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AVA 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: AVA 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 AVA 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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This provision shall not affect the reproduction for internal use.

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 AVA 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 AVA 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 AVA 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 AVA 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.

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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.

1.2.5 Reporting of serious adverse events

User should report the serious adverse events to Vigilance and post-market surveillance module at EUDAMED website https://health.ec.europa.eu/medical-devices-eudamed/overview_en and Carilex's contact window: eu@carilexmedical.com

1 Important Notes for Safe Use

1.3 Procedures for Accident Prevention

The AVA 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.

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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.

1.3.4 Home Healthcare Environment

- This is any place a patient lives (either their own home or a nursing home) and other places where patients are present (e.g. being outdoors; in a wheelchair; traveling by any mode and whilst at work)
- Exclusions are: professional healthcare facilities where staff with medical training are continually on hand when patients are present (e.g. hospitals;doctors surgeries; dental surgeries)
- Since the Home Healthcare Environment includes a variety of environments, there is a chance that the medical equipment may be used in locations with unreliable electrical sources and poor electrical grounding.

1 Important Notes for Safe Use

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

Intended purpose

Anti-decubitus Air Alternating Pressure Mattress 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: 200kg for Envelop Lux / 250kg for FIT.

Use environment:

The support system can be used on Home Healthcare Environment and 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.
- While the AVA Envelop systems have been designed to manage patients up to the weight limits at 250kg, those approaching this upper limit are likely to have additional care and mobility needs and may be better suited to a specialist bariatric system.

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 AVA 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.

1 Important Notes for Safe Use

- Contact Injuries : Check for any skin irritation due to prolonged contact with the equipment.
- 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.

EMC notices

1.4.3 EMC Compliance Statement

Use of accessories and/or cables other than those specified or provided by the manufacturer of the AVA Envelop Pump Model SR394 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 C17 connector.
  - Safety approved AC Plug, Cord Type H05VV-F 2 x Min. 0.75mm²
- Use of the SR394 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 SR394, 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.
- Do not expose the Home Healthcare System to the sunlight or the dusty environment.
- Keep the Home Healthcare System out of reach of children.
- 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.

1 Important Notes for Safe Use

Warranty terms and conditions

1.5 Warranty

The supplier shall ensure the safety and correct functioning of the AVA 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)
	Double Insulated, Class II Equipment		NRTL_Safety Certified: SGS_Q Mark logo
IP21	Protected against ingress of solid foreign objects ≥12.5mm diameter. Protected against vertically falling water drops.		Machine Wash Warm : Max. 60°C
			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 Side Up		Fragile, Handle with Care
	Recycling		Handle with Care
	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.

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.

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.

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CAUTION

- Ensure no points, springs protruding from mattress which may pierce the air cells.
- DO NOT expose the AVA Envelop System to the sunlight or the dusty environment.
- May experience potential allergic reactions to accessible material used in the AVA Envelop System.
- Keep the AVA 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

AVA 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

AVA Envelop System is delivered with the following components:

- Control unit
  Including: Control unit x 1
  Power cord set 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 rotor 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

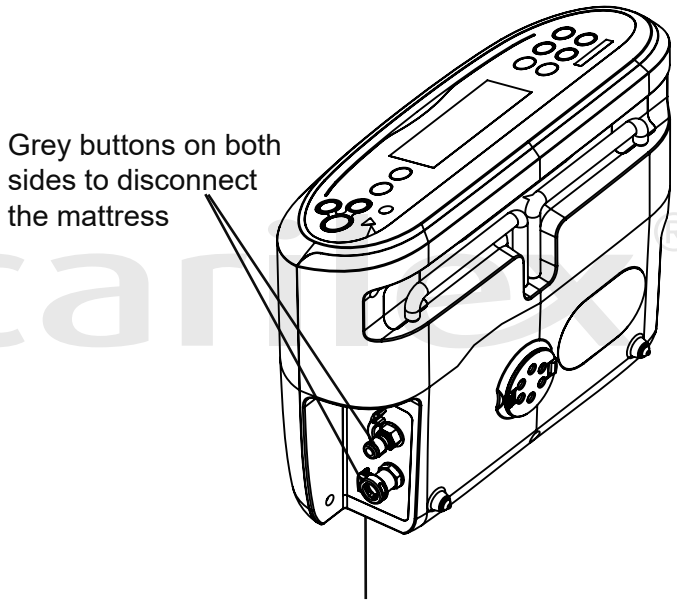
The CPR function is activated by a round type valve located on the right side of the mattress near the torso area. With a rapid maneuver opening the CPR valve, the mattress deflates in the torso area, allowing the Cardiac Pulmonary Resuscitation procedure to be activated. The CPR valve, well-marked and built-in the side of the mattress prevents accidental opening, and it can be opened with a short rotation, 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 both of the grey buttons on the quick coupling and pull.
- For function test details, please refer to Chapter 5 Features, and 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

