



Carilex® VT • 100

Negative Pressure Wound Therapy

Instructions for Use

Table of contents

A. Introduction	3
B. Indication for use	3
C. Contraindications	4
D. Precautions	4
E. Warnings	5
F. Safety Instructions before use	6
G. Important Notes	7
1. Battery	7
2. Collection Canister	8
3. Dressing	8
H. Operating	10
1. Illustrations	10
2. Display Panel and Screen	11
3. Symbols and Keys	11
4. Operation Procedure	11
5. Reminder	15
6. Alarm indicators	15
I. Trouble-shooting	16
J. Cleaning and Maintenance	17
K. Disposal	17
L. Technical Data	18
M. Signs and Symbols	20
N. Warranty	21

A. Introduction

Thank you for your choosing the Carilex VT·100 device for use in negative pressure wound therapy (NPWT). **PLEASE READ THIS INSTRUCTIONS FOR USE CAREFULLY BEFORE USING THIS DEVICE.** VT·100 is an advanced suction therapy unit that is part of an integrated wound management program. The VT·100 device provides two types of vacuum modes (continuous and intermittent), uses a state-of-the-art electronic measuring system, and has acoustic and visual alarms to ensure optimal performance and to enhance patient safety. It is a user-friendly, quiet, and light weight solution for negative pressure wound therapy.

B. Indication for Use

Carilex VT·100 suction therapy unit 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·100 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.



NOTE: The device is intended for use in acute, institutional, and long-term care settings and only when prescribed by a physician or other qualified medical caregiver.

C. 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

D. Precautions



Precautions should be taken for patients with the following conditions:

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

General Precautions for all indication for use



It is important that a physician or other qualified healthcare provider evaluates the patient to ensure that the use of the VT·100 is an appropriate therapy.

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. In addition, a healthcare provider should wear gloves, a gown, and goggles if there is the possibility of contact with the patient's body fluids.

E. 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.

- *Physician should consider the patient's size and weight when prescribing this device.*
- *The device is not safe for use with an MRI and must be disconnected from the patient prior to MRI.*
- *Do not use the VT 100 suction therapy unit in a Hyperbaric Chamber or in the presence of flammable gases. The patients dressing may remain in place when disconnected from the unit.*
- *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.*
- *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.*
- *If necessary, all wounds should be debrided prior to application of the therapy and/or dressings.*
- *Ensure that there are no pockets left in the wound after application of the dressings.*
- *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.*
- *Patient who do not have adequate hemostasis, and on whom anticoagulation or platelet aggregation inhibitors are being used, have an increased risk of bleeding with or without the VT·100.*
- *All arteries, veins, tendons, ligaments, nerves, and organs must be covered completely prior to application of the VT·100.*
- *The patient with increased 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.

- *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.*

Note: The device is intended for use in acute, institutional, and long-term care setting and only when prescribed by a physician or other qualified medical caregiver.

F. Safety Instructions before use



For your safety

- *The VT · 100 suction therapy unit only is administered by persons who have been trained in its operation according to the instruction guidelines issued by the supplier or qualified medical staff.*
 - *Before using VT · 100 as vacuum source and treatment system, please read the indications, warnings, precautions and contraindications.*
 - *Check function of the unit prior to use.*
 - *Prior to connecting the power supply adapter, check whether the voltage corresponds with the in building voltage (100 – 240 V / 47 – 63 Hz)*
 - *Never connect the power supply adapter to defective power sockets. Keep power supply adapter and cable away from external heat sources. DO NOT cover the power supply adapter.*
 - *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*
- In any case, remove the power supply adapter from the electrical socket and have the unit checked by qualified personnel authorized by Carilex® Medical.*
- *The VT · 100 therapy unit must be placed carefully and securely at the patient's beside. 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.*

