MODEL #: CMPP-100
Revision 1.8 2018_1228

accelephase

NISUS®

NEGATIVE PRESSURE
WOUND THERAPY SYSTEM

Instructions for Use

Table of Contents: Clinical Safety and Precautions

Table of Contents: Use of Device

Clinical Safety and Precautions

The following types of patients are at an increased risk of bleeding, which if not controlled could be potentially fatal:

- Patients who would have weakened or friable blood vessels or organs in or around the wound as a result of, but limited to suturing of blood vises, infection, trauma, and radiation
- Patients without adequate wound hemostasis
- Patients who have been administered anticoagulants or platelet aggregation inhibitors
- Patients who do not have adequate tissue coverage over vascular structures

If active bleeding develops suddenly or large amounts of frank (bright red) blood is seen in the tubing or canister, immediately stop therapy, leave dressing in place, take measures to stop the bleeding, and seek immediate medical assistance. The Nisus NPWT System should not be used to prevent, minimize or stop vascular bleeding.

Protect Vessels and Organs: All exposed or superficial vessels and organs in or around the wound must be completely covered and protected prior to the administration of the Nisus NPWT.

Large Wounds: Caution should be taken when treating large wounds that may contain hidden vessels which may not be readily apparent. The patient should be closely monitored for bleeding in a setting deemed appropriate by the treating physician.

Infected Blood Vessels: Infection may erode blood vessels and weaken the vascular wall which may increase susceptibility to vessel damage through abrasion or manipulation. The patient should be closely monitored for bleeding in a care setting deemed appropriate by the treating physician.

Hemostasis, Anticoagulants, and Platelet Aggregation Inhibitors: Due to the increased risk for bleeding, consideration should be given to the negative pressure setting and therapy mode used when initiating therapy. These patients should be treated and monitored in a care setting deemed appropriate by the treating physician.

Hemostatic Agents Applied at the Wound Site if disrupted, may increase the risk of bleeding which, if uncontrolled, could be potentially fatal. Consideration should be given to the negative pressure setting and therapy mode used when initiating therapy.

Sharp Edges or bone fragments must be covered or eliminated from the wound area to prevent them from puncturing blood vessels or organs prior to the application of the Nisus NPWT System. Use caution when removing dressing components from the wound so that the wound tissue is not damaged by unprotected sharp edges.

Vascular Surgical Wounds of the Lower Extremities: Regardless of the treatment, wound complications from peripheral vascular surgery, especially those situated in the groin, are not uncommon and have the potential for severe consequences including significant blood loss.

Infected Wounds: Wound infections should be closely monitored and may require more frequent dressing changes. If there are any signs of the onset of systemic infection or advancing infection at the wound site, contact the treating physician immediately to determine if the Nisus NPWT Pump should be discontinued.

Osteomyelitis: Nisus NPWT should not be initiated on a wound with untreated osteomyelitis.

Tendons, Ligaments and Nerves: Protect exposed tendons, ligaments and nerves with natural tissue, meshed non-adherent material or bio-engineered tissue to help minimize risk.

Foam Placement: Always use dressings from sterile packages that have not been opened or damaged. Do not place foam dressing into blind/unexplored tunnels. Always count the total number of pieces of foam used in the wound and document on the patient chart.

Foam Removal: Always count the total number of pieces of foam removed from the wound and ensure the same number of foam pieces are removed as were placed, as the dressings are not bio-absorbable. Regardless of treatment, disruption of the new granulation tissue during any dressing change may result in bleeding at the wound site.

Keep Nisus NPWT System turned on: Never leave the foam dressing in place without the Nisus NPWT System for more than 2 hours if therapy is turned off. If the therapy is off for more than 2 hours, remove the wound dressing and irrigate the wound; either apply a new Cork Medical NPWT wound dressing and restart the unit, or apply alternative dressing at the direction of the physician.

Defibrillation: If defibrillation is required in the area of dressing placement, remove the dressing immediately, as failure to remove may inhibit transmission of electrical energy and/or patient resuscitation.

Precautions should be taken for patients who are or may be receiving anticoagulant therapy, patients with known hemolytic disease, untreated for malnutrition, and who are non-compliant or combative.

Universal Precautions: Hand washing must be performed prior to starting any procedure. Gloves must be donned prior to any direct patient contact. In addition to gloves, use gown and goggles if exposure to body fluid is likely. Always follow your institutional guidelines on infection control practices.

Patient Size and Weight: The size and weight of the patient should be considered when prescribing negative pressure wound therapy. Infants, children, certain small adults and elderly patients should be closely monitored for fluid loss and dehydration. Also, patients with highly exudating wounds or large wounds in relation to the patient size and weight should be closely monitored, as they may have a risk of excessive fluid loss and dehydration. When monitoring fluid output, consider the volume of fluid in both the tubing and canister.

Spinal Cord Injury: In the event a patient experiences autonomic hyperreflexia (sudden elevation in blood pressure or heart rate in response to stimulation of the sympathetic nervous system), discontinue therapy immediately and seek immediate medical assistance.

Bradycardia: The dressing should not be placed near the vagus nerve as this may cause bradycardia.

Enteric Fistulas: Nisus NPWT System is not intended for containment of drainage of enteric fistulas. Nisus may be used with enteric fistulas in the aid of promoting wound healing and not the sole purpose of containment of drainage. The physicians ordering the Nisus for enteric fistulas need to closely monitor the patient for any complications that may occur.

