(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 February 2015 (19.02.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/023515 A1

(51) International Patent Classification:
A61M 1/00 (2006.01) *A61F 13/02* (2006.01)

(21) International Application Number:
PCT/US2014/050233

(22) International Filing Date:
7 August 2014 (07.08.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/865,516 13 August 2013 (13.08.2013) US

(71) Applicant: **SMITH & NEPHEW, INC.** [US/US]; 1450 Brooks Road, Memphis, TN 38116 (US).

(72) Inventors: **JAECKLEIN, William, Joseph**; c/o Smith & Nephew, Inc., 970 Lake Carillon Dr., #110, Saint Petersburg, FL 33716 (US). **QUINTANAR, Felix, C.**; c/o Smith & Nephew, Inc., 970 Lake Carillon Dr., #110, Saint Petersburg, FL 33716 (US).

(74) Agent: **ALTMAN, Daniel, E.**; Knobbe, Martens, Olson & Bear, LLP, 2040 Main Street, 14th Floor, Irvine, CA 92614 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,

[Continued on next page]

(54) Title: SYSTEMS AND METHODS FOR APPLYING REDUCED PRESSURE THERAPY

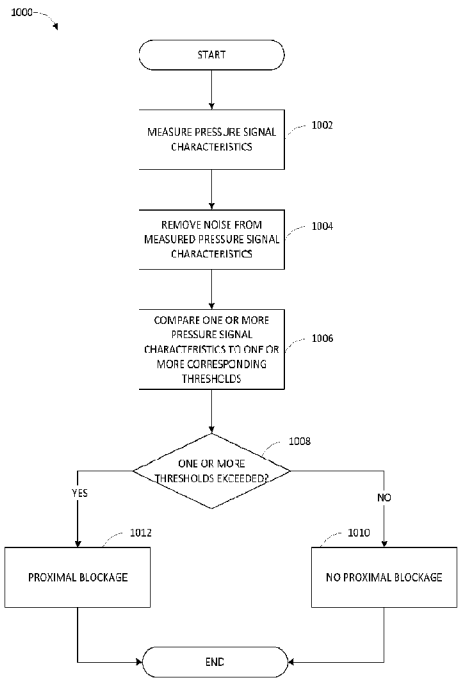

FIG. 10

(57) Abstract: Embodiments of negative pressure wound therapy apparatuses and methods for using such apparatuses are disclosed. In some embodiments, a negative pressure wound therapy apparatus includes a controller configured to determine a level of exudate in a canister (or a dressing) based at least in part on one or more characteristics of pressure signals generated by a negative pressure source and monitored by a pressure sensor. One such characteristic of the pressure signals can be amplitude, which may increase as a level of exudate in the canister (or dressing) increases. The canister (or dressing) can include a filter configured to become occluded in order to prevent overflow of the canister (or dressing). The controller can be additionally configured to detect and indicate a canister (or dressing) pre-full condition before the filter becomes occluded. More efficient and reliable operation of the negative pressure wound therapy apparatus can thereby be attained.

WO 2015/023515 A1

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

SYSTEMS AND METHODS FOR APPLYING REDUCED PRESSURE THERAPY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/865,516, filed on August 13, 2013, the disclosure of which is hereby incorporated by reference in its entirety.

BACKGROUND

Field

[0002] Embodiments of the present disclosure relate to methods and apparatuses for dressing and treating a wound with reduced pressure therapy or topical negative pressure (TNP) therapy. In particular, but without limitation, embodiments disclosed herein relate to negative pressure therapy devices, methods for controlling the operation of TNP systems, and methods of using TNP systems.

Description of the Related Art

[0003] Embodiments of the present disclosure relate to methods and apparatuses for dressing and treating a wound with reduced pressure therapy or topical negative pressure (TNP) therapy. In particular, but without limitation, embodiments disclosed herein relate to negative pressure therapy devices, methods for controlling the operation of TNP systems, and method of using TNP systems. In addition, embodiments disclosed herein relate to attachment mechanisms or systems for negative pressure therapy devices.

SUMMARY

[0004] In some embodiments, a negative pressure wound therapy apparatus includes a negative pressure source configured to be in fluid communication with a wound dressing, the negative pressure source configured to provide negative pressure to the wound, a canister configured to be in fluid communication with the dressing and the negative pressure source, the canister configured to collect exudate removed from the wound, and a pressure sensor configured to monitor one or more characteristics of pressure signals generated by the negative pressure source. The apparatus also includes a controller

configured to determine a level of exudate in the canister based at least in part on the measured one or more characteristics of the pressure signals.

[0005] The apparatus of the preceding paragraph may also include any combination of the following features described in this paragraph, among others described herein. The measured one or more characteristics of the pressure signals can include magnitude of the pressure signals, and the magnitude of the pressure signals can increase as the level of exudate in the canister increases. The canister can include a filter configured to become occluded in order to prevent overflow of the canister and the controller can be further configured to detect a canister pre-full condition before the filter becomes occluded. The controller can also provide an indication of the canister pre-full condition to a user. The controller can be configured to determine the level of exudate in the canister based at least in part on the measured one or more characteristics of the pressure signals and a measured activity level of the negative pressure source. The negative pressure source can include a vacuum pump and the activity level of the negative pressure source corresponds to a speed of the vacuum pump. The apparatus can include a tachometer configured to measure the speed of the vacuum pump.

[0006] The apparatus of any of the preceding paragraphs may also include any combination of the following features described in this paragraph, among others described herein. The apparatus can include a fluid flow path configured to fluidically connect the dressing, the canister, and the negative pressure source, and the controller can be further configured to determine a leak rate of fluid in the flow path based at least in part on the activity level of the negative pressure source and determine the level of exudate in the canister based at least in part on the measured one or more characteristics of the pressure signals and the determined leak rate. The controller can be configured to remove noise from the measured one or more characteristics of the pressure signals. The controller can be configured to determine the level of exudate in the canister based at least in part on comparing the measured one or more characteristics of the pressure signals to one or more thresholds. The measured one or more characteristics can include magnitude and frequency of pressure pulses and the controller can be configured to determine the level of exudate in the canister based at least in part on the magnitude and frequency of the pressure signals. The magnitude of the pressure signals can increase as the level of exudate in the canister

increases and the frequency of the pressure signals can decrease as the level of exudate in the canister increases.

[0007] The apparatus of any of the preceding paragraphs may also include any combination of the following features described in this paragraph, among others described herein. The controller can be configured to determine the level of exudate in the canister irrespective of an intensity of a leak present in a fluid flow path configured to fluidically connect the dressing, the canister, and the negative pressure source. The controller can be configured to determine the level of exudate in the canister based at least in part on a change in the measured one or more characteristics of the pressure signals. The apparatus can include a wound dressing configured to be placed over a wound.

[0008] In certain embodiments, a method of operating a negative pressure wound therapy apparatus includes monitoring pressure signals generated by a negative pressure source in fluid communication with a wound dressing and a canister and determining a level of aspirated exudate in the canister based at least in part on one or more characteristics of the monitored pressure signals.

[0009] The method of the preceding paragraph may also include any combination of the following features described in this paragraph, among others described herein. One or more characteristics of the monitored pressure signals can include magnitude of the pressure signals, and the magnitude of the pressure signals can increase as the level of exudate in the canister increases. The canister can include a filter configured to become occluded in order to prevent overflow of the canister and the method can further include detecting a canister pre-full condition before the filter becomes occluded. An indication of the canister pre-full condition can be provided to a user. The method can include measuring activity level of the negative pressure source and determining the level of exudate in the canister based at least in part on the one or more characteristics of the monitored pressure signals and the measured activity level. The negative pressure source can include a vacuum pump and the activity level of the negative pressure source corresponds to a speed of the vacuum pump. A tachometer can used to measure the speed of the vacuum pump. The method can include determining a leak rate of fluid in a flow path based at least in part on the activity level of the negative pressure source and determining the level of exudate in the canister based at least in part on the one or more characteristics of the monitored pressure signals and the determined

leak rate. The fluid flow path can fluidically connect a dressing placed over a wound, the negative pressure source, and the canister.

[0010] The method of any of the preceding paragraphs may also include any combination of the following features described in this paragraph, among others described herein. The method can include removing noise from the pressure signal measurements. The method can include determining the level of exudate in the canister based at least in part on comparing the one or more characteristics of the monitored pressure signals to one or more thresholds. The one or more characteristics of the monitored pressure signals can include magnitude and frequency of the pressure signals and the method can further include determining the level of exudate in the canister based at least in part on the magnitude and the frequency of the monitored pressure signals. The magnitude of the pressure signals can increase as the level of exudate in the canister increases and the frequency of the pressure signals can decrease as the level of exudate in the canister increases. Determining the level of aspirated exudate in the canister is performed irrespective of an intensity of a leak present in a fluid flow fluidically connecting the dressing, the canister, and the negative pressure source. The method can include determining the level of exudate in the canister based at least in part on a change in the one or more characteristics of the monitored pressure signals.

[0011] In various embodiments, a negative pressure wound therapy apparatus includes a dressing configured to be placed over a wound, the dressing configured to collect exudate removed from the wound, a negative pressure source configured to be in fluid communication with the dressing, the negative pressure source configured to provide negative pressure to the wound, and a pressure sensor configured to monitor one or more characteristics of pressure signals generated by the negative pressure source. The apparatus also includes a controller configured to determine a level of exudate in the dressing based at least in part on the monitored one or more characteristics of the pressure signals.

[0012] The apparatus of any of the preceding paragraphs may also include any combination of the following features described in this paragraph, among others described herein. The monitored one or more characteristics of the pressure signals can include magnitude of the pressure signals, and the magnitude of the pressure signals can increase as the level of exudate in the dressing increases. The dressing can include a filter configured to become occluded in order to prevent overflow and the controller can be further configured to

detect a dressing pre-full condition before the filter becomes occluded and provide an indication of the dressing pre-full condition to a user. The controller can be further configured to determine the level of exudate in the dressing based at least in part on the monitored one or more characteristics of the pressure signals and a measured activity level of the negative pressure source. The apparatus can further include a fluid flow path configured to fludicially connect the dressing and the negative pressure source and the controller can be further configured to determine a leak rate of fluid in the flow path based at least in part on the activity level of the negative pressure source and to determine the level of exudate in the dressing based at least in part on the monitored one or more characteristics of the pressure signals and the determined leak rate.

[0013] The apparatus of any of the preceding paragraphs may also include any combination of the following features described in this paragraph, among others described herein. The controller can be configured to determine the level of exudate in the dressing based at least in part on comparing the monitored one or more characteristics of the pressure signals to one or more thresholds The monitored one or more characteristics of the pressure signals can include magnitude and frequency of the pressure signals and the controller can be further configured to determine the level of exudate in the dressing based at least in part on the magnitude and the frequency of the pressure signals. The magnitude of the pressure signals can increase as the level of exudate in the dressing increases and the frequency of the pressure signals can decrease as the level of exudate in the dressing increases. The controller can be configured to determine the level of exudate in the dressing irrespective of an intensity of a leak present in a fluid flow path configured to fluidically connect the dressing and negative pressure source. The controller can be configured to determine the level of exudate in the dressing based at least in part on a change in the monitored one or more characteristics of the pressure signals.

[0014] In some embodiments, a method of operating a negative wound therapy apparatus includes monitoring pressure signals generated by a negative pressure source in fluid communication with a wound dressing and a canister and determining a level of aspirated exudate in the dressing based at least in part on one or more characteristics of the monitored pressure signals.

[0015] The method of any of the preceding paragraphs may also include any combination of the following features described in this paragraph, among others described herein. The monitored one or more characteristics of the pressure signals include magnitude of the pressure signals, and wherein the magnitude of the pressure signals increases as the level of exudate in the dressing increases. The dressing can include a filter configured to become occluded in order to prevent overflow and the method can further include detecting a dressing pre-full condition before the filter becomes occluded and providing an indication of the dressing pre-full condition to a use. The method can further include measuring activity level of the negative pressure source and determining the level of exudate in the dressing based at least in part on the monitored one or more characteristics of the pressure signals and the measured activity level.

[0016] The method of any of the preceding paragraphs may also include any combination of the following features described in this paragraph, among others described herein. The method can include determining a leak rate of fluid in the flow path based at least in part on the activity level of the negative pressure source, the fluid flow path fludicially connecting the dressing and the negative pressure source and determining the level of exudate in the dressing based at least in part on the monitored one or more characteristics of the pressure signals and the determined leak rate. The method can include determining the level of exudate in the dressing based at least in part on comparing the monitored one or more characteristics of the pressure signals to one or more thresholds. The monitored one or more characteristics of the pressure signals can include magnitude and frequency of the pressure signals and the method can further include determining the level of exudate in the dressing based at least in part on the magnitude and the frequency of the pressure signals. The magnitude of the pressure signals can increase as the level of exudate in the dressing increases and the frequency of the pressure signals can decrease as the level of exudate in the dressing increases. The method can further include determining the level of exudate in the dressing irrespective of an intensity of a leak present in a fluid flow path fluidically connecting the dressing and negative pressure source.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Embodiments of the present invention will now be described hereinafter, by way of example only, with reference to the accompanying drawings in which:

[0018] Figure 1 illustrates a reduced pressure wound therapy system according to some embodiments.

[0019] Figures 2A-2E illustrate a pump assembly and canister according to some embodiments.

[0020] Figure 3 illustrates fluid flow paths according to some embodiments.

[0021] Figure 4 illustrates a graph of pressure signals according to some embodiments.

[0022] Figures 5A-5D illustrate graphs of pressure signals according to some embodiments.

[0023] Figures 6A-6D illustrate graphs of pressure signals according to some embodiments.

[0024] Figures 7A-7D illustrate graphs of pressure signals according to some embodiments.

[0025] Figures 8A-8D illustrate graphs of pressure signals according to some embodiments.

[0026] Figure 9 illustrates sensed pressure magnitude ripple according to some embodiments.

[0027] Figure 10 illustrates a process of detecting proximal blockages according to some embodiments.

DETAILED DESCRIPTION

Overview

[0028] Embodiments disclosed herein relate to systems and methods of treating a wound with reduced pressure. As is used herein, reduced or negative pressure levels, such as –X mmHg, represent pressure levels relative to normal ambient atmospheric pressure, which can correspond to 760 mmHg (or 1 atm, 29.93 inHg, 101.325 kPa, 14.696 psi, etc.). Accordingly, a negative pressure value of –X mmHg reflects absolute pressure that is X mmHg below 760 mmHg or, in other words, an absolute pressure of (760–X) mmHg. In

addition, negative pressure that is "less" or "smaller" than X mmHg corresponds to pressure that is closer to atmospheric pressure (e.g., –40 mmHg is less than –60 mmHg). Negative pressure that is "more" or "greater" than –X mmHg corresponds to pressure that is further from atmospheric pressure (e.g., –80 mmHg is more than –60 mmHg). In some embodiments, local ambient atmospheric pressure is used as a reference point, and such local atmospheric pressure may not necessarily be, for example, 760 mmHg.

[0029] Embodiments of the present invention are generally applicable to use in topical negative pressure ("TNP") or reduced pressure therapy systems. Briefly, negative pressure wound therapy assists in the closure and healing of many forms of "hard to heal" wounds by reducing tissue oedema, encouraging blood flow and granular tissue formation, and/or removing excess exudate and can reduce bacterial load (and thus infection risk). In addition, the therapy allows for less disturbance of a wound leading to more rapid healing. TNP therapy systems can also assist in the healing of surgically closed wounds by removing fluid. In some embodiments, TNP therapy helps to stabilize the tissue in the apposed position of closure. A further beneficial use of TNP therapy can be found in grafts and flaps where removal of excess fluid is important and close proximity of the graft to tissue is required in order to ensure tissue viability.

[0030] In some embodiments, a negative pressure wound therapy apparatus includes a dressing configured to be placed over a wound and a source of negative pressure configured to be in fluid communication with the dressing. The source of negative pressure is configured to provide negative pressure to the wound. The apparatus can also include a canister configured to collect exudate removed from the wound. The canister can be configured to be in fluid communication with the dressing and the negative pressure source. The apparatus also includes a pressure sensor configured to monitor pressure signals generated by the negative pressure source and a controller. The controller can be configured to determine a level of exudate in the canister (or in the dressing) based at least in part on one or more characteristics of the monitored pressure signals. The one or more characteristics of the pressure signals can change as a level of exudate in the canister increases.

[0031] In various embodiments, a method of operating a negative pressure wound therapy apparatus includes monitoring pressure signals generated by a negative pressure source in fluid communication with a dressing and a canister. The method also includes

determining a level of exudate in the canister (or in the dressing) based at least in part on one or more characteristics of the monitored pressure signals. The one or more characteristics of the pressure signals can change as a level of exudate in the canister increases.

