

PROSPERA[®] SPECTRUM

Negative Pressure Wound Therapy System

DeRoyal[®]



Patient and Clinician User Manual

INTRODUCTION

The Prospera Spectrum® Negative Pressure Wound Therapy (NPWT) System is a prescription medical device for use under the instruction of a licensed and trained clinician. Read and understand all contraindications, warnings, cautions, and instructions completely and carefully before use.



This user manual is not intended as a training document. All licensed clinicians should receive adequate NPWT training before operating the unit. Failure to do so may result in serious injury to the patient.

THIS USER MANUAL CONTAINS

Intended use, contraindications, and warnings

Listing of all symbols and icons with definitions

Instructions for licensed and trained clinician use, including accessories

Instructions for patient and caregiver use, including accessories

Travel, storage, and disposal

Reprocessing and cleaning instructions

Warranty and service program

Detailed technical data

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IMPORTANT SAFETY INFORMATION

The Prospera Spectrum® Negative Pressure Wound Therapy System is a prescription medical device for use under the instruction of a licensed and trained clinician. Read and understand all contraindications, warnings, cautions, and instructions completely and carefully before use. This user manual is not intended as a training document. All licensed clinicians should receive adequate NPWT training before operating the system.

Failure to do so may result in serious injury to the patient. Only trained, licensed clinicians should apply NPWT and wound dressings.

Local wound care by NPWT cannot overcome the deficits of unrelieved malnutrition, pressure, trauma, or compromised blood flow. Initiate interventions to reduce or relieve factors contributing to impaired wound healing in order to achieve optimum outcomes.

Read and understand all safety instructions to ensure proper use and to minimize risk of injury.

- This User Manual is a component of the Prospera Spectrum® NPWT System.
- Keep this User Manual in an accessible location.
- Include this User Manual when transferring the unit to third parties.
- Include the Quick Reference Guide when transferring the unit to third parties.
- Read and understand all safety instructions and directions for use included with all NPWT wound dressing components, canisters and accessories.
- For additional copies of any Prospera Spectrum® literature, please contact DeRoyal Customer Service (within the US: 1-800-251-9864).
- Prospera Spectrum® literature may also be downloaded from the DeRoyal website at www.deroyal.com.

To comply with service documentation specified by the manufacturer, and to comply with technical and hygienic precautionary measures, opening of the unit or service and/or repairs must be performed only by DeRoyal or by DeRoyal-authorized professionals.



IN CASE OF AN EMERGENCY, CONTACT A LOCAL EMERGENCY SERVICE IMMEDIATELY (DIAL 911 WITHIN THE US).

INTENDED USE

The Prospera Spectrum® Negative Pressure Wound Therapy System is a wound management system intended for use in acute, extended and home care settings. When used on open wounds, it is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. When used on closed surgical incisions, it is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

INDICATIONS

The Prospera Spectrum® NPWT System is indicated for use in the following applications:

- Chronic wounds
- Subacute wounds
- Dehisced wounds
- Closed surgical incisions
- Flaps
- Acute wounds
- Traumatic wounds
- Grafts
- Partial thickness burns
- Ulcers (diabetic, pressure, or venous insufficiency)

CONTRAINDICATIONS

The Prospera Spectrum® NPWT System is contraindicated for the following applications:

- Necrotic tissue with eschar present
- Untreated osteomyelitis
- Exposed anastomotic site
- Unexplored or non-enteric fistulas
- Wounds containing malignant tissue
- Exposed arteries, nerves – including vagus nerve – blood vessels, veins, internal organs

WARNINGS

Patients are to discuss any serious medical conditions(s) with their prescribing clinician. Before administering NPWT, clinicians are to review and use caution on patients with any serious medical condition, consider patient exposure to potential complications while under treatment with NPWT, and understand that use of NPWT in the presence of such complications could cause further, potentially fatal, injury.

If therapy is discontinued or disrupted for more than two (2) hours, contact a medical provider. For emergencies, dial 911 (within the US).

PATIENTS AND CAREGIVER ONLY

- DO NOT change wound dressing(s). Only a trained clinician should dress/undress a wound.
- DO NOT attempt to adjust the **Therapy Settings** on the unit. Only a trained clinician should access and change settings.

ALL USERS

- Before use, thoroughly inspect unit, including all accessories, tubing and cables, for breaks, cracks, damage or defects. Contact the trained clinician or equipment provider for further instructions if the unit or its accessories are damaged.
- Clinician should follow facility's protocol for wound site preparation, debridement, dressing technique and proper placement of unit when in use. Discard disposables according to instructions provided by a trained clinician monitoring care and in accordance with local, state, and federal laws.
- Before dressing wound, check all undermining and/or tunneling wounds for excess wound fillers (foam, gauze, etc.). Ensure all previous wound fillers are removed and take care to ensure wound fillers DO NOT rip or tear during removal.
- The Prospera Spectrum® NPWT unit has only been tested with the Prospera Spectrum® NPWT canisters. The Prospera Spectrum® Unit must be connected to a Prospera Spectrum® NPWT canister to enable its continuous and safe operation. Read and understand all safety instructions and directions for use included with all DeRoyal® NPWT canisters, and appropriate NPWT wound dressing components and accessories.

WARNINGS, CONT.

- Ensure dressing has a compressed appearance at the dressing surface. A compressed appearance means the dressing has properly adhered to the skin, the Prospera Smart Propel™ Dome has properly adhered to the dressing, and negative pressure is active.
- Check the system, including wound dressings, canister and unit settings (pressure, alarms, battery life, etc.) per facility protocol or every two (2) hours.
- Keep a written record of type and number of wound dressing pieces placed in the wound when using the system.
- Protect fragile periwound skin with appropriate sealing films, hydrocolloid, or transparent film dressings. To avoid risk of maceration or injury, DO NOT allow contact between foam dressing and healthy skin.
- Take extra caution to ensure dressing integrity is maintained when using NPWT in Variable Pressure Mode.
- All components contaminated with wound exudate must be reprocessed, cleaned, and disinfected or disposed of after each use.
- DO NOT clean the unit while it is plugged in or powered on.
- If therapy is discontinued or disrupted for more than two (2) hours, seek emergency medical attention.
- If patient shows signs of an allergic reaction, discontinue use, and rinse wound and surrounding skin. Use clinical discretion before restarting therapy or if symptoms of allergic reaction persist.
- Monitor exudate for changes in color or consistency as these may indicate an infection or wound worsening. Signs of infection may include: redness, pain, warmth, swelling at or near the wound, or changes in a wound's odor or discharge. Contact a trained clinician if changes occur.
- Monitor infected wounds closely. Infected wounds may require more frequent dressing changes. Examine exudate for any sign of infection, worsening infection, or other complications.
- Monitor wound exudate in canister for signs of excess blood loss or other complications. If active bleeding occurs, clamp dressing, apply direct pressure over the dressed wound, and disconnect from canister. Contact a health care provider or local emergency service (dial 911 within US) immediately.
- If the patient experiences a sudden change in blood pressure or heart rate (light headedness) contact a health care provider or local emergency service (dial 911 within US) immediately.

WARNINGS, CONT.

- Immediately stop NPWT and treat patients exhibiting autonomic dysreflexia (sudden changes in blood pressure or heart rate stimulated by the sympathetic nervous system).
- Avoid direct contact between wound dressing and all exposed or superficial organs, vessels, nerves, tendons and ligaments in or around wound. Cover and protect all such areas before using NPWT.
- To minimize the risk of bradycardia, do not place the NPWT system in proximity to the vagus nerve.
- Take extreme caution when administering NPWT to patients with friable vessels or potentially infected blood vessels.
- DO NOT modify, open or attempt to perform internal maintenance on the Prospera Spectrum® Unit without authorization of DeRoyal.

TAKE THE FOLLOWING PATIENT CONDITIONS INTO CONSIDERATION WHEN TREATING WITH NPWT:

- Patient's height and weight before prescribing the NPWT system – closely monitoring patients sensitive to fluid loss or at risk for dehydration
- Patients with heavily exudating wounds or large wounds – closely monitoring for excessive fluid loss and dehydration
- Patients suffering paralysis associated with the affected area or spinal cord injuries
- Patients at risk for maceration or injury
- Patients requiring circumferential dressing application
- Patients suffering from untreated malnutrition
- Patients with complicated wound hemostasis, anticoagulants, and platelet aggregation inhibitors
- Patients with irradiated vessels and tissues and/or vascular anastomosis
- Patients with bone fragments present
- Patients being treated for osteomyelitis
- Patients with enteric fistulas
- Non-adherent or non-responsive patients

WARNINGS, CONT.

ENVIRONMENTAL CONSIDERATIONS:

- Secure all tubing or cords, such as suction dome, canister or power supply to minimize fall hazard or risks associated with strangulation and asphyxiation.
- Before traveling, ensure NPWT unit is fully charged and power supply is kept with unit at all times.
- DO NOT use the unit while showering or bathing. Facility caregivers should consult a clinician for instructions on proper personal care while receiving therapy.
- Ensure unit is operating in a safe environment free from hazards including, but not limited to, splashing liquids, household pets, excessive lint/dust, small children, heaters and humidifiers.
- This system contains small parts. Keep all parts away from mouth and nose to avoid inhalation or swallowing.
- DO NOT bring the NPWT system into a magnetic resonance imaging (MRI) environment. Discontinue therapy, check for the presence of and remove all dressings and wound fillers prior. NPWT is not suitable in this environment and may be a safety hazard.
- Speak to a trained clinician before using in conjunction with other medical therapies, including X-ray or any other specialized environments.
- DO NOT use the NPWT system in a hyperbaric oxygen chamber. NPWT is not suitable in this environment and may be a fire hazard. Refer to facility treatment protocol for dressing management guidance.
- In the event defibrillation is required, disconnect the NPWT unit from wound dressing prior to defibrillation. Remove wound dressing if it interferes with defibrillation.
- Avoid exposure of unit, dressings, canisters or accessories to direct sunlight, extreme heat or cold.
- The Prospera Spectrum® NPWT System has not been tested for use on aircraft. Please consult prescribing provider prior to air travel.

OVERVIEW OF SYMBOLS, INDICATORS & BUTTONS



Warning – Associated with a potential hazard which could lead to serious injury



Type BF, Applied Part



Caution – Associated with a potential hazard, take caution



MR Unsafe



Follow Instructions for Use



Non-Ionizing Radiation



Keep Dry



Humidity Limitation



Manufacturer



Storage Temperature Range



Date of Manufacture



This product is designated for separate collection at an appropriate collection point. DO NOT dispose of as household waste.



Class II - Double Insulated Appliance

R_x Only

Prescription Only



Ingress Protection 22¹



To Indicate an Alarm Condition



To Indicate the Alarm System is in Audio Paused State











To Indicate the Alarm System is in the Alarm Paused State

For a list of symbols used in this manual, visit DeRoyal.com/symbols.



¹ Protected from touch by fingers and objects greater than twelve (12) millimeters. Protected from water spray less than fifteen (15) degrees from vertical.

