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DESCRIPTION

Background

[0001] Pressure wave therapy (also called shock wave therapy) is used for treatment of a number of physiological conditions. A radial pressure wave device generates acoustic pulses that may be used in therapeutic applications and may be beneficial in treating painful conditions involving tendons, muscles and joints. Other clinical objectives of radial pressure wave therapy may include increasing circulation, increasing metabolism, activating myofascial trigger points, treating disorders of tension insertion, and activation of muscle and connective tissue, to speed healing and decrease pain. Because patient characteristics and conditions vary widely, treatment settings (e.g., pressure wave and frequency) must be customized for each patient in order to achieve successful treatment without causing intolerable discomfort. However, many pressure wave therapy devices require an operator to specify treatment settings prior to treatment, before the patient or operator knows which settings will cause discomfort to the patient. With such systems, an operator estimates an appropriate setting and applies the pressure wave therapy device to the patient. If the patient experiences discomfort during the therapy, the operator stops the therapy session, manually re-adjusts the settings, then begins treatment again. This procedure is time-consuming and may cause extended pain and discomfort to the patient.

From US 2003/233061 A1, an external counterpulsation apparatus and method for minimizing end diastolic pressure are known that include a fluid distribution assembly interconnecting a plurality of inflatable devices adapted to be received about the lower extremities of the patient and a source of compressed fluid to be distributed by the fluid distribution assembly to the inflatable devices. The controller in communication with the fluid distribution assembly controls inflation and deflation of the inflatable devices to minimize end diastolic pressure. The controller controls deflation of the inflatable devices without reducing venous return and then minimizes energy spent in ventricular isovolumetric contraction. Further, the controller controls inflation of the inflatable devices to inflate a distal inflatable device prior to inflating a proximal inflatable device. Further, the controller controls a plurality of inflation functions including rate of pressure applied, the magnitude of pressure applied, the duration of time that external pressure is applied, and the duration of time to deflate the inflatable devices.

Summary

[0002] The invention is defined by the appended claims. The systems and techniques described herein improve these pressure wave therapy devices by allowing an operator to more easily determine the proper pressure wave therapy settings for a particular patient, and easily (in some cases, automatically) establish the proper settings, while minimizing patient discomfort.

[0003] In general, the processor-controlled, energy-based therapy apparatuses disclosed herein provide a device configured to provide therapeutic energy to a patient and a processor that controls the output of the device. The output of the device is based on output profiles programmed into the processor. The output profiles include a therapeutic energy output profile and a ramp-up energy profile. In certain embodiments, the therapeutic energy output profile includes a desired target energy level and a therapeutic duration for controlling the output of the device during a therapeutic period. The ramp-up energy output profile may include an initial treatment energy level and a ramp-up duration for controlling the output of the device during a ramp-up period. The energy output specified by the ramp-up energy output profile incrementally increases over the ramp-up duration as a function of the desired target energy level and the ramp-up duration.

[0004] According to the invention, the ramp-up profile can control delivery of pneumatic energy pulses during the ramp-up period. Such a ramp-up profile provides a pneumatic pressure level that incrementally increases as a function of the number of pulses delivered. In certain implementations, the apparatus provides a steady-state level of pneumatic therapy at an energy level that is at or below a patient tolerance level. When the ramp-up energy output profile reaches the desired target energy level, the processor may maintain the application of the energy to a patient after the ramp-up period.

[0005] According to the invention, the apparatus also includes a user input for identifying when a threshold level of energy has been reached or exceeded. The apparatus may additionally or alternatively include a user interface used by an operator for adjusting the ramp-up profile, a ramp-up function, a desired target energy output, and a steady state energy level. In certain implementations, the processor can save in memory information related to one or more output profiles.

Brief Description of the Drawings

[0006]

Figure 1 is a system diagram of a system for delivering pressure wave therapy.

Figure 2(a) is a flow diagram for delivering pressure wave therapy.

Figure 2(b) is a flow diagram of an energy level change protocol for use in the method of Figure 2(a).

Figure 2(c) is a flow diagram of a duration change protocol for use in the method of Figure 2(a).

Figure 3 is an illustration of a user interface for controlling a system for delivering pressure wave therapy.

Figure 4 is a plot showing an amount of energy delivered in pulses of pressure wave therapy

implementations.

Detailed Description

[0007] In general, the systems described herein provide a processor-controlled, energy-based therapy apparatus for providing therapeutic energy to a patient. In particular, a device for providing therapeutic energy is controlled by a processor, and the output of the device is based on output profiles programmed into the processor. The output profiles include a therapeutic energy output profile and a ramp-up energy profile. In certain embodiments, the therapeutic energy output profile includes a desired target energy level and a therapeutic duration for controlling the output of the device during a therapeutic period. The ramp-up energy output profile may include an initial treatment energy level and a ramp-up duration for controlling the output of the device during a ramp-up period. The energy output specified by the ramp-up energy output profile may incrementally increase over the ramp-up duration as a function of the desired target energy level and the ramp-up duration.

[0008] In some implementations, the device for providing therapeutic energy is a radial pressure wave device. Acoustic pulses may be created, for example, by compressed air which accelerates a ballistic projectile through a tube inside an applicator component. Acceleration of the projectile results in the creation of kinetic energy, which may become acoustic energy if the projectile impacts a transmitter tip at the end of the tube. The dimensions, materials, and other properties of the components of the radial pressure wave device may be chosen to generate acoustic pulses that may reach different penetration depths that are selected for different clinical applications (e.g., 1-3 cm). Different applicator components may also be chosen for different clinical objectives.

[0009] Pressure wave therapy treatment sessions may vary according to a patient's therapeutic needs and other constraints. One treatment session includes 2000 pulses per treatment area, with an average of two treatment areas per patient, but the number of pulses per treatment and treatment areas per patient may take any values.

[0010] Figure 1 depicts a system diagram of a system for controlling and delivering pressure wave therapy. The pressure wave therapy system 100 includes a control unit 102, a pressure wave therapy device 110, and a pain threshold indicator 112. The control unit 102 includes at least a user interface 104, a processor 106, and a memory 108. The control unit 102 and the pressure wave therapy device 110 are both operated by an operator, who may be a medical professional or physical therapist using the system 100 to apply therapy to a patient. The pain threshold indicator 112 may be operated by either the patient or by the operator, who can observe the patient's reaction to the therapy to determine when the patient's pain threshold can be reached.

[0011] The pressure wave therapy device 110 operates in a similar manner to the radial pressure wave device described above. The control unit 102 is in connection with the pressure wave therapy device 110 and sends commands to the pressure wave therapy device 110 to control, for example, the energy being delivered in pressure wave pulses, the frequency of the pulses, and the duration of the treatment. The system may contain a plurality of pressure wave therapy devices varying in energy range, shape, material, therapeutic applications, etc., that the operator can choose from. In some implementations, the control unit 102 may be configured to control the operation of multiple pressure wave therapy devices simultaneously, as needed for therapy.