[0032] In some embodiments, systems and methods for determining an amount of flow restriction or reduced volume in front of a negative pressure utilize one or more characteristics of monitored pressure signals. For example, the magnitude of the pressure signals can increase as restriction to flow increase, which effectively reduces the volume in front of a negative pressure source. The volume in front of the negative pressure source may decrease due to filling of a canister or dressing with exudate removed from a wound.

Negative Pressure System

[0033] Figure 1 illustrates an embodiment of a negative or reduced pressure wound treatment (or TNP) system 100 comprising a wound filler 130 placed inside a wound cavity 110, the wound cavity sealed by a wound cover 120. The wound filler 130 in combination with the wound cover 120 can be referred to as wound dressing. A single or multi lumen tube or conduit 140 is connected the wound cover 120 with a pump assembly 150 configured to supply reduced pressure. The wound cover 120 can be in fluidic communication with the wound cavity 110. In any of the system embodiments disclosed herein, as in the embodiment illustrated in Figure 1, the pump assembly can be a canisterless pump assembly (meaning that exudate is collected in the wound dressing is transferred via tube 140 for collection to another location). However, any of the pump assembly embodiments disclosed herein can be configured to include or support a canister. Additionally, in any of the system embodiments disclosed herein, any of the pump assembly embodiments can be mounted to or supported by the dressing, or adjacent to the dressing. The wound filler 130 can be any suitable type, such as hydrophilic or hydrophobic foam, gauze, inflatable bag, and so on. The wound filler 130 can be conformable to the wound cavity 110 such that it substantially fills the cavity at atmospheric pressure, and also may have a substantially reduced compressed volume when under negative pressure. The wound cover 120 can provide a substantially fluid impermeable seal over the wound cavity 110. In some embodiments, the wound cover 120 has a top side and a bottom side, and the bottom side adhesively (or in any other suitable manner) seals with wound cavity 110. The conduit

140 or any other conduit disclosed herein can be formed from polyurethane, PVC, nylon, polyethylene, silicone, or any other suitable material.

[0034] Some embodiments of the wound cover 120 can have a port (not shown) configured to receive an end of the conduit 140. In some embodiments, the conduit 140 can otherwise pass through and/or under the wound cover 120 to supply reduced pressure to the wound cavity 110 so as to maintain a desired level of reduced pressure in the wound cavity. The conduit 140 can be any suitable article configured to provide at least a substantially sealed fluid flow pathway between the pump assembly 150 and the wound cover 120, so as to supply the reduced pressure provided by the pump assembly 150 to wound cavity 110.

[0035] The wound cover 120 and the wound filler 130 can be provided as a single article or an integrated single unit. In some embodiments, no wound filler is provided and the wound cover by itself may be considered the wound dressing. The wound dressing may then be connected, via the conduit 140, to a source of negative pressure, such as the pump assembly 150. In some embodiments, though not required, the pump assembly 150 can be miniaturized and portable, although larger conventional pumps such can also be used.

[0036] The wound cover 120 can be located over a wound site to be treated. The wound cover 120 can form a substantially sealed cavity or enclosure over the wound site. In some embodiments, the wound cover 120 can be configured to have a film having a high water vapour permeability to enable the evaporation of surplus fluid, and can have a superabsorbing material contained therein to safely absorb wound exudate. It will be appreciated that throughout this specification reference is made to a wound. In this sense it is to be understood that the term wound is to be broadly construed and encompasses open and closed wounds in which skin is torn, cut or punctured or where trauma causes a contusion, or any other surficial or other conditions or imperfections on the skin of a patient or otherwise that benefit from reduced pressure treatment. A wound is thus broadly defined as any damaged region of tissue where fluid may or may not be produced. Examples of such wounds include, but are not limited to, acute wounds, chronic wounds, surgical incisions and other incisions, subacute and dehisced wounds, traumatic wounds, flaps and skin grafts, lacerations, abrasions, contusions, burns, diabetic ulcers, pressure ulcers, stoma, surgical wounds, trauma and venous ulcers or the like. In some embodiments, the components of the

TNP system described herein can be particularly suited for incisional wounds that exude a small amount of wound exudate.

[0037] Some embodiments of the system are designed to operate without the use of an exudate canister. Some embodiments can be configured to support an exudate canister. In some embodiments, configuring the pump assembly 150 and tubing 140 so that the tubing 140 can be quickly and easily removed from the pump assembly 150 can facilitate or improve the process of dressing or pump changes, if necessary. Any of the pump embodiments disclosed herein can be configured to have any suitable connection between the tubing and the pump.

[0038] In some embodiments, the pump assembly 150 can be configured to deliver negative pressure at a desired negative pressure setpoint, which can be selected or programmed to be approximately -80 mmHg, or between about -20 mmHg and -200 mmHg (e.g., as selected by a user). Note that these pressures are relative to normal ambient atmospheric pressure thus, -200 mmHg would be about 560 mmHg in practical terms. In some embodiments, the pressure range can be between about -40 mmHg and -150 mmHg. Alternatively a pressure range of up to -75 mmHg, up to -80 mmHg or over -80 mmHg can be used. Also in other embodiments a pressure range of below -75 mmHg can be used. Alternatively a pressure range of over approximately -100 mmHg, or even 150 mmHg, can be supplied by the pump assembly 150.

[0039] In some embodiments, the pump assembly 150 is configured to provide continuous or intermittent negative pressure therapy. Continuous therapy can be delivered at above -25 mmHg, -25 mmHg, -40 mmHg, -50 mmHg, -60 mmHg, -70 mmHg, -80 mmHg, -90 mmHg, -100 mmHg, -120 mmHg, -140 mmHg, -160 mmHg, -180 mmHg, -200 mmHg, or below -200 mmHg. Intermittent therapy can be delivered between low and high negative pressure set points. Low set point can be set at above 0 mmHg, 0 mmHg, -25 mmHg, -40 mmHg, -50 mmHg, -60 mmHg, -70 mmHg, -80 mmHg, -90 mmHg, -100 mmHg, -120 mmHg, -140 mmHg, -160 mmHg, -180 mmHg, or below -180 mmHg. High set point can be set at above -25 mmHg, -40 mmHg, -50 mmHg, -60 mmHg, -70 mmHg, -80 mmHg, -90 mmHg, -100 mmHg, -120 mmHg, -140 mmHg, -160 mmHg, -180 mmHg, -200 mmHg, or below -200 mmHg. During intermittent therapy, negative pressure at low set point can be delivered for a first time duration, and upon expiration of the first time duration, negative

pressure at high set point can be delivered for a second time duration. Upon expiration of the second time duration, negative pressure at low set point can be delivered. The first and second time durations can be same or different values. The first and second durations can be selected from the following range: less than 2 minutes, 2 minutes, 3 minutes, 4 minutes, 6 minutes, 8 minutes, 10 minutes, or greater than 10 minutes. In some embodiments, switching between low and high set points and vice versa can be performed according to a step waveform, square waveform, sinusoidal waveform, and the like.

[0040] In operation, the wound filler 130 is inserted into the wound cavity 110 and wound cover 120 is placed so as to seal the wound cavity 110. The pump assembly 150 provides a source of a negative pressure to the wound cover 120, which is transmitted to the wound cavity 110 via the wound filler 130. Fluid (e.g., wound exudate) is drawn through the conduit 140, and can be stored in a canister. In some embodiments, fluid is absorbed by the wound filler 130 or one or more absorbent layers (not shown).

[0041] Wound dressings that may be utilized with the pump assembly and other embodiments of the present application include Renasys-F, Renasys-G, Renasys AB, and Pico Dressings available from Smith & Nephew. Further description of such wound dressings and other components of a negative pressure wound therapy system that may be used with the pump assembly and other embodiments of the present application are found in U.S. Patent Publication Nos. 2012/0116334, 2011/0213287, 2011/0282309, 2012/0136325, 2013/0110058, which are incorporated by reference in their entireties. In other embodiments, other suitable wound dressings can be utilized.

Pump Assembly and Canister

[0042] Figure 2A illustrates a front view 200A of a pump assembly 230 and canister 220 according to some embodiments. As is illustrated, the pump assembly 230 and the canister are connected, thereby forming a device. The pump assembly 230 comprises one or more indicators, such as visual indicator 202 configured to indicate alarms and visual indicator 204 configured to indicate status of the TNP system. The indicators 202 and 204 can be configured to alert a user to a variety of operating and/or failure conditions of the system, including alerting the user to normal or proper operating conditions, pump failure, power supplied to the pump or power failure, detection of a leak within the wound cover or

flow pathway, suction blockage, or any other similar or suitable conditions or combinations thereof. In some embodiments, the pump assembly 230 can comprise additional indicators. In some embodiments, a single indicator is used. In other embodiments, multiple indicators are used. Any suitable indicator can be used such as visual, audio, tactile indicator, and so on. The indicator 202 can be configured to signal alarm conditions, such as canister full (or dressing full in case of a canisterless system), power low, conduit 140 disconnected, seal broken in the wound seal 120, and so on. The indicator 202 can be configured to display red flashing light to draw user's attention. The indicator 204 can be configured to signal status of the TNP system, such as therapy delivery is ok, leak detected, and so on. The indicator 204 can be configured to display one or more different colors of light, such as green, yellow, etc. For example, green light can be emitted when the TNP system is operating properly and yellow light can be emitted to indicate a warning.

[0043] The pump assembly 230 comprises a display or screen 206 mounted in a recess 208 formed in a case of the pump assembly. In some embodiments, the display 206 can be a touch screen display. In some embodiments, the display 206 can support playback of audiovisual (AV) content, such as instructional videos. As explained below, the display 206 can be configured to render a number of screens or graphical user interfaces (GUIs) for configuring, controlling, and monitoring the operation of the TNP system. The pump assembly 230 comprises a gripping portion 210 formed in the case of the pump assembly. The gripping portion 210 can be configured to assist the user to hold the pump assembly 230, such as during removal of the canister 220. In some embodiments, the canister 220 can be replaced with another canister, such as when the canister 220 has been filled with exudate. The canister 220 can include solidifier material.

[0044] The pump assembly 230 comprises one or more keys or buttons 212 configured to allow the user to operate and monitor the operation of the TNP system. As is illustrated, in some embodiments, there buttons 212a, 212b, and 212c are included. Button 212a can be configured as a power button to turn on/off the pump assembly 230. Button 212b can be configured as a play/pause button for the delivery of negative pressure therapy. For example, pressing the button 212b can cause therapy to start, and pressing the button 212b afterward can cause therapy to pause or end. Button 212c can be configured to lock the display 206 and/or the buttons 212. For instance, button 212c can be pressed so that the user

does not unintentionally alter the delivery of the therapy. Button 212c can be depressed to unlock the controls. In other embodiments, additional buttons can be used or one or more of the illustrated buttons 212a, 212b, or 212c can be omitted. In some embodiments, multiple key presses and/or sequences of key presses can be used to operate the pump assembly 230.

[0045] The pump assembly 230 includes one or more latch recesses 222 formed in the cover. In the illustrated embodiment, two latch recesses 222 can be formed on the sides of the pump assembly 230. The latch recesses 222 can be configured to allow attachment and detachment of the canister 220 using one or more canister latches 221. The pump assembly 230 comprises an air outlet 224 for allowing air removed from the wound cavity 110 to escape. Air entering the pump assembly can be passed through one or more suitable filters, such as antibacterial filters. This can maintain reusability of the pump assembly. The pump assembly 230 includes one or more strap mounts 226 for connecting a carry strap to the pump assembly 230 or for attaching a cradle. In the illustrated embodiment, two strap mounts 226 can be formed on the sides of the pump assembly 230. In some embodiments, various of these features are omitted and/or various additional features are added to the pump assembly 230.

[0046] The canister 220 is configured to hold fluid (e.g., exudate) removed from the wound cavity 110. The canister 220 includes one or more latches 221 for attaching the canister to the pump assembly 230. In the illustrated embodiment, the canister 220 comprises two latches 221 on the sides of the canister. The exterior of the canister 220 can formed from frosted plastic so that the canister is substantially opaque and the contents of the canister and substantially hidden from plain view. The canister 220 comprises a gripping portion 214 formed in a case of the canister. The gripping portion 214 can be configured to allow the user to hold the pump assembly 220, such as during removal of the canister from the apparatus 230. The canister 220 includes a substantially transparent window 216, which can also include graduations of volume. For example, the illustrated 300 mL canister 220 includes graduations of 50 mL, 100 mL, 150 mL, 200 mL, 250 mL, and 300 mL. Other embodiments of the canister can hold different volume of fluid and can include different graduation scale. The canister 220 comprises a tubing channel 218 for connecting to the conduit 140. In some embodiments, various of these features, such as the gripping portion 214, are omitted and/or various additional features are added to the canister 220.

[0047] Figure 2B illustrates a rear view 200B of the pump assembly 230 and canister 220 according to some embodiments. The pump assembly 230 comprises a speaker port 232 for producing and/or radiating sound. The pump assembly 230 includes a filter access door 234 for accessing and replacing one or more filters, such as odor filter, antibacterial filters, etc. In one embodiment, the access door 234 can be used to access a chamber (such as a plenum chamber) in which noise suppressing or sound absorbing material is placed. The chamber and sound absorbing material can be part of a silencing system that is used to suppress or absorb noise generated by the source of negative pressure. Sound absorbing material can serve to break up sound waves as travel (or reverberate) through the chamber. Sound absorbing material can further function as an odor suppressant. In one embodiment, for example, sound absorbing material can be impregnated with activated charcoal for odor suppression. The access door 234 can further include a seal (such as a sealing gasket) for tight closure of the chamber. Additional details of the silencing system are described in U.S. Patent Publication No. 2010/0185165, which is incorporated by reference in its entirety.

[0048] The pump assembly 230 comprises a gripping portion 236 formed in the case of the pump assembly. As is illustrated, the gripping portion 236 is a recess formed in the outer casing of the pump assembly 230. In some embodiments, the gripping portion 236 may include rubber, silicone, etc. coating. The gripping portion 236 can be configured (e.g., positioned and dimensioned) to allow the user to firmly hold the pump assembly 230, such as during removal of the canister 220. The pump assembly 230 includes one or more covers 238 configured as screw covers and/or feet or protectors for placing the pump assembly 230 on a surface. The covers 230 can be formed out of rubber, silicone, or any other suitable material. The pump assembly 230 comprises a power jack 239 for charging and recharging an internal battery of the pump assembly. In some embodiments, the power jack 239 is a direct current (DC) jack. In some embodiments, the pump assembly can comprise a disposable power source, such as batteries, so that no power jack is needed.

[0049] The canister 220 includes one or more feet 244 for placing the canister on a surface. The feet 244 can be formed out of rubber, silicone, or any other suitable material and can be angled at a suitable angle so that the canister 220 remains stable when placed on the surface. The canister 220 comprises a tube mount relief 246 configured to allow one or

more tubes to exit to the front of the device. The canister 220 includes a stand or kickstand 248 for supporting the canister when it is placed on a surface. As explained below, the kickstand 248 can pivot between an opened and closed position. In closed position, the kickstand 248 can be latched to the canister 220. In some embodiments, the kickstand 248 can be made out of opaque material, such as plastic. In other embodiments, the kickstand 248 can be made out of transparent material. The kickstand 248 includes a gripping portion 242 formed in the kickstand. The gripping portion 242 can be configured to allow the user to place the kickstand 248 in the closed position. The kickstand 248 comprises a hole 249 to allow the user to place the kickstand in the open position. The hole 249 can be sized to allow the user to extend the kickstand using a finger.

[0050] Figure 2C illustrates a view 200C of the pump assembly 230 separated from the canister 220 according to some embodiments. The pump assembly 230 includes a vacuum attachment or connector 252 through which a vacuum pump communicates negative pressure to the canister 220. The connector 252 can correspond to the inlet of the pump assembly. The pump assembly 230 comprises a USB access door 256 configured to allow access to one or more USB ports. In some embodiments, the USB access door is omitted and USB ports are accessed through the door 234. The pump assembly 230 can include additional access doors configured to allow access to additional serial, parallel, and/or hybrid data transfer interfaces, such as SD, Compact Disc (CD), DVD, FireWire, Thunderbolt, PCI Express, and the like. In other embodiments, one or more of these additional ports are accessed through the door 234.

[0051] Figure 2D illustrates a view 200D of the interior components of the pump assembly 230 according to some embodiments. The pump assembly 230 can include various components, such as a canister connector 252 which includes a sealing ring 253, control printed circuit board (PCB) 260, peripherals PCB 262 (e.g., for USB connectivity), power supply PCB 264, vacuum pump 266, power supply 268 (e.g., rechargeable battery), speaker 270, and light guide or pipe 272 (e.g., for status indication using guided light emitted by one or more LEDs). Further details of status indication are provided in U.S. Patent No. 8,294,586, which is incorporated by reference in its entirety. Other components can be included, such as electrical cables, connectors, tubing, valves, filters, fasteners, screws,

holders, and so on. In some embodiments, the pump assembly 230 can comprise alternative or additional components.

