

Contents

Overview.....	4
Chapter 1- General Information	5
1.1 Intended Use.....	5
1.2 Device Description	5
1.3 Materials.....	6
1.4 How Supplied	6
1.5 Indications	7
1.6 Contraindications.....	7
1.7 General Warnings, Precautions and Cautions	7
1.8 Applications.....	8
1.9 Shelf Life	10
1.10 Available Product Sizes, Ref Number and Drawing	10
1.11 Packing and Labelling.....	20
1.12 Storage.....	20
1.13 Return	21
1.14 Disposal.....	21
1.15 Inspection and Handling	21
1.16 Cleaning Inspection	21
1.17 Wrapping	22
1.18 Operation, Storage and Transport.....	22
Chapter 2- Illustrations.....	23
Chapter 3 - Operative System	24
3.1 System Start Up	24
3.2 Menu Controls	25
3.3 Pump	27
3.3.1 Pump Assembly.....	27
Chapter 4 – Troubleshooting.....	28
4.1 General Troubleshooting	28
Chapter 5 - Cleaning, Disinfection, Preventive Maintenance	28
5.1 Electrical Safety Check	28
5.2 Cleaning and Disinfection Instructions	29
5.2.1 Clean and Disinfect/Sterilize Reusable Items	29
5.2.2 Touchscreen Cleaning	29
5.2.3 Technical Assistance.....	29

5.2.4 Maintenance	29
Chapter 6- Service, Repair and Technical Correspondence	30
6.1 Repair, Service and Replacement Parts.....	30
6.2 Pump Head Replacement.....	30
6.3 Important Notice.....	31
Chapter 7- Appendices.....	32
7.1 Rear Label of the Pump.....	32
7.2 Markings on the Front and Rear Panel of the Generator	32
7.3 Symbols for the Product Labels.....	33
7.4 Technical Specification	34
7.5 EMC Statement.....	35
7.6 Electromagnetic Interference	35
7.6.1 TABLE I	35
7.6.2 TABLE II.....	35
7.6.3 TABLE III	37
7.7 Electrical Safety Statements	38
7.8 Environmental Statements.....	38
7.9 General Safety Statements	38
7.10 Conventions Warning and Cautions.....	38
7.11 Disclaimer	39
7.13 Trademark Information	40
Limited Warranty	41
Limited Liability	41

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Overview

Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences. This manual contains important information for operation of the Minus™ Negative Pressure Wound Therapy System.

It should be kept where it may be referenced during usage, especially for screen translations.

Print or copy pages as necessary to keep nearby.

Important: This manual is designed to provide instructions for use of the Minus™ Negative Pressure Wound Therapy System. It is not a reference to surgical techniques.

CAUTION:

This Operator Manual of the Minus™ Negative Pressure Wound Therapy System is not a guarantee or warranty. It is intended only as an operational guide. For additional information and questions, please contact Maverá Medical Devices representative at +90 312 341 50 27 and info@maveramedical.com.tr.

In order for the Minus™ Negative Pressure Wound Therapy System to provide safe, reliable, and proper performance, the following conditions must be met. Failure to comply with these conditions will void all pertinent warranties.

There are no user serviceable components at Maverá Medical Devices. All assembly, operation, adjustment, modification, maintenance, and/or repair must be carried out only by qualified personnel authorized by Maverá Medical Devices.

The electrical installation of the room in which the device will be used complies with the appropriate national electrical standards.

The product must be used in accordance with this manual and all associated labeling and the Instructions for Use.

Any device that does not function as expected must be returned to Maverá Medical Devices.

Notice to Users:

CAUTION: As with any prescription medical device, failure to follow product instructions or changing settings and performing therapy applications without the express direction and/or supervision of a trained clinical caregiver may lead to improper product performance and the potential for serious or fatal injury.

Conventions on Warnings and Cautions

WARNING Denotes potentially dangerous situation that could result in death or serious injury to patient, operator or staff.

CAUTION Denotes potentially dangerous situation that could result in moderate injury to patient, operator or staff.

Chapter 1- General Information

1.1 Intended Use

Minus™ Negative pressure wound therapy system is intended for acute and chronic wounds that have been resistant to other forms of wound care, and for minimizing scarring on acute wounds by promoting healing through granulation tissue formation and re-epithelialization. Therefore, it may be used as either a primary or secondary line of treatment, depending on the type of wounds.

The Minus™ Negative Pressure Wound Therapy System addresses to adult patients of both sexes, ages from 18 and older. No clinical study presented and consulted for pediatric patients, pregnant women and disabled persons, within the scope of this report. These products are not directly intended to be used in pediatric cases, pregnant women and disabled persons.

1.2 Device Description

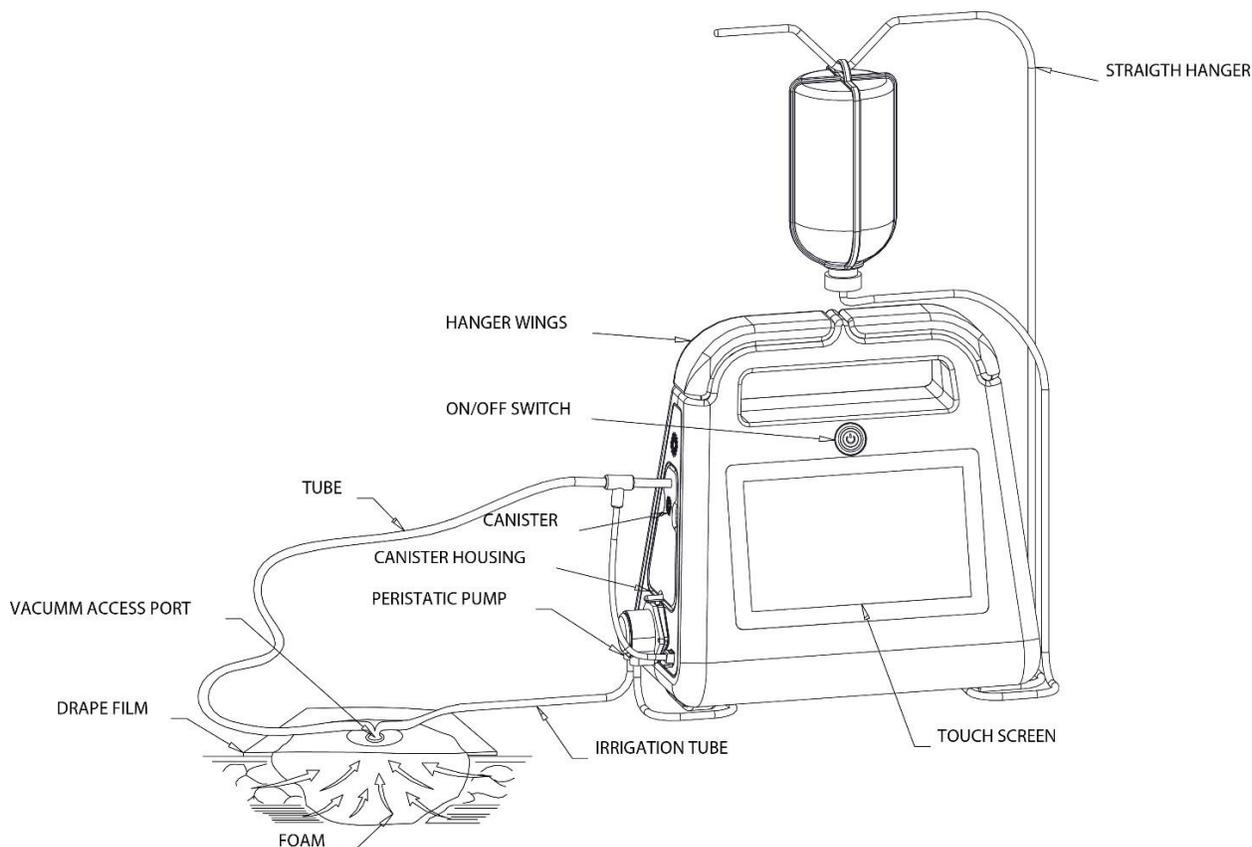
The NPWT consists of an open-pore polyurethane ether foam sponge, an adhesive cover, fluid collection system, and suction pump that generate negative pressure. Direct application of sponge to blood vessels, bone, nerves or intact skin is avoided. A vacuum source is used to create sub-atmospheric pressure in the local wound environment to promote healing. This is achieved by connecting a vacuum pump to a tube that is threaded into wound gauze or foam filler dressing covered with a drape. This concept in wound treatment has been shown to be useful in treating different wound infections, including diabetic wounds as well as complex infections of the abdomen and thorax. NPWT has been used in the world for over two decades and its use is steadily increasing.

There is the main device, which holds the features of all variants, and 3 different variants of the main device in the negative pressure wound therapy system. The main difference between the variants is the condition of the O2 transmission. The main device has the features of concentrated O2 delivery, vacuum, and irrigation. The variants of that device change in terms of these features. 571 Pump does only vacuum on the wounded area, whereas HMI Major Pump has also the irrigation feature besides vacuum. 646 Pump is a single use version of the device which has only vacuum feature.

Features Devices	Vacuum	Irrigation	Concentrated O2
Gamechanger	X	X	X
HMI Major	X	X	
571	X		
646	X		

NPWT systems include a vacuum pump, drainage tubing, and a dressing set. The pump may be stationary or portable, rely on AC or battery power, allows for regulation of the suction strength, has alarms to indicate loss of suction, and has a replaceable collection canister. The dressing sets may contain either foam or gauze

dressings to be placed in the wound and an adhesive film drape for sealing the wound. The drainage tubes come in a variety of configurations depending on the dressings used or wound being treated.