[0012] The user interface 104 is configured to output treatment information and receive input from the operator related to the treatment via a touch screen, a keyboard or keypad, a mouse, dials, a connectable memory module, or any other suitable input device. The processor 106 determines control parameters from the input from the operator. It is understood that the term "processor" refers to any device capable of performing the steps (or a subset of the steps) for delivering pressure wave therapy, which is depicted in Figure 2 and described in detail below in relation to Figure 2. Thus, the processor may include any combination of special-purpose hardware, general purpose hardware, and software (e.g., embedded software).

[0013] The processor 106 may access treatment parameters and treatment programs for different types of therapies (e.g., for use on different parts of the body) stored in a memory 108. In addition to treatment information, the memory 108 may also contain reference information related to the treatment programs for the operator, such as diagrams for where and how to position the pressure wave unit 110 on the patient's body and which pressure wave therapy device to use. This reference information is output on the user interface 104. The memory 108 may additionally store patient-specific treatment information, such as the type of treatment a patient received in previous sessions and the patient's pain threshold determined in previous treatment sessions. The memory may store other information related to shockwave therapy, such as background and rationale for using shockwave therapy and contraindications (e.g., pregnancy, hemophilia, anticoagulant pharmaceuticals). In some implementations, the elements of the control unit 102 are integrated into the pressure wave therapy device 110.

[0014] During treatment, the operator or patient can use the pain threshold indicator 112 to indicate when the patient's pain threshold has been reached. During a ramp-up phase, the amount of energy delivered per pulse increases. If the energy level is unbearable, the patient or user engages the pain threshold indicator 112 to stop increasing the amount of energy or start delivering a slightly lower amount of energy. In some implementations, engaging the pain threshold indicator 112 stops therapy completely. The pain threshold indicator 112 may be, for example, a microphone, a touch screen input, a button or dial on a handheld component of the pressure wave therapy system, a particular series of inputs (such as a double-click on a button or trigger on a handheld device), a button on a dedicated patient tolerance indicator signal line, a physiological sensor (such as an EEG sensor, an EMG sensor, an accelerometer, etc.) capable of detecting patient discomfort, or any combination thereof. In some implementations, the pain threshold indicator 112 is on the pressure wave therapy device 110 to be easily

accessible by the operator.

[0015] The control system, implemented by the processor 106 in Figure 1, is configured to perform the process 200 depicted in Figure 2(a). It will also be understood that the steps depicted in Figure 1 may be performed in any suitable order, and certain steps may be removed entirely (e.g., when the pressure wave therapy device is not capable of performing a particular step, or the step is performed by another device).

[0016] At the step 202, the processor 106 identifies a desired frequency of pressure wave treatment. In certain embodiments, this frequency is input by an operator (e.g., via a touch screen, connectable memory module, dial, or other suitable input device). One suitable implementation for receiving user input is shown in Figure 3. In other embodiments, this frequency is automatically identified by the processor when an operator selects a treatment program or protocol that is stored in a look-up table in the memory 108 coupled to the processor 106. In certain embodiments, this frequency is selected from a range of possible frequencies (e.g., approximately 0.5-35 Hz). In certain examples, the processor is configured to drive the opening and closing of a pneumatic valve to cause pressure waves at the desired frequency.

[0017] At the step 204, the processor 106 identifies a desired duration of pressure wave treatment. As was discussed above with reference to the step 202, this duration may be input by an operator or automatically identified by the processor 106. The duration may be identified in terms of a number of desired pulses (e.g., selected from the approximate range of about 10-10000 pulses) or a defined period of time (e.g., selected from the approximate range of about 20-4000 seconds).

[0018] At the step 206, the processor 106 identifies a desired target energy level for pressure wave treatment. As was discussed above with reference to the step 202, this target energy level may be input by an operator or automatically identified by the processor 106. In certain examples, the processor 106 is configured to drive the opening and closing of a pneumatic valve a determined distance, thereby transmitting an amount of pneumatic energy corresponding to the desired target energy level. The energy level may be identified in terms of a desired pressure (e.g., selected from the range 1.4-5.0 bar) or any other desired unit of acoustic energy.

[0019] At the step 208, the processor 106 determines whether the pressure wave treatment should include an initial ramp portion. In making this determination, the processor 106 may determine whether an operator input has been received indicating that a ramp portion should not be included (e.g., by reading the value of a binary ramp variable set by the processor 106 during a device set-up procedure). If the processor 106 determines at the step 208 that an initial ramp portion should not be included in the pressure wave treatment, the processor 106 then determines a therapy profile (the step 220, discussed in detail below).

[0020] If the processor determines at the step 208 that an initial ramp portion should be

included in the pressure wave treatment, the processor 106 will determine a ramp profile at the step 216. The ramp profile created by the processor 106 may be based on one or more ramp profile parameters. In Figure 2(a), at the step 210, the processor 106 identifies a desired duration for the ramp portion. In certain embodiments, the duration of the ramp portion is a predetermined fraction of the treatment duration identified at the step 204. For example, if the treatment duration is identified at the step 204 as 3000 pulses and the predetermined fraction is 1/3, the duration of the ramp portion identified at the step 214 is 1000 pulses. In certain embodiments, the duration of the ramp portion is input by an operator. In other embodiments, the duration of the ramp portion is automatically identified by the processor as discussed above with reference to the step 202. The profile may be a function of the number of energy pulses to be applied, and bounded by a pre-determined upper energy limit that is pre-programmed into the processor 106.

[0021] At the step 212, the processor 106 identifies an initial treatment energy level for the ramp portion. The initial treatment energy level is the energy level which will be transmitted to the patient by the pressure wave therapy device 110 at the beginning of the ramp portion at the start of treatment. In certain embodiments, the initial treatment energy level is less than the target treatment energy level identified at the step 206. The initial treatment energy may be a treatment energy level that is expected to be comfortably received by the patient (i.e., with minimal or no pain). In certain embodiments, the initial treatment energy level is a starting point from which the treatment energy will be gradually increased (i.e., ramped) to the target treatment energy level identified at the step 206. The initial treatment energy level may be identified in terms of a desired pressure (e.g., selected from the approximate range of about 1.0-5.0 bar) or any other desired unit of acoustic energy. As discussed above with reference to the step 202, the initial treatment energy level may be input by an operator or automatically identified by the processor 106. In certain embodiments, the initial treatment energy level is approximately 1.4 bar.