[0052] Figure 2E illustrates another view 200E of the interior components of the pump assembly 230 according to some embodiments. As is explained below, the pump assembly 230 includes an antenna 276. The connector 252 between the vacuum pump 266 and the canister 220 includes a flow restrictor 278. As is explained below, the flow restrictor 278 can be a calibrated flow restrictor used for measuring flow in the fluid flow path and for determining various operating conditions, such as leaks, blockages, high pressure (over-vacuum), and the like. In some embodiments, flow across the restrictor 278 can be determined by measuring a pressure differential (or pressure drop) across the flow restrictor. In various embodiments, flow across the restrictor 278 can be characterized as high flow (e.g., due to a leak), low flow (e.g., due to a blockage or canister being full), normal flow, etc. As is illustrated, pressure sensor 284 measures pressure upstream (or on the canister side) of the flow restrictor 278. Pressure sensor 284 can be an electronic pressure sensor mounted on the control PCB 264. Conduit or lumen 286 can connect the upstream side of the flow restrictor 278 with the pressure sensor 284. Pressure sensors 280 and 282 measure pressure downstream (or on the vacuum pump side) of the flow restrictor 278. Pressure sensors 280 and 282 can be electronic pressure sensors mounted on the control PCB 264. Conduit or lumen 288 can connect the downstream side of the flow restrictor 278 with the pressure sensors 280 and 284 via a Y-connector 289.

[0053] In some embodiments, one of pressure sensors 280 and 282 can be designated as a primary pressure sensor and the other as a backup pressure sensor in case the primary pressure sensor becomes defective or inoperative. For example, pressure sensor 280 can be the primary pressure sensor and pressure sensor 282 can be the backup pressure sensor. Pressure drop across the flow restrictor 278 can be determined by subtracting pressure measured by sensor 280 and sensor 284. If pressure sensor 280 fails, pressure drop across the flow restrictor can be determined by subtracting pressure measured by sensor 282 and sensor 284. In certain embodiments, the backup pressure sensor can be used for monitoring and indicating high pressure conditions, that is when the pressure in the flow path exceeds a maximum pressure threshold. In some embodiments, one or more differential pressure sensors can be used. For example, a differential pressure sensor connected to the

upstream and downstream sides of the flow restrictor 278 can measure the pressure drop across the flow restrictor. In some embodiments, one or more of these components, such as the flow restrictor 278, are omitted and/or additional components, such as one or more flow meters, are used.

Flow Rate Monitoring

[0054] Figure 3A illustrates a fluid flow path 300A according to some embodiments. The flow path 300A includes a wound cavity 310, canister 320, pressure sensor 330, and source of negative pressure 340. The flow of fluid is from left to right (e.g., from the wound 310 to the negative pressure source 340). Figure 3B illustrates a fluid flow path 300B according to some embodiments. The flow path 300B includes the wound 310 cavity, pressure sensor 320, canister 320, and source of negative pressure 340. The flow of fluid is from left to right (e.g., from the wound cavity 310 to the negative pressure source 340). As is illustrated, the difference between flow paths 300A and 300B is the positioning of the pressure sensor 320. In fluid flow path 300A the pressure sensor 320 is located downstream of the canister 320 (e.g., at the inlet of the negative pressure source 340), while in the fluid flow path 300B the pressure sensor 320 is located upstream of the canister 320.

[0055] Some embodiments of the system monitor and/or determine a rate of flow of fluid in the system. In certain embodiments, flow rate monitoring can be performed by a controller or processor. Monitoring the flow rate can be used, among other things, to ensure that therapy is properly delivered to the wound, to detect blockages, canister full (or dressing full in case of a canisterless system) conditions, and/or leaks in the fluid flow path, high pressure, ensure that the flow rate is not unsafe (e.g., dangerously high), etc.

[0056] In some embodiments, the system performs flow rate monitoring indirectly by measuring and/or monitoring activity of the negative pressure source. For example, speed of vacuum pump motor can be measured, such as, by using a tachometer. A pump control processor can continuously monitor the pump speed using the tachometer feedback from the pump. If pump speed falls below a threshold value over a particular period of time, such as 2 minutes, it can be determined that a blockage is present in the flow path, particularly in systems in which an minimum pump speed is expected (e.g., due to a presence of a controlled leak). The blockage can be due to a blockage in a tube or lumen,

canister (or dressing) being full, etc. An alarm can be triggered and the system can wait for the user to take one or more actions to resolve the blockage. In some embodiments, activity of the negative pressure source can be measured by one or more other suitable techniques, such as by using a pump speed sensor (e.g., Hall sensor), measuring back EMF generated by the pump motor, and the like. A pump control processor can continuously monitor voltage and/or current at which the pump is being driven, and determine the activity of the negative pressure source based on the monitored voltage and/or current and load on the pump. In some embodiments, pulse frequency (e.g., pressure signal frequency) can be monitored (e.g., using one or more pressure sensors) to determine the activity of the negative pressure source. For example, a count of pressure pulses can be used as an indicator of the activity of the negative pressure source.

[0057] In various embodiments, tachometer can be read periodically, such as every 100 msec, and periodic readings made over a time duration, such as 2.5 seconds, 32 second, or any other suitable duration can be combined (e.g., averaged). Combined tachometer readings can be used for leak detection, blockage detection, limiting the maximum flow rate, etc. Combined tachometer readings (e.g., in counts) can be converted to a flow rate (e.g., in mL/min) using one or more conversion equations and/or tables so that a current flow rate is determined. In some embodiments, the flow rate is determined according to the following equation:

[0058] $FR = C_1*F*P + C_2$

[0059] where FR is the flow rate, F is the frequency of the pump tachometer signal, P is pressure produced by the pump (or pressure setpoint), and C_1 and C_2 are suitable constants. The determined flow rate can be compared to various flow rate thresholds, such as blockage threshold, leakage threshold, and maximum flow rate threshold, to determine a presence of a particular condition, such as a blockage, leakage, and over-vacuum.

[0060] Other suitable ways for determining flow rate can be used. For example, the flow rate can be periodically computed, such as every 250 milliseconds or any other suitable time value, according to the following formula:

[0061] $FR = Slope*Tachometer + Intercept$

[0062] where Tachometer is an average of tachometer readings (e.g., in Hz), such as over last 2.5 second or any other suitable period of time, and Slope and Intercept are

constants that are based on the pressure setpoint. The values for Slope and Intercept can be determined for possible pressure setpoints (e.g., -25 mmHg, -40 mmHg, -50 mmHg, 60 mmHg, -70 mmHg, -80 mmHg, -90 mmHg, -100 mmHg, -120 mmHg, -140 mmHg, 160 mmHg, -180 mmHg, -200 mmHg) for a given vacuum pump type. The flow as a function of the pump speed may not be a best fit as a single line because the vacuum pump can be designed to be more efficient at lower flow rates. Because of this, slope and intercept values can be pre-computed for various setpoints and various pumps. Flow rate can be measured in standard liters per minute (SLPM) or any other suitable measurement unit.

[0063] In some embodiments, a blockage condition is detected when the determined flow rate falls below a blockage threshold. A blockage alarm can be enabled if the blockage condition is present over a period of time, such as 30 seconds. The blockage alarm can be disabled when the determined flow rate exceeds the blockage threshold. In some embodiments, the system can differentiate between a blockage in a tube or lumen and canister (or dressing) full conditions. In some embodiments, a leakage condition is detected when the determined flow rate exceeds a leakage threshold. A leakage alarm can be enabled if the leakage condition is present over a period of time, such as 30 seconds. The leakage alarm can be disabled when the detected flow rate falls below the leakage threshold. In some embodiments, in order to prevent an over-vacuum condition, a maximum flow rate is imposed, such as 1.6 liters/min. Pump drive signal, such as voltage or current signal, can be limited not exceed the flow rate threshold.

[0064] In certain embodiments, one or more pressure sensors can be placed in suitable locations in the fluid flow path. Pressure measured by the one or more sensors is provided to the system (e.g., pump control processor) so that it can determine and adjust the pump drive signal to achieve a desired negative pressure level. The pump drive signal can be generated using PWM. Additional details of flow rate detection and pump control are provided in U.S. Patent Application No. 2013/0150813, which is incorporated by reference in its entirety.

[0065] In some embodiments, flow rate monitoring is performed by measuring flow through a flow restrictor placed in a portion of the fluid flow path. In certain embodiments, flow restrictor 278 illustrated in Figure 2E can be used. The flow restrictor can be calibrated such that it can be used to reliably monitor flow rate for different types of

wounds, dressings, and operating conditions. For example, a high precision silicon flow restrictor can be used. As another example, the flow restrictor can be built using other suitable materials. The flow restrictor can be located at any suitable location in the flow path, such as between the source of the negative pressure and the canister, such as upstream of the source of the negative pressure and downstream of the canister. A differential pressure sensor or two pressure sensors can be used to measure a pressure drop across the flow restrictor. For example, as explained above in connection with Figure 2E, the pressure drop across the flow restrictor 278 can be measured using sensors 282 and 284. In certain embodiments, if the pressure drop falls below a pressure differential threshold, which indicates low flow, the measured flow rate is compared to a flow rate threshold. If the measured flow rate falls below the flow rate threshold, blockage condition is detected. Additional details of blockage detection are provided in U.S. Patent Publication No. 2011/0071483, which is incorporated by reference in its entirety. In some embodiments, the measured flow rate is compared to a leakage threshold. If the measured flow rate exceeds the leakage threshold, a leak is detected. Additional details of leakage detection are provided in U.S. Patent No. 8,308,714, which is incorporated by reference in its entirety.

Blockage Detection

[0066] In some embodiments, blockages and presence of exudate in one or more tubes or lumens are detected by processing data from one or more pressure sensors, such as sensors 280, 282, and 284. This detection can be enhanced by changing one or more settings of the vacuum pump, such as increasing vacuum level delivered by the pump, decreasing the vacuum level, stopping the pump, changing the pump speed, changing a cadence of the pump, and the like. In some embodiments, as the pump operates, it generates pressure pulses or signals that are propagated through the fluid flow path. The pressure signals are illustrated in the pressure curve 402 of Figure 4 according to some embodiments. As is illustrated in region 404, pressure in the fluid flow path varies or oscillates around a particular pressure setting or set point 408 (e.g., as selected by the user) during normal operation of the system. Region 406 illustrates pressure pulses in the flow path when there is a blockage distal to the negative pressure source, such as the canister (or dressing) becomes full and/or a canister filter is occluded or blocked. As is illustrated, a distal blockage causes

a reduced volume to be seen upstream of the canister (or dressing), and the amplitude of the pressure pulses increases. The frequency of a pressure signal is slowed or decreased in some embodiments. In certain embodiments, this change or "bounce" in the magnitude (or frequency) of the pressure pulse signal can be magnified or enhanced by varying the pump speed, varying the cadence of the pump, such as by adjusting PWM parameters, and the like. Such adjustments of pump operation are not required but can be performed over short time duration and the changes can be small such that the operation of the system remains relatively unaffected. In some embodiments, the canister filter can be hydrophobic so that the flow of liquid is substantially blocked while the flow of air is allowed. Additional details of flow rate detection are described in U.S. Patent Publication No. 2012/0078539, which is incorporated by reference in its entirety.

[0067] In some embodiments, canisterless systems use absorbent dressing for exudate removed from the wound. Such dressing may include absorbing or superabsorbing material to collect and/or retain exudate so that it is not aspirated into the negative pressure source. Similar to a canister filter, a dressing filter (which may be hydrophobic) may be used to prevent the exudate from reaching the negative pressure source. In such systems, detection of a dressing full condition or dressing filter (which may be) occluded condition can be an equivalent to detection of a canister full condition.

[0068] In some embodiments, changes in characteristics of pressure signals can be used to determine distal blockages, level of exudate in the canister (or dressing), canister (or dressing) full conditions, and the like. The characteristics can include signal magnitude, frequency, shape (e.g., envelope), etc. In some embodiments, the system can detect canister (or dressing) pre-full condition or the level of exudate in the canister (or dressing) reaching a certain threshold, which may be less than being approximately 100% full. For example, the system can detect the canister (or dressing) being 75% full, 80% full, 95%, and so on. Advantageously, such detection mechanisms can provide earlier indication of the need to change the canister (or dressing) and avoid prolonged interruption of the delivery of therapy. Sensitivity of alarms can be increased. In various embodiments, the level of a leak in present in the fluid flow path does not affect accurate determination of the level of exudate in the canister and/or detection of the canister (or dressing) pre-full or full conditions.

[0069] Figures 5A-5D illustrates graphs of pressure signals according to some embodiments. The illustrated graphs can correspond to a particular pressure setting, such as 40 mmHg. The illustrated graphs can also correspond to various leak levels of leak rates in the system. For example, Figure 5A may correspond to 60 mL/min leak (e.g., low leak), Figure 5B may correspond to a 150 mL/min leak, Figure 5C may correspond to a 450 mL/min leak, and Figure 5D may correspond to a 1000 mL/min leak (e.g., very high leak). Figure 5A illustrates a magnitude curve 502A of the pressure signal in the flow path as sensed by one or more pressure sensors over a period of time. Curve 502A can correspond to a signal observed when the canister is relatively empty. For example, the canister may be configured to hold up to 750 mL fluid volume, and curve 502A can correspond to the empty volume of 515 mL. As is illustrated, the bounce in the pressure signal magnitude curve 502A is relatively small as the curve is substantially flat. The bounce of the pressure signal can be measured using a variety of techniques, such as by measuring peak-to-trough change and selecting the largest such change as being indicative of the largest bounce. Curve 502A can correspond to the voltage reading, current reading, etc. Curve 504A corresponds to a pump speed signal (e.g., as measured by a tachometer, PWM signal, etc.).

[0070] Figure 5B illustrates a magnitude curve 502B of the pressure signal in the flow path as sensed by one or more pressure sensors over a period of time. Curve 502B can correspond to a signal observed when the canister is relatively full. For example, the canister may be configured to hold up to 750 mL volume, and curve 502B can correspond to the empty volume of 60 mL. As is illustrated, the bounce in the pressure signal magnitude curve 502B is larger than that in curve 502A. Curve 504B corresponds to the pump speed signal. Figure 5C illustrates a magnitude curve 502C of the pressure signal in the flow path as sensed by one or more pressure sensors over a period of time. Curve 502C can correspond to a signal observed when the canister is almost full. For example, the canister may be configured to hold up to 750 mL volume, and curve 502C can correspond to the empty volume of 30 mL. As is illustrated, the bounce in the pressure signal magnitude curve 502B is larger than that in curves 502A and 502B. Curve 504C corresponds to the pump speed signal.

[0071] Figure 5D illustrates a magnitude curve 502D of the pressure signal in the flow path as sensed by one or more pressure sensors over a period of time. Curve 502D can

correspond to a signal observed when the canister is nearly full. For example, the canister may be configured to hold up to 750 mL volume, and curve 502D can correspond to the empty volume of 15 mL. As is illustrated, the bounce in the pressure signal magnitude curve 502D is larger than that in curves 502A, 502B, and 502C. Curve 504D corresponds to the pump speed signal.

[0072] Table 1 illustrates the largest magnitude bounces or peak-to-trough changes (e.g., in voltage as indicated by V_{p-p}) measured for the curves 502A, 502B, 502C, and 502D according to some embodiments. With reference to the first row (row 1), column A corresponds to curve 502A and indicates the largest change of 0.010 V, column B corresponds to curve 502D and indicates the largest change of 0.078 V, column C corresponds to curve 502C and indicates the largest change of 0.122 V, and column D corresponds to curve 502D and indicates the largest change of 0.170 V. These increasing bounce values confirm that the bounce in the pressure signal magnitude increases as the canister fills up. Level of exudate in the canister (or the dressing) can be detected by comparing the determined pressure magnitude bounce to one or more magnitude thresholds, which can be determined experimentally for canisters (or dressing) of various sizes. For example, canister (or dressing) pre-full condition may be set to the canister having 30 mL or less empty volume. Using Table 1, a pre-full threshold can be set to approximately 0.12 V peak-to-trough bounce. In some embodiments, measures other than or in addition to peak-to-trough can be used, such as average bounce, etc.

