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(54) **PATIENT TEMPERATURE RESPONSE CONTROL SYSTEM**

PATIENTENTEMPERATURREAKTIONSTEUERUNGSSYSTEM

SYSTÈME DE COMMANDE DE RÉPONSE DE TEMPÉRATURE DE PATIENT

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Description

FIELD OF THE INVENTION

[0001] The present teachings relate to the field of induced hypothermia, and in particular, to a system and method that facilitates the control of patient shivering discomfort associated with induced hypothermia therapy.

BACKGROUND OF THE INVENTION

[0002] Hypothermia is a condition in which body temperature is at a level lower than normal body temperature. Therapeutic induced mild-moderate hypothermia can be beneficial for people suffering stroke, myocardial infarction, cardiac arrest serious head trauma and other conditions involving reduced blood supply. One method for lowering body temperature is to insert a cooling device into an artery of the patient and to internally cool the patient's body by introducing a cooling fluid into the device. A non-invasive technique for lowering body temperature is to externally cool the exterior surface of the patient's body. Such exterior surface cooling could be achieved, for example, by direct contact with a cooling fluid, such as by immersing the patient's body in the cooling fluid or by directing the flow of the cooling fluid around the patient's body. The cooling fluid could be, for example, cool water or cool air. Another technique for external surface cooling is to apply a contact-cooling pad to the exterior surface of the patient and to circulate a cooling fluid, such as water or an aqueous solution, through the contact pad to cool the patient.

[0003] For therapeutic purposes, it is often desirable for the mild-moderate hypothermia to be induced very quickly. With endovascular cooling, heat is removed directly from blood flowing through blood vessels. Blood with reduced temperature moves through blood vessels to cool other parts of the body. With exterior surface cooling, heat is removed across the patient's skin. Cooling of the skin increases conduction of heat from deeper within the body, thereby cooling internal body tissue. Blood moving through blood vessels in a cooled portion of the body is also cooled, and distribution of that cooled blood to other parts of the body thereby contributes to cooling other parts of the body.

[0004] Quick inducement of hypothermia requires that the patient's body temperature be rapidly reduced to the desired level, and involves a high rate of transfer of heat from the body. Impediments to inducing hypothermia include the patient's thermoregulatory responses to cooling. Shivering is a common thermoregulatory response that, in some cases, can increase body heat production to as much as 600% above basal levels. Anti-shivering drugs, and particularly meperidine, have been administered prior to or during active cooling to help suppress the shivering response. Such pharmacological treatment to suppress shivering is often successful, resulting in more rapid lowering of the patient's body temperature to more quickly induce a desired degree of hypothermia, reducing patient tiring attendant to shivering, and also reducing patient discomfort associated with shivering.

[0005] EP 0 846 440 describes a system for remotely monitoring personnel status including a plurality of sensors disposable on a soldier or other person for developing signals which may be used to determine the physiological status. The sensors communicate with a soldier unit which can process the information to ensure that the sensor data falls within acceptable ranges and communicate with remote monitors. The soldier unit also includes a global positioning system. By using the sensor data and the global positioning system. leaders and medics can quickly and accurately track and treat casualties in battle. The system enables more rapid location of the casualty, as well as remote triage/initial diagnosis, thereby assuring that those who are most in need of treatment are attended to first.; Typically, the system monitors both body surface and ambient temperature, heart rate, shivering, motion status and body condition. Additional sensors can be provided to supply information on other physiological parameter which may be desired for more thorough diagnosis. The physiological information may be stored and kept with the soldier to enable improved care as the soldier is moved to higher levels of care.

[0006] US 7.294.112 describes a motion monitoring apparatus and method for monitoring a patient under medical care. A sensor arrangement is provided in the form of a pad which the patient lies on. The sensor arrangement provides a signal which can be monitored to observe motion of the patient and provide an alarm should the motion meet certain predetermined conditions. The apparatus and method are described as being particularly applicable for monitoring patients under sedation, recovering from anaesthesia, or in intensive care. The device is described as being particularly useful for veterinary patients.

[0007] US 6.238.354 describes a monitoring assembly designed to continuously monitor the temperature of a patient, such as but not exclusively limited to a child, and including a sensor assembly having at least a first sensor structure removably attachable to the patient in preferably direct contact and engagement with the skin at a predetermined location.

[0008] A display assembly includes a first display structure associated with a remotely located casing which may vary in size and configuration and further wherein the display assembly includes a second display unit mounted on the housing which is removably attachable to the patient being monitored. A control assembly includes operative, electronic control circuitry interconnecting the sensor assembly to the display assembly such that the temperature readings are converted to a visual display on both the first and second display structures and further wherein a control assembly includes a transmission assembly designed for wireless communication between the remote casino and the patient mounted housing tor purposes of activating a reset assembly and/or transmit-

ting temperature data and sound from the patient to the remotely located casing.

[0009] WO 96/36950 describes a patient movement monitoring device including a sensor (11) for generating motion signals, a signal edge detector, an integrator (A-B), a threshold detector for generating an alarm signal, and preferably a radio transmitter for relaying the alarm signal. The sensor is in the form of an intermittent switch comprising a conductive rolling sphere (13) in a cylindrical chamber (15) having a conductive wall (17) as one electrical pole and end plates (19, 21) electrically insulated from the conductive wall and forming the other electrical pole such that movement of the device will generate intermittent electrical contacts between an end plate and the cylinder wall.

SUMMARY OF THE INVENTION

[0010] Particular aspects and embodiments of the invention are set out in the appended claims. The invention is defined in the appended claims. Aspects, embodiments and examples disclosed herein which do not fall within the scope of the appended claims do not form part of the invention, and are merely provided for illustrative purposes.

[0011] In view of the foregoing, one objective of the present teachings is to facilitate control over, and thereby reduce, patient shivering (e.g. in response to induced hypothermia).

[0012] A related objective of the present teachings is to facilitate a reduction in patient shivering, and attendant patient heat production, patient tiring and patient discomfort(e.g. in induced hypothermia procedures) via a system and method that provide an output to facilitate anti-shivering response by medical personnel and that otherwise exhibit user-friendly functionalities.

[0013] Yet another objective is to facilitate a reduction in patient shivering (e.g. during induced hypothermia procedures) in a manner that enhances the efficiency of medical personnel in the performance of thermotherapy related activities.

[0014] One or more of the above objectives and additional advantages may be realized in a medical apparatus that includes a monitoring device for monitoring patient shivering or at least one physiological response of a patient to a change in the temperature of the patient and to provide a monitoring signal responsive thereto. The presently taught apparatus may further include an output device for providing an output to a user responsive to the monitoring signal. In this regard, the output may be indicative of at least one measure of a physiological response, such as a magnitude, degree or progressive stage of shivering and/or information regarding potential response treatment option(s). By way of example, a visual and/or auditory output may be provided to a user that indicates that a predetermined level or stage of shivering has been detected and/or other information that may be useful in addressing a detected patient shivering condition.

[0015] In one arrangement, the medical apparatus may further comprise at least one of an energy storage device and a wireless energy conversion device, interconnected to the monitoring device, for powering the monitoring device. In one approach, a wireless signal receiver and rectifier arrangement may be employed for receiving a wireless signal and transducing electrical energy therefrom to power the monitoring device. In conjunction with such approach, a wireless signal transmitter may be employed for transmitting a wireless signal corresponding with the monitoring signal. Alternatively, a transceiver may be employed for both receiving a wireless signal and transmitting a wireless signal corresponding with the monitoring signal.

[0016] In another approach, a battery may be employed as an energy storage device for powering the monitoring device. In conjunction with such approach, the battery may be interconnected with a transmitter for transmission of a wireless signal corresponding with the monitoring signal. Further, when a rechargeable battery is employed, a wireless signal receiver and rectifier may be included to transduce electrical energy from a wireless charging signal for recharging the rechargeable battery.

[0017] In conjunction with either of the above-noted approaches, an energy storage device and/or wireless energy conversion device may be interconnected to a monitoring device for co-movement therewith. More particularly, such components may be directly connected or interconnected to a common support member for co-movement, free from hardwire or other physical interconnections with a power source.

[0018] In a related arrangement, the monitoring device may be non-invasive. In turn, use of the monitoring device may be initiated without compounding patient anxiety, patient tiring or patient discomfort otherwise attendant to the use of invasive devices.

[0019] In a further related arrangement, the monitoring device may be provided to be selectively interconnectable to and disconnectable from a patient. When connected, the monitoring device may be maintainable in fixed relation to a given location on a patient. By way of example, the monitoring device may be interconnectable to a patient via a hook and loop fastener arrangement, a peel and stick adhesive surface arrangement or other like techniques.

[0020] In one approach, the monitoring device may comprise at least one motion sensor, e.g. an accelerometer selectively interconnectable/disconnectable to a patient, e.g. adhesively connectable to a patient's jaw (e.g. the masseter region). Such accelerometer(s) may be provided to measure acceleration in one and/or a plurality of orthogonal axes (e.g. one, two or three orthogonal axes).

[0021] In conjunction with such approach, a plurality of accelerometers may be interconnected to a patient at different locations to provide separate monitoring signals that may be employed together to facilitate the provision

of an output indicative of a magnitude, degree or stage of patient shivering. For example, accelerometers may be separately interconnected to a patient's jaw (e.g. the masseter region), to a patient's chest (e.g. the pectoral region), to a patient's arm (e.g. the bicep region) and/or to a patient's leg (e.g. the quadriceps region), wherein corresponding monitoring signals from such accelerometers may be utilized to monitor a degree and for progressive stage of shivering. In this regard, each of the monitoring signals may comprise pre-determined signal portions (e.g. corresponding with a predetermined motion frequency range or ranges) whose presence and/or magnitude may be identified and utilized to generate a user output.

[0022] In another approach, the monitoring device may comprise a vasoconstriction measurement device for measuring blood flow at two to offset locations, e.g. at a fingertip and at corresponding forearm. In an additional approach, the monitoring device may comprise one or more electromyography (EMG) surface sensors for monitoring muscular electrical activity. In another approach, the monitoring device may comprise a pulse oximeter sensor for monitoring blood oxygen saturation levels of a patient. In yet a further approach, the monitoring device may comprise one or more capnography input sensors for concentration and/or partial pressure of carbon dioxide in patient respiratory gases.

[0023] In relation to each of these approaches, the monitored parameter may have a known relationship to patient shivering, wherein a magnitude of the measured parameter may be related to a corresponding degree or stage of patient shivering. Further, in relation to such approaches, a plurality of sensors that measure the same parameter and/or different ones of the noted parameters may be employed to combinatively yield a monitoring signal.

[0024] In certain embodiments, a processor and/or logic circuit may be employed to process one or more monitoring signal(s) to generate an output control signal for controlling an output device. In this regard, one or more predetermined algorithms may be employed for frequency domain processing and/or time domain processing of one or a plurality of monitoring signal(s) provided by one or a plurality of motion monitoring device(s) (e.g. one or a plurality of accelerometer(s)).

[0025] In one approach, a monitoring signal comprising three-dimensional accelerometer output data values may be processed utilizing a frequency domain transfer algorithm. In this regard, successive overlapping frames of data sets which each comprise three dimensional acceleration data values may be deinterleaved into three data sets corresponding with each of the three dimensions, windowed (e.g. utilizing a Kaiser or other windowing technique) and transformed utilizing a frequency transform technique (e.g. a Fourier transform). A square of the modulus of the transformed data may be determined, and the results thereof may be summed to yield spectral data for each frame of data. In turn, the spectral data for a plurality of frames may be analyzed in relation to a plurality of predetermined frequency ranges to assess a magnitude or degree of patient shivering, wherein at least one of the predetermined frequency bands includes a frequency level indicative of patient shivering (e.g. a band including a frequency level of about 9.5Hz).

[0026] In another arrangement, the processor may be pre-programmed to process the monitoring signal and provide information for use in administering at least one anti-shivering medicament to a patient. By way of example, such information may comprise the identification of one or more anti-shivering medicaments employable by medical personnel in controlling patient shivering. Further, the output may comprise information corresponding with dosage and/or administration frequency of one or more anti-shivering medicaments. In one approach, dosage and frequency information may be based upon, at least in part, a monitored magnitude of patient shivering, as reflected by the monitoring signal.

[0027] The anti-shivering medicament may comprise one or more substance effective for suppressing shivering. A variety of such anti-shivering medicaments are known or may be identified in the future. Examples of some reported anti-shivering medicaments include certain non-opioid analgesics (e.g. tramodol and nefopan), certain opioid analgesics (e.g. alfentanil, morphine, fentanyl, meperidine, naloxone and nalbuphine), certain α_2-andrenergic agonists (e.g. clonidine and dexmedetomidine) and certain serotonin antagonists (e.g. ketanserin and ondansetron). Also, multiple anti-shivering medicaments may be used to the extent they are pharmacologically compatible. Moreover, it should be appreciated that medicaments are often administered in the form of pharmacologically acceptable salts, so, for example, the anti-shivering medicament may be such a salt of any of the foregoing listed compounds. Meperidine, or a salt thereof, is particularly preferred for use as the anti-shivering drug.

[0028] Given the variety of anti-shivering medicaments that may be employable, and in another arrangement, the processor may be preprogrammed to generate information, at least in part, in accordance with a user-established protocol that specifies one or more user-preferred anti-shivering medicaments and that comprises data and/or algorithms that provide for the automated generation of an output regarding dosage and/or frequency information for the preferred medicament(s). For example, a given user may pre-establish a protocol that contemplates the use of a particular medicament and a corresponding dosage amount and/or frequency of dosage administration rate, as well as a preset correlation between such data and measured magnitude(s) of monitored patient response to temperature change (e.g. a monitored magnitude of patient shivering).

[0029] In an additional arrangement, the processor may be operable to process the monitoring signal to assess a given patient's shivering response to at least one prior administration of an anti-shivering medicament, and

in turn, to provide output comprising updated information employable in a subsequent administration of the same or different anti-shivering medicament. Stated differently, the processor may process the monitoring signal on an ongoing basis so as to establish trend data corresponding with a patient's response to a given anti-shivering medicament, and in turn, to utilize such trend data in the provision of further updated information regarding a recommended dosage in/or frequency for one or more subsequent administration(s) of an anti-shivering medicament.

