USER MANUAL

DeRoyal® Prospera® PRO Series Negative Pressure Wound Therapy System PRO-II® and PRO-III®

DeRoyal®

Improving Care. Improving Business.®

AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005), CAN/CSA-C22.2 No. 60601-1 (2008)

Table of Contents

1 User Information

1.1 Using this Instruction Manual

Read the **entire User Manual** before operating the DeRoyal® Prospera® PRO-II® (NP-2000) or PRO-III® (NP-3000) negative pressure wound therapy devices (hereinafter the "PRO-II®" and "PRO-III®" devices, respectively) for the first time.

- Read the safety instructions (chapter 1.6) to avoid hazards.
- The User Manual is a component of the PRO-II® and PRO-III® devices.
- Keep the User Manual in an easily accessible location.
- Include the User Manual when passing the PRO-II® or PRO-III® device onto third parties.
- For additional copies of the User Manual, contact DeRoyal Customer Service within the US, please call 1-800-251-9864; internationally please call +1-865-938-7828.

1.2 Icons

1.2.1 General Symbols

Symbol	Meaning	Symbol	Meaning
	**CAUTION** Warning of possible bodily injury or health risk.		**WARNING** Warning of severe bodily injury or resulting death.
	**ATTENTION** Warning of possible property damage.		**NOTE** Note containing useful information and tips.
	Radiofrequency - RF		MRI - Unsafe

1.2.2 Device and Packaging

Symbol	Meaning	Symbol	Meaning
	Protect from moisture.		This device must not be disposed of in domestic waste.
	Protection class II		Order number
	Air pressure limitation		Serial number
	Humidity limitation		Lot number
	Follow the instruction for use.		Date of manufacture
	Protection class: **Type BF** (Body Floating)		Manufacturer
	Temperature limitation		Do not use if packaging is damaged!
	Power supply unit		Do not reuse
	Only available on prescription		

1.2.3 Display

Symbol	Meaning	
	Battery full	
	Battery low	
	Battery empty	
	Up	
	Down	
	OK (On, Enter)	
	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.	
	Alarm display settings	X = Represents Sensitivity of "System closed" alarms Y = Represents Sensitivity of "Check dressing seal" alarms

1.3 Symbol Convention

Symbol	Meaning
•	Enumeration
1. **2.** **3.**	Perform the process in the specified order.

1.4 Glossary

A	
approx.	Abbreviation for “approximately”
C	
Contamination	Contamination means that liquids, exudate, bacteria and/or viruses from the wound or environment have come into contact with the interior of the device.
E	
e.g.	For example, abbreviation for Latin “exempli gratia”
I	
incl.	Abbreviation for “inclusive” or “including”
IP22	International Protection / Protection Class The Protection Class defines the degree of protection of the device against contact and ingress of liquids. The PRO-II® and PRO-III® are protected against finger access and falling water drops at an inclination of up to 15°.
O	
Overflow	Overflow means that wound exudate is sucked into the interior of the device.
W	
Wound exudate	The term wound exudate denotes all liquids and particles collected that may be formed or present in a wound. The wound exudate is aspirated from the wound using the PRO-II® and PRO-III® devices and collected in a disposable exudate canister.

1.5 Intended Use

These negative pressure wound therapy systems are 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 or at the patient's bedside and are indicated for home use.

1.5.1 Indications

- Chronic Wounds
- Acute Wounds
- Subacute Wounds
- Traumatic Wounds
- Dehisced Wounds
- Partial Thickness Burns
- Ulcers (Such as diabetic or pressure)
- Flaps
- Grafts

1.5.2 Contraindications

The PRO-II® and PRO-III® devices are contraindicated for the following applications:

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

1.5.3 Precautions

Precautions must be taken in the following circumstances:

- Patients who receive anticoagulants and have active bleeding
- Patients with complicated wound hemostasis
- Use of the device in direct proximity to blood vessels, organs, muscles and fascias
- Irradiated vessels and tissues
- Bone fragments
- Non-compliant/non-responsive patients
- Untreated malnutrition
- Paralysis associated with the affected area or spinal cord injuries
- Circumferential dressing application
- Take extreme caution when the negative pressure wound therapy system is applied in close proximity to friable vessels or potentially infected blood vessels.
- Infected wounds should be closely monitored and may require more frequent dressing changes than non-infected wounds. View exudates for any sign of infection, worsening infection, or other complications.
- Before using the negative pressure wound therapy system, all exposed or superficial organs and vessels, nerves, tendon and ligaments in or around wound must be completely covered and protected to avoid direct contact with wound dressing.
- When using the negative pressure wound therapy system, clinicians or caregivers must keep written record of the type and number of wound dressing pieces that are placed in the wound.
- Use of the negative pressure wound therapy system in a hyperbaric oxygen chamber is prohibited. Negative pressure wound therapy is not suitable in this environment and may be a fire hazard.

- In the event defibrillation is required, disconnect the DeRoyal negative pressure wound therapy device from the wound dressing prior to defibrillation. Remove the wound dressing if it will interfere with defibrillation.
- The patient height and weight should be considered before prescribing the DeRoyal negative pressure wound therapy system. Infants, children, some small adults and elderly patients should be closely monitored for excessive fluid loss and dehydration. In addition, patients with heavily exudating wounds or large wounds should be monitored carefully because they may have a risk of excessive fluid loss and dehydration.
- NPWT must not be placed in proximity to the vagus nerve to minimize the risk of bradycardia.
- If the patient appears to have autonomic dysreflexia (sudden changes in blood pressure or heart rate stimulated by the sympathetic nervous system), immediately stop negative pressure wound therapy to minimize the sensory stimulation and immediately call for medical assistance.
- Protect fragile periwound skin with adhesive sealing films, hydrocolloid, or transparent film dressing. Do not cover intact skin with gauze/foam dressing to avoid risk of maceration or injury to tissue.
- Check the wound dressings at shift change or **every 8 hours**. Look for a wrinkled appearance at the surface of the dressing, which indicates an occlusive environment, thus maintaining proper suction.

1.5.4 Restrictions on use

- In medical rooms where potential equalization is necessary (e.g. heart surgery)
- In hazardous areas
- When patients use the device outside or outdoors, advise to not drop, overly shake or permit the device to get wet or be exposed to other elements.

1.6 Basic Safety Instructions

CAUTION!	**Health risks due to the handling of infectious liquids or pathogenic germs.** Infectious and pathogenic germs in the wound exudate cause health risks. • Perform wound treatment carefully. • Follow the hygiene, cleaning and decontamination instructions.
WARNING!	**Risk of damage due to improper power supply.** Improper operation causes overvoltage in the device, which may be transmitted to the operator. • Ensure prior to startup that the power supply is designed to operate at supply voltages of 100-240 V alternating current. • Ensure prior to startup in UL listed markets such as the USA and Canada that the main supply is designed to operate at a supply voltage of 120 V alternating current. • Only operate the device with the provided power supply unit. • Never connect the power supply unit to defective power sockets.
ATTENTION!	**Risk of damage due to electromagnetic phenomena.** 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 (see chapter 7.3).

