US 20060129022A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2006/0129022 A1

Venza et al. (43) Pub. Date: Jun. 15, 2006

(54) METHOD AND APPARATUS FOR THERAPEUTIC TREATMENT OF INFLAMMATION AND PAIN WITH LOW FLUX DENSITY, STATIC ELECTRO-MAGNETIC FIELDS

(76) Inventors: **Glenn E. Venza**, Riverdale, NJ (US); **Gerard Malady**, Fort Lee, NJ (US); **Robert Sylvester**, River Edge, NJ (US)

Correspondence Address:
JONES, TULLAR & COOPER, P.C.
P.O. BOX 2266 EADS STATION
ARLINGTON, VA 22202

(21) Appl. No.: **11/289,395**

(22) Filed: **Nov. 30, 2005**

Related U.S. Application Data

(60) Provisional application No. 60/631,433, filed on Nov. 30, 2004.

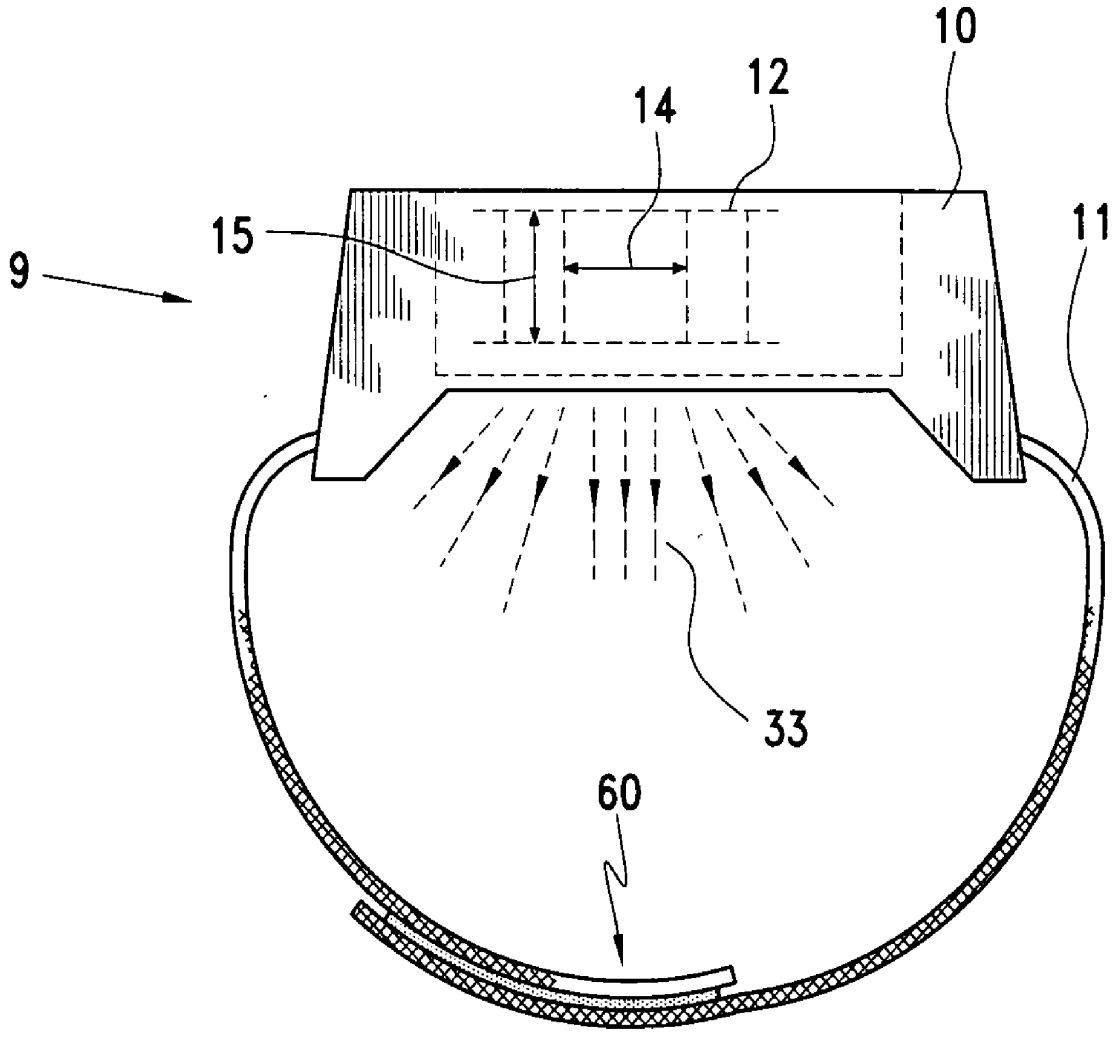
Publication Classification

(51) **Int. Cl.**
A61N 1/00 (2006.01)

(52) **U.S. Cl.** **600/13**

(57) **ABSTRACT**

A portable Static Electro Magnetic Field (SEMF) generating device and method for the therapeutic treatment of inflammatory and painful disorders of the human limbs including fingers, hands, wrists, forearms, elbows, toes, feet and ankles preferably includes a wearable, portable battery powered solenoid or coil. The coil is configured to focus a substantially time invariant magnetic flux field onto a selected part of the body. The SEMF generating device's coil, when energized, works by slightly changing the charges associated with voltage-dependant ion channels in the cell membranes of the human body, thereby stabilizing abnormal fluid transport into the cells through aquaporin channels and the sodium ions relating to them, treating inflammation and altering the flow of calcium, chloride and potassium ions through their respective neuronal ion channels and treating pain.



