carilex®

Centrius

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 the requirements for the 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: Centrius System
The serial number is shown on the label on the rear panel of the power unit and on the tag sewn on the mattress.

Validity of the documentation

Details of the Device Documentation
This manual describes the Centrius System. It is part of the device documentation. Do not pass this device to a third party without these Instructions for Use.
For the confirmation of the up-to-date status of the documentation, the end page of the Instructions for Use is marked by edition version and date.

Subject to change

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

Translations

For translations into languages other than English, the English version of these Instructions for Use is authentic. In the event of any clarification, question or dispute as to the contents of these Instructions for Use, the English version shall prevail.

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About This Document

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Sales and service

For Support or Complaints
In the event of a complaint, or if you have any questions about the use of the device or a need for spare parts, please contact the supplier that delivered the device to you or your patients.

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1 Important Notes for Safe Use

Named groups of persons

1.1 Designation of the Groups of Individuals

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

Operators

An operator (surgical supplier, health insurance, clinic, etc.) is any legal person, who owns Centrius System and uses it, or on whose behalf the device is in use. The operator is responsible for providing a safe device and to instruct the user properly on the operation and safe use of the device.

Users

Users are people who are entitled, due to their training or a corresponding instruction to:

- Operate the Centrius System
- Supervised 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 has to be carried out and the proper condition of the device has to be checked and confirmed by the user before each use or transfer for use.

Professionals

The authorized persons are skilled personnel, who are as a rule, the 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 and are able to detect possible hazards during work.

In countries in which the pursuit of an activity in the medical-technical area is certified, the classification as qualified personnel is subject to appropriate approvals.

Patients

Patients in the sense of these instructions are persons in need of care, who use the Centrius System for therapy or care purposes.

Lay Operator

A person without the relevant specialized training, the lay operator should contact with manufacturer or manufacturer's representative under following conditions:

- for assistance, if needed, 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 Centrius System should only be used by persons who have been trained in the operation and the intended use of the device.

1.2.1 Instruction

Training on the device

The training of users on how to use the device must be carried out by the qualified personnel of the operator using the device. If the device is approved for use, then it is obligatory to comply with the instructions of this guidance

1.2.2 Handing Over the Device

Device approval

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

1.2.3 Maintenance and Installation

The maintenance and/or repair of the equipment or parts must only be carried out by an authorized service agent.

1.2.4 Information and Test Obligation of the User

Obligation of the user

Read these Instructions for Use carefully before the first use of the device. This will allow you to experience all the benefits that the device offers and avoid possible personal injury and property damage.
A review of the functions has to be carried out and the proper condition of the device has to be confirmed by the user before each use or transfer for use by patients.
In case of specific issues, which are not covered in enough details in these Instructions for Use please contact the supplier or operator for further guidance.

1.3 Procedures for Accident Prevention

The Centrius System is made according to the current state of the art technology and is reliable. However, hazards may arise during the use of this device 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.

Hygiene measures

1.3.2 Qualification Requirements Hygiene Staff

The nature of hygiene measures is determined by the use environment of the device.

- If the device is used in clinical areas (e.g. in hospitals, clinics, nursing home, elderly homes etc.) the cleaning and disinfection must be carried out on the product or parts only by appropriately qualified personnel, who are familiar with the relevant hygiene regulations.
- When using the device in non-clinical areas the users or trained cleaning personnel can perform cleaning of the device.

Obligation to provide information

1.3.3 Availability of the Instructions for Use

The Instructions for Use are an integral part of the device and must be stored in a place so that the safety instructions and other important information are accessible at any time and can reviewed by the 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 a current and valid Instructions for Use document is supplied with the device.

1 Important Notes for Safe Use

1.4 Purpose of the Device

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

Intended use

1.4.1 Intended Use

The therapeutic air alternating mattress / cushion 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 treat and prevent pressure ulcers by facilitating blood circulation and decreasing pressure of each tissue's contact area.

