submitted,

Dated: September 17, 2014

By:



Gary Abelev
Patent Office Reg. No. 40,479

ANDREWS KURTH L.L.P.
540 Lexington Avenue
New York, New York 10017

Attorney(s) for Applicant(s)
(212) 850-2881

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POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:



Practitioners associated with Customer Number:

26710

OR

Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number

Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignments documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:



The address associated with Customer Number:

26710

OR


Firm or Individual Name		
Address		
City		
Country		
Telephone		Email

Assignee Name and Address: The General Hospital Corporation
 55 Fruit Street
 Boston, MA 02114

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of the practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	9/10/14
Name	Irene Abrams	Telephone	
Title	Executive Director of Innovation, for the General Hospital Corporation		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Electronic Acknowledgement Receipt

EFS ID:	20749984
Application Number:	14458644
International Application Number:	
Confirmation Number:	1016
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	120944
Filer:	Jack M. Cook/Sara Kerstein
Filer Authorized By:	Jack M. Cook
Attorney Docket Number:	036213.US.08-32865-216897
Receipt Date:	20-NOV-2014
Filing Date:	13-AUG-2014
Time Stamp:	10:45:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	mgf_1120_appdata.pdf	108624 34688498648ad100c06ae84baf8eacd8d01ee3	no	5

Warnings:

Information:

This is not an USPTO supplied ADS fillable form					
2	Assignee showing of ownership per 37 CFR 3.73.	mgh_1120_statement.pdf	76292	no	2
			ba4010799e15d0e42a9b47767e881eb36b1db67e		
Warnings:					
Information:					
3	Power of Attorney	POA_MGH.pdf	92899	no	1
			8e1c2eea2fc1e6d8115ea748b717b154af9bf60d		
Warnings:					
Information:					
Total Files Size (in bytes):			277815		
<p>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.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> 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.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> 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>					

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 Data Sheet 37 CFR 1.76		Attorney Docket Number	036213.US.08-32865-216897
		Application Number	
Title of Invention	Method and Apparatus for Dermatological Treatment and Tissue Reshaping		
<p>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.</p> <p>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.</p>			

Secrecy Order 37 CFR 5.2

<input type="checkbox"/>	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
--------------------------	---

Inventor Information:

Inventor 1					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name		Suffix	
	Dieter		Manstein			
Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service						
City	Coral Gables	State/Province	FL	Country of Residence	US	
Mailing Address of Inventor:						
Address 1		287 Carabela Court				
Address 2						
City	Coral Gables	State/Province	FL			
Postal Code	33143	Country	US			
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.						Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).	
<input type="checkbox"/> An Address is being provided for the correspondence Information of this application.	
Customer Number	420044 26710
Email Address	PTONY@andrewskurth.com Add Email Remove Email

Application Information:

Title of the Invention	Method and Apparatus for Dermatological Treatment and Tissue Reshaping		
Attorney Docket Number	036213.US.08-32865-216897	Small Entity Status Claimed <input type="checkbox"/>	
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	4	Suggested Figure for Publication (if any)	
Filing By Reference :			

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	036213.US.08-32865-216897
		Application Number	
Title of Invention	Method and Apparatus for Dermatological Treatment and Tissue Reshaping		

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

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

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

Publication Information:

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

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

Representative Information:

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

Please Select One:	<input checked="" type="radio"/> Customer Number	<input type="radio"/> US Patent Practitioner	<input type="radio"/> Limited Recognition (37 CFR 11.9)
Customer Number	120944 <u>26710</u>		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this 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 blank.

Prior Application Status	Pending	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
<u>14458644</u>	Continuation of	12914201	2010-10-28		
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12914201	Division of	11098030	2005-04-01	7824394	2010-11-02
Prior Application Status	Expired	Remove			

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	036213.US.08-32865-216897
		Application Number	
Title of Invention	Method and Apparatus for Dermatological Treatment and Tissue Reshaping		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
11098030	Claims benefit of provisional	60558476	2004-04-01
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			

Foreign Priority Information:

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

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

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

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

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

Authorization to Permit Access:

<input checked="" type="checkbox"/> Authorization to Permit Access to the Instant Application by the Participating Offices
--

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	036213.US.08-32865-216897
		Application Number	
Title of Invention	Method and Apparatus for Dermatological Treatment and Tissue Reshaping		

If 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 World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.			
Applicant 1			
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.			
<input type="button" value="Clear"/>			
<input checked="" type="radio"/> Assignee		<input type="radio"/> Legal Representative under 35 U.S.C. 117	
<input type="radio"/> Person to whom the inventor is obligated to assign.		<input type="radio"/> Person who shows sufficient proprietary interest	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:			
Name of the Deceased or Legally Incapacitated Inventor : <input type="text"/>			
If the Applicant is an Organization check here. <input checked="" type="checkbox"/>			
Organization Name	<u>The General Hospital Corporation</u>		
Mailing Address Information For Applicant:			
Address 1	<u>55 Fruit Street</u>		
Address 2			
City	<u>Boston</u>	State/Province	<u>MA</u>
Country	<u>US</u>	Postal Code	<u>02114</u>
Phone Number		Fax Number	

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	036213.US.08-32865-216897
		Application Number	
Title of Invention	Method and Apparatus for Dermatological Treatment and Tissue Reshaping		
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.			
Assignee 1			
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.			
If the Assignee or Non-Applicant Assignee is an Organization check here. <input checked="" type="checkbox"/>			
Organization Name	The General Hospital Corporation		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1	55 Fruit Street		
Address 2			
City	Boston	State/Province	MA
Country ⁱ	US	Postal Code	02114
Phone Number		Fax Number	
Email Address			
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.			

Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications.					
Signature	/Jack M. Cook/			Date (YYYY-MM-DD)	2014-11-20
First Name	Jack M.	Last Name	Cook	Registration Number	56098
Additional Signature may be generated within this form by selecting the Add button.					

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STATEMENT UNDER 37 CFR 3.73(c)Applicant/Patent Owner: The General Hospital CorporationApplication No./Patent No.: 14/458,644 Filed/Issue Date: August 13, 2014Titled: Method and Apparatus for Dermatological Treatment and Tissue ReshapingThe General Hospital Corporation, a corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☒ The assignee of the entire right, title, and interest.
2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):
- ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.
- ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (e.g., bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 033526, Frame 0515, or for which a copy thereof is attached.
- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:
1. From: _____ To: _____
- The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.
2. From: _____ To: _____
- The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

[Page 1 of 2]

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. 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.

QB 125141.01120

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STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.☐ Additional documents in the chain of title are listed on a supplemental sheet(s).☐ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Jack M. Cook/

Signature

Jack M. Cook

Printed or Typed Name

November 20, 2014

Date

Reg. No. 56,098

Title or Registration Number



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
14/458,644	08/13/2014	3769	2480	036213.US.08-32865-216897	31	3

CONFIRMATION NO. 1016

REPLACEMENT FILING RECEIPT



26710
QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

Date Mailed: 12/02/2014

Receipt is acknowledged of this non-provisional 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 APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Dieter Manstein, Coral Gables, FL;

Applicant(s)

The General Hospital Corporation, Boston, MA

Assignment For Published Patent Application

The General Hospital Corporation, Boston, MA

Power of Attorney: The patent practitioners associated with Customer Number 26710

Domestic Priority data as claimed by applicant

This application is a CON of 12/914,201 10/28/2010
which is a DIV of 11/098,030 04/01/2005 PAT 7824394

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 08/21/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/458,644**

Projected Publication Date: 12/04/2014

Non-Publication Request: No

Early Publication Request: No
Title

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

Preliminary Class

606

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

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/458,644	08/13/2014	Dieter Manstein	036213.US.08-32865-216897

CONFIRMATION NO. 1016

POA ACCEPTANCE LETTER



26710
QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

Date Mailed: 12/02/2014

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 11/20/2014.

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.

/zabaha/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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14/458,644	08/13/2014	Dieter Manstein	036213.US.08-32865-216897

CONFIRMATION NO. 1016

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Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

PUBLICATION NOTICE



OC000000072192760

Title:METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

Publication No.US-2014-0358069-A1

Publication Date:12/04/2014

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

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In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <http://pair.uspto.gov/>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

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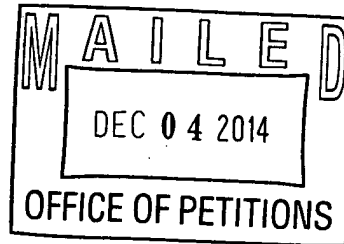
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SUITE 2350
MILWAUKEE WI 53202-4426



Doc Code: TRACK1.GRANT

**Decision Granting Request for
Prioritized Examination
(Track I or After RCE)**

Application No.: 14/458,644

The petition, filed September 17, 2014, requesting reconsideration of the decision, mailed August 26, 2014, which initially dismissed the Request for Prioritized Examination, Track 1, is **GRANTED**.

1. THE REQUEST FILED August 13, 2014 IS **GRANTED**.

The above-identified application has met the requirements for prioritized examination

- A. ☒ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination.** The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

- A. filing a **petition for extension of time** to extend the time period for filing a reply;
B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;
C. filing a **request for continued examination**;
D. filing a notice of appeal;
E. filing a request for suspension of action;
F. mailing of a notice of allowance;
G. mailing of a final Office action;
H. completion of examination as defined in 37 CFR 41.102; or
I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to Brian W. Brown at 571-272-5338.

/Brian W. Brown/
[Signature]

Petitions Examiner, Office of Petitions
(Title)

PATENT
Customer No. 26,710
Application No.: 14/458,644
Attorney Docket Nos. 125141.01120.MGH02587

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Dieter MANSTEIN) Group Art Unit: 3769
)
Application No.: 14/458,644) Examiner: Ahmed M. Farah
)
Filed: August 13, 2014)
)
For: METHOD AND APPARATUS FOR)
DERMATOLOGICAL)
TREATMENT AND TISSUE)
RESHAPING)

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

Commissioner:

PRELIMINARY AMENDMENT

Please amend the above-identified patent application as follows:

Amendments to the Claims begin on page 2.

Remarks follow the amendment section.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1-46. (Cancelled).

47. (New) A skin treatment device comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured to receive radio frequency (RF) energy from a RF energy source; and

a control module for regulating delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein, wherein the regulation of the delivery of the RF energy is configured to stimulate formation of new collagen in the skin.

48. (New) The device of claim 47, wherein the plurality of needles are associated with each other in groups of bipolar pairs, wherein the control module is configured to control the delivery of the RF energy to bipolar pairs to cause areas of non-ablative damage within the dermal layer, and wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles.

49. (New) The device of claim 47, wherein at least one of the plurality of needles is a monopolar needle.

50. (New) The device of claim 47, wherein further comprising selecting an application-specific setting for the energy source to cause the energy source to vary at least one of a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting.

51. (New) The device of claim 47, wherein at least two of the plurality of needles have differing lengths.

52. (New) The device of claim 47, further comprising a cooler for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.

53. (New) The device of claim 47, wherein at least one of the plurality of needles is a hollow needle, and further comprising a delivery mechanism for delivering an analgesic via the hollow needle to tissue surrounding a tip of the hollow needle.

54. (New) The device of claim 47, further comprising detector for detecting a presence of a nerve near a tip of at least one of the plurality of needles.

55. (New) The device of claim 47, further comprising a spacer having holes through which the needles are configured to move.

56. (New) The device of claim 47, wherein the control module is configured to regulate RF energy delivery in order to induce damaged regions surrounding each tip of each of the plurality of needles, with substantially undamaged regions between the damaged regions.

57. (New) The device of claim 47, wherein each of the needles has a tip, and wherein the control module is configured to cause at least two adjacent regions of thermal damage, with a small localized area of thermal damage surrounding each tip.

58. (New) The device of claim 47, further comprising a vibrator for vibrating at least one of the plurality of needles.

59. (New) The device of claim 58, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

60. (New) The device of claim 58, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm .

61. (New) A skin treatment device, comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured to receive radio frequency (RF) energy from a RF energy source; and

a control module for regulating delivery of the RF energy from the RF energy source to the plurality of needles to cause a pattern of fractional damage to be produced in the dermal layer in a vicinity of the tips of the needles,

wherein regulating the delivery of the RF energy is controlled to cause a pattern of regions of thermal damage within the dermal layer, and wherein at least two adjacent regions of thermal damage have an undamaged region therebetween.

62. (New) The device of claim 61, wherein the control module is configured to cause necrosis in the dermal layer.

63. (New) The device of claim 61, further comprising a vibrator for vibrating at least one of the plurality of needles.

64. (New) The device of claim 63, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

65. (New) The device of claim 63, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm .

66. (New) A skin treatment device comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base and arranged in a group of bipolar pairs, the plurality of needles being further configured to receive radio frequency (RF) energy from a RF energy source; and

a control module for regulating delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,

wherein the pattern of fractional damage includes damaged regions between tips of needles of the bipolar pairs, and substantially undamaged regions between bipolar pairs of needles in the group.

67. (New) The device of claim 66, wherein the control module is configured to cause the damaged regions to be elongated between the needles of the bipolar pairs.

68. (New) The device of claim 66, wherein the control module is configured to cause necrosis.

69. (New) The device of claim 66, further comprising a vibrator for vibrating at least one of the plurality of needles.

70. (New) The device of claim 69, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

71. (New) The device of claim 69, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm .

72. (New) A skin treatment device comprising:

a housing configured to support a plurality of monopolar needles arranged for insertion into a dermal layer of skin, the plurality of monopolar needles being attached to a base and configured to receive radio frequency (RF) energy from a RF energy source; and

a control module for regulating delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,

wherein the pattern of fractional damage includes damaged regions in a vicinity of each tip of each of the plurality of monopolar needles, and substantially undamaged regions between the damaged regions.

73. (New) The device of claim 72, wherein the control module is configured to cause necrosis.

74. (New) The device of claim 72, further comprising a vibrator for vibrating at least one of the plurality of needles.

75. (New) The device of claim 74, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

76. (New) The device of claim 74, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm .

REMARKS

By this amendment, Applicant cancels claims 16-46, and adds new claims 47-76. No new matter is added. Claims 47-76 remain pending, of which claims 47, 61, 66, and 72 are independent. To maintain Track 1 priority status, this application as amended contains no more than four independent claims and no more than thirty total claims.

Please grant any extensions of time required to enter this paper and charge any additional required fees to Deposit Account 170055.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: /Kai Rajan/
Kai Rajan
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and

QUARLES & BRADY, L.L.P.

By: /Jack M. Cook
Jack M. Cook
Reg. No. 56,098
(414) 277-5405
on behalf of the Patent Owner

Dated: May 29, 2015

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14458644
	Filing Date		2014-08-13
	First Named Inventor	Dieter Manstein	
	Art Unit	3769	
	Examiner Name	Ahmed M. Farah	
	Attorney Docket Number	125141.01120.MGH02587	

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5284154		1994-02-08	Raymond et al.	
	2	5928158		1999-07-27	Aristides	
	3	7824394		2010-11-02	Manstein	
	4	8608737		2013-12-17	Mehta et al.	
	5	8882753		2014-11-11	Mehta et al.	
	6	6905497		2005-06-14	Truckai et al.	

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U.S.PATENT APPLICATION PUBLICATIONS						
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	Art Unit	3769		
	Examiner Name	Ahmed M. Farah		
	Attorney Docket Number	125141.01120.MGH02587		

	1	20020091377	A1	2002-07-11	Anderson et al.	
	2	20030144652		2003-07-31	Baker et al.	

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	1	2000342617	JP		2000-12-12	Hattori Heating Kogyo KK		<input type="checkbox"/>
	2	2001510702	JP		2001-08-07			<input type="checkbox"/>
	3	WO 0137728	WO		2001-05-31	Nuvasive, Inc.		<input type="checkbox"/>
	4	WO 02102265	WO		2002-12-27	Medizinische Hochschule Hannover		<input type="checkbox"/>

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(Not for submission under 37 CFR 1.99)

Application Number	14458644
Filing Date	2014-08-13
First Named Inventor	Dieter Manstein
Art Unit	3769
Examiner Name	Ahmed M. Farah
Attorney Docket Number	125141.01120.MGH02587

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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

Application Number	14458644
Filing Date	2014-08-13
First Named Inventor	Dieter Manstein
Art Unit	3769
Examiner Name	Ahmed M. Farah
Attorney Docket Number	125141.01120.MGH02587

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jack M. Cook/	Date (YYYY-MM-DD)	2015-05-29
Name/Print	Jack M. Cook	Registration Number	56098

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PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum
Internationales Büro



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17. Juni 2002 (17.06.2002)

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(71) Anmelder (für alle Bestimmungsstaaten mit Ausnahme von
US): **MEDIZINISCHE HOCHSCHULE HANNOVER**
[DE/DE]; Carl-Neuberg-Strasse 1, 30625 Hannover (DE).

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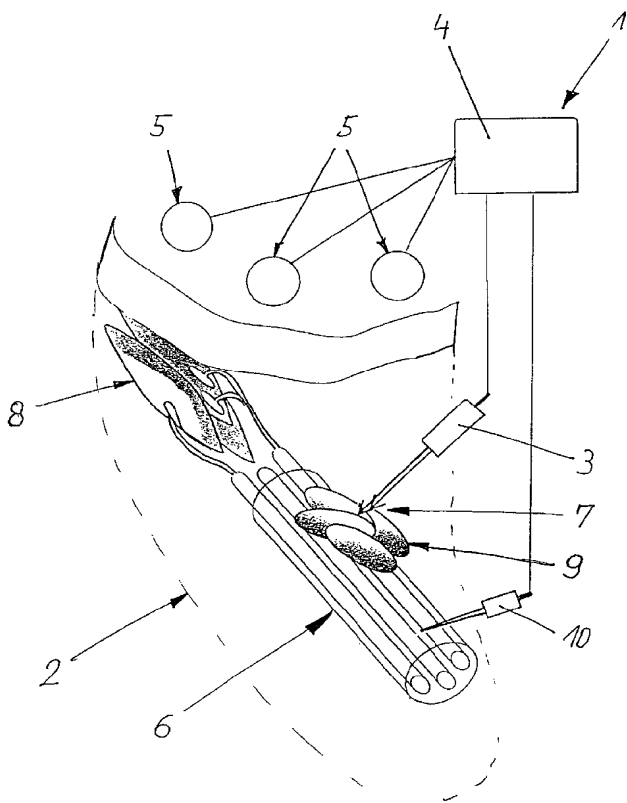
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(81) Bestimmungsstaaten (national): AU, JP, US.

[Fortsetzung auf der nächsten Seite]

(54) Title: DEVICE FOR TREATING THE HUMAN OR ANIMAL BODY

(54) Bezeichnung: VORRICHTUNG ZUR BEHANDLUNG DES MENSCHLICHEN ODER TIERISCHEN KÖRPERS



(57) Abstract: The invention relates to a device (1) for treating the human or animal body (2) comprising an actuator (3) for performing surgery in the body (2). This actuator (3), which is provided in the form of an operation laser, can be controlled by means of control unit (4) with regard to essential parameters, which are based on body-inherent signals, particularly stimulation signals that are triggered by the device (1) during surgery. A neuronal or muscular sensor (5) that, together with the transmission paths of the body-inherent stimulation signals, forms the required control loop of the device (1) serves to detect stimulations. The stimulation signals that can be extensively drawn upon in such a manner enable a control of the actuator that, in turn, makes it possible to largely prevent injury to the patient. The device (1) is thus distinctly superior to purely visual-monitored systems.

(57) Zusammenfassung: Die Erfindung betrifft eine Vorrichtung (1) zur Behandlung des menschlichen oder tierischen Körpers (2), die einen Aktor (3) für den operativen Eingriff in den Körper (2) hat. Dieser insbesondere als Operationslaser ausgeführte Aktor (3) ist mittels einer Steuereinheit (4) hinsichtlich wesentlicher Parameter steuerbar, die auf körpereigenen Signalen, insbesondere Reizsignalen, basieren, die ihrerseits durch die Vorrichtung (1) bei dem Eingriff ausgelöst werden. Zur Reizerfassung dient dabei ein neuronaler oder muskulärer Sensor (5), der gemeinsam mit den Übertragungswegen der körpereigenen Reizsignale den erforderlichen Regelkreis der Vorrichtung (1) bildet. Die so umfassend heranziehbaren Reizsignale ermöglichen so eine Ansteuerung des Aktors, durch die eine Schädigung des Patienten weitgehend vermeidbar ist. Die

Vorrichtung (1) ist damit rein visuell überwachten Systemen deutlich überlegen.



(84) Bestimmungsstaaten (regional): europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

Veröffentlicht:

- *mit internationalem Recherchenbericht*
- *vor Ablauf der für Änderungen der Ansprüche geltenden Frist; Veröffentlichung wird wiederholt, falls Änderungen eintreffen*

Vorrichtung zur Behandlung des menschlichen oder tierischen Körpers

Die Erfindung betrifft eine Vorrichtung zur Behandlung des menschlichen oder tierischen Körpers, mit einem für den Eingriff in den Körper bestimmten Aktor, dessen Ansteuerung mittels einer Steuereinheit hinsichtlich wesentlicher Parameter festlegbar ist.

- 5 Eine solche Vorrichtung ist beispielsweise durch die WO 99/38 444 A1 bekannt, die bereits ein Kontrollsystem für einen Operationslaser beschreibt. Der Operateur wird dabei durch ein Informationssystem über die wesentlichen Parameter informiert, so daß dieser unverzüglich reagieren kann, falls ein Grenzwert überschritten wird. Hierzu sind Bedienelemente an einem Handstück des Operationslasers angeordnet, so daß weiteres Hilfspersonal zur Überwa-
- 10 chung und Steuerung des Operationslasers nicht erforderlich ist. Weiterhin wird bereits beschrieben, wie die Parameter des Lasers in eine Schutzbrille des Operateurs eingeblendet werden können.

- Als nachteilig bei diesem Stand der Technik hat sich in der Praxis erwiesen, daß der Operationsbereich oftmals durch den Operateur nur eingeschränkt visuell überwacht werden kann
- 15 und dadurch der Eingriff in den Körper einem Risiko unterliegt. Dabei erweist sich auch der geringe zur Verfügung stehende Platz als hinderlich.

- Es ist auch bereits durch offenkundige Vorbenutzung bekannt, den Operationsbereich mittels
- 20 einer Optik oder einer speziellen Kamera zu überwachen und dem Operateur auf einem Bildschirm darzustellen. Jedoch kann insbesondere bei einer Entfernung eines Tumors von einem Nerv eine Grenzfläche zwischen dem Nerv und dem Tumor auch bei Vergrößerung nicht mit hinreichender Genauigkeit visuell bestimmt werden. Daher führen mikrochirurgische Eingriffe an Nerven, insbesondere die Entfernung von intrakraniellen Nerventumoren, bei
- 25 bekannten chirurgischen Verfahren aufgrund der mechanischen Belastung häufig zu einer

Schädigung des Nervs. Auch eine rein visuelle Beurteilung unter Nutzung eines Operationsmikroskops ermöglicht keine ausreichende Kontrolle. Den betroffenen Patienten kann durch motorische oder sensorische Ausfälle ein erheblicher Leidensdruck entstehen.

5 Der Erfindung liegt die Aufgabe zugrunde, eine Vorrichtung zur Behandlung des menschlichen oder tierischen Körpers zu schaffen, durch die eine Schädigung des Körpers im wesentlichen ausgeschlossen ist. Insbesondere soll die zuverlässige Entfernung von Tumoren sichergestellt und das damit verbundene Risiko einer chirurgischen Schädigung durch eine gezielte Unterstützung des Operateurs vermindert werden.

10 Diese Aufgabe wird erfindungsgemäß mit einer Vorrichtung gemäß den Merkmalen des Patentanspruchs 1 gelöst. Die Unteransprüche betreffen besonders zweckmäßige Weiterbildungen der Erfindung.

15 Erfindungsgemäß ist also eine Vorrichtung vorgesehen, bei der mittels eines mit der Steuereinheit verbundenen Sensors wesentliche, durch die Vorrichtung auslösbare körpereigene Signale, insbesondere Reizsignale, bestimmbar sind, auf deren Grundlage die Ansteuerung des Aktors festlegbar ist. Auf diese Weise wird der Körper bzw. die körpereigenen Signale in den Regelkreis einbezogen, so daß eine mögliche Schädigung des Körpers weitestgehend
20 ausgeschlossen werden kann. Dabei wird durch die Vorrichtung, insbesondere durch den Aktor, beim Eingriff ein Reizsignal ausgelöst, welches mittels des Sensors erfaßbar ist, wodurch auch unsichtbare Schädigungen rechtzeitig erkannt und damit verhindert werden können. Zugleich kann das körpereigene Signal mittels der Steuereinheit einer Bewertung unterzogen werden, um so einen Grenzwert ermitteln zu können. Aufgrund dieser unmittelbaren
25 Umsetzung der erfaßten Signale in die Ansteuerung des Aktors wird der Operateur von seiner Überwachungsfunktion wesentlich entlastet, so daß Bedienungsfehler weitgehend verhindert werden können.

30 Eine besonders vorteilhafte Ausführungsform der Erfindung wird auch dadurch geschaffen, daß mittels der Steuereinheit die Ansteuerung des Aktors derart festlegbar ist, daß eine Schädigung des Körpers weitgehend vermeidbar ist. Hierdurch kann ein unbeabsichtigter Eingriff sowie eine mögliche Schädigung des Patienten sowohl durch den unmittelbaren Eingriff mittels des Aktors, als auch durch unvorhergesehene Nebenwirkungen vermieden werden. Dabei geht die Kontrolle weit über den nach dem Stand der Technik bekannten unmittelbaren Operationsbereich hinaus und ermöglicht dadurch einen Eingriff mit bisher unerreichbarem Risiko.
35

Dabei ist es besonders praxisnah, wenn mittels des Sensors ein körpereigenes Aktionspotential des Körpers erfaßbar ist, welches bei überschwelliger, beispielsweise mechanischer, thermischer oder pharmakologischer Belastung erzeugt wird. Dabei kann die synchrone Überlagerung als Summenaktionspotential erfaßt werden.

- 5

Eine andere besonders zweckmäßig Ausgestaltung der vorliegenden Erfindung wird auch dadurch erreicht, daß mittels des Sensors das Reizsignal an einem Muskelgewebe erfaßbar ist. Hierdurch kann die sensorische Bestimmung des Reizsignals wesentlich vereinfacht werden. Insbesondere gestattet die am Muskelgewebe vorgenommene Reizsignalerfassung eine wesentlich vereinfachte Handhabung des Sensors. Zugleich wird der ohnehin nur eingeschränkt zugängliche Operationsbereich nicht zusätzlich durch den Sensor behindert.

10

Eine andere besonders zuverlässige Abwandlung der Vorrichtung wird auch dadurch geschaffen, daß der Sensor zur Erfassung eines Reizsignals an einem Nerv ausgeführt ist. Hierdurch kann die Reizsignalerfassung in unmittelbarer räumlicher Nähe des Operationsbereiches vorgenommen werden, so daß eine mögliche Verzögerung des Übertragungsverhaltens vermieden wird. Zudem kann dadurch die Bestimmung des Reizsignals auch bei unbekannter Zuordnung des Reizsignals vorgenommen werden. Es ist hierbei ferner auch die Reizsignalüberwachung erregbarer oder sensorischer Zellen oder Zellverbände möglich.

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Dabei ist es besonders erfolgversprechend, wenn der Sensor zur flächendeckenden Reizerfassung ausgeführt ist, um so auch eine mögliche Schädigung einer einzelnen Nervenzelle eines Nerven mit vergleichsweise geringem Aufwand erfassen zu können.

25

Besonders erfolgversprechend ist auch eine Abwandlung der erfindungsgemäßen Vorrichtung, bei welcher der Aktor ein Operationslaser, insbesondere Er:YAG-Laser, ist. Dieser ermöglicht einen berührungslosen Eingriff in den Körper, so daß die Operation im wesentlichen frei von mechanischen Belastungen durchgeführt werden kann. Der Einsatz des Er:YAG-Lasers verringert dabei die thermische Schädigung des Gewebes auf ein vertretbares Maß.

30

Hierzu ist es besonders zweckmäßig, wenn als wesentliche Parameter die Pulsenergie, die Energiedichte oder die Repetitionsrate festlegbar sind, wodurch die wesentlichen Einflußgrößen des Operationslasers auf den Körper überwacht werden und entsprechend festlegbar sind.

35

Dabei ist es auch besonders praxisnah, wenn mittels der Steuereinheit der durch die Vor-

Schädigung des Körpers zu vermindern. Hierzu werden mittels der Steuereinheit die wesentlichen Parameter der Ansteuerung festgelegt.

Eine besonders zuverlässige Weiterbildung der Erfindung ist auch dadurch geschaffen, daß
5 mittels des Sensors ein von einem Reizapplikator der Vorrichtung erzeugbares Reizsignal erfaßbar ist. Hierbei kann eine Funktionstrennung zwischen dem Aktor, der für den operativen Eingriff an dem Körper vorgesehen ist, und dem Reizapplikator, der zu einem körpereigenen Reizsignal führt, ohne hingegen dadurch bereits zu einer Schädigung des Körpers zu führen, vorgenommen werden. Ein mögliches zeitverzögertes Übertragungsverhalten kann
10 dadurch nicht zu einer Schädigung des Körpers führen, weil der Reizapplikator nicht bereits zu einer Schädigung führen kann. Der Reizapplikator kann hierzu beispielsweise ein in seiner Leistung erheblich verringerter, schädigungsfreier Laser sein.

Es ist weiterhin besonders zweckmäßig, wenn mittels der Steuereinheit eine Verzögerung
15 zwischen einer Signalerzeugung und deren Erfassung mittels des Sensors erfaßbar ist. Hierdurch kann das Übertragungsverhalten des körpereigenen Reizsignals in die Ansteuerung des Aktors einbezogen werden. Insbesondere wird der operative Fortschritt des Eingriffs auf dieser Basis derart gering bemessen, daß eine Schädigung während der Dauer der Verzögerung ausgeschlossen ist.

Dabei ist es auch besonders hilfreich, wenn mittels der Steuereinheit auf der Basis der ermittelten Abhängigkeit zwischen dem Eingriff und dem durch den Eingriff erzeugten Signal ein Grenzwert für wesentliche Parameter bestimmbar ist. Hierbei wird das Reizsignal einer Bewertung, beispielsweise durch Zuordnung einer Rangstufe, unterzogen, auf deren Basis
25 anschließend der Grenzwert ermittelt wird. Hierzu können zusätzlich auch Erfahrungswerte herangezogen werden, die so eine individuelle Abstimmung des Eingriffs auf den jeweiligen Patienten ermöglichen.

Besonders vorteilhaft ist es auch, wenn der Sensor als Elektrode oder zur Bestimmung eines
30 Magnetfeldes ausgeführt ist und dadurch zur flächigen Erfassung keinen zusätzlichen operativen Eingriff an dem Körper erfordert.