OVERVIEW OF SYMBOLS, INDICATORS & BUTTONS

ICONS, INDICATORS & GRAPHICS








	BATTERY	Fully charged
	BATTERY	Battery under normal use; Approximately 80% remaining battery life
	BATTERY	Battery under normal use; Approximately 60% remaining battery life
	BATTERY	Battery under normal use; Approximately 40% remaining battery life
	BATTERY	Battery Low; Approximately 20% remaining battery life
	BATTERY	Battery very low; Less than one-hour remaining battery life; connect unit to external power supply
	BATTERY & ALARM	Battery critical; Connect unit to external power supply immediately
	CHARGING INDICATOR	Illuminated when plugged into external power source and charging

THERAPY INDICATOR

	THERAPY INDICATOR ACTIVE	Continuous rotation confirms therapy active and maintaining pressure
	THERAPY INDICATOR ALARM	Confirms active alarm. See <i>Troubleshooting Guide</i> or <i>Alarms</i> section in this manual.

OVERVIEW OF SYMBOLS, INDICATORS & BUTTONS

BUTTONS

	POWER	Power system ON or OFF
	HOME	Access Home screen from any menu
	LOCK	System is locked (Patient Mode) when icon is not illuminated. System is unlocked (Clinician Mode) when icon is illuminated green.
	OK	Confirm selection
	BACK	Return to previous screen
	UP	Move current selection up to next or to increase pressure or time requirements
	DOWN	Move current selection down to next or to decrease pressure or time requirements

OVERVIEW AND SET UP OF THE PROSEPERA SPECTRUM® SYSTEM

THE PROSEPERA SPECTRUM® SYSTEM COMPONENTS

The Prospera Spectrum® System is comprised of the following components:

- Prospera Spectrum® Unit with power supply and associated accessories
- Prospera Spectrum® Disposable Exudate Collection Canister(s)
- Prospera Smart Propel™ Dome

As with any prescription medical device, please follow all instructions and directions provided by a trained clinician.

AVAILABLE PRODUCT	DESCRIPTION	SINGLE USE / SINGLE PATIENT USE / REUSABLE
NP-7000 NP-7000-GPS	Prospera Spectrum® NPWT Unit	Reusable
NP-190U	Prospera Smart Propel™ Dome	Single Use
NP-7300 NP-7500 NP-7300N NP-7500N	Prospera Spectrum® NPWT Canisters (with or without solidifier)	Single Patient Use
NP-7201	Carrying Bag	Single Use
NP-7202	Power Cord	Reusable
NP-7205	Bed Rail and IV Pole Mount	Reusable

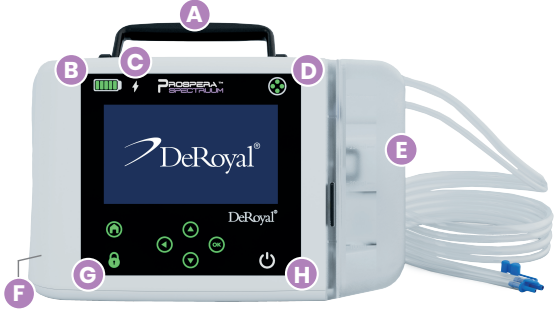
Additional products may be available, contact DeRoyal for latest offerings.

COMPONENT DESCRIPTIONS

The following figures have been provided as graphical representation of the entirety of the Prospera Spectrum® System and component accessories.

NEGATIVE PRESSURE WOUND THERAPY (NPWT) SYSTEM

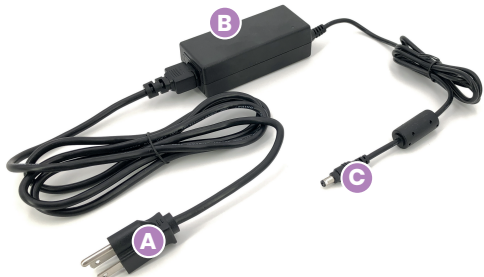
- A. Handle
- B. Battery Indicator
- C. Charging Indicator
- D. Therapy Indicator
- E. Canister
- F. Power Port
- G. Lock Button
- H. Power Button



- I. IV Pole/Bed Rail Mount Hook
- J. Back Canister Tab/Release Tab
- K. Unit Back Latch

POWER SUPPLY

- A. Power Cord
- B. Power Adaptor
- C. Charging Cord



COMPONENT DESCRIPTIONS, CONT.

EXUDATE CANISTER

- A. Canister Body
- B. Back Canister Tab/
Release Tab
- C. Solidifier
- D. Viewing Window
- E. Graduation Marks
- F. Canister Tubing
- G. Canister Adapter
- H. Canister Cap



DOME

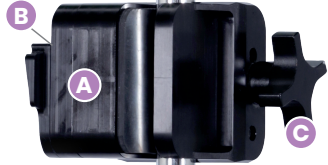
- A. Dome
- B. Tubing Clamp
- C. Silicone Connector
- D. Dressing Tubing



COMPONENT DESCRIPTIONS, CONT.

IV POLE/BED RAIL MOUNT

- A. IV Pole/Bed Rail Mount
- B. Unit Mounting Point
- C. Adjustment Clamp



CARRY BAG

- A. Strap
- B. Viewing Window
- C. Carry Bag Access
- D. Power Port



USING THE PROSPERA SPECTRUM® SYSTEM

The Prospera Spectrum® Unit must be connected only to components or accessories provided by DeRoyal, including power supply, disposable exudate canisters, domes, and dressing components. The Prospera Spectrum® Negative Pressure Wound Therapy System has been evaluated for safe and effective use with the compatible Prospera Spectrum® NPWT Black Foam Convenience Kits. These NPWT dressing kits contain the following dressing components:

- Black Foam wound filler dressing
- Semi-occlusive wound drape
- Prospera Smart Propel™ Dome

For continuous operation, keep device connected to an external power source.

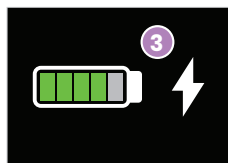
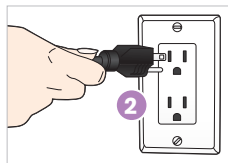
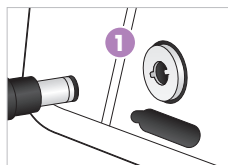
CONNECTING UNIT TO A POWER SUPPLY

A power cord is provided with the Prospera Spectrum® Unit. For best battery performance, unit should be connected by the power cord to external power outlet when available. It also operates by its internal rechargeable battery. To recharge the battery, the unit must be connected to an external power outlet. A full charge is attained in approximately four (4) hours. The life of service for the battery is approximately three (3) years and is reflected by the Use By date on the product label.

⚠ CAUTION: Ensure the power cord is compatible with the external power source. Avoid the use of extension cords (inclusive of power strips and surge protectors) and use care not to place cords on the floor.

TO CHARGE UNIT


1. Plug jack end of power cord into port on side of the unit (1).
2. Plug 3-prong connector into external power outlet (2).
3. Charging indicator will illuminate white when connected properly (3).



CONNECTING UNIT TO A POWER SUPPLY, CONT.








The Prospera Spectrum® Unit should be charged daily with the DeRoyal provided power supply. When in use, place the unit upright on a secure surface, avoiding areas where the unit is prone to falling or being damaged.

 **CAUTION:** DO NOT attempt to access the unit's USB port.

 **CAUTION:** Never clean the unit when powered on or when connected to an external power source, canister, dressing or patient. See *Cleaning* section for instructions.

BATTERY LIFE

Battery level is displayed at top left corner of unit user interface.

	BATTERY	Fully charged
	BATTERY	Battery under normal use; Approximately 80% remaining battery life
	BATTERY	Battery under normal use; Approximately 60% remaining battery life
	BATTERY	Battery under normal use; Approximately 40% remaining battery life
	BATTERY	Battery Low; Approximately 20% remaining battery life
	BATTERY	Battery very low; Less than one-hour remaining battery life; connect unit to external power supply
	BATTERY & ALARM	Battery critical; Connect unit to external power supply immediately

INSTALLING CANISTER PRIOR TO BEGINNING THERAPY

Disposable exudate canisters of two different volumes are available for use with the Prospera Spectrum® Unit: 300cc and 500cc.



⚠ CAUTION: The Prospera Spectrum® NPWT System should only be connected to components or accessories provided by DeRoyal, including power supply, disposable exudate canisters, domes, and dressing components to enable continuous and safe operation. Read and understand all safety Instructions For Use included with all NPWT wound dressing components and accessories.

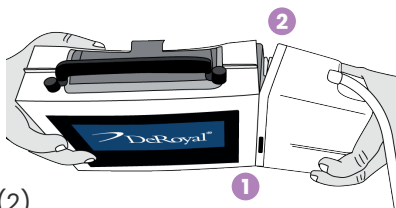
⚠ CAUTION: Contact a trained clinician if there are signs of infection. These may include redness, pain, warmth, swelling at or near the wound, or changes in the wound's odor or discharge. Clinical care is necessary to diagnose or treat an infection.

⚠ CAUTION: Monitor wound exudate in the canister for signs of excess blood loss or other complications. If active bleeding occurs: clamp dressing, apply pressure, and disconnect from the canister. Contact a health care provider or local emergency service (dial 911 within the U.S.) immediately.

INSTALLING CANISTER, CONT.

⚠ CAUTION Confirm canister and accessories are within reach prior to beginning any canister change procedures. Inspect all packaging for damage or defects. Replace the canister if the packaging is damaged. Pause therapy prior to initiating any canister changes.

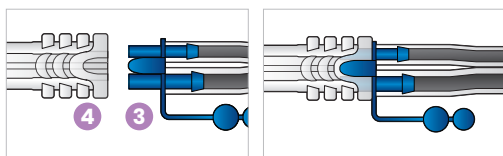
1. Remove exudate canister from packaging.
2. Align canister slot onto front unit tab (1) and rock towards the back of the unit, aligning the canister tab with the back latch (2).



3. Press the canister against the unit to engage the canister tab with the unit back latch (2). There will be an audible click when canister is securely attached to the unit.



4. Hold the end of the canister tubing, identify the canister adapter (3) and match it to the Prospera Spectrum® silicone tubing (4). The two should connect easily without force. The adapter and silicone tubing can only connect as shown in the image below. If excessive force is required check that the two components are aligned properly.



⚠ CAUTION Monitor wound exudate in canister for signs of excess blood loss or other complications. If active bleeding occurs, clamp the tubing of the dressing, apply direct pressure over the dressed wound, and disconnect from canister. Contact prescribing provider for further instruction.

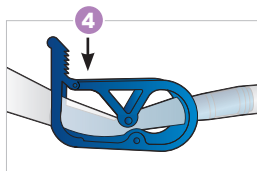
REPLACING THE CANISTER

1. Prepare a new compatible DeRoyal® canister
2. Press any button to “wake” unit.
3. Select **Pause Therapy** option and pause therapy for 5 minutes.

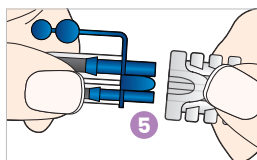


REPLACING THE CANISTER, CONT.

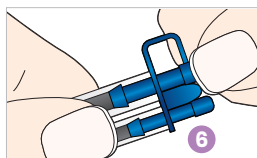
4. Press blue tubing clamp until closed to ensure dressing remains under vacuum during the canister change process (4).



