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(54) **Title**: METHODS AND DEVICES FOR TREATING HYPERTENSION

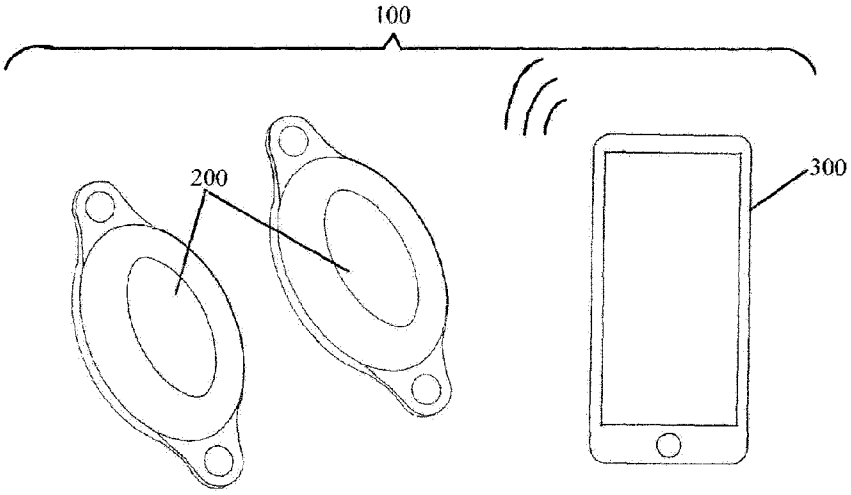

Figure 1

(57) **Abstract**: Devices, systems and methods are described which control blood pressure and nervous system activity by stimulating baroreceptors. By selectively and controllably activating baroreceptors and/or nerves, the present invention reduces blood pressure and alters the sympathetic nervous system; thereby minimizing deleterious effects on the heart, vasculature and other organs and tissues. A baroreceptor activation device or other sensory activation device is positioned near a dermal bone to provide the treatment.

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METHODS AND DEVICES FOR TREATING HYPERTENSION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application No. 61/549,007 filed October 19, 2011 titled " Hypertension and Heart Rate Reduction," and U.S. Provisional Patent Application No. 61/648,060 filed May 16, 2012 titled "Methods and Devices for Treating Hypertension," and U.S. Provisional Patent Application No. 61/681,469 filed August 9, 2012 titled "Methods and Devices for Treating Hypertension Using and Electroactive Transducer," and U.S. Provisional Patent Application No. 61/681,513 filed on August 9, 2012 titled "Support Assemblies For The Treatment of Hypertension," the entireties of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] This invention relates generally to methods and devices for the treatment of hypertension. More specifically, methods and devices which treat hypertension using devices disposed extra corporally.

[0003] Hypertension, or high blood pressure, affects millions of people every day and is a serious health hazard. Hypertension is associated with an elevated risk for heart attack, heart failure, arterial aneurysms, kidney failure and stroke. There are many factors that may affect blood pressure, such as: salt intake, obesity, occupation, alcohol intake, smoking, pregnancy, stimulant intake, sleep apnea, genetic susceptibility, decreased kidney perfusion, arterial hardening and medication(s). Many times people are unaware that they suffer from hypertension until it is discovered during a medical check-up with their health care practitioner (HCP), or worse, it is discovered when they are hospitalized for a hypertension related condition such as a heart attack or stroke.

[0004] Blood pressure is controlled by a complex system within the body, one component of this system is known as the arterial baroreflex (ABR). The baroreflex is the fastest autonomic reflex responding to changes in blood pressure. The baroreceptor nerve endings are embedded in vessels throughout the circulatory system

and encode both mean pressure and rate of change of pressure as a frequency. Centers in the brainstem process spikes in the frequency information, integrating it with other information and providing a signal to the sinoatrial (SA) pacemaking node of the heart via efferent fibers in the vagus nerve. When blood pressure becomes too high, the resulting vagal nerve signal triggers the release of acetylecholine at the SA node of the heart, slowing the heart rate and thus lowering the blood pressure.

[0005] Baroreceptors are located in the transverse aortic arch and the carotid sinuses of the left and right internal carotid arteries. The baroreceptors found within the aortic arch monitor the pressure of blood delivered to the systemic circuit, and the baroreceptors within the carotid arteries monitor the pressure of the blood being delivered to the brain.

[0006] As described above, the arterial baroreceptors are stretch receptors that are stimulated by distortion of the arterial wall when pressure changes. The baroreceptors can identify the changes in the average blood pressure or the rate of change in pressure with each arterial pulse. Action potentials triggered in the baroreceptor endings are then conducted to the brainstem where central terminations (synapses) transmit this information to neurons within the solitary nucleus. Reflex responses from such baroreceptor activity can trigger increases or decreases in the heart rate. Arterial baroreceptor (ABR) sensory endings are simple, sprayed nerve endings that lie in the tunica adventitia of the artery. An increase in the mean arterial pressure increases depolarization of these sensory endings, which results in action potentials. These action potentials are conducted to the solitary nucleus in the central nervous system by axons and have a reflex effect on the cardiovascular system through autonomic neurons.

[0007] At normal resting blood pressures, baroreceptors discharge at approximately 1 out of every 3 heart beats. If blood pressure falls, the arteries retract in diameter and the baroreceptor firing rate decreases with the drop in blood pressure the brain send a signal to the heart to increase blood pressure by increasing heart rate. Signals from the carotid baroreceptors are sent via the glossopharyngeal nerve (cranial nerve IX). Signals from the aortic baroreceptors travel through the vagus nerve (cranial nerve X). Arterial baroreceptors inform reflexes about arterial blood pressure.

[0008] The arterial baroreflex system is a dynamic system that is capable of adapting to ever changing situations. The ABR is the reason why we do not pass out when moving from a seated to standing position. In this instance the ABR senses a change in blood pressure and accommodates the change by sending the appropriate signal to regulate blood pressure. The ABR system also performs an essential function to regulate blood pressure during exercise, wherein during exercise your heart rate increases as well as your blood pressure, however, at a certain point during exercise the ABR will intervene, allowing the heart rate to further increase but not allowing the blood pressure to further increase.

[0009] As stated above, hypertension currently affects a large and growing population. Currently treatments for hypertension range from prescribed lifestyle changes and the use of pharmaceutical products. Within the past couple of years, new surgical therapies are emerging. These surgical therapies either lead to the implantation of a device for stimulating a patient's carotid baroreceptor or to the disconnection of the nerves of the renal arteries.

[0010] If prescribed lifestyle changes do not address a patient's hypertension, their HCP will typically prescribe drug therapy to treat their hypertension. There are multiple classes of pharmaceutical products that can be utilized to treat hypertension. These include vasodilators to reduce the blood pressure and ease the workload of the heart, diuretics to reduce fluid overload, inhibitors and blocking agents of the body's neurohormonal responses, and other medicaments. Many times, a HCP will prescribe one or more of these products to a patient to be taken in combination in order to lower their blood pressure. However, the use of pharmaceutical products is not without their risks. Many of these products carry severe warnings of potential side effects. Additionally, each patient may respond differently to the products, therefore multiple office visits may be required before the right dosage and type of pharmaceutical products are selected, which leads to greater health care costs. Further still there are a number of patients who either do not respond to medication, refuse to take medication, or over time the medication no longer provides a therapeutic effect. Recently, new clinical trial data has drawn correlations between the use of diuretic pharmaceutical products to treat high blood pressure and the formation of diabetes within the patient.

[0011] For patients who do not respond to drug therapy, there are medical devices and treatments that can be utilized to treat high blood pressure. Some of these devices involve invasive surgical procedures including the implantation of a permanent medical device within a patient's artery to impart a force at a specific location within the artery which then may cause a lowering of blood pressure. However, these devices are relatively new or are still under development and have not been proven over a long period of time. Also, since the device is a permanent implant, there is always the possibility of complications during the implantation process or infections related to the implantation.

[0012] As described above, another type of invasive medical device is an electrical signal generating implant, where electrodes are placed adjacent to the carotid artery. With this process, the surgeon must be careful not to sever any of the nerves while implanting the device. If the nerves are severed, then the device will not function properly and may lead to long term health complications for the patient. However, even more troubling is that the patient has now permanently lost a baroreceptor for controlling blood pressure naturally, which may lead to complications later, which are currently unknown. Additionally, the implant device requires regular battery replacement, which to do so requires another invasive surgical procedure.

[0013] Another type of invasive medical device and procedure being developed is the use of ablation catheter to denervate the carotid body, specifically the chemoreceptors of the carotid body. Similar to the device and procedure described above, this device permanently causes a disconnection between the chemoreceptors and the nervous system/brain. The long term effects are unknown, additionally, other nerves maybe destroyed or disconnected during the procedure which may lead to other side effects.

[0014] Another type of invasive medical procedure to treat hypertension being developed is to use an ablation catheter placed within the renal artery, where a series of energy pulses are performed to ablate (sever) the nerves surrounding the artery, thereby effectively disconnecting the nerves of the kidney from the body. This procedure results in a permanent and non-reversible change to the patient's nervous system, this procedure is being referred to as renal nerve ablation or renal

denervation. The long term effects of such a permanent treatment are unknown at this time as this approach is relatively new on the market. Recently published data has shown that not all patients respond to this surgical procedure, that is after the procedure, some of the patients show little to no changes in their blood pressure. This may be concerning as now these patients have had their renal arteries permanently disconnected from their kidneys, which may lead to long term effects which are unknown at this time. Additionally, the costs associated with an invasive medical procedure are not insignificant, only to prove that the procedure had no effect, thus, instead of potentially lowering the cost of treatment for these patients, the cost of treating their hypertension was significantly added to.

[0015] Additionally, the recently published data also shows that patients who respond to renal denervation may still remain hypertensive. Thus, the renal denervation procedure may not be a "cure," instead it may be seen as an adjunctive therapy, as such these patients may remain on drug therapies or are recommended to remain on drug therapy after having undergone renal denervation.

[0016] Yet another invasive surgical approach to address hypertension is a combination of a device and a pharmaceutical product, wherein a catheter with a needle disposed near its distal end are placed within the renal artery. Once in position, a liquid pharmaceutical product is injected into the wall of the artery, whereby the pharmaceutical product is designed to chemically ablate the renal nerves. Here again, this treatment procedure is considered to be a permanent solution, whereby the nerves are permanently severed. Long term efficacy of the severing of the renal nerves is unknown. Additionally, long term effects of the procedure are also unknown.

[0017] Human skin acts as the protective barrier between our internal body systems and the outside world. Our skin in combination with our bodies nerves provides for the ability to perceive touch sensations and gives our brains a wealth of information about the environment around us, such as temperature, pain, and pressure. Without such a nervous system, we wouldn't be able to feel our feet hitting the floor when we walked, we wouldn't sense when something sharp cut us, and we wouldn't feel the warmth of the sun on our skin.

[0018] Human skin is composed of several layers. The very top layer is the epidermis and is the layer of skin you can see. In Latin, the prefix "epi-" means "upon" or "over," thus the epidermis is the layer upon which the dermis is disposed (the dermis is the second layer of skin). The epidermis, made of dead skin cells, is waterproof and serves as a protective wrap for the underlying skin layers and the rest of the body. It contains melanin, which protects against the sun's harmful rays and also gives skin its color. When you are in the sun, the melanin builds up to increase its protective properties, which also causes the skin to darken. The epidermis also contains very sensitive cells called touch receptors that give the brain a variety of information about the environment the body is in.

[0019] The second layer of skin is the dermis. The dermis contains hair follicles, sweat glands, sebaceous (oil) glands, blood vessels, nerve endings, and a variety of touch receptors. The dermis' primary function is to sustain and support the epidermis by diffusing nutrients to it and replacing the skin cells that are shed off the upper layer of the epidermis. New cells are formed at the junction between the dermis and epidermis, and they slowly push their way towards the surface of the skin so that they can replace the dead skin cells that are shed. Oil and sweat glands eliminate waste produced at the dermis level of the skin by opening their pores at the surface of the epidermis and releasing the waste.

[0020] The bottom skin layer is the subcutaneous tissue which is composed of fat and connective tissue. The layer of fat acts as an insulator and helps regulate body temperature. It also acts as a cushion to protect underlying tissue from damage when you bump into things. The connective tissue keeps the skin attached to the muscles and tendons underneath.

[0021] Our sense of touch is controlled by a huge network of nerve endings and touch receptors disposed within the skin which is known as the somatosensory system. This system is responsible for all the sensations we feel; cold, hot, smooth, rough, pressure, tickle, itch, pain, vibrations, and more. Within the somatosensory system, there are four main types of receptors; mechanoreceptors, thermoreceptors, nociceptors, and proprioceptors.

[0022] It is important to understand how specialized receptors adapt to a change in stimulus (anything that touches the skin and causes sensations such as hot, cold, pressure, tickle, etc.). A touch receptor is considered rapidly adapting if it responds to a change in stimulus very quickly. This means that it can sense right away when the skin is touching an object and when it stops touching that object. However, rapidly adapting receptors can't sense the continuation and duration of a stimulus touching the skin (how long the skin is touching an object). These receptors best sense vibrations occurring on or within the skin. A touch receptor is considered slowly adapting if it does not respond to a change in stimulus very quickly. These receptors are very good at sensing the continuous pressure of an object touching or indenting the skin but are not very good at sensing when the stimulus started or ended.

[0023] Mechanoreceptors are receptors which perceive sensations such as pressure, vibrations, and texture. There are four known types of mechanoreceptors whose only function is to perceive indentions and vibrations of the skin: Merkel's disks, Meissner's corpuscles, Ruffini's corpuscles, and Pacinian corpuscles.

[0024] The most sensitive mechanoreceptors, Merkel's disks and Meissner's corpuscles, are found in the very top layers of the dermis and epidermis and are generally found in non-hairy skin such as the palms, lips, tongue, soles of feet, fingertips, eyelids, and the face. Merkel's disks are slowly adapting receptors and Meissner's corpuscles are rapidly adapting receptors so your skin can perceive both when you are touching something and how long the object is touching the skin.

[0025] Located deeper in the dermis and along joints, tendons, and muscles are Ruffini's corpuscles and Pacinian corpuscles. These mechanoreceptors can feel sensations such as vibrations traveling down bones and tendons, rotational movement of limbs, and the stretching of skin.

[0026] Another type of receptors are thermoreceptors, as their name suggests, these receptors perceive sensations related to the temperature of objects the skin feels. They are found in the dermis layer of the skin. There are two basic categories of thermoreceptors: hot and cold receptors.

[0027] Cold receptors start to perceive cold sensations when the surface of the skin drops below 95 ° F. They are most stimulated when the surface of the skin is at 77 ° F and are no longer stimulated when the surface of the skin drops below 41 ° F. This is why your feet or hands start to go numb when they are submerged in icy water for a long period of time.

[0028] Hot receptors start to perceive hot sensations when the surface of the skin rises above 86 ° F and are most stimulated at 113 ° F. But beyond 113 ° F, pain receptors take over to avoid damage being done to the skin and underlying tissues.

[0029] Thermoreceptors are found all over the body, but cold receptors are found in greater density than heat receptors. The highest concentration of thermoreceptors can be found in the face and ears.

[0030] Another type of receptor are pain receptors, commonly known as nociceptors, "Noci-" in Latin means "injurious" or "hurt." These receptors detect pain or stimuli that can or does cause damage to the skin and other tissues of the body. There are over three million pain receptors throughout the body, found in skin, muscles, bones, blood vessels, and some organs. They can detect pain that is caused by mechanical stimuli (cut or scrape), thermal stimuli (burn), or chemical stimuli (poison from an insect sting).

[0031] These receptors cause a feeling of sharp pain to encourage you to quickly move away from a harmful stimulus such as a broken piece of glass or a hot stove stop. They also have receptors that cause a dull pain in an area that has been injured to encourage you not to use or touch that limb or body part until the damaged area has healed. While it is never fun to activate these receptors that cause pain, these receptors play an important part in keeping the body safe from serious injury or damage by sending these early warning signals to the brain.

[0032] Another receptor type are proprioceptors, the word "proprius" means "one's own" and is used in the name of these receptors because they sense the position of the different parts of the body in relation to each other and the surrounding environment. Proprioceptors are found in tendons, muscles, and joint capsules. This location in the body allows these special cells to detect changes in muscle length and muscle tension.

Without proprioceptors, we would not be able to do fundamental things such as feeding or clothing ourselves.

[0033] While many receptors have specific functions to help us perceive different touch sensations, almost never is just one type active at any one time. When drinking from a freshly opened can of soda, your hand can perceive many different sensations just by holding it. Thermoreceptors are sensing that the can is much colder than the surrounding air, while the mechanoreceptors in your fingers are feeling the smoothness of the can and the small fluttering sensations inside the can caused by the carbon dioxide bubbles rising to the surface of the soda. Mechanoreceptors located deeper in your hand can sense that your hand is stretching around the can, that pressure is being exerted to hold the can, and that your hand is grasping the can. Proprioceptors are also sensing the hand stretching as well as how the hand and fingers are holding the can in relation to each other and the rest of the body.

[0034] None of the sensations described above and felt by the somatosensory system would make any difference if these sensations could not reach the brain. The nervous system of the body takes up this important task. Neurons, which are specialized nerve cells that are the smallest unit of the nervous system, receive and transmit messages with other neurons so that messages can be sent to and from the brain. This allows the brain to communicate with the body. When your hand touches an object, the mechanoreceptors in the skin are activated, and they start a chain of events by signaling to the nearest neuron that they touched something. This neuron then transmits this message to the next neuron which gets passed on to the next neuron and on it goes until the message is sent to the brain. Now the brain can process what your hand touched and send messages back to your hand via this same pathway to let the hand know if the brain wants more information about the object it is touching or if the hand should stop touching it.

[0035] Vibration experiments have been conducted to test the effects of vibration, the results of such an experiment were published in 1961 in the Journal of Physiol. (1961), 159 pp 391-409, entitled "Response of Pacinian Corpuscles to Sinousoidal Vibration, by M. Sato. In this experiment it was proven that vibrations can excite the nervous system similar to utilization of electrical stimulation.

[0036] Other experiments have shown that the 1st Node of Ranvier gaps can be excited by either mechanical transduction or acoustic stimulation. The 1st Node of Ranvier gaps are gaps formed between myelin sheaths between different cells.

[0037] In a 1967 publication entitled "The Relative Sensitivity to Vibration of Muscle Receptors of the Cat," M.C. Brown, I. Engberger and P.B.C. Matthews, Journal Physiol. (1967), 192 PP 773-800, the authors tested vibrations and concluded that vibratory effects persist as long as the vibration continues. Additionally, the authors cited another publication, 1966 Matthews, "Reflex excitation of the soleus muscle of the decerebrate cat caused by vibration applied to tendon" where vibration, was applied to a non-contracting muscle, provides a way of selectively activating nearly all of the nerve fibers from the primary endings to discharge repetitively. In contrast to electrical stimulation, vibration provides for a more selective activation.

[0038] Electrical stimulation will stimulate those nerves which are located in the close proximity to the electrical source, however, electrical stimulation will seek the lowest resistance pathway and is typically localized to the area of application. In contrast, vibrational stimulation carries the benefit of exciting afferent fibers at a distance from the location of the application of the vibration.

[0039] In 2000 a publication by Alfrey entitled "Characterizing the Afferent Limb of the Baroreflex" Rice University, Houston Texas, April 2000, UMI Microform 99-69-223. The author concluded that the baroreflex is the fastest autonomic reflex responding to changes in blood pressure. Baroreceptor nerve endings embedded in vessels throughout the circulatory system encode both mean pressure and rate of change of pressure as a frequency-modulated train of action potentials (spikes). Centers in the brainstem process the spike train information, integrating it with information from higher centers and providing a signal to the sinoatrial (SA) pacemaking node of the heart via efferent fibers in the vagus nerve. When blood pressure becomes too high, the resulting vagal signal triggers the release of acetylcholine at the SA node of the heart slowing heart rate and thus lowering blood pressure.

[0040] In another paper, published in 2004 by Syntichaki et al., entitled "Genetic Models of Mechanotransduction: The Nematode *Caenorhabditis elegans*" Physol

Rev. 84: 1097-1153, 2004 10.1152/physrev.0043.2003, it was found that all vertebrates respond to similar mechanosensory stimuli, therefore it's likely that two humans would have similar response to the same wavelengths or frequencies.

[0041] Lastly, while there are number of different therapies available on the market and new therapies emerging, there are patient populations that cannot be treated through the use of the existing drugs or devices.

[0042] One such population is patients who develop high blood pressure during pregnancy. Health care practitioners are generally hesitant to prescribed pharmaceutical products in these situations as there may be unknown side effects to the mother and unborn child. Furthermore, many hypertensive pharmaceutical products have not been properly tested for use during pregnancy; therefore, there is much hesitancy on behalf of the prescribing physician to use such drug products due to potential untested side-effects as well as potential litigation arising from a side-effect. Pregnancy induced hypertension, gestational hypertension or preeclampsia may not be a permanent condition and may be resolve after delivery. Therefore, the use of permanent therapies, such as renal denervation, may not be warranted in this situation. Additionally, surgical procedures are not generally recommended during pregnancy.

[0043] There is yet another hypertensive population emerging in today's world is the hypertensive adolescent. Over the past 30 years, the number of adolescent hypertensives has risen to a rate of over 3.7% diagnosed hypertensive and 3.4% diagnosed pre-hypertensive. Only 1 in 4 adolescents are currently diagnosed. Many of the currently available pharmaceutical products have not been tested on an adolescent population, therefore, as described above, many physicians are hesitant to prescribe drug therapies due to unknown side effects or long term effects they may have. Furthermore, the adolescent population poses yet another difficulty in that they are still developing and undergoing puberty and bone growth. Therefore, there is a need for a non-invasive, non-pharmaceutical solution to address this growing patient population.

[0044] Thus, it would be desirable to provide improved methods, devices and systems for artificial and selective activation of a patient's baroreflex or nervous

system in order to achieve a variety of therapeutic objectives, including the control of hypertension, renal function, heart failure, and the treatment of other cardiovascular disorders. It would be particularly desirable if such methods and systems were non-invasive, reversible, safe and/or external to the patient.

BRIEF DESCRIPTION OF THE INVENTION

[0045] In accordance with the present invention there is provided a device for treatment of hypertension, comprising, a housing, the housing have a proximal end and a distal end; and a driver assembly within the housing, the driver assembly electrically coupled to an energy source, the energy source disposed within the housing.

[0046] In accordance with the present invention there is provided a device for imparting energy to a patient, comprising, a housing, the housing having a proximal end, a distal end and defining a volume therebetween; a driver assembly is disposed within the volume of the housing; an energy source coupled to the driver assembly; and an electronics module coupled to the driver assembly and the energy source, wherein the electronics module controls the driver assembly.

[0047] In accordance with the present invention there is provided a device for treating hypertension, the device comprising, a housing, the housing having a proximal surface and a distal surface, wherein the housing further includes a mounting system, the mounting system including a first member and a second member, the first member associated with the housing and the second member configured to be received by tissue; and a driver assembly within the housing.

[0048] In accordance with the present invention this is provided a device for imparting energy to a patient, the device comprising: a housing, the housing having a first surface and a second surface, the surfaces defining a volume therebetween, wherein the housing further includes a mounting system, the mounting system including a first member and a second member, the first member associated with the housing and the second member configured to be received by tissue; a driver assembly disposed within the volume of the housing; an energy source coupled to the

driver assembly; and an electronics module coupled to the driver assembly and the energy source.

[0049] In accordance with the present invention there is provided a method of providing therapy, the method comprising: applying a therapy applying device to a collar bone of a patient; and activating a driver assembly within the therapy applying device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0050] Figure 1 is an exemplary embodiment of the therapy system in accordance with the present invention;

[0051] Figure 2 is a isometric view of a therapy providing device in accordance with the present invention;

[0052] Figures 3A-3D are exemplary illustrations of housings of the therapy providing device in accordance with the present invention;

[0053] Figure 4A is a top view of a housing of the therapy providing device in accordance with the present invention;

[0054] Figure 4B is a cross-sectional view of the housing of Figure 4A taken about line B-B;

[0055] Figure 4C is a cross-sectional view of another housing in accordance with the present invention;

[0056] Figure 5 is an exploded view of a therapy providing device in accordance with the present invention;

[0057] Figure 6 is an isometric view of a circuit board in accordance with the present invention;

[0058] Figure 7 is a plan view of a haptic speaker in accordance with the present invention;

[0059] Figure 8 is an isometric view of an electroactive polymer transducer in accordance with the present invention;

[0060] Figure 9 illustrates a cross-sectional view of the electroactive polymer transducer of Figure 8 in communication with a driver;

[0061] Figure 10 is a plan view of an alternative embodiment of an electroactive polymer transducer in accordance with the present invention;

[0062] Figure 11 is an isometric view of a charging/base station in accordance with the present invention;

[0063] Figure 12 is a side view of the therapy providing device of the present invention in combination with a CPAP mask assembly;

[0064] Figure 13A is a bottom view illustrating a therapy device including an adhesive mounting system;

[0065] Figure 13B illustrates the therapy device of Figure 13A as disposed on a user;

[0066] Figures 14A and 14B illustrates and alternative mounting arrangement for the therapy device of the present invention;

[0067] Figure 14C is a cross-sectional view of the mounting system of Figures14A and 14B;

[0068] Figures 15A and 15B illustrate another mounting arrangement for the therapy device of the present invention;

[0069] Figures 16A and 16B illustrate a magnetic mounting system in accordance with the present invention;

[0070] Figures 17 and 18 illustrate embodiments of support structures for use with the present invention;

[0071] Figures 19A-19C illustrates another housing in accordance with the present invention, the housing configured to be received about a user's shoulders;

[0072] Figures 20A and 20B illustrate alternative clothing mounting arrangements for the therapy device of the present invention;

[0073] Figure 21A illustrates an exemplary embodiment of a computing device in accordance with the present invention;

[0074] Figure 21B illustrates and exemplary screen view of a program displayed on the exemplary computing device of Figure 21A in accordance with the present invention;

[0075] Figure 22 illustrates a flow diagram for a software program in accordance with the present invention;

[0076] Figure 23A illustrates a therapeutic frequency curve for the therapy provided by an exemplary embodiment of the present invention;

[0077] Figure 23B illustrates a timed therapy sequence in accordance with an embodiment of the present invention;

[0078] Figure 24A illustrates a patient's blood pressure reading over a twenty-four hour period, showing a hypertensive patient; and

[0079] Figure 24B illustrates the blood pressure of the patient of Figure 24A after receiving therapy in accordance with the device and methods of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0080] The following detailed description illustrates embodiments of the invention by way of example and not by way of limitation. The description clearly enables one skilled in the art to make and use the disclosure, describes several embodiments, adaptations, variations, alternatives, and uses of the disclosure, including what is presently believed to be the best mode of carrying out the disclosure.

[0081] This written description uses examples to disclose the invention, including the best mode, and also to enable any person skilled in the art to practice the invention, including making and using any devices or systems and performing any incorporated methods. The patentable scope of the invention is defined by the claims, and may include other examples that occur to those skilled in the art. Such other

examples are intended to be within the scope of the claims if they have structural elements that do not differ from the literal language of the claims, or if they include equivalent structural elements with insubstantial differences from the literal languages of the claims.

[0082] In accordance with the present invention there is provided devices and methods for the treatment of hypertension. The device of the present invention is configured to be detachably attached to a user, wherein the device is aligned with a bone of the user's body. Once affixed to the patient, the device can be activated either manually or remotely, wirelessly or wired, through the use of a software program running on a computing device or a software program within the device. The activation may be timed to coincide with a patient's sleep pattern, such that therapy is provided by the device to the patient in the evening and again in the morning prior to the patient waking up. It is believed that providing therapy during a sleep cycle is beneficial.

[0083] In accordance with embodiments of the present invention the device is detachably attached to a patient's tissue and is intended to engage a portion of the patient's skeletal frame, particularly the clavicle. It shall be understood that although the present invention is described in reference to the collar bone or clavicle, it shall be understood that this should not be limiting in any manner. As described above, in a preferred embodiment the methods and devices of the present invention utilize the clavicle. However, the methods and devices of the present invention may be utilized with other dermal bones such as the skull, jawbone, knee cap (patella) or non-dermal bones such as the wrist bone, ribs, scapula. Methods and devices of the present invention can also be used above any portion of the body containing somatory sensors such as proprioceptors, nociceptors, mechanoreceptors or thermoreceptors. Dermal bones are unique in that dermal bone does not form from cartilage first and then calcify. Dermal bone is formed within the dermis and it grows by accretion only; that is, the outer portion of the bone is deposited by osteocytes. Dermal bones have been utilized to transmit sound for other devices such as in hearing aids.

[0084] Referring now to Figure 1, there is shown the therapy system 100 in accordance with the present invention. As shown in Figure 1, the therapy system 100

in accordance with the present invention may include a pair of therapy providing devices 200 and optionally a computing device 300. The therapy providing system 100 may further include a charging/storage system as will be described in detail below with reference to Figure 11. Additionally, the therapy providing device 200 may further include an integrated or separate attachment system to detachably attach the system 100 to a user's skin as will be described in greater detail below.

[0085] As shown in Figure 1, the computing device 300 in one aspect is configured to communicate with the therapy providing device 200 through a wireless communication protocol such as through the use of wifi, Bluetooth, ZigBee, RFID, NFC, ANT+, cellular, infrared or other known wireless communication protocols. Alternatively, the computing device 300 and the therapy providing devices 200 may be communicatively coupled together using a physical connection such as an electrical wire, a plurality of electrical wires, electrical cable, fiber optic or using other known physical connections capable of transmitting signals between the devices. As shown in Figure 1, it is contemplated that the methods of use in accordance with the present invention would utilize two therapy providing devices 200 as shown. If two therapy providing devices 200 are utilized, they are intended to be disposed on a user about the left and right clavicle. In accordance with the present invention a single therapy providing device 200 may be utilized for treatment according to the present invention, or multiple therapy providing devices 200 may be utilized for therapy. The two therapy providing devices 200 can be communicatively coupled together utilizing a physical connection or a wireless connection such as those described above.

[0086] Referring now to Figure 2, there is shown an isometric view of a therapy providing device 200. As shown in Figure 2, the therapy providing device 200 includes a housing 210. The housing 210 defined by a proximal end 212 and a distal end 211, and first surface 214 and a second surface 215 (not shown), the proximal end, distal end and first and second surfaces and defining a volume therebetween, wherein the volume includes additional structures and components as will be described below. As shown in Figure 2, the first surface 214 includes a power button 260, a LED indicator light 262, and at least one pair of charging pins 265. The multiple charging pins 265 may be including on the therapy providing device 200,

whereas the multiple pins 265 are disposed symmetrically about an axis (not shown) passing through the power button 260. Placement of the charging pins 265 about an axis extending through the power button 260 allows for the therapy providing device 200 to be placed within a charger without care as to orientation as each side of the therapy providing device 200 includes charging pins 265, such that the therapy providing device 200 will engage the changing pins in the charging station in either orientation. Additional details with regard to a charging station/base will be described in greater detail below with reference to Figure 11. Additionally, the housing 201 may further include magnets 230 or a metallic material disposed within recesses formed in the first and second ends 211,212 of the housing 210. Alternatively, the magnets 230 may be integrally formed with the housing 210 during a manufacturing process such as injection molding.

[0087] The housing 210 may be formed of multiple pieces which may then be assembled using known assembly methods such as glue, ultrasonic welding, heat welding, rotational welding, snap-fit construction, use of fasteners such as screws or pins, or the like. In accordance with the invention, the housing 210 may be formed of two pieces or multiple pieces, wherein one section of the housing 210 includes all sides except the second surface 215, thereby forming a shell into which the components can be disposed, then the second surface 215 could be attached to the other portion of the housing 210 to form the therapy providing device 200. The housing 210 may be constructed of biocompatible materials such as polymers, plastics, fabrics or metals. The housing 210 may be formed using manufacturing processes such as machining, injection molding, 3-d printing, vacuum forming, deep drawing or the like. In accordance with the invention, the materials utilized in construction of the housing 210 of the therapy providing device 200 shall be chosen such that the materials have good biocompatibility as it is intended that the therapy providing device 200 will be placed in skin contact during use, where in certain usages the skin contact may be for prolonged time.

[0088] Further still, it is contemplated that the therapy providing device 200 may be wrapped with a biocompatible membrane. An example of a suitable membrane is available from 3M and sold under the tradename of Tegaderm.

[0089] Referring now to Figures 3A-3D there are shown exemplary embodiment of the second surface 215 in accordance with the present invention. As shown in Figure 3A, the second surface 215 may be formed as a planar surface. Referring now to Figure 3B, in this figure, the second surface 215 is formed of multiple pieces, wherein one component 216 is configured to be received by the other portion of the housing and the second component 217 is configured to be received by a user's tissue, this portion 217 may be formed of a more pliable or conformable material than the first component 215, wherein the more pliable material 217 may conform or shape to the user's anatomy more readily. In accordance with the invention, the second component 217 may be formed of a compliant material such as and open or closed cell foam material, such that when the therapy providing device 200 is disposed upon a user for therapy, the compliant foam surface conforms to the user's anatomy. Additionally, the materials selected may be chosen such that they are anti-microbial/bacterial.

[0090] Referring now to Figures 3C and 3D there is shown another exemplary embodiment wherein the second surface 218 is shown having a first thickness, wherein the material of which the first surface 218 is formed is selected such that the material may be shaped or contoured to be received by a patient's skin, particularly in an area adjacent the patient's clavicle. The shaped surface may be in the form of a concave shape. Further still, the material 218 of Figures 3C and 3D may be selected such that the material defines a deformable structure, such that when the housing is placed over the patient's clavicle the housing conforms to the patient's anatomy as shown in Figure 3D. In yet another embodiment, a portion of the housing may be custom formed to each individual user through the application of heat, whereby the housing or a portion of the housing is heated and then pressed onto the patient, the heated portion of the housing conforming to the patient's anatomy, or heated and molded by through an application of force. In another aspect, the second component 217 may be embodied in the form of a flexible membrane in which an expandable foam material may be injected into. In use, the therapy providing device would be placed on the user in a chosen location, the expandable foam material could then be injected into the flexible membrane while the therapy providing device is held against the user. As the foam expands and cures, the second component 217 would take the shape of the user's anatomy, thereby providing a customized fit. Lastly, it is further

contemplated that the housing includes an enlarged or thickened surface that can be ground or machined away to conform to the patient's anatomy. Further still, a mold may be taken of the patient's anatomy, whereby a housing can then be manufactured from the mold taken from the user's anatomy, thereby customizing the fit of the therapy providing device to each user.

[0091] Referring now to Figures 4A-C there are shown additional housing designs in accordance with the present invention. As shown in Figure 4A the alternative housing is formed in a generally circular fashion, wherein the housing contains additional components as will be described in greater detail below. Also as shown in Figure 4A, the housing 270 may further include a wire or cable connection extending from the housing 270 as described above. Referring now to Figure 4B, there is shown a cross-sectional view of the housing 270 of the therapy providing device 200" of Figure 4A taken about line B-B of Figure 4A. As shown in the cross-sectional view, the alternative housing 270 is formed having a generally convex shape. Referring now to Figure 4C there is shown a cross-sectional view of yet another alternative embodiment of a housing 272, in this embodiment the housing 272 has a generally convex shape as previously described, however, in this embodiment the housing 272 includes concave portions 271. In use, the housing 272 is placed on a user, adjacent to the user's clavicle, wherein a force can be applied to the housing 272 adjacent to each concave portion 271 forcing air out of the concave portions 271, thereby causing a vacuum to be formed thereby suctioning the housing 272 to the user's tissue. It is contemplated that the housings 270 and 272 shown in Figures 4A-4C may be constructed of a biocompatible flexible material, such that the housing conforms to the user's anatomy when placed thereupon. Examples of suitable materials of which the housings 270, 272 may be formed from are: silicone, urethanes, rubber, silicone, latex and the like.

[0092] Referring now to Figure 5, there is shown an exploded view of a therapy providing device 200 in accordance with the present invention. As described above and shown in Figure 2-4, the therapy providing device includes a housing 210, wherein the housing includes provisions for a power switch 260 as well as provisions for LED indicators 262 and charging pins 265 as described above. The power switch 260 maybe a separate component disposed within the housing 210 or it may be

embodied as a reduced thickness portion (not shown) of the housing 210 which can be formed to project slightly above the first surface 214 of the housing 210, whereby in use, a user can apply a light force to the raised portion to active a switch disposed beneath the raised portion. Forming a raised portion integral to the first surface of the housing 210 to be utilized as a switch simplifies construction, eliminates additional components, this construction also eliminates the need to form a hole within the first surface of the housing which may require sealing against liquids. Further, the provisions for the LED 262 and the charging pins 265 may be in the form of openings formed within the housing to receive such items. Alternatively, the LED 262 provision may be embodied in the form of an opaque or clear section within the housing 210 during manufacture to allow light to project therethrough from a LED 503 mounted on a circuit board 500 disposed below the housing 210. Additionally, it is contemplated that the charging pins 265 may also be integrally formed during the manufacture of the housing 210. For example, if the housing 210 is manufactured using an injection molding process, the charging pins 265 could be disposed within the injection mold as an insert, whereby the charging pins 265 would be captured in the housing 210 during the molding process. Alternatively, the housing 210 can include openings for charging pins 265 to project through. Further still, the housing 210 may include openings having tapered wall portions, forming pockets within the first surface 214, thereby providing access to charging pads/pins 504 disposed on a circuit board 500 disposed below the first surface 214 of the housing 210. The housing 210 may further include an indentation 229 formed therein or a plurality of indentations 229, allowing a user to grasp the housing 210.

[0093] As shown in Figure 5, the therapy device 200 further includes a first circuit board 500 and a second circuit board 550. The first circuit board 500 is disposed adjacent to the first surface 214 of the housing 210, wherein the first circuit board 500 includes a power switch component 502, at least one indicator LED 503 configured to indicate the power status of the therapy providing device 200. The first circuit board 500 further includes charging pins/pads 504, wherein the charging pins/pads may be configured to project through the housing 210 as described above, or alternatively, the housing 210 may include openings formed therein to access the charging pins/pads 504. The power switch 502 may be embodied as a physical switch, such as a slide switch, or may be embodied as a touch sensitive or capacitive sensitive switch, or

may be embodied as a pressure sensitive switch. The first circuit board 500 further includes a connector (not shown) which is configured to electrically connect the first and second circuit boards. The connector may be embodied as solder holes in which wires can be disposed into or may be embodied in the form of a plug or header assemble, wherein the plug/header are configured to accept a cable, wire, ribbon cable or a flexible pcb to facilitate electrical communication between the boards. The first and second circuit boards may be constructed of known materials and methods, whereby the boards may be hard rigid board assemblies or may be constructed using flexible board manufacturing technologies. Although, it is described above that the present invention utilizes two circuit boards, this should not be considered limiting in any manner, it is contemplated that the electronic components of the present invention may be embodied on a single circuit board or on multiple circuit boards.

