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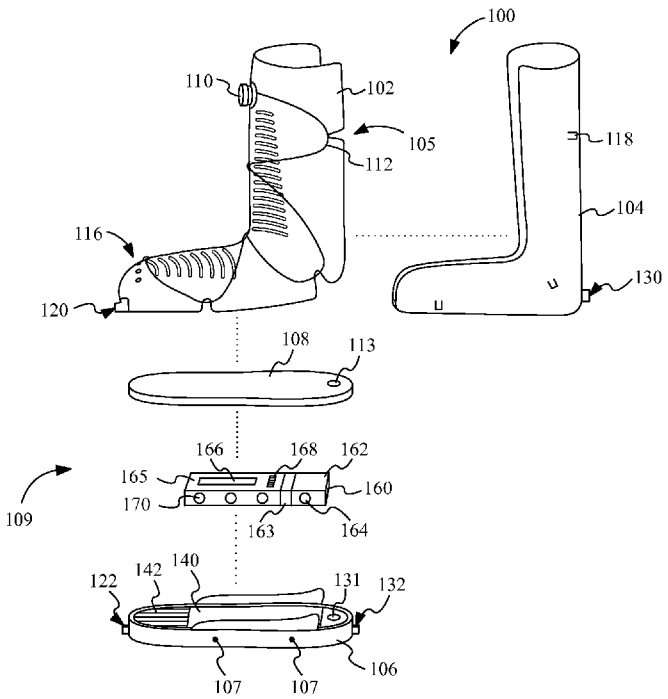


Fig. 1

(57) Abstract: According to the invention, a pneumatic cast is disclosed. The pneumatic cast may include a first shell and a second shell. The first shell and the second shell may be coupled together to form an outer casing that encloses a portion of a patient's leg. The pneumatic cast may also include an inflatable bladder and/or a sensor disposed within the outer casing. The sensor may measure an air pressure of the inflatable bladder. The pneumatic cast may further include a control mechanism. The control mechanism may be pneumatically coupled with the inflatable bladder and/or communicatively coupled with the sensor. The controller may be configured to adjust the air pressure within the inflatable bladder based on the air pressure measurement of the inflatable bladder.

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SELF-ADAPTIVE PNEUMATIC CAST

CROSS-REFERENCES TO RELATED APPLICATIONS

This application claims priority to Provisional U.S. Patent Application Number 61/290,700, filed December 29, 2009, entitled "Self-Adaptive Pneumatic Cast," the entire disclosure of which is hereby incorporated by reference, for all purposes, as if fully set forth herein.

BACKGROUND OF THE INVENTION

The subject invention relates generally to pneumatic casts that are used by patients and more specifically to self-adjusting pneumatic casts that may automatically adjust the air pressure within one or more inflatable bladders.

Casts are often used to help people heal from one or more injuries, such as broken bones, sprains, diabetic ulcers, etc. For example, it is estimated that about 23,000 ankle sprains occur every day, or roughly 8.5 million ankle sprains occur every year. Casts are commonly placed on or around the foot and/or leg to stabilize the foot and/or leg while still allowing the patient to walk. One problem with such casts is that they may cause or promote development of foot and/or leg ulcers. The development or promotion of foot and/or leg ulcers is greatly increased in individuals suffering from diabetes due to neuropathy and/or poor circulation associated with diabetes.

It is estimated that over 1 million people in the United States suffer from some form of diabetic foot and/or leg ulcers. It is also estimated that the number of people suffering from such ulcers will increase in the future and may double within the next 25 years. In severe cases, foot and/or leg ulcers and especially diabetic foot and/or leg ulcers, may result in amputation of the patient's leg due to infection and/or the inability to properly heal the infected ulcer. About 71,000 individuals suffering from such ulcers will have a lower limb amputated due to failed or lack of treatment for the infected ulcer. Further, a significant number of amputees will die within 5 years of the amputation. In addition to these unfortunate statistics, diabetic foot and/or leg ulcers alone cost the current healthcare system around $12B annually. For these and other reasons, there exists a need for improved casts that reduce and/or eliminate the development of foot and/or leg ulcers and that effectively treat pre-existing ulcers.

BRIEF SUMMARY OF THE INVENTION

In one embodiment, a self-adjusting pneumatic cast is provided. The self-adjusting pneumatic cast may include a front shell that is configured to be placed on the front of a patient's leg. The self-adjusting pneumatic cast may also include a rear shell that is configured to be placed on the back of a patient's leg. The self-adjusting pneumatic cast may further include a locking mechanism that couples or locks the front shell and the back shell together to form an outer casing that surrounds the patient's leg to enclose at least a portion of the patient's leg within the outer casing. In some embodiments, the locking mechanism may not be unlockable by a patient fitted with the self-adjusting pneumatic cast to thereby prevent the patient from removing the outer casing from around the leg. The locking mechanism may be unlockable only by an authorized person, such as a doctor, therapists, and/or physician.

The self-adjusting pneumatic cast may also include a bottom shell that may be removably coupled with a bottom portion of the outer casing. Removal of the bottom shell from the bottom portion of the outer casing may provide access to a patient's foot enclosed within the outer casing. This may allow a patient and/or a physician to access and treat the patient's foot without having to remove the entire pneumatic cast (i.e., the outer casing) from about the patient's leg. The self-adjusting pneumatic cast may additionally include a plurality of inflatable bladders and/or a plurality of sensors disposed within the outer casing. The sensors may be configured to measure an air pressure within one or more of the plurality of inflatable bladders.

The self-adjusting pneumatic cast may additionally include a control mechanism that may be pneumatically coupled with one or more of the plurality of inflatable bladders and/or communicatively coupled with one or more of the plurality of sensors. The control mechanism may be configured to adjust the air pressure within one or more of the inflatable bladders based on the air pressure measurement of one or more of the inflatable bladders. The self-adjusting pneumatic cast may additionally include a skin toughening mechanism configured to toughen at least a portion of the sole of the patient's foot. The skin toughening mechanism may be positioned adjacent to the bottom shell between the bottom shell and the patient's foot.

In another embodiment, a pneumatic cast is provided. The pneumatic cast may include a first shell and a second shell coupled with the first shell to form an outer casing enclosing at least a portion of a patient's leg therein. The pneumatic cast may also include at least one inflatable bladder and/or at least one sensor disposed within the outer casing. The sensor may

be configured to measure an air pressure of the at least one inflatable bladder. The pneumatic cast may further include a control mechanism pneumatically coupled with the at least one inflatable bladder and/or communicatively coupled with the at least one sensor. The control mechanism may be configured to adjust the air pressure within the at least one inflatable bladder based on the air pressure measurement of the at least one inflatable bladder. The control mechanism may be configured to incrementally increase or decrease the air pressure within the at least one inflatable bladder one or more times over a predefined period. For example, the controller may be programmed to increase the air pressure in the at least one inflatable bladder by a predefined amount every day or week. In addition, the controller and/or the sensor may recognize edema (i.e., swelling) and/or atrophying of the patient's leg. In response, the controller may adjust the air pressure within the at least one inflatable bladder based on the edema or atrophying of the leg.

The pneumatic cast may additionally include a third shell removably coupled with a bottom portion of the outer casing. Removal of the third shell from the bottom portion of the outer casing may provide access to the patient's foot that is enclosed within the outer casing. The third shell may include a top portion and a bottom portion that is coupled with the top portion. The top portion and the bottom portion may define a chamber that houses the control mechanism. In addition, the top portion and the bottom portion may be coupled so as to be fluid tight and thereby protect the control mechanism that is housed within the chamber. The pneumatic cast may additionally include an additional pressure sensor positioned adjacent the third shell, which is configured to measure a pressure exerted by the patient's foot on the third shell.

The pneumatic cast may additionally include one or more temperature sensors disposed within the outer casing. The temperature sensors may be configured to measure the temperature of one or more portions of the patient's leg. The pneumatic cast may additionally include a skin toughening mechanism disposed between the third shell and the patient's foot. The skin toughening mechanism may be configured to toughen the sole of the patient's foot. In one embodiment, the skin toughening mechanism may include an inflatable bladder, which may exert an increasing pressure on the sole of the patient's foot as the inflatable bladder is inflated.

The pneumatic cast may additionally include a pumping mechanism that is operatively coupled with the third shell and that is configured to inflate the inflatable bladder by movement of the pneumatic cast. The pumping mechanism may convert the kinetic energy associated with movement of the pneumatic cast into potential energy (i.e., pressurized air)

that is used to inflate the inflatable bladders. The pneumatic cast may also including an air reservoir that is pneumatically coupled to the pumping mechanism and/or the at least one inflatable bladder. The air reservoir may be pressurized by the pumping mechanism as the pneumatic cast moves and/or the pressurized air in the air reservoir may inflate the at least one inflatable bladder.

The pneumatic cast may additionally include a shear reducing material disposed between the first shell and the patient's leg to reduce friction on the patient's leg. The pneumatic cast may additionally include a locking mechanism that couples or locks the first shell and the second shell together to form the outer casing. In some embodiments, the locking mechanism may not be unlockable by a patient fitted with the pneumatic cast to thereby prevent the patient from removing the outer casing from the leg. The pneumatic cast may additionally include one or more indicators that indicate one or more conditions of the patient's leg (e.g., formation of an ulcer, high or low inflatable bladder pressure, etc.) and/or that indicate one or more conditions of the pneumatic cast (e.g., low battery, controller malfunction, structural damage, improper locking of the third shell and the outer casing, etc.). The indicators may include one or more LED lights built into the pneumatic cast and operatively coupled with the controller.

