More than Vacuum Therapy

TOPIVAC® TOPICAL VACUUM TREATMENT UNIT
WOUND CARE

HAND

USER MANUAL FOR CLASSICAL VACUUM ASSISTED (NPWT) WOUND CLOSURE THERAPY DEVICE

New Case Series

AMEDUS®

TOPIVAC® TOPICAL VACUUM TREATMENT UNIT
WOUND CARE

'' Dear User,

This user manual has been prepared for the use of TOPIVAC HAND Classic Vacuum Assisted (NPWT) Wound Closure Therapy Device. Before you start using our product, we kindly ask you to read the "User Manual" carefully and keep it as a reference.

Consult your doctor before using the device.

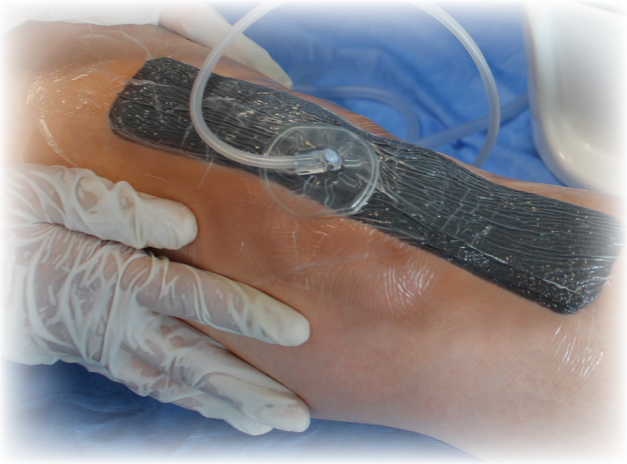
Make sure to have your wound treatment done by authorized persons who are experts in their field.

Topivac Hand Wound Treatment Device and TopiVac brand wound treatment dressing sets are compatible and integrated. Using any other accessory except for Topical Vacuum Therapy dressing sets with the device is not recommended.

Our products, produced with the latest technology and standards are within the scope of the MDD 93/42/EC-2007/47/EC Medical Devices Directive and are certified by international inspection organizations.

For more details please visit www.topivac.com web address.

Your satisfaction is the best reward for us.



CONTENTS

• GRAPHIC SYMBOLS


These symbols indicate that the product is part of the recovery/recycling process.


This symbol indicates that tdevice should be kept away from sunlight.


This symbol indicates that device is fragile and should be carried/transported carefully.


This symbol indicates that device should be kept died.


This symbol mentions the manufacturer.


This symbol shows the date of manufacture.


This symbol indicates that device should not be disposed of with untreated urban waste.(only for EU)

This symbol indicates the Manufacturer's catalog number of the device.

This symbol indicates the serial number of the device.


Please the read user before using the device.

Medical Device

Device Unique Identification

This symbol indicates protection method against hard objects with a diameter > 12.5 mm against hazardous impacts.


Storage temperature


This symbol indicates class II protection against electric shock by double insulation or reinforced insulation.

This symbol indicates the device's compliance with the main requirements 93/42/EEC the Council of EU Medical Devices Directive.

• PRODUCT INFORMATION

TOPIVAC HAND CLASSIC VACUUM ASSISTED (NPWT) WOUND CLOSING THERAPY DEVICE

Topivac is a wound treatment system consisting of a vacuum assisted device and dressing set to treat open wounds (e.g., acute, traumatic or chronic), burns, diabetic wound, pressure ulcers, etc., that are difficult to heal.

USING PURPOSE OF TOPIVAC HAND DEVICE

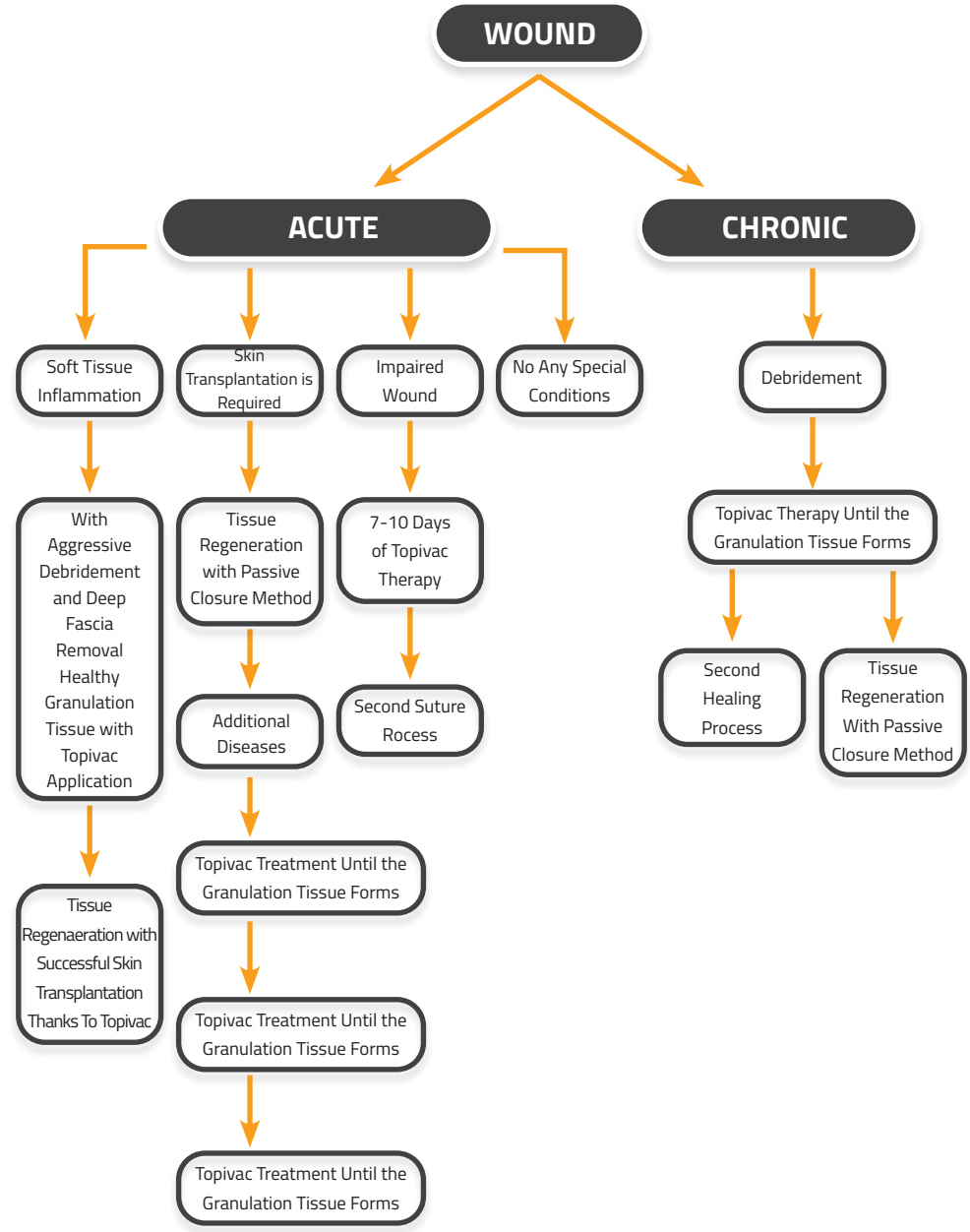
It is an active hybrid system that supports healing in noninvasive acute, infected and chronic wounds, applies controlled local negative pressure, and washes the wound bed with topical fluids. While increasing the patient's life quality , it reduces treatment costs. It heals wounds more quickly and effectively than conventional vacuum assisted devices used in the market. Topivac is a treatment system that allows acute - chronic all wounds and burn wounds to heal quickly in optimal conditions, away from new infection risks.

