carilex®

VT · One 60 Days

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 · One 60 Days 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.

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This provision shall not affect the reproduction for internal use.

About This Document

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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 the local 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.

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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 VT · One 60 Days Powered Suction Pump, 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 VT · One 60 Days Powered Suction Pump.
- 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 VT · One 60 Days Powered Suction Pump 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 VT · One 60 Days should only be used by persons who have been trained in the operation and the intended purpose of the device.

Training on the device

1.2.1 Instruction

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.

Device approval

1.2.2 Transferring the Device

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 · One 60 Days 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.

1 Important Notes for Safe Use

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 VT · One 60 Days NPWT device.

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 VT · One 60 Days 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.

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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 VT · One 60 Days 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 · One 60 Days 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 · One 60 Days, 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

1 Important Notes for Safe Use

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_SGS_Q Mark Listing or MET Classified
EN / IEC 60601-1-11:2015
EN ISO 14971:2012
IEC/EN 62133-2:2017+A1 and UN38.3_v6, Certified report for Li-ion Battery Pack

Warranty terms and conditions

1.5 Warranty

The manufacturer guarantees the safety and correct functioning of the Powered Suction Pump 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

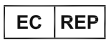
Advice to wear safety goggles

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		NRTL _Safety Certified: SGS_Q Mark logo
	Serial Number		Medical Device
	Follow Instructions for Use		Caution (ISO 7000-0434A)
	The CE mark indicates compliance with European harmonized legislation, and the numbers represent the supervision of a Notified Body		Type BF Applied Part
	The CE mark indicates compliance with European harmonized legislation		Waste Electrical and Electronic Equipment (WEEE Logo)
	Double Insulated, Class II AC Adapter		Temperature limit
IP22	Protected against ingress of solid foreign objects ≥12.5mm diameter. Protected from water spray less than 15 degrees from vertical		MR unsafe-Keep away the device from Magnetic resonance imaging (MRI) equipment
			Packaging unit
	Federal (US) law restricts this device to sale by or on the order of a physician.		Consult instruction for use
	Model Number		

1.7 Safety Instructions Before Use

(1) The Powered Suction Pump 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 Pump 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.
(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 Pump must be placed carefully and securely at the patient's bedside with optional VT accessories. An optional carrying bag is available for mobile use; however, it is the responsibility of the clinician or trained caregiver to determine if the patient's condition allows for mobile use.
(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 Pump must never be used to remove explosive gases and inflammable or corrosive fluids.
(10) The unit must not be operated in damp rooms or when taking a bath or shower.
(11) Avoid moisture on plug and switches. Never plunge the unit into water or liquids, not even when it is switched off.
(12) The unit must not be operated in splash water range or in locations where there is a danger of explosion.
(13) Operation of the Powered Suction Pump 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.

1 Important Notes for Safe Use

(18) The Powered Suction Pump must be switched off and disconnected from the power supply adapter before cleaning and maintaining unit.
(19) The Powered Suction Pump 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 Pump 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.
S1004-0022	VT · One 60 Days	Good for general NPWT purpose
S1004-3022	VT · One 60 Days	VT · One 60 Days 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 Pump is delivered with the following components:

1. One Powered Suction Pump control unit
2. One canister
3. External AC Adapter
4. Instructions for Use
5. Carrying bag (Optional)

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 Pump to a wall outlet.

2.4 Operating & Transport & Storage Conditions

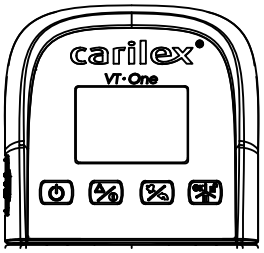
Recommended environmental conditions:

- For Operating Conditions

Temperature range: 5°C (41°F) to 40°C (104°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%



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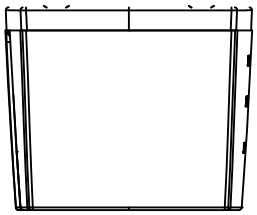
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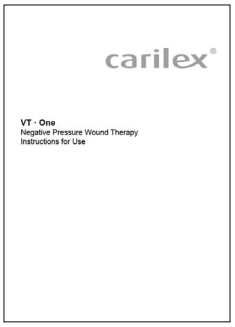

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For long-term storage the power unit should be covered with a dust protector and the battery needs to be recharged every 3 months.

ATTENTION

Storage of the Powered Suction Pump

- 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.
- DC socket 5 to connect to power cord.

Power cord and charge 6

Select the correct AC adapter plug for your country then plug into the main outlet.

Power cord and charger

The power cord charger 6 consists of:

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

How to replace the plug 7

1. Press the "PUSH" lever down and hold
2. Push the plug towards OPEN arrow
3. Replace with the suitable plug

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

Carrying bag 8

The carrying bag for power unit

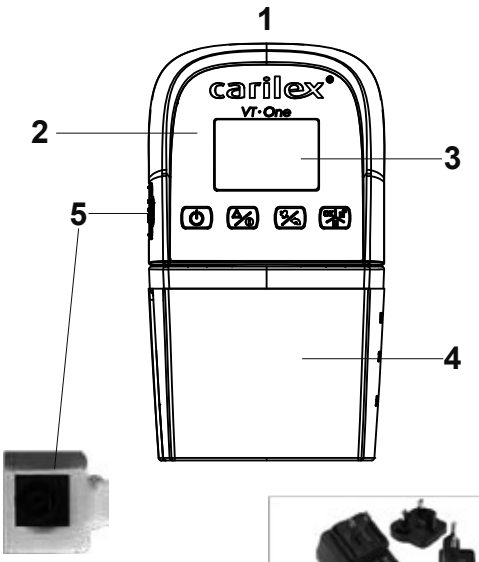
- Portable Case
- Belt

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.



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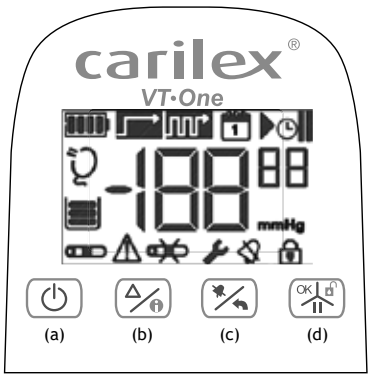
3 Device and Functional Description

3.2 Functional Description

Carilex Powered Suction Pump is a Negative Pressure Wound Therapy device that has been prescribed by your healthcare provider.
This device has shown that it may help promote the healing of several different kind of wounds. When in use, negative pressure (suction) is delivered to the wound through the pump.
The suction of the pump will help remove excess fluids from the wound. 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 Pump 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) Select / Info
(c) Mute / Return
(d) OK / Unlock / Pause



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.

