Anti-Decubitus
Air Alternating Pressure Cushion
Replacement System

Cari Chair

Operation Manual

carilex®

Carilex Medical GmbH
www.Carilex.de

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Thank you for purchasing Carilex anti-decubitus air alternating pressure cushion replacement system. PLEASE READ THESE INSTRUCTIONS CAREFULLY BEFORE USE AND OBSERVE THE SAFETY INSTRUCTIONS AND THE REQUIREMENTS FOR THE OPERATION AND MAINTENANCE OF THE DEVICE.

Use genuine Carilex components are essential for optimal performance. If you do not fully understand all the instructions, safety precautions, and warnings, do not use this device. In case you have questions, please contact your local Carilex distributor.

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1.0 Indications


Attention! Please read enclosed document thoroughly


Authorized Representative


Declaration of Conformity to Medical Device Directive


Type BF Equipment


Double insulated (Class II)


Dissposal of Electrical & Electrical Equipment (WEEE)


Manufacturer


Date of manufacture


Catalog number

IP22
Protected against solid foreign objects up to 12.5mm diameter (finger) and protected against vertically dripping water.


Machine Wash Warm (Max. 71°C)


Tumble Dry Medium-Gentle Cycle


DO NOT Iron


DO NOT Dry Clean


DO NOT Bleach

SGS Q certification mark

Indications

This anti-decubitus air alternating pressure cushion replacement system is designed for patients who are at high risk for pressure ulcer to be placed in a variety of mobile devices and potential patients who wish to reduce the likelihood of pressure ulcer. This device is intended to prevent pressure ulcers by facilitating blood circulation and decreasing pressure of each tissue's contact area. If there's any question, please always consult a physician or health professional before using this device.

Contraindications

Certain patient conditions (e.g. unstable cervical fracture, fracture of unstable vertebrae and illness of unstable vertebrae) are contraindicated for use with this device. If there's any question, please always consult a physician or health professional before using this device.

Users

The device should only be used by people who have been trained in operation and intended use of the device.

The trained users on the operation and the dedicated use of the device must be carried out by the qualified operator before using the device.

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

2.0 Safety Precautions

[1] To ensure the safety operation of the device, please inspect and verify all parts are installed and secured properly. DO NOT place anything on top of the power unit. Make sure the power cord and power adapter are underneath chair frame to prevent possible hazards.

[2] DO NOT use this device near the open flames, lighters, or cigarettes due to the possible flammability hazard. Fail to do so could results in serious patient injury or device damage.

[3] DO NOT use this device in damp rooms to avoid of moisture on plug and switch. Never plunge the power unit into water or liquids, not even when it is switch off.

[4] The degraded or loosen components may affect the performance of device. If the device doesn't function well, please contact your authorized local distributor for assistance.

[5] The touching live parts can result in a death or serious injury by electric shock. Check if the plug and the power cord of power unit are damaged before connecting. Do NOT use the damaged components for connection.

[6] If the device operates at ambient temperatures outside the state temperature range (see technical data), the performance may be affected and the device or the electronics and battery may get damaged.

[7] This device should be disinfected thoroughly between patients to avoid of cross contamination.

[8] Be sure to verify the patient weight does not exceed system weight capacity. The maximum weight capacity of this device is 113 kg/ 250 lb.

[9] Charging the power unit at least 8 hours before the first use.

[10] The power unit meets the requirements of IEC 60601-1 / EN 60601-1-2 / EN 60601-1-11 Electromagnetic Compatibility Medical Electrical Devices.

3.0 Warnings

[1] Use this cushion on proper chair frame and ensure to secure the cushion with the straps provided. Assist the patient sitting on the center of cushion. Fail to do so could results in serious patient injury or device damage.

[2] Do NOT disassemble the power unit if you are not a qualified technician. Please contact your authorized local distributor for service.

[3] This device is NOT AP/ APG protected.

[4] Re-position the patient once awhile is still necessary when using this device.

[5] Follow the national requirement to dispose power unit / accessories / waste products / residues etc.

[6] The AC power adapter plug is served to disconnect the device, not to position the equipment to make it difficult to operate the disconnection device.

[7] Any modification of this device is NOT allowed.

[8] The power unit should be turned off when stopping operation is required.

[9] Keep the device away from the children, pet and pests as they can damage the device and impact the performance. Keep the device free from dust and lint.

[10] DO NOT use the device in Hyperbaric Chamber or in the presence of flammable gases.

CAUTION:
ENSURE THAT THERE ARE NO PROTRUDING OBJECTS, SHARP POINTS OR CHAIR SPRINGS UNDER THE CUSHION AS THESE COULD PUNCTURE THE AIR CELLS AND AFFECT THE PERFORMANCE.

