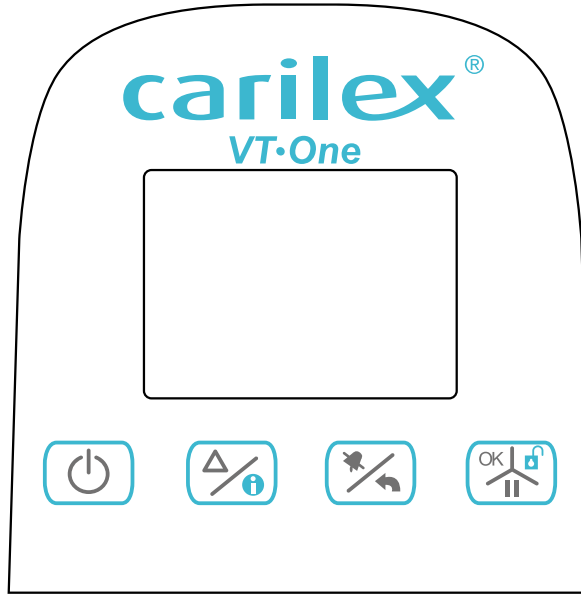
Instructions for Use

Negative Pressure Wound Therapy

Carilex® VT • One



About this document

Thank you for purchasing the product: Carilex® VT • One
Please read these Instructions carefully before use and observe the safety instructions and the requirements for the operation and maintenance of the device.

Device identification

Identification details of the device.
These Instructions for use are intended exclusively for devices with the following specification:
Product name : Carilex® VT • One suction pump
Type designation (Model): VT • One
Art. Number : S1004-XXXX
The serial number is shown on the label on the rear of the control unit.

Validity of the documentation

Details of the device documentation:
This manual describes the Carilex® VT • One suction pump. It is part of the device documentation. Do not pass this device to a third party without these Instructions for use.
For the confirmation of the up-to-date status of the documentation, this manual is marked by an identity number and the date of the edition.

Identification of the documentation

This marking is binding for the validity of this manual and must not be removed regardless of the nature of the publication (in print form, in data form or in excerpts).
No. of the Instructions for use: U-2S1004-30121-G V1.0 Edition
Date : 5/2015

Subject to change

The contents of the Instructions for use may be changed at any time by manufacturer without prior notice.

Translations

For translations into foreign languages, the English version of these Instructions for use are authentic.

Copyright

About this document

Manufacturer

Information of the manufacture
Carilex Medical Inc.
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Sales and Services

For support or complaints
In the event of a complaint, or if you have any questions about the use of the device or a need for accessories, please contact the supplier that delivered the device to you or your patients.

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1 Important notes for safe use

1.1 Designation of the groups of individuals

Named groups of persons

The named groups of persons in these Instructions for use are as follows

Operators
An operator (surgical supplier, health insurance, clinic, etc.) is any legal person, which owns the Carilex® VT • One suction pump and uses it, or on whose behalf the device is in use. The operator is responsible for providing a safe device and to instruct the user properly on the operation and the use of the device.

User
Users are people who are entitled, due to their training or a corresponding instruction, to:

- Operate the Carilex® VT • One suction pump
- Supervise patients using the device for therapy purposes

Users are fully responsible for the safe and correct use of the device. A review of the functions has to be carried out and the proper condition of the device has to be checked and confirmed by the user before each use or transfer for use.

Professionals
The authorized persons are skilled personnel, who are as a rule, the employees of the operator and who:

- Have acquired their knowledge through professional training in the medical-technical field
- Carry out their activity on the basis of professional work experience and instructions according to safety-related regulations and are able to detect possible hazards during work.

In countries in which the pursuit of an activity in the medical-technical area is certified, the classification as qualified personnel is subject to appropriate approvals.

Patients
Patients in the sense of these instructions are persons in need of care, who use the Carilex® VT • One suction pump for therapy purposes.

1.2 Notes for the users

Training on the device

Note that the Carilex® VT • One suction pump should only be used by persons who have been trained in the operation and the intended use of the device.

1.2.1 Instruction
The training of users on how to use the device must be carried out by the qualified personnel of the operator using the device. If the device is approved for the customer, then it is obligatory to comply with the instructions of this guidance.

1 Important notes for safe use

Device approval

1.2.2 Handing over the device

The device may only be used, if the operator has released it for therapeutic use and if the hand over was carried out properly and under the supervision of authorized personnel. After the hand over the users are fully responsible for the safe and dedicated use of the device.

1.2.3 Maintenance and installation

The repair of the equipment or parts can only be carried out by an authorized service agent. Please contact Carilex® Medical, Inc.

Obligations of the user

1.2.4 Information and Test obligation of the user

Read these Instructions for use carefully before the first use of the device. This will allow you to experience all the benefits that the device offers and avoid possible personal injury and property damage.

A review of the functions has to be carried out and the proper condition of the device has to be confirmed by the user before each use or transfer for use by patients.

In case of specific issues, which are not covered enough in detail in these instructions for use, please contact the supplier or operator for further guidance.

1.3 Notes for the users

The Carilex® VT • One suction pump is made according to the current state of the art and is reliable. However, hazards may arise during the use of this device if it is operated by untrained personnel or it is not operated as described in these instructions for use.

Procedures for accident prevention

1.3.1 Handing over the device

In order to comply with the regulations of accident prevention and to prevent accidental damage, the following procedural guidelines are to be followed when handing over the device:

(1)The device must be thoroughly cleaned and disinfected before the first use.