		D	C	B	A
	Pressure Magnitude (V_{p-p}) at 40 mmHg	15 mL volume	30 mL volume	60 mL volume	515 mL volume
1	60 mL/min	0.170	0.122	0.078	0.010
2	150 mL/min	0.174	0.120	0.074	0.012
3	450 mL/min	0.178	0.118	0.068	0.008
4	1000 mL/min	0.124	0.082	0.050	0.012

Table 1: Pressure Magnitude Bounce at 40 mmHg

[0073] In some embodiments, signal processing techniques can be utilized on the detected pressure signal. For example, sensed pressure values can be processed, such as low-pass filtered (e.g., via averaging), to remove noise. As another example, detected pressure

signal can be converted into frequency domain, for example by using the Fast Fourier Transform (FFT). The signal can be processed and analyzed in frequency domain.

[0074] Figures 6A-6D illustrates graphs of pressure signals according to some embodiments. Similar to Figures 5A-5D, these graphs illustrate pressure magnitude curves and pump speed curves at 150 mL/min leak for unfilled canister volumes of 515 mL, 60 mL, 30 mL, and 15 mL. As is illustrated in Figures 6A-6D and confirmed by the values in the second row (row 2) of Table 1, the bounce in the pressure signal increases as the canister fills up. Figures 7A-7D illustrates graphs of pressure signals according to some embodiments. Similar to Figures 5A-5D, these graphs illustrate pressure magnitude curves and pump speed curves at 450 mL/min leak for unfilled canister volumes of 515 mL, 60 mL, 30 mL, and 15 mL. As is illustrated in Figures 7A-7D and confirmed by the values in the third row (row 3) of Table 1, the bounce in the pressure signal increases as the canister fills up. Figures 8A-8D illustrates graphs of pressure signals according to some embodiments. Similar to Figures 5A-5D, these graphs illustrate pressure magnitude curves and pump speed curves at 1000 mL/min leak (which is a very high leak) for unfilled canister volumes of 515 mL, 60 mL, 30 mL, and 15 mL. As is illustrated in Figures 8A-8D and confirmed by the values in the fourth row (row 4) of Table 1, the bounce in the pressure signal increases as the canister fills up. From the illustrations in Figures 5-8 and the values in Table 1, it can be seen that detection of the level of exudate in the canister (or in the dressing) and/or canister (or dressing) pre-full condition can be performed irrespective of the leak rate in the fluid flow path.

[0075] As is illustrated in Figures 5-8 and Table 1, the bounce or ripple in the observed pressure magnitude increases as the canister fills up and the volume "seen" by the pump decreases. Figure 9 illustrates sensed pressure magnitude ripple according to some embodiments. The y-axis represents largest peak-to-trough voltage changes. The x-axis corresponds to canister unfilled volumes (e.g., volume ahead or upstream of the pump). A 750 mL canister is used according to some embodiments. There are four curves illustrated corresponding to target pressure settings of 40 mmHg, 80 mmHg, 120 mmHg, and 200 mmHg. Vertical bars on the curves represent variation resulting from the changes to the leak rate. Table 2 illustrates the plotted values according to some embodiments. As is illustrated in Figure 9 and Table 2, magnitude of the pressure bounce increases as the canister becomes full irrespective of the leak rate for various pressure settings.

V_{p-p} *	15 mL volume	30 mL volume	60 mL volume	515 mL volume
40 mmHg	0.174 ± 0.008	0.120 ± 0.004	0.073 ± 0.010	0.010 ± 0.004
80 mmHg	0.119 ± 0.015	0.081 ± 0.006	0.049 ± 0.002	0.008 ± 0.000
120 mmHg	0.095 ± 0.005	0.061 ± 0.005	0.037 ± 0.002	0.006 ± 0.000
200 mmHg	0.056 ± 0.000	0.037 ± 0.009	0.027 ± 0.009	0.008 ± 0.000

Table 2 (**1000 mL/min data was excluded*)

[0076] In some embodiments, thresholds for determining the level of exudate in the canister (or the dressing) and/or canister (or dressing) pre-full condition can be determined for various pressure settings and various canister volumes. For example, Table 3 illustrates the largest magnitude bounces or peak-to-trough changes for 80 mmHg pressure setting according to some embodiments. Similar tables can be constructed for other possible pressure settings. Level of exudate in the canister/dressing (and, accordingly, a measure of how empty the canister/dressing is), canister/dressing pre-full condition, and/or canister/dressing full condition can be determined at run time by loading a table corresponding to a particular selected pressure setting and comparing the monitored pressure signal magnitude bounce to one or more thresholds. Other suitable data structures can be used in place of a table, such as array, list, index, graph, etc.

		D	C	B	A
	Pressure Magnitude (V_{p-p}) at 80 mmHg	15 mL volume	30 mL volume	60 mL volume	515 mL volume
1	60 mL/min	0.114	0.078	0.048	0.008
2	150 mL/min	0.116	0.084	0.050	0.008
3	450 mL/min	0.128	0.080	0.050	0.008
4	1000 mL/min	0.092	0.058	0.034	0.010

Table 3: Pressure Magnitude Bounce at 80 mmHg

[0077] In some embodiments, frequency of the detected pressure signal can be used in addition to or instead of changes in amplitude for detection of canister (or dressing) pre-full conditions and/or for determining the level of exudate in the canister (or dressing). For example, Table 4 illustrates pressure signal frequencies at 40 mmHg pressure setting for various unfilled canister volumes at various leak rates according to some embodiments. As is shown in Table 4, the frequency of the detected pressure signal decreases or drops as the canister becomes full (e.g., compare column A corresponding to 515 mL unfilled canister volume to column D corresponding to 15 mL unfilled canister volume). This change in the frequency is observed irrespective of the leak rate. The frequency of the detected pressure

signal can be compared to one or more frequency thresholds, which may be determined experimentally, to detect canister (or dressing) pre-full condition and/or detect the level of exudate in the canister (or dressing).

		D	C	B	A
	Pressure Frequency at 40 mmHg (Hz)	15 mL volume	30 mL volume	60 mL volume	515 mL volume
1	60 mL/min	2.59	2.67	2.67	2.62
2	150 mL/min	3.51	3.76	3.75	3.53
3	450 mL/min	6.62	6.94	6.99	6.94
4	1000 mL/min	13.16	12.99	12.66	13.89

Table 4: Pressure Signal Frequency at 40 mmHg

[0078] In some embodiments, similar tables can be constructed for other possible pressure settings. For example, Table 5 illustrates pressure signal frequencies at 80 mmHg pressure setting for various unfilled canister volumes at various leak rates according to some embodiments. Level of exudate in the canister (or dressing), canister (or dressing) pre-full condition, and/or canister (or dressing) full condition can be determined at run time by loading a table (or another suitable data structure) corresponding to a particular selected pressure setting and comparing the monitored pressure signal frequency to one or more thresholds. The thresholds can be determined experimentally for various canister (or dressing) volumes.

		D	C	B	A
	Pressure Frequency at 80 mmHg (Hz)	15 mL volume	30 mL volume	60 mL volume	515 mL volume
1	60 mL/min	3.76	3.83	3.82	3.82
2	150 mL/min	4.98	4.67	4.81	4.88
3	450 mL/min	8.26	8.47	8.26	8.20
4	1000 mL/min	15.38	15.63	15.15	15.87

Table 5: Pressure Signal Frequency at 80 mmHg

[0079] In some embodiments, additional attributes can be used for canister (or dressing) pre-full detection and/or determination of the level of exudate in the canister (or dressing). For example, flow rate through the flow path can be used in addition to analyzing the pressure magnitude. In some embodiments, flow rate can be measured indirectly by measuring and analyzing the pump speed as is disclosed in U.S. Patent Publication No.

2012/0001762, which is incorporated by reference in its entirety. In some embodiments, flow rate can be measured directly by using a flow meter. In some embodiments, increase in the pressure magnitude bounce and decrease in the flow rate (e.g., pump speed, such as reflected by a slowing tachometer) indicates a canister (or dressing) full condition. Decrease in the pump speed alone may not be a reliable indicator of the canister full condition as such decrease can be caused by an improved seal and resulting lowering of the leak rate. In addition, presence of a small leak in the flow path may cause the pump to continue working even though the canister may be nearly full or full, which can cause inaccurate detection of the canister full condition.

[0080] In some embodiments, detection of canister (or dressing) pre-full and/or full conditions using the characteristics of the pressure signals can allow the system to differentiate between blockage conditions in the fluid flow path and blockages in the canister (or in the dressing). In some embodiments, alarm sensitivity is improved. For example, canister full detection mechanisms in systems that do not use characteristics of the pressure signal may rely solely on the flow rate measurements (e.g., as indicated by pump speed measurements) for determining whether the canister is full. Using characteristics of the pressure signal as disclosed herein can trigger the canister full alarm much earlier, such as for example 20 or more minutes earlier. Advantageously, improving alarm sensitivity can result in increasing safety and patient comfort as the canister can be changed timely before it becomes full and therapy is interrupted. **[0081]** Figure 10 illustrates a process 1000 of detecting proximal blockages according to some embodiments. The process 1000 can be implemented by a controller of processor. The process 1000 measures one or more pressure signal characteristics in block 1002. For example, pressure signal magnitude, frequency, etc. can be measured. In block 1004, the process 1000 removes noise from the one or more measured pressure signal characteristics. For example, the pressure signal can be low pass filtered. In block 1006, the process 1000 compares the one or more pressure signal characteristics to one or more thresholds. If in block 1008 the process 1000 determines that the one or more thresholds have been satisfied (e.g., exceeded), the process transitions to block 1012 where it determines that there is a proximal blockage (e.g., due to the canister being full). The process 1000 can activate one or more alarms or indicators. If in block 1008 the process 1000 determines that the one or more thresholds have not been satisfied

(e.g., not exceeded), the process transitions to block 1010 where it determines that there is no proximal blockage. In some embodiments, the process 1000 can use hysteresis in block 1008. For example, the process 1000 can transition to block 1012 provided that a threshold has been met (e.g., exceeded) for a duration or period of time. In some embodiments, the one or more thresholds utilized by the process 1000 can be selected to determine canister (or dressing) pre-full condition and/or a particular level of exudate in the canister (or dressing). Process 1000 can be implemented by systems with canisters or by canisterless systems.

[0082] In some embodiments, canister (or dressing) full condition can be detected as follows. A plurality of pressure sensor readings, each performed over a time duration (e.g., 2 seconds or any other suitable duration which may be vary between sample periods), are collected. A number of readings of the plurality of readings, such as 25 sample periods out of 30 or any other suitable number, are checked to determine if each indicates that the canister is full. This can performed by determining maximum and minimum pressure values captured over the time duration of a particular sample period. The values can be voltage values, current values, or any other suitable values that correspond to pressure. A difference between maximum and minimum values for a particular sample period corresponds to peak-to-through pressure (which is indicative of change in pressure pulse amplitude). If it is determined that the peak-to-through pressure for a particular sample period exceeds a threshold pressure value, then the particular sample period indicates that the canister is full.

[0083] The threshold value can be any suitable pressure threshold, such as a value selected or determined based on the negative pressure setpoint and the current level of activity of the pump, which as explained above can be determined using a tachometer average (such as averaged tachometer readings or any other suitable measure of the flow rate). For example, threshold values listed in Table 1 can be used for comparing to peak-to-through pressure. These values correspond to a particular pump motor and particular pressure sensor.

	Tachometer Frequency (in Hz)			Peak-to-Through Pressure (in mV)		
Setpoint (in mmHg)	Low	Med	High	Low	Med	High
25	17	25	< 25	50	110	215
40	23	35	< 35	75	135	220
50	30	50	< 50	90	175	225
60	30	55	< 55	80	185	225
70	40	60	< 60	115	185	235
80	40	60	< 60	100	165	235
90	45	65	< 65	110	170	235
100	45	65	< 65	105	165	235
120	45	75	< 75	105	175	235
140	50	85	< 85	110	190	235
160	60	90	< 90	110	165	220
180	75	100	< 100	130	165	220
200	75	100	< 100	125	155	210

Table 6: Threshold values for detecting canister full condition

[0084] Canister full determination can be performed on a sliding window basis. For example, a sliding window of 25 out of 30 sample periods can be analyzed and if 25 sample periods are determined to indicate that the canister is full, the pump concludes that the canister (or dressing) is full. Assuming that the sample period is 2 seconds, using a sliding window of 25 out of 30 sample periods effectively results in determining whether change in pressure pulse amplitude exceeds the threshold for 60 seconds. If the tachometer average becomes greater than a leak threshold (e.g., flow rate associated with presence of a leak in the flow path) or canister pressure (as measured by a pressure sensor) becomes less than a low vacuum pressure threshold (e.g., flow rate associated with a low vacuum condition in the flow path), canister full detection can be suspended or terminated. For example, if a sliding window of 25 out of 30 sample periods with each sample period having duration of 2 seconds in used, 60 second timer for canister full detection can be reset when it has been determined that the tachometer average becomes greater than the leak threshold or canister pressure becomes less than the low vacuum pressure threshold. This can prevent generation of unnecessary and undesirable alarms.

[0085] Alternatively or additionally, canister full condition can be detected if a single sample period indicates that the canister is full. However, performing canister full

detection using a plurality of sample periods can mitigate the effects of one or more transient conditions in the fluid flow path or one or more errant pressure readings. Alternatively or additionally, canister full detection can be performed by measuring the frequency of detected pressure signal and comparing the measured frequency to one or more suitable thresholds.

[0086] In some embodiments, additional or alternative mechanisms can be used for detecting proximal blockages. One or more additional pressure sensors can be used to measure differential pressure across the canister (e.g., at the canister inlet and outlet). One or more additional conduits (e.g., dual lumens) can be used to inject a signal through one lumen for detection by another lumen. Flow rate can be measured directly or indirectly and used for canister blockage detection. A bias leak can be introduced into the flow path and maintained such that flow rate dropping below the bias leak rate indicates a presence of a blockage in the flow path. Optical sensors, ultrasonic sensors, and/or weight sensors can be used to determine the level of exudate in the canister (or dressing). Lasers can also be used. One or more sensors that are not related to measuring pressure and/or flow, such as a capacitive sensor or a strain gauge, can be used.

[0087] In some embodiments, temporary blockages caused by slugs or boluses of fluid in tubes and/or lumens are detected by turning off the pump and monitoring the pressure change in the fluid flow path. The pump can be turned off for a short duration of time as to not affect the operation of the system. Presence of temporary blockages in the system due to boluses of fluid can cause a detectable difference in pressure decay in the device including a discontinuous "stair and risers" pattern in a system with a distal leak. Such discontinuous decaying pattern may be due to boluses of fluid moving through the fluid flow path and arriving at the canister inlet, which can suddenly change the volume seen by the pressure sensor (and the canister or the dressing). When boluses of fluid are not present, a more continuous decaying pattern may be is observed. In certain embodiments, when the discontinuous "stairs and risers" pattern is detected, the system can increase the level of vacuum produced by the pump to clear the boluses. An alarm can be asserted if the tubes and/or lumens cannot be cleared.

[0088] In some embodiments, one or more flow sensors and/or flow meters can be used to directly measure the fluid flow. In some embodiments, the system can utilize one or more of the foregoing flow rate monitoring techniques. The system can be configured to

suitably arbitrate between flow rates determined using multiple flow rate monitoring techniques if one or more such techniques are executed in parallel. In certain embodiments, the system execute one of the techniques, such as the flow rate determination based on the pump speed, and utilize one or more other techniques as needed. In various embodiments, the system can utilize one or more other techniques in cases the determined flow rate or flow path condition is perceived to be inaccurate or unreliable. In some embodiments, the system can utilize one or more of the techniques to detect a sudden change in a flow rate suggesting change to the dressing leak characteristics (e.g., a greater flow indicates the development of a leak and a lesser flow indicating a sudden restriction or blockage).

Other Variations

[0089] Any value of a magnitude, frequency, threshold, limit, duration, etc. provided herein and/or illustrated in the figures is not intended to be absolute and, thereby, can be approximate. In addition, any magnitude, frequency, threshold, limit, duration, etc. provided herein and/or illustrated in the figures can be fixed or varied either automatically or by a user. Moreover, any value of a magnitude, frequency, threshold, limit, duration, etc. provided herein and/or illustrated in the figures is illustrative and can change depending on an embodiment. For example, the values provided in the tables (Tables 1-5) can vary depending on canister (or dressing) volume, sensor range, etc. Furthermore, as is used herein relative terminology such as exceeds, greater than, less than, etc. in relation to a reference value is intended to also encompass being equal to the reference value. For example, exceeding a reference value that is positive can encompass being equal to or greater than the reference value. In addition, as is used herein relative terminology such as exceeds, greater than, less than, etc. in relation to a reference value is intended to also encompass an inverse of the disclosed relationship, such as below, less than, greater than, etc. in relations to the reference value.

