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**UTILITY
PATENT APPLICATION
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(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No. 036213.US.07-475387-779

First Inventor Dieter Manstein

Title Method and Apparatus for

Express Mail Label No.

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☐ **Fee Transmittal Form** (e.g., PTO/SB/17)
2. ☒ **Applicant claims small entity status.**
See 37 CFR 1.27.
3. ☒ **Specification** [Total Pages 22]
Both the claims and abstract must start on a new page
(For information on the preferred arrangement, see MPEP 608.01(a))
4. ☒ **Drawing(s)** (35 U.S.C. 113) [Total Sheets 4]
5. **Oath or Declaration** [Total Sheets]
a. ☐ Newly executed (original or copy)
b. ☒ A copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 18 completed)
i. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s)
name in the prior application, see 37 CFR
1.63(d)(2) and 1.33(b).
6. ☒ **Application Data Sheet.** See 37 CFR 1.76
7. ☐ **CD-ROM or CD-R** in duplicate, large table or
Computer Program (Appendix)
☐ Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission**
(if applicable, items a. – c. are required)
a. ☐ Computer Readable Form (CRF)
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9. ☐ **Assignment Papers** (cover sheet (PTO-1595) & document(s))
Name of Assignee _____
10. ☐ **37 CFR 3.73(b) Statement** ☐ **Power of Attorney**
(when there is an assignee)
11. ☐ **English Translation Document** (if applicable)
12. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
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18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76.

☐ Continuation☒ Divisional☐ Continuation-in-part (CIP)

of prior application No.: 11/098,030

Prior application information:

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Art Unit: 3769

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Lumenis Ex. 1003

U.S. Patent No. 9,510,899

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 anestheticum, 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

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 formation of damaged tissue over a larger volume within the tissue being treated.

The needle arrays may have any geometry appropriate for the desired treatment being performed. The spacing between adjacent needles is preferably greater than about 1 mm 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 with some precision by adjusting the intensity and duration of power transmitted to single needles or pairs of needles.

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.

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.

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 milliamperage 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.

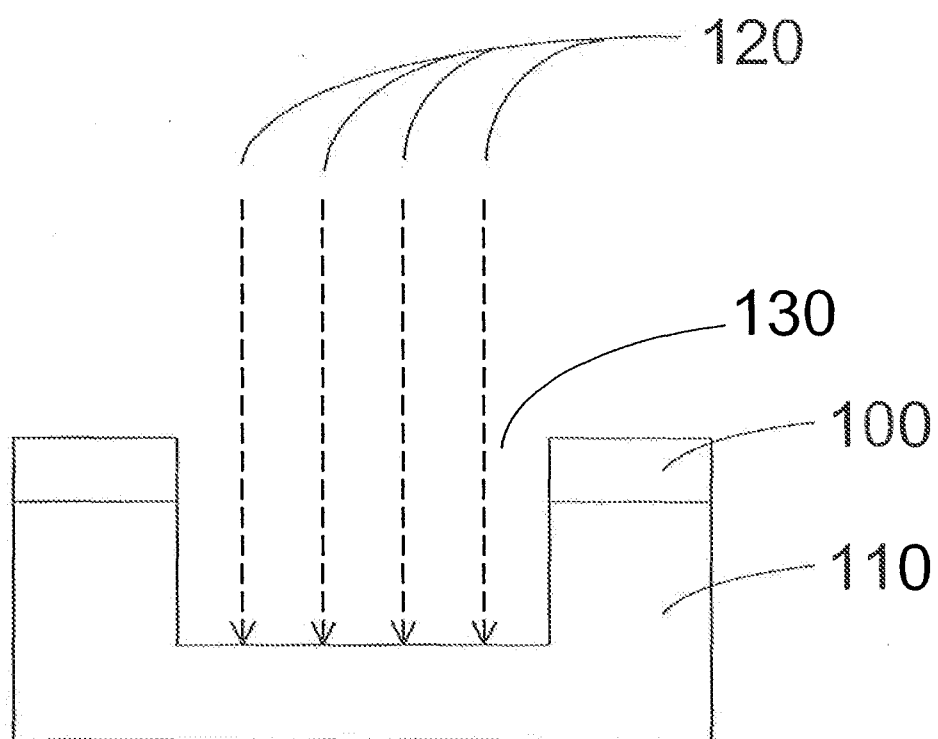


FIG. 1

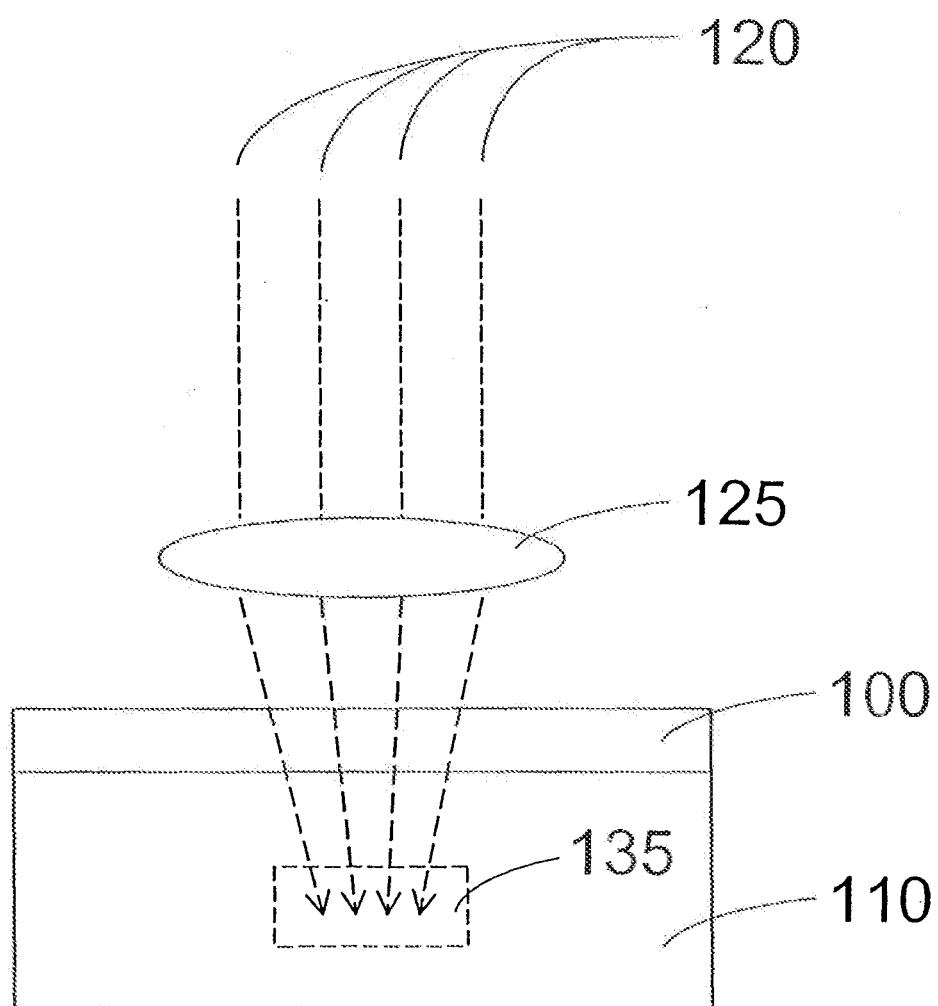


FIG. 2

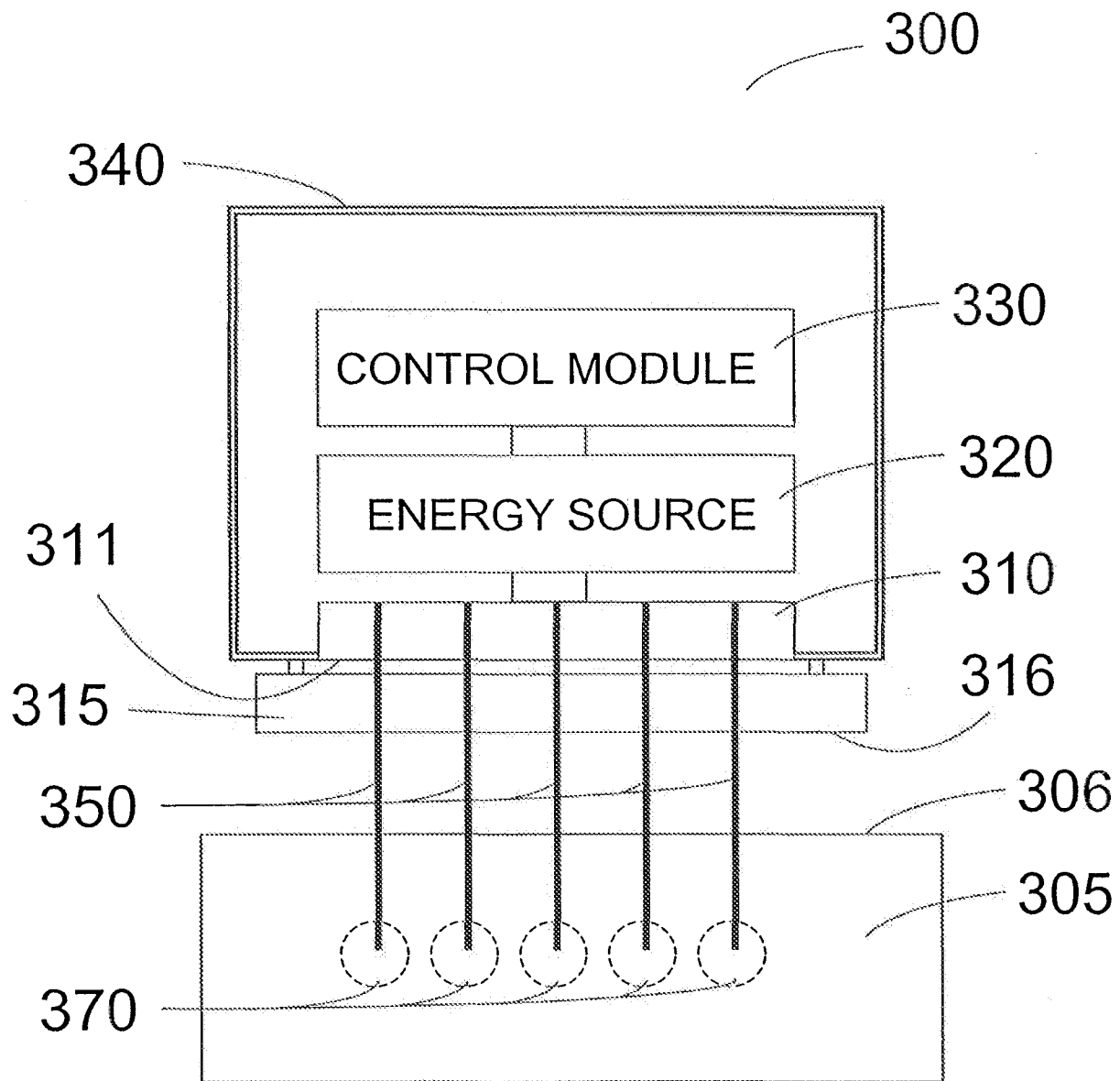


FIG. 3

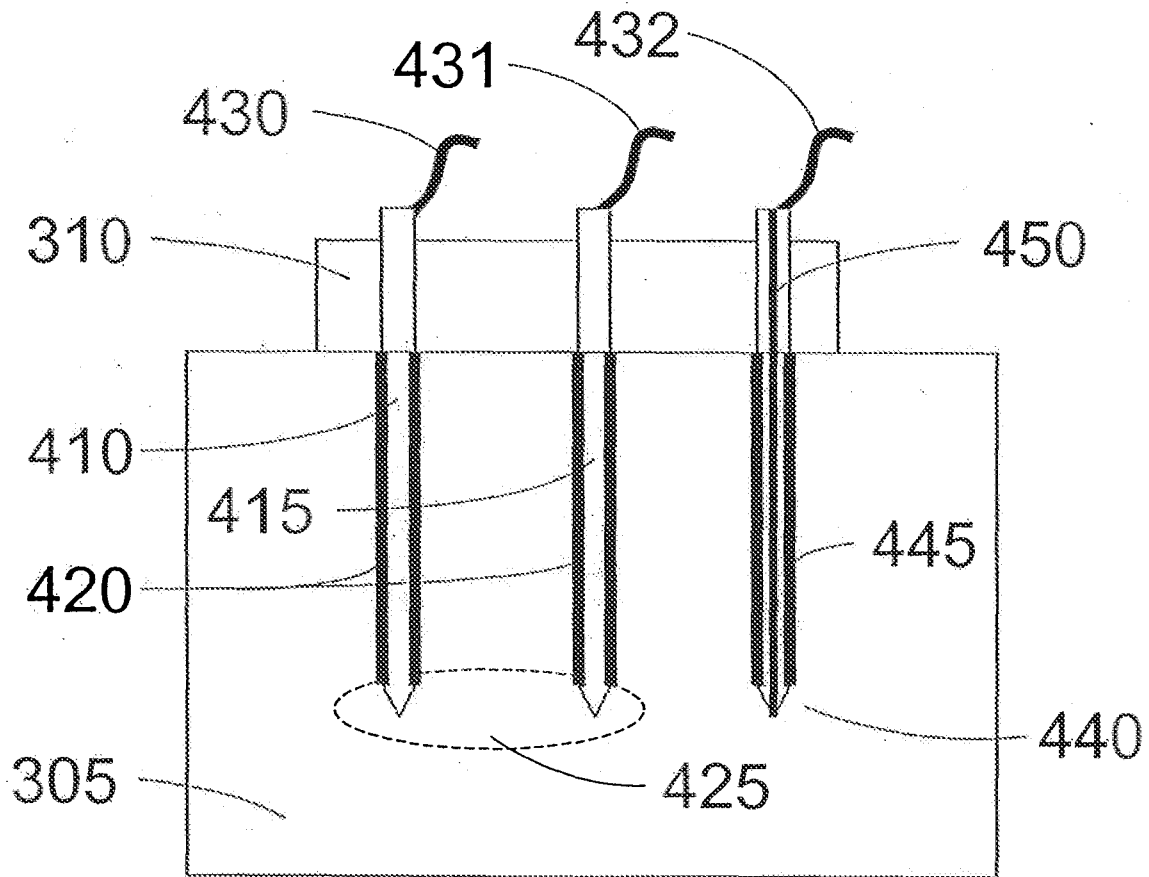


FIG. 4

DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

(Under 37 CFR § 1.63; includes reference to PCT International Applications)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention ENTITLED:

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

the specification of which:

- ☐ is attached hereto
- ☒ was filed on 1 April 2005 as:
- ☒ United States Application Serial No. 11/098,030
- ☒ which claims priority to U.S. Provisional Patent Application No. 60/558,476, filed 1 April 2004
- ☐ as a National Phase or Continuation or Continuation-in-Part or Divisional of
- ☐ PCT Application No. _____, filed _____
- ☐ and designating the U.S., and published as _____ on _____
- ☐ with amendments through _____ (if applicable, give details).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT International application(s) designating at least one country other than the United State of America listed below and have also identified below any foreign application for patent or inventor's certificate or any PCT International applications designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) on which priority is claimed:

Prior Foreign/PCT Application(s) [list additional applications on separate page]:

<u>Country (or PCT)</u>	<u>Application Number:</u>	<u>Filed (Day/Month/Year)</u>	Priority Claimed:	
			<u>Yes</u>	<u>No</u>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States application listed below:

<u>60/558,476</u>	<u>1 April 2004</u>
(Application Number)	(Filing Date)

I hereby claim the benefit under Title 35, United States Code § 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S. (or U.S.-designating PCT) Application(s) [list additional applications on separate page]:

U.S. Serial No.: Filed (Day/Month/Year) PCT Application No. Status (patented, pending, abandoned)

I hereby appoint Thomas J. Kowalski, Registration No. 32,147, Steven P. Marsh, Registration No. 53,271 and Frommer Lawrence & Haug LLP, or their duly appointed associate, my attorneys, with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to file continuation and divisional applications thereof, to receive the Patent, and to transact all business in the Patent and Trademark Office and in the Courts in connection therewith, and to insert the Serial Number of the application in the space provided above, and specify that all communications about the application are to be directed to the following correspondence address:

Thomas J. Kowalski, Esq.
c/o FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151

Direct all telephone calls to: (212) 588-0800
to the attention of: Thomas J. Kowalski

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

INVENTOR(S):

Signature:

Full name of sole or first inventor:

Residence:

Citizenship:

Dieter Manstein

4 Longfellow Place, Apt. 2005, Boston, MA 02114

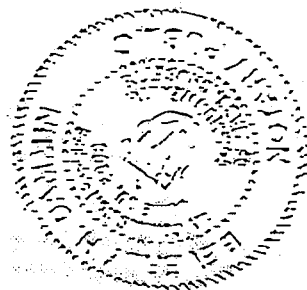
Germany

Date:

4/20/05

Beverly H. Dammin

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



APPLICATION DATA SHEET

Application Information

Application Type:: US Divisional
Subject Matter:: Utility
CD-ROM or CD-R?: None
Title:: METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING

Attorney Docket No.: 036213.US.07 – 475387-779
Request for Early Publication?: No
Request for Non-Publication?: No
Suggested Drawing Figure:
Total Drawing Sheets:: 4
Small Entity:: Yes
Petition included?: No
Secrecy Order in Parent Appl.?: No

Applicant Information

Applicant Authority Type:: Inventor
Primary Citizenship Country:: USA
Status:: Full Capacity
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Country of Residence:: USA
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City of Mailing Address:: Miami
State of Mailing Address:: Florida
Country of Mailing Address:: USA
Postal or Zip Code of Mailing Address:: 33129

Correspondence Information

Correspondence Customer No.: 30873

Phone Number: (212) 415-9200

Fax Number: (212) 953-7201

Representative Information

Representative Customer Number:	30873
---------------------------------	-------

Foreign Priority Information

Country:	Application Number:	Filing Date:	Priority Claimed:

Domestic Priority Information

Application:	Type:	Priority Claimed:	Filing Date:
60/558,476	Provisional	Yes	April 1, 2004
11/098,030	Non-Provisional	Yes	April 1, 2005

Assignee Information

Assignee Name: The General Hospital Corporation

Street of Address: 55 Fruit Street

City of Mailing Address: Boston

State of Mailing Address: Massachusetts 02114

Country of Mailing Address: U.S.A.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Dieter MANSTEIN

Serial No. : To be assigned (Divisional of Serial No. 11/098,030)

Filed : Filed herewith (October 27, 2010)

For : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING

Examiner : To be assigned

Art Unit : To be assigned

Confirmation No. : To be assigned

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

PRELIMINARY AMENDMENT

SIR:

Kindly amend the above-identified application before examination as follows:

IN THE SPECIFICATION:

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

REMARKS

This Preliminary Amendment amends the originally-filed specification of the above-referenced U.S. application to add a Statement Regarding Federally Sponsored Research for the above-referenced application and information associated therewith, and to indicate that it is a divisional application U.S. Patent Application Serial No. 11/098,030 filed on April 1, 2005, and thus claims priority therefrom.

Further, originally-filed claims 16-19 have been amended to clarify the subject matter recited therein, and claims 1-15 were cancelled without prejudice. New claims 20-26 have been added, and depend from amended independent claim 16. Accordingly, claims 16-26 are now under consideration in the above-identified application. As pending claims 16-19 of the present application have been restricted in the parent U.S. Patent Application Serial No. 11/098,030 via a restriction requirement, and thus were cancelled therefrom, claims 16-19 (as amended) are presented herein. The cancellation of claims 1-15, the amendments to claims 16-19 and the addition of new claims 20-26 as identified above comply with 37 C.F.R. § 1.121. Applicants further respectfully assert that the amendment to the specification, the amendments to claims 16-19 and the addition of new claims 20-26 do not add new matter to the application.

Applicants assert that the present invention is new, non-obvious, and useful.

Prompt consideration and allowance of the pending claims are respectfully requested.

Respectfully submitted,

Dated: October 28, 2010

By: 

Gary Abelev
Reg. No. 40,479

Attorney(s) for Applicant(s)
DORSEY & WHITNEY LLP
250 Park Avenue
New York, New York 10177
(212) 415-9371

4817-9524-0455\1

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:	Emil Bradley Gould/Miesha Hollingsworth			
Attorney Docket Number:	036213.US.07-475387-779			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	82	82
Utility Search Fee	2111	1	270	270
Utility Examination Fee	2311	1	110	110
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				462

Electronic Acknowledgement Receipt

EFS ID:	8722452
Application Number:	12914201
International Application Number:	
Confirmation Number:	5359
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Emil Bradley Gould/Miesha Hollingsworth
Filer Authorized By:	Emil Bradley Gould
Attorney Docket Number:	036213.US.07-475387-779
Receipt Date:	28-OCT-2010
Filing Date:	
Time Stamp:	14:37:53
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$462
RAM confirmation Number	855
Deposit Account	502054
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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	Specification		2	17	
	Claims		18	22	
	Abstract		23	23	
	Drawings-only black and white line drawings		24	27	
	Oath or Declaration filed		28	29	
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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.

RELATED APPLICATIONS

The present application is a divisional of U.S. Patent Application Serial No. 11/098,030 filed on April 1, 2005. This application also claims priority to U.S. Provisional Application Serial No. 60/558,476 filed on April 1, 2004.

