carilex®

AVA Cure

Anti-Decubitus Air Alternating Pressure Mattress System
Instructions for Use

About This Document

Congratulations and thank you for purchasing this high quality antidecubitus system.
Please read this Instructions for Use carefully before use and observe the safety instructions and requirements for the proper operation and maintenance of the device.

Device identification

This Instructions for Use are intended exclusively for devices with the following specification:
Device name: AVA Cure System
The serial number is shown on the label on the rear of the power unit and on the tag sewn on the mattress.

Validity of the documentation

This manual describes the AVA Cure System. It is part of the device documentation. Do not pass this device to a third party without this Instructions for Use.
The end page of this Instructions for Use shows the current document edition.

Subject to change

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

Translations

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

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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

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

1.1.1 Operators

An operator (surgical supplier, health insurance, clinic, etc.) is any legal person that owns and uses the AVA Cure 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.

1.1.2 Users

Users are caregivers or guardians who have undergone user education and operation training, have read the Instruction for Use , and are able to:

- Operate the AVA Cure System
- Supervise patients using the device for therapy or care purposes.

Users are fully responsible for the safe and correct use of the device.

1.1.3 Professionals

These authorized persons are skilled personnel who may be employees of the operator and who:

- Have obtained knowledge through medical-technical training.
- Carry out their duties based on professional experience and in accordance with safety regulations.
- Are able to detect possible hazards during work.

In countries where activities in the medical-technical field require certification, classification of qualified personnel is subject to appropriate approvals.

1.1.4 Patients

Patients are persons in need of care and who use the AVA Cure System for therapy or care purposes.

1 Important Notes for Safe Use

1.2 User Notes & Accident Prevention

1.2.1 Operation and Training

- The device must only be operated by qualified personnel.
- Users must follow the Instructions for Use.
- Initial start-up and handover must be performed by authorized personnel, with documentation confirming the user understands operation and therapeutic/care use.

1.2.2 User Responsibility and Handover

- After handover, the user is fully responsible for safe and dedicated use.
- Do not pass the device to third parties without the Instructions for Use.

1.2.3 Maintenance and Cleaning

- To ensure safety and that EMC performance is not affected, all maintenance, servicing, and replacement of detachable or interchangeable parts must be performed only by qualified service personnel or an authorized service agent.
- The battery is built-in and not user-removable or replaceable. For battery service or replacement, please contact an authorized service center.
- In clinical areas (hospitals, clinics, nursing/elderly homes), cleaning and disinfection must be carried out by qualified personnel familiar with hygiene regulations.
- In non-clinical areas, users or trained cleaning personnel may clean the device.

1.2.4 Device Check and Instructions Availability

- Before each use or transfer to a patient, the user must perform the checks in accordance with Section 4.1.
- The Instructions for Use is an integral part of the device and must be readily accessible at all times.
- If the Instructions for Use do not cover a specific issue, contact the distributor or operator for guidance.

1.2.5 Accident Prevention Accident Prevention Reminders

- Hazards may arise if the device is operated by untrained personnel or not according to the Instructions for Use.
- Proper handover, operation, maintenance, and cleaning reduce the risk of injury or device damage.
- To protect the Patient safely during operating the device, please make sure to turn off the power unit before servicing or maintaining.

⚠ WARNING

Do not short-circuit, crush, puncture, or dispose of the battery in fire, as this may cause explosion, fire, or personal injury.

1 Important Notes for Safe Use

1.3 Purpose of the Device

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

1.3.1 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.

1.3.2 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: 65 lbs
- Patient maximum weight:400lbs.

1.3.3 Use environment

The support system can be used in Professional Healthcare facilities.

1.3.3 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.

1.3.4 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

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.

1 Important Notes for Safe Use

1.3.5 Limitations

Patients with unstable fractures, burns, intolerance to motion, or other conditions that may be complicated by a soft or moving surface must be assessed by a treating physician before device placement and use.

1.3.6 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.

⚠ WARNING

- Always consult a physician or health professional before using the AVA Cure 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.

