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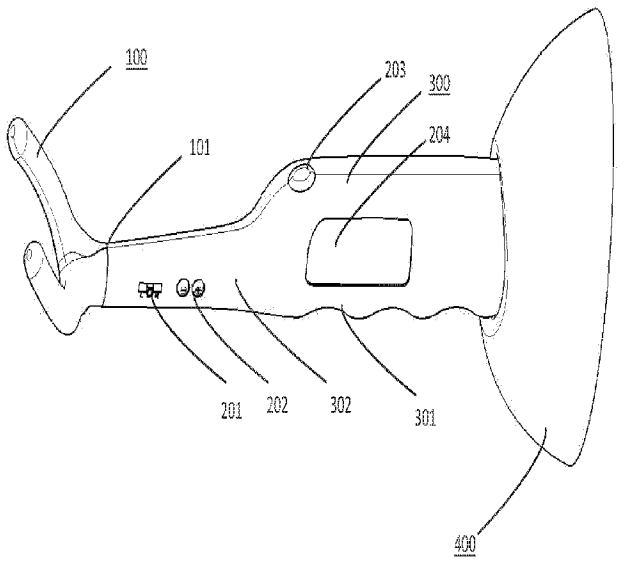

Figure 2

(57) Abstract: A pain abatement device utilizing sensory inputs such as vibratory motion, tactile sensation, heat, and cold to compete with the noxious pain signal and to diminish injection site pain, pain associated with minor surgeries, and pain associated with non- ocular laser treatments. The device is designed to resist heat transferred by laser surgery treatment beams, and to shield the device from harm from said laser. A plurality of vibrating head attachments allow the device to be used on any contour of the human body. The vibrating head attachments comprise a Peltier thermoelectric device to transmit heat or cold to the patient's skin, dependant on the temperature setting the clinician chooses. Each of the plurality of head attachments take advantage of a corresponding silicone or plastic sterile disposable cover with a variety of surface textures, providing a sterile point of contact with the patient and an additional stimulation of the nervous system.

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METHOD AND APPARATUS FOR LOCALIZED VIBRATORY, TACTILE, AND OTHER STIMULUS FOR PAIN ABATEMENT ASSOCIATED WITH INJECTIONS FOR MINOR SURGICAL PROCEDURES AND COSMETIC LASER TREATMENTS

Background of the Invention

Field of the Invention

[0001] The invention relates to the field of pain abatement systems for injections and minor surgeries and laser treatments, specifically the use of a device employing vibration, tactile, temperature variations, and other stimulus to diminish or abolish patient perception of pain without the use of drugs.

[0002] *Description of the Prior Art*

[0003] The pain from minor surgical procedures and injections causes many patients to be reluctant to visit their doctors for easily treatable conditions. In the case of childhood immunizations and other necessary shots, traumatic early experiences can foster a lifelong aversion to even the simplest medical procedure. Alternatively, adult patients may delay a procedure too far beyond its recommended administration time for particularly painful injections, such as injections into joints and epidural injections of steroids and pain relievers.

[0004] To alleviate the pain of minor surgical procedures and cosmetic laser treatment, the medical community has developed a variety of methods. While the ultimate goal is non-invasive analgesia in most cases, any clinically significant decrease of perceived pain can greatly increase the tolerability of various treatments. These methods fall generally into the categories of use of drugs (topical anesthesia, regional anesthetic nerve blocks, local anesthesia), altering of the patient's perception of the pain (talkestheia a.k.a. talking and holding hand to calm patient, vibration, heat, cold, tactile input, or other sensory

inputs), or diminution of nerve activity through non-drug means such as cooling the area of injection. Each technique has its own unique advantages and disadvantages, which will be discussed below. When necessary, various techniques can be combined to achieve the optimal treatment modality.

[0005] The first general category of treatments utilized to relieve injection site pain is that of anesthetic drugs. In the context of minor surgical procedures and injections, use of drugs usually limited to local anesthesia.

[0006] Local anesthetics vary in their pharmacological properties and they are used in various techniques of local anesthesia such as: Topical anesthesia (surface), Plexus block, Infiltration (injection directly into local tissues), Spinal anesthesia (subarachnoid block), and Epidural (extradural) block.

[0007] In many simple procedures, such as cosmetic laser treatments and Botox® injection, physicians are ethically and legally limited to non-invasive pain abatement procedures, which include analgesic creams and cooling temperature applied to the site of the minor treatment with the 'cooling head' utilized in may laser treatment devices. These options, and invasive treatments that are applicable to procedures causing a higher level of pain perception, are discussed below.

[0008] Topical anesthetic or analgesic creams applied to the skin represent a widely-used method of local pain perception control. Topical anesthetics are a simple and noninvasive technique involving rubbing a liquid, cream, or gel onto the skin of the patient. Many topical anesthetics, including EMLA™, Elamax™, liposome-encapsulated lidocaine cream, amethocaine, cetacaine, and benzocaine products, can aid in minimizing the pain of cutaneous procedures including intralesional lidocaine infiltration. This technique can be effective in treating some aspects of injection site pain and the discomfort associated with minor surgeries. However, the use of these anesthetics can be time consuming and cause occasional complications. This technique provides only limited pain relief and take anywhere from 20 minutes to over an hour to begin to function on the patient. The most common complication of topical anesthesia is contact dermatitis. The use of Elamax™, which does not contain

prilocaine, may minimize the possibility of contact dermatitis. EMLA™, in particular, is associated with extensive corneal deepithelialization, purpura and petechiae and even methemoglobinemia if applied to large areas.

[0009] Localized pain may be minimized by using cold temperatures applied to the patient's skin. Cold therapy is an effective and non-invasive way to relieve localized pain from injections or minor surgeries. This additionally reduces pain sensation and swelling, and is well known to those familiar with the healing arts. Application of cold reduces nerve sensation by reducing nerve activity through reduction of energy available to the nerve.

[0010] A simple version of this method involves ice created from frozen water, often wrapped in a thick cloth that is applied to the skin several minutes prior to beginning of the minor procedure. Alternatively, cold therapy may be applied via instant cold packs, or reusable non-toxic gel packs. These are readily available in any pharmacy or supermarket. An additional alternative for minor treatment site pain is the use of 'cold spray', which is the generic name for an aerosol-type spray utilized by clinicians to cool injection sites and therefore minimize pain.

[0011] In the case of cosmetic laser treatments, the cosmetic laser apparatus can be fitted with a 'cooling head'. Several varieties of this type of technology are currently available. One example would be the 'cooling head' on the CoolGlide™ Laser System by Cutera XEO. Another example of this type would be the V Beam® line of cosmetic lasers from Candela Corporation. These technologies are widely used, commercially available, and utilize a fine spray of refrigerant or cryogen onto the skin of the patient at the treatment site. For example, the V Beam ® Perfecta by Candela Corporation uses HFC 134a as a cryogen. This cryogen quickly cools the patient's skin at the treatment area then evaporates.

[0012] However, cold therapy must be utilized with some caution. If a cold therapy source is at a low enough temperature, or an excessive amount of cryogen from a cosmetic laser's 'cooling head' is applied, it is possible to cause an ice burn to the area of contact with the patient. Also, some redness on the

treatment area after treatment with a cold compress is common, but will often vanish shortly. When a 'cooling head' is utilized for cosmetic laser treatments, it is of only minor assistance in avoiding dermal burning. Further, many cosmetic laser treatments, such as laser dermabrasion, intentionally remove several layers of damaged skin. Such procedures can be highly uncomfortable to patients after treatment, however cold therapy may assist with perceived pain during the treatment, and minimize swelling and discomfort afterwards.

[0013] Invasive pain management techniques may also be used by the physician. Pain management is invasive when it requires the entry of a needle, catheter, or other instrument into a part of the body. There are a wide range of invasive procedures in order to help minimize the patient's experience of pain, ranging from simple localized infiltration of tissue at a specific site, to general anesthesia techniques. Generally, the wider the analgesic or anesthetic effect, the higher dosage of medication is required, and the greater chance of undesirable side effects. Specifically, the greater amount of anesthetic fluid administered, the lower the border between healthy and distressed tissue becomes. Additionally, for injections into the joints of patients (e.g. a cortisone injection into the spine of a patient to treat chronic back pain), higher quantities of injected fluid are associated with movement of loose or foreign bodies in and around the injection site.

[0014] Infiltration is a mildly invasive administration of anesthesia directly into tissue using a syringe. The tissue becomes anesthetized, however, the anesthetization is extremely localized, and does not help with the pain of deeper injections, such as epidural (extradural) blocks and injections into joint areas.

[0015] Regional nerve block (plexus block, spinal anesthesia (subarachnoid block), and epidural (extradural) block) is a general term used to refer to the injection of local anesthetic onto or near nerves for temporary control of pain. Permanent nerve block can be produced by destruction of nerve tissue. It can also be used as a diagnostic tool to identify specific nerves as pain generators. These procedures function under the same basic principle, that of blocking nerve signal transmission at a certain point stops transmission to the

central nervous system beyond that point. Nerve blocks carry the possibility of side effects and complications from the procedure, needle puncture, and medications used. The most critical factor in the efficacy of a nerve block is the proper location of the target nerve.