5. Disconnect the canister tubing from the dressing tubing (5).



6. Place blue tubing cap onto the end of canister tubing (6).



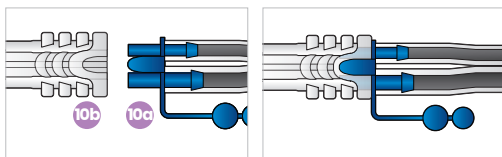
7. Release the canister by pressing the canister release tab (7a) and pulling away from the unit. Canister slides easily without applying force. If canister resists detachment, ensure canister release tab (7a) is fully depressed and disengaged from the unit back latch (7b).



8. Remove the new canister from the packaging.

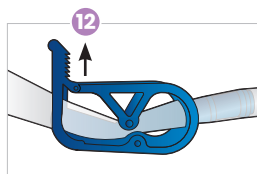
9. Connect new canister to unit. Ensure canister tab (7a) is fully engaged with the unit back latch (7b).

10. Hold the end of the canister tubing, identify the canister adapter tubing (10a) and match it to the Prospera Smart Propel™ Dome silicone tubing (10b). The two should connect easily without force. The adapter and silicone tubing can only connect as shown in the image below. If excessive force is required, check that the 2 components are aligned properly.



11. Check dressing and canister tubing for kinks and straighten where necessary.

12. Unclamp blue tubing clamp (12).



13. Select **Restart Therapy**.

14. Discard used canister according to trained clinician instructions and federal, state, and local law.


USE OF THE PROSPERA SPECTRUM® SYSTEM WITH NPWT DRESSING COMPONENTS

The Prospera Spectrum® Unit must be connected only to components or accessories provided by DeRoyal, including power supply, disposable exudate canisters, domes, and dressing components. The Prospera Spectrum® NPWT System has been evaluated for safe and effective use with the compatible Prospera Spectrum® Negative Pressure Wound Therapy Black Foam Convenience Kits. These NPWT dressing kits contain the following dressing components:

- Black Foam wound filler dressing
- Semi-occlusive wound drape
- Prospera Smart Propel™ Dome

Patients: DO NOT discard any unused kits or packaging (including shipping boxes) unless directed to by the equipment provider or a trained clinician.

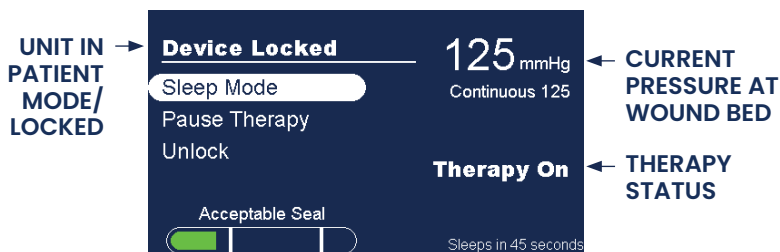
Dressing changes should be performed by trained clinicians, following provider's prescribed treatment. **THIS USER MANUAL IS NOT INTENDED AS A TRAINING DOCUMENT.** All licensed clinicians must receive adequate training before operating the unit or attempting to change wound dressings. Improper use or inadequate training may result in serious injury to the patient.

 **CAUTION:** Check the system, including wound dressings, canister and unit settings (pressure, alarms, battery life, etc.) per provider recommendations or at least every two (2) hours. Verify a compressed appearance at dressing surface. A compressed appearance means the dressing is properly adhered to the skin, the Prospera Smart Propel™ Dome has properly adhered to the dressing, and negative pressure is active.

PATIENT OPERATION OF THE PROSPERA SPECTRUM® UNIT



The Prospera Spectrum® Unit includes a user interface display screen and a set of buttons to enable user selections. The most common screens a patient will observe are the locked screen (Patient Mode) and the screen in Sleep Mode. Example of a locked screen is shown below.



THERAPY SETTINGS

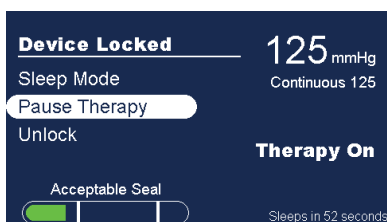
⚠ CAUTION: Only a trained clinician should change **Therapy Settings**.

PAUSE THERAPY

Press any button to “wake” unit. Select **Pause Therapy** from the menu. The unit will not actively maintain pressure while paused. Pause therapy to change the canister or to disconnect the unit from the dressing to perform personal care activities as directed by a trained clinician.

⚠ CAUTION: DO NOT use the unit while showering or bathing. The trained clinician will provide instructions on proper personal care while receiving therapy.

1. When **Pause Therapy** is selected from the screen, 2 options are available:
 - 1) **5 Minute Pause**
 - 2) **30 Minute Pause**
2. Select either **5 Minute Pause** or **30 Minute Pause**. The screen displays **Therapy Paused**, and a timer counts down for the duration of the selected pause. Resume therapy at any time by selecting **Restart Therapy**.
3. An alarm sounds at the end of the pause period. The maximum total pause time is thirty (30) minutes. The **Restart Pause** option disappears at the end of thirty (30) minutes, and the unit will alarm until **Restart Therapy** is selected.
4. Select **Restart Therapy** and Press **OK** to resume therapy after therapy is paused.




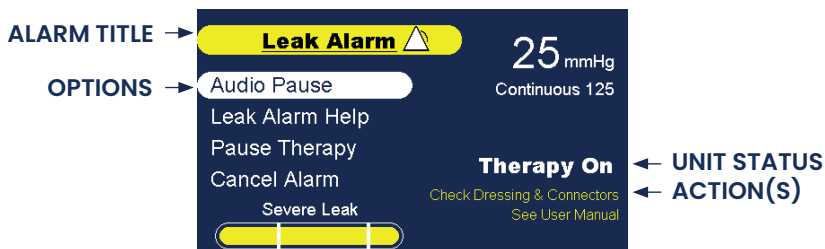
PATIENT & CAREGIVER ALARMS

The Prospera Spectrum® Unit is equipped with alarms to warn users of potential issues of with unit. All alarms require immediate attention to ensure the prescribed therapy is being delivered. In the event of an alarm, the unit will simultaneously signal with the following: a yellow banner, a yellow blinking therapy indicator and an audible tone.

If the unit is alarming, either resolve the cause of the alarm or choose from the options displayed on the screen:






- **Audio Pause:** Pauses audio alarm for five (5) minutes.
- **Alarm Help:** Displays alarm and basic trouble-shooting information.
- **Pause Therapy:** Allows user to pause therapy by selecting a pause duration option displayed on screen.
- **Cancel Alarm:** Cancels alarm, returns user to home screen. If alarm condition still exists after 1 minute, the alarm will reactivate.

 **CAUTION:** Contact equipment provider if action does not resolve alarm condition. In an emergency, call local emergency service (dial 911 within US) immediately.




PATIENT & CAREGIVER ALARMS, CONT.

ALARMS TROUBLE SHOOTING GUIDE

ALARM TITLE	UNIT STATUS	POTENTIAL ALARM ORIGINS	ACTION / TIPS
<p>LEAK ALARM</p> 	Attempting to provide therapy	<ul style="list-style-type: none"> » Disposable exudate canister not connected or improperly connected » Disposable exudate canister tubing not connected to dressing tubing » Dressing has major opening; dressing film does not adhere to skin 	<ul style="list-style-type: none"> » Check connection » Check connection between canister and tubing » Check dressing film for leaks or creases; apply additional film dressing and/or smooth out dressing
<p>CANISTER FULL</p> 	Therapy automatically paused	<ul style="list-style-type: none"> » Disposable exudate canister full » Canister improperly connected » Filter blocked 	<ul style="list-style-type: none"> » Replace disposable exudate canister; Restart Therapy » Contact equipment provider
<p>BLOCKED ALARM</p> 	Attempting to provide therapy	<ul style="list-style-type: none"> » System has determined that blockage is present » Exudate flow obstructed (clamp / cap closed, tubing kinked, stenosis in tubing) 	<ul style="list-style-type: none"> » Check clamps, caps and all tubing and tubing connections. Ensure tubing is not kinked or compressed » Ensure a dime-sized hole was cut in drape underneath dome a smaller hole or X cut may cause functionality issues » Ensure dome avoids skin fold or crease that could block flow at dome site
<p>BATTERY CRITICAL</p> 	Unit is ON, powering OFF imminent	<ul style="list-style-type: none"> » Battery nearly depleted 	<ul style="list-style-type: none"> » Connect unit to external power supply immediately » Ensure power chord is connected securely to unit » Fewer dressing leaks extend battery life
<p>THERAPY INACTIVE</p> 	Therapy is OFF	<ul style="list-style-type: none"> » Unit turned on, but therapy not started » Unit not turned off at end of therapy 	<ul style="list-style-type: none"> » Contact your healthcare provider immediately » Communicate therapy must be selected and initiated by clinician
<p>THERAPY PAUSE TIME ELAPSED</p> 	Unit is ON and therapy is paused	<ul style="list-style-type: none"> » Therapy paused but not restarted after dressing or canister change 	<ul style="list-style-type: none"> » Ensure canister and dressing are reconnected to unit » Restart therapy

PATIENT & CAREGIVER ALARMS, CONT.

ALARMS TROUBLE SHOOTING GUIDE, CONT.

SYSTEM ERROR			
	Therapy status unknown	» Unit damaged from drop or other unknown event	» DO NOT use unit; contact equipment provider

LEAK ALARM

The Prospera Spectrum® Unit is able to detect leaks in the system. In the event of a severe leak, a Leak Alarm will occur.

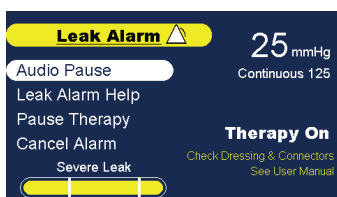
A Leak Alarm may trigger if one of the following occurs:

- Canister is not securely attached to unit;
- Canister tubing is not securely connected to dome tubing; and/or
- Dressing film does not maintain a complete seal.

The Leak Alarm will continue to sound until leak is resolved or unit battery is depleted.

TO RESOLVE A SEVERE LEAK:

1. Check for secure connection between canister and unit. If not secure, detach and reattach canister (see *Replacing The Canister* section).
2. Check for secure connection between canister tubing and dome tubing. Disconnect and rejoin to ensure a snug fit.
3. Ensure dressing film adheres to skin all around wound. Apply light pressure to assist with film adherence.
4. Leak Check Indicator automatically changes on display screen as leaks are addressed. Alarm continues to sound until leak is resolved or unit battery is depleted.



CANISTER FULL ALARM

⚠ WARNING: When Canister Full alarm is triggered, unit stops providing therapy.

A Canister Full Alarm triggers if the canister is full or the canister filter is covered by exudate.

1. If canister is full, change canister and connect to dressing. Restart therapy. See *Replacing The Canister* section for instructions on how to change canister.
2. If canister is not full, verify device is stable and up-right on sturdy surface, or mounted on bed rail or I.V. pole. Secure and stabilize unit. Restart therapy.
3. If alarm persists, change canister and reconnect to dressing. Restart therapy.

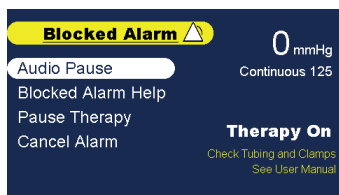


BLOCKED ALARM

A Blocked Alarm triggers if there is a block in the system.

