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(54) **PORTABLE, PRE-CALIBRATED AND WEARABLE LASER DEVICE FOR TREATING PAIN AND INFLAMMATION**

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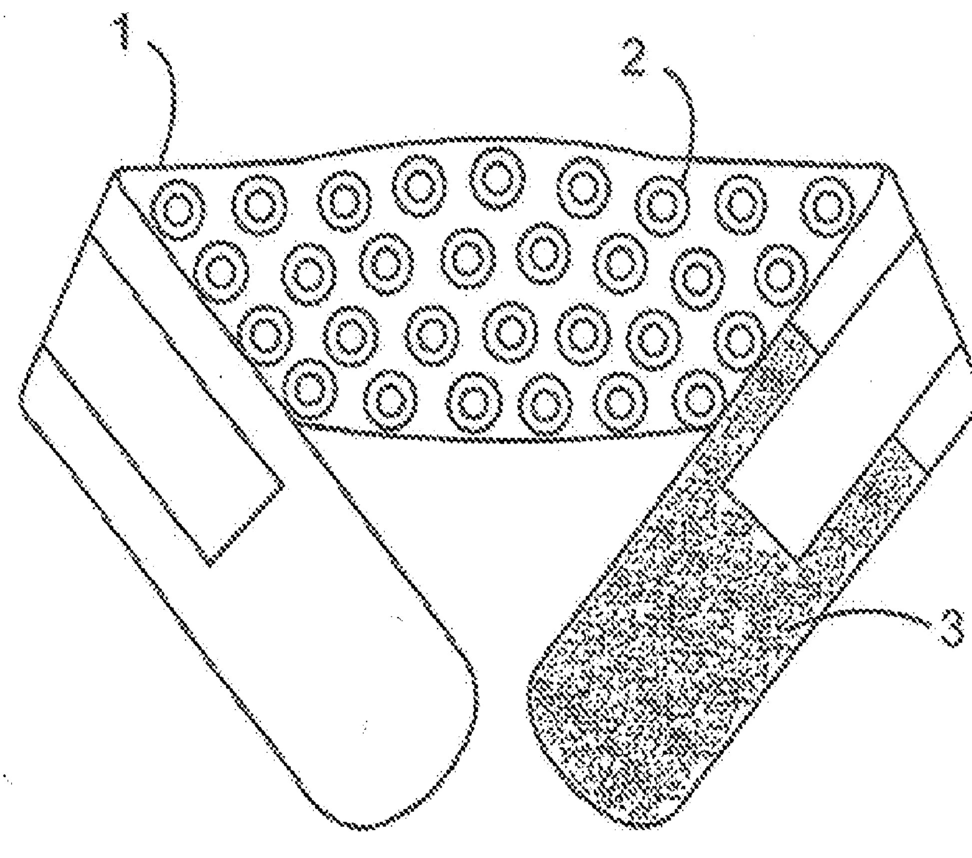
CPC ***A61N 5/0613*** (2013.01); ***A61B 5/02055*** (2013.01); ***A61B 5/4836*** (2013.01); *A61B 5/021* (2013.01)

(57) **ABSTRACT**

Various types of low level laser therapy (LLLT) wrap devices, methods of use, and a system comprising a mobile application, for the treatment of pain from musculoskeletal injuries or medical conditions, and to capture "patient's vitals". Each wrap is fitted to a specific body part (e.g. knee), lightweight, portable so that it is wearable beneath clothing; and with a battery-powered electrical circuit embedded within the wrap, comprising: a plurality of laser diodes to treat surface and/or deep tissue pain; sensors (e.g. safety and/or patient vital sign monitoring); and a wireless transceiver for transmitting data (sensor and patient pain levels) to a mobile application. The wrap may also function as an orthopedic support; and is pre-calibrated for a specific duration to deliver a clinical strength dosage from 630 nm to 904 nm that is specific to the medical disorder and/or the user anatomical area, with an automatic shut-off after dose delivery.