4.0 System Package

Power Unit Package

* Power unit x 1
* Power Adapter x 1
* Operation Manual x 1

Geri Chair Cushion Package

* Geri Chair Cushion with Coverlet x 1

MobiCare Cushion Package

* MobiCare Cushion with Coverlet x 1

Wheelchair Cushion Package

* Wheelchair Cushion with Coverlet x 1

Optional Accessory

* Carry Bag
* Bed Hanger
* IV Pole Hanger

5.0 Features

Control Panel Features

Figure 5a on page 6

Power/ Mute/ Unlock Button

[1] Press this button to turn on the power unit and light up the green LED. The screen displays  to indicate the device is in default Geri Chair mode.

[2] When audible indicator is sounding, pressed this button to mute the audible indicator.

Comfort Level Button

Simply press this button to adjust the patient sensation from 1 to 5 according to each individual need. The scale is only an approximation. Please adjust the comfort level when patient feels the cushion is too soft or too firm. Caregivers should always perform a hand check by placing their hands underneath patient's pelvis area to check if there is sufficient air support to ensure the patient is not bottoming out.

Static Mode Button

Press this button then the green LED lights up and the Multi-Cycle Time displays 0 means the device is in Static Mode. The pressure re-distribution function provides optimal internal pressure for each different comfort level. Simply press  to return the device to Alternating Mode.

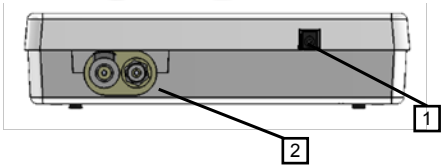
Pressure Monitoring Indicator

Power unit features an integrated pressure sensor which can monitor cushion's internal pressure 24 hours to achieve optimal internal pressure and to ensure maximum pressure relief. The yellow LED indicates the device is monitoring the cushion's internal pressure while the compressor is inflating.

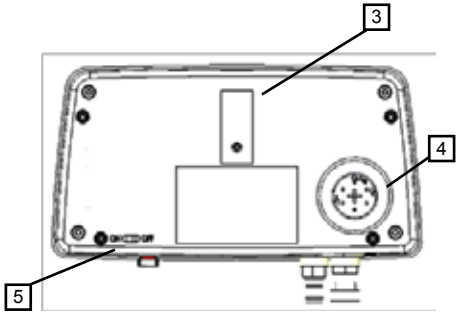
Battery Indicator

The green LED bar indicates the battery level or charging status. If the power unit is low on power, the orange LED will light up to indicate that the power unit needs to charge for 4 hours to battery full.

Control Panel Features (Figure 5a)



Side Panel Features (Figure 5b)



Rear side Panel Features (Figure 5c)

The battery failure will be triggered when orange LED is flashing with audible indicator. The battery is not user replaceable, please contact your authorized local distributor for assistance.

Multi-Cycle Time Button

Press the button to set up the alternating cycle time as 10, or 15, or 20 minutes to meet a variety of patient's requirements.

Low Pressure Indicator

Both continuous flashing of orange LED and audible indicator will be triggered to notify medical staff when the cushion has insufficient internal pressure. The power unit will automatically turn off if the low pressure indicator stays for 15 minutes.

Panel Lock/ Unlock

The power unit locks automatically when the function buttons are not touched for 3 minutes or so. All function buttons are locked out. Simply press for 3 seconds to unlock the power unit and panel.

Seating Cushion Mode

Press and simultaneously for at least 3 seconds, the display will change from to which indicates the device has already switched

from Geri Chair Mode to Seating Cushion Mode.

Side Panel Features (Figure 5b on page 6)

Power Receptacle (1)
Insert power adaptor firmly into receptacle.

Couplers (2)
Quick release couplers are used to secure cushion air hoses to power unit.

Rear Panel Features

Figure 5c on page 6

Hanger Install location (3)
The user can install Carilex optional hangers to hook the power unit on almost any foot board or IV pole.

Air Filter and Filter Cap (4)
Carilex recommends that the filter should be cleaned or replaced once a month to ensure optimal performance of the device.

Rocker Switch (5)
Main power switch of the power unit.

6.0 Cushion and Device Installations

[1] Remove existing article from geriatric chair, recliner, or wheelchair.
[2] Place Carilex cushion on the chair. Secure the cushion at each side by using anchor strap. Please verify all chair functions are working properly without interference before proceeding to the next step.
[3] Secure the power unit to the rear of the chair by using dedicated carry bag.
[4] Firmly connect the air hose couplings to the quick release couplers on the power unit's air outlet.
[5] Push the rocker switch to "on" position at the rear side panel.
[6] Press to turn on the power unit. Please switch to Geri Chair Mode or Seating Cushion Mode for your corresponding cushion.