[0030] In another arrangement, the apparatus may include a user interface as an output device for providing output information in at least one of an audible and visual form. By way of example, the information may be provided via an interactive display. In turn, the interactive display may be provided to receive user input, e.g. to identify an anti-shivering medicament and/or to establish a protocol for subsequent use in generating an information output in a given thermotherapy procedure.

[0031] As noted above, the monitoring device(s) may be adapted to provide the monitoring signal(s) as a wireless signal(s). In turn, the apparatus may include a receiver, interconnected to a processor, for receiving a wireless monitoring signal and providing the signal to the processor. In turn, the process may process the monitoring signal(s) as indicated above.

[0032] In yet another arrangement, the processor may be operable to employ the monitoring signal in conjunction with the generation of an input signal that is provided to a temperature control system (e.g. a system for cooling and/or warming a patient). For example, the input signal may be utilized in conjunction with establishing the temperature of a cooling medium utilized to cool a patient.

[0033] The present teachings can also provide a method for use in controlling a shivering response of a patient during therapeutic patient cooling. The method may comprise the steps of monitoring at least one physiological response of a patient to a change in temperature of the patient, and automatically providing an output responsive to the monitoring signal.

[0034] In one approach, the output may be indicative of at least one measure of the patient shivering response. For example, the output may comprise a visual and/or audible output indicating to a user a predetermined magnitude, degree and/or stage of patient shivering. In another approach, the output may be based at least in part on a monitored response for employment by a user in controlling the patient's shivering response to a temperature change. For example, the output may comprise information regarding the dosage and/or frequency of administration of an anti-shivering medicament.

[0035] In one taught approach, the method may further include the step of powering the monitoring device by at least one of an energy storage device and a wireless energy conversion device (e.g. comprising a receiver antenna and rectifier) interconnected to the monitoring device for co-movement therewith. By way of example, the monitoring device (e.g. a motion sensor) and an energy storage device and/or a wireless energy conversion device may each be interconnected to a common support structure (e.g. a printed circuit board located within a protective housing), wherein an adhesive backing may be provided on the support structure with a removable liner to facilitate selective interconnection to and disconnection from a patient.

[0036] In a further taught approach, the method may include the steps of transmitting the monitoring signal as a wireless signal, and receiving the wireless monitoring signal for use in the providing step. Further, the powering step may include converting a wireless power signal to an electrical signal utilizing a wireless energy conversion device, wherein the electrical signal provides power to the monitoring device for use in the monitoring step and to a transmitter for use in the transmitting step.

[0037] In a further taught approach, the monitoring step may include utilizing a motion sensor interconnected to a patient to provide a monitoring signal that is indicative of patient motion. In turn, the providing step may include processing of motion data comprising the monitoring signal utilizing frequency domain processing. By way of example, the motion data may include three-dimensional accelerometer data. The processing step may include the steps of windowing the three-dimensional motion data, and transforming the windowed three-dimensional motion data to frequency domain data. In turn, a statistical analysis may be performed on the frequency domain data in a relation to a plurality of predetermined frequency bands.

[0038] In yet another taught approach, the monitoring step may comprise at least one of monitoring motion of the patient (e.g. shivering-related motion), monitoring vasoconstriction of the patient (e.g. based on relative blood flow measurements at offset vascular locations), monitoring muscular electrical activity of the patient (e.g. using EMG surface sensors), monitoring carbon dioxide concentration and/or partial pressure of respiratory gases of the patient, and/or monitoring blood oxygen saturation levels of the patient. By way of example, a motion sensor may be selectively interconnected to a patient to monitor a magnitude of patient shivering and to provide a monitoring signal reflective thereof. In turn, the generating step may entail a comparison of the monitored shivering magnitude value to one or more preset, reference values. For example, a comparison may yield an indication of moderate shivering magnitude, which in turn may yield an output that indicates that administration of a moderate dosage of a given anti-shivering medicament may be in order.

[0039] In another taught approach, the method may include the step of administering at least one anti-shivering medicament. For example, the medicament may be administered in accordance with output information that comprises dosage and/or frequency information for one or more identified anti-shivering medicaments.

[0040] In a related taught approach, following admin-

istration of an anti-shivering medicament, the method may provide for repeating the monitoring and processing steps a plurality of times, on an ongoing basis during induced thermo therapy, and utilizing data inputted by a user that corresponds with the prior administering step (e.g. the time and dosage of administration) in a subsequently performed processing step to provide updated output information employable in a subsequent administering step. Stated differently, after the administration of a given anti-shivering medicament, the monitoring and processing steps may establish trend data regarding a patient's response to the anti-shivering medicament. In turn, such trend data may be utilized in the further generation of an output reflecting dosage and/or frequency information for the further administration of an anti-shivering medicament.

[0041] In another taught approach, the generating step of the inventive method may comprise utilizing patient specific data provided by a user. For example, a user may input data regarding a patient's age, weight, sex, physical condition and/or other patient specific data that may impact the type, amount and/or frequency of medicament administration.

[0042] In a further related taught approach, the method may provide for outputting information to a user in at least one of a visual form and an audible form. Relatedly, an interactive user interface may be provided for receiving input from a user for use in completing the generating step.

[0043] Additional aspects and advantages in the present teachings will be apparent to those skilled in the art upon consideration of the further description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

[0044]

Fig. 1 is a schematic illustration of one apparatus.
Fig. 2 is a process flow diagram of one method.
Fig. 3 illustrates a system embodiment.
Fig. 4 illustrates one embodiment of a monitoring device employable in the system embodiment of Fig. 3.
Fig. 5 illustrates one embodiment of an output device employable in conjunction with implementations.
Fig. 6 illustrates the output embodiment device of Fig. 5.
Figs. 7A, 7B and 7C illustrate perspective views of a motion sensor embodiment and component parts thereof employable to generate a monitoring signal in conjunction with implementations.
Figs. 8A, 8B, 8C and 8D illustrate steps corresponding with a frequency domain processing embodiment for processing a monitoring signal.
Figs. 9A, 9B and 9C illustrates steps of a time domain processing embodiment for processing a monitoring signal.

DETAILED DESCRIPTION

[0045] Fig. 1 illustrates one embodiment. As shown, a monitoring device **10** is provided to monitor at least one physiological response R of a patient P to a change of temperature of the patient and to provide a monitoring signal **12** responsive thereto. By way of example, therapeutic hypothermia may be induced by a cooling system **50.** Cooling system **50** may comprise any of a number of different modalities for selective cooling of a patient, including for example cooled contact pads, vascular cooling, patient emersion approaches and/or other systems for rapidly cooling a patient, e.g. systems as described in U.S. Patent Nos. 6,669,715, 6,827,728, 6,375,674, and 6,645,232, and published PCT Application PCT/US2007/066893.

[0046] With further reference to Fig. 1, the monitoring signal **12** may be provided to a processor and/or logic circuit **20** via a hardwire and/or wireless interface between monitoring device **10** and processor and/or logic circuit **20.** In turn, processor and/or logic circuit **20** may be preprogrammed or otherwise provided to utilize the monitoring signal **12** to provide an output **22.**

[0047] In one approach, processor and/or logic circuit **20** may be provided to assess the monitoring signal **12** and provide an output **22** employable to indicate at least one measure of a shivering response of a patient. For example, the output **22** may be employable to provide a visual and/or audible output at a user interface **30** or other output device (e.g. one or more lights (e.g. one or more light emitting diodes) co-located with the patient P), wherein such output provide a user with an indication of a magnitude, degree and/or stage of a patient shivering response to a cooling therapy.

[0048] In another approach, an output **22** may be provided that is employable for use in controlling a shivering response of the patient P to changes of the bodily temperature of the patient P. In one embodiment, an output **22** may be provided at user interface **30**which comprises information that corresponds with one or more approaches for controlling patient shivering response via the administration of one or more anti-shivering medicaments.

[0049] By way of example, processor **20** may comprise preprogrammed logic, or algorithms/data, in a treatment module **24** for processing the monitoring signal **12** to provide an output **22** comprising information relating to one or more anti-shivering medicament administration actions that may be followed by medical personnel to treat patient shivering response to bodily cooling. In this regard, the treatment module **24** may comprise stored data/algorithms in relation to a plurality of preset treatment protocols, including protocols that have been established by a user, e.g. via user input at interface **30.** For example, each pre-established protocol may include data/algorithms relating to one or more of the following:

Data corresponding with different anti-shivering medicament option(s), including different types

and/or combinations of anti-shivering medicaments; and

Dosage/frequency data and/or algorithms for each anti-shivering medicament option.

As may be appreciated, the processor **20** and the user interface **30** may be provided for interactive operations therebetween. More particularly, in conjunction with a given patient cooling procedure, a user may utilize user interface **30** to access and select a given one of a plurality of treatment protocols, e.g. corresponding with a given protocol established at a given user site (e.g. for a particular physician). In turn, such protocol may provide for the selection of a given one of a plurality of different anti-shivering medicament options (e.g. via an interactive menu).

[0050] In turn, for a selected option, the processor **20** may be operative to provide treatment-dosage (e.g. amount) and frequency-of-dosage information to a user at user interface **30.** Such information may be provided so as to take into account specific data inputted by a user at a user interface **30** for a given procedure, including for example, patient-specific information (e.g. age, weight, sex etc.), and patient procedure-specific information (e.g. thermotherapy pursuant to stroke, thermotherapy pursuant to head trauma, etc.). Additionally and/or alternatively, the information comprising the output **22** may be based, at least in part, upon a magnitude of the measured patient response R reflected by monitoring signal **12.** For example, a magnitude measure may be obtained from the signal **12** and compared with pre-established reference data to assess how much and/or how often a given anti-shivering medicament may be appropriate for administration.

[0051] As illustrated in Fig. 1, processor **20** may further comprise a response module **26** comprising algorithms and/or data for processing the monitoring signal **12** on an ongoing basis, e.g. after initiation of patient shivering response actions by a user (e.g. administration of an anti-shivering medicament), to assess the effectiveness of such actions, wherein such assessment may then be automatically employed in the generation of subsequent output **22.** To yield such functionality, user interface **30** may be employable to receive user input regarding the patient shivering response actions taken by a user, e.g. the identification of the type(s), dosage amount(s) and time(s) of administration of one or more anti-shivering medicament(s). Such input may be store and/or otherwise employed by response module **26** in completing the above-noted assessment. By way of example, the above-noted assessments may include an algorithmic assessment as to the degree of patient shivering reduction and/or the duration of shivering reduction and/or the degree of shivering reduction on a time-scale basis associated with a given anti-shivering medicament administration procedure (e.g. collectively "trend data"). In turn, the response module **26** may be provided to interface with treatment module **24** to provide information in output **22** regarding potential further treatment action on an ongoing basis during a given patient cooling procedure. Such ongoing treatment information may be provided to a user through user interface **30,** wherein such further information is based in part on the trend data assessment.

[0052] In addition to the above-described functionalities, the processor **20** may be further adapted for providing an input signal **28** to the cooling system **50.** Such input signal **28** may employ with a patient temperature sensor **52** output signal **54** to establish a degree of cooling and/or rate of cooling of the given patient P. For example, based upon a measured magnitude of patient response R, a cooling rate may be increased (e.g. when no shivering is detected and more rapid cooling is therapeutically desired) or decreased (e.g. when an undesirably high degree of shivering is detected and therapeutic rapid cooling is realizable at a lower cooling rate).

[0053] Reference is now made to Fig. 2, which illustrates one of embodiment of a method according to the present teachings. Initially, pursuant to a given patient treatment condition, e.g. a stroke, serious head trauma or other like event, a patient cooling procedure may be initiated, pursuant to which a patient is as rapidly cooled to reduce risk of neurological damage, step **102.** In conjunction with the patient cooling procedure, the method may provide for monitoring a physiological response of a patient to a change in the patient's temperature, step **104.** More particularly, the monitoring may include the step of selective interconnection of a non-invasive monitoring device to a patient. In one approach, one or more interconnectable/disconnectable monitoring device(s) may be fixedly positioned to a patient to measure patient motion. For example, patient shivering response may be monitored, via attachment of an accelerometer to a patient's jaw (e.g. masseter region) and/or via attachment of an accelerometer to a patient's chest (e.g. pectoral region) and/or via attachment of an accelerometer to a patient's arm (e.g. bicep region) and/or via attachment of an accelerometer to a patient's leg (e.g. quadricep region), wherein one or a plurality of accelerometers are utilized to provide one or a corresponding plurality of accelerometer output signal(s) employable to assess the magnitude and/or stage of shivering and provide an output indication of at least one measure of the of the patient shivering response to cooling.

[0054] In other approaches that correlate shivering to a monitored parameter, a blood flow monitoring device may be attached to a patient to measure a degree of vasoconstriction reflective of a degree of shivering (e.g. by measuring relative blood flow at a fingertip and at a corresponding forearm location). In an additional approach, the monitoring device may comprise one or more electromyography (EMG) surface sensors for monitoring muscular electrical activity. In yet a further approach, the monitoring device may comprise one or more capnography input sensors for concentration and/or partial pressure of carbon dioxide in patient respiratory gases. In yet

another correlative approach, a pulse oximeter sensor may be interconnected to a patient to measure a patient's blood oxygen saturation level, wherein such level may be correlated to a degree of shivering.

[0055] With further reference to Fig. 2, the method may provide for the generation of an output based upon, at least in part, a monitored patient temperature response, step **106.** By way of example, such output generation may entail the provision of a visual or auditory output. In one embodiment the method may further include processing of a monitoring signal in accordance with the selected one of a plurality of treatment protocols comprising corresponding preset data/algorithms. In one approach, use of a given protocol may provide for user selection of a given anti-shivering medicament or combination(s) thereof, as well as a corresponding output of information relating to dosage and/or frequency information for the selected medicament(s).