[0090] Features, materials, characteristics, or groups described in conjunction with a particular aspect, embodiment, or example are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed (such as

the process illustrated in Figure 10), may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The protection is not restricted to the details of any foregoing embodiments. The protection extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

[0091] While certain embodiments have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of protection. Indeed, the novel methods and systems described herein may be embodied in a variety of other forms. Furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein may be made. Those skilled in the art will appreciate that in some embodiments, the actual steps taken in the processes illustrated and/or disclosed may differ from those shown in the figures. Depending on the embodiment, certain of the steps described above may be removed, others may be added. For example, the actual steps and/or order of steps taken in the disclosed processes may differ from those shown in the figure. Depending on the embodiment, certain of the steps described above may be removed, others may be added. For instance, the various components illustrated in the figures may be implemented as software and/or firmware on a processor, controller, ASIC, FPGA, and/or dedicated hardware. Furthermore, the features and attributes of the specific embodiments disclosed above may be combined in different ways to form additional embodiments, all of which fall within the scope of the present disclosure.

[0092] User interface screens illustrated and described herein can include additional and/or alternative components. These components can include menus, lists, buttons, text boxes, labels, radio buttons, scroll bars, sliders, checkboxes, combo boxes, status bars, dialog boxes, windows, and the like. User interface screens can include additional and/or alternative information. Components can be arranged, grouped, displayed in any suitable order.

[0093] Although the present disclosure includes certain embodiments, examples and applications, it will be understood by those skilled in the art that the present disclosure extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses and obvious modifications and equivalents thereof, including embodiments

which do not provide all of the features and advantages set forth herein. Accordingly, the scope of the present disclosure is not intended to be limited by the specific disclosures of preferred embodiments herein, and may be defined by claims as presented herein or as presented in the future.

WHAT IS CLAIMED IS:

1. A negative pressure wound therapy apparatus, comprising:

a negative pressure source configured to be in fluid communication with a wound dressing, the negative pressure source configured to provide negative pressure to the wound;

a canister configured to be in fluid communication with the dressing and the negative pressure source, the canister configured to collect exudate removed from the wound;

a pressure sensor configured to monitor one or more characteristics of pressure signals generated by the negative pressure source; and

a controller configured to determine a level of exudate in the canister based at least in part on the measured one or more characteristics of the pressure signals.

2. The apparatus of claim 1, wherein the measured one or more characteristics of the pressure signals comprises magnitude of the pressure signals, and wherein the magnitude of the pressure signals increases as the level of exudate in the canister increases.

3. The apparatus of any of preceding claims, wherein the canister comprises a filter configured to become occluded in order to prevent overflow of the canister and the controller is further configured to detect a canister pre-full condition before the filter becomes occluded.

4. The apparatus of claim 3, wherein the controller is further configured to provide an indication of the canister pre-full condition to a user.

5. The apparatus of any of preceding claims, wherein the controller is further configured to determine the level of exudate in the canister based at least in part on the measured one or more characteristics of the pressure signals and a measured activity level of the negative pressure source.

6. The apparatus of claim 5, wherein the negative pressure source comprises a vacuum pump and the activity level of the negative pressure source corresponds to a speed of the vacuum pump.

7. The apparatus of claim 6, further comprising a tachometer configured to measure the speed of the vacuum pump.

8. The apparatus of any of claims 5 to 7, further comprising a fluid flow path configured to fluidically connect the dressing, the canister, and the negative pressure source, wherein the controller is further configured to determine a leak rate of fluid in the flow path based at least in part on the activity level of the negative pressure source, and wherein the controller is configured to determine the level of exudate in the canister based at least in part on the measured one or more characteristics of the pressure signals and the determined leak rate.

9. The apparatus of any of preceding claims, wherein the controller is further configured to remove noise from the measured one or more characteristics of the pressure signals.

10. The apparatus of any of preceding claims, wherein the controller is configured to determine the level of exudate in the canister based at least in part on comparing the measured one or more characteristics of the pressure signals to one or more thresholds.

11. The apparatus of any of preceding claims, wherein the measured one or more characteristics comprises magnitude and frequency of pressure pulses and wherein the controller is configured to determine the level of exudate in the canister based at least in part on the magnitude and frequency of the pressure signals, wherein the magnitude of the pressure signals increases as the level of exudate in the canister increases and the frequency of the pressure signals decreases as the level of exudate in the canister increases.

12. The apparatus of any of preceding claims, wherein the controller configured to determine the level of exudate in the canister irrespective of an intensity of a leak present in a fluid flow path configured to fluidically connect the dressing, the canister, and the negative pressure source.

13. The apparatus of any of preceding claims, wherein the controller is configured to determine the level of exudate in the canister based at least in part on a change in the measured one or more characteristics of the pressure signals.

14. The apparatus of any of preceding claim, further comprising the wound dressing configured to be placed over a wound.

15. A method of operating a negative pressure wound therapy apparatus, comprising:

monitoring pressure signals generated by a negative pressure source in fluid communication with a wound dressing and a canister; and

determining a level of aspirated exudate in the canister based at least in part on one or more characteristics of the monitored pressure signals.

16. The method of claim 15, wherein the one or more characteristics of the monitored pressure signals comprises magnitude of the pressure signals, and wherein the magnitude of the pressure signals increases as the level of exudate in the canister increases.

17. The method of any of claims 15 to 16, wherein the canister comprises a filter configured to become occluded in order to prevent overflow of the canister and the method further comprises detecting a canister pre-full condition before the filter becomes occluded.

18. The method of claim 17, further comprising providing an indication of the canister pre-full condition to a user.

19. The method of any of claims 15 to 18, further comprising measuring activity level of the negative pressure source and determining the level of exudate in the canister based at least in part on the one or more characteristics of the monitored pressure signals and the measured activity level.

20. The method of claim 19, wherein the negative pressure source comprises a vacuum pump and the activity level of the negative pressure source corresponds to a speed of the vacuum pump.

21. The method of claim 20, further comprising measuring the speed of the vacuum pump with a tachometer.

22. The method of any of claims 19 to 21, further comprising determining a leak rate of fluid in a flow path based at least in part on the activity level of the negative pressure source, and determining the level of exudate in the canister based at least in part on the one or more characteristics of the monitored pressure signals and the determined leak rate, wherein the fluid flow path fluidically connects a dressing placed over a wound, the negative pressure source, and the canister.

23. The method of any of claims 15 to 22, further comprising removing noise from the pressure signal measurements.

24. The method of any of claims 15 to 23, further comprising determining the level of exudate in the canister based at least in part on comparing the one or more characteristics of the monitored pressure signals to one or more thresholds.

25. The method of any of claims 15 to 24, wherein the one or more characteristics of the monitored pressure signals comprise magnitude and frequency of the pressure signals, and wherein the method further comprises determining the level of exudate in the canister based at least in part on the magnitude and the frequency of the monitored pressure signals, wherein the magnitude of the pressure signals increases as the level of exudate in the canister increases and the frequency of the pressure signals decreases as the level of exudate in the canister increases.

26. The method of any of claims 15 to 25, wherein determining the level of aspirated exudate in the canister is performed irrespective of an intensity of a leak present in a fluid flow fluidically connecting the dressing, the canister, and the negative pressure source.

27. The method of any of claims 15 to 26, further comprising determining the level of exudate in the canister based at least in part on a change in the one or more characteristics of the monitored pressure signals.

28. A negative pressure wound therapy apparatus, comprising:

a dressing configured to be placed over a wound, the dressing configured to collect exudate removed from the wound;

a negative pressure source configured to be in fluid communication with the dressing, the negative pressure source configured to provide negative pressure to the wound;

a pressure sensor configured to monitor one or more characteristics of pressure signals generated by the negative pressure source; and

a controller configured to determine a level of exudate in the dressing based at least in part on the monitored one or more characteristics of the pressure signals.

29. The apparatus of claim 28, wherein the monitored one or more characteristics of the pressure signals comprises magnitude of the pressure signals, and wherein the magnitude of the pressure signals increases as the level of exudate in the dressing increases.

30. The apparatus of any of claims 28 to 29, wherein the dressing further comprises a filter configured to become occluded in order to prevent overflow and the controller is further configured to detect a dressing pre-full condition before the filter becomes occluded and provide an indication of the dressing pre-full condition to a user.

31. The apparatus of claim any of claims 28 to 30, wherein the controller is further configured to determine the level of exudate in the dressing based at least in part on the monitored one or more characteristics of the pressure signals and a measured activity level of the negative pressure source.

32. The apparatus of claim 31, further comprising a fluid flow path configured to fludicially connect the dressing and the negative pressure source, wherein the controller is further configured to determine a leak rate of fluid in the flow path based at least in part on the activity level of the negative pressure source, and wherein the controller is configured to determine the level of exudate in the dressing based at least in part on the monitored one or more characteristics of the pressure signals and the determined leak rate.

33. The apparatus of any of claims 28 to 32, wherein the controller is configured to determine the level of exudate in the dressing based at least in part on comparing the monitored one or more characteristics of the pressure signals to one or more thresholds.

34. The apparatus of any of claims 28 to 33, wherein the monitored one or more characteristics of the pressure signals comprise magnitude and frequency of the pressure signals, and wherein controller is further configured to determine the level of exudate in the dressing based at least in part on the magnitude and the frequency of the pressure signals, wherein the magnitude of the pressure signals increases as the level of exudate in the dressing increases and the frequency of the pressure signals decreases as the level of exudate in the dressing increases.

35. The apparatus of any of claims 28 to 34, wherein the a controller configured to determine the level of exudate in the dressing irrespective of an intensity of a leak present in a fluid flow path configured to fluidically connect the dressing and negative pressure source.

36. The apparatus of any of claims 28 to 35, wherein the controller is configured to determine the level of exudate in the dressing based at least in part on a change in the monitored one or more characteristics of the pressure signals.

37. A method of operating a negative wound therapy apparatus comprising:

monitoring pressure signals generated by a negative pressure source in fluid communication with a wound dressing and a canister; and

determining a level of aspirated exudate in the dressing based at least in part on one or more characteristics of the monitored pressure signals.

38. The method of claim 37, wherein the monitored one or more characteristics of the pressure signals comprises magnitude of the pressure signals, and wherein the magnitude of the pressure signals increases as the level of exudate in the dressing increases.

39. The method of any of claims 37 to 38, wherein the dressing comprises a filter configured to become occluded in order to prevent overflow and the method further comprises detecting a dressing pre-full condition before the filter becomes occluded and providing an indication of the dressing pre-full condition to a user.

40. The method of any of claims 37 to 39, further comprising measuring activity level of the negative pressure source and determining the level of exudate in the dressing based at least in part on the monitored one or more characteristics of the pressure signals and the measured activity level.

41. The method of claim 40, further comprising determining a leak rate of fluid in the flow path based at least in part on the activity level of the negative pressure source, the fluid flow path fludicially connecting the dressing and the negative pressure source, and determining the level of exudate in the dressing based at least in part on the monitored one or more characteristics of the pressure signals and the determined leak rate.

42. The method of any of claims 37 to 41, further comprising determining the level of exudate in the dressing based at least in part on comparing the monitored one or more characteristics of the pressure signals to one or more thresholds.

43. The method of any of claims 37 to 42, wherein the monitored one or more characteristics of the pressure signals comprise magnitude and frequency of the pressure signals, and the method further comprises determining the level of exudate in the dressing based at least in part on the magnitude and the frequency of the pressure signals, wherein the magnitude of the pressure signals increases as the level of exudate in the dressing increases and the frequency of the pressure signals decreases as the level of exudate in the dressing increases.

44. The method of any of claims 37 to 43, further comprising determining the level of exudate in the dressing irrespective of an intensity of a leak present in a fluid flow path fluidically connecting the dressing and negative pressure source.

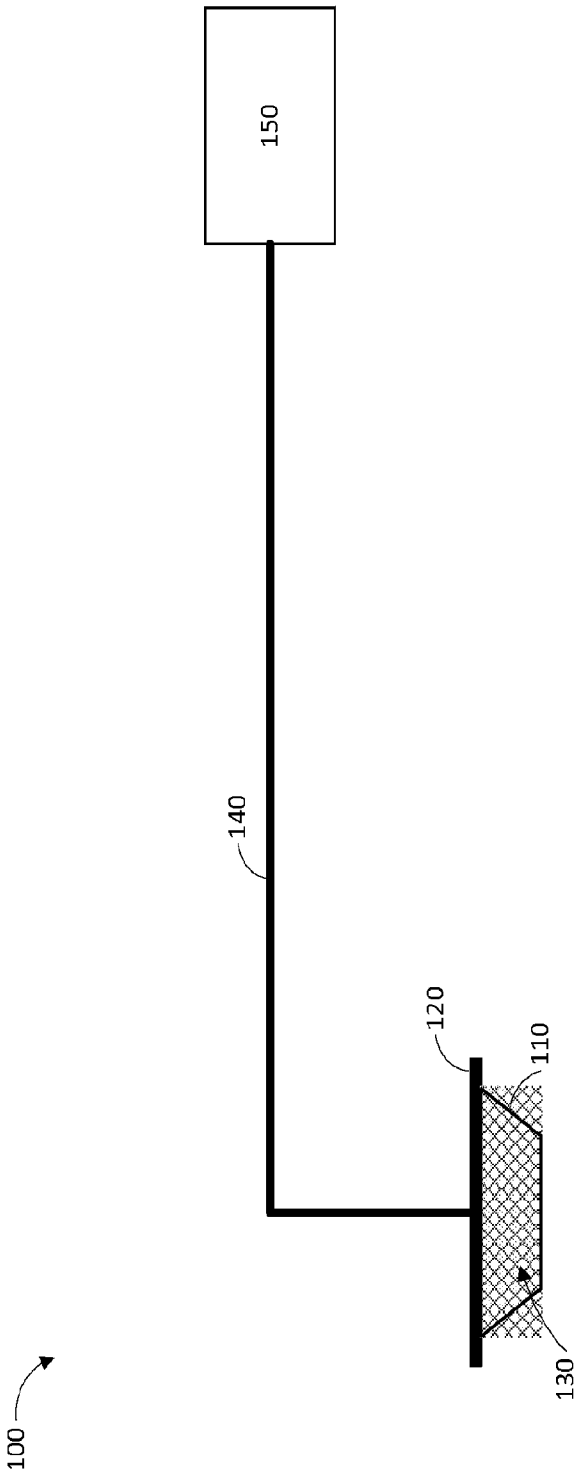

FIG. 1

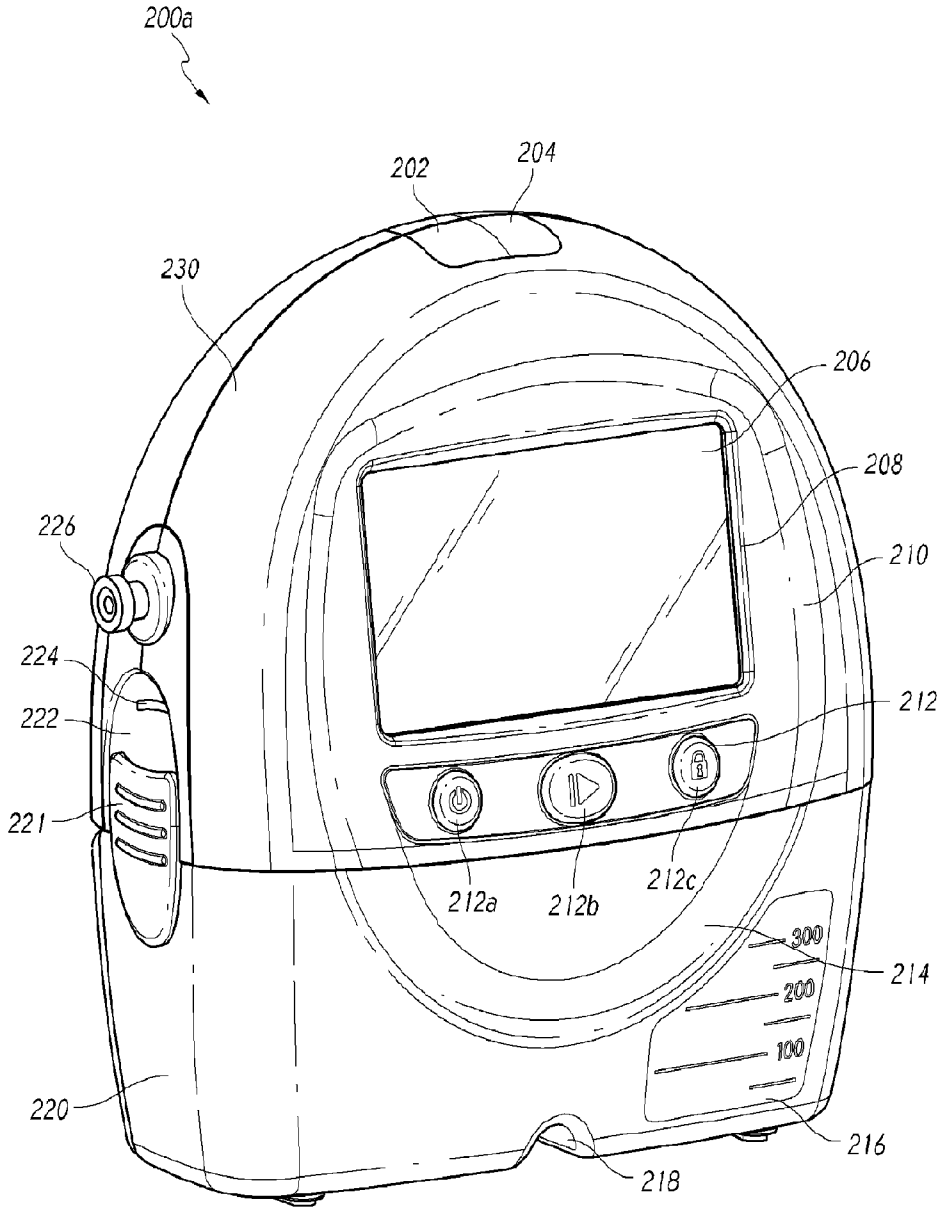
200a
202
204
230
206
208
226
210
224
212
222
221
212a
212b
212c
300
214
200
100
220
216
218

