LIGHTSTONE
MEDICAL

Tzoar Negative Pressure Wound Therapy System

INSTRUCTIONS FOR USE

Model #Tzoar 207

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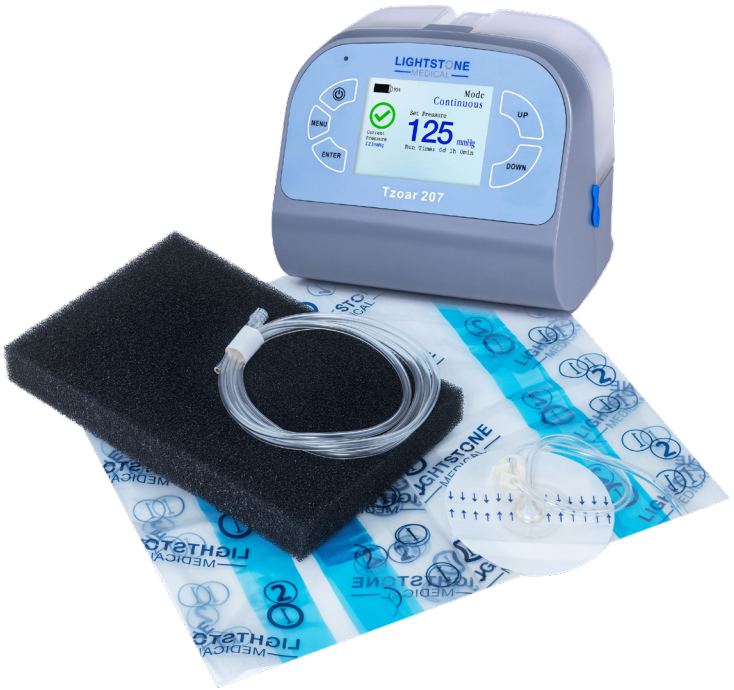
Introduction

The Tzoar 207 Negative Pressure Wound Therapy (NPWT) System is a multi-purpose negative pressure pump and dressing system.

The Tzoar 207 NPWT Pump is a portable, battery powered pump which may promote wound healing through the drainage and removal of wound exudates, infectious material, and tissue debris from the wound bed using continuous and/or intermittent negative pressure.

The Tzoar NPWT One Piece Dressing and the Tzoar NPWT Foam Kits are both Tzoar Wound Dressings intended to be used with an NPWT device to manage acute and chronic wounds. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, diabetic ulcers, neuropathic ulcers, pressure ulcers, flaps and grafts may benefit from this system.



The Tzoar 207 NPWT Pump and Tzoar Wound Dressings are able to produce a negative pressure environment in either

Continuous or Intermittent Mode.
This allows the user to program the specific pressure ranges.
In Continuous Mode, the pressure is ranged from 40mmHg to 200mmHg.

In Intermittent Mode,
the pump will alternate between the up pressure for 5 continuous minutes and down pressure for 2 minutes. The up pressure can be selected between 40 and 200mmHg while the down pressure can be selected between 20 and 120 mmHg.
The pressure is applied to the wound as long as the pump is powered on based on the previous settings. The factory default is 125 mmHg in Continuous Mode, unlocked.

The Tzoar 207 NPWT Pump is meant for continuous use (at least 22 of 24 hours per day).

The Tzoar 207 NPWT Pump will have an expected service life of 3 years.

Notice to Healthcare Providers

The Tzoar 207 Negative Pressure Wound Therapy (NPWT) System is prescription only. The Tzoar 207 Negative Pressure Wound Therapy (NPWT) System is intended for use on patients in physician-directed circumstances and settings by trained medical and healthcare personnel adhering to the instructions for use.

The Tzoar 207 Negative Pressure Wound Therapy (NPWT) System is intended for use under close supervision and may only be applied by persons who have been trained in its operation (physician / prescriber, healthcare professional or trained provider) according to the instruction guidelines issued by the supplier or medical staff.

Introduction

CAUTION!
Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

All operations such as pressure level adjustment, mode and all other settings / operations may only be performed by trained provider/personnel and by prescribed orders.

The Tzoar 207 Negative Pressure Wound Therapy (NPWT) System operation, including dressing application and removal, may only be applied by persons who have been trained, according to the instruction guidelines. It is the responsibility of the prescriber/ healthcare professional to determine if the patient may be trained to perform some limited functions i.e., charging the device battery.

The keypad and device menus should be locked by the healthcare professional to prevent the patient from changing the settings prescribed by the physician.