(2)The initial start-up of the device, as well as the hand over to the user must be carried out by an authorized personnel assigned by the operator.

(3)After completion, the training it must be documented that the user has understood the operation and use of the device for special therapy or care purposes.

1 Important notes for safe use

Hygiene measures

1.3.2 Qualification requirements on the hygiene staff

When using the device, the disinfection and cleaning must be carried out on the product or parts only by appropriately qualified personnel, who are familiar with the relevant hygiene regulations.

Obligation to provide information

1.3.3 Availability of the instructions for use

The Instructions for use are an integral part of the device and must be stored in a place so that the safety instructions and other important information are accessible at any time and can reviewed by the users.

Do not pass the device to a third party without these Instructions for use. Using the ID number and the edition date as a guide always ensure that a current and valid Instructions for use document is supplied with the device.

1.4 Purpose of the device

The device meets all the requirements of a medical device class IIa comply with 93/42/EEC and class II comply with 21 CFR 878.4780. To ensure the security of patients and users, the device can only be used for its intended use.

Intended use

1.4.1 Intended use

Carilex® VT • One is indicated for patients who benefit from wound management therapy via the application of negative pressure wound therapy for removal of fluids and excess exudates, infectious material, and tissue debris, which may promote wound healing.

The VT • One suction therapy unit is indicated on use with patients with the following wounds:

- Traumatic
- Dehisced wounds
- Partial-thickness burns
- Chronic wounds including pressure ulcers, diabetic foot ulcers and venous leg ulcers
- Acute wounds
- Flaps and grafts

NOTE

This product is for use only by individuals who have been adequately trained in use of NPWT devices and who have had medical training in wound care. Operating this device or changing the setting should only be done under order of a physician or other qualified clinical caregiver.

1 Important notes for safe use

1.4.2 Contraindications

Contraindicated for patients with the following conditions:

- Presence of necrotic tissue
- Malignancy
- Untreated Osteomyelitis
- Untreated malnutrition
- Exposed arteries, veins, nerves, or organs
- Use over anastomotic sites
- Unexplored or non-enteric fistulas

1.4.3 Precautions

The following statements describe medical conditions that may require special care to be exercised by practitioner for the safe and effective use of the VT•One NPWT device.

(1)Patients on anticoagulation medicine or who have active bleeding or who have difficult wound hemostasis should be treated with caution. These patients are at an increasing risk for bleeding and bleeding complications and should be treated and monitored by properly trained medical caregivers in a controlled setting.

(2)Close proximity of blood vessels, organs, muscle, and fascia. All blood vessels, organs, muscles, and fascia that are in close proximity to the wound site and/ or are exposed and /or are near the skin surface should be properly protected prior to initiating NPWT. Patient with infections in the wound and or other parts of the body have to receive proper systemic treatment.

(3)Irradiated vessels and tissue. These patients are at an increasing risk for bleeding and bleeding complications and should be treated and monitored by properly trained medical caregivers in a controlled setting.

(4)Bony fragments. Sharp edges from bony fragment may puncture blood vessels, organs, muscles, and fascia and may lead to bleeding. Proper care should be taken to cover the bony fragments and protect the wound area and other areas from bleeding.

1.4.4 General Precautions for indication for use

(1)It is important that a physician or other qualified healthcare provider evaluates the patient to ensure that the use of the VT• One is an appropriate therapy.

(2)To reduce the risk of transmission of blood-borne pathogens, regardless of their diagnosis or presumed infection status, all patients should take medical standard operating procedure precautions against infection control.

(3)Caregiver should wear gloves, a gown, and goggles if there is the possibility of contact with the patient's body fluids.

(4)Change dressing if the pump has stopped for more than 2 hours.

(5)Consider mode of therapy- intermittent versus continuous.

1.4.5 Warnings

The following Warning statements describe the potential for serious consequences to the patient, such as death, injury, or adverse reactions. Failure to read and follow all instructions in this manual prior to use may result in death or injury of the patient.

(1)Physician should consider the patients' size and weight when prescribing this device.

(2)The device is not safe for use with an MRI or PET and must be disconnected from the patient prior to MRI or PET.

1 Important notes for safe use

(3)Do not use the VT • One suction pump in a Hyperbaric Oxygen Therapy (HBO) when disconnected from the unit.
(4)The device may be used in the event that defibrillation is needed, provided there is no electrical connection between the patient and the device. In such case, the device must be completely disconnected from the patient. Be especially vigilant about removing wound dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit transmission of electrical energy and/or patient resuscitation.
(5)To prevent unintentional gauze/foam retention, all dressings should be carefully removed from the wound and the entire wound bed. Upon removal of the dressings, the wound bed should be cleaned in accordance with standard wound care practices (or facility guidelines), prior to the application of new sterile dressing.
(6)If necessary, all wounds should be debrided prior to application of the therapy and/or dressings.
(7)Ensure that there are no pockets left in the wound after application of the dressings.
(8)Infected wounds may need more frequent dressing changes, up to twice a day, and the patient and the wound must be inspected regularly for signs of increased infection or sepsis.
(9)Patient who do not have adequate hemostasis and or platelet aggregation inhibitors are being used, have an increasing risk of bleeding with or without the VT • One suction pump.
(10)All arteries, veins, tendons, ligaments, nerves, and organs must be covered completely prior to application of the VT • One suction pump.
(11)The patient with increasing risks of bleeding due to having weakened or friable blood vessels or organs, such as suture of the blood vessel (native anastomoses or grafts) / organs, infection, trauma, and radiation, which, if not controlled well, could be potentially fatal.
(12)Infected tissue such as blood vessels may have a weakened structure and have to be treated with care. Infected blood vessels may bleed more readily than normal blood vessels.
(13)Strangulation resulting from breathing system hoses.
(14)Skin irritation due to prolonged exposure to APPLIED PARTS or other ACCESSORIES.