[0016] Complications for a regional nerve block often include infection (often at site of injection, but it can become systemic), allergic reactions to the medication used, and increased pain at the site if the procedure is unsuccessful. Also, in the context of minor surgeries and injections, nerve blocks are of limited use because of the desire to minimize immediate postoperative disability, and because of the time involved in utilizing the procedure. Postoperative disability is a significant issue, because it limits the ability of a patient to drive home. For example, with the dermatological procedure of administering botulinum type A injection to the hands and feet to reduce normal perspiration, the doctor must commonly limit the procedure to one hand or foot in a single visit. (Kevin C. Smith, MD, et al., *Vibration anesthesia: A non-invasive method of reducing discomfort prior to dermatologic procedures*, Dermatology Online Journal, Vol. 10, No. 2, 2004.) Also, when treating injection site pain, it is important to weigh the pain associated with the anesthesia treatment against the pain of the injection. For many standard inoculations, for example, a nerve block procedure would be more invasive and painful than the primary procedure.

[0017] Alternatively, the clinician could choose to attempt to alter the perception of pain within the patient. This is usually accomplished through talkestheia (talking to the patient, and holding their hand to calm them), or addition of sensory input on or near the area of the minor surgical procedure. The sensory input commonly includes vibration, heat, cold, and tactile input, but may include other types of distractions as well.

[0018] The current invention functions based upon the gate control theory of pain sensation, which was put forward by Ronald Melzack and Patrick David Wall in 1962 and 1965. This theory holds that the perception of physical pain is not a direct result of activation of nociceptors, but instead is modulated by interaction between different neurons, both pain-transmitting and non-pain-

transmitting. The theory asserts that activation of nerves that do not transmit pain signals can interfere with signals from pain fibers and inhibit an individual's perception of pain. Therefore, activation of a nerve with a non-noxious stimulus, such as vibration, lessens the perception of the noxious stimulus, such as injection site pain. This is especially the case when non-noxious stimulus can be applied to the same dermatome as is subject to the noxious stimulus. The effect is that the patient is distracted from the pain on both a conscious and biological level. While differing sensations travel along nerve tissue at differing speeds, any sensation can function to limit localized pain response. In clinical use, the most commonly used stimulus include heat, cold, and vibration.

[0019] The gate control theory of pain is given additional credence based upon current understanding of the speed of transmission of various sensations along sensory fibers in the human body. The Erlanger-Gasser classification of nerve fibers categorizes nerve cells by their function and form. Various nerve types transmit information at drastically varied speeds. For example, Delta sensory fibers transmit pain sensation at an average speed of 15 meters per second, while vibratory sensation is transmitted along Beta sensory fibers at an average speed of 55 meters per second. Utilizing this information, the gate control theory of pain can be utilized to greater effect by applying a non-noxious sensation to the nerve area that is capable of faster transmission than the noxious pain response.

[0020] Sensory input can be provided to the patient in a great variety of ways to treat minor surgery pain and injection pain. For example, there are many commercially available vibrators to add a vibratory sensation around an injection site. The AccuVibe Softtouch™ is a rechargeable personal massager that can be used for vibratory anesthesia. The Hitachi Magic Wand™ and the ConAir™ double-headed massager can also be used. As a sterilization procedure, medium to large sized vibration units can be overlaid with a sterile surgical glove at the point of contact with the patient. Other devices such as the Vibrating Fingertip Massager can be worn on a clinician's hand and provide a small point

of contact with the patient's skin, and can be covered with disposable finger cots from a provider such as Henry Schein, Inc.

[0021] When the clinician wishes to use temperature, a great variety of products currently exist on the market. Hot pack gel packs are available from any sporting goods supply or the local drug store. Cold compresses can be purchased at the same locations. These items are available in re-usable packs that can be re-frozen, or in instant cold compress disposable devices that provide an independent cold source.

[0022] There are many sources that teach the art of utilizing the gate control theory of pain to minimize localized pain from minor surgeries. Vibration anesthesia is taught by Kevin C. Smith, MD, et al. in *Vibration anesthesia: A non-invasive method of reducing discomfort prior to dermatologic procedures.* (Dermatology Online Journal, Vol. 10, No. 2, 2004) and by Timothy J. Palmesano, et al. in *Effect of High-Frequency Vibration on Experimental Pain Threshold in Young Women When Applied to Areas of Different Size* (The Clinical Journal of Pain, Vol. 5, pp337-342, 1989). The use of certain vibrations per minute to maximize therapeutic value is taught, and generally falls into the range of 50 Hz to 150Hz. A further study of this is done by E. Nanitsos et al. in *The effect of vibration on pain during local anesthesia injections (*Australian Dental Journal, Vol. 54, pp 94-100, 2009) regarding Novocain injections before dental work can be performed.

[0023] Use of cold as a therapeutic aid to avoid pain associated with minor surgical procedures is taught by Simon C. Hayward, et al. in *Ice reduces needle-stick pain associated with a digital nerve block of the hallux (*The Foot, Vol. 16, pp 145-148, 2006) and by Kevin C. Smith, MD., et al. in *Ice Minimizes Discomfort Associated with Injection of Botulinum Toxin Type A for the Treatment of Palmar and Plantar Hyperhidrosis*, (Dermatologic Surgery, Vol. 33, pp S88-S91, 2007). Treatment with cold generally includes holding a cold object (such as an ice cube) on the injection site for 30 seconds to a minute before the injection, then holding the cold object in close vicinity to the injection site during the injection. Significant reduction in pain can be accomplished with this technique. In

Minimizing Discomfort during the injection of Radiesse™ with the use of either local anesthetic or ice, (Dermatology Online Journal, Vol. 13 N. 3, 2007), Stephen Comite, MD, et al. recommend the use of ice in many instances because it is faster and there are fewer adverse effects to the patient.

[0024] One particular product currently available on the market allows for the application of cold and vibration to an injection site. This product, the Buzzy, by Buzzy Pain Management (www.needle-pain-management.com) utilizes a small vibrating device and either a disposable water-filled cold pack, or a re-freezable cold pack. While this device may be able to provide relief for injection site pain, it does not teach a way to heat the site of the minor surgery, it does not allow vibration in waves near the site of injection, and the cold pack must be kept in a freezer before use. Further, there is no way to adjust or measure the temperature of the cold pack.

[0025] Special care must be taken when devices are subject to use in conjunction with laser treatment therapies. Materials must be capable of withstanding direct exposure to standard commercially available cosmetic laser devices without significant damage or consequence. The dangers of laser surgery treatments is highlighted by prior art, including the writing of Rod J. Rohrich, MD, et al., who discusses this issue in the paper *CO2 Laser Safety Considerations in Facial Skin Resurfacing (*Plastic & Reconstructive Surgery, Vol. 100, No. 5, pp 1285-1290, Oct. 1997). This paper discusses the risks of fire associated with laser surgeries, and specifically notes that shielding (often damp cloth) is critical to patient safety. The paper also discusses the significant risk of fire with dry materials struck by therapeutic laser beams. In Darrell J. Fader, MD's *Principles of CO_2/Erbium Laser Safety* (Dermatol Surg, Vol. 26, pp. 235–239, 2000), general laser safety and patient shielding techniques are discussed. Again, wet clothes are often utilized. Further Robert A. Caplan, MD, et al., discuss this issue further in *Practice Advisory for the Prevention and Management of Operating Room Fires: A Report by the American Society of Anesthesiologists Task Force on Operating Room Fires* (Anesthesiology, Vol.

108, No. 5, pp. 786-801, May 2008). In this paper, laser treatments are discussed within the context of fire risks in general.

[0026]

[0027] In summary, what is needed is a device and method that provides a superior application of the techniques taught in the prior art by bringing together a variety of sensory outputs into one easily usable device to alleviate the perception of injection site pain, pain perception of minor surgeries, and pain associated with laser treatments.

[0028] Brief Summary of the Invention

[0029] The limitations of the above noted prior art are surmounted by the illustrated embodiments of the invention presented here. The illustrated embodiments of the invention teach the use of a plurality of sensory inputs to minimize the perception of pain associated with minor invasive procedures and laser treatment therapies. Various sensory inputs may be utilized simultaneously for maximum effect for that individual patient. Previous sensory input techniques include: use of temperature, including heat and cold by way of a Peltier element which allows for temperature fluctuation between hot and cold; tactile input, by way of various surface textures to the 'head' which acts as the point of contact with the patient by way of the various sterile head covers for the device; and vibration by utilizing multiple small vibratory motors, allowing for selection of various 'wave' and 'pulse' sensations for the patient. By creation of a device that provides for multiple sensory inputs for the patient at once, and by providing for multiple sensory inputs in novel ways, the illustrated embodiments of the invention surmount the limitations presently existent in the prior art.

[0030] In general terms, the illustrated embodiments of the invention include a portable, hand held device that applies a temperature controlled surface, tactile input, and vibration to a patient's skin for the purpose of minimizing pain perception. A form-fitted housing allows for easy grip by the clinician. Controls are simple to understand, and retain the settings from the previous use, so that a clinician may utilize the device with their favorite

configuration repeatedly with the touch of one button. The clinician can rely upon the built-in direct current rechargeable power source, or plug the unit into a wall outlet for easy continuous use. Finally, the clinician need not worry about the device becoming damaged or overheated when struck by the beam in therapeutic laser treatments.

[0031] Heating and cooling at tip of the device is accomplished by the thermoelectric principle using the Peltier effect to create a heat flux between two different types of materials usually constructed with solid-state materials. This solid-state active heat pump has no moving parts and transfers heat from one side of the device to the other side against the temperature gradient (from cold to hot), with consumption of electrical energy.