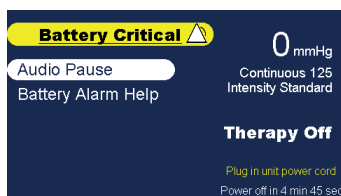
A Blocked Alarm has many potential causes:

1. If patient is laying on tubing, rearrange patient/tubing.
2. If tubing is kinked, straighten tubing to remove kink.
3. If blue tubing clamp is closed, unclamp/open blue tubing clamp to restore vacuum pressure.
4. If exudate/blood has blocked canister tubing, change canister (see *Replacing The Canister* section).
5. If exudate/blood has blocked dome tubing, contact the trained clinician or equipment provider immediately to request a dressing change.



BATTERY CRITICAL ALARM

The Battery Critical Alarm triggers when unit has less than 5% battery capacity remaining. Immediately connect unit to external power source.



Battery level critical.

THERAPY INACTIVE (IDLE) ALARM

The Therapy Inactive (Idle) Alarm triggers if unit is ON for more than fifteen (15) minutes without active therapy or user interaction.

Start Therapy, power off the unit, or contact the health care provider immediately.



THERAPY PAUSED TIME ELAPSED ALARM

A Therapy Paused Time Elapsed Alarm triggers at the end of the selected pause period. To resolve, either select **Restart Therapy** or **Restart Pause**.

The total allowable pause time is thirty (30) minutes; therapy cannot be paused for longer than thirty (30) minutes total.

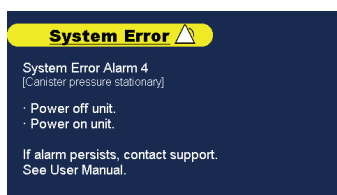
Once the thirty (30) minute pause time has elapsed, the **Restart Pause** option is no longer available. The unit will continue to alarm until **Restart Therapy** is selected.

Select **Restart Therapy** to continue therapy.



SYSTEM ERROR ALARM

If a System Error Alarm triggers, restart the system by powering it off and on again (see *Powering Off* and *Powering On* sections). If issue does not resolve, discontinue use by powering off unit and disconnecting from dressing.



CAUTION: Contact equipment provider if action does not resolve alarm condition. In an emergency, call local emergency service (dial 911 within US) immediately.

ALARM FUNCTIONALITY TEST

To verify functionality of the alarm system, attach a canister to the Prospera Spectrum® Unit, ensuring the canister adapter is not capped, and start therapy. During alarm functionality testing the unit user should be within the unit's Operator Position. The unit's Operator Position is any distance from the unit in which the operator may receive and interpret an alarm condition. The Leak Alarm should occur within two (2) minutes of therapy being started. If Leak Alarm is not activated within this time frame, check canister attachment and contact equipment provider.



INTELLIGENT ALARM SYSTEM

When alarm conditions occur, the Prospera Spectrum® Unit shows one (1) alarm at a time. If the alarm condition is resolved, the unit will discontinue the alarm.

Alarms will be displayed based on their priority level with the highest priority level taking precedence. Alarms are prioritized based on their criticality:

1. System Error Alarm (highest priority)
2. Battery Critical Alarm
3. Canister Full Alarm
4. Leak Alarm
5. Blocked Alarm
6. Therapy Pause Time Elapsed Alarm
7. Therapy Inactive Alarm (lowest priority)

CLINICIAN OPERATION OF THE PROSPERA SPECTRUM® UNIT

⚠ WARNING: This section of instructions is intended for licensed and trained clinicians ONLY. Patients and Caregivers should refer only to Patient Operation of the Prospera Spectrum® Unit section) of this manual.

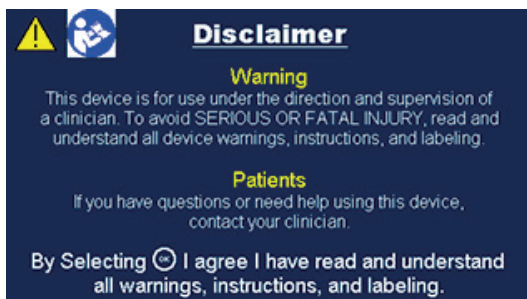


POWERING ON

1. To power on the unit, press **POWER** located on the bottom right side of the front panel.
2. The following text will appear on the display screen:

⚠ WARNING This device is for use under the direction and supervision of a clinician. To avoid **SERIOUS OR FATAL INJURY**, read and understand all device warnings, instructions, and labeling. Patients, if you have questions or need help using this device, contact your clinician. By selecting **OK** I agree I have read and understand all warnings, instructions, and labeling.

3. Press **OK** to indicate user has read, understood, and agreed with information in Disclaimer.



POWERING OFF

1. To power OFF the unit, press and hold **Power Button** located on the bottom right side of the front panel for at least 1 second.
2. Press the **Power Button** a second time prior to the count on the screen reaching zero to acknowledge the intent to stop therapy and power OFF the unit. This will power OFF the unit and therapy will be stopped.
3. If **Power Button** is not pushed prior to count reaching zero, the unit will return to the previous screen.



STARTING THERAPY

⚠ CAUTION: Before starting therapy, follow these important steps:

1. Confirm therapy pressure settings on Home screen match prescribed therapy (see *Therapy Settings* section).
2. Confirm wound dressing is applied properly and is connected to a canister.
3. Confirm canister is securely connected to Prospera Spectrum® Unit.
4. Ensure unit is operating in a safe environment free from hazards including, but not limited, to splashing liquids, and humidifiers.
5. Ensure unit is placed on a stable surface to avoid accidental tipping or falling during therapy.
6. Confirm all canisters are provided by DeRoyal.



From the Home screen, with Start Therapy option selected:

1. Press **OK** to start therapy. Prescribed pressure level is attained within ten (10) seconds to one (1) minute, depending upon intensity setting selected. Foam or gauze should be compressed in the wound bed.
2. At therapy start, the green LED therapy indicator will continuously rotate to confirm unit is maintaining pressure. Display screen also indicates current pressure setting.



STARTING THERAPY, CONT.

- Unit automatically locks to Patient Mode and preserves current settings after five (5) minutes of user interface inactivity.

UNIT LOCKED/ IN
PATIENT MODE →



DISPLAY SCREEN DISPLAYS A LOCKED UNIT
(ALSO CALLED PATIENT MODE)

- Unit "sleeps" for sixty (60) seconds after locking. Press any button to "wake" unit.

LEAK CHECK INDICATOR

The leak check indicator reports on integrity of wound dressing seal and status of any leaks around the wound dressing seal, along system tubing, and at the point of connection between canister and unit. See *Alarms* section for more information. Leak indicator displays Acceptable Seal, Moderate Leak, or Severe Leak. If indicator is green, all seals are acceptable.

LEAK CHECK
INDICATOR DISPLAYS
ACCEPTABLE SEAL →



If leak is moderate, indicator remains green. A Moderate Leak does not affect efficacy of therapy, but it can reduce battery life if unit is not connected to an external power source. Leak indicator automatically changes on display screen as adjustments are made.

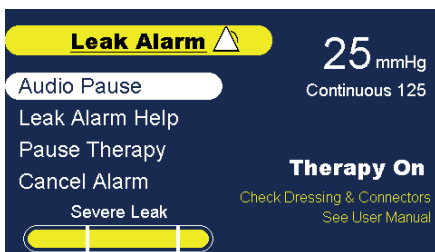
LEAK CHECK INDICATOR, CONT.

To resolve Moderate Leak:

1. Check for secure connection between canister and unit. If not secure, detach and reattach canister (see *Replacing The Canister* section).
2. Check for secure connection between canister tubing and dome tubing. Disconnect and rejoin to ensure a snug fit.
3. Check that dressing film adheres to skin all around wound. Apply additional dressing film, if necessary, to reduce or eliminate leak. Look for areas where dressing film is folded.



If leak is severe, an alarm sounds, display screen shows alarm message in yellow, and green LED therapy indicator stops rotating and flashes yellow, signaling therapy is compromised. Take immediate corrective measures.



A Leak Alarm triggers if one of the following occurs: canister is not securely attached to unit, canister tubing is not securely connected to the dome tubing, and/or dressing film does not adhere to skin all around the wound.

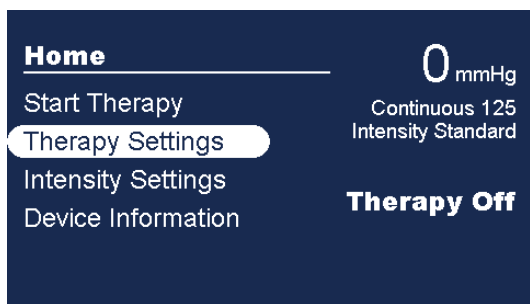
Leak indicator automatically changes on display screen as leaks are addressed. Alarm continues to sound until leak is resolved or unit battery is depleted. See *Alarms* section for information about other alarms.

THERAPY SETTINGS

CAUTION: Only a trained clinician should change **Therapy Settings**.

Access the **Therapy Settings** menu.

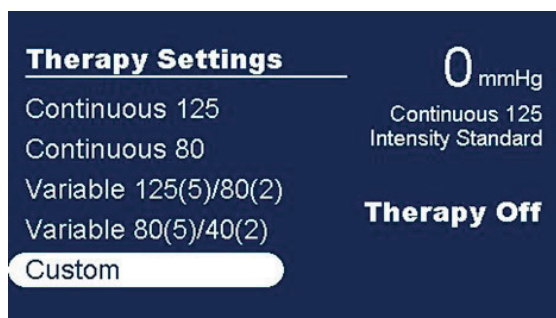
When therapy is OFF, access **Therapy Settings** menu from the Home screen. Factory default setting is Continuous 125mmHg with standard intensity.



HOME SCREEN WITH DEFAULT THERAPY SETTINGS SELECTED

THERAPY SETTINGS MENU:

Select **Therapy Settings** option. Five (5) settings are available and displayed on the **Therapy Settings** screen:

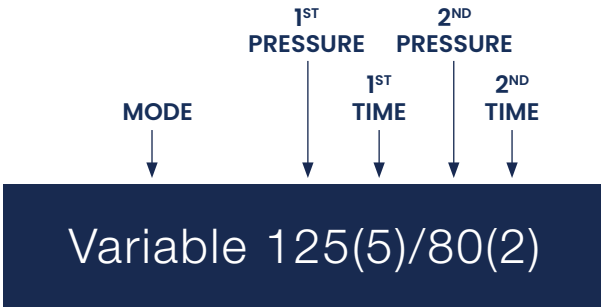


THERAPY SETTINGS, CONT.

THERAPY SETTINGS OPTIONS

CONTINUOUS 125	Maintains continuous 125mmHg negative pressure therapy at wound bed.
CONTINUOUS 80	Maintains continuous 80mmHg negative pressure therapy at wound bed.
VARIABLE 125 (5)/80(2)	Maintains 125mmHg negative pressure for 5 minutes, then 80mmHg for 2 minutes; repeats until therapy is paused or stopped.
VARIABLE 80 (5)/40(2)	Maintains 80mmHg negative pressure for 5 minutes, then 40mmHg for 2 minutes; repeats until therapy is paused or stopped.
CUSTOM	Allows variable customized pressure and time settings.

For Variable pressure therapy, the screen displays pressure levels and length of time associated with each pressure..



THERAPY SETTINGS, CONT.

CUSTOM THERAPY SETTINGS

The Prospera Spectrum® Unit allows clinicians to set customized therapy to meet clinical requirements. Select **Custom** option in the **Therapy Settings** menu to create custom **Therapy Settings**.

