CardinalHealth
*Essential to care™*

# Cardinal Health™ Negative Pressure Wound Therapy PRO/PRO TO GO

# Clinician User Manual

**CAUTION:** This Cardinal Health™ NPWT PRO/PRO to GO Clinician User Manual is not a guarantee or warranty. It is intended only as an operational guide. For additional information and questions, please contact Cardinal Health Customer Service at 1.866.484.6798.

In order for the Cardinal Health™ NPWT PRO/PRO to GO 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/PRO to GO. All assembly, modification, maintenance, and/or repair must be carried out only by qualified personnel authorized by Cardinal Health. Unauthorized modification of the PRO/PRO to GO may result in physical hazards, including delayed therapy, electrocution, and fire that may lead to injury or death.
- The electrical installation of the room in which the PRO/PRO to GO will be used complies with the appropriate electrical standards.
- The PRO/PRO to GO must be used in accordance with this Clinician User Manual and all associated labeling.
- Any PRO/PRO to GO that does not function as expected must be returned to Cardinal Health.

**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.

# Safety and Warnings

**Note to healthcare personnel providing training to lay users or lay caregivers (lay responsible organizations):** Be sure to include all of the warnings below when providing training to lay operators, especially in a home care environment. Lay users and caregivers should contact Customer Support if there is a change in the performance of the PRO/PRO to GO. Additionally, lay users and caregivers should be instructed on proper cleaning procedures to avoid hazards such as electric shock. Lay users and caregivers should also be trained on inappropriate environments for use (e.g. bathtub). For guidance on training, please contact Customer Support.

**WARNING:** Strangulation hazard. Do not leave A.C. Power Adapter cord, tubing or other choking hazards where infants or young children can become caught. If these objects get wrapped around the neck, strangulation and death can occur.

**WARNING:** The PRO/PRO to GO contains small parts, which could become detached and pose a choking hazard. Some of these components could be inhaled or swallowed by a small child, toddler or infant, which could result in suffocation or death. Keep all parts of the PRO/PRO to GO out of reach of small children.

**WARNING:** Do not modify this equipment without authorization from the manufacturer. Modification of this system could result in physical hazards, including delayed therapy, electrocution and fire. These hazards could result in injury or death.

**WARNING:** Use only the Cardinal Health™ NPWT Dressing and accessories listed in this manual. Use of other dressings and accessories can create hazardous situations, including improper therapy or delayed therapy. This could result in improper healing, damage to the wound area and infection.

**CAUTION:** Use the PRO/PRO to GO only as described in this user manual. Do not interconnect the PRO/PRO to GO with other devices not included in this user manual. Failure to comply could result in improper therapy and could result in damage to the PRO/PRO to GO.

**CAUTION:** This system is not intended to be used in MRI environments or in the presence of strong magnetic fields. Do not use this device in any areas with strong magnetic fields. The system contains metal components which could cause unintended movement. This unintended movement could cause clinician or patient harm due to falling objects or collisions.

**CAUTION:** If you are in an environment with pet hair, please use caution when adhering the wound dressing to the wound site. Pet hair could contaminate the wound site and prevent adhesion of the wound dressing. This could result in possible infection of the wound or reduced effectiveness of the system.

**CAUTION:** The PRO/PRO to GO system can be used outdoors for short periods of time (not more than 24 hours). Shelter from the rain.

# Table of Contents

# 1. Introduction

The PRO/PRO to GO Negative Pressure Wound Therapy (NPWT) system is comprised of the PRO/PRO to GO, the NPWT Dressing Kit, the NPWT Canister and the A.C. Power Adapter. In order to assure the highest safety, quality and efficacy, the PRO/PRO to GO should only be used with the Cardinal Health™ NPWT Dressing Kits and Cardinal Health™ NPWT disposables. Use of any other brand of wound dressings are not compatible with the PRO/PRO to GO and are not recommended.

## 1.1 Indications for Use

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

## 1.2 Contraindications

The PRO/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 black foam dressing over exposed blood vessels or organs. The Cardinal Health™ NPWT Dressings are also contraindicated for hydrogen peroxide and solutions which are alcohol based or contain alcohol. It is not recommended to deliver fluids to the thoracic cavity.

## 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 foam from the NPWT Dressing Kit 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 polyurethane drape from the dressing, a blood vessel or an organ. Wounds with enteric fistula require special precautions in order to optimize negative pressure wound therapy.

- **Defibrillation:** Remove the 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 PRO/PRO to GO is not MRI-compatible and cannot be used in the presence of strong magnetic fields. Do not take the PRO/PRO to GO into the MRI area or any area of high magnetic fields. The PRO/PRO to GO contains metal components that could cause unintended movement resulting in harm due to falling objects or collisions.

- **Hyperbaric Oxygen Therapy (HBO):** Do not take the PRO/PRO to GO — whether on or off — into a hyperbaric chamber. Clamp the tubing and disconnect the PRO/PRO to GO prior to HBO treatment.
- **DO NOT USE** for infants, pediatric patients or any other patients with low fluid volume, or patients at high risk of major hemorrhage.
- During negative pressure wound therapy, the PRO/PRO to GO and NPWT Dressing Kit are a closed system and are NOT vented to atmosphere.
- When the NPWT Canister is full, replace immediately. Wound exudate is not removed from dressing if the canister is full. See **3.3 Removing the NPWT Canister** and **3.2 Inserting the NPWT Canister**.

## 1.4 Safety Tips

### Keep Therapy On

The PRO/PRO to GO should be operated at least 22 hours out of every 24-hour period. Remove the 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 at least every 48 to 72 hours. Dressing changes for infected wounds should be accomplished more frequently than 48 to 72 hours. Follow established facility protocols regarding clean versus sterile technique.

### Monitoring the Wound

Inspect the dressing frequently to ensure that the dressing is collapsed and that negative pressure wound therapy is being consistently delivered. Monitor peri-wound exudates for signs of active bleeding. Monitor peri-wound tissue and exudate for signs of infection or other complications.

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, refractory hypotension, orthostatic hypotension or peri-wound induration (redness and increased skin temperature around wound) may be added signs of more serious complications of infection. If any sign of infection is noted, discontinue the use of the PRO/PRO to GO system until the infection is diagnosed and properly treated.

### Discomfort

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

**Unstable Structures**
Use the lowest Pressure Setting on the PRO/PRO to GO 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 therapy 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 dressing.

**NOTE:** All dressing components of the 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 NPWT Dressing Kits are not made with natural rubber latex.

Be sure to comply with **1.2 Contraindications** and **1.3 Precautions**.

**CAUTION:** Do not pack the NPWT foam dressings into any areas of the wound. Forcing dressings into any wound compromises negative pressure wound therapy and wound healing.

## 1.5 Features

**Simple Operation:** Negative pressure wound therapy activation and changing of Pressure Settings can be accomplished with the push of a button. Pressure Settings can be locked by the clinical caregiver (**4.4 Negative Pressure Wound Therapy Selection Lock/Unlock**). Lights next to the Pressure Settings clearly indicate current therapeutic settings.

**Light Weight/Impact Resistant:** The PRO/PRO to GO weighs only 0.4kg (0.9 lb.) and can be easily carried. The cover of the PRO/PRO to GO is impact resistant to help prevent damage from dropping.

**Noise:** The PRO/PRO to GO is quiet in its normal operation with a well-sealed dressing.

**Battery:** An internal battery in the PRO/PRO to GO provides up to 24 hours of operation from a fully-charged battery. The battery charges while PRO/PRO to GO is plugged into an outlet with the A.C. Power Adapter. If the battery charge is less than 20 percent, a "3" shows in the Alert Display and the PRO/PRO to GO beeps three times.

**Power/Charging Status:** Indicates the PRO/PRO to GO is charging the internal battery.

**Intermittent Mode:** The PRO/PRO to GO can be set to operate intermittently (5-minute ON/2-minute OFF cycle). The PRO/PRO to GO maintains pressure at -25mmHg during the "OFF" cycle to prevent loss of dressing seal.