Eine andere erfolgversprechende Ausgestaltung der Erfindung wird dann erreicht, wenn der Sensor zur optischen Erfassung eines unter dem Einfluß der Reizsignale veränderlichen
35 Kontrastmittels ausgeführt ist. Hierdurch wird eine schnelle und zuverlässige Erfassung der Reizsignale erreicht, wobei zudem mögliche Handhabungsfehler beim Anbringen des Sen-

Die Erfindung läßt verschiedene Ausführungsformen zu. Zur weiteren Verdeutlichung ihres Grundprinzips ist eine davon in der Zeichnung dargestellt und wird nachfolgend beschrieben. Diese zeigt in einer schematischen Darstellung eine erfindungsgemäße Vorrichtung 1 zur . 5 Behandlung des menschlichen oder tierischen Körpers 2 mittels eines als Operationslaser ausgeführten Aktors 3. Die Ansteuerung des Aktors 3 erfolgt mittels einer Steuereinheit 4, durch welche die wesentlichen Parameter zur Ansteuerung des Aktors 3 festlegbar sind. Der insbesondere manipulatorgeführte Aktor 3 wird in Echtzeit mit Hilfe abgeleiteter evozierter Aktionspotentiale geregelt, die mittels eines Sensors 5 erfaßt werden. Der Sensor 5 nutzt 10 dabei für die Erfassung der Reizsignale eine einen Nerv 6 umfassende Signalstrecke, so daß eine weitere Sensorik in einem Operationsbereich 7 entfällt. Die Ableitung des Aktionspotentials kann dabei direkt von dem Nerv 6 oder von einem Zielorgan, beispielsweise Muskelgewebe 8, erfolgen. Von wesentlicher Bedeutung ist die Abstimmung der Parameter des Aktors 3. Die lokale Begrenzung der Reizerzeugung führt zu relativ kleinen und örtlich diskret 15 auftretenden Aktionspotentialen. Die zuverlässige Detektion der Reizsignale erfolgt daher unter Verwendung einer quasi flächendeckenden, elektrophysiologischen Überwachung mit insbesondere hoher Elektrodendichte und einer hohen Sensitivität und Störunterdrückung der gesamten elektrophysiologischen Meßkette. Die Parameter der Ansteuerung, insbesondere die Pulsenergie, die Energiedichte sowie die Repetitionsrate, sind derart festgelegt, daß 20 jeder Einzelpuls des Lasers in Echtzeit elektrophysiologisch bewertet und zur Regelung des Lasers Verwendung finden kann. Die Bewertung der Reizsituation entscheidet, ob ein weiterer Puls zugelassen werden darf. Im Sinne einer praktikablen Arbeitsgeschwindigkeit werden Pulszüge mit einer hohen Repetitionsrate verwendet. Limitierender Faktor ist hier der akkumulierende Wärmeeintrag und die Verzögerung in der Regelstrecke. Auf diese Weise kann 25 eine zuverlässige Grenzflächenunterscheidung des Nerven 6 gegenüber einem zu entfernden Tumor 9 realisiert werden, so daß bei dem Eingriff eine Schädigung des Patienten durch den Aktor 3 weitgehend vermieden wird.

Neben der Anwendung der Vorrichtung mit Bezug auf Nerven 6 ist auch eine gezielte und 30 definierte Reizgenerierung erregbarer Zellen und Zellverbände bzw. die Modulation spontaner und durch einen zusätzlichen Reizapplikator 10 primär evozierter elektrischer Erregung mit physikalischen Methoden realisierbar. Durch die Registrierung und Bewertung der erzeugten bzw. modulierten elektrophysiologischen Signale wird die Gefährdung der Zellen oder der Zellverbände sowie der Einfluß des Aktors 3 beschrieben. Bei bekannten Wechselwirkungen zwischen dem Aktor 3 und dessen applizierter Energieform oder Energiedosis 35 und dem Wirkort kann der Wirkprozeß mit Hilfe der bewerteten Signale derart beeinflusst

zu der unmittelbaren Reizsignalerzeugung durch die Einwirkung des Lasers können auch zur in-vitro-Manipulation an Zellverbänden intra- und extrazelluläre neuronale Aktionspotentiale sowie Summenaktionspotentiale bewertet und zur Prozeßregelung verwendet werden. Am intakten Organismus werden vorzugsweise intra- und extrazelluläre muskuläre Summenaktionspotentiale abgeleitet und zur Regelung verwendet. Der Aktor 3 kann abweichend von der beschriebenen Konfiguration auch auf anderen physikalischen Wirkprinzipien beruhen, wobei entsprechend auszuwählende Sensoren 5 zum Einsatz kommen können.

Patentansprüche

1. Vorrichtung (1) zur Behandlung des menschlichen oder tierischen Körpers (2), mit einem für den Eingriff in den Körper (2) bestimmten Aktor (3), dessen Ansteuerung mittels einer Steuereinheit (4) hinsichtlich wesentlicher Parameter festlegbar ist, dadurch gekennzeichnet,
5 daß mittels eines mit der Steuereinheit (4) verbundenen Sensors (5) wesentliche, durch die Vorrichtung (1) auslösbare körpereigene Signale, insbesondere Reizsignale, bestimmbar sind, auf deren Grundlage die Ansteuerung des Aktors (3) festlegbar ist.
2. Vorrichtung (1) nach Anspruch 1, dadurch gekennzeichnet, daß mittels der Steuereinheit
10 (4) die Ansteuerung des Aktors (3) derart festlegbar ist, daß eine Schädigung des Körpers (2) weitgehend vermeidbar ist.
3. Vorrichtung (1) nach den Ansprüchen 1 oder 2, dadurch gekennzeichnet, daß mittels des Sensors (5) ein körpereigenes Aktionspotential des Körpers (2) erfaßbar ist.
15
4. Vorrichtung (1) nach zumindest einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß mittels des Sensors (5) das Reizsignal an einem Muskelgewebe (8) erfaßbar ist.
- 20 5. Vorrichtung (1) nach zumindest einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß der Sensor (5) zur Erfassung eines Reizsignals an einem Nerv (6) ausgeführt ist.
- 25 6. Vorrichtung (1) nach zumindest einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß der Sensor (5) zur flächendeckenden Reizerfassung ausgeführt ist.

7. Vorrichtung (1) nach zumindest einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß der Aktor (3) ein Operationslaser, insbesondere Er:YAG-Laser, ist.

8. Vorrichtung (1) nach Anspruch 7, dadurch gekennzeichnet, daß als wesentliche Parameter die Pulsenergie, die Energiedichte oder die Repetitionsrate festlegbar sind.

9. Vorrichtung (1) nach zumindest einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß mittels der Steuereinheit (4) der durch die Vorrichtung (1) auf den Körper (2) wirkende Wärmeeintrag erfaßbar ist.

10. Vorrichtung (1) nach zumindest einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß mittels des Sensors (5) ein von einem Reizapplikator (10) der Vorrichtung (1) erzeugbares Reizsignal erfaßbar ist.

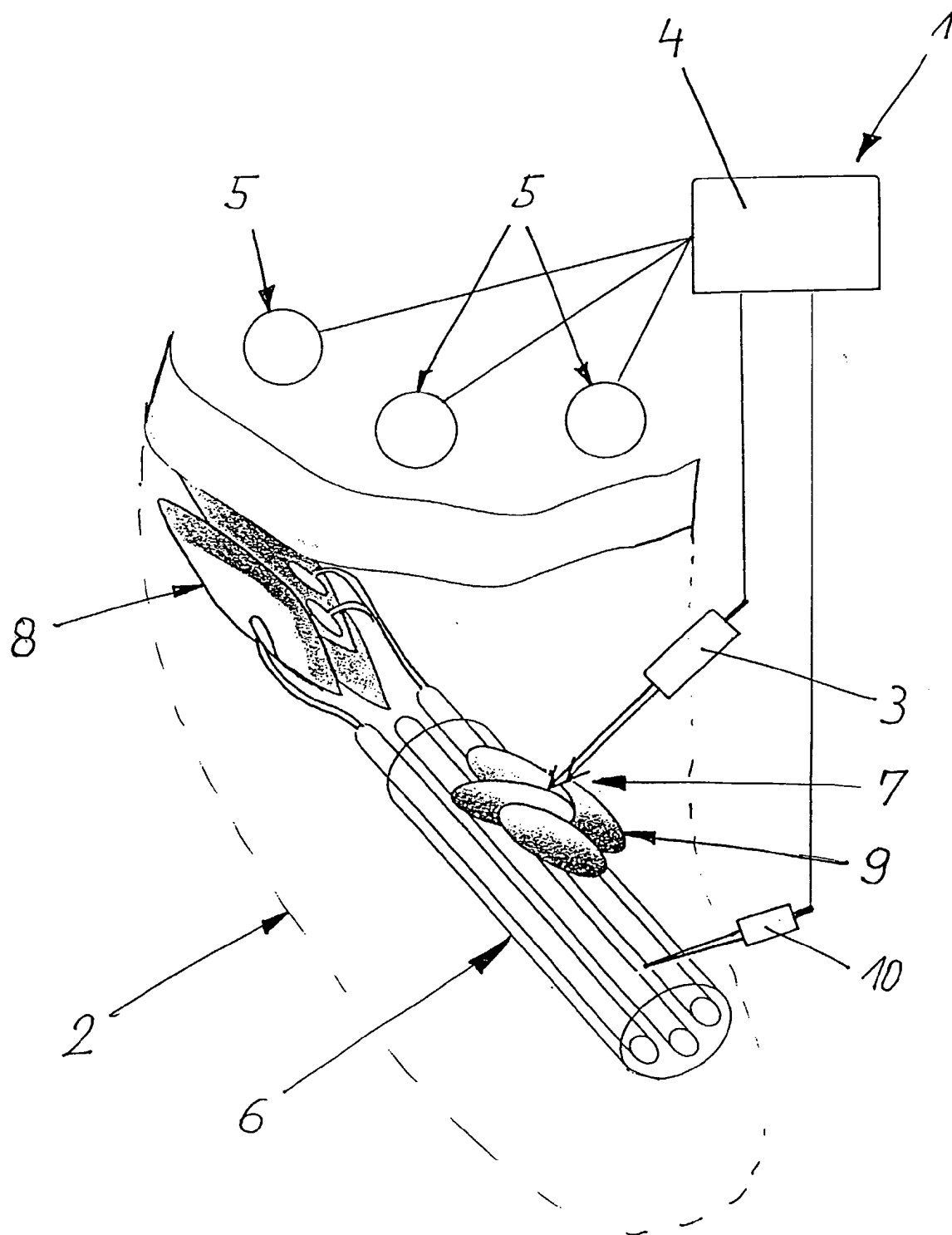
11. Vorrichtung (1) nach zumindest einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß mittels der Steuereinheit (4) eine Verzögerung zwischen einer Signalerzeugung und deren Erfassung mittels des Sensors (5) erfaßbar ist.

12. Vorrichtung (1) nach zumindest einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß mittels der Steuereinheit (4) auf der Basis der ermittelten Abhängigkeit zwischen dem Eingriff und dem durch den Eingriff erzeugten Signal ein Grenzwert für wesentliche Parameter bestimmbar ist.

13. Vorrichtung (1) nach zumindest einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß der Sensor (5) als Elektrode ausgeführt ist.

14. Vorrichtung (1) nach zumindest einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß der Sensor (5) zur Bestimmung eines Magnetfeldes ausgeführt ist.

15. Vorrichtung (1) nach zumindest einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß der Sensor (5) zur optischen Erfassung eines unter dem Einfluß der Reizsignale veränderlichen Kontrastmittels ausgeführt ist.



INTERNATIONAL SEARCH REPORT

Interr Application No
PC1, DE 02/02195

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

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☒ Further documents are listed in the continuation of box C.

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INTERNATIONAL SEARCH REPORT

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IPK 7 A61B18/20

B. RESEARCHED AREAS

IPK 7 A61B A61N

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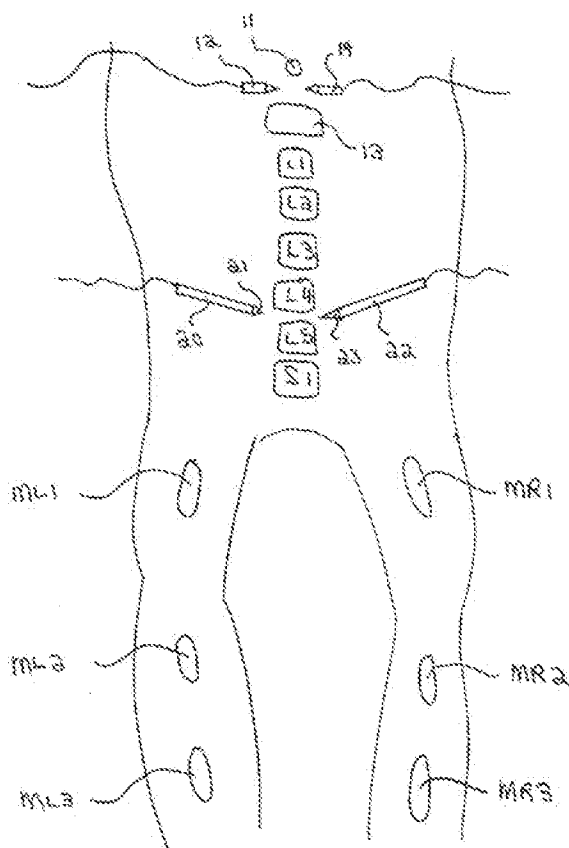
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(54) Title: ELECTROMYOGRAPHY SYSTEM



(57) Abstract: A method for detecting the presence of a nerve adjacent the distal end of at least one probe (20, 22). The method includes determining the relative neuro-muscular response onset values for a plurality of spinal nerves; emitting a stimulus pulse from the probe (20, 22); detecting neuro-muscular responses to the stimulus pulse with electrodes positioned at myotome locations (ML1, ML2, ML3, MR1, MR2, MR3) corresponding to the plurality of spinal nerves; and concluding that an electrode (21, 23) disposed on the probe (20, 22) is positioned adjacent to a first spinal nerve when the neuro-muscular response detected in the first spinal nerve is detected as a current intensity level less than or equal to a corresponding neuro-muscular response onset value in the first spinal nerve. Status electrodes (11, 12, 13, 14) are used to depolarize a portion of the cauda equina in determining the relative neuro-muscular onset values for the plurality of spinal nerves.

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ELECTROMYOGRAPHY SYSTEM

RELATED APPLICATION

The present application is a regular filing of and claims the benefit of priority from U.S.
5 Patent Application Ser. No. 60/167,416, filed November 24, 1999, the full disclosure of which is incorporated herein by reference in its entirety for all purposes.

TECHNICAL FIELD

The present invention relates to electromyography (EMG) and to systems
10 for detecting the presence of nerves during surgical procedures.

BACKGROUND OF THE INVENTION

It is important to avoid unintentionally contacting a patient's nerves when performing surgical procedures, especially when using surgical tools and procedures that
15 involve cutting or boring through tissue. Moreover, it is especially important to sense the presence of spinal nerves when performing spinal surgery, since these nerves are responsible for the control of major body functions. However, avoiding inadvertent contact with these nerves is especially difficult due to the high nerve density in the region of the spine and *cauda equina*.

20 The advent of minimally invasive surgery offers great benefits to patients through reduced tissue disruption and trauma during surgical procedures. Unfortunately, a downside of such minimally invasive surgical procedures are that they tend to offer a somewhat reduced visibility of the patient's tissues during the surgery. Accordingly, the danger of inadvertently contacting and/or severing a patient's nerves can be increased.

25 Systems exist that provide remote optical viewing of a surgical site during minimally invasive surgical procedures. However, such systems can not be used when initially penetrating into the tissue. Moreover, such optical viewing systems can not reliably be used to detect the location of small diameter peripheral nerves.

Consequently, a need exists for a system that alerts an operator that a
30 particular surgical tool, which is being minimally invasively inserted into a patient's body is in close proximity to a nerve. As such, the operator may then redirect the path of the tool to avoid inadvertent contact with the nerve. It is especially important that such a system alerts an operator that a nerve is being approached as the surgical tool is advanced

into the patient's body, and prior to contact with the nerve, such that a safety distance margin between the surgical tool and the nerve can be maintained.

A variety of antiquated, existing electrical systems are adapted to sense whether a surgical tool is positioned adjacent to a patient's nerve. Such systems have
5 proven to be particularly advantageous in positioning a hypodermic needle adjacent to a nerve such that the needle can be used to deliver anesthetic to the region of the body adjacent the nerve. Such systems rely on electrifying the needle itself such that when a nerve is approached, the electrical potential of the needle will depolarize the nerve causing the muscle fibers coupled to the nerve to contract and relax, resulting in a visible
10 muscular reaction, seen as a "twitch".

A disadvantage of such systems is that they rely on a visual indication, being seen as a "twitch" in the patient's body. During precision minimally invasive surgery, uncontrollable patient movement caused by patient twitching, is not at all desirable, since such movement may itself be injurious. In addition, such systems rely on
15 the operator to visually detect the twitch. Accordingly, such systems are quite limited, and are not particularly well adapted for use in minimally invasive surgery.

SUMMARY OF THE INVENTION

The present invention provides methods and apparatus for informing an
20 operator that a surgical tool or probe is approaching a nerve. In preferred aspects, the surgical tool or probe may be introduced into the patient in a minimally invasive cannulated approach. In alternate aspects, the surgical tool or probe comprises the minimally invasive cannula itself.

In a first aspect, the present invention provides a system for detecting the
25 presence of a nerve near a surgical tool or probe, based upon the current intensity level of a stimulus pulse applied to the surgical tool or probe. When a measurable neuro-muscular (EMG) response is detected from a stimulus pulse having a current intensity level at or below a pre-determined onset level, the nerve is considered to be near the tool or probe and thus, detected.

30 In an optional second aspect of the invention, the onset level (i.e.: the stimulus current level at which a neuro-muscular response is detected for a particular nerve) may be based on EMG responses measured for a probe at a predetermined location relative to the nerve. Specifically, onset levels may first be measured for each of a plurality of spinal nerves, (yielding an initial "baseline" set of neuro-muscular response

onset threshold levels), which are then used in the first (nerve detection) aspect of the invention. Therefore, in accordance with this optional second aspect of the invention, a system for determining relative neuro-muscular onset values (i.e.: EMG response thresholds), for a plurality of spinal nerves is also provided. Accordingly, the pre-determined onset level may be compared to the current level required to generate a measurable EMG response for a tool or probe being advanced toward one or more nerves of interest.

In alternate aspects, however, the neuro-muscular onset values which are used to accomplish the first (nerve detection) aspect of the invention are not measured for each of the patient's plurality of spinal nerves. Rather, pre-determined levels of current intensity (below which neuro-muscular responses are detected in accordance with the first aspect of the invention) can instead be directly pre-set into the system. Such levels preferably correspond to specific expected or desired onset threshold values, which may have been determined beforehand by experimentation on other patients.

In the aspect of the invention where initial "baseline" neuro-muscular onset values are determined prior to nerve detection, such onset values can optionally be used to calibrate the present nerve-detection system (which in turn operates to detect whether an minimally invasive surgical tool or probe is positioned adjacent to a spinal nerve).

It is to be understood, therefore, that the present invention is not limited to systems which first determine relative neuro-muscular onset values, and then use these neuro-muscular onset values to detect the presence of a nerve. Rather, the present invention includes an optional system to first determine relative neuro-muscular onset values and a system to detect the presence of a nerve (using the neuro-muscular onset values which have been previously determined). As such, the present invention encompasses systems which also use fixed neuro-muscular onset values (which may simply be input into the system hardware/software by the operator prior to use) when performing electromyographic monitoring of spinal nerves to detect the presence of a spinal nerve adjacent a tool or probe.

In optional aspects, the preferred method of sensing for the presence of a nerve may be continuously repeated as the probe/surgical tool is physically advanced further into the patient such that the operator is warned quickly when the probe/surgical tool is closely approaching the nerve.

In the first (nerve sensing) aspect of the invention, the present nerve-detection system comprises an electrode or electrodes positioned on the distal end of the surgical tool or probe, with an electromyographic system used to detect whether a spinal nerve is positioned adjacent to the surgical tool or probe. A conclusion is made that the surgical tool or probe is positioned adjacent to a spinal nerve when a neuro-muscular (e.g.: EMG) response to a stimulus pulse emitted by the electrode or electrodes on the surgical tool or probe is detected (at a distant myotome location, such as on the patient's legs) at or below certain neuro-muscular response onset values (i.e.: pre-determined current intensity levels) for each of the plurality of spinal nerves. The stimulus pulse itself may be emitted from a single probe, but in an optional aspect, the stimulus pulse may be emitted from separate left and right probes with the signals being multiplexed. As stated above, such pre-determined levels may be pre-input by the operator (or be pre-set into the system's hardware or software) and may thus optionally correspond to known or expected values. (For example, values as measured by experimentation on other patients).

In accordance with the optional second (neuro-muscular response onset value determination) aspect of the invention, the neuro-muscular response onset values used in nerve detection may instead be measured for the particular patient's various nerves, as follows.

Prior to attempting to detect the presence of a nerve, an EMG stimulus pulse is first used to depolarize a portion of the patient's *cauda equina*. This stimulus pulse may be carried out with a pulse passing between an epidural stimulating electrode and a corresponding skin surface return electrode, or alternatively, between a pair of electrodes disposed adjacent to the patient's spine, or alternatively, or alternatively, by a non-invasive magnetic stimulation means. It is to be understood that any suitable means for stimulating (and depolarizing a portion of) the patient's *cauda equina* can be used in this regard.

After the stimulus pulse depolarizes a portion of the patient's *cauda equina*, neuro-muscular (i.e., EMG) responses to the stimulus pulse are then detected at various myotome locations corresponding to a plurality of spinal nerves, with the current intensity level of the stimulus pulse at which each neuro-muscular response is first detected being the neuro-muscular response "onset values" for each of the plurality of spinal nerves.

It is to be understood that the term "onset" as used herein is not limited to a condition in which all of the muscle fibers in a bundle of muscle fibers associated with a

particular nerve exhibit a neuro-muscular response. Rather, an "onset" condition may comprise any pre-defined majority of the muscle fibers associated with a particular nerve exhibit a neuro-muscular response.

5 In an additional aspect of the invention, the relative neuro-muscular response onset values can be repeatedly re-determined (at automatic intervals or at intervals determined by the operator) so as to account for any changes to the response onset values caused by the surgical procedure itself. Accordingly, a further advantage of the present invention is that it permits automatic re-assessment of the nerve status, with the relative neuro-muscular response onset values for each of the plurality of spinal
10 nerves being re-determined before, during and after the surgical procedure, or repeatedly determined again and again during the surgical procedure. This optional aspect is advantageous during spinal surgery as the surgery itself may change the relative neuro-muscular response onset values for each of the plurality of nerves, such as would be caused by reducing the pressure on an exiting spinal nerve positioned between two
15 adjacent vertebrae. This periodic re-determination of the onset values can be carried out concurrently with the nerve sensing function.

Accordingly, an advantageous feature of the present invention is that it can simultaneously indicate to an operator both: (1) nerve detection (i.e.: whether the surgical tool/probe is near a nerve); and (2) nerve status changes (i.e.: the change in each nerve's
20 neuro-muscular response onset values over time). The surgeon is thus able to better interpret the accuracy of nerve detection warnings by simultaneously viewing changes in the various onset levels. For example, should the surgeon note that a particular onset value (i.e.: the current level of a stimulus pulse required to elicit an EMG response for a particular nerve) is increasing, this would tend to show that this nerve pathway is
25 becoming less sensitive. Accordingly, a "low" warning may be interpreted to more accurately correspond to a "medium" likelihood of nerve contact; or a "medium" warning may be interpreted to more accurately correspond to a "high" likelihood of nerve contact.

Optionally, such re-assessment of the nerve status can be used to automatically re-calibrate the present nerve detection system. This can be accomplished
30 by continually updating the onset values which are then used in the nerve detection function.

In preferred aspects, the neuro-muscular response onset values for each of the plurality of spinal nerves are measured at each of the spaced-apart myotome locations, and are visually indicated to an operator (for example, by way of an LED scale). Most preferably, the measuring of each of the various neuro-muscular response onset values is repeatedly carried out with the present and previously measured onset value levels being simultaneously visually indicated to an operator such as by way of the LED scale.

Accordingly, in one preferred aspect, for example, different LED lights can be used to indicate whether the value of each of the various neuro-muscular response onset values is remaining constant over time, increasing or decreasing. An advantage of this optional feature of the invention is that a surgeon operating the device can be quickly alerted to the fact that a neuro-muscular response onset value of one or more of the spinal nerves has changed. Should the onset value decrease for a particular nerve, this may indicate that the nerve was previously compressed or impaired, but become uncompressed or no longer impaired.

In a particular preferred embodiment, example, a blue LED can be emitted at a baseline value (i.e.: when the neuro-muscular response onset value remains the same as previously measured); and a yellow light can be emitted when the neuro-muscular response onset value has increased from that previously measured; and a green light being emitted when the neuro-muscular response onset value has decreased from that previously measured.

In an alternate design, different colors of lights may be simultaneously displayed to indicate currently measured onset values for each of the plurality of spinal nerve myotome locations, as compared to previously measured onset values. For example, the present measured onset value levels for each of the plurality of spinal nerve myotome locations can appear as yellow LED lights on the LED scale, with the immediately previously measured onset value levels simultaneously appearing as green LED lights on the LED scale. This also allows the operator to compare presently measured (i.e. just updated) neuro-muscular response onset values to the previously measured neuro-muscular response onset values.

In preferred aspects, the present system also audibly alerts the operator to the presence of a nerve. In addition, the volume or frequency of the alarm may change as the probe/tool moves closer to the nerve.

In a preferred aspect of the present invention, the neuro-muscular onset values, (which may be detected both when initially determining the relative neuro-

muscular response onset values in accordance with the second aspect of the invention, and also when detecting a neuro-muscular onset response to the emitted stimulus pulse from the probe/tool in accordance with the first aspect of the invention), are detected by monitoring a plurality of distally spaced-apart myotome locations which anatomically correspond to each of the spinal nerves. Most preferably, these myotome locations are selected to correspond to the associated spinal nerves which are near the surgical site. Therefore, these myotome locations preferably correspond with distally spaced-apart on the patient's legs (when the operating site is in the lower vertebral range), but may also include myotome locations on the patient's arms (when the operating site is in the upper vertebral range). It is to be understood, however, that the present system therefore encompasses monitoring of any relevant myotome locations which are innervated by nerves in the area of surgery. Therefore, the present invention can be adapted for use in cervical, thoracic or lumbar spine applications.

During both the optional initial determination of the relative neuro-muscular response onset values for each of the plurality of spinal nerves (i.e.: the second aspect of the invention) and also during the detection of neuro-muscular onset responses to the stimulus pulse from the surgical probe/tool (i.e.: the first aspect of the invention), the emission of the stimulus pulse is preferably of a varying current intensity. Most preferably, the stimulus pulse is incrementally increased step-by-step in a "staircase" fashion over time, at least until a neuro-muscular response signal is detected. The stimulus pulse itself may be delivered either between a midline epidural electrode and a return electrode, or between two electrodes disposed adjacent the patient's spine, or from an electrode disposed directly on the probe/tool, or by other means.

An important advantage of the present system of increasing the level of stimulus pulse to a level at which a response is first detected is that it avoids overstimulating a nerve (which may cause a patient to "twitch"), or cause other potential nerve damage.

In optional preferred aspects, the "steps" of the staircase of increasing current intensity of the stimulus pulse are carried out in rapid succession, most preferably within the refractory period of the spinal nerves. An advantage of rapidly delivering the stimulus pulses within the refractory period of the spinal nerves is that, at most, only a single "twitch" will be exhibited by the patient, as opposed to a muscular "twitching" response to each level of the stimulation pulse as would be the case if the increasing

levels of stimulus pulse were instead delivered at intervals of time greater than the refractory period of the nerves.

In another optional preferred aspect, a second probe is added to the present system, functioning as a "confirmation electrode". In this optional aspect, an electrode or
5 electroded surface on the second probe is also used to detect the presence of a nerve, (using the same system as was used for the first probe to detect a nerve). Such a second "confirmation electrode" probe is especially useful when the first probe is an electrified cannula itself, and the second "confirmation electrode" probe is a separate probe which can be advanced through the electrified cannula. For example, as the operating
10 (electrified) cannula is advanced into the patient, this operating cannula itself functions as a nerve detection probe. As such, the operating cannula can be advanced to the operating site without causing any nerve damage. After this cannula has been positioned at the surgical site, it may then be used as the operating cannula through which various surgical tools are then advanced. At this stage, its nerve sensing feature may be optionally
15 disabled, should this feature interfere with other surgical tools or procedures. Thereafter, (and at periodic intervals, if desired) the second "confirmation electrode" probe can be re-advanced through the operating cannula to confirm that a nerve has not slipped into the operating space during the surgical procedure. In the intervals of time during which this second "confirmation electrode" probe is removed from the operating cannula, access is
20 permitted for other surgical tools and procedures. The second "confirmation electrode" probe of the present invention preferably comprises a probe having an electrode on its distal end. This confirmation electrode may either be mono-polar or bi-polar.

In an optional preferred aspect, the second "confirmation electrode" probe may also be used as a "screw test" probe. Specifically, the electrode on the secondary
25 "confirmation" probe may be placed in contact with a pedicle screw, thereby electrifying the pedicle screw. Should the present invention detect a nerve adjacent such an electrified pedicle screw, this would indicate that pedicle wall is cracked (since the electrical stimulus pulse has passed out through the crack in the pedicle wall and stimulated a nerve adjacent the pedicle).

30 An advantage of the present system is that it may provide both nerve "detection" (i.e.: sensing for the presence of nerves as the probe/tool is being advanced) and nerve "surveillance" (i.e.: sensing for the presence of nerves when the probe/tool had been positioned).

A further important advantage of the present invention is that it simultaneously monitors neuro-muscular responses in a plurality of different nerves. This is especially advantageous when operating in the region of the spinal cord due to the high concentration of different nerves in this region of the body. Moreover, by simultaneously monitoring a plurality of different nerves, the present system can be used to indicate when relative nerve response onset values have changed among the various nerves. This information can be especially important when the surgical procedure being performed can alter the relative nerve response onset value of one or more nerves with respect to one another.

A further advantage of the present system is that a weaker current intensity can be applied at the nerve detecting electrodes (on the probe) than at the stimulus (i.e.: nerve status) electrodes.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an illustration of various components of the present invention in operation.

Fig. 2 shows a current intensity staircase for an electromyographic stimulation (nerve status) electrode.

Fig. 3 shows a current intensity staircase for an electromyographic stimulation pulse for a nerve detection electrode disposed on a probe.

Fig. 4 corresponds to Fig. 1, but also shows exemplary "high", "medium" and "low" warning levels corresponding to exemplary neuro-muscular response onset levels.

Fig. 5 shows a patient's spinal nerves, and corresponding myotome monitoring locations.

Fig. 6 is an illustration of the waveform characteristics of a stimulus pulse and a corresponding neuro-muscular (EMG) response as detected at a myotome location.

Fig. 7 is a schematic diagram of a nerve detection system.

Fig. 8A is an illustration of the front panel of one design of the present nerve status and detection system.

Fig. 8B is an illustration of the front panel of another design of the present nerve status and detection system.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention sets forth systems for detecting when a nerve is near or adjacent to an electrified surgical tool, probe, cannula, or other surgical instrument.

- 5 The present invention also involves optional systems for simultaneously determining the "status" (e.g.: sensitivity) of a plurality of nerves.

As will be explained, the present system involves applying a signal with a current level to a probe near a nerve and determining whether an electromyographic "EMG" (i.e.: neuro-muscular) response for a muscle coupled to the nerve is present.

- 10 In preferred aspects, the present system applies a signal with a known current level (mA) to a "probe" (which could be midline probe, a cannula, a needle, etc.) Depending on the current level, distance to the nerve, and health of the nerve, an EMG may be detected in a muscle coupled to the nerve. In accordance with preferred aspects, an EMG response is determined to have been detected when the peak-to-peak response of
15 the EMG signal is greater than some level (mVolts). In other words, an EMG response is determined to have been detected when the stimulus current level generates an EMG having a peak-to-peak value greater than a pre-determined level (for example, 60mV or 80mV in spinal nerve applications.) Such stimulus current level at which an EMG response is detected is termed the "onset" current level for the nerve.