5.1 Control Panel

Power

Press power button to power on or off the control unit. Please make sure that the power cord is securely inserted into the proper wall socket. The system will automatically start the initial inflating and calculating the mattress. The LCD screen will show "CALCULATING" on the bottom right corner. After the calculation is completed, the LCD screen will show "READY" to indicate that the system is ready for patient placement.

To reset the control unit to default setting (reset comfort boost to "0" and start up in dynamic mode with 10 minutes cycle time), press and hold the Power button for 10 seconds when the power is on.

Comfort Boost

AVA Envelop is a completely automatic system. Comfort Boost is an optional function that can increase the pressure setting according to each patient's comfort preferences. The Comfort Boost has 4 levels from 0 to +4. Please also use the Comfort Boost to prevent patient bottoming out when necessary. Please note that increasing the pressure setting may cause a reduce in therapeutic effect.

Auto Setting

The manual Auto-Setting button can be used when a new patient is on the mattress, or after patient repositioned. Press and hold the Auto-Setting button for 3 seconds. Once the manual Auto-Setting is activated, the system will re-detect the load of the patient and adjust the system setting accordingly.

5 Features

Mode

Press Mode button to change the therapy between Static Mode and Dynamic Mode:

Static Mode ●●●●●
Static Mode or Continuous Low Pressure mode is the therapy in which all air cells maintain a constant low pressure support. This therapy mode allows the maximized envelopment of the patient; molding the air around the patient contact surface, therefore creating the optimal pressure redistribution.

Dynamic Mode ●○●○●
Dynamic Mode is a therapy mode in which air cells continuously 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.

Multiple Cycle Time

This button is used to select cycle time in dynamic mode. The number indicators correspond to the time for 1 complete cycle. Three cycle times can be selected: 5, 10 and 15 minutes.

Max. Inflation

By pressing the Max. Inflation button, the system will rapidly bring the mattress to maximum steady pressure, which allows caregiver to perform the daily nursing procedures. A blue LED and icon with count down of remaining Max. inflation time on LCD indicates the activation of this function. In Max. Inflation mode, only Max. Inflation, Power, Auto Setting, Transport and Unlock button could be activated. Press this button again to stop this function with one beeping or the system will automatically return to previous setting after 20 minutes with two beepings.

Transport Mode

The transport mode is used to maintain the pressure of mattress for when transporting a patient. Once the Transport button is pressed, the blue LED and the icon will flash on LCD to indicate this mode is activating. When the transport mode is ready, the LED and icon will stay lit, which signals the user to unplug the power cord. Press this button again to cancel transport mode manually or reconnect the power cord after finish transporting the patient, and the control unit will return to previous mode automatically. If the transport mode is selected, but the power cord is not unplugged, nor the mode is manually canceled, the system will return to the previous setting automatically after 30 minutes.

Mute

User may press this button to turn off the audible indicator. After mute, the audible indicator will not re-start again and only have LED flashing to visually notify the caregivers until the problem is solved.

