CardinalHealth™

NPWT PRO and PRO to GO

CLINICIAN USER MANUAL

CAUTION: This Cardinal Health™ NPWT PRO / PRO to GO (herein after referred to as the Cardinal Health™ NPWT PRO family of devices) CLINICIAN User Manual is not a guarantee or warranty. It is intended only as an operational guide.
For additional information and questions, please contact the Cardinal Health Customer Service department at 1.866.484.6798.

In order for the Cardinal Health™ NPWT PRO family of devices to provide safe, reliable, and proper performance, the following conditions must be met. Failure to comply with these conditions will void all pertinent warranties.

- There are no user serviceable components in the Cardinal Health™ NPWT PRO family of devices. All assembly, operation, adjustment, modification, maintenance, and/or repair must be carried out only by qualified personnel authorized by Cardinal Health.
- The electrical installation of the room in which the device will be used complies with the appropriate national electrical standards.
- The product must be used in accordance with this manual and all associated labeling and the Instructions for Use.
- Any device that does not function as expected must be returned to Cardinal Health.

Notice to Users: CAUTION: Federal law restricts this device to sale by or on the order of a physician. As with any prescription medical device, failure to follow product instructions or changing settings and performing therapy applications without the express direction and/or supervision of a trained clinical caregiver may lead to improper product performance and the potential for serious or fatal injury.

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1. Introduction

1.1 Indications

The Cardinal Health™ NPWT PRO and PRO to GO systems are an integrated wound management system, indicated for the application of continual or intermittent negative pressure wound therapy to the wound as the device may promote wound healing by the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials. The Cardinal Health™ NPWT PRO and PRO to GO systems are intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The Cardinal Health™ NPWT PRO and PRO to GO systems are intended for use in acute, extended and home care settings.

1.2 Contraindications

The Cardinal Health™ NPWT PRO and PRO to GO is contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistulas, or necrotic tissue with eschar present. Do not place the Cardinal Health™ NPWT foam dressing over exposed blood vessels or organs.

1.3 Precautions

Precautions should be taken for patients with infected wounds, active bleeding, difficult wound hemostasis, or who are on anticoagulants. When placing the Cardinal Health™ NPWT foam dressing in close proximity to blood vessels or organs, take care to ensure that they are adequately protected with overlying fascia, tissue or other protective barriers. Exposed tendon, nerves or blood vessels should be protected by moving available muscle or fascia over them or by a layer of synthetic material. Greater care should be taken with respect to weakened, irradiated or sutured blood vessels or organs. Bone fragments or sharp edges could puncture a dressing barrier, vessel or organ. Wounds with enteric fistula require special precautions in order to optimize therapy.

1.4 Additional Precautions

- **Defibrillation:** Remove the Cardinal Health™ NPWT Dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit electrical current transmission and/or patient resuscitation.
- **Magnetic Resonance Imaging (MRI):** The Cardinal Health™ NPWT PRO family of devices is not MRI-compatible. Do not take the device into the MRI area.
- **Hyperbaric Oxygen Therapy (HBO):** NEVER allow a device—whether on or off—inside a hyperbaric chamber. The device must be disconnected from the patient prior to HBO treatment.
- **Large Canisters:** Use of Large Canisters (>500ml) may increase serious risks associated with excessive fluid loss. Monitor patient status continually.
- **DO NOT USE** for infants or other patients with low fluid volume, nor for patients at high risk of major hemorrhage.
- During Negative Pressure Wound Therapy, the Cardinal Health™ NPWT PRO family of devices and Cardinal Health™ NPWT Dressing are a closed system and are NOT vented to atmosphere.
- During Negative Pressure Wound Therapy, when a canister fills with fluid, it should be replaced immediately as fluids such as wound exudate will not be removed from the dressing once the canister is full.

1.5 Safety Tips

KEEP THERAPY ON

The Cardinal Health™ NPWT PRO family of devices should be operated at least 22 hours out of every 24 hour period. Remove the Cardinal Health™ NPWT foam dressing if therapy is terminated or is off for more than 2 hours in a 24 hour period.

DRESSING CHANGES

Clean the wound per physician order prior to dressing application. Routine dressing changes should occur every 48 to 72 hours. Dressing changes for infected wounds should be accomplished more frequently than 48 to 72 hours. Always replace with sterile disposables from unopened packages. Follow established institution protocols regarding clean versus sterile technique.

MONITORING THE WOUND

Inspect the dressing frequently to ensure that the foam is collapsed and that therapy is being delivered in a consistent manner. Monitor wound exudates for signs of active bleeding. Monitor periwound tissue and exudate for signs of infection or other complications.* Extra care and attention should be given if there are any signs of possible infection or related complications. Infection can be serious. With or without the Cardinal Health™ NPWT PRO family of devices, infection can lead to many adverse complications including pain, discomfort, fever, gangrene, toxic shock, septic shock, and various other complications. With signs of more serious complications of infection, discontinue the use of the Cardinal Health™ NPWT PRO family of devices until the serious infection is diagnosed and properly treated.

DISCOMFORT/ADHERENCE

If patient complains of discomfort during dressing change, consider pre-medication, use of a non-adherent wound contact layer prior to foam placement or irrigation of a topical anesthetic agent such as 1% Lidocaine prior to dressing removal.

UNSTABLE STRUCTURES

Use the lowest pressure setting on the Cardinal Health™ NPWT PRO family of devices over unstable body structures such as unstable chest wall or non-intact fascia.

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 the use of the Cardinal Health™ NPWT PRO family of devices to help minimize sensory stimulation.

UNDERLYING STRUCTURES

Underlying structures must be covered by natural tissues or synthetic materials that form a complete barrier between the underlying structures and the Cardinal Health™ NPWT Dressing.

Cardinal Health™ NPWT DRESSING USE

The Cardinal Health™ NPWT Dressings distributed by Cardinal Health are to be used exclusively with the Cardinal Health™ NPWT PRO family of devices.

NOTE: All dressing components of the Cardinal Health™ NPWT Dressing kit are packaged sterile. The decision to use clean versus sterile/aseptic technique is dependent upon wound pathophysiology and physician/clinician preference. All components of the Cardinal Health™ NPWT PRO disposable set are made without natural rubber latex.

Be sure to comply with all other **1.2 CONTRAINDICATIONS** and **1.3 PRECAUTIONS** for the Cardinal Health™ NPWT PRO family of devices.