Topivac enables you to administer the most accurate treatment to the patient according to the condition of the wound as fast as possible with its user-friendly main menu and interface .

HOW DOES THE TOPIVAC HAND DEVICE WORK?

Device typically consists of a dressing (e.g., open-cell foam, etc.), an airtight sticky cover, a drain hose, a collection container(canister), and a mains-powered charger, microprocessor control card, sensors, touchscreen, battery and vacuum pump. Device draws exudate into the canister by applying continuous or intermittent vacuum through the dressing set on the wound. It decompresses capillaries/lymph channels, improves blood/interstitial fluid circulation, provides wound edges get closer to each other, helps formation process of granulation tissue and prepares the wound bed for closure.

With Topivac Devices;
Therapy methods such as classical vacuum, bidistilled water, oxygenated water, ozonated water or gas therapy, tens therapy may be applied based on the doctor's prescription and case type (wound type, shape).



• TOPIVAC TOPICAL VACUUM ASSISTED WOUND CARE DEVICES

TOPIVAC HAND T-NPWT

- Intermittent and Incremental Vacuum Therapy
- Classic Negative Pressure Vacuum Therapy

TOPIVAC HAND T-NPWT IRRIGATION

- Intermittent and Incremental Vacuum Therapy
- Classic Negative Pressure Vacuum Therapy
- Moistening
- Irrigation with Bidistillated Water
- Special Irrigation

TOPIVAC MEDIUM V2

- Intermittent and Incremental Vacuum Therapy
- Conventional NPWT
- Moistening
- Instillation/Irrigation with O_2
- O_2 Gas Therapy
- Special Irrigation

TOPIVAC MEDIUM CLINIC (V4)

- Intermittent and Incremental Vacuum Therapy
- Conventional NPWT
- Moistening
- Instillation/Irrigation with O_2 / O_3
- Electrostimulation
- O_2 / O_3 Gas Therapy
- Special Irrigation

* Ozonbag Ozone Therapy for Burn Treatment

• WOUND CARE SETS USING WITH TOPIVAC TOPICAL VACUUM ASSISTED WOUND CARE DEVICES

SINGLE SUCTION DRESSING SET	
DESCRIPTION	**PRODUCT**
SINGLE SUCTION -SMALL Only Vacuum Therapy	
SINGLE SUCTION MEDIUM Only Vacuum Therapy	
SINGLE SUCTION BIG Only Vacuum Therapy	

DOUBLE SUCTION DRESSING SET WITH IRRIGATION	
DESCRIPTION	**PRODUCT**
DOUBLE SUCTION SMALL Only Vacuum Therapy	
DOUBLE SUCTION MEDIUM Only Vacuum Therapy	
DOUBLE SUCTION BIG Only Vacuum Therapy	
DOUBLE SUCTION ABDOMINAL Only Vacuum Therapy	

TOPISET-CANISTER-MULTICASE

TOPISET
(MultiCase, canister, deionized water, tens, electrode, multiDress, oxygen connection, ruler, medical sponge, medical drape, skin cleaner, disposable dressing kit, medical waste bag)

CANISTER – 1000 Ml EXSUDE COLLECTION CONTAINER

MULTICASE - 1000 Ml. (Includes 500 Ml De-ionized Water)
It is used to oxygenate bidistilled water and obtain oxygenated bidistilled water in wound moistening and irrigating. It is also used for ozonizing Bidistilled water and obtaining ozonated Bidistilled water.

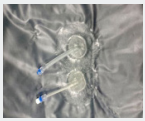
CANISTER – 500 Ml

MULTICASE – 500 Ml

OZONEBAG SET

BURN TREATMENT OZONEBAG SET FOR HAND (SMALL-MEDIUM-BIG)

BURN TREATMENT OZONEBAG SET FOR FOOT (SMALL-MEDIUM-BIG)



BURN TREATMENT OZONEBAG SET FOR WHOLE BODY (SMALL-MEDIUM-BIG)

MULTIDRESS

MultiDRESS Small
(Vacuum, Irrigation ve Gassing) Can be Used in Medium Clinical Devices.

MultiDRESS Medium
(Vacuum, Irrigation ve Gassing) Can be Used in Medium Clinical Devices.

MultiDRESS Big
(Vacuum, Irrigation ve Gassing) Can be Used in Medium Clinical Devices.

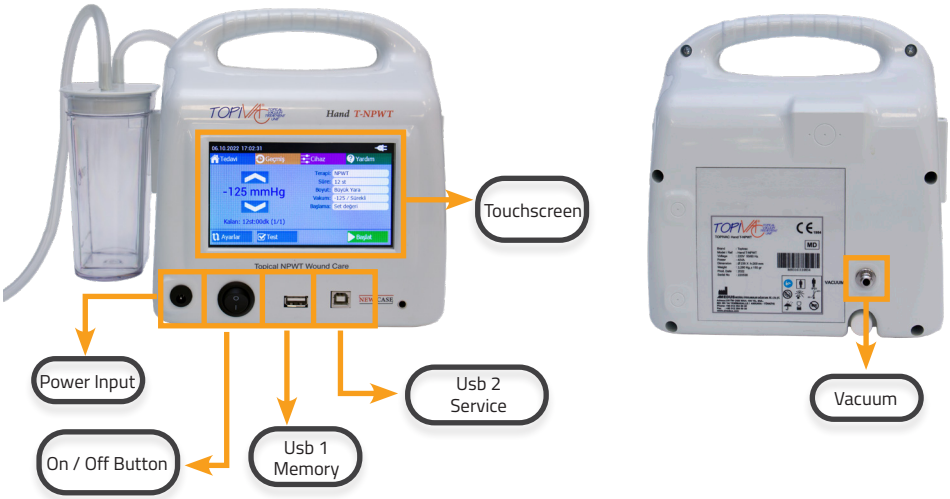
Y CONNECTOR & ELECTROTENS CABLE & ELECTRODE

