(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 May 2007 (18.05.2007)

PCT

(10) International Publication Number
WO 2007/056474 A2

(51) International Patent Classification:
A41D 13/08 (2006.01)

(21) International Application Number:
PCT/US2006/043537

(22) International Filing Date:
9 November 2006 (09.11.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/270,687 9 November 2005 (09.11.2005) US

(71) Applicant *(for all designated States except US)*: **BIONICARE MEDICAL TECHNOLOGIES, INC.** [US/US]; 47 R. LOVETON CIRCLE, Sparks, MD 21152 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **HOFFMAN, Kent, C.** [US/US]; 18814 FOX CHASE COURT, Parkton, MD 21120 (US).

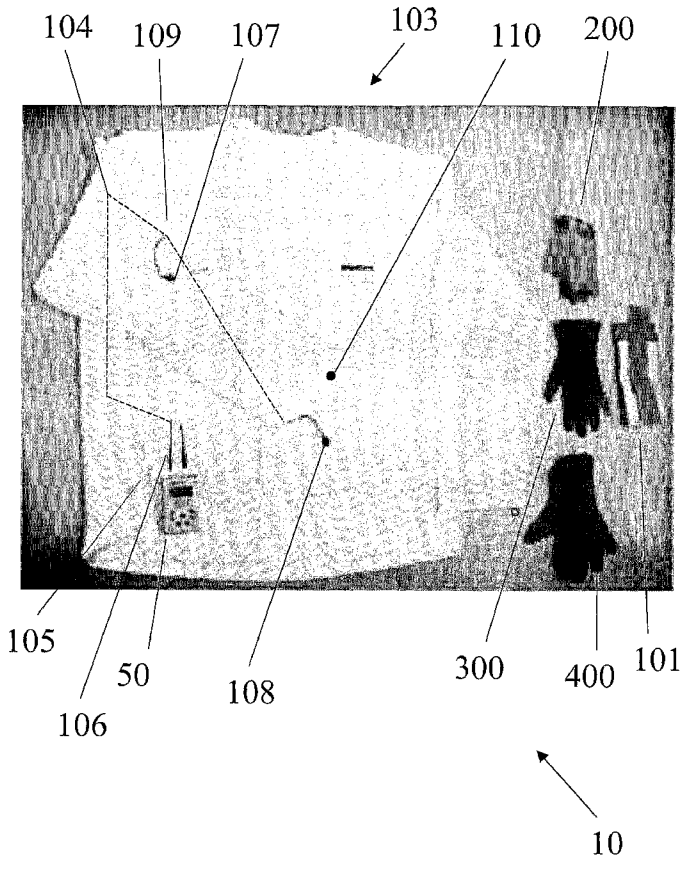
(74) Agents: **DIENER, Michael, A.** et al.; WILMER CUTLER PICKERING HALE AND DORR LLP, 60 STATE STREET, Boston, MA 02109 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: PROTECTIVE GLOVE WITH ELECTRICAL SIGNAL INTERRUPT FEATURE



(57) Abstract: A medical device treats diseases of the hand, wrist, and arm, including osteoarthritis and osteoarthrosis of the joints of the human hand. The medical device includes a multi-layer glove system, an arm wrap, a signal generator, lead wires, and a garment. The multi-layer glove system serves as the treatment electrode and the arm • wrap serves as the return electrode. The multi-layer glove has a protective outer layer, which protects an underlying electrically conductive layer and prevents accidental electrical contact between the conductive layer and areas of a patient's skin. The signal generator produces a specific, spike shaped electrical signal, together with the multi-layer glove system, at the treatment site. The device can reduce pain and increase joint function of the treated joints.

WO 2007/056474 A2

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PROTECTIVE GLOVE WITH ELECTRICAL SIGNAL INTERRUPT FEATURE

BACKGROUND

[0001] The present invention generally relates to treating joints, such as a human hand and wrist.

[0002] The hand and wrist are affected by a number of diseases including several forms of arthritis, such as rheumatoid arthritis and osteoarthritis. Rheumatoid arthritis is a chronic, systemic inflammatory disease of unknown etiology characterized by the manner in which it involves the joints. The onset of the disease may be acute or insidious. Articular involvement is manifested clinically by pain, stiffness, loss of motion, deformity of joints, and the signs of inflammation. Rheumatoid arthritis affects many joints, most commonly the hands and wrists.

[0003] Osteoarthritis or osteoarthrosis is a degenerative joint disease, which commonly affects both axial and peripheral diarthrodial joints in humans. The effects of this increase steadily with age, so it is more common in the elderly. Osteoarthritis causes progressive deterioration and loss of articular cartilage from the surfaces of joints, and reactive changes at joint margins and in the underlying bone. Symptoms that are treatable include joint pain, stiffness, limitation of motion, and synovitis or joint inflammation. The treatments for rheumatoid arthritis and osteoarthritis of the hand and wrist are distinctly different, often individualized, and may include application of an electrical signal to the joints.

[0004] In U.S. Pat. No. 5,273,033 to Hoffman, which is specifically incorporated by reference herein, a device is shown that is said to decrease pain and improve joint function in patients with osteoarthritis of the knee.

SUMMARY

[0005] Embodiments are disclosed for a medical device that treats diseases of bones and joints, including the hand, wrist, and arm, such as rheumatoid arthritis and osteoarthritis. In one embodiment, the medical device includes a multi-layer glove system, an arm wrap, a signal generator, lead wires, and a garment. The multi-layer glove system serves as a treatment electrode and the arm wrap serves as a return electrode. The multi-layer glove has a protective outer layer, which protects an underlying electrically conductive layer and prevents accidental electrical contact between the conductive layer and areas of a patient's skin. The signal generator produces a desired waveform, such as a spike shaped electrical signal, through the multi-layer glove system, at the treatment site. The garment has lead wires for connecting the multi-layer glove system and arm wrap to the signal generator. The garment keeps the lead wires in place and helps prevent the user from becoming tangled in the wires.