1.4 Safety Statement

To ensure continued compliance with specifications, maintain safety, and ensure proper device operation, please follow these guidelines:

- Operate the device in accordance with this Instruction for Use to avoid electromagnetic interference or abnormal performance.
- Use only genuine accessories, parts, and materials as described in this manual. In particular, use the specified power cord.
- Avoid placing the device adjacent to or closer than 30 cm to RF communications equipment (including antennas and manufacturer-specified cables).
- If abnormal display or interruptions occur in a strong electromagnetic field, move the device away from the interference source and restart it.
- Do not operate the device under the following conditions, as they may compromise EMC performance:
  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.

⚠ CAUTION

- The system is not AP/APG protected.
- AVOID ELECTRIC SHOCK, DO NOT OPEN AIR PUMP!

1 Important Notes for Safe Use

1.5 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.

1.5.1 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.

1.5.2 Identification of Material Damage

ATTENTION!

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

1.5.3 Identification of Additional Information

NOTE!

Means application tips and useful information.

1 Important Notes for Safe Use

1.5.4 Additional Symbols to the Safety Information

Additional symbols to the safety information are those listed below

	Manufacturer		Country and date of manufacture
	Catalogue Number		Unique Device Identifier
	Serial Number		Model Number
	Follow Instructions for Use		Medical Device
	Consult Instructions for Use		Caution (ISO 7000-0434A)
	Waste Electrical and Electronic Equipment (WEEE Logo)		Type BF Applied Part
IP22	Protected against ingress of solid foreign objects ≥12.5mm diameter. Protected against vertically falling water drops when enclosure titled up to 15°		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		Fragile, Handle with Care
	This Way Up		Keep Away from Rain
	Use No Hooks		Alarm indicator

2 Delivery and Environment

2.1 Delivery Inspection

Upon delivery of the device, please check the following immediately

- Completeness of the delivery
- Condition of the device and packaging
- Use caution when opening the box to avoid damaging the contents

AVA Cure System is delivered with the following components

- Power unit
  Including: Power 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.

2.2 Environmental Conditions

2.2.1 Operating Conditions

- Temperature: 5°C to 40°C
- Humidity: 15% to 90%
- Atmospheric pressure: 700 hPa to 1060 hPa

2.2.2 Storage and Transport

- Ambient temperature: -25°C to 70°C
- Relative humidity: 0% to 90%
- After storage or transport, allow the device to sit at room temperature for at least 3 hours before powering on.

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.
- Place in plastic bag of storage.
- DO NOT expose the AVA Cure System to the sunlight or the dusty environment. For long-term storage the control unit should be covered with a dust protector.

3 Device Overview, Inspection, and Warranty

3.1 Device Description

3.1.1 Principle of operation

The power unit generates air by blower then the alternating control valve set delivers the air into the mattress through air tube inside the power unit.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 then distribute the air to air cell by manifold.

Power unit

The power unit controls components such as the compressor, turntable, and pressure sensor through the control panel, allowing for precise regulation of the air system.

Mattress

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

3.2 Inspection

Prior to each use or at the initial start-up of the power unit, the operator must verify the following to ensure the safe use of the AVA Cure System.

- Verify that there are no obvious cracks or signs of damage on the power unit exterior.
- Verify that there is no moisture or water stains on the power unit surface.
- Slightly shake the equipment to determine if there are any abnormal sounds coming from power unit inside.
- Verify that there are no obstructions in the power unit air vent.

NOTE

If any component of the device or the bed is damaged, please contact the distributor.

3.3 Warranty

The supplier can ensure the safety and proper functioning of the AVA Cure System only under the following conditions:

- The device is used as intended and maintained in accordance with the Instructions for Use.
- Only original spare parts or accessories approved by the manufacturer are used.
- No structural modifications are made to the device.
- Inspections and maintenance work are carried out by certified personnel according to specified time intervals.
- The expected service life of the equipment is 10 years under normal use and maintenance conditions.