Two therapy modes are available: Continuous or Variable.



CUSTOM CONTINUOUS PRESSURE THERAPY

Select **Continuous** for continuous pressure therapy. Screen displays a pressure of 125mmHg. Pressure can be adjusted in increments of 5mmHg and range from 25mmHg to 200mmHg.



At the Select Pressure screen, press **UP** and **DOWN** arrows to adjust the desired pressure. Press **OK** to select and save pressure setting. Press **OK** again to start therapy.

THERAPY SETTINGS, CONT.

CUSTOM VARIABLE PRESSURE THERAPY

Select **Variable** to access variable pressure settings:



1. Set high-pressure value

Pressure is adjusted in increments of 5mmHg and range from 40mmHg to 200mmHg. Use **UP / DOWN** arrows to adjust settings. Press **OK** to continue.



2. Set duration of high-pressure therapy.

Time settings are adjusted in increments of one minute and range from one (1) minute – sixty-one (61) minutes. Use **UP / DOWN** arrows to adjust settings. Press **OK** to continue.



THERAPY SETTINGS, CONT.

CUSTOM VARIABLE PRESSURE THERAPY, CONT.

3. Set low-pressure value.

Use **UP** / **DOWN** arrows to adjust low pressure. Default low-pressure setting is 40mmHg less than high-pressure setting. Pressure settings adjust in increments of 5mmHg. Minimum difference between pressure settings is 40mmHg. Minimum low-pressure setting is 0mmHg. Use **UP** / **DOWN** arrows to adjust settings. Press **OK** to continue.

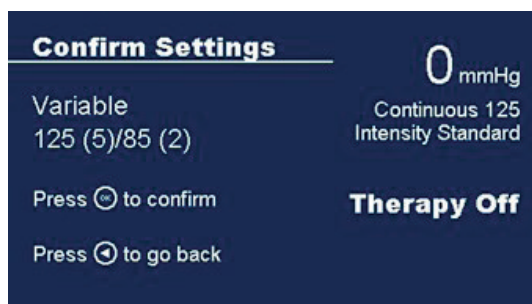


4. Set duration of low-pressure therapy.

Use **UP** and **DOWN** arrows to adjust the second time period. Time adjusts in increments of one (1) minute and ranges from one (1) minute – sixty-one (61) minutes. Press **OK** to continue.



5. Press **OK** to save custom Variable Therapy Settings.



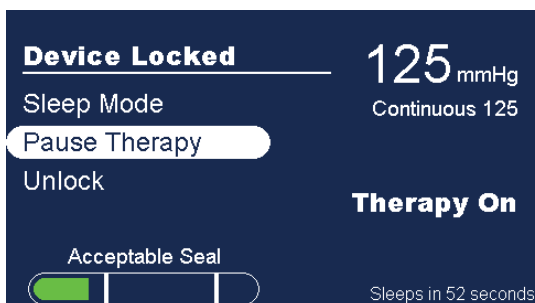
6. Press **OK** again to start therapy.

LOCKING / UNLOCKING THE UNIT

CAUTION: Only a trained clinician should change **Therapy Settings**.

DEVICE LOCKED MENU

After therapy is initiated, lock device by selecting **Lock** button to enter Patient Mode. The Prospera Spectrum® Unit automatically enters Patient Mode after 5 minutes of inactivity. Device will not lock if therapy has not started. When locked, unit will default to Sleep Mode at one (1) minute after last user interaction. Press any button to “wake” unit. The screen displays three options: 1) Sleep Mode, 2) Pause Therapy, and 3) Unlock.



SLEEP MODE

While therapy is on and unit is locked, unit will enter Sleep Mode after one (1) minute of user interface inactivity. Display screen turns OFF during sleep mode. The therapy indicator remains visible when unit is in sleep mode. Press any button to “wake” unit and activate Device Locked screen. Timer is reset to one (1) minute each time a button is pressed. Device Locked screen presents options to go back to Sleep Mode, Pause Therapy, or Unlock.

UNLOCK / ACCESS CLINICAL SETTINGS

1. Press any button to “wake” unit (if in sleep mode).

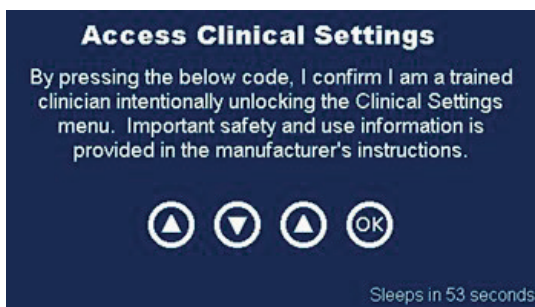


LOCKING / UNLOCKING THE UNIT, CONT.

2. On unit display scroll down to unlock, press **OK**.



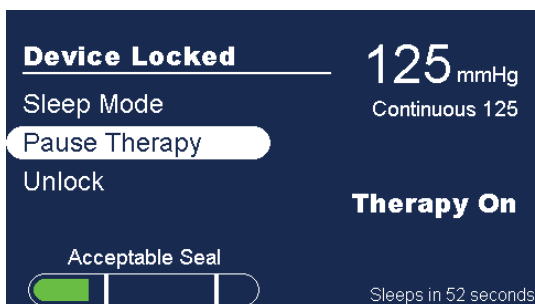
3. Read **Access Clinical Settings** screens and confirm user is a clinician by pressing **OK**.



4. Continue reading **Access Clinical Settings** screens and confirm user is a clinician by pressing **UP, DOWN, UP, OK**.
5. You now have access to clinical settings and unit returns to Home Screen.

PAUSE THERAPY

Select **Pause Therapy** to interrupt therapy for canister changes, dressing changes, or temporarily disconnect from the dressing to perform personal care activities that otherwise cannot be performed on or by the patient while connected to the device.



PAUSE THERAPY, CONT.

1. When **Pause Therapy** is selected from the unlock screen, two options are available:
 - 1) **5 Minute Pause**
 - 2) **30 Minute Pause**



2. Select either **5 Minute Pause** or **30 Minute Pause**. The screen displays **Therapy Paused**, and a timer counts down for the duration of the selected pause. Resume therapy at any time by selecting **Restart Therapy**.



3. An alarm sounds at the end of the pause period. The maximum total pause time is thirty (30) minutes. The **Restart Pause** option disappears at the end of thirty (30) minutes, and the unit will alarm until **Restart Therapy** is selected.



4. Press OK to **Restart Therapy**.

INTENSITY SETTINGS

WARNING: Only a trained clinician should change **Therapy Settings**.

1. When therapy is OFF, access **Intensity Settings** menu from the Home screen. Intensity settings control how quickly pressure increases from 0mmHg to prescribed pressure. The factory default setting is Standard Intensity. The Slow Intensity Setting can be used throughout therapy without affecting treatment.

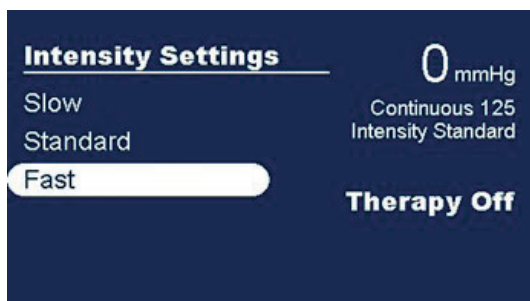


2. Choose from three (3) Settings: 1) Slow, 2) Standard, and 3) Fast

INTENSITY SETTINGS	INTENSITY SETTING AFTER PRESSURE REACHED
Slow (30s to achieve desired pressure)	Slow
Standard (15s to achieve desired pressure)	Standard
Fast (as fast as possible to achieve desired pressure)	Standard

CAUTION: Use caution when choosing Fast as an Intensity Setting as this may increase patient discomfort at start of therapy.

3. Intensity setting is visible until pressure is reached on right side of screen.



4. Intensity setting is saved on unit and will not automatically change between uses.

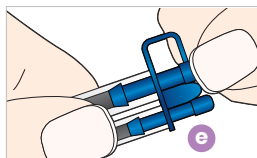
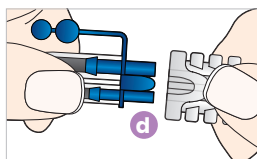
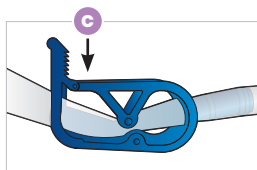
CHANGING DRESSINGS

CAUTION: Only a trained clinician should change dressings.

Dressing changes should be performed by trained clinicians, following physician's prescribed treatment. **THE USER MANUAL IS NOT INTENDED AS A TRAINING DOCUMENT.** All licensed clinicians must receive adequate training prior to operating the unit or attempting to change wound dressings. Improper use or inadequate training may result in serious injury to the patient.

1. Directions to disconnect dressing from unit.

- Press any button to "wake" unit.
- Select **Pause Therapy** for five (5) Minutes or thirty (30) minutes.
- Depress blue clamp between canister tubing and dome tubing.
- Disconnect canister tubing from dome tubing.
- Secure blue tubing cap onto end of canister tubing.



2. If needed, detach canister from unit and discard according to facility protocol and federal, state and local law.

3. Remove dressing.

- Remove dressing films from skin surrounding wound.
- Remove all wound fillers from inside the wound.


WARNING: Check all undermining and / or tunnels for excess wound fillers. Ensure all wound fillers are removed. Take care to ensure wound fillers DO NOT rip or tear during removal.


4. Apply new wound dressing according to facility protocol and wound dressing instructions.

CAUTION: Contact equipment provider if action does not resolve alarm condition. In an emergency, call local emergency service (dial 911 within US) immediately.


CHANGING DRESSINGS, CONT.

5. Attach dressing to unit.
 - a) Attach new canister to unit, if needed (see *Replacing The Canister* section).
 - b) Connect dome tubing to canister tubing.
6. Select **Restart Therapy** from Therapy Paused screen.
 - a) Confirm dressing has compressed appearance at surface.
 - b) If dressing is not compressed, check all connections and release the blue clamp if depressed.
7. Place unit in sleep mode by selecting **Sleep Mode** from **Device Locked** screen.

 **WARNING:** Document the type and number of wound dressing pieces that are placed in the wound when using the NPWT system. Compressed appearance means the drape is properly adhered to skin, the Prospera Smart Propel™ Dome is properly adhered to the drape, and negative pressure is active.

 **CAUTION:** Check the system, including wound dressings, canisters and unit settings (pressure, alarms, battery life, etc.) per facility protocol or every two (2) hours. Verify a compressed appearance at dressing surface. A compressed appearance means the drape is properly adhered to skin, the Prospera Smart Propel™ Dome is properly adhered to the drape, and negative pressure is active.

STOPPING THERAPY

 **CAUTION:** Only a trained clinician should change **Therapy Settings**.

NOTE: Pausing therapy may be an appropriate alternative to stopping therapy in some situations. Maximum pause time is thirty (30) minutes. (see *Pause Therapy* section).