1.3 Materials

Patient Contact Materials	
Foam, Dressing	Medical Grade Polyurethane Foam
Film Drape	Medical Grade Polyurethane Film
Non-Tissue Contact Materials	
Pump Case	Acrylonitrile Butadiene Styrene Plastic Frame
Canister	Acrylonitrile Butadiene Styrene Plastic
Connectors	Acrylonitrile Butadiene Styrene Plastic
Vacuum Access Port	Medical Grade Polyurethane and/or PVC Medical Grade
Tubing	Medical Grade Polyurethane and/or PVC Medical Grade

1.4 How Supplied

Product not made with natural rubber latex. 2.2.2; 2.7.3 Be latekso

It is a disposable, single-patient-use product. The Minus™ Negative Pressure Wound Therapy System is provided. STERILE using an ethylene oxide (EO) process.

1.5 Indications

MINUS™ Negative Pressure Wound Therapy System is a non-pharmacological method for the patients who would benefit from a suction device. It is intended to use to physically promote wound healing by means of removal of fluids, including irrigation, and body fluids wound exudates and infectious materials. The patients with the following wounds are indicated: Acute Wounds, Chronic Wounds Pressure Ulcers, Diabetic Foot Ulcers, Venous Leg ulcers, Traumatic wounds, Dehisced wounds, Partial thickness burns, Flaps, and grafts. No Studies are done on the use of Minus™ NPWT System on pregnant and pediatric patients. To use the device on such patients is at surgeons' own disposal. Patient size and age should be considered when prescribing the device.

The Minus™ Negative Pressure Wound Therapy System is intended for use in acute and chronic wounds at continual, intermittent and variable mode of settings.

1.6 Contraindications

- The Minus™ Negative Pressure Wound Therapy System contraindicated for the following situations;
- The Minus™ Negative Pressure Wound Therapy System is contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistulas, or necrotic tissue with eschar present.
- Do not place the MINUS™ NPWT Dressing over exposed blood vessels or organs.
- MINUS™ NPWT Dressings are also contraindicated for hydrogen peroxide and solutions which are alcohol based or which contain alcohol.

1.7 General Warnings, Precautions and Cautions

Patients on anticoagulation medicine or who have active bleeding or who have difficult wound homeostasis.

Due to the risk of puncturing organs or blood vessels while under negative pressure, sharp edges or bone fragments in a wound must be covered or removed prior to use.

Do not use defibrillation with Minus™ system simultaneously

The Pump is not MRI or CT compatible and do not bring the system in the sphere of scanner or MRI suite.

Universal precautions should be taken and observed when operating, transporting, repairing or disposing, universal precaution should be observed whenever working with potentially contaminated parts or equipment

Precautions should be taken for patients who are or may be receiving anticoagulant therapy or platelet aggregation inhibitors, actively bleeding or have weakened blood vessels or organs, suffering from difficult wound homeostasis, untreated for malnutrition, noncompliant or combative, suffering from wounds in close proximity to blood vessels or delicate fascia.

This device should only be used by qualified and authorized personnel. The user must have the necessary specialist knowledge of the specific medical application for which Minus Negative pressure wound therapy System is being used.

If the device has been at temperatures below freezing, the device must be brought to room temperature prior to use or the pumping unit may be damaged.

Ensure the tubing is installed completely and without any kinks to avoid leaks or blockages in the vacuum circuit.

Position the device and tubing appropriately to avoid the risk of causing a trip hazard and so the patient does not lie on the tubing.

When bathing/showering, the patient must be disconnected from the device.

If any liquids penetrate the pump, discontinue use and return to your authorized provider for service. Check the overflow protection/bacteria filter and replace as necessary.

Bone and tendons must be covered by the non-adherent dressing layer.

Inspect the dressing site as appropriate based on therapeutic need.

The use of negative pressure presents a risk of tissue ingrowth into the foam/gauze.

Tissue ingrowth may be reduced by lowering therapy pressure, using a wound contact layer or by increasing the frequency of dressing changes.

Minus is only to be used with Maveria authorized components.

Prior to use, instructions for use should be read thoroughly.

Use only physician order.

Dispose used dressings according to local guidelines.

Therapy should remain ON for the duration of the treatment. A dressing should not be left in place without active negative pressure wound therapy.

Patients on anticoagulation medicine or who have active bleeding or who have difficult wound homeostasis.

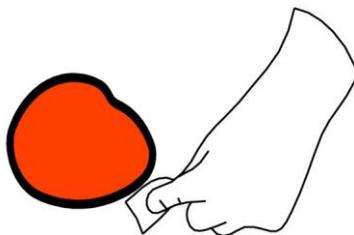
Due to the risk of puncturing organs or blood vessels while under negative pressure, sharp edges or bone fragments in a wound must be covered or removed prior to use.

1.8 Applications

This device must only be used by surgeons who are - trained in the types of surgical procedures that are to be carried out and - trained in the specific use of ultrasonic surgical instruments.

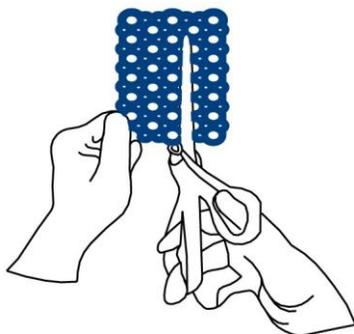
Application

1



- Prepare the wound according to local clinical practice.
- Select an appropriate dressing size for the wound. Ensure that the surrounding skin is clean and dry.
- Cleanse and Pat Dry

2



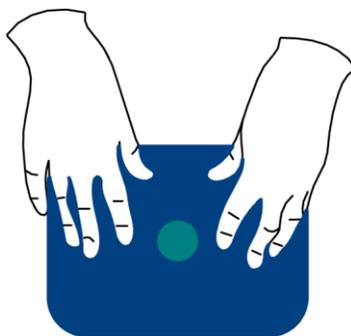
- Remove the dressing from the pouch using aseptic technique.
- If cutting the dressing, discard any open and unused dressing.

3



- Moisten the dressing with sterile saline if preferred.

4



- Loosely place the foam and ensure that the dressing is in direct contact with the wound surface. If more than one piece of dressing is used, check that all pieces are in direct contact with each other to ensure an even distribution of negative pressure. Count the pieces of dressing used and record the total in the patient's records.
- Ensure that the wound foam has no direct contact with intact skin.

5



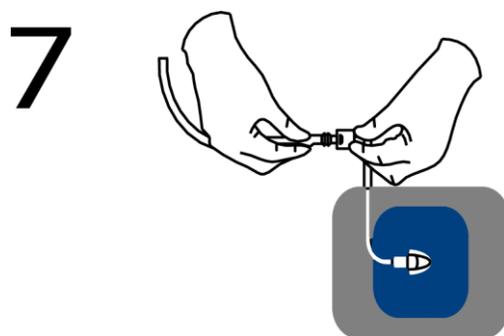
- Cut the drape at the appropriate size overlapping 3-5mm onto the skin.
- Drill or open a gap around 1cm diameter.
- Cover the foam with the drape and assure it is airtight. If not use extra film to provide airtightness.

6



- Seal the port onto the drape centering the predrilled hole and make sure the port entry is centralized.

- Connect the suction port tubing to canister.



- Turn on the device and start the negative pressure.
- Attention is required to observe the foam is shaped into a firm structure under pressure and the film is airtight.
- Proceed as directed for the NPWT system used.
- The pressure level should be set according to the physician's instruction and be based on indication and wound condition.

1.9 Shelf Life

- The expiration date is printed on the package.
- Do not use products if their shelf life is exceeded.
- To keep the kits sterile, store the product in its original packaging.

1.10 Available Product Sizes, Ref Number and Drawing

Brand	Definition	Feature	Reference	
Minus™ Negative Pressure Wound Therapy System	NPWT PUMP HMI	N/A		
	GameChanger (Non-Sterile, Reusable)		MNSGMCHMI	
	NPWT PUMP HMI MAJOR (Non-Sterile, Reusable)	N/A	MNSHMIMJR	
	NPWT PUMP 571 (Non-Sterile, Reusable)	N/A	MNS571	
	NPWT PUMP 646 (Non-Sterile, Reusable)	N/A	MNS646	
	NPWT PUMP ADAPTOR (Non-Sterile, Reusable)	N/A	MNSADPT	
	NPWT PUMP SERUM HANGER (Non-Sterile, Reusable)	N/A	MNSHNG	
	NPWT PUMP CARRYING BAG (Non-Sterile, Reusable)	N/A	MNSCBG	
	NPWT CLOSURE SET O2 DELIVERY EXTRA SMALL (Sterile – Single Use)	O2 DELIVERY		MNS02CSDEXS
	NPWT CLOSURE SET O2 DELIVERY SMALL (Sterile – Single Use)	O2 DELIVERY		MNS02CSDES

