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(54) Title: DEVICE FOR PRODUCING CONTINUOUS NEGATIVE ABDOMINAL PRESSURE

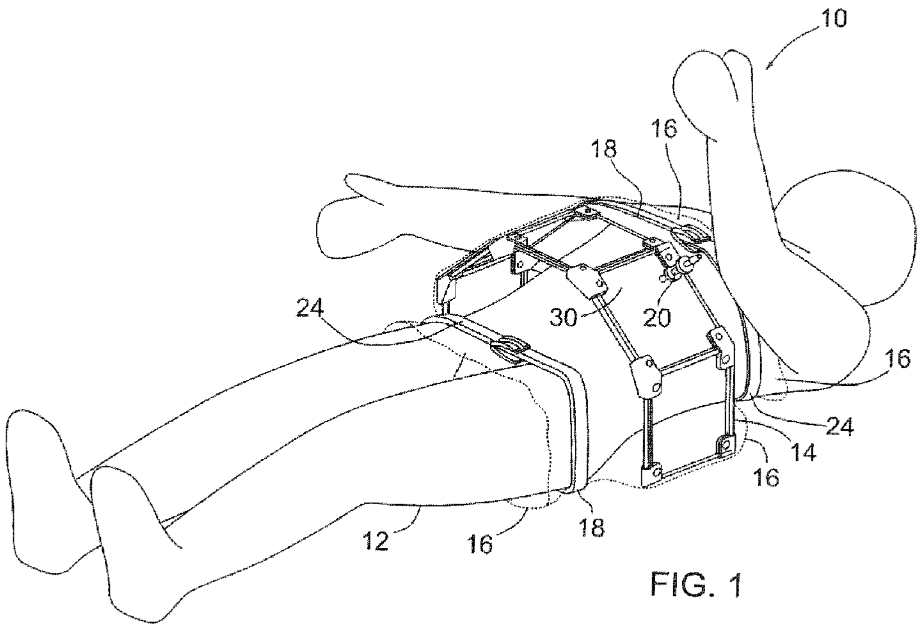

FIG. 1

(57) Abrégé/Abstract:
This disclosure relates to device for providing continuous negative abdominal pressure (CNAP) which selectively recruits (inflates) the dorsal (spinal region) collapsed areas of the lung, while enabling the patient to remain in the supine (usual) position. The CNAP device includes a rigid frame configured to have a shape and size to envelop a patient's lower chest and abdominal area while in a supine position with the frame having opposed edges which sit on a surface on which the supine patient is resting. A series of panels are mounted in the frame such that the series of panels extend around the patient's lower chest and abdominal area. A flexible sheet wrapped around the outside of the panels and is long enough to extend up to the patient's upper chest and down to the patient's thighs and wide enough to envelop the supine patient's lower chest and abdominal area. Sealing members are to seal the flexible sheet over the frame and panels and around the patient's lower chest and pelvis, wherein a chamber is formed between the patient and said device when the patient is enveloped by the device. An air inlet coupling extends through one of the panels and is attachable to a suction source which is configured to generate negative pressure of between about -5 to about -10 cm H_2O inside the chamber.

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(54) Title: DEVICE FOR PRODUCING CONTINUOUS NEGATIVE ABDOMINAL PRESSURE

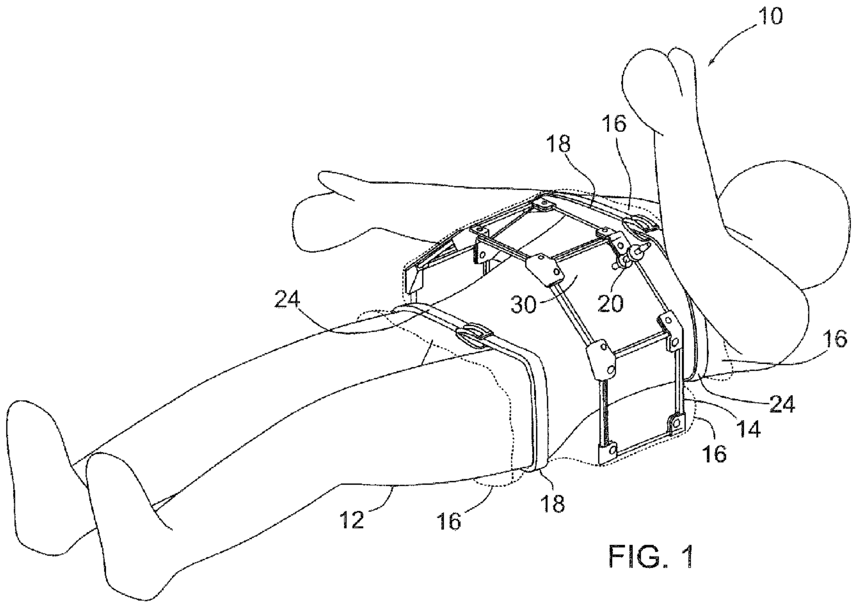

FIG. 1

(57) **Abstract:** This disclosure relates to device for providing continuous negative abdominal pressure (CNAP) which selectively recruits (inflates) the dorsal (spinal region) collapsed areas of the lung, while enabling the patient to remain in the supine (usual) position. The CNAP device includes a rigid frame configured to have a shape and size to envelop a patient's lower chest and abdominal area while in a supine position with the frame having opposed edges which sit on a surface on which the supine patient is resting. A series of panels are mounted in the frame such that the series of panels extend around the patient's lower chest and abdominal area. A flexible sheet wrapped around the outside of the panels and is long enough to extend up to the patient's upper chest and down to the patient's thighs and wide enough to envelop the supine patient's lower chest and abdominal area. Sealing members are to seal the flexible sheet over the frame and panels and around the patient's lower chest and pelvis, wherein a chamber is formed between the patient and said device when the patient is enveloped by the device. An air inlet coupling extends through one of the panels and is attachable to a suction source which is configured to generate negative pressure of between about -5 to about -10 cm H_2O inside the chamber.