1.4.6 Exclusion clause for use

Any and all application outside of the conditions specified above is regarded as improper. The user and the operator respectively are exclusively liable for any damage resulting from the improper use.

1 Important notes for safe use

1.5 Markings and certification references

Certificates, standards, guidelines:
The device is a medical product class IIa in the sense of the (MDD) 93/42/EEC and class II in the sense of 21 CFR 878.4780.

Declaration of Conformity
The distributor confirms the conformity of the product with regards to essential requirements in accordance with MDD Annex I and documents this by the application of a CE-mark.

Standards and Guidelines
The device meets the safety requirements of the following standards and guidelines:
DS/EN ISO 14971 - Risk management medical devices

1.6 Warranty

Warranty terms and conditions

The supplier shall ensure the safety and the correct functioning of the VT•One suction pump only under the following conditions:

- The device is used for the intended use and maintained only in accordance with the information provided by these Instructions for use;
- Only original spare parts or accessories approved by the manufacturer are used;
- No structural changes are made on the device;
- Inspections and maintenance work are carried out according to the specified time intervals.

1 Important notes for safe use

1.7 Safety information and symbols of the Instructions for use

The safety instructions in this manual are marked with symbols and key words. Signal words like WARNING, CAUTION or ATTENTION designate the classification of the risk.

1.7.1 Identification of risks of injury

WARNING

Means a hazardous situation, which may lead to death or severe injury if it is not avoided.

CAUTION

Means a hazardous situation, which may lead to minor or severe injury if it is not avoided.

1.7.2 Identification of material damage

ATTENTION

Describes a situation that could lead to property damage if it is not avoided.

1.7.3 Identification of additional information

NOTE

Means application tips and useful information.

1.7.4 Additional symbols to the safety information

Additional symbols to the safety information are those listed below Warning and command signs.

Warning against electric shock

Warning of damage to equipment surfaces

Advice to wear safety goggles

Advice to wear safety gloves

Advice to wear mouth and nose protectors

1 Important notes for the safe use

1.8 Symbols on the device

The following symbols are attached to the control unit of the negative pressure wound therapy.

Conformity marking: confirms the conformity in accordance with the guidelines of the EU.

Follow instructions for use.

Type BF Equipment

This product is designed for separate collection at an appropriate collection point. Do not dispose of as household waste.

Manufacturer & Date of Manufacture

Do not re-use

Packaging unit for canisters of VT • One

Rx only

Federal (US) law restricts this device to sale by or on the order of a physician.

Do not use if package is damaged or open

1 Important notes for the safe use

1.9 Safety Instructions before use

(1)The VT • One suction pump can only be administered by persons who have been trained in its operation according to the instruction guidelines issued by the supplier or qualified medical staff.
(2)Before using VT • One as a vacuum source and treatment system, please read the indications, warnings, precautions and contraindications.
(3)Check function of the unit prior to use.
(4)Never connect the power supply adapter to defective power sockets.
(5)Keep power supply adapter and cable away from external heat sources. DO NOT cover the power supply adapter.
(6)The device should not be charged or started up:
If the power cord or plug are defective;
If the device is not functioning properly;
If the device has been damaged / dropped;
If the device has been dropped into water;
If obvious defects might restrict safe operation
(7)In any case, remove the power supply adapter from the electrical socket and have the unit checked by qualified personnel authorized by Carilex® Medical Inc.
(8)The VT • One suction pump must be placed carefully and securely at the patient's bedside with optional VT accessories. An optional carrying bag is available for mobile use; however, it is the responsibility of the clinician or trained caregiver to determine if the patient's condition allows for mobile use. It must be ensured that in between different patients use the bag is disinfected or a new bag is used.
(9)The VT • One suction pump must never be used to remove explosive gases and inflammable or corrosive fluids.
(10)The unit must not be operated in damp rooms or when taking a bath or shower.
(11)Avoid moisture on plug and switches. Never plunge the unit into water or liquids, not even when it is switched off.
(12)The unit must not be operated in splash water range or in locations where there is a danger of explosion.
(13)Operation of the VT • One suction pump is possible while the battery is charging.
(14)Pay attention to the ambient conditions described in the technical data.
(15)If the unit is operated at ambient temperatures outside the stated temperature range (see "Technical Data"), the performance may be reduced and the unit or the electronics and battery may get damaged.
(16)The unit should be operated on a firm, level surface.
(17)When the device is switched on, DO NOT leave it unattended.
(18)At regular intervals, parts of the unit should be checked for correct function and safety-related defects, please refer to service manual.
(19)The VT • One suction pump must be switched off and disconnected from power supply adapter before cleaning and maintaining the unit.
(20)The VT • One suction pump is a medical device not a toy. Keep away from children, and pests as they can damage the dressing and therapy unit and affect performance. Keep Therapy unit free of dust and lint.
(21)Advise patient to NOT SUBMERGE therapy unit or dressing in liquid and to ensure therapy unit is not pulled into a tub or sink where it may become submerged.
(22)Only use original, genuine Carilex® Medical accessories and spare parts.
(23)The unit must only be used with a genuine VT • One collection canister.