5 Features

Pulsate Mode

The Pulsate mode, also called DBE (Deep Breathing Exercise) is a function in which the system will cycle between Max. Inflation and proper setting. A blue LED and icon on LCD indicates the activation of this function. The system will inflate the mattress within 60 seconds to maximum the pressure and maintain the maximized pressure for approximately 60 seconds, then release the air to reduce the pressure to the proper pressure setting in 70 seconds and maintain for approximately 60 seconds. Press ⊕ to select the pulsate mode cycle time: 20, 40 and 60 minutes. The default cycle time is 60 minutes. After a cycle is complete, the system will switch back to the previous setting automatically.

Variable Dynamic Mode

VDM Mode is the same as dynamic mode, in which air cells continuously alternate in an A-B-A-B pattern. However, the cycle time will not stay the same, and it will change after every cycle is finished. The patent of variable cycle is: 5 min-10min-15min-5min-10min-15min…..and on. When VDM mode is selected, the system will finish the current cycle, and change to the next cycle time as above patent. A blue LED and icon on LCD indicates the activation of this function.

Panel Unlock

When there is no operation after 2 minutes, system will automatically lock the control panel. The blue LED will light and icon will show on LCD to indicate the panel is locked. All buttons will be locked except the Max. Inflation and Mute button which allow user to mute audible alert. Simply press and hold this button for 3 seconds to release it from locking.

Alert LED

This orange LED is to indicate that the mattress has abnormal pressure including insufficient pressure, excessive pressure and service required. There will be both audible beeping and visual LED indicators. Audible indicator will turn off after pressing the Mute button and it will not start beeping again, to avoid acoustic pollution, but the LED will stay flashing until the problem has been solved.

Pressure Monitoring LED (IPS)

AVA Envelop System is features with an intelligent pressure sensing technology which could monitor the mattress' pressure 24 hours to achieve optimal pressure and to ensure maximum pressure relief. The blue LED will light while the control unit is inflating.

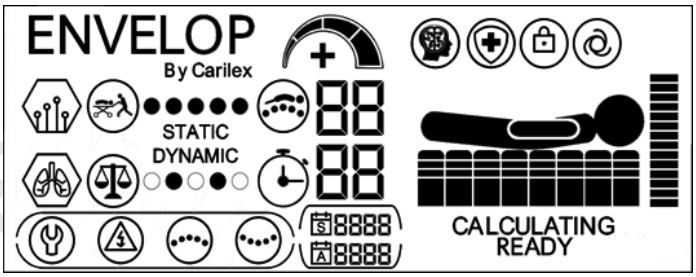
5 Features

Light Bar

AVA Envelop System features with a light bar to indicates the condition of system.

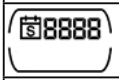
- The light bar is shown in static blue light when the system is functioning normally and the light will turn off automatically when the system is idle for 3 mins.
- The light bar is shown in orange light when the system is experiencing abnormality. The light bar will stay static and continuously on, until the problem is solved.
- The light bar is shown in breathing with blue light when the pump changes mode settings until the new setting is achieved.
- When Max inflate key pressed, the blue light bar starts to breath and continue for the duration of the max inflate until the max inflate mode finished.

5.2 LCD Icon



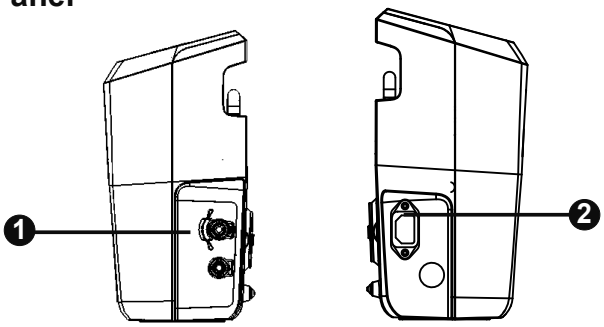
	Inflating
	panel lock
	upright protection
	SMART for calculating
	transport
	Auto Setting
	VDM
	DBE
	comfort adjust
	Max. Inflation count down
	dynamic/DBE cycle time
STATIC	static
DYNAMIC	dynamic