[0022] At the step 214, the processor 106 identifies a ramp function to be followed during the ramp portion. The ramp function may specify how the pressure wave generated by the therapy device 110 will change over the ramp portion (e.g., increasing or decreasing in magnitude). In certain embodiments, the ramp function is one or more of a linear function, an affine function, a polynomial function, an exponential function, or any other suitable function. Various ramp functions are described further in relation to Figure 4. As discussed above with reference to the step 202, the ramp function may be input by an operator or automatically identified by the processor 106. In certain embodiments, the ramp function specifies the energy to be transmitted to the patient over the duration of the ramp portion. In other embodiments, the ramp function specifies the change in energy to be applied from pulse to pulse as a function of the number of pulses applied during the ramp portion. For example, in certain embodiments using a linear ramp function, the ramp function specifies the pulse-to-pulse change in energy according to the following equation:

$$\text{Energy Change per Pulse} = \frac{\text{Target Energy} - \text{Initial Energy}}{\frac{1}{3} * \text{Pulses in Treatment Duration}}$$

For example, using the linear ramp function defined above, if the target treatment energy is 2.0

bar, the initial energy is 1.4 bar, and there are 3000 pulses in the treatment duration, the energy change per pulse is calculated as follows:

$$\frac{2.0\text{ bar} - 1.4\text{ bar}}{\frac{1}{3}*3000\text{ pulses}} = 0.0006\text{ bar/pulse.}$$

[0023] At the step 216, the processor 106 determines a ramp profile which specifies the characteristics of the pressure wave to be transmitted to the patient over the duration of the ramp period. In certain embodiments, the ramp profile is determined based on one or more of the ramp duration identified at the step 210, the initial treatment energy level identified at the step 212, and the ramp function identified at the step 214. For the example given above, the ramp profile is defined as a linear ramp function with an initial treatment energy of 1.4, delivered over (1/3 * 3000) = 1000 pulses, and increasing 0.0006 bar per pulse.

[0024] At the step 220, the processor 106 determines a therapy profile which specifies the characteristics of the pressure wave to be transmitted to the patient over the course of the pressure wave treatment. If the processor determined that a ramp portion was to be included in the pressure wave treatment (at the step 208), the therapy profile will include the ramp profile determined at the step 216.

[0025] At the step 222, the processor 106 evaluates the therapy profile determined at the step 220 against a set of pressure wave treatment criteria. These criteria may be stored in the memory 110 coupled to the processor 106, and may represent limitations of the pressure wave therapy device 110 (e.g., ranges of energy level and frequency that the pressure wave therapy device is capable of providing), patient safety limitations (e.g., a maximum energy level that should not be exceeded for a particular treatment site), or any combination of such criteria. If the processor 106 determines that the therapy profile does not meet required criteria, the therapy profile is adjusted at the step 224. In certain embodiments of the step 224, the processor 106 prompts the operator to input different treatment parameters (e.g., by performing one or more of the steps 202-214). In other embodiments of the step 224, the processor 106 automatically adjusts the therapy profile so that it meets the required criteria. To do this, the processor 106 may implement any one of a number of optimization techniques. For example, the processor 106 may determine the sensitivity of the required criteria to perturbations in the parameters of the therapy profile, and then adjust selected parameters to which the criteria are most sensitive.

[0026] If the processor 106 determines that the therapy profile meets the required criteria at the step 222, the processor determines (at the step 226) the control commands to be issued to the pneumatic and mechanical components of the pressure wave therapy device in order to achieve the therapy profile. For example, the processor may generate and transmit voltage control signals to a variable pneumatic pressure device and/or a mechanical switch. Therapy devices including similar components, suitable for use with the systems and techniques disclosed herein, are described in Wess, U.S. Patent No. 5,795,311, issued August 18, 1998; Wess, U.S.Patent No. 6,059,741, issued May 9, 2000; Marlinghaus, U.S. Patent Application

Publication No. 2002/0002345, published January 3, 2002; Schulz et al., U.S. Patent Application Publication No. 2006/0025710, published February 2, 2006; Hagelauer, U.S. Patent Application Publication No. 2009/0156894, published June 18, 2009; Heine et al., U.S. Patent Application Publication No. 2009/0326425, published December 31, 2009; and Marlinghaus et al., and U.S. Patent Application Publication No. 2009/0221940, published August 13, 2009. In certain embodiments, to determine the necessary control signals to provide to the pneumatic and mechanical devices, the processor 106 uses a look-up table or function stored in the memory 108 to identify the appropriate control signals to send to these devices to achieve the pressure wave treatment specified by the therapy profile.

[0027] At the step 228, the processor 106 provides the control signals to the pressure wave therapy device 110 to provide treatment according to the therapy profile determined at the step 220 or 224. In certain embodiments, as described above, the treatment includes a ramp portion, during which the energy of the pressure wave transmitted to the patient increases from an initial level to a target level. At the step 230, the processor 106 determines whether the treatment has been applied for the duration identified at the step 204 and is thus complete. If the treatment is complete, the processor 106 executes the step 232 (discussed in detail below). If the treatment is not yet complete (e.g., during or after the ramp portion), the processor 106 may execute a number of checks on the performance of the pressure wave therapy device and inputs from the operator and patient. For example, at the step 234, the processor determines whether the operator has changed the target energy level from the level identified at the step 206. If the energy level has been changed, the processor performs an energy level change protocol at the step 236. In some embodiments, the energy level change protocol includes ignoring the change in target energy level and continuing to provide treatment according to the therapy profile determined at the step 220 or 224.

[0028] An exemplary energy level change protocol is illustrated in Figure 2(b). At the step 250, the processor 106 determines whether the ramp portion has been completed. If the ramp portion has been completed, in the step 252, the processor 106 may adjust the energy level; the processor 106 may additionally or alternatively terminate the applied treatment, at which point the processor 106 may return to an earlier step in the process (e.g., the step 206). If the ramp portion has not been completed, the processor 106 determines at the step 254 whether the new target energy level is less than or equal to the current energy level being delivered to the patient. If the new target energy is less than or equal to the current energy level being delivered to the patient, at the step 256, the processor 106 adjusts the therapy profile so the remaining treatment is provided at the new target energy level. If the new target energy level is greater than the currently energy level, at the step 258, the processor 106 will adjust the therapy profile according to the ramp function. For a linear ramp function, one or more subsequent pulses increase in energy according to the following equation:

$$\text{Energy Change per Pulse} = \frac{\text{New Target Energy} - \text{Current Energy}}{(\frac{1}{3} * \text{Pulses in Treatment Duration}) - \text{Pulses Already Delivered}}$$

For example, if the new target treatment energy is 2.2 bar, the current energy is 1.7 bar, there are 3000 pulses in the treatment duration, and 500 pulses have already been delivered, the new energy change per pulse is calculated as follows:

$$\frac{2.2 \text{ bar} - 1.7 \text{ bar}}{(\frac{1}{3} * 3000 \text{ pulses}) - 500 \text{ pulses}} = 0.001 \text{ bar/pulse.}$$