In another embodiment, a method of adjusting a pneumatic cast is provided. The method may include providing a pneumatic cast that includes one or more of the features described herein, such as a first shell, a second shell, a third shell, one or more inflatable bladders, one or more sensors, and/or a control mechanism that controls inflation and/or deflation of the inflatable bladders. The method may also include measuring, via one or more of the sensors, an air pressure of one or more of the inflatable bladders. The method may further include communicating the air pressure measurement(s) to a control mechanism and adjusting, via the control mechanism, the air pressure within one or more of the inflatable bladders based on the air pressure measurement(s).

The method may additionally include accessing and/or treating a patient's foot by removing a third shell from the bottom portion of an outer casing of the pneumatic cast. The method may additionally include pressurizing an air reservoir with a pumping mechanism. The pumping mechanism may pressurize the air reservoir through movement of the pneumatic cast, such as by using or utilizing the kinetic energy associated with the cast's movement to drive a micro pump or mechanical pump. The method may additionally include inflating one or more of the inflatable bladders from the pressurized air in the air reservoir.

The method may additionally include measuring with a temperature sensor, a temperature within the pneumatic cast, communicating the temperature measurement to the control mechanism, and adjusting, via the control mechanism, the air pressure within one or more of the inflatable bladders based on the temperature measurement. The method may additionally include incrementally increasing a pressure exerted on the bottom of the patient's foot to toughen the skin on the sole of the patient's foot. The method may additionally include recognizing either an edema or an atrophying of the patient's leg enclosed within the pneumatic cast and adjusting (i.e., inflating or deflating) the air pressure in one or more inflatable bladders based on the edema or atrophying of the leg so as to maintain a predefined air pressure within one or more of the inflatable bladders.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention is described in conjunction with the appended figures:

Fig. 1 is an exploded view of a pneumatic cast illustrating various components of the pneumatic cast in accordance with an embodiment of the invention.

Fig. 2 is a front view illustrating various inflatable bladders of the pneumatic cast in accordance with an embodiment of the invention.

Fig. 3 is front view a pneumatic cast illustrating the bottom shell removed from a locked position in accordance with an embodiment of the invention.

Fig. 4 is a top view of the bottom shell of the pneumatic cast in accordance with an embodiment of the invention.

Fig. 5 is a diagram illustrating a patient's leg and foot positioned within the pneumatic cast and further illustrating various components of the pneumatic cast in accordance with an embodiment of the invention.

Fig. 6 is a schematic of a control/feedback loop of a logic unit in accordance with an embodiment of the invention.

Fig. 7 is a flow diagram of a method of adjusting/using the pneumatic cast in accordance with an embodiment of the invention.

In the appended figures, similar components and/or features may have the same numerical reference label. Further, various components of the same type may be distinguished by following the reference label by a letter that distinguishes among the similar components and/or features. If only the first numerical reference label is used in the specification, the

description is applicable to any one of the similar components and/or features having the same first numerical reference label irrespective of the letter suffix.

DETAILED DESCRIPTION OF THE INVENTION

The ensuing description provides exemplary embodiments only, and is not intended to limit the scope, applicability or configuration of the disclosure. Rather, the ensuing description of the exemplary embodiments will provide those skilled in the art with an enabling description for implementing one or more exemplary embodiments. It being understood that various changes may be made in the function and arrangement of elements without departing from the spirit and scope of the invention as set forth in the appended claims.

Specific details are given in the following description to provide a thorough understanding of the embodiments. However, it will be understood by one of ordinary skill in the art that the embodiments may be practiced without these specific details. For example, processes and/or structures in the invention may be shown as components in block diagram or simplified form in order not to obscure the embodiments in unnecessary detail. In other instances, processes and structures may be shown without unnecessary detail in order to avoid obscuring the embodiments. Also, it is noted that individual embodiments may be described as a process which is depicted as a flowchart, a flow diagram, or a block diagram. Although a flowchart may describe the operations as a sequential process, many of the operations can be performed in parallel or concurrently. Further, it should be noted that one or more of the structures or processes may be omitted without departing from the spirit of the invention. In addition, the cast is described herein as a "pneumatic cast" for ease of description, although it should be realized that the cast may likewise be used with gels.

The pneumatic cast is designed to off load the pressure exerted on one or more areas of a patient's foot and/or leg to help heal foot or leg ulcers. Specifically, the pneumatic cast may off load the weight placed on the plantar surface of a patient's foot while still providing the patient with mobility. Off loading the pressure on the plantar surface may include transferring the downward force from walking to the sides of the pneumatic cast through one or more inflatable bladders. Keeping weight off a diabetic patient's feet is very important because walking on an ulcer can prevent or slow healing, increase the size of the ulcer, and/or force an infection deeper into the foot, which may increase the risk of amputation.

A feature of the pneumatic cast is the ability to self-regulate or adjust depending on the pressure exerted by or upon one or more inflatable bladders. This pressure may be due to edema or atrophying of the leg and/or may be due to the manner in which a patient walks or

wears the pneumatic cast. One or more of the inflatable bladders may be inflated or deflated by a mechanism and/or control within and/or connected to the body of the cast to maintain a desired pressure.

The pneumatic cast may include a control mechanism that regulates the pressure within one or more inflatable bladders. The pneumatic cast may also include a pumping mechanism to convert some of the energy used in walking with the cast into a form of energy that may inflate the inflatable bladders. Another feature of the pneumatic cast is the ability to toughen a patient's foot in preparation for walking without the assistance of the pneumatic cast to reduce the reoccurrence of foot and/or leg ulcers. An additional feature is the ability to remove the bottom portion of the cast while the cast remains fixed about the patient's leg to allow the patient and/or a physician to treat any ulcers. These and other features of the pneumatic cast will become more apparent with reference to the figures.

Turning now to Figs. 1-4, various components of the pneumatic cast are shown. Fig. 1 shows an exploded view of the pneumatic cast 100. The pneumatic cast 100 may include a front shell 102 that is shaped and constructed to fit on the front of a patient's leg. Specifically, the front shell 102 may be designed to include a horizontal section that covers the top of a patient's foot and a vertical section that extends up the front of the patient's foot to mid-calf or to at or below the knee. The vertical section may wrap around the patient's leg while including an opening toward the rear to allow the front shell 102 to be placed about the leg.

The pneumatic cast 100 may also include a rear shell 104 that is shaped and constructed to fit on the back of a patient's leg. Specifically, the rear shell 104 may be designed to also include a vertical section that extends up the back of the patient's foot to roughly the same height as the front shell 102 and may include a horizontal section that runs along the side of a patient's foot, such as a pair of horizontal extending wings. The bottom of the rear shell 104 is generally left open.

The front and rear shells, 102 and 104, may be constructed of a rigid material, such as various plastics, so that the shells protect the patient's leg and also protect one or more components disposed within the shells. The front and rear shells, 102 and 104, may be secured together via a locking mechanism to form an outer casing that encloses the patient's leg and provides a rigid outer protecting layer. Fig. 3 shows a front view of the outer casing (i.e., the combined front and rear shells) and Fig. 5 shows a patient's leg enclosed within the outer casing. The rear shell 104 may include one or more tabs 118 that are designed to receive and secure a wire 112 attached to front shell 102 so that shells may be secured or locked together. The

tabs 118 may fit into recessed portions 105 on the rear edge of the front shell 102. In this manner, a patient's leg may be positioned between the front and rear shells, 102 and 104, and the shells may be brought together to enclose a portion of the patient's leg within the outer casing of the pneumatic cast.

The wire may be attached to a lock 110 that may adjust the tension in wire 112 to secure the shells together and/or release the shells. Lock 110 may be configured so that the lock 110 is only unlockable by a doctor or other physician to prevent a patient from unlocking the lock 110 and removing the pneumatic cast from the patient's leg by decoupling the shells. In this manner, the concern about a patient's compliance with wearing the pneumatic cast 100 is lessened. Increased compliance may improve healing of ulcers. The front and rear shells, 102 and 104, may be secured together using other means as well, such as clamps, adhesives, pins, belts, bolts, screws, compliant members, etc. In addition, the front shell 102 and/or rear shell 104 may include a plurality of vents (not numbered but see front shell 102) that allow the pneumatic cast to breathe.

The bottom of the front and rear shells, 102 and 104, may be open so that when the shells are secured together, the patient's foot is exposed. The pneumatic cast 100 may further include a bottom shell 109 that couples to the bottom of the outer casing to fully enclose the patient's foot within the pneumatic cast 100. The bottom shell 109 may be removable from the outer casing to thereby allow a patient, physician, and/or anyone else to access and treat the patient's foot while the outer casing remains enclosed about the patient's leg.