When deemed appropriate by the physician or prescriber, the responsible healthcare professional may train the patient to identify and respond emergency situations or issues and/or situations requiring intervention from the physician/prescriber and/or healthcare professional.

Symbol list

 Warning/Caution	 Manufacture Lot Number
 Single Use Only	 Class II Equipment
 Date of Manufacture	 Use by
 Type BF applied part	 Manufacturer
 Keep Dry	 Catalog/ Model Number
 Serial Number	 Sterilized Using Ethylene Oxide
 Power Button	 Waste Electrical
 Intertek registered certification mark Conforms to IEC 60601-1/AAMI ES 60601-1	
IP21 Ingress Protection - Protected against solid foreign objects of 12.5mm and greater and vertically falling water drops.	
 Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.	

Device Specifications

Dimensions	6.3″ length x 4.5″ Depth x 5.7″ Height (159mm x 115mm x 145mm)
Weight	1.8 lbs (0.816 kg)
Battery Type	Rechargeable Lithium Battery 18650, 11.1V, 2600mAh
AC/DC Adapter	Input:100~240V, 50/60Hz, 1.5A Output: DC 15V, 4A, 60W
Vacuum Modes	Continuous or Intermittent
Operating Conditions	Temperature: +5°C to 40°C (41°F to 104°F) Humidity: 15-85%
Pressure Options	Continuous: 40-200mmHg (+/-10mmHg) Intermittent: 40-200mmHg (up) (+/-10mmHg) 20-120mmHg (down) (+/-10mmHg)
Charging Time	3 Hours
Barometric Pressure	800hPa-1060hPa
Storage/Transportation Conditions	Temperature: -10°C to 45°C Humidity: < 93% non-condensing
Altitude Range	<2000m
Ingress Protection	6.3″ length x 4.5″ Depth x 5.7″ Height (159mm x 115mm x 145mm)
Protection Against Electrical Shock	Class II
Patient Protection	Type BF

Accessories

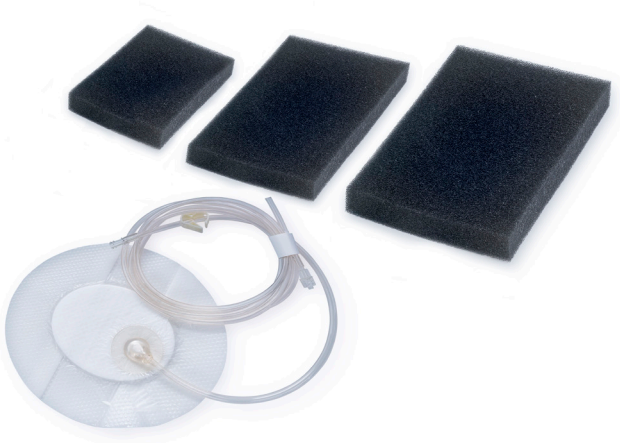
1.

AC/DC Adapter:
Please only use the AC/DC adapter provided.

2.

Canister:
Available in 400cc.

3.



Dressings:
Please reference Tzoar NPWT One Piece Dressings and Tzoar NPWT Foam Dressings User Manuals for a complete listing of all current dressing options.

Indications for Use

The Tzoar 207 Negative Pressure Wound Therapy (NPWT) System is indicated for wound management via the application of negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed.

The Tzoar 207 Negative Pressure Wound Therapy (NPWT) System is indicated for the following wound types:

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

Contraindications for Use

The Tzoar 207 NPWT System should NOT be used in the following conditions:

Exposed vessels, organs, or nerves.

Anastomotic sites.

Exposed arteries or veins in a wound.

Fistulas, unexplored or non-enteric.

Untreated osteomyelitis.

Malignancy in the wound.

Excess amount of necrotic tissue with eschar.

Caution should be taken when treating wounds that may contain hidden vessels which may not be readily apparent. The patient should be closely monitored for bleeding in a setting deemed appropriate by the treating physician. Inability to be followed by a medical professional or to keep scheduled appointments.

Allergy to urethane dressings and adhesives.

Use of topical products which must be applied more frequently than the dressing change schedule allows.

Warnings!

Review this manual prior to using the Tzoar 207 Negative Pressure Wound Therapy (NPWT) System. Do not attempt to operate the Tzoar 207 NPWT System without first reading and understanding the Instructions for Use, Device Operations, Warnings and Precautions. If clarification is needed, contact technical personnel, otherwise injury or damage may result.

If you are unable to understand the Instructions for Use, Device Operations, Warnings and Precautions, contact a healthcare professional, device provider or domestic distributor.

