NEGATIVE PRESSURE WOUND THERAPY APPARATUS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 62/095,721, filed December 22, 2014, titled "NEGATIVE PRESSURE WOUND THERAPY APPARATUS AND METHODS," the disclosure of which is hereby incorporated by reference in its entirety herein.

INCORPORATION BY REFERENCE

[0002] Further components, features, and details of pump assemblies, wound dressings, wound treatment apparatuses and kits, and negative pressure wound treatment methods that may be used with any of the embodiments disclosed in this application are found in the following applications and/or publications, which are hereby incorporated by reference in their entireties herein.

[0003] U.S. Patent Application No. 14/715,527, filed May 18, 2015, titled "FLUIDIC CONNECTOR FOR NEGATIVE PRESSURE WOUND THERAPY."

[0004] U.S. Patent Application No. 14/418,908 (U.S. Patent Publication No. 2015/0190286), filed January 30, 2015, titled "WOUND DRESSING AND METHOD OF TREATMENT."

[0005] U.S. Patent Application No. 14/403,036 (U.S. Patent Publication No. 2015/0141941), filed November 21, 2014, titled "APPARATUSES AND METHODS FOR NEGATIVE PRESSURE WOUND THERAPY."

[0006] PCT International Application No. PCT/IB2013/001513 (International Publication No. WO/2013/171585), filed May 15, 2013, titled "NEGATIVE PRESSURE WOUND THERAPY APPARATUS."

[0007] PCT International Application No. PCT/IB2013/000847 (International Publication No. WO/2013/136181), filed March 12, 2013, titled "REDUCED PRESSURE APPARATUS AND METHODS."

[0008] U.S. Patent Application No. 13/092,042 (U.S. Patent Publication No. 2011/0282309), filed April 21, 2011, titled "WOUND DRESSING AND METHOD OF USE."

[0009] Each and all of the foregoing patent applications are hereby incorporated by reference in their entireties and made part of this disclosure.

BACKGROUND OF THE DISCLOSURE

Field of the Disclosure

[0010] Embodiments or arrangements disclosed herein relate to methods and apparatuses for dressing and treating a wound with topical negative pressure (TNP) therapy. For example but without limitation, any embodiments disclosed herein relate to treating a wound with reduced pressure provided from a pump kit. Although not required, any embodiments of the pump kit can be sterile. As another non-limiting example, any embodiments disclosed herein relate to apparatuses and methods for controlling the operation of a TNP system.

Description of the Related Art

[0011] Many different types of wound dressings are known for aiding in the healing process of a human or animal. These different types of wound dressings include many different types of materials and layers, for example, pads such as gauze pads and/or foam pads. Topical negative pressure ("TNP") therapy, sometimes referred to as vacuum assisted closure, negative pressure wound therapy, or reduced pressure wound therapy, is widely recognized as a beneficial mechanism for improving the healing rate of a wound. Such therapy is applicable to a broad range of wounds such as incisional wounds, open wounds and abdominal wounds or the like.

[0012] TNP therapy assists in the closure and healing of wounds by reducing tissue oedema; encouraging blood flow; stimulating the formation of granulation tissue; removing excess exudates, and may reduce bacterial load and thus reduce the potential for infection of the wound. Furthermore, TNP therapy permits less outside disturbance of the wound and promotes more rapid healing.

SUMMARY OF SOME EMBODIMENTS

[0013] Embodiments of the present disclosure relate to apparatuses and methods for wound treatment. Some of the wound treatment apparatuses described herein comprise a pump system for providing negative pressure to a wound site. Wound treatment apparatuses may also comprise wound dressings that may be used in combination with the pump assemblies described herein, and connectors for connecting the wound dressings to the pump assemblies.

[0014] In some embodiments, an apparatus for use in negative pressure wound therapy comprises a pump assembly, comprising an electrically conductive coil, a magnet, a diaphragm, and a dampener. The coil can be directly or indirectly coupled with the diaphragm and can be configured to move at least a portion of the diaphragm to pump a fluid through the pump assembly in response to a drive signal applied to the coil.

[0015] The apparatus, which may be or include a pump apparatus, may be arranged such that the pump assembly includes an electrically conductive upper pole, an electrically conductive lower pole, and one or more valves, wherein the magnet is positioned between at least a portion of the upper pole and the lower pole, and wherein the coil is positioned between at least a portion of the upper pole and the lower pole. The pump apparatus may be arranged such that the pump housing includes a chamber within which the dampener can be positioned. The pump apparatus may be arranged such that the dampener is retained within the chamber via an interference fit. The pump apparatus may be arranged such that the pump housing includes an exhaust channel designed to communicate fluid flow out of the pump assembly, the chamber being in communication with the exhaust channel. The pump apparatus may be arranged such that the chamber includes an opening. The pump apparatus may be arranged such that the chamber includes one or more ribs, the ribs spacing the dampener from the opening. The pump apparatus may be arranged such that the opening is positioned at an end of the exhaust channel.

[0016] The pump apparatus may be arranged such that it includes a manifold positioned between the pump assembly and a wound dressing. The pump apparatus may be arranged such that it includes a second dampener within the manifold. The pump apparatus may be arranged such that it includes a control board. The pump apparatus may be arranged such that it includes an electrical conduit for connecting the control board to the electrically

conductive coil. The pump apparatus may be arranged such that it includes a wound dressing designed to sealingly surround a wound. The pump apparatus may be arranged such that it includes a spring member wherein a periphery of the spring member is supported within the pump assembly so as to be in a fixed position relative to the diaphragm and a middle portion of the spring member is designed to deflect relative to the periphery of the spring member when a middle portion of the diaphragm axially deflects.

[0017] In some embodiments disclosed herein, the pump system can optionally form part of a wound treatment apparatus that also includes a wound dressing. In some embodiments, the pump system and/or a wound dressing can optionally have one or more sensors therein. For example, in some embodiments disclosed herein, the pump system and/or dressing can have a pressure monitor configured to monitor the pressure within the pump housing, dressing, or conduit or chambers within the pump system or between the pump system and the dressing, or in any combination of such. Additionally, some pump embodiments disclosed herein can use orifices or other features or components to control a flow or rate of flow of fluid through the pump system.

[0018] Some embodiments disclosed herein may also relate to a negative pressure therapy kit for reduced pressure wound therapy. The negative pressure therapy kit in some embodiments may include a pump system having an outer housing, a pump assembly supported within the housing, and a controller supported within or by the outer housing. In some embodiments, at least one switch or button may be supported by the outer housing. The at least one switch or button can be in communication with the controller and can be accessible to a user so as to permit a user to control one or more modes of operation of the pump system.

[0019] In some embodiments disclosed herein, though not required, a negative pressure therapy system can comprise a dressing configured to form a substantially fluid tight seal over a wound and a conduit coupleable with the dressing and the pump system and configured to provide a substantially or completely enclosed fluid flow pathway from the pump system to the dressing.

[0020] In some embodiments, a method for controlling a pump system can include calculating at least one of an amplitude and an offset for a drive signal based at least in part on previously calculated parameters and a negative pressure setting, generating the

drive signal with the at least one calculated amplitude and offset, and applying the drive signal to the pump system. In some embodiments, the method can be performed under control of a controller of the pump system.

[0021] In some embodiments, the previously calculated parameters can include a plurality of calibrated amplitudes at a plurality of negative pressure settings. In some embodiments, the previously calculated parameters can include a plurality of calibrated offsets at a plurality of negative pressure settings. In some embodiments, the previously calculated parameters can include at least 3 parameters. In some embodiments, the previously calculated parameters can be specific to the pump system. In some embodiments, calculating the at least one of the amplitude and the offset for a drive signal can include calculating both the amplitude and the offset for the drive signal. In some embodiments, calculating the at least one of the amplitude and the offset for the drive signal can include interpolating between at least two previously calculated amplitudes or offsets. In some embodiments, the interpolation can be a linear interpolation. In some embodiments, the pump system can include a voice coil actuator connected to a diaphragm. In some embodiments, the pump system can include a spring which can affect a resonant frequency of the pump system.

[0022] In some embodiments, the method can include applying a start up signal when the pump system has been activated after a period of inactivity, the start up signal having at least one of an amplitude and an offset different from at least one of the amplitude and the offset of the drive signal. In some embodiments, the method can include calculating at least one of an amplitude and an offset for the start up signal based at least in part on previously calculated parameters and a negative pressure setting less than the negative pressure setting for calculating the drive signal. In some embodiments, the method can include generating the start up signal with the at least one calculated amplitude and offset.

[0023] In some embodiments, a pump system for negative pressure wound therapy can include a pump assembly, having an actuator and a diaphragm, and a controller which can control operation of the pump system. In some embodiments, the controller can calculate at least one of an amplitude and an offset for a drive signal based at least in part on previously calculated parameters and a negative pressure setting, generate the drive signal

with the at least one calculated amplitude and offset and apply the drive signal to the pump system.

[0024] In some embodiments, the previously calculated parameters can include a plurality of calibrated amplitudes at a plurality of negative pressure settings. In some embodiments, the previously calculated parameters can include a plurality of calibrated offsets at a plurality of negative pressure settings.

[0025] In some embodiments, the controller can calculate both the amplitude and the offset for the drive signal. In some embodiments, the controller can interpolate between at least two previously calculated amplitudes or offsets. In some embodiments, the controller can linearly interpolate between at least two previously calculated amplitudes or offsets. In some embodiments, the previously calculated parameters can include at least 3 parameters. In some embodiments, the previously calculated parameters can be specific to the pump system. In some embodiments, the actuator can include a voice coil actuator connected to the diaphragm. In some embodiments, the pump assembly can include a spring which can affect a resonant frequency of the pump assembly.

[0026] In some embodiments, the controller can apply a start up signal when the pump system has been activated after a period of inactivity, the start up signal having at least one of an amplitude and an offset different from at least one of the amplitude and the offset of the drive signal. In some embodiments, the controller can calculate at least one of an amplitude and an offset for the start up signal based at least in part on previously calculated parameters and a negative pressure setting less than the negative pressure setting for calculating the drive signal and generate the start up signal with the at least one calculated amplitude and offset.

[0027] In some embodiments, a method for calibrating a pump system for negative pressure wound therapy can include generating a drive signal, actuating the pump system with the drive signal, measuring movement of a component of the pump system, calculating a first dimension based on the measured movement of the component and determining whether a convergence condition has been satisfied, wherein the convergence condition comprises a first condition that the first dimension be within a first tolerance of a first target value. In some embodiments, the method can be performed under control of a controller of the pump system.

[0028] In some embodiments, the method can include calculating a second dimension based on the measured movement of the component. In some embodiments, the convergence condition can include a second condition that the second dimension be within a second tolerance of a second target value. In some embodiments, the convergence condition can include a third condition that the first condition and the second condition are satisfied substantially simultaneously. In some embodiments, in response to determining that the convergence, the method can include storing a set of parameters associated with the drive signal condition is met. In some embodiments, in response to determining that the convergence condition is not satisfied, the method can include adjusting one or more parameters of the drive signal based at least in part on the measured movement of the component, generating an adjusted drive signal, actuating the pump system with the adjusted drive signal, measuring the movement of the component of the pump assembly, and determining whether the convergence condition has been satisfied.

[0029] In some embodiments, generating the drive signal includes selecting an amplitude of the drive signal. In some embodiments, generating the drive signal includes selecting an offset of the drive signal. In some embodiments, at least one of the first and second dimensions includes a travel of the component. In some embodiments, at least one of the first and second dimensions includes an average position of the component. In some embodiments, the component includes a piston connected to a diaphragm.

[0030] In some embodiments, a calibration system for calibrating a pump system for negative pressure wound therapy can include a sensor and a controller which can control operation of the calibration system. In some embodiments, the controller can generate a drive signal, actuate the pump system with the drive signal, measure movement of a component of the pump system with the sensor, and calculate a first dimension based on the measured movement of the component, and determine whether a convergence condition has been satisfied, wherein the convergence condition can include a first condition that the first dimension be within a first tolerance of a first target value.

[0031] In some embodiments, the controller can calculate a second dimension based on the measured movement of the component. In some embodiments, the convergence condition can include a second condition that the second dimension be within a second tolerance of a second target value. In some embodiments, the convergence condition can

include a third condition that the first condition and the second condition are satisfied substantially simultaneously. In some embodiments, upon determining that the convergence condition is met, the controller can store a set of parameters associated with the drive signal. In some embodiments, upon determining that the convergence condition is not satisfied, the controller can adjust one or more parameters of the drive signal based at least in part on the measured movement of the component, generate an adjusted drive signal, actuate the pump system with the adjusted drive signal, measure the movement of the component of the pump assembly with the sensor, and determine whether the convergence condition has been satisfied. In some embodiments, the controller can select an amplitude of the drive signal when generating the drive signal. In some embodiments, the controller can select an offset of the drive signal when generating the drive signal. In some embodiments, at least one of the first and second dimensions can include a travel of the component. In some embodiments, at least one of the first and second dimensions can include an average position of the component. In some embodiments, the component can include a piston connected to a diaphragm.

[0032] In some embodiments, a method for controlling a pump system for negative pressure wound therapy can include providing negative pressure, via a flow path, to a wound dressing positioned over a wound, the flow path fluidically connecting the pump system to the wound dressing, measuring a first pressure value in the flow path at a first time, measuring a second pressure value in the flow path at a second time, calculating a first rate of pressure change using the first and second pressure values and in response to determining that the calculated first rate of pressure change satisfies a threshold rate, providing an indication that the wound dressing is full. In some embodiments, the method can be performed under control of a controller of the pump system.

[0033] In some embodiments, the method can include measuring a third pressure value in the flow path at a third time, measuring a fourth pressure value within the flow path at a fourth time, calculating a second rate of pressure change using the third and fourth pressure values, and providing the indication that the wound dressing is full in response to determining that the calculated first and second rates of pressure change satisfy the threshold rate. In some embodiments, the pressure in the fluid flow path is between a maximum

pressure and a minimum pressure. In some embodiments, the method can include determining whether the second pressure value is less than a minimum pressure.

[0034] In some embodiments, a pump system for negative pressure wound therapy can include a pump assembly to provide a negative pressure, via a flow path, to a wound dressing positioned over a wound, the flow path fluidically connecting the pump system to the wound dressing, a sensor which can measure a pressure in the flow path, and a controller which can control operation of the pump system. In some embodiments, the controller can measure a first pressure value in the flow path at a first time, measure a second pressure value in the flow path at a second time, calculate a first rate of pressure change using the first and second pressure values and provide an indication that the wound dressing is full in response to determining that the calculated first rate of pressure change satisfies a threshold rate.

[0035] In some embodiments, the controller can measure a third pressure value in the flow path at a third time, measure a fourth pressure value within the flow path at a fourth time, calculate a second rate of pressure change using the third and fourth pressure values and provide the indication that the wound dressing is full in response to determining that the calculated first and second rates of pressure change satisfy the threshold rate. In some embodiments, the pressure in the fluid flow path is between a maximum pressure and a minimum pressure. In some embodiments, the controller can determine whether the second pressure value is less than a minimum pressure.

[0036] In some embodiments, a method for controlling a pump system for negative pressure wound therapy can include applying a drive signal to a pump assembly of the pump system, the drive signal alternating between a positive amplitude and a negative amplitude and the drive signal having an offset and sampling a pressure within a fluid flow path connecting the pump system to a wound dressing placed over a wound during one or more time intervals, wherein each of the one or more time intervals occurs when the drive signal is approximately at an amplitude that is substantially at one or more sampling amplitudes. In some embodiments, the method can be performed under control of a controller of the pump system.

[0037] In some embodiments, the sampling amplitude can include a local maxima of the amplitude. In some embodiments, the sampling amplitude can include a local minima

of the amplitude. In some embodiments, the sampling amplitude can include a zero crossing of the amplitude. In some embodiments, the sampling amplitude can include an offset crossing of the amplitude. In some embodiments, the method can include, during each of the one or more time intervals, sampling the pressure at least twice. In some embodiments, the method can include averaging the pressure samples during each time interval.

[0038] In some embodiments, a pump system for negative pressure wound therapy can include a pump assembly, having an actuator and a diaphragm, and a controlled which can control operation of the pump system. In some embodiments, the controller can apply a drive signal to the pump assembly, the drive signal alternating between a positive amplitude and a negative amplitude and the drive signal having an offset and sample a pressure within a fluid flow path connecting the pump assembly to a wound dressing placed over a wound during one or more time intervals, wherein each of the one or more time intervals occurs when the drive signal is approximately at an amplitude that is substantially at one or more sampling amplitudes.

[0039] In some embodiments, the sampling amplitude can include a local maxima of the amplitude. In some embodiments, the sampling amplitude can include a local minima of the amplitude. In some embodiments, the sampling amplitude can include a zero crossing of the amplitude. In some embodiments, the sampling amplitude can include an offset crossing of the amplitude. In some embodiments, during each of the one or more time intervals, the controller can sample the pressure at least twice. In some embodiments, the controller can average the pressure samples during each time interval.

[0040] In various embodiments, a pump system configured for negative pressure wound therapy is described. The pump system can include a pump assembly configured to provide a negative pressure, via a flow path, to a wound dressing configured to be positioned over a wound, the flow path configured to fluidically connect the pump system to the wound dressing. The pump system can include a sensor configured to measure a pressure in the flow path. The pump system can include a controller configured to control operation of the pump system. The controller can be configured to measure a first pressure value in the flow path at a first time, measure a second pressure value in the flow path at a second time, calculate a first rate of pressure change using the first and second pressure values, and

provide an indication that the wound dressing is full in response to determining that the calculated first rate of pressure change satisfies a threshold rate of change.

[0041] In various embodiments, a method for controlling a pump system configured for negative pressure wound therapy is described. The method can include causing provision of negative pressure, via a flow path, to a wound dressing configured to be positioned over a wound, the flow path configured to fluidically connect the pump system to the wound dressing. The method can include measuring a first pressure value in the flow path at a first time. The method can include measuring a second pressure value in the flow path at a second time. The method can include calculating a first rate of pressure change using the first and second pressure values. In response to determining that the calculated first rate of pressure change satisfies a threshold rate of change, the method can include providing an indication that the wound dressing is full. The method can be performed under control of a controller of the pump system.

[0042] Any of the features, components, or details of any of the arrangements or embodiments disclosed in this application, including without limitation any of the pump embodiments (for example, any of the voice coil pump embodiments) and any of the negative pressure wound therapy embodiments disclosed below, are interchangeably combinable with any other features, components, or details of any of the arrangements or embodiments disclosed herein to form new arrangements and embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0043] Embodiments of the present disclosure will now be described hereinafter, by way of example only, with reference to the accompanying drawings in which:

[0044] **Figure 1** is a front perspective view of an embodiment of a pump system having an outer housing with an optional mounting component attached thereto.

[0045] **Figure 2** is a front view of the pump system of Figure 1.

[0046] **Figure 3** is a rear perspective view of the pump system of Figure 1.

[0047] **Figure 4** is a rear view of the pump system of Figure 1.

[0048] **Figure 5** is a top view of the pump system of Figure 1.

[0049] **Figure 6** is a bottom view of the pump system of Figure 1.

[0050] **Figure 7** is a right side view of the pump system of Figure 1.

[0051] **Figure 8** is a left side view of the pump system of Figure 1.

[0052] **Figure 9** is a rear view of the outer housing of Figure 1, without the optional mounting component.

[0053] **Figure 10** is a rear view of the outer housing of Figure 9, with a cover removed to expose cavity within the outer housing.

[0054] **Figure 11** is a front perspective view of the outer housing of Figure 1, with a front portion of the outer housing removed to expose an embodiment of a circuit board and pump assembly.

[0055] **Figure 12** is a rear perspective view of the outer housing of Figure 1, with a rear portion of the outer housing removed to expose an embodiment of a circuit board and pump assembly.

[0056] **Figure 13** is a front perspective view of the outer housing of Figure 1, with a front portion of the outer housing and the circuit board removed to expose the pump assembly.

[0057] **Figure 14** is a front perspective view of an embodiment of a pump assembly and an intake manifold.

[0058] **Figure 15** is a rear view of the pump assembly and intake manifold of Figure 14.

[0059] **Figure 16** is a front view of the pump assembly and intake manifold of Figure 14.

[0060] **Figure 17A** is a cross sectional view of the intake manifold of Figure 14.

[0061] **Figure 17B** is a cross sectional view of the intake manifold with an outer housing and a control board.

[0062] **Figure 18** is a cross sectional view of the pump assembly of Figure 14.

[0063] **Figures 19-20** are exploded views of the pump assembly of Figure 14

[0064] **Figure 21** is a rear view of an embodiment of a pump housing

[0065] **Figure 22** is a front view of the pump housing of Figure 21.

[0066] **Figures 23-24** are perspective views of an embodiment of a valve.

[0067] **Figure 25** is a perspective view of an embodiment of a pump chamber body.

[0068] **Figure 26** is a front view of the pump chamber body of Figure 25.

[0069] **Figure 27** is a rear view of the pump chamber body of Figure 25.

[0070] **Figures 28-29** are perspective view of an embodiment of a diaphragm.

[0071] **Figure 30** is a side view of the diaphragm of Figures 28-29.

[0072] **Figure 31** is a side, cross-sectional view of the diaphragm of Figures 28-29.

[0073] **Figure 32** is a perspective view of an embodiment of a spacer.

[0074] **Figure 33** is a side, cross-sectional view of the spacer of Figure 32.

[0075] **Figures 34-35** are perspective views of an embodiment of a support member.

[0076] **Figure 36** is a perspective view of an embodiment of a shaft.

[0077] **Figure 37** is a side view of the shaft of Figure 36.

[0078] **Figure 38** is a perspective view of an embodiment of a spring.

[0079] **Figures 39-40** are perspective views of an embodiment of a bushing.

[0080] **Figure 41** is a rear view of an embodiment of the pump housing of Figure 21 with a dampening element.

[0081] **Figure 42** is a side, cross-sectional view of the pump housing and dampening element of Figure 41.

[0082] **Figure 43** is a perspective view of an embodiment of a detachable chamber.

[0083] **Figure 44** is a perspective view of another embodiment of a pump housing.

[0084] **Figure 45** is a perspective view of another embodiment of a pump housing.

[0085] **Figure 46** is a side, cross-sectional view of another embodiment of a manifold.

[0086] **Figure 47** is a perspective view of another embodiment of a pump housing.

[0087] **Figure 48** is a front view of the circuit board of Figure 11.

[0088] **Figure 49** is a rear view of the circuit board of Figure 11.

[0089] **Figure 50** is a perspective view of another embodiment of a support member and coil.

[0090] **Figure 51** is a schematic, cross-sectional view of an embodiment of wiring for the coil and support member of Figure 50.

[0091] **Figure 52** is a schematic, cross-sectional view of another embodiment of wiring for the coil and support member of Figure 50.

[0092] **Figure 53** is a schematic, cross-sectional view of another embodiment of wiring for the coil and support member of Figure 50.

[0093] **Figure 54** is a schematic, cross-sectional view of another embodiment of wiring for the coil and support member of Figure 50.

[0094] **Figure 55** is a perspective view of an embodiment of a combined spring and electrical conduit.

[0095] **Figure 56** is an embodiment of an arrangement of icons for a display.

[0096] **Figure 57A** is a top view of an embodiment of a pump system attached to a wound dressing.

[0097] **Figure 57B** is a view of an embodiment of a pump system configured to be attached to a wound dressing.

[0098] **Figure 58** is a top view of an embodiment of a weld contour between a pump housing and a pump chamber body.

[0099] **Figure 59** is a top view of an embodiment of a weld contour between a pump chamber body and a bushing.

[0100] **Figure 60** is a schematic of an embodiment of a pump system.

[0101] **Figure 61** is a schematic of another embodiment of a pump system.

[0102] **Figure 62** is a schematic of another embodiment of a pump system.

[0103] **Figure 63** is a top level state diagram according to some embodiments.

[0104] **Figure 64** is an exemplary pressure versus time graph according to some embodiments.

[0105] **Figure 65** is an exemplary drive signal for a source of negative pressure according to some embodiments.

[0106] **Figure 66** is a schematic illustrating the generation of a drive signal according to some embodiments.

[0107] **Figure 67** is an embodiment of a calibration method for generating parameters of a drive signal.

[0108] **Figure 68** is an exemplary travel versus iteration graph according to some embodiments.

[0109] **Figure 69** is an exemplary average position versus iteration graph according to some embodiments.

[0110] **Figure 70** is an embodiment of a method for determining a filter blockage.

[0111] **Figure 71** is an exemplary pressure versus time graph according to some embodiments.

[0112] **Figure 72** is another embodiment of a method for determining a filter blockage.

[0113] **Figure 73** is a front perspective view of the pump system of Figure 1 without the optional mounting component attached.

[0114] **Figure 74** is a front view of the pump system of Figure 73.

[0115] **Figure 75** is a rear perspective view of the pump system of Figure 73.

[0116] **Figure 76** is a rear view of the pump system of Figure 73.

[0117] **Figure 77** is a top view of the pump system of Figure 73.

[0118] **Figure 78** is a bottom view of the pump system of Figure 73.

[0119] **Figure 79** is a right side view of the pump system of Figure 73.

[0120] **Figure 80** is a left side view of the pump system of Figure 73.

[0121] **Figure 81** is a front perspective view of a pump mounting component.

[0122] **Figure 82** is a front view of the pump mounting component of Figure 81.

[0123] **Figure 83** is a rear perspective view of the pump mounting component of Figure 81.

[0124] **Figure 84** is a rear view of the pump mounting component of Figure 81.

[0125] **Figure 85** is a top view of the pump mounting component of Figure 81.

[0126] **Figure 86** is a bottom view of the pump mounting component of Figure 81.

[0127] **Figure 87** is a right side view of the pump mounting component of Figure 81.

[0128] **Figure 88** is a left side view of the pump mounting component of Figure 81.

DETAILED DESCRIPTION OF SOME EMBODIMENTS

[0129] Embodiments disclosed herein relate to apparatuses and methods of treating a wound with reduced pressure, including pump and wound dressing components and apparatuses. The apparatuses and components comprising the wound overlay and packing materials, if any, are sometimes collectively referred to herein as dressings.

[0130] It will be appreciated that throughout this specification reference is made to a wound. 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 disclosed herein, the components of the TNP system described herein can be particularly suited for incisional wounds that exude a small amount of wound exudate.

[0131] It will be understood that embodiments of the present disclosure are generally applicable to use in topical negative pressure ("TNP") 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 and by helping 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.

[0132] As is used herein, reduced or negative pressure levels, such as –X mmHg, represent pressure levels that are below standard atmospheric pressure, which corresponds to 760 mmHg (or 1 atm, 29.93 mmHg, 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).

[0133] The operating negative pressure range for some embodiments of the present disclosure can be between approximately -20 mmHg and approximately -200 mmHg, between approximately -50 mmHg and approximately -150 mmHg, between approximately -70 mmHg and -90 mmHg, any subrange within these ranges, or any other range as desired. In some embodiments, an operating negative pressure range of up to -70 mmHg, up to -80 mmHg, up to -90 mmHg, up to -100 mmHg, up to -110 mmHg, or up to any other pressure as desired can be used. For example, in some embodiments, the pump system can maintain negative pressure wound therapy at -80 mmHg (nominal) +/- 20 mmHg to a wound dressing and/or to a wound surface. Other details regarding the operation of the pump system are set forth in U.S. Publication Nos. 2011/0282309, 2013/0110058 and 2013/0331823 as well as International Patent Publication No. 2013/171585, and all embodiments, configurations, details, and illustrations of these publications are hereby incorporated by reference in their entireties as if made part of this disclosure.

[0134] Any of the embodiments disclosed herein can include a pump and/or a pump and dressing kit. However, the pump apparatuses and embodiments of the present disclosure are not limited to use with a dressing or for wound therapy. Any of the pump embodiments disclosed herein can be used independently of the dressing components disclosed herein. Further, any of the pump embodiments disclosed herein can be used, or can be adapted for use, for other purposes outside of negative pressure wound therapy. As such, any of the pump embodiments disclosed herein can be used, or can be adapted for use, to move fluids (gaseous and/or liquid) in any system or application. Any of the embodiments disclosed herein can be used on an exuding wound. For example, in some embodiments, the pump and/or kit can be used on wounds where the level of exudate is low (e.g., 0.6g (nominal) of liquid exudate/cm^2 of wound area per 24 hours), or on wounds where the level of exudate is moderate (e.g., 1.1g (nominal) of liquid exudate/cm^2 of wound area per 24

hours). In some embodiments, exudate from the wound is managed by the dressings disclosed herein through a combination of absorption in the dressing and an evaporation of moisture through the dressing. In some embodiments, exudate from the wound is managed by the dressings disclosed herein through absorption in the dressing or evaporation of moisture through the dressing. In embodiments where evaporation of exudate moisture through the dressing is intended, occlusive materials positioned over the dressing area can impair the intended evaporation.

Overview of the Mechanical Aspects of the Pump System

[0135] The pump system embodiments described herein can have a compact, small size. In some embodiments disclosed herein, a pump assembly of the pump system can have a diameter (e.g., equivalent diameter) or lateral size between 15 mm and 35 mm, less than 15 mm, less than 25 mm, less than 35 mm, or less than 50 mm. For example, in some embodiments, the pump system can have a diameter or lateral size of 10 mm, 23 mm, or 40 mm, or can have a diameter or lateral size in the range of approximately 26 mm to approximately 27 mm, between approximately 22 mm or smaller and approximately 28 mm. In some embodiments disclosed herein, the pump assembly can have a thickness or height of approximately 8 mm, between approximately 6 mm and approximately 10 mm, or a thickness or height of less than 20 mm. For example, in some embodiments, the thickness or height of the pump assembly can be 5 mm, 12 mm, or 20 mm. For example and without limitation, in some embodiments the pump assembly can have a volume of approximately 6.2 cubic centimeters, between approximately 5.0 cubic centimeters or less to approximately 7.0 cubic centimeters, or a volume of less than 10.0 cubic centimeters. For example, in some embodiments, the volume of the pump assembly can be 4.0 cubic centimeters, 6.0 cubic centimeters, or 8.0 cubic centimeters. In some embodiments, the housing of can have a lateral size of approximately 60.0 mm, between approximately 40.0 mm and approximately 80.0 mm, or a lateral size of less than 90 mm, and a height of approximately 15.0 mm, between approximately 10.0 mm and approximately 20.0 mm, or a height of less than 30 mm. For example, in some embodiments, the housing can have a Length x Width x Height dimension of 72 mm x 66 mm x 21 mm, approximately 72 mm x 66 mm x 21 mm, 70-73 mm x 64-67 mm x 20-22 mm, or a Length x Width x Height dimension of less than 90 mm x less

than 90 mm x less than 30 mm. For example, in some embodiments, the Length x Width x Height dimension of the housing can be 68 mm x 62 mm x 18 mm, 65 mm x 78 mm x 21 mm, 65 mm x 79 mm x 21 mm, or 80 mm x 74 mm x 25 mm. In some embodiments, the pump system can have a mass of 150 grams, approximately 150 grams, between 100-150 grams, or a mass of less than 200 grams, or a mass of less than 300 grams. For example, in some embodiments, the mass of the pump system can be 90 grams, 125 grams, 150 grams, or 220 grams. Of course, the pump system can be any miniaturized size and have any mass and volume that is manufacturable, and the overall power output and efficiency meet the needed requirements for the desired application, within or outside of wound therapy. As used herein, efficiency can be defined as (fluid power out) / (electrical power in).