[0029] Returning back to Figure 2(a), at the step 138, the processor 106 determines whether the operator has changed the treatment duration from the duration identified at the step 204. If the treatment duration has been changed, the processor performs a treatment duration change protocol at the step 240. An exemplary treatment duration change protocol is illustrated in Figure 2(c). At the step 260, the processor 106 determines whether the ramp portion has been completed. If the ramp portion has been completed, in the step 262, the processor 106 in some implementations adjusts the remaining treatment duration, and in other implementations terminates the applied treatment, at which point the processor 106 may return to an earlier step in the process (e.g., the step 206). If the ramp portion has not completed, the processor 106 identifies at the step 264 a new ramp duration using the new treatment duration (e.g., using any of the techniques described above for the step 210). At the step 266, the processor 106 then determines whether the new ramp duration is less than or equal to the applied duration (e.g., the number of pulses already applied or the elapsed time). If the new ramp duration is less than or equal to the applied duration, at the step 268, the processor 106 ends the ramp portion and adjusts the remaining treatment duration. In other implementations, rather than suddenly increasing the energy level, the processor 106 may finish the ramp portion and only adjust the duration of the treatment portion after the ramp, or the processor 106 may be configured to accelerate, but not completely eliminate, the remainder of the ramp portion. If the new ramp duration is greater than the applied duration, at step 270, the processor 106 will adjust the therapy profile according to the ramp function. For a linear ramp function, one or more subsequent pulses increase in energy according to the following equation:

$$\text{Energy Change per Pulse} = \frac{\text{Target Energy} - \text{Current Energy}}{(\frac{1}{3} * \text{Pulses in New Duration}) - \text{Pulses Already Delivered}}$$

For example, if the target treatment energy is 2.0 bar, the current energy is 1.7 bar, 500 pulses have been delivered, and the new treatment duration is 1800 pulses, the new energy change per pulse is calculated as follows:

$$\frac{2.0 \text{ bar} - 1.7 \text{ bar}}{(\frac{1}{3} * 1800 \text{ pulses}) - 500 \text{ pulses}} = 0.003 \text{ bar/pulse.}$$

[0030] At the step 242, the processor 106 determines whether an indication has been received that a patient tolerance threshold has been reached. A patient tolerance threshold is reached when the patient or the operator has determined that the patient's discomfort is maximally tolerable (or too great) to continue the same treatment. The indication may be received by the processor 106 using any of a number of user inputs described in relation to the pain threshold indicator 112 in Figure 1. The indicator may be received at any point during the treatment, including during a ramp portion of the treatment.

[0031] If the processor 106 determines at the step 242 that a patient tolerance threshold indicator has been received, the processor 106 identifies the characteristics (e.g., energy level,

frequency) of the treatment delivered to the patient at the time or approximate moment at which the indicator was received. These settings may be displayed for the operator and patient and/or recorded in memory. At the step 246, the processor 106 determines whether the treatment should be discontinued. The processor 106 may make this determination by querying the memory 108 in which an operator or patient preference has been stored. In certain embodiments, an operator is given the option to specify that treatment is to be discontinued when a patient tolerance indicator is received. When such an option has been selected by an operator and a patient tolerance indicator is received at the step 242, treatment will be discontinued and the processor 106 will execute the step 232 (described in detail below).

[0032] If the processor 106 determines that treatment is not to be discontinued at the step 246, the processor proceeds to the step 248 and adjusts the remaining therapy profile to alleviate the patient's discomfort. In certain embodiments, the processor performs the step 248 by adjusting the energy level of the remaining treatment to a level below the energy level at which the patient tolerance indicator was received (referred to as the "tolerance energy level"). The energy level may be reduced to a level that is a fixed amount below the tolerance energy level (e.g., 0.1 bar below the tolerance energy level). The energy level may be reduced to a level that is a fixed percentage below the tolerance energy level (e.g., 95% of the tolerance energy level). The energy level may be reduced to a predetermined level (e.g., 2 bar). Once the processor 106 has adjusted the therapy profile for the remaining treatment, the processor 106 provides control signals to the pressure wave therapy device 110 in accordance with this adjusted therapy profile (returning to the step 228).

[0033] Once the treatment duration has been reached (as determined at the step 230), or the 106 processor determines that the treatment should be terminated at the step 246, the processor 106 indicates to the operator (e.g., via a display or printout), and/or records in memory 108, parameters describing the completed therapy session. Suitable parameters include any one or more of the therapy profile, the ramp profile, treatment characteristics at the time of patient tolerance indicators, physiological feedback or performance data indicating patient response to the treatment, or any data useful to a care provider or patient for tracking the patient's progress during and across pressure wave treatment sessions.

[0034] A simplified treatment editing screen 300 from the user interface 104 of the control unit 102 is shown in Figure 3. In this embodiment, the user interface 104 is a touchscreen display. The edit treatment screen 300 includes treatment selection buttons 302-306, treatment selection number lines 308-312, a save button 314, and navigation buttons 316 and 318. The mode button 402 opens a subscreen or navigates to a different screen to allow the operator to select a treatment mode, e.g., pulses applied continually or in bursts or sets. The ramp button 404 opens a subscreen or navigates to a different screen to allow the operator to identify how much of the total treatment duration should be used in the ramp portion. The handpiece button 406 opens a subscreen or navigates to a different screen to allow the operator to identify which pressure wave therapy device is connected. The number lines for energy 408, frequency 310, and number of pulses 412 show the settings for the treatment factors. The operator can adjust

these by sliding the marker along the number line or using the up and down arrows to move in discrete steps. Once the operator is satisfied with the treatment parameters, the operator may save the treatment settings for future use with the save protocol button 314. The save protocol button 314 may cause an on screen keyboard to appear, allowing the operator to enter a title for the protocol. The back button 316 returns the interface to a previous screen, and the home button 318 returns the interface to a home screen. A screen containing similar information including the mode, ramp, handpiece, energy, pulses, and frequency of the treatment session could be displayed at the end of the treatment session. Such a treatment results screen may include the option to save the protocol so that it may be used again.

[0035] As discussed above, in addition to manually entering the treatment parameters, the user interface may allow the operator to retrieve treatment programs saved on memory for particular therapies or patients. When the operator selects a saved treatment program, he may be allowed to edit it through the edit treatment screen 300 before starting the treatment.

[0036] A plot showing several treatment profiles is shown in Figure 4. The plot 400 shows the amount of energy delivered in each pulse in according to various types of ramp-up functions that may be used in pressure wave therapy. The vertical axis of graph 400 shows the energy delivered in each pulse, and the horizontal axis shows a duration, determined by number of pulses. Labeled on the horizontal axis is a number of pulses T, which is the cutoff between the ramp-up portion and the therapeutic portion. In these example profiles, roughly one third of the total duration is dedicated to the ramp-up portion of duration T. The total duration of the ramp-up portion and therapeutic portion combined may be in the range of 10-10000 pulses.

