WoundPro®

Negative Pressure Wound Therapy System

Negative Pressure Wound Therapy Operator's Manual

Pensar Medical

Creative Thinking – Innovative Solutions

Pensar Medical
Creative Thinking – Innovative Solutions

Table of Contents

DANGER

Explosion hazard – Do not use around flammable gases or in the presence of flammable gases.

Never drop or insert any object into the openings on the WoundPro® control unit.

WARNINGS

Failure to observe these warnings may cause serious injury or death to the patient.

All instructions and guidelines in this manual and the dressing kits should be read and followed.

This manual provides general guidelines for the proper use of the WoundPro® NPWT System. These guidelines do not replace instructions from the patient's physician. Failure to obtain and follow instructions from the treating physician could result in injury or death.

Be aware of bone fragments, hardware or staples in the wound bed. These items could puncture the protective barrier. If the protective barrier is punctured serious injury or death could result.

Coming into direct contact with bodily fluids is potentially dangerous. Direct contact could result in serious illness, up to and including death. Follow universal precautions if there is any risk of coming into contact with the contents in the WoundPro canister, tubing or dressing.

Do not use the WoundPro NPWT System if tamper-evident seal is broken or missing.

ADDITIONAL PRECAUTIONS

Care should be taken:

- When using the WoundPro on patients taking blood thinners or platelet aggregation inhibitors.
- On patients with active bleeding.
- When using the WoundPro on patients with wound hemostasis, care should also be taken:
  - on patients that have a history of irradiated blood vessels.
  - on wounds that involve a fistula.
  - on wounds with sinus tracks and wounds with tunneling.
  - when using the WoundPro in close proximity to blood vessels or organs.
  - to avoid injury to the patient's skin where it comes into contact with the tubing from the dressing.

CAUTIONS

Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Service work is to be done by Pensar Medical authorized personnel only.

Do not immerse or spray any type of liquid directly onto the WoundPro control unit. Instead, spray a cloth and wipe down the exterior as described in the cleaning procedure (page 24). The control unit is designed to cover all internal components; however internal components are not sealed from liquid immersion, over-saturated wipes, or direct spray.

Interrupting WoundPro therapy for more than two hours may increase the presence of bacteria in the wound bed. An increase in bacteria may raise the risk of infection. If the WoundPro therapy is interrupted for more than two hours remove the old dressing, irrigate the wound, and apply a new sterile dressing before resuming WoundPro therapy.

Introduction

Thank you for purchasing the Pensar Medical WoundPro® Negative Pressure Wound Therapy System. The heart of the WoundPro system is a state-of-the-art negative pressure control unit. When used in conjunction with either foam or gauze dressings it can assist in the healing process of chronic wounds.

The WoundPro Control Unit was one of the first to offer full user discretion on types of therapies (Continuous, Intermittent and Variable intermittent), therapy times and levels of negative pressure to provide patients with the therapy that works best for their particular type of wound.

For added convenience, the control unit contains a built-in rechargeable battery for portable operation for at least 24 hours.

Like any sophisticated system, the WoundPro provides optimal therapy and long-lasting operation only if it is used correctly. So please take the time to read this manual carefully, and if you have any questions, please do not hesitate to give us a call at 800-669-4757.

Indications For Use

The WoundPro Negative Pressure Wound Therapy System may promote wound healing, through the drainage and removal of infectious material and other fluids from the wound site. The WoundPro can provide continuous, intermittent and variable intermittent negative pressure therapies to achieve this goal. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts may benefit from the use of this device. At no time should the WoundPro, or any NPWT device, be used without an order from a physician.

Types of wounds indicated are:

- Diabetic/Neuropathic ulcers
- Pressure ulcers
- Chronic wounds
- Acute wounds
- Dehisced wounds

Contraindications For Use

The use of the WoundPro NPWT system is not recommended for patients with any malignancy of the wound, untreated osteomyelitis, non-enteric or unexplored fistulas, and necrotic tissue with the presence of eschar.

- The WoundPro NPWT system may be used after debridement of necrotic tissue and the complete removal of eschar.
- Never use the WoundPro NPWT system where there are exposed blood vessels, organs, or exposed bone. Do not place the WoundPro dressings over anastomosis, sutured vessels, or exposed nerves.
- In the cases of exposed blood vessels, organs or bone, they must first be covered with a porous, non-adherent wound contact layer prior to initiating negative pressure therapy to the area.

