COMPRESSION GARMENT COMPLIANCE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from U.S. Provisional Patent Application Serial No. 62/239,566, filed October 9, 2015, entitled "Compression Garment Compliance," U.S. Provisional Patent Application Serial No. 62/239,527, filed October 9, 2015, entitled "Determining a Configuration of a Compression Garment," U.S. Provisional Patent Application Serial No. 62/239,493, filed October 9, 2015, entitled "Determining a Configuration of a Compression Garment," and U.S. Provisional Patent Application Serial No. 62/329,233, filed April 29, 2016, entitled "Determining a Configuration of a Compression Garment." The entire contents of the above-identified applications are expressly incorporated herein by reference, including the contents and teachings of any references contained therein.

BACKGROUND

[0002] Intermittent pneumatic compression (IPC) systems include devices used to apply pressurized fluid, such as air, to a limb of a patient or wearer. In some instances, pressurized air is applied to the lower limb of a patient at risk for the formation of deep vein thrombosis (DVT). An IPC system typically includes a pumping unit to manage pressurization of the fluid, a tubing set to extend the delivery of fluid beyond the pumping unit, and a compression garment which is wrapped around the patient's limb and contains the pressurized fluid. The IPC system intermittently pressurizes the garment to apply therapeutic compression to the patient's limb, moving blood from that area of the limb. The effectiveness of such IPC systems for DVT prophylaxis, however, depends on the patient’s adherence to a prescribed treatment protocol including the IPC system.

SUMMARY

[0002a] In a first aspect, the present disclosure refers to a compression device controller for monitoring the compliance of a user with respect to wearing a compression device, the controller comprising: a memory device configured for storing one or more monitored parameters; one or more processors coupled to the memory device; and computer-executable instructions embodied on a computer readable storage medium, the computer-executable instructions including instructions for causing the one or more processors to: direct a flow of fluid from a pressurized fluid flow source to inflate and deflate at least one inflatable bladder of

a compression garment configured to be wrapped around a limb of a wearer of the garment; receive first pressure signals indicative of fluid pressure in the at least one inflatable bladder from a pressure sensor communicatively coupled thereto during at least one of inflation and deflation of the at least one inflatable bladder in a first compression cycle; receive second pressure signals indicative of fluid pressure in the at least one inflatable bladder from the pressure sensor communicatively coupled thereto during at least one of inflation and deflation of the at least one inflatable bladder in a second compression cycle; process the received first and second pressure signals; detect a variance between the first pressure signals and the second pressure signals, the variance therein indicative of a change in condition of the compression garment; change a state of at least one of the monitored parameters in the memory device in response to detecting the variance, wherein the changed state of the monitored parameter is representative of the change in condition of the compression garment; and wherein the changed state of the monitored parameter is selected from a group consisting of the garment being wrapped around the limb of the wearer of the garment, and the garment not being wrapped around the limb of the wearer of the garment.

[0002b] In another aspect, the present disclosure refers to a computer-implemented method for monitoring the compliance of a user with respect to wearing a compression device, the system comprising: controlling, by computer-executable instructions executing on one or more processors, a pressurized fluid flow source through a cycle of operation in which at least one inflatable bladder of a compression garment configured to be wrapped around a limb of a patient is inflated and deflated; receiving, by the one or more processors executing instructions therefor, first pressure signals indicative of fluid pressure in the at least one inflatable bladder from a pressure sensor communicatively coupled thereto during at least one of inflation and deflation of the at least one inflatable bladder in a first compression cycle; receiving, by the one or more processors executing instructions therefor, second pressure signals indicative of fluid pressure in the at least one inflatable bladder from the pressure sensor communicatively coupled thereto during at least one of inflation and deflation of the at least one inflatable bladder in a second compression cycle; detecting, by computer-executable instructions executing on the one or more processors, a variance between the first pressure signals and the second pressure signals, the variance in the received pressure signals indicative of a change in condition of the compression garment during the inflation and deflation of the at least one inflatable bladder; and changing, by computer-executable instructions executing on the one or more processors, a state of at least one monitored parameter stored in a memory device in response to detecting the

variance, wherein the memory device is coupled to the one or more processors, and wherein the changed state of the monitored parameter is representative of a change in condition of the compression garment; wherein the changed state of the monitored parameter is selected from a group consisting of the garment being wrapped around the limb of the wearer of the garment, and the garment not being wrapped around the limb of the wearer of the garment.

