carilex®

VT · 200

Negative Pressure Wound Therapy System
Medical Powered Suction Pump with Canister
Instructions for Use

About This Document

Congratulations and thank you for purchasing this high quality NPWT. Please read these Instructions carefully before use and observe the safety instructions and requirements for the proper 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:
Device name: Negative Pressure Wound Therapy System - Medical Powered Suction Pump with Canister

The serial number is shown on the label on the rear of the power unit.

Validity of the documentation

Details of the Device Documentation
This manual describes the VT · 200 Powered Suction Pump. It is part of the device documentation. Do not share this device with a third party without including these Instructions for Use.

The end page of these Instructions for Use shows the current document edition.

Subject to change

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

Translations

The English version of these Instructions for Use is authentic. In the event of any clarification, question or dispute as to the content of any translation of these Instructions for Use, the English version shall prevail.

Copyright

The resulting rights for reprinting, photomechanical, digital processing, or copying of the content, or any part thereof, are permitted only with prior written approval from Carilex Medical Inc.

This provision shall not affect the reproduction for internal use.

About This Document

Manufacturer
Carilex Medical, Inc.
No. 77, Keji 1st Rd., Guishan Dist., Taoyuan City 333, Taiwan

EC REP

EU Representative:
Emergo Europe B.V.
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

If the user or/and patient occur any serious incident in relation to the device should be reported to Carilex and European Authorized Representative immediately.

Sales and service

For Support or Complaints
If you have any questions or concerns about the device or need accessories, please contact the distributor that delivered the device to you or your patients.

Table of Contents

Table of Contents

1 Important Notes for Safe Use

Named groups of persons

1.1 Designation of the Groups of Individuals

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 who owns and uses a Powered Suction Unit, or on whose behalf the device is used. The operator is responsible for providing a safe device and to instruct users properly on the operation and safe use of the device.

Users

Users are people who have been trained to:

- Operate the Powered Suction Unit.
- Supervise patients using the device for therapy or care purposes.

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

Professionals

These authorized persons are skilled personnel who may be 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.
- Are able to detect possible hazards during work.

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

Patients

Patients are persons in need of care and who use the Powered Suction Unit for therapy or care purposes.

Lay Operator

A lay operator is a person without relevant specialized training. The lay operator should contact the manufacturer or manufacturer's representative under following conditions:

- For assistance in setting up, using or maintaining the ME Equipment System; or
- To report unexpected operation or events.

1.2 Notes for the Users

Note that the medical device should only be used by persons who have been trained in the operation and the intended purpose of the device.

1.2.1 Instruction

Training on the device

Training on how to use the device must be carried out by qualified personnel. If the device is approved for use, then users must comply with the Instructions for Use.

1.2.2 Transferring the Device

Device approval

The device may be used only if the operator has released it for therapeutic or care use and if the transfer was carried out properly and under the supervision of authorized personnel.

After the transfer, users are fully responsible for the safe and dedicated use of the device.

1.2.3 Maintenance and Installation

The maintenance and/or repair of the equipment or parts must be carried out only by an authorized service agent.

1.2.4 Information and Test Obligation of the User

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 must be carried out and the proper condition of the device must be confirmed by the user before each use or transfer for use by patients.
In case of specific issues that are not covered in enough detail in these Instructions for Use, please contact the distributor or operator for further guidance.

1.3 Procedures for Accident Prevention

The VT · 200 is made according to current, reliable, state of the art technology. However, hazards may arise if it is operated by untrained personnel or it is not operated as described in these Instructions for Use.

1.3.1 Procedures for Transferring the Device

In order to comply with the regulations of accident prevention and to prevent accidental damage, follow these procedural guidelines when transferring the device:

- The device must be thoroughly cleaned and disinfected before the first use.
- The initial start-up of the device, as well as the transfer to the user, must be carried out by authorized personnel assigned by the operator.
- After completion of the training, it must be documented that the user understands the operation and use of the device for therapy or care purposes.

Hygiene measures

1.3.2 Qualification Requirements Hygiene Staff

The nature of hygiene measures is determined by the use environment of the device.

- If the device is used in clinical areas (e.g. hospitals, clinics, nursing homes, elderly homes, etc.) cleaning and disinfection must be carried out on the product or parts only by appropriately qualified personnel who are familiar with relevant hygiene regulations.
- When using the device in non-clinical areas, users or trained cleaning personnel may clean the device.

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 users.
Do not pass the device to a third party without these Instructions for Use. Using the edition version as a guide always ensures that the current and valid Instructions for Use document is supplied with the device.

1.4 Purpose of the Device

To ensure the safety of patients and users, the device must be used only for its intended purpose.

1.4.1 Intended Purpose

Carilex ”Negative Pressure Wound Therapy System” (NPWT) is indicated for patients who would benefit from wound management via the application of negative pressure for removal of fluids and excess exudates, irrigation fluids, infectious material, and tissue debris which may promote wound healing. To help provide safe and effective use, Carilex pump is to be used only with the Carilex disposable components: canister and dressing kits.
Intended users: Medical practitioner (Clinician use only)
Intended patient populations: No restriction in patient population.
Use environment: Carilex ”NPWT” is intended to be used in hospitals, clinics, nursing home, elderly homes.
Indications:

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

Contraindications:

Patients with the following conditions:

- Presence of necrotic tissue
- Malignancy (except for quality of life reason for terminal patients)
- Exposed arteries, veins, nerves, organs or vascular graft
- Use over anastomotic sites

- Untreated osteomyelitis
- Unexplored or non-enteric fistulas

Relative Contraindications

- Ischemic wounds
- Ongoing infection
- Fragile skin
- Adhesive allergy

Clinical benefit:

NPWT benefits include rapid wound healing, reduction of dressing changes, reduced infection risk, reduced treatment costs, control of exudate, reduction of oedema and provision of a closed moist wound healing environment, concurrent rehabilitation, and better patient comfort and tolerance.

1.4.2 Precautions

The following statements describe medical conditions that may require special care to be exercised by a practitioner for the safe and effective use of the Powered Suction Unit.

1. Difficult wound hemostasis, or who are on anticoagulants
   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. Exposed tendon, nerves or blood vessels should be protected
   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. Weakened, irradiated or sutured blood vessels or organs
   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. Bone fragments or sharp edges
   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.
5. Infected wound
   Patient with infections in the wound and or other parts of the body have to receive proper systemic treatment. Infected wounds may need more frequent dressing changes, up to twice a day, and the patient and wound must be inspected regularly for signs of increased infection or sepsis.
6. For patients a known history of autonomic dysreflexia, please increase number of monitoring during the treatment as well as inspection for displacement of dressings.
7. Do not use NPWT if person experiences autonomic dysreflexia.

1.4.3 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 Powered Suction Unit is an appropriate therapy.
2. To reduce the risk of transmission of blood-borne pathogens, regardless of their diagnosis or presumed infection status, all users should take medical standard operating procedure precautions against infection control.
3. Caregivers should wear gloves, a gown, and goggles if there is the possibility of contact with the patient's body fluids.
4. Change the dressing if the pump has stopped for more than two hours.
5. Consider mode of therapy-intermittent versus continuous operation.

NOTE

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

1.4.4 Caution

The following caution 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. Infants, children, certain small adults and elderly patients should be closely monitored for fluid loss and dehydration.
2. The device is not safe for use with an MRI or PET scan and must be disconnected from the patient prior to MRI or PET scan.
3. The device is not safe for use with a Hyperbaric Oxygen Therapy (HBO) chamber and must be disconnected from the patient prior to entering the chamber.
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. Residues of gauze/foam that may increase the risk associated with wound infection and bleeding. 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. Apply the dressing on the exposed arteries, veins, nerves, organs, or anastomotic site, that may increase the risk associated with wound bleeding. Please properly protect the wound site prior to initiating NPWT.
9. Apply the device over the unexplored an ischemia of soft tissue that may increase the risk associated with ischemic fasciitis. Please check the contraindications and properly protect the wound site prior to initiating NPWT.
10. Dressing does not be sealed that may increase the risk associated with wound infection. Please put the pump carefully in the carrying bag or fixed it, to avoid that excessively tension act on tube after pump fall and then leading the dressing come off from the skin.
11. Strangulation resulting from canister or dressing tube.
12. Skin irritation due to prolonged exposure to APPLIED PARTS or other ACCESSORIES.
13. To minimize the risk bradycardia, this device should not be placed in proximity to the vagus nerve.
14. Care should be taken if a patient has a spinal cord injury (potential for stimulation of the sympathetic nervous system.
15. Use of NPWT presents a risk of tissue ingrowth; users should be informed of means to reduce this risk (i.e. reducing therapy pressure, increasing the frequency of dressing changes, and monitoring).
16. This Powered Suction Unit is Not AP / APG protected. Do not use it under Oxygen enriched environment and flammable anesthetics.
17. Unapproved stop the therapy risks to patients because they have not been evaluated by the physician for wound assessment. Without physician evaluate, there is no way to know if the wound is healthy, whether the wound is infection or worsened. Do not stop the therapy by yourself, or, contact your caregiver if any problem.

1.4.5 Exclusion clause for use

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

1.4.6 EMC CAUTION Statement

1. Warning: Use of the VT · 200 adjacent to or stacked with other RF (radio frequency) communication equipment (including antennas) should be avoided and used no closer than 30cm to any part of the VT · 200, including cables specified by the manufacturer. This could result in improper operation and/or degradation of the essential performance of this equipment.

2. The compliance statement of emission class and group and immunity test level for each emission and test standard specified by IEC60601-1-2 are summarized on EMC Declaration.
3. Accessories may affect EMC performance.

1.4.7 Safety CAUTION Statement

1. An identifying marking provided referring to instructions in IFU for battery pack intended to be changed only by service personnel using a tool.
2. A warning provided indicating replacement of Li-ion Battery pack IF incorrect replacement would result in an unacceptable risk.
3. A warning indicating that replacement by inadequately trained personnel could result in hazard.
4. Do not modify this equipment without authorization of the manufacturer.

Certificates, standards, guidelines:
The device is a medical product class IIb in the sense of the MDD 93/42/EEC as amended by Directive 2007/47/EC and class II to comply with FDA regulation 21 CFR 878.4780.

Declaration of conformity

The manufacturer confirms the conformity of the product with regards to general safety and performance requirement in accordance with MDR Annex I and documents this by the application of CE Marking and Notified Body Number.

Standards and Guidelines

The device meets the Safety and EMC requirements of the following standards and guidelines:
EMC and Safety Certified Standards for Powered Suction Pump
IEC 60601-1:2005 + A1:2012
EN 60601-1:2006 + A1:2013
IEC 60601-1-2:2014
EN 60601-1-2:2015
ANSI / AAMI ES60601-1_v3.1 + CAN/CSA C22.2 No.60601-1:14
Certified by NRTL_MET Classified
AS/NZS IEC 60601.1:2015
IEC 60601-1-11:2015
EN 60601-1-11:2015
EN ISO 14971:2019
Safety Certified Standard for Secondary Li-Ion Battery Pack
IEC/EN 62133-2:2017 and UN38.3_v7

Warranty terms and conditions

1.5 Warranty

The manufacturer guarantees the safety and correct functioning of the Powered Suction Unit only under the following conditions:

- The device is used for the intended purpose 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 to the device.
- Inspections and maintenance work are carried out by certified personnel according to specified time intervals.

