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(71) Applicant: **COCO INDUSTRIES PTY LTD** [AU/AU]; 18 Jameson Street, Swanbourne, Western Australia 6010 (AU).

(72) Inventor: **MITCHELL, Christopher**; 18 Jameson Street, Swanbourne, Western Australia 6010 (AU).

(74) Agent: **ARGON IP ADVISORY PTY LTD**; 132 Cremorne Street, Richmond, Victoria 3121 (AU).

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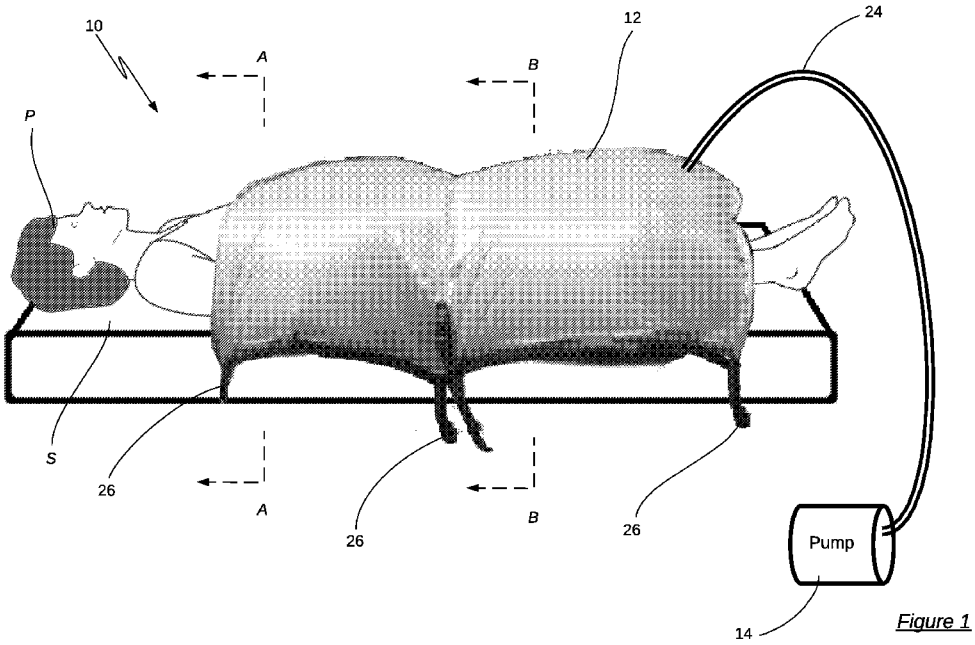


Figure 1

(57) Abstract: A corporeal compression system for use in applying compression to a patient positioned upon a supporting surface has an overlay, and a gas supply system. The overlay includes flexible sheet material that is arranged into at least two layers to define an internal region therebetween, an inlet orifice that opens into the internal region, and restraints that, in use, locate and restrain edge portions of the flexible sheet material. The layers are repositionable with respect to each other such that the sheet material can assume a deflated state in which the volume of the internal region is a minimum. In use of the corporeal compression system, the flexible sheet material of the overlay is draped over the patient, the flexible sheet material is restrained relative to the support surface by the restraints, and the gas supply system is operable to deliver gas to increase the volume of the internal region from the deflated state and establish an elevated pressure within the internal region, thereby compressing the patient between the posterior layer of the overlay

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and the supporting surface.

A Corporeal Compression System

Field of the invention

The present invention relates to a corporeal compression system. More particularly, the present invention relates to a system for use in applying compression to a patient for management and/or assistance in medical interventions or investigations.

Background

There are instances in which it is desirable to apply compression for management and/or assistance in medical interventions or investigations. Compression can be advantageous in managing internal fluid pressure or distribution within a patient's body. Further, compression can be advantageous in partial immobilisation of a patient in order to limit discomfort and/or prevent exacerbation of an existing condition.

As an example of managing blood pressure of a person or animal (hereinafter referred to as a "patient"), it may be desirable to increase a patient's venous blood pressure in response to an adverse indication, or as a part of an investigative or surgical procedure. It is known that a decrease in venous blood pressure is detrimental to the ability of the heart to move blood into the arterial side of the cardiovascular system. This is because cardiac output is directly linked to venous return, which is partly determined by the venous blood pressure.

In many occurrences, a decrease of venous blood pressure can be attributed to loss of blood volume (by internal bleeding or external bleeding), and/or venodilation. Venodilation can be caused by many conditions, including sepsis, anaphylaxis, spinal injury, and drug interactions.

Currently known pharmacological treatments of acute, severe venodilation are limited and have a low efficacy. For example, in the case of anaphylaxis, administration of adrenaline can increase peripheral vascular resistance and cardiac function but does not

increase venous tone. Consequently, the primary treatment methodologies are administration of adrenaline, infusion of fluids, cardio-pulmonary resuscitation, and time.

In surgery, about 1 in 10,000 patients suffer an anaphylactic reaction to drugs that are administered during the procedure. Compared with typical anaphylactic reactions to allergens to encountered orally or by contact, anaphylactic reactions in surgical environments commonly have a rapid on-set and are severe. Further, when a patient suffers an anaphylactic response to intravenously administered drugs, the histamine released in response to the allergen causes widespread venodilation, which results in a greater blood volume to fill the veins, and less blood volume available to stretch the veins and create venous blood pressure. The drop in venous blood pressure reduces venous return and cardiac output often resulting in anaphylactic shock, which has a reported mortality of 4% despite current management strategies.

There is a need to address the above, and/or at least provide a useful alternative.

Summary

There is provided a corporeal compression system for use in applying compression to a patient positioned upon a supporting surface, the corporeal compression system comprising:

an overlay having:

flexible sheet material that is arranged into at least two layers to define an internal region therebetween, the layers being repositionable with respect to each other such that the sheet material can assume a deflated state in which the volume of the internal region is a minimum, and

an inlet orifice that opens into the internal region;

one or more restraints that, in use, locate and restrain edge portions of the flexible sheet material relative to the supporting surface with at least part of the patient's body between the supporting surface and the flexible sheet material; and

a gas supply system that has a discharge port that is connected to, or is connectable to, the inlet orifice, the gas supply system being configured to deliver gas through the discharge port,

wherein, in use of the corporeal compression system:

the flexible sheet material of the overlay is draped over the patient so as to provide a posterior layer that is in contact with the patient and an anterior layer that is spaced from the patient by the posterior layer,

the flexible sheet material is restrained relative to the support surface by the restraints, and

the gas supply system is operable to deliver gas via the inlet orifice to increase the volume of the internal region from the deflated state and establish an elevated pressure within the internal region, thereby compressing the patient between the posterior layer of the overlay and the supporting surface.

In at least some embodiments, the gas supply system further comprises one or more of:

a containment vessel that is configured to contain pressurized gas, and a gas distribution circuit interconnects the containment vessel with the discharge port;

a pump having the discharge port through which to discharge gas; and

an inflow connector and gas distribution circuit, the inflow connector interconnecting the discharge port with an independent supply of pressurized gas via the gas distribution circuit,

wherein, in use of the corporeal compression system, the gas supply system is operable to deliver gas to the overlay at a first flow rate and at a second flow rate, wherein the first flow rate is higher than the second flow rate, and wherein the gas supply system is configured to deliver gas at the second flow rate when the pressure within the internal region is above atmospheric.

There is also provided an overlay for use in applying compression to a patient positioned upon a supporting surface, the overlay comprising:

flexible sheet material that is arranged into at least two layers to define an internal region therebetween, the layers being repositionable with respect to each other such that the sheet material can assume a deflated state in which the volume of internal region is a minimum; and

an inlet orifice that opens into the internal region,

wherein, in use of the overlay:

the flexible sheet material in the deflated state is draped over the patient so as to provide a posterior layer that is in contact with the patient and an anterior layer that is spaced from the patient by the posterior layer,

the flexible sheet material is restrained relative to the support surface, and

gas is introduced to the internal region via the inlet orifice to increase the volume of the internal region from the deflated state and establish an elevated pressure within the internal region, thereby compressing the patient between the posterior layer of the overlay and the supporting surface.

Preferably, in use of the corporeal compression system, a portion of the posterior layer conforms to the patient, and the anterior layer is distended when an elevated pressure is established within the internal region.

Preferably, the overlay includes restraints with which to restrain the flexible sheet material to the supporting surface.

In at least some embodiments, the restraints are affixed to the flexible sheet material. In certain embodiments, each restraint is configured to encircle the supporting surface. In such embodiments, each restraints can include a releasable coupling. The releasable coupling can be hook and loop fastener materials. In some alternative embodiments, the releasable coupling is a quick release buckle. Each restraint can include length adjustment.

The layers of the overlay can include an inner layer that is to provide the posterior layer in use of the overlay, and an outer layer that is to provide the anterior layer in use of

the overlay. The inlet orifice can be formed in the outer layer. In embodiments in which the restraints are affixed to the flexible sheet material, at least some of the restraints are affixed to the outer layer.

The inner layer can include one or more pleats that extend in the length direction of the overlay. Alternatively or additionally, the inner layer can be made of flexible sheet material that has a higher elasticity in at least one direction than the material of the outer layer. In certain embodiments, the inner layer is made of flexible sheet material that has elasticity in at least a transverse direction of the overlay that is higher than the elasticity of the flexible sheet material of the outer layer. The outer layer can be made of flexible sheet material that includes low elasticity strands. Alternatively or additionally, the overlay can include one or more elongate members that are configured to support hoop stresses in one or more directions from the outer layer when the pressure within the internal region is elevated.

Preferably, the outer layer is made of a flexible sheet material that is substantially inelastic. In certain embodiments, the outer layer is made of a flexible sheet material that includes woven material and a coating that reduces the porosity of the woven material. In some embodiments, the inner layer is made of a flexible sheet material that includes woven material and a coating that reduces the porosity of the woven material. The outer layer can be formed of a material that has a lower gas permeability than the material of the inner layer.

The flexible sheet material can include a superior peripheral edge and an inferior peripheral edge, whereby in use of the overlay the inferior peripheral edge is to be further from the patient's head than the superior peripheral edge. In some embodiments, the overlay is wider at the superior peripheral edge than at the inferior peripheral edge. Alternatively or additionally, the width of the overlay tapers in a direction away from the superior peripheral edge.

Preferably, the overlay has one or more markings to facilitate positioning of the flexible sheet material with respect to the patient at a prescribed position.

The layers of flexible sheet material can be arranged to form distinct peripheral edges to the internal region. In some embodiments, at least some of the peripheral edges of the internal region are spaced internally from the peripheral edges of the outer layer.

The layers of the overlay can be made from separate pieces of flexible sheet material that are joined at the peripheral edges of the internal region.

In some embodiments, the layers of the flexible sheet material are joined at the peripheral edges by at least one of: plastic welding, adhesives, sewn seams. In examples in which the layers of the flexible sheet material are joined at the peripheral edges by sewn seams, the overlay further comprises seal seam material across or within the seams.

In some embodiments, the inlet orifice is part of an inlet connector, and the discharge port is part of an outflow connector that interconnects with the inlet connector. The inlet connector can include an inlet valve that is normally closed. In some embodiments, connecting the outflow connector to the inlet connector causes the inlet valve to open. In some alternative embodiments, the inlet valve includes an actuator that is operable to open the inlet valve.

The overlay can include a plurality of inlet orifices.

In some embodiments, the overlay includes one or more partitions of flexible sheet material that divide the internal region into two or more pockets, wherein the partitions inhibit flow of gas between the pockets, and wherein one of the inlet orifices opening into the internal region within each respective pocket.

In at least some embodiments, the flexible sheet material of the overlay is configured so as to be in the deflated state when draped over the patient.

The overlay can include an overpressure relief valve to vent excess pressure from the internal region to the atmosphere. In some embodiments, the overpressure relief valve opens when the internal pressure within the internal region exceeds a predetermined pressure. In some examples, the predetermined pressure is 60 cm of water or less.

There is also provided a gas supply system for use with an overlay of a corporeal compression system, the flowable material supply system comprising:

a discharge port that is connected to, or is connectable to, the inlet orifice of the overlay,

one or more of:

a pump that is in communication with the discharge port via a conduit;

a containment vessel that is in communication with the discharge port via a gas distribution circuit, the containment vessel being configured to contain pressurized gas; and

a gas distribution circuit that includes an inflow connector that is to interconnect with an independent supply of pressurized gas, and one or more conduits that direct gas from the inflow connector to the discharge port;

wherein in use of the gas supply system within the corporeal compression system:

the gas supply system is operable to deliver gas to the overlay at a first flow rate and at a second flow rate, the first flow rate being higher than the second flow rate, and

the gas supply system is configured to deliver gas at flow rates up to the second flow rate when the pressure within the internal region is above a pre-determined pressure.

In some embodiments in which the gas supply system includes a pump, the pump preferably includes:

an electric motor connected to a rotor that is rotatable to displace gas from an intake, through a chamber in which the rotor is housed, to a discharge port;

a discharge connector that interconnects the discharge port with a complementary connector that is in communication with the inlet orifice of the overlay;

at least one of a flow sensor and a pressure sensor located between the chamber and the discharge port;

a controller that controls the operation of the electric motor, the controller being configured to receive information from the flow sensor and/or the pressure sensor, and to drive the electric motor to vary the flow rate of gas to the discharge port in response to the received information; and

at least one of: a self-contained source of electrical power, and a connector with which to connect the pump to an independent source of electrical power, that provides electrical power to the electric motor.

The controller can be configured such that the pump is operable at a first flow rate to inflate the overlay, and at flow rates up to a second flow rate to establish and/or maintain an elevated pressure within the internal region, the first flow rate being higher than the second flow rate.

In certain embodiments, the controller is configured so that when initialised, the controller is set to initially drive the electric motor to supply gas to the discharge port at the first flow rate.

In some embodiments, the controller is configured so that when initialised, the controller drives the electric motor to supply gas to the discharge port at the first flow rate for a pre-determined period of time. In some embodiments in which the pump includes a flow sensor, the controller is configured so that when initialised, the controller drives the electric motor to supply gas to the discharge port at the first flow rate to discharge a pre-determined volume of gas, and thereafter drives the electric motor to supply gas to the discharge port at flow rates up to the second flow rate. In some in which the pump includes a pressure sensor, the controller is configured so that when the sensed pressure is at or below a pre-determined threshold pressure, the controller drives the electric motor to supply gas to the discharge port at the first flow rate to discharge a pre-determined volume of gas, and when the sensed pressure is above the pre-determined threshold pressure, the

controller drives the electric motor to supply gas to the discharge port at flow rates up to the second flow rate.

In at least some embodiments, the controller has a pre-determined set point pressure and the controller is configured to operate to the electric motor to vary the flow rate of gas to the discharge port to maintain the pressure within the internal region of the overlay at the set point pressure. Preferably, the pump has an input user interface that enables a user to set the pre-determined set point pressure. Alternatively or additionally, the set point pressure is adjustable during operation of the pump.