2.1.9 Komplektuojama su paciento nešiojimo krepšiu, suderinamu su įrenginiu

NPWT CLOSURE SET O2 DELIVERY MEDIUM (Sterile – Single Use)	O2 DELIVERY	MNSO2CSDEM
NPWT CLOSURE SET O2 DELIVERY LARGE (Sterile – Single Use)	O2 DELIVERY	MNSO2CSDEL
NPWT CLOSURE SET O2 DELIVERY EXTRA LARGE (Sterile – Single Use)	O2 DELIVERY	MNSO2CSDEXL
NPWT CLOSURE SET O2 DELIVERY ABDOMINAL (Sterile – Single Use)	O2 DELIVERY	MNSO2CSDEA
NPWT CLOSURE SET HAND (Sterile – Single Use)	O2 DELIVERY	MNSO2CSDEH
NPWT CLOSURE SET O2 DELIVERY FOOT (Sterile – Single Use)	O2 DELIVERY	MNSO2CSDEF
NPWT CLOSURE SET O2 DELIVERY BRIDGE (Sterile – Single Use)	O2 DELIVERY	MNSO2CSDEB
NPWT CLOSURE SET EXTRA SMALL (Sterile – Single Use)	IRRIGATION	MNSXSI
NPWT CLOSURE SET SMALL (Sterile – Single Use)	IRRIGATION	MNSSI
NPWT CLOSURE SET MEDIUM (Sterile – Single Use)	IRRIGATION	MNSMI
NPWT CLOSURE SET LARGE (Sterile – Single Use)	IRRIGATION	MNSLI
NPWT CLOSURE SET EXTRA LARGE (Sterile – Single Use)	IRRIGATION	MNSXLI
NPWT CLOSURE SET ABDOMINAL (Sterile – Single Use)	IRRIGATION	MNSAI
NPWT CLOSURE SET HAND (Sterile – Single Use)	IRRIGATION	MNSHI
NPWT CLOSURE SET FOOT (Sterile – Single Use)	IRRIGATION	MNSFI
NPWT CLOSURE SET BRIDGE (Sterile – Single Use)	IRRIGATION	MNSBI
NPWT INCISION DRESSING SET LARGE (Sterile – Single Use)	N/A	MNSLID
NPWT INCISION DRESSING SET MEDIUM (Sterile – Single Use)	N/A	MNSMID
NPWT INCISION DRESSING SET SMALL (Sterile – Single Use)	N/A	MNSSID
NPWT ZIPPER DRESSING SET LARGE (Sterile – Single Use)	N/A	MNSSZD
NPWT ZIPPER DRESSING SET MEDIUM (Sterile – Single Use)	N/A	MNSMZD

NPWT ZIPPER DRESSING SET SMALL (Sterile – Single Use)	N/A	MNSLZD
NPWT MCT DRESSING SET LARGE (Sterile – Single Use)	N/A	MNSSMD
NPWT MCT DRESSING SET MEDIUM (Sterile – Single Use)	N/A	MNSMMD
NPWT MCT DRESSING SET SMALL (Sterile – Single Use)	N/A	MNSLMD
NPWT UNIBODY DRESSING SET XSMALL (Sterile – Single Use)	N/A	MNSXSUD
NPWT UNIBODY DRESSING SET SMALL (Sterile – Single Use)	N/A	MNSSUD
NPWT UNIBODY DRESSING SET MEDIUM (Sterile – Single Use)	N/A	MNSMUD
NPWT UNIBODY DRESSING SET LARGE (Sterile – Single Use)	N/A	MNSLUD
NPWT UNIBODY DRESSING SET XLARGE (Sterile – Single Use)	N/A	MNSXLUD
NPWT UNIBODY DRESSING SET SACRUM (Sterile – Single Use)	N/A	MNSDS
NPWT UNIBODY DRESSING SET KNEE (Sterile – Single Use)	N/A	MNSDK
NPWT UNIBODY DRESSING SET CORNER (Sterile – Single Use)	N/A	MNSDC
NPWT UNIBODY DRESSING SET FOOT (Sterile – Single Use)	N/A	MNSDF
NPWT DRESSING SET BRIDGE (Sterile – Single Use)	N/A	MNSDB
NPWT CLOSURE SET EXTRA SMALL (Sterile – Single Use)	STANDARD	MNSXS
NPWT CLOSURE SET SMALL (Sterile – Single Use)	STANDARD	MNSS
NPWT CLOSURE SET MEDIUM (Sterile – Single Use)	STANDARD	MNSM
NPWT CLOSURE SET LARGE (Sterile – Single Use)	STANDARD	MNSL
NPWT CLOSURE SET EXTRA LARGE (Sterile – Single Use)	STANDARD	MNSXL
NPWT CLOSURE SET ABDOMINAL (Sterile – Single Use)	STANDARD	MNSA
NPWT CLOSURE SET HAND (Sterile – Single Use)	STANDARD	MNSH

2.2 Tvarsčių rinkinys S dydžio

2.3 Tvarsčių rinkinys M dydžio

2.4 Tvarsčių rinkinys L dydžio

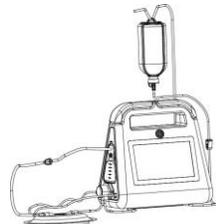
NPWT CLOSURE SET FOOT (Sterile – Single Use)	STANDARD	MNSF
NPWT CLOSURE SET BRIDGE (Sterile – Single Use)	STANDARD	MNSB
NPWT CLOSURE SET EXTRA SMALL (Sterile 70*50*20 mm)	SLIM	MNSXSS
NPWT CLOSURE SET SMALL (Sterile 70*100*20 mm)	SLIM	MNSSS
NPWT CLOSURE SET MEDIUM (Sterile 120*180*20 mm)	SLIM	MNSMS
NPWT CLOSURE SET LARGE (Sterile 150*180*20 mm)	SLIM	MNSLS
NPWT CLOSURE SET EXTRA LARGE (Sterile 250*400*20 mm)	SLIM	MNSXLS
NPWT CLOSURE SET ABDOMINAL (Sterile – Single Use)	SLIM	MNSAS
NPWT CLOSURE SET HAND (Sterile – Single Use)	SLIM	MNSHS
NPWT CLOSURE SET FOOT (Sterile – Single Use)	SLIM	MNSSF
NPWT CLOSURE SET BRIDGE (Sterile – Single Use)	SLIM	MNSBS
NPWT FOAM STANDARD EXTRA SMALL (Sterile – Single Use)	N/A	MNSFXS
NPWT FOAM STANDARD SMALL (Sterile – Single Use)	N/A	MNSFS
NPWT FOAM STANDARD MEDIUM (Sterile – Single Use)	N/A	MNSFM
NPWT FOAM STANDARD LARGE (Sterile – Single Use)	N/A	MNSFL
NPWT FOAM STANDARD EXTRA LARGE (Sterile – Single Use)	N/A	MNSFXL
NPWT FOAM STANDARD ABDOMINAL (Sterile – Single Use)	N/A	MNSFA
NPWT FOAM STANDARD HAND (Sterile – Single Use)	N/A	MNSFH
NPWT FOAM STANDARD FOOT (Sterile – Single Use)	N/A	MNSFF
NPWT FOAM STANDARD BRIDGE (Sterile – Single Use)	N/A	MNSFB
NPWT FOAM SLIM EXTRA SMALL (Sterile – Single Use)	N/A	MNSSFXS
NPWT FOAM SLIM SMALL (Sterile – Single Use)	N/A	MNSSFS
NPWT FOAM SLIM MEDIUM (Sterile – Single Use)	N/A	MNSSFM
NPWT FOAM SLIM LARGE (Sterile – Single Use)	N/A	MNSSFL

	NPWT FOAM SLIM EXTRA LARGE (Sterile – Single Use)	N/A	MNSSFXL
	NPWT FOAM SLIM ABDOMINAL (Sterile – Single Use)	N/A	MNSSFA
	NPWT FOAM SLIM HAND (Sterile – Single Use)	N/A	MNSSFH
	NPWT FOAM SLIM FOOT (Sterile – Single Use)	N/A	MNSSFF
	NPWT FOAM SLIM BRIDGE (Sterile – Single Use)	N/A	MNSSFB
	NPWT FILM DRAPE STANDARD	N/A	MNSFDS
2.7 Plėvelė 2.7.4 Išmatavimai 36cm x 36cm	NPWT FILM DRAPE LARGE (Sterile 360*360 mm)	N/A	MNSFDL
	NPWT IRRIGATION TUBING N/A (Sterile – Single Use)	IRRIGATION	MNSTI
2.5 Drenas 2.5.1 Supakuotas po vieną atskiroje pakuotėje	NPWT VACUUM ACCESS PORT™ STANDARD (Sterile – Single Use)	STANDARD	MNSVAPS
	NPWT VACUUM ACCESS PORT™ IRRIGATION (Sterile – Single Use)	IRRIGATION	MNSVAPIR
	NPWT VACUUM ACCESS PORT™ O2 DELIVERY (Sterile – Single Use)	O2 DELIVERY	MNSVAP02DE
	NPWT VACUUM TUBING N/A (Sterile – Single Use)	N/A	MNSVT
	NPWT O2 DELIVERY TUBING N/A (Sterile – Single Use)	O2 DELIVERY	MNS02DET
	NPWT PERILSTATIC PUMP TUBING N/A (Sterile – Single Use)	N/A	MNSPPT
2.6 Konektorius 2.6.1 Y formos sujungimo priemonė	NPWT Y CONNECTOR TUBING N/A (Sterile – Single Use)	N/A	MNSYT
	NPWT EXTRA LONG TUBING N/A (Sterile – Single Use)	N/A	MNSXTRLT
	NPWT CONNECTOR N/A (Sterile – Single Use)	N/A	MNSCON
	NPWT Y CONNECTOR N/A (Sterile – Single Use)	N/A	MNSYCON
	NPWT MULTI LUMEN CONNECTOR (Sterile – Single Use)	N/A	MNSMLCON
	NPWT CONNECTOR STANDARD (Sterile – Single Use)	N/A	MNSCONS
	NPWT SERUM TUBING (Sterile – Single Use)	N/A	MNSST
	NPWT COLLECTION SET 250ML (Non-Sterile)	N/A	MNS250
	NPWT COLLECTION SET 500ML (Non-Sterile)	N/A	MNS500