[0094] As shown in Figure 5, disposed below the first circuit board 500 is an energy source 240. The energy source 240 may be in the form of a battery pack. The battery pack may be a rechargeable pack or a single use pack which may be embodied as gel batteries or absorbed glass mat batteries. Suitable examples of batteries that may comprise the pack are lithium ion (Li-ion), lead-acid, nickel-cadmium (NiCd), nickel-zinc (NiZn), zinc-oxide, nickel metal hydride (NiMH), Lithium ferrous-oxide (LiFo) or other known battery technologies. It is further contemplated that instead of utilizing a battery for an energy source a capacitor and related circuitry could be utilized.

[0095] In the event that the energy source 240 is embodied as a battery pack, the battery pack may be embodied in the form of a fabricated pack, where individual cells are soldered together, or alternatively, the battery pack could be arranged to utilize conventional battery sizes such as AAA, AA, CR2032, LR44, 9-volt, A23 and the like.

[0096] It is further contemplated that the battery pack may be further divided into a primary battery pack and a backup battery pack. In use, the primary battery would be initially utilized, if the pack malfunctions or loses its charge or its charge is used, the backup battery pack would then be enabled to continue the therapy.

[0097] If the battery pack as described above is chosen to be a rechargeable, there is a need to provide a charging circuit within the circuit boards 500 or 550. The charging circuit may utilize either a physical connection to enable charging or may use a non-contact or inductive charging arrangement. If a physical connection is utilized, the plug may be a USB style plug, headphone style, spring loaded pins/contact pads or other types of plugs, such a plug can be integrated into the housing 210 and electrically connected to the battery through either circuit board. Alternatively, a plug may be directly mounted onto one of the circuit boards. It is further contemplated that the charging plug can also be utilized both for charging as well as communication between multiple therapy providing devices 200 or the computing module 300 as described above using a compatible cable.

[0098] As described above, the present invention may utilize pins or pads disposed on or coupled to the first circuit board to enable charging of the battery disposed within the device. It is further contemplated that a non-contact charging assembly could be utilized with the present invention. If a non-contact charging arrangement is selected, then the charging pins 265 and/or openings within the first surface of the housing 210 may not be necessary. Instead, the therapy providing device 200 would include a charging coil (not shown) disposed about the perimeter of the first circuit board 500. The use of a non-contact charging coil would further necessitate the inclusion of additional integrated circuits to enable and control the charging function. These additional circuits can be disposed on either of the two circuit boards. Suitable examples of a non-conductive or inductive charging would utilize an electromagnetic field to transfer energy between the charger and the battery pack. In this embodiment a charging station would be provided in which the therapy providing device 200 could be stored and charged simultaneously as will be described below. It is also contemplated that the storage/charging container may be a smart container that is it may contain a microprocessor and/or a wireless communication chipset. Thus, once the therapy device is removed from the storage container, the integrated wireless chipset within the storage container may cause the therapy device to power on. Suitable examples of components to enable non-contact charging are available from Wurth Electronics Inc., part numbers 760308201 wireless charging receiving coil and 760308101 wireless charging transmitting coil.

[0099] In accordance with the present invention, it is contemplated that the energy source 240 may be embodied in the form of an integrated generator, wherein the generator would be configured to create energy from movement of the therapy providing device 200, much like and automatic watch movement.

[00100] As described above, the therapy providing device 200 shown in Figure 5 includes two circuit boards, 500 and 550. The circuit board 500 having been previously described above. Referring now to Figures 5 and 6 there are shown exemplary embodiments of the circuit board 550 in accordance with the therapy providing device 200 of the present invention. As described above, the second circuit board 550 is configured to be coupled with the first circuit board 500, wherein components may be disposed on either of the two boards and interconnected through an appropriate connection as previously described using a header or solder holes formed in the circuit board 550. Referring now to Figure 6, there is shown a general schematic of the second circuit board 550, wherein the second circuit board 500 includes a processor 551, optional memory chip 552, an audio amplification circuit 553 and a communication port 554. The communication port 554 may embodied as a physical port such as a mini-usb, micro-usb, firewire, thunderbolt or other known similar communication ports. The audio amplification circuit 553 may include one or two audio amplifiers, wherein the incoming signal from the processor 551 is amplified such that the amplified signal can then be connected to a driver assembly 220 as described below. As shown in Figures 5 and 6, the second circuit board 550 may be shaped to be received within a shaped housing. As shown in Figures 5 and 6, the second circuit board is shown having an elliptical shape with an aperture formed through the center thereof. The aperture can be sized to receive a portion of the driver assembly 220, thereby allowing the overall size of the device to be reduced by allowing components to 'nest' when assembled. The second circuit board 550 may contain additional electronic components such as audio filters, booster circuits, timing circuit and data logging capability. In accordance with the present invention, the processor 551 may be sourced from CSR PLC, Churchill House, Cambridge Business Park, Cowley Road, Cambridge, CB4 0WZ Churchill House, Cambridge Business Park, Cowley Road, Cambridge, CB4 0WZ, having part number 8670.

[00101] The second circuit board 550 may further include a communications chipset (not shown) such: Bluetooth, wifi, ZigBee, RFID, NFC, Ant+, infrared, 3G/4G, CDMA, TDMA or other known wireless communication protocols.

[00102] The first or second circuit board 500/550 may further include a clock circuit (not shown). The clock circuit generates and sets the timing of operations performing within the therapy providing device 200. The clock generator may be utilized to activate the therapy providing device 200, or may be utilized to record timed events, such as when the therapy providing device is on or off or in use.

[00103] Further still, either circuit board 500/550 may alternatively include an impedance sensor or pair of impedance sensors, the impedance sensors in association with the processor 551 can be used to determine if the housing 210 is coupled to a user's skin or if the housing is not coupled to the skin. If the housing 210 is coupled to a user's skin, then the impedance sensor would provide a signal to the processor 551 indicating such a condition, thereby the program stored in the memory of the processor or transmitted to the microprocessor could be initiated to conduct therapy according to the invention. If the impedance sensor is not coupled to the user's skin, then an open condition would occur, whereby the program would not be initiated and a visual signal may be generated through the program/processor to alert the user that the therapy providing device 200 is not placed properly and needs to be repositioned.

[00104] In yet another embodiment, the electronics module may include a microphone, whereby a test signal can be initiated and delivered by the driver assembly 220 or other audio/vibration device. The microphone would be utilized by the processor 551 to listen for a reflection of the test signal off of the user's clavicle, skin or other bone or structure to determine if the therapy providing device 200 has been placed properly. If the reflected sound matches that of one stored in memory, then the program can be run to provide therapy. If the reflected sound does not match the sound stored in memory, then an error message would be generated. The error message may be in the form of an audio signal or in the form of a visual signal such as a blinking light or a series of blinking lights.

[00105] Additionally, the microphone could be coupled with a blood pressure monitor, wherein the microphone would listen for Korotkoff sounds, whereby the data

generated from the blood pressure monitor and specifically the Korotkoff sounds captured by the microphone can be utilized to enable a closed loop control system or closed loop feedback system. It is contemplated, that the therapy provided by the therapy providing device 200 can be dynamically modified in response to the data received from the microphone coupled to the processor 551.

[00106] The circuit board 500 or 550 may further incorporate a pressure sensitive switch coupled to the processor 551. In use, the pressure sensitive switch would be in a normally open position or off position. When the therapy providing device 200 is placed on the user's skin, the pressure sensitive switch would be depressed, thereby turning the therapy providing device 200 on. The actuation of the switch can also be associated with the clock circuit to associate a time with the on/off state of the switch. These events can be written to the memory of the processor 551 or other memory storage location. The data can then be transmitted, wired or wirelessly, to a personal computer for analysis/storage. By tracking the actual on/off time of the therapy providing device, user compliance may be tracked by the user or by a third party such as a health care provider.

[00107] In yet another embodiment, the circuit board 500 or 550 may include an optical sensor, wherein the optical sensor is utilized to detect whether the therapy providing device is affixed to a user's skin. In this embodiment, the optical sensor can include a light sensor, whereby when the therapy providing device 200 is affixed to the user's skin the light is blocked to the sensor. In another embodiment, the optical sensor can be a reflective sensor, wherein the color of the light reflected back indicates whether the device is affixed to a user's skin or not.

[00108] In another aspect of the present invention, the light sensor may be utilized to monitoring blood oxygen level, wherein data received from monitoring the user's blood oxygen level can be stored in memory or transmitted to another device such as a pulse-oximetry monitor or another computing device. Further still, the blood oxygen data may be utilized by a program of the therapy providing device to alter therapy provided to the user or otherwise control the therapy providing device 200.

[00109] In another aspect of the present invention, the light sensor may be used to measure alteration in blood-reflectance color, whereby the program controlling the

therapy providing device may utilize this signal as a representation of heart rate or heartbeat. Accordingly the program controlling the therapy providing device 200 may use this data to determine blood pressure and accordingly provide therapy to the user based on the received data.

[00110] It is further contemplated, that an accelerometer and/or compass and/or tilt sensor and/or GPS sensor can be incorporated into either of the circuit boards described above. The inclusion of such a sensor can be utilized to determine the position and/or orientation of the device. In use, as described below, a user would affix the housing 210 to their person using an adhesive patch, harness, specialized clothing article as will be described below. In this embodiment, the accelerometer/compass in communication with the processor 551 can be utilized to determine when to activate the therapy providing device or devices 200. If the signal coming back from the accelerometer/compass/tilt sensor indicates that a therapy providing device 200 is in a vertical position, then the program contained within the memory of the processor 551 or computing device 800 would not be initiated. Once the signal from the accelerometer/compass/tilt/GPS sensor indicates that the user is in a prone position, likely a sleep position, then the program contained within the memory can be run. Additionally, the clock timer can be associated with the accelerometer/compass/tilt /GPS sensor such that a user's sleep pattern can be stored in memory of the processor 551 or computing device 800. Data generated from such sensors could be stored in memory, of either the therapy providing device or the computing device to track usage of the device as well as the physical location of the devices. Such data could be transmitted to a third party using know wireless communication methods.

[00111] The circuit boards or the housing or therapy providing device 200 may be provided with a unique identifier such as a serial number or patient information identifier so that the therapy providing device 200 may be tracked. Additionally, using the unique identifier it may be possible for a physician or a user to utilize a computer program, such as a website which when placed in communication with the therapy providing device, either wired or wirelessly, would allow continuous monitoring of usage of the device, such as date and time monitoring, duration of use, patient compliance and the like. The website could also provide information

regarding hypertension and additionally be configured to communicate with other devices such as a scale to track the user's weight, a blood pressure monitor to track blood pressure measurements, a glucose meter, a heart rate monitor or other fitness tracking device such as Fitbit or BodyBug. Each of these devices would be interfaced with the website, such that data collected from these devices could be uploaded to the website where the data could be presented to the user or alternatively, the data could be shared with anyone that the users chooses to do so. For example, the user may desire to share the data with their health care provider, dietician or other individual(s).

[00112] In accordance with the invention, it is contemplated that one or both circuit boards along with the battery may be housed within a separate housing from the therapy providing device 200. In this embodiment, the circuit board(s) and battery would be coupled to the therapy providing device either through a cable connection or through a wireless connection. If a wireless connection is utilized, then the therapy providing device would include the necessary electronics disposed within its housing to facilitate the communication between the electronics module and the therapy providing device as well as a power source such as the battery.

[00113] Referring to Figure 5, disposed below the second circuit board 550 is a driver assembly 220. The driver assembly 220 is disposed within the volume 213 of the housing 210. The driver assembly may comprise a conventional coil speaker, an ultrasonic generator, a piezoelectric speaker, a haptic speaker, a pneumatic device, a suction device, a mechanical vibratory device, a hydraulic actuation device, or a photo-acoustic excitation device. Examples of drivers assemblies 220 that can be used with the present invention may be purchased from HiWave Technologies PLC, Regus House, 1010 Cambourne Business Park, Cambourne, Cambridge CB23 6DP United Kingdom. Referring now to Figure 7 there is shown an exemplary haptic speaker or haptic exciter 220' which may be utilized with the therapy providing device 200 of the present invention. As shown in Figure 7, the haptic speaker 220' includes a frame member 221, a voice coil 222 and a plurality of flexible members 223. Additionally, the haptic speaker 220' includes electrical connections 224, thereby allowing the haptic speaker 220' to be electrically connected to the audio amplifier circuit as previously described. In use, the flexible members 223 allow the

voice coil 222 of the haptic speaker 220' to translate relative to the frame 221, thereby producing sound or movement.

[00114] In yet another embodiment, the driver assembly 220 may be embodied as an electroactive polymer transducer 315 as shown in Figures 8-10. Electroactive polymer transducers are made up of a first thin elastic polymer 320, which is also referred to as a film or membrane, this is sandwiched between compliant electrodes 340 and 345. When voltage is applied across the electrodes, the unlike charges in the two electrodes are attracted to each other, these electrostatic attractive forces compress the polymer film 320 (along the z-axis). The repulsive forces between like charges in each electrode stretch the film in the plane (along the X and Y axis'). As the transducer 315 deflects, the deflection can be utilized to perform work. In the present invention, the work that is performed is the development of vibrations, wherein the vibrations being developed by the transducer 315 are developed within a certain frequency range as will be discussed in greater detail below. Additional information regarding electrostatic transducers can be found in US Patent No. 7,898,159 and US Patent No. 7,608,989, the entireties of which are hereby incorporated by reference.

[00115] It is further contemplated that the transducer 315 as described above may be further coupled to another assembly, wherein the other assembly would have an increased mass. Through use, the transducer would be activated by providing a voltage to the electrodes, thereby exciting the polymer, wherein the weighted assembly would be excited thereby delivering greater vibrational energy.

[00116] In accordance with another aspect of the present invention, the electroactive polymer transducer 315 can be formed to have a curved shape, or be attached to a housing having a curved shape, such that the housing or curved excited can be readily received by a user's anatomy, specifically the user's clavicle or collarbone.

[00117] The electroactive polymer transducer 315 of the present invention may be embodied in different geometric shapes. It is contemplated that the transducer 315 may be embodied in the form a circular shape, oblong shape, square, rectangular or other known geometric shapes. Further still, it is contemplated that the transducer may be formed with at least one bar-arm type of arrangement as shown in Figure 3D.

In this embodiment, the bar-arm 347 is configured to vibrate in response to the charge placed on the electrodes. The number of bars and shape of the bars can be configured to adjust the acoustic/vibrational properties of the assembly.

[00118] Use of an electroactive polymer transducer as described above further includes a circuit driver 350, the circuit driver 350 may be incorporated into the first or second circuit boards 500/550 as described above. Alternatively, the circuit driver 350 may be embodied as a separate circuit board (not shown) which may be electrically coupled with either the first or second circuit boards of the present invention. The circuit driver 350 further includes an audio input 360 and at least one output 370, but preferably a pair of outputs 371 and 372. The outputs 371, 372 are coupled to the electrodes 340, 345 of the transducer 315.

[00119] The circuit driver 350, may further include additional components such as an amplifier, a filter, a voltage step-up circuit, a charge controller, voltage step-down.

[00120] Further still it is contemplated that the driver assembly may be embodied as multiple elements, for example any combination of driver assemblies may be use, such as a combination of a haptic speaker and a piezo, a haptic speaker and an electro active polymer transducer, an electroactive polymer transducer and a piezo or multiples of the same driver type within the same housing. The examples provided herein should not be considered limiting in any manner. Alternatively, the driver assembly may be a vibrating motor or coin cell motor.

[00121] As described above and in accordance with the present invention, it is contemplated that two therapy providing devices 200 may be utilized together to provide therapy to a user, wherein the two therapy units may be interconnected with a physical connection. It is contemplated that one of the therapy devices may have a complete set of electronics disposed therein, wherein the complete set of electronics would include the communication, memory and other chipset(s) and associated circuitry. Wherein the other therapy providing module 200 could then include a simplified electronics module, wherein the simplified electronics module would not have the complete chipset of the complete electronics module. For example, the simplified electronics module would not need to have a battery charging circuit or other chips as well it may have less or no memory. By providing the other therapy

providing device with a slimmed down electronics module a larger energy source may be fitted, through this arrangement the combined therapy providing devices 200 could be utilized for a longer time before the energy source would need to be replaced or recharged.

[00122] Referring now to Figure 11 there is shown a charging/base station 570 in accordance with the present invention. As shown in Figure 11, the base station 570 includes a housing 571, wherein the housing 571 includes recessed portions 572 configured to receive the therapy providing device 200 therein. The recessed portions 572 are configured to include charging pins 574, which when the therapy providing device 200 is disposed within the recess will align with the charging pins/pads 265 of the therapy providing device. In addition to the charging pins 574, other pins may be included both on the base 570 and the therapy providing device 200 which may be used for other purposes such as downloading data stored within memory of the therapy providing device(s) 200. The base station 570 may further include a wired or wireless connection to the internet or other network such that the data received from the therapy providing device(s) can be transmitted or uploaded to a webpage as described above or transmitted to another location such as a health care provider or other location for storage. It is further contemplated that the base 570 may include additional features such as an alarm clock or clock 573, a cellular telephone or tablet charging station. As will be described in greater detail below with regard to Figures 13L and 13M, the therapy providing device may include extensions 219 extending from the housing 210 each extension 219 containing a magnet 230. It is contemplated that the recessed portions of the charging base 570 may be shaped to receive the extensions 219 of the housing 210 shown in Figure 13L. The recessed portions 572 may be adapted to receive the extensions 219 or may further include a metallic member or a magnet disposed therein, such that when the therapy providing device is placed into the recessed portion, the magnets 230 within the housing 210 of the therapy providing device 200 are attracted to the metal or magnet of the charging station 570, thus, temporarily affixing the therapy providing device 200 to the charging station. In addition to temporarily affixing the therapy providing device 200 to the charging station 570, by temporarily affixing the therapy providing device 200 to the charging/base station 570 providing better contact between the therapy providing device 200 and the charging pins 574. It is contemplated that other

arrangements to increase contact between the therapy providing device and the charging pins of the charging/base station may be utilized. For example, the charging pins 574 in the base station 570 may be configured to move linearly and be held with a spring force, whereby the charging pins 574 retract or partially retract when a therapy providing device 200 is placed into the recessed portion 572 for charging. Additionally, another member (not shown), such as a plate or weights may be placed onto the therapy providing devices after the therapy providing devices have been disposed within the recessed portions. Further still, the charging pins 574 may be disposed on a lid (not shown) of the charging base 570, such that the therapy providing device 200 is placed within a recessed portion 572 of the charging base 570 and the lid is closed, thereby completing the electrical connection between the charging pins 574 of the charging base and the charging pins/pads 256 of the therapy providing device 200.

[00123] In accordance with the invention, the base 570 may be further embodied as another medical device or incorporate other medical devices. It is contemplated that the base 570 may incorporate, or be incorporated into another medical device such as a pulse-oximetry meter, a blood pressure monitoring device, a glucose meter, an infusion pump, a glucose pump, sleep tracking device, temperature measuring device, or a sleep apnea device such as those offered by ResMed and Respironics. Presently, sleep apnea devices utilize a console which houses the electronics necessary to control a blower to deliver pressurized air to a patient interface. The patient interface may be embodied in the form of a full-face mask, nasal mask, oro-nasal mask, mouth mask, nasal prongs, or other suitable configurations know in the art. Also, any suitable headgear arrangements may be utilized to comfortably support the patient interface in a desired position.

[00124] In yet another aspect of the present invention, referring now to Figure 12 there is shown the therapy providing device 200 of the present invention, wherein the therapy providing device 200 has been adapted to interface with a sleep apnea patient interface. As show in Figure 12, the therapy providing device 200 is configured to be received or engage or is integrated into the headgear arrangement of a sleep apnea patient interface device, wherein the therapy providing device of the present invention is configured to engage the patient's jawbone or skull.

[00125] In yet another aspect of the present invention, the therapy providing device 200 may be incorporated into other devices which are configured to engage a patient's tissue and skeletal bones such as bone conduction hearing aids, one such example is being offered by Sonitus Medical under the tradename SoundBite.

[00126] Referring now to Figures 13A, 14A, 14B, 15A, 15B, 16A and 16B there are shown multiple embodiments of the housing 210 of the therapy providing device 200 in accordance with the present invention. As shown in these figures, the housing 210 is shown having a variety of mounting assemblies that can be utilized to affix the therapy providing device 200 to the patient.

[00127] As shown in Figure 13A, one surface of the therapy providing device is provided with a slot 260. A bandage 265 can be passed through the slot 260, wherein a rib 261 formed by slot 260 retains the therapy providing device 200 onto the bandage 265. The bandage 265 further includes a biocompatible adhesive, such that the therapy providing device 200 can be affixed to the patient as shown in Figure 13B. The bandage may be a one-time use construction, wherein the bandage is disposed of after a single use. Alternatively, the bandage 265 may be a multiple-use product, wherein the biocompatible adhesive is selected such that the bandage can be placed and removed from a user's skin multiple times. Additionally, it is contemplated that the biocompatible adhesive may be renewed. The adhesive may be renewed by spreading new adhesive over the existing adhesive, washing the adhesive surface with a substance to renew the surface or the adhesive may be embodied having multiple thin layers, wherein the user removes the used layers and disposes of the used layer, thereby exposing a new layer of adhesive for use again. A suitable example of an adhesive for a reusable bandage are hydrogel adhesives, similar to those utilized on electrodes for electrical muscle stimulation devices, otherwise known as a TENS unit. Such electrodes are manufactured and sold by 3M as well as others. It is contemplated, that a temporary marking may be applied to the user's body initially to indicate the location of where the therapy providing device. For example, the temporary marking may be in the form of a temporary tattoo or a henna tattoo.

[00128] Alternatively, a bandage large enough to cover the entire housing of the therapy providing device 200 may be utilized. In this embodiment, the bandage

would hang over the edge of the housing by a sufficient amount, such that when the therapy providing device 200 is placed against the tissue of the user, the bandage could be affixed to the tissue to hold the therapy providing device in a desired position. In this embodiment, the bandage may include an aperture, an opaque section or otherwise transparent section, such that when the bandage is placed over the therapy providing device 200, the button 260, LEDs 262 and charging pins/ports 265 on the top surface of the housing 210 of the therapy providing device 200 described above are visible and accessible if the housing includes such components. Such as bandage maybe constructed to further include a one-way membrane, wherein moisture under the bandage may be transported or migrate from the tissue surface through the bandage, however, the bandage would not allow fluid to pass from the outside to the therapy providing device 200 or the user's tissue.

[00129] Referring now to Figures 14A-14C there is shown an alternative design for affixing the therapy providing device 200 to the patient. In this embodiment, one surface of the therapy providing device includes a first fitting 280 disposed on the second surface 215 of the housing 210. A bandage 400 is provided, wherein the bandage 400 has a proximal surface 402 and a distal surface 401. A biocompatible adhesive is disposed on the distal surface of the bandage 401. A second fitting 281 is disposed on the proximal surface 402 of the bandage 400. The first fitting 280 and the second fitting 281 are designed to be received by each other and to form a detachable locking attachment as shown in Figure 14C. Suitable examples of such detachable fittings may be a screw thread, quarter turn fasteners, grooved pathways, a tapered fitting and the like. A safety lock (not shown) may be incorporated into either of the fittings, wherein the safety lock would engage after the two fittings are brought together in a locking arrangement. The safety lock would prevent the fittings from releasing without an additional application of force or motion to the safety lock to enable the fittings to be separated. The bandage 400 may be a single use product or may be a re-usable bandage as described above. In another aspect, the bandage of the present invention may be fabricated to include multiple layers, wherein each layer includes a new glue surface. After use, the layer of the bandage having been in contact with tissue is peeled off by the user and properly disposed of, thereby exposing a new glue layer for further use.

[00130] Referring now to Figures 15A and 15B there is shown another alternative design for affixing the therapy device 200 to a patient. In this embodiment, a surface of the therapy device 200 includes a magnet 290 disposed thereon or incorporated into the surface. As described above bandage 400 is provided, wherein the bandage 400 has a proximal surface 402 and a distal surface 401. A biocompatible adhesive is disposed on the distal surface of the bandage 401. A metallic member 292 is incorporated into the bandage 400 as shown in Figure 15B. In use, the user would apply the bandage 400 to their body, wherein the center of the bandage would align with their clavicle. In one embodiment, the bandage 400 would be replaced daily. In another embodiment, the bandage 400 would be reused for a period of time and then replaced. Further still, in another embodiment, the glue surface of the bandage 400 may be refurbished after each use to prolong the useful life of the bandage 400. Once the bandage 400 is affixed to the user, the therapy providing device 200 as shown in Figure 15A and described above would then be coupled to the bandage through the magnetic coupling between the magnet 290 of the therapy providing device 200 and the metallic member 292 of the bandage 400. It shall be understood that the combination of using a magnet 290 and a metallic member 292 could be reversed. For example, the bandage 400 may contain the magnet 290 and the therapy providing device 200 would have the metallic member 292. Alternatively, both the bandage 400 and the therapy providing device 200 may include a magnet 290, whereby the magnets 290 assist in self-aligning the therapy providing device to the bandage 400. Further still, it is contemplated that the magnet or metallic member of either the bandage 400 or the therapy providing device 200 may be offset from an axis extending through the center of the bandage 400, thereby providing for two different orientations in which the therapy providing device 200 may disposed upon the bandage 400 in for use. Further still, it is contemplated that the driver 220 of the therapy providing device may be offset within the housing 210 from an axis running longitudinally through the housing 210. Offsetting the driver 220 within the housing 210, achieves the same effect of providing multiple mounting orientations of the therapy providing device 200 during use. In yet another embodiment, the magnet 290 or metallic member 292 could be implanted under the user's skin, therefore eliminating the need for the bandage 400. In this embodiment, the therapy providing device 200 could be coupled to the patient's skin directly.

[00131] In another embodiment (not shown) the bandage may include an aperture formed therethrough, wherein the metallic member 292 would be disposed about the aperture. The aperture is sized to receive a portion of the therapy providing device 200 therein. It is further contemplated that the therapy providing device may include a second bandage or an enlarged surface similar in size to the bandage 400. The enlarged surface would contain magnets 290 as described above; therefore, when the therapy providing device 200 is disposed within the aperture of the bandage 400, the enlarged surface covers the bandage.

[00132] In further embodiments, the magnets and the metallic members may be interchanged, wherein the bandage contains the magnets and the housing may be a metallic member, a portion may be metallic or a portion may be magnetic. Additionally, instead of utilizing magnets and metallic members, other known detachable systems may be utilized, for example a hook and loop configuration or reusable adhesive surface.

[00133] Referring now to Figures 16A and 16B there is shown a housing in accordance with the present invention, wherein the housing 210 includes extensions 219. The extensions 219 further include magnets 230 disposed therein. Referring now to Figure 16B there is shown a bandage 420 to be utilized with the housing shown in Figure 16A. The bandage 420 further includes an aperture 431 formed therethrough, the aperture sized to accept a portion of the therapy providing device 200. The bandage 420 further includes magnets 430 disposed therein. The bandage 420 may be formed of a multilayer construction, wherein the bandage may include a glue layer a glue support layer and a backing layer. It is contemplated that the magnets 430 could be disposed within the glue support layer, wherein the magnets 430 would be encapsulated in the bandage 420 by the glue layer and the backing layer. In use, the user would place the bandage 420 onto their skin, wherein the user can use the aperture 431 to properly align the bandage in the example where the therapy providing device is placed over the clavicle. The glue layer of the bandage 420 may be a re-usable adhesive, such as that described above and commonly utilized on tens electrodes, wherein the glue layer allows for repositioning of the bandage. After placement of the bandage 420, the therapy providing device, having a housing shown in Figure 16A is disposed over the bandage. The magnets 230 of the housing

extensions 219 and the magnets 430 of the bandage act to attach and center the therapy providing device to the bandage. In accordance with the invention, it is contemplated that either the magnets 230 of the housing or the magnets 430 of the bandage may be replaced by metallic members.

[00134] In yet another aspect of the invention, as described herein the magnets, which may be positioned in the device housing, the bandage or both, may be utilized to control the function of the therapy providing device 200. In this example, at least one of the magnets can be used as a switch to control or complete a power circuit. The power circuit can be activated such as to power the therapy providing device 200 on, thereby initiating therapy. If the magnetic connection is broken, then the therapy providing device would be powered off. It is further contemplated, that in addition to the above, the magnet within the device or bandage may be manufactured with specific properties, such that the therapy providing device will only operate with original equipment manufacturing products, thereby preventing the therapy providing device 200 from being utilized with non-approved or counterfeit bandages. A benefit of utilizing the magnets to switch the device on/off is that the user does not have to activate any buttons on the device, additionally, the device can be simplified through the eliminate of the button on the therapy providing device as described herein. Another benefit is the preservation of battery life of the device, as the device will be powered off as soon as the magnetic connection is broken. Additionally, if the therapy providing device is being utilized at night time during sleep and the device becomes dislodged from the user, the device will automatically power off, thus providing an additional safety feature.

[00135] Further still, it is contemplated, that the therapy providing device 200 and/or bandage may include a security feature, such as an optical scanner disposed within the therapy providing device, such that the optical scanner is configured to scan a QR code, bar code or other coded printed on the bandage or bandage packaging. As described above, this combination of a scanner and specific code can be utilized to control the activation of the therapy providing device 200. Additionally, the use of a security code/barcode can be combined with the magnetic activation of the therapy providing device 200 as described above to ensure that the bandage being utilized is an approved product that has been designed to be specifically utilized with

the therapy providing device 200 and that the bandage is not a third-party un-approved product or a counterfeit product. It is contemplated that other types of security systems can be utilized to achieve the same or similar functions. For example, the bandage may include a protrusion (not shown) that projects above the surface of the bandage, the protrusion would be received within an aperture of the second surface of the housing where it would activate a switch within the housing. Another example would be the use of an electronic circuit or chip disposed upon or within the bandage, the circuit or chip would interface with the therapy providing device, thereby completing a circuit to enable activation of the therapy providing device.

[00136] Referring now to Figure 17 there is shown an alternative design for a mounting device to be utilized with the therapy system 100 in accordance with the present invention. As shown in Figure 17 there is shown a support structure 600. The support structure 600 can be configured to position therapy providing devices 200 according to the present invention in a preferred location over a user's clavicle. The user can also adjust the positioning of the location of the therapy providing devices 200 by adjusting both the angle of the arm about pivot 610 and buy adjusting the length through the telescoping assembly 620.

[00137] The support structure 600 further includes a ball and cup joint 660 at the distal ends 640 of the arms 630. The ball and cup joint 660 is arranged to hold the therapy providing device 200 and allows a user to align the therapy providing device 200 substantially parallel to a surface of the user at the desired location to insure that as much as possible of the therapy providing device 200 is in contact with the user.

[00138] The support structure 600 further includes a pad 650 connected to the arms 630. In accordance with embodiments of the present invention, the pad may contain the electronics module 320 and the power source.

[00139] The arms 630 of the support structure 600 can also be configured to include a spring force to push the therapy providing device 200 against the body. For example, the arms 630 of the support structure 600 depicted in Figures 17 are curved and are configured to apply a spring force between the therapy providing units 200 and the pad 650 when the support structure 600 is placed over a user's shoulders.

[00140] Referring now to Figure 18 there is shown another example, of a support structure 700 in accordance with the present invention. As shown in Figure 4H, the support structure 700 includes a pad 750, a first arm 730, and second arms 731. The support structure 700 further includes joints 740, the joints 740 join the first arm 730 to the second arms 731. The joints 740 are configured to allow for rotational motion between the first arm 730 and the second arms 731 in order to allow a user to align the therapy providing devices 200 in accordance with the methods of the present invention. The second arms 731 further include telescoping sections 745. The telescoping sections 745 allow the user to adjust the length of the second arms 731 to position the therapy providing units properly. The second arms 731 further include a ball joint assembly 760 disposed at their distal ends, the ball joint assemblies 760 couple the therapy providing units to the second arms 731. The ball joint assemblies 760 allow the therapy providing units to lay flat against the user's collar bones and account for differences in anatomy. The support structure 700 further includes a pad 750 coupled to the first arm 730. As described above the pad 750 may contain the electronics module 320 and the power source. In certain embodiments the electronics module and power source would be user replaceable. In other embodiments, the electronics module and battery would not be user replaceable and the entire assembly would be replaced including the therapy providing devices.

[00141] The support structures 600 and 700 can be made of an elastic material. The elasticity of the design provides for a spring or clamping force, such that the support structure and therapy providing devices remain in position during use.

[00142] The support structures described herein can be configured to fit snugly without being too compressive on the body, are straightforward to put on over the shoulders or around the torso, and can be worn underneath clothing without significantly altering the profile of the clothing.

[00143] Referring now to Figures 19A-19C, there are shown additional embodiments of the present invention. As shown in Figures 19A-19C, the therapy providing device 200 of the present invention may be incorporated into a support structure 800, wherein the support structure 800 includes a proximal end 802 and a distal end 801 and an elongate member 803 extending between the two ends. The support structure further includes a control panel 810, wherein the control panel 810

may include an indicator such as a light or LED 811 to indicate the function of the therapy providing devices 200. The control panel 810 further includes a switch 813, the switch 813 being in electrical communication with the therapy providing devices 200 and the electronics module 230 and the energy source 240, each of which have been described above. The support structure 800 may be fabricated of fabric such as cotton, nylon, polyester or the like, wherein the body 803 is in the form of a tubular, square, rectangular or cylindrical shape, thereby forming an inner chamber. As shown in Figure 4I, the therapy providing devices 200 and the electronics module 230 and energy source 240 are shown disposed within the inner chamber. These components may be held within the inner chamber through the use of pockets formed within the inner chamber. It is further contemplated that the inner chamber may be filled with a material to increase the weight of the overall device. Examples of materials that can be utilized to fill the chamber are rice, beans, sand, metallic materials, polymer materials and other such materials that are known to one skilled in the art.

[00144] As shown in Figures 19B and 19C, the support structure 800 can be worn around a user's neck and shoulders, wherein the therapy providing device 200 would be adjusted by the user to fall onto and make contact with the user's clavicle. The support structure 800 may be disposed over the top of a user's clothing as shown in Figure 19B, or alternatively the support structure 800 may be disposed directly against a user's skin as shown in Figure 19C.

[00145] In accordance with the embodiment shown in Figures 19A-19C, it is contemplated that the support structure may further include a removable cover (not shown), wherein the removable cover can be disposed about the support structure 800. The removable cover may include a zipper, velcro or snaps to open and close the cover. Additionally, the removable cover may include additional items such as pads placed along a portion or a length thereof. For example, a pad may be disposed on the cover near the user's neck area.

[00146] It is further contemplated that the support structure 800 in accordance with the present invention may include additional features. For example, a heating element

may be incorporated into the support structure 800, whereby the heating element may be utilized by the user to address sore muscles or neck pain.

[00147] Referring now to Figure 20A and 20B, there are shown exemplary embodiments of clothing articles which can be utilized with the therapy providing device 200 of the present invention.

[00148] As shown in Figure 20A, in one embodiment, the clothing article is embodied as a t-shirt 600, wherein the t-shirt 600 includes pockets 602 formed therein to receive the therapy providing device 200. The pockets 602 are aligned over the user's clavicle in order to provide treatment as will be described below.

[00149] Referring now to Figure 20B there is shown an alternative embodiment of a piece of clothing configured to retain the therapy device 200 in accordance with the present invention. As shown in Figure 5B the clothing can be embodied in the form of a sports bra 610. The sports bra 610 further includes pockets 612 configured to receive the therapy device 200. Alternatively, instead of pockets, other attachment mechanisms such as those described above, wherein instead of pockets, magnets, hook and loop fasteners, snap fasteners, twist and lock or similar types of fastening systems may be utilized to retain the therapy providing device 200 in position.

[00150] Additionally, the clothing devices described above may further include an additional pocket or pockets to receive the computing device, or in embodiments wherein the electronics or energy source are separate from the therapy providing device, pockets or other retention means to retain these additional components.

[00151] The clothing devices may further include a structure formed therein or attached thereto (not shown) wherein the structure is configured to apply a downward force upon the therapy providing device(s). Structures similar to those shown in Figures 17, 18 and 19 may be utilized.

[00152] In accordance with the present invention, the therapy providing device 200 may include addition features. One such additional feature can be the inclusion of a thermometer to track the user's temperature during use. Another additional feature can be the inclusion of a sleep sensor or sleep tracking program, wherein the therapy providing device can be utilized to track the user's sleep. For example, the sleep

program may utilize the GPS/accelerometer of the therapy providing device to track movement during sleep, wherein the sleep program could further utilize the temperature data as well. Another aspect of the invention could be to utilize the therapy providing device to be further utilized to diagnose sleep apnea, wherein the therapy providing device could further include a microphone to enable audio recording of the user's breathing during sleep. Additionally, the microphone recording of the breathing can be combined with the accelerometer data or GPS/tilt data to correlate the breathing recordings to the specific user.

[00153] Referring now to Figure 21A and 21B there is shown a computing device 800 in accordance with the present invention. The computing device 800 includes a processor, memory, energy source (such as a battery), and a display 810. The computing device may be a custom manufactured device for use with the therapy device 200 as described above, or alternatively, the computing device 800 may be a commercially available device such as a smartphone or tablet. Examples of such commercially available devices are iOS enabled devices such as the iPhone®, iPad®, iPod®, Android based phones and/or tablets, laptops or computers. As shown in Figure 15B, the computing device may be configured to display a user's heart rate and blood pressure when connected to a therapy providing device having those measurement capabilities or where other compatible devices are utilized with the therapy providing device. Alternatively, the computing device may display data received from one or more therapy providing devices, this data may include start/stop times of therapy provided by the therapy providing device 200, battery status of one or more therapy providing devices and the like.

[00154] In accordance with the present invention, the computing device 300 is configured to run a program 320. In accordance with the present invention, the program 320 is configured to communicate with the therapy device 200. The communication between the program 320, computing device 300 and the therapy device 200 may be conducted using Bluetooth, wifi, ZigBee, NFC, RFID, ANT+, 3G/4G, cellular connection or other known wireless communication protocols. Alternatively, the computing device may be coupled to at least one of the therapy devices through a cable connection.

[00155] In an alternative embodiment, the program 820 is stored on memory located within the memory of the therapy providing device 200. The program maybe initiated manually through the use of a physical button pressed by the user. Alternatively, the program 820 may be initiated automatically by a timer located within the therapy providing device 200. The timer may further utilize data inputs from an accelerometer/compass or tilt sensor to indicate when the user is in a prone position to initiate the program 820. Further still, the timer may receive input from an impedance sensor indicating whether the therapy providing device 200 is in proper placement on the users body. The program would then be initiated based on the inputs received. The device may be activated further by the light sensor either from the darkness against the skin. The device may be activated from the reduced light from the users surroundings, for example when the user is sleeping.