2 Delivery and storage

2.1 Packaging

The VT • One suction pump is supplied sturdy cardboard packaging. All packaging materials are recyclable and can be separated: Packing: Cardboard, waste paper

2.2 Models

Art. No.	model	Spec.
S1004-0012	Carilex® VT • One suction pump	Good for general NPWT purpose.

2.3 Delivery control

Check immediately after delivery of the device:
- The completeness of the delivery
- The delivery status of the device

The VT • One suction pump is delivered with the following components:
(a) One suction pump power unit
(b) One VT • One canister
(c) one Power supply
(d) One VT • One instruction for use
(e) Carrying bag (Optional)
(f) Portable bag (Optional)

If the delivery is incomplete or the device and/or the packaging are damaged, in particular in the case of damage caused by moisture or water, you should promptly inform the carrier, as well as the supplier.
When first turned on, the VT • One pump needs to be attached to a wall outlet in order to fully charge the battery.

2.4 Operating & Transportation & Storage

Recommended transportation, storage and environmental conditions:
- Operation temperature: 5˚C (41˚F) - 40˚C (104˚F)
- Transportation & storage temperature range: -25˚C (-13˚F) - 70˚C (158˚F)
- Relative humidity range: 0% - 93%
- Air pressure: 700 hPa - 1060 hPa

ATTENTION
Storage of the VT • One
- Keep away from high voltage
- Keep away from humidity
- Keep away from heat
- Keep out of the reach of children
- Should be stored in the box properly
- Do not put any other extrinsic object

(a) Power unit

(b) VT • One canister

(c) Power supply

(d) VT • One instruction for use

(e) Portable bag

(f) Carrying bag

For long-term storage the control unit should be covered with a dust protector and battery needs to be removed from its outer-case and to be recharged every 3 months.

3 Device and functional description

3.1 Device description

Power unit
The Power unit 1 is used as the housing for the compressed air unit as well as the compressed air system and also features:

- A control panel 2 with buttons to turn unit on/off and select functions.
- Display panel 3 for information.
- Canister 4 to collect fluid.
- DC socket 5 to connect to power cord.

Power Cord and Charger
The power cord charger 6 consists of :

- Sinpro Electronics Co. Ltd. (HPU15-105) AC/DC adapter.
- 4 detachable plugs.

How to Replace the Plug 7

1. Press the 'PUSH' tenon and hold
2. Push the plug towards OPEN arrow
3. Replace with the suitable plug

(Select the correct AC adaptor plug for your country then plug into the main outlet)

ATTENTION
When change to a different AC adapter plug, make sure that the plug is firmly connected, until you hear a "click" sound. Failure to do so will cause power failure.

Carrying Bag 8
The Carrying bag for Power Unit

- Portable Case
- Belt

Portable Bag 9

- The Portable bag for canister and adaptor

Quick User Guide

- Quick User Guide for the VT • One

Instruction for Use

- Instruction for use for the VT • One

NOTE
*Please read the instruction for use prior to first use

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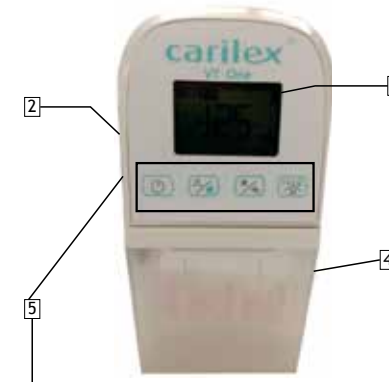

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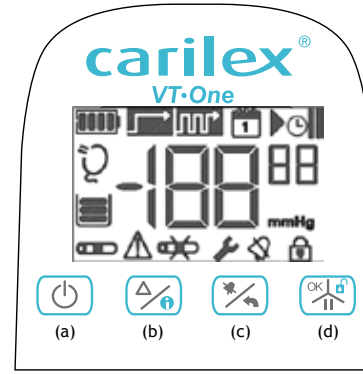
3 Device and functional description

3.2 Functional description

Carilex® VT • One suction pump is a Negative Pressure Wound Therapy device that has been prescribed by your healthcare provider. This device has shown that it may help promote the healing of several different kind of wounds.
When in use, negative pressure (suction) is delivered to the wound through the pump. The suction of the pump will help remove excess fluids from the wound and may help close the wound. A special dressing will be placed onto your wound by healthcare professional and a tube will be connected from your wound to the canister on the pump. After the dressing and tube are correctly applied and connected, turn on the VT • One device and set to the pressure setting that is prescribed by your healthcare provider. The VT • One canister will then collect the excess fluid.



Function of the control unit
The vacuum air suction pump in the control unit suck the air from the wound through the connecting hose and dressing to create a negative pressure environment of the wound.

CONTINUOUS MODE:
When employed there will be same negative pressure as selected apply in all time.
INTERMITTENT MODE:
Therapy unit changes between high and low pressure range in fixed time interval settings.