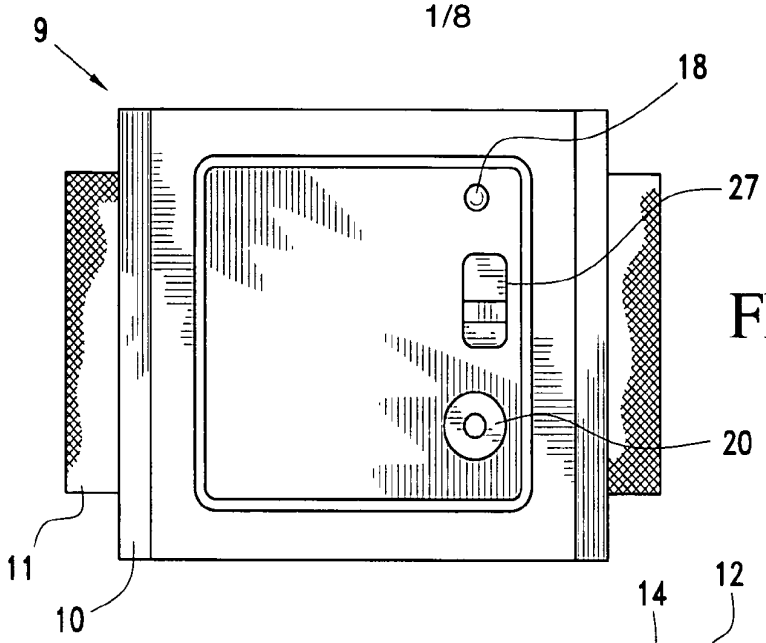


FIG. 1

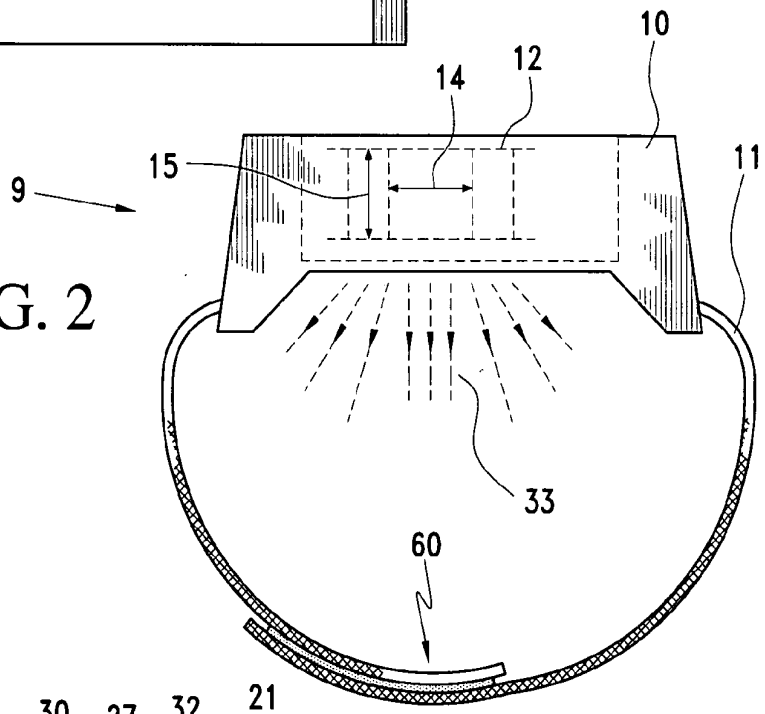


FIG. 2

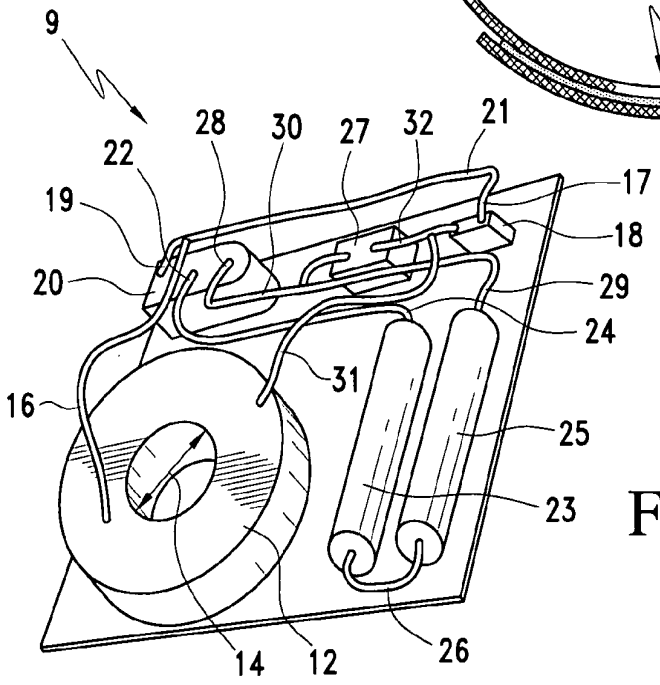


FIG. 3

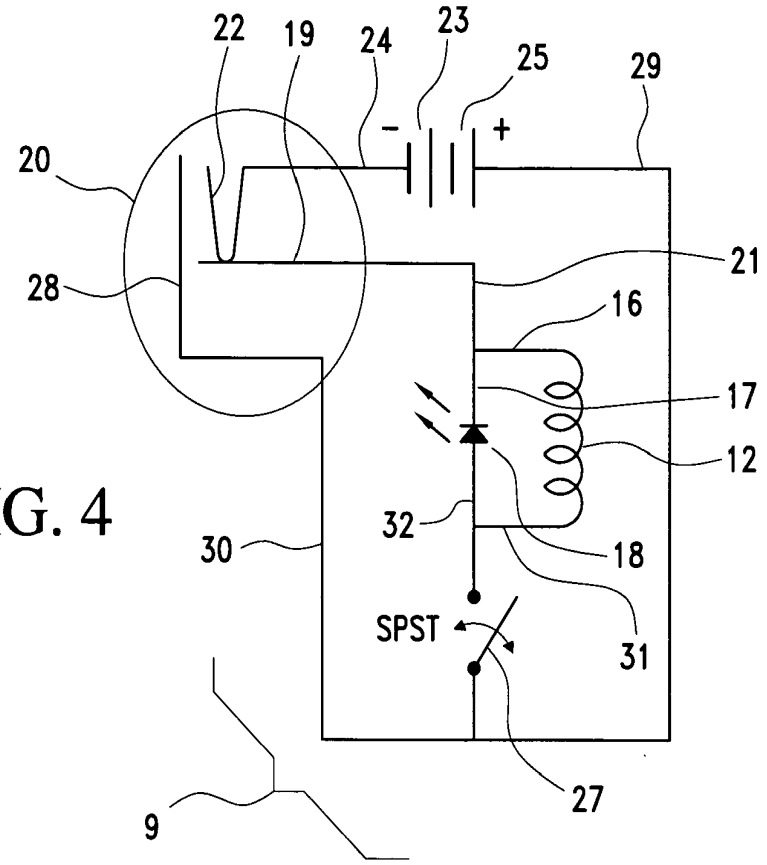


FIG. 4

FIG. 5

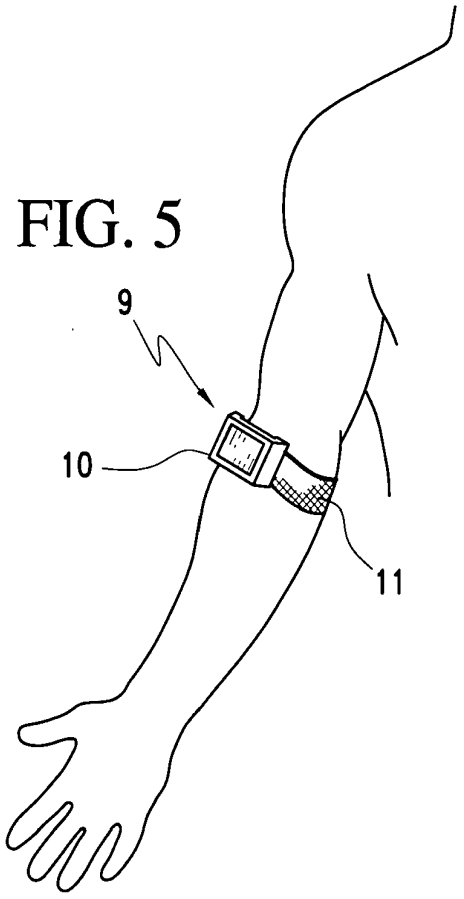


FIG. 6

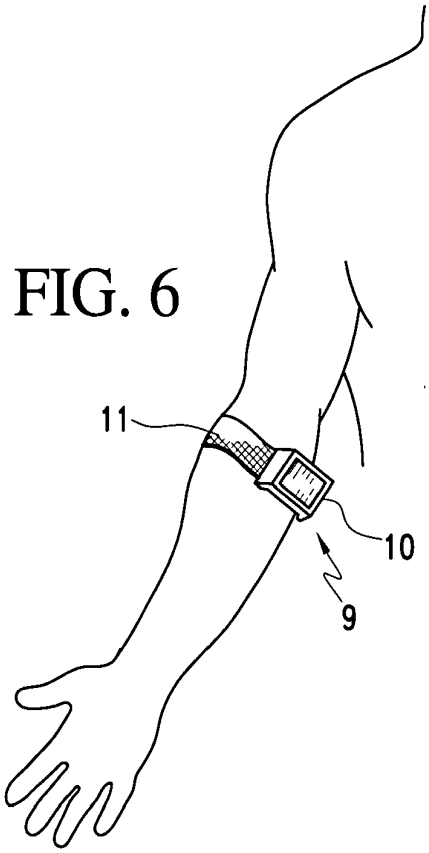
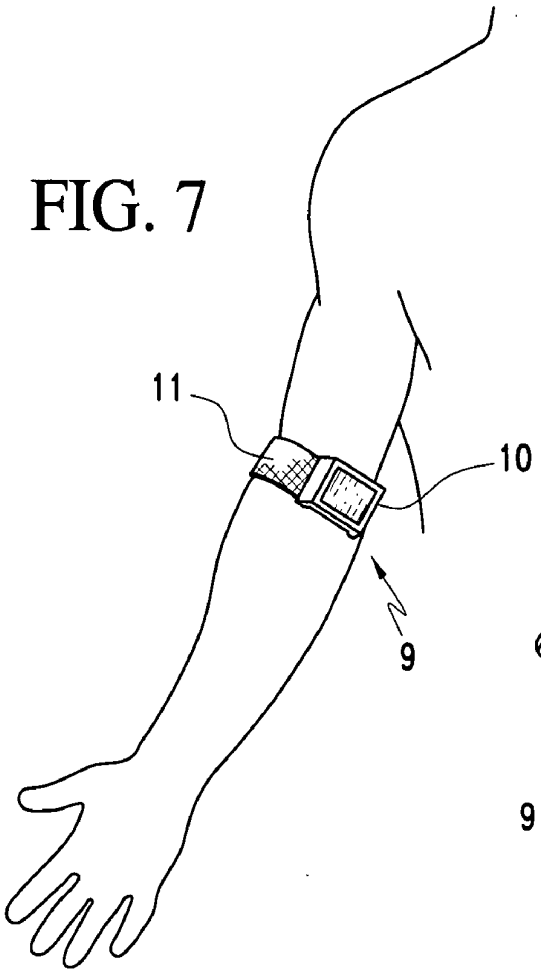