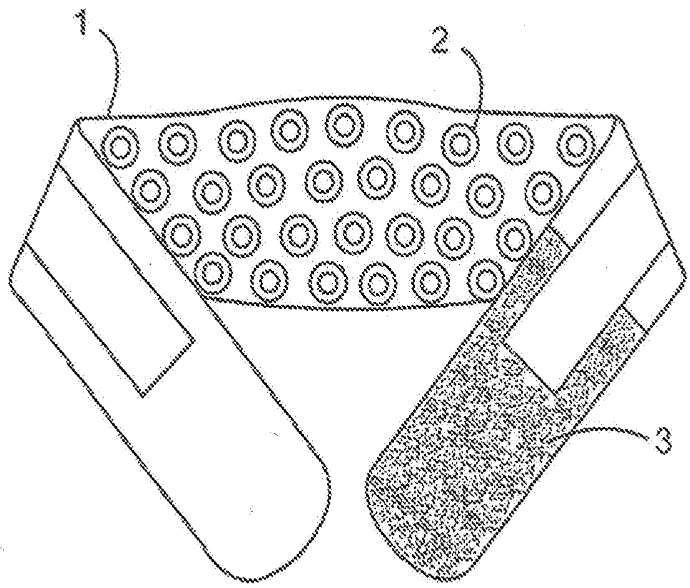


FIG.1A

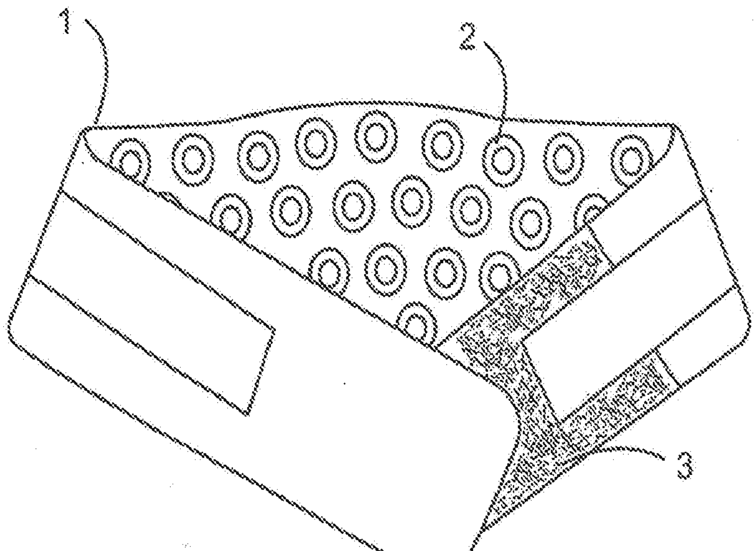


FIG.1B

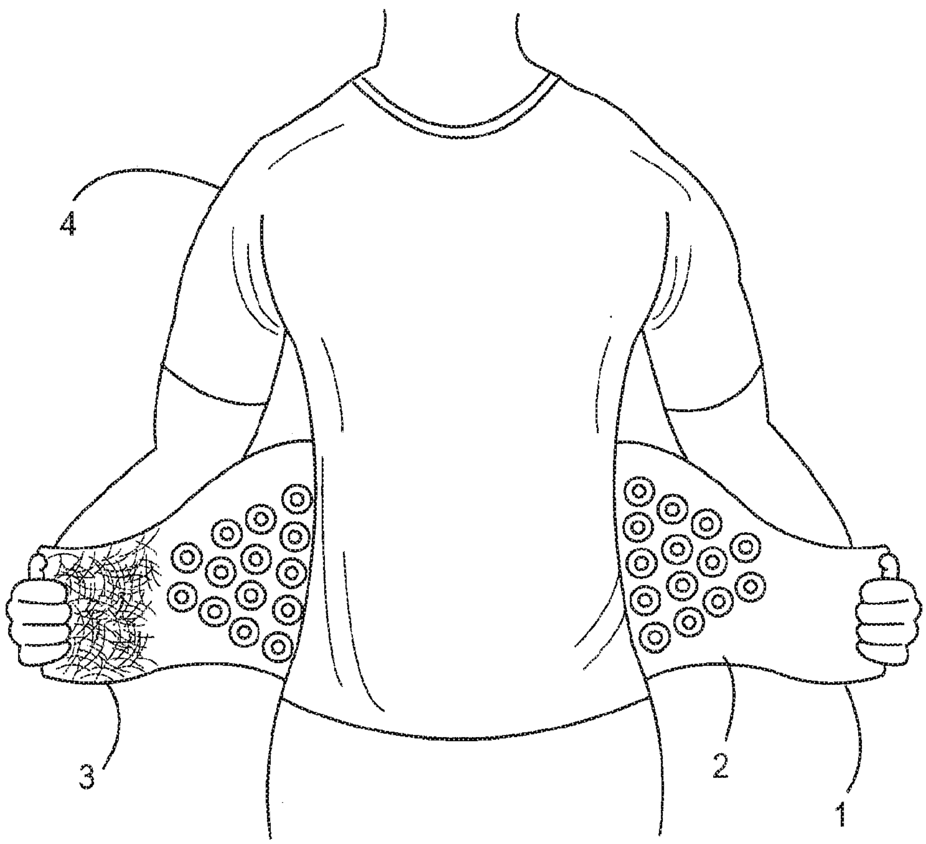


FIG.2

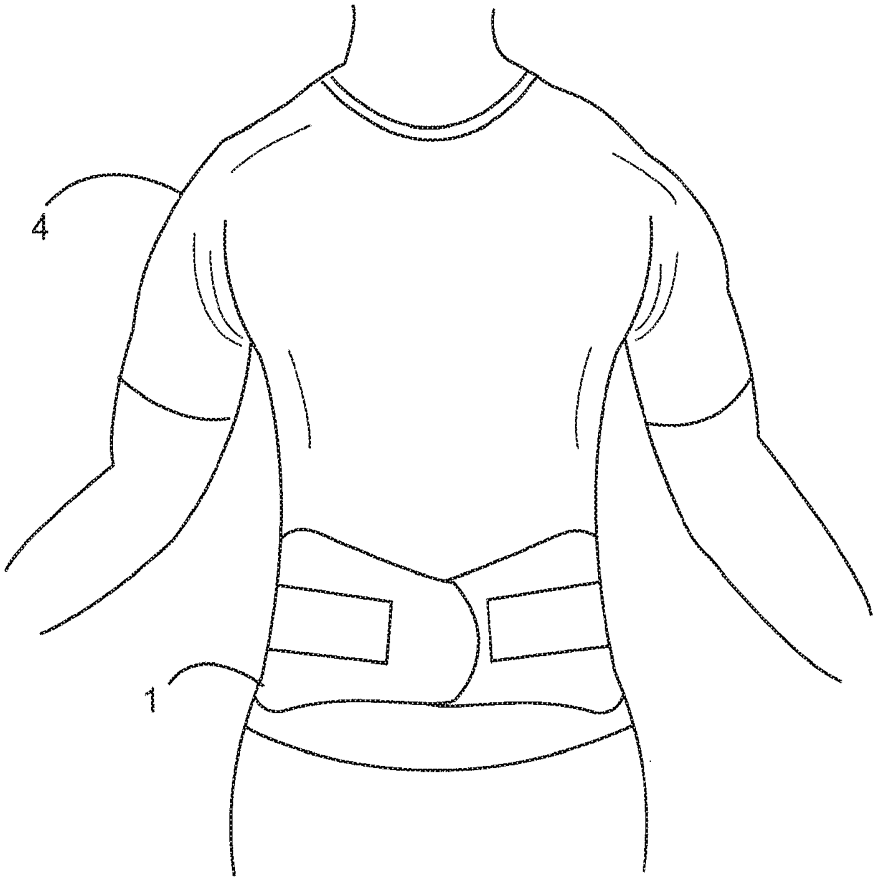


FIG.3

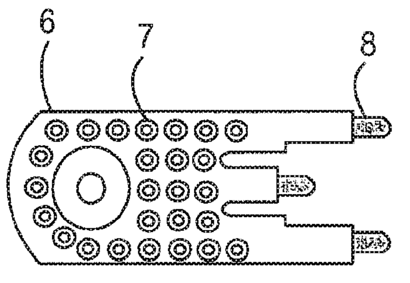


FIG.4A

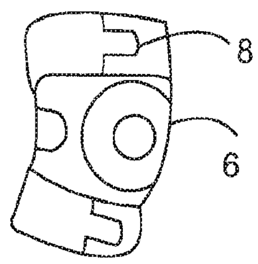


FIG.4B

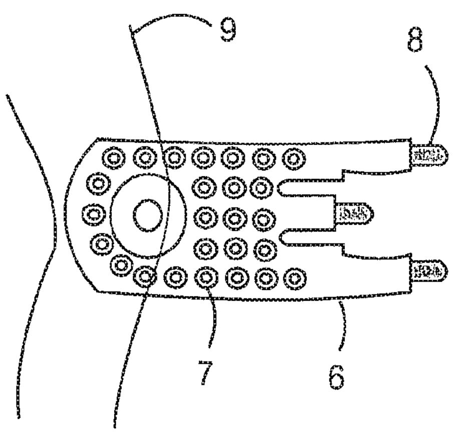


FIG.4C

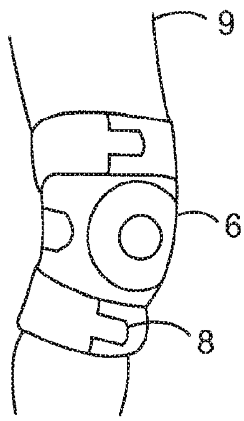


FIG.4D

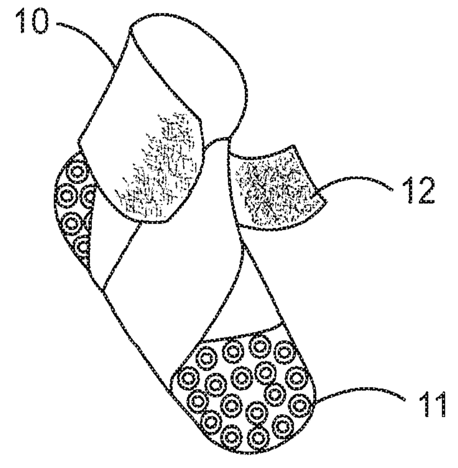


FIG.5A

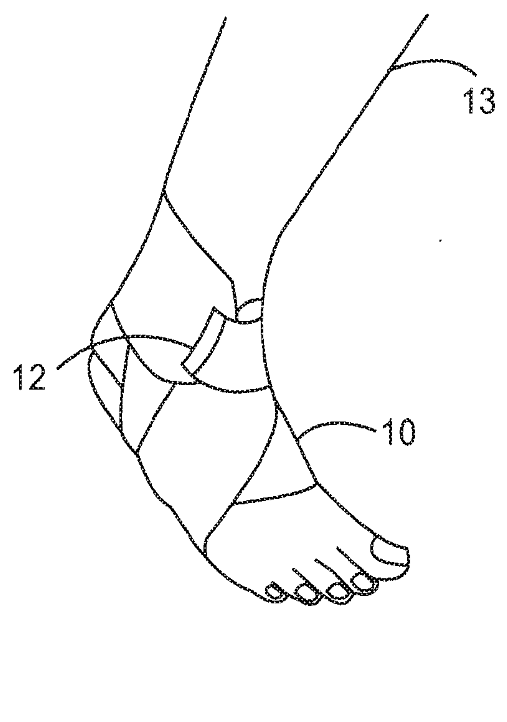


FIG.5B

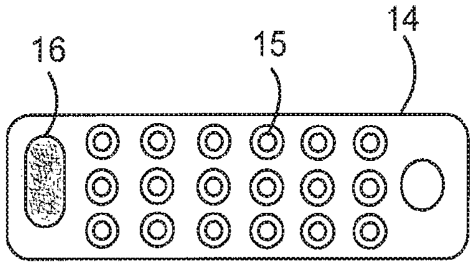


FIG.6A

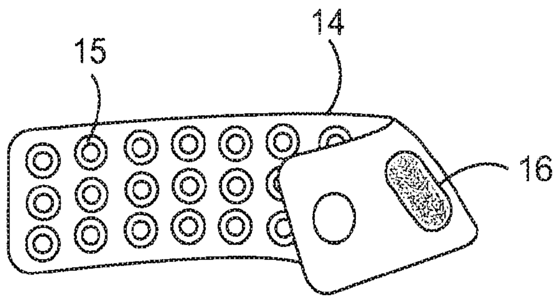


FIG.6B

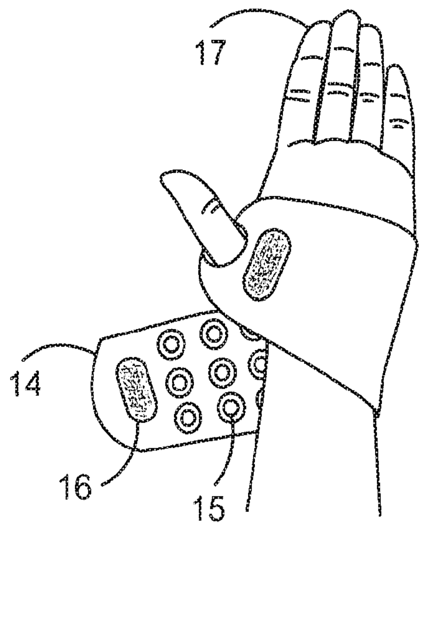


FIG.6C

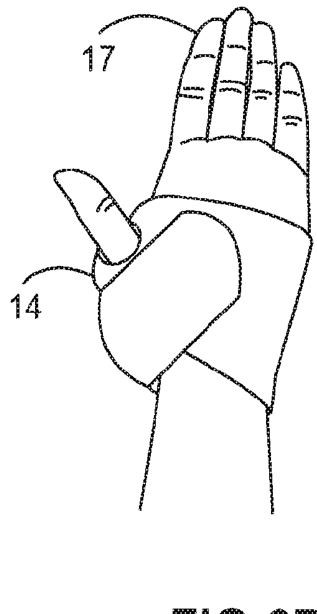


FIG.6D

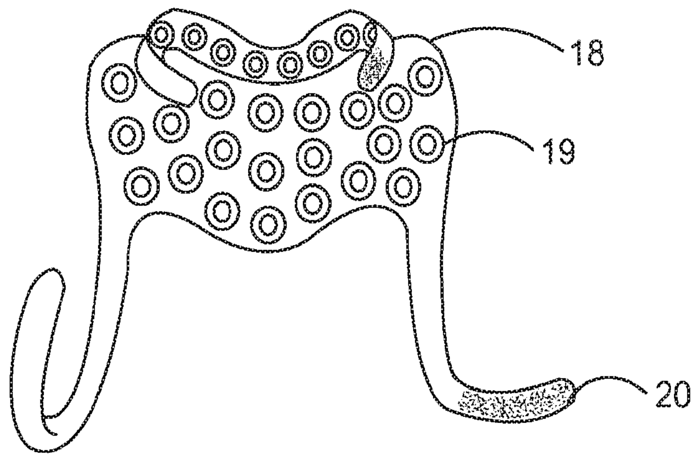


FIG.7A

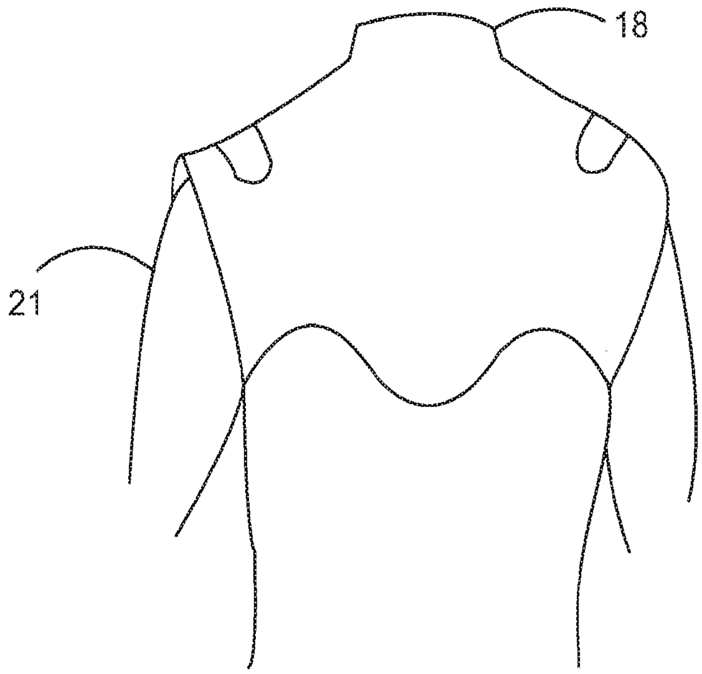


FIG.7B

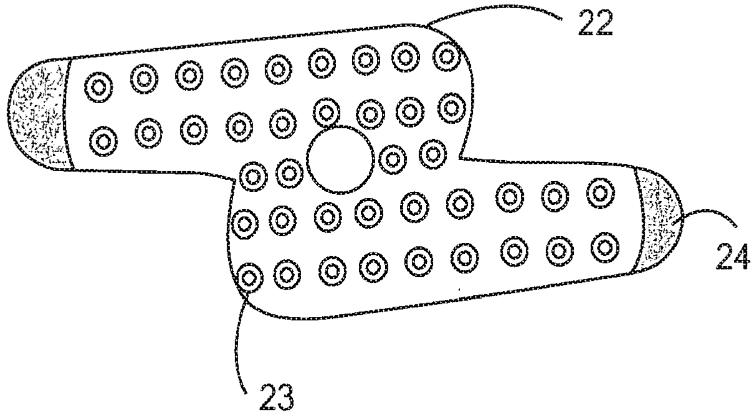


FIG.8A

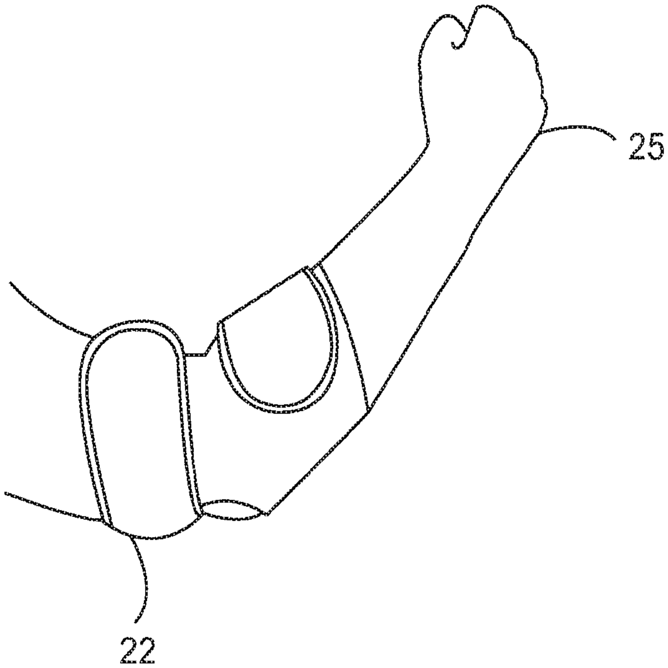


FIG.8B

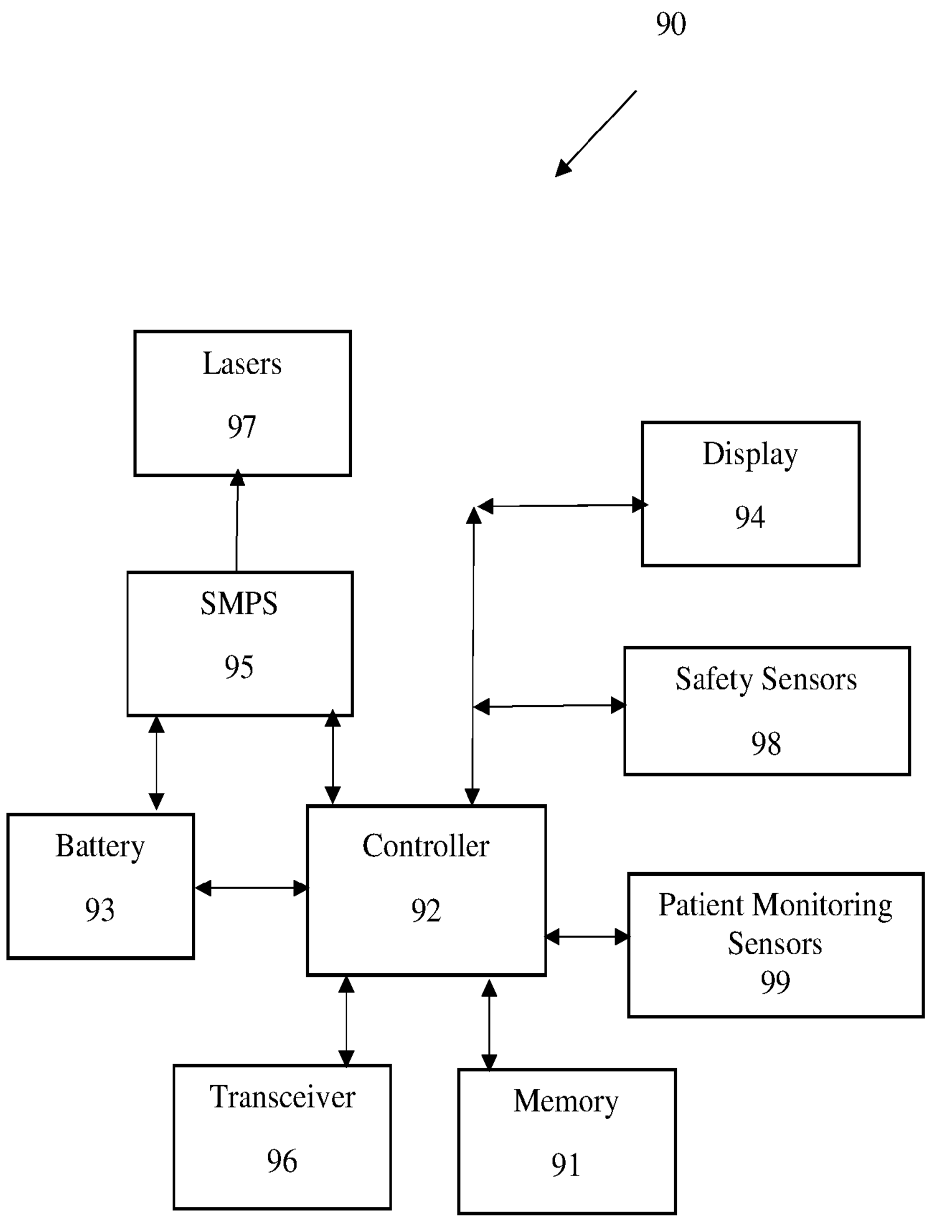

90
Lasers
97
Display
94
SMPS
95
Safety Sensors
98
Battery
93
Controller
92
Patient Monitoring
Sensors
99
Transceiver
96
Memory
91