1.6 Safety Information and Symbols of These Instructions for Use

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

1.6.1 Identification of Risks of Injury

WARNING
Means a hazardous situation, which may lead to death or severe injury.

CAUTION
Means a hazardous situation, which may lead to minor or severe injury.

1.6.2 Identification of Material Damage

ATTENTION!
Describes a situation that could lead to property damage.

1.6.3 Identification of Additional Information

NOTE!
Means application tips and useful information.


Warning of damage to equipment surfaces

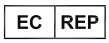

Advice to wear safety goggles


Advice to wear safety gloves


Advice to wear mouth and nose protecton.

1.6.4 Additional Symbols to the Safety Information

Additional symbols to the safety information are those listed below

	Manufacturer		Country and date of manufacture
	Authorized Representative in the European Community		Unique Device Identifier
	Catalogue Number		US NRTL - MET Classified Mark
	Serial Number		Medical Device
	Follow Instructions for Use		Caution (ISO 7000-0434A)
	Declaration of Conformity to MDD 93/42/EEC		Type BF Applied Part
	Double Insulated, Class II AC Adapter		Waste Electrical and Electronic Equipment (WEEE Logo)
IP22	Protected against ingress of solid foreign objects ≥12.5mm diameter. Protected from water spray less than 15 degrees from vertical		Temperature limit
			MR unsafe-Keep away the device from Magnetic resonance imaging (MRI) equipment
	Federal (US) law restricts this device to sale by or on the order of a physician.		Packaging unit
	Model Number		Consult instructions for use

1.7 Safety Instructions before use

(1) The Powered Suction Unit can be administered only by persons or qualified medical staff who have been trained in its operation according to the instruction guidelines issued by the manufacturer.
(2) Before using the Powered Suction Unit as a vacuum source and treatment system, please read the indications, warnings, precautions, and contraindications.
(3) Check function of the unit prior to each 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.

1 Important Notes for Safe Use

(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) The Powered Suction Unit 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.

(8) It must be ensured that in between different patients use the carrying bag is disinfected or a new carrying bag is used.

(9) The Powered Suction Unit 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 Powered Suction Unit is possible while the battery is charging.

(14) 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.

(15) The unit should be operated on a firm, level surface.

(16) When the device is switched on, DO NOT leave it unattended.

(17) Parts of the unit should be checked for correct function and safety-related defects at regular intervals. Please refer to the service manual.

(18) The Powered Suction Unit must be switched off and disconnected from the power supply adapter before cleaning and maintaining unit.

(19) The Powered Suction Unit is a medical device; it is not a toy. Keep away from children and pets as they can damage the dressing and therapy unit and affect performance.

(20) Keep 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 be used only with a genuine collection canister.

CAUTION

AVOID ELECTRIC SHOCK, DO NOT OPEN SUCTION PUMP!

WARNING

Electric shock!

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

ATTENTION

Device fall may bump on the patients causing swelling and pain, please fix the device on the I.V. stand or bed frame, carrying bag.

2 Delivery and Storage

2.1 Packaging

The Powered Suction Unit is supplied with sturdy cardboard packaging. All packaging materials are recyclable and can be separated: Packing: Cardboard, waste paper.

2.2 Models

Catalogue number	Model	Spec.
S1002-0012	VT · 200	Good for general NPWT purpose
S1002-3012	VT · 200	VT · 200 P.U.

2.3 Delivery control

Check immediately after delivery of the device :

- The completeness of the delivery
- The delivery status of the device

The Powered Suction Unit is delivered with the following components:

1. One Powered Suction Pump control unit
2. One 300ml canister
3. External AC Adapter
4. Instructions for Use

If the delivery is incomplete or the device and/or the packaging are damaged, in particular that caused by moisture or water, promptly inform the carrier as well as the distributor.
To fully charge the battery, and prior to the first start, attach the Powered Suction Unit to a wall outlet.

2.4 Operating & Transport & Storage Conditions

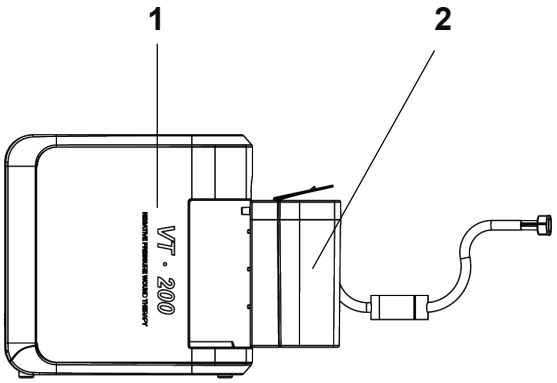
Recommended environmental conditions:

- For Operating Conditions

Temperature range: 5°C (41°F) to 35°C (95°F)
Relative Humidity range: 15% to 90%
Atmospheric Pressure range:700 hPa to 1060 hPa

- For Transport and Storage Conditions

Temperature range: -25°C (-13°F) to 70°C (158°F)
Relative Humidity range: 0% to 90%



For long-term storage the power unit should be covered with a dust protector and the battery needs to be recharged every 3 months.

ATTENTION

Storage of the Powered Suction Unit

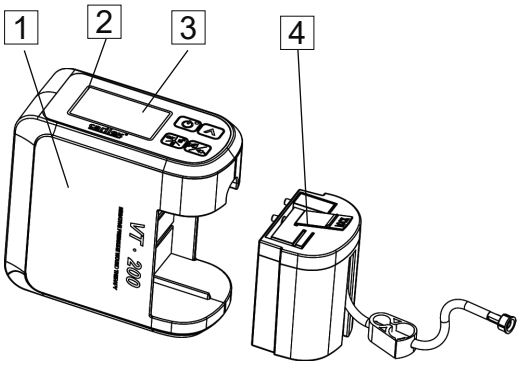
- Keep away from high voltage
- Keep away from humidity
- Keep away from heat
- Keep out of the reach of children
- Properly store in its box
- Do not store with other equipment

3 Device and Functional Description

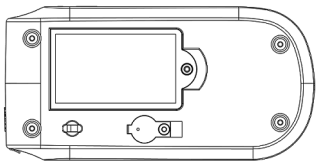
3.1 Device description

Powered unit
The power unit 1 is used as the housing for the compressed air unit as well as the compressed air system. It 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.



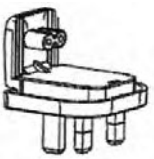
Power cord and charge 5
Select the correct AC adapter plug for your country then plug into the main outlet.



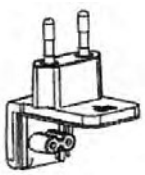
5

P/N R-NA-2(R)
North America
China
Japan

P/N R-SAA-2(R)
Australia



P/N R-UK-2(R)
United Kingdom
Hong Kong
Singapore



P/N R-EU-2(R)
Europe
South America

ATTENTION
When changing to a different AC adapter plug, you will hear a “click” sound when the plug is firmly connected. Failure to fully connect will cause power failure.

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

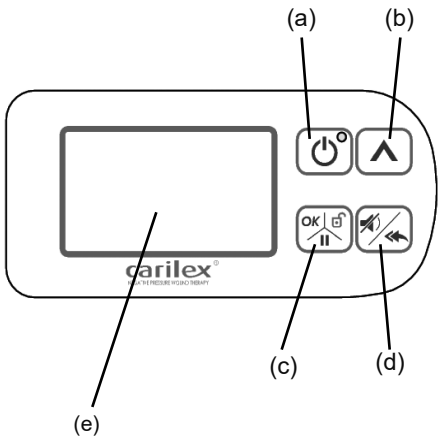
3 Device and Functional Description

3.2 Functional Description

Carilex Powered Suction Unit 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. A special dressing will be placed onto your wound by healthcare professional and 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 Powered Suction Unit and set to the pressure setting that is prescribed by your healthcare provider. The canister will then collect excess fluid.

3.2.1 Panel of the power unit

(a) On / Off
(b) Arrow up
(c) OK / Unlock / Stop
(d) Mute / Return
(e) Display Screen



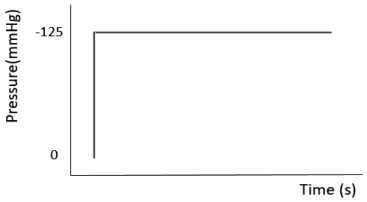
3.2.2 Function of the power unit

The vacuum air suction pump in the power unit sucks the air from the wound through the connecting tube and dressing to create a negative pressure environment in the wound.

3.2.3 Therapy mode

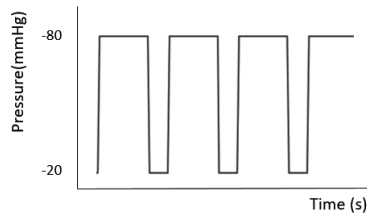
Contnuous mode:

When employed via the screen panel, the therapy unit will apply negative continuously. Default pressure for continuous mode is -125mmHg.



Intermittent mode:

When employed via the screen panel, the therapy unit changes between a high and low pressure range in a fixed time interval.
Default pressure is -80mmHg 5 minutes / -20mmHg 2 minutes.



3.2.4 Symbols on the display

Battery status
Low power
Battery cannot charge. Please contact your distributor for service.
Charging
Panel locked
Error indicator
The machine is running
Call for service
Battery malfunction but still working

4 Getting Started

NOTE
Before using, inspect the dressing kits to make sure there is no damage to the packaging, which may compromise the sterility of the contents. DO NOT use the contents of a damaged package; instead, dispose of 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. Bars on the battery display will indicate that charging is occurring. Long battery life lasts up to 24 hours, for uninterrupted therapy and portability.

ATTENTION
When changing to a different AC adapter plug, make sure you hear a “click” sound to confirm that that the plug is firmly connected. Failure to do so will cause power failure. Upon initial receipt of the Powered Suction Unit and prior to first use, charge the battery for at least 6~8 hours in order to create optimum battery memory and maximize the number of charging cycles over the lifetime of the battery.

ATTENTION
The battery must be fully charged prior to first use of the Powered Suction Unit. If therapy unit is in warehouse / inventory and not used for more than 3 months, the battery needs to be recharged. Powered Suction Unit 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 stated as 7500 hours. Storage and usage of the battery must be within the temperature ranges stated in the section 2.4.

ATTENTION
The pump can still be charged when the battery is broken or unconnected for urgent needs, but users are not suggested to use the pump under these circumstances.

4 Getting Started

NOTE
For long term storage, disconnect the power adapter from the electrical outlet. When the machine is not used, it is recommended to fully charge the battery every 3 months to maintain battery life and ensure proper functioning.

NOTE
Dispose of the battery according to local or facility guidelines.

To protect the environment, dispose of useless devices at appropriate collection sites according to national or local regulations.

4.2 Collection Canister

Always make sure the canister is properly inserted. You will hear a "click" for proper installation, and it must remain in an upright (display side up) position during use.
The VT · 200 Powered Suction Pump is protected against penetration from solid / fluid substances by a hydrophobic membrane integrated with an activated carbon filter. If this filter fails, the Power Suction Unit must be replaced.

The VT · 200 system is designed for detecting when canister is full. When the liquid absorber reaches the canister full level, audible and visual indicators will be triggered and the message indicator "canister full" will be seen on the display panel. To avoid breaking of the suction inlet on the canister, do not pull the tubing of the canister horizontally.
The 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 users or otherwise as needed.