**Alert Display:** Automated alerts for Low Pressure/Leak, Canister Full, Low Battery and Therapy Timer. Alerts are both visual and audible. Alerts self-reset once the problem is corrected or can be manually reset by turning the PRO/PRO to GO off and then back on. Audible alerts can be muted for 5 minutes by pressing and holding the ON button until a series of beeps is heard. The alert continues to flash in the Alert Display while the PRO/PRO to GO is muted.

**NOTE:** Alert 4 cannot be silenced or reset. See **4.8 Troubleshooting**.

**Tubing with SpeedConnect™:** 8-foot, single-lumen tubing set with an adhesive SpeedConnect™ makes connection to the dressing easy.

**Canisters:** 300cc and 500cc canisters with gel solidifiers are available. Both canisters can be used for normal and highly exudating wounds.

**CAUTION:** Monitor patient status continually. DO NOT USE for infants, pediatrics or other patients with low fluid volume, or for patients at high risk of hemorrhage.

# 2. Care & Cleaning

Carefully read **1.3 Precautions** and **1.4 Safety Tips** before cleaning the PRO/PRO to GO.

Standard Precautions should be used to minimize the risk of infection and contact with the contaminated blood or bodily fluids during the dressing changes and cleaning of the PRO/PRO to GO. It is important to protect all skin and mucous membranes by using Personal Protective Equipment (PPE). PPE includes:

- Disposable gloves
- Protective eyewear
- Protective mask
- Disposable impervious gown

## 2.1 Cleaning the PRO/PRO to GO

Perform a visual inspection of the PRO/PRO to GO. Check for any signs of contamination or fluid going into the canister ports. Ensure that the PRO/PRO to GO is functioning properly. If the PRO/PRO to GO is not operating properly, refer to the Troubleshooting guide in Section **4. Operating Instructions** or contact Cardinal Health at 1.866.484.6798.

To help reduce the risk of infection and contact with contaminated blood and bodily fluids, it is recommended to wear personal protective equipment (PPE) when cleaning the PRO/PRO to GO.

**NOTE:** Always follow Standard Precautions. Follow facility protocols regarding clean versus sterile technique.

**NOTE:** Cleaning of the PRO/PRO to GO must not be performed when the PRO/PRO to GO is connected to a patient or power source. Disconnect the PRO/PRO to GO from the patient and power source before cleaning.

The following cleaning procedure must be performed at least once a week and must be performed between patients. Wipe the PRO/PRO to GO with a diluted solution of 5 milliliters bleach in 1 liter of warm water (approximately 1 teaspoon bleach in 1 quart water). Use a coarse cloth and wring out any excess solution until the cloth is damp and not dripping. Bleach based disinfecting wipes for cleaning medical equipment may also be used.

1) Clean all surfaces of the PRO/PRO to GO, including the ports and the A.C. Power Adapter, then allow the solution to air dry on the PRO/PRO to GO.
2) If there is visible soilage on the PRO/PRO to GO, clean it a second time after the first cleaning has removed the soilage.
3) Wipe down the PRO/PRO to GO with a clean, dry cloth to remove any bleach residue.
4) Visually inspect the PRO/PRO to GO and A.C. Power Adapter for damage. If damage is noted, take the PRO/PRO to GO or the A.C. Power Adapter out of service and replace per protocol.

**CAUTION:** 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. Do not spray liquids directly on to PRO/PRO to GO.

**CAUTION:** Avoid spilling liquid on any part of the PRO/PRO to GO. Spilling liquid on the PRO/PRO to GO may cause the PRO/PRO to GO to operate erratically, possibly causing a potential hazard to the patient or clinical caregiver.

***Carrying Case and IV Pole Adapter*:** Follow the same procedure as above.

### 2.2 A.C. Power Adapter Inspection

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

**CAUTION:** The PRO/PRO to GO must be used with the supplied A.C. Power Adapter. Use of another adapter/power cord could result in physical hazards, including delayed therapy, electrocution and fire. These hazards could result in injury or death.

# 3. Patient Care

Review all Sections of this Clinician User Manual before use of the PRO/PRO to GO. Carefully read **1.1 Indications**, **1.2 Contraindications**, **1.3 Precautions** and **1.4 Safety Tips** before using the PRO/PRO to GO for patient care.

## 3.1 Applying the NPWT Dressing

1. Cleanse wound according to facility 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™ NPWT Drape or Cardinal Health™ NPWT SensiSkin™ Drape.
6. Take measurements of the wound dimensions and note wound type. Select the appropriate dressing size based on wound assessment. Open the sterile kit to expose the black foam, the tubing with SpeedConnect™ and the drape. Set aside the tubing with SpeedConnect™ and drape from the NPWT Dressing Kit.
7. Cut the black foam to a size that is appropriate for the wound (**Figure 1**). Document the number of black foam pieces used to fill the wound in the patient's chart.

   **CAUTION:** Do not cut the black foam dressing over or around the wound to avoid debris from the black foam from falling into the wound (**Figure 2**).
8. Place the black foam in the wound, taking care to avoid contact with the peri-wound skin (**Figure 3**). Black foam should be higher than skin level and cover the entire wound base. Black foam may be stacked for deep wounds.

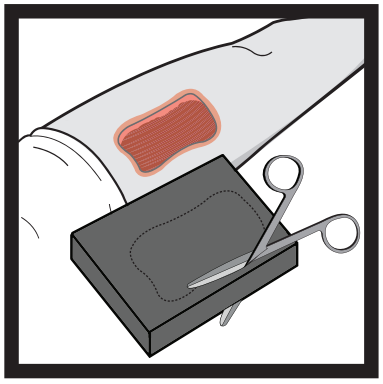


Figure 1

Figure 2

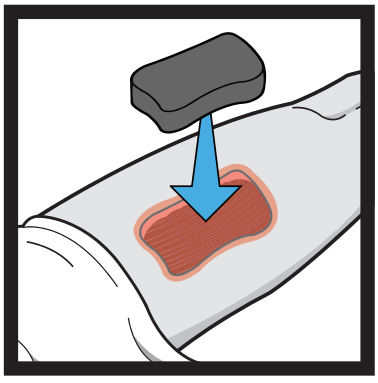


Figure 3

**CAUTION:** Do not pack the black foam into any areas of the wound. Forcing foam into any wound is contrary to approved protocols. Loosely fill all visible dead space in the wound. Do not thin black foam as thinning may cause over collapse of the dressing and prevent fluid from moving away from wound base.

### *Use of White Foam*

Per clinician's discretion, white foam may be used in wounds needing extra protection, such as protrusion of bone and in small tunneling and undermining. White foam should be used in an intact, single layer and covered with black foam when not used in small tunnels or in undermining. If the white foam needs to be cut to size, please note that non-linear shape cuts (e.g., curves, spirals, etc.) and straight cuts less than 3cm wide may increase the likelihood that the white foam will tear upon removal.

9. Remove the drape from the Dressing Kit. Size and trim the drape to cover the wound plus a 3-5cm border of intact skin (extra pieces of drape can be used to seal dressing leaks if needed). Always keep one side of the drape intact for ease of dressing application (**Figure 4**).

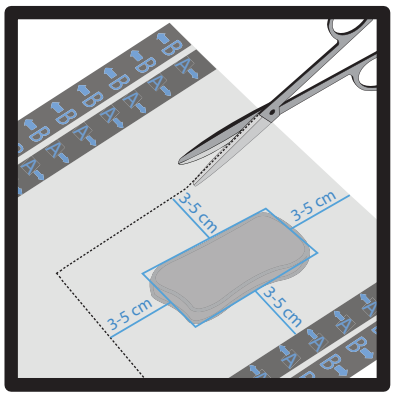
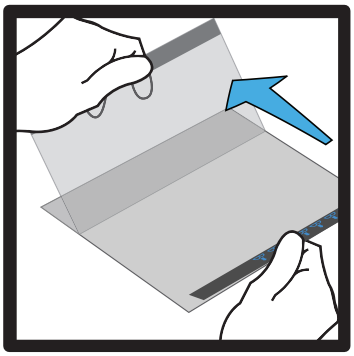



Figure 4

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



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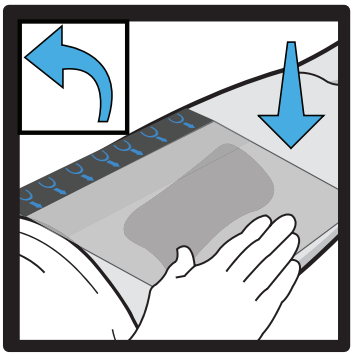


