Negative Pressure Wound Therapy Device

Advanced Wound Care Device

Rx Only

USER MANUAL

For Clinicians Only

NoWound™ Smart Healing

by MEDVITAL VENTURES

CAUTION: The NoWound NPWT Healing Device User's Manual is not a guarantee or warranty. It is intended only as an operational guide. For additional information, please contact Medvital Ventures Private Limited.

- The electrical installation of the room in which the device will be used must comply with the appropriate national electrical standards.
- The product must be used in accordance with the User Manual and the Instructions for Use (IFU).

If the NoWound NPWT Healing Device does not function properly, it must be returned to Medvital Ventures Private Limited.

- or to an authorized service center.
- The NoWound NPWT Healing Device must only be used by or under the supervision of a trained medical practioner.

NOTE:

If the medical device is not used as per the instructions as stated in the user manual or if the therapy settings are changed during the therapy without the supervision of a trained medical practioner, the medical device may cause injury.

INTRODUCTION

Indications

NoWound NPWT Healing Device is an innovative and easy to use device that assists in wound healing and is used for the removal of infectious material from the wound.

NoWounds's advanced, precisely controlled negative pressure wound therapy (NPWT) helps in faster healing of wound as it inhibits bacterial growth, increases blood flow, and promotes granulation tissue formation, leading to faster wound healing.

Effective in following types of Wounds:

- **Traumatic wounds**
- **Pressure ulcers**
- **Grafts and flaps**
- **Diabetic foot ulcers**
- **Venous ulcers**
- **Incisional wounds**
- **Surgical dehiscence**

The NPWT DEVICE has two therapy modes:

- **Continuous Mode:** This mode will provide continuous negative pressure at the wound bed ranging from 40 to 200 mm Hg.
- **Intermittent Mode:** This mode will cycle between high negative pressure and low negative pressure at defined intervals of time.

Contraindications

The NoWound NPWT Healing Device is contraindicated for patients with:

- **Malignancy in the wound:** The device should not be used on malignant tissue. Its stimulatory effect on tissue growth is undesirable in the context of malignancy. Furthermore, malignant tissue is prone to hemorrhage due to its disorganized vasculature.
- **Necrotic tissue** with eschar present. However, the device can be used after debridement of necrotic tissue and complete removal of eschar.
- **Contact with fragile tissue:** The device foam dressing should not be in direct contact with exposed blood vessels, nerves, organs of anastomotic sites. There is an increased risk of fistulae formation in the presence of exposed organs or hemorrhage with exposed blood vessels.
- **Infection:** Infections (including osteomyelitis) should be treated or debrided fully before the application of the device.
- **Bleeding:** Bleeding should be well controlled before the application of the device. If bleeding occurs then the therapy should be discontinued and further medical care should be provided under appropriate clinical supervision.
- **Allergy:** To foam based dressing or adhesive dressing
- **Other:** Ischaemic wounds, fragile skin, non-enteric, and unexplored fistula.

Precautions

- Do not use the device when there is active bleeding or risk of bleeding.
- Do not use the device if the patient is on blood thinner medication, medical supervision is required.
- Do not use the device when there is uncontrolled pain experienced by the patient.
- Do not place the foam dressing on overexposed blood vessels or organs.
- Do not use the device when there is a systematic infection or advancing infection at the wound site.
- Do not use the device on difficult wounds before hemostasis.
- Do not use the device when the person is having an enteric fistula.
- Do not use the device when there is inadequate tissue coverage over vascular structures.
- Make sure that the tubes connected to the device are not folded or compressed.
- Input power to the device must be within the specified range.
- Keep the device away from strong electromagnetic fields.
- Do not spill water on the device.
- Do not tilt the device during the therapy.
- Keep the battery in a charged state
- Do not store the device in discharged state.
- If the device has not been used for more than 15 days, charge the device before use.