Y CONNECTOR PINCH VALVE CONNECTION HOSE

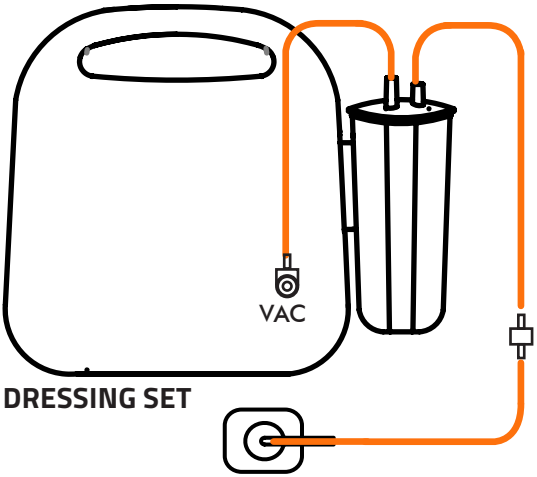
ELEKTROTENS CABLE

TENS ELEKTRODE

▪ CLASSICAL VACUUM ASSISTED (NPWT) WOUND CLOSURE THERAPY DEVICE



• CONNECTION DIAGRAM OF TOPIVAC HAND CLASSIC NPWT THERAPY DEVICE AND DRESSING SET



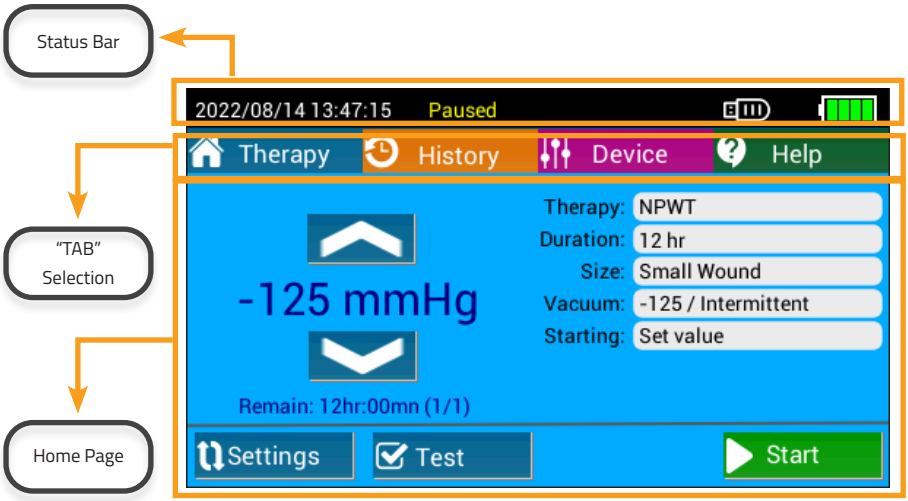
Do not perform dressing treatment without reading the dressing set user manual.

FOLLOW THE STEPS BELOW BEFORE STARTING TOPIVAC HAND WOUND THERAPY.

- Prepare your Topivac Hand NPWT device for use.
- Plug the charger of the device into the socket.
- Make sure the battery is fully charged before operating.
- Attach the exudate collection container (canister) to the device.
- Connect the short hose of the canister to the Luer port on the back of the device..
- Choose the appropriate dressing set to the conditions of your wound.
- Apply your wound care dressing kit so that leakage does not occur.
- Place the Canister in the slot on the left side of the device
- Connect the short hose of the canister to the Luer on the back of the device.
- Connect Canister's long hose with the suction cup attached hose included in your dressing set.
- Turn your device on.
- Enter your optional patient data.
- Select your treatment type and vacuum value.
- You can optionally perform a dressing test leak check before starting therapy.
- It is recommended to perform a dressing leak test before starting therapy. (-125mmHg)
- Start therapy by pressing the start button in the lower right corner of the screen.
- If there is a vacuum leakage in the dressing and/or if the vacuum absence, remove the leakage in the dressing.
- After removing the dressing leakages, you can continue the wound treatment you have chosen by pressing the 'Start' button.
- In case the canister is full or the dressing set needs to be changed Replace them.

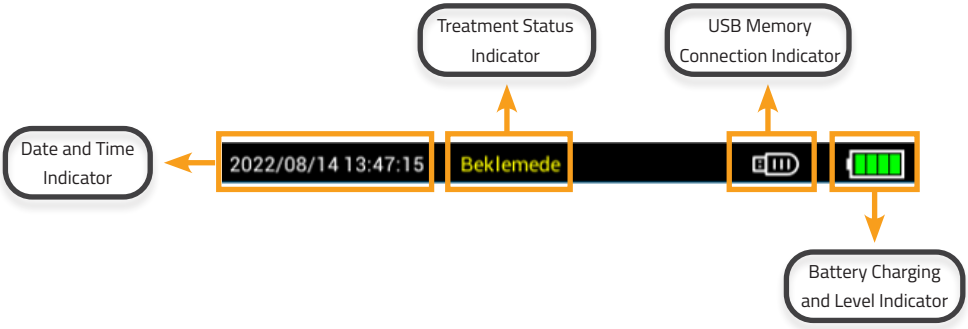
• TOPIVAC HAND T-NPWT OPERATION SCREEN MAIN PAGE STRUCTURE

The Topivac Hand T-NPWT has a TAB navigation bar. In this way, it is possible to navigate between TAB and to follow the status of the treatment even while the device is operating.



→ 1. STATUS BAR

The status bar is the section that contains the general status information of the device. It is used to monitor the status of the treatment during the navigation between TAB.



• 1.1 Date and Time Indicator

Displays the date and time of the device. Settings could be changed from the regional settings page with the "Expert" button located right bottom of the "Device" Tab.

1.2 Treatment Status Indicator

Colored texts show the condition of the treatment. The orange and red texts refer to alarms. They alert by blinking while the alarm is active. The alarm details will be thoroughly examined by "Help" TAB.

- «Running»(Green)
- «Pause» (Yellow)
- «Please check dressing and connections!»(Orange)
- «Canister is full or clogged!» (Orange)
- «May be leakage!» (Orange
- «Charge the device!»(Red)

1.3 USB Memory Connection Indicator

Appears when USB memory is inserted into the device.

1.4 Battery, Charging and Level Indicator

Indicates that device is charging or the battery level.

Indicator	Description
	Indicates that the device is charging. It does not appear when a faulty or wrong charger is inserted.
	Appears when the battery level is above 90%.
	Appears when the battery level is above 75%.
	Appears when the battery level is above 50%. In this case, you are expected to plug the device into charger with a visual warning.
	Appears when the battery level is above 25%. Device stops therapy. Expected to plug the device into the charger.