 **CAUTION!**	**Hazards may be caused by improper handling.** • Use the device for its intended purpose only. • When using the power supply unit, make sure the power supply unit is connected to the main supply (100 V - 240 V AC) only after the power cord plug of the power supply unit has first been connected to the suction device. • The separation of the power supply unit from the main supply must occur in exactly the opposite sequence (first separate the power supply unit from the mains supply (100 V - 240 V AC) and then the power cord plug from the suction device).
 **ATTENTION!**	**Damage to the device due to improper handling.** • Never aspirate flammable, corrosive or explosive liquids or gases. • Do not drop the device. • Do not use the device if there is damage to the exterior housing.
 **CAUTION!**	**Safety defects due to improper accessories and spare parts.** The use of accessories, canisters and spare parts other than those recommended by and sold from DeRoyal may compromise the safety and function of the device. Warranty does not cover damage caused by using non-recommended accessories and spare parts or by improper use in any case. • Only use DeRoyal approved accessories and spare parts.
 **ATTENTION!**	**Damage to the device by intake/exposure of liquids.** • Do not use the device near splashing water. • Do not use the device in damp rooms or while bathing/showering. • Do not allow the power supply unit, plug and display film to get wet. • Never submerge the device in water or other liquids.
 **ATTENTION!**	**Damage to the device by heat.** • Do not cover the power supply unit. • Keep the device as well as the power cord and power supply unit away from other heat sources.

 **CAUTION!**	**Hazard of persons due to strangulation.** People may strangle themselves on the tubing or the power cord. • Ensure that no unauthorized/uninvolved personnel is near the device during use. • Store the device and accessories in the shipping carton or other approved DeRoyal provided hard-exterior carrying cases.
 **ATTENTION!**	**Known or identifiable conditions for medical care within a domestic environment** • Children and pets must be kept away from the device to ensure that the device is not knocked over or dropped. • Prior to connecting the power supply unit, ensure that the voltage of the device corresponds to the domestic power supply. • Do not use the device in damp rooms, baths or showers. • Do not allow the power supply unit or plug or device to get wet. • Never submerge the device in water or other liquids. • Incandescent light may affect the readability of the display negatively.

1.7 User Requirements

The PRO-II® or PRO-III® device must only be operated and used by instructed and trained personnel.

Familiarize yourself with the functions of the PRO-II® or PRO-III® device prior to startup.

Training on the operation of PRO-II® and PRO-III® devices is provided by DeRoyal or an authorized distribution partner of DeRoyal. Product training takes approximately one to two hours and includes an explanation of the design and function of the device, the handling of the device, the alarm system, and the cleaning and disinfection of the device.

Training should be repeated on a regular basis or at least every 24 months.

1.8 Information on Product Liability

The liability for the operation of the device is channeled to the operator in the following cases:

- the device is used outside its intended use,
- the device is not used in accordance with the instruction for use,
- the device is opened by unauthorized personnel,
- installation, settings, enhancements, routine maintenance or repairs are performed by unauthorized personnel,
- unauthorized accessories and spare parts have been used, or
- the device is used beyond its lifetime of 3 years.

1.9 Material Compatibility

ATTENTION!

Aggressive substances may damage the device and the accessories.

- Please follow the cleaning and care instructions (chapter 4.1)

2 Product Description

2.1 Whole View

2.1.1 PRO-II® Device

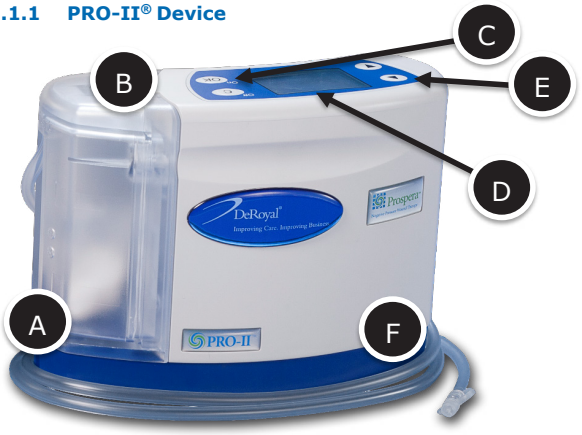


Fig. 1 PRO-II® Device

A Disposable exudate canister (250 cc canister shown) with integrated suction tube
B Canister locking mechanism
C (OK) (On) and (C) (Off) buttons
D Display
E (▲) and (▼) arrow buttons
F PRO-II® device

2.1.2 PRO-II® Device product contents

- PRO-II® device
- 2 x disposable exudate canister (250 cc) with integrated bacterial filter, carbon filter, solidifier and suction tube
- power supply unit
- instruction for use
- multilingual charging instructions
- instructions for safe handling of battery packs
- DeRoyal warranty statement
- optional accessories (depending on the order)

A separate Quick Reference Guide for use of the PRO-II® device for in-home care is available for download via the internet (www.deroyal.com) under Negative Pressure Wound Therapy.

2.1.3 Pro-III® Device

Fig. 2 PRO-III®

A Disposable exudate canister system (800 cc)
B Holder for external canister
C Display
D Control panel (OK (On) and C (Off) buttons and ▲ and ▼ arrow buttons)
E PRO-III® device

2.1.4 PRO-III® Device product contents

- PRO-III® device
- disposable exudate canister system
  (comprising the external canister, holder for external canister, connecting tube)
- power supply unit
- instruction for use
- multilingual charging instructions
- instructions for safe handling of battery packs
- DeRoyal warranty statement
- optional accessories (depending on the order)

A separate Quick Reference Guide for use of the PRO-III® device for in-home care is available for download via the internet (www.deroyal.com) under Negative Pressure Wound Therapy.

2.2 Product Properties

The PRO-II® and PRO-III® devices are lightweight, portable, battery-powered negative pressure devices for mobile and stationary use for the application of negative pressure wound therapy resulting in the removal of wound exudate. They are intended for exudate removal in the low vacuum range and can be used in the hospital and doctor's office, during patient transport as well as during in-home care.

The PRO-II® and PRO-III® devices are operated via the internal battery or via the supplied power supply unit that also is used to recharge the battery.

The vacuum is generated by a maintenance-free electric motor driven membrane pump. After it is switched on, the vacuum pump creates a vacuum in the tubing system and disposable exudate canister, which is used to extract wound exudate. The wound exudate is directed away from the patient and collected in the disposable exudate canister. If the disposable exudate canister is full, the device triggers the "System closed" alarm via an integrated overflow protection system and stops the pump.

The PRO-II® and PRO-III® devices must only be operated with DeRoyal supplied disposable exudate canisters.