[0056] Pursuant to the generation of an output based upon a monitored patient response, the method may encompass use of the output to control a patient shivering response, step 108. For example, information regarding dosage and/or frequency of a given anti-shivering medicament may be employed by a user in conjunction with the actual administration of the medicament.

[0057] As illustrated by Fig. 2, the steps of monitoring **104,** generating **106** and/or using **108** may be repeated on an ongoing basis during a given thermotherapy procedure, wherein as part of the monitoring step, the patient's response to prior actions taken to control shivering may be assessed (e.g. via trend data assessment) and the output provided in step **108** may take into account the results of such assessment.

[0058] As further illustrated in Fig. 2, output may be provided in relation to the generation step **106** that may be utilized in conjunction with controlling a degree of cooling provided by a cooling system, step **110.** By way of example, in the generating step **106** an input signal may be provided to a cooling system. Such input signal may be utilized by the cooling system to increase, decrease or maintain a rate of patient cooling.

[0059] Referring now to Figs. 4 and 5, a further embodiment will be described. As shown, a patient P may be cooled utilizing a cooling system comprising contact pads **200** and a control unit **202** that circulates cooled fluid via supply line(s) **204** and return line(s) **206** though the contact pads **200** (e.g. under negative pressure). In this embodiment, the control unit **202** may further comprise a transceiver **210** for transmitting/receiving wireless signals to/from a motion sensor monitoring device **220a** interconnected to the chin of a patient P.

[0060] By way of example, and with reference to Fig. 4, the motion sensor **220a** may include an accelerometer housed within a housing **222** having an adhesive backing **224** and removable liner **226** initially provided therewith. To initiate patient use, the liner **226** may be selectively removed, wherein the adhesive backing **224** may be mounted to a jaw of a patient. In one approach, an on-board battery may be housed in housing **222,** e.g. for powering the accelerometer and an on-board transmitter for transmitting a monitoring signal **214** indicative of a magnitude of motion of the patient's chin.

[0061] In another approach, the transceiver **210** provided with the control unit **202** may be adapted to transmit a query/power signal **212** to the motion sensor **220a.** In turn, the motion sensor **220a** may transmit a monitoring signal **214** to the transceiver **210** which is indicative of a degree of motion of the patient's chin. More particularly, the motion sensor **220a** may comprise a transreceiver and rectifier arrangement for receiving a query/power signal **212,** transducing electrical energy therefrom, and using the energy to generate and transmit the monitoring signal **214.**

[0062] As may be appreciated, a plurality of motion sensors **220** may be employed. For example, motion sensors **220b** and **220c,** of like configuration to motion sensor **220a,** may be selectively interconnected to different body regions (e.g. an arm and leg of a patient). In such an arrangement, each of the sensors **220a, 220b** and **220c** may provide a wireless monitoring signal **214.**

[0063] The monitoring signal(s) **214** may be processed at the control unit **202** in accordance with the described functionalities to provide an output (e.g. a visual or auditory output) at a user interface **230.** As previously noted, the output may provide an indication of a magnitude or stage of patient shivering. Additionally or alternatively, such output may provide anti-shivering medicament related information, e.g. dosage and/or frequency information for use by medical personnel in the administration of an anti-shivering medicament. As further reflected by Fig. 4, control unit **202** may include a user input **240** (e.g. a keyboard, touch-screen or point-and-click interface) for user selection of a given anti-shivering treatment protocol, for inputting instructions and/or data regarding the type, amount and timing of medicament administration, and/or for inputting patient-specific information. In conjunction with control operations, the control unit 202 may be further provided for use in controlling patient cooling in accordance with a pre-established protocol(s), e.g. as taught by U.S. Patent Nos. 6,620,187, 6,692,518, 6,818,012, and 6,827,728.

[0064] As further reflected by Fig. 3, and as an option to control unit **202,** a handheld unit **250** may be provided that includes a transceiver **252** for use in transmitting signals **254** and receiving signals **256** to/from the monitoring device **220.** As illustrated, the hand held unit may **250** comprise a user output **258** for providing treatment related information.

[0065] In further relation to the above-described functionality, reference is now made to Figs. 5 and 6 which illustrate an embodiment of a user interface **230** that may be provided at control unit **202.** As illustrated in Fig. 5, the user interface **230** may be provided to allow a user to selectively access various interactive screens for use in conjunction with a given patient therapy in which control unit **202** may be employed to circulate cooled and/or

warmed fluid through contact pads **200** to adjust a patient's temperature in accordance with a predetermined and/or otherwise controllable protocol.

[0066] As shown in Fig. 5, an interactive screen 300 may be provided at user interface **230** which includes a graphic display portion **310** that graphically illustrates temperature-related data in a first region **312** as a function of time, and that further illustrates patient motion data, e.g. shivering data, as a function of time in a second region **314.** The first region **312** may present a first plot **320** of a target patient temperature level as a function of time, e.g. a predetermined patient temperature adjustment rate plot reflecting a desired patient temperature to be reached by controlling the temperature of the circulated fluid. Further, a second plot **322** of a measured patient temperature as a function of time may be presented. Additionally, a third plot **324** of a measured temperature of the fluid circulated by control unit **202** though contact pads **200** may be provided.

[0067] In relation to the target patient temperature plot **320,** the control unit **202** may include an on-board processor pre-programmed or otherwise programmable to facilitate automated control over patient temperature adjustment therapy. In the later regard, the control unit **202** may be provided with a pre-programmed control module to facilitate automated control over the temperature of the circulated fluid so as to cool a patient in accordance with programmable protocol data during a first phase of treatment, and to re-warm a patient in accordance with another programmable protocol during a second phase of treatment.

[0068] As shown by Fig. 5, the second region **314** of the screen **300** may be provided to visually display patient motion data in relation to a predetermined magnitude scale. By way of example, a plurality of predetermined levels of patient motion, or degrees of shivering, may be graphically presented as a function of time. In the illustrated example, four levels of detected patient motion may be provided to a user, wherein no visual indication is provided for a low, or "zero" level of motion, and wherein increasing level of motions may be graphically presented by one, two or three stacked "box" indicators.

[0069] As may be appreciated, by visually monitoring the magnitude of shivering response displayed in the second region **314** of the screen **300,** medical personnel may assess the need and/or desirability for taking responsive action. For example, such responsive action may include the administration of anti-shivering medicaments and/or the application of surface warming therapy to selected patient body regions and/or a modification to the patient cooling/warming protocol discussed hereinabove (e.g. decreasing a target patient cooling rate and/or a increasing targeted temperature for patient cooling).

[0070] As reflected by Fig. 6, screen **300** may also be employable in conjunction with the operation of one or a plurality of motion sensors employable to provide a monitoring signal. By way of example, such motion sensors may be in the form of motion sensors **220a, 220b** and **220c** discussed hereinabove in relation to Fig. 3. As shown in Fig. 6, interactive screen **300** may be provided to visually facilitate the establishment of wireless communications with each of the sensors, to visually indicate the communication signal strength for each of the motion sensors **220a, 220b** and **220c,** to visually indicate a battery power level at each of the motion sensors **220a, 220b** and **220c** (e.g. as reflected by a portion of corresponding wireless monitoring signals), and/or to visually indicate a detected shivering magnitude corresponding with each of the sensors **220a, 220b** and **220c.**

[0071] Reference is now made to Figs. 7A, 7B and 7C illustrating another embodiment of a motion sensor **400.** As shown in Fig. 7A, the sensor **400** may include a base pad **402** initially provided with a removable liner **404** overlaying an adhesive bottom surface of the base pad **402.** As may be appreciated, the liner **404** may be selectively removed prior to adhesive interconnection of the motion sensor **400** to a patient. The motion sensor **400** further includes a housing portion **408** that houses a sealed sensor assembly **410** which is shown in Fig. 7B. As illustrated in Fig. 7C, of the sensor assembly **410** may include an accelerometer module **412**_that is located between opposing circuit elements mounted on opposing, inside surface(s) of a wrap-around circuit board **414.** In the illustrated embodiment, a transceiver device **416,** e.g. an RF antenna, may be patterned on a stub portion **418** of the circuit board 414 for wireless transception of monitoring signals and power signals. In the later regard, circuit correspondingly located on circuit board **414** may include a rectifier and/or battery for powering the sensor operations. In other embodiments, the patterned antenna **416** may be replaced by a chip transceiver mounted on the circuit board 414.

[0072] Referring again now to Fig. 1, and as noted above, a processor or logic circuit **20** may be provided to utilize one or a plurality of monitoring signal(s) **12** provided by one or a plurality of monitoring device(s) **10** to yield an output **22.** In that regard, and by way of example, a processor **20** may be preprogrammed for time domain and/or frequency domain processing of a monitoring signal provided by a monitoring device **10** that includes a three-dimensional accelerometer as a motion sensor, and for providing a monitoring signal indicative of acceleration in each of three-dimensions as a function of time. In this regard, it may be desirable for the accelerometer to sample at about twice the highest frequency component of interest (e.g. at least about 40Hz). Reference is now made to Figs. 8A-8C which illustrate a frequency domain processing embodiment.

[0073] As shown in Fig. 8A, a monitoring signal **12** may be provided as a sensor input comprising a stream of sequential data sample sets, wherein each data set comprises data corresponding with a measured magnitude related to acceleration in each of the three dimensions, x, y and z, (e.g. a measured voltage magnitude for each of three-dimensions). In turn, overlapping frames of data sets may be processed, wherein each frame m compris-

es a plurality of data sets n and wherein sequential ones of such frames at least partially overlap and are at least partially different, (e.g. the "hop" reference in Fig. 8A). In one embodiment, each frame may comprise about 512 data sets.

[0074] As shown in Fig. 8B, for each frame m of n data sets, the corresponding data sets may be de-interleaved to yield three data portions corresponding with each of the three dimensions, e.g. x(n), y(n) and z(n). Then, the three data portions may be windowed, e.g. utilizing a Kaiser windowing approach. The windowed data may be further processed according to a Fourier transform function to obtain frequency domain data. In turn, a square of the modulus of the frequency domain data may be determined for each of the three-dimensional data sets corresponding with a given frame, and the resultant values may summed to generate a spectral output for each frame. In turn, the spectral output for a plurality of frames of data may be analyzed on an ongoing basis to detect and assess patient motion.

[0075] In this regard, reference is now made to Fig. 8C which illustrates exemplary spectral data corresponding with multiple frames of data (e.g. about 130 frames). In particular, for each frame of data a corresponding spectral distribution across a predetermined frequency range of about 0Hz to about 20Hz is shown, wherein the magnitude corresponding with a given frequency is reflected by the number or concentration of data points. In relation to the illustrated example, the spectral data may be analyzed in relation to a plurality of frequency bands, e.g. a first band of about 0Hz to 5.5 Hz, a second band of about 5.5Hz to 12.5 Hz, a third band of about 12.5Hz to 16Hz, and optionally a fourth band of about 16Hz to 20Hz.

[0076] Of particular interest is the spectral data corresponding with the second frequency band of about 5.5Hz to about 12.5Hz. In this regard, it has been recognized that shivering is most frequently reflected by a patient motion component that is centered at about 9.5Hz. In the example of Fig. 8C, for the second frequency band, it may be seen that patient shivering may be indicated in relation to the spectral data corresponding with data frames beginning at about frame "40", wherein increasing degrees of shivering are reflected from about frame "110" to frame "120". Non-shivering motion may be reflected by the spectral data corresponding with the data frames preceding frame "40".

[0077] As may be appreciated from the example shown in Fig. 8C, spectral data corresponding with a plurality of successive data frames may be statistically analyzed and processed on an ongoing basis in relation to each of a plurality frequency of bands. In particular, and with reference to Fig. 8C, for a given frame or set of frames, the spectral data points within each frequency band may be collected into a corresponding data set. In turn, for each of the data sets corresponding with each frequency band, a mean square energy value, a peak energy value and a crest factor value may be determined, as shown in Fig. 8D. Thereafter, the mean square energy values, peak energy values, crest factor values for each of the frequency bands may be compared to one another and/or with corresponding values in previous frame sets to detect a predetermined magnitude or degree of motion corresponding with patient shivering.

[0078] By way of example, in one approach the mean square energy values and crest factor values for two or more frequency bands may be compared (e.g. a "low" frequency band of about 0Hz to 5.5Hz, a "middle" frequency band of about 5.5Hz to 12.5Hz, and an "upper" frequency band of about 12.5Hz to 16Hz), wherein a calculated mean square energy value of the lower band which is greater than or equal to a calculated mean square energy value for the upper band, together with a crest factor value for all three bands that is less than a predetermined value (e.g. a relatively low value), may indicate the absence of or a relatively low level of patient motion. Further, a rise in the mean square energy value and crest factor value for each of the bands may indicate patient motion. And, a rise in the mean square energy value for the middle band (e.g. encompassing the 9.5Hz level typically related to shivering) relative to the low and high bands, together with a decrease in the crest factor value for the middle band, may indicate the presence and/or a degree of patient shivering.

[0079] As noted above, a monitoring signal **12** may also be processed via time domain processing. In one embodiment shown in Figs. 9A-9C, a monitoring signal, or sensor input, three-dimensional accelerometer output data may be filtered and processed to yield power values associated with a predetermined plurality of frequency bands. In turn, the power values may be analyzed to obtain an indication of a magnitude degree and/or stage of shivering. By way of example, and as shown in Fig. 9A, the monitoring signal may comprise sets of three-dimensional data that may be filtered to block, or remove, DC frequency components (e.g. to reduce or remove gravitational influences). In turn, a square of a modulus value corresponding with the three-dimensional data sets may be computed and summed for each and/or a plurality of frames of data sets. Such processing may be conducted without frequency filtering to obtain a first power value. Further, such processing may be conducted after applying a high-pass filter (e.g. to filter out or remove frequency components in a lower band (of about 5.5Hz or less)) to obtain a second power value, and after applying both a high-pass filter and a low-pass filter (e.g. filter out or remove frequency components above about 12.5Hz) to obtain a third power value. The second and third power values may be subtracted from the first power value to obtain a power value associated with a lower, or "below-shiver", frequency band (e.g. about 0Hz to 5.5Hz). Further, the third power value may be subtracted from the second value to obtain a power value associated with a higher, or "above-shiver", frequency band (e.g. above about 12.5Hz). Finally, the third power value may be understood to be associated with a middle frequency band, or "shiver band", (e.g. about 5.5Hz to 12.5Hz).

