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(54) Benævnelse: **VAKUUM-UNDERSTØTTET SYSTEM TIL BEHANDLING AF VÆV**

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DESCRIPTION

TECHNICAL FIELD

[0001] This invention relates generally to tissue treatment systems. More particularly this invention relates to vacuum assisted treatment systems that aid in the healing of open wounds.

BACKGROUND ART

[0002] Vacuum induced healing of open wounds has recently been popularized by Kinetic Concepts, Inc. of San Antonio, Texas, by its commercially available V.A.C.® product line. The vacuum induced healing process has been described in commonly assigned U.S. patent 4,969,880 issued on November 13, 1990 to Zamierowski, as well as its continuations and continuations in part, U.S. patent 5,100,396, issued on March 31 1992, U.S. patent 5,261,893, issued November 16, 1993, and U.S. patent 5,527,293, issued June 18, 1996. Further improvements and modifications of the vacuum induced healing process are also described in U.S. patent 6,071,267, issued on June 6, 2000 to Zamierowski and U.S. patents 5,636,643 and 5,645,081 issued to Argenta et al. on June 10, 1997 and July 8, 1997 respectively. Additional improvements have also been described in U.S. patent 6,142,982, issued on May 13, 1998 to Hunt, et al.

[0003] In practice, the application to a wound of negative gauge pressure, commercialized by Assignee or its parent under the designation "Vacuum Assisted Closure" (or "V.A.C.®") therapy, typically involves the mechanical-like contraction of the wound with simultaneous removal of excess fluid. In this manner, V.A.C.® therapy augments the body's natural inflammatory process while alleviating many of the known intrinsic side effects, such as the production of edema caused by increased blood flow absent the necessary vascular structure for proper venous return. As a result, V.A.C.® therapy has been highly successful in the promotion of wound closure, healing many wounds previously thought largely untreatable.

[0004] The frequency at which negative pressure is applied to the wound, as well as the frequency of the pressure change over time, has a direct impact on the rate of wound healing. A variation of pressure change over time, not provided by current vacuum assisted therapy devices, is thought to significantly increase the rate of wound healing. Similarly, a rapid return to normal activities for the patient receiving wound therapy, may also improve the rate of wound healing, as increased physical activity is often accompanied by increased vascular circulation, which in turn leads to improved blood flow at the wound site. One barrier to a return to normal activities is limited battery life, which is a result of the electrical power required to power existing vacuum assisted wound therapy systems. Additionally, frequent inspection of the wound site is required in order to ensure the wound is not becoming infected. However, a rapid return to normal activities must not preclude the precautions that must be utilized during use of vacuum assisted therapy to prevent inadvertent spillage of wound exudates from the canister, or entry of wound exudates into the pumping mechanism.

[0005] Additional limitations are associated with the use of fixed frequency oscillating pumps in the prior art. Such limitations are the result of the size of the pump required to maintain the desired negative pressure at the wound site, and/or a reduction in battery life due to the power required to operate the oscillating pumps. Oscillating pumps, as known in the art, are typically designed for limited operating conditions. For example, to maximize low pressure flow rate at a fixed frequency. Typically the mass and/or stiffness of various components are altered to change the resonant frequency of the pump under the design operating conditions. If the pressure across the pump increases, the stiffness of the system is increased by back pressure across the diaphragm of the oscillating pump. The resonant frequency of the pump changes and the fixed frequency drive is not driving the pump at the optimum frequency. As a result, flow rate drops quickly and the capability of the pump to drive air at high pressure is limited. Accordingly, in order to provide increased flow rate at higher pressures requires either a sacrifice in flow rate at low pressures, or a pump of significantly greater size, when utilizing a fixed frequency oscillating pump.

[0006] WO 00/61206 discloses a porous pad, an airtight dressing, a means for applying negative pressure to a wound site, and a canister with a hydrophobic filter.

[0007] For the foregoing reasons, there is a need for a vacuum assisted wound treatment system that is capable of automated pressure change over time. Additionally, there is a need for a more efficient vacuum assisted wound treatment system, that allows the patient more mobility, while reducing the risk of exudate spillage or pump contamination

[0008] It is therefore an object of the preferred embodiment of the present invention to provide a vacuum assisted wound treatment system that provides a means for increasing the stimulation of cellular growth by a variation of pressure over time.

[0009] A further object of the preferred embodiment of the present invention is to provide a system that is capable of extended operation in the absence of an alternating current power supply.

[0010] An additional object of the preferred embodiment of the present invention is to provide a sanitary and cost effective means for sampling fluids drawn from the wound site without necessitating removal of the canister, or disturbing of the wound site.

[0011] Still another object of the preferred embodiment of the present invention is to provide a vacuum assisted wound therapy device that can be secured to an object so as to reduce the likelihood of disturbance to the device, while still allowing convenient placement for its operation.

