Read these operating instructions carefully prior to starting the unit.
Keep this manual near the unit for future reference!

PRO-II – ENGLISH
Doc. No.: NP126A

Prospera® PRO-II™

AC / DC Powered
Negative Pressure Wound Therapy Pump System

- Instructions for Use
- General Operating Information
- Technical Data
- Warranty

CLASSIFIED C UL US

CE 0483

Rehab Technologies, LLC

1-800-237-6708

Table of contents

The document is subject to technical alterations!

1.0 INTRODUCTION

This manual contains important information regarding safe and effective use and operation of **Prospera® PRO-II™**.

CAUTION!

This device must be used by qualified and authorized staff. The user must have adequate knowledge of the specific medical application for which the **PRO-II™** Negative Pressure Wound Therapy System is being applied.

1.1 Standard equipment

Prospera® PRO-II™ System:

- **PRO-II™** pump
- Collection canister with integrated bacteria and carbon filter, solidifier and PVC tubing
- Power supply adapter

1.2 Explanation of symbols and keys


”Caution: pay attention to Operating instructions“, acc. to DIN EN 980:2003.


“Caution: pay attention to accompanying documents”, acc. to DIN EN 980:2003


Degree of protection: **Type BF** (Body Floating)


Protection class II


Operating time with battery


Power supply adapter is connected


High pressure / Max time


Low pressure / Min time


Packaging unit for **PRO-II™** canister


Equipment must not be disposed of with household waste. Dispose of or recycle in accordance with local regulations


Up


Down

OK (Enter, On)

Cancel (Off)


Battery full


Battery low


Battery empty


Key lock:
automatically activated after 15 minutes and/or manually activated/deactivated by pressing the ▲ ▼ keys simultaneously (only when pump is running, green display)

1.3 For your safety – CAUTION!

- Operation of the **Prospera® PRO-III™** is possible even **during the battery charging procedure**.

- **Use only with Prospera® FRIWO FW 7555M/12 power supply adapter.**

- The safety standard of the **Prospera® PRO-III™** corresponds with recognized medical and technical regulations and the guidelines relating to medical products.

- The **Prospera® PRO-III™** bears the **CE identification symbol CE0483** in accordance with the EEC Medical Devices Directive – Directive 93/42/EEC and meets the basic requirements of Annex I to this Directive.

- The **Prospera® PRO-III™** has been designed according to **EEC Directive 93/42/EEC Annex IX** and has been classified as suction unit of **Class IIa**.

- The **Prospera® PRO-III™** meets the immunity to interference requirements of **IEC 601-1-2/EN 60601-1-2 "Electromagnetic compatibility - Medical Electrical Devices"**. Electromagnetic interference and interaction are thus reduced to a minimum.

- The **Prospera® PRO-III™** may only be applied by persons who have been trained in its operation according to the instruction guidelines issued by the supplier or medical staff.

- Prior to connecting the power supply adapter, check whether the voltage corresponds with in-building voltage.

- Never connect the power supply adapter to defective power sockets. Keep power supply adapter and cable away from external heat sources. Do not cover the power supply adapter.

- Check function of the unit prior to use.

- The unit may only be used with the original **Prospera® PRO-III™** collection canister.

- The unit must not be operated in damp rooms or when taking a bath or shower. Avoid moisture on plug and switches. Never plunge the unit into water or other liquids, not even when it is switched off.

- The unit must not be operated in splash water range and in locations where there is a danger of explosion.

- Pay attention to the ambient conditions described in the technical data.

- The unit should be operated on a firm, level surface.

- The unit should not be charged or started up:
  - if power cable or plug are defective;
  - if it has been dropped;
  - if obvious defects might restrict safe operation;
  - if it has been dropped into water.

  In any case, remove the power supply adapter from the socket and have the unit checked by qualified personnel authorized by DeRoyal®.

- In regular intervals, parts of the unit must be checked for proper function and safety-related defects, e.g. plug and socket connections, collection canister, housing etc.

- Opening the unit may only be performed by **qualified personnel** authorized by DeRoyal®. Only use original accessories and spare parts.

- The **Prospera® PRO-III™** has been designed for aspiration of body fluids in medical application; it is especially suitable for wound or surgical drainage (except for thorax suction).
  It must never be used to remove explosive gases and inflammable or corrosive fluids.

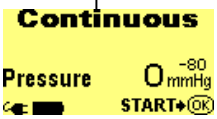
- The **Prospera® PRO-III™** must be switched off and disconnected from the power supply adapter:
  - before cleaning and maintaining the unit;
  - before removing the collection canister.

- When operating the unit at ambient temperatures outside the stated temperature range (see "Technical Data"), the performance may be reduced and the unit or the electronics and the battery may get damaged.

- Only use recommended wound dressing kits and protocols.