[0002c] In another aspect, the present disclosure refers to a system for monitoring the compliance of a user with respect to wearing a compression device, the system comprising: a compression garment including at least one inflatable and deflatable bladder, the compression garment securable about a limb of a wearer; and a controller comprising: a memory device configured for storing one or more monitored parameters; one or more processors coupled to the memory device; and computer-executable instructions embodied on a computer readable storage medium, the computer-executable instructions including instructions for causing the one or more processors to: direct a flow of fluid from a pressurized fluid flow source to inflate and deflate the bladder of the compression garment; receive first pressure signals indicative of fluid pressure in the bladder from a pressure sensor communicatively coupled thereto during at least one of inflation and deflation of the at least one inflatable bladder in a first compression cycle; receive second pressure signals indicative of fluid pressure in the at least one inflatable bladder from the pressure sensor communicatively coupled thereto during at least one of inflation and deflation of the at least one inflatable bladder in a second compression cycle; process the received first and second pressure signals; detect a variance between the first pressure signals and the second pressure signals, the variance therein indicative of a change in condition of the compression garment; and change a state of at least one of the monitored parameters in the memory device in response to detecting the variance, wherein the changed state of the monitored parameter is representative of the change in condition of the compression garment; wherein the changed state of the monitored parameter is selected from a group consisting of the compression garment being secured around the limb of the wearer, and the compression garment not being secured around the limb of the wearer.

[0003] In an example, the present disclosure is directed to systems and methods of monitoring a wearer's compliance with a compression treatment regimen for use of a compression system. In another example, the present disclosure is directed to systems and methods of determining whether a compression garment is applied to a limb of a wearer.

[0004] In one example, a compression device controller includes a memory device, one or more processors coupled to the memory device, and computer-executable instructions

embodied on a computer readable storage medium. The memory device is configured for storing monitored parameters. The computer-executable instructions include instructions for causing

the one or more processors to direct the flow of fluid from a pressurized fluid flow source to inflate and deflate an inflatable bladder of a compression garment. The compression garment is configured to be wrapped around a limb of a wearer of the garment. Also included are instructions for causing the one or more processors to receive pressure signals indicative of fluid pressure in the inflatable bladder from a pressure sensor communicatively coupled to the bladder. The one or more processors, when caused by the instructions, process the received pressure signals during at least one of inflation and deflation of the inflatable bladder. The pressure signals are used to detect variance in the signals indicative of a change in condition of the compression garment. The instructions also cause the one or more processors to change a state of at least one of the monitored parameters in the memory device in response to detecting variance in the received pressure signals. The changed state of the monitored parameter is representative of the change in condition of the compression garment.

[0005] In another example, a computer-implemented method includes computer-executable instructions executing on one or more processors controlling a pressurized fluid flow source through a cycle of operation in which at least one inflatable bladder of a compression garment configured to be wrapped around a limb of a patient is inflated and deflated. The one or more processors receive pressure signals indicative of fluid pressure in the bladder from a pressure sensor communicatively coupled to the bladder. Computer-executable instructions executing on the one or more processors detect variance in the received pressure signals indicative of a change in condition of the compression garment during the inflation and deflation of the bladder. Computer-executable instructions executing on the one or more processors also change a state of at least one monitored parameter stored in a memory device in response to detecting variance in the received pressure signals. The memory device is coupled to the one or more processors and the changed state of the monitored parameter is representative of the change in condition of the compression garment.

[0006] In yet another example, a system includes a compression garment and a controller. The compression garment includes at least one inflatable and deflatable bladder and is securable about a limb of a wearer. The controller includes a memory device, one or more processors coupled to the memory device, and computer-executable instructions embodied on a computer readable storage medium. The memory device is configured for storing monitored parameters. The computer-executable instructions include instructions for causing the one or

more processors to direct the flow of fluid from a pressurized fluid flow source to inflate and deflate the bladder of the compression garment. Also included are instructions for causing the one or

WHAT IS CLAIMED IS:

1. A compression device controller for monitoring the compliance of a user with respect to wearing a compression device, the controller comprising:

a memory device configured for storing one or more monitored parameters;

one or more processors coupled to the memory device; and

computer-executable instructions embodied on a computer readable storage medium, the computer-executable instructions including instructions for causing the one or more processors to:

direct a flow of fluid from a pressurized fluid flow source to inflate and deflate at least one inflatable bladder of a compression garment configured to be wrapped around a limb of a wearer of the garment;

receive first pressure signals indicative of fluid pressure in the at least one inflatable bladder from a pressure sensor communicatively coupled thereto during at least one of inflation and deflation of the at least one inflatable bladder in a first compression cycle;

receive second pressure signals indicative of fluid pressure in the at least one inflatable bladder from the pressure sensor communicatively coupled thereto during at least one of inflation and deflation of the at least one inflatable bladder in a second compression cycle;

process the received first and second pressure signals; detect a variance between the first pressure signals and the second pressure signals, the variance therein indicative of a change in condition of the compression garment; and

change a state of at least one of the monitored parameters in the memory device in response to detecting the variance, wherein the changed state of the monitored parameter is representative of the change in condition of the compression garment;

wherein the changed state of the monitored parameter is selected from a group consisting of the garment being wrapped around the limb of the wearer of the garment, and the garment not being wrapped around the limb of the wearer of the garment.

2. The compression device controller of claim 1, wherein the instructions for causing the one or more processors to change the state of at least one of the monitored parameters include instructions to one of increment a compliance timer and pause the compliance timer.

3. The compression device controller of claim 1, the computer executable instructions including instructions for causing the one or more processors to:

in response to the detected variance, verify the change in condition of the compression garment using at least one confirmatory analysis over subsequent cycles of inflation and deflation of the at least one inflatable bladder; and

based at least in part on the results of the at least one confirmatory analysis, change the state of the monitored parameter,

wherein changing the state of the monitored parameter comprises one of ceasing to increment a timer representative of the time the wearer is in compliance with the compression therapy regimen and starting to increment the timer.

4. The compression device controller of claim 1, the computer-executable instructions including instructions for causing the one or more processors to actuate a vent valve to maintain a non-therapeutic pressure in the at least one bladder.

5. The compression device controller of claim 1, wherein the variance is an oscillating amplitude as a function of time representative of a pulse of the wearer of the compression garment.

6. The compression device controller of claim 5, wherein the instructions to receive first and second pressure signals indicative of fluid pressure in the at least one inflatable bladder include instructions to receive the first and second pressure signals indicative of fluid pressure while the at least one inflatable bladder is inflated to a non-therapeutic pressure.

7. The compression device controller of claim 5, wherein the instructions to process the received first and second pressure signals include instructions to:

band-pass filter the received first and second pressure signals to extract frequencies of 0.5 Hz to about 5 Hz;

low-pass filter the band-pass filtered signals at a frequency of 5 Hz or under;

time-slice the low-pass filtered signals into a plurality of sample groups; and

detect an anomaly comprising at least a portion of the low-pass filtered signals within one or more of the plurality of sample groups by calculating a standard deviation of the plurality of sample groups as a whole and calculating a standard deviation of each sample group.

8. The compression device controller of claim 7, wherein the instructions to process the received first and second pressure signals include instructions to detect peaks in the low-pass filtered signals in a frequency range of 0.5 Hz to 3.5 Hz.

9. A computer-implemented method for monitoring the compliance of a user with respect to wearing a compression device, the system comprising:

controlling, by computer-executable instructions executing on one or more processors, a pressurized fluid flow source through a cycle of operation in which at least one inflatable bladder of a compression garment configured to be wrapped around a limb of a patient is inflated and deflated;

receiving, by the one or more processors executing instructions therefor, first pressure signals indicative of fluid pressure in the at least one inflatable bladder from a pressure sensor communicatively coupled thereto during at least one of inflation and deflation of the at least one inflatable bladder in a first compression cycle;

receiving, by the one or more processors executing instructions therefor, second pressure signals indicative of fluid pressure in the at least one inflatable bladder from the pressure sensor communicatively coupled thereto during at least one of inflation and deflation of the at least one inflatable bladder in a second compression cycle;

detecting, by computer-executable instructions executing on the one or more processors, a variance between the first pressure signals and the second pressure signals, the variance in the received pressure signals indicative of a change in condition of the compression garment during the inflation and deflation of the at least one inflatable bladder; and

changing, by computer-executable instructions executing on the one or more processors, a state of at least one monitored parameter stored in a memory device in response to detecting the variance, wherein the memory device is coupled to the one or more processors, and wherein the changed state of the monitored parameter is representative of a change in condition of the compression garment;

wherein the changed state of the monitored parameter is selected from a group consisting of the garment being wrapped around the limb of the wearer of the garment, and the garment not being wrapped around the limb of the wearer of the garment.