Patient Risk Factors/ Characteristics to Consider

Patients at high risk for bleeding and hemorrhage: Certain patients are at high risk of bleeding complications with or without the use of the WoundPro NPWT System. Patients that are at an increased risk of bleeding (which, if uncontrolled, could be potentially fatal) include the following:

- Patients with weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to:
  - Suturing of the blood vessel/organ
  - Infection – infected wounds should be monitored closely and may require more frequent dressing changes. The treating physician should determine if WoundPro NPWT needs to be discontinued and what treatment steps need to be taken.
  - Trauma
  - Radiation
- Patients without adequate wound hemostasis
- Patients on anticoagulants or platelet aggregation inhibitors
- Patients without adequate tissue coverage over vascular structures.
- Patients with Vascular Anastomosis
- Patients with Osteomyelitis
- Patients with exposed organs, vessels, nerves, tendons, ligaments
- Sharp edges in the wound (i.e. bone fragments) which could puncture protective barriers, vessels or organs, which could lead to bleeding.

If WoundPro NPWT has been prescribed for patients with an increased risk for bleeding/ hemorrhage, the patient should be closely monitored by the treating physician.

If active bleeding develops suddenly or in large amounts during WoundPro NPWT, immediately stop therapy (DO NOT REMOVE THE DRESSING), take appropriate measures to stop the bleeding and seek immediate medical assistance.

800cc Canister: The 800cc canister SHOULD NOT be used on patients with a high risk of bleeding, or on patients unable to tolerate a large loss of fluid volume. When using this canister, monitoring capability should be taken into account as well as patient risk factors. This canister is recommended when a patient's status can be closely monitored, such as in an acute care facility.

Exposed Vessels/Organs and Sharp Edges: If there are any exposed vessels, organs or sharp edges in the wound, they must be completely covered and protected prior to the use of WoundPro NPWT.

MRI (Magnetic Resonance Imaging): The WoundPro NPWT unit is MRI-unsafe and should never be taken into an MRI machine. The WoundPro unit was not designed for this and should be considered a fire hazard. Replace the WoundPro Dressing with an approved dressing for use in an MRI machine.

Hyperbaric Oxygen Therapy: The WoundPro NPWT unit has not been tested for hyperbaric oxygen therapy and should be considered unsafe for use with hyperbaric oxygen therapy. Never take the WoundPro unit into a hyperbaric chamber. The WoundPro unit was not designed for this and should be considered a fire hazard.

Precautions

Standard Precautions: Implement standard institutional protocol to reduce the risk of transmission of bloodborne pathogens.

Continuous vs. Intermittent negative pressure therapy: Research is constantly revealing the benefits of both types of therapy in different cases. The patient's treating physician should decide which Therapy Mode is appropriate for the wound and the circumstances.

Patient Size and Weight: Patient size and weight should be considered when prescribing WoundPro NPWT. Fluid loss and dehydration should be closely monitored in all patients. Large wounds in relation to patient size and weight can have excessive fluid loss and lead to dehydration. Monitor at-risk patients closely. This device has not been evaluated for use with children and infants.

Bradycardia: The WoundPro NPWT MUST NOT be placed in proximity to the vagus nerve.

Circumferential Dressing Application: Caution should be taken when using these dressings to ensure that the circulation distal to the dressing is not impaired.

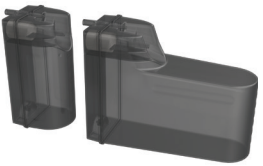
System Components

Control Unit

The WoundPro Control Unit is the heart of this highly sophisticated system that provides negative pressure therapy. Sleek and lightweight in its design, the WoundPro offers the highest levels of effective negative pressure wound therapy, all at the touch of a button.

Canister Sets

The WoundPro unit comes with a standard 300cc canister. An 800cc canister can be ordered if necessary for heavily exudating wounds. Both canisters come with 5 feet of extension tubing, a connector to the patient's wound dressing and hose connectors.



The canister comes with a built-in coagulant to reduce the risk of fluid spills. When fluid comes into contact with the coagulant, it turns it into gel. There is no discernable difference in the level of fluid in the canister with coagulant when compared to a canister without coagulant.

The disposal of used canisters should be done in a manner that is consistent with state and local requirements for medical waste. If you are unsure of your local and state requirements, contact the physician.

CAUTION: Do not use the 800cc canister on patients that are at high risk of bleeding. Do not use it on patients that cannot tolerate large losses of fluid volume, including children and elderly patients. If considering the use of the 800cc canister, consider the size and weight of the patient, wound type, monitoring capability and care setting. It is recommended this canister be used in settings where patients can be monitored closely by medically trained personnel.

Power Supply

The WoundPro Control unit comes equipped with an external switching power supply. This unique feature enables the user to power the system in a variety of countries without having to purchase a separate and bulky power adaptor.

Dressing Kits

A variety of dressing kits are available for use with the WoundPro. Select the dressing kit based on the wound that is being treated. All dressing kits come with all required materials to properly apply the dressing.

EZ Clasp™ System

Our easily attachable EZ Clasp System allows you to fasten the control unit to an IV pole or the head/foot board of the bed. Simply open the clamp by turning the handle counterclockwise. Next determine which direction you want the clamp to face (side to side for pole mount, or up and down for footboard mount). Then tighten the Philips screw on the back of the clamp into the receptacle on the back of the pump. Finally, position the clamp on the pole or footboard and turn the handle clockwise to close clamp.