The expected lifetime of a PRO-II® and/or PRO-III® device is 36 months.

The provided disposable exudate canister for the PRO-II® device as well as the disposable canister and tubing for the PRO-III® device are intended for single use.

2.2.1 Disposable exudate canister for PRO-II® Device

The disposable exudate canister consists of a canister with a connected suction tube. The disposable exudate canister has an integrated bacterial filter, carbon filter and may be available with and without solidifier. This integrated filter helps to prevent an overflow in the event of an operational error. If the liquid reaches this filter, suction is no longer possible and the error message "System closed" appears on the display. The therapy will be discontinued. The disposable exudate canister must be replaced. The carbon filter in the disposable exudate canister also may help reduce the spread of odor.

Solidifier:
Disposable exudate canisters filled with wound exudate can be transported and disposed in a leak-proof manner by using the solidifier. The wound exudate solidifies after an average gelling time of 2 to 5 minutes (depending on the consistency of the wound exudate), irrespective of the pressure settings.

The **disposable exudate canister including the suction tube** is intended for **single use**. Replace the disposable exudate canister in accordance to the respectively applicable hygiene instructions, if it is full, prior to each new patient or every 3-5 days.

2.2.2 Information on the filter system for the PRO-II® Device

The filter system of the PRO-II® device consists of the external bacterial filter integrated in the disposable exudate canister and the internal filter installed in the device (for devices manufactured prior to Jan 1, 2016 – internal filters were not included).

The filter system effectively protects the interior of the device from contamination and overflow.

Service life and reuse

The internal filter is not intended for reuse. To ensure consistent performance, the internal filter must be replaced **after contact with the exudate (blocked), after the filter service life has expired** (symbol in the display) or during **maintenance/repair**.

The internal filter must be replaced by DeRoyal or an authorized service partner of DeRoyal.

2.2.3 Information on the carbon filter of the PRO-II® Device

An additional filter in the exhaust air vent of the PRO-II® device removes undesirable odor out of the exhaust air of the device. This filter consists of a thin activated carbon-coated nonwoven. The activated carbon in the nonwoven absorbs the odor particles of the exhaust air and neutralizes them. Spreading of odor will be effectively reduced.

Service life and reuse

The carbon filter is not intended for reuse. To ensure consistent performance, the carbon filter must be replaced during **maintenance or after 2 years of use (approximately 8,000 hours).**

The carbon filter must be replaced by DeRoyal or an authorized service partner of DeRoyal.

2.2.4 Disposable exudate canister system for PRO-III® Device

The disposable exudate canister system consists of the external canister, silicone tubing, external filter, and is available with and without solidifier. The external filter prevents an overflow in the event of an operational error. If the liquid reaches this filter, suction will no longer be possible and the error message "System closed" appears on the display. The negative pressure therapy will be discontinued. The canister and all tubing must be replaced.

Solidifier:
Disposable exudate canisters filled with wound exudate can be transported and disposed in a leak-proof manner by using the solidifier. The wound exudate solidifies after an average gelling time of 2 to 5 minutes (depending on the consistency of the wound exudate), irrespective of the pressure settings.

The **canisters and suction tubing** are intended for **single use**. Replace the disposable exudate canister and tubing in accordance to the respectively applicable hygiene instructions, if it is full, prior to each new patient or every 3-5 days.

2.2.5 Information on the double filter system for PRO-III® Device

The double filter system consists of the external bacterial filter integrated in the canister tubing and the internal filter installed in the device.

The external bacterial filter is incorporated in the available connection tubing provided by DeRoyal.

The double filter system effectively protects against overflow and contamination of the interior of the device.

Service life and reuse

To ensure consistent performance, the internal filter must be replaced **after contact with the exudate (blocked), after the filter service life has expired (8,000 hours)** ([!] symbol in the display) or during **maintenance/repair**.

The internal filter must be replaced by DeRoyal or an authorized service partner of DeRoyal.

2.2.6 Battery

The charge level of the battery is shown in the display.

It is strongly recommended to fully charge the battery prior to first startup of the PRO-II® and PRO-III® devices and to repeat this after the each use.

The PRO-II® and PRO-III® devices are equipped with a lithium-ion battery, which, unlike traditional types of rechargeable batteries, have a low self-discharge rate.

The PRO-II® and PRO-III® devices should ideally be stored and charged at room temperature in accordance with the ambient conditions specified in the technical data.
Never store the device incl. battery in a discharged state.
Fully recharge the battery if the device is not operated for a longer period of time (approx. 10 months).

Lithium-ion rechargeable batteries do not have a memory effect. They can, therefore, be recharged at any time after initial charging. Only frequent short-time charging should be avoided.

The batteries of the PRO-II® and PRO-III® devices are protected against deep discharge, but the charging information listed above must nevertheless be followed. The batteries also are protected against overheating during charging. If the battery temperature is exceeded during charging due to improper ambient conditions, charging is temporarily discontinued to allow for cooling. The purpose of this measure is to ensure safe operation and to protect the battery.

The operational service life of the battery is 2 years. According to the manufacturer of the battery, the battery has a remaining capacity of more than 80% after 300 charge cycles.

2.2.7 Pressure settings

Once the PRO-II® or PRO-III® device has been switched on, the pressure settings can be individually adjusted by a healthcare professional.

The pressure settings can be adjusted in a range from -20 mmHg to -200 mmHg (in steps of 5 mmHg). The setting of the pressure and time values is described in chapter 3.2.

Adjustments to device settings must only be made if instructed to do so and only by healthcare professionals. Prior to switching on the PRO-II® or PRO-III® device it must be ensured that the device is equipped with a disposable exudate canister.

2.3 Warranty

These devices 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 6 months from purchase date. DeRoyal 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.

CAUTION: 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; this includes using any non-DeRoyal provided accessories (kits, canisters, etc.) (3) the special 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 device). Any maintenance or service repair that is not covered by the warranty may be performed by DeRoyal at a cost of $75 per hour. A minimum of $75 may be charged and billed appropriately. Any repair charges less than $500.00 will be automatically billed, unless otherwise instructed by customer at time service is requested.

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

- original DeRoyal accessories and spare parts are used,
- maintenance and repair 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 and within its intended use.

DeRoyal does not warrant accurate function of the devices PRO-II® and PRO-III® devices 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.