1.4 Illustrations

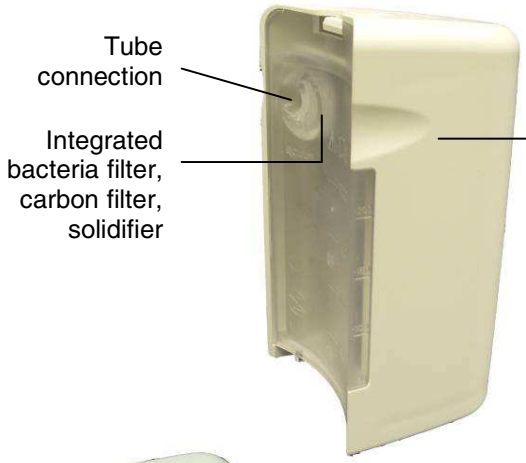
Background colors of display pad



Yellow: Pump is idle

Green: Pump is running

Red: Error message



2.0 WOUND APPLICATION INSTRUCTIONS

Indications for use
The **Prospera®** **PRO-II™** Powered Suction Pump is indicated for patients that would benefit from a suction device particularly as the device may promote wound healing.

Contraindications
The **PRO-II™** is contraindicated in the presence of:

- Necrotic tissue
- Unexplored or non-enteric fistulas
- Untreated osteomyelitis
- Malignancy in the wound
- Exposed arteries, veins, or organs

Precautions
Precautions should be taken for patients who are or have:

- On anticoagulation or active bleeding
- Difficult wound hemostasis
- Close proximity of blood vessels, organs, muscle, and fascia requiring adequate protection
- Irradiated vessels and tissue
- Bony fragments
- Untreated Malnutrition
- Non-compliant

Prospera® Self-Contained Collection Canister
The **PRO-II™** pump is supplied with a Prospera® built-in disposable 250 cc canister. Replace canister at a fill level of approx. 200 cc, weekly or between each patient use.

Prospera® Wound Dressing Material Selection
Antimicrobial gauze is the recommended choice for wound dressing material and is included in the Prospera® Wound Dressing Kit. Always moisten antimicrobial gauze with sterile saline prior to sealing the wound with transparent dressing provided.

Prospera® PRO-II™ Pump Placement
The **PRO-II™** unit may be placed at the patient's bedside. An optional carrying case is available for mobile use; however, it is the responsibility of the clinician or trained provider to determine if the patient's condition allows for mobile use. In addition, the **PRO-II™** can also be used in horizontal position.

Negative Pressure Settings
Lower levels of pressure settings are effective and well tolerable – for example:

(a)- Continuous pressure setting of
-60…-80mmHg

(b)- Intermittent (VPT®) settings
High -60…-80mmHg @ 2-5 min interval
Low -20…-40mmHg @ 2-5 min interval

Once the **PRO-II™** pump is switched on, the pressure settings can by adjusted by a trained provider.

Reminder:

- Use the lowest level of pressure setting possible. All pressure settings and modalities must be prescribed by a medical provider.
- Ensure that the canister is in place before **PRO-II™** pump is switched on.
- Check the wound dressings **every 6-8 hours or sooner**. Look for a wrinkled appearance at the surface of the dressing, which indicates an occlusive environment, thus maintaining proper suction.

3.0 OPERATION

3.1 Preparing the Prospera® PRO-II™ NPWT System for Operation

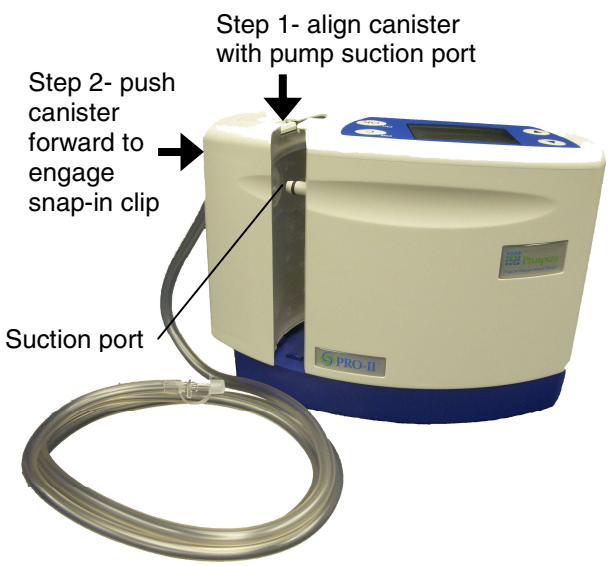
Inspect all tubing for any splits, cuts, or other damage. Care must be taken to avoid kinks while connecting the tubing. Ensure that the canister is properly connected before **PRO-II™** pump is switched on.