2.8,4 Talpos dydis 600ml

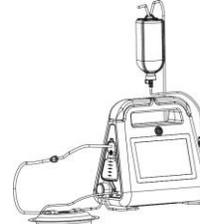
NPWT COLLECTION SET 600ML (Non-Sterile)	N/A	MNS600
NPWT COLLECTION SET 1000ML (Non-Sterile)	N/A	MNS1K
NPWT CANISTER 250ML N/A (Non-Sterile)	N/A	MNSCNS25
NPWT CANISTER 500ML N/A (Non-Sterile)	N/A	MNSCNS50
NPWT CANISTER 600ML N/A (Non-Sterile)	N/A	MNSCNS60
NPWT CANISTER 1000ML N/A (Non-Sterile)	N/A	MNSCNS1K
NPWT FILTER CARTRIDGE FOR HMI GAMECHANGER PUMP (Non-Sterile, Reusable)	N/A	MNSFLTRGMC
NPWT FILTER CARTRIDGE FOR HMI MAJOR PUMP (Non-Sterile, Reusable)	N/A	MNSFLTRMJR
NPWT FILTER CARTRIDGE FOR 571 PUMP (Non- Sterile, Reusable)	N/A	MNSFLTR571

NPWT PUMP HMI GameChanger



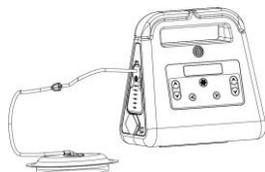
NPWT PUMP 571

NPWT PUMP HMI MAJOR

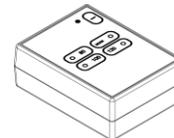


NPWT PUMP 646

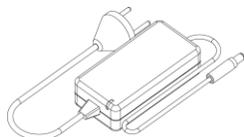
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NPWT PUMP ADAPTOR



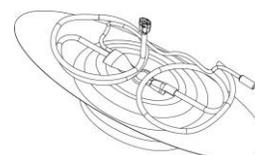
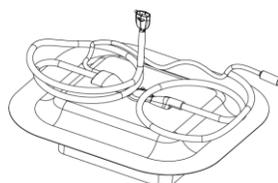
NPWT PUMP SERUM HANGER



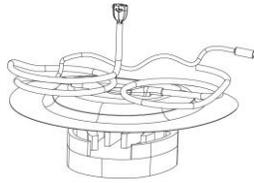
NPWT CLOSURE SET O2 Delivery XS/S/M/L/XL



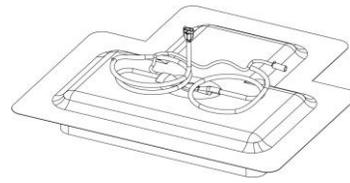
NPWT CLOSURE SET O2 Delivery ABDOMINAL



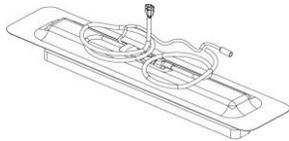
NPWT CLOSURE SET O2 Delivery HAND



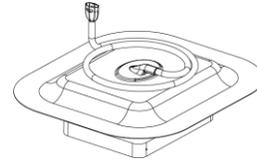
NPWT CLOSURE SET O2 Delivery FOOT



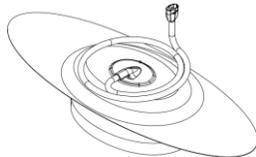
NPWT CLOSURE SET O2 Delivery BRIDGE



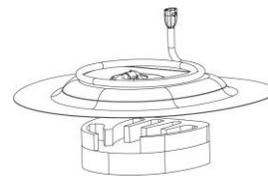
NPWT CLOSURE SET XS,S,M,L,XL



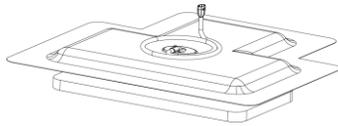
NPWT CLOSURE SET ABDOMINAL



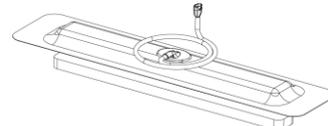
NPWT CLOSURE SET HAND



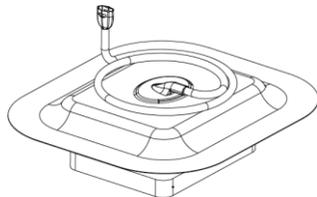
NPWT CLOSURE SET FOOT



NPWT CLOSURE SET BRIDGE



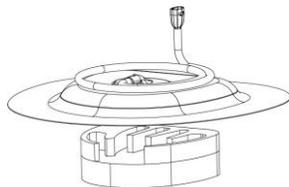
NPWT CLOSURE SET SLIM XS,S,M,L,XL



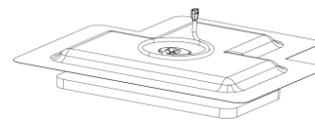
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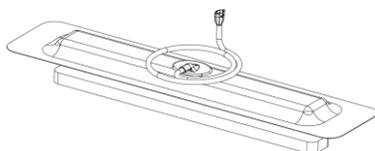
NPWT CLOSURE SET SLIM HAND