Figure 6

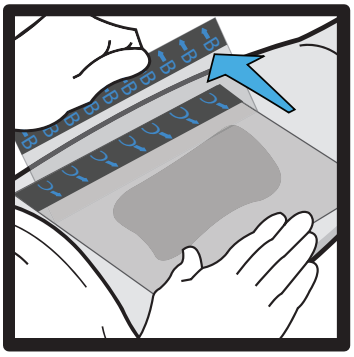


Figure 7

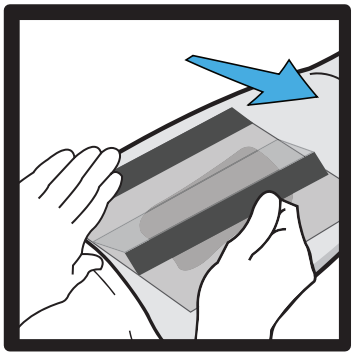


Figure 8

Figure 9

11. Cut a 1cm diameter hole in the top of the drape at a convenient location over the dressing by pinching and lifting the drape (**Figure 10**).
12. Remove the tubing from the NPWT Dressing Kit. Locate the SpeedConnect™ and peel the backing to expose adhesive. Place it over the hole made in Step 11 (**Figures 11-12**). Using the tips of the fingers, press around the top of the SpeedConnect™ to ensure a good seal to the drape.

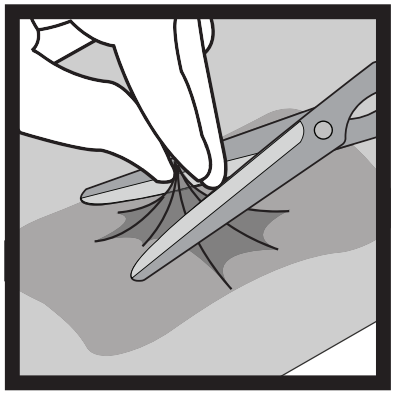


Figure 10

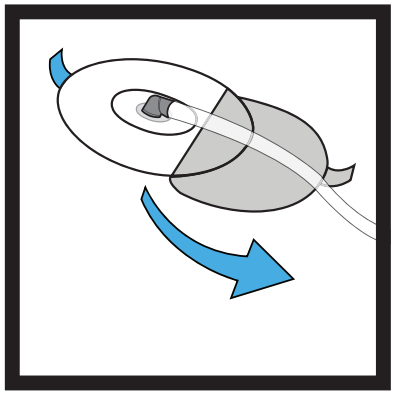


Figure 11

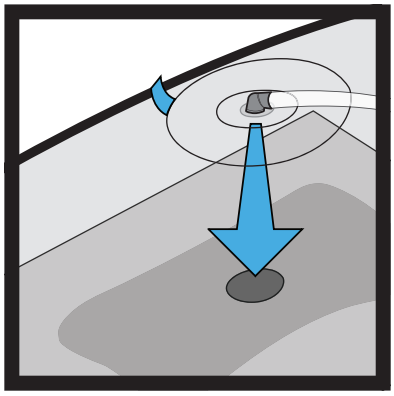


Figure 12

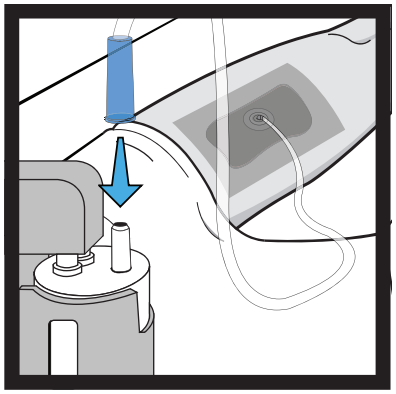


Figure 13

## 3.2 Inserting the NPWT Canister

1. To insert the canister, line up the two ports on the canister with the two ports on the PRO/PRO to GO. Press the canister up and into the PRO/PRO to GO until it clicks and locks into place.

   **NOTE:** Always use a new canister with a new patient.

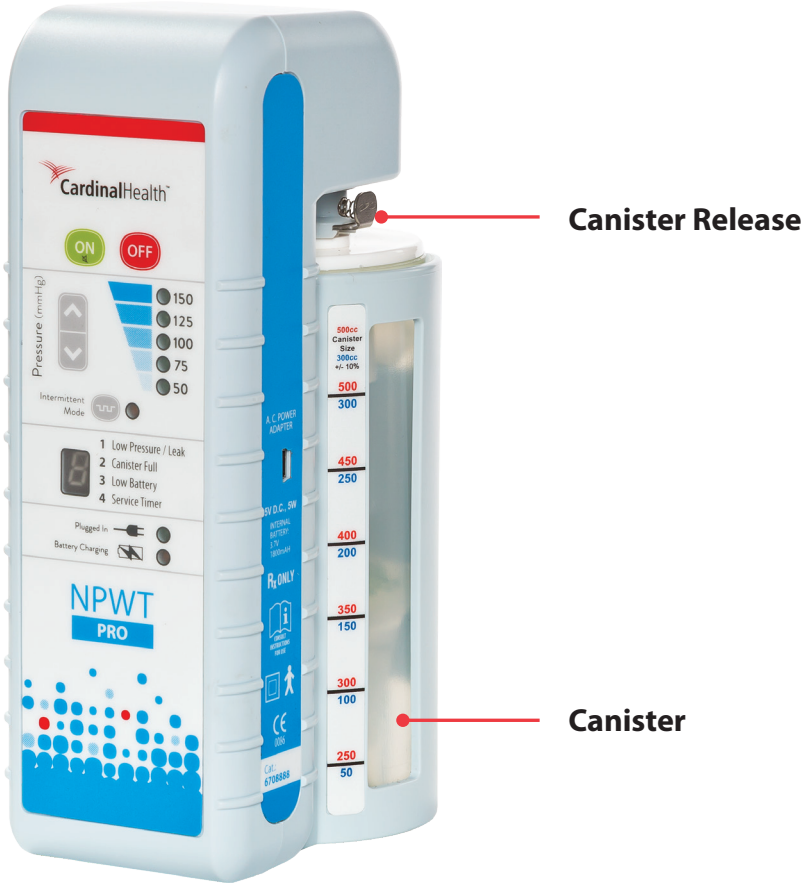



Figure 14

2. 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**).

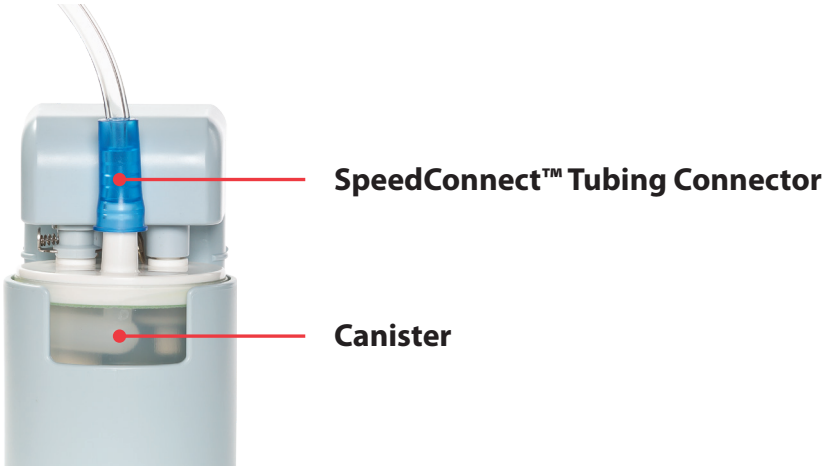



Figure 15


Figure 16

3. Verify the dressing application is correct, the tubing is connected and the SpeedConnect™ tubing clamp is open.

4. Begin negative pressure wound therapy (see **4. Operating Instructions**).

## 3.3 Removing the NPWT Canister

1. Close the tubing clamp.
2. Press the OFF button on the PRO/PRO to GO.
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 gently pull the bottom of canister down to remove from the PRO/PRO to GO.
5. Cap the canister. Dispose of canister according to facility protocols as well as local, state and federal regulations and institutional protocols.

