Prospera®

PRO-II®

NPWT System by DeRoyal®

PROSPERA® PRO-II® NPWT System

Clinician Quick Reference Guide

WARNING: Important safety information accompanies this document. To avoid **SERIOUS OR FATAL INJURY**, read and understand all user manuals, warnings, instructions and labeling of this device. This prescription device is for use under the direction and supervision of a clinician. **THIS GUIDE IS A SUPPLEMENTAL DOCUMENT FOR CLINICIAN USE ONLY.**

CAUTION: Use only DeRoyal® NPWT kits, canisters, and accessories with this PROSPERA® PRO-II® device to enable continuous and safe operation.

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DISPLAY SYMBOLS

	Battery full
	Battery low
	Battery empty
	Up
	Down
OK	OK (On, Enter)
C	Cancel (Off, Back)

	Device is connected to external power source.
	Max pressure / Max time
	Min pressure / Min time
	Keylock (symbol in display) activated automatically during operation.
	Filter run time elapsed; service required.
X/Y	Alarm display settings

A Disposable exudate canister (250 cc canister shown) with integrated therapy tube

B Canister locking mechanism

C (OK) and (C) buttons

D Display

E (▼) and (▲) arrow buttons

F PRO-II® device

DeRoyal® NPWT Dressing Kits

The PRO-II® device is designed to operate safely and effectively using only DeRoyal® negative pressure dressing kits. A normal compressed dressing should appear shrunk, similar to a raisin, compacted or vacuumed. It may feel slightly hard. This is a sign the NPWT is working. If the dressing has lost its vacuumed appearance therapy may be interrupted. See page 12 for troubleshooting dressing seals. If unable to find the problem area and/or the alarms do not sound, review detailed User Manual and Kit instructions for use.

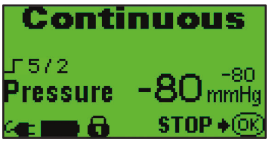
Dressing changes should be performed by trained clinicians, following physicians' prescribed treatment. Improper use or inadequate training may result in serious injury to the patient.

⚠ CAUTION Before Starting Therapy, Confirm

1. Pressure (mmHg) settings on home screen match prescribed pressure (mmHg)
2. Sensitivity settings are set per healthcare provider's direction
3. DeRoyal® canister is securely connected to device
4. Dressing tubing is connected to canister
5. Device is operating in a safe environment and placed on a stable surface

Be aware of signs of infection. These may include: redness, pain, warmth, swelling at or near your wound or changes in your wound's odor or discharge. Clinical care is necessary to diagnose or treat infection.

Display screen and status by color:



Green
Device is providing appropriate therapy.

Yellow
Caution screen. Device requires action. Device is idle or needs to be plugged in.

Red
System states error alarm, therapy may be interrupted.

An error message can read as: System Open, System Closed, Check Dressing Seal, Battery Low, Battery Empty, or Re-start Pump.

Contact your Durable Medical Equipment provider for any equipment questions or concerns.

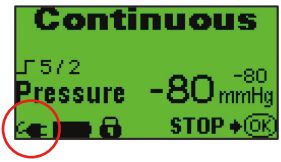
CAUTION: Clinicians should routinely check the system, including wound dressings, canister and device display (pressure, alarms, battery life, etc.) per facility protocol. Look for a compressed appearance at dressing surface. A compressed appearance means dressing is properly adhered to the skin, the dressing dome has properly adhered to the dressing, and negative pressure is active.

Battery Alarms

The Battery Alarm triggers when the device needs to be charged. Immediately connect device to external power source.

To Charge Device

1. Plug jack end of power cord into port on bottom of the device.
   - Use caution not to invert device if canister is attached when connecting power cord.
2. Plug pronged connector into external power outlet.
3. When connected properly, the plug icon will appear on the display screen.

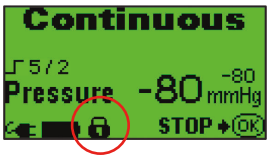


The PROSPERA® PRO-II® device should be charged daily with the DeRoyal provided power supply.

