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(71) Applicant: **CASCADE WELLNESS TECHNOLOGIES, INC.** [US/US]; 18160 Cottonwood Road, #756, Sunriver, Oregon 97707 (US).(72) Inventors: **SCHAEFER, David**; 18160 Cottonwood Road, #756, Sunriver, Oregon 97707 (US). **SMITH, Richard**; 17025 Torrance Road, Sunriver, Oregon 97707 (US).(74) Agent: **SHONKWILER, Charles M.**; Leber Patent Law P.C., 4 Laurel Road, Lynnfield, Massachusetts 01940 (US).

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(54) Title: THERMAL CONTRAST THERAPY DEVICES, METHODS, AND SYSTEMS

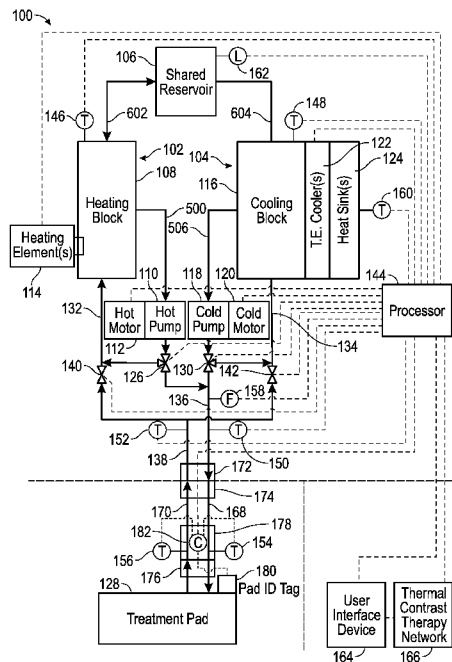


FIG. 1

(57) Abstract: The present disclosure relates to thermal contrast therapy devices, treatment methods for providing thermal contrast therapy, and systems for providing and managing thermal contrast therapy treatments. The thermal contrast therapy devices disclosed herein are configured to provide a sequence of alternating cooling periods and heating periods to one or more areas of a patient's body. A thermal contrast therapy device may comprise a source of hot fluid, a source of cold fluid, and one or more pumps configured to circulate fluid through one or more treatment pads in fluid communication with the device. The thermal contrast therapy devices disclosed herein are configured to rapidly and efficiently transition between alternating cooling periods and heating periods.



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THERMAL CONTRAST THERAPY DEVICES, METHODS, AND SYSTEMS**RELATED APPLICATIONS**

This application claims priority to U.S. Application Serial No. 14/682,295, filed April 9, 2015, and U.S. Application Serial No. 14/340,904, filed July 25, 2014, each of which claim priority to U.S. Provisional Application Serial No. 62/028,952 filed July 25, 2014, the complete disclosures of which are hereby incorporated by reference into this application.

BACKGROUND

The present disclosure relates to thermal contrast therapy devices, treatment methods for providing thermal contrast therapy, and systems for providing and managing thermal contrast therapy treatments.

Thermal contrast therapy comprises therapeutic treatments in which a sequence of alternating cooling periods and heating periods are provided to one or more areas of a patient's body. The alternating cooling periods and heating periods respectively deliver or remove heat from the treatment area. The treatment sequence may be continued for a specified period of time or a specified number of heating periods and/or cooling periods. For example, the sequence may continue for an amount of time effective to achieve a desired therapeutic result.

Without wishing to be constrained by theory, the inventors understand that thermal contrast therapy can cause cycles of vasodilation and vasoconstriction, thus creating a pumping action which improves blood circulation and quality. Applying heat to body tissue may cause vasodilation, or dilation or widening of blood vessels. When

blood vessels dilate, the flow of blood through the vessels increases due to a decrease in vascular resistance. Therefore, dilation of arterial blood vessels (mainly the arterioles) is believed to decrease blood pressure in the dilated vessels. Applying cold to body tissue may cause vasoconstriction, or contraction or narrowing of blood vessels, which is
5 believed to increase blood pressure in the contacted blood vessels. When blood vessels constrict, the flow of blood is restricted or decreased, forcing blood to move to other parts of the body.

Blood delivers oxygen and nutrients to, and removes wastes from, tissues and organs. If circulation is poor or slow, delivery of healing nutrients or removal of toxins
10 may be inadequate or suboptimum, which may delay healing or even cause degeneration of tissues or organs. It is believed that by improving the circulation and quality of blood, more nutrients are made available for cells to use, and that as such, toxins may be managed more efficiently.

Additionally, lymph vessels contract when exposed to cold and relax in response
15 to heat. The lymph system, unlike the circulatory system, lacks a central pump. Without wishing to be constrained by theory, it is believed that alternating periods of heating and cooling cause lymph vessels to dilate and contract to essentially “pump” and move fluid from one area to another. This movement of fluid positively affects the inflammation process, which is the body's primary mechanism for healing damaged tissue.

20 Given these and other physiological effects known in the art, thermal contrast therapy may be an effective treatment for a number of different conditions. The therapy may be applied to any part of the body, for example, a part of the body that is inflamed, congested, injured, fatigued, or recovering from a surgical procedure. General

therapeutic uses of thermal contrast therapy include management of pain, swelling, fever, toxins, spasms, constipation, and immune function. Thermal contrast therapy may be used generally to reduce edema or swelling, reduce or soothe pain, encourage healing of bones and tissue, and rehabilitate injuries to bone, muscle, ligaments, tendons, and skin.

5 Thermal contrast therapy may also be an effective treatment for patients with hypothermia or frostbite, for example, to enhance circulation in affected tissue.

Thermal contrast therapy may also be used after an acute injury or surgery to reduce pain and swelling, and to promote healing. Athletes have also used thermal contrast therapy after or between competitions or training sessions, to speed recovery or
10 reduce delayed onset muscle soreness by helping to flush lactic acid from sore muscles. Thermal contrast therapy may also be used to relax joint tissue such as ligaments and tendons, which may help increase range of motion. Thermal contrast therapy may also be an effective treatment for patients with spinal cord or nerve damage, for example, to enhance blood flow to the injured nerve tissue, or prevent or mitigate disruption of the
15 tenuous blood supply.

Thermal contrast therapy may also be an effective therapy for diabetes and related physiological complications, for example, gangrene, or for lymphedema or other disorders associated with vascular or lymphatic insufficiency, for example, chronic venous insufficiency, venous stasis ulcers, post-mastectomy edema or chronic
20 lymphedema, and for peripheral vascular disease or any other circulatory deficiency syndrome, for example, arteriosclerosis, deep vein thrombosis, Buerger's disease, or thromboangiitis obliterans. Thermal contrast therapy may provide therapeutic relief for multiple sclerosis and other autoimmune disorders, for example to treat pain and/or

improve blood circulation. Other studies indicate that thermal contrast therapy may positively influence the immune system. Thermal contrast therapy may also be an effective therapy for destruction of subcutaneous lipid cells.

Thermal contrast therapy may be performed manually, such as by alternately
5 immersing an area of the body (e.g., a foot, ankle, or leg) in a cold water whirlpool or bath and a warm whirlpool or bath, or by alternately applying a heat source, such as a heating pad or hydrocollator pack, and a cold source, such as an ice pack, or the like. Alternatively, thermal contrast therapy devices are commercially available which circulate water or other fluid through a treatment pad surrounding an area of the body
10 sought to be treated. Such manual treatments and existing devices, however, may be unsuitable or ineffective for treating some conditions and/or patients.

Without wishing to be constrained by theory, it is believed that the effectiveness of thermal contrast therapy may be enhanced by providing a customized treatment sequence. Existing devices and treatment methods may offer only a finite number of pre-
15 programmed therapies, with only limited ability to vary parameters of the treatment sequence. There is therefore a need for improved devices and methods for providing customized thermal contrast therapy treatment sequences. Some customized treatment sequences disclosed herein require a level of accuracy, precision, and control – for example, of the fluid temperature, the specified measure of heat transfer, and/or various
20 other parameters of the treatment sequence – which may not be feasible with existing devices or manual treatments. There is therefore a further need for improved thermal contrast therapy devices having one or more of the various aspects disclosed herein.

Additionally, without wishing to be constrained by theory, it is believed that in some instances, the effectiveness of thermal contrast therapy may be enhanced by providing treatment sequences that include rapidly alternating cooling periods and heating periods and/or rapid transitions between such periods. Such treatment sequences may, among other things, be effective to enhance vasoconstriction and/or vasodilation and corresponding therapeutic effects. Existing devices may be unsuitable for providing such rapidly alternating periods and/or rapid transitions between periods. For example, existing devices may have an unsuitably large thermal mass in fluid communication with the fluid.

Various components of a thermal contrast therapy device each have a given thermal mass, which may be expressed as:

$$C_{th} = mc_p \quad (1)$$

where m is the mass of the component and c_p is the isobaric specific heat capacity of the component averaged over the temperature range in question. The cumulative thermal mass attributable to the various components in thermal communication with fluid circulating through a thermal contrast therapy device may be expressed as:

$$C_{th_total} = \sum_{n=1}^n C_{th_1} + C_{th_2} + \dots + C_{th_n} \quad (2)$$

Such components in thermal communication with circulating fluid may absorb thermal energy from hot fluid (e.g., during heating periods) and dissipate thermal energy to cold fluid (e.g., during cooling periods).

When transitioning between periods of a treatment sequence, the duration of time required for the circulating fluid and the various components in thermal communication with the fluid to attain equilibrium temperature depends on, among other things, the

thermal mass attributable to such components. When a thermal contrast therapy device has a relatively large thermal mass in thermal communication with the fluid circulating through the device, the duration of time required for the fluid to attain equilibrium temperature may be unsuitably large due to heat transfer with the thermal mass. For
5 example, upon transitioning from a heating period to a cooling period, such thermal mass may accumulate heat from the hot fluid, which heat will then transfer to the cold fluid during the cooling period. Thus, when transitioning between periods some duration of time elapses before the fluid in thermal communication with the thermal mass attains equilibrium temperature with respect to heat transfer with such thermal mass. With some
10 devices, the duration of time required to attain equilibrium temperature may exceed the duration of time specified for effecting transitions between alternating periods of a treatment sequence and/or the duration of time specified for such alternating periods, such as with rapidly alternating cooling periods and heating periods and/or rapid transitions between such periods. Consequently, the temperature of fluid circulating
15 through a device may drift over the course of a given period or sequence of alternating periods due to heat transfer with such thermal mass. Also, the heating and/or cooling requirements for providing fluid to a treatment pad at a given temperature increase with increasing thermal mass in thermal communication with the fluid circulating through the treatment pad. Accordingly, devices having a relatively large thermal mass attributable
20 to components in thermal communication with fluid circulating through a treatment pad may be unsuitable for performing certain treatment sequences disclosed herein. There is therefore an even further need for improved thermal contrast therapy devices.

Because of these and other limitations, it is believed that existing thermal contrast therapy devices and/or treatment methods may frequently provide a suboptimum treatment. Moreover, in some situations, a treatment provider or a user may administer treatments which could actually be harmful to the body. For example, if too much heating or cooling is provided, blood flow may be detrimentally restricted and/or tissue may be damaged. Such blood flow restriction may arise from blood pooling caused by excessive heating, or from constriction of blood vessels caused by excessive cooling. Thermal contrast therapy may be optimized, and injury may be avoided, by providing customized treatment sequences. Thus, it would be advantageous to provide thermal contrast therapy devices, methods, and systems as disclosed herein, which provide greater ability to vary and control treatment parameters, enhanced treatment precision and accuracy, and the ability to administer customized treatment sequences.

The skilled artisan will appreciate that research into the effects and benefits of thermal contrast therapy under various treatment conditions is relatively underdeveloped, and in many instances practitioners may desire further research as to the best way to treat a particular patient, body part, injury, ailment, or condition. It would therefore be advantageous to provide researchers and practitioners with devices, methods and systems that facilitate further research on the subject of thermal contrast therapy.

It is to be understood that thermal contrast therapy may be provided to any human or other mammalian patient, and as such, the present disclosure has applicability in both the medical and veterinary arts. The reader will appreciate that references in the present disclosure to a person, patient, user, and/or recipient of thermal contrast therapy treatments also means and refers to any other mammalian species.

SUMMARY

A summary of certain embodiments disclosed herein is set forth below. It should be understood that these aspects are presented merely to provide the reader with a brief
5 summary of these certain embodiments and that they are not intended to limit the scope of the present disclosure.

The present disclosure relates to thermal contrast therapy devices, treatment methods for providing thermal contrast therapy, and systems for providing and managing thermal contrast therapy treatments. It should be understood that the thermal contrast
10 therapy devices, methods, and systems disclosed herein may be implemented alone, together, or in combination with one another or with other devices, methods, or systems known in the art.

A thermal contrast therapy device may include one or more features disclosed herein. Such features may be effective to increase the thermodynamic efficiency of the
15 device. A thermal contrast therapy device may be configured with features effective to reduce the thermal mass attributable to components in thermal communication with fluid circulating through the treatment pad, e.g., to minimize the thermal mass needing to be overcome before attaining equilibrium temperature when transitioning between heating periods and cooling periods. In some embodiments, a thermal contrast therapy device
20 may be configured to provide rapidly alternating cooling periods and heating periods, and/or to rapidly transition between alternating cooling periods and heating periods. Such transitions may be effected at least as quickly as the duration of time determined by dividing the volume of fluid in a treatment pad by the flow rate of the fluid.

In some embodiments, a thermal contrast therapy device may include a cooling system having a first pump configured to circulate cold fluid and a heating system having a second pump configured to circulate hot fluid, in a sequence of alternating cooling periods and heating periods. Upon a transition between a first period and a second
5 period, fluid having a first temperature corresponding to the first period displaces fluid having a second temperature corresponding to the second period. The cooling system may include a cold fluid recirculation line and/or the heating system may include a hot fluid recirculation line. The cooling system and the heating system may converge at an outflow fluid line, the outflow fluid line configured to discharge fluid from the device. In
10 some embodiments, a thermal contrast therapy device may be configured to route circulating fluid either to the heating system and/or the cooling system based, at least in part, on the temperature of the fluid.

The use of a first pump configured to circulate cold fluid and a second pump configured to circulate hot fluid may be effective to reduce the thermal mass needing to
15 be overcome before attaining equilibrium temperature when transitioning between alternating heating periods and cooling period, thereby increasing the thermodynamic efficiency of the cooling system and/or the heating system. Fluid flowing through an outflow fluid line may therefore attain equilibrium temperature rapidly. In some embodiments, a thermal contrast therapy device and/or the cooling system and/or the
20 heating system thereof may be configured such that only a nominal change in temperature of the fluid occurs (if any), when flowing from the cooling block to the discharge of the device. In some embodiments, a thermal contrast therapy device and/or the cooling system and/or the heating system thereof may be configured such that there

exists only a nominal cumulative thermal mass attributable to components in thermal communication with the fluid between a first point at which fluid discharges from the cooling system and a second point at which fluid discharges from the device.

In some embodiments, a thermal contrast therapy device may include a shared
5 reservoir configured to supply fluid to the cooling system and the heating system. The shared reservoir may be in fluid communication with the cooling system and the heating system, and displaced fluid from the heating system and/or cooling system may be exchanged with fluid in the shared reservoir. The shared reservoir may hold a first
10 volume of fluid from the cooling system and a second volume of fluid from the heating system. The shared reservoir may be configured such that the first volume of fluid increases upon a transition from a cooling period to a heating period, and the second volume of fluid increases upon a transition from a heating period to a cooling period. The volume of fluid in the shared reservoir may remain substantially constant during the sequence of alternating cooling periods and heating periods. In some embodiments, the
15 shared reservoir allows stratification of hot fluid and cold fluid, and the heating system may preferentially draw stratified hot fluid from the shared reservoir and/or the cooling system may preferentially draw stratified cold fluid from the shared reservoir. Fluid communication between the shared reservoir and the heating system may occur through a first opening in the shared reservoir and fluid communication between the shared
20 reservoir and the cooling system may occur through a second opening in the shared reservoir, with the first opening located at an elevation above the elevation of the second opening.

The cooling system may include a cooling block configured to hold a first volume of fluid, and the heating system may include a heating block configured to hold a second volume of fluid. The cooling block and/or the heating block may have a plurality of baffles defining a serpentine path for fluid travel between an inlet and an outlet. The cooling block and/or heating block may also be provided without such baffles. The cooling system may be configured to circulate cold fluid through a treatment pad, and the heating system may be configured to circulate hot fluid through the treatment pad. Fluid returning from the treatment pad may be routed to either the cooling system or the heating system based, at least in part, on the temperature of the fluid. In some embodiments, fluid circulates through the cooling system during heating periods, and/or fluid circulates through the heating system during cooling periods, for example, to adjust or maintain the temperature of the circulating fluid.

A thermal contrast therapy device may be configured to effect a pressure pulse in the treatment pad. In some embodiments, the cooling system may have a first supply valve and a first return valve, and the heating system may have a second supply valve and a second return valve. The valves may be magnetic solenoid valves. The pressure pulse may be effected at least in part by alternating a valve between opened and closed positions. In some embodiments, a thermal contrast therapy device may be configured to synchronize the frequency of a pressure pulse with the heart rate of a patient receiving treatment. In some embodiments, a thermal contrast therapy device may be configured to provide a pressure pulse effective to induce cycles of vasodilation and vasoconstriction. In some embodiments, cycles of vasodilation and vasoconstriction may be induced by alternating heating periods and cooling periods, and without providing pressure pulses.

In some embodiments, a thermal contrast therapy device may be configured to function with a plurality of different treatment pads. A treatment pad may comprise a network of interconnected cells or capillaries or a serpentine conduit, or combinations thereof, with an inflow port configured to receive fluid via an inflow tube, and an outflow port configured to return fluid via an outflow tube. In some embodiments, a treatment pad having a serpentine conduit allows for more rapid transitions between alternating heating periods and cooling periods. A serpentine conduit may comprise a plurality of conduit patterns, including hairpin corners, a Fermat's spiral, a modified Fermat's spiral, and combinations thereof. In some embodiments, a treatment pad may be provided having a configuration effective to provide a substantially uniform rate of heat transfer across the effective surface area of the treatment pad. In some embodiments, a pad ID tag may be embedded within a treatment pad or within a fitting configured to be attached to a treatment pad. A cuff having any desired shape or configuration may be provided for securing a treatment pad to an area of a patient's body sought to be treated. In some embodiments, a quick-release extension cord may be provided for fluid and data communication between a thermal contrast therapy device and a treatment pad. In some embodiments, a pad ID reader, one or more temperature sensors, and/or other electronics may be embedded in a quick-release extension cord.

The thermal contrast therapy devices disclosed herein may be configured to provide customized thermal contrast therapy treatment sequences. For example, a device may be configured to receive an indication effective to identify a treatment pad operably connected to the device and to cause the device to perform a thermal contrast therapy

treatment sequence that is calibrated for the particular treatment pad operably connected to device.

The thermal contrast therapy devices disclosed herein may be configured to automatically adjust one or more sequence parameters during a selected treatment sequence or between a series of treatments. In some embodiments, a thermal contrast therapy device may be configured to allow a user to select or input customized sequence parameters, which may include, among other things, a customized time duration, pressure pulse frequency of the fluid, cuff compression, temperature-change profile, fluid temperature, and/or flow rate. The customized sequence parameters may correspond to one or more of the periods within a sequence, one or more sequences within a series of treatment sequences, or a series of treatment sequences within an ongoing treatment program. In some embodiments, a thermal contrast therapy device may be configured to receive an indication from one or more temperature sensors and/or flow meters and to effect a desired measure of heat transfer between the fluid and the patient's tissue, for example, by automatically adjusting the temperature and/or flow rate of the fluid. In some embodiments, a thermal contrast therapy device may be configured to receive an indication of one or more physiological parameter values exhibited by a patient and to perform a customized thermal contrast therapy treatment sequence based, at least in part, on the one or more physiological parameter values.

In some embodiments, a thermal contrast therapy device may be configured to transmit data to or receive data from a thermal contrast therapy system. Such data may include, for example, physiological parameter values exhibited by a patient, for example, during treatment. In some embodiments, subsequent additional treatments may be

provided based, at least in part, on data corresponding to previous treatments. In some embodiments, a thermal contrast therapy device may be configured to perform a treatment sequence derived, at least in part, from an input received from a thermal contrast therapy system. The treatment sequence may be prescribed by a treatment provider or selected by a user of the thermal contrast therapy device. A treatment sequence may be based on, for example, current or previously provided treatment sequences, physiological parameter values exhibited by a patient during a current or previous treatment, and/or therapeutic effects observed in a patient during a current or previous treatment.

The methods disclosed herein include computer-implemented methods of providing thermal contrast therapy. In some embodiments, computer-implemented methods of providing thermal contrast therapy include circulating fluid from a thermal contrast therapy device through a treatment pad, the treatment pad having been applied to a patient, while providing a sequence comprising a plurality of alternating cooling periods and heating periods. Any one or more variables in the thermal contrast therapy sequence may be modified in order to provide a customized thermal contrast therapy treatment sequence. As examples, a customized treatment sequence may include automatically changing the fluid temperature and/or flow rate, the duration of one or more periods, the number of periods, and/or prescribing a sequence for one or more future thermal contrast therapy treatments.

A customized thermal contrast therapy treatment sequence may be prescribed by a treatment provider or selected by a user of a thermal contrast therapy device. The program may be selected, for example, from a database associated with a thermal contrast

therapy system configured to provide customized thermal contrast therapy treatments. Customized sequence parameters may be based, for example, on a physiological parameter value exhibited by the patient, an area of the body sought to be treated, a particular symptom or condition sought to be treated, and/or a particular desired
5 therapeutic result. In some embodiments, a customized treatment sequence may include effecting a desired measure of heat transfer between the fluid and the patient's tissue during one or more of the cooling periods and heating periods. The desired measure of heat transfer may be effected by automatically adjusting the flow rate of the fluid and/or the temperature of the fluid.

10 In some embodiments, a thermal contrast therapy treatment sequence may include rapidly alternating cooling periods and heating periods and/or rapid transitions between such periods. Such a sequence may be effective to induce cycles of vasoconstriction and vasodilation, which, in turn, may be effective to cause an increase in blood circulation and/or blood oxygen content in a patient's tissue.

15 In some embodiments, a thermal contrast therapy treatment sequence may be automatically adjusted to optimize one or more physiological parameters. For example, a treatment sequences may be automatically adjusted so as to optimize the magnitude of an increase in blood circulation and/or blood oxygen content induced by cycles of vasoconstriction and vasodilation. In some embodiments, a treatment sequence may be
20 automatically adjusted when the patient exhibits a physiological parameter value that corresponds to a predefined value. In some embodiments, automatic adjustments to a thermal contrast therapy treatment sequence may include: changing a setting for the fluid temperature and/or flow rate; changing the duration of one or more of the cooling

periods, heating periods, and/or transition periods; changing the number of cooling periods, heating periods, and/or transition periods; changing the frequency of the pressure pulse of the fluid; changing the compression of the treatment pad; changing the rate of change of the temperature and/or flow rate of the fluid; and/or prescribing a sequence for
5 one or more future thermal contrast therapy treatments.

The thermal contrast therapy systems disclosed herein include systems comprising a thermal contrast therapy network, and one or more thermal contrast therapy devices configured to transmit data to and receive data from the thermal contrast therapy network. The thermal contrast therapy devices may be associated with one or more users,
10 and the system may be configured to provide customized thermal contrast therapy to the users. In some embodiments, customized thermal contrast therapy treatment programs may be automatically generated based on data housed in a database associated with a thermal contrast system.

In accordance with the present disclosure, one or more computer-readable media
15 bearing computer-readable instructions may be provided, that, when executed by a processor such as in an automated thermal contrast therapy device, cause the device to perform one or more of the computer-implemented methods of providing thermal contrast therapy. In addition to the foregoing, various other systems, devices, and methods, and non-transitory computer-readable media are set forth and described in the
20 present disclosure.

The foregoing summary may contain simplifications, generalizations, inclusions, and/or omissions of detail; and consequently, those skilled in the art will appreciate that the summary is illustrative only and is not intended to be in any way limiting. In addition

to the illustrative aspects, embodiments, and features described above, further aspects, embodiments, and features will become apparent by reference to the drawings, the following detailed description of illustrative embodiments, and the claims.

5

DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a schematic of an exemplary thermal contrast therapy device.

Fig. 2 shows a front perspective view of an exemplary thermal contrast therapy device.

Fig. 3 shows a rear perspective, exploded view of the exemplary thermal contrast therapy device of Fig. 2.

Fig. 4 shows a perspective view of the inside of the rear panel of the exemplary thermal contrast therapy device of Fig. 2.

Fig. 5 shows a perspective view of the pump and valve module of the thermal contrast therapy device of Fig. 2.

Figs. 6A and 6B respectively show cross-sectional views from the left side and from the right side of the exemplary thermal contrast therapy device of Fig. 2.

Figs. 7A and 7B show perspective views of corresponding parts to an exemplary heat transfer block for use in a thermal contrast therapy device.

Fig. 7C shows in perspective view, an exemplary embodiment utilizing the heat transfer block of Figs. 7A and 7B for cooling fluid for use in a thermal contrast therapy device.

Fig. 8A shows an exemplary treatment pad for administering thermal contrast therapy.

Fig. **8B** shows a perspective, exploded view of an exemplary cuff configured to receive a treatment pad, such as the treatment pad of Fig. **8A**.

Figs. **8C** and **8D** show additional exemplary treatment pads for administering thermal contrast therapy.

5 Fig. **9A** shows a perspective view of an exemplary quick-release extension cord for providing fluid and data communication between a thermal contrast therapy device and a treatment pad.

Fig. **9B** shows a cross-sectional side view of the pad-side fitting of the quick-release extension cord of Fig. **9A**.

10 Fig. **9C** shows a cross-sectional top view of the pad-side fitting of the quick-release extension cord of Fig. **9A**.

Fig. **10** shows a perspective view of an exemplary device interface fitting for coupling the quick-release extension cord of Figs. **9A-C** to a thermal contrast therapy device.

15 Fig. **11** shows a perspective view of an exemplary pad interface fitting for coupling the quick-release extension cord of Figs. **9A-C** to a treatment pad.

Fig. **12A** shows a flow chart illustrative of an exemplary process for providing a desired measure of heat transfer during a thermal contrast therapy treatment sequence.

20 Fig. **12B** shows a flow chart illustrative of an exemplary process for providing a desired measure of heat transfer during a thermal contrast therapy treatment sequence, utilizing flow rate to control the rate of heat transfer.

Figs. **13A** and **13B** show a flow chart illustrative of an exemplary process for providing a customized thermal contrast therapy treatment sequence, dynamically controlled to optimize a physiological parameter value.

5 Figs. **14A-1** and **14A-2**; **14B-1** and **14B-2**; **14C-1** and **14C-2**; and **14D-1** and **14D-2** show exemplary customized thermal contrast therapy treatment sequences configured to provide a desired fluid temperature during the various periods of the sequence.

10 Figs. **14E-1** and **14E-2**; **14F-1** and **14F-2**; and **14G-1** and **14G-2** show exemplary customized thermal contrast therapy treatment sequences configured to provide a desired measure of heat transfer during the various periods of the sequence.

Fig. **15** shows a schematic of an exemplary thermal contrast therapy system.

Fig. **16A** shows a schematic of an additional exemplary thermal contrast therapy device.

15 Fig. **16B** shows a schematic of a further additional exemplary thermal contrast therapy device.

Fig. **17** shows an exemplary user or patient profile page for a thermal contrast therapy device or system.

Fig. **18A** shows an exemplary user interface for a treatment provider to utilize a thermal contrast therapy system.

20 Fig. **18B** shows an exemplary user interface for a treatment provider to manage patients receiving thermal contrast therapy treatments via a thermal contrast therapy system.

Fig. **18C** shows an exemplary user interface for a treatment provider to manage thermal contrast therapy treatments prescribed to a patient via a thermal contrast therapy system.

Fig. **18D** shows an exemplary user interface for searching a thermal contrast therapy system database for customized thermal contrast therapy treatments.

Fig. **18E** shows an exemplary user interface for operation of thermal contrast therapy device providing a selection of manual or preprogrammed operation.

Fig. **18F** shows an exemplary user interface for a user to cause a thermal contrast therapy device to perform a customized thermal contrast therapy treatment.

Fig. **18G** shows an exemplary user interface for manual operation of thermal contrast therapy device.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

In the following detailed description of illustrative embodiments, thermal contrast therapy devices, treatment methods for providing thermal contrast therapy, and systems for providing and managing thermal contrast therapy treatments will be described in greater detail, with reference to several embodiments thereof as disclosed herein and illustrated in the accompanying figures. Further exemplary thermal contrast therapy devices, methods and systems are described in U.S. Patent Application Serial No. 14/340,904, the complete disclosure of which is hereby incorporated by reference into this application. In the following detailed description of illustrative embodiments, numerous specific details are set forth in order to provide a thorough understanding of the disclosed systems, devices, and methods. It will be apparent, however, to one skilled in

the art, that the presently disclosed devices, methods, and systems each may be practiced without some or all of these specific details. In other instances, well known process steps and/or structures have not been described in detail in order to not unnecessarily obscure the present disclosure. The following detailed description of illustrative embodiments is
5 therefore not to be taken in a limiting sense, and it is intended that other embodiments are within the scope of the presently disclosed devices, method, and systems. The features and advantages of the presently disclosed subject matter may be better understood with reference to the figures and discussions that follow. The claimed subject matter is defined by the appended claims and their equivalents.

10

I. Thermal Contrast Therapy Devices, Treatment Pads, and Quick Release Extension Cords

Exemplary thermal contrast therapy devices, treatment pads, and quick release extension cords will now be discussed. The thermal contrast therapy devices disclosed
15 herein are configured to provide a sequence of alternating cooling periods and heating periods to one or more areas of a patient's body to which a treatment pad may be applied. A thermal contrast therapy device may comprise a source of hot fluid, a source of cold fluid, and one or more pumps configured to circulate fluid through any one or more treatment pads in fluid communication with the device. In some embodiments, the
20 thermal contrast therapy devices, treatment pads, and/or quick release extension cords disclosed herein may be configured with features effective to reduce the thermal mass attributable to components in thermal communication with fluid circulating through a device and/or a treatment pad.

Thermal Contrast Therapy Devices

Referring to Fig. 1, a schematic of an exemplary thermal contrast therapy device **100** is shown. Those skilled in the art will appreciate that numerous other embodiments of thermal contrast therapy devices are within the spirit and scope of the present disclosure.

The thermal contrast therapy device **100** shown in Fig. 1 comprises a heating system **102** configured to provide hot fluid, a cooling system **104** configured to provide cold fluid, and a shared reservoir **106** configured to hold a volume of fluid to supply both the heating system and the cooling system. A heating system may comprise a heating block **108**, a hot pump **110** operably coupled to a hot motor **112**, and one or more heating elements **114** that impart heat energy to the fluid. A cooling system may comprise a cooling block **116**, and a cold pump **118** operably coupled to a cold motor **120**. In some embodiments, the hot pump and the cold pump may be operably connected to a single motor. A cooling system may further comprise one or more cooling elements to draw heat energy from the fluid. The one or more cooling elements may be thermoelectric coolers **122** in thermal communication with the cooling block and one or more heat sinks **124**. The shared reservoir **106** may be in fluid communication with the cooling system and the heating system, for example, via tubing or other means that permit fluid flow between the shared reservoir and each of the heating block and the cooling block. The shared reservoir may be positioned at an elevation such that fluid from the share reservoir gravity feeds both to the heating block and to the cooling block.

The heating system and cooling system are each configured to circulate fluid. The hot pump circulates fluid drawn from the heating block, and one or more hot supply

valves **126** direct the fluid either back to the heating block and/or onward to one or more treatment pads **128**. The cold pump circulates fluid drawn from the cooling block, and one or more cold supply valves **130** direct the fluid either back to the cooling block and/or onward to the one or more treatment pads. The hot supply valve **126** and the cold supply valve **130** may comprise three-way valves having one inlet and two outlets. When a first outlet of such a three-way valve is open, fluid flows to the heating block via recirculation line **132** or to the cooling block via cold recirculation line **134**, respectively, and when a second outlet is open, fluid flows towards the one or more treatment pads via an outflow fluid line **136**. Fluid circulated through the one or more treatment pads returns to the device via return fluid line **138**, and may be directed either to the heating block via hot return valve **140** and/or to the cooling block via cold return valve **142**. In some embodiments, fluid circulating through a treatment pad may be directed to either the heating block and/or the cooling block based on the temperature of the fluid, for example, so as to optimize the heating and cooling efficiency of the thermal contrast therapy device.

Fluid may be periodically or continuously circulated through the heating system and/or the cooling system so as to provide a volume of fluid having a desired temperature. Fluid from either the heating system and/or the cooling system may be circulated through the treatment pad during alternating heating periods and or cooling periods. For example, during heating periods, hot fluid may be circulated through the treatment pad, via the second outlet of the hot supply valve **126** and the hot return valve **140**, while cold fluid circulates through the cooling system via the first outlet of the cold supply valve **130**. Similarly, during cooling periods, cold fluid may be circulated through

the treatment pad, via the second outlet of the cold supply valve **130** and the cold return valve **142**, while hot fluid circulates through the heating system via the second outlet of the hot supply valve **126**. In some embodiments, a portion of the fluid discharged from the hot pump **110** may be routed through the first outlet of the hot supply valve **126** to the heating block during heating periods, for example, to maintain circulation of fluid through the heating block or to augment the flow rate of the hot fluid circulated through the treatment pad. Similarly, a portion of the fluid discharged from cold pump **118** may be routed through the first outlet of the cold supply valve **130** to the cooling block during cooling periods, for example, to maintain circulation of fluid through the cooling block or to augment the flow rate of the cold fluid circulated through the treatment pad. In some embodiments, a portion of the fluid that circulates through the treatment pad during a heating period may be routed to the cooling block, via the cold return valve **142**, for example, to adjust the temperature of the fluid in the cooling block. Similarly, a portion of the fluid that circulates through the treatment pad during a cooling period may be routed to the heating block, via the hot return valve **140**, for example, to adjust the temperature of the fluid in the heating block.

The thermal contrast therapy devices disclosed herein may be configured to rapidly and efficiently transition between alternating cooling periods and heating periods. Upon transitioning between a first period and a second period, fluid having a first temperature corresponding to the first period displaces fluid having a second temperature corresponding to the second period. For example, upon initiating a transition from a heating period to a cooling period, hot fluid will have been circulating through the treatment pad and to the heating block, thus providing fluid having a temperature

corresponding to the temperature specified for the heating period. At the transition from the heating period to the cooling period, fluid having a temperature corresponding to the temperature specified for the cooling period displaces the fluid from the heating period. The displaced fluid flows either to the heating block via the hot return valve **140** and/or to
5 the cooling block via the cold return valve **142**. In some embodiments, displaced fluid from the heating period flows through the hot return valve **140** until about such time as a substantial portion of the fluid from the heating period has been displaced and, for example, returned to the heating system, at which point the hot return valve **140** closes and fluid then flows through the cold return valve **142** to the cooling system. At the
10 transition from a cooling period to a heating period, fluid having a temperature corresponding to the temperature specified for a heating period similarly displaces the fluid from the cooling period.

In some embodiments, a thermal contrast therapy device may be configured to minimize the thermal mass needing to be overcome before attaining equilibrium fluid
15 temperature when transitioning between alternating heating periods and cooling periods. This may be accomplished, for example, by minimizing the thermal mass attributable to components in thermal communication with fluid from the heating block and with fluid from the cooling block, e.g., during alternating heating periods and cooling periods. For example, as shown in Fig. **1**, a heating system **102** and a cooling system **104** are provided
20 having separate, dedicated pumps, valves, and recirculation lines. As shown in Fig. **1**, the heating system **102** and the cooling system **104** converge at and outflow fluid line **136**, and fluid circulating through the treatment pad returns either to the heating system and/or the cooling system via return fluid line **138**. As such, when circulating fluid through the

treatment pad **128**, fluid pumped to the treatment pad from the heating block **108** and fluid pumped to the treatment pad from the cooling block **116** commonly interact only with the thermal mass of components beginning from the outflow fluid line **136** and ending with the return fluid line **138**. Given this, when transitioning between periods of a treatment sequence, only a nominal period of time elapses before the fluid circulating through the treatment pad, and the various components in thermal communication with such fluid, attain equilibrium temperature with respect to the thermal mass of such components. Thus, thermal contrast therapy devices may be configured to provide treatment sequences having rapidly alternating periods and/or rapid transitions between periods.

In some embodiments, thermal contrast therapy devices may exhibit enhanced thermodynamic efficiency, such as with respect to the cooling system and/or the heating system. As an example, heating and cooling loads of are reduced by minimizing the thermal mass attributable to components in thermal communication with fluid from the heating block and with fluid from the cooling block, and as such, the energy required to provide fluid to a treatment pad at a given temperature may be reduced. By contrast, when a pump, recirculation line, and/or valve are commonly used to supply the treatment pad with fluid from the heating block and with fluid from the cooling block, a larger thermal mass will be in thermal communication with the fluid circulating through the treatment pad. As such, when transitioning between periods of a treatment sequence, a longer duration of time will elapse at a given fluid temperature and flow rate before fluid circulating through a treatment pad attains equilibrium temperature with respect to such thermal mass in thermal communication with the fluid.

In some embodiments, a thermal contrast therapy device may be configured such that upon transitioning from a heating period to a cooling period or from a cooling period to a heating period, the fluid flowing towards one or more treatment pads via outflow fluid line **136** attains equilibrium temperature, with respect to such thermal mass in thermal communication with the fluid, within less than about 120 seconds to less than about 5 seconds, for example, within less than 120 seconds, less than 110 seconds, less than 100 seconds, less than 90 seconds, less than 80 seconds, less than 70 seconds, less than 60 seconds, less than 50 seconds, less than 40 seconds, less than 30 seconds, less than 20 seconds, less than 10 seconds, or less than 5 seconds. Such equilibrium temperature may be considered attained when the temperature of the fluid falls within 1 °F of the equilibrium temperature of the fluid with respect to such thermal mass in thermal communication with the fluid.

In some embodiments, a thermal contrast therapy device may be provided having a heating system and/or a cooling system configured such that upon transitioning from a heating period to a cooling period or from a cooling period to a heating period, any change in temperature of the fluid attributable to thermal communication with the thermal mass from the heating block **108** or from the cooling block **116**, as applicable, to the discharge of the thermal contrast therapy device (e.g., the discharge of outflow fluid line **136**), may be less than about 5 °F, less than about 4 °F, less than about 3 °F, less than about 2 °F, less than about 1 °F, less than about 0.5 °F, or less than 0.1 °F. In some embodiments, a thermal contrast therapy device may be configured such that any change in temperature of the fluid when flowing from the heating block **108** or from the cooling block **116** to the treatment pad **128** may be less than about 5 °F, less than about 4 °F, less

than about 3 °F, less than about 2 °F, less than about 1 °F, less than about 0.5 °F, or less than 0.1 °F. Such changes in temperature may be determined by measuring the temperature of the fluid when flowing from the heating block or cooling block, as applicable, and the temperature of the fluid when flowing out of the device or into the treatment pad, as applicable, and calculating the difference between those temperatures.

In some embodiments, a thermal contrast therapy device may be equipped with a heating system and/or a cooling system configured such that the cumulative thermal mass, C_{th_total} , attributable to the various components in thermal communication with the fluid, from between the discharge of the heating system **102** and/or the cooling system **104** (e.g., the convergence thereof at the outflow fluid line **136**) to the discharge of the thermal contrast therapy device (e.g., the discharge of outflow fluid line **136**), may be less than about 0.5 BTU/°F, less than about 0.4 BTU/°F, less than about 0.3 BTU/°F, less than about 0.2 BTU/°F, less than about 0.1 BTU/°F, less than about 0.05 BTU/°F, or less than about 0.01 BTU/°F.

Further referring to Fig. **1**, when performing a thermal contrast therapy treatment sequence, fluid may be supplied to a treatment pad during a given period either by the hot pump **110**, by the cold pump **118**, or in part by the hot pump and in part by the cold pump. For example, in some embodiments, fluid corresponding to a heating period may include fluid supplied by the hot pump, and fluid corresponding to a cooling period may include fluid supplied by the cold pump. In some embodiments, fluid from the heating block may be tempered with fluid from the cooling block, for example, to provide fluid to the treatment pad during a heating period having a temperature that is less than the temperature of the fluid discharged from the hot pump. Similarly, fluid from the cooling

block may be tempered with fluid from the heating block, for example, to provide fluid to the treatment pad during a cooling period having a temperature that is greater than the temperature of the fluid discharged from the cold pump. By such tempering, a multitude of intermediate fluid temperatures may be provided through mixing various proportions of hot and cold fluid, and without first having to heat or cool a volume of fluid to the desired intermediate temperature. In some embodiments, when fluid from the hot pump and cold pump are mixed with one another, fluid returning from the treatment pad may be routed in part to the heating block and in part to the cooling block. In some embodiments, all of the fluid returning from the treatment pad may be routed to either the heating block or the cooling block. The routing of fluid returning from the treatment pad as between the heating block and the cooling block may be determined based on the resulting loads of the heating system and/or cooling system, and the corresponding energy efficiency of the device.

When transitioning between a first period and a second period, displaced fluid from the first period causes a corresponding volume of fluid to be exchanged with fluid from the shared reservoir **106**. For example, when fluid from the cooling block displaces fluid from a heating period with fluid for a cooling period, the displaced fluid may flow to the heating block, which causes a corresponding volume of fluid to flow from the heating block to the shared reservoir, and from the shared reservoir to the cooling block. Over a sequence of alternating cooling periods and heating periods, fluid flows between the heating block, the shared reservoir, and the cooling block, in alternating directions. The shared reservoir allows the volume of fluid in the heating system and the cooling system to balance, for example, when displacing fluid during transitions between periods,

when fluid from the hot pump and cold pump are mixed with one another in various proportions, and/or when fluid returning from the treatment pad is routed in part to the heating block and in part to the cooling block in various proportions. While fluid flows in and out of the shared reservoir in alternating directions, the volume of fluid in the shared reservoir remains substantially constant, as fluid gravity feeds to the heating block and the cooling block in the opposite direction of fluid flowing into the shared reservoir, as discussed below with respect to Figs. **6A** and **6B**.

In some embodiments, fluid communication between the shared reservoir and the heating block occurs through a first opening in the shared reservoir, and fluid communication between the shared reservoir and the cooling block occurs through a second opening in the shared reservoir. The first opening may be located at an elevation above the elevation of the second opening. Such configuration may be effective to allow stratification of hot fluid and cold fluid within the shared reservoir. Fluid in the cooling block may stratify, for example, when fluid exchange with the shared reservoir takes place with minimal agitation or turbulence such as under substantially laminar flow conditions. Stratification of hot fluid and cold fluid in the shared reservoir may reduce the heating and cooling demands of the heating block and the cooling block, respectively, as fluid flowing from the shared reservoir to the hot system may preferentially draw from the stratified hot fluid, while fluid flowing from the shared reservoir to the cold system may preferentially draw from the stratified cold fluid. Such stratification may be enhanced by minimizing the degree of turbulence in the shared reservoir caused by fluid flowing in and out of the shared reservoir. This may be achieved, for example, by configuring the shape and size of the shared reservoir and/or locations where the heating

block and/or cooling block interface with the shared reservoir, so as to minimize turbulence. Such turbulence in the shared reservoir may be of particular concern, for example, when flow rates exceedingly depart from laminar flow conditions, and/or when providing pressure pulses. Such pressure pulses may create turbulence that disrupts stratification in the shared reservoir. One or more inline pulse dampeners may be used to mitigate such disruptions caused by pressure pulses. Baffles and/or diffusers may also be used to minimize turbulence in the shared reservoir. Configurations that provide laminar flow (as opposed to turbulent flow) may also enhance stratification in the shared reservoir.

In some embodiments, one or more baffles and/or plate diffuser elements may be provided in the shared reservoir to enhance stratification between hot fluid and cold fluid. For example, such an element may be positioned at about the expected line of stratification between hot fluid and cold fluid. In some embodiments, such an element may be configured to float or adjust in conjunction with the line of stratification within the shared reservoir.

Further referring to Fig. 1, a thermal contrast therapy device may be equipped with a processor 144 to control the operation of device. The processor may be configured to cause the thermal contrast therapy device to perform customized thermal contrast therapy treatment sequences, for example, by monitoring and/or controlling various aspects of the device, including the heating element(s), thermoelectric cooler(s), heat sink(s), pump(s), and valve(s). In some embodiments, a thermal contrast therapy device may be equipped with one or more temperature sensors and/or flow meters, from which the processor may be configured to receive an input which may be used to monitor and/or

control operation of the device. For example, a heating block temperature sensor **146** may be provided to measure the temperature of the fluid at the heating block, and/or a cooling block temperature sensor **148** may be provided to measure the temperature of the fluid at the cooling block. Further temperature sensors may be provided; for example, a fluid supply line temperature sensor **150** may be provided (e.g., along the outflow fluid line **136**), and/or a fluid return line temperature sensor **152** may be provided (e.g., along the return fluid line **138**).

In some embodiments, the processor **144** may be configured to receive an input from temperature sensors that are external to the device, for example, a treatment pad inlet temperature sensor **154** and/or a treatment pad outlet temperature sensor **156**, which temperature sensors may be proximately located at about a treatment pad's inlet and outlet, respectively. In some embodiments, a flow meter **158** may be provided, for example, to measure the flow rate of fluid circulating through the treatment pad. Further temperature sensors, flow meters, and other instrumentation may also be provided. The temperature of the heat sink may be monitored via heat sink temperature sensor **160**, for example, to monitor and control cooling of fluid effected by the cooling system. In some embodiments, the shared reservoir may be equipped with a level sensor **162**. Such level sensor may provide an indication as to whether the fluid level in the shared reservoir departs from an allowable operating range, which may occur in the event of fluid evaporation and/or in the event of a disruption in device operations such as a stoppage or decrease in fluid flow.

The processor **144** may be configured to control the temperature of the fluid, utilizing temperature measurements from any one or more temperature sensors. The

processor may also be configured to control the flow rate of the fluid, utilizing flow measurements from any one or more flow meters. These temperature and/or flow rate measurements may be utilized in thermodynamic calculations to provide customized thermal contrast therapy treatment sequences. Such treatment sequences may include
5 effecting a specified measure of heat transfer (i.e., a quantity of heat and/or a rate of heat transfer).

In some embodiments, a thermal contrast therapy device may be configured to interact with a user interface device **164**, for example, to allow a user to control the operation of the thermal contrast therapy device, such as by selecting or inputting
10 customized treatment sequence parameters. The user interface device may include any suitable interface, such as a touch screen, monitor, keypad, mouse, or other interface device or any combination thereof. The user interface device may be integrated with a thermal contrast therapy device, for example, a touch screen may be integrated with the device's casing **200** (Fig. 2), e.g., on the frontward face of the casing. Alternatively, a
15 user interface device may be provided separately. For example a personal computer, tablet, mobile phone, or other hand-held device may be provided for interacting with a thermal contrast therapy device. In some embodiments, the processor may be configured to interact with a thermal contrast therapy network **166**. The processor may be configured to perform a treatment sequence derived, at least in part, from an input
20 received from a thermal contrast therapy network. The treatment sequence may be prescribed by a treatment provider or selected by a user of the thermal contrast therapy device. The selected treatment may be chosen from a database of available treatment sequences supplied through the thermal contrast therapy network, or manually input, via

a user interface. The processor may also be configured to automatically adjust one or more sequence parameters so as to perform a selected treatment sequence.