FIG. 7



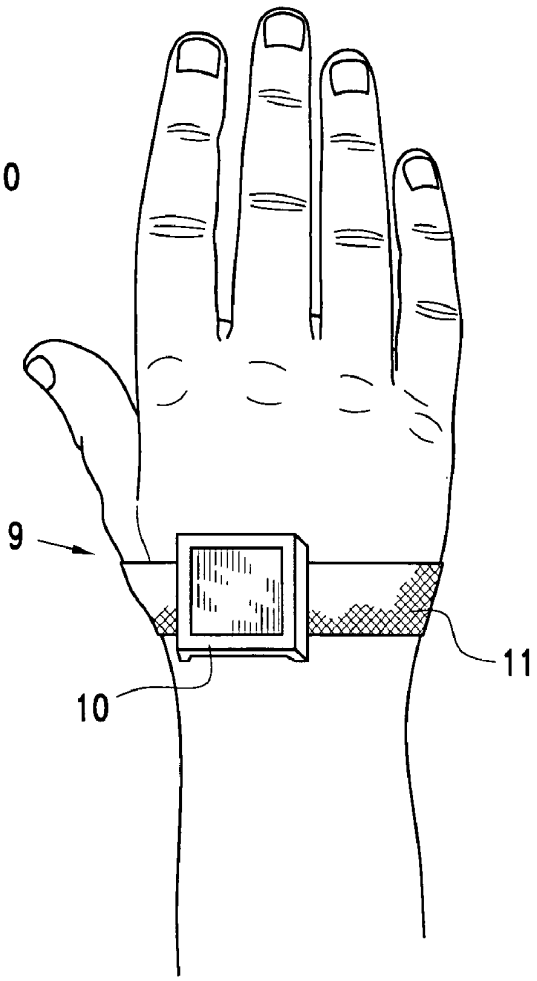


FIG. 9

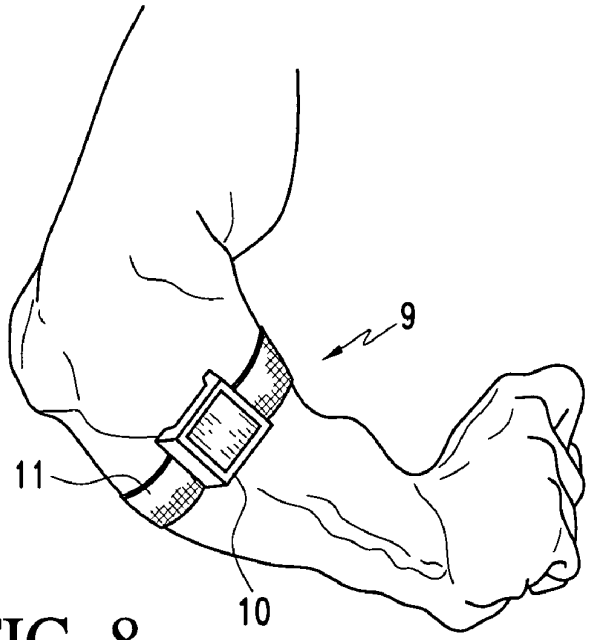
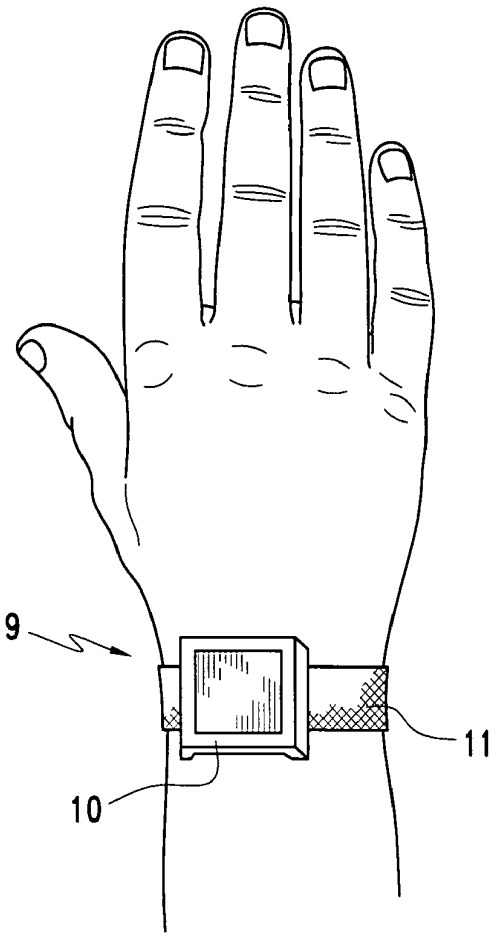


FIG. 8

FIG. 10



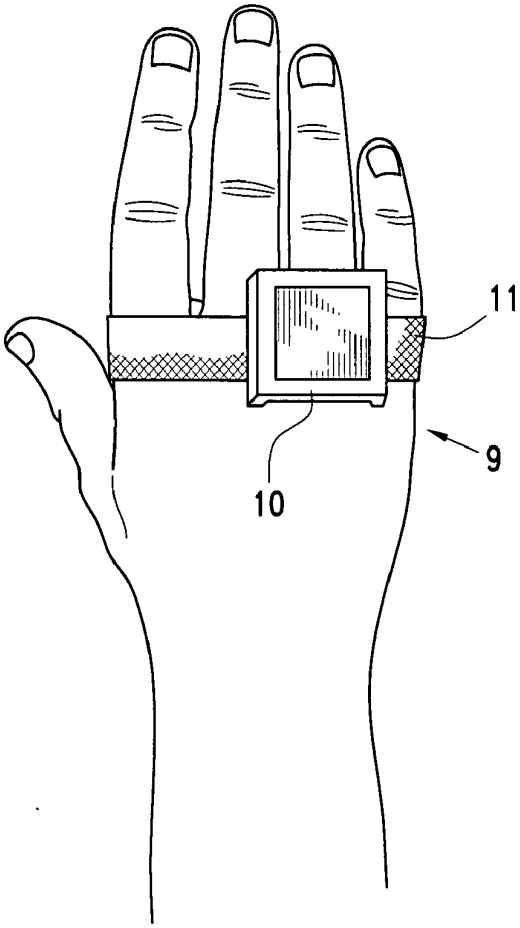


FIG. 11

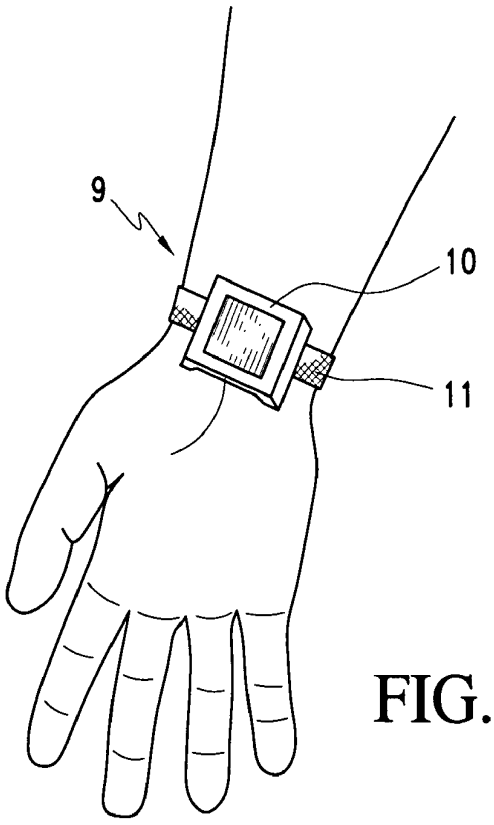


FIG. 12

FIG. 13

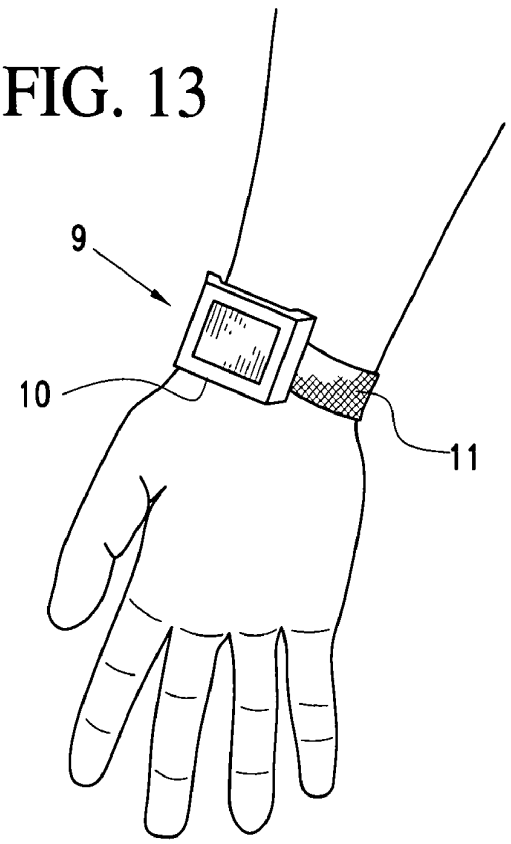
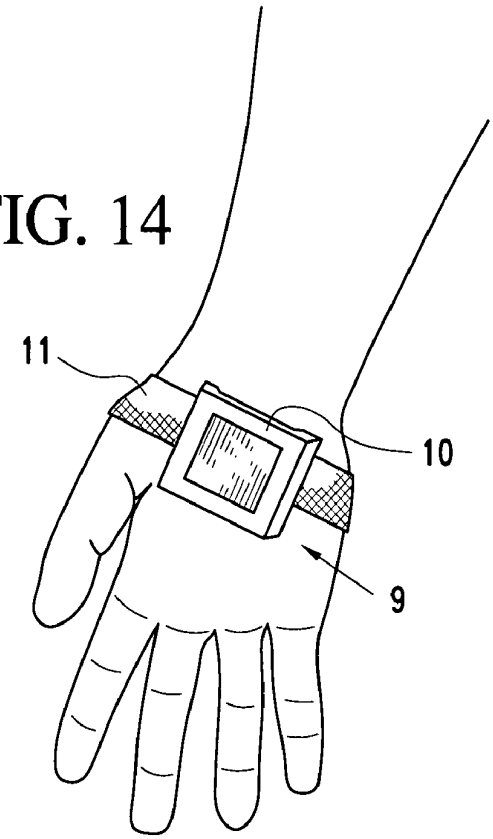


