SYSTEM AND METHOD FOR DETERMINING A FILL STATUS OF A CANISTER OF FLUID IN A REDUCED PRESSURE TREATMENT SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates generally to medical devices and more specifically to detection methods and systems for determining a fill status of a canister of fluid used with medical devices.

2. Description of Related Art

[0002] The treatment of open wounds and sores such as decubitis ulcers and those ulcers found on the feet of diabetics is problematic. Proper treatment of such wounds which are frequently infected with bacterial pathogens is multifactorial. Surgery is usually required to remove dead and necrotic tissue. Antibiotics are used to inhibit the growth or kill the pathogenic bacteria, if possible. At the same time, proper nutrition is necessary to maintain the health status of the patient and more importantly, proper wound care is essential to healing of the wound or sore.

[0003] Proper wound care requires keeping the wound clean and dry. When the wound is infected, the underlying tissue expresses serous fluids and possibly a purulent exudate, both of which have to be removed to promote wound healing. Traditional methods of removing the aforementioned fluids required a mechanical scrubbing of the wound and drying of the wound with sponges. This procedure is not only painful for the patient but also increases the possibility of superinfection of the wound by bacteria introduced into the wound during treatment.

[0004] An alternative to this mechanical scrubbing of the open wound is a negative pressure wound closure device. This negative pressure wound closure device consists of a foam pad which is placed over the wound to form a relatively air tight and leak proof seal around the wound. The negative pressure wound closure device also has a vacuum pump fluidly coupled to the pad which is seated over the patient's wound. When the vacuum pump is activated, a negative pressure is created inside the pad covering the wound. The fluids expressed by the wound are removed through the foam pad by the negative pressure and transported through a tube connecting the foam pad to a canister. The canister collects the

fluids removed from the wound. When the canister is full of fluid removed from the wound, the canister is emptied and reengaged to the vacuum system. Attempts have been made to alert the user when the canister is full of wound fluid. These methods have been aimed at directly measuring the amount of wound fluid in the canister.

[0005] However, existing methods of directly measuring the amount of wound fluid in the canister have proved unreliable because, generally, the wound fluid is viscous. The fluid also frequently foams, bubbles, and traps air, which may result in the fluid not settling to the bottom of the canister. There remains a need in the art for a reliable system and method to alert the user when the canister for collection of wound fluid is full and in need of emptying.

SUMMARY OF THE INVENTION

[0006] The problems with existing canister detection systems are solved by the systems and method of the present invention. In accordance with one embodiment of the present invention, a method for detecting a fill status of a canister of fluid in a tissue treatment system is provided. The method includes creating a reduced pressure in a fluid communication path of the tissue treatment system and applying the reduced pressure to a tissue site. Fluid is collected from the tissue site in the canister. The reduced pressure is released, and a decay of the reduced pressure is measured. A fill status of the canister is determined from the measured decay.

[0007] In another embodiment of the present invention, a reduced pressure treatment system includes a canister fluidly connected to a tissue site and configured to receive fluid drawn from the tissue site under the influence of a reduced pressure. A reduced pressure source is configured to provide the reduced pressure and is fluidly connected to the tissue site by a fluid communication path. The fluid communication path includes a source conduit, the canister, and a target conduit. The canister is positioned between the reduced pressure source and the tissue site and is fluidly connected to the reduced pressure source by the source conduit. The canister is also fluidly connected to the tissue site by the target conduit. The reduced pressure treatment system further includes a sensing device in communication with the source conduit and configured to sense a pressure in the source conduit. A valve is provided in communication with the source conduit to selectively vent the reduced pressure. A processing unit is in communication with the sensing device and the valve. The processing unit is configured to open the valve for a selected amount of time, receive sensing data from

the sensing device during the selected amount of time to determine a decay of reduced pressure, and determine a fill status of the canister based on the decay of reduced pressure.

[0008] In still another embodiment of the present invention, a reduced pressure treatment system includes a reduced pressure source to provide a reduced pressure. A porous pad is positioned at the tissue site and is fluidly connected to the reduced pressure source. A canister is fluidly connected between the porous pad and the reduced pressure source to collect fluid drawn from the tissue site. The system further includes a solenoid valve that is fluidly connected to a conduit between the canister and the reduced pressure source. Means is provided for determining a pressure decay in the conduit when the solenoid valve is opened.