- 20 In optional aspects, the present invention also sets forth systems for determining these onset current values (i.e.: determining the stimulus current level at which an EMG response is detected with a maximum peak-to-peak value greater than a predetermined level). Such onset values may be determined for a plurality of nerves either in absolute terms, or in relation to one another.

- 25 The first aspect of the present invention involves nerve detection. In the optional second aspect of the invention, nerve status information may be used to aid nerve detection. The nerve status aspect determines the minimum current level of a signal applied to a probe near a nerve needed to generate onset EMG response for a muscle coupled to a nerve of interest. The present invention may use this determined minimum
30 current level when determining whether a probe is near the same nerve.

In optional aspects, the present invention may involve determining an initial set of "baseline" neuro-muscular response onset values for a plurality of different spinal nerve pathways. This optional second (nerve status) aspect of the present invention is preferably carried out prior to the first (nerve detection) aspect of the invention, with

the initial set of "baseline" neuro-muscular onset values then optionally being used in the nerve detection function, as will be explained below. As the optional second aspect of the invention is carried out prior to carrying out the first aspect of the invention, it will be described first herebelow.

- 5 In the nerve status determination, the minimum current level of a signal applied to a probe needed to generate an onset neuro-muscular response (i.e.: EMG response) is first determined for each of a plurality of nerves, as follows. Referring to Fig. 1, a patient's vertebrae L1, L2, L3, L4, L5, and S1 are shown. In a preferred aspect of the present invention, a portion of the patient's *cauda equina* is stimulated (i.e. depolarized).
- 10 This depolarization of a portion of the patient's *cauda equina* may be achieved by conducting a stimulus pulse having a known current level between an epidural stimulating electrode 11 and a patient return electrode 13. Electrodes 11 and 13 are referred to herein as "status" electrodes, as they assist in determining the initial status of the various nerve pathways). The epidural electrode is placed in the epidural space of the spine.
- 15 Alternatively, the depolarization of a portion of the patient's *cauda equina* may be achieved by conducting a stimulus pulse having a known current level between a pair of status (baseline) electrodes 12 and 14, which may be positioned adjacent the (thoracic/lumbar) T/L junction (above vertebra L1), as shown. Status electrodes 12 and 14 may be positioned in-line at the T/L junction, (as shown in Fig. 1). Status electrodes 12
- 20 and 14 could also be positioned on opposite lateral sides of the T/L junction.

 In a preferred aspect, neuro-muscular (i.e., EMG), responses to the stimulus pulse by muscles coupled to nerves near the stimulating electrode are detected by electrodes positioned at each of a plurality of myotome locations MR1, MR2, and MR3 on the patient's right leg, and myotome locations ML1, ML2, and ML3 on the

25 patient's left leg. The sensing of neuro-muscular responses at these locations may be performed with needle electrodes, or electrodes placed on the surface of the patient's skin, as desired. An EMG response at each location MR1 to MR6 is detected when the maximum peak-to-peak height of the EMG response to the stimulus pulse is greater than a predetermined mV value (called "onset"). Accordingly, the current level required to

30 elicit an onset EMG response is called the "onset" current level. As described below, the current level of the stimulus pulse or signal applied to the electrode 11 or electrodes 12, 14 may be incremented from a low level until an onset EMG response is detected for one or more of the myotome locations MR1 to ML3.

It is to be understood that myotome sensing may be carried out at more than the three distal locations illustrated on each of the patient's legs in Fig. 1. Generally, as greater numbers of distal myotome locations are monitored, a greater number of spinal nerves corresponding to each of these myotome locations can be individually monitored, thereby enhancing the present system's nerve detection ability over a larger section of the patient's spinal column.

It is also to be understood that the present invention can be easily adapted to cervical or thoracic spinal applications (in addition to the illustrated lumbar application of Fig. 1). In this case an appropriate portion of the spinal column is depolarized and myotome sensing locations are selected according to the physiology of the associated nerves for portion of the spinal column of interest. In exemplary aspects, therefore, preferred myotome sensing locations may therefore include locations on the patient's arms, anal sphincter, bladder, and other areas, depending upon the vertebrae level where the spinal surgery is to be performed.

In a preferred aspect, the current level of the stimulus signal conducted between status electrodes 11 and 13 (or 12 and 14) is incrementally increased in a staircase fashion as shown in the current staircase of Fig. 2 from a low value until an onset EMG response is detected at one or more myotome locations. In a preferred embodiment, onset EMG response peak-to-peak value is between 60mV and 80mV. (It is noted, however, that depending on the location the stimulating electrode relative to the nerve corresponding to a myotome and the nerve health/status, an onset EMG response may not be detected as the current level is incremented from the lowest level to the highest level shown in Fig.2.) In the illustrated exemplary aspect, the current level is shown as increasing from 4 mA to 32 mA, in eight 4 mA increments where the current level is incremented until an onset EMG response is detected. The present invention is not limited to these values and other current ranges (and other numbers "steps" in the staircase) may also be used, as is desired.

At lower current levels, an onset neuro-muscular (i.e., EMG) responses to the stimulus pulse may not be detected at each myotome ML1 to MR3 location. However, as the current level of the stimulus signal is incrementally increased (i.e.: moving up the staircase, step-by-step), an onset neuro-muscular (i.e., EMG) response may eventually be detected at each of the various myotome locations ML1 through MR3 for each of the six associated spinal nerves. As noted whether an onset EMG response is detected for myotome depends on the location of the electrode relative to the corresponding nerve and

the nerve status/health. For example, when a nerve is compressed or impaired, the current level required to generate an onset EMG response may be greater than the similar, non-compressed nerve at a similar distance from the stimulating electrode. Accordingly, the onset neuro-muscular response for each of the various myotome ML1 to MR3 locations may be elicited at different stimulus current levels due at least in part to the various individual spinal nerves being compressed, impaired, etc., and also due simply to differences in the individual nerve pathway sensitivities.

For example, referring to the example illustrated in Fig. 1, a stimulus signal having an initial current level is conducted between electrodes 11 and 13 (or between electrodes 12 and 14). The current level of the stimulus pulse is increased step-by-step according to the intensity staircase shown in Fig. 2 until an onset EMG response is detected at one or more selected myotomes. In particular, a response to the increasing current level stimulus pulse is detected at each of the various myotome locations ML1 through MR3. Because each of the spinal nerve paths corresponding to the various myotome locations ML1 through MR3 may have different sensitivities (as noted), different onset EMG responses may be detected at the different onset current levels for different myotome locations.

For example, Table 1 illustrates the current level required to elicit an onset EMG response for myotome location. As seen in Table 1, myotome location ML1 detected an onset EMG response to the stimulus pulse for a current level of 4 mA. Similarly, myotome MR2 detected an onset neuro-muscular/EMG response to the stimulus pulse for a current level of 24 mA, etc. Summarizing in tabular form:

TABLE 1
Stimulus Current Level at Which Onset EMG Response is Detected:

ML1 – 4 mA	MR1 – 16 mA
ML2 – 16 mA	MR2 – 24 mA
ML3 – 20 mA	MR3 – 12 mA

The above detected stimulus current levels may then be optionally scaled to correspond to stimulus staircase levels 1 through 8, with the maximum signal strength

of 32 mA corresponding to "8", as follows, and as illustrated for each of Myotome locations ML1 to MR3, as shown in Table 2 based on the levels shown in Table 1.

TABLE 2

Scaled Neuro-muscular Response Onset Values:

ML1 - 1	MR1 - 4
ML2 - 4	MR2 - 6
ML3 - 5	MR3 - 3

Accordingly, by depolarizing a portion of the patient's *cauda equina* and by then measuring the current amplitude at which an onset neuro-muscular (i.e., EMG) response to the depolarization of the *cauda equina* is detected in each of a plurality of spinal nerves, (i.e.: at each of the myotome locations corresponding to each of the individual spinal nerves), a method for determining the relative neuro-muscular response for each of the plurality of spinal nerves is provided. As such, the relative sensitivities of the various spinal nerve pathways with respect to one another can initially be determined. This information may represent the relative health or status of the nerves coupled to each myotome location where the stimulating electrode is approximately the same distance from each of the corresponding nerves. For example, the nerve corresponding to myotome location MR2 required 24mA to elicit an onset EMG response in the corresponding muscle. Accordingly, this nerve may be compressed or otherwise physiologically inhibited.

These respective stimulus pulse current levels at which an onset neuro-muscular response is detected for each of myotome locations ML1 through MR3 are detected may then be electronically stored (as an initial "baseline" set of onset EMG response current levels). In a preferred aspect, these stored levels may then be used to perform nerve detection for a probe at a location other than the midline as will be explained. As noted, once an onset neuro-muscular or EMG-response has been detected for each of the myotome locations, it is not necessary to apply further increased current level signals. As such, it may not be necessary for the current level of the signal to reach the top of the current level staircase (as shown in Fig. 2) (provided a response has been detected at each of the myotome locations).

By either reaching the end of the increasing current amplitude staircase, (or by simply proceeding as far up the staircase as is necessary to detect a response at each myotome location), the present system obtains and stores an initial "baseline" set of current level onset values for each myotome location. These onset values may be stored
5 either as absolute (i.e.: mA) or scaled (i.e.: 1 to 8) values. As noted these values represent the baseline or initial nerve status for each nerve corresponding to one of the myotome locations. This baseline onset current level may be displayed as a fixed value on a bar graph of LEDs such as shown in Fig. 8A or 8B. At a later point, the nerve status of the nerves corresponding to the myotomes may be determined again by applying a varying
10 current level signal to the midline electrodes. If a procedure is being performed on the patient, the onset current level for one or more of the corresponding nerves may change.

When the onset current level increases for a nerve this may indicate that a nerve has been impacted by the procedure. The increased onset current level may also be displayed on the bar graph for the respective myotome (Fig. 8A/8B). In one embodiment,
15 the baseline onset current level is shown as a particular color LED in the bar graph for each myotome location and the increased onset current level value is shown as a different color LED on the bar graph. When the onset current level decreases for a nerve this may indicate that a nerve has been aided by the procedure. The decreased onset current level may also be displayed on the bar graph for the respective myotome. In a preferred
20 embodiment, the decreased onset current level value is shown as a third color LED on the bar graph. When the onset current level remains constant, only the first color for the baseline onset current level is shown on the bar graph. In one embodiment, a blue LED is depicted for the baseline onset current level, an orange LED is depicted for an increased (over the baseline) onset current level, and a green LED is depicted for a decreased onset
25 current level. In one embodiment when the maximum current level in the staircase does not elicit an onset EMG response for a myotome, the baseline LED may be set to flash to indicate this condition. Accordingly, a clinician may periodically request nerve status (midline stimulation) readings to determine what impact, positive, negative, or neutral, a procedure has had on a patient. The clinician can make this assessment by viewing the bar
30 graphs on the display shown in Fig. 8 for each of the myotome locations.

The above determined initial set baseline neuro-muscular response onset current levels for each nerve pathway (myotome location) may then be used in the first (i.e.: nerve sensing) aspect of the present invention, in which a system is provided for detecting the presence of a spinal nerve adjacent to the distal end of a single probe 20, or

either of probes 20 or 22. (It is to be understood, however, that the forgoing nerve status system (which may experimentally determine neuro-muscular response onset values) is an optional aspect of the present nerve detection system. As such, it is not necessary to determine such relative or absolute neuro-muscular response baseline onset current levels as set forth above prior to nerve detection. Rather, generally expected or previously known current onset levels may instead be used instead. Such generally expected or previously known current onset levels may have been determined by experiments performed previously on other patients.

In accordance with the first aspect of the present invention, nerve detection (performed as the surgical tool or probe is advancing toward the operative site), or nerve surveillance (performed in an ongoing fashion when the surgical tool or probe is stationary has already reached the operative site) may be carried out, as follows.

The first (nerve detection/surveillance) aspect of the invention will now be set forth.

Returning to Fig. 1, a system is provided to determine whether a nerve is positioned closely adjacent to either of two probes 20 and 22. In accordance with the present invention, probes 20 and 22 can be any manner of surgical tool, including (electrified) cannulae through which other surgical tools are introduced into the patient. In one aspect of the invention only one probe (e.g.: probe 20) is used. In another aspect, as illustrated, two probes (e.g.: 20 and 22) are used. Keeping within the scope of the present invention, more than two probes may also be used. In one preferred aspect, probe 20 is an electrified cannula and probe 22 is a "confirmation electrode" which can be inserted through cannula/probe 20, as will be explained. Probes 20 and 22 may have electrified distal ends, with electrodes 21 and 23 positioned thereon, respectively. (In the case of probe 20 being a cannula, electrode 21 may be positioned on an electrified distal end of the cannula, or alternatively, the entire surface of the electrified cannula may function as the electrode).

Nerve detection is accomplished as follows. A stimulus pulse is passed between electrode 21 (disposed on the distal end of a probe 20) and patient return electrode 30. In instances where a second probe (22) is also used, a stimulus pulse is passed between electrode 23 (disposed on the distal end of a probe 22) and patient return electrode 30. In one aspect, electrodes 21 or 23 operate as cathodes and patient return electrode 30 is an anode. In this case, probes 20 and 22 are monopolar. Preferably, when

simultaneously using two probes (20 and 22) the stimulus pulse emitted by each of electrodes 21 and 23 is multiplexed, so as to distinguish between their signals.

It should be understood that electrodes 21 and 23 could be replaced by any combination of multiple electrodes, operating either in monopolar or bipolar mode. In the case where a single probe has multiple electrodes (replacing a single electrode such as electrode 21) probe 20 could instead be bi-polar with patient return electrode 30 no longer being required.

Subsequent to the emission of a stimulus pulse from either of electrodes 21 or 23, each of myotome locations ML1 through MR3 are monitored to determine if they exhibit an EMG response.

In a preferred aspect, as shown in Fig. 3, the intensity of the stimulus pulse passing between electrodes 21 and 30 or between 22 and 30 is preferably varied over time. Most preferably, the current intensity level of the stimulus pulse is incrementally increased step-by-step in a "staircase" fashion. As can be seen, the current may be increased in ten 0.5 mA steps from 0.5 mA to 5.0 mA. This stimulus pulse is preferably increased one step at a time until a neuro-muscular (i.e., EMG) response to the stimulus pulse is detected in each of myotome locations ML1 through MR3.

For myotome locations which exhibit an EMG response as a result of the stimulus pulse, the present invention then records the lowest amplitude of current required to elicit such a response. Subsequently, this stimulus level is interpreted so as to produce an appropriate warning indication to the user that the surgical tool/probe is in close proximity to the nerve.

For example, in a simplified preferred aspect, the staircase of stimulus pulses may comprise only three levels, (rather than the 8 levels which are illustrated in Fig. 3). If an EMG response is recorded at a particular myotome location for only the highest level of stimulation (i.e.: the third step on a 3-step staircase), then the system would indicate a "low" alarm condition (since it took a relatively high level of stimulation to produce an EMG response, it is therefore unlikely that the tool/probe distal tip(s) are in close proximity to a nerve). If an EMG response is instead first recorded when the middle level of stimulation (i.e.: the second step on the 3-step staircase) is reached, then the system could indicate a "medium" alarm condition. Similarly, if an EMG response is recorded when the lowest level of stimulation (i.e.: the first step on the 3-step staircase) is reached, then it is likely that the probe tips(s) are positioned very close to a nerve, and the system, could indicate a "high" alarm condition.

As can be appreciated, an important advantage of increasing the stimulus current intensity in a "staircase" function, increasing from lower to higher levels of current intensity is that a "high" alarm condition would be reached prior to a "low" alarm condition being reached, providing an early warning to the surgeon. Moreover, as soon as a "high" alarm condition is reached, the present invention need not continue through to the end (third step) of the staircase function. In preferred aspects, when the current level of the applied signal to the probe (20 or 22) elicits an EMG response greater than the pre-determined onset EMG response, the current level is not increased.

In the above described simplified (only three levels of stimulation) illustration of the invention, it was assumed that all nerves respond similarly to similar levels of stimulation, and the proximity (nerve detection) warning was based upon this assumption. Specifically, in the above-described simplified (three levels of stimulation) illustration, there was an assumed one-to-one (i.e. linear) mapping of the EMG onset value data onto the response data when determining what level of proximity warning indication should be elicited, if any. However, in the case of actual spinal nerve roots, there is not only a natural variability in response onset value thresholds, but there is often a substantial variation in neuro-muscular response onset values between the nerve pathways caused as a result of certain disease states, such as nerve root compression resulting from a herniated intervertebral disc.

Accordingly, in a preferred aspect of the present invention, the initial "baseline" neuro-muscular EMG response onset value data set which characterizes the relative EMG onset values of the various nerve roots of interest, (as described above), is used to guide the interpretation of EMG response data and any subsequent proximity warning indication, as follows.

Referring back to Fig. 1 and Table 1, the stimulation staircase transmitted between electrodes 11 and 13 (or 12 and 14) resulted in measures neuro-muscular (i.e.: EMG) response onset values of 4, 16, 20, 16, 24 and 12 mA at myotome locations ML1, ML2, ML3, MR1, MR2 and MR3, respectively. As can be seen, twice the intensity of current was required to produce a neuro-muscular response at MR2 as was required to produce a neuro-muscular response at MR3. (since "24" mA is twice as big as "12" mA). Thus, the nerve pathway to MR3 is more "sensitive" than to MR2, (since MR3 is able to exhibit a neuro-muscular response at $\frac{1}{2}$ of the current intensity required to exhibit a neuro-muscular response at MR2). Consequently, during nerve detection, when electrode 21 or 23 (positioned on the distal end of tool/probe 20 or 22) is positioned adjacent the

nerve root affiliated with MR3, twice the current stimulation intensity was required to produce an EMG response. In contrast, when electrode 21 or 23 (on the distal end of tool/probe 20 or 22) was positioned adjacent to the nerve root affiliated with MR2, the same level of stimulation that produced a response at MR3 would not produce a response at MR2.

In accordance with preferred aspects of the present invention, the sensitivities of the various spinal nerve pathways (to their associated myotomes) are incorporated into the nerve detection function of the invention by incorporating the various neuro-muscular response onset values, as follows.

A decision is made that either of electrodes 21 or 23 are positioned adjacent to a spinal nerve when a neuro-muscular response is detected at a particular myotome location at a current intensity level that is less than, (or optionally equal to), the previously measured or input EMG response onset value for the particular spinal nerve corresponding to that myotome. For example, referring to myotome location ML1, the previously determined neuro-muscular response onset level was 4 mA, as shown in Table 1. Should a neuro-muscular response to the stimulus pulse be detected at a current intensity level at or below 4 mA, this would signal the operator that the respective probe electrode 21 (or 23) emitting the stimulus pulse is in close proximity to the spinal nerve. Similarly, the neuro-muscular response onset value for myotome location ML2 was determined to be 16 mA, as shown in Table 1. Accordingly, should a neuro-muscular response be detected at a current intensity level of less than or equal to 16 mA, this would indicate that respective probe electrode 21 (or 23) emitting the stimulus pulse is in close proximity to the spinal nerve.

In addition, as illustrated in Fig. 4, "high", "medium" and "low" warning levels may preferably be mapped onto each stimulation staircase level for each myotome location. For example, the neuro-muscular onset level for ML1 was 4 mA, corresponding to the first level of the 8-level status electrode current staircase of Fig. 2. Thus, the first (4 mA) step on the staircase is assigned a "high" warning level. Level two (8 mA) is assigned a "medium" warning level and level three (12 mA) is assigned a "low" warning level. Thus, if an EMG response is recorded at ML1 at the first stimulation level, (4 mA), a "high" proximity warning is given. If a response is detected at the second level (8 mA), then a "medium" proximity warning is given. If a response is detected at the third level (12 mA), then a "low" proximity warning is given. If responses are detected only above the third level, or if no responses are detected, than no warning indication is given.

Similarly, for ML2, with a onset value of 16 mA, (i.e.: the fourth level in the status electrode current staircase sequence), the "high", "medium" and "low" warning levels are assigned starting at the fourth step on the status electrode current staircase, with the fourth step being "high", the fifth level being "medium" and the sixth level being "low", respectively, as shown. Accordingly, if an EMG response is detected for ML2 at (or above) the first, second, third, or fourth surveillance levels, (i.e.: 4, 8, 12 or 16 mA), then a "high" warning indication will be given. For a response initially detected at the fifth level (i.e.: 20 mA), then a "medium" warning indication is given. If a response is not detected until the sixth level, (i.e.: 24 mA), then a "low" warning indication is given. If responses are detected only above the sixth level, or not at all, then no indication is given. Preferably, each of myotome locations ML1 through MR3 are monitored at conditions indicating "high", "medium" and "low" likelihood of a nerve being disposed adjacent the surgical tool/probe.

As can be seen in Fig. 4, ten levels are shown for each of the myotome locations, whereas the illustrated status electrode current staircase has only eight levels. These optional levels "9" and "10" are useful as follows. Should scaled level 8 be the minimum onset level at which a neuro-muscular response is detected, levels "9" and "10" can be used to indicate "medium" and "low" warning levels, respectively.

As explained above, the various neuro-muscular response current onset levels used in detection of spinal nerves may either have been either determined in accordance with the second aspect of the present invention, or may simply correspond to a set of known or expected values input by the user, or pre-set into the system's hardware/software. In either case, an advantage of the present system is that different neuro-muscular response onset value levels may be used when simultaneously sensing for different nerves. An advantage of this is that the present invention is able to compensate for different sensitivities among the various spinal nerves.

As can be seen comparing the current intensities of stimulus electrodes 11 and 13 (or 12 and 14) as shown in Fig. 2 (i.e.: up to 32 mA) to the current intensities of probe electrodes 21 and 23 as shown in Fig. 3 (i.e.: up to 5.0 mA), the current intensities emitted by probe electrodes 21 and 23 are less than that of electrodes 12 and 14. This feature of the present invention is very advantageous in that electrodes 21 and 23 are positioned much closer to the spinal nerves. As such, electrodes 21 and 23 do not depolarize a large portion of the *cauda equina*, as do electrodes 12 and 14. In addition,

the placement of electrode 11 in the epidural space ensures that the electrode is at a relatively known distance from the spinal nerves.

In an optional preferred aspect of the invention, if a neuro-muscular response (greater than the onset EMG response) is detected for all six myotome sensing locations ML1 through MR3 before all of the steps on the staircase is completed, the
5 remaining steps need not be executed.

Moreover, if it has been determined that a maximal level of stimulation is required to elicit an EMG response at a particular myotome sensing location, then only the top three stimulation levels need to be monitored during the neuro-muscular response
10 detection sequence. In this case, the top three monitored levels will correspond to "high", "medium", and "low" probabilities of the surgical tool/probe being disposed adjacent the a nerve. In another optional aspect, if any of the myotome locations do not respond to the maximum stimulation level (i.e.: top step on the staircase), they are assigned the maximum scale value (i.e.: a "low" warning indication).

Preferably, each of the spinal nerves monitored at myotome locations ML1 through MR3 will correspond to nerves exiting from successive vertebrae along the spine. For example, as shown in Fig. 5, a main spinal nerve 50 will continuously branch out
downwardly along the spinal column with spinal nerve 51 exiting between vertebrae L2 and L3 while nerve 52 passes downwardly. Spinal nerve 53 exits between vertebrae L3
20 and L4 while spinal nerve 54 passes downwardly to L4. Lastly, spinal nerve 55 will exit between vertebrae L4 and L5 while spinal nerve 56 passes downwardly. As can be seen, neuro-muscular (i.e., EMG) response measurements taken at myotome location MR1 will correspond to EMG signals in spinal nerve 51, response measurements taken at myotome location MR2 correspond to EMG signals in spinal nerve 53, and response measurements
25 taken at myotome location MR3 correspond to EMG signals in spinal nerve 55.

In accordance with the present invention, the detection of a neuro-muscular (EMG) response, whether in accordance with the first (i.e.: nerve detection), or second (i.e.: establishing initial "baseline" neuro-muscular response onset values) aspect of the invention, may be accomplished as follows.

Referring to Fig. 6, an illustration of the waveform characteristics of a stimulus pulse and a corresponding neuro-muscular (EMG) response as detected at a myotome location is shown. An "EMG sampling window" 200 may be defined at a fixed
30 internal of time after the stimulus pulse 202 is emitted. The boundaries of window 200 may be determined by the earliest and latest times that an EMG response may occur

relative to stimulus pulse 202. In the case of stimulation near the lumbar spine, these time are, for example, about 10 milliseconds and 50 milliseconds, respectively.

During EMG sampling window 101, the EMG signal may optionally be amplified and filtered in accordance with guidelines known to those skilled in the art. The signal may then be rectified and passed through a threshold detector to produce a train of pulses representing the number of "humps" of a certain amplitude contained in the EMG waveform. A re-settable counting circuit may then count the number of humps and a comparator may determine whether the number of pulses is within an acceptable range. By way of example only, the number of acceptable pulses for EMG responses elicited by stimulation in the lumbar spine region may range from about two to about five. If only one pulse is counted, then it is unlikely that a true EMG response has occurred, since true EMG waveforms are typically biphasic (having at least one positive curved pulse response and one negative curved pulse response) resulting in at least two pulses. This pulse-counting scheme helps to discriminate between true EMG waveforms and noise, since noise signals are typically either spurious and monophasic (and therefore produce only one pulse) or repetitive (producing a high number of pulses during the EMG sampling window).

In a further optional refinement, a separate noise sampling window may be established to remove noise present in the EMG responses to increase the ability of the system to discriminate between true EMG responses and false responses caused by noise. The boundaries of noise sampling window are chosen such that there is no significant change of a true EMG signal occurring during the window. For example, it may be deemed acceptable that one curved pulse of an EMG response may be comprised primarily of noise, but if more than one curved response of an EMG response is primarily comprised of noise an alarm would be triggered indicating that excess noise is present on that particular channel.

In preferred aspects of the present invention, both the optional second aspect of determining the neuro-muscular response onset values for each of the plurality of spinal nerves, and the first aspect of sensing to detect if a nerve is positioned adjacent to a surgical tool/probe are repeated over time. Preferably, the sensing of whether a nerve is positioned adjacent to a surgical tool/probe is continuously repeated in very short intervals of time, such that the operator can be warned in real time as the surgical tool/probe is advanced toward the nerve. The present system of determining the neuro-

muscular response onset values for each of the plurality of spinal nerves is also preferably repeated, and may be repeated automatically, or under operator control.

Typically, the above two aspects of the present invention will not be carried out simultaneously. Rather, when the neuro-muscular response onset values are being determined (using electrodes 11 and 13 or 12 and 14), the operation of probe electrodes 21 and 23 will be suspended. Conversely, when sensing to determine whether a nerve is positioned adjacent either of probes 20 or 22, the operation of stimulation electrodes 11 and 13 or 12 and 14 will be suspended. A standard reference electrode 32 may be used for grounding the recording electrodes at the myotomes.

Fig. 6 depicts a particular exemplary embodiment of the present invention. Other embodiments are also possible, and are encompassed by the present invention. Pulse generator 100 creates pulse trains of an appropriate frequency and duration when instructed to do so by controller 118. By way of example, the pulse frequency may be between 1 pulse-per-second and 10 pulses-per-second, and the pulse duration may be between 20 μ sec and 300 μ sec. Pulse generator 100 may be implemented using an integrated circuit (IC), such as an ICL75556 (Intensity) or it may be generated by a software module. Amplitude modulator 102 produces a pulse of an appropriate amplitude as instructed by controller 118, and may comprise a digital-to-analog converter such as a DAC08 (National Semiconductor). The output of amplitude modulator 102 drives output stage 103, which puts out a pulse of the desired amplitude. Output stage 103 may comprise a transformer coupled, constant-current output circuit. The output of output stage 103 is directed through output multiplexer 106 by controller 118 to the appropriate electrodes, either to status (baseline) electrodes 11 and 13, or to a combination of screw test probe 109, probe electrode 21, 23 and patient return electrode 13. Impedance monitor 104 senses the voltage and current characteristics of the output pulses and controller 118 elicits an error indication on error display 127 if the impedance falls above or below certain pre-set limits. Input keys 116 may be present on a front panel of a control unit of the present invention, as depicted in Fig. 8, to allow the user to shift between modes of operation.

EMG inputs 128 to 138 comprise the six pairs of electrodes used to detect EMG activity at six different myotome locations. It will be appreciated that the number of channels may vary depending upon the number of nerve roots and affiliated myotomes that need to be monitored. A reference electrode 140 may also be attached to the patient

at a location roughly central to the groupings of EMG electrodes 128 to 138 to serve as a ground reference for the EMG input signals. Electrodes 128 to 140 may either be of the needle-type or of the gelled foam type, or of any type appropriate for detecting low-level physiological signals. EMG input stage 142 may contain input protection circuit

5 comprising, for example, gas discharge elements (to suppress high voltage transients) and/or clamping diodes. Such clamping diodes are preferably of the low-leakage types, such as SST-pads (Siliconix). The signal is then passed through amplifier/filter 144, which may amplify the signal differentially using an instrumentation amplifier such as an AD620 (Analog Devices). The overall gain may be on the order of about 10,000:1 to

10 about 1,000,000:1, and the low and high filter bands may be in the range of about 1-100 Hz and 500 to 5,000 Hz, respectively. Such filtering may be accomplished digitally, in software, or with discrete components using techniques well known to those skilled in the art. The amplified and filtered signal then passes through rectifier 141, which may be either a software rectifier or a hardware rectifier. The output of rectifier 146 goes to

15 threshold detector 147 which may be implemented either in electronic hardware or in software. The output of threshold detector 147 then goes to counter 148 which may also be implemented by either software or hardware.

Controller 118 may be a microcomputer or microcontroller, or it may be a programmable gate array, or other hardware logic device. Display elements 120 to 127

20 may be of any appropriate type, either individually implemented (such as with multicolor LEDs) or as an integrated display (such as an LCD).

WHAT IS CLAIMED IS:

- 1 1. A method of determining relative neuro-muscular response onset values for a
2 plurality of spinal nerves, comprising:
 - 3 (a) depolarizing a portion of the patient's cauda equina; and
 - 4 (b) measuring the current intensity level at which a neuro-muscular response to
5 the depolarization of the cauda equina is detected in each of the plurality of spinal nerves.
6
- 1 2. The method of claim 1, wherein depolarizing a portion of the patient's cauda
2 equina comprises:
 - 3 passing a stimulus pulse between a pair of calibration electrodes.
4
- 1 3. The method of claim 2, wherein,
2 the pair of calibration electrodes are disposed adjacent the T-L junction.
3
- 1 4. The method of claim 3, wherein,
2 the pair of calibration electrodes are disposed one above another at the T-L junction.
3
- 1 5. The method of claim 2, wherein, the method of claim 1 is repeatedly performed
2 while the current intensity level of the stimulus pulse is varied over time.
3
- 1 6. The method of claim 5, wherein the current intensity level of the stimulus pulse is
2 varied incrementally.
3
- 1 7. The method of claims 5 or 6, wherein the current intensity level of the stimulus
2 pulse is increased over time.
3
- 1 8. The method of claim 1, wherein the plurality of spinal nerves comprise:
2 nerves exiting from successive vertebrae.
3
- 1 9. The method of claim 8, wherein measuring the current intensity level at which a
2 neuro-muscular response to the depolarization of the cauda equina is detected in each of
3 the plurality of spinal nerves comprises:
 - 4 detecting the neuro-muscular responses at a plurality of distally spaced apart
5 myotome locations corresponding to each of the spinal nerves.

6

1 10. The method of claim 9, wherein the plurality of distally spaced apart myotome
2 locations are distally spaced apart on the patient's legs.

3

1 11. The method of claim 1, wherein measuring the current intensity level at which a
2 neuro-muscular response to the depolarization of the cauda equina is detected in each of
3 the plurality of spinal nerves comprises:

4 detecting the neuro-muscular responses at a plurality of distally spaced apart
5 peripheral nerve locations corresponding to each of the spinal nerves.