4 Features

4.1 Control Panel

Stand-by Mode
After powering up, the system will remain in standby mode until further operation.

ON/OFF
At stand-by mode, press the ON/OFF button to activate the system. The backlight of the ON/OFF key will flash green, indicating that the system is initializing. After a moment, the backlight will remain steady green, indicating that the system is ready.

Power Off
Press the power key once, and the backlight of the power key will turn off, indicating that the system is powered off.

Comfort Level
Press to adjust the comfort level: -2, -1, 0, 1, 2. Set the comfort level based on the patient's weight (see the table below).A higher comfort level setting results in lower mattress envelopment, and vice versa. Adjust the comfort level according to the patient's body weight and clinical status to ensure adequate clearance between the patient's buttocks and the mattress surface.This ensures optimal support and prevents bottoming out.

	Patient weight				
	65-130lbs	130-200lbs	200-260lbs	260-330lbs	330-400lbs
Comfort level	-2	-1	0	1	2

Preparing
The system will initiate mattress inflation and continue until the optimal pressure level is achieved. During this time, the Preparing indicator will flash continuously.

While in Preparing mode, you may set the therapy mode cycle time and comfort level in advance. However, ***the patient must not be placed on the mattress*** until the Preparing indicator turns off, indicating that the system is ready for use.

4 Features

Max. Inflation

Pressing the Max Inflate button sets the mattress maximum pressure to assist caregivers during nursing procedures.

The system will revert to the previous settings either upon manual deactivation by pressing the Max Inflate button again or automatically after the 20 minute countdown expires.

Static Mode

Static Mode is a therapy mode in which all air cells maintain constant low pressure support and maximize patient's contact area to redistribute pressure.

Dynamic Mode

Dynamic mode is a treatment function that alternately inflates and deflates air cells in odd- and even-numbered rows to reduce pressure and enhance the patient's blood circulation.

Cycle Time

Press to select the cycle time in dynamic mode. The cycle time can be set to 5, 10, or 15 minutes by repeatedly pressing the Dynamic button.

Upright Mode

When the bed frame is set to the upright position, pressing the Upright button will automatically increase internal pressure to help prevent the patient bottoming out. Pressing the button again will deactivate the function and restore the system to its previous configuration.

Panel Unlock

When there is no operation after 2 minutes, system will automatically lock the control panel. Press the Panel Unlock key for 3 seconds to unlock the panel.

Audio Off

In section 5.2 Alarm Indicators, four situations that can trigger an alarm are listed. At this point, the Audio Off key can be used to silence the auditory alarm to avoid acoustic pollution.

NOTE: The Max. Inflation & Upright functions are available only after the system has finished preparing. It cannot be activated while the Preparing indicator is flashing.

4 Features

4.2 Alarm Indicators

The AVA Cure System is equipped with an alarm system that helps users distinguish between four different alarm conditions: Call for Service, Low Pressure, High Pressure and Power Failure.

If the system detects any of these issues, the alarm indicator will flash a yellow light, and an alarm will sound. The seven-segment display will also show the corresponding message. Users can identify the current alarm status by referring to the seven-segment display. They can press the Audio Off key to silence the alarm; however, the alarm indicator will continue flashing until the issue is resolved. (For related troubleshooting methodsa and alarm scenarios, please refer to Section 8 on page 22-23.)

Call For Services

Indicates that the rotor valve is malfunctioning.

Power Failure

When the system experiences an unexpected power outage, an alarm will activate, and the power key will flash with a yellow backlight.

Low Pressure

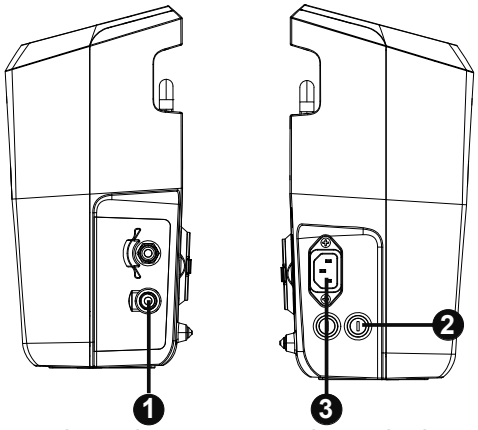
Indicates that the internal pressure of mattress is too low.