From Sleep Mode:

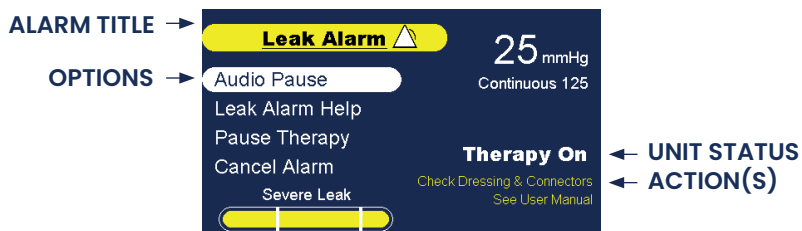
1. Press any button to “wake” unit.
2. Select **Unlock** option.
3. Read **Access Clinical Settings** screens and confirm user is a clinician by pressing **OK**.
4. Continue reading **Access Clinical Settings** screens and confirm user is a clinician by pressing **UP, DOWN, UP, OK**.
5. Select **Stop Therapy**.
6. Press **OK** to confirm and stop therapy.
7. Unit reduces pressure to 0mmHg.
8. Wait for pressure to reach 0mmHg before disconnecting canister tubing from dressing tubing.
9. When therapy is stopped, the green LED therapy indicator stops rotating.
10. Turn unit OFF. If unit is left ON after therapy is stopped, unit alarms after fifteen (15) minutes of inactivity (see *Therapy Inactive (Idle) Alarm* section).

CLINICIAN ALARMS

The Prospera Spectrum® Unit is equipped with alarms to warn users of potential issues of with unit. All alarms are considered MEDIUM priority and require immediate attention to ensure the prescribed therapy is being delivered. In the event of an alarm, the unit will simultaneously signal with the following: a yellow screen, a yellow blinking therapy indicator and an audible tone.



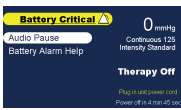


If the unit is alarming, either resolve the alarm or choose from the options displayed on the screen:

- **Audio Pause:** Pauses audio alarm for five (5) minutes; (see unit interface for therapy status)
- **Alarm Help:** Displays alarm and basic trouble-shooting information (see unit interface for therapy status)
- **Pause Therapy:** Pauses therapy options display on screen
- **Cancel Alarm:** Cancels alarm, returns user to home screen. If alarm conditions still exists after one (1) minute, the alarm will activate again (see unit interface for therapy status)



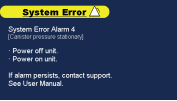

CLINICIAN ALARMS, CONT.

ALARMS TROUBLE SHOOTING GUIDE

ALARM TITLE	UNIT STATUS	POTENTIAL ALARM ORIGINS	ACTION / TIPS
<p>LEAK ALARM</p> 	Attempting to provide therapy	<ul style="list-style-type: none"> » Disposable exudate canister not connected or improperly connected » Disposable exudate canister tubing not connected to dressing tubing » Dressing has major opening; dressing film does not adhere to skin 	<ul style="list-style-type: none"> » Check connection » Check connection between canister and tubing » Check dressing film for leaks or creases; apply additional film dressing and/or smooth out dressing
<p>CANISTER FULL</p> 	Therapy automatically paused	<ul style="list-style-type: none"> » Disposable exudate canister full » Canister improperly connected » Filter blocked 	<ul style="list-style-type: none"> » Replace disposable exudate canister; Restart Therapy » Contact equipment provider
<p>BLOCKED ALARM</p> 	Attempting to provide therapy	<ul style="list-style-type: none"> » System has determined that blockage is present » Exudate flow obstructed (clamp / cap closed, tubing kinked, stenosis in tubing) 	<ul style="list-style-type: none"> » Check clamps, caps and all tubing and tubing connections. Ensure tubing is not kinked or compressed » Ensure a dime-sized hole was cut in drape underneath dome a smaller hole or X cut may cause functionality issues » Ensure dome avoids skin fold or crease that could block flow at dome site
<p>BATTERY CRITICAL</p> 	Unit is ON , powering OFF imminent	<ul style="list-style-type: none"> » Battery nearly depleted 	<ul style="list-style-type: none"> » Connect unit to external power supply immediately » Ensure power chord is connected securely to unit » Fewer dressing leaks extend battery life
<p>THERAPY INACTIVE</p> 	Therapy is OFF	<ul style="list-style-type: none"> » Unit turned on, but therapy not started » Unit not turned off at end of therapy 	<ul style="list-style-type: none"> » Contact your healthcare provider immediately » Communicate therapy must be selected and initiated by clinician
<p>THERAPY PAUSE TIME ELAPSED</p> 	Unit is ON and therapy is paused	<ul style="list-style-type: none"> » Therapy paused but not restarted after dressing or canister change 	<ul style="list-style-type: none"> » Ensure canister and dressing are reconnected to unit » Restart therapy

CLINICIAN ALARMS, CONT.

ALARMS TROUBLE SHOOTING GUIDE, CONT.

SYSTEM ERROR			
 <p>System Error </p> <p>System Error Alarm 4 (Critical pressure disturbance)</p> <p>Power off unit. Power on unit.</p> <p>If alarm persists, contact support. See User Manual.</p>	Therapy status unknown	» Unit damaged from drop or other unknown event	» DO NOT use unit; contact equipment provider

LEAK ALARM

The Prospera Spectrum® Unit is able to detect leaks in the system. In the event of a severe leak, a Leak Alarm will occur.

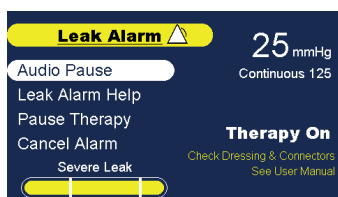
A Leak Alarm may trigger if one of the following occurs:

- Canister is not securely attached to unit;
- Canister tubing is not securely connected to dome tubing; and/or
- Dressing film does not maintain a complete seal.

The Leak Alarm will continue to sound until leak is resolved or unit battery is depleted.

TO RESOLVE A SEVERE LEAK:

1. Check for secure connection between canister and unit. If not secure, detach and reattach canister (see *Replacing The Canister* section).
2. Check for secure connection between canister tubing and dome tubing. Disconnect and rejoin to ensure a snug fit.
3. Ensure dressing film adheres to skin all around wound. Apply light pressure to assist with film adherence.
4. Leak Check Indicator automatically changes on display screen as leaks are addressed. Alarm continues to sound until leak is resolved or unit battery is depleted.



CANISTER FULL ALARM

⚠ WARNING: When Canister Full alarm is triggered, unit stops providing therapy.

A Canister Full Alarm triggers if the canister is full or the canister filter is covered by exudate.

1. If canister is full, change canister and connect to dressing. Restart therapy. See *Replacing The Canister* section for instructions on how to change canister.
2. If canister is not full, verify device is stable and up-right on sturdy surface, or mounted on bed rail or I.V. pole. Secure and stabilize Unit. Restart therapy.
3. If alarm persists, change canister and reconnect to dressing. Restart therapy.

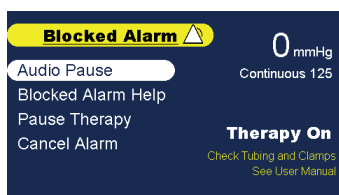


BLOCKED ALARM

A Blocked Alarm triggers if there is a block in the system.

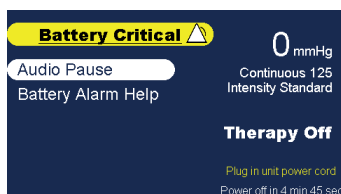
A Blocked Alarm has many potential causes:

1. If patient is laying on tubing, rearrange patient/tubing.
2. If tubing is kinked, straighten tubing to remove kink.
3. If blue tubing clamp is closed, unclamp/open blue tubing clamp to restore vacuum pressure.
4. If exudate/blood has blocked canister tubing, change canister (see Replacing The Canister section).
5. If exudate/blood has blocked dome tubing, contact the trained clinician or equipment provider immediately to request a dressing change.



BATTERY CRITICAL ALARM

The Battery Critical Alarm triggers when unit has less than 5% battery capacity remaining. Immediately connect unit to external power source.



Battery level critical.

THERAPY INACTIVE (IDLE) ALARM

The Therapy Inactive (Idle) Alarm triggers if unit is ON for more than fifteen (15) minutes without active therapy or user interaction.

Start Therapy, power off the unit, or contact the health care provider immediately.



THERAPY PAUSED TIME ELAPSED ALARM

A Therapy Paused Time Elapsed Alarm triggers at the end of the selected pause period. To resolve, either select **Restart Therapy** or **Restart Pause**.

The total allowable pause time is thirty (30) minutes; therapy cannot be paused for longer than thirty (30) minutes total.

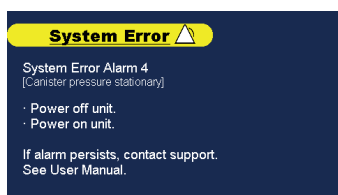
Once the thirty (30) minute pause time has elapsed, the **Restart Pause** option is no longer available. The unit will continue to alarm until **Restart Therapy** is selected.

Select **Restart Therapy** to continue therapy.



SYSTEM ERROR ALARM

If a System Error Alarm triggers, restart the system by powering it off and on again (see *Powering Off* and *Powering On* sections). If issue does not resolve, discontinue use by powering off unit and disconnecting from dressing.



CAUTION: Contact equipment provider if action does not resolve alarm condition. In an emergency, call local emergency service (dial 911 within US) immediately.

ALARM FUNCTIONALITY TEST

To verify functionality of the alarm system, attach a canister to the Prospera Spectrum® Unit, ensuring the canister adapter is not capped, and start therapy. During alarm functionality testing the unit user should be within the unit's Operator Position. The unit's Operator Position is any distance from the unit in which the operator may receive and interpret an alarm condition. The Leak Alarm should occur within two (2) minutes of therapy being started. If Leak Alarm is not activated within this time frame, check canister attachment and contact equipment provider.



INTELLIGENT ALARM SYSTEM

When alarm conditions occur, the Prospera Spectrum® Unit shows one (1) alarm at a time. If the alarm condition is resolved, the unit will discontinue the alarm.

Alarms will be displayed based on their priority level with the highest priority level taking precedence. Alarms are prioritized based on their criticality:

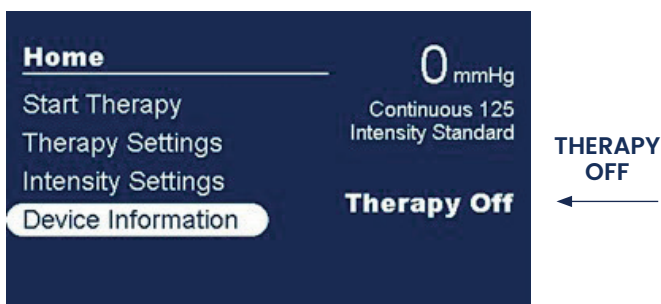
1. System Error Alarm (highest priority)
2. Battery Critical Alarm
3. Canister Full Alarm
4. Leak Alarm
5. Blocked Alarm
6. Therapy Pause Time Elapsed Alarm
7. Therapy Inactive Alarm (lowest priority)

CLINICIAN DEVICE INFORMATION

The Prospera Spectrum® Unit is equipped with a **Device Information** menu which provides supplementary information relating to troubleshooting and unit operation and performance data. There are three (3) menus within Unit Information: Help, Language, and Device History.

There are two ways to access device Information: when (1) therapy is off or (2) therapy is running and the unit is unlocked.