[0032] The head contains the Peltier element, which is capable of pumping heat in one direction or another depending on the direction of the current applied to the element. With one side of the element held at room temperature (25-30 °C) by using an integrated heat sink on the head, the active side can be heated or cooled by temperature difference ΔT. This is done by supplying current across the Peltier element.

[0033] The maximum temperature difference between the faces between the Peltier plates, expressed as ΔTmax, is set by a microcontroller to 30 °C to prevent burns on the skin. With a 10 Watt Peltier element at the tip, the device can heat or cool by moving about 1.5 Watt (15% efficiency) of heat across its surface, enough to momentarily provide hot/cold sensation.

[0034] Accordingly the illustrated embodiments of the invention may have one or more of the following advantages described by the objects below.

[0035] It is therefore an object of the illustrated embodiments of the invention that the device utilizes a thermoelectric cooling and heating system, for example a Peltier thermoelectric device.

[0036] It is further an object of the illustrated embodiments of the invention that the device utilizes a variety of vibratory modes, selectable by the clinician, in order to provide the most effective treatment to an individualized patient.

[0037] It is an object of the illustrated embodiments of the invention that the device may utilize a plurality of vibration head attachments. These are designed to come in various shapes and sizes. The shapes and sizes of the device heads allow access to the many contours of the human body, letting the physician to utilize the device at any site where injection or cosmetic laser treatments may be administered.

[0038] It is an object of the illustrated embodiments of the invention that several shapes of vibration, temperature, and tactile stimulus head attachments be constructed of material that is manually bendable, so that the clinician may bend the vibration and stimulus head into the shape of their choosing, thereby maximizing the usefulness of the device on a particular patient.

[0039] It is an object of the illustrated embodiments of the invention that the device, including vibration, temperature, and tactile stimulus head attachments and the handle body of the device be constructed from materials that allow for the equipment to maintain a temperature range that is not damaging to the skin while being struck with the laser light beam from cosmetic laser device. Further, the materials selected enable the illustrated embodiments of the invention to be highly tolerant to being exposed to the laser beam of cosmetic laser devices, which allows for longevity of the useful life of the device and its components.

[0040] It is an object of the illustrated embodiments of the invention that disposable sterile coverings for the various heads are created, enabling a particular vibratory and stimulus head to be re-used with multiple patients while still maintaining a sterile point of contact with each patient.

[0041] It is additionally an object of the illustrated embodiments of the invention that these said disposable sterile coverings be made with a variety of surface textures, providing for a variety of tactile input sensations to the patient.

[0042] In summary, the illustrated embodiments include a hand held device for providing pain abatement during medical procedures or non-ocular laser treatments. The device comprises a handle, a removable controllable vibration head coupled to the distal end of the handle to selectively generate

vibrational energy, a controllable thermoelectric pad disposed on the removable vibration head to selectively generate thermal energy, an LCD display disposed within the handle coupled to the vibration head to display at least one parameter of the vibrational energy generated by the vibration head and coupled to the thermoelectric pad to display at least one parameter of thermal energy generated by the thermoelectric pad, and a power supply coupled to the vibration head, thermoelectric pad, and LCD display and disposed within the proximal end of the handle. The vibration head and thermoelectric pad are controlled in a coordinated fashion to delivered selected kinds and amounts of vibrational energy and/or thermal energy to effectively abate the perception of pain by the patient. Selection of the kind and amount of vibrational energy and/or thermal energy which is delivered is experientially selected according to the perception of each patient, and the nature, location and type of pain which is sought to be abated.

[0043] The removable vibration head includes in one embodiment a U-shaped vibration head including a plurality of eccentric weight motors. For example, the removable vibration head includes in one embodiment a solid vibration head including a plurality of coin-type motors.

[0044] The device further includes a vibration control switch for selecting one of a plurality of predetermined vibrational frequencies at which the removable vibration head operates. For example, the device includes a vibration control switch for selecting a vibrational frequency at which the removable vibration head operates within a frequency range of 0 Hz to at least 250 Hz.

[0045] The device further includes in one embodiment a microcontroller disposed within the handle, wherein the microcontroller controls the vibrational frequency of the removable vibration head and the temperature of the thermoelectric pad according to the teachings of the illustrated embodiments of the invention. For example, the microcontroller controls the temperature of the thermoelectric pad between a minimum and a maximum threshold temperature. The microcontroller controls the vibrational frequency at which the removable

vibration head operates to create waves of vibration or synchronized vibration among the plurality of vibration motors.

[0046] The display shows the temperature of a patient's skin at the treatment site in real-time.

[0047] The power supply includes in one embodiment a charging connector disposed in the proximal end of the handle. The charging connector is inserted or connected into and electrically coupled with the charging dock, or the charging connector disposed in the proximal end of the handle may be electrically coupled to an outside source via a power cord. Alternatively the power supply includes in one embodiment a plurality of rechargeable batteries disposed within the handle.

[0048] The illustrated embodiments of the invention include within their scope a method for abating pain in or on the skin during medical procedures or non-ocular laser treatments using a hand held device comprising the steps of selecting a predetermined vibration setting of a removable vibration head coupled to the distal end of a handle of the device by means disposed on the handle of the device, selecting a corresponding predetermined temperature setting of the removable vibration head by means disposed on the handle of the device, positioning the removable vibration head against the skin of a patient adjacent to a treatment site, and stimulating the skin of the patient with heat and/or vibration at or adjacent to the treatment site while performing the medical procedure or non-ocular laser treatment at the treatment site. The setting of the vibration and temperature to predetermined values is determined experientially depending on the perception of the patient, and the nature and location of the pain which is sought to be abated.

[0049] The illustrated embodiments of the method further include, prior to positioning the removable vibration head against the skin at the treatment site, the step of selecting one of a plurality of removable vibration heads according to the specific contour of the patient's skin to undergo treatment and coupling the selected head to the distal end of the handle of the device.

[0050] The step of selecting the temperature setting of the removable vibration head by means disposed on the handle of the device includes in one embodiment the step of selecting the temperature setting of a Peltier thermoelectric pad disposed on the removable vibration head.

[0051] The illustrated embodiments of the method further include the step of maintaining the temperature of the removable vibration head between a predetermined minimum and maximum threshold temperature.

[0052] The illustrated embodiments of the method further include the step of displaying the temperature of the patient's skin adjacent to the treatment site on an LCD display disposed within the handle of the device.

[0053] The illustrated embodiments of the method further include the step of supplying power to the device from an outside power source via a power cord.

[0054] The illustrated embodiments of the method further include the step of supplying power to the device from a plurality of rechargeable batteries.

[0055] The illustrated embodiments of the method further include the step of recharging the plurality of rechargeable batteries by coupling the handle of the device with a charging dock which is electrically coupled to the plurality of rechargeable batteries.

[0056] While the apparatus and method has or will be described for the sake of grammatical fluidity with functional explanations, it is to be expressly understood that the claims, unless expressly formulated under 35 USC 112, are not to be construed as necessarily limited in any way by the construction of "means" or "steps" limitations, but are to be accorded the full scope of the meaning and equivalents of the definition provided by the claims under the judicial doctrine of equivalents, and in the case where the claims are expressly formulated under 35 USC 112 are to be accorded full statutory equivalents under 35 USC 112. The invention can be better visualized by turning now to the following drawings wherein like elements are referenced by like numerals.

[0057] Brief Description of the Drawings

[0058] Fig. 1 is a depiction of one use of the pain abatement stimulus device where the hand of a clinician is shown holding the device against the patient's shoulder in preparation for an inoculation.

[0059] Fig. 2 is a magnified view of the left side of the device seen in Fig. 1 showing an LCD screen, a power button, a plurality temperature control buttons, and a vibratory control button.

[0060] Fig. 3 is a partial cut-away view of the inside of the device seen in Fig. 2 showing the internal components and a U-shaped vibratory temperature control head.

[0061] Fig. 4 is a magnified view of the controls of the device seen in Fig. 2 with an alternative circular embodiment for the control head. The coupling between the removable control head and the body of the device is shown.

[0062] Fig. 5a is a magnified view of the circular head sensory input seen in Fig. 4 including the small vibration units disposed within the control head.

[0063] Fig. 5b is a magnified view of the detached and replaceable U-shaped vibration head seen in Fig. 3 including the soft heating and cooling pad disposed on the head.

[0064] Fig. 5c is a magnified view of an alternative embodiment of the control head comprising a detachable and replaceable solid vibration head including the soft heating and cooling pad disposed on the head.

[0065] Fig. 6 is a schematic diagram depicting the LCD screen and temperature control circuitry logic.

[0066] The invention and its various embodiments can now be better understood by turning to the following detailed description of the preferred embodiments which are presented as illustrated examples of the invention defined in the claims. It is expressly understood that the invention as defined by the claims may be broader than the illustrated embodiments described below.

[0067] Detailed Description of the Preferred Embodiments

[0068] Fig. 1 depicts a clinician's hand 10 administering treatment utilizing the pain abatement stimulation device 1, herein after referred to as "device", on the shoulder 11 of a patient. The patient receives stimulus from the device 1 at a region of interaction 12 between the patient and the device 1. The positioning of the device 1 seen in Fig. 1 would be common for intramuscular inoculations administered to children and is meant to be for illustrative purposes only. It is to be expressly understood that the device 1 may be used at other regions of interaction 12 anywhere else on the body of the patient without departing from the original spirit and scope of the invention.