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

3 Operation

CAUTION!	**Hazard of persons due to improper handling.** • Use the device for its intended purpose only. • Read chapter 3.1 and 3.2.
ATTENTION!	**Malfunction due to wound exudate overflow.** • Ensure that the disposable exudate canister of the PRO-II® and PRO-III® device is replaced on a regular basis. If the disposable exudate canister is full, the integrated overflow protection system will be triggered. This disrupts the aspiration process. • Switch the device off when replacing the disposable exudate canister. • If the internal filter of the PRO-II® or the PRO-III® device is blocked, the device must be serviced by DeRoyal. or by an authorized service partner of DeRoyal.
WARNING!	**Hazard of persons due to inadequate monitoring of patient.** Adequate monitoring of patients is mandatory in cases of highly exuding wounds, wounds with viscous or strongly deposited exudate and strong bleeding. Particular attention must be paid to exudate retention in the wound dressing and the proper sealing of the dressing. The establishment of monitoring intervals must be dependent on the wound situation, the health of the patient and the settings of the alarm sensitivities.
WARNING!	**Hazard of persons due to decreasing the alarm sensitivities.** When greatly decreasing alarm sensitivities, it is possible that a blockage or leakage in the wound and tube system may not be detected and thus no alarm will be triggered. The PRO-II® and PRO-III® devices are designed to build up a vacuum in the wound drainage system and to extract the exudate. The devices are not designed to detect strong bleeding of the wound. For this reason, you must not rely solely on the alarm system of the PRO-II® and PRO-III® devices. The regular monitoring of the patient and the wound dressing can reduce a severe deterioration of health of the patient dramatically.
WARNING!	**Hazard of persons during operation in a domestic environment.** Due to the increasing mobility of patients in a domestic environment, there is an increasing risk of forming leaks or blockages in the wound dressing or tube system. For this reason, detailed training and instruction for patients as well as performing regular monitoring of the wound dressing and negative pressure wound therapy system by trained personnel is mandatory.

3.1 Setup and Startup

3.1.1 Startup

It is important to follow the safety instruction in chapter 1.6 prior to initial startup. Always have one backup disposable exudate canister for the PRO-II® and one backup disposable canister and tubing for the PRO-III® device ready since it is absolutely necessary for safe operation.

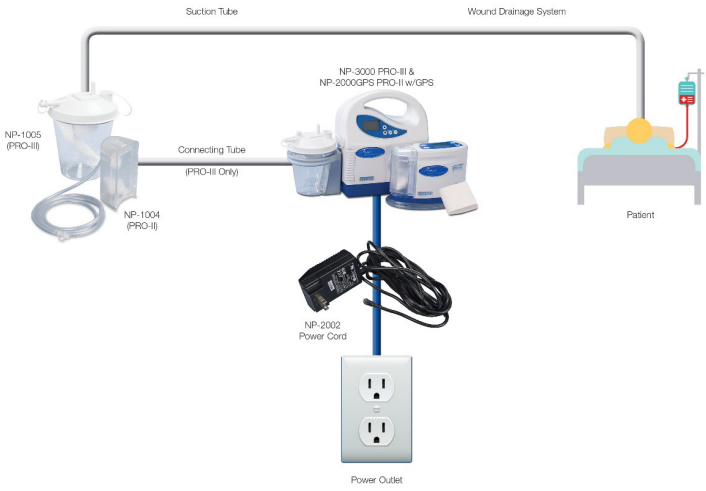
- Please read the entire instruction for use before operating the PRO-II® or PRO-III® device for the first time.
- Remove the device and the accessories from the packaging.
- Always place the device on a sturdy and flat surface. Take care to correctly position the device.
- Inspect all tubing as well as the power supply unit for damage prior to each startup of the PRO-II® and PRO-III® device. It is important to avoid kinking when connecting the tubing. Ensure prior to switching on the unit that the disposable exudate canister and all tubing are properly connected.
- Fully charge the battery prior to initial startup.
- Perform a function test (Please refer to chapter 5.1).

3.1.2 Connecting the PRO-II® and PRO-III® Devices

Use the socket for power supply unit of the PRO-II® device (chapter 2.1.1, fig.1 (G)) or the socket for power supply unit of the PRO-III® device (chapter 2.1.3, fig.2 (G)) to connect the device to the main power supply via the supplied power supply unit for charging or operation as required.

Use the supplied power supply unit only. First connect the power supply unit to the socket for power supply unit of the PRO-II® or PRO-III® device and then to the main power supply.

Fig. 3 Connecting the PRO-II® and PRO-III® devices to the patient and accessories



3.1.3 Positioning of the PRO-II® Devices

The PRO-II® device can be placed next to the patient bed or attached via the DeRoyal® PRO-II® device Holder (NP-170). An optional carrying bag (NP-2001) is available for portable use. Note: The PRO-II® device carrying bag is single patient use.

It is up to the physician/healthcare provider to decide whether the condition of the patient permits portable use.

To ensure optimum extraction of the wound exudate, place the PRO-II® device below the wound to be treated. It should be noted that the suction tube does not form a dip and is situated at least on patient level.

3.1.4 Connecting the disposable exudate canister of the PRO-II® Device

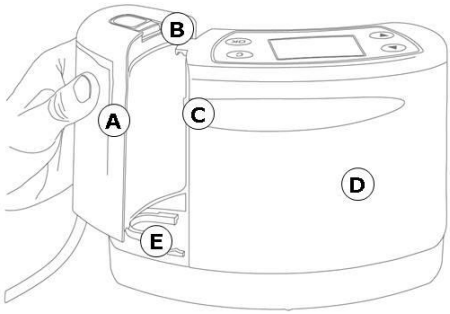


Fig.5 Connecting the disposable exudate canister

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

1. Remove the disposable exudate canister (fig. 5 (A)) from the packaging.
2. Slide the canister on the guiding rails (fig. 5 (E)) of the PRO-II® device until the disposable exudate canister clicks into place in the locking mechanism (fig. 5 (B)).
3. To remove from the device after use, press the "Press Here" button on the top of the canister prior to sliding back along the guiding rails.

3.1.5 Positioning of the PRO-III® Device

The PRO-III® device can be placed next to the patient bed or attached via the DeRoyal PRO-III® device bed holder (NP-140). An optional carrying bag (NP-3001) is available for portable use, as well as IV Pole holder. Note: The PRO-III® carrying bag is single patient use.

To ensure optimum extraction of the wound exudate, place the PRO-III® device below the wound to be treated. It should be noted that the suction tube does not form a dip and is situated at least on patient level.

3.1.6 Connecting the DeRoyal® disposable exudate canister system of the PRO-III® Device

The original DeRoyal® disposable exudate canister system consists of the external canister, the holder for the external canister, and the connecting tube with external filter.

3.1.7 Connecting a wound drainage system

Connect the suction tube to the wound drainage system, such as the DeRoyal® TopDraw® Medium Black foam Kit with Triple Release Transeal® (NP-0501). For a complete listing of approved DeRoyal wound draining kits, please visit www.deroyal.com/npwt.

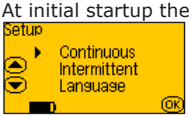
The suction tube must never come into direct contact with the aspiration area.

