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(54) **SYSTEM FOR PERFORMING REMOTE ISCHEMIC CONDITIONING**

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(58) **Field of Classification Search**
None
See application file for complete search history.

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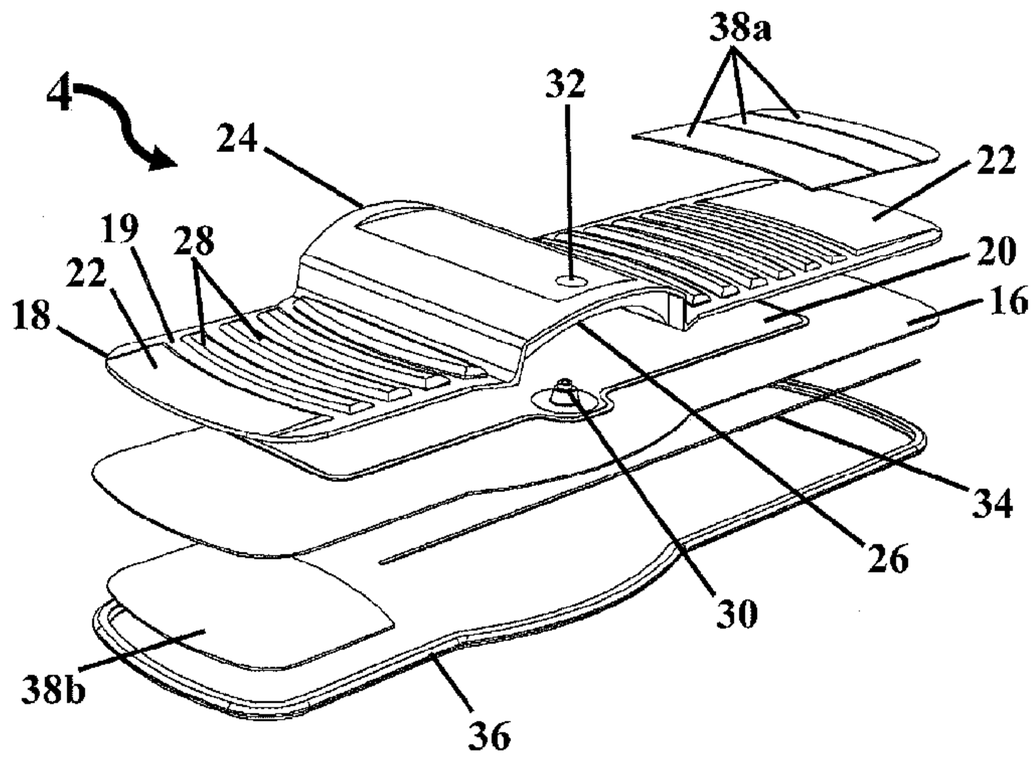
(57) **ABSTRACT**

A system for performing remote ischemic conditioning includes an inflatable cuff configured to encircle a limb of a subject and a controller removably attached to the cuff. The controller includes a pump; a manifold in fluid communication with the pump; a connector in fluid communication with the manifold and in removable fluid communication with the inflatable cuff; a pressure sensor; and a control circuit configured to implement a remote ischemic conditioning treatment protocol.

40 Claims, 7 Drawing Sheets



(51) **Int. Cl.**

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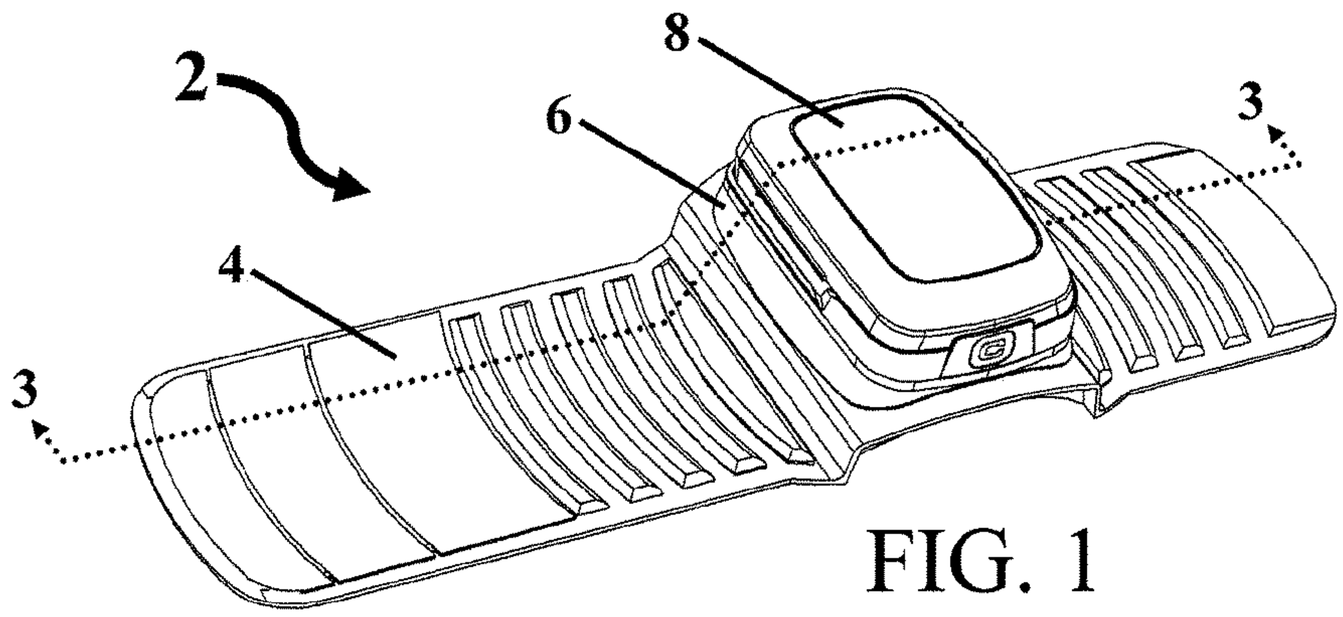

