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(19) **United States**(12) **Patent Application Publication****Schonenberger et al.**(10) **Pub. No.: US 2005/0203444 A1**(43) **Pub. Date: Sep. 15, 2005**(54) **ULTRASOUND THERAPEUTIC DEVICE****Publication Classification**

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(51) **Int. Cl.⁷ A61H 1/00; A61B 8/00**(52) **U.S. Cl. 601/2**(57) **ABSTRACT**

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(73) Assignee: **Compex Medical S.A.**(21) Appl. No.: **11/066,102**(22) Filed: **Feb. 25, 2005****Related U.S. Application Data**

(62) Division of application No. 10/281,090, filed on Oct.
 25, 2002, now Pat. No. 6,860,852.

The ultrasound therapeutic system of the present invention generally includes a generator unit, at least one transducer treatment head, and a programmable controller. The generator is in operable communication with the at least one transducer treatment head such that electric power outputted from the generator to the head is converted into acoustic power by the head. Re-programmable software at the controller generally controls all features and functions for the system. In particular, the controller calculates an initial optimal treatment dose, maintains effective acoustic power transmitted to the patient through the at least one treatment head, performs calibration procedures for the at least one treatment head, controls outputting for each supported treatment mode, and provides for various other features and functions.

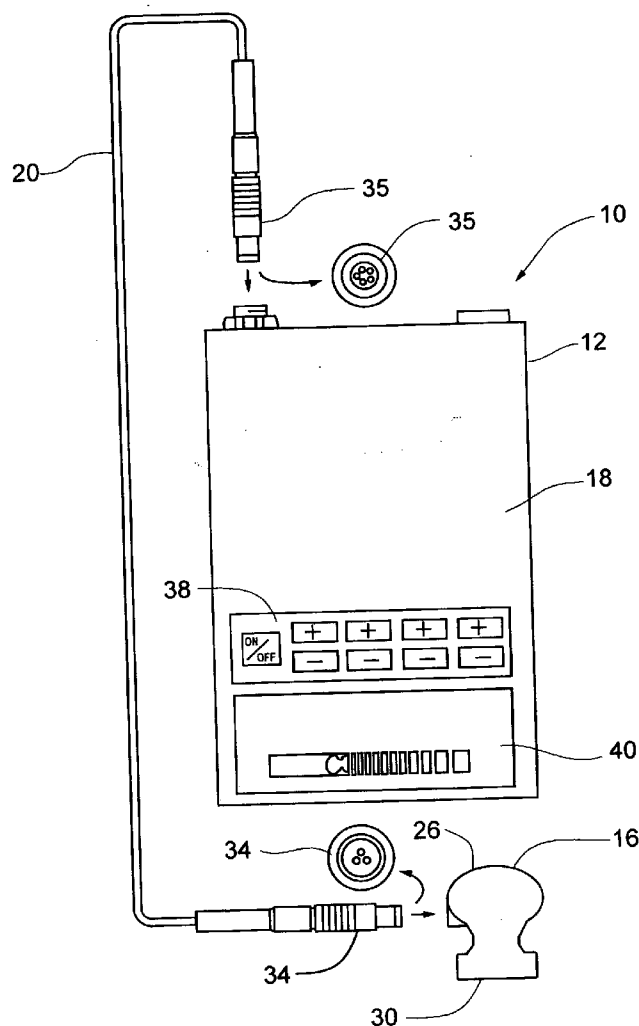


Fig. 1

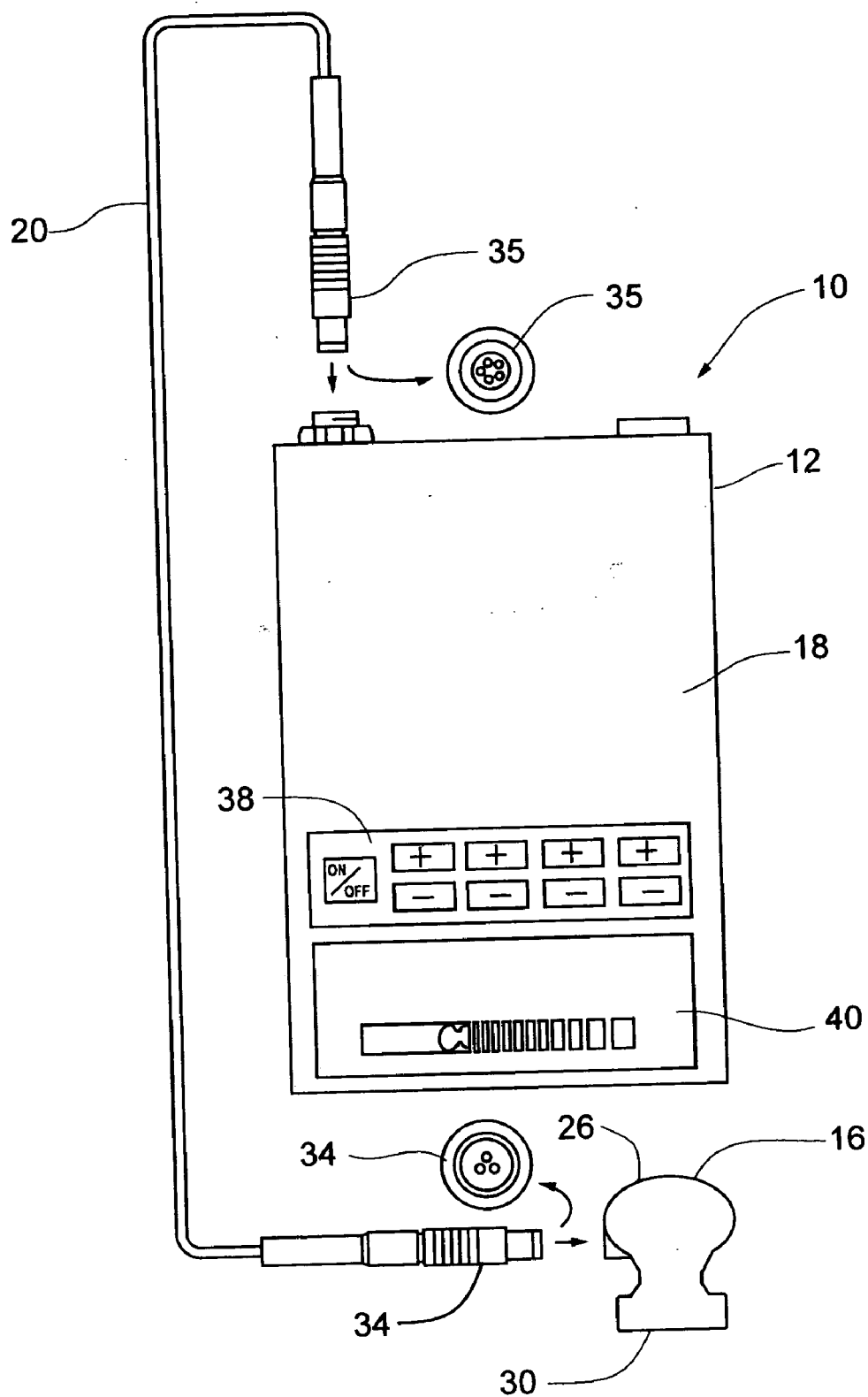


Fig. 2a

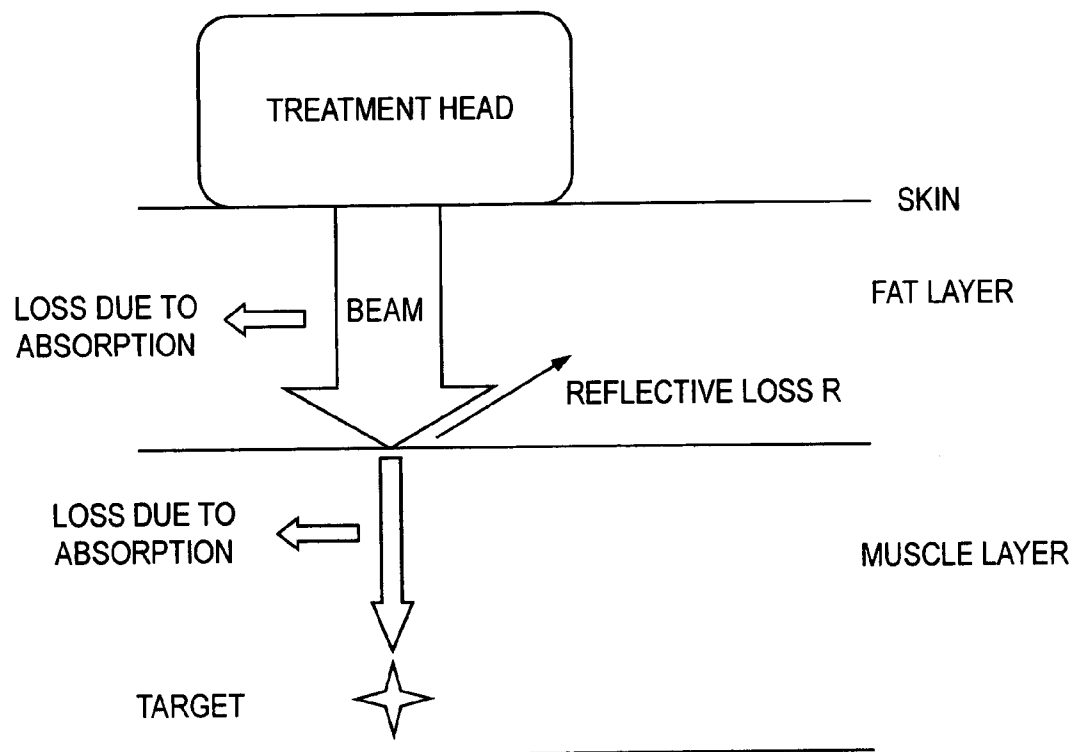


Fig. 2b

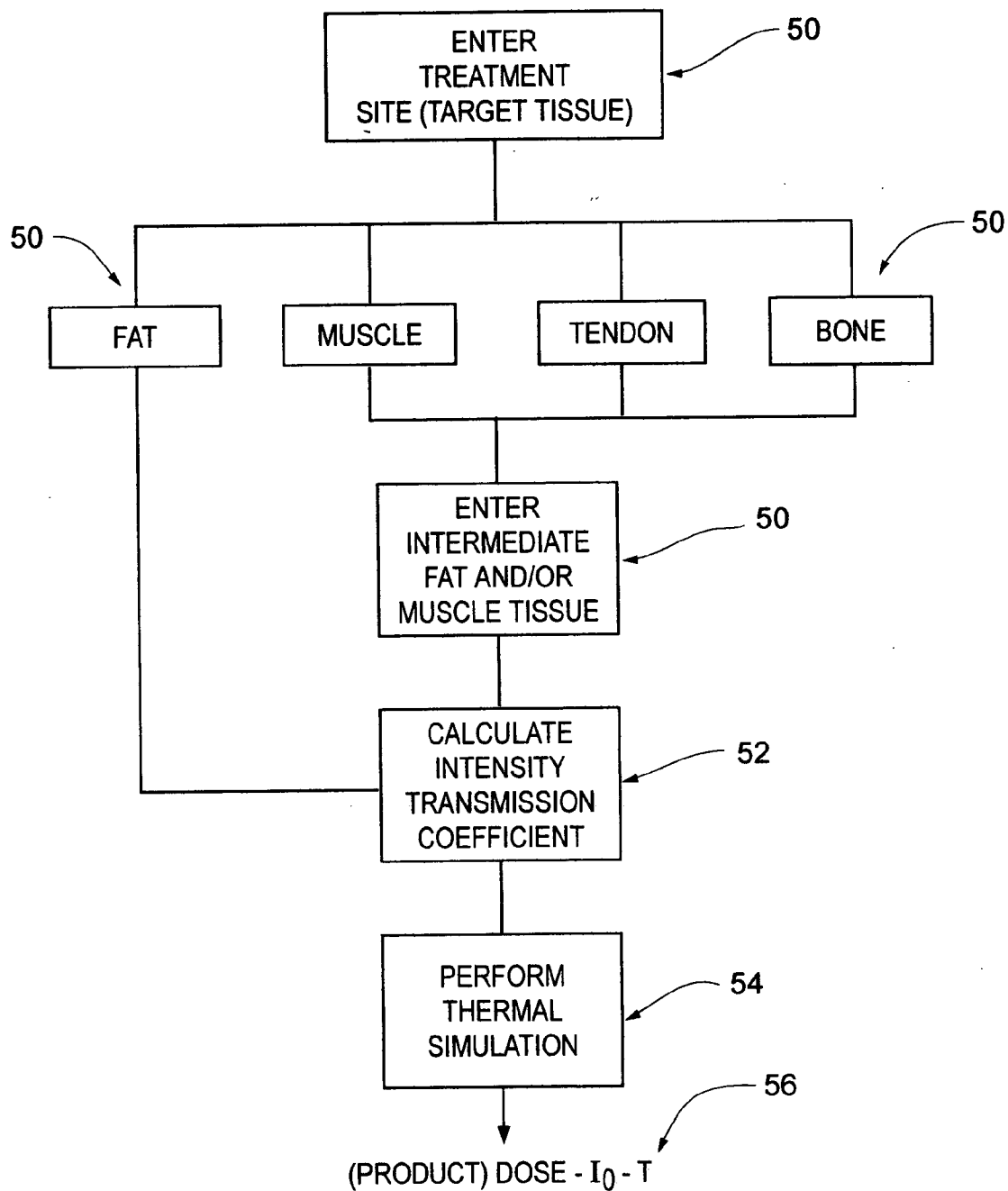


Fig. 3

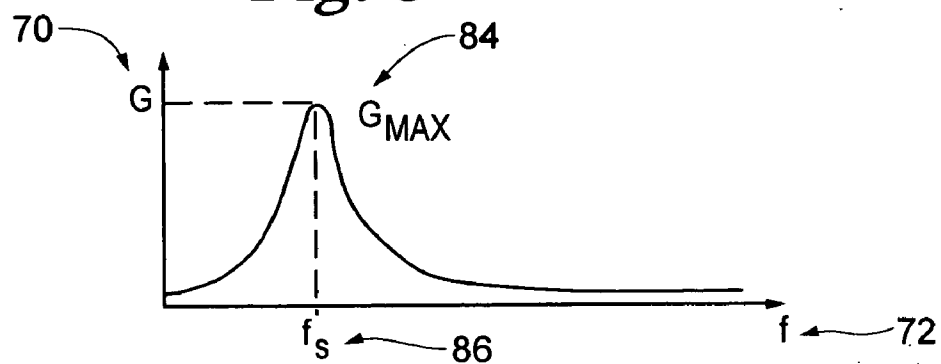


Fig. 4a

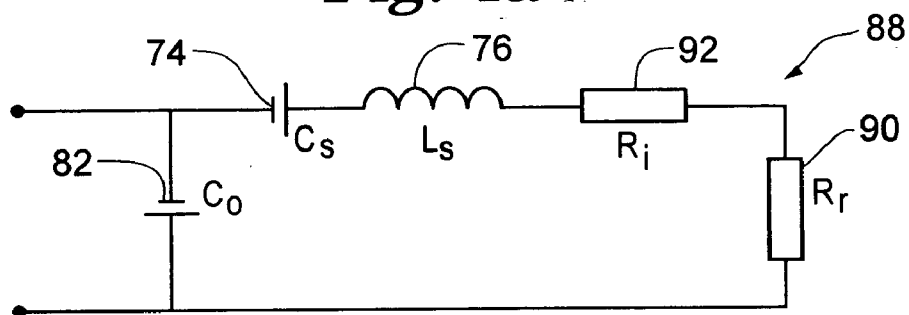
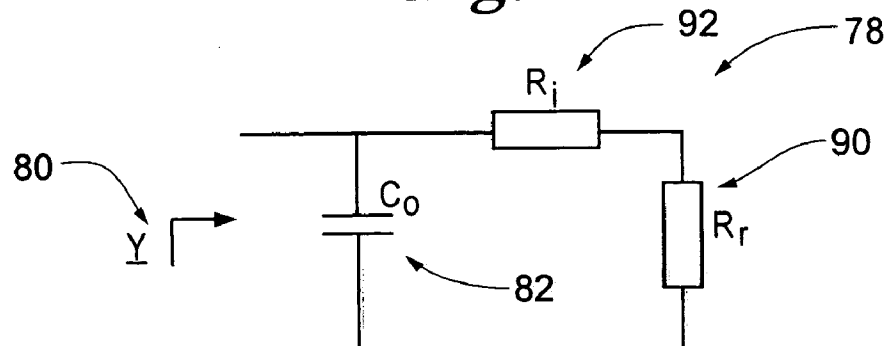