3.2 Operation of the PRO-II® and PRO-III® Devices

3.2.1 Operation at initial startup

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

2. At initial startup the unit will open with Continuous Mode set to -80mmHg:



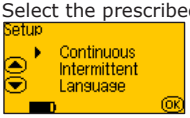
3. Use the (▲)(▼) arrow buttons to select the *Language* menu.

4. Use the (OK) button to confirm your choice.

5. Use the (▲)(▼) arrow buttons to select the desired language:

6. Use the (OK) button to confirm your choice.

7. Select the prescribed operating mode in the *Setup* menu.



8. Use the (OK) button to confirm your choice.

9. Perform the desired treatment (please refer to chapter 3.2.2 or 3.2.3).

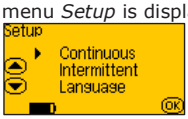
10. Switch off the PRO-II® or PRO-III® device by pressing the (C) button for 3 seconds.

3.2.2 Continuous operation

In the continuous operating mode, the PRO-II® and PRO-III® devices maintain 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. The default value is -80 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.

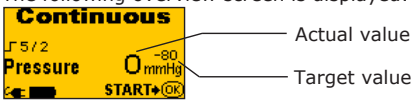


3. Use the ▲▼ arrow buttons to select the *Continuous* menu.

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

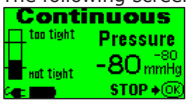
5. Use the ▲▼ arrow buttons to set the prescribed vacuum value.

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



7. Press the OK button to start the therapy.
(Default target value: -80 mmHg)

8. The following screen is displayed for one minute after the therapy has been started:

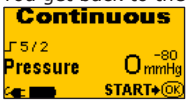


The bar symbolizes the tightness of the wound dressing. If the bar is in the "too tight" or "not tight" range, the wound dressing must be adjusted or may need to be reapplied. The wound dressing is properly applied if the bar is in the middle range.

9. If the bar graph screen is no longer displayed, the following therapy screen is displayed:

10. Press the OK button again to stop the therapy. User may have to unlock screen using ▲▼ arrow buttons.

11. You get back to the overview screen:



12. Switch off the PRO-II® or PRO-III® device by pressing the C button for 3 seconds.

3.2.3 Intermittent operation

In the intermittent operating mode, the PRO-II® and PRO-III® devices alternates between a high and a low vacuum within predefined time intervals.
The time intervals for high or low vacuum can be set separately from 2 to 10 minutes in increments of 0.5 minutes.

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.

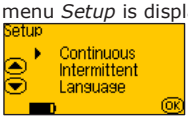
The setting of the low vacuum cannot be set higher than the setting of the high vacuum.

The following values are preset:

High Vacuum	-80 mmHg
Low Vacuum	-40 mmHg
Max Time	10 minutes
Min Time	2 minutes

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 *Intermittent* menu.

4. Use the OK button to confirm your choice.

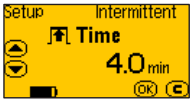
5. Use the ▲▼ arrow buttons to set the prescribed high vacuum value.

6. Confirm the setting by pressing the OK button.

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

8. Confirm the setting by pressing the OK button.

9. Use the ▲▼ arrow buttons to set the prescribed time value for the high vacuum.



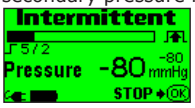
10. Confirm the setting by pressing the OK button.

11. Use the ▲▼ arrow buttons to set the prescribed time value for the low vacuum.

12. Confirm the setting by pressing the OK button.

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

14. Press the OK button to start the therapy. A timing bar will appear to visually display the amount of time remaining for the prescribed pressure level prior to changing to the secondary pressure level.



or


15. Press the OK button to stop the therapy again.

16. You get back to the overview screen.

17. Switch off the PRO-II® or PRO-III® devices by pressing the (C) button for 3 seconds.

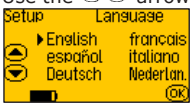
3.2.4 Language selection

The PRO-II® and PRO-III® devices allow the user to select a **language** at initial startup. The selected language is stored and automatically loaded at each startup. To customize the language, follow these steps:

1. Press the (OK) button for 1-2 seconds to switch on the PRO-II® or PRO-III® devices. 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 *Language* menu.
4. Use the (OK) button to confirm your choice.
5. Use the (▲)(▼) arrow buttons to select the desired language:



6. Use the (OK) button to confirm your choice.

3.2.5 Alarm delay at startup

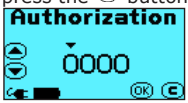
At startup of the PRO-II® or PRO-III® device, the alarm "System closed" for kinked tubing or too tight wound dressing and the alarm "Check dressing seal" are delayed for 60 seconds to ensure that the wound dressing can be placed without activating alarms.

3.3 Patient Mode

The PRO-II® and PRO-III® devices allow the user to select **patient mode** at startup. In patient mode, the settings for the alarm sensitivities "System closed" and "Check dressing seal" as well as the patient runtime can be viewed and reset. To select the patient mode, follow these steps:

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

2. While the start screen is displayed, press and hold down the C button and additionally press the OK button for 1-2 seconds. The *Authorization* screen is displayed.

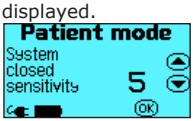


3. Use the ▲▼ arrow buttons to enter the "1111" code.
   Press the ▲ arrow button until the desired digit of the code is displayed and confirm the entry with the OK button. Select the other digits of the code with the ▲ arrow button and confirm them with the OK button as well.

   The authorization code may only be passed to specially trained personnel. You will get the training and the authorization code by DeRoyal or an authorized distribution partner of DeRoyal.

   Passwords must be treated as confidential information to prevent misuse.

4. After the authorization, the sensitivity setting of the alarm "System closed" is displayed.



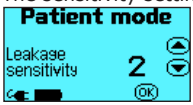
   The sensitivity can be adjusted with the ▲▼ arrow buttons.

1 ----------	5	----------9
low sensitivity (delayed triggering of the alarm)	default	high sensitivity (rapid triggering of the alarm)

   When the sensitivity is set to "1," the device detects a full canister or a blocked filter only.
   For this setting, it is highly recommended to reduce the interval time for checking the dressing seal by the healthcare personnel to detect potential blockings in the aspirating system promptly.

5. Press the OK button to confirm the entry.

6. The sensitivity setting of the alarm “Check dressing seal” is now displayed.



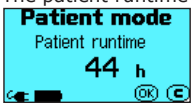
The sensitivity can be adjusted with the ▲▼ arrow buttons.

“L”	1 ----------	2	---------- 5
See Below	low sensitivity	default	high sensitivity
Displays as: Leakage System	(delayed triggering of the alarm)		(rapid triggering of the alarm)

WHEN THE SENSITIVITY IS SET TO LEAKAGE SYSTEM, 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.

7. Press the OK button to confirm the entry.

8. The patient runtime is now displayed.



9. Press the C button for 3 seconds to reset the patient runtime to zero.

10. Exit the patient mode by pressing the OK button.

CAUTION!