IN THE CLAIMS:

Please cancel originally-filed claims 1-15 without prejudice, and amend claims 16-19, and add new claims 20-26, as provided below. The listing of the claims as pending in this application are provided on separate sheets as follows:

Claims 1-15 (Cancelled).

16. (Currently Amended) A method of treating at least one portion of 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 optical energy to more than one of the needles to induce a pattern of damage in the tissue surrounding the needles.

17. (Currently Amended) The method of claim 16, further comprising:

providing a control module, ~~wherein the control module permits~~ facilitates a variation of the characteristics of optical 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. (Currently Amended) The method of claim 16, further comprising:

wherein the providing one or more hollow needles are hollow needles attached to the base and further comprising injecting an analgesic through the hollow needles into a the surrounding tissue of the at least one portion after the needles are inserting into the skin.

19. (Currently Amended) The method of claim 16, further comprising:

~~providing a control module, wherein the control module permits a variation of the characteristics of energy supplied by the energy source and~~

~~providing a cooling means arrangement to cool a the surface of the at least one portion 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.~~

20. (New) The method of claim 19, further comprising providing a cooling arrangement configured to cool the needles, before inserting the needles into the skin.

21. (New) The method of claim 16, further comprising providing a detection device in communication with one or more of the needles, the detection device configured to receive information from the at least one portion based on the impact thereof by the optical energy.

22. (New) The method of claim 16, further comprising:

detecting a presence of a nerve near the needles; and

preventing the energy source from supplying the energy to any of the needles if the nerve has been detected near a particular one of the needles.

23. (New) The method of claim 16, wherein the needles include hollow needles containing light fibers or light guides in communication with the optical energy source.

24. (New) The method of claim 23, further comprising supplying the optical energy to the light fibers or the light guides to induce a thermal damage in the at least one portion of the tissue surrounding the hollow needles

25. (New) The method of claim 16, wherein the energy source and the control module are configured to deliver the optical energy to a plurality of pairs of needles in a bipolar mode.

26. (New) The method of claim 16, wherein the optical energy is provided to the at least one portion through an epidermal layer of the at least one portion to reach and optically irradiate the dermis of the at least one portion.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 12/914,201		Filing Date 10/28/2010		<input type="checkbox"/> To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY <input checked="" type="checkbox"/> OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	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			N/A			N/A	
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$	=		X \$	=		X \$	=
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=		X \$	=		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 \$250 (\$125 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.										
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	10/28/2010	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 11	Minus	** 20	= 0	X \$26 =	0		X \$ =	
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0	X \$110 =	0		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	0		TOTAL ADD'L FEE	
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =			X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =			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			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.										

Legal Instrument Examiner:
/LAJUAN HICKSON/

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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DATE: 10/28/10

Approved for use through 7/31/2006. OMB 0651-0032

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

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

12/914,201

APPLICATION AS FILED – PART I

FOR	NUMBER FILED (Column 1)	NUMBER EXTRA (Column 2)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A
TOTAL CLAIMS (37 CFR 1.16(i))	11	minus 20 =
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1	minus 3 = *
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$270 (\$135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR	
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))		

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

SMALL ENTITY

RATE (\$)	FEE (\$)
N/A	82
N/A	270
N/A	110
x\$26	
x\$110	
195	
TOTAL	462

APPLICATION AS AMENDED – PART II

AMENDMENT A	(Column 1)	(Column 2)	(Column 3)
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total (37 CFR 1.16(i))	*	Minus **	=
Independent (37 CFR 1.16(h))	*	Minus ***	=
Application Size Fee (37 CFR 1.16(s))			
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			

SMALL ENTITY

RATE (\$)	ADDITIONAL FEE (\$)
X =	
X =	
N/A	
TOTAL ADD'T FEE	

OTHER THAN SMALL ENTITY

RATE (\$)	FEE (\$)
N/A	
N/A	
N/A	
x\$52	
x\$220	
390	
TOTAL	

OTHER THAN SMALL ENTITY

RATE (\$)	ADDITIONAL FEE (\$)
X =	
X =	
N/A	
TOTAL ADD'T FEE	

AMENDMENT B

AMENDMENT B	(Column 1)	(Column 2)	(Column 3)
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total (37 CFR 1.16(i))	*	Minus **	=
Independent (37 CFR 1.16(h))	*	Minus ***	=
Application Size Fee (37 CFR 1.16(s))			
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			

SMALL ENTITY

RATE (\$)	ADDITIONAL FEE (\$)
X =	
X =	
N/A	
TOTAL ADD'T FEE	

OTHER THAN SMALL ENTITY

RATE (\$)	FEE (\$)
X =	
X =	
N/A	
TOTAL ADD'T FEE	

OTHER THAN SMALL ENTITY

RATE (\$)	ADDITIONAL FEE (\$)
X =	
X =	
N/A	
TOTAL ADD'T 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.

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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
12/914,201	10/28/2010	3769	462	036213.US.07-475387-779	11	1

CONFIRMATION NO. 5359

30873

DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
250 PARK AVENUE
NEW YORK, NY 10177

FILING RECEIPT



OC000000044415297

Date Mailed: 11/12/2010

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**

Applicant(s)

Dieter Manstein, Boston, MA;

Assignment For Published Patent Application

The General Hospital Corporation, Boston, MA

Power of Attorney:

Thomas Kowalski--32147

Steven Marsh--53271

Domestic Priority data as claimed by applicant

This application is a DIV of 11/098,030 04/01/2005 PAT 7,824,394

Foreign Applications

If Required, Foreign Filing License Granted: 11/09/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/914,201**

Projected Publication Date: 02/24/2011

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

Preliminary Class

606

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/914,201	10/28/2010	Dieter Manstein	036213.US.07-475387-779

CONFIRMATION NO. 5359

PUBLICATION NOTICE

30873
DORSEY & WHITNEY LLP - NEW YORK (PT/18)
ATTENTION: INTELLECUAL PROPERTY/PATENT DEPARTMENT
250 PARK AVENUE
NEW YORK, NY 10177-1500



OC000000046170170

Title:METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING

Publication No.US-2011-0046615-A1

Publication Date:02/24/2011

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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.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

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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	12/914,201
				Filing Date	October 28, 2010
				First Named Inventor	Dieter Manstein
				Art Unit	3769
				Examiner Name	TBA
Sheet	1	of	5	Attorney Docket No: 36213.US.07-475387-779	

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) 2 Applicant is to place a check mark here if English language Translation is attached

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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	12/914,201
				Filing Date	October 28, 2010
				First Named Inventor	Dieter Manstein
				Art Unit	3769
				Examiner Name	TBA
Sheet	2	of	5	Attorney Docket No: 36213.US.07-475387-779	

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

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Substitute Disclosure Statement Form (PTO-1449)

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				Application Number	12/914,201
				Filing Date	October 28, 2010
				First Named Inventor	Dieter Manstein
				Art Unit	3769
				Examiner Name	TBA
Sheet	3	of	5	Attorney Docket No: 36213.US.07-475387-779	

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.	

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

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	12/914,201
				Filing Date	October 28, 2010
				First Named Inventor	Dieter Manstein
				Art Unit	3769
				Examiner Name	TBA
Sheet	4	of	5	Attorney Docket No: 36213.US.07-475387-779	

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.	
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		20080125775	May 2008	Morris	
		20080221649	Sep 2008	Echague et al.	

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			

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS
--

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

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 <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	12/914,201
				Filing Date	October 28, 2010
				First Named Inventor	Dieter Manstein
				Art Unit	3769
				Examiner Name	TBA
Sheet	5	of	5	Attorney Docket No: 36213.US.07-475387-779	

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
		Urmey 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.	

EXAMINER**DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

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4852-9360-3081\1

Electronic Acknowledgement Receipt

EFS ID:	10060157
Application Number:	12914201
International Application Number:	
Confirmation Number:	5359
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Paul Douglas Ackerman/Agata Glinska
Filer Authorized By:	Paul Douglas Ackerman
Attorney Docket Number:	036213.US.07-475387-779
Receipt Date:	10-MAY-2011
Filing Date:	28-OCT-2010
Time Stamp:	16:18:40
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	Transmittal Letter	IDS_Letter779.pdf	62995 91ba0efc34c190fe57bcde7501d87306ba99c251	no	2

Warnings:

Information:

2	Information Disclosure Statement (IDS) Filed (SB/08)	SB08_779.pdf	262979 e96c38da9b721cb8186d61460afc21391f38165b	no	5
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
Total Files Size (in bytes):				325974	
<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 et al.
Serial No. : 12/914,201
Filed : October 28, 2010
Entitled : METHOD AN APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Group Art Unit : 3769
Examiner : TBA
Confirmation No. : 5359

INFORMATION DISCLOSURE STATEMENT

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

Dear Sir:

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-1449, and respectfully request that the listed documents be considered by the Examiner and made of record in the above-captioned application.

The above-referenced patent application is a divisional of a parent U.S. Patent application No. 11/098,030, filed April 1, 2005. All references cited on enclosed Form PTO/SB/08 were previously cited in U.S. Patent Application No. 11/098,030. Therefore, pursuant to 37 C.F.R. § 1.98(d), no copies of the cited references are included herewith.

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 before any substantive action by the U.S. Patent and Trademark Office on the merits. 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. 50-2054.

Respectfully submitted,

DORSEY & WHITNEY, LLP

Date: May 10, 2011



Paul D. Ackerman
PTO Reg. No. 39,891
Attorney for Applicants
(212) 415-9372

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	12/914,201
Filing Date	October 28, 2010
First Named Inventor	Dieter Manstein
Art Unit	3769
Examiner Name	To be assigned
Attorney Docket Number	036213.US.07-475387-779

Sheet 1 of 2

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US- 20090124958	05/14/2009	L. Kasey	
		US- 20080082090	04/03/2008	D. Manstein	
		US- 20080312647	12/18/2008	P. Knopp	
		US- 20070106143	05/10/2007	J. Flaherty	
		US- 6,277,116	08/21/2001	D. Utely	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

Examiner
Signature

Date
Considered

*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 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours 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, 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 (1-800-786-9199) and select option 2.

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	12/914,201
Filing Date	October 28, 2010
First Named Inventor	Dieter Manstein
Art Unit	3769
Examiner Name	To be assigned
Attorney Docket Number	036213.US.07-475387-779

Sheet 2 of 2

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
		International Search Report mailed on February 1, 2011 for International Application No. PCT/US2010/037950	
		International Written Opinion mailed on February 1, 2011 for International Application No. PCT/US2010/037950	

Examiner
SignatureDate
Considered

*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. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours 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, 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 (1-800-786-9199) and select option 2.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 036213.WO.06	FOR FURTHER ACTION		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2010/037950	International filing date (day/month/year) 09 JUNE 2010 (09.06.2010)	(Earliest) Priority Date (day/month/year) 09 JUNE 2009 (09.06.2009)	
Applicant THE GENERAL HOSPITAL CORPORATION et al			

This International search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 7 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

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

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

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (See Box No. III)

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 4

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figure is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2010/037950

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. ☒ Claims Nos.: 18-23
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 18-23 are directed to a method including the steps for inserting a needle or a needle arrangement into the biological tissue. This method falls into the category of a method for treatment of the human body by surgery, therapy or diagnostic methods [Article 17(2)(a)(i), Rule 39.1(iv) PCT].
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

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 and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/037950**A. CLASSIFICATION OF SUBJECT MATTER***A61B 18/18(2006.01)i, A61B 18/20(2006.01)i, A61M 37/00(2006.01)i, A61L 31/02(2006.01)i*

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)

A61B 18/18; A61B 5/04; A61H 33/00; A61B 18/14; A61B 18/20; A61N 5/067; A61N 1/00

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & Keywords: dermatological treatment, optical energy, needle arrangement, waveguide

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009-0124958 A1 (LI KASEY K. et al.) 14 May 2009	1,8,12
Y	See paragraphs 46, 47, 50, 53-56, 61, 64, claims 1, 22, figs. 8-10	14,15
A		1-7,9-11,13,16,17
Y	US 2008-0082090 A1 (DIETER MANSTEIN) 03 April 2008	14,15
A	See abstract, paragraphs 21, 33, 61, claims 1, 5, 16, 20, figs. 4, 5	1-12,16-17
A	US 2008-0312647 A1 (KNOPP PETER G. et al.) 18 December 2008	1-17
	See paragraphs 62, 63, 88, 89, claims 2, 15-17, 39, figs. 2A, 4A	
A	US 2007-0106143 A1 (J. FLAHERTY) 10 May 2007	1-17
	See paragraphs 123, 169, 170, 172, 178, 180-182, claims 1, 4, 5, figs. 1, 2	
A	US 6277116 B1 (UTELY; DAVID et al.) 21 August 2001	1-17
	See abstract, col. 7 line 40-col. 9 line 45, claims 7, 8, figs. 6-8	

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

31 JANUARY 2011 (31.01.2011)

Date of mailing of the international search report

01 FEBRUARY 2011 (01.02.2011)

Name and mailing address of the ISA/KR

Korean Intellectual Property Office
Government Complex-Daejeon, 139 Seonsa-ro, Seo-
gu, Daejeon 302-701, Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

OH Seung Jae

Telephone No. 82-42-481-8469



INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2010/037950

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009-0124958 A1	14.05.2009	None	
US 2008-0082090 A1	03.04.2008	US 2005-0222565 A1 US 2008-082090 A1 US 7824394 B2	06.10.2005 03.04.2008 02.11.2010
US 2008-0312647 A1	18.12.2008	EP 2162084 A1 US 2009-0036958 A1 WO 2008-157400 A1	17.03.2010 05.02.2009 24.12.2008
US 2007-0106143 A1	10.05.2007	None	
US 6277116 B1	21.08.2001	AU 1995-24321 B2 AU 1998-63327 A1 AU 1999-31049 A1 AU 2000-36964 A1 AU 2000-36964 B2 AU 2000-54621 A1 AU 2001-243264 B2 AU 2001-43264 A1 AU 2002-246952 B2 AU 2003-231734 A1 AU 2003-248461 A1 AU 3696400 A AU 757624 B2 CA 2362276-A1 CA 2399933-A1 CA 2433396-A1 CA 2438913-A1 CA 2449375-A1 CA 2449379-A1 CA 2449454-A1 CN 1371259 A0 EP 0760626 A1 EP 0760626 B1 EP 0820096 A2 EP 0820096 A3 EP 0820096 B1 EP 0998331 A1 EP 1006885 A2 EP 1006885 B1 EP 1063931 A2 EP 1152701 A2 EP 1191892 A1 EP 1191892 B1 EP 1259167 A2 EP 1259167 B1 EP 1357848 A2 EP 1357848 A4	20.01.2000 30.08.1999 11.10.1999 04.09.2000 27.02.2003 31.01.2001 02.02.2006 03.09.2001 30.11.2006 29.03.2004 17.03.2005 04.09.2000 27.02.2003 24.08.2000 30.08.2001 01.08.2002 17.09.2004 12.12.2002 12.12.2002 12.12.2002 25.09.2002 26.09.2001 26.09.2001 21.01.1998 30.08.2000 17.02.2010 10.05.2000 14.06.2000 20.09.2006 03.01.2001 14.11.2001 03.04.2002 12.07.2006 27.11.2002 02.11.2005 05.11.2003 27.07.2005

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2010/037950

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		EP 1357848 B1	11.03.2009
		EP 1395178 A2	10.03.2004
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		US 05458596A A	17.10.1995
		US 05569242A A	29.10.1996
		US 05954716A A	21.09.1999
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2010/037950

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 2004-0111136 A1	10.06.2004
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		US 2004-0127963 A1	01.07.2004
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2010/037950

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		WO 99-40969 A1	19.08.1999
		WO 99-47058 A2	23.09.1999

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

ABELEV GARY

DORSEY & WHITNEY LLP 250 PARK AVENUE NEW
YORK NY 10177 USA

PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **01 FEBRUARY 2011 (01.02.2011)**

Applicant's or agent's file reference
036213.WO.06

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US2010/037950

International filing date (day/month/year)

09 JUNE 2010 (09.06.2010)

Priority date(day/month/year)

09 JUNE 2009 (09.06.2009)

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

A61B 18/18(2006.01)i, A61B 18/20(2006.01)i, A61M 37/00(2006.01)i, A61L 31/02(2006.01)i

Applicant

THE GENERAL HOSPITAL CORPORATION et al

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

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

2. **FURTHER ACTION**

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

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

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

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
Government Complex-Daejeon, 139
Seonsa-ro, Seo-gu, Daejeon 302
-701, Republic of Korea
Facsimile No. 82-42-472-7140

Date of completion of this opinion

31 JANUARY 2011 (31.01.2011)

Authorized officer

OH Seung Jae

Telephone No.82-42-481-8469



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2010/037950

Box No. I Basis of this opinion

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

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

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

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

a. a sequence listing filed or furnished

- ☐ on paper
- ☐ in electronic form

b. time of filing or furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

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

5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2010/037950

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 18-23

because:

☒ the said international application, or the said claims Nos. 18-23

relate to the following subject matter which does not require an international search (*specify*):

The subject matter of claims 18-23 are directed to a method including the steps for inserting a needle or a needle arrangement into the biological tissue. This method falls into the category of a method for treatment of the human body by surgery, therapy or diagnostic methods [Article 34(4)(a)(i), Rule 43bis.1(b); Rule 67.1(iv) PCT shall apply mutatis mutandis].

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 18-23

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2010/037950

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

1. Statement

Novelty (N)	Claims	2-7,9-11,13-17	YES
	Claims	1,8,12	NO
Inventive step (IS)	Claims	2-7,9-11,13,16-17	YES
	Claims	1,8,12,14-15	NO
Industrial applicability (IA)	Claims	1-17	YES
	Claims	NONE	NO

2. Citations and explanations :

Reference is made to the following documents:

D1: US 2009-0124958 A1 (LI KASEY K. et al.) 14 May 2009
D2: US 2008-0082090 A1 (DIETER MANSTEIN) 03 April 2008
D3: US 2008-0312647 A1 (KNOPP PETER G. et al.) 18 December 2008
D4: US 2007-0106143 A1 (J. FLAHERTY) 10 May 2007
D5: US 6277116 B1 (UTELY; DAVID et al.) 21 August 2001

1. Novelty and Inventive Step

1.1 Independent claim 1

Claim 1 of the present invention relates to an apparatus for providing optical energy and a substance to a biological tissue, comprising a delivery needle arrangement and a waveguide arrangement.

Document D1, which is regarded as the closest prior art to the present invention, discloses device and methods for altering the appearance of a tissue region such as the facial region. D1 teaches that laser energy may be applied to a tissue region via an optical fiber advanced through a lumen of at least one needle (see paragraph 46, 47, 50, 56, claims 1, 22, figs. 8-10) and fluid may also be infused or injected into the tissue region through at least one needle (see paragraph 47, claim 1, figs. 8-10).

Accordingly, the subject matter of claim 1 is substantially the same as D1. Therefore, claim 1 lacks novelty under PCT Article 33(2).

1.2 Dependent claim 8

The additional feature of claim 8 relates to a plurality of delivery needles and a plurality of waveguides. D1 discloses the structure (70) containing needles (22) arranged in a grid-like pattern. The Each needle may also contain an optical fiber (26) or be used for fluid delivery; however selective use of each needle may be regulated by the controller (30), depending on treatment strategy and/or the target tissue (see figs.9-10, paragraph 61).

As the feature of claim 8 is disclosed in D1, this claim is anticipated by D1. Claim 8 lacks novelty under PCT Article 33(2).

Continued on Supplemental Box

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2010/037950

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of :

Box V

1.3 Dependent Claim 12

The additional feature of claim 12 relates to the light source provided in communication with the waveguide arrangement. D1 discloses the device including a laser generator (24) for delivering laser energy through the shaft 18 to the distal end portion (20), which is in optical communication with the proximal end of at least one optical fiber (26) positioned through the device (16) with the terminal end of the optical fiber 26 placed between or adjacent to the needle (22) (see figs.9-10, paragraph 47).

The additional feature of claim 12 is already disclosed in D1. Therefore, claim 12 lacks novelty under PCT Article 33(2).

1.4 Dependent claims 14 and 15

Claims 14 and 15 differ from D1 in that the light source comprises at least one of a laser diode or an LED. The technical features of claims 14 and 15 are not explicitly disclosed in D1. However, D2 discloses an apparatus for providing an electromagnetic radiation which is provided by at least one of a diode laser, a diode-pumped solid state laser, an LED, an intense pulsed light source, etc(see claim 16, paragraphs 21, 33, 61)

Accordingly, claims 14 and 15 would have been obvious over D1 in view of D2. Therefore, claims 14 and 15 lack an inventive step under PCT Article 33(3).

1.5 Dependent claims 2-7, 9-11, 13, 16-17

The additional features of dependent claims 2-7, 9-11, 13, 16-17 are neither disclosed nor suggested by any one of the available prior art documents. Therefore, a combination of at least one of these claims with the claims to which they refer could be considered as novel and inventive under PCT Article 33(2) and (3).

2. INDUSTRIAL APPLICABILITY

The subject matter of claims 1-17 are industrially applicable under PCT Article 33(4).