**NOTE:** The canister should immediately be replaced when full or at least once every week to minimize odors and the potential for contamination.

## 3.4 Delivering Simultaneous Irrigation™ Technology

Cardinal Health offers two irrigation tubing set options that deliver irrigation and negative pressure wound therapy simultaneously. The NPWT Irrigation Tubing with SpeedConnect™ consists of a single-lumen tubing with SpeedConnect™ and a luer lock connector to connect to the irrigation of choice. The NPWT Irrigation Delivery Set consists of a single-lumen tubing with SpeedConnect™ and an irrigation delivery bag that allows the irrigation of choice to be delivered through the delivery bag. Both tubing options deliver irrigation solution to the wound.

**Precautions**

- Simultaneous Irrigation™ Technology can be utilized with the PRO/PRO to GO. Appropriate solutions for Simultaneous Irrigation™ Technology may include normal saline or other solutions indicated for topical wound treatment.
- Any solution cleared for use in topical wound irrigation can be used.
- Various topical agents, such as hydrogen peroxide and solutions containing alcohol, are not intended for extended tissue contact. If in doubt about the appropriateness of using a solution with the PRO/PRO to GO, contact the solution's manufacturer.
- Do not apply solutions in conflict with the manufacturer's instructions for use.
- During irrigation therapy, the dressing is a closed system and is NOT vented to atmosphere.
- Do not use where temperature of fluid could cause an adverse reaction, such as a change in patient's core body temperature.
- During irrigation therapy, check the irrigation bag periodically to ensure proper fluid delivery. In addition, when a canister fills with fluid, it should be immediately replaced as irrigation fluid and wound exudate are not removed from the wound if the canister is full.

**Instructions**

1. Make sure the irrigation fluid supply remains clamped off until the therapy is started and target pressure is achieved.
2. Obtain a physician order for irrigation solution type and delivery rate.
3. Apply NPWT Dressing (**3.1 Applying the NPWT Dressing**).
4. Connect NPWT Irrigation Tubing attachment to the irrigation solution container or use the NPWT Irrigation Delivery Set, which incorporates an irrigation bag with a tubing set together. Close the irrigation clamp completely.
5. Hang irrigation bag on IV pole higher than the wound.
6. Select desired location for Irrigation SpeedConnect™. Cut a 1cm diameter hole in the top of the drape where the Irrigation SpeedConnect™ is to be placed (**Figures 17 and 18**).

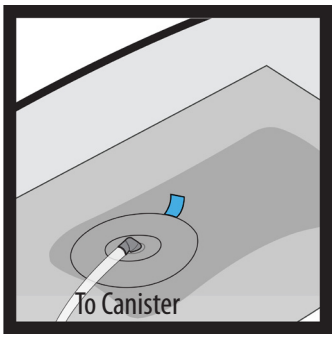



Figure 17

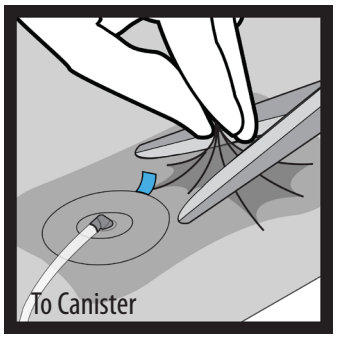



Figure 18

7. Peel off the SpeedConnect™ backing to expose the adhesive pad and place over hole made in Step 5 (**Figure 19**). Using the tips of the fingers, gently press down around the Irrigation SpeedConnect™ to ensure a good seal to the dressing.

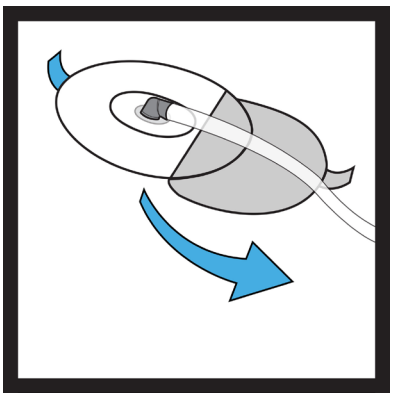
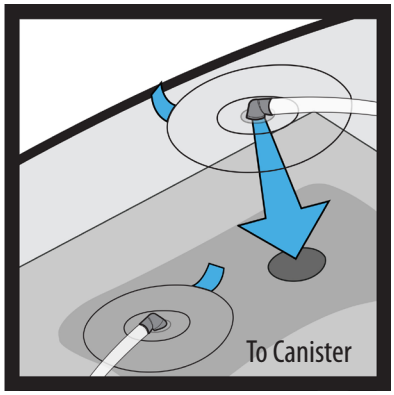
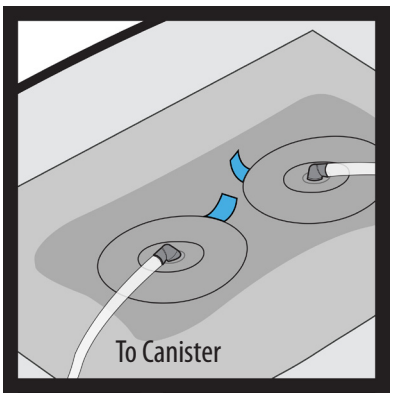


Figure 19



**NOTE:** The Irrigation SpeedConnect™ may be placed in close proximity to the SpeedConnect™, or in larger wounds may be placed over another area of the wound distal to the SpeedConnect™.

8. Turn on PRO/PRO to GO and allow dressing to reach set pressure.
9. Open the clamp on the Irrigation tubing to allow irrigation solution to flow until the solution begins to move through the tubing and into the canister.
10. Set the drip rate per the physician order. The drip rate does not need to be exact with continuous wound irrigation.

    **NOTE:** The irrigation rate remains constant unless the Pressure Setting is changed or if PRO/PRO to GO is in Intermittent Mode.

## 3.5 Removing the NPWT Dressing

Carefully read the **1.4 Safety Tips** before 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 as determined by the clinician. Infected wounds must be monitored continuously. For infected wounds, dressings may need to be changed more often than 48 to 72 hours based on a clinical evaluation of the wound.

Standard Precautions should be used to minimize the risk of infection and contact with contaminated blood or bodily fluids during the dressing changes. It is important to protect all exposed skin and mucous membranes by using Personal Protective Equipment (PPE). PPE includes:

- Disposable gloves
- Protective eyewear
- Protective mask
- Disposable impervious gown

1. With the PRO/PRO to GO ON, lift a corner of the drape to allow air to enter the system, moving any fluid in the tubing into the canister.
2. Close tubing clamp.
3. Press the OFF button on the PRO/PRO to GO.
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 or dressing laterally and slowly pull up and away from skin. Lateral stretching of the drape or dressing will help release the adhesive and minimize trauma to the patient's skin.

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

6. Remove foam from wound. Make sure that the number of pieces removed from the wound matches the number of pieces that were placed into the wound. If the numbers do not match, further procedures may have to be performed to resolve the difference.
7. Discard used foam, tubing, canister and drape in accordance with applicable rules, regulations and infection control protocols and always follow Standard Precautions.

## 3.6 Disposal of Used Components

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

- The NPWT foam dressing and polyurethane drape
- The canister
- The tubing
- Irrigation tubing set and irrigation delivery set

Dispose of all used components in accordance with facility protocols as well as local, state and federal regulations.

# 4. Operating Instructions

Carefully read the **1.3 Precautions** and **1.4 Safety Tips** before attempting to operate and adjust the PRO/PRO to GO.

**CAUTION:** The PRO/PRO to GO must be used with the supplied A.C. Power Adapter. Use of any other adapter/power cord could create a shock hazard for the patient or caregiver, cause fire and/or severely damage the PRO/PRO to GO. If a replacement A.C. Power Adapter is needed, call Cardinal Health at 1.866.484.6798.

## 4.1 On/Off

The ON and OFF buttons are located on the front of the PRO/PRO to GO.

