carilex®

Envelop

Anti-Decubitus Air Alternating Pressure Mattress System
Instructions for Use

About This Document

Congratulations and thank you for purchasing this high quality anti-decubitus system.
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: Envelop System
The serial number is shown on the label on the rear of the control unit and on the tag sewn on the mattress.

Validity of the documentation

Details of the Device Documentation
This manual describes the Envelop System. It is part of the device documentation. Do not pass this device to a third party without 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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About This Document

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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.

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1 Important Notes for Safe Use

1.1 Designation of the Groups of Individuals

Named groups of persons

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

Operators

An operator (surgical supplier, health insurance, clinic, etc.) is any legal person who owns and uses a Envelop System, 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 Envelop System
- 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 Envelop System 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 Important Notes for Safe Use

1.2 Notes for the Users

Note that the Envelop System 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 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 Handing Over the Device

Device approval

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

1.2.3 Maintenance and Installation

The maintenance and/or repair of the equipment or parts must only be carried out 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 Envelop System 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 Handing Over the Device

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

- The initial start-up of the device, as well as the hand over to the user must be carried out by an authorized personnel assigned by the operator.
- After completion of the training, it must be documented that the user has understood the operation and use of the device for therapy or care purposes.

1.3.2 Qualification Requirements Hygiene Staff

Hygiene measures

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.

1.3.3 Availability of the Instructions for Use

Obligation to provide information

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 use.

1.4.1 Intended Purpose

Intended purpose

Anti-decubitus Air Alternating Pressure Mattresses System is designed for patients who endure pressure ulcer and potential patients who wish to reduce the likelihood of pressure ulcer. The device is intended to prevent and manage pressure ulcers by facilitating blood circulation and decreasing pressure of each tissue's contact area.

Intended users:

The intended user of this medical device is caregiver who has undergone user education and training and has read the instruction manual or a guardian who takes care of patients

Intended patient populations:

- Patients who endure of all categories of pressure ulcer and potential patients who wish to reduce the likelihood of pressure ulcer.
- Patient minimum weight: 30kg.
- Patient maximum weight: 300kg for Standard Mattress / 450kg for Bariatric Mattress.

Use environment:

The support system can be used on Professional Healthcare facility environment.

Indication:

The therapeutic support surface system is indicated for the prevention and/or management of all categories of pressure ulcer. The use of this system allows combined with the regular repositioning, monitoring, and nursing of the patient.

Contraindications:

Certain patient conditions are not suitable for using this type of device such as fracture of instable vertebrae and illness of instable vertebrae (include Spinal cord injury, Cervical traction).

⚠ WARNING

For Patients with unstable fractures, burns, or an intolerance to motion, need to consult the treating physician prior to patient placement and product use. Individual patient conditions may vary.

1 Important Notes for Safe Use

WARNING

Always consult a physician or health professional before using this device. The use of this system is still required the regular repositioning, monitoring, and nursing of the patient. In accordance with the NPUAP/EPUAP directives, Carilex recommends that repositioning the patient every two hours. However, the determination of individualized repositioning schedule should be made based upon the patient's condition.

Limitations:

- If patients have other unstable fractures, or conditions which may be complicated by a soft or moving surface, advice should be sought from an appropriate clinician before use.

Type of Contact and Duration of contact:

Control unit: non-contact with patient's body.
Mattress: indirectly contact with whole body as long as the patient is lying on the mattress.
The system is suitable for continuous therapy.

Clinical benefit:

The device is intended to prevent and manage pressure ulcers by facilitating blood circulation and decreasing pressure of each tissue's contact area.

1.4.2 Attention

Attention

Always consult a physician or health professional before using the Envelop System. Any and all applications outside of the conditions specified above are regarded as unapproved. The user and the operator respectively are exclusively liable for any damage resulting from the unapproved use.

If existing wounds do not improve or the patient's condition changes the overall therapy regimen should be reviewed by the consult physicians.

- Strangulation by extra-long cables and hoses : To avoid entanglement, keep children clear of hoses.
- Choking caused by small parts being inhaled or swallowed : Identify any loose or detached small parts that may be an issue.
- Potential allergic reactions to accessible materials used in the equipment : Identify any rubber or latex that could be an issue.
- Contact Injuries : Check for any skin irritation due to prolonged contact with the equipment.

1 Important Notes for Safe Use

- Protection against strangulation or asphyxiation : Means shall be provided to control the risk of strangulation and asphyxiation of the patient and other to an acceptable level by routing wires or tubing, and using retention devices.
- To prevent the effects caused by pets, pests or children.
- To avoid the effects of degraded sensors or loosened electrodes, that can degrade performance or cause other problems.

1.4.3 EMC Compliance Statement

EMC notices

Use of accessories and/or cables other than those specified or provided by the manufacturer of the Envelop Pump Model SR388 may negatively affect EMC performance.

- Power cord set: It is non-shielding, and the typical length of power cord is 4.5m max. molded with IEC 60320 C13 connector.
- Use of the SR388 adjacent to or stacked with other RF communications equipment (including antennas) should be avoided and to be used no closer than 30cm to any part of the SR388, including cables specified by the manufacturer because it could result in improper operation.
- Medical Equipment Immunity Performance Criteria Unacceptable Operating Conditions:
  a. Component failures or error of display numerical value.
  b. Change or failure in programmable parameters if any.
  c. Initiation of any unintended operation or false audible indicator.
  d. Cessation, change or interruption of any intended operating mode.
- All necessary instructions for maintaining Basic Safety and Essential Performance with regards to ElectroMagnetic Disturbances for the expected service life.