Additional Precautions

- **Defibrillation:** Remove the dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit electrical current transmission and/or patient resuscitation. Disconnect the device from the dressing by disconnecting the NPWT tube and the Oxygen supply tube.
- **Magnetic Resonance Imaging (MRI):** The device is not MRI-compatible. Do not take into the MRI area.
- **Hyperbaric Oxygen Therapy (HBO):** NEVER allow the device - whether on or off - inside a hyperbaric chamber. The device must be disconnected from the patient prior to HBO treatment.

Safety Tips

NoWound NPWT Healing Device is indicated for the application of suction (negative pressure) to the wound bed to promote wound healing and for the removal of wound exudates and infectious materials.

Keep Therapy On

Remove the foam dressing if therapy is terminated or is off for more than 2 hours in a 24-hour period.

Dressing Use

The compatible dressings are to be used exclusively with the NoWound NPWT Healing Device.

Dressing Changes

The wound should be cleaned as per the clinician's order prior to dressing application. The dressing should be changed after 72 hours or as per clinician's instructions.

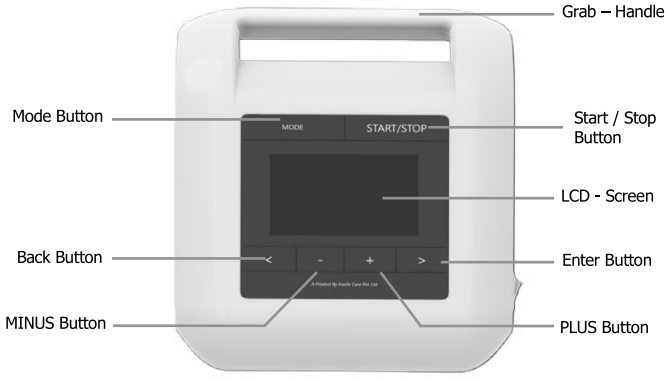
FEATURES

- **Easy-to-use One-Touch Operation:** Therapy start and change of parameter settings can be accomplished with the push of a button.
- **Light Weight/Impact Resistant:** NPWT DEVICE weighs only 1.30 Kg and can be easily carried and transported. The enclosure is impact resistant to help prevent damage from accidental dropping.
- **Modes:** NPWT DEVICE consists of two therapy modes.

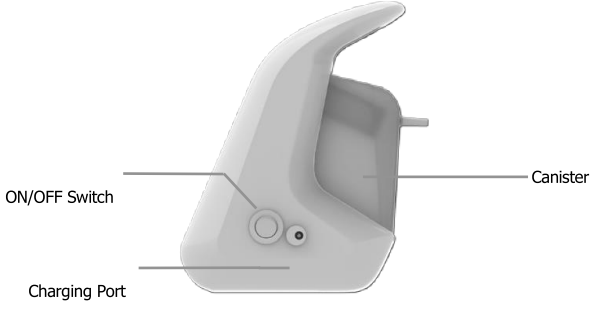
MODES	NEGATIVE PRESSURE
Continuous Mode	40-200 mmHg
Intermediate Mode -P high -P low	40-200 mmHg

- **Power Supply:** The NoWound NPWT Healing Device has an internal battery that provides up to 6 hours of operation from a single full charge. The battery charges while the unit is operating with the DC (12 V) adapter. The device will indicate a low battery sign on the screen indicating the battery has gone below 15% and the device can be further run on a plugged-in DC adapter.
- **Alarms:** Automated alarms for dressing leakage, full canister, tube blockage and low battery. Alarms provide both a visual and audible indication. Alarms will turn off once the problem is corrected or can be reset manually by turning the device OFF and ON.
- **Single-Use Disposable Canisters:** The canister is made from a disposable and transparent material and collects wound exudate from the wound bed. The maximum collection capacity of the canister is 600 ml.