DISCLOSURE OF THE INVENTION

[0012] In accordance with the foregoing objects, the preferred embodiment of the present invention generally comprises a porous pad for insertion substantially into a wound site and a wound drape for air-tight sealing enclosure of the pad at the wound site. A distal end of a tube is connected to the dressing in order to provide negative pressure at the wound site. A fluid sampling port is provided on the tube to allow for sampling of wound fluids being drawn through the tube from the wound site. A source of negative pressure is in communication with a proximal end of the tube. A collection canister is removably connected to the tube for collection of fluid removed from the wound during the application of negative pressure. A first filter is incorporated into an opening of the canister, and a second filter is positioned between the canister and the source of negative pressure. As the source of negative pressure may be an electric pump, supplied by alternating or direct current, a power management device, and its associated power management protocol, is incorporated to maximize battery life when the unit is being supplied by direct current. A clamping mechanism is utilized to secure the system to a stationary object, such as a bed rail, or pole, such as that used to suspend a container of intravenous fluid.

[0013] The pad, comprised of a foam having relatively few open cells in contact with the areas upon which cell growth is to be encouraged so as to avoid unwanted adhesions, but having sufficiently numerous open cells so that drainage and negative pressure therapy may continue unimpaired, is placed in fluid communication with a vacuum source for promotion of fluid drainage, as known in the art. The porous pad may be comprised of polyvinyl alcohol foam. The fluid communication may be established by connecting a tube to a dressing, such as that described in International Application WO 99/13793, entitled "Surgical Drape and Suction Heads for Wound Treatment."

[0014] Upon placement of the pad, an airtight seal is formed over the wound site to prevent vacuum leakage. Such a seal may be provided by placing a drape over the wound, such that the drape adheres to the healthy skin surrounding the wound site, while maintaining an airtight seal over the wound itself.

[0015] A conduit or tube is placed in fluid communication with the foam pad, its distal end communicating with a fluid drainage canister which is in fluid communication with a vacuum source. A constant or intermittant negative pressure therapy is conducted as described in the prior art. The negative pressure is varied over time, so as to further stimulate cell growth, which in turn may shorten the healing process. The negative pressure induced on the wound adjusts to meet a varying target pressure, which oscillates between a target maximum and target minimum pressure.

[0016] Flow rate of a variable displacement pump, used in accordance with the preferred embodiment of the present invention, is maximized over a pressure range by varying the drive frequency of the pump. The optimum drive frequency is continuously adjusted by a system that periodically or continuously monitors the pressure across the pump to determine the optimum drive frequency for that pressure. Pump performance is thereby improved over variable displacement pumps utilized in the prior art, without increasing pump size or weight. Similarly, pump performance of a typical variable displacement pump can be achieved with a smaller pump, which in turn reduces the size and weight of the overall system in order to improve ease of use and portability for the patient. An alternative negative pressure source, such as a fixed displacement pump, sometimes referred to as a positive displacement pump, may also be utilized.

[0017] The power management system is utilized to maximize battery life when the present invention is being supplied with electric power under direct current. The power management system comprises deactivation of a backlight to a display terminal, or touch screen liquid crystal display (LCD) control panel, after a predetermined interval. Battery life is further extended when the power management system prevents electric power from reaching an electric motor until the targeted power setting is actually large enough to activate the motor. In such an instance, the motor is utilized to provide negative pressure by driving an electric pump as known in the art.

[0018] According to the present invention, there is provided a system for stimulating the healing of tissue according to claim 1.

[0019] Preferably said means for varying said negative pressure comprises means for adjusting actual pressure to meet a varying target pressure.

[0020] Conveniently said varying target pressure oscillates between a target maximum and a target minimum pressure.

[0021] Advantageously the electric pump has a power supply source to power the electric pump, and the system incorporates a means for managing the power supply source.

[0022] Preferably said means for managing said power supply source is comprised of means for preventing electric power from reaching an electric motor of the pump until sufficient power has been generated to activate said motor.

[0023] Conveniently said power supply for said electric pump comprises a portable power unit.

[0024] Advantageously said electric pump is an oscillating pump has a means for maximising pump flow rate over a predetermined pressure range.

[0025] Preferably said means for maximising pump flow rate comprises a means for varying a drive frequency of a drive circuit driving the oscillating pump.

[0026] Conveniently said means for varying said drive frequency comprises:

a pressure sensor for measuring pressure across said pump;

a control system for determining optimum drive frequency for said pump relative to pressure detected by said pressure sensor; and

said variable frequency drive circuit for driving said pump.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] These and other features and advantages of the invention will now be described with reference to the drawings of certain preferred embodiments, which are intended to illustrate and not to limit the invention, and wherein like reference numbers refer to like components, and in which:

Figure 1 is a schematic block diagram of a tissue treatment system utilized in accordance with the present invention.

Figure 2a is a perspective view of a fluid sampling port utilized in accordance with the present invention.

Figure 2b is a perspective view of an alternative embodiment of a fluid sampling port utilized in accordance with the present invention.

Figure 3a is a perspective view of the back portion of a pump housing utilized in accordance with the present invention.

Figure 3b is a perspective view of the front portion of a pump housing utilized in accordance with the present invention.