[00156] In certain embodiments, the program 820 is pre-configured to deliver therapy using the therapy providing device through pre-programmed parameters. The HCP may adjust the therapy parameters within the program 820, such that the therapy provided to the user may be customized to the user. The customization of the therapy may be changes to the wavelength, amplitude, duration, start/stop times. The customization may be done by the HCP while providing services to the patient, for example, the HCP may apply the therapy providing device to the patient, initiate therapy and monitor the patient's response. Through this active monitoring, the HCP may change the parameters of the program to elicit a response in the patient. For example, it is contemplated that certain patients may have different bone densities; therefore the therapy provided by the device may need to be adjusted accordingly. It is further contemplated, that once programmed, the user cannot change the therapy parameters of the program, or alternatively, certain parameters or all parameters may be open to change by the end user or remotely. Alternatively, the HCP, after determining the best therapy parameters, can choose from multiple programs stored within memory of the therapy providing device. Further still, the HCP may be provided with a dedicated programming device, or may couple the device to a personal computer, smartphone, tablet or other internet enabled device, such that the HCP can utilize the dedicated programmer or download over a secure internet connection, programs to be uploaded into the therapy providing device.

[00157] Referring now to Figure 22, there is shown a flow diagram illustrating the program 820 in accordance with one embodiment of the present invention. As shown in Figure 22, the program 820 may configured to be run on the computing device 800 to control the therapy applied to the user by the therapy providing device 200. Alternatively, it is contemplated that the program 820 may reside within memory within the therapy providing device 200 as described above.

[00158] At Box 830, the user activates the program on the computing device 800 or therapy providing device 200.

[00159] At Box 840, the program checks the time on the computing device 800 or internally from the clock circuit of the therapy providing device 200.

[00160] At Box 850, the program determines whether to turn the therapy providing device on based upon the time check in Box 840. If the time is before a pre-programmed time or a user set time, then the program returns to Box 840. If the time is after the pre-set time or user set time, then the program turns the therapy providing device on. In accordance with the invention, if the time is received from the computing device, a user may adjust the time of the computing device, for example if the computing device is moved from one time zone to another. Alternatively, the computing device may automatically update the time.

[00161] At Box 860, the therapy providing device 200 is provided with a signal generated by the program and transmitted from the computing device 800 through a selected transmission method. In alternative embodiments, the therapy providing device contains a processor and memory, wherein a program is retained within the memory of the therapy providing device. In this embodiment, the signal provided by the computing device 800, is a power on/off signal, wherein once powered on the program residing within the memory of the therapy providing device will begin to run.

[00162] At Box 870, the therapy device provides therapy to the patient. In the process of providing therapy, a signal is transmitted to the therapy device 200 by the computing device 800 through as directed by the program 820, or as described above, the program residing in the memory of the therapy providing device runs. In one

embodiment, the therapy is applied for a set period of time. In alternative embodiments, the time duration of the therapy may be determined based upon data received from other sensors disposed upon the user or about the user. In yet another embodiment, the user may manually deactivate the therapy providing device/program.

[00163] At Box 880, the therapy is stopped. The therapy may be stopped based upon a time event, motion event, manually by the user, automatically by the program.

[00164] During each of the steps described above and shown in the flow diagram of Figure 22, the user may be presented with displays on the screen 810 of the computing device. The screen 810 may display the start and stop times of the therapy, these times may be set by the user or may be set for the user by a health care provider. Alternatively, the times maybe automatically generated in response to data received from other sensors as will be described in detail below.

[00165] According to the invention, the program includes a non-transitory computer readable medium having computer executable program code embodied thereon, the computer executable program code configured to send appropriate signals to the circuit board(s) 500/550 to provide therapy in accordance with the methods of the present invention utilizing the therapy providing device 200 of the present invention.

METHODS OF USE

[00166] In accordance with the present invention, methods of use of the present invention will be described below. The methods described shall be considered to be exemplary and should not be considered limiting in any manner.

[00167] In accordance with one embodiment of the present invention, the therapy device includes a driver assembly, wherein the driver assembly is embodied as a speaker as shown in Figures 5 and 73. The speaker may be a haptic speaker, a piezoelectric speaker, an electroactive polymeric transducer, or a magnetic coil speaker. The computing device 800 and program 810 are configured to provide a signal to the speaker to cause the speaker to vibrate at certain frequencies or to oscillate or translate through a range of frequencies.

[00168] In accordance with embodiments of the present invention, the frequencies contemplated for use with the present invention range between 0 Hz to 20,000 Hz, 0 Hz and 10,000 Hz, 0 Hz and 5,000 Hz, 0 Hz and 2,500 Hz, 0 Hz and 1,750 Hz, 0 Hz and 875 Hz, 0 Hz and 435 Hz, 0 Hz and 200 Hz, 0 Hz and 150 Hz, 1 Hz and 150 Hz, 2 Hz and 150 Hz, 3 Hz and 150 Hz, 4 Hz and 150 Hz, 5 Hz and 150 Hz, 6 Hz and 150 Hz, 7 Hz and 150 Hz, 8 Hz and 150 Hz, 9 Hz and 150 Hz, 10 Hz and 150 Hz, 11 Hz and 150 Hz, 12 Hz and 150 Hz, 13 Hz and 150 Hz, 14 Hz and 150 Hz, 15 Hz and 150 Hz, 16 Hz and 150 Hz, 17 Hz and 150 Hz, 18 Hz and 150 Hz, 19 Hz and 150 Hz, 20 Hz and 150 Hz, 21 Hz and 150 Hz, 22 Hz and 150 Hz, 23 Hz and 150 Hz, 24 Hz and 150 Hz, 25 Hz and 150 Hz, 26 Hz and 150 Hz, 27 Hz and 150 Hz, 28 Hz and 150 Hz, 28 Hz and 150 Hz, 29 Hz and 150 Hz, 30 Hz and 150 Hz, 31 Hz and 150 Hz, 32 Hz and 150 Hz, 33 Hz and 150 Hz, 34 Hz and 150 Hz, 35 Hz and 150 Hz, 36 Hz and 150 Hz, 37 Hz and 150 Hz, 38 Hz and 150 Hz, 39 Hz and 150 Hz,40 Hz and 150 Hz, 41 Hz and 150 Hz, 42 Hz and 150 Hz, 43 Hz and 150 Hz, 44 Hz and 150 Hz, 45 Hz and 150 Hz, 46 Hz and 150 Hz, 47 Hz and 150 Hz, 48 Hz and 150 Hz, 49 Hz and 150 Hz, 50 Hz and 150 Hz, 51 Hz and 150 Hz, 52 Hz and 150 Hz, 53 Hz and 150 Hz, 54 Hz and 150 Hz, 55 Hz and 150 Hz, 56 Hz and 150 Hz, 57 Hz and 150 Hz, 58 Hz and 150 Hz, 59 Hz and 150 Hz, 60 Hz and 150 Hz, 61 Hz and 150 Hz, 62 Hz and 150 Hz, 63 Hz and 150 Hz, 64 Hz and 150 Hz, 65 Hz and 150 Hz, 66 Hz and 150 Hz, 67 Hz and 150 Hz, 68 Hz and 150 Hz, 69 Hz and 150 Hz, 70 Hz and 150 Hz, 71 Hz and 150 Hz, 72 Hz and 150 Hz, 73 Hz and 150 Hz, 74 Hz and 150 Hz, 75 Hz and 150 Hz, 76 Hz and 150 Hz, 77 Hz and 150 Hz, 78 Hz and 150 Hz, 79 Hz and 150 Hz, 80 Hz and 150 Hz, 81 Hz and 150 Hz, 82 Hz and 150 Hz, 83 Hz and 150 Hz, 84 Hz and 150 Hz, 85 Hz and 150 Hz, 86 Hz and 150 Hz, 87 Hz and 150 Hz, 88 Hz and 150 Hz, 89 Hz and 150 Hz, 90 Hz and 150 Hz, 91 Hz and 150 Hz, 92 Hz and 150 Hz, 93 Hz and 150 Hz, 94 Hz and 150 Hz, 95 Hz and 150 Hz, 96 Hz and 150 Hz, 97 Hz and 150 Hz, 98 Hz and 150 Hz, 99 Hz and 150 Hz, 100 Hz and 150 Hz, 101 Hz and 150 Hz, 102 Hz and 150 Hz, 103 Hz and 150 Hz, 104 Hz and 150 Hz, 105 Hz and 150 Hz, 106 Hz and 150 Hz, 107 Hz and 150 Hz, 108 Hz and 150 Hz, 109 Hz and 150 Hz, 110 Hz and 150 Hz, 111 Hz and 150 Hz, 112 Hz and 150 Hz, 113 Hz and 150 Hz, 114 Hz and 150 Hz, 115 Hz and 150 Hz, 116 Hz and 150 Hz, 117 Hz and 150 Hz, 118 Hz and 150 Hz, 119 Hz and 150 Hz, 120 Hz and 150 Hz, 121 Hz and 150 Hz, 122 Hz and 150 Hz, 123 Hz and 150 Hz, 124 Hz and 150 Hz, 125 Hz and 150 Hz, 126 Hz and

150 Hz, 127 Hz and 150 Hz, 128 Hz and 150 Hz, 129 Hz and 150 Hz, 130 Hz and 150 Hz, 131 Hz and 150 Hz, 132 Hz and 150 Hz, 133 Hz and 150 Hz, 134 Hz and 150 Hz, 135 Hz and 150 Hz, 136 Hz and 150 Hz, 137 Hz and 150 Hz, 138 Hz and 150 Hz, 139 Hz and 150 Hz, 140 Hz and 150 Hz, 141 Hz and 150 Hz, 142 Hz and 150 Hz, 143 Hz and 150 Hz, 144 Hz and 150 Hz, 145 Hz and 150 Hz, 146 Hz and 150 Hz, 147 Hz and 150 Hz, 148 Hz and 150 Hz, 149 Hz and 150 Hz, 150 Hz and 150 Hz, 60 Hz and 100 Hz, 61 Hz and 100 Hz, 62 Hz and 100 Hz, 63 Hz and 100 Hz, 64 Hz and 100 Hz, 65 Hz and 100 Hz, 66 Hz and 100 Hz, 67 Hz and 100 Hz, 68 Hz and 100 Hz 69 Hz and 100 Hz, 70 Hz and 100 Hz, 60 Hz and 99 Hz, 61 Hz and 99 Hz, 62 Hz and 99 Hz, 63 Hz and 99 Hz, 64 Hz and 99 Hz, 65 Hz and 99 Hz, 66 Hz and 99 Hz 67 Hz and 99 Hz, 68 Hz and 99 Hz, 69 Hz and 99 Hz and 70 Hz and 99 Hz, and 61 Hz and 98 Hz, 62 Hz and 98 Hz, 63 Hz and 98 Hz, 64 Hz and 98 Hz, 65 Hz and 98 Hz, 66 Hz and 98 Hz, 67 Hz and 98 Hz, 68 Hz and 98 Hz, 69 Hz and 98 Hz and 70 Hz and 98 Hz.

[00169] In a preferred embodiment the signal causes the driver assembly to vibrate at a frequency or sweep through a range of frequencies between about 40 Hz and 150 Hz, more preferably between 50 Hz and 125 Hz, most preferably between about 60 Hz and 115 Hz. In accordance with the present invention, a therapeutic response has been achieved utilizing a frequency range between 65 Hz and 100 Hz.

[00170] It is further contemplated that these frequencies may be doubled and still achieve the therapeutic lowering of blood pressure in accordance with the present invention. It is further contemplated that these frequencies may be halved and still achieve the therapeutic lowering of blood pressure in accordance with the present invention.

[00171] In additional embodiment of the present invention, the driver assembly may vibrate or sweep or step between frequencies of between 60 Hz, 61 Hz, 62 Hz, 63 Hz, 64 Hz, 65 Hz, 66 Hz, 67 Hz, 68 Hz, 69 Hz, 70 Hz, 71 Hz, 72 Hz, 73 Hz, 74 Hz, 75 Hz, 76 Hz, 77 Hz, 78 Hz, 79 Hz, 80 Hz, 81 Hz, 82 Hz, 83 Hz, 84 Hz, 85 Hz, 86 Hz, 87Hz, 88 Hz, 89 Hz, 90 Hz, 91 Hz, 92 Hz, 93 Hz, 94 Hz, 95 Hz, 96 Hz, 97 Hz, 98 Hz, 99 Hz and 100 Hz.

[00172] Referring now to Figure 23A and 23B, there is shown a further embodiment wherein the therapy is provided utilizing a combination of single frequencies and a sweeping frequency. For example, the driver assembly would be driven to vibrate at a single frequency, F1, for a period of time, then driven to sweep through a range of frequencies, F2, then driven at a single frequency, F3, different than the first single frequency, F1, and then finally driven backwards through the sweep of frequencies above, F4. This cycle may be repeated for a set period of time, turned off for a period of time and then repeated again, until an overall time period of therapy is reached.

[00173] It is further contemplated that multiple signals utilizing separate frequencies may be transmitted by the program to the speaker. For example, one signal may be transmitted at one frequency and a second signal at another frequency. The signals may be transmitted simultaneously, independently or in an alternating fashion. If at least two therapy providing devices 200 are utilized, then one therapy providing device 200 may receive a first signal and the other receives a second signal.

[00174] In one embodiment, at least two therapy providing devices 200 are utilized. In use a signal will be sent to one of the two therapy providing devices 200, causing the speaker to emit a signal having a chosen frequency or range of frequencies. The signal is transmitted to a first therapy providing device 200 for a pre-determined period of time. After such time, the signal is terminated. Upon termination of the first signal, a second signal is generated and transmitted to the other therapy providing device. This second signal causes the speaker to emit a signal having a chosen frequency or range or frequencies. The chosen frequency may be the same as that transmitted to the first therapy providing device or it may be at a different frequency. The second signal will be transmitted to the second therapy providing device for a pre-determined period of time. After such time, the signal is terminated. The program will continued to run, however, during this time no signal will be transmitted to either therapy providing device 200, thereby creating a pause between activation of the therapy providing devices 200. After the pre-determined time period of the pause has passed, the program will then enter a loop and repeat the process described above. This pattern of therapy will repeat for as long as the program has been instructed to do so.

[00175] In the embodiment where two therapy providing devices 200 are utilized, each of the devices deliver a waveform to the user's left and right clavicle. The waveform is transmitted from the speaker in each of the therapy providing devices to the user's clavicles. The waveform is transmitted through the clavicle on the left and right side, where both waves meet at the sternum to create a standing wave.

[00176] Further still, in accordance with the present invention, the amplitude of the signal can be adjusted to adjust the sound pressure generated by the driver assembly 220 of the therapy providing device 200. It is contemplated that the amplitude may be doubled or increased even more to deliver the therapy in accordance with the present invention. In accordance with the invention, the therapy providing device 200 may be configured to provide a sound pressure between: 0 to 150 decibels, 0 to 100 decibels, 0 to 99 decibels, 0 to 98 decibels, 0 to 97 decibels, 0 to 96 decibels, 0 to 95 decibels, 0 to 94 decibels, 0 to 93 decibels, 0 to 92 decibels, 0 to 91 decibels, 0 to 90 decibels, 0 to 89 decibels, 0 to 88 decibels, 0 to 87 decibels, 0 to 86 decibels, 0 to 85 decibels, 0 to 84 decibels, 0 to 83 decibels, 0 to 82 decibels, 0 to 81 decibels, 0 to 80 decibels, 0 to 79 decibels, 0 to 78 decibels, 0 to 77 decibels, 0 to 76 decibels, 0 to 75 decibels, 0 to 74 decibels, 0 to 73 decibels, 0 to 72 decibels, 0 to 71 decibels, 0 to 70 decibels, 0 to 69 decibels, 0 to 68 decibels, 0 to 67 decibels, 0 to 66 decibels, 0 to 65 decibels, 0 to 64 decibels, 0 to 63 decibels, 0 to 62 decibels, 0 to 61 decibels, 0 to 60 decibels, 0 to 59 decibels, 0 to 58 decibels, 0 to 57 decibels, 0 to 56 decibels, 0 to 55 decibels, 0 to 54 decibels, 0 to 53 decibels, 0 to 52 decibels, 0 to 51 decibels, 0 to 50 decibels, 0 to 49 decibels, 0 to 48 decibels, 0 to 47 decibels, 0 to 46 decibels, 0 to 45 decibels, 0 to 44 decibels, 0 to 43 decibels, 0 to 42 decibels, 0 to 41 decibels, 0 to 40 decibels, 0 to 39 decibels, 0 to 38 decibels, 0 to 37 decibels, 0 to 36 decibels, 0 to 35 decibels, 0 to 34 decibels, 0 to 33 decibels, 0 to 32 decibels, 0 to 31 decibels, 0 to 30 decibels, 0 to 29 decibels, 0 to 28 decibels, 0 to 27 decibels, 0 to 26 decibels, 0 to 25 decibels, 0 to 24 decibels, 0 to 23 decibels, 0 to 22 decibels, 0 to 21 decibels, 0 to 20 decibels, 0 to 19 decibels, 0 to 18 decibels, 0 to 17 decibels, 0 to 16 decibels, 0 to 15 decibels, 0 to 14 decibels, 0 to 13 decibels, 0 to 12 decibels, 0 to 11 decibels, 0 to 10 decibels, 0 to 9 decibels, 0 to 8 decibels, 0 to 7 decibels, 0 to 6 decibels, 0 to 5 decibels, 0 to 4 decibels, 0 to 3 decibels, 0 to 2 decibels, 0 to 1 decibels, 0 to .5 decibels, 0 to .25 decibels, 10 to 100 decibels, 20 to 100 decibels, 30 to 100 decibels, 40 to 100 decibels, 50 to 100 decibels, 60 to 100 decibels, 70 to 100 decibels, 80 to

100 decibels, 90 to 100 decibels, 10 to 75 decibels, 20 to 75 decibels, 30 to 75 decibels, 40 to 75 decibels, 50 to 75 decibels, 60 to 75 decibels, 70 to 75 decibels, 10 to 65 decibels, 20 to 65 decibels, 30 to 65 decibels, 40 to 65 decibels, 50 to 65 decibels and 60 to 65 decibels, 20 to 30 decibels, 30 to 40 decibels, 40 to 50 decibels, 50 to 60 decibels, 60 to 70 decibels, 70 to 75 decibels, 80 to 90 decibels, 50 to 75 decibels and 50 to 65 decibels.

[00177] Further still, in accordance with the present invention, the standing wave may be of half-octave, double octave, or reflective incidence. Thus the frequencies delivered at the collarbone may independently collide across the breastbone or sternum and create a new frequency which is of a different or same frequency as the generating waves.

[00178] In accordance with the present invention, the frequency selected for therapy may be held constant while the sound pressure level can be increased or decreased, alternatively, the sound pressure level may be held constant and the frequency varied. The measurement of a sound pressure level is related to the displacement of a portion of the delivery device 220. The portion of the delivery device 220 may be displaced between: 0 mm and 20 mm, 0 mm to 10mm, 0 mm to 9mm, 0 mm and 8 mm, 0mm to 7 mm, 0 mm to 6 mm, 0 mm to 5 mm, 0 mm and 4 mm, 0 mm and 3 mm, 0 mm and 2 mm, 0 mm and 1 mm, 0 mm and .5 mm, 0 mm to .05mm , 0 mm to .005 mm, 0 mm to .0005 mm, .5 mm to .05 mm, .5 mm to .005 mm, .05 mm to .005. If the delivery device 220 is selected to be the haptic speaker 220', then the portion of the haptic speaker 220' being displaced is the coil of the haptic speaker.

[00179] In accordance with the present invention, it is contemplated that each therapy providing device may be activated to provide therapy for a time period between about 1 second and 24 hours. In other embodiments, the therapy providing devices may be activated to provide therapy for a time period of between about 1 second and 12 hours, 1 second and 11 hours, 1 second and 10 hours, 1 second and 9 hours, 1 second and 8 hours, 1 second and 7 hours, 1 second and 6 hours, 1 second and 5 hours, 1 second and 4 hours, 1 second and 3 hours 1 second and 2 hours, and 1 second and 1 hour, 1 second and 45 minutes, 1 second and 30 minutes, 1 second and

20 minutes, 1 second and 15 minutes, 1 second and 10 minutes, 1 second and 5 minutes and 1 second and 1 minute.

[00180] The overall therapy process may be conducted for a time period between 1 second and 24 hours, 1 second and 23 hours, 1 second and 22 hours, 1 second and 21 hours, 1 second and 20 hours, 1 second and 19 hours, 1 second and 18 hours, 1 second and 17 hours, 1 second and 16 hours, 1 second and 15 hours, 1 second and 15 hours, 1 second and 14 hours, 1 second and 13 hours, 1 second and 12 hours, 1 second and 11 hours, 1 second and 10 hours, 1 second and 9 hours, 1 second and 8 hours, 1 second and 7 hours, 1 second and 6 hours, 1 second and 5 hours, 1 second and 4 hours, 1 second and 3 hours, 1 second and 2 hours, 1 second and 1 hour, 1 second and 45 minutes, 1 second and 30 minutes, 1 second and 15 minutes, 1 second and 10 minutes, 1 second and 5 minutes, 1 second and 1 minute.

[00181] In an alternative embodiment, instead of activating one therapy providing device 200 at a time to conduct the therapy, both therapy providing devices 200 may be activated at the same time.

[00182] In accordance with the present invention, the therapy device may be factory programmed to utilize a certain frequency or range of frequencies to provide therapy. Alternatively, the frequencies may be selected and programmed or chosen from memory by a health care provider based upon a patient's response to a specific frequency or range of frequencies.

[00183] It is further contemplated that the computing device may be additionally in communication with other sensors, such as a blood pressure monitor, heart rate monitor, pulse oximetry monitor, electrocardiogram (EKG/ECG), or glucose sensor.

[00184] In one embodiment the computing device 800 would receive data from the blood pressure monitor, or other sensor, such that the user's blood pressure would be recorded before, during and after the application of therapy in accordance with the present invention. This data, along with the therapy data could be provided to the user and/or a health care provider. Based upon the data, the frequency or range of frequencies selected for therapy could be adjusted. The adjustments may be made automatically by the program, or by a health care provider or by the user themselves.

[00185] In another embodiment, the processor of the therapy providing device 200 may be in communication with other sensors, such as those described above, wherein the other sensors would be coupled in communication with the therapy providing device. The processor within the therapy providing device 200 can receive data from various other sensors, such as a blood pressure monitor. The data received from the blood pressure monitor may be utilized by the program within the memory of the electronics module to further control the therapy providing device 200.

[00186] The signals generated by the program and transmitted to the therapy providing device are preferably in the form of a sine wave. However, other wave forms may be utilized, such as a square waveform, sawtooth waveform or triangle waveform.

[00187] It is further contemplated that additional sensors maybe utilized with the methods and devices in accordance with the present invention. For example, a blood pressure monitor may be affixed to the patient as described above. Other sensors, such as a sleep sensor, movement sensor, pulse oximetry sensor, temperature sensor, heart rate monitor, EKG, microphone, digital stethoscope, light sensor, sleep apnea device (CPAP) or camera may be used in combination with the therapy system 100 in accordance with the present invention. The sensors listed above could be used separately or in combination to provide additional data to the user or a health care provider as to the health of the user as well as to the response of the user to the therapy provided by the therapy system 100.

[00188] It is further contemplated that any of the above sensors could be incorporated into the therapy providing device 200 in accordance with the present invention. If incorporated into the therapy providing device 200, the data from each of the additional sensors could be utilized by the program to alter the therapy provided based upon data received from the various sensors. In an alternative embodiment, the data from each of the additional sensors could be stored on the resident memory contained within the therapy providing device 200. The therapy providing device 200 could then be turned into a service center after a period of time, wherein the data contained within the memory can be retrieved and analyzed. In yet another embodiment, the data stored within the memory can be downloaded from the

therapy providing device 200 each time the therapy providing device is placed on the inductive charging pad. The data can then be transmitted to a collection center and analyzed. Additionally, the data could be uploaded to a server or other internet/network connected personal computer, such that the data could be viewed by the user, a health care provider or others.

[00189] In another embodiment, the device will store the number of uses and durations of usage to allow the health care practitioner to determine compliance of the patient. As in sleep apnea devices, reimbursement is only allowed if the patient is 70 percent compliant, by tracking and recording the usage of the therapy providing device of the present invention, this data could be utilized for reimbursement purposes.

[00190] In another embodiment, the therapy system 100 of the present invention could be associated with a home health system, such as Honeywell's HomMed system. In this embodiment, the therapy system 100 in accordance with the present invention would be coupled to a monitoring system. In this embodiment, a health care provider could remotely monitor users as well as their response to the therapy being provided. Further still, the therapy system 100 may be configured to recognize an emergency, such as excessively high blood pressure, excessively low blood pressure, high heart rate or low heart rate and generate an alert, such as an alarm or notification to an emergency response unit to request help for the user.

[00191] In accordance with the present invention, the therapy device 200 as described herein is disposed adjacent to or thereabout the clavicle just above the brachial plexus of the user. It is contemplated that the therapy providing device 200 may be placed at other locations on the user such as the sternum, jaw, scapula, kneecap, wrist or skull. When activated, the driver assembly 220 of the therapy device generates a frequency in the form of a sound wave; this sound wave is transmitted to the clavicle and the skin adjacent the clavicle. The sound waves transmitted to the clavicle are transmitted in the form of vibrations. The vibrations travel through the clavicle and into the skin, the arteries, vessels, nerves, sensory corpuscles, airways,bones near the clavicle, ligaments and tendons. As a result, the vibrations are eventually transmitted to the baroreceptors, the nociceptors, the proprioreceptors and other somatasory sensors. Here, the vibrations interact with the

baroreceptors and other sensors in a manner to lower blood pressure. In a preferred embodiment, the clavicle is chosen because it's easily accessible location as well as its ability to transmit sound or vibrations. The clavicle is easy to identify by a health care provider and a patient as it resides close to the surface of the skin regardless of body mass.

[00192] In accordance with the methods and devices of the present invention, activation of both the carotid and aortic baroreceptors as well as other somatasory sensors can be achieved. It is believed that activation of both the carotid and aortic baroreceptors is beneficial in achieving lower blood pressure. It is believed that the methods provided according to the present invention mimic exercise, and therefore achieve a lowering of blood pressure.

[00193] In accordance with the invention, the therapy may be provided at night time either right before the patient enters a sleep cycle or during a sleep cycle of the patient. It may be beneficial to provide the therapy in accordance with the present invention at night time as it is believed that one of the most important times to lower blood pressure is during the night. By providing therapy at night time in accordance with the present invention, the therapy can be utilized to address nighttime hypertension. Additionally, at nighttime, systemic drug levels are at their lowest, therefore there is a need for additional blood pressure control at this time.

[00194] In accordance with another embodiment of the present invention, it is believed that through the use of a single therapy providing device instead of two therapy providing devices can be utilized to lower only Diastolic blood pressure, wherein the use of both therapy providing devices can be utilized to lower both Systolic and Diastolic blood pressure.

[00195] In accordance with the invention, the therapy may be provided prior to a users sleep cycle and again in the morning either before they awake or shortly after they have woken up.

[00196] In accordance with the invention, the therapy providing device may be programmed with frequencies, wherein other frequencies may be utilized to raise blood pressure at such times whereby raising the blood pressure would be therapeutic

and beneficial to a patient. It may be desirable to raise blood pressure after childbirth or to counteract episodes of hypotension.

[00197] It is further contemplated that the device and methods according to the present invention may be utilized at any time. For example, it may be desirable to utilize the device during the day time, where the device could be utilized in combination with a blood pressure monitor, or alternatively, incorporate a blood pressure monitor for closed loop control. In this embodiment, the program would monitor the user's blood pressure and apply therapy on an as needed basis. The user could select to turn the system off if desired, for example if they are planning to engage in physical activity which will raise their blood pressure.

TEST RESULTS

[00198] In accordance with the present invention, and referring to Figures 24A and 24B, the following blood pressure results were achieved through use of the device and methods described herein. Figures 24A and 24B illustrate ambulatory blood pressure readings over a 24 hour period. Line 910 is the European Society of Hypertension (ESH), the UK National Institute for Health and Clinical Excellence (NICE) and American Society of Hypertension (ASH) recommended limits for Systolic blood pressure. Between the hours of 10pm and 7am a blood pressure of below 125 mmHg is considered to be at goal. During the daytime between the hours of 7 am and 10 pm, a blood pressure below 140mmHg is considered to be at goal. Line 930 is the ESH, NICE and ASH recommended limits for Diastolic blood pressure, similar to the Systolic line 910, between the hours of 10pm and 7am an at-goal Diastolic pressure is considered to be 80 mmHg, and between the hours of 7am to 10 pm a measurement of 90 mmHg is considered to be at goal.

[00199] As shown in Figure 24A, lines 900 and 920 represent twenty-four (24) hour ambulatory blood pressure measurements of an individual, wherein blood pressure measurements were taken every fifteen (15) minutes. The user presented in Figure 24B would be considered to be hypertensive, that is to have high blood pressure. This can be determined by looking specifically at lines 900 and lines 920, wherein any time these lines are above the recommend guideline pressures, lines 910 and 930 the user would be considered to be hypertensive.

[00200] Referring now to Figure 24A there is shown a graph of the same user after having received therapy in accordance with the present invention. In this instance, the user received therapy at twice for two hours (2 hours) each time as depicted items 940 and 950. Comparing the user's actual blood pressure measurements, lines 900 and 920 of Figure 24A, with the user's treated actual blood pressure measurements, lines 901 and 902 of Figure 24A, it can be clearly seen that the user's blood pressure was significantly lowered through the application of therapy utilized the device and methods of the present invention.

[00201] To achieve the results depicted in Figure 24A, two therapy providing devices were utilized, one on the left clavicle and one on the right clavicle. A frequency between 60 and 100 Hz was delivered by the speaker of each therapy providing device. The therapy providing devices were utilized for a total of 4 hours of therapy, wherein the frequency of 65Hz was played for 8 seconds, followed by a sweep of frequencies from 65 Hz to 98 Hz lasting 1 second, afterwards 98 Hz was played for 8 seconds, followed by a sweep of frequencies from 98 Hz to 65 Hz lasting for 1 second. Therapy was provided, repeatedly for 120 minutes following this cycle. After 120 minutes the therapy was suspended for a period of 4 hours. After 4 hours of silence, an additional 120 minutes of therapy was delivered utilizing the cycle above.

[00202] Blood pressure measurements were taken before the application of the therapy, whereby the user's Systolic blood pressure averaged 131 mmHg at night time and 144 mmHg during the day. Diastolic blood pressure was 72 mmHg at night time and 87 mmHg during the day. After using the therapy for one evening (one 8 hour session as described above), Systolic blood pressure averaged 116 mmHg at nighttime and 131 mmHg at daytime and diastolic blood pressure averaged 66 mmHg at nighttime and 80 mmHg at daytime.

METHOD OF ACTION

[00203] In accordance with the present invention, as described in detail above and with reference to the included publications, it is understood that baroreceptors and nerves affect blood pressure through a measured response generated by stretching or contraction of the arterial wall.

[00204] Nerve fibers, including baroreceptors, have the following input-output characteristics; threshold pressure, saturation, post-excitory depression (PED), Asymmetric Rate Sensitivity and hysteresis.

[00205] As long as pressure within an artery remains below a certain level, no nerve firing occurs, this is referred to as the nerve threshold pressure. Above the threshold pressure, the fiber responds by producing action potentials, i.e. as signal. Individual fibers within humans and animals possess a wide range of pressure threshold values.

[00206] As pressure increases within the artery, the firing rate of individual fibers increases. However, at certain pressure, further increases in input yield no further increase in output frequency, thereby reaching the saturation of the baroreceptor nerve.

[00207] If pressure input within the artery is stepped from a low pressure, which is higher than the threshold pressure, to a higher pressure, then returning to a lower pressure level, will result in a brief period of shutoff, that is there will be no firing of the baroreceptor nerve, also referred to as post-excitatory depression (PED). The baroreceptor nerve will return to its original firing rate after time.

[00208] Baroreceptor nerve frequency response to rising pressure is more pronounced than the response to falling pressure, otherwise known as asymmetric rate sensitivity.

[00209] Lastly, periodic inputs produce looping in pressure-frequency plots, another indication of the asymmetry between responses to rising and falling pressures otherwise referred to as hysteresis.

[00210] In accordance with the present invention, utilization of the devices in accordance with the methods described herein cause an activation of the nervous system which affect blood pressure. The nerve terminal endings respond to stretch or acoustic vibration, and produce a frequency-modulated train of action potentials which can override the natural frequencies to elicit a response. Wherein the therapy provided by the invention, utilizes acoustic vibration of specific frequencies applied at specific time intervals to activate the body's nervous system to elicit a blood pressure response. The therapy of the present invention is applied in a cyclic manner as it is

believed that the baroreceptors may become saturated if stimulated for too long of a period of time. If the therapy was applied continuously it is believed that the baroreceptors would stop responding.

[00211] According to a method of the present invention, the therapy providing device is disposed adjacent to a user's clavicle. The clavicle being a Dermal bone, is capable of transmitting vibrations. The clavicle lies above the cerviocoaxillary which holds auxiliary arteries, veins, airways and the brachial plexus of nerves that supply the upper limb of the arm. Vibrating the clavicle is believed to create micro-pulsations which travel to the Aortic Baroreceptors and the Carotid Bulb Baroreceptors. These micro-pulsations are believed to be perceived as an increase in heart rate by the baroreceptors which then send a signal to the brain. Thereby causing the body to lower blood pressure.

[00212] Selective stimulation of primary nerve endings can be obtained with careful control of the amplitude, displacement and the mode of application of the vibration or micro-pulsations.

CLAIMS

1. A device for treating hypertension, comprising:

a housing, the housing having a proximal surface and a distal surface, wherein the housing further includes a mounting system, the mounting system including a first member and a second member, the first member associated with the housing and the second member configured to be received by tissue; and

a driver assembly coupled to the housing.

2. The device according to Claim 1, wherein the second member includes a first surface and a second surface and one of the surfaces includes an adhesive.

3. The device according to Claim 2, wherein the second member is configured to be placed over the clavicle of a user.

4. The device according to Claim 1, further comprising an electronics module.

5. The device according to Claim 4, wherein the electronics module further includes a wireless communication chip.

6. The device according to Claim 4, further including a memory chip.

7. The device according to Claim 1, wherein the driver assembly is a haptic transducer.

8. The device according to Claim 1, wherein the driver assembly is a magnetic speaker.

9. The device according to Claim 1, further including an energy source disposed within the housing.

10. The device according to Claim 9, wherein the energy source is removable.

11. The device according to Claim 9, wherein the energy source is rechargeable.

12. The device according to Claim 11, wherein the energy source is rechargeable through a non-contact charger.

13. A device for imparting energy to a patient, comprising:

a housing, the housing having a first surface and a second surface, the surfaces defining a volume therebetween, wherein the housing further includes a mounting system, the mounting system including a first member and a second member, the first member associated with the housing and the second member configured to be received by tissue;

a driver assembly disposed within the volume of the housing;

an energy source coupled to the driver assembly; and

an electronics module coupled to the driver assembly and the energy source.

14. The device according to Claim 13, wherein the electronics module further includes a wireless communication module.

15. The device according to Claim 14, further including a computing device, the computing device configured to run a program.

16. The device according to Claim 15, wherein the computing device is in wireless communication with the electronics module and the program running on the computing device controls the electronics module to activate or deactivate the driver assembly.

17. The device according to Claim 13, wherein the driver assembly is a speaker.

18. The device according to Claim 13, wherein the driver assembly is a haptic transducer.

19. The device according to Claim 13, wherein the driver assembly produces a frequency within the range of .1 Hz and 20,000 Hz.