The thermal contrast therapy devices disclosed herein may be configured to function with a plurality of different treatment pads of various sizes and/or configurations. Treatment pads having different sizes may be provided (e.g., small, medium, large, extra-large, etc.), for example, to accommodate different sized patients. Treatment pads having different configurations may be provided, for example, to accommodate different body parts (e.g., for the arm, leg, knee, foot, ankle, hip, lumbar, back, shoulder, elbow, wrist, neck, or cranium, etc.). As shown in Fig. 1, fluid from the thermal contrast therapy device circulates through a treatment pad through supply line **168** and return line **170**. Fluid lines may be coupled to the thermal contrast therapy device and treatment pad via any suitable means. In some embodiments, fluid lines may be coupled to the thermal contrast therapy device via a device interface fitting **172** configured to releasably mate with a corresponding device-side fitting **174** on the fluid lines. Similarly, fluid lines may be coupled to the treatment pad via a pad interface fitting **176** configured to releasably mate with a corresponding pad-side fitting **178** on the opposite end of the fluid lines. A treatment pad ID tag **180** may be embedded in the treatment pad or in a pad interface fitting **176**. A treatment pad ID tag may be used, for example, to identify a treatment pad and associate thermal contrast therapy treatments and related data with the treatment pad in service. A pad ID reader **182** may be built into pad-side fitting **178**, for example, to interact with treatment pad ID tag and/or temperature sensors **154**, **156** embedded in the pad-side fitting or elsewhere, and to transmit data to the thermal contrast therapy device. The pad ID reader may, in turn,

interact with a processor, for example, to relay inputs that may be used to monitor and control thermal contrast therapy treatments and/or record and store data associated with such treatments.

In some embodiments, a thermal contrast therapy device may be configured to automatically adjust one or more parameters of a treatment sequence based, at least in part, on one or more characteristics of a particular treatment pad. Such parameters include fluid temperature, flow rate, and/or duration of time for one or more periods of a treatment sequence. Such automatic adjustments may be configured to enable a thermal contrast therapy device to effect a desired treatment across a plurality of different treatment pads having varying dimensions and/or configurations. In some embodiments, a thermal contrast therapy device may be configured to effect a specified measure of heat transfer (i.e., a quantity of heat and/or a rate of heat transfer) by automatically adjusting one or more of: fluid temperature, flow rate, and/or duration of time, based, at least in part, on the identification a particular treatment pad operably connected to the device and/or one or more characteristics of such treatment pad.

In some embodiments, a thermal contrast therapy device may be configured to perform a treatment sequence based, at least in part, on the identification a particular treatment pad operably connected to the device and/or one or more characteristics of such treatment pad. For example, if the device identifies a treatment pad associated with knee treatments, the device may perform a treatment sequence intended for treating knees; or, if the device identifies a cuff associated with the lumbar region, the device may perform a treatment sequence intended for treating the lumbar region. Such treatment sequences

may be provided based on virtually any treatment pad associated with virtually any area of the body or condition sought to be treated.

An exemplary configuration of a thermal contrast therapy device will now be discussed. It is to be understood that various other configurations are within the spirit and scope of the present disclosure. Referring now to Fig. 2, a front perspective view of an exemplary thermal contrast therapy device **100** is shown. The various components of the device may be contained within a casing **200**, which may be configured with handles **202** for portability. The casing may be fabricated from any suitable material or combinations thereof, including plastics such as acrylonitrile butadiene styrene, polyvinyl chloride, metals, composites, or other materials. Vents **204**, **206** provide ventilation to various components within the device. The shared reservoir **106** may be accessed via a cap **208** for adding or removing fluid. The cap **208** may be configured with a pressure relief vent or valve, so as to equalize pressure that may accumulate within the thermal contrast therapy device. Such pressure may accumulate from vapor produced by heating fluid.

A device interface fitting **172** may be conveniently located, such as on the front of the casing as shown in Fig. 2. The device interface fitting may have a supply line fitting **210**, a return line fitting **212**, and a data fitting **214**, and each of which may be configured to releasably mate with corresponding receptacles on a device-side fitting **174** (Fig. 1). The data fitting **214** may interface with a cable configured to transmit data between the thermal contrast therapy device and associated electronic components, such as a pad ID reader **182**, temperature sensors **154**, **156**, a treatment pad ID tag **180**, an auxiliary device, and/or other components (Fig. 1). Indicator lights **216** provide users with

information about the status of the device. A data port **218** may be provided on the front of the device as a convenient location to transmit data to or from the device, for example, to upload or download data associated with a user of the device or thermal contrast therapy treatments, and/or to enable the device to interact with one or more auxiliary
5 devices or other electronic components.

Referring now to Fig. **3**, a rear perspective, exploded view of the exemplary thermal contrast therapy device of Fig. **2** is shown. A removable rear panel **300** provides access to components within the thermal contrast therapy device. A pump and valve module **302** slides between brackets **304**, **306** configured to secure the pump and valve
10 module within the casing **200**. The cooling block **116** and one or more thermoelectric cooler(s) **122** (both not shown) and heat sink(s) **124** reside adjacent to the pump and valve module, and the heating block **108** resides opposite thereof. A partition **308** provides structural integrity to the casing, and also insulates the cooling block, thermoelectric cooler(s), and heat sink(s) from other components within the casing.
15 Vents **310**, **312** provide ventilation to various components within the device. As shown in Fig. **4**, various electronic components may be mounted to the inside of the removable rear panel **300**, including a circuit board **400**, having a processor **144**, a USB hub **402**, a USB port **404**, a counter **406**, a power input **408**, and a power supply **410**. Such electronic components are well known in the art, and the skilled artisan may select from
20 among any suitable alternatives. Referring again to Fig. **3**, the USB port **404**, the counter **406**, and the power input **408** are each accessible from the rear of the device.

The power supply **410** provides power to operate the thermal contrast therapy device, e.g., 12 volt DC power. In some embodiments, a modular configurable power

supply may be used to power a thermal contrast therapy device. Pulse width modulation may be used to control the amount of power delivered to various components of the thermal contrast therapy device, such as pump motors, valves, heating elements, thermoelectric coolers, heat sinks, and other components. Exemplary modular
5 configurable power supplies include UtiliMod power supplies such as the UX6 1200W power supply, available from Excelsys Technologies, Rockwall, TX.

Referring now to Fig. 5, a perspective view of the pump and valve module **302** is shown. The pump and valve module provides a conveniently removable platform for mounting pumps, motors, and valves. The pump and valve module may include
10 mounting locations for any number of components. For example, as shown in Fig. 5, the pump and valve module may be configured to support the hot pump **110** operably coupled to a hot motor **112**, and the cold pump **118** operably coupled to a cold motor **120**. A thermal contrast therapy device may utilize any one or more pumps known in the art suitable to circulate fluid through the reservoirs and one or more treatment pads. Pumps
15 are well known in the art, and any suitable pump may be used. As shown in Fig. 5, gear pumps may be used. For example, suitable gear pumps are available from TCS Micropumps Ltd., Faversham, England. In some embodiments, a diaphragm pump may be used. Suitable diaphragm pumps are available from KNF Neuberger Inc., Trenton NJ. When using a diaphragm pump, in some embodiments an unwanted pressure pulse may
20 be created. Such pressure pulse may be dampened using an inline pulse dampener, which may be located, for example, before or after the supply valves (i.e., hot supply valve **126** and/or cold supply valves **130**), e.g., along the outflow fluid line **136**. In some embodiments, a small segment of expandable tubing may be effective as an inline pulse

dampener. In some embodiments, when using a diaphragm pump, a desired pressure pulse in a treatment pad may be provided using one or more of the return valves (i.e., hot return valve **140** and/or cold return valve **142**). Alternatively, one or more low pressure peristaltic pumps or “tube pumps” may be used. Suitable peristaltic pumps are available
5 from Anko Products Inc., Bradenton, FL, or from Watson Marlow, Wilmington, MA. In some embodiments, the hot pump **110** and the cold pump **118** may be configured to each provide fluid at a flow rate of at least between about 10 to 100 mL per minute, for example, between 10 to 25 mL/min, 25 to 50 mL/min, 50 to 100 mL/min, 100 to 150 mL/min, 150 to 250 mL/min, 250 to 500 mL/min, or 500 to 1000 mL/min, or any
10 intermediate flow rate, lesser flow rate, or greater flow rate.

The pump and valve module **302** may be further configured to support the hot supply valve **126**, the cold supply valve **130**, the hot return valve **140**, and the cold return valve **142**. The hot pump draws fluid from the heating block **108** (Fig. 1) through hot feed line **500**. Fluid discharged from the hot pump may be routed through the hot supply
15 valve’s first outlet of **502** to the heating block **108**, or through the hot supply valve’s second outlet **504** to a treatment pad **128** (Fig. 1). The cold pump draws fluid from the cooling block **116** (Fig. 1) through cold feed line **506**. Fluid discharged from the cold pump may be routed through the cold supply valve’s first outlet of **508** to the cooling block **116**, or through the cold supply valve’s second outlet **510** to a treatment pad. Fluid
20 returning from the treatment pad may be routed through the hot return valve **140** to the heating block, and/or through the cold return valve **142** to the cooling block. In some embodiments, a thermal contrast therapy device may be configured to route fluid returning from the treatment pad to the heating block **108** and/or the cooling block **116**

based, at least in part, on the temperature of the fluid. For example, fluid may be routed to the heating block if the temperature of the fluid exceeds a specified temperature, to the cooling block if the temperature of the fluid does not exceed a specified temperature, and/or fluid may be routed in part to the heating block and in part to the cooling block. A fluid return line temperature sensor **152** (Fig. **1**) may be used to ascertain the temperature of the fluid, e.g., for purposes of determining which reservoir(s) to which the fluid shall be routed.

Valves are well known, and any one or more suitable valves may be used in a thermal contrast therapy device. In some embodiments, the hot supply valve **126** and the cold supply valve **130** may be three-way magnetic solenoid valves, and the hot return valve **140** and the cold return valve **142** may be two-way magnetic solenoid valves. In some embodiments, valves may be selected that are constructed from a plastic, composite, or other material having a relatively low specific heat capacity, for example to minimize the thermal mass of the valves. Exemplary magnetic solenoid valves include the Series 3825 three-way valve, and the Series 3826 two-way valve, each of which are available from Spartan Scientific, Boardman, OH. In some embodiments, solenoid valve coils **512** generate heat during valve operation. Some solenoid valves may be configured such that fluid flows through the valve coils, in which case heat generated by the coils may affect the temperature of the fluid flowing through such valves. Heat transfer from solenoid valve coils may be of particular concern for cold fluid, for example due to the potentially large temperature differential between the fluid and the coil. As shown in Fig. **5**, fluid does not flow through the solenoid valve coils **512**, but rather, the solenoid valve coils are positioned adjacent to the valves, and perpendicular to the direction of fluid

flow. Such a configuration for solenoid valves may be effective to minimize the amount of thermal mass in thermal communication with the fluid flowing through the valve.

As further shown in Fig. **5**, a flow meter **158** may be provided. Flow meters are well known in the art and any suitable flow meter may be used, such as a rotary flow meter available from PendoTECH, Princeton, NJ. A flow meter may be used to control the flow rate of the fluid, for example, to provide customized thermal contrast therapy treatment sequences.

Various fluid lines and other components within a thermal contrast therapy device may be insulated, for example, to economize the efficiency of the heating system and/or cooling system. Insulation may also enhance the accuracy and/or precision of a thermal contrast therapy device. In some embodiments, the ability of a thermal contrast therapy device to provide certain treatment sequences may depend, at least in part, on having adequate insulation on fluid lines and other components. For example, insulation may enhance the ability of a device to provide treatment sequences involving rapid changes in the rate of heat transfer and/or rapid transitions between specified measures of heat transfer, with a high degree of precision and accuracy. Any suitable insulation may be used. In some embodiments, fluid lines may be insulated using fiberglass braided sleeves.

Referring now to Figs. **6A** and **6B**, cross-sectional views are shown from the left side and from the right sides of the exemplary thermal contrast therapy device of Fig. **2**. Fig. **6A** shows a cross-section of the heating block **108**, and Fig. **6B** shows a cross-section of the cooling block **116**. Shared reservoir **106** resides at about a central location within the casing, supported by a bracket **600** and a partition **308** which divides the

casing into two zones. Fluid gravity feeds from the shared reservoir to the heating block via a heating block supply line **602**, and to the cooling block **116** via cooling block supply line **604**. During operation of the device, the heating block and the cooling block will be filled with fluid, and the shared reservoir fluid level **606** will be at least above the
5 top of the interface point between the heating block supply line and the corresponding opening in the shared reservoir. The heating block supply line provides fluid communication with the shared reservoir at about the middle to upper portion of the shared reservoir, and the cooling block supply line provides fluid communication at about the lower portion of the shared reservoir. The supply lines **602**, **604** are sloped to allow
10 air to escape to the shared reservoir. The interface points for the supply lines **602**, **604** facilitate stratification of hot fluid and cold fluid within the shared reservoir as fluid exchanges between the heating block, the shared reservoir, and the cooling block, during alternating heating periods and cooling periods. These reservoir supply line interface points also allow the heating block and the cooling block to each preferentially draw fluid
15 from stratified hot fluid and cold fluid within the shared reservoir.

In some embodiments, as shown in Fig. **6A**, the heating block has a plurality of heating block baffles **608** defining a serpentine path **610** for fluid travel between the heating block inlet **612** and the heating block outlet **614**. The heating block baffles may be configured in any desired manner. In some embodiments, a heating block may be
20 provided without baffles. As shown, the heating block inlet may be positioned at a lower elevation of the heating block and the heating block outlet may be positioned at an upper elevation of the heating block. One or more heating elements **114** impart heat energy to the fluid. Heating elements are well known in the art, and any suitable heating element

may be used. Such as 12V cartridge heaters. The heating block baffles **608** allow fluid to gradually accumulate heat while traveling through the heating block. As such, the heating block may store fluid having a temperature gradient between the heating block inlet and the heating block outlet. An insulating material **616** may surround all or part of the heating block, which may be effective to improve heating efficiency within the heating block, and/or to protect various other components from heat radiating from the heating block. Closed cell foam may be used as an insulating material.

As shown in Fig. **6B**, the cooling block may similarly comprise a plurality of cooling block baffles **618** defining a serpentine path **620** for fluid travel between a cooling block inlet **622** and a cooling block outlet **624**. The cooling block baffles may be configured in any desired manner. In some embodiments, a cooling block may be provided without baffles. The cooling block inlet may be positioned at an upper elevation of the cooling block and the cooling block outlet may be positioned at a lower elevation of the cooling block. One or more thermoelectric coolers may be provided to extract heat from the fluid, as described in more detail below. The cooling block baffles **618** allow fluid to gradually cool while traveling through the cooling block. As such, the cooling block may store fluid having a temperature gradient between the cooling block inlet and the cooling block outlet.

Referring now to Fig. **7A** and **7B**, corresponding parts of an exemplary heat transfer block **700** are shown. In some embodiments, the heat transfer block **700** may be used both as a heating block and/or as a cooling block, for example, as shown with respect to the heating block **108** shown in Fig. **6A** and the cooling block **116** shown in Fig. **6B**. The heat transfer block has a main body **702** (Fig. **7A**) and a side cap **704** (Fig.

7B). Both the main body and the side cap may be machined or forged from any desired metal alloy, for example, aluminum alloy. A corrosion resistant surface coating or plating may be applied to the heat transfer block using any suitable corrosion resistant material, including for example, nickel, chrome, zinc, tungsten carbide or other
5 composites, or the like. Such corrosion resistant materials and coating or plating processes are well known in the art. The side cap may be fixedly secured to the main body to form a complete heat transfer block. As shown in Fig. **7A**, the heat transfer block has a plurality of baffles **706** defining a serpentine path **708** for fluid travel through the heat transfer block. The baffles **706** may be configured in any desired manner. In some
10 embodiments, a heat transfer block may be provided without baffles. The heat transfer block may be configured with a plurality of orifices for use with various applications. Orifices may be provided for inflow and outflow lines, heating elements, temperature sensors, and other instruments. Unused orifices may be sealed, for example, with a plug. As shown in Fig **7A**, six orifices are provided on the vertical face of the heat transfer
15 block: a first orifice **710** and a second orifice **712** provide access to the bottom channel of the serpentine path, a third orifice **714** and a fourth orifice **716** provide access to the top channel of the serpentine path, and a fifth orifice **718** and a sixth orifice **720** provide access to middle channels of the serpentine path. Such multiple orifices allows a single heat transfer block to be utilized both for the heating block and the cooling block even
20 though different access points may be desired for respective fluid lines and components. In some embodiments, when the heat transfer block of Fig. **7A-B** is configured for use as a heating block **108**, the first orifice **710** may be used for the heating block inlet **612** and the third orifice **714** may be used for the heating block outlet **614**. Heating elements **114**

may be installed at the fifth orifice **718** and/or the sixth orifice **720**, and a heating block temperature sensor **146** may be installed at the fourth orifice **716**, while the second orifice **712** may be sealed, for example, with a plug. In some embodiments, when the heat transfer block of Fig. **7A-B** is configured for use as a cooling block **116**, the fourth orifice **716** may be used for the cooling block inlet **622**, the second orifice **712** may be used for the cooling block outlet **624**, and a cooling block temperature sensor **148** may be installed at the first orifice **710**, while the third, fifth, and sixth orifices **718**, **720**, and **714** may be sealed, for example, with a plug. Other heat transfer block configurations, orifice positions thereon, and uses thereof are also within the spirit and scope of the present disclosure.

In some embodiments, the one or more baffles **706** within the heat transfer block may have a sloped surface, for example, as provided by baffles having a cross-sectional thickness at the base which exceeds that of the tip. Such a sloped surface allows air which may be introduced into the heat transfer block to escape through a top orifice **722** at the top of the heat transfer block. When a heat transfer block **700** is configured for use as heating block **108** or as a cooling block **116**, the top orifice **722** may be utilized to provide fluid communication with the heating block supply line **602** or the cooling block supply line **604**, as applicable. As shown in Figs. **6A** and **6B**, the heating block supply line and the cooling block supply line each are sloped to allow air to pass through the supply lines and into the shared reservoir **106**.

The baffles **706** of the heat transfer block **700** may be effective to enhance heat transfer with fluid in the block, for example, because the baffles isolate fluid having been heated or cooled to a desired temperature from fluid entering the heat transfer block and

having yet to be heated or cooled, as applicable. Given this, the baffles may also be effective to mitigate potential temperature fluctuations in the fluid within the heat transfer block which might otherwise be caused by variations in the temperature of fluid entering the heat transfer block. Such variations in temperature may arise, for example, due to
5 varying measures of heat transfer effected while circulating fluid and/or due to exchanging fluid between the heating block and the cooling block.

In some embodiments, a heating system may be configured to provide fluid having a temperature between about 85 °F to 130 °F, or from about 100 °F to 110 °F, for example, at least about 85 °F, 90 °F, 95 °F, 100 °F, 105 °F, 110 °F, 115 °F, 120 °F, 125
10 °F, 130 °F, or any intermediate temperature, cooler temperature, or warmer temperature. Other temperatures will also be apparent to the skilled artisan.

Referring now to Fig. 7C, an exemplary embodiment of a cooling block 116 utilizing heat transfer block 700 is shown. The third orifice 716 is used as the cooling block inlet 622, and the first orifice 712 is used as the cooling block outlet 624. A
15 temperature sensor 148 is provided at the first orifice 710. The second orifice 714, the fifth orifice 718, and the sixth orifice 720 each are sealed with a plug. A plurality of thermoelectric coolers 122 are positioned along opposite sidewalls of the cooling block. Heat sinks 124 comprising a plurality of horizontally arranged heat transfer fins (not shown) are provided on opposite sides of the thermoelectric coolers. A plurality of fans
20 724 are provided to draw air across the heat transfer fins to dissipate heat. Thermoelectric coolers are well known, and any suitable thermoelectric coolers may be used. In the exemplary embodiment shown in Fig. 7C, six (6) thermoelectric coolers are provided on each side of the heat transfer block, each measuring approx. 16 sq. cm.

Suitable thermoelectric coolers are available from TE Technology, Inc., Traverse City, MI. Heat sinks are also well known and any suitable heat sinks may be used. Suitable fans are available from Newark element14, Chicago, IL. It will be appreciated that the heat transfer capacity of the thermoelectric coolers and heat sinks may be selected for the
5 desired operating range of a thermal contrast therapy device.

In some embodiments, a cooling system may be configured to provide fluid having a temperature between about 30 °F to 70 °F, or from about 40 °F to 50 °F, for example, less than at least about 30 °F, 35 °F, 40 °F, 45 °F, 50 °F, 55 °F, 60 °F, 65 °F, 70 °F, or any intermediate temperature, cooler temperature, or warmer temperature. Other
10 temperatures will also be apparent to the skilled artisan.

In some embodiments, the thermal contrast therapy device may be configured so as to cause the heat sink fans **724** to draw air from outside of the casing, thereby avoiding recirculation of air from within the casing, which may otherwise affect cooling efficiency. For example, heat sinks **124** on opposite sides of the cooling block may
15 respectively rest snugly against the sidewall of the casing **200** and the partition **308** (Fig. **3**), and optionally, a seal **626** (Fig. **6B**), may be provided so as to form a duct that directs airflow from the vents **206** to the heat sinks and out of the casing through vents **310** (Fig. **3**). The seal may span the substantial distance between the sidewall of the casing and the partition **308**, thus assuring that the fans draw fresh air from outside of the casing.

The skilled artisan will appreciate that the size of heat transfer block **700** for use
20 as a heating block and/or as a cooling block in a thermal contrast therapy device may be determined based on a number of factors, including intended use of the thermal contrast therapy device, and the desired heating capacity or cooling capacity of the heating system

or cooling system, as applicable. In some embodiments, the heat transfer block may be configured to hold a fluid volume of between about 5 to 100 ounces, for example, about 5 ounces, 10 ounces, 20 ounces, 30 ounces, 40 ounces, 50 ounces, 60 ounces, 70 ounces, 80 ounces, 90 ounces, or 100 ounces.

5 Fluid for a thermal contrast therapy device may comprise any suitable heat transfer medium. In some embodiments, the fluid may include an anti-freeze or anti-boil agent such as ethylene glycol, propylene glycol, glycerol, or combinations thereof. The fluid may also include a corrosion inhibitor. The fluid may be dyed, for example, so that it may be easily viewed within transparent, semi-transparent, or translucent fluid lines
10 and/or treatment pads. In some embodiments, the fluid may comprise a thermochromic material, such as a reversible thermochromic pigment. The thermochromic material may provide a visual indication as to the temperature of fluid within a fluid line or treatment pad, for example, to indicate transitions between heating periods and cooling periods and/or to indicate that the fluid is within a desired temperature range. In some
15 embodiments, a thermochromic film may be provided on fluid lines and/or treatment pads, in addition or as an alternative to providing a thermochromic pigment within the fluid. Suitable thermochromic pigment are available from OliKrom, Pessac, France.

Treatment Pads

20 Thermal contrast therapy generally may be administered via one or more treatment pads applied to a patient's body. The thermal contrast therapy devices disclosed herein may be configured to function with a plurality of different treatment pads. A treatment pad may comprise a network of interconnected cells or capillaries or a serpentine conduit, or combinations thereof, with an inflow port configured to receive

fluid via an inflow tube, and outflow port configured to return fluid via an outflow tube. Various shapes and sizes of treatment pads may be provided in order to accommodate different patient sizes and/or different areas of the body, and/or in order to accommodate or integrate with various orthopedic braces, casts, and other devices.

5 Fig. **8A** shows an exemplary treatment pad **800** having a serpentine conduit **802** occupying a substantial surface area of the treatment pad. During thermal contrast therapy, fluid enters the treatment pad through an inflow port **804**, then passes through the serpentine conduit, and then exits the treatment pad through an outflow port **806**. In some embodiments, a treatment pad is configured such that the inflow port corresponds
10 to the side of the serpentine conduct which provides the shortest distance to the central region of the treatment pad. A treatment pad may be formed from a pair of thermoplastic panels which may be sealed together by conductive heat fusion, a process which is well known in the art. The thermoplastic panels may be formed from polyurethane, polyvinyl chloride, or any other suitable material.

15 The serpentine conduit **802** allows fluid within the pad to be displaced by fresh fluid entering the pad. By contrast, a treatment pad having a network of interconnected cells or capillaries may allow fluid within the pad to mix with fresh fluid entering the pad. In some embodiments, a treatment pad having a serpentine conduit allows for more rapid transitions between alternating heating periods and cooling periods. A treatment
20 pad having a serpentine conduit may be transitioned from a first period to a second period of a thermal contrast therapy treatment sequence at least as quickly as the duration of time determined by dividing the volume of fluid in the treatment pad by the flow rate of the fluid passing through the serpentine conduit. In some embodiments, such volume of

fluid may be reduced by a volume corresponding to portions of the treatment pad which are not in substantial thermal communication with the patient's body. In some embodiments, such calculated duration of time for effecting a transition may also account for the volume of fluid in outflow fluid line **136** and/or supply line **168** or a portion thereof, and/or other components from within which fluid is to be displaced upon transition between periods. Such calculated duration of time may also account for time required to overcome thermal loading of system components from the previous period. By contrast, in some embodiments, a treatment pad having a network of interconnected cells or capillaries may provide a more gradual transition between alternating heating periods and cooling periods.

In some embodiments, a pad ID tag **180** may be embedded within a treatment pad. Alternatively, in some embodiments a pad ID tag **180** may be embedded within a fitting configured to be attached to a treatment pad, such as a pad interface fitting, as discussed below. A thermal contrast therapy device may be configured to receive an indication from a pad ID tag effective to identify a treatment pad operably connected to the thermal contrast therapy device, thereby enabling the thermal contrast therapy device to acquire information about the particular treatment pad operably connected to the device, and/or to perform a treatment sequence that is calibrated for the particular treatment pad operably connected to the device. For example, a pad ID tag may transmit an indication that a treatment pad is configured for use with a given body part, and upon a thermal contrast therapy device having received such indication, the device may perform a treatment sequence intended to treat such body part. In some embodiments, by identifying the particular treatment pad operably connected to the device, a substantially similar

treatment sequence may be provided using any one of a plurality of different treatment pads, notwithstanding differences in the dimensional or physical characteristics of such treatment pads. This includes, for example, effecting a desired measure of heat transfer between the fluid and the patient's tissue, using any one of a plurality of various treatment pads. A pad ID tag **180** may be a microchip, RFID tag, RUBEE® tag, UWB tag, ZIGBEE® tag, or other suitable component capable of enabling a tag reader or processor to identify at least one characteristic of a treatment pad. In some embodiments, for example, in lieu of a pad ID tag, a treatment pad may be identified manually, for example by an input via a user interface.

Once a particular treatment pad has been identified by a thermal contrast therapy device, operating parameters of the device may be automatically adjusted so as to correspond to one or more characteristics of the particular treatment pad operably connected to the device. With some treatment sequences, treatment pads having various dimensional or physical characteristics may require different fluid flow rates and/or fluid temperatures in order to deliver desired treatment conditions. For example, as between various treatment pads, some treatment sequences may require different flow rates and/or fluid temperatures in order to effect a specified measure of heat transfer (i.e., a quantity of heat and/or a rate of heat transfer) as called for by the treatment sequence. A thermal contrast therapy device may be configured to automatically adjust one or more parameters of a treatment sequence based, at least in part, on one or more characteristics of a particular treatment pad. Such adjustments may be configured to enable a thermal contrast therapy device to effect a given treatment sequences consistently across a plurality of different treatment pads having various dimensions and/or configurations, for

example, by varying the temperature and/or flow rate of the fluid as between various treatment pads, based, at least in part, on one or more characteristics of a given treatment pad operably connected to the device. Such automatic adjustments enable a thermal contrast therapy device to provide enhanced accuracy, precision, and control of treatment sequence parameters across a plurality of various treatment pads.

In some embodiments, one or more temperature sensors may be positioned at various locations on or within a treatment pad. Such temperature sensor(s) may be configured to measure the temperature of the patient's tissue proximate to the treatment cuff. Additionally and/or in the alternative, one or more temperature sensors may be configured to measure the temperature of fluid at a given point within the treatment cuff. Such temperature measurements may be used to provide customized thermal contrast therapy treatment sequences.

In some embodiments, a cuff may be provided for securing a treatment pad to an area of a patient's body. Cuffs of various shape or sizes may be provided, to accommodate different treatment pads and/or to fit different parts of the body or different sized patients. For example, Fig. 9 shows a perspective, exploded view of a cuff **808** configured to receive the treatment pad of Fig. **8A**. The cuff **808** comprises a contact surface **810**, secured on three sides to a main wrap **812** so as to create a pocket **814** configured to receive the treatment pad. Hook and loop fastener elements **816**, **818** may be provided on opposite sides of the contact surface and the main wrap to secure the treatment pad within the pocket. The contact surface may be fabricated from a thin material such as perforated nylon mesh, or any other material that may provide a comfortable surface to the touch while also minimizing interference with heat

conduction. A first hook-fastener element **820** may be provided at the end of the cuff to allow the cuff to be removably secured around a body part of a patient. The main body may be fabricated from a material configured to catch the first hook-fastener element **820**, for example, hook-compatible neoprene such as airprene, thus providing an adjustable fit. The main body may be configured with an extension element **822** to wrap around the inflow port **804** and outflow port **806** of the treatment pad. The extension element may be removably secured with a second hook-fastener element **824**, so as to provide insulation and/or structural support to the inflow port and the outflow port.

The serpentine conduit or network of interconnected cells or capillaries within a treatment pad may be formed in any desired configuration. A serpentine conduit may embody a variety of different conduit patterns or combinations of patterns. As shown in Fig. **8A**, a serpentine conduit may comprise a plurality of hairpin corners, thus directing fluid back and forth across the pad. In some embodiments, as shown in Fig. **8C**, a serpentine conduit may comprise a Fermat's spiral **826**, thus directing fluid in a spiral pattern that doubles-back on itself. In some embodiments, as shown in Fig. **8C**, a serpentine conduct may comprise a modified Fermat's spiral **828**, in which fluid follows a pattern comprising a spiral pattern that doubles-back on itself and a plurality of hairpin corners.

During thermal contrast therapy, resulting heat transfer between the fluid and a patient's tissue changes the temperature of fluid passing through a treatment pad. Thus, the temperature of fluid at inflow port **804** may differ from the temperature of fluid at outflow port **806**. Similarly, the temperature of fluid may differ as between any two points within a treatment pad. The rate of heat transfer effected by the fluid depends on

fluid temperature, and as such, the rate of heat transfer may differ as between two points within a treatment pad. Consequently, some treatment pad configurations may yield a perceptible or measureable difference in the rate of heat transfer as between two regions of the treatment pad.

5 In some embodiments, a treatment pad may be provided having a configuration effective to provide a substantially uniform rate of heat transfer across the effective surface area of the treatment pad. A treatment pad having a serpentine conduit, for example, a serpentine conduit having a Fermat's spiral configuration, may be effective to provide a substantially uniform rate of heat transfer across the effective surface area of
10 the treatment pad. In some embodiments, a treatment pad may be provided having a configuration effective to impart a substantially uniform rate of heat transfer as between various regions of the treatment pad, for example, as between a first region and a second region. The rate of heat transfer of a first region and a second region may in some embodiments be within less than about 5%, 4%, 3%, 2%, or 1% of one another. In some
15 embodiments, a treatment pad may be configured such that the temperature of fluid entering the pad is conductively tempered through countercurrent conductive heat transfer between an adjacent aspect of the pad. For example, fluid having traveled a first distance through the serpentine conduit may be conductively tempered by fluid having traveled a second distance through the serpentine conduit. Conductive tempering of fluid
20 may occur, for example, due to countercurrent conductive heat transfer as between any adjacent points within a treatment pad, and may be effective to allow a treatment pad to impart a substantially uniform rate of heat transfer as between various regions of the treatment pad. In some embodiments, when a serpentine conduit having a Fermat's

spiral (e.g., Fig. **8C**) is provided, a first aspect of the serpentine conduit located a linear distance along the conduit from the inflow port **804** may be adjacent to a second aspect of the serpentine conduit that is located an approximately equivalent linear distance along the conduit from the outflow port **806**. With such a configuration, the temperature gradient between fluid passing the first aspect and fluid passing the second aspect will tend to be approximately proportional to the linear distance along the serpentine conduit between the first aspect and the second, with such temperature gradient decreasing as such linear distance decreases. As such, in some embodiments, a serpentine conduit having a Fermat's spiral configuration may be effective to maximize countercurrent conductive heat transfer, thereby minimizing relative temperature differences across various aspects of the treatment pad. In some embodiments, with a serpentine conduit having a modified Fermat's spiral (e.g., Fig. **8D**), fluid flow alternates between a left region and a right region of a treatment pad, such that entering inflow port **804** serpentine a plurality of times through both the left region and the right region of the treatment pad before having traveled past the point in the serpentine path which is equidistant from the fluid inflow port and the fluid outflow port **806**. Likewise, fluid having passed such equidistant point along the serpentine path further serpentine a plurality of times through both the left region and the right region of the treatment pad before exiting the fluid outflow port **806**. With such a configuration, fresh fluid may be uniformly distributed through the surface area of the treatment pad, which may be effective to minimize the time required to supply a specified fluid temperature and/or measure of heat transfer with the patient's tissue across a substantial distribution of the treatment pad..

Quick Release Extension Cords

Referring now to Figs. **9A-9C**, Fig. **10**, and Fig. **11**, an exemplary quick-release extension cord for providing fluid and data communication between a thermal contrast therapy device and a treatment pad (Figs. **9A-9C**) and corresponding device interface fitting (Fig. **10**) and pad interface fitting (Fig. **11**) will now be discussed.

Fig. **9A** shows a perspective view of exemplary quick-release extension cord **900** for providing fluid and data communication between a thermal contrast therapy device and a treatment pad. A device-side fitting **174** releasably couples with the device interface fitting of Fig. **10**, and pad-side fitting **178** releasably couples with the pad interface fitting of Fig. **11**. Supply line **168** and return line **170** provide fluid communication between the device-side fitting and the pad-side fitting, such that when attached to the device interface fitting **172** and the pad interface fitting **176**, the extension cord provided fluid communication between the thermal contrast therapy device and the treatment pad. Quick-release buttons **902**, **904** on opposite ends of the extension cord respectively release prongs within the device-side fitting and the pad-side fitting, which snap into place over corresponding notches on the device interface fitting **210**, **212** (Fig. **10**) and the pad interface **1104**, **1106** (Fig. **11**). Fluid lines **168**, **170** attach to hose barbs on opposite ends of the device interface fitting and the pad interface fitting. A data cable **906** runs between a data plug **908** configured to mate with data fitting **214**, and a pad ID reader **182** (Figs. **9B-9C**) embedded within the pad-side fitting **178** as discussed below. A housing **910** surrounds the supply line, return line, and data cable, to insulate the fluid in the supply line and return line and/or to prevent the various lines from becoming tangled. As shown in Fig. **9A**, the housing is cut-away slightly from the device-side

fitting **174** and the pad-side fitting **178** so as to partially show the supply line, return line, and data cable. In some embodiments, the housing may be partitioned, as shown in Fig. **9A**, with different segments provided for the fluid supply line and return line. The housing and may be configured from any suitable material, for example a fabric or a plastic. Insulation may be provided within the housing, for example, to insulate the fluid supply line and return line from the outside elements and/or from one another. Insulation is well known, and any suitable insulation may be used, such as closed-cell foam, elastomeric materials, fiberglass, or the like.

Figs. **9B** and **9C** respectively show a cross-sectional side view and a cross-sectional top view of the pad-side fitting of the quick-release extension cord of Fig. **9A**. Fluid from supply line **168** flows through a supply channel **912** to a treatment pad, and fluid from the treatment pad flow through a return channel **914**. Temperature sensors **154**, **156** measure the temperature of fluid passing through the supply channel and return channel, respectively. Such temperature sensors, being proximately located to the inflow port **804** and outflow port **806** of a treatment pad (Fig. **8A**), may be used to measure the temperature of fluid entering and exiting the treatment pad and the corresponding change in temperature may be used for calculating the measure of heat transfer effected by fluid passing through the treatment pad. The skilled artisan will appreciate that for purposes of measuring the temperature change of the fluid between the entrance and exit of the treatment pad, temperature measurements obtained at or near the inflow port and/or the outflow port of the treatment pad may be more accurate than measurements obtained at more distant locations. This may be of particular concern to the artisan when performing a treatment sequence requiring a high degree of precision, for example, a treatment

sequence configured to effect a desired measure of heat transfer. In some embodiments, the pad-side fitting includes a built-in pad ID reader **182**, which may be coupled to a data cable **906**, for example, to transmit data to a thermal contrast therapy device. Temperature sensors **154**, **156** may also be coupled to the pad ID reader, or such sensors
5 may be directly coupled to a data cable leading to the thermal contrast therapy device. In some embodiments, the pad ID reader may include a local processor configured to perform various desired operations, for example using data collected from a pad ID tag, temperature sensors, or other sources.

A quick release extension cord **900** may be any desired length, for example,
10 between about 3 feet to 12 feet, about 3 feet to 6 feet, or about 4 feet to 8 feet. In some embodiments, a quick release extension cord may be at least about 3 feet, 4 feet, 5 feet, 6 feet, 7 feet, 8 feet, 9 feet, 10 feet, 11 feet, 12 feet, or longer.

Fig. **10** shows a perspective view of an exemplary device interface fitting **172** for coupling fluid lines and a data line to a thermal contrast therapy device. The device interface fitting spans an opening in the casing **200** of the thermal contrast therapy device
15 **100** (Fig. **2**). Flanges **1000**, **1002** reside on opposite sides of the opening in the casing, with a notch **1004** receiving the perimeter of the opening, so as to secure the device interface fitting in place. An outflow fluid line **136** and return fluid line **138** may be secured to respective hose barbs **1006**, **1008** on the device interface fitting. A supply
20 line fitting **210** and a return line fitting **212** may releasably couple with corresponding fluid-line receptacles on a device-side fitting **174**. Similarly, a data fitting **214** may interface with a corresponding cable receptacle on the device-side fitting. A device-side

data cable **1010** coupled to data fitting **214** provides data communication to the thermal contrast therapy device.

Fig. **11** shows a perspective view of an exemplary pad interface fitting **176**, for coupling fluid lines to a treatment pad. The inflow port **804** and outflow port **806** of a treatment pad (Fig. **8A**) attach to respective hose barbs **1100**, **1102**, and fittings **1104**, **1106** releasably couple with corresponding receptacles on the pad-side fitting **178**. In some embodiments, a pad ID tag **180** such as a microchip, RFID tag, RUBEE® tag, UWB tag, ZIGBEE® tag, or other wireless transmitter may be embedded within the pad interface fitting. The pad ID tag may be configured to enabling a tag reader or processor to identify at least one characteristic of a treatment pad to which the pad-interface fitting is attached and which may be operably connected to a thermal contrast therapy device.

Temperature Control

In some embodiments, a processor **144** may be configured to control the temperature of the fluid, utilizing temperature measurements from any one or more temperature sensors. For example, temperature sensors **154** and/or **156** within the quick release extension cord **900** may be used to control the temperature of the fluid based on the temperature of the fluid entering or exiting the treatment pad, respectively. Additionally or in the alternative, fluid temperature may be controlled based on the temperature of the patient's tissue proximate to the treatment pad and/or the temperature of the fluid at a given point within the treatment pad. Such temperature control may be configured to enable a thermal contrast therapy device to provide customized treatment sequences based, at least in part, on fluid temperature.

Customized thermal contrast therapy treatment sequence may be provided, for example, by varying the temperature of the fluid during heating periods and/or cooling periods, and providing fluid of a desired temperature to a treatment pad. In some embodiments, the temperature of the fluid in the heating block **108** and/or the cooling block **116** may be increased or decreased during the course of a thermal contrast therapy treatment so as to provide fluid having a desired temperature during the various heating periods and/or cooling periods. Alternatively, the respective temperatures of the hot fluid and cold fluid may be maintained relatively constant, and the two fluids may be mixed in various proportions to provide a desired fluid temperature. Such mixing allows a thermal contrast therapy device to provide a range of desired fluid temperatures depending on the degree of mixing, without having to repeatedly heat or cool a reservoir of fluid to the desired temperature. Thus, during a heating period, hot fluid may be tempered with a measure of cold fluid via cold supply valve **130** so as to attain a desired fluid temperature at the treatment pad. Similarly, during a cooling period, cold fluid may be tempered hot supply valve **126** with a measure of hot fluid.

Flow Control

In some embodiments, a processor **144** may be configured to control the flow rate of the fluid that circulates through a thermal contrast therapy device and/or a treatment pad, utilizing flow measurements from any one or more flow meters. For example, a flow meter **158** may be configured to measure the flow rate of fluid in the outflow fluid line **136**. The flow rate of fluid circulating through a thermal contrast therapy device may be varied to control the measure of heating and/or cooling that takes place in the heating block and cooling block, respectively. The flow rate of fluid circulating through a

treatment pad may be controlled in order to effect a specified measure of heat transfer between fluid in the treatment pad and a patient's tissue. In some embodiments, the flow rate of the fluid may be controlled, at least in part, by varying the speed of one or more pumps **110, 118**, for example by adjusting the power supplied to the respective motors **112, 120** via pulse width modulation technology. Alternatively or in addition, the flow rate of fluid may be controlled, at least in part, using one or more valves. For example, the flow rate of fluid that passes through a magnetic solenoid valve may be controlled by pulsing the valve between open and closed positions at a given frequency. The flow rate of hot fluid that circulates through a treatment pad may be controlled by varying the proportion of fluid flowing through the first outlet and second outlet of hot supply valve **126**, for example, by providing a pulse sequence for the first outlet and the second outlet effective to yield the desired flow rate to the treatment pad. Similarly, the flow rate of cold fluid that circulates through a treatment pad may be controlled by varying the proportion of fluid flowing through the first outlet and second outlet of cold supply valve **130**. Such flow rate control may be configured to enable the device to provide customized thermal contrast therapy treatment sequences based, at least in part, on fluid flow rate. In some embodiments customized thermal contrast therapy treatment sequences may be based, at least in part, on both flow rate and temperature of the fluid.

Pulsation and Compression

In some embodiments, a thermal contrast therapy device may be configured to provide pulsation in the treatment pad and/or compression of the cuff. Such pulsation and/or compression may be provided during all or part of a treatment sequences. Pulsation may be provided by cycling one or more valves within the thermal contrast

therapy device between the open and closed position. The hot supply valve **126**, the cold supply valve **130**, the hot return valve **140**, and/or the cold return valve **142** may be used to provide pulsation. In some embodiments, one or more magnetic solenoid valves may be used to generate a pressure pulse in the fluid. The pressure pulse may be generated by cycling a magnetic solenoid valve between opened and closed positions. The frequency of the pressure pulse may be controlled based on the timing between opening and closing events of the one or more valves. In addition to magnetic solenoid valves and peristaltic pumps, other means for generating pressure pulses are within the scope of the present disclosure.

In some embodiments, a treatment cuff may be configured to provide compression during the thermal contrast therapy. Compression enhances the contact between the treatment pad and the patient's tissue, thereby providing a more efficient heat transfer between the fluid and the patient's tissue. Compression may be provided, for example, via air pumped into a bladder within the treatment cuff from an air hose. The treatment cuff may have an air bladder configured to receive and hold air at a pressure effective to provide the desired level of compression. Air may be provided via any suitable air compressor known in the art. Such compression may be provided during all or part of a treatment sequences. For example, compression may be provided during heating periods but not cooling periods, during cooling periods but not heating periods, only during transition periods, during both heating periods and cooling periods, during only a subset of periods, or during all of the periods. In some embodiments, the level of compression may be varied. For example, the rate of heat transfer between the fluid and the patient's tissue proximate to the treatment pad may be varied by varying the level of

compression effected by the treatment cuff. The compression level may be automatically adjusted to effect a desired rate of heat transfer. In some embodiments, pulse compression may be provided by alternating between a plurality of pressure levels, for example, to pulse massage the patient's tissue.

5 Without wishing to be constrained by theory, it is believed that a therapeutic effect may be achieved by synchronizing the frequency of a pressure pulse with patient's heart rate. Such pressure pulse may be provided via a pressure pulse in the fluid and/or compression of the treatment cuff. In some embodiments, a thermal contrast therapy device may be configured to receive an indication of a patient's heart rate, and to provide
10 a pressure pulse having a frequency which is at least approximately synchronized with the patient's heart rate. Such synchronized pressure pulse may be provided during at least part of the treatment sequence. Synchronization may be achieved by measuring the patient's heart rate, for example, with a heart rate monitor auxiliary device, and adjusting the frequency of the valve sequencing accordingly. Without wishing to be constrained by
15 theory, it is further believed that a therapeutic effect may also be achieved by providing a pressure pulse frequency selected to correspond to a desired heart rate. For example, it is believed that under certain conditions a pressure pulse frequency may effect a change in the patient's heart rate, in which the heart rate shifts towards and/or substantially synchronizes with the frequency of the pressure pulse. The range within which a
20 patient's heart rate may be manipulated depends on physiological limitations of the patient, as well as the degree with which the particular patient may respond to the pressure pulse. In this way, a desired therapeutic effect may include inducing a desired heart rate during thermal contrast therapy.

Calibration

In some embodiments, a thermal contrast therapy device may be calibrated based on variations in the device and/or the preferences of one or more users of the device. A given treatment sequence may yield different effects due to differences between various devices (e.g., different manufacturers or model numbers), variations between devices (e.g., manufacturing differences between production runs), or set-up configurations (e.g., the length of the inflow and/or outflow lines between the device and treatment pad). These differences may be compensated for by calibrating treatment sequences for a particular device. A thermal contrast therapy device may be calibrated, for example, by measuring fluid temperature and/or flow rate, etc. with calibration equipment and adjusting calibration settings for the device. Calibration allows for customized thermal contrast therapy treatment sequences to be provided with consistency across a plurality of devices and/or for a plurality of users.

The artisan will appreciate that a given treatment sequence may yield different effects on different patients due to differences between patients, such as physiological attributes or personal preference. These differences may similarly be compensated for by providing a calibration adjustment corresponding to a particular patient. For example, a treatment sequence may be calibrated for a particular patient by providing a calibration adjustment to any one or more treatment sequence parameters. Providing a calibration adjustment may include, for example, shifting a set-point corresponding to a sequence parameter by a factor. As examples, one or more fluid temperature set-points in a treatment sequence may be shifted up or down; one or more set-points for a desired measure of heat transfer (i.e., rate of heat transfer or quantity of heat transfer) in a

treatment sequence may be shifted up or down; or the number of periods in a treatment sequences and/or the duration of a treatment sequences may be shifted up or down. The calibration adjustment and/or factor may be based on a percentage, an absolute value, a formula, or the like. The calibration adjustment and/or factor may be derived empirically
5 for an individual patient, and/or from data in a database associated with a thermal contrast therapy system, for example, data that relates to treatment sequences associated with other users. Such calibration adjustments may be applied to all treatment sequences, a subset of treatment sequences, or to a particular device, etc., and/or any of the foregoing as associated with a particular user.

10

II. Methods for Providing Thermal Contrast Therapy

Exemplary treatment methods for providing thermal contrast therapy will now be discussed. Those skilled in the art will appreciate that numerous other methods for providing thermal contrast therapy are within the spirit and scope of the present
15 disclosure. Various thermal contrast therapy treatment methods may be performed using the devices and systems described herein. In some embodiments, various treatment methods for providing thermal contrast therapy may be performed using other devices and systems. The methods disclosed herein include computer-implemented methods of providing thermal contrast therapy.

20

Thermal contrast therapy may be provided by circulating fluid from a thermal contrast therapy device through a treatment pad applied to a patient, while providing a sequence of alternating cooling periods and heating periods. The alternating cooling periods and heating periods respectively deliver or remove heat from the treatment area.