Figures 4a and 4b are flow charts representing the preferred steps in the implementation of a power management system utilized in accordance with the present invention.

Figure 5 is a flow chart illustrating the preferred steps in the implementation of pulse therapy utilized in accordance with the present invention.

MODES OF CARRYING OUT THE INVENTION and INDUSTRIAL APPLICABILITY

[0028] Although those of ordinary skill in the art will readily recognize many alternative embodiments, especially in light of the illustrations provided herein, this detailed description is exemplary of the preferred embodiment of the present invention, the scope of which is limited only by the claims that are drawn hereto.

[0029] The present invention is a vacuum assisted system for stimulating the healing of tissue.

[0030] Referring now to Figure 1 in particular, there is illustrated the primary components of a system that operates in accordance with the present invention. The present invention 10 includes a foam pad 11 for insertion substantially into a wound site 12 and a wound drape 13 for sealing enclosure of the foam pad 11 at the wound site 12. The foam pad 11 may be comprised of a polyvinyl alcohol (PVA) open cell polymer material, or other similar material having a pore size sufficient to facilitate wound healing. A pore density of greater than 38 pores per linear inch is preferable. A pore density of between 16 pores per cm (40 pores per linear inch) and (50 pores per linear inch) 20 pores per cm is more preferable. A pore density of (45 pores per linear inch) 18 pores per cm is most preferable. Such a pore density translates to a pore size of approximately 400 microns.

[0031] Addition of an indicating agent, such as crystal violet, methylene blue, or similar agents known in the art causes a color change in the foam 11 when in the presence of a bacterial agent. As such, a user or health care provider can easily and readily ascertain if an infection is present at the wound site 12. It is contemplated that the indicating agent may also be placed in line of the conduit 16, between the wound site 12 and the canister 18. In such a configuration (not shown), the presence of bacterial contaminants in the wound site 12, could be easily and readily ascertained without disturbing the wound bed, as there would be a nearly immediate color change as bacterially infected wound exudates are drawn from the wound site 12 and through the conduit 16 during application of negative pressure.

[0032] It is also contemplated that the foam pad 11 may be coated with a bacteriostatic agent. Addition of such an agent, would serve to limit or reduce the bacterial density present at the wound site 12. The agent may be coated or bonded to the foam pad 11 prior to insertion in the wound site, such as during a sterile packaging process. Alternatively, the agent may be injected into the foam pad 11 after insertion in the wound site 12.

[0033] After insertion into the wound site 12 and sealing with the wound drape 13, the foam pad 11 is placed in fluid communication with a vacuum source 14 for promotion of fluid drainage and wound healing, as known to those of ordinary skill in the art. The vacuum source 14 may be a portable electrically powered pump, or wall suction as commonly provided in medical care facilities.

[0034] According to the preferred embodiment of the present invention, the foam pad 11, wound drape 13, and vacuum source 14 are implemented as known in the prior art, with the exception of those modifications detailed further herein.

[0035] The foam pad 11 preferably comprises a highly reticulated, open-cell polyurethane or polyether foam for effective permeability of wound fluids while under suction. The pad 11 is preferably placed in fluid communication, via a plastic or like material conduit 16, with a canister 18 and a vacuum source 14. A first hydrophobic membrane filter 20 is interposed between the canister 18 and the vacuum source 14, in order to prevent wound exudates from contaminating the vacuum source 14. The first filter 20 may also serve as a fill-sensor for canister 18. As fluid contacts the first filter 20, a signal is sent to the vacuum source 14, causing it to shut down. The wound drape 13 preferably comprises an elastomeric material at least peripherally covered with a pressure sensitive adhesive for sealing application over the wound site 12, such that a vacuum seal is maintained over the wound site 12. The conduit 16 may be placed in fluidic communication with the foam 11 by means of an appendage 17 that can be adhered to the drape 13.

[0036] According to the present invention, a second hydrophobic filter 22 is interposed between the first filter 20 and the vacuum source 14. The addition of the second filter 22 is advantageous when the first filter 20 is also used as a fill sensor for the canister 18. In such a situation, the first filter 20 may act as a fill sensor, while the second filter 22 further inhibits contamination of wound exudates into the vacuum source 14. This separation of functions into a safety device and a control (or limiting) device, allows for each device to be independently engineered. An odor vapor filter 23, which may be a charcoal filter, is interposed between the first filter 20 and the second filter 22, in order to counteract the production of malodorous vapors present in the wound exudates. A second odor filter 15 may be interposed between the vacuum source 14 and an external exhaust port 25, in order to further reduce the escape of malodorous vapors from the present system. According to the invention the first 20 and second filters 22 are incorporated as an integral part of the canister 18 to ensure that the filters 20, 22, at least one of which are likely to become contaminated during normal use, are automatically disposed of in order to reduce the exposure of the system to any contaminants that may be trapped by the filters 20 and 22.