20. The device according to Claim 19, wherein the driver assembly produces a frequency in the range of 40 Hz to 100 Hz.

21. The device according to Claim 20, wherein the driver assembly produces a frequency in the range 60 Hz to 100 Hz.

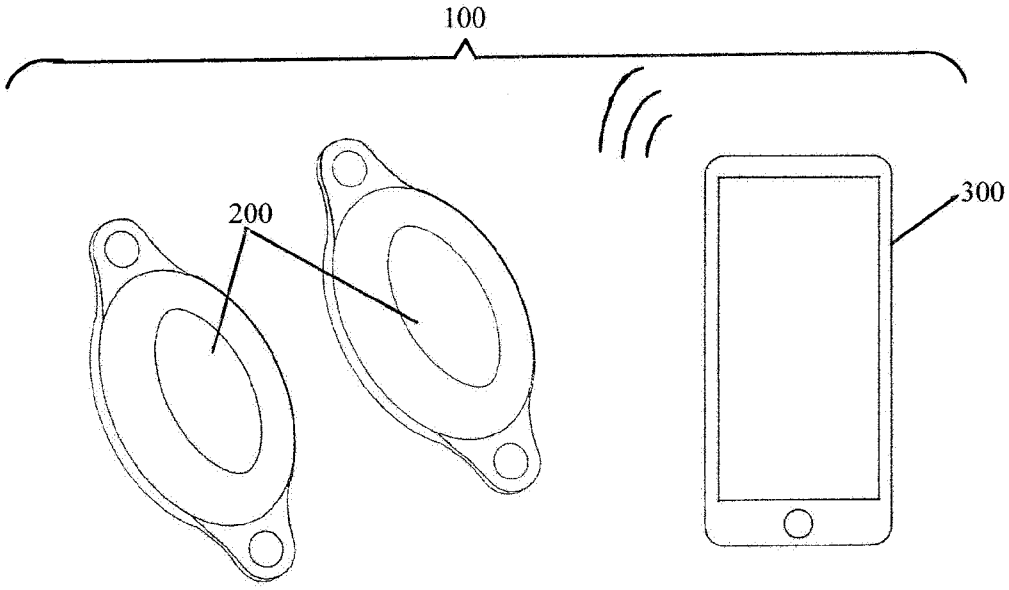


Figure 1

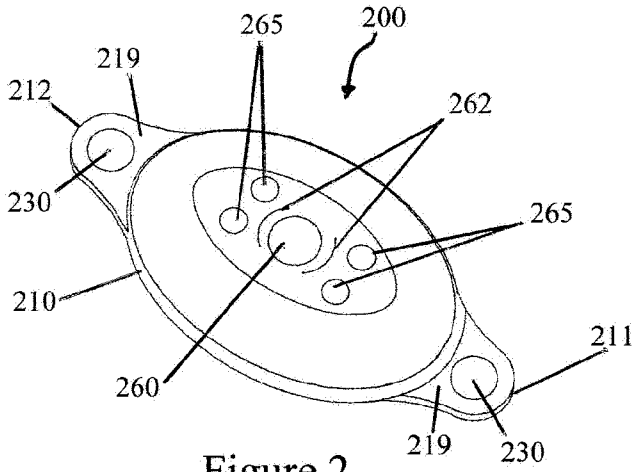


Figure 2

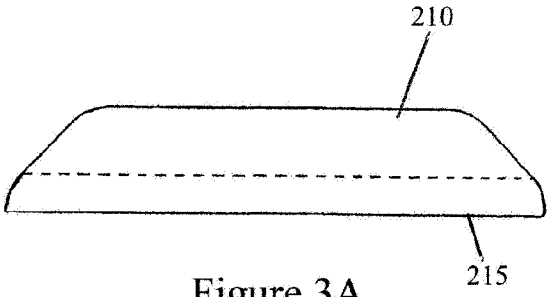


Figure 3A

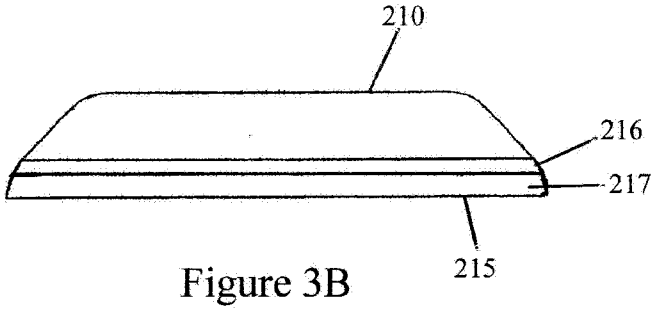


Figure 3B

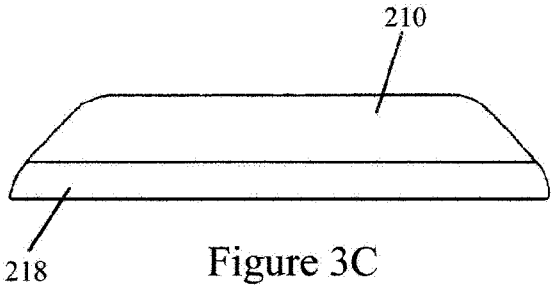


Figure 3C

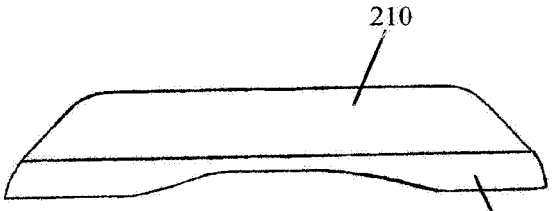


Figure 3D

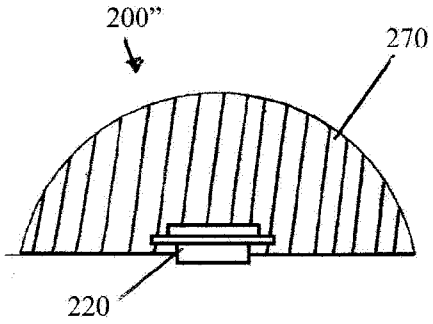
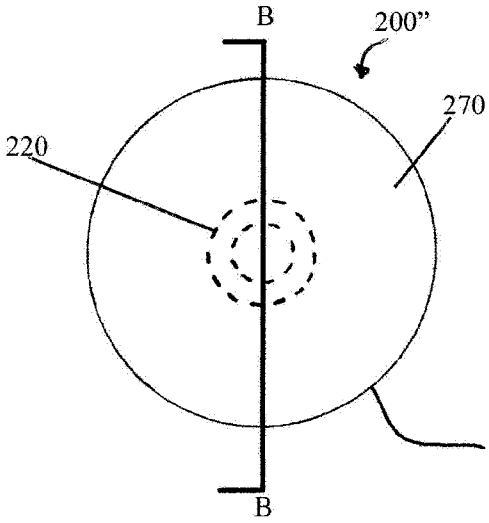


Figure 4B



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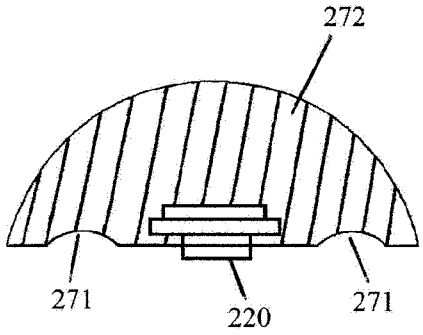

Figure 4C

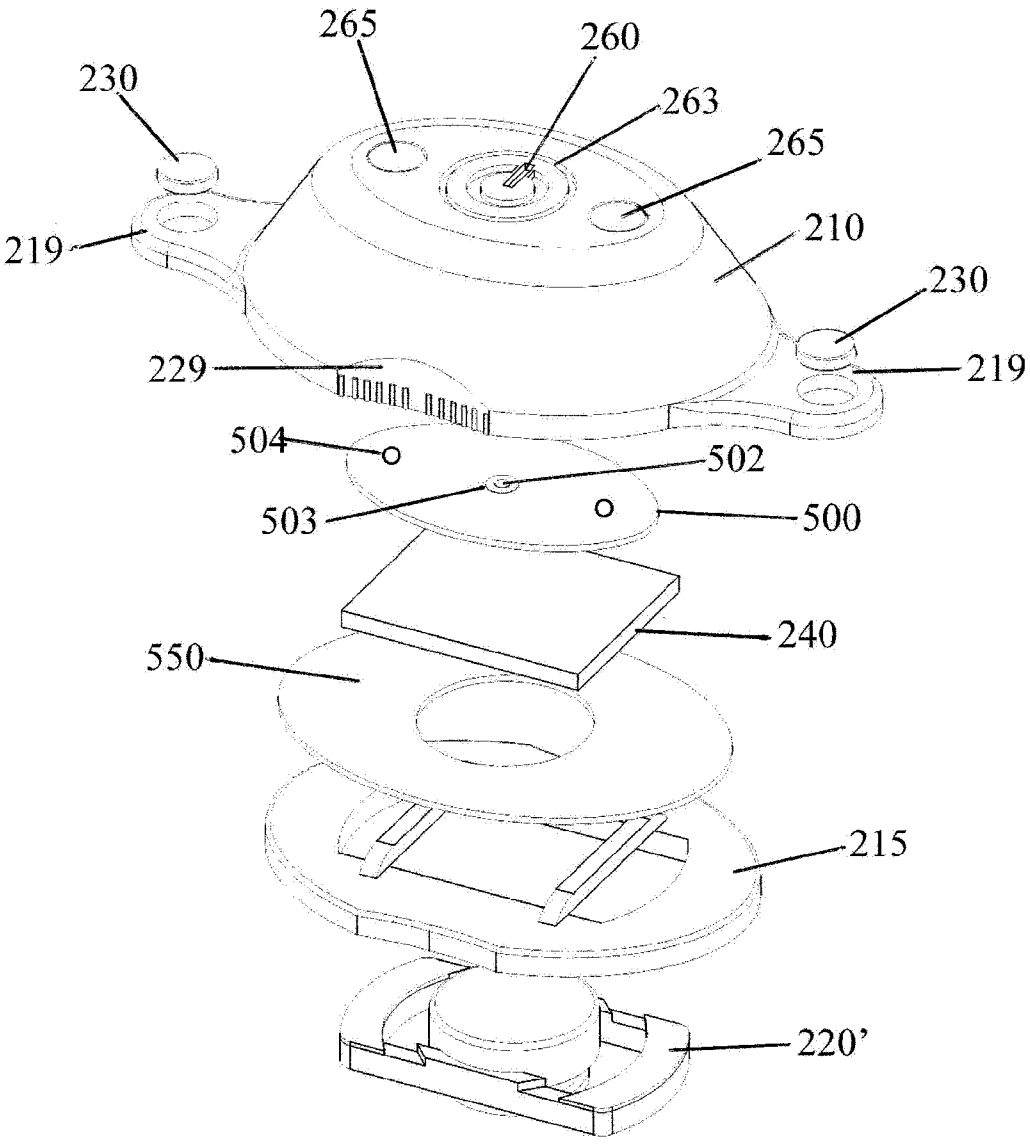
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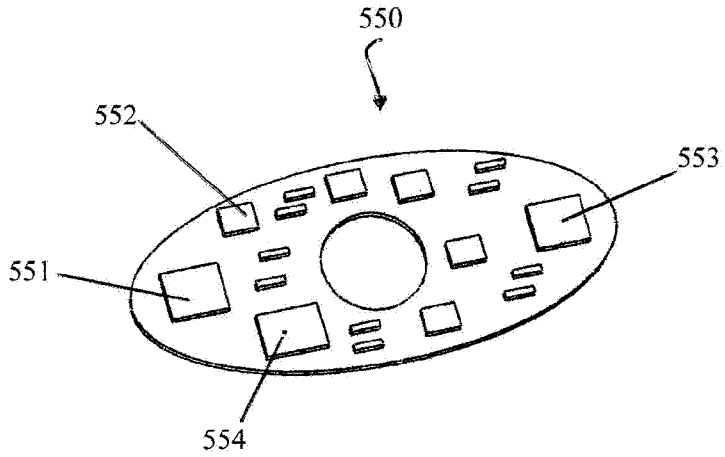
Figure 5



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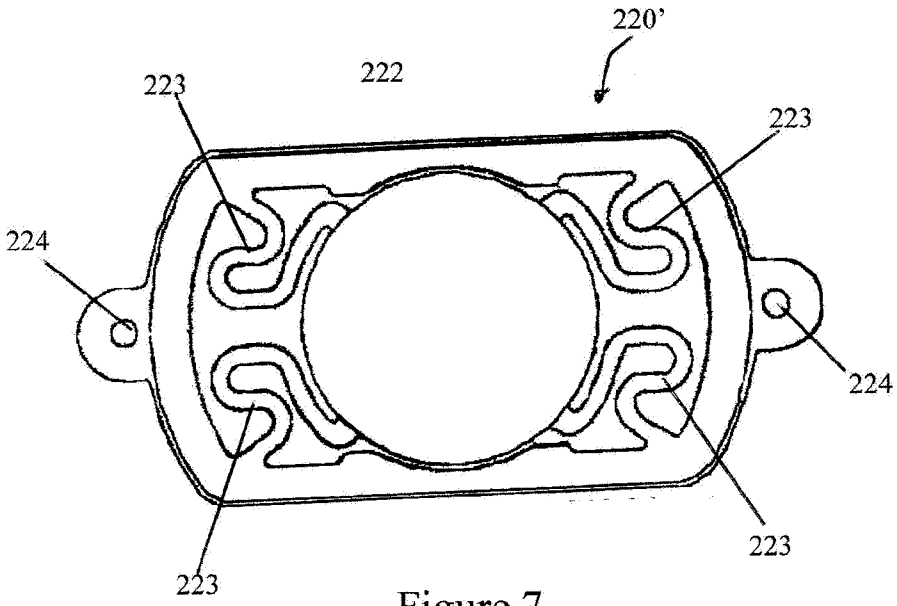

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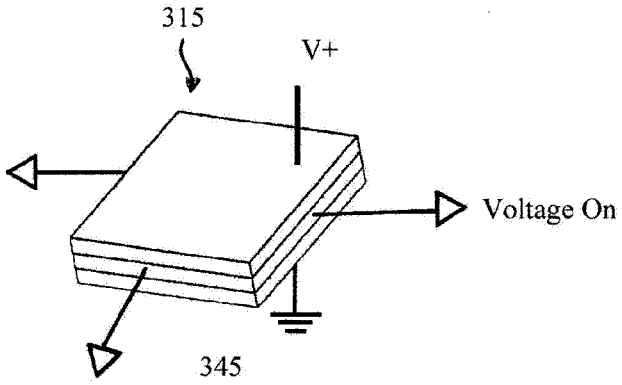

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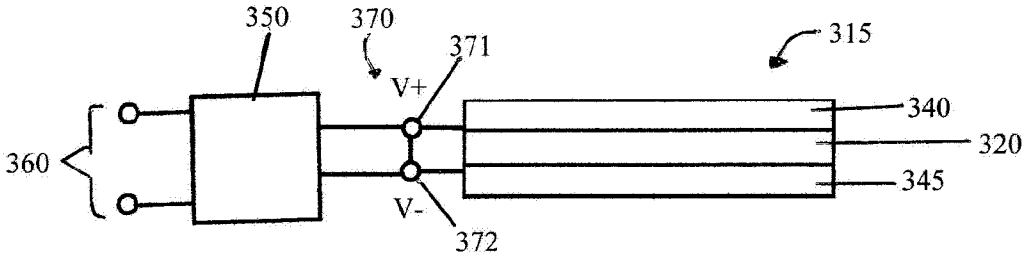
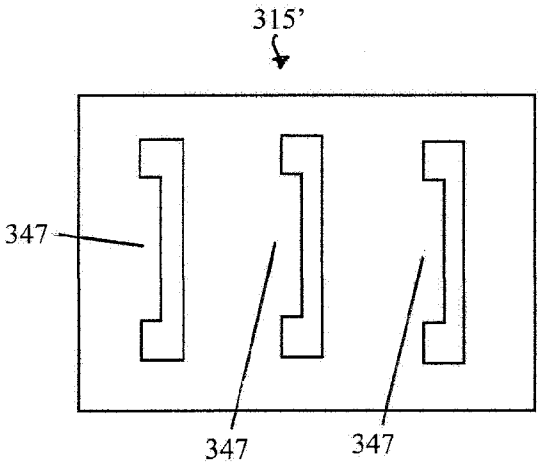


Figure 9



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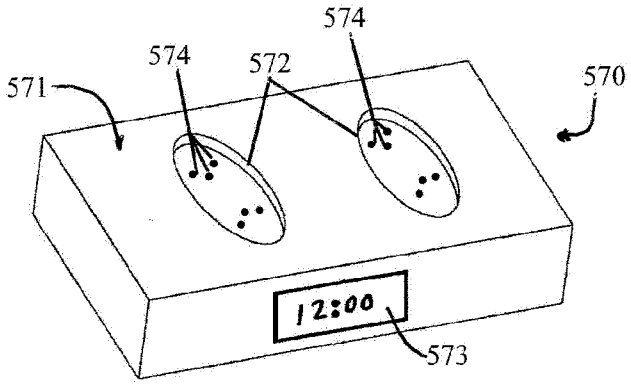

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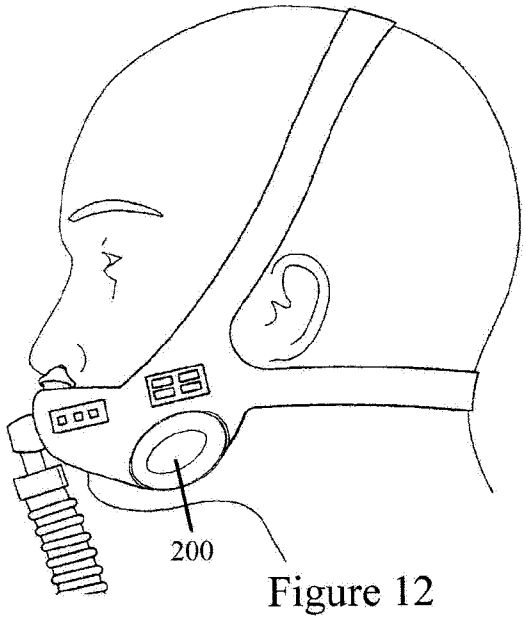


Figure 12

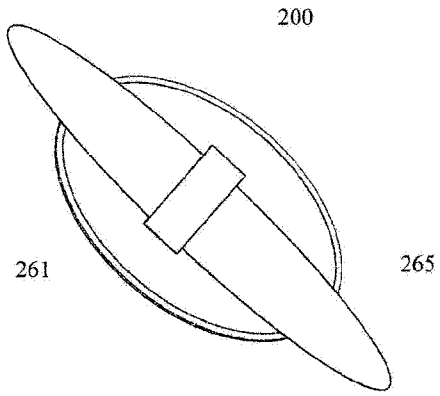


Figure 13A

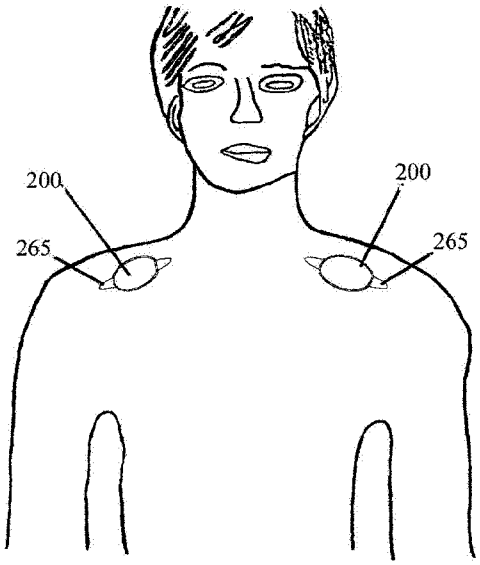


Figure 13B

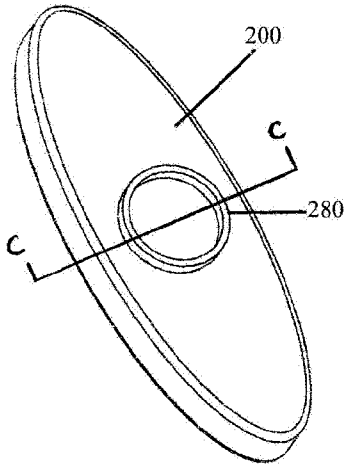


Figure 14A

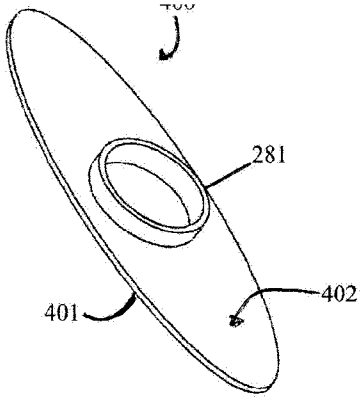


Figure 14B

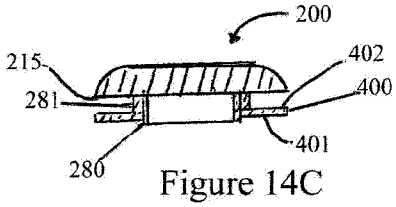
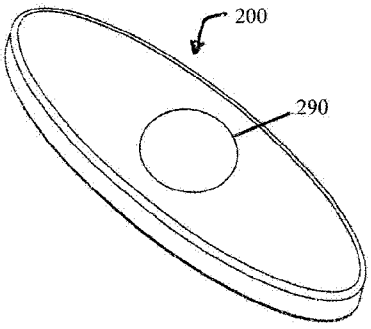


Figure 14C



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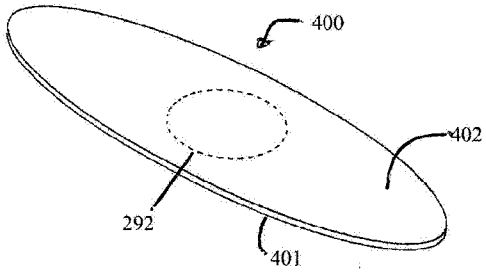
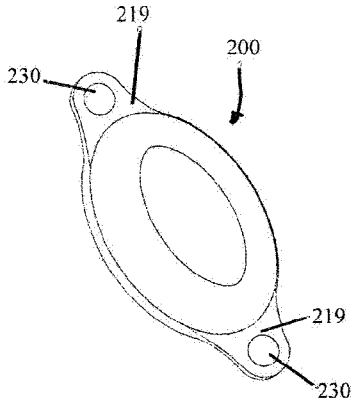


Figure 15B



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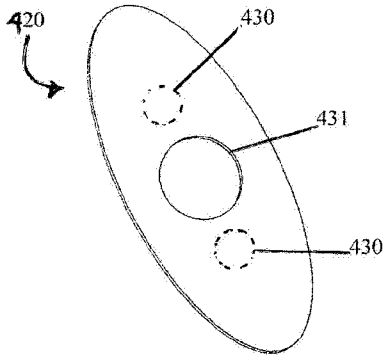
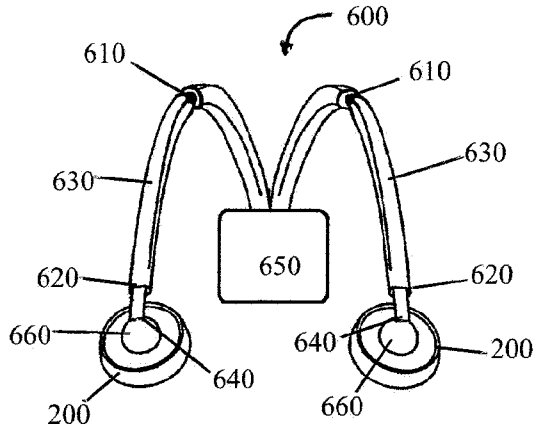


Figure 16B



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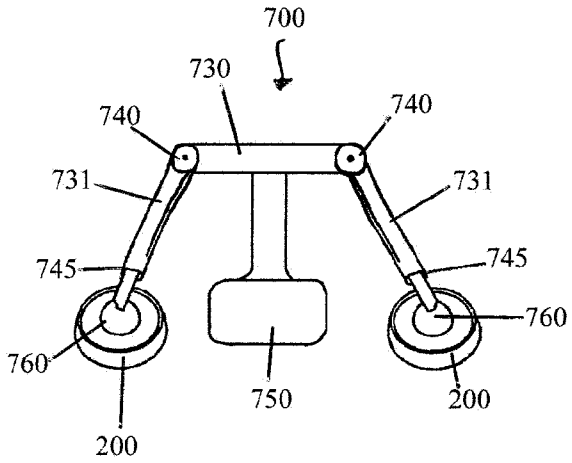

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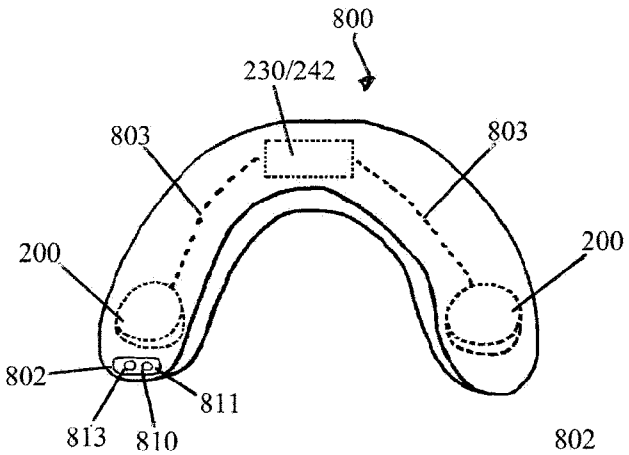

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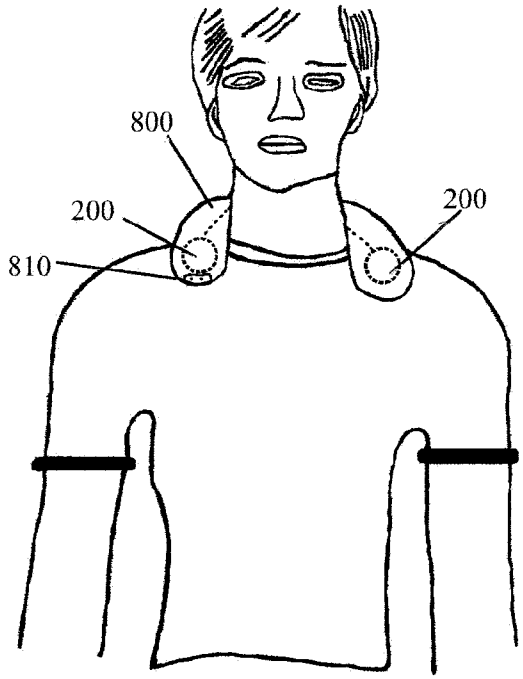
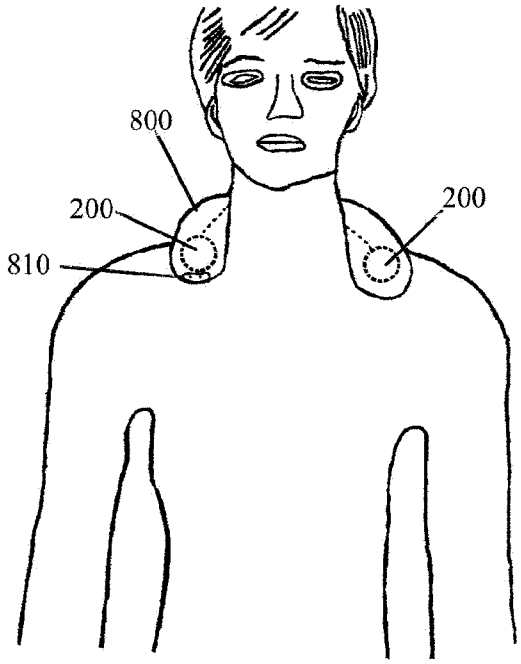


Figure 19B



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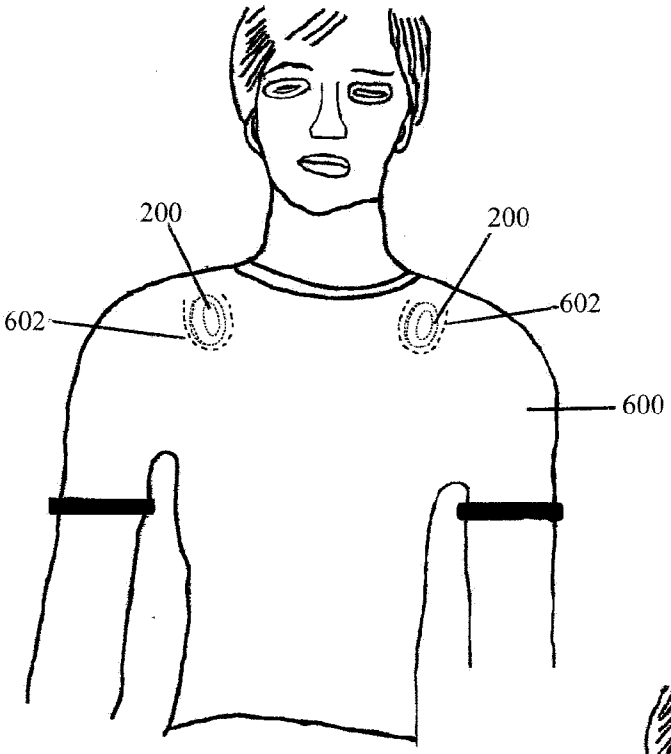

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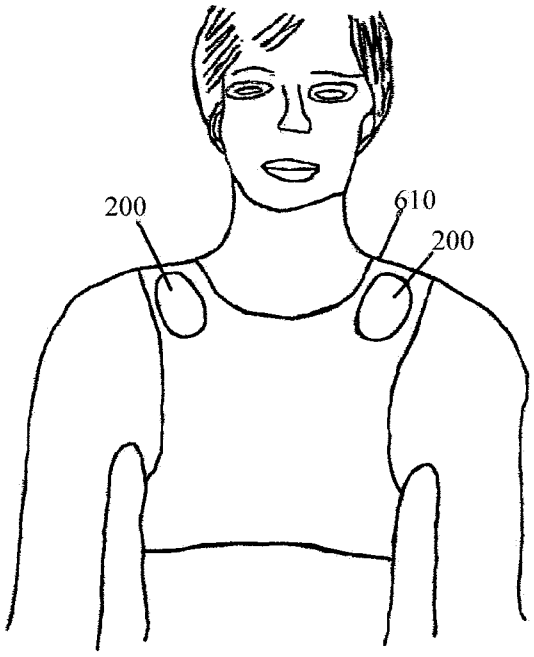
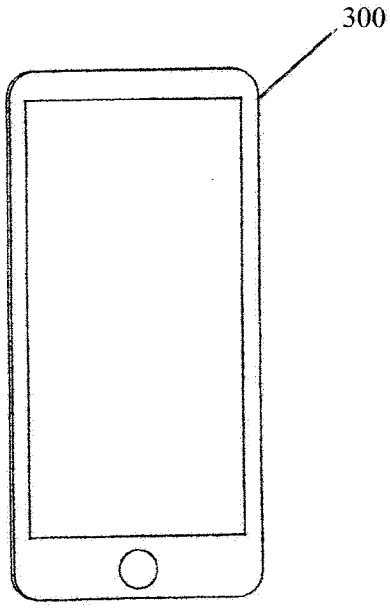


Figure 20B



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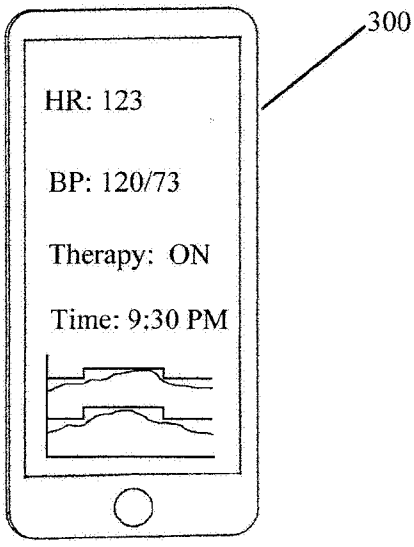
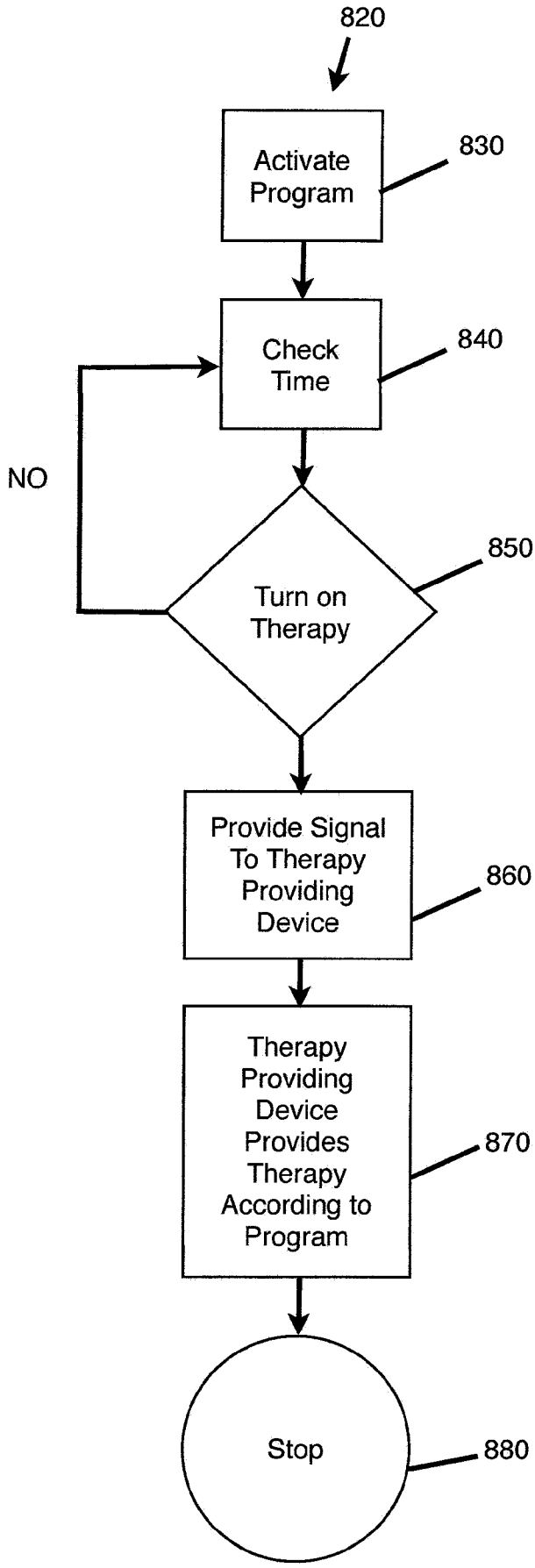


Figure 21B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Activate Program
830
Check Time
840
NO
Turn on Therapy
850
Provide Signal To Therapy Providing Device
860
Therapy Providing Device Provides Therapy According to Program
870
Stop
880

Figure 22

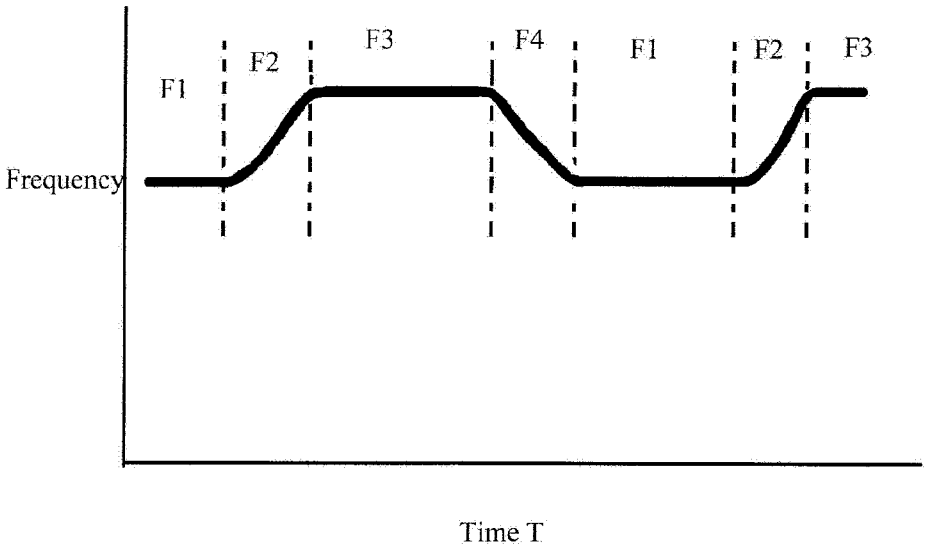

Figure 23A

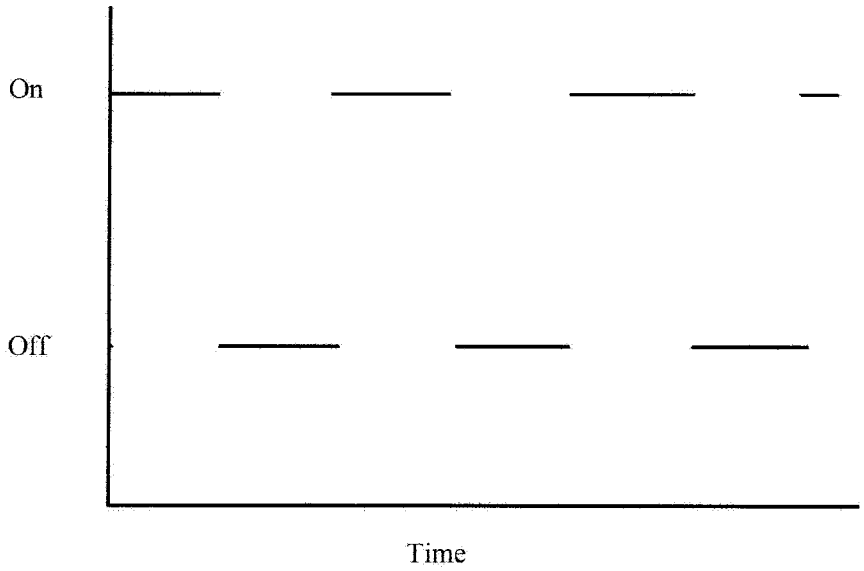

Figure 23B

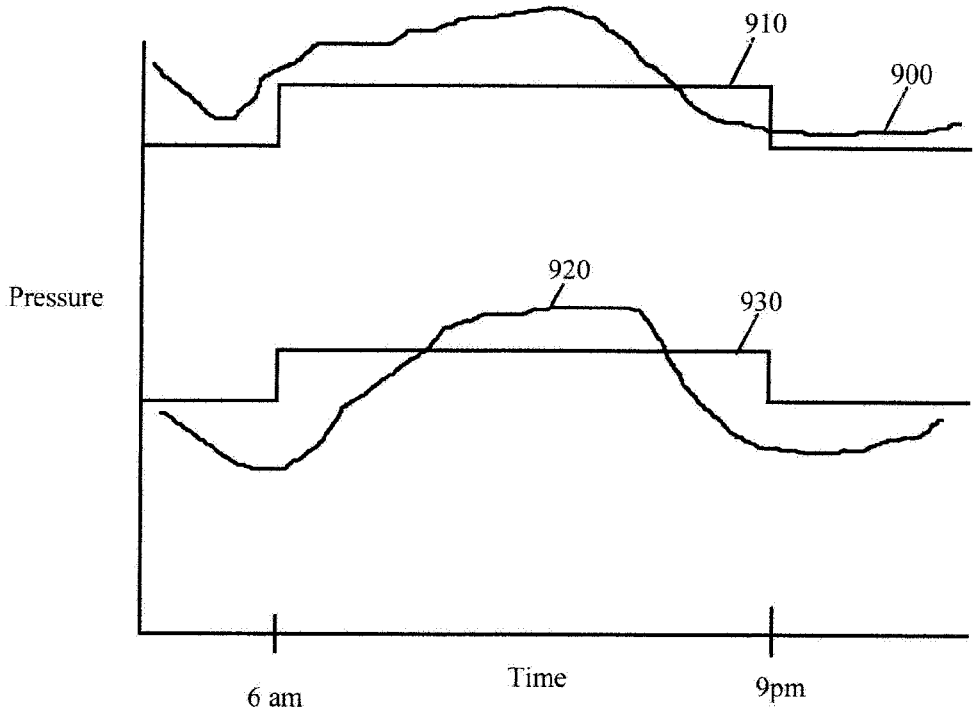

Figure 24A

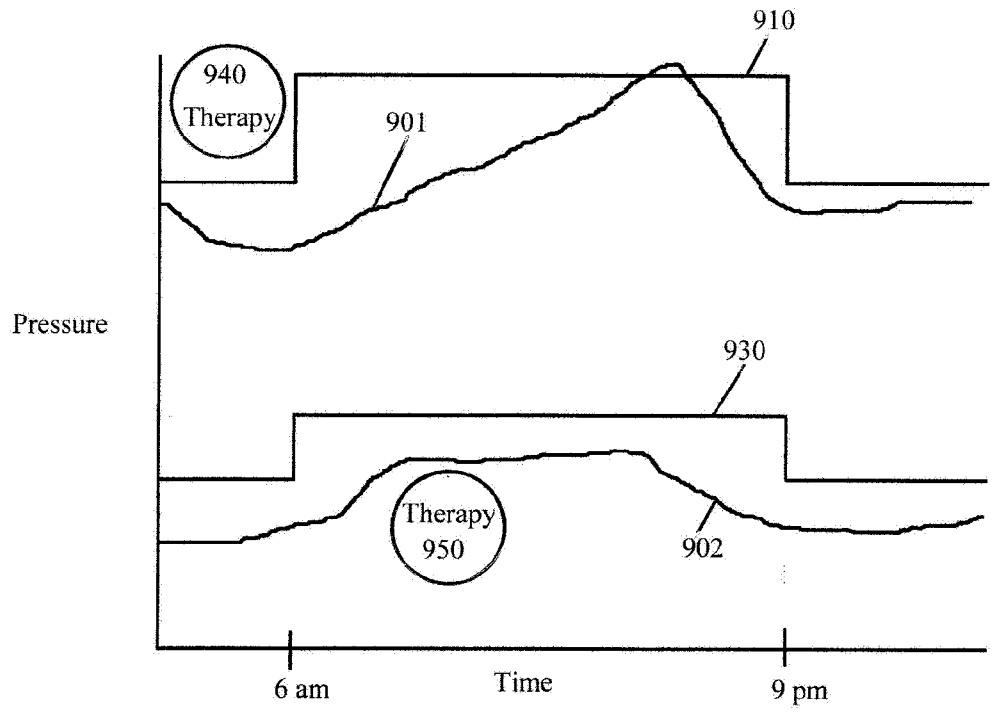

Figure 24B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/061118

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 7/00 (2012.01)
USPC - 607/96
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 5/00, 6/02, 5/0205, 5/0225, 5/025, 5/0245, 5/0255; A61F 7/00, 7/02, 7/08, 7/12; A61N 1/00, 5/06 (2012.01)
USPC - 600/9, 10, 15, 300, 301, 306, 310, 311, 390, 391, 411, 477, 480, 483, 493, 503, 504, 506; 607/96, 99, 108, 112, 114