* Signs of possible infection may include fever, tenderness, redness, swelling, itching, and rash, increased warmth in the wound area, sudden increase in pain, purulent discharge or a strong odor. Nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucous membrane, disorientation, high fever (>102°F, 38.8°C), refractory hypotension, orthostatic hypotension, or periwound induration (a sunburn-like rash) may be added signs of more serious complications of infection.

WARNING: Do not pack the Cardinal Health™ NPWT foam dressings into any areas of the wound. Forcing dressings in a compressed manner into any wound is contrary to approved protocols.

1.6 Features

Easy-to-use "One-Touch" Operation: Therapy activation and change of pressure settings can be accomplished with the push of a button. Therapy settings can be locked by the caregiver (see **4.8 THERAPY SELECTION LOCK/UNLOCK**). Lighted LEDs clearly indicate current therapeutic settings.

Light Weight/Impact Resistant: The Cardinal Health™ NPWT PRO family of devices weighs only 0.9 lb. (0.43 Kg) and can be easily carried and transported. The polymer enclosure is impact resistant to help prevent damage from dropping.

NoiseGuard: Device is virtually silent in its normal operation with a well-sealed dressing.

PowerGuard: An internal battery provides up to 24 hours of operation from a single full-charge. Battery charges while device is operating with the AC adapter. While running on battery, a low-battery alarm will sound and the front-panel LED display will indicate a low battery alarm condition when remaining capacity of the battery is less than 20%.

Self-limiting Pump: The pump is designed to mechanically self-limit the amount of suction that can be applied to the wound site. Electronic sensors limit the maximum applied suction to -200 mmHg (±10%).

Intermittent Mode: The Cardinal Health™ NPWT PRO family of devices can be set to operate intermittently (5-minute ON/2-minute OFF cycle). Device maintains pressure at -25 mmHg during the "OFF" state to prevent loss of dressing seal.

TherapyGuard: Automated alarms for leak/low pressure, full canister and low battery. Alarms provide both a visual and audible indication. Alarms will self-reset once a problem is corrected or can be manually reset by turning the therapy device OFF and ON. Audible alarms can be muted for five minutes by pressing the MUTE button.

SpeedConnect™: Eight-foot single-lumen tubing set with adhesive port facilitates connection to dressing.

Single Patient Use Canisters: 300cc and 500cc canisters with and without gel solidifier for normal and highly exudating wounds.

CAUTION: Use of large canisters (>500cc) may increase serious risks associated with excessive fluid loss. Monitor patient status continually. DO NOT USE for infants or other patients with low fluid volume, nor for patients at high risk of hemorrhage.

2. Care & Cleaning

2.1 Introduction

The following instructions are the Cardinal Health recommended cleaning and infection control procedures for the Cardinal Health™ NPWT PRO family of devices. The Caregiver should review this manual in its entirety before attempting to use the product. Carefully read the **1.3 PRECAUTIONS** and **1.5 SAFETY TIPS** in the **1. INTRODUCTION** section before attempting to perform cleaning procedures on the Cardinal Health™ NPWT PRO family of devices.

2.2 Protective Equipment

Universal Safety Precautions should be used to minimize the risk of infection and contact with contaminated blood or bodily fluids during the dressing changes or disposal and cleaning of the device; it is important to protect all exposed skin and mucous membranes.

The protective equipment includes:

- Disposable gloves (latex or latex-free).
- Protective eyewear to help prevent splashing of cleaning solutions and/or blood or bodily fluids.
- Protective mask (to protect the nose and mouth from inadvertent fluid ingress).
- Disposable impervious gown (if splashing of blood or bodily fluids is possible).

2.3 Disposal

After patient use, all disposable components of the system should be treated as contaminated.

These include:

- The Cardinal Health™ NPWT Foam Dressing components.
- Exudate collection canister.
- Tubing, connectors and clamps.

Dispose of all disposable components in accordance with local, state, and federal regulations and institution protocols.

NOTE: Cleaning procedures should not be performed when device is connected to a patient. Disconnect the device from the patient and power source before cleaning or servicing.

2.4 Daily Care and Cleaning

Perform a visual inspection of the device. Check for any sign of contamination and in particular any fluid ingress and ensure that the device is functioning properly. If the device is not operating properly, refer to the Alarm Troubleshooting guide in the **4. OPERATING INSTRUCTIONS** section of this manual or contact Cardinal Health to replace the device.

2.5 Between Patient and Weekly Care and Cleaning

To help reduce the risk of infection and contact with contaminated blood and bodily fluids, please wear the protective equipment identified above when cleaning the Cardinal Health™ NPWT PRO family of devices.

NOTE: Always follow Universal Safety Precautions. Follow established institution protocols regarding clean versus sterile technique.

The following cleaning procedure must be performed at least once a week and must be completed between patients. The Cardinal Health™ NPWT PRO family of devices should be wiped with either a diluted solution of 5 milliliters bleach in 1 liter of warm water (approximately 1 teaspoon bleach in 1 quart water) or mild disinfectant. Use a coarse cloth and wring out any excess solution until the cloth is damp and not dripping.

A.C. ADAPTER INSPECTION

The A.C. Adapter should be inspected regularly for damage and/or unusual wear. Replace damaged or worn Power Supplies immediately. Replacement A.C. Adapters are available from Cardinal Health.

WARNING: The Cardinal Health™ NPWT PRO family of devices should only be used with the supplied A.C. Adapter. Use of an incorrectly rated adapter could create a shock hazard for the patient or caregiver and/or severely damage the device.

WARNING: Avoid spilling liquid on any part of the therapy device. Liquids can cause corrosion when left on electronic controls which can lead to failure. Component failure may cause the therapy device to operate erratically, possibly causing a potential hazard to the patient or Caregiver.

WARNING: Particular care must be taken when handling undiluted germicide concentrate or chlorine bleach, including proper shielding of eyes. Always mix by adding concentrated germicide or chlorine bleach to the water. NEVER intermix germicides or mix germicides with chlorine bleach.

3. Patient Care

It is recommended that all sections of this manual be reviewed prior to using the product. Carefully read the **1.1 INDICATIONS**, **1.2 CONTRAINDICATIONS**, **1.3 PRECAUTIONS** and **1.5 SAFETY TIPS** in the **1. INTRODUCTION** section before attempting to perform patient care with the Cardinal Health™ NPWT family of devices.

3.1 Applying the Dressing

1. Cleanse wound according to institutional protocols or physician order.
2. Debride all necrotic tissue including eschar and slough.
3. Be certain the wound has achieved hemostasis.
4. Visually examine and palpate wound bed to locate any blood vessels or delicate underlying structure in close proximity.
5. Prepare area around wound to permit adhesion of the polyurethane drape.