In some embodiments, a treatment sequence may include a plurality of transition periods, each occurring between alternating cooling periods and heating periods. During such transition periods, fluid having a first temperature corresponding to the first period displaces fluid having a second temperature corresponding to the second period. Thus, the rate of heat transfer between the patient's tissue and the fluid is transitioned from a first heat transfer rate which corresponds to the first period to a second heat transfer rate which corresponds to the second period.

Without wishing to be constrained by theory, it is believed that a patient's response to thermal contrast therapy may be enhanced by providing customized treatment sequences. Thus, in some embodiments, a customized thermal contrast therapy treatment sequence may be provided. A customized treatment sequence may be based upon, for example, any one or more of the following: characteristics of the patient sought to be treated, the area of the body sought to be treated, one or more symptoms or conditions sought to be treated, one or more desired therapeutic effects, and other considerations. In some embodiments, a customized treatment sequence may be based, at least in part, on a physiological parameter value exhibited by the patient.

A patient's response to thermal contrast therapy may depend on certain characteristics of the patient, including, for example, the patient's age, gender, body mass, fat content, physical fitness, energy level, and general state of health. Physiological characteristics as well as thermodynamic properties may also impact a patient's response to thermal contrast therapy. This includes a patient's ability to generate body heat, ability to repair the loss of heat, and ability to support the loss of heat without negatively impacting the body's vital processes, as well as the condition of the

patient's nervous system at the time of treatment, and the extent to which the patient is accustomed to thermal contrast therapy. Other variables which may affect a patient's response to thermal contrast therapy include factors related to any particular chronic or acute condition or ailment affecting the patient, including a condition or ailment sought to
5 be treated with thermal contrast therapy.

A patient's response to thermal contrast therapy may also depend on any one or more of a number of variables related to the conditions of the treatment sequence, including the rate of heat transfer between the fluid and the patient's tissue, the temperature of the heating periods and/or cooling periods, the pressure applied during
10 treatment, the quantity and sequence of the heating periods and/or cooling periods, the various cycle times for each heating period and/or cooling period; the duration of, and rate of change during, transitions between heating periods and/or cooling periods, including whether a neutral temperature period is provided between heating periods and/or cooling periods, the duration of the thermal contrast therapy treatment sequence,
15 the frequency with which thermal contrast therapy treatment is to be provided, the dimensions and configuration of the one or more treatment pads, the pulsation frequency of the fluid, and other variables.

Customized thermal contrast therapy treatment sequences may be provided based, at least in part, on any one or more of the variables disclosed herein, and/or other factors.
20 Additionally, a series of treatment sequences making up a treatment program may be prescribed based on any one or more of the variables disclosed herein, and/or other factors. A treatment sequence may be customized, for example, in respect of the time duration for one or more periods, the number of periods in the treatment sequence, the

fluid temperature corresponding to cooling periods and/or heating periods, the measure of heat transfer (i.e., quantity and/or rate) to be effected between the fluid and the patient's tissue during a treatment sequence and/or the respective heating periods and cooling periods thereof, or customization of any other operating variable of a thermal contrast therapy device. In some embodiments, a processor 144 may be configured to receive an indication from one or more temperature sensors and/or flow meters and to effect a desired measure of heat transfer between the fluid and the patient's tissue. Changes to the rate of heat transfer may be effected, for example, by automatically adjusting the temperature and/or flow rate of the fluid. The flow rate and/or fluid temperature may be changed according to any desired transition curve. In some embodiments, the processor 144 may be configured to receive an indication of one or more physiological parameter values and to cause the thermal contrast therapy device to perform a customized thermal contrast therapy treatment sequence based, at least in part, on the one or more physiological parameter values.

A customized treatment sequence may correspond to a treatment program having been prescribed to a user, or selected by a user of a thermal contrast therapy device. In some embodiments, a customized treatment sequence may be uploaded or stored in a database accessible by a thermal contrast therapy system or device. For example, a treatment provider or a user may select a treatment from a menu of one or more treatment options in a database associated with a thermal contrast therapy system configured to provide customized thermal contrast therapy treatment programs. Alternatively, a customized treatment sequence may be manually input by a treatment provider or a user.

Heat Transfer

A thermal contrast therapy treatment may be quantified based on measures of heat transfer, for example, the rate of heat transfer and/or the quantity of heat transfer effected during the respective heating periods and cooling periods of a treatment sequence. Without wishing to be constrained by theory, it is believed that various therapeutic effects of thermal contrast therapy may be enhanced by providing customized treatments which effect a specified measure of heat transfer (i.e., a rate of heat transfer and/or quantity of heat transfer). In some embodiments, a customized thermal contrast therapy treatment sequence includes effecting a specified measure of heat transfer between the fluid and the patient's tissue during one or more of the cooling periods and heating periods. The specified measure of heat transfer may be effected by automatically adjusting the flow rate and/or temperature of the fluid.

The rate of heat transfer between fluid in a treatment pad and a patient's tissue may be expressed as:

$$q = \frac{m}{t} c_p \Delta T \quad (3)$$

where q is the mean heat transfer rate, $\frac{m}{t}$ is the mass flow rate per unit time, c_p is the specific heat capacity of the fluid, and ΔT is the temperature gradient between the fluid and the patient's tissue. Those skilled in the art will appreciate that q represents an optimum heat transfer rate, and that in practice, while the vast majority of heat transfer during a thermal contrast therapy treatment will be between the fluid and the patient's tissue proximate to the treatment pad, a portion of the heat transferred will be attributable to other considerations. For example, a portion of the heat will transfer to the cuff material and/or the surrounding atmosphere, etc. These considerations may be quantified empirically and/or by principles of thermodynamics known in the art, and the

mean heat transfer rate during a given heating period or cooling period within a thermal contrast therapy treatment sequence may thus be expressed as:

$$q_{TCT} = k \frac{m}{t} c_p \Delta T \quad (4)$$

where k is an efficiency constant which represents the proportion of heat transferred to
5 the tissue proximate to the treatment pad.

The total heat transferred during a given heating period or cooling period may be obtained from:

$$Q_{TCT} = q_{TCT} \Delta t \quad (5)$$

where Δt is the duration of the applicable heating period or cooling period. Likewise, the
10 heat transferred from the various heating periods and/or cooling periods may be summed to provide the total heat transferred during n periods, where n represents all or a subset of the periods comprising a thermal contrast therapy treatment sequence, as follows:

$$Q_{TCT} = \sum_{n=1}^n q_{TCT_1} \Delta t_1 + q_{TCT_2} \Delta t_2 + \dots + q_{TCT_n} \Delta t_n \quad (6)$$

In some embodiments, it may be advantageous to sum the heating periods and
15 cooling periods separately, so as to ascertain the total heat transferred to the patient during heating periods and the total heat transferred from the patient during cooling periods.

In some embodiments it may be advantageous to model the heating and/or cooling of a patient's tissue during thermal contrast therapy. Such models may be used to
20 evaluate treatment outcomes relative to model predictions, to perform research on various thermal contrast therapy treatment sequences and parameters thereof, and/or to suggest and evaluate new treatment strategies, etc.

The general factors to consider when quantifying heat transfer during thermal contrast therapy include heat transfer effected during the treatment, heat production due to metabolic processes, heat transfer due to blood perfusion, geometry of the thermal contrast therapy treatment area (e.g., as defined by the one or more treatment pads), the thermophysical properties of various types of body tissue, and thermoregulatory mechanisms.

Across a control volume, the principle of conservation of energy provides that the balance of thermal energy can be stated as:

$$q_{TCT} = q_{storage} + q_{loss} + q_{met} + W \quad (7)$$

where q_{TCT} is the heat energy gained by the control volume, for example from a given heating period or cooling period during a thermal contrast therapy treatment, $q_{storage}$ is the heat energy stored within the control volume of tissue and fluid, q_{loss} is the heat energy lost through the boundary of the control volume, q_{met} is the heat energy produced by metabolic heating, and W is work performed on the control volume.

Heat is transferred by conduction, convection, evaporation, and radiation. The two primary mechanisms for heat transfer inside tissue during thermal contrast therapy are convection and conduction. Under most conditions for thermal contrast therapy, heat transfer by evaporation (or perspiration) and radiation, as well as the work, W , are negligible. The temperature gradient inside the tissue drives heat transfer through conduction, and blood perfusion drives heat transfer through convection.

According to Fourier's law, the conductive heat transfer between two layers is found by the relation:

$$q_{cond} = -kA \frac{dT}{dx} \quad (8)$$

where q_{cond} is the conductive heat transfer per unit time, k is the thermal conductivity, A is the cross sectional area and dT/dx is the temperature gradient in the direction of heat transfer across a material of thickness x .

Those skilled in the art will appreciate that several approaches exist for modeling heat transfer from blood perfusion and that any one or more of such models may be used. Approaches for modeling heat transfer from blood perfusion include: the Pennes bioheat model; the Wulff continuum model; the Klinger continuum model; the Chen-Holmes (CH) continuum model; the Weinbaum, Jiji and Lemons (WJL) bioheat model; and the Simplified Weinbaum-Jiji model; the Zolfaghari and Maerefat simplified thermoregulatory bioheat model. These models generally employ a certain level of approximation, particularly because blood circulates in a variety of vessels ranging in lumen diameter from the approximately 2.5 cm, in the case of the aorta, to the approximately 6-10 μm , in the case of capillaries. More precise models based on computer algorithms or empirical research may also be utilized.

These aforementioned blood perfusion models generally rely on the basis of one of two main approaches: the continuum approach and the discrete vessel (vascular) approach. In the continuum approach, the thermal impact of all blood vessels are modeled with a single global parameter; and in the vascular approach, the impact of each vessel is modeled individually. The Pennes bioheat model is one of the most widely used approaches for modeling heat transfer from blood perfusion. The Pennes bioheat model assumes that the rate of heat transferred by the circulating blood at the capillary level equals the difference between the venous and arterial temperatures multiplied by the flow rate, as follows:

$$q_{blood} = \rho_b c_b w_b (T_a - T_v) \quad (9)$$

where ρ_b is the density of the patient's blood, c_b is the specific heat of the patient's blood, w_b is the perfusion rate, T_a is the arterial blood temperature, and T_v is the venous blood temperature.

5 The heat energy stored in the control volume can be expressed as follows:

$$q_{storage} = \int_v \rho c(\bar{x}) \frac{dT(\bar{x}, t)}{dt} dv \quad (10)$$

where ρ is the tissue density, c is the specific heat, and T is the tissue temperature.

The terms of equations (8), (9), and (10) may be substituted into equation (7) and integrated over the entire volume and surface area, to obtain the Pennes bioheat equation:

$$10 \quad \rho c \frac{\partial T}{\partial t} = \nabla k \nabla T + \rho_b c_b w_b (T_a - T_v) + q_{met} \quad (11)$$

The Pennes bioheat equation can thus be used to analyze heat transfer in various body tissues under various thermal contrast therapy treatment sequences, including the customized treatment sequences disclosed herein.

The Pennes bioheat model assumes that the blood perfusion effect is homogenous
 15 and isotropic and that thermal equilibration occurs in the microcirculatory capillary bed due to the low blood flow velocity at the capillary level. Thus, the Pennes bioheat model assumes that blood enters capillaries at the temperature of arterial blood, T_a , where convective heat transfer occurs to bring the temperature to that of the surrounding tissue, such that the temperature at which the blood enters the venous circulation is that of the
 20 local tissue.

Pennes performed a series of studies to validate this model, which show reasonable agreement between the model and experimental data. Those skilled in the art will appreciate that while the Pennes bioheat model is often adequate, there are certain

shortcomings in this model due to its inherent simplicity, and that other models, for example, those which utilize the discrete vessel (vascular) approach, may be more suitable in situations where enhanced precision is desired. For example, the Pennes bioheat model does not account for countercurrent heat transfer between adjacent vessels, or directionality effects due to the presence of larger blood vessels, or heat exchange with larger vessels in which complete thermal equilibrium may not be assumed. The CH continuum model and the WJL bioheat model, for example, address these issues. Accordingly, such other models may be used to analyze heat transfer as an alternative or in addition to the Pennes bioheat model.

Conditions particular to the patient intended to receive treatment and/or the particular area of the body sought to be treated, among other factors, may cause a given thermal contrast therapy treatment sequence to effect a different measure of heat transfer (i.e., a different rate of heat transfer and/or a different quantity of heat transfer). For example, various thermodynamic properties and other factors affecting heat transfer may be attributable to a patient's age, gender, body mass, body fat percentage, body mass index, metabolic rate, neural sensitivity, physical fitness, energy level, and general state of health. This includes the thermal conductivity, density, and heat capacity of a patient's body tissues and fluids, the surface thickness of various layers (e.g., dermis, epidermis, fat, muscle) of a patient's body tissue, factors related to a patient's blood perfusion, including blood pressure, blood flow rate, venous structure (e.g., capillary density, lumen diameter distribution, etc.), and a patient's metabolic rate. Likewise, given the various factors which may impact the measure of heat transfer effected during a given thermal contrast therapy treatment sequence, as between two patients and/or body parts sought to

be treated, a different treatment may be required as between them in order to effect the same measure of heat transfer during the respective treatments. Furthermore, different thermal contrast therapy treatment sequences may be required for the same patient as, when, and if factors change which may impact the measure of heat transfer effected
5 during a given treatment sequence.

Customized thermal contrast therapy treatment sequences may be configured to effect a specified measure of heat transfer during the treatment sequence and/or the one or more of the heating periods and/or cooling periods thereof. The specified measure of heat transfer (i.e., rate of heat transfer and/or quantity of heat transfer) may depend on
10 any one or more of the factors affecting thermal contrast therapy treatments such as the factors disclosed herein, including: conditions particular to the patient intended to receive treatment, the particular area of the body sought to be treated, the particular symptom or condition sought to be treated, the particular desired therapeutic result, and/or other considerations.

Relationship Between Flow Rate and Heat Transfer

15

The rate of heat transfer between fluid in a treatment pad and a patient's tissue is directly proportional to the flow rate of the fluid. An increase in the flow rate increases the rate of heat transfer and a decrease in the flow rate decreases the rate of heat transfer. As heat transfer occurs between the fluid and the patient's body proximate to the
20 treatment pad, the temperature of the fluid within the treatment pad will shift towards the temperature of the patient's tissue. The magnitude of this change in temperature is inversely proportional to the flow rate of the fluid. A relatively high flow rate will yield a relatively low change in temperature between the inflow and outflow ports of the

treatment pad, and thus a relatively high driving force for heat transfer. Conversely, a relatively low flow rate will yield a relatively high change in temperature between the inflow and outflow ports of the treatment pad, and thus a relatively low driving force for heat transfer. Thus, the rate of heat transfer effected by the fluid depends on flow rate, and the rate of heat transfer effected during heating periods and/or cooling periods may be controlled by varying the flow rate of the fluid. Accordingly, at a constant fluid temperature entering the treatment pad, the rate of heat transfer may be increased by increasing the flow rate of the fluid, to the point where the change in temperature of the fluid between the inflow port and the outflow port of the treatment pad approaches zero. Conversely, the rate of heat transfer may be decreased by decreasing the flow rate of the fluid, to the point where the difference in temperature between the patient's body and the fluid approached zero.

The following example illustrates the relationship between the flow rate of fluid and the rate of heat transfer effected by the fluid. A cooling period was provided, via a thermal contrast therapy device having a treatment pad attached to a patient's lower leg. The temperature of the fluid (water) entering the treatment pad was maintained at about 40 °F. At a flow rate of about 120 mL per minute, the fluid exiting the treatment pad was about 58 °F. At a flow rate of about 240 mL per minute, the fluid exiting the treatment pad was about 53 °F. Thus, using equation (3), the rate of heat transfer to the fluid was about 4.7 BTU per minute when the flow rate was 120 mL per minute ($120 \text{ mL/min} \times 1 \text{ sq. ft}/28,316.8 \text{ mL} \times 62.24 \text{ lb/sq. ft} \times 1 \text{ BTU/lb-}^\circ\text{F} \times 18 \text{ }^\circ\text{F}$), and about 6.9 BTU per minute when the flow rate was 240 mL per minute ($240 \text{ mL/min} \times 1 \text{ sq. ft}/28,316.8 \text{ mL} \times 62.24 \text{ lb/sq. ft} \times 1 \text{ BTU/lb-}^\circ\text{F} \times 13 \text{ }^\circ\text{F}$).

Thus, customized thermal contrast therapy treatment sequences may be provided which are based, at least in part, on providing a specified flow rate of the fluid. For example, a specified measure of heat transfer may be provided by varying the flow rate of the fluid. In some embodiments, a specified rate of heat transfer may be effected solely
5 by varying the flow rate of the fluid. Alternatively, the specified measure of heat transfer may be attained by varying both the flow rate and the temperature of the fluid. For example, in some embodiments, the temperature of the fluid may be varied to attain a close approximation of a specified rate of heat transfer, and then the flow rate of the fluid may be varied to provide fine-tuning to more precisely control the rate of heat transfer.

10 In some embodiments, the artisan may derive advantages from utilizing changes in flow rate, in addition to or as an alternative to changes in fluid temperature, to effect a specified rate of heat transfer. For example, the heating and cooling loads on a thermal contrast therapy device may be reduced by using flow rate to effect a desired rate of heat transfer. This may yield more efficient, cost-effective devices, as well as enhanced
15 ability to provide customized treatment sequences. Additionally, the rate of heat transfer may, in some embodiments, be more effectively controlled via the flow rate of the fluid than via the temperature of the fluid. This may be the case, for example, regarding embodiments having configurations such that the rate of heat transfer may be changed more rapidly and/or more precisely via a change in flow rate than via a change in
20 temperature. In some embodiments a treatment pad having a small fluid volume may enhance the effect of flow rate on the rate of heat transfer, and consequently the range of control over the rate of heat transfer via flow rate. In certain embodiments where flow rate control facilitates more precise and/or more rapid control over the rate of heat

transfer, customized thermal contrast therapy treatment sequences may be provided based, at least in part, on flow rate control which may not otherwise be feasible using only fluid temperature to control the rate of heat transfer. For example, a customized treatment sequences may include rapidly transitioning between heating periods and
5 cooling periods, rapidly changing the rate of heat transfer, and/or more precisely controlling the rate of heat transfer.

During a thermal contrast therapy treatment sequence, the temperature gradient between the fluid entering the treatment pad and the patient's tissue proximate to the treatment pad may decrease as a result of the ensuing heat transfer. Thus, at a constant
10 flow rate and constant temperature of fluid entering the treatment pad, the rate of heat transfer may decline over the course of a heating period or cooling period due to such decreasing temperature gradient. In some embodiments, a customized thermal contrast therapy treatment sequence may be provided in which the flow rate of the fluid is adjusted so as to maintain a desired rate of heat transfer notwithstanding changes in the
15 temperature of the tissue proximate to the treatment pad. Such changes in flow rate may be effected, for example, over the course of a given heating period and/or cooling period, and/or from one period to the next over the course of the treatment sequence. For example, as the tissue proximate to the treatment pad changes temperature in response to heat transfer, the flow rate of the fluid may be increased so as to offset the decreasing rate
20 of heat transfer that would otherwise result as tissue temperature proximate to the treatment pad shifts towards the temperature of the fluid in the treatment pad.

Additionally, temperature changes to a patient's tissue effected during one heating period or cooling period may impact the rate of heat transfer in a subsequent period.

For example, alternating heating periods and cooling periods may provide a greater temperature gradient between the patient's tissue and the fluid in subsequent alternating periods. Thus, the driving force for heat transfer in a subsequent period may be enhanced, at least initially, due to the change in tissue temperature effected by the preceding period. Such enhanced temperature gradient may be desirable or undesirable, depending on the desired effects of the particular treatment sequence. In some embodiments, the flow rate of the fluid may be modified based, at least in part, on the temperature gradient between the patient's tissue and the fluid. This may include effecting a change in the flow rate of the fluid in consideration of an enhanced temperature gradient effected by one or more preceding periods. In some embodiments, a sequence of alternating cooling periods and heating periods may be configured to provide an enhanced temperature gradient in one or more subsequent periods in the sequence. In some embodiments, a neutral period may be provided between one or more of the alternating cooling periods and heating periods so as to provide a subdued temperature gradient in one or more subsequent periods in the sequence, for example, the period following the neutral period. In some embodiments, the flow rate of the fluid may be varied to effect a desired temperature gradient during at least a portion of a heating period and/or cooling period.

In some situations, thermal contrast therapy may be provided under circumstances where a patient may be particularly sensitive to hot and/or cold fluid temperatures. This may be the case, for example, with patients suffering from frostbite or hypothermia, elderly patients, patients with diabetes and related physiological complications (e.g., gangrene), patients with lymphedema or other disorders associated with vascular or

lymphatic insufficiency (e.g., chronic venous insufficiency, venous stasis ulcers, post-mastectomy edema or chronic lymphedema), patients with peripheral vascular disease or other circulatory deficiency syndrome (e.g., arteriosclerosis, deep vein thrombosis, Buerger's disease, or thromboangiitis obliterans). Such sensitive patients may be unable
5 to tolerate certain fluid temperatures without severe discomfort or injury to tissue. In these instances, it may be infeasible to use aggressive fluid temperatures to increase the rate of heat transfer without exceeding some discomfort or injury threshold. Instead, the rate of heat transfer may be enhanced by increasing the flow rate of the fluid, while maintaining a fluid temperature that is within the patient's pain tolerance and/or which
10 will not cause injury to tissue. This approach may enable some sensitive patients to receive the benefit of enhanced cycles of vasoconstriction and vasodilation, enhanced improvements in blood flow, and/or other enhanced therapeutic effects, while maintaining a moderate fluid temperature that is suitable for sensitive patients.

Dynamically Controlled Treatment Sequences

15 A customized thermal contrast therapy treatment sequence may include dynamically controlling the sequence to effect a desired treatment and/or to attain a desired therapeutic effect. Any one or more variables of the treatment sequence may be dynamically controlled in order to provide a customized treatment sequence. In some embodiments, automatic adjustments to a thermal contrast therapy treatment sequence
20 may include: changing a setting for the temperature and/or flow rate of the fluid; changing the duration of one or more of the cooling periods, heating periods, and/or transition periods; changing the number of cooling periods, heating periods, and/or transition periods; changing the rate of change of the temperature and/or flow rate of the

fluid; and/or prescribing a sequence for one or more future thermal contrast therapy treatments.

Specified Measure of Heat Transfer

In some embodiments, the treatment sequence may be dynamically controlled to
5 provide a desired measure of heat transfer (i.e., a rate of heat transfer and/or quantity of heat transfer) during one or more of the heating periods and/or cooling periods. The measure of heat transfer during one or more of the heating periods and/or cooling periods may be controlled, for example, using equations (4) and/or (5) and by adjusting the flow rate and/or temperature of the fluid, and/or the duration of the one or more periods. The
10 rate of heat transfer, q_{TCT} , may be controlled for a given period, for example, using equation (4) and then adjusting the temperature gradient between the fluid and the patient's tissue proximate to the treatment pad, ΔT . The quantity of heat transfer, Q_{TCT} , may be controlled, for example, using equation (5) and then adjusting the rate of heat transfer, q_{TCT} and/or the duration of the period, Δt . The temperature gradient may be
15 controlled by adjusting the temperature and/or the flow rate of the fluid. Dynamically controlled thermal contrast therapy treatment sequences may be provided which utilize any one or more equations for modeling blood perfusion (e.g., the Pennes bioheat model), and/or which take into account other factors which may impact heat transfer during thermal contrast therapy. Such factors include heat production due to metabolic
20 processes, geometry of the thermal contrast therapy treatment area (e.g., as defined by the treatment pads), the thermophysical properties of various types of body tissue, and/or thermoregulatory mechanisms.

Referring to Fig. 12A, a flow chart is shown which illustrates an exemplary process for providing a specified measure of heat transfer during a thermal contrast therapy treatment sequence. The thermal contrast therapy device initiates the thermal contrast therapy treatment sequence. For each period of the treatment sequence, fluid is
5 circulated to the treatment pad, the temperature of the fluid being approximately that which is required to provide the desired rate of heat transfer. Throughout the course of the treatment period, the rate of heat transfer is ascertained, and a determination is made as to whether the actual rate of heat transfer matches the target rate of heat transfer. The target may be a specific value or a range. If the rate of heat transfer does not match the
10 target rate, then the rate of heat transfer is adjusted. The rate of heat transfer may be adjusted by changing the temperature and/or flow rate of the fluid.

Throughout the course of each treatment period within the sequence, the quantity of heat transfer effected is ascertained and a determination is made as to whether the actual quantity of heat transfer is less than or equal to the target quantity. In some
15 embodiments, the period is concluded when the quantity of heat transfer reaches or exceeds the target quantity. Alternatively, the period may continue for a specified duration of time and conclude when the specified duration has elapsed.

When the treatment period has concluded, it is ascertained whether there are additional periods remaining in the sequence. If there are additional periods remaining,
20 the device proceeds through such remaining periods until all of the periods have been administered. The treatment sequence concludes when all of the periods have been administered, at which point data associated with the treatment sequence may be transmitted to a thermal contrast therapy system.

Referring to Fig. **12B**, a flow chart is shown illustrating an exemplary process for providing a specified measure of heat transfer during a thermal contrast therapy treatment sequence, utilizing flow rate to modify the rate of heat transfer. The process described in Fig. **12B** proceeds similar to that of Fig. **12A**, with the additional step of controlling the
5 rate of heat transfer by varying the flow rate of the fluid.

Physiological Parameter Values

In some embodiments, a customized thermal contrast therapy treatment sequence may be dynamically controlled to optimize one or more physiological parameter values. For example, one or more variables of a treatment sequence may be automatically
10 adjusted when the patient exhibits a physiological parameter that corresponds to a predefined value. The physiological parameter values may be based on the patient's vital signs. A predefined value may include, for example, an increase from a previous value, a decrease from a previous value, a previous value, and/or a target value.

Physiological parameters which may be monitored and utilized to dynamically
15 control a thermal contrast therapy treatment sequence include: body temperature (e.g. core temperature, local temperature, etc.), heart rate, blood pressure, blood flow, blood oxygen level, or other vital signs. Such vital signs may be monitored using any number of devices known in the art. For example, a thermal contrast therapy treatment sequences may be automatically adjusted so as to optimize the magnitude of an increase in blood
20 circulation and/or blood oxygen content induced by cycles of vasoconstriction and vasodilation. In some embodiments, a thermal contrast therapy treatment sequence may include rapidly alternating cooling periods and heating periods and/or rapid transition between alternating cooling periods and heating periods. Such a sequence may be

effective to induce cycles of vasoconstriction and vasodilation. Cycles of vasoconstriction and vasodilation may be provided in a manner effective to cause an increase in blood circulation and/or blood oxygen content in a patient's tissue. In some embodiments, a thermal contrast therapy treatment sequence may be dynamically controlled to optimize vasoconstriction and vasodilation exhibited by the patient.

In some embodiments, a treatment sequence may be dynamically controlled based on a physiological parameter value exhibited by a patient during treatment. For example, based on a patient's vital signs, adjustments may be made during treatment to any one or more of: the fluid temperature provided during heating periods and/or cooling periods, the duration and/or number of heating periods and/or cooling periods, the quantity of heat transfer and/or rate of heat transfer during one or more of the heating periods and/or cooling periods. A treatment sequence may also be dynamically controlled based on a physiological parameter value exhibited by a patient prior to a treatment or during a previous treatment.

Referring to Figs. **13A and 13B**, a flow chart is shown illustrating an exemplary customized thermal contrast therapy treatment sequence, dynamically controlled to optimize a physiological parameter value. The treatment may be configured to optimize a physiological parameter value during any one or more of the periods, and/or for subsequent periods within the sequence, and/or for subsequent treatments within a treatment program. During a treatment period, it is ascertained whether the sequence calls for optimizing a physiological parameter value during the period. If so, the physiological parameter value is ascertained, and if the value is less than or greater than a predefined target value, one or more measures of heat transfer (i.e., the rate of heat

transfer and/or the quantity of heat transfer) to be provided during the period are modified, e.g., to optimize the physiological parameter value. A predefined value corresponding to a physiological parameter may be one or more of: a target value, a minimum value, a maximum value, a range, an average, a standard deviation, an upper
5 control limit, a lower control limit, a calculated value, a previous value, a change in the value, an increase from a previous value, a decrease from a previous value, a safety threshold, a deviation from any of the foregoing, an ascertained difference between a physiological parameter value and any of the foregoing and/or any other value desirable for dynamically controlling a thermal contrast therapy treatment sequence. A predefined
10 value may, for example, be obtained from a treatment provider or derived from a database. Alternatively or in addition, a thermal contrast therapy device and/or system may provide one or more preconfigured predefined values. Such preconfigured values may be modified by a user and/or a treatment provider.

When a treatment period has concluded, it is ascertained whether the sequence
15 calls for optimizing a physiological parameter value for subsequent periods within the sequence. If so, the physiological parameter value(s) exhibited during the concluded period and/or other previously concluded periods are ascertained, and if the value(s) are less than or greater than a predefined target value, one or more measures of heat transfer to be provided during one or more subsequent periods in the sequence are modified, e.g.,
20 to optimize the physiological parameter value.

When a treatment sequence has concluded, it is ascertained whether the sequence calls for optimizing a physiological parameter value for subsequent treatment sequences within a treatment program. If so, the physiological parameter value(s) exhibited during

the concluded sequence and/or other previously concluded sequences are ascertained, and if the value(s) are less than or greater than a predefined target value, one or more measures of heat transfer to be provided during one or more subsequent treatment sequences are modified, e.g., to optimize the physiological parameter value. At the conclusion of the treatment sequence, data associated with the sequence may be transmitted to a thermal contrast therapy system, e.g., to be stored in a database for future use.

Automatic Adjustments to a Treatment Sequence

Dynamically controlled treatment sequences may include one or more automatic adjustments to a treatment sequence. Automatic adjustments may occur at any desired time during the course of the sequence. A sequence may be automatically adjusted during the course of one or more cooling periods or heating periods within the sequence, for example, based on a physiological parameter value exhibited during the same period. Such automatic adjustment may be provided, for example, to attain a desired effect from a particular period within the sequence during which the one or more adjustments occur. Additionally, or in the alternative, one or more subsequent periods within a sequence may be automatically adjusted based on the effects of one or more prior periods, for example, based on a physiological parameter value exhibited during a previous cooling period or heating period. Automatic adjustments in a subsequent period or periods may be provided, for example, to attain a desired effect from such subsequent period or periods. Automatic adjustments to a treatment sequence may be effected at any time during the course of treatment, for example, to attain a desired effect from the particular treatment.

Automation adjustments may also be effected over the course of several treatments, for example, to attain a desired effect from a series of treatments.

In some instances, the particular settings which might be expected to produce a desired therapeutic effect may not be known, or may be uncertain. Given this, in some
5 embodiments a thermal contrast therapy treatment sequence, and/or series of treatments within a treatment program may be configured to administer varying heating periods and/or cooling periods, treatment sequences, and/or overall treatment programs, while monitoring physiological parameter values, other therapeutic effects, and/or other factors related to the treatment, and then to cause the treatment sequence(s), period(s), or
10 program(s) to be dynamically modified, e.g., to optimize one or more physiological parameter values or other desired therapeutic effects. Such automatic adjustments may be made to heating periods and/or cooling periods within a treatment sequence, to one or more treatment sequences making up a treatment program, and/or to an overall treatment program.

15 In some embodiments, a dynamically controlled treatment sequence may be provided, in which the dynamic control is configured to provide conditions intended to correspond to conditions of a prior treatment sequence. This may include reproducing or replicating conditions of a prior treatment, or adjusting one or more variables which may affect the treatment, a physiological parameter value, and/or a therapeutic effect of the
20 treatment, for example, based at least in part on conditions corresponding to one or more prior treatments.

In some embodiments, a thermal contrast therapy treatment sequence may be dynamically controlled or automatically adjusted based on a patient's comfort level. For

example the sequence may be adjusted based on input as to whether the treatment feels painful or uncomfortable, too hot or too cold, or just right. Such patient input may be derived from one or more physiological parameter values, such as vital signs, or input may be provided directly by patient, for example via a user interface.

5 Those skilled in the art will appreciate that both feed-back and feed-forward control loops may be utilized with the dynamically controlled treatment sequences disclosed herein.

Exemplary Customized Thermal Contrast Therapy Treatments

Exemplary customized thermal contrast therapy treatments will now be discussed.

10 Those skilled in the art will appreciate that numerous other treatment sequences are within the spirit and scope of the present disclosure. Customized thermal contrast therapy treatment sequences may be provided based on any one or more variables, including the variables disclosed herein. Customized treatment sequences may be provided based on the preference of the practitioner or therapist, or the patient receiving
15 treatment. Treatment sequences may be developed on the basis of research and/or results attained by users associated with a thermal contrast therapy system.

Treatment sequences may be customized based on the area of the body sought to be treated, the particular symptom or condition sought to be treated, or the particular desired therapeutic result(s). As examples, customized treatment sequences may be
20 provided for any area of the body, such as the hand, wrist, forearm, elbow, upper arm, shoulder, foot, ankle, calf, shin, knee, thigh, hip, pelvic region, abdomen, lumbar, mid-back, upper-back, neck, and cranium.

Customized treatment sequences may also be provided for any one or more conditions or symptoms sought to be treated, such as: edema or swelling, fever, toxins, spasms, constipation, immune function inflammation, sprains, strains, general pain, neuropathy, arthritis, carpal tunnel, non-healing wounds, gangrene, migraine headaches, 5 whiplash associated disorders, hair loss, muscular spasms, sinus pressure, disorders associated with lack of proper blood flow, bed sores, and respiratory ailments, among other things. Customized treatments may also be provided for patients with hypothermia or frostbite, for example, to enhance circulation in affected tissue.

As further examples, customized treatments may be provided to encourage 10 healing of bones and tissue, and to rehabilitate injuries to bone, muscle, ligaments, tendons, and skin. Customized treatments may also be provided after an acute injury or surgery, for example, to reduce pain and swelling and promote healing. Customized treatments may be provided to athletes after or between training sessions to speed recovery or reduce delayed onset muscle soreness, by helping to flush lactic acid from 15 sore muscles. Customized treatments may also be provided to relax joint tissue, such as ligaments and tendons, to increase range of motion. Customized treatments may also be provided for patients with spinal cord or nerve damage, for example, to enhance blood flow to the injured nerve tissue, or prevent or mitigate disruption of the tenuous blood supply.

20 Customized treatments may also be provided as a therapy for diabetes and related physiological complications, for example, gangrene, or for lymphedema or other disorders associated with vascular or lymphatic insufficiency, for example, chronic venous insufficiency, venous stasis ulcers, post-mastectomy edema or chronic

lymphedema, and for peripheral vascular disease or other circulatory deficiency syndrome, for example, arteriosclerosis, deep vein thrombosis, Buereger's disease, or thromboangiitis obliterans, or to positively influence the immune system.

Treatments may also be customized based on one or more desired therapeutic effects sought to be attained. As examples, therapeutic effects sought to be attained from thermal contrast therapy may include increased blood flow, increased blood oxygen levels, reduced inflammation, pain reduction, accelerated healing, increased medication effectiveness and focus, improved distal perfusion, improved arterial inflow, improved venous return flow, toxin removal, reduction of inflammatory kinins, and assistance to a chronically decompensated heart by complementing the heart cycle.

Without wishing to be constrained by theory, it is believed that thermal contrast therapy performed on one area of the body may cause a sympathetic response in a different area of the body. For example, treatment performed on one limb (e.g., an arm or leg) may effect a therapeutic response in the opposite limb. Accordingly, in some embodiments customized treatments may be provided to effect a sympathetic response. The sympathetic response may include activation of the sympathetic nervous system, associated sensations associated with therapy in a limb opposite to the limb receiving direct treatment, increased blood flow, enhanced tissue healing and rehabilitation, and other desired therapeutic effects. In some embodiments, thermal contrast therapy may be provided so as to effect a sympathetic response in a different area of the body in addition to or as an alternative to providing therapy directly to such area. This may be effective to enhance the therapeutic effects of thermal contrast therapy in patients and/or particular

areas of the body which may be particularly sensitive and therefore unable to tolerate certain fluid temperatures without severe discomfort or injury to tissue.

The total treatment time for a thermal contrast therapy sequence may range from a few minutes to several hours in duration, for example, from 10 minutes to 2.5 hours, or
5 from 20 minutes to 75 minutes. As further examples, the total treatment time may be between about any two of the following durations: 5 minutes, 10 minutes, 15 minutes, 20 minutes, 25 minutes, 30 minutes, 35 minutes, 40 minutes, 45 minutes, 50 minutes, 55 minutes, 60 minutes, 65 minutes, 70 minutes, 75 minutes, 80 minutes, 85 minutes, 90 minutes, 95 minutes, 100 minutes, 105 minutes, 110 minutes, 115 minutes, 120 minutes,
10 125 minutes, 130 minutes, 135 minutes, 140 minutes, 145 minutes, 150 minutes, or any intermediate time period, or longer.

A treatment sequence may begin with either a heating period or a cooling period. Different therapeutic effects may be attained depending on whether therapy begins with a heating period or a cooling period. The duration of a heating period or a cooling period
15 may range from a few seconds to several minutes. As examples, the duration of heating periods and/or cooling periods may range from about 5 seconds to 60 seconds, from about 1 minute to 5 minutes, from about 5 minutes to 20 minutes, or longer. A period may last, for example, between about any two of the following durations: 5 seconds, 10 seconds, 15 seconds, 20 seconds, 25 seconds, 30 seconds, 35 seconds, 40 seconds, 45
20 seconds, 50 seconds, 55 seconds, 60 seconds, 65 seconds, 70 seconds, 75 seconds, 80 seconds, 85 seconds, 90 seconds, 95 seconds, 100 seconds, 105 seconds, 110 seconds, 115 seconds, 120 seconds, 125 seconds, 130 seconds, 135 seconds, 140 seconds, 145 seconds, 150 seconds, 155 seconds, 160 seconds, 165 seconds, 170 seconds, 175 seconds,

180 seconds, 185 seconds, 190 seconds, 195 seconds, 200 seconds, 205 seconds, 210 seconds, 215 seconds, 220 seconds, 225 seconds, 230 seconds, 235 seconds, 240 seconds, 250 seconds, 260 seconds, 270 seconds, 280 seconds, 290 seconds, 300 seconds, 10 minutes, 15 minutes, 20 minutes, 25 minutes, 30 minutes, or any intermediate time
5 period, or longer. Alternatively, in some embodiments, a cooling or heating period may be provided which comprises continuous application of hot or cold.

Transition time may be limited by the time required for fluid corresponding to a first period to be displaced by fluid corresponding to a second period, and/or the time required to overcome the thermal mass of various components of the thermal contrast
10 therapy device, fluid lines, and treatment pad which may be in thermal communication with the fluid, particularly those components which are in thermal communication with fluid from the heating block and with fluid from the cooling block. The thermal contrast therapy devices disclosed herein may facilitate rapid transitions between alternating heating periods and cooling periods, for example, by minimizing the time required to
15 displace fluid and/or by minimizing the thermal mass in thermal communication with fluid from the heating block and with fluid from the cooling block.

Transition time may also depend on a desired therapeutic effect. In some instances a rapid transition may be desired, whereas in other instances a more gradual transition may be desired. For example, when treating a physically fit patient for muscle
20 spasms, a rapid transition may be desired, whereas an elderly person afflicted by poor circulation may be unable to withstand a high level of contrasting heat transfer, and as such, a mild transition may be desired. In some embodiments, a rapid transition may enhance the pumping effect of vasoconstriction and vasodilation. Transition times

between alternating heating periods and cooling periods may range from a few seconds to several minutes, for example, from about 5 seconds to 30 minutes, from about 5 seconds to 90 seconds, from about 15 seconds to 300 seconds, from about 30 seconds to 90 seconds, from about 60 seconds to 180 seconds, from about 5 minutes to 10 minutes, or
5 from about 10 minutes to 30 minutes. Transition times may be, for example, less than about 5 seconds, 10 seconds, 15 seconds, 20 seconds, 25 seconds, 30 seconds, 35 seconds, 40 seconds, 45 seconds, 50 seconds, 55 seconds, 60 seconds, 65 seconds, 70 seconds, 75 seconds, 80 seconds, 85 seconds, 90 seconds, 120 seconds, 180 seconds, 240 seconds, 300 seconds, 10 minutes, 15 minutes, 20 minutes, 25 minutes, 30 minutes, or
10 any intermediate time period, or longer period.

In some embodiments, a neutral period comprising a neutral temperature and/or rate of heat transfer may be provided between some or all of the heating periods and cooling periods. The neutral period may be provided as part of the transition between heating periods and cooling periods, or the neutral period may be treated as its own
15 distinct period. The duration of a neutral period may range from a few seconds to several minutes. As examples, the duration of neutral periods may range from about 5 seconds to 60 seconds, from about 1 minute to 5 minutes, from about 5 minutes to 20 minutes, or longer. A neutral period may last, for example, between about any two of the following durations: 5 seconds, 10 seconds, 15 seconds, 20 seconds, 25 seconds, 30 seconds, 35
20 seconds, 40 seconds, 45 seconds, 50 seconds, 55 seconds, 60 seconds, 65 seconds, 70 seconds, 75 seconds, 80 seconds, 85 seconds, 90 seconds, 95 seconds, 100 seconds, 105 seconds, 110 seconds, 115 seconds, 120 seconds, 125 seconds, 130 seconds, 135 seconds, 140 seconds, 145 seconds, 150 seconds, 155 seconds, 160 seconds, 165 seconds, 170

seconds, 175 seconds, 180 seconds, 185 seconds, 190 seconds, 195 seconds, 200 seconds, 205 seconds, 210 seconds, 215 seconds, 220 seconds, 225 seconds, 230 seconds, 235 seconds, 240 seconds, 5 minutes, 10 minutes, 15 minutes, 20 minutes, 25 minutes, 30 minutes, or any intermediate time period, or longer.

5 In some embodiments, a thermal contrast therapy treatment sequence may be provided in which the fluid temperature and/or rate of heat transfer exhibits a continuous cyclical change at least for a portion of the treatment sequence. For example, the sequence may continuously cycle between alternating heating periods and cooling periods. When performing such a sequence, a thermal contrast therapy device may be
10 configured to effect a first specified temperature and/or rate of heat transfer, and then transition to a second specified temperature and/or rate of heat transfer upon having attained the first specified temperature and/or rate of heat transfer. Such a sequence may continuously cycle between any number of specified temperatures and/or rates of heat transfer. When a treatment sequence or a portion thereof exhibits a continuous cyclical
15 change between specified temperatures and/or rates of heat transfer, the continuous cyclical change may be characterized as having heating periods and/or cooling periods with a duration approaching zero seconds (e.g., less than 15 seconds, less than 10 seconds, less than 5 seconds, less than 1 second, or zero seconds), and transition periods consuming the balance of the duration of time attributed to the continuous cyclical
20 change.

Fluid temperatures during heating periods may range from about 85 °F to 130 °F, or from about 100 °F to 110 °F. The fluid temperature during a heating period may be, for example, greater than about 85 °F, 90 °F, 95 °F, 100 °F, 105 °F, 110 °F, 115 °F, 120

$^{\circ}\text{F}$, 125°F , 130°F , or any intermediate temperature, cooler temperature, or warmer temperature. Other temperatures for heating periods will also be apparent to the skilled artisan.

During cooling periods, fluid temperatures may range from about 30°F to 70°F ,
5 or from about 40°F to 50°F . As further examples, cold fluid temperatures may be less than about 30°F , 35°F , 40°F , 45°F , 50°F , 55°F , 60°F , 65°F , 70°F , or any intermediate temperature, cooler temperature, or warmer temperature. Other temperatures for cooling periods will also be apparent to the skilled artisan.

Transition periods may provide fluid of any temperature which is between the
10 temperature corresponding to the period preceding the transition period and the temperature which corresponds to the period following the transition period. For example, fluid temperatures during a transition period may be between about any two of the following temperatures: 30°F , 35°F , 40°F , 45°F , 50°F , 55°F , 60°F , 65°F , 70°F , 75°F , 80°F , 85°F , 90°F , 95°F , 100°F , 105°F , 110°F , 115°F , 120°F , 125°F , 130°F ,
15 or any intermediate temperature, cooler temperature, or warmer temperature. Other temperatures for transitions will also be apparent to the skilled artisan.

Transition periods may be configured to provide a customized transition curve. The transition curve between two periods may be rapid or gradual, may comprise various rates of change during the transition, and may include a neutral period comprising
20 providing for a specified period of time, a desired rate of heat transfer, and/or a desired temperature for the fluid, which is between that of the period preceding the neutral period and the period following the neutral period.

Flow rates of fluids may range from about 10 mL/min to 1000 mL/min. For example, flow rates may be at least about 10 mL/min, 50 mL/min, 100 mL/min, 150 mL/min, 200 mL/min, 250 mL/min, 300 mL/min, 350 mL/min, 400 mL/min, 450 mL/min, 500 mL/min, 550 mL/min, 600 mL/min, 650 mL/min, 700 mL/min, 750 mL/min, 800 mL/min, 850 mL/min, 900 mL/min, 950 mL/min, 1000 mL/min, or any intermediate flow rate, higher flow rate, or lower flow rate. Flow rates may be increased where a high rate of heat transfer is desired, or decreased where a low rate of heat transfer is desired. In some embodiments, flow rate may be reduced to zero to provide a gradually declining rate of heat transfer. In some embodiments, flow rate may be increased to a point where the temperature difference between the fluid entering and exiting a treatment pad approaches a target value, for example, a minimum value, or approximately zero.

Rates of heat transfer may range from about 0.5 BTU/min to 25 BTU/min. For example, the rate of heat transfer during a given period may be between about any two of the following rates: 0.5 BTU/min, 1 BTU/min, 1.5 BTU/min, 2 BTU/min, 2.5 BTU/min, 3 BTU/min, 3.5 BTU/min, 4 BTU/min, 4.5 BTU/min, 5 BTU/min, 5.5 BTU/min, 6 BTU/min, 6.5 BTU/min, 7 BTU/min, 7.5 BTU/min, 8 BTU/min, 8.5 BTU/min, 9 BTU/min, 9.5 BTU/min, 10 BTU/min, 10.5 BTU/min, 11 BTU/min, 11.5 BTU/min, 12 BTU/min, 12.5 BTU/min, 13 BTU/min, 13.5 BTU/min, 14 BTU/min, 14.5 BTU/min, 15 BTU/min, 15.5 BTU/min, 16 BTU/min, 16.5 BTU/min, 17 BTU/min, 17.5 BTU/min, 18 BTU/min, 18.5 BTU/min, 19 BTU/min, 19.5 BTU/min, 20 BTU/min, 20.5 BTU/min, 21 BTU/min, 21.5 BTU/min, 22 BTU/min, 22.5 BTU/min, 23 BTU/min, 23.5 BTU/min, 24 BTU/min, 24.5 BTU/min, 25 BTU/min, 30 BTU/min 40 BTU/min 50 BTU/min 100

BTU/min 150 BTU/min, or any intermediate rate, greater rate, or lesser rate. Other heat transfer rates will also be apparent to the skilled artisan.

Referring to Figs. **14A-1** and **14A-2** through **14G-1** and **14G-2**, a selection of exemplary thermal contrast therapy treatment sequences are shown. As shown in Figs.

5 **14A-1** and **14A-2**, **14B-1** and **14B-2**, **14C-1** and **14C-2**, and **14D-1** and **14D-2**, a treatment sequence may be configured to provide a desired fluid temperature during the various periods of the treatment sequence, and as shown in Figs. **14E-1** and **14E-2**, **14F-1** and **14F-2**, and **14G-1** and **14G-2**, a treatment sequence may be configured to provide a desired measure of heat transfer during the various periods of the treatment sequence.