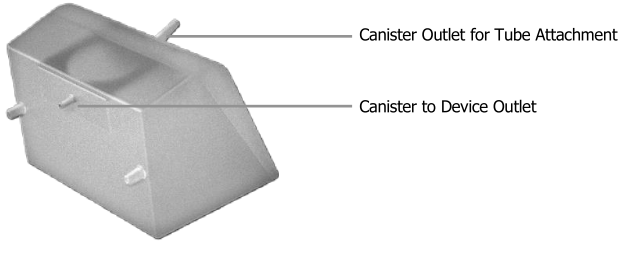
THE DEVICE



Front



Side



Canister

THE DISPLAY'S INTERFACE

There are two modes in the device and each will indicate different functions. The User Interface is designed in such a way that it is very simple to operate and self-explanatory.

Continuous Mode: In Continuous Mode, the device can be used with a constant Negative pressure setting at the wound bed. The range of negative pressure can be selected from 40 to 200 mm Hg.

Figure 1: The screen showing Continuous Mode

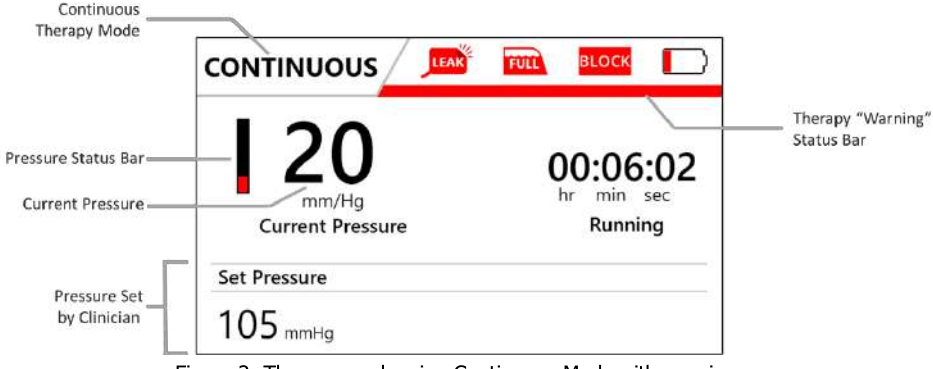


Figure 2: The screen showing Continuous Mode with warnings

Intermittent Mode: In this Mode, the device will be used with alternating NPWT settings with high and low negative pressure cycles at regular intervals of time. The black highlighted pressure setting will indicate the current Intermittent Mode settings and the light grey pressure setting will indicate the upcoming Intermittent Mode settings.

Figure 3: The Screen showing Intermittent Mode

Warning Signs: The screen will show warning signs to indicate any issue with the therapy. The green therapy status bar will change to a Blinking Red bar which will be visible on the screen. The corresponding warning symbols will also change to red. The warning indicators are as follows:-

1. Leak 

2. Canister Full 

3. Blockage (Block) 

4. Low Battery 

CARE & CLEANING

Introduction

The following instructions are recommended for cleaning and infection control procedures for the NoWound NPWT Healing Device.

Protective Equipments

Universal Safety Precautions should be used to minimize the risk of infection due to wound exudate during the dressing changes or disposal. It is important to protect all exposed skin and mucous membranes. The protective equipment includes:

- Disposable gloves (latex or latex-free).
- Protective cap and mask.
- Disposable impervious gown.

Disposal

The used dressings, adhesive drape, canister, tubings, connectors and clamps are serious biomedical hazards and should be disposed off according to the Biomedical Waste Management Rules.

Dispose off all the disposable components mentioned above in accordance with local, state, and medical waste regulations and institution protocols.

Cleaning the NPWT DEVICE

Perform a visual inspection of the device. Check for any sign of contamination and wipe the device surface using 70% alcohol to clean it.

A.C. ADAPTER INSPECTION - The A.C. Adapter should be inspected regularly for damage. Replace damaged power supplies immediately. A.C. Adapters will be available from No Wound.

⚠ **WARNING:** The NoWound NPWT Healing Device should only be used with the supplied A.C. Adapter. Use of an incorrectly rated adapter could create a shock hazard for the patient or the user.

⚠ **WARNING:** Avoid spilling liquid on any part of the device. Liquids can cause corrosion when left on electronic controls which can lead to failure. Component failure may cause the device to operate erratically, possibly causing a potential hazard to the patient or user.