- *Wipe disinfection of the VT 100 Therapy unit between use for different patients is mandatory.*
- *The VT · 100 therapy unit must never be used to remove explosive ases and inflammable or corrosive fluids.*
- *The unit must not be operated in damp rooms or when taking a bath or shower. Avoid moisture on plug and switches. Never plunge the unit into water or liquids, not even when it is switched off.*
- *The unit must not be operated in splash water range or in locations where there is a danger of explosion.*
- *Operation of the VT · 100 is possible while the battery is charging.*
- *Pay attention to the ambient conditions described in the technical data.*
- *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.*
- *The unit should be operated on a firm, level surface.*
- *When the device is switched on, DO NOT leave it unattended.*
- *At regular intervals, parts of the unit should be checked for correct function and safety-related defects , please refer to service manual.*
- *The VT · 100 therapy unit must be switched off and disconnected from power supply adapter:*
 - *Before cleaning and maintaining the unit.*
 - *Before removing or installing the collection canister.*
- *The VT · 100 therapy unit meets the requirements of IEC60601-1-2/EN60601-1-2 “Electromagnetic Compatibility Medical Electrical Devices”.*
- *The safety standard of the VT · 100 therapy unit corresponds with recognized medical and technical regulations and the guidelines relating to medical products.*
- *Opening the unit should only be performed by qualified personnel authorized by Carilex® Medical.*
- *Only use original, genuine Carilex® Medical accessories and spare parts.*
- *The unit must only be used with a genuine VT · 100 collection canister.*

G. Important Notes

1. Battery

Charging instruction for battery

To charge the battery, connect VT·100 power cord to an electrical outlet and **switch the battery switch on**, which is at bottom side of VT · 100.



Upon initial receipt of the VT·100 therapy unit 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. The battery must be fully charged prior to first use of the VT·100 therapy unit.

When battery is fully charged all three bars are constantly shown in the battery symbol in the display.

If therapy unit is in warehouse/inventory and not used for more than three months, the battery need to be recharged.

VT·100 therapy unit is equipped with a lithium-ion battery. The batter will discharge depending on the run time of the therapy unit and through extended periods of inactivity. Unlike common Nickel-Cadmium (NiCad) batteries, Lithium-ion batteries do not lose their energy storage capacity when recharged after partial use or partial discharge. After the initial twelve hours charging, the VT·100 battery can be recharged at any time without impacting its energy storage capacity, although frequent short-time charging should be avoided. Depending on usage, the battery life cycle will vary between 300-500 charges. Storage and usage of the battery must be within the temperature ranges stated in the section under “Technical Data”.



For long term storage, please turn off the battery switch located on the underside of the therapy unit and disconnect the power cord from the electrical outlet. When the machine is not used, it is recommended to fully charge the battery every three months to maintain battery life and ensure proper functioning.

If you observe that the operation time under full charge diminishes or that the usual charging time is shorter, it may mean that the battery needs to be replaced and the battery need to be replaced.

NOTE: Please dispose of the battery according to local or facility guidelines.

2. Collection Canister



Always make sure the canister is properly inserted, this is signalled by a click and the lid of the canister goes up.

Inside the VT·100 collection canister is hydrophobic membrane integrated together with an activated carbon filter to avoid cross contamination and for odor control.

The VT·100 system is designed for detecting when canister is full. When the liquid absorber reaches the canister full level, the audible and visual alarms will be triggered and the message indicator “canister full” will be displayed on the display panel.

The VT·100 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.

3. Dressing

Only Genuine Carilex Dressing Kits are to be used in conjunction with the VT·100 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.