When in use, place the device upright on a secure surface, avoiding areas where device is prone to falling or being damaged.

Unlocking Device

A patient or caregiver should never unlock the device.



1. To unlock the device, press the ▼ ▲ arrow keys simultaneously
2. Device will beep once and the lock icon will disappear when unlocked.
3. To lock device, press the ▼ ▲ arrows until icon appears on screen (therapy must be started to lock device)

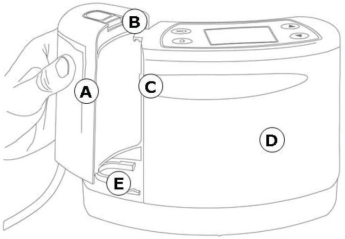
Powering Off

A patient or caregiver should never power off the device.

1. Ensure therapy is stopped prior to attempting to power off.
2. To power off the device, press the (C) button for 3 seconds or until the display turns off.

Canister Exchange

CAUTION: Initiate canister changes only when "Error System Closed" alarm is activated and/or canister appears full. Ensure therapy is paused prior to initiating any canister changes. Confirm canisters and accessories are within arms reach prior to beginning any canister change procedures. Inspect all canisters for damage or defects. Replace the canister if it is damaged.



A Disposable exudate canister including therapy tube

B Locking mechanism for canister

C Aspiration port

D PRO-II® device

E Guiding rail

1. Ensure the PRO-II® device is not actively providing therapy.
2. Clamp tubing using the blue clamp.
3. Separate the dressing tubing from the canister tubing and close the canister connector with the protective cap.
4. Press on the "Push Here" (B) button on the top of the canister and keep it pressed while pulling the disposable exudate canister horizontally away from the device.
5. Dispose of the disposable exudate canister and the integrated therapy tubing following applicable protocol, federal, state, and local law.
6. Connect a new disposable exudate canister to the device. Ensure the disposable exudate canister is properly attached to the device.
7. Connect the dressing tubing to the canister tubing.
8. Unclamp dressing tubing.
9. Press (OK) to start therapy.

WARNING: Monitor wound exudate in canister for signs of excess blood loss or other complications. If active bleeding occurs, clamp dressing, apply pressure, and disconnect from canister. Contact local emergency service (dial 911 within US) immediately, if not at a health care facility.

DEVICE SETTINGS & OPERATION

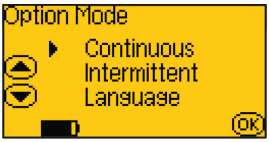
Device preserves previous settings between use or when powered off.

Continuous Operation

In the continuous operating mode, the PRO-II® device maintains a continuous vacuum in the wound dressing.
The vacuum pressure value can be set from -20 mmHg to -200 mmHg in increments of 5 mmHg.

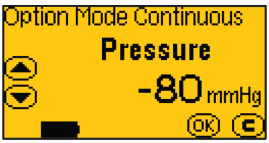
1. Press the OK button for 1-2 seconds to switch on the PRO-II® device. The following start screen is displayed for 5 seconds

2. While the start screen is displayed, simultaneously press the ▼▲ arrow buttons. The menu Setup is displayed.



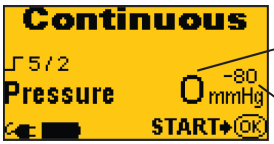
3. Use the ▼▲ arrow buttons to select the Continuous menu.

4. Use the OK button to confirm your choice. The following screen is displayed:



5. Use the ▼▲ arrow buttons to set the prescribed vacuum value.

6. Confirm the setting by pressing the OK button. The following overview screen is displayed:



Actual value

Target value

7. Press the OK button to start the therapy.

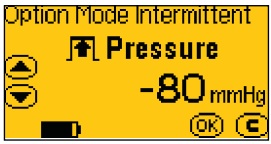
Intermittent-VPT Operation

The low vacuum can be set in a range from -20 mmHg to -100 mmHg in increments of 5 mmHg. The high vacuum can be set in a range from -30 mmHg to -200 mmHg in increments of 5 mmHg.

The setting of the low vacuum cannot be set higher than the setting of the high vacuum.