FIG. 9

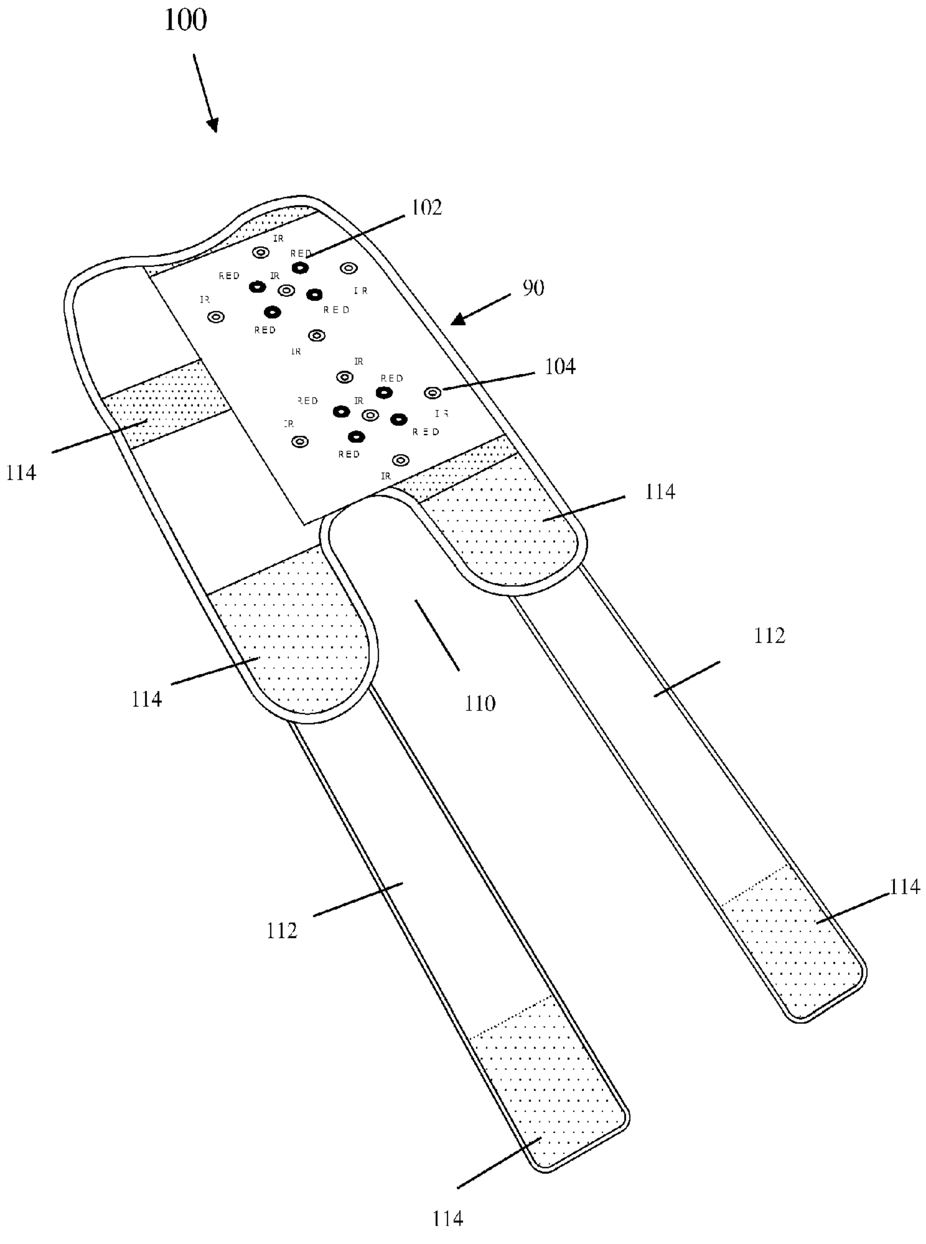


FIG. 10

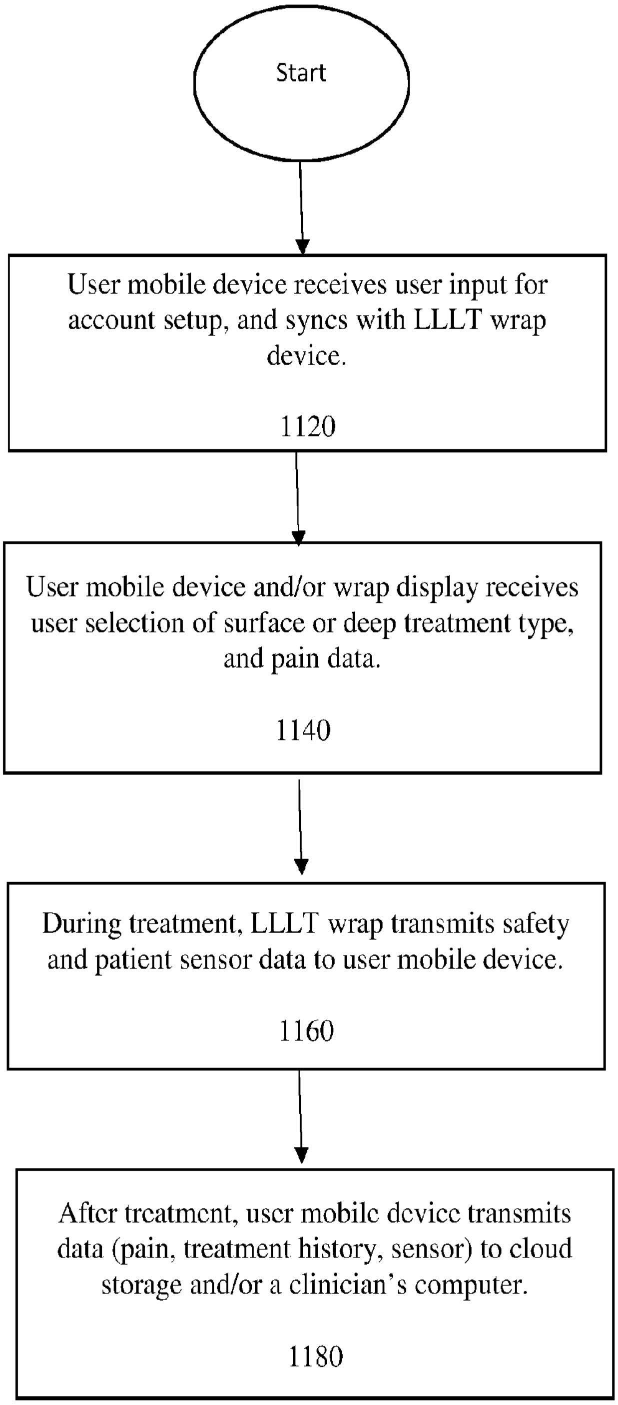

Start
User mobile device receives user input for account setup, and syncs with LLLT wrap device.
1120
User mobile device and/or wrap display receives user selection of surface or deep treatment type, and pain data.
1140
During treatment, LLLT wrap transmits safety and patient sensor data to user mobile device.
1160
After treatment, user mobile device transmits data (pain, treatment history, sensor) to cloud storage and/or a clinician's computer.
1180

FIG. 11

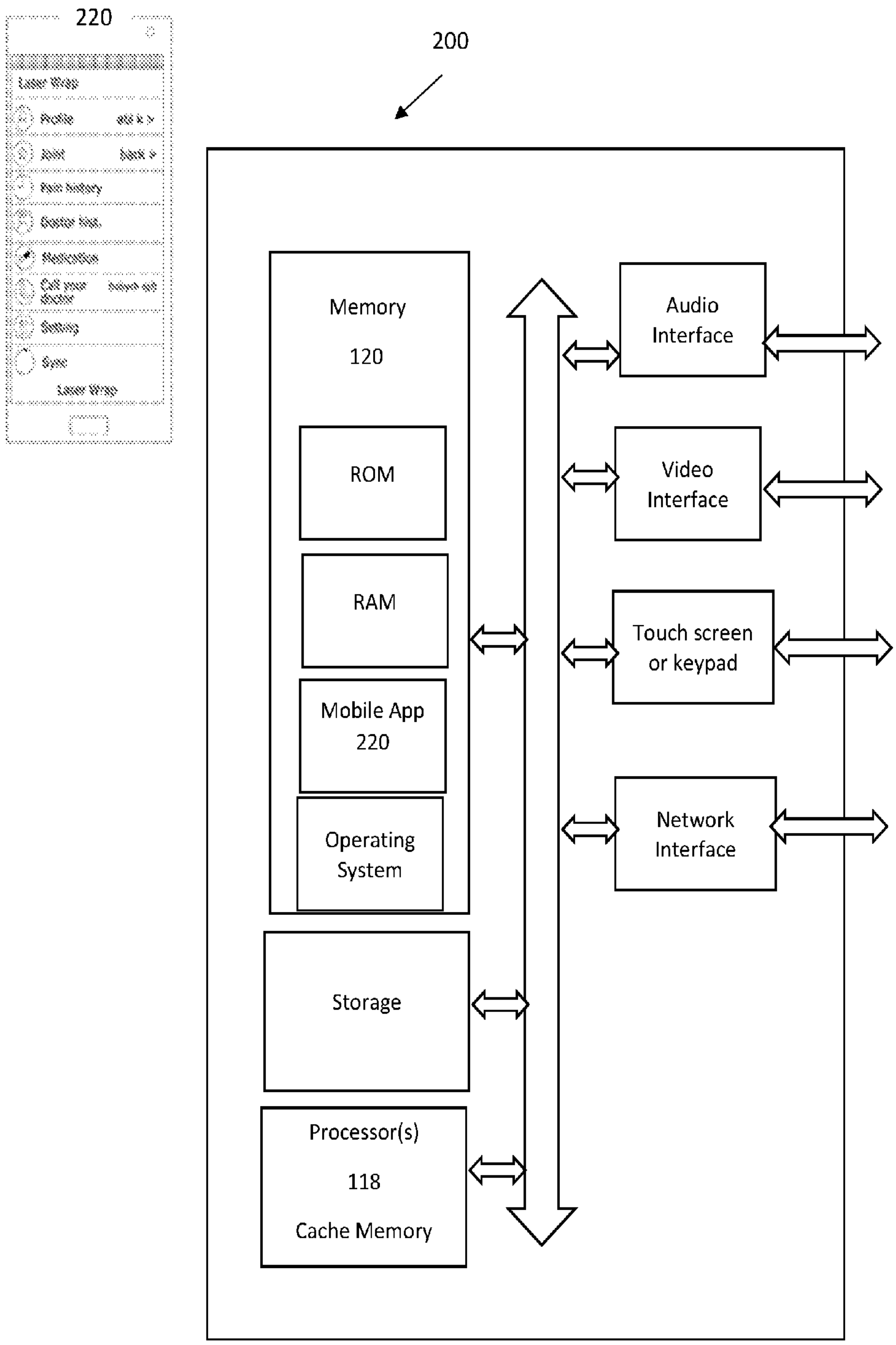

220
200
Memory
120
ROM
RAM
Mobile App
220
Operating
System
Storage
Processor(s)
118
Cache Memory
Audio
Interface
Video
Interface
Touch screen
or keypad
Network
Interface

FIG. 12

PORTABLE, PRE-CALIBRATED AND WEARABLE LASER DEVICE FOR TREATING PAIN AND INFLAMMATION

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to and benefit from U.S. patent application Ser. No. 14/583,792 filed on Dec. 29, 2014, the entire contents of which is hereby expressly incorporated by reference.

TRADEMARKS DISCLAIMER

[0002] The product names used in this document are for identification purposes only. All trademarks and registered trademarks are the property of their respective owners.

FIELD OF THE INVENTION

[0003] The present invention disclosed herein relates generally to the field of over-the-counter (OTC) medical devices, and, in particular, to various embodiments comprising methods, a system, devices and computer media, using portable low level laser technology (LLLT) devices that are pre-programmed with clinical strength doses, and used for pain and/or inflammation therapy.

BACKGROUND OF THE INVENTION

[0004] Arthritis and osteoporosis are the most common joint pain diseases, and they affect millions of people each year. A patient may suffer from arthritis in a variety of locations on their body. Arthritis may impair a daily routine of the patient. Such impairment can affect the ability of a patient to work or enjoy leisurely activities. Treatments for the pain associated with arthritis comprise medications, injections, and creams. Symptoms of arthritis comprise pain, swelling, inflammation, limited range of motion, and redness. Medications for treating the pain include acetaminophen, (e.g., Tylenol®), NSAIDS—non-steroidal anti-inflammatory drugs (e.g., Advil®, Motrin®, Aleve®), and tramadol.