FIG. 1

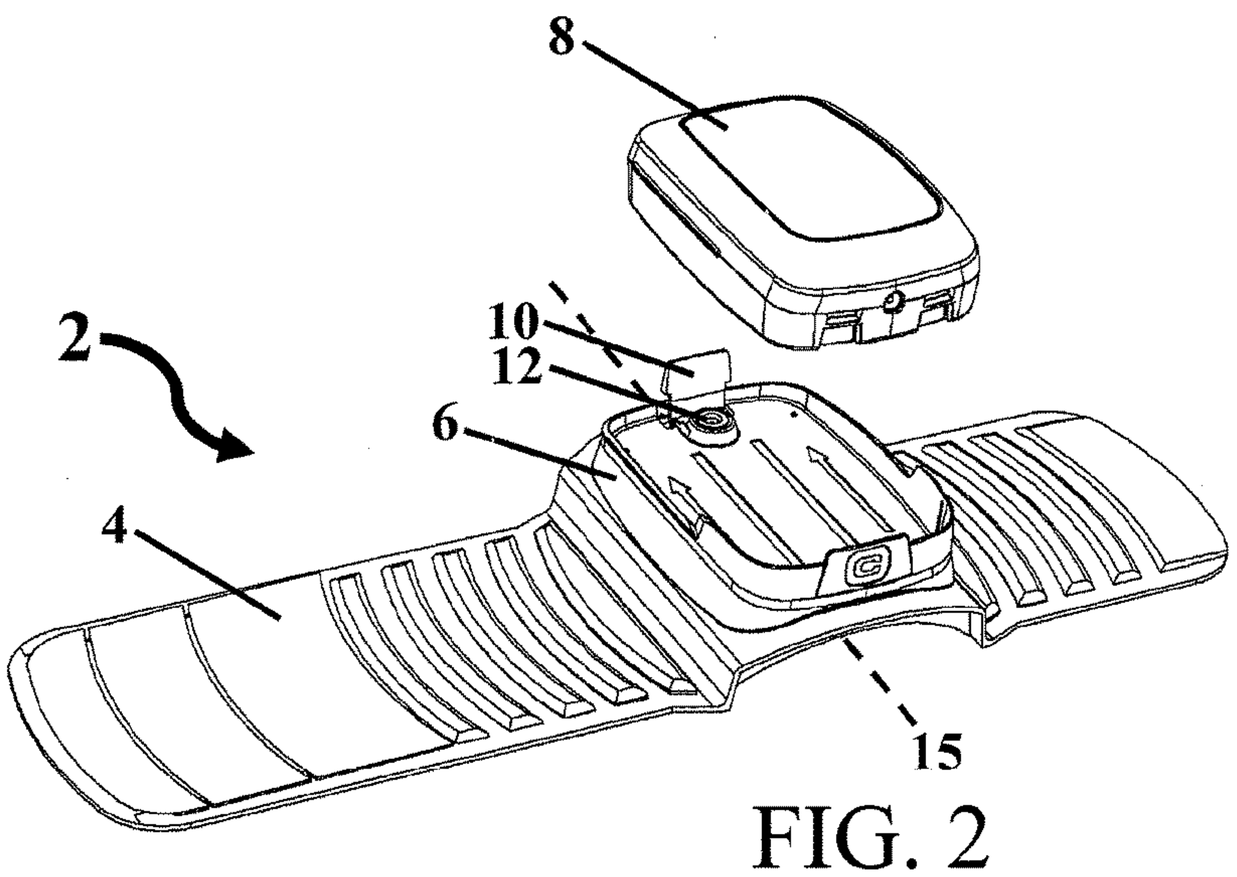

FIG. 2

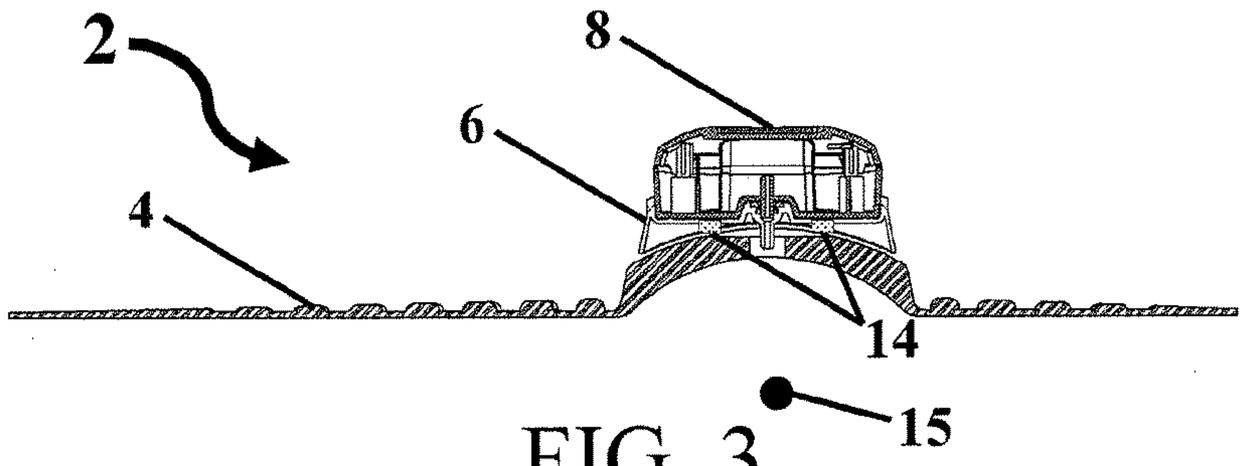

FIG. 3

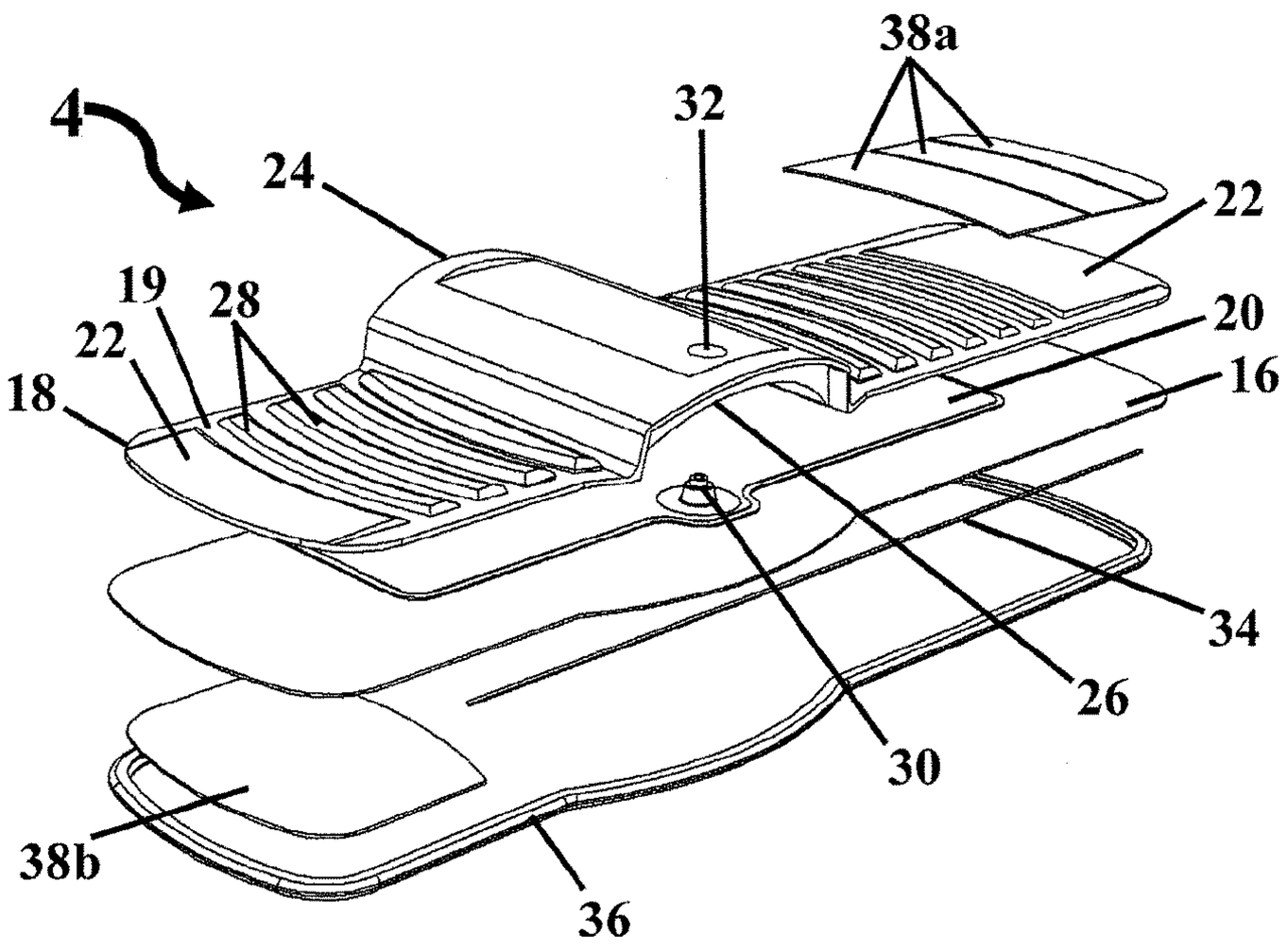

FIG. 4

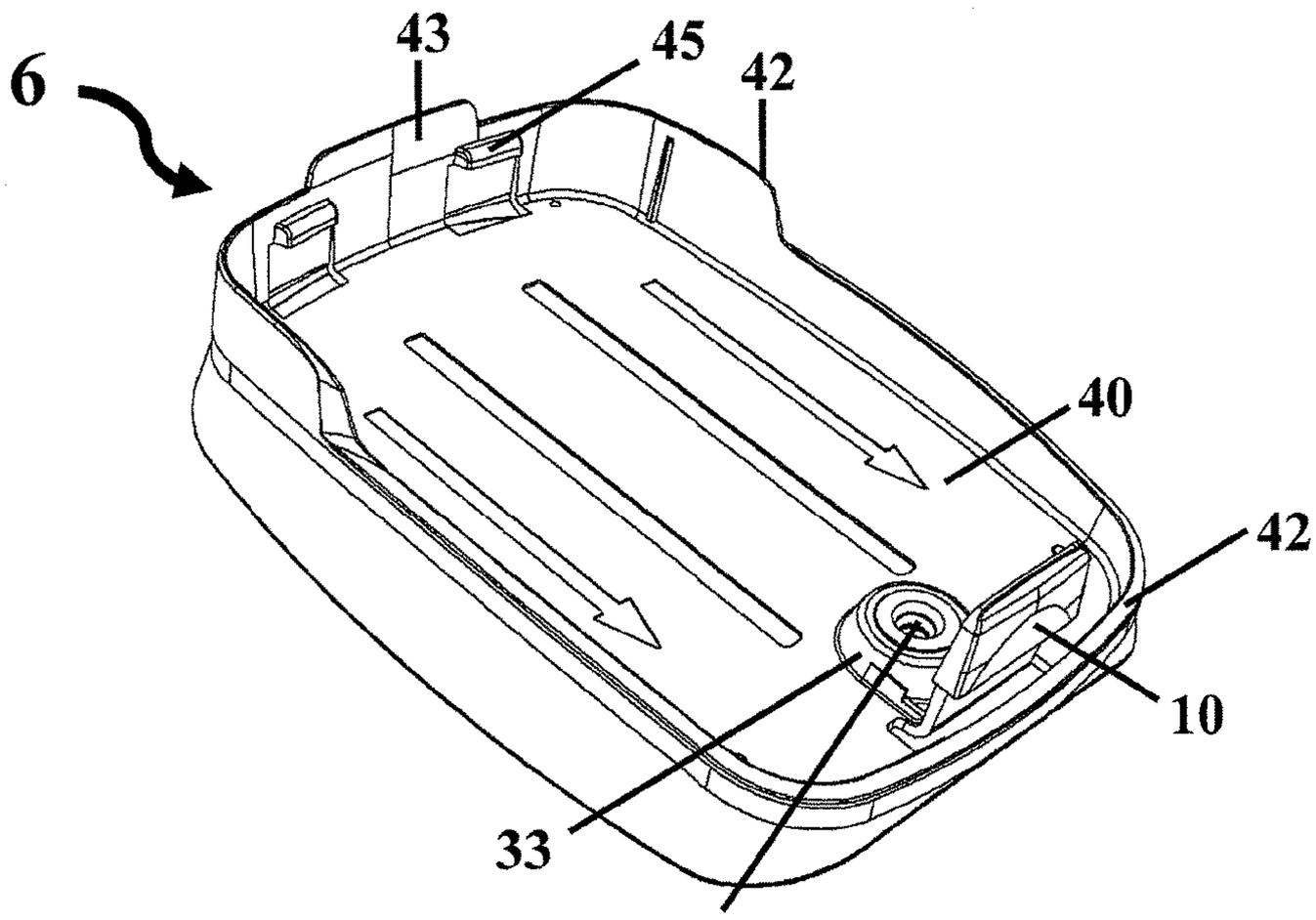

FIG. 5

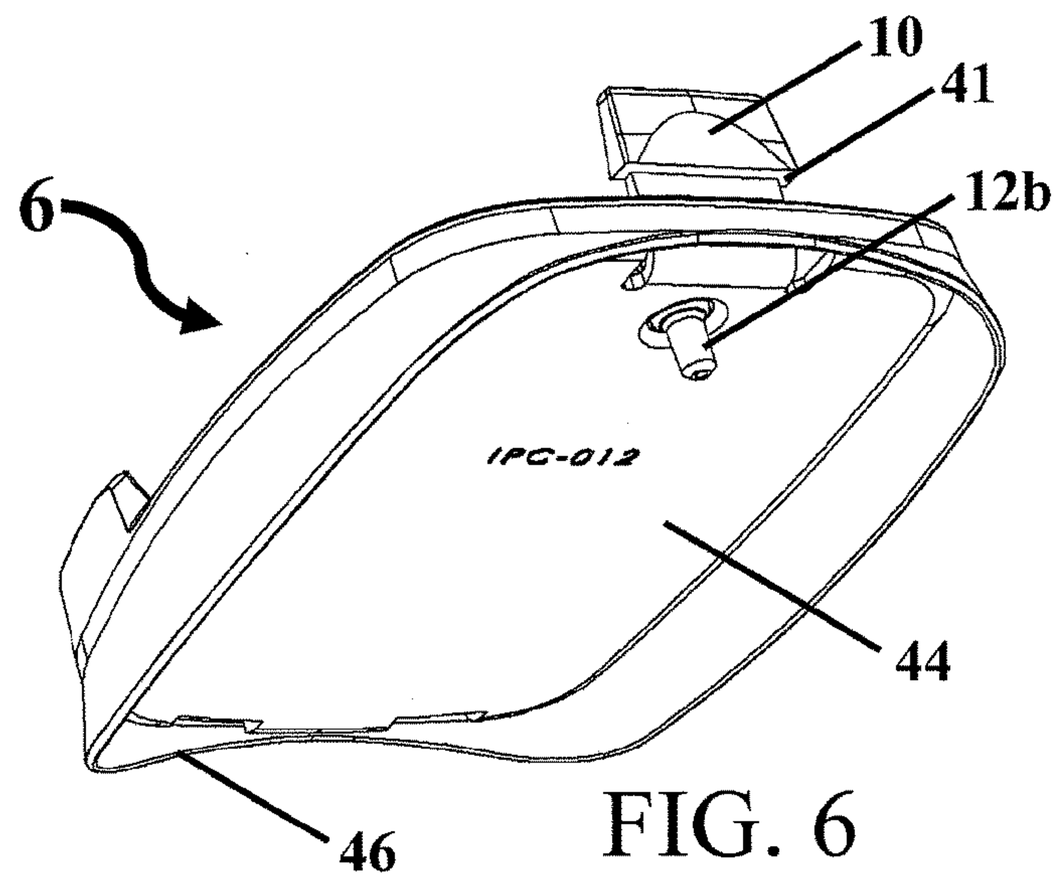

FIG. 6

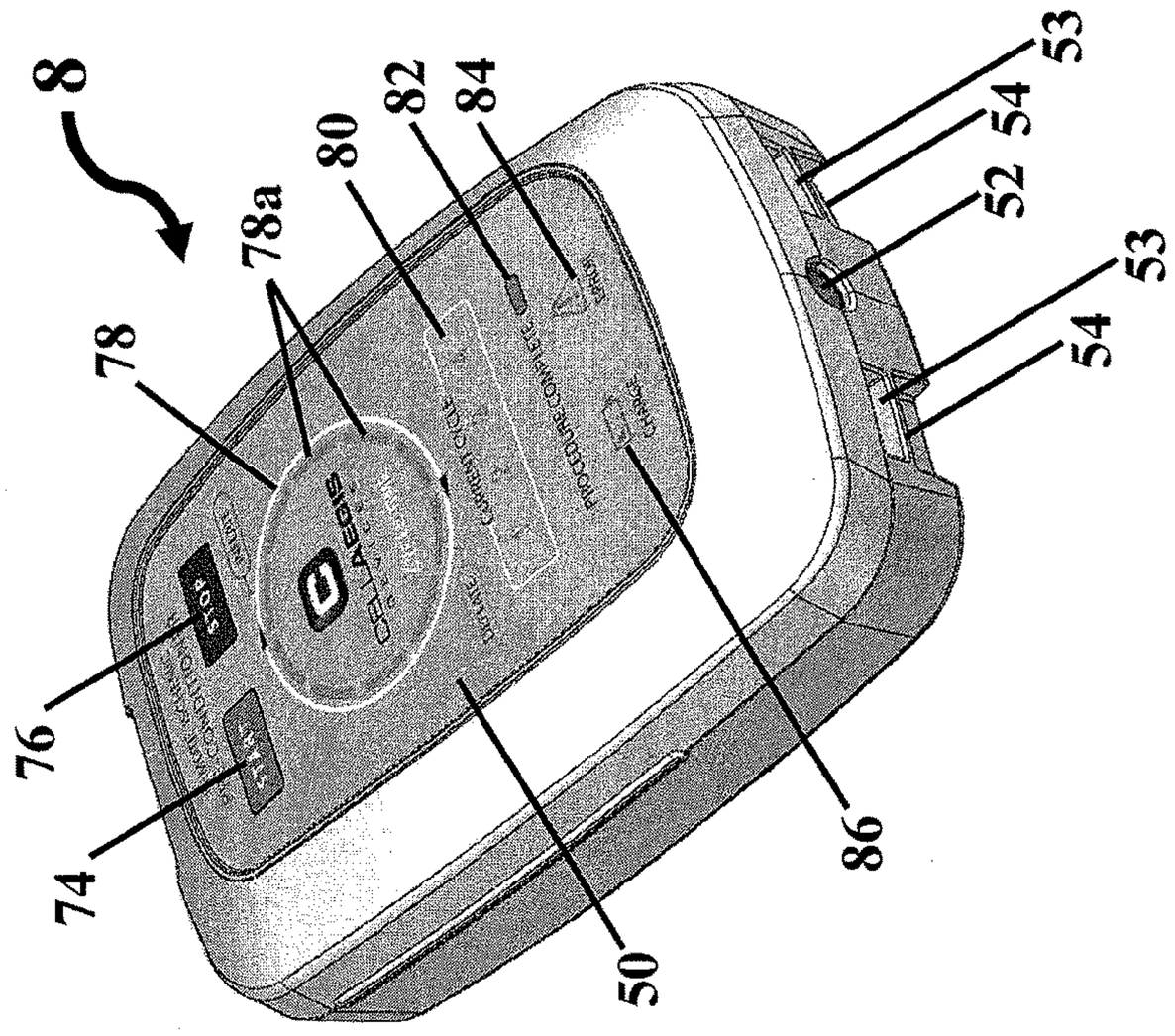

FIG. 8

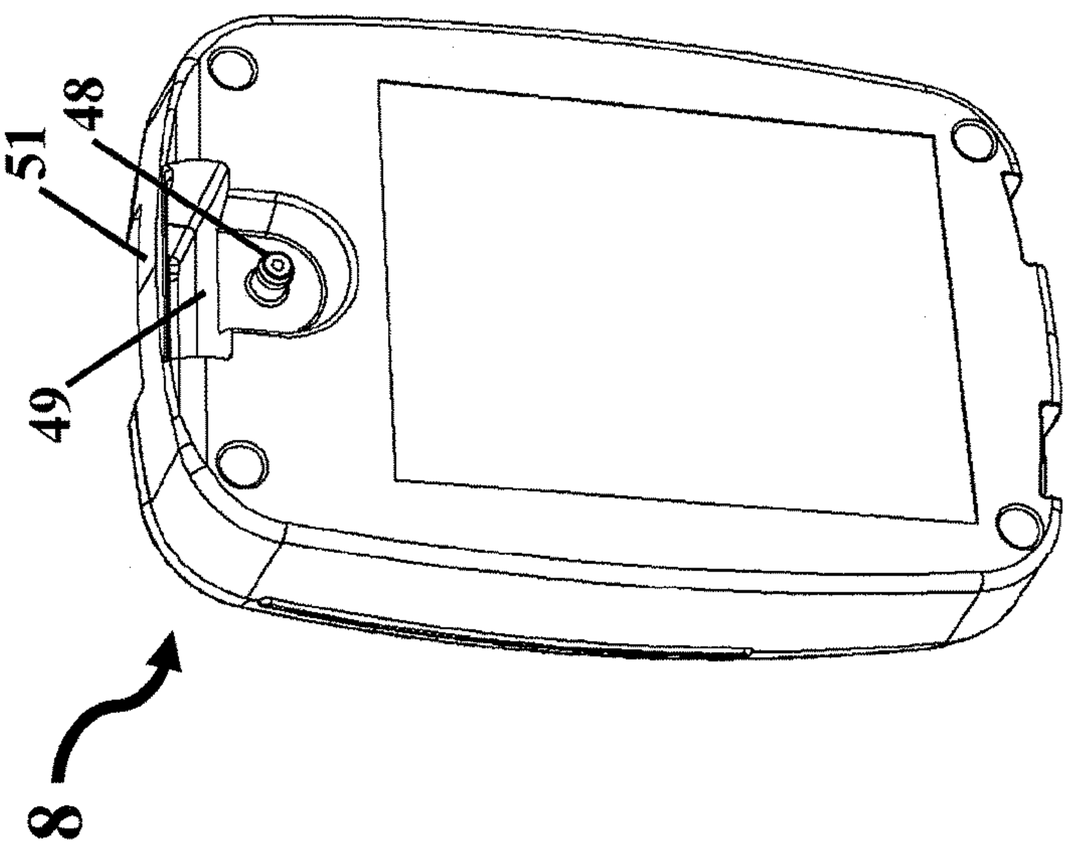

FIG. 7

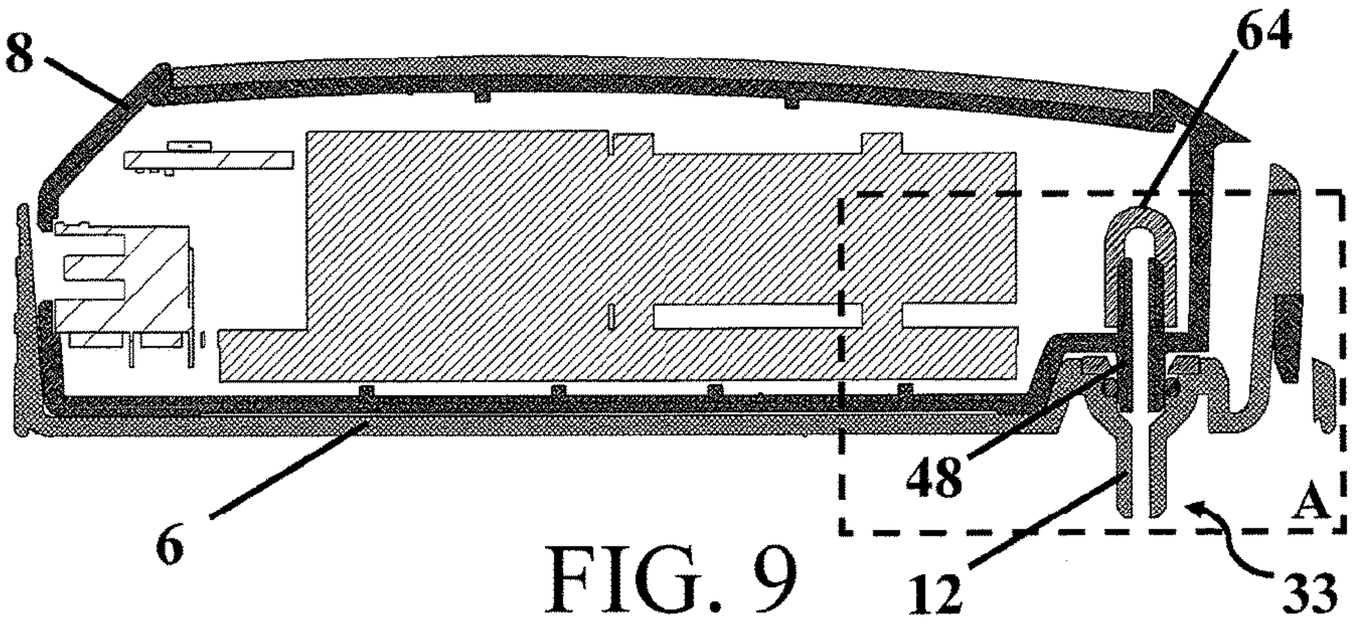

FIG. 9

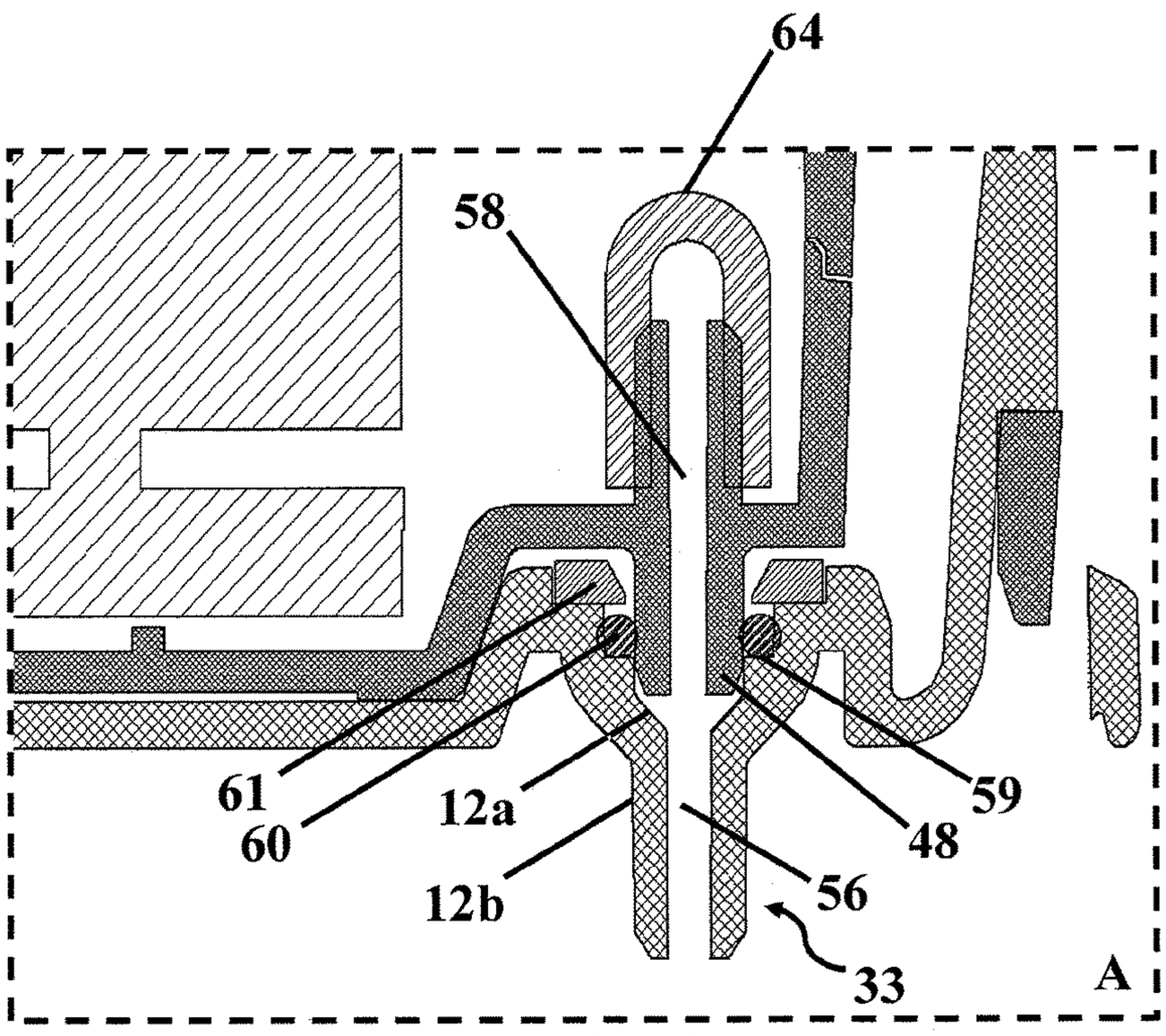

FIG. 9A

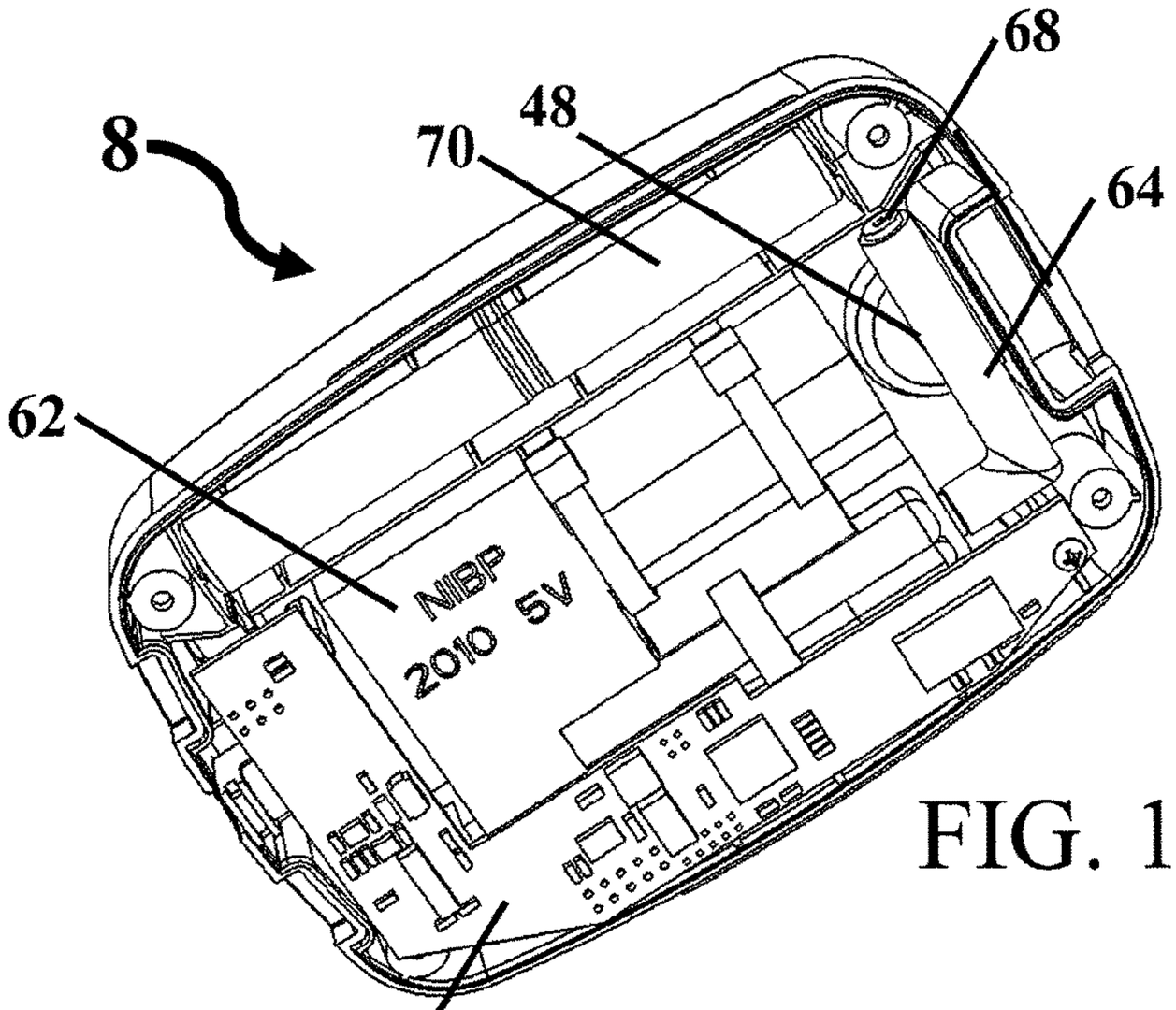

FIG. 10

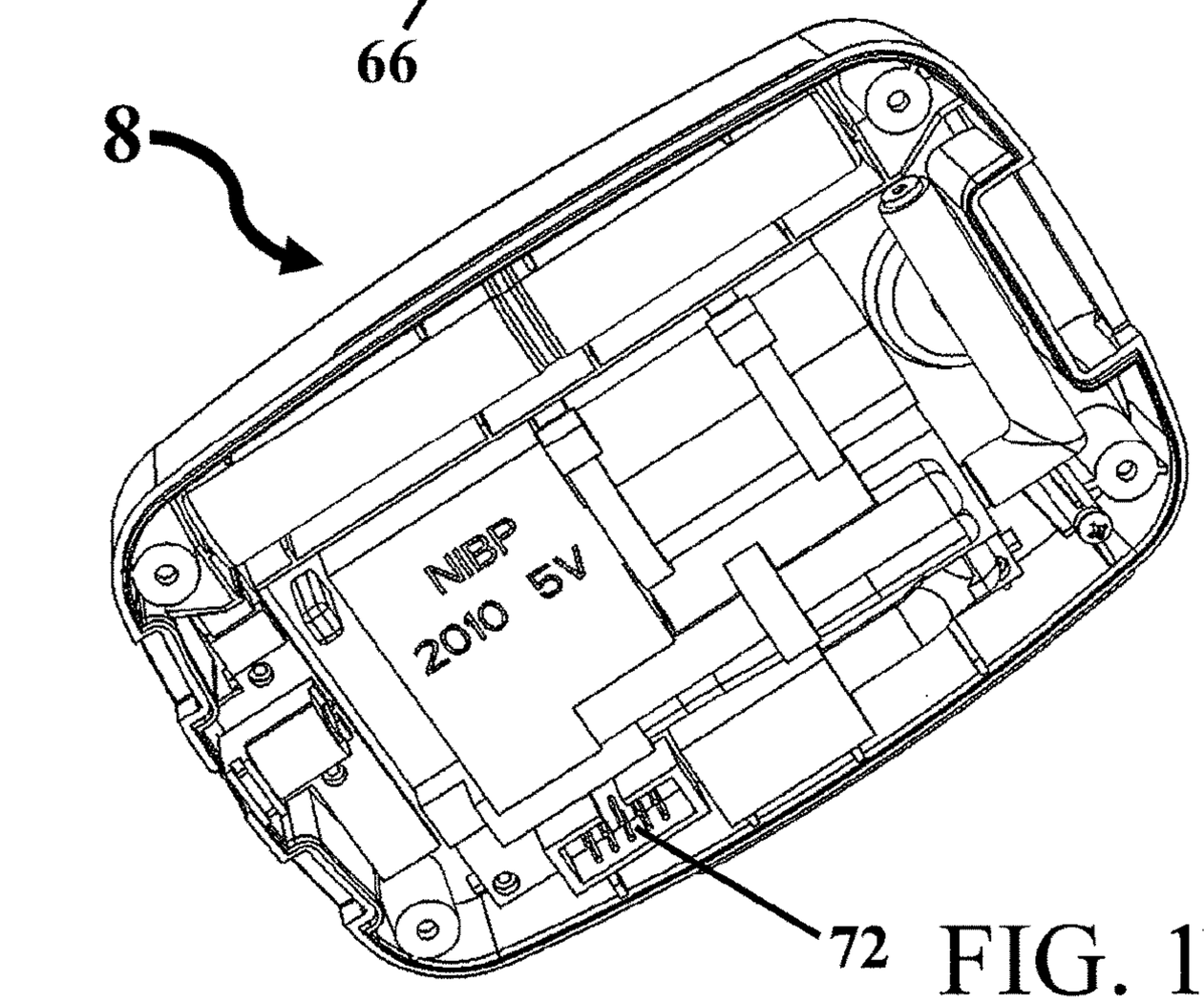

FIG. 11

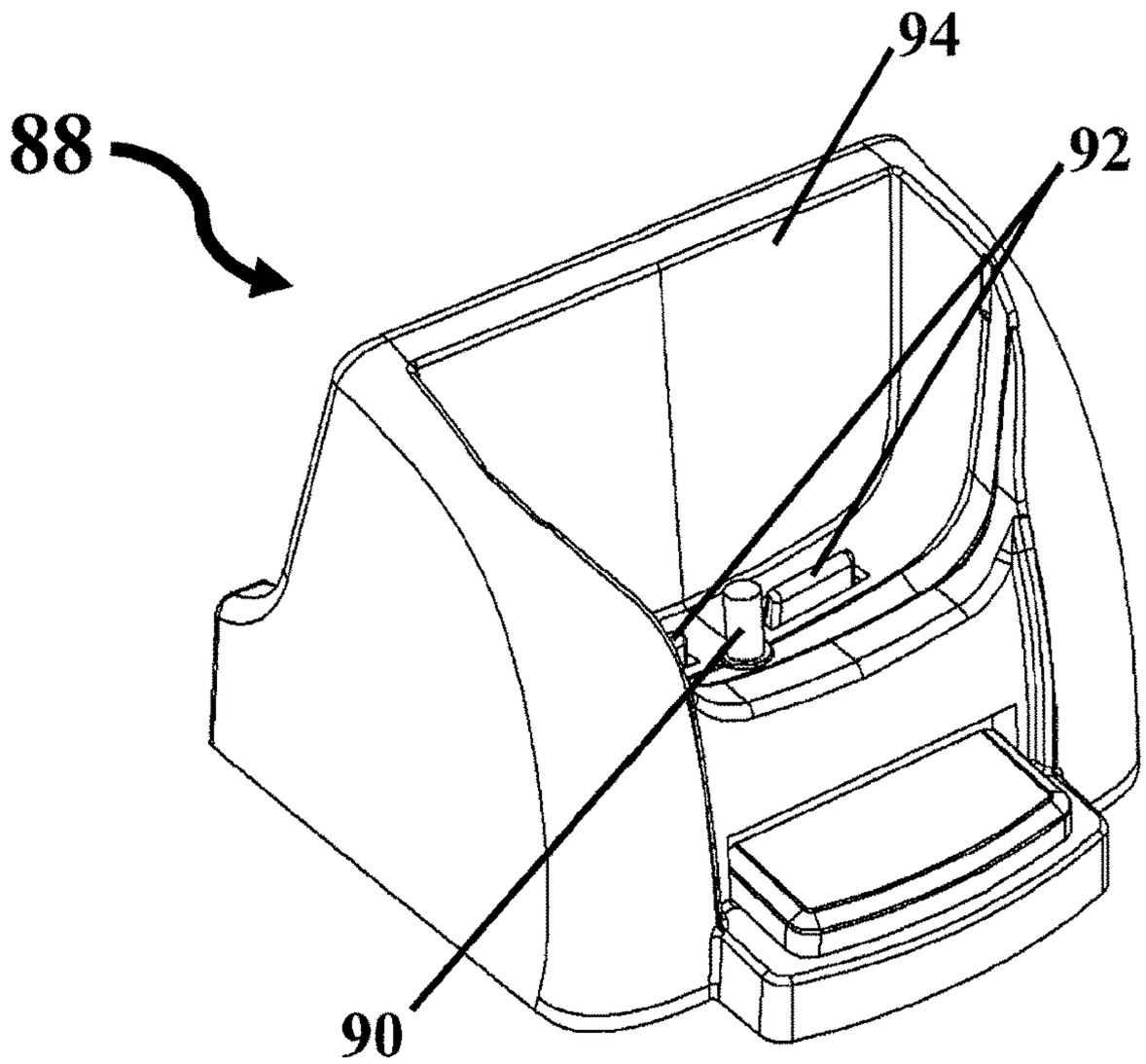

FIG. 12

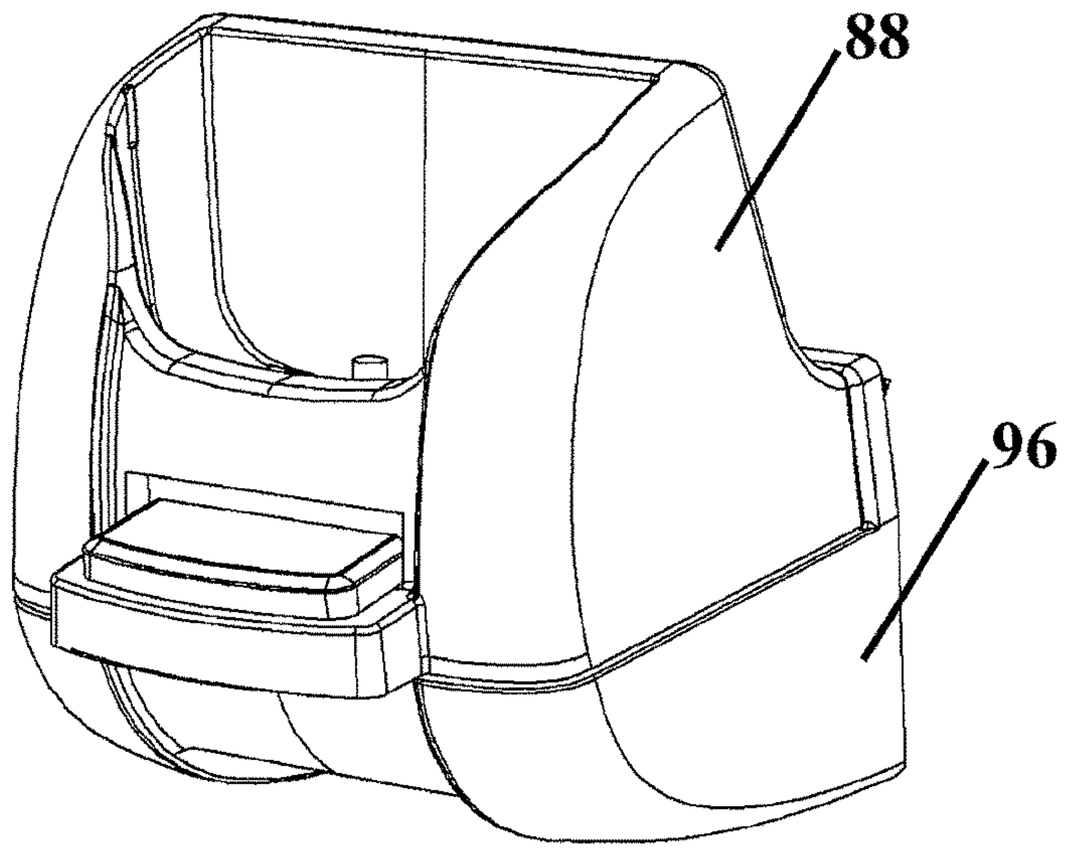

FIG. 13

SYSTEM FOR PERFORMING REMOTE ISCHEMIC CONDITIONING

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

RELATED APPLICATIONS

This application is a continuation of and claims priority to U.S. patent application Ser. No. 13/088,243, entitled "System For Performing Remote Ischemic Conditioning," filed Apr. 15, 2011, the entire disclosure of which is incorporated herein by reference.

FIELD

This invention relates generally to systems for performing remote ischemic conditioning, and more particularly, to systems for performing remote ischemic conditioning incorporating a removable controller.

BACKGROUND