[0136] The pump system can be produced for a low cost and can operate at high efficiencies, making it beneficial for portable, disposable, and/or single use applications. This pump can optionally be used in an ultra-portable single-use negative-pressure wound therapy (NPWT) device. In some embodiments, the pump system can run for 10 days on a small primary cell without the need for battery replacement or recharging. In some embodiments the pump system can run up to 10 days on a 3V, 2000mAh cell (e.g., with the pump working for about 20% of the time). In some embodiments, the pump system can be powered by two 1.5 volt, 2500-3000 mAh batteries connected in series. In some embodiments, the pump system can run for a week on a small primary cell such as one or more batteries having a total capacity of 3000 mAh at 3V without the need for battery replacement or recharging. Additionally, in some embodiments, the pump system can be subjected to X-ray scans during its use without interfering with its function. For example, in some embodiments, the pump system can be worn during computed tomography (CT) scans, computerized axial tomography (CAT) scans, and the like.

[0137] **Figures 1-8** illustrate multiple views of an embodiment of a pump system **100** having an outer housing **102** and an optional mounting component **104**, and **Figures 73-80** illustrate additional views of the pump system **100** with the optional mounting component **104** removed. As shown in the illustrated embodiment in **Figures 1-8**, the pump system **100** can include an outer housing **102** for containing and/or supporting components of the pump system **100**. The outer housing **102** can be formed from one or more portions, such as a front

portion **102a** and a rear portion **102b** as shown in **Figure 1**, which can be removably attached to form the outer housing **102**.

[0138] In some embodiments, the pump system **100** can optionally include a mounting component **104** which can be designed to advantageously allow the pump system **100** to be mounted on another object such as, but not limited to, a user's person. For example, **Figures 81-88** illustrate multiple views of an optional mounting component **104** that can be attached to a pump system **100**, and which is shown attached to the pump system **100** in **Figures 1-8**. In some embodiments, the mounting component **104** can include a clip **106** (as shown in **Figures 3-8**) designed to retain the mounting component **104** on a user's outerwear, such as on a user's pocket, a pouch, a belt, a flap, or otherwise. The clip **106** can be integrally formed with the base **108** of the mounting component **104** such that the clip **106** can provide a clamping force via resiliency of the material used to form the clip **106**. In some embodiments, the clip **106** can be a separate component from the base **108** and can include a biasing component, such as a coil spring, bent spring or the like, to provide a clamping force to retain the clip **106** on the user's person. In some embodiments, the clamping force can be low enough that a user can open the housing from the clamped position, but strong enough so that it will remain clamped about the pocket, flap, or other material.

[0139] In some embodiments, the mounting component **104** can be removably attached to the outer housing **102** such that the pump system **100** can be used with or without the mounting component **104**. For example, **Figures 1-8** illustrate the pump system **100** with the optional mounting component **104**, and **Figures 73-80** illustrate the pump system **100** without the optional mounting component **104**. As shown in these figures, this can beneficially give the user the option to reduce the overall form factor of the pump system **100** should the user decide to forego use of the optional mounting component **104** as illustrated in **Figures 73-80**. Moreover, this can advantageously allow a user to more easily replace one mounting component with another mounting component should the user decide to do so. As shown in the illustrated embodiment, the mounting component **104** can include one or more retention features, such as clasps **110** extending from the periphery of the base **108**, to retain the mounting component **104** on portions of the outer housing **102**. In the illustrated

embodiment, the mounting component **104** can be retained on the pump system **100** in a snap fit manner via use of the clasps **110**. In some embodiments, the retention features can be mechanical fasteners such as screws, nuts, bolts, snap-fit connectors, or the like.

[0140] With continued reference to the pump system **100** of **Figures 1-8**, the outer housing **102** can include a display **112** which can be designed to provide a user with information (e.g., information regarding an operational status of the pump system **100**). In some embodiments, the display **112** can include one or more indicators, such as icons **114**, which can alert the user to one or more operating and/or failure conditions of the pump system **100**. For example, the indicators can include icons for alerting the user to normal or proper operating conditions, pump failure, power failure, the condition or voltage level of the batteries, the condition or capacity of a wound dressing, detection of a leak within the dressing or fluid flow pathway between the dressing and the pump assembly, suction blockage, or any other similar or suitable conditions or combinations thereof. An exemplary set of icons **114'** of a display **112'** is illustrated in **Figure 56** which, from left to right, can include an "OK" indicator which can indicate normal operation of the pump system **100**, a "leak" indicator which can indicate the existence of a leak in the pump system **100** or components attached thereto, a "dressing full" indicator which can indicate that a wound dressing is at or near capacity, and a "battery critical" indicator which can indicate that the battery is at or near a critical level. In some embodiments, the icons **114** or **114'** can have a green and/or orange color, and/or can be illuminated with a green and/or orange light (e.g., colored LEDs).

[0141] In the illustrated embodiment, one or more icons **114** can be printed directly on the display **112** of the outer housing **102**. In some embodiments, one or more of the icons **114** can be provided on a label attached to a portion of the outer housing **102**. One or more of the icons **114** can be illuminated when the status corresponding to that icon exists in the system. As will be discussed in further detail below, one or more illumination components, such as LEDs, can be positioned within the outer housing **102** to illuminate the icons **114**. To enhance illumination of the icons using an illumination component within the outer housing **102**, portions of the outer housing **102** proximate and/or underlying one or more of the icons **114** can be reduced in thickness to increase the translucency of the outer housing **102** proximate and/or underlying the icons **114**. In some embodiments, portions of

the outer housing **102** proximate and/or underlying one or more of the icons **114** can be made from a transparent material. For example, in some embodiments, the display 112 of the outer housing 102 can comprise an illumination panel that is thinned and/or made of transparent and/or translucent material. Thinning portions of the outer housing 102 and/or making portions of the outer housing 102 from a transparent and/or translucent material can allow light from the illumination components to pass through the housing 102 and illuminate the icons 114. Advantageously, as no openings are formed in the outer housing **102** to provide illumination for the one or more icons **114** with a thinner or transparent and/or translucent housing, the potential for leakage around the icons **114** is eliminated or at least significantly reduced.

[0142] In some embodiments, the pump housing can include a display integrated with the housing such that the display includes part of the housing. In some embodiments, the display can include one or more indicators configured to be illuminated by one or more corresponding illumination sources positioned within the housing. In some embodiments, the one or more illumination sources can include one or more light emitting diodes (LEDs). In some embodiments, the pump housing can also include a nonhomogeneous thickness, the nonhomogeneous thickness including at least a first thickness and a second thickness such that the first thickness is less than the second thickness. In some embodiments, the first thickness can be proximate (e.g., adjacent) the second thickness. In some embodiments, a portion of the display can include the first thickness and at least a portion of the housing proximate the display can include the second thickness. In some embodiments, a portion of the display can include the one or more indicators. In some embodiments, a portion of the display can include translucent and/or transparent material, wherein the transparent material is contiguous with the portion of the housing proximate the display.

[0143] To prevent the illumination of one icon from bleeding into and illuminating another icon, baffles can be positioned on one or more portions of one or more interior surfaces of the outer housing 102 proximate the one or more illumination components positioned within the outer housing 102. The baffles can be attached to and/or formed integrally with interior surfaces of the outer housing 102 and/or with one or more components and/or surfaces of components positioned within the outer housing 102. For example, in some embodiments, the baffles can comprise portions of the outer housing 102

that have not been reduced in thickness. In some embodiments, an integrally formed or separately attached baffle can surround the perimeter of each icon on the inside of the outer housing 102. Of course, any suitable baffle is appreciated and envisioned, such as, for example, baffles integrally formed with the outer housing 102 having a reduced thickness but having a dark or opaque color relative to the transparent material underlying the one or more icons 114. The skilled artisan will also appreciate that any suitable baffle placement is envisioned. In some embodiments, more than one type of baffle can be used and/or combined with one or more different types of baffles. The baffles can inhibit (e.g., prevent) one or more of the illumination components from illuminating one or more of the icons 114 when one or more of the illumination components are illuminated. Advantageously, the baffles can help reduce the potential of users misreading the icons by preventing light that was intended for one icon from erroneously illuminating another icon. For example, with reference to the exemplary set of icons 114' of display 112' shown in Figure 56, the baffles can be positioned under the display 112' so that each of the four icons can be separately illuminated without bleeding light into one of the three other icons.

[0144] With continued reference to the pump system **100** illustrated in **Figures 1-8**, the pump system **100** can include one or more user input features, such as button **116**, designed to receive an input from the user for controlling the operation of the pump system **100**. In the embodiment shown, a single button is present which can be used to activate and deactivate the pump system **100** and/or control other operating parameters of the pump system **100**. For example, in some embodiments, the button **116** can be used to activate the pump system **100**, pause the pump system **100**, clear indicators such as icons **114**, and/or be used for any other suitable purpose for controlling an operation of the pump system **100** (e.g., by sequentially pushing on the button **116**). The button can be a push style button that can be positioned on an outside, front surface of the housing. In other embodiments, multiple input features (e.g., multiple buttons) can be provided on the pump system **100**.

[0145] In some embodiments, the button **116** can be designed to eliminate or at least reduce the potential for leakage around the button **116**. In some embodiments, a peripheral portion of the button **116** can be placed in an interference fit with a surrounding lip of the outer housing **102**. In some embodiments, the entirety or portions of the button **116**

can be formed of a deformable material capable of forming a relatively hermetic seal when abutted against a surface, such as rubber, silicon, or any other suitable material.

[0146] In some embodiments, the pump system **100** can include a connector **302** for connecting a tube or conduit to the pump system **100**. For example, as shown in **Figures 57A and 57B**, the connector **302** can be used to connect the pump system **100** to a dressing **950**. As shown in the illustrated embodiment, the wound dressing **950** can include a port **952** for receiving an end of the conduit **954**. In some embodiments, the port **952** can include a connector portion **953** for receiving the conduit **954**. In some embodiments, the conduit **954** can be connected directly to the connector **302** of the pump system **100**. In some embodiments, such as that shown in **Figure 57A**, an intermediate conduit **956** can be used and attached to conduit **954** via a connector, such as a quick release connector **958**, **960**.

[0147] In some embodiments, the pump system can be configured to operate in a canisterless system, in which the wound dressing, such as wound dressing **950**, retains exudate aspirated from the wound. Such a dressing can include a filter, such as a hydrophobic filter, that prevents passage of liquids downstream of the dressing (toward the pump system). In other embodiments, the pump system can be configured to operate in a system having a canister for storing at least part of exudate aspirated from the wound. Such canister can include a filter, such as a hydrophobic filter, that prevents passage of liquids downstream of the dressing (toward the pump system). In yet other embodiments, both the dressing and the canister can include filters that prevent passage of liquids downstream of the dressing and the canister.

[0148] As will be described in further detail below in connection with **Figures 13-17B**, the connector **302** can be part of an intake manifold **300** of the pump system **100** which can form an initial fluid flow pathway through the pump system **100**. As shown in the illustrated embodiment, the connector **302** can include one or more retention features, such as threading, snap-fit mounts such as clips, bayonet mounts, or the like to more securely retain a connected component to the connector **302**.

[0149] **Figures 9-10** illustrate rear elevation views of an embodiment of the pump system **100** without the optional mounting component **104** attached to the outer housing **102**. As shown in the illustrated embodiment, the rear portion **102b** of the outer housing **102** can include a removable cover **118** for placement over a cavity **120**. The cavity **120** can include

one or more recesses **122** designed to receive one or more power sources, such as batteries, for powering the device. In some embodiments, an outer periphery **124** of the cavity **120** can include features which can cooperate with respective features of the cover **118** to reduce the likelihood that moisture will enter the cavity **120**. For example, in some embodiments, the outer periphery **124** can include a rib along the bottom periphery, a side periphery, a top periphery, and/or a combination of one or more peripheries to reduce the likelihood of moisture ingress into the cavity **120**. In some embodiments, the outer periphery **124** can include a recess along the bottom periphery, a side periphery, a top periphery, and/or a combination of one or more peripheries to redirect moisture, such as water droplets, away from the cavity **120**.

[0150] **Figures 11-12** illustrate perspective views of an embodiment of a pump system **100** with portions of the outer housing **102** removed to expose an embodiment of a circuit board **200**, an intake manifold **300**, and a source of negative pressure such as a pump assembly **400**. **Figure 13** illustrates a perspective view of an embodiment of pump system **100** with a front portion of the outer housing **102** removed as well as the circuit board **200** to expose the intake manifold **300** and pump assembly **400**. As shown in the illustrated embodiment, the circuit board **200**, the intake manifold **300**, and/or the pump assembly **400** can be positioned within and/or supported by the outer housing **102**.

[0151] The control board **200** can be designed to control the function of the pump system **100** such as the pump assembly **400**. The control board **200**, such as a printed circuit board assembly (PCBA), can be designed to mechanically support and electrically connect various electrical/electronic components of the pump system **100**. For example, in some embodiments, the control board **200** can connect one or more batteries **202** to the pump assembly **400** to provide power to operate the pump assembly **400**. In some embodiments, the control board **200** can include a pressure monitor **204**. The pressure monitor **204** can be supported by the control board **200** and can be designed to monitor a level of pressure in a fluid flow passageway. The control board **200**, in conjunction with the pressure monitor **204**, can be designed to protect the pump assembly **400** from exceeding a predefined threshold pressure and/or can be designed to maintain a target pressure at the wound.

[0152] The circuit board **200** can be designed to cut power to the pump assembly **400** if the pressure reading reaches a predetermined value, and be designed to resume when the pressure level drops below the predetermined value or a second predetermined value that can be higher or lower than the first predetermined value. Additionally, the control board **200** can be programmed to prevent such over-pressurization.

[0153] In some embodiments, the control board **200** can include indicator lights, audible alarms, and/or a combination of such features. For example, in some embodiments, the control board **200** can include indicator lights in the form of one or more LEDs **206**. As discussed above in connection with **Figures 1-8**, the one or more LEDs **206** can be used to illuminate one or more icons **114** of the display **112** on the outer housing **102**. In some embodiments, each LED **206** can correspond to one or more icons **114**. In some embodiments, the control board **200** can have one or more features **208** (e.g., pressure sensitive switch(es)) to receive an input from the control button **116**.

[0154] **Figure 13** illustrates a front perspective view of a pump system **100** with a front portion of the outer housing **102** removed as well as the control board **200**, to expose the intake manifold **300** and the pump assembly **400**. As shown in the illustrated embodiment, the manifold **300** and the pump assembly **400** can be positioned within and/or supported by one or more portions of the outer housing **102**.

[0155] **Figures 14-17B** illustrate various views of the intake manifold **300** and the pump assembly **400**. As shown in the illustrated embodiment, the intake manifold **300** can be in fluid communication with an intake port **426** (shown in **Figures 21-22**) of the pump assembly **400**. The intake manifold **300** can be formed from one or more portions, such as a top portion **301a** and a bottom portion **301b**, which can be removably attached to form the intake manifold **300**. For example, as shown most clearly in **Figure 17A**, the top portion **301a** can be received within the bottom portion **301b** in a friction and/or interference fit. In some embodiments, the top portion **301a** and the bottom portion **301b** can be a monolithic structure. In some embodiments, the intake manifold **300** can include a connector **302** at an end of the top portion **301a** which can protrude from the outer housing **102** to connect a tube or conduit to the intake manifold **300**. As discussed above, the connector **302** can include one or more retention features, such as the illustrated threading, to secure the tube or conduit

to the connector **302** and reduce the likelihood of accidental detachment. The intake manifold **300** can include a sealing member **304**, such as an O-ring, positioned around a top portion **301a** of the intake manifold **300**. The sealing member **304** can advantageously be positioned between the intake manifold **300** and the outer housing **102** to eliminate or reduce the potential for leakage around the intake manifold **300**. For example, the sealing member **304** can be positioned within an extension **126** of the outer housing **102** as shown in **Figure 17B**. In some embodiments, the sealing member **304** can be made from silicon.

[0156] The intake manifold **300** can include a port **306** designed to be in fluid communication with the pressure monitor **204**. For example, as shown in **Figure 17B**, the port **306** can directly receive a portion of the pressure monitor **204** within the port **306**. This can beneficially reduce the total amount of plumbing through the pump system **100** and/or reduce the potential for leakage. The port **306** can be positioned on the bottom portion **301b** of the intake manifold **300** although it can also be positioned along any other portion of the intake manifold **300** as desired. The intake manifold **300** can include an outlet port **308** for connection to the intake port **426** of the pump assembly **400**. As shown in the illustrated embodiment, the intake manifold **300** does not include a check valve or one-way valve. In some embodiments, the intake manifold **300** can include a check valve or one-way valve to allow flow into the pump system **100** but inhibit flow out of the pump system **100**.

[0157] **Figure 18** illustrates a cross-section of an embodiment of a pump assembly **400** in an assembled configuration. **Figures 19-20** illustrate an exploded view of the pump assembly **400** illustrating these various components. As shown in the illustrated embodiment, the pump assembly **400** can include a cover **410**, a pump housing **420**, one or more valves **450**, and a pump chamber body **470**. The one or more valves **450** can be used to control the flow of fluids through a diaphragm chamber **472** which can be defined between the pump chamber body **470** and a diaphragm **550**. As will be discussed in further detail below, the diaphragm **550** can move relative to the pump chamber body **470** to alter the volume of the diaphragm chamber **472**. This change in volume can result in changes in pressure within the diaphragm chamber **472** which can generate fluid flow into and out of the diaphragm chamber **472**. For example, the one or more valves 450 can be designed to alternately open and close in response to the changes in pressure within the diaphragm

chamber 472. The one or more valves **450** can be designed to control the fluid flow through the diaphragm chamber **472** such that fluid enters from one or more intake openings and fluid is expelled from one or more exhaust openings which can be different from the intake openings.

[0158] As shown in the illustrated embodiment, the pump assembly **400** can include an upper pole **500**, a lower pole **520**, and a magnet **540**. The magnet **540** can provide a permanent magnetic field through at least a portion of the pump assembly **400**. In some embodiments, the upper pole **500** and/or the lower pole **520** can support the magnet **540**. In some embodiments, the upper pole **500** and/or the lower pole **520** can be arranged to more effectively align the magnetic field with respect to one or more components of the pump assembly **400**, such as a coil **600**. For example, in some embodiments, the upper pole **500** and/or the lower pole **520** can be arranged to shape the magnetic field of the magnet **540** so that it is normal to any current that flows through the coil. In so doing, the efficiency of the pump assembly **400** can advantageously be increased. In some embodiments, the upper pole **500** and/or the lower pole **520** can optionally include magnetic material.

[0159] As shown in the illustrated embodiment, the pump assembly **400** can include a voice coil actuator (VCA). The pump assembly **400** can include a coil **600** attached to a piston sub-assembly which can include a support member **650** designed to support the coil **600**, a shaft **700**, and/or a spring member **750**. The pump assembly **400** can also include a bearing or bushing **800**. The VCA can be used to generate vertical harmonic movements of the shaft 700 by passing a current inside a wire fully absorbed in the permanent magnetic field of the magnet 540. An electric current can flow through the coil **600** to generate a magnetic field such that a magnetic force can be applied to the coil **600** by virtue of the permanent magnetic field provided by magnet **540**. In some embodiments, the magnetic forces applied to the coil 600 can be transferred to the support member 650 and then to the diaphragm 550 through a mechanical connection between the coil 600 and the support member 650. For example, the support member **650** and the spring member 750 can be designed to transmit forces applied to the coil **600** to the shaft **700**, which can be connected to the diaphragm **550**, such that forces applied to the coil **600** are ultimately transmitted to the diaphragm **550**. By controlling the current flow through the coil **600**, movement of the

diaphragm **550** can ultimately be controlled. In some embodiments, the spring member **750** can be attached to the shaft **700** to alter a resonance frequency for the pump assembly **400** thereby enhancing efficiency around that frequency. In some embodiments, the bushing **800** can be used to help maintain alignment of the pump assembly **400** components during operation.

[0160] As noted above, **Figures 19-20** illustrate an exploded view of the pump assembly **400** illustrating various components such as a cover **410** and a pump housing **420**. In some embodiments, the pump housing **420** can be adapted to support and protect many of the components of the pump assembly **400**. The pump housing **420** can have one or more air channels, such as intake channel **422** and exhaust channel **424**, formed in and/or along an outer surface of the pump housing **420** as shown most clearly in **Figure 22**.

[0161] The intake channel **422** can be used to channel or communicate fluid, such as air, from an intake port **426** which can be in communication with a wound dressing via the connector **302** towards an inlet opening **427** for an intake valve chamber formed between the pump housing **420** and the pump chamber body **470** and in which the intake valve resides. The exhaust channel **424** can be used to channel or communicate fluid, such as air, from an outlet opening **429** for an exhaust valve chamber formed between the pump housing **420** and the pump chamber body **470** and in which the exhaust valve resides. The exhaust channel **422** can channel or communicate such fluid towards an exhaust port **428** and into an interior of a chamber **430** where it can eventually be exhausted into the atmosphere within the outer housing **102**. As will be discussed in further detail below, chamber **430** can form part of a noise reduction system for the pump assembly **400** to reduce the amount of noise generated by the pump assembly **400** during operation. As shown in the illustrated embodiment, the chamber **430** can include one or more ribs **431**.

[0162] The cover **410** can be positioned over the outer surface of the pump housing **420**. The cover **410** can be an adhesive backed foil, film, paper, plastic sheet or label, or other similar object. In some embodiments, the cover **410** can be a thermal transfer polyester such as 3M's 7815 with a topcoat such as FLEXcon's Compucal Excel 10442. In some embodiments, the cover **410** can be a plate made from plastic, metal, or the like and can include a gasket for positioning between the cover **410** and the outer surface of the pump

housing **420** to enhance the seal between the cover **410** and the outer surface of the pump housing **420**. The cover **410**, when positioned over the outer surface of the pump housing **420**, can cooperate with intake and exhaust channels **422**, **424** to form enclosed air passageways. For example, in some embodiments, the cover 410 can be designed to prevent an air short-circuit between the intake and exhaust channels 422, 424. In some embodiments, the cover **410** can be monolithically formed with the outer surface of the pump housing **420**.

[0163] With reference to **Figure 21**, the pump housing **420** can include one or more additional openings **432** to allow for components to pass from one side to another. For example, as will be discussed in further detail below, the one or more openings **432** can be used to allow an electrical conduit **604** to connect the coil **600** to the circuit board **200**. The openings **432** can also be used to allow for additional clearance for pump assembly **400** plumbing, electronics such as wiring, and the like. For example, in some embodiments, the openings 432 can be used to allow a flexible circuit board to connect to a main circuit board by allowing the flexible circuit board to extend through the openings 432. For example, as shown in Figure 14, an electrical conduit 604 can extend from an additional opening 432 so that the electronics inside the pump assembly can be electrically connected to the main circuit board 200 (shown in Figure 11) of the pump system 100 (shown in Figure 11). In this and other ways, as will be appreciated by the skilled artisan, the openings 432 can advantageously facilitate the management of wires within and around the pump housing 420. In some embodiments, the pump housing **420** can include one or more indexing features, such as the illustrated cutouts **434**, which can be designed to facilitate assembly and ensure that components are properly oriented when assembled. In some embodiments, the pump housing **420** can be made from plastics such as polycarbonate, metals, composites, or the like, or a combination of materials.

[0164] **Figures 23-24** illustrate various views of an embodiment of a valve **450** which can be used with the pump assembly **400**. The valve **450** can have a flexible and/or deflectable tab portion or member **452** supported in a middle portion of the valve **450**. The tab portion **452** can be surrounded along its periphery by a frame portion **454** and can be attached to the frame portion **454** via a neck **456** extending from the tab portion **452**. As shown in the illustrated embodiment, an opening or gap **458** can exist between the tab

portion **452** and the frame portion **454** to facilitate the passage of fluid around the tab portion **452** and past the valve **450**. In some embodiments, the opening or gap **458** can have a width of approximately 0.4 mm, or from approximately 0.3 mm to approximately 0.5 mm, and can surround approximately 80% of a perimeter of the tab portion **452**.

[0165] As shown in the illustrated embodiment, the tab portion **452** can be supported in cantilever fashion via the neck portion **456**, such that the tab portion **452** can bend or deflect away from a relaxed or closed position as shown in **Figures 23-24**. In some embodiments, the valve **450** can have one or more hinges, joints, articulations, or curves therein at or adjacent to the neck portion **456** of the tab portion **452** to improve the ability of the tab portion **452** to bend and deflect, thereby potentially improving the efficiency of the valves. In some embodiments, the valves and valve supports can be configured such that the valves are biased against the intake side of the valve or valve supports for improved seal and pump efficiency. As discussed above, movement of the diaphragm 550 can cause the valves to move in opposite directions away from their respective bias. In some embodiments, the valves can be designed such that some degree of leakage past the valve occurs under low pressure conditions. For example, in some embodiments, the valves **450** can be designed to leak at a rate of between about 0.1 mL/min to about 10 mL/min, or a leak rate of less than 10 mL/min, at low pressure conditions, between about 0.1 mL/min to about 5 mL/min, or a leak rate of less than 5 mL/min, at low pressure conditions, between about 0.1 mL/min to about 2 mL/min, or a leak rate of less than 2 mL/min, at low pressure conditions, any subrange within these ranges, or any other leakage rate as desired. Such leakage can facilitate sterilization of the device.

[0166] As shown in the illustrated embodiment, the valve **450** can include one or more indexing features, such as alignment tabs **460a**, **460b**, which can be matched to corresponding indexing features on another component, such as the pump chamber body **470**. This can advantageously facilitate the placement, securement, and alignment of the valve **450** relative to the component. As shown in the illustrated embodiment, the alignment tabs **460a**, **460b** can extend from a periphery of the frame portion **454** and can have different shapes to reduce the likelihood of improper installation. In some embodiments, the valve member **450** can have just one alignment tab, such as alignment tab **460a** or **460b**.

[0167] As shown in the illustrated embodiment, the valve **450** can have a raised surface or rib **462** (also referred to as a compression ring) extending away from a surface of the valve **450**. As shown in the illustrated embodiment, the rib **462** can be positioned along a periphery of the frame portion **454**. The rib **462** can advantageously function as a spacer to ensure that a gap exists between the tab portion **452** and an exhaust side of the valve **450** such that the tab portion **452** has adequate space to bend or deflect to an open position. The rib 462 can also advantageously function to create a preload (also referred to as bias) against an inlet or exhaust nozzle to increase the seal between the valve and the nozzle. As discussed above, in some embodiments, the valve 450 can be secured (also referred to as sandwiched) between a pump chamber body and the pump housing such that the valve is compressed between the pump chamber body and the pump housing. In some embodiments, as will be described in further detail below, the pump chamber body can be laser welded to the pump housing. When the valve 450 is secured, the rib 462 can compress. In some embodiments, compression of the rib 462 allows the preload to form against the inlet and exhaust nozzles.

[0168] For example, in some embodiments, compression of the rib 462 preloads the tab portion 452 in a direction away from the rib, such as, for example, toward the intake sides of the inlet or exhaust nozzle openings. The tab portion 452 can be designed to inflect (also referred to as flex) itself until it contacts the nozzle planes of the inlet exhaust openings when the rib 462 is compressed. For example, with reference to Figures 23, 25, and 26, the valve 450 can be placed in the intake and exhaust recesses 476a, 476b such that the rib 462 faces toward the surface of the intake recess 476a and faces away from the surface of the exhaust recess 476b. When the rib 462 is compressed, the tab portion 452 of the valve 450 in the intake recess 476a is forced toward the inlet opening in the pump housing, and the tab portion 452 of the valve 450 in the exhaust recess 476b is forced toward the exhaust opening in the pump chamber body 470. In this way, the tab portion 452 of the one or more valves 450 can interfere with the inlet and exhaust nozzles such that the tab portion is biased across the planes of the inlet and exhaust nozzles.

[0169] In some embodiments, the valve **450** can be made from polymers such as rubbers, silicon, or the like, or a combination of materials. In some embodiments, the valve 450 can be dimensioned to meet a desired initial preload and total stiffness. The initial

preload can be designed so as to provide a seal against the nozzles. For example, in some embodiments, the valve 450 can have an initial preload against the inlet or exhaust nozzle of approximately 0.03 millimeters and can have a total stiffness of about 12 Newtons/meter, although any suitable initial preload and total stiffness is envisioned.

[0170] **Figures 25-27** illustrate various views of an embodiment of a pump chamber body **470** which can form part of the pump assembly **400**. The pump chamber body **470** can cooperate with the diaphragm **550** to form a diaphragm chamber **472** (shown in **Figure 18**). Via movement of the diaphragm **550** relative to the pump chamber body **470**, the diaphragm **550** can effectively alter the volume of the diaphragm chamber **472** to generate fluid flow into and out of the diaphragm chamber **472**.

[0171] As discussed above, the fluid flow into and out of the diaphragm chamber 472 can be controlled by the one or more valves 450, which can be designed to passively move in response to the volume and pressure changes within the diaphragm chamber. For example, in some embodiments, the tab portions 452 of the one or more valves 450 can passively move in response to the volume and pressure changes within the diaphragm chamber. In some embodiments, the volume inside the diaphragm chamber 472 can increase when the shaft 700 moves the diaphragm 550 (e.g., by deforming it) away from the pump chamber body 470 (e.g., toward the bushing 800). This increase in volume can generate a vacuum condition by reducing the pressure inside of the diaphragm chamber 472 below the surrounding atmospheric pressure. When the shaft 700 moves to create a vacuum condition, it can be said to be in suction travel. For example, during suction travel, the shaft 700 can move the diaphragm 550 downward and/or away from the inlet and exhaust nozzles of the pump chamber body 470 and/or toward a bottom dead center (BDC) of the pump assembly 400. When a vacuum condition forms in the diaphragm chamber 472 as a result of suction travel of the shaft 700, the inlet valve can open and the outlet valve can close. For example, the vacuum condition can cause the tab portion of the inlet valve to move away from the nozzle plane of the inlet nozzle, thereby opening the inlet valve, and can cause the tab portion of the outlet valve to be pushed against the nozzle plane of the exhaust nozzle, thereby closing the outlet valve. Similarly, in some embodiments, the volume inside the diaphragm chamber 472 can decrease when the shaft 700 moves the diaphragm 550 (e.g., by deforming it) toward the pump chamber body 470 (e.g., away from the bushing 800). This

decrease in volume can generate an overpressure condition by increasing the pressure inside of the diaphragm chamber 472 above the surrounding atmospheric pressure. When the shaft 700 moves to create an overpressure condition, it can be said to be in pumping travel. For example, during pumping travel, the shaft 700 can move the diaphragm 550 upward and/or toward the inlet and exhaust nozzles of the pump chamber body 470 and/or toward a top dead center (TDC) of the pump assembly 400. When an overpressure condition forms in the diaphragm chamber 472 as a result of pumping travel of the shaft 700, the outlet valve can open and the inlet valve can close. For example, the overpressure condition can cause the cause the tab portion of the outlet valve to move away from the nozzle plane of the exhaust nozzle, thereby opening the outlet valve, and can cause the tab portion of the inlet valve to be pushed against the nozzle plane of the inlet nozzle, thereby closing the inlet valve.