[0009] Other objects, features, and advantages of the present invention will become apparent with reference to the drawings and detailed description that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Figure 1 depicts a reduced pressure treatment system having full canister detection capabilities according to an embodiment of the present invention;

[0011] Figure 2 depicts a block diagram of a processing unit of the reduced pressure treatment system of FIG. 1;

[0012] Figure 3 depicts a graphical representation of the results of a test conducted with a system employing a full canister detection method according to an illustrative embodiment of the present invention;

[0013] Figure 4 depicts a graphical representation of the results of a test conducted with a system employing a full canister detection method according to an illustrative embodiment of the present invention;

[0014] Figure 5 depicts a graphical representation of the results of a test conducted with a system employing a full canister detection method according to an illustrative embodiment of the present invention; and

[0015] Figure 6 depicts a graphical representation of the results of a test conducted with a system employing a full canister detection method according to an illustrative embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0016] In the following detailed description of the illustrative embodiments, reference is made to the accompanying drawings that form a part hereof. The invention may be practiced using these illustrative embodiments. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention. Other embodiments may be utilized, and that logical, structural, mechanical, electrical, and chemical changes may be made without departing from the spirit or scope of the illustrative embodiments. To avoid detail not necessary to enable those skilled in the art to practice the invention, the description may omit certain information known to those skilled in the art. Therefore, the following detailed description should not be taken as limiting. The scope of the illustrative embodiments is defined by the appended claims.

[0017] The term "reduced pressure" as used herein generally refers to a pressure less than the ambient pressure at a tissue site that is being subjected to treatment. In most cases, this reduced pressure will be less than the atmospheric pressure at which the patient is located. Although the terms "vacuum" and "negative pressure" may be used to describe the pressure applied to the tissue site, the actual pressure applied to the tissue site may be significantly less than the pressure normally associated with a complete vacuum. Consistent with this nomenclature, an increase in reduced pressure or vacuum pressure refers to a relative reduction of absolute pressure, while a decrease in reduced pressure or vacuum pressure refers to a relative increase of absolute pressure.

[0018] The term "tissue site" as used herein refers to a wound or defect located on or within any tissue, including but not limited to, bone tissue, adipose tissue, muscle tissue, dermal tissue, vascular tissue, connective tissue, cartilage, tendons, or ligaments. The term "tissue site" may further refer to areas of any tissue that are not necessarily wounded or defective, but are instead areas in which it is desired to add or promote the growth of additional tissue. For example, reduced pressure tissue treatment may be used in certain tissue areas to grow additional tissue that may be harvested and transplanted to another tissue location.

[0019] Referring to FIG. 1, a reduced pressure treatment system 11 includes a porous pad 20, or other distribution manifold positioned at a tissue site 15. The porous pad 20 is fluidly connected to a canister 17 by a target conduit 21. A reduced pressure source 19 is fluidly connected to the canister 17 by a source conduit 24. In operation, the reduced pressure source 19 delivers a reduced pressure to the tissue site through a fluid communication path,

which is collectively comprised of the source conduit 24, the canister 17, and the target conduit 21.

[0020] A solenoid or other suitable valve 18 is fitted to the source conduit 24 and serves to release the reduced pressure within the fluid communication path to the atmosphere when opened. The solenoid valve 10 may communicate with and be controlled by a processing unit 26, which is described in more detail below. The processing unit 26 may further communicate with a sensing device 28 that is used to determine a pressure in source conduit 24.

[0021] The reduced pressure treatment system 11 is capable of reliably determining the fill status of a canister (i.e. whether the canister is full or not full of fluid). The system 11 relies on the volume of the fluid communication path being fixed and thus, relief of the vacuum from this known volume should occur within a set time after the valve 18 is opened. When the processing unit 26 detects a blockage within the fluid communication path by any reliable blockage detection method, the processing unit 26 signals the valve 18 to open for a selected amount of time (e.g. 1 second) to vent the reduced pressure from the fluid communication path to atmosphere. The processing unit 26 receives sensing data from the sensing device 28 and monitors the pressure decay over this 1 second period. If the pressure decays quickly, then processing unit 26 determines that the canister 17 is full as the volume of the chamber being vented is small. Accordingly, the processing unit 26 will signal an alarm if a canister full status is determined.