[0005] Use of acetaminophen can cause liver damage, especially if the patient consumes alcohol. Acetaminophen may also affect the efficacy of other medications taken by the patient. Side-effects of non-steroidal anti-inflammatory drugs include gastric ulcers, cardiovascular problems, and gastrointestinal bleeding. Tramadol may cause nausea and constipation. A patient may try creams as an alternative to, or in addition to, medications. Side effects of creams include irritation or redness on the application site of the cream. Both medications and creams have undesirable side-effects.

An Introduction to LLLT (Low Level Laser Therapy)

[0006] Low level laser therapy (LLLT) is a non-invasive treatment that has been used for many years to relieve pain from sports injuries, joint related arthritic illnesses, neck and back pain, shoulder, wrist, knee and ankle related joint pains.

[0007] Low levels of laser energy have a non-thermal, bio-stimulative effect on biological tissues. The therapeutic application of low level laser energy, frequently known as low level laser therapy (LLLT), produces beneficial clinical effects in the treatment of musculoskeletal, neurological and soft tissue conditions. LLLT is non-invasive and avoids the potential side effects of drug therapy. More specifically, LLLT delivers photons to targeted tissue, penetrating the layers of skin to reach internal tissues to produce a specific, non-thermal photochemical effect at the cellular level.

[0008] Low level laser therapy (LLLT) is the application of light (usually a low power laser or LED/VCSEL in the range of 10 mW-500 mW power) to a pathology (e.g. skin surface of an afflicted joint) to promote pain-relief, reduce inflammation and promote tissue regeneration. The light is typically of a narrow spectral width in the red or near infrared (NIR) spectrum (600 nm-900 nm), with a power density (irradiance) between 5 mW-500 mW/cm^2. It is typically applied to the injured anatomical area for a few minutes or so, a few times a week for several weeks. Unlike other medical laser procedures, LLLT is not an ablative or thermal mechanism, but rather a photochemical effect comparable to photosynthesis in plants whereby the light is absorbed and exerts a chemical change.

LLLT is Therapeutic in Two Ways for Pain Relief

[0009] 1. Anti-inflammatory. When cells are stressed (e.g. during states of arthritis, osteoporosis, sports injuries), nitric oxide (NO) inhibits oxygen consumption by mitochondrial cytochrome c oxidase. This reduces production of ATP and causes oxidative stress leading to increased inflammation and reduced production of ATP. LLLT displaces nitric oxide (NO) from cytochrome c oxidase thereby reducing inflammation and restoring ATP production, relieving pain and helping tissues heal more quickly. LLLT reduces oxidative stress by applications to injuries of light of suitable wavelength, sufficient irradiance and time of exposure to cause cytochrome c oxidase to displace mtNO, thereby reducing oxidative stress and increasing ATP production. A cascade of downstream metabolic effects lead to a reduction in inflammatory markers including prostaglandin E2, interleukin 1β and tumor necrosis factor α.

[0010] 2. Analgesia. LLLT creates a nerve block. Higher irradiance/energy treatments can induce an analgesic effect by disrupting fast axonal transport in small diameter fibers, in particular nociceptors. This temporary (reversible) inhibition of A-delta and C fiber transmission reduces tonic peripheral nociceptive afferent input and facilitates reorganization of the modulation of synaptic connections. Repeated treatments lead to a reduction in central sensitization.

[0011] In LLLT, one or more laser beams allow for the use of a carefully selected wavelength, coherently directed to specific tissue/cells, that provides energy to selectively stimulate processes in living cells. This process can help in increasing blood flow, excite cell activity and intensify inter-cell communications. Laser light has been used to effectively treat joint related musculoskeletal pain caused by illnesses including: tendonitis (back pain, knee tendonitis, hand tendonitis, Achilles tendonitis); tennis elbow; carpel-tunnel; arthritis; osteoporosis; plantar fasciitis; and tissue healing from sports injuries and bursitis.

[0012] LLLT can also comprise a specific type called "non-invasive laser acupuncture" comprising the application of low intensity laser radiation (i.e., non-thermal intensities) to classical meridian points or trigger points. Recent scientific studies have demonstrated the therapeutic efficacy of treating the following disorders with non-invasive laser acupuncture: myofascial pain (power is greater than 10 mW, and a dosage of 0.5 Joules per point); post-operative nausea and vomiting (power is greater than 10 mW and a dosage of

0.3 Joules per point); and chronic tension and headaches (see Baxter, G D et al. *Clinical Effectiveness of Laser Acupuncture*: A Systematic Review. J Acupunct Meridian Stud 2008; 1(2): 65-82).

[0013] Until now, the industry has been using either invasive drugs or large expensive laser machines where patients need to be treated clinically with nurse supervision, causing inconvenience and repetitive expenses. More recent inventions comprise hand-held LLLT devices that require the user to treat themselves. These devices for use at home do not deliver clinical strength accuracy or therapeutic efficacy; and they are highly inconvenient because of the lack of device ergonomics and the nature of treatment makes it difficult for the user to apply the device to the user's body in hard to reach areas. Consequently, current solutions available today are comparatively less effective than the present invention of LLLT wraps that are able to encircle and stay in position on a user's body without the user having to hold the device in position during the treatment.

[0014] And these prior art hand held LLLT devices do not accurately provide the required treatment power density in joules/cm^2, due to the following factors. 1. The prior art devices do not treat below the skin surface, whereas the present invention provides both surface and deep tissue treatment options and laser light doses. 2. The prior art devices do not provide a targeted dose at a magnitude equivalent to a LLLT device in a clinical facility, and neither are they pre-calibrated for a specific disorder—e.g. arthritis versus acute injury. 3. Due to the inherent nature of handhelds, the user must hold the device over the target area with a constant pressure for up to 10 minutes duration, which is physically difficult to do; but the present invention's wraps are hands free devices. 4. Current solutions are complex and most handhelds are inconvenient and uncomfortable to use due to the hard edges on the skin surface contact areas, thus making them less efficient because they do not conform to the body contour, thus easily missing the target areas, especially when self-treated by patient at home. 5. As evidenced by laser acupuncture, the laser dosage needs to be applied at an exact location, and for the doctor recommended duration, for the patient to realize the therapeutic benefits; and the present invention delivers this with precision due to the wearable, hands free, wrap with specifically positioned laser diodes that are preprogrammed to emit a clinical strength dosage.

Other Portable Phototherapy Devices

[0015] The prior art discloses a few portable, phototherapy devices, such as United States Published Patent Application No. 2008/0255640, filed L by Kipp et al., which discloses a portable phototherapy device for treating skin conditions that is packable and can treat various parts of the body. However, Kipp et al. discloses a device that is rigid, uses an ultraviolet blub, and has only one setting. Kipp et al. does not disclose a flexible and pre-programmable phototherapy device.

[0016] Also, US Published Patent Application No. 20110144727, filed by Mellen-Thomas Benedict, claims a device for all solutions to use on all body parts, but it does not solve or alleviate the symptoms of any particular malaise, nor does it show sufficient therapeutic efficacy as compared to the LLLT device of the present invention

[0017] Similarly, also in the field of portable phototherapy devices, U.S. Pat. No. 6,312,451 B1, filed by Jackson Streeter, discloses a low-level laser therapy apparatus that treats many conditions, but it does not provide the modality for home self-care for patients to use at their convenience in their home, and is it complicated to use and requires a mandatory clinician to treat the patient.

[0018] Typically, persons wishing to benefit from phototherapy must go to a spa or a professional health provider/clinic. This is because the phototherapy devices currently available are complicated-to-use and bulky and large. Additionally, until recently, a professional was needed to program and monitor a phototherapy session because optimal parameters, such as wavelength range, relative distribution of the wavelengths within the range (spectrum), time interval for continuous exposure, time interval between two continuous exposures, time rate of energy delivered, accumulated energy density for exposures, and body component(s) irradiated, were not yet available. Now, many of the optimal parameters are better understood. For example, U.S. Pat. No. 6,524,329, issued to Mellen-Thomas Benedict discloses a method of illuminating body components that provides some beneficial treatment.

[0019] Still, the complexity of the current laser devices that are used for self-treatment, the inherent in-efficacy of the devices, the dependence on another individual for treatments, and the huge costs to purchase, has made it prohibitive to enable over-the-counter home self-care for patients suffering from joint pain and inflammation.

[0020] Thus, there is a need to provide a LLLT device with pre-programmed clinical strength doses, completely portable with a battery powered, wirelessly enabled, electrical circuit embedded within an orthopedic wrap-brace to treat pain in a human while providing joint support. It should be pre-calibrated to treat a specific joint for optimal pain relief and/or inflammation reduction, and able to be operated as the user engages in their normal routine. The present invention provides a LLLT wrap-brace device with these features due to the specific ergonomic fit of the wrap-brace, as well as the accuracy of the LLLT treatment delivery method to the injured area, thus bringing the clinic to the home and making it incredibly simple to use and treat the hard to reach joint pains.

SUMMARY OF THE INVENTION

[0021] The present invention comprises various types of low level laser therapy (LLLT) wrap devices, each designed to fit around a specific anatomical area of a human body (e.g. neck and shoulders, knee, foot and ankle, back, wrist, and elbow), and their method of use, for the treatment of pain and inflammation and to promote tissue regeneration in a human. Each LLLT wrap device is lightweight, hands-free (once in position on the user's body and activated), and completely portable so that the user may wear the wrap while continuing their normal routine. And each LLLT wrap device is pre-calibrated to deliver a clinical strength dosage of infrared and/or near infrared (e.g. red) light in the wavelength from 630 nm to 904 nm that is specific to the medical disorder and/or the user anatomical body part. In an embodiment, all of the laser diodes are of the same type and the user merely activates the device. In another embodiment, the user selects a type of treatment (deep pain versus surface pain) and then activates the power to the laser diodes.

[0022] LLLT Wrap Shape and Components:

[0023] The various types of LLLT wrap device of the present invention comprise a LLLT wrap shaped for encircling a particular area of a user's body, such as: arm; leg; hand; low back; knee; ankle-foot; hand-wrist; neck-upper back-shoulders; and elbow-forearm. But, it is noted that the present disclosure covers a LLLT wrap of any shape for use in relieving pain and/or inflammation associated with a musculoskeletal injury and/or medical condition in a human.

[0024] And the wrap device may comprise a variety of types of materials (e.g. rubber/neoprene/cloth/resin) to make it flexible to wrap tightly round a user's body, while providing enough stiffness to provide structural support so the wrap can also function as an orthopedic support brace. When the wrap device is in place on the user, the laser diodes are automatically positioned over the target areas to be treated, and thus resulting in a significant therapeutic treatment modality. Thus, in another embodiment, the present invention comprises a LLLT wrap device for delivering non-invasive laser acupuncture by delivering targeted laser beams to acupuncture meridian points and/or trigger points in a user's body and at a sufficient power and dose to be therapeutically effective against the disorder being treated. For example, in the knee wrap, acupuncture laser treatment is delivered to various points surrounding the patella (medial, lateral, proximal, distal, posterior, and anterior).

[0025] Each device is also a unisex wrap that comes with different sizes (S/M/L/XL) to fit all user-patients; and a fixation means for attaching the wrap securely to the user's body (e.g. Velcro-like straps, hooks, snaps, etc.).

[0026] Portable:

[0027] The various embodiments of the LLLT wrap of the present invention further comprise a lightweight (e.g. 150-200 g) and completely portable device due to an embedded electrical circuit comprising: a rechargeable and replaceable battery; a central processing unit; a wireless transceiver; a display for inputting commands; a power switch for automatic shutoff; a plurality of sensors (e.g. laser safety sensors, and/or patient monitoring sensors); and a plurality of laser diodes.

[0028] Laser Diodes:

[0029] The present invention comprises two primary embodiments of laser diodes with each type of LLLT wrap device: 1) all of the laser diodes are of the same type and/or emit the same dose; and 2) two different types of laser diodes are within the wrap to emit either skin surface treatment, or deep surface treatment.

[0030] In the first embodiment, each type of LLLT wrap device comprises a plurality of the same type of laser diode, evenly spaced over the treated area (in front and back, or completely encircling, or only covering the top of), wherein each laser diode emits electromagnetic energy (pulsed or continuously) in wavelengths ranging from 630 nm to 904 nm wavelength, with a mean power output during the total treatment of laser energy dosage from about 1 joule/treatment point to about 20 joules/treatment point. The actual power emittance of the laser diodes is pre-programmed to deliver a dose prescribed by clinicians for a specific body part and/or medical condition, and then to automatically shut-off after the prescribed dose is emitted.

[0031] In the second embodiment, the user selects from the mobile app on their smartphone or on the LLLT device display whether to receive treatment for surface pain or deep tissue pain. Hence, the LLLT wrap device comprises a plurality of two different types of laser diodes, one type for treating surface pain (i.e. by emitting electromagnetic energy in the 630 nm to 670 nm wavelength with red light visible lasers), and one type for treating deep tissue pain (i.e. by emitting in the 780 nm to 904 nm which are known as infrared-invisible wavelength emitters). The two types of laser diodes are co-located, or are located on the LLLT wrap at separate locations specific to the treatment protocol (e.g. per FIG. **10**), such as in line with acupuncture meridian points or trigger points.