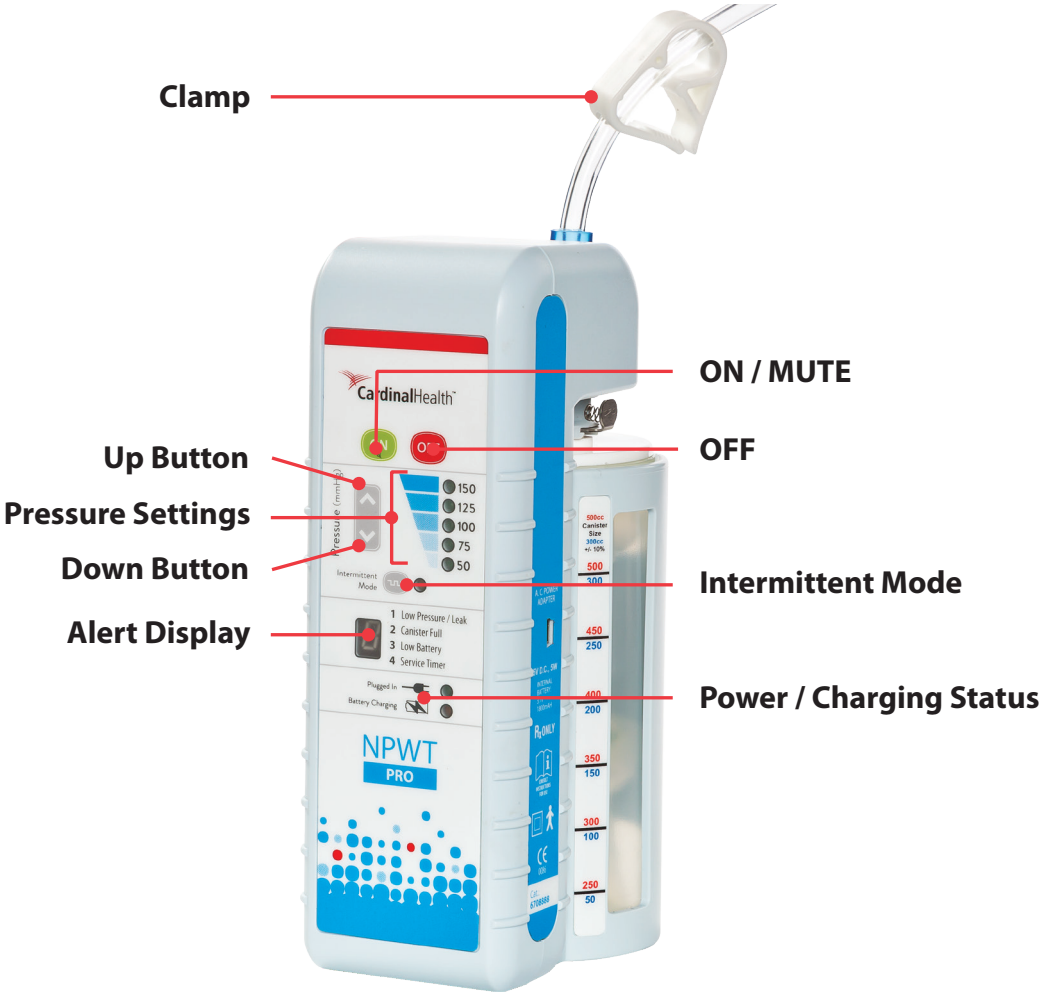



Figure 20

## 4.2 Power-Up Procedure

1. Verify the dressing application is correct, the tubing is connected and the clamp is open.
2. Keep the PRO/PRO to GO upright. The PRO/PRO to GO can be placed on a table, or attached to an IV pole using the IV pole adapter, but it is recommended to keep level with or below the wound.

**CAUTION:** The clamp on the IV pole adapter should only be used on poles that are in excess of 2.2cm (0.9 in.) diameter and are securely attached to a suitable stand. To ensure stability of the PRO/PRO to GO on the IV pole, ensure the clamp is no higher than two times the width of the pole base. The clamp should be tightened to ensure that the PRO/PRO to GO cannot slide down the pole.

3. Press the ON button. All indicators sequentially light up during the power-on self-test.
4. The Alert Display flashes the following:

   **PRO**: Four numbers which represent the number of hours the device has been in use.

   **PRO to GO**: The letter "d" followed by two numbers representing remaining days, then "h" followed by two numbers representing remaining hours.

5. The dressing should slowly collapse indicating the presence of negative pressure. Once dressing integrity is verified, adjust the PRO/PRO to GO for desired Pressure Setting.

   **NOTE:** It is recommended that the PRO/PRO to GO is connected to the A.C. Power Adapter while attempting to obtain an initial dressing seal.
6. Carefully check dressing for leaks, and repair with additional drape, if necessary.
7. The PRO/PRO to GO should be operated at least 22 hours out of every 24-hour period. Remove the dressing if negative pressure wound therapy is terminated or the PRO/PRO to GO is off for more than 2 hours in a 24-hour period.

## 4.3 Negative Pressure Wound Therapy Setting Adjustment

**CAUTION:** Only a physician can prescribe the proper settings and protocols for the PRO/PRO to GO. Failure to follow instructions or adjusting settings or performing negative pressure wound therapy without the express direction and/or supervision of your trained clinical caregiver may lead to improper performance and the potential for serious or fatal injury.

There are five Pressure Settings: -50mmHg, -75mmHg, -100mmHg, -125mmHg and -150mmHg. The UP button increases the pressure setting and the DOWN button decreases the Pressure Setting.

When the PRO/PRO to GO is turned on, the current Pressure Setting is selected automatically (unless Pressure Setting has been locked previously by the clinical caregiver, see **4.4 Negative Pressure Wound Therapy Selection Lock/ Unlock**).

To change the Pressure Setting, press either the UP button or DOWN button until desired Pressure Setting is indicated by the green light next to the Pressure Setting.

The green light next to the Pressure Setting number flashes, indicating the selection has been made and continues flashing until the desired pressure level has been achieved. Once the desired pressure has been achieved, the green light next to the Pressure Setting remains stable. If the green light begins to flash during therapy, the PRO/PRO to GO is unable to maintain the therapeutic setting.

## 4.4 Negative Pressure Wound Therapy Selection Lock/Unlock

The PRO/PRO to GO has a Pressure Setting lockout feature designed to prevent unauthorized individuals from changing the Pressure Setting.

### Locking

To lock the PRO/PRO to GO, press and hold the ON button for 3 seconds until three audible beeps are heard. The PRO/PRO to GO is locked. The Pressure Setting is set even if the PRO/PRO to GO is powered off and then back on. The PRO/PRO to GO remains locked.

### Unlocking

To unlock the PRO/PRO to GO, press and hold the ON button until three audible beeps are heard. The PRO/PRO to GO is unlocked and Pressure Settings can be changed. If the PRO/PRO to GO is powered off and on, the PRO/PRO to GO remains unlocked.

## 4.5 Intermittent Mode ON/OFF

The PRO/PRO to GO can operate in an intermittent 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, the PRO/PRO to GO provides desired pressure during the "on" part of the cycle and approximately -25mmHg during the "off" part of the cycle. Cycling to this lower pressure while the PRO/PRO to GO is off helps maintain the integrity of the drape seal.

## 4.6 Alert Volume

The volume of the alert can be adjusted. To increase the alert volume, press and hold the ON button while pressing the Up Button. To decrease the alert volume, press and hold the ON button while pressing the Down Button. The Alert Display indicates the volume level, which ranges from 1 to 5. The factory set alert volume level is 2.

## 4.7 Battery Operation

**NOTE:** The PRO/PRO to GO continues to operate while the internal battery is charging.

### Battery Life

The battery life of the PRO/PRO to GO 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 and using Intermittent Mode can reduce overall battery longevity.

### Average Time for Recharging

After approximately 2 hours of charging, the PRO/PRO to GO achieves 80 percent of the total battery capacity. To ensure that the battery is fully charged, the PRO/PRO to GO should be connected to an outlet for approximately 3 hours.

### Low Battery Alert

While running on battery, a Low-Battery Alert is activated when remaining capacity of the battery is less than 20 percent. A number 3 will show in the Alert Display window, and three audible beeps will be heard (**4.8 Troubleshooting**). Typically, the PRO/PRO to GO continues to operate for 30-60 minutes after the Low-Battery Alert is activated.