System Features

Control Unit Features

- Quiet, compact and lightweight
- Easy-to-read and user-friendly graphics
- System lock-out feature to avoid untrained operation
- Constant system monitoring with a host of audible and visual alarms
- Audible alarm mute feature

Canister Features

- Two sizes (300cc and 800cc)
- High impact plastic to reduce risk of spillage of contents
- Integrated filter
- Positive locking mechanism to help ensure canister stays firmly attached to control unit
- Semi-translucent to help camouflage negative appearance of canister contents
- Coagulant in canister to help reduce the risk of spillage of contents

Pensar Medical
Creative Thinking – Innovative Solutions

System Specifications

Weight:
Control Unit - 3.8 lbs. (1.7 Kg)

Dimensions:
Control Unit – 6 ¾ (W) x 8 ½ (H) x 3 ½ (D) in. (17 x 21 x 9 cm)

Electrical Specifications

18VDC, 25W
Switching Power Adapter
Model: TR30RAM180
IEC 60601-1 EN55011 Class B
Input: 90-264VAC, 0.8-0.4A, 47-63Hz
Output: 18VDC 1.67A

Equipment Symbols


Refer to user manual

SN Serial Number


Type CF

Li-Ion Battery


Do not dispose with Municipal Waste. Special Collection/ Disposal Required


CE Mark

Environmental Conditions

IP33
Operating Conditions:

Ambient Temperature:	+10°C to +40°C
Relative Humidity:	30% to 75% Non-Condensing

Storage and Shipping Conditions:

Ambient Temperature:	-10°C to +40°C
Relative Humidity:	10% to 100%

Agency Approvals

UL Classified Medical Equipment UL 60601-1
CSA C22.2 No. 601.1-M90
IEC/EN 60601-1
IEC 60601-1-2 (2007)

IEC 60601-1-2 Table 201

Electromagnetic Emissions

The following Electromagnetic Emissions information is provided for healthcare facilities where the use of this device around other devices could result in electromagnetic interference.

All WoundPro® NPWT Systems are designed so that they can be used in electromagnetic environments. The use of these products in these environments should be restricted as listed in the following table.		
Emission Test	**Compliance with Standard**	**Guidelines**
RF Emissions CISPR 11	Group 1 (one)	WoundPro® products produce very little RF energy in the course of operation. The RF emissions created by the WoundPro® products are very low and should not cause any interference with other electronic devices located in close proximity.
RF Emissions CISPR 11	Class B	In terms of RF emissions all WoundPro® products are safe for use in all types of buildings including private residences. In terms of RF emissions the WoundPro® products are safe for use in buildings that are directly connected to low voltage public service used to supply residential buildings.
Harmonic Emissions IEC 6100-3-2	Class A	With respect to harmonic emissions all WoundPro® products are safe for use in all types of buildings including private residences. In terms of harmonic emissions the WoundPro® products are safe for use in buildings that are directly connected to low voltage public service used to supply residential buildings.
Voltage Fluctuations / Flicker Emissions IEC 6000-3-3	Complies	With respect to voltage fluctuations and flicker emissions all WoundPro® products can be used in all types of buildings including private residences. WoundPro® products may be used in buildings that are directly connected to low voltage public service used to supply residential buildings.

WARNING: Whenever possible the WoundPro® NPWT Systems should not be used when in close proximity to other electrical devices. Whenever possible do not stack the WoundPro pump on or under other electronic devices. If it is necessary to use the WoundPro in close proximity to or stacked on or under other electrical devices, care must be taken to ensure the WoundPro is performing as expected.

IEC 60601-1-2 Table 202

Electromagnetic Immunity

The following Electromagnetic Immunity information is provided for healthcare facilities where the use of this device around other devices could result in electromagnetic interference.

All WoundPro® NPWT Systems are designed for use in electromagnetic environments. The use of these products in these environments should be restricted as listed in the following table.			
Immunity Tests	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials like carpet, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 seconds	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 seconds	Main power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that an uninterruptible power supply is used to power the WoundPro® NPWT system.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels of a typical commercial or hospital environment.
NOTE 1: UT is the A.C. mains voltage prior to application of the test level.			

IEC 60601-1-2 Table 204

Electromagnetic Immunity (continued)

The following Electromagnetic Immunity information is provided for healthcare facilities where the use of this device around other devices could result in electromagnetic interference.

All WoundPro® NPWT systems are designed for use in electromagnetic environments. The use of these products in these environments should be restricted as listed in the following table.