NOTE: If peri-wound area is excessively moist or oily, a medical-grade liquid adhesive may improve sealing. For fragile skin, use a skin sealant prior to drape application, or frame the wound with a skin barrier layer, such as a hydrocolloid or the Cardinal Health™ Drape or Cardinal Health™ SensiSkin™ Drape. Cut the drape to a size large enough to cover the foam and the barrier layer only.

6. Take measurements of the wound dimensions and note wound type. Select the appropriate foam based on wound assessment. Cut the Cardinal Health™ NPWT foam dressing to a size that is appropriate for the wound (**Figure 1**). Document the number of foam pieces used to fill the wound.

NOTE: Do not trim the foam dressing over or around the wound site to help prevent debris from the foam dressing from falling into the wound (**Figure 2**).

7. Place the Cardinal Health™ NPWT foam dressing in the wound site taking care to avoid contact with the peri-wound skin (**Figure 3**).

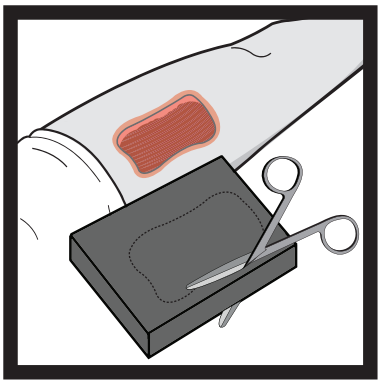


Figure 1

Figure 2

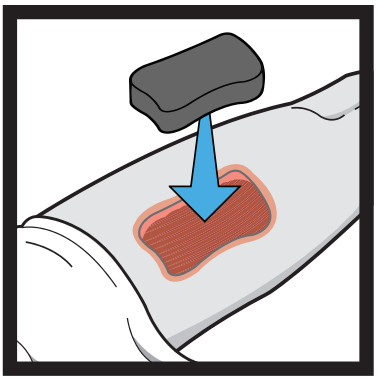


Figure 3

WARNING: Do not pack the Cardinal Health™ NPWT foam dressings into any areas of the wound. Forcing dressings in a compressed manner into any wound is contrary to approved protocols. Loosely fill all visible and invisible dead space in the wound.

NOTE: The Cardinal Health™ NPWT foam dressing should cover the entire wound base, including tunneling and undermining. However, the Cardinal Health™ NPWT foam dressing should not be in contact with intact skin.

8. Size and trim the Cardinal Health™ Polyurethane Drape to cover dressing plus a 3-5 cm border of intact skin (extra pieces of drape can be used to seal dressing leaks) (**Figure 4**).

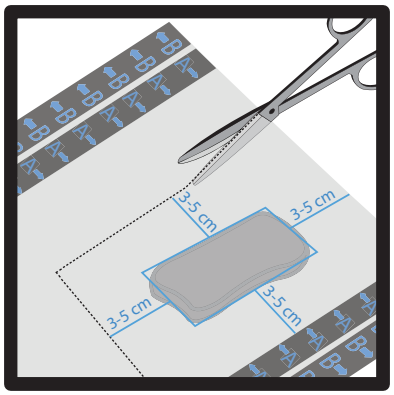
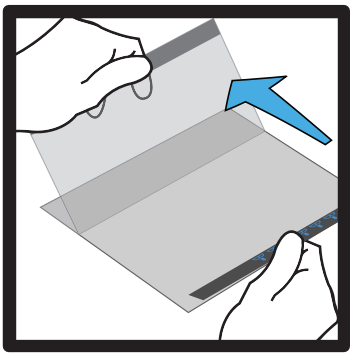


Figure 4

9. Remove the drape's release liner starting with tab A (**Figure 5**). Invert and place over the Cardinal Health™ NPWT foam dressing and peri-wound (**Figure 6**) and continue removing the contact layer with tabs B and C (**Figures 7-8**). Remove the remaining perforated tab (**Figure 9**). Gently press drape material down around the wound site and over the Cardinal Health™ NPWT foam dressing to ensure dressing is properly sealed.



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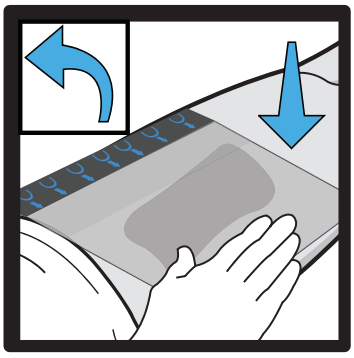

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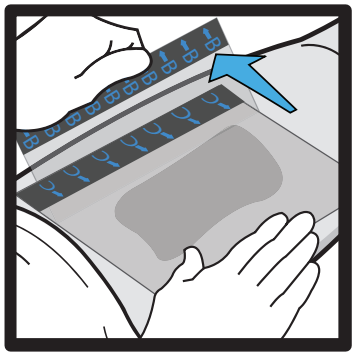

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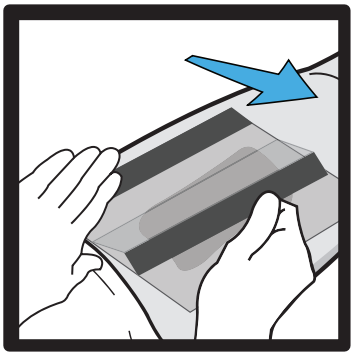


Figure 8

Figure 9

10. Cut a 1 cm diameter hole in the top of the drape at a convenient location over the foam dressing by pinching and lifting the drape (**Figure 10**).
11. Peel the backing from the SpeedConnect™ port and place it over the hole made in Step 10 (**Figures 11-12**). Using the tips of the fingers, press around the top of the SpeedConnect™ port to ensure a good seal to the dressing.
12. Connect the distal end of the SpeedConnect™ tubing with the blue tapered connector to the open port of the Canister (**Figure 13**). Gently twist and push the connector on just enough to secure and seal it.