Panel of the control unit
(a) On / Off

(b) Select / Info

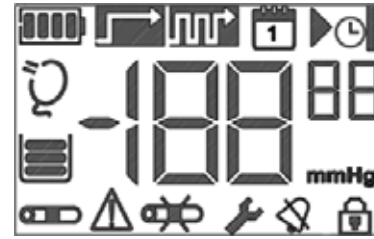
(c) Mute / Return

(d) OK / Unlock / Pause

4 Preparation to get started

Symbols on the Display

	Battery status
	Low Power
	Canister full
	Leakage Indicator
	Blockage Indicator
	Blockage Indicator when indication is disabled
	Call for service
	Mute
	Panel locked
	The machine is operating
	Pause
	Continuous Mode
	Intermittent Mode
Lifetime already used in days and hours	



4 Preparation to get started

NOTE
Before using, please inspect the dressing kits to make sure there is no damage to the packaging, which may comprise the sterility of the contents.DO NOT use the contents of a damaged package; instead, dispose it properly.

4.1 Battery

Charging instruction for battery
Select the correct AC adapter plug for your country. Connect the power supply adapter to the AC main outlet and open the protective rubber cover of the unit for Direct Current (DC) socket. Moving bars on the battery display will indicate charging is occurring.

ATTENTION
When changing to a different AC adapter plug, make sure that the plug is firmly connected until you hear "click" sound. Failure to do so will cause power failure. Upon initial receipt of the VT • One suction pump and prior to first use, charge the battery for at least 4 hours in order to create optimum battery memory and to maximize the number of charging cycles over the lifetime of the battery.

4 Preparation to get started

ATTENTION

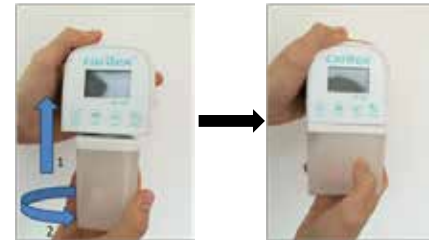
The battery must be fully charged prior to first use of the VT • One suction pump. If therapy unit is in warehouse / inventory and not used for more than three months, the battery needs to be recharged.

VT • One is equipped with a Li-ion battery. The battery will discharge depending on the run time of the therapy unit and through extended periods of inactivity.

Depending on usage, the battery life cycle is 300 times approx. Storage and usage of the battery must be within the temperature ranges stated in the section under “Technical Data”.

NOTE

Please dispose of the battery in accordance with local or facility guidelines.



4.2. Collection Canister

Always make sure the canister is properly inserted and hear "click" for proper engagement, and must remain in an upright (carrying case) or lying (display side up) position during use.

The VT • One suction pump is protected against the penetration from solid / fluid substances by a hydrophobic membrane integrated together with an activated carbon filter. If this filter fails, the VT • One suction pump must be replaced.

1. Insert the VT • One Canister into VT • One connecting port. Keep Canister vertical with VT • One pump (Level marker on the left side)
2. Rotate the canister clockwise to fully engage. Please make sure hear "click" after canister is fully engaged and the level markers side in the same direction as display.

The VT • One system is designed for detecting when canister is full. When the liquid absorber reaches the canister full level, the audible and visual indicators will be triggered and the message indicator “canister full” will be displayed on the display panel. Do not pull the tubing of the canister horizontally to avoid the breaking of the suction inlet on the canister.

The VT • One collection canister is to be properly discarded when full; it must be replaced after every patient use. The canister should also be inspected and replaced weekly or between patient uses or otherwise as needed.

NOTE

The VT • One canister is designed for single patient use only. **DO NOT re-use the canister to avoid the cross infection in between the patients.**

4 Preparation to get started

4.3. Dressing

Only Genuine Carilex Dressing Kits are to be used in conjunction with the VT • One system and must be in sterile condition. Carilex Dressing Kits should be applied in accordance with the Dressing Kit Instructions for Use, supplied with the dressings.
An intensive, thorough wound cleansing should be performed by a physician or trained caretaker prior to dressing application.
Routine dressing checks and changes should be performed every 48hours or according to the facility protocol or physician order.

Before using, please inspect the dressing kits to make sure there is no damage to the packaging, which may comprise the sterility of the contents.

NOTE
DO NOT use the contents of a damaged package; instead, dispose it properly.
DO NOT re-use the dressing kit to avoid cross infection. Follow IFU for dressing kits.

5 Operation Procedure

5.1 Check points before using VT • One

Before using the VT • One, it is important to check for the following point:

- Damage to the power cord and plug
- Damage to the pump
- Completeness of the packaging
- Battery status

5.2 Insert Canister to the VT • One

(Please follow instruction on 4.3 collection canister)

(1)Insert the VT • One canister into the VT • One suction pump connecting port.

(2)Rotate the canister clockwise to fully engage.

Please make sure the level markers on the VT • One is on the same side as the display screen.

5.3. Connect the VT • One tubing connector to Carilex Dressing kit tubing connector, and screw tightly to ensure airlock.

WARNING

Electric shock!

The touching live parts can result in a death or serious injury by an electric shock. Check for damage of the plug and the main power cable of the control unit before connecting.

- Damaged components may not be used for connection.

5.4. Turn the unit On/Off

(1)On-Switch VT • One suction pump on by pressing the on/off key for 3 seconds.