[0037] A means for sampling fluids may also be utilized by providing a resealable access port 24 from the conduit 16. The port 24 is positioned between the distal end 16a of the conduit 16 and the proximal end 16b of the conduit 16. The port 24, as further detailed in Figures 2a and 2b, is utilized to allow for sampling of fluids being suctioned from the wound site 12. Although the port 24 is shown as an appendage protruding from the conduit 16, it is to be understood that a flush mounted port (not shown) will serve an equivalent purpose. The port 24 includes a resealable membrane 26 that after being punctured, such as by a hypodermic needle, the seal is maintained. Various rubber-like materials known in the art for maintaining a seal after puncture can be utilized.

[0038] The process by which wound fluids are sampled, utilizing the present invention, comprises penetrating the membrane 26 with a fluid sampler 28, such as a hypodermic needle or syringe. The sampler 28 is inserted through the membrane 26 and into the port 24 until it is in contact with wound fluids flowing through the inner lumen 30 of the conduit 16. As illustrated in Figure 2b, and further described in U.S. Patent 6,142,982, issued to Hunt, et al. on May 13, 1998, the inner lumen 30 may be surrounded by one or more outer lumens 31. The outer lumens 31 may serve as pressure detection conduits for sensing variations in pressure at the wound site 12. In an alternative embodiment (not shown), the outer lumen or lumens 31 may act as the negative pressure conduit, while the inner lumen 30 may act as the pressure detection conduit. In the present invention, the fluid sampling port 24, communicates only with the inner lumen 30, so as not to interfere with pressure detection that may be conducted by the outer lumens 31. In an alternate embodiment (not shown) in which the outer lumen 31 serves as the negative pressure conduit, the fluid sampling port 24 communicates with the outer lumen 31.

[0039] The vacuum source 14 may consist of a portable pump housed within a housing 32, as illustrated in Figures 3a and 3b. A handle 33 may be formed or attached to the housing 32 to allow a user to easily grasp and move the housing 32.

[0040] According to the preferred embodiment of the present invention, a means for securing the housing 32 to a stationary object, such as an intravenous fluid support pole for example, is provided in the form of a clamp 34. The clamp 34, which may be a G-clamp as known in the art, is retractable, such that when not in use is in a stored position within a recess 36 of the housing 32. A hinging mechanism 38 is provided to allow the clamp 34 to extend outward from the housing 32, to up to a 90 degree angle from its stored position. An alternative embodiment (not shown) allows the clamp 34 to be positioned at up to a 180 degree angle from its stored position. The hinging mechanism 38 is such that when the clamp 34 is fully extended, it is locked in position, such that the housing 32 is suspended by the clamp 34. A securing device 40, such as a threaded bolt, penetrates through an aperture 42 of the clamp 34, to allow the clamp 34 to be adjustably secured to various stationary objects of varying thickness.

[0041] Alternatively, the securing device 40, may be comprised of a spring actuated bolt or pin, that is capable of automatically adjusting to various objects, such as intravenous fluid support poles, having varying cross-sectional thicknesses.

[0042] The present invention preferably also allows for management of a power supply to the vacuum source 14, in order to maximize battery life when the present invention is utilizing a direct current as its power supply. In the preferred embodiment, as illustrated in the flow chart of Figure 4a, a motor control 44 determines if the actual pressure is less than or equal to a target pressure 46. If the actual pressure is less than the target pressure, a tentative motor drive power required to reach the target pressure is calculated 48. If the tentative motor drive power required to reach the target pressure is greater or equal to the stall power 49, the tentative motor drive power is actually applied to the motor 50. If the actual pressure is greater than the target pressure, the tentative motor drive power is decreased and a determination is made as to whether additional power is needed to overcome the stall power 52. If it is determined that the tentative power is inadequate to overcome the stall power, the tentative power is not supplied to the motor 54. If the tentative power is adequate to overcome the stall power, the tentative power is actually applied to the motor 50. The motor control 44 functions as a closed loop system, such that the actual pressure is continuously measured against the predetermined target pressure. The advantage of such a system is that it prevents power from being supplied to the motor when it is not necessary to maintain the target pressure specified for V.A.C therapy. Accordingly, battery life is extended because power is not needlessly used to power the motor when it is not necessary.

[0043] Battery life is further extended, as illustrated in the flow chart shown in Figure 4b, by providing a means, such as an integrated software program in a computer processor, for automatically disengaging a backlight of the visual display 19 of the present invention 10 (as seen in Figure 3b). User input of information 55, such as target pressure desired, or duration of therapy, activates 57 a backlight of the visual display 19 shown in Figure 3b. User input 55 may also be simply touching the visual display 19, which may be a touch activated or a pressure sensitive screen as known in the art. Activation of an alarm 55 may also activate 57 the backlight of the display 19. An alarm may be automatically activated if an air leak is detected at the wound site 12. Such a leak may be indicated by a drop or reduction in pressure being detected at the wound site 12. The backlight remains active until a determination is made as to whether a preset time interval has elapsed 58. If the time interval has not elapsed, the backlight remains active 57. If the time interval has elapsed, the backlight is automatically extinguished 59, until such time as the user inputs additional information, or an alarm is sounded 55.