### Low Battery Shutoff

If the battery charge falls below a critical level, the PRO/PRO to GO shuts off and negative pressure wound therapy is discontinued. At this point, the PRO/PRO to GO must be plugged into an A.C. Power Adapter for therapy to resume. Once the A.C. Power Adapter is plugged in, pressing the ON button will restart the device.

### Recharging the Battery

Plug the A.C. Power Adapter into the Battery Charging Port on the side of the PRO/PRO to GO. Plug the A.C. Power Adapter into a wall outlet.

When the PRO/PRO to GO is connected to an outlet, the green light next to the Plugged In symbol and the amber light next to the Battery Charging symbol on the front of the PRO/PRO to GO lights up.

**NOTE:** If the PRO/PRO to GO is plugged in and green light does not turn on, check to make sure outlet is working properly.

Once the battery is fully charged, the amber light next to the Battery Charging symbol turns off, showing the battery is fully charged. When the A.C. Power Adapter is disconnected from the outlet, the PRO/PRO to GO automatically switches over to the internal battery and continues to operate.

## 4.8 Troubleshooting

### Clearing an Alert Condition

To manually reset alert types 1-3, turn the PRO/PRO to GO off and then back on. Pressing the ON button after an alert silences the alert for 5 minutes. The alert clears when the PRO/PRO to GO is turned off and then back on. Alert Type 4 cannot be manually reset or muted.

| What you see or hear | Problem | What to do | More information |
|---|---|---|---|
| **"1" flashing in Alert Display.**<br><br>**Single beep.**<br><br>**PRO/PRO to GO is making more noise.** | Possible air leak in either the dressing or the tubing connections.<br><br>Leaks often occur over areas of moist skin, creases or folds in skin, and wrinkles in the drape. They can occur if the drape snags on clothing or bed sheets. | • Clamp the tubing.<br>• If audible alert resets, there is a leak between the clamp and the dressing – 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.<br>• If "1" continues flashing in the Alert Display and alert beep continues, there is a leak between the clamp and the PRO/PRO to GO. Check tubing connection at the canister. Check to ensure the canister is fully sealed and locked. Check for cracks in the canister or lid separation. If found, replace the canister.<br>• Open the clamp. | If the leak is properly sealed, pump becomes quiet and the alert stops. If alert continues, call Cardinal Health at 1.866.484.6798 for more assistance. |
| **"2" flashing in Alert Display.**<br><br>**Two beeps.** | The canister is full. | • Visually assess the canister to see if full. If the canister is full, change the canister.<br>• If the canister is not full, turn the PRO/PRO to GO off by pressing the OFF Button and then turn the PRO/PRO to GO back on to resume therapy.<br>• If changing the canister and/or turning the PRO/PRO to GO off and then back on does not resolve the alert, look for occlusions in the tubing or possibly in the dressing. Change the tubing and/or dressing as needed to resolve the alert. | The Canister Full alert begins when the canister is 90 percent full, but the PRO/PRO to GO will continue to work until the canister completely fills.<br><br>If the PRO/PRO to GO is placed on its front, fluid entering the canister causes a false Canister Full alert and the canister must be changed.<br><br>If alert continues, call Cardinal Health at 1.866.484.6798 for more assistance. |

| What you see or hear | Problem | What to do | More information |
|---|---|---|---|
| **"3" flashing in Alert Display.**<br><br>**Three beeps.** | The battery is low and has approximately 30 minutes before the battery will be too low to support continued operation of the PRO/PRO to GO. | Plug in the PRO/PRO to GO. A green light shows next to the Plugged In symbol and a yellow light shows next to the Battery Charging symbol to indicate that the battery is charging. The yellow light turns off after battery is fully charged. | Use only the A.C. Power Adapter that came with the PRO/PRO to GO.<br><br>If alert continues or replacement A.C. Power Adapter is needed, call Cardinal Health at 1.866.484.6798 for more assistance. |
| **"4" flashing in Alert Display.**<br><br>**Four beeps.** | PRO/PRO to GO therapy has timed out. | Call Cardinal Health at 1.866.484.6798 for assistance. | This alert cannot be muted or manually reset by turning the PRO/PRO to GO off and on. |
| **Pressure Setting will not change.** | Pressure lock-out is engaged. | Unlock the PRO/PRO to GO by pressing and holding ON Button for 3 seconds.<br><br>The PRO/PRO to GO beeps three times indicating that the setting is unlocked. Pressure Setting can now be changed. | To lock pressure setting, press and hold the ON Button for 3 seconds. The PRO/PRO to GO beeps three times indicating Pressure Setting is locked. |
| **PRO/PRO to GO is quiet and fluid is not moving in the tubing.** | This is NOT a problem. The dressing has a good seal and the PRO/PRO to GO is maintaining target pressure. | No action needed. | Change the PRO/PRO to GO to Intermittent Mode to move fluid in the tubing to the canister. |
| **An amber light is showing on the front of the PRO/PRO to GO below the Pressure Setting.**<br><br>**The PRO/PRO to GO is making more noise every 5 minutes.** | This is NOT a problem. The PRO/PRO to GO is operating in Intermittent Mode. | No action needed. | Intermittent Mode maintains target pressure for 5 minutes and decreases to -25mmHg for 2 minutes. |

**NOTE:** If an alert persists and cannot be resolved, please contact Cardinal Health at 1.866.484.6798.

**CAUTION:** In the event of an emergency, please contact the treating physician, caregiver or emergency responders.

# 5. Symbols Glossary

## Symbols Recognized by Standard/Law

| Symbol | Standard/Law Reference | Standard/Law Title | Symbol Title/ Text Reference | Explanatory Text |
|---|---|---|---|---|
|  | ISO 13225-1, Clause 5.1.1 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Manufacturer | Indicates the medical device manufacturer. |
| | ISO 7000-3082 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.1.3 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Date of Manufacture | Indicates the date when the medical device was manufactured. |
| | ISO 7000-2497 | Graphical symbols for use on equipment | | |
|  | EN 60417-6049 | Graphical symbols for use on equipment | Country of Origin | To identify the country of manufacture of products. To identify country abbreviation, see https://www.iso.org/obp/ui/#-search. |
| | ISO 3166-1 | Codes for the representation of names of countries and their subdivisions - Part 1: Country Codes | | |
|  | ISO 15223-1, Clause 5.1.2 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Authorized European Representative | Indicates the Authorized Representative in the European Union. |
|  | ISO 15223-1, Clause 5.1.6 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Catalogue or Model Number | Indicates the manufacturer's catalogue number so the device can be identified. |
| | ISO 7000-2493 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.1.7 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Serial Number | Indicates the manufacturer's serial number so that a specific device can be identified. |
| | ISO 7000-2498 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.1.5 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Batch/Lot Code | Indicates the manufacturer's batch/lot code so that the batch or lot can be identified. |
| | ISO 7000-2492 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.1.4 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Use by Date | Indicates the date after which the medical device is not to be used. |
| | ISO 7000-2607 | Graphical symbols for use on equipment | | |