Immunity Tests	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz To 80 MHz	3 Vrms	Portable and mobile RF communications devices should not be used any closer to any part of the WoundPro® NPWT system than the distance calculated using the following frequency formulas: 80 MHz to 800 MHz = $d = 1.2 \sqrt{P}$ 800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$ Where "P" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 6100-4	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 3: Field strengths from fixed RF transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength exceeds the applicable RF compliance level above, WoundPro operations should be closely observed to verify normal WoundPro operation. If abnormal operation is observed additional measures may be necessary such as relocating the WoundPro.

NOTE 4: The frequency ranges of 150 kHz to 80 MHz the field strengths should be less than 3 V/m

Safety Instructions

1. To avoid damaging the WoundPro control unit, be sure the power available at your location matches the power call-out on the rear of the Control Unit (i.e. 110VAC, USA; 220VAC Europe/ Australia)
2. Do not spill food or liquids onto the WoundPro Control Unit. If a spillage does occur, disconnect it from its power supply and allow at least 24 hours for drying.
3. Do not insert items into any openings of the WoundPro Control Unit. Doing so may cause fire or electrical shock by shorting internal components.
4. Keep unit away from radiators or other heat sources.
5. Be sure nothing is placed on the power cable and ensure it is located where it cannot be stepped on or tripped over.
6. Do not attempt to service the Control Unit except as explained in this guide. Always follow installation and servicing instructions closely.

WARNING: Service and repair must be performed only by an authorized Pensar Medical Products, LLC. technician.

Instructions for Use

CAUTION: These instructions are general guidelines. Refer to the instructions in the dressing kit for dressing changes.

The physician should set the frequency for dressing changes. The physician should establish the expectations for the amount of fluid that the sysem will remove in 24 hours.

Coming into direct contact with bodily fluids is potentially dangerous. Direct contact could result in serious illness up to and including death. Follow universal precautions if there is any risk of coming into contact with the contents in the WoundPro canister, tubing or dressing.

The following instructions are general guidelines and are not intended to replace your facility's established wound care protocol.

NPWT should never be used without an order from a physician.

All instructions provided in this manual are general guidelines and should be reviewed and approved by the physician.

Initial Startup:

When the WoundPro is first powered on, the entire display will illuminate as the system performs an automatic self-check, to ensure proper operation.

After a short time, the screen will change to display the software revision number. Next, the unit will display **the last therapy setting used**, either Continuous (figure A) or Intermittent (figure B). To easily tell the difference in the display, when in the Continuous Mode the display will only show one number as opposed to four in Intermittent Mode.

Figure A

No matter what screen is displayed, the unit will be in Standby Mode, and will not be in Therapy Mode; as is confirmed by the Lock/ Standby symbol on the display.

At this point, the control unit will be waiting for the user to set the parameters for therapy as prescribed by the physician. Programming instructions begin on the next page.

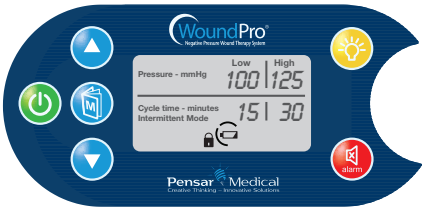


Figure B

Programming the WoundPro:

Enter the Programming Mode by pressing and holding the Power button and then pressing the Menu button. The mode that is currently selected (either Continuous or Intermittent) will be flashing on the display screen. To change between Continuous and Intermittent Modes press either the Up or Down arrow buttons.

Continuous Mode Programming:

- The current mode will be flashing. If the display shows that the unit is in Intermittent Mode press the Up ▲ or Down ▼ arrow buttons to change to the Continuous Mode.
- Depress the Menu button to enter the Pressure Adjustment Mode. The pressure setting will begin to flash. Use the Up ▲ and Down ▼ Arrows to adjust the pressure. Use the Up arrow to increase the pressure and the Down arrow to decrease the pressure. You can set the pressures from 20 mmHg to 200 mmHg in 5 mmHg increments.
- When you are finished making changes press the power button to exit Programming Mode and enter Standby Mode. Depressing power button again begins pump operation.

Intermittent Mode Programming:

- While in the Programming Mode, if unit is in the Continuous setting, press either the up or down arrow to change to the Intermittent setting (Intermittent Mode will continually flash).
- Then press the Menu button to set intermittent mode.
- Repeated pressing of the Menu button will enable the user to cycle between the high and low pressure settings as well as setting the cycle times for each parameter.
- Each parameter can be adjusted when it is flashing. Pressing the Up or Down arrow buttons will adjust the parameter accordingly (see table below).
- When a desired setting is achieved, press the Menu button to move on to the next parameter to be programmed.
- When finished programming, press the Power button to exit the Programming Mode.
- During Intermittent Mode operation, the flashing therapy cycle on the control panel indicates which therapy (high or low) is being delivered to the patient at any given time.