[0069] The device 1 comprises a handle 300 comprising a housing 302 as seen in Fig. 2 that is comprised of easily gripped, slip resistant material that allows the clinician 10 to use the device 1 while wearing sterile medical gloves. An example of this material would be an injection molded plastic with a rubberized coating as is found on many electric toothbrushes, however other types of plastic or plastic composites may be used within the scope of the art. The device 1 comprises an ergonomic portion 301 which assures a reliable grip and allows the clinician to apply pressure to a point of contact on the patient's skin. An on/off button 203 allows for easy manipulation of the power of the unit with one simple thumb press and is made of a non-slip material such as plastic or rubber as is known in the art. A plurality of temperature control buttons 202 for temperature adjustment are located on the 'neck' of the housing 302, out of the reach of the ergonomic portion 301, yet still easily reachable by the clinician. This configuration minimizes accidental temperature control changes. The temperature at the point of contact with the patient is displayed on a liquid crystal display (LCD) 204. A vibration control switch 201 sets the device to output to approximately 50 Hz, 100Hz, or 150Hz, as determined by the clinician and based upon the patient's comfort levels. The specific vibrational intensities listed above are meant to be for illustrative purposes only. Other rates of vibration may be used without falling outside the scope of this invention.

[0070] A stimulus head connector 101 which couples a head 100 to the distal end of the body 302 is shown in Figs. 2, 4, and 5b. The stimulus head connector 101 comprises multiple pin connections enabling electrical flow and control of the various functions of the replaceable and removable vibration heads 100, 110.

[0071] Fig. 2 depicts a replaceable U-shaped vibration head 100, the handle 300, and a charging dock 400. The combination of the handle 300 and charging dock 400 as seen in Fig. 2 is representative of how the device would stand on a surface in an examining room of a clinician's office. The vibration control switch 201 allows the clinician control over the vibration. The vibration control switch's 201 easy access allows the clinician to adjust this setting to the needs of their patients swiftly and easily. The temperature control buttons 202 are equally accessible to the clinician, facilitating delicate temperature controls when needed. The master on/off button 203 is positioned so that the clinician's thumb can reach it without loosening or changing grip on the ergonomic portion 301 defined within the housing 302. The housing 302 encloses the electronics, controls, and displays in a robust shell. The liquid crystal display 204 displays information critical to the treatment of the patient, such as the current temperature of the surface of the U-shaped vibration head 100.

[0072] The underside of the housing 302, as best seen in Fig. 3, shows the location of a charging dock connector 401 at the distal end of the handle 300. The charging dock connector 401 is preferably coupled to the charging dock 400 through a magnetic connection, such as MagSafe™ by Apple, Inc., allowing for easy breakaway as an additional safety factor, while providing a secure power connection should the power chord be necessary. Other power connections, such as standard physical force-fit plastic connections may be utilized and fall within the original vision and scope of the invention. The device 1 relies upon a battery power supply 402, 403 to provide cordless power. Shown in Fig. 3 are two standard NiMH rechargeable C sized batteries. However, should additional cordless power be needed, a higher weight/size to power ratio battery chemistry, such as Lithium Polymer, can be utilized. The charging dock connector 401

couples to the charging dock 400 which is in turn coupled to an AC wall outlet which provides the power required to charge the batteries 402, 403. Alternatively, the same charging connector 401 can be coupled to a power chord (not seen) for use extended beyond the life of the batteries 402, 403.

[0073] Fig. 3 further shows the internal components of the replaceable U-shaped vibration head 100. A plurality of micro-vibration motors 102, 103, 104, 105 with eccentric weights can be seen. By utilizing multiple small vibration motors 102, 103, 104, 105, the vibration head 100 can offer its own vibration strength and sequence, providing sensations of bursts or waves of vibration to the patient. Fig. 3 also shows an embodiment of the placement of a printed circuit board (PCB) 500 that acts as a controller for the device 1. The control PCB 500 regulates the input and output, and comprises means for recalling previous settings chosen by the clinician to facilitate use of the device 1.

[0074] Fig. 4 is a representation of an alternative embodiment of device 1 with handle 300 being coupled with a replaceable solid vibration head 110. The solid vibration head 110 is substantially disk shaped and comprises a correspondingly shaped Peltier thermoelectric pad which allows heating and cooling of the surface adjacent to the patient's skin. Again, the on/off button 203, housing 302, and LCD 204 are shown. Fig. 3 also highlights the functioning of the stimulus head connector 101 to the handle 300, showing the curved nestled insert with electrical pin connectors for power and sensor data flow.

[0075] Fig. 5a shows the embodiment of the replaceable solid vibration head 110. A plurality of at least four micro-vibration coin-type motors 112, 113, 114, 115 are shown within the solid vibration head 110 which provide vibratory stimulus to the patient. As discussed with respect to Fig. 3 above, by utilizing multiple small vibration motors, a great variety of stimulus options are made available by using different heads.

[0076] Fig. 5b shows the replaceable U-shaped vibration head 100 and highlights the stimulus head connector 101 which is coupled to the handle 300 of the device 1. The U-shaped vibration head 100 comprises a correspondingly

shaped Peltier thermoelectric pad 111 with a soft covering which provides heat and cold sensation to the patient's skin.

[0077] Fig. 5c is a magnified view of the replaceable solid vibration head 110. The stimulus head connector 101 which is coupled to the handle 300 of the device 1 is shown again. The Peltier thermoelectric pad 111 with soft covering corresponding with the shape of the solid vibration head 110 is shown, which provides heat and cold sensation to the patient's skin.

[0078] Fig. 6 depicts a microcontroller 501 and its supporting devices that are disposed upon the control PCB 500. The microcontroller 501 is enabled with a variety of temperature adjustment settings, including the important safety feature of a maximum and minimum allowable threshold temperature of the device 1. The control PCB 500 acts as an intermediary device between all controlling components seen in Fig. 6. A temperature sensor 511 coupled to the microcontroller 501 senses the temperature at the point of contact of that particular vibration head for example the U-shaped vibration head 100 seen in Fig. 5b or the solid vibration head 110 seen in Fig. 5c. The microcontroller 501 automatically adjusts the temperature of the device 1 based upon the calculations for thermal conductivity of the sterile cover (not shown) for the respective head 100, 110 that is used. The temperature settings of the vibration head 100, 110 default to standards where there is no cover, thereby assuring that the patient is not injured or burned by the device 1, as the cover would add thickness and reduce thermal conductivity under normal circumstances. The LCD 204 is capable of displaying the actual temperature at the point of contact of the vibration head 100, 110 with the patient's skin, or the temperature as adjusted to compensate for the sterile cover, or both. A voltage regulator 502 coupled to the microcontroller 501 controls the voltage output to the other aspects of the device and acts as a secondary safety system by limiting the electronic energy shunted to the Peltier thermoelectric element 111 and vibration motors 112-115, 102-105 to safe levels. The microcontroller 501 provides exact control over the Peltier thermoelectric heating control 521 and cooling control 522. The microcontroller 501 also provides control over the vibration motors

102-105, 112-155 via a plurality of connections 531, 532, 533, 534 which allow the vibration motors 102-105, 112-115 may be controlled at different cycles to create 'waves' of vibration, or to vibrate in synchronization, based upon the programming of the microcontroller 501. Also shown in Fig. 6. is a control for vibration intensity 201 and control button for temperature adjustment 202 which will instruct the microcontroller 501 to heat or cool the vibration head 100, 110 according to the clinician's desired settings.

[0079] The following example represents one embodiment of the temperature control programming contained within the microcontroller 501 of the current device 1. The example presented below in pseudocode provides for the necessary safety parameter by setting a maximum and minimum temperature thresholds. This example is meant for demonstrative purposes only, and should not be construed to encapsulate the complete embodiment of this invention.

```
Variables
    TempMode = {Off, Cool, Heat}
    DesiredTemp
    CurrentTemp
    VibeMode = {Off, Pattern1, Pattern2, ..., PatternN}
    DesiredVibLevel

Algorithm
    while() {
        /* get current temperature from sensor */
        ReadTempSensor (CurrentTemp)
        Display (CurrentTemp)

        /* ensure desired temp is within safety bounds */
        if (DesiredTemp > TEMPMAX) DesiredTemp = TEMPMAX
        if (DesiredTemp < TEMPMIN) DesiredTemp = TEMPMIN

        /* turn off cooler when desired temp reached */
```

```
        if (TempMode == Cool) {
          if (CurrentTemp < DesiredTemp) PELTIER_COOLER(OFF)
          if (CurrentTemp > DesiredTemp) PELTIER_COOLER(ON)
        }

        /* turn off heater when desired temp reached */
        if (TempMode == Heat) {
          if (CurrentTemp < DesiredTemp) PELTIER_HEATER(ON)
          if (CurrentTemp > DesiredTemp) PELTIER_HEATER(OFF)
        }

        if (TempMode == Off) {
          PELTIER_HEATER(OFF)
          PELTIER_COOLER(OFF)
        }

        if (VibeMode != Off) {
          ActivateVibrator (DesiredVibLevel, VibeMode)
        }
    }
```

[0080] The vibration heads 100, 110 as exemplified in Fig. 5b and 5c, show only two examples of the plurality of types of heads that can be attached to the handle 300 of the device 1. The heads will come in a variety of shapes and sizes to suit the gamut of surfaces of the human body. This will allow the device to be utilized wherever an injection or minor surgical procedure is to occur. The vibration head 100, 110 utilizes a soft heating and cooling pad 111 to provide comfort to the patient, while also applying the local topical temperature needed for pain abatement

[0081] In one embodiment, the device 1, including the handle 300 and vibration heads 100, 110, are protected from damage and undue heat absorption

by the choice of materials and shielding used in comprising the device 1. This shielding is utilized to minimize heat absorption from the beam of a commercially available cosmetic laser, so that when the device 1 is struck by the laser beam, the device 1 does not overheat and injure the patient. The use of heat absorption materials also expands the useful lifespan of the device 1 by reducing or eliminating the degradation of its components due to exposure to laser beams and heat. The shielding utilized may include ceramic plating and other shielding compositions such as those well known to those in the art. The device 1 may comprise a plurality of shielding techniques or types in order to protect the device 1 against the wide range of wavelengths, powers, and durations utilized for various laser treatment techniques.