CAUTION:
Please ensure to charge the power unit at least 8 hours before the first use.

7.0 Program Settings

[1] Assist the patient sitting on the center of cushion. Adjust the cushion's internal pressure according to the patient sensation by Comfort Level Button. If the patient feels the cushion is too soft or firm, increases or decreases the cushion's internal pressure one increment at a time and wait for the device to stabilize the internal pressure before making another change until a comfortable state is achieved.
[2] Caregivers should always perform a hand check by placing their hands underneath patient's pelvis area to check if there is sufficient air support to ensure the patient is not bottoming out.
[3] IMPORTANT: TUCKING THE SHEET IN TIGHTLY REDUCES THE EFFECTIVENESS OF THE DEVICE.

8.0 Cleaning Instruction

Cushion, coverlet and power unit must be cleaned thoroughly between patients to avoid of cross contamination, potential allergy, and virus infection. The following is a suggested guideline, but local infection control policies should be followed as well.

[1] Regular cleaning can be performed at chair side with disinfectant and water followed by drying with a clean dry cloth.

[2] Use only mild detergents and water to clean the coverlet and the cushion. Any appropriate NON-PHENOLIC cleaning agent may be used for heavy soiling with urine, blood or other body fluids. Please ensure cushion and coverlet are completely dry before the patient sitting on the surface again.

[3] The recommended washing temperature is at 71℃. If the washing temperature is at 95℃, the fabric shrinkage rate is 1% higher and the color might run insignificantly.

[4] DO NOT use electric or tumble dryers.

[5] DO NOT iron.

WARNING! Always unplug the power unit before cleaning. Routine cleaning of power unit can be done by wiping down with damp cloth using disinfectant and water or mild neutral detergent. Never spray liquids directly on the power unit itself.

9.0 Routine Maintenance

Open the filter cap from the rear panel of the power unit to clean or replace the air filter. It is recommended to inspect the filter for dirt or dust and clean it with mild soap and water once a month. Re-insert the dried air filter after cleaning and ensure the cap is secured.

Replace with genuine air filter once a year is recommended to prolong device lifetime. Only disinfected and dry devices are to be stored. Be sure to disconnect the air hoses from the power unit.

The repair of the device or parts may only be carried out by Carilex authorized service agent.

In case of specific issues which are not covered enough in details in these instructions for use, please contact Carilex or the authorized distributor for assistance.

10.0 Troubleshooting

Problem	Inspection Procedure	Possible Solutions
1. Power unit does not function.	Check if it is “Low Battery”	Connect the adapter to the power outlet to charge the power unit.
	Check if the rocker switch is in ON position.	Turn rocker switch to ON position.
	Check if both of orange LED is blinking and audible indicator sounds simultaneously.	Please contact your authorized local distributor for assistance.
2. Low pressure LED is flashing during operation.	Check if there is leakage in air tubes or air cells.	Please contact your authorized local distributor for assistance.
3. Power Unit is working, but cushion is not inflating.	Check if cushion’s air hose couplings are properly connected to power unit’s quick release couplers.	Secure air hose couplings firmly into place.
	Verify if patient weight setting is correct.	Increase or decrease weight setting until appropriate pressure is reached.
	Inspect air filter for dust.	Clean or replace air filter.
	Lift cushion coverlet up to check if air cells are connected correctly.	Make sure all air cells are properly linked to air supply
	Lift cushion coverlet up to check if air tubes are kinked or obstructed.	Check and adjust air tubes positions.
	Check if air cells are cut or cracked.	Replace with genuine spare parts or contact your local distributor.
4. Alternating and static setting is not available.	Check if the panel lock	Simply press this Multi-Function Button for 3 seconds to unlock the panel.
	Possible control failure	Please contact your authorized local distributor for assistance.
5. Patient is not getting pressure relief due to system failure (reddening of skin)		Contact your physician and/ or nursing service immediately.
If power unit does not respond to the possible solution, please contact your authorized local distributor for assistance.		

11.0 Returns for Service

This device is not self-serviceable. Service and repair must be performed by an authorized technician or representative. All returned devices must be cleaned and disinfected prior to shipping. Unsanitary or soiled systems will be returned without servicing.

12.0 Warranty

Carilex Medical GmbH warrants the product to be free from defects from the date of purchase. Please inspect all accessories when you purchase our product. If there is any damage or missing accessories when you receive the product, please ask for a replacement from your local distributor within three days of purchase.