6

1 12. The method of claim 1, further comprising:
2 visually indicating to an operator the intensity level of the neuro-muscular
3 response onset values for each of the plurality of spinal nerves.

4

1 13. The method of claim 12, further comprising:
2 repeating the method of claim 1, thereby measuring sequential sets of neuro-
3 muscular response onset values for each of the plurality of spinal nerves over time; and
4 simultaneously visually displaying to an operator the measured levels of at least
5 two sets of the neuro-muscular response onset values for each of the plurality of spinal
6 nerves.

7

1 14. The method of claim 1, further comprising:
2 repeating the method of claim 1, thereby measuring sequential sets of neuro-
3 muscular response onset values for each of the plurality of spinal nerves.

4

1 15. A method for detecting the presence of a nerve adjacent the distal end of at least
2 one probe, comprising:

3 (a) determining relative neuro-muscular response onset values for a plurality of
4 spinal nerves;

5 (b) emitting a stimulus pulse from a probe or surgical tool;

6 (c) detecting neuro-muscular responses to the stimulus pulse in each of the
7 plurality of spinal nerves; and

8 (d) concluding that the electrode disposed on the distal end of the at least one
9 probe is positioned adjacent to a first spinal nerve when the neuro-muscular response

detected in the first spinal nerve is detected as a current intensity level less than or equal to the neuro-muscular response onset value of the first spinal nerve.

16. The method of claim 15, wherein the stimulus pulse is emitted from an electrode disposed on the distal end of the at least one probe or surgical tool.

17. The method of claim 15, wherein, determining relative neuro-muscular response onset values for a plurality of spinal nerves is accomplished as set forth in claim 1.

18. The method of claim 15, wherein emitting a stimulus pulse from a probe or surgical tool comprises:

emitting a stimulus pulse from separate left and right probes introduced into the patient on opposite lateral sides of the patient's spine.

19. The method of claim 18, wherein, the stimulus pulses emitted by the separate left and right probes are multiplexed.

20. The method of claim 7, wherein emitting a stimulus pulse from a probe or surgical tool comprises:

emitting a stimulus pulse from an electrode disposed at a distal end of a cannulated nerve surveillance probe.

21. The method of claim 15, wherein emitting a stimulus pulse from a probe or surgical tool comprises:

emitting a stimulus pulse from an electrode disposed adjacent an inner cutting surface of a rongeur.

22. The method of claim 15, wherein, detecting neuro-muscular responses to the stimulus pulse in each of the plurality of spinal nerves comprises:

detecting the neuro-muscular responses at a plurality of distally spaced apart myotome locations corresponding to each of the spinal nerves.

23. The method of claim 15, further comprising::

2 repeating the method of claim 15, while the current intensity level of the electrical
3 stimulus pulse is varied over time.

1 24. The method of claim 23, wherein the current intensity level of the stimulus pulse
2 is varied incrementally.

1 25. The method of claims 23 or 24, wherein the current intensity level of the stimulus
2 pulse is increased over time.

1 26. The method of claim 15, wherein, the plurality of spinal nerves comprise:
2 nerves exiting from successive vertebrae.

1 27. The method of claim 26, wherein measuring the current intensity level at which a
2 neuro-muscular response to the depolarization of the cauda equina is detected in each of
3 the plurality of spinal nerves comprises:

4 detecting the neuro-muscular responses at a plurality of distally spaced apart
5 myotome locations corresponding to each of the spinal nerves.

1 28. The method of claim 27, wherein the plurality of distally spaced apart myotome
2 locations are distally spaced apart on the patient's legs.

1 29. The method of claim 27, wherein measuring the current intensity level at which a
2 neuro-muscular response to the depolarization of the cauda equina is detected in each of
3 the plurality of spinal nerves comprises:

4 detecting the neuro-muscular responses at a plurality of distally spaced apart
5 peripheral nerve locations corresponding to each of the spinal nerves.

1 30. The method of claim 15, wherein the method of claim 15 is performed in a
2 repeating sequence.

1 31. The method of claim 30, wherein the method of claim 15 is repeated
2 automatically.

- 1 32. The method of claim 30, wherein the method of claim 15 is repeated under
2 operator control.
3
- 1 33. The method of claim 15, further comprising:
2 visually indicating to an operator the current intensity of the stimulus pulse which
3 elicits a neuro-muscular response in each of the plurality of spinal nerves.
4
- 1 34. The method of claim 33, further comprising:
2 repeating the method of claim 15, thereby detecting and measuring sequential sets
3 of neuro-muscular responses for each of the plurality of spinal nerves; and
4 simultaneously visually displaying to an operator the measured levels of at least
5 two sets of the neuro-muscular responses for each of the plurality of spinal nerves.
6
- 1 35. The method of claim 1, further comprising:
2 visually indicating to an operator that a spinal nerve is positioned near the distal
3 end of the at least one probe or surgical tool.
4
- 1 36. The method of claim 1, further comprising:
2 audibly indicating to an operator that a spinal nerve is positioned near the distal end of the
3 at least one probe or surgical tool.
4
- 1 37. The method of claim 36, wherein audibly indicating comprises:
2 sounding an alarm as the nerve is approached.
3
- 1 38. The method of claim 36, further comprising:
2 varying the volume of the alarm as the nerve is approached.
3
- 1 39. The method of claim 37, further comprising:
2 varying the frequency of the alarm as the nerve is approached.
3
- 1 40. The method of claim 15, wherein the at least one probe or surgical tool comprises:
2 separate left and right probes disposed on opposite lateral sides of the patient's spine.
3
- 1 41. The method of claim 40, wherein,

each of the left and right probes emit a stimulus pulse, with the left and right stimulus pulses being multiplexed.

42. A method of determining the status of a spinal nerve, comprising:

- (a) applying a signal with a known current level to the spinal nerve;
- (b) measuring a neuro-muscular response of the spinal nerve to the applied signal;
- (c) determining whether the neuro-muscular response is greater than a predetermined onset level;
- (d) increasing the known current level until the determined neuro-muscular response is greater than the predetermined onset level; and
- (e) determining the status of the spinal nerve based on the current level required to generate a neuro-muscular response greater than the predetermined onset level.

43. The method of claim 42, wherein the signal is applied to the spinal nerve by conducting the signal between an electrode passing the epidural space adjacent to the spinal nerve and a return electrode.

44. The method of claim 42, wherein the neuro-muscular response is an electromyography response from a muscle coupled to the spinal nerve.

425. The method of claim 44, wherein the maximum peak-to-peak level of the EMG response is measured and compared to the predetermined onset level.

46. The method of claim 42, wherein the status of the spinal nerve is determined again and compared to the previously determined status.

47. A method of determining the location of a surgical probe relative to a spinal nerve, comprising:

- (a) applying a first signal with a known current level to an electrode at a known location relative to the spinal nerve;
- (b) measuring a neuro-muscular response of the spinal nerve to the first applied signal;
- (c) determining whether the neuro-muscular response is greater than a predetermined onset level;

- 9 (d) increasing the known current level of the first applied signal until the
10 determined neuro-muscular response is greater than the predetermined onset level;
11 (e) determining the status of the spinal nerve based on the current level required to
12 generate a neuro-muscular response greater than the predetermined onset level;
13 (f) applying a second signal with a know current level to the surgical probe;
14 (g) measuring a neuro-muscular response of the spinal nerve to the second applied
15 signal;
16 (h) determining whether the neuro-muscular response to the second applied signal
17 is greater than a predetermined onset level;
18 (i) increasing the known current level of the second applied signal until the
19 determined neuro-muscular response is greater than the predetermined onset level; and
20 (j) determining the location of the surgical probe relative to the spinal nerve based
21 on the current level of the second applied signal required to generate a neuro-muscular
22 response greater than the predetermined onset level.

23

1 48. The method of claim 47, wherein the first signal is applied to the spinal nerve by
2 conducting the signal between an electrode passing the epidural space adjacent to the
3 spinal nerve and a return electrode.

4

1 49. The method of claim 47, wherein the neuro-muscular response is an
2 electromyography response from a muscle coupled to the spinal nerve.

3

1 50. The method of claim 49, wherein the maximum peak-to-peak level of the EMG
2 response is measured and compared to the predetermined onset level.

3

1

FIG 1

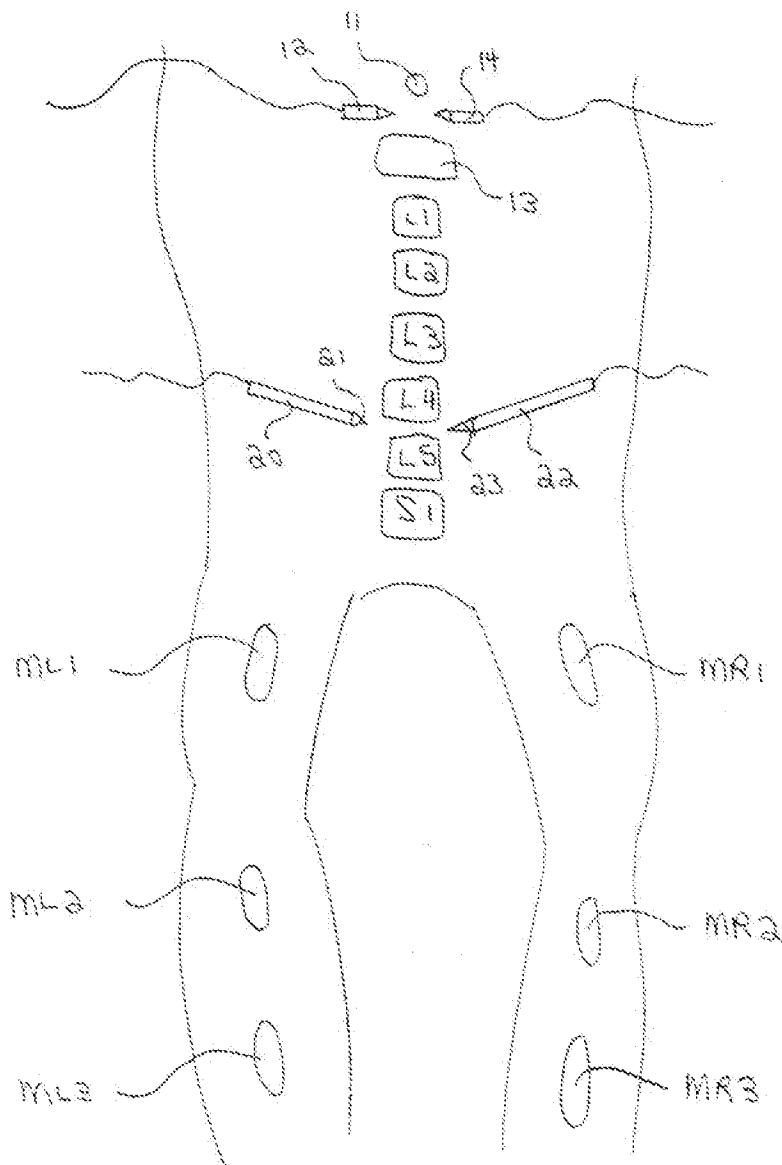


FIG 2

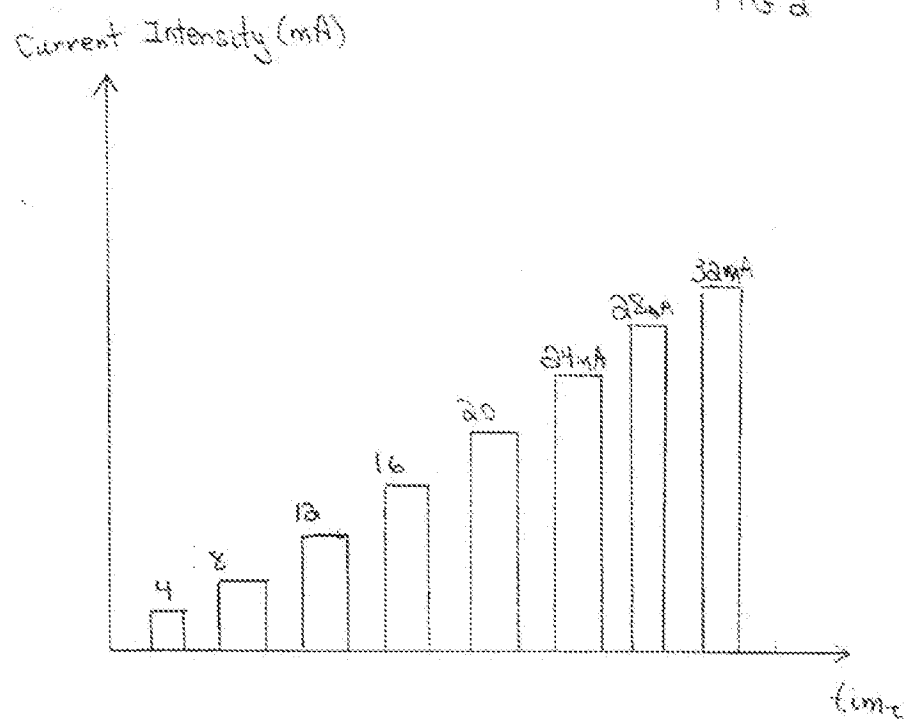


FIG 3

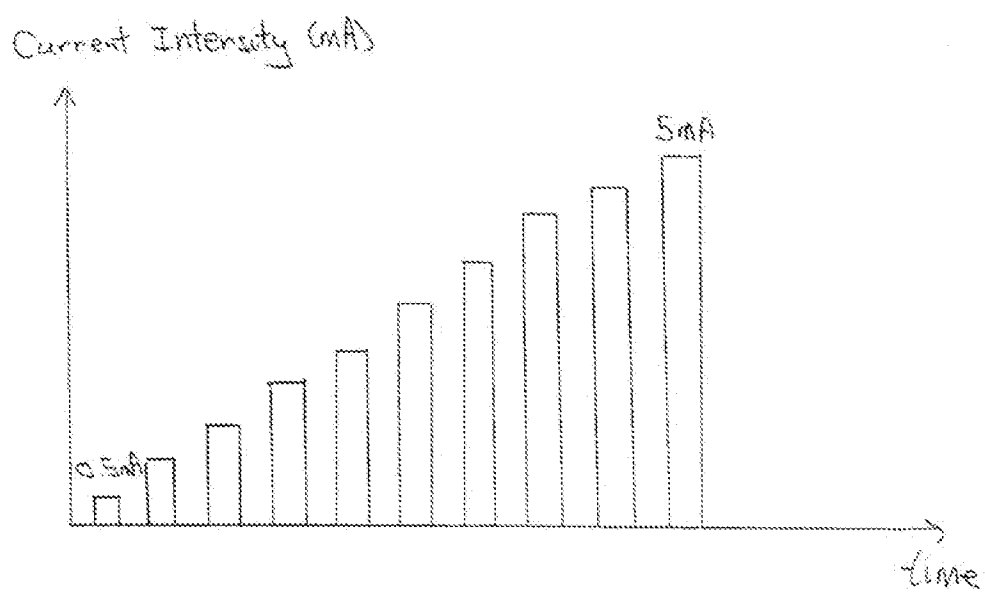
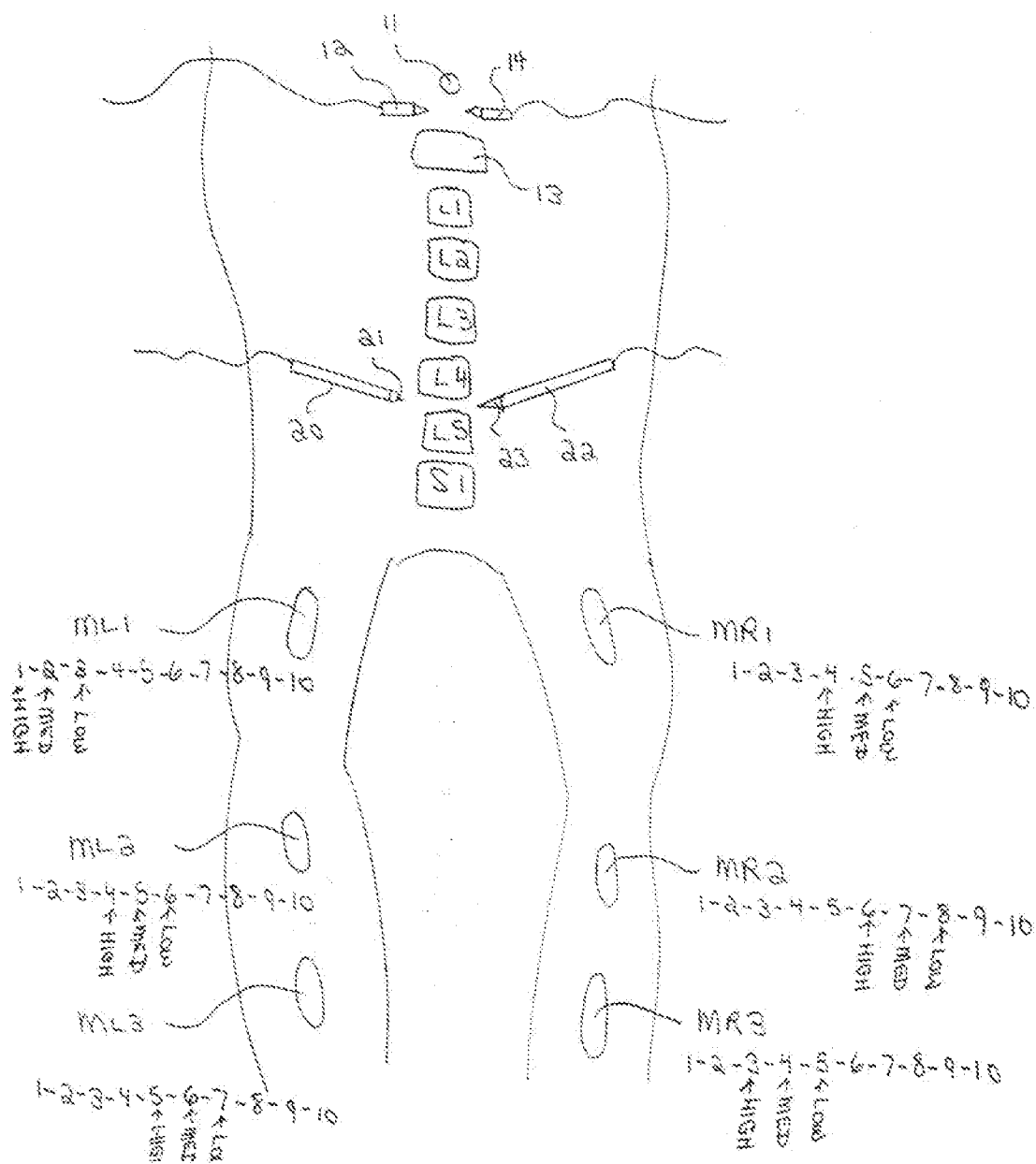
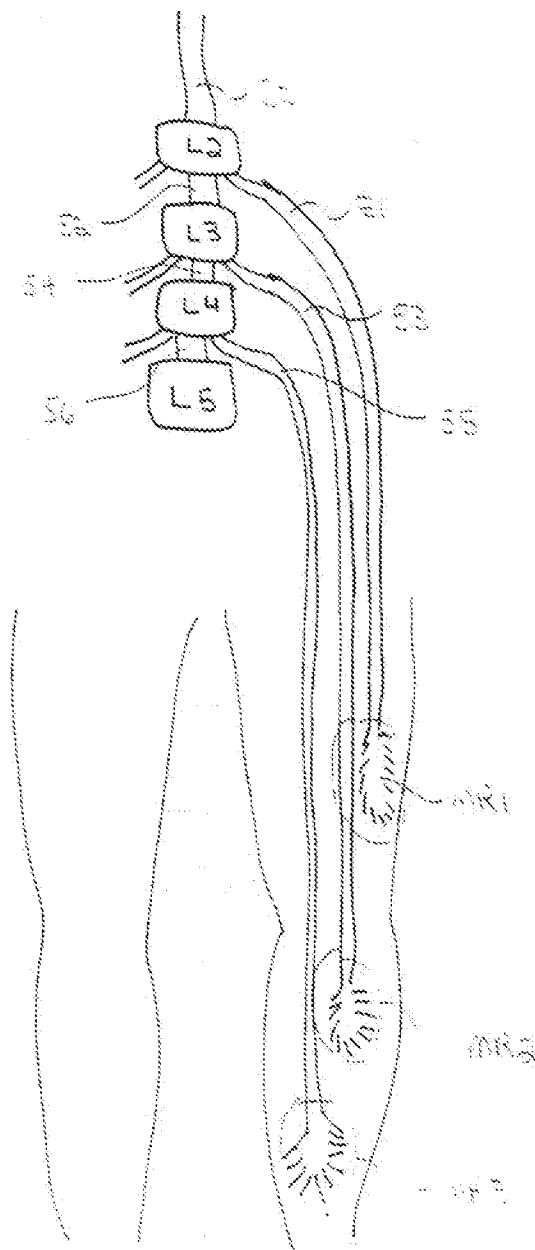
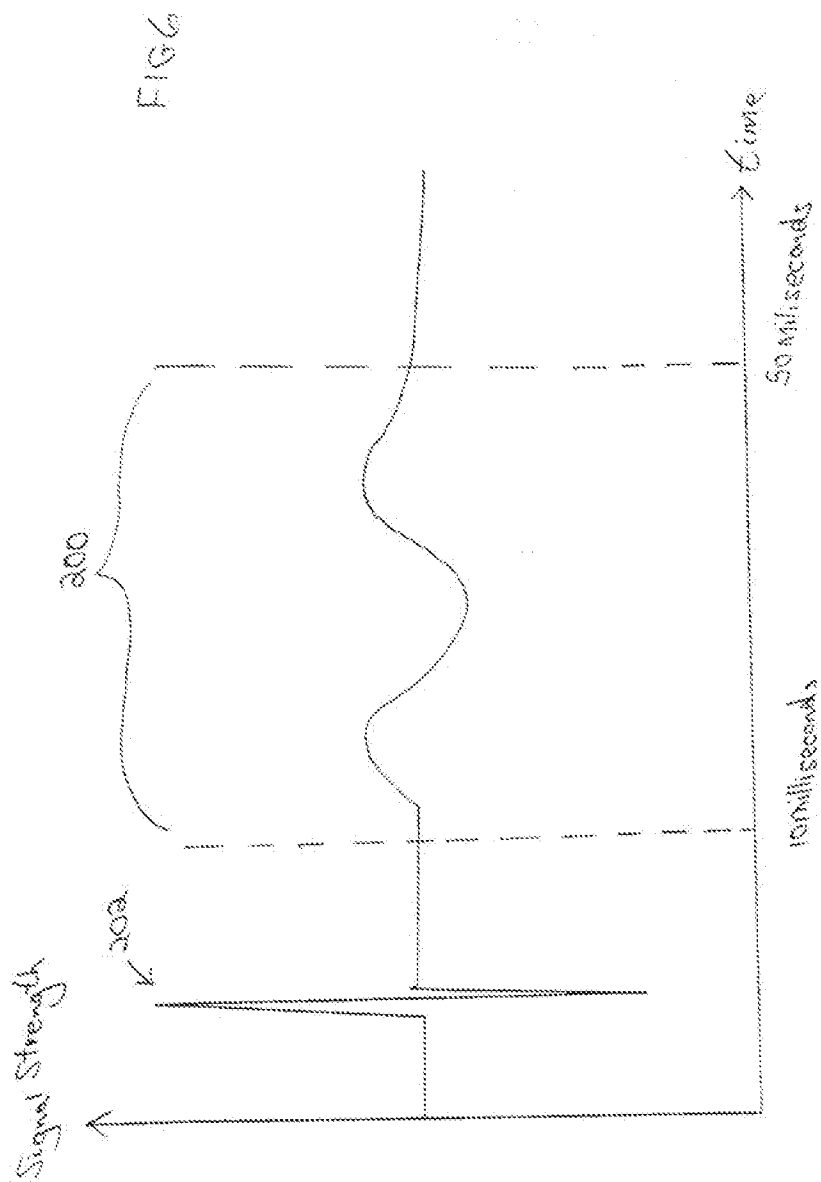


FIG 4



Page 5





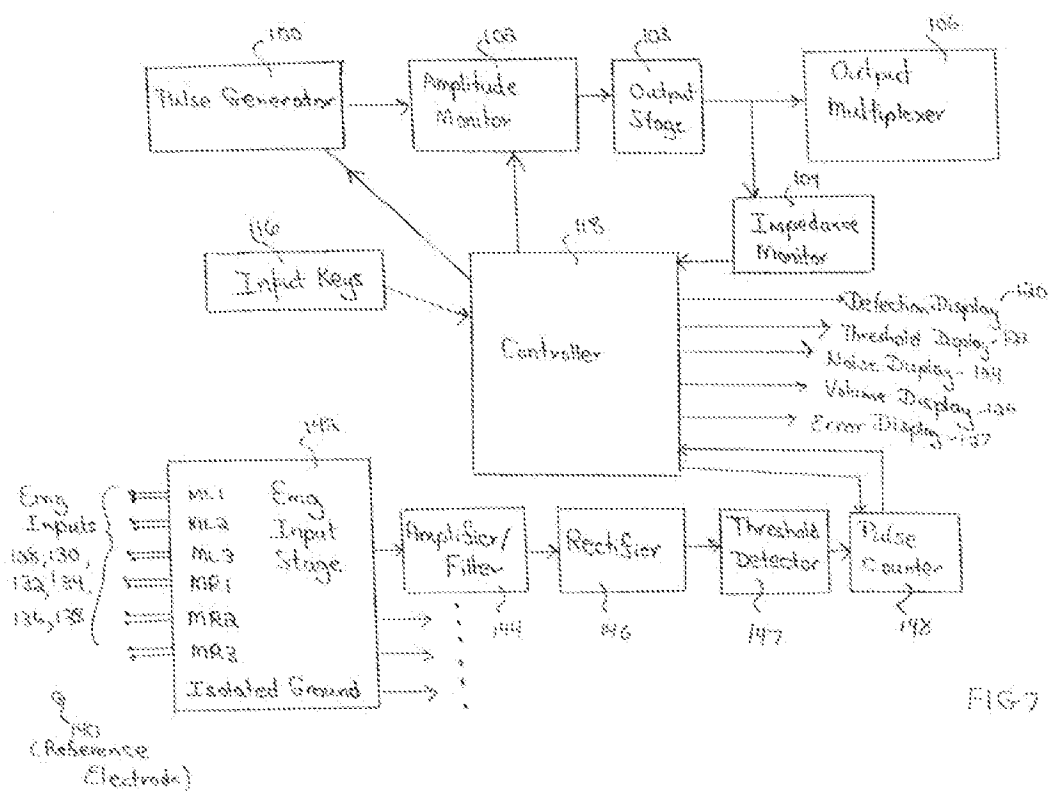
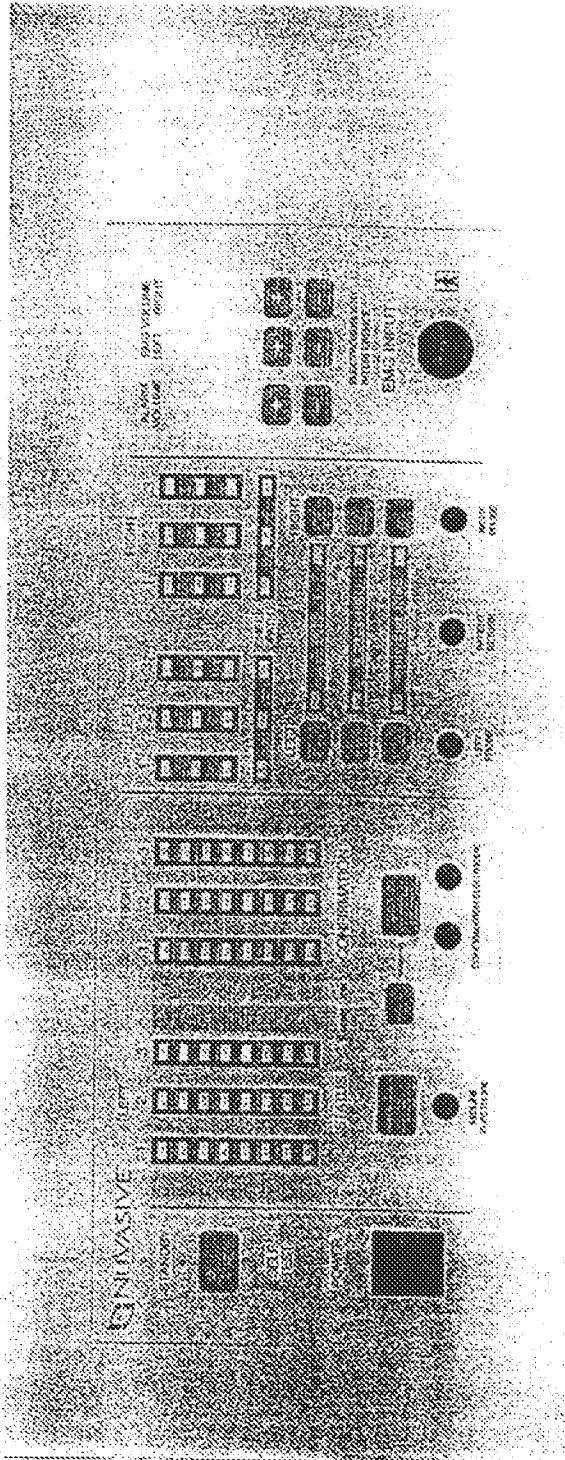


FIG. 7

FIG 8A



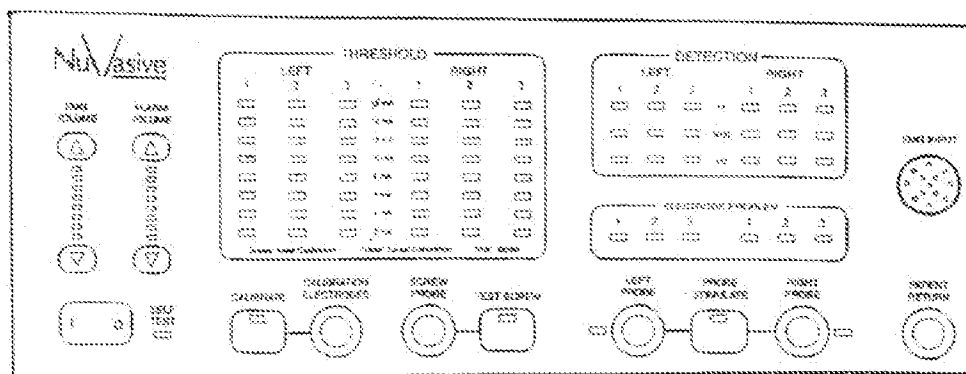


FIG 8B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/32329

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 5/04, 5/05

US CL : 600/546

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/546, 547, 554

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,962,766 A (HERZON) 16 October 1990, see entire document.	1-4,8-12,15, 16,18-22,26-29, 33-50
A	US 5,284,153 A (RAYMOND et al) 08 February 1994, see entire document.	1-4,8-12,15, 16,18-22,26-29, 33-50
A	US 5,775,331 A (RAYMOND et al) 07 July 1998, see entire document.	1-4,8-12,15, 16,18-22,26-29, 33-50



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	* Y	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* X document defining the general state of the art which is not considered to be of particular relevance	* X	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* E earlier document published on or after the international filing date	* Y	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is questioned with one or more other such documents, such combinations being obvious to a person skilled in the art
* L document which may throw doubt on priority (date(s)) or which is cited to establish the publication date of another citation or other special reason (as specified)		
* O document referring to an oral disclosure, use, exhibition or other means	* X	document member of the same patent family
* P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

26 MARCH 2001

Date of mailing of the international search report

27 APR 2001

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

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Authorized officer

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/22329

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,779,642 A (NIGHTENGALE) 14 July 1998, see entire document.	1-4, 8-12, 15, 16, 18-22, 26-29, 33-50

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US90/23329

B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

EAST

search terms: spinal nerve, depolarizing, cauda equina, EMG, neuromuscular response, current intensity, status, location, probe, cannula, needle, tool, electrode

INTERNATIONAL SEARCH REPORT
Form PCT/ISA/210 (continuation of first sheet(1)) (July 1998)

International application No.
PCT/US00/32329

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 5-7,13,14,17,23-25,30-32
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(s).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.