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

Safety Notice :

- Keep children clear from the extra-long cable and hoses to avoid entanglement and strangulation.
- Choking hazard caused by small parts being inhaled or swallowed. Identify any loose or detached small parts and keep them away from children.
- Identify any rubber or latex potential allergic reactions to materials used in the equipment.
- Contact Injuries-Check for any skin irritation due to prolonged contact with the equipment.

- Protection against strangulation or asphyxiation. A medical professional shall provide the means to control the risk of strangulation and asphyxiation of the patient and others by routing wires appropriately.

4.3 Dressing

Only the VT Dressing Kit is to be used in conjunction with the VT · 200 system and must be in sterile condition. VT Dressing Kit should be applied in accordance with the Dressing Kit Instructions for Use, supplied with the dressings.

A physician or trained caretaker should perform an intensive, thorough wound cleaning prior to applying the dressing.

Perform routine dressing checks and changes every 48 hours or according to the facility protocol or physician's order.

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

CAUTION

DO NOT use the contents of a damaged package; instead, dispose of it properly.

DO NOT re-use the dressing kit to avoid cross infection. Follow IFU for dressing kits.

Wound infection that may increase the risk associated with wound worsen, sepsis or osteomyelitis. Please be careful to seal the dressing, or, contact your caregiver when the dressing come off from the skin.

4.4 Lay Operator Briefing Information

The equipment and accompanying Operation Manual should be simple to understand and straightforward to use for the Lay Operator, according to IEC60601-1-11 regulation, a Lay Operator needs to have at least 8 years of education. The healthcare professional should brief the Lay Operator on the use of the equipment and any precautions to be taken, including:

- Precautions to be taken in the event of changes in the performance of the equipment.
- Precautions to be taken regarding the exposure of the equipment to reasonably foreseeable environmental conditions.(e.g. magnetic and electromagnetic fields, external electrical influences, electrostatic discharge, variations in pressure etc.)
- Information about medicinal substances that the equipment is designed for, including any that the equipment is NOT designed for.
- Information about medicinal substances or blood products incorporated into the equipment as an essential part.
- The accuracy of equipment with a measuring function.

"Carilex" Canister lists		
1	S1001-6020	Canister for VT · 100 - 500ml lock
2	S1001-6040	Canister for VT · 100 - 1000ml lock
3	S1001-6060	Canister for VT · 100 - 300ml lock
4	S1001-6100	Canister for VT · 100 - 300ml luer lock
5	S1001-6110	Canister for VT · 100 - 500ml luer lock

"Carilex" Dressing lists		
1	S1001-2040	VT Dressing Kit S Carilex
2	S1001-2050	VT Dressing Kit M Carilex
3	S1001-2060	VT Dressing Kit L Carilex
4	S1001-2100	VT Spiral Dressing Kit Black Lock
5	S1001-2120	VT Dressing Kit XL Carilex
6	S1001-2130	VT Drape and Port Set Kit S Lock
7	S1001-2140	VT Drape and Port Set Kit M Lock
8	S1001-2150	VT Drape and Port Set Kit L Lock
9	S1001-2200	VT Dressing Kit TS S Carilex
10	S1001-2210	VT Dressing Kit TS M Carilex
11	S1001-2220	VT Dressing Kit TS L Carilex

5.1 Check points before using Powered Suction Unit

Before using the Powered Suction Unit, it is important to check for the following:

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

5.2 Insert Canister into the Powered Suction Unit

(Please follow the instructions on 4.2 Collection Canister section)
Insert the canister into the Powered Suction Unit connecting port.
Make sure the level marker of the canister on the Powered Suction Unit is on the same side as the display screen of the pump.

5.3 Connect the Powered Suction Unit tubing connector to the Carilex VT Dressing Kit tubing connector, and screw tightly to ensure a tight airlock.

WARNING
Electric Shock!

Touching live parts can result in a death or serious injury by an electric shock. Check for damage to the plug and the main power cable before connecting.

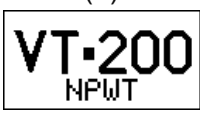
- Do not use damaged components.

5.4 Using the function keys

1. Power
   Press and hold button for 3 seconds to turn on the power unit. The LED will display a "green" color.
2. Mute / Return
   After receiving an audible notification, you may press button it turn off. Press the button system to return to the previous menu. In the sub-menu, press button to return to the main menu.
3. Arrow up
   In the continuous and intermittent setting mode, press to select the desired pressure or minutes. -5mmHg or 1minute per step.
4. OK / Unlock / Stop
   Press button to select item. In main-menu, press button to get to the sub-menu of options. In therapy mode, press to stop the therapy.
   When the control panel is locked, press button for 3 seconds to unlock.

5.5 Turn the unit ON / OFF

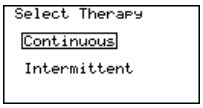
(a)



1. Turn on the unit
   To turn on the unit, press the power button on the control panel for 3 seconds until the screen is displayed as Figure (a).
2. Turn off the unit
   To turn off the unit, press the power button on the control panel for 3 seconds. If the therapy unit is locked, press for 3 seconds to unlock it, then press the power button for 3 seconds to turn off the unit. The display screen will go blank after the unit is turned off.

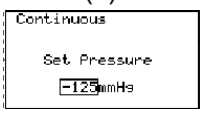
5.6 Therapy mode setting

(b)



1. To select therapy mode, switch on the therapy unit with the power key.
2. When the screen shows VT · 200, immediately press key if you want to continue with the previous setting, or wait for 5 seconds until the screen displays Figure (b).
3. Use keys to move the cursor to the prescribed therapy mode and press to confirm.

(c)



Continuous mode setting (c)

1. Press to change the constant pressure level from -30mmHg to -200mmHg. The default pressure for continuous mode is -125mmHg.
2. Press to start the therapy.

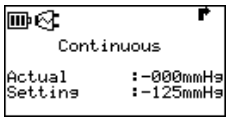
5 Operation Procedure

(d)

Intermittent mode setting (d)

1. Press [^] to change the high pressure level from -50mmHg to -200mmHg. Default pressure for high is -80mmHg. Press [OK] to confirm the high pressure setting.
2. Press [^] to change the high pressure therapy time from 1 to 10 minutes. Default time for high pressure is 5 minutes. Press [OK] to confirm the high pressure time setting.
3. Press [^] to change the low pressure level from -20mmHg to -80mmHg. Default pressure for low pressure is -20mmHg. Press [OK] to confirm the low pressure setting.
4. Press [^] to change the low pressure therapy time from 1 to 10 minutes. Default time for low pressure is 2 minutes. Press [OK] to confirm the low pressure time setting.

(e)



Others

1. When left untouched for 3 minutes, the panel will lock. To unlock the panel, press [OK] for 3 seconds.
2. If the therapy needs to be stopped, press [OK] to stop. Press [OK] again to restart.
3. If the prescribed pressure / therapy mode needs to be changed, press [OK] to unlock the panel, and then press [OK] to go back to the original setting.
4. During the therapy, press [^] and the setting details (e) will be displayed for 5 seconds.
5. To save power, the screen will turn dark after 3 minutes.

ATTENTION
If the suction that regulates the pressure does not perform properly, the device may apply higher pressure than the intended value and may cause bleeding and blood loss. If the device stops working or pressure is too low, it can cause delayed healing, loss of viable tissue or contamination of the wound.

ATTENTION
If the suction that regulates the pressure does not perform properly, the device may apply higher pressure than the intended value and may cause loss of soak functionality.

ATTENTION
If the suction that regulates the pressure does not perform properly, the device may apply lower pressure than the intended value and may cause over soak to induce contamination of the wound.

carilex

5.7 Mute / Return

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

The Powered Suction Unit is made from various electronics and plastics. When the Powered Suction Unit is ready for disposal, follow local governing guidelines regarding appropriate and proper disposal procedures of the 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 or co-mingled with household or facility refuse. Incorrect disposal may have harmful effects to the environment and public health.

5.8 Change Powered Suction Unit canister

The canister has to be changed by visual check or according to the instructions on the display.
The VT · 200 system is designed for detecting when the canister is full. When the liquid absorber reaches the canister full level, sound and visual indicators will trigger and the message "canister full" will show on the display panel.
Do not pull the canister tubing horizontally to avoid the breaking the suction inlet on the canister.
Properly discard the collection canister when full; it must be replaced after every patient use. Also, inspect and replace the canister weekly and/or between patient uses, or otherwise as needed.

ATTENTION
Avoid cross infection between patients and DO NOT re-use the canister.

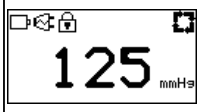
The procedure of changing canister:

1. Wash hands and wear disposable gloves.
2. Switch the Powered Suction Unit off by pressing for 3 seconds.
3. Close the clip on the tube, both the dressing and canister's side, and then disconnect the canister connector from the dressing.
4. Detach the full canister. Discard the used canister by following local governing guidelines.
5. Attach a new canister to Powered Suction Unit. (Refer to 4.2 Collection Canister section for instructions.)

6 Error Indicators

6.1 Error Indicators

If the Powered Suction Unit detects any of the following Error Messages, the display screen turns on with an acoustic warning signal simultaneously. Press the mute key to turn off the acoustic indicator. The orange light will blink (1 sec on/ 1 sec off) until the issue is resolved.

Error Message	Display	Possible causes	Remedy
Leakage		Dressing is not tight. Tube is not well connected or leakage occurred in the dressing.	Press ⏻ for 3 seconds to turn off the power suction pump. Check the system for leakage. Turn on the power suction 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 power suction pump. Replace with new canister.
Low Battery		Battery low	Press 🔇 for 3 seconds to mute the acoustic signal. The remaining battery time is approximately 10 minutes. Charge the battery. The visual symbol blinks and the acoustic signal will be activated until the battery is empty.
Call for Service		Failure of PCBA, Battery, or Vacuum Motor	Press ⏻ for 3 seconds to turn off the power unit. 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

Comply with all 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 and between each patient.

CAUTION

If the Powered Suction Unit fails to function normally for one hour, regardless of the circumstances, stop using the VT · 200 system immediately. Turn off the power, remove the canister, and remove the VT dressing from the wound site and replace it with traditional wound dressing.

CAUTION

Do not leave the idle Powered Suction Unit with dressing in the wound site for more than one hour to avoid risk of cross contamination.

Check the dressing checked regularly to avoid blockage and leakage.

CAUTION

A loose power cord may cause tripping and serious injury. Make sure any cords and tubing is safely stowed.

CAUTION

Improper use of the Powered Suction Unit 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 unit must be completed before first use and between patients. If there is a identifiable disease according to the Federal Law concerning epidemics, consult a hygiene expert prior to disinfection and cleaning.

Standard Precautions are designed to reduce the risk of cross contamination of microorganisms from both known and unknown sources. Regardless of the patients' diagnosis or presumed infection status, this Precautions should be suitable to apply to all of them. Especially when users who had contact with blood and body fluids. This also includes secretions and excretions (except sweat) regardless of whether blood is visible or not, non-intact skin (i.e., open wounds) and mucous membranes.

All the disposable items such as tubing, connectors, clamps, used canisters, used dressing..etc. should discard in accordance with local medical waste disposal regulations. Improper disposal may run the risk of regulatory non-compliance.