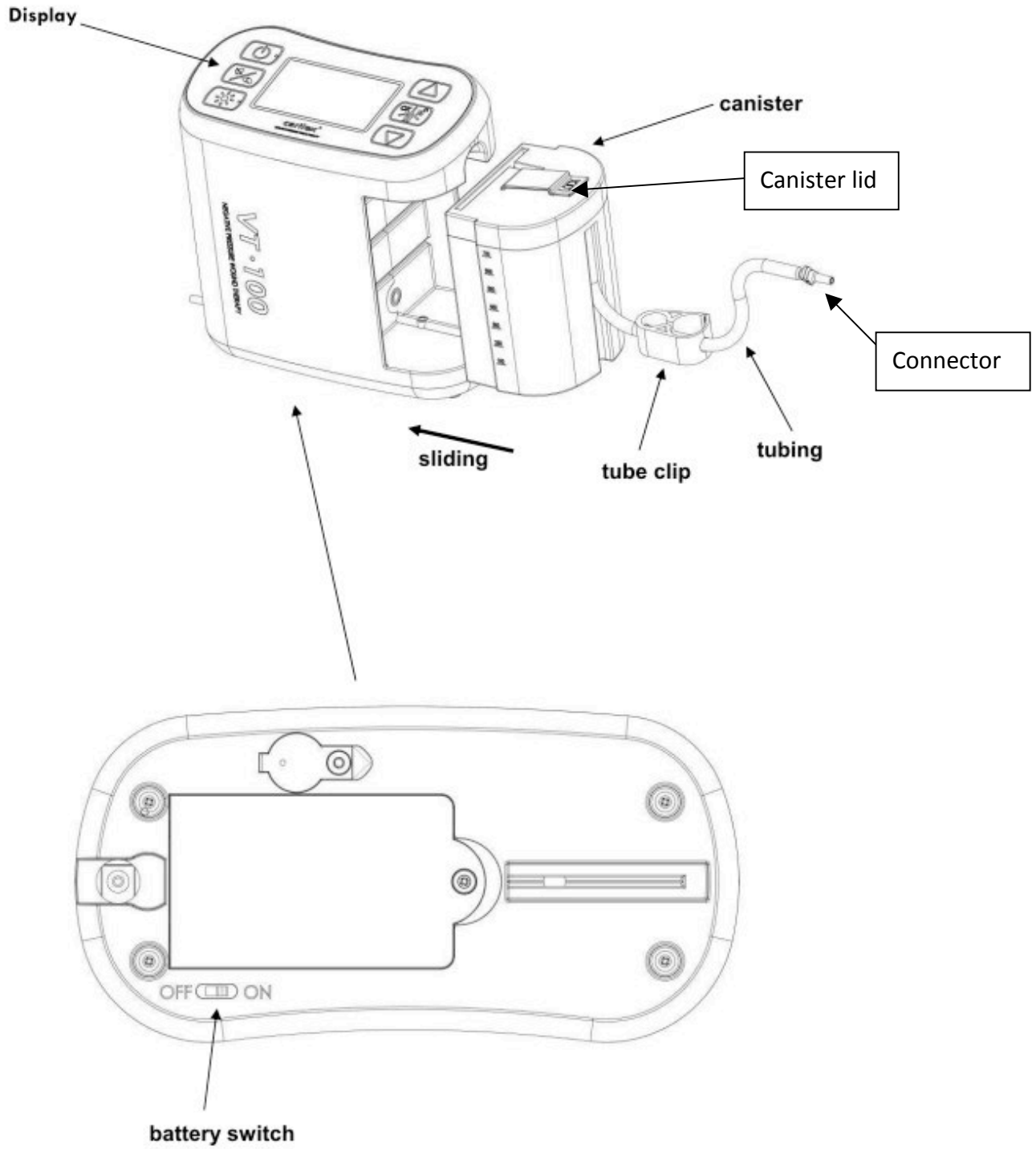
NOTE: Before using, please inspect the dressing kits to make sure there is no damage to the packaging, which may comprise the sterility of the contents. DO NOT use the contents of a damaged package; instead, dispose of properly.

NOTE: DO NOT re-use the dressing kit to avoid the cross infection.

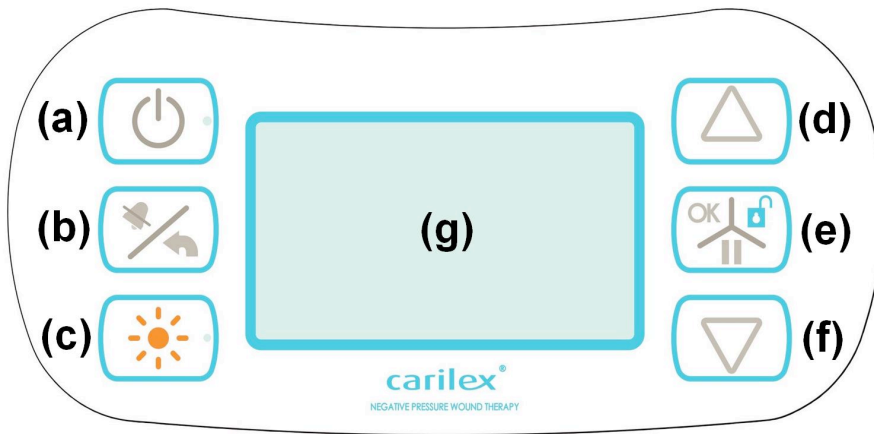
H. Operating

1. Illustrations

VT·100 Therapy unit and collection canister



2. Display Panel and Screen



(a) Power

(b) Alarm mute/Return

(c) Light for display screen

(d) Arrow up

(e) Ok/Unlock /Stop

(f) Arrow down

(g) Display screen

3. Symbols and keys



Battery status.