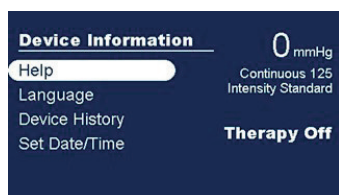
When therapy is off, **Device Information** can be accessed as the fourth (4th) option listed on the Home screen



When therapy is on, **Device Information** cannot be accessed.

HELP

Access the Help menu by selecting Help and pressing **OK**. The Help menu contains 2 options: **General Information** and **Alarm Help**.



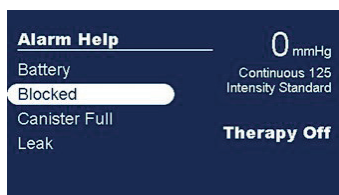
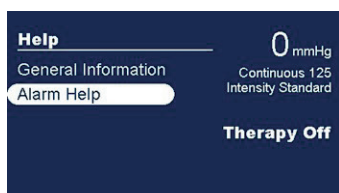
GENERAL INFORMATION

This is a prescription medical device to be used under the instruction of a licensed and trained clinician. Read and understand all warnings, cautions, and instructions completely and carefully before use. The general information and help menus are not a comprehensive user guide. All licensed clinicians should receive adequate NPWT training prior to operating the device. Failure to do so may result in serious injury to either the patient or the user.



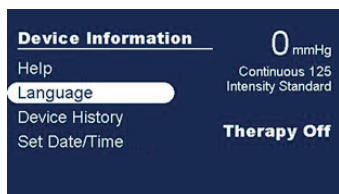
ALARM HELP

The Alarm Help screen displays four alarm help options: Battery, Blocked, Canister Full, and Leak. Selecting any of these alarm options provides specific troubleshooting information for resolving that alarm condition.



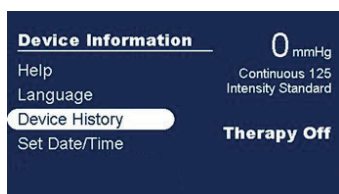
LANGUAGE

The user interface is available in the English.



DEVICE HISTORY

Device History contains operational and performance data for that specific unit. There are five (5) options within Device History: Event Log, Alarm History, Run Time History, Version Information, and Reset.



In certain instances, it may be necessary to erase some of the information stored within Device History. This can be accomplished by selecting Reset (see *Reset* section).

DEVICE HISTORY, CONT.

EVENT LOG

The Event Log displays the five hundred (500) most recent events. Any prior events not displayed in the log will be maintained in internal memory of the unit. These events will only be accessible by an authorized service provider. The Event Log records the duration of treatment and/or key parameters for specific wound treatment. The Event Log stores information since the last reset. In the event the unit experiences a total loss of power, the event log will not be reset.



yy-mm-dd	Time	Event
25/09/29	13:45:44	Running on Battery
25/09/29	13:45:41	Setting Intensity Standard
25/09/29	13:45:40	Setting Cont. 125
25/09/29	13:45:39	Power On
25/09/29	13:45:36	Power Off
25/09/29	13:45:04	Therapy Stop
25/09/29	13:45:02	Device Unlocked
25/09/29	13:44:49	Device Wake
25/09/29	13:41:32	Start Sleep Mode
25/09/29	13:40:26	Device Locked

Version: 0.1.19 Serial#: 999999999

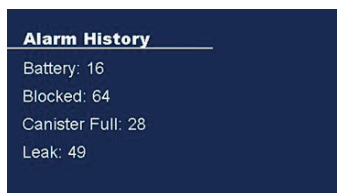
When therapy is running, Event Log can be accessed as the second (2nd) option listed on the Home screen. The unit must be unlocked and in Clinician mode.



↑
THERAPY ON

ALARM HISTORY

The Alarm History lists number of alarm events occurring since last reset command. In the event the unit experiences a total loss of power, the alarm history will not be reset.



RUN TIME HISTORY

Run Time History provides the following information relating to unit operation:

- Total run time: Total time powered on.
- Total therapy time: Total time providing NPWT.
- Current run time: Time powered on since last Reset.
- Current therapy time: Time providing NPWT since last Reset



DEVICE HISTORY, CONT.

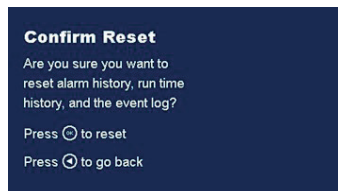
VERSION INFORMATION

The Version Information page provides unit firmware information.



RESET

The Reset function allows certain data displayed in the Event Log, Alarm History, and Run Time History menus to be erased. Resetting unit may be used as a means of preparing the unit for the next patient or storage. Information erased through the Reset function cannot be recovered.




MENU	DATA ERASED
Event Log	All Data Erased
Alarm History	All Data Erased
Run Time History	Only "Current run time" and "Current therapy time" erased.


To Reset unit, select **Reset** from **Device History** menu. When prompted, click **OK** to confirm Reset.

TRANSPORT

Clinicians must clean and disinfect the Prospera Spectrum® Unit according to instructions in *Reprocessing and Cleaning* section before providing to new patients.

DeRoyal recommends using original packaging and shipping boxes whenever shipping or transporting unit between locations. New or additional shipping boxes can be purchased through DeRoyal Customer Service within the US at 1-800-251-9864.

 **CAUTION:** Verify environmental factors and restrictions when shipping device to ensure safe, dry, and temperature-controlled conditions.

 **WARNING:** DO NOT expose the NPWT unit, dressings, canister or accessories to extreme heat or cold.

STORAGE

The DeRoyal® Prospera Spectrum® Unit and accessories should be stored in a dry, temperature-controlled environment. Avoid exposing unit or any accessories to extreme temperatures. The time required for the Prospera Spectrum® Unit to warm from the minimum storage temperature or to cool from the maximum storage temperature between uses until it is ready for intended use is twenty-four (24) hours.

To ensure unit is operational at all times, charge battery before placing the Prospera Spectrum® Unit in storage.

Fully recharge the Prospera Spectrum® Unit if not used for long periods of time. Long periods of time are approximately six (6) months.

Verification of alarm functionality should be performed every six (6) months or if an issue with the alarm system is believed to exist. It is the responsibility of the owner of the unit to perform this test.

DISPOSAL

Patients and clinicians must discard of disposables according to instructions provided by the trained clinician monitoring care and in accordance with federal, state, and local laws.

Clinicians must dispose all components of the Prospera Spectrum® System at end of product life. Decontaminate unit and any reusable accessories/components before disposing.

Ensure disposed components are clean and carefully sorted by material. Housing material has a material symbol mark and is fully recyclable.

Unit may be disposed via DeRoyal or the service partner.

Outside the US: Follow disposal requirements as set by country of residence.

CLEANING

- Spot cleaning of the Prospera Spectrum® NPWT system may be necessary after daily use.
- DO NOT spray or submerge the unit . A dry or lightly dampened cloth may be used to spot clean the unit. Unit can be damaged by use of improper cleaning agents.
- DO NOT use disinfectants that contain acetone, as these may damage or deform housing components and accessories.
- Follow instructions for use provided by the manufacturers of disinfectants, particularly with respect to material and surface compatibility.

REPROCESSING & CLEANING BETWEEN PATIENT USE

The Prospera Spectrum® NPWT unit is reusable. Between patients, procedures, and as necessary, this unit requires professional hygienic reprocessing from a healthcare facility to clean and disinfect it. The following instructions pertain to the Prospera Spectrum® NPWT unit only. Prospera Spectrum® Canisters and domes are single use and should be disposed after use.


For unit reprocessing and cleaning, follow the user's facility protocol, and these steps:

- Use disposable gloves during cleaning and/or disinfecting.
- Before cleaning and/or disinfecting, turn off unit and disconnect external power supply. DO NOT clean the unit when powered on or when connected to a power source, canister, dressing or patient.
- Before cleaning, conduct a thorough visual inspection of the unit and cables, for breaks, cracks, damage, or defects. If unit is damaged, DO NOT reuse unit and contact equipment provider.
- Clean all visible soil, contamination, or bodily fluids from the unit prior to disinfection.
- Use hospital-grade cleaning agents and disinfectants in accordance with facility protocol.
- Wipe the entire unit, handle, and plug.
- Allow unit, handle and plug to dry completely before using the unit or re-starting therapy.
- Visually inspect the unit following cleaning and drying and prior to use for any visual contamination. If seen, repeat these steps.

REPROCESSING & CLEANING BETWEEN PATIENT USE, CONT.

The unit can be damaged by use of improper cleaning agents. Follow instructions for use provided by the manufacturers of disinfectants, particularly with respect to material and surface compatibility. DO NOT use disinfectants that contain acetone, as these may damage or deform housing components and accessories. DO NOT submerge or spray liquids directly on the unit. If user has questions or concerns, contact the durable medical equipment provider or DeRoyal Customer Service at 800-251-9864.

The Prospera Spectrum® Canister and Dome are single use devices.

 **WARNING:** DO NOT reprocess or re-sterilize any part of the canister or dome. Reuse, reprocessing, or re-sterilization may damage the canister or dome.

WARRANTY

DeRoyal® NPWT units are warranted to be free of defects in material and workmanship for one year from date of shipment. All operational aspects (mechanical and electrical) are covered by this warranty. The warranty does not cover accessories, spare parts, and consumables. Batteries are covered by a warranty of six (6) months from purchase date. DeRoyal's warranty is neither extended nor renewed by warranty/service work.

TO THE EXTENT ALLOWED BY LAW, DEROYAL'S WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Warranty claims will not be accepted if (1) the unit has been opened or repaired by unauthorized individuals, (2) the unit has not been used in accordance with proper guidelines; (3) the tamper proof seal is missing or broken, or (4) the unit has been rendered inoperable due to physical damage (inclusive of drops or falls of the unit).

WARRANTY, CONT.

DeRoyal is responsible for impacts on safety, reliability, and specified performance only if:

- Original DeRoyal accessories and spare parts are used,
- Maintenance and repairs are performed by professionals authorized by DeRoyal; or by DeRoyal itself,
- The affected product is used and operated in accordance with the instruction for use; intended use and within its useful lifetime which is three (3) years from date of shipment.

DeRoyal does not warrant accurate function of the unit and is not liable for a loss of property or personal injury in the following circumstances:

- Non-original DeRoyal accessories or spare parts are used,
- Use information of this instruction for use are ignored,
- Installation, settings, changes, upgrades or repairs are not carried out by DeRoyal or by professionals authorized by DeRoyal,
- The safety seal is broken or removed, and/or
- The unit is used beyond its lifetime of three (3) years.

All warranty claims are voided if the unit is opened by unauthorized individuals, the safety seal(s) are removed/damaged, or repairs have been performed by unauthorized individuals.

SERVICE & REPAIR PROCEDURES

Patients, contact the durable medical equipment provider with any questions or concerns regarding service or repairs.


For any service or repair request by unit owner, please contact DeRoyal Customer Service (within the US call: 1-800-251-9864). Customer service provides step-by-step instructions, along with **Return Authorization Documentation** that must be placed in the shipping box. Units sent to DeRoyal without proper notice and documentation may be returned or discarded without customer notification.

Customers are responsible for shipping items back to DeRoyal to be serviced. DeRoyal will cover the return shipping costs. DeRoyal advises use of a national carrier that will provide tracking information, proof of delivery, and insurance. Customers are responsible for their product until DeRoyal signs for its delivery.

SERVICE & REPAIR PROCEDURES, CONT.