Electronic Acknowledgement Receipt

EFS ID:	12951922
Application Number:	12914201
International Application Number:	
Confirmation Number:	5359
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Gary Abelev/Kim Dufault
Filer Authorized By:	Gary Abelev
Attorney Docket Number:	036213.US.07-475387-779
Receipt Date:	06-JUN-2012
Filing Date:	28-OCT-2010
Time Stamp:	17:27:41
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		475387-779.pdf	869037 5f6daa14d07d7b73d3ed95be920a491a2f192479	yes	16

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Miscellaneous Incoming Letter	1	2
	Information Disclosure Statement (IDS) Form (SB08)	3	4
	Foreign Reference	5	11
	Foreign Reference	12	16

Warnings:

Information:

Total Files Size (in bytes):	869037
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Dieter Manstein et al.
Serial No. : 12/914,201
Filed : October 28, 2010
Entitled : METHOD AN APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Group Art Unit : 3769
Examiner : To be assigned
Confirmation No. : 5359

INFORMATION DISCLOSURE STATEMENT

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

Dear Sir:

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 foreign references are enclosed.

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 applicant determines that the cited documents do not constitute "prior art" under

U.S. 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 before any substantive action by the U.S. Patent and Trademark Office on the merits. 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. 50-2054.

Respectfully submitted,

Date: June 6, 2012

By: 

Gary Abelev, Esq.
Reg. No. 40,479

DORSEY & WHITNEY, L.L.P.
51 West 52nd Street
New York, New York 10019

Attorney for Applicant(s)
(212) 415-9200

4822-6525-4927\1



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/914,201	10/28/2010	Dieter Manstein	036213.US.07-475387-779	5359

30873 7590 02/28/2014
DORSEY & WHITNEY LLP - NEW YORK
ATTENTION: INTELLECTUAL PROPERTY - PATENT DOCKET
51 WEST 52ND STREET
NEW YORK, NY 10019-6119

EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
----------	--------------

3769

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

02/28/2014

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):

ny.patent.docketing@dorsey.com
hollingsworth.miesha@dorsey.com
dufault.kim@dorsey.com

Office Action Summary	Application No. 12/914,201	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 10/28/2010.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-19 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) 1-19 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. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a tissue reshaping apparatus comprising plurality of needles in communication with RF energy source, and a control system adapted to control the output of the energy source , classified in 606/41.

II. Claims 16-19, drawn to a method of treating skin, classified in 128/898.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case other and materially different apparatus can be used for treating skin, for example an apparatus comprising a light delivery means in communication with a treatment light source, and control system configured to control the output of the light source.

4. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

The claimed inventions 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 an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve 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 restriction 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 upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions 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 inventions 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 invention.

5. A telephone call was made to the office of the applicant's representative on February 21, 2014 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 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

February 24, 2014

Application/Control Number: 12/914,201
Art Unit: 3769

Page 5

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA/82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	12/914,201
Filing Date	October 28, 2010
First Named Inventor	Dieter Manstein
Title	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
Art Unit	3769
Examiner Name	Ahmed M. Farah
Attorney Docket Number	036213.US.07-32865-215480

SIGNATURE of Applicant or Patent Practitioner

Signature	/Gary Abelev/	Date (Optional)	02/28/2014
Name	Gary Abelev	Registration Number	40479
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

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



*Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Doc Code: PA..

Document Description: Power of Attorney

PTO/AIA/82B (07-13)

Approved for use through 11/30/2014. OMB 0651-0051

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

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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date
12/914,201	10/28/10

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- ☒ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:
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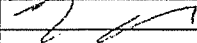
I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

--

- ☐ Inventor or Joint Inventor (title not required below)
- ☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)
- ☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)
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SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	1/27/12
Name	Richard Stevens		
Title	Director, IP Management Group		

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

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Electronic Acknowledgement Receipt

EFS ID:	18332541
Application Number:	12914201
International Application Number:	
Confirmation Number:	5359
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Gary Abelev/Kim Dufault
Filer Authorized By:	Gary Abelev
Attorney Docket Number:	036213.US.07-475387-779
Receipt Date:	28-FEB-2014
Filing Date:	28-OCT-2010
Time Stamp:	11:48:30
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	Power of Attorney	32865-215480POA.pdf	104663 7771fd8ab7f831d7888bfbe17014912ed43ad332	no	2

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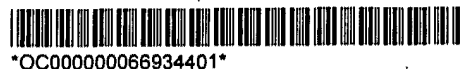
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/914,201	10/28/2010	Dieter Manstein	036213.US.07-475387-779

CONFIRMATION NO. 5359

30873
 DORSEY & WHITNEY LLP - NEW YORK
 ATTENTION: INTELLECTUAL PROPERTY - PATENT DOCKET
 51 WEST 52ND STREET
 NEW YORK, NY 10019-6119



OC000000066934401

Cc: ANDREWS KURTH LLP
 ATTENTION: INTELLECTUAL PROPERTY - PATENT DOCKET
 450 LEXINGTON AVENUE
 NEW YORK, NY 10017

Date Mailed: 03/05/2014

DENIAL OF REQUEST FOR POWER OF ATTORNEY

The request for Power of Attorney filed 02/28/14 is acknowledged. However, the request cannot be granted at this time for the reason stated below.

- ☐ The Power of Attorney you provided did not comply with the new Power of Attorney rules that became effective on June 25, 2004. See 37 CFR 1.32.
- ☐ The revocation is not signed by the applicant, the assignee of the entire interest, or one particular principal attorney having the authority to revoke.
- ☒ The Power of Attorney is from an assignee and the Certificate required by 37 CFR 3.73(c) has not been received.
- ☐ The person signing for the assignee has omitted their empowerment to sign on behalf of the assignee.
- ☐ The inventor(s) is without authority to appoint attorneys since the assignee has intervened as provided by 37 CFR 3.71.
- ☐ The signature(s) of ____, a co-inventor in this application, has been omitted. The Power of Attorney will be entered upon receipt of confirmation signed by said co-inventor(s).
- ☐ The person(s) appointed in the Power of Attorney is not registered to practice before the U.S. Patent and Trademark Office.
- ☐ Only one Customer Number can be designated for the Power of Attorney in an application. The Customer Number that was captured is the first Customer Number provided on the Power of Attorney document.

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- ☐ A request under 37 CFR 1.48 to add an inventor was granted in this application, however, no power of attorney consistent with the power of attorney granted by the originally named inventive entity has been received. Thus, the addition of the inventor has resulted in the loss of power of attorney in the application. See 37 CFR 1.32(e).
- ☐ The power of attorney has not been accepted because the party who is giving power of attorney 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 patent owner who was not the applicant must appoint any power of attorney in compliance with 37 CFR 3.71 and 3.73. See 37 CFR 1.32(b)(4).
- ☐ The power of attorney from the inventors has not been accepted because it is a copy from a prior national application for which benefit is claimed and the continuing application names an inventor who was not named as an inventor in the prior application.
- ☐ The power of attorney from the inventors has not been accepted because the power of attorney must be signed by the applicant for patent. See 37 CFR 1.32(b)(4).
- ☐ Any request to correct or update the name of the applicant must include an application data sheet (ADS) in compliance with 37 CFR 1.76 specifying the correct or updated name of the applicant in the applicant information section. Any request to change the applicant after an original applicant has been specified under 37 CFR 1.46(b) must include a new ADS in compliance with 37 CFR 1.76 specifying the applicant in the applicant information section and comply with 37 CFR 3.71 and 3.73. See 37 CFR 1.46(c).

Any inquiries regarding this notice should be directed to the Application Assistance Unit at 571-272-4200.

A handwritten signature in cursive script, likely belonging to a representative of the Application Assistance Unit.

Application Assistance Unit
571-272-4200



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/914,201	10/28/2010	Dieter Manstein	036213.US.07-475387-779

CONFIRMATION NO. 5359

MISCELLANEOUS NOTICE

30873
DORSEY & WHITNEY LLP - NEW YORK
ATTENTION: INTELLECTUAL PROPERTY - PATENT DOCKET
51 WEST 52ND STREET
NEW YORK, NY 10019-6119



Date Mailed: 03/06/2014

A communication which cannot be delivered in electronic form has been mailed to the applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Dieter MANSTEIN
Serial No. : 12/914,201
Filed : October 28, 2010
For : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Examiner : Ahmed M. Farah
Art Unit : 3769
Confirmation No. : 5359

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

Commissioner:

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

This paper is filed in response to the Restriction Requirement dated February 28, 2014 for the above-identified application (the "Restriction Requirement"). Please consider the comments as set forth below.

IN THE CLAIMS:

Please cancel previously-pending claims 16-26 without prejudice, and add new claims 27-47, as provided below. The listing of the claims as pending in this application are provided on separate sheets as follows:

1-26. (Canceled)

27. (New) A skin treatment method comprising:

inserting a plurality of needles 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

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 surrounding the needles.

28. (New) The method of claim 27, wherein regulating the delivery of the RF energy is controlled to cause a formation of new collagen in the skin.

29. (New) The method of claim 27, 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 a substantially undamaged region therebetween.

30. (New) The method of claim 29, wherein the thermal damage to the dermal layer includes necrosis.

31. (New) The method of claim 27, wherein regulating the delivery of the RF energy is controlled to substantially prevent a skin ablation.

32. (New) The method of claim 27, wherein the plurality of needles are associated with each other in groups of bipolar pairs, wherein regulating the delivery of the RF energy includes controlling the RF energy being delivered 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 the each bipolar pair of the plurality of needles.

33. (New) The method of claim 32, wherein the areas of non-ablative damage are elongated regions, each provided between each bipolar pair of the plurality of needles.

34. (New) The method of claim 32, wherein regulating the delivery of the RF energy includes delivering about 100 mJ per the bipolar pair of the plurality of needles.

35. (New) The method of claim 27, wherein regulating the delivery of the RF energy includes delivering up to 8 W of power to each of the plurality of needles.

36. (New) The method of claim 27, wherein the plurality of needles are arranged on the base in a substantially rectangular array.

37. (New) The method of claim 27, wherein at least one of the plurality of needles is a mono-polar needle.

38. (New) The method of claim 27, further comprising enabling a user to select treatment parameters, the treatment parameters comprising duration and intensity of the RF energy.

39. (New) The method of claim 27, further comprising facilitating a user to select an application-specific setting for the energy source to cause the energy source to vary a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting.

40. (New) The method of claim 27, wherein at least two of the plurality of needles have differing lengths.

41. (New) The method of claim 27, further comprising cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.

42. (New) The method of claim 27, further comprising vibrating at least one of the plurality of needles.

43. (New) The method of claim 42, wherein vibrating at least one of the plurality of needles includes generating a vibration at a frequency of between about 10 Hz to about 10 kHz.

44. (New) The method of claim 42, wherein vibrating at least one of the plurality of needles includes generating a vibration at an amplitude of between about 50 μm and about 500 μm .

45. (New) The method of claim 27, wherein at least one of the plurality of needles is a hollow needle, and further comprising delivering an analgesic via the hollow needle to tissue surrounding a tip of the hollow needle.

46. (New) The method of claim 27, further comprising detecting a presence of a nerve near a tip of at least one of the plurality of needles.

47. (New) The method of claim 27, wherein inserting the plurality of needles into the dermal layer of skin comprises passing the plurality of needles through a plurality of holes formed in a spacer disposed between the base and a surface of the dermal layer of skin, wherein the plurality of needles are movable relative to the spacer.

REMARKS

I. INTRODUCTION

Prior to the present Amendment and Response, in the Preliminary Amendment dated October 28, 2010, original claims 1-15 have been previously cancelled, without prejudice, claims 16-19 were amended and new claims 20-26 were added.

In the present Amendment and Response, previously-pending claims 16-26 have been cancelled herein above, without prejudice. Applicant reserves the right to pursue such cancelled claims, and any other subject matter described in the present application in one or more continuing applications claiming priority from the present application, and any application from which the present application claims priority. New claims 27-47 have been added. Accordingly, claims 27-47 are now under consideration in the present application.

Provided above, please find a claim listing indicating the current cancellation of claims 16-26, the addition of new claims 27-47, and the status of other claims on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

II. RESTRICTION REQUIREMENT

In the Restriction Requirement, the Examiner alleges that the above-identified application contains claims directed to more than one invention. For such reason, the Examiner believes that the restriction of claims is proper, and now requires Applicant to elect one of the following alleged inventions:

Group I: corresponding to original claims 1-15, allegedly drawn to a tissue reshaping apparatus comprising a plurality of needles

in communication with RF source, and a control system adapted to control the output of energy source, purportedly classified in Class 606, subclass 41; and

Group II: corresponding to original claims 16-19, allegedly drawn to a method for treating skin purportedly classified in Class 128, subclass 898.

However, it appears that the Examiner did not take into consideration the prior cancellation of original claims 1-16 contained in the Preliminary Amendment filed on October 28, 2010, together with the present application. Thus, the restriction of the claims contained in the Restriction Requirement was based on the Examiner's consideration of an incorrect set of claims. Indeed, at least based on the prior cancellation of original claims 1-16 in such Preliminary Amendment, the restriction contained in the Restriction Requirement should be withdrawn.

III. CONCLUSION

In light of the foregoing, Applicant respectfully submits that pending claims 27-47 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,

Dated: April 23, 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 Patent Application Fee Transmittal

Application Number:	12914201			
Filing Date:	28-Oct-2010			
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.07-475387-779			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	2202	1	40	40
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				40

Electronic Acknowledgement Receipt

EFS ID:	18840646
Application Number:	12914201
International Application Number:	
Confirmation Number:	5359
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	30873
Filer:	Gary Abelev/Kim Dufault
Filer Authorized By:	Gary Abelev
Attorney Docket Number:	036213.US.07-475387-779
Receipt Date:	23-APR-2014
Filing Date:	28-OCT-2010
Time Stamp:	16:16:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$40
RAM confirmation Number	2564
Deposit Account	502849
Authorized User	ABELEV, GARY

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		32865-215480POA.pdf	211210	yes	5
			4dfb83f9058122432f48f9be0809e85ae28b0e97		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Power of Attorney		1	1	
	Assignee showing of ownership per 37 CFR 3.73.		2	2	
	Miscellaneous Incoming Letter		3	5	
Warnings:					
Information:					
2	Response to Election / Restriction Filed	32865-215480RR.pdf	71547	no	7
			260bb62d35309c51d12c60d666e0d28ef6f337bd		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30209	no	2
			c4295dce994839e62a0d1d84d34697a1795bae2b		
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Total Files Size (in bytes):			312966		

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New International Application Filed with the USPTO as a Receiving Office

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

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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 a signed 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:



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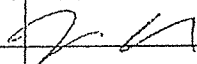
<input type="checkbox"/>	Firm or Individual Name			
	Address			
	City			
	Country			
	Telephone		Email	

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

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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 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/86 (06-04)

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

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

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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, or
2. ☐ 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 _____, Frame _____, 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, 2005
Date

KRIS BETTES
Typed or printed name
Kris B
Signature

LICENSING 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

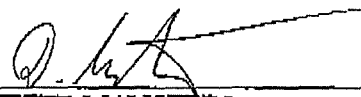
WHEREAS, THE GENERAL HOSPITAL CORPORATION, a Corporation of Massachusetts, having an office for the transaction of business at 55 Fruit Street, Boston, Massachusetts 02114, is desirous of acquiring our entire right, title and interest in and to said invention and any improvements thereon, and in and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

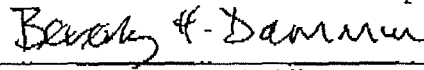
AND I, the said DIETER MANSTEIN for the considerations aforesaid, do hereby covenant and agree to and with said THE GENERAL HOSPITAL CORPORATION, its successors and assigns, that we have the full power to make this assignment, and that the rights assigned are not encumbered by any grant, license or right 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



4816-4948-3520\1

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/914,201	Filing Date 10/28/2010	<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	04/23/2014	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 21	Minus	** 20	= 1	X \$40 =	40
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X \$210 =	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	40

(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
/LAVINIA JOHNSON/

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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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/914,201	Filing Date 10/28/2010	<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	04/23/2014	CLAIMS REMAINING AFTER AMENDMENT	Minus	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 21	Minus	** 20	= 1	x \$40 =	40
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	x \$210 =	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							40

(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
/LAVINIA JOHNSON/

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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/914,201	10/28/2010	Dieter Manstein	036213.US.07-475387-779

CONFIRMATION NO. 5359

POA ACCEPTANCE LETTER

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



Date Mailed: 05/01/2014

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/23/2014.

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.

/tgebre/

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



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United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/914,201	10/28/2010	Dieter Manstein	036213.US.07-475387-779

CONFIRMATION NO. 5359

POWER OF ATTORNEY NOTICE

30873
DORSEY & WHITNEY LLP - NEW YORK
ATTENTION: INTELLECTUAL PROPERTY - PATENT DOCKET
51 WEST 52ND STREET
NEW YORK, NY 10019-6119



Date Mailed: 05/01/2014

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/23/2014.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/tgebre/

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



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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.
12/914,201	10/28/2010	Dieter Manstein	036213.US.07-475387-779	5359

120944 7590 05/09/2014
Andrews Kurth LLP
Attention: Intellectual Property - Patent Docket
450 Lexington Avenue
New York, NY 10017

EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3769

NOTIFICATION DATE	DELIVERY MODE
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05/09/2014

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):

ptony@andrewskurth.com

Office Action Summary	Application No. 12/914,201	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 04/23/2014.
☐ 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) 27-47 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) 27-42 and 45-47 is/are rejected.
- 8) ☒ Claim(s) 43 and 44 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>05/10/11 and 06/06/12</u> . | 4) <input type="checkbox"/> Other: _____ |

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Note: In the Office Action (OA) mailed on February 28, 2014, the examiner considered the original claims filed October 28, 2010 but inadvertently missed the preliminary amendment to the claims, which was filed the same day. Based on this inadvertent oversight for examining incorrect set of claims, the examiner issued a Restriction Requirement. In this OA, the examiner withdraws the restriction requirement of the claims.

Claim Rejections - 35 USC § 112

1. 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.

2. Claims 29, 31, and 36 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. Claim 29 recites the term “substantially undamaged region” in line 4; claim 31 recite that the RF energy is controlled to “substantially prevent” skin ablation in line 2; and claim 36 recites the term “substantially rectangular array” in line 2. However, the scope of such limitations cannot be determined from the claims languages. Furthermore, the applicant's written description

fails to clearly describe scope/boundaries of such limitations. Hence, said limitations render the claims indefinite.

3. The term "substantially" in claim 29, line 4 is a relative term which renders the claim indefinite. The term "substantially undamaged region" 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.

4. The term "substantially" in claim 31, line 2 is a relative term which renders the claim indefinite. The term "substantially prevent a skin ablation" 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.

5. The term "substantially" in claim 36, line 2 is a relative term which renders the claim indefinite. The term "substantially rectangular array" 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.

Appropriate correction or explanation is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3769

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 27, 28, 30, 32, 33, 36, 38-40, and 45-47 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Utely et al. US Patent No. 6,277,116.

With respect to claim 27, Utely et al. discloses a apparatus and methods of use for shrinking collagen tissue, the method comprising: inserting into skin tissue a plurality of needles 82, 90, in communication with radio-frequency energy source 32 (see Fig. 2), wherein the needles are attached to a base 80,88, that is attached to a housing or part of the housing (see Figs. 6 and 8); and a controlling a control module 48 configured to permit variation of the characteristics of the energy supplied by the energy source (see col. 6, line 59 through col. 7, line 3). Controlling of the treatment energy provides a pattern of fractional damage in the dermal layer surrounding the needles thereby shrinking collagen in the dermal skin region.

With respect to claims 28 and 30, the recited claims languages are directed to expected results. The claims languages lack method steps adapted to provide the recited treatments. Furthermore, skin treatment method of Utely et al. would provide the claimed treatments to cause shrinking collagen tissue in the dermis.

With respect to claims 32 and 33, the plurality of needles are associated with each other in groups of bipolar pairs, and the energy control module controls the treatment energy delivered to the bipolar pairs for heating the target tissue to provide the treatment as claimed (see col. 7, lines 64-67).

With respect to claim 36, the plurality of the are arranged in substantially rectangular arrays as claimed (see Figs. 6 and 8).

With respect to claims 3 and 39, the control module is configured to enable the user to select and vary parameters of the desired treatment such as the duration, intensity, power, etc. of the treatment RF energy transmitted to the plurality of needles as claimed.

With respect to claim 40, Utley et al. teach that each of the plurality of the needles electrodes can have a length of between 0.5 to 3 mm.

With respect to claim 41, Utely et al. further teach the step of cooling the skin surface in combination with the RF treatment energy (see col. 6, lines 34-43).

With respect to claims 45, at least one of the plurality of the needles is a hollow needle adapted for delivering treatment fluid/analgesic to tissue surrounding the tip of the hollow needle (see col. 9, lines 11-17).

With respect to claim 46, the recited claim language is devoid of any method step(s) or technique for detecting the presence of the nerve tissue. furthermore, it is common medical procedure to determine or avoid nerve tissue when injecting a needle to a patient's body.

With respect to claim 47, the apparatus of Utley et al. further comprises spacers 62 disposed between the base and skin surface, the spacer having a pattern of small holes through which the plurality of the needles protrude (see Fig. 3).