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DEVICE FOR PRODUCING CONTINUOUS NEGATIVE ABDOMINAL PRESSURE

FIELD OF THE DISCLOSURE

This disclosure relates to device for providing continuous negative abdominal pressure (CNAP) which selectively recruits (inflates) the dorsal (dependent region) collapsed areas of the lung, while enabling the patient to remain in the supine (usual) position.

BACKGROUND

Acute Respiratory Distress syndrome (ARDS) is a serious pulmonary disease affecting adults and children. It has a high mortality and there is no specific therapy. Outcome (mortality greater than 40% in severe cases) is unchanged in the last 20 years.

Lung Injury occurs mostly in ventilated, non-dependent lung regions, termed the ‘baby’ lung (1). Recruitment of dependent atelectasis (collapsed areas of lung) involves elevating airway pressure with high levels of Positive End-Expiratory Pressure (PEEP) or high frequency ventilation, and increasing the amount of the baby lung reduces its susceptibility to injury from inspiratory stretch. But clinical studies of these techniques have resulted in marginal benefit (2), possibly because before recruiting (inflating) atelectatic lung, increased airway pressure first overinflates (and potentially injures) already aerated regions (3).

Mechanical ventilation is the mainstay of management, and this assists the patient by increasing oxygenation and removal of carbon dioxide. Despite optimizing tidal volume, driving pressure and PEEP, patients with ARDS develop large areas of atelectasis and poor oxygenation. There are few additional ventilator approaches that have proven to be useful in preventing this type of injury.

A major aim of ventilator support is recruitment of atelectatic lung, but while this is supported by excellent rationale and laboratory data, the conventional clinical approaches have not been associated with a significant improvement in patient outcome. Most atelectasis in ARDS occurs in the dorsal (along the spine, lower-most) lung regions, and these are near the diaphragm (which separates the chest from the abdomen).

The main ways to recruit (inflate) lung are to increase the airway distending pressure (increase the force in which air is pushed into the lungs), but this over-expands and damages the already-inflated lung regions or, to turn the patient into the prone position. However, clinicians are reluctant to utilize this approach, (despite evidence that it may increase survival), because of the concerns that most patients have many monitoring devices and indwelling catheters that may become dislodged while turning the patient prone.

Abdominal pressure is a key factor that increases the propensity to dependent atelectasis (4). Negative pressure applied outside the abdomen can lower the intra-abdominal pressure in patients (5, 6), and could potentially decrease dorsal atelectasis by caudal (toward the feet) shift of the diaphragm. The present inventors (7) and others (6, 8) have previously attempted this, but its impact may have been limited by ineffective transmission of external negative pressure (6, 8) or the use of a rodent model (7).

Providing a device that can provide continuous negative abdominal pressure (CNAP) that aims to selectively recruit (inflate) the dorsal (spinal region) collapsed areas of the lung, while enabling the patient to remain in the supine (usual) position would be very advantageous in the treatment of ARDS.

SUMMARY

Provided is a continuous negative abdominal pressure (CNAP) device which aims to selectively recruit (inflate) the dorsal (spinal region) collapsed areas of the lung, while enabling the patient to remain in the supine (usual) position.

There is provided a device for providing continuous negative abdominal pressure comprises a rigid frame configured to have a shape and size to envelop a patient’s lower chest and abdominal area while in a supine position. The frame has opposed edges which sit on a surface on which the supine patient is resting when in use. A series of panels are mounted in the frame such that the series of panels extend around the patient’s lower chest and abdominal area. A flexible sheet is wrapped around the outside of the panels and is long enough to extend up to the patient’s upper chest and down to the patient’s thighs and wide enough to envelop the supine patient’s lower chest and abdominal area. The CNAP device includes sealing members to seal the flexible sheet around the patient’s lower ribcage (xyphoid level) and pelvis (hipbone level), wherein a chamber is formed between the patient and the device when the patient is enveloped by the device. One of the series of panels includes an air inlet coupling attachable to a suction source which is configured to generate negative pressure of between about -5 to about -10 cm H_2O inside the chamber.

The device may include a pressure sensor mounted to the frame for measuring a pressure inside the chamber and the pressure sensor is connected to a display for displaying the pressure inside the chamber during use.

The panels may be flat panels, and in this case the rigid frame is configured such that when the flat panels are mounted to the frame the flat panels are at a preselected angle with respect to each other.