[0006] When a patient operates the medical device, a desired electrical signal is delivered to the joints of the hand and elbow. The system can reduce pain and increase the function of the treated joints. Other features and advantages will become apparent from the following detailed description, drawings, and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] For a more complete understanding of various embodiments of the present invention, reference is now made to the following descriptions taken in connection with the accompanying drawings in which:

[0008] FIG. 1 is a pictorial view of a medical device according to an embodiment of the inventions.

[0009] FIG. 2 is a side view of an arm wrap as worn.

[0010] FIGS. 3A-3C are pictorial views of an insulating inner glove, a conductive glove, and a protective outer glove according to one embodiment.

[0011] FIG. 4A is a pictorial view of the protective outer glove of FIG. 3C, with a current-interrupting safety feature.

[0012] FIG. 4B is an exploded, partial cross-sectional side view of the multi-layered glove system as worn.

[0013] FIG. 5 is a front plan view of a signal generator according to one embodiment.

[0014] FIG. 6 is a bottom plan view of the signal generator of FIG. 5.

[0015] FIG. 7 is an example of a voltage waveform illustrating characteristics of the electrical treatment signal under no load conditions as produced by an embodiment of the invention.

DETAILED DESCRIPTION

[0016] FIG. 1 illustrates an embodiment of a medical device 10 that includes a multi-layer glove system (shown by 200, 300, and 400), an arm wrap 101, a signal generator 50, a garment 103, and at least one lead wire 104. The user wears the glove system on the hand, arm wrap 101 around the upper arm, and garment 103 like a jacket. The garment has a pocket 105 for holding signal generator 50. The signal generator, glove system, the patient's hand and wrist, the patient's arm, and the arm wrap form an electrical path. When used, signal generator 50 provides periodic electrical signals that pass to the glove system, up the patient's arm, through the arm

wrap 101, and back to the signal generator to try to alleviate the effects of bone and joint diseases.

[0017] In one embodiment, garment 103 is a jacket worn over a patient's clothing. Garment 103 may be made of a variety of materials, including traditional clothing fabric or a woven polymer fabric and can be designed for comfort. Garment 103 has at least one lead wire 104 sewn into the material of garment 103, but could have two lead wires, one for treating the left side of the patient's body and one for treating the right side.

[0018] Lead wire 104 has a signal generator connection 106, an arm wrap connection 107, and a glove connection 108. Signal generator connection 106 may be a keyed shape to ensure proper connection to the signal generator, also described below. Arm wrap connection 107 and glove connection 108 may be metal snaps, although other releasable connection mechanisms may be used. The connections may be color-coded to ensure connection to the proper component.

[0019] Lead wire 104 is attached to, or held within, garment 103 so that when garment 103 is worn, each connection is held for easy attachment to the desired components of medical device 10. In addition, garment 103 helps to prevent the patient from becoming entangled in the lead wires. Signal generator connection 106 is held near pocket 105 for attachment to signal generator 50 in the pocket. Arm wrap connection 107 is held near a point about half way between the elbow and shoulder of the patient for attachment to arm band 101. Garment 103 has a flap 109 to allow the patient easy access to arm wrap 101. Glove connection 108 is held near the wrist for attachment to the multi-layer glove system. A like design would apply to a second lead wire (not shown) for use on the other side of the body.

[0020] Garment 103 may have snaps or other releasable connection mechanisms at the locations recited above. The snaps may be used to hold the various connections when not in use. For example, a snap 110 is located near the wrist of the patient and may hold glove connection 108 when the multi-layer glove system is not connected.

[0021] FIG. 2 illustrates a side view of arm wrap 101 worn on the patient's arm about half way between the elbow and the shoulder. Arm wrap 101 has a lead wire connection 111, which connects to arm wrap connection 107 of lead wire 104 of FIG. 1. Arm wrap 101 has at least one electrically conductive surface, which is placed in contact with the skin of the upper arm. The electrically conductive surface may be made from silver plated nylon. Other electrically conductive surfaces, such as traditional transcutaneous electrical nerve stimulation electrode pads, may be used.

[0022] FIGS. 3A, 3B, and 3C illustrate three separate components of the multi-layer glove system. All three components of the multi-layer glove system are worn simultaneously and in layers. Referring to FIG. 3A, an electrically insulating inner glove 200 is worn on a hand of the patient. The finger-covering members of insulating inner glove 200 are shortened and open-ended. Thus, when insulating inner glove 200 is worn, the skin covering the interphalangeal joints (the "outer knuckles") of the hand is exposed, but insulating material covers the palm and back portions of the hand and wrist, including the skin covering the metacarpophalangeal joints (the "inner knuckles") of the fingers and thumb. For example, an exposed finger portion 201 protrudes from a shortened, open-ended finger-covering member 202. Insulating inner glove 200 is made of an electrically insulating material, such as vinyl, neoprene, or polyurethane, and should be made comfortable to wear even over many hours.

[0023] Referring to FIG. 3B, an electrically conductive glove 300 is worn on the hand of the patient, over the previously fit insulating inner glove 200 of FIG. 3A.

Conductive glove 300 makes electrical contact with the exposed finger portions that protrude from the shortened finger-covering members of insulating inner glove 200. However, conductive glove 300 does not make electrical contact with the palm and back portions of the hand due to insulating inner glove 200. A patient may massage conductive gel into the finger portions of conductive glove 300 to improve the electrical conductivity between the surface of the skin and conductive glove 300. Conductive glove 300 is flexible so it can be worn. Conductive glove 300 could be made entirely of a conductive material, but would typically be made of a suitable combination of conductive and non-conductive materials, such as a silver plated nylon.