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 power unit.
- Unplug it 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 protective.

ATTENTION

Incompatible cleaning agents!

Parts of the Negative Pressure Wound Therapy device are made of plastic. Solvents can damage plastic and coatings. Strong acids or alkalis can cause them to become brittle.

8 Disinfection and Cleaning

8.1 Disinfection and Cleaning

Hygiene requirements of the operator

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

Disinfection procedures
Please follow the procedure required by your local health authority.

Disinfection procedures

Disinfection operation
Manual disinfection by wiping 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 disinfection.
(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 power unit.

CAUTION
For repair, contact your local distributor.
Please follow hygiene control regulations of your local government authority.

9 Care and Maintenance

9.1 Inspection

The operator must check the condition of the Negative Pressure Wound Therapy for each use; during use by patients; and at least once in a year especially in relation to the following:

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

9.2 Maintenance

When the Powered Suction Unit is not in use, please remove the battery from the case and it every 3 months.

carilex®

carilex®

10 Troubleshooting

Problem	Inspection Procedure	Possible Solution
1.) Power unit does not function	1.1) Check if power cord is firmly plugged into wall outlet	1.1) Secure power cord into wall socket
	1.2) Check if battery is empty	1.2) Connect the power supply adapter to the electrical outlet to recharge battery
	1.3) Check if the unit is in the Setting mode.	1.3) Complete the settings
2.) Insufficient performance	2.1) Check if the tube is partially kinked or the clip is engaged	2.1) Release clip, or remove kinks or check the system for blockages.
	2.2) Check system for leaks	2.2) Connect the tubing / canister properly. Seal dressings properly.
	2.3) Check if battery is almost empty	2.3) Charge the battery
	2.4) Check that the height of the suction unit is not more than one meter above the wound	2.4) Move unit to within one meter height of wound
3.) No suction	3.1) Check if tubing is blocked	3.1) Release clip, remove kinks or check the system for blockages. Remove clogs by applying a new dressing kit or pressing ^ & OK to start the suction at full speed to clear the blockage. ⚠ The blockage removal function is designed to aid the removal of blockage. Due to the varying condition of individual wounds, this function may not guarantee complete and successful removal of any blockage. ⚠ The blockage removal function will create high pressure suction, which may cause excessive bleeding. Please consult with the physician prior to activating the blockage removal function.
	3.2) Check if the canister is full	3.2) Replace the canister
If the troubleshooting procedures do not return the system to normal performance, stop using the system immediately and contact the authorized distributor for technical service.		

carilex®

carilex®

11 Technical Data

The VT · 200 is suitable for continuous operation.

Powered Suction pump

Model .....VT · 200
Dimensions (WxHxD).....18 x 17.9 x 8.9cm
Weight (with empty canister) 1.35kg
Nominal voltage 9.1Vdc
Medical device.....Class IIb
(comply with 93/42/EEC as amended by 2007/47/EC)
.....Class II (Comply with 21 CFR 878.4780)
IP Code IP22
Applied Part.....Type BF
IEC/EN 60601-1_v3.2 .....

AC Adapter

Eljintek_GMPU30UI-2 Electrical Class.....Class II
Power input.....100-240Vac 50/60Hz 1.0-0.6A
Power output.....9.1Vdc 3.3A max.

Li-Ion BP

Carilex Model .....59H-0186-506-G or 59H-0186-508-G;
Rechargeable Li-Ion Battery Pack; 2S2P
Normal Rating.....7.2Vdc 5.4Ah or 7.2Vdc 6.6Ah

Be aware of country-specific, local and facility regulations regarding disposal, especially of used batteries, electronics, and medical waste.

Operating Conditions
Temperature Range: 5°C to 35°C
Relative Humidity Range: 15% to 90%
Atmosphere Range: 700hPa to 1060hPa
This system is not AP / APG protected.

The NPWT must be decontaminated before disposal.
Disposal of old electrical and electronic equipment - valid in the European Union: WEEE Directive 2012/19/EU.

This symbol on the product or on its packaging indicates that this product should not be treated as household waste. Instead, this product should be taken to the appropriate place of disposal for the recycling of electrical waste and electronic equipment.

Declaration of Conformity

For EN 60601-1-2 (4th Ed.)

Company Name:	**Carilex Medical, Inc.**
Company Address:	**No. 77, Keji 1st Road, Guishan District, Taoyuan City 33383, Taiwan (R.O.C.)**
Product Name:	**NPWT, Powered Suction Pump**
Model No.:	**VT · 100, VT · 200, VT · 200-i**
Report Number:	**ETC 22-08-RBO-034**
Power Supply:	**1) 100-240Vac 50-60Hz or 50/60Hz…External AC Adapter** **2) 7.2Vdc……..…Internal Li-Ion Battery Pack**

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment

The Powered Suction Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Powered Suction Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Powered Suction Pump 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 $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

Declaration – electromagnetic emissions

The Powered Suction Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Powered Suction Pump should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Powered Suction Pump 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 Powered Suction Pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

12 EMC Declaration

Declaration – electromagnetic emissions and immunity – for EQUIPMENT and SYSTEMS that are use in the professional healthcare facility environment or in the home healthcare environment

The Powered Suction Pump declaration – electromagnetic immunity

The Powered Suction Pump system is intended for use in the electromagnetic environment specified below.
The customer or the user of the Powered Suction Pump system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level		Compliance level		Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms ; 6 Vrms 150 kHz to 80 MHz		3 Vrms ; 6 Vrms 150 kHz to 80 MHz		Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	3 V/m ; 10V/m 80 MHz – 2.7 GHz 80%		10V/m 80 MHz – 2.7 GHz 80%		
Proximity fields from RF wireless Communications equipment IEC 61000-4-3	27 V/m	385 MHz	27 V/m	385 MHz	
	28 V/m	450 MHz	28 V/m	450 MHz	
	9 V/m	710 MHz	9 V/m	710 MHz	
		745 MHz		745 MHz	
		780 MHz		780 MHz	
	28 V/m	810 MHz	28 V/m	810 MHz	
		870 MHz		870 MHz	
		930 MHz		930 MHz	
	28 V/m	1720 MHz	28 V/m	1720 MHz	
		1845 MHz		1845 MHz	
		1970 MHz		1970 MHz	
	28 V/m	2450 MHz	28 V/m	2450 MHz	
	9 V/m	5240 MHz	9 V/m	5240 MHz	
		5500 MHz		5500 MHz	
		5785 MHz		5785 MHz	

Declaration – electromagnetic immunity

The Powered Suction Pump system is intended for use in the electromagnetic environment specified below.
The customer or the user of the Powered Suction Pump system 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	±8 kV contact ±2 kV , ±4 kV , ±8 kV , ±15 kV air	±8 kV contact ±2 kV , ±4 kV , ±8 kV , ±15 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV ±1 kV differential mode ±2 kV common mode	±0.5 kV ±1 kV differential mode ±2 kV common mode	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	0 % U_T ; 0 , 5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycle Single phase: at 0°	0 % U_T ; 0 , 5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycle Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

13 Recommendations for Li-Ion Battery Pack

The following represents a typical, but non-exhaustive, list of suggestions provided by the equipment manufacturer to end-users.

1. Do not short-circuit a cell or battery. Do not store cells or batteries haphazardly in a box or drawer where they may short-circuit each other or be short-circuited by conductive materials. Do not dismantle, open, or shred secondary cells or batteries.
2. Do not remove a cell or battery from its original packaging until required for use.
3. Do not subject cells or batteries to mechanical shock.
4. In the event of cell leakage, do not allow the liquid to come into contact with skin or eyes. If contact is made, wash the affected area with copious amounts of water and seek medical attention.
5. Do not mix cells of different manufacture, capacity, size or type within this medical device.
6. Seek medical advice immediately if a cell or battery has been swallowed.
7. Keep cells and batteries clean and dry.
8. Wipe the cell or battery terminals with a clean dry cloth if they become dirty.
9. Secondary cells and batteries need to be charged before use.
10. After extended periods of storage, it may be necessary to charge and discharge the cells or batteries several times to obtain maximum performance.
11. The Li-Ion Battery Pack should be charged at temperature between 10ºC and 45ºC
12. The Li-Ion Battery Pack should be discharged at temperature between 10ºC and 60ºC
13. Do not use any charger other than that specifically provided for use with the equipment.
14. Do not use any cell or battery which is not designed for use with the equipment.
15. Battery usage by children should be supervised.
16. Always purchase the battery recommended by the device manufacturer for the equipment.
17. Do not leave a battery on prolonged charge when not in use.
18. Use only the cell or battery in the application for which it was intended.
19. When possible, remove the battery from the equipment when not in use.
20. Dispose of properly.

WARNING

The risk of battery thermal runaway may causing patient burn. Therefore, user shall follow the info of IFU, proper maintain battery.

carilex®

Document no.: 6EG-IS1002-PEN0117 ; Date of issue: 2024-10-21

carilex®

“暄達” 負壓傷口治療機

"Carilex" VT·200

Negative Pressure Wound Therapy System

衛部醫器製字第 006172 號

使用前務必詳閱使用手冊並遵照指示使用

負壓傷口治療中文使用手冊

目錄

1 安全須知

前言

感謝您選擇了“暄達”負壓傷口治療機(“Carilex” VT·200 Negative Pressure Wound Therapy System)。本產品擁有3C的特點：承諾(Commitment)、方便(Convenience)、符合法規(Compliance)，且介面人性化設計，為安全和有效的負壓傷口治療機。

請於第一次使用“暄達”負壓傷口治療機(以下簡稱本產品)前詳閱此使用手冊。以避免個人損傷或財產損害，並達到本產品之最大效用。為確保安全且有效使用，本產品僅能與"暄達"傷口敷料套組(衛部醫器製字第006172號)合併使用。

1.1 產品目標族群

使用手冊所指的人員如下：

• 經營者：
經營者(經銷商、健康保險公司、醫療院所等)，是指任何合法擁有本產品並且使用之，或以經營者名義使用之人員。經營者之責任為：提供安全的產品、指導人員正確的操作和使用產品。

• 使用者：
使用者為受過訓練或指導，而有資格操作本產品的人。使用者需為安全、正確的使用本產品並承擔責任，於每次使用前或轉換使用者時，需檢視本產品之功能和狀況並確認完整性。

• 專業人員 ：
專業人員為經授權、訓練之人員，通常是經營者之員工或是於醫療技術領域受專業訓練之人員。根據安全相關之規範而有的專業工作經驗和接受之指導，並且能在工作中發現可能的危害。

• 病患：
病患為依據專業醫師判斷，因醫療需求而使用本產品進行負壓傷口治療的患者。

注意

對使用者之提醒，本產品用於病患時，僅限由受過傷口護理、專業醫療抽吸程序、負壓傷口治療等訓練之醫護人員操作。若本產品已合法販售給經銷商、健康保險公司、醫療院所等，則有義務遵循此使用手冊向使用者及專業人員進行教學，以確保充分瞭解本產品的操作與用途。

• 本產品之交接：
若經營者將本產品釋出用於醫療用途，且適當的交接並經授權人員監督。交接後使用者須為本產品之安全使用負起責任。每次使用前請仔細閱讀使用手冊，以避免使用不當，導致產品性能及致命性的傷害。使用手冊需妥善保存，以利隨時檢視安全指示和其他重要資訊。