Alternatively, the frame may comprise of two arcuate shaped frame sections configured and fitted together to allow for relative sliding motion of each arcuate shaped frame section with respect to the other for enabling adjustment of the overall size of the device, and thus the panels are arcuate shaped panels matching an arcuate shape of the frame sections.

A further understanding of the functional and advantageous aspects of the present disclosure can be realized by reference to the following detailed description and drawings.

BRIEF DESCRIPTION OF DRAWINGS

This disclosure will be more fully understood from the following detailed description thereof taken in connection with the accompanying drawings, which form part of this application, and in which:

FIG. 1 is a perspective view of a patient positioned within a device for providing continuous negative abdominal pressure constructed in accordance with the present disclosure.

FIG. 2 is an enlarged view of part of the device of **FIG 1**.

FIG. 3 is a perspective view of a patient positioned within a second embodiment of a device for providing continuous negative abdominal pressure constructed in accordance with the present disclosure.

FIG. 4 is an enlarged view of part of the device of **FIG 3**.

DETAILED DESCRIPTION

The devices described herein are directed, in general, to patient compliance measuring and recording devices for measuring and recording patient compliance with using a wearable treatment for a medical condition. Although embodiments of the present invention are disclosed herein, the disclosed embodiments are merely exemplary and it should be understood that the invention relates to many alternative forms, including different shapes and sizes. Furthermore, the Figures are not drawn to scale and some features may be exaggerated or minimized to show details of particular features while related elements may have been eliminated to prevent obscuring novel aspects. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting but merely as a basis for the claims and as a representative basis for enabling someone skilled in the art to employ the present invention in a variety of manners.

As used herein, the terms “comprises”, “comprising”, “includes” and “including” are to be construed as being inclusive and open ended, and not exclusive. Specifically, when used in this specification including claims, the terms “comprises”, “comprising”, “includes” and “including” and variations thereof mean the specified features, steps or components are included. These terms are not to be interpreted to exclude the presence of other features, steps or components.

As used herein, the terms “about” and “approximately”, when used in conjunction with ranges of dimensions, compositions of mixtures or other physical properties or characteristics, is meant to cover slight variations that may exist in the upper and lower limits of the ranges of dimensions so as to not exclude embodiments where on average most of the dimensions are satisfied but where statistically dimensions may exist outside this region. It is not the intention to exclude embodiments such as these from the present disclosure.

In an embodiment the device for providing continuous negative abdominal pressure comprises a rigid frame configured to have a shape and size to envelop a patient’s lower chest and abdominal area while in a supine position. The frame has opposed edges which sit on a surface on which the supine patient is resting when in use. A series of panels are mounted in the frame such that the series of panels extend around the patient’s lower chest and abdominal area. A flexible sheet is wrapped around the outside of the panels and is long enough to extend up to the patient’s upper chest and down to the patient’s thighs and wide enough to envelop the supine patient’s lower chest and abdominal area. The CNAP device includes sealing members to seal the flexible sheet around the patient’s lower chest and pelvis, wherein a chamber is formed between the patient and the device when the patient is enveloped by the device. One of the series of panels includes an air inlet coupling attachable to a suction source which is configured to generate negative pressure of between about -5 to about -10 cm H_2O inside the chamber.

In an embodiment the device includes a pressure sensor mounted to the frame for measuring a pressure inside the chamber and the pressure sensor is connected to a display for displaying the pressure inside the chamber during use.

In an embodiment the panels may be flat panels, and in this embodiment the rigid frame is configured and constructed such that when the flat panels are mounted to the frame the flat panels are at a preselected angle with respect to each other.

In an embodiment the frame comprises two arcuate shaped frame sections configured and fitted together to allow for relative sliding motion of each arcuate shaped frame section with respect to the other for enabling adjustment of the overall size of the device, and thus the panels are arcuate shaped panels matching an arcuate shape of the frame sections.

Referring to **FIGS. 1** and **2**, a patient encased in a device for providing continuous negative abdominal pressure (CNAP) constructed in accordance with the present disclosure is shown generally at **10**. The patient **12** is shown in the preferred supine position with a continuous negative abdominal pressure device **14** enveloping his lower chest and abdominal area.

Continuous negative abdominal pressure device **14** includes a series of panels **30** with each panel **30** attached to a neighboring panel **30** using braces **36**. Each panel has a rod **32** extending along each outer edge of the panel. Each brace **36** has three channels to receive the ends of three rods **32** to allow each panel **30** to be coupled to its neighboring panel **30**. Each brace **36** has two channels at about 45 degrees so that when panels **30** are connected together they fit around the chest and abdomen of the patient with the outer ends of the two end panels **30** resting on either side of the patient on the surface/bed on which the patient is lying.

As shown in **FIG. 1**, one of the panels **30** located above the patient's torso includes a barbed pipe connector **20**. Connector **20** is connected to the wall vacuum line to create negative pressure inside the chamber formed between the patient and CNAP **14**. This negative pressure is transmitted through the abdomen and pulls the diaphragm towards the direction of the patient's feet when the device **14** is secured around the patient **12**.