[0032] Medical Disorder:

[0033] The LLLT wrap devices are pre-programmed to treat a specific user anatomical body part (e.g. knee, low or upper back, neck and shoulders, wrist, elbow, foot-ankle, etc.) and/or to provide pain relief, inflammation reduction, and/or tissue regeneration for a specific medical condition, such as by way of non-limiting examples: tendonitis (back pain, knee tendonitis, hand tendonitis, Achilles tendonitis); tennis elbow; carpel-tunnel; arthritis; osteoporosis; plantar fasciitis; and tissue healing from sports injuries and bursitis. The pre-programmed dose comprises a set amount of energy density, duration, and intensity to be delivered to specific points on the user's body, and then the device automatically shuts-off. The pre-programmed dose is computed from medical research shown to provide the most beneficial therapeutic outcome for using LLLT and/or non-invasive laser acupuncture therapy.

[0034] LLLT Wrap System:

[0035] Each type of LLLT wrap device may further comprise a computer program product (e.g. mobile application) of the present invention installed on a user electronic computing device (e.g. smartphone, laptop, tablet, etc.) for transmitting and receiving patient data, treatment protocols and history of treatments, etc. to produce a LLLT wrap system. In an embodiment, the mobile application automatically syncs (pairs) with the LLLT wrap via a Bluetooth chip in both the user's device and the wrap's transceiver unit, and is thus able to transmit treatment and sensor data from the wrap device to the user's electronic computing device, and/or user operating commands from the user device to the wrap. The mobile application also enables the transmission from the LLLT device to the user's electronic computing device of one or more of the following: user self-reported pain data that they input into the LLLT device display; patient monitoring and sensor data (e.g. blood pressure, body temperature, etc.); history of LLLT device usage; etc. This data can also be wirelessly transmitted from the mobile application to cloud storage.

[0036] Therapeutic Effect:

[0037] The LLLT wrap devices of the present invention produce beneficial clinical effects in the treatment of pain and/or inflammation and/or to promote tissue regeneration for musculoskeletal, neurological and soft tissue conditions, while being non-invasive and avoiding the potential side effects of drug therapy. More specifically, each type of LLLT wrap device of the present invention delivers photons to targeted tissue, penetrating the layers of the user's skin to reach internal tissues to produce a specific, non-thermal photochemical effect at the cellular level. Pain associated with medical disorders treatable using the LLLT wrap device comprises, by way of non-limiting examples, pain associated with: tendonitis of the back, knee, hand, and Achilles tendon; tennis elbow; carpel-tunnel; arthritis (rheumatoid and osteoarthritis); osteoporosis; plantar fasciitis; bursitis; muscle and/or tissue inflammation and damage from acute and chronic injuries.

[0038] In particular, the analgesic effects from each treatment with the LLLT wrap device lasts for about 48 hours. There is also significant reduction of inflammation equal to or better than non-steroidal anti-inflammatory drugs (NSAIDs) within 2-12 hours of treatment. And the healing time of chronic tendinopathies is reduced by about 70%. And there are no adverse side effects from the treatments. In one embodiment, optimal pain relief is achieved with a plurality of treatments, such as the recommended treatments of 5-10 times a week for a period of 5-12 minutes per session is applied, depending on the joint being treated.

Method of Use

[0039] Usage: Each type of LLLT wrap device is pre-calibrated for the amount of dosage it emits (e.g. duration, power, etc.) using specifically required laser wavelengths (nM) to achieve the desired tissue penetration depth for optimal treatment. Due to the "pre-calibration", the patient merely places the specific type of LLLT wrap device over or around their afflicted anatomical area, turns on the power button, and the device treats the area by delivering the optimum number of photons required for the type of joint or anatomical area and/or the type of medical disorder. The same power button acts as the "Pause-Restart" button if required, such as if the user needs to take a break. The device shuts-off automatically after the programmed pre-determined and calibrated treatment time is achieved. In one embodiment, depending on the joint being treated, the self-care treatment is most accurate for optimal pain relief when recommended treatments of 5-10 times a week for a period of 5-12 minutes per session is applied.

[0040] These pre-programmed treatment protocols provide for proven optimal healing and pain-relief at home or work. The LLLT laser wrap device allows patients to treat the hard-to-reach target areas that cause joint pains. Furthermore, each type of pre-programmed, calibrated LLLT wrap device ensures optimal accuracy of the treatments to the afflicted areas without a clinician's assistance, thus making it a simple to use outside of a clinical facility.

[0041] During and/or after each treatment session, the LLLT wrap device wirelessly transmits the user's history of treatment sessions, self-reported pain measurement levels, pain medication intake, device's patient monitoring sensor data (e.g. vital signs data, such as by way of non-limiting examples: blood pressure, body temperature, etc.) to one or more of the following: the user electronic computing device, cloud server, or clinician's computer.

[0042] In one embodiment, the method of use of the LLLT wrap device comprises the following steps: the user cleans the anatomical area so that their skin is conducive to treatment; the user inputs their selection of the type of treatment (i.e. treating skin surface pain, or deep pain requiring penetration of the laser light into the tissue) on their mobile device display, or on the LLLT device display; the user adjusts the laser diodes power output to their comfort level (e.g. one-third, one-half, or one hundred percent of the maximum power output) and pushes the power button; the LLLT wrap device emits a pre-calibrated does of irradiation based on the type of wrap (knee, neck, etc.) and/or the medical condition, after which it automatically shuts off. The user can pause the LLLT wrap device at any time to attend to other things and resume until completion of treatment. Before, during, or after treatment, the user can input into the mobile application on their electronic computing device, or the LLLT wrap device display, their pain level and/or their consumed pain medication.

[0043] In summary, the various type of LLLT wrap devices disclosed herein enable patients to have an affordable, hands-free, easy-to-use, clinical strength, pre-calibrated, worry-free, pain-relief medical device for use at home, with the added ability to track the patient's vital signs data through monitoring sensors embedded in the devices. Thus, the LLLT wrap devices of the present invention enable self-care, allow loved ones to monitor the patients on their mobile phones, and empower the patient to improve their lives tremendously. This invention is also a portable, hands-free and wearable LLLT wrap, as well as an orthopedic support brace, that provides a pre-calibrated laser energy power dosage (e.g. within the range of 5 mW-500 mW) that is administered automatically, for specific durations and treatment depth, to the specific desired area. This targeted treatment ensures maximum therapeutic efficacy through ergonomic fit so as to effectively treat the specific joints and thus provide optimal joint-pain relief. It also saves the user time and money by not having to commute to a clinician's office for treatment, and pay for the clinician's services.

BRIEF DESCRIPTION OF THE DRAWINGS

[0044] The above and other features, aspects, and advantages of the present invention will become better understood with regard to the following description, appended claims, and accompanying drawings where:

[0045] FIG. **1**A is a sectional view of an open wide belt (**1**) for treating a variety of body areas (e.g. neck, bicep, calf, quadricep, etc.) containing multiple lighted lasers (**2**) with a Velcro-like system (**3**) to hold the belt in place.

[0046] FIG. **1**B is a sectional view of a closed belt (**1**) containing multiple lighted lasers (**2**) with a Velcro-like system (**3**) holding the belt in place.

[0047] FIG. **2** is a sectional view of an open wide belt (**1**) containing multiple lighted lasers (**2**) with a Velcro-like system (**3**) where subject (**4**) is about to wear the belt for treating low back pain.

[0048] FIG. **3** is a sectional view of a closed belt (**1**) containing multiple lighted lasers (**2**) with a Velcro-like system (**3**) where subject (**4**) has strapped the belt in place around his waist (**5**)

[0049] FIG. **4**A is a sectional view of an open wide Knee Wrap (**6**) containing multiple lighted lasers (**7**) with a Velcro-like system (**8**).

[0050] FIG. **4**B is a sectional view of a closed wide Knee Wrap (**6**) containing multiple lighted lasers (**7**) with a Velcro-like system (**8**) holding the closed secure fit.

[0051] FIG. **4**C is a sectional view of an open wide Knee Wrap (**6**) containing multiple lighted lasers (**7**) with a Velcro-like system (**8**) being applied on the user's Knee (**9**).

[0052] FIG. **4**D is a sectional view of a closed wide Knee Wrap (**6**) containing multiple lighted lasers (**7**) with a Velcro-like system (**8**) showing the closed secure fit on user's Knee (**9**).

[0053] FIG. **5**A is a sectional view of a closed Ankle Wrap (**10**) containing multiple lighted lasers (**11**) with a Velcro-like system (**12**) showcasing a secure fit.

[0054] FIG. **5**B is a sectional view of a closed Ankle Wrap (**10**) containing multiple lighted lasers (**11**) with a Velcro-like system (**12**) showcasing a secure fit around the user's ankle (**13**).

[0055] FIG. 6A is a sectional view of an open Hand Wrap (14) containing multiple lighted lasers (15) with a Velcro-like system (16) used to secure the hand wrap (14).

[0056] FIG. 6B is a sectional view of a closed Hand Wrap (14) containing multiple lighted lasers (15) with a Velcro-like system (16) showing the securely closed hand wrap (14).

[0057] FIG. 6C is a sectional view of an open Hand Wrap (14) containing multiple lighted lasers (15) with a Velcro-like system (16) where the user is about to wrap it around their hand (17).

[0058] FIG. 6D is a sectional view of a closed Hand Wrap (14) containing multiple lighted lasers (15) with a Velcro-like system (16) showing the Hand Wrap (14) securely fastened on the user's hand (17).

[0059] FIG. 7A is a sectional view of an open Neck & Shoulder Brace Wrap (18) containing multiple lighted lasers (19) with a Velcro-like belt system (20).

[0060] FIG. 7B is a sectional back view of a closed Neck & Shoulder Brace Wrap (18) containing multiple lighted lasers (19) with a Velcro-like belt system (20) used to securely wrap the shoulder brace around the user's shoulders (21).

[0061] FIG. 8A is a sectional view of an open Elbow Brace Wrap (22) containing multiple lighted lasers (23) with a Velcro-like wrap & belt system (24) showcasing the secure fit.

[0062] FIG. 8B is a sectional view of a closed Elbow Brace Wrap (22) of FIG. 8A shown being worn securely on subject's elbow (25).

[0063] FIG. 9 a schematic diagram of an exemplary electrical circuit embedded within each LLLT wrap device that is used to power the device and wirelessly transmit user data to a mobile application installed on a user electronic computing device.

[0064] FIG. 10 is top perspective view of a knee LLLT wrap device unfolded, and comprising two sets of dual lasers: surface diodes emitting red light between 630-670 nm, and deep penetration laser diodes emitting infrared light between 780-904 nm.

[0065] FIG. 11 is a flowchart of the method of use of the LLLT wrap device and the mobile application synced with the LLLT wrap device.

[0066] FIG. 12 is a schematic block diagram of a user electronic computing device for use with the mobile application of FIG. 11 and having the mobile application of the present invention installed thereon.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Types of LLLT Wrap Devices

[0067] The present invention includes the following exemplary types of LLLT wrap devices listed below: low back; knee; ankle-foot; hand-wrist; neck-shoulder; and elbow.

[0068] Low Back LLLT Wrap:

[0069] LW-Back-1000-Laser-wrap device (FIG. 1A, 1B, 2, 3; item 1) placed on the human upper or lower back (FIG. 2, 3; item 4)—for treating musculoskeletal back pain associated with arthritis, osteoporosis, muscle strain-sprain, etc. In the embodiments exemplified in FIGS. 1A, 1B, 2, 3, each hand-wrist LLLT wrap device 1 further comprises: a plurality of evenly spaced laser diodes 2; a Velcro-like member or tab 3 on both opposing ends of the device to affix the device to the user's low back; and an embedded portable electrical circuit not shown (e.g. FIG. 9, 90).

[0070] Knee LLLT Wrap:

[0071] LW-Knee-1000-Laser-wrap (FIGS. 4A-4D; item 6) for the human knee (FIGS. 4C, 4D; item 9)—for treating musculoskeletal knee pain associated with arthritis (rheumatoid and/or osteoarthritis), osteoporosis, muscle strain-sprain, and acute and chronic injuries to the various tendons and ligaments, bone, and cartilage of the knee. In the embodiments exemplified in FIGS. 4A-4D, each knee LLLT wrap device 6 further comprises: a plurality of evenly spaced laser diodes 7 that cover the right and left and back side of the knee, and a single row around a circular opening for the patella-kneecap; a plurality (e.g. three) Velcro-like tabs 8 on parallel extensions of the device to affix the device to the user's knee above, below and behind the knee joint; and an embedded portable electrical circuit not shown (e.g. FIG. 9, 90).

[0072] Ankle-Foot LLLT Wrap:

[0073] LW-Ankle & Foot-1000 Laser-wrap (FIGS. 5A, 5B; item 10) for the human foot/ankle (FIG. 5B, item 13)—for treating pain associated with ankle and/or foot pain, such as plantar fasciitis, neuropathology (e.g. associated with diabetes), ankle or foot muscle sprains-strains, etc. In the embodiments exemplified in FIGS. 5A and 5B, each LLLT wrap device 10 further comprises: a plurality of evenly spaced laser diodes 11 covering the foot (FIG. 5A) and covering the ankle (not shown FIG. 5B); rectangular-shaped strips encircling the foot arch (which may further comprise laser diodes 11); a plurality (e.g. at least two) Velcro-like tabs 12 on the ends of the strips that wrap around the ankle; and an embedded portable electrical circuit not shown (e.g. FIG. 9, 90).