FIG. 14



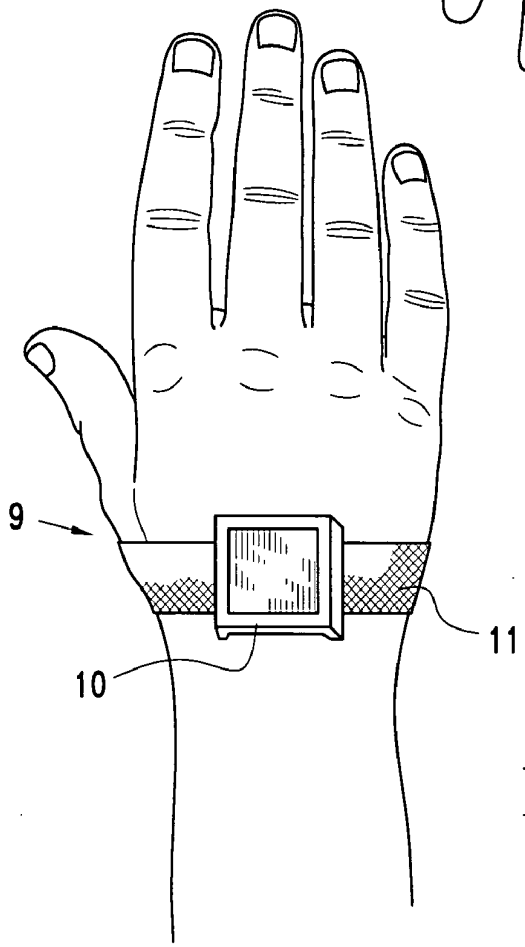


FIG. 15

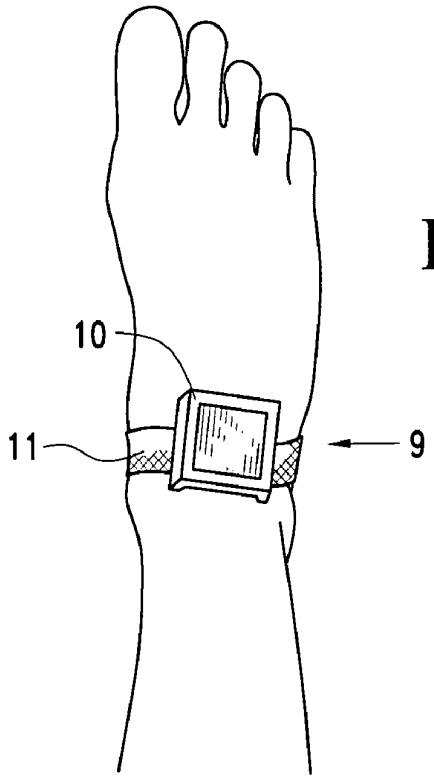


FIG. 16

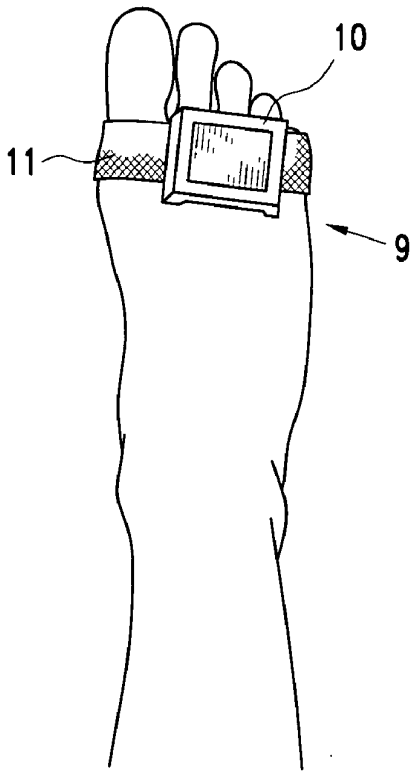


FIG. 17

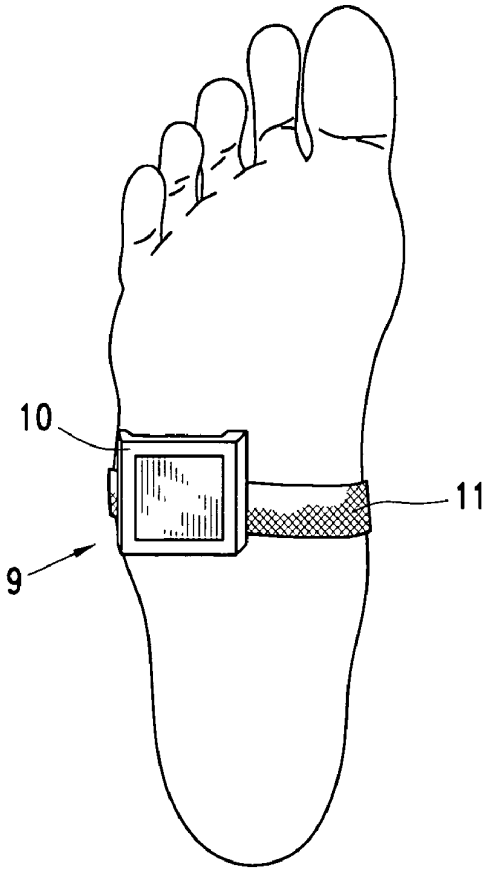


FIG. 18

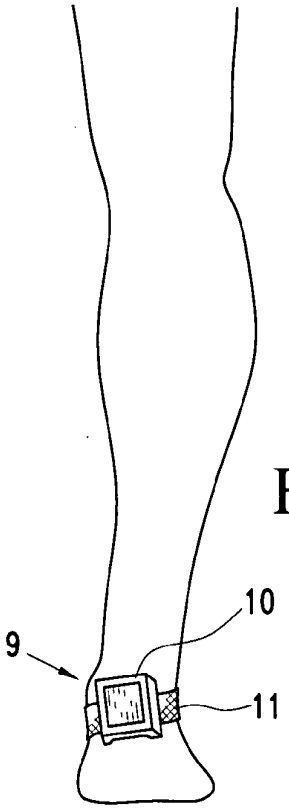


FIG. 19

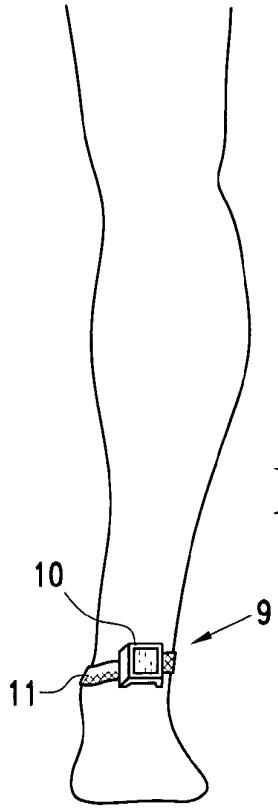


FIG. 20

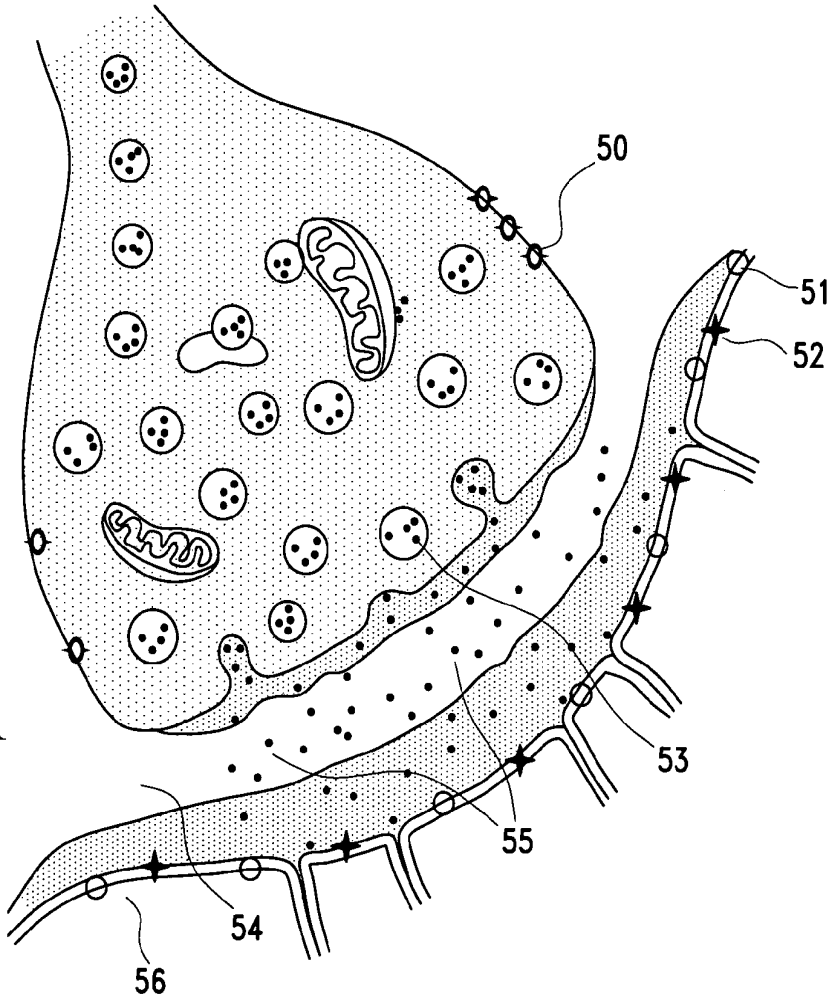


FIG. 21

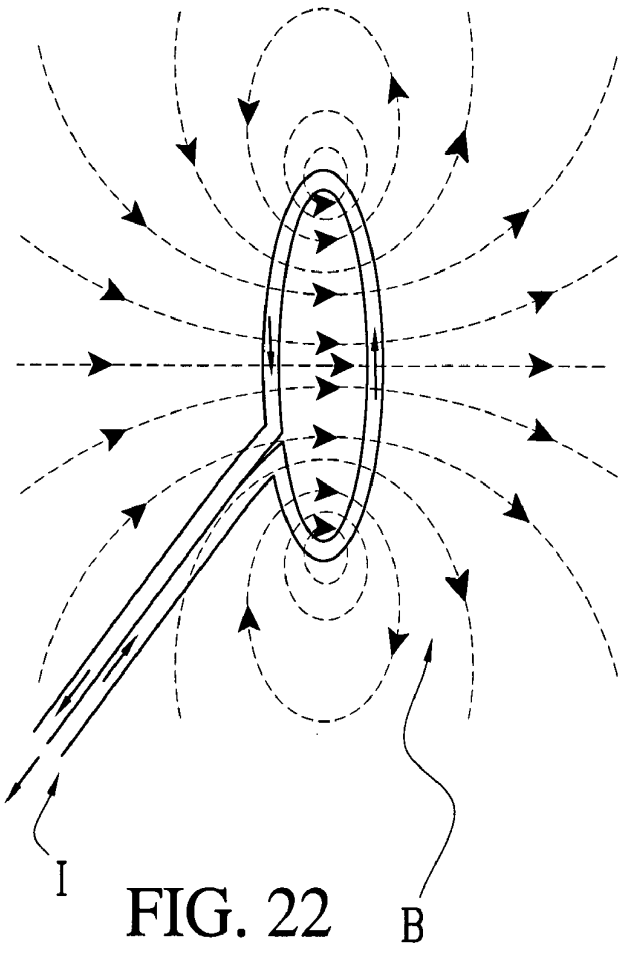


FIG. 22

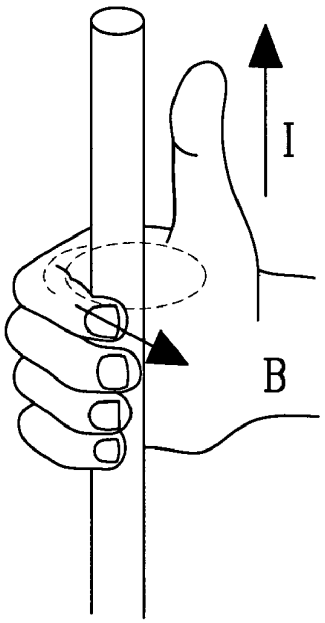


FIG. 24

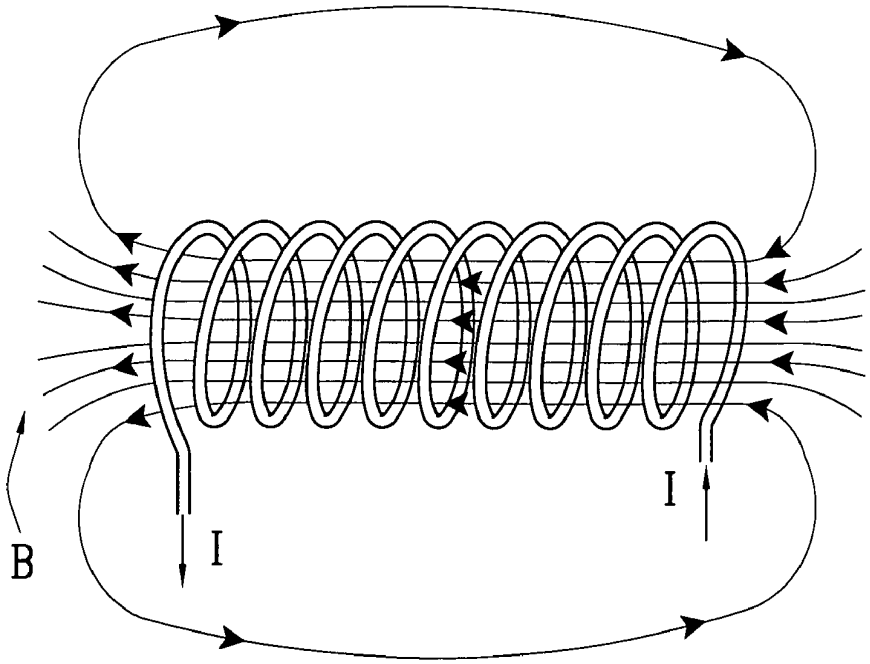


FIG. 23

METHOD AND APPARATUS FOR THERAPEUTIC TREATMENT OF INFLAMMATION AND PAIN WITH LOW FLUX DENSITY, STATIC ELECTRO-MAGNETIC FIELDS

[0001] This application is a continuation-in-part of and claims priority to the filing date of U.S. provisional application Ser. No. 60/631,433, filed Nov. 30th, 2004, the entire disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to therapeutic application of electromagnetic fields to the body, and more particularly to a method and apparatus for therapeutic treatment of inflammation and pain by exposing an inflamed or painful area of the body to a low flux density static electro magnetic field ("SEMF").

[0004] 2. Discussion of the Prior Art

[0005] Many people suffer from musculoskeletal ailments and disorders of the limbs and experience inflammation and pain. These disorders include Carpal Tunnel Syndrome (Median Nerve Entrapment), Arthritic Wrist Pain, Lateral Epicondylitis, Medial Epicondylitis, DeQuervain's Disease, Forearm Tendonitis, Wrist Tendonitis, Trigger Finger, Intersection Syndrome, Hand-Arm Vibration Syndrome, Ulnar Nerve Entrapment, Acute Ankle Sprains, Posterior Tibial Tendonitis, Achilles Tendonitis, Plantar Fascitis and Morton's Neuroma.

[0006] In response, many have turned to use of over the counter pain medications or sought a variety of other remedies that have proven to be inconvenient, ineffective, expensive or painful. Some have experimented with electric fields or with magnetic fields.

[0007] The planet Earth has a static, surface geomagnetic field that is superficially similar to that of a permanent bar magnet. The coordinated motion of negatively charged electrons within (e.g., iron) atoms creates the magnetic fields in permanent magnets. Those coordinated orbits become randomized at the Curie point temperature of 1043 degrees Kelvin and magnetism degrades. The temperature of the Earth's core however, is much higher than that and yet the Earth's geomagnetic field remains. One can surmise therefore that the Earth's geomagnetic field and its related magnetosphere are not due to magnetized iron deposits. The latest school of thought is that as portions of the molten outer core of the Earth cool and fall inward, oceans of iron rich liquid magma rise towards the surface. The rotation of the planet forces the magma into a helical motion, regenerating the Earth's magnetism.

gloves, socks, insoles, straps, mattress pads, belts, braces, jewelry etc. are available through print ads, the Internet, infomercials and the shelves of local pharmacies with worldwide sales in excess of five billion dollars. Until recently, the therapeutic action of SMFs was a complete mystery, however studies within the last decade have shed new light on how static magnetic fields influence cells and help the body to heal itself.

[0009] The safety of SMFs has led to a useful diagnostic tool, namely Magnetic Resonance Imaging (MRI) as described in U.S. Pat. No. 3,024,410. The MRI scanner is a tube surrounded by a very large circular magnet. The magnet creates a strong magnetic field, often as much as 70,000 times stronger than the geomagnetic field, and yet is harmless to the patient. This magnetic field aligns the protons of hydrogen atoms in the body, allowing a computer to process the information and create an image.