Ischemic diseases are significant causes of mortality in industrialized nations. It is well established that tissue damage results from ischemia (insufficient blood flow to a tissue) followed by reperfusion (reflow of blood to the tissue). Ischemia and reperfusion cause disturbance of microcirculation with ensuing tissue damage and organ dysfunction. Organs such as the kidney, heart, liver, pancreas, lung, brain and intestine are known to sustain damage following ischemia and reperfusion.

In ischemic conditioning (IC), a tissue or organ or region of a subject's body is deliberately subjected to brief ischemic episodes, followed by brief reperfusion episodes. IC has been found to render the tissue, organ or region resistant to injury during subsequent ischemic episodes. The phenomenon of ischemic conditioning has been demonstrated in most mammalian tissues. IC is now recognized as one of the most potent innate protective mechanisms against ischemia-reperfusion (I-R) injury.

Remote ischemic conditioning (RIC) refers to the deliberate induction of transient ischemia in a subject at a region remote from at least some of the tissue to be protected. Often, RIC includes inducing transient ischemia in a subject's limb to protect organs remote from the limb, such as the myocardium. Myocardial protection has been demonstrated by a variety of remote stimuli, including renal ischemia, liver ischemia, mesenteric artery ischemia, and skeletal muscle hind limb ischemia.