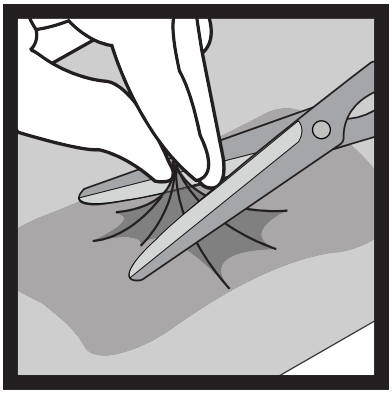
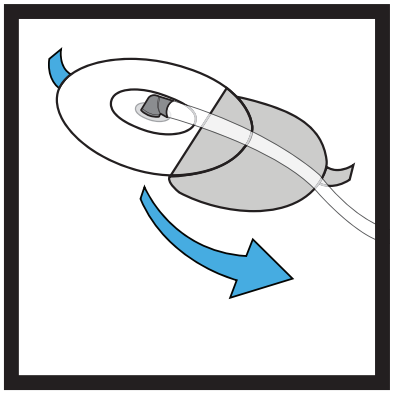


Figure 10



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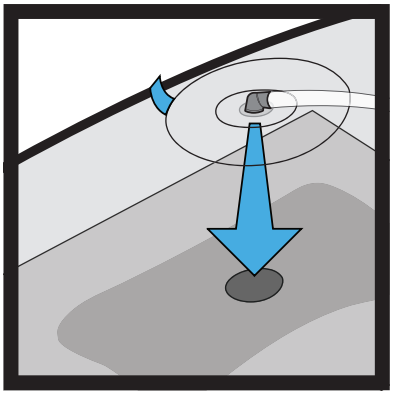

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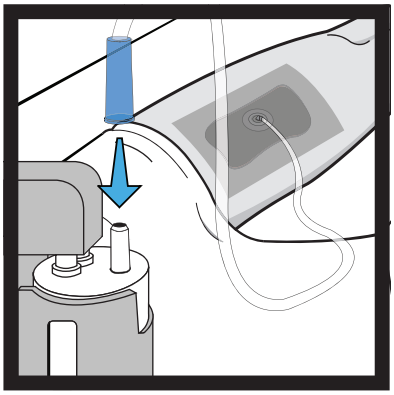


Figure 13

3.2 Canister Installation

1. Ensure that a Cardinal Health™ Canister is properly inserted in the connector located on the back side of the therapy device (**Figure 14**). The canister should "snap" into place and lock. The canister release button may need to be depressed to permit canister insertion. **NOTE:** Always use a new canister with a new patient.

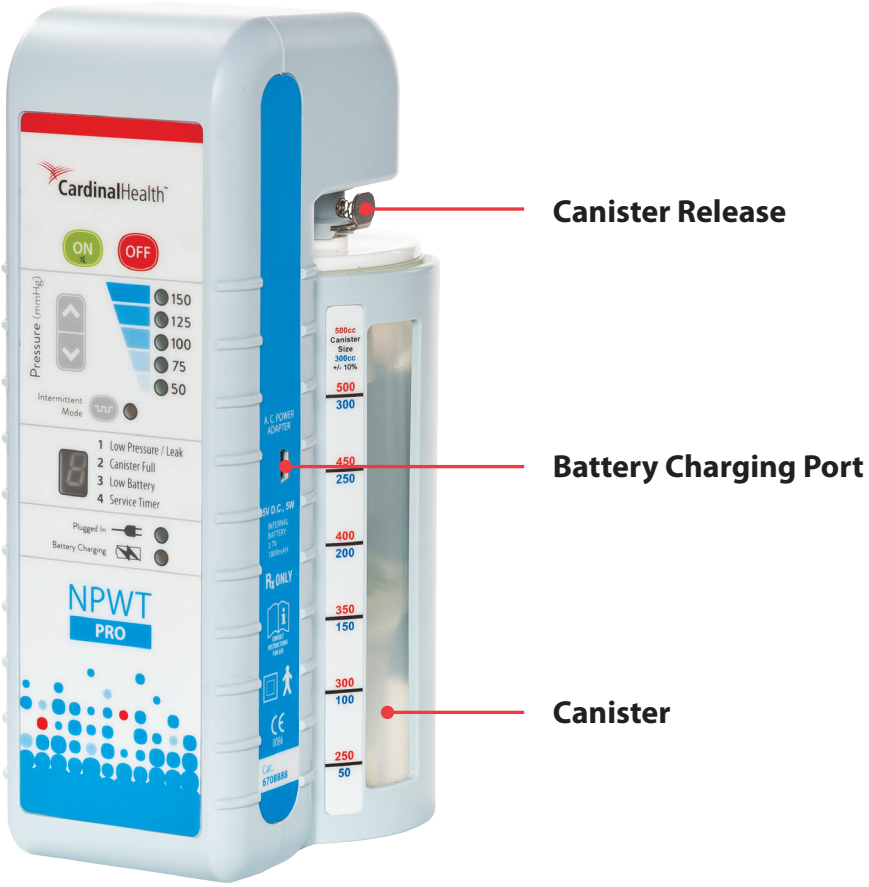


Figure 14

2. Inspect the SpeedConnect™ tubing port to ensure that they are properly connected to the Cardinal Health™ NPWT Dressing and that the connections are well sealed.

3. Connect the distal end of the SpeedConnect™ tubing with the blue tapered connector to the patient port of the Canister (**Figure 15**). Gently twist and push the connector on just enough to secure and seal it. Also, make sure that the clamp on the SpeedConnect™ tubing is open (**Figure 16**).