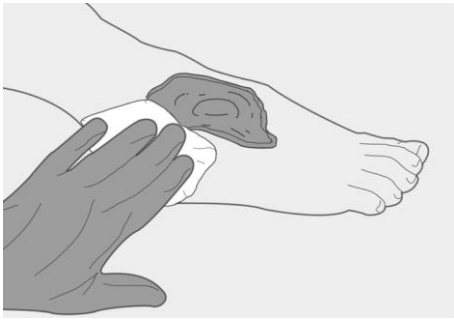
NOTE: Cleaning procedures should not be performed when a unit is connected to a patient. Disconnect the unit from the patient and power source and switch off the device before cleaning or servicing.

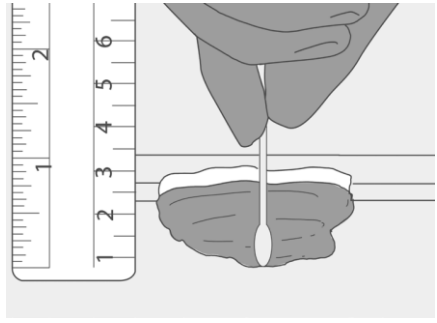
PATIENT CARE

It is recommended that all sections of this manual be reviewed prior to using the product. Carefully read the **INDICATIONS, CONTRAINDICATIONS, PRECAUTIONS** and **SAFETY TIPS** before attempting to perform the therapy on the patients with the NoWound NPWT Healing Device.

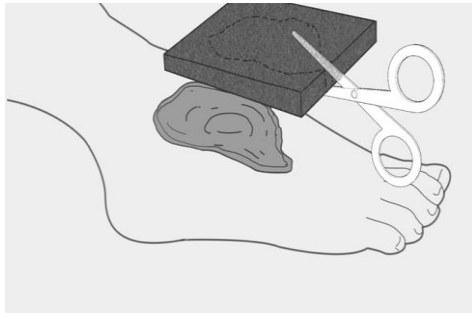
Applying the Dressing

- Clean the wound according to institutional protocols or clinical order.
- Debride all necrotic tissue including Escher and hardened slough from the wound.
- Ensure that the wound has achieved hemostasis.
- Visually examine and palpate wound bed to locate any blood vessels or delicate underlying structure in close proximity.
- Prepare the wound to permit adhesion of the polyurethane drape.





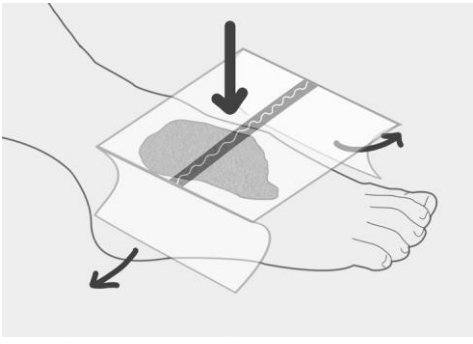
- Use the ruler method to measure the length and breadth of the wound. Use a cotton-tip applicator to measure the depth of the wound. Take a note of the wound type. Then, cut the foam dressing according to the size of the wound.

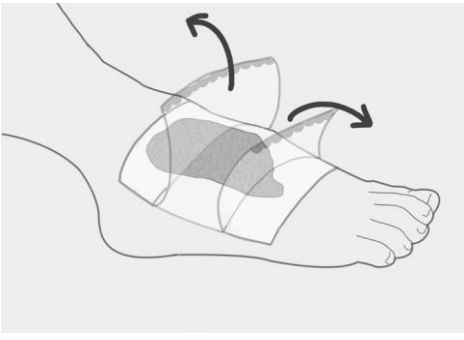


- Cut the foam dressing according to the shape and size of the wound. Place the polyurethene foam on the wound, taking care to avoid contact with the peri-wound skin. The foam should be higher than skin level and cover the entire wound base.