1 安全須知

• 製造業者 EMC 聲明：
對使用者之提醒，本產品依據最新之技術製作並且具備可靠性。
(1) 警告：使用本產品時，應避免可攜式和行動高頻或其他射頻通訊設備（包括天線）相鄰近或堆疊在一起，使用射頻通訊設備應保持與本產品的任何部分包含製造業者提供之電線均應保持 30cm 以上之安全間距，否則可能導致本產品性能下降。
(2) 本產品依 IEC 60601-1-2 法規要求符合輻射(Emission)與電磁抗擾性(Immunity)測試標準符合性聲明，相關之輻射等級，組別與電磁抗擾性測試和等級與指導原則，彙整於電磁相容 EMC 宣告書中，請詳閱本使用手冊第 8 單元電磁相容性。
(3) 使用非製造業者指定之配件可能影響 EMC 性能。

• 安全警示宣告：
(1) 警示標籤，請依相關規定。
(2) 充電鋰電池之更換，只能由完整受訓之授權經銷商人員進行，以避免產生危害。
(3) 未經製造業者之許可請勿改裝本產品。
(4) 請勿將未隨附使用手冊之本產品交予第三人。參考產品編號與版本，以確認隨附之使用手冊為最新且有效的版本。

• 意外預防程序：
為求與意外預防規範相符並防止意外損害，應遵循以下規定
(1) 每次使用本產品前應完整的清潔與消毒。
(2) 本產品之啟用與交接須由經營者指派之專業人員進行之。
(3) 應保有訓練紀錄，確保使用者瞭解本產品的設定模式及照護之操作與用途。

• 維修與組裝：
本產品或零件之維修僅能經由製造業者授權之經銷商人員進行。

• 本產品之清潔人員資格：
對本產品進行清潔與消毒的專業人員，需為熟悉衛生主管機關規範之專業人員執行。

1.2 產品用途
本產品是一種針對醫療院所設計的負壓傷口治療機，藉由在傷口床內形成負壓環境，達到移除傷口清洗溶液（ 如生理食鹽水）、傷口滲液、體液及感染物質等，以促進傷口癒合。

1.3 適應症
本產品可適用於下列開放性之急性及慢性傷口：
• 創傷傷口（ 或外傷性傷口）
• 術後撕裂式傷口
• 皮膚移植
• 糖尿病足
• 壓瘡

注意

本產品需經專業醫師評估傷口類型及情況，由醫師處方指示適用於負壓傷口治療。

1 安全須知

1.4 禁忌症

有以下情況病患不建議使用負壓傷口治療：

- 存在痂皮的壞死組織的傷口
- 惡性腫瘤傷口
- 未經治療的骨髓炎
- 暴露之血管、器官或神經、器官或體腔的瘻管
- 非腸道性瘻管及未經檢查之瘻管

1.5 警告

保護血管和器官：使用本產品前，必須完全覆蓋並保護傷口內部或傷口周圍的所有淺層血管與器官，並隨時確認本產品未與血管或器官直接接觸。

注意

醫護人員需對病患進行嚴密的出血監控，及考量初始治療時所設定的負壓值與模式。

出血：不論是否使用本產品，部分患者可能處於出血併發症的高度風險狀態下。若未受到適當的護理照護，下述病患可能增加出血的風險，嚴重可能導致死亡：因血管或器官縫合、感染、創傷或放射治療等相關因素，而造成傷口內部或器官或周圍血管脆弱或衰弱的病患；未對傷口進行充分止血的病患；已接受抗凝血劑或凝血抑制劑藥物治療的病患；病患血管縫合位置上無適當組織覆蓋。

注意

治療期間，如果發生突然出血或大量出血或管道中或滲液收集罐中可看到明顯（鮮紅色）血液時，請立即中斷本產品，採取止血措施並通知醫護人員。

- 突出的骨碎片或銳利邊緣：可能刺穿保護屏障、血管或器官，進而引起損傷造成出血。小心傷口內組織、血管或器官相對位置的可能偏移，因為這可能會增加與銳利邊緣接觸的可能性。必須覆蓋或排除傷口區域內的銳利邊緣或骨頭碎片，防止它們在使用本產品治療前造成血管或器官穿刺。移除傷口敷料時必須特別留意，避免無保護的銳利邊緣造成傷口組織受傷。
- 受感染血管：感染可能會侵蝕血管並造成血管壁弱化，進而可能增加易受磨損或操作造成之血管損傷影響的可能性。
- 施用於傷口位置處的止血劑：如果非縫合性止血劑（如：骨蠟、吸收性明膠海綿、或傷口密合噴劑）破裂的話，會增加出血風險，而未加以控制時，嚴重可能導致死亡。

1 安全須知

受感染傷口：依據傷口狀況、治療目標、與清洗治療參數（適用本產品），受感染傷口應接受嚴密監控且敷料更換頻率應比未受感染傷口頻繁。

- 不論使用何種傷口治療，醫護人員與照護者皆應經常監控病患的傷口、傷口周圍組織與分泌物是否有感染、感染惡化、或其他併發症的徵象。
- 部份感染徵象為發燒、壓痛、發紅、腫脹、發癢、起疹子、傷口床或傷口周圍區域溫度上升、流膿或惡臭。
- 感染狀況可能很嚴重，並導致疼痛、不適、發燒、壞疽、中毒性休克、敗血性休克抑或致命性損傷等併發症。
- 全身性感染的部份徵象或併發症有噁心、嘔吐、腹瀉、頭痛、頭昏、暈炫、伴隨黏膜腫脹的喉嚨痛、方向感喪失、高燒、姿勢性低血壓或剝屑性皮膚炎。
- 如果傷口位置出現任何上述提及的感染症狀，請立即與主治醫師聯繫以決定是否停止使用本產品。

未經治療的骨髓炎：禁止使用本產品，未經治療的骨髓炎傷口床施以敷料可能會導致感染擴散。

脊髓損傷：若病患出現脊髓損傷且發生自主神經反射亢進，必須中斷負壓傷口治療。

磁振造影(MRI)：本產品非核磁共振安全裝置。禁止將本產品攜入MR環境中。

高壓氧療法(HBO)：禁止將本產品帶入高壓氧艙。本產品不適合在此環境中使用，可能會有火災危害。在關閉本產品後，於HBO治療期間需使用HBO相容的材料替換負壓傷口治療敷料；或者在HBO治療過程中用濕紗布覆蓋引流管的開口端並用濕毛巾完全覆蓋敷料（包括引流管）。HBO治療時，不可夾住本產品管道系統。

維持本產品的運作狀態：置入傷口敷料後，本產品的中斷時間不得超過2小時。若中斷超過2小時，請取出置入的敷料並重新清洗傷口；以未開封的無菌包裝中取出全新的本產品搭配性敷料充填傷口床，並重新開啟治療，或依主治醫師指示施以替代敷料。

注意

中斷時間愈長時，愈可能導致傷口床滲液滯留和局部浸潤的現象，亦可能在黑色海棉敷料內產生凝血現象而使傷口敷料阻塞，皆可能增加傷口床感染的危險性。

1 安全須知

1.6 注意事項

- 病患的健康狀況：在進行任何負壓傷口治療時，必須考量病人的體重和整體情況。應嚴密監控幼兒、體格纖細成年人和老年病患的體液流失與脫水現象。病患傷口屬於大量分泌液或大範圍的情形時，皆應嚴密監控是否有過量體液流失與脫水風險；監控體液流出時，亦應觀察管道與滲液收集罐內的液體量。

- 有易燃或爆炸性氣體或液體：本產品不得使用於有易燃物或爆炸性氣體或液體的處所。

注意

本產品不適用於有爆炸危險和高含氧的區域內。使用可燃性麻醉劑（或與空氣、氧氣或氧化亞氮混合）、皮膚清潔劑及消毒劑的區域，皆有發生爆炸的風險。

- 標準預防措施：為降低血液傳播病菌的風險，請依據衛生主管機關規範對所有病患採用標準之感染控制預防措施。如果有接觸暴露體液的可能性，除配戴手套外，亦請穿戴手術衣、護目鏡及口鼻保護套等。

- 治療模式：本產品除連續模式及間歇模式外，亦提供清洗模式供負壓傷口治療選擇。清洗模式為搭配外部的點滴設備供給傷口清洗液，利用重力式滴注清洗溶液供給傷口床，並依據醫師開立醫囑，設置滴注速率及清洗時間。

注意

滴注速率需由主治醫師視傷口床尺寸與狀態而訂定。未取得醫師處方或監督狀況下，不可對本產品進行參數設定或執行治療應用。

- 負壓傷口治療機的壓力上升：在極少數狀況下，本產品如有故障，使負壓超
- 過 -200㎜Hg 以上，觸發警報且螢幕出現文字顯示，請立即關機、停止使用產品，
- 並參照使用手冊或與製造業者及醫療器材商聯繫。

注意

不正確操作本產品可能會導致病患疼痛或受傷。過高的負壓設定或傷口的感染可能導致病患疼痛或出血。為避免交叉感染，負壓傷口治療機之全機消毒與清潔須於轉換使用者時進行。若病患患有需通報性之傳染疾病，請向專家諮詢後再進行消毒與清潔。

注意

本產品使用期間，醫護人員及照護人員需定期巡檢病患傷口、敷料及本產品狀況，需檢視傷口與傷口邊緣是否有滲漏、浸潤、感染以及失去負壓的情形。檢查過程中，傷口敷料的密封性也須注意。如有以上情況，請立即通知醫護人員。

1 安全須知

1.7 產品清潔

- 清潔本產品機台外殼時，請務必拔除電源線並關閉電源，以避免觸電。
- 本產品為重複使用，每次使用前，須以符合當地醫療機關所規定之消毒清潔程序，並穿戴手套，清理本產品機台、攜帶背包以及其他可能接觸病人之配件。
- 收集罐為單次使用(single use)，使用後，請依生物醫療廢棄物規定處理後丟棄。
- 清潔本產品，應穿戴個人保護設備，以進行感染控制：

 護目鏡  保護手套  口鼻保護罩

 注意

負壓傷口治療機之機台或配件的消毒，僅能由熟悉院所清潔規範之專業人員進行。經營者須知悉關於負壓傷口治療機及衛生主管機關的相關規範。

- 消毒程序

清潔前，請確實移除並丟棄所有拋棄式配件，例如收集罐、敷料套組之膠布、黑色海棉及 Port 導管組；控制組件之消毒可採用濕布擦拭消毒。
濕布擦拭清潔與消毒之步驟：

1. 消毒前
   (1) 確實配戴手術型手套與口罩
   (2) 以 75% 之酒精或其他符合地方衛生主管機關規範之清潔液清潔雙手
   (3) 以清潔液擦拭表面
   (4) 依照清潔液製造業者之指示使用
2. 清潔
   (1) 以符合地方衛生主管機關規範方式，以清潔液擦拭累積之灰塵，並進行消毒
   (2) 以乾淨、柔軟之布料與清水，微濕狀態下擦拭表面
   (3) 以乾淨、柔軟之布料拭乾表面
3. 控制
   檢查本產品控制組件之功能，若需維修，請聯絡製造業者或經授權的經銷商人員