Clinical Safety and Precautions

Operating Precautions

When operating, transporting, repairing, or disposing of Nisus NPWT devices and accessories, the risk of infectious liquid being aspirated, or contamination of the device assembly through incorrect use, cannot be eliminated. Universal precautions should be observed when working with potentially contaminated parts or equipment.

In the event materials of the Nisus NPWT System cause skin irritation or an allergic reaction, cease use immediately and contact a physician.

Use of the Nisus NPWT System must be prescribed by a physician per the stated indications for use. As a condition of use, the Nisus NPWT System should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which negative pressure wound therapy is being used.

The Nisus NPWT System should remain on and in use for the duration of the prescribed treatment. If the patient must disconnect the pump from the NPWT wound dressing, the ends of the tubing should be clamped prior to disconnecting. The length of time a patient may be disconnected from the Nisus device is a clinical decision based on individual characteristics of the patient and the wound. Factors to consider include the location of the wound, the volume of drainage, the integrity of the NPWT wound dressing seal, the assessed bacterial burden, and the patient's risk of infection.

The Nisus NPWT pump is not intended to be in use during transport or ambulatory use. In the event a patient using the Nisus NPWT System needs to be transported or ambulatory, the ends of the tubing should be clamped and disconnected from the NPWT wound dressing. The length of time a patient may be disconnected from the Nisus device is a clinical decision based on individual characteristics of the patient and the wound. Factors to consider include the location of the wound, the volume of drainage, the integrity of the NPWT wound dressing seal, the assessed bacterial burden, and the patient's risk of infection.

Ensure all components of the Nisus NPWT Wound Dressing Kit are installed correctly and that the port pad assembly tubing is not kinked to avoid leakage and blockage during NPWT therapy. Position the Nisus NPWT System and drainage tubing appropriately to avoid the risk of causing a trip hazard. When possible, position the pump device and drainage tubing at or below the level of the wound.

Tubing from the Nisus NPWT Wound Dressing Kit and wound drainage canisters are long and represent a possible strangulation hazard. The battery charger cable also represents a possible strangulation hazard. Position the Nisus NPWT System, its tubing, and cables appropriately to avoid the risk of strangulation.

Ensure the environment where Nisus NPWT System is to be used is clean and free of excessive dirt, lint, dust, and debris. Avoid using or storing Nisus NPWT System in an unclean environment. When not in use, store the device and accessories in a cool, dry place.

Continuous Therapy Versus Variable Intermittent Therapy:

Continuous Therapy is recommended for unstable structures, such as an unstable chest wall or non-intact fascia. Continuous Therapy is also generally recommended for patients at risk of bleeding, highly exudating wounds, fresh flaps and grafts, and wounds with acute enteric fistulae.

Protect Periwound Skin:

Consider the use of a skin preparation product to protect periwound skin. Do not allow wound filler to overlap onto intact skin. Protect fragile/friable periwound skin with additional hydrocolloid or other transparent film.

- Multiple layers of the transparent film dressing may decrease the moisture vapor transmission rate, which may increase the risk of maceration.
- If any signs of irritation or sensitivity to the film dressing, wound filler or tubing assembly appear, discontinue use and consult a physician.
- To avoid trauma to the periwound skin, do not pull or stretch the transparent film over the wound filler dressing during film application.
- Extra caution should be used for patients with neuropathic etiologies or circulatory compromise.

Circumferential Dressing Application:

Avoid use of circumferential dressings except in the presence of anasarca or excessively weeping extremities, where a circumferential film technique may be necessary to establish and maintain a seal. Consider using multiple small pieces of transparent film rather than one continuous piece to minimize the risk of decreased distal circulation. Extreme care should be taken not to stretch or pull the film when securing it, but let it attach loosely and stabilize edges with an elastic wrap if necessary.

When using circumferential film techniques, it is crucial to systematically and recurrently palpate distal pulses and assess distal circulatory status. If circulatory compromise is suspected, discontinue therapy, remove dressing and contact a physician.

Physician Orders

Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.

Use of the Nisus NPWT System must be prescribed by a physician per the stated indications for use. As a condition of use, the Nisus NPWT System should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which negative pressure wound therapy is being used.

Prior to placement of the Nisus NPWT System, the medical professional treating the patient must assess how to best use the system for an individual wound. It is important to carefully assess the wound and patient to ensure clinical indications for negative pressure wound therapy are met.

All orders should include:

- Wound location, size, and type
- Dressing kit type
- Negative pressure settings
- Frequency of dressing changes
- Secondary dressings

Clinical Safety and Precautions: User

The Nisus NPWT System is designed for use by licensed healthcare professionals only. Patients may be trained to perform some limited functions, but the keypad and device menus are locked by the healthcare professional to prevent the patient from changing the setting prescribed by the physician.

NOTE: Patient functions are limited to power on/off, ability to respond to any alarm condition, and navigating to troubleshooting screen (should an alarm occur).

Indications for Use

The Nisus Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material, and tissue debris.

Contraindications

The Nisus NPWT System is contraindicated for patients with:

- Malignancy in the wound
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Necrotic tissue with eschar present (NOTE: After debridement of necrotic tissue and complete removal of eschar, Nisus NPWT system may be used.)