Preferably, the pump has a default set point pressure, and the controller is initialised with the pre-determined set point pressure being the default set point pressure.

In some embodiments, the pre-determined threshold pressure is less than the set point pressure. Alternatively or additionally, the pre-determined threshold pressure is a proportion of the set point pressure.

In some embodiments of the corporeal compression system in which the gas supply system comprises an electrically powered pump:

the pump includes an outflow connector that forms the discharge port, and an electrical switch that is operable to activate the electric motor of the pump; and

the overlay includes a conduit that is interconnected at a first end to the flexible sheet material so as to open into the inlet orifice, the second end of the conduit including an inlet connector that is releasably couplable to the outflow connector,

wherein the action of coupling the inlet connector with the outflow connector operates the electrical switch.

Preferably, the inlet connector and outflow connector are configured such that an elevated pressure within the conduit biases the inlet connector and outflow connector into the coupled state. Alternatively or additionally, the pump can include a spring that is positioned to bias the inlet connector and outflow connector into the coupled state.

In at least one form, the inlet connector and outflow connector form a bayonet mount, and the electrical switch is positioned relative to the outflow connector so as to be actuated after the first movement of coupling the inlet connector and outflow connector is complete. Alternatively or additionally, the electrical switch is positioned relative to the outflow connector so as to be actuated during the first movement of decoupling the inlet connector and outflow connector.

In some embodiments in which the gas supply system includes a containment vessel, the gas supply system further includes:

a discharge flow regulator that regulates the flow of gas from the containment vessel to the discharge port, the regulator being configured:

to discharge gas to the discharge port at flow rates up to the first flow rate when the pressure within the internal region is at or below a threshold pressure, and

to discharge gas to the discharge port at flow rates up to the second flow rate when the pressure within the internal region is above the threshold pressure and below the pre-determined pressure and/or the selected set point pressure.

In some embodiments, the first flow rate corresponds with substantially unregulated discharge of gas from the containment vessel to the discharge port.

In some embodiments, the discharge flow regulator has a plurality of pneumatically operated valves that are in fluid communication with the internal region via the inlet orifice and the discharge port, wherein each valve is operable to be open at a unique threshold pressure. The discharge flow regulator can include a first stage regulator that when open regulates flow of gas out of the containment vessel at flow rates up to the first flow rate, and a second stage regulator that regulates flow of gas to the discharge port to flow rates up to the second flow rate when the pressure within the internal region is above the pre-determined pressure, wherein the pre-determined pressure is less than a set point pressure.

In some alternative embodiments, the discharge flow regulator includes:

one or more electrically operated valves;

at least one of a flow sensor and a pressure sensor located between the chamber and the discharge port;

an electronic controller that controls the operation of the valves, the controller being configured to receive information from the flow sensor and/or the pressure sensor, and operate valves in response to the received information; and

at least one of: a self-contained source of electrical power, and an independent source of electrical power, that provides electrical power to the electronic controller.

There is also provided an overlay for use in applying compression to a patient positioned upon a supporting surface, the overlay comprising:

flexible sheet material that is arranged into at least two layers to define an internal region therebetween, the layers being repositionable with respect to each other such that the sheet material can assume a deflated state in which the volume of internal region is a minimum;

a compressible open cell material contained within the internal region;

an inlet orifice that opens into the internal region;

an inlet valve that is operable to selectively allow passage of air through the inlet orifice; and

restraints with which to restrain the flexible sheet material to the supporting surface, the restraints being length adjustable,

wherein, in use of the overlay:

the inlet valve is opened to allow the compressible open cell material to fill the internal region, and then closed to isolate the internal region from the atmosphere;

the overlay is placed over the patient so as to provide a posterior layer that is in contact with the patient and an anterior layer that is spaced from the patient by the posterior layer, and

the restraints are used to restrain the flexible sheet material relative to the support surface, and the length of the restraints are adjusted to establish tensile forces in the anterior layer so as to establish an elevated pressure within the internal region, thereby

compressing the patient between the posterior layer of the overlay and the supporting surface.

In such embodiments, the overlay includes at least one overpressure relief valve to vent excess pressure from the internal region to the atmosphere.

Brief description of the drawings

In order that the invention may be more easily understood, embodiments will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1: is a schematic view of a corporeal compression system according to a first embodiment of the present invention;

Figure 2: is a plan view of the anterior side of the overlay of the corporeal compression system of Figure 1;

Figure 3: is a plan view of the posterior side of the overlay of Figure 2;

Figure 4: is a schematic cross section view of the corporeal compression system as viewed along the line *A–A* in Figure 1;

Figure 5: is a schematic cross section view of the corporeal compression system as viewed along the line *B–B* in Figure 1;

Figure 6: is a schematic cross section view of the corporeal compression system as viewed along the line *A–A* in Figure 1, showing the overlay in a deflated state;

Figure 7: is a schematic block diagram of the pump of the corporeal compression system of Figure 1;

Figure 8: is a view of the User Interface of the pump of the corporeal compression system of Figure 1;

Figure 9: is a chart showing overlay fill volume and internal region pressure against time for a corporeal compression system of Figure 1;

Figure 10: is a schematic view of a gas supply system according to a second embodiment of the present invention;

Figure 11: is a schematic view of a gas supply system according to a third embodiment of the present invention;

Figure 12: is a schematic view of a corporeal compression system according to a fourth embodiment of the present invention;

Figure 13: is a plan view of the anterior side of an overlay fir a corporeal compression system according to a fifth embodiment of the present invention; and

Figure 14: is a plan view of the posterior side of the overlay of Figure 13.

Detailed description

Figures 1 to 6 show a corporeal compression system 10 according to an embodiment of the present invention. The compression system 10 in use is to apply compression to a patient *P* positioned upon a supporting surface *S*, which may be for example the upper surface of a theatre bed.

The compression system 10 has an overlay 12, and a flowable material supply system, which in this embodiment is in the form of a pump 14. The overlay 12 has flexible sheet material that is arranged into layers 16, 18. An internal region 20 is defined between the layers 16, 18. As the sheet material of the layers 16, 18 is flexible, the layers can be repositioned with respect to each other. In this way, the sheet material of the overlay 12 can assume a deflated state in which the volume of the internal region 20 is a minimum. Figure 6 shows schematically the overlay 12 in a deflated state, and draped over the patient *P*. In this particular embodiment, the flexible sheet material of the overlay 12 is arranged to form a posterior layer 16 that is in contact with the patient *P* when the overlay 12 is draped over the patient *P*, and an anterior layer 18 that is spaced from the patient *P* by the posterior layer 16.

Figure 2 shows the anterior side of the overlay 12, and thus the anterior layer 18. Figure 3 shows the posterior side of the overlay 12, and thus the posterior layer 16.

As shown in Figure 2, the overlay 12 further has an inlet connector 22 within the anterior layer 18. The inlet connector 22 defines an inlet orifice that opens into the internal region 20. The pump 14 has an outlet pipe 24 that, in this particular embodiment, is releasably connectable to the inlet connector 22. In this way, gas from the pump 14 is delivered through the outlet pipe 24, and into the internal region 20.

In this example, the pump 14 has an intake (not shown) that draws in atmospheric air, and a rotor (not shown) that is rotatable to displace gas from the intake, through a chamber (not shown) in which the rotor is housed, to the discharge port.

The compression system includes restraints 26 that are to locate and restrain lateral edge portions of the flexible sheet material of the overlay 12 relative to the supporting surface *S*. In this particular embodiment, the restraints 26 are integral with overlay 12. In Figures 1 and 4 to 6, the restraints 26 extend underneath, and thus around, the theatre bed.

In use of the corporeal compression system 10, the overlay 12 in the deflated state is draped over the patient *P*, such that the posterior layer 16 is in contact with the patient *P*, and also with the support surface *S*. The anterior layer 18 faces outwardly and away from the patient *P*. The overlay 12 is restrained relative to the support surface *S* by the restraints 26. The pump 14 is then operated to deliver air via the inlet orifice to increase the volume of the internal region 20 from the deflated state. Once the internal region 20 has been filled to the available capacity, the pump 14 then establishes an elevated pressure within the internal region 20. The pressure differential between the internal region 20 and the surrounding atmosphere, together with tensile forces generated in the restraints 26, compress the patient *P* between the posterior layer 16 of the overlay 12 and the supporting surface *S*. Due to the flexibility of the sheet material, the posterior layer 16 conforms at least in part to the patient's body. In this regard, it will be appreciated that, due to various factors, there will be air gaps in certain regions between the patient *P* and the overlay, and in some instances also between the supporting surface *S*. Notwithstanding such air gaps, the compressive forces applied by the overlay 12 are distributed across the substantially

around the external surfaces of the patient's body that are facing away from the supporting surface *S*.

As shown in Figure 1, the superior edge 28 of the overlay 12 is to be positioned approximately level with the patient's xiphisternum, when the overlay 12 is in its deflated state and draped over the patient *P*. The inferior edge 30 of the overlay 12 (which is the edge furthest from the patient's head) will locate in a position on the patient that is determined by the height of the patient *P* and the length of the overlay 12. To facilitate the correct optimal location of the overlay 12 on a patient, the anterior layer 18 of the overlay 12 has markings 32 to facilitate positioning of the flexible sheet material with respect to the patient at a prescribed position. As shown in Figure 2, in this example, the markings 32 consist of the word "XIPHISTERNUM" and an arrow with the tip pointing to the centre of the superior edge 28. In the illustrated example, the inferior edge 30 of the overlay 12 is positioned proximally of the patient's ankles.

As will be apparent, when the overlay 12 is inflated and pressurized, the compression system 10 applies pressure that compresses the patient *P* and effectively "squeezes" the portion of the patient body that is beneath the flexible sheet material. Depending on the magnitude of the pressure applied by the compression system 10, there are a variety of advantages that may be obtained through use of the compression system 10. For a patient experiencing widespread venodilation, compression in this manner can increase the patient's venous return, which has the consequence of increasing cardiac output. Preliminary trials indicate that compression achieved by air pressures within the internal region 20 of up to, and including 60 centimetres of water (hereinafter "cm H_2O") is beneficial in redistributing venous blood to restore functional cardiac output where venodilation is present. In this regard, the preliminary trials indicate that compression achieved by air pressures within the internal region 20 in the range of 15 to 45 centimetres of water (hereinafter "cm H_2O") is particularly beneficial. Further, the trials suggest that compression achieved by air pressures within the internal region 20 in the range of 25 to 35 centimetres of water (hereinafter "cm H_2O") may be highly effective in treatment of venodilation.

In the illustrated example, the squeezed portion of the patient *P* is their abdomen and legs. A large proportion of a person's venous blood volume is stored in a person's abdomen and legs. Use of the compression system 10 on a patient as illustrated in Figure 1 can redistribute a patient's venous blood to their head and chest region.

By way of example, a patient suffering an anaphylactic reaction during a surgical procedure to anaesthetic drugs that have been administered intravenously is likely to have had the allergen delivered rapidly through their blood stream. The widespread presence of the allergen can induce a histamine response through much of their body. The subsequent venodilation will rapidly decrease venous blood pressure, which then lowers venous return and thus limits cardiac output. In severe cases, extensive venodilation can result in the patient's death. Use of the compression system 10 facilitates the management of the anaphylactic reaction in this setting by redistributing the venous blood, which may avoid cardiac arrest due to loss of cardiac output. With the patient stabilized by the external compression, the patient's natural histamine response, possibly augmented with an infusion of adrenaline, has sufficient time to reverse the anaphylactic response. In other words, the corporeal compression system can provide additional care to the use of adrenaline, intravenous fluids and time, in the treatment of an anaphylactic response.

As will be appreciated, the compression system 10 of this embodiment utilizes the supporting surface *S* on which the patient *P* is lying in the application of compression. This has the distinct advantage of minimizing, if not eliminating, need to move the patient in the fitting of the overlay to the patient.

With regard to a patient who has sustained certain injuries, such as internal venous bleed due to a pelvic fracture, the application of compression using the compression system 10 of this embodiment can limit venous bleeding in the abdomen and/or lower limbs. As will be apparent, limiting venous bleeding can improve the prospects of recovery from the injuries. By way of example, pelvic fractures are frequently accompanied by internal bleeding, which in some cases occurs from the venous circulation. As pelvic fractures are

usually the result of accidental trauma, attending emergency medical services (EMS) team initially stabilize the patient at the accident location, prior to transporting the patient to a hospital. While transporting the patient, it may be necessary to introduce fluids to compensate for the venous bleeding and maintain venous return. A corporeal compression system according to an embodiment of the invention can be used by the EMS team during the transport, to limit venous bleeding and then limit the fluid infusion required. To this end, the patient can be loaded onto the EMS stretcher, and the overlay of the compression system draped over the patient and restrained to the EMS stretcher using the system's restraints. Once the flexible sheet material is inflated and pressurized, the overlay together with the stretcher co-operate to compress the patient, the compression operating to limit the extent of venous bleeding.

It will be appreciated that the compression system of embodiments can alternatively or additionally be used in transporting patients with other injuries. One particular benefit being that the stability of the patient with respect to the support surface on which they are positioned can be enhanced by the compression, which can assist in limiting the patient's discomfort.

A further benefit of use of the compression system in transport is that it operates in a manner similar to the safety restraints that are often fitted to a patient during transport.

To facilitate movement of the posterior layer 18 during inflation, the posterior layer 18 is provided with a pair of pleats 35. Each pleat 35 extends in the length direction of the overlay 12.

As will be appreciated, the available capacity (in other words, the maximum available volume) of the internal region depends on several factors, including the size of the patient *P* (and in particular their girth), the geometries of the supporting surface *S* and the anterior layer 16, and the elasticity of the anterior layer 16. The anterior layer 16 in some embodiments may be made of a flexible sheet material that is substantially inelastic. This has the benefits of minimizing stretching of the anterior layer, which increases the

available capacity, avoiding a change in permeability of the anterior layer (which can occur with some materials when stretched), and/or minimizing the likelihood of the anterior layer material tearing.

In one example, the anterior layer 16 is made of a flexible sheet material that includes woven material and a coating that reduces the porosity of the woven material. The coating may be, for example, a polymer coating, such as a polyurethane or acrylics materials, may be applied to the woven material during manufacture of the sheet material. Such polymer coatings can be beneficial in blocking pores in the sheet material, and thus limiting gas permeability. Similarly, with regard to the posterior layer 18.

In this particular embodiment, the overlay 12 is wider at the superior peripheral edge 28 than at the inferior peripheral edge 30. Further, the width of the overlay 12 tapers in a direction away from the superior peripheral edge 28. This has the benefit of maximizing the contact surface between the overlay 12 and the patient *P*, while also minimizing the maximum volume of the internal region 20.