- 不相容之清潔劑：

本產品的部分組件是由塑膠所構成，有機或無機酸鹼溶劑可能會造成腐蝕性損壞。強酸或強鹼可能會導致塑膠之脆化。清潔本產品請勿使用烴溶劑或含有強酸、強鹼之洗滌劑及研磨清潔材料。

- 不相容之消毒液：

清潔本產品，請勿使用含油漆稀釋劑、鹼、酸及醛類等。含有醛類和胺類的消毒劑，可能會造成本產品褪色。

1 安全須知

注意

接觸清潔液可能危害健康與受汙染可能性而導致感染。清潔劑與消毒液可能含有害成分，請依照清潔劑與消毒液製造業者使用說明執行，尤其是針對濃度調配的部分，並留意材料相容性和接觸時間的部分。

注意

符合衛生主管機關規範之負壓傷口治療機的機台並非於無菌狀態下組裝。每次使用前，請清潔並消毒機台後再使用。

注意

清潔時，散落的電源線可能會導致絆倒和嚴重傷害。

注意

應避免本產品使用狀態下與液體接觸，由於水具有高度導電性，可能導致致命性觸電。

注意

本產品須由受過訓練之專業人員，於每次使用前進行操作安全性的檢查，尤其是控制組件之功能與控制標示正確性；長期未使用的狀況下，至少每年例行檢查一次。

1 安全須知

1.8 產品使用須知

(1) 本產品為醫療器材，僅限醫護人員或製造業者授權之產品相關的專業人員操作。

(2) 本產品使用前，需閱讀本使用手冊，確實瞭解產品適應症、禁忌症、警告及相關安全注意事項，以避免誤用導致病患疼痛或造成危害。

(3) 本產品限使用製造業者原廠之零配件、傷口敷料套組、收集罐，以確保產品之安全及效能。

(4) 每次使用本產品前，必須執行例行性檢查。

(5) 本產品需於穩固、平整之環境操作。使用期間，本產品必須全程保持直立。

(6) 本產品不得用於吸痰、或吸取爆炸性氣體與可燃／具腐蝕性的液體。

(7) 當產品開機狀態時，切勿無人監控。

(8) 請勿讓本產品曝露於高溫、洗澡或淋浴等潑濺範圍內，或存在爆炸危險的環境中。

(9) 勿將產品零組件或配件浸泡於液體中，或將其置於浴缸或水槽使其有浸水之危險。即便未開機，也不得將產品浸泡在水裡。

(10) 請遵照技術資料所載明之建議儲存環境及操作溫度條件。若本產品於該溫度範圍以外使用，可能會降低效能且造成機械和電池組損毀。

(11) 需定期檢查本產品功能和其他與安全相關的問題，請參考維修手冊。

(12) 溢流保護：細菌過濾器能保護本產品幫浦抵抗溢流（幫浦內流體流動），當過濾器潮濕或堵塞時，幫浦抽吸功能會被中斷。

(13) 本產品應遠離孩童、並注意環境衛生，避免蟲害、塵土及棉絮等，會損害產品零組件進而影響效能。

(14) 本產品與配件需小心、安全的放置於病患之床邊，避免連接管纏繞病患。產品有提供攜帶背包，可供攜帶本產品使用。需經過醫師進行評估病患情況是否適合攜帶使用。若轉換病患使用時，需確認該攜帶背包經過消毒或更換新的背包。

(15) 本產品為帶電之醫療器材，請注意用電安全：

- 在產品插電前，請檢查電力供應設備規格是否符合操作環境規範。
- 請勿將插頭接於損壞之插座。
- 避免插頭與開關接觸到濕氣或沾濕。
- 確保插頭和電線遠離外在熱源。
- 維修與清潔時，須將本產品關機並拔除電源。
- 針對電磁相容性(Electro Magnetic Compatibility, EMC) 採取特別的安全措施，必須按所附 EMC 訊息安裝及運作。
- 攜帶式和移動式射頻(RF) 通訊設備可能會影響醫療產品。
- 充電電池:產品使用前先充電，充電電池依使用狀況大約可重覆充電 300-500 次。如果長時間不使用本產品，建議每三個月將電池充飽電，以增加電池壽命。如果操作時間或充電時間變短，請更換電池，若未遵守更換電池注意事項規定而導致故障，本公司概不負責。
- 充電時，本產品亦能操作使用。
- 在下列情形下，請勿充電或啟動產品，並請將電源線從插座拔除，聯絡製造業者或醫療器材商檢查：電源線或電源座損壞、本產品無法正常運轉、本產品有損壞、掉落、泡水情況或有明顯會影響本產品安全運作的情況。

(16) 本產品是由電路版與塑膠殼搭配組成。欲報廢時，應遵循當地政府規範消毒與丟棄相關規定。任何組件皆不得與家庭／醫療機構廢棄物共同丟棄，尤其本產品內含電池。

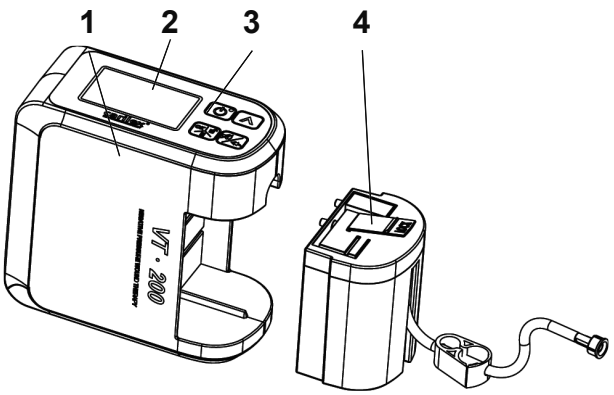
(17) 用過的收集罐、引流管與敷料之拋棄，應遵循當地或醫療機關處理生物醫療廢棄物規範。不正確之丟棄方式可能會造成環境與公共衛生之危害。

carilex®

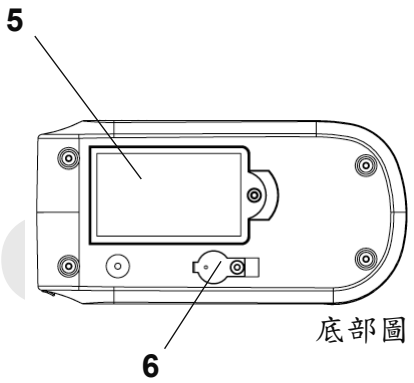
2 操作元件及功能描述

2.1 操作元件

- 本產品內含幫浦 1 是抽吸功能的主要元件
- 顯示螢幕 2 顯示資訊
- 操作面板 3 開關及選擇功能鍵
- 收集罐 4 用來收集液體
- 充電鋰電池 5
- 過濾棉 6
- 電源線及插頭 7 包含
  - > 電源供應器
  - > 四個可更換的插座頭。



立體圖



底部圖

注意

當需要更換充電鋰電池及過濾棉時，請聯繫經授權之經銷商人員，依本產品之維修手冊進行更換作業。

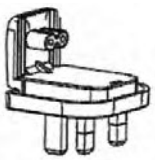
注意

當更換不同插座頭時，請確認其確實接合。如果連結失敗的話會造成電力故障。

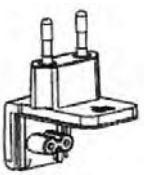
P/N R-NA-2(R)
北美
中國
日本

P/N R-SAA-2(R)
澳洲

7



P/N R-UK-2(R)
英國
香港
新加坡



P/N R-EU-2(R)
歐洲
南美

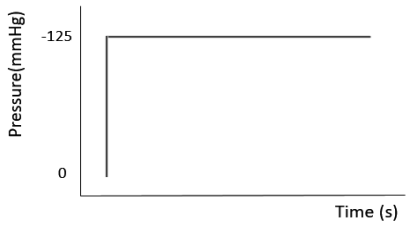
2 操作元件及功能描述

2.2 功能描述

本產品透過抽吸幫浦讓傷口床達到所設定的負壓環境，將傷口的滲出液引流離開傷口床，進入到傷口敷料和管道，再進到本產品收集罐。

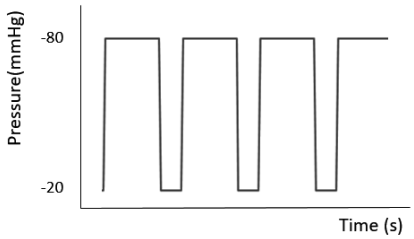
• 連續模式：

在此模式中，傷口床將會在設定的負壓中維持恆定。預設參數為 -125mmHg，示意如下圖：



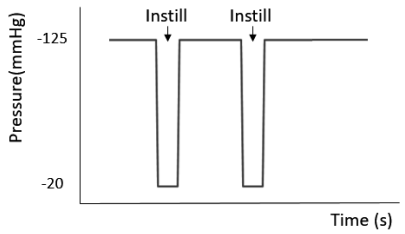
• 間歇模式：

在此模式中，壓力會依設定的高壓及低壓值之間，規律的切換。預設參數為 5 分鐘高壓 -80mmHg，2 分鐘低壓 -20mmHg，示意如下圖：



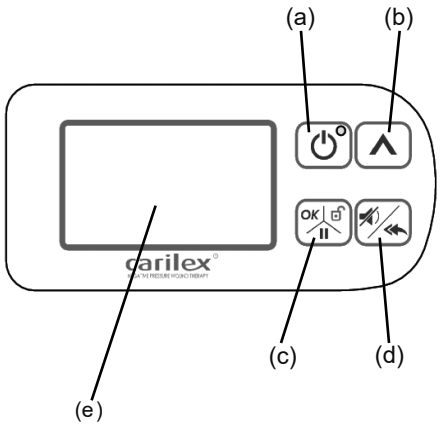
• 清洗模式：

在此模式中，可設定傷口清洗溶液由點滴滴注的時間和負壓值，再搭配連續負壓模式將滲液、感染物質和傷口清洗液移除，且可調整清洗模式循環次數。例如設定參數為一小時連續模式 -125mmHg，清洗模式 -20mmHg 兩次 10 分鐘），示意如下圖：



注意

各種治療模式、負壓值或滴注參數設定，均須由醫師開立醫囑，依據傷口情況指示使用。



操作介面

(a) 開 / 關機鍵

(b) 移動鍵

(c) OK / 解鎖 / 暫停

(d) 靜音 / 返回上頁

(e) 顯示螢幕

符號說明

	電池狀態
	待充電
	無法充電
	充電中
	操作介面鎖定
	錯誤 / 異常
	機器運轉中
	維修
	電池故障

3 使用前注意事項

3.1 電池

• 充電須知

選擇符合當地使用的插座頭，接上插座。螢幕上的電池閃爍，即表示本產品充電中。

注意

在首次使用本產品前，須至少充電四小時至完全充飽，才能產生最佳的電池表現及增加電池使用次數。如果本產品未被使用超過三個月，電池需再度充電。

注意

本產品電池使用時間會根據使用狀況而有所不同，其平均使用次數為 300 次。其使用及儲存環境請詳閱第 7 單元技術規格及第 9 單元電池安全性之內容。

注意

拋棄本產品電池時，請依照當地政府規範之相關規定執行。

3.2 收集罐

- 請確認收集罐正確地安裝於本產品上。
- 使用本產品時，必須全程保持直立（螢幕向上）。
- 收集罐使用具活性碳過濾功能的防水透氣膜，避免固體或液體滲入機器。

組裝步驟：

1. 將收集罐連接凹槽裝入幫浦的對應點。
2. 收集罐上有標示容量的那側必須和本產品機身字樣同側且與 LED 螢幕保持垂直。
3. 平滑收集罐直到與本產品兩者完全接合，並聽到喀擦聲。