[0044] Referring now back to Figure 1, battery life is further extended by means of a variable frequency pump drive system 80, when the pump 14, used in accordance with the present invention, is an oscillating pump. The pump drive system 80 consists of a pressure sensor 82, a control system 84, and a variable frequency drive circuit 86. In the preferred embodiment the pressure sensor 82 measures the pressure across the pump, which is relayed to the control system 84. The control system 84 determines the optimum drive frequency for the pump 14 given the pressure measured and relayed by the pressure sensor 82. The optimum drive frequency for the pump 14 may be determined by the control system 84 either repeatedly or continuously. The control system 84 adjusts the variable frequency drive circuit 86 to drive the pump at the optimum frequency determined by the control system 84.

[0045] The use of the variable frequency pump drive system 80 allows the pressure of the pump 14 to be maximized. In tests on sample oscillating pumps, the maximum pressure achieved was doubled by varying the drive frequency by only 30%. Additionally, the system 80 maximizes flow rate over the extended frequency range. As a result, performance of the pump 14 is significantly improved over existing fixed frequency drive system pumps without increasing the pump size or weight. Consequently, battery life is further extended, thus giving the user greater mobility by not having to be tethered to a stationary power source. Alternatively, a similar performance level to the prior art fixed frequency drive system pumps can be achieved with a smaller pump. As a result, patient mobility is improved by improving the portability of the unit.

[0046] The preferred embodiment also increases the stimulation of cellular growth by oscillating the pressure over time, as illustrated in the flow chart of Figure 5. Such an oscillation of pressure is accomplished through a series of algorithms of a software program, utilized in conjunction with a computer processing unit for controlling the function of the vacuum source or pump. The program is initialized when a user, such as a health care provider, activates the pulsing mode of the pump 60. The user then sets a target pressure maximum peak value and a target pressure minimum peak value 62. The software then initializes the pressure direction to "increasing" 63. The software then enters a software control loop. In this control loop, the software first determines if the pressure is increasing 64.

[0047] If the actual pressure is increasing in test 64, a determination is then made as to whether a variable target pressure is still less than the maximum target pressure 70. If the variable target pressure is still less than the maximum target pressure the software next determines whether the actual pressure has equaled (risen to) the ascending target pressure 66. If the actual pressure has attained the ascending target pressure, the software increments the variable target pressure by one interval 68. Otherwise, it refrains from doing so until the actual pressure has equaled the ascending target pressure. If the variable target pressure has reached the maximum target pressure in the test of block 70 the software sets the pressure direction to "decreasing" 69 and the variable target pressure begins to move into the downward part of its oscillatory cycle.

[0048] The interval may be measured in mmHg or any other common unit of pressure measurement. The magnitude of the interval is preferably in the range of about 1 to 10 mmHg, according to the preference of the user.

[0049] If the actual pressure is decreasing in test 64, a determination is then made as to whether the variable target pressure is still greater than the minimum target pressure 74. If the variable target pressure is still greater than the minimum target pressure the software next determines whether the actual pressure has attained (fallen to) the descending target pressure 76. If the actual pressure has equaled the descending target pressure the software decrements the variable target pressure by one interval 72. Otherwise it refrains from doing so until the actual pressure has equaled the descending target pressure. If the variable target pressure has reached the minimum target pressure in the test of block 74, the software sets the pressure direction to "increasing" 73 and the variable target pressure begins to move into the upward part of its oscillatory cycle. This oscillatory process continues until the user de-selects the pulsing mode.

[0050] While the invention has been described herein with reference to certain preferred embodiments, these embodiments have been presented by way of example only, and not to limit the scope of the invention. Accordingly, the scope of the invention should be identified only in accordance with the claims that follow.

REFERENCES CITED IN THE DESCRIPTION

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Patentkrav

1. System (10) til stimulering af vævsheling, omfattende:

et porøst indlæg (11);

en lufttæt bandage (13);

organ til at forbinde en distal ende (16b) af en ledning (16) igennem bandagen (13);

organ (14) til at påføre negativt tryk til et sårsted;

et organ til at variere det negative tryk inden for et tidsinterval;

en beholder (18) aftageligt forbundet til en proksimal ende (16a) af ledningen (16);

et hydrofobisk filter (20) positioneret mellem beholderen (18) og organet (14) til påføring af negativt tryk;

et yderligere hydrofobisk filter (22) positioneret mellem det hydrofobiske filter (20) og organet (14) til påføring af reduceret tryk, hvor det hydrofobiske filter (20) og det yderligere hydrofobiske filter (22) er en integreret del af beholderen (18); og

et lugtdampfilter (23) indskudt mellem det første hydrofobiske filter (20) og det andet hydrofobiske filter (22).

2. System (10) ifølge et hvilket som helst af krav 1, hvor organet (14) til påføring af negativt tryk omfatter elektrisk pumpe (14) og en energiforsyningskilde til at drive den elektriske pumpe (14), og systemet inkorporerer et organ (44) til at håndtere energiforsyningskilden.