Claim Rejections - 35 USC § 103

Art Unit: 3769

8. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 34, 35 and 37 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Utley et al.

10. Utley et al., described above, teach the step of varying the power of the RF energy delivered to the needles but do not specifically teach the range of power or energy delivered to the needles as recited claims 34 and 35. However, the use of RF energy and power in the recited ranges for treating skin/body tissue is known in the art. The examiner further notes that the use of mono-polar electrode for delivering treatment RF energy to body tissue is well known in the art. Furthermore, the applicant failed to teach that the use of mono-polar electrode for the recited treatment provides an advantage, is used for a specific purpose, or solves a stated problem. Hence, at the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art use an RF energy having energy and power within the recited ranges for shrinking the body tissue. Furthermore, one of ordinary skill in the art would have expected that a bipolar or mono-polar electrode to provide the treatment as presently claimed.

11. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

Allowable Subject Matter

12. Claims 43 and 44 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.

Conclusion

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 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

May 5, 2014.

Notice of References Cited	Application/Control No. 12/914,201	Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER	
	Examiner AHMED FARAH	Art Unit 3769	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,277,116	08-2001	Utely et al.	606/42
*	B	US-6,503,231	01-2003	Prausnitz et al.	604/272
	C	US-			
	D	US-			
	E	US-			
	F	US-			
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	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
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	P					
	Q					
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	S					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
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Receipt date: 05/10/2011

12914201 - GAU: 3769

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	12/914,201
				Filing Date	October 28, 2010
				First Named Inventor	Dieter Manstein
				Art Unit	3769
				Examiner Name	TBA
Sheet	1	of	5	Attorney Docket No: 36213.US.07-475387-779	

US PATENT DOCUMENTS					
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				Examiner Name	TBA
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				Art Unit	3769
				Examiner Name	TBA
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Application Number	12/914,201
Filing Date	October 28, 2010
First Named Inventor	Dieter Manstein
Art Unit	3769
Examiner Name	To be assigned
Attorney Docket Number	036213.US.07-475387-779

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Sheet 2	of 2	Attorney Docket Number	036213.US.07-475387-779

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		International Search Report mailed on February 1, 2011 for International Application No. PCT/US2010/037950	
		International Written Opinion mailed on February 1, 2011 for International Application No. PCT/US2010/037950	

Examiner Signature	/Ahmed Farah/	Date Considered	05/05/2014
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EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	((("6277116") or ("6503231")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/05/05 11:17
L2	0	1 and (monopoler bipoler (mono adj poler) (bi adj poler))	US-PGPUB; USPAT	OR	OFF	2014/05/05 11:18
L3	0	1 and (monopoler bipoler (mono adj poler) (bi adj poler))	US-PGPUB; USPAT	OR	ON	2014/05/05 11:18
L4	0	1 and (monopole bipole (mono adj pole) (bi adj pole))	US-PGPUB; USPAT	OR	ON	2014/05/05 11:18
L5	1	1 and (monopolar bipolar (mono adj polar) (bi adj polar))	US-PGPUB; USPAT	OR	ON	2014/05/05 11:19
L6	1	5 and (cool\$3 with (skin tissue))	US-PGPUB; USPAT	OR	ON	2014/05/05 11:20
L7	0	1 and (vibrat\$3 with needle)	US-PGPUB; USPAT	OR	ON	2014/05/05 12:18
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 cell) with death)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:03
S8	0	S1 and ((tissue cell) with injur\$3)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:04
S9	2	S1 and ((tissue cell) 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

5/ 5/ 2014 1:50:14 PM**C:\ Users\ afarah\ Documents\ EAST\ Workspaces\ 12914201.wsp**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Dieter MANSTEIN
Serial No. : 12/914,201
Filed : October 28, 2010
For : METHOD AND APPARATUS FOR DERMATOLOGICAL
TREATMENT AND TISSUE RESHAPING
Examiner : Ahmed M. Farah
Art Unit : 3769
Confirmation No. : 5359

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

AMENDMENT AND RESPONSE TO NON-FINAL OFFICE ACTION

Sir:

This paper is filed in response to a non-final Office Action dated May 9, 2014 (the "Office Action"), and in view of the telephone interview held between the undersigned and Examiner Farah on July 30, 2014 (the "Interview"). Initially, please amend the above-identified application as set forth below, and consider the arguments that follow.

In The Claims:

Please cancel claim 28 without prejudice, and amend claims 27, 29, 31, 36 and 42, as provided below in the associated claim listing on separate sheets:

Claims 1-26. (Canceled).

27. (Currently Amended) A skin treatment method comprising:

inserting a plurality of needles 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

regulating delivery of the RF energy from the RF energy source to the plurality of needles to induce ~~cause~~ a pattern of fractional damage ~~to be produced~~ in the dermal layer surrounding the needles when inserted therein, wherein the regulation of the delivery of the RF energy is configured to cause a formation of a new collagen structure in the skin.

Claim 28 (Cancelled).

29. (Currently Amended) A skin treatment ~~The method of claim 27, wherein~~ comprising:

inserting a plurality of needles 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

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 surrounding 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 a ~~substantially~~ undamaged region therebetween.

30. (Previously Presented) The method of claim 29, wherein the thermal damage to the dermal layer includes necrosis.
31. (Currently Amended) The method of claim 27, wherein regulating the delivery of the RF energy is controlled to ~~substantially~~ prevent a skin ablation.
32. (Previously Presented) The method of claim 27, wherein the plurality of needles are associated with each other in groups of bipolar pairs, wherein regulating the delivery of the RF energy includes controlling the RF energy being delivered 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.
33. (Previously Presented) The method of claim 32, wherein the areas of non-ablative damage are elongated regions, each provided between each bipolar pair of the plurality of needles.
34. (Previously Presented) The method of claim 32, wherein regulating the delivery of the RF energy includes delivering about 100 mJ per the bipolar pair of the plurality of needles.
35. (Previously Presented) The method of claim 27, wherein regulating the delivery of the RF energy includes delivering up to 8 W of power to each of the plurality of needles.

36. (Currently Amended) The method of claim 27, wherein the plurality of needles are arranged on the base in a ~~substantially~~ rectangular array.

37. (Previously Presented) The method of claim 27, wherein at least one of the plurality of needles is a mono-polar needle.

38. (Previously Presented) The method of claim 27, further comprising enabling a user to select treatment parameters, the treatment parameters comprising duration and intensity of the RF energy.

39. (Previously Presented) The method of claim 27, further comprising facilitating a user to select an application-specific setting for the energy source to cause the energy source to vary a duration, intensity, and sequence of the RF energy transmitted to the plurality of needles based on the selected setting.

40. (Previously Presented) The method of claim 27, wherein at least two of the plurality of needles have differing lengths.

41. (Previously Presented) The method of claim 27, further comprising cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.

42. (Currently Amended) A skin treatment ~~The method of claim 27, further comprising:~~
inserting a plurality of needles 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;
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
surrounding the needles; and
vibrating at least one of the plurality of needles.
43. (Previously Presented) The method of claim 42, wherein vibrating at least one of the plurality of needles includes generating a vibration at a frequency of between about 10 Hz to about 10 kHz.
44. (Previously Presented) The method of claim 42, wherein vibrating at least one of the plurality of needles includes generating a vibration at an amplitude of between about 50 μm and about 500 μm .
45. (Previously Presented) The method of claim 27, wherein at least one of the plurality of needles is a hollow needle, and further comprising delivering an analgesic via the hollow needle to tissue surrounding a tip of the hollow needle.
46. (Previously Presented) The method of claim 27, further comprising detecting a presence of a nerve near a tip of at least one of the plurality of needles.

47. (Previously Presented) The method of claim 27, wherein inserting the plurality of needles into the dermal layer of skin comprises passing the plurality of needles through a plurality of holes formed in a spacer disposed between the base and a surface of the dermal layer of skin, wherein the plurality of needles are movable relative to the spacer.

REMARKS

I. INTRODUCTION

Applicant gratefully acknowledges the Examiner's confirmation that claims 43 and 44 include allowable subject matter.

In addition, Applicant appreciates the Examiner's participation in the Interview with Applicant's representative – the undersigned.

Claims 1-16 have been previously cancelled, without prejudice. Claim 28 has been cancelled herein without prejudice, and the subject matter thereof has been included substantially in independent claim 27 herein above. Applicant reserves the right to pursue the subject matter of the cancelled claims in one or more continuing applications claiming priority from the present application. Independent claim 27 has been amended to include, substantially, the subject matter of now-cancelled claim 28. Claims 29 and 42 have been rewritten in independent claim format. Claims 29, 31 and 36 have been amended above to clarify the subject matter recited therein, but not for any reason relating to patentability thereof. Accordingly, claims 27 and 29-47 are now under consideration in the above-referenced application. Provided above, please find a claim listing indicating the cancellation of claim 28, the amendments to previously-pending claims 27, 29, 31, 36 and 42, and the status of other claims on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

II. INTERVIEW SUMMARY

During the Interview, Applicant's representative and the Examiner discussed the fact that in the Office Action, claims 29 and 42 were not rejected as being anticipated or obvious over any prior art of record. The Examiner confirmed that no such rejection was made, and Applicant can submit such claims in independent form. It is the understanding of Applicant's representative based on such discussion that such claims 29 and 42 (and the claims which depend therefrom) would be indicated as being allowed in a subsequent communication, unless the Examiner reopens prosecution.

In addition, Applicant's representative and the Examiner discussed the proposed amendment to independent claim 27 (as provided herein above). In such discussion, the Examiner agreed that the amendment to independent claim 27 would likely overcome the present rejection of such claim in view of the Utely Patent.

III. REJECTION UNDER 35 U.S.C. § 112, PARA. 2 SHOULD BE WITHDRAWN

Claims 29, 31 and 36 stand rejected under 35 U.S.C. § 112(b), or 35 U.S.C. § 112 (pre-AIA), second paragraph as being allegedly indefinite. In particular, the Examiner objects to these claims as including the term "substantially", and for such reason, believes that such term renders claims 29, 31 and 36 indefinite.

While Applicant respectfully disagrees with the Examiner's reasoning for such objection, to expedite the prosecution of the present application, the recitation of the term "substantially" has been removed in claims 29, 31 and 36, as amended herein above.

Accordingly, for all such reasons, Applicant respectfully asserts that the rejection of claims 29, 31 and 36 under 35 U.S.C. § 112(b), or 35 U.S.C. § 112 (pre-AIA), second paragraph is now moot, and should therefore be withdrawn.

IV. REJECTIONS UNDER 35 U.S.C. §§ 102 AND 103 SHOULD BE WITHDRAWN

Claims 27, 28, 30, 32, 33, 36, 38-40 and 45-47 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated U.S. Patent No. 6,277,116 issued to Utely et al. (the “Utely Patent”). Claims 35, 36 and 37 stand rejected 35 U.S.C. §103(a) as being allegedly unpatentable over the Utely Patent. Applicant respectfully asserts that the Utely Patent fails to teach, suggest or disclose the subject matter recited in amended independent claim 27 and the claims which depend therefrom, for at least the following reasons.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, §2131; *also see Lindeman Maschinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

Under 35 U.S.C. § 103(a), a person is not entitled to a patent even though the invention is not identically disclosed or described as set forth in §102, “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law, whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the applicant (the “TSM test”). See *In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit’s application of the TSM test, see *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007) the Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited in the *Graham v. John Deere* decision. *Id.*; see *In re Translogic Technology, Inc.*, No. 2006-1192, 2007 U.S. App. LEXIS 23969, *21 (October 12, 2007). Further, the Court underscored that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or motivation to make the claimed invention is merely one factor that may be weighed during the obviousness

determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not an automaton, constrained by a rigid framework. *Id.* at 1742. However, "the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure." *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The prior art cited in an obviousness determination should create a reasonable expectation, but not an absolute prediction, of success in producing the claimed invention. *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988). Both the suggestion and the expectation of success must be in the prior art, not in applicant's disclosure. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). Further, the implicit and inherent teachings of a prior art reference may be considered under a Section 103 analysis. See *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

Secondary considerations such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results, if present, can also be considered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983). Although these factors can be considered, they do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

The Utely Patent relates to a tissue reshaping apparatus that includes a plurality of shafts attached to a base, where the base is attached to housing, an energy source in communication with one or more of the needles, and a control module. Indeed, the apparatus described in the Utely Patent shrinks collagen tissue in the dermis in a non-invasive manner, which leaves the outer layer of skin intact and undamaged. (See Utely

Patent, Abstract). As specifically stated in the Utely Patent, this publication describes “systems and methods of achieving the cosmetically beneficial effects of *shrinking collagen tissue in the dermis* in an effective, non-invasive manner, which leaves the outer layer of skin intact and undamaged.” (*Id.*, col. 1, Ins. 60-64, *emphasis added*).

Applicant’s amended independent claim 27 relates to a skin treatment method, which comprises, *inter alia*:

inserting a plurality of needles 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

regulating delivery of the RF energy from the RF energy source to the plurality of needles to **induce a pattern of fractional damage** in the dermal layer surrounding the needles when inserted therein,

wherein **the regulation of the delivery of the RF energy is configured to cause a formation of a new collagen structure in the skin.**

As an initial matter, Applicant respectfully asserts that the Utely Patent fails to teach, suggest or disclose a skin treatment method in which **a new collagen structure of the tissue is formed by regulating the delivery of radio frequency energy**, as explicitly recited in amended independent claim 27. Indeed, the Utely Patent describes affecting collagen in the tissue, but such effect is provided to ***shrink collagen tissue in the dermis***. Thus, the Utely Patent discloses shrinking collagen, but not the formation of a new collagen structure. The Utely Patent is concerned with a reduction and removal of collagen. To form new collagen would be wholly *contrary* to the purpose of the device and method of the Utely Patent. The removal of collagen described in the Utely Patent clearly does not **configure a regulation of the delivery of the RF energy to cause a formation of new collagen**, which would be against the intent and purpose of the Utely Patent. Indeed, in

the Office Action, the Examiner admits that the Utely Patent causes “shrinking [of] collagen tissue in the dermis.” (Office Action, p. 4, Ins. 18-19).

Thus, it is clear that the Utely Patent fails to teach, suggest or disclose a formation of a new collagen structure by regulating the delivery of radio frequency energy, and indeed teaches away from the subject matter recited in amended independent claim 27, which specifically requires a formation of a new collagen structure in the tissue.

In addition, Applicant respectfully asserts that the Utely Patent fails to teach, suggest or disclose **inducing a pattern of fractional damage in the tissue surrounding the needles when inserted therein**, as also recited in amended independent claim 27. Indeed, the Utely Patent fails to describe inducing such fractional damage to the areas surrounding the needles when inserted into the tissue. Certainly, any production of fractional damage is outside the disclosure of the Utely Publication.

Thus, for at least these reasons, Applicant respectfully asserts that the Utely Patent fails to render the subject matter recited in amended independent claim 27 anticipated or obvious. Claims 28, 30, 32, 33, 36, 38-40 and 45-47 which depend from amended independent claim 27 are also not taught, suggested or disclosed by the Utely Patent for at least the same reasons.

Accordingly, withdrawal of the rejections of claims 27, 28, 30, 32, 33, 36, 38-40 and 45-47 of the present application under 35 U.S.C. § 102(b) as being anticipated, and of claims 35, 36 and 37 of the present application under 35 U.S.C. § 103(a) as being unpatentable, both over the Utely Patent, is respectfully requested.

V. UNREJECTED INDEPENDENT CLAIMS 29 AND 42 AND DEPENDENT CLAIMS

In the Office Action, previously-pending claims 29 and 42 were not rejected under 35 U.S.C. § 102 or under 35 U.S.C. § 103 as being anticipated or unpatentable over any prior art. During the Interview, as indicated herein above, Applicant informed the Examiner of such fact, and requested a confirmation that such claims were not rejected in view of any prior art in the present Office Action. The Examiner confirmed that no such prior art rejections of previously-pending claims 29 and 42 are contained in the Office Action, and suggested that these claims be rewritten in independent claim form when a response is filed to the Office Action.

To that end, claims 29 and 42 have been rewritten in independent claim form to include the subject matter of previously-pending independent claim 27. In addition, claim 29 has been further amended to obviate any reason for the rejection thereof under 35 U.S.C. § 112 as being allegedly indefinite.

Accordingly, for at least such reason, Applicant respectfully asserts that independent claims 29 and 42 and the claims which dependent therefrom are allowable. Applicant respectfully request the Examiner to confirm the allowability of independent claims 29 and 42 (as well as of the claims which depend therefrom) in a subsequent communication to Applicant's representative.

VI. ALLOWABLE SUBJECT MATTER

In the Office Action, the Examiner confirmed that claims 43 and 44 include allowable subject matter, and would be allowed if rewritten in independent form to include all of the limitations of the claims from which they depend.

Claims 43 and 44 depend from claim 42 (which has been rewritten in independent form to include the subject matter of previously-pending claim 27). Thus, for the same reason as presented herein above for independent claim 42, and for the additional reasons confirmed by the Examiner in the Office Action regarding claims 43 and 44, claims 43 and 44 are believed to be allowable over the art of record.

Applicant respectfully request the Examiner to again confirm the allowability of claims 43 and 44 (as well as of claim 42) in a subsequent communication to Applicant's representative.

VII. CONCLUSION

In light of the foregoing, Applicant respectfully submits that pending claims 27 and 29-47 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,

Dated: August 8, 2014



Gary Abelev
Patent Office Reg. No. 40,479

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Attorney(s) for Applicant(s)
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2867771

Electronic Acknowledgement Receipt

EFS ID:	19816397
Application Number:	12914201
International Application Number:	
Confirmation Number:	5359
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.07-475387-779
Receipt Date:	08-AUG-2014
Filing Date:	28-OCT-2010
Time Stamp:	14:27:23
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	32865-215480.pdf	152035 61ae6351cc0af319464454fe826c8a4691c7dfed	no	15

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

New International Application Filed with the USPTO as a Receiving Office

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/914,201	Filing Date 10/28/2010	<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	08/08/2014	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 20	Minus	** 21	= 0	X \$40 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X \$210 =	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
/POLIN ANG/

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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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

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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.

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.07-475387-779
		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	Miami	State/Province	FL	Country of Residence US
Mailing Address of Inventor:				
Address 1		1865 Brickell Avenue		
Address 2		Unit A2009		
City	Miami	State/Province	FL	
Postal Code	33129	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	30873 <u>26710</u>
Email Address	Add Email Remove Email

Application Information:

Title of the Invention	Method and Apparatus for Dermatological Treatment and Tissue Reshaping		
Attorney Docket Number	036213.US.07-475387-779	Small Entity Status Claimed	<input checked="" 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.07-475387-779
		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	30873 <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	<u>Patented</u>		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
<u>12914201</u>	Division of	11098030	2005-04-01	<u>7824394</u>	<u>2010-11-02</u>
Prior Application Status	Expired		Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
11098030	Claims benefit of provisional	60558476	2004-04-01		

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	036213.US.07-475387-779
		Application Number	
Title of Invention	Method and Apparatus for Dermatological Treatment and Tissue Reshaping		

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:

☒ Authorization to Permit Access to the Instant Application by the Participating Offices

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	036213.US.07-475387-779
		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.

Clear

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

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

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. ☒

Organization Name The General Hospital Corporation

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.07-475387-779
		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)	2014-10-24
First Name	Jack M.	Last Name	Cook	Registration Number	56098
Additional Signature may be generated within this form by selecting the Add button.					

STATEMENT UNDER 37 CFR 3.73(c)Applicant/Patent Owner: The General Hospital CorporationApplication No./Patent No.: 12/914,201 Filed/Issue Date: October 28, 2010Titled: 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 032739, Frame 0147, 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 125141.01010

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

October 24, 2014

Date

Reg. No. 56,098

Title or Registration Number

Electronic Acknowledgement Receipt

EFS ID:	20506891
Application Number:	12914201
International Application Number:	
Confirmation Number:	5359
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.07-475387-779
Receipt Date:	24-OCT-2014
Filing Date:	28-OCT-2010
Time Stamp:	11:05:57
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	Power of Attorney	POA_MGH.pdf	92899 8e1c2eea2fc1e6d8115ea748b717b154af9b f60d	no	1

Warnings:

Information:

2	Application Data Sheet	MGH.pdf	137900 1aa7835a22098ddb52fa2bb027dbd1d0159e520d	no	5
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
3	Assignee showing of ownership per 37 CFR 3.73.	Statement_Under_37_CFR_3_73_MGH_1010.PDF	231447 d6a7aace3c0c92357216c55fcd724cbb4a6e8054	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			462246		
<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

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/914,201	10/28/2010	Dieter Manstein	036213.US.07-475387-779

CONFIRMATION NO. 5359

POWER OF ATTORNEY NOTICE



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

Date Mailed: 10/29/2014

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/24/2014.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/tnguyen/

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



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/914,201	10/28/2010	Dieter Manstein	036213.US.07-475387-779

CONFIRMATION NO. 5359

POA ACCEPTANCE LETTER



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

Date Mailed: 10/29/2014

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/24/2014.

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.