Information:

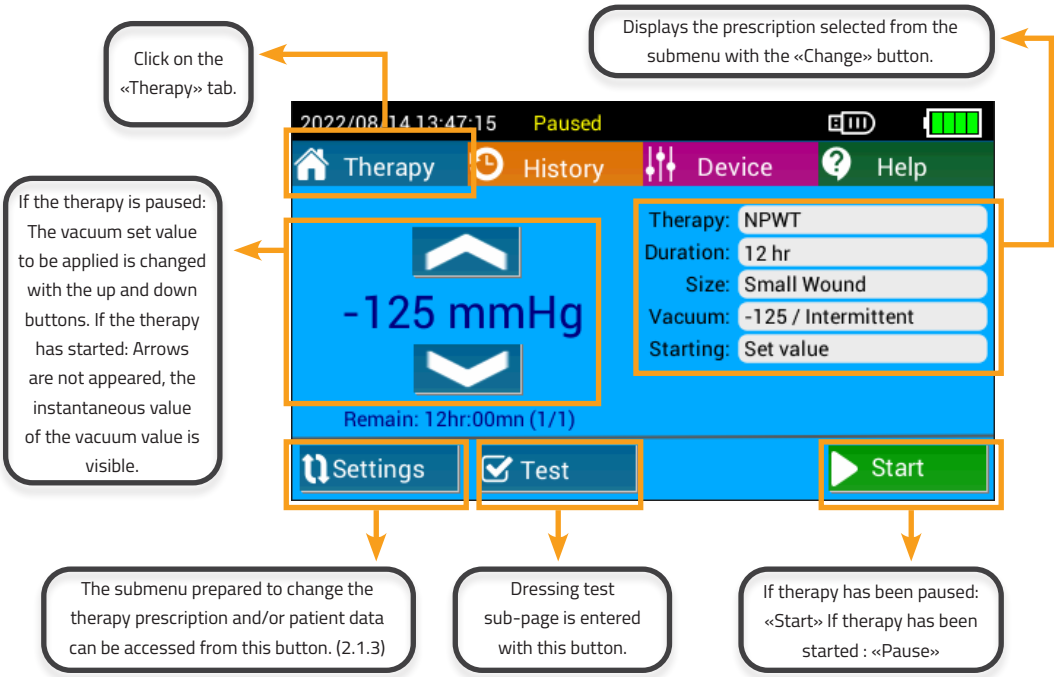
When the device battery is fully charged, it has the capacity to continue the treatment for many hours (although it depends on the size of the wound). However, it is recommended to use the device continuously for charging, for a longer battery life.

2. TABS

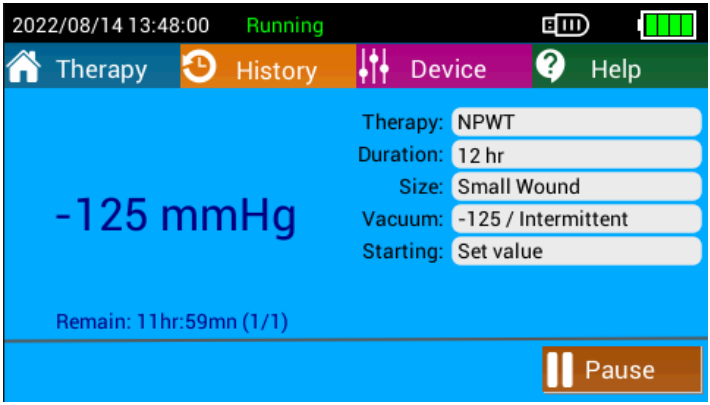
2.1 Therapy Page

This page is the home page of therapy. Therapy selection, dressing test, and treatment start/ pause buttons are located on this page.

2.1.1 Therapy Page (If Treatment is Paused)

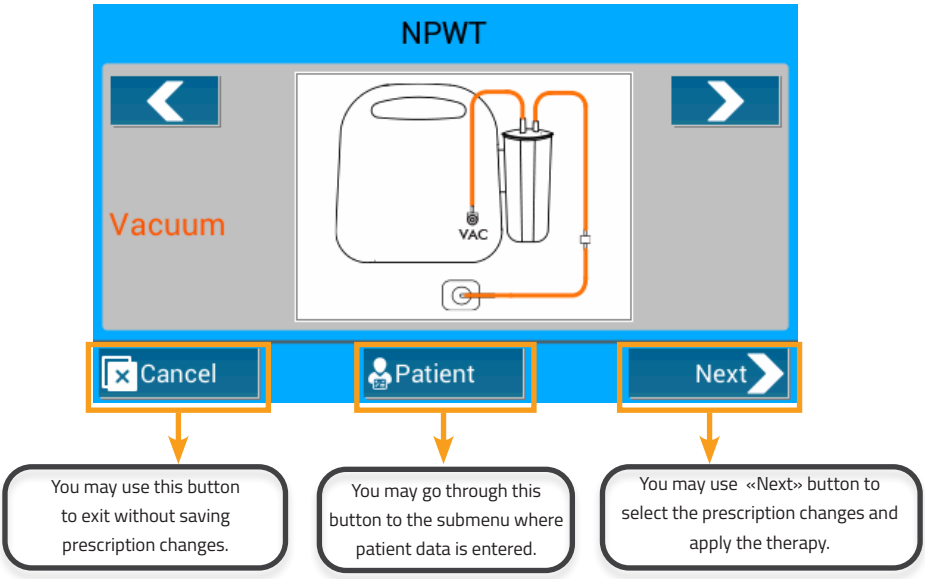


2.1.2 Therapy Page (If therapy has been started)



2.1.3 Changing The Prescription

From this page, you can insert patient data and/or change the prescription of therapy.



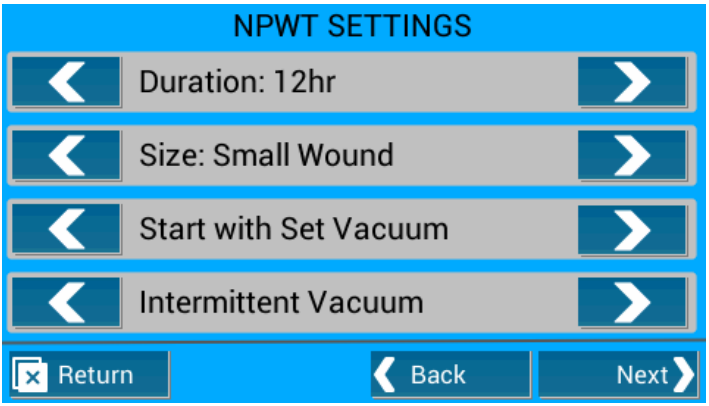
2.1.3.1 NPWT Settings

Duration: Indicates the total time that the treatment will be administered. At the end of this period, the treatment stops.