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ------ Y	US 2008/0288035 A1 (GILL et al) 20 November 2008 (20.11.2008) entire document	13-21 --------- 1-12
Y	US 2010/0217295 A1 (FORSELL) 26 August 2010 (26.08.2010) entire document	1-12
A	US 2011/0125204 A1 (LOUISE) 26 May 2011 (26.05.2011) entire document	1-21

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 December 2012	08 JAN 2013
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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

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(71)申请人 辛帕拉医疗有限公司
地址 美国加利福尼亚州
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(74)专利代理机构 北京集佳知识产权代理有限公司 11227
代理人 康建峰 杨华
(51)Int.Cl.
A61F 7/00(2006.01)

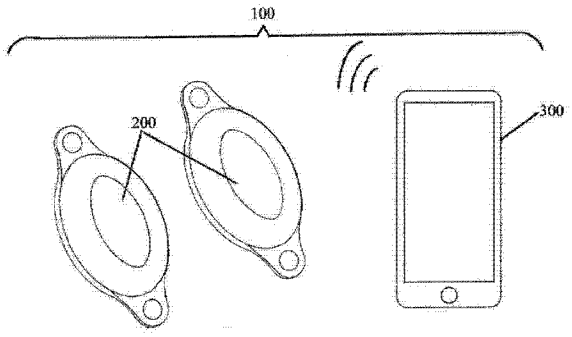
权利要求书1页 说明书28页 附图13页

(54)发明名称

用于治疗高血压的方法和设备

(57)摘要

描述了通过刺激压力感受器来控制血压和神经系统活动的设备、系统和方法。通过选择性地并且可控地激活压力感受器和/或神经，本发明降低了血压并且更改了交感神经系统；从而使对心脏、血管及其它器官和组织的有害影响最小化。压力感受器激活设备或其它感觉激活设备被定位于真皮骨附近以提供治疗。



CN 103997994 A

1. 一种用于治疗高血压的设备，包括：

壳体，所述壳体具有近表面和远表面，其中，所述壳体还包括安装系统，所述安装系统包括第一构件和第二构件，所述第一构件与所述壳体相关联，并且所述第二构件被配置成由组织接纳；以及

耦接到所述壳体的驱动器组件。

2. 根据权利要求 1 所述的设备，其中，所述第二构件包括第一表面和第二表面，并且所述第一表面和所述第二表面中的一个包括粘合剂。

3. 根据权利要求 2 所述的设备，其中，所述第二构件被配置成被放置在用户的锁骨上方。

4. 根据权利要求 1 所述的设备，还包括电子装置模块。

5. 根据权利要求 4 所述的设备，其中，所述电子装置模块还包括无线通信芯片。

6. 根据权利要求 4 所述的设备，还包括存储器芯片。

7. 根据权利要求 1 所述的设备，其中，所述驱动器组件是触觉换能器。

8. 根据权利要求 1 所述的设备，其中，所述驱动器组件是磁扬声器。

9. 根据权利要求 1 所述的设备，还包括被布置在所述壳体内的能量源。

10. 根据权利要求 9 所述的设备，其中，所述能量源是可移除的。

11. 根据权利要求 9 所述的设备，其中，所述能量源是可再充电的。

12. 根据权利要求 11 所述的设备，其中，所述能量源是通过非接触式充电器可再充电的。

13. 一种用于给予患者能量的设备，包括：

壳体，所述壳体具有第一表面和第二表面，在所述第一表面与所述第二表面之间限定有体积，其中，所述壳体还包括安装系统，所述安装系统包括第一构件和第二构件，所述第一构件与所述壳体相关联，并且所述第二构件被配置成由组织接纳；

驱动器组件，所述驱动器组件被布置在所述壳体的所述体积内；

能量源，所述能量源耦接到所述驱动器组件；以及

电子装置模块，所述电子装置模块耦接到所述驱动器组件和所述能量源。

14. 根据权利要求 13 所述的设备，其中，所述电子装置模块还包括无线通信模块。

15. 根据权利要求 14 所述的设备，还包括计算设备，所述计算设备被配置成运行程序。

16. 根据权利要求 15 所述的设备，其中，所述计算设备与所述电子装置模块无线通信，并且在所述计算设备上运行的所述程序控制所述电子装置模块激活或去激活所述驱动器组件。

17. 根据权利要求 13 所述的设备，其中，所述驱动器组件是扬声器。

18. 根据权利要求 13 所述的设备，其中，所述驱动器组件是触觉换能器。

19. 根据权利要求 13 所述的设备，其中，所述驱动器组件产生在 0.1Hz 至 20,000Hz 的范围内的频率。

20. 根据权利要求 19 所述的设备，其中，所述驱动器组件产生在 40Hz 至 100Hz 的范围内的频率。

21. 根据权利要求 20 所述的设备，其中，所述驱动器组件产生在 60Hz 至 100Hz 的范围内的频率。

用于治疗高血压的方法和设备

[0001] 对相关申请的交叉引用

[0002] 本申请要求于2011年10月19日提交的标题为“Hypertension and Heart Rate Reduction”的美国临时专利申请号61/549,007、于2012年5月16日提交的标题为“Methods and Devices for Treating Hypertension”的美国临时专利申请号61/648,060、于2012年8月9日提交的标题为“Methods and Devices for Treating Hypertension Using and Electroactive Transducer”的美国临时专利申请号61/681,469和于2012年8月9日提交的标题为“Support Assemblies For The Treatment of Hypertension”的美国临时专利申请号61/681,513的优先权，它们的全部公开内容通过引用合并到本申请中。

背景技术

[0003] 本发明总体上涉及用于治疗高血压的方法和设备。更具体地，使用被布置在体外的设备来治疗高血压的方法和设备。

[0004] 高血压(hypertension)或高血压(high blood pressure)每天影响数以百万计的人并且是严重的健康危害。高血压与心脏病、心脏衰竭、动脉瘤、肾衰竭和中风的风险升高有关。存在很多可能影响血压的因素，如：盐的摄入量、肥胖、职业、饮酒、吸烟、怀孕、兴奋剂摄入、睡眠呼吸暂停、遗传易感性、肾脏血流灌注减少、血管硬化和药物。很多时候人们不知道他们患有高血压，直到在通过他们的保健医生的医疗检查过程中发现高血压，或更糟的是，当他们由于高血压相关的情况如心脏病或中风住院时发现高血压。

[0005] 血压受到体内的复杂系统的控制，该系统的一个组成部分被称为动脉压力感受性反射(ABR)。压力感受性反射是对血压的变化反应最快的自主反射。在整个循环系统中，压力感受器神经末梢嵌入在血管中并且将平均压力和压力的变化率二者编码为频率。脑干中的中枢处理频率信息中的波峰，将其与其它信息结合并且经由迷走神经中的传出纤维向心脏的窦房结的起搏点提供信号。当血压变得过高时，所产生的迷走神经信号激活在心脏的窦房结的乙酰胆碱的释放，使心率变慢并且从而使血压下降。

[0006] 压力感受器位于左颈内动脉和右颈内动脉的横主动脉弓和颈动脉窦内。位于主动脉弓内的压力感受器监视输送到体循环的血液的压力，位于颈动脉窦内的压力感受器监视递送到大脑的血液的压力。

[0007] 如上所述，动脉压力感受器是当压力改变时由动脉壁的变形激发的牵张感受器。压力感受器能够识别平均血压的变化或随着每个动脉搏动的压力的变化率。在压力感受器末梢激活的动作电位然后被传导至脑干，在脑干处中央末端（突触）将该信息传送到孤束核内的神经元。来自这样的压力感受器活动的反射性反应能够激活心率的升高或下降。动脉压力感受器(ABR)是位于动脉的外膜中的简单的、散布的神经末梢。平均动脉压的升高使这些感觉末梢的去极化升高，这产生动作电位。这些动作电位通过轴突被传导至中枢神经系统的孤束核，并且通过自主神经元对心血管系统产生反射效应。

[0008] 在正常的静息血压处，压力感受器在每3次心跳中的约1次处放电。如果血压下降，则动脉直径收缩并且压力感受器放电率随血压的降低而下降，大脑向心脏发送信号以

通过增大心率来使血压升高。来自颈动脉压力感受器的信号经由舌咽神经（颅神经 IX）被发送。来自主动脉弓压力感受器的信号行进通过迷走神经（颅神经 X）。动脉压力感受器告知关于动脉血压的反射。

[0009] 动脉压力感受性反射系统是能够适应不断变化的情况的动态系统。ABR 是为什么当我们从坐移动至站立姿势时不昏倒的原因。在本示例中，ABR 感测血压的变化并且通过发送适当的信号来适应变化以调节血压。ABR 系统还执行基本功能以在锻炼过程中调节血压，其中在运动过程中你的心率和血压升高，然而，在运动过程中的某个点 ABR 会干预，使得心率进一步上升而使得血压不进一步上升。

[0010] 如上所述，高血压目前影响庞大且不断增长的人口。目前高血压的治疗包括从规定的生活习惯的改变到药物产品的使用。在过去的几年中，新的手术治疗方法不断出现。这些外科治疗或者导致用于刺激患者的颈动脉压力感受器的设备的植入或者导致肾动脉神经的切断。

[0011] 如果规定的生活习惯的改变没有解决患者的高血压，则他们的 HCP 通常会指定药物疗法来治疗他们的高血压。存在能够用于治疗高血压的多个类别的药物产品。这些包括降低血压并且减轻心脏的工作量的血管扩张剂、减轻液体过剩的利尿剂、身体的神经内分泌反应的抑制剂和阻断剂以及其它药物。很多时候，HCP 会开这些产品中的一种或更多种给患者以组合服用以便降低他们的血压。然而，药物产品的服用不能避免其风险。这些产品中的许多产品携带潜在副作用的严重警告。另外，每个患者对产品的反应可能不同，因此，在选择药物产品的正确剂量和种类之前可能需要到多个诊室就诊，这导致较大的医疗成本。另外还存在或者对药物无反应、或者拒绝服用药物、或者经过一段时间药物不再提供疗效的大量的患者。最近，新的临床试验资料已经在使用利尿药物产品来治疗高血压与患者中糖尿病的形成之间得出相关性。

[0012] 对于对药物治疗没有反应的患者，存在能够用于治疗高血压的医疗设备和治疗方法。这些设备中的一些包括侵入性外科手术，包括在患者动脉内植入永久的医疗设备以在动脉内的具体位置处给予然后可使血压降低的力。然而，这些设备相对比较新或仍处于开发阶段，并且没有经过长时间的验证。而且，因为设备是永久植入，所以在植入过程中总是存在并发症或者与植入相关的感染的可能性。

[0013] 如上所述，另一类型的侵入性医疗设备是电信号生成植入物，其中电极相邻于颈动脉而放置。在这个过程中，外科医生必须小心在植入设备时不阻断神经中的任何一个。如果神经被阻断，则设备将不能正常工作，并且可能导致患者的长期的健康并发症。然而，更令人不安的是患者现在永久地失去了用于自然地控制血压的压力感受器，这在将来可能导致目前仍未知的并发症。另外，植入设备需要定期的电池更换，这样做需要另一侵入性外科手术。

[0014] 另一类型的正在开发的侵入性医疗设备和手术是使用消融导管来使颈动脉体具体地为颈动脉体的化学感受器去神经支配。类似于上述设备和手术，该设备永久性地造成化学感受器和神经系统 / 大脑之间的断开。长期的影响是未知的，另外，在手术过程中其它神经可能被破坏或被切断，这可能导致其它副作用。

[0015] 另一类型的正在开发的用于治疗高血压的侵入性医疗手术是使用被放置在肾动脉内的消融导管，其中执行一系列能量脉冲以烧蚀（阻断）围绕动脉的神经，从而有效地将

肾脏的神经与身体断开。该手术导致患者的神经系统的永久性的不可逆的改变，该手术被称为肾神经消融或肾脏去神经支配。因为该手术在市场上相对比较新，所以此时这样的永久性治疗的长期影响是未知的。最近公布的数据表明，并非所有的患者对该手术过程有反应，即在手术后，患者中的一些患者显示他们的血压无变化。这可能是令人忧虑的，因为现在这些患者的肾动脉已经永久性地与他们的肾脏断开，这可能导致目前未知的长期影响。另外，与侵入性医疗手术相关的成本很高，仅仅为了证明该手术没有效果，因而，显著地增加了治疗他们的高血压的成本，而不是潜在地降低了对于这些患者的治疗的成本。

[0016] 另外，近期公布的数据也显示，对肾脏去神经支配有反应的患者仍然继续患有高血压。因而，肾脏去神经支配手术可能不是“治疗”，相反，其可以被视为辅助治疗，因为这些患者在已经接受肾脏去神经支配后可能继续保持药物治疗或者被建议继续保持药物治疗。

[0017] 又一治疗高血压的侵入性手术方法是设备和药物产品的组合，其中，在其远端附近布置有针的导管被放置在肾动脉内。一旦就位，液体药物产品被注射入动脉壁，由此，药物产品用于化学地烧蚀肾神经。在此，这种治疗方法再次被认为是永久解决方案，由此，神经被永久性地阻断。肾神经阻断的长期影响是未知的。另外，过程的长期影响也是未知的。

[0018] 人类皮肤用作我们的内部身体系统与外界之间的保护屏障。我们的皮肤与我们的身体神经组合提供感知触觉的能力并且给予我们的大脑关于我们周围的环境的大量信息，如温度、疼痛和压力。如果没有这样的神经系统，则当我们行走时我们不能感知我们的脚触及地面，当锋利的物品切到我们时我们不能感觉，并且我们不能感觉阳光在我们皮肤上的温暖。

[0019] 人类皮肤包括若干层。最上层是表皮，是能看到的一层皮肤。在拉丁文中，前缀“epi-”表示“在上方”，因而表皮是在其上布置有真皮的层（真皮是皮肤的第二层）。表皮由死皮细胞组成，是防水的并且作为下面的皮肤层和身体的其余部分的防护包装。其含有保护免受阳光的有害射线的伤害并且向皮肤提供其颜色的黑色素。当你在阳光下时，黑色素聚集以增加其防护性能，者也使皮肤变黑。表皮还包含向大脑提供关于身体所在的环境的多种信息的被称为触觉感受器的非常敏感的细胞。

[0020] 第二层皮肤是真皮。真皮包括毛囊、汗腺、皮脂腺（油）腺体、血管、神经末稍、以及各种触觉感受器。真皮的主要功能是通过向真皮传播营养物质并且替换从表皮的上层脱落的皮肤细胞来维持和支撑表皮。新的细胞在真皮和表皮之间的交界处形成，并且它们缓慢地移动至皮肤的表面使得它们能够替换脱落的死皮细胞。油脂和汗腺通过在表皮的表面打开它们的毛孔并且排出废物来消除在皮肤的真皮水平产生的废物。

[0021] 底层皮肤是包括脂肪和结缔组织的皮下组织。脂肪层作为绝缘体，并且帮助调节体温。其还作为缓冲以在撞向物体时保护下层组织免受损伤。结缔组织保持皮肤附着至下方的肌肉和肌腱。

[0022] 我们的触觉受到设置在皮肤内的被称为躯体感觉系统的神经末梢和触觉感受器的巨大网络的控制。该系统负责我们感到的所有感觉：冷、热、光滑、粗糙、压力、痒、痛、震动等。在躯体感觉系统内，存在四种主要类型的感受器：机械感受器、热感受器、伤害感受器和本体感受器。

[0023] 重要的是理解专用的感受器如何适应刺激的改变（接触皮肤并且造成感觉如热、冷、压力、痒等的任何事物）。如果触觉感受器非常快速地响应于刺激的改变则认为其是快

速适应的。这表示当皮肤接触物体时并且当皮肤停止接触该物体时其能够立刻感测。然而，快速适应感受器不能感测接触皮肤的刺激的连续和持续时间（皮肤接触物体多长时间）。这些感受器最善于感测发生在皮肤上或皮肤内的振动。如果触觉感受器不非常快速地响应于刺激的变化则其被认为是慢适应的。这些感受器非常善于感测接触或压入皮肤的物体的连续压力，但是不善于在刺激开始或结束时感测。

[0024] 机械感受器是感知感觉如压力、振动和质地的感受器。存在四种已知类型的机械感受器，其唯一的功能是感知皮肤的压痕和振动：美克耳体、梅氏小体、鲁菲尼氏小体和帕西尼小体。

[0025] 最敏感的机械感受器即美克耳体和梅氏小体存在于真皮层和表皮层的最上层，并且通常存在于非多毛的皮肤如手掌、嘴唇、舌头、脚底、手指、眼睑和面部。美克耳体是慢适应感受器，而梅氏小体是快速适应感受器，所以皮肤能够感知当接触某物时以及物体接触皮肤多长时间二者。

[0026] 位于真皮的较深处并且沿着关节、肌腱和肌肉的鲁菲尼氏小体和帕西尼小体。这些机械感受器能够感受感觉如向下行进至骨骼和肌腱的振动、肢体的旋转运动和皮肤的拉伸。

[0027] 另一类型的感受器是热感受器，如其名称所表示的，这些感受器感知与皮肤感受的物体的温度相关的感觉。他们存在于皮肤的真皮层。存在两种基本类别的热感受器：热感受器和冷感受器。

[0028] 当皮肤的表面下降到低于95℉时，冷感受器开始感知冷觉。当皮肤表面处于77℉时冷感受器最受激，而当皮肤的表面下降到低于41℉时不再受激。这是为何当你的脚或手长时间地浸入冰水时开始麻木的原因。

[0029] 热感受器在皮肤的表面上升高于86℉时开始感知热觉并且在113℉时最受激。但是在高于113℉时，痛觉感受器接管以避免对皮肤和皮下组织造成伤害。

[0030] 热感受器遍及全身，但是冷感受器的密度大于热感受器。热感受器的最高密度存在于面部和耳部。

[0031] 另一类型的感受器是痛觉感受器，通常被称为伤害感受器。“Noci-”在拉丁文中意思是“伤害”。这些感受器检测能够或确实对皮肤或身体的其它组织造成伤害的疼痛或刺激。全身存在超过三百万痛觉感受器，存在于皮肤、肌肉、骨骼、血管和一些器官中。他们能够检测由机械刺激（切割或刮削）、热刺激（灼烧）、或化学刺激（来自昆虫叮咬的毒素）造成的疼痛。

[0032] 这些感受器产生剧痛感以激励你快速地远离有害的刺激如一块碎玻璃或热炉档块。也存在已经受伤的区域产生钝痛以激励你不使用或触摸该肢体或身体部分直到该受伤区域已经治愈的感受器。虽然激活这些产生疼痛的感受器不具有乐趣，但是这些感受器在通过向大脑发送这些早期警告信号来使身体安全，免于受到严重的伤害或损害方面起到重要的作用。

[0033] 另一感受器类型是本体感受器。单词“固有的”表示“自己的”，并且在这些感受器的名称中使用因为他们感测身体的不同部分相对于彼此和周围环境的位置。本体感受器存在于肌腱、肌肉和关节囊中。体内的该位置使得这些特殊细胞能够检测肌肉长度和肌张力的变化。如果没有本体感受器，则我们不能做基本的事情如喂自己进食或给自己穿衣。

[0034] 虽然许多感受器具有具体的功能以帮助我们感知不同的触觉，但是几乎从来不是在任何一次仅激活一种类型。当从新打开的汽水罐喝汽水时，仅通过手持汽水罐你的手就能够感知许多不同的感觉。热感受器感测罐比周围空气更凉，而手指中的机械感受器感受罐的平滑和由于二氧化碳气泡上升到汽水的表面产生的细微振动感。位于手中较深处的机械感受器能够感测你的手正在围绕罐张开，施加该压力以握住罐，并且你的手正抓住罐。本体感受器也在感测手的张开以及手和手指是如何相对于彼此以及相对于身体的其余部分来握住罐的。

[0035] 如果感觉不能到达大脑，则上述并且由躯体感觉系统感受的感觉不能起到任何作用。身体的神经系统承担了这项重要的任务。神经元是专门的神经细胞，是神经系统的最小单元，神经元与其它神经元接收和发送消息使得能够将消息发送到大脑并且能够从大脑发送消息。这使得大脑能够与身体通信。当你的手触摸物体，皮肤中的机械感受器被激活，并且他们通过以信号告知最近的神经元他们触摸到某物来开始一系列事件。该神经元然后将该消息发送到下一个神经元，消息被传递给下一个神经元并且继续传递直到被发送到大脑。现在大脑能够处理你的手触摸的物体并且经由该同一路径将消息发送回你的手以使手知道大脑是否需要关于手正在触摸的物体的更多信息或者是否手应当停止触摸该物体。

[0036] 已经进行了振动实验以测试致动的影响，这样的实验的结果由 M.Sato 于 1961 年在期刊 Physiol.(1961),159pp391-409 中公布，标题为“Response of Pacinian Corpuscles to Sinousoidal Vibration”。在该实验中证明了振动能够激发神经系统，类似于电刺激的使用。

[0037] 其它实验已经示出，可以或者通过机械传导或者声刺激来激发郎飞氏间隙的第一节点。郎飞氏间隙的第一节点是在不同的细胞之间的髓鞘之间形成的间隙。

[0038] 由 M.C.Brown、I.Engberger 和 P.B.C.Matthews 在 1967 年 Journal Physiol.(1967),192PP773-800 中的标题为“The Relative Sensitivity to Vibration of Muscle Receptors of the Cat”的出版物中，作者测试了振动并且得出只要振动继续则振动的影响就继续存在的结论。另外，作者引用了另一出版物，Matthews 在 1966 年的“Reflex excitation of the soleus muscle of the decerebrate cat caused by vibration applied to tendon”，其中向非收缩肌肉施加振动，提供了从原始末梢选择性地激活几乎所有神经纤维以重复放电的方式。与刺激相比，振动更具选择性的激活。

[0039] 电刺激将刺激很靠近电源的那些神经，然而，电刺激会寻找最低阻抗路径并且通常局限于施加的区域。相反，振动刺激具有在远离应用振动的距离处激发传入纤维的优点。

[0040] 在 2000 年 Alfrey 在 Rice University,Houston Texas,April2000,UMI Microform99-69-223. 中的标题为“Characterizing the Afferent Limb of the Baroreflex”的出版物中。作者得出压力感受性反射是响应与血压的变化的最快的自动反射。遍及整个循环系统的嵌入血管的压力感受器神经末梢将平均压力和压力的变化率编码为频率调制的动作电位（尖峰）序列。脑干中的中枢处理尖峰序列信息，将其与来自较高级中枢的信息整合并且经由迷走神经中的传出纤维向心脏的窦房结 (SA) 起搏点提供信号。当血压变得过高时，所产生的迷走神经信号激活在心脏的 SA 节点处乙酰胆碱的释放，使心率变缓并且从而使血压下降。

[0041] 在另一论文中，由 Syntichaki 等人在 2004 年在 Physol

Rev.84:1097-1153,200410.1152/physrev.0043.2003 发布，标题为“Genetic Models of Mechanotransduction:The Nematode Caenorhabditis elegans”，发现所有脊椎动物都对类似机械感觉刺激做出反应，因此，两个人可能对同一波长或频率具有相似的反应。

[0042] 最后，虽然市场上可获得多个不同的治疗，并且新的治疗不断出现，仍然存在不能够通过现有的药物或设备的使用来治疗的患者人群。

[0043] 一个这样的人群是在怀孕过程中出现高血压的患者。通常医疗保健从业者在这些情况下不愿开出药物产品因为对于母亲和未出生的孩子可能存在未知的副作用。另外，许多高血压药物产品没有对于怀孕期间的使用进行适当的测试；因此，由于潜在的未测试副作用以及由于副作用引起的潜在诉讼，开处方的医生使用这样的药品方面可能存在很多犹豫。妊娠诱发高血压、妊娠高血压或先兆子痫可能不是永久性的情况，并且在分娩后可以解决。因此，永久性治疗如肾脏去神经支配的使用在这种情况下可能是不必要的。另外，在怀孕期间通常不建议使用外科手术。

[0044] 当今世界出现的又一高血压人群是高血压青少年。在过去的30年中，青少年高血压的数量已经上升至超过确诊高血压的3.7％和确诊的前期高血压的3.4％的比率。4个青少年中就有1个目前被诊断。目前可用的药物产品中的许多还没有对青少年人群进行测试，因此，如上所述，由于它们可能具有的未知的副作用或长期影响，许多医生不愿开出药物疗法。另外，青少年人群产生又一困难在于他们仍在发育并且正在经历青春期和骨骼生长。因此，需要非创性、非药物方案来解决该日益增长的患者人群。

[0045] 因此，理想的是提供改进的方法、设备和系统，用于患者的压力感受器或神经系统的人工的和选择性的激励以实现多种治疗目的，包括高血压、肾功能、心脏衰竭的控制和其它心血管疾病的治疗。特别理想的是如果这样的方法和系统对患者来说是非创性的、可逆的、安全的和／或外用的。

发明内容

[0046] 根据本发明，提供了一种用于治疗高血压的设备，包括：具有近端和远端的壳体；以及位于壳体内的驱动器组件，驱动器组件电耦接到能量源，能量源被布置在壳体内。

[0047] 根据本发明，提供了一种用于给予患者能量的设备，包括：壳体，壳体具有近端、远端并且在近端与远端之间限定有体积；驱动器组件，驱动器组件被布置在壳体的体积内；能量源，能量源耦接到驱动器组件；以及电子装置模块，电子装置模块耦接到驱动器组件和能量源，其中电子装置模块控制驱动器组件。

[0048] 根据本发明，提供了一种用于治疗高血压的设备，设备包括：壳体，具有近表面和远表面，其中，壳体还包括安装系统，安装系统包括第一构件和第二构件，第一构件与壳体相关联，而第二构件被配置成由组织接纳；以及壳体内的驱动器组件。

[0049] 根据本发明，提供了一种用于给予患者能量的设备，该设备包括：壳体，壳体具有第一表面和第二表面，在第一表面与第二表面之间限定有体积，其中，壳体还包括安装系统，包括第一构件和第二构件，第一构件与壳体相关联，而第二构件被配置成由组织接纳；驱动器组件，驱动器组件被布置在壳体的体积内；能量源，能量源耦接到驱动器组件；以及电子装置模块，电子装置模块耦接到驱动器组件和能量源。

[0050] 根据本发明，提供了一种提供治疗的方法，包括：向患者的锁骨应用治疗应用设

备；以及在治疗应用设备内激活驱动器组件。

附图说明

[0051] 图 1 是根据本发明的治疗系统的示例实施方式；

[0052] 图 2 是根据本发明的治疗提供设备的等距视图；

[0053] 图 3A 至图 3D 是根据本发明的治疗提供设备的壳体的示例图示；

[0054] 图 4A 是根据本发明的治疗提供设备的壳体的顶视图；

[0055] 图 4B 是图 4A 的壳体关于线 B-B 截取的横截面图；

[0056] 图 4C 是根据本发明的另一壳体的横截面图；

[0057] 图 5 是根据本发明的治疗提供设备的分解图；

[0058] 图 6 是根据本发明的电路板的等距视图；

[0059] 图 7 是根据本发明的触觉扬声器的平面图；

[0060] 图 8 是根据本发明的电活性聚合物换能器的等距视图；

[0061] 图 9 示出了与驱动器通信的图 8 的电活性聚合物换能器的横截面图；

[0062] 图 10 是根据本发明的电活性聚合物换能器的可替选实施方式的平面图；

[0063] 图 11 是根据本发明的充电站 / 基站的等距视图；

[0064] 图 12 是本发明的治疗提供设备与 CPAP 面罩组件的组合的侧视图；

[0065] 图 13A 是示出了包括粘合性安装系统的治疗设备的底视图；

[0066] 图 13B 示出了被布置在用户上的图 13A 的治疗设备；

[0067] 图 14A 和图 14B 示出了用于本发明的治疗设备的可替选安装布置；

[0068] 图 14C 是图 14A 和图 14B 的安装系统的横截面图；

[0069] 图 15A 和图 15B 示出了用于本发明的治疗设备的另一安装布置；

[0070] 图 16A 和图 16B 示出了根据本发明的磁安装系统；

[0071] 图 17 和图 18 示出了用于与本发明一起使用的支撑结构的实施方式；

[0072] 图 19A 至图 19C 示出了根据本发明的另一壳体，该壳体被配置成关于用户的肩部被接纳；

[0073] 图 20A 和图 20B 示出了用于本发明的治疗设备的可替选衣物型安装布置；

[0074] 图 21A 示出了根据本发明的计算设备的示例实施方式；

[0075] 图 21B 示出了根据本发明的在图 21A 的示例计算设备上显示的程序的示例屏幕视图；

[0076] 图 22 示出了根据本发明的软件程序的流程图；

[0077] 图 23A 示出了由本发明的示例实施方式提供的治疗的治疗频率曲线；

[0078] 图 23B 示出了根据本发明的实施方式的定时治疗序列；

[0079] 图 24A 示出了在 24 小时内患者的血压读数，示出了高血压患者；以及

[0080] 图 24B 示出了图 24A 的患者在接受根据本发明的设备和方法的治疗之后的血压。

具体实施方式

[0081] 以下详细描述通过实例而不是限制的方式示出了本发明的实施方式。描述清楚地使本领域的技术人员能够制造和使用本公开内容，描述了若干实施方式、修改、变化、可替

选方案以及公开内容的使用，包括目前被认为是执行公开内容的最佳模式。

[0082] 本书面描述使用实例来公开本发明，包括最佳模式，并且还使本领域的技术人员能够实施本发明，包括制作和使用任何设备或系统，以及执行任何所包括的方法。本发明的专利范围由权利要求限定，并且可包括对本领域技术人员发生的其它示例。如果其它示例具有不与权利要求的字面语言不同的结构元素，或者如果其它示例包括与权利要求的字面语言无实质差异的等效结构元素，则这些其它示例旨在在权利要求的范围内。

[0083] 根据本发明，提供了用于高血压的治疗的设备和方法。本发明的设备被配置成可分离地附接到用户，其中设备与用户的身体的骨骼对准。一旦附接到患者，就能够人工地或远程地、无线地或有线地通过在计算设备上运行的软件程序或设备内的软件程序的使用来激活设备。可以对激活进行定时以与患者的睡眠模式一直，使得在夜间通过设备将治疗提供给患者，并且在早晨患者醒来之前再次将治疗提供给患者。据认为，在睡眠周期期间提供治疗是有益的。

[0084] 根据本发明的实施方式，设备可分离地附接到患者的组织并且旨在接合患者的骨架的一部分，特别是锁骨(clavicle)。需要理解，尽管关于锁骨描述了本发明，应当理解，这不应限于任何方式。如上所述，在优选实施方式中本发明的方法和设备使用锁骨。然而，本发明的方法和设备也可用于其它真皮骨如颅骨，下颚骨，膝盖骨（髌骨）或非真皮骨如手腕骨，肋骨，肩胛骨。本发明的方法和设备还能够用在包括体觉感受器如本体感受器、伤害感受器、机械感受器或热感受器的身体的任何部分上方。经皮骨的独特之处在于经皮骨不首先从软骨形成然后再钙化。真皮骨在真皮内形成并且其仅通过沉积来生长，即，骨的外层部分是由骨细胞沉积形成的。已经使用真皮骨来向其它设备传送声音，如在助听器中。

[0085] 现在参见图 1，示出了根据本发明的治疗系统 100。如图 1 所示，根据本发明的治疗系统 100 可以包括一对治疗提供设备 200 并且可选地包括计算设备 300。治疗提供系统 100 还可以包括如将在下文参照图 11 详细描述的充电 / 存储系统。另外，治疗提供设备 200 还可以包括集成或独立的附接系统以可分离地将系统 100 附接到用户的皮肤，如将在下文更详细地描述的。

[0086] 如图 1 所示，在一方面计算设备 300 被配置成通过无线通信协议如通过 WiFi、蓝牙、ZigBee、RFID、NFC、ANT+、蜂窝、红外线或其它已知的无线通信协议的使用来与治疗提供设备 200 通信。可替选地，计算设备 300 和治疗提供设备 200 可以使用物理连接如电线、多个电线、电缆、光纤或使用能够在设备之间传送信号的其它已知物理连接来在通信上耦接在一起。如图 1 所示，可以预期，根据本发明的使用方法会使用如所示两个治疗提供设备 200。如果使用两个治疗提供设备 200，则意在将它们布置在用户上、左锁骨和右锁骨附近。根据本发明可以使用单个治疗提供设备 200 来用于根据本发明的治疗，或可以使用多个治疗提供设备 200 用于治疗。两个治疗提供设备 200 可以使用物理连接或无线连接如上述无线连接来被通信上耦接到彼此。

[0087] 现在参见图 2，示出了治疗提供设备 200 的等距视图。如图 2 所示，治疗提供设备 200 包括壳体 210。壳体 210 由近端 212 和远端 211 以及第一表面 214 和第二表面 215（未示出）限定，在近端、远端、第一表面和第二表面之间限定有体积，其中该体积包括如将在下文描述的另外的结构和部件。如图 2 所示，第一表面 214 包括电力按钮 260、LED 指示灯 262 和至少一对充电引脚 265。多个充电引脚 265 可以包括在治疗提供设备 200 上，而多个

引脚 265 关于穿过电力按钮 260 的轴（未示出）对称地被布置。充电引脚 265 关于延伸通过电力按钮 260 的轴的放置使得治疗提供设备 200 能够被放置在充电器内而不需要考虑方向，因为治疗提供设备 200 的每个面都包括充电引脚 265，使得治疗提供设备 200 可以在任何一个方向接合充电站中的充电引脚。在下文将参照图 11 更详细地描述关于充电站 / 充电基座的另外的细节。另外，壳体 201 还可以包括磁体 230 或被布置在形成于壳体 210 的第一端 211 和第二端 212 中的凹部内的金属材料。可替选地，可以在制造过程如注射成型期间与壳体 210 一体地形成磁体 230。

[0088] 可以由然后使用已知的组装方法如胶合、超声焊接、热焊接、旋转焊接、扣合构造、紧固件例如螺钉或销钉的使用等组装的多个片来形成壳体 210。根据本发明，壳体 210 可以由两片或多个片形成，其中壳体 210 的一个部分包括除了第二表面 215 以外的所有侧面，从而形成壳，部件能够被布置入该壳，然后第二表面 215 可附接到壳体 210 的另一部分以形成治疗提供设备 200。壳体 210 可以由生物相容性材料如聚合物、塑料、纤维或金属构成。可以使用制造过程如机械加工、注射成型、3-D 打印、真空成型、深拉等来形成壳体 210。根据本发明，在治疗提供设备 200 的壳体 210 的构造中使用的材料应当被选择为使得所述材料具有良好的生物相容性，因为意图是治疗提供设备 200 会在使用过程中以皮肤接触的方式放置，其中在某些用途中皮肤接触可能持续延长的时间。

[0089] 更近一步地，可以预期，可以使用生物相容性膜来包裹治疗提供设备 200。合适的膜的示例可从 3M 购买并且以 Tegaderm 为商品名出售。

[0090] 现在参照图 3A 至图 3D，示出了根据本发明的第二表面 215 的示例实施方式。如图 3A 所示，第二表面 215 可以形成为平坦表面。现在参照图 3，在该图中，第二表面 215 由多个片形成，其中一个部件 216 被配置成由壳体的另一部分接纳，并且第二部件 217 被配置成由用户的组织接纳，该部分 217 可以由比第一部件 215 更柔软或更顺从的材料形成，其中更柔软的材料 217 可以更容易地符合或成形为用户的解剖结构。根据本发明，第二部件 217 可以由顺应材料如开孔或闭孔的泡沫材料形成，使得当治疗提供设备 200 被布置在用户上用于治疗时，顺应泡沫表面与用户的解剖结构符合。另外，所选择的材料可以被选择为使得它们抗微生物 / 抗菌。

[0091] 现在参照图 3C 和图 3D，使出了另一示例实施方式，其中示出第二表面 218 具有第一厚度，其中形成第一表面 218 的材料被选择为使得材料可以被成形为或被构造轮廓为由患者的皮肤、具体地为相邻于患者的锁骨的区域中的皮肤接纳。成形的表面可以呈凹形状的形式。更进一步地，图 3C 和图 3D 的材料 218 可以被选择为使得材料限定可变形结构，使得当壳体被放置在患者的锁骨上方时壳体符合患者的解剖结构，如图 3D 所示。在又一实施方式中，壳体的一部分可以通过热量的施加来对每个个体用户定制地形成，由此，壳体或壳体的一部分被加热并然后被压在患者上，壳体的被加热的部分符合患者的解剖结构，或者被加热并通过力的施加来成型。在另一方面，第二部件 217 可以以柔性薄膜的形式实施，可以在其中注入可膨胀的泡沫材料。在使用时，可以将治疗提供设备放置在用户上选定的位置，然后当保持治疗提供设备紧靠用户时，可以将可膨胀泡沫材料注射入柔性薄膜。当泡沫膨胀并固化时，第二部件 217 将呈用户的解剖结构的形状，从而提供客户化的配合。最后，还可以设想，壳体包括可被研磨或机加工以符合患者的解剖结构的放大的或加厚的表面。更近一步地，模具可以采取患者的解剖结构，由此然后可根据从用户的解剖结构获取的模