1.4.4 Safety Caution Statement

- A warning indicating that replacement by inadequately trained personnel could result in hazard.
- Skin irritation due to prolonged exposure to mattress or other accessories.
- No modification of this system is allowed.
- For cleaning & disinfection processes of ME equipment being performed by a Lay Operator shall be investigated by the Usability Engineering Process.
- Burn wound with severe exudate with the high risk of infection.
- An identifying marking provide referring to instruction in IFU for battery pack intended to be changed only by service personnel using a tool for replacement.
- A warning indication that replacement of Li-Ion battery pack if incorrect, the replacement would result in an unacceptable risk.

1 Important Notes for Safe Use

Warranty terms and conditions

1.5 Warranty

The supplier shall ensure the safety and correct functioning of the Envelop System 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 if it is not avoided.

CAUTION

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

1.6.2 Identification of Material Damage

ATTENTION!

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

1.6.3 Identification of Additional Information

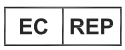
NOTE!

Means application tips and useful information.

1 Important Notes for Safe Use

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		Model Number
	Serial Number		Medical Device
	Follow Instructions for Use		Caution (ISO 7000-0434A)
	Consult Instructions for Use		Type BF Applied Part
	Declaration of Conformity to MDR 2017/745		Waste Electrical and Electronic Equipment (WEEE Logo)
	Protective Earth		Machine Wash Warm : Max. 70°C
	Lot Number		Machine Wash Warm : Max. 71°C
	Do Not Bleach		Do Not Iron
	Do Not Dry Clean		Tumble Dry Medium - Gentle Cycle
	Do Not Wash		Hang Dry
	Humidity Low and High Limits		Temperature Low and High Limit
	This Way Up		Fragile, Handle with Care
	Use No Hooks		Keep Away from Rain

2 Security Norms

2.1 Correct Use of the System

(1) In order to guarantee the correct operation, ensure that the system is perfectly assembled and securely fasten the mattress with the specific straps to the bedframe. Make sure that the straps do not interfere with the bed movements.
(2) Hang the control unit to the bed footboard using the specific hanger hooks and do not place any objects onto the control unit. Insert the power cord set into one of the two cable holders placed at each side of mattress base and fix by the press studs on the cable holder. Ensure that power cord set is not kinked or tighten up.
(3) A single layer bed linen separates the patient from air mattress to avoid direct contact with the air mattress coverlet. Ensure that the bed linen fits properly and not too tight to prevent from hammocking.
(4) Do not use the system in presence of live flame or sources of heat. The control unit extracts the air from the environment and despite its filter system, smoke can damage the internal components.
(5) After each use the system must be disinfected and sanitized to prevent cross-infection.
(6) Ascertain that the patient's weight does not exceed the weight allowed on the bedframe and the maximum therapeutic capacity of the anti-decubitus system.
(7) Never use the product if the power cable, plug of the control unit or power supply housing is defective, if the control unit housing is damaged, or if it is not functioning properly. Contact an authorized service technician for examination and repair.

2 Security Norms

2.2 Advice

(1) DO NOT open or dismantle the control unit if you are not a qualified technician. In case of problems, get in touch with the authorized assistance service.
(2) Safety in the presence of inflammable anesthetic gases: the system is not AP/APG protected.
(3) Use of the present system does not exclude repositioning and changes of posture of the patient wherever possible.
(4) Environmental conditions for operating the Medical Electrical system:
Temperature: 5°C to 40°C
Humidity: 15% to 90%
Atmospheric pressure: 700 hPa to 1060 hPa
(5) The plug is used for disconnecting the device. Do not position the control unit in the way which will be difficult to disconnect.
(6) No modification of this system is allowed.
(7) CAUTION:
AVOID ELECTRIC SHOCK, DO NOT OPEN AIR PUMP!
(8) Not using genuine accessories, parts and materials not described in the Operation Manual.

CAUTION

- Ensure no points, springs protruding from mattress which may pierce the air cells.
- DO NOT expose the Envelop System to the sunlight or the dusty environment.
- May experience potential allergic reactions to accessible material used in the Envelop System.
- Keep the Envelop System out of reach of children.
- Skin irritation due to prolonged exposure to matress or other accessories.

3 Delivery and Storage

3.1 Packaging

Envelop System is supplied in sturdy cardboard packaging. All packaging materials are recyclable and can be separated.

3.2 Delivery Control

Check immediately after delivery of the device:

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

Envelop System is delivered with the following components:

- Control unit
  Including: Control unit x 1
  Power cord set x 1
  Lithium-ion battery pack x 1
  Instruction for Use x 1
- Mattress
  Including: Mattress x 1
  Coverlet x 1

If the delivery is incomplete or the device and/or the packaging are damaged, in particular in the case of damage caused by moisture or water, you should promptly inform the carrier, as well as the supplier.

3.3 Storage and Transport

Recommended environmental conditions for storage and transport:

- Ambient temperature: -25°C to 70°C
- Relative humidity: 0% to 90%

⚠ ATTENTION

Storage of the mattress

- Always roll the mattress, do not fold or bend.
- Do not put or store with any sharp instruments or tool with sharp tips.

For long-term storage the control unit should be covered with a dust protector.

4 Device and Functional Description

4.1 Device Description

Principle of operation

The control unit generates air by compressor then the solenoid valve delivers the air into the mattress through air tube inside the control unit then pass through the air outlet.

The mattress will perform the operation status base on the selected operation mode by control panel. The air tube from mattress connects to the air outlet to receive the air from control unit then distribute the air to air cell by manifold.

Control unit

The control unit is used as the housing for the air source as well as control features:

- A control panel with buttons and lights to adjust the air system.
- Two hooks on the back to hang the control unit to a bedframe.
- A receptacle for an air filter on the rear panel.
- Two air outlets for quick coupling.
- A power cord set with a plug to connect the device into a wall socket.

Mattress

The mattress consists of multiple set of air cells which work in dynamic or static mode to relief and redistribute pressure.