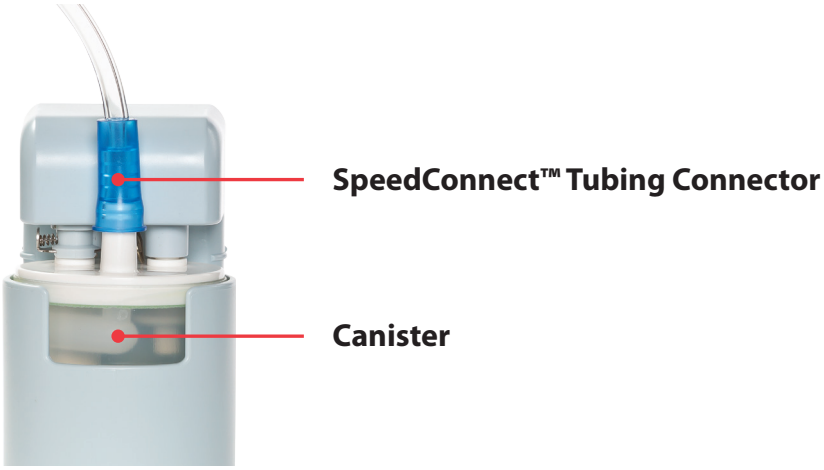


Figure 15

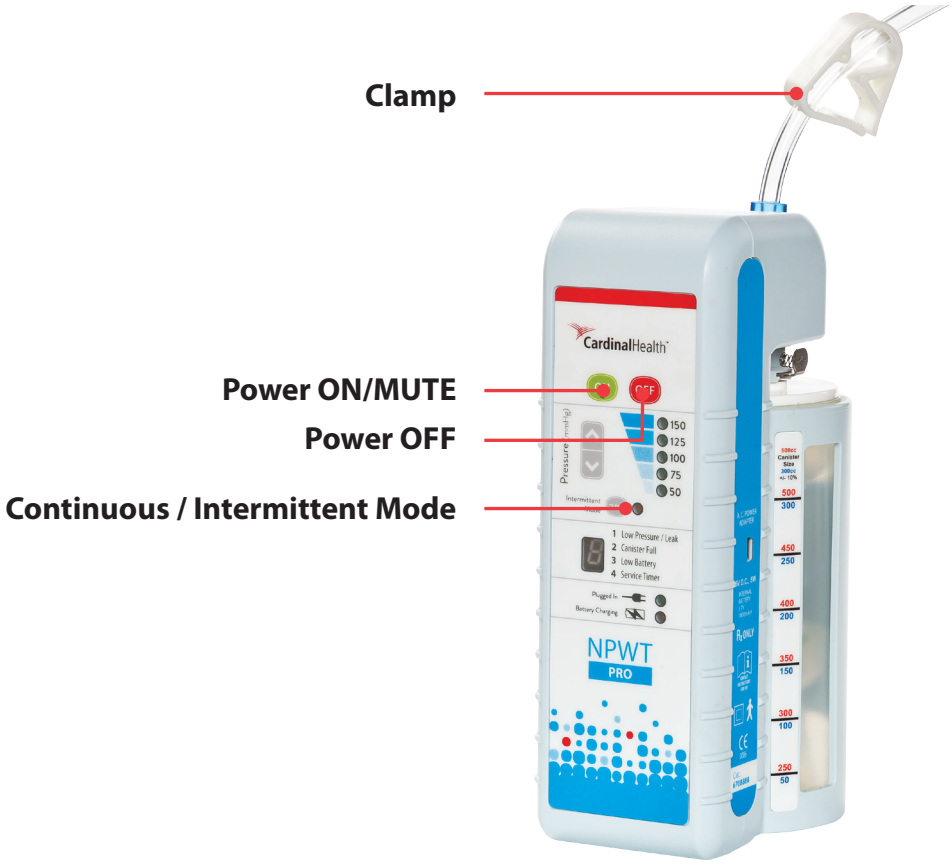


Figure 16

4. Plug the device's A.C. Adapter into a suitable 100-240 VAC, 50-60Hz, outlet. Insert the power plug into the Battery Charging Port on the side of the device (**Figure 14**). The Cardinal Health™ NPWT PRO family of devices should only be used with the supplied A.C. Adapter. Use of an incorrectly rated adapter could create a shock hazard for the patient and caregiver.

5. Verify the dressing application is correct, the tubing is connected, and the SpeedConnect™ tubing clamp is open.
6. Begin therapy (see **4. OPERATING INSTRUCTIONS**).

3.3 Canister Removal

1. Close suction tubing clamp.
2. Press the OFF button to turn the therapy off.
3. Disconnect SpeedConnect™ tubing from top of canister. Twisting the tapered connector will make removing the Suction tube from the canister easier.
4. Press canister release button and withdraw canister from bottom of device.
5. Dispose of canister according to local, state and federal regulations as well as institutional protocols.

NOTE: The canister should be replaced when full (the Canister Full alarm activates) or at least once every week to minimize the potential for contamination and production of odors.

3.4 Dressing Removal

Carefully read the **1.5 SAFETY TIPS** in the **1. INTRODUCTION** section of this guide prior to removing the dressing.
NOTE: Wounds must be carefully monitored at regular intervals. In a non-infected wound, dressings should be changed every 48 to 72 hours; but no less than 3 times per week, with the frequency of dressing change determined by the clinician. Infected wounds must be monitored continuously. For infected wounds, dressings may need to be changed more often than 48-72 hours; the dressing change interval should be based on a clinical evaluation of the wound condition rather than a fixed schedule.

1. With the device ON, lift a corner of the drape to allow air to enter the system, moving any fluid in the SpeedConnect™ tubing into the canister.
2. Close suction tubing clamp.
3. Press the OFF button to turn the therapy off.
4. Disconnect SpeedConnect™ tubing from top of canister. Twisting the tapered connector will make removing the suction tube from the canister easier.
5. Gently stretch the drape laterally and slowly pull up and away from skin. Lateral stretching of the drape will help release the adhesive and minimize trauma to the patient's skin.

NOTE: If the Cardinal Health™ NPWT foam dressing adheres to the wound during removal, refer to the **1.5 SAFETY TIPS** section of this manual.

6. Discard disposables in accordance with applicable rules, regulations and infection control protocols, and always follow Universal Safety Precautions.

3.5 Disposal of Dressings, Canister and Other Disposables

To minimize the risk of infection and contact with contaminated blood or bodily fluids during the dressing changes or disposal, it is important to protect all exposed skin and mucous membranes.
The protective equipment includes:

- Disposable gloves (latex or latex-free).
- Protective eyewear to help prevent splashing of cleaning solutions and/or blood or bodily fluids.
- Protective mask (to protect the nose and mouth from inadvertent fluid ingress).
- Disposable impervious gown (if splashing of blood or bodily fluids is possible).

After patient use, all disposable components of the system should be treated as contaminated.
These include:

- The Cardinal Health™ NPWT foam dressing and Cardinal Health™ Polyurethane Drape.
- The exudate collection canister.
- SpeedConnect™ tubing, connectors & clamps.

Dispose of all disposable components in accordance with local, state, and federal regulations and institution protocols.

4. Operating Instructions

This section contains instructions for setting and adjusting functions of the Cardinal Health™ NPWT PRO family of devices. The section explains the procedure for activating therapy and explains the major functions that are adjusted from the control panel.

Carefully read the **1.3 PRECAUTIONS** and **1.5 SAFETY TIPS** in the **1. INTRODUCTION** section before attempting to operate and adjust the Cardinal Health™ NPWT PRO family of devices.

WARNING: The Cardinal Health™ NPWT PRO family of devices should only be used with the supplied A.C. Adapter. Use of an incorrectly rated adapter could create a shock hazard for the patient or caregiver. The part number for the adapters can be found in the **6. REPLACEMENT PARTS** section of this manual.