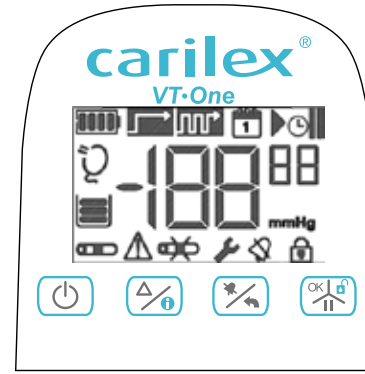
(2)Off-Switch VT • One suction pump off by pressing the on/off key for 3 seconds. VT • One suction pump will turn off display screen will darken

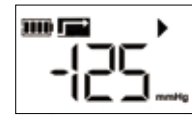
5.5 Therapy Mode Setting

(1)Turn on the power unit, the screen will start blinking Press to select therapy mode.

(2)Press to choose therapy mode.

(3)Press to adjust pressure level.





Continuous mode ( )

Intermittent mode ( )

5 Operation Procedure

Pressure setting for **Continuous mode** ( )

(1)When the screen shows , press to choose continuous mode.
(2)Press to change the constant pressure level from -50 mmHg to -150mmHg. Default pressure for continuous mode is -125 mmHg.

Pressure setting for Intermittent mode ( )
(1)When the screen shows , press to choose intermittent mode.
(2)Press to change the high pressure level from -50 mmHg to -150 mmHg. Default high pressure for intermittent mode is -125 mm Hg.
(3)Press to confirm high pressure.
(4)After setting the high pressure level, the screen will start blinking again. Press to select the low pressure level of intermittent mode from -20 mmHg to -40 mmHg. Default low pressure for intermittent mode is -20 mmHg.

Note
Intermittent mode is pre-set at fixed alternating time for 5 minutes High and 2 minutes Low.

ATTENTION
The pressure may only be changed when instructed by a physician or qualified healthcare professional.

5.6. Select/Info

Press to select therapy modes and pressure level.
Press for three seconds to see usage time.
Usage time in days
Usage time in hours

5.7. Blockage / Leakage alert indicator setting mode (Optional)

The VT• One suction pump provides the option for the operators to choose the sensitivity for the blockage/leakage indicator or disable the blockage/leakage indicator. Adjusting the sensitivity of blockage/leakage indicator may influence the VT• One's function, all setting changed should be under physician or qualified medical caregiver's order. The physician or qualified medical caregiver should consider patient and patient wound's condition to determine the appropriate sensitivity for patient.

Disable blockage/leakage indicator may increase risk of exudate accumulation, infection, maceration or loss of Negative Pressure Wound Therapy (NPWT) as blockage/leakage occurs in the vacuum system.

Disable blockage/leakage indicator should be under physician or qualified medical caregiver's order. In the event of disabled blockage/leakage indicator, regular monitoring and more frequent dressing changes may be require.

The patient, device and dressing should be carefully monitored to check if there are any signs of bleeding, exudate accumulation, infection, maceration or failure of Negative Pressure Wound Therapy (NPWT). The frequency should be determined by the physician or qualified medical caregiver based on individual characteristics of the patient and wound.

The blockage/leakage notification function of VT• One suction pump may be influenced by various conditions based on system configuration, set-up and individual characteristics of the patient and wound (e.g. exudate characteristics, wound size). In addition, VT• One is not designed to detect or issue an alert condition based on the presence of bleeding or pooling. These conditions may only be detected by frequent monitoring.

If partial blockage/leakage occurs, the change in pressure status detected by power unit may not be significant enough to activate blockage/leakage indicator. Over time if fully blockage/leakage occurs, blockage/leakage indicator will be activated.

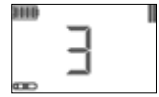
If a fully occlusion occurs in the system, but an air leak is present between occlusion and device, the blockage indicator may not activate. Ensure all connections are secure and no air leaks are present in system.

Blockage formation within the wound dressing may not trigger blockage indicator because it has occurred outside of the monitored vacuum system; however, it may influence the pressure status at the wound site. It is highly recommended that wound dressing should be appropriately frequent monitored in order to confirm adequate delivery of therapy.

5 Operation Procedure

Enable/ Disable the blockage alert indicator

Press and simultaneously for 3 seconds during therapy mode, Press to select modes until the following symbol appears on the display:



Press to select the sensitivity of blockage indicator or disable the blockage indicator.

: Blockage indicator disabled

: Low sensitivity

: Medium sensitivity

: High sensitivity (default)

After choose the appropriate sensitivity of blockage indicator, press to go back to selected therapy mode. Adjusting the sensitivity of blockage indicator may influence the VT• One's function, all setting changed should be under physician or qualified medical caregiver's order. The physician or qualified medical caregiver should consider patient and wound's condition to determine the appropriate sensitivity for patient.

5 Operation Procedure

Enable/ Disable the leakage alert indicator

Press and simultaneously for 3 seconds during therapy mode. Press to select modes, until the following symbol appears on the display:

Press to select the sensitivity of leakage indicator or disable the leakage indicator.

: Leakage alert indicator disabled

: Low sensitivity (25mmHg tolerance)

: Medium sensitivity (15mmHg tolerance)

: High sensitivity (default; with no tolerance)

After choose the appropriate sensitivity of leakage indicator, press to go back to selected therapy mode. Adjusting the sensitivity of leakage indicator may influence the VT• One's function, all setting changed should be under physician or qualified medical caregiver's order. The physician or qualified medical caregiver should consider patient and wound's condition to determine the appropriate sensitivity for patient.

5 Operation Procedure

5.8. Mute/ Return

Press to mute the pump when acoustic signals occur.
When the pump is operating in CONTINUOUS MODE, press to adjust pressure level.
When the pump is operating in INTERMITTENT MODE, press to adjust pressure level.
Press three times to go back to therapy mode selection.