[0010] At the other end of the magnetic picture, the dangers and risks of high frequency magnetic radiation are well known and well documented. Three or four decades ago scientists worldwide began investigations into the safety of Electro Magnetic Fields (EMFs) generated by high-tension power lines. As current travels through a conductor a magnetic field is generated perpendicularly to the direction of the flow of the current.

[0011] Supposed cancer clusters allegedly caused by these low frequency EMFs precipitated these investigations and numerous studies of the subject. These 60 cycle/second EMFs were an enigma until these studies showed that there was not sufficient evidence to link cancer clusters and the magnetic fields. The studies that were launched by this investigation all dealt with frequency modulated magnetic fields. In other words, the field was turned on and off (pulsed) any specified times per second using a variety of wave geometries such as square waves, saw tooth waves (triangular) and sine waves. These myriad studies varied the frequency of the field from just a few cycles per second to many thousands of cycles per second. Many of the scientists involved in these studies knew of the subjective successes that experimenters had with SMFs and thus studied the efficacy of Pulsed Electro Magnetic Fields (PEMFs) on human ailments ranging from simple headaches to fibromyalgia to the treatment of cancer, with results ranging from promising to effective.

[0012] For years, science has recognized that the roughly sixty-five trillion cells in the human body generate, employ and exude electric and magnetic charges. For example Electroencephalograms (EEGs) U.S. Pat. No. 2,409,033 and Electrocardiograms (EKGs) U.S. Pat. No. 2,262,936 are the electrical measurements of brain and heart functions respectively. There are current studies being done to evaluate the

magnetic fields. There is one major difference between electric and magnetic charges as they relate to the human body. In order to either measure (EKG, EEG) an electrical charge generated by the body, or to deliver (DEFIBRILLATOR U.S. Pat. No. 3,050,695, TENS [Transcutaneous Electrical Nerve Stimulator U.S. Pat. No. 2,375,575]) an electrical charge to the body, physical contact of conducting electrodes must be used. This is not true of a magnetic field, as we know by the use of an MRI. Not only is the magnetic field effective without contact, but it is also barely affected by hard tissue such as bone, allowing penetration of the field

[redacted]

[0013] Appropriate magnetic fields have not been exploited as a mechanism for pain relief in a practical form, however, for use by individuals when engaged in their everyday activities.

[0014] There is a need, therefore, for a safe and effective portable device for treating musculoskeletal ailments and disorders of the limbs by reducing inflammation and pain.

SUMMARY OF THE INVENTION

[0015] The present invention includes a method and apparatus for treating physical disorders of the human body using a Low Flux Density, Static Electro-Magnetic Field (SEMF). The invention preferably comprises a safe and effective portable device which the patient can operate. The non-heating, non-ionizing SEMF generated by the method and apparatus of the present invention effectively treats a wide variety of musculoskeletal ailments and disorders of the limbs by reducing inflammation and pain. These disorders include but are not limited to Carpal Tunnel Syndrome (Median Nerve Entrapment), Arthritic Wrist Pain, Lateral Epicondylitis, Medial Epicondylitis, DeQuervain's Disease, Forearm Tendonitis, Wrist Tendonitis, Trigger Finger, Intersection Syndrome, Hand-Arm Vibration Syndrome, Ulnar Nerve Entrapment, Acute Ankle Sprains, Posterior Tibial

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] **FIG. 1** is a top or plan view, in elevation, of a wearable static electro magnetic field generating therapeutic device, illustrating the position of the indicating LED and the actuating switch, in accordance with the present invention.