[0082] In an alternate embodiment, the vibration control switch 201 utilizes a fully adjustable setting such as a dial or slidable aperture, allowing any vibration cycle that the clinician chooses ranging between no vibration and a very high vibration, for example 250Hz or more.

[0083] In an alternate embodiment, the neck of the handle 300 comprises a lockable hinge, allowing an adjustable alteration to the orientation of the vibration heads coupled to the device 1.

[0084] In an alternate embodiment, the plurality of vibration heads may utilize synchronized and fully controllable vibration functions for each of the plurality of micro vibration motors such as eccentric weight motors 102-105, exemplified in Fig. 3, or micro vibration coin-type motors 112-115, exemplified in Fig. 5b. Independently controlled vibration motors allow for a greater range of vibratory sensations to the patient, including a 'wave' like vibration of the treatment site, allowing the patient's sensory input to vary over the course of the treatment to maximize noxious sensory block via the gate control theory of pain.

[0085] In an alternate embodiment, the plurality of vibration heads 100, 110 comprise a separate heating and cooling element, both of which are of solid state construction. A standard metal resistance heating element may be used as is known in the art. This configuration allows for novel non-invasive treatment options. For example, by quickly switching between hot and cold, the patient is

able to experience sensatory anesthesia. It further allows for a use of a plurality of sensory outputs to a patient to alleviate the pain of minor surgical procedures, injections, and non-ocular laser treatments. This would be applicable to any minor surgical procedure or injection. Examples of this would be, but are not limited to: dermatological procedures involving injection (i.e. Botox™, Radiesse™); administration of epidural nerve block injections; tattoo art and body piercing administration procedures; blood sampling for chronic diseases such as pinpricks for daily diabetes testing; Intravenous (IV) starts, blood draws; inoculation and standard injections (especially in children); and Novocain and other dental injections (utilizing the device 1 on the skin of the face to minimize injection pain within the mouth).

[0086] The device 1 is designed for use in minor surgical procedures, injections, non-ocular laser treatments, and cosmetic laser treatments. During certain procedures where vibration of the patient is not optimal (e.g. ocular laser surgery), the vibration settings of this device 1 are not to be used, or a negative outcome of the procedure will likely result.

[0087] For general use, the charging dock 400 will remain plugged into an AC wall outlet power source at all times. The handle 300 of the device 1 is nested into the charging dock 400 in order to maintain full charge for the rechargeable batteries 402, 403 of the device 1. This maximizes the cordless use of the device 1 when it is desired. The clinician will lift the handle 300 out of the charging dock 400, select the proper vibration head, for example the replaceable U-shaped vibration head 100, and fit it with a sterile barrier device (not shown) to protect the patient from infection. The clinician will choose the vibration and temperature settings as deemed appropriate for the patient receiving treatment utilizing the corresponding switches 201, 202 disposed on the handle 300. The clinician will then manually position the vibration head 100 at the appropriate location on the patient, which will usually be adjacent to the treatment site. Stimulus may also be applied to other locations, such as on the same nerve where discomfort will be experienced by the patient, but with a shorter distance to the spinal column than from the operation site. The exact

placement of the stimulus will be determined by the clinician, who will be able to utilize feedback from the patient for proper placement and settings choice.

[0088] The sensory input provided by the vibration head 100 will then provide stimulus to the patient to alleviate the perception of pain during the procedure. If the batteries 402, 403 cease to have sufficient power remaining to properly provide for the functioning of the unit, the handle 300 may be directly plugged into an AC wall power outlet via a chord connected to the charging connector 401 disposed in the proximal end of the handle 300. Optionally, the batteries 402, 403 may be replaced with a new fully charged set of batteries.

[0089] Many alterations and modifications may be made by those having ordinary skill in the art without departing from the spirit and scope of the invention. Therefore, it must be understood that the illustrated embodiment has been set forth only for the purposes of example and that it should not be taken as limiting the invention as defined by the following invention and its various embodiments.

[0090] Therefore, it must be understood that the illustrated embodiment has been set forth only for the purposes of example and that it should not be taken as limiting the invention as defined by the following claims. For example, notwithstanding the fact that the elements of a claim are set forth below in a certain combination, it must be expressly understood that the invention includes other combinations of fewer, more or different elements, which are disclosed in above even when not initially claimed in such combinations. A teaching that two elements are combined in a claimed combination is further to be understood as also allowing for a claimed combination in which the two elements are not combined with each other, but may be used alone or combined in other combinations. The excision of any disclosed element of the invention is explicitly contemplated as within the scope of the invention.

[0091] The words used in this specification to describe the invention and its various embodiments are to be understood not only in the sense of their commonly defined meanings, but to include by special definition in this specification structure, material or acts beyond the scope of the commonly

defined meanings. Thus if an element can be understood in the context of this specification as including more than one meaning, then its use in a claim must be understood as being generic to all possible meanings supported by the specification and by the word itself.

[0092] The definitions of the words or elements of the following claims are, therefore, defined in this specification to include not only the combination of elements which are literally set forth, but all equivalent structure, material or acts for performing substantially the same function in substantially the same way to obtain substantially the same result. In this sense it is therefore contemplated that an equivalent substitution of two or more elements may be made for any one of the elements in the claims below or that a single element may be substituted for two or more elements in a claim. Although elements may be described above as acting in certain combinations and even initially claimed as such, it is to be expressly understood that one or more elements from a claimed combination can in some cases be excised from the combination and that the claimed combination may be directed to a subcombination or variation of a subcombination.

[0093] Insubstantial changes from the claimed subject matter as viewed by a person with ordinary skill in the art, now known or later devised, are expressly contemplated as being equivalently within the scope of the claims. Therefore, obvious substitutions now or later known to one with ordinary skill in the art are defined to be within the scope of the defined elements.

[0094] The claims are thus to be understood to include what is specifically illustrated and described above, what is conceptionally equivalent, what can be obviously substituted and also what essentially incorporates the essential idea of the invention.

We claim:

1. A hand held device for providing pain abatement during medical procedures or non-ocular laser treatments comprising:

a handle;

a controllable removable vibration head coupled to the distal end of the handle to selectively generate vibrational energy;

a controllable thermoelectric pad disposed on the removable vibration head to selectively generate thermal energy;

an LCD display disposed within the handle coupled to the vibration head to display at least one parameter of the vibrational energy generated by the vibration head and coupled to the thermoelectric pad to display at least one parameter of thermal energy generated by the thermoelectric pad; and

a power supply coupled to the vibration head, thermoelectric pad, and LCD display and disposed within the proximal end of the handle.

2. The device of claim 1 where the removable vibration head comprises a U-shaped vibration head including a plurality of eccentric weight motors.

3. The device of claim 1 where the removable vibration head comprises a solid vibration head including a plurality of coin-type motors.

4. The device of claim 1 further comprising a vibration control switch for selecting one of a plurality of predetermined vibrational frequencies at which the removable vibration head operates.

5. The device of claim 1 further comprising a vibration control switch for selecting a vibrational frequency at which the removable vibration head operates within a frequency range of 0 Hz to at least 250 Hz.

6. The device of claim 1 further comprising a microcontroller disposed within the handle, wherein the microcontroller controls the vibrational frequency of the removable vibration head and the temperature of the thermoelectric pad.

7. The device of claim 6 where the microcontroller controls the temperature of the thermoelectric pad between a minimum and a maximum threshold temperature.

8. The device of claim 6 further comprising a plurality of vibration motors disposed in the vibration head and where the microcontroller controls the vibrational frequency at which the removable vibration head operates to create waves of vibration or synchronized vibration among the plurality of vibration motors.

9. The device of claim 1 where the LCD display displays the temperature of a patient's skin at the treatment site in real-time.

10. The device of claim 1 in combination with a charging dock and where the power supply comprises a charging connector disposed in the proximal end of the handle, the charging connector for electrically nesting within the charging dock.

11. The device of claim 1 where the power supply comprises a charging connector disposed in the proximal end of the handle, the charging connector for electrically coupling to an outside source via a power cord.

12. The device of claim 1 where the power supply comprises a plurality of rechargeable batteries disposed within the handle.

13. A method for abating pain in or on the skin during medical procedures or non-ocular laser treatments using a hand held device comprising:

selecting a predetermined vibration setting of a removable vibration head coupled to the distal end of a handle of the device by means disposed on the handle of the device;

selecting a corresponding predetermined temperature setting of the removable vibration head by means disposed on the handle of the device;

positioning the removable vibration head against the skin of a patient adjacent to a treatment site; and

stimulating the skin of the patient with heat and/or vibration at or adjacent to the treatment site while performing the medical procedure or non-ocular laser treatment at the treatment site.