[0172] As a result of pressure changes within the diaphragm chamber 472 caused by the suction and pumping travel of the shaft 700, in some embodiments, the inlet and exhaust valves can synchronously move in opposite directions with respect to each other when they open and close (e.g., when the inlet and outlet valves are both positioned on the inside or outside of a diaphragm chamber defined between the diaphragm and the pump chamber body), or can synchronously move in the same direction with respect to each other when they open and close (e.g., when the inlet and outlet valves are positioned such that one is on the inside of the diaphragm chamber and one is positioned on the outside of the diaphragm chamber defined between the diaphragm and the pump chamber body).

[0173] In some embodiments, the inlet and exhaust valves can have near synchronous movement in which the inlet or outlet valve closes before the other valve opens. This asynchronous movement (also referred to as near synchronous movement) can be the result of the preload of the tab portion 452 of the one or move valves 450 against the intake sides of the inlet and exhaust nozzle openings of the pump chamber body 470 as described above. The amount of preload can be the same or different for the inlet and outlet valves. In some embodiments, the preload can represent the amount of force that the pressure in the diaphragm chamber must overcome to open the inlet and outlet valves. For example, the forces associated with the preloads of the tab portions of inlet and outlet valves can correspond to the threshold pressures that are required to open the inlet and outlet valves, respectively. The threshold pressures can be any suitable pressure differential relative to any

suitable reference pressure, such as, for example, -10 mmHg for the inlet valve and 10 mmHg for the outlet valve, where 0 mmHg is the reference atmospheric pressure.

[0174] For example, during suction travel of the shaft 700, an inlet valve 450 can open under a specific change in pressure (e.g., -10 mmHg) while an outlet valve 450 is pushed against the nozzle plane of the outlet nozzle to seal (also referred to as close) the outlet, and during pumping travel of the shaft 700, an outlet valve 450 can open under a specific change in pressure (e.g., 10 mmHg) while an inlet valve is pushed against the nozzle plane of the inlet nozzle to seal (also referred to as close) the inlet. When a vacuum condition is caused by suction travel of the shaft 700, the outlet valve can close before the inlet valve opens because it takes a short amount of time for the vacuum condition to form within the diaphragm chamber to overcome the preload of the inlet valve following an overpressure condition. Similarly, when an overpressure condition is caused by pump travel of the shaft 700, the inlet valve can close before the outlet valve opens because it takes a short amount of time for the overpressure condition to form within the diaphragm chamber to overcome the preload of the outlet valve following a vacuum condition. As discussed, when vacuum and overpressure conditions generated by diaphragm movement exceed the amount of the preload, the tab portions 452 of the inlet and exhaust valves 450 can open. This can allow fluid to flow into and out of the diaphragm chamber 472. In addition to the preload against the inlet and exhaust nozzle openings helping to seal the valve against the nozzles, the valves 450 can also be designed such that the vacuum and overpressure conditions generated within the diaphragm chamber 472 during pumping action helps push the tab portions 452 of the inlet and exhaust valves against the inlet and exhaust nozzles.

[0175] In some embodiments, to control the flow of fluid into and out of the diaphragm chamber **472**, the pump assembly **400** can include one or more valves, such as valves **450**. In some embodiments, the pump chamber body **470** can include a valve support portion **474** designed to receive and support one or more valves of the pump assembly **400**. As discussed above, in some embodiments, the one or more valves 450 can be secured between the pump chamber body 470 and the pump housing 420. In some embodiments, the placement of the one or more valves between the pump chamber body 470 and the pump housing 420 can define one or more corresponding pre-chambers adjacent the diaphragm chamber 472 between the pump chamber body 470 and the pump housing 420. In some

embodiments, the pre-chambers can be sealed to avoid short-circuits of air between them by a laser welding process that can connect the pump chamber body 470 to the inside of the pump housing 420.

[0176] As shown in the illustrated embodiment, the valve support portion **474** can include one or more recesses, such as an intake or inlet recess **476a** and exhaust or outlet recess **476b**, formed along a surface **475** of the valve support portion **474**. The recesses **476a**, **476b** can be designed to receive and support one or more valves. In some embodiments, the recesses 476a, 476b are larger than the valves that they are designed to receive. The larger recesses can advantageously function to accommodate for the material deformation that can occur when the valve is compressed. The inlet recess **476a** can include an inlet opening **478a** which can be in fluid communication with the diaphragm chamber **472**. The inlet recess **476a** can cooperate with an intake valve to allow fluid passage into the diaphragm chamber **472** during an intake phase of the pump assembly **400**. The outlet recess **476b** can include an outlet opening **478b** which can be in fluid communication with the diaphragm chamber **472**. The outlet recess **476b** can cooperate with an exhaust valve to allow fluid passage into the diaphragm chamber **472** during an exhaust phase of the pump assembly **400**. In some embodiments, surface **475** can be designed to be positioned proximate or adjacent an inner surface of the pump housing **420**. Accordingly, the inner surface of the pump housing **420** can cooperate with inlet recess **476a** to form an intake valve chamber and an exhaust valve chamber via outlet recess **476b**. In some embodiments, a sealant or gasket can be positioned between the surface **475** and an inner surface of the pump housing **420** to enhance the seal between the two components.

[0177] In some embodiments, the pump chamber body **470** can be welded, such as laser welded, to the pump housing **420**. For example, a laser beam can be used to weld an absorber material of the pump chamber body 470 to a transparent material of the pump housing 420 by heating up the absorber material to its melting point after passing through the transparent material. The transparent material can allow the laser to pass through the pump housing and heat the absorber material on and/or within the pump chamber body. Similarly, the absorber material can include any suitable laser absorbing pigment that facilitates the absorption of light from the laser such that the temperature of the absorber material can be increased to its melting point. Whereas the transparent material can allow the laser to pass

through, the absorber material can allow the laser to be absorbed. To facilitate absorption of energy from the laser, and to in turn increase the temperature of the absorber material to its melting point, the absorber material can include a pigment that absorbs the wavelength(s) of light emitted by the laser. In some embodiments, the pigment of the absorber material can be darker relative to the transparent material. For example, in some embodiments, the absorber material can have a well-defined percentage of black pigment, such as, for example, between 1%-10% black pigment, between 1%-100% black pigment, between 5%-100% black pigment, between 50%-100% black pigment, between 80%-100% black pigment, between 90%-100% black pigment, or between any other suitable percentages, or less than 100% black pigment, less than 90% black pigment, less than 50% black pigment, less than 15% black pigment, or less than any other suitable percentage. For example, in some embodiments, the percentage of black pigment in the absorber material can be 1%, 30%, 80%, 95%, 100%, or any other suitable percentage. In some embodiments, the higher the percentage of laser absorbing pigment that the absorber material has, the faster the absorber material will melt for any given laser intensity. In some embodiments, only the portion of the pump chamber body 470 that is to be welded to the pump housing 420 is black. During the welding process, the pump housing 420 and the pump chamber body 470 can be held together with a constant, increasing, or decreasing pressure to prevent the two components from moving in any dimension relative to one another using, for example, a clamp. For example, in some embodiments, a spring clamp or an air-operated clamp can be used, although any suitable tension providing clamp is envisioned. While the pump housing 420 and the pump chamber body 470 are held together, a laser beam can be guided along a designed melt contour. For example, in some embodiments, the pump chamber body 470 can have a laser absorbing pigment along the melt contour. The resultant melt contour represents the laser weld between the pump housing and the pump chamber body. In some embodiments, the melt contour 490 that connects the pump housing and the pump chamber body together can be designed as shown in Figure 58. Of course, any other suitably shaped contour is envisioned. Once the melt contour solidifies, a strong connection between the pump chamber 470 and pump housing 420 is created. In some embodiments, the transparent and absorbent materials can be chosen such that they are chemically compatible. For example, the transparent and absorbent materials can be different pigments of the same

molecules. With reference to Figure 19, the pump chamber body 470 can be laser welded to the pump housing 420 from the underside of the pump housing 420. In some embodiments, the intake and outtake channels on the surface of the pump housing 420 can be sloped (as shown in FIG. 22) to prevent sudden changes in laser diffraction when the laser passes over the channels during the welding process. For example, the intake and exhaust channels 422, 424 can have one or more sloped portions 435 as shown in FIG. 22. In some embodiments, the one or more sloped portions 435 can have straight and/or curved profiles.

[0178] As shown in the illustrated embodiment, the recesses **476a**, **476b** can have one or more indexing features, such as the recesses **480a**, **480b**, sized and shaped to receive corresponding indexing features of the valve, such as alignment tabs **460a**, **460b** of the valve member **450**. The positioning of the alignment tabs **460a**, **460b** and the recesses **480a**, **480b** can ensure that the valve members **450** will be in the proper orientation and alignment when positioned in the recesses **476a**, **476b**. As should be noted, in some embodiments, the same valve **450** can function as either an intake valve or an exhaust valve depending on the orientation of the valve **450**. Accordingly, the position of the alignment tabs **460a**, **460b** and recesses **480a**, **480b** can ensure that the valve **450** is properly oriented to function as an intake valve or an exhaust valve depending on the recess, such as inlet recess **476a** or outlet recess **476b**, in which the valve **450** is placed. Proper placement of the valve **450** can ensure that the rib **462** will be facing in a desired direction and that the tab portion **452** will cover an appropriate opening when in a relaxed or closed state such as the inlet opening of the pump housing **420** outlet opening **478b** of the pump chamber body.

[0179] Moreover, as shown in the illustrated embodiment, the pump chamber body **470** can include one or more indexing features, such as bosses **481**, which can be matched to corresponding indexing features on another component, such as the cutouts **434** of the pump housing **420**. In some embodiments, the pump chamber body **470** can be made from plastics such as polycarbonate, metals, composites, or the like, or a combination of materials.

[0180] **Figures 28-31** illustrate various views of an embodiment of a diaphragm **550** which can form part of the pump assembly **400**. As shown in the illustrated embodiment, the diaphragm **550** can include a connection portion **560** and a peripheral portion **570**. In some embodiments, the connection portion **560** can be positioned generally

along an axial centerline of the diaphragm **550** such that the connection portion **560** is generally centered on the diaphragm **550**. The connection portion **560** can include a recess **562** into which another component, such as the shaft **700**, can be inserted. In some embodiments, diaphragm 550 can be designed to help maintain the radial alignment of the shaft **700** with the remainder of the pump assembly **400**. The recess **562** can include an undercut portion **564** thereby forming a lip **566** around at least a periphery of the recess **562**. In some embodiments, the undercut portion 564 can have a radius that is configured to reduce the amount of stress that is applied to the diaphragm. The lip **566** can advantageously releasably secure the other component, such as the shaft **700**, to the diaphragm **550** such that movement of the other component can result in movement of the diaphragm **550**. As shown in the illustrated embodiment, the lip can include filleted and/or chamfered edges which can enhance the lifespan of the diaphragm **550**. For example, the filleted edges and/or chamfered edges can reduce the amount of stress applied to the connection portion **560** as the diaphragm **550** is removed from a production tool.

[0181] As shown in the illustrated embodiment, the peripheral portion **570** can include a body portion **572**, in the form of an annular ring, and a lip **574** extending from a bottom surface of the body portion **572**. The lip **574** can be formed integrally with the body portion **572**. The increased thickness that results from the lip **574** can improve the sealability of the peripheral portion **570** of the diaphragm and hence improve the sealability of the diaphragm **550**.

[0182] As shown in the illustrated embodiment, the connection portion **560** can be attached to the peripheral portion **570** via a web **580**. The web **580** can be sized and shaped to allow the connection portion **560** to move relative to the peripheral portion **570** to allow an interior volume **552** of the diaphragm **550** to be altered. In some embodiments, the web **580** can be made out of a resilient material having a suitable modulus of elasticity. This can allow the web **580** to temporarily deform in response to forces exerted on the web **580**. In some embodiments, the web **580** can be designed with excess material to allow for relative movement between the connection portion **560** and the peripheral portion **570**. For example, as shown in the illustrated embodiment, the web **580** has excess material such that the web **580** has some slack and takes on a curved shape in an initial configuration. Should the

connection portion **560** be moved away from the peripheral portion **570**, the web **580** can straighten to some degree via loss of slack in the web **580**. In some embodiments, it can be advantageous to reduce the radius of the connection portion **560** relative to the peripheral portion **570** to increase total length of the web **580**. This can beneficially enhance the longevity of the diaphragm **550** which can be subjected to constant and cyclical motion. In some embodiments, it can be advantageous to increase the radius **582** of the web **580** proximate the connection portion **560** when the web **580** is in an initial configuration such as is shown in **Figures 28-31**. For example, the radius 582 can be increased so that the junction between the web 580 and the connection portion 560 is thicker. This can reduce the strain at the junction between the web 580 and the connection portion 560, which can in turn reduce fatigue and decrease the likelihood of the diaphragm 550 breaking near or around the radius 582. In some embodiment, the radius 582 can be uniform or can get progressively larger closer to the connection portion 560. In some embodiments, it can be advantageous to decrease the diameter of the connection portion 560 so that the length of the web 580 can be increased. Similarly, in some embodiments, it can be advantageous to increase the thickness and/or radius of the web 580 between the connection portion 560 and the peripheral portion 570. This can reduce the strain of the web 580 between the connection portion 560 and the peripheral portion 570, which can in turn reduce fatigue and decrease the likelihood of the diaphragm 550 breaking between the connection portion 560 and the peripheral portion 570 of the web 580. In some embodiments, the diaphragm **550** can be made from polymers such as rubbers, silicon, or the like, or a combination of materials.

[0183] **Figures 32-33** illustrate various views of an embodiment of a spacer **590** which can form part of the pump assembly **400**. In some embodiments, the spacer **590** can be positioned above diaphragm **550** when in an assembled state to maintain the diaphragm **550** in position relative to the pump chamber body **470**. For example, the spacer **590** can be positioned such that the spacer **590** maintains the diaphragm **550** in compression against the pump chamber body **470** thereby maintaining sealing engagement between the diaphragm **550** and the pump chamber body **470**.

[0184] As shown in the illustrated embodiment, the spacer **590** can include a body portion **592** such as the illustrated ring. The body portion **592** can include one or more alignment tabs **594** extending from the body portion **592** which can facilitate positioning and

orientation of the spacer **590** within the pump assembly **400**. For example, the alignment tabs **594** can correspond to slots **482** formed on the pump chamber body **470** (as shown in **Figure 25**). In some embodiments, the body portion **592** can include a radially inward protrusion **596** to increase the surface area of the contact surface **598** between the body portion **592** and the diaphragm **550**. This can reduce the localized stress applied to the diaphragm **550** along the contact surface **598** and reduce the likelihood of failure of the diaphragm **550**. In some embodiments, the spacer **590** can be made from materials such as plastics, metals, composites, or the like, or a combination of materials. In some embodiments, the spacer **590** can be made from polyphenylene ether (PPE).

[0185] With reference back to Figures **18-20**, the pump assembly **400** can include a magnetic assembly which can include an upper pole **500**, a lower pole **520**, and a magnet **540**. One or both of the upper pole **500** and lower pole **520** can support the magnet **540**. In some embodiments, the arrangement and/or placement of the upper pole **500** and/or lower pole **520** beneficially align the magnetic field of the magnet **540** to enhance the efficiency of the pump assembly **400**. Such alignment of the magnetic field can improve efficiency of the pump assembly **400**. Details regarding the alignment of the magnetic field are described in greater detail in U.S. Publication Nos. 2013/0331823 and International Patent Publication No. 2013/171585, both of which have been hereby incorporated by reference in their entireties as if made part of this disclosure.

[0186] The upper pole **500** can have an opening **502** formed through an axial centerline of the upper pole **500**. The bushing **800** can be positioned within the opening **502** and/or supported by the upper pole **500**. In some embodiments, the upper pole **500** can include a first portion **504** and a second portion **506** extending transverse to the first portion. As shown in the illustrated embodiment, the first portion **504** can be generally planar and extend in a direction generally perpendicular to the axial centerline of the upper pole **500**. The second portion **506** can extend away from the first portion **504** in a direction generally parallel to the axial centerline at approximately a 90 degree angle relative to the first portion **504**. In some embodiments, the second portion **506** can extend away from the first portion **504** at an angle greater than or less than a 90 degree angle relative to the first portion **504**, such as, but not limited to, between about 10 degrees to about 170 degrees, between about 30

degrees to about 150 degrees, between about 45 degrees to about 135 degrees, between about 60 degrees to above 120 degrees, any subranges within these ranges, or any other degree relative to the first portion **504** as desired. In some embodiments, the upper pole **500** can be made from materials such as mild steel, a sintered soft magnetic metal such as GKN 72-IBP2 (S-FeP-130), or sintered steel (or any suitable magnetic or ferromagnetic material).

[0187] The lower pole **520** can include an opening **522** formed through an axial centerline of the lower pole **520**. The opening **522** can be sized and shaped such that the second portion **506** of the upper pole **500** can pass therethrough. As shown in the illustrated embodiment, the lower pole **520** can be spaced apart from the upper pole **500** and can be supported by the pump housing **420**. The lower pole **520** can be made from mild steel, a sintered soft magnetic metal such as GKN 72-IBP2 (S-FeP-130), or sintered steel (or any suitable magnetic or ferromagnetic material).

[0188] The magnet **540** can be positioned between the upper pole **500** and the lower pole **520**. The magnet **540** can have an opening **542** formed through an axial centerline of the magnet **540**. In some embodiments, a top surface of the magnet **540** can be positioned proximate or adjacent a bottom surface of the first portion **504** of the upper pole **500**. In some embodiments, a bottom surface of the magnet **540** can be positioned proximate or adjacent a top surface of the lower pole **520**. In some embodiments, the magnet **540** can be positioned such that the second portion **506** of the upper pole **500** extends through the opening **542** of the magnet **540**. In such an arrangement, the magnetic field can be shifted away from the first portion **502** of the upper pole **500** and closer to the center of the coil **600**. The magnet **540** can be made from Neodymium-Iron-Boron (NdFeB) – N 45 M, Neodymium N33, or any other suitable material magnetic material. This material can be used to maximize field strength and minimize losses, thereby increasing the efficiency of the pump assembly **400**.

[0189] With continued reference to **Figures 18-20**, the pump assembly **400** can include a coil **600**. The coil **600** can have a body **602** formed from a length of wound conductive wire, such as without limitation copper wire or any other electrically conductive material. Accordingly, upon application of a current through the body **602**, a magnetic field can be generated generally directed along a direction parallel to an axial centerline for the coil **600**. As should be understood, the direction of the magnetic field can be reversed by

reversing the direction of current flow through the coil **600**. To provide current to the coil **600**, an electrical conduit **604** can be connected to both ends of the coil **600**. In some embodiments, the electrical conduit **604** can be a flexible printed circuit (FPC) attached to the circuit board **200**. Other types of electrical conduits **604**, such as elongate wires, can also be used.

[0190] As shown in the illustrated embodiment, the coil **600** can have an opening **606** which can be sized and shaped to allow the second portion **506** of the upper pole **500** to pass therethrough. As shown **Figure 18**, the coil **600** can be positioned between the upper pole **500** and the lower pole **520** and positioned proximate the magnet **540**. Accordingly, as the voltage supplied to the coil **600** oscillates between a positive voltage and a negative voltage, the coil **600** can oscillate up and down in the pump assembly **400** between the two poles **500**, **520**.

[0191] In some embodiments, the coil **600** can be formed by winding approximately 160 turns of wire, or from approximately 100 turns or less to 200 turns or more of wire, which can be but is not required to be, 42 gauge (approximately 0.102 mm diameter) wire. For example, in some embodiments, the coil 600 can be formed by winding approximately 144 turns of wire. In some embodiments, Lorentz's law can be used to determine the appropriate number of turns of wire that are needed so that the desired level of force is applied to the coil 600 when current passes through the coil 600. The wire used can be self-bonding wire that bonds to adjacent sections of wire upon application of heat. The wire can also be non-self-bonding wire. In some embodiments, approximately 200 turns of wire, or up to approximately 260 turns of wire, can be used to form the coil. Increasing the number of turns of wire can potentially reduce ohmic losses and improve the overall efficiency of the pump assembly **400** by between approximately 22% and approximately 24%. As the number of turns of wire is increased, thereby increasing the efficiency of the pump, the size or thickness of the magnet can be decreased, thereby reducing the magnetic field outside of the pump assembly **400** that can potentially interfere with the function of pacemakers and other implanted cardiac devices (ICDs). **[0178]** **Figures 34-35** illustrate an embodiment of a support member **650**, such as a spider, which can be designed to support the coil **600** and connect the coil **600** to other components of the pump assembly **400** such as the diaphragm **550**. As shown in the illustrated embodiment, the support member **650** can

include a peripheral portion **660** with longitudinally extending fingers **662**. The fingers **662** can be received within the opening **606** of the coil **600**. In some embodiments, the protrusions **662** can be sized and positioned such that the protrusions **662** are received within the opening **606** in a friction and/or interference fit to maintain the coil **600** in a desired position relative to the support member **650**. In some embodiments, the coil **600** can be affixed to the support member **650** via a mechanical fastener and/or chemical fastener, such as an adhesive. The peripheral portion **660** can include a ring **664** which can have one or more raised platforms **666** extending from a surface of the annular ring **664**. The raised platforms **666** can be designed to space the coil **600** from the annular ring **664**.

[0192] As shown in the illustrated embodiment, the support member **650** can include a base portion **670** attached to the peripheral portion **660** via one or more arms **672**. The arms **672** can be aligned with the slots **482** of the pump chamber body **470**, the slots **508** of the upper pole **500**, and/or slots between wall members **804** on the bushing **760**. In some embodiments, the arms **672** can be sized and/or shaped with respect to such slots to limit rotation along an axial centerline of the support member **650** during operation of the pump assembly **400**. The arms **672** can be designed to be relatively rigid to limit the amount of flex in the arms **672** when the peripheral portion **660** is moved relative to the base portion **670** and vice versa.

[0193] The base portion **670** can include an opening **674** for allowing another component of the pump assembly **400**, such as the shaft **700**, to pass therethrough. As shown in the illustrated embodiment, the opening **674** can include a collet **676**, or other form of clamping member, to more securely fasten the component to the base portion **670** in an interference and/or friction fit. The base portion **670** can include one or more indexing features, such as openings **678**, to facilitate positioning and alignment of the base portion **670** relative to other components of the pump assembly **400**, such as the shaft **700**.

[0194] **Figures 36-37** illustrate various views of an embodiment of a shaft **700** which can form part of the pump assembly **400**. The shaft **700** can include a first end portion **710**, an intermediate portion **720**, and a second end portion **730**. In some embodiments, the shaft **700** can be used to connect the diaphragm **550** to the support member

650. In this manner, the shaft **700** can transmit motion from the coil **600** to the diaphragm **550**.

[0195] As shown in the illustrated embodiment, the first end portion **710** of the shaft **700** can be received within the recess **562** formed in the connection portion **560** of the diaphragm **560**. The end portion **710** can include an undercut portion **712** and an annular lip **714** for securing the shaft **700** to the connection portion **560** of the diaphragm **550**. The edges of the annular lip **714** can include fillets and/or chamfers similar to those of the undercut portion **564** of the recess **562**. The end portion **710** can be retained on the connection portion **560** of the diaphragm **550** in an interference fit. This can beneficially reduce the amount of play between the shaft **700** and the connection portion **560** of the diaphragm **550**. In some embodiments, the shaft **700** can be further secured to the connection portion **560** of the diaphragm **550** with an adhesive

[0196] The intermediate portion **720** can include features for connection to the support member **650**. For example, as shown in the illustrated embodiment, the intermediate portion **720** can include one or more tapered features **722**, **724** which can cooperate with the collet **676**. The shaft **700** can include one or more indexing features, such as longitudinally extending ribs **726**, which can cooperate with the indexing features of one or more components of the pump assembly **400**, such as the openings **678** of the support member **650**. In some embodiments, the shaft **700** can be made from materials such as plastics, metals, composites, or the like, or a combination of materials. In some embodiments, the shaft **700** can be made from polybutylene terephthalate (PBT).

[0197] **Figure 38** illustrates a perspective view of an embodiment of a spring **750** which can form part of the pump assembly **400**. The spring **750** can include an opening **752** through which a component of the pump assembly **400** can pass through, such as the shaft **700**. As shown in **Figure 18**, the spring **750** can be positioned between a platform **728** of the shaft **700** and the collet **676** of the support member **650**. The spring **750** can include one or more indexing features, such as cutouts **754**, which can correspond to indexing features on the shaft **700** to facilitate alignment and orientation of the spring **750** with respect to the shaft **700**. In some embodiments, an outer periphery of the spring **750** can be positioned between the spacer **590** and the bushing **800**. Accordingly, as the shaft **700** is moved relative to the

bushing **800**, the force applied to the shaft **700** by the spring **750** can vary. In some embodiments, the spring **750** can include one or more cutouts **758** to allow deformation of the middle portion of the spring **750** relative to an outer periphery of the spring **750**. The length and width of these cutouts **758** can be changed to alter the spring constant of the spring **750**. In some embodiments, the width of the cutouts can be chosen to avoid potential interference between portions of the spring **750** during operation of the pump assembly **400**.

[0198] In some embodiments, the spring member **750** can be sized and designed to provide frequency tuning or adjustment to the resonance frequency of the diaphragm **550** and/or other oscillating components pump assembly **400**. In some embodiments, the spring member **750** can be designed to help maintain the radial alignment of the diaphragm **550**, coil **600**, support member **650**, and/or shaft **700** with the remainder of the pump assembly **400**. In some embodiments, the spring can provide both functions. The spring member **750** can be made from stainless steel such as AISI 301 H03 ¾ hard – stainless steel, spring steel, bronze, or any other suitable material.

[0199] **Figures 39-40** are various views of an embodiment of a bushing **800** which can form part of the pump assembly **400**. The bushing **800** can be designed to help maintain the radial alignment of the diaphragm **550**, coil **600**, support member **650**, and/or shaft **700** with the remainder of the pump assembly **400**. The bushing **800** can also be used to limit the movement of components of the pump assembly **400**, such as the support member **650**, to avoid damage to other components of the pump assembly **400**, such as the diaphragm **550**.

[0200] As shown in the illustrated embodiment, the bushing **800** can include a base **802** which can extend in a direction generally radially outward from an axial centerline of the bushing **800**. The base **802** can include one or more wall members **804** which can extend generally transverse to the base **802**. In the illustrated embodiment, the one or more wall members **804** extend in a direction generally parallel with the axial centerline of the bushing **800**. For example, as shown in Figure 39, the base 802 can have three wall members 804. The wall members 804 of bushing 800 can be designed to push the spring 750 and the spacer 590 against the peripheral portion 570 of the diaphragm 550 such that the lip 574 of the diaphragm 550 is compressed against the pump chamber body 470. As discussed above,

compressing the lip 574 of the diaphragm 550 against the pump chamber body 470 can improve the sealability of the diaphragm 550. For example, in some embodiments, compressing the lip 574 against the pump chamber body 470 can help seal the diaphragm chamber 472. The base **802** can include a protrusion **806** extending from a surface **808** of the base **802**. The protrusion **806** can be generally centered on the base **802** and can be designed to serve as a stop for the support member **650** as shown more clearly in **Figure 18**. For example, the protrusion **806** can contact the support member **650** at top dead center ("TDC") for the pump assembly. In this manner, the support member **650** can be prevented from over-extending the diaphragm **550** thereby reducing the likelihood of damage to the diaphragm **550**. As will be described in further detail below, the pump chamber body 470 and the bushing 800 can be designed so that they can be laser welded together. In this way, the bushing 800 and the pump chamber body 470 are designed so that they do not move with respect to the oscillating components of the pump, such as for example, the shaft 700, the support member 650, and the diaphragm 550.

[0201] In some embodiments, the radial dimension of the protrusion **806**, as measured from the axial centerline of the bushing **800**, can be less than the radial dimension of the base **802**, such as less than about 75% of the radial dimension of the base **802**, less than about 50% of the radial dimension of the base **802**, less than about 25% of the radial dimension of the base **802**, between about 25% to about 75% the radial dimension of the base **802**, between about 40% to about 60% of the radial dimension of the base **802**, about 50% of the radial dimension of the base, any subrange within these ranges, or any other percentage as desired. In some embodiments, the depth of the protrusion **806** relative to the base **802** in addition to the radial dimension of the protrusion **806** relative to the base **802** can be chosen to account for flex in the arms **672** of the support portion **650** such that the arms **672** do not contact the base **802** during operation of the pump assembly **400**.

[0202] As shown in the illustrated embodiment, the bushing **800** can include indexing features, such as the illustrated fingers **810** and ribs **812**, which can facilitate in orienting and aligning the bushing **800** with respect to other components in the pump assembly **400**. Moreover, the fingers **810** and ribs **812** can be used to maintain radial alignment of the bushing **800** with respect to other components of the pump assembly **400**.

In some embodiments, the bushing **800** can include an opening **814** for receiving a component therein, such as a second end portion **730** of the shaft **700**. The opening **814** can be formed through an axial centerline of the bushing **800**. The diameter of the opening **814** can be designed to reduce wobble in the shaft **700** without applying a significant degree of friction to the shaft **700**. The bushing **800** can be formed from a low friction material (polymeric or otherwise) or any other suitable material. For example the bushing **800** can be made from polycarbonate, phosphor bronze, oilite, PTFE, acetal, nylon, PTFE, or the like, or a combination of materials.

[0203] In some embodiments, the bushing **800** can be laser welded to the pump chamber body **470**. For example, as discussed above with respect to laser welding the pump housing 420 to the pump chamber body 470, a laser beam can be used to weld an absorber material of the pump chamber body 470 to a transparent material of the bushing 800 by heating up the absorber material to its melting point after passing through the transparent material. The transparent material can allow the laser to pass through the bushing and heat the absorber material on and/or within the pump chamber body. Similarly, the absorber material can include any suitable laser absorbing pigment that facilitates the absorption of light from the laser such that the temperature of the absorber material can be increased to its melting point. Whereas the transparent material can allow the laser to pass through, the absorber material can allow the laser to be absorbed. To facilitate absorption of energy from the laser, and to in turn increase the temperature of the absorber material to its melting point, the absorber material can include a pigment that absorbs the wavelength(s) of light emitted by the laser. In some embodiments, the pigment of the absorber material can be darker relative to the transparent material. For example, in some embodiments, the absorber material can have a well-defined percentage of black pigment, such as, for example, between 1%-10% black pigment, between 1%-100% black pigment, between 5%-100% black pigment, between 50%-100% black pigment, between 80%-100% black pigment, between 90%-100% black pigment, or between any other suitable percentages, or less than 100% black pigment, less than 90% black pigment, less than 50% black pigment, less than 15% black pigment, or less than any other suitable percentage. For example, in some embodiments, the percentage of black pigment in the absorber material can be 1%, 30%, 80%, 95%, 100%, or any other suitable percentage. In some embodiments, the higher the

percentage of laser absorbing pigment that the absorber material has, the faster the absorber material will melt for any given laser intensity. In some embodiments, only the portion of the pump chamber body 470 that is to be welded to the bushing 800 is black. For example, as shown in Figures 25 and 27, the pump chamber body 470 can include three vertical flanges 485 each having a mechanical stop 483 and two circumferential weld surfaces 484. In some embodiments, only the weld surfaces 484 are black. The mechanical stops 483 can be designed to control the penetration of the bushing 800 into the pump chamber body 470 during welding. As shown in Figures 25 and 27, the three vertical flanges 485 can be separated by the three slots 482 described above with reference to spacer 590. In some embodiments, the bushing 800 can have three ribs 812. The ribs 812 can advantageously function to stop penetration of the bushing 800 into the pump chamber body 470 during welding at the desired amount of penetration. For example, the ribs 812 can be designed such that a bottom surface comes into contact with the mechanical stops 483 of the pump chamber body 470. In this way, the extent of the bushing 800 penetration can be controlled.