Fig. 4b



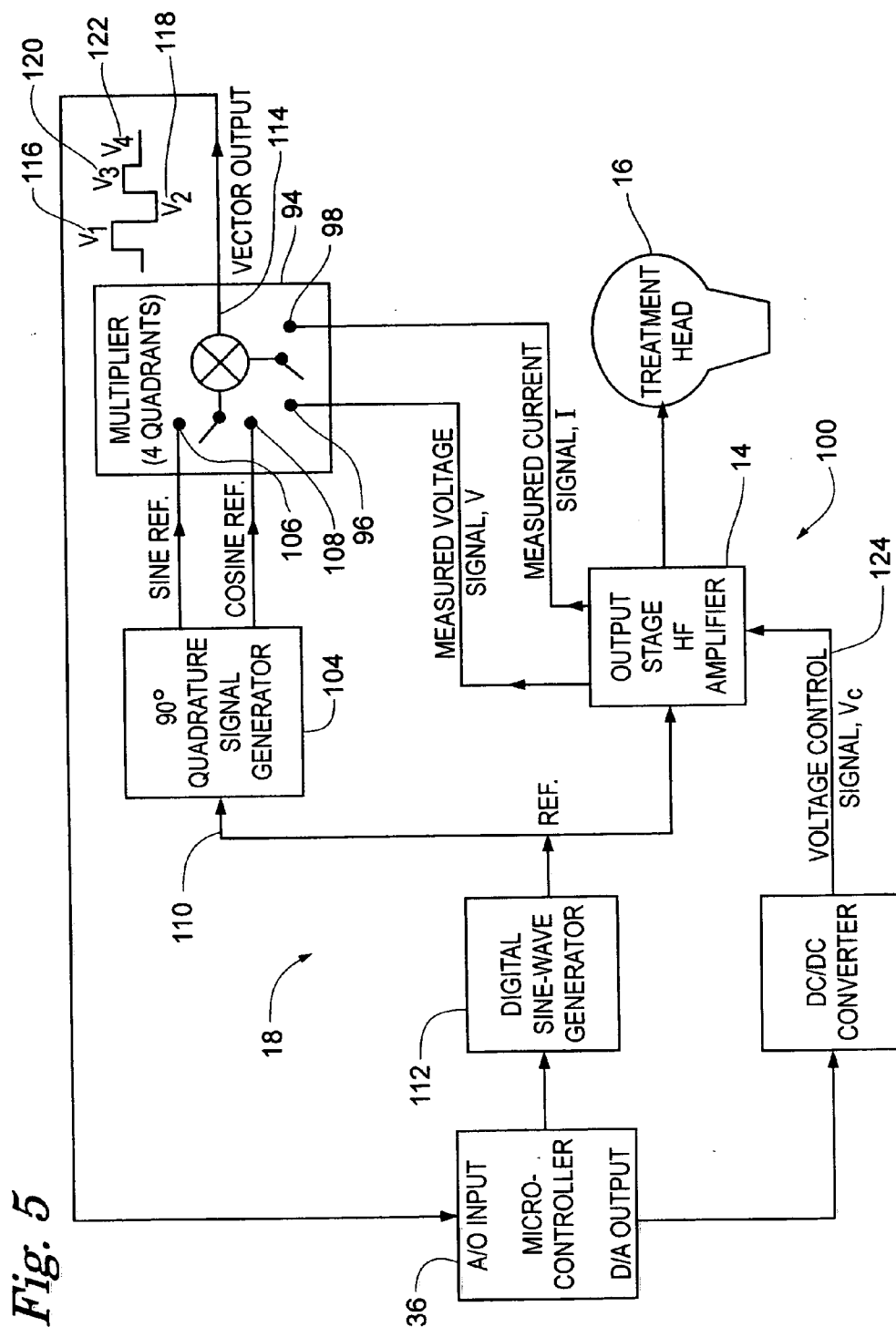
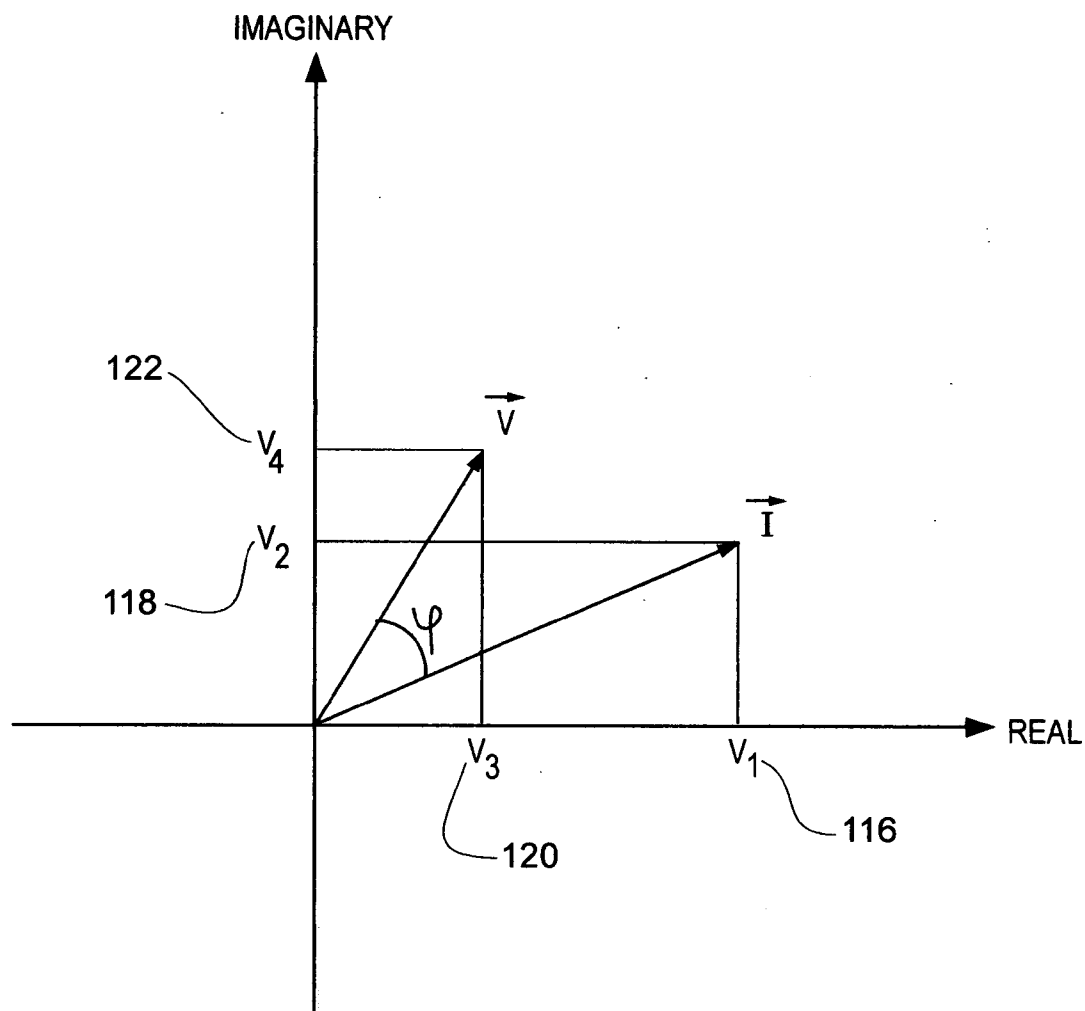


Fig. 6



ULTRASOUND THERAPEUTIC DEVICE

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a divisional application of co-pending U.S. application Ser. No. 10/281,090, entitled "Ultrasound Therapeutic Device," filed on Oct. 25, 2002, which will issue as U.S. Pat. No. 6,860,852, Mar. 1, 2005.

FIELD OF THE INVENTION

[0002] The present invention generally relates to the field of ultrasound treatment. More specifically, the present invention relates to an ultrasound therapeutic device capable of automatically determining a considerate treatment dose, controlling acoustic power output efficiency, and performing adjustable calibration functions.

BACKGROUND OF THE INVENTION

[0003] Therapeutic ultrasound devices have long been utilized in the treatment of musculoskeletal and tissue injuries. Greater understanding of ultrasound, and the application of ultrasound to human skin and tissue, have expanded the scope of possible uses for these devices. For instance, in addition to the thermal or vibratory focus of more traditional devices, developments have been made in which ultrasound devices can be directed toward introducing various drugs into the human body through the skin. However, the increase in potential uses and advantages for these therapeutic ultrasound devices has come at a price. Namely, advancements in the technology and the understanding of the potential applications, has correspondingly led to the complication of setup procedures, inefficient power adjustments, and the need for more precise calibration procedures.

[0004] Initial Parameter Inputs

[0005] Ultrasonic therapy devices impose mechanical vibrations on tissue and skin to cause various thermal and non-thermal effects. An ultrasound generator outputs electric power to a treatment head. The treatment head includes a transducer which converts the power from the generator into ultrasonic energy or acoustic power. It is this acoustic power that is transmitted for therapeutic treatment through the patient's tissue. The requisite acoustic power can vary greatly depending on the treatment goals, the target tissue type, the target tissue depth, and other like factors. In addition, the duration of the ultrasonic treatment dosage to the patient is important. Treatment goals, the unique characteristics of the target tissue, and like considerations dictate the treatment duration.

[0006] Conventional ultrasound treatment devices generate a treatment dose based on manually inputted values or parameters. Parameters such as treatment time/duration, frequency, and treatment intensity are inputted by the end user. Generally, with such devices, calculations and determinations are made by the user. Consequently, it is up to the device user to come up with the ideal treatment parameters required for a specific patient, assuming specific treatment goals for that patient.

[0007] There are many drawbacks with manually operated devices. Specifically, it is problematic that these manual systems are reliant upon the skills and knowledge of the individual user. This problem manifests itself in at least two

respects. First, there is no way to know or control exactly what factors are being considered by the user in calculating the proper treatment parameters. For example, there are no guarantees that the end user will properly consider the target tissue characteristics, the target tissue type, or the existence and depth of any intermediate tissue between the treatment head and the target tissue. These are all highly relevant factors that should play a primary role in determining the proper treatment outputs and durations for any effective ultrasound therapeutic treatment. In addition, accidental parameter entries, and the varying level of user training introduce still more uncertainty into the likelihood of providing optimized ultrasound treatment for the patient.

[0008] As indicated, the unique and specific characteristics of the target tissue, and the nature and thickness of intermediate tissue and/or the target tissue, are requisite factors to be considered in determining a proper ultrasound treatment dose. This is true since both the thermal and non-thermal effects of ultrasound are dependent upon these factors. Despite the fundamental importance of these considerations, conventional ultrasound therapeutic devices simply have not advanced methods and apparatus that properly consider and process known histological tissue characteristics in generating a treatment dose.

[0009] U.S. Pat. No. 5,413,550 ("the '550 Patent") discloses an attempt to provide for considerate dose control. The '550 Patent is directed to an ultrasound device including a controller programmed to calculate a treatment dose. The treatment dose consists of treatment frequency, output intensity, and treatment time. The programmed controller determines and generates the dosage parameters based on the inputting of numerous treatment parameters by the end user. Specifically, the device requires values for the following primary treatment parameters in order to calculate a dosage: depth of tissue to be treated, the desired tissue temperature rise, the tissue area to be treated, and the selection of an ultrasound couplant. In addition the user may input the tissue type, and a duty factor value as secondary parameters. The device of the '550 patent performs routine checks to determine if treatment parameters have been entered. If the controller determines that specific primary treatment parameters have not been inputted, the controller circuitry inserts a default value in place of the missing parameter(s). As a result, it is possible to enter only one of the primary treatment parameters, with each of the remaining parameters being substituted for default values. Such a default-driven device and process is problematic and fails to properly focus the ultrasound treatment on ultrasound effects and histological tissue data.

[0010] The use of default parameters to calculate dosage, by definition, fails to take into account the unique circumstances and characteristics of the patient, the treatment goals for the specific target tissue of the patient, and like goals and considerations that are essential in providing highly efficient and effective ultrasound treatment. As indicated herein, knowledge and specific consideration of the unique target treatment tissue, and the depth of that tissue or the thickness of intermediate tissue, are essential in generating an optimal treatment dose. Generating a dose, regardless of the automated nature of the calculation, is deficient if it fails to account for the true tissue structure, such as the energy losses produced as a result of tissue heating, and the losses caused by adjacent tissue structure. Ignoring such essential

characteristics of treatment on complex tissue structures dilutes the efficacy of the dosage calculation. Proper acoustic power outputs and treatment durations must be specified, monitored, and updated in a manner most beneficial for the treatment goals for the unique individual patient, after fully understanding and processing data pertaining to the target tissue, intermediate tissue, and tissue depths.