CPR for Standard Mattress

The CPR function is activated by a special valve with circular mechanism located on the right side of the mattress near the torso area. With a rapid maneuver opening the CPR valve, the mattress deflates in the torso area, allowing the Cardiac Pulmonary Resuscitation procedure to be activated. The CPR valve, well-marked and built-in the side of the mattress prevents accidental opening, and it can be opened with a short clockwise rotation, with a single movement and with the use of one hand only.

CPR for Bariatric Mattress

The CPR function is activated by a special five ports CPR located on the right side of the mattress where the manifolds starts. With a rapid maneuver remove the CPR plug, the mattress deflates in the feet area, allowing the Cardiac Pulmonary Resuscitation procedure to be activated. The CPR, well-marked and built-in the side of the mattress prevents accidental opening, and it can be opened by simply pull out the CPR plug, with a single movement and with the use of one hand only.

4 Device and Functional Description

4.2 Operation and Functional Test

To perform a functional test and at the initial start-up of the control unit take the following actions:

- Fully lay out the mattress. Both air hoses must be able to move easily without any kinks or pressure points.
- Make sure that the CPR valve is closed.
- Push in the quick coupling of the mattress firmly into the air outlet of the control unit.
- To disconnect mattress from control unit, simply just press the button on the coupling and pull.
- For function test details, please refer to Chapter 5 Features, please make sure all functions work normally before use.

Turning on the control unit

Electric shock!

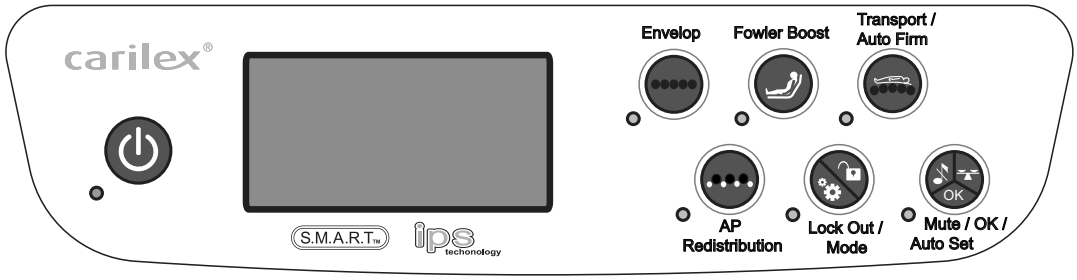
Touching live parts can result in a death or serious injury by an electric shock. Check for damage of the plug and the main power cable of the control unit before connecting.

- Damaged components may not be used for connection!

5 Features

⚠ CAUTION:
Different mattress systems have different settings. Using the wrong setting may cause severe system failure and risk of harming patient.

5.1 Control Panel



Identity Correct Mattress System

In order to provide better therapeutic effect to patients, Carilex offers multiple mattress systems including Standard and Bariatric size mattress. Therefore, it is important for the user to identify and select the correct setting on the control unit corresponding to the mattress system that is being used.

How to select function on the control panel of the control unit:

(1) Plug the power cord into the proper wall socket, and switch on the rocker switch.
(2) Turn on the control unit by press Power/Standby button. After the startup screen, press Lock Out/Mode button to select the proper mattress type, Standard mattress with CPR valve near the torso area which support patient weights from 30 to 350kg or Bariatric mattress without CPR valve near the torso area which support patient weights from 350 to 450kg.
(3) Press the Mute/OK/Auto Set button to confirm the mattress setting selection.
(4) The control unit will start the initialization of the system.
(5) After finish the initialization and "SYSTEM READY" appears on the LCD screen, the system is ready for patient placement.

How to reset the mattress size:

(1) Turn off the control unit by the power button on the panel foil and keep the rocker switch on.
(2) After press the press power button again, the user could select the correct mattress size.

Power / Standby

When the rocker switch on the left side panel is switched on, the control unit is in standby mode and the orange LED will be lit. To turn on the control unit, press Power/Standby and the standby orange LED will be off.

Envelop (Static Mode)

Envelop Mode is the therapy in which all air cells maintain constant pressure support and maximize patient's contact area to redistribute pressure.

5 Features

AP Redistribution (Dynamic Mode)

AP Redistribution Mode is a therapy mode in which air cells alternate in an A-B-A-B (odd and even number of air cell sets) pattern to relief pressure and increase blood flow of the patient tissue. The 3 cells at the head are always excluded from the alternating. AP Redistribution mode will take 10 minutes to finish a complete cycle. For battery mode, the system will take 15 minutes to finish a complete cycle.

Fowler Boost (Upright Mode)

Fowler Boost Mode is used to prevent patient from bottoming out in an upright position. Once fowler boost button is pressed, the green LED will light up and the symbol in LCD will display to indicate this mode is in operation.

Transport / Auto Firm

By pressing the Transport/Auto Firm button, the system will rapidly bring the mattress to maximum steady pressure, which allows caregiver to perform the daily nursing procedures. A green LED will light up and the symbol in LCD will display to indicate this mode is in operation. Press this button again to stop this function or the system will automatically return to previous setting after 20 minutes.

Mute / OK / Auto Set

This button would work for three functions. Mute function, it is used to turn off the audible indicator, otherwise the system will continue to sound for 1 minute and then stop for 4 minutes as a loop until the abnormality is solved. After mute the audible alert manually, it will not start beeping again, to avoid acoustic pollution, but the green LED will light and the mute symbol will display on LCD screen. The mute function is only operational when the audible alert is in effect.

The OK function is only functional when confirm the mattress type, Standard or Bariatric.

For Auto Set function, press the button for 3 seconds when the system auto setting is required. Then the system will re-detect the weight of patient and set the suitable pressure.

Lock Out / Mode

When there is no operation after 3 minutes, system will automatically lock the control panel. The lock function can also be activated any time by pressing this button. All buttons will be locked except the Mute/ OK/Auto Set button which allow user to mute audible alarm and the Transport/Auto Firm button. Simply press and hold the Lock Out button for 3 seconds to release the system from locking.