[0080] As further reflected by Fig. 9A after high-pass and low-pass filtering of the monitoring signal, the filtered data sets may be further processed via a prediction error filter (PEF) to yield a prediction error power value. In this regard, an adaptive filter (e.g. a first-order least mean squares adaptive filter) may be applied, as reflected by Fig. 9B. Further, an output of the predictive error filter may be employed in conjunction with a single value decomposition (SID) spatial analysis to obtain a condition ratio value and minor axis of motion value, as reflected by Fig. 9B.

[0081] In turn, the above-noted values may be utilized to assess shivering. For example, in one approach the below-shiver band, above-shiver band and shiver-band power values may be compared, wherein a below-shiver band power value that is greater than or equal to that of the other bands, together with a condition ratio that is less than a predetermined value (e.g. a relatively low value), may indicate the absence of or a relatively low level of patient motion. Further, a rise in the shiver-band power value, a rise in the condition ratio, and a rise in a shiver-band power value-to-prediction error power value ratio, (e.g. shiver-band power value/prediction error power valve) may combinatively indicate patient motion. Further, a rise in the shiver-band power value, coupled with a decrease in the condition ratio and a decrease in the shiver-band power value-to-prediction error power value ratio, may indicate the presence and/or a degree of patient shivering.

[0082] Additional embodiments to those described above will be apparent. For example, in relation to the motion sensor **400** of Fig. 7A-7C, the sensor **400** may be modified to include one or more output devices for providing an output at sensor **400** indicative of a detected magnitude or level of detected patient shivering, e.g. one or more LED (i.e. light emitting diode) interconnected to the sensor **400** for co-movement therewith (e.g. wherein illumination of an LED indicates detected shivering above a predetermined level and/or wherein illumination of different ones or sets of a plurality of LED's may be employed to indicate corresponding degrees of detected shivering). In turn, an on-board processor for processing the monitoring signal, and an on-board power source (e.g. a battery) and/or an on-board wireless energy receiving device (e.g. an RF signal receiver and rectifier) may be included to power the components.

[0083] The embodiment descriptions provided above are for purposes illustration and are not intended to limit the scope of the present invention. Additions and modifications will be apparent to those skilled in the art.

Claims

1. A system for use in a patient cooling therapy procedure, comprising:

a monitoring device for monitoring patient shivering and for providing a monitoring signal responsive thereto, wherein the monitoring device is selectively interconnectable in fixed relation to and disconnectable from a patient;

a control unit configurable to cool and warm a fluid circulated through at least one contact pad for thermal exchange with a patient, including:

at least one processor programmed to:

control automatically a temperature of the circulated fluid so as to cool and warm a patient in different treatment phases in accordance with a predetermined protocol; and,

process said monitoring signal to provide an output signal indicative of a magnitude of patient shivering; and,

a user interface to graphically display, on an ongoing basis as a function of time during a patient cooling therapy procedure, each of the following:

patient motion data, responsive to said output signal, indicating a magnitude of patient shivering as a function of time, wherein said patient motion data is displayed in relation to a predetermined magnitude scale having a plurality of predetermined levels of patient motion indicative of increasing degrees of patient shivering;

a predetermined patient temperature adjustment rate plot indicating a desired patient temperature to be reached as a function of time;

a measured patient temperature plot indicating a measured patient temperature as a function of time; and,

a measured circulated fluid temperature plot indicating a measured temperature of said circulated fluid as a function of time.

2. A system as recited in Claim 1, wherein said user interface provides a screen that includes:

a graphic display portion that graphically displays said predetermined patient temperature adjustment rate plot, said measured patient temperature plot, and said measured circulated fluid temperature plot in a first region of the graphic display portion, relative to a temperature scale and time scale.

3. A system as recited in Claim 2, wherein said graphic display portion graphically displays said patient motion data in a second region of the graphic display portion, relative to said time scale.

4. A system as recited in Claim 1, further comprising:
at least one of a battery and a wireless energy conversion device, interconnected to said monitoring device for direct co-movement therewith, for powering said monitoring device free from hardwire interconnection with a power source.

5. A system as recited in Claim 4, wherein said at least one of a battery and a wireless energy conversion device being one of directly connected to said monitoring device and interconnected to a common support member together with said monitoring device for co-movement therewith.

6. A system as recited in Claim 4, further comprising:
a transmitter for transmission of a wireless signal corresponding with said monitoring signal, wherein said transmitter comprises an antenna and is interconnected to said monitoring device for co-movement therewith.

7. A system as recited in Claim 1, wherein said processor is operable to employ said monitoring signal to generate an input for use in controlling the temperature of the circulated fluid.

8. A system as recited in Claim 1, wherein said monitoring device is for one of the following:

monitoring blood oxygen saturation of a patient;
monitoring vasoconstriction of a patient;
surface monitoring of muscular electrical activity of a patient;
monitoring at least one carbon dioxide parameter of a respiratory gas of a patient; and,
monitoring motion of a patient.

9. A system as recited in Claim 1, wherein said monitoring device comprises a motion sensor including:
a three-dimensional accelerometer, wherein said monitoring signal comprises three-dimensional acceleration data and comprises a stream of sequential data sets.

10. A system as recited in Claim 9, wherein said at least one processor is programmed to:
process said monitoring signal utilizing frequency domain processing to provide said output signal, wherein in said process said at least one processor is programmed to process a plurality of frames of said sequential data sets on an ongoing basis to determine spectral data corresponding with each different one of said plurality of frames of said sequential data sets, wherein each frame of said plurality of frames of said sequential data sets comprises a plurality of said sequential data sets, wherein sequential ones of said plurality of said frames of said sequential data sets are partially overlapping and partially non-overlapping, and wherein for said plurality of frames of said sequential data sets the at least one processor is programmed to collect and analyze spectral data sets corresponding with each different one of a plurality of different, predetermined frequency bands to detect said magnitude of patient shivering.

11. A system as recited in Claim 10, wherein each of said sequential data sets comprises data corresponding with a measured magnitude related to acceleration in each of said three dimensions.

12. A system as recited in Claim 11, wherein for each frame of said plurality of frames said at least one processor is programmed to:

de-interleave said frame to obtain three data portions corresponding with each of said three dimensions;
window said three data portions; and,
transform the three windowed data portions to obtain three corresponding frequency domain data portions.

13. A system as recited in Claim 12, wherein for each frame of said plurality of frames said at least one processor is programmed to:
utilize the three corresponding frequency domain data portions to obtain a corresponding spectral output.

14. A system as recited in Claim 10, wherein said plurality of different, predetermined frequency bands includes at least a predetermined first frequency band and a different, predetermined second frequency band, wherein only one of said predetermined first frequency band and said predetermined second frequency band includes a frequency of 9.5 Hz.

15. A system as recited in Claim 10, wherein for each frame of said plurality of frames the at least one processor is programmed to:

analyze the spectral data sets corresponding with each of said plurality of different, predetermined frequency bands to determine a mean square energy value, a peak energy value and a crest factor; and,
compare the mean square energy values, peak energy values, and crest factor values for each of the plurality of different, predetermined frequency bands to one another or with previously determined, corresponding values to detect a degree of motion corresponding with patient shivering.

Patentansprüche

1. System zur Verwendung in einem Patientenkältetherapieverfahren, umfassend:

   eine Überwachungsvorrichtung zur Überwachung des Zitterns eines Patienten und zur Bereitstellung eines Überwachungssignals als Reaktion darauf, wobei die Überwachungsvorrichtung selektiv in einer fixen Beziehung mit einem Patienten verbindbar und von diesem lösbar ist;
   eine Steuereinheit, die zum Kühlen und Erwärmen einer Flüssigkeit, die durch zumindest ein Kontaktkissen für einen Wärmeaustausch mit einem Patienten zirkuliert wird, auslegbar ist, umfassend:
   mindestens einen Prozessor, der dazu programmiert ist:

      automatisch eine Temperatur der zirkulierten Flüssigkeit zu kontrollieren, um einen Patienten in verschiedenen Behandlungsphasen nach einem vorgegebenen Protokoll zu kühlen und zu wärmen; und
      das Überwachungssignal zu verarbeiten, um ein Ausgangssignal bereitzustellen, das auf ein Ausmaß des Zitterns des Patienten hinweist; und
      eine Benutzerschnittstelle, um in Abhängigkeit von der Zeit während eines Patientenkältetherapieverfahrens fortlaufend grafisch jedes der folgenden anzuzeigen:

         Patientenbewegungsdaten als Reaktion auf das Ausgangssignal, die auf ein Ausmaß des Zitterns des Patienten in Abhängigkeit von der Zeit hinweisen, wobei die Patientenbewegungsdaten bezüglich einer vorgegebenen Größenskala mit einer Vielzahl von vorgegebenen Ausmaßen an Patientenbewegung, die auf zunehmende Grade des Zitterns des Patienten hinweisen, angezeigt werden;
         ein Diagramm der vorgegebenen Anpassungsrate der Temperatur des Patienten, das auf eine gewünschte Patiententemperatur hinweist, die in Abhängigkeit von der Zeit erreicht werden soll;
         ein Diagramm der gemessenen Temperatur des Patienten, das auf eine gemessene Patiententemperatur in Abhängigkeit von der Zeit hinweist; und
         ein Diagramm der gemessenen Temperatur der zirkulierten Flüssigkeit, das auf eine gemessene Temperatur der zirkulierten Flüssigkeit in Abhängigkeit von der Zeit hinweist.

2. System nach Anspruch 1, wobei die Benutzerschnittstelle eine Bildschirm bereitstellt, der Folgendes aufweist:
   einen grafischen Anzeigeabschnitt, der das Diagramm der vorgegebenen Anpassungsrate der Patiententemperatur, das Diagramm der gemessenen Temperatur des Patienten und das Diagramm der gemessenen zirkulierten Flüssigkeit in einem ersten Bereich des grafischen Anzeigeabschnitts grafisch anzeigt, im Verhältnis zu einer Temperaturskala und einer Zeitskala.

3. System nach Anspruch 2, wobei der grafische Anzeigeabschnitt die Patientenbewegungsdaten in einem zweiten Bereich des grafischen Anzeigeabschnitts im Verhältnis zur Zeitskala grafisch anzeigt.

4. System nach Anspruch 1, ferner umfassend:
   mindestens eine Batterie und eine drahtlose Energieumwandlungsvorrichtung, die mit der Überwachungsvorrichtung für eine direkte gleichzeitige Bewegung damit verbunden ist, um die Überwachungsvorrichtung ohne eine festverdrahtete Verbindung mit einer Stromquelle mit Strom zu versorgen.

5. System nach Anspruch 4, wobei die mindestens eine einer Batterie und einer drahtlosen Energieumwandlungsvorrichtung entweder direkt mit der Überwachungsvorrichtung verbunden ist oder mit einem gemeinsamen Unterstützungsglied zusammen mit der Überwachungsvorrichtung für eine gleichzeitige Bewegung damit verbunden ist.

6. System nach Anspruch 4, ferner umfassend:
   einen Sender zum Senden eines Funksignals, das dem Überwachungssignal entspricht, wobei der Sender eine Antenne umfasst und mit der Überwachungsvorrichtung für eine gleichzeitige Bewegung damit verbunden ist.

7. System nach Anspruch 1, wobei der Prozessor betätigbar ist, um das Überwachungssignal zum Erzeugen einer Eingabe zur Verwendung bei der Kontrolle der Temperatur der zirkulierten Flüssigkeit zu verwenden.

8. System nach Anspruch 1, wobei die Überwachungsvorrichtung eines der Folgenden dient:

   Überwachung der Blutsauerstoffsättigung eines Patienten;
   Überwachung der Vasokonstriktion eines Patienten;
   Oberflächenüberwachung der elektrischen Muskelaktivität eines Patienten;
   Überwachung mindestens eines Kohlendioxid-

parameters eines Atemgases eines Patienten; und
Überwachung der Bewegung eines Patienten.

9. System nach Anspruch 1, wobei die Überwachungsvorrichtung einen Bewegungssensor umfasst mit:
einem dreidimensionalen Beschleunigungsmesser, wobei das Überwachungssignal dreidimensionale Beschleunigungsdaten umfasst und einen Strom von sequentiellen Datensätzen umfasst.

10. System nach Anspruch 9, wobei der mindestens eine Prozessor dazu programmiert ist:
das Überwachungssignal unter Verwendung von Frequenzdomänenverarbeitung zur Bereitstellung des Ausgangssignals zu verarbeiten, wobei in diesem Verfahren der mindestens eine Prozessor zur fortlaufenden Verarbeitung einer Vielzahl von Frames der sequentiellen Datensätze programmiert ist, um Spektraldaten zu bestimmen, die jedem verschiedenen der Vielzahl von Frames der sequentiellen Datensätze entsprechen, wobei jeder Frame der Vielzahl von Frames der sequentiellen Datensätze eine Vielzahl der sequentiellen Datensätze umfasst, wobei sequentielle der Vielzahl von Frames der sequentiellen Datensätze sich teilweise überlappen und sich teilweise nicht überlappen, und wobei für die Vielzahl von Frames der sequentiellen Datensätze der mindestens eine Prozessor dazu programmiert ist, Spektraldatensätze, die jedem verschiedenen einer Vielzahl von unterschiedlichen vorgegebenen Frequenzbändern entsprechen, zu erfassen und auszuwerten, um das Ausmaß des Zitterns des Patienten nachzuweisen.

11. System nach Anspruch 10, wobei jeder der sequentiellen Datensätze Daten umfasst, die einer gemessenen Größe bezüglich der Beschleunigung in jeder der drei Dimensionen entsprechen.