A transparent flexible sheet **16** is wrapped around the outside of the panels **30** and is long enough to extend up to the patient's upper chest and down to the patient's thighs as well as being wide enough to be fully wrapped around the patient. The barb pipe connector **20** is pushed through the plastic sheet **16**, a hose connected to the negative wall pressure is attached to the barb pipe connector **20.** Once belt **24** is tightened around the patient's lower ribcage (level with xyphoid) on the outside of the sheet **16** and is tight enough to form a seal to prevent leakage of air from the chamber formed by device **14**. Similarly a second belt **24** is tightened around the patient's pelvis (level with hip bones) to seal sheet **16** around the patient's pelvis to prevent leakage from the chamber.

It will be appreciated by those skilled in the art that continuous negative abdominal pressure device **14** may be built for different sized patients, whether they are young babies or fully-grown adults, the device **14** may be built to accommodate any age or sized patient.

In operation, once the continuous negative abdominal pressure device **14** is secured around the patient **12** as shown in **FIG. 1**, tubing is connected to valve **20** and wall suction is applied to generate negative pressure of -5 to -10 cm H_2O inside the CNAP device chamber. This negative pressure is transmitted through the abdomen and causes the dorsal portion of the diaphragm to be pulled inferiorly which in turns draws air into the dorsal atelectatic regions of the lung without overstretching the already open ventral regions of the lung. This will increase the patient's oxygenation without increasing the airway pressure.

A negative pressure sensor module and associated display screen (not shown) may be mounted on one of the panels **30** and configured to measure the negative pressure inside the device and display it on the screen.

In studies using 12 healthy adults, the present CNAP device **14** of **FIGS. 1** and **2** was secured onto the abdomen of the volunteers and -5 cm H_2O of negative pressure was applied for 30 minutes. Patient comfort, heart rate, respiratory rate, pulse oximetry and blood pressure were monitored throughout the 30 minutes. The results showed that the present CNAP had no significant effect on blood pressure, pulse oximetry, or on heart or respiratory rate. The volunteers reported no significant level of discomfort.

Referring to **FIGS. 3** and **4**, the patient **12** is shown encased in another embodiment of a device for providing continuous negative abdominal pressure (CNAP) constructed in accordance with the present disclosure shown generally at **50**. The patient **12** is shown in the preferred supine position with a continuous negative abdominal pressure device **54** enveloping his lower chest and abdominal area.

Continuous negative abdominal pressure device **54** includes two concentric 120 degree arcuate shaped arches **58** and **60** which comprise the frame of the device **54**. The arches **58** and **60** are fitted together to allow for relative sliding motion, enabling adjustment of the overall size of the structure **54**. Aluminum braces **62** are used to increase the rigidity of arches **58** and **60**. Two transparent panels **66** and **68** are placed over the arches **58** and **60**. A negative pressure sensor module **72** is embedded into arch **60** and the negative pressure inside the device is displayed on a screen **74**.

As shown in **FIG. 3**, arch **58** includes a built-in barbed pipe connector **20** similar to that shown in **FIG. 1**. Pipe connector **20** is connected to the wall vacuum line to create negative pressure inside the chamber. This negative pressure is transmitted through the abdomen and pulls the diaphragm towards the direction of the feet when the device **14** is secured around the patient **12**.

Transparent flexible sheet **16** in **FIG. 1** is wrapped around the outside of the device **54** and is long or wide enough to extend up to the patient's upper chest and down to the patient's thighs. One belt **24** is tightened around the patient's lower ribcage (level with xyphoid) upper chest on the outside of the sheet and is tight enough to form a seal to prevent leakage of air from the chamber formed by device **54**. Similarly a second belt **24** is tightened around the patient's pelvis (level with hip bones) to seal the sheet around the patient's pelvis to prevent leakage from the chamber.

It will be appreciated by those skilled in the art that continuous negative abdominal pressure device **54** may be built for different sized patients, whether they are young babies or fully-grown adults, the device **54** may be built to accommodate any age or sized patient.

In operation, the CNAP device **54** operates essentially the same as CNAP device **14**, so that once the continuous negative abdominal pressure device **54** is secured around the patient **12** as shown in **FIG. 1**, an air tubing hose is connected to connector **20** and wall suction is applied to generate negative pressure of -5 to -10 cmH_2O inside the CNAP device chamber. This negative pressure is transmitted through the abdomen. It causes the dorsal portion of the diaphragm to be pulled inferiorly which in turns draws air into the dorsal atelectatic regions of the lung without overstretching the already open ventral regions of the lung. This will increase the patient's oxygenation without increasing the airway pressure.

In summary, an embodiment of a device is disclosed for providing continuous negative abdominal pressure comprises a rigid frame configured to have a shape and size to envelop a patient's lower chest and abdominal area while in a supine position. The frame has opposed edges which sit on a surface on which the supine patient is resting when in use. A series of panels are mounted in the frame such that the series of panels extend around the patient's lower chest and abdominal area. A flexible sheet is wrapped around the outside of the panels and is long enough to extend up to the patient's upper chest and down to the patient's thighs and wide enough to envelop the supine patient's lower chest and abdominal area. The CNAP device includes sealing members to seal the flexible sheet around the patient's lower ribcage (xyphoid level) and pelvis (hipbone level), wherein a chamber is formed between the patient and the device when the patient is enveloped by the device. One of the series of panels includes an air inlet coupling attachable to a suction source which is configured to generate negative pressure of between about -5 to about -10 cm H_2O inside the chamber.