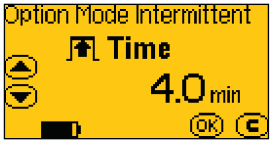
1. Repeat steps 1-2 from page 6. Use the ▼▲ arrows to select intermittent.

2. Use the ▼▲ arrow buttons to set the prescribed high vacuum value. Confirm the setting by pressing the OK button.

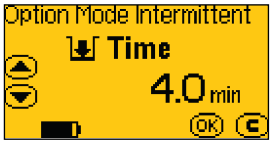


3. Use the ▼▲ arrow buttons to set the prescribed low vacuum value. Confirm the setting by pressing the OK button.

4. Use the ▼▲ arrow buttons to set the prescribed time value for the high vacuum. Confirm the setting by pressing the OK button.

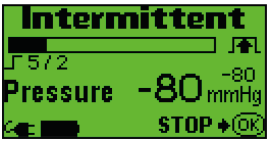


5. Use the ▼▲ arrow buttons to set the prescribed time value for the low vacuum. Confirm the setting by pressing the OK button.



6. The display shows the set parameters in an overview again.

7. Press the OK button to start the therapy.



Intended Use

The PROPSERA® PRO-II® device is indicated for patients that would benefit from a therapy device particularly as the device may promote wound healing by removal of wound exudate, debris, and infectious material or for the aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious material from the patient's airway or respiratory support system. These devices may be used during surgery.

Indications/Contraindications

The PROSPERA® PRO-II® Negative Pressure Therapy System is a prescription medical device for use under instruction of a licensed and trained clinician.

CONTRAINDICATIONS

The PROSPERA® PRO-II® Negative Pressure Therapy System should not be used on:

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

The PROSPERA® PRO-II® Negative Pressure Wound Therapy (NPWT) System is a prescription medical device. Read and understand all warnings, cautions, and instructions completely and carefully before use. Using accessories, canisters or spare parts other than those recommended by and sold from DeRoyal® may compromise the safety and function of the device. Use of NPWT can cause complications, exacerbate existing conditions or cause serious or fatal injury when used on patients with certain co-morbidities. **IF THERAPY IS DISCONTINUED OR DISRUPTED FOR MORE THAN TWO HOURS, SEEK EMERGENCY MEDICAL ATTENTION.**

Local wound care by NPWT cannot overcome the deficits of unrelieved malnutrition, pressure, trauma, compromised blood flow, etc. Follow all instruction and interventions as directed by a health care provider to reduce or relieve factors contributing to impaired wound healing in order to achieve optimum outcomes.

In case of an emergency, contact your local emergency service immediately (dial 911 within the US).

NOTES

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Part# 0-690 | Rev. 10/20

Troubleshooting Guide

Alarm Message	Device Status	Potential Alarm Origin	Action
ERROR System Open	Therapy automatically paused	Disposable exudate canister not connected or improperly connected	Check connections between canister-device and canister-tubing
		Dressing has major opening; dressing film does not adhere to skin	Check dressing seal for leaks or creases
Check Dressing Seal	Attempting to provide therapy	Dressing has minor opening; dressing film does not adhere to skin	Check dressing seal for leaks or creases
ERROR System Closed	Therapy automatically paused	Exudate flow obstructed (clamp/cap closed, tubing kinked, stenosis in tubing)	Check clamps, caps and all tubing and tubing connections. Ensure tubing is not kinked.
		Disposable exudate canister full	Replace disposable exudate canister; restart therapy
		Alarm triggered when canister not connected, filter is blocked	Do not use device. Contact equipment provider
ERROR Battery Empty or Battery Low	Device powering off imminent	Battery nearly or completely depleted	Connect device to external power source
ERROR Re-start Pump	Therapy is off	Device turned on, but therapy not started	Start therapy or power down device
		Device not turned off at end of use	
ERROR Internal Error	Status unknown	Device damaged from drop or other unknown event	Do not use device; contact equipment provider

If any of the troubleshooting methods do not solve the problem, refer to user manual or facility protocols.