[0037] In the graphs shown on plot 400, the energy per pulse during the therapeutic portion 412, i.e., in the duration after T, is constant. This is often the case in pressure wave therapy, unless the treatment is interrupted or the energy is decreased due to patient pain. However, many different ramp-up functions may be used. Three illustrative ramp-up graphs 406-410 illustrating different ramp-up functions are shown. Graph 406 shows a linear ramp-up, where each subsequent pulse is at a slightly higher energy than the previous pulse, and the incremental energy is constant. Graph 408 shows a curved ramp-up, where each subsequent pulse is again at a slightly higher energy than the previous pulse, but the incremental energy decreases with each subsequent pulse. Graph 410 shows a stepped ramp-up, where the energy increases after a fixed number of pulses, and the incremental energy is greater than in graph 406 or graph 408.

[0038] In addition to ramping the energy per pulse, the processor 106 may be configured to ramp the frequency of the pulses. During the ramp-up portion, the processor 106 may additionally cause the frequency of pulses to increase, which decreases the time between pulses. This may further help a patient ease into the treatment.

[0039] It is to be understood that while system and components have been described in conjunction with the various illustrative examples, the forgoing description is merely illustrative and does not limit the scope of the disclosure. While several examples have been provided in

the present disclosure, it should be understood that the disclosed systems, and components may be embodied in many other specific forms without departing from the scope of the present disclosure.

[0040] Variations and modifications will occur to those of skill in the art after reviewing this disclosure. The disclosed features may be implemented, in any combination and subcombinations (including multiple dependent combinations and sub-combinations), with one or more other features described herein. The various features described or illustrated above, including any components thereof, may be combined or integrated in other systems. Moreover, certain features may be omitted or not implemented.

[0041] Examples of changes, substitutions, and alterations are ascertainable by one skilled in the art and could be made without departing from the scope of the information disclosed herein.

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- US20090221940 [0026]

Patentkrav

1. Processorstyret, energibaseret terapiapparat, der omfatter: en indretning, der er indrettet til at tilvejebringe terapeutisk energi til en patient; og en processor, der styrer indretningens energioutput baseret på outputprofiler, der er programmeret i processoren, hvor outputprofilerne omfatter: en terapeutisk energioutputprofil, der omfatter et ønsket målenerginiveau og en terapeutisk varighed til styring af indretningens output i det terapeutiske tidsrum, og en øgningsenergioutputprofil med et indledende behandlingsenerginiveau og en øgningsvarighed til styring af indretningens output i et øgningstidsrum, hvor det energioutput, der specificeres af øgningsenergioutputprofilen trinvist stiger i løbet af øgningsvarigheden som en funktion af det ønskede målenerginiveau og øgningsvarigheden;
kendetegnet ved, at øgningsprofilen er beregnet til at styre afgivelse af pneumatiske energiimpulser i løbet af øgningstidsrummet og til at tilvejebringe et pneumatisk trykniveau, er trinvist stiger som en funktion af antallet af afgivne impulser.

2. Apparat ifølge krav 1, hvor apparatet er indrettet til at tilvejebringe et stationært niveau af pneumatisk terapi ved et energiniveau, der er på eller under et patienttoleranceniveau.

3. Apparat ifølge et af kravene 1 eller 2, hvor øgningsenergioutputprofilen når det ønskede målenerginiveau, og processoren er indrettet til ikke yderligere at forøge den energi, der påføres på en patient efter øgningstidsrummet.

4. Apparat ifølge et af kravene 1-3, endvidere omfattende et brugerinput til at identificere, når et energitærskelniveau er nået eller overskredet.

5. Apparat ifølge et af kravene 1-4, endvidere omfattende en brugergrænseflade, der er indrettet til at indstille øgningsprofilen, en øgningsfunktion, et ønsket målenergioutput og et stationært energiniveau.

6. Apparat ifølge et af kravene 1-5, hvor processoren er indrettet til at gemme information i hukommelsen, der angår en eller flere outputprofiler.