High Pressure

Indicates that the internal pressure of mattress is too high

4 Features

4.3 Side Panel

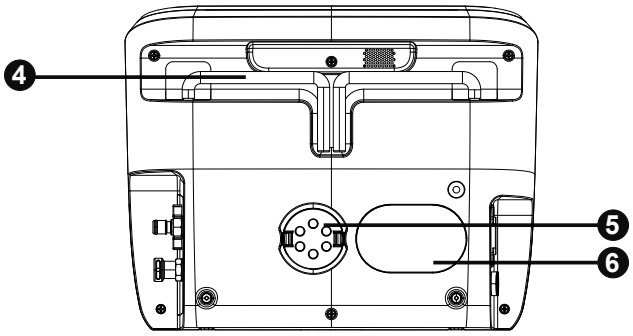


Air Outlet(1)
Air is delivered from the power unit to the mattress through the air outlet.Press the quick coupling to release the connection between the mattress and the device.

Fuse Holder (2)
Fuses should only be inspected or replaced by authorized service personnel. The fuse rating is indicated next to the fuse holder.

Power Receptacle (3)
Three pin IEC 60320 C14 AC inlet to accept power cord set with C13 connector (non-shielded, maximum length 4.5 m).

4.4 Rear Panel



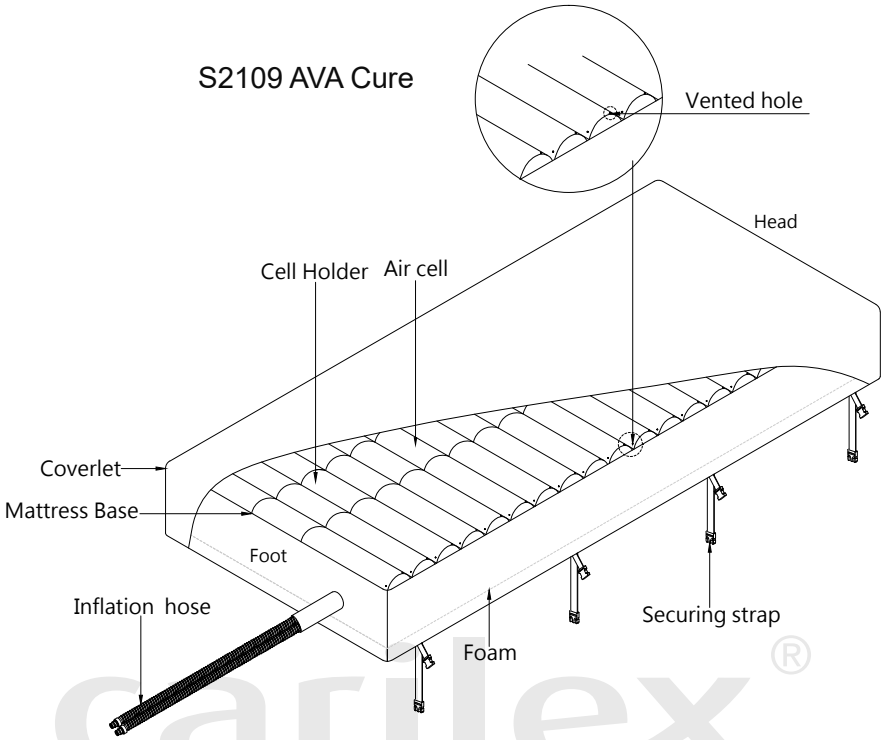
Hanger Hooks (4)
The hooks are designed to fit footboards of different widths. When not in use, they can be folded into the rear cover for storage.

Air Filter (5)
Monthly inspection and cleaning of this filter are recommended. Inadequate maintenance may lead to equipment failure or reduced service life.
Always use the standard filter supplied by Carilex when replacing the filter.
It is recommended to inspect and clean the air filter regularly. For cleaning instructions, refer to Section 8.4.