Hazard of persons due to incorrect settings.
Prior to using the PRO-II® or PRO-III® device on a new patient, it must be verified that the currently set alarm sensitivities are appropriate for this patient.

It is important to adapt the alarm system and sensitivities to the particular wound and situation of the patient.
The adjustment of alarm sensitivities may only be carried out by qualified and authorized healthcare personnel.

Always take care that the alarm sensitivities must be set contrary. That means you have to increase the sensitivity of the alarm “System closed” if you have a low sensitivity of the alarm “Check dressing seal” to detect possible changes in the wound therapy for the patient treatment.

3.4 Canister Exchange

3.4.1 Replacement of the disposable canister of the PRO-II® Device

1. Close the tubing clamp at the wound drainage system (fig.3) to maintain the vacuum in the PRO-II® device.
2. Switch off the PRO-II® device.
3. Separate the suction tube from the wound drainage system and close the connector with the protective cap.
4. 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.
5. Dispose of the disposable exudate canister and the integrated suction tube in a proper manner. (Please refer to chapter 6.3 "Disposal").
6. Place a new disposable exudate canister on the device. Ensure that the disposable exudate canister is properly connected to the device.
7. Connect the suction tube to the wound drainage system.
8. Switch on the PRO-II® device.
9. Loosen the tubing clamp at the wound drainage system.

3.4.2 Replacement of the disposable canister of the PRO-III® Device

1. Close the tubing clamp at the patient tubing (fig.3) and at the wound drainage system (TopDraw® tubing) to maintain the vacuum in the wound.
2. Turn off the PRO-III® device.
3. Separate the patient tubing from the wound drainage system.
4. Separate the canister tubing with filter from the disposable canister.
5. Remove the disposable canister and patient tubing.
6. Dispose of the canister and patient tubing in a proper manner. (Please refer to Chapter 6.3 "Disposal").
7. Place a new canister as specified in 3.1.6. Ensure that the canister tubing and lid are properly connected to each other and the device.
8. Attach a new patient tube to the patient connection of the disposable canister and connect it to the TopDraw® wound drainage system.
9. Switch on the PRO-III® device.
10. Loosen the tubing clamp at the wound drainage system.

4 Maintenance

4.1 Cleaning and Care

4.1.1 General Information

CAUTION!	**Health risks due to the handling of infectious or pathogenic germs.** Infectious & pathogenic germs in the wound exudate cause health risks. • Wear appropriate disposable gloves when replacing the disposable exudate canister or any tubing. • Use of the disposable exudate canister or any tubing is for one patient only. • Replace the disposable exudate canister(s) in accordance to the respectively applicable hygiene instructions, if it is full, prior to each new patient or every 3-5 days. • For each new patient, ensure unit has been cleaned following established facility protocols. • Components that have come into contact with the wound exudate must be cleaned, disinfected or disposed of after each use. • The disposal of wound exudate and contaminated components must be performed in a proper manner.
CAUTION!	**Health risks due to the handling of disinfectants.** • The use of appropriate disposable gloves during disinfection is recommended. • Follow the manufacturer's disinfectant instructions.
CAUTION!	**Possible bodily injury by electric shock.** Prior to cleaning and/or disinfection, switch off the device, disconnect the power supply by unplugging it from the wall and then disconnect the power supply from the unit of the PRO-II® or PRO-III® device.
ATTENTION!	**Risk of damage to the device due to improper cleaning agents.** • Do not use disinfectants that contain acetone. These may damage or disfigure the housing components and the accessories. • Follow the instruction for use provided by the manufacturers of the utilized disinfectants, particularly with respect to material and surface compatibility as well as the concentration information. • DeRoyal recommends Incidin LIQUID for wipe and spray disinfection of the device.

Disinfection is not mandatory if the device is used for one patient only (in in-home care). Disinfection is mandatory if used in an in-patient setting and between each new patient use: in-home or in-patient.

4.1.2 Cleaning and disinfection of the surface of the device

- Clean and disinfect the surfaces of the device at least once a week or in accordance to the respectively applicable facility protocols.
- The devices may be wiped with a damp, lint-free cloth.
- Follow the information on wipe disinfection provided in the chapter 4.1.1.
- Never clean or disinfect the device when turned on.

Minor discolorations may occur on the plastic housing components after prolonged use. These do not affect the function of the device.

If the interior of the device comes into contact with liquid, the device must be inspected by DeRoyal or an authorized service partner of DeRoyal.

4.1.3 Disposal of the disposable exudate canister incl. the suction tube for PRO-II® Device

1. Close the suction tube of the disposable exudate canister by using the closure cap of the suction tube.
2. Dispose of the disposable exudate canister incl. suction tube in a proper manner. (Please refer to chapter 6.3). It is a single-use item.

4.1.4 Disposal of the disposable canister and the suction tube for PRO-III® Device

1. Close the tubing clamp at the suction tube (fig. 3).
2. Separate the connecting tube of the canister from the device.
3. Remove the disposable canister and tubing from device.
4. Dispose of the disposable canister and tubing in a proper manner. (Please refer to chapter 6.3 "Disposal").

4.2 Maintenance and Service

The PRO-II® and PRO-III® devices are maintenance free if used according to the instruction for use.

Perform a visual and functional inspection prior to each use. (Please refer to chapter 5.1). Also include the accessories of the device in the inspection.

Opening of the device and repairs must only be performed by DeRoyal or by authorized professionals of DeRoyal in compliance with the service documentation specified by the manufacturer as well as with technical and hygienic precautionary measures.

The device may be sent back for repair to DeRoyal directly or via the specialty dealer from which the device was purchased.

Clean and disinfect all accessories prior to returning the device. The device itself must be treated with a surface disinfectant. Please note the guidelines referring to decontamination before shipping (chapter 6.1).

DeRoyal neither ensures proper functioning of the PRO-II® and PRO-III® medical suction devices nor is DeRoyal liable for property damage or personal injury if

- original DeRoyal accessories or spare parts are not used,
- the user instructions in this instruction for use have not been followed,
- installation, settings, modifications, enhancements and repairs are not performed by DeRoyal or authorized personnel of DeRoyal,
- the safety seal has been removed or is damaged,
- or any other portion of the warranty program or user manual are violated, omitted or disregarded in any way.

4.3 Testing the PRO-II® or PRO-III® Devices

DeRoyal offers its partners and customers fast and proper testing services.

5 Problem Solving

5.1 Function Test

Perform a function test of the device without the connected canister prior to use in therapy. Perform the following steps to do so:

1. Switch on the device as described in 3.2.
2. Start the therapy and allow the device to run in free flow. The alarm "System open" must be displayed after no more than 2 minutes. However, if instead the alarm "System closed" is displayed, the internal filter of the PRO-II® or PRO-III® device is blocked and must be replaced by service.
3. Press the OK button to confirm the alarm.
4. Next, hold the tube attachment closed with a finger or using a clamp and restart the therapy. The alarm "System closed" must be displayed after no more than 5 seconds. If the alarm is not displayed even after repeating the test, have the device inspected by a service partner.