In an embodiment the device may include a pressure sensor mounted to the frame for measuring a pressure inside the chamber and the pressure sensor is connected to a display for displaying the pressure inside the chamber during use.

In an embodiment the panels are flat panels, and the rigid frame is configured such that when the flat panels are mounted to the frame the flat panels are at a preselected angle with respect to each other.

In an alternative embodiment the frame is comprised of two arcuate shaped frame sections configured and fitted together to allow for relative sliding motion of each arcuate shaped frame section with respect to the other for enabling adjustment of the overall size of the device, and thus the panels are arcuate shaped panels matching an arcuate shape of the frame sections.

The specific embodiments described above have been shown by way of example, and it should be understood that these embodiments may be susceptible to various modifications and alternative forms. It should be further understood that the claims are not intended to be limited to the particular forms disclosed, but rather to cover all modifications, equivalents, and alternatives falling within the spirit and scope of this disclosure.

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THEREFORE WHAT IS CLAIMED IS:

1. A device for providing continuous negative abdominal pressure, comprising:

a rigid frame configured to have a shape and size to envelop a patient's lower chest and abdominal area while in a supine position, the frame having opposed edges which sit on a surface on which the supine patient is resting when in use, a series of panels mounted in said frame such that said series of panels extend around the patient's lower chest and abdominal area;

a flexible sheet wrapped around the outside of the panels and being long enough to extend up to the patient's upper chest and down to the patient's thighs and wide enough to envelop the supine patients lower chest and abdominal area;

sealing members to seal said flexible sheet around the patient's lower rib cage and pelvis, wherein a chamber is formed between the patient and said device when the patient is enveloped by the device; and

one of said panels including an air inlet coupling attachable to a suction source which is configured to generate negative pressure of between about -5 to about -10 cm H_2O inside the chamber.

2. The device according to claim 1, further comprising a pressure sensor mounted to said frame for measuring a pressure inside said chamber, said pressure sensor connected to a display for displaying the pressure inside said chamber during use.

3. The device according to claim 1 or 2, wherein said panels are flat panels, and wherein said rigid frame is configured such that when said flat panels are mounted to the frame the flat panels are at a preselected angle with respect to each other.

4. The device according to claim 1 or 2, wherein said frame comprises two arcuate shaped frame sections configured and fitted together to allow for relative sliding motion of each arcuate shaped frame section with respect to the other for enabling adjustment of the overall size of the device, and wherein said panels are arcuate shaped panels matching an arcuate shape of said frame sections.