Caution, do not place dressing directly in contact with:

- Exposed blood vessels
- Anastomotic sites
- Organs
- Nerves

Contact Information

Accelephase Wound Care
3356 Big Pine Trail, Suite D
Champaign, IL 61822

Toll Free: 800.982.1835
Fax: 800.808.8768

Use of Device: Introduction

The Nisus Instructions for Use provides information regarding safe and effective operation of the Nisus Negative Pressure Wound Therapy System. This manual may be used in training of personnel and reference for the caregiver/beneficiary. Disregarding the information on safety and use of this device is considered abnormal use.

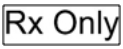
Warnings

DO NOT OPERATE THIS EQUIPMENT WITHOUT FIRST READING AND UNDERSTANDING THIS MANUAL. IF YOU ARE UNABLE TO UNDERSTAND THE WARNINGS, CAUTIONS AND INSTRUCTIONS, CONTACT A HEALTHCARE PROFESSIONAL, DEALER OR TECHNICAL PERSONNEL IF APPLICABLE BEFORE ATTEMPTING TO USE THIS EQUIPMENT. OTHERWISE INJURY OR DAMAGE MAY RESULT.

REFER SERVICING TO QUALIFIED PERSONNEL ONLY. BEFORE PERFORMING ANY MAINTENANCE TO THE CONSOLE, DISCONNECT THE POWER CORD FROM THE WALL OUTLET. GROUNDING RELIABILITY DEPENDS UPON A PROPERLY GROUNDED WALL OUTLET. DO NOT POWER UNIT IN THE PRESENCE OF FLAMMABLE GASES SUCH AS ANESTHETIC AGENTS

WARNING/CAUTION NOTICES APPLY TO HAZARDS OR UNSAFE PRACTICES WHICH COULD RESULT IN PERSONAL INJURY OR PROPERTY DAMAGE.

Symbols

	Class II, Internally Powered
	Applied Part, Type BF
	Read instructions as a mandatory action
	Do not dispose
IP22	Ingress protection - protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water
	Intertek registered certification mark of nationally recognized testing laboratory (NRTL)
	Used canisters are considered biohazardous and should be disposed of accordingly after use.
	Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.
	**MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment**

Warnings and Safety Standards

Read all instructions prior to use. When using an electrical medical device, basic safety precautions should always be followed. To reduce the risk of burns, electrocution, fire, and/or injury to persons using this device:

- ALWAYS unplug the device immediately after using or once charging is complete.
- Do not use while bathing or store product where it can fall into a tub or sink.
- Do not place or drop into water or other liquid.
- Do not retrieve the device in the event is has fallen into water. Unplug immediately.
- The device should not be left unattended when plugged in.
- Supervision is recommended when this product is used near infants and children.
- The device should only be used for its intended use as described in this manual.
- Do not use accessories and components unless recommended by Cork Medical Products.
- Do not operate this device if it has been dropped, damaged or submerged into water.
- Do not use the battery charger if the cord and/or plug is damaged.
- Keep the battery charger cord away from heated surfaces.
- Do not operate the device if drowsy or impaired.
- Unplug the battery charger from the outlet when not in use.
- When not in use, store the device and accessories in a cool, dry place.
- Do not attempt to service or repair the device. Contact your dealer or Cork Medical Products in these circumstances.

The use of battery charger and accessories other than those identified, provided, and specified by Accelephase may result in increased electromagnetic emissions or decrease the immunity of the NPWT pump.

When Nisus accessories and NPWT products (Type BF applied part) are used, patient leakage current will not exceed limits set for this device.

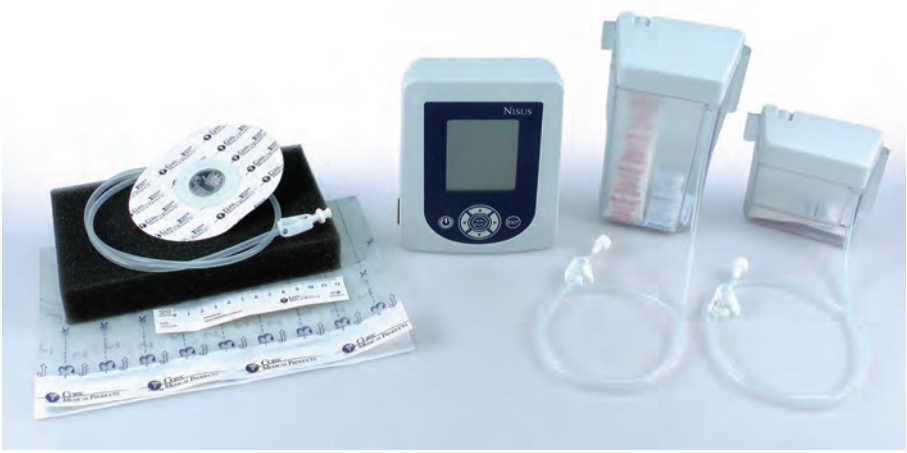
The micro-USB port is covered and strictly limited for use by Accelephase. Do not remove sticker.

The Nisus NPWT pump has been tested and complies with IEC 60601-1 3rd edition Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.

MR ***Magnetic Resonance Imaging (MRI):*** MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment. Do not take the Nisus NPWT System in to the MRI environment. The dressing can typically remain on the patient with minimal risk in an MRI environment.