Intermittent mode:
When employed via the screen panel, the therapy unit changes between a high and low pressure range in a fixed time interval.

3.2.4 Symbols on the Display

Battery status
Low power
Canister full
Leakage indicator
Blockage Indicator
Call for service
Mute
Panel locked
The machine is operating
Pause
Continuous Mode
Intermittent Mode
Life time already used in days and hours

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 12 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 Pump and prior to first use, charge the battery for at least 4 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 Pump. If therapy unit is in warehouse / inventory and not used for more than three months, the battery needs to be recharged. Powered Suction Pump 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 5700 hours. Storage and usage of the battery must be within the temperature ranges stated in the section 2.4.

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 three 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 Getting Started

4.2 Collection Canister

As indicated by arrow 1 in the diagram on the right, connect the collection canister into the corresponding slot on the pump. The front of the collection canister should have a blue marking, which must be on the same side as the red marking on the left of the pump, and it should be kept in a vertical position.

As indicated by arrow 2 in the diagram on the right, rotate the collection canister clockwise until they are fully engaged, aligning the red markings on the collection canister and the pump.

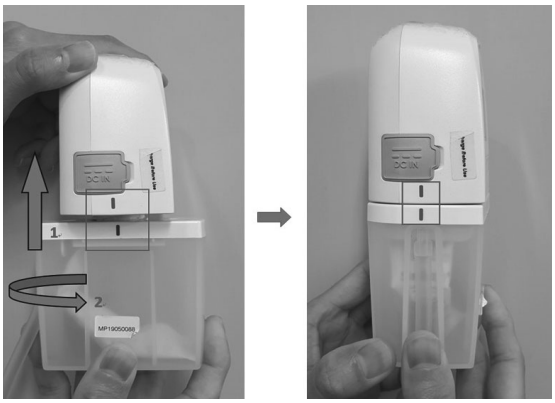
Always make sure the canister is properly inserted. It must remain in an upright position during use.

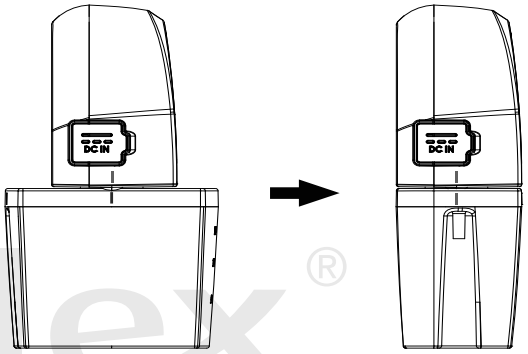
The Powered Suction Pump is protected against penetration from solid / fluid substances by a hydrophobic membrane integrated with an activated carbon filter. If this filter fails, the Power Suction Pump must be replaced.

The Powered Suction Pump 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.

"Carilex" Canister lists		
1	S1004-6010	Canister for VT · One - 150ml
2	S1004-6030	Canister for VT · One - 150ml Luer Lock

4 Getting Started

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 · One 60 Days 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.

Due to the lower suction power of the VT · One 60 Days system, it is recommended to use it with wound sizes that are close to the dimensions of the S foam dressing. If using larger foam dressings, they may need to be trimmed to match the size of the S foam dressing.

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.

"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	S1001-2130	VT Drape and Port Set Kit S Lock
6	S1001-2140	VT Drape and Port Set Kit M Lock
7	S1001-2150	VT Drape and Port Set Kit L Lock
8	S1001-2200	VT Dressing Kit TS S Carilex
9	S1001-2210	VT Dressing Kit TS M Carilex
10	S1001-2220	VT Dressing Kit TS L Carilex

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.

5 Operation Procedure

5.1 Check Points before Using Powered Suction Pump

Before using the Powered Suction Pump, 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 Pump

(Please follow the instructions on 4.2 Collection Canister section)

- Insert the canister into the Powered Suction Pump connecting port.
- Rotate the collection canister clockwise until they are fully engaged.

Make sure the aligning the red markings on the collection canister and the pump.

5.3 Connect the Powered Suction Pump 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.

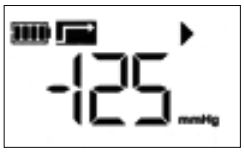
- Do not use damaged components.

5.4 Turn the Unit On / Off

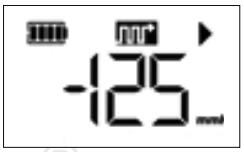
1. On-Switch Powered Suction Pump on by pressing the on/off key ⏻ for 3 seconds.
2. Off-Switch Powered Suction Pump off by pressing the on/off key ⏻ for 3 seconds. Powered Suction Pump will turn off display screen will darken.

5.5 Therapy Mode Setting

1. Turn on the power unit, the screen will start blinking press ⚠ to select therapy mode.
2. Press OK to choose therapy mode.
3. Press ⚠ to adjust pressure level.



Cotinuous mode



Intermittent mode

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.

5 Operation Procedure

Pressure setting for Continuous mode

(1) When the screen shows , press to choose continuous mode.

(2) Press to change the constant pressure level from -50mmHg to -150mmHg. Default pressure for continuous mode is -125mmHg.

Pressure setting for Intermittent mode

(1) When the screen shows , press to choose intermittent mode.

(2) Press to change the high pressure level from -50mmHg to -150mmHg. Default high pressure for intermittent mode is -125mmHg.

(3) Press to confirm high pressure.

(4) After setting the high pressure level, the screen will start blinking again. Press to select the low pressure level of intermittent mode from -20mmHg to -40mmHg. Default low pressure for intermittent mode is -20mmHg.

NOTE

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

ATTENTION

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

5.6 Select / Info

Press to select therapy modes and pressure level.

Press for three seconds to see usage time.

Usage time in days

Usage time in hours

5.7 Blockage / Leakage Alert Indicator

The patient, device and dressing should be carefully monitored to check if there are any signs of bleeding, exudate accumulation, infection, maceration or failure of Negative Pressure Wound Therapy (NPWT).

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

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

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

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

5.8 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 three times to go back to therapy mode selection menu.

The Powered Suction Pump is made from various electronics and plastics. When the Powered Suction Pump 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.

5.9 Change Powered Suction Pump Canister

The canister has to be changed by visual check or according to the instructions on the display.
The VT · One 60 Days 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.

5 Operation Procedure

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.

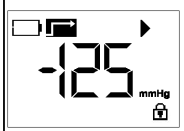
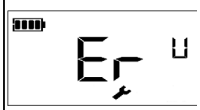
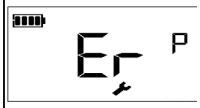
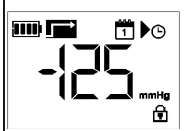
The procedure of changing canister:

1. Wash hands and wear disposable gloves.
2. Switch the Powered Suction Pump 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 Pump. (Refer to 4.2 Collection Canister section for instructions.)