Size: According to the size of the wound, select "SMALL" for wounds up to 100 cm^2, "MEDIUM" for 101-225 cm^2 wounds, and "LARGE" for wounds larger than 225 cm^2.

Incremental Vacuum: Therapy can be started directly with the set value or gradually increasing. You may select "Start with set value" or incremental vacuum.

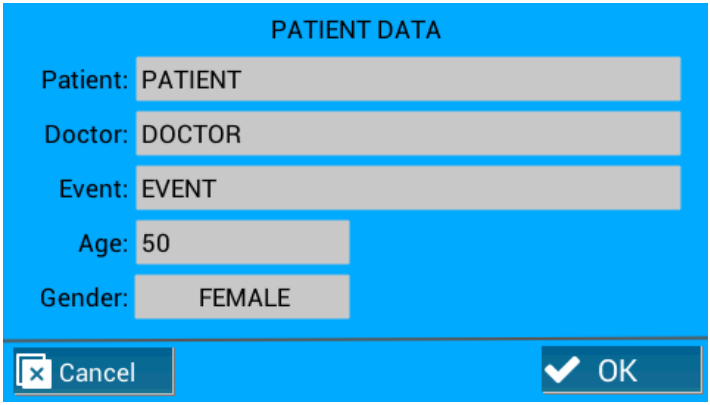
Intermittent Vacuum: It is used to increase or decrease the vacuum in accordance with the parameters in 2.3.1 during the therapy period.

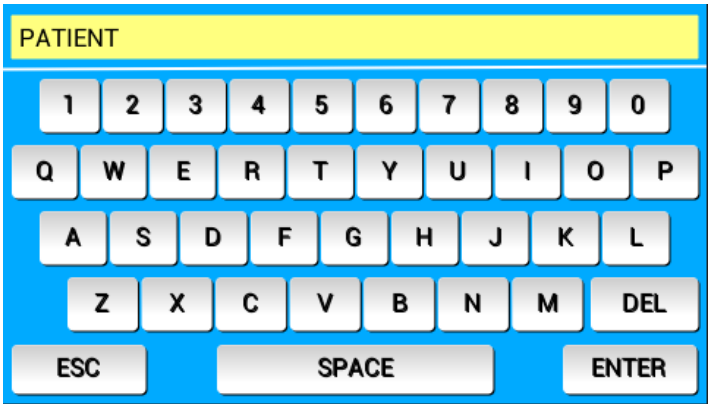


2.1.3.2 Entering Patient Data

Patient data can be entered on this page. QWERTY keyboard or numeric keyboard will appear for the text you want to change. Just click the box for «Gender» data.

Information: QWERTY keyboard has been tried to be prepared in accordance with the keyboard of each language. Each text can consist of up to 30 characters.



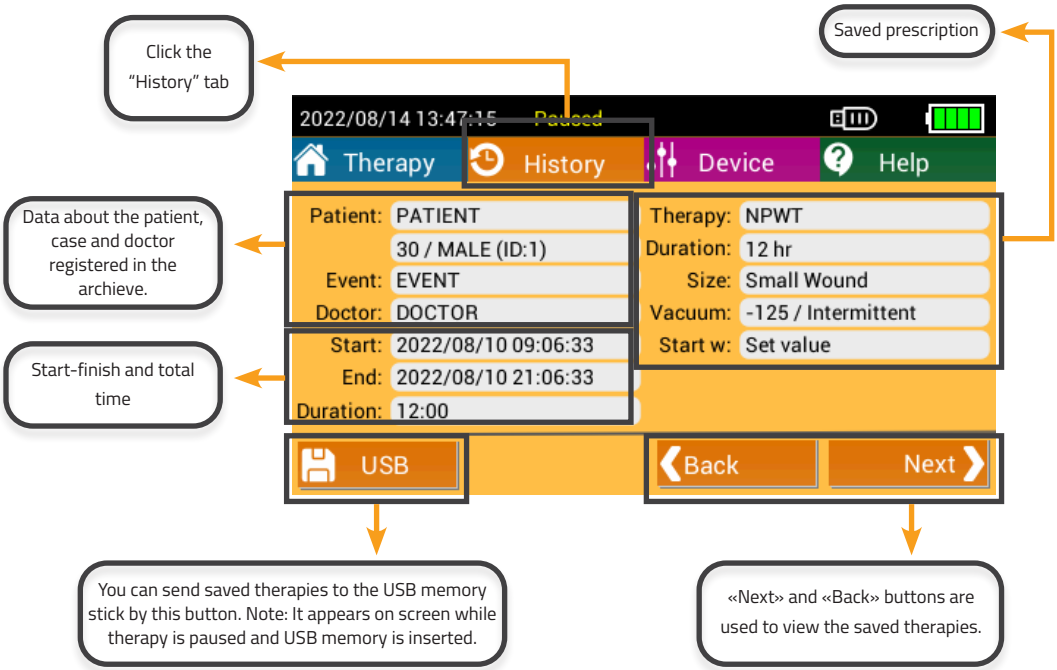


2.2 Therapy History Page

This page is the main page of therapy history. Device can store the data of up to 50 therapies in its own memory. After 50 records, the oldest record is deleted and the new one is added.

Recorded therapies can be transferred to USB memory stick. USB memory stick to be installed should be formatted in the FAT32 file format.

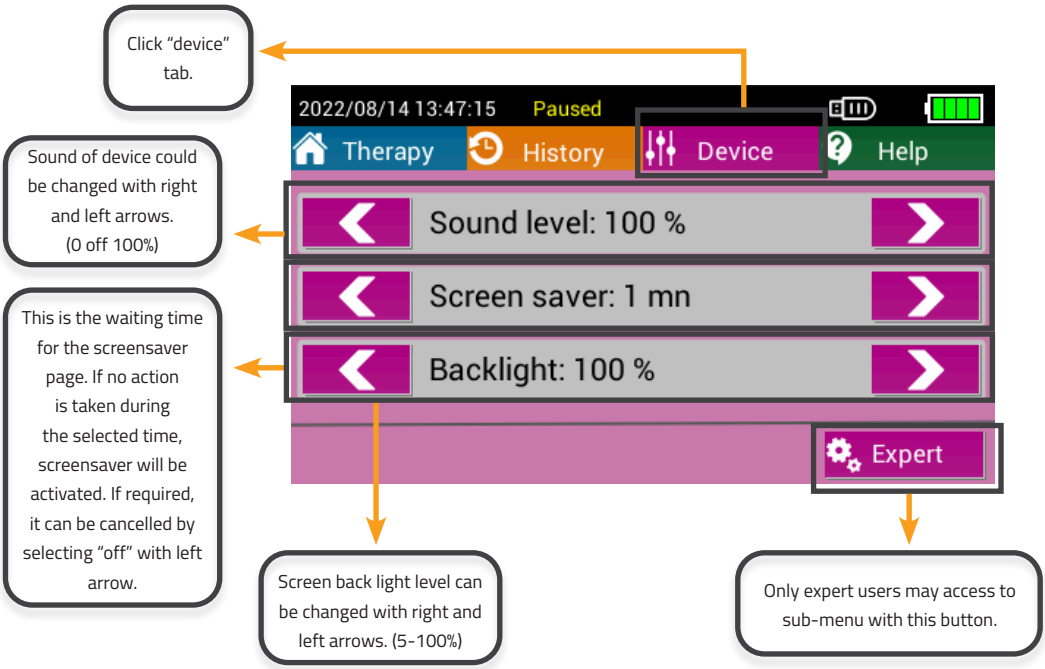
Information: USB port is not suitable for charging purposes.