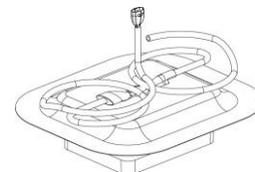
NPWT CLOSURE SET SLIM FOOT



NPWT CLOSURE SET SLIM BRIDGE

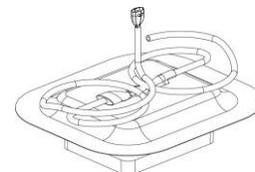


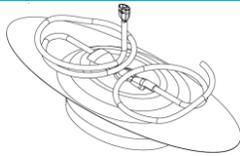
NPWT CLOSURE SET IRRIGATION XS,S,M,L,XL



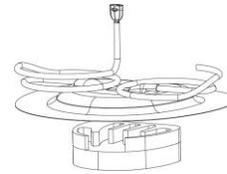
NPWT CLOSURE SET IRRIGATION ABDOMINAL

NPWT CLOSURE SET IRRIGATION HAND

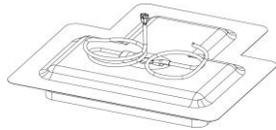




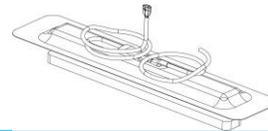
NPWT CLOSURE SET IRRIGATION FOOT



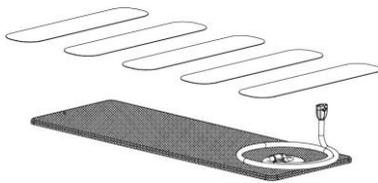
NPWT CLOSURE SET IRRIGATION BRIDGE



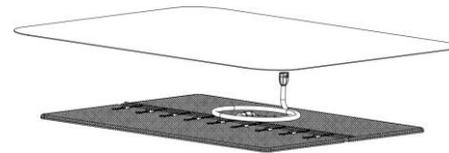
NPWT INCISION DRESSING SET S,M,L



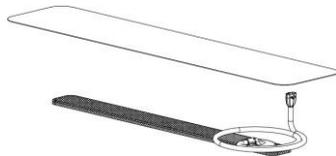
NPWT ZIPPER DRESSING SET S,M,L



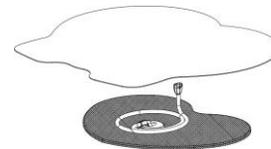
NPWT UNIBODY DRESSING SET XS,S,M,L,XL



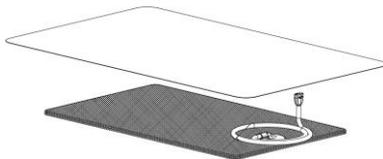
NPWT UNIBODY DRESSING SET SACRUM



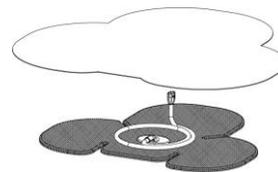
NPWT UNIBODY DRESSING SET KNEE



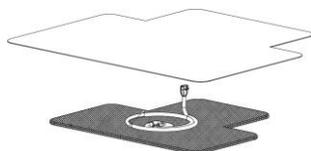
NPWT UNIBODY DRESSING SET CORNER



NPWT UNIBODY DRESSING SET FOOT



NPWT UNIBODY DRESSING SET BRIDGE



NPWT FOAM STANDARD/SLIM XS,S,M,L,XL



NPWT FOAM STANDARD/SLIM ABDOMINAL



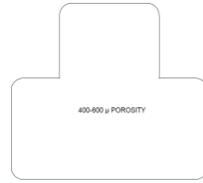
NPWT FOAM STANDARD/SLIM HAND



NPWT FOAM STANDARD/SLIM FOOT



NPWT FOAM STANDARD/SLIM BRIDGE



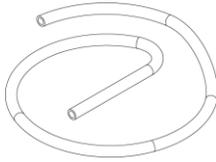
NPWT FILM DRAPE STANDARD/LARGE



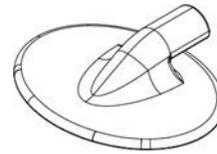
NPWT IRRIGATION TUBING N/A



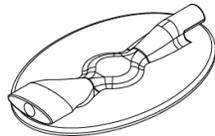
NPWT VACUUM ACCESS PORT™ Standard



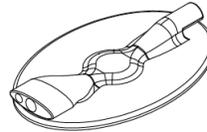
NPWT VACUUM ACCESS PORT™ Irrigation



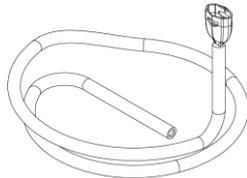
NPWT VACUUM ACCESS PORT™ O2 Delivery



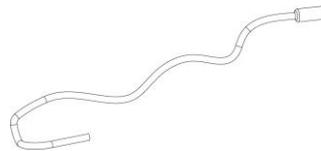
NPWT VACUUM TUBING N/A



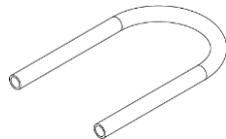
NPWT O2 DELIVERY TUBING N/A



NPWT PERILSTATIC PUMP TUBING N/A



NPWT Y CONNECTOR TUBING N/A



NPWT EXTRA LONG TUBING N/A



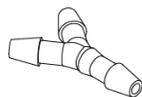
NPWT CONNECTOR N/A



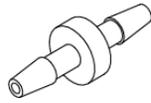
NPWT Y CONNECTOR N/A



NPWT MULTI LUMEN CONNECTOR



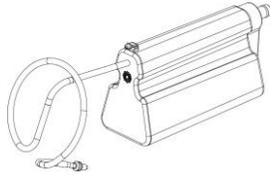
NPWT CONNECTOR STANDARD N/A



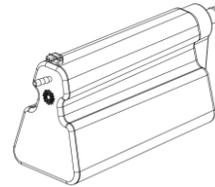
NPWT SERUM TUBING



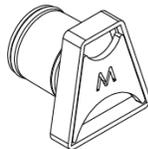
NPWT COLLECTION SET N/A

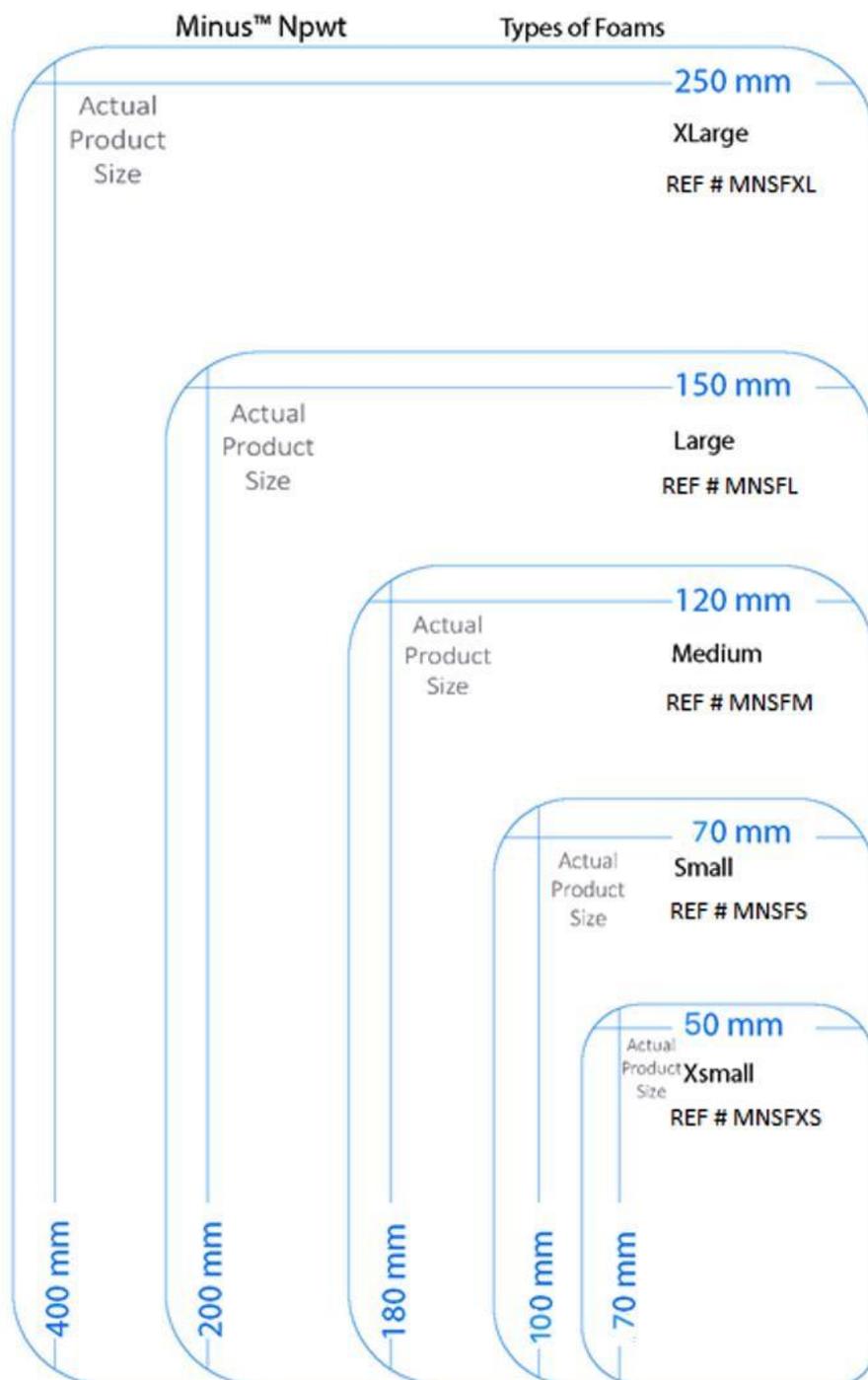


NPWT CANISTER N/A



**NPWT FILTER CARTRIDGE FOR HMI
GameChanger/MAJOR/571**





1.11 Packing and Labelling

2.2.1; 2.3.1; 2.4.1; 2.5.4; 2.7.1 Sterilus

The single-use product come individually sterile blister packs. Inspect the product and the packaging for damage prior to use. Confirm that the device is consistent with the package label. Discard and replace any damaged devices. Store the products in a clean, dry place in accordance with the storage conditions.

1.12 Storage

Store sterile packaged instruments in a manner that provides protection from dust, moisture, insects, vermin, and extremes in temperature and humidity. Temperature: 0 to +58°C; Relative humidity: 0 - 70%, non-condensing; Ambient pressure extremes 14,125m.

1.13 Return

Before returning the Minus™ system or any individual components to the manufacturer, please ensure that washing and sterilization have been carried out. All equipment must undergo a valid cycle. A certification of decontamination must accompany the system or any individual components on their return.

The instructions provided above have been validated by the manufacturer as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing is performed using equipment, materials and personnel in the processing facility to achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

1.14 Disposal

The Minus™ Negative Pressure Wound Therapy 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 Minus™ wound dressings, tubing, and canister can be disposed of according to policy for wound care dressings after use.

Symbol	Designation
	A device marked with this symbol must be put into the separate waste collection for electrical and electronic devices. Disposal is carried out free of charge by the manufacturer within the European Union.

Disposal of Dressings, Canister and Other Disposables

After patient use, all disposable components of the system should be treated as contaminated. These include: The Minus™ NPWT Foam Dressing components. Exudate collection canister. Tubing, connectors and clamps (and irrigation delivery set if irrigating).

Dispose of all disposable components in accordance with local, state and institution protocols.

1.15 Inspection and Handling

- Reuse of this product, including after reprocessing and/or re-sterilization may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information, all of which present a potential risk to patient safety.
- Do not use if the pouch is opened or damaged. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.
- Store in a cool, dark, dry place.
- Use the system prior to the "Use By" date specified on the package.
- Do not use if the product is partially deployed in straight shape upon removal from the package, or before starting the deployment procedure.
- Do not expose the delivery system to organic solvents (e.g. alcohol).

1.16 Cleaning Inspection

- Inspect all instruments prior to sterilization or storage to ensure the complete removal of solid surfaces
- Visually inspect instruments, if soil is still present clean instruments again.
- Inspect cables for wear and damage, ensuring that no cracks, tears, or other damage is found.
- Check to see that waveguides are free of scratches.

- Report any damage found to the Minus™ representative.

1.17 Wrapping

- Double wrap in accordance with local procedures, using standard procedures wrapping techniques such as those described in ANSI/AAMI ST46-1993.
- Label contents of wrapped tray using indelible marker or other sterilization compatible label system.