/tnguyen/

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



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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.
12/914,201	10/28/2010	Dieter Manstein	036213.US.07-475387-779	5359

26710 7590 12/04/2014

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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12/04/2014

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. 12/914,201	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 08/08/2014.
☐ 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) 27 and 29-47 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 42-44 is/are allowed.
- 7) ☒ Claim(s) 27,29-41 and 45-47 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <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: ____. |

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 27, 29, 30, 32, 33, 36, 38-40, and 45-47 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Utely et al. US Patent No. 6,277,116.

With respect to claim 27, Utely et al. discloses an apparatus and methods of use for shrinking collagen tissue, the method comprising: inserting into skin tissue a plurality of needles 82, 90, in communication with radio-frequency energy source 32 (see Fig. 2), wherein the needles are attached to a base 80,88, that is attached to a housing or part of the housing (see Figs. 6 and 8); and a controlling a control module 48 configured to permit variation of the characteristics of the energy supplied by the energy source (see col. 6, line 59 through col. 7, line 3). Controlling of the treatment energy provides a pattern of fractional damage in the dermal layer surrounding the needles thereby shrinking collagen in the dermal skin region.

With respect to claim 29, the needles 82,90 deliver controlled RF energy to heat the dermal layer, wherein at least two adjacent regions of thermally damaged tissue have undamaged region between them (see Fig. 7 and col. 2, lines 13-18).

With respect to claim 30, the recited claims languages are directed to expected results. The claims languages lack method steps adapted to provide the recited treatments. Furthermore, skin treatment method of Utely et al. would provide the claimed treatments to cause shrinking collagen tissue in the dermis.

With respect to claims 32 and 33, the plurality of needles are associated with each other in groups of bipolar pairs, and the energy control module controls the treatment energy delivered to the bipolar pairs for heating the target tissue to provide the treatment as claimed (see col. 7, lines 64-67).

With respect to claim 36, the plurality of the needles are arranged in substantially rectangular arrays as claimed (see Figs. 6 and 8).

With respect to claims 3 and 39, the control module is configured to enable the user to select and vary parameters of the desired treatment such as the duration, intensity, power, etc. of the treatment RF energy transmitted to the plurality of needles as claimed.

With respect to claim 40, Utley et al. teach that each of the plurality of the needles electrodes can have a length of between 0.5 to 3 mm.

With respect to claim 41, Utely et al. further teach the step of cooling the skin surface in combination with the RF treatment energy (see col. 6, lines 34-43).

With respect to claims 45, at least one of the plurality of the needles is a hollow needle adapted for delivering treatment fluid/analgesic to tissue surrounding the tip of the hollow needle (see col. 9, lines 11-17).

With respect to claim 46, the recited claim language is devoid of any method step(s) or technique for detecting the presence of the nerve tissue, furthermore, it is common medical procedure to determine or avoid nerve tissue when injecting a needle to a patient's body.

With respect to claim 47, the apparatus of Utley et al. further comprises spacers 62 disposed between the base and skin surface, the spacer having a pattern of small holes through which the plurality of the needles protrude (see Fig. 3).

Claim Rejections - 35 USC § 103

3. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 34, 35, and 37 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Utley et al.

5. Utley et al., described above, teach the step of varying the power of the RF energy delivered to the needles but do not specifically teach the range of power or energy delivered to the needles as recited claims 34 and 35. However, the use of RF energy and power in the recited ranges for treating skin/body tissue is known in the art. The examiner further notes that the use of mono-polar electrode for delivering treatment RF energy to body tissue is well known in the art. Furthermore, the applicant failed to teach that the use of mono-polar electrode for the recited treatment provides an

Art Unit: 3769

advantage, is used for a specific purpose, or solves a stated problem. Hence, at the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art use an RF energy having energy and power within the recited ranges for shrinking the body tissue. Furthermore, one of ordinary skill in the art would have expected that a bipolar or mono-polar electrode to provide the treatment as presently claimed.

Allowable Subject Matter

6. Claims 42-44 are allowed.

Response to Arguments

7. Applicant's arguments filed on August 8, 2014 have been fully considered but they are not persuasive. The applicant's arguments are mainly related to the claim language in amended claim 27 that "the regulation of the delivery of the RF energy is configured to cause a formation of a new collagen structure in the skin." Hence, the applicant argues that Utely et al. teach a method for shrinking the collagen tissue, and teach away a method formation of the collagen tissue.

8. In response to this argument, the examiner agrees with the applicant that Utely et al. teach a method for shrinking collagen tissue in the dermis. It is known in the art that thermal damage to the collagen tissue also promotes formation of new collagen. The applicant further admits that collagen shrinkage promotes formation of new collagen by stating the following:

"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."

See Par. 0009 of the published application. Furthermore, the applicant's written description fails to teach a specific method, or how the RF energy is configured, to cause formation of a new collagen structure in the skin. Hence, the examiner maintains his rejection of the claims.

Conclusion

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 Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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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

November 29, 2014.

**RESPONSE UNDER 37 C.F.R. § 1.116
EXPEDITED PROCEDURE REQUESTED
EXAMINING GROUP 3769**

Customer No. 26,710

Attorney Docket Nos. 125141.01010.MGH02587.10 / 11706.0033-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Dieter MANSTEIN)	Group Art Unit: 3769
)	
Application No.: 12/914,201)	Examiner: Ahmed M. Farah
)	
Filed: October 28, 2010)	Confirmation No.: 5359
)	
For: METHOD AND APPARATUS FOR)	<u>VIA EFS-WEB</u>
DERMATOLOGICAL TREATMENT)	
AND TISSUE RESHAPING)	

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Commissioner:

AMENDMENT AFTER FINAL AND REQUEST FOR RECONSIDERATION

Applicant appreciates the courtesies extended by Examiner Farah in an in-person interview held on March 24, 2015 to discuss the Final Office Action mailed December 4, 2014.

This Amendment is submitted, consistent with discussions in the interview, to place the application in condition for allowance.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 8 of this paper.

AMENDMENTS TO THE CLAIMS:

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

1-26. (Cancelled).

27. (Currently Amended) A skin treatment method comprising:

inserting a plurality of needles 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

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 ~~surrounding the needles~~ when the needles are inserted therein, wherein the regulation of the delivery of the RF energy is configured to ~~cause a~~ stimulate formation of [[a]] new collagen ~~structure~~ in the skin.

28. (Cancelled).

29. (Currently Amended) A skin treatment method, comprising:

inserting a plurality of needles 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

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 ~~surrounding 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 ~~[[a]]~~ an undamaged region therebetween.

30. (Previously Presented) The method of claim 29, wherein the thermal damage to the dermal layer includes necrosis.

31. (Cancelled).

32. (Previously Presented) The method of claim 27, wherein the plurality of needles are associated with each other in groups of bipolar pairs, wherein regulating the delivery of the RF energy includes controlling the RF energy being delivered 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.

33. (Cancelled).

34. (Cancelled).

35. (Cancelled).

36. (Cancelled).

37. (Previously Presented) The method of claim 27, wherein at least one of the plurality of needles is a mono-polar needle.

38. (Cancelled).

39. (Currently Amended) The method of claim 27, further comprising ~~facilitating a user to select~~ 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.

40. (Previously Presented) The method of claim 27, wherein at least two of the plurality of needles have differing lengths.

41. (Previously Presented) The method of claim 27, further comprising cooling a surface of the skin when inserting the plurality of needles into the dermal layer of skin.

42. (Previously Presented) A skin treatment method comprising:

inserting a plurality of needles 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;

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 surrounding the needles; and
vibrating at least one of the plurality of needles.

43. (Previously Presented) The method of claim 42, wherein vibrating at least one of the plurality of needles includes generating a vibration at a frequency of between about 10 Hz to about 10 kHz.

44. (Previously Presented) The method of claim 42, wherein vibrating at least one of the plurality of needles includes generating a vibration at an amplitude of between about 50 μm and about 500 μm .

45. (Previously Presented) The method of claim 27, wherein at least one of the plurality of needles is a hollow needle, and further comprising delivering an analgesic via the hollow needle to tissue surrounding a tip of the hollow needle.

46. (Previously Presented) The method of claim 27, further comprising detecting a presence of a nerve near a tip of at least one of the plurality of needles.

47. (Previously Presented) The method of claim 27, wherein inserting the plurality of needles into the dermal layer of skin comprises passing the plurality of needles through a plurality of

holes formed in a spacer disposed between the base and a surface of the dermal layer of skin, wherein the plurality of needles are movable relative to the spacer.

48. (New) The method of claim 27, wherein regulating delivery of RF energy further includes inducing damaged regions surrounding each tip of each of the plurality of needles, with substantially undamaged regions between the damaged regions.

49. (New) A skin treatment method comprising:

inserting a plurality of needles 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

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.

50. (New) The method of claim 49, wherein the damaged regions are elongated between the needles of the bipolar pairs.

51. (New) The method of claim 49, wherein the fractional damage is sufficient to cause necrosis.

52. (New) A skin treatment method comprising:

inserting a plurality of monopolar needles 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

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.

53. (New) The method of claim 52, wherein the fractional damage is sufficient to cause necrosis.

54. (New) The method of claim 27, wherein each adjacent region of thermal damage includes a small localized area of thermal damage surrounding each tip.

REMARKS

Summary of Interview

Applicant appreciates the courtesies extended by the Examiner during an in-person interview on March 24, 2015. Prior to the interview, in the Office Action dated 12/4/14, claims 42-44 were indicated allowable. In the interview, the subject matter of previously presented independent claims 27 and 29, and proposed independent claims 49 and 52, presented below, were discussed in view of the pending rejections and the *Utely* reference (U.S. Patent No. 6,277,116). It was discussed that *Utely* and the present embodiments rely on differing principles in order to reshape tissue, where *Utely*, for example, delivers RF energy in an attempt to achieve uniform heating at a prescribed depth in the dermis layer (e.g., at col. 4, lines 23-30 and col. 11 lines 21-30), whereas exemplary embodiments of the present application regulate delivery of RF energy to induce a pattern of fractional damage by the RF energy in the dermal layer. During the interview, it was agreed that independent claim 27 would overcome the rejections based on *Utely* with a minor clarifying amendment to specify that the pattern of fractional damage is induced “by the RF energy,” and it was agreed that independent claim 29 as previously presented overcomes the rejections based on *Utely*.

Newly proposed independent claims 49 and 52 were also discussed, and the Examiner agreed that those claims, too, patentably distinguish over *Utely*. Dependent claims mentioning necrosis were also discussed, and the Examiner also agreed that *Utely* does not teach or suggest necrosis.

Summary of Amendments

Applicant has amended the claims herein consistent with the substance of the interview in order to place the application in condition for allowance. Specifically, Applicant amends

independent claim 27 to clarify that the plurality of needles “induce a pattern of fractional damage *by the RF energy* in the dermal layer” (emphasis added), and presents new independent claims 49 and 52, and new dependent claims 48, 50, 51, 53 and 54.

In addition to the amendments discussed in the interview, counsel made two relatively minor changes to conform the claim language to the language of the specification. To expedite the Examiner’s review, examples of support for those changes are noted as follows:

Previous Claim Language	Amended Claim Language	Example of Support in the Originally-Filed Specification
cause a formation of a new collagen structure (clm. 27)	stimulate formation of new collagen	“Additionally, the thermal damage tends to stimulate the formation of new collagen.” Pg. 6:26
surrounding the needles (clm. 29)	in a vicinity of the tips of the needles	”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.” Pg. 6:22-24

Applicant also proposes amending claim 29 solely to address a non-substantive typographical error. By this amendment, Applicant proposes cancelling claims 31, 33-36, and 38 without prejudice or disclaimer of any subject matter. Upon entry of this amendment, claims 27, 29, 30, 32, 37, and 39-54 will remain pending, of which claims 27, 29, 49, and 52 are in independent form. In view of the amendments and the following reasons, Applicant respectfully requests reconsideration and withdrawal of the rejections and the timely allowance of the presently pending claims.

35 U.S.C. §§ 102(b) and 103(a) Rejections

Independent claims 27 and 29 are allowable because *Utely* fails to disclose each and every element of the claims.

Claim 27 recites a unique combination including, *inter alia*, “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”. Applicant respectfully submits that *Utely* not only fails to disclose this combination, but also teaches away.

Indeed, *Utely* relies upon a different operation principle than claim 27, in order to reshape tissue in a different way. *Utely* discloses delivering RF energy to achieve a uniform target temperature at a target depth in the dermis. In a number of locations, *Utely* emphasizes the desire to achieve this uniformity:

The system 24 applies energy to the dermis to elevate **and maintain** its temperature at a predetermined temperature condition, at or about 65° C., without increasing the temperature of the epidermis beyond 47° C. *Utely*, 4:23-30 (emphasis added).

By varying the power of radio frequency energy applied and the rate of surface cooling (when appropriate), the controller 48 can adjust the maximum tissue temperature TMAX to **achieve the desired control point temperature**, which for collagen shrinkage is 65° C. *Id.*, at 3:21-25 (emphasis added).

The controller 48 can also **establish and maintain a control depth D(TMAX) at which the desired control point temperature occurs**, e.g., at a skin depth of 200um to 300 um (pre-set or set by the physician), to achieve optimal collagen shrinkage. *Id.*, at 11:26-30 (emphasis added).

In other words, *Utely* discloses regulating heat delivery through needles in order to achieve uniformity of heating at a collagen shrinkage target temperature. Significantly, *Utely* does not disclose, *inter alia*, inducing “a pattern of fractional damage by the RF energy in the dermal layer” as recited in amended claim 27. By way of example only, Applicant’s originally filed specification provides a number of non-limiting examples of “a pattern of fractional damage,” such as in Fig. 3; Fig. 4; and at Pg. 6:19-28; Pg. 8:1-18; Pg. 9:7-25; and Pg. 10:6-16.

In contrast to *Utely*, claim 27 recites a unique combination, including, *inter alia*, “regulating delivery of the RF energy from the energy source to the plurality of needles to induce a pattern of fractional damage by the RF energy in the dermal layer”. That is, RF energy is regulated for purposeful non-uniformity of heating to achieve a pattern of fractional damage. Applicant’s originally filed specification provides a number of non-limiting examples, such as at Pg. 7: 3-9; Pg. 8:3-4; and Pg. 8:8-14.

Thus, while *Utely* discloses an array of needles for delivering RF energy, it does not disclose a method for inducing “a pattern of fractional damage by the RF energy in the dermal layer”. For at least these reasons, *Utely* does not disclose each and every element of amended claim 27, and therefore *Utely* does not anticipate amended claim 27.

Regarding independent claim 29, the Examiner agreed that the claim as previously presented distinguishes over *Utely*. Indeed, similar to the reasons discussed above with respect to claim 27, *Utely* does not disclose the unique combination of claim 27 including, *inter alia*, “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”. Furthermore, *Utely* does not disclose “wherein at least two adjacent regions of thermal damage have an undamaged region therebetween” as recited in amended claim 29.

Thus, for at least the foregoing reasons, it is respectfully requested that independent claims 27 and 29, and dependent claims 30, 32, 37, 39, 40, and 41, which are allowable at least by virtue of their dependence from claim 27 or 29, be passed to allowance. The rejection of claims 31, 33, 36, 38, and 39 is moot in view of the cancellation of those claims. Accordingly, Applicant respectfully requests that the rejection of claims 27, 29, 30, 32, 37, 40, and 41 be withdrawn, and the claims be passed to allowance.

Conclusion

Applicant respectfully submits that the pending claims are in condition for allowance. Should the Examiner identify any impediment to allowance, it is respectfully requested that the Examiner contact the undersigned, Kai Rajan, at 202 408-4307, in an effort to resolve any open issue.

The Final Office Action contains characterizations of the invention and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Final Office Action.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 17-0055.

Respectfully submitted,

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By: /Kai Rajan/
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and

QUARLES & BRADY, L.L.P.

By: /Kai Rajan/, Reg. No. 70,110, on behalf of
Jack M. Cook
Reg. No. 56,098
(414) 277-5405
on behalf of the Patent Owner

Dated: March 26, 2015

Electronic Acknowledgement Receipt

EFS ID:	21888919
Application Number:	12914201
International Application Number:	
Confirmation Number:	5359
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	26710
Filer:	Kai Rajan/Dena Bohannon
Filer Authorized By:	Kai Rajan
Attorney Docket Number:	125141.01010.MGH02587.10
Receipt Date:	26-MAR-2015
Filing Date:	28-OCT-2010
Time Stamp:	15:36:47
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		117060033AAF.pdf	61036 a598960080936dfca6fb9b534718308fbee6a3a3	yes	12

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Response After Final Action	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	12
Warnings:			
Information:			
Total Files Size (in bytes):		61036	
<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>			

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0		
Practitioner Docket No.: 125141.01010.MGH02587.10	Application No.: 12/914,201	Filing Date: October 28, 2010
First Named Inventor: Dieter MANSTEIN	Title: METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING	
<p>APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.</p> <ol style="list-style-type: none"> 1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (<i>e.g.</i>, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c). 2. The above-identified application contains an outstanding final rejection. 3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect. 4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection. 5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response. 6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web). 7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, <i>e.g.</i>, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.] 8. By filing this certification and request, applicant acknowledges the following: <ul style="list-style-type: none"> • Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0. • The examiner will verify that the AFCP 2.0 submission is compliant, <i>i.e.</i>, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions: <ul style="list-style-type: none"> ○ The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, <i>e.g.</i>, by mailing an advisory action. ○ If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview. <ul style="list-style-type: none"> ▪ The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate. ▪ If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116. 		
Signature /Kai Rajan/, Reg. No. 70,110, on behalf of Jack M. Cook	Date March 26, 2015	
Name (Print/Typed) Jack M. Cook	Practitioner Registration No. 56,098	
Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.		
<input checked="" type="checkbox"/> * Total of <u>1</u> forms are submitted.		

Privacy Act Statement

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	21894099
Application Number:	12914201
International Application Number:	
Confirmation Number:	5359
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	26710
Filer:	Kai Rajan/Donna Beckford
Filer Authorized By:	Kai Rajan
Attorney Docket Number:	125141.01010.MGH02587.10
Receipt Date:	26-MAR-2015
Filing Date:	28-OCT-2010
Time Stamp:	20:52:04
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	After Final Consideration Program Request	After_Final_Consideration_Pilot_Request.pdf	228167 6c40f0a4ef3e13bf9254c11f771d255ac11dfb35	no	2

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 12/914,201	Filing Date 10/28/2010	<input type="checkbox"/> To be Mailed
---	---	----------------------------------	---------------------------------------

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	03/26/2015	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 20	Minus	** 21	= 0	x \$40 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	x \$210 =	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
/CHERYL CLARK/

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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/914,201	Filing Date 10/28/2010	<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	03/26/2015	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 20	Minus	** 21	= 0	X \$40 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X \$210 =	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
/CHERYL CLARK/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/914,201	10/28/2010	Dieter Manstein	125141.01010.MGH02587.10	5359

26710 7590 04/15/2015

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
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04/15/2015

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

<i>Applicant-Initiated Interview Summary</i>	Application No. 12/914,201	Applicant(s) MANSTEIN, DIETER	
	Examiner AHMED FARAH	Art Unit 3769	

All participants (applicant, applicant's representative, PTO personnel):

(1) AHMED FARAH. (3) Kai Rajan (Reg. No. 70,110).

(2) Jack Cook (Reg. NHo. 56,098). (4) Gerson Panitch (Reg. No. 33,751).

Date of Interview: 24 March 2015.

Type: ☐ Telephonic ☐ Video Conference
 ☒ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
 If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☐Others
 (For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: claims 27 and 29.

Identification of prior art discussed: U.S. Pat. No.6,277,116) to Utely et al.

Substance of Interview
 (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Claims 27 and 29 were discussed in view of the prior art of record. In particular, the limitations in the claims directed to the induced patterns of fractional damage provided by the RF energy delivery needles were discussed in detail in light of Uley's teachings. It was agreed that claim 27 would overcome the teachings of Utley et al. with a minor amendment to clearly state the claimed invention. With respect to claim 29, the way in which the controlled RF energy causes patterns of thermally damaged regions were discussed, and it was agreed that Utely et al. do not teach a method of controlling the RF energy to form patterns of thermally damaged regions as claimed. Proposes new claims presented by the applicant's representatives were further discussed during the interview. Applicant's representative indicated that they will file an official amendment containing the discussed/agreed amendment to claim 27 and the proposed new claims.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/AHMED FARAH/ Primary Examiner, Art Unit 3769	
--	--

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		12914201
	Filing Date		2010-10-28
	First Named Inventor	Dieter Manstein	
	Art Unit	3769	
	Examiner Name	Ahmed Farah	
	Attorney Docket Number	125141.01010	

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5284154		1994-02-08	Raymond et al.	
	2	5928158		1999-07-27	Aristides	
	3	7824394		2010-11-02	Manstein	

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

Add

U.S.PATENT APPLICATION PUBLICATIONS						Remove
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020091377	A1	2002-07-11	Anderson et al.	
	2	20020120260	A1	2002-08-29	Morris et al.	