In the illustrated example, layers 16, 18 of the overlay 12 are made from separate pieces of flexible sheet material that are joined at the peripheral edges of the internal region 20. In this way, the layers 16, 18 of flexible sheet material form distinct peripheral edges to the internal region 20.

The restraints 26 are affixed to the flexible sheet material of the overlay 12. In the embodiment as illustrated in Figures 2 and 3, each restraint 26 has a length that is greater than that required to encircle the supporting surface *S* when a patient *P* is resting on that the surface. Each restraint 26 has a releasable coupling that, in this embodiment is in the form of hook and loop fastener materials 34, 36. In this example, the hook material 34 is provided on a portion of the "free" section of the restraint 26. The loop material 36 is provided across the width of the flexible sheet material, and on the external surface of the anterior layer 18.

To facilitate restraining the overlay 12 to a bed that provides the support surface *S*, there is a looped handle 38 at the terminal end of each restraint 26. When locating and restraining the overlay 12, the "free" section of each restraint 26 is passed underneath the support surface *S*, and then positioned to interconnect the hook and loop fastener materials 34, 36. Two surgical attendants can quickly pass the looped handle 38 beneath the patient *P* and support surface *S* while fitting the overlay 12.

Figure 7 is a block diagram of the components of the pump 14 of the corporeal compression system 10 of Figure 1.

The pump 14 of this embodiment includes a brushless DC Motor Blower 40. Within the motor blower 40 is an electric motor that is connected to a rotor that is rotatable within a chamber. The Motor Blower 40 displace air that is drawn from an intake 42, through the chamber by the rotation of the rotor, and discharged to a discharge port 44. As previously described, the pump 14 includes an outlet pipe 24, and in this particular embodiment, the discharge port 44 is formed at the inner terminal end of the outlet pipe 24 that is permanently connected to the pump housing. At the outer end of the outlet pipe 24, the pump 14 has discharge connector (not shown) that interconnects the discharge port with the (complementary) inlet connector 22 that is in communication with the inlet orifice of the overlay 12.

The pump 14 includes a flow sensor 46 and a pressure sensor 48 that are located between the chamber and the discharge port of the pump 14. In this way, the flow sensor 46 measures the flow rate of air discharged from the pump 14. From information obtained from the flow sensor 46, the fill volume of the internal region 20 of the overlay 12 can be at determined, at least with sufficient accuracy. The pressure sensor 48 measures the pressure of air discharged from the pump 14. As will be appreciated, the air pressure is substantially similar to the internal pressure within the internal region 20.

The pump 14 further has a controller 50 that controls the operation of the Motor Blower 40. As indicated in Figure 7, the controller 50 is configured to receive information

from the flow sensor 46 and the pressure sensor 48. Accordingly, the controller 50 is able to vary the electric motor speed to vary the flow rate of air to the discharge port, in response to the received information.

In this particular embodiment, the pump 14 also a self-contained source of electrical power, which in this embodiment is a non-isolated power supply 52 such as a battery. An electrical connector (not shown) is also provided, with which to connect the pump to an independent source of electrical power, such as a mains AC power supply. The electrical connector is coupled to an isolated AC/DC power supply 54. In this way, the pump 14 can be powered by either a battery, or from mains AC power supply.

The controller 50 of this embodiment is configured such that the pump 14 is operable at a first flow rate to inflate the overlay 12, and at flow rates up to a second flow rate to establish and/or maintain an elevated pressure within the internal region 20. The first flow rate is higher than the second flow rate. In particular, the first flow rate can be utilized to provide a high-volume flow into the internal region 20, which can enable rapid inflation of the overlay 12. Once the maximum available capacity of the internal region 20 has been reached, the pump 14 can then be operated at the second flow rate that establishes and/or maintains the elevated pressure within the internal region 20. As will be appreciated, the second flow rate can ideally match the air leakage from the overlay 12, and in embodiments in which the air leakage is negligible, the pump 14 may be operable from flow rates that approach nil.

Once the maximum available capacity of the internal region 20 has been reached, the controller 50 can operate in a cyclical manner, involving alternating between the second flow rate and no output, in order to maintain the elevated pressure. Alternatively, the controller 50 can utilize a feedback loop control system in which the second flow rate is adjusted based on inputs from the pressure sensor 48, and in some cases also the flow sensor 46.

The controller 50 can also be configured so that, when initialised, the Motor Blower 40 is initially driven to supply air to the discharge port at the first flow rate. In this way, the controller 50 is operating on the initialisation assumption that the overlay 12 is in its deflated state. A barometric pressure sensor 47 is also be provided, which enables comparison of the atmospheric pressure (obtained via the barometric pressure sensor) and data obtained by the pressure sensor 48. In particular, the pressure differential between atmospheric pressure, and the pressure at the outlet of the Motor Blower 40.

Figure 9 is a chart showing the overlay 12 fill volume (shown in a plotted solid line of the chart, and indicated by arrow *V*) and internal region pressure (shown in a plotted dash line of the chart, and indicated by arrow *D*), against time on the horizontal axis. Figure 9 also shows the flow rate of air discharged by the pump 14 (shown in a plotted dash–dot line of the chart, and indicated by arrow *F*).

At time *T = 0*, the overlay 12 is in its deflated state, and thus the fill volume *V* and internal region pressure *D* are both zero. Time *T = 0* represents the time at which the gas supply system is activated. In this example, the gas supply system delivers a substantially constant high flow rate of air to the overlay 12 between time *T= 0* and time *T = t1*. Accordingly, during this period the overlay 12 is being inflated at a substantially constant rate (which is the higher first flow rate of the pump 14) and the fill volume *V* increases substantially linearly from zero to a volume approaching the maximum available capacity.

At time *T = t1*, the overlay 12 is approaching its available capacity, and hence between time *T = t1* and time *T = t2* the internal region pressure *D* increases, in a non-linear manner, from zero to an elevated pressure. Accordingly, during this period in which the internal region 20 of the overlay 12 is being pressurized to the elevated pressure, and the pump 14 is operating at the lower second flow rate.

After time *T = t2*, the internal region pressure *D* is to be maintained at the elevated pressure. As will be appreciated, air leakage from the overlay 12 will cause the pressure within the internal region 20 to fall over time in the absence of an inflow of air into the

internal region 20. Accordingly, after time *T = t2*, the pump 14 is operated at flow rates that are up to the second flow rate.

In this example, the controller 50 is configured so that when the sensed pressure – obtained from the pressure sensor 48 – is above a pre-determined threshold pressure, the controller 50 drives the Motor Blower 40 to switch the flow rate of discharged air from the first flow rate, to flow rates up to the second flow rate. The pre-determined threshold pressure in this example is sensed at time *T = t1*.

It will be appreciated that the chart of Figure 9 is schematic only, and illustrative of one manner in which the pump 14 may be operated.

As shown in Figure 7, the pump 14 has a user interface 55, that includes an input user interface 56 that enables a user to operate the pump, and an output user interface 58 that provides visual information for the user to ascertain the operational status of the pump 14. In one example, the user interface 55 includes a touchscreen display, as illustrated in Figure 8.

As shown in Figure 8, the user interface 55 enables the user to set a pre-determined set point pressure, which is the desired maximum elevated pressure of the internal region 20. The input user interface 58 can enable a user to adjust the set point pressure during operation of the pump 14. To this end, the user interface 55 has "Quick Start" inputs 80 that allow selection of operation of the pump to initial set point pressures of 20 cm H_2O, 40 cm H_2O, and 60 cm H_2O. The set point pressure can be adjusted, either decreasing the set point pressure using a pressure decrease input 82, or increasing the set point pressure using a pressure decrease input 84. A user can immediately cease operation of the Motor Blower 40 via a "STOP" input 88.

The output user interface 58 portion of the user interface 55 shows the "SET PRESSURE" in display region 86. Further, the output user interface 58 portion of the user interface 55 includes a pump operating parameter display portion 90 that includes digital

gauges and numerical values for each of the sensed pressure (via the pressure sensor 48), the Motor Blower 40 rotational speed, and the temperature of air flowing through the Motor Blower 40.

In this particular embodiment, the output user interface 58 also provides information audibly via a speaker from which the user can ascertain the operational status of the pump 14.

As will be appreciated, compression systems of embodiments of the invention can be used in the treatment of other conditions, including (but not limited to) distributive shock, hypotension, and external venous bleeding in the abdomen and/or lower limbs. It will be appreciated that the level of compression, which is correlated with the internal pressure of the internal region, may be different depending on many factors, including (but not limited to) the condition being treated, the instant event being treated, particulars of the individual being treated.

Furthermore, it is known that compression is beneficial in managing lactic acid build up in soft tissues. A compression system according to certain embodiments may be efficacious in sports recovery. In such embodiments, it may be desirable for the air that is delivered to the internal region to be chilled in order to provide the dual benefits of compression and cold therapy. In such circumstances the compression system may include a heat exchanger that is configured to lower the temperature of air that is being delivered to the internal region. Such embodiments may include an air return line from the overlay to the intake to the pump. The gas supply system may optionally include an atmospheric air intake and a valve that switches the intake air being drawn into the pump from atmospheric air and air from the air return line. The heat exchanger can be provided on any of the air return line, the intake to the pump downstream of the valve, and the air discharge line from the pump to the overlay. In this way, air within the internal region of the overlay may be kept at a temperature below ambient temperature.

Figure 10 shows schematically a gas supply system 114 according to a further embodiment. The gas supply system 114 includes a containment vessel, which in this embodiment is in the form of a gas cylinder 160, and a discharge flow regulator. The discharge flow regulator is configured to regulate the flow of gas from the gas cylinder 160 to the discharge port 144. The gas supply system 114 also includes conduits, such as hoses (not shown in Figure 10), that interconnect various components of the gas supply system 114. The gas supply system 114 also includes a discharge connector (not shown) that interconnects the discharge port 144 with the (complementary) inlet connector that is in communication with the inlet orifice of the overlay.

The regulator is configured to discharge gas to the discharge port 144:

a. at flow rates up to a first flow rate, when the pressure within the internal region is within a first pressure range that includes atmospheric pressure and up to a threshold pressure, and
b. at flow rates up to a second flow rate, which is lower than the first flow rate, when the pressure within the internal region is within a second pressure range that is above the threshold pressure and a pre-determined pressure and/or the selected set point pressure.

The pre-determined pressure / selected set point pressure is greater than the threshold pressure; and the threshold pressure is greater than atmospheric pressure.

In the illustrated embodiment, the regulator includes a 1st Stage Regulator 162 that reduces the pressure of gas from the gas cylinder 160. As indicated schematically in Figure 10, a conduit 164 on the outlet side of the 1st Stage Regulator 162 branches to a 2nd Stage Primary Regulator 166, and a 2nd Stage Secondary Regulator 168. On the discharge port side of each of the 2nd Stage Primary and Secondary Regulators 166, 168, are a pair of conduits 170 that join to lead to the discharge port 144.

As will be appreciated, in use of the gas supply system 160 within a corporeal compression system, the pressure within the pair of conduits 170 is substantially equal to the internal pressure of the internal region of the overlay. The 2nd Stage Primary Regulator

166 is configured to gas at a high flow rate (which is the first flow rate) into conduit 170a, and so to the discharge port 144. The 2nd Stage Primary Regulator 166 is a demand valve that is open when the pressure within the conduit 170a is below the threshold pressure. When the pressure within the conduit 170a rises above the threshold pressure, the 2nd Stage Primary Regulator 166 closes.

The 2nd Stage Secondary Regulator 168 is configured to gas at a low flow rate (which is the second flow rate) into conduit 170b, and so to the discharge port 144. The 2nd Stage Secondary Regulator 168 is a demand valve that is closed when the pressure within the conduit 170b is at atmospheric pressure. As the pressure within the conduit 170b rises and approaches the threshold pressure, the 2nd Stage Secondary Regulator 168 opens. Further, when the pressure within the conduit 170b is at the pre-determined pressure / selected set point pressure, the 2nd Stage Secondary Regulator 168 closes, such that there is no gas flowing to the discharge port 144. As will be appreciated, it is advantageous for both the 2nd Stage Primary and Secondary Regulators 166, 168 to be open in a narrow pressure range that includes the threshold pressure, to ensure continuity of flow to the overlay during inflation.

The gas supply system 160 includes a pair of valves 172 on the pair of conduits 170, which provides the capacity to manually adjust the flow rate through either conduit 170a, 170b if desired.

The 2nd Stage Secondary Regulator 168 can include an adjuster that enables the set point pressure to be adjusted, if desired.

Figure 11 shows schematically a gas supply system 214 according to another embodiment. The gas supply system 214 includes a contained source of pressurized gas, which in this embodiment is in the form of a gas cylinder 260, and a gas distribution circuit 270 that includes an inflow connector 272 that is to interconnect with an independent supply of pressurized gas, such as a medical gas supply line 290.

The gas supply system 214 includes a first conduit 274 that is connected to the outlet of the gas cylinder 260, a second conduit 276 that is connected to the inflow connector 272. The first and second conduits 274, 276 are joined at a junction 278, and a third conduit 280 extends from the junction 278 to the discharge port 244. In this way, gas can flow from the medical gas supply line 290, through the inflow connector and the second and third conduits 276, 280, to the discharge port 244. Further, gas can also flow from the gas cylinder 260, through the first and third conduits 274, 280, to the discharge port 244.

A gate valve 282, and a check valve 283 are provided in the second conduit 276. In this example, the gas cylinder 260 is a single use cylinder. The action of opening the gate valve 282 simultaneously pierces the seal on the gas cylinder 260 to release gas from within the cylinder. In this embodiment, the flow of gas from the gas cylinder 260 is substantially unregulated. The volume of gas that is contained within the cylinder (at the elevated pressure) is substantially equal to the maximum available capacity of the internal region of the overlay. In this way, the overlay is inflated as gas from the gas cylinder 260 is depleted. Thus, in this particular embodiment, the first flow rate corresponds with the substantially unregulated discharge of gas from the gas cylinder 260.

Once the gas cylinder is substantially depleted, the inflow of gas from the medical gas supply line 290 will dominate, and provide a flow of gas at the lower, second flow rate to the discharge port 244. The gate valve 282 is also configured to operate as a demand valve, whereby flow through the second conduit 276 is only enabled when the pressure within the second conduit 276 is below the set point pressure. The check valve 283 prevents back flow of gas from the system 214 into the medical gas supply line 290.

As will be appreciated, the medical gas supply line 290 may have a suitable pressure to achieve the desired set point pressure in use of the corporeal compression system, but may have a flow rate that is so low that the time to inflate the overlay is unacceptably long. The "hybrid" gas supply that is provided by the gas supply system 214 enables rapid

inflation of the overlay using gas from the gas cylinder 260, and also a reliable and continuous supply of pressurized gas from the medical gas supply line 290.