[0024] Referring to FIG. 3C, a protective outer glove 400 is worn on the hand of the patient, over the previously fit conductive glove 300 and insulating inner glove 200. Protective outer glove 400 completely covers conductive glove 300 to protect conductive glove 300 against damage and to insulate the outer surface of conductive glove 300.

[0025] Referring back to FIG. 3B, conductive glove 300 has a conductive hook-and-loop fastener 301 (such as a VELCRO brand hook-and-loop fastener) attached to the top, exterior wrist-area of conductive glove 300. Conductive hook-and-loop fastener 301 is in electrical contact with conductive glove 300, and is positioned to make contact with a complementary conductive hook-and-loop fastener of protective outer glove 400. Other conductive releasable mechanisms may be used in place of the conductive hook-and-loop fasteners, but would typically allow easy connection and disconnection when desired, while being sufficiently well connected to not become undone with ordinary movement.

[0026] Protective outer glove 400 has a lead wire connection 401 positioned on the back of the glove, in the area covering the patient's wrist. Lead connection 401 releasably connects to the glove connection 108 of lead wire 104 (shown in FIG. 1). Lead connection 401 may be a metal snap or some other releasable conductive mechanism that is easily removed manually when desired without tools. Lead connection 401 passes through the fabric of protective outer glove 400 and is in electrical contact with a conductive hook-and-loop fastener 402 (shown in FIG. 4A) mounted on the inside surface of protective outer glove 400. FIG. 4A illustrates protective outer glove 400 with a portion of the fabric turned inside-out, exposing conductive hook-and-loop fastener 402, as attached to the inner surface of the glove.

[0027] FIG. 4B shows an exploded, partial cross-sectional right side view of the multi-layer glove system as worn by the patient on the right hand (the layers of the glove system are separated for viewing convenience). Conductive hook-and-loop fastener 402 is positioned to make electrical contact with conductive hook-and-loop faster 301 of conductive glove 300 when all three glove layers are worn. Insulating inner glove 200 is worn closest to the skin. Conductive glove 300 is worn over insulating inner glove 200. Protective outer glove 400 is worn over both other gloves. Thus, an electrical connection is established between the finger portion 201 and lead wire 104 by way of conductive glove 300, the complementary conductive hook-and-loop fasteners 301 and 402, wire connection 401, and glove connection 108.

[0028] Protective outer glove 400 may be made from any fabric traditionally used to manufacture gloves. It may also have a coating on its inner surface to prevent the conductive gel used with conductive glove 300 from saturating the fabric of protective outer glove 400. Protective outer glove 400 can be made, for example, from spandex fiber with an inner rubberized coating.

[0029] This embodiment of the multi-layer glove system has a number of useful features. Protective outer glove 400 prevents conductive glove 300 from making accidental electrical contact with areas of the patient's skin other than the finger portions as described above. The patient may handle objects or use his or her hands during treatment without interfering with the electrical signal. In addition, the inner surface coating contains the conductive gel to inhibit the gel from being deposited on other areas of the patient's skin, the patient's clothing, and objects that the patient may handle during treatment. Similarly, the inner surface coating also helps prevent the conductive gel from drying-out during treatment, thereby prolonging the effectiveness of the gel.

[0030] The complementary conductive hook-and-loop fasteners also perform a safety function. When the patient removes the protective outer glove, the electrical connection between the complementary conductive hook-and-loop fasteners is broken automatically and without additional action being required. Thus, the conductive glove is de-energized when the protective outer glove is removed. Should the patient accidentally leave the signal generator on before removing the glove system, this feature prevents the patient from accidentally completing the electrical circuit with an area of the skin other than the desired treatment area.

[0031] The glove system can isolate the finger portions as a treatment area. It is believed that isolating the finger portions as a treatment area is effective in treating symptoms associated with diseases of the joints, such as rheumatoid arthritis of the hand. It is theorized that isolation of the finger portions as a treatment area allow for superior ion conduction through the cartilage of the treated joints, thereby increasing the current through the joints. The increased current produces an increased electrical

field in the cartilage, which is believed to mimic the electrical potentials found in healthy cartilage that cause the body to produce new cartilage.

[0032] Although the beneficial effects are thought to decrease as the distance from the treatment area increases, the glove system may be effective in treating aliments of the elbow. Use of the medical device disclosed herein is believed to reduce the patient's evaluation of pain and symptoms in the treated joints and increase the patient's evaluation of function in the treated joints. The ability of the glove system to isolate the fingertips may also have applications in traditional transcutaneous electrical nerve simulation therapy.

[0033] Turning to the electrical components and waveforms, FIG. 5 is a front plan view of an embodiment of a signal generator 50. Signal generator 50 may be a device such as the one described in U.S. Pat. No. 5,273,033 to Hoffman. Signal generator 50 may also be a traditional commercially available transcutaneous electrical nerve stimulator. Signal generator 50 is a battery powered electrical stimulator, which produces a specific, periodic, spike shaped electrical signal to the multi-layer glove system at the treatment site. Suitable sources of power include an alkaline battery or a Nickel Metal Hydride battery. Signal generator 50 has at least one treatment channel, which includes a complete electrical circuit when the signal generator output is connected to the arm wrap and multi-layer glove system described above.

[0034] Signal generator 50 has an LCD display 501, which allows the patient to read information concerning the level of treatment, duration of treatment, battery status, signal generator status, and other information. Signal generator 50 has an On / Off button 502 which allows the patient to turn the unit on and off, a stimulation increase button 503 that may be pressed to increase the level of electrical stimulation produced by a treatment channel of signal generator 50, and a stimulation decrease

button 504 that may be pressed to change the level of electrical stimulation produced with suitable thresholds. Signal generator 50 may have multiple treatment channels, each having a set of stimulation increase and decrease buttons. The generator could have selectable alternative waveforms.