2.3 Device Settings Page

This page is the main page of the device settings . Patient can modify the screen and audio settings from this page. As well as this, other variables below can be made with the “Expert” button. (Password: 1234)

- System Language change,
- Date time adjustment ,
- Incremental Vacuum Settings,
- Intermittent Vacuum Settings

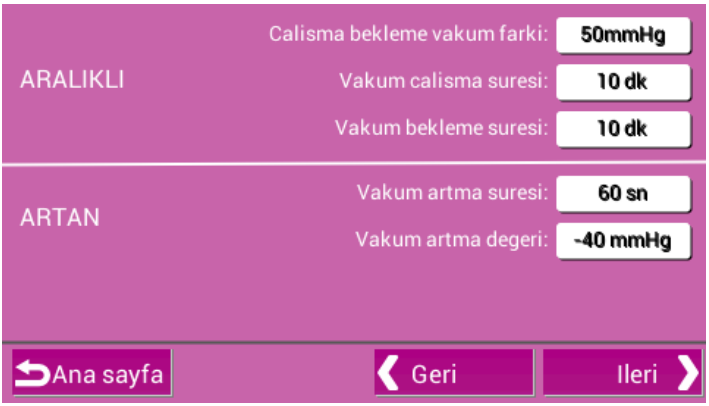


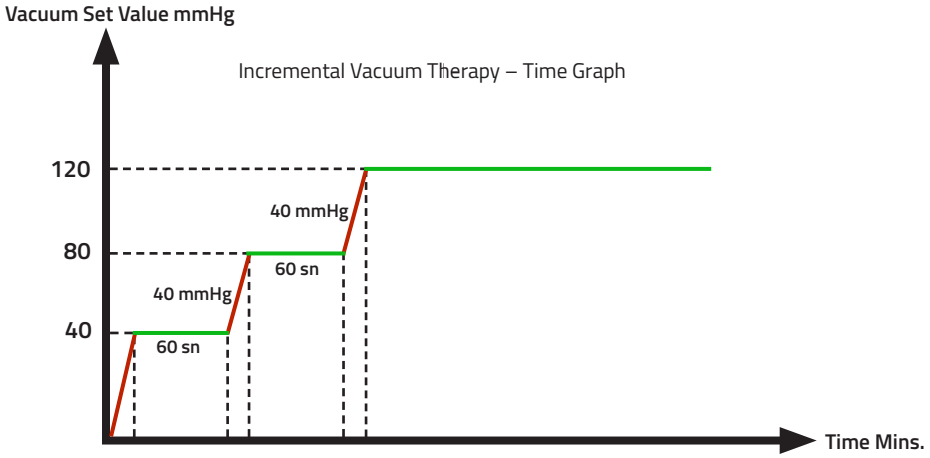
2.3.1 Incremental / Intermittent Vacuum Settings Page (Vacuum Settings)

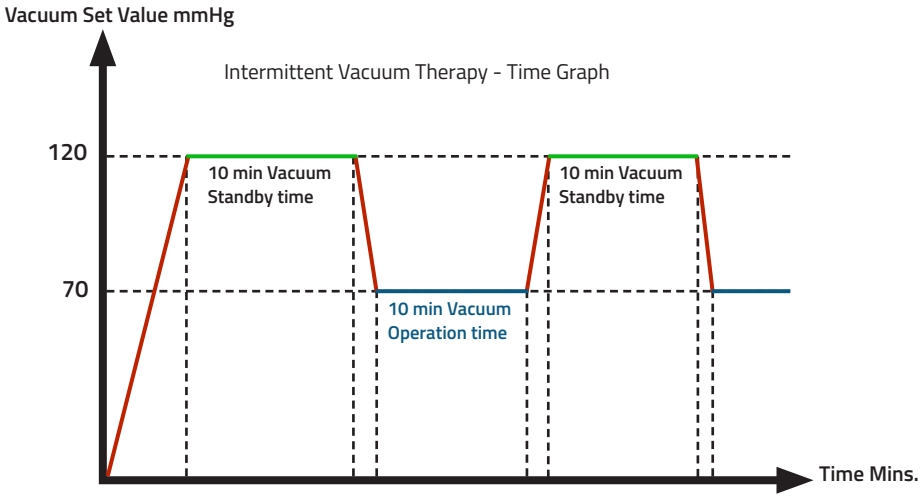
Intermittent Vacuum Settings: Therapy options can be created, as seen in the graph below, with start-pause vacuum difference, values inserted into vacuum runtime.

Incremental Vacuum Settings: As seen in below graph, it is possible to create therapy starting options with the parameters inserted to incremental vacuum duration and incremental vacuum values. This setting is only applied when starting therapy.

Information: Selected therapy type is valid throughout therapy.







2.3.2 Language and Date Setting Page

The system language and date/time of the device can be changed on this page.

Information: After the language change, you will need to change the patient, doctor and case information. Also, when changes to the date and time of therapy started will affect recordings. It is recommended that changes to this page be made before or after treatment begins.

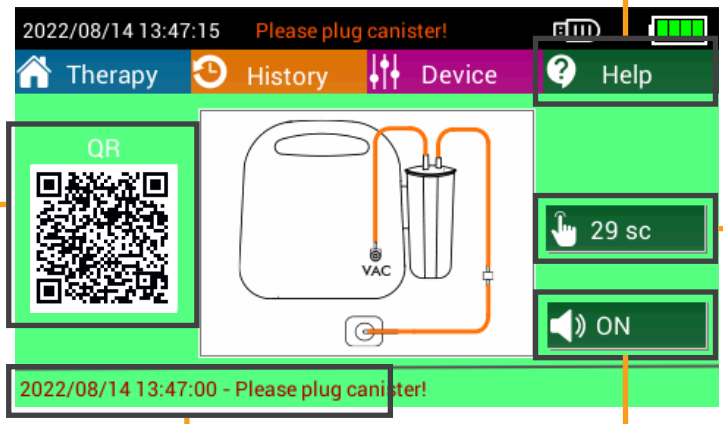
2.4 Topivac Hand T- NPWT Device Help Page

This page has been prepared for the solution of problems that may occur during therapy. When any alarm occurs, you will be redirected to help page.