RIC, in the broadest sense, involves deliberate induction of an ischemic period followed by a reperfusion period. The ischemic period may involve complete cessation of blood flow (blood flow occlusion). Such ischemic periods may be induced by applying super-systolic pressures on a region of the body, such as for example a limb. Alternatively, ischemic periods may also be induced by applying a less than systolic pressure.

RIC may be performed prior to (pre-), during (per-) and/or following (post-) an ischemic injury or other injury which

benefits from RIC. RIC has shown benefit in reducing or preventing damage resulting from, myocardial infarction and trauma, inter alia.

SUMMARY

In one aspect, a device for performing RIC includes an inflatable cuff configured to encircle a limb of a subject and a controller removably attached to the cuff. The controller includes a pump; a manifold in fluid communication with the pump; an outlet in fluid communication with the manifold and in removable fluid communication with the inflatable cuff; a pressure sensor; and a control circuit configured to implement a RIC treatment protocol.

In another aspect, a cuff assembly may be adapted to encircle a limb of a subject. The cuff assembly includes an inner layer, an outer layer, and a bladder disposed between the inner layer and the outer layer. The outer layer includes two flexible foam sections spaced apart in a longitudinal direction of the cuff assembly. The outer layer also includes an intermediate section disposed between the two flexible foam sections. The intermediate section may have a greater rigidity than the two flexible foam sections.

In a further aspect, a device includes an inflatable cuff and a controller attachment section. The inflatable cuff may be configured to encircle a limb of a subject. The cuff has an axial direction substantially parallel to an axis of the limb when the cuff is in the fitted state. The controller attachment section may be operatively attached to the cuff by at least one attachment joint oriented substantially parallel to the axial direction of the cuff. The controller attachment section may include a connector adapted for removable attachment of a controller. The controller attachment section may provide fluid communication between the controller and cuff in a location removed from the connector when the controller is in an attached state.

It should be appreciated that all combinations of the foregoing aspects and additional concepts discussed in greater detail below (provided such concepts are not mutually inconsistent) are contemplated as being part of the inventive subject matter disclosed herein.