Intermittent Mode Parameters	Description of Feature
High Pressure	Pressures can be set from 20 to 200mmHg in 5mmHg increments
High Pressure Cycle Time	Times can be set from 1 to 10 minutes in 1 minute increments and then as long as 95 minutes in 5 minute increments
Low Pressure	Pressure can be set at 0 mmHg or from 20 to 200mmHg in 5 mmHg increments • The range for low pressure settings is affected by the high pressure settings. (i.e. low pressure settings automatically will not exceed high pressure settings)
Low Pressure Cycle Time	Times can be set from 1 to 10 minutes in 1 minute increments and then as long as 95 minutes in 5 minute increments

Canister Changes:

- Check the volume of fluid in canister. Each canister provides graduated measurement marks on the side of the canister. Document the volume change since last dressing or canister change in patient's chart. If canister is nearing the full mark replace the canister and extension tubing.

- To replace the canister
  - ❍ Turn the WoundPro off by depressing the power button for 3 seconds.
  - ❍ Disconnect the tubes and create a circular loop on each set of tubes.
  - ❍ Depress the blue canister release button on the top of the unit while pulling the canister away from the unit.
  - ❍ Release the canister release button and slide the new canister into the unit. To ensure a secure fit, you should hear an audible "click".

CAUTION: Always monitor the amount of fluid in the canister since the last dressing change. Be sure to note how much fluid was in the canister when it was changed.

WARNING: If the amount of fluid from the wound is more than expected, a serious medical condition could exist.

Dressing Changes

- Determine the proper dressing size based on the diameter, depth, and location of the wound. As a general guideline, dressings should be changed every 48 hours unless directed otherwise by physician.
- Verify that all kit components are accounted for and that there is no damage to the packaging of the individual items.
- Disconnect the tubes from the canister and dressing.
  - Create a circular loop to prevent any leakage.

- Turn WoundPro unit off by depressing the power button for 3 seconds.
- Remove the old dressing from wound, making sure that all components are removed.
- Clean wound and periwound area as per facility's wound care protocol.
- Measure wound per facility's wound-measuring protocol.
- Irrigate wound with saline, blotting away any excess saline using a sterile gauze sponge

Applying the Gauze Wound Dressing Set

- Step 1 – Debride any necrotic tissue and cleanse wound and periwound area according to institution guidelines and physician's orders.
- Step 2 – Cut non-adherent petroleum gauze to the shape of the wound. Cover the entire wound bed with the gauze. [See Figure A]
- Step 3 – Saturate one of the antimicrobial gauze sponges with saline, wring out excess saline, and place in the wound bed. [See Figure B]
- Step 4 – Trim the drain (flat or round) so the groove or holes are confined to the wound bed. Place it directly on top of the gauze applied in Step 4.

  Caution: Do not place the drain in a fistula tract. [See Figure C]
- Step 5 – Saturate additional antimicrobial gauze with saline, wring out excess saline, open and fluff into the wound to completely cover the drain and fill the wound with antimicrobial gauze to skin level.

  Caution: Care should be taken to ensure that the gauze is restricted to the wound area and does not protrude onto the periwound area. [See Figure D]
- Step 6 – Apply skin prep to the periwound area and allow to dry until tacky.

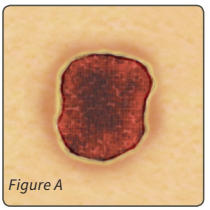


Figure A

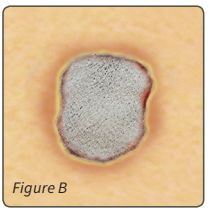


Figure B

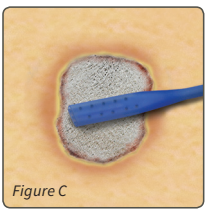


Figure C

- Step 7 – Apply a thin strip of stoma paste (approx. 1" long x 1/8" thick) on the periwound area where the drain leaves the wound. Taper the ends of the stoma paste down to a paper-thin thickness. Lay the drain tube across the strip of stoma paste. Apply a second thin strip of stoma paste (approximately 1" long x 1/8" thick) over the top of the drain tube. Press drain tube into stoma paste creating a seal around the drain tube. [See Figure E]

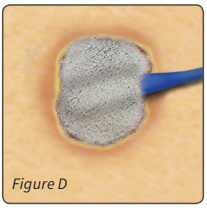


Figure D

- Step 8 – Cut a piece of transparent dressing 1-2 inches beyond the wound border on each side. Create an airtight seal by applying the transparent dressing, starting with the side opposite the tubing. Press the dressing down firmly around the entire wound to ensure the wound environment is sealed. [See Figure F]

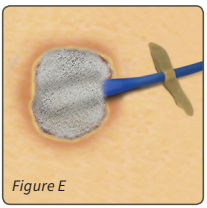


Figure E

- Step 9 – Attach the drain tubing to the patient connector on the extension tubing, which is attached to the canister, by pushing the end of the patient connector into the drain tube.
- Step 10 – Press the Power button to turn the unit on.
- Step 11 – Adjust the setting on the pump as directed by physician.
- Step 12 – Select either Continuous or Intermittent Mode.
- Step 13 – Set the pressures and times as directed by physician.