注意

收集罐僅供單次使用，禁止重複使用，以避免交叉感染。

4 使用步驟

1. 使用前，請確實檢查：

- 電源線或電源插座有無損壞
- 本產品有無損壞
- 包裝完整度
- 電池狀態

2. 請參考 3.2 將收集罐和幫浦接合。

3. 將收集罐上之引流管接頭與敷料引流管接頭確實鎖上。

注意

碰觸到帶電的組件可能會導致人員觸電而死亡或產生嚴重傷害。在連接前，請檢查電源座和操作面版的電源線有無損壞。損壞之組件不得再使用。

4. 功能鍵使用

(1) 開 / 關機鍵

> 開機：按壓開 / 關機鍵 持續三秒鐘
> 關機：按壓開 / 關機鍵 持續三秒鐘，螢幕會轉暗。

(2) 靜音 / 返回上頁

在接收警示後，接壓 以解除聲音訊息。

按壓 ，系統會回到前一選單，按壓 以從副選單回到主選單。

(3) 移動鍵

於連續模式或間歇模式，按壓 以選擇所需求的壓力或分鐘。每次調整幅度為 -5mmHg 或一分鐘。

(4) OK / 解鎖 / 暫停

按壓 以選擇項目。按壓 以從主選單進入副選單。

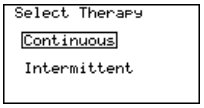
於療程模式，按壓 以停止療程。

當顯示螢幕被鎖定時，按壓 三秒以解鎖。

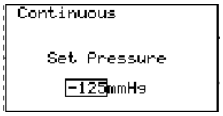
4 使用步驟

(a)

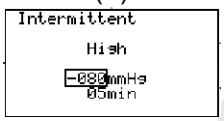
(b)



(c)



(d)



5. 開 / 關機

(1) 開機：按下電源鍵三秒鐘，電源鍵綠色 LED 燈即會亮起，且顯示螢幕會出現畫面 (a)。
(2) 關機：按下電源鍵三秒以關閉機器。若機器已被鎖定，則按壓 OK 三秒鐘以解鎖，再按下電源鍵三秒以關閉機器。

6. 療程模式設定
(1) 按壓開關機鍵開機以選擇療程模式。
(2) 當螢幕出現 VT • 200 的圖樣，若想回到上次的設定，立刻按壓 OK 或等待 5 秒 - 螢幕顯示 (b).
(3) 按壓 ^ 以移動游標至所需求之模式，再按下 OK。

6.1 連續模式中壓力設定 (c)

(1) 按壓 ^ 選擇從 -30mmHg 到 -200mmHg 間的壓力設定，系統預設值為 -125mmHg。
(2) 選定療程壓力後，按壓 OK 開始療程。

6.2 間歇模式中壓力設定 (d)

(1) 按壓 ^ 選擇 -50mmHg 到 -200mmHg 間的高壓設定，系統預設值為 -80mmHg，最後再按壓 OK 確認。

(2) 按壓 ^ 選擇高壓療程從 1 到 10 分鐘的時間設定。系統預設值為 5 分鐘，最後再按壓 OK 確認。

(3) 按壓 ^ 選擇 -20mmHg 到 -80mmHg 間的低壓設定，系統預設值為 -20mmHg，最後再按壓 OK 確認。

(4) 按壓 ^ 選擇低壓療程從 1 到 10 分鐘的時間設定。系統預設值為 2 分鐘，最後再按壓 OK 確認。

4 使用步驟

7. 負壓傷口治療操作步驟

使用本產品進行負壓傷口治療需經醫師評估傷口狀況後開立醫囑，指示所需使用之治療模式（連續、間歇或清洗模式），必要時可指定清洗模式的傷口清洗溶液種類（常見為生理食鹽水）和滴注速率。

注意

請確實將收集罐安裝完成，並聽到喀擦聲。

清洗模式僅能在受過訓練的醫護人員監督下使用。

操作步驟如下：

(1) 清創傷口床，並擦乾傷口周圍的皮膚。

(2) 從無菌敷料包中取出黑色泡棉與防水透氣膠布及 Port 組貼片。

(3) 依照傷口裁剪適當大小的泡棉敷料置入傷口床，並避免泡棉接觸到健康的皮膚。

(4) 裁剪適當大小的膠布 (A)，並確保四邊至少有 3~5 公分以上的邊緣能夠黏附在乾燥、完整且健康的皮膚上。

(5) 於膠布貼片上剪出約 2 公分的孔洞 (B)，此端供負壓治療移除傷口滲液。

(6) 將 Port 組貼片背膜撕下，貼附於負壓孔洞處並固定 (C)，此端連接至本產品收集罐。

選擇連續或間歇治療模式，請跳至步驟 (11)

選擇清洗模式，請接著以下步驟：

(7) 獲得醫師開立使用清洗模式之醫囑及各項參數（負壓值、清洗時間和次數）等。

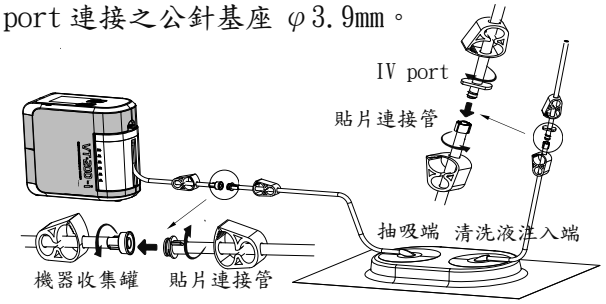
(8) 將傷口清洗溶液準備於 IV 端，且完全關閉滴注狀態。

(9) 於膠布貼片上另一端剪出約 2 公分的孔洞，此端供清洗模式注入傷口清洗溶液。

注意

確保傷口清洗溶液保持關閉，直到清洗治療開始；清洗孔洞建議放置在遠離負壓抽吸口的傷口區域。

(10) 取出另一個 Port 組將背膜撕下，黏接於清洗孔洞處並固定，此連接端須使用與 IV port 連接之公針基座 φ3.9mm。



注意

本產品的所有耗材皆僅供單次使用，為確保產品使用之安全及有效性，請搭配＂暄達＂傷口敷料套組（衛部醫器製字第 005375 號）合併使用；請選用具醫療器材許可的公針基座。

(11) 檢查所有連接管路，確保已連接緊密。

(12) 確認負壓抽吸端白色管夾已鬆開。

(13) 在啟動機器前，請確實詳閱“暄達”負壓傷口治療機的使用手冊。

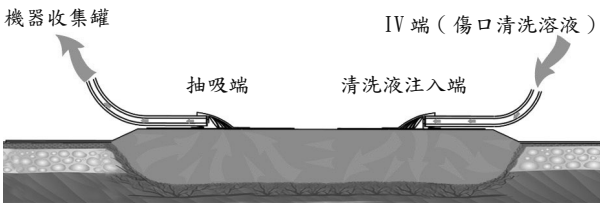
(14) 啟動機器，待傷口床達到設定的壓力。

注意

傷口床愈大，達到目標壓力所需時間愈長。

(15) 模式啟動後，須檢查敷料的密封性。

(16) 鬆開 IV 端管夾，讓傷口清洗溶液滴注入清洗端至傷口床，確認清洗溶液（下圖箭頭流向）通過負壓抽吸端進入收集罐中。



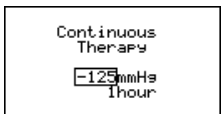
(17) 當聽到清洗模式結束提示音，請關閉 IV 端管夾，停止清洗液注入傷口床。若清洗模式設定大於一次，第二次起接續步驟 (15) 開始。

注意

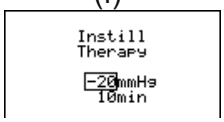
傷口清洗模式時可不需精準的滴速；除非治療壓力值改變，否則滴注速率建議保持恆定。

4 使用步驟

(e)



(f)



注意事項

(1) 若需要停止療程，則按壓 以停止。若要重新啟動療程，則再次按壓 以重啟。

(2) 若三分鐘沒有動作，系統會自動鎖定螢幕。再次按壓 三秒鐘以解鎖。

(3) 若需求之壓力或時間需要變更，按壓 以解鎖，再次按壓 以回到主設定畫面。

(4) 療程期間，按壓 以檢視設定細節 5 秒鐘。(e, f)

(5) 螢幕於 3 分鐘後轉暗節電。

8. 靜音 / 返回上頁

(1) 按壓 一次以關閉聲音警示。

(2) 當幫浦在連續模式運轉中，按壓 以返回上頁設定參數。

(3) 接續 (2)，再按壓 一次，返回上頁選擇療程模式。

9. 收集罐更換步驟

更換之判斷基準為目測或由顯示螢幕之滿瓶警示，本產品能夠偵測收集罐已滿。當收集罐充滿傷口床移除之液體，會出現聲音和文字警示，於顯示螢幕上。請勿橫向拉扯收集罐之引流管，以避免破壞收集罐之吸入口。收集罐滿瓶時須妥善丟棄；於不同病患使用時收集罐應更換。收集罐更換、檢視之時機為每周、更換病患時或於其他需要時。

(1) 洗淨雙手並戴上拋棄式手套。

(2) 將敷料端及收集罐端的引流管上的管夾夾緊，然後從引流管上的鎖頭上將收集罐和敷料分離。

(3) 以按壓的方式，平滑地將裝滿液體的收集罐自機器取下。收集罐的丟棄方式必須依當地法規規定。

(4) 依照 3.2 指示的方式裝上新的收集罐。

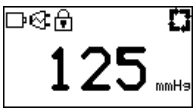
注意

請勿重複使用收集罐，以避免病患間之交叉感染。

5 警報指示

本產品如偵測到以下情形，螢幕會亮起同時出現聲音和文字警示。

按壓 [^] 以調整訊號音量。當按壓靜音鍵後，聲音訊號會被解除，但橘燈會持續閃動(1 秒亮/1 秒暗)，直到問題獲得解決。警示會出現於顯示螢幕。

警示	顯示	可能發生原因	解決方式
洩漏		(1) 收集罐沒有正確安裝 (2) 引流管脫落沒有正確連接 (3) 敷料沒有完全密封	(1) 按壓靜音鍵以解除聲音訊號 (2) 密封敷料或正確的使用 (3) 當問題獲得解決後，幫浦即會恢復運作
阻塞		(1) 引流管折管 (2) 引流管管夾關閉 (3) 引流管堵塞	(1) 按壓靜音鍵以解除聲音訊息 (2) 檢查並確認引流管沒有折管、阻塞或管夾關閉之情形 (3) 若阻塞訊息仍未消失，於傷口上換上新敷料或同時按壓 [OK] 及 [^] 以啟動阻塞排除功能。阻塞排除功能之設計為協助排除阻塞，當兩鍵同時按壓時幫浦會持續全速運轉；當鬆開按鍵後，此功能即會停止。依據不同病患之傷口狀況，此功能不能確保所有傷口之阻塞的完全排除。阻塞排除功能會產生高強度吸力，可能會導致大量流血。 請於啟動此功能前與醫師討論。
滿瓶		收集罐滿瓶	(1) 按壓靜音鍵以解除聲音訊號 (2) 更換新的收集罐 (3) 按壓 OK 鍵
低電力		低電力	使用電源線為裝置充電
聯絡維修人員		設備故障	請聯絡授權的經銷商以尋求協助