The bottom shell 109 may be removably coupled to the outer casing using a variety of means. For example, Fig. 1 illustrates the bottom shell 109 include a front tab 122 and a rear tab 132 that respectively correspond with a front tab 120 positioned on the front shell 102 and a rear tab 130 positioned on the rear shell 104. When the front and rear shells, 102 and 104, are secured together to form the outer casing, one or more elastic bands or cords may be placed around the front tabs, 120 and 122, and rear tabs, 130 and 132, to secure the bottom shell 109 to the outer casing and thereby enclose the patient's foot within the pneumatic cast. The bottom shell 109 and/or front and rear shells, 102 and 104, may include more tabs to provide additional securing points.

Fig. 3 illustrates the front and rear shells, 102 and 104, assembled to form the outer casing 300 with the bottom shell 109 uncoupled from the bottom of the outer casing 300 to expose a patient's foot. Fig. 3 further shows an additional method of removably coupling the bottom shell 109 with the front and rear shells, 102 and 104, which includes one or more locking tabs

332 positioned around the periphery of the bottom shell 109 that are designed to fit and lock into one or more locking apertures 330 positioned around the periphery of the bottom of the outer casing 300. Specifically, the locking tabs 332 may be positioned around the periphery of a top portion or sole 304 of the bottom shell 109 and the bottom portion of either or both the front shell 102 and rear shell 104 may include locking apertures 330. Other means of securing bottom shell 109 to the outer casing are contemplated herein, which may include buckles, sliding joints, etc.

The bottom shell 109 may be connected to the bottom of the outer casing 300 by one or more hinges 306 so that the bottom portion 109 may swing open and allow access to the patient's foot, but remain connected to the outer casing 300. In this manner, the patient or physician will be reminded to re-secure the bottom shell 109 to the outer casing 300 after treating the patient's foot. Further, with the bottom shell hinged 306 to the outer casing 300, walking or moving without first re-securing the bottom shell 109 to the outer casing 300 may be difficult or uncomfortable. The bottom shell 109 may include a locking tab, 332 and/or 132, positioned opposite hinges 306. The locking tab, 332 and/or 132, may correspond with a locking aperture 330 and/or locking tab, 130 to secure the bottom shell 109 to the bottom of the outer casing 300. If hinges 306 are not used, the bottom shell 109 may be completely removed from the bottom of the outer casing 300. The arrow corresponding to 320 illustrates that when the bottom shell 109 is uncoupled and/or removed, the patient's foot is exposed.

As shown in Figs. 1 and 4, the bottom shell 109 may include a top member or sole 108 and a bottom member 106. The sole 108 and bottom member 106 may be coupled together so that the bottom shell 109 is fluid tight to prevent water and other fluids or contaminants from penetrating into bottom shell 109. Bottom member 106 may include a recessed portion 140 and one or more compartments 142 positioned adjacent the recessed portion 140.

The recessed portion 140 may be shaped and sized to correspond with a control mechanism 160 that controls various operations of the pneumatic cast 100 as described herein. The control mechanism 160 may be housed within recessed portion 140 so that the control mechanism 160 is encased or fully enclosed, and thereby protected, within the bottom shell 109 when sole 108 and bottom member 106 are coupled together. Compartments 142 may house one or more components such as solenoid valves, an air reservoir, batteries, tubing, and/or healing elements (e.g., a light source for low level laser therapy, magnets, etc.). For example, one or more light sources may be positioned in the compartments 142 to provide light to a patient's foot, thereby promoting healing of an ulcer on the patient's foot.

Bottom member 106 and/or sole 108 may include one or more apertures (107, 113, and/or 131) that provide access to the control mechanism 160 housed within the bottom shell. For example, aperture 107 may allow one or more electrical components, such as an external computer, to communicatively couple with the control mechanism 160 to download information from the control mechanism 160 and/or upload programs thereto. For example, aperture 107 may include a Universal Serial Bus (USB) port, an Ethernet port, or any other interface to electrically couple an external computer with the logic unit 163 of the control mechanism. Similarly, as shown in Fig. 3, the outer casing 300 may include one or more ports 310 that provide access to or externally couple the control mechanism 160 to an outside source (i.e., port 310 may be a USB port, an Ethernet port, etc.).

Aperture 107 may alternatively or additionally include one or more lumens (i.e., tubes or passages) that connect a pumping mechanism 166 to the surrounding environment to provide an air source for pumping mechanism 166 so that the pumping mechanism 166 can pressurize an air reservoir 162. Similarly, the lumens of aperture 107 may connect to an air reservoir 162 so that pressurized air can be fed from an external air source into the air reservoir 162 to pressurize the air reservoir. The apertures 107 may include valves and/or gaskets that close off the apertures 107 so that the bottom shell 109 remains liquid tight when the apertures 107 are not connected with an external source, such as an external computer or air supply.

Aperture 131 may provide a conduit for various tubing or wires to connect one or more components of the pneumatic cast 100 with the control mechanism 160. For example, the aperture 131 may provide a conduit for tubing so that the control mechanism 160, specifically an air control mechanism 165 and/or air reservoir 162, are pneumatically coupled with one or more inflatable bladders. Similarly, various electrical wires may run through aperture 131 and connect to one or more sensors, such as a temperature sensor and/or pressure sensor. Sole 108 may include an aperture 113 that corresponds with aperture 131 to provide a conduit for various wires and/or tubing. In one embodiment, aperture 131 and/or aperture 113 replace apertures 107 so that all tubing and wires run through aperture 131 and/or aperture 113.

In addition, the bottom shell 109 may include additional apertures that function similar to 131 so that some of the wires or tubing pass through aperture 131 and other wires or tubing pass through the other apertures. For example, the bottom shell may have an aperture specifically for tubing that connects the pumping mechanism 166 and/or air reservoir 162 to an external air source.

The control mechanism 160 may include an air control mechanism 165, a logic unit 163, and/or an air reservoir 162, although some embodiments may include more or less components than these. The control mechanism 160 may further include one or more sensors 168 and apertures, 164 and 170. The air control mechanism 165 may include one or more control valves (represented by apertures 164) that are pneumatically connected/coupled to one or more inflatable bladders 200 (shown in Fig. 2) via various tubing that may run through conduit 131. The control valves 164 may include solenoid valves that selectively open and close upon input from the logic unit 163 to inflate one or more of the inflatable bladders 200. Each one of the control valves 164 may be pneumatically coupled with an inflatable bladder so that the inflation and deflation of specific bladders may be closely controlled. For example, the air control mechanism 165 shown in Fig. 1 illustrates three control valves 164 on one side (although more or less valves are possible). Each of these control valves 164 may be pneumatically coupled with a specific inflatable bladder so that the one, two, or all three (or more) of the bladders may be inflated. In one embodiment, the air bladders are inflated to between 2 psi and 10 psi.

The tubing that connects the air control mechanism 165 and the inflatable bladders 200 may also connect to a pressure sensor 168 so that the pressure inside the inflatable bladders 200 may be measured. Element 168 shows a series of pressure sensors that may each correspond with a specific inflatable bladder so that the pressure within each and every bladder may be measured and monitored. In one embodiment, the inflatable bladders 200 may include a pressure sensor 220 in replacement of or in addition to pressure sensor 168 so that pressure may be measured directly from the inflatable bladder.

The air control mechanism 165 may include an air manifold (not shown) that connects to each of the solenoid valves 164 to provide a central air source for all the inflatable bladders 200. The air reservoir 162 may be pneumatically coupled to the air manifold. In one embodiment, the air reservoir 162 functions as the air manifold. In another embodiment, the air control mechanism 165 does not include an air manifold and the solenoid valves 164 connect directly with the air reservoir 162. The air control mechanism 165 may further include one or more relief valves to control the pressure within the air control mechanism, inflatable bladders 200, and/or air reservoir 162. The solenoid valves 164 may act as a relief valves to depressurize or deflate the inflatable bladders by opening one or more solenoid valves 164. In one embodiment, the solenoid valves 164 may be positioned both upstream and downstream of the inflatable bladders 200. In another embodiment, the solenoid valves

164 are positioned downstream of the inflatable bladders 200, where the solenoid valves 164 function as pressure relief valves.

The air control mechanism 165 may also include one or more micro pumps (not shown) that function to inflate the inflatable bladders 200. In one embodiment, each inflatable bladder is pneumatically coupled with a micro pump and the control mechanism 160 does not include an air reservoir. In such an embodiment, the micro pumps may be pneumatically coupled directly with the inflatable bladders 200 so that activation of a micro pump inflates a corresponding inflatable bladder (e.g., inflates the bladder from 2 psi to 5 psi). The inflatable bladders may be deflated by opening a solenoid valve 164 downstream of the inflatable bladder (e.g., from 8 psi to 4 psi). In another embodiment, a solenoid valve 164 or one way valve may be positioned between the micro pump and the inflatable bladder.

In an additional embodiment, one or more micro pumps may connect to the air reservoir 162 to keep the air reservoir 162 pressurized. The air reservoir 162 in turn may be connected to the solenoid valves 164, which are opened when an inflatable bladder needs inflation. In still another embodiment, one or more micro pumps are connected to the air manifold, which is in turn connected to the solenoid valves 164 that may be opened to inflate one or more bladders. Such an embodiment may or may not include an air reservoir. The micro pumps may be electrically coupled to a power source (not shown), such as one or more batteries (not shown) disposed within the pneumatic cast 100 and/or bottom shell 109. For example, the batteries may be housed within one or more of the compartments 142.