Do not use the Tzoar 207 NPWT Pump around explosive or flammable material.

Do not use the pump in an MRI environment or hyperbaric chamber. Disconnect prior to defibrillation.

This device should be used only under the direction of a trained professional, such as a doctor or nurse.

Larger canister sizes such as 400cc or larger should only be used in a facility where drainage can be closely monitored due to the increased risk of injury to the patient due to bleeding when using the 400cc canister. Precautionary measures should be taken for patients who have an increased risk of bleeding (Please see Precautions Section) when using larger canisters.

Negative Pressure Wound Therapy has not been cleared for use on children.

Only use the charger provided by the original manufacturer to charge the lithium battery. Incorrect voltage and/or current can cause fire.

Do not place this device at temperatures greater than 170°F (76°C) for more than 2 hours which may cause a battery fire.

If battery swells, gets hot, or smokes while charging, disconnect the charger immediately. This may cause the battery to leak, and the reaction with air may cause the chemicals to ignite, resulting in fire.

Only use the battery provided by the original manufacturer. Incorrect battery can explode or cause fire.

Battery may need to be replaced after 500 discharge cycles. When needed, contact the distributor for replacement.

Avoid heat from a fireplace or radiant heater or from sunlight.

Keep children away from the device.

Use the device in a clean environment; one that is free from dirt, dust, pets, hair, etc.

Position the device to ensure easy, unobstructed access to a power outlet.

** There is a risk of strangulation if one gets tangled in the cables or tubing.*

Keep away from babies and children.

Precautions

Be aware for any of the following conditions:

Never leave a Tzoar Wound Dressing in place on or in a wound without active Negative Pressure Wound Therapy for more than two hours.

There are additional conditions to take into account before using Tzoar 207 Negative Pressure Wound Therapy, such as:

A BLEEDING

There is a risk of bleeding/hemorrhaging with negative pressure wound therapy. Patients with weakened or friable blood vessels or infected vascular anastomosis, organs in or around the wound as a result of, but not limited to suturing of blood vessels, infection, trauma, and radiation may have an increased risk for bleeding. If hemostasis cannot be achieved, if the patient is on anticoagulants or platelet aggregation factors, does not have adequate tissue coverage over vascular structures, he or she may have an increased risk of bleeding; accordingly these patients should be treated in an inpatient care facility per their treating physician.

If active bleeding develops suddenly or large amounts of frank (bright red) blood is seen in the tubing or canister, immediately stop therapy, leave dressing in place, take measures to stop the bleeding, and seek immediate medical assistance. The Tzoar 207 NPWT System should not be used to prevent, minimize or stop vascular bleeding.

B VESSEL AND BONE PROTECTION

Precautionary measures should be taken if any bones, vessels, ligaments or tendons are exposed. Additionally, sharp edges (due to bone fragments) require special attention; these areas should be covered and smoothed wherever possible. These conditions should be factored into the therapy prescription as the attending clinician sees fit.

NOTE A thick layer of natural tissue is preferred. Several layers of fine meshed non-adherent material or bio-engineered tissue may be an alternative. Ensure that protective materials will maintain their position throughout therapy.

C ENVIRONMENT

Do not take the Tzoar 207 NPWT Pump into a hyperbaric oxygen chamber. Tzoar 207 NPWT Pumps are not designed for this environment and should be considered a fire hazard in such an environment. After disconnecting the Tzoar 207 NPWT Pump, either

- replace the Tzoar Wound Dressing with another HBO compatible material during the hyperbaric treatment, or
- cover the unclamped end of the Tzoar tubing. For HBO therapy, the Tzoar tubing must not be clamped.

D INFECTION

Wound infections that require frequent monitoring may require more frequent dressing changes. If there are any signs of the onset of systemic infection or advancing infection at the wound site, contact the treating prescriber immediately to determine if NPWT Pump should be discontinued.

Osteomyelitis: Tzoar 207 NPWT System should not be initiated on a wound with untreated osteomyelitis.

E PATIENT SIZE AND WEIGHT

Wounds heavily draining or large wounds in relation to the patient size and weight should be closely monitored, as they may have a risk of excessive fluid loss and dehydration. When monitoring fluid output, consider the volume of fluid in both the tubing and canister.

F SPINAL CORD INJURY

If a patient experiences autonomic dysreflexia (sudden changes in blood pressure or heart rate because of sympathetic nervous system stimulation), discontinue Tzoar 207 NPWT System therapy to minimize sensory stimulation and seek immediate medical assistance.