10 Additionally, treatment sequences may be configured to effect both a desired fluid temperature and a desired measure of heat transfer. Treatment sequences configured to effect a desired measure of heat transfer may provide for a desired rate of heat transfer and/or a desired quantity of heat transfer. Where a treatment sequence provides for a desired quantity of heat transfer, the duration of the treatment periods within the sequence

15 may depend on the rate of heat transfer. In addition or as an alternative, treatment sequences configured to effect a desired rate of heat transfer may provide for treatment periods having a predefined time duration, where the desired quantity of heat transfer depends on such time duration.

Figs. **14A-1** and **14A-2** show an exemplary customized thermal contrast therapy treatment sequence configured to provide a desired fluid temperature during the various

20 periods of the treatment sequence, for a first treatment of an athletic injury to a knee or elbow in a healthy/ strong patient within the first 24 hours after the injury, to reduce inflammation. The treatment may be suitable, as an example, for an athlete to treat a

knee injury that has occurred within 24 hours prior to treatment. The sequence shown in Figs. **14A-1** and **14A-2** may be the first treatment of this injury, and as such the temperature contrast starts mildly and builds up through the treatment by decreasing the temperature of the fluid during cooling periods while maintaining constant temperature during the heating periods. Mid-way through the sequence, the treatment region is allowed to calm with lesser contrast (by gradually increasing the temperature during the cooling periods), so as to reduce a sudden shock when the treatment it stopped.

Figs. **14B-1** and **14B-2** show an additional exemplary treatment sequence configured to provide a desired fluid temperature during the various periods of the treatment sequence. This treatment sequence may be suitable, as an example, for subsequent treatment of an athletic injury to a knee or elbow in a healthy/ strong patient after the first 24 hours following the injury, to reduce inflammation and increase blood flow. For example, the sequence shown in Figs. **14B-1** and **14B-2** may be provided as a subsequent treatment after previously having provided the sequence shown in Figs. **14A-1** and **14A-2**. Here, vasodilation and vasoconstriction may be enhanced by providing a gradually increasing fluid temperature during the heating periods and a gradually declining fluid temperature during cooling periods. Mid-way through the sequence, the region is allowed to calm with lesser contrast (by gradually increasing the temperature during the cooling periods and decreasing the temperature during heating periods), so as to reduce a sudden shock when the treatment it stopped.

Figs. **14C-1** and **14C-2** show yet an additional exemplary treatment sequence configured to provide a desired fluid temperature during the various periods of the treatment sequence, which may be suitable for ongoing treatment during rehabilitation of

an athletic injury to a knee or elbow. This treatment sequence may be suitable for a strong/ healthy patient after the first 48 hours following the injury, to reduce inflammation, increase blood flow, and for pain management. For example, the sequence shown in Figs. **14C-1** and **14C-2** may be provided as a subsequent treatment after
5 previously having provided the sequence in Figs. **14B-1** and **14B-2**. Here, rapid consecutive alternating heating periods and cooling periods are provided, as indicated by the short transition times, and temperature differences between heating periods and cooling periods are large, with treatment temperatures intended to be at the threshold of a patient's tolerance so as to attain the maximum tolerable effect.

10 Figs. **14D-1** and **14D-2** show an exemplary thermal contrast therapy treatment sequence configured to provide a desired fluid temperature during the various periods of the treatment sequence, which may be suitable for treatment of gangrene below the knee. This treatment sequence may be suitable for an elderly patient in relatively poor physical condition, with a desired therapeutic effect of increasing blood flow and revitalizing
15 tissue. Here, relaxed transitions and more modest temperature variations are used, given the patient's physical condition and sensitive nature of the tissue being treated.

As shown in Figs. **14E-1** and **14E-2**, **14F-1** and **14F-2**, and **14G-1** and **14G-2**, a treatment sequence may be configured to provide a desired measure of heat transfer during the various periods of the treatment sequence. Figs. **14E-1** and **14E-2** show an
20 exemplary thermal contrast therapy treatment sequence configured to provide a desired measure of heat transfer during the various periods of the treatment sequence, which may be suitable for a first treatment of an athletic injury to a knee or elbow in a healthy/ strong patient within the first 24 hours after the injury, to reduce inflammation. The treatment

may be suitable, as an example, for an athlete with a knee injury that has occurred within 24 hours prior to treatment. The sequence shown in Figs. **14E-1** and **14E-2** may be the first treatment of this injury, and as such the contrasting rates of heat transfer start mildly and builds up through the treatment by decreasing the temperature of the fluid cooling periods while maintaining constant temperature during the heating periods. Mid-way through the sequence, the region is allowed to calm with lesser contrast (by gradually increasing the temperature during the cooling periods), so as to reduce a sudden shock when the treatment it stopped.

Figs. **14F-1** and **14F-2** show an exemplary thermal contrast therapy treatment sequence configured to provide a desired measure of heat transfer during the various periods of the treatment sequence, which may be suitable for subsequent treatment of an athletic injury to a knee or elbow in a healthy/ strong patient after the first 24 hours following the injury, to reduce inflammation and increase blood flow. For example, the sequence shown in Figs. **14F-1** and **14F-2** may be provided as a subsequent treatment after previously having provided the sequence in Figs. **14A-1** and **14A-2** or Figs. **14E-1** and **14E-2**. Here, vasodilation and vasoconstriction may be enhanced by providing a gradually increasing rate of heat transfer during the heating periods and a gradually increasing rate of heat transfer during cooling periods. Then, towards the end of the treatment sequence, the rate of heat transfer during cooling periods is gradually decreased to lessen vasoconstriction and to encourage increased blood flow in the tissue. Mid-way through the sequence, the region is allowed to calm with lesser contrast (by gradually decreasing the rate of heat transfer), so as to reduce a sudden shock when the treatment it stopped.

Figs. **14G-1** and **14G-2** show an exemplary thermal contrast therapy treatment sequence configured to provide a desired measure of heat transfer during the various periods of the treatment sequence, which may be suitable for ongoing treatment during rehabilitation of an athletic injury to a knee or elbow. This sequence may be suitable for a strong/ healthy patient after the first 48 hours following the injury, to reduce inflammation increase blood flow, and for pain management. For example, the sequence shown in Figs. **14G-1** and **14G-2** may be provided as a subsequent treatment after previously having provided the sequence in Figs. **14B-1** and **14B-2** or Figs. **14F-1** and **14F-2**. Here, rapid consecutive alteration between heating periods and cooling periods are provided, as indicated by the short transition times, and contrasting rates of heat transfer between heating periods and cooling periods are large, with such heat transfer rates intended to be at the threshold of a patient's tolerance so as to attain the maximum tolerable effect.

Each of the treatments sequences shown in Figs. **14A-1**, **14A-2** through **14G-1**, **14G-2** may be modified or combined with other sequences, features, or alternative embodiments. For example, the sequences shown in Figs. **14A-1**, **14A-2** through **14D-1**, **14A-2** may be configured to provide a desired measure of heat transfer during the various periods rather than a desired fluid temperature. Additionally, any of the sequences may be dynamically controlled. For example, treatment sequence parameters may be automatically adjusted to optimize a physiological parameter value, and/or to effect a desired measure of heat transfer.

In the case of treating a recent injury, one or more of the heating periods may be replaced by a neutral period. Once the swelling has been controlled, heating periods may

be introduced to increase contrast and therefore increase the blood flow to that region to provide pain reduction and to further encourage healing.

In the case of a weak or elderly patient, one or more of the cooling periods may be replaced by a neutral period. As the patient becomes increasingly accustomed to thermal contrast therapy, the cooling periods may be introduced.

Those skilled in the art will appreciate that various other treatment sequences are within the scope of the present disclosure, all as may be selected based on the preference of the practitioner, therapist, or the patient receiving treatment, the area of the body sought to be treated, the particular symptom or condition sought to be treated, the particular desired therapeutic result, and/or other considerations.

III. Thermal Contrast Therapy Systems

The present disclosure additionally relates to, among other things, thermal contrast therapy systems configured to provide customized thermal contrast therapy, for example via automated thermal contrast therapy devices configured to interact with such systems and to perform computer-implemented methods of providing thermal contrast therapy. Referring to Fig. 15, an exemplary embodiment of a thermal contrast therapy system is shown. Those skilled in the art will appreciate that numerous other embodiments of thermal contrast therapy systems are within the spirit and scope of the present disclosure.

The thermal contrast therapy system shown in Fig. 15 depicts a thermal contrast therapy network 1500 comprising a server 1502, and a database 1504. The server may be configured to manage network connections, cause data to be stored and/or retrieved from

the database, and transmit and receive data through various sources via network connections. One or more thermal contrast therapy devices **1506** may be associated with a thermal contrast therapy system. These thermal contrast therapy devices may transmit data to and receive data from the thermal contrast therapy network. Connectivity may be
5 accomplished through means well known in the art, including wired or wireless connections, including USB type connections, Bluetooth, and Wi-Fi.

Data may be stored in the database and subsequently transmitted to a thermal contrast therapy device. Such data may include treatment programs, for example customized treatment programs such as those disclosed herein. In some embodiments, a
10 thermal contrast therapy treatment program may be uploaded or stored in a database accessible by a thermal contrast therapy system or device, and users thereof. The treatment program may be prescribed by a user's therapist, physician, care provider, or the like, or selected by a user, for example, from a menu of one or more treatment options.

15 Treatment programs may be developed by thermal contrast therapy treatment providers, for example therapists, physicians, care providers, and the like, researchers, manufacturers, or service providers, for example providers of paid or subscription-based thermal contrast therapy services, users of a thermal contrast therapy device or system, or any other party associated with the thermal contrast therapy system. As described in
20 more detail below, thermal contrast therapy treatment programs may be associated with various patient profiles, particular areas of the body sought to be treated, particular symptom or conditions sought to be treated, particular desired therapeutic results, and/or other considerations.

Data may be transmitted across a thermal contrast therapy network and stored in the database. For example, data associated with a thermal contrast therapy treatment may be transmitted from a thermal contrast therapy device, a personal device configured to operate a thermal contrast therapy device (e.g., via a user interface), an auxiliary device
5 configured to monitor physiological parameter values, and/or any other device. Databases associated with the thermal contrast therapy systems disclosed herein may house data such as: information related to a patient receiving treatment, thermal contrast therapy treatment programs and treatment sequences, physiological parameter values exhibited by patients (e.g., during treatments), and therapeutic effects observed in
10 patients (e.g., following treatments), or other desired information. In some embodiments, customized thermal contrast therapy treatment programs may be prescribed to the users based, at least in part, on data housed in a database associated with a thermal contrast system. In some embodiments, customized thermal contrast therapy treatment programs may be automatically generated based on such data.

15 In some embodiments, users may interact with a thermal contrast therapy system or a thermal contrast therapy device via a user interface, e.g., on a user interface device **1508**. Such use interface may be configured to control a thermal contrast therapy device. For example, a user interface may be configured to allow a user (e.g., a treatment provider and/or a patient) to select from among a plurality customized thermal contrast therapy
20 treatment programs and to cause a thermal contrast therapy device to perform the selected treatment program. Exemplary embodiments of user interfaces are described in more detail below. In some embodiments, the thermal contrast therapy systems disclosed herein may be configured to allow a user to define a customized thermal contrast therapy

treatment sequence and cause the sequence to be stored in a database associated with the system, thereby making the sequence available to one or more of the users of the system.

Users of a thermal contrast therapy system in accordance with the present disclosure include patients or other users of thermal contrast therapy devices, treatment providers
5 (e.g., therapists, physicians, care providers, and the like), and communities or groups of researchers, treatment providers, and/or users of thermal contrast therapy devices.

In some embodiments, the thermal contrast therapy systems disclosed herein may include one or more auxiliary devices **1510**. Such auxiliary devices may be associated with a thermal contrast therapy device and/or thermal contrast therapy network. The
10 auxiliary devices may be configured to measure one or more physiological parameters (e.g., vital signs), and to transmit data corresponding to such physiological parameter values to a thermal contrast therapy device and/or to a thermal contrast therapy network. Physiological parameter values which may be measured by such an auxiliary device include: body temperature (e.g. core temperature, local temperature, etc.), heart rate,
15 blood pressure, blood flow, blood oxygen level, or other vital signs. Such physiological parameter values may be monitored using any number of devices which are well known in the art. In some embodiments, a thermal contrast therapy device may be configured to provide customized thermal contrast therapy treatment sequences based, at least in part, on data from an auxiliary device.

20 In some embodiments, the thermal contrast therapy systems disclosed herein may be configured to provide thermal contrast therapy prescribed to a patient from a remote location, and/or to remotely manage thermal contrast therapy to be performed at any one or more of a plurality of locations. As examples, such locations may include: a hospital,

an urgent care facility, a medical clinic, a physical therapy clinic, a chiropractic clinic, a naturopathic clinic, an acupuncture facility, a sports facility, a gym, and a patient's home.

In some embodiments, a treatment provider may prescribe a thermal contrast therapy program for a patient, upload the program to a database associated with a thermal contrast therapy system where it will be accessible by the patient and/or the patient's thermal contrast therapy device, for example, via a user interface. The patient may then administer the prescribed thermal contrast therapy treatment, for example at home or any other location. When a patient administers a thermal contrast therapy treatment, data associated with treatment may be stored in the database where it may be accessible by the patient's treatment provider, who may review the data and provide ongoing treatments. Subsequent treatments may be modified based on the results of previous treatment and/or the treatment provider's review of such data. Similarly, paid or subscription-based service providers may review treatment data and provide ongoing subscription-based treatments or other services.

In some embodiments, a thermal contrast therapy system may be configured to administer safety protocols, for example to ensure that treatments are properly administered. Thermal contrast therapy devices may require access credentials in order for the device to function. In some embodiments, access credentials may define or limit the functionality of the device, for example the range of operation, availability of features, treatment programs which may be administered, frequency of treatments, etc. These access credentials may be assigned to a user by a treatment provider, manufacturer or service provider, or established by a user when creating a user profile.

In some embodiments, a thermal contrast therapy system may be accessible by manufacturers, service providers, and/or other third parties. These parties may provide customer service and technical support, diagnostics, updates and upgrades, off-site programming and monitoring of devices, paid or subscription/lease-based services (e.g.,
5 for device rentals and/or treatment services), selections of thermal contrast therapy treatment programs accessible by users and/or treatment providers, and various other services. Where thermal contrast therapy is provided to users on a subscription basis, the thermal contrast therapy systems disclosed herein may be configured to control the functionality of a user's thermal contrast therapy device based, at least in part, on the
10 status of the user's subscription.

IV. Further Thermal Contrast Therapy Devices

Further thermal contrast therapy devices, as disclosed in U.S. Application Serial No. 14/340,904, filed July 25, 2014, will now be discussed. Referring to Fig. **16A**, a
15 schematic of an exemplary thermal contrast therapy device is shown. Those skilled in the art will appreciate that numerous other embodiments of thermal contrast therapy devices are within the spirit and scope of the present disclosure.

The thermal contrast therapy device shown in Fig. **16A** comprises a hot reservoir **1600** configured to store heat transfer fluid for heating periods, a cold reservoir **1602**
20 configured to store heat transfer fluid for cooling periods, a heating element **1604** configured to heat the fluid in the hot reservoir, and a cooling module **1606** configured to cool the fluid in the cold reservoir. A feed pump **1608** circulates heat transfer fluid from

the respective fluid reservoirs to one or more treatment cuffs **1610**. The heat transfer fluid flows through the treatment cuff and back to one of the fluid reservoirs.

Fluid is directed to the feed pump by one or more feed control valves **1612**. The flow rate of the fluid delivered to the one or more treatment cuffs is regulated by one or
5 more flow control valves/ flow regulators **1614**. Fluid exiting the treatment cuff is directed to a designed fluid reservoir by one or more return control valves **1616**.

As further depicted in Fig. **16A**, thermal contrast therapy devices may be equipped with a processor **1618** to control the operation of device. The processor may be configured to cause the thermal contrast therapy device to perform customized thermal
10 contrast therapy treatment sequences, by monitoring and/or controlling various aspects of the device, including the heating element, cooling module, pump(s), and valve(s).

In some embodiments, a thermal contrast therapy device may be equipped with one or more temperature sensors and/or flow meters. For example, as depicted in Fig. **16A**, temperature sensors **1620** and **1622** are positioned at the inflow and/or outflow lines
15 to and from the treatment cuff, respectively, and temperature sensors **1624** and **1626** are positioned at the cold reservoir and the hot reservoir, respectively. As additionally depicted in Fig. **16A**, flow meter **1628** is positioned at the inflow line to the treatment cuff. Processor **1618** may be configured to control the temperature of the heat transfer fluid, utilizing temperature measurements from any one or more temperature sensors,
20 and/or the flow rate of the heat transfer fluid, utilizing flow measurements from the flow meter. Such temperature and/or flow control may be configured to enable the device to provide customized thermal contrast therapy treatment sequences based, at least in part, on fluid temperature and/or flow rate in accordance with the present disclosure.

In some embodiments, the processor may be configured to interact with a thermal contrast therapy network **1500** as described in the present disclosure. For example, the processor may be configured to perform a treatment sequence derived, at least in part, from an input received from a thermal contrast therapy system. The treatment sequence may be prescribed by a treatment provider or selected by a user of the thermal contrast therapy device. The selected treatment may be chosen from a database of available treatment sequences on a thermal contrast therapy network, or manually input, via a user interface. The processor may be configured to automatically adjust one or more sequence parameters so as to perform a selected treatment sequence.

In some embodiments, a thermal contrast therapy device may be configured to allow a user to select or input customized sequence parameters, which may include, among other things, a customized time duration, pressure pulse frequency of the heat transfer fluid, cuff compression, temperature-change profile, fluid temperature, and/or flow rate corresponding to one or more of the periods. In some embodiments, the processor **1618** may be configured to receive an indication from one or more temperature sensors and/or flow meters and to effect a desired measure of heat transfer between the fluid and the patient, for example, by automatically adjusting the temperature and/or flow rate of the heat transfer fluid. In some embodiments, the processor **1618** may be configured to receive an indication of one or more physiological parameter values and to cause the thermal contrast therapy device to perform a customized thermal contrast therapy treatment sequence based, at least in part, on the one or more physiological parameter values.

Power to operate the thermal contrast therapy device may be provided via a low voltage power source, for example, a 12 volt DC power source. Such low voltage power source may be safely converted from AC power using a converter.

Treatment Cuffs

5 Thermal contrast therapy is generally administered via one or more treatment cuffs. The thermal contrast therapy devices disclosed herein may be configured to function with a plurality of different treatment cuffs. A treatment cuff generally comprises a bladder configured to hold heat transfer fluid, a pouch configured to receive the bladder, which may be constructed of fabric or other material comfortable to a
10 patient's skin, and an attachment mechanism configured to secure the cuff to a patient's body. The attachment mechanism may be configured to provide adjustable dimensions for the treatment cuff, such as provided by Velcro attachments. Treatment cuff bladders may be constructed of a network of interconnected cells or capillaries, with an inflow port configured to receive heat transfer fluid via an inflow tube, and outflow port
15 configured to return heat transfer fluid via an outflow tube. Various shapes and sizes of treatment cuffs may be provided in order to accommodate different patient sizes and/or different areas of the body, and/or in order to accommodate or integrate with various orthopedic braces, casts, and other devices.

In some embodiments, heat transfer fluid temperature and/or flow rate may be
20 measured at point where fluid enters and/or exits the treatment cuff, for example, at the inflow port and/or the outflow port of the bladder. These temperature and/or flow rate measurements may be utilized in thermodynamic calculations to provide customized thermal contrast therapy treatment sequences in accordance with the present disclosure.

Such treatment sequences may include effecting a particular measure of heat transfer (i.e., a particular quantity of heat and/or a particular rate of heat transfer). Temperature may also be measured at the fluid reservoirs, or along any point of the inflow tube and/or outflow tube.

5 In some embodiments, treatment cuffs may be configured with one or more sensors operably connected with the cuff. For example, temperature sensors **1620** and **1622**, and/or flow meter **1628**, may be operably connected with a treatment cuff. Such treatment cuff sensors may be configured to measure treatment conditions and transmit those measurements to a processor **1618** in a thermal contrast therapy device and/or to a
10 thermal contrast therapy system.

The skilled artisan will appreciate that for purposes of measuring the temperature change of the heat transfer fluid between the entrance and exit of the treatment cuff, temperature measurements obtained at or near the inflow port and/or the outflow port of the treatment cuff bladder may be more accurate than measurements obtained at more
15 distant locations. This may be of particular concern to the artisan when performing a treatment sequences requiring a high degree of precision, for example, a treatment sequence which effects a desired measure of heat transfer.

In some embodiments, a thermal contrast therapy device may be configured to receive an indication effective to identify a treatment cuff operably connected to the
20 thermal contrast therapy device and to cause the thermal contrast therapy device to perform a treatment sequence that is calibrated for the particular treatment cuff. By identifying the particular treatment cuff operably connected to the device, a substantially similar treatment sequence may be provided using any one of a plurality of different

treatment cuffs, notwithstanding differences in the dimensional or physical characteristics of the cuffs. This includes, for example, effecting a desired measure of heat transfer between the fluid and the patient, using any one of a plurality of different treatment cuffs. As depicted in Fig. **16A**, a treatment cuff may be electronically tagged or encoded with an identification number via a cuff ID chip **1630**. The cuff ID chip may be a microchip, RFID chip, or other suitable component capable of enabling a processor in a thermal contrast therapy device to identify which treatment cuff is attached to the device. Alternatively, a cuff identification number may be input manually, for example via a user interface associated with a thermal contrast therapy device or system.

Once a particular treatment cuff has been identified by a thermal contrast therapy device, the device may adjust its operating parameters to correspond to the characteristics of the particular treatment cuff operably connected to the device. In some embodiments, treatment cuffs having different dimensional or physical characteristics may require different fluid flow rates and/or fluid temperatures in order to deliver desired treatment conditions. For example, some treatment sequences in accordance with the present disclosure may require a different flow rates and/or temperature of the heat transfer fluid in order to effect a desired measure of heat transfer (i.e., a particular quantity of heat and/or a particular rate of heat transfer). Identification of the particular treatment cuff enables the thermal contrast therapy device to provide enhanced accuracy, precision, and control of the treatment sequence, for example, by varying the temperature and/or flow rate of the heat transfer fluid based, at least in part, on characteristics of the treatment cuff having been identified as operably connected to the device. Thus, customized thermal

contrast therapy treatment sequences may be provided with consistency across a plurality of different treatment cuffs.

Additionally, in some embodiments, a thermal contrast therapy device may be configured to perform a specified treatment sequence or program based on the particular treatment cuff operably connected to the device. For example, if the device identifies a treatment cuff associated with knee treatments, the device may perform a treatment sequence or program designed to treat knees; or, if the device identifies a cuff associated with the lumbar region, the device may perform a treatment sequence designed to treat the lumbar region. Such specified treatment sequences may be provided based on virtually any treatment cuff associated with virtually any area of the body or condition sought to be treated.

In some embodiments, a treatment cuff may be configured to provide compression during the thermal contrast therapy. Compression enhances the contact between the treatment cuff and the patient's tissue, thereby providing a more efficient heat transfer between the heat transfer fluid and the patient's tissue proximate to the treatment cuff. Such compression may be provided, for example, during at least part of any one of the treatment sequences disclosed herein. For example, compression may be provided during heating periods but not cooling periods, during cooling periods but not heating periods, only during transition periods, during both heating periods and cooling periods, during only a subset of periods, or during all of the periods.

In some embodiments, the level of compression may be varied. For example, the rate of heat transfer between the heat transfer fluid and the patient's tissue proximate to the treatment cuff may be varied by varying the level of compression effected by the

treatment cuff. The compression level may be automatically adjusted to effect a desired rate of heat transfer. In some embodiments, pulse compression may be provided by alternating between a plurality of chosen pressure levels, for example, to pulse massage the tissue.

5 Compression may be provided, for example, via a gas pumped into the treatment cuff from an air hose. Here, the treatment cuff may be configured with an air bladder configured to receive and hold air at a pressure effective to provide the desired level of compression. Air may be provided via any suitable air compressor known in the art.

Peristaltic Pumps

10 A thermal contrast therapy device may utilize any one or more pumps known in the art suitable to transfer fluid from the reservoirs to one or more treatment cuffs. In some embodiments, one or more low pressure peristaltic pumps or “tube pumps” may be used. A peristaltic pump is a positive displacement pump comprising a rotor with a plurality of roller (or, shoes, wipers, or lobes) attached to the external circumference of
15 the rotor. The rollers compresses flexible, non-reinforced, extruded tubing fitted around the rotor to pump fluid through the tubing. As the rotor turns, part of the tubing under compression is pinched, thus forcing the fluid to be pumped through the tube. Additionally, as the tube opens to its natural state after the rollers pass, fluid flow is induced into the pump. Peristaltic pumps are well known in the art, and any suitable
20 peristaltic pump may be used. For example, suitable peristaltic pumps include the MITYFLEX 908, Model No. 908-058, commercially available from Anko Products Inc., or the Watson Marlow Bredel Series, Model 313D, coupled with a Crouzet 12VDC gear motor, commercially available from Watson Marlow.

In some embodiments, customized thermal contrast therapy treatment sequences may be provided which are based, at least in part, on the flow rate of the feed pump **208**. The flow rate of a peristaltic pump is determined by several factors, including the tubing inner diameter (higher flow rate with larger inner diameter), the pump head outer diameter (higher flow rate with larger outer diameter), and the rate of rotation of the pump head (higher flow rate with higher rate of rotation).

In some embodiments, a thermal contrast therapy device may be configured to provide a pulsation in the fluid. Such pulsation may be provided during at least part of any one of the treatment sequences disclosed herein. As an example, fluid pumped via a peristaltic pump exhibits a pressure pulse caused by the occlusion and return of the tubing as the rollers pass over the tubing. The frequency of the pressure pulse correlates to the rotational rate of the rollers. Control of the feed pump may be configured to adjust the frequency of the pulsation. Additionally, increasing the number of rollers increases the frequency of the pressure pulse, whereas reducing the number of rollers increases the amplitude of the pressure pulse. In some embodiments, a recirculation line may be utilized in conjunction with a peristaltic pump to control flow independently from the parameters of the peristaltic pump, for example, via one or more flow control valves/flow regulators **1614**. The flow control valves may also be accompanied by a recirculation line to recirculate a portion of the fluid back to the feed pumps in conjunction with the flow control.

Without wishing to be bound by theory, it is believed that a therapeutic effect may be achieved by synchronizing the frequency of a pressure pulse, for example generated by a peristaltic pump, with patient's heart rate. Accordingly, in some embodiments, a

thermal contrast therapy device may be configured to receive an indication of a patient's heart rate, and to provide a pressure pulse having a frequency which is at least approximately synchronized with the patient's heart rate. Such synchronized pressure pulse may be provided during at least part of the treatment sequence. Synchronization
5 may be achieved by measuring the patient's heart rate, for example, with a heart rate monitor auxiliary device, and adjusting the rotational rate of the peristaltic pump rollers.

Without wishing to be bound by theory, it is believed that a therapeutic effect may also be achieved by providing a pressure pulse frequency selected to correspond to a desired heart rate. For example, it is believed that under certain conditions a patient's
10 heart rate may be manipulated by providing a certain pressure pulse frequency to one or more treatment cuffs. A pressure pulse frequency may effect a change in the patient's heart rate, in which the heart rate shifts towards and/or substantially synchronizes with the frequency of the pressure pulse. The range within which a patient's heart rate may be manipulated depends on physiological limitations of the patient, as well as the degree
15 with which the particular patient responds to the pressure pulse. In this way, a desired therapeutic effect may include inducing a desired heart rate during thermal contrast therapy.

In addition to peristaltic pumps, other means for transferring fluid from the reservoir to the one or more treatment cuffs, and/or other means for generating pressure
20 pulses are within the scope of the present disclosure.

Temperature Control

A thermal contrast therapy device may be equipped with a hot reservoir **1600** and a cold reservoir **1602**. The hot reservoir is configured to store a volume of hot heat

transfer fluid for use primarily during heating periods, and the cold reservoir is configured to store a volume of cold heat transfer fluid for use primarily during cooling periods. Hot heat transfer fluid is pumped from the hot reservoir to a treatment cuff during heating periods, and cold heat transfer fluid is pumped from the cold reservoir to a treatment cuff during cooling periods.

Hot heat transfer fluid may be heated via a heating element **1604** to a temperature sufficient to provide fluid of a desired temperature for heating periods. Heating may be accomplished by any means known in the art, for example using a cartridge heater mounted within the hot reservoir. Hot heat transfer fluid may be heated to a range of temperatures based on the desired temperature of the heat transfer fluid to be supplied to the treatment cuff.

Similarly, cold heat transfer fluid may be cooled via a cooling module **1606** to a temperature sufficient to provide fluid of a desired temperature for cooling periods. Cooling may be accomplished by any means known in the art, for example, using compressor/refrigerant systems, heat exchanger, or thermoelectric cooling technology such as a Peltier cooler. Cold heat transfer fluid may be cooled to a range of temperatures based on the desired temperature of the heat transfer fluid to be supplied to the treatment cuff.

In some embodiments, a thermal contrast therapy device may be equipped with one or more temperature sensors. For example, as depicted in Fig. **16A**, temperature sensors **1620** and **1622** are positioned at the inflow and/or outflow lines to and from the treatment cuff, and temperature sensors **1624** and **1626** are positioned at the cold reservoir and the hot reservoir, respectively. As depicted in Fig. **16B**, one or more

temperature sensors **1638** may be positioned at various locations on or within the treatment cuff **1610**. Temperature sensor(s) **1638** may be configured to measure the temperature of the patient's tissue proximate to the treatment cuff. Additionally and/or in the alternative, temperature sensor(s) **1638** may be configured to measure the temperature of heat transfer fluid at a given point within the treatment cuff.

Processor **1618** may be configured to control the temperature of the heat transfer fluid, utilizing temperature measurements from any one or more temperature sensors. For example, temperature sensors **1620** and/or **1622** may be used to control the temperature of the heat transfer fluid based on the temperature of the fluid entering or exiting the treatment cuff, respectively. Temperature sensor(s) **1638** may be configured to control the temperature of the heat transfer fluid based on the temperature of the patient's tissue proximate to the treatment cuff and/or the temperature of the fluid at a given point within the treatment cuff. Such temperature control may be configured to enable the device to provide customized thermal contrast therapy treatment sequences based, at least in part, on fluid temperature in accordance with the present disclosure.

Customized thermal contrast therapy treatment sequence may be provided, for example, by varying the temperature of the heat transfer fluid during heating periods and/or cooling periods, and providing fluid of a desired temperature to a treatment cuff. In some embodiments, the temperature of the heat transfer fluid in the hot reservoir and/or the cold reservoir may be increased or decreased during the course of a thermal contrast therapy treatment so as to provide heat transfer fluid having a desired temperature during the various heating periods and/or cooling periods. In other embodiments, the respective temperatures of the hot heat transfer fluid and cold heat

transfer fluid may be maintained relatively constant, and the two fluids may be used in combination to temper one another in various proportions. Such tempering allows a thermal contrast therapy device to provide a range of desired fluid temperatures depending on the degree of tempering, without having to repeatedly heat or cool a reservoir of heat transfer fluid to the desired temperature. Thus, during a heating period, hot heat transfer fluid may be tempered with a measure of cold heat transfer fluid via control valve(s) **1612** so as to attain a desired fluid temperature at the treatment cuff. Similarly, during a cooling period, cold heat transfer fluid may be tempered via control valve(s) **1612** with an amount of hot heat transfer fluid.

In some embodiments, as depicted in Fig. **16B**, a thermal contrast therapy device may be equipped with a neutral reservoir **1632** configured to store neutral-temperature heat transfer fluid. The neutral-temperature heat transfer fluid may be used to provide neutral temperature periods, or to temper hot heat transfer fluid and/or cold heat transfer fluid during respective heating periods and/or cooling periods. Heat transfer fluid in the neutral reservoir may be maintained at a range of appropriate neutral temperatures. Additionally and/or in the alternative, hot heat transfer fluid may be mixed with cold heat transfer fluid to provide a desired temperature for the neutral-temperature fluid.

Heat transfer fluid exiting a treatment cuff may be returned to any one or more of the reservoirs, as depicted in Fig. **16B**, via one or more fluid return control valves **1616**.

In some embodiments, fluid returning from the treatment cuff may be directed to a given reservoir based on the temperature of the fluid, for example, so as to optimize the heating and cooling efficiency of the thermal contrast therapy device. Alternatively, fluid returning from the treatment cuff may be routed to a neutral reservoir **1632**, for example,

so that mixing of fluids from heating periods and cooling periods may provide a fluid temperature approximately close to the desired temperature for neutral treatments. Additionally, neutral-temperature heat transfer fluid may be adjusted by tempering with hot or cold heat transfer fluid, as appropriate. For example, as depicted in Fig. **16B**, the temperature of the fluid in the neutral reservoir may be adjusted with fluid from the hot reservoir and/or the cold reservoir using a circulation pump **1634** and one or more circulation valves **1636** configured to transfer fluid from the hot reservoir and/or the cold reservoir to the neutral reservoir. Alternatively, neutral-temperature heat transfer fluid may be tempered with hot or cold heat transfer fluid via one or more feed control valves **1612**.

Heat transfer fluids may comprise any fluid or combination of fluids known in the art for effecting heat transfer. Exemplary fluids include water, propylene glycol, saline, or combinations thereof.

Flow Control

In some embodiments, a thermal contrast therapy device may be equipped with one or more flow meters. For example, as depicted in Fig. **16A**, flow meter **1628** may be positioned at the inflow line to the treatment cuff. Processor **1618** may be configured to control the flow rate of the heat transfer fluid, utilizing flow measurements from any one or more flow meters. The flow rate of the heat transfer fluid may be modified, for example, by varying the speed of one or more feed pumps **1608** and/or by varying the positioning of one or more flow control valves/ flow regulators **1614**. Such flow control may be configured to enable the device to provide customized thermal contrast therapy treatment sequences based, at least in part, on fluid flow rate in accordance with the

present disclosure. Additionally, in some embodiments customized thermal contrast therapy treatment sequences may be based, at least in part, on both flow rate and temperature of the heat transfer fluid.

The driving force for heat transfer during thermal contrast therapy is the
5 difference in temperature between the patient's body and the heat transfer fluid. As heat transfer occurs between the heat transfer fluid and the area of the patient's body proximate to the treatment cuff, the temperature of the heat transfer fluid within the treatment cuff will shift towards the temperature of the patient's body. The magnitude of this change in temperature is inversely proportional to the flow rate of the heat transfer
10 fluid. A relatively high flow rate will yield a relatively low change in temperature between the inflow and outflow ports of the treatment cuff bladder, and thus a relatively high driving force for heat transfer. Conversely, a relatively low flow rate will yield a relatively high change in temperature between the inflow and outflow ports of the treatment cuff bladder, and thus a relatively low driving force for heat transfer. Thus, the
15 rate of heat transfer effected by the heat transfer fluid depends on flow rate, and the rate of heat transfer effected during heating periods and/or cooling periods may be controlled by varying the flow rate of the heat transfer fluid. Accordingly, at a constant fluid temperature entering the treatment cuff, the rate of heat transfer may be increased by increasing the flow rate of the heat transfer fluid, to the point where the change in
20 temperature of the heat transfer fluid between the inflow port and the outflow port of the treatment cuff approaches zero. Conversely, the rate of heat transfer may be decreased by decreasing the flow rate of the heat transfer fluid, to the point where the difference in temperature between the patient's body and the heat transfer fluid approached zero.

Thus, customized thermal contrast therapy treatment sequences may be provided in accordance with the present disclosure which are based, at least in part, on providing a specified flow rate of the heat transfer fluid. For example, a customized thermal contrast therapy treatment sequence which calls for effecting a desired measure of heat transfer
5 may be provided by varying the flow rate of the heat transfer fluid. In some embodiments, a desired rate of heat transfer during heating periods and/or cooling periods may be effected solely by varying the flow rate of the respective hot heat transfer fluid and/or cold heat transfer fluid. Alternatively, the desired measure of heat transfer may be attained by varying both the flow rate and the temperature of the heat transfer
10 fluid. For example, in some embodiments, the temperature of the heat transfer fluid may be varied to attain a close approximation of the desired rate of heat transfer, and then the flow rate of the heat transfer fluid may be varied to provide fine-tuning to more precisely control the rate of heat transfer.

In some situations, thermal contrast therapy may be provided under circumstances
15 where a patient may be particularly sensitive to hot and/or cold heat transfer fluid temperatures. This may be the case, for example, with patients suffering from frostbite or hypothermia, elderly patients, patients with diabetes and related physiological complications (e.g., gangrene), patients with lymphedema or other disorders associated with vascular or lymphatic insufficiency (e.g., Chronic Venous Insufficiency, venous
20 stasis ulcers, post-mastectomy edema or chronic lymphedema), patients with peripheral vascular disease or other circulatory deficiency syndrome (e.g., arteriosclerosis, deep vein thrombosis, Buerger's disease, or thromboangiitis obliterans). Such sensitive patients may be unable to tolerate certain fluid temperature levels without severe discomfort or

injury to tissue. In these instances, providing heat transfer fluid of a given temperature may not be a viable means for effecting a desired rate of heat transfer because the fluid temperature may exceed the patient's pain tolerance and/or cause injury to tissue. Instead, the rate of heat transfer may be increased by increasing the flow rate of the heat transfer fluid, while maintaining a more moderate fluid temperature which is within the patient's pain tolerance and/or which will not cause injury to tissue. Thus, at a given fluid temperature which is tolerable to a sensitive patient, an enhanced rate of heat transfer may be provided by increasing the flow rate of the heat transfer fluid. This enables the induction of enhanced cycles of vasoconstriction and vasodilation, enhanced improvements in blood flow, and other enhanced therapeutic effects, while maintaining a moderate fluid temperature that is suitable for sensitive patients.

During a thermal contrast therapy treatment sequence, the temperature gradient between the heat transfer fluid entering the treatment cuff bladder and the patient's tissue proximate to the treatment cuff may decrease as a result of the ensuing heat transfer. Thus, at a constant flow rate and temperature of the heat transfer fluid entering the treatment cuff bladder, the rate of heat transfer may decline over the course of a heating period or cooling period due to such decreasing temperature gradient. In some embodiments, a customized thermal contrast therapy treatment sequence may be provided in which the flow rate of the heat transfer fluid is adjusted so as to maintain a desired rate of heat transfer notwithstanding changes in the temperature of the tissue proximate to the treatment cuff. Such changes in flow rate may be effected, for example, over the course of a given heating period and/or cooling period, and/or from one period to the next over the course of the treatment sequence. For example, as the tissue proximate

to the treatment cuff changes temperature in response to heat transfer, the flow rate of the heat transfer fluid may be increased so as to offset the decreasing rate of heat transfer that would otherwise result as tissue temperature proximate to the treatment cuff shifts towards the temperature of the heat transfer fluid entering the treatment cuff.

5 Additionally, temperature changes to a patient's tissue effected during one heating period or cooling period may impact the rate of heat transfer in a subsequent period. For example, alternating heating periods and cooling periods may provide a greater temperature gradient between the patient's tissue and the heat transfer fluid in subsequent alternating periods. Thus, the driving force for heat transfer in a subsequent period may
10 be enhanced, at least initially, due to the change in tissue temperature effected by the preceding period. Such enhanced temperature gradient may be desirable or undesirable, depending on the desired effects of the particular thermal contrast therapy treatment sequence. In some embodiments, the flow rate of the heat transfer fluid may be modified based, at least in part, on the temperature gradient between the patient's tissue and the
15 heat transfer fluid. This may include effecting a change in the flow rate of the heat transfer fluid in consideration of an enhanced temperature gradient effected by one or more preceding periods. In some embodiments, a sequence of alternating cooling periods and heating periods may be configured to provide an enhanced temperature gradient in one or more subsequent periods within the sequence. In some embodiments, a neutral
20 period may be provided between one or more of the alternating cooling periods and heating periods so as to provide a subdued temperature gradient in one or more subsequent periods within the sequence, for example, the period following the neutral period. In some embodiments, the flow rate of the heat transfer fluid may be varied to

effect a desired temperature gradient during at least a portion of a heating period and/or cooling period.

In some embodiments, the artisan may derive advantages from utilizing changes in flow rate, in addition to or as an alternative to changes in fluid temperature, to effect a
5 desired rate of heat transfer. In some embodiments, the heating and cooling loads on a thermal contrast therapy device may be reduced by using flow rate to effect a desired rate of heat transfer. This may yield more efficient, cost-effective devices, as well as enhanced ability to provide customized treatment sequences in accordance with the present disclosure. Additionally, the rate of heat transfer may, in some embodiments, be
10 more effectively controlled via flow rate of the heat transfer fluid than via the temperature of the heat transfer fluid. This may be the case, for example, regarding embodiments having configurations such that the rate of heat transfer may be changed more rapidly and/or more precisely via a change in flow rate than via a change in temperature. In certain embodiments where flow rate control facilitates more precise
15 and/or more rapid control over the rate of heat transfer, customized thermal contrast therapy treatment sequences may be provided based, at least in part, on flow rate control. Some such sequences may not be feasibly attained in certain embodiments except via flow rate control. For example, a customized treatment sequences may include rapidly transitioning between heating periods and cooling periods, rapidly changing the rate of
20 heat transfer, and/or more precisely controlling the rate of heat transfer. These rapid changes may be feasible via flow rate control but not via temperature control in certain embodiments.

Additionally, in some embodiments, the artisan may desire to minimize or eliminate the transition times between heating periods and cooling periods. To accomplish this, treatment cuffs may be provided which are equipped with a bladder having a relatively small fluid capacity so as to enable heat transfer fluid to be more rapidly flushed from the bladder. A small fluid capacity may enhance the effect of flow rate on the rate of heat transfer, and consequently the range of control over the rate of heat transfer via flow rate. Accordingly, in some such embodiments, the rate of heat transfer may be more rapidly changed via a change in the flow rate of the heat transfer fluid than via a change in the temperature of the heat transfer fluid.

Calibration

In some embodiments, a thermal contrast therapy device may be calibrated based on variations in the device and/or the preferences of one or more users of the device. A given treatment sequence may yield different effects due to differences between various devices (e.g., different manufacturers or model numbers), variations between devices (e.g., manufacturing differences between production runs), or set-up configurations (e.g., the length of the inflow and/or outflow lines between the device and treatment cuff). These differences may be compensated for by calibrating treatment sequences for a particular device. A thermal contrast therapy device may be calibrated, for example, by measuring fluid temperature and/or flow rate, etc. with calibration equipment and adjusting calibration settings for the device. Calibration allows for customized thermal contrast therapy treatment sequences to be provided with consistency across a plurality of devices and/or for a plurality of users.

The artisan will appreciate that a given treatment sequence may yield different effects on different patients due to differences between patients, such as physiological attributes or personal preference. These differences may similarly be compensated for by providing a calibration adjustment corresponding to a particular patient. For example, a treatment sequence may be calibrated for a particular patient by providing a calibration adjustment to any one or more treatment sequence parameters. Providing a calibration adjustment may include, for example, shifting a set-point corresponding to a sequence parameter by a factor. As examples, the set-point for all heat transfer fluid temperatures in a treatment sequence may be shifted up or down; the set-point for all desired measures of heat transfer (i.e., rate of heat transfer or quantity of heat transfer) in a treatment sequence may be shifted up or down; or the number of periods in a treatment sequences and/or the duration of a treatment sequences may be shifted up or down. The calibration adjustment and/or factor may be based on a percentage, an absolute value, a formula, or the like. The calibration adjustment and/or factor may be derived empirically for an individual patient, and/or from data in a database associated with a thermal contrast therapy system, for example, data that provides a correlation to treatment sequences associated with other users. Such calibration adjustments may be applied to all treatment sequences, a subset of treatment sequences, or to a particular device, etc., and/or any of the foregoing as associated with a particular user.

V. Further Methods for Providing Thermal Contrast Therapy

Methods for providing thermal contrast therapy, as disclosed in U.S. Application Serial No. 14/340,904, filed July 25, 2014, will now be further discussed. In accordance

with the present disclosure, various methods are described herein for providing thermal contrast therapy treatments using the systems and devices described herein. The methods disclosed herein include computer-implemented methods of providing thermal contrast therapy.

5 Thermal contrast therapy comprises circulating heat transfer fluid from a thermal contrast therapy device through a treatment cuff, the treatment cuff having been applied to a patient, while providing a sequence comprising a plurality of alternating cooling periods and heating periods. In some embodiments, a treatment sequence may include a plurality of transition periods, each occurring between alternating cooling periods and
10 heating periods. During such transition periods, the rate of heat transfer between the patient's tissue proximate to the treatment cuff and the heat transfer fluid is transitioned from a first heat transfer rate which corresponds to the period preceding the transition period to a second heat transfer rate which corresponds to the period following the transition period. Changes to the rate of heat transfer may be effected by varying the
15 flow rate and/or temperature of the heat transfer fluid. The flow rate and/or fluid temperature may be changed according to any desirable transition curve, and may also include providing a period of neutral-temperature heat transfer fluid and/or neutral rate of heat transfer.

In some embodiments, a customized thermal contrast therapy treatment sequence
20 is provided. A customized treatment sequence may correspond to a treatment program having been prescribed to a user, or selected by a user of a thermal contrast therapy device. The customized treatment sequence may be based upon, for example, conditions particular to the patient intended to receive treatment, a physiological parameter value

exhibited by the patient, the particular area of the body sought to be treated, the particular symptom or condition sought to be treated, the particular desired therapeutic result, and/or other considerations. In some embodiments, a customized treatment sequence may be uploaded or stored in a database accessible by a thermal contrast therapy system or device. For example, a treatment provider or a user may select a treatment from a menu of one or more treatment options in a database associated with a thermal contrast therapy system configured to provide customized thermal contrast therapy treatment programs. Alternatively, a customized treatment sequence may be manually input by the treatment provider or user.

It is believed that a patient's response to thermal contrast therapy depends on a number of variables related to the conditions of the treatment sequence, including the rate of heat transfer between the heat transfer fluid and the patient's tissue proximate to the treatment cuff, the temperature of the heating periods and/or cooling periods, the pressure applied during treatment; the quantity and sequence of the heating periods and/or cooling periods, the various cycle times for each heating period and/or cooling period; the duration and rate of change of transitions between heating periods and/or cooling periods, including whether a neutral temperature period is provided between heating periods and/or cooling periods, the duration of the thermal contrast therapy treatment sequence, the frequency with which thermal contrast therapy treatment is to be provided, the dimensions and configuration of the treatment cuffs, the pulsation frequency of the heat transfer fluid, and other variables. Any one or more of these variables may, in accordance with the present disclosure, form the basis of a customized thermal contrast therapy treatment sequence, for example, to provide a treatment sequence or series of

treatments optimized to enhance one or more therapeutic effects of thermal contrast therapy.

A patient's response to thermal contrast therapy may additionally depend on certain characteristics particular to the patient, including, for example, the patient's age, gender, body mass, fat content, physical fitness, energy level, and general state of health. Physiological characteristics as well as thermodynamic properties may also impact a patient's response to thermal contrast therapy. This includes a patient's ability to generate body heat, ability to repair the loss of heat, and to support the loss of heat without negatively impacting the body's vital processes, as well as the condition of the patient's nervous system at the time of treatment, and the extent to which the patient is accustomed to thermal contrast therapy.

Other variables which may affect a patient's response to thermal contrast therapy include factors related to any particular chronic or acute condition or ailment affecting the patient, including a condition or ailment sought to be treated with thermal contrast therapy. Thermal contrast therapy treatment sequences, as well as frequencies between treatments, may be provided which depend on these and other characteristics particular to the patient intended to be treated. Thermal contrast therapy procedures may be formulated or provided which depend on the particular body part(s) sought to be treated, particular conditions or symptoms sought to be treated, and/or the desired therapeutic result sought to be attained from the treatment. Exemplary treatments, procedures, and sequences are described in detail herein.