The air control mechanism 165 may also include a pumping mechanism 166 that is used to pressurize the air reservoir 162. The pumping mechanism 166 may convert the kinetic energy of walking into potential energy in the form of pressurized air. The pumping mechanism 166 may replace or be in addition to the micro pumps. For example, the pumping mechanism 166 may include a pump (or pumps) that is connected to or coupled with the sole 108 so that as the patient walks and exerts a force on sole 108, the pump(s) is compressed and air is forced into the air reservoir 162. In one embodiment, the pumping mechanism 166 includes 5 pumps. As described above, pumping mechanism 166 may be connected to the external environment to provide an air source for pumping mechanism 166, such as through apertures 107 and/or apertures 131 and 113. As the patient continues to walk and lifts the pneumatic cast off the ground, or otherwise relieves the pressure exerted on sol 108, air from the external environment may flow into the pump and the pumping process may be repeated.

Apertures 107, 131, and/or 113 and/or the pump may include one way valves to allow air to enter the pump from the external environment, but prevent the air from flowing back through the apertures or tubing to the external environment. For example, a series of one way valves may be positioned with respect to a compressible air bladder so that one valve is positioned before an air entrance port of the bladder and a one valve is positioned after an air exit port of the bladder. These valves may allow the compressible air bladder to re-inflate between steps while preventing backflow. In one embodiment, a portion 402 (Fig. 4) of sole 108 may be a compliant member that flexes as a forces is exerted on compliant portion 402 as the patient walks. The compliant portion 402 of sole 108 may be part of or connected to the pump to pressurize the air reservoir 162 as previously described. Further, the compliant portion 402 may comprise the compressible air bladder and may be positioned above the sole 108.

The pumping mechanism 166 may also include or utilize piezoelectric materials, such as crystals, ceramics, fibers, etc. that generate a charge when pressure is applied from a patient's foot during movement. The generated charge may power one or more micro pumps to inflate the bladders and/or pressurize air reservoir 162. In this manner the need for a battery source may be reduce or eliminated. The portion 402 of sole 108 may include the piezoelectric materials and may electrically couple to the micro pumps.

The air reservoir 162 may be couplable to an external air source so that the air reservoir 162 may be pressurized from the external source. For example, aperture 107 may include a port that is connectable to an air source, such as a hand pump so that the air reservoir 162 may be pressurized periodically by the user. Connecting to an external air source may replace the need or a micro pump or pumping mechanism 165 or be in addition thereto. The air reservoir 162 may include air entrance ports and air exit ports (collectively shown by element 170). The air entrance ports 170 may connect with the pumping mechanism 166, micro pumps, and/or external air source to allow the air reservoir 162 to be pressurized. Likewise, the air exit ports 170 may be connected to the air control mechanism 165 to provide air to the solenoid valves 164 and/or air manifold. The air entrance and/or exit ports 170 may include one way valves to control the direction of the air flow.

The logic unit 163 may include any combination of hardware and software components. For example, the logic unit 163 may include a processor (not shown); a storage medium (not shown), such as ram, rom, flash memory, etc.; a communication device (not shown); etc. The logic unit 163 may electrically couple with one or more sensors (e.g., 168 and 404) to receive input therefrom. For example, the logic unit 163 may receive signals from pressure sensors 168 and/or pressure sensors 220 that indicate the pressure in one or more of the inflatable

bladders. The logic unit 163 may further receive signals from one or more temperature sensors 222 that indicate the temperature in one or more areas within the pneumatic cast 100 and/or may receive signals from additional pressure sensor 404 that measure the force exerted by the patient's foot on sole 108.

Based on the input received, the processor may process the information and generate one or more outputs to perform one or more operations, such as inflating/deflating the bladders, providing one or more signals, sending a communication to a patient or physician, etc. The air control mechanism 165 may electrically couple with the logic unit 163 to receive signals to control the opening and closing of the solenoid valves and/or to activate one or more micro pumps to inflate the bladders. For example, if the air pressure in one of the bladders is too low or the pressure exerted by the patient's foot on sole 108 is too high, the logic unit 163 may signal the air control mechanism to inflate the air bladders surrounding the patient's legs to decrease the pressure from the patient's foot on sole 108 and thereby off load the pressure on the patient's plantar surface.

The logic unit 163 may also provide visual signals to the patient, physician, or some other individual through one or more indicators 116. For example, indicators 116 may include a series of LED lights. The logic unit 163 may activate one or more of the LED lights based on a sensed or determined condition. For example, if the logic unit 163 malfunctions, one of the LED lights may activate; if a temperature reading is too high, another LED light may activate; and/or if a battery or bottom shell needs replacement, an additional LED light may activate. Further, if the bottom shell 109 is not properly re-secured to the outer casing, a LED light may activate or if the patient has removed the bottom shell 109 for extended periods, an additional LED light may activate to inform the physician. The LED lights may be configured to provide any visual indications desired.

The communication device (not shown) of the logic unit 163 may allow the logic unit to communicate with external devices and/or systems and/or receive instructions therefrom. In one embodiment, the communication device is a Bluetooth device or other wireless device that provide wireless communication with external devices. In this manner, the logic unit 163 may provide and receive communication (e.g., instruction, updates, etc.) without having to open bottom shell 109. The Bluetooth device may allow a physician or doctor to program the logic unit 163 for a specific patient. Likewise, the program may be altered wirelessly to suit the specific needs of the patient, such as by adjusting the air pressures, temperature sensing ranges, pressure exerted on the sole of the patient's foot, etc. Thus, a single pneumatic cast 100 may be easily adapted to suit individual patients and specific conditions. Further, with

the wireless communication, a doctor of physician may remotely monitor, control, and/or adjust the pneumatic cast 100. For example, the logic unit 163 could provide periodic reports that the doctor or physician may view.

In one embodiment, the doctor of physician sets an air pressure or air pressure range for each inflation bladder and/or sets a program to incrementally increase or decrease the pressure over a specified time period. The logic unit 163 then receive signals/input from the various sensors and provides instructions/output to the various components to control the cast and ensure the cast functions in accordance with the specified program. Additional functions of the logic unit will be described in relation to Fig. 6.

As briefly mentioned above, sole 108 may further include an additional pressure sensor 404 that measures the force exerted on the patient's foot and/or exerted by the patient's foot on sole 108. The pressure sensor 404 may send input or signals to the logic unit 163 so that the logic unit may determine if too much pressure is placed on the plantar surface of the foot. Pressure sensor 404 may also be part of a skin toughening mechanism that is used to recondition the foot for walking without the pneumatic cast by inducing hypertrophy, thickening, and/or reconditioning the skin on the soles of the feet. To do so, pressure sensor 404 may be used to ensure that a proper pressure is applied to the foot in accordance with a predefined program.

Fig. 2 illustrates a plurality of inflation bladders 200 that may be disposed within the outer casing. The bladders may be positioned within the outer casing so that the bladders only press on large muscles, since soft tissue can be more prone to developing lesions under smaller amounts of shear. The bladders may be bags formed of a plastic material having the edges sealed so as to be air tight. Each bladder may include on or more injection valves or ports 210 that allow air to enter and/or exit the bladder to inflate or deflate the bladder. Each of the inflation bladders may be independently inflated or deflated according to a patient's need and/or condition. The injection bladders 200 may include a front bladder 208 that is positioned between the front shin of a patient's leg and the inner surface of the front shell 102. The front bladder may vertically extend along the length of the vertical portion of the front shell 102.

The inflation bladders 200 may also include a rear bladder 202 that is positioned between the back of the patient's leg (i.e., the calf) and the inner surface of the rear shell 104. The rear bladder 202 may extend vertically along the length of the vertical portion of rear shell 104. The rear bladder 202 may be divided into three portions with the middle portion positioned

between the patient's calf and the inner surface of the rear shell 104 and each of the two side portions positioned between the inner surface or the rear shell 104 and the rear sides of the patient's leg.

The inflation bladders 200 may further include a right bladder and a left bladder (represented by bladder 204) that are positioned on the right and left sides of the patient's leg, respectively, between the front and/or rear shells, 102 and 104, and the patient's leg. The right and left bladders may extend vertically along the length of the vertical portion of the shells, and may also extend horizontally along the length of the horizontal portion of the shell so that the right and left bladders 204 are positioned between the sides of the patient's foot and the front and rear shells, 102 and 104.

The inflation bladders 200 may additionally include a bottom bladder 206 that is positioned between the sole of the patient's foot and the bottom shell 109. The bottom bladder 206 may be part of a skin toughening mechanism, where the bottom bladder 206 is inflated to apply a pressure to the sole of the patient's foot and thereby induce hypertrophy, thickening, and reconditioning of the skin in preparation for return to full weight bearing after prolonged use of the pneumatic cast. The pressure exerted on the sole of the patient's foot may be intermittently increased over a period of time to control hypertrophy, thickening, and/or recondition of the sole of the foot and prevent ulcers from forming. The gradual toughening of the skin on the patient's sole may help the patient re-adjust to walking without the pneumatic cast and may prevent or reduce the formation of new ulcers on the patient's foot. The bottom bladder 206 may function in cooperation with pressure sensor 404 to thicken and recondition the skin. For example, the pressure within bottom bladder 206 may be measured and maintained so that a predefined pressure is exerted on the patient's sole when the patient is not walking. Likewise, the pressure exerted by the patient's foot on sole 108 may be measured by sensor 404 when the patient is walking so that bladders 202, 204, 206, and/or 208 may be inflated or deflated to maintain the predefined pressure on the patient's sole.