Label (6)
This label includes all the information for medical device and safety requirements.

4 Features

4.5 Mattress Diagram



5 System Installation, Operation

5.1 System installation

(1) Select the proper bedframe size:
- Ensure that the mattress size matches the bedframe to avoid improper fitting.

(2) Prepare the bedframe:
- Remove the existing mattress.
- Place the bedframe in the supine (flat) position.

(3) Install the mattress:
- Place the mattress on the bedframe with the logo at the foot of the mattress.
- Fasten the mattress using the straps, ensuring:
  - The mattress is securely attached to prevent sliding or shifting.
  - The bedframe's functions and movements are not impeded.
- Check that the mattress does not interfere with the adjustment mechanism of the bedframe.
- Lay an additional bed sheet between the coverlet and the patient to avoid the patient indirectly contacting the coverlet.
- Ensure that the straps between the coverlet and the mattress base are properly fixed to minimize wrinkles that could increase friction and shear forces during patient movement.
- Ensure no points, springs protruding from mattress which may pierce the air cells.

(4) Connect the power unit:
- Confirm that the power cable, control unit plug, and power supply housing are undamaged, then insert the power cord into a wall outlet.
- Hang the power unit at the foot of the bedframe using the hanger hooks, ensuring it is securely fixed.
- Secure the power cord inside the cable holders to prevent it from obstructing operators, hindering the movement of the bedframe, or getting caught between the side rails.

(5) Connect the mattress to the power unit:
- Connect the quick coupling of the mattress to the air outlet of the power unit.
- Ensure the air hoses are routed without bends, kinks, or pressure points.

(6) Final check:
- Follow the user manual to ensure all installation steps are correctly completed.
- Perform all checks to guarantee the safety and functionality of the system.

⚠ CAUTION

- During the use of the AVA Cure System, medical and nursing staff, as well as caregivers, must regularly check the patient's skin to prevent irritation from prolonged contact with the mattress or other accessories, and the system does not replace the need for patient repositioning and changes of posture whenever possible.
- Installation mistake with mattress that will lead loss of functionality, to increase the risk associated with pressure ulcers. Please install the system properly.

5 System Installation, Operation

5.2 Operation

(1) Start the system to begin Inflating the Mattress. Refer to Section 5.1 for details.
(2) Once the ***Preparing indicator stops flashing*** and the system has completed initial inflation, position the patient on the mattress according to local patient care guidelines. Ascertain that the patient's weight does not exceed the weight allowed on the bedframe. Ensure the patient is centered on the mattress, with equal distance from both the left and right edges. The patient's head should be properly positioned so that it rests fully on the head air cells.
(3) Select the appropriate comfort level on the control panel. If the mattress seems too soft or too rigid, please adjust the comfort level again to conform to each patient's requirements. Please adjust the setting one click at a time, and allow time for the mattress to stabilize at each setting before adjusting again.
(4) Ensure to select the appropriate therapy mode and cycle time, according to the physician's decision.
(5) IMPORTANT:
Ensure that the zipper on the coverlet is completely closed.

5.3 CPR

In the case of emergency, pull hard to remove the mattress' CPR latch and detach the quick release coupling from the control unit for emergency deflation and turn off the power unit by pressing the On/OFF button on the control panel at the same time. The air will discharge from the mattress with patient's own weight. To resume normal operation, simply reinsert CPR latch securely, press the On/OFF button again and reset the patient comfort.

CAUTION

- Improperly routed power cords, wires, or tubing may cause tripping, strangulation, or asphyxiation, leading to serious injury. Always use proper cable management and keep children away from extra-long cords or tubing.
- Do not use the system near open flames or heat sources, as smoke may damage internal components, and keep the AVA Cure System out of reach of children.

WARNING!

- Always raise and secure the safety side rails when leaving a patient. Ensure no gaps exist between the bed frame, side rails, and mattress that could trap the patient or cause injury.