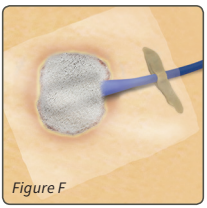


Figure F

- Step 14 – Press the power button to initiate negative pressure therapy. The dressing surface should contract considerably when the pump is set to run. The system will immediately start checking for leaks. If it determines there is a leak that it cannot overcome, audible and visual alarms will sound and display (see alarms section).
- Step 15– Monitor the dressing to ensure that the dressing maintains a vacuum (dressing is contracted) and the volume of exudate being removed from wound is within physician's expectation.

  Caution: If exudate volumes exceed physician's expectations, notify physician immediately for further instructions.

Applying the Foam Wound Dressing Set

- Step 1 – Debride any necrotic tissue and cleanse wound and periwound area according to institution guidelines and physician's orders.
- Step 2 – Cut foam dressing to the shape of the wound. Care should be taken to ensure that cut pieces of foam do not fall into wound bed. [See Figure A]
- Step 3 – Place foam into wound bed. A proper fit will result in wound area being completely covered with no foam extending beyond the wound edges onto the periwound area. [See Figure B]
- Step 4 – Cut a piece of transparent dressing 1-2 inches beyond the wound border on each side. Apply skin prep to the periwound area and allow to dry until tacky. Create an airtight seal by applying the transparent dressing over the wound and periwound area. [See Figure C]
- Step 5 – Gently pull up on the transparent dressing over the center of the wound. Using scissors cut a small hole (between ½ to 1 inch round) over the center of the dressing. [See Figures D & E]
- Step 6 – Remove the protective backing on the suction bell. Apply the suction bell over the hole cut in the transparent fill in step 4 above. Make sure that the hole is completely covered with the suction bell. [See Figure F]

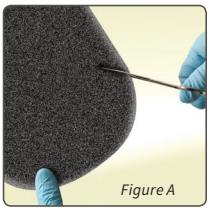


Figure A

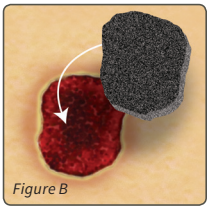


Figure B

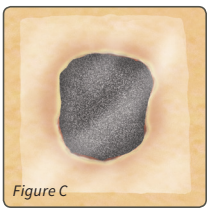


Figure C

- Step 7 – Attach the StingRay™ tubing to the Patient connector.
- Step 8 – Attach the drain tubing to the patient connector on the extension tubing, which is attached to the canister. Attach the corresponding connectors on each set of tubes. Twist until you hear them lock together.
- Step 9 – Press the Power button to turn the unit on.
- Step 10 – Adjust the setting on the pump as directed by physician.
- Step 11 –Select either Continuous or Intermittent Mode.
- Step 12 –Set the pressures and times as directed by physician.
- Step 13 – Press the power button to initiate negative pressure therapy. The dressing surface should contract considerably when the pump is set to run. The system will immediately start checking for leaks. If it determines there is a leak that it cannot overcome, audible and visual alarms will sound and display (see alarms section).
- Step 14 – Monitor the dressing to ensure that the dressing maintains a vacuum (dressing is contracted) and the volume of exudate being removed from the wound is within the physician's expectations.

  Caution: If exudate volumes exceed physician's expectations, notify physician immediately for further instructions.

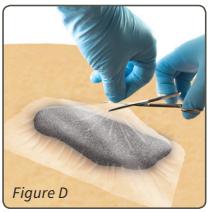


Figure D

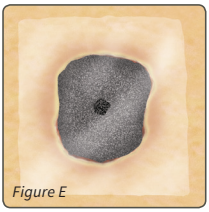


Figure E

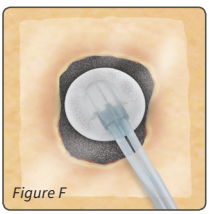
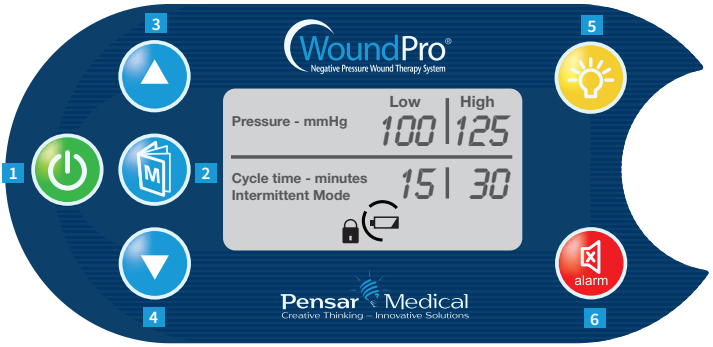


Figure F

INFORMATION: Periodically check dressing to ensure that it is in place and that the airtight seal is intact. Check canister and determine volume of drainage.