The foregoing and other aspects, embodiments, and features of the present teachings can be more fully understood from the following description in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings are not intended to be drawn to scale. In the drawings, each identical or nearly identical component that is illustrated in various figures is represented by a like numeral. For purposes of clarity, not every component may be labeled in every drawing. Various embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

FIG. **1** is a schematic perspective view of an assembled system for remote ischemic conditioning with a removable controller;

FIG. **2** is a schematic perspective view of the system for remote ischemic conditioning depicted in FIG. **1** with the controller removed;

FIG. **3** is a cross sectional view of the system for remote ischemic conditioning depicted in FIG. **1** taken along the line **3-3** in FIG. **1**;

FIG. **4** is an exploded schematic perspective view of the cuff of the system depicted in FIG. **1**;

FIG. **5** is a schematic top perspective view of the controller attachment section of the system depicted in FIG. **1**;

FIG. **6** is a schematic bottom perspective view of the controller attachment section of the system depicted in FIG. **1**;

FIG. **7** is a schematic bottom perspective view of the controller of the system depicted in FIG. **1**;

FIG. **8** is a schematic top perspective view of the controller of the system depicted in FIG. **1**;

FIG. **9** is a cross sectional view of the controller and controller attachment section while coupled to the system depicted in FIG. **1**;

FIG. **9**A is a detailed view of FIG. **9** corresponding to box A of FIG. **9**;

FIG. **10** is a schematic perspective view of the controller of the system depicted in FIG. **1** with the cover removed;

FIG. **11** is a schematic perspective view of the controller of the system depicted in FIG. **1** with the cover and PCB removed;

FIG. **12**. is a schematic perspective view of a charging cradle to be used with the controller; and

FIG. **13** is a schematic perspective view of the charging cradle of FIG. **12** with an optional wall mount.

DETAILED DESCRIPTION

The illustrative embodiments described herein are not necessarily intended to show all aspects of the invention. Aspects of the invention are not intended to be construed narrowly in view of the illustrative embodiments. It should be appreciated that the various concepts and embodiments introduced above and those discussed in greater detail below may be implemented in any of numerous ways, as the disclosed concepts and embodiments are not limited to any particular manner of implementation. In addition, it should be understood that aspects of the invention may be used alone or in any suitable combination with other aspects of the invention.

In one aspect, a system for performing RIC includes an inflatable cuff, a controller attachment section joined to the cuff, and a controller selectively removable from the controller attachment section. The controller may control the inflation and deflation of the inflatable cuff. Furthermore, the controller may include a control circuit programmed to implement an RIC protocol. In another aspect the cuff may be soft, rigid, and made from thermoformable materials.

Turning now to the figures, several possible embodiments are described in further detail.

FIGS. **1** and **2** illustrate one embodiment of a system **2** for RIC. System **2** may include an inflatable cuff **4**, a controller attachment section **6**, and a controller **8**. In some embodiments, as depicted in FIG. **2**, the controller **8** is selectively removable from system **2**. The controller attachment section **6** may include an interlocking retaining tab **10** adapted to provide removable attachment of the controller. The controller attachment section may also include a conduit **12** that provides, sealed, fluid communication between the controller **8** and inflatable cuff **6**.

In one aspect, cuff **4** is axially rigid while being soft or non-irritating to the skin. In one embodiment, cuff **4** may include an inner layer **16**, a layer **18**, and a selectively inflatable bladder **20** disposed between layers **16** and **18**, as depicted in FIG. **4**. Cuff **4** may be adapted to encircle a limb of an individual. Axis **15** represents the approximate center of a circular configuration formed when cuff **4** is wrapped about a patient's limb. An axial direction of cuff **4** corresponds to the approximate direction of axis **15**. Cuff **4** has a

longitudinal direction extending down the length of cuff **4** which is substantially perpendicular to the above defined axial direction. Cuff **4** may also be intended to be a disposable item for use with removable controller **8**. Inner layer **16** typically is positioned adjacent to, and often in contact with, the skin of an individual wearing system **2**. Since inner layer **16** may be in contact with skin, the inner layer may be made from a soft and/or non-irritating material. The inner layer **16** may be made from a knit, woven, or felted cloth. The cloth may include either natural or synthetic materials. Possible cloths include brushed polyester, brushed nylon, and/or other suitable materials as would be apparent to one of skill in the art. Alternatively, inner layer **16** may be made from a foam. In some embodiments, inner layer **16** may be further adapted to provide moisture absorption, wicking, and/or breathability to cuff **4**.

In some embodiments, cuff **4** may include two sections **22** spaced apart in a longitudinal direction and an intermediate section **24** disposed between the sections **22**. Intermediate section **24** may be constructed to have a greater rigidity than sections **22**. The increased rigidity of the intermediate section **24** may be created either by an inherent material property difference, a difference in the physical construction (e.g. a thicker section and/or inclusion of reinforcing features), or both. In one embodiment, the intermediate section **24** may include a substantially flat outer surface **25** for attachment to the controller attachment section **6**. Intermediate section **24** may also include an inner surface **26** which is curved in the longitudinal direction of the cuff **4**. The curved inner surface **26** may be constructed so as to generally conform to the curvature of a limb. In some embodiments, the size and curvature of the cuff **4** may be suited for a variety of sizes and ages of patients ranging from neonates to obese adults. The cuff **4** may also be sized for either attachment to an arm or a leg. The intermediate section **24** may be constructed from thermosetting plastics, thermoforming plastics, and/or foamed materials. Sections **22** and the intermediate section **24** may be integrally formed with one another, or they may be formed separately and subsequently joined using any appropriate method including, but not limited to, a sewn seam, ultrasonic welds, adhesives, rivets, clamping structures, and/or mechanically interlocking features. Section **22** may be formed of a foam material or any other suitably flexible yet strong material.

In one embodiment, cuff **4** may also include a plurality of reinforcing structures **28** substantially aligned in the axial direction of the cuff assembly. Reinforcing structures **28** typically may be formed in outer layer **18** of sections **22**. Reinforcing structures **28** provide axial rigidity to the cuff **4**. The increased axial rigidity provided by reinforcing structures **28** helps to distribute the pressure applied by cuff **4** in the axial direction to provide a substantially uniform pressure across the axial width of the cuff **4**. Reinforcing structures **28** may also help to prevent kinks in cuff **4** when it is placed around the arm or leg of an individual. Reinforcing structures **28** may be spaced apart in a longitudinal direction to permit the cuff **4** to easily bend around an encircled limb while still providing increased axial rigidity. Reinforcing structures **28** may be curved or straight in shape in the axial direction. In some embodiments, the reinforcing structures **28** may be integrally formed with the foam in sections **22** such as by the application of heat and/or pressure (e.g. thermoforming) to selectively melt and/or compress portions of the foam in sections **22**. The uncompressed and/or unmelted portions of foam in sections **22** form the

raised reinforcing structures **28**. Alternatively, reinforcing structures **28** may be separately formed and subsequently joined to sections **22**.

Layer **18** may also include a cloth layer **19** applied to an exterior surface. Cloth layer **19** may be formed of a low stretch or non-stretch cloth. The low stretch or non-stretch properties may be an inherent property of the cloth selected. Alternatively, cloth layer **19** may be a made from thermoformable materials and may be laminated to the exterior surface of layer **18**. The lamination process may alter the thermoformable fabric to be a low stretch or non-stretch material. In one embodiment, the cloth may be applied to and laminated with layer **18** in a flat layout prior to forming reinforcing structures **28**. Reinforcing structures **28** may subsequently be thermoformed to a final desired shape. The resulting sections **22** may be soft and have low stretch or non-stretch properties. Furthermore, sections **22** may be thermoformable enabling subsequent processing steps.

Selectively inflatable bladder **20** may be disposed between inner layer **16** and layer **18**. Bladder **20** may have a valve **30** arranged and adapted to provide a fluid inlet to the interior of bladder **20**. Valve **30** extends through a hole **32** in the intermediate section **24** of cuff **4**. Valve **30** may be placed in sealed fluid communication with a corresponding structure **33** on controller attachment section **6** which may also be in sealed fluid communication with an outlet **48** of controller **8**. When connected to outlet **48** of controller **8** through structure **33** of the controller attachment section **6**, valve **30** may provide pressurized gas such as air to bladder **20**. In some embodiments, bladder **20** may be a component separate from layers **16** and **18**. Bladder **20** may be formed such as by bonding two separate sheets of thermoplastic polyurethane together. In other embodiments, bladder **20** may be formed from air impermeable layers incorporated into layers **16** and **18** of cuff **4**. Layers of bladder **20** may be bonded together in an air tight manner using any number of methods including adhesives, ultrasonic welding, beads of material around the edges, and/or other appropriate methods as would be apparent to one of skill in the art. Bladder **20** may also be formed as a unitary structure without separate layers.

Layers **16**, **18**, **19**, and bladder **20** of cuff **4** may be held together at their edges in any suitable fashion, such as by a binding material **36** wrapped around the edge of cuff **4** and sewn to cuff **4**, as shown in FIG. **4**. Alternatively, cuff **4** may be held together using adhesives, rivets, ultrasonic welds, or other appropriate methods as would be apparent to one of skill in the art.

In one aspect, it may be desirable to provide a non-slip interface to prevent cuff **4** from moving on the limb of a subject, since system **2** may be worn for protracted periods of time. To provide a non-slip interface, at least one non-slip structure **34** may be disposed on the face of inner layer **16**. The non-slip structure **34** may be printed, glued, sewn, applied as a bead of material using a guided tool, or by hand. The non-slip structure **34** may include, but is not limited to, one or more strips of silicone.

The cuff **4** may also include fasteners to hold the cuff on a limb of a subject and to adjust the circumferential size of the cuff **4** when in the fitted state. Such fasteners include, but are not limited to, hook and loop fasteners, latches, ratchet mechanisms, clasps, snaps, buckles, and other appropriate structures as would be apparent to one of skill in the art. For example, the fastener may be a hook and loop fastener including a plurality of adjacent unconnected hook sections **38**a disposed on layer **18** or **19** and loop sections **38**b disposed on inner layer **16**. Hook sections **38**a may extend in the axial direction of the cuff **4**. The width of each hook section **38**a, with respect to the longitudinal direction of the cuff, may be selected to provide a flexible cuff able to wrap around different sized limbs.