5 Features

For Mode function, press Lock Out/Mode to select the mattress type between Standard and Bariatric.

Language

Envelop system is equipped with multi-languages setting including Espanol, Italiano, Deutsch, Francais and English. The default language of the system is English. To change the language, simply press Envelop and Fowler Boost button when the rocker switch is on and the system power is off. Use Envelop button to select the desired language, and press Mute/OK/Auto Set to confirm the selection.

Low Pressure Alert

Both continuous audible and visual indicators on LCD display will be triggered to notify caregivers when the mattress has insufficient pressure. User may press mute button to turn off the audible alarm.

Battery Mode

The system will switch to battery mode when abnormal power outages occur. While in battery mode, the system will change the alternating cycle time from the default 10 minutes to 15 minutes. Furthermore, if the system goes into low battery mode, it will switch to static mode to do further power saving.

Low Battery

Once the battery contains less than 30% battery life, the light of LCD screen will switch off to prolong the operating time. The audible indicator will sound 15 times in 1 minute then stop for 4 minutes as circulation until power is returned. The users could press the mute button to turn off the audible alert.

CPC Detection

Once the CPC connector of the mattress is disconnected from the air outlets, the system will trigger both audible alert and visual indicators on LCD display notify users. The users could press the mute button to turn off the audible alert.

Timer

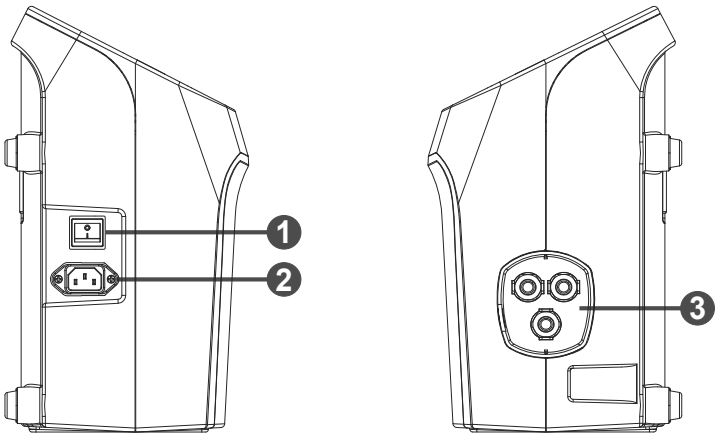
To view the total operating time of the control unit on the LCD display, ensure the rocker switch is switched on and the system power is off, then press both Fowler Boost and Transport/Auto Firm simultaneously.

Main Power off

Press the button and then switching off the rocker switch on the left side panel.

5 Features

5.2 Side Panel



Left Side Panel

Rocker Switch (1)

Main power switch of control unit

Power Receptacle (2)

Three pin IEC 60320 C14 AC inlet to accept power cord set with C13 connector.

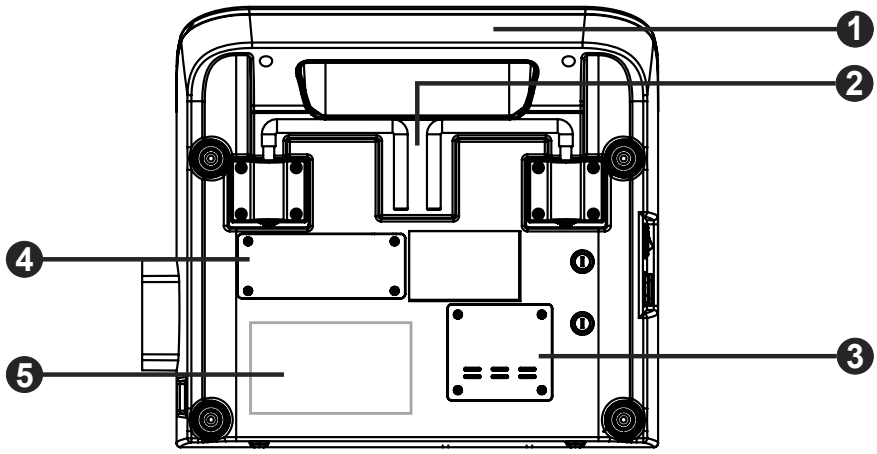
Right Side Panel

CPC Connector (3)

Quick couplings enable a rapid and firm connection between the mattress and the control unit.

5 Features

5.3 Rear Panel



Convenient Handle (1)
It provides additional gripping surface for user to carry the control unit.

Hanger Hooks (2)
The hooks are designed to fit with multiple footboard widths.