Contraindications:
Certain patient conditions are not suitable for using this type of device such as fracture of instable vertebrae and illness of instable vertebrae. Always consult a physician or health professional before using this device. The use of this system does not replace the regular repositioning, monitoring, and nursing of the patient.

Attention

1.4.2 Attention

Always consult a physician or health professional before using the Centrius 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.

- Strangulation by extra-long cables and hoses: To avoid entanglement, keep children clear of hoses.
- Choking caused by small parts being inhaled or swallowed: Identify any loose or detached small parts that may be an issue.
- Potential allergic reactions to accessible materials used in the equipment: Identify any rubber or latex that could be an issue.
- Contact Injuries: Check for any skin irritation due to prolonged contact with the equipment.
- Protection against strangulation or asphyxiation: Means shall be provided to control the risk of strangulation and asphyxiation of the patient and other to an acceptable level by routing wires or tubing, and using retention devices.
- To prevent the effects caused by pets, pests or children.
- To avoid the effects of degraded sensors or loosened electrodes, that can degrade performance or cause other problems.

1 Important Notes for Safe Use

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 SR363 may negatively affect EMC performance.

- Power cord set: It is non-shielding, and the typical length of power cord is 4.5m max. molded with IEC 60320 C13 connector.
  - Safety approved AC Plug, Cord Type H05VV-F 3 x Min. 0.75mm²
- Use of the SR363 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 SR363, 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 Electro Magnetic Disturbances for the expected service life

1.4.4 Safety Caution Statement

- A warning indicating that replacement by inadequately trained personnel could result in hazard.
- Skin irritation due to prolonged exposure to mattress or other accessories.
- No modification of this system is allowed.
- For cleaning & disinfection processes of ME equipment being performed by a Lay Operator shall be investigated by the Usability Engineering Process.

1 Important Notes for Safe Use

Warranty terms and conditions

1.5 Warranty

The supplier shall ensure the safety and the correct functioning of the Centrius System only under the following conditions:

- The device is used for the intended use 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 the 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

	Machine Wash Warm : Max. 60°C
	Machine Wash Warm : Max. 71°C
	Hang to Dry
	Tumble Dry Medium - Gentle Cycle
	Do Not Bleach
	Do Not Iron
	Do Not Dry Clean
	Do Not Wash
	Consult Instructions for Use
	Type BF Applied Part
	Earth (ISO 7000-5017)
	NRTL_SGS Q Mark Listing logo
	Waste Electrical and Electronic Equipment (WEEE Logo)
	Manufacturer
	Country and date of manufacture
	Caution (ISO 7000-0434A)
	Catalogue Number
IP21	Protected against ingress of solid foreign objects ≥12.5mm diameter. Protected against vertically falling water drops.

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 power unit to the bed footboard using the specific hanger hooks and do not place any objects onto the power 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) Take care to ensure that the sheets are fitted correctly and not too tight to prevent hammocking. Too many layers of sheets could reduce the effects of the mattress system. Only breathable incontinence sleepers may be used.

(4) Do not use the system in presence of live flame or sources of heat. The power 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) Information for the Lay Operator:
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.

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

2 Security Norms

2.2 Advice

(1) Use the mattress within the bed side rails and assure that the space between the sides of the bedframe and the mattress is not big enough to insert the patient's head and neck. Neglecting this could cause serious injuries to the patient.
(2) DO NOT open or dismantle the power unit if you are not a qualified technician. In case of problems, get in touch with the authorized assistance service.
(3) Safety in the presence of inflammable anesthetic gases: the system is not AP/APG protected.
(4) Use of the present system does not exclude repositioning and changes of posture of the patient wherever possible.
(5) 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
(6) Do not position the power unit in the way which will be difficult to operate.
(7) No modification of this system is allowed.
(8) CAUTION: AVOID ELECTRIC SHOCK, DO NOT OPEN AIR PUMP!
(9) Not using genuine accessories, parts and materials not described in the Operation Manual.