[0074] Hand-Wrist LLLT Wrap:

[0075] LW-Wrist-1000-Laser-wrap device (FIGS. 6A-6D; item 14) for the human hand-wrist (FIGS. 6C, 6D; item 17)—for treating joint pain associated with carpel tunnel, hand and/or wrist sprains, etc. In one embodiment exemplified in FIGS. 6A-6D, each hand-wrist LLLT wrap device further comprises: a plurality of evenly spaced laser diodes 15; a Velcro-like tab 16 on both opposing ends of the device to affix the device to the hand; a thumb hole to slip the device over; and an embedded portable electrical circuit (not shown) (e.g. FIG. 9, 90).

[0076] Neck-Shoulder LLLT Wrap:

[0077] LW-Neck & Shoulder-1000 Laser-wrap (FIGS. 7A, 7B; item 18) for the human neck/shoulder (FIG. 7B; item 21) for treating pain in the user's neck and/or shoulders. In one embodiment exemplified in FIGS. 7A and 7B, each neck-shoulder LLLT wrap device 18 further comprises: a plurality of evenly spaced laser diodes 19 on the inner (i.e. skin side) collar and the inner upper back and shoulder area; a Velcro-like tab 20 on both opposing ends of the device straps that wrap from the bottom of the back side of the wrap under the armpits and affixing to the front outer surface of the LLLT wrap device; and an embedded portable electrical circuit not shown (FIG. 9, 90).

[0078] Elbow LLLT Wrap:

[0079] LW-Elbow-1000 Laser-wrap (FIGS. 8A, 8B; item 22) for the human elbow of arm 25 for treating elbow joint pain, such as associated with arthritis, bursitis, tennis elbow, etc. In one embodiment exemplified in FIGS. 8A and 8B, each elbow LLLT wrap device further comprises: a plurality of evenly spaced laser diodes **23** on the inner (i.e. skin side); a Velcro-like tab **24** on both opposing ends of the device straps for securing each end of the wrap around the user's arm—one upper arm strap and one forearm strap; a center hole for the encircling the elbow; and an embedded portable electrical circuit (not shown)(FIG. **9**, **90**).

[0080] It is further appreciated that the laser diodes shown in FIGS. **1A-8B** could readily be replaced with various configurations of surface and deep tissue laser diodes by one of skill in the art, and as exemplified in the knee wrap of FIG. **10**.

Electrical Circuit

[0081] FIG. **9** is a block diagram of an exemplary electrical circuit **90** embedded in the wrap-brace of the present invention. Each type of wrap device is embedded with an electrical circuit that is pre-programmed to treatment disorders associated with the particular joint or body part that the type of wrap device covers. Therefore, each type of wrap is pre-programmed to emit irradiation at a set dose (intensity and duration) and to automatically turn off when the dose is completely administered.

[0082] The present invention is a battery powered and the battery can be recharged using a 230/110V charger that will be provided in the LLLT wrap system. The battery may also be replaceable by the user or manufacturer. All LLLT wrap device components, including the printed circuit board (PCB), the battery, the display unit, and controller, are positioned ergonomically and fixed (e.g. sewn, glued, etc.) into the orthopedic wraps to make a sleek form-fitting design that is comfortable to wear by the patient, easily hidden beneath their clothing, while maintaining the treatment efficacy of using the device.

[0083] As illustrated, the printed circuit board (PCB) comprises electrical circuit **90** with the following components: a computer memory module/chip **91**; a microprocessor or controller **92**; a portable power source (battery) **93**; a display or graphical user interface (GUI) **94**; a power switch **95**; a wireless data transceiver, or transmitter, or receiver unit **96**; and a plurality of laser diodes **97**.

[0084] Sensors: The wraps may further comprise various types of sensors **98**, **99** embedded within the LLLT wrap device that are connected to the electrical circuit **90**, thus powered by the power source **93** and transmitting data wirelessly via unit **96**. And/or, at least one type of sensor embedded within the LLLT wrap device is powered by and/or wirelessly transmitting-receiving data independently from the electrical circuit **90** via circuity connected to and/or within the sensor. By way of non-limiting example, various types of sensors within the LLLT wrap comprise: at least one laser safety-irradiation sensor **98**; and/or at least one patient monitoring sensor **99** (see infra).

[0085] The computer memory **91** stores pre-calibrated, pre-programmed treatment protocols comprising doses of irradiation (duration and intensity) for at least one protocol, such as surface and/or deep penetration session suitable for the type of wrap, body part, and disorder being treated. It may further record the number of times each type of treatment has been completed by the user. The record may further comprise a time stamp of the date and time of day of the treatment completion. This data may be wirelessly transmitted to the user's electronic computing device, cloud storage, clinician's computer storage, etc.

[0086] The microcontroller or processor **92** executes one of the stored programs at a time.

[0087] In the exemplified embodiment, the portable power source **93** is a re-chargeable battery (e.g. nickel cadmium battery), that supplies power to the entire electrical circuit **90** and thus enables the wrap to be completely portable. The user is thus able to continue their normal routine while undergoing treatment.

[0088] The display or graphical user interface (GUI) **94** displays the selection of treatment protocols and user instructions, and receives user input for selecting the desired protocol (e.g. surface treatment versus deep penetration treatment). Display **94** may also display a clock-timer that counts up or down the pre-programmed treatment duration.

[0089] The power switch **95**, or switched mode power supply (SMPS), comprises an automatic shut-off mode of power to the lasers when the treatment session is complete, and/or when the sensors indicate a safety alert. The power switch **95** may further emit a sound (e.g. beep) to indicate a power state. For example, a single short duration beep indicates that the power has been turned on in the LLLT wrap; two beeps indicate the end of a treatment session; and a single long duration beep is emitted when a treatment session is activated or in pause mode.

[0090] The wireless transmitter or a transmitter/receiver unit **96** sends, and/or sends and receives, data from the wrap electrical circuit **90**. All modes of data transmission are wireless, thus unit **96** comprises a WiFi enabled unit for internet transmissions to any location (e.g. a remote doctor's office computer), and/or a paired short range radio frequency transmission to a co-located user's electronic computing device (e.g. smartphone with mobile application of the present invention installed thereon). In one exemplified embodiment, unit **96** comprises a Bluetooth chip paired with a Bluetooth chip in a user's electronic computing device, but other wireless transceiver units are readily apparent to the skilled artisan.

Laser Diodes

[0091] The present invention comprises two primary embodiments of laser diodes with each type of LLLT wrap device: 1) all of the laser diodes are of the same type and/or emit the same dose; and 2) two different types of laser diodes are within the wrap to emit either skin surface treatment, or deep surface treatment, depending on the treatment protocol that the user selects.

[0092] When the LLLT wrap device is in-place on a user's body, each laser diode **97** should be aligned to emit a beam substantially perpendicular in to a user's skin surface. The depth of penetration of the beam is dependent upon the type of treatment the user selected (surface pain treatment or deep pain treatment). Each type of LLLT wrap device is specifically designed so that a plurality of irradiation beams enter the user's skin at anatomical locations pre-determined by clinicians and medical research to optimally treat a user's condition (i.e. optimal treatment as defined herein refers to the most therapeutic effective outcome for the reduction of a user's pain, inflammation, etc.) and is due to the location of the laser diodes **97**, their level of emittance-intensity and duration, and thus the total dose of irradiation delivered at the afflicted anatomical site.

[0093] In one embodiment, each type of LLLT wrap device comprises a plurality of the same type of laser diode, evenly spaced over the treated area (in front and back, right and left side, or completely encircling, or only covering the top of), wherein each laser diode emits between 630 nm to 904 nm wavelengths, with a mean power output during the total treatment of laser energy dosage from about 1 joule/treatment per point to about 20 joules/treatment per point. The actual power emittance of the laser diodes is pre-programmed in to deliver a dose prescribed by clinicians for a specific body part and/or medical condition and then to automatically shut-off.

[0094] In another embodiment, as illustrated in the knee LLLT wrap device **100** of FIG. **10**, the user selects whether to receive treatment for surface pain or deep tissue pain. Hence, the LLLT wrap device comprises a plurality of two different types of laser diodes, one type **102** for treating surface pain (i.e. by emitting in the 630 nm-670 nm for which are known as red light visible lasers diodes **102**), and one type **104** for treating deep tissue pain (i.e. by emitting in the 780 nm-900 nm which are known as infrared laser diodes **104**, or invisible wavelength emitters). The two types of laser diodes are co-located, or are located on the wrap at separate locations specific to the treatment protocol. For example, the knee LLLT wrap device **100** of FIG. **10** comprises two sets of four red light emitters diodes **102** for treating surface pain that are arranged within two sets of five infrared laser diodes **104**. The two sets of surface diodes **102** and deep penetrating diodes **104** can be arranged on the knee wrap **100** to be situated medial-lateral, or anterior-posterior.

[0095] The knee wrap **100** further comprises a substantially rectangular shaped member that the diodes **102**, **104** are directly attached to. The rectangular member further resides on a substantially larger rectangular member with a semi-circular cutout **110** for the user's patella to not be covered when the wrap **100** in positioned on the user. Furthermore, one strap **112** extends from both opposing sides of the cutout **110** to wrap around the user's knee—one around the femur-lower thigh and one around the tibia-upper calf. To keep the knee wrap device **100** in position on the user's knee, the wrap **100** further comprises a plurality of fixation members, such as Velcro-like material **114** attached to the rectangular members and to straps **112** (e.g. FIG. **10**, Velcro is depicted as dotted patterns).

[0096] A variety of different types of laser diodes **97** may be used within the LLLT wrap device, e.g. continuous emission or pulsed emission. Table 1, infra, provides a disclosure on the requirements for any type of laser diode used in the present invention, such as: up to 200 mW in micro-pulses or continuous emission, and energy density of 0.9-20 joules per minute per centimeter**2; a peak energy emittance per minute of 14/4 joules over the entire afflicted skin area being treated; a coherent beam—meaning that the dose emitted is equal over the cross-sectional area of the laser diode

[0097] For example, surface pain treatment may comprise, for example, a plurality of Mitsubishi® laser diode type ML101J23, that emit 658 nm of visible light, with a high-power output 30 mW pulsed. And deep pain treatment may comprise, for example, a plurality of QL80R4S-A/B/D/C/D/E-Z5 laser diodes manufactured by Quantum Semiconductor International Co., Ltd®; and each diode emits 808 nm infrared light wavelength, with an optical output power of 200 mW. It is noted that one of skill in the art would readily know of the type of laser diodes to use with the various LLLT wrap devices disclosed herein.

[0098] Pre-Calibration of Dose:

[0099] In either embodiment, it is not the total number of joules delivered at a certain skin depth that is important. Instead, the important parameter is the energy density; that is, energy per unit area, more commonly called dose with units of J/cm2. Stated otherwise, the "Energy Density" calculation comprises: power density in units of Watts/cm2 multiplied by treatment time in seconds yields dose in units of Joules/cm2. This is the energy deposited per area of irradiated tissue.

[0100] From the depth dose profile, a distinct version of which is necessary for each wavelength, frequency, and power setting as well as for every type of material through which the laser beam will penetrate (skin, bone, soft tissue, fat, etc.), the LLLT wrap electric circuit is pre-programmed to output the intensity and the power density across a desired area. From the power density at a given tissue depth, the dose can be computed: e.g., power density in units of Watts/cm2 multiplied by treatment time in seconds yields dose in units of Joules/cm2.

[0101] An exemplary computation of the dosage and total energy (Joules) for a surface treatment versus a deep tissue treatment for a LLLT knee wrap device comprises:

TOTAL ENERGY (J)=Average Power (Watts)×Time (sec)

Surface Treatment

[0102] 8 diodes at 5 MW=40 mW of total power

[0103] Total joules provided to treatment area (Joules=power in MW*Time)

[0104] 10 Joules=0.04 W (40 mW)×250 secs (4.1 minutes)

Deep Tissue Treatment

[0105] 10 diodes of 30 MW=300 MW of total power

[0106] Total joules provided to treatment area (Joules=power in MW*Time)

[0107] 10 Joules=0.3 W (300 MW)×30 secs (½ min)

Energy Density (J/cm^2)=Total amount of energy (J)/Irradiation area (cm^2)

Example energy density=10 J/80 cm^2 (treatment area)=0.125 joules/cm^2

Wrap Sensors

[0108] Sensors:

[0109] The wraps may further comprise various types of sensors embedded within the LLLT wrap device, such as: at least one laser safety-irradiation sensor **98**; and/or at least one patient monitoring sensor **99**.

[0110] Safety-Irradiation Sensors:

[0111] One or more different types of safety-irradiation sensor **98** may be embedded within the LLLT wrap, such as: a sensor to monitor the amount of laser irradiation dosage being emitted; and/or a sensor to prevent the over-heating of the laser diodes such that the diodes are at risk of being damaged and/or burning the user's skin; and/or a proximity sensor to prevent the laser diodes **97** from turning on unless an object (e.g. a user's skin) is within a fixed distance from the diodes **97** (e.g. about 1 inch or less).