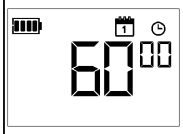
6 Error Indicators

6.1 Error Indicators

If the Powered Suction Pump 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 ⏻ 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	 or 	Failure of Valve or High pressure	Press ⏻ for 3 seconds to turn off the power unit. Contact your authorized local distributor for assistance.
EOL Notice		Service Life Near End	Replace a new Powered Suction Pump.

6 Error Indicators

Error Message	Display	Possible causes	Remedy
60 Day Limit Reached		Device Expired	Replace a new Powered Suction Pump.

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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 Pump fails to function normally for one hour, regardless of the circumstances, stop using the Powered Suction Pump 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 Pump 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 Pump 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 Pump is not in use, please recharge it every 3 months.

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
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
3.) No suction	3.1) Check if tubing is blocked	3.1) Release clip, remove kinks or check the system for blockages.
	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.		

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11 Technical Data

The VT · One 60 Days is suitable for continuous operation.

Powered Suction pump

Model .....VT · One 60 Days
Dimensions (WxHxD).....8.5 x 15 x 5cm
Weight (with empty canister) 350g
Negative Pressure Range..... Continous: -50mmHg~-150mmHg
Intermittent: High -50mmHg~-150mmHg
Low -20mmHg~-40mmHg
Suction Flow Rate.....0.6L/min
Power Consumption.....15W max.
Nominal voltage .....12 Vdc Rated
Medical device....Class IIb (Comply with 2017/745 as amended by 2019/5)
.....Class II (Comply with 21 CFR 878.4780)
IP Code IP22
Applied Part.....Type BF

AC Adapter

IEC/EN 60601-1_v3.2 .....Sinpro Type HPU15-105
Electrical Class .....Class II
Power input.....100-240Vac 47-63Hz 0.4-0.2A
Power output.....12 Vdc 1.25A

Li-Ion BP

Carilex Model.59H-0145-003-G; 2S1P Normal Rating ... 7.4Vdc 800mAh
Battrey Using Time.....16 hours max.
Charging Time.....4 hours

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 40°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.

12 EMC Declaration

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.)**
Trade Name:	**NPWT, Suction Pump**
Model No.:	**VT · One, VT · One 60 Days**
Report Number:	**ETC 19-08-RBO-021**
Power Supply:	**AC Adaptor Input: 100-240Vac 47-63Hz 0.4-0.2A, Output: 12Vdc 1.25A Suction Pump Input: 12Vdc Internal Li-Ion Battery Pack: 7.4Vdc 730mAh or 7.4Vdc 800mAh**

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

The NPWT, Suction Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NPWT, Suction Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NPWT, 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 NPWT, Suction Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the NPWT, 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 NPWT, 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 NPWT, 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 NPWT, Suction Pump declaration – electromagnetic immunity

The NPWT, Suction Pump system is intended for use in the electromagnetic environment specified below. The customer or the user of the NPWT, 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%		3 V/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 NPWT, Suction Pump system is intended for use in the electromagnetic environment specified below. The customer or the user of the NPWT, 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	±1 kV differential 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®

CE
2460

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carilex®

“暄達”負壓傷口治療系統

"Carilex" VT·One 60 Days
Negative Pressure Wound Therapy System

衛部醫器製字第 005719 號

使用前務必詳閱使用手冊並遵照指示使用

負壓傷口治療機－輕巧六十天型
負壓傷口治療中文使用手冊

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1 關於

1.1 前言

感謝您選擇了 Carilex VT ・ One 60 Days™先進的負壓傷口治療臨床解決方案，VT ・ One 60 Days 擁有 3C 的特點：承諾(Commitment)、方便(Convenience)、遵從(Compliance)，且介面人性化設計，只需簡單的清洗，為安全和有效的負壓傷口治療。

1.2 產品用途

本產品是一種針對醫院、護理之家和家居照護而設計的負壓傷口治療產品，可在傷口內形成負壓環境，移除灌洗液和體液、傷口滲液及感染物質等液體，以促進傷口癒合。

產品目標族群

說明手冊所指的人如下

- 經營者

經營者（外科手術工具供應者、健康保險公司、診所等），是指任何合法擁有 Carilex® VT ・ One 60 Days 並且使用之，或以經營者名義使用之人。經營者之責任為：提供安全的儀器、指導人員正確的操作和使用儀器。

- 使用者

使用者為受過訓練或相應指導，而有資格：
操作 Carilex® VT ・ One 60 Days 抽吸幫浦
監督病患將儀器用於醫療

使用者需為安全、正確的使用儀器承擔責任。
在每次使用前或轉換使用者前，使用者需檢視儀器之功能和狀況並確認之。

- 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：

於醫療技術領域受有專業訓練之人
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
在從事醫療技術相關活動需經許可之國家，合格人員需經適當之認證

- 病患

病患在此手冊中所指為因醫療需求而使用 Carilex® VT ・ One 60 Days 之人。

對使用者之提醒

Carilex® VT ・ One 60 Days 之操作僅能由受過儀器及適用範圍訓練之人員進行。

使用者之訓練需由使用儀器之經營單位之合格人員進行之。
若此儀器已合法賣給客戶，其則有義務遵循此說明手冊之指導。

1 關於

儀器之交接
若經營單位將儀器釋出用於醫療用途，並且適當的交接並經授權人員監督。交接後使用者須為儀器之安全使用負起責任。

維修與組裝
儀器或零件之維修僅能由經授權之人員進行，請聯絡暄達醫學科技。

請於第一次使用儀器之前詳閱此說明書。如此能夠使您避免個人損傷或財產損害，並且能獲得儀器之最大效用。在每次使用前或轉換使用者前，使用者需檢視儀器之功能和狀況並確認之。
若有特定之細節，而於說明書中未詳述，請聯繫供應商或經營者。

EMC 警示宣言
對使用者之提醒
Carilex® VT ‧ One 60 Days 是依據最新之技術製作並且具備可靠性。但若經未受訓之人員或未依照此使用手冊操作，危害仍可能會發生。

(1) 醫療電器用品關於 EMC 須有特別之預防措施，必且須依 EMC 訊息安裝。
(2) 攜帶式和移動式射頻(RF)通訊設備可能會影響醫療電器用品
(3) 電線與配件清單
(4) 警告 其他電線與配件可能會對 EMC 之表現有負面的影響
(5) 警告 與其他儀器之堆疊或相鄰
(6) 警告 使用其他儀器之件可能會導致不符合事項

安全警示宣告

(1) 貼有辨識標籤，指示使用手冊的相關規定：鋰離電池組之更換只能由維修人員以工具為之
(2) 未經完整受訓人員之人員更替電池可能會產生危害
(3) 未經製造廠之許可請勿改裝此儀器