3. System (10) ifølge krav 2, hvor organet (44) til håndtering af energiforsyningskilden består af organ til at forhindre elektrisk energi i at nå en elektrisk motor (50) af pumpen (14), indtil tilstrækkelig energi er blevet genereret til at aktivere motoren (50).

4. System (10) ifølge krav 2 og krav 3, hvor energiforsyningen til den elektriske pumpe (14) omfatter en bærbar energienhed.

DRAWINGS

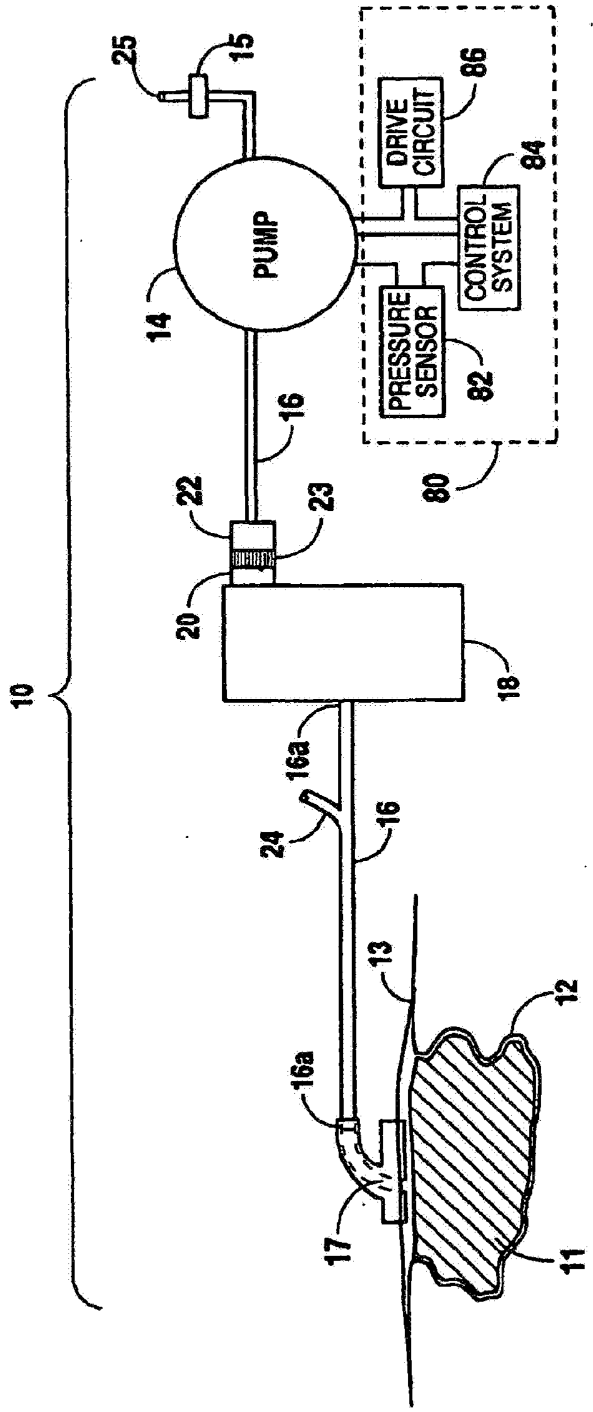

Fig. 1

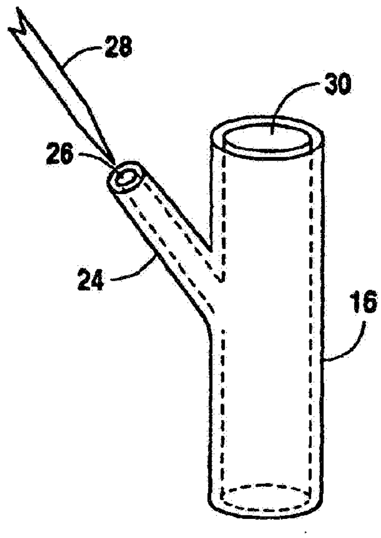

Fig. 2a

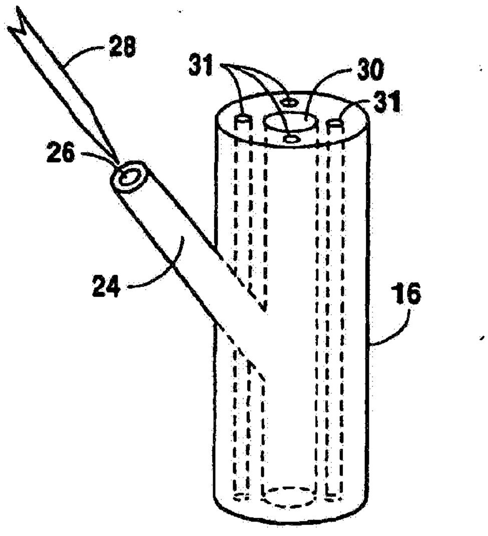