6 Transfer and Transport of Patient

6.1 Transfer

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

6.2 Transport

Use Max. Inflate mode to inflate the entire mattress to maximum pressure. After the mattress inflates to maximum pressure, power off the power unit and detach the quick coupling of the mattress from the air outlets of the power unit. Then connect the two quick couplings together to retain air in the mattress and the mattress will stay inflated over 15 hours.

Once the transportation phase is complete, reconnect the mattress to the power unit and follow Section 6 to resume normal operation. It is not necessary to move the patient from mattress during the reinflating maneuver.

7 Cleaning and Disinfection

7.1 General Guidelines

- Always unplug the power cord before cleaning or disinfecting to avoid electric shock.
- Do not immerse the control unit in water or any liquid.
- Use a soft cloth dampened with mild detergent or approved disinfectant.
- Avoid strong solvents, abrasive cleaners, or high-pressure water sprays.
- Always wear gloves and protective equipment during cleaning.

7.2 Control Unit

7.2.1 Cleaning

(1) Wipe the exterior with a soft cloth dampened with a mild, neutral detergent and water.
(2) Remove any dust or dirt around air filters and vents.
(3) Dry all surfaces completely with a clean soft cloth.

7.2.2 Disinfection

(1) Wipe with 75% alcohol or 1000 ppm sodium hypochlorite using a clean cloth.
(2) Allow the surface to air dry completely before reuse.

7.3 Mattress

7.3.1 Cleaning

(1) Wipe off dirt with a soft cloth dampened with a mild, neutral detergent and water.
(2) Wipe cleaned areas with soft dry cloth.
(3) If heavily soiled, the coverlet may be machine-washed using a commercially available detergent.
(4) Always follow the treatment on the washing instruction label.
(5) Thoroughly dry the coverlet after washing, ensuring that no moisture remains in folds or creases.

7.3.2 Disinfection

(1) Wipe with 75% alcohol or 1000 ppm sodium hypochlorite using a clean cloth. (This method is not applicable to Aeotex coverlet.)
(2) Ensure full coverage, especially at seams and high-contact areas.
(3) Allow to air dry fully before reuse.

7.4 Air Filter – Cleaning

To maintain peak performance, clean the air filter regularly or replace it when dirty.

(1) Wipe cleaned areas with soft dry cloth.
(2) Remove air filter from the rear panel by opening the air filter cap.
(3) Clean the dust off with an air duster (or a soft brush) or install a new filter.
(4) Ensure the filter is completely dry and clear before reinserting.

CAUTION!

- To prevent cross-contamination, the System must be cleaned and disinfected between patients. Any contaminants should be disposed of according to local or facility biohazard waste guidelines.
- Do not mix disinfectant (e.g., alcohol and chlorine).
- The coverlet must be replaced if its water-resistant properties are lost.

8 Troubleshooting

Problem	Control Procedure	Possible Solution
1.) Low pressure alarm	1.1) Verify that the quick coupling is correctly connected to the air outlets of power unit.	1.1) Firmly connect the quick coupling.
	1.2)Verify that the CPR latch/valve is correctly closed.	1.2) Firmly close the CPR latch/ valve.
	1.3)Verify that air flows freely through the tubes and the mattress manifold. Check for any cuts, blockages, breakages, or abnormal air loss from the mattress.	1.3) If the tubes or the manifold are kinked or twisted, reposition them. In case of cuts or rips, replace the air cells or hoses. Replace any components with abnormal air loss using authentic replacement parts.
2.) The patient sinks into the mattress.	2.1) Check the comfort level setting on the power unit.	2.1) Increase the patient's comfort level level until the correct support pressure is achieved.
	2.2) Check the air filter.	2.2) Clean or replace the air filter.
3.) High pressure alarm	3.1)The internal components may be malfunctioning.	3.1) Turn off the system and unplug the power cord. 3.2) Contact the authorized distributor for technical service.
4.) Power failure alarm	4.1) Verify that the power cord set is plug into the proper socket.	4.1) Insert the power cord set of power unit into an appropriate socket and turn the power on.
	4.2) Verify that the power cord set is properly connected to the power unit.	4.2) Insert the power cord set into the power unit and turn the power on.
	4.3) Verify that the power cord set is not damaged.	4.3) Replace with a functioning power cord set.
	4.4) The power unit is not responding to the control procedures listed above.	4.4) Contact the authorized distributor for technical service.
5.) The power unit cannot power on.	5.1) Verify 3.1~3.4 5.2) Verify that the fuses are not burned out.	5.2) Contact the authorized distributor for technical service.
6.) Call for service alarm	6.1) The alternating valve is not working correctly.	6.1) 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.