12. System nach Anspruch 11, wobei für jeden Frame der Vielzahl von Frames der mindestens eine Prozessor dazu programmiert ist:

den Frame zu entschachteln, um drei Datenabschnitte zu erhalten, die jeder der drei Dimensionen entsprechen;
die drei Datenabschnitte zu fenstern; und
die drei gefensterten Datenabschnitte zu transformieren, um drei entsprechende Frequenzdomänendatenabschnitte zu erhalten.

13. System nach Anspruch 12, wobei für jeden Frame der Vielzahl von Frames der mindestens eine Prozessor dazu programmiert ist:
die drei entsprechenden Frequenzdomänendatenabschnitte zum Erhalten einer entsprechenden Spektralausgabe zu verwenden.

14. System nach Anspruch 10, wobei die Vielzahl von unterschiedlichen vorgegebenen Frequenzbändern mindestens ein vorgegebenes erstes Frequenzband und ein unterschiedliches vorgegebenes zweites Frequenzband aufweist, wobei nur eines des vorgegebenen ersten Frequenzbands und des vorgegebenen zweiten Frequenzbands eine Frequenz von 9,5 Hz aufweist.

15. System nach Anspruch 10, wobei für jeden Frame der Vielzahl von Frames der mindestens eine Prozessor dazu programmiert ist:

die Spektraldatensätze, die jedem der Vielzahl von unterschiedlichen vorgegebenen Frequenzbändern entsprechen, zur Bestimmung eines mittleren quadratischen Energiewerts, eines Spitzenenergiewerts und eines Scheitelfaktors auszuwerten; und
die mittleren quadratischen Energiewerte, die Spitzenenergiewerte und die Scheitelfaktorwerte für jedes der Vielzahl von unterschiedlichen vorgegebenen Frequenzbändern miteinander oder mit zuvor bestimmten entsprechenden Werten zu vergleichen, um einen dem Zittern eines Patienten entsprechenden Grad an Bewegung nachzuweisen.

Revendications

1. Système destiné à être utilisé dans une procédure thérapeutique de refroidissement d'un patient, comprenant :

un dispositif de surveillance pour surveiller des frissons d'un patient et pour fournir un signal de surveillance en réponse à ceux-ci, le dispositif de surveillance pouvant être interconnecté sélectivement en relation fixe à un patient et pouvant être déconnecté de celui-ci ;
une unité de commande configurable pour refroidir et réchauffer un fluide circulant dans au moins une plage de contact pour un échange thermique avec un patient, comprenant :
au moins un processeur programmé pour :

commander automatiquement une température du fluide en circulation afin de refroidir et réchauffer un patient dans différentes phases de traitement conformément à un protocole prédéterminé ; et,
traiter ledit signal de surveillance pour fournir un signal de sortie indicatif d'une amplitude des frissons d'un patient ; et,

une interface utilisateur pour afficher graphiquement, de façon continue en fonction du temps

pendant une procédure thérapeutique de refroidissement d'un patient, chacun des éléments suivants :

des données de mouvement d'un patient, en réponse audit signal de sortie, indiquant une amplitude des frissons d'un patient en fonction du temps, lesdites données de mouvement d'un patient étant affichées en fonction d'une échelle d'amplitude prédéterminée ayant une pluralité de niveaux prédéterminés de mouvement d'un patient, indicatifs des degrés d'augmentation des frissons d'un patient ;
une courbe de vitesse d'ajustement d'une température prédéterminée d'un patient indiquant une température souhaitée d'un patient à atteindre en fonction du temps ;
une courbe de température mesurée d'un patient indiquant une température mesurée d'un patient en fonction du temps ; et,
une courbe de température mesurée d'un fluide en circulation indiquant une température mesurée dudit fluide en circulation en fonction du temps.

2. Système selon la revendication 1, ladite interface utilisateur fournissant un écran comprenant :
une partie d'affichage graphique qui affiche graphiquement ladite courbe de vitesse d'ajustement d'une température prédéterminée d'un patient, ladite courbe de température mesurée d'un patient et ladite courbe de température mesurée du fluide en circulation dans une première région de la partie d'affichage graphique, par rapport à une échelle de température et à une échelle de temps.

3. Système selon la revendication 2, ladite partie d'affichage graphique affichant graphiquement lesdites données de mouvement d'un patient dans une seconde région de la partie d'affichage graphique, par rapport à ladite échelle de temps.

4. Système selon la revendication 1, comprenant en outre :
au moins l'un parmi une batterie et un dispositif de conversion d'énergie sans fil, interconnectés audit dispositif de surveillance pour un mouvement conjoint direct avec celui-ci, pour alimenter ledit dispositif de surveillance sans interconnexion câblée avec une source d'alimentation.

5. Système selon la revendication 4, ledit au moins un parmi une batterie et un dispositif de conversion d'énergie sans fil étant soit directement connecté audit dispositif de surveillance soit interconnecté à un élément de support commun conjointement avec ledit dispositif de surveillance pour un mouvement conjoint avec celui-ci.

6. Système selon la revendication 4, comprenant en outre :
un émetteur pour une transmission d'un signal sans fil correspondant audit signal de surveillance, ledit émetteur comprenant une antenne et étant interconnecté audit dispositif de surveillance pour un mouvement conjoint avec celui-ci.

7. Système selon la revendication 1, ledit processeur pouvant fonctionner pour utiliser ledit signal de surveillance pour générer une entrée destinée à commander la température du fluide en circulation.

8. Système selon la revendication 1, ledit dispositif de surveillance étant destiné à l'une des opérations suivantes :

la surveillance de la saturation en oxygène du sang d'un patient ;
la surveillance de la vasoconstriction d'un patient ;
la surveillance de surface de l'activité électrique musculaire d'un patient ;
la surveillance d'au moins un paramètre de dioxyde de carbone d'un gaz respiratoire d'un patient ; et,
la surveillance des mouvements d'un patient.

9. Système selon la revendication 1, ledit dispositif de surveillance comprenant un capteur de mouvement comprenant :
un accéléromètre tridimensionnel, ledit signal de surveillance comprenant des données d'accélération tridimensionnelles et comprenant un flux d'ensembles de données séquentielles.

10. Système selon la revendication 9, ledit au moins un processeur étant programmé pour :
traiter ledit signal de surveillance utilisant un traitement dans le domaine fréquentiel pour fournir ledit signal de sortie, dans ledit processus, ledit au moins un processeur étant programmé pour traiter une pluralité de trames desdits ensembles de données séquentielles de façon continue pour déterminer des données spectrales correspondant à chacune des différentes trames de ladite pluralité de trames desdits ensembles de données séquentielles, chaque trame de ladite pluralité de trames desdits ensembles de données séquentielles comprenant une pluralité desdits ensembles de données séquentielles, les trames séquentielles de ladite pluralité desdites trames desdits ensembles de données séquentielles se chevauchant partiellement et ne se chevauchant pas partiellement, et pour ladite pluralité de trames desdits ensembles de données séquentielles, l'au moins un processeur étant programmé pour collec-

ter et analyser des ensembles de données spectrales correspondant à chacune des bandes de fréquences différentes parmi une pluralité de bandes de fréquences différentes prédéterminées, pour détecter ladite amplitude des frissons d'un patient.

11. Système selon la revendication 10, chacun desdits ensembles de données séquentielles comprenant des données correspondant à une amplitude mesurée liée à une accélération dans chacune desdites trois dimensions.

12. Système selon la revendication 11, pour chaque trame de ladite pluralité de trames, ledit au moins un processeur étant programmé pour :

désentrelacer ladite trame pour obtenir trois parties de données correspondant à chacune desdites trois dimensions ;
fenêtrer lesdites trois parties de données ; et,
transformer les trois parties de données fenêtrées pour obtenir trois parties de données correspondantes de domaine fréquentiel.

13. Système selon la revendication 12, pour chaque trame de ladite pluralité de trames, ledit au moins un processeur étant programmé pour :
utiliser les trois parties de données correspondantes de domaine fréquentiel pour obtenir une sortie spectrale correspondante.

14. Système selon la revendication 10, ladite pluralité de bandes de fréquences prédéterminées différentes comprenant au moins une première bande de fréquences prédéterminée et une seconde bande de fréquences prédéterminée différente, une seule de ladite première bande de fréquences prédéterminée et de ladite seconde bande de fréquences prédéterminée comprenant une fréquence de 9,5 Hz.

15. Système selon la revendication 10, pour chaque trame de ladite pluralité de trames, l'au moins un processeur étant programmé pour :

analyser les ensembles de données spectrales correspondant à chacune de ladite pluralité de bandes de fréquences prédéterminées différentes pour déterminer une valeur d'énergie quadratique moyenne, une valeur d'énergie de pointe et un facteur de crête ; et,
comparer les valeurs d'énergie quadratique moyenne, les valeurs d'énergie de pointe et les valeurs de facteur de crête pour chacune de la pluralité de bandes de fréquences prédéterminées différentes les unes par rapport aux autres ou à des valeurs correspondantes préalablement déterminées pour détecter un degré de mouvement correspondant aux frissons d'un patient.

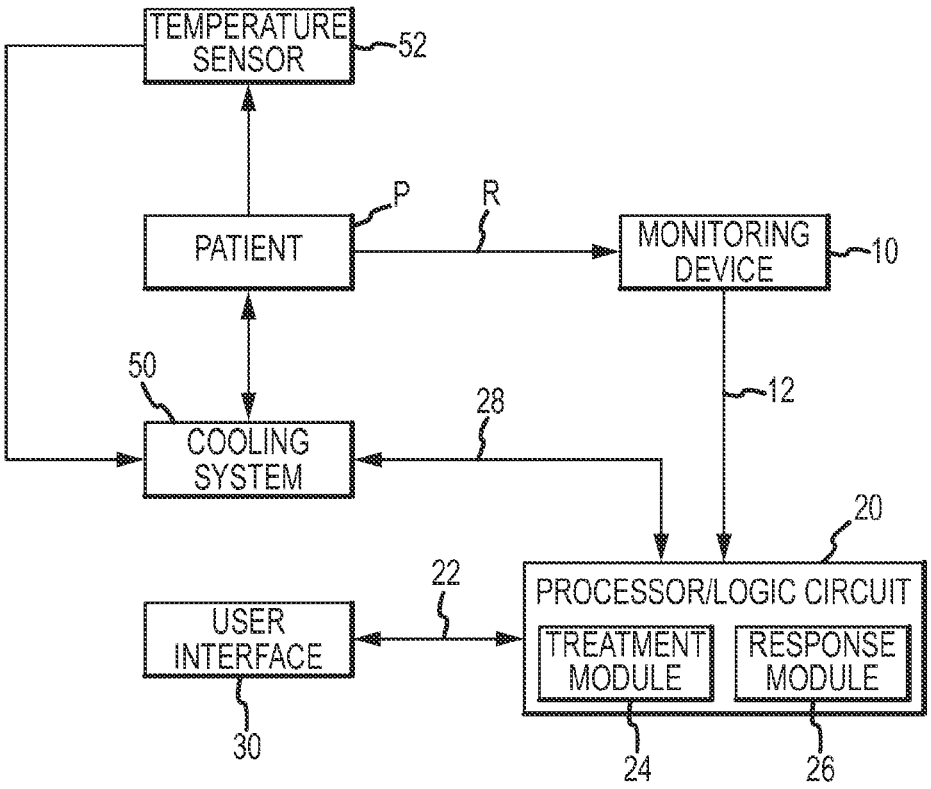

TEMPERATURE SENSOR
52
P
R
PATIENT
MONITORING DEVICE
10
50
12
28
COOLING SYSTEM
20
22
PROCESSOR/LOGIC CIRCUIT
USER INTERFACE
TREATMENT MODULE
RESPONSE MODULE
30
24
26

FIG.1

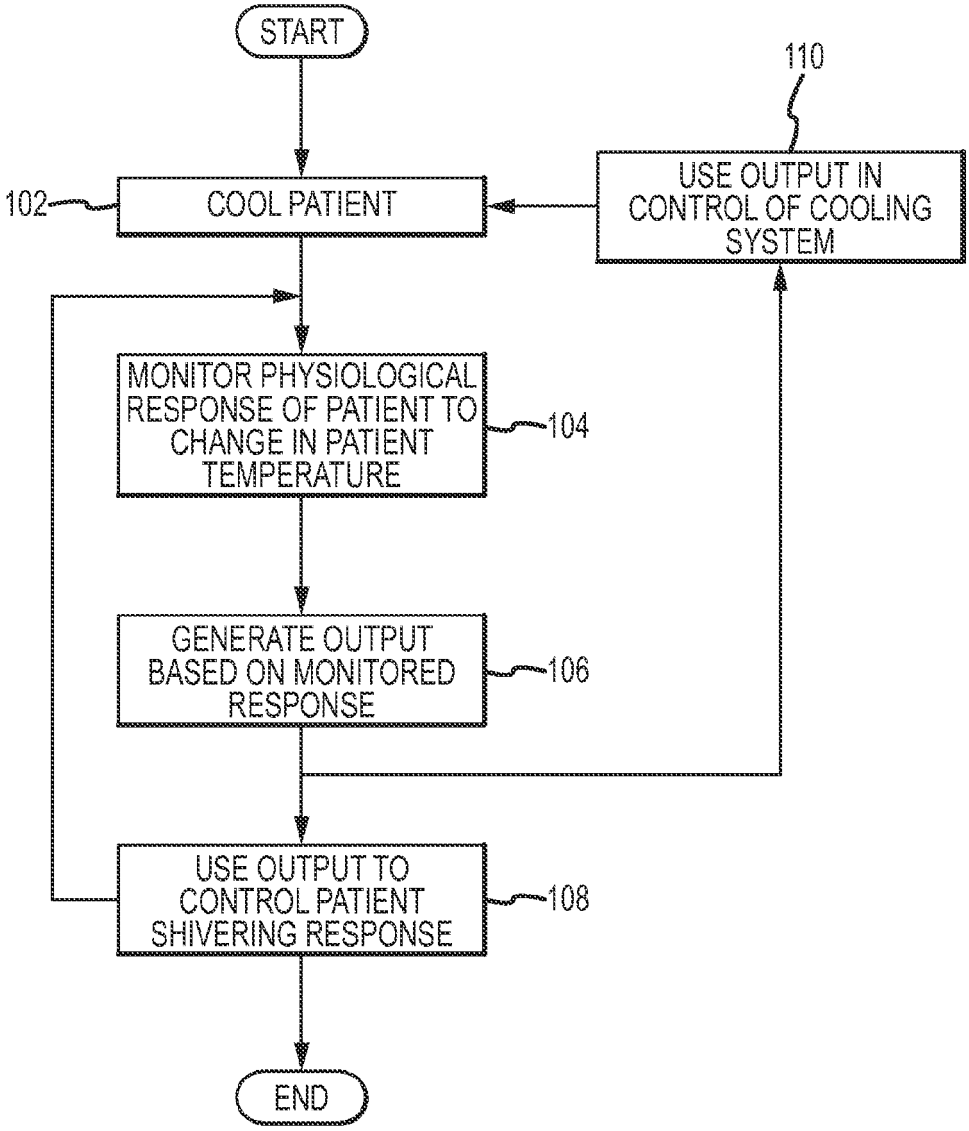

START
110
USE OUTPUT IN CONTROL OF COOLING SYSTEM
102
COOL PATIENT
MONITOR PHYSIOLOGICAL RESPONSE OF PATIENT TO CHANGE IN PATIENT TEMPERATURE
104
GENERATE OUTPUT BASED ON MONITORED RESPONSE
106
USE OUTPUT TO CONTROL PATIENT SHIVERING RESPONSE
108
END