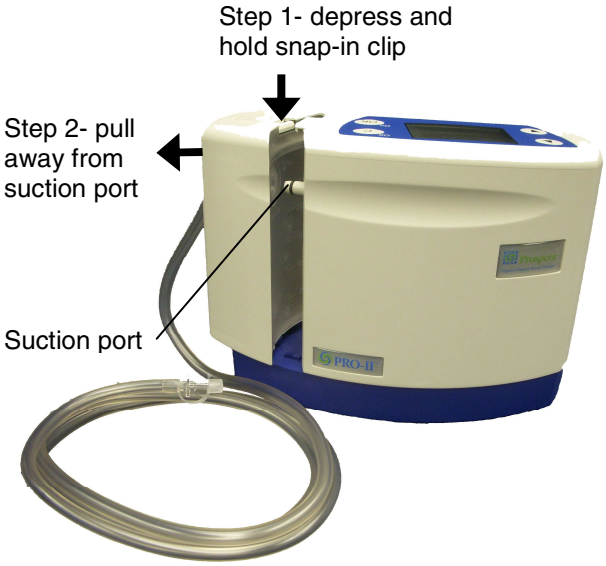
The **Prospera® PRO-II™** is designed for in-patient and primarily for mobile use and is most suitable for use in low vacuum range application for medical suction procedures where secretions, blood and body fluids are 250cc or less between dressing changes. Application includes all patient care settings.

3.1.1 Prospera® PRO-II™ Canister – Installation and removal instructions

Installation of canister: Attach a new canister to THE **PRO-II™** pump by aligning the bottom grooves of the canister with THE tracks on the **PRO-II™** unit. Slide and push the canister FORWARD until it attaches to the suction port and the canister snap-in clip is engaged.

Removal of canister: While holding both the pump and the canister firmly, depress and hold the snap-in clip and gently disengage the canister from the **PRO-II™** pump by PULLING THE CANISTER AWAY from the suction port. Properly discard canister and integrated PVC tubing.





Replacement of canister:
Follow installation instructions above.

3.2 Operating the PRO-II™ NPWT System

Connect the power supply adapter to the AC outlet and to the unit. To switch the unit on, press and hold the OK key for 1-2 seconds until the Start screen appears:

By default, the pump will then show the factory setting *Continuous* mode and a pressure of -80mmHg:

Remove the collection canister in order to perform the tests described below.

Press OK key to start operation. Allow to run for 10 seconds.

Internal suction circuit: (system closed)
Seal the **PRO-II™** suction port by covering it with your thumb. The internal circuit is tight when the vacuum pressure gauge indicates -**80mmHg** and the error message "system closed" appears on the display. Confirm the error message by pressing the OK key and press the OK key again to stop the pump.

Internal suction circuit: (system open)
Press the OK key to turn the pump on. After 30 seconds running without canister, the error message "System open" alarm will sound.

External suction circuit:
Attach the collection canister to the pump and press the OK key to turn the pump on (see internal suction circuit). If there is a leakage, the error message "check dressing seal" alarm will sound. External components may be checked by sealing the end of the tubing circuit and following the same procedure as above.

NOTE!
If the **PRO-II™** passes the internal suction circuit check but not the external suction check then a leak is present in the external circuit. Review the external suction circuit step by step, from the pump to the patient, to find where any leaks occur.

Overflow Protection Device/Bacteria Filter
The **PRO-II™** pump uses an integrated bacteria filter (inside the canister) for protection of the pump against overflow and the spread of aspirated microorganisms. Only use the original Prospera® **PRO-II™** collection canister with integrated filter. In case of an application error, this integrated bacteria filter will prevent fluid and microorganisms from entering the interior of pump. If liquid reaches this filter, suction will no longer be possible and the error message "system closed" will appear repeatedly.
In addition, an activated carbon filter is integrated in the canister for odor control.

Prospera® Suction Canister
Prospera® canister should be changed and discarded when full, weekly or between patient use.

Cleaning and Disinfecting
Follow facility policies and guidelines concerning cleaning and disinfecting.
(Also refer to sections 4.1 and 4.2).

Housing
The outside of the pump should be cleaned with a damp cloth. Cleaning agents and disinfectants should be used in a diluted form.

Suction Canister and Tubing
The **Prospera® PRO-II™** canister and all tubing are **disposable** and should never be autoclaved.

3.3 Continuous and Intermittent (VPT®) Operation

The **PRO-II™** is designed to operate in *Continuous* or *Intermittent (VPT® - **V**ariable **P**ressure **T**herapy)* modes.

Continuous:
PRO-II™ is pre-set to a low vacuum pressure. When the pump is switched on, the vacuum is generated up to the set target value and is then controlled and kept at this level.
Low vacuum pressure values may be adjusted by the medical staff or by the trained personnel as needed.