Espacenet

Bibliographic data: JP2001510702 (A) — 2001-08-07
CLUSTER ABLATION ELECTRODE SYSTEM
Inventor(s):
Applicant(s):

Classification: - international: A61B18/14; A61B17/00; A61B18/00; A61B18/02; (IPC1-7): A61B18/14
 - cooperative: A61B18/14; A61B18/1477; A61B2017/00084; A61B2018/00011; A61B2018/00023; A61B2018/0016; A61B2018/00434; A61B2018/00702; A61B2018/00744; A61B2018/00791; A61B2018/00875; A61B2018/025; A61B2018/1253; A61B2018/143

Application number: JP20000503777 19980724

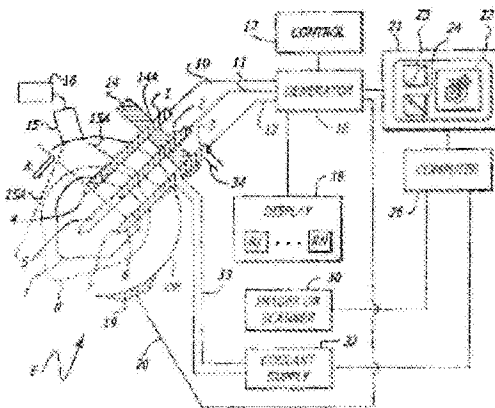
Priority number(s): US19970900682 19970725 ; WO1998US15435 19980724

Also published as: JP4203224 (B2) WO9904710 (A1) AU752140 (B2) AU8512998 (A) CA2297846 (A1) more

Abstract not available for JP2001510702 (A)

Abstract of corresponding document: WO9904710 (A1)

A multiplicity of high frequency electrodes in a cluster configuration may be inserted into tissue of a patient's body for producing heat ablation of abnormal tissue such as a tumor. The electrodes are connected coherently to the voltage output of a high frequency generator. An enlarged ablation volume is accomplished by the electrode cluster with reduced risk of hemorrhage because of the smaller diameter of the individual electrodes of the cluster. The electrodes terminate in conductive tips, which are cooled by a fluid coolant to further facilitate enlarged ablation volumes. Very large ablation volumes



are accomplished by this process and apparatus. Various cluster electrode configurations may be adapted to meet specific clinical requirements.

【公報種別】特許法第17条の2の規定による補正の掲載

【部門区分】第1部門第2区分

【発行日】平成18年1月5日(2006.1.5)

【公表番号】特表2001-510702(P2001-510702A)

【公表日】平成13年8月7日(2001.8.7)

【出願番号】特願2000-503777(P2000-503777)

【国際特許分類】

A61B 18/14 (2006.01)

【F I】

A61B 17/39 317

【手続補正書】

【提出日】平成17年7月25日(2005.7.25)

【手続補正1】

【補正対象書類名】明細書

【補正対象項目名】特許請求の範囲

【補正方法】変更

【補正の内容】

【特許請求の範囲】

【請求項1】

患者の目標体内組織内のコヒーレント高周波熱アブレーションボリュームを誘発するため高周波発電機(16)とともに使用する集合電極システムであって、

患者の前記目標体内組織へ挿入するように構成され、それぞれが導電性チップ(4、5、6)まで延びる複数の電極(1、2、3)であって、

各電極(1、2、3)が前記高周波発電機(16)に電気的に接続されており、前記高周波発電機(16)からの出力電圧を各導電性チップ(4、5、6)に供給し、これによって前記目標体内組織にコヒーレント加熱効果を誘発するようになった、電極を備えた集合電極システムにおいて、

各電極が中空で、シールされた導電性チップをゆうしており、内部で流体の循環を許容するようになっていることを特徴とする集合電極システム。

【請求項2】

各電極(1、2、3)が、絶縁された外部表面の部分有する剛性シャフトであり、前記導電性チップ(4、5、6)が前記それぞれの電極(1、2、3)の先端部に接続されていることを特徴とする請求項1に記載の集合電極システム。

【請求項3】

少なくとも2つの電極(40、41)が実質的に平行と斜行のいずれかの形態として与えられていることを特徴とする上記いずれかの請求項に記載の集合電極システム。

【請求項4】

少なくとも3つの電極(46、47および48)が実質的に平面上および三角形状のいずれかで配置されていることを特徴とする上記いずれかの請求項に記載の集合電極システム。

【請求項5】

少なくとも4つの電極(42-45または、50、51、53および54)が実質的に平面上および矩形形状のいずれかで配置されていることを特徴とする上記いずれかの請求項に記載の集合電極システム。

【請求項6】

少なくとも5つの電極(58-62)が実質的に平面上および五角形状のいずれかで配置されていることを特徴とする上記いずれかの請求項に記載の集合電極システム。

【請求項7】

さらに各電極（1、2、3）を介して冷媒を循環させる冷却システムを備えており、
前記冷却システムが、
冷媒源（32）と、

害冷媒源（32）から各電極（1、2、3）の内部に延び、前記導電性チップ部分（4、5、6）の内部に冷媒を導入する内部流通管（144）と、前記導電性チップ部分から冷媒を排出するための出口ポート（143）とを有することを特徴とする上記いずれかの請求項に記載の集合電極システム。

【請求項8】

前記導電性チップ（4、5、6）が実質的に互いに平行でありかつ隣接する導電性チップ（4、5、6）の任意のペアが任意の導電性チップ（4、5、6）の断面の大きさの10倍より大きくない距離だけ隔離していることを特徴とする上記いずれかの請求項に記載の集合電極システム。

【請求項9】

各電極（1、2、3）が実質的に互いに平行であり、かつ直径が3mmを超えないものであり、各電極（1、2、3）が電極（1、2、3）の平行面の方向に対して垂直な平面によって規定される15mmの円の範囲内に位置していることを特徴とする上記いずれかの請求項に記載の集合電極システム。

【請求項10】

さらに前記電極（1、2、3）を前記目標の体内組織に指向させるガイド（14）を備えていることを特徴とする上記いずれかの請求項に記載の集合電極システム。



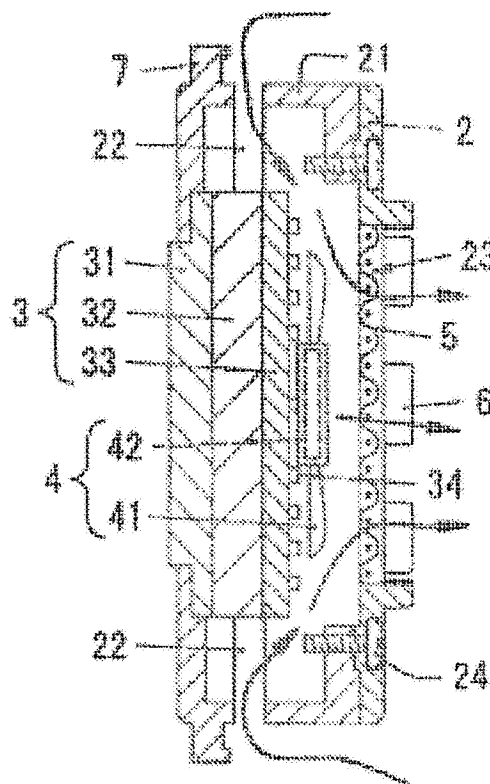
Espacenet

Bibliographic data: JP2000342617 (A) — 2000-12-12
PAIN ALLAYING APPARATUS AND PROBE USING THE SAME

Inventor(s): HATTORI EIICHI ± (HATTORI EIICHI)
Applicant(s): HATTORI HEATING KOGYO KK ± (HATTORI HEATING KOGYO KK)
Classification: - international: A61F7/00; (IPC1-7): A61F7/00
 - cooperative:
Application number: JP20000099202 20000331
Priority number(s): JP20000099202 20000331 ; JP19990095743 19990402

Abstract of JP2000342617 (A)

PROBLEM TO BE SOLVED: To impart a required stimulation to a patient to effectively allay the pain of the patient in an artificial dialysis or the like where an injection needle is continuously pierced for a long time by reversing the direction of the DC carried to a Peltier element built in a probe at a prescribed time interval, and alternately repeating warming and cooling. **SOLUTION:** A probe 2 connected to a treatment apparatus body to warm and cool a lesion is provided with a warming and cooling block 3 and a radiating means 4 within a frame body 21. The warming and cooling block 3 has a heat receiving plate 31 to be directly touched to the affected part, a Peltier element 32 for warming and cooling it, and a heat panel 33 for radiating the heat. The radiating means 4 has a motor 41 and a fan 42 connected thereto. When the direction of the DC carried to the Peltier element 32 is reversed at a prescribed



time interval, and the fan 41 is rotated only in the cooling of the heat receiving plate 31 in order to operate the heat receiving plate 31 in a rhythm mode, a well-modulated stimulation consisting of warming and cooling can be imparted to the affected part touched to the heat receiving plate 31 to allay the pain.

✖

(19) 日本国特許庁 (J P)

(12) 公開特許公報 (A)

(11) 特許出願公開番号
特開2000-342617
(P2000-342617A)

(43) 公開日 平成12年12月12日 (2000. 12. 12)

(51) Int.Cl. ⁷	識別記号	F I	テーマコード* (参考)
A 6 1 F 7/00	3 1 0	A 6 1 F 7/00	3 1 0 J 4 C 0 9 9

審査請求 未請求 請求項の数9 O L (全 11 頁)

(21) 出願番号 特願2000-99202(P2000-99202)
(22) 出願日 平成12年3月31日(2000. 3. 31)
(31) 優先権主張番号 特願平11-95743
(32) 優先日 平成11年4月2日(1999. 4. 2)
(33) 優先権主張国 日本 (J P)

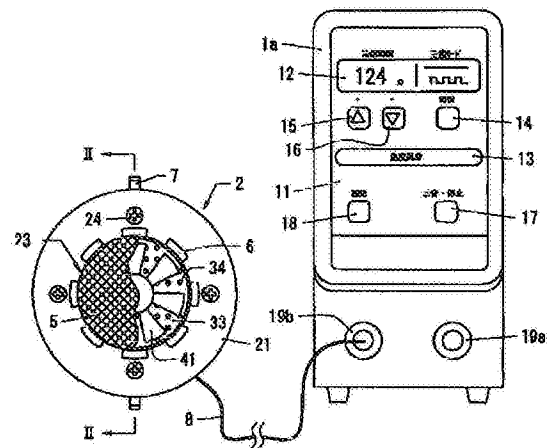
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服部ヒーティング工業株式会社
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Fターム(参考) 4C099 AA03 CA19 CA20 EA02 GA30
JA02 LA21 NA02 PA01 PA06

(54) 【発明の名称】 疼痛緩和器、及びこれに用いたプローブ

(57) 【要約】

【課題】 ペルチェ素子を用いて治療患部を加温又は冷却するものでは、加温又は冷却だけの刺激であったため、特に長時間注射針を刺した状態での疼痛を和らげるには刺激が単調で、治療効果が不十分であった。

【解決手段】 本発明は、疼痛治療患部に当てる受熱板31の加温と冷却とを交互に繰り返すリズムモードを設けた。前記リズムモードでの運転時に前記ペルチェ素子32に流す直流電流の向きを所定時間間隔で反転させるように制御する。



【特許請求の範囲】

【請求項1】 ペルチェ素子の温熱又は冷熱が伝達される受熱板によって疼痛患部を加温又は冷却して刺激を与える疼痛緩和器であって、

前記ペルチェ素子を内蔵し、前記受熱板を露出させたプローブと、

前記ペルチェ素子に流す直流電流の向きを所定の時間間隔で反転させることにより加温と冷却とを所定の時間間隔で交互に繰り返すリズムモード運転を実行する制御部とを備えたことを特徴とする疼痛緩和器。

【請求項2】 請求項1に記載の疼痛緩和器において、前記制御部は、前記リズムモード運転における加温と冷却との時間間隔となる加温時間と冷却時間を設定する設定部を具備することを特徴とする疼痛緩和器。

【請求項3】 ペルチェ素子の温熱又は冷熱が伝達される受熱板によって疼痛患部を加温又は冷却して刺激を与える疼痛緩和器であって、

前記ペルチェ素子を内蔵し、前記受熱板を露出させた複数のプローブと、

前記複数のプローブそれぞれについて、加温のみ又は冷却のみとする連続モード運転とするか、加温と冷却とを所定の時間間隔で繰り返すリズムモード運転とするかの選択を行う切替部と、

前記複数のプローブそれぞれについて、前記切替部で選択した運転モードにおける治療温度および治療時間の設定を行う条件設定部と、

前記複数のプローブそれぞれについて、前記条件設定部で設定した治療温度および治療時間に基づいて前記切替部で選択した運転モードの実行を前記プローブに指示する指示部とを備えたことを特徴とする疼痛緩和器。

【請求項4】 請求項3に記載の疼痛緩和器において、前記切替部と前記条件設定部とによって一のプローブの条件設定が完了すると、次のプローブについての条件設定に移行させる移行部を備えたことを特徴とする疼痛緩和器。

【請求項5】 請求項1ないし4のいずれかに記載の疼痛緩和器において、

前記受熱板の実際温度が設定温度に対して一定範囲を超えた場合に運転を停止させる安全装置を備えたことを特徴とする疼痛緩和器。

【請求項6】 ペルチェ素子の温熱又は冷熱が伝達される受熱板によって疼痛患部を加温又は冷却して刺激を与える疼痛緩和器に用いられ、前記ペルチェ素子を内蔵し、前記受熱板を露出させたプローブであって、

全体が扁平で把持可能に形成され、その側部に空気取入口を設け且つ上面部に空気排出口を設けた棒本体と、

前記棒本体内部に収容され、前記ペルチェ素子を内蔵する温冷ブロックと、

前記棒本体内部に収容され、前記温冷ブロック上に配置された放熱手段と、

前記棒本体上面部の空気排出口を覆うように取付けた保護網とを備え、

前記温冷ブロックは、前記棒本体底面部から露出させて疼痛患部を加温又は冷却する受熱板と、この受熱板の上面に配置されて受熱板に温熱又は冷熱を伝達するペルチェ素子と、このペルチェ素子の上面に配置されてペルチェ素子の上面部の温熱又は冷熱を放散させるヒートパネルとを具備し、

前記放熱手段は、前記ヒートパネル周辺の空気を循環させるファンと、このファンを駆動する駆動モータとを具備することを特徴とするプローブ。

【請求項7】 請求項6に記載のプローブにおいて、前記棒本体は、その上面部の空気排出口を囲うように所定ピッチで形成した複数の突起を有することを特徴とするプローブ。

【請求項8】 ペルチェ素子の温熱又は冷熱が伝達される受熱板によって疼痛患部を加温又は冷却して刺激を与える疼痛緩和器に用いられ、前記ペルチェ素子を内蔵し、前記受熱板を露出させたプローブであって、

全体が扁平で把持可能に形成され、前部を円弧状の丸み部とし後部を前記丸み部に連続形成する略矩形形状の矩形部とする棒本体と、

前記棒本体の側部に設けた空気取入口と、

前記棒本体の丸み部の上面部に設けた複数の空気排出小窓と、

前記棒本体の矩形部における対向する側部に各々設けたブリッジ状のバンド取付け部と、

前記棒本体内部の丸み部に収容され、前記ペルチェ素子を内蔵する温冷ブロックと、

前記棒本体内部の丸み部に収容され、前記温冷ブロック上に配置された放熱手段とを備え、

前記温冷ブロックは、前記棒本体底面部から露出させて疼痛患部を加温又は冷却する受熱板と、この受熱板の上面に配置されて受熱板に温熱又は冷熱を伝達するペルチェ素子と、このペルチェ素子の上面に配置されてペルチェ素子の上面部の温熱又は冷熱を放散させるヒートパネルとを具備し、

前記放熱手段は、前記ヒートパネル周辺の空気を循環させるファンと、このファンを駆動する駆動モータとを具備することを特徴とするプローブ。

【請求項9】 請求項6ないし8のいずれかに記載のプローブにおいて、

前記温冷ブロックのヒートパネルは、その表面に複数の放熱用突起を有することを特徴とするプローブ。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】本発明は、ペルチェ効果を利用した疼痛緩和器の技術分野に属し、特に、人工透析、点滴、輸血時等の注射針を長時間刺した状態にある場合その注射針を刺している患部を加温又は冷却して刺激を

与えることで疼痛を和らげる疼痛緩和器及びこれに用いたプローブに関するものである。

【0002】

【従来の技術】従来、ペルチェ素子を用いた治療器として、例えば、特開平7-24000号公報に開示されたものが知られている。図12は、前記公報に記載の治療器における温冷バック40を示し、この温冷バック40は、可撓性シートに複数のペルチェ素子を取付けたパッド30を配置し、これを膝に巻付けて固定し患部を加温するか又は冷却するものである。これは、ペルチェ素子に直流電流を流すことで一方の面が発熱すると共に他方の面が吸熱し、また、電源極性を変えると発熱面と吸熱面とが入れ替ることを利用して、患部の症状に応じて加温又は冷却を行う。また、この温冷バック40は、パッド30上面の発熱を吸収するため、ノズル200を通して冷却水を流すようにしている。

【0003】また、前記公報には、図13に示すように、長細い筒体の先端に形成した指圧突起400を患部に押し当てる温冷マッサージ器が開示されている。このマッサージ器は、指圧突起400にペルチェ素子31を接触させて指圧突起400を加温又は冷却し、また、指圧突起400の冷却時に発熱するペルチェ素子31背面を、放熱ブロック440に接触させ、筒体中央の後方寄り部分に配置したファン460をモータ450にて回転させて放熱する。

【0004】

【発明が解決しようとする課題】しかしながら、前記治療装置は、いずれもペルチェ素子を用いて治療患部を加温するのみ又は冷却するのみであるが、このような加温又は冷却だけの刺激では、特に長時間注射針を刺した状態での疼痛を和らげるには刺激が単調で、治療効果が不十分であった。

【0005】そして、治療患部に接触させる端末部分として、図12に示す可撓性シートを用いたものでは、治療患部の周辺をじわじわ加温又は冷却するものであるため、患部への局所的な加温、冷却が困難であった。また、図13に示す長細い筒体で形成した温冷マッサージ器では、筒体を手で持って患部に押し当てておく必要があるため、その姿勢を長時間保持するのは辛いものであり、長時間注射針を刺した状態での疼痛を和らげるための治療には適さない。

【0006】ところで、人工透析では体から取り出した血液をダイアライザ（人工腎臓）で濾した後に体の中に戻すので、体に刺す針は血液の取り出し側と戻し側の2本必要となる。体から血液を取り出すにはある程度の血流量が必要である。この場合、血液の取り出し側の針を動脈に刺すとよいが、動脈刺しは非常に痛みを伴うので、実際は痛みの少ない静脈に針を刺す。そして、通常は手術で手首周辺の動脈と静脈の一部をつなげたシャントというものをつくり、動脈の血液が静脈に流れ込むよ

うにしてその静脈の血流量が多くなるようにしている。しかしながら、静脈刺しの痛みが少ないといっても、週に3、4回で、1回につき3、4時間かかる人工透析のたびに疼痛を我慢するのは非常に辛いことである。本発明は、上記事情に鑑みてなされたものであり、人工透析時等の注射針を長時間刺した状態にある場合その疼痛を和らげるのに効果的な刺激を与えるための疼痛緩和器及びこれに用いたプローブを実現することをその課題とする。

【0007】

【課題を解決するための手段】前述した課題を解決するために講じた本発明の技術的手段は、『ペルチェ素子の温熱又は冷熱が伝達される受熱板によって疼痛患部を加温又は冷却して刺激を与える疼痛緩和器であって、前記ペルチェ素子を内蔵し、前記受熱板を露出させたプローブと、前記ペルチェ素子に流す直流電流の向きを所定の時間間隔で反転させることにより加温と冷却とを所定の時間間隔で交互に繰り返すリズムモード運転を実行する制御部とを備えたことを特徴とする疼痛緩和器』である。

【0008】前記技術的手段は、次のように作用する。前記制御部によるリズムモード運転においてペルチェ素子に流す直流電流の向きを所定の時間間隔で反転させるように制御することにより、疼痛患部に当てる受熱板の加温と冷却との切替え応答を素早くできる。これにより、受熱板の加温と冷却との交互変化が敏感に行われ、そのため、前記受熱板を当てた疼痛患部における末端神経を敏感に刺激し血行を促進させることができる。すなわち、加温時には血管が膨張し冷却時には血管が収縮するが、例えば加温時間を長く冷却時間を短くすると、冷却による血管収縮が適度な刺激となって加温による血管膨張時の血行をより一層促進させることができる。

【0009】前記技術的手段において、『前記制御部は、前記リズムモード運転における加温と冷却との時間間隔となる加温時間と冷却時間を設定する設定部を具備する』ものでは、疼痛患部の症状に応じて加温と冷却との時間間隔を設定することができ、従って、疼痛患部の症状に応じた治療を行うことができる。

【0010】また、他の技術的手段としては、『ペルチェ素子の温熱又は冷熱が伝達される受熱板によって疼痛患部を加温又は冷却して刺激を与える疼痛緩和器であって、前記ペルチェ素子を内蔵し、前記受熱板を露出させた複数のプローブと、前記複数のプローブそれぞれについて、加温のみ又は冷却のみとする連続モード運転とするか、加温と冷却とを所定の時間間隔で繰り返すリズムモード運転とするかの選択を行う切替部と、前記複数のプローブそれぞれについて、前記切替部で選択した運転モードにおける治療温度および治療時間の設定を行う条件設定部と、前記複数のプローブそれぞれについて、前記条件設定部で設定した治療温度および治療時間に基

いて前記切替部で選択した運転モードの実行を前記プローブに指示する指示部とを備えたことを特徴とする疼痛緩和器』である。

【0011】前記技術的手段によると、複数のプローブを備えるので、例えば人工透析で2本の針を刺したそれぞれの疼痛患部にプローブを当てることができる。そして、前記切替部、前記設定部、前記指示部によって複数のプローブのそれぞれに別の運転モードやその運転モードでの治療温度および治療時間の設定、その実行が行えるので、2本の針を刺した各疼痛患部に応じて各々のプローブを動作制御できる。例えば、血液の取り出し側での針を刺した疼痛患部におけるプローブは加温と冷却を繰り返すリズムモード運転とし、血液の戻し側での針を刺した疼痛患部におけるプローブは加温のみの連続モード運転とする等、種々のバリエーションを実現できる。これにより、人工透析時の2本の針を刺した各疼痛患部の末端神経を刺激して血行を促進させることにより、各疼痛患部の痛み具合に応じて適切にその痛みを和らげることができる。

【0012】一方、前記複数のプローブのそれぞれを別々の患者にあてがうこともできる。この場合も、複数の患者の個々の痛み具合に応じて各プローブを動作制御すれば、複数の患者に対して同時に疼痛を和らげることも可能である。

【0013】前記技術的手段において、『前記切替部と前記条件設定部とによって一のプローブの条件設定が完了すると、次のプローブについての条件設定に移行させる移行部を備えた』ものによると、一のプローブの条件設定が完了するまでは次のプローブの条件設定ができないので、各プローブの条件設定を誤りなく行える。

【0014】前記各技術的手段において、『前記受熱板の実際温度が設定温度に対して一定範囲を超えた場合に運転を停止させる安全装置を備えた』ものでは、運転中に何らかのトラブルが発生して温度異常が起こっても直ちに運転が停止されるから、万一火傷などを負うようなことも防止できる。

【0015】次に、疼痛緩和器に用いたプローブにおける発明の技術的手段としては、『ペルチェ素子の温熱又は冷熱が伝達される受熱板によって疼痛患部を加温又は冷却して刺激を与える疼痛緩和器に用いられ、前記ペルチェ素子を内蔵し、前記受熱板を露出させたプローブであって、全体が扁平で把持可能に形成され、その側部に空気取入口を設け且つ上面部に空気排出口を設けた棒本体と、前記棒本体内に収容され、前記ペルチェ素子を内蔵する温冷ブロックと、前記棒本体内に収容され、前記温冷ブロック上に配置された放熱手段と、前記棒本体上面部の空気排出口を覆うように取付けた保護網とを備え、前記温冷ブロックは、前記棒本体底面部から露出させて疼痛患部を加温又は冷却する受熱板と、この受熱板の上面に配置されて受熱板に温熱又は冷熱を伝達するペ

ルチェ素子と、このペルチェ素子の上面に配置されてペルチェ素子の上面部の温熱又は冷熱を放散させるヒートパネルとを具備し、前記放熱手段は、前記ヒートパネル周辺の空気を循環させるファンと、このファンを駆動する駆動モータとを具備することを特徴とするプローブ』である。

【0016】前記プローブによれば、その全体が扁平で把持可能な棒本体で形成されているので、このプローブを手にとって容易に扱える。従って、楽な姿勢で手軽に所望の疼痛患部にプローブの受熱板を当てることができる。

【0017】また、前記温冷ブロックは、ペルチェ素子において受熱板を配置した反対側にヒートパネルを配置するので、このヒートパネルによって受熱板と異なる温熱又は冷熱を効率よく放散させることができる。これにより、ペルチェ素子から受熱板への熱伝導を効率良く行うことができる。特に、受熱板の冷却時には、ヒートパネル上に配置した前記放熱手段のファンを回転させ、棒本体側部の空気取入口から空気を取込むと共に棒本体上面部の空気排出口から空気を排出して空気循環させることにより、ヒートパネルへ放散させたペルチェ素子の熱を効果的に放熱できる。従って、プローブの受熱板の温冷変化に一層のめりはりを付けることができ、これにより、リズムモード運転時に患部の血行をより一層促進させ、人工透析時等の疼痛を和らげるのに非常に効果的なものが得られる。さらに、前記棒本体上面部の空気排出口は、保護網で覆っているため、指をファンに巻き込んだりすることも確実に防止できる。

【0018】前記プローブにおける発明の技術的手段において、『前記棒本体は、その上面部の空気排出口を囲うように所定ピッチで形成した複数の突起を有する』ものでは、プローブを疼痛患部に固定した状態で上から服などを羽織っても空気排出口を塞いでしまうことがない。従って、前記空気排出口からの排気を円滑に行うことができ、前記ヒートパネルの放熱を低下させるようなことを防止できる。

【0019】また、プローブにおける発明の他の技術的手段としては、『ペルチェ素子の温熱又は冷熱が伝達される受熱板によって疼痛患部を加温又は冷却して刺激を与える疼痛緩和器に用いられ、前記ペルチェ素子を内蔵し、前記受熱板を露出させたプローブであって、全体が扁平で把持可能に形成され、前部を円弧状の丸み部とし後部を前記丸み部に連続形成する略矩形の矩形部とする棒本体と、前記棒本体の側部に設けた空気取入口と、前記棒本体の丸み部の上面部に設けた複数の空気排出小窓と、前記棒本体の矩形部における対向する側部に各々設けたブリッジ状のバンド取付け部と、前記棒本体内の丸み部に収容され、前記ペルチェ素子を内蔵する温冷ブロックと、前記棒本体内の丸み部に収容され、前記温冷ブロック上に配置された放熱手段とを備え、前記温冷ブ

ロックは、前記棒本体底面部から露出させて疼痛患部を加温又は冷却する受熱板と、この受熱板の上面に配置されて受熱板に温熱又は冷熱を伝達するペルチェ素子と、このペルチェ素子の上面に配置されてペルチェ素子の上面部の温熱又は冷熱を放散させるヒートパネルとを具備し、前記放熱手段は、前記ヒートパネル周辺の空気を循環させるファンと、このファンを駆動する駆動モータとを具備することを特徴とするプローブである。

【0020】このものによると、前述のものと同様の効果を有する他に、棒本体後部の円弧状の丸み部を手のひらで包み込むようにし、且つ、棒本体前部の略矩形状の矩形部を親指と人差し指等で挟むようにすることで、このプローブを手を持って一層容易に扱える。また、棒本体上面部の複数の空気排出小窓からファンによって空気を排出させるが、これら空気排出小窓は指を侵入させない大きさに設定されるから、指が棒本体内部のファンに巻き込まれる心配もない。さらに、前記棒本体の矩形部における対向側部に各々設けたブリッジ状のバンド取付け部にバンドを取付け、プローブを疼痛治療患部に配置させた後、前記バンドを腕にまわしておけば、該プローブを腕の疼痛治療患部に安定して固定しておくことができる。

【0021】前記プローブにおける各技術的手段において、『前記加温手段のヒートパネルは、その表面に複数の放熱用突起を有する』ものでは、この複数の放熱用突起によってヒートパネルの表面積を増加させることができ、これにより、ヒートパネルの放熱をさらに向上させることができる。

【0022】

【発明の効果】本発明は、前記構成であるから次の特有の効果を有する。本発明の疼痛緩和器によれば、リズムモード運転により受熱板の加温と冷却との変化が交互に敏感に行われるため、この受熱板を当てた疼痛患部に加温、冷却のめりはりのある刺激を与え、患部の末端神経を敏感に刺激して血行を促進させることができる。従って、人工透析時等の注射針を長時間刺した状態にある場合に疼痛患部の血行を促進してその疼痛を和らげるのに効果的なものが得られる。

【0023】そして、複数のプローブを備えることで、人工透析時に2本の針を刺した各疼痛患部の痛み具合に応じて適切にその痛みを和らげることができ、また、同時に複数の患者に対して疼痛を和らげることも可能である。また、前記プローブによれば、その全体が扁平で把持可能な棒本体で形成されているので、このプローブを手を持って容易に扱えるから、楽な姿勢で手軽に所望の疼痛患部にプローブの受熱板を当てることができる。

【0024】

【発明の実施の形態】以下に、本発明の実施の形態について図面を参照しながら説明する。図1は、本発明の実施の形態による疼痛緩和器を示す平面図、図2は、図1

に示すプローブ2のI-I断面図、図3は、前記プローブ2の側面図、図4は、前記プローブ2の底面図である。

【0025】本実施の形態の疼痛緩和器は、図1に示すように、後述の制御部を有する治療器本体1と、この治療器本体1とコード線8で繋がれ、疼痛患部に当てて加温、冷却するプローブ2とを備えたものである。

【0026】前記治療器本体1は、前面の操作パネル11には、左側に治療時間などを表示する時間表示部と右側に治療モードを表示するモード表示部とを有する表示パネル12と、治療時間や治療温度の設定を行うための設定ボタン15、16と、連続モードとリズムモードとの運転モードの切替えを行うための切替ボタン14と、温度異常を表示する温度異常表示パネル13と、治療を開始するための開始ボタン18と、治療終了を知らせるブザーの停止や運転モード・設定モードの切替えを行うための消音・停止ボタン17とを有する。また、前記操作パネル11の下方には、プローブ2に繋がれたコード線8を接続するためのコネクタ部19a、19bが2つ設けられている。なお、本実施の形態では、コネクタ部19を2箇所所有するが、1箇所でも良く、3箇所以上設けても良い。