1.18 Operation, Storage and Transport

Operating conditions:

- Temperature: -25 to 70 °C;
- Relative humidity: 15-93% (non-condensing)
- Standard atmospheric pressure 700hPa – 1060hPa
- Duration: Less than 3 days

Storage conditions:

- Temperature: 0 to +58°C;
- Relative humidity: 0 - 70%, non-condensing
- Ambient pressure extremes 14,125m

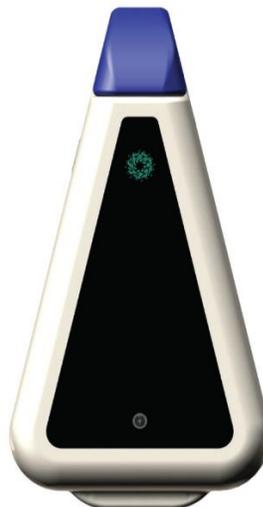
Chapter 2- Illustrations



Rear



Charging Side



Illustration

Components and Parts

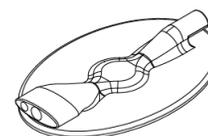
- **DISPLAY/TOUCH SCREEN**
Displays system information and services as interface for adjusting controls and settings.



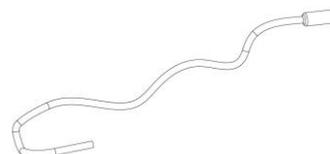
- **POWER ON/OFF SWITCH**
Glow blue when the pump is powered up



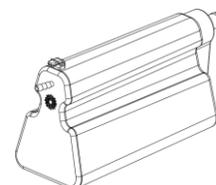
- **Vacuum Access Port**



- **Tubing**



- **Canister**



- **Peristaltic Pump Head**



Chapter 3 - Operative System

3.1 System Start Up

Power on, the touchscreen will appear the following interface:

Power Settings	<u>On/Off Switch</u>
System Startup Menu	<u>You can follow the instructions as the interface guides you</u>
Continuous or Pulse Options	<u>Rather than having a categorical Pulse and Continuous options, parameters and pulse can be manually set by increasing and decreasing the level on the indicator.</u>
Language	<u>You can select the language by clicking on the flag.</u>

Alert When the system runs, it gives sound and if not there is no sound heard.

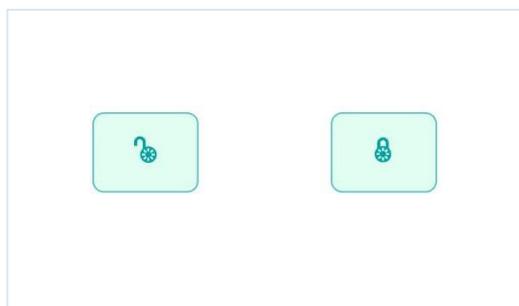
3.2 Menu Controls

SYSTEM START



LOCK UNLOCK

2.1.7 Užrakto funkcija neleidžianti pacientui keisti slėgio parametrų



Key Lock Home Page

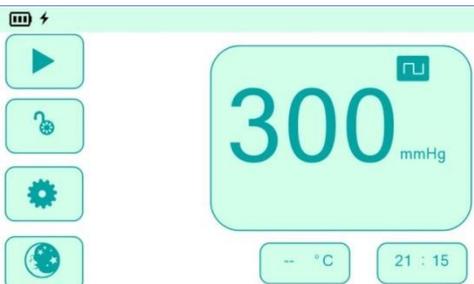


At Operation

(Key Unlock)



MENU Day Mode



MENU Night Mode



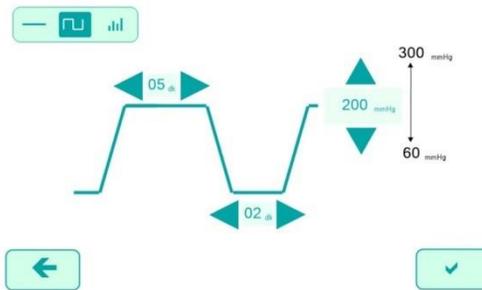
NOT :

Liquid Delivery and Oxygen Therapy can only be activated in intermittent mode. Liquid Delivery and Oxygen Therapy cannot be activated at the same time.

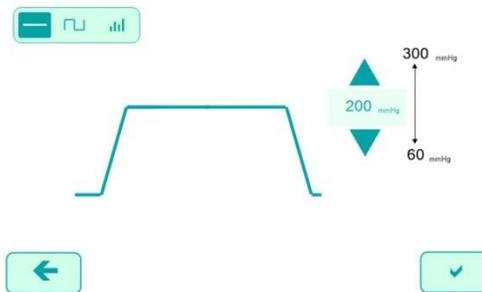
- Therapy Setting
- Timing Settings
- Liquid Delivery
- Oxygen Therapy
- Language

Choice of Treatment

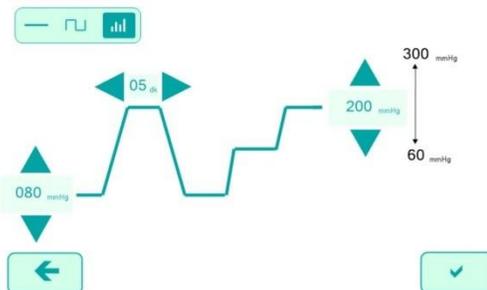
Variable Mode Setting



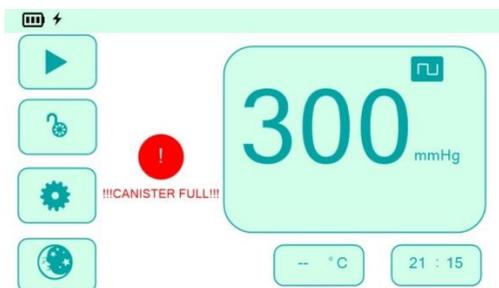
Continuous Mode Setting



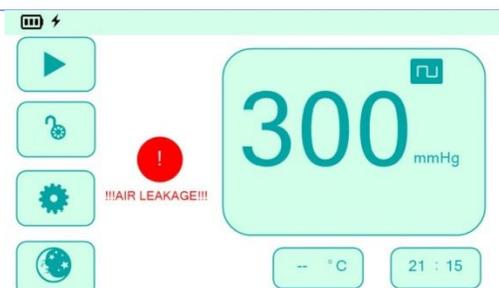
Random Mode Setting



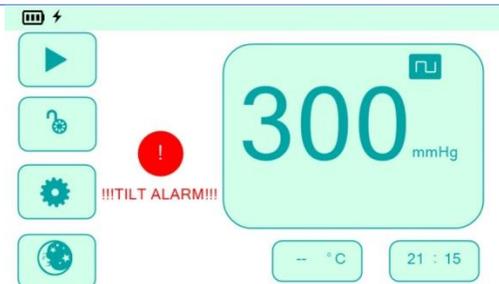
Caution Canister Full



Caution Air Leakage

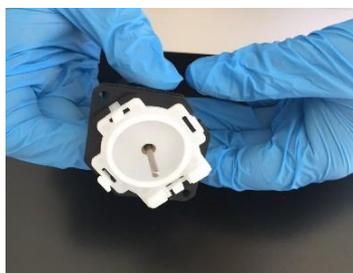


Caution Tilt Alarm

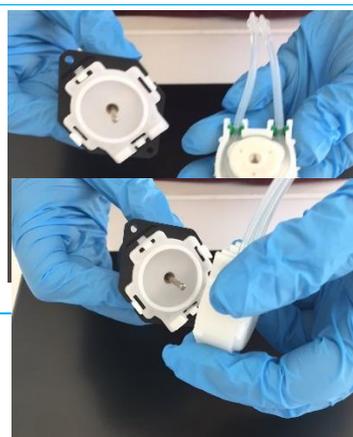


3.3 Pump

3.3.1 Pump Assembly



- Ensure that the buckle is on its own place and claws are locked.

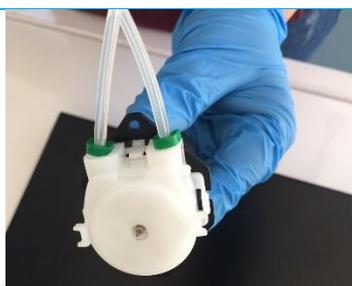


- Place the Pump Head onto pump.

- Centralise the head into the shaft of motor.



- Ensure that claws are tightly locked.



Make sure the tubing is in place.

Chapter 4 – Troubleshooting

4.1 General Troubleshooting

The user interface for the generator has a number of informative screens to guide the efficient use of the generator. Informative screens will maintain a consistent dark background to differentiate them from the alarm screens shown below.

Malfunction	Description	Trouble Shooting
Low Battery Alarm	When the battery is low level, and alert will be heard and seen on the screen about battery level	Plug in the device and start recharging. Attention should be paid to avoid interruption during the treatment.
Blockage Alarm	If any hard material like scar tissue may block the inner lumen of the tube either longitudinal or at the connection parts.	Please check the tubing as the way head is clear.
Canister Full Alarm	When the canister full, alarm is heard.	Check the canister and Replace it.
Troubleshooting Malfunction At Pump Startup	If the pump is not administer the target liquid at the desired level, the alarm is heard.	Check the pump and make sure the tubing is in line with 3 circles over rollers.

2.1.6 Garsiniai ir vaizdiniai
įspėjamieji signalai:
1. Išsekusios baterijos

Chapter 5 - Cleaning, Disinfection, Preventive Maintenance

5.1 Electrical Safety Check

The hospital is responsible for ensuring that the unit has an electrical safety check performed by qualified service personnel at least once a year. Do not remove the cover of the device. Removing the cover voids the device warranty.

5.2 Cleaning and Disinfection Instructions

Follow Standards for Decontamination, Cleaning and Sterilization

Follow ANSI/AAMI ST35, Good Hospital Practice: Handling and Biological Contamination of Reusable Medical Devices (1991), or other such guidelines as may be directed by Hospital or Clinic GHP's.