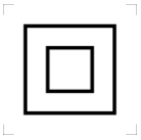
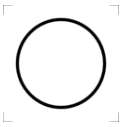
| Symbol | Standard/Law Reference | Standard/Law Title | Symbol Title/ Text Reference | Explanatory Text |
|---|---|---|---|---|
|   | ISO 15223-1, Clause 5.5.1 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | *In Vitro* Diagnostic Medical Device | Indicates that a medical device is intended to be used as an *in vitro* diagnostic medical device. |
|  | IEC 60601-1, Table D.1, Symbol 10 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | Caution | Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. |
| | ISO 7000-0434 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.3.7 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Temperature Limit | Indicates the temperature limits to which the medical device can be safely exposed. |
| | ISO 7000-0632 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.3.8 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Humidity Limitation | Indicates the range of humidity to which the medical device can be safely exposed. |
| | ISO 7000-2620 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.3.4 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Keep Dry | Indicates a medical device that needs to be protected from moisture. |
| | ISO 7000-0626 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.3.1 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Fragile, Handle with Care | Indicates a medical device that can be broken or damaged if not handled carefully. |
| | ISO 7000-0621 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.4.2 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Do Not Reuse | Indicates a medical device that is intended for one use or for use on a single patient during a single procedure. |
| | ISO 7000-1051 | Graphical symbols for use on equipment | | |
|   | ISO 15223-1, Clause 5.2.6 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Do Not Resterilize | Indicates that a medical device should not be resterilized. |
| | ISO 7000-2608 | Graphical symbols for use on equipment | | |

| Symbol | Standard/Law Reference | Standard/Law Title | Symbol Title/ Text Reference | Explanatory Text |
|---|---|---|---|---|
|  | ISO 15223-1, Clause 5.2.1 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Sterile | Indicates a medical device that has been subjected to a sterilization process. |
| | ISO 7000-2499 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.2.2 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Sterile Using Aseptic Techniques | Indicates medical device that has been sterilized by using accepted aseptic technique. |
| | ISO 7000-2500 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.2.3 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Sterilized by Ethylene Oxide | Sterilized by ethylene oxide |
| | ISO 7000-2501 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.2.4 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Sterilized Using Irradiation | Indicates a medical device that has been sterilized using irradiation. |
| | ISO 7000-2502 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.2.5 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Sterilized Using Steam or Dry Heat | Indicates a medical device that has been sterilized using steam or dry heat. |
| | ISO 7000-2503 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.2.9 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Sterile Fluid Path | To identify the presence of a sterile fluid path within the medical device when other parts of the medical device are not necessarily supplied sterile. |
| | ISO 7000-3084 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.3.2 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Keep Away from Sunlight | Indicates a medical device that needs protection from light sources. |
| | ISO 7000-0624 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.2.7 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Non-sterile | Indicates a medical device that has not been subjected to a sterilization process. |
| | ISO 7000-2609 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.4.3 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Consult Instructions for Use | Indicates user needs to consult instructions for use. |
| | ISO 7000-1641 | Graphical symbols for use on equipment | | |

| Symbol | Standard/Law Reference | Standard/Law Title | Symbol Title/ Text Reference | Explanatory Text |
|---|---|---|---|---|
|  | IEC 60601-1, Table D.2, Symbol 10 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | Refer to Instruction Manual/Booklet | Indicates user needs to consult instructions for use. |
|  | IEC 60601-1-2:2007, Clause 5.1.1 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests | Non-ionizing Electro-magnetic Radiation | To indicate generally elevated, potentially hazardous, levels of nonionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment. |
| | IEC 60417-5140 | Graphical symbols for use on equipment | | |
| | IEC 60878-5140 | Graphical symbols for electrical equipment in medical practice | | |
|  | ISO 15223-1, Clause 5.3.9 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Atmospheric Pressure Limits | Indicates the range of atmospheric pressure to which the medical device can be safely exposed. |
| | ISO 7000-2621 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.6.3 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Non-pyrogenic | Indicates that the medical device is non-pyrogenic. |
| | ISO 7000-2724 | Graphical symbols for use on equipment | | |
|  | ISO 15223-1, Clause 5.2.8 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Do Not Use if Package is Damaged | Indicates that the medical device should not be used if the package holding device has been damaged or opened. |
| | ISO 7000-2606 | Graphical symbols for use on equipment | | |
|  | ISO 7000-3079 | Graphical symbols for use on equipment | Open Here | Indicates where the package can be opened and to indicate method of opening it. |
|   | ASTM F2503 | Standard practice for marking medical devices and other items for safety in the magnetic resonance environment | Magnetic Resonance (MR) unsafe | Keep device away from magnetic resonance imaging (MRI) equipment. |
|   | IS EN-15986:2011 | Symbol for use in the labeling of medical devices. Requirements for labeling of medical devices containing phthalates. | Contains Presence of Phthalates | Indicates presence of Bis (2-ethylexyl) phthalate (DEHP). |

| Symbol | Standard/Law Reference | Standard/Law Title | Symbol Title/ Text Reference | Explanatory Text |
|---|---|---|---|---|
|  | ISO 15223-1, Clause 5.4.5, Annex B.2 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Does Not Contain Natural Rubber Latex | The medical device or the packaging of the medical device does not contain natural rubber latex. |
|  | ISO 15223-1, Clause 5.4.5, Annex B.2 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Does Not Contain Natural Rubber Latex | The medical device or the packaging of the medical device does not contain natural rubber latex. |
|  | ISO 15223-1, Clause 5.4.5 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied | Contains or Presence of Natural Rubber Latex | Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device. |
|  | EN 50419 | Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE). | WEEE Wheeled Bin | This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose of or recycle this product in accordance with local laws or regulations that apply. |
|  | IEC 60601-1, Table D.1, Symbol 20 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | Type BF Applied Part | Identifies a type BF applied part complying with IEC 60601-1-11. |
| | ISO 7000-5333 | Graphical symbols for use on equipment | | |
|  | IEC 60601-1, Table D.1, Symbol 19 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | Type B Applied Part | Identifies a type B applied part complying with IEC 60601-1. |
| | ISO 7000-5840 | Graphical symbols for use on equipment | | |

| Symbol | Standard/Law Reference | Standard/Law Title | Symbol Title/ Text Reference | Explanatory Text |
|---|---|---|---|---|
| IPN$_1$N$_2$ | IEC 60601-1, Table D.3, Symbol 2 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | Degrees of Ingress Protection Provided by Enclosure | Manufacturer-determined degree of particle and water ingress where N1= degree of protection from particles (scale of 0-6) and N2=degree of protection from water (scale of 0-8). |
| | IEC 60529 | Degrees of protection provided by enclosures (IP Code) | | NOTE: When a characteristic numeral is not required to be specified, it is replaced by the letter ÒXÓ. |
| IP28 | IEC 60529 | Degrees of protection provided by enclosures (IP Code) | Degrees of Ingress Protection Provided by Enclosure | Protected against solid foreign objects of 12.5mm and greater, and against the effects of continuous immersion in water. |
| IP48 | IEC 60529 | Degrees of protection provided by enclosures (IP Code) | Degrees of Ingress Protection Provided by Enclosure | Protected against solid foreign objects of 1.0mm and greater, and against the effects of continuous immersion in water. |
| IPX8 | IEC 60529 | Degrees of protection provided by enclosures (IP Code) | Degrees of Ingress Protection Provided by Enclosure | Protected against the effects of continuous immersion in water. |
| IPX7 | IEC 60529 | Degrees of protection provided by enclosures (IP Code) | Degrees of Ingress Protection Provided by Enclosure | Protected against the effects of temporary immersion in water. |
| IP22 | IEC 60530 | Degrees of protection provided by enclosures (IP Code) | Degrees of Ingress Protection Provided by Enclosure | Protection against the effects of insertion of fingers and will not be damaged or become unsafe when exposed to vertically or nearly vertical dripping water. |
| **R$_x$ ONLY** | 21 CFR Part 801.1(c)(1)(i)F | Labeling - Medical devices; prominence of required label statements | Prescription Use Only | Requires prescription for sale in the United States and is used in place of the statement below:<br><br>**CAUTION**: Federal law restricts this device to sale by or on the order of a physician, dentist or licensed practitioner. |
| | 21 CFR Part 801.109 | Labeling - Prescription devices | | |

| Symbol | Standard/Law Reference | Standard/Law Title | Symbol Title/ Text Reference | Explanatory Text |
|---|---|---|---|---|
| CE | Directive 93/42/ EEC Articles 4, 11, 12, 17 Annex 12 | Council Directive 93/42/EEC of 14 June 1993 concerning medical devices | The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive. | Signifies European technical conformity. |
| | Directive 93/68/ EEC | CE Marking | | |
|  | IEC 60417-5172 Section 7.2.6 | Class II equipment | Marking Requirements for Class II Equipment | Power adaptor meets the safety requirements specified for Class II equipment according to IEC 61140. |
|  | ISO 7000-2616 | External cord connected | External Cord Connected | Indicates that device is connected to an external power source. |
|  | ISO 7000-5008 | OFF (power) | OFF (Power) | To indicate disconnection from power. |
|  | ISO 7000-5007 | ON (power) | ON (Power) | To indicate connection to power. |
|  | ISO 7000-5417 | Programmable duration | Programmable Duration | To identify the control of a programmable timer to start an operation at a specific point in time and to stop the operation at a specific point in time or after a specific duration; or to identify a dis-play of the programmed or to-be-programmed duration. |
|  | ISO 7000-5546 | Battery check | Battery Check | To identify the batter condition indicator. |
|  | ISO 7000-0623 | This way up | This Way Up | To indicate correct upright position of the transport package. |