[0204] During the welding process, the pump chamber body 470 and the bushing 800 can be held together with a constant, increasing, or decreasing pressure to prevent the two components from moving in any dimension relative to one another using, for example, a clamp. For example, in some embodiments, a spring clamp or an air-operated clamp can be used, although any suitable tension providing clamp is envisioned. While the pump chamber body 470 and the bushing 800 are held together, a laser beam can be guided along a designed melt contour. For example, in some embodiments, the pump chamber body 470 can have a laser absorbing pigment along the melt contour. The resultant melt contour represents the laser weld between the pump chamber body 470 and the bushing 800. In some embodiments, the melt contour 890 that connects the pump chamber body and the bushing together can be designed as shown in Figure 59. Of course, any other suitably shaped contour congruent with a weld surface 484 of the vertical flange 485 is envisioned. Once the melt contour solidifies, a strong connection between the pump chamber body 470 and bushing 800 is created. In some embodiments, the transparent and absorbent materials can be chosen such that they are chemically compatible. For example, the transparent and absorbent materials can be different pigments of the same molecules. With reference to

Figure 19, the pump chamber body 470 can be laser welded to the bushing from the topside of the bushing 800.

[0205] **Figures 41-46** illustrate embodiments of noise reduction systems. As shown in the illustrated embodiment in Figure 41, the noise reduction system can include a chamber **430** formed integrally with the pump housing **420**. For example, in some embodiments, the chamber 430 can be integrally formed with the pump housing 420 as shown Figure 42, which is a side cross-sectional view of the pump housing of Figure 41 along line AA. Figures 21 and 22 also show embodiments having a chamber 430 integrally formed with a pump housing 420. Of course, the chamber 430 shown in Figures 41, 42, 21, and 22 is exemplary and non-limiting and the skilled artisan will appreciate that any other suitable integrally formed chamber is envisioned. In some embodiments, the chamber **430** can be separate from the pump housing **420** and can be attached to the pump housing **420**. For example, Figures 44 and 45 show a pump housing 420', 420'' in which the chamber 430 has been separated from the pump housing 420', 420''. It will be appreciated that the chamber 430 can be attached to the pump housing 420 in Figures 44 and 45 at any suitable location along the fluid flow path, such as, for example, somewhere along the exhaust channel 424' in Figure 44 or somewhere around the opening 436'' in Figure 45.

[0206] The chamber **430** can be designed to receive a dampening component **902** (also referred to as a silencer). The dampening component can reduce noise emissions from the pump. For example, in some embodiments, the outtake flow of the pump can be passed through the dampening component such that frequencies and/or amplitudes of the pressure waves in the outtake flow are reduced, which in turn dampens the noise emitted by the pump. The dampening component 902 can be integrated into a pump housing by being placed in the pump chamber 430. As described above, in some embodiments, the pump chamber 430 can be integrally formed with the pump housing 420, and in other embodiments, the pump chamber 430 can be separately attached to the pump housing 420'. For example, as shown in Figures 41, 42, 21, and 22, the dampening component 902 can be integrated with the pump housing 420 by being placed within the chamber 430. In other embodiments, the dampening component can be placed within a chamber 430 that is separately attached to the pump housing 420. As shown in the illustrated embodiments, the dampening component **902** can be received within (also referred to as integrated with) the chamber **430** in a friction and/or

interference fit, although any suitable connection between the dampening component 902 and the chamber 430 is appreciated and envisioned. In some embodiments, the dampening component **902** can be prevented from exiting the chamber **430** via one or more features of the outer housing **102**. In some embodiments, the orientation of the chamber **430** shown in Figures 41, 42, 21, and 22 can be flipped as is shown in **Figure 47** which illustrates a pump housing **420'''** and chamber **430'''**. In some embodiments, the chamber 430''' can be integrally formed with the pump housing 420'''. In addition, as discussed above with reference to FIG. 22 and other related figures, in some embodiments, the exhaust channel **422** can channel or communicate fluid towards an exhaust port **428** and into an interior of a chamber **430** where it can eventually be exhausted into the atmosphere within the outer housing **102** after being channeled or communicated through a silencer 902.

[0207] The dampening component **902** can be made from any material capable of allowing fluid passage, such as air, through the dampening component **902** while reducing noise. For example, in some embodiments, the dampening component **902** can be formed from a porous material such as foam, including but not limited to urethane foam, which can advantageously allow fluid flow through the foam while reducing noise generated. In some embodiments, the material of the dampening component 902 can be medical grade. The thickness of the dampening component **902** can be chosen based on numerous factors including the type of material used, the desired fluid flow out of the dampening component **902**, and the amount of noise reduction desired. In some embodiments, the dampening component **902** can also serve as a filter which can reduce undesirable components in the fluid as the fluid flows through the dampening component **902**. For example, in some embodiments, the dampening component can be a foam insert 3 millimeters thick. The skilled artisan will appreciate that the foam insert can take on any suitable shape capable of fitting into the chamber 430, such as, for example, cylindrical or polygonal. Of course, other shapes and sizes are also envisioned. For example, in some embodiments, the foam insert can range in thickness from approximately 1 millimeter to approximately 5 millimeters.

[0208] As shown in the illustrated embodiment, the chamber **430** can include one or more ribs **431** extending from an inner surface **433** of the chamber **430**. The ribs **431** can beneficially space the dampening component **902** from the inner surface **433** such that a gap is formed between the dampening component **902** and the inner surface **433**. This gap can

allow for fluid flow from the exhaust port **428** to expand into the gap prior to flowing through the dampening component **902**. This can beneficially reduce the likelihood of choking the exhaust flow. In some embodiments, the exhaust port **428** can be designed to have a diffuser 437 shape similar to that illustrated in **Figure 43** to further control expansion of the fluid as the fluid passes through the exhaust port **428** and into the chamber **430**.

[0209] In some embodiments, the noise reduction system can involve redirecting at least some portion of the exhaust gases back into the pump housing **420**. For example, as shown in **Figure 44**, a pump housing **420′** can include an opening **436′** positioned along the exhaust channel **424′** for redirecting at least some of the exhaust flow back into an internal volume of the pump housing. This can separate flow between the channel **424′** and the internal volume of a pump assembly where the sound-wave encounters different geometries and may thereby be dampened. In some embodiments, such as that illustrated in **Figure 45**, the entirety of the exhaust flow can be directed back into the internal volume of the pump housing **420″** via opening **436″**.

[0210] With reference to **Figure 46**, in some embodiments, a manifold **300′** of the pump system **100** can incorporate noise reducing features. For example, as shown in the illustrated embodiment, the manifold **300′** can include an inlet passageway **310′** having an inlet opening **312′** designed to be in fluid communication with a wound dressing and an outlet opening **314′** which can be in fluid communication with an intake of the pump assembly, such as intake port **426** of the pump housing **420**. The inlet passageway **310′** can include one or more additional ports, such as port **316′**, designed to be in fluid communication with other components of the pump system **100**, such as the pressure monitor **204**. The manifold **300′** can include an outlet passageway **318′** having an inlet opening **320′** designed to be in fluid communication with an exhaust of the pump assembly, such as exhaust port **428** of the pump housing **420**, and an outlet opening **322′** designed to exhaust the fluid into the atmosphere such as within the outer housing **102**. In some embodiments, the manifold 300' can be used to attenuate the noise produced by the pump assembly. For example, the inlet passageway **310′** and/or the outlet passageway **318′** can be designed to receive a dampening component **902′** to reduce noise generated by the pump assembly. In some embodiments, the dampening component 902' can be used to help stabilize the air

volume in the manifold so that the pressure monitor 204 can return more accurate readings. For example, in some embodiments, the dampening component 902' can be used to attenuate the noise generated from the harmonic dynamics (also referred to as the resonance) of the pump. In some embodiments, the inlet opening **312'**, the outlet opening **314'**, the inlet opening **320'**, and/or the outlet opening **322'** can be designed to have a diffuser shape and/or nozzle shape to help control the expansion or compression of fluid. In some embodiments, the manifold can have an internal volume of approximately 870 mm^3.

[0211] With reference back to **Figures 14-16**, in some embodiments, the pump assembly **400** can have one or more dampening components **904** attached to a surface of the device. The dampening components 904 can be designed to reduce noise and/or vibration generated by movement of the pump assembly **400** within the outer housing **102**. In some embodiments, one or more dampening components 904 can be attached to the front and rear surfaces of the pump assembly 400. For example, as shown in Figures 14-16, the pump assembly 400 can have six dampening components 904, three on a rear side of the pump assembly as shown in Figure 15, and three on a front side of the pump assembly as shown in Figures 14 and 16. Advantageously, the one or more dampening components 904 can be used to decouple and/or cushion the pump assembly 400 from one or more of the hard components that surround the pump assembly and/or from the main circuit board of the pump system. For example, in some embodiments, the one or more dampening components 904 on the front side of the pump assembly 400 can be designed to be placed between the front side of the pump assembly and the circuit board 200 (shown in Figure 13), and the one or more dampening components 904 on the rear side of the pump assembly 400 can be designed to be placed between the rear side of the pump assembly and the rear portion of the outer housing 102b (shown in Figure 11). In some embodiments, the dampening components **904** can be made from any material having noise and/or vibration dampening characteristics such as foam. For example, the one or more dampening components can be foam cylinders, although any suitable shape is envisioned. In some embodiments, a layer of open foam or other material can be wrapped at least partially around an outside surface of the pump assembly **400** to reduce noise and/or vibration produced by the pump assembly **400**. Additionally, in some embodiments, the pump assembly **400** can have one or more weights, cushions, foam (such as a viscoelastic foam), plastic (such as ABS, polyurethane, urethane, or otherwise), or

other pads, panels, sheets, or segments supported by the pump or positioned adjacent to one or more outside surfaces of the pump. In some embodiments, the pump assembly **400** can have mass based or compliant damping materials. Such components or materials (not illustrated) can damp vibration and/or attenuate noise produced by the pump.

[0212] **Figures 48-49** are various views illustrating wiring of the pump system **100** within the outer housing **102**. As shown in the illustrated embodiment, the pump system **100** can include terminals **210** for connecting the circuit board **200** to a power source, such as batteries **202**. The circuit board **200** can route power from the power source to the coil **600** via an electrical conduit **604** attached to a connector **212** of the circuit board **200**. In some embodiments, the electrical conduit **604** can be a flexible printed circuit (FPC) to facilitate assembly. In some embodiments, the electrical conduit **604** can be connected directly to the coil **600**. For example, the ends of the FPC corresponding to a positive and negative terminal can be attached, such as via soldering and/or via adhesives, to ends or terminals of the coil **600**. For example, the coil 600 can have two terminals that can be soldered to two corresponding solder pads of the FPC. However, the wire used to manufacture the coil can be protected by an insulation layer and a self-bonding coating layer that can make manual soldering difficult and/or unreliable since manual soldering can expose the FPC to temperatures of 400 degrees Celsius for too long a time, which can damage the FPC substrate. To mitigate this problem, in some embodiments, a micro welding process can be used to electrically connect the FPC to the two terminals of the coil 600. In micro welding, a high current spike can be generated for a few milliseconds between the terminals of the coil and the pads of the FPC. The current spike can result in a localized temperature spike that can vaporize the insulating and self-bonding layers of the wire so that the wire of the coil can be bonded to the pads of the FPC. For example, the temperature spike can be 400 degrees Celsius or higher. However, since the temperature spike is limited to a few milliseconds using the micro welding process, the FPC substrate is not damaged.

[0213] **Figures 50** illustrates an embodiment of a coil **600′** and a support member **650′**. The support member **650′** can incorporate electrically conductive pins **651′** which can connect terminals of the coil **600′** to a power source, such as control board **200**. As shown in the illustrated embodiment, the terminals of the coil **600′** can be attached to the pins **651′** via soldering and/or adhesives.

[0214] **Figure 51** illustrates one example of a connection mechanism for connecting the coil **600** to the power source. As shown in the illustrated embodiment, the pins **651′** can extend past the pump chamber body **470′** and into contact with a leaf spring **214′**. The leaf spring **214′** can be connected to terminal ends of an electrical conduit **604′** for a power source, such as terminal ends of an FPC. Accordingly, as the support member **650`′** moves in the vertical direction, the leaf spring **214′** can maintain contact with the pins **651′**.

[0215] **Figure 52** illustrates another example of a connection mechanism for connecting coil **600′** to the power source. As shown in the illustrated embodiment, an electrically conductive coil spring **215'** can extend into the pump chamber body **470′** and into contact with one or more terminals of the coil **600′**. Accordingly, as the coil **600′** moves in the vertical direction, the coil spring **215'** can compress and/or expand. In some embodiments, the electrically conductive coil spring **215'** can be in contact with pins (not shown) on the support member **650′**. The coil spring **215'** can be connected to terminal ends of an electrical conduit for a power source, such as terminal ends of an FPC.

[0216] **Figure 53** illustrates another example of a connection mechanism for connecting coil **600′** to the power source. As shown in the illustrated embodiment, an electrically conductive zebra connector **218′** can extend into the pump chamber body **470′** and into contact with one or more terminals of the coil **600′**. Accordingly, as the coil **600′** moves in the vertical direction, the zebra connector **218′** can maintain contact with terminals of the coil **600′**. In some embodiments, the zebra connector **218′** can be in contact with pins (not shown) on the support member **650′**. The zebra connector **218′** can be connected to terminal ends of an electrical conduit for a power source, such as terminal ends of an FPC, or contacts **219′**.

[0217] **Figure 54** illustrates another example of a connection mechanism for connecting coil **600′** to the power source. As shown in the illustrated embodiment, one or more individual terminals of the coil **600′** can be encased together in a membrane **220′** which extends out of pump chamber body **470′**. The membrane **220′** can be made from any suitable material, such as silicone. The individual terminals can then be attached, via soldering and/or adhesives, to more robust wiring **222′** for routing towards the power source.

[0218] **Figure 55** illustrates another example of a connection mechanism for connecting coil **600′** to the power source. As shown in the illustrated embodiment, the electrical conduit **604′** can be integrated with the spring **750′**.

[0219] In some embodiments, the pump system **100** can be configured such that the battery connections or terminals have polarity protection. For example and without limitation, one or more of the battery contacts can be designed to have plastic or other non-conductive protrusions adjacent to the battery terminal contacts to inhibit the contact between the battery contact and the incorrect side of a battery that is inserted into the battery compartment in the incorrect orientation. In some embodiments, the one or more protrusions can be sized and designed to prevent the negative side of a standard cylindrical battery from contacting the battery contact adjacent to the one or more protrusions, while permitting a positive side of such battery to contact the battery contact. Generally, with this configuration, the battery can generally only make contact with the contact if the battery is inserted in the battery compartment in the correct orientation, thereby providing polarity protection to the pump assembly. Alternatively or additionally, a control board of the pump assembly can be designed to have polarity protective features or components. Additionally, a control board of the pump assembly can have one or more fuses to protect against overpower conditions or surge power conditions.

[0220] In any of the embodiments disclosed herein, the control board **200** can be a flexible circuit board and/or can have one or more flexible components. A flexible circuit board is generally a patterned arrangement of printed circuitry and components that utilizes flexible based material with or without flexible overlay. These flexible electronic assemblies can be fabricated using the same components used for rigid printed circuit boards, but allowing the board to conform to a desired shape (flex) during its application. In their simplest form, flexible circuits are PCBs made of materials that allow for a non-planar positioning within the end product. Typical materials a polyimide-based, and can go under trade names such as Kapton (DuPont). Additionally, any of the control boards or controllers disclosed herein can have a combination of flexible and rigid substrates laminated into a single package.

Overview of the Electrical Aspects of the Pump System

[0221] **Figure 60** illustrates a schematic of an embodiment of a pump system **1000**. In some embodiments, the pump system **1000** can have any of the same or similar components, features, materials, sizes, configurations, and other details of any other pump system embodiments disclosed or incorporated by reference herein, including the embodiment of the pump system **100** described above. In some embodiments, the pump system **1000** can be miniaturized and portable, although larger conventional portable or non-portable (e.g., wall suction) pumps can also be used.

[0222] As shown in the illustrated embodiment, the pump system **1000** can include a switch or a button **1002**, one or more indicators **1004**, and a control board **1006**. The button **1002** and/or the one or more indicators **1004** can be in electrical communication with the control board **1006**. As is explained in further detail below, in some embodiments the button **1002** can be used for any suitable purpose for controlling an operation of the pump system **1000**. For example, button **1002** can be used to activate the pump system **1000**, pause the pump system **1000**, clear system indicators **1004**, and/or be used for any other suitable purpose for controlling an operation of the pump system **1000**. Button **1002** can by any type of switch or button, such as a touchpad, touch screen, keyboard, and so on. In some embodiments, the button **1002** can be a press button. For example, the button **1002** can be similar to button **116** of pump system **100**.

[0223] In some embodiments, the one or more indicators **1004** can indicate one or more operating and/or failure conditions of the pump system **1000**. In some embodiments, each of the one or more indicators **1004** can provide an indication regarding a different operating and/or failure condition. For example, an active (e.g., lit) indicator **1004** can represent normal operation. Another indicator **1004**, for example a dressing indicator, can provide an indication as to presence of leaks in the system. For example, an active (e.g., lit) dressing indicator can represent a leak. Another indicator **1004**, for example a dressing capacity indicator, can provide an indication as to the remaining fluid capacity of a dressing. For example, an active (e.g., lit) dressing capacity indicator can represent that the dressing is at or nearing capacity. Another indicator **1004**, such as a battery indicator, can provide an indication as to remaining capacity or life of a power source, such as batteries. For example, an active (e.g., lit) battery indicator can represent a low capacity. In some embodiments, an

indicator **1004** can represent a combination of the above operating and/or failure conditions of the pump system **1000** and/or other operating and/or failure conditions.

[0224] With continued reference to the embodiment of pump system **1000** illustrated in **Figure 60**, in some embodiments, the one or more indicators **1004** can be icons. For example, the one or more indicators **1004** can be similar to the icons **114** of pump system **1004** and can be activated (e.g., lit) via an illumination source such as LEDs **206** of pump system **100**. In some embodiments, the one or more indicators **1004** can be of a different color, two different colors (e.g., two indicators can share the same color), or the same color. Although the pump system **1000** can include four icons and a push play/pause button, other configurations, locations, and types of indicators, alarms, and switches can alternatively be used. In some embodiments, the pump system **1000** can include visual, audible, tactile, and other types of indicators or alarms configured to signal to the user various operating conditions. Such conditions include system on/off, standby, pause, normal operation, dressing problem, leak, error, and the like. The indicators can include speakers, displays, light sources, etc., and/or combinations thereof.

[0225] As shown in the illustrated embodiment, the pump system **1000** can be powered by a power source **1008** such as a battery power cell. The pump system **1000** can also include a source of negative pressure **1010**, such as a pump assembly having a pump **1012** powered by an electric motor **1014**, and a pressure sensor **1016**, such as pressure monitor **204** of pump system **100**. In some embodiments, the pump system **1000** can include an inlet **1018** to connect the pump system **1000** to a wound dressing. For example, in some embodiments, the inlet **1018** can be a connector for connecting the inlet **1018** to a conduit which is in fluid communication with a wound dressing. The connector can be similar to connector **302** of pump system **100**. The pump **1012** can be connected to an outlet **1020**. In some embodiments, the outlet **1020** can vent air to the atmosphere. In some embodiments, a filter (not shown) can be interposed between the outlet and the atmosphere. The filter can provide filtration of the air prior to venting to the atmosphere. In some embodiments, the filter can be a bacterial filter, odor filter, etc. or any combination thereof. In some embodiments, a dampening component (not shown), such as a noise dampening component, can be interposed between the outlet and the atmosphere. The dampening component can reduce the noise generated by the pump system **1000** during operation. In some

embodiments, the dampening component can be similar to dampening component **902** of pump system **100**.

[0226] In some embodiments, the pump system **1000** can include a valve (not shown), such as a one-way valve, in a flow passage between the wound dressing and an inlet of the pump **1012**. The valve can help maintain a level of negative pressure when the pump **1012** is not active. In some embodiments, the valve can help avoid leaks. The valve can also help prevent fluids and/or exudate aspirated or removed from the wound from entering the pump system **1000**.

[0227] **Figure 61** illustrates an electrical component schematic of a pump system **1100** according to an embodiment. In some embodiments, the pump system **1100** can have any of the same or similar components, features, materials, sizes, configurations, and other details of any other pump system embodiments disclosed or incorporated by reference herein, including the embodiment of the pump system **100**, **1000** described above. Pump system **1100** can include one or more buttons **1102**, one or more indicators **1104**, one or more pressure sensors **1106**, power source **1108**, a source of negative pressure **1109**, and/or a module **1110**. In some embodiments, the one or more buttons **1102**, one or more indicators **1104**, one or more pressure sensors **1106**, power source **1108**, and/or source of negative pressure **1109** can be similar to button **1002**, indicators **1004**, pressure sensor **1016**, power source **1008**, and/or source of negative pressure **1010** of pump system **1000**. Module **1110**, which can be a control board (e.g., PCBA), can include an input/output (I/O) module **1112**, controller **1114**, and memory **1116**. In some embodiments, module **1110** can include additional electric/electronic components, for example, fuse or fuses, or external memory (such as flash-memory). The controller **1114** can be a microcontroller, processor, microprocessor, etc. or any combination thereof. For example, the controller **1114** can be of the STM8L MCU family type from ST Microelectronics, such as STM8L 151G4U6 or STM8L 151K6U6TR, or of MC9S08QE4/8 series type from Freescale, such as MC9S08QE4CWJ. Preferably, the controller **1114** is a low power or ultra low power device, but other types of devices can alternatively be used. Memory **1116** can include one or more of volatile and/or nonvolatile memory modules, such as one or more of read-only memory (ROM), write once read many memory (WORM), random access memory (e.g.., SRAM,. DRAM. SDRAM, DDR, etc.), solid-state memory, flash memory, Magnetoresistive random-

access memory (MRAM), magnetic storage, etc. or any combination thereof. Memory **1116** can be configured to store program code or instructions (executed by the controller), system parameters, operational data, user data, etc. or any combination thereof. In some embodiments, one or more components of the pump system **1100** can form part of a monolithic unit. In some embodiments, the memory **1116** can be 16 megabits, 32 megabits, or of another suitable size depending on the amount of data configured to be logged during operation of the pump system **1100**. In some embodiments, the logged data can be stored to advantageously gather information that is relevant to clinical trial(s). In some embodiments, one or more components of the pump system **1100** can be removable from other components. For example, in some embodiments, memory **1116** can be removable flash memory.

[0228] **Figure 62** illustrates an electrical component schematic of a pump system **1200** according to an embodiment. In some embodiments, the pump system **1200** can have any of the same or similar components, features, materials, sizes, configurations, and other details of any other pump system embodiments disclosed or incorporated by reference herein, including the embodiment of the pump system **100**, **1000**, **1100** described above. Electrical components can operate to accept user input, provide output to the user, operate the pump system and the source of negative pressure, provide network connectivity, and so on. Electrical components can be mounted on one or more PCBs (not shown). The pump system can include a controller or processor **1202**. In any embodiments disclosed herein, the controller **1202** can be a general purpose processor, such as a low-power processor. In other embodiments, the controller **1202** can be an application specific processor. In any embodiments disclosed herein, the controller **1202** can be configured as a "central" processor in the electronic architecture of the pump system, and the controller **1202** can coordinate the activity of other controllers, such as a user interface controller **1204**, I/O interface controller **1206**, negative pressure control module **1208**, communications interface controller **1210**, and the like.

[0229] The pump system **1200** can also include a user interface controller or processor **1204** which can operate one or more components for accepting user input and providing output to the user, such as buttons, indicators (e.g., LEDs), displays, etc. Input to the pump system **1200** and output from the pump system **1200** can be controlled via one or more input/output (I/O) ports **1212** controlled by a I/O interface module or controller **1206**.

For example, the I/O module **1206** can receive data from one or more I/O ports **1212**, such as serial, parallel, hybrid ports, expansion ports, and the like. In any embodiments disclosed herein, I/O ports **1212** include one or more of USB ports, SD ports, Compact Disc (CD) drives, DVD drives, FireWire ports, Thunderbolt ports, PCI Express ports, and the like. The controller **1202**, along with other controller or processors, can store data in one or more memory modules **1214**, which can be internal and/or external to the system **1200**. Any suitable type of memory can be used, including volatile and/or non-volatile memory, such as RAM, ROM, WORM, magnetic memory, solid-state memory, MRAM, and the like or any combination thereof. The pump system **1200** can be powered by a power source **1216**, which can comprise one or more disposable or rechargeable batteries, power from mains, etc. The power source **1216** can be internal or external to the system **1200**.

[0230] With continued reference to the embodiment of pump system **1200** illustrated in **Figure 62**, in some embodiments, a negative pressure or pump control module **1208** can be configured to control the operation of a negative pressure source **1218**. The negative pressure source **1218** can be a voice coil pump. Other suitable pumps include diaphragm pumps, peristaltic pumps, rotary pumps, rotary vane pumps, scroll pumps, screw pumps, liquid ring pumps, diaphragm pumps operated by a piezoelectric transducer, and the like. The pump control module **1208** can include a driver module **1220** configured to control the operation of the negative pressure source **1218**. For example, the driver module **1220** can provide power to the negative pressure source **1218**. Power can be provided in a form of a voltage and/or current signal. In any embodiments disclosed herein, the driver module **1220** can control the negative pressure source **1218** using pulse-width modulation (PWM). A control signal for driving the negative pressure source **1218** (or pump drive signal) can be a 0-100% duty cycle PWM signal. The drive module **1220** can control the negative pressure source **1218** using any other suitable control, such as proportional-integral-derivative (PID).

[0231] The controller **1202** can receive information from one or more sensors, such as pressure sensors **1206**, placed in a suitable location in a fluid flow path, such as pressure monitor **204** placed within intake manifold **300** of pump system **100**. In any embodiments disclosed herein, the controller **1202** can measure pressure in the fluid flow path, using data received from one or more pressure sensors **1206**, calculate the rate of fluid

flow, and control the negative pressure source **1218** so that desired level of negative pressure is achieved in a wound cavity or under the dressing. The desired level of negative pressure can be pressure set or selected by a user. Pressure measured by the one or more sensors can be provided to the controller **1202** so that the controller can determine and adjust the pump drive signal to achieve the desired negative pressure level. In any embodiments disclosed herein, the tasks associated with controlling the negative pressure source **1218** can be offloaded to the pump control module **1208**, which can include one or more controllers or processors.

[0232] In any embodiments disclosed herein, it may be advantageous to utilize multiple processors for performing various tasks. In any embodiments disclosed herein, a first processor can be responsible for user activity and a second processor can be responsible for controlling the negative pressure source. This way, the activity of controlling the negative pressure source, which may necessitate a higher level of responsiveness, can be offloaded to a dedicated processor and, thereby, will not be interrupted by user interface tasks, which may take longer to complete because of interactions with the user.

[0233] A communications interface controller or processor **1210** can be configured to provide wired and/or wireless connectivity. The communications processor **1210** can utilize one or more antennas (not shown) for sending and receiving data. In any embodiments disclosed herein, the communications processor **1210** can provide one or more of the following types of connections: Global Positioning System (GPS) technology, cellular or other connectivity, such as 2G, 3G, LTE, 4G, WiFi, Internet connectivity, Bluetooth, zigbee, RFID, and the like. Additionally, any embodiments disclosed herein can be configured to synchronize, upload, or download data to and/or from the pump apparatus to and/or from a portable data device, such as a tablet, smart phone, or other similar devices.

[0234] Connectivity can be used for various activities, such as pump system location tracking, asset tracking, compliance monitoring, remote selection, uploading of logs, alarms, and other operational data, and adjustment of therapy settings, upgrading of software and/or firmware, and the like. In any embodiments disclosed herein, the communications processor **1210** can provide dual GPS/cellular functionality. Cellular functionality can, for example, be 3G and/or 4G functionality. In such cases, if the GPS module is not be able to establish satellite connection due to various factors including atmospheric conditions,

building or terrain interference, satellite geometry, and so on, the device location can be determined using the 3G and/or 4G network connection, such as by using cell identification, triangulation, forward link timing, and the like. In any embodiments disclosed herein, the pump system **1200** can include a SIM card, and SIM-based positional information can be obtained.

Pump System Control

[0235] **Figure 63** illustrates a top level state diagram **1300** of operation of the pump system according to some embodiments. In some embodiments, the pump system, such as pump systems **100**, **1000**, **1100**, **1200** and any other embodiments disclosed herein, can control the operation of the system. For example, the pump system can provide a suitable balance between uninterrupted delivery of therapy and/or avoidance of inconveniencing the user by, for example, frequently or needlessly pausing or suspending therapy and a desire to conserve power, limit noise and vibration generated by the negative pressure source, etc. In some embodiments, the controller, such as controllers **1114**, **1202**, can be configured to implement the flow of the state diagram **1300**. As is illustrated in **Figure 63**, the operation of the pump system can, in some embodiments, be grouped into three general modes: initialization **1302**, operational **1310**, which includes maintenance **1350**, and end of life **1390**. As is illustrated in **Figure 63**, categories **1302**, **1310**, and **1350** can each include multiple states and transitions between states.

[0236] In some embodiments, so long as a power source is not connected or removed, or the pump system has not been activated (e.g., by pulling an activation strip, triggering the switch, or the like), the pump system can remain in an inactive state. While remaining in this state, the pump system can remain inactive. When the power source is connected and/or the pump system has been activated from the inactive state, such as being activated for the first time, the pump system can transition to an initialization mode **1302**, where a bootloader **1301** can initiate a sequence of startup procedures as shown in block 1304. The bootloader **1301** can be stored on any suitable non-volatile memory such as, for example, read only memory (ROM), erasable programmable read only memory (EPROM), electrically erasable programmable read-only memory (EEPROM), and the like. In some embodiments, controllers **1114** or **1202** can execute the bootloader **1301** upon startup. The

startup procedures can include power on selftest(s) (POST) and other tests or procedures that can be performed as shown in startup block **1304**. As shown in Figure 63, the bootloader **1301** can initiate one or more of the POST(s) and/or one or more of the other tests. In some embodiments, the startup procedures can advantageously prepare and/or ensure that the pump system will deliver negative pressure wound therapy safely during operation.