具来制造壳体，从而定制治疗提供设备对每个用户的匹配。

[0092] 现在参照图 4A 至图 4C，示出了根据本发明的另外的壳体设计。如图 4A 所示，可替选壳体形成为大致圆形的形式，其中壳体包含如将在下文更详细地描述的另外的部件。同样如图 4A 所示，壳体 270 还可以包括如上所述从壳体 270 延伸的线或线缆连接。现在参照图 4B，示出了关于图 4A 的线 B-B 截取的图 4A 的治疗提供设备 200'' 的壳体 270 的横截面图。如该横截面图所示，可替选壳体 270 形成为具有大致凸起的形状。现在参照图 4C，示出了壳体 272 的又一可替选实施方式的横截面图，在该实施方式中，壳体 272 具有如前所述的大致凸起的形状，在该实施方式中壳体 272 包括凹陷部分 271。在使用中，壳体 272 相邻于用户的锁骨而被放置在用户上，其中能够相邻于每个凹陷部分 271 而向壳体 272 施加力，使空气从凹陷部分 271 排出，从而使得形成真空从而使壳体 272 吸住用户的组织。可以设想，图 4A 至图 4C 中示出的壳体 270 和 272 可以由生物相容性柔性材料构成，使得当壳体被放置在用户上时壳体符合用户的解剖结构。形成壳体 270、272 的合适的材料的示例有：有机硅、聚氨酯、橡胶、硅树脂、乳胶等。

[0093] 现在参照图 5，示出了根据本发明的治疗提供设备 200 的分解图。如上所述并且如图 2 至图 4 所示，治疗提供设备包括壳体 210，其中壳体包括如上所述的用于电力开关 260 的供应物以及用于 LED 指示器 262 和充电引脚 265 的供应物。电力开关 260 可以是被布置在壳体 210 内的单独部件，或者它可以被实施为可形成为略高于壳体 210 的第一表面 214 而突出的壳体 210 的减小了厚度的部分（未示出），由此，在使用中，用户能够向该凸出部分施加轻微的力以激活被布置在凸起部分下方的开关。形成与壳体 210 的第一表面一体的凸起部分以用作开关简化了构造，消除了额外的部件，该构造还消除了可能需要对液体密封的在壳体的第一表面内形成孔的需要。另外，用于 LED262 和充电引脚 265 的供应物可以采用在壳体内形成以接纳这样的物品的开口的形式。可替选地，LED262 供应物可以在制造过程中以壳体 210 内不透明或透明的部分的形式来实施以使得光能够从安装在被布置在壳体 210 下方的电路板 500 上的 LED503 通过其投射。另外，可以设想，也可以在壳体 210 的制造过程中一体地形成充电引脚 265。例如，如果使用注模工艺制造壳体 210，充电引脚 265 可作为插入件被布置在注射模内，由此，在成型过程中可以将充电引脚 265 固定在壳体 210 中。可替选地，壳体 210 能够包括用于使充电引脚 265 突出穿过的开口。再者，壳体 210 可以包括具有内锥壁部分的开口，在第一表面 214 内形成口袋，从而提供对被布置在设置在壳体 210 的第一表面 214 下方的电路板 500 上的充电垫 / 充电引脚的访问。壳体 210 还可以包括在其中形成的凹槽 229 或多个凹槽 229，使用户能够抓住壳体 210。

[0094] 如图 5 所示，治疗设备 200 还包括第一电路板 500 和第二电路板 550。第一电路板 500 相邻于壳体 210 的第一表面 214 而布置，其中第一电路板 500 包括电力开关部件 502、被配置成指示治疗提供设备 200 的电力状态的至少一个指示器 LED503。第一电路板 500 还包括充电引脚 / 充电垫 504，其中充电引脚 / 充电垫可以被配置成如上所述那样通过壳体 210 突出，或者可替选地，壳体 210 可以包括在其中形成的开口以访问充电引脚 / 垫 504。电力开关 502 可以被实现为物理开关如滑动开关，或可以被实现为触敏开关或电容敏感开关，或者可以被实现为压力敏感开关。第一电路板 500 还包括被配置成电连接第一电路板和第二电路板的连接器（未示出）。连接器可以被实现为能够将线布置入其中的焊接孔，或者可以以插头或管座组件的形式来被实现，其中插头 / 管座被配置成接受线缆、线、带状线

缆或柔性PCB以促进板之间的电通信。第一电路板和第二电路板可以由已知的材料和方法构造，其中板可以是硬质电路板组件或可以使用柔性电路板制造技术来构造。尽管上文描述了本发明使用两块电路板，这不应当被认为是以任何方式进行限制，可以设想可以将本发明的电子部件实施在单个电路板上或多个电路板上。

[0095] 如图5所示，被布置在第一电路板500下方的是能量源240。能量源240可以是电池组的形式。电池组可以是可以被实施为胶体电池或被吸收的玻璃垫电池的可再充电电池组或单次使用电池组。可以包括电池组的电池的适当示例是锂离子(Li离子)、铅酸、镍镉(NiCd)、镍锌(NiZn)，氧化锌、镍金属氢化物(NiMH)、锂铁氧化物(LiFo)或其它已知电池技术。还可以设想，代替将电池用于能量源，可以使用电容器和相关电路。

[0096] 在能量源240被实施为电池组的情况下，可以以编制组的形式来实施电池组，其中将单个电池焊接在一起，或者可替选地，电池组可以被布置为使用传统电池规格如AAA、AA、CR2032、LR44、9伏、A23等。

[0097] 还可以设想，可以将电池组进一步分为主电池组和备用电池组。在使用中，最初会使用主电池，如果电池组故障或失去其电荷或其电荷耗尽，则然后将启用备用电池组以继续治疗。

[0098] 如果上述电池组被选择为是可再充电的，则需要在电路板500或550内提供充电电路。充电电路可以使用物理连接以使得能够进行充电，或者可以使用非接触式或感应式充电布置。如果使用物理连接，则插头可以是USB式插头、耳机插孔式插头、弹簧加载式管脚/接触垫或其它类型的插头，可以将这样的插头集成到壳体210中并且通过任何一个电路板电连接到电池。可替选地，可以将插头直接安装在电路板之一上。还可以设想，充电插头还可以用于如上述使用兼容线缆的多个治疗提供设备200之间或计算模块300之间的充电与通信。

[0099] 如上所述，本发明可以使用被布置在第一电路板上或耦接到第一电路板的引脚或垫以使得能够对被布置在设备内的电池进行充电。还可以设想，非接触式充电组件可与本发明一起使用。如果选择非接触式充电布置，则可能不需要壳体210的第一表面内的充电引脚265和/或开口。相反，治疗提供设备200可以包括被布置在第一电路板500的周长周围的充电线圈(未示出)。非接触式充电线圈的使用还需要包括另外的集成电路以实现并且控制充电功能。这些另外的电路能够被布置在两块电路板中的任何一块上。非导电性或感应充电的合适的示例可以使用电磁场来在充电器和电池组之间传输能量。在该实施方式中，可以提供充电站，其中如将在下文中描述的可以同时地储存治疗提供设备200并且对治疗提供设备200进行充电。还可以设想，储存/充电容器可以使可以包含微处理器和/或无线通信芯片的智能容器。因此，一旦从储存容器移除治疗设备，则储存容器内的集成无线芯片可以使治疗设备上电。使得能够进行非接触式充电的部件的适当的示例可以从Wurth Electronics Inc.部件编码760308201的无线充电接收线圈和部件编码760308101的无线充电发送线圈得到。

[0100] 根据本发明，可以设想，能量源240可以以集成式发电机的形式来实施，其中发电机将被配置成从治疗提供设备240的移动来产生能量，类似于自动手表机芯。

[0101] 如上所述，图5所示的治疗提供设备200包括两个电路板500和550。之前在上文已描述了电路板500。现在参见图5和图6，使出了根据本发明的治疗提供设备200的电路

板 550 的示例实施方式。如上所述，第二电路板 550 被配置成与第一电路板 500 耦接，其中部件可以被布置在这两个电路板中的任何一个上并且通过如前面所述的使用在电路板 550 中形成的管座或焊接孔的合适连接来互连。现在参见图 6，示出了第二电路板 550 的总体示意图，其中第二电路板 500 包括处理器 551、可选的存储器芯片 552、音频放大电路 553 和通信端口 554。通信端口 554 可以被实施为物理端口如迷你 USB、微型 USB、火线、thunderbolt 或其它已知的类似通信端口。音频放大电路 553 可以包括一个或两个音频放大器，其中放大来自处理器 551 的传入信号使得然后能够将经放大的信号连接到驱动器组件 220，如下文所述。如图 5 和图 6 所示，第二电路板 550 可以被成形为被接纳于成形的壳体内。如图 5 和图 6 所示，示出第二电路板具有椭圆的形状，通过其中心形成有孔。孔的大小可被设置为接纳驱动器组件 220 的一部分。从而通过在组装时使得部件能够“套叠”来使得能够减小设备的总体尺寸。第二电路板 550 可以包含另外的电子部件如音频滤波器、升压电路、计时电路和数据记录能力。根据本发明，处理器 551 可以从剑桥，考利路，剑桥商业园，Churchill House，CSR 公司，剑桥，考利路，剑桥商业园，Churchill House CB4OWZ 获得，其部件编码为 8670。

[0102] 第二电路板 550 还可以包括通信芯片集（未示出）如：蓝牙、wifi、ZigGee、RFID、NFC、Ant+、红外线、3G/4G、CDMA、TDMA 或其它已知无线通信协议。

[0103] 第一电 500 或第二电路 550 还可以包括时钟电路（未示出）。时钟电路生成并且设置在治疗提供设备 200 内执行的操作的时序。时钟发生器可以用于激活治疗提供设备 200，或者可以用于记录定时时间，如当治疗提供设备接通或关断或在使用中时。

[0104] 更进一步地，电路板 500/550 中的任何一个可以可替选地包括阻抗传感器或一对阻抗传感器，与处理器 551 相关联的阻抗传感器能够用于确定壳体 210 是耦接到用户的皮肤还是壳体没有耦接到皮肤。如果壳体 210 耦接到用户的皮肤，则阻抗传感器会向处理器 551 提供信号表示这样的情况，从而启动存储在处理器的存储器中的程序或被发送到微处理器的程序以实施根据本发明的治疗。如果阻抗传感器没有耦接到用户的皮肤，则会发情开放情况，由此不会启动程序并且可以通过程序 / 处理器来生成视觉信号以警告用户没有正确地放置治疗提供设备 200 并且需要重新定位治疗提供设备 200。

[0105] 在又一实施方式中，电子装置模块可以包括麦克风，由此，测试信号能够被启动并由驱动器组件 220 或其它音频 / 振动设备递送。可以通过处理器 551 使用麦克风来听测试信号经用户的锁骨、皮肤或其它骨或结构的反射以确定治疗提供设备 200 是否已经被正确地放置。如果反射的声音与存储在存储器中的声音匹配，则能够运行程序以提供治疗。如果反射的声音与存储在存储器中的声音不匹配，则会生成错误消息。操作消息可以是音频信号的形式或者是视觉信号的形式如闪光或一系列闪光。

[0106] 另外，麦克风可以与血压监视器耦接，其中麦克风可以听柯氏音，由此从血压监视器生成的数据以及具体地由麦克风捕捉的柯氏音可用于实现闭环控制系统或闭环反馈系统。可以设想，可响应于从耦接到处理器 551 的麦克风接收的数据来动态地修改由治疗提供设备 200 提供的治疗。

[0107] 电路板 500 或电路板 550 还可以包括耦接到处理器 551 的压敏开关。在使用中，压敏开关可以正常地处于开启位置或关闭位置。当将治疗提供设备 200 放置在用户的皮肤上时，可以按下压敏开关，从而接通治疗提供设备 200。开关的起动还能够与时钟电路相关联

以将时间与卡关的接通 / 关断状态相关联。可以将这些事件写入处理器 551 的存储器或其它存储器存储位置。然后可以将数据有线地或无线地传送到个人计算机用于分析 / 存储。通过跟踪治疗提供设备的实际接通 / 关断时间，可以由用户或第三方如健康护理提供者来跟踪用户服从度。

[0108] 在又一实施方式中，电路板 500 或 550 可以包括光学传感器，其中光学传感器用于检测治疗提供设备是否贴合至用户的皮肤。在该实施方式中，光学传感器能够包括光传感器，由此当治疗提供设备 200 贴合至用户的皮肤时，光被被阻止到达传感器。在另一实施方式中，光学传感器可以是反射传感器，其中反射回的光的颜色指示设备是否贴合至用户的皮肤。

[0109] 在本发明的另一方面，光传感器可以用于检测血氧水平，其中根据检测用户的血氧水平而接收的数据能够存储在存储器中并且被传送到另一设备如脉搏血氧饱和度监视器或另一计算设备。更进一步地，可以由治疗提供设备的程序来使用血氧数据以更改被提供给用户的治疗或者控制治疗提供设备 200。

[0110] 在本发明的另一方面，光传感器可以用于测量血液反射率颜色的更改，由此控制治疗提供设备的程序可以使用该信号作为心率或心搏的表现。因此控制治疗提供设备 200 的程序可以使用该数来确定血压并且因此基于所接收的数据来向用户提供治疗。

[0111] 还可以设想，能够将加速度计和 / 或指南针和 / 或倾斜传感器和 / 或 GPS 传感器包括在上述电路板中的任何一块电路板中。对这样的传感器的包括能够用于确定设备的位置和 / 或方向。在使用中，如下文所述，用户使用如下文所述的粘合性补片、系带、专用衣物物品来将壳体 210 贴合至他们的身体。在该实施方式中，与处理器 551 通信的加速度计 / 指南针能够用于确定什么时候激活治疗提供设备或设备 200。如果从加速度计 / 指南针 / 倾斜 /GPS 传感器返回的信号表示治疗提供设备 200 处于竖直位置，则不会启动包括在处理器 551 或计算设备 800 的存储器内的程序。一旦来自加速度计 / 指南针 / 倾斜 /GPS 传感器的信号表示用户处于倾斜位置，例如睡眠位置，则可以运行包括在存储器内的程序。另外，可以将时钟计时器与加速度计 / 指南针 / 倾斜 /GPS 传感器相关联使得能够将用户的睡眠模式存储在处理器 551 或计算设备 800 的存储器中。可以将从这样的传感器生成的数据存储在或者治疗提供设备或者计算设备的存储器中以跟踪设备的使用和设备的物理位置。可以使用已知的无线通信方法将这样的数据传送给第三方。

[0112] 可以向电路板、壳体或治疗提供设备 200 提供唯一标识符如序列号或患者信息标识符以使得治疗提供设备可以被跟踪。另外，使用唯一标识符，医生或用户可以使用计算机程序，如当处于与治疗提供设备的有线或无线的通信时会使得能够进行设备的使用比如日期和时间监视、使用的持续时长、患者顺应性等的连续监视的网站。网站还可以提供关于高血压的信息并且另外被配置成与其它设备通信，比如与称通信以跟踪用户的体重，与血压监视器通信以跟踪血压测量，血糖仪，心率监视器或其它健康跟踪设备如 Fitbit 或 BodyBug。这些设备中的每个可以与网站接口，使得能够将从这些设备收集的数据上载至能够将数据呈现给用户或者可替选地，可以与用户选择分享数据的任何人分享数据的网站。例如，用户可以期望与他们的健康护理提供者、营养师或其它个人分享数据。

[0113] 根据本发明，可以设想，可以将一块或两块电路板和电池容纳在与治疗提供设备 200 分开的壳体中。在该实施方式中，电路板和电池可以或者通过线缆连接或通过无线连接

来耦接到治疗提供设备。如果使用无线连接，则治疗提供设备将包括被布置在其壳体内的必要的电子装置以便利于电子装置模块与治疗提供设备以及电源如电池之间的通信。

[0114] 参照图 5，被布置在第二电路板 550 下方的是驱动器组件 220。驱动器组件 220 被布置在壳体 210 的体积 213 内。驱动器组件 220 可以包括传统的音圈扬声器、超声发生器、压电扬声器、触觉扬声器、气动设备、抽吸设备、机械振动设备、液压致动设备或光声激励设备。能够与本发明一起使用的驱动器组件 220 的示例可以从位于英国剑桥 CB236DP，剑桥，Cambourne，1010Cambourne 工业园，Regus House 的 HiWave Technologies PLC 得到。现在参照图 7，示出了能够与本发明的治疗提供设备 200 一起使用的触觉扬声器或触觉激励器 220’的示例。如图 7 所示，触觉扬声器 220’包括框架构件 221、音圈 222 和多个柔性构件 223。另外，触觉扬声器 220’包括电连接点 224 从而使得触觉扬声器 220’能够电连接到如前所述的音频放大电路。在使用中，柔性构件 223 使得触觉扬声器的音圈 222 能够相对于框架 221 平移，从而产生声音或运动。

[0115] 在又一实施方式中，驱动器组件 220 可以被实施为如图 8 至图 10 所示的电活性聚合物换能器 315。电活性聚合物换能器 315 由第一薄弹性聚合物 320 组成，第一薄弹性聚合物 320 也被称为胶片或薄膜，其被夹在柔性电极 340 和柔性电极 345 之间。当跨越电极施加电压时，两个电极中的异性电荷相互吸引，这些静电引力压缩聚合物薄膜 320（沿 Z 轴）。每个电极中的相同电极之间的排斥力在平面内伸展薄膜（沿 X 轴和 Y 轴）。当换能器 315 偏转时，偏转可以用于执行工作。在本发明中，所执行的工作是振动的形成，其中在某个频率范围内形成由换能器 315 形成的振动，这在下文更详细地讨论。可以在美国专利号 7,898,159 和美国专利号 7,608,989 中找到关于静电换能器的另外的信息，其全部内容通过引用合并到本申请中。

[0116] 还可以设想，上述换能器 315 还可以耦接到另一组件，其中其它组件可能具有增加的质量。通过使用，可以通过向电极提供电压来激活换能器，从而激发聚合物，其中可以激发加重的组件从而提供更大的振动能量。

[0117] 根据本发明的另一方面，电活性聚合物换能器 315 能够形成为具有弯曲的形状，或者可以附接到具有弯曲形状的壳体，使得壳体或弯曲的激发的换能器能够容易地被用户的解剖结构（具体地，用户的锁骨）接受。

[0118] 可以以不同的几何形状来实施本发明的电活性聚合物换能器 315。可以设想，可以以圆形、椭圆形、正方形、矩形或其它已知几何形状的形式来实现换能器 315。另外，可以设想换能器可以形成具有如图 3D 所示的至少一个杆臂型布置。在该实施方式中，杆臂 347 被配置成响应与位于电极上的电荷而振动。可以配置杆的数量和杆的形状以调节组件的声学 / 振动特性。

[0119] 如上所述的电活性聚合物换能器的使用还包括电路驱动器 350，电路驱动器 350 可以被合并到上述第一电路板 500 或第二电路板 550 中。可替选地，电路驱动器 350 可以实施为可以与本发明的第一电路板或第二电路板电耦接的单独电路板（未示出）。电路驱动器 350 还包括音频输入端 360 和至少一个输出端 370，但是优选地是一对输出端 371 和 372。输出端 371、372 耦接到换能器 315 的电极 340、电极 345。

[0120] 电路驱动器 350 还可以包括另外的部件如放大器、滤波器、升压电路、充电控制器、降压电路。

[0121] 另外，可以设想，驱动器组件可以实施为多个元件，例如可以使用驱动器组件的任何组合如触觉扬声器和压电扬声器的组合、触觉扬声器和电活性聚合物换能器的组合、电活性聚合物换能器和压电扬声器或同一壳体内多个相同的驱动器类型的组合。本文中提供的示例不应当认为是以任何方式的限制。可替选地，驱动器组件可以是振动电机或纽扣电池电机。

[0122] 如上所述并且根据本发明，可以设想，两个治疗提供设备 200 可以一起使用以向用户提供治疗，其中可以使用物理连接来互连两个治疗单元。可以设想，两个治疗设备中的一个可以具有被布置在其中的完整的一组电子装置，其中完整的一组电子装置将包括通信、存储器和其它芯片组以及相关联的电路。其中另一治疗提供模块 200 于是可包括简化的电子装置模块，其中简化的电子装置模块将不具有完整电子装置模块的完整芯片组。例如，简化的电子装置模块将不需要具有电池充电电路或其它芯片，以及其可以具有较少的存储器或没有存储器。通过提供具有精简的电子装置模块的另一治疗提供设备，可以装配更大的能量源，通过该布置，在能量源需要被替换或被再充电之前，组合的治疗提供设备可被使用更长时间。

[0123] 现在参见图 11，示出了根据本发明的充电站 / 基站 570。如图 11 所示，基站 570 包括壳体 571，其中壳体 571 包括被配置成在其中接纳治疗提供设备 200 的凹陷部分 572。凹陷部分 572 被配置成包括充电引脚 574，当治疗提供设备 200 被布置在凹陷内时，凹陷会对准治疗提供设备的充电引脚 / 垫 265。除了充电引脚 574 之外，其它引脚也可以包括在基座 570 和治疗提供设备 200 上，其可以用于其它目的如下载存储在（多个）治疗提供设备 200 的存储器内的数据。基站 570 还可以包括到互联网或其它网络的有线或无线连接使得能够将从（多个）治疗提供设备接收的数据传送或上载至上述网址或传送到另一位置如健康护理提供者或用于存储的其它位置。还可以设想，基座 570 可以包括另外的特征如闹钟或时钟 573、移动电话或平板电脑充电站。如将在下文关于图 13L 和图 13M 更详细地描述的，治疗提供设备可以包括从壳体 210 延伸的延伸部分 219，每个延伸部分 219 包括磁体 230。可以设想，充电基座 570 的凹陷部分可以被成形为接纳图 13L 中示出的壳体 210 的延伸部分 219。凹陷部分 572 可以适于接纳延伸部分 219 或者还可以包括被布置在其中的金属构件或磁体，使得当治疗提供设备被放置入凹陷部分时，治疗提供设备 200 的壳体 210 内的磁体 230 被吸附到充电站 570 的金属或磁体，从而暂时地将治疗提供设备 200 附贴至充电站。除了暂时地将治疗提供设备 200 附贴至充电站 570 之外，通过暂时地将治疗提供设备 200 附贴至充电站 / 基站 570 来提供治疗提供设备 200 和充电引脚 574 之间的更好的接触。可以设想，可以使用增强治疗提供设备和充电站 / 基站 570 的充电引脚之间的接触的其它布置。例如，充电站 / 基站的充电引脚可以被配置成线性地移动并且使用弹簧力来保持，由此当治疗提供设备 200 被放置入凹陷部分 572 用于充电时，充电引脚 574 回缩或部分回缩。另外，在治疗提供设备已被布置在凹陷部分中之后，另一构件（未示出）如板或重物可以被放置到治疗提供设备上。另外，充电引脚 574 可以被布置在充电基座 570 的盖（未示出）上，使得将治疗提供设备 200 放置在充电基座 570 的凹陷部分 572 中并且关闭盖，从而完成充电基座的充电引脚 574 和治疗提供设备 200 的充电引脚 / 垫 256 之间的电连接。

[0124] 根据本发明，基座 570 还可以被实施为另一医疗设备或包括其它医疗设备。可以设想，基座 570 可以包括另一医疗设备，或者可以被包括在另一医疗设备中如脉搏血氧

仪、血压监视设备、血糖仪、输液泵、血糖泵、睡眠跟踪设备、温度测量设备、或如由瑞思迈(ResMed)及伟康(Respironics)提供的睡眠呼吸暂停设备。目前,睡眠呼吸暂停设备使用容纳控制送风机以向患者接口传送加压的空气所需的电子装置的控制台。患者接口可以以全脸面罩、鼻罩、口鼻面罩、口罩、鼻塞或现有技术中已知的其它合适的配置的形式来实施。同样,可以使用任何合适的头戴布置来舒适地将患者接口支撑在期望的位置。

[0125] 在本发明的又一方面,现在参见图12,示出了本发明的治疗提供设备200,其中治疗提供设备200用于与睡眠呼吸暂停设备的接口对接。如图12所示,治疗提供设备200被配置成由呼吸暂停患者接口设备的头戴布置来接纳、或接合呼吸暂停患者接口设备的头戴布置、或被集成入呼吸暂停患者接口设备的头戴布置,其中本发明的治疗提供设备被配置成接合患者的颚骨或颅骨。

[0126] 在本发明的又一方面,治疗提供设备200可以被包括入被配置成接合患者组织和骨骼的其它设备如骨导助听器,一个这样的示例由Sonitus Medical以商品名SoundBite提供。

[0127] 现在参照图13A、14A、14B、15A、15B、16A和16B,示出了根据本发明的治疗提供设备200的壳体210的多个实施方式。如这些图所示,壳体210被示出具有能够用于将治疗提供设备200贴合至患者的多种安装组件。

[0128] 如图13A所示,治疗提供设备的一个表面上设置有狭缝260。绷带265可以穿过狭缝260,其中由狭缝260形成的肋拱261将治疗提供设备200保持在绷带265上。绷带265还包括生物相容性粘合剂,使得治疗提供设备200能够附贴至患者,如图13B所示。绷带可以是一次性使用的结构,其中绷带在单次使用后丢弃。可替选地,绷带265可以是多次使用产品,其中生物相容性粘合剂被选择为使得能够多次放置绷带和从用户的皮肤移除绷带。另外,可以设想,可以更新生物相容性粘合剂。可以通过如下方式来更新粘合剂:在现有的胶黏剂上展开新的粘合剂,使用物质来洗涤粘合剂的表面来更新表面,或者粘合剂可以被实施为具有多个薄层,其中用户移除用过的层并且丢弃用过的层,从而暴露粘合剂的新层用于再次使用。用于可再使用的绷带的粘合剂的合适的示例是水凝胶粘合剂,类似于那些用在用于肌肉电刺激设备(或者被称为TENS单元)的探头上的粘合剂。这样的探头由3M以及其它公司制造和销售。可以设想,最初可以向用户的身体施加临时标记以指示治疗提供设备的位置。例如,临时标记可以是临时纹身或印度彩绘的形式。

[0129] 可替选地,可以使用足够大以覆盖治疗提供设备200的整个壳体的绷带。在该实施方式中,足够量的绷带会悬在壳体的边缘上,使得当放置治疗提供设备200紧靠用户的组织时,绷带能够贴附到组织以将治疗提供设备保持在期望的位置。在该实施方式中,绷带可以包括孔、不透明部分或者透明部分,使得当将绷带放置在治疗提供设备200上方时,上述治疗提供设备200的壳体210的上表面上的按钮260、LED262和充电引脚/端口265(如果壳体包括这样的部件)是可见的并且可访问的。可以构造这样的绷带以进一步包括单向膜,其中,绷带下的水分可以从组织表面被输送或移动穿过绷带,但绷带将不允许流体从外部传递到治疗提供设备200或用户的组织。

[0130] 现在参照图14A至图14C,示出了用于将治疗提供设备200附贴至患者的可替选设计。在该实施方式中,治疗提供设备的一个表面包括被布置在壳体210的第二表面215上的第一配合件280。提供有绷带400,其中绷带400具有近表面402和远表面401。生物相容

性粘合剂被布置在绷带的远表面 401 上。第二配合件 281 被布置在绷带 400 的近表面 402 上。第一配合件 280 和第二配合件 281 被设计成彼此接纳以形成可分离的锁定附属物，如图 14C 所示。这样的可分离配合件的合适的示例可以是螺纹螺钉、四分之一转紧固件、有槽通路、锥形配合件等。配合件中的任何一个可以包括安全锁（未示出），其中在两个配合件在锁定布置中结合在一起之后安全锁会接合。安全锁可以阻止配合件松脱而不需要另外向安全锁施加力或运动来使得配合件能够分离。如上所述绷带 400 可以使一次性使用产品或者可以使可再使用的绷带。在另一方面，本发明的绷带可以被制造成包括多层，其中每层包括新的胶表面。在使用后，用户剥离绷带已与组织接触的层并且妥善丢弃，从而暴露新的胶层以供进一步使用。

[0131] 现在参照图 15A 和图 15B，示出了用于将治疗设备 200 附贴至患者的另一可替选设计。在该实施方式中，治疗设备 200 的表面包括被布置在其上或被合并到表面中的磁体 290。如上所述，提供了绷带 400，其中绷带 400 具有近表面 402 和远表面 401。生物相容性粘合剂被布置在绷带的远表面 401 上。金属构件 292 被合并到绷带 400 中，如图 15B 所示。在使用中，用户将绷带 400 施加于他们的身体，其中绷带的中心将与他们的锁骨对准。在一种实施方式中，可以每天更换绷带 400。在另一实施方式中，再使用的绷带一段时间然后更换绷带。另外，在另一实施方式中，可以在每次使用后翻新绷带 400 的胶表面以延长绷带 400 的使用寿命。一旦将绷带 400 附贴至用户，如图 15A 所示并且在上文描述的治疗提供设备 200 然后将通过治疗提供设备 200 的磁体 290 与绷带 400 的金属构件 292 之间的磁耦合被耦接到绷带。应当理解，使用磁体 290 和金属构件 292 的组合可以反过来。例如，绷带 400 可以包含磁体 290 而治疗提供设备 200 将具有金属构件 292。可替选地，绷带 400 和治疗提供设备 200 二者都可以包括磁体 290，由此磁体 290 帮助将治疗提供设备与绷带 400 自动对准。另外，可以设想，绷带 400 或治疗提供设备 200 中的任何一个的磁体或金属构件可以从延伸通过绷带 400 的中心的轴偏移，从而提供在使用中治疗提供设备 200 可以被布置在绷带 400 上的两个不同的定向。另外，可以设想，治疗提供设备的驱动器 220 可以在壳体 210 内从通过壳体纵向延伸的轴偏移。在壳体 210 内使驱动器 220 偏移实现了在使用期间提供治疗提供设备 200 的多个安装定向的相同效果。在又一实施方式中，可以将磁体 290 或金属构件 290 植入用户的皮肤之下，因此不再需要绷带 400。在该实施方式中，治疗提供设备 200 可直接耦接到患者的皮肤。

[0132] 在另一实施方式（未示出）中，绷带可以包括穿过其形成的孔，其中金属构件 292 将被布置在孔附近。孔的尺寸被设置为在其中接纳治疗提供设备 200 的一部分。还可以设想，治疗提供设备可以包括第二绷带或尺寸与绷带 400 相似的扩大的表面。扩大的表面可以包括如上所述的磁体 290；因此，当治疗提供设备 200 被布置在绷带 400 的孔内时，扩大的表面覆盖绷带。

[0133] 在另一实施方式中，磁体和金属构件可以互换，其中绷带包含磁体而壳体可以是金属构件，一部分可以是金属或一部分可以是磁性的。另外，除了使用磁体和金属构件之外，可以使用其它已知的可分离系统，例如，钩环结构或可再使用的粘合性表面。

[0134] 现在参照图 16A 和图 16B，示出了根据本发明的壳体，其中壳体 210 包括延伸部分 219。延伸部分 219 进一步包括被布置在其中的磁体 230。现在参照图 16B，示出了待与图 16A 示出的壳体一起使用的绷带 420。绷带 420 还包括穿过其形成的孔，设置孔的尺寸以接

受治疗提供设备 200 的一部分。绷带 420 还包括被布置在其中的磁体 430。绷带 420 可以由多层结构组成，其中绷带可以包括胶层、胶支撑层和背衬层。可以设想，磁体 430 可以被布置在胶支撑层内，其中磁体 430 可以通过胶层和背衬层被封装在绷带 420 中。在使用中，用户将绷带 420 放置在他们的皮肤上，其中在治疗提供设备被放置在锁骨上方的示例中用户能够使用孔 431 来正确地对准绷带。绷带 420 的胶层可以是可再使用的粘合剂，如上述粘合剂和通常用在 TENS 探头上的粘合剂，其中粘合剂层使得能够重新定位绷带。在绷带 420 被放置之后，具有图 16A 示出的壳体的治疗提供设备被布置在绷带上方。壳体延伸部分 219 的磁体 230 和绷带的磁体 430 用于将治疗提供设备附接到绷带并且将治疗提供设备定位在绷带中心。根据本发明，可以设想，可以用金属构件代替壳体的磁体 230 或绷带的磁体 430 中的任意一个。

[0135] 在本发明的又一实施方式中，如本文中所描述，可以被定位于设备壳体内的磁体、绷带或二者可以用于控制治疗提供设备 200 的功能。在该示例中，磁体中的至少一个可以用作控制电源电路或使电源电路完整的开关。能够激活电源电路以使治疗提供设备 200 上电，从而启动治疗。如果磁连接被断开，则治疗提供设备会被关断。还可以设想，除上述之外，设备或绷带内的磁体可以被制造具有特定属性，使得治疗提供设可以仅与原设备制造商的产品一起操作，从而防止治疗提供设备 200 与未经批准的或伪造的绷带一起使用。使用磁体来切换设备上电 / 掉电的优点是用户不需要激活设备上的任何按钮，另外，通过如本文所述的去除治疗提供设备上的按钮可以简化设备。另一优点是保持设备的电池寿命，因为只要磁连接断开，设备将被关断。另外，如果在晚间在睡眠过程中使用治疗提供设备并且设备从用户脱落，则设备会自动关断，从而提供另外的安全特性。

[0136] 另外，可以设想，治疗提供设备 200 和 / 或绷带可以包括安全特性，如被布置在治疗提供设备内的光扫描仪，使得光扫描仪被配置成扫描印刷在绷带或绷带包装上的 QR 码、条形码或其它编码。如上所述，扫描仪和具体编码的组合可以用于控制治疗提供设备 200 的激活。另外，安全码 / 条形码的使用可以与上述治疗提供设备 200 的磁激活结合以确保所使用的绷带是被设计成具体地与治疗提供设备 200 一起使用的批准的产品，以及绷带不是第三方未批准产品或伪造产品。可以设想，可以使用其它类型的安全系统来实现同样的或相似的功能。例如，绷带可以包括凸出绷带的表面的凸起（未示出），凸起可以被接纳于壳体的第二表面的孔内，在该处其将激活壳体内的开关。另一示例可以是使用被布置在绷带上或绷带内的电子电路或芯片，电路或信号可以与治疗提供设备接口，从而使电路完整以使得能够激活治疗提供设备。

[0137] 现在参照图 17，示出了根据本发明的用于待与治疗系统 100 一起使用的安装设备的可替选设计。如图 17 所示，示出了支撑结构 600。支撑结构 600 可被配置成将根据本发明的治疗提供设备 200 定位于用户的锁骨上方的优选位置。用户还可以通过调节臂关于枢轴 610 的角度以及通过调节通过伸缩组件 620 的长度来调整治疗提供设备 200 的位置的定位。

[0138] 支撑结构 600 在臂 630 的远端 640 还包括球窝接头 660。球窝接头 660 被布置成支撑治疗提供设备 600 并且使得用户能够调整治疗提供设备 200 在期望的位置处与用户的表面基本平行以确保治疗提供设备 200 与用户尽可能多地接触。

[0139] 支撑结构 600 还包括连接到臂 630 的垫 650。根据本发明的实施方式，垫可以包含

电子装置模块 320 和电源。

[0140] 支撑结构 600 的臂 630 还可以被配置成包括弹簧力以推动治疗提供设备 200 紧靠身体。例如，图 17 中描绘的支撑结构 600 的臂 630 呈弧形并且被配置成当将支撑结构 600 放置在用户肩部上方时在治疗提供单元 200 和垫 650 之间施加弹簧力。

[0141] 现在参照图 18，示出了根据本发明的支撑结构 700 的另一示例。如图 4H 所示，支撑结构 700 包括垫 750、第一臂 730 和第二臂 731。支撑结构 700 还包括接头 740，接头 740 将第一臂 730 连接到第二臂 731。接头 740 被配置成使得第一臂 730 和第二臂 731 之间能够进行旋转运动以使得用户能够对准根据本发明的方法的治疗提供设备 200。第二臂 731 还包括伸缩部 745。伸缩部 745 使得用户能够调节第二臂 731 的长度以正确地放置治疗提供单元。第二臂 731 还包括被布置在其远端的球窝接头组件 760，球窝接头组件 760 将治疗提供单元耦接到第二臂 731。球窝接头组件 760 使得治疗提供单元能够倚靠用户的锁骨而平放并且把解剖结构的差异考虑在内。支撑结构 700 还包括耦接到第一臂 730 的垫 750。如上所述，垫 750 可包括电子装置模块 320 和电源。在某些实施方式中，电子装置模块和电源可以是用户可更换的。在其它实施方式中，电子装置模块和电池不是用户可更换的，可以更换整个组件，包括治疗提供设备。

[0142] 支撑结构 600 和支撑结构 700 可以由弹性材料制成。涉及的弹性提供了弹簧力或夹持力使得支撑结构和治疗提供设备在使用过程中保持在适当位置。

[0143] 本文中描述的支撑结构可被配置成紧贴配合而不在身体上过分挤压，是直接地放在肩部上方或围绕躯干，并且能够在衣服下面佩戴而不显著地更改衣物的轮廓。

[0144] 现在参照图 19A 至图 19C，示出了本发明的另外的实施方式。如图 19A 至图 19C 所示，本发明的治疗提供设备 200 可以包括在支撑结构 800 中，其中支撑结构 800 包括近端 802 和远端 801 以及在这两个端之间延伸的细长构件 803。支撑结构还包括控制面板 810，其中控制面板 810 可以包括指示器如等或 LED811 以指示治疗提供设备 200 的功能。控制面板 810 还包括开关 813，开关 813 与治疗提供设备 200、电子装置模块 230 和能量源 240 电通信，上文已描述了治疗提供设备 200、电子装置模块 230 和能量源 240 电通信中的每一个。支撑结构 800 可以由织物如棉、尼龙、聚酯等制成，其中主体 803 是管状、正方形、矩形或圆柱形的形状，从而形成内室。如图 4I 所示，示出了治疗提供设备 200、电子装置模块 230 和能量源 240 被布置在内室中。可以通过在内室内形成的口袋的使用来将这些部件保持在内室内。还可以设想，可以使用材料来填充内部控制以增加整个设备的重量。能够用于填充室的材料的示例有米、豆类、沙、金属材料、聚合物材料和本领域技术人员已知的其它这样的材料。

[0145] 如图 19B 和图 19C 所述，可围绕用户的颈部和肩部佩戴支撑结构 800，其中治疗提供设备 200 将由用户调节以落在用户的锁骨上并且与用户的锁骨接触。如图 19B 所示，支撑结构 800 可以被布置在用户的衣物上方，或者可替选地，支撑结构 800 可以被布置直接地紧靠用户的皮肤，如图 19C 所示。

[0146] 根据图 19A 至图 19C 示出的实施方式，可以设想，支撑结构还可以包括可移除盖（未示出），其中可移除盖可以被布置在支撑结构 800 上。可移除盖可以包括拉链，尼龙搭扣或按扣以打开和关闭盖。另外，可移除盖可以包括另外的物品如沿着其部分或长度放置的垫。例如，垫可以被布置在用户颈部区域附近的盖上。

[0147] 还可以设想，根据本发明的支撑结构800可以包括另外的特征。例如，加热元件包括包括在支撑结构800中，由此用户可以使用加热元件来解决肌肉酸痛或颈部疼痛。