Precautions

G **MODE**

In unstable anatomical structures, Continuous rather than Intermittent therapy is recommended to help minimize movement and instability. Continuous therapy is also recommended in patients with an increased bleeding risk, profusely exudating wounds, fresh grafts and/or flaps, and wounds with acute enteric fistulae.

H **ENTERIC FISTULAS**

Wounds with enteric fistulas require special consideration to be effective in negative pressure wound therapy.
If enteric fistula effluent management or containment is the only goal of such therapy, the Tzoar 207 NPWT system is not recommended.

I **CIRCUMFERENTIAL DRESSING**

Do not use circumferential dressings.

J **BRADYCARDIA**

Avoid placement of the Tzoar NPWT Wound Dressings next to the vagus nerve to minimize the risk of bradycardia.

K **DEFIBRILLATION**

If defibrillation is required in the area of dressing placement, remove the dressing immediately, as failure to remove may inhibit transmission of electrical energy and/or patient resuscitation.

L **PERIWOUND SKIN**

Ensure that the skin that will be under the dressing is clean, dry, free of surfactants and oil. Any hair should be clipped.

- The periwound area should be cleaned and allowed to air dry. The use of a skin preparation wipe is also recommended.
- Do not allow wound filler to overlap wound borders onto intact skin.

- Periwound skin may be protected with hydrocolloid, silicone strips, transparent film, or other skin prep methods such as ostomy putty or paste. Transparent film may be used to protect periwound skin, however multiple layers of the transparent film dressing may decrease the moisture vapor transmission rate, which may increase the risk of maceration.

- To avoid trauma to the periwound skin, do not pull or stretch the transparent film over the wound filler dressing during film application.

- Monitor skin for any signs of irritation or irregularity. If this occurs, stop treatment and consult physician.

NOTE | If any of this information is not understood, contact the domestic distributor before using the device.

Device Features

Model# Tzoar 207

Clinical Safety Precautions

The Tzoar 207 Negative Pressure Wound Therapy (NPWT) System should be frequently monitored to ensure the pump is turned on and delivering Negative Pressure Wound Therapy. Ensure wound filler is not left in place without NPWT for more than 2 hours, if therapy is turned off. If the therapy is off for more than 2 hours, remove the wound dressing and consult the patient's prescriber for direction.

Foam Placement and Removal

Always ensure that only dressings from sterile, unopened dressing kits are used. Black Foam dressings should not be placed into tunnels or areas in the wound unable to be visualized. The prescriber may consider a non-adherent, non-occlusive alternate for those areas. Always count the total number of pieces of foam used in the wound and document on the patient chart. Always count the total number of pieces of foam removed from the wound and ensure the same number of foam pieces are removed as were placed.

Prior to Therapy

- Patient should be assessed, and measures should be taken to optimize and stabilize their medical condition. Nutrition, medication, blood glucose, blood pressure, and circulation as well as other medical issues should be addressed.

- The wound should be recently debrided by whatever measure is appropriate and the amount of necrotic tissue should be minimized.

- Issues of infection should be addressed.

  Clean and debride the wound as necessary. Any bleeding should be controlled. Follow facility protocol for wound prep and infection control. The type of Tzoar Wound Dressings chosen for use is dependent on the wound type, size, and location. Tzoar Wound Dressings size and type is labeled on each package.

- Care should be taken to avoid stretching of the dressing.
- Avoid pleating the Tzoar Wound Dressings. Additional tape and transparent film may be applied to secure the Tzoar Wound Dressing in place.
- Do not use as a circumferential dressing.
- Additional wrap dressing may be applied over the Tzoar Wound Dressings to further secure the Tzoar Wound Dressings and provide additional support.
- If used on anatomically challenging areas or where adhesion is a problem, a thin layer of ostomy paste or putty may be applied as an aid to create / maintain a seal.
- Refer to instructions for specific information regarding each Tzoar Wound Dressings.
- In a non-infected and monitored wound, dressings should be changed no less frequently than every 72 hours. Refer to instructions for specific information regarding Tzoar NPWT Wound Dressings removal.

Dressing Application

Tzoar Wound Dressings include Tzoar NPWT One Piece Dressings and Tzoar Foam Kits. Follow detailed instructions that come with your Tzoar Wound Dressing to apply the dressing.

The clinician may loosely place extra non-adherent, non-occlusive dressing material into areas of undermining and tunneling, at the order of the prescriber. The decision type for material used is based on clinician preference. Document the amount of additional packing material used.

Tzoar Wound Dressings should be changed as needed but may not stay in place longer than 72 hours.