5.2 Troubleshooting

Malfunction	Probable causes	Remedy
Device cannot be switched on.	• Battery is empty.	• Connect the power supply unit.
Therapy does not start.	• Tubing clamp is closed. • Overflow protection system is blocked (disposable exudate canister is full or tubing is blocked). • Internal filter is blocked. • Device is still in the *Setup* mode.	• Verify proper connection of the tubing. • Replace disposable exudate canister for PRO-II® device. • Replace disposable tubing for PRO-III® device. • Please contact customer service. • Finalize the selection (please refer to 3.2) and start the device.

Contact DeRoyal or your service partner if the malfunction cannot be corrected by the described measures.

5.3 Error Messages

- The alarms are solely system-triggered alarms since these are identified by the monitoring of device-specific variables.
- All alarm messages (except "Internal error") must be confirmed by pressing the OK button.
- Alarm messages of high priority are shown in the display with a **red blinking background** and the beeper is sounded (3x, pause, 2x, 3x, pause, 2x) every 3 seconds.
- Alarm messages of low priority are shown in the display with a **static yellow background** and the beeper is sounded periodically (2x) every 16 seconds.

Error message	Status	Probable cause	Remedy
	Pump off. Discontinuation of the current operating mode.	Disposable exudate canister is not connected or not properly connected; disposable exudate canister is connected but the tube is opened.	Check for proper connection. Start pump.
	Pump off. Discontinuation of the current operating mode.	Disposable exudate canister is full.	Switch off the device. Replace the disposable exudate canister.
		Exudate flow obstructed (tubing is kinked or stenosis in the tubing).	Check the tubing.
		If the alarm is displayed even if the canister is not connected, the internal filter is blocked.	Contact your service partner.
	Current operating mode continues to run in the background.	Wound dressing is leaking.	Switch off the device. Check the wound dressing and re-apply if necessary. Switch on the device again.
		Additional probable causes: Tubing or canister is not properly connected.	Check the tubing connection and the canister.
	Pump off. Discontinuation of the current operating mode.	Battery is empty.	Connect the power supply unit.

Error message	Status	Probable cause	Remedy
	Pump off.	Internal error.	Shortly plug in the power supply unit and unplug again. If the error reoccurs 60 seconds after restarting, contact your service partner!
	Current operating mode continues to run in the background.	Low battery charge level.	Connect the power supply unit soon.
	(Alarm after 15 minutes). Current operating mode continues to run in the background.	The therapy was not initiated.	Start therapy.
		The device was not switched off.	Switch off the device.

Contact DeRoyal or your service partner if the malfunction cannot be corrected by the described measures.

6 Transport, Storage and Disposal

6.1 Decontamination prior to Shipment

Prior to passing on the PRO-II® or PRO-III® device to new users, the devices must be properly cleaned and disinfected.

DeRoyal offers its partners and customers fast and proper instructions as well as required testing services. (Please refer to chapter 4).

The PRO-II® and PRO-III® devices must be cleaned and disinfected prior to shipment to DeRoyal for service. Please follow the instructions in chapter 4.1.2. Please give DeRoyal advance notice of your product return by contacting customer service and following the instructions provided by the customer service representative. Units sent to DeRoyal without proper notice and documentation may be returned or discarded with/without customer notification.

6.2 Storage

Store the PRO-II® and PRO-III® devices as indicated in the Technical Data (chapter 7).

The battery of the PRO-II® or PRO-III® device must be charged prior to storage of the device. This ensures that the device is operational at all times.
Fully recharge the battery if the PRO-II® or PRO-III® device is not used for a longer period of time (approx. 10 months).

6.3 Disposal

- The components of the device must be disposed of in a proper manner at the end of the product's service life.
- Ensure that the disposed components are clean and carefully sorted by material.
- The housing material has a material symbol mark and is fully recyclable.
- Decontaminate the device and any accessories prior to disposal.
- According to EU Directives 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) and 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II), the device must not be disposed of in domestic waste.
- The device and accessories may be disposed of via DeRoyal or the service partner.
- Outside of the US: Follow the disposal requirements as set by the country of residence.

7 Technical Data

7.1 PRO-II® Device

Flow rate	Max. 8 l/min
Pressure	Max. -200 mmHg; Conversion factor: 1 kPa ~ 7.5 mmHg
Canister	Disposable exudate canister (250 ml or 450 ml)
Suction tube	Suction tube with silicone tubing connector ~ length 150 cm
Power supply unit	FRIWO FW 7555M/12 or DeRoyal supplied power adapter
Nominal voltage of the power supply unit	In: AC 100 – 240 V~ / 50-60 Hz / 350 – 150 mA In (UL only): 120 Vac / max. 350 mA / 50-60 Hz Out: DC 12 V / 1,25 A
Maximum load current at 12 V	1.25 A
Nominal voltage of the circuit board at 12 V	12 V
Power consumption	15 W
Permissible input voltage	1.25 A
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
UL marking	AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005), CAN/CSA-C22.2 No. 60601-1 (2008)
Sound emission	Operation: 35 dB (A) High priority alarm: 52 dB (A) Low priority alarm: 49 dB (A)
Ambient conditions	Transport/Storage: -25°C to +60°C humidity of max. 93% non-condensing
	Operation: +5°C to +40°C humidity 15% to 93% non-condensing
	Air Pressure: 700 hPa to 1060 hPa
Battery, rechargeable	7.4 V, 4.4 Ah – Lithium ions
Charging time if battery is empty Charging time if battery is approx. 50% full	6 - 7 hours 3 - 3.5 hours
Dimensions (H x W x D) in mm	165 x 220 x 90
Weight (base unit)	1.2 kg
Pressure measurement accuracy	Target pressure > -80 mmHg max. Δ 5 % Target pressure < -80 mmHg max. Δ 10 %
Operating time	Continuous operation
Battery-powered runtime	approx. 24 – 48 hours, depending on the run time of the motor
Item number	NP-2000; NP-2000GPS