[0237] Power on self test(s) can include performing various checks to ensure proper functionality of the system, such as testing one or more components of the system including, but not limited to, memory such as memory **1116**, **1214** (e.g., performing a check, such as a cyclic redundancy check (CRC check), of the program code to determine its integrity, testing the random access memory, etc.), reading the pressure sensor such as pressure sensors or monitors **204**, **1016**, **1106**, **1206**, to determine whether the pressure values are within suitable limits, reading the remaining capacity or life of the power source (e.g., battery voltage, current, etc.) to determine whether it is within suitable limits, testing the negative pressure source, and the like. Other tests or procedures can include waiting for automatic test equipment (ATE), initializing a watch dog timer (WDT), checking whether the pump system has previously entered a non-recoverable error (NRE), and determining whether the pump system has reached the end of its allotted operational lifespan (also referred to as its end of life (EOL)), and the like. For example, in some embodiments, the WDT can advantageously be used as a countermeasure to a firmware execution hanging conditions, the check for a previous NRE can advantageously prevent the reuse of a device that has transitioned to an NRE state, and the check of whether the device has reached its end of life can advantageously prevent the reuse of a device that has transitioned to an EOL state.

[0238] In some embodiments, the bootloader **1301**, which can be executed by the controllers **1114**, **1202**, can also initiate the operational mode **1310**. For example, as shown in Figure 63, the bootloader can execute initialization of the operational mode **1310** after the initialization mode 1302 has been performed. In some embodiments, one or more indicators (such as icons **114**, **114'** and/or indicators **1004**, **1104**) can indicate to the user (e.g., by blinking or flashing once) that the pump system is undergoing POST test(s). In some embodiments, during the initialization mode **1302**, all indicators can continuously remain on.

[0239] In some embodiments, the one or more indicators can blink or flash intermittently or continuously to indicate to the user that the system has passed the POST(s)

and/or other tests and procedures. For example, as discussed above with reference to Figure 56, in some embodiments, the one or more indicators can include a set of four icons **114'** that include an "OK" indicator which can indicate normal operation of the pump system **100**, a "leak" indicator which can indicate the existence of a leak in the pump system **100** or components attached thereto, a "dressing full" indicator which can indicate that a wound dressing is at or near capacity, and a "battery critical" indicator which can indicate that the battery is at or near a critical level. In some embodiments, the one or more indicators can be individually or cooperatively illuminated to indicate to the user that the pump system has passed POST(s) and/or other tests and procedures. For example, in some embodiments, the set of four icons **114'** can be cooperatively illuminated to indicate that the system has passed the one or more tests such that the "OK" LED flashes once, the "leak" LED flashes once, the "dressing full" LED flashes once, and the "battery critical" LED flashes once. Similarly, if a previous non-recoverable error is discovered during startup or subsequently encountered during pump operation, the set of four icons **114'** can be cooperatively illuminated such that the "OK" LED is solid, the "leak" LED is solid, the "dressing full" LED is solid, and the "battery critical" LED is solid. Any suitable individual or cooperative LED arrangement is envisioned in certain embodiments. In various embodiments, in addition to or instead of providing the visual indication using the one or more indicators, other indications can be provided, including audible, tactile, and the like.

[0240] In some embodiments, if one or more of the POST test(s) or other tests or procedures fail, the pump system can transition to a retry state **1306**. The retry state **1306** can include a delay and/or require user input before retrying the POST test(s) or other tests or procedures. In some embodiments, the retry state **1306** can be executed until each test or procedure that is part of the initialization mode passes or otherwise does not fail. In some embodiments, if one or more of POST test(s) fail after one or more retries, the pump system can transition to a non-recoverable error state. While in this state, the pump system can deactivate therapy, and indicators can indicate to the user that an error was encountered. In some embodiments, all indicators can remain active. Based on the severity of error, in some embodiments, the pump system can recover from the error and continue operation (or transition to the non-recoverable error state **1394**). As is illustrated, the pump system can transition to the non-recoverable error state **1394** upon encountering a fatal error during

operation. Fatal errors can include program memory errors, program code errors (e.g., encountering an invalid variable value), controller operation errors (e.g., watchdog timer expires without being reset by the controller such as controller **1114**, **1202**), component failure (e.g., inoperative negative pressure source such as negative pressure sources **1010**, **1109**, **1218**, inoperative pressure sensor such as pressure sensors or monitors **204**, **1016**, **1106**, **1206**, etc.), and any combination thereof.

[0241] With continued reference to the embodiment discussed in connection with **Figure 63**, in some embodiments, when initialization has been successfully completed in state **1304**, the pump system can transition to the operational mode **1310**. This transition can be indicated to the user by deactivating and/or activating one or more indicators. In some embodiments, when the pump system transitions into the operational mode **1310**, the pump system can first enter a standby or paused state **1312**. While the pump system remains in the standby state **1312**, the user can be provided an indication, such as by deactivating and/or activating indicators (e.g., an OK indicator and/or a dressing indicator). In some embodiments, the user can be provided an indication of the standby state **1312** by deactivating all indicators. In some embodiments, therapy can be suspended while the pump system remains in the standby state **1312**. For example, the source of negative pressure such as sources of negative pressure **1010**, **1109**, **1218**, can be deactivated (or turned off). In some embodiments, indication can be provided to the user by deactivating the source of negative pressure.

[0242] In some embodiments, the pump system can be configured to make a transition from the standby state **1312** to an initial pump down ("IPD") state **1314** (where the pump system is configured to deliver therapy) in response to receiving a signal from the user. For example, the user can press a button to start, suspend, and/or restart therapy. In some embodiments, the pump system can monitor the duration of time the pump system remains in the standby state **1312**. This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be reset and started when the pump system transitions into the standby state **1312**. The pump system can automatically make the transition from the standby state **1312** to the IPD state **1314** when the time duration exceeds a threshold (e.g., times out). In some embodiments, such threshold can be a preset value, such as between 1 minute or less and 1 hour or more. In some

embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or on any combination thereof. For example, as the pump system nears the end of life (as is explained below), the threshold can be decreased used over the lifespan of the pump system. This can advantageously ensure that the battery is used more efficiently over the lifespan of the pump system by reducing the amount of time spent in the standby state **1312** and utilizing more of the battery by activating the pump sooner. In some embodiments, the pump system can monitor the entire amount of time spent in the standby state and store this information in memory.

[0243] During the IPD state **1314**, the pump system can activate the source of negative pressure to begin therapy and reduce pressure in the system or some portion thereof, such as a fluid flow path between a source of negative pressure and a wound dressing. In some embodiments, the pump system can reduce pressure in the system to a desired pressure, such as a low pressure threshold. The pump system can intermittently and/or continuously monitor the pressure in the pump system or some portion thereof. For example, the pump system can monitor the pressure in the pump system or some portion thereof at a preset sampling rate of approximately 100 ms. In some embodiments, the sampling rate can be between approximately 20 ms and approximately 500 ms, between approximately 50 ms and 250 ms, between approximately 80 ms and 150 ms, approximately 100 ms, any value and/or subrange with these ranges, or any other sampling rate as desired. In some embodiments, the pump system can also calculate the rate of pressure change to estimate the amount of time until the pump system reaches a desired pressure, such as the low pressure threshold.

[0244] In some embodiments, one or more indicators can blink or flash intermittently or continuously to indicate to the user that the pump system is in the IPD state. For example, as discussed above with reference to Figure 56, in some embodiments, the one or more indicators can include a set of four icons **114'** that include an "OK" indicator which can indicate normal operation of the pump system **100**, a "leak" indicator which can indicate the existence of a leak in the pump system **100** or components attached thereto, a "dressing full" indicator which can indicate that a wound dressing is at or near capacity, and a "battery critical" indicator which can indicate that the battery is at or near a critical level. In some embodiments, the one or more indicators can be individually or cooperatively illuminated to indicate to the user that the system is in the IPD state. For example, in some embodiments,

the set of four icons **114'** can be cooperatively illuminated to indicate that the system is in the IPD state such that the "OK" LED is flashing, the "leak" LED is flashing, the "dressing full" LED is off, and the "battery critical" LED does not change (on, off, or flashing). Any suitable individual or cooperative LED arrangement is envisioned in certain embodiments. Once a desired negative pressure is reached during the IPD state, the one or more indicators can be individually or cooperatively illuminated to indicate that the desired negative pressure has been reached. For example, in some embodiments, the set of four icons **114'** can be cooperatively illuminated to indicate that the negative pressure has been reached such that the "OK" LED is flashing, the "leak" LED is off, the "dressing full" LED is off, and the "battery critical" LED does not change (on, off, or flashing). In some embodiments, this same illumination pattern can also be used to indicate that the pump system is functioning properly, such as during the IPD state to indicate that the pump system is functioning properly during the IPD state, in addition to flashing to indicate that the negative pressure has been reached during the IPD state. In various embodiments, in addition to or instead of providing the visual indication using the one or more indicators, other indications can be provided, including audible, tactile, and the like.

[0245] In some embodiments, the user can pause therapy by activating the switch (e.g., pressing the button), thereby causing the pump system to make a transition from the IPD state **1314** to the standby state **1312**. In some embodiments, the pump system can be configured so that the user can only pause therapy, whereas disconnecting the power source (e.g., removing batteries) stops therapy. As such, in some embodiments, the pump system can potentially time out while in the standby state **1312** and resume operation thereby reducing any energy expended while in the standby state **1312**. After being paused by the user, the pump system can transition from the standby state **1312** to the IPD state **1314** upon receiving a user input such as a button press. In some embodiments, after being paused by the user, the pump system can automatically make the transition from the standby state **1312** to the IPD state **1314** when the time duration exceeds a threshold. The threshold can be the same or different than the threshold of the standby state **1312** described above when the pump system enters the standby state **1312** after startup **1304**.

[0246] When the pump system transitions into and remains in the standby state **1312**, the user can be provided an indication. For example, in some embodiments, all

indicators can be deactivated. In some embodiments, the pump system can deactivate an indicator (e.g., an OK indicator) and cause another indicator (e.g., a dressing indicator) to flash or blink. In some embodiments, one or more indicators can blink or flash intermittently or continuously to indicate to the user that the system is in the standby state. For example, as discussed above with reference to Figure 56, in some embodiments, the one or more indicators can include a set of four icons **114'** that include an "OK" indicator which can indicate normal operation of the pump system **100**, a "leak" indicator which can indicate the existence of a leak in the pump system **100** or components attached thereto, a "dressing full" indicator which can indicate that a wound dressing is at or near capacity, and a "battery critical" indicator which can indicate that the battery is at or near a critical level. In some embodiments, the one or more indicators can be individually or cooperatively illuminated to indicate to the user that the system is in the standby state. For example, in some embodiments, the set of four icons **114'** can be cooperatively illuminated to indicate that the system is in the standby state such that the "OK" LED is off, the "leak" LED is off, the "dressing full" LED is off, and the "battery critical" LED is off. In some embodiments, this same illumination pattern can also be used to indicate that the pump system has completed its course of negative pressure wound therapy or to indicate that the batteries have been depleted, in addition to indicating that the pump is in the standby state. Any suitable cooperative LED arrangement is envisioned in certain embodiments. In various embodiments, in addition to or instead of providing the visual indication using the one or more indicators, other indications can be provided, including audible, tactile, and the like. In some embodiments, therapy can be suspended while the pump system remains in the standby state **1312**. For example, the source of negative pressure can be deactivated (or turned off), which provides the indication to the user that the pump system is in the standby state **1312**.

[0247] With continued reference to the embodiment discussed in connection with **Figure 63**, in some embodiments, the pump system can transition from the initial pump down state **1314** into a leak state **1316** when a number of retry cycles exceeds a retry limit and/or when a duty cycle of the pump (explained below) is determined to exceed a duty cycle limit. In some embodiments, exceeding a retry limit and/or duty cycle limit can reflect the presence of a leak in the system. In some embodiments, the pump system can transition from the IPD state **1314** to the leak state **1316** when a threshold pressure is not reached within a

desired amount of time. The inability for the threshold pressure to reach the threshold pressure within a desired amount of time can reflect the presence of a leak in the system. In some embodiments, an indicator (e.g., a leak indicator or dressing indicator) can blink or flash intermittently or continuously to indicate to the user the presence of a leak in the system. In some embodiments, one or more indicators can blink or flash intermittently or continuously to indicate to the user the presence of a leak. For example, as discussed above with reference to Figure 56, in some embodiments, the one or more indicators can include a set of four icons **114'** that include an "OK" indicator which can indicate normal operation of the pump system **100**, a "leak" indicator which can indicate the existence of a leak in the pump system **100** or components attached thereto, a "dressing full" indicator which can indicate that a wound dressing is at or near capacity, and a "battery critical" indicator which can indicate that the battery is at or near a critical level. In some embodiments, the one or more indicators can be individually or cooperatively illuminated to indicate to the user the presence of a leak. For example, in some embodiments, the set of four icons **114'** can be cooperatively illuminated to indicate the presence of a leak such that the "OK" LED is off, the "leak" LED is flashing, the "dressing full" LED is off, and the "battery critical" LED does not change (on, off, or flashing). Any suitable cooperative LED arrangement is envisioned in certain embodiments. In various embodiments, in addition to or instead of providing the visual indication using the one or more indicators, other indications can be provided, including audible, tactile, and the like.

[0248] After entering the leak state **1316**, the pump system can transition from the leak state **1316** to the IPD state **1314** upon receiving a user input such as a button press. This can advantageously give the user some time to mitigate or remove the leak, such as by checking the connections of the wound dressing and/or checking the seal of the wound dressing around the wound. In some embodiments, the pump system can monitor the duration of time the pump system remains in the leak state **1316**. This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be reset and started when the pump system transitions into the leak state **1316**. In some embodiments, after entering the leak state **1316**, the pump system can automatically make the transition from the leak state **1316** to the IPD state **1314** when the time duration exceeds a threshold. The threshold can be the same or different than the other

time thresholds described herein, such as that of the standby state **1312** to the IPD state **1314**. The threshold can be the same or different depending on the state or mode prior to transitioning to the leak state **1316** (e.g., the IPD state **1314** or the maintenance mode **1350**). In some embodiments, such threshold can be a preset value, such as between 1 minute or less and 1 hour or more. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or on any combination thereof. For example, as the pump system nears the end of life (as is explained below), the threshold can be decreased provided the battery has sufficient capacity remaining. This can advantageously ensure that the battery is more efficiently used over the lifespan of the pump system by reducing the amount of time spent in the leak state **1316** and utilizing more of the battery by activating the pump sooner. The pump system can transition into other modes or states, such as the maintenance mode **1350**, after activating the switch or automatically after exceeding the threshold. In some embodiments, the pump system can transition to the IPD state **1314** or the maintenance mode **1350** depending on operating conditions, such as the pressure at the time of the transition.

[0249] As noted above, in some embodiments, the pump system can be configured to operate in a canisterless system, in which the wound dressing retains exudate aspirated from the wound. Such dressing can include a filter, such as a hydrophobic filter, that prevents passage of liquids downstream of the dressing (toward the pump system). In other embodiments, the pump system can be configured to operate in system having a canister for storing at least part of exudate aspirated from the wound. Such canister can include a filter, such as a hydrophobic filter, that prevents passage of liquids downstream of the dressing (toward the pump system). In yet other embodiments, both the dressing and the canister can include filters that prevent passage of liquids downstream of the dressing and the canister.

[0250] With continued reference to the embodiment discussed in connection with **Figure 63**, in some embodiments, the pump system can be configured to transition from the initial pump down state **1314** into a filter blocked state **1318** when the system determines that the filter, such as a wound dressing filter, has encountered a blockage (e.g., caused by the wound dressing being filled with exudate to capacity or nearly to capacity). Example algorithms for determining that the filter has encountered a blockage will be discussed in

further detail below. In some embodiments, an indicator (e.g., a filter blocked indicator) can blink or flash intermittently or continuously to indicate to the user the presence of a blockage. In some embodiments, one or more indicators can blink or flash intermittently or continuously to indicate to the user the presence of a blockage. For example, as discussed above with reference to Figure 56, in some embodiments, the one or more indicators can include a set of four icons **114'** that include an "OK" indicator which can indicate normal operation of the pump system **100**, a "leak" indicator which can indicate the existence of a leak in the pump system **100** or components attached thereto, a "dressing full" indicator which can indicate that a wound dressing is at or near capacity, and a "battery critical" indicator which can indicate that the battery is at or near a critical level. In some embodiments, the one or more indicators can be individually or cooperatively illuminated to indicate to the user the presence of a blockage. For example, in some embodiments, the set of four icons **114'** can be cooperatively illuminated to indicate the presence of a blockage such that the "OK" LED is off, the "leak" LED is off, the "dressing full" LED is flashing, and the "battery critical" LED does not change (on, off, or flashing). Any suitable cooperative LED arrangement is envisioned in certain embodiments. In various embodiments, in addition to or instead of providing the visual indication using the one or more indicators, other indications can be provided, including audible, tactile, and the like. In some embodiments, the transition to the filter blocked state **1318** can be made when a canister filter is blocked (e.g., caused by the canister being full or nearly full).

[0251] After entering the filter blocked state **1316**, the pump system can transition from the filter blocked state **1318** to the IPD state **1314** upon receiving a user input such as a button press. This can advantageously give the user an opportunity to mitigate or remove the blockage, such as by changing the wound dressing (and/or the canister). In some embodiments, the pump system can monitor the duration of time the pump system remains in the filter blocked state **1318**. This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), which can be reset and started when the pump system transitions into the filter blocked state **1318**. In some embodiments, after entering the filter blocked state **1318**, the pump system can automatically make the transition from the filter blocked state **1318** to the IPD state **1314** when the time duration exceeds a threshold. The threshold can be the same or different than the other time

thresholds described herein, such as that of the standby state **1312** to the IPD state **1314** and/or the leak state **1316** to the IPD state **1314**. The threshold can be the same or different depending on the state or mode prior to transitioning to the filter blocked state **1318** (e.g., the IPD state **1314** or the maintenance mode **1350**). In some embodiments, such threshold can be a preset value, such as between 1 minute or less and 1 hour or more. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or on any combination thereof. For example, as the pump system nears the end of life (as is explained below), the threshold can be decreased provided the battery has sufficient capacity remaining. This can advantageously ensure that the battery is more efficiently used over the lifespan of the pump system by reducing the amount of time spent in the filter blocked state **1316** and utilizing more of the battery by activating the pump sooner. The pump system can transition into other modes or states, such as the maintenance mode **1350**, after activating the switch or automatically after exceeding the threshold. In some embodiments, the pump system can transition to the IPD state **1314** or the maintenance mode **1350** depending on operating conditions, such as the pressure at the time of the transition.

[0252] With continued reference to the embodiment discussed in connection with **Figure 63**, in some embodiments, during the IPD state **1314**, once the pump system has detected that the pressure within the pump system or some portion thereof, such as a fluid flow path between a source of negative pressure and a wound dressing, is at or around the low pressure threshold, the pump system can transition into a maintenance mode **1350** and, in particular, to the monitor state **1352**. For example, the low pressure threshold can be approximately -90 mmHg. In some embodiments, the low pressure threshold can be between approximately -50 mmHg and approximately -250 mmHg, between approximately -75 mmHg and approximately -125 mmHg, between approximately -80 mmHg and -115 mmHg, approximately -94 mmHg, any value or subrange within these ranges, or any other value as desired.

[0253] During the maintenance mode **1350**, the pump system can advantageously monitor and maintain the pressure within the pump system or some portion thereof, such as a fluid flow path between a source of negative pressure and a wound dressing, within a target pressure range (or operating range). For example, in some embodiments, during the

maintenance mode **1350**, the pump system can maintain the pump system or some portion thereof between a high pressure threshold and a low pressure threshold. For example, the high pressure threshold can be approximately -70 mmHg. In some embodiments, the high pressure threshold can be between approximately -40 mmHg and approximately -200 mmHg, between approximately -60 mmHg and approximately -100 mmHg, between approximately -70 mmHg and -80 mmHg, approximately -71 mmHg, approximately -67 mmHg, any value or subrange within these ranges, or any other value as desired. The low pressure threshold can be approximately -90 mmHg. In some embodiments, the low pressure threshold during the maintenance mode **1350** can be the same as the low pressure threshold during the IPD state **1314**. In some embodiments, the low pressure threshold during the maintenance mode **1350** can be different from the low pressure threshold during the IPD state **1314**. As shown in the illustrated embodiment, the maintenance mode **1350** can include a monitor state **1352** and a maintenance pump down ("MPD") state **1354**.

[0254] In some embodiments, one or more indicators can blink or flash intermittently or continuously to indicate to the user that the system is in the MPD state. For example, as discussed above with reference to Figure 56, in some embodiments, the one or more indicators can include a set of four icons **114'** that include an "OK" indicator which can indicate normal operation of the pump system **100**, a "leak" indicator which can indicate the existence of a leak in the pump system **100** or components attached thereto, a "dressing full" indicator which can indicate that a wound dressing is at or near capacity, and a "battery critical" indicator which can indicate that the battery is at or near a critical level. In some embodiments, the one or more indicators can be individually or cooperatively illuminated to indicate to the user that the system is in the MPD state. For example, in some embodiments, the set of four icons **114'** can be cooperatively illuminated to indicate that the system is in the MPD state such that the "OK" LED is flashing, the "leak" LED is off, the "dressing full" LED is off, and the "battery critical" LED does not change (on, off, or flashing). Any suitable cooperative LED arrangement is envisioned in certain embodiments. Once a desired negative pressure is reached during the MPD state, the one or more indicators can be cooperatively illuminated to indicate that the negative pressure has been reached. For example, in some embodiments, the set of four icons **114'** can be cooperatively illuminated to indicate that the negative pressure has been reached such that the "OK" LED is flashing,

the "leak" LED is off, the "dressing full" LED is off, and the "battery critical" LED does not change (on, off, or flashing). In some embodiments, this same illumination pattern can also be used to indicate that the pump system is functioning properly, such as during the MPD state to indicate that the pump system is functioning properly during the MPD state, in addition to flashing to indicate that the negative pressure has been reached during the MPD state. In various embodiments, in addition to or instead of providing the visual indication using the one or more indicators, other indications can be provided, including audible, tactile, and the like.

[0255] During the monitor state **1352**, the pump system can monitor the pressure in the pump system or some portion thereof, such as a fluid flow path between a source of negative pressure and a wound dressing, to ensure that the pressure within the pump system or the monitored portion thereof is maintained between a high pressure threshold and a low pressure threshold. The source of negative pressure can be deactivated during the monitor state **1352**. The pump system can intermittently and/or continuously monitor the pressure in the pump system or some portion thereof. For example, the pump system can monitor the pressure in the pump system or some portion thereof at a preset sampling rate of approximately 1 second. In some embodiments, the sampling rate can be between approximately 50 ms and approximately 5 seconds, between approximately 200 ms and 2 seconds, between approximately 500 ms and 2 seconds, approximately 1 second, any value and/or subrange with these ranges, or any other sampling rate as desired. In some embodiments, the sampling rate during the monitor state **1352** can be less than the sampling rate during the IPD state **1314** to advantageously reduce power usage and extend the life of the power source. A lower sampling rate can be used in some embodiments as the rate of pressure change during the monitor state **1352** (e.g., when the source of negative pressure is deactivated) can be less than the rate of pressure change when the source of negative pressure is activated. In some embodiments, the pump system can also calculate the rate of pressure change to estimate the amount of time until the pump system reaches a desired pressure, such as a low pressure threshold.

[0256] In some embodiments, one or more indicators can blink or flash intermittently or continuously to indicate to the user that the system is in the monitor state. For example, as discussed above with reference to Figure 56, in some embodiments, the one

or more indicators can include a set of four icons **114'** that include an "OK" indicator which can indicate normal operation of the pump system **100**, a "leak" indicator which can indicate the existence of a leak in the pump system **100** or components attached thereto, a "dressing full" indicator which can indicate that a wound dressing is at or near capacity, and a "battery critical" indicator which can indicate that the battery is at or near a critical level. In some embodiments, the one or more indicators can be individually or cooperatively illuminated to indicate to the user that the system is in the monitor state. For example, in some embodiments, the set of four icons **114'** can be cooperatively illuminated to indicate that the system is in the monitor state such that the "OK" LED is flashing, the "leak" LED is off, the "dressing full" LED is off, and the "battery critical" LED does not change (on, off, or flashing). In some embodiments, this same illumination pattern can also be used to indicate that the pump system is functioning properly during the monitor state, in addition to flashing to indicate that the system is in the monitor state. Any suitable cooperative LED arrangement is envisioned in certain embodiments. In various embodiments, in addition to or instead of providing the visual indication using the one or more indicators, other indications can be provided, including audible, tactile, and the like.

[0257] The pump system can stay in the monitor state **1352** until the pump system detects that the pressure in the pump system or some portion thereof, such as a fluid flow path between a source of negative pressure and a wound dressing, is at or around a high pressure threshold. Upon detecting that the pump system or some portion thereof is at or around the high pressure threshold, the pump system can transition to the MPD state **1354**. During the MPD state **1354**, the pump system can activate the source of negative pressure to begin therapy and reduce pressure in the system or some portion thereof until the pressure is at or near the low pressure threshold. In some embodiments, the low pressure threshold can be the same or similar to the low pressure threshold discussed in connection with the IPD state **1314**. In some embodiments, the low pressure threshold can be different from that in the IPD state **1314**.

[0258] The pump system can continually monitor the pressure in the pump system at a preset sampling rate. In some embodiments, the sampling rate can be the same or similar to the low pressure threshold discussed in connection with the IPD state **1314**. In some embodiments, the sampling rate can be different from the sampling rate during the IPD

state **1314**. In some embodiments, the pump system can also calculate the rate of pressure change to estimate the amount of time until the pump system reaches a desired pressure, such as the low pressure threshold. When the pump system detects that the pressure in the pump system or some portion thereof is at or around the low pressure threshold, the pump system can transition back to the monitor state **1352**.

[0259] With reference back to the embodiment discussed in connection with **Figure 63**, in some embodiments, the user can pause therapy by activating the switch (e.g., pressing the button), thereby causing the pump system to make a transition from the maintenance mode **1350** to the standby state **1312**. After being paused by the user, the pump system can transition from the standby state **1312** to the IPD state **1314** upon receiving a user input such as a button press. In some embodiments, after being paused by the user, the pump system can automatically make the transition from the standby state **1312** to the IPD state **1314** when the time duration exceeds a threshold. The threshold can be the same or different than the thresholds discussed above, such as the threshold when the pump system enters the standby state **1312** from the IPD state **1314** from a button press. In some embodiments, such threshold can be a preset value, such as between 1 minute or less and 1 hour or more. In some embodiments, the threshold can be set or changed by the user. In some embodiments, the threshold can be varied based on various operating conditions or on any combination thereof. For example, as the pump system nears the end of life (as is explained below), the threshold can be decreased provided the battery has sufficient capacity remaining. In some embodiments, the pump system can transition into the maintenance mode **1350** after activating the switch or automatically after exceeding the threshold. In some embodiments, the pump system can transition to the IPD state **1314** or the maintenance mode **1350** depending on operating conditions, such as the pressure at the time of the transition.

[0260] When the pump system transitions into and remains in the standby state **1312**, the user can be provided an indication. For example, in some embodiments, all indicators can be deactivated. In some embodiments, the pump system can deactivate an indicator (e.g., an OK indicator) and cause another indicator (e.g., a dressing indicator) to flash or blink. In some embodiments, therapy can be suspended while the pump system remains in the standby state **1312**. For example, the source of negative pressure can be

deactivated (or turned off), which provides the indication to the user that the pump system is in the standby state **1312**.

[0261] With continued reference to the embodiment discussed in connection with **Figure 63**, in some embodiments, the pump system can transition from the maintenance mode **1350** into a leak state **1316** when a threshold pressure is not reached within a desired amount of time. The inability for the threshold pressure to reach the threshold pressure within a desired amount of time can reflect the presence of a leak in the system. In some embodiments, the pump system can transition from the maintenance mode **1350** to the leak state **1316** when a number of retry cycles exceeds a retry limit and/or when the duty cycle of the pump is determined to exceed a duty cycle limit. In some embodiments, exceeding a retry limit and/or duty cycle limit can reflect the presence of a leak in the system. In some embodiments, an indicator (e.g., a leak indicator or dressing indicator) can blink or flash intermittently or continuously to indicate to the user the presence of a leak in the system.

[0262] With continued reference to the embodiment discussed in connection with **Figure 63**, in some embodiments, the pump system can be configured to transition from the maintenance mode **1350** into a filter blocked state **1318** when the system determines that the filter, such as the wound dressing filter (and/or the canister filter), has encountered a blockage (e.g., caused by the wound dressing being filled with exudate to capacity or nearly to capacity). Example algorithms for determining that the filter has encountered a blockage will be discussed in further detail below. In some embodiments, an indicator (e.g., a filter blocked indicator) can blink or flash intermittently or continuously to indicate to the user the presence of a blockage.

[0263] With continued reference to the embodiment discussed in connection with **Figure 63**, in some embodiments, the pump system can be configured to monitor the remaining capacity or life of the power source (e.g., by periodically reading or sampling the battery voltage, current, etc.). The pump system can be configured to indicate to the user the remaining capacity. For example, if the power source is determined to have a normal remaining capacity (e.g., as a result of comparison to a threshold, such as 2.7V, 2.6V, 2.5V, etc.), an indicator (e.g., a battery indicator) can be deactivated. If the power source is determined to have low remaining capacity, the pump system, can provide an indication to the user by, for example, causing an indicator (e.g., a battery indicator) to blink or flash. In

some embodiments, an indicator (e.g., a battery indicator) can be configured to be blinking or flashing intermittently or continuously regardless of the state the pump system is in or only in particular states.

[0264] In some embodiments, when the remaining capacity of the power source is determined to be at or near a critical level (e.g., as a result of comparison to a threshold, such as 2.4V, 2.3V, 2.2V, etc.), the pump system can transition into an under voltage or battery critical state **1392**. In some embodiments, the pump system can remain in this state until the capacity of the power source is increased, such as by replacing or recharging the power source. The pump system can deactivate therapy while remaining in the battery critical state **1392**. In addition, the pump system can be configured to indicate to the user that the power source is at or near the critical level by, for example, deactivating all indicators. In some embodiments, when the pause/resume button is pressed after the pump system has transitioned to the under voltage state **1392**, the pump system can be configured to indicate that the device has not yet reached its end of life (EOL) by, for example, flashing a battery indicator LED.

[0265] With continued reference to the embodiment discussed in connection with **Figure 63**, in some embodiments, the pump system can be configured to provide therapy for a predetermined period of time, such as approximately 1 day, 2-10 days, up to 30 days, etc. following a first activation. In some embodiments, such period of time can be a preset value, changed by the user, and/or varied based on various operating conditions or on any combination thereof. The pump system can be disposed upon the expiration of such period of time. Once the pump system has been activated, the pump system can monitor the duration it has remained active. In some embodiments, the pump system can monitor the cumulative duration the system has remained active. This can be accomplished, for example, by maintaining a timer (in firmware, software, hardware or any combination thereof), that reflects such duration.