Hyperbaric Oxygen Therapy (HBO): The Nisus NPWT System is not designed for the HBO environment and should be considered a fire hazard. Disconnect the Nisus NPWT System and replace the wound dressing with another HBO compatible material during the hyperbaric treatment. If dressing is left in place, cover the luer lock end with gauze and leave Port unclamped. If treatment is longer than 2 hours, wound dressing must be changed.

Nisus NPWT System Components and Accessories



WOUND DRESSING KIT NISUS PUMP 500 ML CANISTER 250 ML CANISTER

Nisus NPWT System Accessories

- Nisus NPWT Wound Dressing Kits
- Nisus Canisters
- Nisus NPWT Wound Dressing Accessories


TARGET PRESSURE
TIME & DATE
TOTAL RUN TIME
BATTERY INDICATOR
THERAPY MODE
LOCK INDICATOR
NISUS
02:37 PM
Apr 24, 2018 70%
125 mmHg
Run Time: 0h:42m
Continuous
MENU SELECT
EXIT
CHARGING LED
EXIT BUTTON
POWER CHARGER PORT
MENU/SELECT BUTTON
POWER BUTTON
UP/DOWN & LEFT/RIGHT BUTTONS

Use of Device: Battery

The Nisus NPWT Pump is designed to run on a lithium-ion rechargeable battery.
The pump can also operate with the provided battery charger plugged in.

Specifications: 14.8volt / 16.8volt max, 1300mah, Lithium Polymer pack with safety circuit

Battery Charger

ONLY USE THE BATTERY CHARGER PROVIDED BY CORK MEDICAL PRODUCTS.

Once the charger is attached to a Nisus pump, the charging process will begin.
The lithium ion charger has an LED status indicator to inform the user of its status.

GREEN-indicates no charging needed
RED-indicates charging in process

The battery status and percentage of life are displayed on the pump LCD in the upper right hand corner of the display.

When the battery life is less than 20%, an alarm and notification shall display indicating that the user needs to plug in the battery charger to recharge the battery.

If the battery charger is not plugged in at this time, a critical battery alarm will sound until the user connects the battery charger or the pump will power down.

Applying NPWT Wound Dressing:

Use only Nisus NPWT Wound Dressing Kits with the Nisus NPWT System. Follow instructions for use when applying the wound dressing provided with the kits.

Attaching the Drainage Canister to Pump:

Use only Nisus NPWT Canisters with Nisus NPWT System.

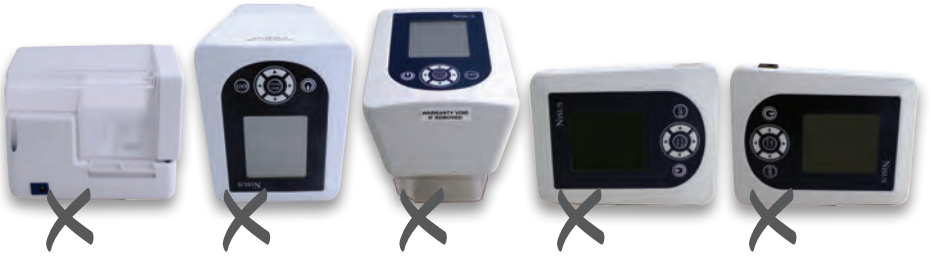
1. Canisters are available in two sizes, 250-mL or 500-mL. Attach the canister to the back of the Nisus NPWT System by hooking the canister onto the pump hinge post then rotating to lock the canister into place.
2. The drainage canister is snapped into place and will be secure once properly attached by the user. Gently tug on the canister to ensure it is secured.
3. The canister includes drainage tubing with a luer fitting. Attach the drainage tubing from the canister to the drainage tubing from the wound dressing kit.
4. Once the canister is in place and the drainage tubing is connected to the wound dressing kit, the Nisus NPWT System may then be powered on.
5. Within a few days, the canister will fill with wound drainage. Once full, alarm will sound – discard full canister and replace with a new, unused canister.

Nisus NPWT Pump – General Settings:

The Nisus device must be used only in the upright position.

Correct Orientation:

Incorrect Orientation:



Device Operations

1. The Nisus NPWT System has a membrane switch keypad which is used to help the user navigate the device. The membrane switch has the following keys: Power, Menu/Select, Exit, Up Arrow, Down Arrow, Left Arrow, and Right Arrow. An image of the keypad is listed below:

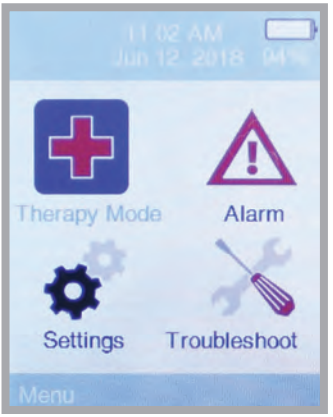
2. Power on the Nisus NPWT System by pressing the POWER button on the keypad. NOTE: When powered on, the pump shall run according to the previous pump mode and pressure settings. If the pump is being powered on for the first time, the default setting is Continuous Mode at a pressure of 125-mmHg.

3. In the event the pump needs to be powered down, press and hold the POWER button for 3 seconds.

4. The setting of the pump can be locked (and unlocked) by holding the up and down arrow keys simultaneously.

5. The pump can be put into sleep mode by holding down the left and right arrow keys simultaneously. When the pump goes into sleep mode, an "S" will appear in the footer of the screen and the screen will shut down after a few minutes. The pump will continue to run. To wake the screen, press any button. To take the pump out of sleep mode, press and hold the left and right arrow keys.