As shown by bladders 202, 204, and 206, the bladders may be partitioned or divided so that separate sections of the bladder are inflatable/deflatable. For example, bladder 206 illustrates that the bottom bladder 206 may be divided into four sections that each include an injection valve or port. The pressure within each of the partitions may be controlled based in the patient's need or condition. For example, the back partition and side partitions may be inflated to thicken and recondition the skin while the front partition is deflated to heal an ulcer. In one embodiment, the bottom bladder 206 may include between 2 and 10 partitions.

The other bladders 202, 204, and 208 may likewise include partitions that each have an injection valve or port.

One or more of the bladders may also include one or more pressure sensors 220 and/or temperature sensors 222. The pressure sensor(s) 220 may measure the air pressure within the bladder directly from the bladder. The temperature sensor(s) 222 may measure the temperature within the outer casing adjacent to the sensor. This information may be provided to the logic unit 163 to monitor and control conditions within the pneumatic cast 100. For example, the temperature sensor(s) 222 may provide an early indication of the formation of an ulcer on the patient's leg and/or foot. This temperature indication of an ulcer may provide early warning of the development of an ulcer even before the ulcer is visible. Such information may be provided to a doctor or physician, via the communication device, to alert the physician or doctor of the development and location of the ulcer. In addition, the logic unit 163 may activate one or more LED indicators 116 to visually inform the patient of the development of an ulcer. Further, the logic unit 163 may recognize the onset of the ulcer and take preventative measure to reduce of reverse the formation of the ulcer, such as deflating the bladder or partition of the bladder adjacent the developing ulcer.

The bladders may also include a shear reducing material, which is illustrated by the dashes on bladder 208. The shear reducing material may reduce friction or a shear force between the patient's leg and/or foot and the pneumatic cast. For example, the shear reducing material may be positioned between the patient's tibia and the outer casing. Exemplary materials that may be used as shear reducing materials include fabrics such as polyester, nylon 6, nylon 6,6 polymers, etc. The fabrics may be inflatable air cushions so that the patient's leg and/or foot is cushioned against the air cushion. In one embodiment, the fabric is attached to the outer surface of an inflatable bladder. In another embodiment, the fabric is attached to the inner surface of the front shell without an airbag therebetween.

Turning now to Fig. 5, illustrated is a patient's lower leg and foot 500 fully enclosed within a pneumatic cast 502, such as that described above. Specifically, the figure illustrates the bladders inflated against the patient's leg and/or foot. The pneumatic cast include an air control mechanism 514, which may also include a pumping mechanism that controls and adjusts the pressure within one or more of the inflatable bladders and/or converts kinetic energy (i.e., walking with the cast) into potential energy by pressurizing air. The air control mechanism 514 may be pneumatically coupled with the bladders through a series of tubes 530. For example, Fig. 5 illustrates right side bladder 506, left side bladder 508, and rear bladder 510 pneumatically coupled with air control mechanism 514 through tubes 530.

Fig. 5 further shows the pneumatic cast having a logic unit 522 (element 522 may also represent the air reservoir and/or air control mechanism). The logic unity 522 may wirelessly receive conditions from a doctor, such as a pressure for each bladder or a command to off load the weight on the patient's foot be a certain amount. To off load the weight on the patient's foot, the logic unity 522 may output a command to the air control mechanism 514 to inflate one or more of the right side bladder 506, the left side bladder 508, the front bladder 504, and/or the rear bladder 510. In response to the command, one or more micro pumps (not shown) may activate and/or one or more solenoid valves may open to inflate one or more of the air bladders with the micro pump and/or pressurized air in an air reservoir.

One or more sensors may measure the pressure in some or all of the inflatable bladders until the specified pressure is reached, afterwhich, the logic unit 522 may shut off the micro pump and/or close the solenoid valve. The logic unit 522 may also recognize when the leg and/or foot is experiencing edema or atrophying and adjust one or more of the inflatable bladders accordingly. For example, if the diameter of the patient's leg grows due to edema, the logic unit 522 may determine that the pressure in one of the bladders (e.g., the rear bladder 510 and/or side bladder 506 and 508) is too high. In response, the logic unity 522 may generate appropriate commands to open a solenoid valve and vent air from the bladder. Such adjustment may prevent wounds from developing and/or from being further aggravated due to an over-pressurized bladder.

Similarly, if the diameter of the leg shrinks due to atrophy, the logic unit 522 may determine that the pressure in one of the bladders (e.g., the rear bladder 510 and/or side bladders 506 and 508) is too low. In response, the logic unity 522 may generate appropriate commands to activate a micro pump and/or open a solenoid valve and inflate the bladder. Such adjustment may keep the leg properly supported within the cast, thereby ensuring that the patient's body weight is off loaded from the foot.

Fig. 5 illustrates that the pneumatic cast may also include a skin toughening mechanism 520 such as an inflatable bottom bladder. The bottom bladder may be pneumatically coupled with the air control mechanism 514 so that the bottom bladder may be inflated and press against the sole of the patient's foot. The bottom bladder may be intermittently inflated over a period of time to gradually increase the pressure on the sole from no pressure to the patient's full body weight. The intermittent pressure increase or decrease in the bottom bladder may be input from a doctor or physician after an ulcer heals in order to condition the patient's foot for walking without the cast. Further, one or more pressure sensors may be used in combination with the skin toughening mechanism to vary the pressure within the

bottom bladder based on if the patient is resting or walking and putting pressure on the sole of the bottom shell. Element 512 illustrates that one or more components (e.g., the solenoid valves, micro pumps, batteries, etc.) may be housed outside of the bottom shell, such as by coupling a housing for the components to the front or rear shell and/or housing the components inside the outer cast. In one embodiment, the element 512 represents the air reservoir positioned outside the bottom shell and mounted to the front shell of the pneumatic cast. In other words, the air reservoir may be positioned outside the bottom shell to provide more room within the bottom shell for the air control mechanism, pumping mechanism, logic unit, or any other mechanism or unit.

Turning now to Fig. 6, illustrated is a control/feedback loop program 600 that may be employed in the logic unit to pressurize and/or adjust the pressure in one or more bladders. The control/feedback loop 600 may represent an iterative process for a single inflatable bladder. The process generally begins at 610 with a doctor or physician setting a pressure for each bladder that is input into the logic unit (the doctor could also set an acceptable high and low pressure for the bladder). At 606, the logic unit controls one or more micro pumps and/or valves to inflate the bladder to the prescribed pressure. As the bladder is inflating, a pressure sensor 614 measures the difference between the chamber pressure (i.e., pressure in the bladder) and the pressure set point 610 provided by the doctor. When the pressure is within a predefined threshold, the logic unit shuts off the micro pump or closes a valve.

During use of the pneumatic cast, the patient's leg and/or foot may swell or atrophy, one or more bladders may leak, the bladders may adjust within the outer casing, the patient may begin to develop ulcers, etc., which may cause the pressure within the bladder to fall below (or rise above) the level prescribed by the doctor or physician or may require that the pressure be decreased within the bladder (e.g., to reduce or reverse ulcer formation). At 608, the logic unit may recognize these environmental disturbances and changes. In response, in the case of a loss of pressure, the logic unit may activate micro pumps or solenoid valves to re-pressurize the bladder. In the case of a rise in pressure and/or the development of an ulcer, the logic unit may activate a relief valve, such as a solenoid valve, to deflate or de-pressurize the bladder.

At 602, the logic unit may check a program to see if the a pressure setting has been increased or decreased. For example, upon review of the patient's condition, a doctor may adjust the pressure within the bladder, and/or the pressure setting may change based on a predefined program, such as a program that intermittently increases or decreases the pressure to place more weight on the patient's foot and/or to induce hypertrophy, thicken, and/or recondition the skin. The iterative process of Fig. 6 may be continually repeated so that the defined

pressure is always or nearly always maintained regardless of a change in one or more conditions and so that the pneumatic cast adjusts to protect the patient when an ulcer or other problem arises.

Turning now to Fig. 7, illustrated is a method 700 of using a pneumatic cast. At block 710, a self-adaptive pneumatic cast, such as the pneumatic cast described above, may be provided (i.e., placed about a patient's foot and/or leg. At block 715, the logic unit of the cast may receive (wirelessly or wired) one or more inputs from a doctor or physician, such as a treatment program specific to the patient. For example, the doctor or physician could set a pressure level for each of the bladders within the cast and/or set a program for a bottom bladder to sequentially increase the pressure in the bottom bladder to thicken and recondition a patient's foot (i.e., cause callus regrowth).