[0022] If the decay is slow, which is to say that in the 1 second period that the solenoid valve 18 is opened, the vacuum does not decay to a pre-determined level, the processing unit 26 will conclude that the canister 17 is not full. The processing unit will then assume that the blockage condition originally detected is caused by an actual blockage in the target conduit 21 and not a canister full condition. The processing unit 26 in this particular instance may signal a separate alarm to indicate the presence of a blockage. Preferably, the alarms used to notify a user of a canister full of wound fluid and a blockage in the target conduit 21 through which the wound fluid flows are separate and distinct.

[0023] The decay of the reduced pressure may be determined in several ways. For example, the decay may be determined by measuring a reduction in the reduced pressure (i.e. increase in absolute pressure) over a selected amount of time after opening valve 18. As another example, the decay may be determined by measuring the amount of time that is required for the reduced pressure to drop to a threshold pressure. The decay in reduced pressure may also be determined by measuring the reduction in the flow rate in the source

conduit 24 over the selected amount of time after opening valve 18. Other methods of measuring the decay of reduced pressure may also be used in a similar manner and are contemplated within the scope of the illustrative embodiments.

[0024] Additional components may be employed together with the illustrative embodiments to better determine the fill status of canister 17. For example, the target conduit 21 connecting canister 17 to the porous pad 20, through which wound fluids flow, may include optional valve 25. Closing valve 25 at the time of venting to atmosphere through valve 18 may indicate the volume within the canister that is empty. Deducing from this indication of empty volume and knowing the geometry of the canister, one may determine the level of fluid in the canister, and also may determine fluid flow rate from the tissue site 15 if periodically monitored.

[0025] Referring still to FIG. 1, but also to FIG. 2, the processing unit 26 may be contained within a therapy unit housing 40 that may also house the reduced pressure source 19, the sensing device 28, and the valve 18. The processing unit 26 may be configured with one or more processors that are the same or different types. For example, the processing unit 26 may include one or more processors, logic, analog components, or any other electronics that enable signals including information, such as fluid pressure at various locations in the system to be received.

[0026] The processing unit 26 executes software 208 and may further be in communication with (i) a memory 210 for storing data and software code, (ii) an input/output (I/O) unit 218 for communicating with other devices and systems, such as a valves or sensing devices, wirelessly, via a wire, or via a memory input device, (iii) a storage unit 222 that may store one or more data repositories 226a-226n (collectively 226), such as a database having one or more files, (iv) an electronic display 234 that may or may not be touch-sensitive, and (v) one or more alarms 238 that are capable of signaling a user of the reduced pressure treatment system using audio, visual, or other signals. The software 208 may be configured to interface with each of the other devices (e.g., electronic display 234) to allow management and observation of the reduced pressure treatment.

[0027] TEST DATA

[0028] With reference to FIG. 3, this figure depicts a graphical representation of the results of a test conducted with a system similar to reduced pressure treatment system 11. In this test, variation in decay time was noted against fill level at 125 mmHg for a closed canister. The canister was filled with various levels of water from empty to 500 ml in 50 ml increments. Negative pressure for the wound therapy was set to 125 mmHg and the system run until the

pump stopped at slightly over the target pressure. Therapy was then turned off and natural leakage was applied to bring the pressure down to 125 mmHg. At this point, the valve was operated to vent the canister to atmosphere. The pressure profile was recorded at 10 samples per second. The same test was also conducted with a standard large wound attached to the system and resulted in the graphs of FIG. 6.

[0029] Referring to Figure 4, this figure depicts a graphical representation of the results of a test in which differences in decay times between full and nearly full canisters at various pressures with large wound were observed. A standard large wound foam and dressing was prepared on a plastic base and fitted with a reduced pressure delivery pad to allow a syringe to inject liquid so as to fill the canister and cause a blockage alarm. Two sets of curves were plotted at therapy pressures of 50 to 400 mmHg, one at 450ml fluid level and one with a canister filled by wound drainage until a blockage alarm occurred. The 450ml value was chosen because as high a fill level as possible was required for the specific canister used, consistent with no blockage alarm occurring. This situation was contemplated to be the worst case scenario with the understanding that if the system could differentiate between the two situations at a high level, it would only be easier as the level is reduced.