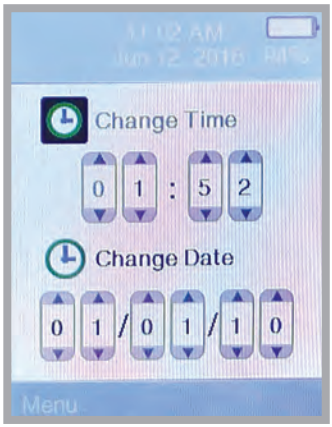
6. To adjust general settings, press the "MENU / SELECT" button on keypad.
7. The menu screen displays:



8. Use left and right arrow keys on keypad to highlight "Settings". Press "MENU/SELECT" button on keypad to select.
9. In the Settings screen, there are several setting options. The items listed are: Language, Change Date/Time, Factory Admin, Software Version, and Run Time.

10. The only settings which can be adjusted in the setting options are date and time. Use up and down arrow keys on the keypad to highlight "Change Date/Time". Press"MENU/SELECT" button on keypad to select.

11. Use up and down arrow keys on the keypad to highlight "Change Time" or "Change Date". Press "MENU/SELECT" button on keypad to select.



12. Use left and right arrow keys on keypad to highlight value to change. Use up and down arrow keys on keypad to change date and time settings. Press "MENU/SELECT" button on keypad to select.
11. Once date and time are set, press "EXIT" on keypad to return to main screen.

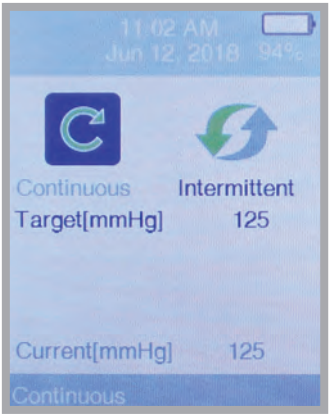
Nisus NPWT System – Therapy Mode Settings:

1. Power on the Nisus NWPT System by pressing the POWER button on the keypad. Upon powering on, the pump will operate at most recent therapy settings. The default settings are Continuous Mode at pressure of 125-mmHg.

2. To adjust therapy mode and pressure settings, press the "MENU / SELECT" button on keypad.
3. The menu screen displays:

4. Use left and right arrow keys on keypad to highlight "Therapy Mode". Press "MENU/SELECT" button on keypad to select therapy mode.

5. The therapy mode screen displays:



6. Use left and right arrow keys on keypad to highlight either "Continuous" or "Variable Intermittent" therapy mode settings. Press "MENU/SELECT" button on keypad to select desired therapy mode settings.

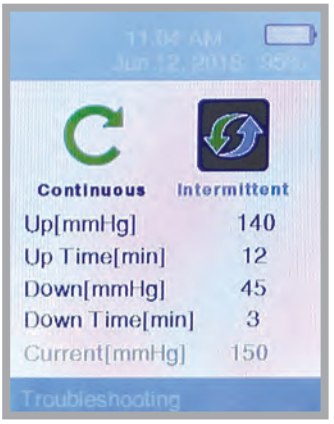
Continuous Mode

7. In the Continuous Mode settings screen, only the target pressure can be adjusted.

8. Use left and right arrow keys on keypad to adjust the pressure up or down to desired settings. Pressure options are available in increments of 5-mmHg. The range of pressure settings can be adjusted from 40-mmHg to 200-mmHg.
9. Once desired pressure has been chosen, press "MENU/SELECT" button on keypad. This becomes the target pressure setting and therapy mode. The current pressure of the pump is displayed next to "Current[mmHg]."
10. Press the "EXIT" button on keypad to return to main screen. The pressure setting chosen is displayed on the middle of the screen. "Continuous" is displayed in the footer of the screen.

Variable Intermittent Mode

11. In the Variable Intermittent Mode settings screen, there are several setting options. The setting options are: up pressure, up time, down pressure, and down time.



12. Use up and down arrow keys on keypad to select the Variable Intermittent setting options to adjust.

13. Use left and right arrow keys on keypad to adjust to the desired pressure and time settings. Pressure options are available in increments of 5-mmHg. The range of pressure settings can be adjusted from 40-mmHg to 200-mmHg. Time settings are available in increments of 1-minute and can be adjusted from 1-minute to 60-minutes.

14. Once desired pressures and times have been chosen, press "MENU/SELECT" button on keypad. This becomes the pressure and time settings for the variable intermittent therapy mode. The current pressure of the pump is displayed next to "Current[mmHg]."

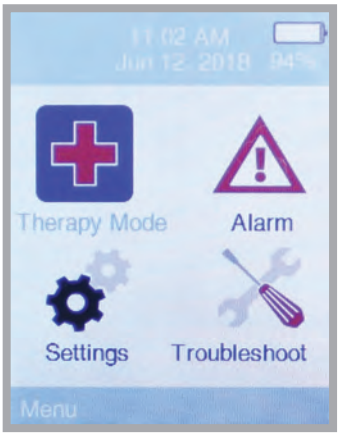
15. Press "EXIT" button on keypad to return to main screen. Up time and down time settings are displayed on the screen. The current pressure setting is displayed on the middle of the screen. "Variable Intermittent" is displayed in the footer of the screen.