At block 720, one or more sensors may measure the pressure within one or more of the bladders and/or may measure the temperature within the pneumatic cast. These measurements may be provided to the logic unit. At block 725, the logic unit and/or air control mechanism may adjust the pressure in one or more of the bladders to correspond with the pressure input from the doctor or physician. At block 730, the logic unit may recognize or determine one or more environmental changes (e.g., shifting of the bladders, leakage of air from the bladder, etc.) and/or may recognize or determine physical changes (e.g., edema or shrinking of the patient's leg) that result in a pressure change within one or more bladders. The changes may be recognized or determined based on pressure sensor measurements provided to the logic unit.

At block 735, the logic unit may recognize or determine the development or onset of an Ulcer or other problem within the pneumatic cast. The development of a Ulcer may be recognized or determined based upon the measurements of the temperature and/or pressure sensor. At block 740, the logic unit and/or air control mechanism may adjust the pressure within one or more of the bladders in response to the changed environmental or physical condition and/or in response to the development of an Ulcer. For example, one or more bladders may be automatically inflated if the pressure is too low or one or more bladders may be deflated if the pressure is too high or is an Ulcer is developing.

At block 745, an air reservoir may be pressurized, for example, by a pumping mechanism and/or an external air source. At block 750, a skin toughening mechanism (e.g., bottom bladder) may be intermittently or sequentially adjusted to induce hypertrophy, thicken, and/or recondition the skin on the sole of the patient's foot. The intermittent or sequential

adjustment may be based on a predefined reconditioning program that is provided by a doctor and that defines a number of pressure increases to make in a predefined time period. At block 755, the bottom shell of the pneumatic cast may be removed so that a patient, physician, and/or doctor may treat a wound on the patient's foot.

In describing the invention, certain embodiments have been used to illustrate the invention and the practices thereof. However, the invention is not limited to these specific embodiments as other embodiments and modifications within the spirit of the invention will readily occur to those skilled in the art on reading this specification. Thus, the invention is not intended to be limited to the specific embodiments disclosed, but is to be limited only by the claims appended hereto.

As used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a process" includes a plurality of such processes and reference to "the device" includes reference to one or more devices and equivalents thereof known to those skilled in the art, and so forth.

Also, the words "comprise," "comprising," "include," "including," and "includes" when used in this specification and in the following claims are intended to specify the presence of stated features, integers, components, or steps, but they do not preclude the presence or addition of one or more other features, integers, components, steps, acts, or groups.

WHAT IS CLAIMED IS:

1. A self-adjusting pneumatic cast comprising:

a front shell configured for placement on the front of a patient's leg;

a rear shell configured for placement on the back of a patient's leg;

a locking mechanism that couples the front shell and the back shell to form an outer casing around the patient's leg to enclose at least a portion of the patient leg within the outer casing;

a bottom shell removably coupled with a bottom portion of the outer casing, wherein removal of the bottom shell provides access to a patient's foot enclosed within the outer casing;

a plurality of inflatable bladders disposed within the outer casing;

a plurality of sensors disposed within the outer casing and configured to measure an air pressure within each of the plurality of inflatable bladders;

a control mechanism pneumatically coupled with the plurality of inflatable bladders and communicatively coupled with the plurality of sensors, wherein the control mechanism is configured to adjust the air pressure within at least one of the inflatable bladders based on the air pressure measurement within the at least one of the inflatable bladders; and

a skin toughening mechanism positioned adjacent the bottom shell and configured to toughen at least a portion of the sole of the patient's foot.

2. The self-adjusting pneumatic cast as in claim 1, wherein the locking mechanism is not unlockable by the patient fitted with the self-adjusting pneumatic cast.

3. A pneumatic cast comprising:

a first shell;

a second shell coupled with the first shell to form an outer casing enclosing at least a portion of a patient's leg therein;

at least one inflatable bladder disposed within the outer casing;

at least one sensor disposed within the outer casing and configured to measure an air pressure of the at least one inflatable bladder; and

a control mechanism communicatively coupled with the at least one sensor, wherein the control mechanism is configured to adjust the air pressure within the at least one inflatable bladder based on the air pressure measurement of the at least one inflatable bladder.

4. The pneumatic cast as in claim 3, further comprising a third shell removably coupled with a bottom potion of the outer casing to provide access to the patient's foot enclosed within the outer casing.

5. The pneumatic cast as in claim 3, further comprising at least one temperature sensor disposed within the outer casing and configured to measure the temperature of a portion of the patient's leg.

6. The pneumatic cast as in claim 4, wherein the third shell comprises a top portion and a bottom portion coupled with the top portion, wherein the top portion and the bottom portion define a chamber that houses the control mechanism.

7. The pneumatic cast as in claim 4, further comprising an additional pressure sensor positioned adjacent the third shell and configured to measure a pressure exerted by the patient's foot on the third shell.

8. The pneumatic cast as in claim 3, wherein the control mechanism is configured to incrementally increase or decrease the air pressure within the at least one inflatable bladder one or more times over a predefined period.

9. The pneumatic cast as in claim 4, further comprising a skin toughening mechanism disposed between the third shell and the patient's foot, wherein the skin toughening mechanism is configured to toughen the sole of the patient's foot.

10. The pneumatic cast as in claim 9, wherein the skin toughening mechanism comprises an inflatable bladder, and wherein inflation of the inflatable bladder exerts a pressure on the sole of the patient's foot.

11. The pneumatic cast as in claim 4, further comprising a pumping mechanism operatively coupled with the third shell and configured to inflate the inflatable bladder from the movement of the pneumatic cast.

12. The pneumatic cast as in claim 11, further comprising an air reservoir pneumatically coupled to the pumping mechanism and the at least one inflatable bladder, wherein the air reservoir is pressurized by the pumping mechanism, and wherein the air reservoir inflates the at least one inflatable bladder.

13. The pneumatic cast as in claim 3, wherein the control mechanism adjusts the air pressure within the at least one inflatable bladder based on an edema or an atrophy of the leg.

14. The pneumatic cast as in claim 3, further comprising a shear reducing material disposed between the first shell and the patient's leg to reduce friction on the patient's leg.

15. A method of adjusting a pneumatic cast comprising:

providing a pneumatic cast comprising:

a first shell;

a second shell coupled with the first shell to form an outer casing enclosing at least a portion of a patient's leg therein;

at least one inflatable bladder disposed within the outer casing;

at least one sensor disposed within the outer casing and configured to measure an air pressure of the at least one inflatable bladder; and

a control mechanism communicatively coupled with the at least one sensor, wherein the control mechanism is configured to adjust the air pressure within the at least one inflatable bladder based on the air pressure measurement of the at least one inflatable bladder;

measuring with the sensor, an air pressure of the at least one inflatable bladder;

communicating the air pressure measurement to the control mechanism; and

adjusting with the control mechanism, the air pressure within the inflatable bladder based on the air pressure measurement.

16. The method as in claim 15, wherein the pneumatic cast further comprises a third shell removably coupled with a bottom potion of the outer casing to provide access to the patient's foot enclosed within the outer casing.

17. The method as in claim 16, further comprising removing the third shell from the bottom portion of the outer casing, and treating the patient's foot.

18. The method as in claim 15, further comprising:

pressurizing an air reservoir with a pumping mechanism, wherein the pumping mechanism pressurizes the air reservoir through movement of the pneumatic cast; and

inflating the at least one inflatable bladder from the pressurized air in the air reservoir.

19. The method as in claim 15, further comprising:

measuring with a temperature sensor, a temperature within the pneumatic cast;

communicating the temperature measurement to the control mechanism; and

adjusting with the control mechanism, the air pressure within the at least one inflatable bladder based on the temperature measurement.

20. The method as in claim 15, further comprising incrementally increasing a pressure exerted on the bottom of the patient's foot to toughen the skin on the sole of the patient's foot.