[0020] **FIG. 2** is a side view in elevation of the wearable static electro magnetic field generating therapeutic device of **FIG. 1**, illustrating the contoured housing and the strap or affixing unit and showing, in hidden lines, location and housing unit, in accordance with the present invention.

[0021] **FIG. 3** is a diagram showing, in perspective, the placement and orientation of the operating electrical and magnetic field generating components of the wearable static electro magnetic field generating therapeutic device of **FIGS. 1 and 2**, in accordance with the present invention.

[0022] **FIG. 4** is a schematic diagram showing the electrical connections among the operating electrical and magnetic field generating components of the wearable static electro magnetic field generating therapeutic device of **FIGS. 1-3**, in accordance with the present invention.

[0023] **FIG. 5** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic device of **FIGS. 1-4**, and illustrating an exemplary fitment appropriate for treatment of Lateral Epicondylitis (Tennis Elbow) on the anterior, human right arm, in accordance with the present invention.

[0024] **FIG. 6** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic device of **FIGS. 1-4**, and illustrating an exemplary fitment appropriate for treatment of Medial Epi-

[0029] **FIG. 11** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic device of **FIGS. 1-4**, and illustrating an exemplary fitment appropriate for treatment of Trigger Finger on the posterior, human right hand, in accordance with the present invention.

[0030] **FIG. 12** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic device of **FIGS. 1-4**, and illustrating an exemplary fitment appropriate for treatment of Wrist Tendonitis on the anterior, human right hand, in accordance with the present invention.

[0031] **FIG. 13** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic device of **FIGS. 1-4**, and illustrating an exemplary fitment appropriate for treatment of Hand-Arm Vibration Syndrome (HAVS) on the anterior, human right hand, in accordance with the present invention.

[0032] **FIG. 14** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic device of **FIGS. 1-4**, and illustrating an exemplary anterior fitment appropriate for treatment of Median Nerve Entrapment (Carpal Tunnel Syndrome) on the anterior, human right hand, in accordance with the present invention.

[0033] **FIG. 15** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic device of **FIGS. 1-4**, and illustrating an exemplary posterior fitment appropriate for treatment of Median Nerve Entrapment (Carpal Tunnel Syndrome) on the posterior of the human right hand, in accordance with the present invention.

[0034] **FIG. 16** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic device of **FIGS. 1-4**, and illustrating an exemplary fitment appropriate for treatment of Acute Ankle Sprains on the dorsal, human right foot, in accordance with the present invention.

[0035] **FIG. 17** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic device of **FIGS. 1-4**, and illustrating an exemplary fitment appropriate for treatment of Morton's Neuroma on the dorsal, human right foot, in accordance with the present invention.

[0036] **FIG. 18** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic device of **FIGS. 1-4**, and illustrating an exemplary fitment appropriate for treatment of Plantar Fascitis on the plantar, human right foot, in accordance with the present invention.

[0037] **FIG. 19** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic device of **FIGS. 1-4**, and illustrating an exemplary fitment appropriate for treatment of Achilles Tendonitis on the posterior, human right ankle, in accordance with the present invention.

[0038] **FIG. 20** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic device of **FIGS. 1-4**, and illustrating an exemplary fitment appropriate for treatment of Posterior Tibial Tendonitis on the posterior, human right ankle, in accordance with the present invention.

[0039] **FIG. 21** is a diagram illustrating the Synaptic Junction within the human body; in accordance with the method of the present invention, application of the SEMF causes calcium ion channels to open, and as the action potential reaches the synaptic cleft, the inrush of ions triggers neurotransmitter vesicles to release their contents of GABA-A and GABA-B **55**; these neurotransmitters, in conjunction with the SEMF, cause potassium ion channels and chloride ion channels to open, forcing the post synaptic neuron to maintain its resting potential.

[0040] **FIG. 22** is a diagram illustrating the magnetic field produced by a single current loop, where "I" indicates the applied current and direction thereof and "B" indicates the electro magnetic field with arrows showing South Pole to North Pole radiation.

[0041] **FIG. 23** is a view of the magnetic field of a solenoid coil from Ampere's Law, where I is the applied current and the magnetic field, indicated by lines and arrows, is bipolar in nature.

[0042] **FIG. 24** is a diagram illustrating the right hand rule where "I" indicates the applied current with the thumb pointing in the direction of that current and B is the generated magnetic field with the fingers indicating the direction of magnetic flux from South Pole to North Pole.

DETAILED DESCRIPTION OF THE INVENTION

[0043] Before turning to a detailed description of the preferred embodiment, the theoretical underpinnings of the present invention will be set forth. Static Electro Magnetic Fields (SEMFs) produced in the fashion that this invention generates them, and their ability to effectuate the reduction of pain and inflammation are based on a plethora of electric, magnetic and biological laws and theories.

[0044] MICHAEL FARADAY had observed how iron filings form patterns of lines under the influence of a magnet. He concluded that space is filled with these invisible lines, forming what we now call a field. He used his idea to explain in 1845 why some substances are diamagnetic (developing a magnetic field opposite to the one surrounding them) and others paramagnetic (developing a magnetic field parallel to the one surrounding them). When Faraday discovered that a magnetic field could affect the polarization of light, he proposed in 1845 that light might be waves in the lines of force of electromagnetism.

[0045] ALBERT EINSTEIN showed, using special relativity, that electric and magnetic fields are two aspects of the same thing (a rank-2 tensor), and that one observer may perceive a magnetic force where a moving observer perceives only an electrostatic force. Thus, using special relativity, magnetic forces are a manifestation of electrostatic forces of charges in motion and may be predicted from knowledge of the electrostatic forces and the movement (relative to some observer) of the charges.

[0046] Electric currents produce MAGNETIC FIELDS, which can be macroscopic currents in wires, or microscopic currents associated with electrons in atomic orbits. Magnetic field sources are essentially dipolar in nature, having a north

and south magnetic pole. In physics, a magnetic field is an entity produced by moving electric charges or electric currents that exerts a force on other moving charges.

[0047] GAUSS' LAW FOR MAGNETISM states that for a magnetic dipole, any closed surface the magnetic flux directed inward toward the South Pole will equal the flux outward from the North Pole. The net flux will always be zero for dipole sources.

[0048] AMPERE'S LAW states the magnetic field in space around an electric current is proportional to the electric current which serves as its source, and the BIOT-SAVART LAW relates magnetic fields to the currents which are their sources. Finding the magnetic field resulting from a current distribution involves the vector product and is

as gates for the channels through the protein membrane of each cell. When the outside of the membrane becomes negatively charged, the positively charged paddles are attracted outward. This action opens the channels allowing ionic flow. Calcium, sodium, chloride and potassium channels are all related by being voltage dependent and having the same voltage sensor in their process. The ubiquity of aquaporin and ion channels throughout the body will allow this invention to be effective for virtually all inflammation and pain.

[0053] A static electromagnetic field ("SEMF") applied to the body in a therapeutic fashion alters the electrical charge of the cell membrane, cytoplasm and surrounding fluid, causing some metabolic operations to accelerate, such as

synaptic neuron **56** to maintain its resting potential. As best seen in **FIG. 21**, the generated negatively charged field, by electromagnetic induction, causes a permutation of the inherent voltage of the cell membrane. This deviation from a typical voltage causes voltage-sensing "paddles" in the aquaporin channels of the cell membrane to open, enhancing the flow of cellular and intracellular water and related sodium ions. Water molecules, at the endocellular level, cluster together into the three-dimensional shape of the dodecahedron around localized sodium ions. These in turn, aggregate into very large clusters within icosahedron shaped, magnetically attracted fascine, which are much too large to traverse the aquaporin channels of the cell membrane. The application of the SEMF of this invention disrupts the magnetic attraction of the icosahedra clusters, allowing the dodecahedral bundles to separate and pass through the cell membrane. This twofold action on hydrated sodium and aquaporin channels at the sub-cellular level results in a reduction of localized edema.

[**0057**] It is also posited that magnetically induced ionic transmembrane conduction is a result of this invention. When the SEMF of the invention is introduced to a region of the body experiencing pain, it causes calcium ion channels to open allowing an inward rush of calcium ions as the action potential reaches the synaptic cleft. This triggers neurotransmitter vesicles to release their contents into the synaptic cleft (exocytosis). The neurotransmitters most likely released under the influence of a SEMF are Gamma Amino Butyric Acid-A and B (GABA-A and GABA-B) which inhibit nerve impulse transmission. The SEMF, working in conjunction with the neurotransmitters GABA-A and GABA-B, cause the "paddles" in potassium ion channels of the receptor cell membrane to open to sanction the outward flow of potassium ions as well as prompting chloride ion channel "paddles" to open allowing a cellular influx of chloride ions forcing the post-synaptic neuron to maintain its resting membrane potential of −70 mV affecting a reduction of acute as well as chronic pain.

[**0058**] Referring to **FIGS. 1-4**, the preferred embodiment of the invention includes a non-ferrous, non-conductive housing unit **10** made, preferably from a tough, resilient plastic material, and has a top or upper surface including an electrical connector **20** or charging socket adapted to receive a detachable connector for recharging an internally carried battery power supply. The upper surface of housing **10** also includes a visible indicator of operating state such as a green Light Emitting Diode (LED) **18**, and provides an access slot adapted to permit access to a user actuable enabling switch such as single-pole, single-throw (SPST) switch **27**. The bottom or lower surface of housing **10** is configured to make contact with the body when worn, and so, in the illustrative embodiment, is contoured to provide a substantially planar back contact surface bounded by opposing angled wall segments configured to position the coil **12** in close proximity to an area of the body to be treated, as best seen in **FIG. 2**.