Navigating Troubleshooting Information

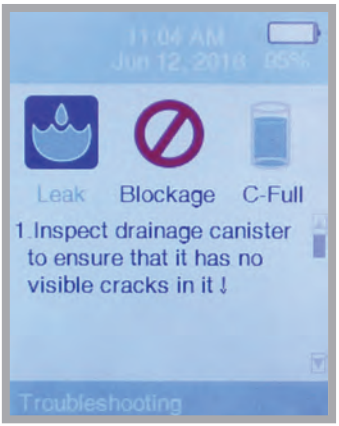
1. Power on the Nisus NPWT System by pressing the POWER button on the keypad.

2. To review troubleshooting, press the "MENU / SELECT" button on keypad.

3. The menu screen displays:



4. Use left and right arrow keys on keypad to highlight troubleshooting for Leak, Blockage, and Canister Full.

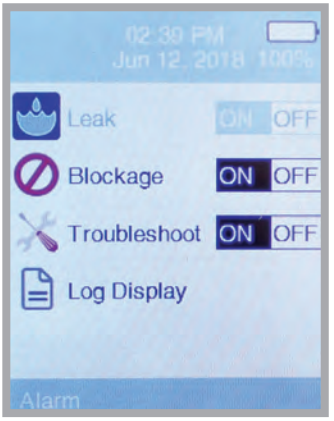


5. Use up and down arrow keys on keypad to review troubleshooting for each item.
6. Press "EXIT" button on keypad to return to main screen.

Alarm Settings

1. Power on the Nisus NPWT System by pressing the POWER button on the keypad.
2. To adjust alarm settings, press the "MENU / SELECT" button on keypad.
3. The menu screen displays:

4. Use left and right arrow keys on keypad to highlight "Alarms". Press "MENU/SELECT" button on keypad to select.
5. In the Alarms screen, there are several setting options. The items listed are: Turn Off/On Leak, Blockage, and Troubleshoot.
   Selecting Log Display will show a log of 04. any alarms triggered during use.



06. Alarms can be turned off and on for the following alarm conditions: Leakage and Blockage. The Canister Full alarm cannot be turned off. Use up and down arrow keys on the keypad to highlight desired alarm. Press "MENU/SELECT" button on keypad to select.
07. Use left and right arrow keys on keypad to highlight value to change. Press "MENU/SELECT" button on keypad to select.
08. Once alarm settings are set, press "EXIT" on keypad to return to main screen.

What Happens When Device Alarms

1. The Nisus NPWT pump device provides audible and visual alarms to patients regarding low battery, pressure leakage, system blockage, and when a collection canister is full. When an alarm condition occurs, a window shall display the specific alarm and give the patient the option to mute the alarm temporarily while troubleshooting and correcting the issue.

This is true for all alarm conditions except critically low battery and canister full. When battery life is critically low, the unit will power down if not connected to the battery charger. When canister is full, canister must be changed to resolve the alarm.

2. Mute "yes" or "no" is selected by using left and right arrow keys on keypad, followed by pressing "MENU/SELECT" button on keypad. The troubleshooting for the particular alarm condition is then displayed on screen. The troubleshooting text for 2. each alarm condition is also listed in this manual.

3. If the alarm was muted and the alarm condition was not corrected, the alarm shall display and sound again 5 minutes later.

What Happens When Device Alarms

The table below describes all the error messages and alarms of the Nisus device. Troubleshooting for each alarm type is described below:

Alarm Types	Notification	Likely Cause(s)
Low Battery 	Visual message displayed along with audible alarm.	**Battery life at or below 20%.** **Pump should be connected to battery charger and plugged in as soon as possible.**
Critical Battery 	Visual message displayed along with constant audible alarm. Cannot be muted.	**Battery life is critically low.** **TAKE ACTION IMMEDIATELY BY CONNECTING TO BATTERY CHARGER AND PLUGGING IN TO PREVENT DEVICE FROM SHUTTING DOWN.**
Leakage 	Visual message displayed along with audible alarm. If muted and not corrected, visual message and audible alarm repeats within 7 minutes.	**Drainage tubing not connected.** **Wound dressing not completely sealed.** **Canister not latched.** **Crack in canister.**
Blockage 	Visual message displayed along with audible alarm. If muted and not corrected, visual message and audible alarm repeats within 7 minutes.	**Pinch clamps activated.** **Drainage tubing kinked.**
Canister Full 	Visual message displayed along with audible alarm. Cannot be muted.	**Collection canister full.** **CHANGE CANISTER IMMEDIATELY TO RESOLVE ALARM**

What Happens When Device Alarms

Low Battery Alarm Troubleshooting:

1. Plug pump into power outlet using charger that was provided.
2. Do not use a switched outlet.
3. Ensure that pump is charging by watching the battery icon. It will flash with a lightning bolt when it is charging properly.

Leakage Alarm Troubleshooting:

1. Inspect drainage canister to ensure that is has no visible cracks in it.
2. Ensure that port pad tubing is connected to canister tubing at luer lock connection.
3. Listen for air leak in and around wound dressing and if heard, use transparent film to seal leak.
4. Contact medical provider if the previous interventions do not resolve alarm.
5. Remove entire dressing and place moist dressing in wound if pump is off for 2 or more hours.