DRAWINGS

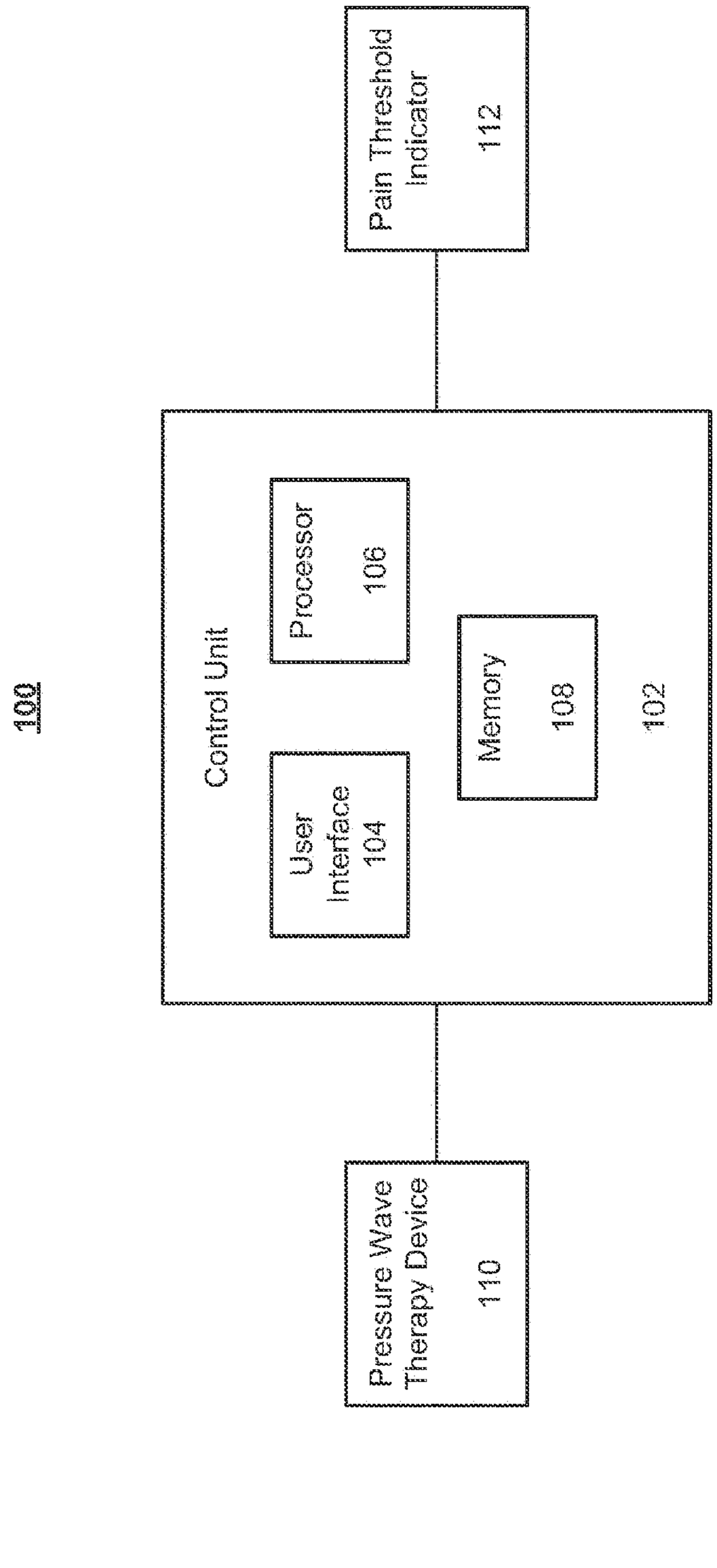

Figure 1

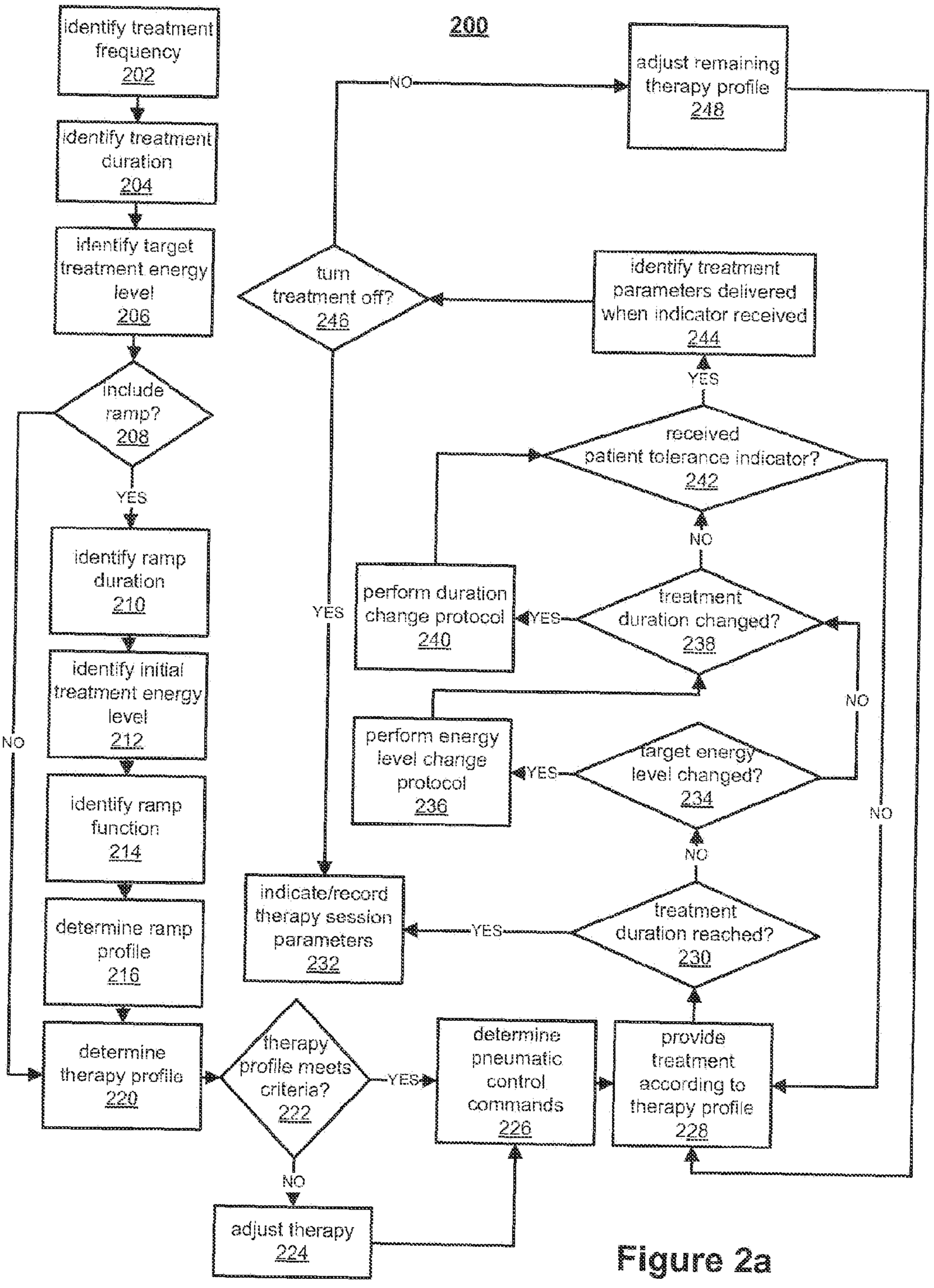
200
identify treatment frequency 202
identify treatment duration 204
identify target treatment energy level 206
include ramp? 208
YES
NO
identify ramp duration 210
identify initial treatment energy level 212
identify ramp function 214
determine ramp profile 216
determine therapy profile 220
therapy profile meets criteria? 222
YES
NO
adjust therapy 224
determine pneumatic control commands 226
provide treatment according to therapy profile 228
treatment duration reached? 230
YES
indicate/record therapy session parameters 232
target energy level changed? 234
YES
NO
perform energy level change protocol 236
treatment duration changed? 238
YES
NO
perform duration change protocol 240
received patient tolerance indicator? 242
YES
NO
identify treatment parameters delivered when indicator received 244
turn treatment off? 246
YES
NO
adjust remaining therapy profile 248