意外預防程序
為求與意外預防規範相符並防止意外損害，交接時應遵循以下規定

(1) 第一次使用時應完整的清潔與消毒儀器
(2) 儀器之啟用與交接並須由經營單位指派之合格人員進行之
(3) 完成訓練後，應留有紀錄，顯示使用者了解儀器特別療程與照護之操作與用途

衛生人員之資格要求
對零件與機器清潔與消毒之進行，需由熟悉衛生規範之合格人員進行之。

使用手冊是儀器不可或缺的部分，需經妥善保存，以利使用者隨時檢視安全指示和其他重要資訊。
請勿將沒有附隨使用手冊之儀器交予第三人。參考產品 ID 與版本，以確認附隨之使用手冊為最新和有效之版本。

1 關於

儀器之用途

Carilex® VT • One 60 Days 之適用範圍為能從傷口管理獲得好處之病患，藉由施以負壓以移除液體、過量分泌物、感染物質及組織碎片以促進傷口癒合。

1.3 適應症

本產品適用於：

- 慢性傷口
- 急性傷口
- 外傷性傷口
- 糖尿病潰瘍
- 壓瘡
- 亞急性及開裂式傷口
- 部分皮層燒傷
- 皮瓣及網狀皮膚移植

本產品僅限由受過專業醫療抽吸程序訓練之傷口護理、負壓傷口治療和居家照護等醫事人員操作。

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
- 惡性腫瘤的傷口
- 未經治療的骨髓炎
- 暴露之血管、器官或神經、器官
- 非腸道性瘻管及未經檢查之瘻管
- 過度用於治療的血管或器官

1.5 注意事項

- 已接受抗凝血劑或抗血栓藥物治療的病患。

未對傷口進行充分止血的病患將面臨出血風險，若不加控制，可能會致命，這些病患應在醫事人員認為適合的護理環境中接受治療和護理。開始治療前應考慮使用的負壓裝置及治療模式並注意接受抗凝血劑或抗血栓藥物治療的病患將面臨較大的出血風險（與傷口類型及複雜性有關）。

- 在使用本產品治療前，傷口內或周圍的所有暴露或淺表血管和器官必須完全覆蓋和受到保護，從頭到尾要確保敷料不直接接觸血管或器官。使用自體組織能提供最有效的保護，若不具備或無法從外科手術獲取此種自體組織，在醫事人員認為替代材料能提供完整的保護前提下，可考慮使用多層細孔防黏材料或生物組織替代。使用防黏材料時，確保其被固定在對應部位中整個治療過程中始終提供保護作用。
- 開始治療時應考慮使用的負壓設置及治療模式。

- 當治療可能含有不易發現的隱藏血管的大創面時，應特別謹慎。患者應在醫事人員認為合適的護理環境中密切監測出血情況。
- 存在銳邊風險

碎片或銳邊可能刺穿保護屏障、血管或器官，因而引起損傷。任何損傷都可能導致出血，若不加控制，可能致命。注意傷口內銳邊與組織、血管或器官相對位置可能發生改變而接觸。使用本產品進行治療前必須清除或覆蓋傷口部位的銳邊或骨頭碎片，來防止可能的刺穿血管或器官。盡可能完全磨平或覆蓋任何殘邊，以防止萬一發生移動時造成的損傷，來降低嚴重損傷或致命傷的風險。從傷口部位移除敷料時應盡可能謹慎，以防止創面組織被未經保護的銳邊劃傷。

- 為了降低血源性病原體傳播的風險，無論何種診斷結果或是否懷疑存在感染，所有病患均可按醫療機構標準作業程序來預防感染。對所有病患及醫療機構規定，無論診斷結果或懷疑有感染情況，均施行標準防護措施來控制感染。如果有接觸體液的可能性，除了戴手套，還應穿防護衣和護目鏡。

1.6 警語

- 若本產品已停止運作 2 小時以上，請移除敷料。
- 病患身高和體重

在為病患給予負壓傷口治療前應考慮病患的身高和體重，且要密切監控嬰兒、兒童、一些體形較小的成人和老年病患的體液流失和脫水情況。另外，密切監控傷口面嚴重滲液或相對身高和體重而言傷口面較大的病患，因為這些病患可能存在體液流失過多及脫水的危險。監控體液流失情況時，也應將引流管及廢液罐中的液體量考慮在內。

- 傷口感染

傷口感染應接受密切監控，綜合傷口情況、治療目標及設定治療參數等因素，其敷料更換頻率高於非感染傷口。任何傷口治療，醫事人員及病患應經常檢查病患的傷口、傷口周圍的組織及滲出液是否存在感染徵兆、感染是否惡化或出現其它的併發症。一些感染徵兆包括發燒、紅、腫、癢、痛、傷口內或傷口周圍組織體表溫度升高、膿液或強烈的氣味。嚴重的感染會導致疼痛、不適、發燒、壞疽、中毒性休克、感染性休克和／或死亡等併發症。全身感染的一些徵兆或併發症包括噁心、嘔吐、腹瀉、頭痛、暈眩、昏厥、心跳加快、高燒。如果出現任何全身或傷口部位的感染徵兆，立刻聯絡醫事人員，以確定是否需停止本產品治療。

- 保護肌腱、韌帶和神經

本產品治療期間應保護肌腱、韌帶和神經，避免其與海綿敷料直接接觸。這些接觸面可用自體組織、網狀防黏材料或生物工程組織覆蓋，以將乾燥或本產品使用說明損傷風險降至最低。

- 保護傷口面周圍的皮膚

不得將海綿敷料疊蓋在完整的皮膚上，另外可使用黏性密封薄膜、水膠體或其他透明薄膜保護傷口面周圍脆弱的皮膚。

- 磁振造影(MRI)

本產品進行負壓傷口治療在 MR 環境中構成危險，禁止將本產品帶入 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，並可能會有火災危害。在關閉負壓傷口治療機後，(1) 在高壓氧治療期間使用另一種與 HBO 相容的材料替換負壓傷口治療敷料；或者 (2) 在高壓氧艙內的整個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)。若患者在高壓氧艙中預計會超過兩個小時，請移除敷料。