【0027】前記プローブ2は、図1、図2を参照して、全体が扁平円筒状で把持可能な棒本体21で形成されている。この棒本体21は、上面の蓋体を胴体にネジ24にて4個所のネジ止めで固定されたものである。前記棒本体21の側部には、図3に示すように、スリット状の空気取入口22が形成されており、また、この空気取入口22より底部寄りには、相対向する位置にそれぞれ1個ずつ係止ピン7が形成されている。この係止ピン7は、上方に向いた爪が形成されている。棒本体21の上面には、円形の空気排出口23が設けられ、この空気排出口23は保護網5が被せられている。前記空気排出口23の周囲には、この空気排出口23を囲うように所定ピッチで8個の突起6が形成されている。また、棒本体21内部には、図2に示すように、温冷ブロック3と、この温冷ブロック3の上に取付けられた放熱手段4とを備える。

【0028】前記温冷ブロック3は、治療患部と接触させる受熱板31、この受熱板31の加温と冷却を行うペルチェ素子32、及びこのペルチェ素子32の熱を放散させるヒートパネル33を有する。受熱板31は、図4に示すように、棒本体21底面部から円形状に露出させて、ここに疼痛治療患部を当ててその患部を加温又は冷却する。なお、この受熱板31には、図示していないがその実際の温度を検知する温度センサが取付けられている。また、ヒートパネル33の上面部には、無数の放熱用突起34が形成されている。前記放熱手段4は、モータ41、及びこのモータ41に連結するファン42を有する。なお、このモータ41への給電は、治療器本体1

を接続する電源Vからコード線8を通じて行われる。

【0029】次に、前記治療器本体1内の回路構成を説明する。図5は、前記治療器本体1の回路構成を示すブロック図である。図5に示すように、治療器本体1は、制御部100、表示部104、及び安全装置105を有する。前記制御部100には、切替部101、設定部102、及び指示部103を有する。

【0030】前記切替部101は、前記プローブ2の受熱板31を、加温のみ又は冷却のみとする連続モードで運転するか、又は加温と冷却とを所定の時間間隔で交互に繰り返すリズムモードで運転するかを選択するものである。この切替部101による運転モードの選択は、図1に示す操作パネル11の切替ボタン14を通じて行われる。

【0031】前記設定部102は、前記切替部101の情報が入力され、各運転モードにおける治療温度や治療時間が設定される。治療温度としては、例えば、20℃～45℃の範囲で0.1℃単位に設定できる。また、治療時間としては、連続モードでは、例えば、1～99分の範囲で1分単位に設定でき、リズムモードでは、例えば、加温時間と冷却時間とは、いずれも1～999秒の範囲で1秒単位に設定できる。このリズムモードにおける加温時間と冷却時間を設定することにより、その設定時間ごとに加温と冷却とを交互に繰り返すこととなる。この設定部102における条件設定は、図1に示す操作パネル11の設定ボタン15、16を通じて行われる。なお、具体的な情報の設定動作は、後述する。

【0032】前記指示部103は、前記設定部102からの設定条件に基づいた運転モードの実行を前記プローブ2に指示するものである。そして、プローブ2の受熱板31を連続モードで運転する場合は、電源Vから電源を取り出し前記ベルチエ素子32に一定方向の直流電流を流すように指示する。また、プローブ2の受熱板31をリズムモードで運転する場合は、電源Vから電源を取り出し前記ベルチエ素子32に流す直流電流の向きを所定の時間間隔で反転させるように指示する。すなわち、加温から冷却、冷却から加温への切り替わりは、前記ベルチエ素子32に流す直流電流の向きを変えることにより行われる。これは、ベルチエ素子32に直流電流を流すことで一方の面が発熱すると共に他方の面が吸熱し、また、電源極性を変えると発熱面と吸熱面とが入れ替ることを利用するものである。また、受熱板31の加温時には、前記プローブ2のファン41を回転させないように指示する。すなわち、前記指示部103は、リズムモード運転の際は、前記プローブ2のファン41を受熱板31の加温時に停止させ、受熱板31の冷却時にのみを回転させるように指示する。さらに、連続モード運転の際は、受熱板31を冷却して運転する冷却連続モードでは前記プローブ2のファン41を回転させ、受熱板31を加温して運転する加温連続モードでは前記プローブ2

のファン41を停止させておくように指示する。このような制御を行うのは、受熱板31の加温時には、ベルチエ素子32の受熱板31と反対面側では冷却状態にあり、ヒートパネル33は冷却されるので、あえてファン41を回転させヒートパネル33の冷却を促進させるまでもないからである。

【0033】前記表示部104は、前記設定部102や前記指示部103からの時間や温度を表示させるものである。この表示部104は、図1に示す前記操作パネル11の表示パネル12や温度異常表示パネル13を構成する。

【0034】前記安全装置105は、本疼痛緩和器の運転中に何らかの原因による温度異常、コード線8の脱落や断線などによる温度測定不可能状態などのトラブルが発生した場合に停止させるものである。温度異常として、具体的には、前記受熱板31の実際温度が設定温度に対して±2℃を超えた場合に運転を停止させ、温度異常ランプ13を点滅し、表示パネル12の左側にある時間表示部に「Err」の表示をし、また、治療器本体1に内蔵するブザーを「ブザー……」と鳴らし続ける。なお、受熱板31の実際の温度は、受熱板31に内蔵する温度センサによって検知され、その温度情報が前記制御部100に入力されることで検知する。また、この受熱板31の温度センサに異常が発生した場合も、前記同様に疼痛緩和器の運転を停止させ、同時に前記「Err」の表示と、ブザーを鳴らし続ける。さらに、コード線8の接続異常として、運転開始直後から3秒間、プローブ2のコード線8とのコネクタ部19との接続の良否を前記制御部100が確認し、コネクタ接続に脱落などの異常が発生した場合には直ちに疼痛緩和器の運転を停止させ、同時に前記「Err」の表示と、ブザーを鳴らし続ける。なお、前記ブザー音は、操作パネル11の消音・停止ボタン17を押すことにより、止めることができる。ただし、疼痛緩和器の運転を再開するには、異常の原因を究明し、所望の対処をした後、電源を再投入する必要がある。

【0035】次に、本疼痛緩和器を用いた治療の動作を説明する。図6は、この疼痛緩和器を用いて治療を行っている状態を示す模式図である。まず、設定動作から説明する。この設定動作は、治療器本体1から行われる。疼痛緩和器における操作パネル11の操作環境は、「運転モード」と「設定モード」に分かれ、治療器本体1に電源を入れると「運転モード」が現れる。この「運転モード」では、治療時間と治療モードとを設定する。治療時間を設定するには、図1に示す設定ボタン15、16を押すことで分単位で設定できる。設定する時間は、前記設定ボタン15、16の入力と同期して表示パネル12左側の時間表示部に表示される。なお、この設定ボタン15、16を押し続けると自動的にインクリメント、またはデクリメントされる。

【0036】治療モードを選択するには、図1に示す切替ボタン14を押して連続モード又はリズムモードのいずれかを選択する。この治療モードの表示は、前記表示パネル12右側のモード表示部に表示され、連続モードを示すときは、平坦な直線が表示され、リズムモードを示すときは、クランク状に折れ曲がった曲線が表示される。

【0037】次に、前記「運転モード」から「設定モード」に切替えるには、図1に示す操作パネル11の消音・停止ボタン17を3秒間以上押し続けることにより切り替わる。この「設定モード」では、(1)「連続モード」での治療温度、(2)「リズムモード」での加温温度、(3)「リズムモード」での加温時間、(4)「リズムモード」での冷却温度、(5)「リズムモード」での冷却時間、をそれぞれ設定する。なお、設定単位としては、温度は0.1℃単位で、時間は秒単位で入力される。

【0038】「設定モード」にすると、はじめに前記(1)「連続モード」での治療温度の入力をする表示が前記表示パネル12左側の時間表示部に現れる。その状態で、前記設定ボタン15、16を押して任意の値に設定する。この設定が終わると切替ボタン14を押すと次の(2)「リズムモード」での加温温度の入力に移る。以後、同様にして、(3)「リズムモード」での加温時間、(4)「リズムモード」での冷却温度、(5)「リズムモード」での冷却時間を設定する。

【0039】すべての項目の設定が終了すると自動的に「運転モード」に戻る。なお、前記「設定モード」での設定途中で消音・停止ボタン17を押すと「運転モード」に戻ることができる。以上で、治療動作の設定が終了する。

【0040】次に、本疼痛緩和器を用いた疼痛治療の動作を説明する。以下では、人工透析時等の注射針を腕に長時間刺した状態にある場合を例にして説明する。図6は、本疼痛緩和器の使用状態を示す模式図である。なお、図中では、腕に刺している注射針は省略している。まず、人工透析の注射針を刺している腕の患部に当て物91を被せる。この当て物91としては、図7に示すように、プローブ2の底面形状よりやや大き目に加工したガーゼのような布製シートや紙製シートなどが用いられる。そして、図6に示すように、この当て物91の上から前記プローブ2を当て、プローブ2底面の受熱板31を患部に配置させる。なお、この例では、前記当て物91を敷くようにしているが、プローブ2底面の受熱板31を患部に直接当てるようにしても良い。

【0041】次に、プローブ2を疼痛治療患部に配置させた後、両端部に穴などの係合部を形成した伸縮自在のバンド9を腕にまわして、その両端部の係合部をプローブ2の側面に形成した係止ピン7に引っ掛けることにより、プローブ2を腕の疼痛治療患部に固定させる。なお、前記のようなバンド9でなくても紐を用いても良

い。

【0042】そして、前記治療器本体1の開始ボタン18を押すと、前述の切替ボタン14で設定した運転モードの運転が開始される。すなわち、連続モードを選択したときは前記設定動作で設定した所定温度、治療時間に従い運転され、一方、リズムモードを選択したときは設定した加温温度、加温時間による加温と、設定した冷却温度、冷却時間による冷却とを交互に繰り返して、設定した治療時間に従い運転される。

【0043】治療時間が終わり運転が終了すると、表示パネル12の左側の時間表示部に「END」と表示されると共にブザーが「ブザー、ブザー、・・・」と鳴り続ける。このとき、消音・停止ボタン17を一回押すとブザー音は停止する。この際、もう一度押すと先ほど終了した治療時間を表示し再度「運転モード」での操作が可能となる。なお、本治療器本体1は、最後に操作した「治療モード」「治療時間」「治療温度」を記憶している。これは設定部102の内部メモリに記憶された情報である。従って、再度、前記設定動作を行わない限り同じ運転動作が実行される。

【0044】以上のように、本実施の形態による疼痛緩和器によれば、リズムモードの運転時、前記制御部100によって前記ベルチエ素子32に流す直流電流の向きを所定の時間間隔で反転させるように制御して、疼痛患部に当てる受熱板31の加温と冷却との切替え応答を素早く行う。これにより、加温と冷却との交互の変化が敏感に行われ、そのため、受熱板31を当てた疼痛患部に加温、冷却のめりはりのある刺激を与え、患部の末端神経を敏感に刺激して血行を促進させることができる。特に、加温時間を2～5分、冷却時間を1～2分の範囲で設定することで、末端神経に適度な刺激を与えることができ、かつ刺激が単調となることを防ぐことができる。なお、加温時間に比べて冷却時間を短くしているのは、加温時には血管が膨張して気持ち良くなり、冷却時には血管が収縮して刺激を与えるためである。従って、人工透析時等の注射針を長時間刺した状態にある場合患部の血行を促進してその疼痛を和らげるのに効果的なものが得られる。

【0045】また、切替部101にて受熱板31を加温のみ又は冷却のみで運転する連続モードと、受熱板31を加温と冷却とを交互に繰り返して運転するリズムモードとを選択することができるので、疼痛患部の症状に応じた所望のモードで治療を行うことができる。

【0046】また、前記安全装置103により、運転中に何らかのトラブルが発生して温度異常が起こっても直ちに運転が停止されるから、万一火傷などを負うようなことも防止できる。

【0047】また、前記プローブ2が全体が扁平円筒状の把持可能な棒本体21で形成されているので、このプローブ2を手にとって容易に移動させ、かつコード線8

の長さの範囲で自由に移動させることができ、これにより、楽な姿勢で手軽に所望の疼痛患部にプローブ2の受熱板31を当てることができる。

【0048】また、前記温冷ブロック3は、そのヒートパネル33によって受熱板31とは反するペルチェ素子32の熱を効率よく放散させ、ペルチェ素子32から受熱板31へ熱伝導を効率良く行うことができる。特に、受熱板31の冷却時には、ヒートパネル33上に配置した前記放熱手段4のファン41を回転させて、棒本体21側部の空気取入口22から上面部の空気排出口23へ空気を循環させることにより、ペルチェ素子32からヒートパネル33へ放散させた熱を効果的に放出することができる。従って、プローブ2の受熱板31の温冷変化をより一層めりはりを付けることができるので、リズムモード運転時に患部の血行をより一層促進させ、人工透析時等の疼痛を和らげるのに非常に効果的なものが得られる。さらに、前記棒本体21上面部の空気排出口23は、保護網5で覆っているため、指をファン41に巻き込んだりすることも確実に防止できる。

【0049】前記プローブ2において、プローブ2を疼痛患部に固定した状態で上から服などを羽織っても空気排出口23を塞いでしまうことがない。従って、前記空気排出口23からの排気を円滑に行うことができ、前記ヒートパネル33の放熱を低下させるようなことを防止できる。また、係止ピン7を利用して、治療患部にプローブ2を当てた状態でその身体部分に紐やバンド9を回しその両端部を前記係止ピン7に引っ掛けることで、前記プローブ2を治療患部に固定しておくことができる。これにより、患部に当てたプローブ2に手を添えてなくても良いので、楽な姿勢で温冷治療をすることができる。また、前記紐やバンド9の両端部をプローブ2の棒本体に設けた係止ピン7に引っ掛けておくので、プローブ上面の空気排出口23を塞いでしまうことも防止できる。

【0050】また、前記プローブ2において、ヒートパネル33の表面に複数の放熱用突起34を形成するので、ヒートパネル33の表面積を増加させることができ、これにより、ヒートパネル33による熱の放散をさらに向上させることができる。

【0051】なお、本実施の形態では、連続モードとリズムモードとを選択できるように構成しているが、リズムモードのみによるものであっても良い。また、リズムモードでは、既述した前記の治療温度、治療時間の最適値を予め設定されたものでも良い。

【0052】また、本実施の形態では、治療器本体1における前記制御部101や安全装置103については所定の電気回路で構成できるが、ソフトウェアで処理を行うようにしても良い。

【0053】また、本実施の形態では、受熱板31の加熱時には、前記プローブ2のファン41を回転させない

ように指示するが、運転中は前記ファン41を回転させるようにしても良い。

【0054】次に、プローブ2の他の例を図8、図9に示す。図8に示すように、このプローブ2aは、全体が扁平で把持可能に形成され、後部を円弧状の丸み部21cとし前部を前記丸み部21cに連続形成する略矩形形状の矩形部21dとする棒本体からなる。この棒本体は、合成樹脂で形成されている。また、前記棒本体は、容器状の胴体21aと、この胴体21aの上部に取付けられる蓋体21bとで構成されている。蓋体21bは、前記棒本体の上面部を構成し、その丸み部21cの中央に複数の空気排出小窓5a、・・・が設けられている。これら空気排出小窓5a、・・・の内側に放熱手段4aのファン41aが配置されている。また、前記棒本体の矩形部21dにおける対向側部に各々ブリッジ状のバンド取付け部7a、7aが設けられており、他の側部に図示しないコード線8を配置するためのコードブッシュ部80が設けられている。

【0055】また、図9に示すように、前記プローブ2aは、棒本体を構成する胴体21aの側部に空気取入口22aが複数箇所に設けられている。そして、前記棒本体内の丸み部21cに、温冷ブロック3aと、この温冷ブロック3a上に取付けられた放熱手段4aとを収容し、また、前記棒本体内の矩形部21dに、前記温冷ブロック3aおよび前記放熱手段4aに接続される中継回路20とを収容する。

【0056】前記温冷ブロック3aは、疼痛治療患部と接触させる受熱板31aと、この受熱板31aの加熱と冷却を行うペルチェ素子32aと、このペルチェ素子32aの熱を放散させるヒートパネル33aとを有する。受熱板31aは、図示しないが前記プローブ2と同様に棒本体底面部から円形状に露出させて、ここに疼痛治療患部を当ててその患部を加熱又は冷却する(図4を参照)。なお、この受熱板31aにおいても前記プローブ2と同様に実際の温度を検知する温度センサが取付けられている。また、ヒートパネル33aの上面部には、無数の放熱用突起34aが形成されている。

【0057】前記放熱手段4aは、モータ41aと、このモータ41aに連結するファン42aとを有する。なお、このモータ41aの駆動はコード線8を通じて電源Vと接続する治療器本体1より指示される。前記中継回路20は、前記コードブッシュ部80にて配置されるコード線8に接続されて治療器本体1からの電気信号を前記ペルチェ素子32aと前記ファン41aのモータ42aに伝達させている。

【0058】このようなプローブ2aによると、上記プローブ2と同様の効果を有する他に、棒本体後部の円弧状の丸み部21cを手のひらで包み込むようにし、且つ、棒本体前部の略矩形形状の矩形部21dを親指と人差し指等で挟むようにすることで、このプローブ2aを手

に持って一層容易に扱える。また、棒本体上面部の複数の空気排出小窓5a、・・・からファン41aによって空気を排出させるが、これら空気排出小窓5a、・・・は指を侵入させない大きさに設定されるから、指が棒本体内部のファン41aに巻き込まれる心配もない。さらに、前記棒本体の矩形部21dにおける対向側部に各々設けたブリッジ状のバンド取付け部7a、7aにバンドを取付け、プローブ2aを疼痛治療患部に配置させた後、前記バンドを腕にまわしておけば、該プローブ2aを腕の疼痛治療患部に安定して固定させておくことができる。

【0059】次に、本発明の他の実施の形態を説明する。図10に示すように、他の実施の形態による疼痛緩和器は、2つのコネクタ部19a、19bのそれぞれにプローブ2a1、2a2が接続されている。治療器本体1aの外観構成は図1に示す治療器本体1と変わらないが、図11に示すように、内部の制御部1aにあっては切替部101a、条件設定部102a、指示部103aによって2個のプローブ2a1、2a2それぞれに別の運転モードやその運転モードでの治療温度および治療時間の設定、その実行を行えるようにする。また、図示しないが、前記制御部1aには前記切替部101aと前記条件設定部102aとによって一のプローブの条件設定が完了すると、次のプローブについての条件設定に移行させる移行部を備える。また、安全装置105aは、指示部103aによる指示情報と各プローブ2a1、2a2からの実際の温度情報とを比べて2個のプローブ2a1、2a2のうちの1つでも温度測定不能状態や温度異常が発生すると、疼痛緩和器の運転を停止させる。

【0060】次に、設定動作を説明する。この他の実施の形態の疼痛緩和器における設定動作は、基本的には前述の図1に示すものと同様であるが、各プローブごとに設定する。

【0061】まず、治療器本体1aの電源を入ると、プローブ2a1での「運転モード」の設定状態となり、表示パネル12の左側にカーソルが点滅表示されるとともに、隅部の任意個所に「P1」と表示される。ここで、「P1」はコネクタ部19aに差し込んだプローブ2a1での設定を意味し、プローブ2a1の条件設定の間は常時表示される。そして、設定ボタン15、16を押して治療時間を入力する。この際、同期して表示パネル12のカーソルが数字に表示される。

【0062】治療時間の入力を終えて数秒すると、表示パネル12右側の直線とクランク状曲線とが点滅され、治療モードの入力待ち状態となる。そして、切替ボタン14を押すと前記直線又は前記クランク状曲線が点灯状態となる。前記直線の点灯が連続モード、前記クランク状曲線の点灯がリズムモードに対応する。

【0063】次いで消音・停止ボタン17を3秒以上押し続ける「運転モード」から「設定モード」に切り替わ

る。すると、前記治療モードの設定時に連続モードを選択していた場合は、表示パネル12の左側にカーソルが点滅表示される。そして、設定ボタン15、16を押して治療温度を入力する。この際、同期して表示パネル12のカーソルが数字に表示される。一方、前記治療モードの設定時にリズムモードを選択していた場合は、リズムモードでの加温温度、加温時間、冷却温度、冷却時間を設定ボタン15、16を押して順次入力する。なお、これら各条件の設定時には、設定項目に応じて表示パネル12の隅部の任意個所に例えば「リズム加温温度」、「リズム加温時間」、「リズム冷却温度」または「リズム冷却時間」等の補助表示が出る。

【0064】前記項目の設定が終わると、制御部1aに備えた移行部（図示せず）によって、次のプローブ2a2の「運転モード」の設定状態に移行させる。この際、表示パネル12左側の「P1」表示が「P2」表示に変わる。「P2」はコネクタ部19bに差し込んだプローブ2a2での設定を意味し、プローブ2a2の条件設定の間は常時表示される。なお、設定動作の操作手順は前記同様に行う。

【0065】以上の設定条件は、条件設定部102aに記憶される。そして、すべての項目設定を終え、各プローブ2a1、2a2を疼痛患部に当てた後、開始ボタン18を押すと、各プローブ2a1、2a2それぞれは前記設定条件に従って運転開始する。すなわち、条件設定部102aに設定された前記設定条件に基づいて指示部103aが各プローブ2a1、2a2の動作制御を行う。なお、その他の動作については図1に示した疼痛緩和器と同様である。

【0066】以上のように、他の実施の形態による疼痛緩和器によると、例えば、血液の取り出し側に針を刺した疼痛患部におけるプローブ2a1は加温と冷却を繰り返すリズムモード運転とし、血液の戻し側に針を刺した疼痛患部におけるプローブ2a2は加温のみの連続モード運転とする等、種々のバリエーションを実現できる。これにより、人工透析時の2本の針を刺した各疼痛患部の末端神経を刺激して血行を促進させることにより、各疼痛患部の痛み具合に応じて適切にその痛みを和らげることができる。

【0067】一方、前記複数のプローブ2a1、2a2のそれぞれを別々の患者にあてがうこともでき、この場合、複数の患者の個々の痛み具合に応じて各プローブ2a1、2a2を動作制御すれば、複数の患者に対して同時に疼痛を和らげることも可能である。

【図面の簡単な説明】

【図1】本発明の実施の形態による疼痛緩和器を示す平面図である。

【図2】図1に示すプローブのI-I断面図である。

【図3】図1に示すプローブの側面図である。

【図4】図1に示すプローブの底面図である。

【図5】図1に示す疼痛緩和器の回路構成を示すブロック図である。

【図6】図1に示す疼痛緩和器の使用状態を示す模式図である。

【図7】プローブを当てる患部に配置させる当て物を示す平面図である。

【図8】他のプローブの例を示す平面図である。

【図9】図8に示すプローブの一部切欠断面図である。

【図10】本発明の他の実施の形態による疼痛緩和器を示す平面図である。

【図11】図10に示す疼痛緩和器の回路構成を示すブロック図である。

【図12】従来の温冷治療器における温冷パックを示す平面図である。

【図13】従来の温冷マッサージ治療装置を示す断面図である。

【符号の説明】

1 治療器本体

2, 2a, 2a1, 2a2 プローブ

3, 3a 温冷ブロック

4, 4a 放熱手段

5 空気排出口

5a 空気排出小窓

6 突起

7 係止ピン

7a バンド取付け部

8 コード線

20 中継回路

21, 21a 棒本体

21c 丸み部

21d 矩形部

22 空気取入口

23 保護網

31, 31a 受熱板

32, 32a ペルチェ素子

33, 33a ヒートパネル

34, 34a 放熱用突起

41, 41a ファン

42, 42a 駆動モータ

100, 100a 制御部

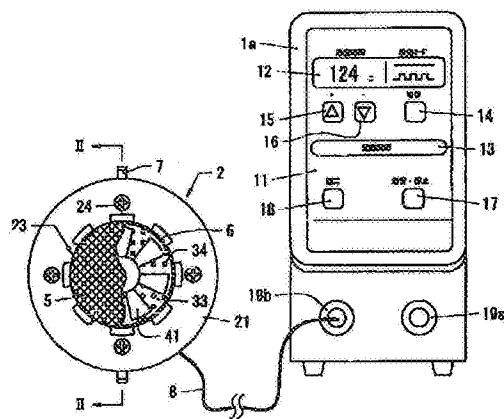
101, 101a 切替部

102 設定部

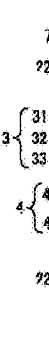
102a 条件設定部

105, 105a 安全装置

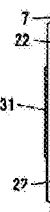
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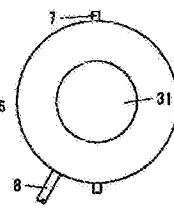
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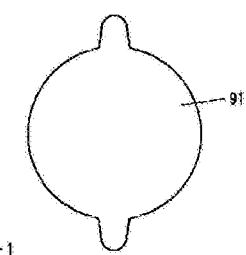
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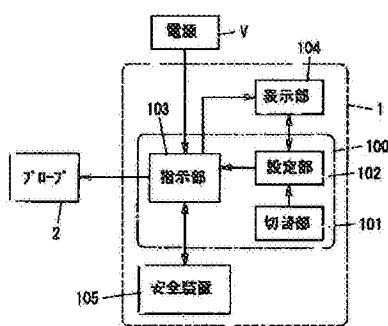
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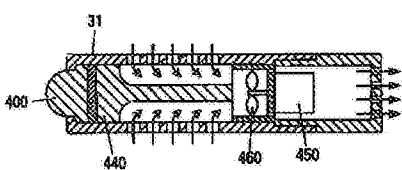
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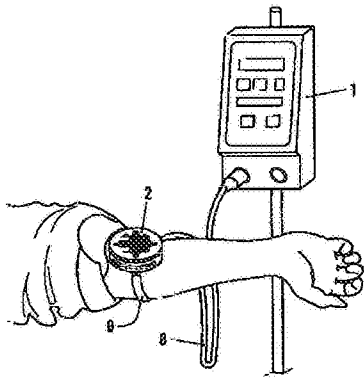
【図5】



【図13】



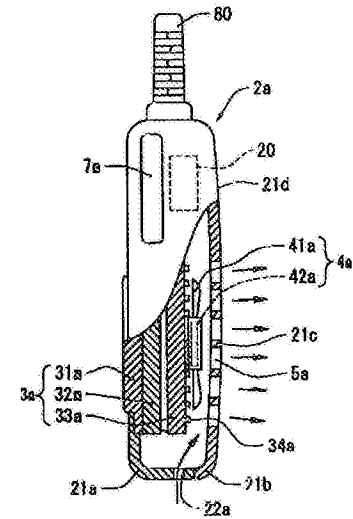
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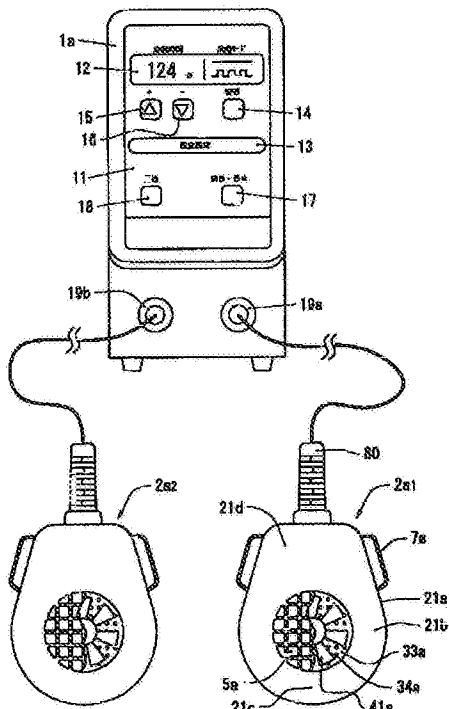
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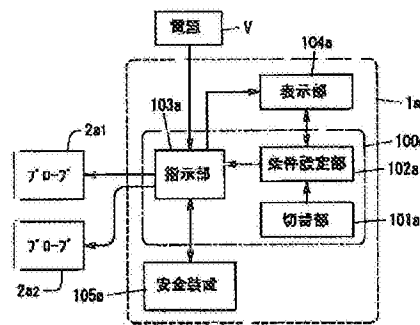
【図9】



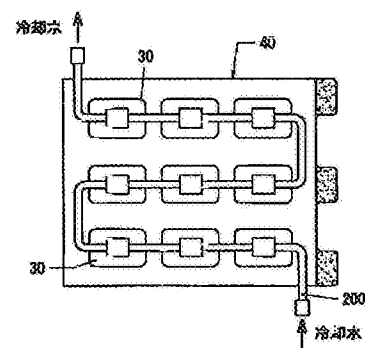
【図10】



【図11】



【図12】



Electronic Acknowledgement Receipt

EFS ID:	22480221
Application Number:	14458644
International Application Number:	
Confirmation Number:	1016
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	26710
Filer:	Jack M. Cook/Sara Kerstein
Filer Authorized By:	Jack M. Cook
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Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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Warnings:

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/458,644	Filing Date 08/13/2014	<input type="checkbox"/> To be Mailed
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ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	05/29/2015	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 30	Minus	** 31	= 0	X \$80 =	0
	Independent (37 CFR 1.16(h))	* 4	Minus	***3	= 1	X \$420 =	420
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))						
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
TOTAL ADD'L FEE						420	

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/TRINA STEPTOE/

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.

Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 06/04/2015

TSTEPTOE	SALE	#00000002	Mailroom Dt:	05/29/2015	170055	14458644
		01	FC : 1201	420.00	DA	

PATENT
Customer No. 26,710
Application No.: 14/458,644
Attorney Docket Nos. 125141.01120.MGH02587

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Dieter MANSTEIN) Group Art Unit: 3769
)
Application No.: 14/458,644) Examiner: Ahmed M. Farah
)
Filed: August 13, 2014)
)
For: METHOD AND APPARATUS FOR)
DERMATOLOGICAL)
TREATMENT AND TISSUE)
RESHAPING)

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

Commissioner:

PRELIMINARY AMENDMENT

Please amend the above-identified patent application as follows:

Amendments to the Claims begin on page 2.

Remarks follow the amendment section.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1-46. (Cancelled).

47. (Currently Amended) A skin treatment device comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured for application of ~~to receive~~ radio frequency (RF) energy from a RF energy source; and

a control module for controlling ~~regulating~~ delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein, wherein the controlled ~~regulation of the~~ delivery of the RF energy is configured to stimulate formation of new collagen in the skin.

48. (Previously Presented) The device of claim 47, wherein the plurality of needles are associated with each other in groups of bipolar pairs, wherein the control module is configured to control the delivery of the RF energy to bipolar pairs to cause areas of non-ablative damage within the dermal layer, and wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles.

49. (Previously Presented) The device of claim 47, wherein at least one of the plurality of needles is a mono-polar needle.

50. (Previously Presented) The device of claim 47, wherein further comprising selecting an application-specific setting for the energy source to cause the energy source to vary at least one of a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting.

51. (Previously Presented) The device of claim 47, wherein at least two of the plurality of needles have differing lengths.

52. (Previously Presented) The device of claim 47, further comprising a cooler for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.

53. (Previously Presented) The device of claim 47, wherein at least one of the plurality of needles is a hollow needle, and further comprising a delivery mechanism for delivering an analgesic via the hollow needle to tissue surrounding a tip of the hollow needle.

54. (Previously Presented) The device of claim 47, further comprising detector for detecting a presence of a nerve near a tip of at least one of the plurality of needles.

55. (Previously Presented) The device of claim 47, further comprising a spacer having holes through which the needles are configured to move.

56. (Currently Amended) The device of claim 47, wherein the control module is configured to control ~~regulate~~ RF energy delivery in order to induce damaged regions surrounding each tip of each of the plurality of needles, with substantially undamaged regions between the damaged regions.