***Intermittent (VPT®)*:**
Intermittent VPT is Prospera's advanced technology which allows the provider to customize the pressure and time interval settings depending on the prescribed requirements.

CAUTION!
All parameters should be programmed into the **PRO-II™** unit by trained personnel and based on medical provider's order.

WARNING:
Universal precautions should be observed when operating or transporting the **PRO-II™** pump and/or disposing of all accessories.

Routine Maintenance and Inspection
The **PRO-II™** system and components should be visually inspected prior to each use.

Battery Operation
The **PRO-II™** battery will provide best performance when fully charged. The **PRO-II™** battery charges when plugged into AC power both during operation and when switched off and not in use.

When the battery charging indicator is displayed on LCD, the **PRO-II™** battery will start charging.

The **PRO-II™** will sound an audible signal indicating a low battery (approx. 25% left in battery time). The unit should be plugged into AC power immediately.
The **PRO-II™** should be stored at 23℉ to 95℉ (-5℃ to 35℃) for optimal performance.

3.4 Settings

CAUTION!
All adjustable settings, such as vacuum pressure values, time intervals during intermittent (VPT®) mode and all other settings **may only be performed by trained provider/personnel and by prescribed orders.**

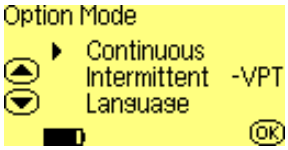
NOTE:
The selected settings remain stored after switching off the pump. When switching on again, the unit will default back to the previously prescribed pressure and time settings.

3.4.1 General description

- To reach the Option Mode menu, switch on the pump with the (OK) key. Immediately after the display screen is illuminated, hold down both arrow (▲)(▼) keys simultaneously and continue holding down for a few seconds until the "*Option Mode"* menu screen appears.
- Use the (▲)(▼) keys to navigate the menu.
- Operating modes, target vacuum pressure values and time values can then be adjusted by means of the four display pad keys.
- The respective entry is confirmed with the (OK) key or cancelled using the (C) key.
- After having finished the settings, confirm and exit the Option Mode menu and store the settings by pressing the (OK) key.
- If the treatment must be interrupted, stop the pump by pressing the (OK) key. (Yellow screen). To resume, start the pump by pressing the (OK) key again. (Green screen).
- **To switch off** the **PRO-II™**: Press and hold down the (C) key for 3 seconds.

3.4.2 Detailed description

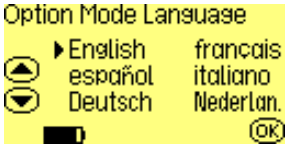
3.4.2.1 Option Mode screen



Option Mode screen:
The cursor points to the desired operating mode (Continuous or Intermittent (VPT®)) or to the language settings.

- Use the ▲ ▼ keys to move the cursor to the respective mode and confirm your selection with the OK key.

Note:
To switch from *Continuous* mode to *Intermittent* (VPT®) mode, **after having confirmed a mode by pressing the OK key**, the pump must be turned off and on again in order to activate the "Option Mode".



Language Settings:

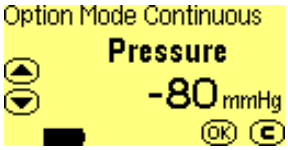
- Use the ▲ ▼ keys to move the cursor to the respective language and confirm your selection with the OK key.

3.4.2.2 Continuous mode

NOTE:
If pump is **idle**:
Display has a **yellow background** color.
If pump is **running**:
Display has a **green background** color.
If pump indicates an **error message**:
Display has **red background** color .

Continuous operation with the prescribed pressure value.
Continuous pressure = -10…-200mmHg
(in steps of 5)

yellow:



***Option Mode* Continuous**:
Use the ▲ ▼ keys to set prescribed pressure.

- The pressure value is confirmed with the OK key.

yellow:

- Start the pump by pressing the OK key.

green:

Operating Screen:

- To stop the pump press the OK key again.

3.4.2.3 Intermittent, Variable Pressure Therapy (VPT®) mode

Intermittent (VPT®) operation:
Changeover between two phases with different prescribed pressure and time interval settings.

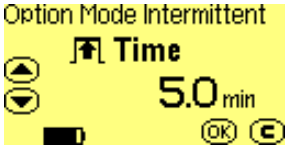
***Option Mode* Intermittent (VPT®):**

- **Pressure Range**

High Pressure = -20...-200mmHg (in steps of 5)

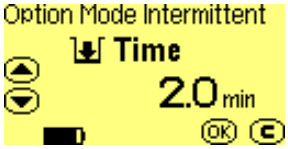
Low Pressure = -10...-100mmHg (in steps of 5)

The Low pressure setting can not be higher than the High pressure setting.