Figure 2a

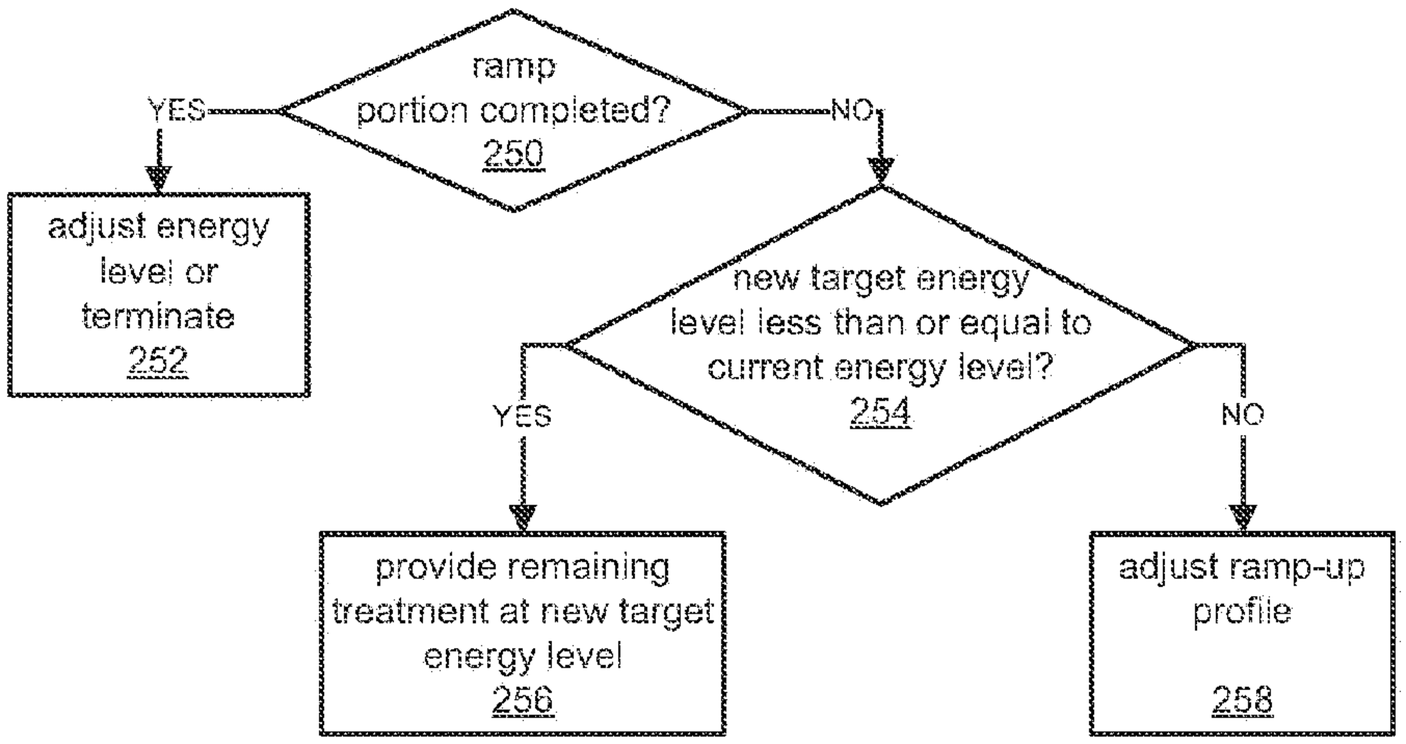

Figure 2b

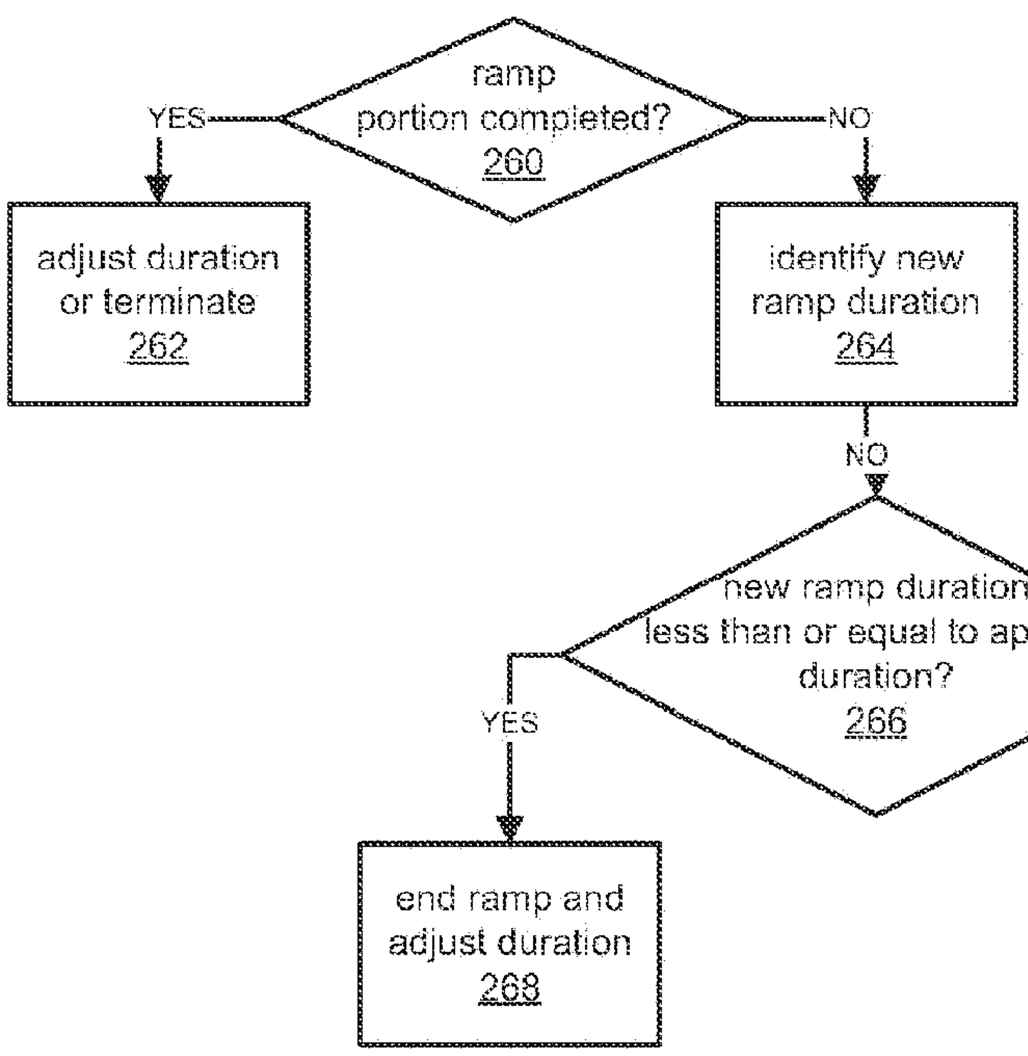

Figure 2c

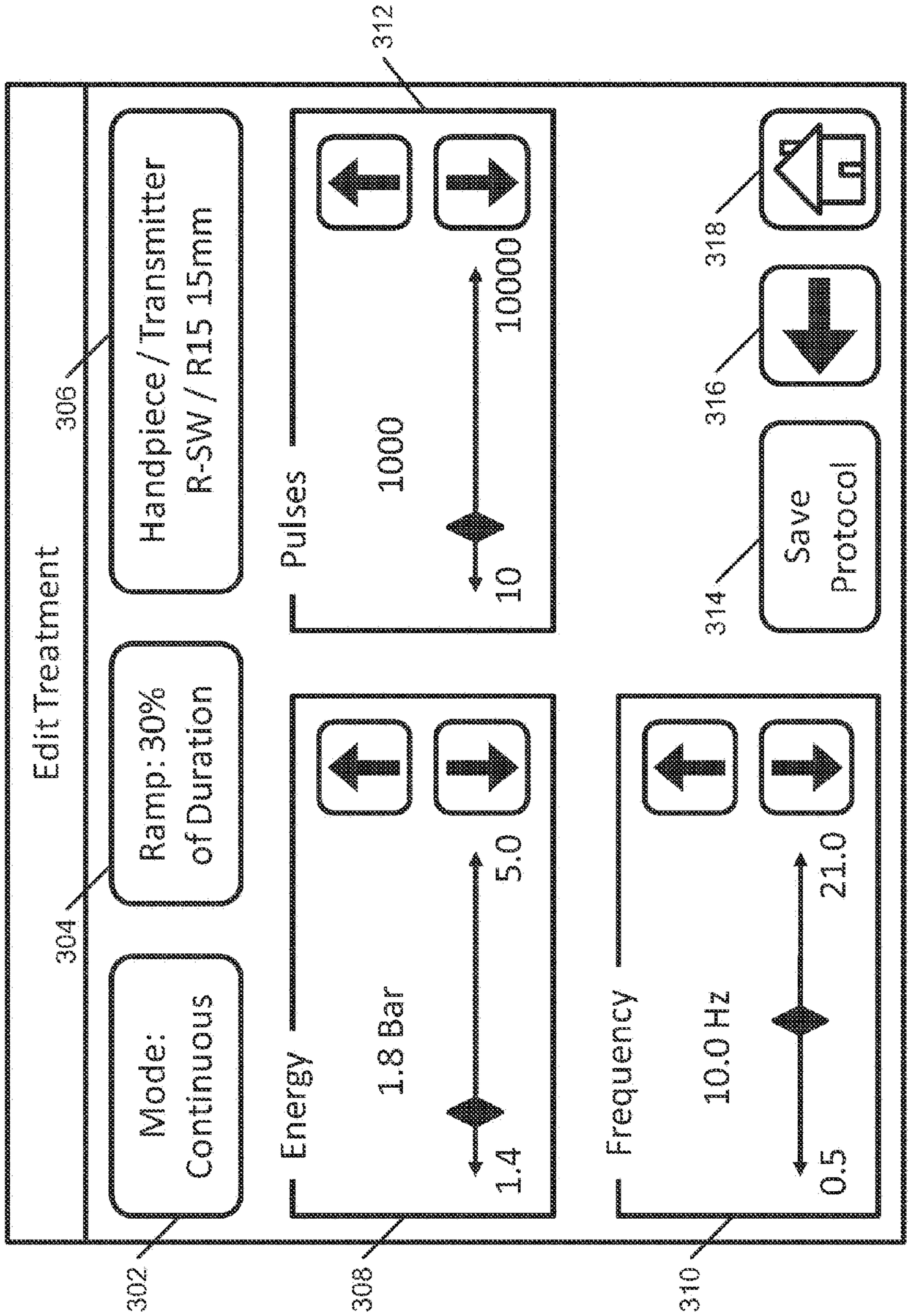
300
Edit Treatment
306
304
Ramp: 30%
of Duration
Mode:
Continuous
302
Handpiece / Transmitter