[0035] A function button 505 may be pressed to display the treatment time on LCD 501. A battery button 506 may be pressed to display the battery charge level on LCD 501.

[0036] FIG. 6 is a bottom plan view of the signal generator of FIG. 5. Signal generator has a lead wire connection 507, which connects to signal generator connection 106 of lead wire 104 (shown in FIG. 1). Lead wire connection 507 may be a keyed shape, complementary to the shape of signal generator connection 106. This ensures proper connection to the signal generator and proper polarity between the treatment electrode and return electrode. In one embodiment, signal generator 50 has an additional treatment channel, in which case, an additional lead wire connection 508 is provided.

[0037] FIG. 8 is a voltage waveform illustrating the characteristics of an exemplary electrical treatment signal produced by the signal generator 50 under no load conditions. In one embodiment, the electrical treatment signal is a voltage-sourced, spike-shaped, monophasic, and asymmetrical DC signal. The frequency is fixed at 100 ± 5 Hz. The voltage range is 0 – 12 volts at the peak. The voltage pulse width is 1.8 ms at the 10% point of peak and 0.64 ms at the 50% point of peak. The current output range is 0 – 24 mA at 500 ohms resistive load, with an average of 0.2 mA at 500 ohms resistive load. The current pulse width is 1.8 ms at the 10% point of peak and 0.64 ms at the 50% point of peak, both at 500 ohms resistive load. The maximum output charge is 20 μC into a load of 500 ohms. The voltage of the

electrical treatment signal may be adjusted by the patient so the signal is subsensory to the patient. Treatment could be applied over many hours, and could be applied overnight. The selected waveform would typically not provide much heat to the treated area.

[0038] As will be realized, the inventions are capable of other and different embodiments and its several details may be capable of modifications in various respects, all without departing from the invention as set out in the appended claims. For example, the treatment signal produced by signal generator 50 may vary from the waveform described above, or the multi-layer glove system may be used with a current-sourced electrical signal generator, such as a traditional transcutaneous electrical nerve stimulator. Accordingly, the drawings and description are to be regarded as illustrative in nature and not in a restrictive or limiting sense with the scope of the application being indicated in the claims.

[0039] What is claimed is:

CLAIMS

1. A medical device comprising:

a multi-layered glove system having a non-invasive conductive layer and a protective layer;

the non-invasive conductive layer having an inner surface and an outer surface, the inner surface making electrical contact with at least a portion of a hand of a patient, the non-invasive conductive layer receiving an electrical signal through a first releasable conductive lead;

the protective layer covering at least substantially all of the outer surface of the non-invasive conductive layer and having an inner surface and an outer surface, the protective layer having a lead for receiving an electrical signal and having a second releasable conductive lead;

the first releasable conductive lead being electrically coupled to the second releasable conductive lead when the layers are worn, the releasable conductive leads constructed and positioned such that the releasable conductive leads are disconnected in order to remove the protective layer from the hand, thereby automatically breaking the electrical connection between the releasable conductive leads.

2. The medical device of claim 1, further comprising a signal generator for producing a desired electrical signal in at least a portion of the patient's body, the signal generator being electrically coupled to the non-invasive conductive layer through the releasable conductive leads.

3. The medical device of claim 2, wherein the desired electrical signal is a periodic signal selected to rebuild cartilage of a joint when applied to a joint of the human body.

4. The medical device of claim 2, wherein the desired electrical signal is a voltage-sourced, spike-shaped, monophasic, repeating, and asymmetrical DC signal characterized by an exponential decay and having a frequency of about 95 to 105 hertz, a voltage of about 0 to 12 volts at the peak, a voltage and current pulse width of about 1.8 ms at the 10% point of peak and about 0.64 ms at the 50% point of peak, and a current of about 0 to 24 mA at 500 ohms resistive load with an average of about 0.2 mA at 500 ohms resistive load.

5. The medical device of claim 2, wherein the desired electrical signal is subsensory.

6. The medical device of claim 2, further comprising a lead wire for coupling to a portion of the patient's arm, the lead wire, signal generator, non-invasive conductive layer, patient's hand and wrist, and patient's arm forming an electrical circuit.

7. The medical device of claim 1, wherein the releasable conductive leads include conductive hook-and-loop connections.

8. The medical device of claim 1, wherein at least a portion of the protective layer is constructed of spandex and has a rubberized coating covering the inner surface.

9. The medical device of claim 1, wherein at least a portion of the non-invasive conductive layer is constructed of silver plated nylon.

10. A method comprising:

covering at least a portion of a hand of a patient with a non-invasive conductive layer, such that an inner surface of the non-invasive conductive layer makes electrical contact with at least a portion of the hand of the patient, the non-

invasive conductive layer having an outer surface and receiving an electrical signal through a first releasable conductive lead;

covering the hand of the patient and the entire outer surface of the non-invasive conductive layer with a protective layer, the protective layer having a lead for receiving an electrical signal and having a second releasable conductive lead;

coupling the conductive leads such that the first releasable conductive lead and second releasable conductive lead are electrically coupled when the protective layer is provided over the non-invasive conductive layer; and disconnects the first releasable conductive lead and second releasable conductive lead when the protective layer is removed to automatically break the electrical connection between the releasable conductive leads.

11. The method of claim 10, further comprising producing a desired electrical signal in at least a portion of the patient's body by electrically coupling the non-invasive conductive layer to a signal generator through the releasable conductive leads.

12. The method of claim 11, wherein the desired electrical signal is a periodic signal selected to rebuild cartilage of a joint when applied to a joint of the human body.