All reusable parts and accessories must be properly decontaminated, cleaned and/or sterilized before each use as per instructions contained in this manual. Failure to do so may lead to infections, which can ultimately cause patient.

5.2.1 Clean and Disinfect/Sterilize Reusable Items

The following instructions are Mavera Medical Devices recommended cleaning and infection control procedures for the Minus™ Negative Pressure Wound Therapy System. The Caregiver should review this manual in its entirety before attempting to use the product.

The Caregiver Protective Equipments

The protective equipment includes:	<ul style="list-style-type: none"> ➤ Disposable gloves (latex or latex-free). ➤ Protective eyewear to help prevent splashing of cleaning solutions and/or blood or bodily fluids. ➤ Protective mask (to protect the nose and mouth from inadvertent fluid ingress). ➤ Disposable impervious gown (if splashing of blood or bodily fluids is possible).
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5.2.2 Touchscreen Cleaning

Clean the device and the touchscreen following the hospital protocol. Before cleaning, turn the pump main power off and unplug the power cord from the grounded electrical outlet.

5.2.3 Technical Assistance

Should the user wish further information or instructions regarding any aspect of cleaning or sterilizing procedures, please contact Mavera or an Authorized Representative.

5.2.4 Maintenance

Item	Guidance
Power adapter	<ul style="list-style-type: none"> • The Minus™ NPWT device should only be recharged using the AC/DC adapter provided or an equivalent IEC 60601-1 compliant adapter with a +5V 1.5A output.
Battery	<ul style="list-style-type: none"> • 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 Devon Medical Products approved battery. 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.

Chapter 6- Service, Repair and Technical Correspondence

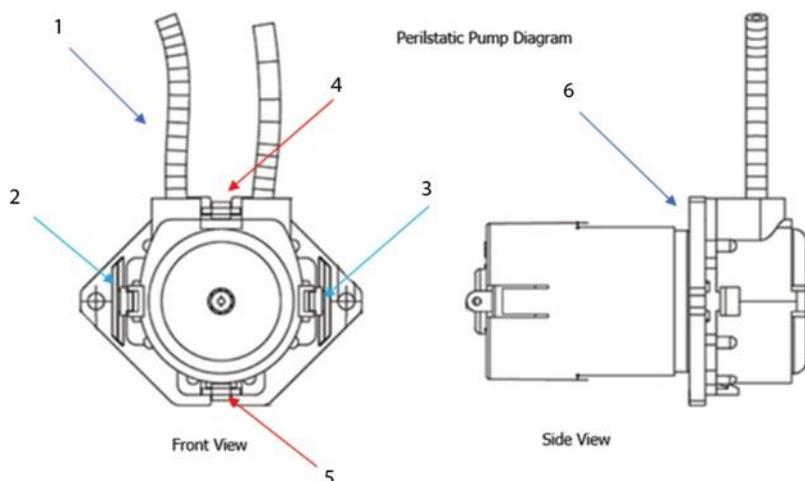
Proper system grounding can only be ensured when an approved, hospital-grade receptacle and matching power cord are used. Install plug and receptacles as per local regulations before operating the unit. Power cord, plug and receptacle should be examined to verify that they are in good working condition before connecting the console. Never pull on the power cord to remove it from the receptacle.

6.1 Repair, Service and Replacement Parts

All requests for repairs and replacement parts should be directed to Maveria or an authorized Maveria representative. Always provide model and serial number of malfunctioning items.

When returning items include model, serial and as well as purchase order number on all documents. Always prepay return shipping and specify method of shipment.

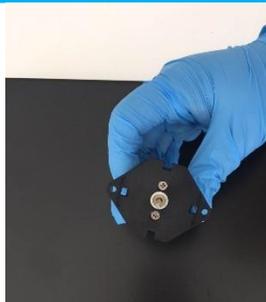
6.2 Pump Head Replacement



1	Tubing	
2	Upper Release Claw	Used to Release the tubing body from the buckle
3	Lower Release Claw	Used to Release the tubing body from the buckle
4	Left Release Claw	Used to Release the body from the main body
5	Right Release Claw	Used to Release the body from the main body
6	Buckle	Supports the pump

Placement of Buckle Head

Buckle Head



- Ensure that the surface of the motor is clean.



- Stackable pump heads need longer mounting screws.

Note

Try your best to tighten the two screws in the same degree. Do not over-tighten the screws to prevent the support block from deforming.

6.3 Important Notice

Please contact Maveria with any questions regarding the specifications, use, sterilization, limitations or maintenance of the The Minus™ Negative Pressure Wound Therapy System:

Maveria Medical Devices, Inc.

Web	www.maveramedical.com.tr
Email	info@maveramedical.com.tr
Phone	+90-312-341-5027
Fax	+90-312-341-5026
Address	YEŞİLBAYIR MAH. SAĞDUYU CAD. NO: 107/C MAMAK / ANKARA / TURKEY
Zip Code	06270

By returning any material to Maveria the customer or the customer's agent must certify that any and all materials so returned are or have been rendered free of any hazardous or noxious matter or radioactive contamination and are safe for handling under normal repair shop conditions.

Do not return any material for which such certification cannot be made without prior approval from Mavera.

The correct return address should read as follows:

Mavera Medical Devices, Inc.

Phone +90-312-341-5027
Address YEŞİLBAYIR MAH. SAĞDUYU
CAD. NO:107/C
MAMAK / ANKARA / TURKEY

Chapter 7- Appendices

7.1 Rear Label of the Pump

Negative Pressure Wound Therapy System
NPWT Pump HMI GameChanger
Negatif Basıncı Yara Tedavi Sistemi
NBYTHMI GameChanger Pompa



Product Name/Ürün Adı :Minus™ NPWT Pump HMI GameChanger
(Non-Sterile, Reusable)
Minus™ NBYT HMI GameChanger
Pompa (Steril Olmayan, Tekrar
Kullanılabilir)

Product Model/Ürün Modeli: NPWT System
Input Power/Giriş Gücü: 100-240 V, 50/60 Hz
Vacuum/Vakum: 300 mmHg
Fluid Flow/Sıvı Akışı: 8 L per minute/ 8 L/dk
Fluid Temperature/Sıvı Sıcaklığı: 38 °C

Üretici Firma
Manufacturer

Mavera Tıbbi Cihazlar A.Ş.
Mavera Medical Devices Inc.
Yeşilbayır Mah. Sağduyu Cad. 107/C Mamak,
Ankara/Türkiye

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www.maveramedical.com.tr

 Kullanım kılavuzunu okuyunuz
Consult instructions for use















Contents/Ea
İçindekiler/Adet

1



Doc./Dök. # : BLBLNPWT-GMCHMI-N Rev. # : 03 Rev. Date/Trh. : 04.03.2020 Pub. Date/Trh. : 20.09.2018

7.2 Markings on the Front and Rear Panel of the Generator

FRONT	LEFT REAR	RIGHT REAR
Power ON/OFF	Canister	Power

Peristaltic Pump

Filter

Oxygen Outlet

7.3 Symbols for the Product Labels

SYMBOL	SYMBOL NAME	SYMBOL	SYMBOL NAME
	Lot Number		Keep Dry
	Serial Number		See instruction manual
	Caution		Manufacturer
	Contents		Catalogue Number
	Do Not Re-sterilize		Sterilized by using ethylene oxide
	Do Not Use If Package Is Damaged		Use By
	Do Not Re-use		Consult Instruction for Use
	Humidity Limitation for Sterile		Type BF insulation
	Risk of Electric Shock		Dispose Electrical Electronic Equipment Correctly
	EC Mark European Conformity		Temperature Limitation for Sterile
	Keep away from sunlight		Shelf Life
	Non-Pyrogenic		Life Cycle
	Temperature Limitation for Non-Sterile		Humidity Limitation for Non-Sterile



Federal USA law restricts this devices to sale by or on the order of a physician

7.4 Technical Specification

2.1.8 Elektros maitinimas 230 V / 50 Hz

External Power Supply Input	100-240 V, 50/60 Hz
External Power Supply Output	12V, 5,0A, 60 W Max
Battery Type	7.4 V, 6000 mAh, Lithium Polymer
Main Fuses	3.0A Slow Glass Tube
Mobility	Portable
Pressure Options	40mmHg-300mmHg
Pump Ratings	1.2A Current max, 6V
Flow Rate	8 L per minute
Vacuum	300 mmHg
Fluid Temperature	38 °C
Degree of Protection	Type B, Applied Part
Against Electric Shock	
Class of Protection	Class II Internally Powered Equipment
Against Electric Shock	
Ingress Protection	IP20
Noise	<45 dB(A) at a distance of 50cm
Mode of Operation	<ul style="list-style-type: none"> • Continuous • Intermittent • Variable
Controls	<ul style="list-style-type: none"> • Mains Power on/off switch (front) • Receptacles for powering • HMI Interface Touch Screen
HMI Interface Touch Screen	<ul style="list-style-type: none"> • Lock and Unlock • O2 Delivery • Liquid Irrigation • Liquid Temperature • Therapy Mode • Timing
Alarms	Tilt Alarm
2.1.6 garsiniai ir vaizdiniai įspėjamieji signalai: 2. Slėgio nutekėjimo; 3. Pilnos talpos; 4. Dreno blokavimo	Canister Full Alarm / Tubing Blockage
	Air Leakage
	Short Circuit Alarm (sound)
Irrigation pump	Peristaltic pump 0.8A Current
Pump flow rate	Max flow ≤ 12 ml/min.
Irrigation tubing	<ul style="list-style-type: none"> • Dedicated Tube set, sterile, single-use • Vented IV-spike, compatible with fluid bags and bottles
Battery Charging Time	~ 12 hours from a fully discharged state
Battery Run Time	~ 12 hours, depending in settings
Barometric Pressure	700hPa – 1060hPa
Operating conditions	<ul style="list-style-type: none"> • Temperature -25 to 70 °C) • Relative humidity 15-93% (non-condensing) • Standard atmospheric pressure 700hPa – 1060hPa

2.1.3 Garso lygis 45 dB

2.1.5 Aparato valdymas liečiamu, spalvotu ekranu

2.1.4 Maksimalus veikimo laikas iš akumuliatoriaus 12 val.

Shipping/storage conditions	<ul style="list-style-type: none"> • Temperature: 0-58 °C • Relative humidity: 0-70% (non-condensing) • Ambient pressure extremes 14,125m
Dimensions	283L x 270H x 153 mm
Weight	2.1 kg
Expected Service Life	3 years

7.5 EMC Statement

The Minus™ Negative Pressure Wound Therapy is designed and tested to comply with IEC EN60601-1-2: 2007 guidelines for EMC.