Blockage Alarm Troubleshooting:

1. Ensure that both clamps are unclamped.
2. Inspect tubing to ensure that there are no kinks in tubing.
3. Ensure that the port pad does not have pressure applied directly on the dome.
4. Contact medical provider if the previous interventions do not resolve alarm.
5. Remove entire dressing and place moist dressing in wound if pump is off for 2 or more hours.

Canister Full Alarm Troubleshooting:

1. Clamp both clamps.
2. Turn pump off.
3. Disconnect canister tubing from port pad tubing at luer lock by turning luer lock counter clockwise.
4. Disposal of used canisters should follow facility policies or local ordinances relating to the handling of potentially infected or bio-hazardous materials.
5. Connect new canister tubing to port pad tubing at luer lock by turning clockwise.
6. Unclamp all tubing.
7. Turn pump on – ensure that suction is being applied by watching if the foam in the dressing is compressing into a raisin like appearance.
8. Contact medical provider if the previous interventions do not resolve alarm.
9. Remove entire dressing and place moist dressing in wound if pump is off for 2 or more hours.

Troubleshooting Malfunction At Pump:

The Nisus NPWT System should begin running after pressing the POWER button. In the event the pump does not power on, press and hold the POWER button for at least 10 seconds. Attempt to power on again. If the unit still does not power on, it is possible that the battery needs to be recharged.

Connect the provided battery charger to the device and wait at least 30 minutes. Attempt to power on the unit again with the battery charger still plugged in. If the unit powers on, continue running with the battery charger connected to fully recharge the battery. If the unit still does not power on, contact Accelephase.

Maintenance

There are no serviceable parts in the device. Do not attempt to open the enclosure. Contact your distributor if service is required.

Before each usage, inspect the device for visible signs of damage. Please contact your distributor if visible signs of abuse and damage have been observed.

The Nisus NPWT Pump shall be serviced annually by Accelephaese. Failure to comply will void the product warranty. Only Nisus authorized resources are able to perform diagnostic maintenance.

Cleaning:

Take precautions to keep Nisus NPWT System components free of dirt, dust, lint, and debris. Maintain cleanliness of the system.

Always adhere to your facility policies on cleaning medical equipment.

Please use bactericidal cleaning product. Place bactericidal solution on a clean cloth and wipe the outer surface of the device. After recommend kill time of agent, wipe the device off with clean, dry cloth.

Do not submerge the device in any liquid and allow no solution to enter the internal portion of the pump. Turn pump off prior to cleaning the device and ensure the device is not plugged into the wall charger during the cleaning process.

If any liquid penetrates the internal portion of device, return to your distributor for service.

Returning the Device:

Prior to returning the device, the product must be cleaned in line with the steps defined within this manual.

All used canisters shall be disposed. Disposal of used canisters should follow facility policies or local ordinances relating to the handling of potentially infected or bio-hazardous materials.

The device should be returned in the original packaging and include the provided battery charger.

Disposal of Device:

The Nisus NPWT device contains batteries. Do not dispose of the device by placing it in the trash. Return the device to Accelephase.

Disposal for Li-Ion Battery Pack:

The rechargeable battery contains the following components that must be disposed of in accordance with local regulations: Lithium Ion cells.

Caution: When the battery is worn out, insulate the connector terminals with adhesive tape or similar material before disposal.

Misuse or improper disposal of the battery pack may cause the battery to become very hot, ignite, or explode. When disposing of a battery pack, contact your local waste disposal service provider regarding local restrictions on the disposal and recycling of batteries.

Electromagnetic Compatibility

Although the Nisus NPWT Pump conforms with the intent of the directive 89 / 336 / EEC in relation to Electromagnetic Compatibility (EMC), all electrical equipment may produce interference. If interference is suspected, move equipment away from sensitive devices or contact the manufacturer.

The Essential Performance Requirements of the Nisus NPWT System, Model CMPP-100, are to maintain 40 – 200-mmHg +/- 10mmHg (60 second average) vacuum pressure with no false alarms.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Radios, cell phones, and similar devices may affect this equipment and should be kept at least 6.5 feet (2 meters) away from the equipment.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in the following tables.

The following tables document compliance levels and guidance from the IEC 60601-1-2: 2007 Standard for the electromagnetic environment in which the Nisus NPWT Pump should be used in a clinical environment. The Nisus NPWT Pump also meets the criteria for Electromagnetic Compatibility related to use in the home care environment, as established in IEC 60601-1-11: 2010 Standard.