You may scan QR Code and go to the Help page.

You can read this QR code on your smartphone or tablet for much more information, videos and documents about your therapy and device.

By clicking the "Help" tab or in case of an alarm notification, you will be automatically redirected to this page.



When there is an alarm status, device gives audible alarm . If this button is not pressed for 30 seconds, sound will turn off and this button will not appear on the screen any more. If it is pressed within 30 seconds, it means you have seen the alarm and you will be directed to the «Treatment» tab.

In addition to the description in status bar, it also shows the date and time of the last alarm.

This button may be used to completely mute the device and volume could only be turned up to 50% level. For much more, "Device" tab should be used.

SAFETY INFORMATION

- Read user and maintenance manual carefully before operating the device. This book contains important information about setting up, using and maintenance the device.
- Manufacturer; is not responsible for the consequences of not considering the instructions written below.
- If new device appears damaged, contact your vendor before starting it.
- This device should only be used by trained persons.
- For safety reasons, the device should not be used in any way other than its intended use.
- The user is prohibited from turning on and interfering with the device.
- During maintenance and cleaning activities, disconnect the device from electricity.
- No any surface-scratching mechanical cleaners and acid cleaners should ever be used in device cleaning.

Do not let any liquid get inside the device and USB sockets.

Do not use USB ports for charging.

- Devices are designed to minimize the expected environmental effects (magnetic fields, etc.). EMC tests are within limits. In case of unexpected environmental effects, the charger of the device is to be unplugged.
- The device does not emit any radiation that affects the environment and living things.
- Labels on the device should not be removed and should not be mechanically cleaned in any way.
- Use only original accessories.

If the above rules are not followed, the **TOPIVAC** manufacturer will not be responsible for any problems resulting from personal injury or financial damage. Failure to comply with these rules will void the warranty completely and immediately.

TOPIVAC NPWT DEVICE OPERATING CONDITIONS

A. Temperature: 5 °C / 35 °C

B. Humidity: Between %20 / %90

C. Pressure: Atmospheric pressure

E. Air contioning: Air exchange is not needed.

AVERAGE SOUND PRESSURE LEVEL <55 dB (A)

Given value is measured value with a device at a distance of 1m.

1- The charger is connected to the mains (220V / 50Hz) and the device is operated by pressing the on / off button.

2- Connections of Multi DRESS, multiCASE, canister and pneumatic lines should be made as described in the manual. Attention should be paid that the hoses have been connected correctly.

3- There are impact-protected bags for Topıvac hand devices. Device should be carried in bag and should be protected from impact and humidity during the storage.

SIDE EFFECTS AND WARNINGS

- TopiVac devices are suitable for use with topical vacuum therapy set (multi dress, multicase, canister, ozone bag and topiset).
- User manuals for sets and device should be carefully read before using. The correct therapy should be determined under the supervision of a doctor.
- Using any other accesories has not been tested. Accessories are not recommended except for the use of topical vacuum therapy sets with the device.
- Before starting to use the device, user training should be taken and the user manual should be read. Unauthorized and incompetent personnel should definitely be prevented from using the device. The device does not contain human/animal blood/derivative.
- User, under doctor supervision, should clean the wound area before intervention and debride if necessary, pay attention to the sterilization conditions while opening and using of sterile sets and reduce the risk of contamination using gloves, protective masks, bone, etc.
- Since the wastes are medical wastes, they have to be put in a medical garbage bag, tied up and junked. Disposable connection apparatus supplied with the set should be renewed at each set replacement and thrown into the medical waste bag together with the other set components.
- Device is intended for use by wound care personnel. It should never be interfered with by the patient or his/her relatives. Misuse of device components may result in conditions which may harm the device or the patient. Excessive moistening of the wound bed or inappropriate therapy type selection prevents the treatment from progressing as expected.

- Auxiliary equipment for the set (user manual, ruler for wound area measurement, connection apparatus, sponge trackpad, film drape/s used in the set) are given in disposable and sterile set packages.

CONTRAINDICATIONS

(Warnings/Articles mentioning the situations in which treatment is inconvenient during the disease)

- Presence of eschar (scab) or necrotic (dead tissue) tissue in the wound,
- Development of a malignant (tumor) lesion in the wound,
- Serious infection,
- Untreated osteomyelitis (bone inflammation),
- Fistulas associated with body cavities and organs (tube-like passage),
- Exposed peripheral nerves (peripheral nervous system: includes nerves connecting the central nervous system in our body to internal organs, muscles and skin),
- Areas with exposed blood vessels (arteries or veins),
- Apart from these, the opinions of doctors as applicable or not applicable to the patient, are important. For example, the application of vac therapy in people with high risk of bleeding or unstoppable bleeding diseases depends on the approval of the doctor.
- Etc.

• RESIDUAL RISKS

Risk analysis report; According to ISO 14971 and medical device directive MDD 93/42/EEC and machinery safety directive 2006/42/EEC, risk assessment tables have been examined, and residual risk table assessment has been reviewed. The risks identified as residual risks are the identified and accepted risks of the product. Responsible persons have been informed about the risks. However, the product is thought to contain some residual risks. Measures to be taken at each stage or for significant business interventions include:

SAFE USE OF THE PRODUCT

RISK	Misuse of the device by the user.
PRECAUTION	Providing user manual and training to the personnel who will use the device. Misuse, has been supported by clinical studies and usability studies. There is an interface on the device screen that prevents the use of people who have not received device training.
RISK	Non-compliance of the components of the device with the standards.
PRECAUTION	There may be risks arising from the material. Material tests were carried out. The products used are CE certified. Critical material list separation is made, production is provided according to EN 60601-1 and EN 60601-1-2, and the device has LVD and EMC test report.
RISK	Giving inappropriate energy to the patient.
PRECAUTION	It is produced according to EN 60601-1 and the device has an LVD test report. The energy output from the device is in the range of 4-9 V. This output is controlled by software. Software validation is available according to EN 62304. An adapter working with 12V is used, and the access of the mains to the device is primarily compensated by the adapter. At the same time, there is a protective circuit element on the electronic card.
RISK	Giving unwanted substance.
PRECAUTION	Irrigation liquid to be given to the patient comes out of the multicase irrigation container, passes through the hose and reaches the wound without contacting the external environment. Therefore, mixing with foreign or unwanted substances is prevented.

MAINTENANCE OF DEVICE EQUIPMENTS

RISK	Risk which may arise during device cleaning
PRECAUTION	The device consists of a plastic chassis, is easy to clean and does not need any chemicals. The surface of the device is antibacterial and the consumables used with the device are disposable in a way that does not allow cross contamination. Use suitable clothing and protective gloves.
RISK	The device does not give correct results due to maintenance and calibration.
PRECAUTION	While the device is in production phase, it was subjected to some test such as patient leakage current, chassis leakage current, grounding etc. Devcie performs self control and gives an alarm in case of any negativities.