## Symbols Not Recognized by Standard/Law

| Symbol | Guidance | Guidance | Symbol Title | Explanatory Text |
|---|---|---|---|---|
|  | INDA and EDANA Flushability Guidelines | INDA and EDANA Flushability Guidelines | Do Not Flush | Do not flush in toilet. |
|   | | | | This container can and should be recycled. |
|   | | | Powder Free | Gloves are powder free. |
|   | | | Synthetic | Indicates medical device contains synthetic latex. |
|   | | | | This glove has been tested for resistance to permeation of various chemotherapy drugs per ASTM D6978, "Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs." |
|   | | | | This glove has been tested for permeation of various chemicals per ASTM F739, "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact." |
|  1 Pair of Gloves | | | 1 Pair of Gloves | Contains a pair of gloves. |
|  | | | Russian Registration Mark | Signifies technical conformity in Russia. |
|   | | | Open Arrow | Open at arrow. |

| Symbol | Guidance | Guidance | Symbol Title | Explanatory Text |
|---|---|---|---|---|
|  | | | Peel Here | Peel here to open package. |
|  Pouch Opening | | | Pouch Opening | Directions on how to open pouch. |
|  1 Single Glove | | | 1 Single Glove | Contains a single glove. |
|  | | | UL Listed | UL has tested representative samples of a product and determined that it meets UL's requirements. These requirements are based on UL's published and nationally recognized Standards for Safety. |
|  | | | UL Listed | Product is certified under UL's Listing and Classification services and for UL certifications for Canada and the USA. |
|  | | | Device Plugged into an Outlet | Indicates that device is connected to an external power source. |
|  | | | Battery Charging | Device is plugged into an outlet and the internal battery is charging. |

# 6. Specifications

**Cardinal Health™ PRO/PRO to GO**

Dimensions ..... 19.3 x 11.1 x 7.1cm (7.6 x 4.4 x 2.8 in.)
Weight ..... 0.4kg (0.9 lb.)
Pressure Settings ..... -50, -75, -100, -125, -150mmHg

**IEC Classification**

- With respect to electric shock, fire, and mechanical hazards, conforms to IEC60601-1.
- 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 ..... 1100-240VAC, 50/60Hz, 0.5Amp Max
External Power Supply Output ..... 5VDC, 1.0Amp

**Environmental and Storage Conditions**

Temperature Range ..... -12°C (10°F) to 43°C (110°F)
Relative Humidity Range ..... 60 +/-25% (35% to 85%)
Atmospheric Pressure Range ..... 50kPa to 110kPa

**Operating Conditions**

Temperature Range ..... 4°C (40°F) to 32°C (90°F)
Relative Humidity Range ..... 60 +/-25% (35% to 85%)
Atmospheric Pressure Range ..... 80kPa to 110kPa
PRO Therapy Timer ..... 1,000 hours
PRO to GO Therapy Timer ..... 10 days

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

## 6.1 Electromagnetic Compatibility

| Guidance and Manufacturer's Declaration: Electromagnetic Emissions (IEC 60601-1-2) | | |
|---|---|---|
| **Emissions Test** | **Compliance** | **Electromagnetic Environment** |
| Harmonic emissions<br>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<br>IEC 61000-3-3 | Complies | |
| RF emissions<br>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)** | | |
|---|---|---|---|
| | **150kHz to 80MHz** | **80MHz to 800MHz** | **800MHz 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 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: 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 | ±6kV contact<br>±8kV air | ±6kV contact<br>±8kV air | Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 percent. |

| | | | |
|---|---|---|---|
| Electrical fast transient/burst | ±2kV for power supply lines<br>±1kV for input/output | ±2kV for power supply lines<br>±1kV for input/output | Mains power quality should be that of a typical commercial and/or hospital environment. |
| Surge<br>IEC 61000-4-5 | ±1kV line to line<br>±2kV line to earth | ±1kV line to line<br>±2kV 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<br>IEC 61000-4-11 | <5% $U_T$<br>(>95% dip in $U_T$) for 0.5 cycle | <5% $U_T$<br>(>95% dip in $U_T$) for 0.5 cycle | Mains power quality should be that of a typical commercial and/or hospital environment. |
| | 40% $U_T$<br>(60% dip in $U_T$) for 5 cycles | 40% $U_T$<br>(60% dip in $U_T$) for 5 cycles | |
| | 70% $U_T$<br>(30% dip in $U_T$) for 25 cycles | 70% $U_T$<br>(30% dip in $U_T$) for 25 cycles | |
| | <5% $U_T$<br>(95% dip in $U_T$) for 5 sec. | <5% $U_T$<br>(95% dip in $U_T$) for 5 sec. | |
| Power frequency (50/60Hz) magnetic field<br>IEC 61000-4-8 | 3A/m | 3A/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. | | | |
| Conducted RF IEC 61000-4-6<br>Radiated RF IEC 61000-4-3 | 3V rms<br>150kHz ~ 80MHz<br>3V/m<br>800MHz ~ 2.5GHz | 3V rms<br>3V/m | 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.<br>**Recommend separation distance**<br>$d = 1.2\sqrt{P}$<br>$d = 1.2\sqrt{P}$ 80MHz to 800MHz<br>$d = 2.3\sqrt{P}$ 800MHz to 2.5GHz<br>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).<br>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]<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| Note 1: At 80MHz and 800MHz, the higher frequency range applies.<br>Note 2: 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 150kHz to 80MHz, field strengths should be less than 3V/m.

# 7. Additional Parts

## 7.1 Replacement Product

A.C. Power Adapter ..... 47-9100

## 7.2 Disposables and Accessories

### Dressings

Cardinal Health™ NPWT Small Foam Dressing Kit 10 x 8 x 3cm (10 per case) ..... 47-1702
Cardinal Health™ NPWT Medium Foam Dressing Kit 20 x 12.5 x 3cm (10 per case) ..... 47-1701
Cardinal Health™ NPWT Large Foam Dressing Kit 25 x 15 x 3cm (10 per case) ..... 47-1700
Cardinal Health™ NPWT X-Large Foam Dressing Kit 58.5 x 33 x 3cm (10 per case) ..... 47-1703
Cardinal Health™ Small White Foam Dressing 9.5 x 9.5 x 0.5cm (10 per case) ..... 47-1751
Cardinal Health™ NPWT Large White Foam Dressing 35 x 25 x 0.635cm (5 per case) ..... 47-1755

### Canisters

Canister without Gel, 300cc (10 per case) ..... 47-4100
Cardinal Health™ NPWT Canister with Gel, 300cc (10 per case) ..... 47-4000
Cardinal Health™ NPWT Canister with Gel, 500cc (10 per case) ..... 47-4500

### Accessories

NPWT Irrigation Delivery Kit (5 per case) ..... 47-6500
NPWT Irrigation Tubing with SpeedConnect™ (5 per case) ..... 47-6000
NPWT Bridging Kit (5 per case) ..... 47-1704
PRO/PRO to GO IV Pole Adapter (1 per case) ..... 47-5600
PRO/PRO to GO Carrying Case (1 per case) ..... 47-9600
NPWT Tubing with SpeedConnect™ (10 per case) ..... 47-2000
NPWT Polyurethane Drape (10 per case) ..... 47-7000
NPWT SensiSkin™ Drape (10 per case) ..... 47-7100

**NOTE:** In order to assure the highest safety, quality and efficacy of the products, the Cardinal Health™ PRO/PRO to GO should only be used with the Cardinal Health™ NPWT products listed above.

# 8. Questions & Information

For questions, comments or additional information pertaining to the Cardinal Health™ PRO/PRO to GO, please contact your local Cardinal Health representative, or:

**Call Customer Service at 1.866.484.6798**

Cardinal Health
Waukegan, IL 60085
www.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.

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