The controller attachment section **6** of FIG. **1** is shown in more detail in FIGS. **3**, **5** and **6**. In one embodiment, controller attachment section **6** may include an upper surface **40** for supporting controller **8** in the attached state, a lower surface **44**, and an upstanding wall **42** surrounding surface **40**. A raised portion **43** of upstanding wall **42** may be located adjacent to and block a power inlet **52** of controller **8** in the attached state. By blocking access to power inlet **52** in the attached state, raised portion **43** may prevent use of the device while controller **8** is connected to an external power source. The controller attachment section **6** may also include a connector, such as retaining tab **10**, arranged to provide removable attachment of controller **8**. In one embodiment, tab **10** is mounted at one end to surface **40** and includes a projecting edge **41** spaced from surface **40** that faces outwardly towards wall **42**. Bosses **45** are disposed on wall **42** on the opposite side of section **6** from tab **10**. When controller **8** is attached to attachment section **6**, the upper portion of tab **10** is pushed inwardly away from wall **42** so that it passes through slot **49** that is disposed between the body of controller **8** and an outer band **51**, as shown in FIG. **7**. At the same time, bosses **45** extend into recesses **53** of controller **8**, as shown in FIG. **8**. Tab **10** has sufficient resilience that when snapped into place, this resilience creates an outward bias on tab **10** that causes edge **41** to overlie the upper edge of band **51**. To release controller **8**, the upper portion of tab **10** is again pushed inwardly against its bias toward controller **8** until edge **41** overlies slot **49** and is clear of band **51** at which time controller **8** may be pulled out of attachment section **6** at the end closest to tab **10**.

In one embodiment, lower surface **44** and/or bottom edge **46** of controller attachment section **6** may be disposed on and substantially conform to the shape of an outer surface of cuff **4**. In some embodiments, bottom surface **44** and/or bottom edge **46** of the controller attachment section **6** may be disposed on and substantially conform to the shape of outer surface **25** of intermediate section **24** of cuff **4** shown in FIG. **4**. As shown in FIG. **3**, the controller attachment section **6** may be joined to outer surface **25** of intermediate section **24** of inflatable cuff **4** along lower surface **44** by at least one and typically two attachment joints **14**. In one embodiment, the attachment joint(s) **14** may be oriented substantially parallel to axis **15** of the cuff. The attachment joint **14** may be formed using any appropriate method including, but not limited to, a sewn seam, an ultrasonic weld, an adhesive, and/or rivets. When two or more attachment joints **14** are included, the joints **14** may be spaced apart in the longitudinal direction to allow the cuff **4** to bend and conform to the shape of different sized limbs.

As shown in FIGS. **9** and **9**A, controller attachment section **6** may provide fluid communication between the controller **8** and bladder **20** of cuff **4** via structure **33**. Structure **33** may include a conduit **12** which is provided in a location spaced from retaining tab **10**, when the controller **8** is in an attached state. Conduit **12** fluidly couples controller **8** to valve **30** of bladder **20**. Conduit **12** may include a female section **12**a that is constructed and arranged to mate with an outlet **48** of controller **8** and a male section **12**b that is constructed and arranged to mate with valve **30** of bladder **20**. Outlet **48** may include a fluid conduit **58**. While a male and female connection have been described, the male and female portions could be reversed or even replaced with other comparable fluid connections, such as a tube or the like. A seal, such as O-ring **60**, may be disposed on a

shoulder **59** located in structure **33**. The O-ring **60** may create a gland seal between female section **12**a and outlet **48**. Alternatively, a compression seal with O-ring **60** may be used. A retaining structure **61** may be included in structure **33** to retain O-ring **60**. Retaining structure **61** may be joined to structure **33** using any appropriate method including, but not limited to, press fitting, ultrasonic welding, and/or adhesives.

As shown in FIG. **8**, controller **8** has a front cover **50**, which may include controls and displays, and a power inlet **52**. Guide structures **54** may be included in controller **8** for alignment and/or engagement with a charging mechanism

The internal components of controller **8** are best shown in FIGS. **10** and **11**, where front cover **50** of controller **8** has been removed. Controller **8** may include a pump **62** in fluid communication with a manifold **64**. Manifold **64** is in fluid communication with relief valve **68** and outlet **48**. Controller **8** may also include a printed circuit board (PCB) **66** which may include a control circuit and memory. The controller **8** may also include a pressure sensor associated with the pressurized components of the system and the control circuit. The pressure sensor (not shown) may be incorporated into pump **62** and/or placed in pressure sensing communication with manifold **64**. Furthermore, the pressure sensor may communicate with the control circuit of PCB **66**. The control circuit may be programmed to implement an RIC treatment protocol. The controller may also determine blood pressure during, or as part of, an RIC treatment protocol. To provide convenient mobile usage of system **2**, batteries **70** may be arranged, typically in series, to provide a higher operating voltage. Alternatively, batteries **70** may be in electrical communication with a transformer adapted to provide a higher operating voltage. In one embodiment, the operating voltage may be approximately 5 to 6 VDC. In other embodiments, the operating voltage may be approximately 12 VDC or any other appropriate voltage. As shown in FIG. **11**, PCB **66** may be connected to the other controller components through plug connector **72**.

The control circuit of PCB **66** may be programmed with certain error conditions which may cause the procedure to be aborted or which may cause an indication of the error to appear on a display or which can be used in other known ways. These error conditions may include, but are not limited to: the cuff is not pressurized within a predefined period, such as 20 seconds, 30 seconds, 40 seconds, 50 seconds, or one minute; there is no communication between pump **62** and PCB **66** upon start up; there is no communication between pump **62** and PCB **66** for more than a predefined period, such as two, three. four, or five seconds; multiple consecutive repumps are needed to maintain cuff pressure; pump **62** continues to run and does not respond to an abort signal after a predefined number of retrys, such as three, four, or five retrys; pressure in cuff **4** is not near zero gage pressure within a predefined period, such as 20 seconds, 30 seconds, 40 seconds, 50 seconds, or one minute after the end of an inflation cycle; pressure in cuff **4** is above a predetermined pressure such as 200, 220, 240 or 260 mmHg for longer than a predefined period, such as 5, 10, 20, or 30 seconds; and the pump **62** CPU does not wake up after a command is sent to it by the control circuit. The error condition may be cleared and/or the system may be reset such as by pressing a stop button **76** on the face of controller **8**.

During usage, controller **8** may be attached to controller attachment section **6** to place controller outlet **48** into fluid communication with cuff **4**. Pressurized gas may then be pumped through controller outlet **48** to inflate the cuff **4**. The cuff pressure may be controlled by selectively opening valve **68** in response to a command from the control circuitry of PCB **66**. In some embodiments, valve **68** may include a pressure safety relief feature that opens valve **68** in response to an over pressure event during an RIC treatment. In one embodiment, valve **68** opens when the pressure in cuff **4** exceeds 260 mmHg. Valve **68** may open in response to either an error command from the control circuitry of PCB **66**, or the valve **68** may include an automatically actuated mechanical system. Controller **8** may also include a slow continuous relief valve. Such a valve would continuously release gas from inflated bladder **20** at a selected rate lower than the rated flow rate of the pump **62**. The slow continuous release of gas from bladder **20** could be used to deflate bladder **20** in case of a mechanism failure.

In some embodiments, the control circuit of PCB **66** may be programmable by a health professional and/or an end user according to a prescribed treatment protocol. Alternatively, the control circuit may only be programmed at the factory and may not be altered afterwards by the end user. The control circuitry may also include non-volatile memory for the logging and storage of treatment history. A health care professional may be able to access this memory to determine the treatment history of a patient and determine compliance with a prescribed treatment regime. In another embodiment, the controller may send this information via wireless, or hard wired, communication to a separate receiver for patient records, monitoring, or call center purposes. In one embodiment, controller **8** may include a start button **74** and stop button **76**. In some embodiments, the start and stop buttons **74** and **76** may be incorporated into a single button. Controller **8** may also include a hard wired and/or emergency stop button and/or a quick release valve (not shown). In other embodiments, other controls may be included to allow expanded control of an RIC treatment.

In addition to controls, controller **8** may include displays related to the current cycle, the number of cycles left in a treatment, whether the treatment is completed, error signals, charge of the system, and other relevant information. In one embodiment, controller **8** may include a cycle time display **78**. Cycle time display **78** may indicate the remaining portion of the inflation/deflation cycle by using illuminated indicators **78**a arranged in a circular pattern corresponding to a full inflation/deflation cycle. Each indicator **78**a of cycle time display **78** may correspond to a set fraction of the inflation/deflation cycle. When all of the indicators **78**a of cycle time display **78** are illuminated, the inflation/deflation cycle is complete. Alternatively, the indicators **78**a of cycle time display **78** may start a cycle fully illuminated and sequentially turn off as the cycle proceeds. When each indicator **78**a of cycle time display **78** is dark, the particular inflation/deflation cycle is complete. While a circular display has been disclosed, cycle time display **78** could also be arranged in other linear, or non-linear, shapes corresponding to a full cycle. Controller **8** may also include a current cycle display **80**, or a digital numeric display, indicating whether the current cycle is the first, second, third, or other cycle. A procedure complete indicator **82** may be illuminated with a solid color or it may blink when the RIC treatment is complete to indicate the end of the procedure. An error display **84** may indicate when an error has occurred by blinking or being fully illuminated. Alternatively, error display **84** may blink in a preset pattern or display a particular color to indicate which error has occurred. A battery charge indicator **86** may indicate the approximate

charge remaining in the batteries **70**, and may also signal that that the remaining charge is only sufficient for one cycle by blinking.

The above described system may be used for implementing an RIC treatment. The treatment includes placing cuff **4** on a limb of a user and attaching controller **8** to controller attachment section **6** on cuff **4**. A user may then press start button **74** to initiate the treatment. Once started the control circuitry of PCB **66** monitors the pressure sensor and turns pump **62** on to inflate the cuff **4**. The pressure is then increased to a desired pressure, such as a blood flow occlusion pressure. In one embodiment, the control circuitry of PCB **66** maintains the cuff pressure between preselected pressure limits such as 200 mmHg to 210 mmHg. In other embodiments, the control circuitry of PCB **66** may first determine a systolic blood pressure. After determining a systolic blood pressure, the control circuitry of PCB **66** may subsequently initiate the RIC treatment protocol with a desired pressure such as a pressure greater than the measured systolic blood pressure. Regardless of the specific pressure used, the pressure may be maintained for a selected ischemic duration. Ischemic durations may last on the order of seconds or minutes. After completing the ischemic duration, the controller may activate valve **68** to deflate cuff **4** and initiate the reperfusion duration. Reperfusion durations generally last for at least a minute, although shorter reperfusion durations may be used. After completion of the reperfusion duration another RIC cycle may be conducted. An RIC treatment may include a single cycle or multiple cycles. In one embodiment, an RIC treatment may include four cycles with ischemic durations of approximately 5 minutes, and reperfusion durations of approximately 5 minutes. At the end of the last cycle the cuff **4** may deflate within 30 seconds and the controller **8** may confirm a near zero gage pressure prior to shutting down.

In some embodiments, controller **8** may be charged using a charging cradle **88**, as shown in FIG. **12**. Charging cradle **88** may include a power connector **90** and mating guide structures **92**. In one embodiment, mating guide structures **92** on the charging cradle mate with guide structures **54** on the controller. Mating guide structures **92** act as alignment features. In other embodiments, mating guide structures **92** may be actuated when controller **8** is inserted into the charging cradle **88** to turn the power on and off to power connector **90**. Charging cradle **88** may also include a raised area **94** to prevent insertion of the controller while controller **8** is connected to cuff **4** or a patient. In addition to the above, charging cradle **88** may optionally connect with a wall mount portion **96** as shown in FIG. **13**.