R-SW / R15 15mm
312
Pulses
1000
10000
10
Energy
1.8 Bar
5.0
1.4
308
318
316
314
Save
Protocol
Frequency
10.0 Hz
21.0
0.5
310

Figure 3

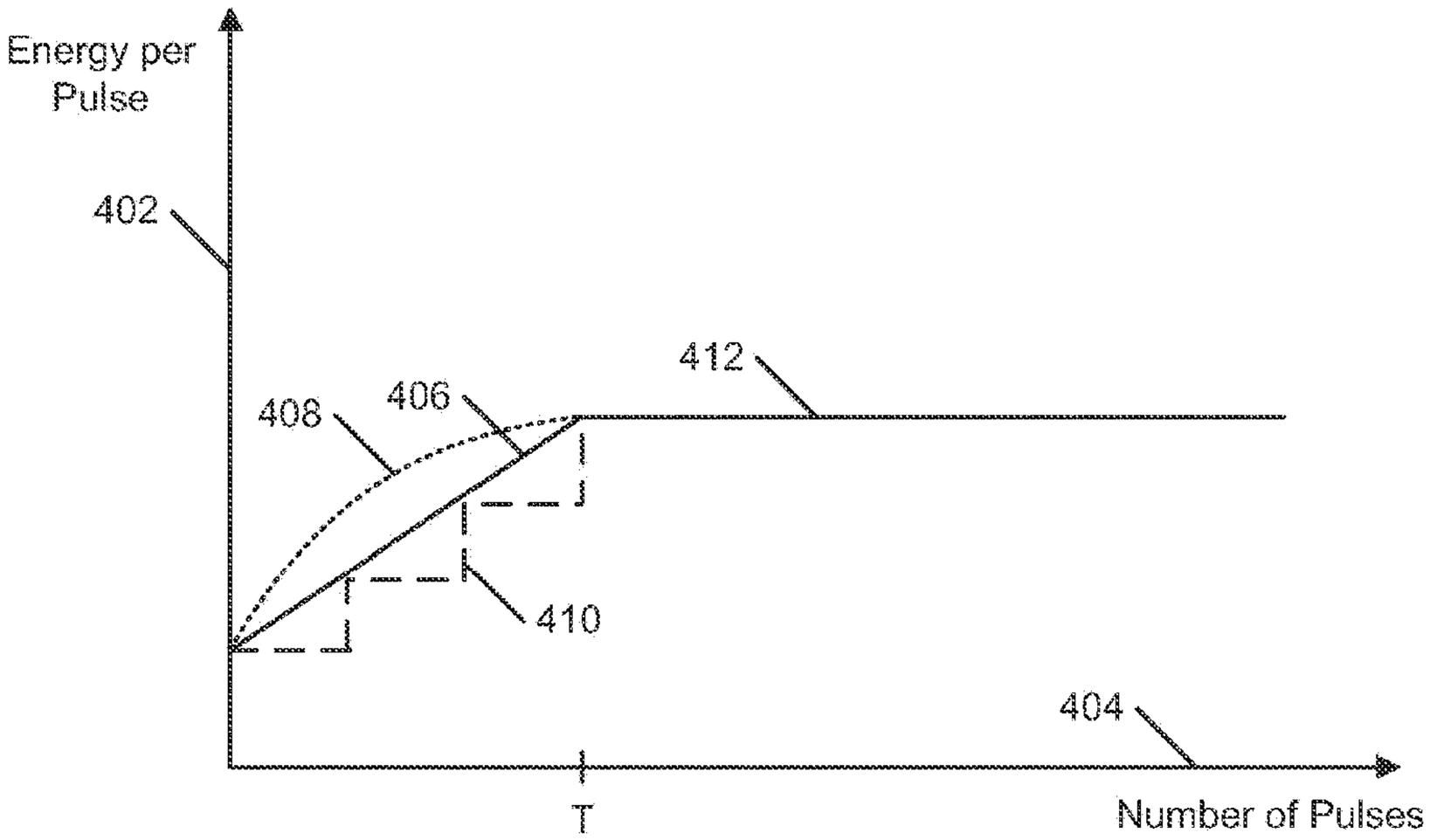
400
Energy per Pulse
402
412
408
406
410
404
T
Number of Pulses

Figure 4