• 脊髓損傷

若病患出現自主反射亢進（受交感神經系統的刺激血壓或心率突然變化大），應立即停止負壓傷口治療，以將感覺刺激降至最低並立刻尋求醫療救助。

• 負壓傷口治療機的壓力上升

極少數情況下，負壓傷口治療的引流管堵塞可能導致真空壓力短時間內上升至 150 mmHg 負壓以上，需要立刻解除造成警報的狀況，並聯絡製造業者。

1.7 設備安全需知

- 當使用本產品為負壓來源與治療系統前，請先閱讀適應症和警告、注意事項及禁忌症。不遵守規範可能會導致病患相當危險。
- 僅限由受過專業醫療抽吸程序訓練之傷口護理、負壓傷口治療和居家照護等醫事人員操作。注意： 不正確使用會導致疼痛且傷害病患。
- 每一次治療病患後必須執行例行性檢查。
- 限使用製造業者配件、敷料包和零件，只有這樣才是正確和安全運轉保證。
- 在設備插電前，請檢查電子供應與設備給定電壓規格是否相同。
- 在以下情況，該設備不能使用，且必須由製造業者維修：
  如果電源線或電源座損壞。
  如果設備不能正常工作。
  如果設備損壞。
  如果設備顯示清楚的安全缺陷。
- 溢流保護／細菌過濾器保護幫浦抵抗溢流（幫浦內流體流動）。
  注意： 當過濾器是濕／潮濕或堵塞時，抽吸會被中斷、在每次使用前和使用過程中定期測試過濾器。
- 幫浦在使用過程中必須直立。
- 該裝置不得用於吸痰、易燃或容易腐蝕的液體下。
- 設備提供的連接管絕不能直接接觸吸入區域。電源線應遠離高溫表面。
- 插頭和電源的 ON/OFF 開關不能接觸到濕氣。
- 切勿於高室溫下、洗澡或淋浴時，或環境中存在爆炸危險時使用設備。
- 當開機時，切勿無人看管時使用設備。
- 切勿將設備置於水或其他液體中。
- 本產品為醫療產品，需對於電磁相容性(Electro Magnetic Compatibility, EMC)採取特別的安全措施，他必須按所附 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。
- 對於與安全有關之檢查，這是假設在整個保養過程中該設備保養及維修遵守保養程序。
- 充電電池： 使用前先充電，充電電池依使用情況大約可重複充電 300-500 次。如果長時間不使用機器，建議每三個月須將把電池充飽電，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機器的故障，本公司將不負責任。

1.8 機台之清潔與保持

- 清潔機台外殼時，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。重複使用收集罐可能會造成交叉感染。

1 關於

1.9 使用前之安全須知

(1)VT ・ One 60 Days 抽吸幫浦之操作僅能由依據供應商手冊受訓之人員或合格醫護人員進行。
(2)在使用 VT ・ One 60 Days 前，請詳閱適應症、警語、設備安全措施與禁忌症。
(3)使用前請檢查功能。
(4)請勿將插頭接於損壞之插座。
(5)確保插頭和電線遠離外在熱源。
(6)在下列情形下，請不要充電或啟動儀器
若電源線或電源插座毀損
若儀器無法正常運作
若儀器經毀損或掉落
若儀器曾落水
若儀器有明顯會影響安全使用之毛病
(7)若有以上之情形，請將電源線從插座拔除，並將其送至經暄達醫學科技核可之人員檢查。
(8)VT ・ One 60 Days 抽吸幫浦與適當之配件需小心、安全的放置於病患之床邊。亦有提供攜帶背包，可供攜帶儀器使用。病患之情況是否適合攜帶使用，醫師和經訓練之照護人員有責進行評估。若轉換使用者，需確認背包經消毒或使用新的背包。
(9)VT ・One 60 Days 絕不能用以吸取爆炸性氣體或可燃性 / 腐蝕性液體。
(10)儀器絕不可於潮濕的房間或於沐浴時操作。
(11)避免插頭與開關沾濕。即便未開機，也請勿將儀器浸泡至水裡。
(12)請勿於潑水範圍內或有爆炸危險之處操作儀器。
(13)充電時 VT ・ One 60 Days 亦能操作使用。
(14)請注意技術資料所標明之常溫。
(15)若儀器於超過技術資料所標明之常溫範圍使用，儀器可能會降低且機械和電池組可能會損毀。
(16)儀器需於穩固、平整之地面上操作。
(17)若儀器已開啟，請勿無人看管。
(18)需定期檢查組件之功能和其他與安全相關的毛病。請參考維修手冊。
(19)於維修與清潔 VT ・ One 60 Days 時須將其關機並拔除電源。
(20) VT ・ One 60 Days 為醫療儀器，而非玩具。請遠離孩童，以及害蟲，以避免其損害敷料或組件而影響效能。請避免組件沾染塵土與棉絮。
(21)建議病患勿將組件或敷料浸泡於液體中，或將其至於浴缸或水槽使其有浸水之危險。
(22)僅使用原廠之配件與零件。
(23)僅能與 VT ・ One 60 Days 之收集罐搭配使用。

1 關於

注意

與衛生規範相符負壓傷口治療機的組件並非於無菌狀態下組裝。請清潔並消毒組件後再使用。

注意

在使用變換壓力與持續高壓模式期間，病患的傷口與傷口四周需定時檢查壓痕，由醫護人員、照護人員或療養院所分派的人員進行之。敷料需定期檢查以避免阻塞或洩漏。

注意

散落的電源線可能會導致絆倒和嚴重傷害。

注意

不正確的使用 VT • One 60 Days 可能會導致病患的疼痛或受傷。過量的負壓或傷口的感染可能會導致病患的疼痛或受傷。

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。若病患根據聯邦法律患有通報性傳染病疾病，人員則須向衛生專家諮詢後再進行消毒與清潔。

水有高度導電性。當於有電壓時與液體接觸會導致致命性觸電。
消毒與清潔程序：
關閉控制組件
將插頭從電源座拔除

注意

健康危害與受汙染之清潔液接觸可能會導致感染。消毒液可能有含有害成分。
請根據消毒液製造商關於消毒液的使用指示與關於操作人員之衛生規定。
請穿戴個人保護設備：

護目鏡

保護手套

口鼻保護罩

注意

不相容之清潔劑 ：負壓傷口治療機的部分組件是由塑膠所構成，溶劑可能會溶解塑膠組件或覆膜。強酸或強鹼可能會導致塑膠之脆化。清潔動力組件：
請勿使用烴溶劑或含有強酸、強鹼之洗滌劑。請勿使用研磨清潔材料。

1 關於

不相容之消毒液清潔控制組件：
使用不含氯化物、鹵化物之消毒液請勿使用含油漆稀釋劑、鹼、酸、酒精、醛(例如：乙醇、丙醇)為避免塑膠組件之脆化：請勿使用含酒精之消毒液。

消毒與清潔
(對經營者的衛生要求)
經營者必須知悉關於負壓傷口治療機的相關規範與其適用之衛生指令。負壓傷口治療機之全機或組件之消毒僅能由熟悉院所衛生規範之清潔專家進行。

消毒程序
控制組件之消毒可由手動擦拭零件完成。
手動擦拭消毒之步驟為：消毒前，清潔，控制。

消毒前
(1) 穿戴手術型手套與口罩
(2) 以 75% 之酒精或其他符合地方衛生單位規範之清潔液清潔雙手
(3) 以清潔液擦拭表面
(4) 依照清潔液製造商之指示讓其發生作用