13. The method of claim 11, wherein the desired electrical signal is a voltage-sourced, spike-shaped, monophasic, repeating, and asymmetrical DC signal characterized by an exponential decay and having a frequency of about 95 to 105 hertz, a voltage of about 0 to 12 volts at the peak, a voltage and current pulse width of about 1.8 ms at the 10% point of peak and about 0.64 ms at the 50% point of peak, and a current of about 0 to 24 mA at 500 ohms resistive load with an average of about 0.2 mA at 500 ohms resistive load.

14. The method of claim 11, wherein the desired electrical signal is subsensory.

15. The method of claim 11, further comprising coupling a lead wire to a portion of the patient's arm, the lead wire, signal generator, non-invasive conductive layer and patient's arm forming an electrical circuit.

16. The method of claim 10, wherein the releasable conductive leads include conductive hook-and-loop connections.

17. The method of claim 10, wherein at least a portion of the protective layer is constructed of spandex and has a rubberized coating covering the inner surface.

18. The method of claim 10, wherein at least a portion of the non-invasive conductive layer is constructed of silver plated nylon.

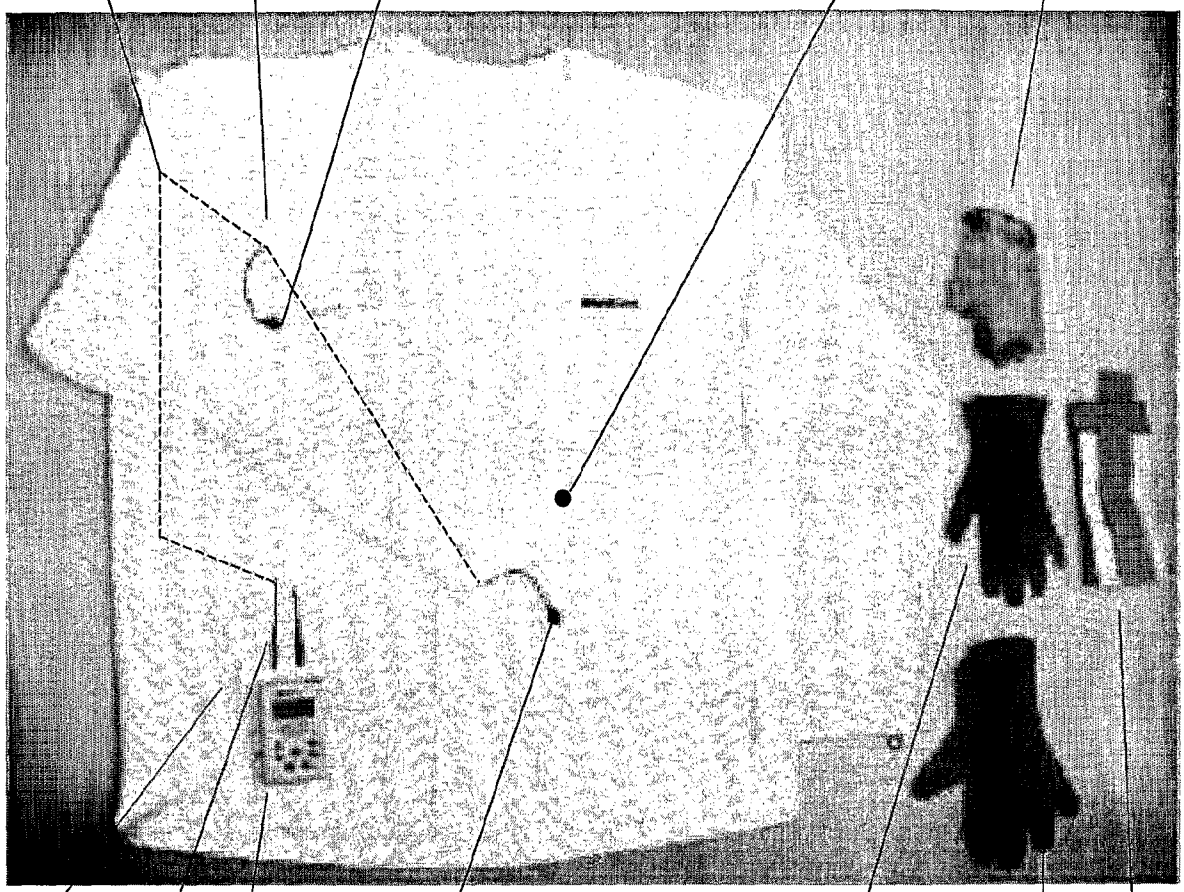


FIG. 1

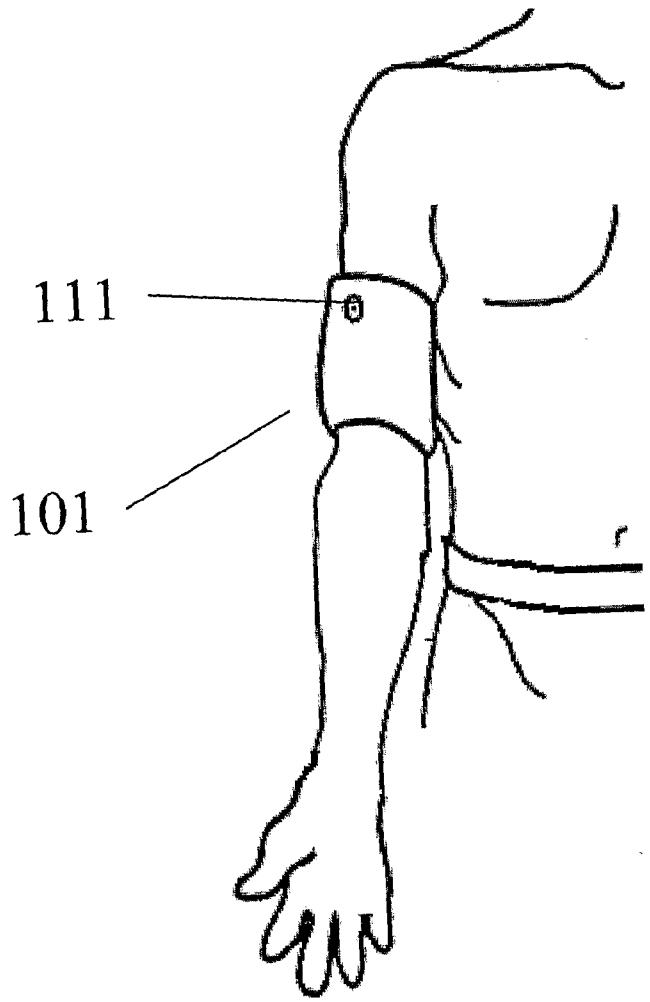