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

Add

FOREIGN PATENT DOCUMENTS								Remove
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T ⁵

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

Application Number	12914201
Filing Date	2010-10-28
First Named Inventor	Dieter Manstein
Art Unit	3769
Examiner Name	Ahmed Farah
Attorney Docket Number	125141.01010

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	A1	2001-05-31	Nuvasive, Inc.	<input type="checkbox"/>
4	WO 02102265	WO	A1	2002-12-27	Medizinische Hochschule Hannover	<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button **Add**

NON-PATENT LITERATURE DOCUMENTS

Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1		<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

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

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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

Application Number	12914201
Filing Date	2010-10-28
First Named Inventor	Dieter Manstein
Art Unit	3769
Examiner Name	Ahmed Farah
Attorney Docket Number	125141.01010

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

- ☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

- ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- ☐ See attached certification statement.
- ☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Jack M. Cook/	Date (YYYY-MM-DD)	2015-04-22
Name/Print	JACK M. COOK	Registration Number	56,098

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
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Electronic Patent Application Fee Transmittal

Application Number:	12914201			
Filing Date:	28-Oct-2010			
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING			
First Named Inventor/Applicant Name:	Dieter Manstein			
Filer:	Jack M. Cook/LYNN HUST			
Attorney Docket Number:	125141.01010.MGH02587.10			
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Electronic Acknowledgement Receipt

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Warnings:					
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2	Foreign Reference	JP2001510702.pdf	954219	no	4
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National Stage of an International Application under 35 U.S.C. 371

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

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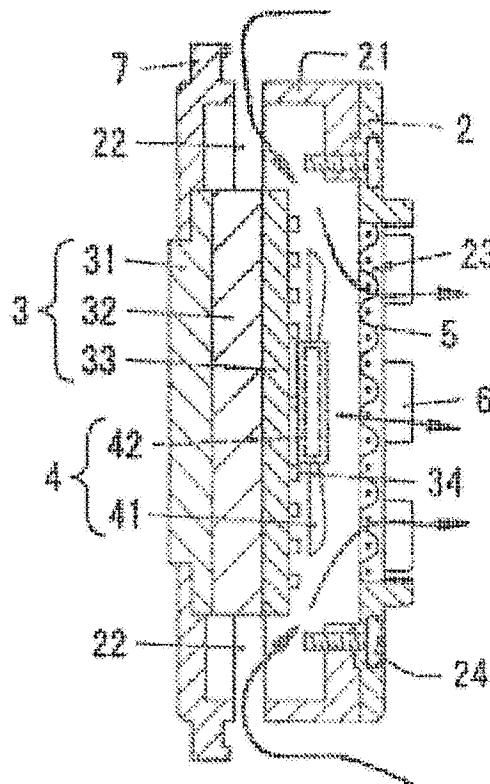
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Bibliographic data: JP2000342617 (A) — 2000-12-12
PAIN ALLAYING APPARATUS AND PROBE USING THE SAME

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.

✱

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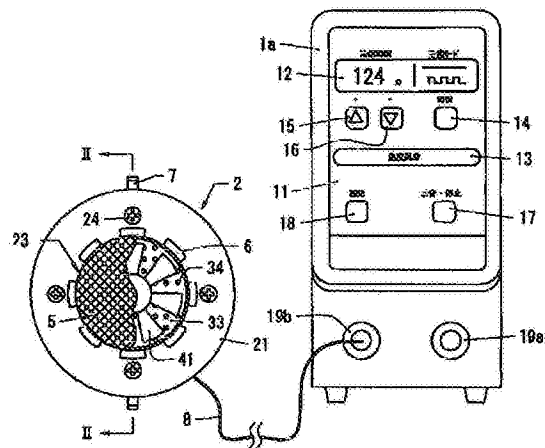
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(54) 【発明の名称】 疼痛緩和器、及びこれに用いたプローブ

(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プと、

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プと、

前記複数のプロープそれぞれについて、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、

前記複数のプロープそれぞれについて、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、

前記複数のプロープそれぞれについて、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プ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プの条件設定が完了すると、次のプロープ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プであって、

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プ。

【請求項7】 請求項6に記載のプロープにおいて、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プ。

【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プであって、

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プ。

【請求項9】 請求項6ないし8のいずれかに記載のプロープにおいて、

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プ。

【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ので、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口小窓と、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、その全体が偏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、全体が偏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ペルチェ素子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ペルチェ素子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、前記ペルチェ素子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、ペルチェ素子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、ペルチェ素子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の加温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温又は冷却する(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の電源を入れると、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

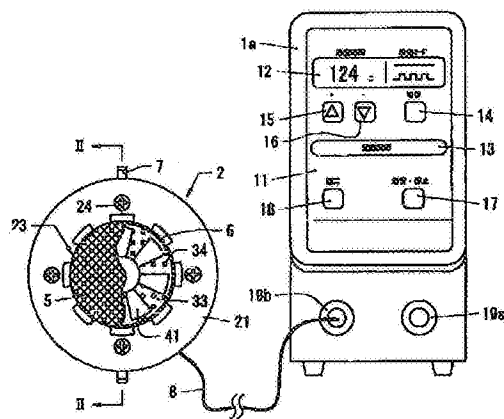
101, 101a 切替部

102 設定部

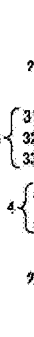
102a 条件設定部

105, 105a 安全装置

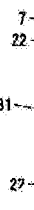
【図1】



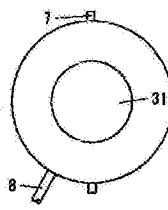
【図2】



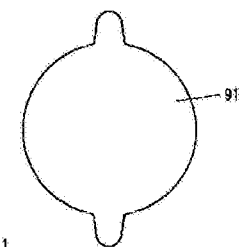
【図3】



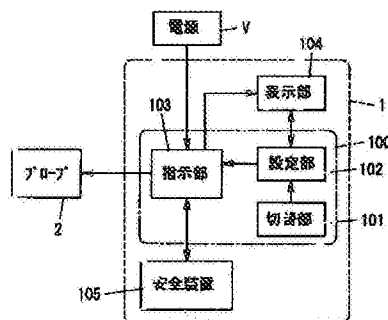
【図4】



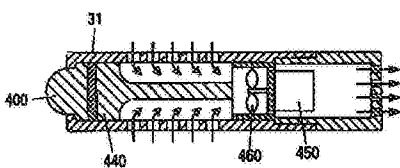
【図7】



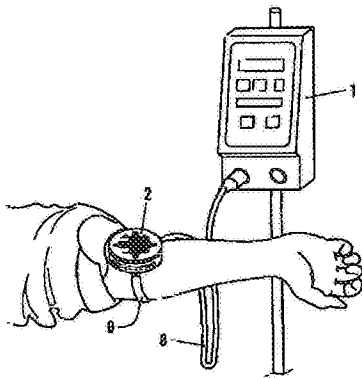
【図5】



【図13】



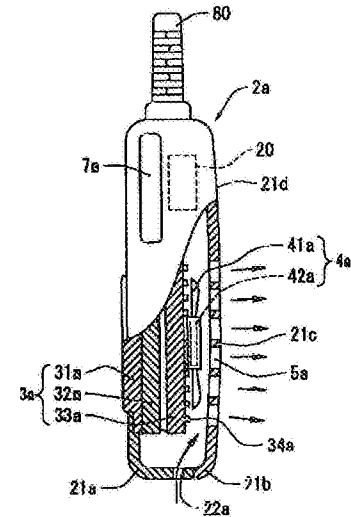
【図6】



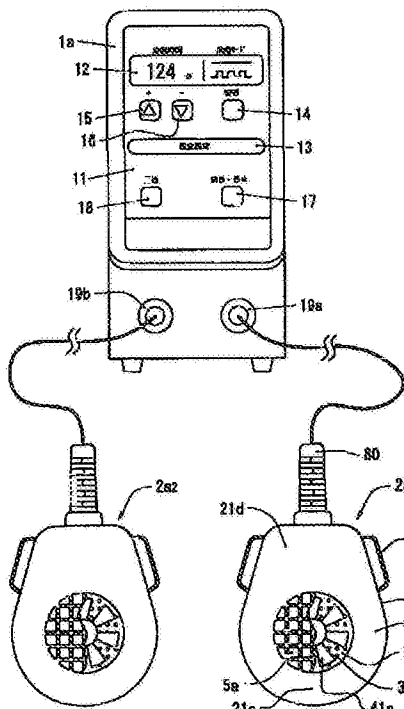
【図8】



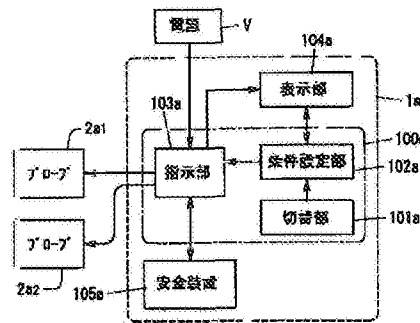
【図9】



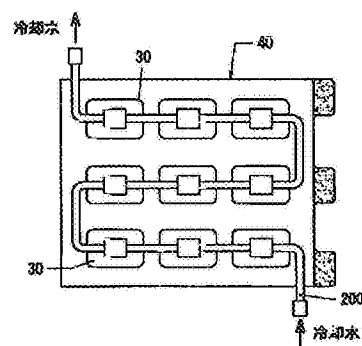
【図10】



【図11】



【図12】





Espacenet

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CLUSTER ABLATION ELECTRODE SYSTEM
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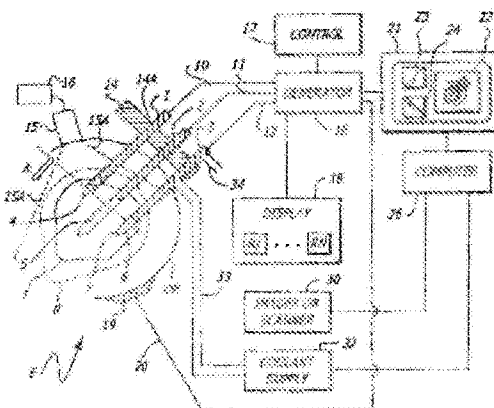
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Abstract not available for JP2001510702 (A)

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.

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【国際特許分類】

A61B 18/14 (2006.01)

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【手続補正書】

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【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。

(2)

【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。

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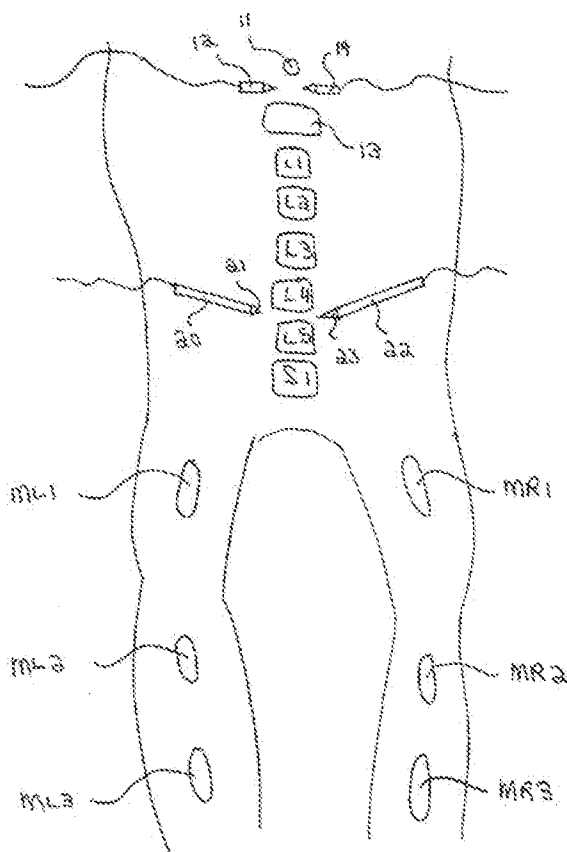
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[Continued on next page]

(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.

WO 01/37728 A1



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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. 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 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 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*.

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.

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 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 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 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 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 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 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.