FIG. 2A

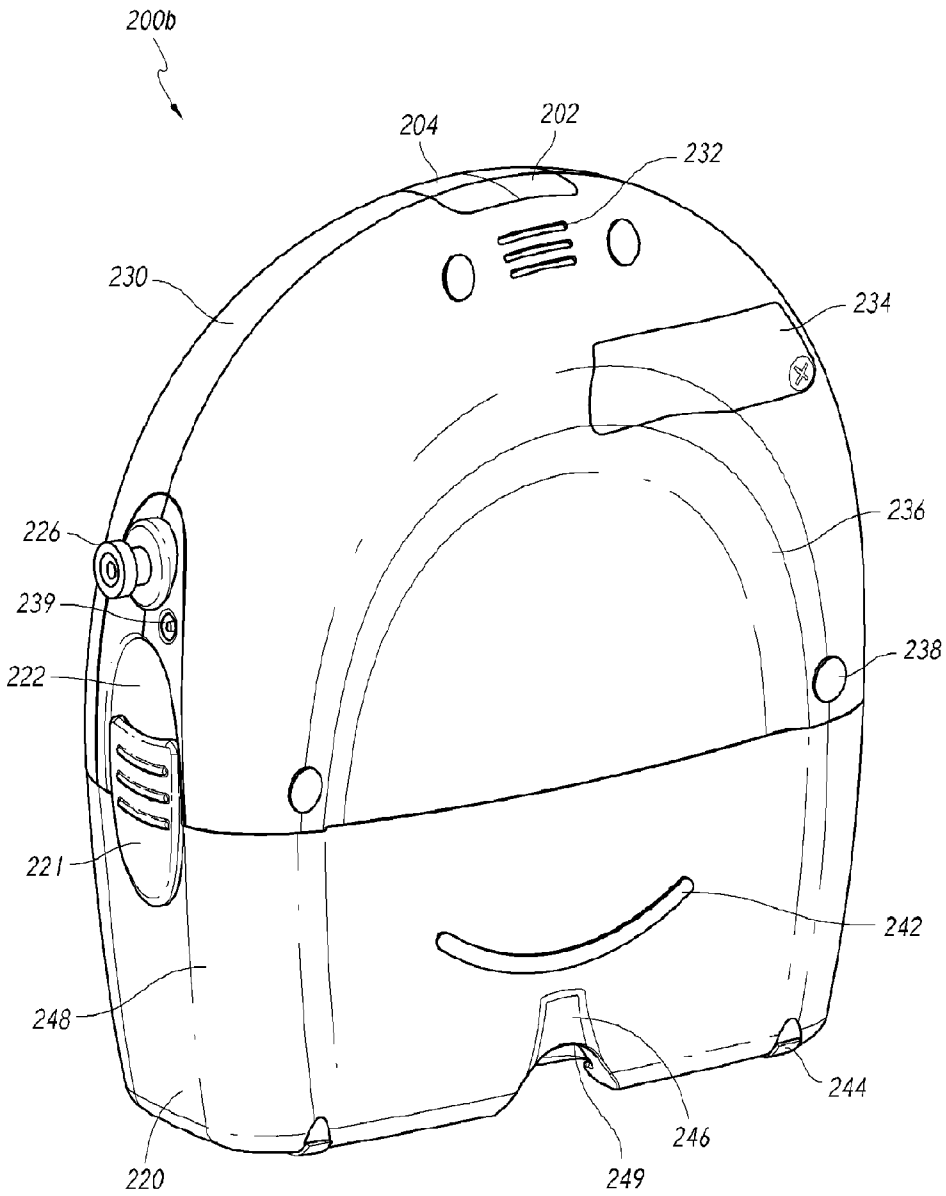
200b
204
202
232
230
234
226
236
239
238
222
221
242
248
244
246
220
249

FIG. 2B

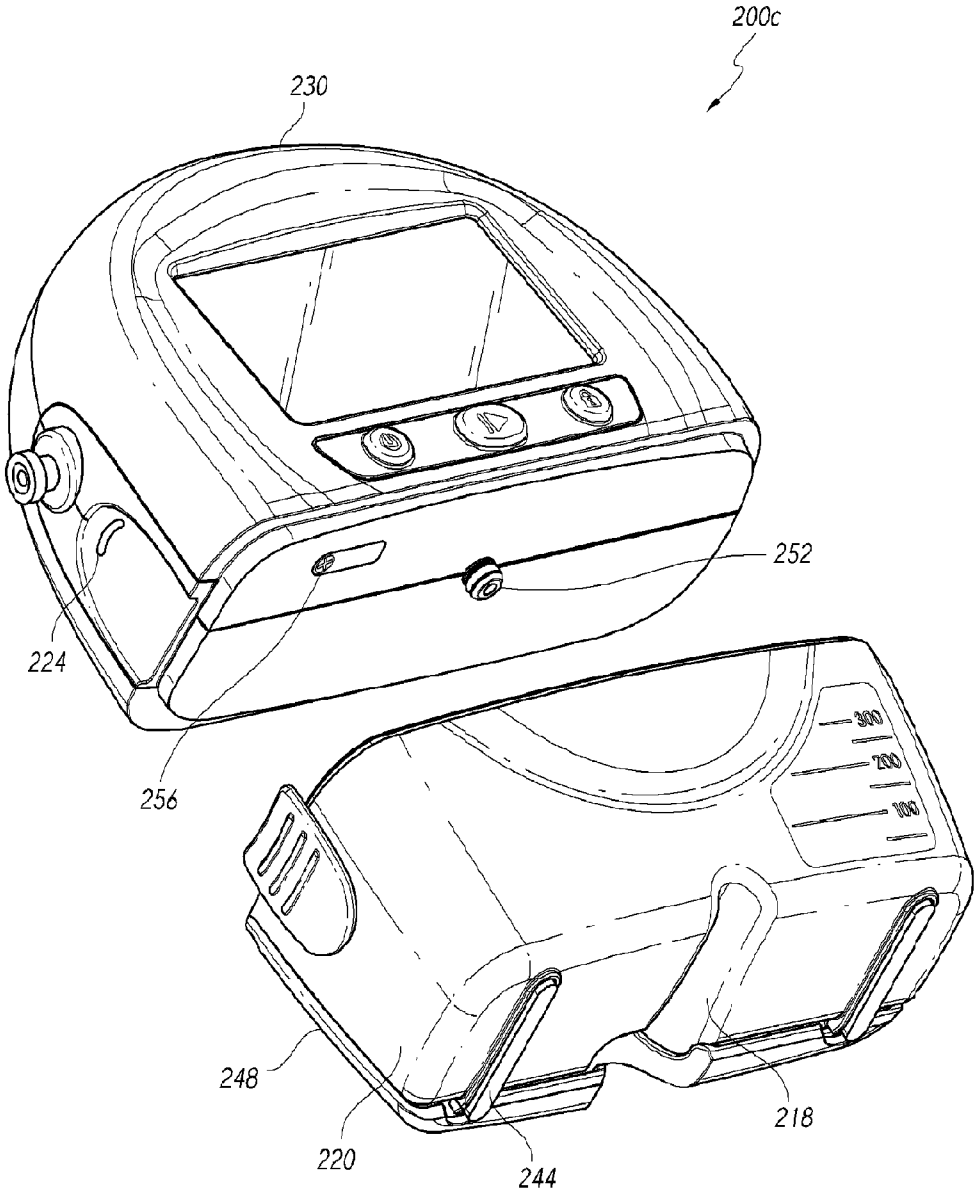

FIG. 2C

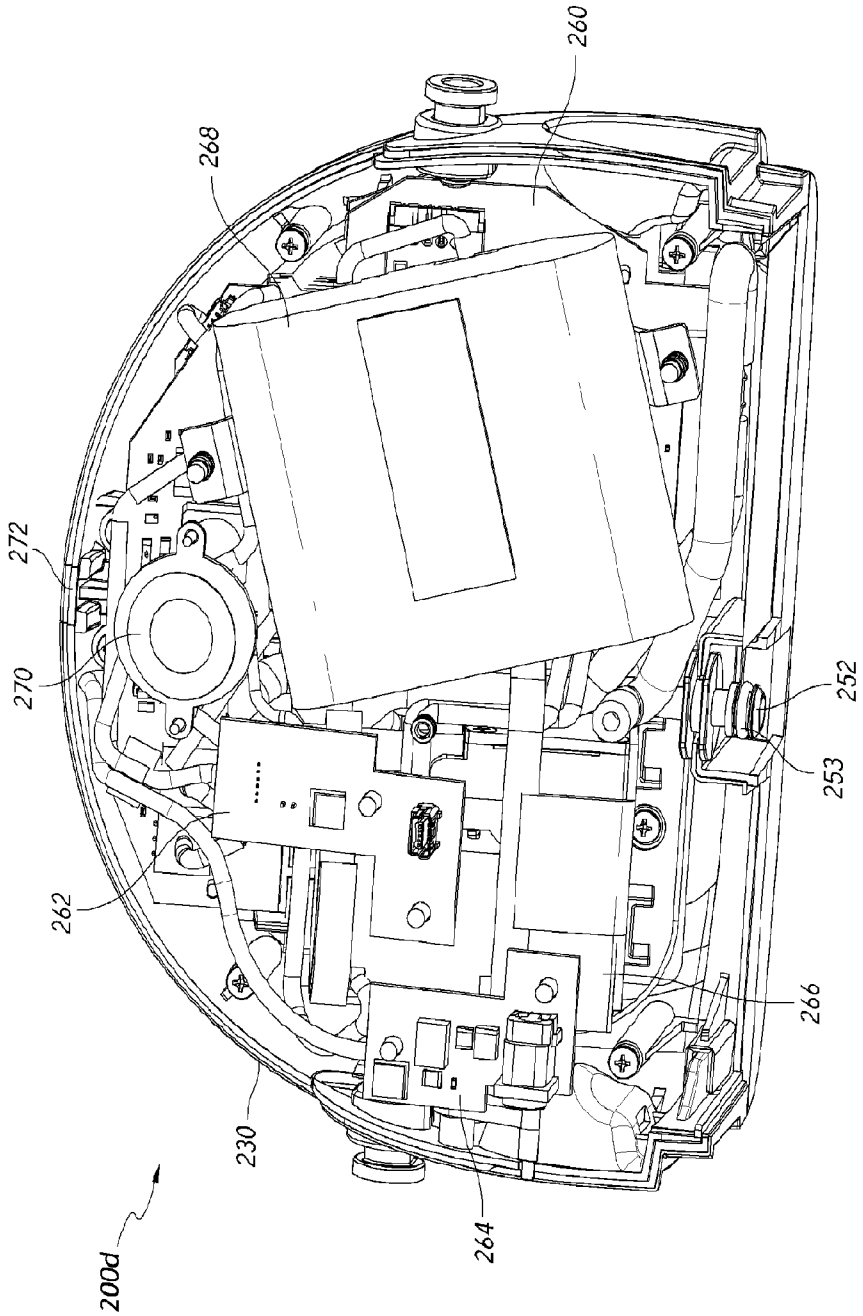

FIG. 2D

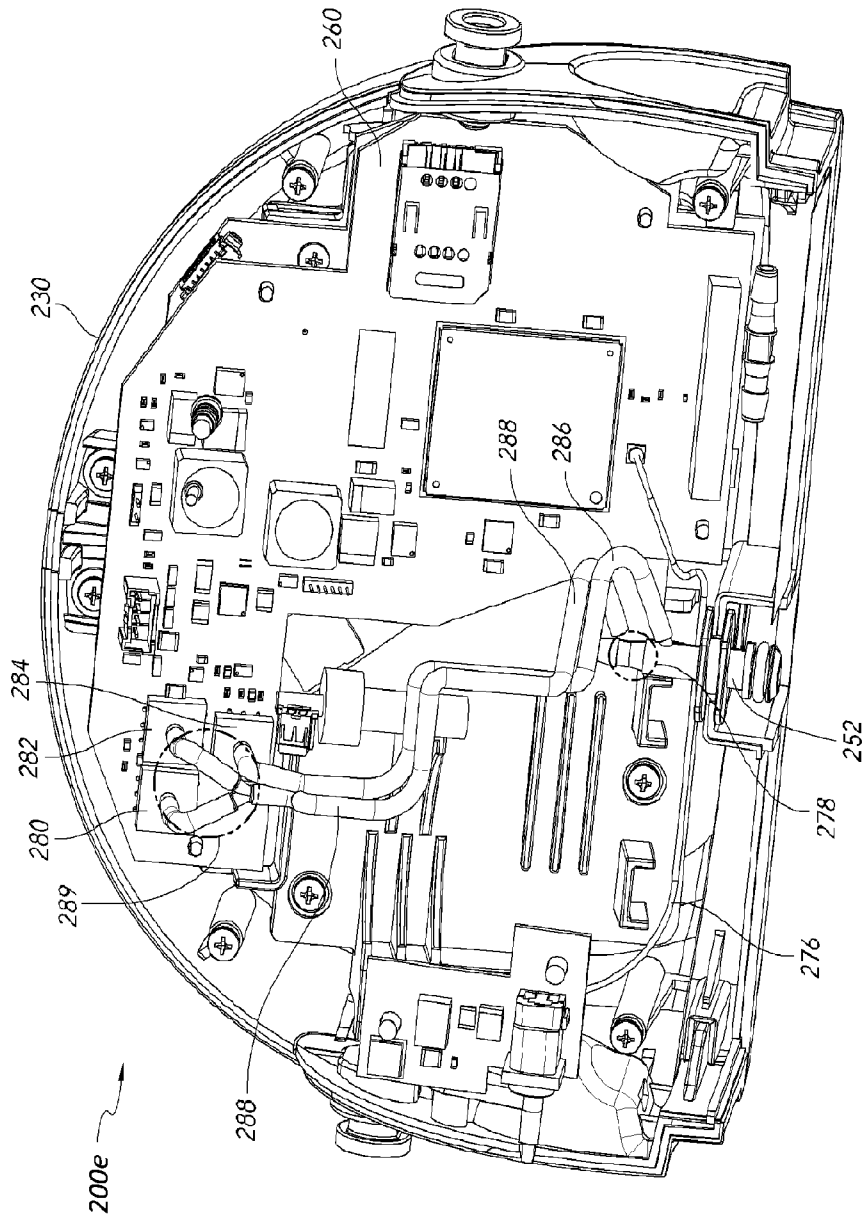

FIG. 2E

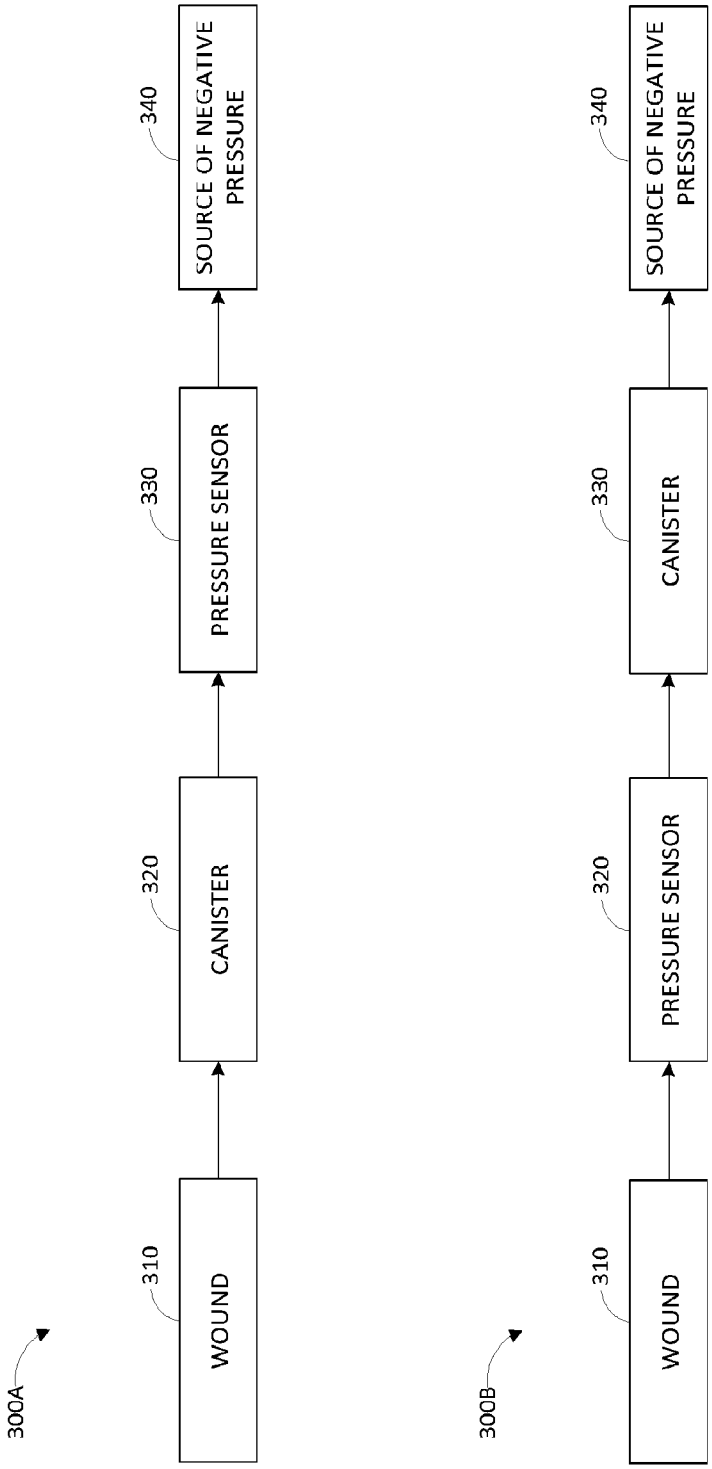
300A
310
WOUND
320
CANISTER
330
PRESSURE SENSOR
340
SOURCE OF NEGATIVE PRESSURE
300B
310
WOUND
320
PRESSURE SENSOR
330
CANISTER
340
SOURCE OF NEGATIVE PRESSURE