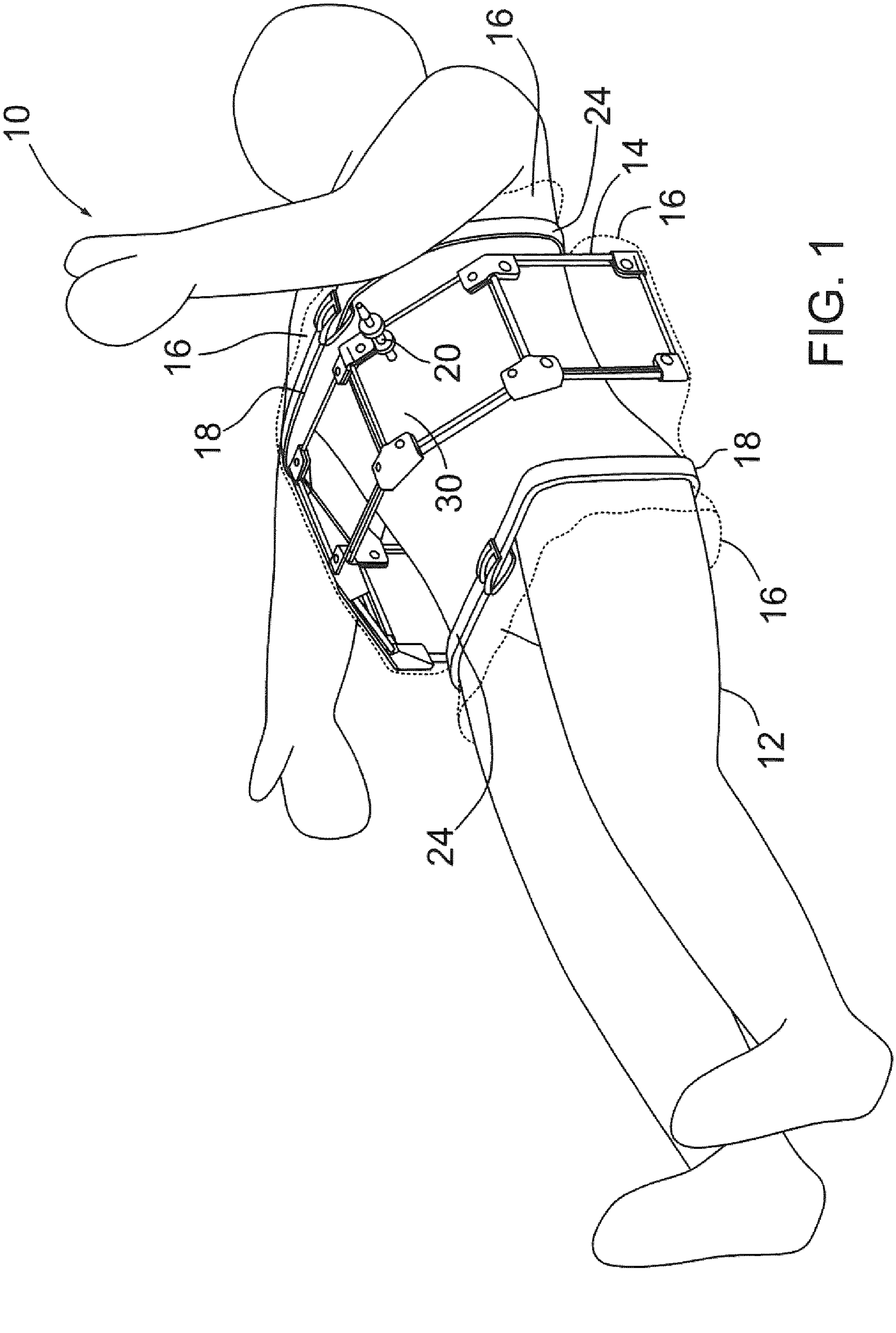

FIG. 1

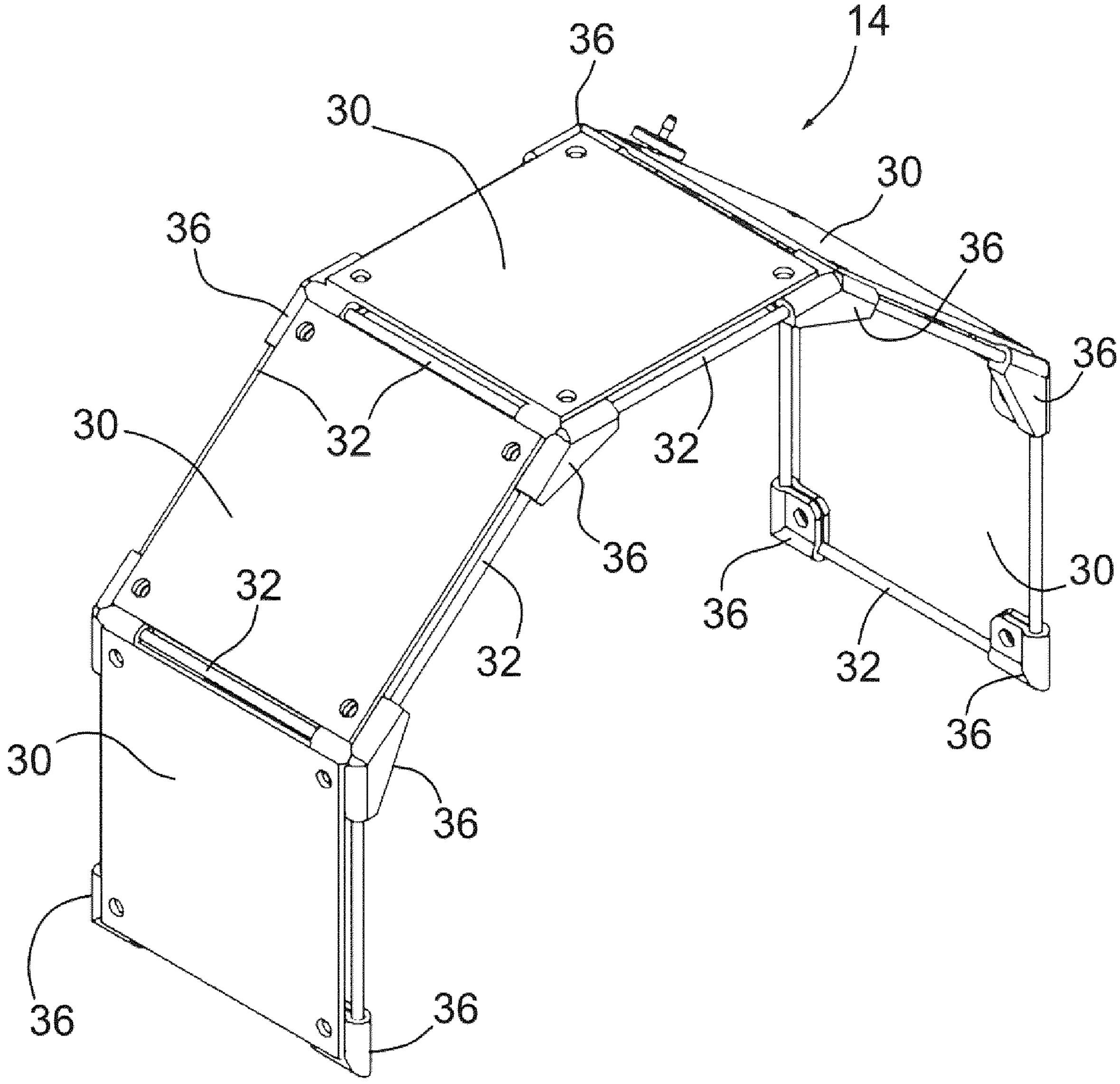