In this particular embodiment, the third conduit 280 includes a bleed valve 284 that releases gas when the pressure within the third conduit 280 exceeds a limit pressure. In the event that the corporeal compression system that includes the gas supply system 214 is used with a patient of particularly large girth, the available capacity may be less than the volume of gas that is contained within the gas cylinder 260 (at the elevated pressure). In this scenario, excess high-pressure gas can be exhausted from the bleed valve 284, which minimizes the likelihood of the overlay attaining an excessive pressure, or damage to the corporeal compression system.

Figure 12 shows a corporeal compression system 310 according to another embodiment of the present invention. The corporeal compression system 310 is substantially similar to the corporeal compression system 10 of Figure 1. Accordingly, components of the corporeal compression system 310 that are similar to components of the corporeal compression system 10 have the same number with the prefix "3".

Figure 12 shows the overlay 312 in its deflated state. The overlay includes a conduit 324 that is interconnected at its first end to the posterior layer 318 of the flexible sheet material so as to open into the inlet orifice. At the second end of the conduit 324 is an inlet connector 392.

The pump 314 includes an outflow connector 394 that forms the discharge port 344, and an electrical switch (not shown) that is operable to activate the electric motor of the pump 314. The inlet connector 392 is releasably couplable to the outflow connector 394. In this example, the inlet connector 392 and outflow connector 394 form a bayonet mount. The action of coupling the inlet connector 392 with the outflow connector 394 operates the electrical switch.

In this example, the electrical switch is positioned relative to the outflow connector 394 so as to be actuated after the first movement of coupling the inlet connector 392 and outflow connector 394 is complete. Further, the electrical switch is positioned relative to the outflow connector 394 so as to be actuated during the first movement of decoupling the inlet connector 392 and outflow connector 394.

Figures 13 and 14 show an overlay 412 according to a fourth embodiment, the overlay 412 being for use in a corporeal compression system. The overlay 412 is substantially similar to the overlay 12 of the corporeal compression system 10 of Figure 1. Accordingly, components of the overlay 412 that are similar to components of the overlay 12 have the same number with the prefix "4".

The overlay 12 has flexible sheet material that is arranged into layers 416, 418. Figure 13 shows the anterior side of the overlay 412, and thus the anterior layer 418. Figure 14 shows the posterior side of the overlay 412, and thus the posterior layer 416.

An internal region (not shown in Figures 13 and 14) is defined between the layers 416, 418. As the sheet material of the layers 416, 418 is flexible, the layers can be repositioned with respect to each other. In a preferred embodiment, the flexible sheet material is a laminate of nylon and thermoplastic polyurethane. This material has the benefit of having low air flow rate through the material. In addition, the material can be joined by heat welding, which minimizes holes (and thus leaks) at the seams.

To facilitate movement of the posterior layer 416 during inflation, the portion of flexible sheet material that forms the posterior layer 416 is wider than the portion of flexible sheet material that forms the anterior layer 418. To accommodate the difference in width in the portions of flexible sheet material for the layers 416, 418, the posterior layer 416 is formed with pleats 435. Each pleat 435 extends in the length direction of the overlay 412, from one the superior edge 428 or inferior edges 430 of the overlay 412. In this particular embodiment, the overlay 412 has eight pleats 435; four pleats 435 being distributed approximately evenly along the superior edge 428, and four pleats 435 at the inferior edge

430. As shown in Figure 14, the middle two of the four pleats 435 at the inferior edge 430 are beside one another at the centreline of the overlay 412.

The overlay 412 further has an inlet connector 422 within the anterior layer 418. The inlet connector 422 defines an inlet orifice that opens into the internal region. The pump 14 has an outlet pipe 24 that, in this particular embodiment, is releasably connectable to the inlet connector 22. In this way, gas from the pump 14 is delivered through the outlet pipe 24, and into the internal region 20.

The overlay 412 has four restraints 426 for restraining the overlay 412 to a support surface *S*, such as a bed. In this embodiment, the restraints 426 are attached to the anterior layer 418. The length of each restraint 426 is sufficient to extend underneath, and thus around, the theatre bed and a patient, and overlap with itself.

Each restraint 426 has a releasable coupling that, in this embodiment is in the form of hook and loop fastener materials 434, 436. In this example, the hook material 434 is provided on a portion of the "free" section of the restraint 426. The loop material 436 is provided across the width of the flexible sheet material, and on the external surface of the anterior layer 418. Each restraint 426 includes a looped handle 438 at the terminal end of the respective restraint 426.

Corporeal compression systems in accordance with embodiments may find possible use in scenarios and fields, including (but not limited to):

treatment of distributive shock, including:

- Sepsis, in short term assessment and/or prolonged treatment, where fluid volume replacement improves vascular status, and
- Anaesthetic related hypotension;

placing of Central Venous Lines (CVL), whereby elevated venous pressure distends the patient's veins, making needling easier;

short term management of venous bleeding;

Central System investigations , including:

- Cardiopulmonary Resuscitation (CPR), to increase cardiac preload;
- Interposed Abdominal Pressure during CPR, by providing compression to the patient's entire body below and including the abdomen;
- Dobutamine Stress echo to stop SAM, caused by redistribution of blood from the dobutamine venodilation), and
- Pre-load stress the heart to assess diastolic heart failure;

transportation of trauma patients suffering:

- intra-abdominal, such as an Abdominal Aortic Aneurysm (AAA), pelvic injuries, including (pelvic fractures), or lower limb bleeding, and
- Lower limb fractures;

and sports recovery and treatments.

One element common to all uses of the corporeal compression system is the need for a transient application of compression to the abdomen and lower limbs of a patient who is positioned on a supporting surface.

As described above, embodiments of the corporeal compression system can be used with a theatre bed and EMS stretchers. It will be appreciated that embodiments of the corporeal compression system can be used with many other objects that provide a supporting surface on which a person can be positioned. These include (but are not limited to) spinal boards, split-board stretchers, hospital trolleys, beds, and procedure specific patient beds.

It will be understood that values of pressure stated throughout this specification and claims are gauge pressure (and not absolute pressure), except where the context indicates otherwise.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and

"comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

CLAIMS:

1. A corporeal compression system for use in applying compression to a patient positioned upon a supporting surface, the corporeal compression system comprising:

an overlay having:

flexible sheet material that is arranged into at least two layers to define an internal region therebetween, the layers being repositionable with respect to each other such that the sheet material can assume a deflated state in which the volume of the internal region is a minimum, and

an inlet orifice that opens into the internal region;

one or more restraints that, in use, locate and restrain edge portions of the flexible sheet material relative to the supporting surface with at least part of the patient's body between the supporting surface and the flexible sheet material; and

a gas supply system that has a discharge port that is connected to, or is connectable to, the inlet orifice, the gas supply system being configured to deliver gas through the discharge port,

wherein, in use of the corporeal compression system:

the flexible sheet material of the overlay is draped over the patient so as to provide a posterior layer that is in contact with the patient and an anterior layer that is spaced from the patient by the posterior layer,

the flexible sheet material is restrained relative to the support surface by the restraints, and

the gas supply system is operable to deliver gas via the inlet orifice to increase the volume of the internal region from the deflated state and establish an elevated pressure within the internal region, thereby compressing the patient between the posterior layer of the overlay and the supporting surface.

2. A corporeal compression system according to claim 1, wherein the gas supply system further comprises one or more of:

a containment vessel that is configured to contain pressurized gas, and a gas distribution circuit interconnects the containment vessel with the discharge port;

a pump having the discharge port through which to discharge gas; and

an inflow connector and gas distribution circuit, the inflow connector interconnecting the discharge port with an independent supply of pressurized gas via the gas distribution circuit,

wherein, in use of the corporeal compression system, the gas supply system is operable to deliver gas to the overlay at a first flow rate and at a second flow rate, wherein the first flow rate is higher than the second flow rate, and wherein the gas supply system is configured to deliver gas at the second flow rate when the pressure within the internal region is above atmospheric.

3. An overlay for use in applying compression to a patient positioned upon a supporting surface, the overlay comprising:

flexible sheet material that is arranged into at least two layers to define an internal region therebetween, the layers being repositionable with respect to each other such that the sheet material can assume a deflated state in which the volume of internal region is a minimum; and

an inlet orifice that opens into the internal region,

wherein, in use of the overlay:

the flexible sheet material in the deflated state is draped over the patient so as to provide a posterior layer that is in contact with the patient and an anterior layer that is spaced from the patient by the posterior layer,

the flexible sheet material is restrained relative to the support surface, and

gas is introduced to the internal region via the inlet orifice to increase the volume of the internal region from the deflated state and establish an elevated pressure within the internal region, thereby compressing the patient between the posterior layer of the overlay and the supporting surface.

4. An overlay according to claim 3, wherein in use a portion of the posterior layer conforms to the patient, and the anterior layer is distended when an elevated pressure is established within the internal region.

5. An overlay according to either claim 3 or 4, wherein the overlay includes restraints with which to restrain the flexible sheet material to the supporting surface.

6. An overlay according to claim 5, wherein the restraints are affixed to the flexible sheet material.

7. An overlay according to either claim 5 or 6, wherein each restraint includes a releasable coupling, in the form of hook and loop fastener materials.

8. An overlay according to any one of claims 3 to 7, wherein the layers of the overlay include an inner layer that is to provide the posterior layer in use of the overlay, and an outer layer that is to provide the anterior layer in use of the overlay.

9. An overlay according to claim 8, wherein the inner layer includes one or more pleats that extend in the length direction of the overlay.

10. An overlay according to either claim 8 or 9, wherein at least one of the inner and outer layers is made of a flexible sheet material that includes woven material and a coating that reduces the porosity of the woven material.

11. An overlay according to any one of claims 3 to 10, wherein the flexible sheet material includes a superior peripheral edge and an inferior peripheral edge,

whereby, in use of the overlay, the inferior peripheral edge is to be further from the patient's head than the superior peripheral edge.

12. An overlay according to claim 11, wherein the overlay is wider at the superior peripheral edge than at the inferior peripheral edge.

13. An overlay according to any one of claims 3 to 12, wherein the inlet orifice is part of an inlet connector, and the discharge port is part of an outflow connector that interconnects with the inlet connector.

14. A gas supply system for use with an overlay of a corporeal compression system, the flowable material supply system comprising:

a discharge port that is connected to, or is connectable to, the inlet orifice of the overlay,

one or more of:

a pump that is in communication with the discharge port via a conduit;

a containment vessel that is in communication with the discharge port via a gas distribution circuit, the containment vessel being configured to contain pressurized gas; and

a gas distribution circuit that includes an inflow connector that is to interconnect with an independent supply of pressurized gas, and one or more conduits that direct gas from the inflow connector to the discharge port;

wherein in use of the gas supply system within the corporeal compression system:

the gas supply system is operable to deliver gas to the overlay at a first flow rate and at a second flow rate, the first flow rate being higher than the second flow rate, and

the gas supply system is configured to deliver gas at flow rates up to the second flow rate when the pressure within the internal region is above a pre-determined pressure.

15. A gas supply system according to claim 14, wherein the pump includes:

an electric motor connected to a rotor that is rotatable to displace gas from an intake, through a chamber in which the rotor is housed, to a discharge port;

a discharge connector that interconnects the discharge port with a complementary connector that is in communication with the inlet orifice of the overlay;

at least one of a flow sensor and a pressure sensor located between the chamber and the discharge port;

a controller that controls the operation of the electric motor, the controller being configured to receive information from the flow sensor and/or the pressure sensor, and to drive the electric motor to vary the flow rate of gas to the discharge port in response to the received information; and

at least one of: a self-contained source of electrical power, and a connector with which to connect the pump to an independent source of electrical power, that provides electrical power to the electric motor.

16. A gas supply system according to claim 15, wherein the controller is configured such that the pump is operable at a first flow rate to inflate the overlay, and at flow rates up to a second flow rate to establish and/or maintain an elevated pressure within the internal region, the first flow rate being higher than the second flow rate.

17. A gas supply system according to either claim 15 or 16, wherein the controller is configured so that when initialised, the controller is set to initially drive the electric motor to supply gas to the discharge port at the first flow rate.

18. A gas supply system according to claim 15, wherein the controller is configured so that when initialised, the controller drives the electric motor to supply gas to the discharge port at the first flow rate to discharge a pre-determined volume of gas, and thereafter drives the electric motor to supply gas to the discharge port at flow rates up to the second flow rate.

19. A gas supply system according to claim 15, wherein the controller is configured so that when the sensed pressure is at or below a pre-determined threshold pressure, the controller drives the electric motor to supply gas to the discharge port at the first flow rate to discharge a pre-determined volume of gas, and when the sensed pressure is above the pre-determined threshold pressure, the controller drives the electric motor to supply gas to the discharge port at flow rates up to the second flow rate.

20. A gas supply system according to any one of claims 15 to 19, further comprising an input user interface that enables a user to set the pre-determined set point pressure.

21. A gas supply system according to claim 20, wherein the set point pressure is adjustable during operation of the pump.

22. A corporeal compression system comprising:

a gas supply system according to any one of claims 15 to 21, wherein the pump further comprises an outflow connector that forms the discharge port, and an electrical switch that is operable to activate the electric motor of the pump,

an overlay according to any one of claims 3 to 12, and further comprising a conduit that is interconnected at a first end to the flexible sheet material so as to open into the inlet orifice, the second end of the conduit including an inlet connector that is releasably couplable to the outflow connector,

wherein the action of coupling the inlet connector with the outflow connector operates the electrical switch.

23. A corporeal compression system according to claim 22, wherein the inlet connector and outflow connector are configured such that an elevated pressure within the conduit biases the inlet connector and outflow connector into the coupled state.

24. A corporeal compression system according to either claim 22 or 23, wherein the pump includes a spring that is positioned to bias the inlet connector and outflow connector into the coupled state.

25. A corporeal compression system according to any one of claims 22 to 24, wherein the inlet connector and outflow connector form a bayonet mount, and the electrical switch is positioned relative to the outflow connector so as to be actuated after the first movement of coupling the inlet connector and outflow connector is complete.

26. A corporeal compression system according to claim 25, wherein the electrical switch is positioned relative to the outflow connector so as to be actuated during the first movement of decoupling the inlet connector and outflow connector.

27. A gas supply system according to claim 14 and in which the gas supply system comprises the containment vessel, the gas supply system further comprises:

a discharge flow regulator that regulates the flow of gas from the containment vessel to the discharge port, the regulator being configured:

to discharge gas to the discharge port at flow rates up to the first flow rate when the pressure within the internal region is at or below a threshold pressure, and

to discharge gas to the discharge port at flow rates up to the second flow rate when the pressure within the internal region is above the threshold pressure and below the pre-determined pressure and/or the selected set point pressure.

28. A gas supply system according to claim 27, wherein the first flow rate corresponds with substantially unregulated discharge of gas from the containment vessel to the discharge port.

29. A gas supply system according to claim 27, wherein the discharge flow regulator has a plurality of pneumatically operated valves that are in fluid communication with the internal region via the inlet orifice and the discharge port, and wherein each valve is operable to be open at a unique threshold pressure.