清潔
(1) 以符合地方衛生單位規範之方式，以清潔液擦拭累積之塵土，進行消毒
(2) 以乾淨、柔軟之布料與清水擦拭表面
(3) 以乾淨、柔軟之布料拭乾表面

控制
檢查控制組件之功能

注意

不適當之維修會有受傷之危險！若有維修需要，請聯絡暄達醫學科技。

檢視
負壓傷口治療機之安全操作狀態須於合格人員於每次使用前檢查，或於病患自行使用之情況下每年至少檢查一次，特別是以下項目
(1) 控制組件之功能與控制標示
(2) 壓縮管與壓縮管之連接

維修
當未使用 VT • One 60 Days 空氣抽吸幫浦時，請將電池組從盒中取出並於每三個月充電一次。

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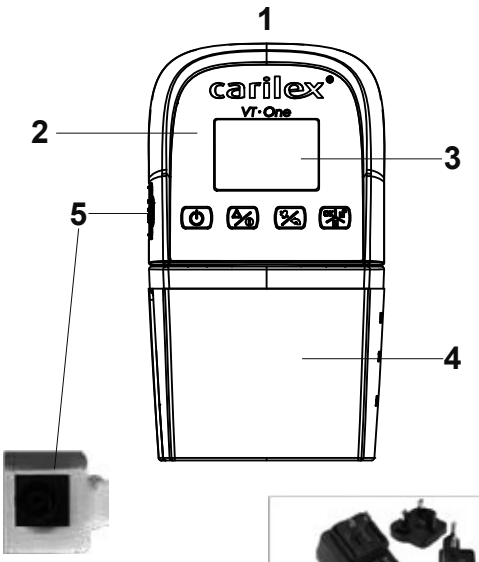
2 操作元件及功能描述

2.1 操作元件

- 本產品內含幫浦 1 是抽吸功能的主要元件
- 操作面板 2 開關及選擇功能鍵
- 顯示螢幕 3 顯示資訊
- 收集罐 4 用來收集液體
- 電源接頭 5 用來連接電源線
- 電源線及插頭 6 包含
  - > 電源供應器
  - > 四個可更換的插座頭
- 如何更換插頭 7
  1. 持續按壓 PUSH 的按扭
  2. 往 OPEN 的箭頭方向推
  3. 更換成適用的插頭

  （選擇適用於當地的插頭並插入插座）
- 機器的背袋 8
  - > 攜帶式背袋
  - > 黑色調整型背帶



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8

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。

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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：

使用時，傷口將會持續維持在選擇的負壓範圍。

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。

操作介面：

(a) 開 / 關

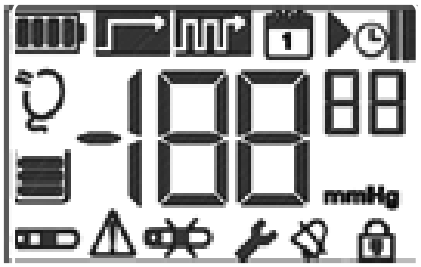
(b) 選擇 / 資訊

(c) 靜音 / 上一頁

(d) OK / 解鎖 / 暫停

符號說明

電池狀態
低電力
收集罐滿瓶
洩漏警報
阻塞警報
請聯絡供應商
靜音
按鍵鎖定
療程進行中
暫停
連續模式
間歇模式
使用天數
使用時間



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3 使用前注意事項

3.1 電池

• 充電須知

選擇符合當地規範的插座頭，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。其使用及儲存環境必須在＂技術規格＂中規範的範圍內。

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。

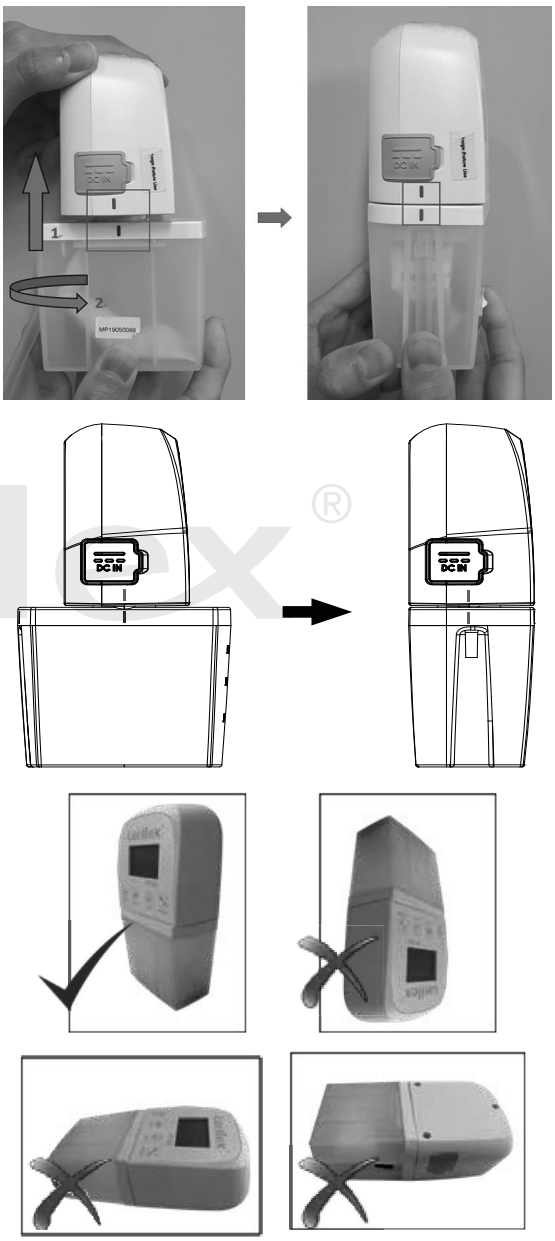
• 收集罐使用具活性碳過濾功能的防水透氣膜，避免固體或液體滲入機器。

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 LED 螢幕同側與保持垂直。
3. 水平滑入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