FIG.2

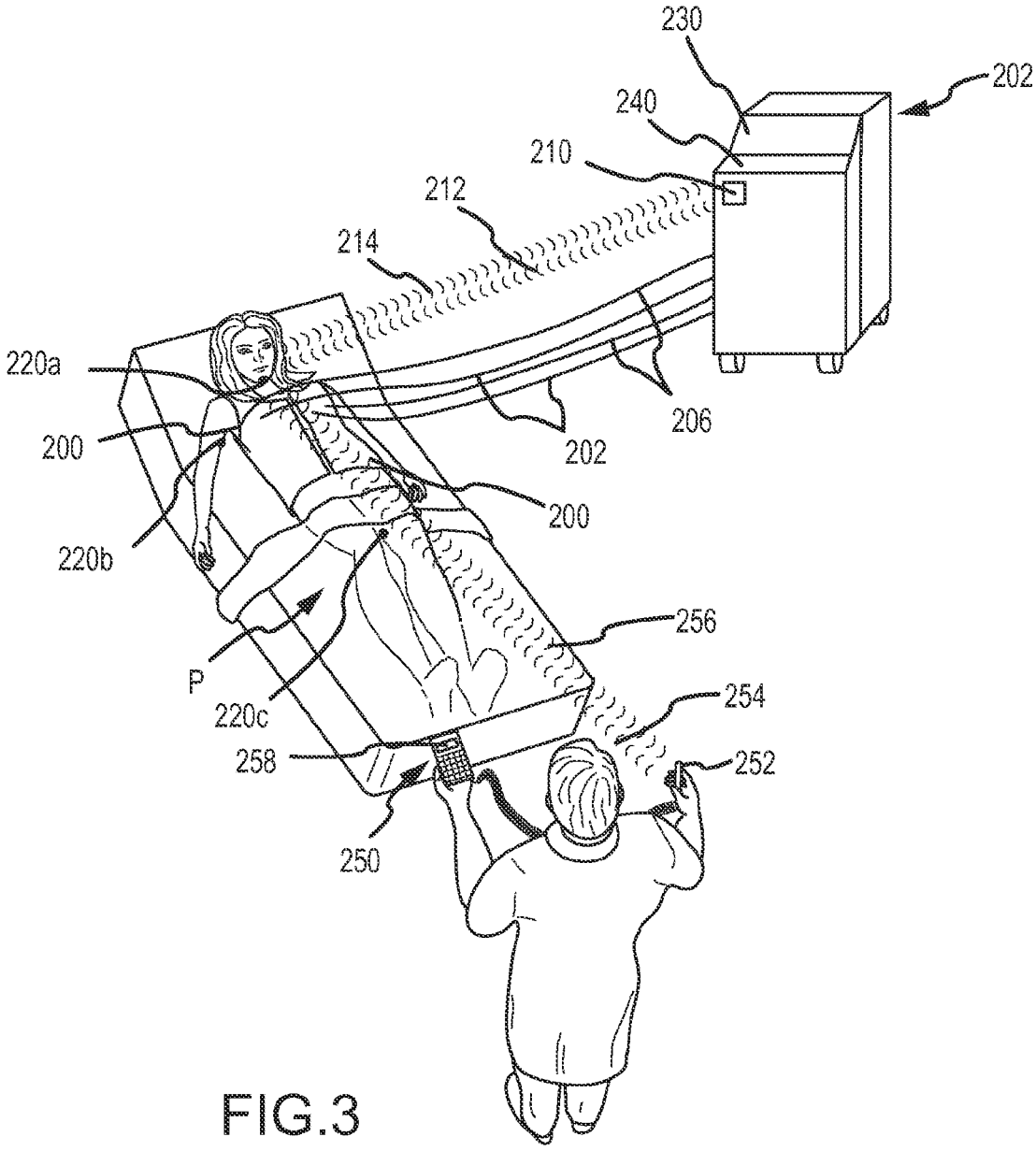

230
202
240
210
212
214
220a
200
206
202
200
220b
256
P
220c
254
258
252
250

FIG.3

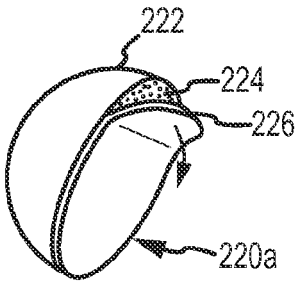

222
224
226
220a

FIG.4

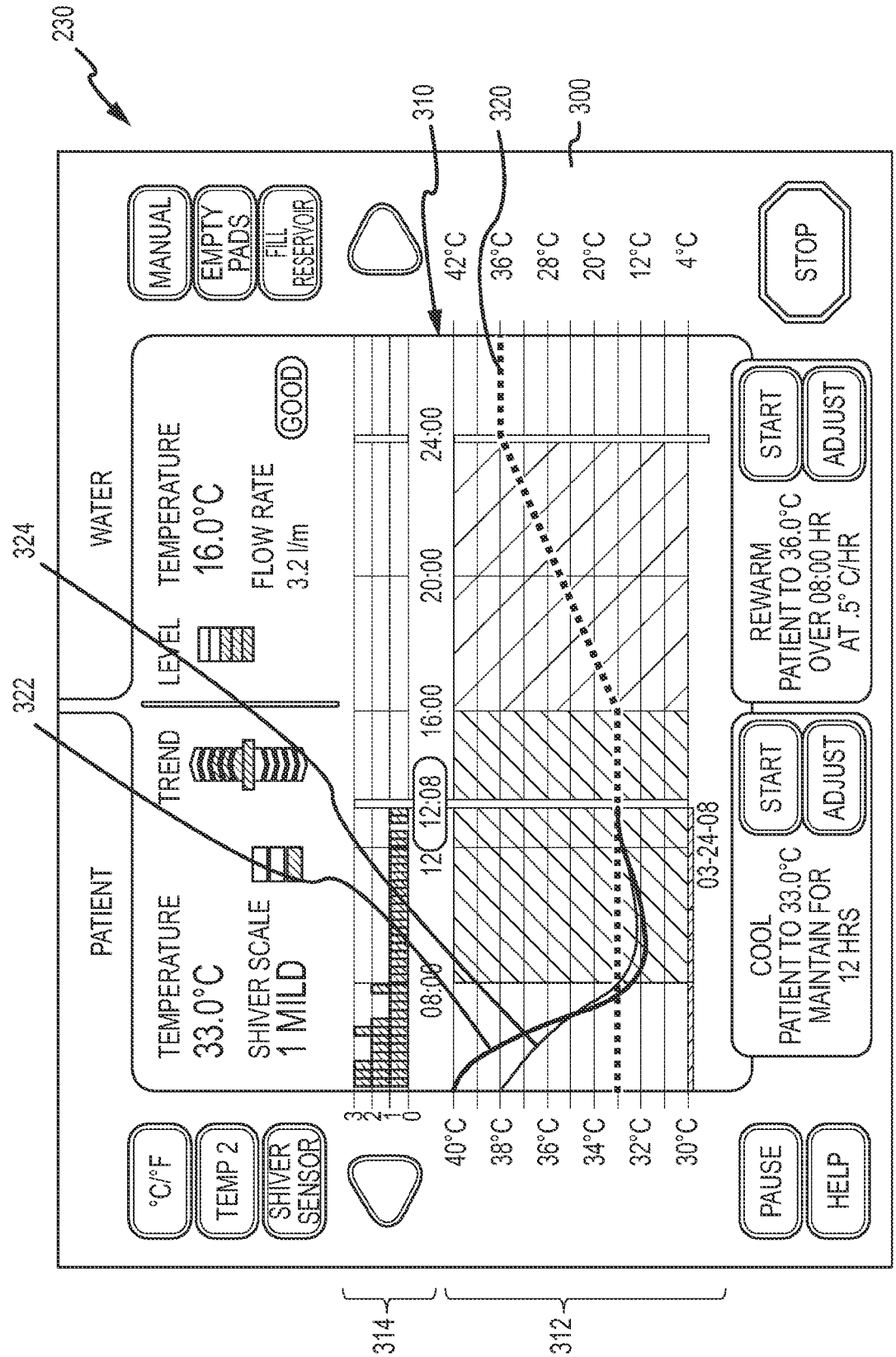

230
310
320
300
324
322
MANUAL
EMPTY PADS
FILL RESERVOIR
STOP
WATER
LEVEL
TEMPERATURE
16.0°C
FLOW RATE
3.2 l/m
GOOD
PATIENT
TREND
TEMPERATURE
33.0°C
SHIVER SCALE
1 MILD
REWARM
PATIENT TO 36.0°C
OVER 08:00 HR
AT .5° C/HR
START
ADJUST
COOL
PATIENT TO 33.0°C
MAINTAIN FOR
12 HRS
START
ADJUST
°C/°F
TEMP 2
SHIVER SENSOR
PAUSE
HELP
08:00
12:08
16:00
20:00
24:00
03-24-08
42°C
36°C
28°C
20°C
12°C
4°C
40°C
38°C
36°C
34°C
32°C
30°C
3
2
1
0
314
312

FIG.5

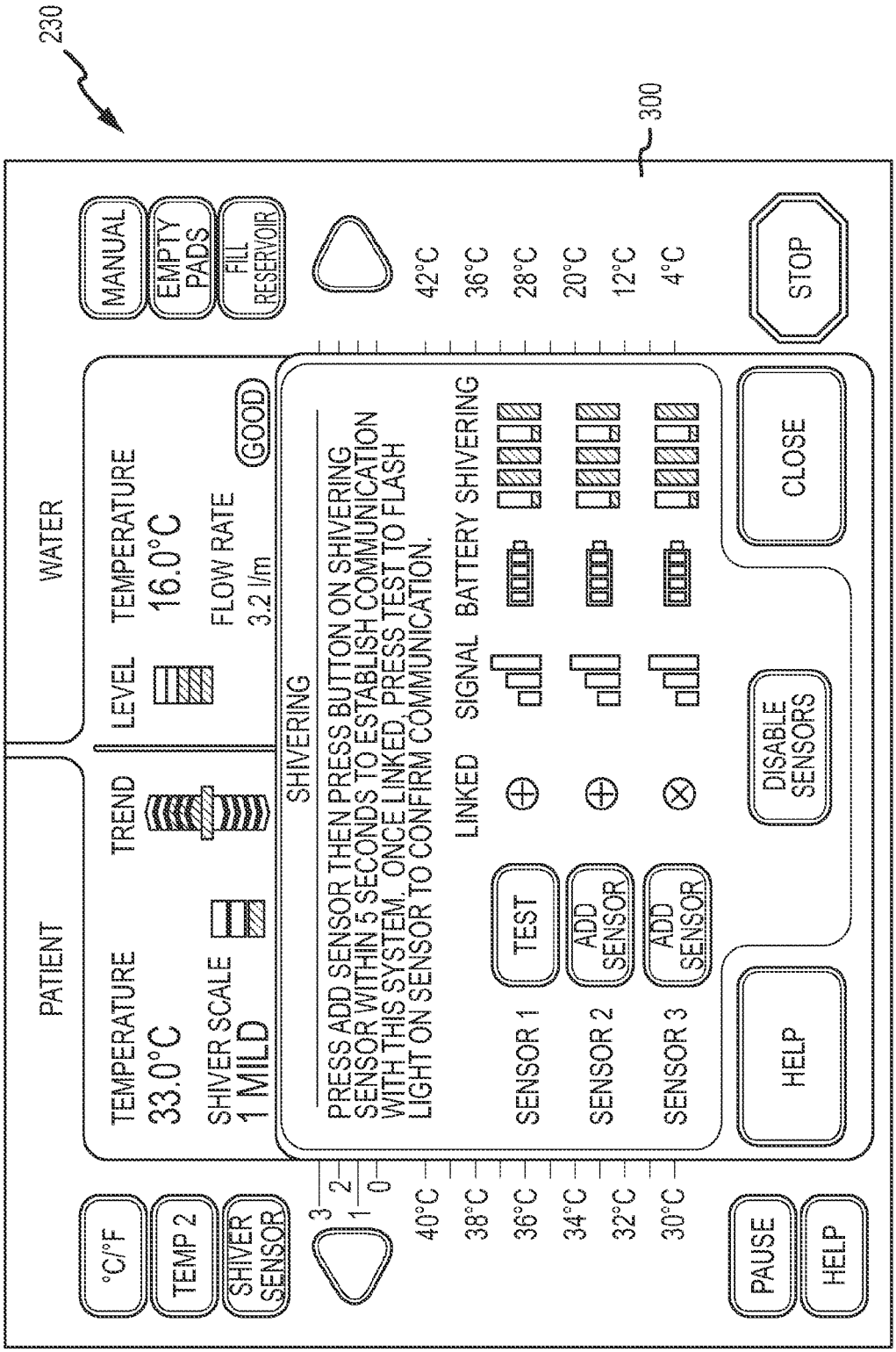

230
300
PATIENT
WATER
°C/°F
TEMP 2
SHIVER SENSOR
PAUSE
HELP
TEMPERATURE
33.0°C
SHIVER SCALE
1 MILD
TREND
LEVEL
TEMPERATURE
16.0°C
FLOW RATE
3.2 l/m
GOOD
MANUAL
EMPTY PADS
FILL RESERVOIR
SHIVERING
PRESS ADD SENSOR THEN PRESS BUTTON ON SHIVERING SENSOR WITHIN 5 SECONDS TO ESTABLISH COMMUNICATION WITH THIS SYSTEM. ONCE LINKED, PRESS TEST TO FLASH LIGHT ON SENSOR TO CONFIRM COMMUNICATION.
LINKED
SIGNAL
BATTERY
SHIVERING
SENSOR 1
SENSOR 2
SENSOR 3
TEST
ADD SENSOR
ADD SENSOR
HELP
DISABLE SENSORS
CLOSE
STOP
3
2
1
0
40°C
38°C
36°C
34°C
32°C
30°C
42°C
36°C
28°C
20°C
12°C
4°C