- The initial Tzoar Wound Dressings should be changed in 24 - 48 hours or when leaking, whichever comes first. Tzoar Wound Dressings should not be left in place longer than 72 hours.

- If the Tzoar Wound Dressings sticks to the wound, moisten with saline or sterile water during removal. Adhesive remover may be used.

- Dispose of soiled Tzoar Wound Dressings according to facility protocol.

Avoid outside sources wetting the Tzoar Wound Dressings. The Tzoar Wound Dressings should be protected from moisture during bathing or changed prior to reconnecting to the pump. Do not use the Tzoar NPWT Pump while showering or bathing. Always disconnect and remove pump from areas of moisture (bathing area or tub). Clamp the tubing when pump is disconnected.

Canister Application

Tzoar 207 NPWT System offers a 400cc canister to collect wound exudates, infectious material, and tissue debris. To install a 400cc canister, remove the canister from the package, hold the canister at a 45-degree angle with the bottom clicking into the slot on the back of pump and gently slide in. Then clip the top of the canister to secure the installation. The clip should click into place and the canister should feel snug. Make sure it is installed properly without gaps.

To remove the canister, locate the canister clips on the top and bottom of the canister. Gently squeeze both the top clip and bottom clip at the same time to disengage the clips from the device. Pull the canister away from device. The canister will disengage and can easily be pulled away from the pump to remove.

Operating the Device

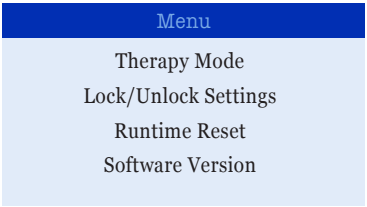
1. Power On/Off

Press and hold the button on the upper left of the screen for 3 seconds to turn on or to turn off the device.

When the device is turned on, the Screen will display the mode and the pressure of the previous setting and will begin providing Negative Pressure Wound Therapy.
The factory default is 125 mmHg in Continuous Mode, unlocked.

2. Navigating the MENU Screen

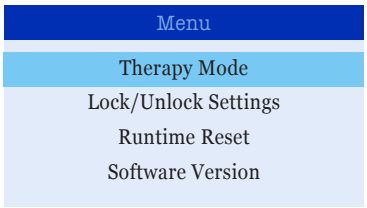
The pump has 3 setting options that can be adjusted by the user: **Therapy Mode, Lock/Unlock Settings and Runtime Reset.** These setting options are adjusted by accessing the MENU SCREEN. The Software Version is also displayed in the MENU SCREEN.



To access the MENU SCREEN – Press the "MENU" button on the left of the screen. The screen will show the MENU SCREEN with Therapy Mode, Lock/Unlock Settings, Runtime Reset and Software Version displayed.

Use the "UP" and "DOWN" button on the right of the screen to select a menu option. Once the desired menu option is highlighted, press the "ENTER" button on the left of the screen to select that option. To Leave menu, Press "MENU" button again.

3. Adjusting Settings Within the MENU Screen



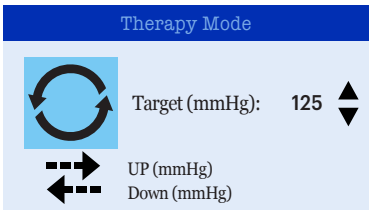
A. THERAPY MODE

Adjusting the pressure levels for Continuous and Intermittent Modes

Highlight **Therapy Mode** by pressing the "UP" or "DOWN" button then press "ENTER"

Continuous Mode

Changing the set pressure level for the Continuous Mode.



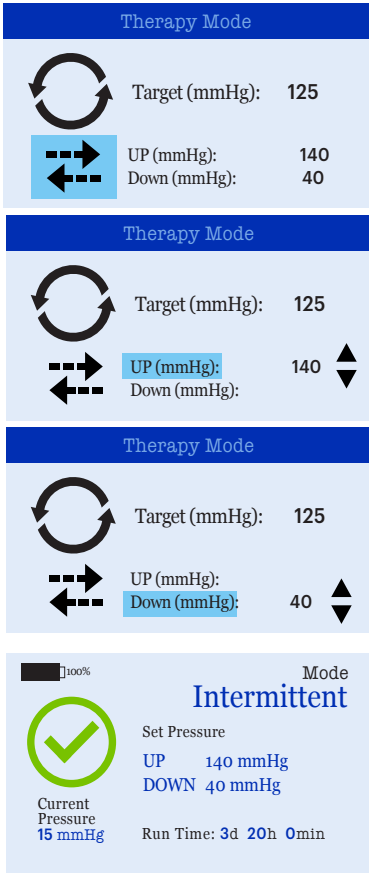
Select "**Continuous Mode**" by highlighting the circular solid arrows icon. Press "ENTER" to confirm. Then select the Target Pressure in mmHg and press the "UP" or "DOWN" buttons to increase or decrease the pressure level in 5 mmHg increments.