4.1 使用前，請確實檢查：

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

4.2 請參考 3.2 將收集罐和幫浦接合。

4.3 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。

4.4 使用功能鍵

(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

當警示蜂鳴器響時，接壓 使其靜音。
在連續模式運行中，按壓 調整壓力。
在間歇模式運行中，按壓 調整壓力。
按壓 三次回到選擇模式選單。

(3) 療程模式設定

1. 開機後，螢幕上標示會開始閃爍。按壓 選擇適當的模式。
2. 選定模式後按壓 進入所選擇的模式。
3. 按壓 設定療程所需壓力。

(4) 選擇 / 資訊

療程中按壓 三秒鐘查看使用時間。
使用天數
使用時數

4 使用步驟

(5) 連續模式中壓力設定

1. 在連續模式中按壓 選擇從 -50mmHg 到 -150mmHg 間的壓力。系統預設的壓力為 -125mmHg。
2. 選定療程壓力後，按壓 開始療程。

(6) 間歇模式中壓力設定

1. 在間歇模式中按壓 選擇 -50mmHg 到 -150mmHg 之間的高壓設定。系統預設值為 -125mmHg。
2. 選定高壓設定值後，按壓 確認。
3. 在設定完高壓之後，螢幕上的符號會再度開始閃爍，此時按壓 選擇 -20mmHg 到 -40mmHg 之間的低壓設定。系統預設值為 -20mmHg。
4. 選定低壓設定值後，按壓 開始療程。

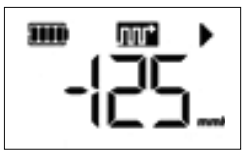
注意

間歇模式是預設為五分鐘高壓及兩分鐘低壓交替。

(7) 更換 VT ・ One 60 Days 收集罐

1. 洗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. 以逆時鐘旋轉的方式將裝滿液體的收集罐自機器中取下。收集罐的拋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。

Continuous mode



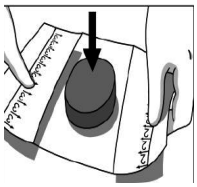
Intermittent mode

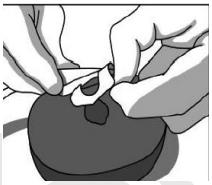
4.5 負壓傷口治療操作步驟
使用本產品進行負壓傷口治療需經醫師評估傷口狀況後開立醫囑，指示
所需使用之治療模式（ 連續、間歇）。

注意

請確實將收集罐安裝完成，並聽到喀擦聲。

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海棉與防水透氣膠布及導管組貼片。
(3)依照傷口裁剪適當大小的海棉敷料置入傷口床，並避免海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)將導管組貼片背膜撕下，貼附於負壓孔洞處並固定(C)，此端連接至本產品收集罐。


(A)

(B)

(C)

選擇連續或間歇治療模式，請跳至步驟 4.6

注意事項：

(1)僅 VT 敷料套件可與 VT · One 60 Days 系統結合使用，且必須處於無菌狀態。應按照敷料隨附的敷料套件使用說明使用 VT 敷料套件。。
(2)由於 VT · One 60 Days 系統的吸力較低，建議在傷口尺寸接近 S 泡棉敷料尺寸時使用。如果使用較大的泡棉敷料，可能需要對其進行修剪以符合 S 泡棉敷料的尺寸。
(3)醫生或經過訓練的護理人員應在敷料之前對傷口進行徹底、徹底的清潔。
(4)每 48 小時或根據設施方案或醫生的命令進行例行敷料檢查和更換。螢幕於 3 分鐘後轉暗節電。
(5)使用前，檢查敷料套件，確保包裝沒有損壞，這可能會影響內容物的無菌性。

4 使用步驟

4.6 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。

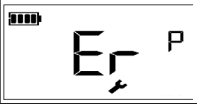
VT ・ One 60 Days 空氣抽吸幫浦是由多種電子器件與塑膠組成。屆拋棄之時，醫療機關應遵循當地政府規範消毒與拋棄相關組件。
使用過的收集罐、引流管與敷料之拋棄，應遵循當地或醫療機關關於處理感染或具生物危害性物質之規範。任何組件皆不應與家庭／設施廢棄物並同丟棄。不正確之丟棄方式可能會產生對環境與公共衛生之危害。

5 警報指示

5.1 錯誤顯示
本產品如偵測到以下情形，螢幕會亮起並同時出現聲音和文字警示。

當按壓靜音鍵後，聲音訊號會被解除，但橘燈會持續閃動（一秒亮／一秒暗），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
阻塞警示		引流管折管 引流管管夾關閉 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) 當問題獲得解決後，螢幕會回到正常運作狀態
洩漏警示		收集罐沒有正確安裝 引流管脫落沒有正確連接 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
滿瓶警示		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	(1) 使用電源轉換器將可充式電池充電。 (2) 使用電源線為裝置充電。
聯絡維修人員	 or 	設備異常	(1) 關閉電源 (2) 請聯絡授權的經銷商以尋求協助。
效期警示		使用時間達到 59 天	(1) 蜂鳴器鳴響，間隔 10 秒鳴響兩次，關閉電源 (2) 更換新幫浦
效期到期		使用時間達到 60 天	(1) 蜂鳴器鳴響，關閉電源 (2) 更換新幫浦

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
機器無法運作	檢查電源線是否插好	將電源線插好
	檢查螢幕上顯示電池的充電狀態	將電源線插上充電
	檢查螢幕是否仍在設定模式	完成設定
	檢查效期是否已達到 60 天	更換新幫浦
運作壓力無法達到設定壓力	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
	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
	檢查螢幕上顯示電池的充電狀態	將電源線插上充電
	檢查抽吸組件是否未高於傷口一公尺	將組件移至傷口一公尺以上
無法抽吸	檢查引流管有沒有折管	鬆開管夾、解決折管
	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

	使用前請詳閱使用手冊		BF 類觸身部件
	請詳閱並依循使用手冊		歐盟認證
	醫療器材商及製造業者		製造日期
	溫度條件		廢棄物之處理
	遠離核磁共振設備		產品批號
	醫療處方專用		警示標誌
	禁止重複使用		包裝破損請勿使用
	包裝數量		有效日期
	產品編號		

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7 技術資料

抽吸量	2.5 L/ 每分鐘
負壓	最大負壓 -200 mmHg
電源輸入	100-240Vac 47-63Hz 0.4-0.2A
電源輸出	12Vdc 1.25A
電源供應器 (AC adaptor)	Sinpro, HPU15-105
最大功率	Max: 15W
尺寸(WxHxD)	W 15 cm (5.9 in) x H 8.5 cm (3.35 in) x D 5 cm (1.97 in)
重量	0.35kg (含收集罐)
可搭配收集罐容量	150cc/ml
防水防塵等級	IP22
操作模式	連續治療模式(Continuous) 負壓設定範圍(Pressure range): -50 to -150mmHg (預設值 : -125mmHg) 時間設定範圍(Time setting): 2 to 5 min
	間歇治療模式(Intermittent) 1. 高壓力設定範圍(High): -50 to -150mmHg (預設值 : -125mmHg) 時間設定範圍(Time setting): 1 to 10min 2. 低壓力設定範圍(Low): -20 to -40mmHg (預設值 : -20mmHg) 時間設定範圍(Time setting): 2 to 5min
可充電電池	鋰電池 (Lithium-ion) Carilex Type 1) 59H-0145-002-G or 2) 59H-0145-003-G 額定電壓 : 7.4Vdc 電池容量 : 1) 1.73Ah or 2) 1Ah 充電時間 : 4hrs 可用時間 : 約 16 小時
Protection class according to IEC 60601-1	
操作環境	溫度 5℃ to 40℃ 相對溼度 0% to 63% 大氣壓力 700hPa to 1060hPa
運輸、儲存條件	溫度 -25℃ to 70℃ 相對溼度 0% to 93%