[0148] 现在参照图20A和20B，示出了能够与本发明的治疗提供设备200一起使用的衣物的示例实施方式。

[0149] 如图20A所示，在一种实施方式中，衣物被实施为T恤衫600，其中T恤衫600包括在其中形成以接纳治疗提供设备200的口袋602。口袋602在用户的锁骨上方对准以便提供治疗，如下文所述。

[0150] 现在参照图20B，示出了根据本发明的被配置成保持治疗提供设备200的一件衣物的可替选实施方式。如图5B所示，衣物可以以运动胸衣610的形式被实施。运动胸衣610还包括被配置成接纳治疗设备200的口袋612。可替选地，除了口袋之外，如上所述其它附接机构，其中除口袋以外，磁体，钩环紧固件，按扣，旋转连接器和锁或类似类型的紧固系统可以用于将治疗提供设备200保持在适当位置。

[0151] 另外，上述衣物设备还可以包括用于接纳计算设备的另外的一个或多个口袋，或者在其中电子装置或能量源与治疗提供设备分开的实施方式中，口袋或其它固位装置用于保持这些另外的部件。

[0152] 衣物设备还可以包括在其中形成的或与其附接的结构（未示出），其中结构被配置成向（多个）治疗提供设备施加向下的力。可以使用类似于在图17、图18和图19中示出的结构。

[0153] 根据本发明，治疗提供设备200可以包括另外的特征。一个这样的另外的特征可以是包括温度计以在使用过程中跟踪用户的温度。另一另外的特征可以是包括睡眠传感器或睡眠跟踪程序，其中治疗提供设备可以用于跟踪用户的睡眠。例如，睡眠程序可以使用治疗提供设备的GPS/加速度计来跟踪睡眠过程中的运动，其中睡眠程序还可以使用温度数据。本发明的另一方面可以是进一步使用治疗提供设备来诊断睡眠呼吸暂停，其中治疗提供设备可以另外包括麦克风以使得能够在睡眠过程中音频记录用户的呼吸。另外，呼吸的麦克风记录可以与加速度计数据或GPS/倾斜数据组合以使呼吸记录与具体的用户关联。

[0154] 现在参照图21A和图21B，示出了根据本发明的计算设备800。计算设备800包括处理器、存储器、能量源（如电池）和显示器810。计算设备可以是用于与上述治疗设备200一起使用的定制制造的设备，或者可替选地，计算设备800可以是市售设备如智能电话或平板电脑。这样的市售设备的示例是启用iOS的设备如**iPhone®、iPad®、iPod®**，基于至roid的手机和/或平板电脑，笔记本电脑或计算机。如图15B所示，计算设备可以被配置成当连接到具有这些测量能力的治疗提供设备时或者在与治疗提供设备一起使用其它兼容设备的情况下显示用户的心率和血压。可替选地，计算设备可以显示从一个或更多个治疗提供设备接收的数据，该数据可以包括由治疗提供设备200提供的治疗的开始/结束时间、一个或更多个治疗提供设备的电池状态等。

[0155] 根据本发明，计算设备300被配置成运行程序320。根据本发明，程序320被配置成与治疗设备200通信。可以使用蓝牙、wifi、ZigBee、NFC、RFID、ANT+、3G/4G、蜂窝连接或其它已知无线通信协议来进行程序320、计算设备300和治疗设备200之间的通信。可替选地，计算设备可以通过线缆连接来耦接到治疗设备中的至少一个。

[0156] 在可替选实施方式中，程序820存储在位于治疗提供设备200的存储器内的存储

器上。可以通过由用户按压的物理按钮的使用来人工地启动程序820。可替选地，可以通过位于治疗提供设备200内的定时器自动启动程序820。定时器还可以使用从加速度计/罗盘或倾斜传感器输入的数据来表示当用户处于卧位时激活程序820。另外，定时器可以从阻抗传感器接收表示治疗提供设备200是否在用户上正确放置的输入。然后可以基于所接收的输入来激活程序。另外可以通过光传感器根据对着皮肤的黑暗来激活设备。可以根据来自用户周围环境的减弱的光线来激活设备，例如当用户睡觉时。

[0157] 在某些实施方式中，程序820被预先配置成通过预编程参数适用治疗提供设备来提供治疗。HCP可以调整程序820内的治疗参数，使得可以给用户定制提供给用户的治疗。治疗的定制可以是波长、幅度、持续时间、开始/停止时间的变化。可以在向用户提供服务时由HCP来进行定制，例如，HCP可以将治疗提供设备应用于患者，启动治疗并且监视用户的响应。通过该主动监视，HCP可以改变程序的参数以引发患者的响应。例如，可以设想，某些患者可能具有不同的骨密度，因此需要相应地调整由设备提供的治疗。还可以设想，一旦被编程，用户不能改变程序的治疗参数，或者可替选地，某些参数或所有参数可以开放给最终用户或远程用户来修改。可替选地，HCP在确定最佳治疗参数后，能够从存储在治疗提供设备的存储器内的多个程序中选择。另外，可以向HCP提供专用编程设备，或可以将设备耦接到个人计算机、智能电话、平板电脑或其它互联网功能设备，使得HCP能够使用专用编程器或从安全的网络连接下载待被上载至治疗提供设备的程序。

[0158] 现在参照图22，示出了说明根据本发明的一种实施方式的程序820的流程图。如图22所示，程序820可以被配置成在计算设备800上运行以控制由治疗提供设备200向用户应用的治疗。可替选地，可以设想，程序820可以保存在治疗提供设备200内的存储器中，如上文所述。

[0159] 在框830，用户出发计算设备800或治疗提供设备200上的程序。

[0160] 在框840，程序检查计算设备800上的时间或检查内部地来自治疗提供设备200的时钟电路的时间。

[0161] 在框850，程序确定是否基于框840中的时间检查来接通治疗提供设备。如果该时间在预编程时间或用户设置时间之前，则程序返回框840。如果该时间在预设时间或用户设置时间之后，则程序接通治疗提供设备。根据本发明，如果时间是从计算设备接收的，例如如果计算设备从一个时区被移动至另一时区，则用户可以调整计算设备的时间。可替选地，计算设备可以自动更新时间。

[0162] 在框860，向治疗提供设备200提供由程序生成的信号以及从计算设备800通过所选的传送方法传送的信号。在可替选实施方式中，治疗提供设备包括处理器和存储器，其中程序被保留在治疗提供设备的存储器内。在该实施方式中，由计算设备800提供的信号是上电/掉电信号，其中一但上电，保留在治疗提供设备的存储器内的程序会开始运行。

[0163] 在框870，治疗提供设备向患者提供治疗。在提供治疗的过程中，由计算设备800通过如由程序820所指导的向治疗设备200发送信号，或如上所述，保留在治疗提供设备的存储器中的程序运行，在一种实施方式中，在设定的时间周期内应用治疗。在可替选的实施方式中，基于从被布置在用户上或在用户周围的其它传感器接收的数据来确定治疗的持续时间。在又一实施方式中，用户可以人工地去激活治疗提供设备/程序。

[0164] 在框880，治疗停止。可以基于时间事件、运动时间来停止治疗，由用户来人工地停

止治疗，由程序来自动地停止治疗。

[0165] 在上述并且在图 22 的流程图中示出的步骤中的每个步骤过程中，可以向用户呈现在计算设备的屏幕 810 上的显示内容。屏幕 810 可以显示治疗的开始时间和停止时间，这些时间可以由用户来设置或者由健康护理提供者对于用户来设置。可替选地，可以对应于从其它传感器接收的数据来自动地生成时间，如将在下文详细描述的。

[0166] 根据本发明，程序包括其上包括有计算机可执行程序的非暂态计算机可读介质，计算机可执行程序代码被配置成向（多个）电路板 500/550 发送适当的信号以根据本发明的方法使用本发明的治疗提供设备 200 来提供治疗。

[0167] 使用方法

[0168] 根据本发明，将在下文描述本发明的使用方法。所描述的方法应当被认为是示例性的并且不应当被认为是以任何方式来限制。

[0169] 根据本发明的一种实施方式，治疗设备包括驱动器组件，其中驱动器组件被实施为如图 5 和图 73 所示的扬声器。扬声器可以是触觉扬声器、压电扬声器、电活性聚合物换能器或磁圈扬声器。计算设备 800 和程序 810 被配置成向扬声器提供信号以使扬声器以某一频率振动或频率范围内振荡或平移。

[0170] 根据本发明的实施方式，所设想用于本发明的频率范围在以下频率范围之间：0Hz 至 20,000Hz、0Hz 至 10,000Hz、0Hz 至 5,000Hz、0Hz 至 2,500Hz、0Hz 至 1,750Hz、0Hz 至 875Hz、0Hz 至 435Hz、0Hz 至 200Hz、0Hz 至 150Hz、1Hz 至 150Hz、2Hz 至 150Hz、3Hz 至 150Hz、4Hz 至 150Hz、5Hz 至 150Hz、6Hz 至 150Hz、7Hz 至 150Hz、8Hz 至 150Hz、9Hz 至 150Hz、10Hz 至 150Hz、11Hz 至 150Hz、12Hz 至 150Hz、13Hz 至 150Hz、14Hz 至 150Hz、15Hz 至 150Hz、16Hz 至 150Hz、17Hz 至 150Hz、18Hz 至 150Hz、19Hz 至 150Hz、20Hz 至 150Hz、21Hz 至 150Hz、22Hz 至 150Hz、23Hz 至 150Hz、24Hz 至 150Hz、25Hz 至 150Hz、26Hz 至 150Hz、27Hz 至 150Hz、28Hz 至 150Hz、28Hz 至 150Hz、29Hz 至 150Hz、30Hz 至 150Hz、31Hz 至 150Hz、32Hz 至 150Hz、33Hz 至 150Hz、34Hz 至 150Hz、35Hz 至 150Hz、36Hz 至 150Hz、37Hz 至 150Hz、38Hz 至 150Hz、39Hz 至 150Hz、40Hz 至 150Hz、41Hz 至 150Hz、42Hz 至 150Hz、43Hz 至 150Hz、44Hz 至 150Hz、45Hz 至 150Hz、46Hz 至 150Hz、47Hz 至 150Hz、48Hz 至 150Hz、49Hz 至 150Hz、50Hz 至 150Hz、51Hz 至 150Hz、52Hz 至 150Hz、53Hz 至 150Hz、54Hz 至 150Hz、55Hz 至 150Hz、56Hz 至 150Hz、57Hz 至 150Hz、58Hz 至 150Hz、59Hz 至 150Hz、60Hz 至 150Hz、61Hz 至 150Hz、62Hz 至 150Hz、63Hz 至 150Hz、64Hz 至 150Hz、65Hz 至 150Hz、66Hz 至 150Hz、67Hz 至 150Hz、68Hz 至 150Hz、69Hz 至 150Hz、70Hz 至 150Hz、71Hz 至 150Hz、72Hz 至 150Hz、73Hz 至 150Hz、74Hz 至 150Hz、75Hz 至 150Hz、76Hz 至 150Hz、77Hz 至 150Hz、78Hz 至 150Hz、79Hz 至 150Hz、80Hz 至 150Hz、81Hz 至 150Hz、82Hz 至 150Hz、83Hz 至 150Hz、84Hz 至 150Hz、85Hz 至 150Hz、86Hz 至 150Hz、87Hz 至 150Hz、88Hz 至 150Hz、89Hz 至 150Hz、90Hz 至 150Hz、91Hz 至 150Hz、92Hz 至 150Hz、93Hz 至 150Hz、94Hz 至 150Hz、95Hz 至 150Hz、96Hz 至 150Hz、97Hz 至 150Hz、98Hz 至 150Hz、99Hz 至 150Hz、100Hz 至 150Hz、101Hz 至 150Hz、102Hz 至 150Hz、103Hz 至 150Hz、104Hz 至 150Hz、105Hz 至 150Hz、106Hz 至 150Hz、107Hz 至 150Hz、108Hz 至 150Hz、109Hz 至 150Hz、110Hz 至 150Hz、111Hz 至 150Hz、112Hz 至 150Hz、113Hz 至 150Hz、114Hz 至 150Hz、115Hz 至 150Hz、116Hz 至 150Hz、117Hz 至 150Hz、118Hz 至 150Hz、119Hz 至 150Hz、120Hz 至 150Hz、121Hz 至 150Hz、122Hz 至 150Hz、123Hz 至 150Hz、124Hz 至 150Hz、125Hz 至 150Hz、126Hz 至 150Hz、

127Hz 至 150Hz、128Hz 至 150Hz、129Hz 至 150Hz、130Hz 至 150Hz、131Hz 至 150Hz、132Hz 至 150Hz、133Hz 至 150Hz、134Hz 至 150Hz、135Hz 至 150Hz、136Hz 至 150Hz、137Hz 至 150Hz、138Hz 至 150Hz、139Hz 至 150Hz、140Hz 至 150Hz、141Hz 至 150Hz、142Hz 至 150Hz、143Hz 至 150Hz、144Hz 至 150Hz、145Hz 至 150Hz,146Hz 至 150Hz、147Hz 至 150Hz、148Hz 至 150Hz、149Hz 至 150Hz、150Hz 至 150Hz、60Hz 至 100Hz、61Hz 至 100Hz、62Hz 至 100Hz、63Hz 至 100Hz、64Hz 至 100Hz、65Hz 至 100Hz、66Hz 至 100Hz、67Hz 至 100Hz、68Hz 至 100Hz、69Hz 至 100Hz、70Hz 至 100Hz、60Hz 至 99Hz、61Hz 至 99Hz、62Hz 至 99Hz、63Hz 至 99Hz、64Hz 至 99Hz、65Hz 至 99Hz、66Hz 至 99Hz、67Hz 至 99Hz、68Hz 至 99Hz、69Hz 至 99Hz、70Hz 至 99Hz、61Hz 至 98Hz、62Hz 至 98Hz、63Hz 至 98Hz、64Hz 至 98Hz、65Hz 至 98Hz、66Hz 至 98Hz、67Hz 至 98Hz、68Hz 至 98Hz、69Hz 至 98Hz 以及 70Hz 至 98Hz。

[0171] 在优选的实施方式中，信号使得驱动器组件以某一频率振动或扫过约 40Hz 至 150Hz 之间、更优选地在 50Hz 至 125Hz 之间、最优选地在大约 60Hz 至 115Hz 之间的频率的范围。

[0172] 还可以设想，这些频率可以加倍但仍然实现根据本发明的血压的治疗性降低。还可以设想，这些频率可以减半但仍然实现根据本发明的血压的治疗性降低。

[0173] 在本发明的另外的实施方式中，驱动器组件可以在以下频率之间振动、扫掠或阶 跃：60Hz、61Hz、62Hz、63Hz、64Hz、65Hz、66Hz、67Hz、68Hz、69Hz、70Hz、71Hz、72Hz、73Hz、74Hz、75Hz、76Hz、77Hz、78Hz、79Hz、80Hz、81Hz、82Hz、83Hz、84Hz、85Hz、86Hz、87Hz、88Hz、89Hz、90Hz、91Hz、92Hz、93Hz、94Hz、95Hz、96Hz、97Hz、98Hz、99Hz 和 100Hz。

[0174] 现在参照图 23A 和图 23B，示出了另一实施方式，其中使用单个频率和扫频的组合来提供治疗。例如，驱动器组件将被驱动以在一段时间内以单个频率 F1 振动，然后被驱动以扫过频率范围 F2，然后被驱动以不同于第一单个频率 F1 的单个频率 F3 振动，最后通过上述频率 F4 的扫掠被向后驱动。可以在一段设定的时间内重复该循环，关断一段时间并且然后再次重复，直到达到治疗的总时间段。

[0175] 还可以设想，可以通过程序向扬声器发送使用不同的频率的多个信号。例如可以以一种频率发送一个信号并且以另一频率发送第二信号。可以同步地、独立地或以交替方式发送信号。如果使用至少两个治疗提供设备 200，则一个治疗提供设备 200 可以接收第一信号并且另一治疗提供设备 200 接收第二信号。

[0176] 在一种实施方式中，使用至少两个治疗提供设备 200。在使用中可以向两个治疗提供设备 200 中的一个治疗提供设备 200 发送信号，使扬声器发射具有选定频率或频率范围的信号。可以在预定时间段内向第一治疗提供设备 200 发送信号。这样的之间之后，信号终止。当第一信号终止时，生成第二信号并且发送到另一治疗提供设备。第二信号使扬声器发射具有选定频率或频率范围的信号。选定频率可以与被发送到第一治疗提供设备的频率相同或其可以是不同的频率。可以在预定时间段内向第二治疗提供设备 200 发送信号。这样的之间之后，信号终止。程序会继续运行，然而，在该时间期间不会发送信号至任何一个治疗提供设备 200，从而在治疗提供设备 200 的激活之间创造停顿。在预定的时间段的停顿过去之后，程序然后会进入循环并且重复上述过程。只要指示程序这样做，该治疗模式就会重复。

[0177] 在使用两个治疗提供设备 200 的实施方式中，每个设备向用户的左锁骨和右锁骨

递送波形。从每个治疗提供设备中的扬声器向用户的锁骨传送波形。波形通过左侧和右侧的锁骨被传送，其中两个波在胸骨处相遇以产生驻波。

[0178] 另外，根据本发明，可以调整信号的幅值以调整由治疗提供设备 200 的驱动器组件 220 生成的声压。可以设想，振幅可以加倍或升高更多以提供根据本发明的治疗。根据本发明，治疗提供设备 200 可以被配置成提供在以下范围内的声压 :0 分贝至 150 分贝、0 分贝至 100 分贝、0 分贝至 99 分贝、0 分贝至 98 分贝、0 分贝至 97 分贝、0 分贝至 96 分贝、0 分贝至 95 分贝、0 分贝至 94 分贝、0 分贝至 93 分贝、0 分贝至 92 分贝、0 分贝至 91 分贝、0 分贝至 90 分贝、0 分贝至 89 分贝、0 分贝至 88 分贝、0 分贝至 87 分贝、0 分贝至 86 分贝、0 分贝至 85 分贝、0 分贝至 84 分贝、0 分贝至 83 分贝、0 分贝至 82 分贝、0 分贝至 81 分贝、0 分贝至 80 分贝、0 分贝至 79 分贝、0 分贝至 78 分贝、0 分贝至 77 分贝、0 分贝至 76 分贝、0 分贝至 75 分贝、0 分贝至 74 分贝、0 分贝至 73 分贝、0 分贝至 72 分贝、0 分贝至 71 分贝、0 分贝至 70 分贝、0 分贝至 69 分贝、0 分贝至 68 分贝、0 分贝至 67 分贝、0 分贝至 66 分贝、0 分贝至 65 分贝、0 分贝至 64 分贝、0 分贝至 63 分贝、0 分贝至 62 分贝、0 分贝至 61 分贝、0 分贝至 6020 分贝、0 分贝至 59 分贝、0 分贝至 58 分贝、0 分贝至 57 分贝、0 分贝至 56 分贝、0 分贝至 55 分贝、0 分贝至 54 分贝、0 分贝至 53 分贝、0 分贝至 52 分贝、0 分贝至 51 分贝、0 分贝至 50 分贝、0 分贝至 49 分贝、0 分贝至 48 分贝、0 分贝至 47 分贝、0 分贝至 46 分贝、0 分贝至 45 分贝、0 分贝至 44 分贝、0 分贝至 43 分贝、0 分贝至 42 分贝、0 分贝至 41 分贝、0 分贝至 40 分贝、0 分贝至 39 分贝、0 分贝至 38 分贝、0 分贝至 37 分贝、0 分贝至 36 分贝、0 分贝至 35 分贝、0 分贝至 34 分贝、0 分贝至 33 分贝、0 分贝至 32 分贝、0 分贝至 31 分贝、0 分贝至 30 分贝、0 分贝至 29 分贝、0 分贝至 28 分贝、0 分贝至 27 分贝、0 分贝至 26 分贝、0 分贝至 25 分贝、0 分贝至 24 分贝、0 分贝至 23 分贝、0 分贝至 22 分贝、0 分贝至 21 分贝、0 分贝至 20 分贝、0 分贝至 19 分贝、0 分贝至 18 分贝、0 分贝至 17 分贝、0 分贝至 16 分贝、0 分贝至 15 分贝、0 分贝至 14 分贝、0 分贝至 13 分贝、0 分贝至 12 分贝、0 分贝至 11 分贝、0 分贝至 10 分贝、0 分贝至 9 分贝、0 分贝至 8 分贝、0 分贝至 7 分贝、0 分贝至 6 分贝、0 分贝至 5 分贝、0 分贝至 4 分贝、0 分贝至 3 分贝、0 分贝至 2 分贝、0 分贝至 1 分贝、0 分贝至 0.5 分贝、0 分贝至 0.25 分贝、10 分贝至 100 分贝、20 分贝至 100 分贝、30 分贝至 100 分贝、40 分贝至 100 分贝、50 分贝至 100 分贝、60 分贝至 100 分贝、70 分贝至 100 分贝、80 分贝至 100 分贝、90 分贝至 100 分贝、10 分贝至 75 分贝、20 分贝至 75 分贝、30 分贝至 75 分贝、40 分贝至 75 分贝、50 分贝至 75 分贝、60 分贝至 75 分贝、70 分贝至 75 分贝、10 分贝至 65 分贝、20 分贝至 65 分贝、30 分贝至 65 分贝、40 分贝至 65 分贝、50 分贝至 65 分贝以及 60 分贝至 65 分贝、20 分贝至 30 分贝、30 分贝至 40 分贝、40 分贝至 50 分贝、50 分贝至 60 分贝、60 分贝至 70 分贝、70 分贝至 75 分贝、80 分贝至 90 分贝、50 分贝至 75 分贝以及 50 分贝至 65 分贝。

[0179] 另外，根据本发明，驻波可以具有半倍频，双倍频，或反射发生率。因此在锁骨处传送的频率可以穿过胸骨 (breastbone) 或胸骨 (sternum) 独立地碰撞并且产生与生成的波相同或不同的新频率。

[0180] 根据本发明，选择用于治疗的频率必须保持恒定而声压水平可以升高或降低，可替选地，声压水平可以保持恒定而频率变化。声压水平的测量与递送设备 220 的部分的位移相关。递送设备 220 的部分可以在以下范围内移动 :0mm 至 20mm、0mm to10mm、0mm to9mm、

0mm 至 8mm、0mm 至 7mm、0mm 至 6mm、0mm 至 5mm、0mm 至 4mm、0mm 至 3mm、0mm 至 2mm、0mm 至 1mm、0mm 至 0.5mm、0mm 至 0.05mm、0mm 至 0.005mm、0mm 至 0.0005mm、0.5mm 至 0.05mm、0.5mm 至 0.005mm、0.05mm 至 0.005mm。如果递送设备 220 被选择为触觉扬声器 220'，则移动的触觉扬声器 220' 的部分是触觉扬声器的声圈。

[0181] 根据本发明，可以设想，可以激活每个治疗提供设备以在大约 1 秒至 24 小时之间的时间段内提供治疗。在其它实施方式中，可以激活治疗提供设备在以下范围之间的时间段内提供治疗：大约 1 秒至 12 小时、1 秒至 11 小时、1 秒至 10 小时、1 秒至 9 小时、1 秒至 8 小时、1 秒至 7 小时、1 秒至 6 小时、1 秒至 5 小时、1 秒至 4 小时、1 秒至 3 小时、1 秒至 2 小时以及 1 秒至 1 小时、1 秒至 45 分钟、1 秒至 30 分钟、1 秒至 20 分钟、1 秒至 15 分钟、1 秒至 10 分钟、1 秒至 5 分支以及 1 秒至 1 分钟。

[0182] 整个治疗过程可以在以下范围之间的时段内进行：1 秒至 24 小时、1 秒至 23 小时、1 秒至 22 小时、1 秒至 21 小时、1 秒至 20 小时、1 秒至 19 小时、1 秒至 18 小时、1 秒至 17 小时、1 秒至 16 小时、1 秒至 15 小时、1 秒至 15 小时、1 秒至 14 小时、1 秒至 13 小时、1 秒至 12 小时、1 秒至 11 小时、1 秒至 10 小时、1 秒至 9 小时、1 秒至 8 小时、1 秒至 7 小时、1 秒至 6 小时、1 秒至 5 小时、1 秒至 4 小时、1 秒至 3 小时、1 秒至 2 小时、1 秒至 1 小时、1 秒至 45 分钟、1 秒至 30 分钟、1 秒至 15 分钟、1 秒至 10 分钟、1 秒至 5 分钟、1 秒至 1 分钟。

[0183] 在可替选的实施方式中，代替一次激活一个治疗提供设备来提供治疗，可以同时激活两个治疗提供设备 200。

[0184] 根据本发明，治疗提供设备可以是出厂时被编程以使用某个频率或频率范围来提供治疗。可替选地，可以由健康护理提供者基于患者对具体频率或频率范围的响应来选择频率并且对频率编程或者从存储器选择频率。

[0185] 还可以设想，计算设备可以另外与诸如血压监视仪、心率监视仪、脉搏血氧饱和度监视器、心电图 (EKG/ECG) 或血糖传感器的其它传感器通信。

[0186] 在一种实施方式中，计算设备 800 可以从血压监视仪或其它传感器接收数据，使得在应用根据本发明的治疗之间、过程中和之后记录用户的血压。可以将该数据连同治疗数据提供给用户和 / 或健康护理提供者。基于该数据，能够调整选择用于治疗的频率或频率范围。可以由程序自动地做出调整，或由健康护理提供者或由用户自己来做出调整。

[0187] 在另一实施方式中，治疗提供设备 200 的处理器可以与其它传感器如上述传感器通信，其中其它传感器将与治疗提供设备在通信上耦接。治疗提供设备 200 内的处理器能够从各种其它传感器如血压监视仪接收数据。从血压监视仪接收的数据可以由电子装置模块的存储器内的程序用来进一步控制治疗提供设备 200。

[0188] 由程序生成并且被发送到治疗提供设备的信号优选地是正弦波的形式。然而，可以使用其它波形，如方波、锯齿波或三角波。

[0189] 还可以设想，另外的传感器可以与根据本发明的方法和设备一起使用。例如，如上所述血压监视仪可以附贴至患者。其它传感器，如睡眠传感器、移动传感器、脉搏血氧饱和度传感器、温度传感器、心率传感器、EKG、麦克风、数字听诊器、光传感器、睡眠呼吸暂停设备 (CPAP) 或摄像机可以与根据本发明的治疗系统 100 组合使用。上面所列出的传感器可以单独使用或组合使用以向用户或健康护理提供者提供另外的关于用户的健康状况以及关于用户对由治疗系统 100 提供的治疗的响应的数据。

[0190] 还可以设想，上述传感器中的任何一个可以被包括在根据本发明的治疗提供设备200中。如果被包括在治疗提供设备200中，程序可使用来自另外的传感器中的每个的数据来更改基于从各种传感器接收的数据提供的治疗。在可替选的实施方式中，可以将来自另外的传感器中的每个的数据存储在包括在治疗提供设备200内的常驻存储器中。一段时间以后治疗提供设备200可以然后变为服务中心，其中可以检索和分析包括在传感器中的数据。在又一实施方式中，每次将治疗提供设备放置在感应充电垫上时可以从治疗提供设备200下载存储在存储器中的数据。然后可以将数据发送到收集中心并且分析数据。另外，可以将数据上载至服务器或其它连接网络的个人计算机，使得用户、健康护理提供者或其它人可以检查数据。

[0191] 在另一实施方式中，设备可以存储使用的次数和使用的持续时间以使得健康护理提供者能够确定用户的服从度。例如在睡眠呼吸暂停设备中，仅在患者是70％服从度的情况下允许提供报销，通过跟踪和记录本发明的治疗提供设备的使用，该数据可以用于报销的目的。

[0192] 在另一实施方式中，本发明的治疗系统100可以与家庭健康系统如霍尼韦尔的居家医疗系统相关联。在该实施方式中，根据本发明的治疗系统可以耦接到监视系统。该该实施方式中，健康护理提供者可以远程地监视用户以及其对所提供的治疗的反应。另外，治疗系统100可以被配置成识别紧急情况，如血压过高、血压过低、高心率或低心率并且生成警示，如警报或通知应急响应单位以请求向用户提供帮助。

[0193] 根据本发明，本文中所描述的治疗设备200被布置成恰好在用户的臂丛上方、与锁骨相邻或在锁骨附近。可以设想，治疗提供设备200可以被放置在用户上的其它位置如胸骨、下颌、肩胛骨、髌骨、手腕或颅骨上。当被激活时，治疗设备的驱动器组件220以声波的形式生成频率；该声波向锁骨和相邻于锁骨的皮肤发送。向锁骨发送的声波以振动的形式发送。振动行进通过锁骨并且进入锁骨、韧带和肌腱附近的动脉、血管、神经、感官小体、呼吸道、骨骼。因此，振动最终被发送到压力感受器、伤害感受器、本体感受器和其它体觉感受器。在此，振动与压力感受器和其它感受器以降低血压的方式相互作用。在优选的实施方式中，选择锁骨是因为其易于访问的位置以及其传送声音和振动的能力。锁骨易于被健康护理提供者和患者所识别，因为无论体重如何其均靠近皮肤的表面。

[0194] 根据本发明的方法和设备，能够实现颈动脉压力感受器和主动脉压力感受器二者以及其它体觉感受器的激活。可以相信颈动脉压力感受器和主动脉压力感受器二者的激活在实现降低血压方面是有益的。可以相信根据本发明提供的方法模仿运动，并且因此实现血压的降低。

[0195] 根据本发明，可以在夜间或在患者进入睡眠周期之前或在患者的睡眠周期过程中提供治疗。因为可以相信夜间是降低血压的最重要的时间之一，所以在夜间提供根据本发明的治疗可以是有利的。通过在夜间提供根据本发明的治疗，治疗可以用于治疗夜间高血压。另外，在夜间，系统药物水平处于其最低水平，因此在该时间需要另外的血压控制。

[0196] 根据本发明的另一实施方式，可以相信单个治疗提供设备而不是两个治疗提供设备的使用仅仅可以降低舒张期血压，其中两个治疗提供设备的使用能够用于降低收缩压和舒张压二者。

[0197] 根据本发明，可以在用户的睡眠周期之前提供治疗，以及在早晨患者醒来之前或

在他们醒来短时间之后再次提供治疗。

[0198] 根据本发明，可以使用频率对治疗提供设备进行编程，其中在升高血压是治疗性的并且对患者有益的情况下可以使用其它频率来升高血压。理想，在分娩后升高血压以抵制低血压的发作。

[0199] 还可以设想，可以在任何时间使用根据本发明的设备和方法。例如，理想，在日间使用设备，其中设备可以与血压监视仪一起使用，或者可替选地，包括血压监视仪用于闭环控制。在该实施方式中，程序可以监视用户的血压并且在需要的基础上应用治疗。在需要的情况下，例如用户计划从事使他们的血压升高的体力活动，用户可以关断系统。

[0200] 测试结果

[0201] 根据本发明，并且参照图 24A 和图 24B，通过本文中描述的设备和方法实现了以下血压结果。图 24A 和图 24B 示出了 24 小时内的动态血压度数。线 910 是欧洲高血压学会 (ESH)，英国国家健康与临床卓越研究院 (NICE) 和美国高血压学会 (ASH) 推荐的收缩压的范围。在下午 10 点至上午 7 点之间低于 125mmHg 的血压被认为达标。在日间上午 7 点至下午 10 点之间低于 140mmHg 的血压被认为达标。线 930 是 ESH、NICE 和 ASH 推荐的对于舒张压的范围，类似于收缩压线 930，在下午 10 点至上午 7 点之间达标舒张压被认为是 80mmHg，且在上午 7 点至下午 10 点之间 90mmHg 的测量被认为达标。

[0202] 如图 24A 所示，线 900 和线 920 表示个人的 24 小时动态血压测量，其中每 15 分钟进行血压测量。图 24B 中出现的用户被认为是高血压，即具有高的血压。这可以通过具体地查看线 900 和线 920 来确定，其中任何时间这些线高于推荐指导血压线 910 和线 930，用户将被认为是高血压。

[0203] 现在参照图 24A，示出了同一用户在已经接受根据本发明的治疗之后的曲线图。在该示例中，用户接受两次 2 小时的治疗，每次如所描绘的项目 940 和 950。将用户的实际血压测量图 24A 的线 900 和线 920 与用户的实际经治疗的血压测量图 24A 的线 901 和线 902 相比较，可以清楚地看到，通过使用本发明的设备和方法的治疗的应用，用户的血压显著地下降。

[0204] 为了实现图 24A 中描绘的结果，使用两个治疗提供设备，一个在左锁骨上，另一个在右锁骨上。每个治疗提供设备的扬声器传送 60Hz 至 100Hz 之间的频率。使用治疗提供设备进行总共 4 小时的治疗，其中播放 65Hz 的频率 8 秒，随后从 65Hz 至 98Hz 的扫频持续 1 秒，然后播放 98Hz 的频率 8 秒，随后从 98Hz 至 65Hz 的扫频持续 1 秒。遵循该循环，重复地提供 120 分钟的治疗。120 分钟之后，治疗暂停 4 小时的时间。4 小时的安静之后，使用上述循环进行另外 120 分钟的治疗。

[0205] 在治疗的应用之前进行血压的测量，由此，用户的收缩压平均值在夜间为 131mmHg 以及在日间为 144mmHg。舒张压在晚间为 72mmHg 以及在日间为 87mmHg。在使用治疗一个晚上（如上所述一个 8 小时的治疗）之后，收缩压平均值在夜间为 116mmHg 以及在日间为 131mmHg，舒张压平均值在夜间为 66mmHg 以及在日间为 80mmHg。

[0206] 行动方法

[0207] 根据本发明，如上面详细描述的，并参考所包括的出版物，应当理解，压力感受器和神经通过由动脉壁的伸展或收缩而产生的测量响应来影响血压。

[0208] 神经纤维，包括压力感受器，具有以下输入输出特性：临界压力、饱和度、后兴奋性

抑郁症 (PED)、非对称速率灵敏度和滞后。

[0209] 只要动脉内的压力保持低于一定的水平，没有神经放电发生时，这被称为神经阈值压力。高于阈值压力，纤维通过产生动作电位即作为信号来响应。人类和动物中的单个纤维具有宽范围的压力阈值。

[0210] 当动脉内的压力升高时，单个纤维的放电率升高，然而，在一定的压力下，输入的进一步升高不产生输出频率的升高，从而达到压力感受器神经的饱和。

[0211] 如果动脉内的压力输入从高于阈值压力的低压力阶跃至较高压力，然后返回较低压力水平，将导致短时间的切断，即不会有压力感受器神经的放电，也被称为兴奋后抑制 (PED)。一段时间后压力感受器神经将返回到其原来的放电率。

[0212] 压力感受器神经频率对于升高的压力的响应比对下降的压力的响应更显著，否则被称为非对称率敏感性。

[0213] 最后，定期输入在压力－频率曲线中产生循环，对升高的压力和下降的压力的响应之间的不对称的另一表示也被称为滞后。

[0214] 根据本发明，根据本文中描述的方法的设备的使用造成影响血压的神经系统的激活。神经末梢响应于伸展或声振动并且产生能够覆盖自然频率以引发响应的动作电位的频率调制序列。其中由本发明提供的治疗使用在具体时间间隔应用的具体频率的声波振动来激活身体的神经系统以引发血压响应。以循环模式应用本发明的治疗，因为可以相信如果压力感受器被刺激过长时间，其可能趋于饱和。如果连续地应用治疗则可以相信压力感受器会停止响应。

[0215] 根据本发明的方法，治疗提供设备相邻于用户的锁骨而布置。锁骨作为真皮骨能够传送振动。锁骨位于支撑辅助动脉，静脉，气管和供应手臂的上肢的臂丛神经的颈腋上方。振动锁骨被认为是产生行进至主动脉压力感受器和颈动脉球压力感受器的微脉动。认为这些微脉动被压力感受器感知为心脏速率升高，压力感受器然后将信号发送到大脑。由此，使得身体降低血压。