4.1 Power ON/OFF

The ON ON and OFF OFF buttons are located on the front top of the control panel. The ON ON and OFF OFF buttons control the application of power to the device.

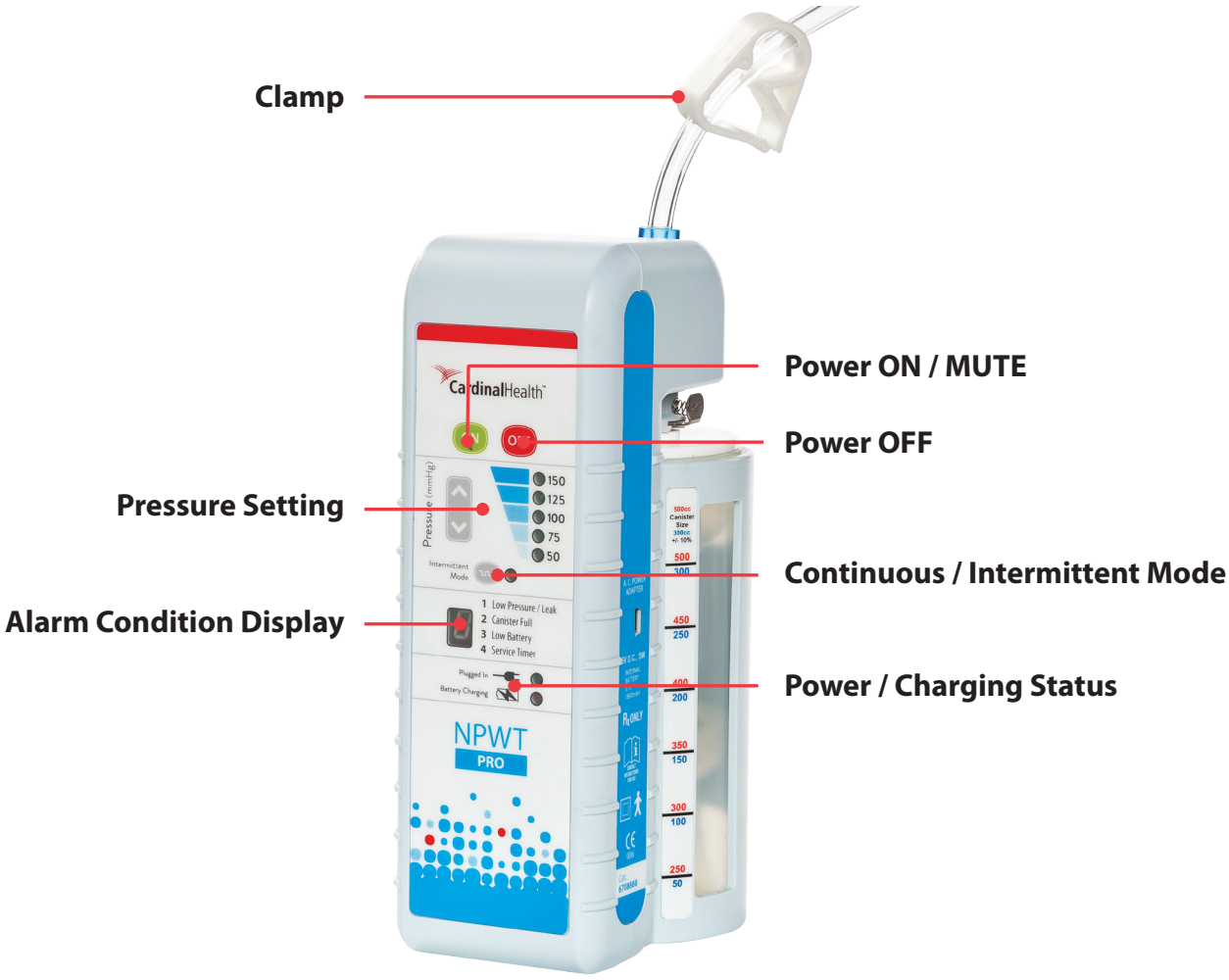


Figure 17

4.2 Power-Up Procedure

1. Verify the dressing application is correct, the tubing is connected, and the SpeedConnect™ tubing clamp is open.
2. Keep the device in an upright position. The device can be placed on a table, or attached to an I.V. pole using the I.V. Pole adapter, but kept as level with or below the wound as possible.

CAUTION: The I.V. pole clamp should only be used on poles that are in excess of 0.9" (2.2 cm) diameter and are securely attached to a bed frame or suitable stand. To ensure stability of the therapy device on the I.V. pole, it should be clamped no higher than two times the width of the pole base. The clamp should be tightened to ensure that the therapy device cannot slide down the pole.

3. Press the ON button. All LED indicators will sequentially illuminate during the power-on self-test.
4. Each time the device is turned on, the systems goes through an initialization sequence including the front panel LED displaying a therapy timer feature.

   NPWT PRO has a count-up timer. When the device is turned ON, the display flashes 4 numbers "XXXX" which represent the number of hours the device has been in use.

   NPWT PRO to GO has a count-down timer. When the device is turned ON, the display flashes the letter "d" followed by two numbers "XX" representing remaining days, then "h" followed by two numbers "YY" representing remaining hours.

5. Upon turning ON the device, the dressing should slowly collapse indicating the presence of suction. Once dressing integrity is verified, adjust the device for desired therapy. **NOTE:** The device must be connected to the A.C. Adapter while attempting to obtain an initial dressing seal.
6. Carefully check dressing for vacuum leaks, and repair with additional Cardinal Health™ Polyurethane Drape, if necessary.
7. The Cardinal Health™ NPWT PRO family of devices should be operated at least 22 hours out of every 24-hour period. Remove the Cardinal Health™ NPWT Dressing if therapy is terminated or is OFF for more than 2 hours in a 24 hour period.

4.3 Therapy Setting Adjustment

CAUTION: Only a physician can prescribe the proper settings and protocols for the device. Failure to follow product instructions or adjusting settings and performing therapy application without the express direction and/or supervision of your trained caregiver may lead to improper product performance and the potential for serious or fatal injury.

Adjusting the Pressure Setting

There are five pressure settings available: -50 mmHg, -75 mmHg, -100 mmHg, -125 mmHg and -150 mmHg. The Pressure Selection buttons are located on the left side of the control panel. The UP button increases the pressure setting and the DOWN button decreases the pressure setting.