14. The method of claim 13 further comprising, prior to positioning the removable vibration head against the skin at the treatment site, selecting one of a plurality of removable vibration heads according to the specific contour of the patient's skin to undergo treatment and coupling the selected head to the distal end of the handle of the device.

15. The method of claim 13 where selecting the temperature setting of the removable vibration head by means disposed on the handle of the device comprises selecting the temperature setting of a Peltier thermoelectric pad disposed on the removable vibration head.

16. The method of claim 13 further comprising maintaining the temperature of the removable vibration head between a predetermined minimum and maximum threshold temperature.

17. The method of claim 13 further comprising displaying the temperature of the patient's skin adjacent to the treatment site on an LCD display disposed within the handle of the device.

18. The method of claim 13 further comprising supplying power to the device from an outside power source via a power cord.

19. The method of claim 13 further comprising supplying power to the device from a plurality of rechargeable batteries.

20. The method of claim 19 further comprising recharging the plurality of rechargeable batteries by coupling the handle of the device with a charging dock which is electrically coupled to the plurality of rechargeable batteries.

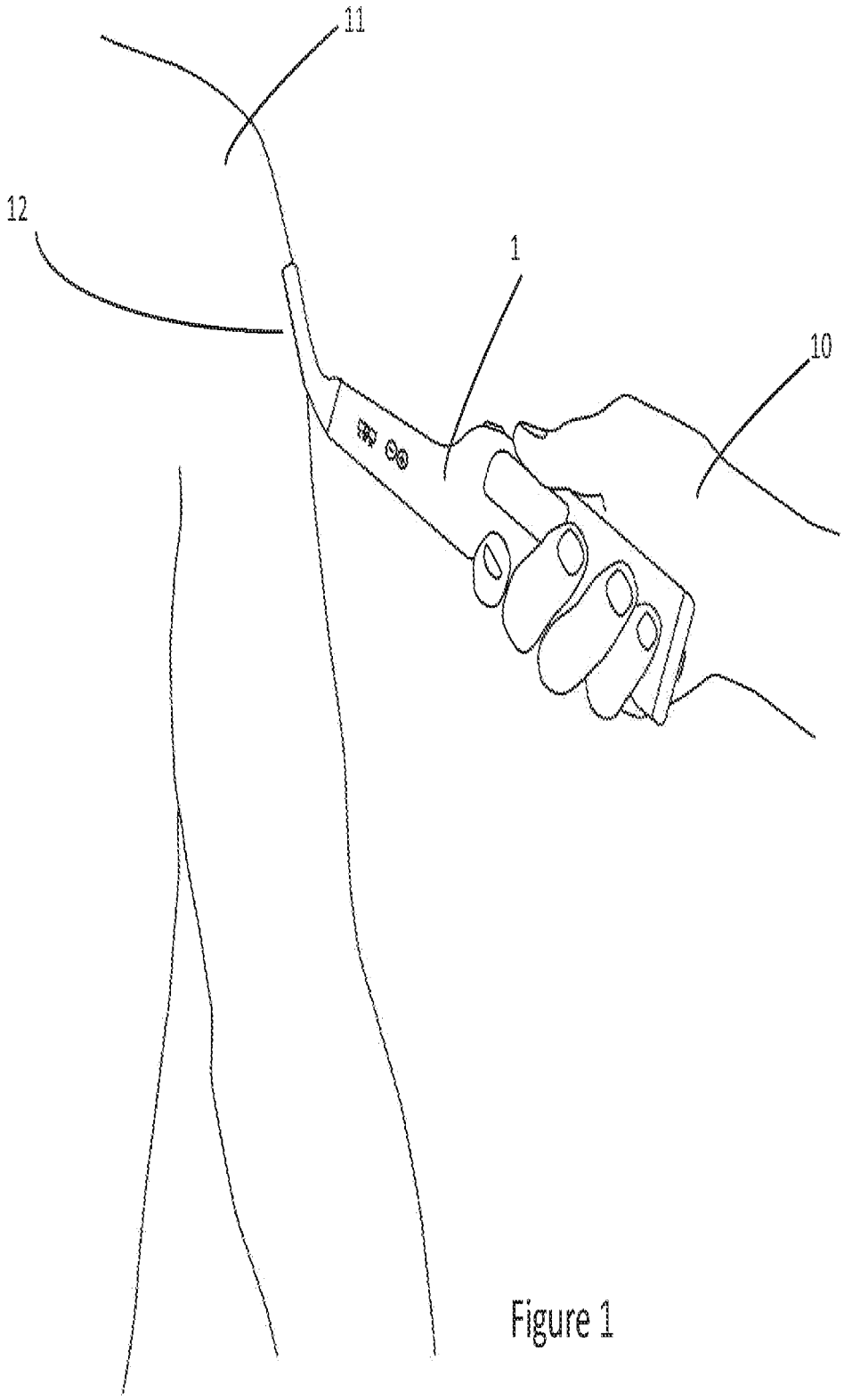

Figure 1

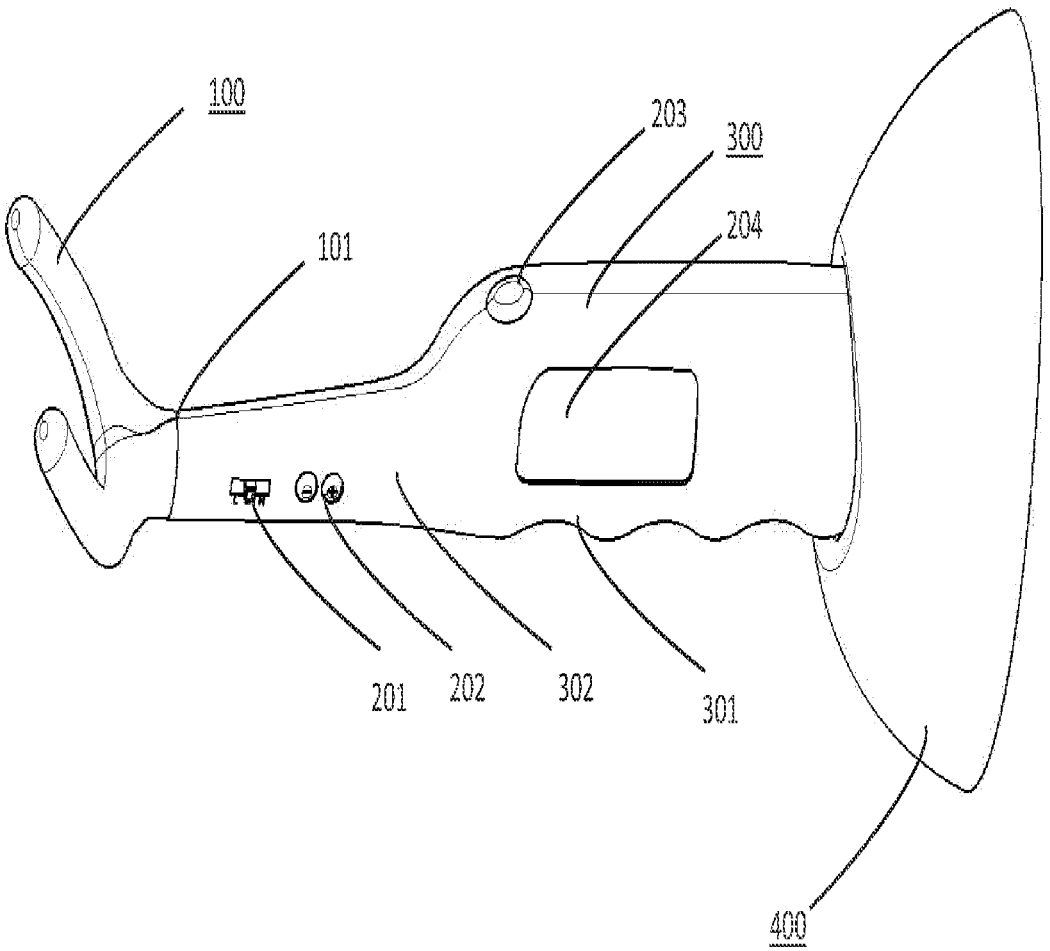

Figure 2

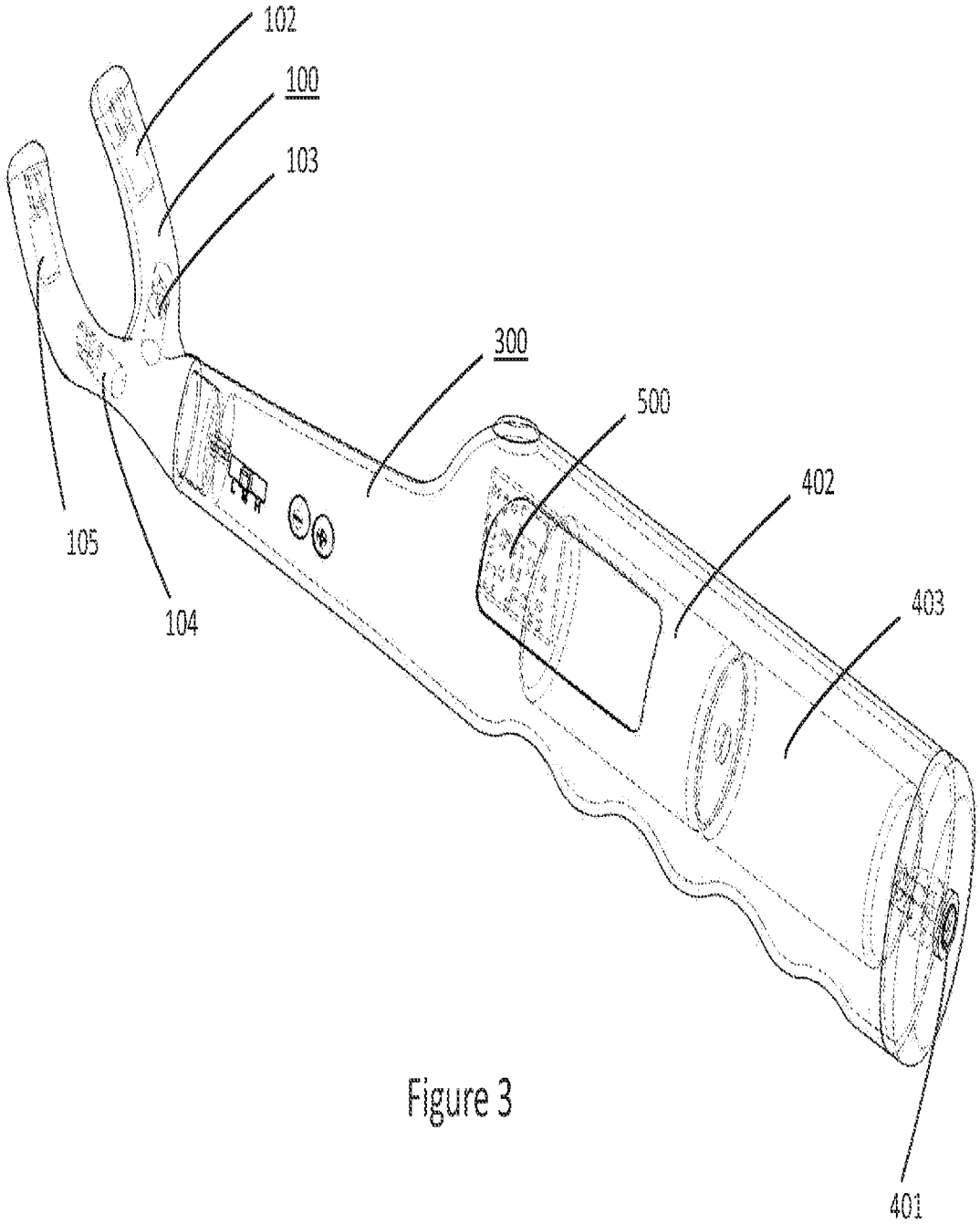

Figure 3

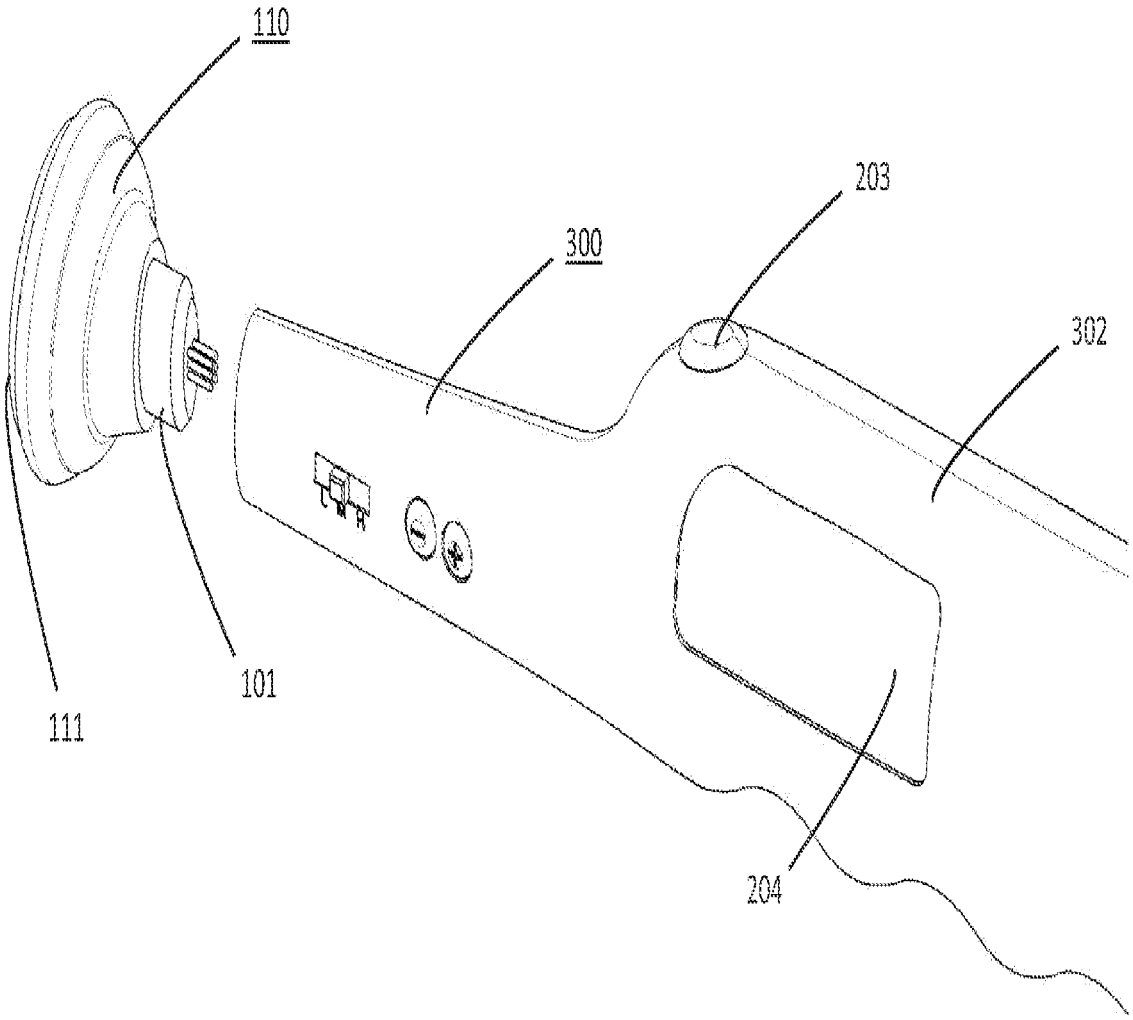

Figure 4

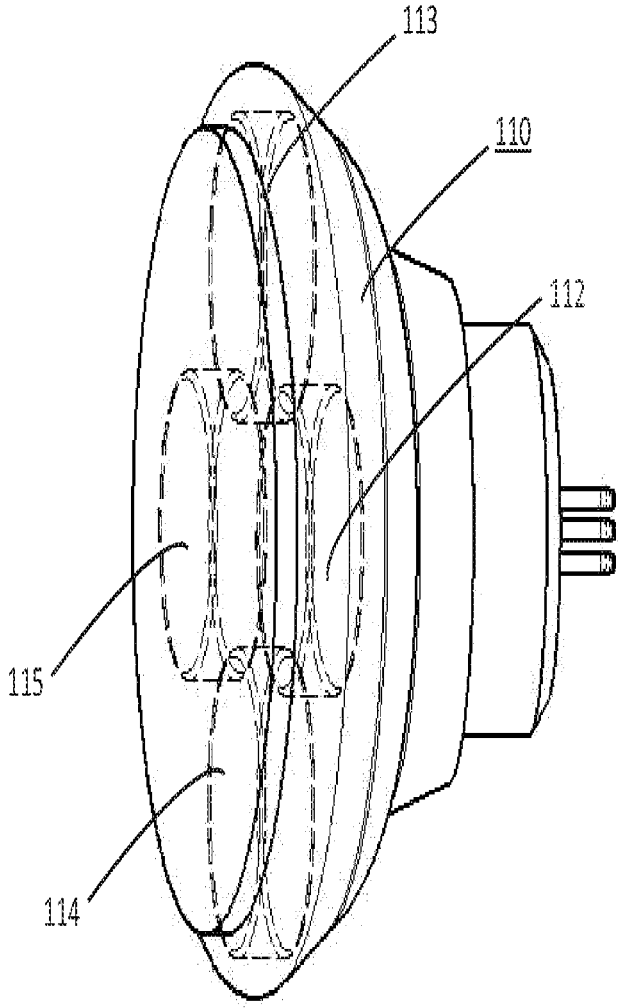

Figure 5A

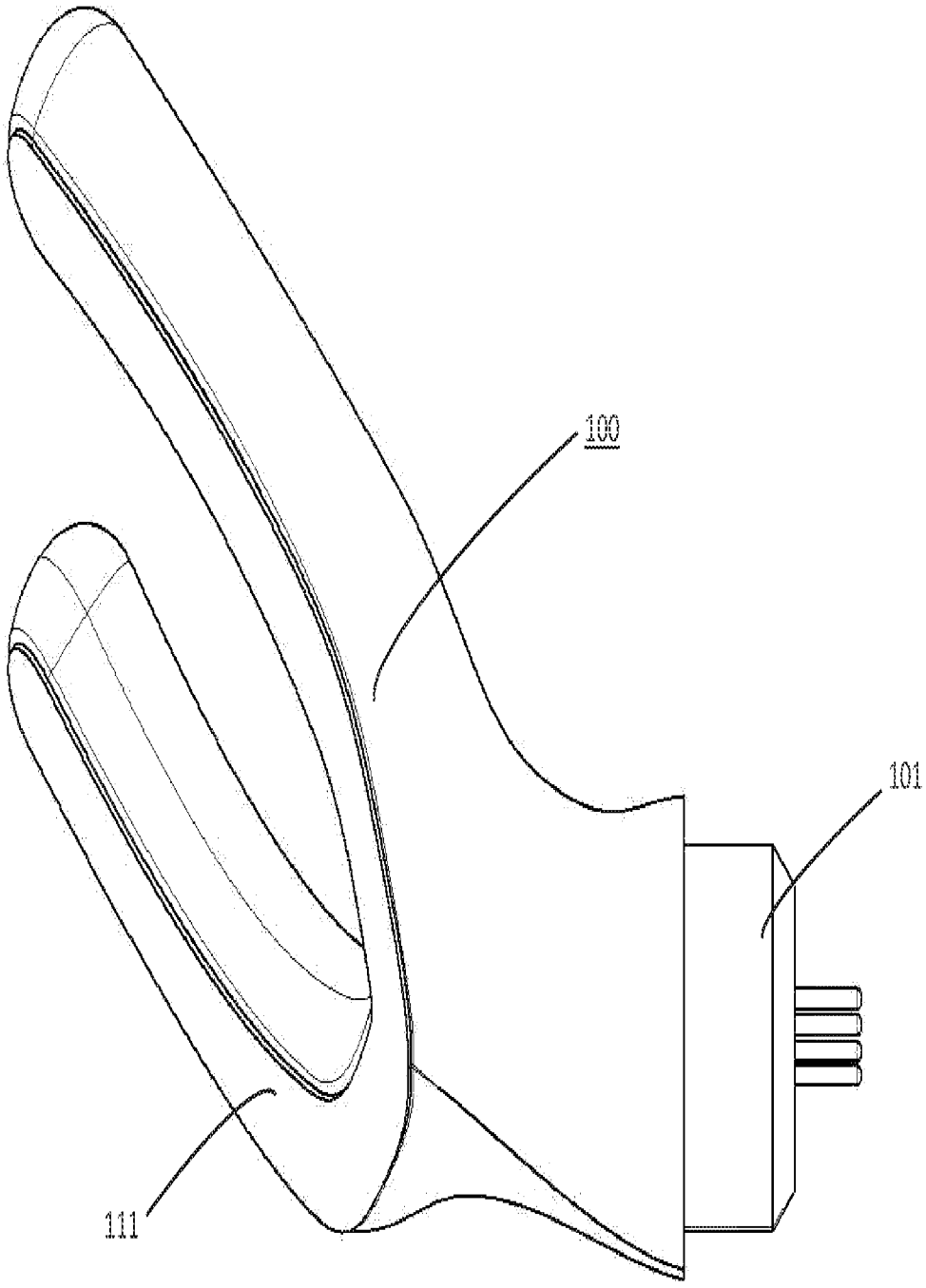

Figure 5B

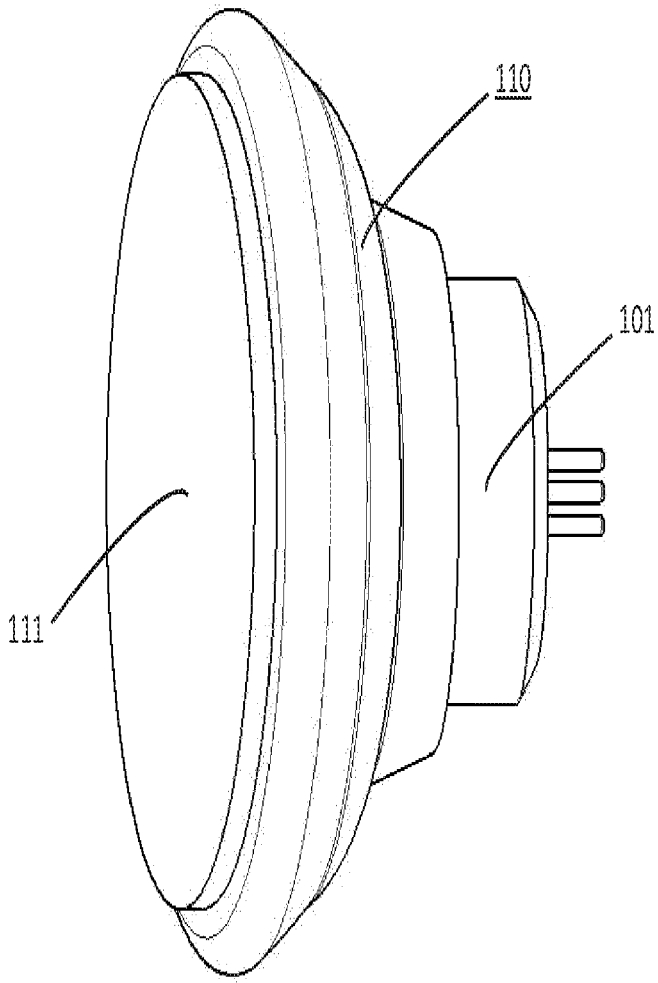

Figure 5C

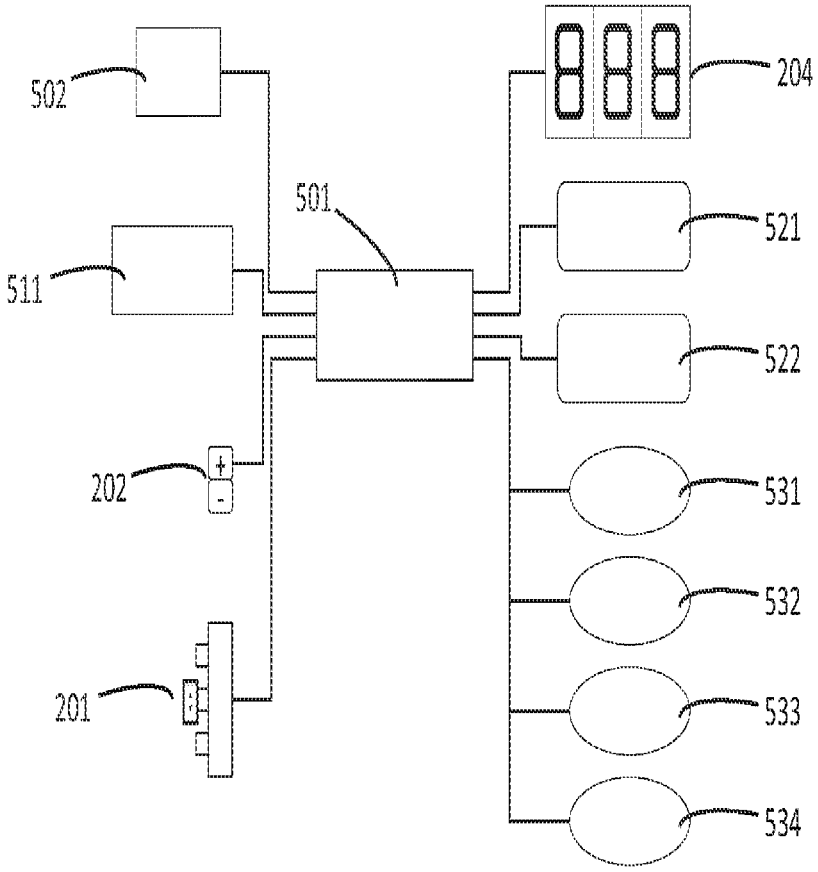

Figure 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/039234

A. CLASSIFICATION OF SUBJECT MATTER

A61N 5/067(2006.01)i, A61H 23/02(2006.01)i, A61B 18/12(2006.01)i, A61N 1/06(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)
A61N 5/067; A61N 7/00; A61H 15/00; A61H 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A	WO 2008-113139 A1 (CYPRO-SSAGE PTY LTD et al.) 25 September 2008 See Abstract, Figures 1,2,6,7,16 and Claims 1,4,5,15,17,21,31.	1,3-12 2
Y A	US 2006-0211961 A1 (ELIZABETH MEYER et al.) 21 September 2006 See Abstract, Figures 1,2,5, and Claims 1,5,7.	1,3-12 2
A	WO 2006-034324 A2 (GOLDBERG, STEVEN, G.) 30 March 2006 See Abstract, Figures 1-3, Pages 1,4,6.	1-12
A	US 2004-0171970 A1 (KURT SCHLEUNIGER et al.) 02 September 2004 See Abstract, Figures 2-4, Claims 1-3,9,13.	1-12

☐ 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	Date of mailing of the international search report
11 APRIL 2011 (11.04.2011)	**12 APRIL 2011 (12.04.2011)**

Name and mailing address of the ISA/KR	Authorized officer
Korean Intellectual Property Office Government Complex-Daejeon, 189 Cheongsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Noh, Young Chul Telephone No. 82-42-481-5617

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/039234

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.: 13-20
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 13-20 pertain to methods for treatment of the human body or animal body by surgery or therapy, as well as diagnostic methods, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

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 addtional 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

Information on patent family members

International application No.

PCT/US2010/039234

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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