[0216] 可通过仔细控制振动或微脉动的幅度，位移和应用模式来获得主神经末梢的选择性刺激。

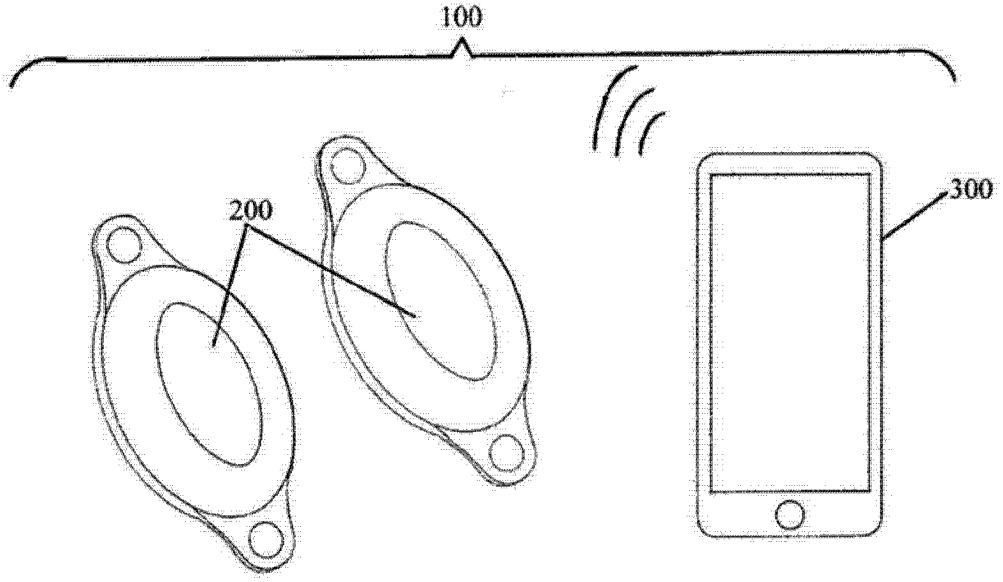


图 1

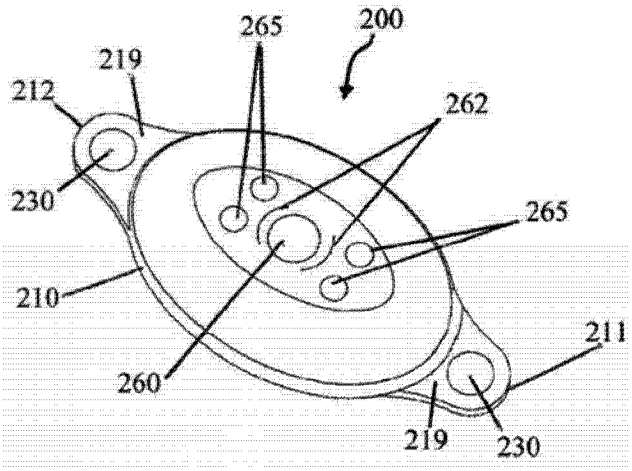


图 2

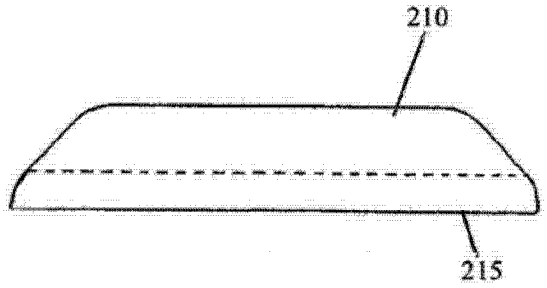


图 3A

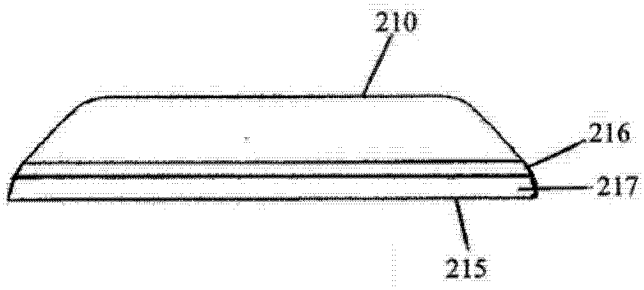


图 3B

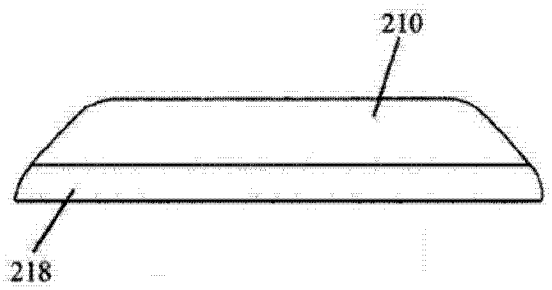


图 3C

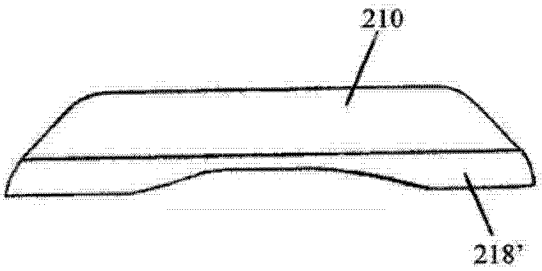


图 3D

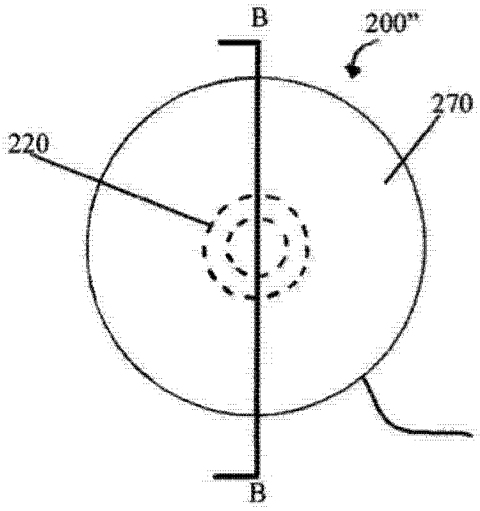


图 4A

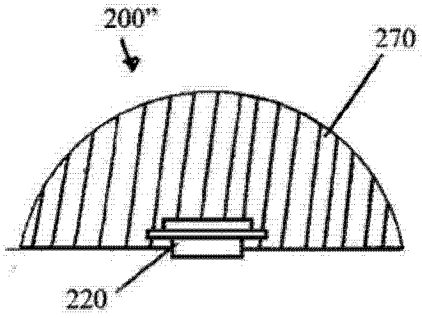


图 4B

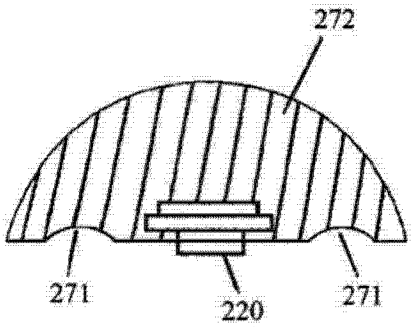


图 4C

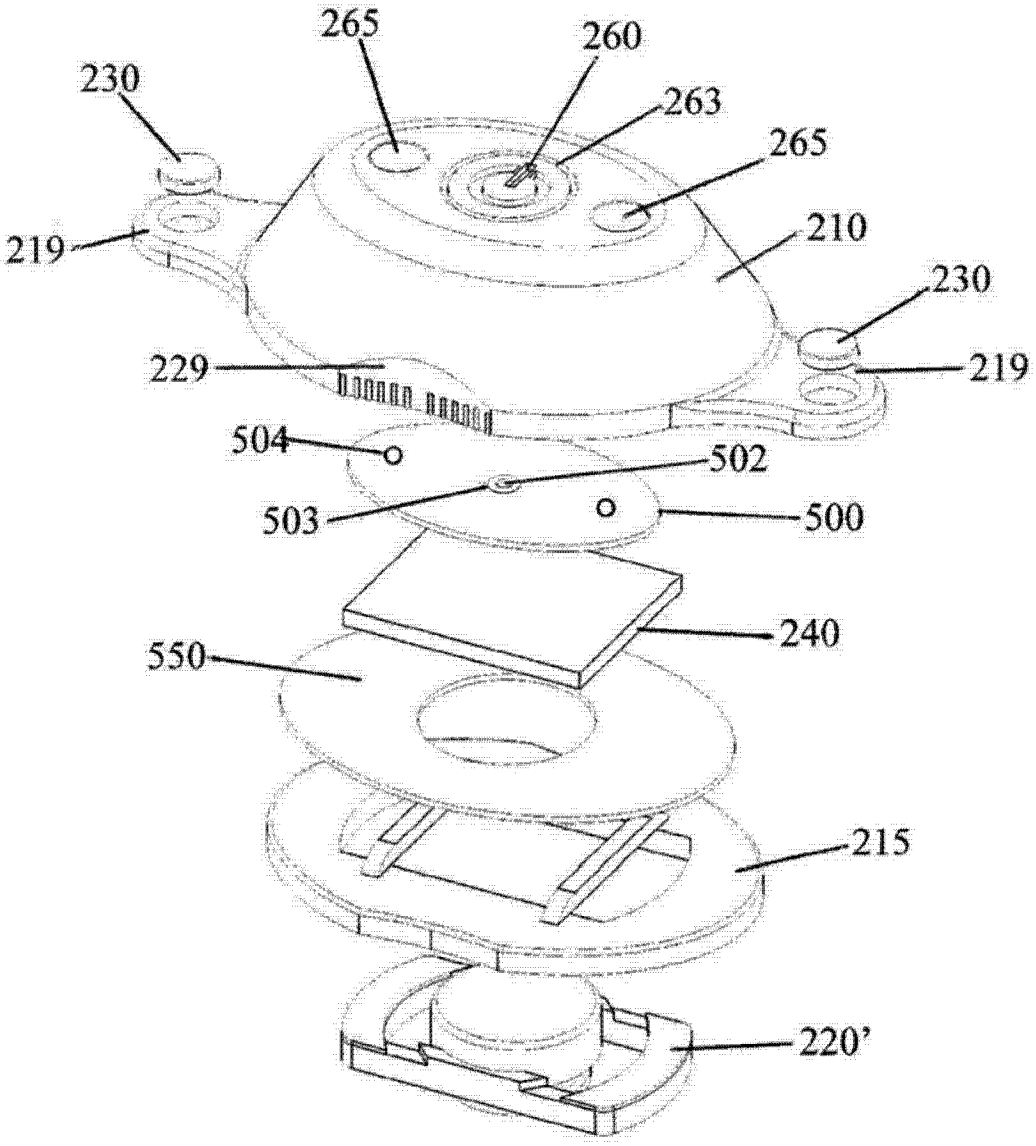

265
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图 5

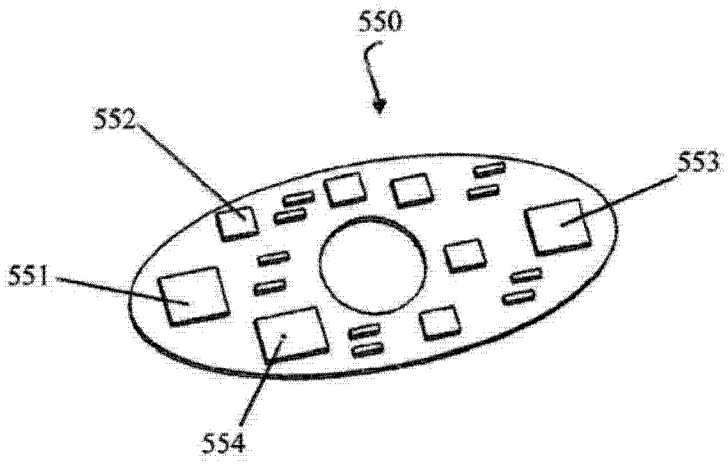

图 6

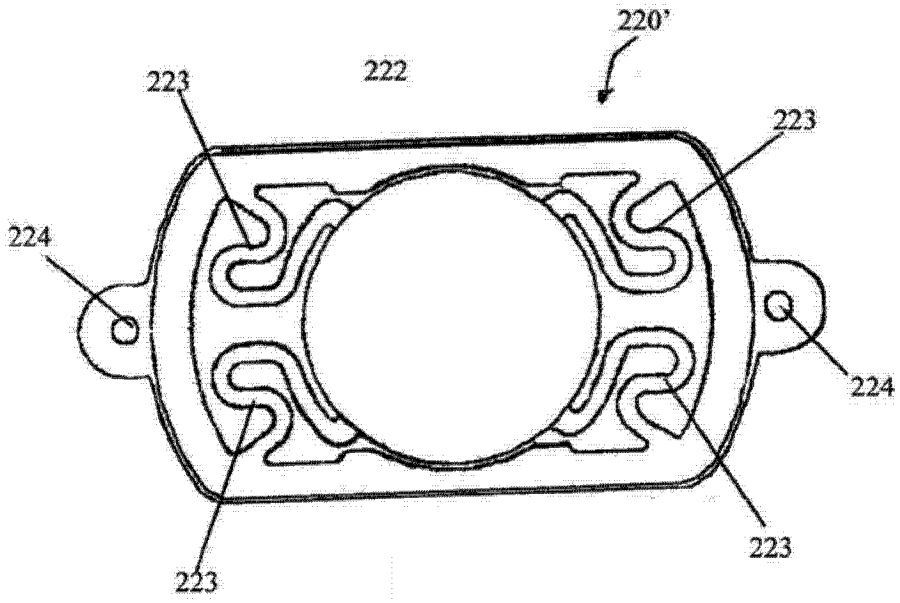

图 7

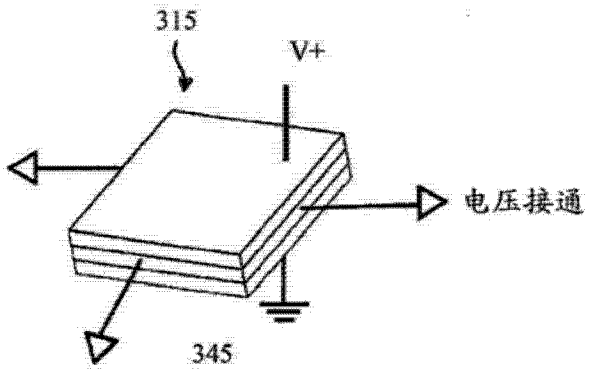
315
V+
电压接通
345

图 8

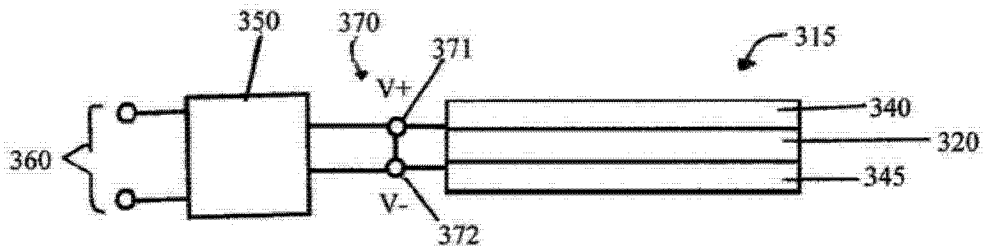
350
370
371
315
V+
340
320
360
345
V-
372

图 9

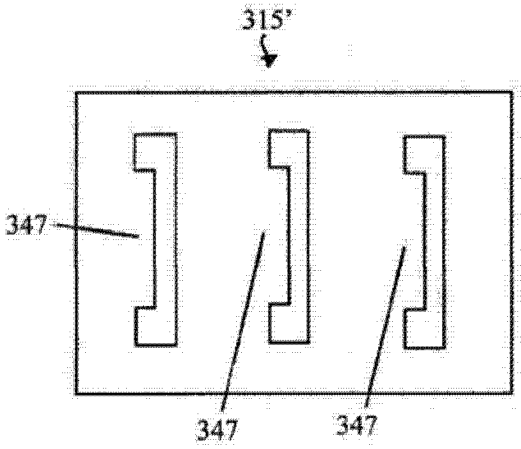
315'
347
347
347

图 10

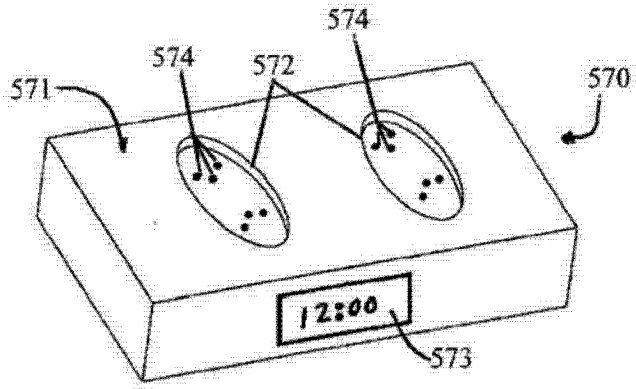
574
574
572
571
570
12:00
573

图 11

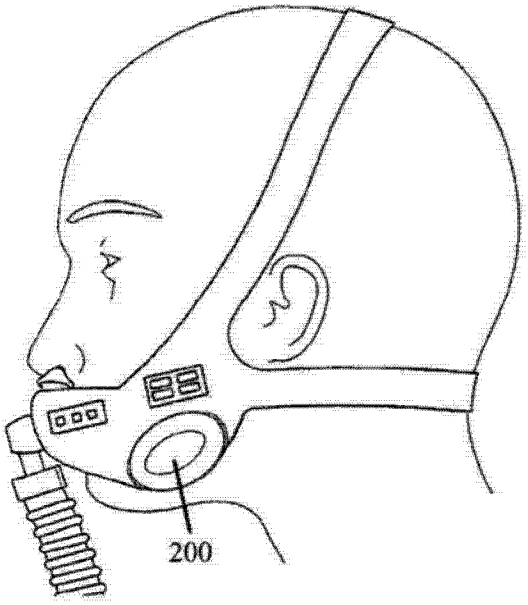

图 12

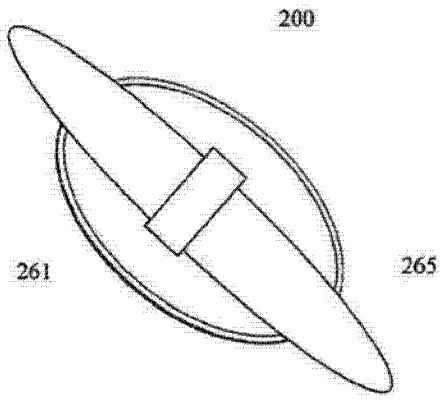

图 13A

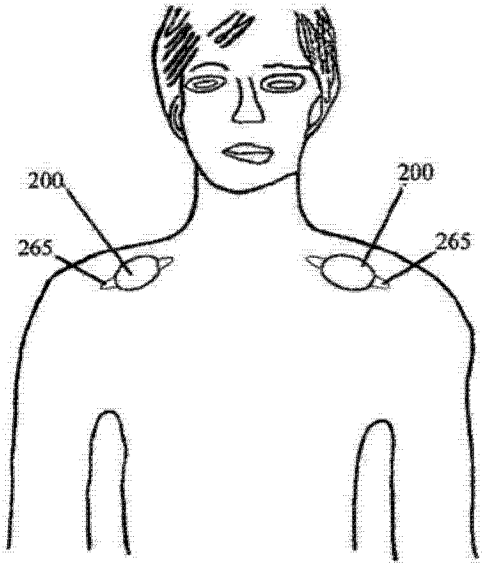

图 13B

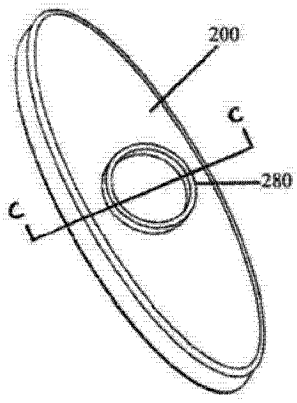

图 14A

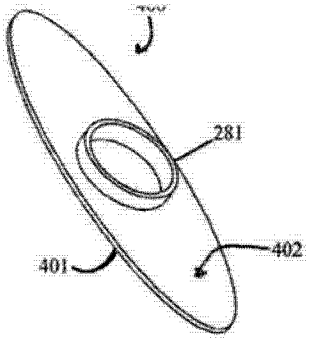

图 14B

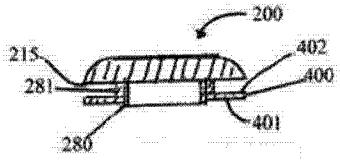

图 14C

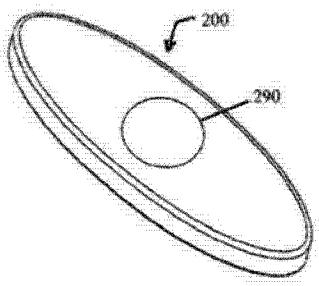

图 15A

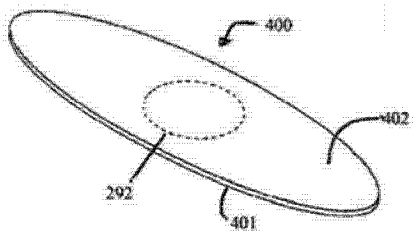

图 15B

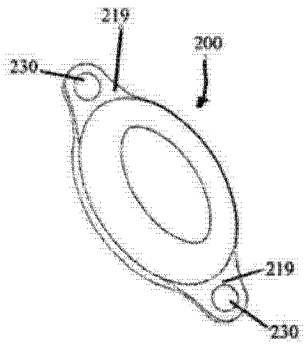

图 16A

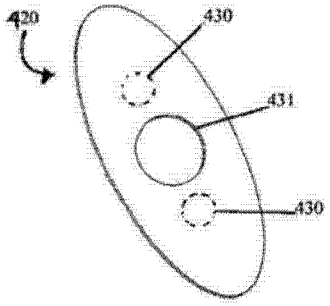

图 16B

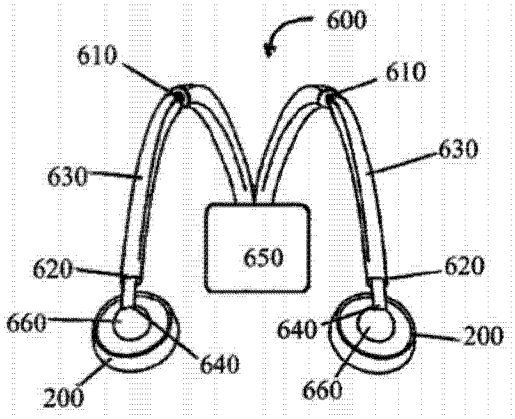

图 17

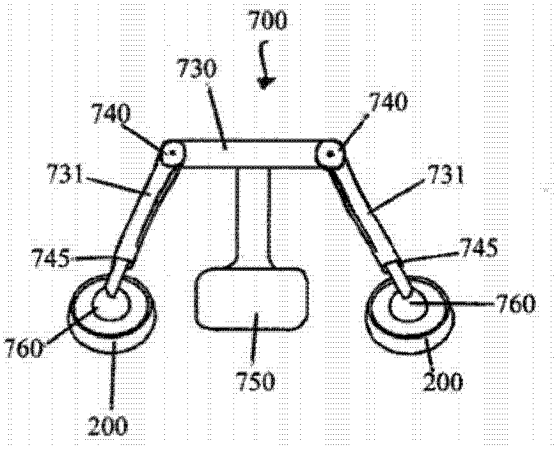

图 18

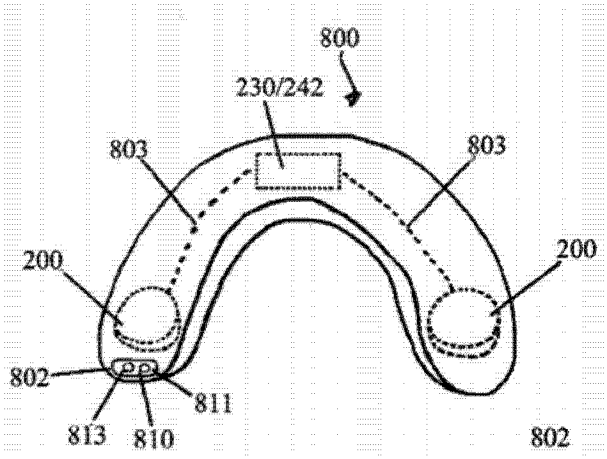

图 19A

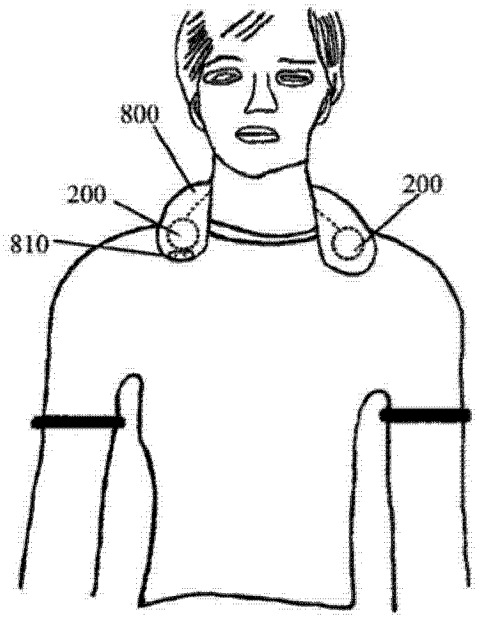

图 19B

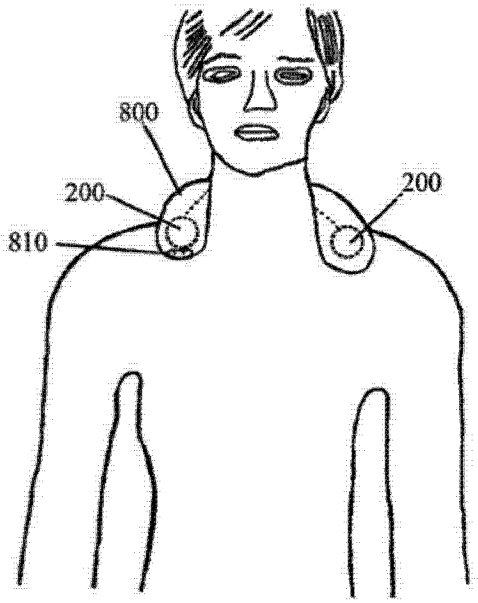

图 19C

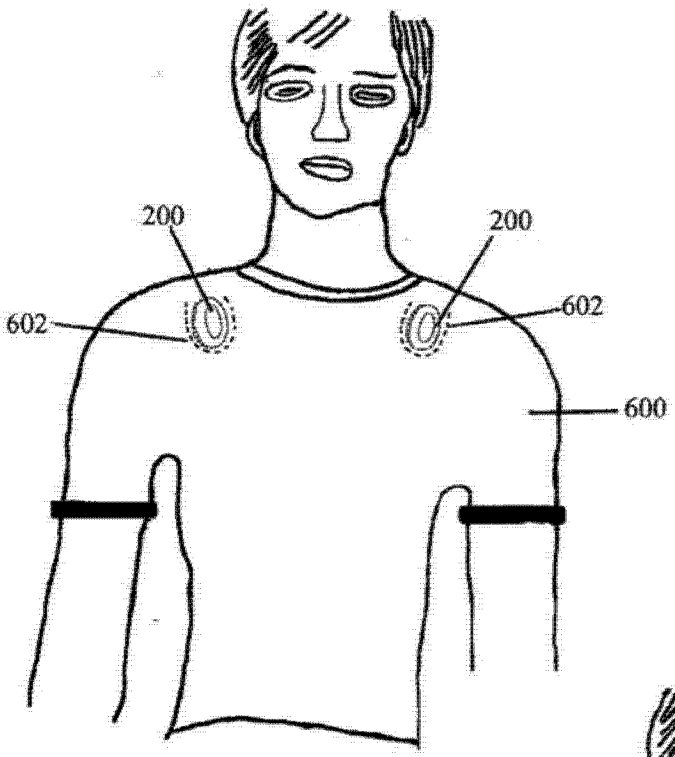

图20A

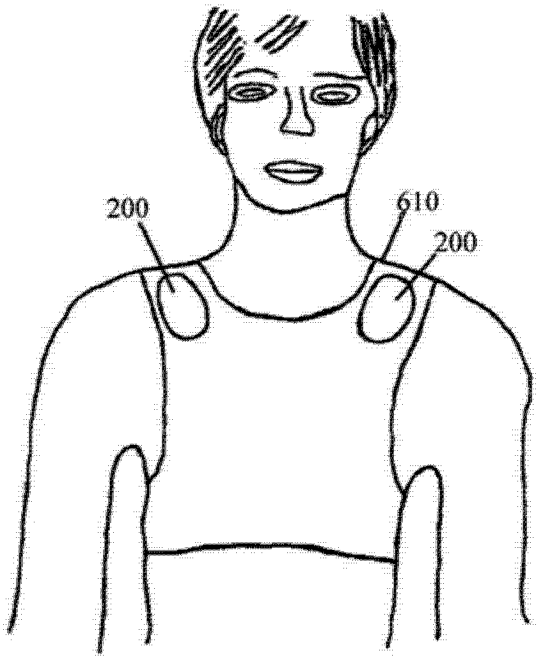

图20B

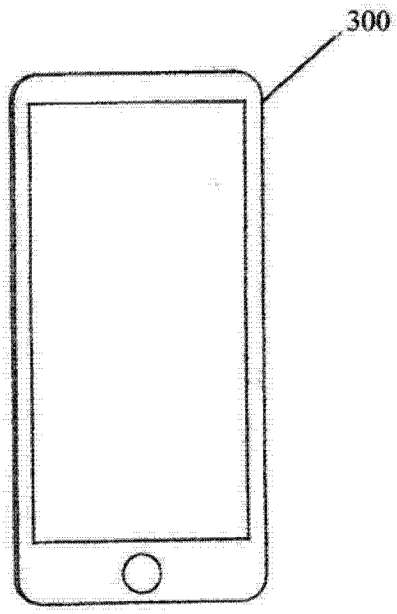

图 21A

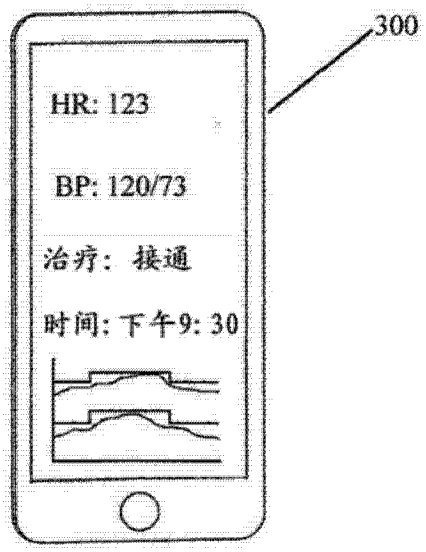

图 21B

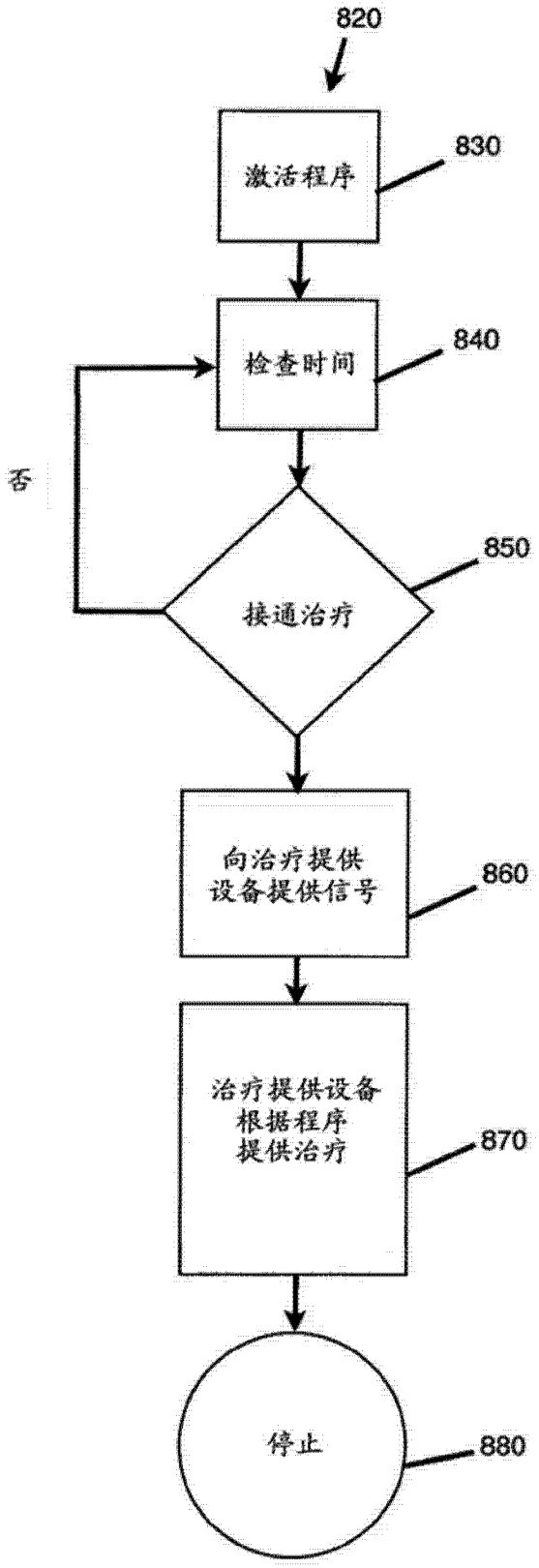
820
激活程序
830
检查时间
840
否
接通治疗
850
向治疗提供
设备提供信号
860
治疗提供设备
根据程序
提供治疗
870
停止
880

图 22

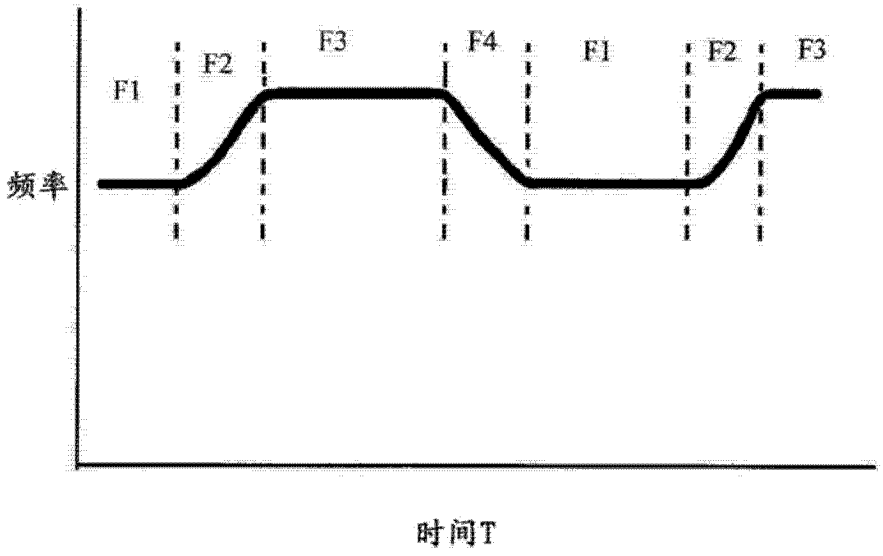

图 23A

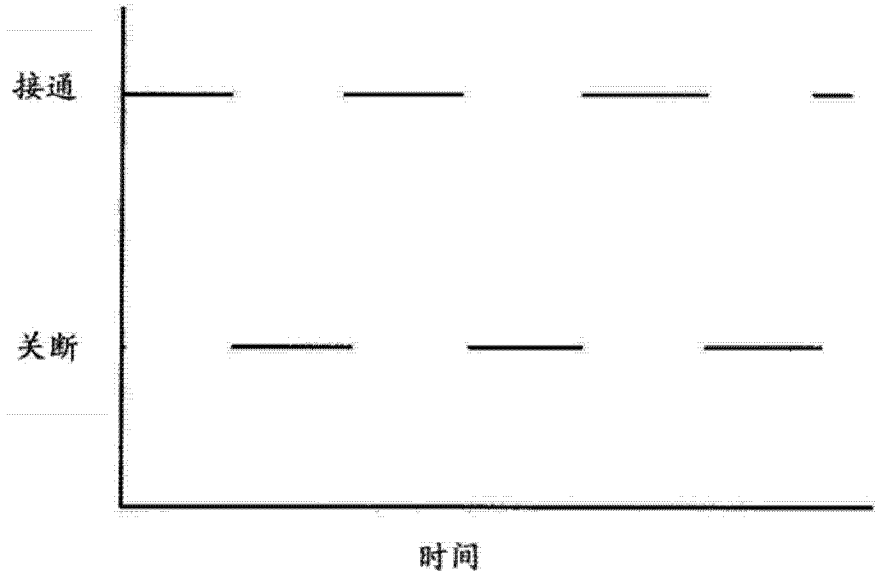

图 23B

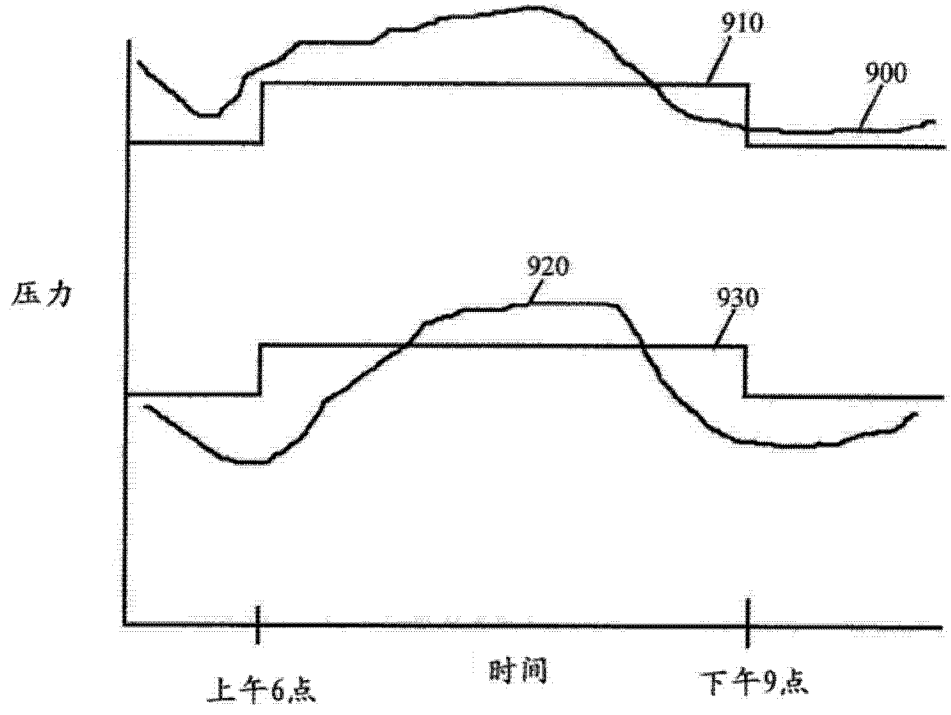
910
900
920
930
压力
上午6点
时间
下午9点

图 24A

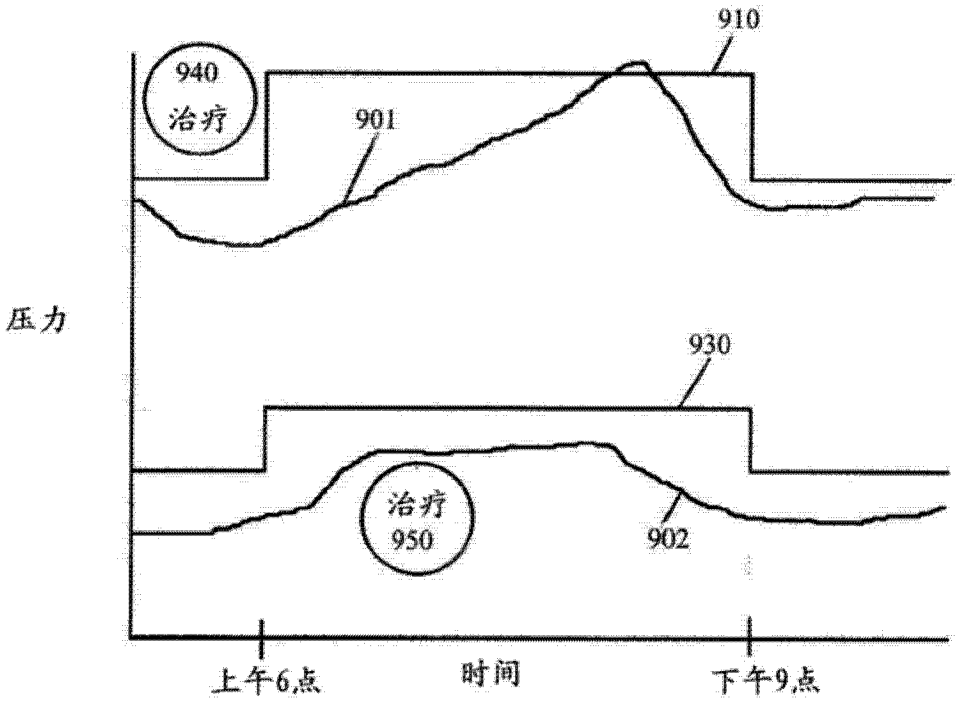
910
940
治疗
901
930
压力
治疗
950
902
上午6点
时间
下午9点

图 24B

Abstract

Devices, systems and methods are described which control blood pressure and nervous system activity by stimulating baroreceptors. By selectively and controllably activating baroreceptors and/or nerves, the present invention reduces blood pressure and alters the sympathetic nervous system; thereby minimizing deleterious effects on the heart, vasculature and other organs and tissues. A baroreceptor activation device or other sensory activation device is positioned near a dermal bone to provide the treatment.