CAUTION

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

3 Delivery and Storage

3.1 Packaging

Centrius 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

Centrius 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
- Optional accessory: Protected foam

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 power unit should be covered with a dust protector.

4 Device and Functional Description

4.1 Device Description

Power unit

The power 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 power 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 CLP or dynamic mode to relief and redistribute pressure.
The Centrius power unit is compatible with following mattress:

- Centrius + Entrix overlay to for medium - high risk patients
- Centrius + Lux to for very high risk patients
- Centrius + FIT to for very high risk patients

CPR of Entrix Mattress

The CPR function is activated by a two-hole CPR set 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 within 15 seconds. The CPR valve, well-marked and built-in the mattress prevents accidental opening, and it can be opened by pulling the latch, with a single movement and with the use of one hand only.

CPR of Lux and FIT Mattress

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 within 15 seconds. The CPR valve, well-marked and built-in the side of the mattress prevents accidental opening, and it can be opened with a short counter clockwise rotation, with a single movement and with the use of one hand only.

4.2 Operation and Functional Test

To perform a functional test and at the initial start-up of the power 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 power unit.
- To disconnect mattress from power unit, simply just press the buttons on the coupling and pull.
- For function test details, please refer to Chapter 5 Features, please make sure all functions work normally before use.

Turning on the power unit

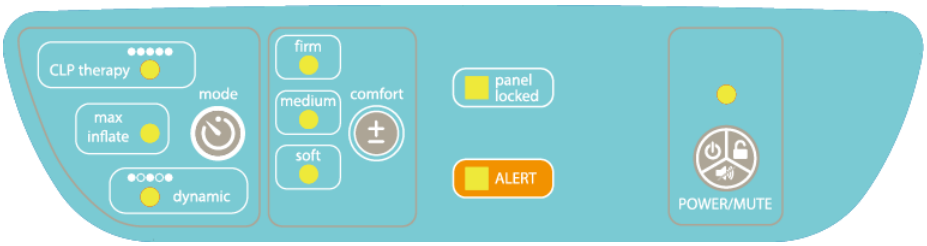
Electric shock!

Touching live parts can result in a death or serious injury by an electric shock. Check for damage of the power cord set of the power unit before connecting.

- Damaged components may not be used for connection!

5 Features

5.1 Control Panel



Power/Mute/Unlock

This button would work for three functions. For Power function, user could use this button to power on or off the power unit when the rocker switch has been switched on. When the power unit power on, the green LED will light. The green LED will change to yellow and there will also have audible beeping to remind users when power cord set is removed without switching the system off by the rocker switch, or when there is an abnormal power outage. After recovering from abnormal power outage, the power unit would restore to the previous setting automatically.

For Mute function, user may press this button to turn off the audible alarm. After mute manually, the audible alarm will re-start again and have visual LED to notify the caregivers until the problem is solved.

When there is no operation after 3 minutes, system will automatically lock the control panel. Simply press and hold this button for 3 seconds to release panel foil from locking. All buttons will be locked except Power/Mute/Unlock button which allows user to mute audible alarm.

Comfort Level Setting

Press button to adjust the comfort setting of patient sensation between soft, medium and firm according to each individual. The comfort setting scale is only indicative. If the mattress seems too soft or too rigid, please adjust the comfort setting to conform to each patient's requirements.

5 Features

Press Mode button to change the therapy between CLP Therapy, Max. Inflate and Dynamic Mode.

CLP Therapy

CLP Therapy is a therapy in which all air cells maintain constant pressure support and maximize patient's contact area to redistribute pressure.

Dynamic Mode

Dynamic Mode is a therapy 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. Alternating mode will take 10 minutes to finish a complete cycle.

Max. Inflate

In Max. Inflate Mode, the system will rapidly bring the mattress to maximum steady pressure, which allows caregiver to perform the daily nursing procedures. Press the mode button to stop this function and change to other mode or the system will automatically change to Dynamic Mode and return the previous comfort setting after 20 minutes.