Heat Transfer

As discussed above, thermal contrast therapy treatment may be quantified based on measures of heat transfer, for example, the rate of heat transfer and/or the quantity of heat transfer effected during the respective heating periods and cooling periods of a treatment sequence. Without wishing to be bound by theory, it is believed that various therapeutic effects of thermal contrast therapy may be enhanced by providing customized treatments which effect a particular measure of heat transfer (i.e., a particular rate of heat transfer and/or quantity of heat transfer). In some embodiments, a customized thermal contrast therapy treatment sequence includes effecting a desired measure of heat transfer between the fluid and the patient's tissue proximate to the treatment cuff during one or more of the cooling periods and heating periods. The desired measure of heat transfer may be effected by automatically adjusting the flow rate and/or temperature of the heat transfer fluid.

The rate of heat transfer is expressed as equation (3) above. Those skilled in the art will appreciate that q represents an optimum heat transfer rate, and that in practice, while the vast majority of heat transfer during a during thermal contrast therapy treatment will be between the heat transfer fluid and the patient's tissue proximate to the treatment cuff, a portion of the heat transferred will be attributable to other considerations. For example, a portion of the heat will transfer to the cuff material and/or the surrounding atmosphere, etc. These considerations may be quantified empirically and/or by principles of thermodynamics known in the art, and the mean heat transfer rate during a given heating period or cooling period within a thermal contrast therapy treatment sequence

may thus be expressed as equation (4) above, where k is an efficiency constant which represents the proportion of heat transferred to the tissue proximate to the treatment cuff.

The total heat transferred during a given heating period or cooling period may be obtained from equation (5) above. Likewise, the heat transferred from the various heating periods and/or cooling periods may be summed to provide the total heat transferred during n periods, where n represents all or a subset of the periods comprising a thermal contrast therapy treatment sequence, as shown in equation (6) above.

In some embodiments, it may be advantageous to sum the heating periods and cooling periods separately, so as to ascertain the total heat transferred to the patient during heating periods and the total heat transferred from the patient during cooling periods.

In some embodiments it may be advantageous to model the heating and/or cooling of a patient's tissue during thermal contrast therapy. Such models may be used to evaluate treatment outcomes relative to model predictions, to perform research on various thermal contrast therapy treatment sequences and parameters thereof, and/or to suggest and evaluate new treatment strategies, etc.

The general factors to consider when quantifying heat transfer during thermal contrast therapy include heat transfer effected during the treatment, heat production due to metabolic processes, heat transfer due to blood perfusion, geometry of the thermal contrast therapy treatment area (e.g., as defined by the one or more treatment cuffs), the thermophysical properties of various types of body tissue, and thermoregulatory mechanisms.

Across a control volume, the principle of conservation of energy provides that the balance of thermal energy can be stated as per equation (7) above.

Heat is transferred by conduction, convection, evaporation, and radiation. The two primary mechanisms for heat transfer inside tissue during thermal contrast therapy are convection and conduction. Under most conditions for thermal contrast therapy, heat transfer by evaporation (or perspiration) and radiation, as well as the work, W , are negligible. The temperature gradient inside the tissue drives heat transfer through conduction, and blood perfusion drives heat transfer through convection.

According to Fourier's law, the conductive heat transfer between two layers is found by the relation in equation (8) above.

Those skilled in the art will appreciate that several approaches exist for modeling heat transfer from blood perfusion and that any one or more of such models may be used in accordance with the present disclosure. Approaches for modeling heat transfer from blood perfusion include: the Pennes bioheat model; the Wulff continuum model; the Klinger continuum model; the Chen-Holmes (CH) continuum model; the Weinbaum, Jiji and Lemons (WJL) bioheat model; the Simplified Weinbaum-Jiji model; the Zolfaghari and Maerefat simplified thermoregulatory bioheat model. These models generally employ a certain level of approximation, particularly because blood circulates in a variety of vessels ranging in lumen diameter from the approximately 2.5 cm, in the case of the aorta, to the approximately 6-10 μm , in the case of capillaries. More precise models based on computer algorithms or empirical research may also be utilized in accordance with the present disclosure.

These aforementioned blood perfusion models generally rely on the basis of one of two main approaches: the continuum approach and the discrete vessel (vascular) approach. In the continuum approach, the thermal impact of all blood vessels are modeled with a single global parameter; and in the vascular approach, the impact of each vessel is modeled individually. The Pennes bioheat model is one of the most widely used approaches for modeling heat transfer from blood perfusion. The Pennes bioheat model assumes that the rate of heat transferred by the circulating blood at the capillary level equals the difference between the venous and arterial temperatures multiplied by the flow rate, as shown in equation (9) above.

The heat energy stored in the control volume can be expressed as shown in equation (10) above.

The terms of equations (6), (7), and (8) may be substituted into equation (5) and integrated over the entire volume and surface area, to obtain the Pennes bioheat equation, shown in equation (11) above.

The Pennes bioheat equation can thus be used to analyze heat transfer in various body tissues under various thermal contrast therapy treatment sequences, including the customized treatment sequences disclosed herein.

The Pennes bioheat model assumes that the blood perfusion effect is homogenous and isotropic and that thermal equilibration occurs in the microcirculatory capillary bed due to the low blood flow velocity at the capillary level. Thus, the Pennes bioheat model assumes that blood enters capillaries at the temperature of arterial blood, T_a , where convective heat transfer occurs to bring the temperature to that of the surrounding tissue,

such that the temperature at which the blood enters the venous circulation is that of the local tissue.

Pennes performed a series of studies to validate this model, which show reasonable agreement between the model and experimental data. Those skilled in the art will appreciate that while the Pennes bioheat model is often adequate, there are certain shortcomings in this model due to its inherent simplicity, and that other models, for example, those which utilize the discrete vessel (vascular) approach, may be more suitable in situations where enhanced precision is desired. For example, the Pennes bioheat model does not account for countercurrent heat transfer between adjacent vessels, or directionality effects due to the presence of larger blood vessels, or heat exchange with larger vessels in which complete thermal equilibrium may not be assumed. The CH continuum model and the WJL bioheat model, for example, address these issues. Accordingly, such other models may be used to analyze heat transfer as an alternative or in addition to the Pennes bioheat model.

Conditions particular to the patient intended to receive treatment and/or the particular area of the body sought to be treated, among other factors, may cause a given thermal contrast therapy treatment sequence to effect a different measure of heat transfer (i.e., a different rate of heat transfer and/or a different quantity of heat transfer). For example, various thermodynamic properties and other factors affecting heat transfer may be attributable to a patient's age, gender, body mass, body fat percentage, body mass index, metabolic rate, neural sensitivity, physical fitness, energy level, and general state of health. This includes the thermal conductivity, density, and heat capacity of a patient's body tissues and fluids, the surface thickness of various layers (e.g., dermis, epidermis,

fat, muscle) of a patient's body tissue, factors related to a patient's blood perfusion, including blood pressure, blood flow rate, venous structure (e.g., capillary density, lumen diameter distribution, etc.), and a patient's metabolic rate. Likewise, given the various factors which may impact the measure of heat transfer effected during a given thermal contrast therapy treatment sequence, as between two patients and/or body parts sought to be treated, a different treatment may be required for each in order to effect the same measure of heat transfer during the respective treatments. Furthermore, different thermal contrast therapy treatment sequences may be required for the same patient as, when, and if factors change which may impact the measure of heat transfer effected during a given treatment sequence.

Customized thermal contrast therapy treatment sequences may be provided in accordance with the present disclosure which comprise effecting a desired measure of heat transfer during the treatment sequence and/or the one or more of the heating periods and/or cooling periods thereof. The desired measure of heat transfer (i.e., rate of heat transfer and/or quantity of heat transfer) may depend on any one or more of the factors affecting thermal contrast therapy treatments such as the factors disclosed herein, including: conditions particular to the patient intended to receive treatment, the particular area of the body sought to be treated, the particular symptom or condition sought to be treated, the particular desired therapeutic result, and/or other considerations.

Relationship Between Flow Rate and Heat Transfer

The rate of heat transfer is directly proportional to flow rate. Increasing flow rate increases the rate of heat transfer and decreasing flow rate decreases the rate of heat transfer.

The following example illustrates the relationship between the flow rate of heat transfer fluid and the rate of heat transfer effected by the heat transfer fluid. A cooling period was provided, via a thermal contrast therapy device having a treatment cuff attached to a patient's lower leg. The temperature of the heat transfer fluid (water) entering the treatment cuff was maintained at about 40 °F. At a flow rate of about 120 mL per minute, the heat transfer fluid exiting the treatment cuff was about 58 °F. At a flow rate of about 240 mL per minute, the heat transfer fluid exiting the treatment cuff was about 53 °F. Thus, using equation (3), the rate of heat transfer to the fluid was about 4.7 BTU per minute when the flow rate was 120 mL per minute ($120 \text{ mL/min} \times 1 \text{ sq. ft}/28,316.8 \text{ mL} \times 62.24 \text{ lb/sq. ft} \times 1 \text{ BTU/lb-}^\circ\text{F} \times 18^\circ\text{F}$), and about 6.9 BTU per minute when the flow rate was 240 mL per minute ($240 \text{ mL/min} \times 1 \text{ sq. ft}/28,316.8 \text{ mL} \times 62.24 \text{ lb/sq. ft} \times 1 \text{ BTU/lb-}^\circ\text{F} \times 13^\circ\text{F}$).

Dynamically Controlled Treatment Sequences

A customized thermal contrast therapy treatment sequence may include dynamically controlling the sequence to effect a desired treatment and/or to attain a desired therapeutic effect. Any one or more variables of the treatment sequence may be dynamically controlled in order to provide a customized treatment sequence in accordance with the present disclosure. In some embodiments, automatic adjustments to a thermal contrast therapy treatment sequence may include: changing a setting for the temperature and/or flow rate of the heat transfer fluid; changing the duration of one or more of the cooling periods, heating periods, and/or transition periods; changing the number of cooling periods, heating periods, and/or transition periods; changing the rate of

change of the temperature and/or flow rate of the heat transfer fluid; and/or prescribing a sequence for one or more future thermal contrast therapy treatments.

In some embodiments, the treatment sequence may be dynamically controlled to provide a desired measure of heat transfer (i.e., a rate of heat transfer and/or quantity of heat transfer) during one or more of the heating periods and/or cooling periods. The measure of heat transfer during one or more of the heating periods and/or cooling periods may be controlled, for example, using equations (4) and/or (5) and by adjusting the flow rate and/or temperature of the heat transfer fluid, and/or the duration of the one or more periods. The rate of heat transfer, q_{TCT} , may be controlled for a given period, for example, using equation (4) and then adjusting the temperature gradient between the heat transfer fluid and the patient's tissue proximate to the treatment cuff, ΔT . The quantity of heat transfer, Q_{TCT} , may be controlled, for example, using equation (5) and then adjusting the rate of heat transfer, q_{TCT} and/or the duration of the period, Δt . The temperature gradient may be controlled by adjusting the temperature and/or the flow rate of the heat transfer fluid. Dynamically controlled thermal contrast therapy treatment sequences may be provided which utilize any one or more equations for modeling blood perfusion (e.g., the Pennes bioheat model), and/or which take into account other factors which may impact heat transfer during thermal contrast therapy. Such factors include heat production due to metabolic processes, geometry of the thermal contrast therapy treatment area (e.g., as defined by the treatment cuffs), the thermophysical properties of various types of body tissue, and/or thermoregulatory mechanisms.

Referring to Fig. 12A, a flow chart illustrative of an exemplary thermal contrast therapy treatment process for providing a desired measure of heat transfer is shown. The

thermal contrast therapy device initiates the thermal contrast therapy treatment sequence. The sequence may be any sequence in accordance with the present disclosure. For each period of the treatment sequence, heat transfer fluid is circulated to the treatment cuff, the temperature of the heat transfer fluid being approximately that which is required to provide the desired rate of heat transfer. Throughout the course of the treatment period, the device ascertains the rate of heat transfer and determines whether the actual rate of heat transfer matches the target rate of heat transfer. The target may be a specific value or a range. If the rate of heat transfer does not match the target rate, then the rate of heat transfer is adjusted. The rate of heat transfer may be adjusted by changing the temperature and/or flow rate of the heat transfer fluid in accordance with the present disclosure.

Throughout the course of each treatment period within the sequence, the thermal contrast therapy device ascertains the quantity of heat transfer effected and determines whether the actual quantity of heat transfer is less than or equal to the target quantity. In some embodiments, the period is concluded when the quantity of heat transfer reaches or exceeds the target quantity. Alternatively, the period may continue for a specified duration of time and conclude when the specified duration has elapsed.

When the treatment period has concluded, the thermal contrast therapy device ascertains whether there are additional periods remaining in the sequence. If there are additional periods remaining, the device proceeds through such remaining periods until all of the periods have been administered. The treatment sequence concludes when all of the periods have been administered, at which point data associated with the treatment

sequence maybe transmitted to a thermal contrast therapy system for use in accordance with the present disclosure.

Referring to Fig. **12B**, a flow chart illustrative of an exemplary thermal contrast therapy treatment process for providing a desired measure of heat transfer, utilizing flow rate to modify the rate of heat transfer, is shown. The sequence depicted in Fig. **12B** proceeds similar to the sequence depicted in Fig. **12A**, except that the rate of heat transfer is controlled entirely by the flow rate of the heat transfer fluid.

In some embodiments, a thermal contrast therapy treatment sequence may include rapidly alternating cooling periods and heating periods. Such a sequence may be effective to induce cycles of vasoconstriction and vasodilation. Cycles of vasoconstriction and vasodilation may be provided in a manner effective to cause an increase in blood circulation and/or blood oxygen content in a patient's tissue proximate to the treatment cuff during thermal contrast therapy.

In some embodiments, a customized thermal contrast therapy treatment sequence may be dynamically controlled to optimize one or more physiological parameter values. For example, one or more variables of a treatment sequence may be automatically adjusted when the patient exhibits a physiological parameter that corresponds to a predefined value. The physiological parameter values may be based on the patient's vital signs. A predefined value may include, for example, an increase from a previous value, a decrease from a previous value, a previous value, and/or a target value.

Physiological parameters which may be monitored and utilized to dynamically control a thermal contrast therapy treatment sequence include: body temperature (e.g. core temperature, local temperature, etc.), heart rate, blood pressure, blood flow, blood

oxygen level, or other vital signs. Such vital signs may be monitored using any number of devices which are well known in the art. For example, a thermal contrast therapy treatment sequences may be automatically adjusted so as to optimize the magnitude of an increase in blood circulation and/or blood oxygen content induced by cycles of vasoconstriction and vasodilation.

In some embodiments, a treatment sequence may be based on a physiological parameter value exhibited by a patient during treatment. For example, based on a patient's vital signs, adjustments may be made during treatment to any one or more of: the fluid temperature provided during heating periods and/or cooling periods, the duration and/or number of heating periods and/or cooling periods, the quantity of heat transfer and/or rate of heat transfer during one or more of the heating periods and/or cooling periods. A treatment sequence may also be based on a physiological parameter value exhibited by a patient prior to a treatment or during a previous treatment.

Referring to Fig. **13A and 13B**, a flow chart illustrative of an exemplary customized thermal contrast therapy treatment process, dynamically controlled to optimize a physiological parameter value is shown. The treatment may be configured to optimize a physiological parameter value during any one or more of the periods, and/or for subsequent periods within the sequence, and/or for subsequent treatments within a treatment program. During a treatment period, the thermal contrast therapy device ascertains whether the sequence calls for optimizing a physiological parameter value during the period. If so, the device ascertains the physiological parameter value, and if the value is less than or greater than a predefined target value, one or more measures of heat transfer (i.e., the rate of heat transfer and/or the quantity of heat transfer) to be

provided during the period is modified in order to optimize the physiological parameter value. A predefined value corresponding to a physiological parameter may be one or more of: a target value, a minimum value, a maximum value, a range, an average, a standard deviation, an upper control limit, a lower control limit, a calculated value, a previous value, a change in the value, an increase from a previous value, a decrease from a previous value, a safety threshold, a deviation from any of the foregoing, an ascertained difference between a physiological parameter value and any of the foregoing and/or any other value desirable for dynamically controlling a thermal contrast therapy treatment sequence. A predefined value may be provide, for example, by a treatment provider or derived from a database. Alternatively or in addition, a thermal contrast therapy device and/or system may provide one or more preconfigured predefined values. Such preconfigured values maybe modified by a user and/or treatment provider.

When a treatment period has concluded, the thermal contrast therapy device ascertains whether the sequence calls for optimizing a physiological parameter value for subsequent periods within the sequence. If so, the device ascertains the physiological parameter value(s) exhibited during the concluded period and/or other previously concluded periods, and if the value(s) are less than or greater than a predefined target value, one or more measures of heat transfer to be provided during one or more subsequent periods in the sequence are modified in order to optimize the physiological parameter value.

When a treatment sequence has concluded, the thermal contrast therapy device ascertains whether the sequence calls for optimizing a physiological parameter value for subsequent treatment sequences within a treatment program. If so, the device ascertains

the physiological parameter value(s) exhibited during the concluded sequence and/or other previously concluded sequences, and if the value(s) are less than or greater than a predefined target value, one or more measures of heat transfer to be provided during one or more subsequent treatment sequences are modified in order to optimize the physiological parameter value. At the conclusion of the treatment sequence, data associated with the sequence maybe transmitted to a thermal contrast therapy system for use in accordance with the present disclosure.

Dynamically controlled treatment sequences may include one or more automatic adjustments to the sequence. Automatic adjustments may occur at any desired time during the course of the sequence. A sequence may be automatically adjusted during the course of one or more cooling periods or heating periods within the sequence, for example, based on a physiological parameter value exhibited during the same period. Such automatic adjustment may be provided, for example, to attain a desired effect from a particular period within the sequence during which the one or more adjustments occur. Additionally, or in the alternative, one or more subsequent periods within a sequence may be automatically adjusted based on the effects of one or more prior periods, for example, a physiological parameter value exhibited during a previous cooling period or heating period. Automatic adjustments in subsequent period or periods may be provided, for example, to attain a desired effect from such subsequent period or periods. Automatic adjustments to a treatment sequence may be effected at any time during the course of treatment, for example, to attain a desired effect from the particular treatment. Automation adjustments may also be effected over the course of several treatments, for example, to attain a desired effect from a series of treatments.

In some instances, the particular settings which might be expected to produce a desired therapeutic effect may not be known, or may be uncertain. Given this, in some embodiments a thermal contrast therapy treatment sequences, and/or series of treatments within a treatment program may be configured to administer varying heating periods and/or cooling periods, treatment sequences, and/or overall treatment programs, while monitoring physiological parameter values, other therapeutic effects, and/or other factors related to the treatment, and then dynamically modify the treatment sequence(s) to optimize one or more physiological parameter values or other desired therapeutic effects. Such dynamic adjustments may be made to heating periods and/or cooling periods within a treatment sequence, to one or more treatment sequences making up a treatment program, and/or to an overall treatment program.

In some embodiments, a dynamically controlled treatment sequence is provided, wherein the dynamic control is configured to provide conditions derived from conditions of a prior treatment sequence. This may include reproducing or replicating conditions of a prior treatment, or adjusting one or more variables which may affect the treatment, a physiological parameter value, and/or a therapeutic effect of the treatment, for example, based at least in part on conditions of one or more prior treatment sequence.

In some embodiments, a thermal contrast therapy treatment sequence may be dynamically controlled based on a patient's comfort level. For example the sequence may be adjusted based on input as to whether the treatment feels painful or uncomfortable, too hot or too cold, or just right. Such patient input may be derived from one or more physiological parameter values, such as vital signs, or input may be provided directly by patient, for example via a user interface.

Those skilled in the art will appreciate that both feed-back and feed-forward control loops may be utilized in accordance with the dynamically controlled thermal contrast therapy treatment sequence of the present disclosure.

Further Exemplary Customized Thermal Contrast Therapy Treatments

5 Exemplary customized thermal contrast therapy treatments will be further discussed. Customized thermal contrast therapy treatment sequences may be provided in accordance with the present disclosure based on any one or more variables, including the variables disclosed herein. Customized treatment sequences may be provided based on the preference of the practitioner or therapist, or the patient receiving treatment.
10 Treatment sequences may be developed on the basis of research and/or results attained by users associated with a thermal contrast therapy system.

Treatment sequences may be customized based on the area of the body being treated, the particular symptom or condition sought to be treated, or the particular desired therapeutic result. Treatment sequences may also be customized based on the particular
15 body part(s) sought to be treated. As examples, customized treatment sequences may be provided for the hand, wrist, forearm, elbow, upper arm, shoulder, foot, ankle, calf, shin, knee, thigh, hips, pelvic region, abdomen, lumbar, mid-back, upper-back, neck, and cranium.

Treatment sequences may also be customized based on the particular conditions
20 or symptoms sought to be treated. As examples, customized thermal contrast therapy may be provided to treat edema or swelling, fever, toxins, spasms, constipation, immune function inflammation, sprains, strains, general pain, neuropathy, arthritis, carpal tunnel, non-healing wounds, gangrene, migraine headaches, whiplash associated disorders, hair

loss, muscular spasms, sinus pressure, disorders associated with lack of proper blood flow, bed sores, and respiratory ailments, among other things. Customized treatments may also be provided for patients with hypothermia or frostbite, for example, to enhance circulation in affected tissue.

5 As further examples, customized treatments may be provided to encourage healing of bones and tissue, and to rehabilitate injuries to bone, muscle, ligaments, tendons, and skin. Customized treatments may also be provided after an acute injury or surgery, for example, to reduce pain and swelling and promote healing. Customized treatments may be provided to athletes after or between training sessions to speed
10 recovery or reduce delayed onset muscle soreness, by helping to flush lactic acid from sore muscles. Customized treatments may also be provided to relax joint tissue, such as ligaments and tendons, to increase range of motion. Customized treatments may also be provided for patients with spinal cord or nerve damage, for example, to enhance blood flow to the injured nerve tissue, or prevent or mitigate disputation of the tenuous blood
15 supply.

Without wishing to be constrained by theory, it is believed that thermal contrast therapy performed on one area of the body may cause a sympathetic response in a different area of the body. For example, treatment performed on one limb (e.g., an arm or leg) may effect a therapeutic response in the opposite limb. Accordingly, in some
20 embodiments customized treatments may be provided to effect a sympathetic response. The sympathetic response may include activation of the sympathetic nervous system, associated sensations associated with therapy in a limb opposite to the limb receiving

direct treatment, increased blood flow, enhanced tissue healing and rehabilitation, and other desired therapeutic effects.

Customized treatments may also be an provided as a therapy for diabetes and related physiological complications, for example, gangrene, or for lymphedema or other disorders associated with vascular or lymphatic insufficiency, for example, Chronic Venous Insufficiency, venous stasis ulcers, post-mastectomy edema or chronic lymphedema, and for peripheral vascular disease or other circulatory deficiency syndrome, for example, arteriosclerosis, deep vein thrombosis, Buereger's disease, or thromboangiitis obliterans, or to positively influence the immune system.

Treatments may also be customized based on one or more desired therapeutic effects sought to be attained. As examples, therapeutic effects sought to be attained from thermal contrast therapy may include increased blood flow, increased blood oxygen levels, reduced inflammation, pain reduction, accelerated healing, increased medication effectiveness and focus, improved distal perfusion, improved arterial inflow, improved venous return flow, toxin removal, reduction of inflammatory kinins, and assistance to a chronically decompensated heart by complementing the heart cycle.

The total treatment time for a thermal contrast therapy sequence may range from a few minutes to several hours in duration, for example, from 10 minutes to 2.5 hours, or from 20 minutes to 75 minutes. As further examples, the total treatment time may be about 5 minutes, 10 minutes, 15 minutes, 20 minutes, 25 minutes, 30 minutes, 35 minutes, 40 minutes, 45 minutes, 50 minutes, 55 minutes, 60 minutes, 65 minutes, 70 minutes, 75 minutes, 80 minutes, 85 minutes, 90 minutes, 95 minutes, 100 minutes, 105

minutes, 110 minutes, 115 minutes, 120 minutes, 125 minutes, 130 minutes, 135 minutes, 140 minutes, 145 minutes, 150 minutes, or any intermediate time period, or longer.

A treatment sequence may begin with either a heating period or a cooling period. Different therapeutic effects may be attained depending on whether therapy begins with a heating period or a cooling period. The duration of a heating period or a cooling period may range from a few seconds to several minutes. As examples, the duration of heating periods and/or cooling periods may range from about 5 seconds to 60 seconds, from about 1 minute to 5 minutes, from about 5 minutes to 20 minutes, or longer. A period may last, for example, about 5 seconds, 10 seconds, 15 seconds, 20 seconds, 25 seconds, 30 seconds, 35 seconds, 40 seconds, 45 seconds, 50 seconds, 55 seconds, 60 seconds, 65 seconds, 70 seconds, 75 seconds, 80 seconds, 85 seconds, 90 seconds, 95 seconds, 100 seconds, 105 seconds, 110 seconds, 115 seconds, 120 seconds, 125 seconds, 130 seconds, 135 seconds, 140 seconds, 145 seconds, 150 seconds, 155 seconds, 160 seconds, 165 seconds, 170 seconds, 175 seconds, 180 seconds, 185 seconds, 190 seconds, 195 seconds, 200 seconds, 205 seconds, 210 seconds, 215 seconds, 220 seconds, 225 seconds, 230 seconds, 235 seconds, 240 seconds, 5 minutes, 10 minutes, 15 minutes, 20 minutes, 25 minutes, 30 minutes, or any intermediate time period, or longer. Alternatively, in some embodiments, a cooling or heating period may be provided which comprises continuous application of hot or cold.

Transition times between a heating period and a cooling period, or vice versa, may range from a few seconds to several minutes, for example, from 5 seconds to 30 minutes. Transition times may be, for example, about 5 seconds, 10 seconds, 15 seconds, 20 seconds, 25 seconds, 30 seconds, 35 seconds, 40 seconds, 45 seconds, 50 seconds, 60

seconds, 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 10 minutes, 15 minutes, 20 minutes, 25 minutes, 30 minutes, or any intermediate time period, or longer.

Transition time may depend on the time required to flush heat transfer fluid from the applicable reservoir, through the tubing and into the cuff. Transition time may also
5 depend on the desired therapeutic effect; for example, in some instances a rapid transition may be desired, whereas in other instances a more gradual transition may be desired. For example, when treating a physically fit patient for muscle spasms, a rapid transition may be provided, whereas an elderly person afflicted by poor circulation may be unable to withstand a high level of contrasting heat transfer, and as such, a mild transition may be
10 required.

In some embodiments, a neutral period comprising a neutral temperature and/or rate of heat transfer may be provided between some or all of the heating periods and cooling periods. The neutral period may be provided as part of the transition between heating periods and cooling periods, or the neutral period may be treated as its own
15 distinct period. The duration of a neutral period may range from a few seconds to several minutes. As examples, the duration of neutral periods may range from about 5 seconds to 60 seconds, from about 1 minute to 5 minutes, from about 5 minutes to 20 minutes, or longer. A neutral period may last, for example, about 5 seconds, 10 seconds, 15 seconds, 20 seconds, 25 seconds, 30 seconds, 35 seconds, 40 seconds, 45 seconds, 50 seconds, 55
20 seconds, 60 seconds, 65 seconds, 70 seconds, 75 seconds, 80 seconds, 85 seconds, 90 seconds, 95 seconds, 100 seconds, 105 seconds, 110 seconds, 115 seconds, 120 seconds, 125 seconds, 130 seconds, 135 seconds, 140 seconds, 145 seconds, 150 seconds, 155 seconds, 160 seconds, 165 seconds, 170 seconds, 175 seconds, 180 seconds, 185 seconds,

190 seconds, 195 seconds, 200 seconds, 205 seconds, 210 seconds, 215 seconds, 220 seconds, 225 seconds, 230 seconds, 235 seconds, 240 seconds, 5 minutes, 10 minutes, 15 minutes, 20 minutes, 25 minutes, 30 minutes, or any intermediate time period, or longer.

Heat transfer fluid temperatures during heating periods may range from about 85
5 °F to 130 °F, or from about 100 °F to 110 °F. The heat transfer fluid temperature during a heating period may be, for example, about 85 °F, 90 °F, 95 °F, 100 °F, 105 °F, 110 °F, 115 °F, 120 °F, 125 °F, 130 °F, or any intermediate temperature, cooler temperature, or warmer temperature. Other temperatures will also be apparent to the skilled artisan.

During cooling periods, heat transfer fluid temperatures may range from about 30
10 °F to 70 °F, or from about 40 °F to 50 °F. As further examples, cold heat transfer fluid temperatures may be about 30 °F, 35 °F, 40 °F, 45 °F, 50 °F, 55 °F, 60 °F, 65 °F, 70 °F, or any intermediate temperature, cooler temperature, or warmer temperature. Other temperatures will also be apparent to the skilled artisan.

Transition periods may provide heat transfer fluid of any temperature which is
15 between the temperature corresponding to the period preceding the transition period and the temperature which corresponds to the period following the transition period. For example, heat transfer fluid temperatures during a transition period may be about 30 °F, 35 °F, 40 °F, 45 °F, 50 °F, 55 °F, 60 °F, 65 °F, 70 °F, 75 °F, 80 °F, 85 °F, 90 °F, 95 °F, 100 °F, 105 °F, 110 °F, 115 °F, 120 °F, 125 °F, 130 °F, or any intermediate temperature,
20 cooler temperature, or warmer temperature. Other temperatures will also be apparent to the skilled artisan.

Transition periods may be configured to provide a customized transition curve. The transition curve between two periods may be rapid or gradual, may comprise various

rates of change during the transition, and may include a neutral period comprising providing for a specified period of time, a desired rate of heat transfer, and/or a desired temperature for the heat transfer fluid, which is between that of the period preceding the neutral period and the period following the neutral period.

5 Flow rates of heat transfer fluids may range from about 10 mL/min to 1000 mL/min. For example, flow rates may be about 10 mL/min, 50 mL/min, 100 mL/min, 150 mL/min, 200 mL/min, 250 mL/min, 300 mL/min, 350 mL/min, 400 mL/min, 450 mL/min, 500 mL/min, 550 mL/min, 600 mL/min, 650 mL/min, 700 mL/min, 750 mL/min, 800 mL/min, 850 mL/min, 900 mL/min, 950 mL/min, 1000 mL/min, or any
10 intermediate flow rate, higher flow rate, or lower flow rate. Flow rates may be increased where a high rate of heat transfer is desired, or decreased where a low rate of heat transfer is desired. In some embodiments, flow rate may be reduced to zero to provide a gradually declining rate of heat transfer. In some embodiments, flow rate may be increased to a point where the temperature difference between the fluid entering and
15 exiting a treatment cuff approaches a target value, for example, a minimum value, or approximately zero.

Rates of heat transfer may range from about 0.5 BTU/min to 25 BTU/min. For example, the rate of heat transfer during a given period may be about 0.5 BTU/min, 1 BTU/min, 1.5 BTU/min, 2 BTU/min, 2.5 BTU/min, 3 BTU/min, 3.5 BTU/min, 4
20 BTU/min, 4.5 BTU/min, 5 BTU/min, 5.5 BTU/min, 6 BTU/min, 6.5 BTU/min, 7 BTU/min, 7.5 BTU/min, 8 BTU/min, 8.5 BTU/min, 9 BTU/min, 9.5 BTU/min, 10 BTU/min, 10.5 BTU/min, 11 BTU/min, 11.5 BTU/min, 12 BTU/min, 12.5 BTU/min, 13 BTU/min, 13.5 BTU/min, 14 BTU/min, 14.5 BTU/min, 15 BTU/min, 15.5 BTU/min, 16

BTU/min, 16.5 BTU/min, 17 BTU/min, 17.5 BTU/min, 18 BTU/min, 18.5 BTU/min, 19 BTU/min, 19.5 BTU/min, 20 BTU/min, 20.5 BTU/min, 21 BTU/min, 21.5 BTU/min, 22 BTU/min, 22.5 BTU/min, 23 BTU/min, 23.5 BTU/min, 24 BTU/min, 24.5 BTU/min, 25 BTU/min, or any intermediate rate, greater rate, or lesser rate. Other heat transfer rates will also be apparent to the skilled artisan.

Referring to Figs. **14A-1** and **14A-2** through **14G-1** and **14G-2**, a selection of exemplary thermal contrast therapy treatment sequences are shown. As depicted in Figs. **14A-1** and **14A-2**, **14B-1** and **14B-2**, **14C-1** and **14C-2**, and **14D-1** and **14D-2**, a treatment sequence may be configured to provide a desired fluid temperature during the various treatment periods, and as depicted in Figs. **14E-1** and **14E-2**, **14F-1** and **14F-2**, and **14G-1** and **14G-2**, a treatment sequence may be configured to provide a desired measure of heat transfer during the various periods. Additionally, treatment sequences may be configured to effect both a desired fluid temperature and a desired measure of heat transfer. Treatment sequences configured to effect a desired measure of heat transfer may provide for a desired rate of heat transfer and/or a desired quantity of heat transfer. Where a treatment sequence provides for a desired quantity of heat transfer, the duration of the treatment periods within the sequence may depend on the rate of heat transfer. In addition or as an alternative, treatment sequences configured to effect a desired rate of heat transfer may provide for treatment periods having a predefined time duration, where the desired quantity of heat transfer depends on such time duration. Figs. **14A-1** and **14A-2** through **14G-1** and **14G-2** are discussed in further detail above.

VI. User Profiles and Interfaces for Thermal Contrast Therapy Systems and Devices

User Profiles

In some embodiments, it is desirable to provide user profiles for managing
5 thermal contrast therapy treatments. User profiles may be used, for example, to store
information about a patient and a patient's treatment history, to prescribe thermal contrast
therapy treatment sequences for one or more users or treatment objectives, to define
device and system settings corresponding to one or more users, and/or to define a
selection of available features of a thermal contrast therapy system or device. Thermal
10 contrast therapy treatment sequences, system settings, and available features may be
defined by a user or characteristics of the user, or by a user's physician, therapist, or
caretaker, etc. Treatment sequences, system settings, and available features of a thermal
contrast therapy system or device may also depend on characteristics particular to a user,
the selected or prescribed treatment, the particular area of the body sought to be treated,
15 the particular symptom or condition sought to be treated, or the particular desired
therapeutic result.

Referring to Fig. 17, an exemplary user or patient profile page for a thermal
contrast therapy device or system is shown. As depicted in Fig. 17, a user profile may
include information about the patient, such as personal information, medical history
20 information, a description of the patient's ailment, injury, or condition sought to be
treated, and information about the thermal contrast therapy treatment(s) which have been
prescribed to the patient and/or selected by the patient, for example, via a thermal
contrast therapy system.

In some embodiments, a selection of available features and operating conditions may be provided depending on information in a user's profile or other information. For example, a treatment provider, such as a physician or therapist may be provided a full selection of features, whereas a patient may be provided a more limited selection of features. Such user profiles may facilitate various thermal contrast therapy treatment sequences for use in clinical settings or for self-provided care at home or outside of a clinical setting. In some embodiments, a physician, therapist, or other caretaker may assign one or more prescribed thermal contrast therapy treatment sequences to a user profile, and the user desiring to self-provide therapy at home or outside of a clinical setting may select the one or more prescribed treatment sequences and cause the user's thermal contrast therapy device to perform the procedure. In some embodiments, the functionality of a user's thermal contrast therapy device may be limited such that the device will only perform one or more thermal contrast therapy treatment sequences prescribed to the user. The user's treatments and corresponding data, vital signs and other information may be recorded and stored in the user's profile, where it may subsequently be viewed by the user or the user's physician, therapist, or other care provider.

User Interfaces

Various user interfaces may be provided to enable users to interface with thermal contrast therapy devices and systems in accordance with the present disclosure. Referring to Figs. **18A** through **18G**, exemplary user interface pages for a thermal contrast therapy device and/or system are shown.

As depicted in Fig. **18A**, an exemplary user interface may include a page configured to enable a treatment provider to utilize a thermal contrast therapy system. For example, a user interface page may be configured to enable a treatment provider to register new patients and manage care for existing patients. In some embodiments, a user interface may be configured to enable a treatment provider to remotely operate a thermal contrast therapy device. For example, a treatment provider may, via a user interface, initiate and monitor a thermal contrast therapy treatment sequence provided to a patient at a remote location. The user interface may also be configured to enable a treatment provider to communicate with the patient via voice, text, or video chat or the like, for example to confirm that the treatment is progressing satisfactorily and address questions or concerns that may arise. In some embodiments, a user interface may be configured to enable a treatment provider to search for a database to locate thermal contrast therapy treatment sequences which may be suitable for a patient, and/or to manually create a new treatment, which may be transmitted to a user's device and/or uploaded to the database for future use by the treatment provider or patient, and/or other treatment providers and patients. In some embodiments, a user interface may include a chat room for corresponding with other thermal contrast therapy treatment providers, subject matter experts, manufacturers, outside service providers, users, and the like.

As depicted in Fig. **18B**, an exemplary user interface may include a page for a treatment provider to manage thermal contrast therapy treatments provided to patients receiving treatment via a thermal contrast therapy system. In some embodiments, a user interface may be configured to enable a treatment provider to view a patient's history

and/or user profile, manage thermal contrast therapy treatments provided to the patient, and send a message to a patient.

As depicted in Fig. **18C**, an exemplary user interface may include a page for a treatment provider to manage thermal contrast therapy treatments prescribed to a patient via a thermal contrast therapy system. For example, a user interface may be configured to enable a treatment provider to prescribe one or more treatment sequences and the time period and frequency with which they are to be administered.

Fig. **18D** shows an exemplary user interface for searching a thermal contrast therapy system database for customized thermal contrast therapy treatments. As depicted in Fig **18D**, a user interface may be configured to enable searching based on a plurality of variables, including, for example, treatment area, type of injury or condition sought to be treated, the status or condition of a patient, and/or the desired therapeutic result sought to be attained. Treatments may be categorized in a database such as depicted in Fig. **18D** based on any number of variables and each such variable may include any number of classifications. In some embodiments, a user interface may be configured to enable a patient to browse a complete listing or subset of treatments from a database.

Figs. **18E**, **18F**, and **18G** each show exemplary user interfaces for operation of thermal contrast therapy device. A user interface may be provided to enable operation of a thermal contrast therapy device to provide customized treatment sequences in accordance with the present disclosure. The user interface may be configured to enable operation of a thermal contrast therapy device from a remote location, for example via a thermal contrast therapy system, and/or locally, for example, via a touch screen or other interface integrated with the device, or via a handheld device configured to interact with

the thermal contrast therapy device. In some embodiments, a user interface may be configured to allow a user to search a database and select a treatment program from the database to be performed by the user's thermal contrast therapy device. The treatment program selected by a user may be a program prescribed by a treatment provider, or any treatment program available in a database, for example, a treatment that matches a search query. As depicted in Fig. **18F**, a user interface may be configured to display a user's prescribed thermal contrast therapy programs, and select a treatment sequence to be performed by the user's thermal contrast therapy device

As depicted in Figs. **18E** and **18F**, an exemplary user interface may include a start/stop button to enable a user to start and stop a thermal contrast therapy treatment sequence, and/or a pause button, for example, to temporarily suspend the sequence. The user interface may be configured to display information about the treatment sequence, including information about the progress of the sequence, such as duration, start time, and time remaining. In some embodiments, a user interface may be configured to allow a user only to perform a prescribed sequence.

As depicted in Fig. **18G**, a user interface may be configured to enable a user to manually operate a thermal contrast therapy device. Manual operation may be configured so as to enable a user to input settings for a thermal contrast therapy device and to cause the device to perform a treatment sequence based such settings. As depicted in Fig. **18G**, manual input settings may include, for example, heat transfer fluid temperature settings, time durations for heating periods, cooling periods, and/or transition periods, frequency of fluid pulsation. Manual input settings may also include settings for desired rates of heat transfer, quantities of heat transfer, flow rates for heat transfer fluid,

levels of compression. In some embodiments, manual operation may include manually starting and stopping a treatment sequence and/or treatment periods, or manually inputting a customized thermal contrast therapy treatment sequence. In some embodiments, manual input settings may be transmitted to a database associated with a thermal contrast therapy system for future use, for example, with subsequent treatment sequences.

VII. Other Embodiments

The foregoing detailed description of illustrative embodiments has set forth various embodiments of thermal contrast therapy devices, treatment methods for providing thermal contrast therapy, and systems for providing and managing thermal contrast therapy treatments. While the devices disclosed herein may be characterized by their applicability for performing certain treatment methods disclosed herein, it will be apparent that numerous other devices may be configured to provide thermal contrast therapy. For example, in some embodiments, a thermal contrast therapy device may be configured to utilize a heat transfer medium other than a fluid. For example, particulate mediums such as cellulose particles, grains, sands, pellets, or the like may be used in a device configured to effect heat transfer through such a particulate medium. Examples of such devices include devices configured to cause fluidization of particles, such as a device having a fluidized bed component, or a device configured to cause the particulate medium to exhibit fluid-like characteristics or to be pumped using fluid type technologies. Additionally, it will be understood that alternating periods of heating and cooling may be provided through virtually any means of respectively delivering and

removing heat from the treatment area, including conduction, convection, radiation, and combinations thereof. When utilizing conduction, an apparatus in physical contact with the treatment area may be provided to effect heat transfer. For example, in some embodiments, heating and/or cooling may be provided to the treatment area via thermoelectric heating and/or cooling modules, respectively. When utilizing convection, heat transfer is effected through a fluid, for example, a gas, liquid, or fluidized particles. When utilizing radiation, no heat transfer medium may be required, for example, where heat transfer is effected through electromagnetic waves.

Similarly, it will be apparent that numerous other treatment methods and treatment sequences may be provided with a thermal contrast therapy device. For example, a thermal contrast therapy device may be configured to provide only heat therapy and/or only cold therapy. Additionally, virtually any treatment sequence may be provided in accordance with the present disclosure.

The foregoing detailed description of illustrative embodiments has set forth various embodiments of thermal contrast therapy devices, treatment methods, and systems via the use of block diagrams, flowcharts, and/or examples. Insofar as such block diagrams, flowcharts, and/or examples contain one or more functions and/or operations, it will be understood by those skilled in the art that each function and/or operation within such block diagrams, flowcharts, or examples can be implemented, individually and/or collectively, by a wide range of hardware, software, firmware, or virtually any combination thereof. In one embodiment, several portions of the subject matter described herein may be implemented via Application Specific Integrated Circuits (ASICs), Field Programmable Gate Arrays (FPGAs), digital signal processors (DSPs), or

other integrated formats. However, those skilled in the art will recognize that some aspects of the embodiments disclosed herein, in whole or in part, can be equivalently implemented in integrated circuits, as one or more computer programs running on one or more computers (e.g., as one or more programs running on one or more computer systems), as one or more programs running on one or more processors (e.g., as one or more programs running on one or more microprocessors), as firmware, or as virtually any combination thereof, and that designing the circuitry and/or writing the code for the software and or firmware would be well within the skill of one of ordinary skill in the art in light of the present disclosure.

In addition, those skilled in the art will appreciate that the mechanisms of the subject matter described herein are capable of being distributed as a program product in a variety of forms, and that an illustrative embodiment of the subject matter described herein applies equally regardless of the particular type of signal bearing media used to actually carry out the distribution. Examples of a signal bearing media include, but are not limited to, the following: recordable type media such as volatile and non-volatile memory devices, floppy and other removable disks, hard disk drives, SSD drives, flash drives, optical discs (e.g., CD ROMs, DVDs, etc.), and computer memory; and transmission type media such as digital and analog communication links using TDM or IP based communication links (e.g., packet links).

In a general sense, those skilled in the art will recognize that the various aspects described herein which can be implemented, individually and/or collectively, by a wide range of hardware, software, firmware, or any combination thereof can be viewed as being composed of various types of “electrical circuitry.” Consequently, as used herein

“electrical circuitry” includes, but is not limited to, electrical circuitry having at least one discrete electrical circuit, electrical circuitry having at least one integrated circuit, electrical circuitry having at least one application specific integrated circuit, electrical circuitry forming a general purpose computing device configured by a computer program
5 (e.g., a general purpose computer configured by a computer program which at least partially carries out processes and/or devices described herein, or a microprocessor configured by a computer program which at least partially carries out processes and/or devices described herein), electrical circuitry forming a memory device (e.g., forms of random access memory), and/or electrical circuitry forming a communications device
10 (e.g., a modem, communications switch, or optical-electrical equipment).

Those skilled in the art will recognize that it is common within the art to describe devices and/or processes in the fashion set forth herein, and thereafter use engineering practices to integrate such described devices and/or processes into data processing systems. That is, at least a portion of the devices and/or processes described herein can be
15 integrated into a data processing system via a reasonable amount of experimentation. Those having skill in the art will recognize that a typical data processing system generally includes one or more of a system unit housing, a video display device, a memory such as volatile and non-volatile memory, processors such as microprocessors and digital signal processors, computational entities such as operating systems, drivers, graphical user
20 interfaces, and applications programs, one or more interaction devices, such as a touch pad or screen, and/or control systems including feedback loops and control elements (e.g., feedback for sensing temperature; control heaters for adjusting temperature). A typical data processing system may be implemented utilizing any suitable commercially

available components, such as those typically found in data computing/communication and/or network computing/communication systems.

The foregoing described aspects depict different components contained within, or connected with, different other components. It is to be understood that such depicted
5 architectures are merely exemplary, and that in fact many other architectures can be implemented which achieve the same functionality. In a conceptual sense, any arrangement of components to achieve the same functionality is effectively “associated” such that the desired functionality is achieved. Hence, any two components herein combined to achieve a particular functionality can be seen as “associated with” each
10 other such that the desired functionality is achieved, irrespective of architectures or intermedial components. Likewise, any two components so associated can also be viewed as being “operably connected”, or “operably coupled”, to each other to achieve the desired functionality. Specific examples of operably couplable include but are not limited to physically mateable and/or physically interacting components and/or wirelessly
15 interactable and/or wirelessly interacting components and/or logically interacting and/or logically interactable components.

All of the above U.S. patents, U.S. patent application publications, U.S. patent applications, foreign patents, foreign patent applications and non-patent publications referred to in this specification and/or listed in any Application Data Sheet, are
20 incorporated herein by reference, in their entirety.

While various aspects and embodiments have been disclosed herein, other aspects and embodiments will be apparent to those skilled in the art. The various aspects and embodiments disclosed herein are for purposes of illustration and are not intended to be

limiting. It is intended that the scope of this disclosure be defined by the following claims and their equivalents:

WHAT IS CLAIMED IS:

1. A thermal contrast therapy device comprising:

a cooling system comprising a first pump configured to circulate cold fluid and a heating system comprising a second pump configured to circulate hot fluid, in a sequence
5 of alternating cooling periods and heating periods;

wherein upon transition between a first period and a second period, fluid having a first temperature corresponding to the first period displaces fluid having a second temperature corresponding to the second period.

10 2. The thermal contrast therapy device of claim 1, wherein the cooling system further comprises a cold fluid recirculation line and/or the heating system further comprises a hot fluid recirculation line.

3. The thermal contrast therapy device of claims 1 or 2, wherein the cooling system
15 and the heating system converge at an outflow fluid line, the outflow fluid line configured to discharge fluid from the device.

4. The thermal contrast therapy device of any one of the above claims, wherein the device is configured to route circulating fluid either to the heating system and/or the
20 cooling system based, at least in part, on the temperature of the fluid.