While the present teachings have been described in conjunction with various embodiments and examples, it is not intended that the present teachings be limited to such embodiments or examples. On the contrary, the present teachings encompass various alternatives, modifications, and equivalents, as will be appreciated by those of skill in the art. Accordingly, the foregoing description and drawings are by way of example only.

What is claimed is:

1. A device for remote ischemic conditioning comprising:

an inflatable cuff configured to encircle a limb of a subject;

a controller removably attached to the cuff, wherein the controller comprises:

a manifold configured to provide fluid communication between the controller and the cuff;

an outlet in fluid communication with the manifold and in removable fluid communication with the inflatable cuff; and

a control circuit configured to implement a remote ischemic conditioning treatment protocol; and

a controller attachment section joined to the cuff, the controller attachment section having a bottom surface that substantially conforms to an outer surface of the cuff, wherein the controller is removably attached to the cuff by selective attachment to the controller attachment section disposed on the cuff, the controller attachment section further comprising:

an upper surface for supporting the controller in an attached state;

an upstanding wall surrounding the upper surface;

a tab mounted at one end of the upper surface and including a projecting edge spaced from the upper surface, the projecting edge facing outwardly toward the upstanding wall; and

bosses disposed on the upstanding wall on the opposite side of the controller attachment section from the tab;

wherein the controller further comprises a slot that is disposed between a body of the controller and an outer band, and wherein the device is arranged such that when the controller is attached to the controller attachment section, an upper portion of the tab is pushed inwardly away from the upstanding wall so that the tab passes through the slot, and the bosses extend into corresponding recesses provided in the controller body.

2. The device of claim **1**, wherein the controller attachment section further includes a conduit that provides sealed, fluid communication between the controller and inflatable cuff.

3. The device of claim **1**, wherein cuff pressure is controllable by selectively opening a valve of the controller in response to a command from control circuitry of the control circuit.

4. The device of claim **3**, wherein the controller attachment section provides fluid communication between the controller and a bladder of the cuff via a structure that includes a conduit that has a female section constructed and arranged to mate with the controller outlet and a male section that is constructed and arranged to mate with a valve of the bladder of the cuff.

5. The device of claim **1**, wherein:

an axial direction of the cuff is substantially parallel to an axis of the limb when the cuff is in a fitted state;

the controller attachment section is operatively attached to the cuff by at least one attachment joint oriented substantially parallel to the axial direction of the cuff; and

the controller attachment section provides fluid communication between the controller and the cuff.

6. The device of claim **1**, wherein the controller comprises a slow continuous relief valve that continually releases gas from the cuff at a flow rate lower than a flow rate of the gas being introduced into the cuff.

7. The device of claim **1**, wherein the controller further comprises at least one valve configured to open in response to an overpressure event, or in response to an error command from the control circuit.

8. The device of claim **7**, wherein the valve opens in response to a command from the controller when a specified condition is detected.

9. The device of claim **1**, wherein the control circuit maintains a cuff pressure between pre-selected pressure

limits during an ischemic duration of the remote ischemic conditioning treatment protocol.

10. A device for remote ischemic conditioning comprising:

an inflatable cuff configured to encircle a limb of a subject;

a controller removably attached to the cuff, wherein the controller comprises:

a manifold configured to provide fluid communication between the controller and the cuff;

an outlet in fluid communication with the manifold and in removable fluid communication with the inflatable cuff; and

a control circuit configured to implement a remote ischemic conditioning treatment protocol; and

a controller attachment section joined to the cuff, the controller attachment section having a bottom surface that substantially conforms to an outer surface of the cuff, wherein the controller is removably attached to the cuff by selective attachment to the controller attachment section disposed on the cuff;

wherein cuff pressure is controllable by selectively opening a valve of the controller in response to a command from control circuitry of the control circuit;

wherein the controller attachment section provides fluid communication between the controller and a bladder of the cuff via a structure that includes a conduit that has a female section constructed and arranged to mate with the controller outlet and a male section that is constructed and arranged to mate with a valve of the bladder of the cuff; and

wherein the controller outlet has an outer dimension at an end spaced from the controller, and the female section of the conduit has an upper opening that is configured to receive the end of the controller outlet, a cross-sectional size of the upper opening of the female section being greater than the outer dimension of the controller outlet and greater than an inner dimension of the male section.

11. The device of claim **10**, further comprising an O-ring seal disposed within the upper opening of the female section, the O-ring seal surrounding and sealing the controller outlet when disposed within the female section.

12. The device of claim **11**, wherein a mouth of the upper opening of the female section includes a retaining structure that has an upper surface that forms an acute angle with respect to a direction of elongation of the controller outlet.

13. A device for remote ischemic conditioning comprising:

an inflatable cuff configured to encircle a limb of a subject;

a controller removably attached to the cuff, wherein the controller comprises:

an outlet in removable fluid communication with the inflatable cuff; and

a control circuit configured to implement a remote ischemic conditioning treatment protocol;

wherein cuff pressure is controllable by selectively opening a valve of the controller in response to a command from control circuitry of the control circuit;

wherein fluid communication between the controller and a bladder of the cuff is provided via a structure that includes a conduit that has a female section constructed and arranged to mate with the controller outlet and a male section that is constructed and arranged to mate with a valve of the bladder of the cuff; and

wherein the controller outlet has an outer dimension at an end spaced from the controller, and the female section of the conduit has an upper opening that is configured to receive the end of the controller outlet, a cross-sectional size of the upper opening of the female section being greater than the outer dimension of the controller outlet.

14. The device of claim 13, wherein the inflatable cuff comprises:

at least two flexible sections spaced apart in a longitudinal direction of the cuff and an intermediate section disposed between the two flexible sections, the intermediate section having a greater rigidity than the two flexible sections; and

a plurality of reinforcing structures disposed on at least one of the two flexible sections and being elongated in an axial direction substantially perpendicular to the longitudinal direction of the cuff, wherein when the cuff is inflated, the reinforcing structures distribute pressure applied by the cuff in the axial direction.

15. The device of claim 14, wherein the plurality of reinforcing structures are spaced apart in a longitudinal direction, and are generally parallel to one another to permit the cuff to bend around an encircled limb while providing increased rigidity in the direction generally perpendicular to the longitudinal direction.

16. The device of claim 14, wherein the reinforcing structures are curved.

17. The device of claim 14, wherein the reinforcing structures are generally linear.

18. The device of claim 14, wherein the reinforcing structures are integrally formed with the flexible sections.

19. The device of claim 18, wherein the reinforcing structures comprise portions of the flexible sections which are uncompressed.

20. The device of claim 14, wherein the reinforcing structures are formed by providing alternating areas of compressed foam and uncompressed foam.

21. The device of claim 14, wherein the reinforcing structures are formed separately from the flexible sections and are attached to at least one of the two flexible sections after formation of the flexible sections.

22. The device of claim 14, wherein the reinforcing structures extend substantially across a width of the cuff.

23. The device of claim 22, wherein the reinforcing structures distribute pressure applied by the cuff across the width of the cuff in the axial direction.

24. The device of claim 14, wherein the reinforcing structures assist in preventing kinks in the cuff assembly.

25. The device of claim 14, further compromising: an outer layer; an inner layer; and an inflatable bladder disposed between the inner layer and the outer layer.

26. The device of claim 25, wherein the reinforcing structures are formed on the outer layer.

27. The device of claim 25, further comprising at least one non-slip structure disposed on an exterior face of the inner layer and configured to face the limb of the subject.

28. The device of claim 27, wherein the non-slip structure comprises a strip formed of silicone.

29. The device of claim 25, wherein the inner layer is formed of a soft, non-irritating material.

30. The device of claim 25, wherein the inner layer is configured to provide moisture absorption, wicking, and/or breathability to the cuff.

31. The device of claim 30, wherein the inner layer comprises a cloth material.

32. The device of claim 31, wherein the cloth material comprises a felt.

33. The device of claim 25, wherein a fluid inlet to the bladder extends from the bladder through the intermediate section of the outer layer.

34. The device of claim 14, further comprising a fastener to couple together ends of the two flexible sections about the limb of the subject.

35. The device of claim 34, wherein the fastener comprises a hook and loop fastener.

36. The device of claim 14, wherein the intermediate section comprises:

a substantially planar upper surface;

an attachment device configured to removably attach the controller to the upper surface; and

the conduit.

37. The device of claim 36, wherein the intermediate section comprises a curved inner surface extending in the longitudinal direction of the cuff.

38. The device of claim 14, further comprising a controller attachment section disposed on the intermediate section, the controller attachment section being configured to permit removable attachment of the controller.

39. The device of claim 38, wherein the controller attachment section is joined to the intermediate section by two attachment joints that are aligned in a direction generally perpendicular to the longitudinal direction of the cuff.

40. A device for remote ischemic conditioning comprising:

an inflatable cuff configured to encircle a limb of a subject;

a controller removably attached to the cuff; and

a controller attachment section joined to the cuff, the controller attachment section having a bottom surface that substantially conforms to an outer surface of the cuff, wherein the controller is removably attached to the cuff by selective attachment to the controller attachment section disposed on the cuff, the controller attachment section further comprising:

an upper surface for supporting the controller in an attached state; an upstanding wall surrounding the upper surface; and

a tab mounted at one end of the upper surface and including a projecting edge spaced from the upper surface, the projecting edge facing outwardly toward the upstanding wall;

wherein the controller further comprises a slot that is disposed between a body of the controller and an outer band, and wherein the device is arranged such that when the controller is attached to the controller attachment section, an upper portion of the tab is pushed inwardly away from the outstanding wall so that the tab passes through the slot.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : RE47,219 E
APPLICATION NO. : 15/783628
DATED : February 5, 2019
INVENTOR(S) : Ganske et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification

At Column 1, please replace the heading "RELATED APPLICATIONS," at Line 12 (approx.) and the words "This application," at Line 14 (approx.), with the following:
--*CROSS REFERENCE TO RELATED APPLICATIONS*

NOTICE: More than one reissue application has been filed for the reissue of U.S. Patent No. 9,205,019 B2. The reissue applications are U.S. Reissue Patent Application Serial No. 16/180,644, filed on November 5, 2018, now abandoned, which is a divisional reissue application of U.S. Reissue Patent Application Serial No. 15/783,628 (the present application), filed on October 13, 2017, now U.S. Reissue Patent No. RE47,219 E, issued February 5, 2019, which is a reissue application of U.S. Patent Application Serial No. 14/302,624, filed on June 12, 2014, now U.S. Patent No. 9,205,019 B2, issued December 8, 2015, which--

Signed and Sealed this
Second Day of August, 2022

Katherine Kelly Vidal

Katherine Kelly Vidal
Director of the United States Patent and Trademark Office