Once all desired pressure level settings have been entered, press the "Menu" button to return to the MENU SCREEN.

To return to the MAIN SCREEN press the "Menu" button again.

Intermittent Mode

Changing the set pressure levels for the Intermittent Mode.



Both the Up Pressure Level and the Down Pressure Level can be adjusted. The pump with cycle through the pressure levels with increments of 5 minutes on the Up Pressure Level and 2 minutes on the Down Pressure Level.

To adjust the Up and Down Pressure Levels: Press the "DOWN" button to highlight the dotted arrows Intermittent Icon then press the "ENTER" button.

The screen will then prompt the user to set the UP Pressure Level. Press the "UP" or "DOWN" buttons to select the desired pressure between 40 to 200mmHg in 5 mmHg increments. Press "Enter" to confirm, once the desired pressure is displayed.

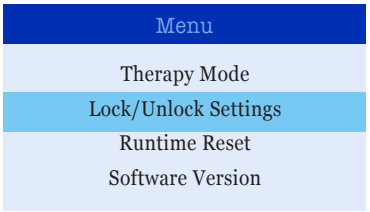
The Down Pressure Level may now be set pressing the "UP" or "DOWN" buttons to select the desired pressure between 20 to 120 mmHg in 5 mmHg increments. Press "ENTER" to confirm.

Once all desired pressure level settings have been entered, press the "Menu" button to return to the MENU SCREEN.

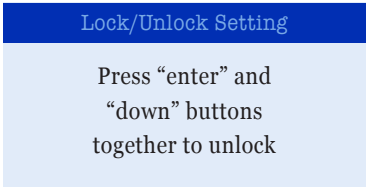
To return to the MAIN SCREEN press the "Menu" button again.

B. LOCK/UNLOCK SETTINGS

The default lock setting for the pump is "Unlocked". The healthcare professional may lock the pump to prevent adjustments to the settings prescribed by the physician.



To access the Lock/Unlock Settings: press the "MENU" button on the left of the screen. Press the "UP" or "DOWN" button to highlight "Lock/Unlock Settings" and press the "ENTER" button.



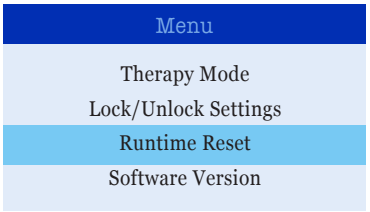
After "ENTER" is pressed to confirm, the Screen Lock message will display. Settings are now locked.

Press "MENU" to go back to the Main Screen. A lock icon will now display on the Main Screen.

NOTE:
To unlock, Press "Enter" and Down" button together to unlock anytime.

C. RUNTIME RESET

The pump is capable of logging the accumulated time NPWT has been actively running. This feature may assist a healthcare professional to ascertain the total time a patient has received Negative Pressure Wound Therapy. To utilize this feature, the healthcare professional may reset the runtime at the start of a patient's therapy and monitor for the duration of treatment.



To access the Runtime Reset option, press the "MENU" button and scroll up or down with the "Up" or "Down" buttons to highlight "Runtime Reset". Press "ENTER" to select.

Menu
Current Runtime
15d 10h 30m
Reset Run Time

Select “Reset Run Time” and press “ENTER” to confirm. Then the runtime on the Main Screen will return to zero.

Once the Runtime has been reset, press the “Menu” button to return to the MENU SCREEN.

To return to the MAIN SCREEN press the “Menu” button again.