USE OF ACCESSORIES

RISK	Use of consumables or accessories that are not compatible with the device.
PRECAUTION	Device cannot be operated with any other consumables except for Topiset. In case of using accessories that are not compatible with the device, the device does not give the desired results. The device has disposable consumables and special interconnection apparatuses that will prevent it from working with other devices. It does not pose a risk in an environment that is not safe for the user, the patient.

UNEXPECTED SITUATIONS

RISK	Breakage-deterioration of device parts by exposure to excessive and unexpected force.
PRECAUTION	There is no connection or equipment on the device that allows the user to exert force. Falling, impact, etc. There are warnings in the user manual against physical strengths such as Near the patient, on a flat surface, protected from impact and falling. positioning is recommended.

• RECYCLING INFORMATION

- Old appliances are not worthless garbage! By undergoing an environmentally friendly removal process, very valuable raw materials can be recycled for reuse.
- Regarding waste, regulations on waste management should be taken into account.
- Disconnect old devices from electricity and disconnect the main network cable under the supervision of an Authorized personnel.
- Your new device has been packed in a suitable package to avoid any damage during transportation.All materials used for the packaging of the new device are hazardous for environment and recyclable. You may help to protect the environment by subjecting the packaging to an environmentally friendly disposal and reuse process.
- Do not give packages and packaging parts to children to play with. Due to folding cardboard boxes and foils, they can become stuffy and drown.
- All packaging materials do not pollute the environment and can be reused. No chemical process is applied to the wooden parts.
- Ask your dealer or your local authority about old device removal methods and waste recycling centres.

• GENERAL WARNINGS AND PRECAUTIONS

FOR THE BEST DEVICE EFFICIENCY, PLACE THE DEVICE ON THE SAME LEVEL WITH THE PATIENT'S WOUND.
YOU CAN POSITION THE DEVICE MAXIMUM 50cm DOWN FROM THE WOUND LEVEL.

- It must be applied under doctor's prescription and control.
- Do not use non-original, damaged, deformed, sterilization wound care sets.
- It should be used by trained personnel in wound care and device use.
- Equipment used in the patient (hose, suction cup, canister, etc.) is never used in another patient.
- Hose and equipment connections on the device should be made correctly.
- The general settings of the device are stabile. Prescription selection is made according to the patient.
- Devices are shipped with factory settings and calibrations.
- After each use, the device should be physically cleaned.
- Disconnect the device from the patient using the luer-locks which are close to the closure set.

CARRY/TRANSPORT IT CAREFULLY, KEEP IT AWAY FROM IMPACTS, DO NOT DROP TO THE GROUND.

Never use any adapter other than the original charging adapter that is supplied with the device.

Do not interfere with the device. In case of any malfunction, notify your dealer/ seller.

• TECHNICAL DATA

• **Dimensions:** w:150 mm, d:190 mm, h:200 mm	• **Weight:** 1,65 Kg
• **Charge:** Input 220 VAC 50-60 Hz output 13.8 VDC, max. 2,4W (stand-by use)	• **Working Mode:** Continously, Intermittent, Incramental, Incramental Intermittent
• **Working Mode Setting:** Intermediate Values Can Be Configurated As Minute From The Menu	• **Storage Temperature:** 5 / 50 ^{0}C
• **Patient Work Env.:** 5 / 35 ^{0}C	• **Working Vacuum:** -20 / -200 mmHg
• **Capacity of The Vacuum Pump:** Max. -450 mmHg	• **Vacuum Flow:** 8±2 lt/dk
• **Sound Volume:** Max. 55dB	• **Power Working time:** AC continously, Battery: 6 hrs
• **Alarms:** Audible & Visual	• **Sound:** Max. 55dB (1m)

• CLEANING THE DEVICE

During general cleaning, the device is turned off, unplugged if necessary, and after making sure that safety precautions are taken, cleaning is started in accordance with the following recommendations. Cleaning the device should be done with a damp cloth. During this process, attention should be paid not to allow water to enter the device through the connection points. Chemicals that may damage the surface should not be used. Waste should be put in a medical garbage bag, tied up and junked.

• FAILURE, MAINTENANCE AND CALIBRATION

The system is built from parts that require minimum maintenance. If there is no display on the screen when the device is turned on, the battery charge should be checked. If there is a problem with charging, it should be fixed and the device should be turned on again. If there is no problem in the electrical connection and device still does not work, it should be reported to the authorized service without any other action. Devices are delivered with factory setstings and calibrations.

• PRODUCT COMPATIBILITY

MDD 93/42/EC MEDICAL DEVICES DIRECTIVE STATEMENT

Product : AMEDUS®

Model : TOPIVAC

CE Class : Rule 9, Class IIa

GMDN: 20395

We Commit that Topivac Topical Vacuum Wound Sealer Meets Class IIa Requirements Compliant with MDD 93/42/EEC - 2007/47/EC - Annex II.3 Annex IX Regulation 9.

RELATED STANDARTS

EN 60601-1, EN 60601-1-2, EN 62304, EN 62366-1, EN 20417, EN 14971, EN 15223-1

RoHS DECLARATION

Our company operates worldwide. It is our responsibility to use the environment and natural resources. We certify that all electronic modules comply with the limits described in 2011/65/EU (RoHS) of TEKNOMAR® brand TOPIVAC series products. RoHS compliance has been ensured in all electrical and electronic equipment and materials used in our product, which has been put on the market, and in the service operations provided thereafter, and its use has been ensured under the limits specified below.

Cd	Cadmium	%0.01 ppm
Hg	Mercury	%0.1 ppm
Cr(VI)	Hexavalent Chromium	%0.1 ppm
Pb	Lead	%0.1 ppm
PBB	Polybrominated Biphenyls	%0.1 ppm
PBDE	Polybrominated Diphenyl Ethers	%0.1 ppm

WEEE DECLARATION

The products offered by TEKNOMAR® are only for B2B (in accordance with WEEE directive). After use, products can be returned to us or disposed of by commercial waste disposal facilities.

EMC DECLARATION

We declare that it complies with 2014/30/EC Electromagnetic Compatibility Directive and harmonized standard EN 60601-1.

LVD DECLARATION

We declare that it complies with the 2014/35/EC low voltage directive and the harmonized standard EN 60601-1-2.

PATIENT POPULATION

Our product does not have a special patient population. It can be applied to every patient group with doctor control and prescription.

Warranty

TOPIVAC® is guaranteed for 1 year against manufacturing defects, excluding user errors.

TOPIVAC®
TOPICAL VACUUM TREATMENT UNIT
WOUND CARE

topi.vac

Topivac NPWT

TopiVac Advanced Wound Care

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