Fig. 2b

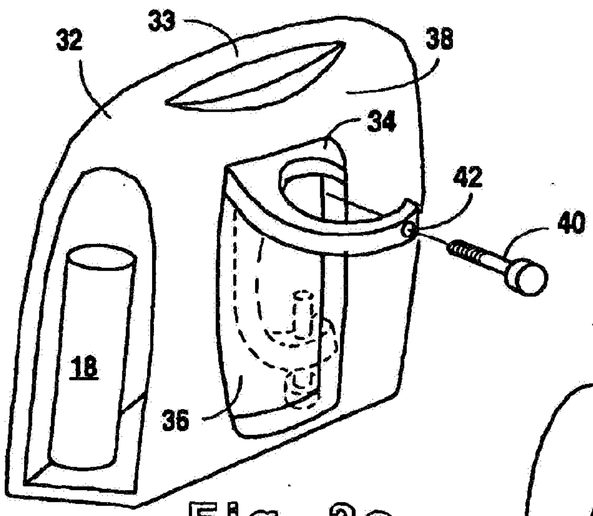

Fig. 3a

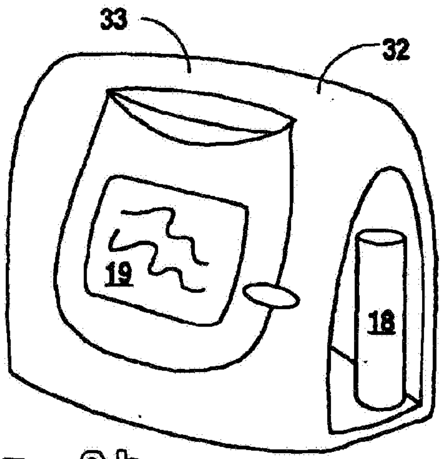

Fig. 3b

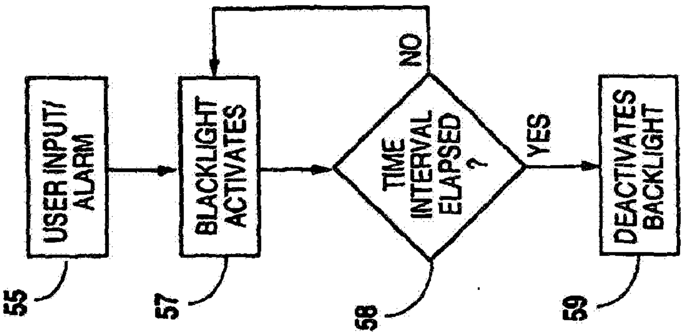
55
USER INPUT/ ALARM
57
BLACKLIGHT ACTIVATES
58
TIME INTERVAL ELAPSED ?
NO
YES
59
DEACTIVATES BACKLIGHT

Fig. 4b

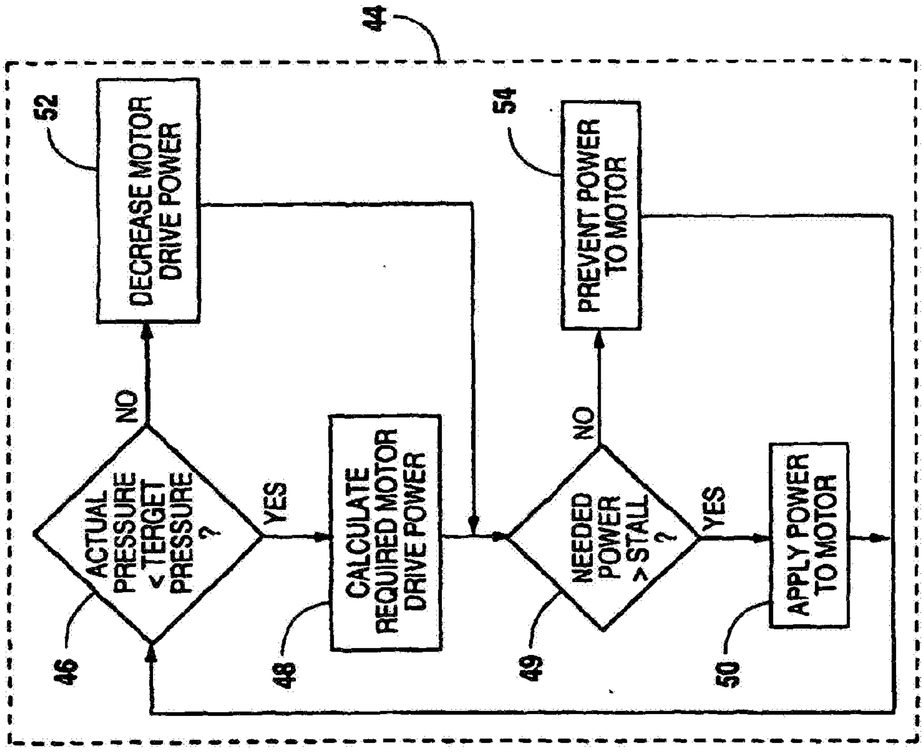
44
46
ACTUAL PRESSURE < TERGET PRESSURE ?
NO
YES
52
DECREASE MOTOR DRIVE POWER
48
CALCULATE REQUIRED MOTOR DRIVE POWER
49
NEEDED POWER > STALL ?
NO
YES
54
PREVENT POWER TO MOTOR
50
APPLY POWER TO MOTOR