30. A gas supply system according to any one of claims 27 to 29, wherein the discharge flow regulator includes a first stage regulator that, when open, regulates flow of gas out of the containment vessel at flow rates up to the first flow rate, and a second stage regulator that regulates flow of gas to the discharge port to flow rates up to the second flow rate when the pressure within the internal region is above the pre-determined pressure, wherein the pre-determined pressure is less than a set point pressure.

31. A gas supply system according to claim 27, wherein the discharge flow regulator includes:

one or more electrically operated valves;

at least one of a flow sensor and a pressure sensor located between the chamber and the discharge port;

an electronic controller that controls the operation of the valves, the controller being configured to receive information from the flow sensor and/or the pressure sensor, and operate valves in response to the received information; and

at least one of: a self-contained source of electrical power, and an independent source of electrical power, that provides electrical power to the electronic controller.

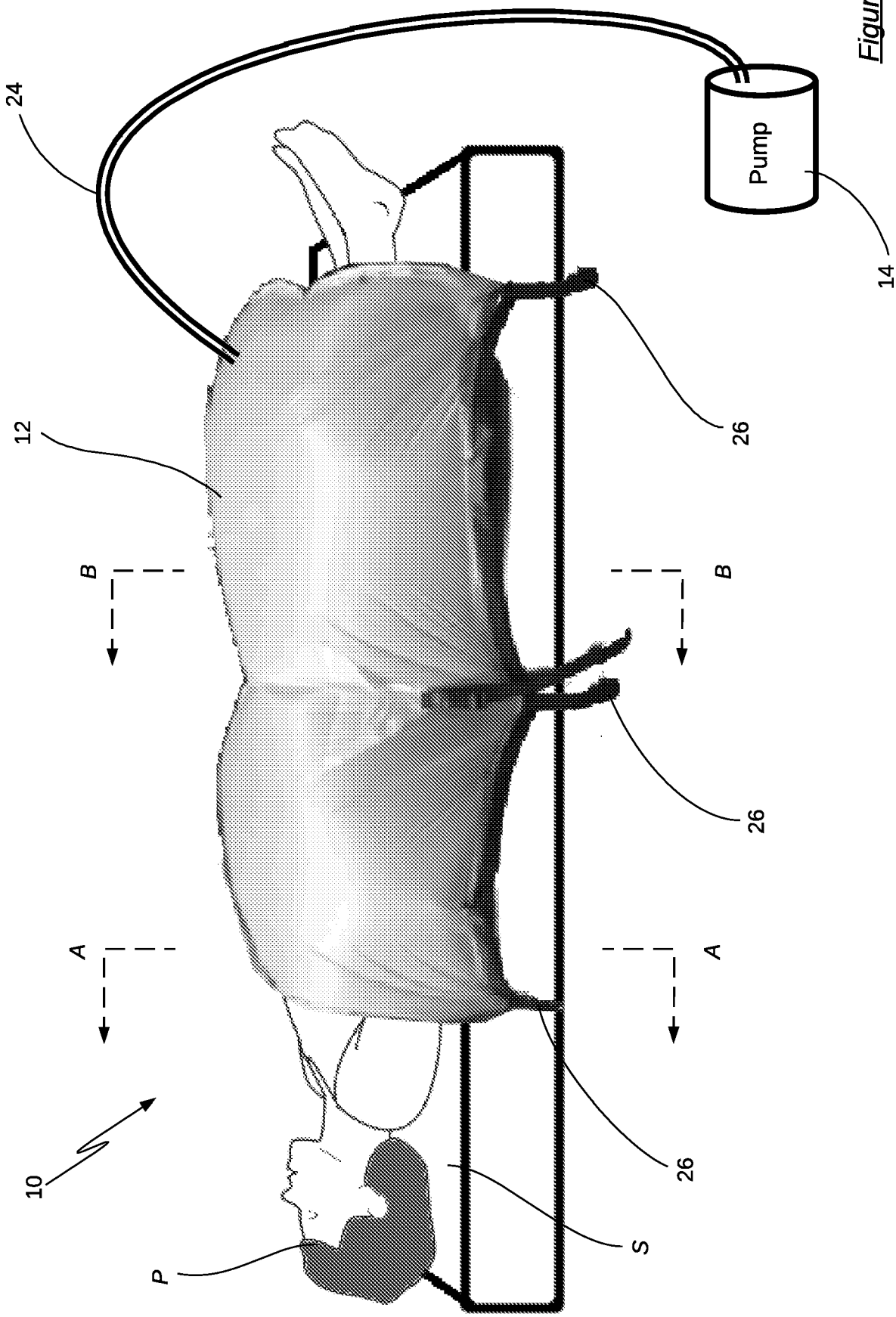


Figure 1

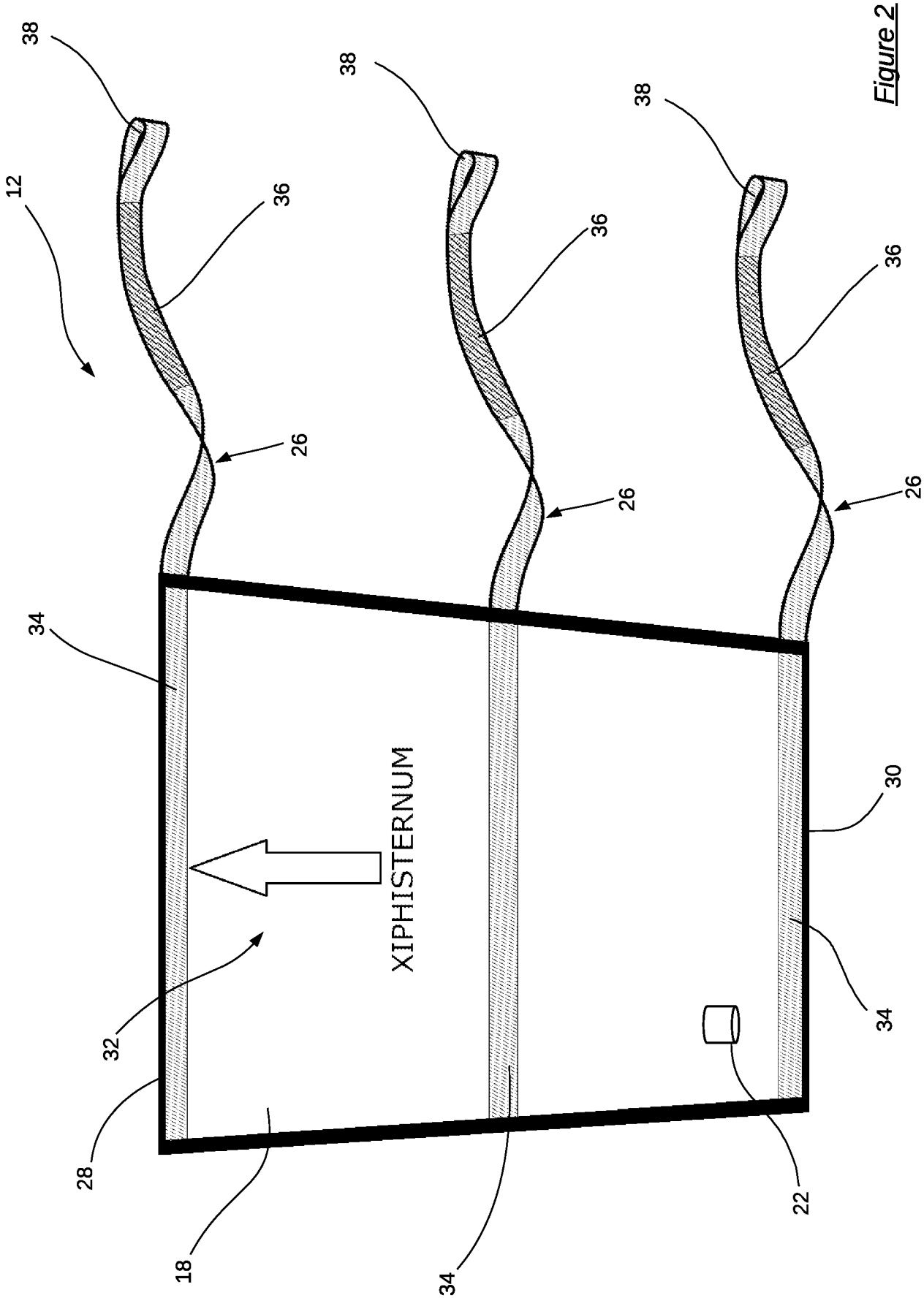


Figure 2

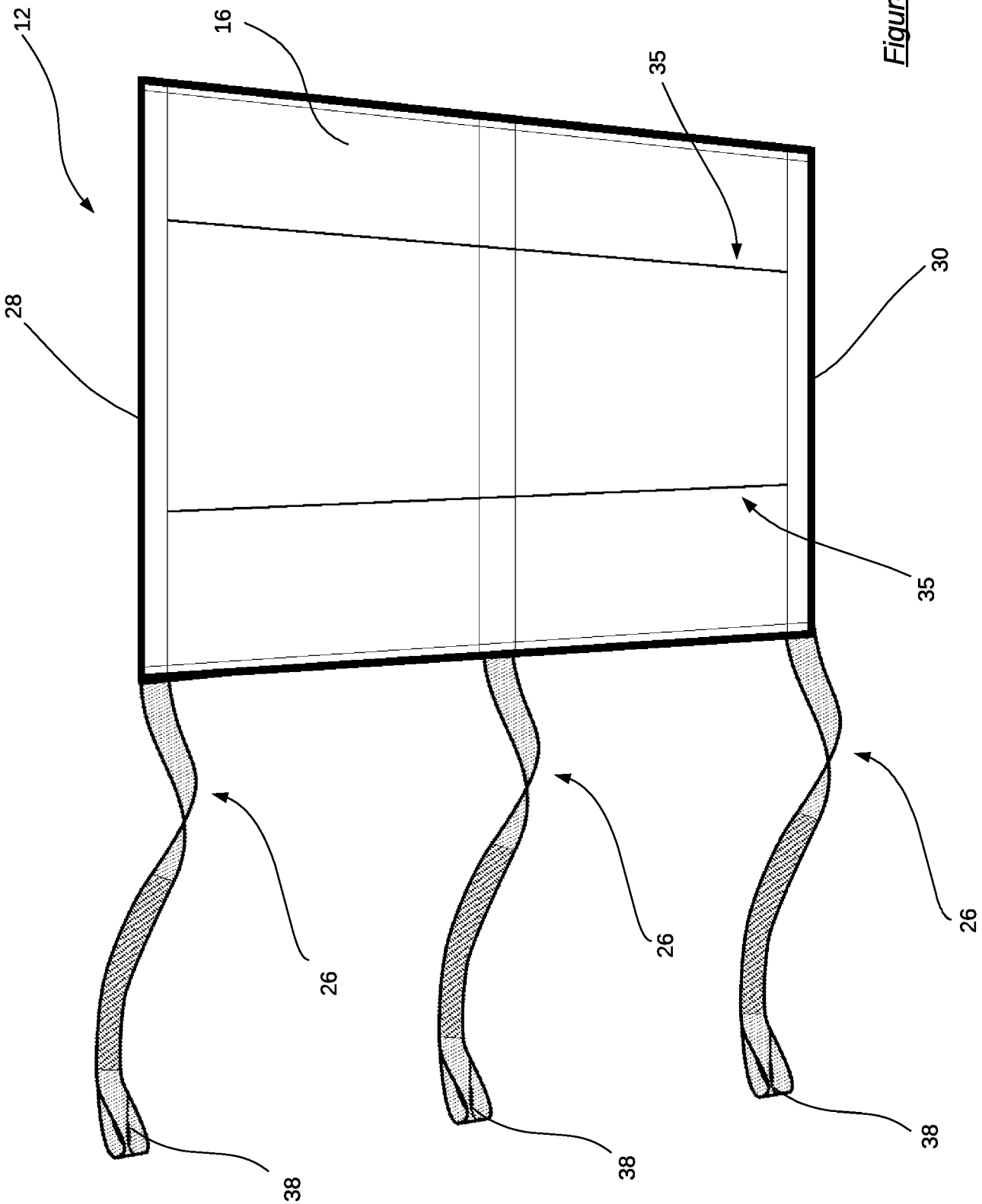


Figure 3

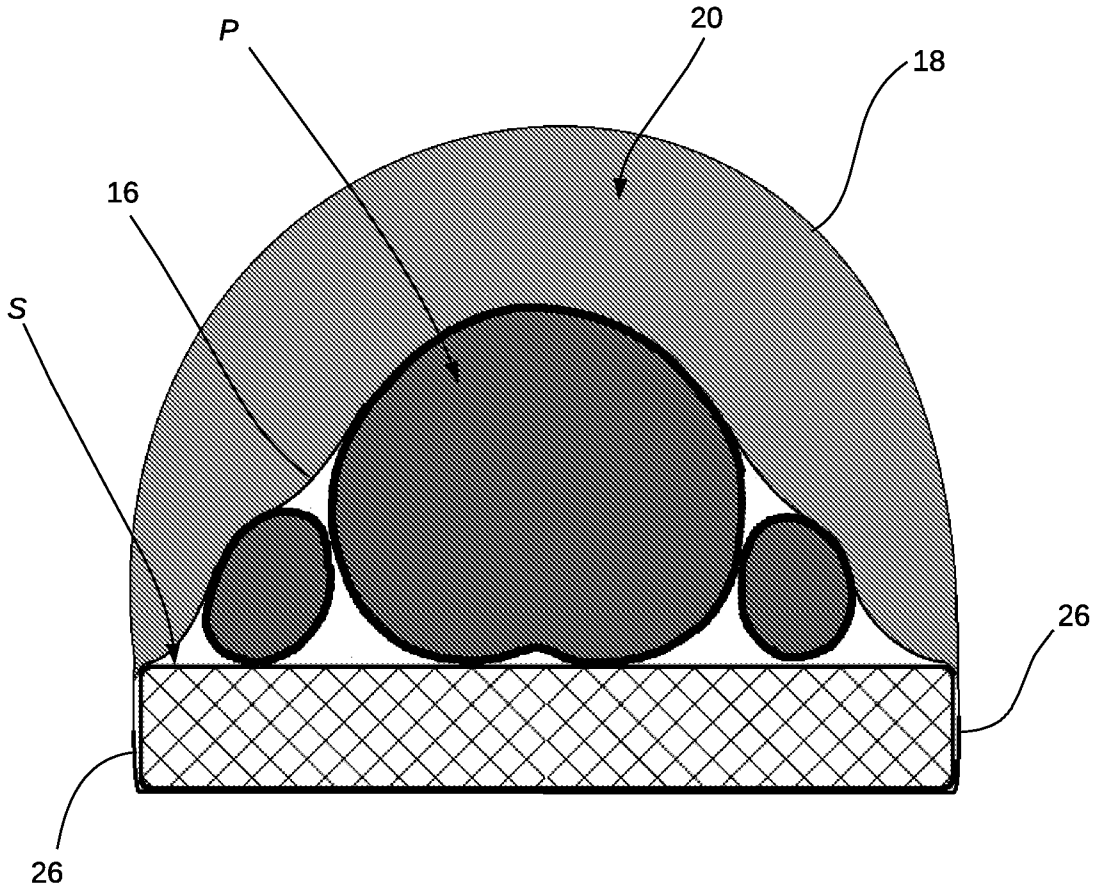


Figure 4

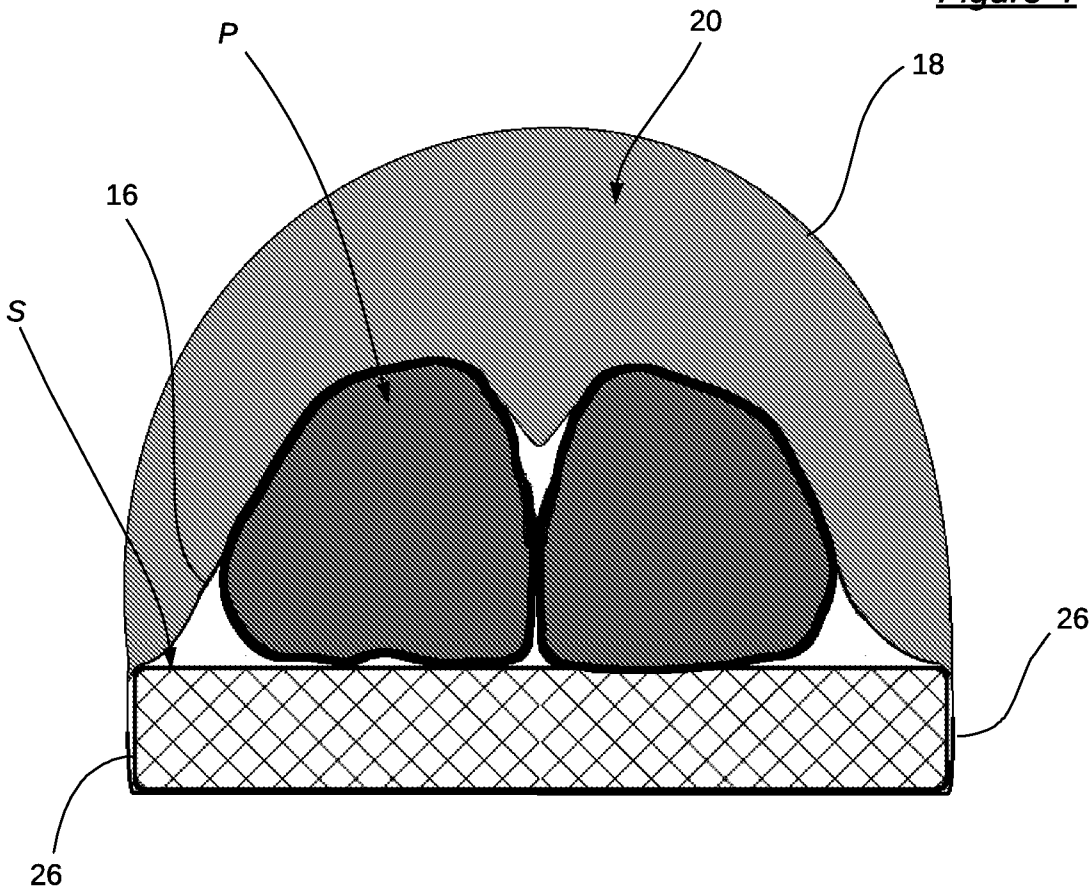


Figure 5

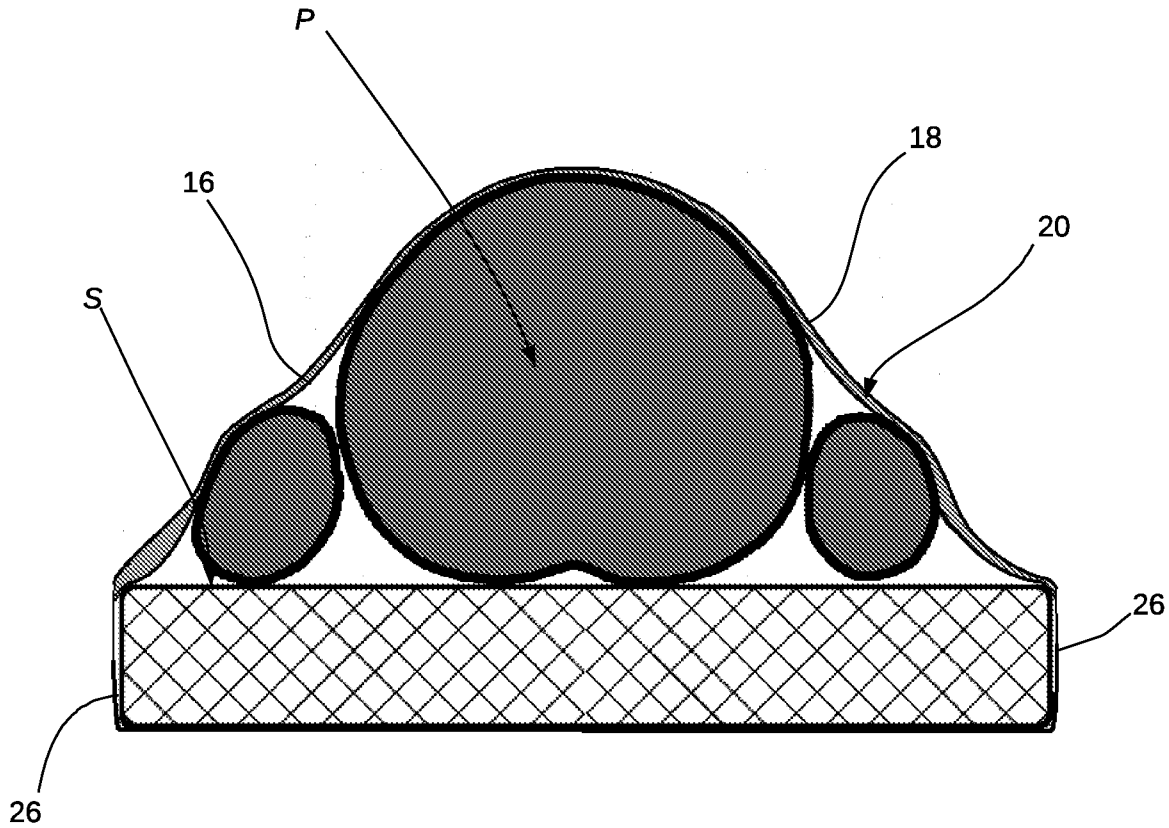


Figure 6

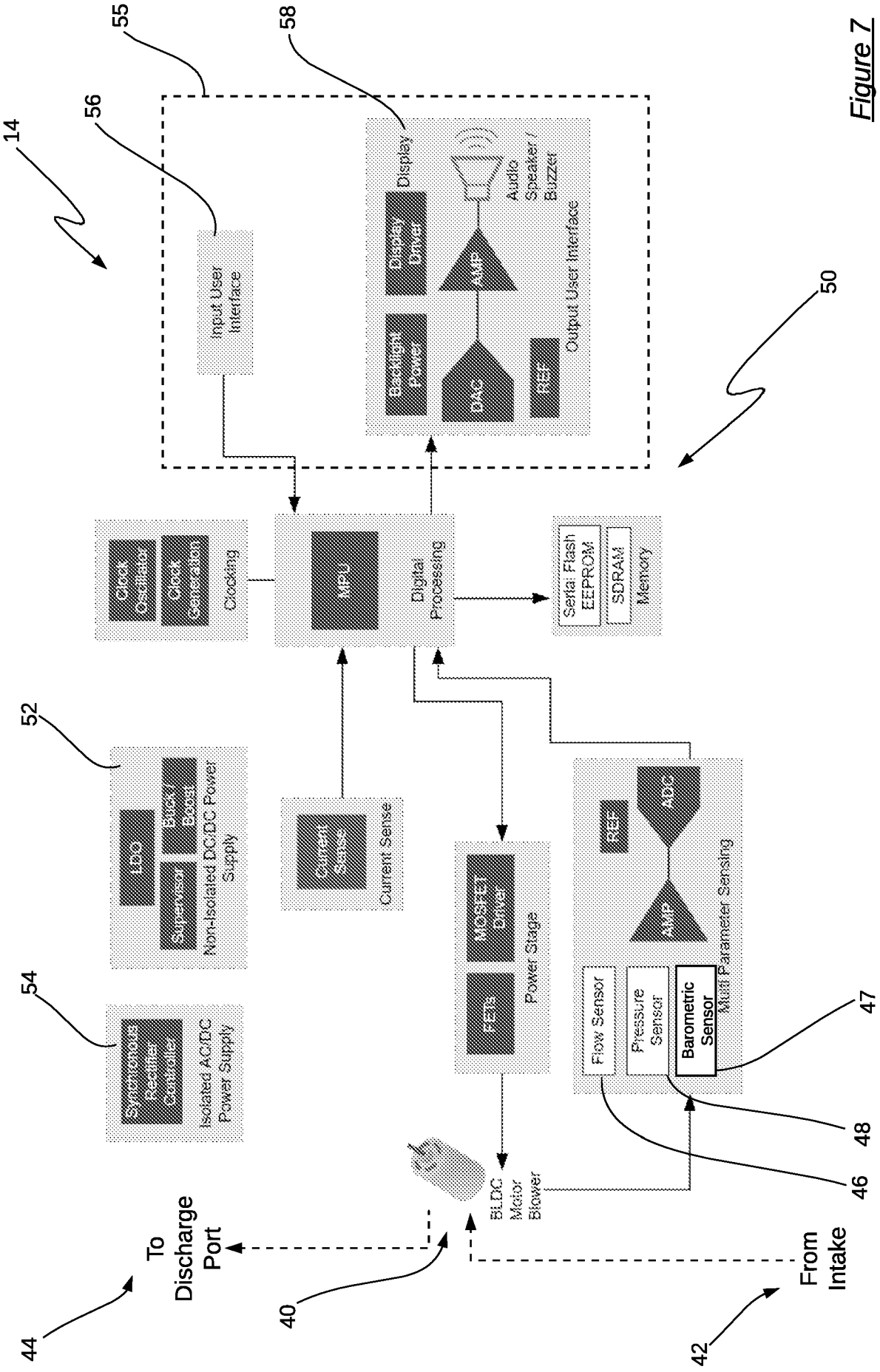

14
55
58
56
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Input User Interface
Display
Audio Speaker / Buzzer
Display Driver
AMP
Backlight Power
DAC
REF
Output User Interface
Clock Oscillator
Clock Generation
Clocking
MPU
Digital Processing
Serial Flash EEPROM
SDRAM
Memory
52
LDO
SMPS / Boost
Supervisor
Non-Isolated DC/DC Power Supply
Current Sense
Current Sense
MOSFET Driver
FETs
Power Stage
REF
ADC
AMP
Flow Sensor
Pressure Sensor
Barometric Sensor
Multi Parameter Sensing
47
54
Synchronous Rectifier Controller
Isolated AC/DC Power Supply
48
46
BLDC Motor Blower
To Discharge Port
From Intake
44
40
42