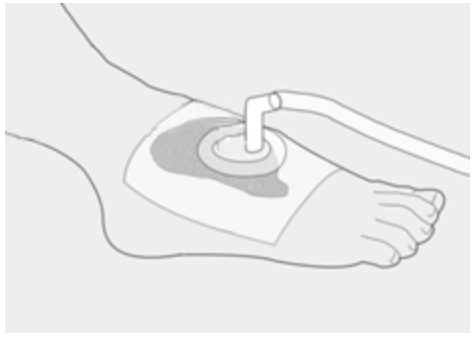
NOTE: If peri-wound area is excessively moist or oily, a medical-grade liquid adhesive may improve sealing. For fragile skin, use a skin sealant prior to drape application, or frame the wound with a skin barrier layer.

- Cut the drape bigger than the wound size and peel off the bottom adhesive layer and stick it over the wound properly. Gently press down on drape material around the wound site and over the foam to ensure dressing is properly sealed and after that remove the top layer as well.
- Verify the dressing application is correct, and the tubings are connected.





- Cut a small hole in dressing and adhere the dual tab over the hole. Insert the double tubings: one to device outlet for oxygen and another to canister inlet as shown.



- To Begin therapy (see OPERATING INSTRUCTIONS).

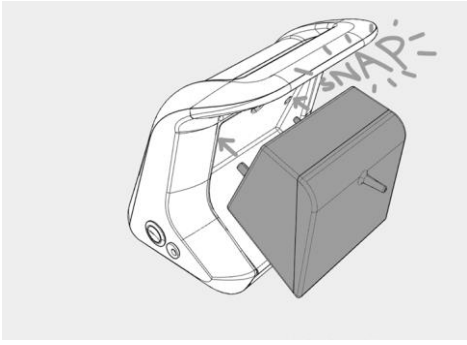
⚠ **WARNING:** Do not tightly pack the foam dressings into any areas of the wound. Forcing dressings in a compressed manner into any wound is contrary to approved protocols.

NOTE: The foam dressing should cover the entire wound margin, including tunnelling and undermining. However, the foam dressing should not be in contact with intact skin.

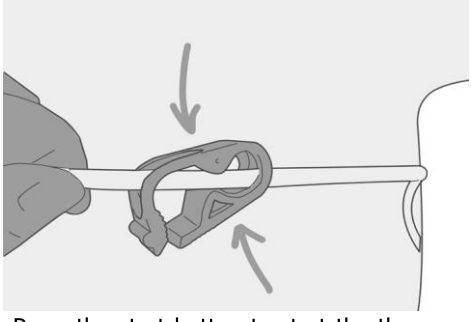
NOTE: Do not trim the foam dressing over or around the wound so that any clippings or debris from the foam do not fall into the wound.

Canister Installation

- Ensure that a canister is properly inserted in the receptacle located on the back side of the device. The canister should "snap" into place and lock.



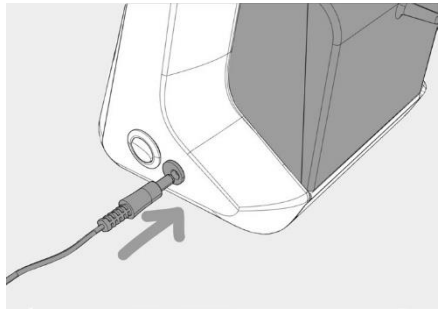
- Connect one of the tubes coming from the wound bed to the canister inlet.
- Close suction tubing clamp.



- Press the start button to start the therapy and ensure that pressure is created in the canister.
- Release the tubing clamp to allow negative pressure to reach the wound. The dressing should compress.
- Inspect the canister connection to ensure that it is properly connected to the dressing and that the connections are well sealed.

NOTE: Canister is a disposable unit. Always use a new canister when starting a new therapy session or when replacing a full canister.