[0011] Treatment Dose Adjustments

[0012] Conventional ultrasonic therapeutic devices and systems are generally deficient when it comes to the continuous and efficient monitoring and controlling of the power being outputted from the generator to the transducer. The typical approach to controlling acoustic power from the transducer head is to merely provide alarm and display notices to the user. For example, U.S. Pat. No. 4,791,915 is directed to a device wherein the coupling efficiency between the transducer and the patient is displayed in the form of a readable bar graph for the user to observe and monitor. However, such systems and devices merely focus on preventing overheating and electrical shorting. Threshold comparisons are merely made in order to prevent catastrophic failures which could cause device malfunction and/or injury to the patient.

[0013] Other conventional ultrasound treatment systems implement adjustment techniques and controls directed to providing for a relatively constant electric power output level to the patient. For instance, U.S. Pat. No. 4,368,410 discloses an ultrasound therapy device wherein an optimal electric output power level is inputted into the device. Feedback signals from a driver circuit proportional to the transducer voltage and current are returned to an analog servo circuit and a voltage representing true electric power is calculated. If the output power represented by the voltage level increases then it is an indication that there is a reduction in the load on the transducer, and the drive signal is decreased. Similarly, if the instant voltage decreases, an increase in the signal is initiated to compensate for an increase in the load on the transducer. The innate problem with such a system is that while it does acknowledge the effects varying treatment techniques, treatment zones, and an individuals body can have on ultrasound treatment, it does not properly use this information in providing for a truly responsive individualized treatment dosage. Focus is on maintaining a constant electric power output and not on performing acoustic analysis. Events and circumstances effecting the ultrasound treatment are not properly considered—i.e., the introduction of intermediate tissue, the natural changes across a patient's body "zones", and the like.

[0014] Treatment Head Calibration

[0015] Each treatment head of an ultrasound therapeutic device requires calibration. Primarily, this calibration is needed in order to accommodate and adjust for various innate properties and characteristics unique to particular heads. The head must be properly calibrated in order to correctly match the specific resonance frequencies of its constituent ceramic. For instance, each ceramic treatment head varies in its material properties. As a result, proper operation and acoustic output for each and every head mandates at least an initial head calibration. Typically, this calibration is done in the factory prior to receipt of the device by the end user. In many cases, this is the only calibration allowed for, and any later re-calibration must

again occur at the factory. However, these factory calibrations are problematic since untimely degeneration can adversely affect treatment quality and effectiveness.

[0016] Even those conventional devices that permit for user-initiated calibration require the initiation of complicated or time-consuming procedures. Specifically, it is common to allow for user calibration by immersing the head in water and making a series of adjustments based on calibration readings displayed by the device. For obvious reasons, such techniques are undesirable and inconvenient. Additionally, conventional devices do not consider complex changes introduced by slight imaginary components in the acoustic impedance of the tissues being treated. Conventional devices are thus unable to transmit an accurate amount of power to the tissue or fully self-calibrate.

[0017] As a result, there is a need for an ultrasonic therapeutic device, and method for operating and controlling thereof, that substantially solves the problems and deficiencies described in the prior art.

SUMMARY OF THE INVENTION

[0018] The ultrasound therapeutic system and methods in accordance with the present invention substantially solve the problems and weaknesses present in the prior art devices and methods. The present invention is generally directed to an ultrasound treatment system wherein it is preferred that each of the described prior art deficiencies are addressed in one device. In general, the ultrasound device and methods of the present invention are directed to providing an optimal initial treatment dose based on complete processing of user-inputted histological tissue data, employing an automatic regulatory feedback loop to maintain optimal acoustic power output to the patient during operation, and providing a simple yet efficient user-initiated treatment head calibration technique. Further, the treatment system of the present invention includes multi-mode treatment techniques/effects, and user-specific memorization functions.

[0019] The ultrasound therapeutic system of the present invention generally includes a generator unit, at least one transducer treatment head, and a programmable controller. The generator is in operable communication with the at least one transducer treatment head such that electric power outputted from the generator to the head is converted into acoustic power by the head. Re-programmable software at the controller generally controls all features and functions for the system. In particular, the controller calculates an initial optimal treatment dose, maintains effective acoustic power transmitted to the patient through the at least one treatment head, performs calibration procedures for the at least one treatment head, controls outputting for each supported treatment mode, and provides for various other features and functions as will be discussed in further detail herein.

[0020] Unlike the prior art, the present invention is directed to intelligent and simplified automatic dosage determination. Specifically, the output dose is calculated by processing values inputted by the user for target tissue type, intermediate tissue type, and tissue depth/thickness. The present invention does not import or process arbitrary default values for treatment couplant, tissue configuration, and the like. Instead, dosage is based on the fundamental tissue data inputted, wherein the controller performs simu-

lation comparisons to derive the smallest dosage needed to optimally achieve the therapeutic treatment effect. Further, the dosage determination of the present invention, through processing of the inputted histological tissue data, takes into account the relevant tissue layer structure to adjust for the effects caused by innate losses through tissue absorption and reflections caused by impedance discontinuities between different tissue layers. Wave reflection and absorption characteristics are dynamically considered in order to properly understand the resulting output that will be delivered to the target tissue of the patient in light of the relevant tissue structure.

[0021] The feedback loop of the present invention is also considerate in its function. Rather than seeking to maintain a constant electrical output, as is often practiced in conventional devices, the ultrasound device of the present invention controls and monitors the effects of the treatment on the transducer head to maintain a constant ideal acoustic power. As a result, changes that may occur naturally during treatment, such as changes caused by the innate acoustic properties of the tissues proximate the treatment head, are properly considered.

[0022] To ensure that the ultrasound device of the present invention is operating safely and effectively, the present invention includes an automatic calibration feature. This feature enables new and replacement treatment heads to be introduced without having to send the entire device away for calibration. The ultrasound device of the present invention automatically determines the complex impedance of the transducer head, after calibration, and maintains acoustic power even in the presence of changes in the real or imaginary portion of the acoustic impedance of the relevant tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] FIG. 1 is a front view of an embodiment of an ultrasound therapeutic device in accordance with the present invention.

[0024] FIG. 2a is a diagram demonstrating ultrasonic beam absorption and reflection losses resulting from a specific human tissue structure.

[0025] FIG. 2b is a block diagram of the operation of thermal dosage control in accordance with an embodiment of the present invention.

[0026] FIG. 3 is a diagram plotting the frequency versus conductance of a transducer in accordance with an embodiment of the present invention.

[0027] FIG. 4a is a diagram of transducer circuitry in accordance with an embodiment of the present invention.

[0028] FIG. 4b is a diagram of transducer circuitry in accordance with an embodiment of the present invention.

[0029] FIG. 5 is a block diagram of the ultrasound system in accordance with an embodiment of the present invention.

[0030] FIG. 6 is a diagram depicting the real and imaginary components of measured voltage and current in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0031] Referring primarily to FIGS. 1 and 5, an ultrasound therapeutic system 10 in accordance with the present

invention is shown. Specifically, the ultrasound system 10 generally includes a device housing 12, a generator/output stage high frequency amplifier 14, at least one transducer treatment head 16, and a programmable controller 18. The generator 14 and controller 18 are housed within the device housing 12, and are both in operable communication with the transducer 6 via a frequency cable 20.

[0032] The generator 14, as shown in FIG. 5, is an electric power source commonly understood by one skilled in the art. For instance, a 48 Volt dc, 0.85 Amp main power source can be utilized in one embodiment, while others could implement similar compatible units. First and second working frequencies of the generator 14 are preferably approximately 1.017 MHz and 3.2 MHz, respectively. It is possible to have a measurable tolerance/deviation of ± 30 KHz on the first frequency and ± 50 KHz on the second frequency. Other output frequencies and permissible frequency tolerances understood to one skilled in the art are also envisioned. The electric power frequency outputs are outputted from the generator 14 to the transducer head 16 through the frequency cable 20.

[0033] The at least one transducer treatment head 16 is a transducer head of a predetermined size, with the head 16 generally including a handling portion 26, a transducer element 28, and a treatment surface 30. Each treatment head 16 utilized for the present invention is preferably watertight for optimal use even if completely submerged. Various embodiments can employ different sized treatment heads 16. For instance, ultrasound treatment needs and human body structure and size for a specific focus treatment region on an individual can influence the size of the treatment head. Generally, a large and small head will be interchangeable using the same frequency cable 20. The ultrasonic transducer element 28 of the treatment head 16 is typically constructed of a ceramic (piezo) material. As such, the element 28 will have a maximum output of acoustic power substantially at its resonance frequency. As will be further discussed herein, the treatment head 16 will require initial and, perhaps, periodic self-calibration to guarantee that this optimal resonance frequency for the respective transmission element 28 is obtained and maintained. While various treatment heads 16 can be exchanged to meet specific ultrasonic treatment requirements, there is no need to switch out the cable 20. Conventional devices utilize a unique cable for each treatment head, a practice that can be quite costly, and that can make transportation and storage cumbersome and inconvenient. As discussed herein in describing the cable 20, the present invention eliminates this innate drawback found in conventional devices.

[0034] In one embodiment of the present invention, the treatment head 16 further includes a configuration monitoring chip to measure, observe and store data. For instance, operation temperature at the head 16, head 16 serial numbers, head size, calibration data, and a myriad of other information can be stored such that the controller 18 in operable communication with the head 16 can store data to, and retrieve data from, the head 16. This storage and reprogramming can be accomplished with the use of EEPROM, or other non-volatile memory and storage technologies. For instance, a Dallas DS-1820 chip (manufactured and sold by Dallas Semiconductor of Dallas Texas), or other chips capable of performing these storage and moni-

toring functions can be utilized without deviating from the spirit and scope of the present invention.