Detailed Explanation of Keypad



1. **Power**
2. **Menu**
3. **Up arrow**
4. **Down arrow**
5. **Canister light**
6. **Alarm mute**

Keypad Functions

1. The Power Button is a multi-functional button that:

- Turns the unit ON and OFF (Press to turn on; Press and Hold for 3 seconds to turn off)
- It saves programming changes and switches pump from Programming to Standby/Lock Out Mode
- It switches the pump from Standby Mode to Therapy Mode with a simple press of the button
  - ❍ It also switches the pump back from Therapy Mode to Standby/Lock Out Mode with another push of the button for dressing or canister changes

2. Menu button

The Menu Button also controls more than one function during the normal operation of the WoundPro Control unit. It is used to:

- Select whatever function of the pump that the caregiver wants to change.
- When in Programming Mode repeated pressings of the Menu button will scroll between:
  - ❍ Types of therapy preferred
  - ❍ Pressure settings
  - ❍ Time settings
- Please see Advanced Controls section (page 21) of the owner's manual to activate Runtime Hours Display

3. Up Arrow Button

The Up Arrow is used to increase the setting of the currently selected function.

4. Down Arrow Button

The Down Arrow is used to decrease the setting of the currently selected function.

5. Canister Light Button

This button is used to illuminate the inside of the canister. This makes it easier to see the fluid level in the canister so you know when to change it.

6. Alarm Mute Button

Alarm Mute is used to either temporarily or permanently mute the WoundPro alarms. This is normally done to allow the provider to correct the reason for the alarm.

- ❍ Press the 'Alarm Mute' button to silence for 30 minutes. Press and hold for 3 seconds to mute all alarms until the unit is powered down. You can also reengage the alarms by pressing the "Alarm Mute" button again.

Advanced Controls:

Patient Runtime Hours Display

- Press the Menu button when the unit is in Standby/Lock out Mode.
- The display will show the total number of hours the WoundPro unit has been in operation since the unit's timer has been reset
- **To reset for a new patient**, press and hold one arrow button and then press the other arrow button
- Press the Menu button to return to Standby/Lock out Mode.

Total Runtime Hours Display

- When Patient Runtime hours are displayed (see above), press the Canister Light button and the Menu button simultaneously to display total runtime hours for the pump
- This number cannot be reset back to zero as it is used to record total working hours of the pump since it was manufactured
- Press Menu button again to return to Standby/Lock Out Mode

Battery Charge Indicator

- When first plugged in to an AC receptacle (and any time the unit is plugged in but off), the battery charging indicator will flash and a percentage of current battery charge will remain on the screen.

CAUTION: In most circumstances it is not recommended to permanently deactivate the alarms. This should only be done when absolutely necessary.

Standby/Lock Out

A special key stroke is required to modify therapy settings. This feature is there to ensure that therapy settings are not changed by accident or by an unauthorized user. When the Lock Out function is engaged the Lock icon is displayed on the screen. This tells you that the therapy settings cannot be adjusted. Settings are locked automatically when exiting the therapy adjustment menu.
To unlock and make adjustments to the settings press and hold the Power button, then press the Menu button.

Alarms

The WoundPro NPWT system monitors several functions and will activate an alarm if it detects a change in normal operation. The unit utilizes both visual and audible alarms. Refer to the following explanation of alarm conditions to correct the issue. If the problem persists contact Pensar Medical's customer service department.

Informational Alarms

Informational alarms are set off when either the battery power is low or the canister has reached its full mark. The unit will continue to operate normally for a period of time to allow the alarm condition to be corrected without interruption in therapy.

Low Power
(3 beeps every minute)

When the battery has less than 10% of its usable life remaining, the battery symbol is displayed and the alarm will sound.

- To correct this alarm, plug the WoundPro control unit into an outlet.

Canister Full canister full
(3 beeps every minute)

This alarm sounds when the fluid level in the canister has reached its capacity.

- To correct this alarm condition pause the pump and then replace the canister.

Warning Alarms

Warning alarms are set off when a suction line is blocked or there is a vacuum leak, or when the unit is left in Standby Mode. These conditions affect the ability of the system to work correctly. The system will stop working until the alarm reason is corrected. Warning alarms must be addressed as quickly as possible.

Suction Line Blocked line blocked
(3 beeps every 5 seconds)

This alarm sounds when the system's pressure sensor detects a change in the pressure created by a blockage in the tubing or canister.

- To correct this alarm condition, pause the pump and replace the canister and tubing.

Vacuum Leak vacuum leak
(3 beeps every 5 seconds)

The unit continues to run for the first 30 minutes of a vacuum leak alarm. If the alarm cause is not fixed within 30 minutes, the pump will stop and the alarm will continue to sound.

