Prospera®

Suction System by DeRoyal®

Prospera® PRO-II® Suction System

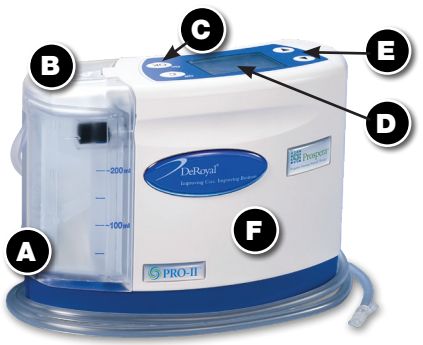
Clinician Quick Reference Guide

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® brand canisters and accessories with this PROSPERA® PRO-II® device to enable continuous and safe operation.

DISPLAY SYMBOLS

	Battery full	
	Battery low	
	Battery empty	
	Up	
	Down	
OK	OK (On, Enter)	
C	Cancel (Off, Back)	
	Power supply unit is connected.	
	Max pressure / Max time	
	Min pressure / Min time	
	Keylock (symbol in display) Activated automatically during operation and can be canceled by simultaneously pressing the Up and Down buttons.	
	Filter run time elapsed; replacement of the internal filter by an authorized DeRoyal service technician is required.	
X/Y	Alarm display settings	X = Represents Sensitivity of "System Closed" alarms
		Y = Represents Sensitivity of Leakage System alarms



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

B Canister locking mechanism

C OK and C buttons

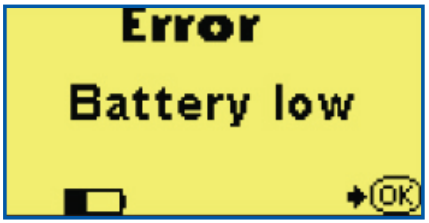
D Display

E ▼ and ▲ arrow buttons

F PRO-II® device

Battery Alarms

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



To Charge Device

1. Plug jack end of power cord into port on bottom of the device.
2. Plug pronged connector into external power outlet. Green LED will illuminate when connected properly.
3. When connected properly, the plug icon will appear on the display screen.

The PROSPERA® 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.

Powering OFF

1. Press the ▼ ▲ simultenously to unlock device.
2. Press OK to confirm and stop suction. When suction is stopped, the screen turns yellow.
3. To power OFF the device, press and hold C located on the bottom right of the control screen.

⚠ CAUTION Before Starting Suction, Confirm

1. Pressure (mmHg) settings on home screen match prescribed pressure (mmHg)
2. Sensitivity settings are set to 5/L as shown
3. DeRoyal® canister is securely connected to device
4. Tubing is applied properly and connected to canister
5. Device is operating in a safe environment and placed on a stable surface

⚠ Confirm all canisters and accessories are within arms reach prior to beginning any procedures. Inspect all packaging for damage or defects. **Stop suction prior to initiating any canister changes.**

Starting device from the Home Screen

1. Press (OK) to turn on device. Prescribed pressure level should be displayed.
2. Press (OK) to start suction.
3. Once suction has started, the display screen will turn green. Display screen also indicates current pressure settings.
4. Device automatically locks and preserves current settings after five (5) minutes of user interface inactivity.

Canister Exchange

Stop suction prior to initiating any canister changes. Confirm canisters and accessories are within arms reach prior to beginning any canister change procedures. Inspect all packaging for damage or defects. Replace the canister if the packaging is damaged.

CONNECTING THE DISPOSABLE EXUDATE CANISTER OF THE PRO-II® DEVICE

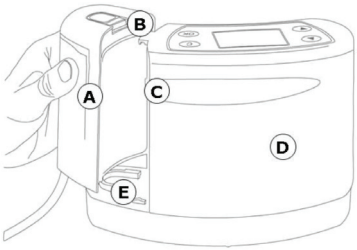


Fig.1 Connecting the disposable exudate canister

A Disposable exudate canister including suction tube
B Locking mechanism for canister
C Aspiration port
D PRO-II® device
E Guiding rail

1. Remove the disposable exudate canister (fg. 1 (A)) from packaging.
2. Slide canister onto guiding rails (fg. 1 (E)) of the PRO-II device until the disposable exudate canister clicks into place in the locking mechanism (fg. 1 (B)).
3. To remove from device after use, press the “Press Here” button on the top of the canister prior to sliding back along the guiding rails.

REPLACEMENT OF THE DISPOSABLE CANISTER OF THE PRO-II DEVICE

1. Ensure the PRO-II device is turned off.
2. Separate the suction tubing from the canister tubing and close the connector with the protective cap.
3. Press on the “Push Here” button on the top of the canister (fig. 5 (B)) and keep it pressed while pulling the disposable exudate canister horizontally away from the device.
4. Dispose of the disposable exudate canister and the integrated suction tube in accordance with facility protocol.
5. Connect a new disposable exudate canister to the device. Ensure that the disposable exudate canister is properly attached to the device.
6. Connect the suction tubing to the canister tubing.
7. Press “OK” to start suction.

Monitor exudate in canister for signs of excess blood loss or other complications. If active bleeding occurs, remove suction.

Continuous Operation

In the continuous operating mode, the PRO-II® device maintains continuous pressure. The 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® or PRO-III®. The following start screen is displayed for 5 seconds:

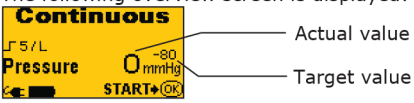
2. While the start screen is displayed, simultaneously press the ▲▼ arrow buttons. The menu *Setup* is displayed.

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:



7. Press the OK button to start suction. The following screen is displayed.

Important Information

This document contains pertinent safety and instructional information pertaining to the Prospera® PRO-II device and PRO-II Canister when used 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.

PRO-II Canisters are for use with the Prospera PRO-II only. PRO-II canisters are prescription medical devices for use under the direction of a licensed and trained clinician. Read and understand all accompanying documentation including all indications, contraindications, warnings, cautions, precautions and instructions for use completely and carefully before use.

For additional copies of any Prospera PRO-II instructional or safety documentation, please contact DeRoyal Customer Service (within the US: 1-800-251-9864). Some documents may also be downloaded from the DeRoyal website at www.deroyal.com.

Licensed clinicians should receive adequate training before operating device. Clinicians should have sufficient clinical knowledge of the device's capabilities and thorough understanding of its safe and effective operation before determining if suction application is clinically appropriate. Failure to receive adequate training may result in serious injury to the patient or user.

Intended Use

The Propsera PRO-II device is indicated for patients that would benefit from a suction 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.

WHEN THE SENSITIVITY IS SET TO LEAKAGE SYSTEM (5/L), THE ALARMS FOR "CHECK DRESSING SEAL" AND "SYSTEM OPEN" ARE DEACTIVATED. THEY WILL NOT BE TRIGGERED EVEN IF A CANISTER IS NOT ATTACHED. Promptly and at increased, regular intervals, check the dressing seal to detect potential leakages in the aspirating system. Never operate the device set to Leakage System when performing negative pressure wound therapy on a patient.

Troubleshooting Guide

Alarm Message	Device Status	Potential Alarm Origin	Action
ERROR System Open	Attempting to provide suction	Disposable exudate canister not connected or improperly connected	Check connections between canister-device and canister-tubing
ERROR System Closed	Suction 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 Suction
		Alarm triggered when canister not connected, filter is blocked	Contact equipment provider
ERROR Battery Empty	Device powering off imminent.	Battery nearly depleted	Connect device to external power supply
ERROR Re-start Pump	Suction is Off	Device turned on, but suction not started.	Turn off or restart suction
		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

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