Clean and disinfect the unit and any accessories prior to returning for service. The unit itself must be treated with a surface disinfectant. Please note the guidelines for cleaning in *Cleaning and Disinfecting* section.

Opening the unit and making repairs must be only performed by DeRoyal or DeRoyal-authorized professionals in compliance with the service documentation specified by the manufacturer in addition to technical and hygienic precautionary measures. Opening the unit and/or making repairs must never be done while the unit is connected to a patient, power supply or any accessories (including the canister, dome, any dressing components, etc.)

 **WARNING:** Only authorized DeRoyal personnel should replace lithium batteries. Improper replacement can result in injury to the patient or user.

The Prospera Spectrum® Unit is free from routine maintenance if used according to Instructions For Use.

DATA COLLECTION

In addition to data collected from the Prospera Spectrum® Unit at times of services, the NPWT unit provided is also enabled with GPS technology. No personal information, health information, or other patient identifying information can be transmitted by the unit. The unit may transmit location, machine status, and battery status at preset intervals.

TECHNICAL DATA

Flow rate	Max 9.8L/min
Pressure Range	0 to 200mmHg or 0 to 26.7kPa or 0 to 0.26atm(bar)
Canister	Disposable exudate canister (300mL and 500mL)
Suction Tube	Suction tube length 122cm (48in)
Power Supply Unit	IN: AC 100-240V AC / 50-60Hz / 2-1 A OUT: DC 15V / 4.33A
Nominal Input Voltage	15V DC
Nominal Current Load	0.1 to 2A
Power Consumption	1.5W to 30W – less than 3.5W on average
Protection class as per IEC 60601-1	Type BF
Protection class as per IEC 60601-1	II
Degree of protection (IP code) as per IEC 60529	IP22
Sound Emission	Operation: less than 50dB (A) Alarm: 60dB (A) at 1m
Transport / Storage Conditions	-13°F (-25°C) to 41°F (5°C) 41°F (5°C) to + 95°F (35°C) at a relative humidity up to 90%, non- condensing >95°F (>35°C) to 158°F (70°C) at a water vapor pressure up to 50 hPa
Environmental Operation Conditions	Temperature: +5oC to 40oC Relative Humidity Range: 15% to 90% non-condensing, but not requiring a water vapor partial pressure greater than 50hPa Atmospheric pressure: 700hPa to 1060hPa
Rechargeable Battery	12V; 5.8Ah – Lithium Ions
Rechargeable Battery Useful life	3 years
Charging time if battery is empty	4-5 hours
Battery-powered run time	Approx. 24 hours, depending on actual pump duty cycle
Charging time if battery is half full	2-3 hours
Dimensions (Height x Width x Depth)	7.5 x 9 x 4 in or 190 x 229 x 101 mm
Weight (Unit without canister)	1.4 Kg
Item number	NP-7000 and NP-7000-GPS

ELECTRICAL SAFETY INFORMATION

Medical electrical equipment is subject to special precautionary measures regarding electromagnetic compatibility and must be installed and operated in accordance with the EMC information provided in the accompanying documentation.

Portable and mobile RF communication equipment may affect medical electrical equipment. DO NOT apply any third-party device to the Prospera Spectrum® Unit without proper testing performed by DeRoyal or by authorized professionals of DeRoyal.

The use of any accessories and/or replacement parts (including transformers and cables, non-permanent third-party devices, etc.) not recommended by DeRoyal may increase the emission of electromagnetic interference or reduce the electromagnetic immunity of the devices. Damage caused by using non-recommended accessories and/or replacement parts or by improper use is not covered by warranty in any case.

Only use original DeRoyal® accessories and replacement parts.

Use of the recommended accessories and replacement parts (incl. transformers and cables) in devices other than the Prospera Spectrum® Unit may increase the emission of electromagnetic interference or reduce the electromagnetic immunity. Damage caused by using recommended accessories and replacement parts in other devices or by improper use is not covered by warranty in any case.

Use the accessories and replacement parts only with the Prospera Spectrum® Unit.

The Prospera Spectrum® Unit must not be used directly adjacent to or stacked with other devices. If operation adjacent to or stacked with other devices is necessary, monitor the devices in this configuration to verify proper operation.

The Prospera Spectrum® Unit meets the requirements of IEC 60601-1-2/EN 60601-1-2 "Electromagnetic Compatibility – Medical Electrical Equipment." Electromagnetic interference is therefore reduced to a minimum.

ELECTROMAGENETIC COMPATIBILITY (EMC)

EMC guidance and manufacturer's declarations for the Prospera Spectrum® NPWT System:

- The Prospera Spectrum® NPWT System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this user manual
- This equipment is intended for use by licensed and trained healthcare professionals only. As with all electrical medical equipment, this equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the Prospera Spectrum® Device or shielding the location.
- Portable and Mobile RF communications equipment, RFID readers, electronic article surveillance (anti-theft) equipment and metal detectors can affect the performance of the Prospera Spectrum® Device. Please use the guidelines and recommendations specified in the Electromagnetic ImmDevicey table below (Recommended separation distances between portable and mobile RF communications equipment and the Prospera Spectrum® Device).
- Other medical equipment or systems can produce electromagnetic emissions and therefore can interfere with the functionality of the Prospera Spectrum® Device. Care should be used when operating the Prospera Spectrum® Device adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Prospera Spectrum® Device and the other equipment should initially be observed to verify normal operation in the configuration in which it will be used.
- The electrical cables, external power supplies and accessories listed or referenced in this manual have been shown to comply with the test requirements listed in the following tables. Care should be taken to use only manufacturer-recommended cables, power supplies and accessories with the Prospera Spectrum® Device. If a third-party supplier offers cables, external power supplies and electrical accessories for use with the Prospera Spectrum® Device and they are not listed or referenced in this manual, it is the responsibility of that third-party supplier to determine compliance with the standards and tests in the following tables.
- The use of electrical cables and accessories other than those specified in this manual or referenced documents may result in increased electromagnetic emissions from the Prospera Spectrum® Device or decreased electromagnetic immunity of the Prospera Spectrum® Device.

ELECTROMAGENETIC COMPATIBILITY (EMC), CONT.

The Prospera Spectrum® NPWT System needs special precautions regarding EMC (Electromagnetic Compatibility) and needs to be used according to the EMC information provided in this user manual.

For EMC compliance, it is important to use only the Prospera Spectrum® Device and its accessories as supplied or recommended by DeRoyal. The user should ensure the system is used in the environments specified below.

Recommendations for actions to assure that the Prospera Spectrum® NPWT System remains safe with regard to EM (electromagnetic) disturbances:

- The Device should be visually inspected regularly for damaged cords and tubing. Damaged cords and tubing should be replaced.
- Although the Prospera Spectrum® NPWT System conforms to the intent of the standard IEC 60601-1-2 in relation to Electromagnetic Compatibility, electrical equipment may produce interference. If interference is suspected, separate the equipment and contact equipment provider.

The Prospera Spectrum® NPWT System intentionally receives and transmits RF electromagnetic energy in the (2, 4, 5 & 12) frequency bands.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The Prospera Spectrum® NPWT System is intended for use in the electromagnetic environment specified below. The customer or the end user of the Prospera Spectrum® Device should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF emissions CISPR 11	Class B	The Prospera Spectrum® Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
Conducted emissions CISPR 11	Class B	The Prospera Spectrum® Device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Complies	The Prospera Spectrum® Device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	The Prospera Spectrum® Device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

ELECTROMAGENETIC COMPATIBILITY (EMC), CONT.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Prospera Spectrum® NPWT System is intended for use in the electromagnetic environment specified below. The customer or the end user of the Prospera Spectrum® Device should assure that it is used in such an environment.


IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	INTENDED ELECTRO MAGNETIC ENVIRONMENT
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8kV contact ± 2, ±4, ±8, and ±15kV air	± 8kV contact ± 15kV air	Floors 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 IEC 61000-4-4	± 1kV for signal, input / output per cable ± 2kV for AC mains and DC input	± 1kV for signal, input / output per cable ± 2kV for AC mains and DC input	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	-Line to line: ± 0.5, ±1kV Line to ground: ± 0.5, ±1, ±2 kV Signal I/O: ± 0.5, ±1, ±2 kV	Line to line: ± 0.5, ±1kV Line to ground: ± 0.5, ±1, ±2 kV Signal I/O: ± 0.5, ±1, ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT (100% dip in UT) -for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° -for 1 cycle at 0° -for 250/300 cycles at 0° 70% UT (30% dip in UT) for 25/30 cycles at 0°	0% UT (100% dip in UT) -for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° -for 1 cycle at 0° -for 250/300 cycles at 0° 70% UT (30% dip in UT) for 25/30 cycles at 0°	Product has internal battery backup. If, in the instance of power mains interruptions, it is required the Prospera Spectrum® Device maintain continuous operation, power should be supplied from an uninterruptable power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 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.			

ELECTROMAGENETIC COMPATIBILITY (EMC), CONT.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The DeRoyal® Prospera Spectrum® NPWT System is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

When the Prospera Spectrum® NPWT System is exposed to electromagnetic (EM) disturbances, the system may show abnormal behavior. For instance, the measured traces may become obscured, the software may crash or, in case of very high-level transient voltage events like for instance ESD, parts of the system may even become defective.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTRO MAGNETIC ENVIRONMENT - GUIDANCE
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150kHz to 80MHz 6Vrms ISM and amateur Bands 3 V/m 80 to 2700 MHz 10 V/m 80 to 2700 MHz 28 V/m 450/810/870/930/ 1720/1845/1970/ 2450 MHz</p> <p>27 V/m 385 MHz</p> <p>9 V/m 710/745/780/ 5240/5500/5785 MHz</p>	<p>3 Vrms Or Complies 6 Vrms Or Complies 10 V/m Or Complies</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the NPWT system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $dd = 1.17\sqrt{PP}$ $dd = 1.17\sqrt{PP} 80MMMMMM tttt 800MMMMMM$ $dd = 2.33\sqrt{PP} 800MMMMMM tttt 2.7GGMMMM$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>The Prospera Spectrum® NPWT System is failure sensitive to conducted and radiated RF. Disturbance of the device is possible at and below the specified test level. It may be necessary to relocate the device or the apply shielding.</p> <p>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:</p> 

ELECTROMAGNETIC COMPATIBILITY (EMC), CONT.

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

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

a. Field strengths from fixed transmitters, such as base stations of radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 80 MHz to 6 GHz, field strengths should be less than 3 V/m

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE DEROYAL® PROSPERA SPECTRUM® DEVICE.

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

⚠ WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Prospera Spectrum® NPWT System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER w	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER M		
	150 kHz to 80 MHz $dd = 1.17\sqrt{PP}$	80 MHz to 800 MHz $dd = 1.17\sqrt{PP}$	800 MHz to 2.5 GHz $dd = 2.33\sqrt{PP}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

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 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

⚠ CAUTION: The use of cables or other electrical accessories not provided as part of the Prospera Spectrum® NPWT System may cause increased electromagnetic emissions or decreased electromagnetic immunity. Essential performance characteristics for safe and effective operation of the unit are to remove wound exudate, provide and maintain prescribed pressure, be compatible with dressing kits, and alarm when performance is reduced below the defined threshold. If essential performance is lost or degraded due to electromagnetic disturbances, these characteristics may be impacted.

**For product support, call:
1 (800) 524-3416**



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