Electromagnetic Compatibility

Product Family		Application			
IEC 60601-1-2		Electromagnetic compatibility requirements and tests for Medical Electrical Equipment, which calls out CISPR and IEC required tests below			
Basic Standards (Emissions)		**Port Tested**	**Test Descriptions**	**Results**	**EUT Configuration per Test**
CISPR 11		Enclosure	Radiated Emissions, Class B	Pass	2
		AC Power Ports	Conducted Emissions, Class B	Pass	2
IEC 61000-3-2	EN61000-3-2	AC Power Ports	Harmonic Current Emission (through Amendment 14 of IEC 61000-4-7)	Pass	1
IEC 61000-3-3	EN61000-3-3	AC Power Ports	Voltage Fluctuation and Flicker	Pass	1
Basic Standards (Immunity)		**Port Tested**	**Test Descriptions**	**Results**	**EUT Configuration per Test**
IEC 61000-4-2	EN 61000-4-2	Enclosure	ESD: ±6kV Contact, ±8kV Air Discharge	Pass	2
IEC 61000-4-3	EN 61000-4-3	Enclosure	Radiated RF Immnity: 3V/m, 80% AM @ 1kHz, 80-2700 MHz 1% step	Pass	1
IEC 61000-4-4	EN 61000-4-4	AC Power Ports DC Power Ports	EFT Burst: ±0.5kV - ±2kV	Pass	2
IEC 61000-4-4	EN 61000-4-4	Signal (>3m), Control & Measurement (>3m)	EFT Burst: ±0.5kV - ±1kV	Pass	N/A[1]
IEC 61000-4-5	EN 61000-4-5	AC Input Ports	Surge: ±1kV Differential Mode (line to line) ±2kV Common Mode (line to ground)	Pass	2
IEC 61000-4-5	EN 61000-4-5	Signal (>30m)	Surge: ±2kV Common Mode	Pass	N/A[1]
IEC 61000-4-6	EN 61000-4-6	AC Power Ports DC Power Ports	Conducted RF Immunity: 3 V 80% AM Modulation @ 1kHz	Pass	1
IEC 61000-4-6	EN 61000-4-6	Signal (>3m), Control & Measurement (>3m)	Conducted RF Immunity: 3 V 80% AM Modulation @ 1kHz	Pass	N/A[1]
IEC 61000-4-8	EN 61000-4-8	Display & Magnetic Sensors	Magnetic Field Immunity: 3 A/M	Pass	2
IEC 61000-4-11	EN 61000-4-11	AC Input Ports	Voltage Dips & Short Interruptions: 70%, 40%, & 5% nominal for 500ms, 100ms, 10ms, and 5 sec (50Hz)	Pass	2

[1] EUT contains no signal cables.

Electromagnetic Compatibility

The Nisus NPWT Pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Recommended separation distances between portable and mobile RF communications equipment and the Nisus NPWT Pump			
The Nisus NPWT Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Nisus NPWT Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Nisus NPWT Pump as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter	Separation distance according to frequency of transmitter in meters		
W	**150 kHz to 80 MHz** **$d = 1.2\sqrt{P}$**	**80 MHz to 800 MHz** **$d = 1.2\sqrt{P}$**	**800 MHz to 2.5 GHz** **$d = 2.3\sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.2	1.2	2.3
10	3.8	3.8	7.4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separate distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: Guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects, and people.			

Electromagnetic Compatibility

Guidance and manufacturer's declaration – electromagnetic immunity			
The Nisus NPWT Pump is intended for use in the electromagnetic environment specified below. The customer or user of the Nisus NPWT Pump should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150K – 80 MHz 3V/meter 80 MHz – 2.5 GHz	3Vrms 150K – 80 MHz 3V/meter 80 MHz – 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Nisus NPWT Pump, including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter. Recommended Separation Distance Battery Operated Device $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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 (1), should be less than the compliance level in each frequency range (2). Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects, and people.			
(1) Field strengths from fixed 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 theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Nisus NPWT Pump is used exceeds the applicable RF compliance level above, the Nisus NPWT Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Nisus NPWT Pump. (2) Over the frequency range 150kHz, field strengths should be less than 3V/m.			

Technical Specifications

Nisus NPWT Canister
Shelf Life: 1 year from date of manufacture
Provided Non-Sterile

Nisus NPWT Wound Dressing Kit
Expiration: 2 years from date of sterilization
Sterilized via Ethylene Oxide and Gamma

Nisus NPWT Pump
Serviced annually by Accelephase
Minimum negative pressure: 40-mmHg
Maximum negative pressure: 200-mmHg
Suction capacity: ~8-10 L/min

Pressure settings in either Continuous or Variable Intermittent modes can be set from 40-mmHg up to 200-mmHg. Pressure setpoints are accurate to +/- 10-mmHg.

The Nisus NPWT System default settings are Continuous Mode at a pressure of 125-mmHg.

WARNING: **REFER SERVICING TO QUALIFIED PERSONNEL ONLY. THE DEVICE SHALL NOT BE MODIFIED IN ANY WAY.**

Dimensions / Weight
Dimensions: 6" (H) x 4.25" (W) x 3" (D) Weight: 2 lbs

Environmental Conditions
Operating Temperature: 18°C to 34°C (65°F to 94°F)
Operating Relative Humidity: 10% - 95%
Operating Pressure: 700-hPA – 1060-hPA (10.15-atm – 15.37-atm) atmospheric pressure

Storage & Shipping Conditions
Storage Temperature: -25^{0}C (-13^{0}F) without relative humidity control to 44^{0}C (111^{0}F) up to 93% relative humidity (non-condensing)

The above storage and shipping conditions apply to the Nisus NPWT between uses.

Patient Protection
Type BF

Compliance
IEC 60601-1:2005, 3rd Edition (AAMI ES 60601-1, CAN/CSA C22.2 No. 60601-1-08, EN 60601-1)
IEC 60601-1-2:2007
IEC 60601-1-6:2010 / IEC 62366:2010
IEC 60601-1-11:2010

Limited Warranty

The Nisus NPWT Pump and Nisus Battery Charger have two-year limited warranties.

Accelephase Wound Care, LLC
3356 Big Pine Trail, Suite D, Champaign, IL 61822
1.800.982.1835