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

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

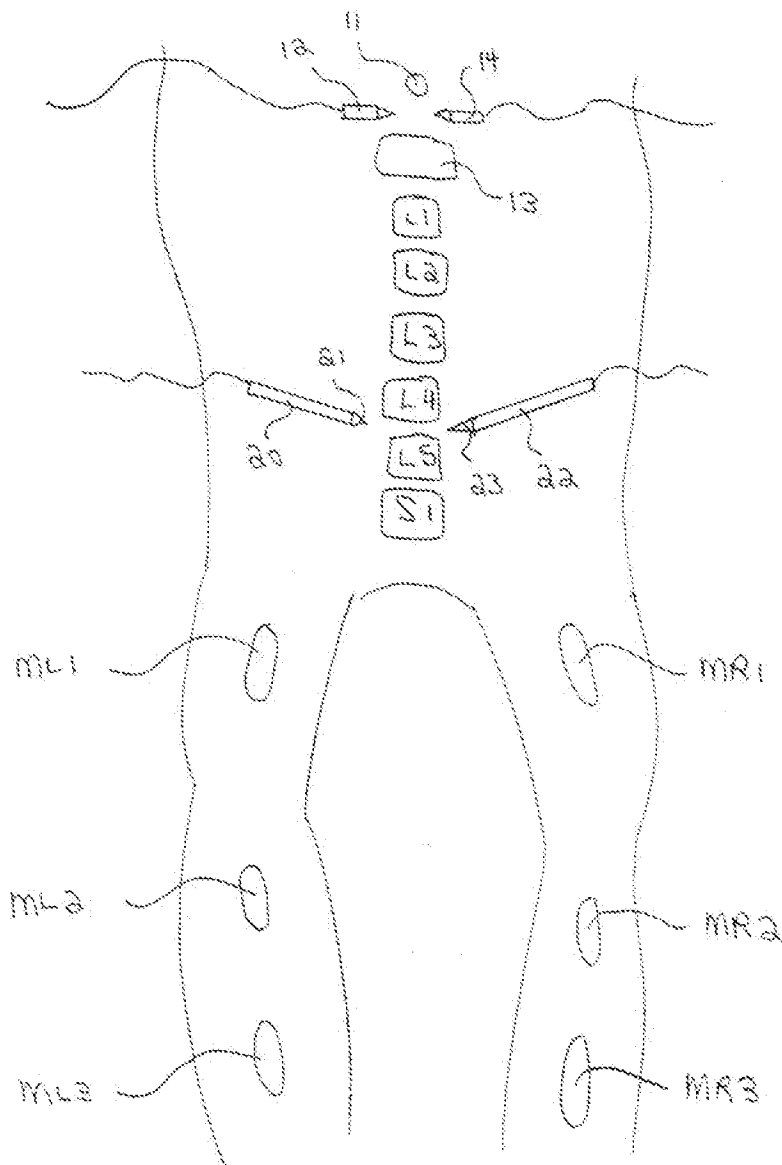


FIG 2

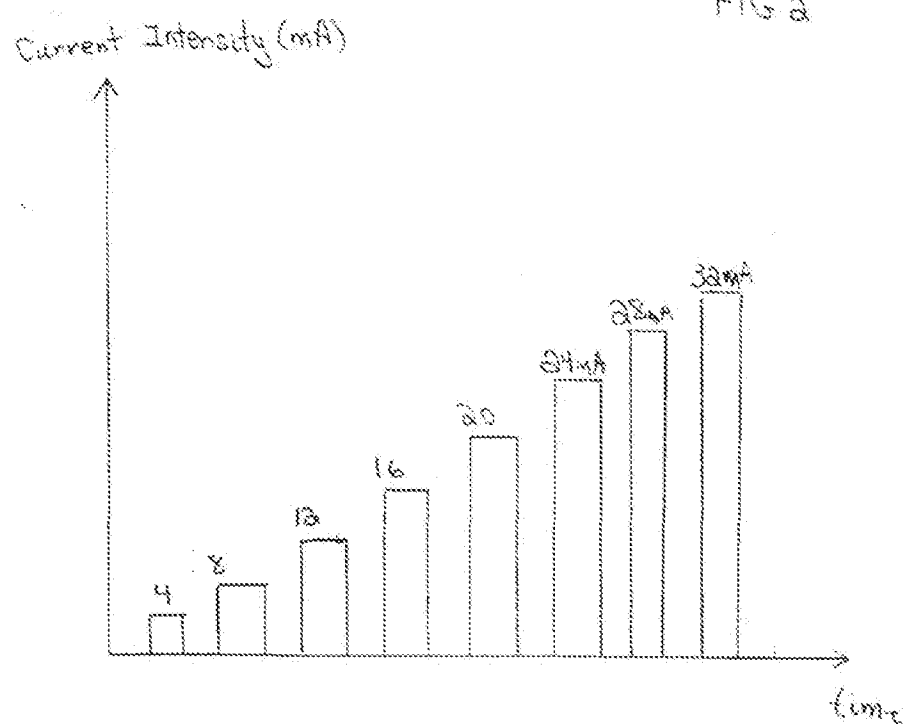


FIG 3

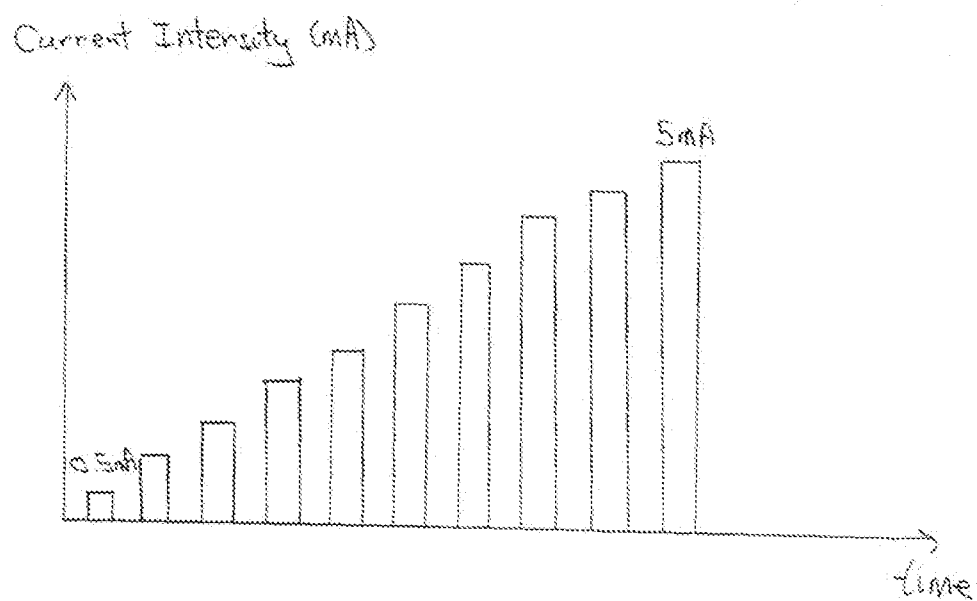


FIG 4

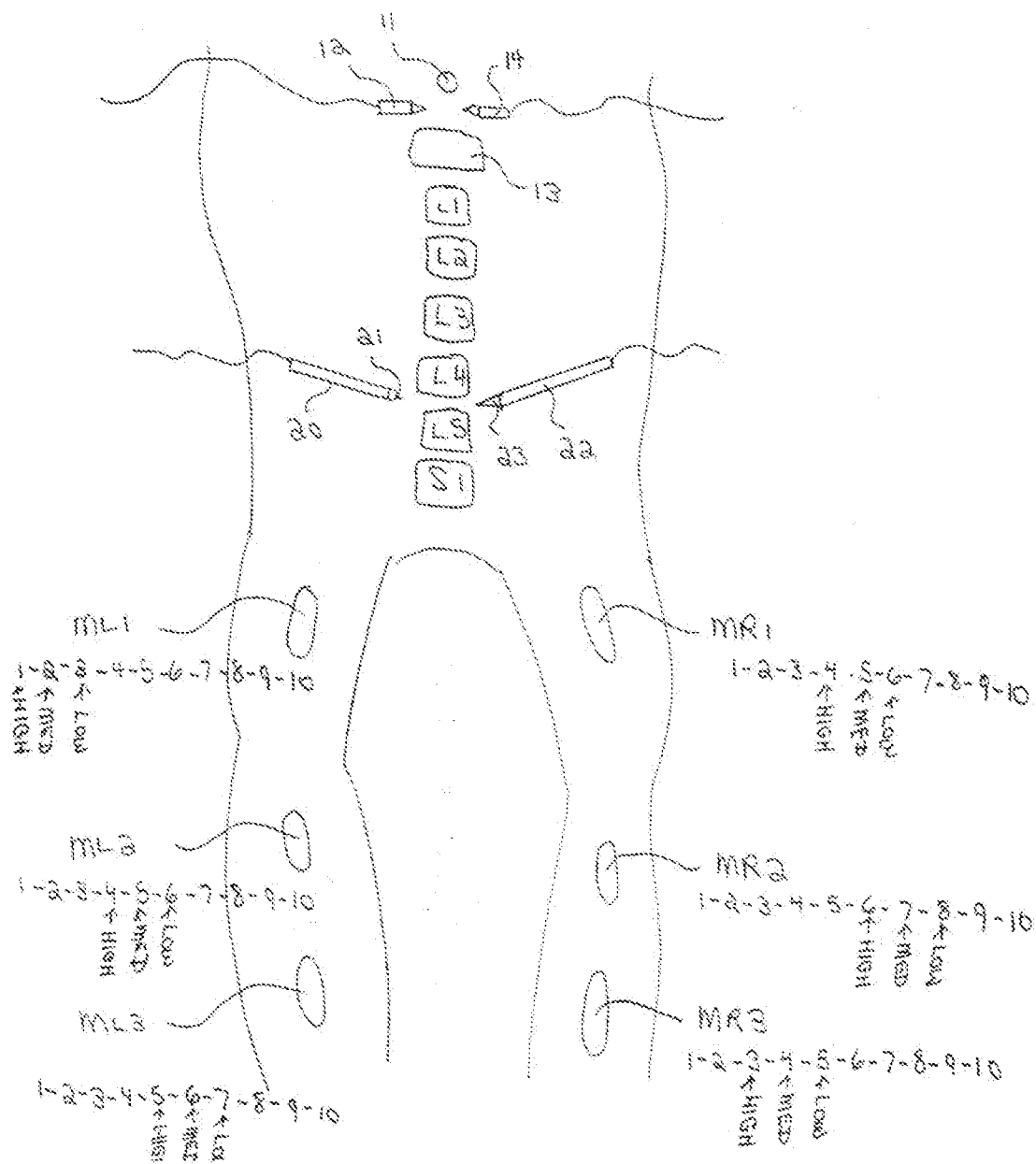
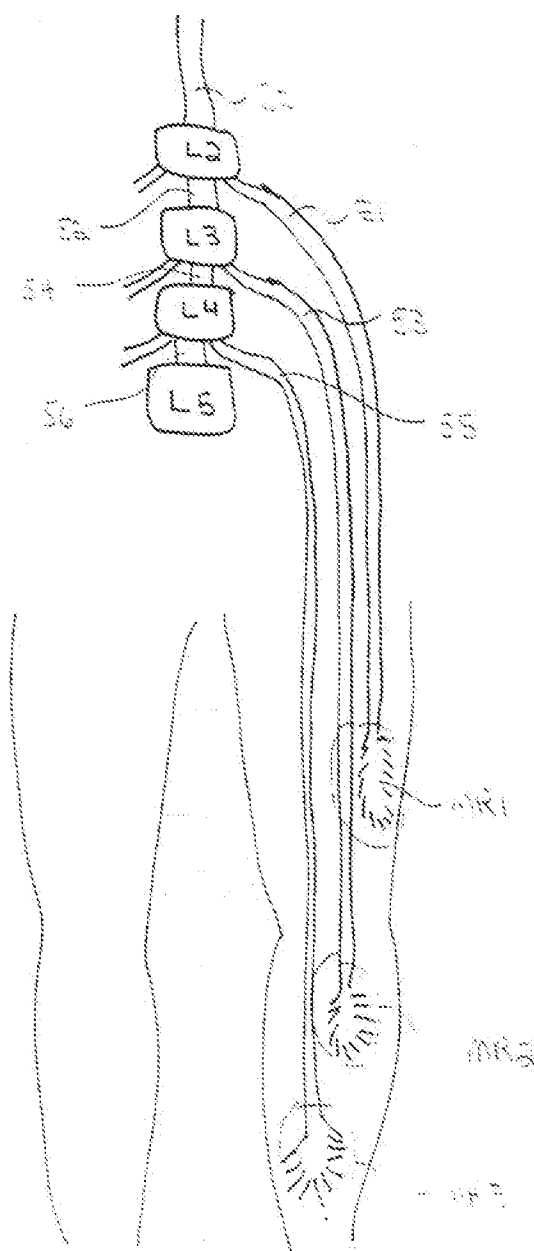
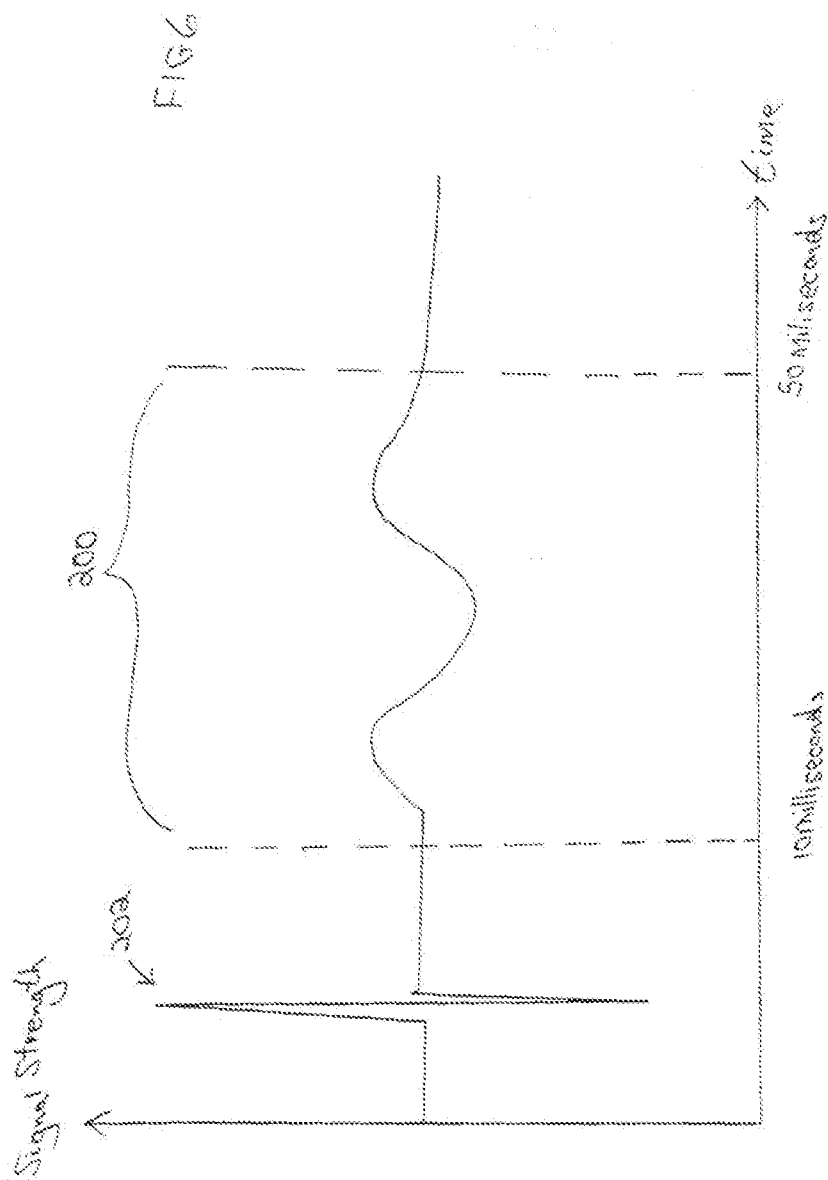


FIG 5





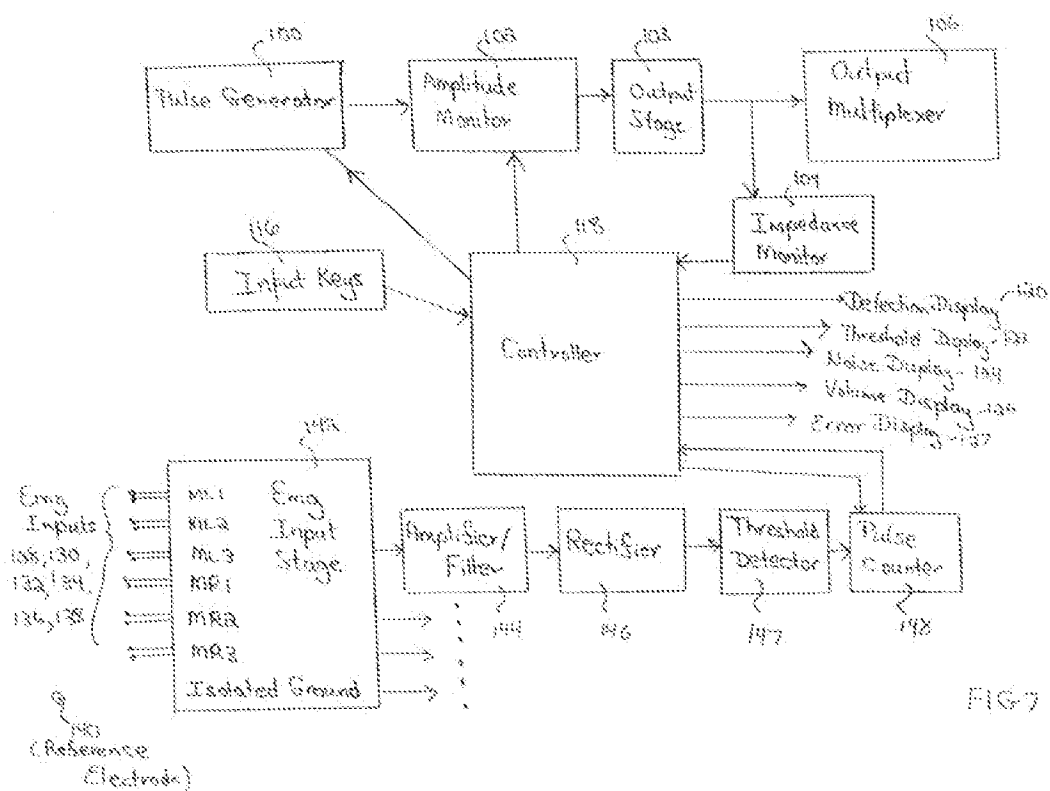
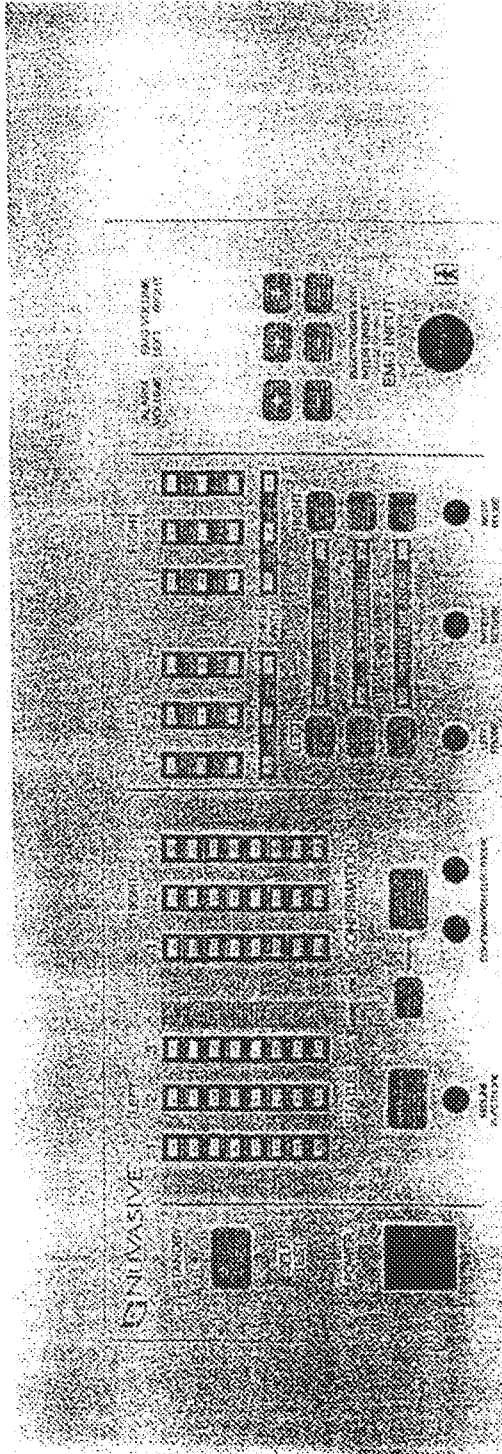


FIG. 7

FIG 8A



8

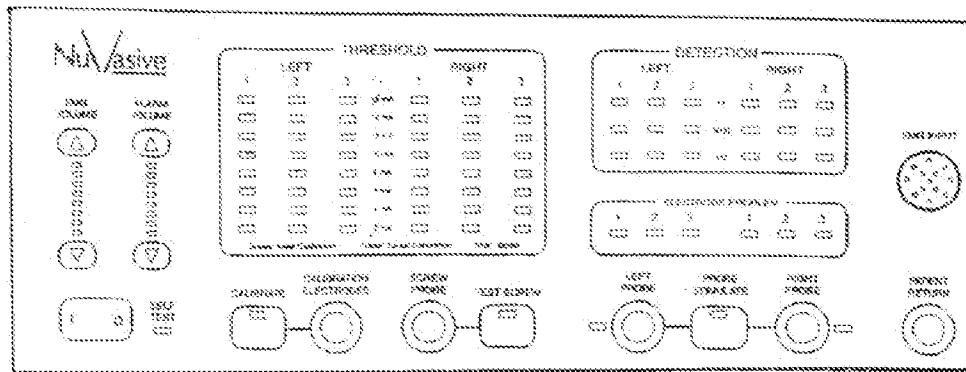


FIG 8B

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US86/93329

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : 361B 504, 505

US CL : 600546

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. : 600546, 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 combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"L" document which may throw doubts on priority (date(s)) or which is cited to establish the publication date of another citation or other special reason (as specified)	"X"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

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
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/32329

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/US99/22329

B. FIELDS SEARCHED

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

EAST

search terms: spinal nerve, depolarizing, canda 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.

(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES
PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

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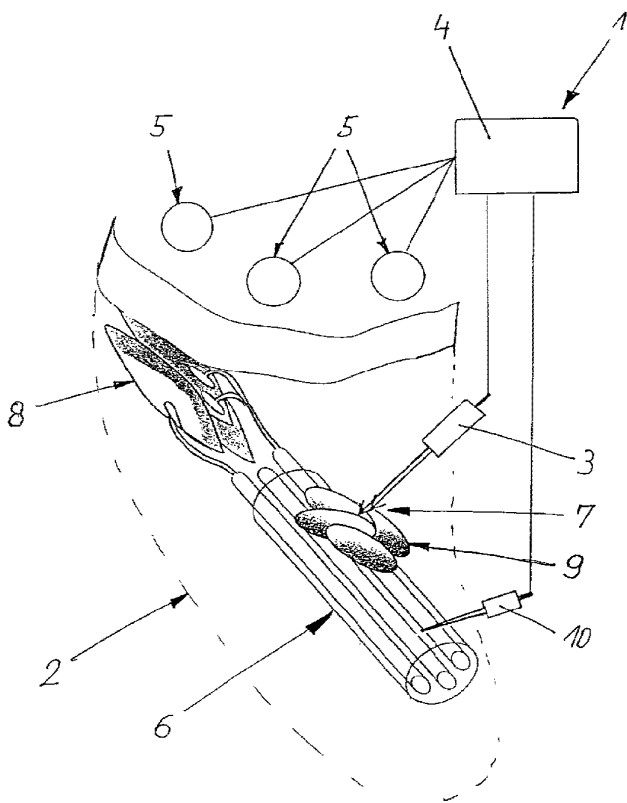
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(81) Bestimmungsstaaten (national): AU, JP, US.

[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.

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(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 10 eine wesentlich vereinfachte Handhabung des Sensors. Zugleich wird der ohnehin nur eingeschränkt zugängliche Operationsbereich nicht zusätzlich durch den Sensor behindert.

Eine andere besonders zuverlässige Abwandlung der Vorrichtung wird auch dadurch geschaffen, daß der Sensor zur Erfassung eines Reizsignals an einem Nerv ausgeführt ist. 15 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.

20 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.

5 Eine besonders zuverlässige Weiterbildung der Erfindung ist auch dadurch geschaffen, daß
mittels des Sensors ein von einem Reizapplikator der Vorrichtung erzeugbares Reizsignal
erfaßbar ist. Hierbei kann eine Funktionstrennung zwischen dem Aktor, der für den operati-
ven 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 sei-
ner Leistung erheblich verringerter, schädigungsfreier Laser sein.

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

20 Dabei ist es auch besonders hilfreich, wenn mittels der Steuereinheit auf der Basis der er-
mittelten 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.

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

35 Eine andere erfolgversprechende Ausgestaltung der Erfindung wird dann erreicht, wenn der
Sensor zur optischen Erfassung eines unter dem Einfluß der Reizsignale veränderlichen
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
15 Sensors (5) ein körpereigenes Aktionspotential des Körpers (2) erfaßbar ist.
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.

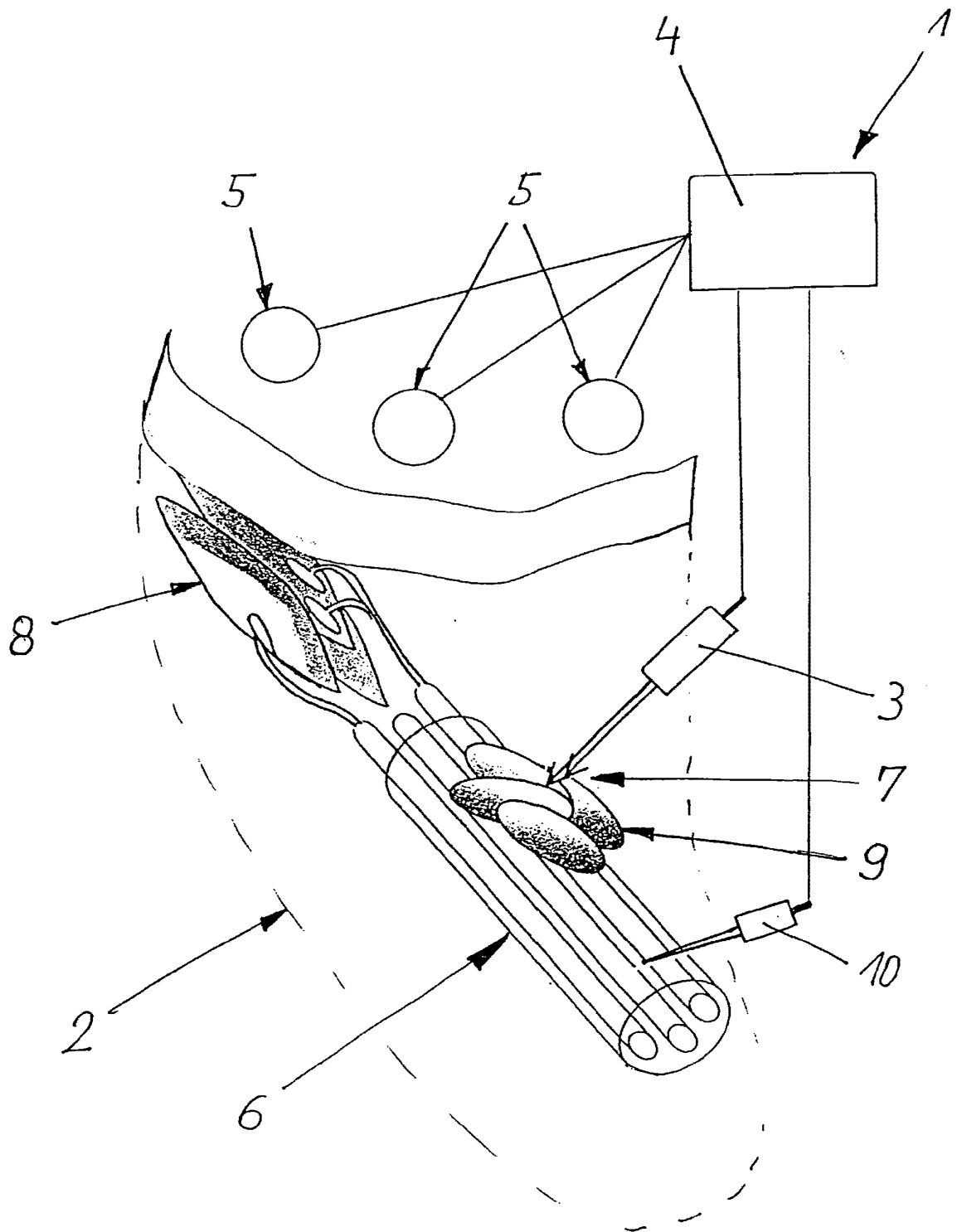
11. Vorrichtung (1) nach zumindest einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß mittels der Steuereinheit (4) eine Verzögerung zwischen einer Signalerzeugung und deren Erfassung mittels des Sensors (5) erfaßbar ist.