FIG. 2

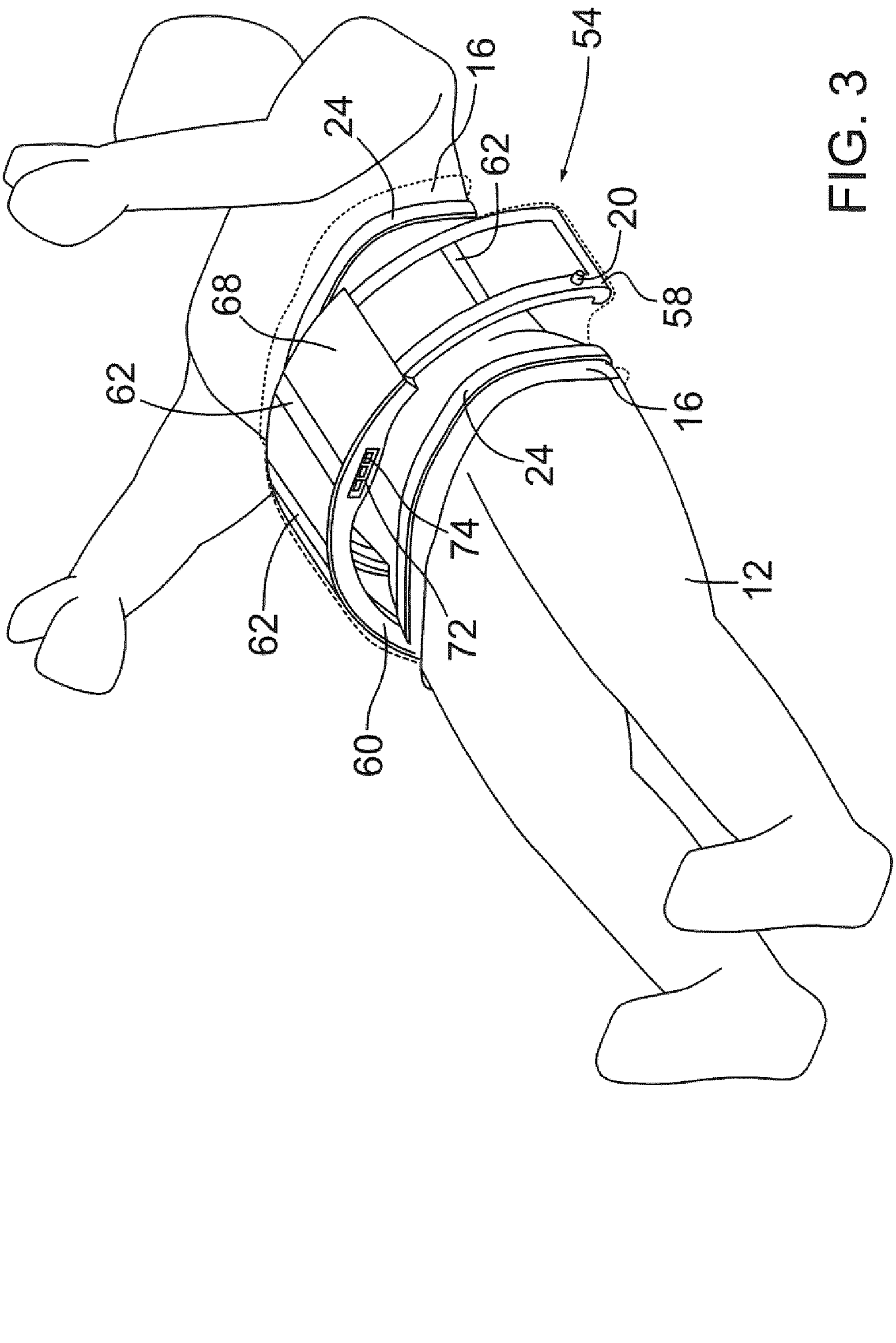

FIG. 3