[**0059**] Housing **10** is supported by and carries a releasable flexible strap or affixing unit **11**. As illustrated by the schematic in **FIG. 4** the Static Electro Magnetic Field generating unit **9** is carried within and protected by housing **10** and can be attached to the body in many possible orientations, as will be discussed in greater detail, below.

[**0060**] Referring to the component layout diagram of **FIG. 3** and schematic diagram of **FIG. 4**, Therapeutic treatment coil or solenoid **12** comprises a plurality of turns of conductor (e.g., copper wire) wound onto a substantially cylindrical non-ferrous bobbin, former or form **13**. Coil form **13**, due to its inherent geometry causes the solenoid coil **12** to have a fixed internal diameter **14** of about three quarters of an inch and a fixed height **15** of about one half inch. Coil **12** is terminated in a first (or start) lead **16** and a second (or finish) lead **31**. Start lead **16** of solenoid coil **12** is permanently affixed and conductively bonded to the cathode **17** of, preferably, a green LED **18**, typically a Panasonic p/n LN322GP, by a soldering process. This connection is also permanently affixed to the normally closed (N-C) pole **19** of an electrical connector for battery charging such as the female charging socket **20** by a length of insulated copper wire **21** and is soldered thereto. The second N-C negative pole **22** of the female charging socket **20** is permanently affixed to the negative pole of the first battery **23**, preferably rechargeable (e.g., NiMH AAA) battery, by a length of insulated copper wire **24** and is soldered thereto. The positive pole of the first rechargeable battery **23** is soldered to the negative pole of a second rechargeable battery **25** using solderable conductive tabs **26** contacting the batteries **23** and **25**. The positive pole of the second battery **25** is permanently affixed to one pole of the SPST switch **27**, typically a Cannon-ITT p/n GS02MCKE, and the positive pole **28** of the female charging socket **20** is connected by insulated copper wires **29** and **30** and soldered thereto. The finish lead **31** of the solenoid coil **12** is preferably permanently connected to the anode **32** of the LED **18** and the other pole of the SPST switch **27** by a soldering process.

[**0061**] When switch **27** is in a closed condition, it closes the circuit causing current to flow at an amplitude of about ninety five milliamps (for a supply voltage 2.66 volts DC) through the field generating unit **9**. The green LED **18** is energized to provide an "ON" indicator and the solenoid coil **12** generates a Static Electro Magnetic Field **33** of about 25 Gauss. When the batteries **23** and **25** are depleted and can no longer provide adequate current, the user may then employ an external charging device (not shown) including a standard pin connector adapted to be plugged into the female charging socket **20**. Standard "wall wart" DC rechargers are available for use with any mains supply (e.g., 120 Volt in the US) wall outlet.

[**0062**] When a male charging plug is inserted into the female charging socket **20**, the solenoid coil **12**, the SPST switch **27** and the green LED **18** are all physically disconnected or removed from the circuit by the N-C negative poles **19** and **22** being forced into an open condition, safely allowing the portable power supply (e.g., batteries **23** and **25**) to be recharged. This opening of the N-C negative poles **19** and **22** renders the embodiment of the field generating unit **9** useless while charging, creating a safe condition.

[**0063**] The housing unit **10** is preferably a molded thermoplastic case, and the mold defines the vias or ports for the LED **18**, the female charging socket **20** and the SPST switch **27**; as well as internal structural protrusions to support and stabilize the batteries **23** and **25** and maintain placement of the solenoid coil **12**.

[**0064**] The strap or affixing unit **11** is a preferably a segment of flexible resilient web material terminated at first

and second ends with sections of affixed hook and loop type fasteners (e.g., at **60** in **FIG. 2**), or can be configured using the same structural features of a watchband or other band, sized to fit on parts of the body, as shown in **FIGS. 5-20**. Alternatively, strap or affixing unit **11** may be an elastic or stretchable band dimensioned to closely fit a selected appendage.

[**0065**] In use, the wearable static electro magnetic field generating therapeutic device **9** of **FIGS. 1-4**, is fitted to an affected part of the body and switch **27** is actuated, whereby solenoid coil **12** is energized to provide a therapeutic effect on a selected appendage or joint within the human body. Referring to **FIG. 5**, an exemplary fitment appropriate for treatment of Lateral Epicondylitis (Tennis Elbow) on the anterior, human right arm, is illustrated. The user dons or wears strap **11** and housing **10** in an orientation placing housing **10** against the anterior, human right arm, and then actuates or energizes solenoid coil **12** to focus magnetic flux into and through the elbow region's Lateral Epicondylitis.

[**0066**] The method is adapted to many other treatments; for example, **FIG. 6** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic device **9**, and illustrating an exemplary fitment appropriate for treatment of Medial Epicondylitis (Golfer's Elbow) on the anterior, human right arm, in accordance with the present invention. **FIG. 7** illustrates the method for applying the wearable static electro magnetic field generating therapeutic device **9**, showing an exemplary fitment appropriate for treatment of Ulnar Nerve Entrapment (Cubital Tunnel Syndrome) on the anterior, human right arm, and **FIG. 8** illustrates the method for applying the wearable static electro magnetic field generating therapeutic device **9** in an exemplary fitment appropriate for treatment of Forearm Tendonitis on the posterior of a human right arm. **FIG. 9** is a diagram illustrating the method for applying the wearable static electro magnetic field generating therapeutic **9** and showing an exemplary fitment appropriate for treatment of DeQuervain's Disease (Blackberry Thumb) on the posterior of the human right hand, and **FIG. 10** shows the method for applying wearable static electro magnetic field generating therapeutic device **9** in an exemplary fitment appropriate for treatment of Intersection Syndrome on the posterior, human right hand. **FIG. 11** shows the method for applying static electro magnetic field generating therapeutic device **9** in an exemplary fitment appropriate for treatment of Trigger Finger on the posterior, human right hand, and **FIG. 12** shows the method for applying the wearable static electro magnetic field generating therapeutic device **9** in an exemplary fitment appropriate for treatment of Wrist Tendonitis on the anterior, human right hand. **FIG. 13** illustrates the method for applying SEMF generating therapeutic device **9** of **FIGS. 1-4**, and shows an exemplary fitment appropriate for treatment of Hand-Arm Vibration Syndrome (HAVS) on the anterior, human right hand, while **FIG. 14** shows an exemplary anterior fitment appropriate for treatment of Median Nerve Entrapment (Carpal Tunnel Syndrome) on the anterior, human right hand.

[**0067**] **FIG. 15** illustrates the method for applying the wearable SEMF generating device **9** in an exemplary posterior fitment appropriate for treatment of Median Nerve Entrapment (Carpal Tunnel Syndrome) on the posterior of the human right hand, and **FIG. 16** shows an exemplary fitment appropriate for treatment of Acute Ankle Sprains on the dorsal, human right foot, in accordance with the present invention. **FIG. 17** is a diagram illustrating the method for an exemplary fitment appropriate for treatment of Morton's Neuroma on the dorsal, human right foot, and **FIG. 18** shows an exemplary fitment appropriate for treatment of Plantar Fascitis on the plantar, human right foot. **FIG. 19** is a diagram illustrating the method for an exemplary fitment appropriate for treatment of Achilles Tendonitis on the posterior, human right ankle, and **FIG. 20** shows an exemplary fitment appropriate for treatment of Posterior Tibial Tendonitis on the posterior, human right ankle, in accordance with the present invention.

INFORMAL STUDIES TO DETERMINE EFFECTIVENESS OF THE INVENTION

[**0068**] Other sections of this application refer to a fifteen or so musculoskeletal disorders that this invention will treat, however at the onset of the invention's development, the inventors were acting on reports from the National Institute for Occupational Safety and Health (NIOSH) regarding the prevalence of Medial Nerve Entrapment, more commonly known as Carpal Tunnel Syndrome (CTS). In America alone there are over 8 million current cases of CTS with an additional 850,000 new cases annually. CTS is painful and crippling to the sufferer. Causes of CTS are varied and include pregnancy, menopause, PMS, rheumatoid arthritis, renal failure, high blood pressure and repetitive movement trauma such as sewing, typing, writing and using hand tools. The medical community, as with many other afflictions, has a typical treatment scenario for CTS, starting with splints and modification of work environments, moving onto anti-inflammatory analgesics and corticosteroids with ultimately more than 50% of cases requiring surgery.

[**0069**] The applicants posited that treating CTS with a Static Electro Magnetic Field would be more effective than a splint, as effective as medication without being invasive and definitely lead to the avoidance of surgery. Thus, the majority of the preliminary studies to determine effectiveness of the invention have been done on the wrist, with some associated elbow pain.

[**0070**] The criteria should be noted for all subjects of all of these studies.

[**0071**] All pain should be due to repetitive movement or other trauma

[**0072**] No degenerative diseases

[**0073**] No anti-inflammatory medication for 12 hours

[**0074**] No pain medication for 12 hours

Study A (Sylvester):

[**0075**] Criteria for evaluating effectiveness of the invention for this study were based on [1] Grip Strength measured three times and averaged, pre- and post-application, using a Hydraulic Hand Dynamometer. [2] Bilateral flexion and extension (Range of Motion) measured three times and averaged, pre- and post-application using a Digital Inclinometer.

[**0076**] Six test subjects had Grip Strength and Range of Motion measured on a painful wrist. They then immediately received a one-time application of the invention on said

wrist, lasting from 45 to 60 minutes. Grip Strength and Range of Motion were then immediately re-measured on the affected wrist.