[0266] When the duration reaches or exceeds a threshold (e.g., 10 days), the pump system can transition to an end of life (EOL) state **1390**. The pump system can deactivate therapy while remaining in state **1390** and to indicate to the user that the end of the pump system's usable life has been reached. For example, the pump system can deactivate all indicators and/or deactivate the button. In some embodiments, when the pump

system is disposable, transitioning to the end of life state **1390** means that the pump system can be disposed of. The pump system can disable reactivation of the pump system once the end of life has been reached. For example, the pump system can be configured to not allow reactivation even if the power source is disconnected and reconnected later, which can be accomplished by storing an indication, value, flag, etc. in the read only memory.

[0267] **Figure 64** illustrates an exemplary graph **1400** of pressure versus time when the negative pressure source is active, such as during the maintenance mode **1350**, according to some embodiments. As illustrated by line **1410**, the system can enter the monitor state **1352** upon detecting that the pressure in the pump system or some portion thereof, such as a fluid flow path between a source of negative pressure and a wound dressing, is at or near a low pressure threshold **1402**. In the illustrated embodiment, the low pressure threshold can be approximately -100 mmHg although other low pressure thresholds can be chosen as discussed above. During the monitor state **1352**, the pressure in the pump system or some portion thereof may begin to gradually decay due to the source of negative pressure being deactivated and the existence of minor leakages in the system. As is illustrated, the pump system can monitor pressure over the period of time **a**, as represented by interval **1430**. In some embodiments, the pressure can be sampled over the interval **1430** after a transient time period has elapsed. For example, in some embodiments, the transient time period can be measured from when the monitor state **1352** begins. After the transient time period has elapsed, pressure can be sampled in consecutive samples, and two or more of the consecutive samples can be averaged.

[0268] When the system detects that the pressure in the pump system or some portion thereof is at or near the high pressure threshold **1412**, the system can switch to the MPD state **1354** and reactivate the source of negative pressure to lower the pressure in the pump system or some portion thereof as illustrated by line **1420**. In the illustrated embodiment, the high pressure threshold can be approximately -60 mmHg although other high pressure thresholds can be chosen as discussed above. As is illustrated, the pump system can activate the over the period of time **b**, as represented by interval **1432**. When the system detects that the pressure in the pump system or some portion thereof is at or near the low pressure threshold **1422**, the system can switch back to the monitor state **1352** and deactivate the source of negative pressure. This process can be repeated as desired.

[0269] In some embodiments, the pump assembly can be configured to monitor the duty cycle of the source of negative pressure (e.g., a pump). As is used herein, "duty cycle" reflects the amount of time the source of negative pressure is active or running over a period of time. In other words, the duty cycle can reflect time that the source of negative pressure is in an active state as a fraction of total time under consideration. For example, as described above, in some embodiments, the pump system can transition from the IPD state **1314** or the maintenance mode **1350** to the leak state **1316** when, for example, the duty cycle of the pump is determined to exceed a duty cycle limit. In such a case, exceeding the duty cycle limit can reflect the presence of a leak in the system. In some embodiments, the duty cycle (DC) of the pump over the period illustrated between intervals **1410** and **1420** (i.e., a + b) can be expressed, on percent scale, as:

[0270] $DC = 100\% * [b / (a + b)]$.

[0271] In some embodiments, the pump assembly can include a controller, such as controller **1114** or **1202**, configured to monitor the duty cycle of the source of negative pressure. Duty cycle measurements can indicate rate of flow through the system and reflect a level of activity of the source of negative pressure. For example, duty cycle can indicate that the source of negative pressure is operating normally, working hard, working extremely hard, etc. Moreover, duty cycle measurements, such as periodic duty cycle measurements, can reflect various operating conditions, such as presence, rate, and/or severity of one or more leaks in the system, rate of flow of fluid (e.g., air, liquid and/or solid exudate, etc.) aspirated from a wound, and the like. Based on the duty cycle measurements, such as by comparing the measured duty cycle to a duty cycle threshold (determined in calibration or at runtime), the controller can execute and/or be programmed to execute algorithms or logic that control the operation of the system in accordance with various system requirements. For example, duty cycle measurements can indicate presence of a high leak in the system, and the controller can be programmed to indicate this condition to a user (e.g., patient, caregiver, physician, etc.) and/or temporarily suspend or pause operation of the source of negative pressure in order to conserve power.

[0272] In some embodiments, the pump system **1000**, **1100**, or **1200** can be configured to periodically monitor the duty cycle, such as once between every 10 seconds or

less and 5 minutes or more. In some embodiments, the pump assembly can be configured to monitor the duty cycle once per minute.

[0273] For example, in order to determine the duty cycle, the pump system **1000**, **1100**, **1200** can be configured to monitor the duration of time that the pump has been active (e.g., the pump run time) and/or inactive. In some embodiments, the pump system (e.g., controller **1114**, **1202**) can be configured to compare the determined duty cycle to a duty cycle threshold, which can be selected from the range between 1% or less and 50% or more. The comparison can, for example, indicate presence of a leak in the system. In other words, if the pump remains active over a period of time so that the duty cycle threshold is reached or exceeded, the source of negative pressure may be working too hard to overcome the leak. In such cases, as explained above, the pump assembly can be configured to suspend or pause the delivery of therapy. The pump assembly can be configured to provide an indication to the user that the pump is working hard (e.g., duty cycle exceeds the duty cycle threshold) by, for example, deactivating the source of negative pressure, activating one or more indicators, and the like. In some embodiments, the duty cycle threshold can be a preset value, set or changed by the user, and/or varied based on various operating conditions or on any combination thereof. In some embodiments, while the duty cycle indicates the level of pump activity, other metrics, such as pump speed, can be used for measuring the level of pump activity. In certain embodiments, the rate of flow of fluid can be measured directly, such as by using a flow meter.

[0274] In some embodiments, the pump system **1000**, **1100**, or **1200** determines and adjusts the duty cycle threshold at run time (or dynamically). For example, the controller **1114** or **1202** can be configured to determine the duty cycle threshold periodically and/or continuously, such as approximately every 1 second or less, 30 seconds or less or more, 1 minute or less or more, 10 minutes or less or more, 30 minutes or less or more, 1 hour or less or more, and so on. The duty cycle threshold can be based at least in part on a capacity of the power source **1108** or **1216** and an operational time of the apparatus (e.g., pump system **100** shown in **Figure 57A**, and pump systems **1000**, **1100**, or **1200** shown in **Figures 60**, **61**, and **62**). As explained above, the pump system can be configured to provide therapy for a predetermined period of time, and deactivate itself a predetermined period of time after an initial activation. For instance, such predetermined period of time (or lifetime

threshold) can be between 1 day or less or 10 days or more, such as 7 days (or 168 hours), 10 days (or 240 hours), etc. The power source **1108** or **1216** can be configured or selected to have sufficient capacity to provide sufficient power to the pump system **100**, **1000**, **1100**, or **1200** to operate for at least an amount of time that equals the lifetime threshold. In some embodiments, the apparatus (e.g., via controller **1114** or **1202**) can be configured to determine the operational time based on a total elapsed time since an initial activation of the apparatus and disable activation of the source of negative pressure when the operational time reaches the lifetime threshold.

[0275] According to some aspects, adjusting the duty cycle threshold may be beneficial for several reasons. In some embodiments, the duty cycle threshold can represent a balance between the desire to provide therapy to the user with none or fewer interruptions and the need to conserve power. For example, in a situation when there is a leak in the system and leak detection is performed based at least partly on monitoring the duty cycle of the pump and comparing the monitored duty cycle to the duty cycle threshold, the pump system **100**, **1000**, **1100**, or **1200** can be configured to provide therapy for a certain period of time before providing an indication to the user that a leak has been detected, which can include deactivating the delivery of therapy. After the leak has been remedied, delivery of therapy can be restarted. However, increasing the duty cycle threshold can advantageously result in fewer interruptions of the delivery of therapy.

[0276] In some embodiments, the duty cycle can be calculated (e.g., by controller **1114** or **1202**) periodically and/or dynamically during operation of the pump system. As discussed above, in some embodiments, the duty cycle threshold can be calculated based on an estimation and/or calculation of the remaining or residual battery life of the pump system. Duty cycle estimations and/or calculations that are a function of residual battery life are dynamic because battery life decreases during operation of the pump system (absent any battery charge). As a result, estimated and/or calculated duty cycle thresholds will be adjusted as the residual battery life decreases and end of life is being approached. For example, in some embodiments, the energy (for example, expressed in joules) consumed by the pump system can be tracked over a time period to determine the amount of residual battery life at any given time. In some embodiments, the actual energy consumed by the

pump system can be tracked, or the estimated number of joules consumed by the pump system can be tracked.

[0277] In some embodiments, the duty cycle threshold can be adjusted based on the determination of the residual battery life. For example, suppose that the pump system is configured to operate for 10 days. During the first day, the duty cycle threshold can be conservatively set to a lower value, such as for example 10%, in order to conserve battery life so that the pump system is able to operate for another 9 days. Now suppose that on day 5 of operation, the residual battery life indicates 75% of remaining battery capacity (not 50% remaining capacity as would be expected half-way through the operational period), and suppose that based on the operational history over the first 5 days of operation, it is estimated that the pump system will consume at most 50% of battery capacity over the last 5 days of operation. The estimated energy consumption of the pump system can be determined in various ways, including taking a conservative estimate of the pump system operating in the presence of one or more leaks, which may be severe. In this example, because the estimated remaining battery capacity on day 5 (or 75%) exceeds the estimated capacity needed for pump operation through the end of life (or 50%), the duty cycle threshold can be increased by 25% (to 12.5%) or by another suitable increment. In another example, the duty cycle threshold can be decreased because the remaining battery capacity is below expected capacity due to, for instance, leaks that had been encountered during operation. In certain embodiments, the duty cycle threshold can be set between minimum and maximum values.

[0278] In some embodiments, duty cycle threshold (DC) can be determined as follows. This determination can be performed by a controller (e.g., by controller **1114** or **1202**). In the following calculations, $T_{predicted,run}$ is the estimated time during which the pump is expected to be active or running (such as in IPD state, MPD state, etc.), $T_{predicted,wait}$ is the estimated time during which the pump is expected to be inactive or idle (such as in monitor state, pause state, etc.), and $T_{residual}$ is remaining amount of time until end of life is reached. $T_{predicted,run}$ can determined as the amount of residual time ($T_{residual}$) the pump system is expected to be active, which can be expressed in terms of the duty cycle threshold as follows:

$$T_{predicted,run} = T_{residual} * DC \qquad (1)$$

$T_{predicted,wait}$ can be determined as the amount of residual time ($T_{residual}$) the pump system is expected to be idle, which can be expressed in terms of DC as follows:

$$T_{predicted,wait} = T_{residual} * (1 - DC) \tag{2}$$

P_{run} and P_{wait} are estimated power consumptions when the pump is running and idle respectively. These values can be determined using one or more of the following techniques: taking into account historical operation of the device, performing a conservative estimate (which, as explained above, can include expecting the system to operate in presence of one or more severe leaks), performing a less conservative estimate (which can include expecting the system to operate in the presence of one or more manageable leaks), and the like. $E_{residual}$ is the estimated residual capacity of the power source, which can be estimated and/or measured. As is shown in the following equation, $E_{residual}$ can also be expressed as the sum of the estimated energy that will be consumed during periods of activity ($T_{predicted,run}$ multiplied by P_{run}) and the estimated energy that will be consumed during periods of inactivity ($T_{predicted,wait}$ multiplied by P_{wait}).

$$E_{residual} = (T_{residual} * DC * P_{run}) + (T_{residual} * (1 - DC) * P_{wait}) \tag{3}$$

Simplifying equation (3) yields:

$$E_{residual} = T_{residual} * (DC * P_{run} + (1 - DC) * P_{wait}) \tag{4}$$

Dividing equation (4) by

$$\frac{E_{residual}}{T_{residual}} = DC * P_{run} + P_{wait} - DC * P_{wait} \tag{5}$$

Rearranging equation (5) yields:

$$\frac{E_{residual}}{T_{residual}} - P_{wait} = DC * (P_{run} - P_{wait}) \tag{6}$$

Solving for the duty cycle (DC) yields:

$$DC = \frac{\frac{E_{residual}}{T_{residual}} - P_{wait}}{P_{run} - P_{wait}} \tag{7}$$

Accordingly, equation (7) can be used to determine the dynamic duty cycle threshold. This determination can be performed periodically.

[0279] Additional details of pump system control are disclosed in U.S. Patent No. 8,734,425, titled "PRESSURE CONTROL APPARATUS," U.S. Patent No. 8,905,985, titled "SYSTEMS AND METHODS FOR CONTROLLING OPERATION OF A REDUCED PRESSURE THERAPY SYSTEM," and U.S. Patent Publication No. 2015/0051560, titled

"CONTROLLING OPERATION OF A REDUCED PRESSURE THERAPY SYSTEM BASED ON DYNAMIC DUTY CYCLE THRESHOLD DETERMINATION," which are incorporated by reference in their entireties as if made part of this disclosure.

[0280] In some embodiments, the pressure during the IPD or MPD state can be sampled after a preset period of time as elapsed from when the IPD or MPD state was initiated. After this time period elapses, the pressure can be sampled in consecutive samples, and two or more of the consecutive samples can be averaged. In some embodiments, sampling of the pressure can be synchronized with the drive signal. For example, sampling of the pressure within the pump system or some portion thereof, such as a fluid flow path between a source of negative pressure and a wound dressing, can be performed when the drive signal is approximately at an amplitude that is substantially at an offset (explained below) and/or at a zero value. In some embodiments, two or more groups of consecutive pressure samples can be averaged to minimize measurement errors due to pressure fluctuations caused by operation of the motor. In some embodiments, averaging two or more groups of consecutive pressure samples can compensate for the time needed to detect the zero value when the pressure samples are synchronized at a zero value. Movement of the pump assembly can highly influence pressure within the pump system, such as a manifold of the pump system. By synchronizing sampling of the pressure with the offset and/or zero value of the drive signal, any measurement errors due to pressure fluctuations caused by operation of the motor can be reduced. In some embodiments, sampling of the pressure can be synchronized with the local maxima and/or local minima of the drive signal. In some embodiments, sampling of the pressure can be synchronized with certain portions of the drive signal, such as portions of the drive signal with a negative rate of change and/or a positive rate of change.

[0281] In some embodiments, the pressure can be sampled one or more times at or around the one or more selected sampling amplitudes such as the offset and/or zero value, local maxima, and/or local minima. This can beneficially reduce the likelihood of sampling errors and compensate for the delay elapsed between detection of the one or more selected sampling amplitudes and sampling of the pressure. For example, in some embodiments, the pump system can take 8 consecutive samples at approximately each offset and/or zero value. Accordingly, the pump system can take 16 samples over a single period of the drive signal.

In some embodiments, the pump system can average some or all of the samples taken over a period.

Pump Actuation and Control

[0282] In any embodiments disclosed herein, the performance and efficiency of the pump can be improved by selecting a suitable signal or waveform for driving the actuator (e.g., coil **600** of the pump system **100**). A suitable driving waveform can be applied to the coil by the controller (e.g., controllers **1006**, **1114** and/or driver module **1220**). In any embodiments disclosed herein, the pressure differential across a diaphragm and the outlet valve of a pump (e.g., diaphragm **550** of pump system **100**) when the diaphragm is drawing against vacuum (or removing gas from the fluid flow pathway) can be determined as the sum of the pressure drop across the valves and the vacuum level under the dressing. For example, in any embodiments disclosed herein, the negative pressure range can be approximately -80 mmHg, which means that the vacuum level of up to 80 mmHg can affect the pressure drop across the diaphragm. When the diaphragm is expelling removed fluid (e.g., expelling removed gas to the atmosphere), the pressure differential across the diaphragm and the outlet valve can be determined as the pressure drop across the valves. In other words, when gas is being expelled, the pressure differential across the diaphragm and the outlet valve is substantially equivalent to the pressure drop across the valves.

[0283] In any embodiments disclosed herein, the force for expelling removed gas can be smaller than the force for drawing vacuum (e.g., removing gas from the fluid flow pathway). If a symmetric signal, such as a square wave or sine wave of equal positive and negative amplitude is applied to the coil, the diaphragm may oscillate about a point that is not its relaxed center state, which may reduce the total diaphragm travel, thereby reducing efficiency.

[0284] **Figure 65** represents an exemplary drive signal for a source of negative pressure according to some embodiments. In any embodiments disclosed herein, a diaphragm can be driven by an offset sinusoidal (or sine) drive signal **1510**. For example, the drive signal can be applied to the actuator of the pump, such as coil **600**, thereby causing the diaphragm to flex and deflect. **Figure 65** illustrates an offset sine waveform **1510** that can be applied to the actuator according to some embodiments. The x-axis represents time

and the y-axis represents amplitude, such as voltage. Although the illustrated amplitude of the sine wave **1510** is the voltage, current can be used for driving the diaphragm.

[0285] The sine wave **1510** is offset from 0 V as is shown by line **1512**, which is about 0.4 V. Any suitable offset can be used, such as 0.05 V, 0.1 V, 0.65 V, etc. The offset can also be negative. As will be described in further detail below, in some embodiments, the offset can be variable depending on operating conditions of the pump system, such as the current and/or desired pressure in the pump system or some portion thereof. The sine wave **1510** can be a signal of a suitable magnitude, such as between -2.7 V and 3.3 V as illustrated in sine wave **1510**. In any embodiments disclosed herein, other suitable magnitudes of voltage can be used, such as between -1.0 V and 1.0V, -2.0 V and 2.0 V, -4.0 V and 4.0 V, and so on. As will be described in further detail below, in some embodiments, the magnitude can be variable depending on operating conditions of the pump system, such as the current and/or desired pressure in the pump system or some portion thereof. In some embodiments, the resonance frequency of the diaphragm and/or other oscillating components of the pump assembly can be matched during operation of the pump system by modifying the offset and/or magnitude of the drive signal during operation. For example, in some embodiments, the drive signal offset and/or magnitude can be continuously modified such that the drive signal oscillates the diaphragm and/or other oscillating components of the pump assembly at the resonant frequencies that are associated with the negative pressure being delivered. For example, in some embodiments, the drive signal can be continuously modified during the IPD state until a target low pressure threshold is satisfied or exceeded. In some embodiments, the drive signal can be similarly continuously modified during the MPD state until a target low pressure is again satisfied or exceeded. By modifying the drive signal offset and/or magnitude during operation, the pump can be advantageously made more efficient and quiet during operation. The sine wave **1510** can be of a suitable frequency, such as approximately 200 Hz as illustrated in sine wave **1510**. In some embodiments, other suitable frequencies can be used, such as from approximately 50 Hz to approximately 200 Hz, or from approximately 25 Hz or less to approximately 300 Hz or more. Other frequencies can be used, such as frequencies below 50 Hz and above 200 Hz.

[0286] In any embodiments disclosed herein, driving the diaphragm with a sine wave signal, such as the offset sine wave **1510** can increase the efficiency of the negative

pressure source. For example, because the sine wave **1510** has a single frequency, that frequency can stimulate a single vibrational or resonance mode of the pump (e.g., the first vibrational mode of the pump is stimulated provided that the other modes have a higher natural or resonant frequency). Efficiency can be optimized if the pump moves or resonates at a single frequency. For instance, the axial spring stiffness of the diaphragm and the offset of the sine wave can be optimized for greater efficiency. In addition, little or no driving energy may be absorbed by components other than the diaphragm, such as rubber components.

[0287] In any embodiments disclosed herein, non-offset sine wave drive signals can be used. In various embodiments, other periodic signals such as cosine waves, tangent waves, square, triangular waves, sawtooth waves, pulse duration modulated waveform, and the like can be used to drive the diaphragm. Signals driving the diaphragm can be symmetrical or asymmetrical and/or offset or not offset. In some embodiments, non-periodic driving signals can be used.

[0288] With continued reference to the exemplary drive signal of **Figure 65**, in some embodiments, the sine wave **1510** can be generated via a combination of one or more other waves. As shown in the illustrated embodiment, two 180 degree phase shifted sine waves **1520** and **1530** can be combined to generate the sine wave **1510**. The sine waves **1520** and **1530** can have different amplitudes, such as peak-to-peak amplitudes. In any embodiments disclosed herein, sine wave **1530** can be subtracted from sine wave **1520** and applied to the source of negative pressure, such as an actuator, as illustrated by schematic **1540**. In any embodiments disclosed herein, the sine waves **1520** and **1530** can be phase shifted with respect to each other with any suitable phase shift value selected from the range between 0 and 360 degrees. In various embodiments, sine waves **1520** and **1530** can be combined in any linear or non-linear manner.

[0289] **Figure 66** illustrates generation of the drive signals, such as the sine waves **1520** and **1530** illustrated in **Figure 65**, according to some embodiments. One or more PWM drive signals **1560** can be generated by a controller **1550** (e.g., controllers **1006**, **1114** and/or driver module **1220**). These PWM drive signals, which can be represented as a combination of square waves at different frequencies, are filtered by a filter **1570**, which can be a low-pass filter. The filter **1570** can be configured to filter out all but one frequency

component of the PWM drive signals. In any embodiments disclosed herein, filtering the one or more PWM drive signals **1560** can produce the sine waves **1520** and **1530**. As shown in the illustrated embodiment, two PWM drive signals **1560** (illustrated as top and bottom signals) can be used to produce the sine waves **1520** and **1530** respectively. Each of the PWM drive signals **1560** can be a signal having appropriate characteristics, such as amplitude, for generating the respective sine wave signal **1520** or **1530**.

[0290] In any embodiments disclosed herein, the voice coil actuator or motor can be used as the filter **1570**. The voice coil motor can behave as a resonant circuit, such as an LC or RLC circuit, that has low-pass filter characteristics. In one embodiment, the motor can have the following characteristics: resistance R = 20 Ω, inductance L = 1 mH, and time constant τ = 50 μs. In any embodiments disclosed herein, a suitable separate filter **1570** can be used. In certain embodiments, the filter **1570** can have high pass, band pass, band stop, and/or notch characteristics. In any embodiments disclosed herein, the sine wave **1510** can be generated directly from the one or more PWM signals.

Calibration of Pump Actuation Parameters

[0291] In any embodiments disclosed herein, one or more parameters of the drive signal, such as sine wave **1510**, can be varied based on the current and/or desired operating conditions of the pump system. For example, in some embodiments, parameters such as the offset and/or amplitude of the drive signal can be varied. Such parameters can be varied based on the current and/or desired pressure for the pump system or some portion thereof, such as a fluid flow path between a source of negative pressure and a wound dressing. As explained below, varying the parameters of the drive signal can increase efficiency of the pump system, reduce power consumption, and reduce noise generated by the components of the negative pressure source.

[0292] In some embodiments, the parameters can be varied to reduce the likelihood of or eliminate contact between components of the pump assembly, such as contact between components of a voice coil actuator, such as a support, shaft, or piston, with mechanical stops such as a mechanical stop at top dead center ("TDC"), where the diaphragm chamber can be at or near a minimum volume, and bottom dead center ("BDC"), where the diaphragm chamber can be at or near a maximum volume. As the vacuum

increases, the offset can be biased more towards BDC and the amplitude may be increased since the piston will exhibit a lesser degree of movement for a given amplitude at higher vacuum conditions. In some embodiments, the diaphragm can be initially biased towards BDC via components of the pump assembly, such as spring, such that the offset for the drive signal can be towards TDC at ambient or atmospheric pressures and reduce in magnitude as the pressures higher negative pressures. By reducing contact between components of the pump assembly, noise, vibration, and harshness of the pump assembly can also be reduced. Moreover, by varying the parameters of the drive signal, the flow through the pump assembly can be maintained at a desired level.

[0293] In some embodiments, the parameters can be varied to alter the rate of pressure decay when the pump assembly is activated. For example, the parameters can be varied such that the rate of pressure decay is generally linear.

[0294] In any embodiments disclosed herein, the pump system can determine (using the controller) and store (in memory) one or more parameters for the drive signal. For example, the pump system can determine and store an offset and/or amplitude for one or more target pressures. In some embodiments, the pump system can store an offset and amplitude at three target pressures. For example, the pump system can determine and store an amplitude and offset at or around 0 mmHg, at or around -71 mmHg (-9.5 kPa), and at or around -94 mmHg (-12.5 kPa). In some embodiments, these pressures are selected because 0 mmHg corresponds to the initial pressure in the system, -71 mmHg is around the high pressure threshold in the monitor mode **1350** (as explained above), and -94 mmHg is around the low pressure threshold in the monitor mode **1350** (as explained above).

[0295] The pump system can determine and store amplitudes and/or offsets at other target pressures, such as at or around -67 mmHg (-9.0 kPa). In some embodiments, the pump system can determine and store amplitudes and/or offsets for pressures corresponding to at or around ambient pressure and at or around pressure thresholds, such as the low pressure threshold and the high pressure threshold. For example, the pump system can determine and store amplitudes and offsets for pressures corresponding to ambient pressure, a negative pressure less than the high pressure threshold and a negative pressure greater than the low pressure threshold. In some embodiments, the pump system can determine and store

amplitudes and/or offsets for pressures outside of the normal operating range during a maintenance mode, such as maintenance mode **1350**.

[0296] The pump system can determine and store an offset and/or amplitude at fewer or greater target pressures as desired. For example, in some embodiments, the pump system can determine and store an offset and/or amplitude at 5 target pressures. Moreover, the pump system can determine and store an offset and/or amplitude at different pressures from those listed as may be desired. For example, storing an offset and/or amplitude at a greater number of pressures can result in a more efficient pump system.

[0297] In some embodiments, the pump system can also determine and store an amplitude and/or offset at a negative pressure value greater than the typical operating range for the pump system. For example, the pump system can determine and store an amplitude and/or offset at or around -218 mmHg (-29 kPa). The stored amplitude and/or offset at or around -218 mmHg can be equal to or less than the stored amplitude and/or offset at the upper operating negative pressure range for the pump system, such as -94 mmHg. In storing such an amplitude and/or offset at a higher negative pressure, the flow through the pump system at higher negative pressures can be reduced and thereby reduce the likelihood of damage to components of the pump system.

[0298] In any embodiments disclosed herein, the pump system can determine or calculate one or more parameters of the drive signal based on operating conditions of the pump, such as the current and/or desired negative pressure. For example, the pump system can calculate an offset and/or amplitude for the drive signal. In some embodiments, the pump system can calculate the offset and/or amplitude for the drive signal based at least on part on the stored parameters in the pump system. This can beneficially reduce the total number of parameters stored on the pump system thereby reducing the amount of memory needed in the pump system. Moreover, as will be discussed in further detail below, this can also reduce the time needed to calibrate the pump. In some embodiments, the pump system can interpolate between two or more of the stored parameters. For example, the pump system can interpolate, such as linearly interpolate, between two or more of the stored parameters. Other types of interpolation can also be used, such as polynomial and spline interpolation. The pump system can use other algorithms for calculating one or more parameters for the drive signal. A combination of such techniques can also be used.

[0299] **Figure 67** illustrates a calibration process or method **1600** for obtaining one or more parameters of the drive signal according to some embodiments. In some embodiments, the one or more parameters stored in the pump system can be based on performance of the pump system during such calibration. The calibration can be performed during manufacturing or production after the pump assembly of the pump system has been partially or fully assembled. Calibration can be particularly beneficial for pump assemblies with low manufacturing or assembly tolerances, such as small-scale pumps including small-scale voice coil pumps which are described herein. For example, minor variances during manufacture and installation can potentially significantly alter the optimal parameters between a first pump assembly and a second pump assembly. Accordingly, calibration can significantly enhance the efficiency of such pump systems. The calibration method **1600** can be used to calibrate any of the pump embodiments disclosed herein.

[0300] In some embodiments, calibration of the pump system can be performed by a calibration system, which can implement the process **1600**. The calibration system (not shown) can include components such as, but not limited to, a pneumatic chamber for applying pressure, one or more sensors for measuring movement of one or more components of the pump system, memory, controller, input and output interfaces, and the like. Calibration can beneficially be used to ensure that a source of negative pressure within the pump system is operating at or near its maximum efficiency for one or more target pressures. Moreover, calibration can also be beneficial for ensuring that components of the source of negative pressure do not contact mechanical stops, thereby preventing wear and tear, malfunction and reducing noise and vibration. With respect to some sources of negative pressure, such as diaphragm pumps having a piston assembly for moving a diaphragm, the force applied to the diaphragm can result in different levels of movement based on the pressure within the pump. Accordingly, the amount of force applied at different pressures should be varied to reduce or eliminate the likelihood that components of the pump, such as the piston assembly, will contact mechanical stops which can cause noise, vibration, and harshness.

[0301] As shown in the illustrated embodiment, when the calibration is first performed on the pump system, the calibration system can perform an initialization step **1602.** During the initialization step **1602**, the calibration system can reset a calibration

attempts counter (e.g., setting the counter to a value such as 0, 1, or any other value as desired). During the initialization step **1602**, the calibration system can generate an initial set of parameters for a drive signal to apply to a pump assembly of the pump system being calibrated. The initial set of parameters, such as an initial offset, initial amplitude and/or initial frequency, can be based on a preset values for the pressure being calibrated. In some embodiments, the initial set of parameters can also be based on the performance of the pump system for previously calibrated pressures. In some embodiments, the initial set of parameters can also be set by the user. This can advantageously reduce the amount of time needed to calibrate the pump system. In some embodiments, the calibration system can test the polarity of the pump system and adjust the parameters accordingly. This can beneficially account for any reversals in polarity during the assembly process.

[0302] In some embodiments, during the initialization step **1602**, the calibration system can measure one or more positions of components of the pump including, but not limited to, a piston assembly of the pump assembly. For example, the calibration system can measure one or more positions of a support such as support member **650**, a shaft such as shaft **700**, a coil such as coil **600**, and/or a diaphragm such as diaphragm **550**. In some embodiments, such as those involving a pump system having a single translational degree of freedom including, but not limited to, pump systems utilizing a voice coil actuator, the calibration system can measure the position of the one or more components when the pump assembly is inactive ("rest"), the position of the one or more components when at a first end for those components ("top dead center"), and/or the position of the one or more components is at the opposite end for those components ('bottom dead center"). In some embodiments, the calibration system can set the coordinate system such that a zero position is the average point between the top dead center and bottom dead center with the top dead center being a positive value and the bottom dead center being a negative value.

[0303] With reference next to step **1604**, the calibration system can determine whether the system should attempt to perform the calibration. In some embodiments, the calibration system can be configured such that the system will perform only a certain number of calibration attempts. This can advantageously prevent or reduce the likelihood that the calibration system will expend significant time and resources in attempting to calibrate the pump system. In some embodiments, the number of calibration attempts can be a preset

number. In some embodiments, the number of calibration attempts can be set by the user. In some embodiments, the number of calibration attempts can be variable and can be based on performance of the pump system for previously calibrated pressures.