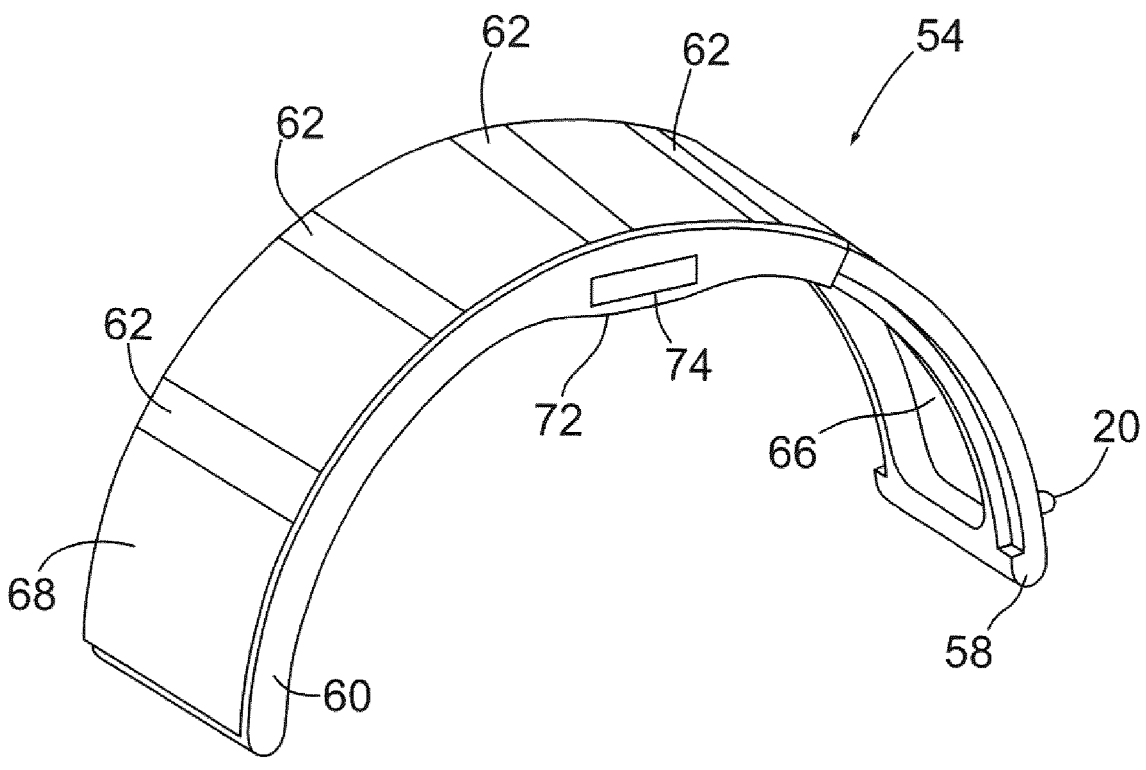

FIG. 4

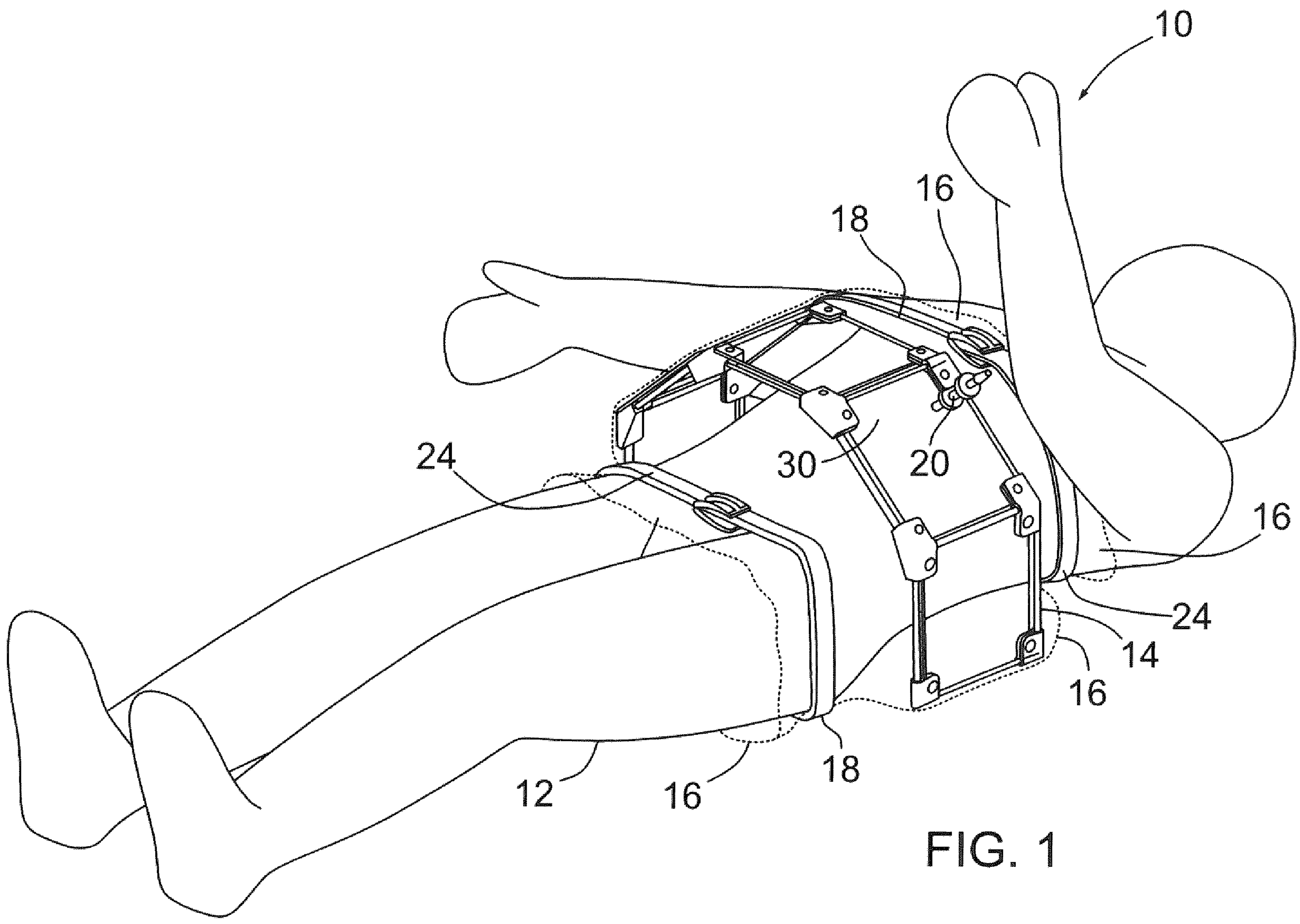

FIG. 1