Fig. 4a

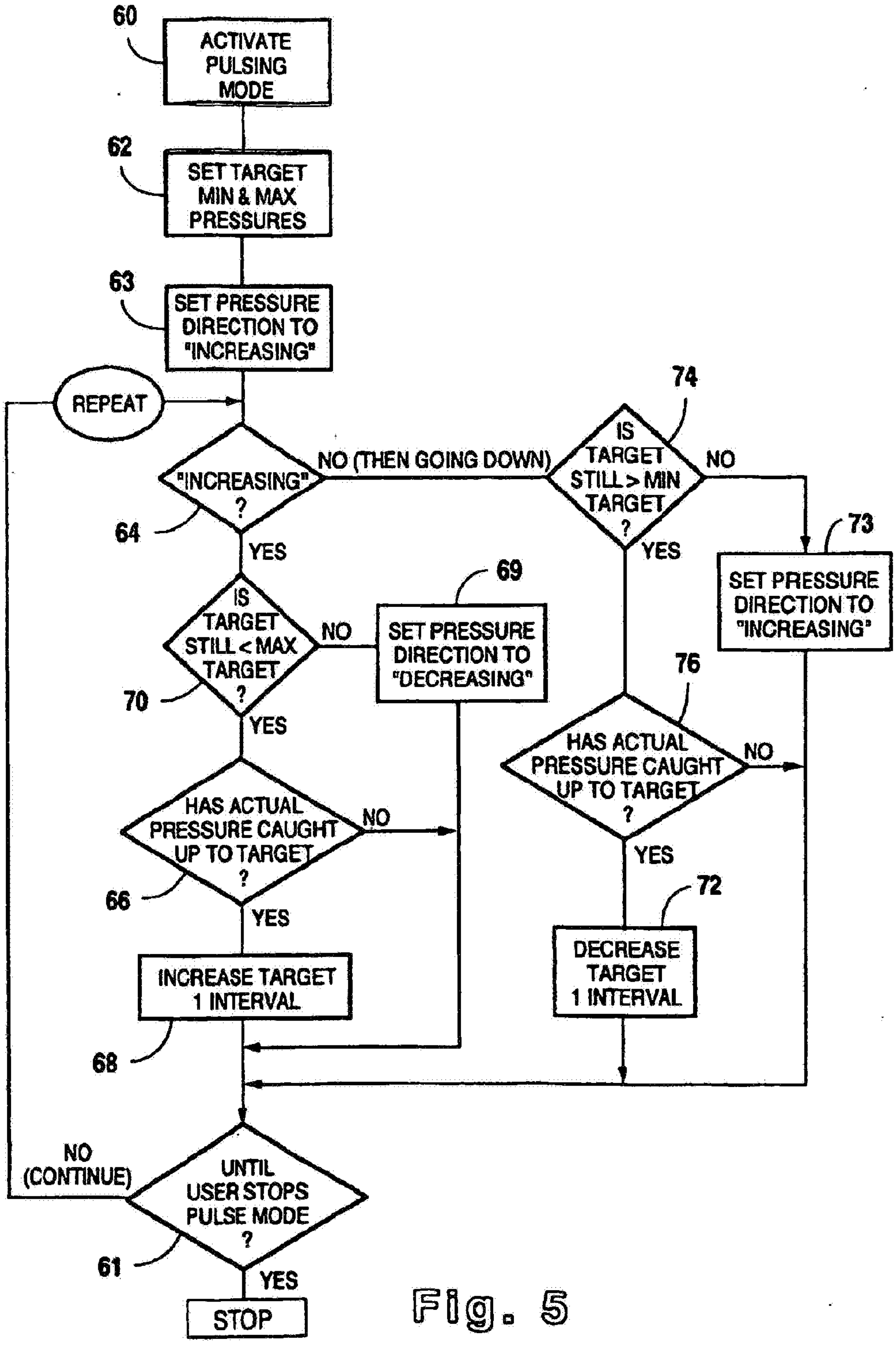
60
ACTIVATE PULSING MODE
62
SET TARGET MIN & MAX PRESSURES
63
SET PRESSURE DIRECTION TO "INCREASING"
REPEAT
"INCREASING" ?
64
NO (THEN GOING DOWN)
YES
74
IS TARGET STILL > MIN TARGET ?
NO
YES
73
SET PRESSURE DIRECTION TO "INCREASING"
IS TARGET STILL < MAX TARGET ?
70
NO
69
SET PRESSURE DIRECTION TO "DECREASING"
YES
76
HAS ACTUAL PRESSURE CAUGHT UP TO TARGET ?
NO
YES
HAS ACTUAL PRESSURE CAUGHT UP TO TARGET ?
66
NO
YES
72
DECREASE TARGET 1 INTERVAL
INCREASE TARGET 1 INTERVAL
68
NO (CONTINUE)
UNTIL USER STOPS PULSE MODE ?
61
YES
STOP

Fig. 5