[0035] The frequency cable **20** shown in **FIG. 1** generally includes at least one set of end connectors **34** and **35** sized and shaped for connecting to respective system **10** components. In particular, at least one end connector **35** can be removably connected to the generator **14** at the housing **12** and the distal end connector **34** of the same cable **20** can be removably connected to the transducer treatment head **16**. As such, various treatment heads **16** can be exchanged for operable use with the one common cable **20**. This unique swap/exchange feature is possible due to the selectively engageable distal end connector **34**. Unlike conventional practice, a fixed and head-specific cable is avoided such that the present invention promotes interchangeability and treatment flexibility, while at the same time promoting storage and transportation. Each of the end connectors **34** and **35** is generally combined or connected to a system component via a socket or plug connection to facilitate maintenance, selective replacement, and adjustable configuration, with each connection preferably being watertight.

[0036] Referring primarily to **FIG. 5**, the controller **18** includes a microprocessor **36** and control circuitry for providing re-programmable software and hardware control of the present invention. The microprocessor **36** is programmed to receive input and execute control software/algorithms in accordance with predetermined and inputted data. The microprocessor **36** is housed within the housing **12** and is in operable communication with the generator/output stage high frequency amplifier **14**, treatment head **16**, and each of the other components directly and/or through the controller **18**. In various embodiments, flash ROM, EEPROM, non-volatile memory, and RAM can be employed in conjunction with the microprocessor **36** at the controller **18** for data storage and retrieval.

[0037] Referring again to **FIG. 1**, the housing **12** generally includes a data input portion **38** and a display portion **40**. The input portion **38** can comprise input keys or other known input devices for receiving data inputted by an end user in response to prompting from the display portion **40** or from volitional decisions to pursue known treatment goals and program routines. The data input portion **38** and display portion **40** are in operable communication with the controller **18**.

[0038] In operation, the system **10** of the present invention can prompt the end user to input specific individualized treatment data, wherein the controller **18** can utilize the data to calculate and initiate ultrasound treatment, and provide responsive output and interface adjustments during treatment. In one embodiment, a treatment session or use of the system **10** will involve the following series of inputs, outputs, and automatic adjustments.

[0039] First, a treatment "type" must be inputted into the system **10** via prompting on the display portion **40**. Generally, there are at least three treatment types: thermal, biological, and phonophoresis. Thermal allows the end user or patient to receive a thermal energy effect from the treatment head **16** at the treatment surface **30**. Specifically, such a treatment selection initiates a specific device configuration at the controller **18** wherein the ultrasound energy transmission is converted into thermal energy. Such a conversion leads to a local temperature elevation which par-

ticularly effects deeper dense tissue of the patient. As further discussed herein, the proper ultrasound transmission is highly dependent upon inputted histological data from the patient/end user.

[0040] The selection of a biological treatment type is directed to a pulsed ultrasound output mode wherein the pulse causes the oscillation of molecules accompanied by marked pressure variations. In turn, this oscillation can lead to the formation of micro-bubbles by cavitation, which in turn can produce a beneficial micro-traumatic stress in indurated tissues, inflammatory foci, local calcified accumulations, and the like.

[0041] The selection of a phonophoresis treatment type permits the patient to take advantage of the increased skin permeability that accompanies ultrasound waves. Radiation pressure at the skin due to the inherent permeability increase promotes penetration of medicines through the epidermis layer of the patient. With this treatment selection, there is generally no need for the patient to input histological data or treatment parameters since ideal penetration of the substance is predetermined to facilitate performance and efficiency. In one embodiment, the selection of the phonophoresis treatment mode will cause the microprocessor **36** to set the treatment parameters to the following values: intensity=1.5 W/cm²; duration=8 minutes; frequency=3.2 MHz; emission mode=pulsed; duty cycle=½. Other variations on these values are envisioned and can be employed and pre-programmed into the microprocessor **36** software without deviating from the spirit and scope of the present invention.

[0042] In addition, a manual setting is selectable so that the patient can control each of the relevant microprocessor-controlled treatment parameters—intensity, duration, frequency, and emission mode. However, in preferred embodiments, these treatment parameters are calculated and adjusted automatically by the controller **18** implementing software algorithms running on the microprocessor **36**.

[0043] Specifically, in thermal and biological treatment modes, histological structure data for the individual patient is needed. This histological data generally comprises the target tissue type (tissue to be treated), and the intermediate tissue type and depth (subcutaneous tissue, if any, between the device and the target tissue). Accurate calculation and inputting of this limited histological data will provide the microprocessor **36** with enough information to provide for a highly controlled and efficient treatment of the patient. The necessary treatment parameters and treatment dosage can be selectively and effectively controlled having only this histological data from the patient/user.

[0044] The target tissue is generally selected at the input **38** panel of the system **10** from a programmable list. This list can comprise bone, muscle, fat, aponeurosis, tendon, or other targets known to one skilled in the art. In some circumstances, the target tissue will be the only inputted/selected histological data. For instance, if the target tissue is fat, there may not be an intermediate tissue to take into account in controlling the ultrasound treatment to the patient. As such, only the depth of the fat target tissue will need to be inputted.

[0045] In other circumstances, the effect of relevant intermediate tissue must be accounted for in determining a treatment dosage. For example, in one operating scenario the

target tissue selection may be muscle. As such, it may be necessary to input the thickness or depth of the intermediate tissue between the treatment head 16 and the target muscle tissue. The intermediate tissue depth can be measured with the use of skinfold pinch calipers, estimated on the basis of the physician's or therapist's knowledge of human anatomy (i.e., palpatory anatomy), and the like. The microprocessor 36 can take the inputted histological data alone and determine the proper intensity, duration, frequency, and emission mode. The software will generally select the individual treatment parameters from the following range list: intensity=0 to 2.3 W/cm²; duration 0 to 30 minutes (1800 seconds); frequency=approximately 1 or 3 MHz; emission mode=continuous (1/1) or pulse (1/2, 1/4, or 1/8).

[0046] Upon the inputting of user selections and the computed parameter settings and feedback controls, the treatment session will begin by applying the treatment head to the target location on the patient. The treatment head 16 output dosage is controlled by the controller 18. If at any time the head 16 is removed from the patient during the designated treatment period, for a predefined period of time, the controller 18 will initiate a shut down procedure to stop output from the generator 14 to the treatment head 16.

[0047] Thermal Treatment Mode

[0048] In thermal mode, the algorithmic simulation functions of the microprocessor 36 automatically calculate and control the treatment dosage to create a tissue temperature elevation based on the relevant histological data. Preferably, the intensity and duration parameters are fully correlated. A change, either manually or automatically, will cause the microprocessor 36 software to automatically change the remaining value correspondingly such that the product of the at least two values remains substantially unchanged. The product of intensity and duration is generally used to produce a target tissue temperature elevation of 7 degrees Celsius. A continuous transmission (1/1), rather than pulsed, is typically initiated by the software in thermal mode since such a transmission promotes the desired tissue temperature elevation.

[0049] This product of acoustic intensity and treatment duration is the treatment dosage. As shown in FIG. 2a, the dosage is a function of the losses from absorption of the ultrasound beam as it travels through relevant tissues and the losses from reflections at the interfaces between adjacent tissues having different acoustic impedances. The quantity of ultrasound which ultimately reaches the target tissue is the therapeutically effective energy which participates in the local elevation of tissue temperature. Since the temperature elevation depends on dosage, the user can change the remaining treatment duration or the intensity at any time.

[0050] The software selects the frequency of the output signal based on the histological data inputted. Specifically, the target depth and intermediate tissue dictate the level of penetration required to provide an effective therapeutic dose. In one embodiment, a frequency of approximately 1 MHz is utilized to penetrate relatively deep tissue since such a signal will be less absorbed by the tissue. Conversely, a frequency of approximately 3 MHz is utilized to penetrate relatively shallow tissue. Preferably, the microprocessor 36 software performs simulations at both the 1 MHz and 3 MHz levels to determine which signal will require the smallest dosage while still obtaining the requisite therapeutic effect. Other

predetermined or variable frequency determinations can be made as well without deviating from the spirit and scope of the present invention.

[0051] Referring to FIG. 2b, one embodiment of the automatic mode dosage determination software is shown. First, the user is required to enter specific data at an initial input stage 50. At this data input stage 50, the user is first prompted to enter a target tissue type. Generally, fat, muscle, tendon, and bone are the tissue types available for selection or input. Once the tissue selection has been made, the user is prompted to input the depth of the tissue between the target and the treatment head 16. It is preferred that this depth be entered in centimeters, but other measurements are also envisioned. For instance, if the target tissue inputted is tendon, it is possible that there is muscle and/or fat intermediate the tendon. As discussed, this tissue intermediate the target tissue must be considered before calculating a truly effective treatment dosage. Tissue depth and thickness calculations can be performed using techniques known to one skilled in the art. For instance, pinch calipers and the physician's or therapist's knowledge of the human anatomy can be employed. Depending on the presence of intermediate fat or muscle, and the corresponding depth for the intermediate tissue, the microprocessor 36 software will process the data at an intensity transmission stage 52.

[0052] At the intensity transmission stage 52, the actual transmission effects of the tissue layer structure are considered in calculating a transmission coefficient τ . Variable τ represents reflection losses caused as a result of the layers and tissue interfaces to assist in providing for needed adjustment in the dosage, wherein τ is represented in equation form as:

$$\tau = 1 - R_{ij}$$

[0053] where R_{ij} is the tissue intensity reflection coefficient between layer i and j . This reflection coefficient depends on the acoustic impedance of layer i (Z_i) and layer j (Z_j):

$$R_{ij} = \frac{(Z_i - Z_j)^2}{(Z_i + Z_j)^2}$$

[0054] Defined tissue impedance levels for bone, skin, tendon, muscle, and fat are known and processed depending on the referenced tissue inputs such that each impedance value corresponds to a wave reflection at the interface of adjacent tissues. For instance, a τ value representing the influence of the reflection characteristics of interfacing fat and tendon tissue (τ_{ft}) will equate to a coefficient of 0.934, which represents a 93.4% transmission intensity and a 6.6% loss due to reflections at the interface. Assuming m=muscle, t=tendon, f=fat, and b=bone, other possible transmission loss characteristics can be accounted for as $\tau_{mt}=0.974$, $\tau_{st}=0.968$, $\tau_{sb}=0.748$, $\tau_{fb}=0.685$, $\tau_{mb}=0.761$, $\tau_{fm}=0.990$, $\tau_{fs}=0.990$, $\tau_{sm}=0.890$, $\tau_{tb}=0.870$, and other transmission coefficients known to one skilled in the art.