6 故障排除及相關符號

6.1 故障排除

問題	檢測步驟	解決方式
機器無法運轉	步驟 1：檢查電源是否插好	將電源線插好
	步驟 2：檢查螢幕上顯示電池的充電狀態	將電源線插上充電
	步驟 3：檢查螢幕是否仍在設定模式	完成設定
運作壓力無法達到設定壓力	步驟 1：檢查引流管是否折管或管夾是否已鬆開	鬆開管夾、解決折管或檢查系統是否阻塞
	步驟 2：檢查敷料或罐子是否正確安裝或洩漏	正確安裝收集罐、引流管及貼妥敷料
	步驟 3：檢查螢幕上顯示電池的充電狀態	將電源線插上充電
	步驟 4：檢查抽吸組件是否高於傷口一公尺	將抽吸組件移靠近傷口，且距離於一公尺內
無法抽吸	步驟 1：檢查引流管有沒有折管	(1) 鬆開管夾、解決折管 (2) 換上新的敷料或同時按壓 OK 及 ∧ 以使抽吸全速運轉以清除阻塞
	步驟 2：檢查收集罐是否已滿	換新的收集罐
如解決方式無法排除問題，請聯絡製造業者或授權的經銷商。		

6 故障排除及相關符號

6.2 相關符號

	醫療器材
	使用前請詳閱使用手冊
	BF 類觸身部件
	製造業者
	製造日期含國別
	第二類電源
	歐盟認證
	產品編號
	產品序號
	產品批號
	廢棄物之處理
	醫療處方專用
	溫度條件
	遠離核磁共振設備
	警示標誌

7 技術規格

品名	" 暄達 " 負壓傷口治療機
抽吸量	4L/ 每分鐘
負壓	最大負壓 -200mmHg(-27kPa)
adaptor 電源輸入	1) 100-240Vac 50-60Hz 1.5A (for GTM91120-3010.5-1.4-T2) or 2) 100-240Vac 50/60Hz 1.0-0.6A (for GMPU30UI-2)
adaptor 電源輸出	1) 9.1Vdc 3.3A 2) 9.1Vdc 3.29A
電源供應器	1) GlobTek GTM91120-3010.5-1.4-T2 or 2) GMPU30UI-2
最大功率	Max:30W
尺寸 (HxLxW)	18x17.9x8.9(±0.5)cm
重量	1.35kg(含收集罐)
收集罐容量	300,500,1000cc/ml
防水防塵等級	IP22
操作模式	Continuous 連續模式 負壓選擇範圍：-30mmHg to -200mmHg 預設參數：-125mmHg
	Intermittent 間歇模式 負壓與時間設定範圍 高壓：-50mmHg to -200mmHg，可設定 1-10 分鐘 低壓：-20mmHg to -80mmHg，可設定 1-10 分鐘 預設參數：高壓 -80mmHg 為 5 分鐘、低壓 -20mmHg 為 2 分鐘
可充電電池	鋰電池 電壓：7.2Vdc 電池容量：6000mAh. 充電時間：8hrs. 可用時間：最長 24 小時
操作環境	操作溫度：5˚C to 35˚C 大氣壓力：700hPa to 1060hPa 相對溼度：15% to 90%
運輸、儲存條件	儲存溫度：-25˚C to 70˚C 相對溼度：0% to 90 % non-condensing

Declaration of Conformity

For EN 60601-1-2 (4th Ed.)

Company Name:	**Carilex Medical, Inc.**
Company Address:	**No. 77, Keji 1st Road, Guishan District, Taoyuan City 33383, Taiwan (R.O.C.)**
Product Name:	**NPWT, Powered Suction Pump**
Model No.:	**VT · 100, VT · 200, VT · 200-i**
Report Number:	**ETC 22-08-RBO-034**
Power Supply:	**1) 100-240Vac 50-60Hz…External AC Adapter 2) 7.2Vdc……..…Internal Li-Ion Battery Pack**

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment

The Powered Suction Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Powered Suction Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Powered Suction Pump 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 $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

Declaration – electromagnetic emissions

The Powered Suction Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Powered Suction Pump should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Powered Suction Pump 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 Powered Suction Pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

8 電磁相容性

Declaration – electromagnetic emissions and immunity – for EQUIPMENT and SYSTEMS that are use in the professional healthcare facility environment or in the home healthcare environment

The Powered Suction Pump declaration – electromagnetic immunity

The Powered Suction Pump system is intended for use in the electromagnetic environment specified below.
The customer or the user of the Powered Suction Pump system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level		Compliance level		Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms ; 6 Vrms 150 kHz to 80 MHz		3 Vrms ; 6 Vrms 150 kHz to 80 MHz		Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	3 V/m ; 10V/m 80 MHz – 2.7 GHz 80%		10V/m 80 MHz – 2.7 GHz 80%		
Proximity fields from RF wireless Communications equipment IEC 61000-4-3	27 V/m	385 MHz	27 V/m	385 MHz	
	28 V/m	450 MHz	28 V/m	450 MHz	
	9 V/m	710 MHz	9 V/m	710 MHz	
		745 MHz		745 MHz	
		780 MHz		780 MHz	
	28 V/m	810 MHz	28 V/m	810 MHz	
		870 MHz		870 MHz	
		930 MHz		930 MHz	
	28 V/m	1720 MHz	28 V/m	1720 MHz	
		1845 MHz		1845 MHz	
		1970 MHz		1970 MHz	
	28 V/m	2450 MHz	28 V/m	2450 MHz	
	9 V/m	5240 MHz	9 V/m	5240 MHz	
		5500 MHz		5500 MHz	
		5785 MHz		5785 MHz	

Declaration – electromagnetic immunity

The Powered Suction Pump system is intended for use in the electromagnetic environment specified below.
The customer or the user of the Powered Suction Pump system should assure that it is used in such an environment.

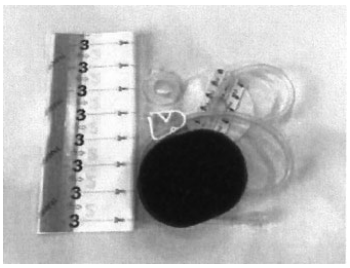
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV , ±4 kV , ±8 kV , ±15 kV air	±8 kV contact ±2 kV , ±4 kV , ±8 kV , ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV ±1 kV differential mode ±2 kV common mode	±0.5 kV ±1 kV differential mode ±2 kV common mode	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	0 % U_T ; 0 , 5 cycle At 0^o , 45^o , 90^o , 135^o , 180^o , 225^o , 270^o and 315^o 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycle Single phase: at 0^o	0 % U_T ; 0 , 5 cycle At 0^o , 45^o , 90^o , 135^o , 180^o , 225^o , 270^o and 315^o 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycle Single phase: at 0^o	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

9 電池安全性

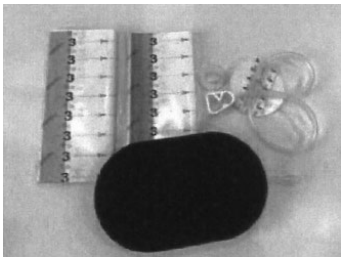
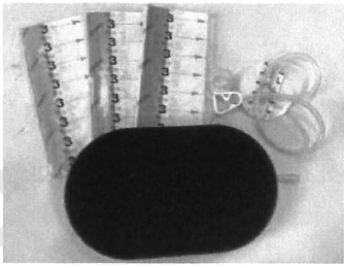
下列為可充式電池製造業者給予本產品製造業者對於終端使用者的產品建議。

1. 請勿連接短路電池或電池組。請勿將電池或電池組任意堆放於抽屜或盒子中，以避免與不同電池或其他傳導性物質相接短路。
2. 在使用前，請勿拆除電池或電池組外包裝。
3. 請勿機械衝擊電池或電池組。
4. 若電池洩漏，請勿讓漏液接觸皮膚或眼睛。若有接觸，請以大量清水沖洗並尋求醫療協助。
5. 請勿將不同製造業者、容量、大小與類型之電池組裝於同一電池組中。
6. 若吞下電池或電池組，請立即請求醫療協助。
7. 保持電池之乾燥與清潔。
8. 若電池或電池組不潔淨，請以乾淨、乾燥之布料擦拭。
9. 於使用可充式電池前須充電。正確的充電方式請參照製造業者之使用說明。
10. 在沒有使用的情形下，請勿將可充式電池持續於充電狀態。
11. 在長期閒置可充式電池後，可能需經充電、放電數次，才可達到其最佳效能狀態。
12. 鋰電池組須於 10°C 至 45°C 之間充電。
13. 鋰電池組須於 10°C 至 60°C 之間放電。
14. 請勿使用非原先隨附之充電器充電。
15. 請勿使用非設計用於本產品之電池或電池組。
16. 購買本產品製造業者所建議使用之電池。
17. 僅將電池用於製造業者產品設計之特定用途。
18. 情況允許下，於未使用時將電池從本產品中取出。
19. 妥善丟棄。

10 產品敘述與圖片

型號	產品述敘	圖片
S1002-0012	“暄達”負壓傷口治療機 “Carilex” VT‧200 Negative Pressure Wound Therapy System	
S1001-6060	“暄達”負壓傷口治療系統 可鎖式接頭收集罐（未滅菌）300 cc/ml “Carilex” Negative Pressure Wound Therapy System-canister 300 CC/ML 衛部醫器製字第 005375 號	
S1001-6020 （選配）	“暄達”負壓傷口治療系統 可鎖式接頭收集罐（未滅菌）500 cc/ml “Carilex”Negative Pressure Wound Therapy System-canister 500 CC/ML 衛部醫器製字第 005375 號	
S1001-6040 （選配）	“暄達”負壓傷口治療系統 可鎖式接頭收集罐（未滅菌）1000 cc/ml “Carilex” Negative Pressure Wound Therapy System-canister 1000 CC/ML 衛部醫器製字第 005375 號	
S1001-2040 （選配）	“暄達”傷口敷料套組 -S（已滅菌） 內含： E03-0403-001-G 黑色海棉－小 614-0202-1800-G Port(導管）組 E05-0008-001-G 膠布一個 衛部醫器製字第 005375 號	

10 產品敘述與圖片

型號	產品述敘	圖片
S1001-2050 （選配）	“暄達”傷口敷料套組 -M（已滅菌） 內含： E03-0404-001-G 黑色海棉－中 614-0202-1800-G Port(導管）組 E05-0008-001-G 膠布兩個 衛部醫器製字第 005375 號	
S1001-2060 （選配）	“暄達”傷口敷料套組 -L（已滅菌） 內含： E03-0405-001-G 黑色海棉－大 614-0202-1800-G Port(導管）組 E05-0008-001-G 膠布三個 衛部醫器製字第 005375 號	

carilex

醫療器材商 / 製造業者名稱：
暄達醫學科技股份有限公司
醫療器材商地址：桃園市龜山區科技一路 77 號
製造業者地址：桃園市龜山區科技一路 77 號 1、2、3 樓

carilex®

carilex®

Document no.: 6EG-IS1002-PTW0111 ; Date of issue: 2024-10-21