Battery depletion or low power. It needs to be charged and display shows Battery Low



Battery cannot charge, please contact to your distributor for service.



Charging.



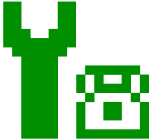
Panel Locked.



Warning with alarm.



The machine is running.



Call for Service.

4. Operation Procedure

4.1 Using the function keys

(a) **Power**

Press and hold button for 3 seconds to turn on the power unit .

(b) **Alarm mute/Return**

You may press button to turn off the audible alarm after notified.

Press button and system will go to the previous item. In the sub-menu,

press button to return to the main-menu.

(c) **Light for display screen**

After 3 minutes, the light for screen will automatically turn dark and blue led will light.

Pressing button when blue led is on and display is dark, display will be lightened.


When display is lightened, press to turn off display led.

(d) **Arrow up / Arrow down**

In the continuous and intermittent setting mode, press or to select the desired pressure or minutes, -5mmHg or 1 minute per step.

(e) **Ok/Unlock/Stop**

Press button to go the next item. In main-menu, press button to get to

the sub-menu of options. In working mode, press shortly  button to stop the therapy unit.

When the display panel is locked, press  button for three seconds to unlock panel.

4.2 Operation of the VT·100 NWPT system

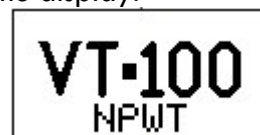
Switch on VT·100

- Turn on the battery switch underneath the therapy unit.


Connect the power supply adaptor to the AC mains

outlet and to the unit. To switch the unit on, press

power key for 3 seconds until the following appears on the display:



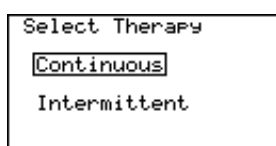
Switch off VT · 100




To switch off VT · 100, press power key. If therapy unit is locked, press 

for three seconds to unlock, then press power key and hold.

Select Therapy Mode

- To select Therapy mode, switch on the therapy unit with power key.
- Immediately after switching on the display is illuminated with VT-100. Press OK key if you want to continue with previous settings or wait for 5seconds until on the display the following appears:



- Use   keys to move the cursor to the prescribed therapy mode and confirm your selection with  key.

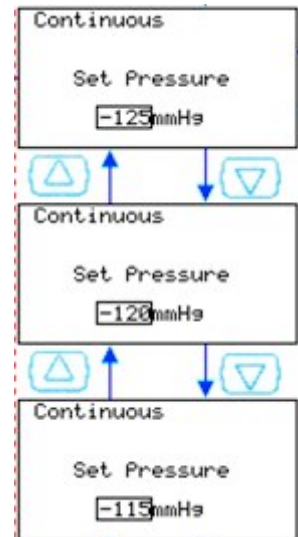
Continuous Mode Setting

Continuous therapy works permanently with prescribed pressure value.

You can choose between -30mmHg to -200mmHg. Default pressure is -125mmHg.

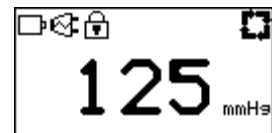
When having selected continuous therapy the picture to the right appears on the display


- Use the  and  key to set prescribed pressure and -5mmHg per press.





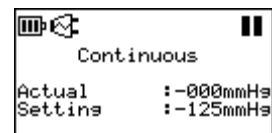
Confirm the selected pressure with  key and power units starts to work.


- The panel will be auto locked after 3minutes and on the display screen appears the display like on the right (in case 125 mmHg is chosen):

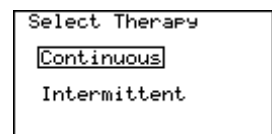




- To unlock the panel, press the  key for 3seconds.

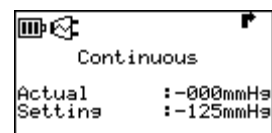
- If the treatment must be interrupted, unlock therapy unit, stop the therapy unit by pressing **shortly** the  key, immediately the therapy unit will stop and on the display the pause sign appears. If you want to continue press again: 



- If the prescribed therapy mode need to be changed, unlock, press  key to get back to select therapy mode.



- The display only displays the current pressure while operating. To see details, press  or  key and the details on display screen appears for 5seconds.