- **Time Range**

Max Time = duration for High pressure
= 0.5...10.0 min (in steps of 0.5 minutes)

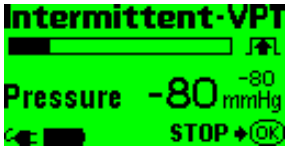


Min Time = duration for Low pressure
= 0.5...10.0 min (in steps of 0.5 minutes)

This display confirms the high and low pressures and time settings for Intermittent (VPT®)

- Start the pump by pressing the OK key.
- To stop the pump press the OK key again.

Operating screen:



Intermittent (VPT®) / high pressure phase:
The timing bar progresses from left to right as the pressure increases to high pressure setting.

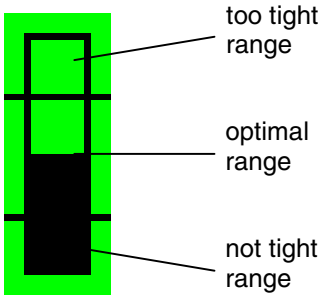
Intermittent (VPT®) / low pressure phase:
The timing bar reverses from right to left as the pressure decreases to low pressure setting.

3.4.2.4 Bargraph

The Bargraph feature is automatically displayed on the screen for 60 seconds after start of the pump in either Continuous or Intermittent (VPT®) Mode. To display the bargraph again, press either of the ▼ ▲ keys and it will remain on for additional 60 seconds.

Bargraph explanation:

The vertical bargraph is used as a guide for the provider to measure the effectiveness of the dressing seal. Once the pump is turned on, the gauge on the graph will start rising. The following demonstrates the various outcomes:



1. If the bar rises to the level marked as “not tight”, this indicates leak in the dressing seal and therefore ”check dressing seal” alarm will sound.

2. If the bar rises beyond the level marked as “too tight” and fills the entire bar, this indicates dressing is too tight, no air flow and the “system closed” alarm will sound.

3. If the bar rises and remains steady at the halfway mark, this indicates the most optimal and desired seal .

The provider may choose to customize the sensitivity levels for “system closed” and “check dressing seal” alarms depending on the patient, location of the wound and the amount of exudate.

Note: The Bargraph will not display or work if the sensitivity for closed system alarm is set to 1.

3.4.2.5 Patient mode

The default key is: 1111

- To reach the Patient Mode, switch on the pump with the OK key. Immediately after the display screen is illuminated, hold down the both keys OK and C simultaneously and continue holding down for a few seconds until the "*Authorization*" menu screen appears. (blue screen)

- Use the ▲ ▼ keys to set the first number to 1 then press the OK key to confirm and proceed to next number. Repeat this step for all 4 numbers.

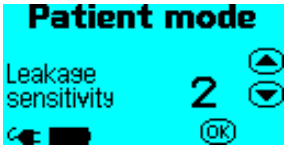
System closed sensitivity

- Use the ▲ ▼ keys to set the sensitivity. Range from 2 to 9

2----------5----------9

lower sensitivity (delayed alarm)	***default***	***higher sensitivity (faster alarm)***

Sensitivity of "1" detects only a full canister or a blocked filter



Leakage sensitivity

- Use the ▲ ▼ keys to set the sensitivity. Range from 1 to 5

1----------2----------5

lower sensitivity (delayed alarm)	***default***	***higher sensitivity (faster alarm)***

Patient Runtime / Compliance

This feature counts (total hours) when the pump is running or display screen is green.

- To reset the counter to zero, press and hold down the C key for 3 seconds.

3.5 Alarm Indicators

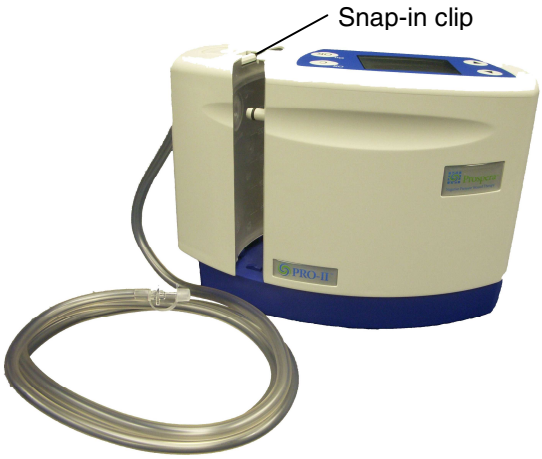
Note: Alarm messages appear with **red** background color.