[0112] If an unsafe situation occurs, sensor **98** may send an electric signal to the power switch **95** to automatically shut-off the laser diodes **97**. Alternatively, or additionally, sensors **98** may display a safety alert on the wrap display **94**, and/or wirelessly transmit via the electric circuit wireless transmitter unit **96** an electronic message to be displayed on a user electronic computing device. It is further noted that the safety sensor features may be built into the laser diodes **97**, or separate from the laser diodes **97** but powered by the electrical circuit **90**, or having their own source of power and/or wireless transceiver while still being embedded within the LLLT wrap.

[0113] User-Patient Monitoring Sensors:

[0114] The wrap may further comprise sensors **99** embedded in the wrap for monitoring a user's vital signs and wirelessly transmitting the data to the user's electronic computing device, cloud storage, doctor's office computer, etc. Sensor **99** is positioned within the wrap to be in contact with the user's skin when the wrap is in position for treatment. The wrap may comprise more than one type of sensor **99**, with each measuring one or more different vital signs. The anatomical position of the wrap may determine which user vital functions are monitored (e.g. a neck-back wrap can be used to monitor pulmonary and cardiovascular conditions; and a knee wrap can be used to monitor neurological conditions). And/or the sensor **99** can measure a vital sign no matter the anatomical location of the wrap, such as user body temperature, heart rate, blood pressure, etc.

[0115] In one embodiment, sensor **99** may comprise a patch (e.g. Healthpatch Biosensor manufactured by Vital Connect®) embedded in the wrap to monitor the user's biometric data and wirelessly transmit the data via the electrical circuit **90** wireless unit **96**. Biometric data comprises, for example, one or more of: pulmonary (respiratory rate), neurologic (gait analysis, fall detection/severity), cardiovascular (heart rate variability, heart rate, single-lead ECG, contextual heart rate), and other (step count, posture, body temperature, summarized activity, energy expenditure, stress).

[0116] And in another or additional embodiment, sensor **99** may comprise a biosensor tattoo (e.g. Laboratory of Nanobioelectronics by Prof. Wang) imprinted into the skin side surface of a wrap that is able to monitor a user's biometric data, e.g. via the user's sweat, pulse, etc., and wirelessly transmit the data via the electrical circuit **90** wireless unit **96**. Biometric data comprises, for example, one or more of: metabolite levels, electrolytes, ammonia, sodium, lactate levels and pH, etc. to measure a user's level of physical activity, and/or a medical condition: glucose level for diabetes, etc.

[0117] In another embodiment, sensor **99** may comprise a disc shaped, metallic sensor connected to the electrical circuit **90** and able to detect a user's body temperature (e.g. MySignals™ by eHealth Medical Development); or a user's pulse rate (e.g. Arduino® sensor).

Mobile Application and Method of Use

[0118] The present invention further comprises a computer program product (e.g. a mobile application comprising a non-transitory computer-readable storage medium) installed on a user's electronic computing device (e.g. smartphone, tablet, laptop, etc.) for wirelessly receiving and displaying data from the wrap electrical circuit (e.g. sensor data, self-reported pain level and/or amount pain medication taken data, timer, etc.), and/or wirelessly transmitting commands to the wrap electrical circuit (e.g. selection of treatment protocol), for example—in order to control the power output ⅓rd, ½, or ⅔rd power.

[0119] FIG. **11** is a flowchart of steps for using the mobile application **220** of the present invention that is installed on the user electronic computing device **200** to collect user pain data and store it on a cloud account and/or a remote clinicians' computer.

[0120] As illustrated in the exemplary embodiment of FIG. **12**, a user's electronic computing device comprises the following components: a central processing unit **118**, a memory unit **120**, that stores machine instructions that when executed by the processor **118**, cause the processor **118** to perform one or more of the operations and methods described herein. Processor **118** may optionally contain a cache memory unit for the temporary local storage of instructions, data, or computer addresses. For example, using instructions retrieved from memory **120**, the processor **118** may control the reception and manipulation of input and output data between components of the user's electronic computing device. In various embodiments, the processor **118** can be implemented as a single-chip, multiple chips and/or other electrical components including one or more integrated circuits and printed circuit boards.

[0121] The processor **118** together with a suitable operating system may operate to execute instructions in the form of computer code and produce and use treatment data. By way of example and not by way of limitation, the operating system may be Windows-based, Mac-based, or Unix or Linux-based; and in particular for smartphones, the operating system comprises one of Android, iOS, and Windows Mobile among other suitable operating systems. Operating systems are generally well known and will not be described in further detail here.

[0122] Memory **120** encompasses one or more non-transitory storage mediums and generally provides a place to store computer code (e.g., software and/or firmware) and data that are used by the use electronic computing device. It may comprise, for example, electronic, optical, magnetic, or any other storage or transmission device capable of providing the processor **118** with program instructions. Memory **120** may further include a floppy disk, CD-ROM, DVD, magnetic disk, memory chip, ASIC, FPGA, EEPROM, EPROM, flash memory, optical media, or any other suitable memory from which processor **118** can read instruction, in computer programming languages.

[0123] Memory **120** may include various other tangible, non-transitory computer-readable media including Read-Only Memory (ROM) and/or Random-Access Memory (RAM). As is well known in the art, ROM acts to transfer data and instructions uni-directionally to the processor **118**, and RAM is used typically to transfer data and instructions in a bi-directional manner

[0124] Processor **118** is generally coupled to a variety of interfaces such as graphics control (e.g. graphical processing unit (GPU)), video interface, audio interface, input interface (e.g. touchscreen data input and/or keypad), and other interfaces, such as camera hardware and software components housed within the user electronic computing device for recording and transmitting, via a wireless network, digital photos, audio and video events (see FIG. **12**).

[0125] Processor **118** is also coupled to a network interface that allows the processor to be wirelessly coupled to another computer (e.g. the wrap device, or telecommunications network—e.g., WiFi network, Bluetooth chip, etc.).

More particularly, the network interface generally allows processor **118** to receive information from and to output information to the wireless network in the course of performing various method steps described in the embodiments herein by, for example, transferring data to and from one or more of the following: the wrap device, a user cloud storage account, a clinician's office computer storing patients' records, etc.

[0126] The user electronic computing device has installed within the device's memory **120** a unit comprising the mobile application **220** of the present invention, which may further comprise: a native application, a web application, or a widget type application to carry out the methods of the embodiments disclosed herein for receiving and transmitting treatment data and instructions to and from the wrap device. In a preferred embodiment, a mobile application **220** (e.g. a computer program product) is installed on the device **200** by downloading from the Internet. It may be written in a language to run on a variety of different types of use electronic computing devices; or it may be written in a device-specific computer programming language for a specific type of device.

[0127] In one embodiment, the mobile application **220** for communicating wirelessly with the wrap device (e.g. via Bluetooth chips) comprises: a non-transitory computer-readable storage medium storing instructions that, when executed by the processor **118**, cause the user electronic computing device **200** to transmit and receive data from the wrapper device **100**, by performing the steps of FIG. **11**. User selections may be input into the LLLT wrap display and transmitted wirelessly to the mobile application **220** or vice versa.

[0128] Per the method of use of the wrap device **100**: before treatment, the user cleans and dries the specific anatomical area (Back/Knee/Wrist/Ankle & Foot/Neck & Shoulder) to be treated so that the skin is conducive to treatment. Soap and water or alcohol is appropriate.

[0129] The user (optionally) utilizes the mobile app **220** to synchronize with the LLLT wrap device **100** and select the treatment protocol (red laser surface or deep tissue IR laser treatment) and the power setting for the session (⅓, ½, ⅔ or full). As illustrated in FIG. **11**, step **1120**, the user electronic computing device **200** receives the user input for activating the mobile application **220** by setting up a user account with secure login credentials, and a cloud storage option, and input further connecting the user electronic computing device **200** wirelessly with the LLLT wrap device **100** (e.g. by pairing or syncing the Bluetooth chips in the wrap with the smartphone).

[0130] The user places the LLLT wrap device **100** that is designed to fit the specific user anatomy (Small, Medium, Large) and for the specific treatment area (wraps around the user's back, knee, wrist, ankle and foot, neck and shoulder) and straps it on securely using the fixation members comprising, for example, Velcro-like tabs, straps, hooks, snaps, etc.

[0131] In step **1140**, the user electronic computing device **200** and/or the LLLT wrap display (FIG. **9**, **94**) receives the user input for their selection of a pre-programmed, pre-calibrated treatment protocol for the particular type of wrap they are using (e.g. knee, back, etc.). In an embodiment, the mobile application **220** of the present invention is universal to all types of LLLT wrap devices, therefore, the user must select which type of wrap that they are using from a plurality of listed wrap types. In another embodiment, the mobile application does not require the user to select the type of wrap, e.g. the mobile application detects the type of wrap.

[0132] The user must also select between a surface treatment session (e.g. about 630-670 nm) penetrating the skin tissue about 1 cm depth, or a deep penetration treatment session (e.g. about 780-904 nm penetrating the skin tissue about 4-5 centimeters) on the mobile application **220**, or on the LLLT wrap display **94**. If the former, then the user input is wirelessly transmitted to the LLLT microprocessor **92** via the Bluetooth chip (unit **96**), which activates the power switch **95** to "On". The laser diodes **97** then emit the pre-set treatment dose (duration and intensity), and shut off automatically at the end of the treatment session.

[0133] The user also enters their pain management data into the mobile application **220** or the display **94**. If the later, then the user electronic computing device **200** receives the pain management data wirelessly from the LLT wrap **100**. In either case, the pain management data comprises, by way of non-limiting examples: doses of pain relief medication (over-the-counter and prescription) that the user has recently taken; and user self-assessed levels of pain.

[0134] In step **1160** the treatment session is activated, and the user electronic computing device **200** receives treatment history data (e.g. duration) and sensor data wirelessly from the LLLT wrap circuit **90**, then processes and displays output on the user device GUI for the user to read before, during and after the treatment session, comprising: safety sensor **98** data (e.g. the lasers are overheating and the wrap device is shutting off); and patient sensor data **99** of the user's vital signs to ensure that they are not experiencing any adverse side effects from the treatment; and timer data (counting up or down the minutes of each treatment session; etc.).

[0135] The LLLT wrap device emits a dose for a surface or a deep tissue treatment session comprising: between 630 nM-904 nm (nanometers) irradiation wavelength, with a power density (irradiance) between 25 mw to 500 mW, generating 1-10 joules/cm2 proven (similar to clinical LLLT products) to effectively reduce inflammation and pain, induce anti-inflammatory cellular activities, induce skin rejuvenation, and/or induce cellular level healing activities. When the dose has been delivered, the LLLT wrap device automatically shuts off. Hence, each type of LLLT wrap device is pre-programmed to operate for a specific duration (e.g. up to 20 minutes, but normally 5-12 minutes) and emit a specific amount of energy density and for the specific joint and/or medical condition for maximum pain relief. The user can pause the LLLT wrap device any time to attend to other things and resume to completion. After the treatment session ends, the LLLT wrap device **100** automatically shuts off.

[0136] In step **1180**, the user data (both transmitted from the LLLT wrap device **100** and user inputted into their electronic computing device **200**) is stored on the user device's memory and/or their secure cloud storage account. And if the user desires, the data (pain, sensor, treatment sessions history) may be electronically transmitted (e.g. via email) to their clinician's computers for storage in their patient file in order to receive remote supervision by their clinician on their medical treatments using the LLLT wrap device.

[0137] In one embodiment, a data table is stored in the LLLT wrap microprocessor memory and the user electronic device memory, and the data includes an identifying code for each previous treatment (for example the date), and the associated dosage(s), treatment times, codes for treatment locations, and other treatment information from previous treatments. In one embodiment, the patent data information includes a code for specifying the level and location of the patient's pain on each previous treatment, and is inputted by the patient using the screen display on the device.

Ergonomic Fit

[0138] The various types of LLLT wrap device of the present invention are shaped for encircling or covering a particular area of a user's anatomical or body part, and may comprise a variety of shapes with different types of fixation members for attaching the wrap securely to the user's body (e.g. Velcro-like straps, hooks, snaps, etc.). Each device is also a unisex wrap that comes with different sizes (S/M/L/XL) to fit all user-patients.

[0139] Each wrap device may further comprise a variety of types of materials (e.g. rubber/neoprene/cloth/resin) to make it flexible to wrap round snuggly around a user's body while providing enough stiffness to provide structural support to function also as an orthopedic brace. The wrap devices may also include other semi-stiff components (e.g. bendable plastic or metal rod members) normally found in orthopedic flexible braces (e.g. knee sport braces). Furthermore, as an example—since the patient wears ergonomic wraps—the tight fit provides additional joint pain relief similar to the arthritic gloves available in the marketplace today.

[0140] The present invention also includes the positioning of the laser diodes **97** in the exact locations required around the afflicted body area for the most effective treatment prescribed by leading orthopedic and chiropractor and laser acupuncture practicing professionals based on extensive medical research available on LLLT for pain relief today. These laser diodes are embedded into the orthopedic wraps at these exact locations such that only their lens is visible towards the treated areas.