Intermittent Mode Setting

Therapy unit changes between two phases with different prescribed pressure and different time interval settings. There is high and low pressure setting available:

High pressure setting is from -50mmHg to -200mmHg.

Default is -80mmHg.





High Pressure time setting range is: 1 to 10 minutes,
Default is 5 minutes.

Low pressure setting is from -20mmHg to -80mmHg.


Default is -20mmHg.


Low pressure time setting range: 1-10 minutes.

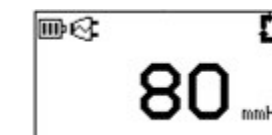
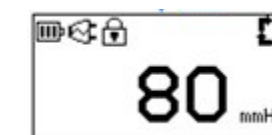
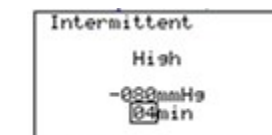
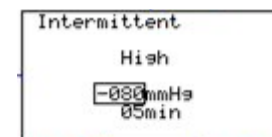
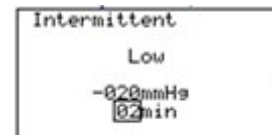
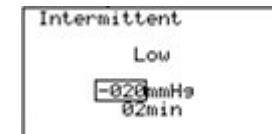
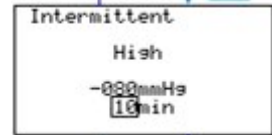
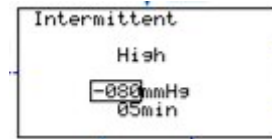
Default is 2 minutes

- Use the  and  key to set prescribed pressure
- Use the  and  key to set prescribed pressure time setting.



Confirm pressure value and time setting

with  After the last setting is confirmed the power unit will start


- The panel will be auto locked after 3 minutes and the following appears on the display:
- To unlock the panel, press the  key

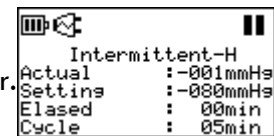



for 3seconds. The display screen turn dark
for power saving after 3 minutes.

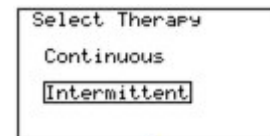
- The display screen only display the current pressure while operating. To see details, press  or  key and the details on display screen appears for 5seconds.



- If the treatment must be interrupted, stop the unlocked therapy unit by pressing the  key, immediately the therapy unit will stop and the screen as to the right will appear.



- If the prescribed therapy mode need to be changed, press  key to get back to select therapy mode.





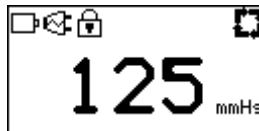

5. Reminder

- Unless otherwise directed by a physician, use the lowest level of pressure setting possible.
- All pressure settings and modalities must be prescribed by a physician or other authorized medical provider.
- Ensure the canister is securely in place (**it should klick and the lid need to go up**) and inspect its fluid level before VT·100 therapy unit is switched on. ? Replace the canister if it is full or if using on a new patient.
- To maintain proper suction, check the wound dressings every 6-8 hours or sooner. Look for a wrinkled appearance at the surface of the dressing, which indicates an air-tight seal environment.
- Make sure battery switch is “on” during use and “off” during longer non-use.

6. Alarm indicators

- If VT·100 therapy unit 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 alarm is suppressed.
- However the orange is always blinking (1sec on/1sec off), until the issue is resolved.

Alarm error messages appear on the display:

Error Message	Display	Possible causes	remedy
Leak		Dressing is not tight Tube not correctly connected or leaks in the dressing.	<ul style="list-style-type: none"> · Press mute key to mute the alarm · Seal the dressing correctly · Power unit will go back in operation mode after problem is solved.
Canister Full		Canister full	<ul style="list-style-type: none"> · Press mute key to mute the alarm · Replace the canister · press ok
Low Battery		Battery low	<ul style="list-style-type: none"> · Charge the rechargeable battery by using the adaptor.
Call for Service		Turn Power off	<ul style="list-style-type: none"> · Please contact your authorized local distributor for assistance.