5 Features

	Require service
	power failure
	low pressure
	high pressure
	single use time
	summary time
	times of error
	Human Symbol
	Mattress Symbol
CALCULATING	Calculating for initial inflating
READY	System ready
	comfort

5 Features

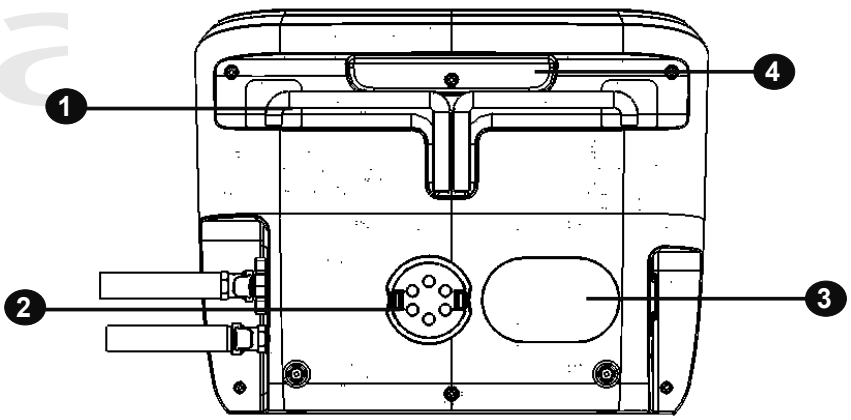
5.3 Side Panel



Air Outlet (1)
Quick couplings enable a rapid and firm connection between the mattress and the control unit.

Power Receptacle (2)
2 Pin_IEC 60320_Type C18 AC inlet to accept power cord set with 2 Pin_IEC 60320_Type C17 connector.

5.4 Rear Panel



Hanger Hooks (1)
The hooks are designed to fit with multiple footboard widths.

Air Filter and Filter Cap(2)
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.

5 Features

Label (3)
This label includes all the information for medical device and safety requirements.

Convenient Handle (4)
It provides additional gripping surface for user to carry the control unit.

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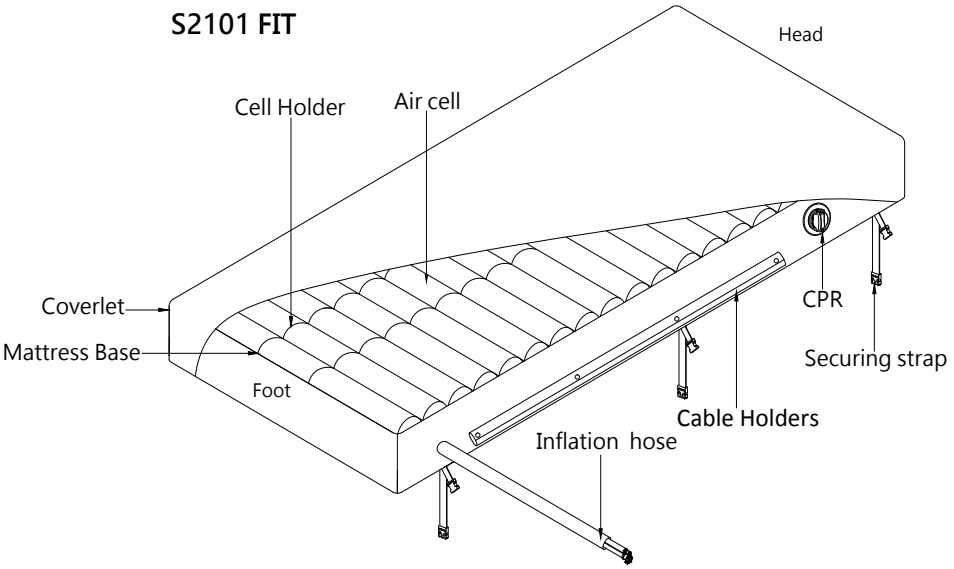
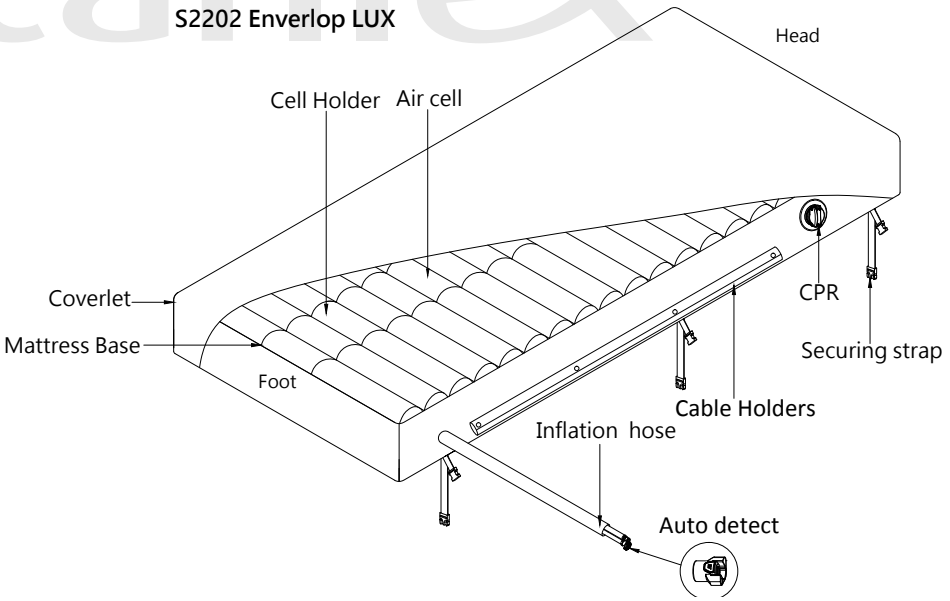
5 Features