1. When the device is powered-up, the current setting is selected automatically (unless therapy setting has been locked previously by caregiver, see **4.8 THERAPY SELECTION LOCK / UNLOCK** Section).
2. To change the Pressure Setting, press either the UP button or DOWN button until desired therapy selection is indicated by the green LED.
3. The green LED indicator will flash indicating the selection has been made and will continue flashing until the desired pressure level has been achieved at which time the LED will remain illuminated. If the green LED indicator begins to flash during therapy, it means the device is unable to maintain the therapeutic setting. This event would most likely be associated with a dressing leak and will require clinician intervention to correct.

4.4 Intermittent Mode ON/OFF

The Cardinal Health™ NPWT PRO devices can operate in an intermittent suction mode with a 5 minute "ON" and 2 minute "OFF" cycle. Press the Intermittent Mode button to turn the Intermittent Mode on and off.

During intermittent operation, Cardinal Health™ NPWT PRO family of devices will provide target therapy pressure during the "ON" part of the cycle and approximately -25 mmHg during the "off" part of the cycle. By maintaining this lower pressure while the device is "OFF," maintains the integrity of the seal to prevent leaks.

4.5 Alarm Volume Adjustment

The volume of the alarm can be adjusted to fit various care settings or patient preferences. To adjust the alarm volume, press and hold the ON button while simultaneously pressing the UP button to increase the volume, or the DOWN button to decrease the volume. The LED display will indicate the volume level which ranges from 1 to 5. The nominal alarm volume level for the device is 2, which is generally sufficient for most care settings.

4.6 Battery Operation

NOTE: The Cardinal Health™ NPWT PRO family of devices is designed to permit use of the product while the internal battery is charging. The therapy device will continue to operate properly while the battery is charging.

Battery Life

The specified battery life of the Cardinal Health™ NPWT PRO family of devices with a fully-charged battery and a well-sealed dressing is up to 24 hours. The actual life is dependent on the integrity of the dressing. A leak in the dressing can reduce overall battery longevity significantly.

Average Time for Recharging

To ensure the battery has been fully charged, the device should be connected to an A.C. supply for approximately 3 hours. After approximately 2 hours of charging, the device will have achieved 80% of total battery capacity.

Low Battery Alarm

While running on battery, a low-battery alarm will activate when remaining capacity of the battery is less than 20% (See **4.7 ALARM OPERATION**). Typically, the device will continue to operate between 30 minutes and 1 hour after the low-battery alarm is activated.

Low Battery Shutoff

If the battery charge falls below a critical level, the device will shutoff automatically and therapy will be discontinued. At this point, the device must be plugged into an A.C. power source for therapy to resume. Once the A.C. Adapter is plugged in, pressing the ON  button will restart the device.

Recharging the Battery

Plug the power cord from the A.C. Adapter into the Battery Charging Port on the side of the therapy device. Plug the A.C. Adapter into a suitable 120 VAC, 60 Hz wall outlet.

When the device is connected to an AC power source, the green "power" LED on the front of the device will illuminate indicating AC power is present and the amber "charging" LED, located just below the "power" LED, will illuminate when the battery is charging.

Once the battery is fully charged, the amber LED will extinguish indicating the charge cycle is complete.

When the Cardinal Health™ NPWT PRO family of devices is disconnected from the AC power source, the devices will automatically switch over to the internal battery and continue to operate without interruption.

4.7 Alarm Operation

Clearing an Alarm Condition

To clear an Alarm Type, remedy the condition using the Troubleshooting table below. Once the condition is corrected, the alarm will automatically reset. To manually reset Alarm Type 1-3, turn the therapy device OFF then ON. The alarm will clear when the power is cycled. Alarm Type 4 cannot be manually reset by cycling power or Muted.

Alarm Troubleshooting

ALARM TYPE	INDICATION	CORRECTIVE ACTION
FLASHING "1" **LOW PRESSURE/ LEAK**	• LED display flashes "1" accompanied by an intermittent single-tone audible beep • Device will continue to alarm until the low pressure/leak condition is corrected or the alarm is cleared.	• Clamp the tubing. • If Low Pressure/Leak LED and audible alarm reset, there is a leak below the clamp – often in the dressing. Reopen the clamp before addressing the leak. Gently press around drape to check for leaks. If leak is found, patch with extra drape material. • If Low Pressure/Leak LED and audible alarm continue, there is a leak above the clamp. Check tubing connection at the canister. Check to ensure the canister is fully seated and locked. Check for cracks in the canister or lid separation. If found, replace the canister. • Open the clamp.
FLASHING "2" **CANISTER FULL**	• LED display flashes "2" accompanied by an intermittent two-tone audible beep. • Device will continue to alarm until the canister is replaced.	• Clamp the tubing. • Turn device off by pressing the OFF button. • Remove canister and replace. • Open the clamp and press the ON button to resume therapy.
FLASHING "3" **LOW BATTERY**	• The LED display flashes "3" accompanied by an intermittent three-tone audible beep. • The device will continue to alarm until connected to an A.C. power source. • When the charge falls below a critical level, the therapy will be discontinued.	• Utilizing an approved Cardinal Health™ A.C. Adapter, connect device to an A.C. power source to provide operating power and to recharge the internal battery.
FLASHING "4" **SERVICE TIMER**	• The LED display flashes "4" accompanied by 4 audible beeps every 10 seconds. • Device is ready to be checked and serviced.	• Return device to representative for service. • This alarm cannot be manually reset by cycling power (turning device OFF and ON). • This alarm cannot be MUTED.

NOTE: Pressing the ON (MUTE) button after an alarm will silence the alarm for 5 minutes. Alarm condition 4 cannot be manually reset by cycling power or Muted.

NOTE: In the event of an emergency, please contact your treating physician, caregiver, or your local emergency responders.

NOTE: If an Alarm Condition persists and cannot be resolved, please contact Cardinal Health for further assistance.

4.8 Therapy Selection Lock/Unlock

The Cardinal Health™ PRO family of devices is equipped with a therapy locking feature designed to prevent unauthorized individuals from inadvertently changing the therapeutic settings.

Locking

To lock the device, press and hold the ON 

button for three seconds until three audible beeps are heard. At this point, the device is locked. The therapeutic setting will be recalled each time the device is powered OFF and ON, and the device will remain locked until it is subsequently unlocked.

Unlocking

To unlock the device, press and hold the ON 

button until three audible beeps are heard. At this point the device is unlocked and therapy settings can be changed. Additionally, when the device is powered OFF and ON, the device will remain unlocked.