8 Troubleshooting

NOTE

- The above alarm scenarios are categorized as medium priority according to IEC 60601-1-8.
- Low pressure and call for servise alarm will be triggered 1 minutes after the alarm condition occurs, and power failure alarm will be triggered without delay.
- The Sound Pressure Level ranges from 60 – 69 dBA, measured at a distance of 1 meter from the alarm speaker.

CAUTION

- Using different alarm presets for the same or similar equipment in any independent area poses potential hazards.
  If the power supply fails unexpectedly while an alarm is active, the alarm state will be reset upon power restoration.

9 Technical Data

The AVA Cure System is suitable for continuous operation.

Power unit

Model.....SR397
Dimensions(W x H x D).....13.35″ × 10.47″ × 5.12″ (±0.2″)
Weight.....5.5Kg
Electrical Rating.....100-120Vac, 60Hz, 0.2A
Power Consumption.....15W max. (normal operation)
Fuse Rating.....T1AL 250V
Electrical Class.....Class I
EMI Class by CISPR 11.....Class B
Applied Part.....Type BF mattress
IP Code.....IP22
Battery Type.....NiMH Battery Type AAA600, rated 3.6Vdc, 600mAh
Compliant with Regulation (EU) 2023/1542 — Portable Batteries

This system is not AP / APG protected.

EMC & Safety Certified Standard
Safety: ANSI/AAMI ES60601-1:2005 + A1:2012 + A2:2021
IEC/EN 60601-1_v3.2
EMC: IEC/EN 60601-1-2_v4.1
Alarm: IEC/EN 60601-1-8_v2.2

Mattress

Min. Patient Weight.....65lbs
Max. Patient Weight.....400lbs
Material of Air Cells.....Nylon with TPU lamination material

The AVA Cure 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 indicates that the product and its battery must not be disposed of with household waste. Please take them to appropriate collection points for recycling in accordance with local regulations.

9 Technical Data

Mattress	
Device Item	S2109 AVA Cure
Article number	S2109-2010 S2109-2020 S2109-2030 S2109-2040
Mattress size& Coverlet size	S2109-2010/36" x 80" S2109-2020/42" x 80" S2109-2030/36" x 84" S2109-2040/42" x 84"
Coverlet material	TDX
Coverlet MVTR	500g/24H/M^2
Coverlet Wash Condition	Coverlet need to be water repellent- 3000mm/H2O after 40 time wash
Base material	100%Polyester with PVC
Air cell material	Nylon + PU
Air cell height/ number	6"/20 CELLS
Protection unit	2” foam
CPR Time	≤ 30sec
Max Weight Capacity	400lbs
Weight of Mattress Set	S2109-2010/10lbs S2109-2020/11lbs S2109-2030/10lbs S2109-2040/11lbs

10 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:	**Air Pump**
Model No.:	**SR397**
Series Model:	**SR361, SR362, SR363, SR366, SR3B1, SR310, SR311, SR338, SR353**
Report Number:	**ETC 25-10-RBO-038**
Power Supply:	**100-120Vac 60Hz 0.2A**

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

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Air Supply 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 Air Supply 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	

10 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 Air Supply declaration – electromagnetic immunity

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

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

Declaration – electromagnetic immunity

The Air Supply system is intended for use in the electromagnetic environment specified below.
The customer or the user of the Air Supply 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 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 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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