57. (Previously Presented) The device of claim 47, wherein each of the needles has a tip, and wherein the control module is configured to cause at least two adjacent regions of thermal damage, with a small localized area of thermal damage surrounding each tip.

58. (Previously Presented) The device of claim 47, further comprising a vibrator for vibrating at least one of the plurality of needles.

59. (Previously Presented) The device of claim 58, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

60. (Previously Presented) The device of claim 58, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm .

61. (Currently Amended) A skin treatment device, comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured for application of ~~to receive~~ radio frequency (RF) energy from a RF energy source; and

a control module for controlling ~~regulating~~ delivery of the RF energy from the RF energy source to the plurality of needles to cause a pattern of fractional damage to be produced in the dermal layer in a vicinity of the tips of the needles,

wherein ~~regulating the~~ delivery of the RF energy is controlled to cause a pattern of regions of thermal damage within the dermal layer, and wherein at least two adjacent regions of thermal damage have an undamaged region therebetween.

62. (Previously Presented) The device of claim 61, wherein the control module is configured to cause necrosis in the dermal layer.

63. (Previously Presented) The device of claim 61, further comprising a vibrator for vibrating at least one of the plurality of needles.

64. (Previously Presented) The device of claim 63, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

65. (Previously Presented) The device of claim 63, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm .

66. (Currently Amended) A skin treatment device comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base and arranged in a group of bipolar pairs, the plurality of needles being further configured for application of to receive radio frequency (RF) energy from a RF energy source; and

a control module for controlling regulating delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,

wherein the pattern of fractional damage includes damaged regions between tips of needles of the bipolar pairs, and substantially undamaged regions between bipolar pairs of needles in the group.

67. (Previously Presented) The device of claim 66, wherein the control module is configured to cause the damaged regions to be elongated between the needles of the bipolar pairs.

68. (Previously Presented) The device of claim 66, wherein the control module is configured to cause necrosis.

69. (Previously Presented) The device of claim 66, further comprising a vibrator for vibrating at least one of the plurality of needles.

70. (Previously Presented) The device of claim 69, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

71. (Previously Presented) The device of claim 69, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm .

72. (Currently Amended) A skin treatment device comprising:

a housing configured to support a plurality of monopolar needles arranged for insertion into a dermal layer of skin, the plurality of monopolar needles being attached to a base and configured for application of ~~to receive~~ radio frequency (RF) energy from a RF energy source; and

a control module for controlling ~~regulating~~ delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,

wherein the pattern of fractional damage includes damaged regions in a vicinity of each tip of each of the plurality of monopolar needles, and substantially undamaged regions between the damaged regions.

73. (Previously Presented) The device of claim 72, wherein the control module is configured to cause necrosis.

74. (Previously Presented) The device of claim 72, further comprising a vibrator for vibrating at least one of the plurality of needles.

75. (Previously Presented) The device of claim 74, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

76. (Previously Presented) The device of claim 74, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm .

REMARKS

By this amendment, Applicant amends claims 47, 56, 61, 66, and 72. No new matter is added. Claims 47-76 remain pending, of which claims 47, 61, 66, and 72 are independent. To maintain Track 1 priority status, this application as amended contains no more than four independent claims and no more than thirty total claims.

Please grant any extensions of time required to enter this paper and charge any additional required fees to Deposit Account 17-0055.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: /Kai Rajan/
Kai Rajan
Reg. No. 70,110
(202) 408-4307
on behalf of the Patent Licensee

and

QUARLES & BRADY, L.L.P.

By: /Jack M. Cook/
Jack M. Cook
Reg. No. 56,098
(414) 277-5405
on behalf of the Patent Owner

Dated: August 18, 2015

Electronic Acknowledgement Receipt

EFS ID:	23235743
Application Number:	14458644
International Application Number:	
Confirmation Number:	1016
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	26710
Filer:	Jack M. Cook/Sherri Krause
Filer Authorized By:	Jack M. Cook
Attorney Docket Number:	125141.01120.MGH02587
Receipt Date:	18-AUG-2015
Filing Date:	13-AUG-2014
Time Stamp:	12:08:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Preliminary Amendment	PreliminaryAmendment_01120.pdf	210382 0351b97bc48762d4f47cbc96d2cfd4a9b9d7abb	no	9

Warnings:

Information:

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

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/458,644	Filing Date 08/13/2014	<input type="checkbox"/> To be Mailed
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 ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	NUMBER FILED (Column 1)	NUMBER EXTRA (Column 2)	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	(Column 1)	(Column 2)	(Column 3)	RATE (\$)	ADDITIONAL FEE (\$)	
	08/18/2015	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0	X \$80 = 0
	Independent (37 CFR 1.16(h))	* 4	Minus	***4	= 0	X \$420 = 0
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE					0	
AMENDMENT	(Column 1)	(Column 2)	(Column 3)	RATE (\$)	ADDITIONAL FEE (\$)	
		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

 LIE
/ADRIENE SELLMAN/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/458,644	08/13/2014	Dieter Manstein	125141.01120.MGH02587	1016

26710 7590 10/08/2015

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3769

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

10/08/2015

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):

pat-dept@quarles.com

Office Action Summary	Application No. 14/458,644	Applicant(s) MANSTEIN, DIETER	
	Examiner AHMED FARAH	Art Unit 3769	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/18/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 47-76 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 47-76 are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 3) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____. | 4) <input type="checkbox"/> Other: ____. |

1. The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Election/Restrictions

2. This application contains claims directed to the following patentably distinct species A (claims 47-65, see Fig. 3 and Par. 0031 of the published application), B (claims 66-71, see Fig. 4, and Pars. 0040 - 0041), and C (claims 72-76, see Fig. 3, and Par. 0037. The species are independent or distinct because the claims to the different species recite the mutually exclusive characteristics of such species. *For example, the claims in species B require bipolar electrodes for patentability, which are not required for the patentability of the claims of species A or C; and the claims in species C require mono-polar electrodes for patentability, which are not required for the patentability of the claims in species A or B.* In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 47 is generic.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: the species or groupings of patentably indistinct species require a different field of search (e.g.,

searching different classes /subclasses or electronic resources, or employing different search strategies or search queries).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the

evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

3. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. A telephone call was made to the office of the applicant's representative on September 30, 2015 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AHMED FARAH whose telephone number is (571)272-4765. The examiner can normally be reached on Mon, Tues, Thurs, and Fr. between 9:30 AM 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomson William can be reached on (571) 272-3718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 3769

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AHMED FARAH/
Primary Examiner, Art Unit 3769

October 1, 2015.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Dieter MANSTEIN) Group Art Unit: 3769
)
Application No.: 14/458,644) Examiner: Ahmed M. Farah
)
Filed: August 13, 2014)
)
For: METHOD AND APPARATUS FOR) Confirmation No.: 1016
DERMATOLOGICAL)
TREATMENT AND TISSUE)
RESHAPING)

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

Commissioner:

RESPONSE TO RESTRICTION REQUIREMENT

In a species restriction requirement mailed on October 8, 2015 (“Restriction Requirement”), the period for response to which extends through December 8, 2015, the Examiner required restriction under 35 U.S.C. § 121 between allegedly patentably distinct species:

- I. Bipolar electrodes, directed to claims 48 and 66-71; and
- II. Monopolar electrodes, directed to claims 49 and 72-76.

Claims 47 and 50-65 are generic.

The election of species requirement is respectfully traversed. To be fully responsive, however, Applicant elects, with traverse, Species 1, directed to claims 47, 48, and 50-71.

Applicant traverses the species election requirement at least on the grounds that the Office has not shown that there would be a serious burden to the search and examination of all of the pending claims in the instant application. *See* M.P.E.P. § 803. In fact, the examination history of U.S. Application No. 12/914,201, now U.S. Patent No. 9,095,397 (the “parent patent”), demonstrates that no serious burden exists.

In an interview held on October 30, 2015, the Examiner agreed to withdraw the restriction requirement and examine all pending claims. During the interview, Applicant's representative explained that the restriction requirement should be withdrawn at least because the claims do not include multiple species that would present a search burden on the Examiner. For example, the claims in the parent patent include both monopolar and bipolar configurations, and therefore the parent patent claims include both species I and II identified in the Restriction Requirement. The Examiner did not require election between these species during the prosecution of the parent patent, and examined all claims. Moreover, references cited during the prosecution of the parent patent include monopolar and bipolar electrode configurations, demonstrating that the scope of search does not diverge significantly between the two identified species.

In view of the foregoing, during the October 30, 2015, interview the Examiner agreed to withdraw the restriction requirement and examine all pending claims. Accordingly, Applicant requests withdrawal of the restriction requirement, and the allowance of pending claims 47-76.

Please grant any extensions of time required to enter this paper and charge any additional required fees to Deposit Account No. 170055.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: /Kai Rajan/
Kai Rajan
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and

QUARLES & BRADY, L.L.P.

By: /Jack M. Cook/
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(414) 277-5405
on behalf of the Patent Owner

Dated: November 30, 2015

Electronic Acknowledgement Receipt

EFS ID:	24205614
Application Number:	14458644
International Application Number:	
Confirmation Number:	1016
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	26710
Filer:	Jack M. Cook/Sherri Krause
Filer Authorized By:	Jack M. Cook
Attorney Docket Number:	125141.01120.MGH02587
Receipt Date:	30-NOV-2015
Filing Date:	13-AUG-2014
Time Stamp:	09:34:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response to Election / Restriction Filed	Response_01120_1.pdf	96659 7df0efcee709eefca99496f57bf2822bc47554b1	no	3

Warnings:

Information:

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

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/458,644	08/13/2014	Dieter Manstein	125141.01120.MGH02587	1016

26710 7590 03/10/2016

QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3769

NOTIFICATION DATE	DELIVERY MODE
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03/10/2016

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):

pat-dept@quarles.com

Office Action Summary	Application No. 14/458,644	Applicant(s) MANSTEIN, DIETER	
	Examiner AHMED FARAH	Art Unit 3769	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/30/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 47-76 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 47-49, 51-55 and 57-65 is/are allowed.
- 7) ☒ Claim(s) 56 and 66-76 is/are rejected.
- 8) ☒ Claim(s) 50 is/are objected to.
- 9) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 3) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date <u>08/13/14, and 05/29/15</u> | 4) <input type="checkbox"/> Other: _____ |

1. The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Election/Restrictions

Note: upon further review of the pending claims, the restriction requirement of the prior Office Action (OA) mailed 10/08/15 has been withdrawn and all of the pending claims are examined on the merits.

Claim Objections

2. Claim 50 is objected to because of the following informalities: the claim recites in line the term “wherein further comprising ..” This term contains a minor informality. In this Office Action (OA), the informality is treated to be a typographic error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 56 and 66-76 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

5. The term "substantially" in claim 56 is a relative term which renders the claim indefinite. The term "substantially undamaged" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Hence, this term renders the claim indefinite.

6. The term "substantially" in claim 66, line 10 is a relative term which renders the claim indefinite. The term "substantially undamaged" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Hence, this recitation renders indefinite claims 66-71.

7. The term "substantially" in claim 72 line 10 is a relative term which renders the claim indefinite. The term "substantially undamaged regions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Hence, this term renders claims 72-76 indefinite.

Allowable Subject Matter

8. Claims 47-49, 51-55, and 57-65 are allowed.

9. Claim 56 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

10. Claims 66-76 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), 2nd paragraph, set forth in this Office action.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. see the following reference:

- Chan et al., U.S. Pat. No. 7,824,395, see Col. 2, lines 36-47, and col. 16, lines 9-16.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AHMED FARAH whose telephone number is (571)272-4765. The examiner can normally be reached on Mon, Tues, Thurs, and Fr. between 9:30 AM 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomson William can be reached on (571) 272-3718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 3769

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AHMED FARAH/
Primary Examiner, Art Unit 3769

March 6, 2016.

Notice of References Cited	Application/Control No. 14/458,644		Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER	
	Examiner AHMED FARAH		Art Unit 3769	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-7,824,395 B2	11-2010	Chan; Kin F.	A61B18/203	128/898
*	B	US-2010/0010484 A1	01-2010	MEHTA; Bankim H.	A61B18/14	606/33
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Calderhead et al. "The Clinical Efficacy And Safety Of Microneedling Fractional Radiofrequency In The Treatment Of Facial Wrinkles: A Multicenter Study With The Infini System In 499 Patients." July 2013.
	V	"Fractional Micro-needle RF skin Refining and Recovery system (RF-cell)" Copyright © 2010 gbsaesthetic.
	W	Micro-needle Fractional RF System-Cryomed, Advanced Anti-aging RF Technology, http://cryomed.com.au/product/secret-rf/
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	To be assigned
				Filing Date	Herewith (August 13, 2014)
				First Named Inventor	Dieter Manstein
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	1	of	5	Attorney Docket No: 036213.US.08-32865-216897	

US PATENT DOCUMENTS					
Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2002/0120260	August 29, 2002	Morris et al.	
		3505993	April 1970	Lewes et al.	
		4985027	January 1991	Dressel	
		5000752	March 1991	Hoskin et al.	
		5102410	April 1992	Dressel	
		5312395	May 1994	Tan et al.	
		5458596	October 1995	Lax et al.	
		5569242	October 1996	Lax et al.	
		5582184	December 1996	Erickson et al.	
		5599342	February 1997	Hsia et al.	
		5660836	August 1997	Knowlton	
		5697281	December 1997	Eggers et al.	
		5697909	December 1997	Eggers et al.	
		5755753	May 1998	Knowlton	
		5807385	September 1998	Keller	
		5814040	September 1998	Nelson et al.	
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		5871524	February 1999	Knowlton	
		5919219	July 1999	Knowlton	
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		5954710	September 1999	Paolini et al.	
		5976129	November 1999	Desai	
		6048352	April 2000	Douglas et al.	
		6106516	August 2000	Massengill	
		6120519	August 2000	Weber et al	
		6206873	March 2001	Paolini et al.	
		6241753	June 2001	Knowlton	
		6277116	August 2001	Utely et al.	
		6311090	October 2001	Knowlton	
		6334856	January 2002	Allen et al.	
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		6377854	April 2002	Knowlton	
		6377855	April 2002	Knowlton	

EXAMINER

DATE CONSIDERED

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				First Named Inventor	Dieter Manstein
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	2	of	5	Attorney Docket No: 036213.US.08-32865-216897	

US PATENT DOCUMENTS					
Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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		6387380	May 2002	Knowlton	
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		6413255	July 2002	Stern	
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		6418232	July 2002	Avrahami	
		6425912	July 2002	Knowlton	
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		6438424	August 2002	Knowlton	
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		6597946	July 2003	Avrahami et al.	
		6605079	Aug 2003	Shanks et al.	
		6605080	Aug 2003	Altshuler et al.	
		6611706	Aug 2003	Altshuler et al.	
		6615079	Sep 2003	Avrahami	
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		6723092	April 2004	Brown et al	
		6743211	June 2004	Prausnitz et al.	
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		6997923	Feb 2006	Anderson et al.	
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Sheet	3	of	5	Attorney Docket No: 036213.US.08-32865-216897	

US PATENT DOCUMENTS					
Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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		7141049	Nov 2006	Stern et al.	
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		20060224148	Oct 2006	Cho et al.	

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				Filing Date	Herewith (August 13, 2014)
				First Named Inventor	Dieter Manstein
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	4	of	5	Attorney Docket No: 036213.US.08-32865-216897	

US PATENT DOCUMENTS					
Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
		WO 2005/007001	January 27, 2005	Resect Medical, Inc.		
		WO 1999/04710	February 4, 1999	Cosman, Eric, et al.		
		DE 19929713	January 2001			
		EP0226336	June 1987			
		WO0048644	Aug 2000			
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		WO03005919	Jan 2003			
		WO2004086947	Oct 2004			
		WO2005096979	Oct 2005			
		WO2005096980	Oct 2005			

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	To be assigned
				Filing Date	Herewith (August 13, 2014)
				First Named Inventor	Dieter Manstein
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	5	of	5	Attorney Docket No: 036213.US.08-32865-216897	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Urney et al. "Percutaneous Electrode Guidance: A Noninvasive Technique for Prelocation of Peripheral Nerves to Facilitate Peripheral Plexus or Nerve Block", Regional Anesthesia and Pain Medicine, vol. 27, no. 3, 2002, pp. 261-267.	
		Copy of International Search Report mailed September 17, 2008 for International Application No. PCT/US2008/061682	
		Harrington, James A. "A Review of IR Transmitting, Hollow Waveguides", Fiber and Integrated Optics, 19:211-217 (2000).	
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		Smartlipo: Laser Lipolysis With Pulsed Nd:YAG Laser Brochure, DEKA M.E.L.A. s.r.l., Italy, 2 pages.	
		TRI-ACTIVE Brochure, DEKA M.E.L.A. s.r.l., Italy, 4 pages.	
		Copy of International Search Report mailed on February 1, 2011 for International Patent Application No. PCT/US2010/037950	
		Copy of International Written Opinion mailed on February 1, 2011 for International Patent Application No. PCT/US2010/037950	

EXAMINER

/Ahmed Farah/

DATE CONSIDERED

03/07/2016

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.¹ Applicant's unique citation designation number (optional) ² Applicant is to place a check mark here if English language Translation is attached

2871551

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	29559	((606/27,28,31,32,41-50) or (607/96,100-102,108-112) or (128/898)).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/07 03:52
L2	7484	1 and ((needle electrode) with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/03/07 03:52
L3	38	2 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/03/07 03:52
S1	2	((("6277116") or ("6503231")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/05/04 23:45
S2	1	S1 and ('RF radiofrequency (radio adj frequency))	US-PGPUB; USPAT	OR	ON	2014/05/04 23:46
S3	0	S1 and (necrosis with thermal)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:02
S4	0	S1 and (necrosis same thermal)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:02
S5	0	S1 and (necrosis same (heat\$3 thermal))	US-PGPUB; USPAT	OR	ON	2014/05/05 00:02
S6	0	S1 and necrosis	US-PGPUB; USPAT	OR	ON	2014/05/05 00:03
S7	0	S1 and ((tissue celll) with death)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:03
S8	0	S1 and ((tissue celll) with injur\$3)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:04
S9	2	S1 and ((tissue celll) with damag\$3)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:04
S10	1	S1 and (thermal with damag\$3)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:04

S11	1	S10 and ('RF radiofrequency (radio adj frequency))	US-PGPUB; USPAT	OR	ON	2014/05/05 00:05
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S14	0	S12 and (monopoler bipoler (mono adj poler) (bi adj poler))	US-PGPUB; USPAT	OR	ON	2014/05/05 11:18
S15	0	S12 and (monopole bipole (mono adj pole) (bi adj pole))	US-PGPUB; USPAT	OR	ON	2014/05/05 11:18
S16	1	S12 and (monopolar bipolar (mono adj polar) (bi adj polar))	US-PGPUB; USPAT	OR	ON	2014/05/05 11:19
S17	1	S16 and (cool\$3 with (skin tissue))	US-PGPUB; USPAT	OR	ON	2014/05/05 11:20
S18	0	S12 and (vibrat\$3 with needle)	US-PGPUB; USPAT	OR	ON	2014/05/05 12:18
S19	2	("6277116").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/11/30 22:47
S20	0	S19 and (collagen with (format\$3 creat\$3))	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/11/30 23:12
S21	1	"12914201"	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/11/30 23:13
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S24	1	("6277116").PN.	USPAT; USOCR	OR	OFF	2015/04/20 11:24
S25	13	("5374283" "5569242" "5588960"	US-PGPUB;	OR	OFF	2015/04/20

		"5769846" "5843078" "5868744" "5919188" "6010500" "6030384" "6068629" "6068653" "6077257" "6081749").PN.	USPAT; USOCR			11:25
S26	118	("6277116").URPN.	USPAT	OR	OFF	2015/04/20 11:26
S27	116	S26 and (treat\$5 with (skin tissue derma\$5 epidermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:28
S28	16	S27 and (needle with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:29
S29	65	S27 and ((needle electrode)with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:29
S30	5	S29 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:30
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S32	302	(Manstein near Dieter).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:46
S33	28104	((606/27,28,31,32,41-50) or (607/96,100- 102,108-112) or (128/898)).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT;	OR	OFF	2015/04/20 11:53

			IBM_TDB			
S34	12	S32 and S33	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:53
S35	12	S34 and (treat\$5 with (skin tissue derma\$5 epidermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:53
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S37	10	S35 not S36	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:54
S38	2791	S33 and (thermal with damag\$3)	US-PGPUB; USPAT	OR	ON	2015/04/20 11:56
S39	1575	S38 and ((needle electrode)with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:56
S40	1575	S38 and ((needle electrode) with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:56
S41	14	S40 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:57
S42	7	(US-20050222565-\$).did. or (US-5868744-\$ or US-8882753-\$ or US-8608737-\$ or US-	US-PGPUB; USPAT	OR	OFF	2015/04/20 11:58

		7824394-\$ or US-7942153-\$ or US-6905497-\$).did.				
S43	2086	(A61B18/04).IPCR.	US-PGPUB; USPAT	OR	OFF	2015/04/20 12:10
S44	796	S43 and ((needle electrode) with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 12:10
S45	4	S44 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 12:10
S46	9648	(A61B18/14).IPCR.	US-PGPUB; USPAT	OR	OFF	2015/04/20 12:12
S47	5282	S46 and ((needle electrode) with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 12:12
S48	21	S47 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 12:12
S49	0	(A61B18/1477).IPCR.	US-PGPUB; USPAT	OR	OFF	2015/04/20 12:13
S50	7	US-5284154-\$.DID. OR US-5928158-\$.DID. OR US-7824394-\$.DID. OR US- 20020091377-\$.DID. OR US-20020120260- \$.DID. OR JP-20001212-\$.DID. OR JP- 20010807-\$.DID. OR WO-0137728-\$.DID. OR WO-02102265-\$.DID. OR US-1331018- \$.DID.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/05/06 09:09
S51	1	S50 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/05/06 09:12

EAST Search History (I nterference)

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3/ 7/ 2016 4:04:32 AM
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Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0651-0031

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		14458644	
	Filing Date		2014-08-13	
	First Named Inventor	Dieter Manstein		
	Art Unit	3769		
	Examiner Name	Ahmed M. Farah		
	Attorney Docket Number	125141.01120.MGH02587		

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5284154		1994-02-08	Raymond et al.	
		ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./				
	2	5928158		1999-07-27	Aristides	
	3	7824394		2010-11-02	Manstein	
	4	8608737		2013-12-17	Mehta et al.	
	5	8882753		2014-11-11	Mehta et al.	
	6	6905497		2005-06-14	Truckai et al.	

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U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	14458644
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First Named Inventor	Dieter Manstein
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Examiner Name	Ahmed M. Farah
Attorney Docket Number	125141.01120.MGH02587

1	20020091377	A1	2002-07-11	Anderson et al.	
2	20030144652		2003-07-31	Baker et al.	

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

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ⁴	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	2000342617	JP		2000-12-12	Hattori Heating Kogyo KK		<input type="checkbox"/>
	2	2001510702	JP		2001-08-07			<input type="checkbox"/>
	3	WO 0137728	WO		2001-05-31	Nuvasive, Inc.		<input type="checkbox"/>
	4	WO 02102265	WO		2002-12-27	Medizinische Hochschule Hannover		<input type="checkbox"/>

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1		<input type="checkbox"/>

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

Application Number	14458644		
Filing Date	2014-08-13		
First Named Inventor	Dieter Manstein		
Art Unit	3769		
Examiner Name	Ahmed M. Farah		
Attorney Docket Number	125141.01120.MGH02587		

EXAMINER SIGNATURE

Examiner Signature	/Ahmed Farah/	Date Considered	03/07/2016
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Dieter MANSTEIN)	Group Art Unit: 3769
)	
Application No.: 14/458,644)	Examiner: Ahmed M. Farah
)	
Filed: August 13, 2014)	
)	
For: METHOD AND APPARATUS FOR)	Confirmation No.: 1016
DERMATOLOGICAL)	
TREATMENT AND TISSUE)	
RESHAPING)	

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

Commissioner:

AMENDMENT

In response to the Office Action dated March 10, 2016, the response deadline to which extends through June 10, 2016, Applicant amends the above-identified patent application as follows:

Amendments to the Claims begin on page 2.

Remarks follow the amendments section.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1-46. (Cancelled).

47. (Previously Presented) A skin treatment device comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and

a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein, wherein the controlled delivery of the RF energy is configured to stimulate formation of new collagen in the skin.

48. (Currently Amended) The device of claim 47, wherein the plurality of needles are associated with each other in groups of bipolar pairs, wherein the control module is ~~configure~~ **configured** to control the delivery of the RF energy to bipolar pairs to cause areas of non-ablative damage within the dermal layer, and wherein each area of non-ablative damage is associated with each bipolar pair of the plurality of needles.

49. (Previously Presented) The device of claim 47, wherein at least one of the plurality of needles is a mono-polar needle.

50. (Currently Amended) The device of claim 47, wherein ~~further comprising selecting~~ **the control module is further configured to receive a selection of** an application-specific setting for the energy source to cause the energy source to vary at least one of a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting.

51. (Previously Presented) The device of claim 47, wherein at least two of the plurality of needles have differing lengths.

52. (Previously Presented) The device of claim 47, further comprising a cooler for cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.

53. (Previously Presented) The device of claim 47, wherein at least one of the plurality of needles is a hollow needle, and further comprising a delivery mechanism for delivering an analgesic via the hollow needle to tissue surrounding a tip of the hollow needle.

54. (Currently Amended) The device of claim 47, further comprising **a** detector for detecting a presence of a nerve near a tip of at least one of the plurality of needles.

55. (Previously Presented) The device of claim 47, further comprising a spacer having holes through which the needles are configured to move.

56. (Currently Amended) The device of claim 47, wherein the control module is configured to control RF energy delivery in order to induce damaged regions surrounding each tip of each of the plurality of needles, with ~~substantially~~ undamaged regions between the damaged regions.

57. (Previously Presented) The device of claim 47, wherein each of the needles has a tip, and wherein the control module is configured to cause at least two adjacent regions of thermal damage, with a small localized area of thermal damage surrounding each tip.

58. (Previously Presented) The device of claim 47, further comprising a vibrator for vibrating at least one of the plurality of needles.

59. (Previously Presented) The device of claim 58, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

60. (Previously Presented) The device of claim 58, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm .

61. (Previously Presented) A skin treatment device, comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base, the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and

a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to cause a pattern of fractional damage to be produced in the dermal layer in a vicinity of the tips of the needles,

wherein delivery of the RF energy is controlled to cause a pattern of regions of thermal damage within the dermal layer, and wherein at least two adjacent regions of thermal damage have an undamaged region therebetween.

62. (Previously Presented) The device of claim 61, wherein the control module is configured to cause necrosis in the dermal layer.

63. (Previously Presented) The device of claim 61, further comprising a vibrator for vibrating at least one of the plurality of needles.

64. (Previously Presented) The device of claim 63, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

65. (Previously Presented) The device of claim 63, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm .

66. (Currently Amended) A skin treatment device comprising:

a housing configured to support a plurality of needles arranged for insertion into a dermal layer of skin, the plurality of needles being attached to a base and arranged in a group of bipolar pairs, the plurality of needles being further configured for application of radio frequency (RF) energy from a RF energy source; and

a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,

wherein the pattern of fractional damage includes damaged regions between tips of needles of the bipolar pairs, and ~~substantially~~ undamaged regions between bipolar pairs of needles in the group.

67. (Previously Presented) The device of claim 66, wherein the control module is configured to cause the damaged regions to be elongated between the needles of the bipolar pairs.

68. (Previously Presented) The device of claim 66, wherein the control module is configured to cause necrosis.

69. (Previously Presented) The device of claim 66, further comprising a vibrator for vibrating at least one of the plurality of needles.

70. (Previously Presented) The device of claim 69, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

71. (Previously Presented) The device of claim 69, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm .

72. (Currently Amended) A skin treatment device comprising:

a housing configured to support a plurality of monopolar needles arranged for insertion into a dermal layer of skin, the plurality of monopolar needles being attached to a base and configured for application of radio frequency (RF) energy from a RF energy source; and

a control module for controlling delivery of the RF energy from the RF energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer when the needles are inserted therein,

wherein the pattern of fractional damage includes damaged regions in a vicinity of each tip of each of the plurality of monopolar needles, and ~~substantially~~ undamaged regions between the damaged regions.

73. (Previously Presented) The device of claim 72, wherein the control module is configured to cause necrosis.

74. (Previously Presented) The device of claim 72, further comprising a vibrator for vibrating at least one of the plurality of needles.

75. (Previously Presented) The device of claim 74, wherein the vibrator is configured to vibrate the at least one needle at a frequency of between about 10 Hz to about 10 kHz.

76. (Previously Presented) The device of claim 74, wherein the vibrator is configured to vibrate the at least one needle at an amplitude of between about 50 μm and about 500 μm .

REMARKS

I. Status of the Claims

Applicant acknowledges the Office Action¹ dated March 10, 2016, in which the Examiner:

- i. objected to claim 50;
- ii. rejected claims 56 and 66-76 under 35 U.S.C. § 112, second paragraph;
- iii. allowed claims 47-49, 51-55, and 57-65; and
- iv. indicated that claims 56 and 66-76 would be allowable if rewritten to overcome the rejections under 35 U.S.C. § 112.

By this amendment, Applicant amends claims 48, 50, 54, 56, 66, and 72. No new matter is added. Claims 47-76 remain pending, of which claims 47, 61, 66, and 72 are independent. In view of the amendments and following remarks, Applicant respectfully requests withdrawal of the objection and rejections.

II. Claim Objection

Applicant has amended claim 50 to improve clarity, and in view of the amendment Applicant respectfully requests withdrawal of the objection.

III. 35 U.S.C. § 112 Rejections

Applicant respectfully disagrees that the term “substantially” in claims 56, 66, and 72 renders the claim indefinite. Solely to advance prosecution, Applicant has amended claims 56, 66, and 72 to remove the term “substantially,” thereby obviating the rejection. Applicant respectfully requests withdrawal of the rejections of claims 56, 66, and 72.

¹ The Office Action contains a number of statements reflecting characterizations of the related art and the claims. Regardless of whether any such statement is identified in this paper, Applicant declines to automatically subscribe to any statement or characterization in the Office Action.

IV. Allowable Claims

Applicant thanks the Examiner for the timely allowance of claims 47-49, 51-55, and 57-65, and for indicating that claims 56 and 66-76 would be allowable but for the 35 U.S.C. § 112 rejections. In view of the amendments discussed above, Applicant respectfully requests the allowance of pending claims 47-76.

CONCLUSION

Please grant any extensions of time required to enter this paper and charge any additional required fees to Deposit Account No. 170055.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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on behalf of the Patent Licensee

and

QUARLES & BRADY, L.L.P.