The VT • One suction pump is made from various electronics and plastics. When the VT • One suction pump is ready for disposal, facilities should follow the local governing guidelines regarding sanitation of disposed device components.

The used canisters, tubes and dressings should be disposed according to the local or facility guidelines for handling infected or bio-hazardous materials. None of the items should be disposed together with household or facility refuse. Incorrect disposal can have harmful effects on the environment and public health.

5.9.Change VT • One canister

The VT • One canister has to be changed on the basis of a visual check or according to the instructions on the display.
The VT • One system is designed for detecting when canister is full.
When the liquid absorber reaches the canister full level, the audible and visual indicators will be triggered and the message indicator “canister full” will be displayed on the display panel.
Do not pull the tubing of the canister horizontally to avoid the breaking of the suction inlet on the canister.
The VT • One collection canister is to be properly discarded when full; it must be replaced after every patient use.
The canister should also be inspected and replaced weekly or between patient uses or otherwise as needed.

NOTE
DO NOT re-use the canister to avoid the cross infection in between the patients

The procedure of changing canister:
(1)Wash hands and wear disposal gloves.
(2)Switch the VT • One suction pump off by pressing for 3 seconds.
(3)Close the clip on both dressing and canister's side, and then disconnect the VT • One canister connector from the dressing.
(4)Detach the full canister by rotating the canister counter clockwise. Discard the used canister followed by local governing guidelines.
(5)Attach a new VT • One canister to VT • One suction pump. (Refer to 4.3 collection canister)

6 Error Indicators

6.1 Error Indicators

If VT • One suction pump detects any of the following situation, the light for display screen always turns on and acoustic warning signal sounds simultaneously. By pressing the mute key, the acoustic indicator is suppressed. However the orange light is always blinking (1sec on/1sec off), until the issue is resolved.
Error message appear on the display

Error Message	Display	Possible causes	Remedy
Leakage		Dressing is not tight. Tube is not well connected or leakage occurs in the dressing.	Press ⏻ for 3 seconds to turn off the pump. Check the system for leakage. Turn on the pump again after leakage issue is resolved.
Blockage		Tubing is kinked or clip closed. Tube clogged.	Press OK to continue therapy. Check the system for blockages. If the blockage issue is still not resolved, blockage indicator will happen again.
Canister Full		Canister full	Press OK for 3 seconds to turn off the pump. Replace with new canister.
Low Battery		Battery low	Press 🔇 for 3 seconds to mute the acoustic signal. Charge battery. The visual symbol blinks and acoustic signal will be activated until battery is empty. The remaining time of the battery is approximately 10 minutes.
Call for Service		Internal fault	Press ⏻ for 3 seconds to turn off the power unit. Please contact your authorized local distributor for assistance.

7 Application of the Negative Pressure Wound Therapy

7.1 Application of the Negative Pressure Wound Therapy

CAUTION

Compliance with the hygiene regulations!

Basic cleaning

The components of the Negative Pressure Wound Therapy are not supplied in a sterile condition. Clean and disinfect the components before the first use.

CAUTION

During the application of the alternating pressure and constant higher pressure system, the periwound skin and wound of the patient must be regularly checked for pressure marks by a medical staff or by a care personnel, or the caring person provided the patient is in a nursing home. Dressing must be regularly checked to avoid blockage and leakage.

CAUTION

Loose power cord may cause tripping and serious injury

CAUTION

Improper use of VT • One may cause pain and injury to the patient.
Excessive negative pressure or an infection of the wound may cause pain and injury to the patient.

8 Disinfection and cleaning

In order to prevent cross-contamination, the disinfection and cleaning of the entire Negative Pressure Wound Therapy must be carried out between use with different patients. If there is a notifiable disease according to the Federal Law concerning Epidemics, a hygiene expert must be consulted if necessary prior to the disinfection and cleaning.

Check electrical components

WARNING

Electric shock!

Water has a high electrical conductivity. Contact with liquid under voltage can lead to a fatal electric shock. For the disinfection and cleaning operations:

- Turn off the control unit.
- Unplug the plug from the power socket.

CAUTION

Health hazard!

The contact with contaminated cleaning fluids can cause infections. Disinfectants can contain harmful substances.
Please follow the Instructions for use of the manufacturer of the disinfectant and the hygiene of the operator during the disinfection and cleaning.
Wear personal protective equipment:

- Safety glasses;
- Protective gloves;
- Mouth and nose protectors

ATTENTION

Incompatible cleaning agents!

The parts of the Negative Pressure Wound Therapy are made of plastics. Solvents can undo plastics and coating. Strong acids or alkalis can cause embrittlement of the plastics.
Cleaning the power unit:

- Do not use hydrocarbon solvents, detergents containing alcohol or acids or alkalis,
- Do not use any abrasive cleaning materials.

Incompatible disinfectants!
Cleaning the control unit:

- Only use disinfectants without chlorides, halides,
- Do not use disinfectants containing gasoline, paint thinner, alkaline, acid, alcohol, or aldehyde (e.g. ethanol, propanol).

In order to avoid the embrittlement of plastic parts:

- Do not use disinfectants containing alcohol.

8 Disinfection and cleaning

8.1 Disinfection and Cleaning

Hygiene requirements of the operator

The operator must be notified about the measures which apply to the Negative Pressure Wound Therapy and the actual hygiene directives for the disinfection. The disinfection of the Negative Pressure Wound Therapy or parts of it can be performed only by cleaning experts, who are familiar with the hygiene requirements of the institution.