5.5 Mattress Diagram

S2101 FIT



S2202 Enverlop LUX



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 directly 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. 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) The system will show the correct height setting of mattress.

(10) 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.

(11) 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) Pressing the power button the system will automatically start the initial inflating and calculating the mattress. The LCD screen will show "CALCULATING" on the bottom right corner. After the calculation is completed, the LCD screen will show "READY" to indicate that the system is ready for patient placement.

(2) AVA Envelop is equipped with the patented SMART technology, and the system will automatically detect patient's load after the patient laid on the mattress. Once the patient is on the mattress, the system will automatically go into “AUTO-SETTING” to calculate the patient load. Once the “AUTO-SETTING” is completed, the system will automatically adjust and customize the pressure setting that is most suitable for the individual patient load.

(3) Ensure to select the appropriate therapy mode and cycle time, according to the physician’s decision.

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

(5) 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.

(6) 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.

(7) 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.

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

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6 System Installation, Operation, Transfer and Transport of Patient

6.3 Transfer and Transport of Patient

Transfer

We recommend carrying out the transfer of the patient by using Max. Inflation to inflate the mattress to maximum pressure and ensure that the bed is well-positioned and steady.

Transport

There are two ways to transport patient with the system. One is using Max. Inflation setting to inflate the entire mattress to maximum pressure. After the mattress inflates to maximum pressure, power off the control unit and detach the quick coupling of the mattress from the air outlets of the control unit. Then connect the two quick couplings together to retain air in the mattress and the mattress will stay inflated over 15 hours.

Another way is using transport mode to keep the entire mattress pressure and the mattress will stay inflated over 12 hours. For longer transport time, press Max. Inflation before activate transport.

Once the transportation phase is complete, reconnect the mattress to the control unit and switch the control unit back on. If transport mode is in operation, simply reconnect the power cord set and the control unit will back to previous setting automatically. It is not necessary to move the patient from mattress during the reinflating maneuver.

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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 AVA Envelop System.
Do not operate the AVA 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. The head cells should be fully inflated before patient placement to ensure that the head position is stable.

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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 AVA 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.

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 AVA 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

Check electrical components

Electric shock!

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.
- 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 AVA 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 AVA 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.

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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 AVA Envelop System and the actual hygiene directives for disinfection. The disinfection of the AVA Envelop System or parts of it can be performed only by trained personnel, who are familiar with the hygiene requirements of the institution.