FIG. 3

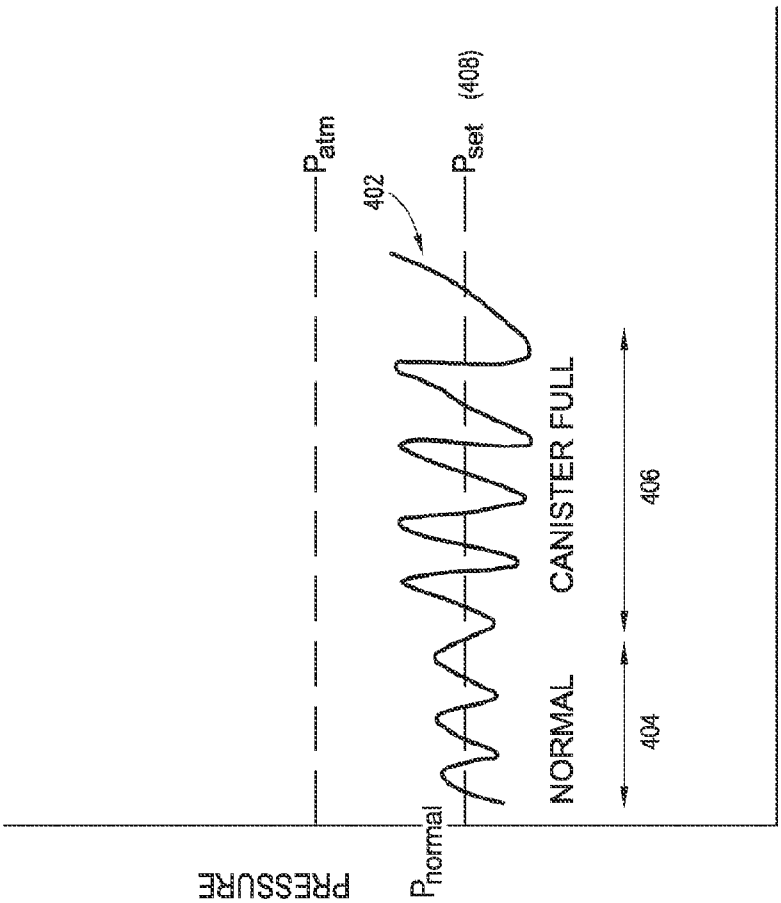
PRESSURE
P_{normal}
P_{atm}
402
P_{set} (408)
NORMAL
CANISTER FULL
404
406
TIME