The warranty periods for Carilex products are according to the regulations in your country, the minimum period is 1 year from date of purchase for the power unit and 6 months for the cushion which is the expected service life. The warranty coverage of any Carilex product is contingent upon its purchase from an authorized dealer. Warranty for any product in the Carilex product line will be honored by the official distributor in your country.

Warranty coverage will not be extended to any product on which the production lot number has been removed or defaced, on which repair has been attempted by any person or agency not authorized by Carilex or if in the sole opinion of Carilex that the system shows evidence of tampering, abnormal or unreasonable abuse, negligence, accident or operation without regard for the restrictions specified in the instructions which accompany the system.

This warranty does not cover normal maintenance such as cleaning, adjustment or parts. If the damage is result from improper operation, a reasonable service fee and part cost will be charged.

The warranty stated above is the only warranty made and is in lieu of all other warranties whether expressed or implied, including any warranty of merchantability or fitness for a particular reason. Carilex Medical GmbH will not be liable for consequential or incidental damages or any kind.

13.0 Environmental protection

The cushion must be decontaminated before disposal.

Disposal of old electrical and electronic equipment –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.

Manufacture:
Carilex Medical, Inc.
No.77, Keji 1st Rd., Guishan, Taoyuan (33383),Taiwan

14.0 Technical Data

Air flow rate of power unit	Open flow 2.5 liters/min
Power Input:	AC 100-240V - 50/60Hz (for Adapter)
Power Output	DC 9.1V 3.33A or DC 9V 3A (for Adapter)
Power Adaptor	GlobalTek, Inc. GTM91120-3010.5-1.4-FW SINPRO HPU32A-104
Power Consumption	Max: 27W (with charger) Max.9W (without charger)
Operation mode	Geri Chair Mode & Seating Cushion Mode
Rechargeable battery	Lithium-ion Capacity: 4400mAh Charging Time: 4hrs Using Time: approx.12 hours Typical operation time (charge & discharge cycle): 300 times
Dimensions (WxHxD)	9.6 x 6.1 x 2.4 inch / 24.5 x 15.5 x 6.1 cm
Weight (basic unit)	2.03lb / 0.92kg
Geri Chair Cushion Set :	Cushion dimension : 70.9 x 19.7 x 5.5 in / 180 x 50 x 14 cm
	26 air cells, 70D nylon with TPU lamination.
	Coverlet: Two way stretch – 40% polyurethane, 60% polyester.
Wheel Chair Cushion Set :	Cushion dimension :17.7 x 17.7 x 3.5 in / 45 x 45 x 9 cm
	10 air cells, 210D nylon with TPU lamination.
	Coverlet: Two way stretch –40% polyurethane, 60% polyester.
MobiCare Cushion Set :	Cushion dimension :17.7 x 17.7 x 3.5 in / 45 x 45 x 9 cm (with foam base)
	10 air cells, 210D nylon with TPU lamination.
	Coverlet: Two way stretch –40% polyurethane, 60% polyester.
	Cushion foam base: PU foam.
IP22	Against ingress of solid foreign objects 12.5 mm diameter. Against direct sprays of water up to 15˚ from the vertical
Protection class according to IEC60601-1	Class II
Operation Conditions	Temperature range: 5˚C(41˚F) to 40˚C(104˚F) Relative Humidity Range: 15%~60% noncondensing. Atmosphere range: 700hPa-1060hPa
Transport and storage conditions	Temperature Range: -25˚C (-13˚F) to 70˚C(158˚F) Relative Humidity Range: 0%~93% noncondensing

15.0 Manufacturer's Manual and Declaration

Manufacturer's Manual and Declaration - Electromagnetic Radiation

Radiation Test	Conformity	Electromagnetic Environment
RF emissions CISPR 11	Group 1	SR321 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	SR321 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	Compliance	

Manufacturer's Manual and Declaration - Electromagnetic Resistance

Resistance Test	Test Level as per IEC 60601	Level of Compliance	Electromagnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV for contact ± 8 kV for air	± 6 kV for contact ± 8 kV for 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	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV in differential mode Not applicable	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	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of SR321 requires continued operation during power mains interruptions, it is recommended that SR321 should be powered from an uninterruptible power supply or a battery.

Resistance Test	Test Level as per IEC 60601	Level of Compliance	Electromagnetic Environment
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	SR321 power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Resistance Test	Test Level as per IEC 60601	Level of Compliance	Electromagnetic Environment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of SR321 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended distances: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in mattress (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated high-frequency phenomena IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which SR321 is used exceeds the applicable RF compliance level above, SR321 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating SR321

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTE At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.