D. SOFTWARE VERSION

Menu
Therapy Mode
Lock/Unlock Settings
Runtime Reset
Software Version

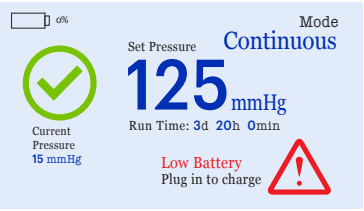
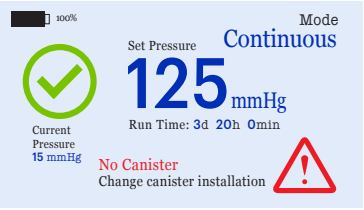
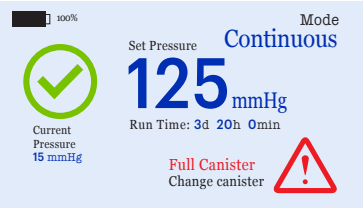
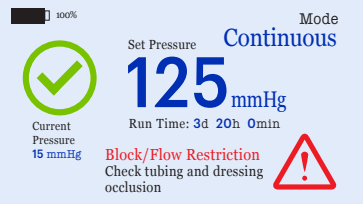
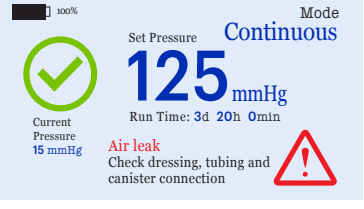
To view the current version of the software, select “Software Version” on the menu.

Software Version
LSM27REV.X.XX

And you will be prompted to see this screen.

Press “MENU” to go back to the main menu and press “MENU” again to go back to the main operating screen.

Alarms & Troubleshooting

Alarm Type	Cause/Description
	When the battery contains less than 10% power, this indicates that the system will shut off soon
	The canister is not detected or is installed incorrectly
	The canister is equipped with full sensors that will be triggered either when the canister is full of exudates, or a false fullness is caused by incorrect use of the system
	The tubing or the dressing clog or blockage
	Pump unable to reach 80% of the preset pressure after 2 minutes of pump effort

Audio Alarm Feature	Visual Alarm Feature	System Status	Suggested Mitigation
3 beeps every 20 seconds	Text on the screen and the yellow LED light flashing every 2 seconds	Pump remains Functioning until the battery depletes completely	Plug in Tzoar 207, allowing it to function and charge at the same time
3 beeps every 20 seconds	Text on the screen and the yellow LED light flashing every 2 seconds	Pump will not run	Properly install the canister
3 beeps every 20 seconds	Text on the screen and the yellow LED light flashing every 2 seconds	Pump will shut off immediately	Install a new canister
3 beeps every 20 seconds	Text on the screen and the yellow LED light flashing every 2 seconds	Pump remains on	Replace with new dressing and tubing set
3 beeps every 20 seconds	Text on the screen and the yellow LED light flashing every 2 seconds	Pump remains on	Check dressings, tubing and canister connection. If necessary, restart the system after adjustment

Maintenance & Replacement Parts

The Tzoar NPWT Device contains no user serviceable parts inside: Opening or tampering with this device will void the warranty. In the event the Tzoar NPWT Device requires repairs, it should be returned to the medical equipment company or to domestic distributors directly. No modification of the device is allowed.

Power adapter

The Tzoar NPWT Device should only be recharged using the AC/DC adapter provided or an equivalent IEC 60601-1 compliant adapter with a DC 15V 4A output.

Battery

Do not attempt to open, disassemble, or service the battery pack. Do not crush, puncture, short external contacts, or dispose of in fire or water. Use only a battery approved by the original manufacturer. If the device will not be in use for an extended period of time, the battery should be maintained by recharging regularly. Battery should be stored in a safe and dry place.

Cleaning

To clean the Tzoar 207 NPWT Device, use a medical grade cleanser (such as Envirocide) and follow the directions indicated by the cleanser. The device should not, for any reason, be immersed in water; additionally, liquid should not be allowed to breach the device's outer shell.

Disposal

The Tzoar 207 NPWT Pump is powered electromechanically by a battery that should be recycled according to the local regulations governing such products and Waste Electrical and Electronic Equipment (WEEE) Directive.

The Tzoar 207 Wound Dressings, tubing, and canisters can be disposed of according to policy for wound care dressings after use. Unplug the power adapter plug when the device is not in use.

Warranty Information

LIMITED WARRANTY

Lightstone Medical warrants its Tzoar 207 Negative Pressure Wound Therapy (NPWT) Pump ("Device") to be free from defects in workmanship and materials for a period of two (2) year from the date the Device is delivered to the original purchaser ("Warranty Period"). This Limited Warranty is extended only to the original purchaser and is non-transferable. Lightstone Medical's sole obligation under this Limited Warranty shall be, at its sole discretion, to repair or replace a Device which is defective in either workmanship or material. This is the sole remedy of the Purchaser. This Limited Warranty excludes the battery, canister, canister clip, power plug, connection tubing, and dressings. In addition, this Limited Warranty does not cover any Device which may have been damaged in transit or has been subject to misuse, neglect, or accident; or has been used in violation of Lightstone Medical's instructions, including, without limitation, the instructions contained in the Operation Manual.