FIG.6

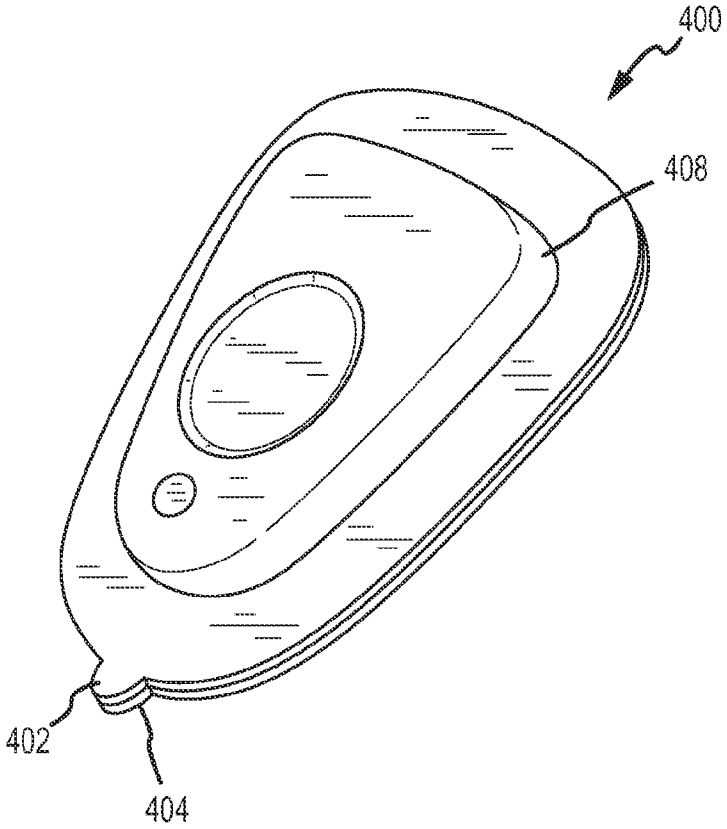


FIG.7A

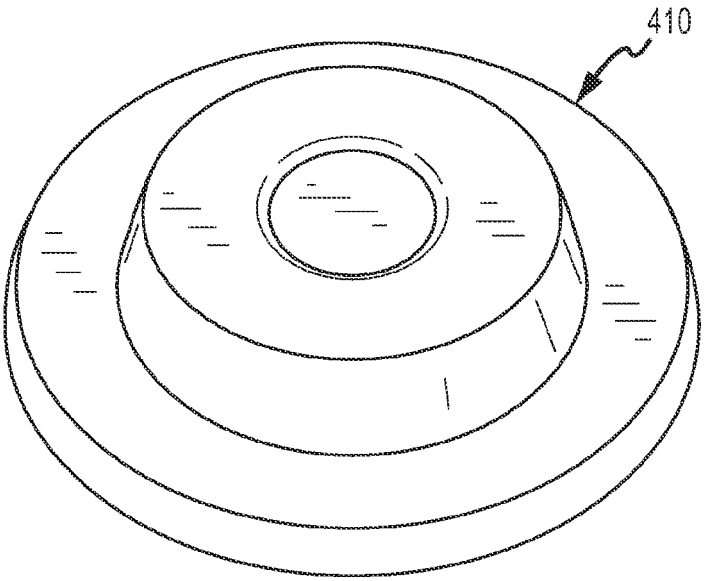


FIG.7B

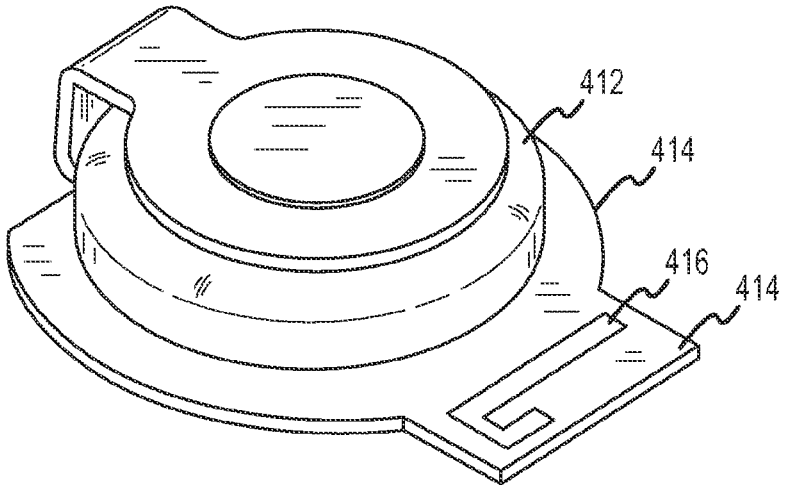


FIG.7C

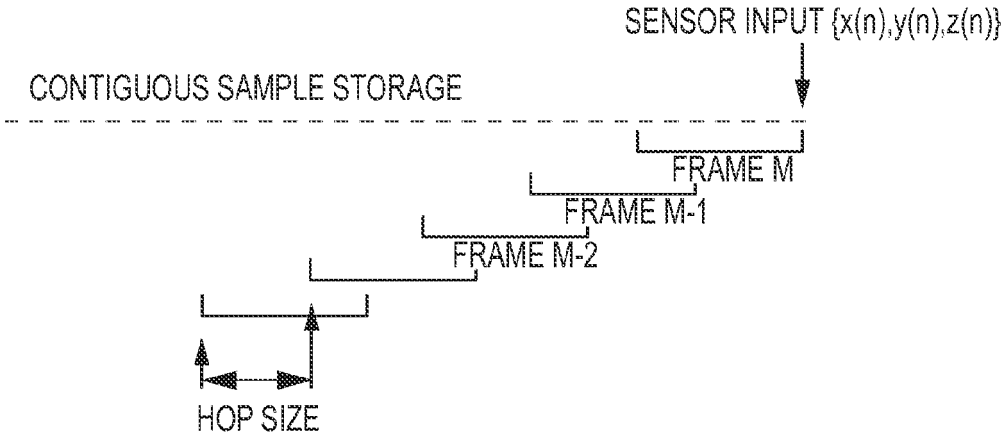

SENSOR INPUT {x(n),y(n),z(n)}
CONTIGUOUS SAMPLE STORAGE
FRAME M
FRAME M-1
FRAME M-2
HOP SIZE

FIG.8A

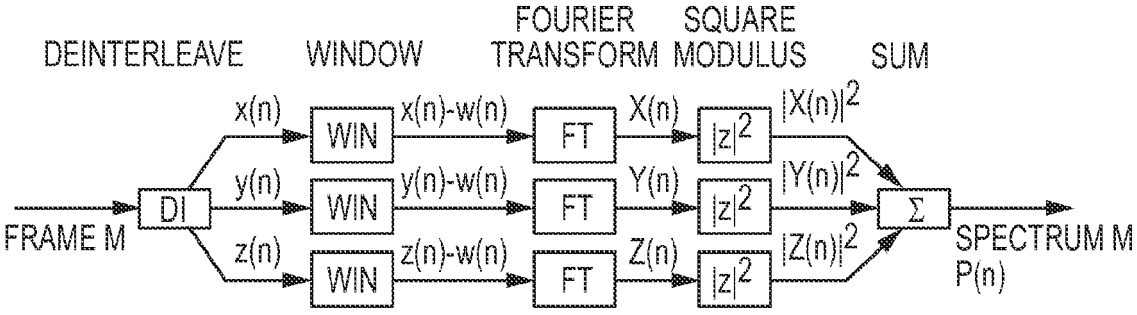

DEINTERLEAVE
WINDOW
FOURIER TRANSFORM
SQUARE MODULUS
SUM
FRAME M
DI
x(n)
y(n)
z(n)
WIN
WIN
WIN
x(n)-w(n)
y(n)-w(n)
z(n)-w(n)
FT
FT
FT
X(n)
Y(n)
Z(n)
|z|2
|z|2
|z|2
|X(n)|2
|Y(n)|2
|Z(n)|2
Σ
SPECTRUM M
P(n)

FIG.8B

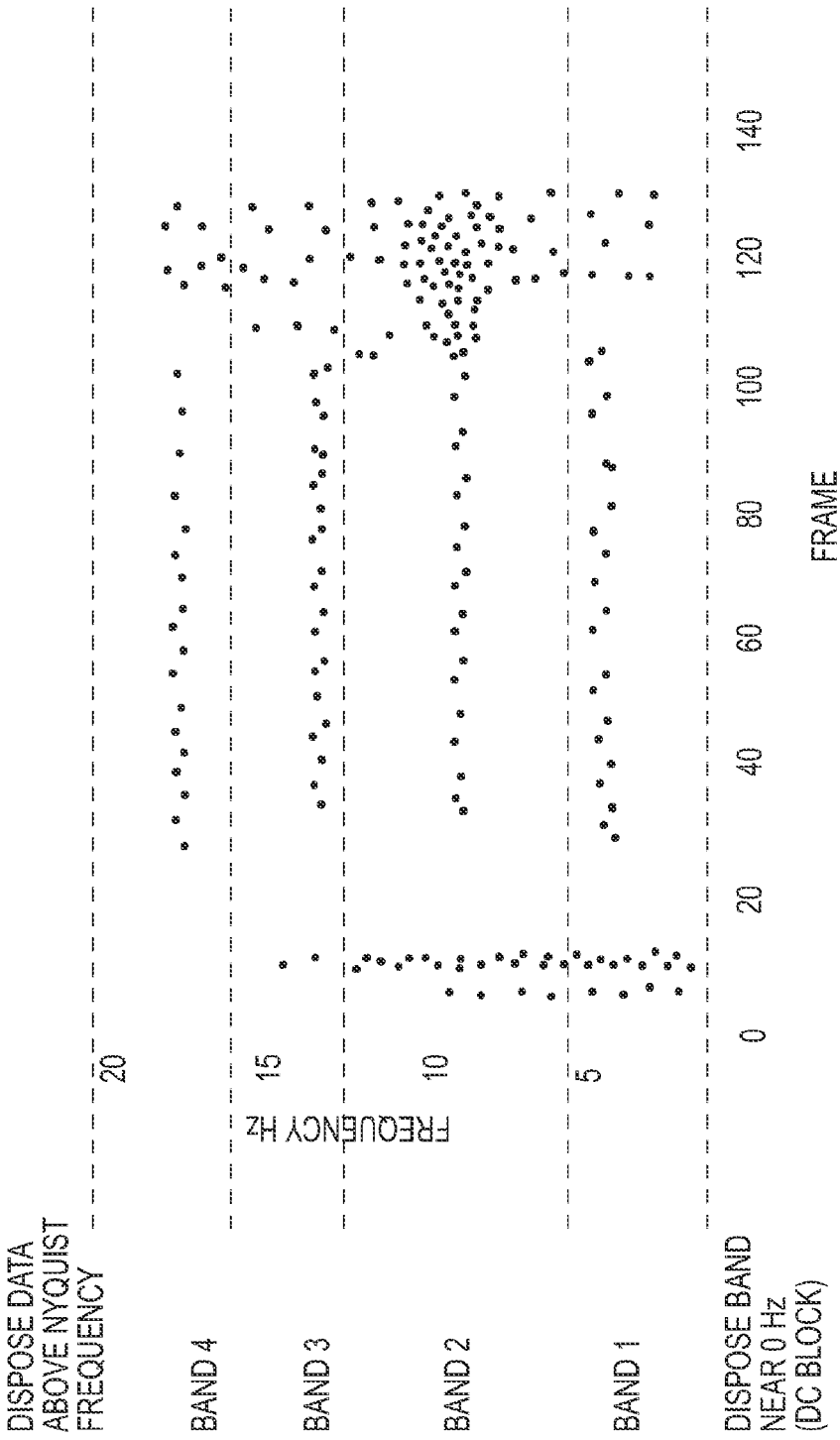

DISPOSE DATA ABOVE NYQUIST FREQUENCY
20
BAND 4
15
BAND 3
FREQUENCY Hz
10
BAND 2
5
BAND 1
DISPOSE BAND NEAR 0 Hz (DC BLOCK)
0
20
40
60
80
100
120
140
FRAME