- Plug the device's A.C. Adapter into a suitable 100-240 v AC, 50-60Hz, outlet. Insert the barrel jack into the Power input connector on the side of the device. The NPWT Device should only be used with the supplied A.C. Adapter. Use of an incorrectly rated adapter could create a shock hazard for the patient and the user.



NOTE: NoWound offers a 12 Volt adapter for safe and continuous working of the device.

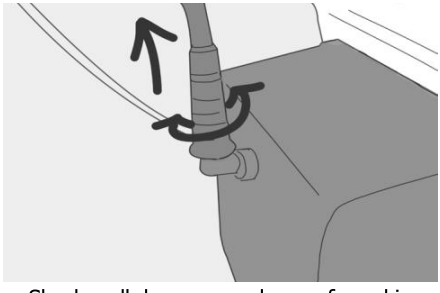
Canister Removal

Carefully read the SAFETY TIPS in the INTRODUCTION section of this guide prior to removing the Canister.

NOTE: Wounds must be carefully monitored at regular intervals. In a non-infected wound, dressings should be changed every 72 hours; but no less than 3 times per week, with the frequency of dressing change determined by the clinician. Infected wounds must be monitored continuously. For infected wounds, dressings may need to be changed more often than 72 hours; the dressing change interval should be based on a clinical evaluation of the wound condition rather than a fixed schedule.

NOTE: The canister should be replaced when full (the Full Canister alarm activates) or at least once every week to minimize the potential for contamination and production of odors.

- Press the OFF button to turn the therapy off.
- Close suction tubing.
- Disconnect suction tube. Twisting the tapered connector will make removing the Suction tube from the Canister easier.



- Slowly pull drape up and away fromskin while gently stretching drape.
- Discard disposables in accordance with the applicable rules, regulations and infection control protocols, and always follow Universal Safety Precautions.

Disposal of Dressings and Canister

To minimize the risk of infection and contact with contaminated blood or bodily fluids during the dressing changes or disposal, it is important to protect all exposed skin and mucous membranes. After patient use, all disposable components of the Device should be treated as contaminated. These include:

- The foam dressing and polyurethanedrape.
- The exudate collection canister.
- tubing, connectors & clamps.

Dispose off biomedical hazards according to the local, state and central regulations as well as institutional protocols.

NOTE: If the foam dressing adheres to the wound during removal, refer to the SAFETY TIPS section of this manual.

NOTE: "Act" means the Environment (Protection) Act, 1986 (29 of 1986)

Device Service

At least once a year or when the device is not working as per specifications, the device should be serviced at NoWound or an authorized service center. Ensure that the canister is removed from the device before sending it for service and never send disposable components/accessories such as the carry bag, canisters, dressings or tubing. The A.C. adapter should be sent along with the device.

OPERATING INSTRUCTIONS

This section contains instructions for setting and adjusting functions of the NoWound NPWT Healing Device. The section explains the procedure for starting therapy and explains the major functions that are adjusted from the control panel.

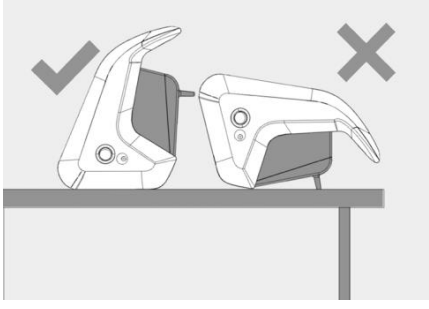
Carefully read the **PRECAUTIONS** and **SAFETY TIPS** in the **INTRODUCTION** section before attempting to operate the NoWound NPWT Healing Device.

Power On/Off

The ON/OFF switch is located on the Right side of the NPWT DEVICE. The ON/OFF switch controls the supply of power to the device.

Power up- Procedure

- Do not tilt the device and try to level it with the wound as possible. The device can be placed on a table.



- The device performs a Power On Self Test (POST) during power up to ensure all the sensors, inputs and outputs are working.
- If errors are encountered during POST the device displays the error code on the screen.
- If no error is encountered during POST, the device powers on and the Continuous Therapy mode screen is displayed.