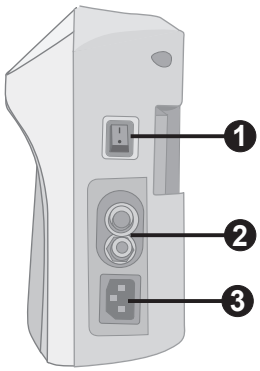
Low Pressure Alert LED

This yellow LED is to indicate that the mattress has insufficient pressure. There will be both audible beeping and visual LED alarms. Audible alarm will turn off after press the Power/Mute/Unlock button and it will not start beeping again, to avoid acoustic pollution, but the LED will stay flashing until the problem has been solved.

Panel Lock LED

The yellow LED will light up to indicate the control panel is locked. Simply press and hold the Power/Mute/Unlock button for 3 seconds to release panel foil from locking.

5 Features



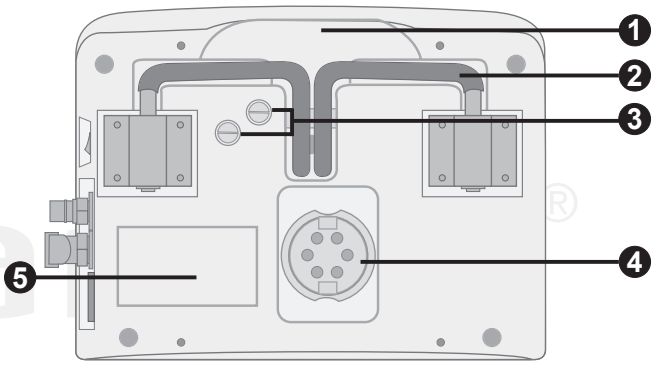
5.2 Side Panel

Rocker Switch (1)
Main power switch of power unit.

Air Outlet (2)
Quick couplings enable a rapid and firm connection between the mattress and the power unit.

Power Receptacle (3)
Three pin IEC 60320 C14 AC inlet to accept power cord set with C13 connector.

5.3 Rear Panel



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

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

Fuse Holder (3)
The fuse holder can be replaced with a flat-head screwdriver for inspection or changing of fuses by authorized service personnel only. The fuse rating is marked adjacent to the fuse holder.

Air Filter and Filter Cap(4)
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 power unit.

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

6 System Installation, Operation, Transfer and Transport of Patient

6.1 System Installation

(1) For Entrix mattress overlay, just place it on the top of original mattress. For Entrix with bottom foam,Lux and FIT mattress replacement, the user should remove the existing mattress.
(2) 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.
(3) Hang the power unit at the foot of the bedframe with aid of the hanger hooks.
(4) Push the quick coupling of the mattress firmly into the air outlet of the power unit.
(5) Insert the power cord set into a wall outlet. Ensure that the cable is not in the way of the operators and the movement of the bedframe.

6.2 Operation

(1) Position the patient on the mattress. Select the appropriate comfort setting on the control panel. If the mattress seems too soft or too rigid, please adjust the comfort setting 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.
(2) Ensure to select the appropriate therapy mode according to the physician’s decision.
(3) IMPORTANT:
Tucking in the coverlet too tensely significantly reduces the mattress's effectiveness.
(4) IMPORTANT:
Regardless of the type of coverlet that has been equipped to the mattress, ensure that the zipper of coverlet is affixed properly to the base of the mattress.

⚠ 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 and/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.

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(5) WARNING!
Use the mattress within the boundaries of the bedframe and assure that the space between the sides of the bedframe and the mattress is not big enough to insert the patient's head and neck. Neglecting this could cause serious lesions to the patient.

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

6.3 Transfer and Transport of Patient

Transfer

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

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 6.2 to resume normal operation. It is not necessary to move the patient from mattress during the re-inflating maneuver.