FIG. 4

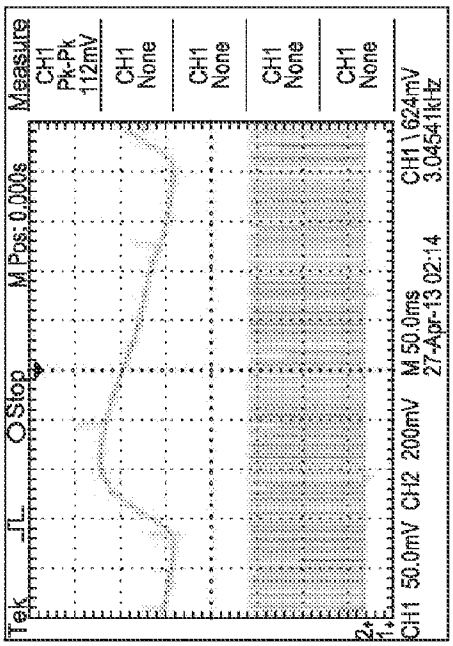

FIG. 5A

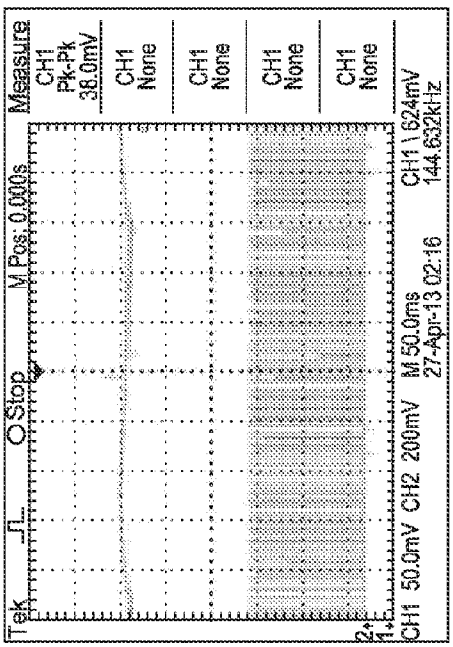

FIG. 5B

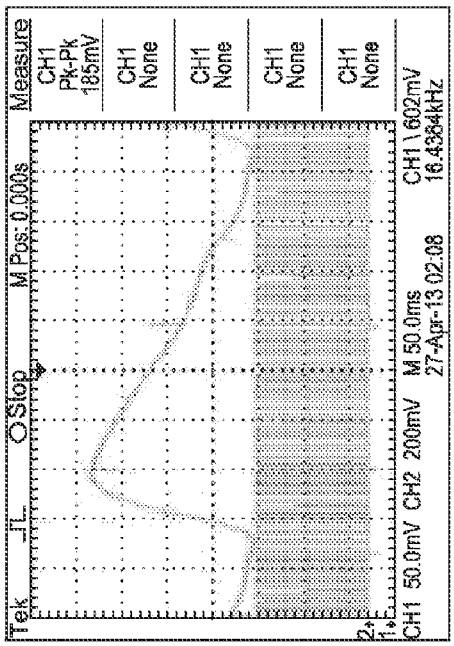

FIG. 5C

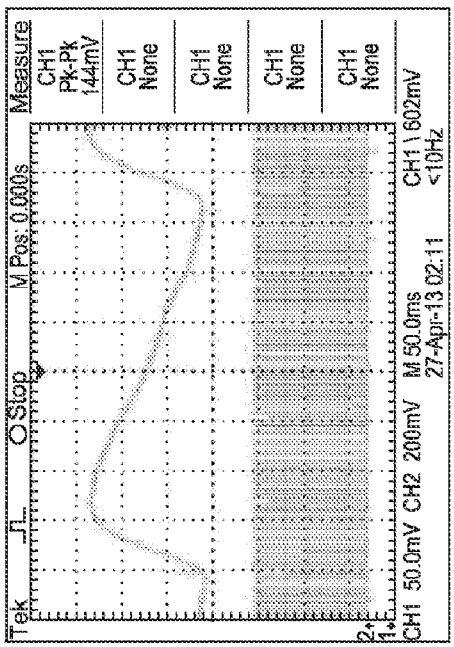

FIG. 5D

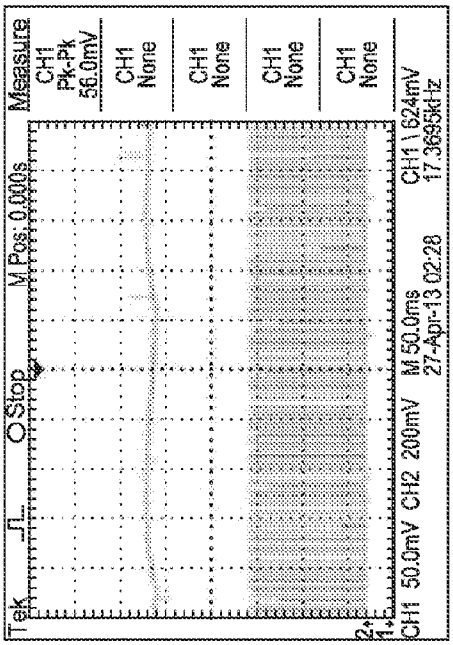

FIG. 6A

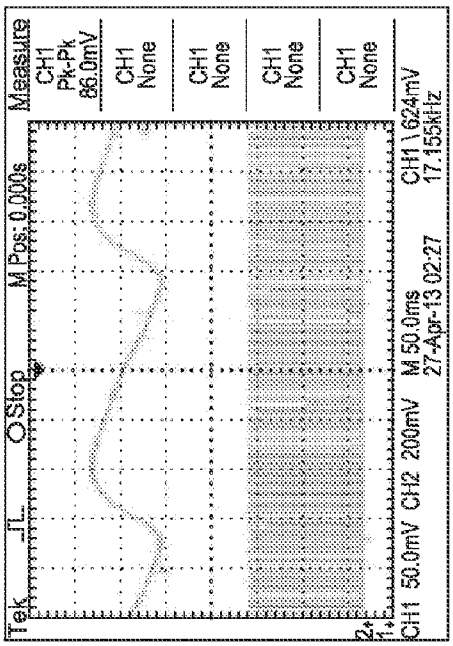

FIG. 6B

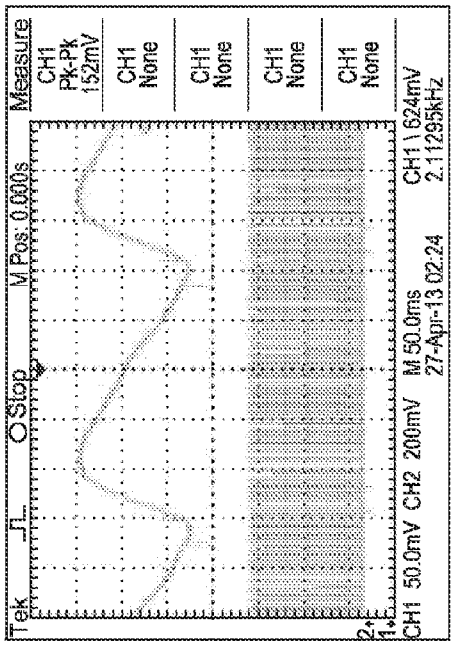

FIG. 6C

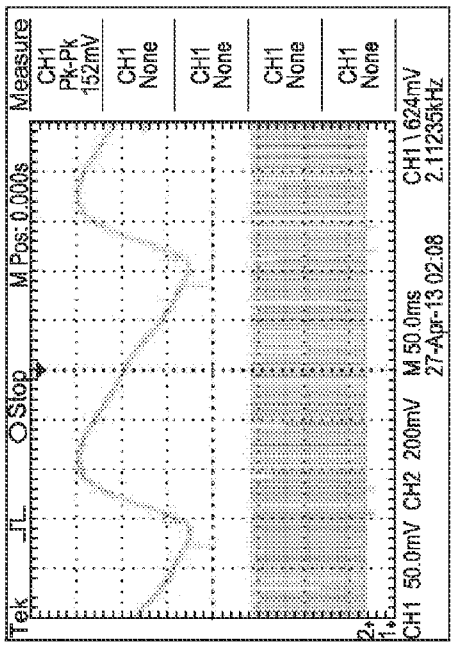

FIG. 6D

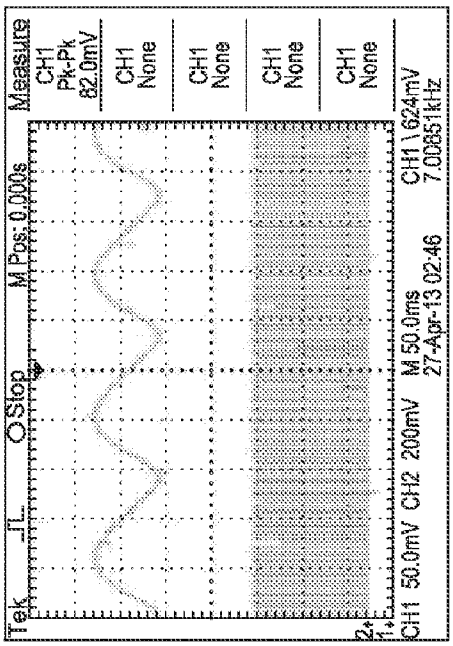

FIG. 7B

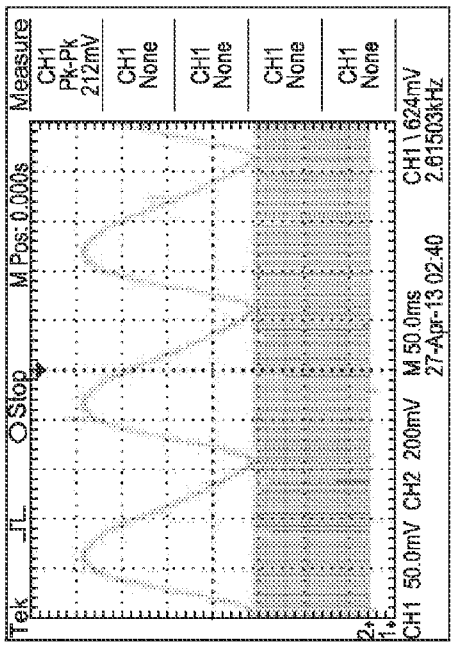

FIG. 7D

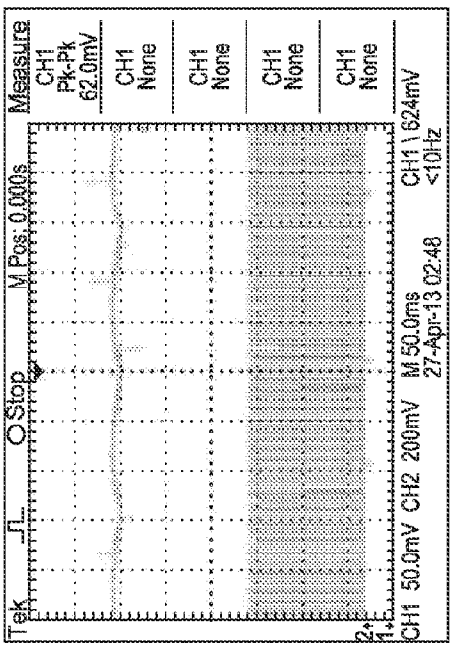

FIG. 7A

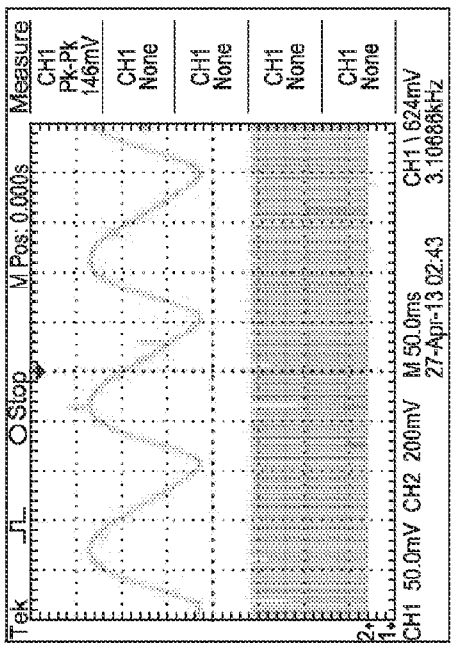

FIG. 7C

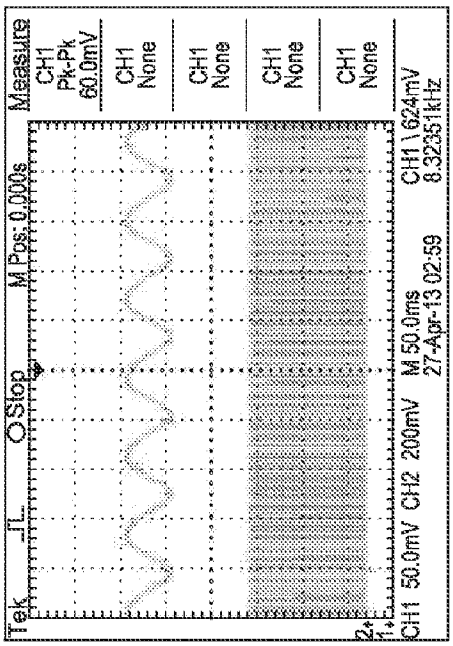

FIG. 8A

FIG. 8B

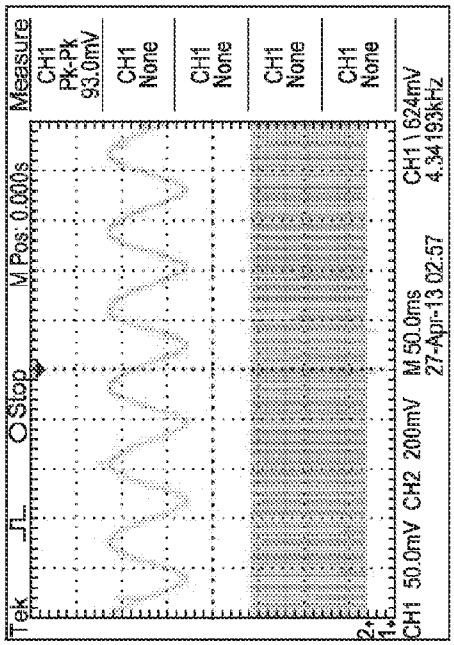

FIG. 8C

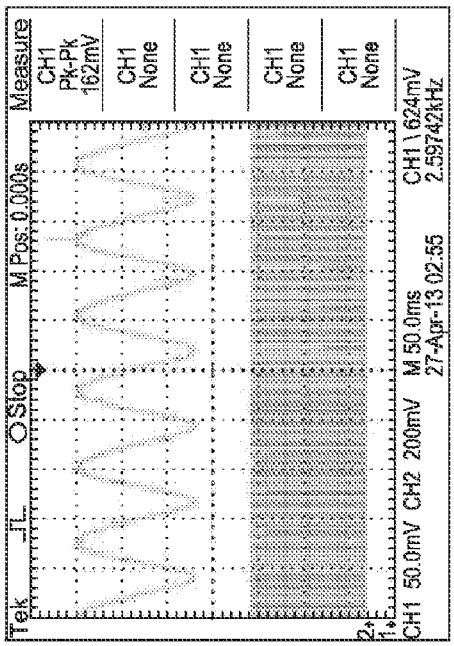

FIG. 8D

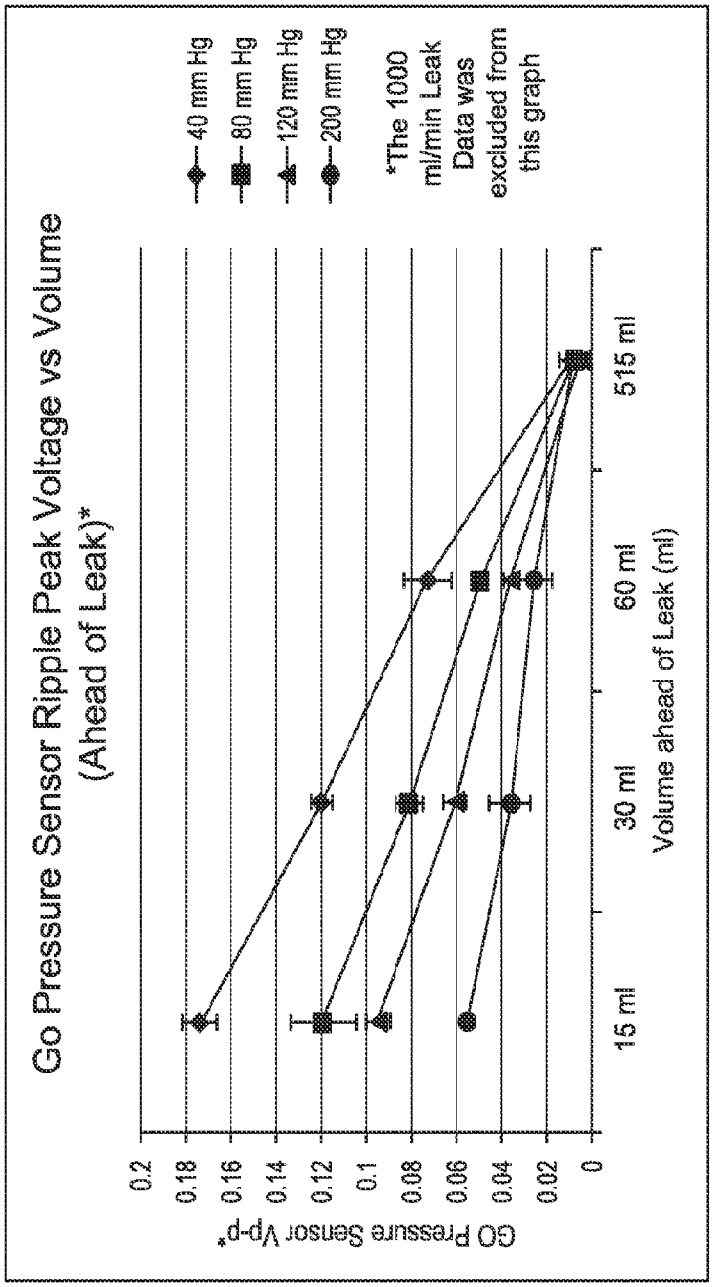
Go Pressure Sensor Ripple Peak Voltage vs Volume
(Ahead of Leak)*
40 mm Hg
80 mm Hg
120 mm Hg
200 mm Hg
*The 1000 ml/min Leak Data was excluded from this graph
GO Pressure Sensor Vp-p*
0.2
0.18
0.16
0.14
0.12
0.1
0.08
0.06
0.04
0.02
0
15 ml
30 ml
60 ml
515 ml
Volume ahead of Leak (ml)

FIG. 9

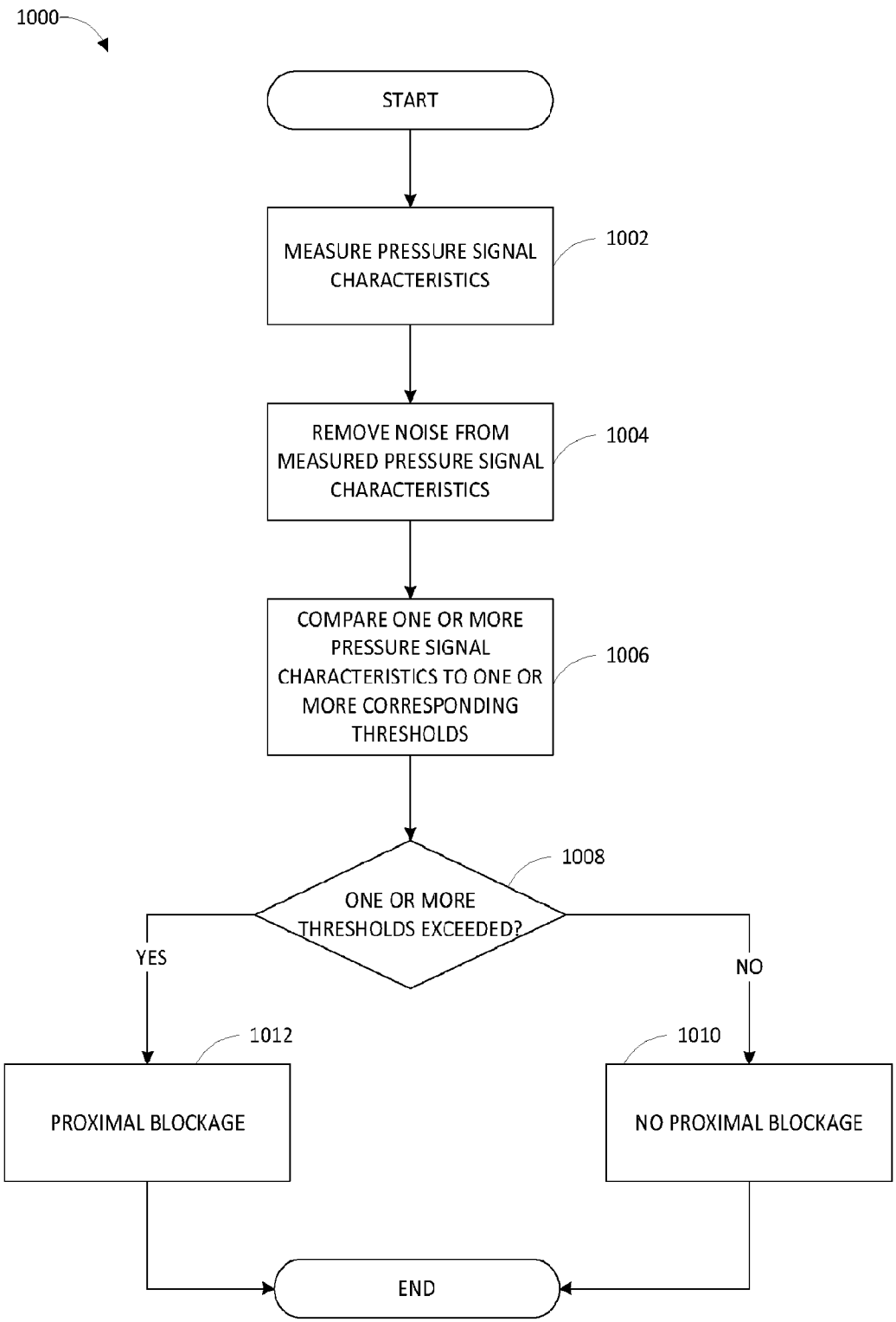
1000
START
MEASURE PRESSURE SIGNAL CHARACTERISTICS
1002
REMOVE NOISE FROM MEASURED PRESSURE SIGNAL CHARACTERISTICS
1004
COMPARE ONE OR MORE PRESSURE SIGNAL CHARACTERISTICS TO ONE OR MORE CORRESPONDING THRESHOLDS
1006
ONE OR MORE THRESHOLDS EXCEEDED?
1008
YES
NO
PROXIMAL BLOCKAGE
1012
NO PROXIMAL BLOCKAGE
1010
END

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/050233

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

see additional sheet

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

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

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

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

Remark on Protest

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

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

☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/050233

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/00 A61F13/02
ADD.

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)
A61M A61F

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)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/078539 A1 (VERNON-HARCOURT EDWARD [GB] ET AL) 29 March 2012 (2012-03-29) cited in the application	1-4,9, 10, 12-18, 23,24, 26,27
Y	claims 1, 2, 5 and 7; paragraphs 0080-0085; figures 1, 11 and 12	5-7, 19-21
X	WO 2008/036360 A2 (KCI LICENSING INC [US]; LOCKE CHRISTOPHER BRIAN [GB]; ROBINSON TIMOTHY) 27 March 2008 (2008-03-27) paragraphs 0019-0021, 0023, 0028, 0033, 0035; figures 1, 3-5	1-4,9, 10, 13-18, 23,24,27

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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

"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
15 December 2014	07/01/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Martin Amezaga, J

11

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/050233

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 342 584 A (KCI MEDICAL LTD [GB]) 19 April 2000 (2000-04-19) pages 5, 6; figures 1, 2	1,9,10, 14,15, 23,24
X	WO 03/101508 A2 (HILL ROM SERVICES INC [US]; RISK JAMES ROBERT JR [US]; PETROSENKO ROBE) 11 December 2003 (2003-12-11) page 15, line 9 - page 16, line 8; figure 6	1,9,14, 15,23
X	US 2007/032763 A1 (VOGEL RICHARD C [US]) 8 February 2007 (2007-02-08) paragraphs 0026-0028, 0030, 0038; figure 5	1,9,14, 15,23
Y	GB 2 235 877 A (TALLURI ANTONIO) 20 March 1991 (1991-03-20) page 4, line 21 - page 5, line 6; page 6, lines 10-17; figure 2	5-7, 19-21
X	WO 2013/078214 A1 (KCI LICENSING INC [US]; PRATT BENJAMIN A [GB]; LOCKE CHRISTOPHER BRIAN) 30 May 2013 (2013-05-30) paragraphs 0083-0091, 0096, 0097; figures 5, 6	28-44
X	US 2011/230849 A1 (COULTHARD RICHARD DANIEL JOHN [GB] ET AL) 22 September 2011 (2011-09-22) paragraph 0043; figure 1	28-44
X	US 2010/305490 A1 (COULTHARD RICHARD DANIEL JOHN [GB] ET AL) 2 December 2010 (2010-12-02) paragraphs 0045, 0114; figures 2, 16	28-44

11

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2014/050233

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2012078539 A1	29-03-2012	AU 2008285521 A1	12-02-2009
		CA 2695409 A1	12-02-2009
		EP 2187990 A1	26-05-2010
		US 2012078539 A1	29-03-2012
		US 2014352407 A1	04-12-2014
		WO 2009019419 A1	12-02-2009
		ZA 201000472 A	29-09-2010
WO 2008036360 A2	27-03-2008	KR 20090074188 A	06-07-2009
		WO 2008036360 A2	27-03-2008
GB 2342584 A	19-04-2000	AT 414547 T	15-12-2008
		CA 2347115 A1	20-04-2000
		CY 1109897 T1	10-09-2014
		DK 1121163 T3	09-03-2009
		EP 1121163 A1	08-08-2001
		ES 2315018 T3	16-03-2009
		GB 2342584 A	19-04-2000
		JP 4068807 B2	26-03-2008
		JP 2002527146 A	27-08-2002
		PT 1121163 E	30-12-2008
		US 7553306 B1	30-06-2009
		WO 0021586 A1	20-04-2000
WO 03101508 A2	11-12-2003	AU 2003238836 A1	19-12-2003
		CA 2487307 A1	11-12-2003
		EP 1565219 A2	24-08-2005
		EP 2650027 A2	16-10-2013
		EP 2650028 A2	16-10-2013
		JP 4558481 B2	06-10-2010
		JP 5118113 B2	16-01-2013
		JP 2005531340 A	20-10-2005
		JP 2010042281 A	25-02-2010
		WO 03101508 A2	11-12-2003
US 2007032763 A1	08-02-2007	AU 2006279074 A1	15-02-2007
		EP 1940485 A2	09-07-2008
		US 2007032763 A1	08-02-2007
		WO 2007019038 A2	15-02-2007
GB 2235877 A	20-03-1991	NONE	
WO 2013078214 A1	30-05-2013	AU 2012340789 A1	24-04-2014
		CA 2854478 A1	30-05-2013
		CN 103930138 A	16-07-2014
		EP 2782615 A1	01-10-2014
		US 2013144227 A1	06-06-2013
		WO 2013078214 A1	30-05-2013
US 2011230849 A1	22-09-2011	AU 2011227481 A1	23-08-2012
		CA 2790411 A1	22-09-2011
		CN 102781493 A	14-11-2012
		EP 2547375 A1	23-01-2013
		JP 2013521939 A	13-06-2013
		TW 201200177 A	01-01-2012
		US 2011230849 A1	22-09-2011
		US 2014330227 A1	06-11-2014
		WO 2011115908 A1	22-09-2011

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2014/050233

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010305490 A1	02-12-2010	NONE	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-27

Negative pressure wound therapy apparatus and method of operation, determining a level of aspirated exudate in the canister based on one or more characteristics of the monitored pressure signals generated by the negative pressure source; and possibly on the measured activity level of the negative pressure source as defined in dependent claim 5.

---

2. claims: 28-44

Negative pressure wound therapy apparatus and method of operation, determining a level of aspirated exudate in the dressing based at least in part on one or more characteristics of the monitored pressure signals generated by the negative pressure source.