Error Message:	Status:		Possible Causes:	Remedy:
	System open	• Alarm on • Motor off • Termination of current operating mode	Motor has run for 30 seconds without generating pressure (canister is not connected)	• Press OK key to remove the error message and to silence the alarm • Check correct connections • Re-start the pump
	System closed (message appears within 5 minutes – depending on the error location)	• Alarm on • Current operating mode continues in the background	Canister full (filter closed) Tube is kinked (near the dressing)	• Press OK key • Switch unit off • Replace the canister • Check the tube
	Battery low	• Alarm on • Current operating mode continues in the background	Low battery charging condition	• Press OK key or • Connect power supply adapter
	Warning message from battery pack	• Alarm on • Motor off • Termination of current operating mode	Battery is empty	• Press OK key • Connect power supply adapter
	Check dressing seal	• Alarm on • Current operating mode continues in the background	Dressing is not tight (tube or canister not correctly connected or leaks in the dressing)	• Press OK key • Switch unit off • Trouble shoot the dressing and tubing
	Pump is switched on but not running	• Alarm sounds after 15 minutes	Pump was not started	• Press OK key to remove the error message and to silence the alarm • Re-start the pump

4.0 CLEANING AND SERVICING

4.1 Replacing the canister

Turn off the **Prospera®** **PRO-II™** and unplug it from AC power. Remove the collection canister from the pump. **Properly discard canister and integrated PVC tubing.**
Replace with a new canister. (see section 3.1.1)



How to remove the canister (see section 3.1.1)

CAUTION!
Follow facility protocol for disposal of hazardous material. In regular intervals, parts of the unit must be checked for proper function and safety-related defects, e.g. power supply adapter, socket connections, canister, etc.

PRO-II™ without canister

Solidifier:
The aqueous fluid in the canister is gelled by the solidifier. This prevents leakage during handling and disposal of this liquid medical waste.

4.2 General

All parts that come into contact with the wound exudate must be disposed according to facility guidelines.

The **PRO-II™** pump may be cleaned and disinfected as shown in the following table.
Observe the manufacturer's instructions for disinfection.
Do not use disinfectants containing acetone.
Gloves should be worn during disinfecting (e.g. disposable gloves).

Part		Cleaning	Disinfecting
Disposable parts	Collection canister (including integrated PVC tubing and bacteria filter) Dressing	Re-use not permitted!	
Pump casing		Wipe with a moist cloth	Wipe with disinfectant

5.0 BATTERY

Rechargeable battery	7.4V, 4.4Ah - lithium-ion battery
Charging time of empty battery **Charging time of ½ empty battery**	6-7 hours 3-3.5 hours
Operating time	DC operation: approx. 24…48 hours, depending on use

5.1 Charging instructions for the battery

It is strongly recommend to charge the battery completely upon receipt of the **PRO-II™** and prior to first use. Repeat this charging procedure during the first applications in order to reach the maximum number of charging cycles (about 500 cycles).

The **PRO-II™** is equipped with a lithium-ion battery. Compared to traditional batteries, lithium-ion batteries have a lower, but temperature-dependent, self-discharging rate of 3-10% per month.

Storage and usage of the battery in the **PRO-II™** must be within the temperature ranges stated in the section under "Technical Data" .

Lithium-ion batteries do not suffer from the memory effect. After initial charging (see above), they can be recharged at any time without damage, although frequent **short-time charging should be avoided**.

The battery of the **PRO-II™** is protected against "total discharge" and "overheating" during charging. Nevertheless, the above charging instructions must be adhered to. If, due to extreme ambient conditions, battery temperature increases above the limit, charging will temporarily be interrupted in order to allow the battery to cool down. This is to enhance the battery's life.

5.2 Recharge the battery

To re-charge the battery connect the power supply adapter to the AC outlet and to the **Prospera® PRO-II™ pump.**

Option: Use the optionally available car connecting cable to operate and charge the unit with a 12V on board supply system.

The battery can be charged in running mode, idle mode and also when the pump is in off mode as shown in the display examples.

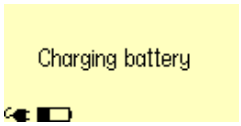
NOTE: During the off mode once the battery is fully charged the display screen will go from a light yellow to blank screen.


full battery


half full battery


empty battery


power supply adapter is connected



light yellow screen

battery charging when pump is in off mode

yellow screen

battery charging in idle mode

green screen

battery charging in running mode

6.0 TROUBLE-SHOOTING

The **Prospera®** **PRO-II™** was subjected to a thorough quality control and inspection before shipment. However, if there is some malfunction, you may be able to solve the problem using the following instructions.

Problem	Possible causes	Remedy
Unit does not start	• Battery is empty	• Connect the power supply adapter
	• Unit is still in the setting mode	• Complete the settings
	• Bacteria filter is moist (canister full)	• Replace the canister
Insufficient performance	• Bacteria filter inside the canister is contaminated/moist	• Replace the canister
	• Leakage within the suction line	• Check proper fit of canister and tube connections
		• Assess dressing
	• Battery almost empty	• Charge the battery
		If the problem still persists, contact the service.
No suction	• Bacteria filter inside the canister is contaminated/moist	• Replace the canister
	• Canister full	• Replace the canister
	• Tubing is kinked	• Check that the tubing is properly placed and connected
		If the problem still persists, contact the service.