Therapy Setting Adjustment

⚠ **CAUTION:** Only a clinician can prescribe the proper settings and protocols for the therapy. Failure to follow product instructions or adjusting settings and applying therapy without the expert direction or supervision may lead to major injury.

Continuous NPWT

Negative Pressure Level Adjustment: The negative pressure will range from 40 to 200 mm Hg. The prssure setting can be changed using the + to increase the pressure and − to decrease the negative pressure setting in increments of 5mmHg.

- Check all tubing connections & dressing, after that click on the start button present just below the screen.

Intermittent

There are two negative pressure settings, (a) **P-Low** (40-100mmHg) (b) **P-High** (40-200mmHg) the pressure selection buttons are located below the screen. The − decreases the negative pressure setting and the + increases the negative pressure setting. The **RIGHT** button selects the next parameter and the **LEFT** button selects the previous parameter to be incremented or decremented.

- Time interval 1-12 hours.
- Check all tubing connections & dressing, after that press the start button present just above the screen.
- To change the negative pressure settings of either P-high or P-low, press **RIGHT** or **LEFT** buttons and to increase

or decrease the negative pressure press **Plus** or **Minus** button. Same steps can be followed for time settings.

Battery Operation

Batery Life

The specified battery life of the NoWound NPWT Healing Device with a fully-charged battery and a well-sealed dressing is up to 6 hours. The actual life is dependent on the integrity of the dressing. A leak in the dressing can reduce overall battery longevity significantly.

Average Time for Recharging

To ensure the battery has been fully charged, the device should be connected to the power supply for approximately 3 hours to 4 hours. After approximately 2 hours of charging, the device will have achieved 80% of total battery capacity.

Low Battery Alarm

While running on battery, a low-battery alarm will activate when remaining capacity of the battery is less than 15% (See "Alarm Operation"). Typically, the unit will continue to operate upto 30 minutes.

Device Power Off Due to Low Battery

If the battery charge falls below a functional level, the device will switch off automatically and therapy will be discontinued. At this point, the device must be plugged into an A.C. power source for therapy to resume. Once the A.C. Adapter is plugged in, pressing the ON button will restart the device.

Recharging the Battery

Plug the power cord from the A.C. Adapter into the power receptacle on the side of the device. Plug the A.C. Adapter into a suitable 110-240 V , 50- 60 Hz wall outlet. When the device is connected to an AC power source battery icon shows charging indicator.

Alarm Operation

To clear an alarm, address the alarm condition. For example to address the leakage alarm, inspect the dressing and identify the point of leakage. Once the leakage has been fixed and the wound bed reaches the set NPWT pressure, the leakage alarm will be cleared automatically. To address the canister alarm, replace the filled canister with a new empty canister and the canister alarm will be cleared automatically. The alarms can also be cleared by turning the device OFF then ON. The alarm beep will be cleared until the alarm condition arises again.

ALARM TROUBLESHOOTING

ALARM TYPE	INDICATION	CORRECTIVE ACTION
Leak	• LED display shows the "LEAK" icon in red accompanied by an audible beep pattern. • Unit will continue to alarm until the leak condition is corrected • The alarm is cleared automatically once leak is fixed	• Press around the drape to check for leaks. If a leak is found, patch with extra drape material. • Check all tubing connections between the device and dressing. • Check to ensure the canister is fully sealed and locked. Replace canister if damaged.
Canister Full	• LED display shows the "CANISTER FULL" icon in red accompanied by an audible beep pattern. • Unit will continue to alarm until the canister is replaced.	• Pause the therapy by pressing the START/STOP button. • Clamp and disconnect the NPWT tube from the canister. • Replace canister, reattach tube and resume the therapy by pressing he START/STOP button.
Low Battery	• LED display shows the "Low Battery" icon accompanied by an audible beep pattern. • The unit will continue to alarm until power supply is reconnected. • When the charge falls below the critical level, the device will shut down and therapy will be interrupted.	• Connect the device to AC Power through the provided authorized adapter to recharge the battery and run the device with external power supply.
Blockage (Block)	• LED display shows the "BLOCK" icon in red along with an audible beep pattern. • Blockage (Block) alarm is raised when there is a blockage in the tube connecting the dressing to the canister. • The blockage may be due to clamps, pinched tube, or thick dry exudate blocking the tube	• Ensure that all clamps on the tube are released. • Ensure the tube is not pinched anywhere. • Ensure that there are no depositions of exudate stuck in the tube