5. The thermal contrast therapy device of any one of the above claims, wherein having a first pump configured to circulate cold fluid and a second pump configured to circulate hot fluid enables fluid flowing through an outflow fluid line to attain
25 equilibrium temperature with respect to a thermal mass within less than 20 seconds after

transition from a heating period to a cooling period, the thermal mass being that which corresponds to components in thermal communication with the fluid between a first point at which fluid discharges from the cooling system and a second point at which fluid discharges from the device.

5

6. The thermal contrast therapy device of any one of the above claims, wherein the device is configured to maintain the temperature of cold fluid discharging from an outflow fluid line within about 2 °F of the temperature at which the cold fluid discharges from the cooling system.

10

7. The thermal contrast therapy device of any one of the above claims, wherein the device has a cumulative thermal mass of less than about 0.1 BTU/°F attributable to components in thermal communication with the fluid between a first point at which fluid discharges from the cooling system and a second point at which fluid discharges from the device.

15

8. The thermal contrast therapy device of any one of the above claims, wherein the device is configured to maintain the temperature of cold fluid discharging from an outflow fluid line within about 2 °F of the temperature at which the cold fluid discharges from the heating system.

20

9. The thermal contrast therapy device of any one of the above claims, wherein the device has a cumulative thermal mass of less than about 0.1 BTU/°F attributable to components in thermal communication with the fluid between a first point at which fluid discharges from the heating system and a second point at which fluid discharges from the device.

25

10. The thermal contrast therapy device of any one of the above claims, further comprising a shared reservoir configured to supply fluid to the cooling system and the heating system.

5 **11.** The thermal contrast therapy device of claim 10, wherein displaced fluid causes a corresponding volume of fluid to be exchanged with fluid in the shared reservoir, the shared reservoir being in fluid communication with the cooling system and the heating system.

10 **12.** The thermal contrast therapy device of claims 10 or 11, wherein the shared reservoir is configured to hold a volume of fluid comprising fluid from the cooling system and fluid from the heating system.

15 **13.** The thermal contrast therapy device of claim 12, wherein the device is configured to cause, upon transition from a cooling period to a heating period, fluid from the cooling system to flow to the shared reservoir, resulting in a first volume of fluid from the shared reservoir flowing to the heating system; and upon transition from a heating period to a cooling period, fluid from the heating system to flow to the shared reservoir, resulting in a second volume of fluid from the shared reservoir flowing to the cooling system.

20

14. The thermal contrast therapy device of any one of claims 10 through 13, wherein the volume of fluid in the shared reservoir remains substantially constant during the sequence of alternating cooling periods and heating periods.

25 **15.** The thermal contrast therapy device of any one of claims 10 through 14, wherein fluid communication between the shared reservoir and the heating system occurs through

a first opening in the shared reservoir and fluid communication between the shared reservoir and the cooling system occurs through a second opening in the shared reservoir, the first opening being located at an elevation above the elevation of the second opening.

- 5 **16.** The thermal contrast therapy device of any one of claims 10 through 15, wherein the heating system is configured to preferentially draw stratified hot fluid from the shared reservoir and/or the cooling system is configured to preferentially draw stratified cold fluid from the shared reservoir.
- 10 **17.** The thermal contrast therapy device of any one of the above claims, wherein the cooling system is configured to circulate cold fluid through a treatment pad, and the heating system is configured to circulate hot fluid through the treatment pad.
- 15 **18.** The thermal contrast therapy device of any one of the above claims, wherein the device is configured to direct fluid returning from the treatment pad to either the cooling system or the heating system based at least in part on the temperature of the fluid.
- 20 **19.** The thermal contrast therapy device of any one of the above claims, wherein the device is configured to circulate fluid through the cooling system during heating periods, and/or to circulate fluid through the heating system during cooling periods.
- 25 **20.** The thermal contrast therapy device of any one of the above claims, wherein the cooling system further comprises a cooling block, the cooling block configured to hold a first volume of fluid, and wherein the heating system further comprises a heating block, the heating block configured to hold a second volume of fluid.

21. The thermal contrast therapy device of claim 20, wherein either one of the cooling block and the heating block comprises a plurality of baffles defining a serpentine path for fluid travel between an inlet and an outlet.

5 22. The thermal contrast therapy device of claims 20 or 21, wherein the cooling block and/or the heating block are configured to allow air to escape to the shared reservoir.

23. The thermal contrast therapy device of **claim 1**, wherein the cooling system further comprises a first supply valve and a first return valve, and the heating system
10 further comprises a second supply valve and a second return valve.

24. The thermal contrast therapy device of any one of the above claims, wherein the device is configured to effect a pressure pulse in a treatment pad, the pressure pulse effected at least in part by alternating a valve between opened and closed positions.

15

25. The thermal contrast therapy device of claim 24, wherein the valve comprises a magnetic solenoid valve.

26. The thermal contrast therapy device of claims 24 or 25, wherein the device is
20 configured to synchronize the frequency of the pressure pulse with the heart rate of a patient receiving treatment.

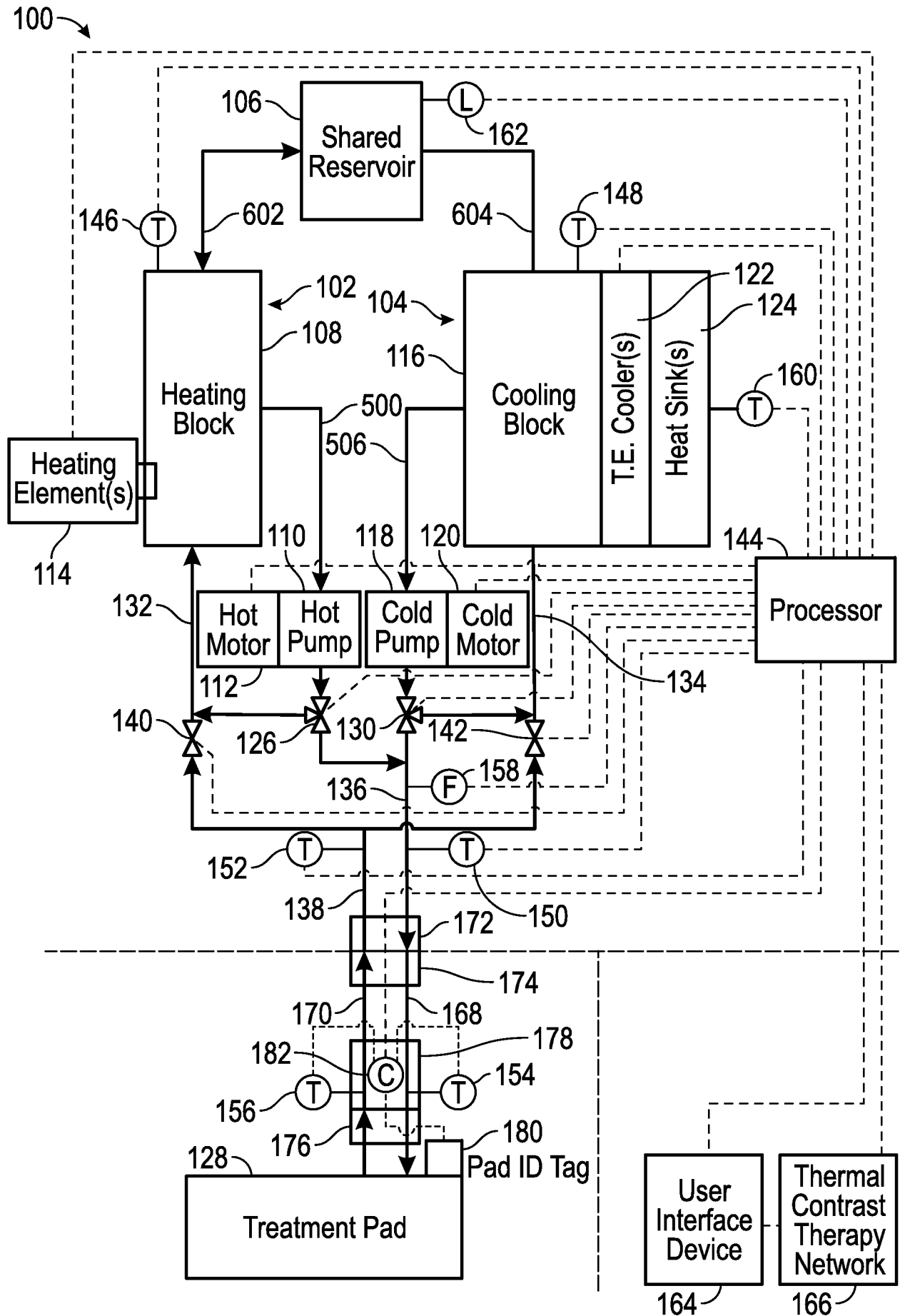
27. The thermal contrast therapy device of any one of the above claims, wherein the device is configured to effect a transition between alternating periods within a duration of
25 between about 5 seconds to 90 seconds.

28. The thermal contrast therapy device of any one of the above claims, wherein the device is configured to provide a sequence having one or more periods of between about 15 seconds to 300 seconds.

5

29. The thermal contrast therapy device of any one of the above claims, wherein the device is configured to provide a sequence comprising a continuous cyclical change in: fluid temperature and/or rate of heat transfer.

10



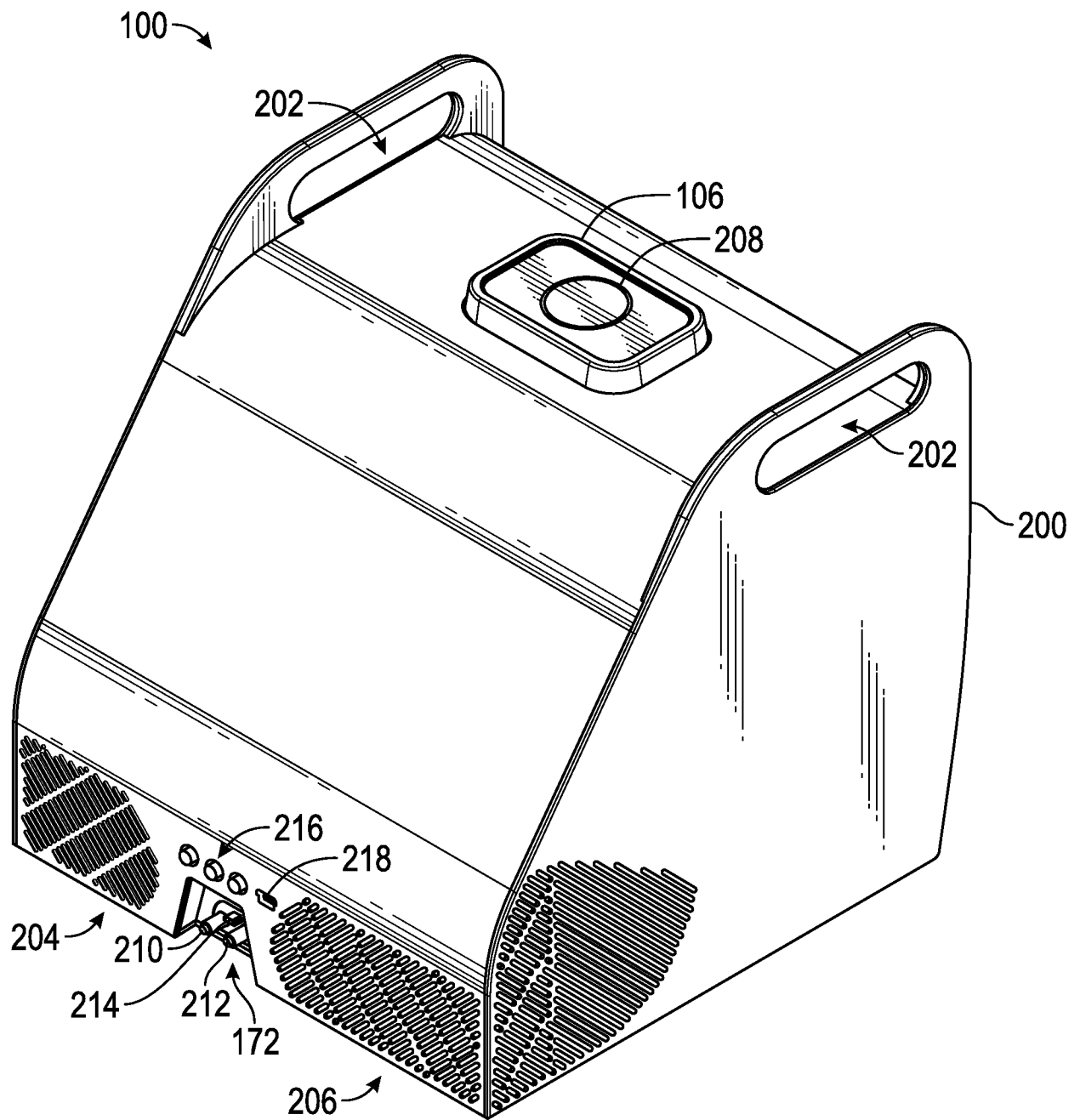
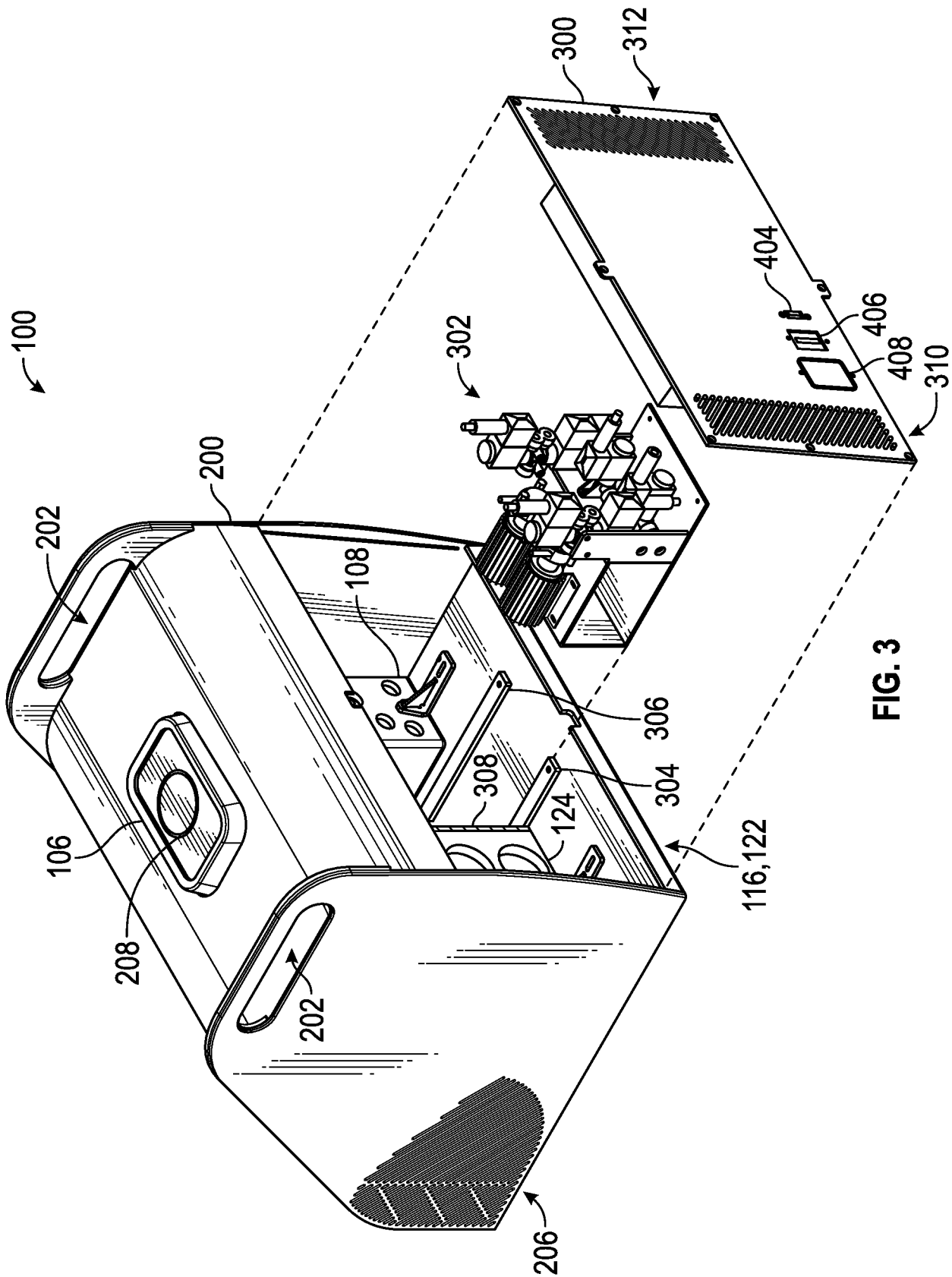


FIG. 2



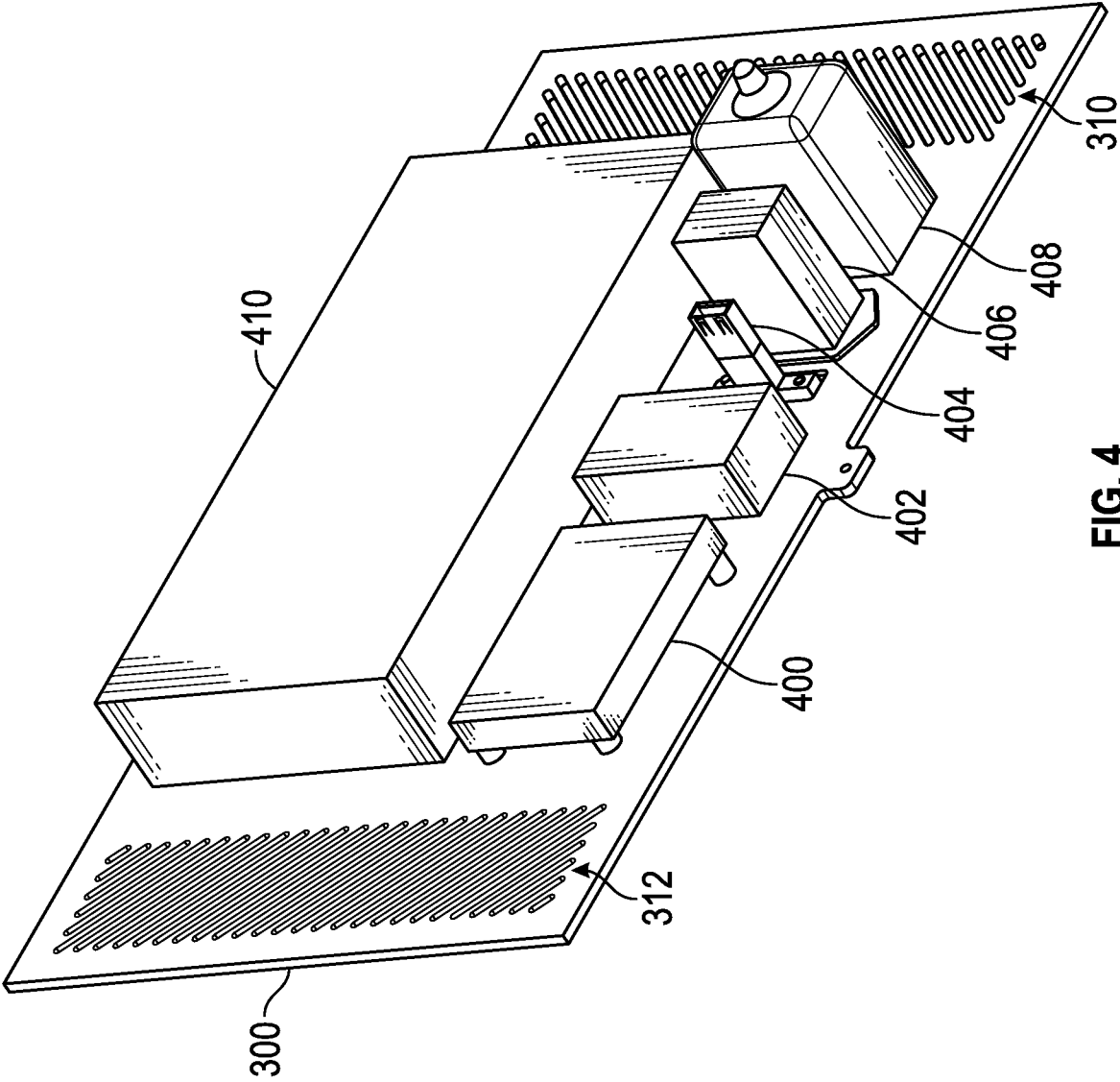


FIG. 4

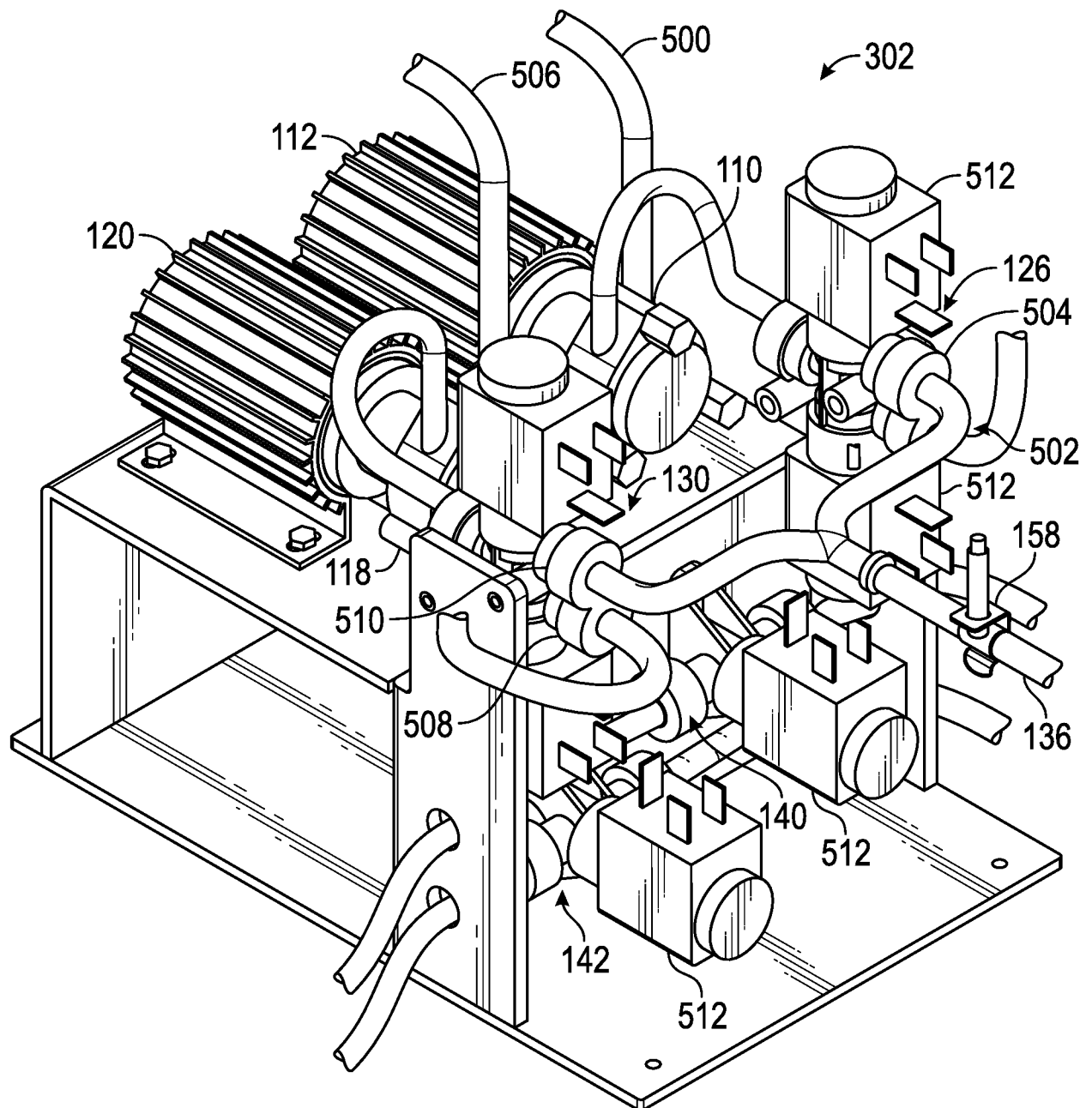


FIG. 5

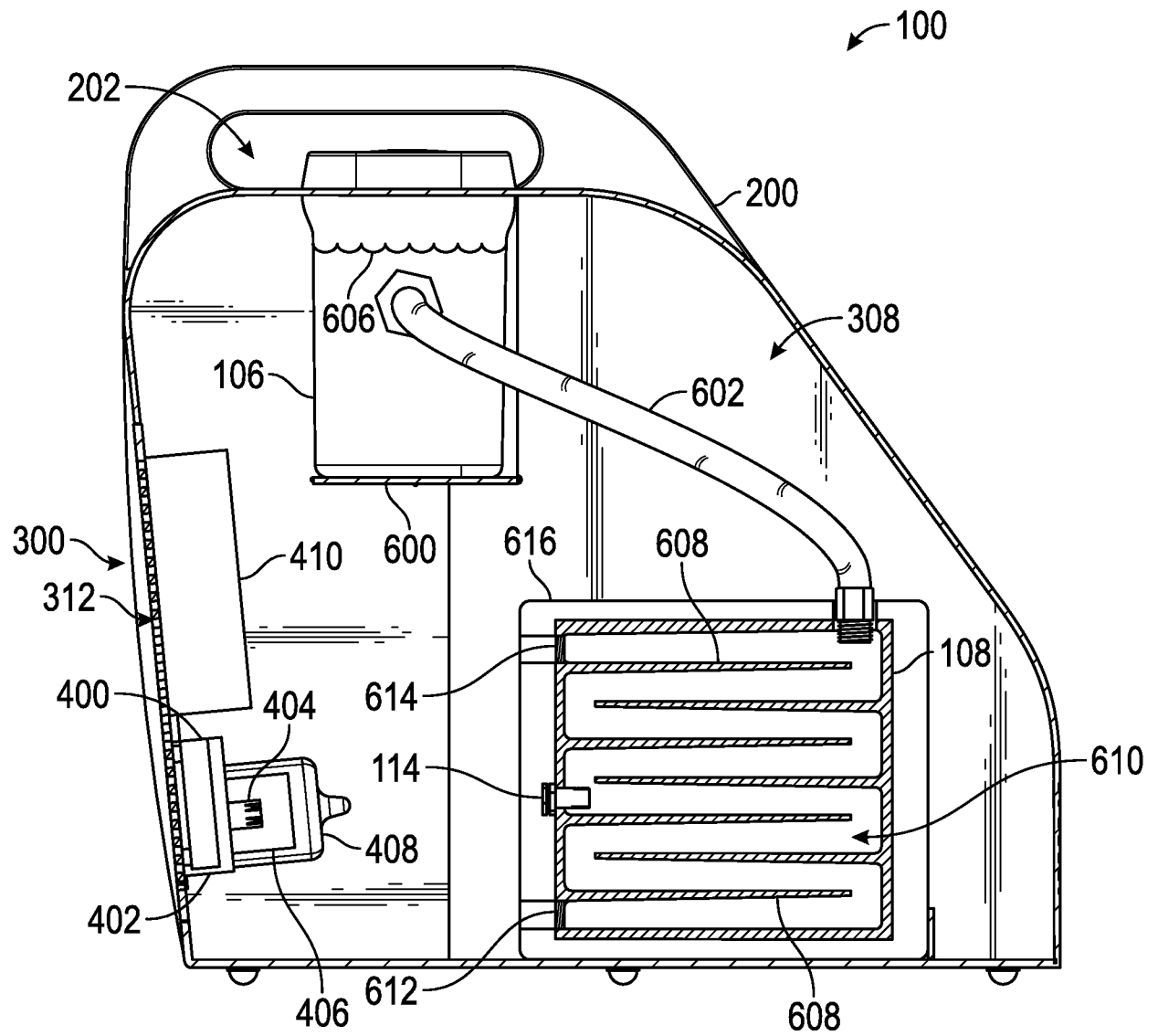


FIG. 6A

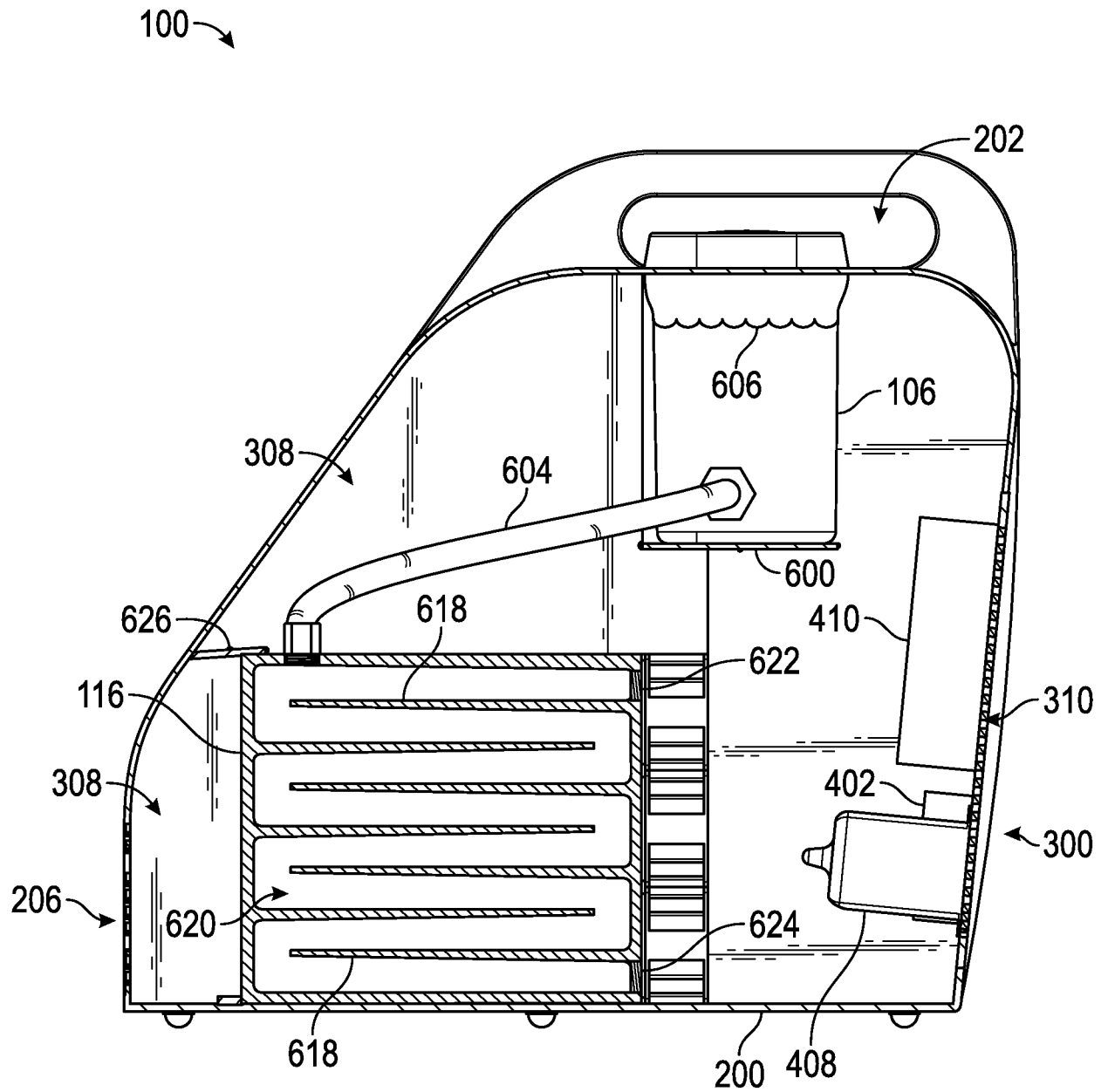
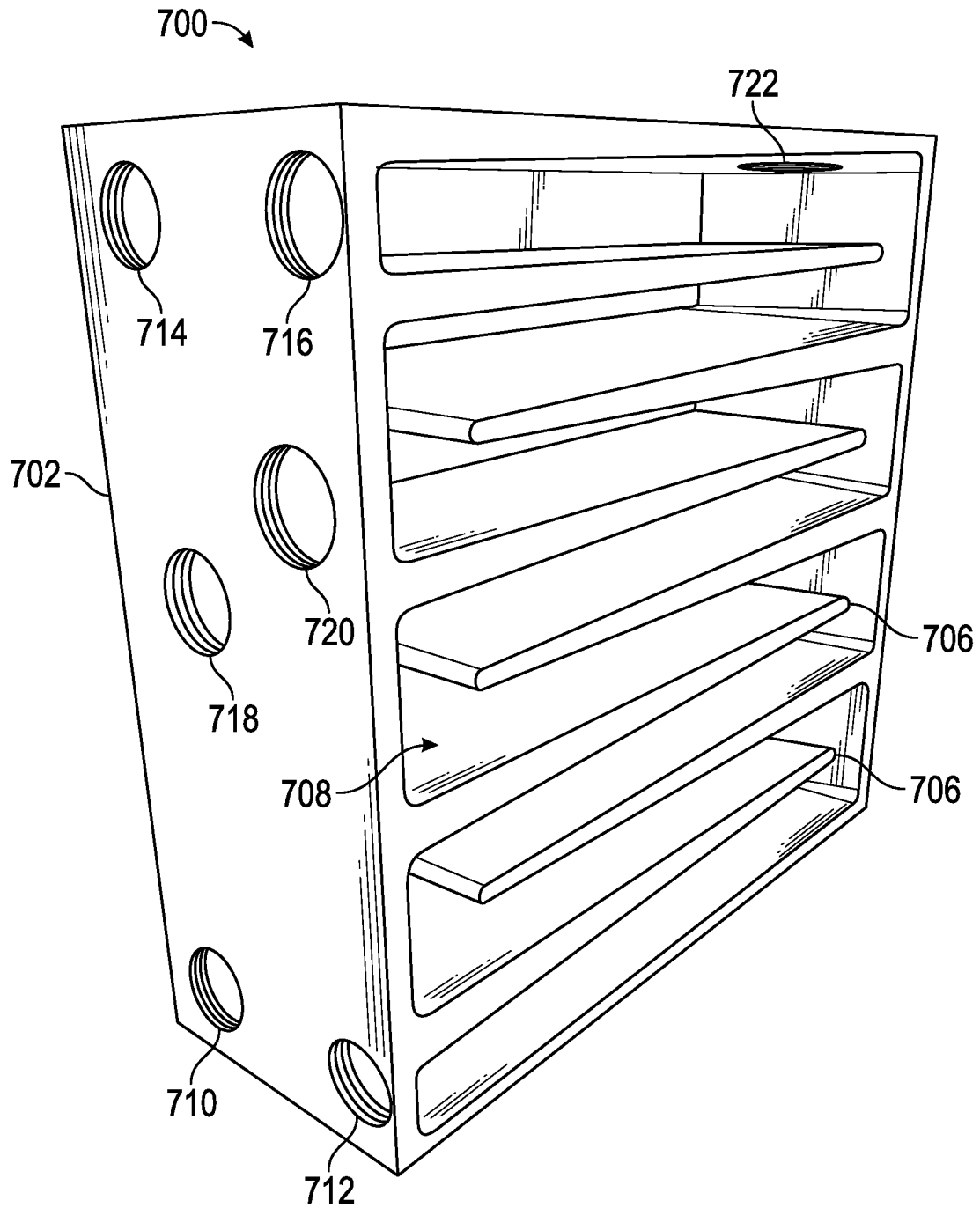