7.6 Electromagnetic Interference

The Minus™ Negative Pressure Wound Therapy System generates, uses, and emits ultrasonic energy. If this equipment is not used in accordance with the instructions in manual, it may cause electromagnetic interference. This device was tested and found conforming to acceptable limits for medical devices in accordance with EN 60601-1-2 standard. If this device is used in accordance with the instructions in manual, these limits indicate that the device provides acceptable protection against electromagnetic interference (EMC). This device is designed and manufactured in accordance with the requirements of EN 60601-1-2 standard. This device may be affected by portable. This device should not be stored with other equipment.

To be informed more about this device and see EMC tables:

7.6.1 TABLE I

Guidance And Manufacturer's Declaration – Electromagnetic Emissions		
The Minus™ Negative Pressure Wound Therapy System is intended for use in the electromagnetic environment specified below. The customer or the user of The Minus™ Negative Pressure Wound Therapy System should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Minus™ Negative Pressure Wound Therapy System 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. The Minus™ Negative Pressure Wound Therapy System is suitable for use in all establishments including domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

7.6.2 TABLE II

Guidance And Manufacturer's Declaration – Electromagnetic Immunity
Mavera Minus™ Negative Pressure Wound Therapy System is intended for use in the electromagnetic environment specified below. The customer or the user of the Minus™ Negative Pressure Wound Therapy System should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 15 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line (s) to line (s) ±2 kV line (s) to earth	±1 kV line (s) to line (s) ±2 kV line (s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle <40 % UT (>60 % dip in UT) for 5 cycles <70 % UT (>30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle <40 % UT (>60 % dip in UT) for 5 cycles <70 % UT (>30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Minus System requires continued operation during power mains interruptions, it is recommend that the Minus System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50Hz	30 A/m, 50Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOT UT is the AC mains voltage prior to application of the test level.			

7.6.3 TABLE III

Guidance And Manufacturer's Declaration – Electromagnetic Immunity			
Mavera Minus™ Negative Pressure Wound Therapy System is intended for use in the electromagnetic environment specified below. The customer or the user of the Minus™ Negative Pressure Wound Therapy System should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance test level	Electromagnetic environment -Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Model 005, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.16\sqrt{P}$ $d = 1.2\sqrt{P}$ 0,15 MHz to 80 MHz $d = 2.3\sqrt{P}$ 80 MHz to 2.7 GHz
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2,5 GHz	3 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOT 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOT 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Minus System is used exceeds the applicable RF compliance level above, the Minus System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the Minus System. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

7.7 Electrical Safety Statements

The Minus™ Negative Pressure Wound Therapy System is designed and tested to comply with EN 60601-1.

7.8 Environmental Statements

This equipment consists of materials that may be recycled if disassembled by a specialized company. Please observe local regulations regarding the disposal of packing materials and old equipment.

7.9 General Safety Statements

The Minus™ system is an electro-mechanical device, which under certain circumstances could present an electrical shock hazard to the operator and/or patient. Please read manual thoroughly and follow directions stated herein to assure maximum safety during operation. This manual shall be kept in close proximity to the system for easy referral when needed.

The Minus™ system is intended to be used in various types of invasive, surgical procedures. There may be indirect danger to the patient should the device fail during the procedure. It is recommended that the facility follows its back-up equipment protocols.

7.10 Conventions Warning and Cautions

Please read this section of the manual carefully. This section highlights the definitions and such critical terms Warning and Caution.

The user is advised to read the entire manual and operate the device only in accordance with all of the instructions contained herein.

Servicing of this device should only be performed by qualified technicians authorized by Maveria.

There are no service controls accessible to the user.

7.11 Disclaimer

A surgeon should rely exclusively on his or her own professional medical/clinical judgment when deciding which particular product to use when treating a patient. Maveria does not dispense medical advice and advocates that surgeons be trained in the use of any particular product before using it in surgery. The content presented is intended to identify the breadth of Maveria Medical product options. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Maveria Medical product. Products may not always be available in all markets in a similar capacity due to the local regulatory and/or medical practices. It is advised that you contact a Maveria Medical representative if you have questions about Maveria Medical products.

Maveria Medical Inc. guarantees that the products is designed, manufactured and packaged on application of the EN ISO 9001 and the EN 13485 certified quality management with all possible care, using the most suitable state-of-the-art processes and applying the principle of integrating safety into its design and manufacture. This system is designed to guarantee the safe use of device when it is employed under condition and for the purposes for which it is intended, in accordance with precautions described in the operator's manual and/or instructions for use and to minimize the risks associated with the use of the device as far as possible, although they cannot be totally eliminated. The device must only be used under the responsibility of specialist medical personnel, taking account of the unavoidable risks and the possible side effects and complications of the treatment for which it is designed, including those referred to in other sections of these instructions for use.

7.12 Contact



Mavera Medical Devices Inc.

YEŞİLBAYIR MAH. SAĞDUYU CAD. NO: 107/C MAMAK / ANKARA / TURKEY

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7.13 Trademark Information

Minus™ and Maveria® are registered trademarks of Maveria Medical Devices Inc, Ankara TURKEY.

Limited Warranty

Mavera Medical Devices warrants its Minus™ Negative Pressure Wound Therapy System ("Device") to be free from defects in workmanship and materials for a period of one (1) 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. Maveria Medical Devices' 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 power plug and connection tubing. 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 Maveria Medical Devices' instructions, including, without limitation, the instructions contained in the Operating Manual.

THERE ARE NO OTHER WARRANTIES THAN THOSE EXPRESSLY STATED HEREIN.

TO THE EXTENT PERMITTED BY LAW, MAVERIA MEDICAL DEVICES 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 MAVERIA MEDICAL DEVICES 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, MAVERIA MEDICAL DEVICES SHALL NOT BE LIABLE FOR ANY EXEMPLARY OR PUNITIVE DAMAGES.

Limited Liability

THE LIABILITY OF MAVERA IS STRICTLY LIMITED TO REPLACING THE DEVICE IF IT SHOULD PROVE DEFECTIVE AT THE TIME OF DELIVERY. UNDER SUCH CIRCUMSTANCES, THE CUSTOMER SHALL DELIVER THE DEVICE TO MAVERA, WHICH RESERVES THE RIGHT TO EXAMINE THE ALLEGEDLY FAULTY DEVICE AND ESTABLISH WHETHER IT ACTUALLY PRESENTS MANUFACTURING DEFECTS. THE WARRANTY SOLELY COVERS REPLACEMENT OF A DEVICE FOUND TO BE DEFECTIVE WITH ANOTHER OF SAME OR EQUIVALENT TYPE MANUFACTURED BY MAVERA.

THE WARRANTY SHALL ONLY APPLY IF THE DEVICE IS RETURNED TO MAVERA, CORRECTLY PACKED, TOGETHER WITH A DETAILED WRITTEN REPORT ON THE DEFECTS COMPLAINED.

IF THE DEVICE IS FOUND TO BE FAULTY AND REPLACED, MAVERA WILL REFUND THE COSTS DIRECTLY INCURRED BY THE CUSTOMER. MAVERA DECLINES ALL LIABILITY IN THE EVENT OF FAILURE TO COMPLY WITH THE DIRECTIONS FOR USE OR PRECAUTIONS SPECIFIED IN THIS INSTRUCTION BOOKLET, OR IN THE CASE OF USE AFTER THE EXPIRY DATE MARKED ON THE PACKING. MAVERA FURTHER DECLINES ALL LIABILITY FOR THE CONSEQUENCES OF MEDICAL DECISIONS AND METHODS OF USE OR APPLICATION OF THE DEVICE, AND SHALL THEREFORE NOT BE LIABLE FOR ANY MATERIAL, BIOLOGICAL OR NON-PECUNIARY LOSS OR INJURY OF ANY KIND RESULTING FROM THE APPLICATION OF THE DEVICE.



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NEGATIVE PRESSURE WOUND THERAPY SYSTEM

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Disclaimer

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Maveria does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Maveria product. Products may not always be available in all markets in a similar capacity due to the local regulatory and/or medical practices. It is advised that you contact a Maveria representative if you have questions about Maveria products. MinusTM is a Registered Trademark of Maveria Medical Devices Inc.