10. The method of claim 9, wherein changing the state of the at least one of the monitored parameters comprises at least one of incrementing and pausing a compliance timer.

11. The method of claim 9, further comprising:

verifying, by computer executable instructions executing on the one or more processors, the change in condition of the compression garment using at least one confirmatory analysis over subsequent cycles of inflation and deflation of the at least one inflatable bladder, wherein said verifying is performed in response to the detected variance; and

changing, by the computer-executable instructions executing on the one or more processors, the state of the monitored parameter based at least in part on the results of the at least one confirmatory analysis.

12. The method of claim 9, wherein the variance is one of a pressure rise and a pressure impulse, the method further comprising indicating, by computer executable instructions executing on the one or more processors, whether the compression garment is worn by the patient.

13. The method of claim 12, further comprising actuating, by the one or more processors executing instructions therefor, a vent valve to maintain a non-therapeutic pressure in the at least one inflatable bladder.

14. The method of claim 9, wherein the variance is an oscillating amplitude as a function of time representative of a pulse of the patient.

15. The method of claim 14, wherein said detecting variance in the received first and second pressure signals comprises:

band-pass filtering, by the computer-executable instructions executing on the one or more processors, the received first and second pressure signals to extract frequencies of 0.5 Hz to 5 Hz;

low-pass filtering, by the computer-executable instructions executing on the one or more processors, the band-pass filtered signals at a frequency of 5 Hz or under;

time-slicing, by the computer-executable instructions executing on the one or more processors, the low-pass filtered signals into a plurality of sample groups;

detecting, by the computer-executable instructions executing on the one or more processors, an anomaly comprising at least a portion of the low-pass filtered signals within one or more of the plurality of sample groups by calculating a standard deviation of the plurality of sample groups as a whole and calculating a standard deviation of each sample group; and

detecting, by the computer-executable instructions executing on the one or more processors, one or more peaks in the low-pass filtered signals in a frequency range of 0.5 Hz to 3.5 Hz.

16. The method of claim 14, wherein said receiving first and second pressure signals indicative of fluid pressure in the bladder comprises receiving the first and second pressure signals while the at least one inflatable bladder is inflated to a non-therapeutic pressure.

17. A system for monitoring the compliance of a user with respect to wearing a compression device, the system comprising:

a compression garment including at least one inflatable and deflatable bladder, the compression garment securable about a limb of a wearer; and

a controller comprising:

a memory device configured for storing one or more monitored parameters;

one or more processors coupled to the memory device; and

computer-executable instructions embodied on a computer readable storage medium, the computer-executable instructions including instructions for causing the one or more processors to:

direct a flow of fluid from a pressurized fluid flow source to inflate and deflate the bladder of the compression garment;

receive first pressure signals indicative of fluid pressure in the bladder from a pressure sensor communicatively coupled thereto during at least one of inflation and deflation of the at least one inflatable bladder in a first compression cycle;

receive second pressure signals indicative of fluid pressure in the at least one inflatable bladder from the pressure sensor communicatively coupled thereto during at

least one of inflation and deflation of the at least one inflatable bladder in a second compression cycle;

process the received first and second pressure signals;

detect a variance between the first pressure signals and the second pressure signals, the variance therein indicative of a change in condition of the compression garment; and

change a state of at least one of the monitored parameters in the memory device in response to detecting the variance, wherein the changed state of the monitored parameter is representative of the change in condition of the compression garment;

wherein the changed state of the monitored parameter is selected from a group consisting of the compression garment being secured around the limb of the wearer, and the compression garment not being secured around the limb of the wearer.

18. The system of claim 17, further comprising:

at least one valve,

wherein the at least one valve is in fluid communication with the pump and the bladder,

wherein the at least one valve is in electrical communication with the controller, and

wherein the computer-executable instructions include instructions for causing the one or more processors to actuate the at least one valve to control fluid communication between the pump and the bladder.

19. The system of claim 17, wherein the pressurized fluid flow source is in electrical communication with the controller, and wherein the computer-executable instructions include instructions for causing the one or more processors to adjust a speed of the pump based at least in part on the detected variance in the pressure signals.

20. The system of claim 17, wherein the at least one inflatable bladder extends around a circumference of the limb of the wearer when secured about the limb of the wearer.