[0141] It is also noted that the laser wrap devices are novel in the delivery method of the solution because the clinical strength lasers are integrated within the laser orthopedic wrap device in a unique combination and configuration that provides maximum pain-relief efficacy. This is due to how the ergonomic orthopedic wrap fits the user snugly for the specific size while providing an accurate delivery of the pre-determined laser energy to the required areas. This is also done while the wrap device is functioning as a brace to provide structural support to the joint to allow the joint muscles to rest. The pre-programmed wavelength provides the injured area the necessary dosage at the proper skin depth penetration, and combined with the pre-calibrated treatment times for the specific joint area, enables the LLLT wrap device to provide a highly effective treatment regime.

TABLE 1

1. Coherence	Perfect coherence (i.e. uniform dose of laser area) all LLLT wrap devices have a coherent beam over an area as large as 1.4-4.5 cm^2 based on the joint being treated.
2. Treatment Area/Time	A very large area of 4.5 $cm^{2\ is}$ covered in each treatment area and time with one completely coherent beam. Due to this high efficiency, a smaller number of shorter treatments are required.
3. Peak power	High - up to 200 mW (a half watt) in micro-pulses or regular, which guarantees maximal penetration and effectiveness.
4. Energy density	High- average 0.9-20 joules per minute per $cm^{2.}$
5. Peak energy/minute	14.4 joules over the entire treated area. Extremely high power contributes to greater effectiveness.
6. Micro-pulses	Unlike continuous waves, micro-pulses allow the beam's power and ability to deeply penetrate to the source of the problem, thus increasing the treatment's effectiveness.
7. Weight	150-200 g - light, portable and rechargeable - ready to use anywhere at any given moment.
8. Operation methods	Wear it and turn device on by pressing the ON button. Device automatically shuts-off after predetermined treatments. Counter displays usage time and No. of usages and other metrics.
9. Historic Pain Data	User can capture pain measurement data on devices. Pain data auto-synchs via WiFi, or Bluetooth ® with Smartphone application provided with device.
10. Sensors	A variety of sensors are utilized in the device: Safety Sensors - Temp sensors and proximity sensors for patient safety Vitals sign monitoring sensors - Monitoring sensors patient vitals such as Body Temperature, Blood Pressure
11. Safety googles	No need for safety goggles - Class 1 safety approval.
12. Wrap Types	Laser Wrap LW-Back-1000 Sample specifications (For Back joint related Pain relief) Laser Wrap LW-Knee-1000 Sample specifications (For Knee joint related Pain relief) Laser Wrap LW-Wrist-1000 Sample specifications (For Wrist joints related Pain relief) Laser Wrap LW-Ankle & Foot-1000 Sample specifications (For Ankle & Foot joints related Pain relief) Laser Wrap LW-Neck & Shoulder-1000 Sample specifications (For Neck & Shoulder joints related Pain relief) Laser Wrap LW-Elbow-1000 Sample specifications (For Elbow joints related Pain relief)

CONCLUSION

[0142] The present invention comprises a flexible home treatment that enables self-care and immediate treatments, thsu improving patient lives while providing for maximum pain relief for the specific related illnesses like osteoporosis and arthritis, Carpel Tunnel, Tennis Elbow, Plantar Fasciitis, and other joint illnesses.

[0143] The present invention's wear-ability provides portable and hands-free convenience using laser wraps-orthopedic braces for the affected areas, with accurate proximity and automated timers for optimal treatment for joint pain relief, and accelerated healing.

[0144] The consumer buys it once and treats himself/herself conveniently and easily by wearing the device, and simply pressing the ON/OFF button, at the comfort of their home or anywhere while going about their daily activities.

[0145] The present invention, since its battery operated—is highly portable for use anywhere patient decides, when they actually feel the pain, making it extremely efficient and convenient, and not having to take invasive drugs, while also avoiding the side effects. It comes with a convenient device holder and DC charger.

[0146] The laser wrap devices of the present invention are already preset using the mobile application controlled by the user, for the optimum clinical strength energy density (i.e. dose) required for the specific area, so the user just has to use the ON/OFF switch for treatment, making it the most convenient device for patient use in the industry.

[0147] Although various features of the invention may be described in the context of a single embodiment, the features may also be provided separately or in any suitable combination. Conversely, although the invention may be described herein in the context of separate embodiments for clarity, the invention may also be implemented in a single embodiment.

[0148] As used herein, the term "about" refers to plus or minus 5 units (e.g. percentage) of the stated value.

[0149] Reference in the specification to "some embodiments", "an embodiment", "one embodiment" or "other embodiments" means that a particular feature, structure, or characteristic described in connection with the embodiments is included in at least some embodiments, but not necessarily all embodiments, of the inventions.

[0150] It is to be understood that the phraseology and terminology employed herein is not to be construed as limiting and are for descriptive purpose only.

[0151] It is to be understood that the details set forth herein do not construe a limitation to an application of the invention.

[0152] Furthermore, it is to be understood that the invention can be carried out or practiced in various ways and that the invention can be implemented in embodiments other than the ones outlined in the description above.

[0153] It is to be understood that the terms "including", "comprising", "consisting" and grammatical variants thereof do not preclude the addition of one or more components, features, steps, or integers or groups thereof and that the terms are to be construed as specifying components, features, steps or integers.

What is claimed is:

1. A portable, pre-programmed, low level laser therapy (LLLT) wrap system for treating pain in a user, comprising:
- a. a flexible wrap device shaped to tightly fit around a user's pain afflicted body part and able to provide orthopedic structural support to the body part;
- b. one or more fixation members to secure the wrap to the user's body, comprising Velcro-like tabs, straps, buckles, ties, hooks or snaps;
- c. an electrical circuit embedded within the flexible wrap device, comprising,
  - i. a plurality of laser diodes comprising two different types of laser diodes to emit different doses for either a skin surface treatment, or a deep surface treatment, during a treatment session;
  - ii. a microprocessor;
  - iii. a memory storing one or more treatment protocols comprising laser energy density, duration, and/or power for a specific type of medical condition or afflicted body part;
  - iv. a rechargeable battery;
  - v. a plurality of sensors able to monitor the wrap device and/or the user;
  - vi. a graphical user interface for inputting and/or displaying a treatment selection and a user data;
  - vii. a power switch with an automatic shut-off when a treatment session is completed; and
  - viii. a wireless data transceiver unit for wirelessly communicating a treatment data.

2. The LLLT system of claim **1**, further comprising a computer program product embedded on a user electronic computing device for wirelessly receiving and storing the treatment data comprising one or more of: a user self-reported pain level data, a treatment session history, and a user monitoring sensor data.

3. The LLLT system of claim **1**, wherein the two different types of laser diodes comprise a plurality of skin surface treatment diodes emitting from 630-670 nanometers of irradiation, and a plurality of deep penetration treatment diodes emitting from 780-900 nanometers of irradiation.

4. The LLLT system of claim **1**, wherein said treatment protocols are based on medical research in LLLT protocols demonstrating the most therapeutic efficacy for the afflicted body part and/or medical condition.

5. The LLLT system of claim **4**, wherein the medical conditions comprise pain associated with: tendonitis of the back, knee, hand, and Achilles tendon; tennis elbow; carpel-tunnel; arthritis (rheumatoid and osteoarthritis); osteoporosis; plantar fasciitis; bursitis; muscle and/or tissue inflammation and damage from acute and chronic injuries.

6. The LLLT system of claim **1**, wherein a type of LLLT wrap device comprises at least one of: a back; a knee; an ankle-foot; a hand-wrist; a neck-shoulder; and an elbow device.

7. The LLLT system of claim **6**, wherein the knee LLLT wrap device further comprises a cut-out to fit over a patella, and the hand-wrist LLLT wrap device further comprises a cut-out to insert a thumb through.

8. The LLLT system of claim **1**, wherein the sensors comprise safety sensors able to monitor the temperature of the laser diodes and/or the user's skin surface beneath or near the laser diodes.

9. The LLLT system of claim **1**, wherein the sensors comprise user monitoring sensors able to measure the one or more of a user's vital signs comprising, body temperature, heart rate, blood pressure, and respiratory rate.

10. A method of treating musculoskeletal pain in a user with a low level laser therapy (LLLT) wrap system, comprising the steps of:
- a. providing a LLLT wrap device comprising,
  - i. a flexible wrap device shaped to tightly fit around a user's pain afflicted body part and able to provide orthopedic structural support to the body part;
  - ii. one or more fixation members to secure the wrap to the user's body, comprising Velcro-like tabs, straps, buckles, ties, hooks or snaps;
  - iii. an electrical circuit embedded within the flexible wrap device, comprising,
    - a plurality of laser diodes, of two different types to emit different doses for either a skin surface treatment, or a deep surface treatment, during a treatment session;
    - a microprocessor;

a memory storing one or more treatment protocols comprising laser energy density, duration, and/or power for a specific type of medical condition or afflicted body part;
a rechargeable battery;
a plurality of sensors able to monitor the wrap device and/or a user's vital signs;
a graphical user interface for inputting and/or displaying a treatment selection and a user data;
a power switch with an automatic shut-off when a treatment session is completed;
a wireless data transceiver unit for wirelessly communicating a treatment data;

b. a user places the LLLT wrap device around the user's afflicted body part and secures the device in place using the fixation members, and the user activates the device;
c. the LLLT wrap device emits a dose of irradiation pre-programmed into the device memory comprising the treatment protocol specific to the user's medical condition, and automatically shuts off after the protocol is complete; and,
d. the LLLT wrap device stores in the memory data comprising, a user self-reported pain level data, a treatment session history, and a user monitoring sensor data; and wirelessly transmits the data to a user electronic computing device, and/or to cloud storage, and/or to a clinician's computer.

11. The method of treating of claim **10**, further comprises providing an analgesic effect from a treatment session, wherein: the effect lasts for about 48 hours; and/or the healing time of chronic medical condition is reduced by about 70%; and/or there is also significant reduction of inflammation equal to or better than non-steroidal anti-inflammatory drugs (NSAIDs) within 2-12 hours of treatment.

12. The method of treating of claim **10**, further comprises repeating steps (a)-(d) 5-10 times a week, and each treatment protocol is for a period of about 5 to 12 minutes each session.

13. The method of treating of claim **10**, further comprising a computer program product comprising non-transitory computer-readable storage media embedded on the user electronic computing device for wirelessly receiving and storing the treatment data comprising the one or more of: a user self-reported pain level data, a treatment session history, and a user monitoring sensor data.

14. The method of treating of claim **10**, wherein the two different types of laser diodes comprise a plurality of skin surface treatment diodes emitting from 630-670 nanometers of irradiation, and a plurality of deep penetration treatment diodes emitting from 780-900 nanometers of irradiation, and the user selects between receiving a skin surface versus a deep penetration treatment.

15. The method of treating of claim **10**, wherein said treatment protocols are based on medical research in LLLT protocols demonstrating the most therapeutic efficacy for the afflicted body part and/or medical condition.

16. The method of treating of claim **15**, wherein the medical conditions comprise pain associated with: tendonitis of the back, knee, hand, and Achilles tendon; tennis elbow; carpel-tunnel; arthritis (rheumatoid and osteoarthritis); osteoporosis; plantar fasciitis; bursitis; and muscle and/or tissue inflammation and damage from acute and chronic injuries.

17. The method of treating of claim **10**, wherein a type of LLLT wrap device comprises at least one of: a low back; a knee; an ankle-foot; a hand-wrist; a neck-shoulder; and an elbow device.

18. The method of treating of claim **17**, and the knee LLLT wrap device further comprises a cut-out to fit over a patella, and the hand-wrist LLLT wrap device further comprises a cut-out to insert a thumb through.

19. The method of treating of claim **10**, wherein the sensors comprise safety sensors able to monitor the temperature of the laser diodes and/or the user's skin surface beneath or near the laser diodes.

20. The method of treating of claim **10**, wherein the sensors comprise user monitoring sensors able to measure the one or more of a user's vital signs comprising, body temperature, heart rate, blood pressure, and respiratory rate.

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专利名称(译)	便携式，预校准和可穿戴激光设备，用于治疗疼痛和炎症		
公开(公告)号	US20170216617A1	公开(公告)日	2017-08-03
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[标]申请(专利权)人(译)	kariguddaiah abijith		
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CPC分类号	A61N5/0613 A61B5/02055 A61B5/4836 A61B5/021 A61B5/02438 A61N2005/0651 A61N2005/067 A61N2005/0645 A61N2005/0662 A61N2005/0659 A61N2005/0626 A61B5/0816 A61F5/0102 A61F5/0109 A61F5/0111 A61F5/0118 A61F5/028 A61N2005/0652		
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摘要(译)

各种类型的低水平激光治疗（LLLT）包裹装置，使用方法和包括移动应用的系统，用于治疗肌肉骨骼损伤或医学病症引起的疼痛，并捕获“患者的生命体征”。每个包裹都适合特定的身体部位（例如膝盖），重量轻，便携，因此它可以穿在衣服下面;并且具有嵌入在包裹物内的电池供电的电路，包括：多个激光二极管，用于治疗表面和/或深部组织疼痛;传感器（例如安全和/或患者生命体征监测）;以及用于将数据（传感器和患者疼痛水平）传输到移动应用程序的无线收发器。包裹物还可以用作整形外科支撑物;并且预先校准特定的持续时间以提供630nm至904nm的临床强度剂量，其特定于医学病症和/或用户解剖区域，在剂量递送后自动关闭。