[0055] Additionally, reduction of the available energy at the target tissue is caused by a beam attenuation (a) phenomenon. First, this attenuation is due to absorption (α), which is a transformation of a fraction of the acoustic beam into heat. Second, beam diffusion or scattering (d) also

contributes to the beam attenuation. As such, $a=\alpha+d$. For scenarios involving soft tissues and at frequencies in the MHz range, scattering may be neglected so that $a=\alpha$, for a unit measurement of Np/cm^2 (Nepers per square centimeters).

[0056] At the thermal simulation stage 54, the appropriate ultrasound frequency intensity (I_0) and treatment duration (T) are calculated such that the product of the intensity and the treatment duration equals the treatment radiation dosage D. In obtaining the correct variables for this dosage formula, an ideal frequency must be calculated. This ideal frequency for the ultrasound intensity I_0 is based on a simulation run for at least two frequencies—1 MHz and 3 MHz. It should be noted that these frequencies, while preferred, are not in any way exhaustive in nature. For instance, other frequency ranges and values can be utilized depending on the particular desired therapeutic effect. In addition, values such as 1 MHz and 3 MHz are obviously rounded for ease of explanation and calculation. In one embodiment, the frequency intensities can be assigned as $1.017 \text{ MHz} \pm 30 \text{ KHz}$, and $3.2 \text{ MHz} \pm 50 \text{ KHz}$. Other values and corresponding ranges are also envisioned.

[0057] In an embodiment performing an individual simulation run for both 1 MHz and 3 MHz levels, the following equation is implemented:

$$D = (I_0 \cdot t) = \frac{TC_v}{2\alpha \cdot f \cdot \tau} e^{2f(a1t1+a2t2+a3t3)}$$

[0058] wherein the frequency value f is inserted by the microprocessor 36 program as either 1 or 3 depending on the particular simulation run, T is the treatment duration (i.e., seconds), C_v is a thermal coefficient (heat capacity per unit volume), a is the attenuation coefficient, and τ again represents consideration of the effects of the actual tissue layer structure in an intensity transmission coefficient. As the appropriate τ value has already been processed in the intensity transmission stage 52, that value is automatically inserted to promote evaluation of true tissue effects during the treatment simulation. The attenuation coefficient a represents absorption within the tissue layer of a level of energy lost in the form of heat. Variable attenuation coefficient values known to one skilled in the art as being representative of these tissue-specific heat absorption effects can be employed without deviating from the spirit and scope of the present invention.

[0059] With calculation and insertion of the appropriate values into the simulation equation, a product A is assigned the resulting dosage product for 1 MHz, and B is assigned the dosage product for 3 MHz. The products A and B are compared and analyzed to determine the smallest dose D that can be employed while still reaching the desired therapeutic effect based on known histological data from the user. Preferably, if $A \geq B$ then a value of 3 MHz is assigned as the output frequency, else a value of 1 MHz is assigned. Next, intensity and treatment duration end points are examined based on the simulation results to determine optimum values for generating the product dosage, wherein the resulting product dosage is processed to determine whether it falls within an acceptable range defined by predetermined minimum and maximum product dosage values. These values, in

one embodiment, can be a minimum dosage value of $6 \text{ Ws}/\text{cm}^2$ (Watt seconds per square centimeter) and a maximum value of $5400 \text{ Ws}/\text{cm}^2$. For instance, if a maximum product dosage of 5400 is calculated based on the above simulation equations, then a set intensity I_0 , is assigned to approximately $3 \text{ W}/\text{cm}^2$, with a corresponding treatment duration of approximately 1800 seconds. Further, the microprocessor 36 can downsize the dosage if it exceeds the maximum, up the dosage if it equates to a value below the acceptable minimum level, and can process variable levels between these end point values. At the completion of the comparison and simulation, the duration T, and intensity I_0 are known values that can be linked at a product dosage stage 56, wherein the product dosage $P=I_0 \cdot T$. This equation links the variables such that a change in one variable can cause the microprocessor 36 program to correspondingly change the other variables to produce a constant dosage.

[0060] Biological Treatment Mode

[0061] In biological mode, the algorithmic simulation functions of the microprocessor 36 take tissue configuration into account and automatically select the treatment parameters that will produce the required mechanical effect and minimize tissue temperature elevation. Whereas a tissue temperature elevation is the desired effect in the thermal treatment mode, a thermal effect is not beneficial and must be minimized in biological mode in favor of a mechanical effect.

[0062] The software automatically determines the intensity, frequency, emission mode and duration of treatment needed in biological mode. In one embodiment, these values are obtained from a look-up table. The desired mechanical effects of biological mode are typically induced using a pulsed emission mode with different duty cycles. The ultrasonic pressure waves produce an oscillation of molecules in the target tissue. This oscillation creates microscopic bubbles called cavitation bubbles that generate small shockwaves in the tissue when they collapse. These small shockwaves induce microscopic mechanical effects in the tissues that enhance the healing process by causing the tissues to grow stronger in reaction to the micro-traumatic stress effect. Biological mode is typically beneficial to indurated tissues, inflamed areas, local calcifications, accumulations of blood such as hematomas, bruises and blood clots, and areas of fibrosis.

[0063] Phonophoresis Treatment Mode

[0064] In phonophoresis mode, ultrasound is employed to aid in the penetration of drugs through the skin and into target tissue. Phonophoresis mode enhances local application of a drug by increasing the permeability of the skin and exerting a radiation pressure that promotes the penetration of drugs deep into tissues.

[0065] In one embodiment, all software parameters in phonophoresis mode are fixed and the dose is held constant. While the intensity and treatment duration may be adjusted, the microprocessor 36 software links the two conditions inversely such that an increase inputted in either will cause the software to decrease the other. Again, phonophoresis treatment mode will generally cause the microprocessor 36 to set the treatment parameters to the following values: intensity= $1.5 \text{ W}/\text{cm}^2$; duration=8 minutes (480 seconds); frequency=3.2 MHz; emission mode=pulsed; duty cycle= $\frac{1}{2}$.

[0066] Automatic Feedback Loop

[0067] Ultrasound treatment is more effective when constant acoustic power is delivered to the tissue. The ultrasound generator **14** includes a novel feedback loop feature that operates to maintain the delivery of acoustic power at a constant level. A simplified block diagram **100** of the feedback loop in accordance with the present invention is shown in **FIG. 5**.

[0068] The feedback loop operates to measure a coupling efficiency between the transducer treatment head **16** and the biological tissue of the patient. The coupling efficiency is a ratio of the acoustic power effectively transmitted into the patient to the electric power delivered to the transducer treatment head **16** from the generator **14**. Thus, the coupling efficiency can be expressed as:

$$\eta = \frac{P_a}{P_e}$$

[0069] where η is the coupling efficiency, P_a is the effective transmitted acoustic power and P_e is the delivered electric power. The coupling efficiency is dependent on patient tissue configuration as tissue impedance varies with tissue type. For example, if the tissue in contact with the transducer treatment head **16** is soft, i.e., skin with a thick layer of fat, the acoustic impedance will be low and the coupling efficiency will be low. If the tissue is instead skin with a thin layer of fat and a large bone near the skin surface, the coupling efficiency will be higher.

[0070] The microprocessor **36** adjusts the electric power, P_e , such that the effective acoustic power transmitted to the patient is maintained constant regardless of the tissue type encountered. While the coupling efficiency, η , can be expressed by the above equation, the microprocessor **36** uses a modified equation to calculate η and determine the transducer efficiency for the purpose of adjusting the electric power to maintain the acoustic power.

[0071] **FIG. 4a** depicts an equivalent circuit **88** of the piezo transducer close to its resonant frequency in accordance with the present invention. In the equivalent circuit **88**, internal mechanical losses are represented by R_i **92**, and R_r **90** represents the radiation resistance. The acoustic power emitted can be viewed as the power dissipated across the radiation resistance, R_r **90**. Where R_s represents the sum of R_i **92** and R_r **90**, the value of R_s can be obtained by measuring the overall admittance (the reciprocal of the overall impedance) of the equivalent circuit at resonant frequency. At resonant frequency, C_s **74** and L_s **76** resonate together and further reduce the equivalent circuit **88** to the circuit **78** depicted in **FIG. 4b**. The overall (complex) admittance, Y **80**, of the circuit **78** (and the equivalent circuit **88** of **FIG. 4a**) is the sum of the admittance of the resistance R_s (where $R_s = R_r + R_i$) and the admittance of the capacitor C_0 **82**, such that:

$$Y = Y_R + Y_C = G + jB = \frac{1}{R_s} + \frac{1}{j\omega C_0}$$

[0072] where G , the conductance, is the real portion of the admittance and B , the susceptance, is the imaginary portion. Thus, the conductance, G , of the equivalent circuit **88** of the transducer at resonant frequency is $1/R_s$, which results in the value of R_s itself.

[0073] **FIG. 3** is a diagram plotting the frequency **72** versus conductance **70** of a transducer **16** in accordance with the present invention. To measure the value of R_s , it is necessary to find the maximum value of the real portion of the admittance, G_{\max} **84**, where

$$G_{\max} = \frac{1}{R_s}$$

[0074] This will also provide the series resonant frequency, f_s **86**. The equation for Y **80**, above holds true only at the resonant frequency f_s **86**, of the piezo transducer **16**, defined by the maximum of the real portion of Y **80**, G_{\max} **84**. **FIG. 4** depicts the shape of a curve of the conductance, G **70**, plotted against frequency, f **72**, and demonstrates the relationship between G_{\max} **84** and f_s **86**. Note that the series resonant frequency f_s **86** will vary for each transducer treatment head **16** used. Calibration of a particular transducer treatment head **16** consists of the microprocessor scanning the frequency of the signal and simultaneously monitoring the conductance, G **70**, in order to detect a maximum (see **FIG. 3**). The locus of the maximum, G_{\max} **84**, defines the resonant frequency, f_s **86**. This calibration procedure is initiated by a user while the transducer **16** is unloaded (e.g., not in contact with any tissue) and is discussed in greater detail in the following section.