By: /Jack M. Cook/
Jack M. Cook
Reg. No. 56,098
(414) 277-5405
on behalf of the Patent Owner

Dated: June 9, 2016

Electronic Acknowledgement Receipt

EFS ID:	26017065
Application Number:	14458644
International Application Number:	
Confirmation Number:	1016
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	26710
Filer:	Jack M. Cook/Sara Kerstein
Filer Authorized By:	Jack M. Cook
Attorney Docket Number:	125141.01120.MGH02587
Receipt Date:	09-JUN-2016
Filing Date:	13-AUG-2014
Time Stamp:	14:14:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	mgm_1120_response.pdf	120659 244cfd8841661c5431dcaa352c3c17774218ef94	no	10

Warnings:

Information:

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

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/458,644	Filing Date 08/13/2014	<input type="checkbox"/> To be Mailed
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ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	(Column 1)	(Column 2)	(Column 3)	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	06/09/2016	CLAIMS REMAINING AFTER AMENDMENT					
	Total (37 CFR 1.16(i))	* 30	Minus	** 31	= 0	X \$80 =	0
	Independent (37 CFR 1.16(h))	* 4	Minus	***4	= 0	X \$420 =	0
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))						
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
TOTAL ADD'L FEE						0	

AMENDMENT	(Column 1)	(Column 2)	(Column 3)	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
		CLAIMS REMAINING AFTER AMENDMENT					
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))						
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
TOTAL ADD'L FEE							

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/KIMBERLY PANNELL/

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

26710 7590 09/14/2016
QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER

FARAH, AHMED M

ART UNIT

PAPER NUMBER

3769

DATE MAILED: 09/14/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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14/458,644

08/13/2014

Dieter Manstein

125141.01120.MGH02587

1016

TITLE OF INVENTION: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	12/14/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

26710 7590 09/14/2016
QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/458,644	08/13/2014	Dieter Manstein	125141.01120.MGH02587	1016

TITLE OF INVENTION: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	12/14/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
FARAH, AHMED M	3769	606-009000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). <input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. <input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.	2. For printing on the patent front page, list (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____ (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. 2 _____ 3 _____
---	---

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____
Typed or printed name _____ Registration No. _____



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.
14/458,644	08/13/2014	Dieter Manstein	125141.01120.MGH02587	1016

26710 7590 09/14/2016
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SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3769

DATE MAILED: 09/14/2016

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 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 14/458,644	Applicant(s) MANSTEIN, DIETER	
	Examiner AHMED FARAH	Art Unit 3769	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 06/09/2016.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 47-76. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some *c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Examiner's Amendment/Comment |
| 2. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 7. <input type="checkbox"/> Other _____. |
| 4. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. | |

/AHMED FARAH/
Primary Examiner, Art Unit 3769

1. The present application is being examined under the pre-AIA first to invent provisions.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance: the prior art of record fails to disclose, teach or suggest a skin treatment apparatus comprising a plurality of RF electrode needles attached to a support base, the plurality of electrodes operably connected to RF source and adapted to be inserted into a dermal layer of a patient's skin; and control system configured to control the output/delivery of the RF energy from the source to the electrodes *to induce fractional damage by the RF energy* in the dermal tissue surrounding the electrodes when inserted therein as presently claimed.

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."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AHMED FARAH whose telephone number is (571)272-4765. The examiner can normally be reached on Mon, Tues, Thurs, and Fr. between 9:30 AM 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomson William can be reached on (571) 272-3718. The fax phone

Art Unit: 3769

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AHMED FARAH/
Primary Examiner, Art Unit 3769

September 6, 2016.

Notice of References Cited	Application/Control No. 14/458,644		Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER	
	Examiner AHMED FARAH		Art Unit 3769	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-8,268,332 B2	09-2012	Manstein; Dieter	A61B18/1477	424/400
*	B	US-6,277,116 B1	08-2001	Utely; David	A61B18/14	606/41
*	C	US-6,503,231 B1	01-2003	Prausnitz; Mark R.	A61B5/1411	604/191
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				


FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes 	Application/Control No. 14458644	Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER
	Examiner AHMED FARAH	Art Unit 3769

CPC- SEARCHED		
Symbol	Date	Examiner
A61B18/18 A61B2018/1495 A61B2018/1869 A61B2018/00571 A61B2018/00577 A61B2018/00589 A61B2018/00607 A61B2018/00636 A61B2018/00696 A61B2018/00702	09/06/2016	AF
A61B18/14 A61B2018/1452 A61B2018/143	09/06/2016	AF
A61B18/12 A61B2018/1253 A61B2018/1263	09/06/2016	AF

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
606	27,28,31,32,41-50 updated	09/06/2016	AF
607	6,100-102,108-112 "	09/06/2016	AF
604	20,21 "	09/06/2016	AF
128	898 "	09/06/2016	AF

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search: IS&R, BRS, and CPC forms, see the attached 'Search History.'	09/06/2016	AF

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
606	27,28,31,32,41-50	09/06/2016	AF
607	6,100-102,108-112	09/06/2016	AF
604	21,22	09/06/2016	AF
607	898	09/06/2016	AF

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BIB DATA SHEET

CONFIRMATION NO. 1016

SERIAL NUMBER 14/458,644	FILING or 371(c) DATE 08/13/2014 RULE	CLASS 606	GROUP ART UNIT 3769	ATTORNEY DOCKET NO. 125141.01120.MGH02587	
APPLICANTS The General Hospital Corporation, Boston, MA; INVENTORS Dieter Manstein, Coral Gables, FL; ** CONTINUING DATA ***** This application is a CON of 12/914,201 10/28/2010 PAT 9095357 which is a DIV of 11/098,030 04/01/2005 PAT 7824394 ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 08/21/2014					
Foreign Priority claimed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Verified and Acknowledged <u>/AHMED M FARAH/</u> Examiner's Signature	<input type="checkbox"/> Met after Allowance AF Initials	STATE OR COUNTRY FL	SHEETS DRAWINGS 4	TOTAL CLAIMS 30	INDEPENDENT CLAIMS 3
ADDRESS QUARLES & BRADY LLP Attn: IP Docket 411 E. WISCONSIN AVENUE SUITE 2350 MILWAUKEE, WI 53202-4426 UNITED STATES					
TITLE METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING					
FILING FEE RECEIVED 2900	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit		

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	338	(Manstein near Dieter).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/09/06 12:00
L2	30063	((606/27,28,31,32,41-50) or (607/96,100-102,108-112) or (128/898)).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/09/06 12:00
L3	17	1 and 2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/09/06 12:01
L4	3	3 and ((needle electrode) with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/09/06 12:01
L5	22	1 and ((needle electrode) with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/09/06 12:02
L6	9	5 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/09/06 12:02
L7	34795	((606/27,28,31,32,41-50) or (607/96,100-102,108-112) or (604/22,21) or	US-PGPUB; USPAT;	OR	OFF	2016/09/06 12:06

		(128/898)).CCLS.	USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
L8	20	1 and 7	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/09/06 12:06
L9	7	8 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/09/06 12:07
L10	3	("6503231").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/09/06 12:36
L11	1	("6277116").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/09/06 12:37
L12	14528	(A61B18/14).cpc. (A61B2018/1452).cpc. (A61B2018/143).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/09/06 12:50
L13	7172	(A61B18/12).cpc. (A61B2018/1253).cpc. (A61B2018/1263).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/09/06 12:51
L14	31526	(A61B18/18).cpc. (A61B2018/1495).cpc. (A61B2018/1869).cpc. (A61B2018/00571).cpc. (A61B2018/00577).cpc. (A61B2018/00589).cpc. (A61B2018/00607).cpc. (A61B2018/00636).cpc. (A61B2018/00696).cpc. (A61B2018/00702).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/09/06 12:54
L15	68969	7 12 13 14	US-PGPUB; USPAT;	OR	OFF	2016/09/06 12:58

			USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			
L16	11914	15 and ((needle electrode) with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/09/06 12:58
L17	72	16 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/09/06 12:58
L18	44	17 and ((control\$4 regualt\$3) with (energy power) with ('RF radiofrequency (radia adj frequendy)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/09/06 13:00
S1	2	((("6277116") or ("6503231")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/05/04 23:45
S2	1	S1 and ('RF radiofrequency (radio adj frequency))	US-PGPUB; USPAT	OR	ON	2014/05/04 23:46
S3	0	S1 and (necrosis with thermal)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:02
S4	0	S1 and (necrosis same thermal)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:02
S5	0	S1 and (necrosis same (heat\$3 thermal))	US-PGPUB; USPAT	OR	ON	2014/05/05 00:02
S6	0	S1 and necrosis	US-PGPUB; USPAT	OR	ON	2014/05/05 00:03
S7	0	S1 and ((tissue cellI) with death)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:03
S8	0	S1 and ((tissue cellI) with injur\$3)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:04
S9	2	S1 and ((tissue cellI) with damag\$3)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:04
S10	1	S1 and (thermal with damag\$3)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:04
S11	1	S10 and ('RF radiofrequency (radio adj frequency))	US-PGPUB; USPAT	OR	ON	2014/05/05 00:05
S12	2	((("6277116") or ("6503231")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/05/05 11:17

S13	0	S12 and (monopoler bipoler (mono adj poler) (bi adj poler))	US-PGPUB; USPAT	OR	OFF	2014/05/05 11:18
S14	0	S12 and (monopoler bipoler (mono adj poler) (bi adj poler))	US-PGPUB; USPAT	OR	ON	2014/05/05 11:18
S15	0	S12 and (monopole bipole (mono adj pole) (bi adj pole))	US-PGPUB; USPAT	OR	ON	2014/05/05 11:18
S16	1	S12 and (monopolar bipolar (mono adj polar) (bi adj polar))	US-PGPUB; USPAT	OR	ON	2014/05/05 11:19
S17	1	S16 and (cool\$3 with (skin tissue))	US-PGPUB; USPAT	OR	ON	2014/05/05 11:20
S18	0	S12 and (vibrat\$3 with needle)	US-PGPUB; USPAT	OR	ON	2014/05/05 12:18
S19	2	("6277116").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/11/30 22:47
S20	0	S19 and (collagen with (format\$3 creat\$3))	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/11/30 23:12
S21	1	"12914201"	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/11/30 23:13
S22	0	("3and(collagenwith(format\$3creat\$3))).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/11/30 23:13
S23	1	S21 and (collagen with (format\$3 creat\$3))	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2014/11/30 23:14
S24	1	("6277116").PN.	USPAT; USOCR	OR	OFF	2015/04/20 11:24
S25	13	("5374283" "5569242" "5588960" "5769846" "5843078" "5868744" "5919188" "6010500" "6030384" "6068629" "6068653" "6077257" "6081749").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/04/20 11:25
S26	118	("6277116").URPN.	USPAT	OR	OFF	2015/04/20 11:26

S27	116	S26 and (treat\$5 with (skin tissue derma\$5 epidermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:28
S28	16	S27 and (needle with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:29
S29	65	S27 and ((needle electrode)with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:29
S30	5	S29 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:30
S31	4	S28 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:44
S32	302	(Manstein near Dieter).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:46
S33	28104	((606/27,28,31,32,41-50) or (607/96,100-102,108-112) or (128/898)).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2015/04/20 11:53
S34	12	S32 and S33	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2015/04/20 11:53

			DERWENT; IBM_TDB			
S35	12	S34 and (treat\$5 with (skin tissue derma\$5 epidermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:53
S36	2	S35 and ((needle electrode)with ('RF' raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:53
S37	10	S35 not S36	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:54
S38	2791	S33 and (thermal with damag\$3)	US-PGPUB; USPAT	OR	ON	2015/04/20 11:56
S39	1575	S38 and ((needle electrode)with ('RF' raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:56
S40	1575	S38 and ((needle electrode) with ('RF' raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:56
S41	14	S40 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:57
S42	7	(US-20050222565-\$).did. or (US-5868744-\$ or US-8882753-\$ or US-8608737-\$ or US-7824394-\$ or US-7942153-\$ or US-6905497-\$).did.	US-PGPUB; USPAT	OR	OFF	2015/04/20 11:58
S43	2086	(A61B18/04).IPCR.	US-PGPUB; USPAT	OR	OFF	2015/04/20 12:10
S44	796	S43 and ((needle electrode) with ('RF	US-PGPUB;	OR	ON	2015/04/20

		raidofrequency (radio adj frequency)))	USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			12:10
S45	4	S44 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 12:10
S46	9648	(A61B18/14).IPCR.	US-PGPUB; USPAT	OR	OFF	2015/04/20 12:12
S47	5282	S46 and ((needle electrode) with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 12:12
S48	21	S47 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 12:12
S49	0	(A61B18/1477).IPCR.	US-PGPUB; USPAT	OR	OFF	2015/04/20 12:13
S50	7	US-5284154-\$.DID. OR US-5928158-\$.DID. OR US-7824394-\$.DID. OR US-20020091377-\$.DID. OR US-20020120260-\$.DID. OR JP-20001212-\$.DID. OR JP-20010807-\$.DID. OR WO-0137728-\$.DID. OR WO-02102265-\$.DID. OR US-1331018-\$.DID.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/05/06 09:09
S51	1	S50 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/05/06 09:12
S52	29559	((606/27,28,31,32,41-50) or (607/96,100-102,108-112) or (128/898)).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/03/07 03:52
S53	7484	S52 and ((needle electrode) with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR;	OR	ON	2016/03/07 03:52


			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S54	38	S53 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/03/07 03:52

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L19	25895	((606/27,28,31,32,41-50) or (607/96,100-102,108-112) or (604/22,21) or (128/898)).CCLS.	US-PGPUB; USPAT	OR	OFF	2016/09/06 13:04
L20	4791	(A61B18/14).cpc. (A61B2018/1452).cpc. (A61B2018/143).cpc.	US-PGPUB; USPAT	OR	OFF	2016/09/06 13:04
L21	2282	(A61B18/12).cpc. (A61B2018/1253).cpc. (A61B2018/1263).cpc.	US-PGPUB; USPAT	OR	OFF	2016/09/06 13:04
L22	10754	(A61B18/18).cpc. (A61B2018/1495).cpc. (A61B2018/1869).cpc. (A61B2018/00571).cpc. (A61B2018/00577).cpc. (A61B2018/00589).cpc. (A61B2018/00607).cpc. (A61B2018/00636).cpc. (A61B2018/00696).cpc. (A61B2018/00702).cpc.	US-PGPUB; USPAT	OR	OFF	2016/09/06 13:04
L23	33085	19 20 21 22	US-PGPUB; USPAT	OR	OFF	2016/09/06 13:05
L24	2551	23 and ((needle electrode) with ('RF raidofrequency (radio adj frequency))).clm.	US-PGPUB; USPAT	OR	ON	2016/09/06 13:05
L25	7	24 and (fractional with (therapy damage thermal)).clm.	US-PGPUB; USPAT	OR	ON	2016/09/06 13:05
L26	7	24 and ((fractional dispersed) with (therapy damage thermal)).clm.	US-PGPUB; USPAT	OR	ON	2016/09/06 13:06
L27	403	24 and ((control\$4 regualt\$3) with (energy power) with ('RF radiofrequency (radia adj frequendy))).clm.	US-PGPUB; USPAT	OR	ON	2016/09/06 13:06
L28	4	27 and ((fractional dispersed)	US-	OR	ON	2016/09/06

	with (therapy damage thermal)).clm.	PGPUB; USPAT		13:07
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9/ 6/ 2016 1:08:07 PM
C:\ Users\ afarah\ Documents\ EAST\ Workspaces\ 14458644.wsp

Issue Classification 	Application/Control No. 14458644	Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER	
	Examiner AHMED FARAH	Art Unit 3769	

CPC						
Symbol					Type	Version
A61B		18	/	1477	F	2013-01-01
A61B		5	/	4893	A	2013-01-01
A61B		2018	/	00452	A	2013-01-01
A61B		2018	/	143	A	2013-01-01
A61B		2018	/	2005	A	2013-01-01
A61B		2018	/	2211	A	2013-01-01
A61B		18	/	18	I	2013-01-01
A61B		2018	/	00005	A	2013-01-01
A61B		2018	/	0016	A	2013-01-01
A61B		2018	/	0019	A	2013-01-01
A61M		5	/	158	I	2013-01-01
A61M		2202	/	048	A	2013-01-01
			/			
			/			
			/			

CPC Combination Sets				
Symbol	Type	Set	Ranking	Version

NONE		Total Claims Allowed:	
		30	
(Assistant Examiner)	(Date)		
/AHMED FARAH/ Primary Examiner.Art Unit 3769	09/06/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3

Issue Classification 	Application/Control No. 14458644	Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER
	Examiner AHMED FARAH	Art Unit 3769

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant															
<input type="checkbox"/> CPA															
<input type="checkbox"/> T.D.															
<input type="checkbox"/> R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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2	48	18	64												
3	49	19	65												
4	50	20	66												
5	51	21	67												
6	52	22	68												
7	53	23	69												
8	54	24	70												
9	55	25	71												
10	56	26	72												
11	57	27	73												
12	58	28	74												
13	59	29	75												
14	60	30	76												
15	61														
16	62														

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	30	
/AHMED FARAH/ Primary Examiner.Art Unit 3769	09/06/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "TEE ADDRESS" for maintenance fee notifications.

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(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/458,644	08/13/2014	Dieter Manstein	125141.01120.MGH02587	1016

TITLE OF INVENTION: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	12/14/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
FARAH, AHMED M	3769	606-009000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Quarles & Brady LLP

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

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

The General Hospital Corporation

Boston, Massachusetts

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☒ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 17-0055 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Jack M. Cook/

Date November 2, 2016

Typed or printed name Jack M. Cook

Registration No. 56,098

Electronic Patent Application Fee Transmittal

Application Number:	14458644			
Filing Date:	13-Aug-2014			
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING			
First Named Inventor/Applicant Name:	Dieter Manstein			
Filer:	Jack M. Cook			
Attorney Docket Number:	125141.01120.MGH02587			
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	1501	1	960	960

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				960

Electronic Acknowledgement Receipt

EFS ID:	27396547
Application Number:	14458644
International Application Number:	
Confirmation Number:	1016
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	26710
Filer:	Jack M. Cook/Angela Schulz
Filer Authorized By:	Jack M. Cook
Attorney Docket Number:	125141.01120.MGH02587
Receipt Date:	02-NOV-2016
Filing Date:	13-AUG-2014
Time Stamp:	17:02:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$960
RAM confirmation Number	110316INTEFSW00003870170055
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	125141_01120_issue_fee.pdf	1627805	no	1
			506e9af4ea907b67e3ecba380b13c43d69d531d6		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30439	no	2
			e38850dbe803ab5106c94841d702606f1ebfc54b		
Warnings:					
Information:					
Total Files Size (in bytes):			1658244		
<p>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.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> 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.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> 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>					

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.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	To be assigned
				Filing Date	Herewith (August 13, 2014)
				First Named Inventor	Dieter Manstein
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	4	of	5	Attorney Docket No: 036213.US.08-32865-216897	

US PATENT DOCUMENTS

Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		20060253112	Nov 2006	Suarez et al.	
		20060293722	Dec 2006	Slatkine et al.	
		20070010811	Jan 2007	Stern et al.	
		20070073367	March 2007	Jones et al.	
		20070173799	July 2007	Hsia	
		20070198003	Aug 2007	Domankevitz et al.	
		20070208340	Sep 2007	Ganz et al.	
		20080125775	May 2008	Morris	
		20080221649	Sep 2008	Echague et al.	
		20090124958	05/14/2009	L. Kasey L	
		20080082090	04/03/2008	D. Manstein	
		20080312647	12/18/2008	P. Knopp	
		20070106143	05/10/2007	J. Flaherty	
		6,277,116	08/21/2001	D. Utely	

Change(s) applied
to document,
/E.M.S./

10/7/2016

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
		WO 2005/007001	January 27, 2005	Resect Medical, Inc.		
		WO 1999/04710	February 4, 1999	Cosman, Eric, et al.		
		DE 19929713	January 2001			
		EP0226336	June 1987			
		WO0048644	Aug 2000			
		WO 0132073	May 2001			
		WO02/060523	Aug 2002			
		WO03005919	Jan 2003			
		WO2004086947	Oct 2004			
		WO2005096979	Oct 2005			
		WO2005096980	Oct 2005			

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

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.

Substitute for form 1449A/PTO					
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	To be assigned
				Filing Date	Herewith (August 13, 2014)
				First Named Inventor	Dieter Manstein
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	2	of	5	Attorney Docket No: 036213.US.08-32865-216897	

US PATENT DOCUMENTS

Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		6381497	April 2002	Knowlton	
		6381498	April 2002	Knowlton	
		6387380	May 2002	Knowlton	
		6405090	June 2002	Knowlton	
		6413255	July 2002	Stern	
		6416531	July 2002	Chen	
		6418232	July 2002	Avrahami 6,148,232	11/2000
		6425912	July 2002	Knowlton	
		6427089	July 2002	Knowlton	
		6430446	August 2002	Knowlton	
		6438424	August 2002	Knowlton	
		6453202	September 2002	Knowlton	
		6461378	October 2002	Knowlton	
		6470216	October 2002	Knowlton	
		6482204	Nov 2002	Lax et al.	
		6503231	Jan 2003	Prausnitz et al.	
		6562054	May 2003	Weber et al.	
		6597946	July 2003	Avrahami et al.	
		6605079	Aug 2003	Shanks et al.	
		6605080	Aug 2003	Altshuler et al.	
		6611706	Aug 2003	Altshuler et al.	
		6615079	Sep 2003	Avrahami	
		6708060	March 2004	Avrahami	
		6711435	March 2004	Avrahami	
		6723092	April 2004	Brown et al	
		6743211	June 2004	Prausnitz et al.	
		6749624	June 2004	Knowlton	
		6766202	July 2004	Underwood et al	
		6997923	Feb 2006	Anderson et al.	
		7006874	Feb 2006	Knowlton	
		7008421	March 2006	Daniel et al.	
		7022121	April 2006	Stern et al.	
		7025765	April 2006	Balbierz et al.	
		7060061	June 2006	Altshuler et al.	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

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.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	To be assigned
				Filing Date	Herewith (August 13, 2014)
				First Named Inventor	Dieter Manstein
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	1	of	5	Attorney Docket No: 036213.US.08-32865-216897	

US PATENT DOCUMENTS

Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2002/0120260	August 29, 2002	Morris et al.	
		3505993	April 1970	Lewes et al.	
		4985027	January 1991	Dressel	
		5000752	March 1991	Hoskin et al.	
		5102410	April 1992	Dressel	
		5312395	May 1994	Tan et al.	
		5458596	October 1995	Lax et al.	
		5569242	October 1996	Lax et al.	
		5582184	December 1996	Erickson et al.	
		5599342	February 1997	Hsia et al.	
		5660836	August 1997	Knowlton	
		5697281	December 1997	Eggers et al.	
		5697909	December 1997	Eggers et al.	
		5755753	May 1998	Knowlton	
		5807385	September 1998	Keller	
		5814040	September 1998	Nelson et al.	
		5861002	January 1999	Desai	
		5871524	February 1999	Knowlton	
		5919219	July 1999	Knowlton	
		5984011	September 1999	Knowlton	5,948,011
		5954710	September 1999	Paolini et al.	
		5976129	November 1999	Desai	
		6048352	April 2000	Douglas et al.	
		6106516	August 2000	Massengill	
		6120519	August 2000	Weber et al	
		6206873	March 2001	Paolini et al.	
		6241753	June 2001	Knowlton	
		6277116	August 2001	Utely et al.	
		6311090	October 2001	Knowlton	
		6334856	January 2002	Allen et al.	
		6350276	February 2002	Knowlton	
		6355054	March 2002	Neuberger	
		6377854	April 2002	Knowlton	
		6377855	April 2002	Knowlton	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

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.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	To be assigned
				Filing Date	Herewith (August 13, 2014)
				First Named Inventor	Dieter Manstein
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	3	of	5	Attorney Docket No: 036213.US.08-32865-216897	

US PATENT DOCUMENTS

Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		7115123	Oct 2006	Knowlton et al.	
		7141049	Nov 2006	Stern et al.	
		7189230	March 2007	Knowlton	
		7217265	May 2007	Hennings et al.	
		7223264	May 2007	Daniel et al.	
		7278991	Oct 2007	Morris et al.	
		7331953	Feb 2008	Manstein et al.	
		7422586	Sept 2008	Morris et al.	
		2002/0115991	Aug 2002	Edwards	
		2002/0120263	Aug 2002	Brown et al.	
		2002/0128641	Sep 2002	Underwood et al.	
		2002/0138049	Sep 2002	Allen et al.	
		2002/0161357	Oct 2002	Anderson et al.	
		20030130655	July 2003	Woloszko et al.	
		20030212394	Nov 2003	Pearson et al.	
		20030216719	Nov 2003	Debenedictis et al.	
		20040048842	March 2004	McMillan	
		20040073277	April 2004	Geronemus et al.	
		20040267335 1 2	Nov 2004	Tulip et al.	
		20050049582	March 2005	Debenedictis et al.	
		20050087198	April 2005	Bruno-Raimondi et al.	
		20050137662	June 2005	Morris et al.	
		20050209564	Sep 2005	Bonner et al.	
		20050209565	Sep 2005	Yuzhakov et al.	
		20050222555	Oct 2005	Manstein et al.	
		20050222565	Oct 2005	Manstein et al.	
		2006/0004306	Jan 2006	Altshuler et al.	
		2006/0004347	Jan 2006	Altshuler et al.	
		20060009750	Jan 2006	Altshuler et al.	
		20060020309	Jan 2006	Altshuler et al.	
		20060058712	March 2006	Altshuler et al.	
		20060122668	June 2006	Anderson et al.	
		20060206110	Sep 2006	Knowlton et al	
		20060224148	Oct 2006	Cho et al.	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./



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.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/458,644	12/06/2016	9510899	125141.01120.MGH02587	1016

26710 7590 11/16/2016
QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

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

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Dieter Manstein, Coral Gables, FL;
The General Hospital Corporation, Boston, MA;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 1

PATENT NO. : 9,510,899

APPLICATION NO.: 14/458,644

ISSUE DATE : December 6, 2016

INVENTOR(S) : Dieter Manstein

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 5, Line 46 change "RF 21' current" to --RF current--

MAILING ADDRESS OF SENDER (Please do not use customer number below):

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Attention Certificate of Corrections Branch, 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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Dieter Manstein
Serial No.: 14/458,644
Filing Date: August 13, 2014
Conf. No.: 1016
Patent No.: 9,510,899
Docket No.: 125141.01120
Title: Method and Apparatus for Dermatological Treatment and Tissue Reshaping

REQUEST FOR CERTIFICATE OF CORRECTION

Commissioner of Patents
P O Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Accompanying this Request for a Certificate of Correction is a completed form PTO/SB/44 entitled Certificate of Correction. In reviewing the above issued patent, Applicants note clerical errors introduced by the USPTO. Applicants are requesting that the Office issue a Certificate of Correction.

No fees are believed to be due with this request. The Commissioner is authorized to charge any fees under that may be due on this application to Deposit Account 17-0055. The Commissioner is also authorized to treat this correction and any future reply in this matter requiring a petition for an extension of time as incorporating a petition for extension of time for the appropriate length of time as provided by 37 CFR § 136(a)(3).

Respectfully submitted,

Date: April 8, 2017

/Jack M. Cook/
Jack M. Cook, Reg. No. 56,098
Attorney for Applicants
QUARLES & BRADY LLP
411 E. Wisconsin Avenue
Milwaukee, WI 53202
Tel. 414-277-5405

Electronic Acknowledgement Receipt

EFS ID:	28872024
Application Number:	14458644
International Application Number:	
Confirmation Number:	1016
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	26710
Filer:	Jack M. Cook/Sara Kerstein
Filer Authorized By:	Jack M. Cook
Attorney Docket Number:	125141.01120.MGH02587
Receipt Date:	08-APR-2017
Filing Date:	13-AUG-2014
Time Stamp:	12:21:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Certificate of Correction	mgh_1120_coc.pdf	103406	no	1
			6abca6622d4567ad5e7bc2483e6570dc9e d981f		

Warnings:

Information:					
2	Request for Certificate of Correction	mgh_1120_letter.pdf	81521	no	1
			09a2189117fe7212bac0ad2c4daba141e4cb1418		
Warnings:					
Information:					
			Total Files Size (in bytes):	184927	
<p>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.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> 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.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> 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>					

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 9,510,899 B2
APPLICATION NO. : 14/458644
DATED : December 6, 2016
INVENTOR(S) : Dieter Manstein

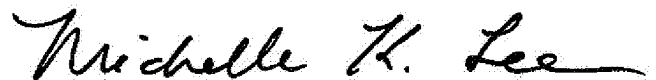
Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification

Column 5, Line 46 change "RF 21' current" to --RF current--

Signed and Sealed this
Sixteenth Day of May, 2017

A handwritten signature in black ink, reading "Michelle K. Lee". The signature is written in a cursive style with a long horizontal flourish at the end.

Michelle K. Lee
Director of the United States Patent and Trademark Office

AO 120 (Rev. 3/04)

TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
---	---

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been
filed in the U.S. District Court District of Massachusetts on the following ☒ Patents or ☐ Trademarks:

DOCKET NO.	DATE FILED 4/9/2018	U.S. DISTRICT COURT District of Massachusetts
PLAINTIFF Syneron Medical Ltd., Candela Corporation, and Massachusetts General Hospital		DEFENDANT EndyMed Medical Ltd. and EndyMed Medical Inc.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 9,510,899	12/6/2016	The General Hospital Corporation
2 9,095,357	8/4/2015	The General Hospital Corporation
3		
4		
5		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY <input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
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CERTIFICATE OF SERVICE

I, Christopher S. Schultz, hereby certify that on this 9th day of April, 2018, the foregoing document was filed electronically through the EFC system, is available for viewing and downloading from the ECF system, will be sent electronically to counsel of record as registered participants identified on the Notice of Electronic Filing and via first class mail to all nonregistered participants identified on the Notice of Electronic Filing.

/s/ Christopher S. Schultz

Christopher S. Schultz (BBO No. 630814)

AO 120 (Rev. 3/04)

TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
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In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been
filed in the U.S. District Court District of Massachusetts on the following ☒ Patents or ☐ Trademarks:

DOCKET NO.	DATE FILED 4/9/2018	U.S. DISTRICT COURT District of Massachusetts
PLAINTIFF Syneron Medical Ltd., Candela Corporation, and Massachusetts General Hospital		DEFENDANT Ilooda Co., Ltd., Cutera, Inc., Emvera Technologies, LLC, Rohrer Aesthetics, LLC
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 9,510,899	12/6/2016	The General Hospital Corporation
2 9,095,357	8/4/2015	The General Hospital Corporation
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In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY <input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading	
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DECISION/JUDGEMENT

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filed in the U.S. District Court District of Massachusetts on the following ☒ Patents or ☐ Trademarks:

DOCKET NO.	DATE FILED 4/9/2018	U.S. DISTRICT COURT District of Massachusetts
PLAINTIFF Syneron Medical Ltd., Candela Corporation, and Massachusetts General Hospital		DEFENDANT Invasix, Inc., Invasix, Ltd., and InMode MD, Ltd.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 9,510,899	12/6/2016	The General Hospital Corporation
2 9,095,357	8/4/2015	The General Hospital Corporation
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DOCKET NO.	DATE FILED 4/9/2018	U.S. DISTRICT COURT District of Massachusetts
PLAINTIFF Syneron Medical Ltd., Candela Corporation, and Massachusetts General Hospital		DEFENDANT Jeisys Medical, Inc. and Perigee Medical LLC
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 9,510,899	12/6/2016	The General Hospital Corporation
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DOCKET NO.	DATE FILED 4/9/2018	U.S. DISTRICT COURT District of Massachusetts
PLAINTIFF Syneron Medical Ltd., Candela Corporation, and Massachusetts General Hospital		DEFENDANT Lumenis Ltd. and Pollogen Ltd.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 9,510,899	12/6/2016	The General Hospital Corporation
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DOCKET NO.	DATE FILED 4/9/2018	U.S. DISTRICT COURT District of Massachusetts
PLAINTIFF Syneron Medical Ltd., Candela Corporation, and Massachusetts General Hospital		DEFENDANT Lutronic, Corp. and Lutronic, Inc.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
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DOCKET NO.	DATE FILED 4/9/2018	U.S. DISTRICT COURT District of Massachusetts
PLAINTIFF Syneron Medical Ltd., Candela Corporation, and Massachusetts General Hospital		DEFENDANT Sung Hwan E&B Co., Ltd., d/b/a SHENB Co. Ltd., d/b/a SHENB, Aesthetics Biomedical, Inc., and Cartessa Aesthetics, LLC
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
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