FIG. 6B

**FIG. 7A**

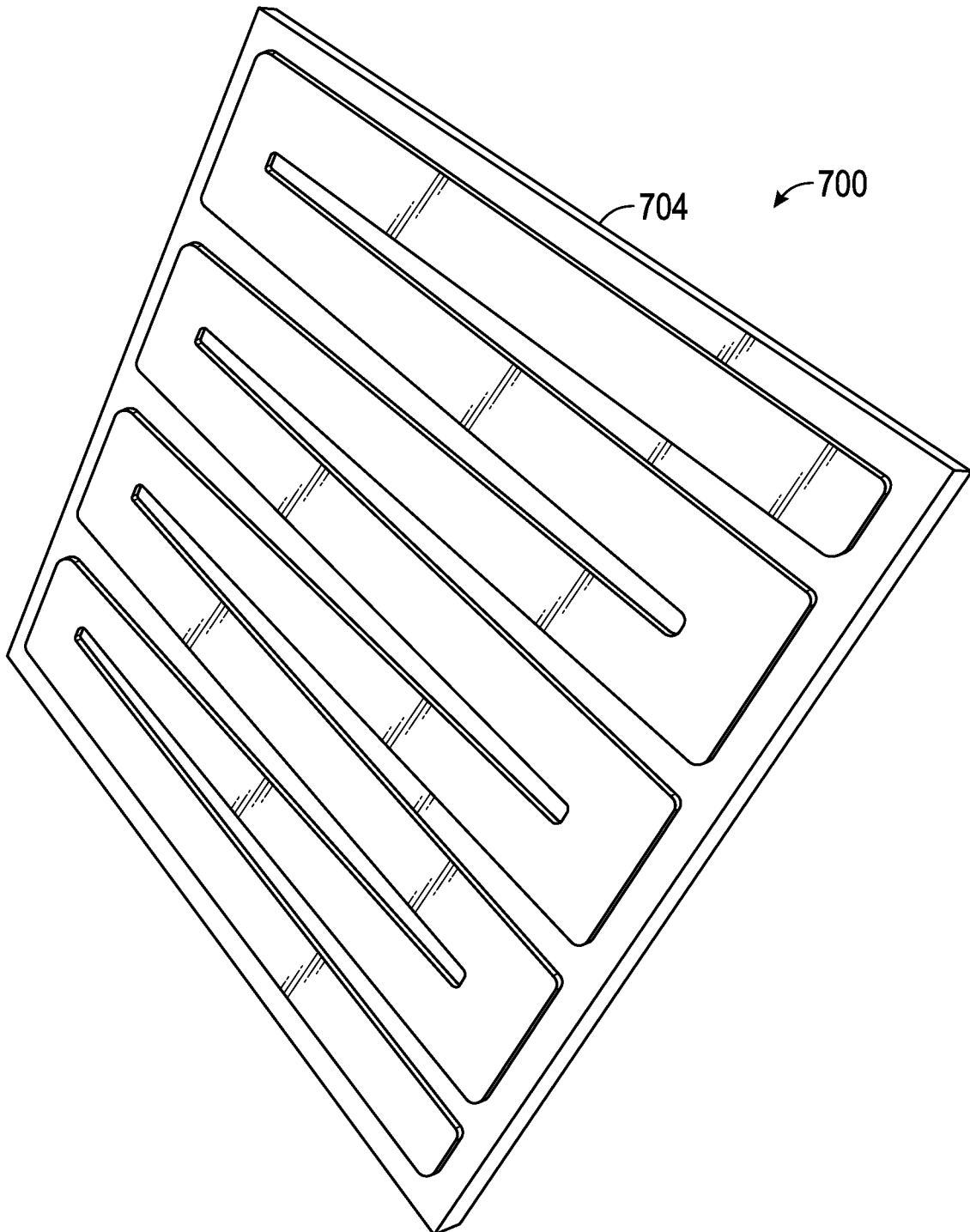


FIG. 7B

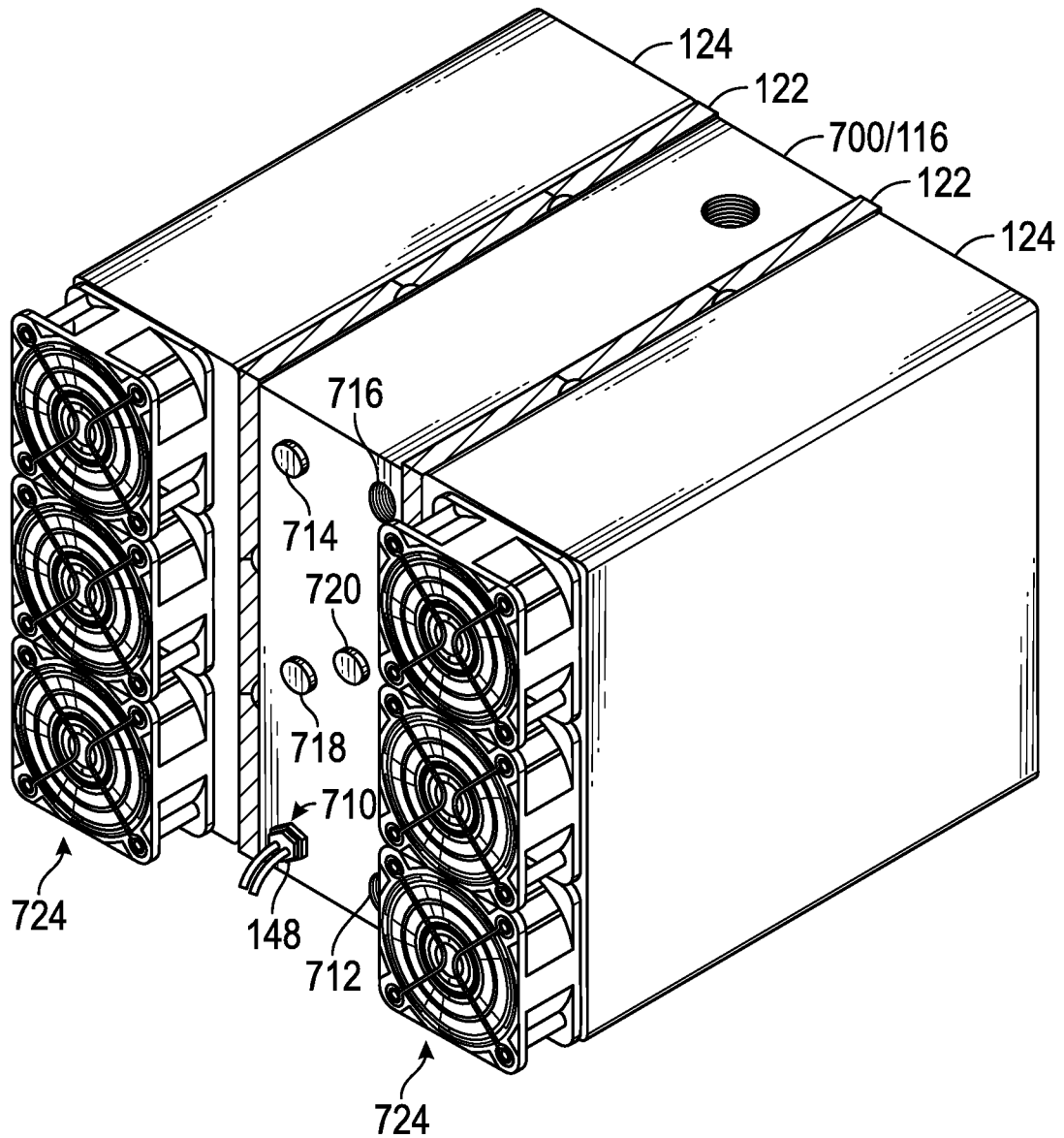


FIG. 7C

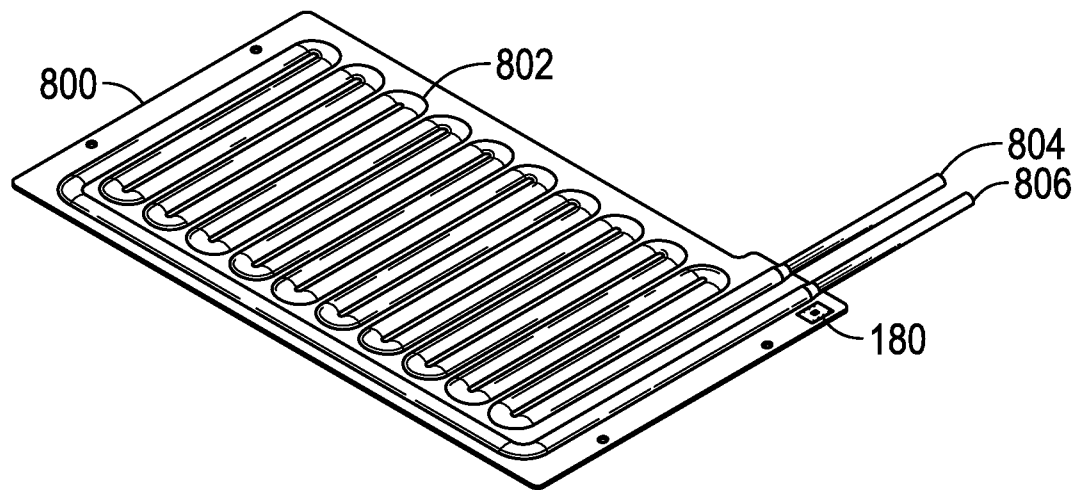


FIG. 8A

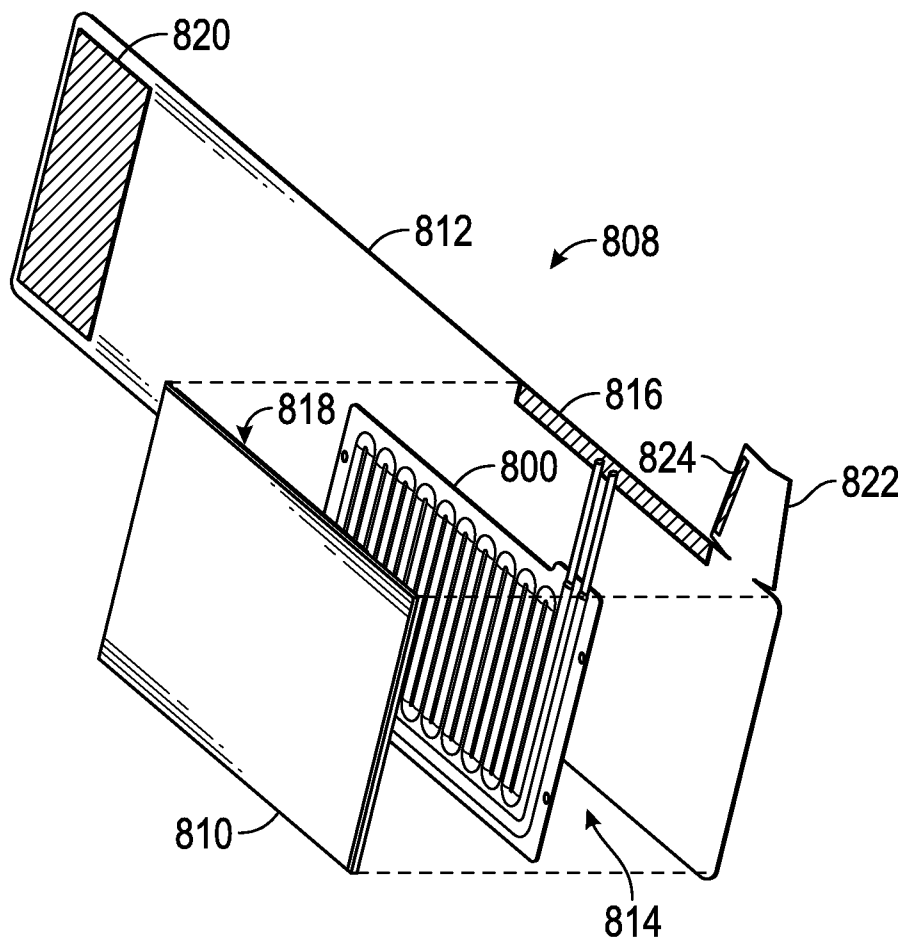


FIG. 8B

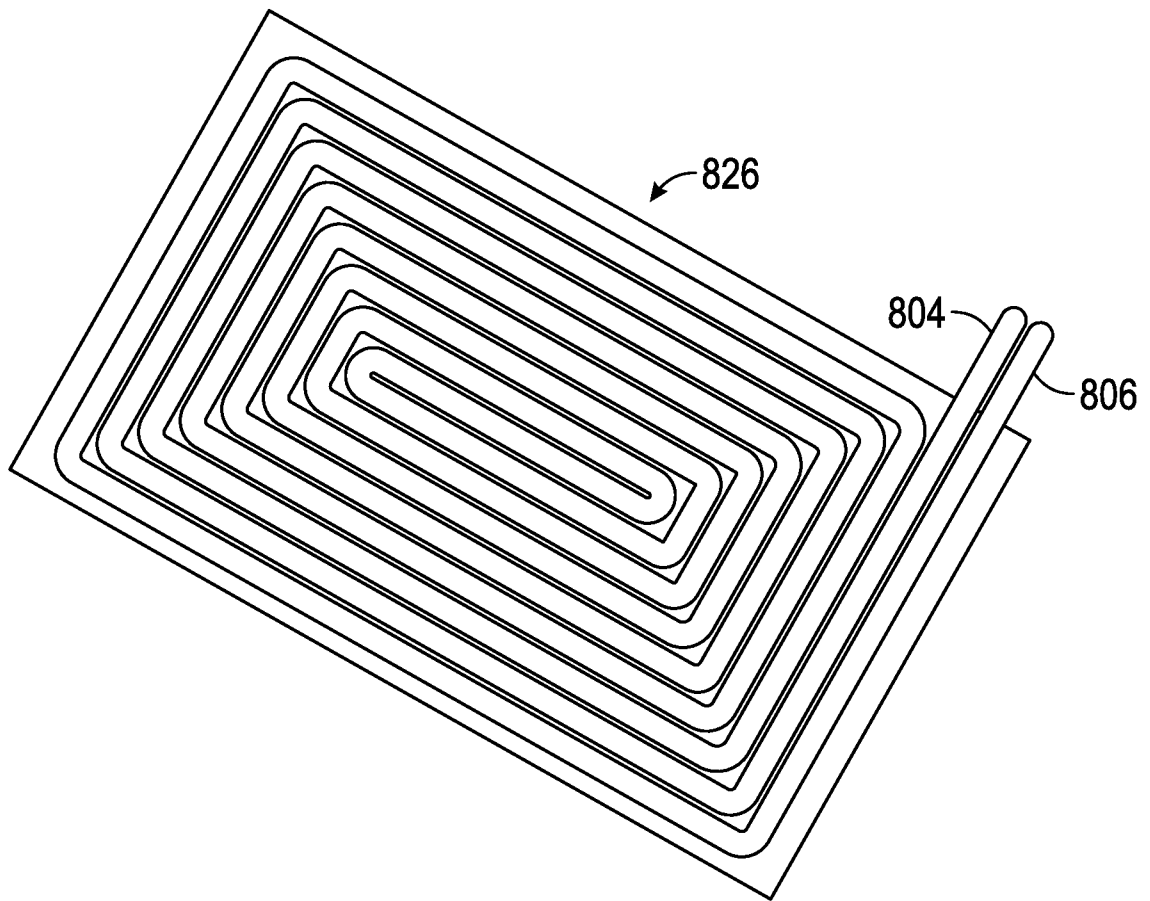


FIG. 8C

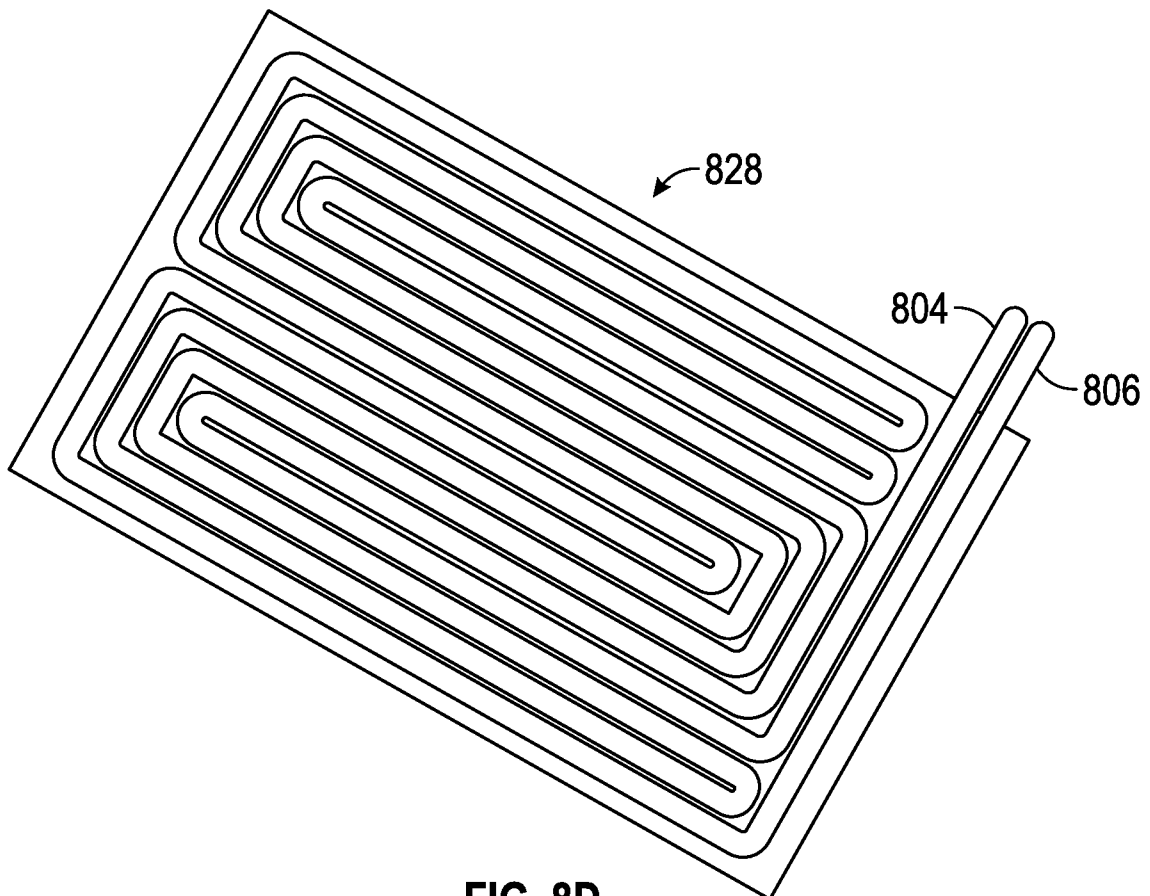


FIG. 8D

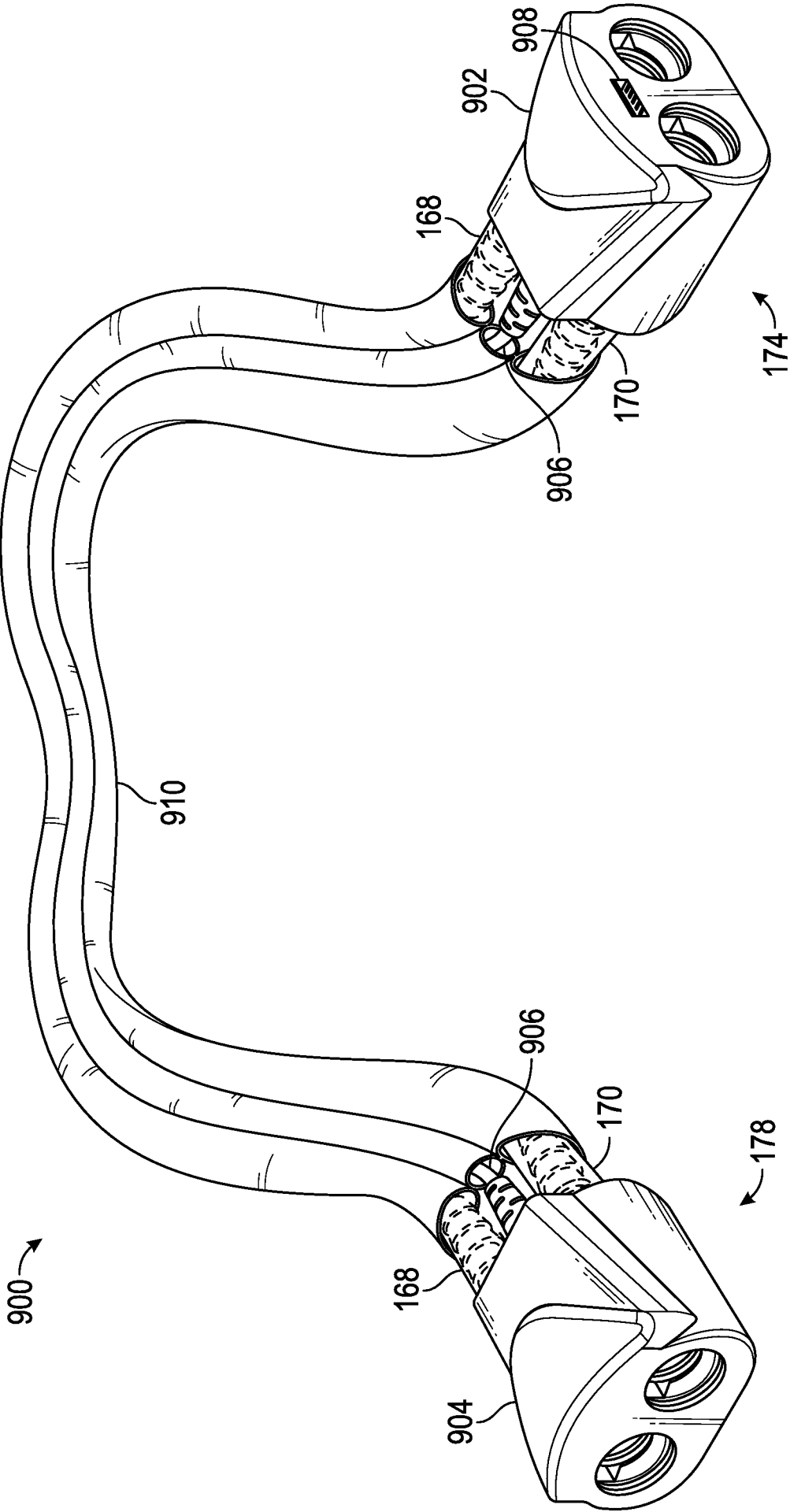


FIG. 9A

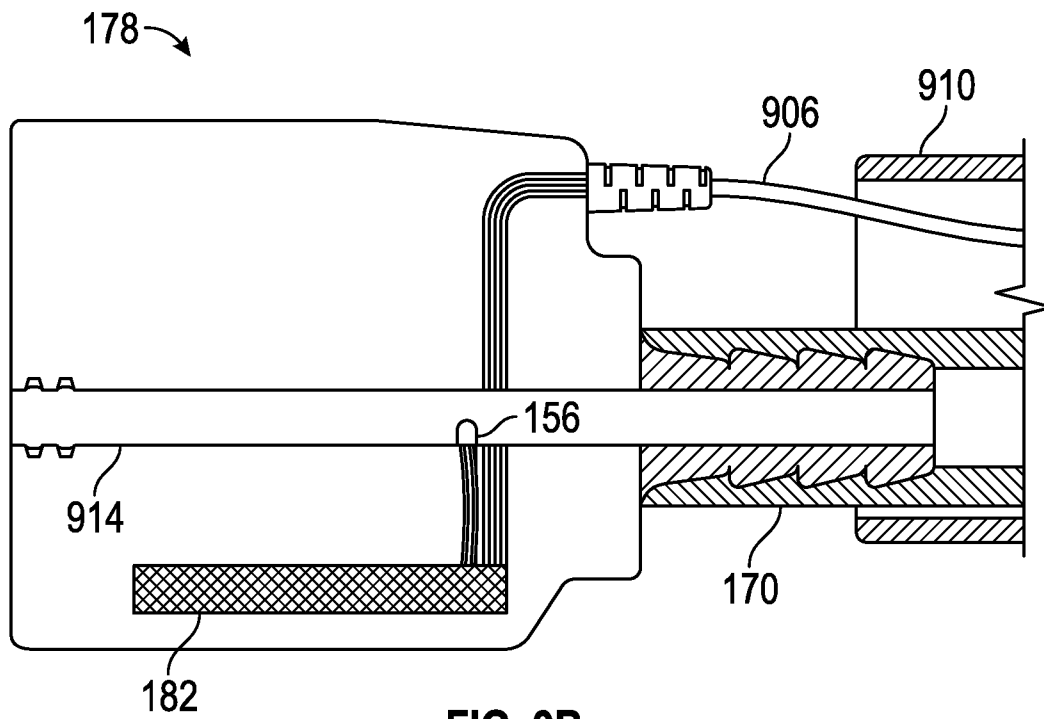


FIG. 9B

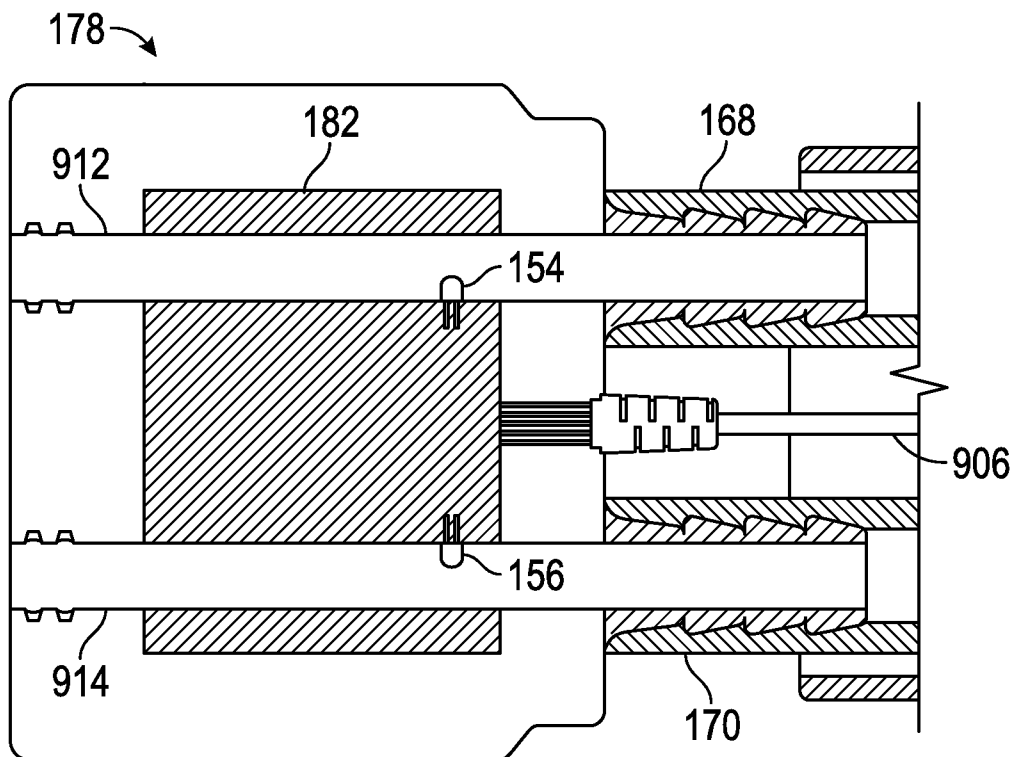


FIG. 9C

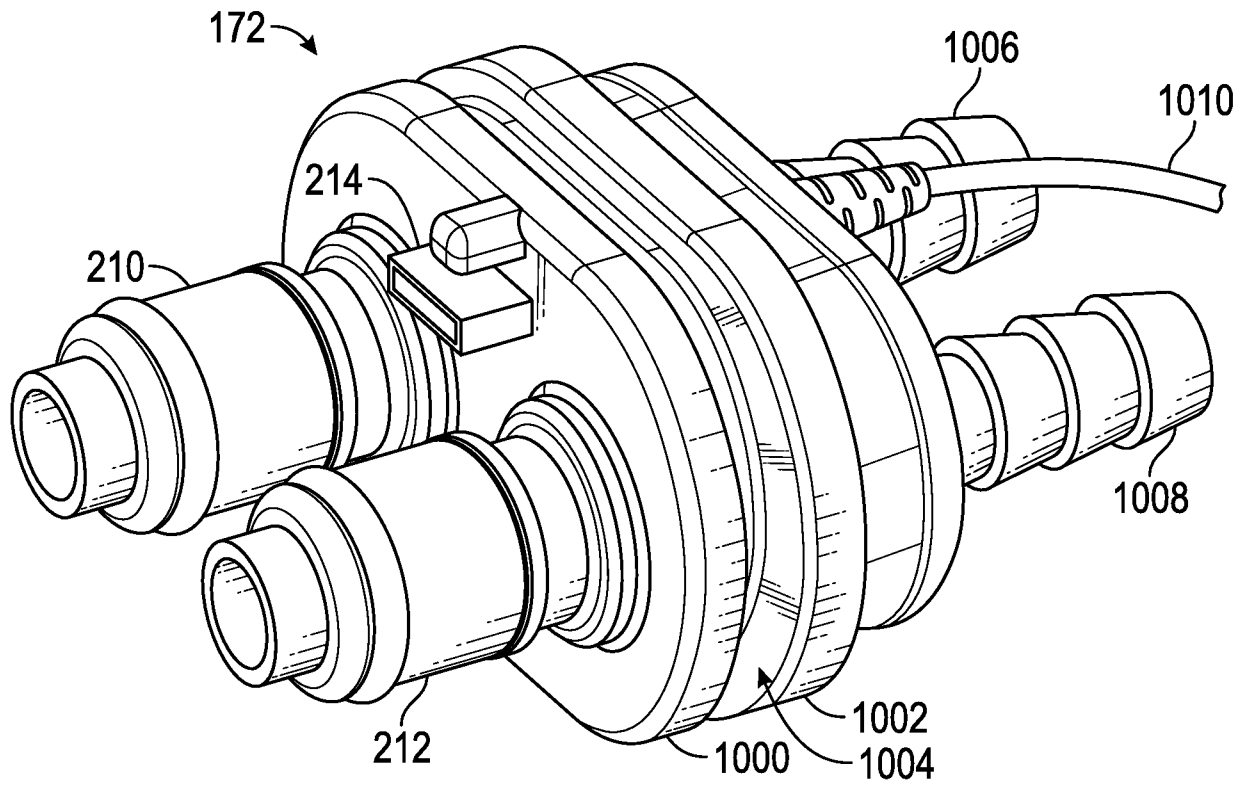


FIG. 10

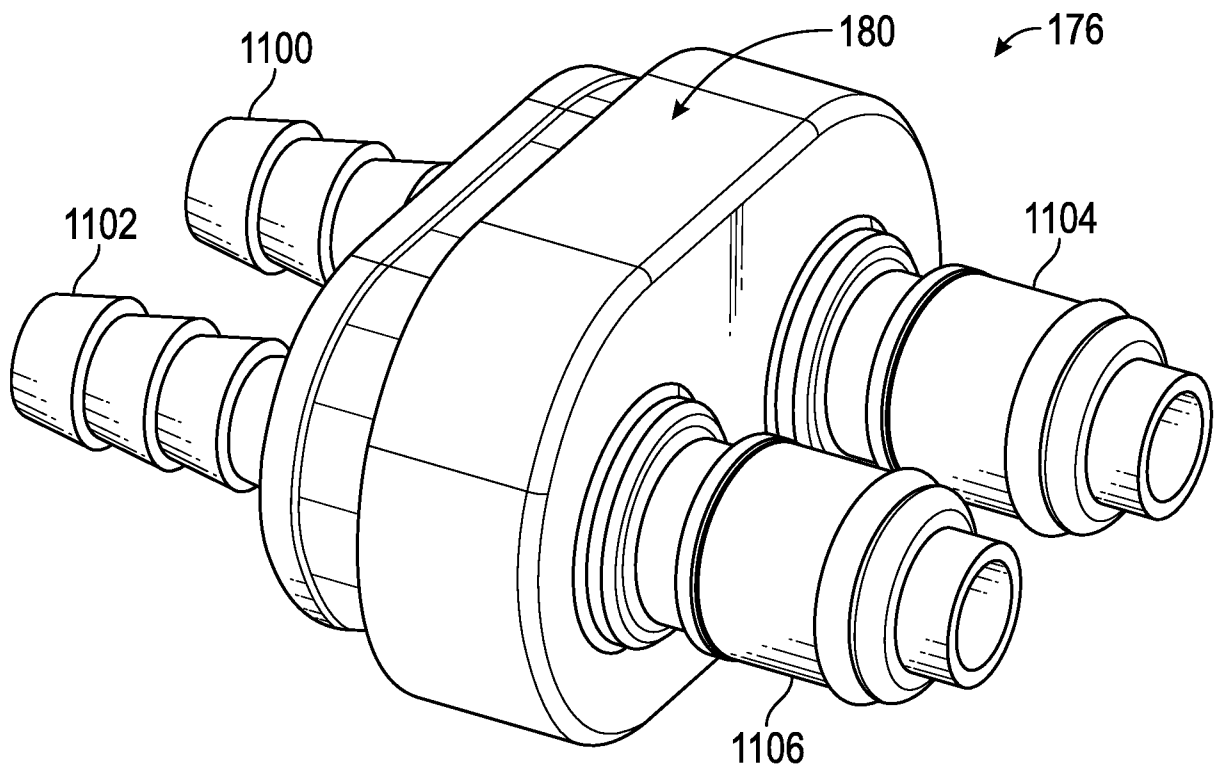


FIG. 11

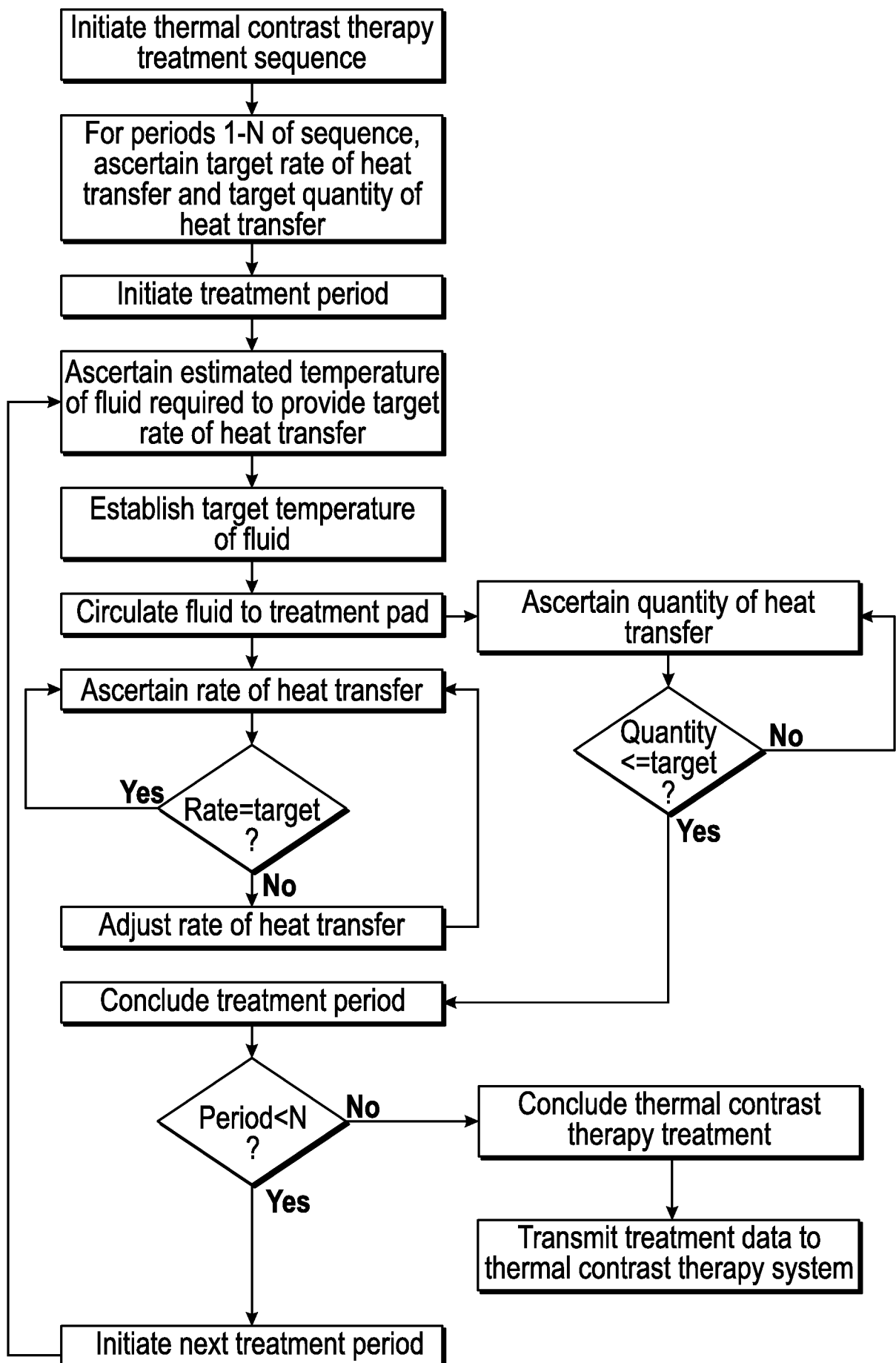


FIG. 12A

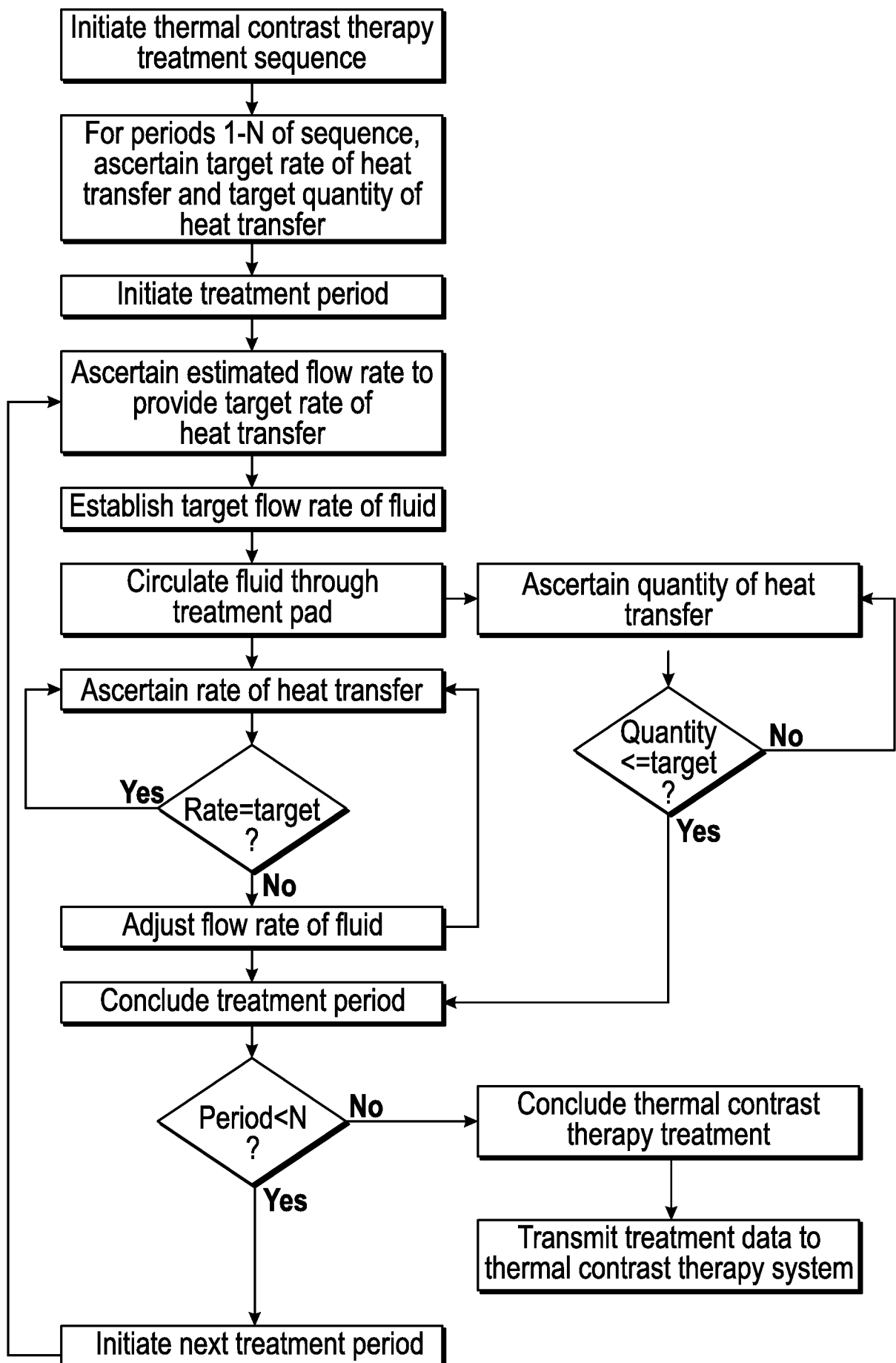


FIG. 12B

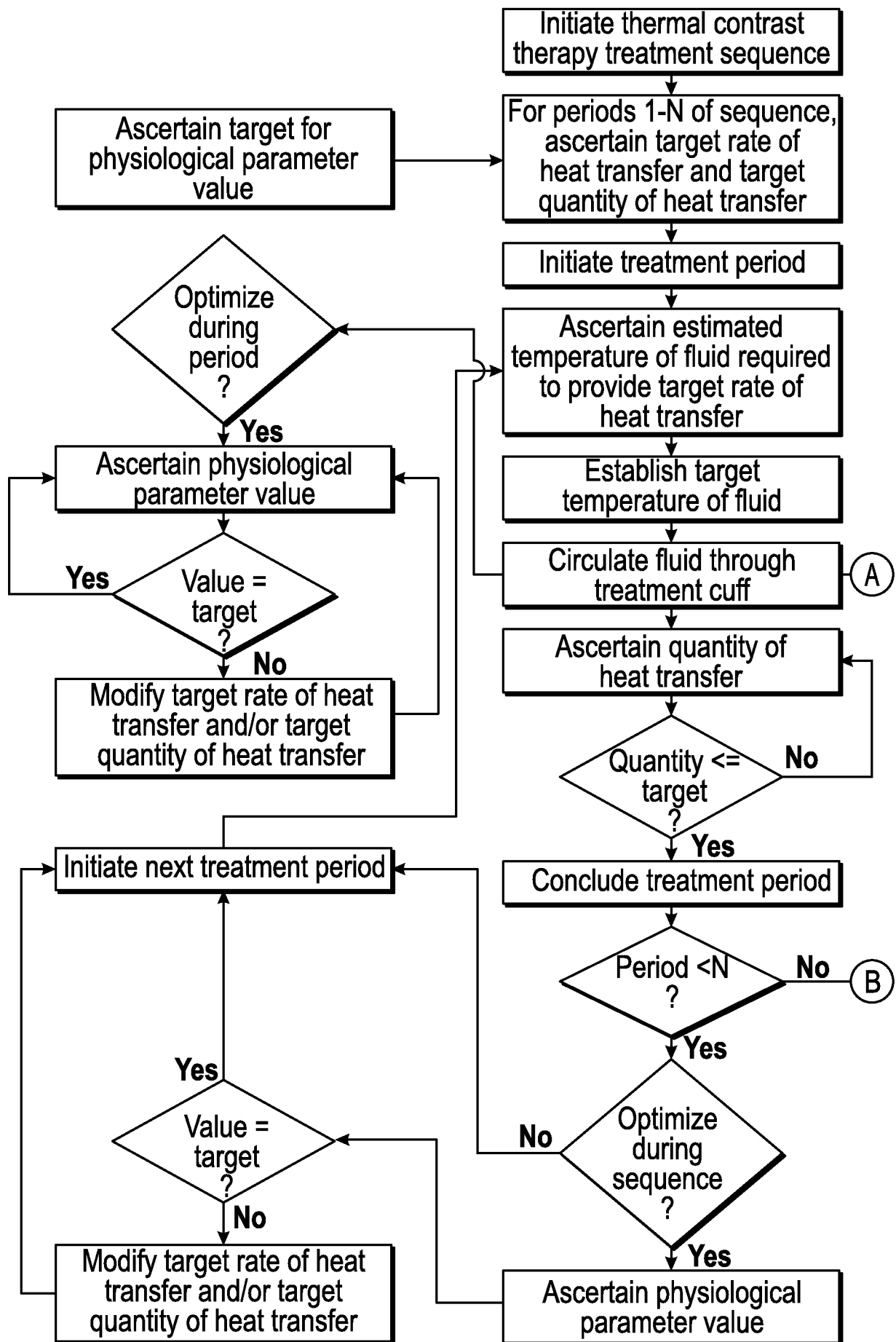


FIG. 13A

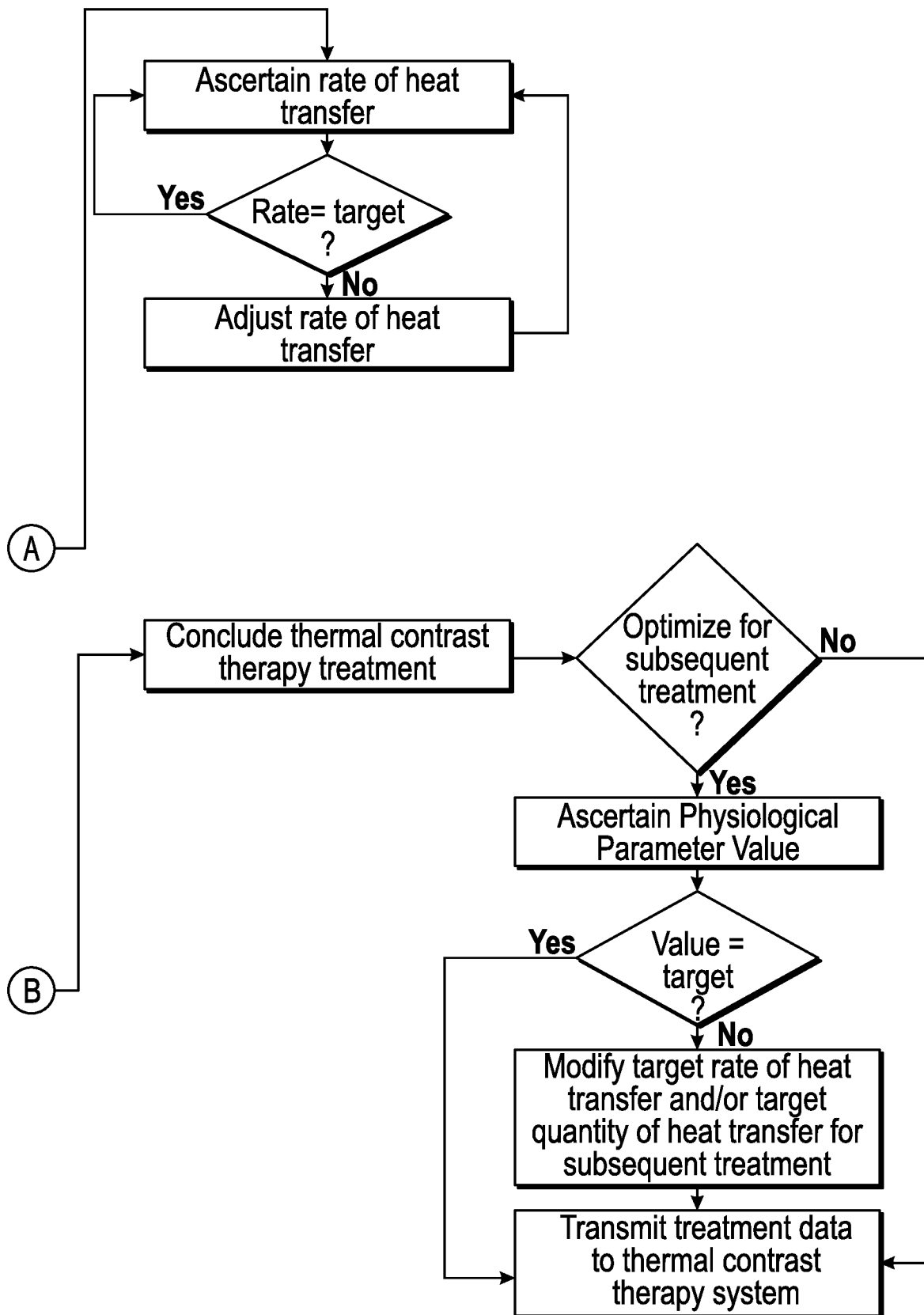


FIG. 13B

EXEMPLARY THERMAL CONTRAST THERAPY TREATMENT SEQUENCE BASED ON FLUID TEMPERATURE
Treatment: First Treatment of Athletic Injury of Knee or Elbow (Within First 24 Hours of Injury)
Patient Condition: Healthy/Strong
Desired Effect: Reduce Inflammation
Duration: 66.1 Min

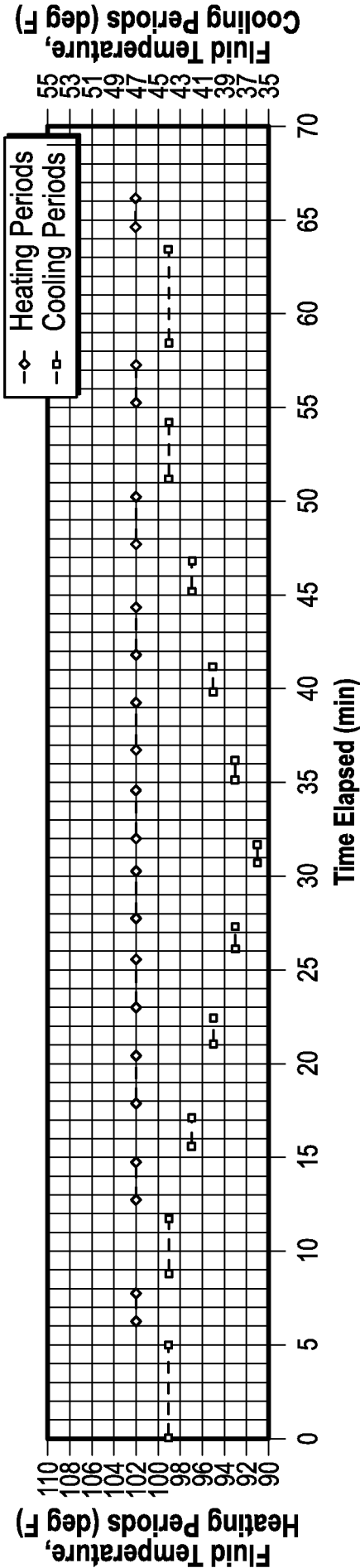


FIG. 14A-1

Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Fluid Temp (°F)	Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Fluid Temp (°F)	Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Fluid Temp (°F)
C1	0	5	5	5	44	T8	25.5	26	0.5	26		T16	44.3	45.1	0.8	45.1	
T1	5	6.2	1.2	6.2		C5	26	27.2	1.2	27.2	38	C9	45.1	46.9	1.8	46.9	42
H1	6.2	7.7	1.5	7.7	102	T9	27.2	27.7	0.5	27.7		T17	46.9	47.7	0.8	47.7	
T2	7.7	8.7	1	8.7		H5	27.7	30.2	2.5	30.2	102	H9	47.7	50.2	2.5	50.2	102
C2	8.7	11.7	3	11.7	44	T10	30.2	30.6	0.4	30.6		T18	50.2	51.2	1	51.2	
T3	11.7	12.7	1	12.7		C6	30.6	31.6	1	31.6	36	C10	51.2	54.2	3	54.2	44
H2	12.7	14.7	2	14.7	102	T11	31.6	32	0.4	32		T19	54.2	55.2	1	55.2	
T4	14.7	15.5	0.8	15.5		H6	32	34.5	2.5	34.5	102	H10	55.2	57.2	2	57.2	102
C3	15.5	17.1	1.6	17.1	42	T12	34.5	35	0.5	35		T20	57.2	58.4	1.2	58.4	
T5	17.1	17.9	0.8	17.9		C7	35	36.2	1.2	36.2	38	C11	58.2	63.4	5	63.4	44
H3	17.9	20.4	2.5	20.4	102	T13	36.2	36.7	0.5	36.7		T21	63.4	64.6	1.2	64.6	
T6	20.4	21	0.6	21		H7	36.7	39.2	2.5	39.2	102	H11	64.6	66.1	1.5	66.1	102
C4	21	22.4	1.4	22.4	40	T14	39.2	39.8	0.6	39.8							
T7	22.4	23	0.6	23		C8	39.8	41.2	1.4	41.2	40						
H4	23	25.5	2.5	25.5	102	T15	41.2	41.8	0.6	41.8							
						H8	41.8	44.3	2.5	44.3	102						

C = Cooling Period; H = Heating Period;
T = Transition Period

FIG. 14A-2

EXEMPLARY THERMAL CONTRAST THERAPY TREATMENT SEQUENCE BASED ON FLUID TEMPERATURE
Treatment: Subsequent Treatment of Athletic Injury of Knee or Elbow (After First 24 Hours of Injury)
Patient Condition: Healthy/Strong
Desired Effect: Reduce Inflammation and Increase Blood Flow
Duration: 75.3 Min

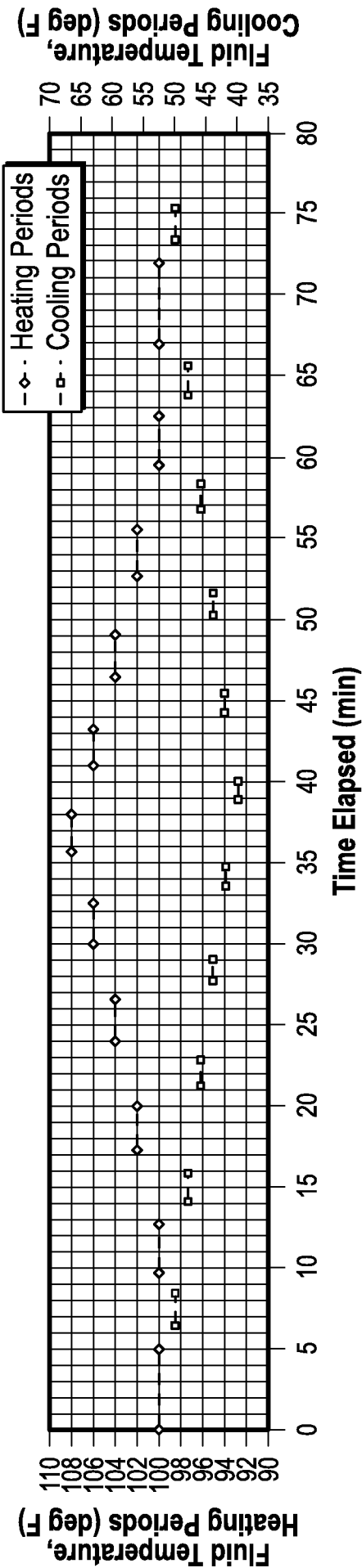


FIG. 14B-1

Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Fluid Temp (°F)	Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Fluid Temp (°F)	Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Fluid Temp (°F)
H1	0	5	5	5	100	T8	29.1	30.2	1.1	30.2	30.2	T16	51.6	52.7	1.1	52.7	
T1	5	6.4	1.4	6.4		H5	30.2	32.6	2.4	32.6	106	H9	52.7	55.5	2.8	55.5	102
C1	6.4	8.4	2	8.4	50	T9	32.6	33.6	1	33.6		T17	55.5	56.7	1.2	56.7	
T2	8.4	9.8	1.4	9.8		C5	33.6	34.8	1.2	34.8	42	C9	56.7	58.3	1.6	58.3	46
H2	9.8	12.8	3	12.8	100	T10	34.8	35.8	1	35.8		T18	58.3	59.5	1.2	59.5	
T3	12.8	14.1	1.3	14.1		H6	35.8	38	2.2	38	108	H10	59.5	62.5	3	62.5	100
C2	14.1	15.9	1.8	15.9	48	T11	38	38.9	0.9	38.9		T19	62.5	63.8	1.3	63.8	
T4	15.9	17.2	1.3	17.2		C6	38.9	40	1.1	40	40	C10	63.8	65.6	1.8	65.6	48
H3	17.2	20	2.8	20	102	T12	40	40.9	0.9	40.9		T20	65.6	66.9	1.3	66.9	
T5	20	21.2	1.2	21.2		H7	40.9	43.3	2.4	43.3	106	H11	66.9	71.9	5	71.9	100
C3	21.2	22.8	1.6	22.8	46	T13	43.3	44.3	1	44.3		T21	71.9	73.3	1.4	73.3	
T6	22.8	24	1.2	24		C7	44.3	45.5	1.2	45.5	42	C11	73.3	75.3	2	75.3	50
H4	24	26.6	2.6	26.6	104	T14	45.5	46.5	1	46.5							
T7	26.6	27.7	1.1	27.7		H8	46.5	49.1	2.6	49.1	104						
C4	27.7	29.1	1.4	29.1	44	T15	49.1	50.2	1.1	50.2							
						C8	50.2	51.6	1.4	51.6	44						

C = Cooling Period; H = Heating Period;
T = Transition Period

FIG. 14B-2

EXEMPLARY THERMAL CONTRAST THERAPY TREATMENT SEQUENCE BASED ON FLUID TEMPERATURE
Treatment: Ongoing Treatment of Athletic Injury of Knee or Elbow (After First 48 Hours of Injury)
Patient Condition: Healthy/Strong
Desired Effect: Reduce Inflammation, Increase Blood Flow, and Pain Management
Duration: 52.2 Min

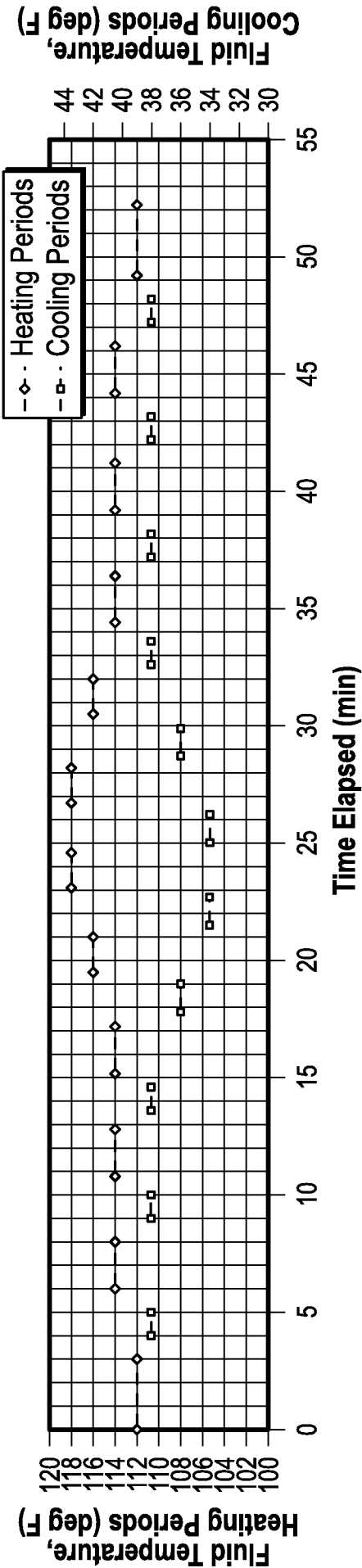


FIG. 14C-1

Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Fluid Temp (°F)	Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Fluid Temp (°F)	Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Fluid Temp (°F)
H1	0	5	3	3	112	T8	21	21.5	0.5	19.5		T16	35.6	36.4	0.8	34.4	
T1	5	6	1	4		H5	21.5	23	1.5	21	116	H9	36.4	38.4	2	36.4	114
C1	6	7	1	5	38	T9	23	23.5	0.5	21.5		T17	38.4	39.2	0.8	37.2	
T2	7	8	1	6		C5	23.5	24.7	1.2	22.7	34	C9	39.2	40.2	1	38.2	38
H2	8	10	2	8	114	T10	24.7	25.1	0.4	23.1		T18	40.2	41.2	1	39.2	
T3	10	11	1	9		H6	25.1	26.6	1.5	24.6	118	H10	41.2	43.2	2	41.2	114
C2	11	12	1	10	38	T11	26.6	27	0.4	25		T19	43.2	44.2	1	42.2	
T4	12	12.8	0.8	10.8		C6	27	28.2	1.2	26.2	34	C10	44.2	45.2	1	43.2	38
H3	12.8	14.8	2	12.8	114	T12	28.2	28.7	0.5	26.7		T20	45.2	46.2	1	44.2	
T5	14.8	15.6	0.8	13.6		H7	28.7	30.2	1.5	28.2	118	H11	46.2	48.2	2	46.2	114
C3	15.6	16.6	1	14.6	38	T13	30.2	30.7	0.5	28.7		T21	48.2	49.2	1	47.2	
T6	16.6	17.2	0.6	15.2		C7	30.7	31.9	1.2	29.9	36	C11	49.2	50.2	1	48.2	38
H4	17.2	19.2	2	17.2	114	T14	31.9	32.5	0.6	30.5		T22	50.2	51.2	1	49.2	
T7	19.2	19.8	0.6	17.8		H8	32.5	34	1.5	32	116	H12	51.2	54.2	3	52.2	112
C4	19.8	21	1.2	19	36	T15	34	34.6	0.6	32.6							
						C8	34.6	35.6	1	33.6	38						