Figure 7

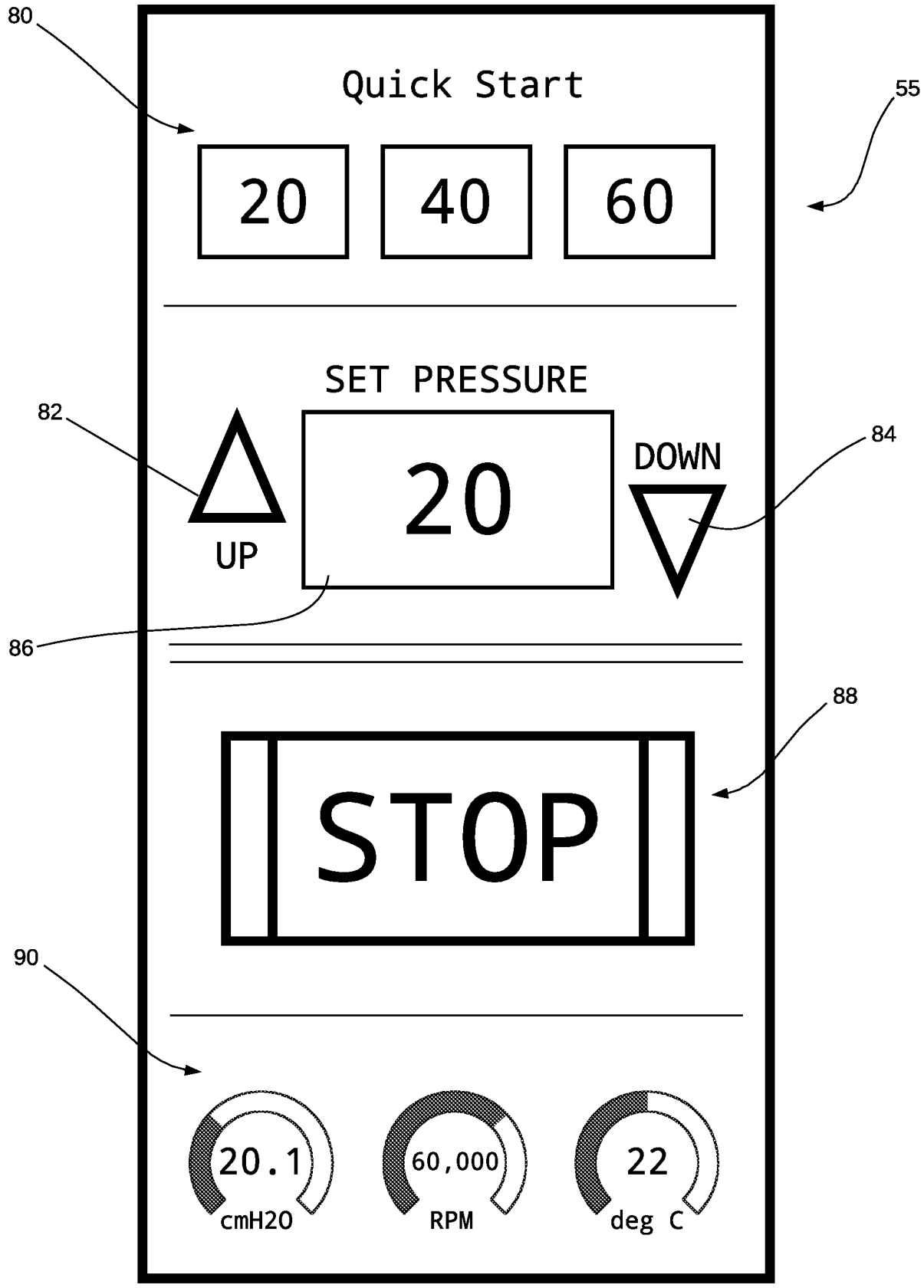

80
Quick Start
55
20
40
60
SET PRESSURE
82
84
DOWN
20
UP
86
88
STOP
90
20.1
cmH2O
60,000
RPM
22
deg C

Figure 8

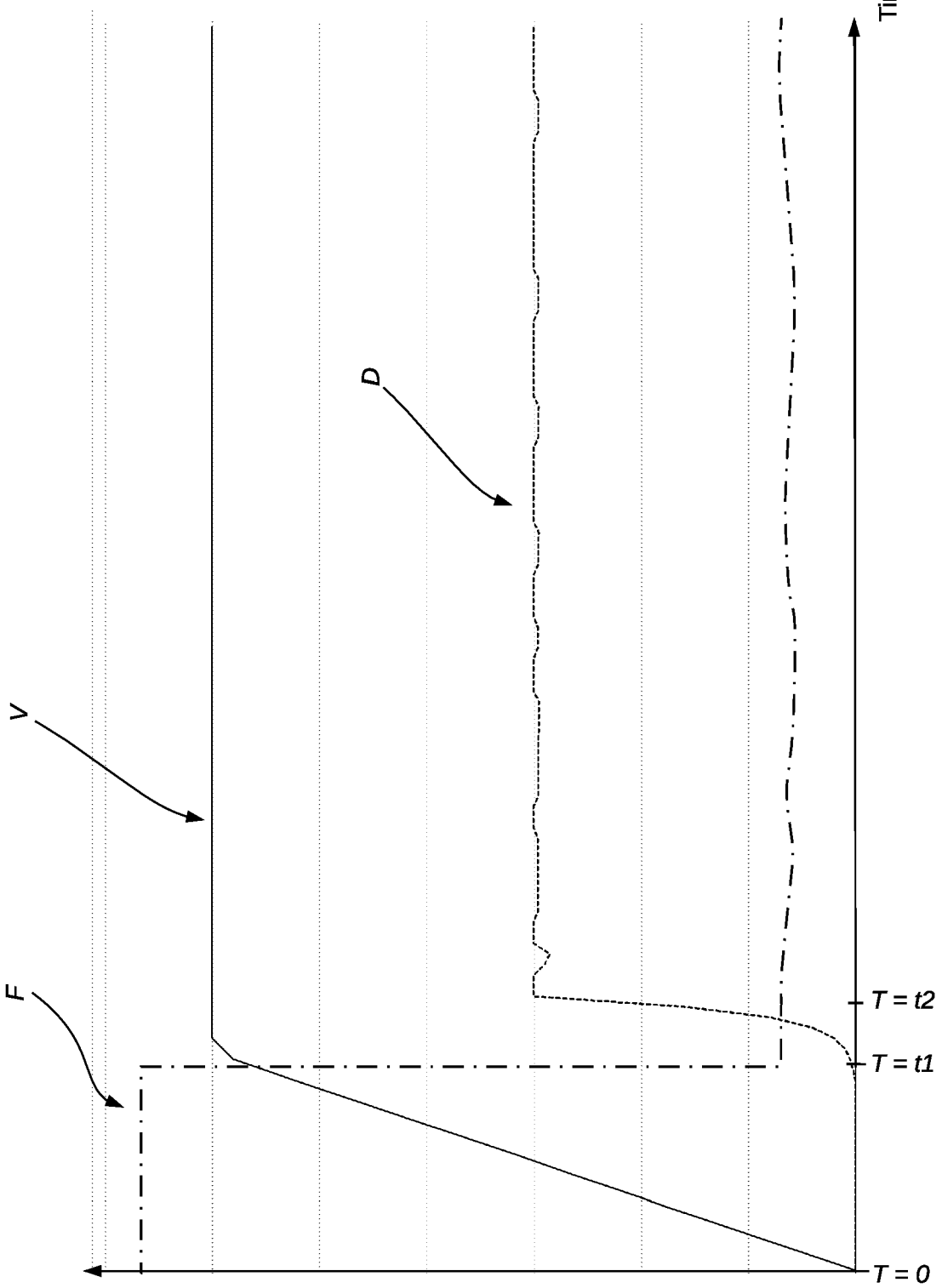


Figure 9

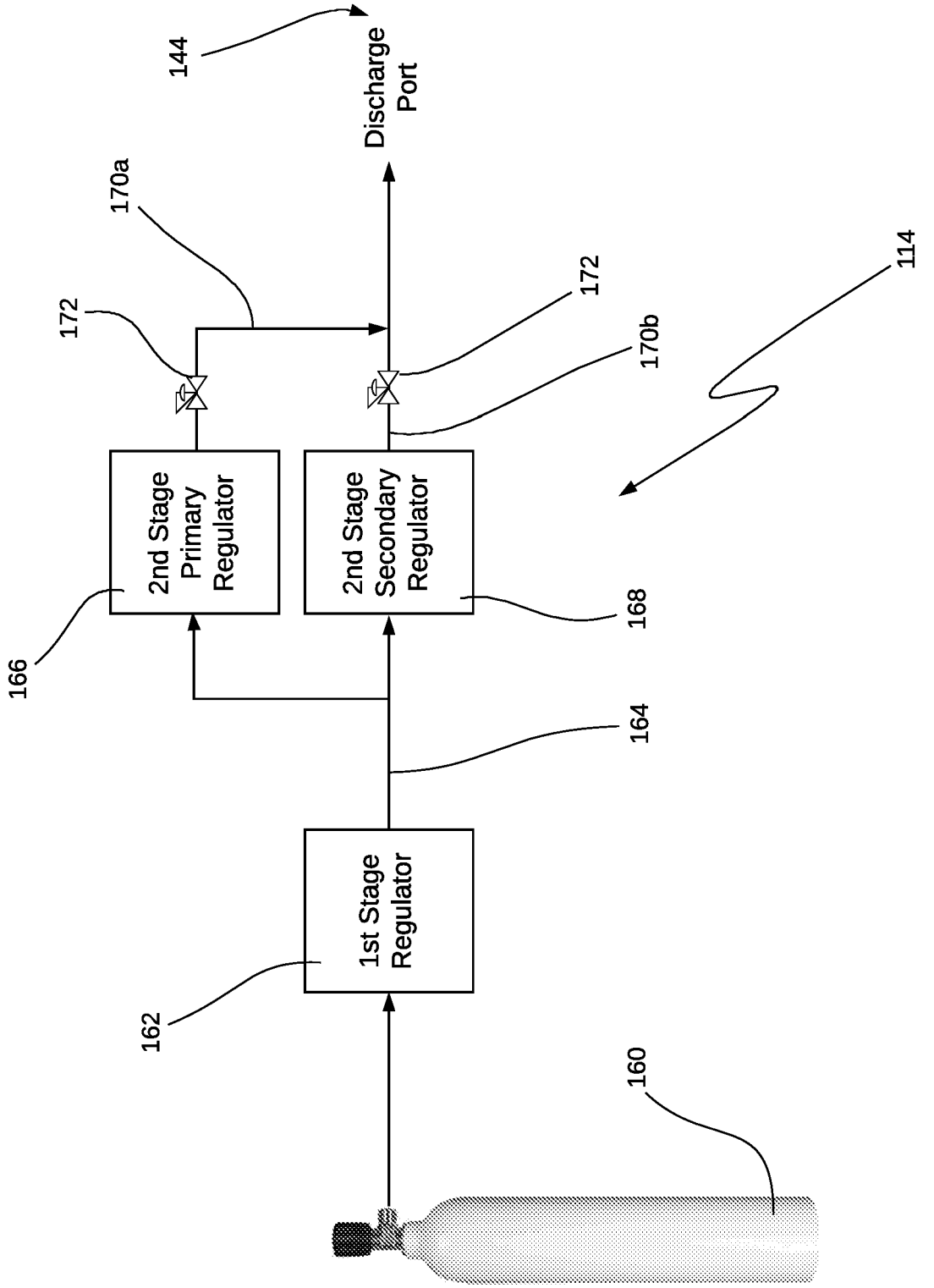

144
Discharge Port
170a
172
172
170b
114
2nd Stage Primary Regulator
2nd Stage Secondary Regulator
166
168
164
1st Stage Regulator
162
160

Figure 10

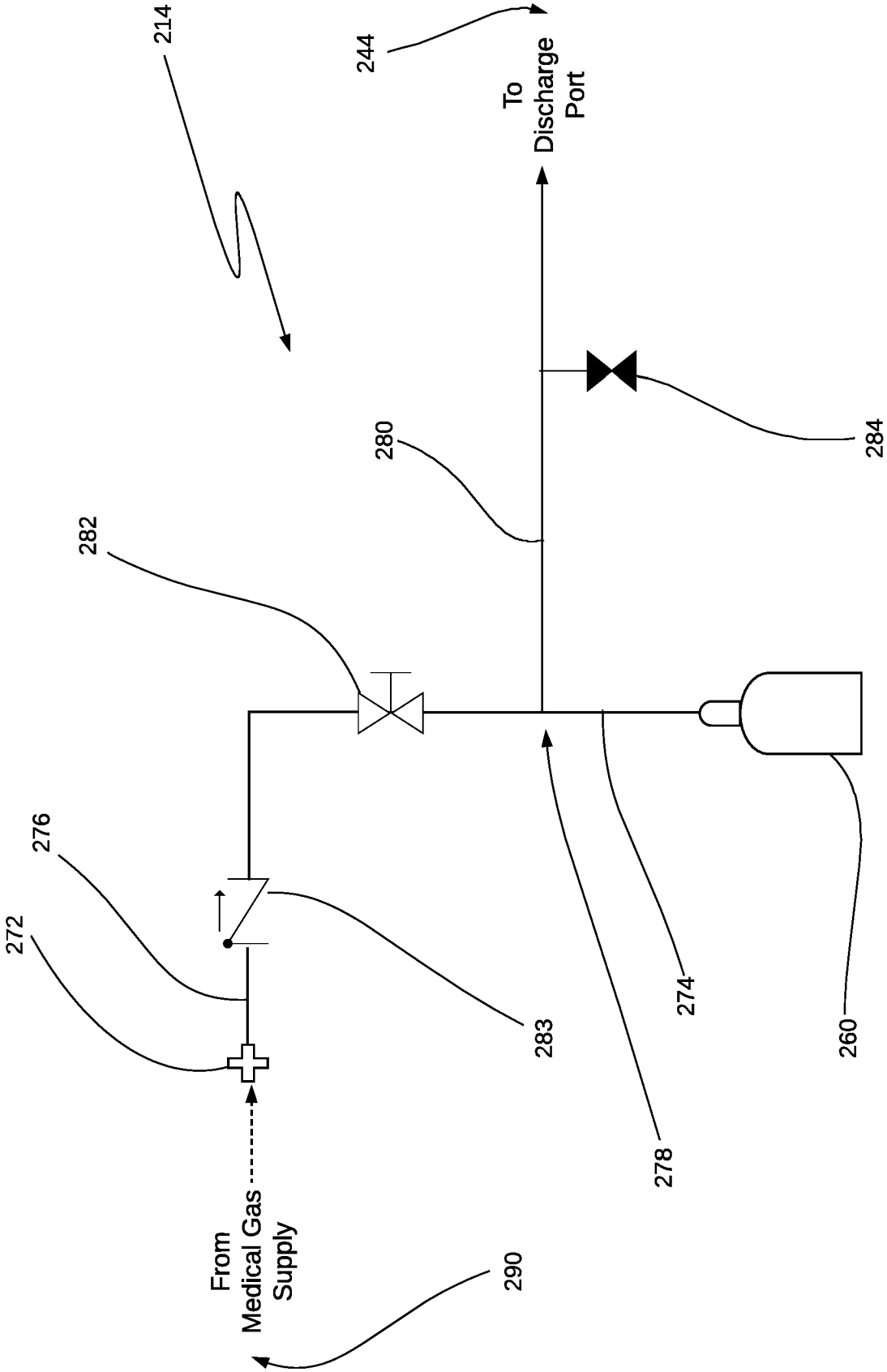

214
244
To Discharge Port
280
284
282
276
272
283
274
278
260
From Medical Gas Supply
290