THERE ARE NO OTHER WARRANTIES THAN THOSE EXPRESSLY STATED HEREIN. TO THE EXTENT PERMITTED BY LAW, LIGHTSTONE MEDICAL DOES NOT MAKE ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AS TO ANY PRODUCT OR DEVICE, WHETHER OR NOT THAT PRODUCT OR DEVICE IS COVERED BY ANY EXPRESS WARRANTY CONTAINED HEREIN.

IN NO EVENT SHALL LIGHTSTONE MEDICAL BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS, USE OR TIME INCURRED BY PURCHASER OR END USER). IN ADDITION, LIGHTSTONE MEDICAL SHALL NOT BE LIABLE FOR ANY EXEMPLARY OR PUNITIVE DAMAGES.

Contact Information

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Appendix I

Product Classification:

- According to the type of protection against electrical shock, this device is classified as a Class II Equipment, and Type BF Equipment that is powered by an external electrical power source.

- According to the degree of protection against harmful ingress of water this system is classified as Ordinary Equipment (IP21: Protected against solid foreign objects of 12.5 mm and greater and vertically falling water drops.)

  CAUTION:
  This device has been tested and confirmed to comply with the IEC 60601-1-2:2014. However, with the proliferation of radio-frequency transmitting equipment, and other sources of electrical noise in a healthcare environment, high levels of interference may induce an abnormal stoppage or other disruption of this device. This device may also cause adverse effects in other nearby equipment. It is strongly recommended that this device be isolated from other electromagnetic equipment when in use.

- This system is classified as Equipment not Suitable for use in the presence of a Flammable Anesthetic Mixture with Air or Oxygen or Nitrous Oxide.

- According to the mode of operation this system is classified as Equipment that can be used for Continuous Operation.

  CAUTION:
  In the USA, Federal Law restricts this device to sale, by or on the order of a physician.

- For reusable medical devices (such as the pump), the shelf life is the same as the warranty. For disposable medical devices (such as the dressings and canisters), the shelf life expires at their respective expiration dates, which can be found on the package labeling.

- Unit is packaged for transportation by common carrier.

Appendix II

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

This Model Tzoar 207 NPWT Device is intended for use in the electromagnetic environment specified below. The customer or the user of the Model Tzoar 207 NPWT Device should assure that it is used in such an environment.

Emissions	Compliances	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The Model Tzoar 207 NPWT Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The Model Tzoar 207 NPWT Device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Appendix III

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Model Tzoar 207 NPWT Device is intended for use in the electromagnetic environment specified below. The customer or the user of the Model Tzoar 207 NPWT Device should assure that it is used in such an environment.

The essential performance of the Tzoar 207 NPWT System is to produce a negative pressure environment in the pre-programmed specific pressure ranges. The absence of this essential performance would result in an unacceptable risk. Therefore, the testing for this essential performance is to ensure that the alarms would trigger when the system cannot create the vacuum. Situations include air leakage, blockage, canister full, no canister and low battery power. The equipment is compliance for each IMMUNITY test specified by the standard, e.g. IMMUNITY test level.

When the worst case occurs in the use of the equipment, the equipment can still ensure safety and effectiveness in electromagnetic events according to the IEC60601-1-2 standard.

NOTE | UT is the AC. mains voltage prior to application of the test level.

Immunity test	IEC 60601-1-2 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 KV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 KV air
Radiated RF EM fields IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See Table 3	See Table 3
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetitio frequency	±2 kV 100 kHz repetitio frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line-to-line; ± 2 kV line(s) to earth	±0.5 kV, ±1 kV line-to-line; ± 2 kV line(s) to earth
Conducted disturbances induced by RF fields IEC 61000-4-6	3V 0.15MHz-80MHz 6V in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz	3V 0.15MHz-80MHz 6V in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz
Power frequency magnetic field immunity IEC 61000-4-8	30A/m,50/60Hz	30A/m,50/60Hz
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT: 0.5 cycle a) At 0o, 45o, 90o, 135o, 180o, 225o, 270o, and 315o.	0% UT: 0.5 cycle a) At 0o, 45o, 90o, 135o, 180o, 225o, 270o, and 315o.
	0% UT: 1 cycle 70% UT: 25/30 cycles Single phase: at 0o	0% UT: 1 cycle 70% UT: 25/30 cycles Single phase: at 0o
	0% UT: 250/300 cycles	0% UT: 250/300 cycles

Test frequency	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ±5kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation [b] 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation [b] 217Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217Hz	2	0.3	28

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Model# Tzoar 207

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