[0077] All six test subjects showed an increase in all three of the evaluation criteria. Grip Strength increases ranged from 2% to 35%. Flexion increases ranged from 4% to 12%, and Extension increases ranged from 5% TO 20%.

Study B (Sylvester):

[0078] Criteria for evaluating effectiveness of the invention for this study were base on the 11 point JHACO pain scale, with 0 (zero) representing no pain and 10 (ten) representing the worst pain ever experienced.

[0079] Thirteen test subjects, 4 males and 9 females, ranging in age from 29 years to 73 years were asked to wear the invention for 5 (five) consecutive days, recording their pain levels immediately prior to application and immediately following application. All subjects experienced a diminishment of pain.

[0080] Results are as follows:

[0081] Average time worn 1.75 hours (30 minutes-5 hours)

[0082] Average prior-application pain scale 4.67 (1.6-9)

[0083] Average post-application pain scale 3.07 (0.5-8)

[0084] Average percent decrease of pain 33.6% (12%-78%)

Study C (Sylvester):

[0085] Criteria for evaluating effectiveness of the invention for this study were base on the 11 point JHACO pain scale, with 0 (zero) representing no pain and 10 (ten) representing the worst pain ever experienced. It should be noted, invention application on all subjects was 30 minutes.

Subject 1

Female—40 years—Constant Epicondylitis of the left elbow due to Repetitive Motion Syndrome.

Application 1

[0086] Pre-application pain scale 9

[0087] Post-application pain scale 5

[0088] Pain decrease 44%

Application 2

[0089] Pre-application pain scale 9

[0090] Post-application pain scale 2

Pain decrease 78%

Subject 2

Female—36 years—Constant wrist pain due to automobile accident.

Application 1

[0091] Pre-application pain scale 8

[0092] Post-application pain scale 5

[0093] Pain decrease 38%

Application 2

[0094] Pre-application pain scale 5

[0095] Post-application pain scale 3

[0096] Pain decrease 40%

Subject 3

Female—44 years—Constant wrist pain due to parrot bite.

Application 1

[0097] Pre-application pain scale 5

[0098] Post-application pain scale 0

[0099] Pain decrease 100%

Application 2

[0100] Pre-application pain scale 3

[0101] Post-application pain scale 0

[0102] Pain decrease 100%

Subject 4

Female—64 years—Constant wrist pain, cause unknown.

Application 1

[0103] Pre-application pain scale 6

[0104] Post-application pain scale 4

[0105] Pain decrease 33%

Application 2

[0106] Pre-application pain scale 7

[0107] Post-application pain scale 5

[0108] Pain decrease 28%

Subject 5

Female—37 years—Constant wrist pain, cause unknown.

Application 1

[0109] Pre-application pain scale 5

[0110] Post-application pain scale 1

[0111] Pain decrease 80%

Application 2

[0112] Pre-application pain scale 5

[0113] Post-application pain scale 2

[0114] Pain decrease 60%

Subject 6

Male—37 years—Constant wrist and elbow pain due to Repetitive Motion Syndrome.

Application 1

[0115] Pre-application pain scale 9

[0116] Post-application pain scale 6

[0117] Pain decrease 33%

Application 2

[0118] Pre-application pain scale 8

[0119] Post-application pain scale 5

[0120] Pain decrease 37%

[0121] Persons of skill in the art will appreciate that the present invention makes available a therapeutic apparatus for reducing inflammation and related pain in a living human body using a Static Electro Magnetic Field, the apparatus comprising a Static Electro Magnetic Field generating unit for generating a Static Electro Magnetic Field that is oriented toward a painful portion of the human body, a housing unit to protect and contain the said Static Electro Magnetic Field generating unit and an affixing unit for affixing the said housing unit to the living human body. In use, the method and apparatus of the present invention provides a means for treating inflammation and related pain is due to Median Nerve Entrapment (Carpal Tunnel Syndrome), Medial Epicondylitis (Golfer's Elbow), DeQuervain's Disease (Blackberry Thumb), Forearm Tendonitis, Wrist Tendonitis, Trigger Finger, Intersection Syndrome, Hand Arm Vibration Syndrome (HAVS), Lateral Epicondylitis (Tennis Elbow), Ulnar Nerve Entrapment (Cubital Tunnel Syndrome), Acute Ankle Sprains, Peroneal Tendonitis, Achilles Tendonitis, Plantar Fascitis, or Morton's Neuroma (Entrapment Neuropathy).

[0122] In the illustrative embodiment, Static Electro Magnetic Field generating unit **9** generates a non-oscillating Static Electro Magnetic Field between about 24 Gauss to 26 Gauss at 0 Hertz and includes solenoid induction coil **12**, a non-oscillating (or DC) voltage source preferably comprising one or more rechargeable batteries, a single pole single throw switch having an opened and closed state, an operating state indicator such as a light emitting diode and an electrical connector for use as a battery re-charging terminal.

[0123] The apparatus **9** preferably includes a solenoid induction coil **12** comprising an electrical conductor such as a copper wire wound around and supported by a non ferrous coil bobbin or form. The non-oscillating voltage source, charging socket **20** and single pole single throw switch **27** are electrically connected or coupled together in a series circuit while the solenoid induction coil **12** and light emitting diode **18** are coupled together in a parallel circuit. The housing unit **10** is a thermoplastic molded case to protect and contain the static electro magnetic field generating device **9** and, preferably, a hook and loop watchband **11** releasably affixes housing unit **10** to the human body.

[0124] Having described preferred embodiments of a new and improved method, it is believed that other modifications, variations and changes will be suggested to those skilled in the art in view of the teachings set forth herein. It is therefore to be understood that all such variations, modifications and changes are believed to fall within the scope of the present invention as defined by the appended claims.

What is claimed is:

1. A portable, wearable therapeutic apparatus for reducing inflammation and related pain in a living human body using a Static Electro Magnetic Field, comprising:

a Static Electro Magnetic Field generating circuit for generating a Static Electro Magnetic Field having a selected field strength of that is oriented toward a painful portion of the human body;

said Static Electro Magnetic Field generating circuit including a magnetic flux generating circuit element powered by a non-oscillating portable power supply, said portable power supply being selectively enabled by operation of an enabling switch;

a housing configured to substantially enclose and protect said Static Electro Magnetic Field generating circuit; and

a releasable strap configured to affix said housing unit against the living human body.

2. The portable, wearable therapeutic apparatus of claim 1, wherein said Static Electro Magnetic Field generating unit generates a non-oscillating Static Electro Magnetic Field having a field strength in the range of 24 Gauss to 26 Gauss at 0 Hertz.

3. The portable, wearable therapeutic apparatus of claim 1, wherein said Static Electro Magnetic Field generating unit flux generating circuit element comprises a solenoid induction coil, and

wherein said non-oscillating portable power supply comprises one or more rechargeable batteries.

4. The portable, wearable therapeutic apparatus of claim 3, further comprising a light emitting diode connected with said coil.

5. The portable, wearable therapeutic apparatus of claim 3, further comprising a charging socket configured to permit recharging the portable power supply.

6. The portable, wearable therapeutic apparatus of claim 3, wherein said solenoid induction coil comprises at least one winding of an electrical conductor supported by a non ferrous coil form;

wherein said non-oscillating voltage source, said charging socket and said single pole single throw switch are coupled together in a series circuit; and

wherein said solenoid induction coil and said light emitting diode are connected in parallel.

7. The portable, wearable therapeutic apparatus of claim 3, wherein said housing unit is a molded plastic case contoured along a body contact surface and said strap comprises a web segment or band sized to affix said housing unit to a selected contact surface of the human body, said web segment or band having first and second terminal ends carrying hook and loop fastener segments.

8. A method for treating inflammation or pain in a selected area of the human body with a portable, wearable device, comprising the method steps of:

(a) providing a Static Electro Magnetic Field generating circuit for generating a Static Electro Magnetic Field having a selected field strength, said circuit being adapted for orientation toward the selected area of the body; said Static Electro Magnetic Field generating circuit including a magnetic flux generating circuit element powered by a non-oscillating portable power supply, said portable power supply being selectively enabled by operation of an enabling switch;

(b) providing a housing configured to substantially enclose and protect said Static Electro Magnetic Field generating circuit;

(c) providing a releasable strap configured to affix said housing unit against the body;

(d) identifying the selected area of the body for treatment with a Static Electro Magnetic Field; and

(e) fitting said housing enclosing said Static Electro Magnetic Field generating circuit against or proximate the selected area of the body in an orientation permitting exposure of the painful area to the Static Electro Magnetic Field generated by the Static Electro Magnetic Field generating circuit.

(f) Energizing said Static Electro Magnetic Field generating circuit to expose the selected area of the body to the Static Electro Magnetic Field.

9. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to Median Nerve Entrapment or Carpal Tunnel Syndrome.

10. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to Medial Epicondylitis or Golfer's Elbow.

11. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to DeQuervain's Disease or Blackberry Thumb.

12. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to Forearm Tendonitis.

13. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to Wrist Tendonitis.

14. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to Trigger Finger.

15. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to Intersection Syndrome.

16. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to Hand Arm Vibration Syndrome or HAVS.

17. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to Lateral Epicondylitis or Tennis Elbow.

18. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to Ulnar Nerve Entrapment or Cubital Tunnel Syndrome.

19. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain is due Acute Ankle Sprain.

20. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to Peroneal Tendonitis.

21. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to Achilles Tendonitis.

22. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to Plantar Fascitis.

23. The method for treating inflammation or pain in an area of the human body with a portable, wearable device of claim 8, wherein step (e) comprises fitting said housing in an orientation permitting treatment of inflammation and related pain due to Morton's Neuroma or Entrapment Neuropathy.

* * * * *