8 電磁相容性

EN60601-1-2 符合性聲明

公司名稱：暄達醫學科技股份有限公司

報告編號：19-08-RBO-02

電源供應：外部 AC 轉換器：100-240Vac 47-63Hz 0.4-0.2A、

內部電池組：7.4 Vdc

建議的防護距離（可攜式和行動射頻或其他射頻設備與 VT·100）			
本產品可於射頻干擾參數受控制的電磁環境中操作，遵守可攜式和行動射頻或其他射頻通訊設備與本產品之間所規定的最短距離，避免電磁干擾，距離受通訊裝置之輸出功率而定。			
最大輸出能量 w	依照傳送器頻率的防護距離 m		
	150kHz-80MHz	80MHz-800MHz	800MHz-2.5GHz
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

本產品已透過測試並符合醫療設備 IEC60601-1-2-2014;EN60601-1-2:2015 之規範。規範目的在確保醫療機構和使用的環境中提供合理的保護，防止有害干擾。本產品產生、使用和發射輻射無線電頻率能量，若未妥善安裝，或未依使用手冊操作，可能會對附近的其他設備產生有害干擾。可攜式和行動高頻通訊系統可能會影響醫療電器裝置。指定規格以外的配件、電流轉換器和連接線，都可能導致電磁發射增加，或使裝置或系統的抗擾性降低。

指導原則和製造業者聲明 - 電磁輻射		
請確保本產品於下列指定電磁環境中使用。本產品曝露在非本使用手冊指定環境的電磁干擾中可能會影響性能。如果遇到問題，請將本產品遠離電磁干擾源。		
輻射測試	符合之標準	電磁環境 - 指導原則
高頻輻射 CISPR11	Group 1	高頻輻射僅於 NPWT 空氣抽吸幫浦內部元件上使用。因其輻射放射量很低，不太可能干擾周遭電子裝置。
高頻輻射 CISPR11	Class B	NPWT 空氣抽吸幫浦適合在所有建築物中使用，適合在各類設施中使用，包括住宅區及直接連接到住宅供電之公共供電網路的設施。
諧波輻射 IEC61000-3-2	Class A	
波動電壓 / 閃爍輻射 IEC61000-3-3	符合	

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8 電磁相容性

<table>
<tr><th colspan="4">指導原則和製造業者聲明 － 電磁抗擾性</th></tr>
<tr><th>抗擾測試</th><th>IEC 60601 測試等級</th><th>符合之標準等級</th><th>電磁環境 － 指導原則</th></tr>
<tr><td>傳導耐受性
（Conducted RF）
IEC 61000-4-6</td><td>3 Vrms
6 Vrms
150 kHz to 80 MHz</td><td>3 Vrms
6 Vrms
150 kHz to 80 MHz</td><td rowspan="3">使用可攜式和行動無線電設備應與本產品之建議安全距離範圍，這個安全距離是依據適用傳輸頻率的公式計算所得。
環境中若具有帶有下列符號的裝置，可能會發生干擾。
 </td></tr>
<tr><td>輻射耐受性
（Radiated RF）
IEC 61000-4-3</td><td>3 V/m
10V/m
80MHz－2.7 GHz
80%</td><td>10V/m
80 MHz－2.7 GHz
80%</td></tr>
<tr><td>射頻無線通信設備鄰近場域
(Proximity fields from RF wireless Communications equipement)
IEC 61000-4-3</td><td>
<table>
<tr><td>27 V/m</td><td>385 MHz</td></tr>
<tr><td>28 V/m</td><td>450 MHz</td></tr>
<tr><td rowspan="3">9 V/m</td><td>710 MHz</td></tr>
<tr><td>745 MHz</td></tr>
<tr><td>780 MHz</td></tr>
<tr><td rowspan="3">28 V/m</td><td>810 MHz</td></tr>
<tr><td>870 MHz</td></tr>
<tr><td>930 MHz</td></tr>
<tr><td rowspan="3">28 V/m</td><td>1720 MHz</td></tr>
<tr><td>1845 MHz</td></tr>
<tr><td>1970 MHz</td></tr>
<tr><td rowspan="3">28 V/m</td><td>2450 MHz</td></tr>
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<tr><td>5500 MHz</td></tr>
<tr><td>9 V/m</td><td>5785 MHz</td></tr>
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8 電磁相容性

指導原則和製造業者聲明 － 電磁抗擾性			
抗擾測試	IEC 60601 測試等級	符合之標準等級	電磁環境 － 指導原則
靜電放電耐受性 （Electrostatic discharge；ESD） IEC 61000-4-2	± 8 kV 接觸放電 ± 2 kV，± 4 kV， ± 8 kV，± 15 kV 空氣放電	± 8 kV 接觸放電 ± 2 kV，± 4 kV， ± 8 kV，± 15 kV 空氣放電	地板材質必須為木質、混凝土或陶瓷地磚。若地板有覆蓋合成纖維物質，相對濕度則必須至少達到30%。
電性快速瞬變脈衝群雜訊耐受性 （Electrical fasttransient/burst） IEC 61000-4-4	電源供應線路 ± 2 kV 輸入 / 輸出線路 ± 1 kV	電源供應線路 ± 2 kV	主要電源規格必須為典型的商用或醫院環境所採用的電源規格。
突波耐受性（Surge） IEC 61000-4-5	±0.5 V ± 1 kV 差模 ±2 kV 共模	±0.5 V ± 1 kV 差模 ±2 kV 共模	主要電源規格必須為典型的商用或醫院環境所採用的電源規格
電壓驟降、短路及電壓改變耐受性 （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°	主要電源規格必須為典型的商用或醫院環境所採用的電源規格。若使用者必須在主要電源電力中斷的情況下繼續操作本產品，建議使用不斷電系統或電池為本產品裝置提供電力。
電源頻率 50/60 Hz 磁場耐受性（Power frequency 50/60 Hz magnetic field） IEC 61000-4-8	30 A/m	30 A/m	電源頻率的磁場應在典型的商業或醫院環境中維持典型的數值。

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
S1004-0022	“暄達”真空動力式抽吸幫浦－輕巧六十天型	
S1001-6010	“暄達”負壓傷口治療系統 可鎖式接頭 收集罐（未滅菌）150 cc/ml	

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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

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