SPECIFICATIONS

NPWT Healing Device

Dimensions	20.5 x 19 x 14 cm
Weight	1.3 kg
Pressure Range	- 40-200 mmHg
Canister Volume	600 mL

IEC Classification

Medical Equipment

Equipment not suitable for use in presence of flammable anaesthetic mixture with air, oxygen, ornitrous oxide.

Continuous Operation

Type B Applied Part

Class II Internally Powered Equipment

IPXO

Battery

Recharging Time	3-4 Hours
Run Time	up to 6 Hours
Battery Type	Li-ion

WARNING: DO NOT ATTEMPT TO REMOVE, REPLACE OR SERVICE THE BATTERY.

Battery is not user replaceable. Only authorized service personnel from NoWound should replace the battery.

Unauthorized access to battery may be dangerous.

Electrical

Input Voltage to AC/DC Adapter

100V – 240V AC, 50-60Hz

Output Power from AC/DC Adapter

12V, 3A (36W)

Input Power to NPWT Device Unit

12V, 3A (36W)

Storage Conditions

Temperature Range	-10 to 60 deg C
Relative Humidity Range	10 to 85%

Operating Conditions

Temperature Range	10 to 30 deg C
Relative Humidity Range	10 to 85%

Service life of NPWT Device

5 years

Explanation of Symbols

Direct Current	Keep dry	Single Use: do not reuse
EIL listing mark	Storage temperature limit	Barch code
Manufacturer	Date of manufacture	Serial number
Refer to instruction manual/booklet	EU: WEEE symbol not for general waste	Product catalogue number
Caution refer to instruction	Relative humidity limitation	Product catalogue number
Do not use if package is damaged	Keep away from sunlight	CE mark
Biological risk	Atmospheric pressure	Non-ionizing electromagnetic radiation
IP22 Enclosure protected against ingress of small objects and dripping water	MRI Unsafe keep away from magnetic resonance imaging (MRI) equipment	℞ ONLY Restricted device
STERILE EO Sterilized using Ehylene oxide	Equipment classification isolation type B applied part	

REPLACEMENT PARTS

Description	Part No.
Device	NoWound 2.xx.xx
A.C. power supply (12v) adapter	CUI SWM30-12
Accessories	NPWT Dressing, Canister

NOTE: The NPWT Healing Device works only with compatible dressings, canisters and other consumables provided by NoWound.

WARRANTY POLICY

Warranty Terms and Conditions

The warranty shall not extend to anyinstrument that:

- Out of warranty period that is 1 year.
- Has been subjected to misuse, negligenceor accidents;
- Errors caused by modification or repair by anyone except Inochi care Pvt ltd authorized person.
- From which Inochi care original serial number tag or product identification markings have been altered or removed;
- Any Act of God or Nature (such accident, fire, flood, etc.) or any other condition that is beyond the control of Inochi care
- Failure resulting from lack of or improper maintenance.

Amendment

Warranty service conditions are subject to change without notice. Please refer regularly to the latest warranty terms and conditions.

NoWound™
Smart Healing

MEDVITAL VENTURES PVT. LTD.
Second Floor, A-131, Vikas Puri, New Delhi- 110018
GSTIN: 07AARCM8651R1ZB
MD License No: RMD/DCD/24/ZO-5995/1147

.Manufactured By
INOCHI CARE PRIVATE LIMITED
C-34, Second floor, DDA sheds, Okhla
Industrial Area, Phase 1, Delhi - 110020
License No. MFG/MD/2023/000912