C = Cooling Period; H = Heating Period;
T = Transition Period

FIG. 14C-2

EXEMPLARY THERMAL CONTRAST THERAPY TREATMENT SEQUENCE BASED ON FLUID TEMPERATURE
Treatment: Ongoing Treatment of Gangrene Below the Knee
Patient Condition: Elderly
Desired Effect: Increase Blood Flow, Revitalize Tissue
Duration: 59 Min

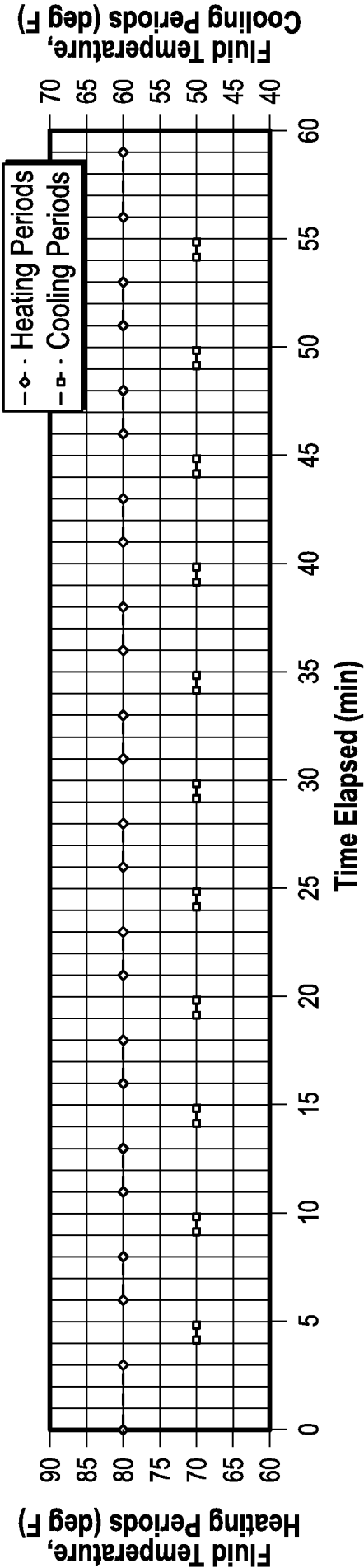


FIG. 14D-1

Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Fluid Temp (°F)	Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Fluid Temp (°F)	Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Fluid Temp (°F)
						T8	21.8	23	1.2	21		T16	41.8	43	1.2	41	
H1	0	5	3	3	80	H5	23	25	2	23	80	H9	43	45	2	43	80
T1	5	6.2	1.2	4.2		T9	25	26.2	1.2	24.2		T17	45	46.2	1.2	44.2	
C1	6.2	6.8	0.6	4.8	50	C5	26.2	26.8	0.6	24.8	50	C9	46.2	46.8	0.6	44.8	50
T2	6.8	8	1.2	6		T10	26.8	28	1.2	26		T18	46.8	48	1.2	46	
H2	8	10	2	8	80	H6	28	30	2	28	80	H10	48	50	2	48	80
T3	10	11.2	1.2	9.2		T11	30	31.2	1.2	29.2		T19	50	51.2	1.2	49.2	
C2	11.2	11.8	0.6	9.8	50	C6	31.2	31.8	0.6	29.8	50	C10	51.2	51.8	0.6	49.8	50
T4	11.8	13	1.2	11		T12	31.8	33	1.2	31		T20	51.8	53	1.2	51	
H3	13	15	2	13	80	H7	33	35	2	33	80	H11	53	55	2	53	80
T5	15	16.2	1.2	14.2		T13	35	36.2	1.2	34.2		T21	55	56.2	1.2	54.2	
C3	16.2	16.8	0.6	14.8	50	C7	36.2	36.8	0.6	34.8	50	C11	56.2	56.8	0.6	54.8	50
T6	16.8	18	1.2	16		T14	36.8	38	1.2	36		T22	56.8	58	1.2	56	
H4	18	20	2	18	80	H8	38	40	2	38	80	H12	58	61	3	59	80
T7	20	21.2	1.2	19.2		T15	40	41.2	1.2	39.2		C = Cooling Period; H = Heating Period; T = Transition Period					
C4	21.2	21.8	0.6	19.8	50	C8	41.2	41.8	0.6	39.8	50						

FIG. 14D-2

EXEMPLARY THERMAL CONTRAST THERAPY TREATMENT SEQUENCE BASED ON DESIRED MEASURE OF HEAT TRANSFER
Treatment: First Treatment of Athletic Injury of Knee or Elbow (Within First 24 Hours of Injury)
Patient Condition: Healthy/Strong
Desired Effect: Reduce Inflammation
Duration: 66.1 Min

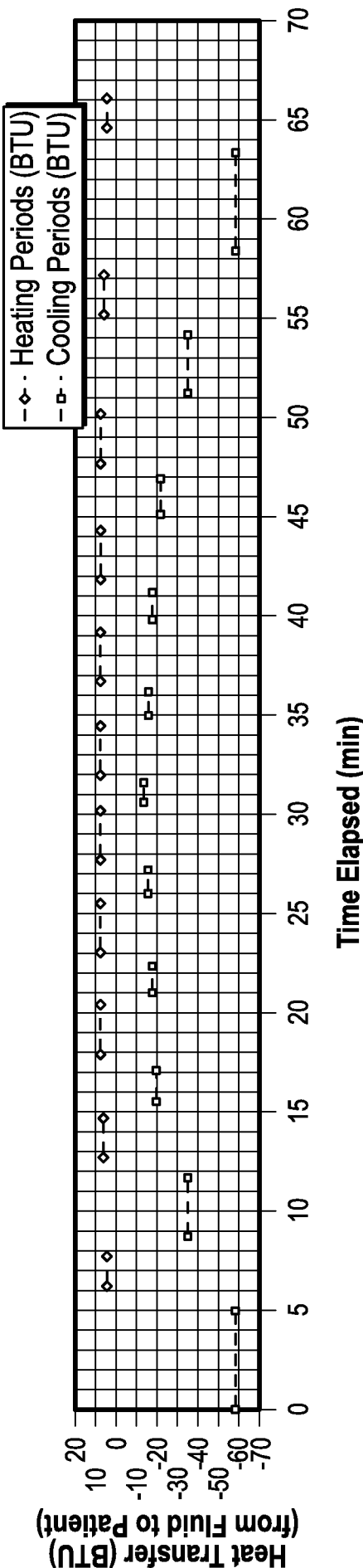
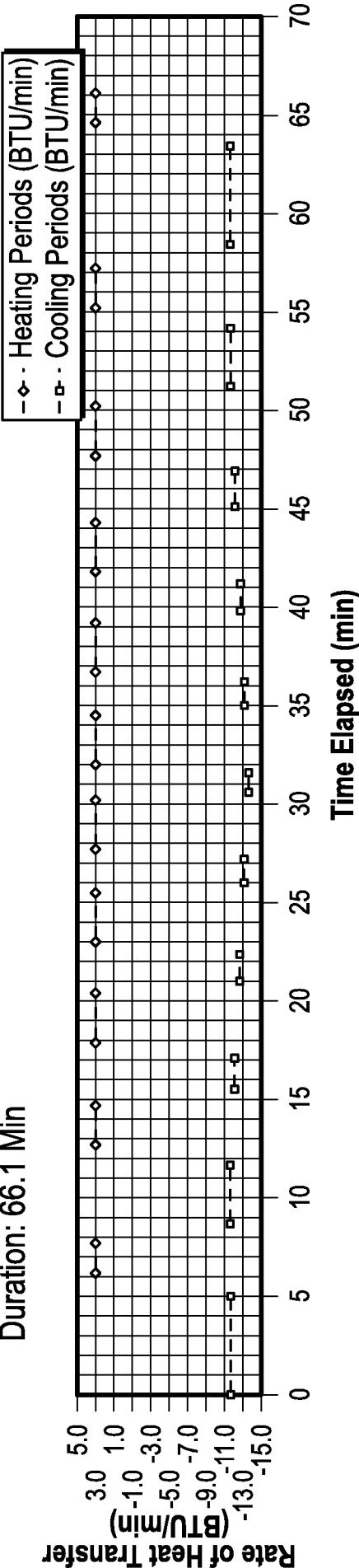


FIG. 14E-1

[illegible]

FIG. 14E-2

EXEMPLARY THERMAL CONTRAST THERAPY TREATMENT SEQUENCE BASED ON DESIRED MEASURE OF HEAT TRANSFER
Treatment: Subsequent Treatment of Athletic Injury of Knee or Elbow (After First 24 Hours of Injury)
Patient Condition: Healthy/Strong
Desired Effect: Reduce Inflammation and Increase Blood Flow
Duration: 75.3 Min

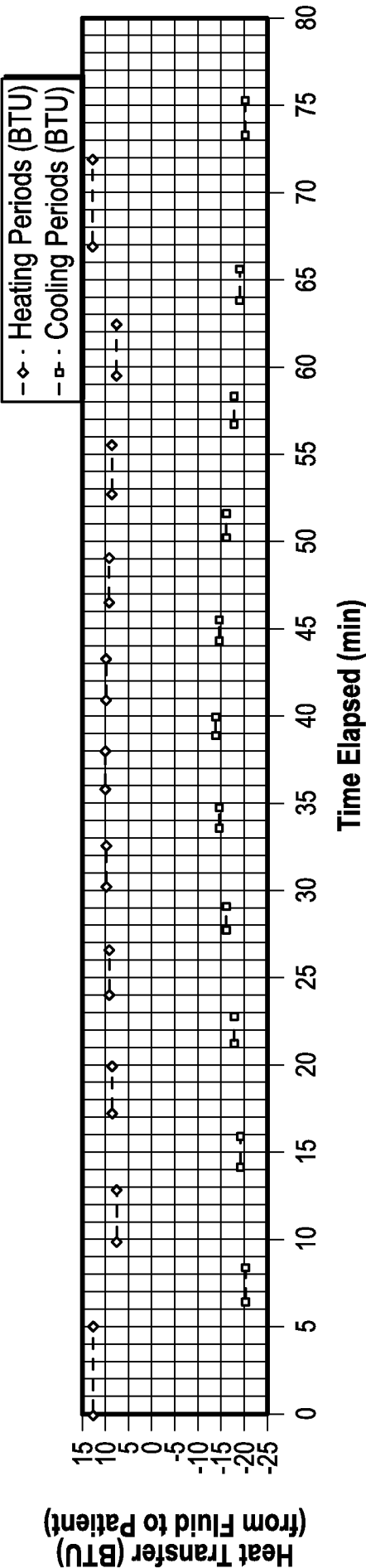
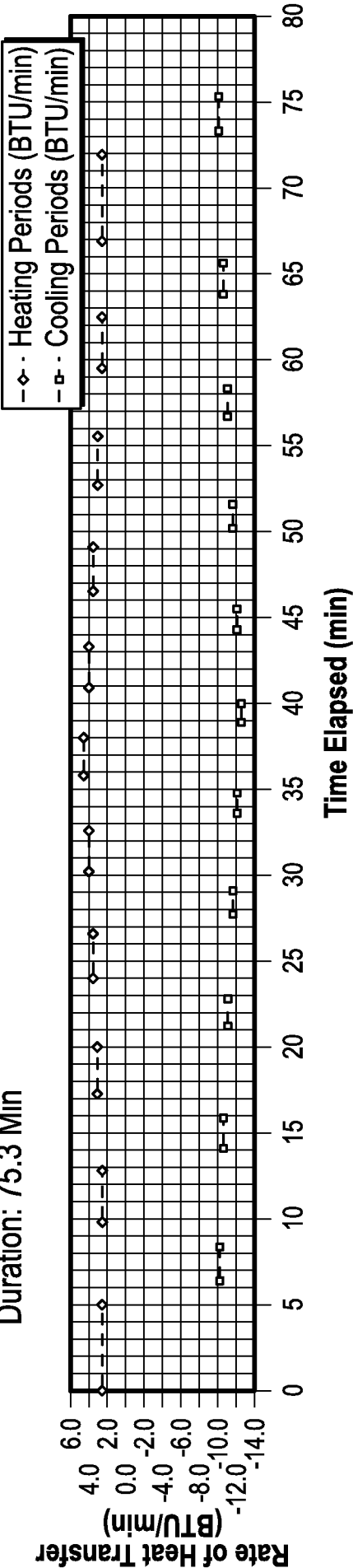


FIG. 14F-1

Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Rate of Heat Transfer (BTU)	Total Heat Transfer (BTU)	Period	Start Time (min)	End Time (min)	Duration (min)	Time Elapsed (min)	Rate of Heat Transfer (BTU)	Total Heat Transfer (BTU)
H1	0	5	5	5	2.5	12.7	T8	29.1	30.2	1.1	30.2	4.0	9.7
T1	5	6.4	1.4	6.4			H5	30.2	32.6	2.4	32.6	4.0	9.7
C1	6.4	8.4	2	8.4	-10.2	-20.3	T9	32.6	33.6	1	33.6		
T2	8.4	9.8	1.4	9.8			C5	33.6	34.8	1.2	34.8	-12.2	-14.6
H2	9.8	12.8	3	12.8	2.5	7.6	T10	34.8	35.8	1	35.8		
T3	12.8	14.1	1.3	14.1			H6	35.8	38	2.2	38	4.5	10
C2	14.1	15.9	1.8	15.9	-10.7	-19.2	T11	38	38.9	0.9	38.9		
T4	15.9	17.2	1.3	17.2			C6	38.9	40	1.1	40	-12.6	-13.9
H3	17.2	20	2.8	20	3.0	8.5	T12	40	40.9	0.9	40.9		
T5	20	21.2	1.2	21.2			H7	40.9	43.3	2.4	43.3	4.0	9.7
C3	21.2	22.8	1.6	22.8	-11.2	-17.9	T13	43.3	44.3	1	44.3		
T6	22.8	24	1.2	24			C7	44.3	45.5	1.2	45.5	-12.2	-14.6
H4	24	26.6	2.6	26.6	3.5	9.2	T14	45.5	46.5	1	46.5		
T7	26.6	27.7	1.1	27.7			H8	46.5	49.1	2.6	49.1	3.5	9.2
C4	27.7	29.1	1.4	29.1	-11.6	-16.3	T15	49.1	50.2	1.1	50.2		
							C8	50.2	51.6	1.4	51.6	-11.6	-16.3
							T16	51.6	52.7	1.1	52.7		
							H9	52.7	55.5	2.8	55.5	3.0	8.5
							T17	55.5	56.7	1.2	56.7		
							C9	56.7	58.3	1.6	58.3	-11.2	-17.9
							T18	58.3	59.5	1.2	59.5		
							H10	59.5	62.5	3	62.5	2.5	7.6
							T19	62.5	63.8	1.3	63.8		
							C10	63.8	65.6	1.8	65.6	-10.7	-19.2
							T20	65.6	66.9	1.3	66.9		
							H11	66.9	71.9	5	71.9	2.5	12.7
							T21	71.9	73.3	1.4	73.3		
							C11	73.3	75.3	2	75.3	-10.2	-20.3

C = Cooling Period; H = Heating Period;
T = Transition Period

FIG. 14F-2

EXEMPLARY THERMAL CONTRAST THERAPY TREATMENT SEQUENCE BASED ON DESIRED MEASURE OF HEAT TRANSFER
Treatment: Ongoing Treatment of Athletic Injury of Knee or Elbow (After First 48 Hours of Injury)
Patient Condition: Healthy/Strong
Desired Effect: Reduce Inflammation, Increase Blood Flow, and Pain Management
Duration: 52.2 Min

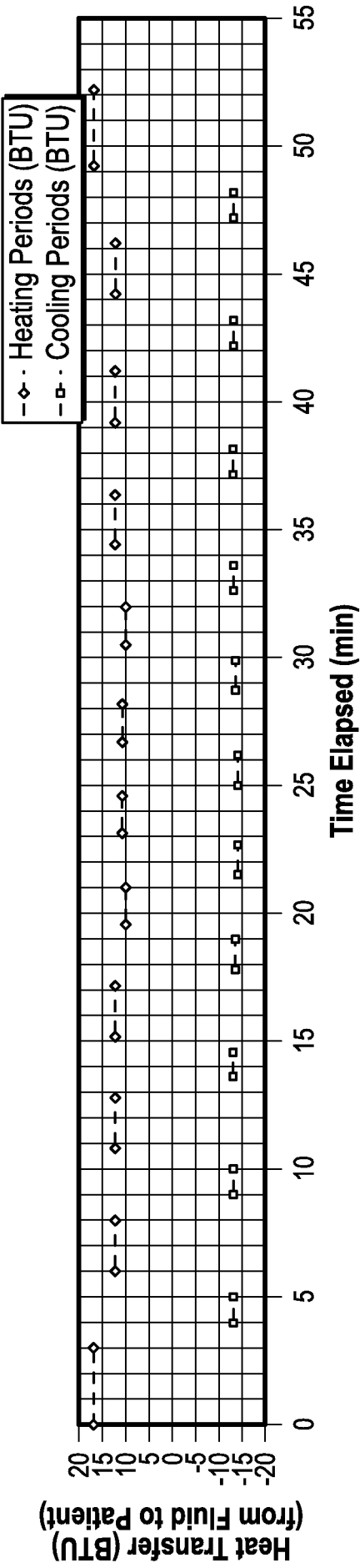
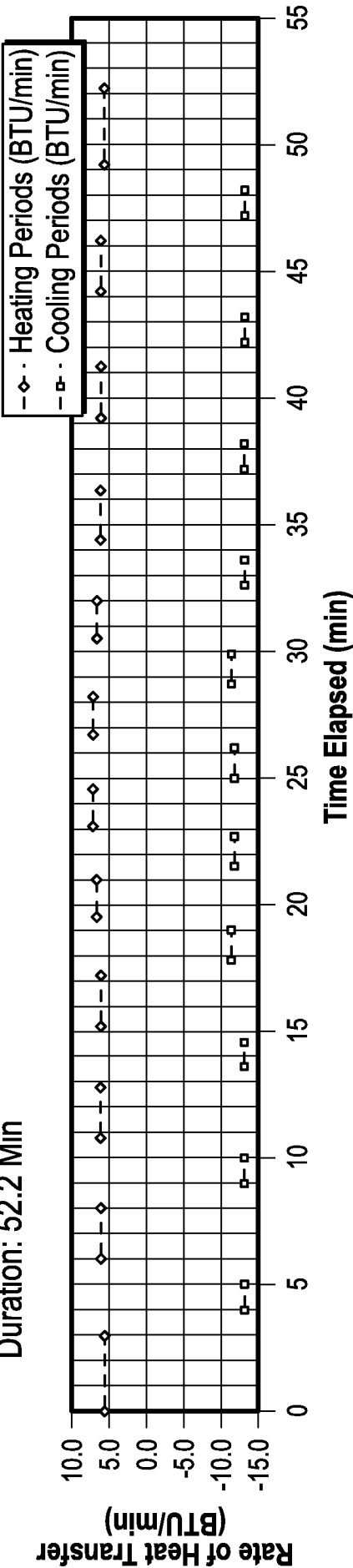


FIG. 14G-1

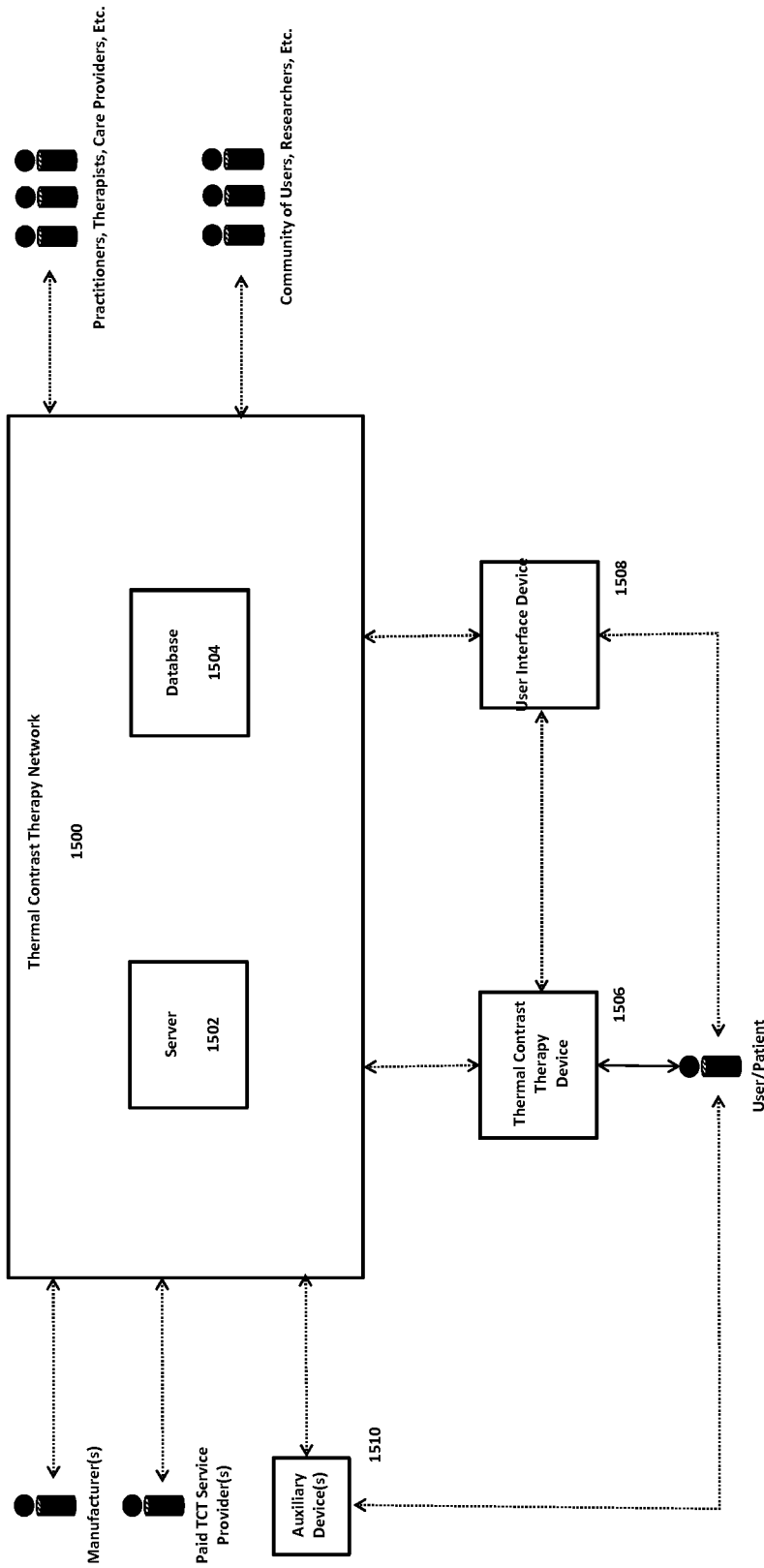


FIG. 15

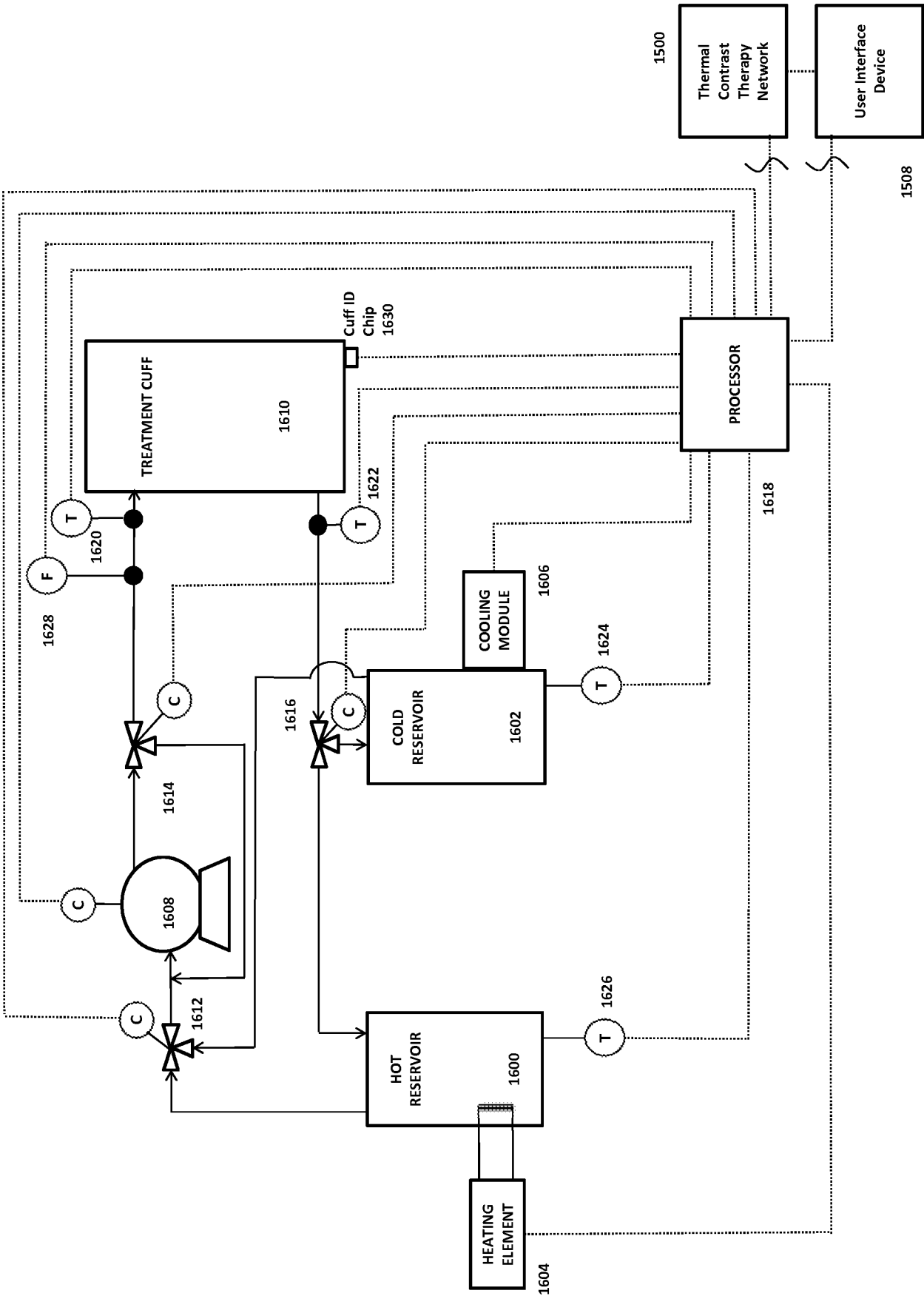


FIG. 16A

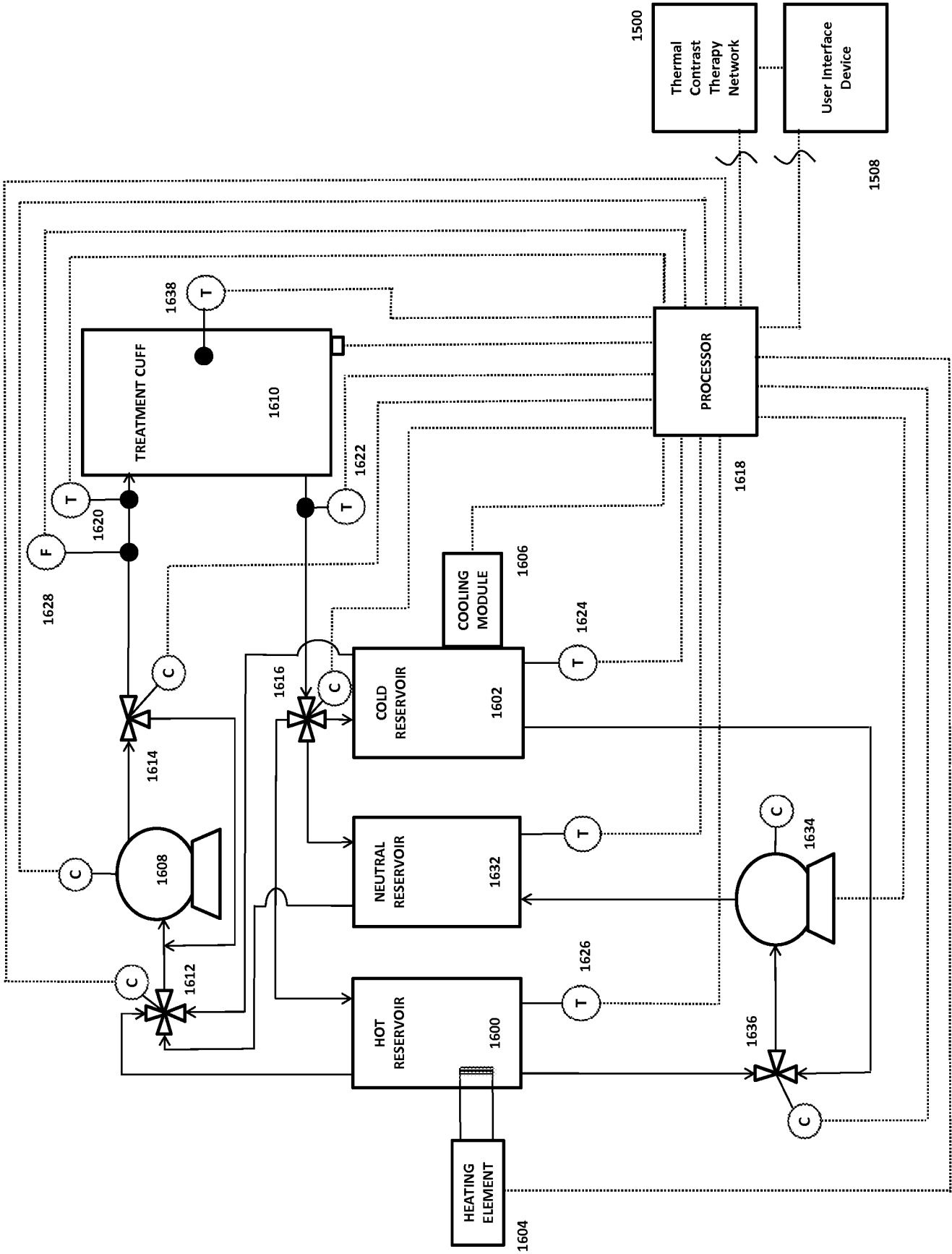


FIG. 16B

PATIENT PROFILE PAGE:ID NUMBER: ASSIGN:YOB: USERNAME: HEIGHT: PASSWORD: WEIGHT: SEX: GENERAL CONDITION (1-10):

DESCRIPTION OF AILMENT OR INJURY:

THERMAL CONTRAST THERAPY TREATMENT PRESCRIPTIONS:TREATMENT SEQUENCE: FREQUENCY OF TREATMENT: DURATION OF TREATMENT: **EXISTING CONDITIONS:**HEART: EPILEPSY OR SEIZURES: ABNORMAL BLOOD PRESSURE: STROKE: DIABETES: PREGNANT: ARTHRITIS: LUNG DISEASE OR TUBERCULOSIS: MIGRAINES: KIDNEY/BLADDER PROBLEMS: ASTHMA: ULCERS OR INTESTINAL CONDITIONS: GLAUCOMA: FAINTING: ANEMIA: OTHER: **CURRENT MEDICATIONS:**

FIG. 17

TREATMENT PROVIDER USER MODE:**TREATMENT PROVIDER'S NAME: DR. JONES**

(SELECT ONE)

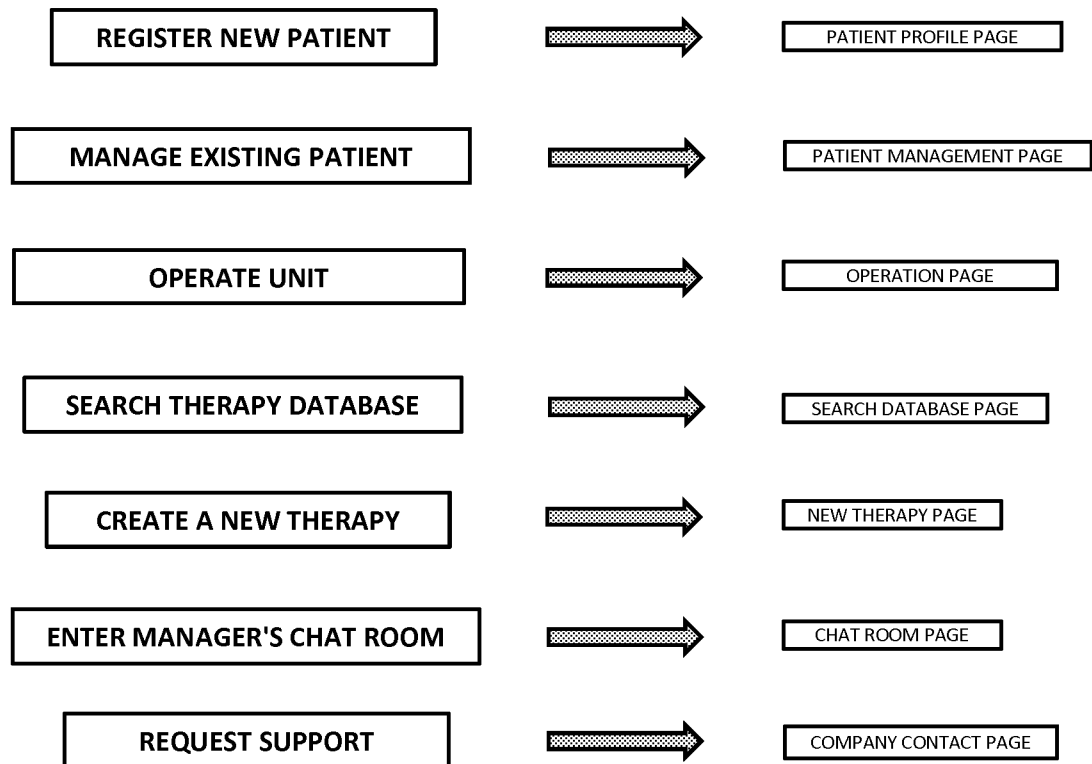


FIG. 18A

PATIENT MANAGEMENT PAGE:

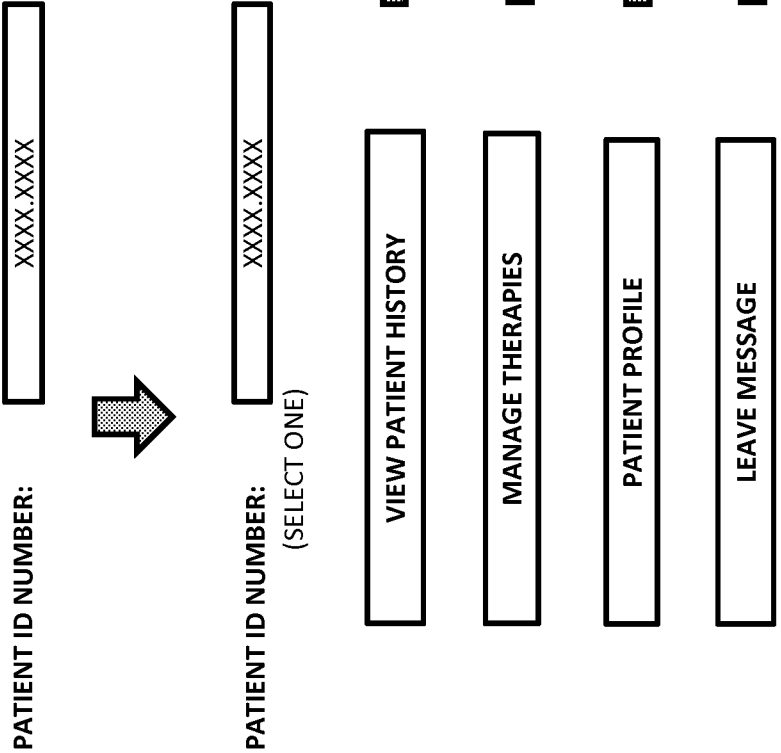


FIG. 18B

MANAGE THERAPY PAGE:

MANAGER'S NAME:	DR.JONES			
PATIENT ID NUMBER:	XXXX.XXXX			
ACTIVE THERAPIES:	CODE:	X/DAY:	DAY/WEEK:	EXPIRATION DATE:
EVENING 1020 MORNING 1304 SWELLING 4031 HAND 2107	1020 1304 4031 2107	1 1 4 2	4 3 7 7	XX/XX/XX XX/XX/XX XX/XX/XX XX/XX/XX

FIG. 18C

SEARCH DATABASE PAGE:

TREATMENT AREA (SELECT ONE)		KNEE FOOT LIMBS NECK HEAD
TYPE OF INJURY (SELECT ONE)		SPRAIN SURGURY RECOVERY BRUISING CARPAL TUNNEL GANGRENE
PATIENT CONDITION (SELECT ONE)		ATHLETIC PREGNANT ELDERLY AVERAGE ADULT CHILD
DESIRED RESULT (SELECT ONE)		INFLAMMATION REDUCTION PAIN REDUCTION INCREASED BLOODFLOW BED SORE THERAPY MUSCLE SPASMS
BROWSE		

FIG. 18D

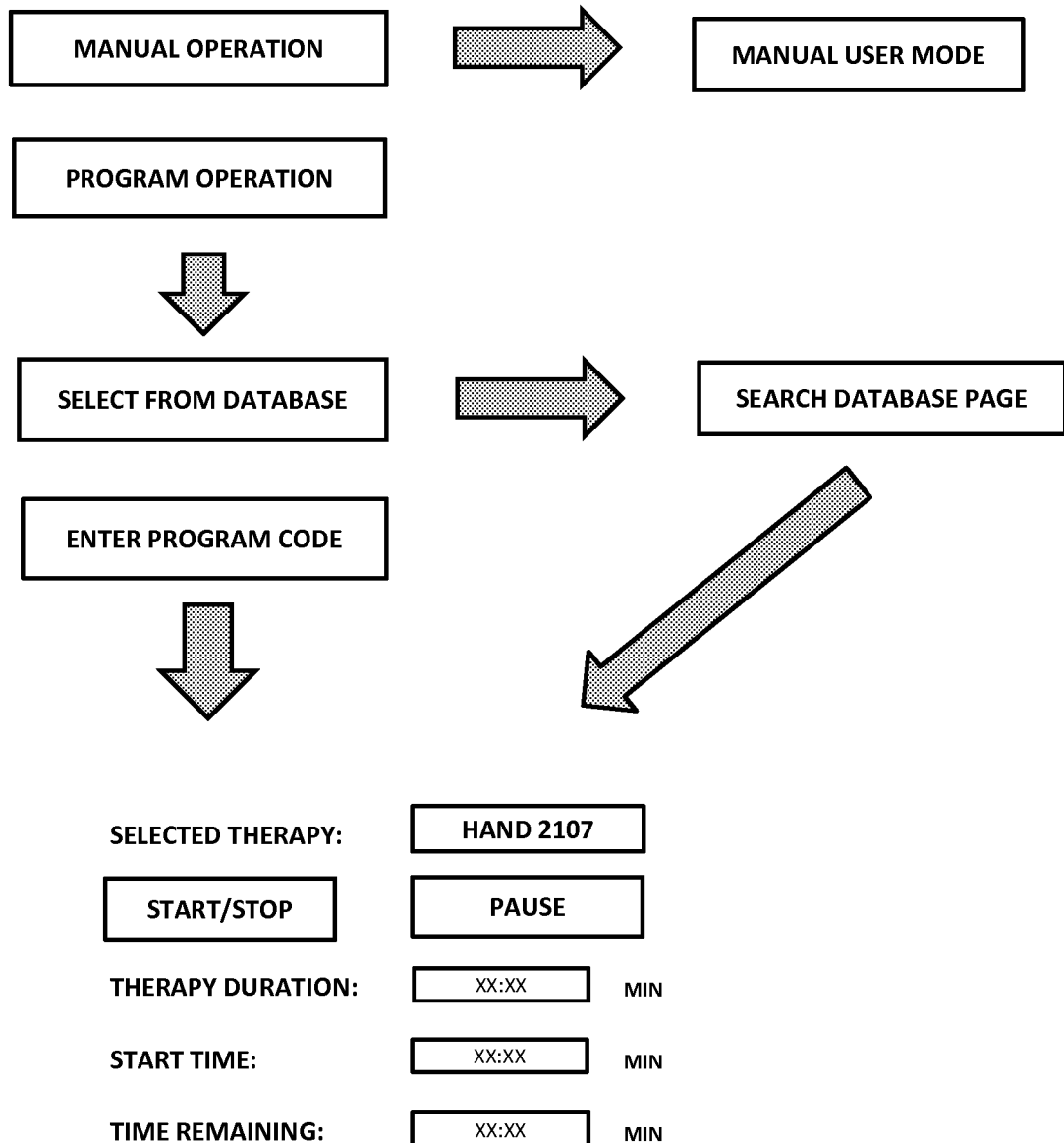
OPERATION PAGE:

FIG. 18E

BASIC USER SCREEN:

TODAYS DATE: TIME:

USER ID:

PASSWORD: (ENTER)

PATIENT NAME: (ENTER)

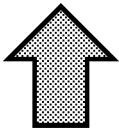
THERAPY MANAGER:

PERSCRIBED THERAPIES:

EVENING 1020
MORNING 1304
SWELLING 4031
HAND 2107

THERAPIES AVAILABLE:
(SELECT ONE)

MORNING 1304
HAND 2107



ACTIVE THERAPY:

START/STOP

HAND 2107

THERAPY DURATION:

XX:XX

MIN

START TIME:

XX:XX

MIN

TIME REMAINING:

XX:XX

MIN

FIG. 18F

MANUAL USER MODE:

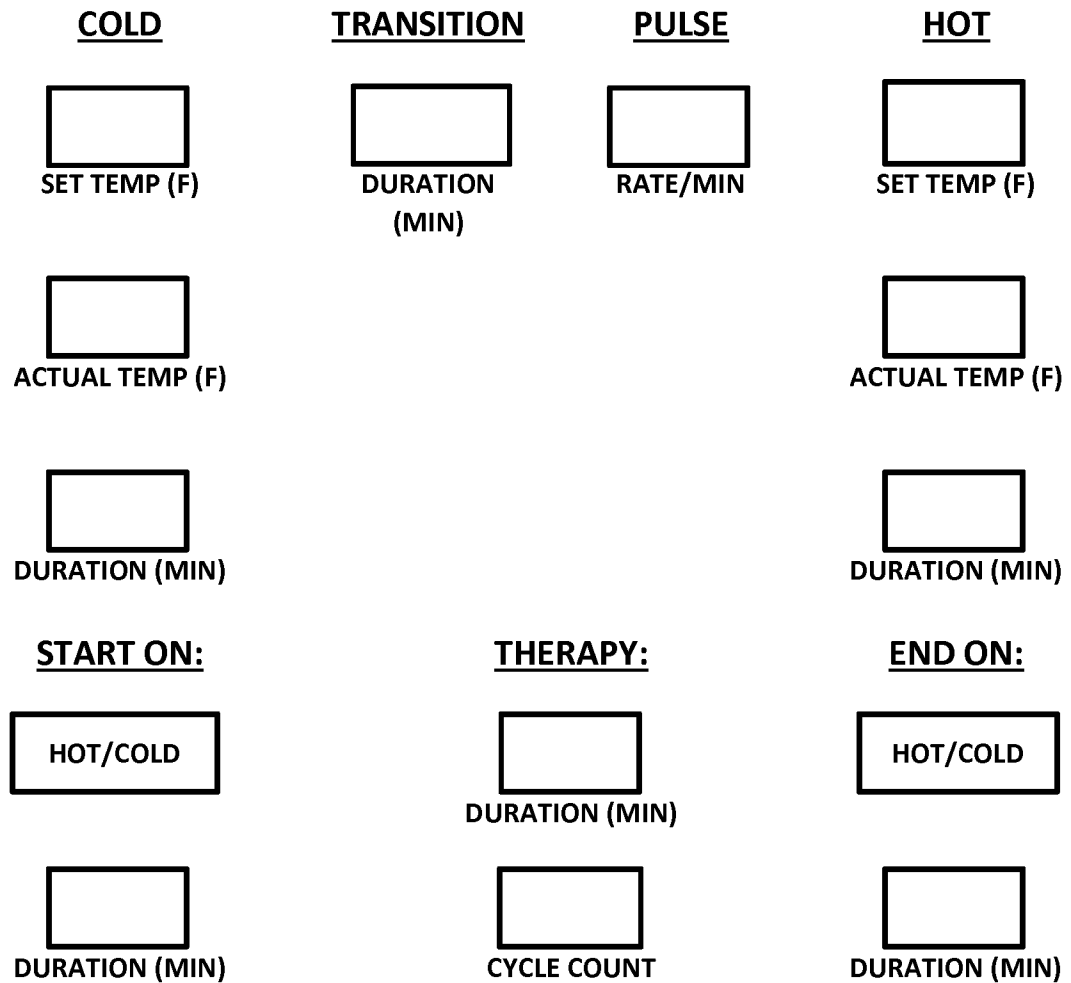


FIG. 18G

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2015/041663

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 7/02 (2015.01)

CPC - A61F 7/02; A61F 2007/0296 (2015.09)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61F 7/00, 7/02, 7/08, 7/10, 7/12 (2015.01)

CPC - A61F 7/00, 7/02, 2007/0295, 2007/0296, 2007/0298 (2015.09) (keyword delimited)

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

USPC - 601/15, 17; 607/96, 104, 108, 109, 110, 111
(keyword delimited)

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

PatBase, Google Patents, Google.

Search terms used: Hot, cool, liquid, alternate, pump, valve, supply, return, contrast, therapy

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,411,541 A (BELL et al) 02 May 1995 (02.05.1995) entire document	1-2, 23
Y		3
Y	WO 2013/013059 A1 (SCR INC) 24 January 2013 (24.01.2013) entire document	3
A	US 2009/0254160 A1 (SHAWVER et al) 08 October 2009 (08.10.2009) entire document	1-3, 23

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

24 September 2015

Date of mailing of the international search report

15 OCT 2015

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Blaine Copenheaver

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2015/041663

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 4-22, 24-29
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.