[0030] The canister was filled to 450ml and a pressure slightly above the target pressure was acquired. The vacuum pump was turned off and as leakage brought the pressure down to the target level, the vent valve was opened as described above. For the blocked family of curves, the canister was filled by injecting water into the wound and running under normal therapy conditions. Results of this test are shown in FIG. 4.

[0031] With reference to FIG. 5, this figure depicts a graphical representation of the results of a test in which decay differences between full and other fluid levels at 350mmHg with a large wound were observed. A standard large wound was prepared as in the test of figures 3 and 4 and pressure curves plotted at 350mmHg for fluid levels from empty to 500 ml, filling externally. This procedure was done under direct control as in the tests described above. The system was run under normal therapy at 200 mmHg and fluid injected into the wound until a blockage alarm occurred. Direct control was resumed at 350 mmHg and the last curve plotted.

[0032] TEST CONCLUSIONS

[0033] The plots obtained with a closed canister in Figure 3 show good linearity between the fill level and the time for the pressure to fall to both zero and 5 mmHg. There is some cross-over in the early stages of the decay, but the trend of the plots appears to indicate that decay time is approximately proportional to fill level.

[0034] The results depicted in Figure 3 were for a closed canister. Additional work as reflected in Figure 6 revealed that when a wound is attached, the cross-over effect is considerably reduced.

[0035] The graph in Figure 4 indicates that there is distinct grouping in the data. With a full canister when filter occlusion had occurred, the pressure fell to under 10 mmHg in less than 0.8 seconds, irrespective of the therapy pressure. When the canister is approximately full but occlusion had not occurred, the time to 10 mmHg was three seconds or more. The differential may have improved if the time to a percentage of initial rather than to an absolute pressure were measured.

[0036] Figure 5 confirms that the decay times for all fill levels from empty to 500ml take a substantial time to fall to near-zero levels from 350 mmHg. The fastest decay rate (500ml) fell to about 20 mmHg after four seconds and was still around 10 mmHg after 10 seconds. By comparison, the blocked curve fell to virtually zero (under 3mmHg) in less than a second.

[0037] The system and method disclosed in the instant application improves upon existing negative pressure treatment systems by reliably alerting the user of the system that the wound fluid canister is full and may have to be emptied. By releasing the pressure in the fluid communication path through a valve, the systems and methods disclosed herein are able to measure the decay of the negative pressure. If the negative pressure inside the fluid communication path decays rapidly, then the system determines that the canister is full and activates an alarm notifying the user that the canister is full of wound fluid. If the negative pressure inside the fluid communication path decays slowly, then the system determines that there is a blockage in the system that should be removed and notifies the user by activating an alarm.

[0038] Even though many of the examples discussed herein are applications of the present invention in the medical field of treatment of wounds, the present invention also can be applied to other types of negative pressure applications including but not limited to suction and fluid collection devices for other medical and non-medical uses.

[0039] One skilled in the art will see that the present invention can be applied in many areas where there is a need to provide an indication of a fill status of a container containing any substance. It should be apparent from the foregoing that an invention having significant advantages has been provided. While the invention is shown in only a few of its forms, it is not just limited but is susceptible to various changes and modifications without departing from the spirit thereof.

CLAIMS

We claim:

1. A method for detecting a fill status of a canister of fluid in a tissue treatment system, the method comprising:

   creating a reduced pressure in a fluid communication path of the tissue treatment system;

   applying the reduced pressure to a tissue site;

   collecting fluid from the tissue site in the canister;

   releasing the reduced pressure;

   measuring a decay of the reduced pressure as the reduced pressure is released; and

   determining from the measured decay a fill status of the canister.

2. The method of claim 1, wherein the reduced pressure is released in at least a portion of the fluid communication path.