[0075] Referring again to **FIGS. 4a** and **4b**, the effective radiation resistance R_r **90** actually represents the transmission of ultrasonic energy out of the transducer. When measuring the transducer radiating into a tissue load, the maximum conductance, G_{\max} **84** of **FIG. 3** as discussed above, actually provides:

$$G_{\max} = G_{\text{tissue}} = \frac{1}{R_{\text{tissue}} + R_i}$$

[0076] When the maximum admittance is measured without any load, the maximum conductance, G_{\max} **84** (the real portion of the admittance), is almost exclusively the internal losses:

$$G_{\max} = G_0 = \frac{1}{R_i}$$

[0077] where G_0 is the series conductance of the unloaded transducer treatment head **16**. Thus, if the dielectric losses are neglected, the transducer **16** efficiency can be approximated by:

$$\eta_{eo} = \frac{G_0 - G_{\text{tissue}}}{G_0}$$

[0078] **FIG. 5** represents a block diagram of the ultrasound system in accordance with an embodiment of the

present invention. In operation, the analog multiplier **94** receives a measured voltage signal **96** and a measured current signal **98** from the generator/output stage high frequency amplifier **14**. The analog multiplier **94** is also connected to a 90-degree quadrature signal generator **104**. The 90-degree quadrature signal generator **104** receives a reference sine wave **110** from the digital sine wave generator **112** and in turn provides the analog multiplier **94** with sine **106** and cosine **108** reference signals. Vector voltage V_i **114**, the output of the analog multiplier **94**, represents V_1 **116**, V_2 **118**, V_3 **120** and V_4 **122**, which are generated by switching the inputs of the analog multiplier **94** circuit as shown in **FIG. 6**.

[0079] The electrical power P_e , can then be calculated from V_i **114**, where:

$$P_e = |\vec{V}| |\vec{I}| \cos \phi$$

[0080] The complex transducer **16** impedance \underline{Z} can be calculated by dividing \underline{V} by \underline{I} , and the conductance G is the real portion of the inverse of \underline{Z} , or the real portion of \underline{I} over \underline{V} . After the efficiency η and the electric power P_e are calculated from the input voltage, the effective transmitted acoustic power P_a can be calculated. The voltage control signal V_c **124** can then be adjusted and readjusted accordingly to maintain the delivery of acoustic power at a constant level.

[0081] In sum, the procedure used by the microprocessor **36** for determining the efficiency of the transducer is as follows: (1) determine vector voltage V_i **114**, having components V_1 **116**, V_2 **118**, V_3 **120** and V_4 **122**, by measurement; (2) calculate the coupling efficiency and the electric power from the vector voltage **114**; (3) calculate the effective transmitted acoustic power; and (4) readjust the voltage control signal **124** accordingly. In operation, the microprocessor **36** is thus able to maintain a constant level of effective acoustic power transmitted to the patient by adjusting the electric power approximately every 20 milliseconds in response to the coupling efficiency calculated in the feedback loop. Additionally, during emission, the microprocessor **36** regularly scans the G_{\max} **84** value in order to detect if f_s **86** has shifted and readjusts accordingly.

[0082] Further, during transmission the microprocessor **36** monitors the feedback loop, with notification provided if the feedback loop fails. A failure of the feedback loop may occur, for example, when the user removes the treatment head **16** from the patient, which results in insufficient acoustic coupling. In the event of such a failure, transmission is stopped and the ultrasound therapeutic system **10** puts itself into resonance search and output calculation mode. Once the acoustic coupling returns to an acceptable level (by the user having placed the treatment head **16** back in contact with a patient's skin), the feedback loop is restarted and normal operation resumes. The microprocessor **36** also monitors the resonant frequency **86** search and centering, and the presence of the treatment head **16**. Throughout, the system **10** continuously scans the frequency over a range around the nominal resonant frequency f_s **86** to ensure that the frequency of the excitation signal remains centered on the maximum conductance G_{\max} **84**.

[0083] Automatic Calibration

[0084] For safe and effective ultrasound treatment, properly calibrated equipment is required. The ultrasound thera-

peutic system **10** in accordance with the present invention generally includes a calibration procedure that enables a user to calibrate the transducer treatment heads **16** whenever necessary without having to send the entire ultrasound therapeutic system **10** back to the factory. In addition, the calibration procedure enables the user to calibrate an entirely new transducer treatment head **16** as soon as it is received, facilitating easy and efficient replacement of worn or dysfunctional parts.

[0085] The calibration procedure of the present invention automatically determines the impedance of the transducer treatment heads **16**. The procedure is based upon the measurement of the series conductance G_0 of the transducer treatment head when it is unloaded. The series conductance is the real portion of the admittance and the reciprocal of the impedance and represents the losses of the transducer treatment head **16** itself. Referring primarily to **FIG. 5**, the microprocessor **36** calibration software scans the generator frequency to determine the maximum value of G_0 that also yields the resonant frequency f_s **86** of the transducer treatment head **16**. The measurement of G_0 is done by a demodulation method in which the current **98** and voltage signals **96** from the treatment head are multiplied by quadrature reference signals **106** and **108**. This method considers the complex impedance and thus accounts for the corresponding phase shifts between current and voltage (θ):

$$\underline{Z} = \frac{\underline{V}}{\underline{I}} = \underline{Z} e^{-j\theta}$$

[0086] where θ is the phase of the complex impedance. The complex admittance \underline{Y} can then be determined, the real part of which is the series conductance G_0 :

$$G_0 = \text{Re}\{\underline{Y}\} = (\underline{R}^{-1})$$

[0087] where $\underline{R} = \underline{R}_s = \underline{R}_i$ as $\underline{R}_r = 0$ with no acoustic loading (see **FIGS. 4a** and **4b**). During the emission of ultrasound energy into a patient's tissue, the ultrasound therapeutic system **10** constantly measures the maximum series conductance under load, G_{tissue} , using the same method:

$$G_{\text{tissue}} = \frac{1}{R_s} = \frac{1}{R_r + R_i}$$

[0088] The system **10** then determines the real-time electro-acoustic coupling efficiency η :

$$\eta = \frac{G_0 - G_{\text{tissue}}}{G_0}$$

[0089] In operation, the user initiates the calibration procedure. Ideally the procedure is run annually, but other periodic calibrations are envisioned as well. With the transducer **16** unloaded, the microprocessor **36** scans the excitation frequency in a predefined range around the resonant frequency **86** and looks for the maximum conductance G_0 . G_0 is representative of the transducer **16** losses as it is the real portion of the impedance when no acoustic energy is

produced by the piezo transducer **16**. The microprocessor **36** records the value of G_0 and the resonant frequency **86** for later use.

[0090] During normal use, the electro-acoustic coupling efficiency η is calculated from the actual loaded conductance G_{tissue} , where $G_{\text{max}} = G_{\text{tissue}}$, and from the recorded value of G_0 adjusted according to the equation above. In one embodiment, this calibration procedure allows the system **10** to compensate for any changes in the electrical characteristics of the transducer **16**, including the acoustic load, changes in the capacitance C_0 due to aging, temperature driven changes, and like characteristics.

[0091] In this automatic calibration procedure, the system **10** considers both impedance amplitude and phase, allowing for consideration of complex changes. Thus, the power transmitted to the tissue remains accurate despite shifts in the resonant frequency **86** due to slight imaginary components in the acoustic impedance of the target tissues being treated.

[0092] Those skilled in the art will appreciate that other embodiments in addition to the ones described herein are indicated to be within the scope and breadth of the present application. Accordingly, the applicant intends to be limited only by the claims appended hereto.

What is claimed is:

1. A method of calibration for an ultrasound therapeutic treatment head, comprising the steps of:

determining the presence of a treatment head in an ultrasound system;

obtaining identification information for the treatment head;

performing a frequency scan around a theoretical resonant frequency using stepped intervals to determine a maximum unloaded conductance value of the treatment head and a corresponding resonant frequency;

storing the maximum unloaded conductance value and the resonant frequency value;

calculating a maximum series conductance under load of the treatment head;

calculating a real-time acoustic coupling efficiency of the treatment head from the maximum unloaded conductance value and the maximum series conductance under load; and

compensating for real and complex changes in the electrical characteristics of the treatment head according to the calculated real-time acoustic coupling efficiency.

2. The method of claim 1, wherein the step of obtaining identification information for a treatment head further comprises retrieving stored identification information from the controller.

3. The method of claim 1, wherein the step of determining the presence of a treatment head further comprises introducing a new treatment head to the ultrasound system.

4. The method of claim 1, wherein the step of determining the presence of a treatment head further comprises reintroducing a previously calibrated treatment head to the ultrasound system.

5. The method of claim 1, wherein the step of obtaining identification information further comprises reading data

stored electronically for the treatment head by a controller in operable communication with the treatment head.

6. An automatic calibration system for use in an ultrasound system for physical therapy comprising:

a generator for generating an ultrasound output signal;

at least one ultrasonic transducer capable of receiving the ultrasound output signal to generate an acoustic output;

an input device for receiving histological tissue data from a user including target treatment tissue type; and

a controller running treatment software and calibration software, wherein the inputted histological tissue data is processed to generate an acoustic intensity value and a treatment duration value.

7. The system of claim 6, wherein the calibration software operably calculates an acoustic coupling efficiency from an actual loaded conductance and an unloaded series conductance to compensate for changes in the electrical characteristics of the ultrasonic transducer.