7 Application

Mandatory bedframe size

It is mandatory to select proper bedframe size for the Centrius System. Do not operate the Centrius 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 power 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 power 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 power unit. The head cells should be fully inflated before patient placement to ensure that the head position is stable.

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 Centrius 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

In order to prevent cross-contamination, the cleaning and disinfection of the entire the Centrius System must be carried out between uses with different patients.

Check electrical components

WARNING

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 power 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 these 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 protective.

ATTENTION

Incompatible cleaning agents!

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

Cleaning the power 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 power 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:

- Do not use disinfectants containing alcohol.

8 Cleaning and Disinfection

8.1 Cleaning

When using the Centrius 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 power unit. Do not spray any cleaning liquid directly onto the power unit.

Cleaning of the power unit

Cleaning of the Surfaces of the Power Unit

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

Cleaning of the coverlet

Cleaning the Coverlet

The coverlet can be easily removed by derailing the zipper between coverlet and the mattress base. 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

Hygiene requirements of the operator

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

Disinfection procedure

Disinfection Procedures

Please follow the procedure required by your local health authority.

CAUTION

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

9 Care and Maintenance

9.1 Inspection

The safe operating condition of the Centrius 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 power 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 power 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 and the Air pump model SR363 and the parts or accessories shipped with the ME equipment model SR363 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

10 Troubleshooting

Problem	Control Procedure	Possible Solution
1.) The power 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 power 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 power 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 power 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 power unit into an appropriate socket and turn the power on.
	3.2) Verify that the power cord set is properly connected to the power unit.	3.2) Insert the power cord set into the power 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 damaged.	3.4) Contact the authorized distributor for technical service.
	3.5) The power unit is not responding to the control procedures listed above.	3.5) Contact the authorized distributor for technical service.

11 Technical Data

The Centrius System is suitable for continuous operation.

Power unit

Model SR363
Dimensions(W x H x D).....29.5 x 22.5 x 12cm
Weight.....2.8Kg
Electrical Rating.....100-120Vac 60Hz 0.2A
.....220-240Vac 50/60Hz 0.2A
actual specification is based on the label on rear panel
Power Consumption.....Max.15W (normal operation)
Fuse Rating.....T1A 250V
Electrical Class .....Class I
EMI Class by CISPR 11.....Class B
Applied Part.....Type BF mattress
IP Code IP21
Replaceable Battery Type..... NiMH Battery Type AAA600, rated 3.6Vdc, 600mAh

This system is not AP / APG protected.

EMC & Safety Certified Standard
Safety: IEC/EN 60601-1_v3.1
AS/NZS IEC 60601.1: 2015
EMC: IEC/EN 60601-1-2_v4.0

Operating Conditions
Temperature Range: 5°C to 40°C
Relative Humidity Range: 15% to 90%
Atmosphere Range: 700hPa to 1060hPa

Mattress

Min. Patient Weight 30Kg
Max. Patient Weight for Entrix 150Kg
for Lux 200Kg
for FIT.....250Kg
Material of Air Cells.....Nylon with TPU lamination material

The Centrius 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.

Declaration of Conformity

For EN 60601-1-2

Company Name:	**CARILEX MEDICAL, INC**
Company Address:	**No. 77, KEJI 1ST RD. GUISHAN DIST., TAOYUAN CITY,333 TAIWAN (R.O.C.)**
Trade Name:	**Carilex**
Report Number:	**ETC 16-08-RBO-002-01 , 16-08-RBO-002-02**
Power Supply:	**1. AC 100 - 120V 60Hz 0.2A 20W max. 2. AC 220 - 240V , 50Hz , 0.2A**

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

The Air Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Air Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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 Air Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the 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 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 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 Air Pump declaration – electromagnetic immunity					
The Air Pump system is intended for use in the electromagnetic environment specified below. The customer or the user of the 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%		3 V/m ; 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 Pump system is intended for use in the electromagnetic environment specified below. The customer or the user of the 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	±0.5 kV ±1 kV differential mode ±2 kV common 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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