[0304] As shown in the illustrated embodiment in **Figure 67**, the calibration system can determine whether the counter is greater than a set value of calibration attempts. If the counter is greater than to the set value of calibration attempts, the calibration system can determine that the calibration has failed as shown in step **1606** and the process **1600** terminates. In some embodiments, the calibration can provide a user with an indication that the calibration has failed such as via a visual and/or audio indicator. If the counter is less than or equal to the set value of calibration attempts, the system can transition to step **1608**.

[0305] With reference to step **1608**, in some embodiments, the calibration system can actuate one or more components of the pump system using the set parameters. For example, the calibration system can actuate a coil of a voice coil actuator with a set frequency, offset, and/or amplitude. In some embodiments, the calibration system can continue to actuate one or more components of the pump system for one or more periods or a set duration of time to help ensure that the pump system has reached a relatively steady state.

[0306] With reference to step **1610**, the calibration system can measure movement of one or more components of the pump system while the pump system is being actuated in accordance with step **1608**. For example, the calibration system can measure one or more positions of a support such as support member **650**, a shaft such as shaft **700**, a coil such as coil **600**, and/or a diaphragm such as diaphragm **550**. In some embodiments, such as those involving a pump system having a single translational degree of freedom including, but not limited to, pump systems utilizing a voice coil actuator, the calibration system can measure a linear position of the one or more components. In some embodiments, the calibration system can begin to measure movement of the pump system after a set number of periods or a set duration of time. This can beneficially help to ensure that the pump system has reached a relatively steady state prior to taking measurements of the device.

[0307] During step **1610**, the calibration system can calculate one or more dimensions based on the measured movement of the one or more components of the pump system. For example, the calibration system can calculate a travel and/or average position of one or more components. In some embodiments, the travel can be based on a linear distance

between a high position (i.e., the highest positive position value measured) and a low position (i.e., the highest negative position value measured) of the one or more components. An exemplary graph **1700** of travel over multiple iterations is illustrated in **Figure 68** with the x-axis being the iteration and the y-axis being the calculated travel. The high position and the low position can be an average position values based on two or more periods of calibration or can be the maximum and minimum position values measured. An exemplary graph **1750** of average position over multiple iterations is illustrated in **Figure 69** with the x-axis being the iteration and the y-axis being the calculated average position. In some embodiments, the calibration system can calculate additional or alternative parameters based on the measure movement or some other characteristic of the pump system, such as expelled fluid volume, flow rate, etc.

[0308] During step **1612**, the calibration system can determine whether the measured movement of the one or more components of the pump system meets a target value within a desired tolerance. For example, the calibration system can determine whether the calculated travel and/or the average position of the one or more components of the pump system meets a target value for travel within a tolerance of 10%. The target value and/or tolerance can be a preset value based on the specific pressure being calibrated. In some embodiments, the tolerance can be between approximately 0.1% to approximately 20%, between approximately 0.5% to approximately 10%, between approximately 1% to approximately 5%, approximately 2%, any sub-range of the following ranges, and/or any other tolerance as desired. In some embodiments, the target value and/or the desired tolerance can be set by the user. In some embodiments, the tolerances can be the same for the travel and average position parameters. In some embodiments, the tolerances can be different.

[0309] In some embodiments, such as those involving a pump system having a single translational degree of freedom including, but not limited to, pump systems utilizing a voice coil actuator, the target value and/or tolerances can be chosen such that components of the pump assembly, such as a piston assembly, do not contact the mechanical stops or at least has a reduced likelihood of contacting the mechanical stops.

[0310] If the calibration system determines that the measure movement of the one or more components of the pump system do not meet the target value within a desired

tolerance, the calibration system can transition to step **1614** and adjust the set parameters, such as the offset and/or amplitude. In some embodiments, the adjustments to the set parameters can be based at least in part on the previous measurements and calculations. The calibration system can then transition back to step **1604**. In some embodiments, the calibration system can increase the counter by one.

[0311] If the calibration system determines that the measure movement of the one or more components of the pump system meet the target value within a desired tolerance, the calibration system can transition to step **1616** and determine whether a convergence condition has been met. In some embodiments, the convergence condition can include meeting the target value within a desired tolerance for a set number of iterations. In some embodiments, the convergence condition can include a condition that the calculated travel satisfies a target travel within tolerances for one or more iterations as shown, for example, in region **1702** of **Figure 68**. In some embodiments, the convergence condition can include a condition that the calculated average position meeting a target average position within tolerances for one or more iterations as shown, for example, in region **1752** of **Figure 69**. In some embodiments, the convergence condition can include that two or more conditions be satisfied substantially simultaneously or simultaneously. If the convergence condition has been met, the calibration system can transition to step **1618** and store the set parameters in the pump system, such as in memory. In step **1618**, the process **1600** terminates successfully. If the convergence condition has not been met, the calibration system can transition to step **1604**. In some embodiments, the calibration system can increase the counter by one.

[0312] In some embodiments, the process **1600** can be repeated for each target pressure in the set of target pressures (such as three target pressures as described above). For each target pressure in the set, parameters can be determined and stored. When the pump system is activated by the user to provide negative pressure wound therapy, stored parameters can be utilized in order to determine how to drive the negative pressure source. For example, when an offset sinusoidal signal is used for driving the actuator, such as the voice coil motor, stored parameters are used to determine the offset and amplitude of the sinusoidal signal in order to achieve a target pressure. When a particular target pressure does not coincide with any of the target pressures in set for which parameters have been

determined (through calibration) and stored, the pump system can determine parameters for achieving the particular target pressure by interpolation, such as linear interpolation. In some embodiments, the stored parameters can be combined in any suitable linear or non-linear manner in order to calculate parameters for achieving the particular target pressure.

Filter Blocked Determination

[0313] **Figure 70** illustrates a process or method **1800** for determining whether a filter blockage is present in a pump system according to some embodiments. The process **1800** can be implemented by the controller of a pump system, such as controllers **1114**, **1202**, and the process **1800** can be implemented as part of executing the state diagram **1300.** The method **1800** can be used to determine the existence of a filter blockage for any of the pump embodiments disclosed herein. In some embodiments, it can be advantageous to alert the user if a filter blockage has occurred so that the user can take remedial actions to relieve the blockage. For example, in embodiments where the filter is contained within a wound dressing, a filter blockage may be triggered if the wound dressing is at or nearing capacity for storing wound exudate and requires replacement. In some embodiments, the rate of execution of the method **1800** can be based on (or be the same as) the pressure sampling rate for the pump system. In other embodiments, the method **1800** can be performed at a rate different from the pressure sampling rate for the pump system.

[0314] Transition of the pump system to an active state, such as the IPD state **1314** or the MPD state **1354** is illustrated in **Figure 70** by the active state **1802**. Upon transitioning to the active state **1802**, the pump system can activate a source of negative pressure, such as a pump assembly as shown in step **1804**.

[0315] In some embodiments, while the pump assembly is in the active state **1802**, the pump system can intermittently and/or continuously monitor the pressure within the pump system or some portion thereof, such as a fluid flow path between a source of negative pressure and a wound dressing. Based on the measured pressure within the pump system or some portion thereof, the pump system can calculate a rate of pressure change based on a difference between two or more pressure values and the amount of time between the measurements. As shown in the illustrated embodiment, the process **1800** can transition from step **1804** to step **1806**, where the process **1800** can determine whether the calculated

rate of pressure change or drop exceeds a threshold value. For example, the threshold value can be approximately -50 mmHg/second (6,750 Pa/s). The threshold value can be between approximately -20 mmHg/second and approximately -200 mmHg/second, between approximately -40 mmHg/second and approximately -100 mmHg/second, between approximately -50 mmHg/second and approximately -75 mmHg/second, approximately -70 mmHg/second, any value or subrange within these ranges, or any other threshold as desired.

[0316] The threshold value can be calculated based on the volume of the fluid flow pathway between the source of negative pressure and the wound dressing, such as the manifold (e.g., manifold **300** of pump system **100**) and conduit (e.g., conduits **904**, **906**), the volume of the wound dressing, and the flow rate of the source of negative pressure. For a given flow rate of the source of negative pressure, the rate of pressure change within the fluid flow path between the source of negative pressure and the wound dressing would vary depending on the amount of exudate or other incompressible fluids within the wound dressing. As the amount of exudate or other incompressible fluids within the wound dressing increases, the rate of pressure change within the fluid flow path would increase as a result of the reduced volume of compressible fluids within the wound dressing. Accordingly, it is possible to estimate the remaining capacity of the wound dressing based on the calculated rate of pressure change. As such, it is possible to estimate the remaining capacity without use of other sensors, such as a dressing sensor, flow sensor, and the like. The threshold value can be set at or around the rate of pressure change exhibited by a wound dressing at or near capacity.

[0317] Should the process **1800** determine that the rate of pressure change satisfies (e.g., exceeds) the threshold rate, the process **1800** can transition from step **1806** to step **1808** and increase the value of a filter block detection counter. In some embodiments, the process **1800** can increase the value of the counter by 1 although any other value can be used. Moreover, in some embodiments, the increase in value of the counter can be based on other factors, such as the calculated rate of pressure drop.

[0318] In some circumstances, it is possible that the calculated rate of pressure change or drop can greatly exceed the threshold rate of pressure change. For example, in circumstances where the conduit is kinked or blocked proximate the manifold, the rate of pressure change can be significant. It can be advantageous to differentiate between such a

transient blockage condition and a more permanent filter blocked condition. As such, in some embodiments, when the process **1800** determines that a calculated rate of pressure change exceeds a maximum rate of pressure change, the process **1800** may not increase the counter and/or may provide a different indication to the user. In some embodiments, the maximum rate can be equal to or greater than approximately 110% of the threshold rate, equal to or greater than approximately 120% of the threshold rate, equal to or greater than approximately 130% of the threshold rate, equal to or greater than approximately 140% of the threshold rate, equal to or greater than approximately 150% of the threshold rate, or any other percentage of the threshold rate.

[0319] When the process **1800** determines that the rate of pressure change does not satisfy (e.g., does not exceed) the threshold rate, the process **1800** can advance to step **1810** and, in some embodiments, decrease the value of the counter. In some embodiments, the process **1800** can decrease the value of the counter by 1 although any other value can be used. For example, the process **1800** can reset the counter to its initial value, such as 0, 1, or any other suitable value. In some embodiments, the decrease in value of the counter can be based on other factors, such as the calculated rate of pressure drop. In some embodiments, the process **1800** can ensure that the value of the counter does not decrease below the initial value, such as 0.

[0320] During step **1812**, the process **1800** can determine whether the counter has reached a set value that represents a threshold number of times that the rate of pressure change has satisfied the threshold rate. The set value can be a preset value from the factory, can be a variable value based on other parameters of the pump, or can be set by the user. In some embodiments, the set value can beneficially be set to a value higher than 1. A value higher than 1 can be advantageous as it can reduce the likelihood of a false positive which may be caused by a factor other than a filter blockage, such as an outlier pressure reading, a kink in the conduit located in the fluid flow path between the pump system and the wound dressing, or other similar factors. If the process **1800** determines that the counter satisfies the set value (e.g., is equal to the set value), the process **1800** can transition to a filter blocked state **1814**. In some embodiments, in state **1814**, the pump system can perform the operations discussed in connection with state **1318** discussed in connection with **Figure 63**.

[0321] If the process **1800** determines that the counter does not satisfy the set value (e.g., is smaller than the set value), the process **1800** system can transition to step **1816** where it determines whether the pressure within the pump system or some portion thereof is at or near a low pressure threshold. If not, the process can continue to maintain the pump in an active state and transition to step **1804**. If the process **1800** determines that the pressure within the pump system or some portion thereof is at or near a low pressure threshold, the process **1800** can transition to the monitor state **1818**, which can be the same as or similar to the monitor state **1352** discussed in connection with **Figure 63**. Accordingly, in some embodiments, the pump system can deactivate the pump and monitor the pressure within the pump system or some portion thereof. As is explained above, the process **1800** can transition to step **1820** where it determines if the pressure within the pump system or some portion thereof is at or near a high pressure threshold. In case that the pressure has reached the high pressure threshold, the process **1800** can then proceed to step **1804** and perform operations explained above.

[0322] An exemplary graph **1900** of pressure versus time during the IPD state **1910**, monitor state **1920**, and MPD state **1930** is illustrated in **Figure 71**. As shown in the illustrated embodiment, during the IPD state **1910**, the pump system can sample the pressure at two or more points in time represented on the graph as points **1912**, **1914** corresponding to pressures P1 at time t1 and P2 at time t2 respectively. The rate of change of pressure between these two points can be calculated according to: $(P2 - P1) / (t2 - t1)$.

[0323] In some circumstances, the abrupt pressure drops from point **1916** to point **1914** represents a transient blockage, such as a kinked conduit in the fluid flow path. As is explained above, the process **1800** can detect this condition by determining that the rate of change of pressure greatly exceeds the threshold, and can refrain from updating the counter.

[0324] **Figure 72** illustrates another process or method **2000** for determining whether a filter blockage is present in a pump system according to some embodiments. The process **2000** can be implemented by the controller of a pump system, such as controllers **1114**, **1202**, and the process **2000** can be implemented as part of executing the state diagram **1300.** The method **2000** can be used to determine the existence of a filter blockage for any of the pump embodiments disclosed herein. In some embodiments, it can be advantageous to alert the user if a filter blockage has occurred so that the user can take remedial actions to

relieve the blockage. For example, in embodiments where the filter is contained within a wound dressing, a filter blockage may be triggered if the wound dressing is at or nearing capacity and requires replacement. In some embodiments, the rate of execution of the method **2000** can be based on (or be the same as) the pressure sampling rate for the pump system. In other embodiments, the method **2000** can be performed at a rate different from the pressure sampling rate for the pump system.

[0325] As shown in the illustrated embodiment, during step **2010** the pump system can determine whether a measured negative pressure within the pump system or some portion thereof pressure is greater than or equal to a high pressure threshold and/or less than or equal to a low pressure threshold. If so, the pump system can store the measured pressure (P1) and the time (t1), such as in memory, as shown in step **2015**. The pump system can then transition to step **2020**.

[0326] During step **2020**, the pump system can determine whether the measured negative pressure is greater than a high pressure threshold. If not, the pump system can transition to step **2025** and delete the stored pressure (P1) and time (t1) and transition back to step **2010**. If the pump system determines that the measured negative pressure is greater than the high pressure threshold, the pump system can transition to step **2030**. During step **2030**, the pump system can determine whether the measured negative pressure is greater than a low pressure threshold. If not, the pump system can transition back to step **2020**. If the pump system determines that the measured negative pressure is greater than the low pressure threshold, the pump system can store the measured pressure (P2) and time (t2) that this occurs as shown in step **2035**. The pump system can then transition to step **2040**.

[0327] During step **2040**, the pump system can determine a rate of pressure change or drop between the two stored pressures. The pump system can determine whether the calculated rate of pressure change or drop exceeds a threshold value. For example, the threshold value can be approximately -50 mmHg/second (6,750 Pa/s). The threshold value can be between approximately -20 mmHg/second and approximately -200 mmHg/second, between approximately -40 mmHg/second and approximately -100 mmHg/second, between approximately -50 mmHg/second and approximately -75 mmHg/second, approximately -70 mmHg/second, any value or subrange within these ranges, or any other threshold as desired.

[0328] When the process **2000** determines that the rate of pressure change does not satisfy (e.g., does not exceed) the threshold rate, the process **2000** can advance to step **2045** and, in some embodiments, decrease the value of a filter block detection counter. For example, if the process **2000** determines that the counter is greater than 0, the pump system can transition to step **2050** and decrease the value of the counter. In some embodiments, the pump system can decrease the value of the counter by 1 although any other value can be used. For example, the process **2000** can reset the counter to its initial value, such as 0, 1, or any other suitable value. In some embodiments, the decrease in value of the counter can be based on other factors, such as the calculated rate of pressure drop. As shown in the illustrated embodiment, the process **2000** can ensure that the value of the counter does not decrease below the initial value, such as 0, as a result of step **2045**. Accordingly, if during step **2045** the process **2000** determines that the counter is not greater than 0, the process **2000** can transition to step **2025**.

[0329] Should the process **2000** determine that the rate of pressure change, shown as (P2-P1)/(t2-t1), satisfies (e.g., exceeds) the threshold rate, the process **2000** can transition from step **2040** to step **2055** and increase the value of the counter. In some embodiments, the process **2000** can increase the value of the counter by 1 although any other value can be used. Moreover, in some embodiments, the increase in value of the counter can be based on other factors, such as the calculated rate of pressure drop.

[0330] As noted above in connection with process **1800** described in connection with **Figure 70**, in some circumstances, it is possible that the calculated rate of pressure change or drop can greatly exceed the threshold rate of pressure change. As such, in some embodiments, when the process **2000** determines that a calculated rate of pressure change exceeds a maximum rate of pressure change, the process **2000** may not increase the counter and/or may provide a different indication to the user. In some embodiments, the maximum rate can be equal to or greater than approximately 110% of the threshold rate, equal to or greater than approximately 120% of the threshold rate, equal to or greater than approximately 130% of the threshold rate, equal to or greater than approximately 140% of the threshold rate, equal to or greater than approximately 150% of the threshold rate, or any other percentage of the threshold rate.

[0331] During step **2060**, the process **2000** can determine whether the counter has reached a set value that represents a threshold number of times that the rate of pressure change has satisfied the threshold rate. The set value can be a preset value from the factory, can be a variable value based on other parameters of the pump, or can be set by the user. In some embodiments, the set value can beneficially be set to a value higher than 1. If the process **2000** determines that the counter satisfies the set value (e.g., is greater than or equal to the set value), the process **2000** can transition to a filter blocked state **2065**. In some embodiments, in state **2065,** the pump system can perform the operations discussed in connection with state **1318** discussed in connection with **Figure 63**. If the process **2000** determines that the counter does not satisfy the set value (e.g., is not greater than or equal to the set value), the process **2000** can transition to step **2025**.

[0332] With respect to the method **2000**, the rate of pressure change is calculated based on two measured negative pressures, the first of which is measured when the negative pressure is between a high pressure threshold and a low pressure threshold and the second of which is measured when the negative pressure is greater than the low pressure threshold. In some instances, the duration of time between the first and second measured negative pressures can be greater than, if not significantly greater than, a sampling rate of the pump system. Accordingly, there can be a lower likelihood of a false positive which may be caused by a factor other than a filter blockage, such as an outlier pressure reading, a kink in the fluid flow path between the pump system and the wound dressing, or other similar factors which may cause a transient pressure change of significant magnitude.

[0333] Other processes or methods for determining whether a filter blockage is present in a pump system are also appreciated, which can be implemented by the controller of a pump system, such as controllers 1114 or 1202, and which can be implemented as part of executing the state diagram 1300. For example, in some embodiments, the presence of a blockage can be determined based on the level of activity of the pump, such as measured duty cycle. In some embodiments, the processes or methods can compare the level of activity of the pump, such as measured duty cycle, to a blockage threshold, which can be adjusted based on whether the pump is operating without or with a canister. In some embodiments, the detection of whether a canister is present can be performed automatically, for example, by the controllers 1114 or 1202. Automatic detection can be performed using

one or more of the following approaches: characteristics of pressure distribution in a fluid flow path (including characteristics of decaying pressure, settling pressure, etc.), sensor indicating attachment and/or presence of the canister, RFID detection, actuating a switch indicating attachment and/or presence of the canister, and the like.

[0334] In any embodiments disclosed herein, the drive signal for the source of negative pressure can be attenuated upon start up to slowly ramp up or "soft start" the source of negative pressure. For example, in some embodiments, parameters such as the offset and/or amplitude of the drive signal can be reduced when the source of negative pressure is first activated after having previously been inactive for some period of time. In soft starting the source of negative pressure, the forces applied to one or more components of the source of negative pressure can be reduced.

[0335] As noted above, at a lower negative pressure, such as 0 mmHg, a lower amplitude for the drive signal may be desirable since the piston will exhibit a greater degree of movement for a given amplitude at the lower vacuum condition whereas at a higher negative pressure, such as -70 mmHg, a higher amplitude may be desirable since the piston will exhibit a lesser degree of movement for a given amplitude at the higher vacuum condition. Accordingly, should the source of negative pressure be subject to a drive signal with amplitude and offset calculated for the target pressure of, for instance -70 mmHg, when the pressure within the diaphragm pump is at 0 mmHg, there is a potential that the source of negative pressure can be over driven, thereby causing a reduction in efficiency. Further, over driving the source of negative pressure can cause contact between one or more components within the source of negative pressure. For example, for a source of negative pressure which utilizes a voice coil actuator, over driving the voice coil actuator can cause components such as a support, shaft, or piston to contact mechanical stops which can cause noise, vibration, and harshness.

[0336] Soft starting the source of negative pressure can be done any time the source of negative pressure is being activated after being inactive. In some embodiments, soft starting can be performed only after the source of negative pressure has been inactive for a set period of time. The set period can be a preset value, a variable parameter based on operating conditions of the pump system, and/or input by the user.

[0337] As noted above, in some embodiments, the pump system can calculate the offset and/or amplitude for the drive signal based at least on part on the stored parameters in the pump system. In some embodiments, during a soft start, the pump system can activate the source of negative pressure with a drive signal corresponding to a lower negative pressure than the measured negative pressure, such as approximately -15 mmHg (-2 kPa) when the measured negative pressure is -70 mmHg. In some embodiments, the pump system can activate the source of negative pressure with other drive signals, such as a drive signal between approximately 0 mmHg and approximately -100 mmHg, between approximately -5 mmHg and approximately -75 mmHg, between approximately -10 mmHg and approximately -50 mmHg, between approximately -15 mmHg and approximately -25 mmHg, any value or subrange within these ranges, or any other pressure as desired. The pressure can be a preset value, a variable parameter based on operating conditions of the pump system, and/or input by the user.

[0338] In some embodiments, the pump system can actuate the source of negative pressure with a soft start drive signal for a set duration of time. The set duration of time can be sufficient to ensure that the source of negative pressure is at or near the measured pressure in the pump system or some portion thereof, such that application of a drive signal at the measured pressure would be less likely to over drive the source of negative pressure. For example, the duration can be approximately 100 ms. In some embodiments, the duration can be between approximately 10 ms and approximately 1000 ms, between approximately 50 ms and approximately 500 ms, between approximately 75 ms and approximately 250 ms, approximately 100 ms, any value or subrange within these ranges, and any other duration as desired. The duration can be a preset value, a variable parameter based on operating conditions of the pump system, and/or input by the user.

Other Embodiments

[0339] The following described embodiments are other embodiments contemplated by this disclosure:

1. An apparatus for use in negative pressure wound therapy, comprising:

   a pump assembly, comprising:

      a pump housing;

      a magnet positioned within the pump housing;

an electrically conductive coil positioned within the pump housing; and

a diaphragm, wherein the coil is directly or indirectly coupled with the diaphragm and is configured to move at least a portion of the diaphragm to pump a fluid through the pump assembly; and

a dampener positioned within the pump assembly configured to reduce sound generated by the pump assembly during operation of the pump assembly.

2. The apparatus of Claim 1, wherein the dampener comprises a porous material configured to allow fluid to flow through the dampener.

3. The apparatus of Claim 2, wherein the porous material is urethane foam.

4. The apparatus of Claim 1, wherein the pump housing comprises a chamber, and wherein the dampener is positioned within the chamber.

5. The apparatus of Claim 4, wherein the chamber is integrally formed with the pump housing.

6. The apparatus of Claims 4, further comprising a diffuser positioned within the chamber, the diffuser configured to facilitate expansion of fluid as it enters the chamber.

7. The apparatus of Claims 4 or 5, wherein the pump housing further comprises an exhaust channel configured to communicate fluid flow out of the pump assembly, and wherein the chamber is in communication with the exhaust channel.

8. The apparatus of Claim 7, wherein the exhaust channel comprises an opening along the channel configured to redirect a portion of a fluid flow from the exhaust channel back into an internal volume of the housing, wherein said redirection is configured to reduce sound generated by the pump assembly during operation of the pump assembly.

9. The apparatus of Claim 8, wherein the portion of the fluid flow from the exhaust channel comprises an entirety of a fluid flow from the exhaust channel.

10. The apparatus of any previous claim, further comprising a manifold positioned such that the manifold is between the pump assembly and a wound dressing when the apparatus is in use.

11. The apparatus of Claim 10, further comprising a diffuser positioned within the manifold.

12. The apparatus of Claim 10, further comprising a second dampener within the manifold.

13. The apparatus of Claim 12, wherein the second dampener comprises a porous material configured to allow fluid to flow through the dampener.

14. The apparatus of Claim 13, wherein the porous material of the second dampener is urethane foam.

15. The apparatus of any previous claim, further comprising a control board.

16. The apparatus of Claim 15, further comprising an electrical conduit for connecting the control board to the electrically conductive coil.

17. The apparatus of any previous claim, wherein the pump assembly further comprises:

an upper pole;

a lower pole spaced apart from the upper pole; and

one or more valves configured to control a flow of fluid through the pump assembly;

wherein at least a portion of the coil is positioned between the upper and the lower pole, and

wherein the magnet is positioned between at least a portion of the upper pole and the lower pole.

18. The apparatus of Claim 17, wherein a portion of each of the one or more valves comprises a rib extending away from a surface of the valve, the rib being configured to compress or deform to increase a seal with a corresponding sealing surface.

19. The apparatus of Claims 17, wherein the pump assembly further comprises a pump chamber body configured to receive the one or more valves in one or more corresponding valve recesses.

20. The apparatus of Claim 19, wherein a sealant is positioned between the pump chamber body and the housing.

21. The apparatus of Claim 19, wherein the pump assembly further comprises one or more valve chambers formed in part by a union between a portion of an outer surface of the pump chamber body and a portion of an inner surface of the housing.

22. The apparatus of Claim 19, wherein the one or more valve recesses further comprise one or more indexing features configured to receive one or more corresponding alignment features of the one or more valves to inhibit improper valve installation into the pump chamber body.

23. The apparatus of any previous claim, further comprising a wound dressing configured to sealingly surround a wound.

24. The apparatus of any previous claim, comprising a spring member, wherein:

a periphery of the spring member is supported within the pump assembly so as to be in a fixed position relative to the diaphragm; and

a middle portion of the spring member is configured to deflect relative to the periphery of the spring member when a middle portion of the diaphragm axially deflects.

25. The apparatus of any previous claim, further comprising an illumination source disposed within the housing, wherein part of the housing is transparent or translucent such that light emitted from the illumination source passes through the housing.

26. The apparatus of any previous claim, wherein the dampener is a filter configured to filter fluid as it flows through the dampener.

27. The apparatus of Claim 1, further comprising a dampener positioned on an exterior surface of the pump housing.

28. A pump apparatus, comprising:

a housing having a first section and a second section; and

an illumination source disposed within the housing adjacent the first section;

wherein the illumination source is configured to illuminate the first section,

wherein the first section is one of transparent and translucent, and

wherein the first section is thinner than the second section as measured perpendicularly from inside to outside the housing.

29. The pump apparatus of Claim 28, wherein the second section is opaque.

30. The pump apparatus of Claims 28, wherein the illumination source comprises light emitting diodes (LED).

31. The pump apparatus of Claim 28, wherein the first section comprises an icon.

32. The pump apparatus of Claim 28, further comprising a pump assembly disposed within the housing configured for negative pressure wound therapy.

33. The pump apparatus of Claim 32, wherein the first section comprises four icons.

34. The pump apparatus of Claim 33, wherein one of the four icons comprises an indicator configured to illuminate when the pump assembly is operating properly, a second of the four icons comprises an indicator configured to illuminate when there is a leak, a third of the four icons comprises an indicator configured to illuminate when a dressing connected to the wound apparatus is full, and a fourth of the four icons comprises an indicator indicating that a battery level is low.

35. The pump apparatus according Claim 28, further comprising a baffle configured to control an illumination of the first section by absorbing light.

36. The pump apparatus of Claim 35, wherein the baffle is configured to inhibit an illumination of one part of the first section from illuminating another part of the first section, wherein illumination comprises light passing through a transparent or translucent portion of the of the first section.

37. The pump apparatus of Claims 35 or 36, wherein the baffle is directly or indirectly connected to or integrally formed with at least one of the first and second sections.

38. A pump apparatus, comprising:

a pump casing with one or more transparent portions configured to allow a laser to pass therethrough; and

a component housing configured to be laser welded to the pump casing, the component housing comprising one or more laser absorbing portions configured to be melted by the laser.

39. The pump apparatus of Claim 38, wherein the one or more laser absorbing portions are darker than the one or more transparent portions.

40. The pump apparatus of Claims 38 or 39, wherein the one or more laser absorbing portions comprises at least one of nontransparent material and laser absorbing material.

41. The pump apparatus of Claim 40, wherein the at least one of nontransparent material and laser absorbing material is positioned on the surface of the component housing or extends through a thickness of the component housing.

42. The pump apparatus of Claims 40 or 41, wherein the at least one of nontransparent material and laser absorbing material comprises 5% to 100% black pigment.

43. The pump apparatus according to any of Claims 38-42, wherein at least a portion of the pump casing is transparent and wherein at least a portion of the component housing is at least one of nontransparent and laser absorbent.

44. The pump apparatus according to any of Claims 38-43, wherein the one or more laser absorbing portions of the component housing represent a weld contour to which the laser is configured to be applied.

45. The pump apparatus according to any of Claims 38-44, wherein the component housing houses at least one of one or more valves, a diaphragm, a magnet, and an electrically conductive coil.

46. The pump apparatus according to any of Claims 38-45, wherein a portion of the one or more transparent portions of the pump casing comprises part of an intake channel and an outtake channel on the exterior of the pump casing, the intake and outtake channels having sloped surfaces to prevent sudden laser diffraction during laser welding.

47. A pump apparatus, comprising:

a transparent pump component configured to allow a laser to pass through during laser welding; and

a housing configured to be laser welded to the transparent pump component, the housing comprising one or more laser absorbing portions configured to be melted by the laser.

48. The pump apparatus of Claim 47, wherein the housing comprises one or more weld surfaces comprising the one or more laser absorbing portions.

49. The pump apparatus of Claim 48, wherein the one or more weld surfaces comprises at least six circumferential weld surfaces.

50. The pump apparatus of Claim 49, wherein the at least six circumferential weld surfaces are equally spaced apart.

51. The pump apparatus according to any of Claims 47-50, the housing further comprising one or more vertical flanges, wherein each vertical flange comprises two weld surfaces and one stop, the stop configured to control a collapse of the transparent pump component into the housing during welding.

52. The pump apparatus of Claim 51, wherein the two weld surfaces of each of the one or more vertical flanges comprises the one or more laser absorbing portions.

53. The pump apparatus according to any of Claims 47-52, wherein the transparent pump component comprises a bushing.

54. The pump apparatus according to any of Claims 47-52, wherein the housing comprises a pump chamber body.

55. An apparatus for use in negative pressure wound therapy, comprising:

a pump system configured for negative pressure wound therapy, comprising:

an outer housing;

a pump assembly positioned within the outer housing, the pump assembly comprising a pump housing that receives a plurality of pump components therein; and

a connector for connecting a tube or conduit to the pump system to deliver negative pressure from the pump assembly to a wound.

56. The apparatus of Claim 55, further comprising an intake manifold within the outer housing providing fluid communication between the connector and the pump assembly.