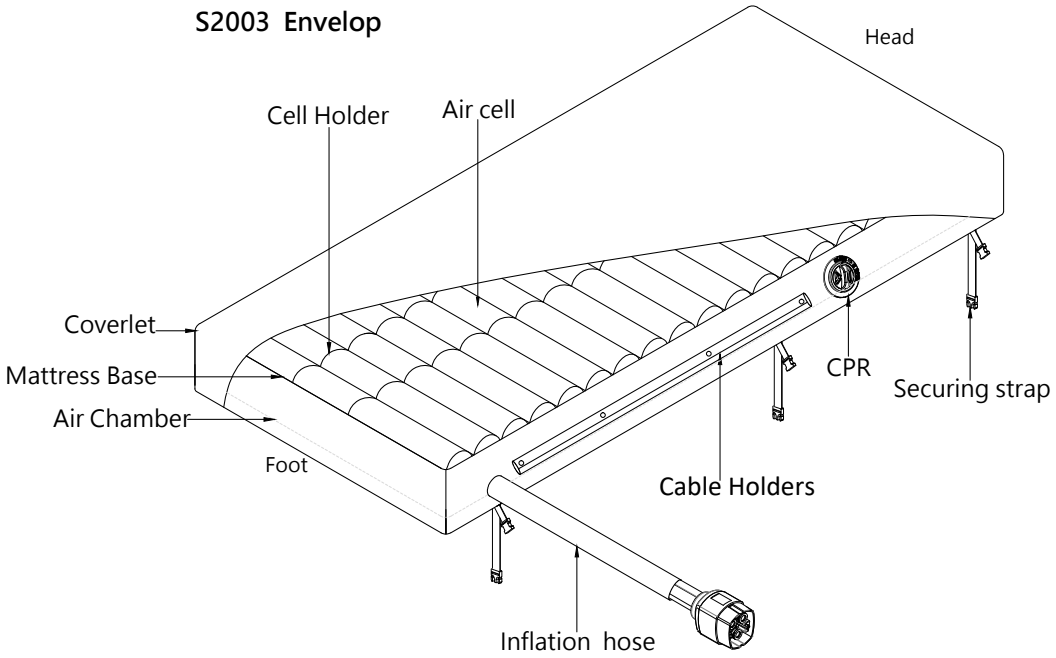
Air Filter and Filter Cap (3)
We recommend inspecting and cleaning this filter monthly or more often, depending on the environment the unit is being used. Failure to keep the filter clean will result in shorter life span of the unit and/or unit failure. When replacing, be sure to use Carilex standard filter to optimize the performance of the control unit.

Battery Compartment (4)
Allows for access for battery replacement. Also includes socket used for upgrading software/firmware. Remove the battery pack when unused for long periods of time.

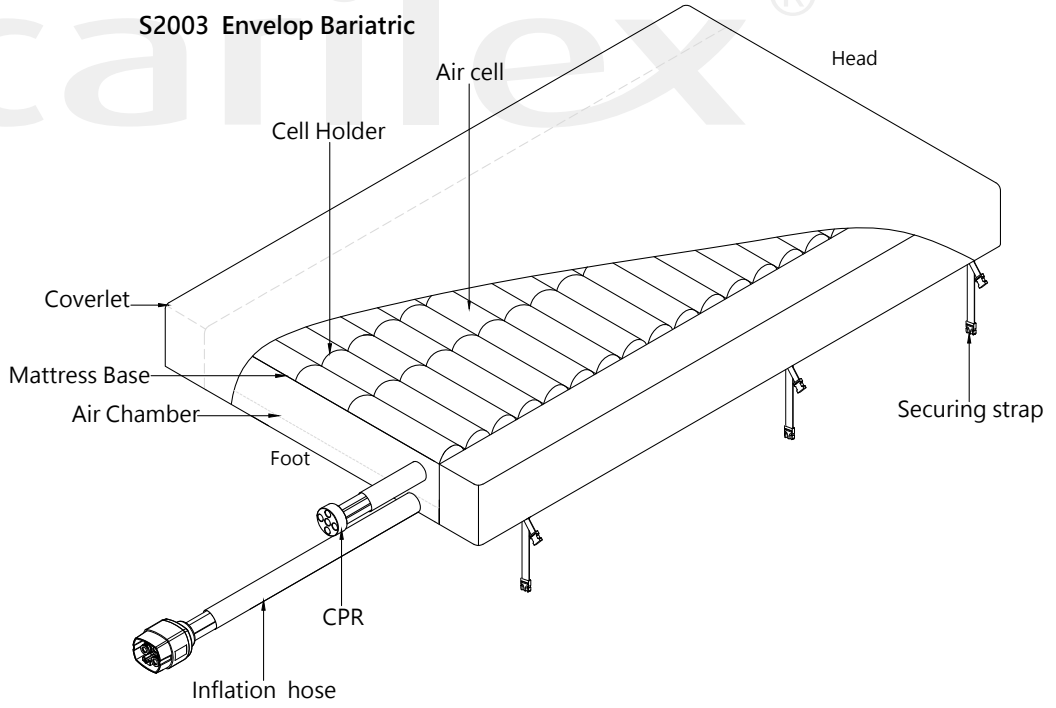
Label (5)
This label includes all the information for medical device and safety requirements.

5.4 Mattress Diagram

S2003 Envelop



S2003 Envelop Bariatric



6 System Installation, Operation, Transfer and Transport of Patient

6.1 System Installation

(1) Remove the existing mattress.

(2) Installation mistake with mattress that will lead loss of functionality, to increase the risk associated with pressure ulcers. Please install the system properly.

(3) Put the mattress on the structure of the bedframe with the logo at the foot of the mattress. Fasten the mattress with the use of the straps ensuring that the functions and movements of the bedframe are not limited before proceeding to the next step.

(4) CAUTION!

Insufficient distance between the top surface of the air mattress and the top of the side rails that may increase the risk associated with fall. Do not install the air mattress that exceeding the allowed height of the bedframe.

(5) CAUTION!

Shear strain (deformation) in the deeper layers of tissue that may increase the risk associated with pressure ulcers. Please make the bed sheet on the air mattress, to avoid the patient indirectly contact with the air mattress, to reduce the excessively frictional force act on the skin of patient and then lead to the deep tissue injury.

(6) Hang the control unit at the foot of the bedframe with aid of the hanger hooks.

(7) Push the quick coupling of the mattress firmly into the air outlet of the control unit.

(8) Insert the power cord set into a wall outlet and switch on the rocker switch on the left side panel. Ensure that the power cord is not in the way of the operators and the movement of the bedframe. Ensure that the power cord is housed in the cable management down the side of the mattress at all times to avoid hazards or accidental damage to the power cord.

(9) Choose the correct setting according to mattress type, Standard or Bariatric, on the control panel. Refer to Section 5.1 to identify the correct mattress system.

(10) CAUTION!

Different mattress systems have different settings. Using the wrong setting may cause severe system failure and risk of harming patient.