Disinfection procedures

Disinfection procedure

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 AVA 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) Power 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 AVA 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.

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⚠ 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 the comfort setting on the control unit.	2.1) Increase the patient's comfort setting until the correct support pressure is achieved.
	2.2) Check for any abnormal air loss from the mattress.	2.2) Replace the components that are abnormally losing air with an authentic replacement part.
	2.3) Check the air filter.	2.3) Clean or replace the air filter.
	2.4) Verify that the CPR valve is closed correctly.	2.4) 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) Verify that the fuses are not burned out.	3.4) Contact the authorized distributor for technical service.
	3.5) The control unit is not responding to the control procedures listed above.	3.5) Contact the authorized distributor for technical service.
4.) Require service indicator.	4.1) The alternating valve is not working correctly.	4.1) 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.

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11 Technical Data

The AVA Envelop System is suitable for continuous operation.

Control unit

Model SR394
Dimensions(W x H x D).....339 x 266 x 130mm
Weight.....3.4Kg
Electrical Rating.....100-240Vac 50/60Hz 0.5-0.3A
Power Consumption.....25W max. (normal operation)
Electrical Class.....Class II
Applied Part.....Type BF mattress
IP Code.....IP21
Rechargeable Coin Cell.....Li-Ion Type LIR2477 or LIR2450
rated 3.7Vdc 200mAh or 3.7Vdc 120mAh
This system is not AP / APG protected.

NRTL_Safety Certified: SGS Q Mark in accordance with ANSI/AAMI ES60601-1:2005+A1+A2 and CAN/CSA C22.2 No.60601-1:14
EMC & Safety Certified Standard
Safety: IEC/EN 60601-1_v3.1
HomeCare: IEC/EN 60601-1-11_v2.0
EMC: IEC/EN 60601-1-2_v4.0

Mattress

Min. Patient Weight 30Kg
Max. Patient Weight for Envelop Lux.....200Kg
for FIT.....250Kg
Material of Air Cells.....Nylon with TPU lamination material

The AVA 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	S2101 FIT
Article number	S2101-2290 S2101-2320 S2101-2340 S2101-2410
Mattress size& Coverlet size	S2101-2290/90x200cm S2101-2320/120x200cm S2101-2340/82x200cm S2101-2410/107x200cm
Coverlet material	VTX: 100% Polyester Jersey
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” / 20 cell
Protection unit	N/A
CPR Time	≤ 15 seconds
Max Weight Capacity	250 kg
Weight of Mattress Set	S2101-2290-10kg±2 S2101-2320-12kg±2 S2101-2340-9kg±2 S2101-2410-11kg±2

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11 Technical Data

Mattress	
Device Item	S2101 FIT
Article number	S2101-2300 S2101-2310 S2101-2330
Mattress size& Coverlet size	S2101-2300/90x200cm S2101-2310/107x200cm S2101-2330/120x200cm
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” / 20 cell
Protection unit	N/A
CPR Time	≤ 15 seconds
Max Weight Capacity	250 kg
Weight of Mattress Set	S2101-2300-10kg±2 S2101-2310-11kg±2 S2101-2330-12kg±2

11 Technical Data

Mattress	
Device Item	S2202 Envelop Lux
Article number	S2202-2420
Mattress size&Coverlet size	90x200cm
Coverlet material	VTX: 100% Polyester Jersey
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	6.5” / 20 cell
Protection unit	N/A
CPR Time	≤ 15 seconds
Max Weight Capacity	200 kg
Weight of Mattress Set	7kg±2

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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:	**Carilex**
Model No.:	**SR392, SR394, SR391, SR393**
Report Number:	**ETC 19-05-RBO-031-A**
Power Supply:	**100-240Vac, 50/60Hz, 0.5-0.3A**

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

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

The Therapeutic Air Pump system is intended for use in the electromagnetic environment specified below.
The customer or the user of the Therapeutic 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%		10 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 Therapeutic Air Pump system is intended for use in the electromagnetic environment specified below.
The customer or the user of the Therapeutic 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 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.

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