7.0 LEGAL INFORMATION

Improper handling of this device releases the manufacturer from its warranty obligation. In particular, these operating instructions must be followed.

CAUTION!

Operational safety of the unit can be guaranteed by the manufacturer only if original accessories and original spare parts are used.

For the power supply via the AC outlet, only use:
Power supply adapter FRIWO
(Type: FW 7555M/12)
Product No. NP-2002

8.0 WARRANTY

DeRoyal® warrants your new PRO-II™ against defects in material and workmanship during the warranty period of one (1) year from the date of purchase. This period is neither extended nor presumed as a result of repairs or replacements carried out. The warranty does not cover accessories, spare parts and consumables.

DeRoyal® can be held responsible for safety, reliability and performance of the unit only if:

- Maintenance and repairs are exclusively carried out by DeRoyal® or by DeRoyal® authorized personnel or technicians.
- The product is used properly in accordance to the instructions in this operating manual.

CAUTION!

Warranty claims will not be accepted if the unit has been opened or repaired by unauthorized individuals, if the unit has not been used in accordance with Prospera® guidelines and if the special tamper proof seal is missing or broken.

9.0 Disposal

When the PRO-II™ is ready for final disposal, the components must be discarded properly observing the applicable waste-control regulations. In doing so, make sure that the materials are in clean condition and that they are carefully separated.
Parts of the collection canister, tubes and filter may be disposed of as normal waste while the basic unit is disposed of as electric scrap. The PRO-II™ does not contain any hazardous materials. The housing is marked with a material abbreviation and can be recycled completely.

CAUTION!

Pay attention to country-specific regulations, especially with regard to disposal of used batteries.

10.0 ELECTROMAGNETIC COMPATIBILITY (EMC)

The **Prospera® PRO-II™** meets the immunity to interference requirements of **IEC 601-1-2/EN 60601-1-2 "Electromagnetic compatibility - Medical Electrical Devices"**. Electromagnetic interference and interaction are thus reduced to a minimum.

Table 1

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Prospera® suction units of the PRO series are intended for use in the electromagnetic environment specified below. The customer or user should ensure that they are used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emission according to CISPR 11	Class B	Prospera® suction units of the **PRO series** are suitable for use in all facilities including those in residential areas and those directly connected to a public utility network also supplying buildings used for residential purposes.
Emission of harmonic oscillations according to IEC 61000-3-2	Not applicable	
Emission of voltage fluctuations/flickers according to IEC 61000-3-3	Not applicable	

Table 2

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Prospera® suction units of the PRO series are intended for use in the electromagnetic environment specified below. The customer or user should ensure that they are operated in such an environment.			
Immunity Test	**IEC 60601 - Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Discharge of static electricity (ESD) according to IEC 61000-4-2	±6kV contact discharge ±8kV air discharge	±6kV contact discharge ±8kV air discharge	Floors should be made of wood or concrete or feature ceramic tiles. If the floor covering consists of synthetic material, the relative humidity should be at least 30%.
Electrical fast transients (EFT) / bursts according to IEC 61000-4-4	±2kV for AC power lines ±1kV for input and output lines	±2kV for AC power lines ±1kV for input and output lines	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Surges according to IEC 61000-4-5	±1kV differential mode ±2kV common mode voltage	±1kV differential mode not applicable	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines according to IEC 61000-4-11	<5% U_T (>95% dip of the U_T) for ½ cycle 40% U_T (60% dip of the U_T) for 5 cycles 70% U_T (30% dip of the U_T) for 25 cycles <5% U_T (>95% dip of the U_T) for 5s	<5% U_T (>95% dip of the U_T) for ½ cycle 40% U_T (60% dip of the U_T) for 5 cycles 70% U_T (30% dip of the U_T) for 25 cycles <5% U_T (>95% dip of the U_T) for 5 s	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment. If the user/operator of the PRO units requires the continuation of functionality after power interruptions/disruptions, it is recommended to provide units with power from an uninterruptible power supply or a battery.
Supply frequency magnetic field (50 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields of the mains power frequency should comply with the typical values of business and hospital environments.
Note: U_T is the mains alternating voltage before applying the test levels.			