(11) CAUTION!

Patient hit against the bedframe/floor that may increase the risk associated with injury or bone fracture. Please follow the section 9.1 Inspection, to check the strut force of mattress after install the system.

(12) CAUTION!

Contact with damaged power cord that may increase the risk associated with an electric shock or burn. Please insert the power cord set into the cable holders of mattress base and then fix it, to avoid that the power cord being trapped between the moving parts of the bed's side rails and then leading a damage.

6 System Installation, Operation, Transfer and Transport of Patient

6.2 Operation

(1) When the mattress is fully inflated and the "SYSTEM READY" appears on LCD, caregivers could position the patient on the mattress. Then the LCD screen will display "AUTO-SETTING", and during this time, the system is taking into account the mattress loading and adjust the appropiate system setting automatically.

(2) Ensure to select the appropriate therapy mode according to the physician’s decision.

(3) IMPORTANT:
Tucking in the coverlet too tensely significantly reduces the mattress's effectiveness.

(4) IMPORTANT:
Regardless of the type of coverlet that has been equipped to the mattress, ensure that the zipper of coverlet is affixed properly to the base of the mattress.

(5) WARNING!
Do not leave a patient unattended on the mattress surface with the safety side rails in the down position. When leaving a patient, secure the safety side rails in the up position. Make sure the safety side rails are high enough to properly protect the patient when the mattress is fully inflated.

(6) WARNING!
Alignment of the bed frame, safety sides and the mattress should leave no gap wide enough to entrap a patient's head or body, or to allow egress to occur in a hazardous manner where entanglement with the mains power cable may result. Care should be exercised to prevent occurrence of gaps by compression or movement of the mattress. Choking or serious injury may occur.

(7) Always turn off the control unit by using the power button and rocker switch. Failure to do so may cause machine malfunction.

6.3 Side Bolster Inflation and Deflation of Envelop Bariatric M-set

There is one extensional bolster located on each side of the Envelop Bariatric M-set, and the control valves to the bolsters are located at the foot end of the mattress on each side, underneath the flap of the top cover labeled “Bolster Control Valve”.

How to inflate the side bolster:

1. Lift the side cover.
2. Ensure the yellow deflating strap on the side bolster is closed.
3. Release the 5 black secure straps upon the side bolster.
4. Switch the bolster control valve located at the relative foot end of the mattress to the bolster to “HIGH” to allow the air flow.

How to deflate and retract the bolster:

1. Switch the bolster control valve located at the relative foot end of the mattress to the bolster to “OFF” to stop the air flow.
2. Pull out the yellow deflating strap on the side bolster to deflate.
3. Tighten the 5 black secure straps to boost the deflation and secure the bolsters in place.
4. Close the yellow deflating strap in step 2 once the bolsters are fully deflated.

NOTE!

The yellow deflating strap deflates only the side bolster, open the CPR located on the right side of the mattress where the manifolds starts to deflate the air cells if emergency.

6.4 Transfer and Transport of Patient

Transfer

We recommend carrying out the transfer of the patient by having the system on Transport mode during transfer and ensure that the bed is well-positioned and steady.

Transport

For Envelop System, there are two ways to transport the patient: 1. Use the Transport/Auto Firm Mode to inflate the entire mattress to maximum pressure. After the mattress inflates to maximum pressure, power off the control unit and detach the CPC connector of the mattress from the air outlets of the control unit. Then insert the transport plug to CPC connector to retain air in the mattress and the mattress will stay inflated over 15 hours.

2. Unplug the power cord set from the wall outlet and the system will switch into battery mode, which will provide the control unit with power for approximately 1.5 hours for uninterrupted therapy.

Once the transportation phase is complete, reconnect the mattress to the control unit and follow Section 6.2 to resume normal operation. It is not necessary to move the patient during the re-inflating maneuver.

ATTENTION

The Low pressure alert will be activated due to sudden loss of pressure, this could happen if the patient is removed from the mattress or if the CPR valve is accidently opened during use, once the CPR valve is closed, the audible beeping will continue while waiting for the mattress pressure to reach the required setting. If it is activated, please follow the information about Low Pressure Alert LED at 5.1 section to mute the sound.

7 Application

Mandatory bedframe size

It is mandatory to select proper bedframe size for the Envelop System. Do not operate the Envelop System without safe installing of the mattress onto the bedframe. Make sure that the fixing of the mattress does not impede the adjustment mechanism of the bedframe.

7.1 Preparing the Application

Fix the mattress

(1) Place the bedframe in the supine (flat) position.
(2) Fix the mattress with the straps onto the bedframe.
(3) Make sure that the CPR valve is closed.
(4) Hang the control unit with the two hooks on to the footboard of the bedframe and check that the fixing is stable.
(5) Connect the quick coupling of the mattress to the air outlet of the control unit. Make sure that the air hoses are routed without bending, kinks or pressure points.

7.1.1 Inflating the Mattress

In preparation for the patient, the air cells should be inflated in advance by the control unit. After "SYSTEM READY" appears on the LCD screen, the system is ready for patient placement.

7.1.2 Patients Positioning

Carry out the positioning of the patient in accordance with the local patient care guidance.

- The patient should be centered on the mattress, with equal distance from the left and right mattress's sides.
- The head of the patient should rest fully on the head air cells.

CAUTION

Pressure points on protective body areas!

During the application of the Envelop System, the skin of the patient must be regularly checked by medical and nursing staff and caregivers.

CAUTION

Loose power cord set may cause tripping and serious injury.

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8 Cleaning and Disinfection

Contact with pollutant that may increase the risk associated with the infection. In order to prevent cross-contamination, the cleaning and disinfection of the entire the Envelop System must be carried out between uses with different patients, and the pollutant should be disposed according to the local or facility guidelines for handling infected or bio-hazardous materials.