FIG.8C

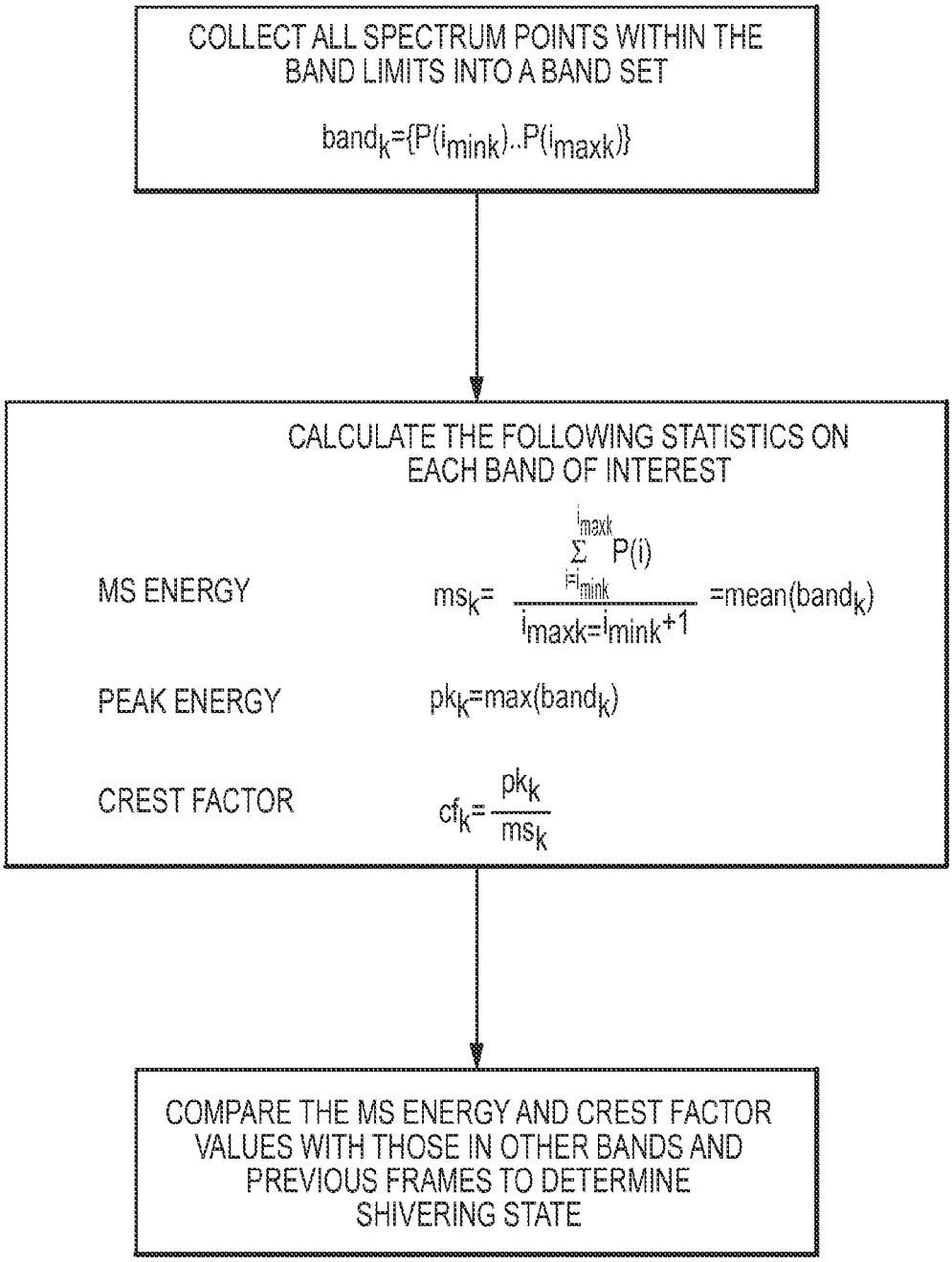

COLLECT ALL SPECTRUM POINTS WITHIN THE BAND LIMITS INTO A BAND SET
$band_k=\{P(i_{mink})..P(i_{maxk})\}$
CALCULATE THE FOLLOWING STATISTICS ON EACH BAND OF INTEREST
MS ENERGY
$ms_k=\frac{\sum_{i=i_{mink}}^{i_{maxk}} P(i)}{i_{maxk}-i_{mink}+1}=mean(band_k)$
PEAK ENERGY
$pk_k=max(band_k)$
CREST FACTOR
$cf_k=\frac{pk_k}{ms_k}$
COMPARE THE MS ENERGY AND CREST FACTOR VALUES WITH THOSE IN OTHER BANDS AND PREVIOUS FRAMES TO DETERMINE SHIVERING STATE

FIG.8D

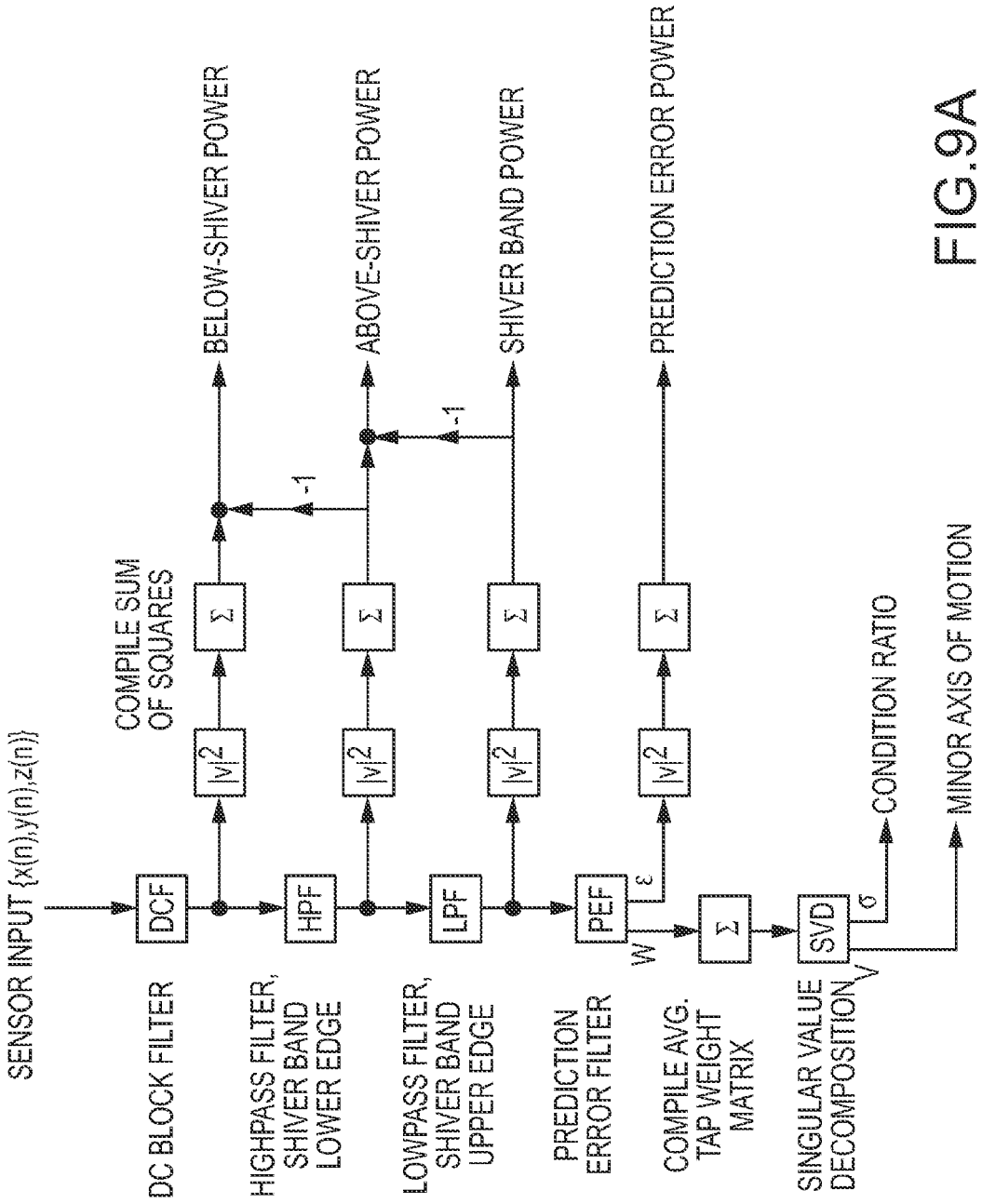
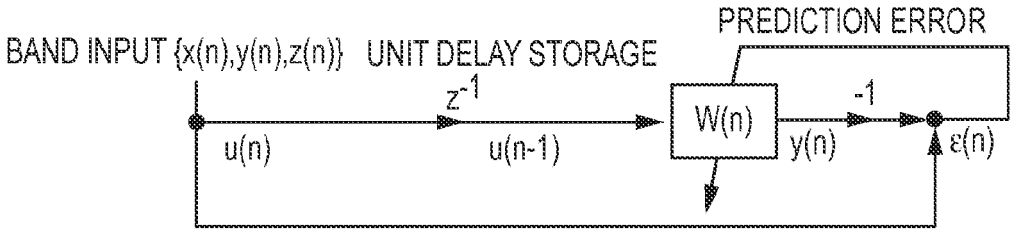

SENSOR INPUT {x(n),y(n),z(n)}
DCF
HPF
LPF
PEF
Σ
SVD
|v|2
ε
W
V
σ
-1
-1
COMPILE SUM OF SQUARES
BELOW-SHIVER POWER
ABOVE-SHIVER POWER
SHIVER BAND POWER
PREDICTION ERROR POWER
CONDITION RATIO
MINOR AXIS OF MOTION
DC BLOCK FILTER
HIGHPASS FILTER, SHIVER BAND LOWER EDGE
LOWPASS FILTER, SHIVER BAND UPPER EDGE
PREDICTION ERROR FILTER
COMPILE AVG. TAP WEIGHT MATRIX
SINGULAR VALUE DECOMPOSITION

FIG.9A

PEF (PREDICTION ERROR FILTER)



FIRST-ORDER LMS ADAPTIVE FILTER

$y(n)=W(n) \cdot u(n-1)$

$\varepsilon(n)=u(n) - y(n)$

$W(n+1)=W(n)+((\mu/(\sigma+|u(n-1)|^2)) (\varepsilon(n) \cdot u(n-1)^T))$

μ AND σ ARE CONSTANT SCALARS THAT TUNE THE ADAPTIVE BEHAVIOR

FIG.9B

SVD (SINGLE VALUE DECOMPOSITION)
SPATIAL ANALYSIS

$W_{avg}=U \cdot \Sigma \cdot V^T$

ELLIPTICAL PARAMETERS (AKA SINGULAR VALUES)

ANALYSIS AXES

THE SMALLEST ELLIPTICAL PARAMETER, σ_{min}, CORRESPONDS TO THE AXIS OF MOST CONSTRAINED MOTION

CONDITION RATIO = $\sigma_{max}/\sigma_{min}$

MINOR AXIS OF MOTION=v_{min}

WHERE v_{min} IS THE COLUMN VECTOR OF V THAT CORRESPONDS TO σ_{min}

$|v_{min}^{(i)} \cdot v_{min}^{(i-1)}|$ YIELDS A VALUE BETWEEN 0 AND 1 THAT REPRESENTS THE PERSISTENCE OF THE PLANE OF MOTION FROM BLOCK TO BLOCK

FIG.9C

REFERENCES CITED IN THE DESCRIPTION

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- US 7294112 B **[0006]**
- US 6238354 B **[0007]**
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- US 6375674 B **[0045]**
- US 6645232 B **[0045]**
- US 2007066893 W **[0045]**
- US 6620187 B **[0063]**
- US 6692518 B **[0063]**
- US 6818012 B **[0063]**

专利名称(译)	患者温度响应控制系统		
公开(公告)号	EP3366199B1	公开(公告)日	2020-01-01
申请号	EP2018156996	申请日	2008-11-17
申请(专利权)人(译)	MEDIVANCE INCORPORATED		
当前申请(专利权)人(译)	MEDIVANCE INCORPORATED		
[标]发明人	VOORHEES MARC CARSON GARY A GRUSZECKI GARY		
发明人	VOORHEES, MARC CARSON, GARY A. GRUSZECKI, GARY		
IPC分类号	A61B5/00 A61B5/01 A61B5/026 A61B5/0488 A61B5/083 A61B5/11 A61B5/1455 A61F7/02 A61F7/00		
CPC分类号	A61B5/01 A61B5/026 A61B5/0488 A61B5/0836 A61B5/11 A61B5/1455 A61B5/4035 A61B5/6814 A61B5/6824 A61B5/6828 A61B5/68335 A61B34/25 A61B2562/0219 A61F7/02 A61B5/1101 A61B5/7435 A61F7/0097 A61F2007/0056 A61F2007/0093		
代理机构(译)	ðYOUNG & CO LLP		
优先权	60/988706 2007-11-16 US PCT/US2008/083818 2008-11-17 WO		
其他公开文献	EP3366199A1		
外部链接	Espacenet		

摘要(译)

提供了一种系统，该系统采用监视设备来监视至少一个患者对患者温度变化的生理反应（例如，根据诱导的低温治疗），其中由监视设备提供监视信号。 继而，可以向用户提供输出（例如视觉和/或听觉输出），该输出指示患者对温度变化的响应的至少一种量度。 提供了处理器以处理监视信号，以提供医务人员可用来控制患者对患者温度变化的颤抖响应的输出。 这样的信息可以包括关于一种或多种抗发抖药物的信息，例如抗炎药。 相应的剂量和/或频率信息，以供医务人员使用抗颤抖药物。

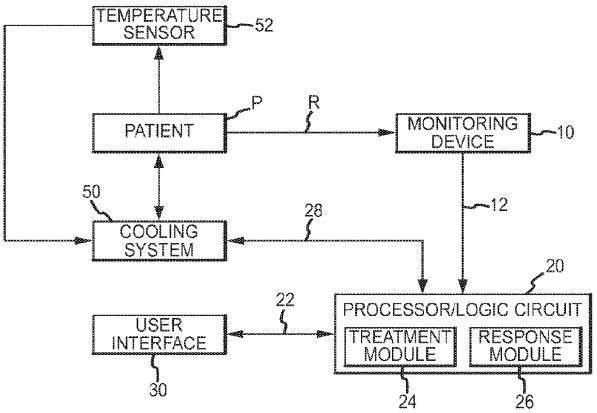

FIG.1