FIG. 2

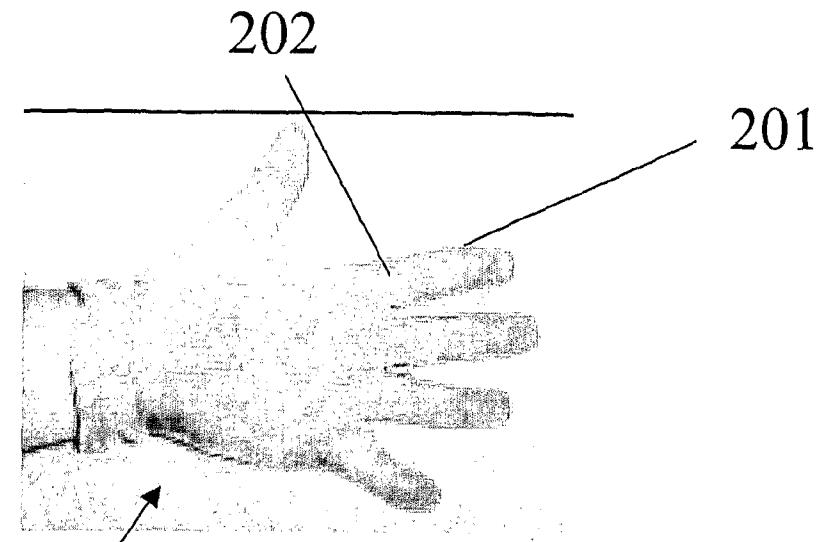


FIG. 3A

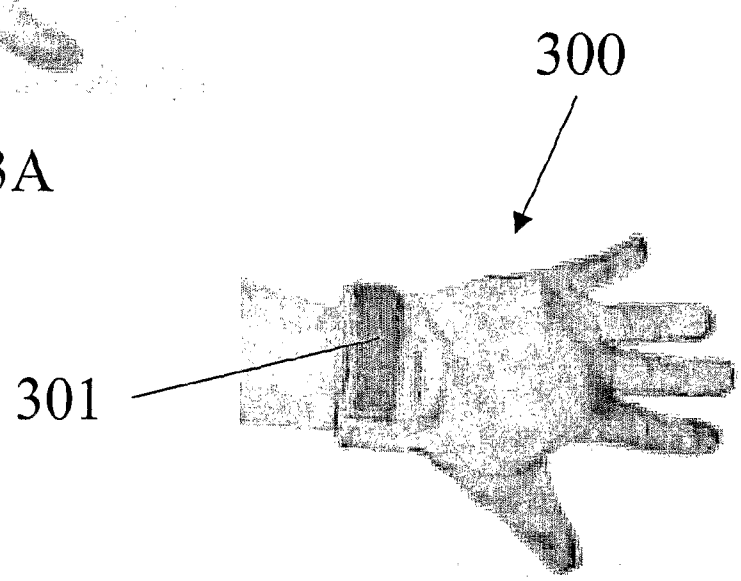


FIG. 3B

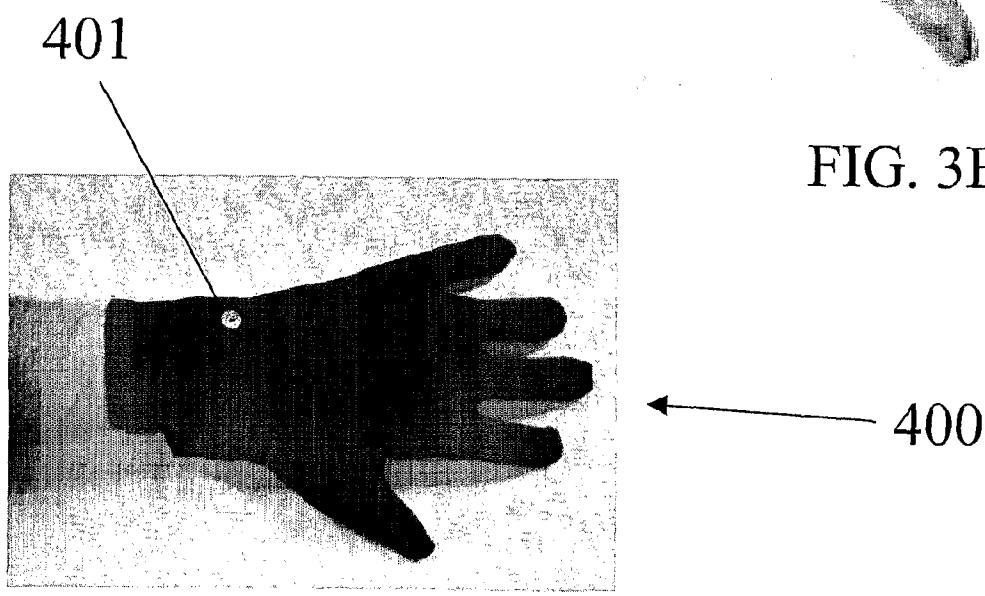


FIG. 3C

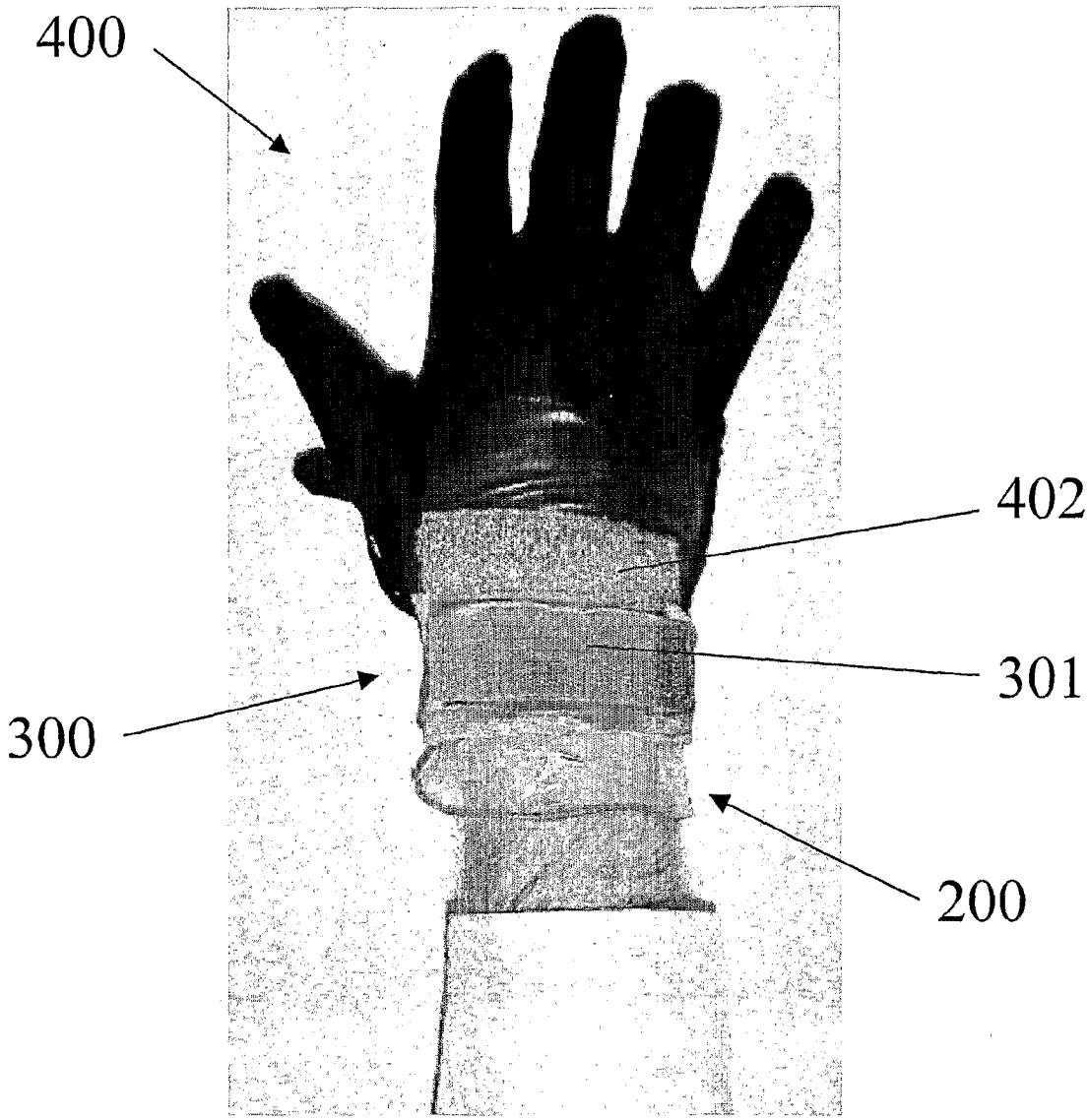


FIG. 4A

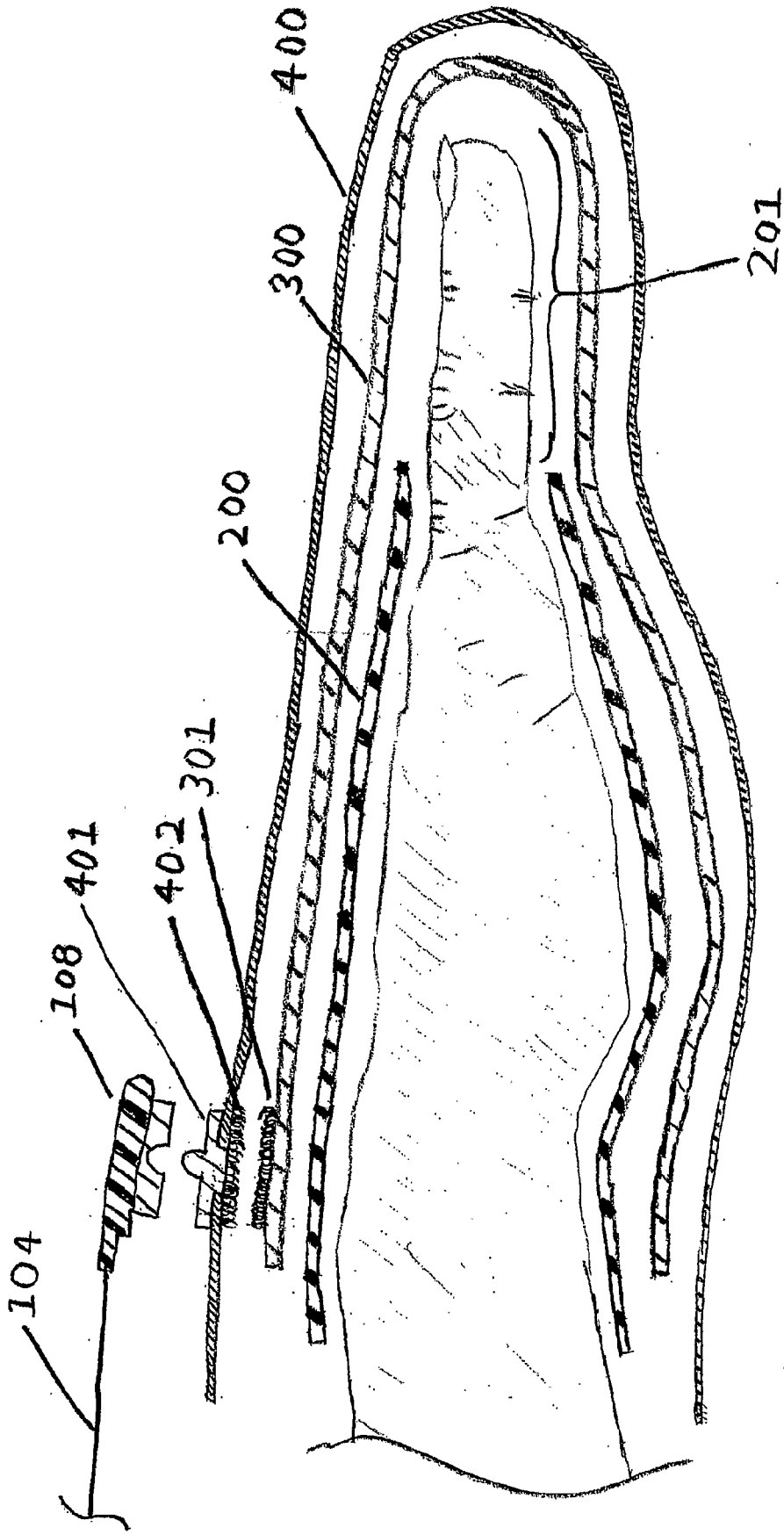


FIG. 4B

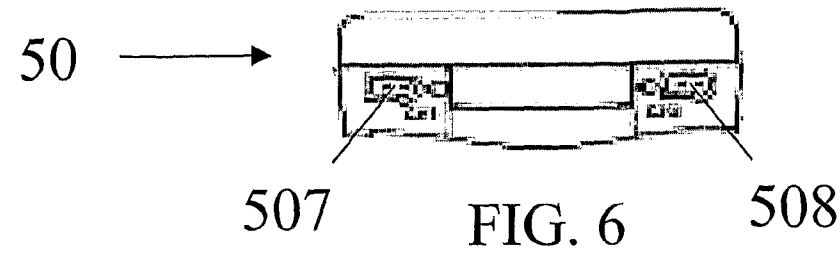


FIG. 6

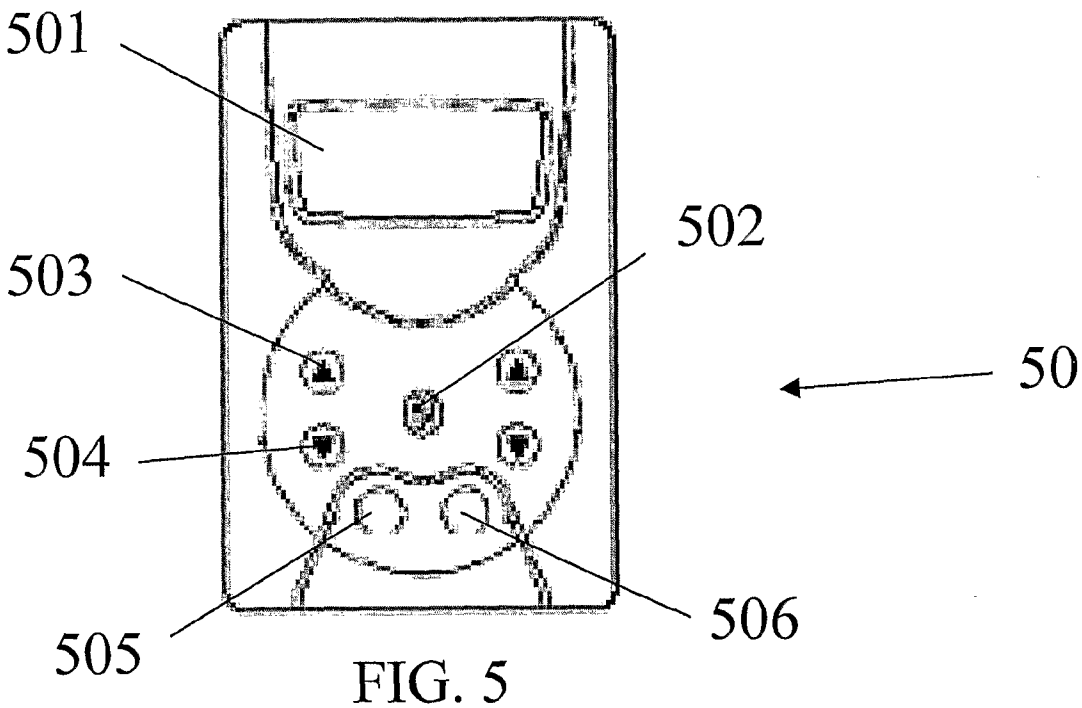


FIG. 5

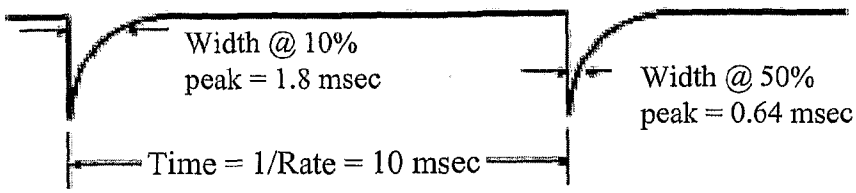


FIG. 7