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/UE 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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 928 158 A (ARISTIDES ARELLANO) 27 July 1999 (1999-07-27) column 2, line 64 -column 3, line 25 column 4, line 66 -column 5, line 28; figures 1A,7 -----	1-7,9, 10,12,13
X	US 6 156 030 A (NEEV JOSEPH) 5 December 2000 (2000-12-05) column 42, line 61-67 column 55, line 12 -column 56, line 38 column 76, line 64 -column 77, line 10; figure 8G -----	1,2,7-9
X	US 4 682 594 A (MOK WALTER Y W) 28 July 1987 (1987-07-28) column 3, line 21 -column 4, line 26; figure 1 ----- -/-	1,2,7,9, 12,15

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

☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

14 October 2002

Date of mailing of the international search report

21/10/2002

Name and mailing address of the ISA

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Authorized officer

Reinbold, F

INTERNATIONAL SEARCH REPORT

Intern: Application No
PCT/DE 02/02195

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 074 382 A (BALLE-PETERSEN OLAV ET AL) 13 June 2000 (2000-06-13) column 4, line 27-37, 58-60 column 5, line 5-37 -----	1, 2, 7-9
A	EP 0 394 662 A (FUJITSU LTD) 31 October 1990 (1990-10-31) page 5, line 38-47 -----	14

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat Application No
PCT/DE 02/02195

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5928158	A	27-07-1999	NONE	
US 6156030	A	05-12-2000	AU 7496998 A EP 0986335 A1 WO 9855035 A1	21-12-1998 22-03-2000 10-12-1998
US 4682594	A	28-07-1987	US 4641650 A AT 76275 T CA 1263711 A1 DE 3685349 D1 EP 0194856 A2	10-02-1987 15-06-1992 05-12-1989 25-06-1992 17-09-1986
US 6074382	A	13-06-2000	AU 8851898 A WO 9911324 A1 EP 1009485 A1 JP 2001514057 T US 6383177 B1	22-03-1999 11-03-1999 21-06-2000 11-09-2001 07-05-2002
EP 0394662	A	31-10-1990	JP 2246926 A DE 69024840 D1 DE 69024840 T2 EP 0394662 A1 US 5285385 A	02-10-1990 29-02-1996 30-05-1996 31-10-1990 08-02-1994

PCT/DE 02/02195

IPK 7 A61B18/20

B. RESEARCHIERTE GEBIETE

IPK 7 A61B A61N

EPO-Internal, WPI Data

-/-

☒ Siehe Anhang Patentfamilie

T Spätere Veröffentlichung, die nach dem internationalen Anmeldedatum oder dem Prioritätsdatum veröffentlicht worden ist und mit der Anmeldung nicht kollidiert, sondern nur zum Verständnis des der Erfindung zugrundeliegenden Prinzips oder der ihr zugrundeliegenden Theorie angegeben ist

***X** Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann allein aufgrund dieser Veröffentlichung nicht als neu oder auf erfinderischer Tätigkeit beruhend betrachtet werden

Y Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als auf erfinderischer Tätigkeit beruhend betrachtet werden, wenn die Veröffentlichung mit einer oder mehreren anderen Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindungen für einen Fachmann naheliegend ist

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21/10/2002

Reinbold, F

INTERNATIONALER RECHERCHENBERICHT

Internat. Aktenzeichen

PCT/DE 02/02195

C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN		
Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 6 074 382 A (BALLE-PETERSEN OLAV ET AL) 13. Juni 2000 (2000-06-13) Spalte 4, Zeile 27-37, 58-60 Spalte 5, Zeile 5-37 ---	1, 2, 7-9
A	EP 0 394 662 A (FUJITSU LTD) 31. Oktober 1990 (1990-10-31) Seite 5, Zeile 38-47 -----	14

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationale Aktenzeichen

PCT/DE 02/02195

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
US 5928158	A	27-07-1999	KEINE
US 6156030	A	05-12-2000	AU 7496998 A 21-12-1998 EP 0986335 A1 22-03-2000 WO 9855035 A1 10-12-1998
US 4682594	A	28-07-1987	US 4641650 A 10-02-1987 AT 76275 T 15-06-1992 CA 1263711 A1 05-12-1989 DE 3685349 D1 25-06-1992 EP 0194856 A2 17-09-1986
US 6074382	A	13-06-2000	AU 8851898 A 22-03-1999 WO 9911324 A1 11-03-1999 EP 1009485 A1 21-06-2000 JP 2001514057 T 11-09-2001 US 6383177 B1 07-05-2002
EP 0394662	A	31-10-1990	JP 2246926 A 02-10-1990 DE 69024840 D1 29-02-1996 DE 69024840 T2 30-05-1996 EP 0394662 A1 31-10-1990 US 5285385 A 08-02-1994



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 04/28/2015
QUARLES & BRADY LLP
Attn: IP Docket
411 E. WISCONSIN AVENUE
SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER

FARAH, AHMED M

ART UNIT

PAPER NUMBER

3769

DATE MAILED: 04/28/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/914,201

10/28/2010

Dieter Manstein

125141.01010.MGH02587.10

5359

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	SMALL	\$480	\$0	\$0	\$480	07/28/2015

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 04/28/2015
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.
12/914,201	10/28/2010	Dieter Manstein	125141.01010.MGH02587.10	5359

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	SMALL	\$480	\$0	\$0	\$480	07/28/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
FARAH, AHMED M	3769	128-898000

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: <input type="checkbox"/> Issue Fee <input type="checkbox"/> Publication Fee (No small entity discount permitted) <input type="checkbox"/> Advance Order - # of Copies _____	4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) <input type="checkbox"/> A check is enclosed. <input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached. <input type="checkbox"/> 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).
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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. _____



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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/914,201	10/28/2010	Dieter Manstein	125141.01010.MGH02587.10	5359

26710 7590 04/28/2015
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SUITE 2350
MILWAUKEE, WI 53202-4426

EXAMINER

FARAH, AHMED M

ART UNIT PAPER NUMBER

3769

DATE MAILED: 04/28/2015

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. 12/914,201	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 amendment filed on 03/26/2015 under AFCP 2.0.
☐ 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 27,29,30,32,37 and 39-54. 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 checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 2. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 6. <input 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 checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>04/20/2015</u> . | |

/AHMED FARAH/
Primary Examiner, Art Unit 3769

1. The present application is being examined under the pre-AIA first to invent provisions.

EXAMINER'S AMENDMENT

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

Authorization for this examiner's amendment was given in a telephone interview with the applicant's representative, Kai Rajan (Reg. No. 70,110), on April 20, 2015.

The application has been amended as follows:

- Rewrite claim 54 as:

54. (Currently Amended) The method of claim 27, wherein each of the needles has a tip, wherein the pattern of fractional damage includes at least two adjacent regions of thermal damage, and wherein each adjacent region of thermal damage includes a small localized area of thermal damage surrounding each tip

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

April 20, 2015.

<i>Examiner-Initiated Interview Summary</i>	Application No. 12/914,201	Applicant(s) MANSTEIN, DIETER	
	Examiner AHMED FARAH	Art Unit 3769	

All participants (applicant, applicant's representative, PTO personnel):

(1) AHMED FARAH. (3) ____.

(2) Kai Rajan (Reg. No. 70,110). (4) ____.

Date of Interview: 20 April 2015.

Type: ☒ Telephonic ☐ Video Conference
 ☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
 If Yes, brief description: ____.

Issues Discussed ☐ 101 ☒ 112 ☐ 102 ☐ 103 ☐ Others
 (For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: claim 54.

Identification of prior art discussed: ____.

Substance of Interview
 (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Minor informality (lack of antecedent basis) in the claim language was discussed and corrective language was agreed. The applicant's representative authorized the examiner to make the agreed changes by Examiner's Amendment (EA). See the attached EA.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/AHMED FARAH/ Primary Examiner, Art Unit 3769	
--	--

Notice of References Cited	Application/Control No. 12/914,201	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	Classification
*	A	US-8,608,737	12-2013	Mehta et al.	606/44
*	B	US-8,882,753	11-2014	Mehta et al.	606/9
*	C	US-6,905,497	06-2005	Truckai et al.	606/49
*	D	US-2003/0144652	07-2003	Baker et al.	606/28
	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	Classification
	N					
	O					
	P					
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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Issue Classification 	Application/Control No. 12914201	Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER	
	Examiner AHMED FARAH	Art Unit 3769	

CPC						
Symbol					Type	Version
A61B		18	/	18	F	2013-01-01
A61B		5	/	4893	A	2013-01-01
A61B		18	/	1477	I	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		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
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			/			


CPC Combination Sets				
Symbol	Type	Set	Ranking	Version

NONE		Total Claims Allowed:	
(Assistant Examiner)		21	
(Date)			
/AHMED FARAH/		O.G. Print Claim(s)	O.G. Print Figure
Primary Examiner.Art Unit 3769		1	3
(Primary Examiner)		(Date)	

Issue Classification 	Application/Control No. 12914201	Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER
	Examiner AHMED FARAH	Art Unit 3769


US ORIGINAL CLASSIFICATION						INTERNATIONAL CLASSIFICATION													
CLASS		SUBCLASS				CLAIMED					NON-CLAIMED								
128		898				A	6	1	B	19 / 00 (2006.01.01)									
CROSS REFERENCE(S)																			
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																		
606	41	44																	
607	96	101																	

NONE		Total Claims Allowed:	
		21	
(Assistant Examiner)	(Date)		
/AHMED FARAH/ Primary Examiner.Art Unit 3769	04/20/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3

Issue Classification 	Application/Control No. 12914201	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
1	27	16	44												
-	28	7	45												
12	29	8	46												
13	30	9	47												
-	31	10	48												
2	32	17	49												
-	-	18	50												
-	-	19	51												
-	-	20	52												
3	37	21	53												
-	38	11	54												
4	39														
5	40														
6	41														
14	42														
15	43														

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 21	
/AHMED FARAH/ Primary Examiner.Art Unit 3769 (Primary Examiner) _____ (Date) _____		O.G. Print Claim(s) 1	O.G. Print Figure 3

Search Notes 	Application/Control No. 12914201	Applicant(s)/Patent Under Reexamination MANSTEIN, DIETER
	Examiner AHMED FARAH	Art Unit 3769

CPC- SEARCHED		
Symbol	Date	Examiner
A61B18/00, A61B18/04, A61B18/14, A61B18/1477	04/202/2015	AF
A61B2018/00315, A61B2018/00452, A61B2018/1425, A61B2018/143, A61B2018/00005, A61B2018/0019	04/202/2015	

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
606	27,28,31,32,41-50 updated	04/202/2015	AF
607	96,100-102,108-112 "	04/202/2015	AF
128	898 "	04/202/2015	AF

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search, BRS, IS&R, and CPC forms, see the attached 'Search History.'	04/202/2015	AF

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
606	27,28,31,32,41-50	04/202/2015	AF
607	96,100-102,108-112	04/202/2015	AF
128	898	04/202/2015	AF

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**RESPONSE UNDER 37 C.F.R. § 1.116
EXPEDITED PROCEDURE REQUESTED
EXAMINING GROUP 3769**

Customer No. 26,710

Attorney Docket Nos. 125141.01010.MGH02587.10 / 11706.0033-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Dieter MANSTEIN)	Group Art Unit: 3769
)	
Application No.: 12/914,201)	Examiner: Ahmed M. Farah
)	
Filed: October 28, 2010)	Confirmation No.: 5359
)	
For: METHOD AND APPARATUS FOR)	<u>VIA EFS-WEB</u>
DERMATOLOGICAL TREATMENT)	
AND TISSUE RESHAPING)	

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Commissioner:

AMENDMENT AFTER FINAL AND REQUEST FOR RECONSIDERATION

Applicant appreciates the courtesies extended by Examiner Farah in an in-person interview held on March 24, 2015 to discuss the Final Office Action mailed December 4, 2014.

This Amendment is submitted, consistent with discussions in the interview, to place the application in condition for allowance.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 8 of this paper.



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BIB DATA SHEET

CONFIRMATION NO. 5359

SERIAL NUMBER 12/914,201	FILING or 371(c) DATE 10/28/2010 RULE	CLASS 606	GROUP ART UNIT 3769 125141.01010.MGH02587.10	ATTORNEY DOCKET NO.	
APPLICANTS INVENTORS Dieter Manstein, Boston, MA; ** CONTINUING DATA ***** This application is a DIV of 11/098,030 04/01/2005 PAT 7824394 ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED *** SMALL ENTITY ** 11/09/2010					
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 MA	SHEETS DRAWINGS 4	TOTAL CLAIMS 21	INDEPENDENT CLAIMS 5
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 502	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	302	(Manstein near Dieter).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:46
L2	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
L3	12	1 and 2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:53
L4	12	3 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
L5	2	4 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
L6	10	4 not 5	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:54
L7	2791	2 and (thermal with damag\$3)	US-PGPUB; USPAT	OR	ON	2015/04/20 11:56
L8	1575	7 and ((needle electrode)with ('RF raidofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT;	OR	ON	2015/04/20 11:56

			IBM_TDB			
L9	1575	7 and ((needle electrode) with ('RF radiofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:56
L10	14	9 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 11:57
L11	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
L12	2086	(A61B18/04).IPCR.	US-PGPUB; USPAT	OR	OFF	2015/04/20 12:10
L13	796	12 and ((needle electrode) with ('RF radiofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 12:10
L14	4	13 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 12:10
L15	9648	(A61B18/14).IPCR.	US-PGPUB; USPAT	OR	OFF	2015/04/20 12:12
L16	5282	15 and ((needle electrode) with ('RF radiofrequency (radio adj frequency)))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 12:12
L17	21	16 and (fractional with (therapy damage thermal))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/04/20 12:12
L18	0	(A61B18/1477).IPCR.	US-PGPUB; USPAT	OR	OFF	2015/04/20 12:13
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;	OR	ON	2014/05/05

			USPAT			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 cell)) with death)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:03
S8	0	S1 and ((tissue cell)) with injur\$3)	US-PGPUB; USPAT	OR	ON	2014/05/05 00:04
S9	2	S1 and ((tissue cell)) 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;	OR	OFF	2014/11/30 23:13

			IBM_TDB			
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

4/ 20/ 2015 12:15:10 PM
C:\ Users\afarah\ Documents\ EAST\ Workspaces\ 12914201.wsp



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/914,201	10/28/2010	Dieter Manstein	125141.01010.MGH02587.10	5359

26710 7590 05/14/2015

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
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05/14/2015

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
12/914,201 125141.01010.MGH02587.10	28 October, 2010	MANSTEIN, DIETER	

QUARLES & BRADY LLP Attn: IP Docket 411 E. WISCONSIN AVENUE SUITE 2350 MILWAUKEE, WI 53202-4426		EXAMINER	
		AHMED FARAH	
		ART UNIT	PAPER
		3769	20150506

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The Information Disclosure Statement (IDS) filed on 04/22/2015 has been considered. See the attached 1449.

/AHMED FARAH/
Primary Examiner, Art Unit 3769

Receipt date: 04/22/2015

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

12914201 - GAI: 3769

P10/05/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		12914201	
	Filing Date		2010-10-28	
	First Named Inventor	Dieter Manstein		
	Art Unit	3769		
	Examiner Name	Ahmed Farah		
	Attorney Docket Number	125141.01010		

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5284154		1994-02-08	Raymond et al.	
	2	5928158		1999-07-27	Aristides	
	3	7824394		2010-11-02	Manstein	

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	1	20020091377	A1	2002-07-11	Anderson et al.	
	2	20020120260	A1	2002-08-29	Morris et al.	

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Receipt date: 04/22/2015 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		12914201	12914201 - GAU: 3769
	Filing Date		2010-10-28	
	First Named Inventor	Dieter Manstein		
	Art Unit	3769		
	Examiner Name	Ahmed Farah		
	Attorney Docket Number	125141.01010		

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	A1	2001-05-31	Nuvasive, Inc.	<input type="checkbox"/>
4	WO 02102265	WO	A1	2002-12-27	Medizinische Hochschule Hannover	<input type="checkbox"/>

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Examiner Signature	/Ahmed Farah/	Date Considered	05/06/2015
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(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/914,201	10/28/2010	Dieter Manstein	125141.01010.MGH02587.10	5359

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	SMALL	\$480	\$0	\$0	\$480	07/28/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
FARAH, AHMED M	3769	128-898000

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.**

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- (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.

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

The General Hospital Corporation

Boston, MA

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 170055 (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 June 30, 2015

Typed or printed name Jack M. Cook

Registration No. 56,098

Electronic Patent Application Fee Transmittal

Application Number:	12914201			
Filing Date:	28-Oct-2010			
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING			
First Named Inventor/Applicant Name:	Dieter Manstein			
Filer:	Jack M. Cook/Sara Kerstein			
Attorney Docket Number:	125141.01010.MGH02587.10			
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:	22782635
Application Number:	12914201
International Application Number:	
Confirmation Number:	5359
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:	125141.01010.MGH02587.10
Receipt Date:	30-JUN-2015
Filing Date:	28-OCT-2010
Time Stamp:	11:31:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$960
RAM confirmation Number	10847
Deposit Account	170055
Authorized User	COOK, JACK

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

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)	mgh_1010_issuefee.pdf	1623724	no	1
			79e60f6a7ee5a892c262b7acffda289ad8ebcb4f		

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30468	no	2
			63bb702a3285fe3e67ec61a019ccdde195c58ce		

Warnings:

Information:

Total Files Size (in bytes):	1654192
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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.

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 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	12/914,201
Filing Date	October 28, 2010
First Named Inventor	Dieter Manstein
Art Unit	3769
Examiner Name	To be assigned
Attorney Docket Number	036213.US.07-475387-779

Sheet 1 of 2

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US- 20090124958	05/14/2009	L. Kasey et al.	
		US- 20080082090	04/03/2008	D. Manstein	
		US- 20080312647	12/18/2008	P. Knopp	
		US- 20070106143	05/10/2007	J. Flaherty	
		US- 6,277,116	08/21/2001	D. Utely	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

Examiner
SignatureDate
Considered

*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 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours 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, 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 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.F./

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Substitute for form 1449A/PTO					
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				<i>Complete if Known</i>	
				Application Number	12/914,201
				Filing Date	October 28, 2010
				First Named Inventor	Dieter Manstein
				Art Unit	3769
				Examiner Name	TBA
(Use as many sheets as necessary)					
Sheet	3	of	5	Attorney Docket No: 36213.US.07-475387-779	

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.	December 30, 2004
		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./

Receipt date: 05/10/2011

12914201 - GAU: 3769

PTO/SB/08a (01-08)

Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Substitute for form 1449A/PTO					
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				<i>Complete if Known</i>	
				Application Number	12/914,201
				Filing Date	October 28, 2010
				First Named Inventor	Dieter Manstein
				Art Unit	3769
				Examiner Name	TBA
(Use as many sheets as necessary)					
Sheet	2	of	5	Attorney Docket No: 36213.US.07-475387-779	

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
		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.	Avrahami, 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 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./

Receipt date: 05/10/2011

12914201 - GAU: 3769

PTO/SB/08a (01-08)

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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Substitute for form 1449A/PTO					
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	12/914,201
				Filing Date	October 28, 2010
				First Named Inventor	Dieter Manstein
				Art Unit	3769
				Examiner Name	TBA
Sheet	1	of	5	Attorney Docket No: 36213.US.07-475387-779	

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	November 16, 1999
		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.	September 19, 2000
		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. 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
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/914,201	08/04/2015	9095357	125141.01010.MGH02587.10	5359

26710 7590 07/15/2015
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 1294 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, 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.

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
-------	-------------------	------

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

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
---	---

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
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		
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3		
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5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
-------	-------------------	------

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

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
---	---

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 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
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		
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3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
-------	-------------------	------

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

CERTIFICATE OF SERVICE

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/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 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
2 9,095,357	8/4/2015	The General Hospital Corporation
3		
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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
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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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Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

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

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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
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 Lutronic, Corp. and Lutronic, 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
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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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/s/ Christopher S. Schultz

Christopher S. Schultz (BBO No. 630814)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1st Named Inventor: Dieter Manstein
Application No.: 12/914,201
Filed: October 28, 2010
Art Unit: 3769
Confirmation No.: 5359
Docket No.: 125141.01010
Title: Method and Apparatus for Dermatological Treatment and
Tissue Reshaping

**PAYMENT OF FEES PURSUANT TO 37 C.F.R. §1.27(g) RELATED TO CHANGE
FROM SMALL ENTITY STATUS TO LARGE ENTITY STATUS**

Commissioner:

In the above-identified application, erroneously and without deceptive intent, back fees made at the small entity rate were not paid up to the large entity rate. Accordingly, please charge the deficiency in payments listed below to Deposit Account No. 17-0055.

Date paid	Fee Code Paid	Amount Paid	Large Entity Fee Code	Amount	Deficiency Due
10/28/2010	4011	82	1011	300	218
10/28/2010	2111	270	1111	660	390
10/28/2010	2311	110	1311	760	650
4/23/2014	2202	40	1202	100	60
				Total	\$1318

Again, the present application was filed with small entity status. However, this was done in error and without deceptive intent. Thus, Applicant hereby takes steps to correct the error and therefore requests the deficiencies to be paid. Should any additional fees or credit be due for the above-identified patent, the Commissioner is hereby authorized to charge them to Deposit Account No. 17-0055.

Respectfully submitted,

Dated: November 16, 2018

/Thomas J. Keating/
Thomas J. Keating, Reg. No. 59,110
Quarles & Brady LLP
Attorney for Applicant
411 East Wisconsin Avenue
Milwaukee, WI 53202-4497
(414) 277-5000

Electronic Acknowledgement Receipt

EFS ID:	34338385
Application Number:	12914201
International Application Number:	
Confirmation Number:	5359
Title of Invention:	METHOD AND APPARATUS FOR DERMATOLOGICAL TREATMENT AND TISSUE RESHAPING
First Named Inventor/Applicant Name:	Dieter Manstein
Customer Number:	26710
Filer:	Thomas J. Keating/Sara Wright
Filer Authorized By:	Thomas J. Keating
Attorney Docket Number:	125141.01010.MGH02587.10
Receipt Date:	16-NOV-2018
Filing Date:	28-OCT-2010
Time Stamp:	18:09:49
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	Miscellaneous Incoming Letter	mgh-1010-request.pdf	100179	no	2
			fe15ce6289ed29646a498bc427d04d783fb e73ac		

Warnings:

Information:	
Total Files Size (in bytes):	100179
<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>	