Figure 11

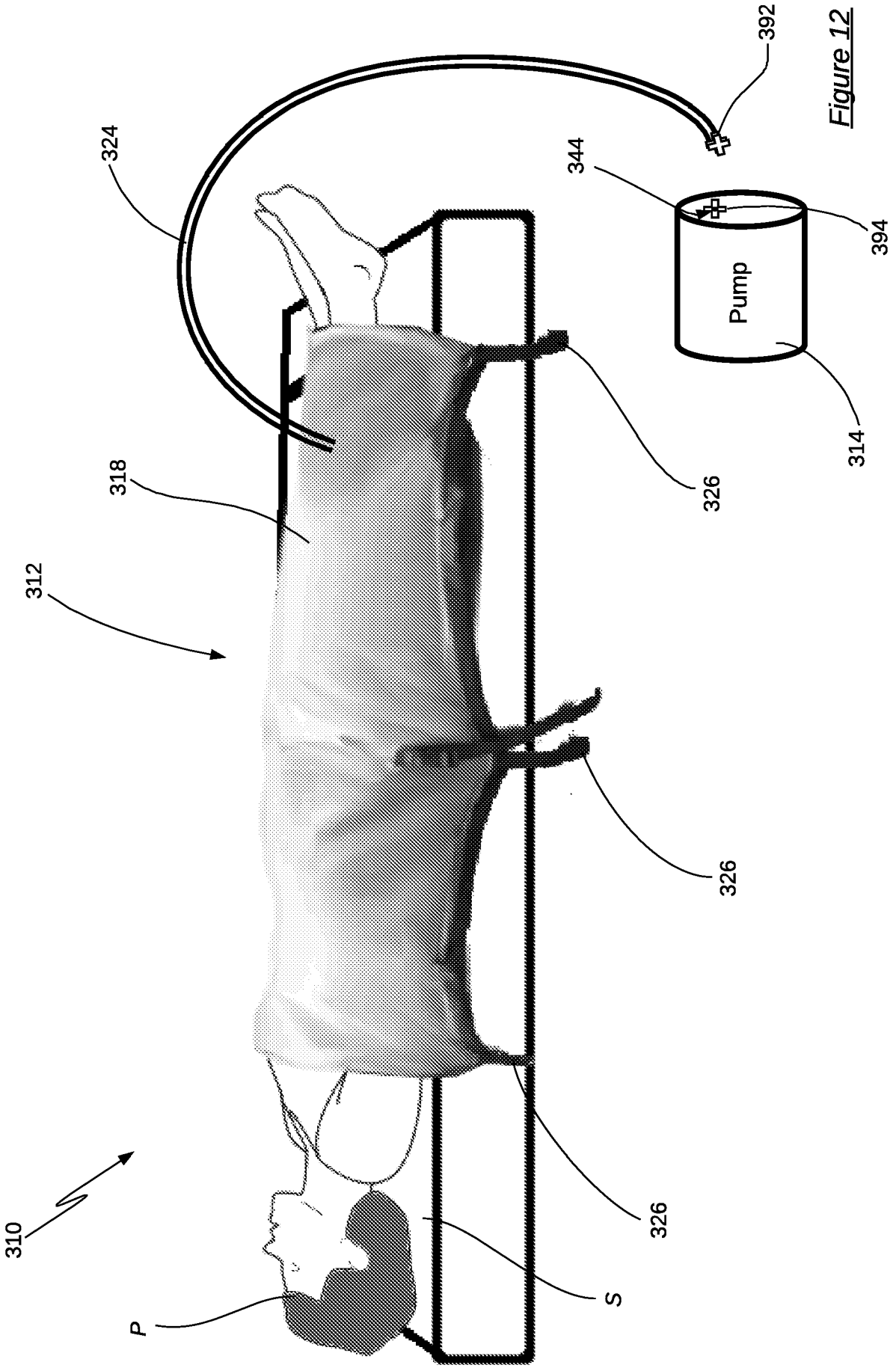


Figure 12

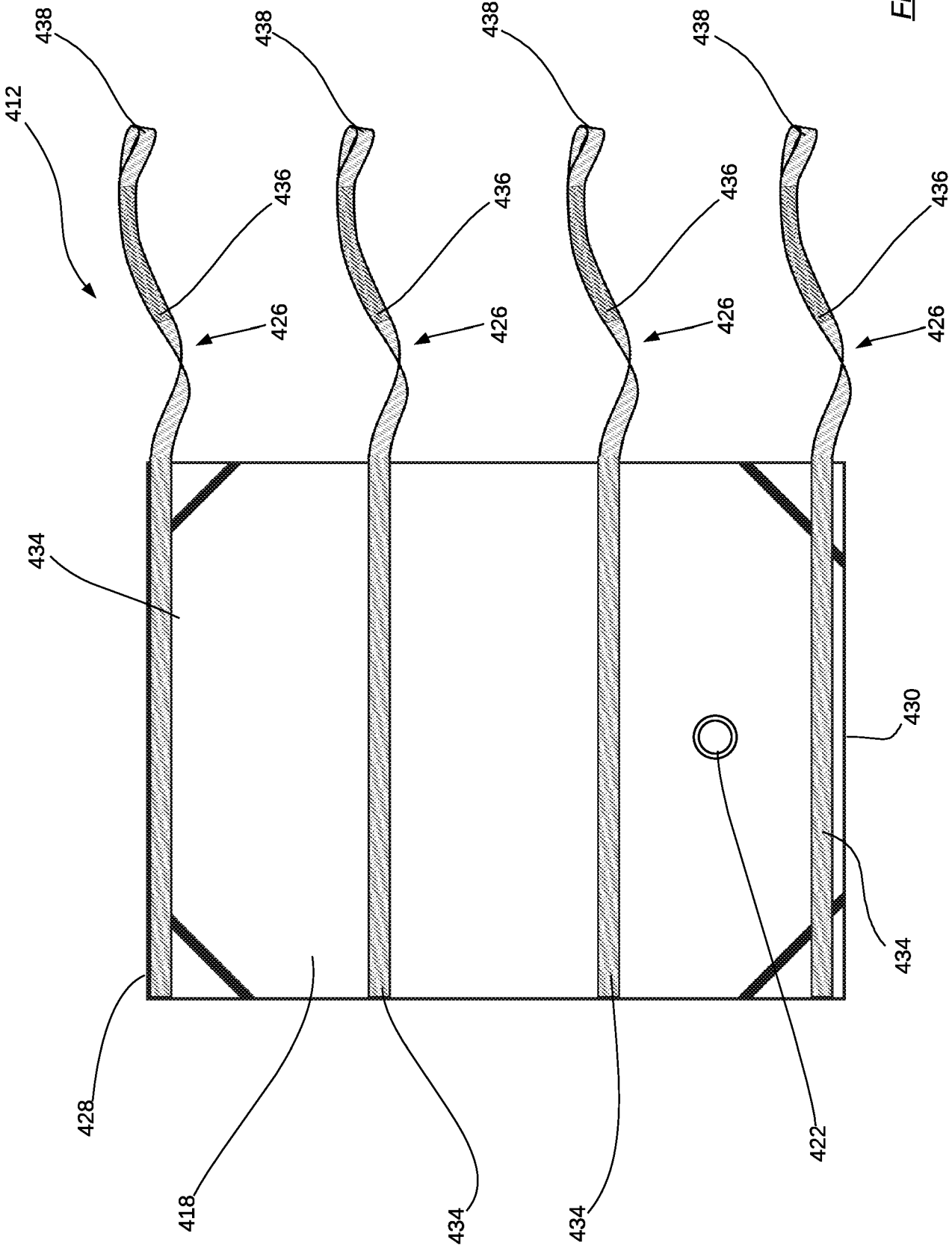

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Figure 13

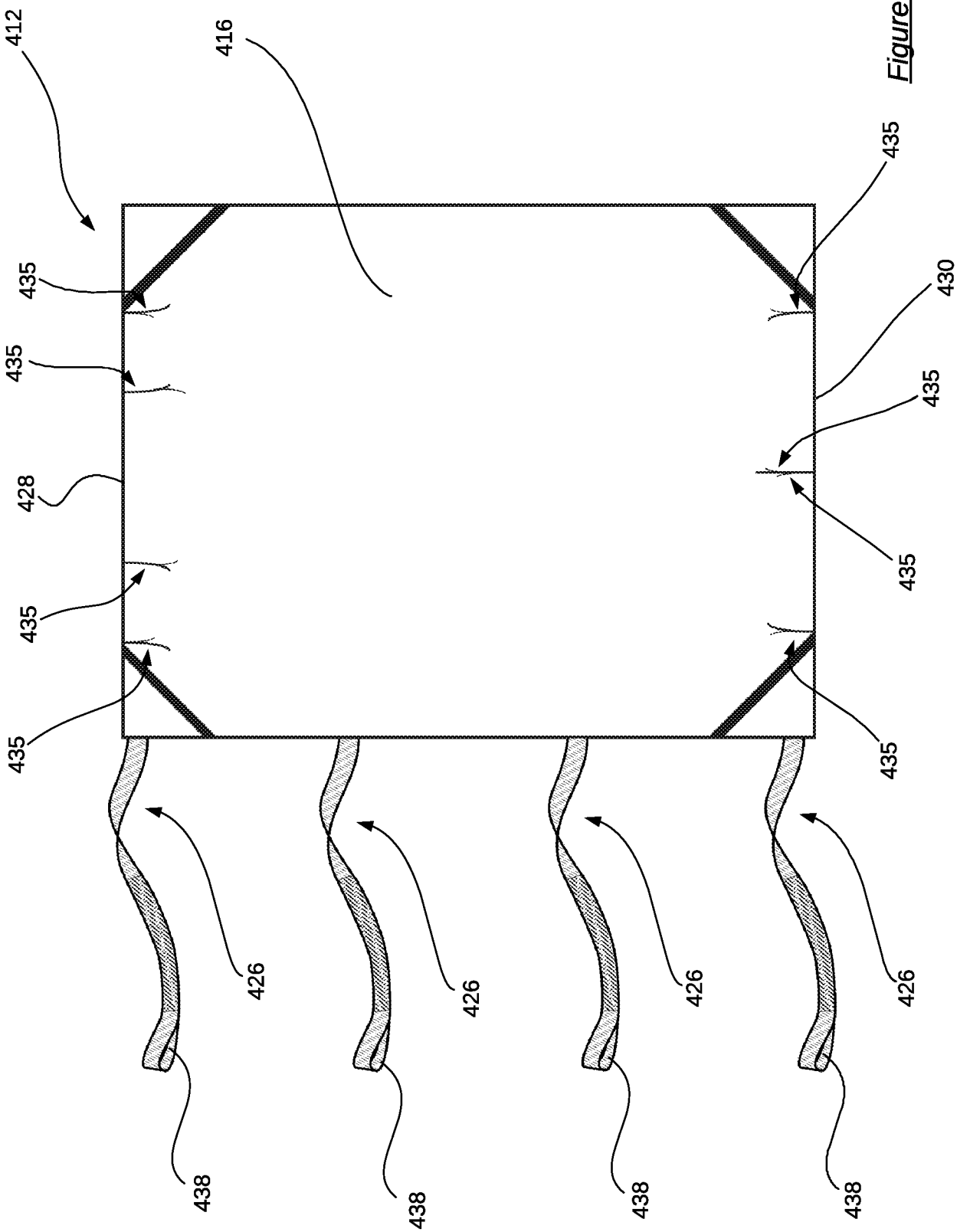

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Figure 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2019/051241

A. CLASSIFICATION OF SUBJECT MATTER

A61F 5/05 (2006.01)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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

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

PATENW: IPC/CPC/FI/FT; A61F7/08, A61F7/0097, A61F2007/0091, A61F2007/0054, A61H9, A61H2201/0142, A61H2203/0443, A61H2201/0138, A61F5/3776, A61B17/132, A61H1/008, A61H9/005, A61H2201/0103, A61H2209/00 and Keywords (restrain+, fasten+, hook?, loop?, tie+, Blanket?, wrap+, cuff+, overlay, cover+, bladder?, inflatable, pump+, blower?, gas, air, fluid, suppl+, source, generat+, STRAP+, TETHER+, TIE?, RESTRAIN+, HARNESS+, BELT+ and like terms)

Google, Google Patents and Espacenet: Keywords as above

Applicant(s)/Inventor(s) name searched in PATENW and internal databases provided by IP Australia

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

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

"D" document cited by the applicant in the international application

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 February 2020	26 February 2020

Name and mailing address of the ISA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
Email address: pct@ipaustralia.gov.au

Authorised officer

Swayam Chintamani
AUSTRALIAN PATENT OFFICE
(ISO 9001 Quality Certified Service)
Telephone No. +61262832202

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/AU2019/051241**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5304213 A (BERKE et al.) 19 April 1994 figure 1, abstract, column 2 lines 42-63	1-13, 22-26
A	US 7090692 B1 (AUGUSTINE et al.) 15 August 2006 figures 1-2, column 1 line 45 - column 2 line 18	1-13, 22-26
A	US 2005/0246834 A1 (WEEDLING et al.) 10 November 2005 abstract, figures 1-4, paragraphs [005]-[0013], [0022]	1-13, 22-26
A	US 3933150 A (KAPLAN et al.) 20 January 1976 abstract, figures 3-4	1-13, 22-26

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2019/051241

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

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

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

See Supplemental Box for Details

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-13, 22-26

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Supplemental Box

Continuation of: **Box III**

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Group I: Claims 1-13. Claims 1-2 are related to a corporeal compression system comprising (a) an overlay having a flexible sheet material, an internal region, an inlet orifice and one or more restraints, (b) a gas supply system having a discharge port and (c) features related to how the system is being used. Claims 3-13 are related to an overlay comprising (a) a flexible sheet material, an internal region, an inlet orifice and (b) features related to how the overlay is being used. Restraints and gas supply system are not a part of the overlay of claims 3-13. The feature of an overlay comprising a flexible sheet material having at least two layers to define an internal region therebetween, the layers being repositionable with respect to each other such that the sheet material can assume a deflated state in which the volume of the internal region is a minimum, and a state where an elevated pressure is established within the internal region is increased, so that a patient lying on a support surface can be compressed between the overlay and the support surface is specific to this group of claims.

- Group II: Claims 14-21, 27-31 are related to a gas supply system comprising (a) a discharge port, one or more of b-d, (b) a pump, (c) a vessel, (d) a distribution network. These claims are characterized by the gas system having two flow rates wherein the first flow rate is higher than the second flow rate and the gas supply system is configured to deliver gas at flow rates up to the second flow rate when the pressure within the internal region is above a pre-determined pressure. Claim 15 although dependent on claim 14, defines further features of the pump. The feature of the gas supply system being operable to deliver gas to the overlay at a first flow rate and at a second flow rate, the first flow rate being higher than the second flow rate, and the gas supply system being configured to deliver gas at flow rates up to the second flow rate when the pressure within the internal region is above a pre-determined pressure is specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

Claims 22-26 are related to a corporeal compression system comprising a gas supply system of claims 15-21 and an overlay of claims 3-12 and therefore can be combined with Group I because they are dependent on claims 3-12. Although the features of claims 15-21 overlap in claims 22-26, they cannot be grouped together with claims 22-26 because claims 15-21 are directed to a gas supply system in isolation and would require an independent search.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied *a priori*.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2019/051241**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		**Patent Family Member/s**	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
US 5304213 A	19 April 1994	US 5304213 A	19 Apr 1994
US 7090692 B1	15 August 2006	US 7090692 B1	15 Aug 2006
		EP 0311336 A1	12 Apr 1989
		EP 0311336 B1	01 Apr 1992
		HK 74792 A	09 Oct 1992
		JP H01160551 A	23 Jun 1989
		JP 2561326 B2	04 Dec 1996
		US 5184612 A	09 Feb 1993
		US 5300101 A	05 Apr 1994
		US 5300102 A	05 Apr 1994
		US 5324320 A	28 Jun 1994
		US 5336250 A	09 Aug 1994
		US 5405371 A	11 Apr 1995
		US 5620482 A	15 Apr 1997
		US 5968084 A	19 Oct 1999
		US 6210428 B1	03 Apr 2001
		US 6287327 B1	11 Sep 2001
		US 6524332 B1	25 Feb 2003
		US 2002042640 A1	11 Apr 2002
		US 6544283 B2	08 Apr 2003
		US 2001041922 A1	15 Nov 2001
		US 6558413 B2	06 May 2003
		US 7101389 B1	05 Sep 2006
US 2005/0246834 A1	10 November 2005	US 2005246834 A1	10 Nov 2005
		US 7243382 B2	17 Jul 2007
		AU 2005240110 A1	17 Nov 2005
		BR PI0510609 A	30 Oct 2007
		CA 2565345 A1	17 Nov 2005
		CN 101001597 A	18 Jul 2007
		EP 1744715 A2	24 Jan 2007
		JP 2007535996 A	13 Dec 2007
		MX PA06012759 A	02 Apr 2007
		WO 2005107675 A2	17 Nov 2005
US 3933150 A	20 January 1976	US 3933150 A	20 Jan 1976

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2019/051241**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
		CA 1021654 A	29 Nov 1977
		FR 2260323 A1	05 Sep 1975
		JP S50108785 A	27 Aug 1975
		JP S5234871 B2	06 Sep 1977

End of Annex

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.