Disinfection procedures

For the control unit a manual disinfection is achieved by wiping the parts.

Disinfection procedure

Operations of disinfection

The manual wiping disinfection is carried out in three steps:

- Pre-disinfection
- Cleaning
- Controls

Pre-disinfection

(1)Wear surgical gloves and surgical mask.
(2)Wash hands with 75% alcohol or other cleansers in accordance with local Competent Health Authority regulation.
(3)Wipe the surfaces with disinfectant.
(4)Allow the disinfectant to take effect according to the manufacturer's instructions.

Cleaning

(1)Use 75% alcohol to wipe off dirt and dust accumulations for disinfection.
(2)Wipe the surfaces with a clean soft cloth and clear water. 3.Dry all the surfaces with a clean soft cloth.

Controls

Check the function of the control unit

⚠ CAUTION

Risk of injury by improper repair!

For repair, please contact Carilex Medical, Inc.

9 Care and maintenance

9.1 Inspection

The safe operating condition of the Negative Pressure Wound Therapy has to be checked at each use by the operator (the competent medical trading partner) or during the use by the patients at least once in a year in particular with regards to the following:

- Function of the control unit with pressure control and control markings
- Condition of the compressed air hoses and connections

9.2 Maintenance

When the VT • One suction pump is not in use, please remove the battery from the case and charge battery every 3 months.

10 Troubleshooting

10.1 Troubleshooting chart

Problem	Inspection procedure	Possible solution
Power unit does not function	1. Check if power cord is firmly plugged into wall outlet	1. Secure power cord into wall socket
	2. Check if battery is empty	2. Connect the power supply adapter to the electrical outlet to recharge battery
Insufficient performance	1. Chec k if the tube is partially kinked or the clip is engaged	1.Release clip, or remove kinks or check the system for blockages.
	2. Check system for leaks	2. Connect the tubing / canister properly. Seal dressings properly.
	3. Check if battery is almost empty	3. Charge the battery
No suction	1. Check if the tubing is not blocked	1. Release clip, remove kinks or check the system for blockages.
	2. Check if the canister is full	2. Replace the canister
If power unit does not respond to the possible solution, please contact your authorized local distributor for assistance.		

11 Technical data

Classification

11.1 Technical data

Control unit

Medical device .....Class IIa (comply with 93/42/EEC ..... Class II (comply with 21 CFR 878.4780)

Model ..... VT • One
Dimensions.....15 x 8.5 x 5 cm
Weight (with empty canister).....350 g
Nominal voltage..... 12 Vdc Rated
Power input 100-240Vac 47-63Hz
Power output 12Vdc 1.25A
(Max) Class.....II
Protective type..... BF
Double insulated and with functional ground wire This system is not AP/APG protected.
Continuous operation
IP22 protected against ingress of solid foreign objects up to 12.5mm diameter (finger) and direct vertical sprays of water up to 15

Disposal

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

Disposal of old electrical and electronic equipment - valid in the European Union: 2002/96/EC (WEEE)

The VT • One suction pump is made from various electronics and plastics. When the VT • One therapy unit is ready for disposal, facilities should follow the local Environmental guidelines regarding sanitation of disposed device components. The used canisters, tubes and dressings should be disposed according to the local or facility guidelines for handling infected or bio-hazardous materials. None of the items should be disposed together with household or facility refuse. Incorrect disposal can have harmful effects on the environment and public health.

12 Electromagnetic Compatibility

This equipment has been tested and found to comply with the limits for medical device to IEC 60601-1-2-2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

Guidance and manufacturer's declaration-electromagnetic emissions

The VT•One, S1004 is intended for use in the electromagnetic environment specified below. The customer or the user of the VT•One, S1004 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The VT•One, S1004 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The VT•One, S1004 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	

Guidance and manufacturer's declaration-electromagnetic immunity

The VT•One, S1004 is intended for use in the electromagnetic environment specified below. The customer or the user of the VT•One, S1004 should assure 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 + 8 kV air	+ 6 kV contact + 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	+ 2kV for power supply lines + 1kV for input/output lines	+ 2kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+ 1kV line(s) to line(s) + 2kV line(s) to earth	+ 1kV differential mode Not applicable	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 VT•One, S1004 requires continued operation during power mains interruptions, it is recommended that the VT•One, S1004 be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The VT•One, S1004 power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

NOTE UT is the a.c. mains voltage prior to application of the test level

12 Electromagnetic Compatibility

Guidance and manufacturer's declaration-electromagnetic immunity			
The VT•One, S1004 is intended for use in the electromagnetic environment specified below. The customer or the user of the VT•One, S1004 should assure that is used in such environment			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 KHz to 80 MHz 3 V/m 80MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the VT•One, S1004 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1,2 √P d = 1,2 √P 80MHz to 800 MHz d = 2,3 √P 800MHz to 2,5 GHz 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 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 VT•One, S1004 is used exceeds the applicable RF compliance level above, the VT•One, S1004 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the VT•One, S1004. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m			

12 Electromagnetic Compatibility

Recommended separation distance between portable and mobile RF communications equipment and the VT•One, S1004			
The VT•One, S1004 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VT•One, S1004 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VT•One, S1004 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz d =1,2√P	**80 MHz to 800 MHz** d =1,2√P	**800 MHz to 2,5 GHz** d =2,3√P
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the aximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people			

13 Note