10.0 ELECTROMAGNETIC COMPATIBILITY (EMC)

Table 3

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Prospera® suction units of the PRO series are intended for use in the electromagnetic environment specified below. The customer or user should ensure that they are operated in such an environment.			
Immunity Test	**IEC 60601 - Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF interference quantities according to IEC 61000-4-6 Radiated RF interference quantities according to IEC 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5GHz	3 V_{eff} 3 V/m	Portable and mobile wireless devices should not be used in closer proximity to the Prospera® suction units of the PRO series (including cables/lines) than the recommended safety distance calculated based on the transmitting frequency and the applicable formula. **Recommended safety 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 with P as the rated output of the transmitter in watts (W) according to the information provided by the manufacturer of the transmitter and d as recommended safety distance in meters (m). Field strengths from fixed RF transmitter as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference is possible in the proximity of devices featuring the following pictograph. 

NOTE 1 The higher frequency range applies in case of 80 MHz and 800 MHz.

NOTE 2 These guidelines may not be applicable in all cases. The spread of electromagnetic quantities differs depending on the absorption and reflection of buildings, objects, and people.

[a] The field strength of stationary transmitters such as base stations of mobile phones and land mobile devices, ham radio stations, AM and FM radio, and TV broadcasters are theoretically not 100% predictable. A site study is recommended to determine the electromagnetic environment as it pertains to the stationary transmitters. If the measured field strength at the proposed installation and operation site of the Prospera® suction units of the PRO series exceeds the concordance levels listed above, the units should be monitored to document proper functionality and operation as intended. Additional measures might become necessary, e.g. modifying orientation or a different location for the units, if unusual performance characteristics are observed.

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

10.0 ELECTROMAGNETIC COMPATIBILITY (EMC)

Table 4

Recommended safety distances between portable and mobile RF telecommunications devices and Prospera® PRO series suction units.

PRO series suction units are intended for use in an electromagnetic environment where RF interference quantities are controlled. The user/operator of the PRO suction units can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF telecommunications devices (transmitters) and the PRO suction units – depending on the output power of the communication device listed below.

Rated output of the transmitter W	**Safety distance based on the transmitting frequency m**		
	150 kHz to 80 MHz d= 1.2 √P	**80 MHz to 800 MHz** d = 1.2 √P	**800 MHz to 2.5 GHz** d = 2.3 √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

The safety distance d in meters (m) for transmitters with a max. rated output not listed in the table above can be calculated by applying the corresponding formula in the respective column. P is the max. rated output of the transmitter in watts (W) as specified by the transmitter manufacturer.

NOTE 1 The higher frequency range applies at 80 MHz and 800 MHz.

NOTE 2 These guidelines are probably not realizable in all cases. The distribution and spread of electromagnetic quantities differs depending on the absorption and reflection of buildings, objects, and people.

11.0 SPARE PARTS

CAUTION!

Regularly check your stock for completeness of these parts.

CAUTION!

Operational safety of the unit can be guaranteed by the manufacturer only if original accessories and original spare parts are used.

REF

Canister set: Including bacteria filter, carbon, solidifier and PVC tubing NP-1004

Power supply adapter, FRIWO (Type: FW 7555M/12) NP-2002

12.0 TECHNICAL DATA	
Air-flow rate of pump	8 liters/min
Negative pressure	max. -200mmHg; Conversion factor: 1kPa ~ 7.5mmHg
Collection canister	Disposable canister systems
Suction tubing	Various drainage systems, depending on supplier and specific application. Type and kind of use are determined by the medical staff.
Nominal voltage of power supply adapter **Maximum load current** **Mains frequency of power supply adapter**	100 - 240V primary / 12VDC secondary 1.25A 50 / 60Hz
Nominal voltage of electronic circuit board	12V
Power consumption	15W (charging and operation) / 10W (charging only)
Current consumption	1.25A
Rechargeable battery	7.4V, 4.4Ah – lithium-ion battery
Charging time of empty battery **Charging time of ½ empty battery**	6-7 hours 3-3.5 hours
Dimensions (W x H x D)	215 x 165 x 90mm (8.4 x 6.5 x 3.5 inch)
Weight (basic unit)	1.3kg (2.65 lbs.), with canister
Operating time	AC operation: continuous operation DC operation: approx. 24…48 hours, depending on use
Degree of protection acc. to IEC 601-1	Type BF 
Risk class according to 93/42/EEC, IX	IIa
Protection class **according to IEC 601-1**	II
UL Classification	 Medical Suction Unit WITH RESPECT TO ELECTRICAL SHOCK FIRE, AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601- 1/CAN/CSA C22.2 No. 601.1 3KCX
CE mark	CE0483
Sound emission	35 dB (A)
Ambient conditions	Transport/storage: -10℃ – +60℃ (14°F – 140°F) Operation: +5℃ – +35℃ (41°F – 95°F) Recommended charging temperature: +15℃ – +30℃ (59°F – 86°F) 5 up to 80% relative humidity, non-condensing Atmospheric pressure: 860hPa…1060hPa
REF	10802

13.0 INDEX