5. Specifications

Cardinal Health™ NPWT PRO family of devices

Dimensions ..... 6 x 4.3 x 2.75 in. (19.3 x 11.0 x 7.0 cm)
Weight ..... 0.9 Lbs (0.43Kg)
Therapy Settings ..... 50, 75, 100, 125, 150 mmHg
Canister Volume 300cc/500cc

With respect to electric shock, fire, and mechanical hazards, conforms to IEC60601-1.

IEC Classification

- Medical Equipment
- Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Continuous Operation
- Type B Applied Part
- Class II Internally Powered Equipment
- IPX0

Battery

Duration (Fully Charged) ..... up to 24 hours

Electrical

External Power Supply Input..... 100-240 VAC, 50-60Hz, 200 mA or 12-24 VDC, 850 mA (Optional)
External Power Supply Output ..... 5 VDC, 1 Amps
Patient & Enclosure leakage Current ..... < 100 Micro amps

Environmental Conditions

Storage Conditions
Temperature Range ..... 10°F (-12°C) to 1100F (43°C)
Relative Humidity Range ..... 20 – 95% Non-condensing
Atmospheric Pressure Range ..... 50 kPa to 110 kPa

Operating Conditions

Temperature Range ..... 40°F (4°C) to 90°F (32°C)
Relative Humidity Range ..... 20 - 75% Non-condensing
Atmospheric Pressure Range ..... 50 kPa to 110 kPa
Service Life ..... 3 years

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

5.1 Explanation of Symbols

Consult Instructions for Use

Power ON/MUTE

Power OFF

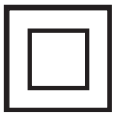
Adjustment Button. UP.

Adjustment Button. DOWN.

Continuos/Intermittent

A.C. Power Status

Battery Charge Status



Class II, Internally Powered Equipment

Type B Applied Part

Alternating Current

IPXO

Not protected against the harmful effects of water

Authorized Representative in the European Union

Manufacturer

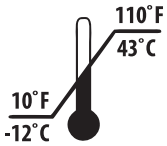
Date of Manufacture

Expiry Date

Lot/Batch Number

Catalog Number

Serial Number



Storage Conditions

Keep Dry

Fragile

Method of Sterilization -- Ethylene Oxide

℞ ONLY

Rx Only

5.2 Electromagnetic Compatibility

Guidance and Manufacturer's Declaration: Electromagnetic Emissions (IEC 60601-1-2)		
Emissions Test	**Compliance**	**Electromagnetic Environment**
Harmonic emissions IEC 61000-3-2	Class A	The PRO is suitable for use in all establishments, including medical facilities, domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	
RF emissions CISPR 14-1	Complies	The PRO is not suitable for interconnection with other equipment.

Recommended separation distance between portable and mobile RF communications equipment and the PRO.

The PRO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PRO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PRO as recommended below, according to the maximum output power of the communications equipment.

Output Power of Transmitter in watt(s)	**Separation distance according to frequency of transmitter in meter(s)**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5GHz**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distanced 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: At 80MHz and 800MHz, the separation distance for the higher frequency range applies Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)

Immunity Test	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	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst	±2 kV for power supply lines ±1 kV for input/output	±2 kV for power supply lines ±1 kV for input/output	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle	<5 % U_T (>95 % dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment.
	40 % U_T (60 % dip in U_T) for 5 cycles	40 % U_T (60 % dip in U_T) for 5 cycles	
	70 % U_T (30 % dip in U_T) for 25 cycles	70 % U_T (30 % dip in U_T) for 25 cycles	
	<5 % U_T (95 % dip in U_T) for 5 sec.	<5 % U_T (95 % dip in U_T) for 5 sec.	
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 characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the A.C. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the PRO including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 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, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF IEC 61000-4-6	3 V rms 150 kHz ~ 80 MHz	3 V rms	
Radiated RF IEC 61000-4-3	3 V/m 800 MHz ~ 2.5 GHz	3 V/m	

Note1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile 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 PRO is used exceeds the applicable RF compliance level above, the PRO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PRO.

[b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

6. Replacement Parts

Cardinal Health™ NPWT PRO family of devices

Cardinal Health™ NPWT PRO device 6708888
Cardinal Health™ NPWT PRO to GO device 47-0010

Power Supply

A.C. Power Adapter 47-9100

Dressings

Cardinal Health™ NPWT Small Foam Dressing Kit (10 per case) 47-1702
Cardinal Health™ NPWT Medium Foam Dressing Kit (10 per case) 47-1701
Cardinal Health™ NPWT Large Foam Dressing Kit (10 per case) 47-1700
Cardinal Health™ NPWT X-Large Foam Dressing Kit (10 per case) 47-1703
Cardinal Health™ White Foam Dressing (10 per case) 47-1751

Canisters

Cardinal Health™ Disposable Canister with Gel, 300 cc (10 per case) 47-4000
Cardinal Health™ Disposable Canister with Gel, 500 cc (10 per case) 47-4500

Accessories

Cardinal Health™ NPWT PRO I.V. Pole Holder 47-5600
Cardinal Health™ NPWT PRO Carrying Bag 47-9600
Cardinal Health™ SpeedConnect™ Tubing 47-2000
Cardinal Health™ NPWT "Y" Connector 47-2500
Cardinal Health™ Polyurethane Drape (10 per pkg.) 47-7000
Cardinal Health™ SensiSkin™ Drape (10 per pkg.) 47-7100

NOTE: In order to assure the highest safety, quality and efficacy of the products, the Cardinal Health™ NPWT PRO family of devices should only be used with the Cardinal Health™ disposables, and Cardinal Health™ NPWT Dressings should only be used with the Cardinal Health™ NPWT PRO family of devices.

7. Questions & Information

For questions, comments or additional information pertaining to the Cardinal Health™ NPWT PRO family of devices, please contact your local Cardinal Health representative, or:

Call our customer support professionals at 1.866.484.6798

Cardinal Health
Waukegan, IL 60085
www.cardinalhealth.com
CustomerServiceNPWT@cardinalhealth.com

Always consult a physician and product instructions for use prior to application.

Caution: Federal law restricts these devices to sale by or on the order of a physician.

Cardinal Health
1500 Waukegan Road
Waukegan, IL 60085 USA
Rev. B 2017-07
cardinalhealth.com
Cat. 6708888, 47-0010

US Pat. 7,532,953, 7,608,066, 8,066,243, 8,142,405, 8,444,613

EC REP
EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

CE
0086

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