7.2 PRO-III® Device

Flow rate	Max. 8 l/min
Pressure	Max. -200 mmHg; Conversion factor: 1 kPa ~ 7.5 mmHg
Canister	Disposable exudate canister system (800 cc)
Power supply unit	FRIWO FW 7555M/12 or DeRoyal supplied power adapter
Nominal voltage of the power supply unit	In: AC 100 – 240 V~ / 50-60 Hz / 350 – 150 mA In (UL only): 120 Vac / max. 350 mA / 50-60 Hz Out: DC 12 V / 1,25 A
Maximum load current at 12 V	1.25 A
Nominal voltage of the circuit board at 12 V	12 V
Power consumption	15 W
Permissible input voltage	1.25 A
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
UL marking	AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005),
Sound emission	Operation: 35 dB (A) High priority alarm: 53 dB (A) Low priority alarm: 51 dB (A)
Ambient conditions	Transport/Storage: -25°C to +60°C humidity of max. 93% non-condensing
	Operation: +5°C to +40°C humidity 15% to 93% non-condensing
	Air Pressure: 700 hPa to 1060 hPa
Battery, rechargeable	7.4 V, 4.4 Ah – Lithium ions
Charging time if battery is empty Charging time if battery is approx. 50% full	6 - 7 hours 3 - 3.5 hours
Dimensions (H x W x D) in mm	290 x 259 + 100 (canister) x 130
Weight (base unit)	2.2 kg
Pressure measurement accuracy	Target pressure > -80 mmHg max. Δ 5% Target pressure < -80 mmHg max. Δ 10%
Operating time	Continuous operation
Battery-powered runtime	approx. 24 – 48 hours, depending on the run time of the motor
Item number	NP-3000

7.3 EMC Information

 **ATTENTION!**	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.
 **ATTENTION!**	Portable and mobile RF communication equipment may affect medical electrical equipment! Do not apply any 3rd party device to unit without proper testing performed by DeRoyal or by authorized professionals of DeRoyal.
 **CAUTION!**	The use of any accessories and/or spare parts (incl. transformers and cables, non-permanent 3rd 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 spare parts or by improper use is not covered by warranty in any case. Only use original DeRoyal accessories and spare parts.
 **CAUTION!**	Use of the recommended accessories and spare parts (incl. transformers and cables) in devices other than the PRO-II® and PRO-III® devices may increase the emission of electromagnetic interference or reduce the electromagnetic immunity. Damage caused by using recommended accessories and spare parts in other devices or by improper use is not covered by warranty in any case. Use the accessories and spare parts only with the PRO-II® and PRO-III® devices.
 **WARNING!**	The PRO-II® and PRO-III® devices 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 PRO-II® and PRO-III® devices in this configuration to verify proper operation!

The PRO-II® and PRO-III® devices meet the requirements of IEC 60601-1-2/EN 60601-1-2 "Electromagnetic Compatibility – Medical Electrical Equipment." Electromagnetic interference is therefore reduced to a minimum.

Table 1

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The PRO-II® and PRO-III® devices are intended for operation in the electromagnetic environment specified below. The customer or the user of the PRO-II® or PRO-III® device must ensure that it is operated in such an environment.		
Emissions measurement	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The PRO-II® and PRO-III® devices use RF energy for their internal function only. Their RF emissions are therefore very low and not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PRO-II® and PRO-III® devices are appropriate for use in all facilities incl. private residences and those directly connected to the public power supply network that supplies buildings used for residential purposes.
Harmonic emissions pursuant to IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions pursuant to IEC 61000-3-3	Complies	

Table 2

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The PRO-II® and PRO-III® devices are intended for operation in the electromagnetic environment specified below. The customer or user of the PRO-II® or PRO-III® device must ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) pursuant to IEC 61000-4-2	±6kV contact discharge ±8kV air discharge	±6kV contact discharge ±8kV air discharge	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical disturbances / bursts pursuant to IEC 61000-4-4	±2kV for power supply lines ±1kV for input and output lines	±2kV for power supply lines ±1kV for input and output lines	Main supply voltage should be of the same quality as in a typical commercial, living or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment – Guidance
Interference voltages / Surges pursuant to IEC 61000-4-5	±1kV voltage differential mode ±2kV common mode	±1kV voltage differential mode ±2kV common mode	Main supply voltage should be of the same quality as in a typical commercial, living or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines pursuant to IEC 61000-4-11	<5% U_T (>95% dip of U_T) for ½ period 40% U_T (60% dip of U_T) for 5 periods 70% U_T (30% dip of U_T) for 25 periods <5% U_T (>95% dip of U_T) for 5s	<5% U_T (>95% dip of U_T) for ½ period 40% U_T (60% dip of U_T) for 5 periods 70% U_T (30% dip of U_T) for 25 periods <5% U_T (>95% dip of U_T) for 5s	Main supply voltage should be of the same quality as in a typical commercial, living or hospital environment. If the user of the PRO-II® or PRO-III® device requires continued operation during mains power outages, it is recommended to power the device from an uninterruptible power supply or a battery.
Magnetic fields at power frequency (50/60 Hz) pursuant to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic for a typical location in a typical commercial, living or hospital environment.
Note: U_T is the AC mains voltage prior to the application of the test levels.			

Table 3

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The PRO-II® and PRO-III® devices are intended for operation in the electromagnetic environment specified below. The customer or user of the PRO-II® or PRO-III® device must ensure that it is used in such an environment.			
Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic Environment – Guidance
Conducted RF disturbances pursuant to IEC 61000-4-6 Radiated RF disturbances pursuant to IEC 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{eff} 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PRO-II® and PRO-III® devices, incl. cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d= 1.2 √P d= 1.2 √P for 80 MHz to 800 MHz d= 2.3 √P for 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be lower than the compliance level in each frequency range.[b] Interference is possible in the vicinity of devices bearing the symbol shown below. 

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 for 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 with respect to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PRO-II® and PRO-III® devices are used exceeds the applicable RF compliance level above, the device should be monitored to verify proper operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] The field strength should be lower than 3 V/m for the 150 kHz to 80 MHz frequency range.

Table 4

Recommended protection ratio between portable and mobile RF communications equipment and the PRO-II® and PRO-III® devices.

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

Rated maximum output power of transmitter (W)	Protection ratio based on the frequency of the transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended protection ratio in meters (m) can be determined 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 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.

8 Ordering Information

8.1 PRO-II® Device

Item number	Description	Included with purchase of new Pro-2
NP-2000	PRO-II® Portable Negative Pressure Device	yes
NP-2002	Power supply unit FRIWO FW 7555M/12 or DeRoyal supplied power supply	yes
NP-0250	Disposable exudate canister (250 ml) with solidifier and integrated tubing	yes (2)
NP-0450	Disposable exudate canister (400 ml) with solidifier and integrated tubing	no
NP-0450N	Disposable exudate canister (400 ml) with integrated tubing (without solidifier)	no
NP-2001	Carrying bag for DeRoyal® PRO-II® Device	no
NP-170	Bed Holder for DeRoyal® PRO-II® Device	no

8.2 PRO-III® Device

Item number	Description	Included with purchase of new Pro-2
NP-3000	PRO-III® Stationary Negative Pressure Device	yes
NP-1006	Disposable exudate canister (800 ml) with tubing, filter and solidifier	no
NP-1009	Disposable exudate canister (800 ml) with tubing, filter; without solidifier	no
NP-3001	Carrying bag for PRO-III® Device	no
NP-140	Bed Holder for PRO-III® Device	no

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