3. The method of claim 1, wherein the fill status indicates that the canister is full or is not full.

4. The method of claim 1, wherein measuring the decay further comprises:

   setting a pressure threshold below the reduced pressure;

   upon release of the reduced pressure, measuring the time for the canister to attain the pressure threshold; and

   determining the fill status of the canister based on the measured time.

5. The method of claim 1, wherein releasing the reduced pressure and measuring the decay further comprises:

   releasing the reduced pressure for a selected amount of time;

   measuring a pressure attained within the at least a portion of the fluid communication path following the selected amount of time; and

   determining the fill status of the canister based on the pressure attained.

6. The method of claim 1, wherein releasing the reduced pressure and measuring the decay further comprises:

releasing the reduced pressure for a selected amount of time;

measuring a flow rate from the fluid communication path during the reduced pressure release; and

determining a fill status of the canister based on the flow rate.

7. The method of claim 1, wherein determining a fill status includes determining a fill level.

8. The method of claim 1 further comprising:

if the fill level of the canister indicates a full canister, alerting a user that the canister is full.

9. The method of claim 1, wherein the fluid communication path includes the canister, a source conduit fluidly connecting the canister to a reduced pressure source, and a target conduit fluidly connecting the canister to the tissue site.

10. A reduced pressure treatment system comprising:

a canister fluidly connected to a tissue site and configured to receive fluid drawn from the tissue site under the influence of a reduced pressure;

a reduced pressure source configured to provide the reduced pressure and fluidly connected to the tissue site by a fluid communication path, the fluid communication path including a source conduit, the canister, and a target conduit, the canister being positioned between the reduced pressure source and the tissue site and being fluidly connected to the reduced pressure source by the source conduit, the canister further being fluidly connected to the tissue site by the target conduit;

a sensing device in communication with the source conduit and configured to sense a pressure in the source conduit;

a valve in communication with the source conduit and configured to vent the reduced pressure; and

a processing unit in communication with the sensing device and the valve and configured to:

open the valve for a selected amount of time;

receive sensing data from the sensing device during the selected amount of time to determine a decay of reduced pressure; and

determine a fill status of the canister based on the decay of reduced pressure.

11. The system of claim 10, wherein the fill status indicates that the canister is full or is not full.

12. The system of claim 10, wherein:

the valve selectively vents the reduced pressure from at least a portion of the fluid communication path; and

the decay of reduced pressure is determined in the at least a portion f the fluid communication path.

13. The system of claim 10, wherein the processing unit is further configured to:

upon opening the valve, determine the time required for the canister to attain a pressure threshold; and

determine the fill status of the canister using the time.

14. The system of claim 10, wherein the processing unit is further configured to:

determine a pressure attained within the fluid communication path following the selected amount of time, and

determining the fill status of the canister based on the pressure attained.

15. The system of claim 10, wherein the processing unit is further configured to determine whether a blockage exists in the fluid communication path:

16. The system of claim 10 further comprising:

a second valve fluidly coupled to the target conduit and configured to close when the first valve is open.

17. The system of claim 16, wherein the first valve and the second valve comprise electrically or mechanically-actuated valves.

18. The system of claim 10 further comprising:

an alarm in communication with the processing unit and configured to alert a user when the canister is full.

19. A reduced pressure treatment system having full canister detection capabilities, the system comprising:

a reduced pressure source to provide a reduced pressure;

a porous pad positioned at the tissue site and fluidly connected to the reduced pressure source;

a canister fluidly connected between the porous pad and the reduced pressure source to collect fluid drawn from the tissue site;

a solenoid valve fluidly connected to a conduit between the canister and the reduced pressure source; and

means for determining a pressure decay in the conduit when the solenoid valve is opened.

20. The system as defined in Claim 19, wherein the means for determining a pressure decay further comprises a flow sensor in communication with the conduit.

21. The system as defined in Claim 19, wherein the means for determining a pressure decay further comprises a pressure sensor in communication with the conduit.

22. The system as defined in Claim 19, wherein the means for determining a pressure decay further comprises a timer to measure an amount of time it takes for pressure in the conduit to reach a selected pressure threshold.

23. The system as defined in Claim 19 further comprising means to activate an alarm in response to the pressure decay being determined to indicate a full canister condition.