I. Trouble-Shooting

Problem	Inspection Procedure	Possible solution
Unit switch off after disconnecting charger	1. Check the battery switch underneath the therapy unit	1. Switch on the battery switch and charge battery
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

	3. Check if the unit is still in the setting mode	3. Complete the settings
Insufficient performance	1. Check if the tube is partially kinked or the clamps are engaged	1. Remove kinks and or release clamps.
	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
	4. Check that the height of the suction unit is not more than one metre above the wound.	Move unit within one metre height of wound.
No suction	1. Check if the tube is partially kinked or the clamps are engaged	1. Remove kinks and or release clamps.
	2. Check if the tubing is not blocked	2. Replace tubing
	3. Check if the canister is full	3. Replace the canister
<p>If power unit does not respond to the possible solution. Please contact your authorized local distributor for assistance.</p>		

J. Cleaning and Maintenance



Always unplug the power unit from electrical outlet before cleaning, comply with in-house directives on hygiene.



Before using with a new patient always disinfect pump, carrying bag and holder.

Power unit:

Wear suitable gloves for cleaning / disinfection. Routine cleaning of power unit can be done by wiping down with damp cloth using disinfectant and water or non-aggressive cleaning material.

**Warning**

Take special precaution to ensure that no cleansing solution is able to penetrate into the equipment.

Collection Canister:

DO NOT re-use canisters (including integrated PVC tubing). Please dispose of properly according to local and facility guidelines.

**Warning!**

Re-use of collection canisters could cause cross infection or serious injury. The PVC tubing connected with the canisters contains DINP, which has been identified as a possible mutagenic.

K. Disposal

The VT-100 therapy unit is made from various electronics and plastics. When the VT-100 therapy unit 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.

Caution !



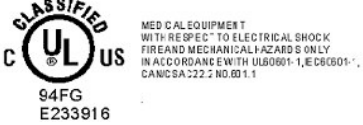




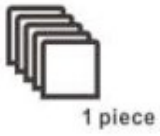
Pay attention to country-specific, local, and facility regulations with respect to disposal, especially with regard to disposal of used batteries.

L. Technical Data

Air flow rate of therapy unit	2.5 liters/min
Negative pressure	Max.-200mmHg (-27kPa)
Power Input:	AC 100-240V / 47-63Hz
Power Output	DC 9V 3A
Power Consumption	Max: 27W
Operation mode	Continuous: Pressure range:-30~-200mmHg Default: -125mmHg Time setting: 1~10minutes
	Intermittent: Pressure range: High -50~200mmHg Default: -80mmHg Low -20~-80mmHg Default: -20mmHg Time setting: 1~10minutes
Rechargeable battery	Lithium-ion Capacity: 4400mAh Charging Time: 4hrs Using Time: approx.24hours

Dimensions (WxHxD)	W18 cm(7 in) x H17 cm(6.7 in) x D9.0 cm(3.5 in)
Weight (basic unit)	1.35 kg(3 lbs) with canister
Canister Capacitor	300cc/ml or 500cc/ml
IP21	Against ingress of solid foreign objects 12.5 mm diameter. Against ingress of water with harmful effects – vertically dripping.
Risk class in accordance with MDD 93/42/EEC as amended by 2007/47/EC Annex IX	Ila
Protection class according to IEC60601-1	 Class II
Environmental Conditions	Operation temperature: 5° C(41° F) to 40° C (104° F) Relative Humidity Range: 0~63% non-condensing.
Transport and storage conditions	Temperature Range: -20° C (-4° F) to 60° C (-140° F) Relative Humidity Range: 0~63% non-condensing.
Storage Atmospheric Pressure	700-1060 hPa

M. Signs & Symbols

	<p>Consult instructions for use</p>
	<p>Type BF Degree of shock protection acc. to IEC 60601-1</p>
	<p>UL Classification</p>
	<p>CE mark</p>
	<p>Date of Manufacture</p>
	<p>Manufacturer</p>
	<p>Do not re-use</p>
	<p>Packaging unit for VT·100 canister</p>

N. Warranty

1. There is a two year warranty for Carilex VT·100 powered suction therapy unit. Warranty card is included in packaging and should be filled out and returned to the manufacturer.
2. When repairing during the warranty period, charges may still be applicable in the following conditions:
 - a. Incorrect operation, inappropriate usage, incorrect maintenance, damage or defect caused by disassembly.
 - b. Damage or defect is caused by moving or dropping after installation.
 - c. Damage or defect is caused by natural disaster, public hazard, abnormal voltage and other events not attributable to the product itself.
 - d. Warranty card is modified or tampered with.



Carilex Medical GmbH
Turmbergstr, 9A,
D-76227 Karlsruhe, Germany
Tel:+49(0)721 16 19 835