8. The system of claim 6, wherein the calibration software operably considers both impedance amplitude and phase to account for complex changes in the ultrasonic transducer and the ultrasound system.

9. The system of claim 6, wherein the at least one ultrasonic transducer is new to the ultrasound system.

10. The system of claim 6, wherein the at least one ultrasonic transducer is an ultrasonic transducer that has been previously calibrated by the ultrasound system.

11. An automatic calibration system for use in an ultrasound system for physical therapy comprising:

means for generating an ultrasound output signal;

at least one ultrasonic transducer capable of receiving the ultrasound output signal to generate an acoustic treatment output;

an input device for receiving histological tissue data from a user including target treatment tissue type, and intermediate tissue structure;

means for running treatment software, wherein the inputted histological tissue data is processed to calculate an ultrasound dosage including an acoustic intensity value and a treatment duration value; and

means for making a calibration adjustment to the ultrasound system that considers impedance amplitude and phase and accounts for complex changes in the electrical characteristics of the ultrasonic transducer.

12. A method of monitoring and controlling the acoustic power delivered to a treatment head of a therapeutic treatment system using a feedback loop, comprising the steps of:

applying electric power from a generator to a treatment head to generate an acoustic power output;

measuring, at a controller in operable communication with the generator, treatment head voltage values at stepped intervals;

calculating at the controller a coupling efficiency of the treatment head and an applied electric power from the measured treatment head voltage values at stepped intervals;

calculating at the controller an effective transmitted acoustic power; and

adjusting the electric power from the generator in response to the calculated coupling efficiency in order to maintain a constant level of effective acoustic power transmitted.

13. The method of claim 12, wherein the step of calculating at the controller a coupling efficiency of the treatment head further comprises:

measuring a vector voltage output of a multiplier in the feedback loop; and

calculating the coupling efficiency of the treatment head and the applied electric power using the vector voltage output.

14. The method of claim 12, wherein the step of adjusting the electric power includes performing the adjustment every 20 milliseconds.

15. The method of claim 12, further comprising the step of notifying a user of the therapeutic treatment system if a feedback loop failure occurs.

16. The method of claim 15, further comprising:

suspending the transmission of electric power from the generator;

commencing a resonance search and output calculation mode;

monitoring the output for a minimum tolerance; and

restarting the feedback loop and resuming normal operation when the output surpasses the minimum tolerance.

17. A feedback loop for monitoring and controlling the acoustic power delivered to a treatment head of a therapeutic treatment system comprising:

at least one ultrasonic transducer capable of receiving an ultrasound output signal to generate an acoustic treatment output;

a generator unit in operable communication with the ultrasonic transducer for generating the ultrasound output signal;

a voltage converter in operable communication with the generator unit to supply a voltage control signal;

a controller running treatment software, wherein inputted histological tissue data is processed to calculate an ultrasound dosage including an acoustic intensity value and a treatment duration value, and wherein the controller is in operable communication with the voltage converter;

an analog multiplier in operable communication with the generator to receive measured voltage and current signals and the controller adapted to supply a vector output signal;

a quadrature signal generator in operable communication with the analog multiplier to provide reference signals; and

a digital sine-wave generator in operable communication with the controller, the generator unit to provide a reference wave, and the quadrature signal generator to provide a reference wave.

18. The feedback loop of claim 17, wherein a coupling efficiency is calculated in the controller and the voltage control signal supplied to the generator unit is adjusted to

operably maintain a constant level of effective acoustic power transmitted from the ultrasonic transducer to a user.

19. The feedback loop of claim 18, wherein the constant level of acoustic power transmitted to the user is maintained by adjusting an electric power in response to the coupling efficiency calculated by the controller.

20. The feedback loop of claim 19, wherein the electric power is adjusted every 20 milliseconds.

21. The feedback loop of claim 18, wherein the controller scans a maximum conductance value of the ultrasonic transducer to detect a shift in a resonant frequency and readjust the electric power in response.

22. A method of ultrasound therapy with a system having a generator, a treatment head, and a programmable controller in operable communication with the generator and the treatment head, comprising the steps of:

inputting histological tissue data by a user, the histological tissue data representing at least tissue type and tissue depth data;

inputting a treatment mode from a selection of thermal, biological, and phonophoresis;

automatically configuring treatment dosage parameters at the controller based on the inputted histological tissue data and treatment mode;

monitoring the operation of the system during treatment of a user; and

maintaining a constant acoustic power transmitted to the user during online use according to values received at the controller from the treatment head.

23. The method of claim 22, wherein the step of monitoring the operation of the system during treatment of a user further comprises:

monitoring a feedback loop within the system for failure;

monitoring a resonant frequency search and centering;

monitoring a presence of the treatment head; and

monitoring a temperature of the treatment head.

24. The method of claim 22, wherein the step of maintaining a constant acoustic power further comprises the steps of:

applying electric power from a generator to the treatment head to generate an acoustic power output;

measuring, at a controller in operable communication with the generator, treatment head voltage values at stepped intervals;

calculating at the controller a coupling efficiency of the treatment head; and

adjusting the electric power from the generator in response to the calculated coupling efficiency in order to maintain a constant level of effective acoustic power transmitted.

25. The method of claim 24, wherein the step of calculating at the controller a coupling efficiency of the treatment head further comprises:

measuring a maximum conductance of the treatment head in an unloaded state;

measuring a maximum conductance of the treatment head in a loaded state; and

calculating the coupling efficiency of the treatment head using the measured maximum conductance of the treatment head in an unloaded state and the measured maximum conductance of the treatment head in a loaded state.

26. The method of claim 24, wherein the step of adjusting the electric power is performed every 20 milliseconds

27. The method of claim 24, further comprising the step of notifying an operator of the system if a feedback loop failure occurs.

28. The method of claim 27, further comprising the steps of:

suspending the transmission of electric power from the generator;

commencing a resonance search and an output calculation mode;

monitoring the output for a minimum tolerance; and

restarting the feedback loop and resuming normal operation when the output surpasses the minimum tolerance.

29. An ultrasound therapeutic treatment system, comprising:

an ultrasound treatment device having

a generator capable of generating an ultrasound output;

an input device adapted to receive histological tissue data from a user including treatment tissue type and tissue depth;

a controller running treatment software to calculate an ultrasound dosage including a treatment duration value, an acoustic intensity value, and an output frequency value;

a plurality of ultrasonic transducer heads capable of receiving the ultrasound output from the generator to generate acoustic output; and

a cable having

a first end connector adapted to attach to the ultrasound treatment device;

and

a second end connector adapted to selectively attach to each of the plurality of ultrasonic transducer heads.

30. The system of claim 29, wherein each of the plurality of ultrasonic transducer heads includes at least one memory device capable of operable communication with the controller.

31. The system of claim 30, wherein the at least one memory device is adapted to operably communicate with the controller to communicate stored data to the controller for each of the plurality of ultrasonic transducer heads.

32. The system of claim 31, wherein the data stored at the at least one memory device is selectable from a group consisting of: temperature data, transducer head serial number, and calibration data.

33. The system of claim 29, wherein the attachment of the second end connector of the cable to each of the plurality of ultrasonic transducer heads results in a substantially watertight attachment.

34. The system of claim 29, wherein each of the plurality of ultrasonic transducer heads are configured to have different acoustic output capabilities.

35. An ultrasound therapeutic treatment system, comprising:

an ultrasound treatment device having

generator means for generating an ultrasound output;

input means for receiving histological tissue data from a user including treatment tissue type and tissue depth;

control means for running treatment software to calculate an ultrasound dosage including a treatment duration value, and an acoustic intensity value;

a plurality of delivery means for receiving the generated ultrasound output from the generator means to deliver acoustic output; and

means for communicating the generated ultrasound output to the delivery means, having

first connector means for attachment to the ultrasound treatment device;

and

second connector means for selective attachment to each of the plurality of delivery means.

36. The system of claim 35, wherein each of the plurality of delivery means includes storage means for storing data at the delivery means for communication with the control means.

37. The system of claim 35, wherein the plurality of delivery means are substantially watertight when attached to the second connector means.

38. The system of claim 35, wherein each of the plurality of delivery means are capable of having different acoustic output capabilities.

39. A method of interchangeably connecting a plurality of transducer treatment heads for use with an ultrasound therapeutic treatment device, the method comprising the steps of:

connecting a first transducer treatment head to a head connector at one end of a cable in operable communication with a generator of the ultrasound therapeutic treatment device;

disconnecting the first transducer treatment head from the head connector; and

connecting a second transducer treatment head to the head connector.

40. The method of claim 39, further including the step of reading, at a controller in operable communication with the cable, data stored at a memory device of the first transducer treatment head.

41. The method of claim 39, further including the step of reading, at a controller in operable communication with the cable, data stored at a memory device of the second transducer treatment head.

42. The method of claim 39, wherein the connecting of the second transducer head includes connecting the second transducer head having a different acoustic output capability than the first transducer treatment head.

43. A feedback loop for monitoring and controlling the acoustic power delivered at a treatment head of a therapeutic treatment system comprising:

at least one ultrasonic transducer capable of receiving an ultrasound output signal to generate an acoustic treatment output;

means for generating the ultrasound output signal in operable communication with the ultrasonic transducer;

means to supply a voltage control signal in operable communication with the means for generating the ultrasound output signal;

control means for running treatment software, wherein inputted histological tissue data is processed to calculate an ultrasound dosage including an acoustic intensity value and a treatment duration value, and wherein the controller is in operable communication with the means to supply a voltage control signal;

means to receive measured voltage and current signals and to supply a vector output signal in operable communication with the means for generating the ultrasound output signal and the control means;

means to provide reference signals in operable communication with the means to receive measured voltage and current signals and to supply a vector output signal; and

means to provide a reference wave in operable communication with the control means, with the means for generating the ultrasound electric output signal to provide a reference wave, and with the means to provide reference signals.

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