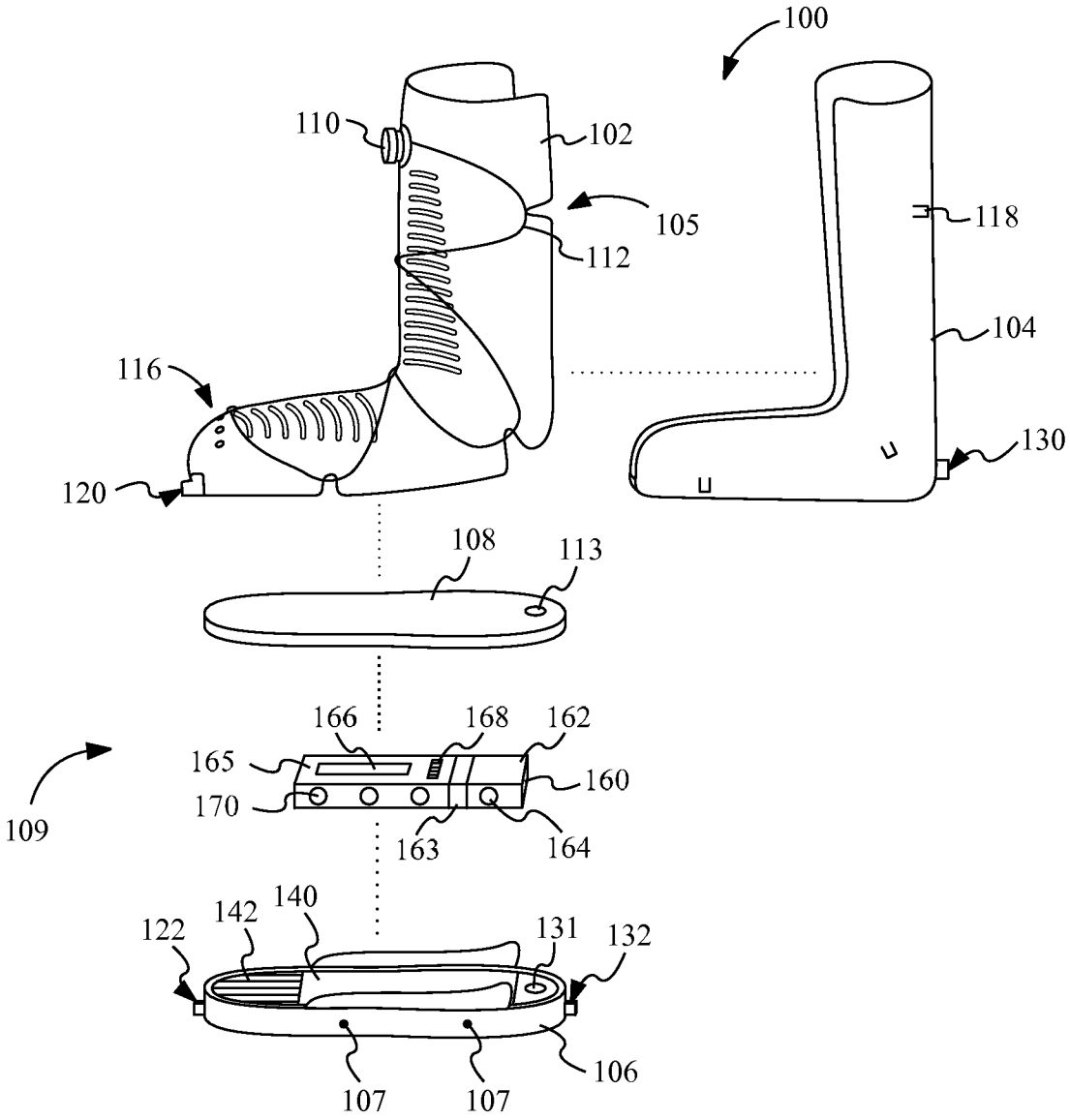

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Fig. 1

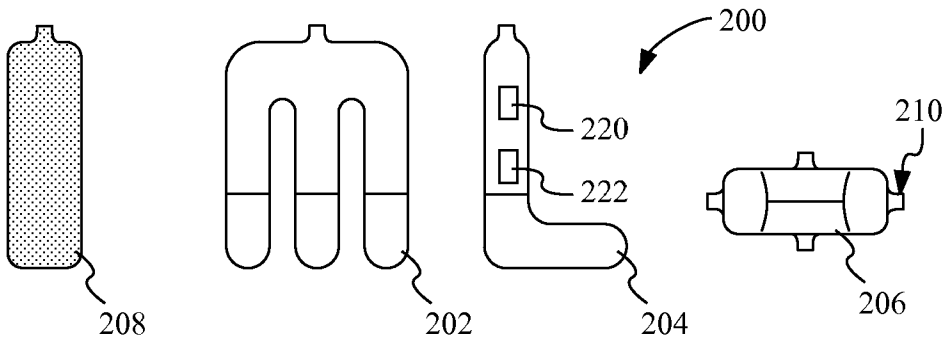

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Fig. 2

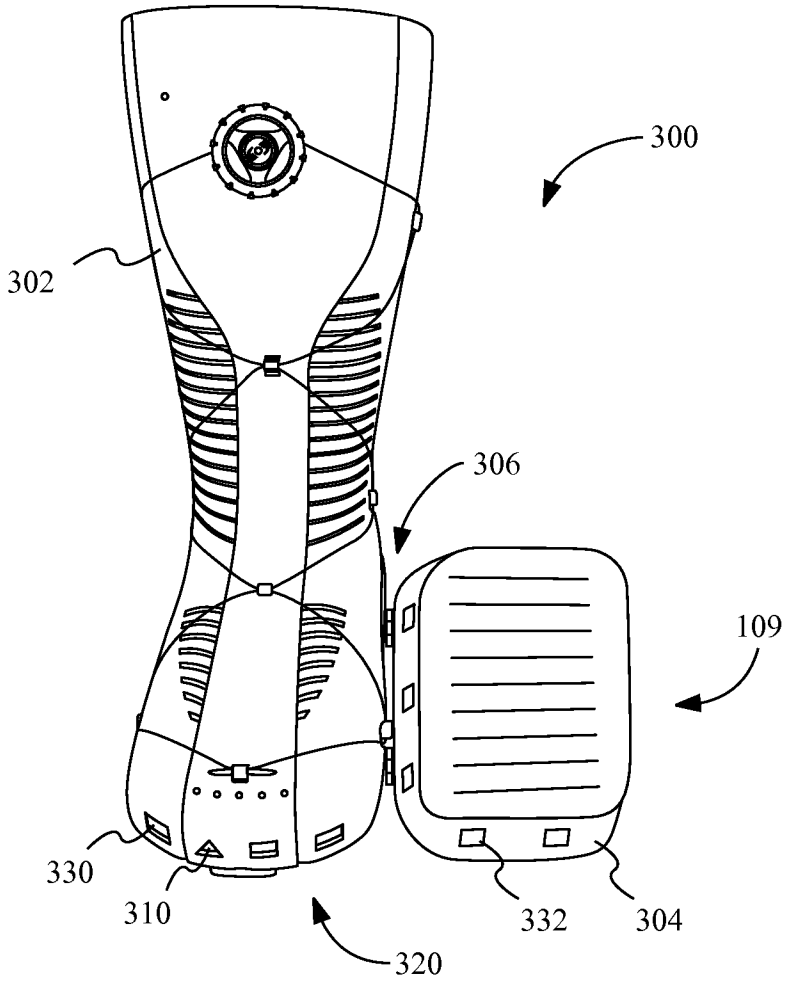


Fig. 3

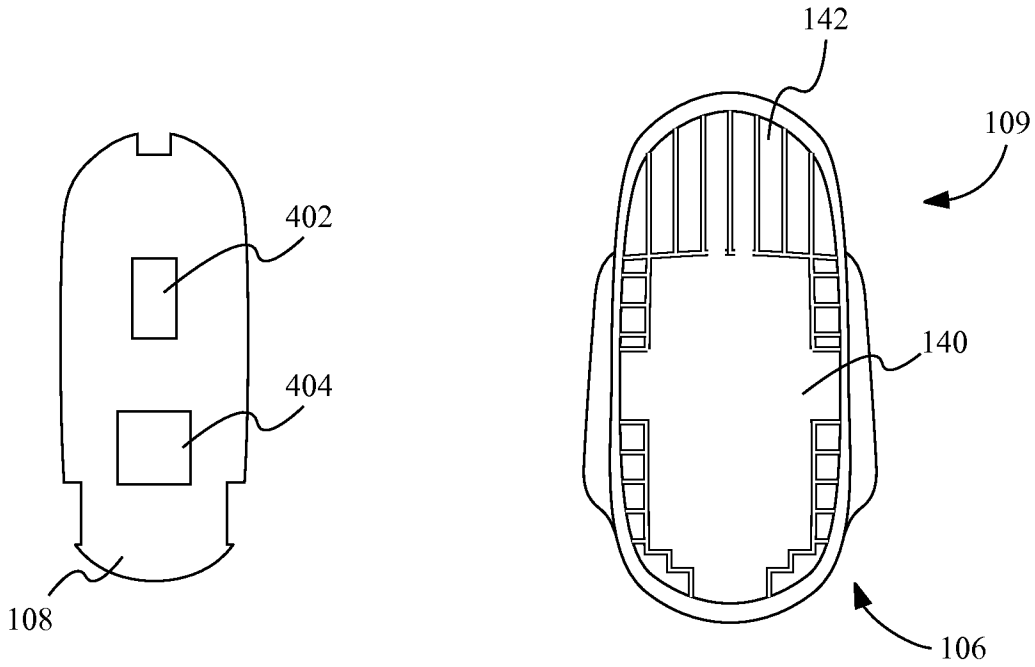


Fig. 4

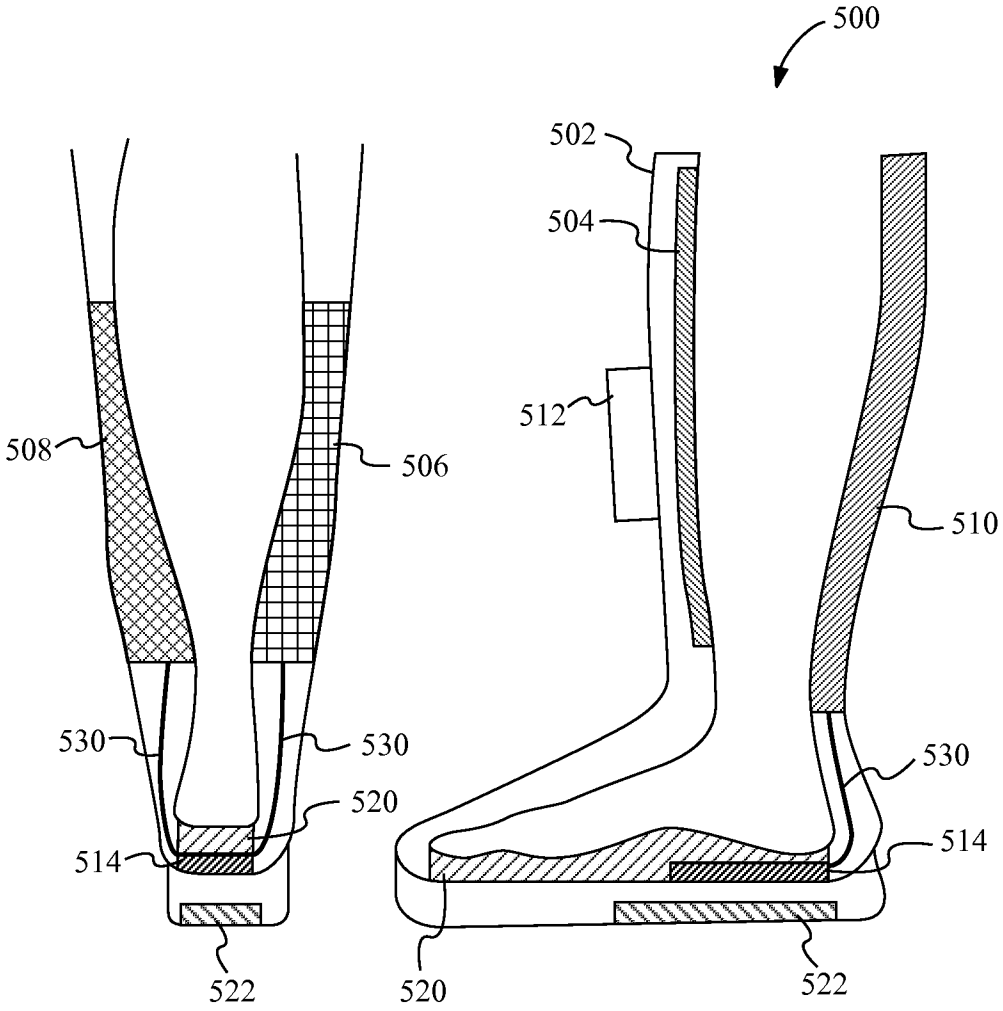

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Fig. 5

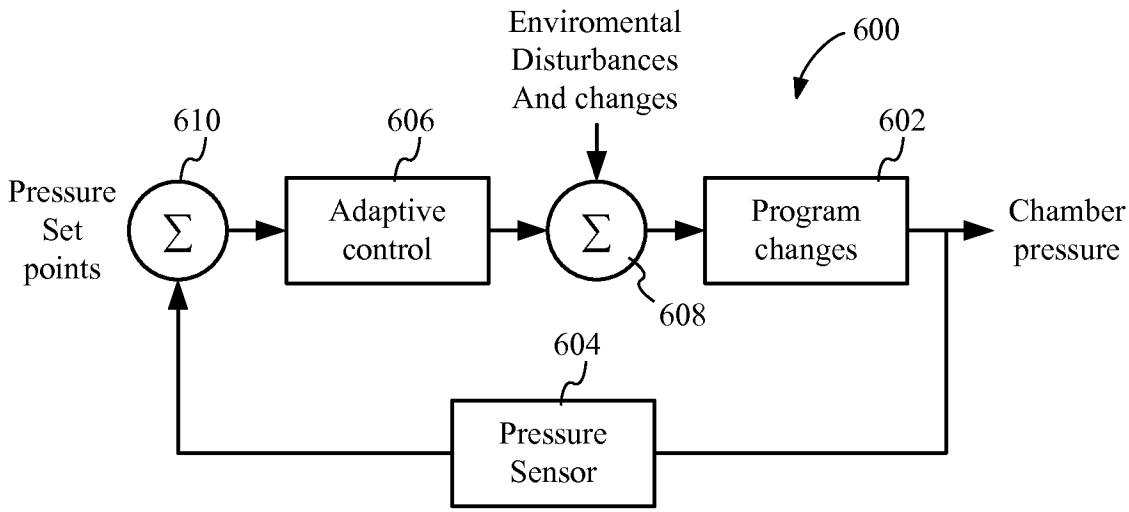

Enviromental
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Fig. 6

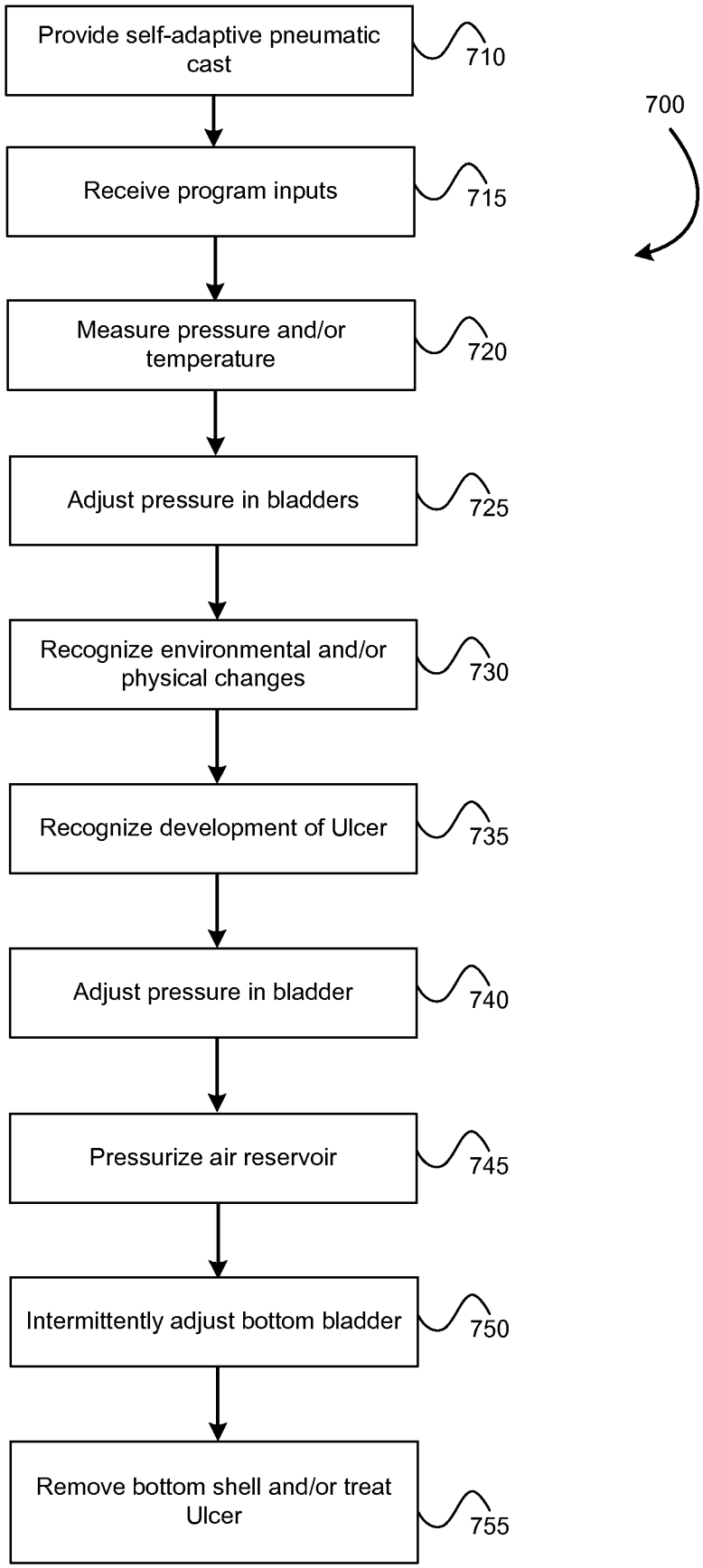

Provide self-adaptive pneumatic cast
710
700
Receive program inputs
715
Measure pressure and/or temperature
720
Adjust pressure in bladders
725
Recognize environmental and/or physical changes
730
Recognize development of Ulcer
735
Adjust pressure in bladder
740
Pressurize air reservoir
745
Intermittently adjust bottom bladder
750
Remove bottom shell and/or treat Ulcer
755

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/062250

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 5/04 (2011.01)
USPC - 264/222
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 5/04 (2011.01)
USPC - 36/43, 44; 264/222, 223, 275, 320; 602/6, 13, 23, 27

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)
MicroPatent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,078,128 A (GRIM et al) 07 January 1992 (07.01.1992) entire document	1-6, 8-20
Y	US 6,708,708 B2 (WINGERT et al) 23 March 2004 (23.03.2004) entire document	1-6, 8-20
Y	US 7,334,350 B2 (ELLIS III) 26 February 2008 (26.02.2008) entire document	1, 2, 9, 10, 20
Y	US 5,399,152 A (HABERMEYER et al) 21 March 1995 (21.03.1995) entire document	2
Y	US 6,840,955 B2 (EIN) 11 January 2005 (11.01.2005) entire document	5, 19
A	US 5,813,142 A (DEMON) 29 September 1998 (29.09.1998) entire document	1-6, 8-20

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 February 2011	15 MAR 2011
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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