To correct this alarm condition, check to ensure:

- the canister is properly attached to the control unit
- the extension tubing is securely attached to the canister
- the drain tubing is securely attached to the extension tubing
- that the dressing is sealed around the drain tubing

Standby Alarm standby

(3 beeps every 5 seconds)

This alarm activates when the unit is left in Standby Mode or Programming Mode for more than 30 minutes. The alarm is used to remind the user that the WoundPro unit must be returned to Therapy Mode after a dressing change or canister change is complete.

- To correct this alarm condition, resume negative pressure Therapy Mode or power down the unit if therapy is no longer required.

WARNING: Warning alarms need to be addressed as soon as possible. The WoundPro stops working as long as the alarm condition is not corrected.

Cleaning and Maintenance

The WoundPro NPWT System is made to keep bodily fluids in the tubing and canister. For instructions see the sheet included with each dressing or refer to dressing instructions above. Care should always be taken to protect yourself from coming in contact with any bodily fluids. Follow your facility's protocol with respect to cleaning medical devices.

WARNING: Coming into direct contact with bodily fluids is potentially dangerous. Direct contact could result in serious illness up to and including death. Follow universal precautions if there is any risk of coming into contact with the contents in the WoundPro canister, tubing or dressing.

General Cleaning Guidelines

1. Cleaning dirty patient care equipment should take place in a designated area. It should be done away from clean or sterile supplies and food preparation areas.
2. Detergent/disinfectants should not be mixed with other germicides or detergents. Using the proper mix ensures the disinfectant will be most effective. Always follow the disinfectant manufacturer's instructions.
3. Wash hands often and well. Wash hands after removal of gloves. Pay particular attention to around and under fingernails and between fingers.

Cleaning Procedure

- Don protective gloves, protective apparel, and an eye protection device.
- Remove the canister, tubing and any dressing materials still connected to the unit. Dispose of by following your Biomedical Waste disposal policy.
- Prepare detergent/disinfectant (registered with the Environmental Protection Agency as a hospital disinfectant) solution according to manufacturer's instructions. Use only hospital-grade quaternary disinfectant cleaners.
- **Using the disinfectant solution prepared as directed above, moisten a clean cloth. Thoroughly wipe down the unit making sure to wipe all surfaces. Avoid using an oversaturated cloth and do not spray liquids directly onto the unit.**
- Dry the unit with a clean cloth and allow to air dry for thirty minutes.
- Dispose of all bodily substances as directed by your facility's Biomedical Waste disposal policy.
- Remove and dispose of gloves and protective apparel, and eye protective device as per facility protocol.
- DO NOT HEAT OR STEAM AUTOCLAVE THE CONTROL UNIT.

Storage and Care

Control Unit

After disinfecting the unit it should be placed in a plastic bag for dust resistance. The unit should be stored in a clean area used to store electromechanical medical devices according to hospital or facility policy.

WARRANTY

This warranty is extended only to the original purchaser. It does not affect statutory rights.

Pensar Medical Products, LLC. (the warrantor) warrants this product to be free from defects in materials and workmanship for a period of three (3) years covering all materials (excluding batteries) and labor costs. If within such warranty period the product shall be proven to the warrantor's reasonable satisfaction to be defective, it shall be repaired or replaced, at warrantor's option; warrantor's sole obligation, and your exclusive remedy under this warranty being limited to such repair or replacement.

Batteries – Rechargeable batteries are warranted for a period of six months from the date of purchase.

If the product is deemed by the warrantor not to be covered under warranty, a quote will be sent to you for your approval before work begins. If you do not want the work performed a minimum charge of $45 will be assessed and your product will be sent back C.O.D. using your shipper.

Warranty service in the United States can be obtained during the warranty period from Pensar Medical Products LLC. Please call 800-669-4757 to obtain a return authorization number (RA number). **No product will be accepted for return without an RA number.**

Shipping – The purchaser is responsible for shipping costs incurred returning broken or defective product to Pensar Medical Products, LLC. Pensar Medical Products, LLC. will pay all shipping costs incurred in returning any parts repaired or replaced under the warranty.

Limits and Exclusions

There are no express warranties except as listed above.

This warranty does not cover normal wear and tear. It does not cover damage which occurs in shipment. It does not cover failures which are caused by products not supplied by the warrantor. It does not cover failures which result from accident, misuse, abuse, neglect, mishandling, misapplication, alteration, faulty installation, modification, or service by anyone other than the warrantor or damage that is attributable to acts of God.

WoundPro®

Negative Pressure Wound Therapy System

Pensar Medical
Creative Thinking–
Innovative Solutions

Pensar Medical Products, LLC
42225 Remington Ave. | #A3 | Temecula, CA 92590
www.pensarmedical.com
800-669-4757

4/15 Rev E UPC 84635400180