WARNING

Electric shock!

Check electrical components

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

- Turn off the control unit by power button and rocker switch.
- Unplug the power cord set 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 cleaning and disinfection. Wear personal protective equipment:

- Safety glasses.
- Protective gloves.
- Mouth and nose protection.

ATTENTION

Incompatible cleaning agents!

The components of the Envelop System are made of thermoplastic polymers. Solvents can spoil synthetic material and coating. Strong acids or alkalis can cause embrittlement.

Cleaning the control unit, the mattress (with air cells) and the coverlet:

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

Incompatible disinfectants

Cleaning the control unit, the mattress (with air cells) and the coverlet:

- Only use disinfectants without chlorides, halides.
- Do not use disinfectants containing gasoline, paint thinner, alkaline, acid, alcohol, or aldehyde (e.g. ethanol, propanol) in order to avoid the embrittlement of thermoplastic materials.

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8 Cleaning and Disinfection

8.1 Cleaning

When using the Envelop System in non-clinical areas the users or appropriately trained cleaning personnel can carry out the cleaning of the device.

⚠ WARNING

Remove the power cord set from the wall socket before cleaning of the control unit. Do not spray any cleaning liquid directly onto the control unit.

Cleaning of the control unit

Cleaning of the Surfaces of the Control unit

(1) Turn off the control unit and unplug the power cord set from the socket.
(2) Wet a soft cloth with water, mix it with commercially available washing-up liquid.
(3) Wipe off dirt and dust accumulations.
(4) Then dry the surfaces with a clean soft cloth.

Cleaning of the coverlet

Cleaning the Coverlet

The coverlet can be easily removed by derailing the zipper. The cleaning of the coverlet can be done by using any of the available disinfectants at their usual concentration. At the end, rinse disinfectant off thoroughly with water and leave to dry. Avoid detergents containing phenols or other corrosive substances. Ensure that the mattress and the coverlet are dry before new use. The hygiene regulations of institution are to be followed in the institutional care environments.

(1) Wet a soft cloth moderately with water, mix it with commercially available washing-up liquid. Wipe off dirt.
(2) Wipe cleaned areas with soft dry cloth.
(3) If heavily soiled the coverlet can be washed in the washing machine using commercially available detergent.
(4) Washing temperature please follow the instruction on the washing care label.
(5) Dry the coverlet thoroughly after washing. Make sure that no moisture remains in folds or creases.
(6) Do not put the coverlet in the dryer or near sources of heat.

8 Cleaning and Disinfection

If the coverlet is soiled or loses its water-resistant properties, it must be replaced.
Any resulting damage of the mattress caused by a spoiled coverlet will be not covered by the warranty.
Please follow the hygiene control regulations of your local authority.

WARNING

If the mattress coverlet is not securely fixed onto the mattress, the air cells and coverlet movement may be unstable and may cause risk of patient injury.

ATTENTION

Unpermitted after-treatment of the coverlet!
As a follow-up treatment of the coverlet:

- Do not bleach.
- Do not iron.
- Do not dry clean.

8.2 Disinfection

The operator must be notified about which measures apply to the Envelop System and the actual hygiene directives for disinfection. The disinfection of the Envelop System or parts of it can be performed only by trained personnel, who are familiar with the hygiene requirements of the institution.

Disinfection procedure

Disinfection procedures

Please follow the procedure required by your local health authority.

CAUTION

For repair, please contact your local distributor.
Please follow the hygiene control regulations of your local authority.

9 Care and Maintenance

9.1 Inspection

The safe operating condition of the Envelop System has to be checked at each use by the operator or during use by the patients and at least once in a year in particular with regards to the following:

- Function of the keys of the control unit.
- Function of the emergency CPR.
- Condition of the air hoses and quick coupling.
- Condition of the air cells.
- Condition of the coverlet.

9.2 Maintenance

The air filter should be cleaned regularly. It should be checked often, and depending on the usage environment may require to be changed often.

(1) Turn off the control unit and unplug the power cord set from the socket.
(2) Remove air filter from the rear panel by opening the air filter cap and clean or replace with a new filter.
(3) The expected service life to Envelop System and the parts or accessories shipped with the ME equipment is 2 years.
(4) To prevent an unacceptable risk, all information necessary for correct replacement of detachable or interchangeable parts should be available and replaced by qualified service personnel only.
(5) Following storage and/or transport of the device, please allow the device to sit idle at room temperature for at least 3 hours before powering on.

9.3 Maintenance of Battery Pack

(1) Remove the battery pack from the control unit and store it separately.
(2) Remove the battery pack from the control unit and well-packaged separately during transportation to prevent the battery pack damaged by shock and vibration.
(3) The routine maintenance is required that the battery pack should be charged and checked the condition every 3 months.
(4) Consider to replace the battery pack with the new Carilex standard battery pack if one of the following conditions is noted:
   - The battery pack has leaking fluids.
   - The wrapping film is damaged.
   - The battery pack appearance is swell or uneven.
   - The battery run time drops below 80% of the original run time.

⚠ CAUTION

The condition of the mattress and control unit should be checked regularly. If damages and/or wears are found, such as broken quick coupling on the control unit, broken or deform air cells, or broken zipper, please contact your local authorized Carilex service center for repair or replacement of damaged items.