57. The apparatus of Claim 55, further comprising a circuit board positioned within the outer housing configured to control the pump assembly.

58. The apparatus of Claim 55, further comprising a wound dressing configured to connect to the tube or conduit.

59. The apparatus of Claim 55, wherein the pump housing comprises a chamber formed integrally with the pump housing, wherein the chamber receives a dampening component.

60. The apparatus of Claim 55, wherein the pump housing comprises an exhaust channel, the exhaust channel configured to redirect a fluid flow from the exhaust channel into an internal volume of the pump housing to reduce sound generated by the pump assembly during operation.

61. The apparatus of Claim 55, wherein the pump assembly comprises a noise reduction system.

62. The apparatus of Claim 55, wherein the pump components received within the pump housing comprise a magnet, an electrically conductive coil, a diaphragm, and a dampener.

63. The apparatus of Claim 62, wherein the pump components received within the pump housing comprise a spring configured to interact with the diaphragm.

64. The apparatus of Claim 62, wherein the pump components received within the pump housing comprise an upper pole, a lower pole, and a valve, wherein the magnet and a portion of the electrically conductive coil are disposed between the upper and lower poles.

65. The apparatus of Claim 64, wherein the valve comprises a rib configured to better seal the rib against a sealing surface.

66. The apparatus of Claim 55, wherein the outer housing comprises a display comprising a plurality of indicators.

67. The apparatus of Claim 55, wherein the outer housing comprises relatively thinner material, transparent material, or translucent material overlying an illumination component on the inside of the outer housing.

68. The apparatus of Claim 67, further comprising baffles attached to or formed integrally with interior surfaces of the outer housing to prevent illumination of one indicator from bleeding into and onto another indicator.

69. The apparatus of Claim 55, further comprising one or more user input features on an outside surface of the outer housing.

70. The apparatus of Claim 55, wherein one or more of the pump housing and the pump components are transparent to facilitate laser welding during assembly of the pump system.

71. A negative pressure pump system comprising:

a pump assembly comprising:

an actuator; and

a diaphragm; and

a controller configured to control operation of the pump system, the controller further configured to:

calculate at least one of an amplitude and an offset for a drive signal based at least in part on previously calculated parameters and a negative pressure setting;

generate the drive signal with the at least one calculated amplitude and offset; and

apply the drive signal to the pump system, thereby causing delivery of negative pressure wound therapy.

72. The negative pressure pump system of embodiment 71, wherein the previously calculated parameters comprise a plurality of calibrated amplitudes at a plurality of negative pressure settings.

73. The negative pressure pump system of embodiment 71 or 72, wherein the previously calculated parameters comprise a plurality of calibrated offsets at a plurality of negative pressure settings.

74. The negative pressure pump system according to any of embodiments 71-73, wherein the controller is further configured to calculate both the amplitude and the offset for the drive signal.

75. The negative pressure pump system according to any of embodiments 71-74, wherein the controller is further configured to interpolate between at least two previously calculated amplitudes or offsets.

76. The negative pressure pump system of embodiment 75, wherein the controller is further configured to linearly interpolate between at least two previously calculated amplitudes or offsets.

77. The negative pressure pump system according to any of embodiments 71-76, wherein the previously calculated parameters comprises at least 3 parameters.

78. The negative pressure pump system according to any of embodiments 71-77, wherein the previously calculated parameters are dependent on one or more properties of the pump system.

79. The negative pressure pump system according to any of embodiments 71-78, wherein the actuator comprises a voice coil actuator, the voice coil actuator being connected to the diaphragm.

80. The negative pressure pump system according to any of embodiments 71-79, wherein the pump assembly further comprises a spring configured to affect a resonant frequency of the pump assembly.

81. The negative pressure pump system according to any of embodiments 71-80, wherein the controller is further configured to apply a start up signal when the pump system has been activated after a period of inactivity, the start up signal comprising at least one of an amplitude and an offset different from at least one of the amplitude and the offset of the drive signal.

82. The negative pressure pump system according to embodiment 81, wherein the controller is further configured to:

calculate at least one of an amplitude and an offset for the start up signal based at least in part on previously calculated parameters and a soft start negative pressure setting that is less than the negative pressure setting; and

apply the start up signal to the pump system.

83. The negative pressure pump system according to embodiment 82, wherein the controller is further configured to apply the start up signal to the pump system over a start up time period until the soft start negative pressure setting is reached under a wound dressing configured to be placed over a wound, and subsequently apply the drive signal to the pump system.

84. The negative pressure pump system according to embodiment 83, wherein the controller is configured to apply the drive signal to the pump system until the negative pressure setting is reached under the wound dressing.

85. The negative pressure pump system according to embodiment 83 or 84, wherein the start up time period is approximately 100 milliseconds.

86. The negative pressure pump system according to embodiment 83 or 84, wherein the start up time period is between approximately 10 milliseconds and approximately 1000 milliseconds.

87. The negative pressure pump system according to embodiment 83 or 84, wherein the start up time period is between approximately 50 milliseconds and approximately 500 milliseconds.

88. The negative pressure pump system according to embodiment 83 or 84, wherein the start up time period is between approximately 75 milliseconds and approximately 250 milliseconds.

89. A calibration system for calibrating a pump system configured for negative pressure wound therapy, the calibration system comprising:

a sensor; and

a controller configured to control operation of the calibration system, the controller further configured to:

cause generation of a drive signal;

cause actuation of the pump system with the drive signal;

measure movement of a component of the pump system with the sensor;

calculate a first dimension based on the measured movement of the component; and

determine whether a first convergence condition has been satisfied by determining that the first dimension is within a first tolerance of a first target value.

90. The calibration system of embodiment 89, wherein the controller is further configured to:

calculate a second dimension based on the measured movement of the component; and

determine whether a second convergence condition has been satisfied by determining that the second dimension is within a second tolerance of a second target value.

91. The calibration system of embodiment 90, wherein the controller is further configured to determine that the first and second convergence conditions are satisfied substantially simultaneously.

92. The calibration system according to any of embodiments 89-91, wherein, upon determining that at least one of the first or second convergence conditions is met, the controller is further configured to store a set of parameters associated with the drive signal in a memory of the pump system.

93. The calibration system according to any of embodiments 89-92, wherein, upon determining that at least one of the first or second convergence conditions is not satisfied, the controller is further configured to:

cause adjustment of one or more parameters of the drive signal based at least in part on the measured movement of the component;

cause generation of an adjusted drive signal;

cause actuation of the pump system with the adjusted drive signal;

measure the movement of the component of the pump assembly with the sensor; and

determine whether the convergence condition has been satisfied.

94. The calibration system according to any of embodiments 89-93, wherein the controller is further configured to cause selection of an amplitude of the drive signal for generation of at least one of the drive signal and the adjusted drive signal.

95. The calibration system according to any of embodiments 89-94, wherein the controller is further configured to cause selection of an offset of the drive signal for generation of at least one of the drive signal and the adjusted drive signal.

96. The calibration system according to any of embodiments 90-95, wherein at least one of the first and second dimensions comprises a travel of the component.

97. The calibration system according to any of embodiments 90-96, wherein at least one of the first and second dimensions comprises an average position of the component.

98. The calibration system according to any of embodiments 90-97, wherein the component comprises a piston connected to a diaphragm.

99. A method for controlling a pump system configured for negative pressure wound therapy, the method comprising:

calculating at least one of an amplitude and an offset for a drive signal based at least in part on previously calculated parameters and a negative pressure setting;

generating the drive signal with the at least one calculated amplitude and offset; and

applying the drive signal to the pump system, and thereby causing delivery of negative pressure wound therapy;

wherein the method is performed under control of a controller of the pump system.

100. The method of embodiment 99, wherein the previously calculated parameters comprise a plurality of calibrated amplitudes at a plurality of negative pressure settings.

101. The method of embodiment 99 or 100, wherein the previously calculated parameters comprise a plurality of calibrated offsets at a plurality of negative pressure settings.

102. The method of according to any of embodiments 99-101, wherein calculating the at least one of the amplitude and the offset for a drive signal comprises calculating both the amplitude and the offset for the drive signal.

103. The method according to any of embodiments 99-102, wherein calculating the at least one of the amplitude and the offset for the drive signal further comprises interpolating between at least two previously calculated amplitudes or offsets.

104. The method of embodiment 103, wherein the interpolation is a linear interpolation.

105. The method according to any of embodiments 99-104, wherein the previously calculated parameters comprises at least 3 parameters.

106. The method according to any of embodiments 99-105, wherein the previously calculated parameters are dependent on one or more properties of the pump system.

107. The method according to any of embodiments 99-106, wherein the pump system comprises a voice coil actuator connected to a diaphragm.

108. The method according to any of embodiments 99-107, wherein the pump system further comprises a spring configured to affect a resonant frequency of the pump system.

109. The method according to any of embodiments 99-108, further comprising applying a start up signal when the pump system has been activated after a period of inactivity, the start up signal comprising at least one of an amplitude and an offset different from at least one of the amplitude and the offset of the drive signal.

110. The method according to embodiment 108, further comprising:

calculating at least one of the amplitude and the offset for the start up signal based at least in part on previously calculated parameters and a soft start negative pressure setting that is less than the negative pressure setting; and

applying the start up signal to the pump system.

111. The method according to embodiment 110, wherein applying the start up signal comprises applying the start up signal to the pump system over a start up time period until the soft start negative pressure setting is reached under a wound dressing configured to be placed over a wound, and subsequently applying the drive signal to the pump system.

112. The method according to embodiment 111, wherein the drive signal is applied to the pump system until the negative pressure setting is reached under the wound dressing.

113. The method according to embodiment 111 or 112, wherein the start up time period is approximately 100 milliseconds.

114. The method according to embodiment 111 or 112, wherein the start up time period is between approximately 10 milliseconds and approximately 1000 milliseconds.

115. The method according to embodiment 111 or 112, wherein the start up time period is between approximately 50 milliseconds and approximately 500 milliseconds.

116. The method according to embodiment 111 or 112, wherein the start up time period is between approximately 75 milliseconds and approximately 250 milliseconds.

117. A method for calibrating a pump system configured for negative pressure wound therapy, the method comprising:

causing generation of a drive signal;

causing actuation of the pump system with the drive signal;

measuring movement of a component of the pump system;

calculating a first dimension based on the measured movement of the component; and

determining whether a first convergence condition has been satisfied by determining that the first dimension is within a first tolerance of a first target value, wherein the method is performed under control of a controller of a calibration system.

118. The method of embodiment 117, further comprising:

calculating a second dimension based on the measured movement of the component; and

determining whether a second convergence condition is satisfied by determining that the second dimension is within a second tolerance of a second target value.

119. The method of embodiment 118, further comprising determining that the first and second convergence conditions are satisfied substantially simultaneously.

120. The method according to any of embodiments 117-119, further comprising in response to determining that at least one of the first or second convergence conditions is met, storing in a memory of the pump system a set of parameters associated with the drive signal.

121. The method according to any of embodiments 117-120, wherein the method further comprises in response to determining that at least one of the first or second convergence conditions is not satisfied:

causing adjustment of one or more parameters of the drive signal based at least in part on the measured movement of the component;

causing generation of an adjusted drive signal;

causing actuation of the pump system with the adjusted drive signal;

measuring the movement of the component of the pump assembly; and

determining whether the convergence condition has been satisfied.

122. The method according to any of embodiments 117-121, wherein causing generation of the drive signal or the adjusted drive signal comprises selecting an amplitude of the drive signal.

123. The method according to any of embodiments 117-122, wherein causing generation of the drive signal or the adjusted drive signal comprises selecting an offset of the drive signal.

124. The method according to any of embodiments 118-123, wherein at least one of the first and second dimensions comprises a travel of the component.

125. The method according to any of embodiments 118-124, wherein at least one of the first and second dimensions comprises an average position of the component.

126. The method according to any of embodiments 118-125, wherein the component comprises a piston connected to a diaphragm.

127. A pump system configured for negative pressure wound therapy, the pump system comprising:

a pump assembly configured to provide a negative pressure, via a flow path, to a wound dressing configured to be positioned over a wound, the flow path configured to fluidically connect the pump system to the wound dressing;

a sensor configured to measure a pressure in the flow path; and

a controller configured to control operation of the pump system, the controller further configured to:

measure a first pressure value in the flow path at a first time;

measure a second pressure value in the flow path at a second time;

calculate a first rate of pressure change using the first and second pressure values; and

provide an indication that the wound dressing is full in response to determining that the calculated first rate of pressure change satisfies a threshold rate of change.

128. The pump system of Claim 127, wherein the controller is further configured to:

measure a third pressure value in the flow path at a third time;

measure a fourth pressure value within the flow path at a fourth time;

calculate a second rate of pressure change using the third and fourth pressure values; and

provide the indication that the wound dressing is full in response to determining that the calculated first and second rates of pressure change satisfy the threshold rate of change.

129. The pump system of Claim 127 or 128, wherein the pressure in the fluid flow path is between a maximum pressure and a minimum pressure.

130. The pump system of any of Claims 127 to 129, wherein the controller is further configured to determine whether the second pressure value is less than a minimum pressure.

131. The pump system of any of Claims 127 to 130, wherein the controller is further configured to provide an indication that the wound dressing is full in response to determining that the calculated first rate of pressure change equals or exceeds the threshold rate of change.

132. The pump system of any of Claims 127 to 131, wherein the threshold rate of change is approximately -50 mmHg/second.

133. The pump system of any of Claims 127 to 131, wherein the threshold rate of change is approximately -70 mmHg/second.

134. The pump system of any of Claims 127 to 131, wherein the threshold rate of change is between approximately -20 mmHg/second and approximately -200 mmHg/second.

135. The pump system of any of Claims 127 to 131, wherein the threshold rate of change is between approximately -40 mmHg/second and approximately -100 mmHg/second.

136. The pump system of any of Claims 127 to 131, wherein the threshold rate of change is between approximately -50 mmHg/second and approximately -75 mmHg/second.

137. The pump system of any of Claims 127 to 136, wherein the controller is further configured to provide an indication of a transient blockage condition in response to determining that the calculated first rate of pressure change satisfies a maximum rate of change.

138. The pump system of any of Claims 127 to 137, wherein the controller is further configured to provide an indication of a transient blockage condition in response to determining that the calculated first and second rates of pressure change satisfy a maximum rate of change.

139. The pump system of Claim 137 or 138, wherein the transient blockage condition comprises at least one of a kink in the flow path and an occlusion in the flow path.

140. The pump system of any of Claims 137 to 138, wherein the maximum rate of change comprises about 110%, about 120%, about 130%, about 140%, or about 150% of the threshold rate.

141. The pump system of any of Claims 137 to 138, wherein the maximum rate of change comprises between about 105% and about 155% of the threshold rate of change.

142. The pump system of any of Claims 137 to 141, wherein the controller is further configured to provide an indication of a transient blockage condition in response to determining that the calculated first rate of pressure change equals or exceeds the maximum rate of change.

143. The pump system of any of Claims 127 to 142 wherein the controller is further configured to sample a pressure within the fluid flow path during one or more time intervals.

144. The pump system of Claim 143, wherein the controller is further configured to sample the pressure at least twice during each of the one or more time intervals.

145. The pump system of Claim 143 or 144, wherein the controller is further configured to average the pressure samples during each of the one or more time intervals.

146. A method for controlling a pump system configured for negative pressure wound therapy, the method comprising:

causing provision of negative pressure, via a flow path, to a wound dressing configured to be positioned over a wound, the flow path configured to fluidically connect the pump system to the wound dressing;

measuring a first pressure value in the flow path at a first time;

measuring a second pressure value in the flow path at a second time;

calculating a first rate of pressure change using the first and second pressure values; and

in response to determining that the calculated first rate of pressure change satisfies a threshold rate of change, providing an indication that the wound dressing is full,

wherein the method is performed under control of a controller of the pump system.

147. The method of Claim 146, further comprising:

measuring a third pressure value in the flow path at a third time;

measuring a fourth pressure value within the flow path at a fourth time;

calculating a second rate of pressure change using the third and fourth pressure values; and

providing the indication that the wound dressing is full in response to determining that the calculated first and second rates of pressure change satisfy the threshold rate of change.

148. The method of Claim 146 or 147, wherein the pressure in the fluid flow path is between a maximum pressure and a minimum pressure.

149. The method of any of Claims 146 to 148, further comprising determining whether the second pressure value is less than a minimum pressure.

150. The method of any of Claims 146 to 149, wherein satisfying the threshold rate of change comprises equaling or exceeding the threshold rate of change.

151. The method of any of Claims 146 to 150, wherein the threshold rate of change is approximately -50 mmHg/second.

152. The method of any of Claims 146 to 150, wherein the threshold rate of change is approximately -70 mmHg/second.

153. The method of any of Claims 146 to 150, wherein the threshold rate of change is between approximately -20 mmHg/second and approximately -200 mmHg/second.

154. The method of any of Claims 146 to 150, wherein the threshold rate of change is between approximately -40 mmHg/second and approximately -100 mmHg/second.

155. The method of any of Claims 146 to 150, wherein the threshold rate of change is between approximately -50 mmHg/second and approximately -75 mmHg/second.

156. The method of any of Claims 146 to 155, further comprising providing an indication of a transient blockage condition in response to determining that the calculated first rate of pressure change satisfies a maximum rate of change.

157. The method of any of Claims 146 to 156, further comprising providing an indication of a transient blockage condition in response to determining that the calculated first and second rates of pressure change satisfy a maximum rate of change.

158. The method of Claim 156 or 157, wherein the transient blockage condition comprises at least one of a kink in the flow path and an occlusion in the flow path.

159. The method of any of Claims 156 to 158, wherein the maximum rate of change comprises about 110%, about 120%, about 130%, about 140%, or about 150% of the threshold rate of change.

160. The method of any of Claims 156 to 158, wherein the maximum rate of change comprises between about 105% and about 155% of the threshold rate of change.

161. The method of Claim any of Claims 156 to 160, wherein satisfying the maximum rate of change comprises equaling or exceeding the maximum rate of change.

162. The method of any of Claims 146 to 161, wherein measuring the pressure values within the flow path comprises sampling a pressure within the fluid flow path during one or more time intervals.

163. The method of Claim 162, further comprising sampling the pressure at least twice during each of the one or more time intervals.

164. The method of Claim 162 or 163, further comprising averaging the pressure samples during each of the one or more time intervals.

165. A pump system configured for negative pressure wound therapy, the pump system comprising:

a pump assembly comprising:

an actuator; and

a diaphragm; and

a controller configured to control operation of the pump system, the controller further configured to:

apply a drive signal to the pump assembly, the drive signal alternating between a positive amplitude and a negative amplitude and the drive signal having an offset; and

sample a pressure within a fluid flow path configured to connect the pump assembly to a wound dressing configured to be placed over a wound during one or more time intervals, wherein each of the one or more time intervals occurs when the drive signal is approximately at an amplitude equal to one or more sampling amplitudes.

166. The pump system of Claim 165, wherein the sampling amplitude comprises a local maxima of the amplitude.

167. The pump system of Claim 165 or 166, wherein the sampling amplitude comprises a local minima of the amplitude.

168. The pump system according to any of Claims 165-167, wherein the sampling amplitude comprises a zero crossing of the amplitude.

169. The pump system according to any of Claims 165-168, wherein the sampling amplitude comprises an offset crossing of the amplitude.

170. The pump system according to any of Claims 165-169, wherein the controller is further configured to sample the pressure at least twice during each of the one or more time intervals.

171. The pump system of Claim 170, wherein the controller is further configured to average the pressure samples during each time interval.

172. The pump system of any of Claims 165-171, wherein the controller is further configured to adjust at least one parameter of the drive signal based on the pressure samples.

173. A method for controlling a pump system configured for negative pressure wound therapy, the method comprising:

applying a drive signal to a pump assembly of the pump system, the drive signal alternating between a positive amplitude and a negative amplitude and the drive signal having an offset; and

sampling a pressure within a fluid flow path configured to connect the pump system to a wound dressing configured to be placed over a wound during one or more time intervals, wherein each of the one or more time intervals occurs when the drive signal is approximately at an amplitude equal to one or more sampling amplitudes,

wherein the method is performed under control of a controller of the pump system.

174. The method of Claim 173, wherein the sampling amplitude comprises a local maxima of the amplitude.

175. The method of Claim 173 or 174, wherein the sampling amplitude comprises a local minima of the amplitude.

176. The method according to any of Claims 173-175, wherein the sampling amplitude comprises a zero crossing of the amplitude.

177. The method according to any of Claims 173-176, wherein the sampling amplitude comprises an offset crossing of the amplitude.

178. The method according to any of Claims 173-177, further comprising sampling the pressure at least twice during each of the one or more time intervals.

179. The method of Claim 178, further comprising averaging the pressure samples during each time interval.

180. The method of any of Claims 173-179, further comprising adjusting at least one parameter of the drive signal based on the pressure samples.

Any apparatus and method described in this application can include any combination of the preceding features described in this and other paragraphs, among other features and combinations described herein, including features and combinations described in subsequent paragraphs, and including any features and combinations described in any application incorporated by reference herein.

[0340] Any value of a threshold, limit, duration, etc. provided herein is not intended to be absolute and, thereby, can be approximate. In addition, any threshold, limit, duration, etc. provided herein can be fixed or varied either automatically or by a user. 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.

[0341] 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 the disclosure. 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 systems and methods described herein may be made without departing from the spirit of the disclosure. The accompanying claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of the disclosure. Accordingly, the scope of the present disclosure is defined only by reference to the claims presented herein or as presented in the future.

[0342] 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 in this section or elsewhere in this specification 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, 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.

[0343] Furthermore, certain features that are described in this disclosure in the context of separate implementations can also be implemented in combination in a single implementation. Conversely, various features that are described in the context of a single implementation can also be implemented in multiple implementations separately or in any suitable subcombination. Moreover, although features may be described above as acting in certain combinations, one or more features from a claimed combination can, in some cases, be excised from the combination, and the combination may be claimed as a subcombination or variation of a subcombination.

[0344] Moreover, while operations may be depicted in the drawings or described in the specification in a particular order, such operations need not be performed in the particular order shown or in sequential order, or that all operations be performed, to achieve desirable results. Other operations that are not depicted or described can be incorporated in the example methods and processes. For example, one or more additional operations can be performed before, after, simultaneously, or between any of the described operations. Further, the operations may be rearranged or reordered in other implementations. 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. Various components illustrated in the figures may be implemented as software and/or firmware on a processor, controller, ASIC, FPGA, and/or dedicated hardware. Hardware components, such as processors, ASICs, FPGAs, and the like, can include logic circuitry. 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. Also, the separation of various system components in the implementations described above should not be understood as requiring such separation in all

implementations, and it should be understood that the described components and systems can generally be integrated together in a single product or packaged into multiple products.

[0345] For purposes of this disclosure, certain aspects, advantages, and novel features are described herein. Not necessarily all such advantages may be achieved in accordance with any particular embodiment. Thus, for example, those skilled in the art will recognize that the disclosure may be embodied or carried out in a manner that achieves one advantage or a group of advantages as taught herein without necessarily achieving other advantages as may be taught or suggested herein.

[0346] Conditional language, such as "can," "could," "might," or "may," unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements, and/or steps. Thus, such conditional language is not generally intended to imply that features, elements, and/or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without user input or prompting, whether these features, elements, and/or steps are included or are to be performed in any particular embodiment.

[0347] Conjunctive language such as the phrase "at least one of X, Y, and Z," unless specifically stated otherwise, is otherwise understood with the context as used in general to convey that an item, term, etc. may be either X, Y, or Z. Thus, such conjunctive language is not generally intended to imply that certain embodiments require the presence of at least one of X, at least one of Y, and at least one of Z.

[0348] Language of degree used herein, such as the terms "approximately," "about," "generally," and "substantially" as used herein represent a value, amount, or characteristic close to the stated value, amount, or characteristic that still performs a desired function or achieves a desired result. For example, the terms "approximately", "about", "generally," and "substantially" may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount. As another example, in certain embodiments, the terms "generally parallel" and "substantially parallel" refer to a value, amount, or characteristic that departs from exactly parallel by less than or equal to 15 degrees, 10 degrees, 5 degrees, 3 degrees, 1 degree, or 0.1 degree.

[0349] The scope of the present disclosure is not intended to be limited by the specific disclosures of preferred embodiments in this section or elsewhere in this specification, and may be defined by claims as presented in this section or elsewhere in this specification or as presented in the future. The language of the claims is to be interpreted broadly based on the language employed in the claims and not limited to the examples described in the present specification or during the prosecution of the application, which examples are to be construed as non-exclusive.

WHAT IS CLAIMED IS:

1. A pump system configured for negative pressure wound therapy, the pump system comprising:

a pump assembly configured to provide a negative pressure, via a flow path, to a wound dressing configured to be positioned over a wound, the flow path configured to fluidically connect the pump system to the wound dressing;

a sensor configured to measure a pressure in the flow path; and

a controller configured to control operation of the pump system, the controller further configured to:

measure a first pressure value in the flow path at a first time;

measure a second pressure value in the flow path at a second time;

calculate a first rate of pressure change using the first and second pressure values; and

provide an indication that the wound dressing is full in response to determining that the calculated first rate of pressure change satisfies a threshold rate of change.

2. The pump system of Claim 1, wherein the controller is further configured to:

measure a third pressure value in the flow path at a third time;

measure a fourth pressure value within the flow path at a fourth time;

calculate a second rate of pressure change using the third and fourth pressure values; and

provide the indication that the wound dressing is full in response to determining that the calculated first and second rates of pressure change satisfy the threshold rate of change.

3. The pump system of Claim 1 or 2, wherein the pressure in the fluid flow path is between a maximum pressure and a minimum pressure.

4. The pump system of any of Claims 1 to 3, wherein the controller is further configured to determine whether the second pressure value is less than a minimum pressure.

5. The pump system of any of Claims 1 to 4, wherein the controller is further configured to provide an indication that the wound dressing is full in response to determining that the calculated first rate of pressure change equals or exceeds the threshold rate of change.

6. The pump system of any of Claims 1 to 5, wherein the threshold rate of change is approximately -50 mmHg/second.

7. The pump system of any of Claims 1 to 5, wherein the threshold rate of change is approximately -70 mmHg/second.

8. The pump system of any of Claims 1 or 5, wherein the threshold rate of change is between approximately -20 mmHg/second and approximately -200 mmHg/second.

9. The pump system of any of Claims 1 or 5, wherein the threshold rate of change is between approximately -40 mmHg/second and approximately -100 mmHg/second.

10. The pump system of any of Claims 1 to 5, wherein the threshold rate of change is between approximately -50 mmHg/second and approximately -75 mmHg/second.

11. The pump system of any of Claims 1 to 10, wherein the controller is further configured to provide an indication of a transient blockage condition in response to determining that the calculated first rate of pressure change satisfies a maximum rate of change.

12. The pump system of any of Claims 1 to 11, wherein the controller is further configured to provide an indication of a transient blockage condition in response to determining that the calculated first and second rates of pressure change satisfy a maximum rate of change.

13. The pump system of Claim 11 or 12, wherein the transient blockage condition comprises at least one of a kink in the flow path and an occlusion in the flow path.

14. The pump system of any of Claims 11 to 13, wherein the maximum rate of change comprises about 110%, about 120%, about 130%, about 140%, or about 150% of the threshold rate.

15. The pump system of any of Claims 11 to 13, wherein the maximum rate of change comprises between about 105% and about 155% of the threshold rate of change.

16. The pump system of any of Claims 11 to 15, wherein the controller is further configured to provide an indication of a transient blockage condition in response to determining that the calculated first rate of pressure change equals or exceeds the maximum rate of change.

17. The pump system of any of Claims 1 to 16 wherein the controller is further configured to sample a pressure within the fluid flow path during one or more time intervals.

18. The pump system of Claim 17, wherein the controller is further configured to sample the pressure at least twice during each of the one or more time intervals.

19. The pump system of Claim 17 or 18, wherein the controller is further configured to average the pressure samples during each of the one or more time intervals.

20. A method for controlling a pump system configured for negative pressure wound therapy, the method comprising:

causing provision of negative pressure, via a flow path, to a wound dressing configured to be positioned over a wound, the flow path configured to fluidically connect the pump system to the wound dressing;

measuring a first pressure value in the flow path at a first time;

measuring a second pressure value in the flow path at a second time;

calculating a first rate of pressure change using the first and second pressure values; and

in response to determining that the calculated first rate of pressure change satisfies a threshold rate of change, providing an indication that the wound dressing is full,

wherein the method is performed under control of a controller of the pump system.

21. The method of Claim 20, further comprising:

measuring a third pressure value in the flow path at a third time;

measuring a fourth pressure value within the flow path at a fourth time;

calculating a second rate of pressure change using the third and fourth pressure values; and

providing the indication that the wound dressing is full in response to determining that the calculated first and second rates of pressure change satisfy the threshold rate of change.

22. The method of Claim 20 or 21, wherein the pressure in the fluid flow path is between a maximum pressure and a minimum pressure.

23. The method of any of Claims 20 to 22, further comprising determining whether the second pressure value is less than a minimum pressure.

24. The method of any of Claims 20 to 23, wherein satisfying the threshold rate of change comprises equaling or exceeding the threshold rate of change.

25. The method of any of Claims 20 to 24, wherein the threshold rate of change is approximately -50 mmHg/second.

26. The method of any of Claims 20 to 24, wherein the threshold rate of change is approximately -70 mmHg/second.

27. The method of any of Claims 20 to 24, wherein the threshold rate of change is between approximately -20 mmHg/second and approximately -200 mmHg/second.

28. The method of any of Claims 20 to 24, wherein the threshold rate of change is between approximately -40 mmHg/second and approximately -100 mmHg/second.

29. The method of any of Claims 20 to 24, wherein the threshold rate of change is between approximately -50 mmHg/second and approximately -75 mmHg/second.

30. The method of any of Claims 20 to 29, further comprising providing an indication of a transient blockage condition in response to determining that the calculated first rate of pressure change satisfies a maximum rate of change.

31. The method of any of Claims 20 to 30, further comprising providing an indication of a transient blockage condition in response to determining that the calculated first and second rates of pressure change satisfy a maximum rate of change.

32. The method of Claim 30 or 31, wherein the transient blockage condition comprises at least one of a kink in the flow path and an occlusion in the flow path.

33. The method of any of Claims 30 to 32, wherein the maximum rate of change comprises about 110%, about 120%, about 130%, about 140%, or about 150% of the threshold rate of change.

34. The method of any of Claims 30 to 32, wherein the maximum rate of change comprises between about 105% and about 155% of the threshold rate of change.

35. The method of Claim any of Claims 30 to 34, wherein satisfying the maximum rate of change comprises equaling or exceeding the maximum rate of change.

36. The method of any of Claims 20 to 35, wherein measuring the pressure values within the flow path comprises sampling a pressure within the fluid flow path during one or more time intervals.

37. The method of Claim 36, further comprising sampling the pressure at least twice during each of the one or more time intervals.

38. The method of Claim 36 or 37, further comprising averaging the pressure samples during each of the one or more time intervals.

39. An apparatus as shown in the figures and described in the application.