10 Troubleshooting

Problem	Control Procedure	Possible Solution
1.) The control unit is working but the mattress is not inflating.	1.1) Verify that air flows liberally across the tubes and the mattress manifold. Check if there are any cuts, blockage or breakages.	1.1) It may be necessary to move the tubes or the manifold if they are kinked or twisted. In case of cuts or rips, replace the air cells or air hoses.
	1.2) Verify that the quick coupling is correctly connected to the air outlets of control unit.	1.2) Firmly connect the quick coupling.
	1.3) Verify that the CPR valve is correctly closed.	1.3) Firmly close the CPR valve.
2.) The patient sinks into the mattress.	2.1) Check for any abnormal air loss from the mattress.	2.1) Replace the components that are abnormally losing air with an authentic replacement part.
	2.2) Check the air filter.	2.2) Clean or replace the air filter.
	2.3) Verify that the CPR valve is closed correctly.	2.3) Firmly close the CPR valve.
3.) The control unit cannot power on.	3.1) Verify that the power cord set is plug into the proper socket.	3.1) Insert the power cord set of control unit into an appropriate socket and turn the power on.
	3.2) Verify that the power cord set is properly connected to the control unit.	3.2) Insert the power cord set into the control unit and turn the power on.
	3.3) Verify that the power cord set is not damaged.	3.3) Replace with a functioning power cord set.
	3.4) The control unit is not responding to the control procedures listed above.	3.4) Contact the authorized distributor for technical service.

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.

11 Technical Data

The Envelop System is suitable for continuous operation.

Control unit

Model.....SR388
Dimensions(W x H x D).....37.5 x 32 x 18.5cm
Weight..... 6kg
SPS.....Murata_ MVAD065-24 or Mean Well_ RPS-60-24
Electrical Rating.....100-240Vac 50/60Hz 1.4A or 1.8-1.0A
Power Consumption.....Max. 60W (normal operation)
Fuse Rating.....T3.15A 250V or T2.5A 250V
Electrical Class.....Class I
Applied Part.....Type BF mattress
Rechargeable Li-Ion Battery Pack.....4S1P,type 2LG-2B4S1P-DP41010
rated 14.4Vdc 3.3Ah
This system is not AP / APG protected.

EMC & Safety Certified Standard
Safety: IEC 60601-1:2005 + A1:2012 + A2:2020
EN 60601-1:2006 + A2:2021
BS EN 60601-1:2006 + A2:2021
AS/NZS IEC 60601.1:2015 + A1:2022
AAM1 ES60601-1:2005 + A1:2012 + A2:2021
CAN/CSA C22.2 No.60601-1:14 + A2:2022
EMC: IEC 60601-1-2:2014 + A1:2020
EN 60601-1-2:2015 + A1:2021

Mattress

Min. Patient Weight for Standard Mattress 30kg
for Bariatric Mattress 300kg
Max. Patient Weight for Standard Mattress 300kg
for Bariatric Mattress 450kg
Material of Air Cells.....Nylon with TPU lamination material

The Envelop System 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.

11 Technical Data

Mattress		
Device Item	S2003 Envelop	S2003 Envelop Bariatric
Article number	S2003-2110 S2003-2170	S2003-2160
Mattress size& Coverlet size	S2003-2110/120x200cm S2003-2170/90x200cm	S2003-2160/120x210cm
Coverlet material	DTX: Polyurethane coated fabric	
Coverlet MVTR	500g/24H/M^2	
Coverlet Wash Condition	Coverlet need to be water repellent- 3000mm/ H_2O after 1.5Hrs*40 wash	
Base material	100%PVC with Webnet base	
Air cell material	Nylon+PU	
Air cell height/ number	8" / 21 cell	8" / 23 cell
Protection unit	2" Air Chamber	
CPR Time	≤ 30 seconds	
Max Weight Capacity	300kg	450kg
Weight of Mattress Set	S2003-2110/17kg±2 S2003-2170/12kg±2	S2003-2160/17kg±2

12 Safety Precautions for Li-Ion Battery Pack

The following represents a typical, but non-exhasutive, list of good advice to be provided to the end-user.

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 a cell leaking, do not allow the liquid to come into contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.
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 50ºF(10ºC) and 113ºF(45ºC).
12. The Li-Ion Battery Pack should be discharged at temperature between 50ºF(10ºC) and 140ºF(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.

12 EMC Declaration

Declaration of Conformity

For EN 60601-1-2 (4.1th Ed.)

Company Name:	**Carilex Medical, Inc.**
Company Address:	**No. 77, Keji 1st Road, Guishan District, Taoyuan City 33383, Taiwan, R.O.C.**
Product Name:	**Envelop_ Air Pump**
Model No.:	**SR388**
Report Number:	**ETC 24-03-RBO-047**
Power Supply:	**1) 100-240Vac 50/60Hz 1.8-1.0A** **2) Li-Ion Battery Pack 14.4Vdc**

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

The Envelop_ Air Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Envelop_ Air Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Envelop_ Air 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 Envelop_ Air Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Envelop_ Air Pump should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Envelop_ Air 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 A	The Envelop_ Air Pump is EMISSIQNS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).
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

The Envelop_ Air Pump declaration – electromagnetic immunity

The Envelop_ Air Pump system is intended for use in the electromagnetic environment specified below.
The customer or the user of the Envelop_ Air 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%		3V/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 Envelop_ Air Pump system is intended for use in the electromagnetic environment specified below.
The customer or the user of the Envelop_ Air 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 professional healthcare facility or home healthcare 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 professional healthcare facility or home healthcare environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T ; 0 , 5 cycle At 0º , 45º , 90º , 135º , 180º , 225º , 270º and 315º 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycle Single phase: at 0º	0 % U_T ; 0 , 5 cycle At 0º , 45º , 90º , 135º , 180º , 225º , 270º and 315º 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycle Single phase: at 0º	Mains power quality should be that of professional healthcare facility or home healthcare 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 professional healthcare facility or home healthcare environment.
Proximity Magnetic Field IEC 61000-4-39	30 kHz (8 A/m) 134.2 kHz (65 A/m) 13.56 MHz (7.5 A/m)	30 kHz (8 A/m) 134.2 kHz (65 A/m) 13.56 MHz (7.5 A/m)	Proximity magnetic fields quality should be that of professional healthcare facility or home healthcare environment.

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