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DualFlex

Anti-Decubitus Air Alternating Pressure Mattress System
Instructions for Use

About This Document

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

Device identification

Identification Details of the Device
These Instructions for Use are intended exclusively for devices with the following specification:
Device name: DualFlex 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

Details of the Device Documentation
This manual describes the DualFlex System. It is part of the device documentation. Do not pass this device to a third party without these Instructions for Use.

The end page of these Instructions for Use shows the current document edition.

Subject to change

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

Translations

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

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This provision shall not affect the reproduction for internal use.

About This Document

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EC REP

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If the user or/and patient occur any serious incident in relation to the device should be reported to Carilex and European Authorized Representative immediately.

Sales and service

For Support or Complaints
If you have any questions or concerns about the device or need accessories, please contact the distributor that delivered the device to you or your patients.

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1 Important Notes for Safe Use

1.1 Designation of the Groups of Individuals

Named groups of persons

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

Operators

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

Users

Users are people who have been trained to:

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

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

Professionals

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

- Have acquired their knowledge through professional training in the medical-technical field,
- Carry out their activity on the basis of professional work experience and instructions according to safety-related regulations.
- Are able to detect possible hazards during work.

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

Patients

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

Lay Operator

A lay operator is a person without relevant specialized training. The lay operator should contact the manufacturer or manufacturer's representative under following conditions :

- For assistance in setting up, using or maintaining the ME Equipment System; or
- To report unexpected operation or events.

1 Important Notes for Safe Use

1.2 Notes for the Users

Note that the DualFlex System should only be used by persons who have been trained in the operation and the intended purpose of the device.

1.2.1 Instruction

Training on how to use the device must be carried out by qualified personnel. If the device is approved for use, then users must comply with the Instructions for Use.

1.2.2 Handing Over the Device

Device approval

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

1.2.3 Maintenance and Installation

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

1.2.4 Information and Test Obligation of the User

Obligation of the user

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

1.2.5 Reporting of serious adverse events

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

1.3 Procedures for Accident Prevention

The DualFlex System is made according to current, reliable, state of the art technology. However, hazards may arise if it is operated by untrained personnel or it is not operated as described in these Instructions for Use.

1.3.1 Procedures for Handing Over the Device

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

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

1.3.2 Qualification Requirements Hygiene Staff

Hygiene measures

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

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

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1.3.3 Availability of the Instructions for Use

Obligation to provide information

The Instructions for Use are an integral part of the device and must be stored in a place so that the safety instructions and other important information are accessible at any time and can reviewed by users.
Do not pass the device to a third party without these Instructions for Use. Using the edition version as a guide always ensures that the current and valid Instructions for Use document is supplied with the device.

1.3.4 Home Healthcare Environment

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

1 Important Notes for Safe Use

1.4 Purpose of the Device

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

1.4.1 Intended Purpose

Intended purpose

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

Intended users:

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

Intended patient populations:

- Patients who endure of all categories of pressure ulcer and potential patients who wish to reduce the likelihood of pressure ulcer.
- Patient minimum weight: 30kg.
- Patient maximum weight: 250kg.

Use environment:

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

Indication:

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

Contraindications:

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

WARNING

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

1 Important Notes for Safe Use

WARNING

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

Limitations:

- If patients have other unstable fractures, or conditions which may be complicated by a soft or moving surface, advice should be sought from an appropriate clinician before use.
- While the DualFlex systems have been designed to manage patients up to the weight limits at 250kg, those approaching this upper limit are likely to have additional care and mobility needs and may be better suited to a specialist bariatric system.

Type of Contact and Duration of contact:

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

Clinical benefit:

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

1.4.2 Attention

Attention

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

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

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

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

1.4.3 EMC Compliance Statement

EMC notices

Use of accessories and/or cables other than those specified or provided by the manufacturer of the DualFlex Pump Model SR353 may negatively affect EMC performance.

- Use of the SR353 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 SR353, including cables specified by the manufacturer because it could result in improper operation.
- Medical Equipment Immunity Performance Criteria Unacceptable Operating Conditions:
  a. Component failures or error of display numerical value.
  b. Change or failure in programmable parameters if any.
  c. Initiation of any unintended operation or false audible indicator.
  d. Cessation, change or interruption of any intended operating mode.
- All necessary instructions for maintaining Basic Safety and Essential Performance with regards to ElectroMagnetic Disturbances for the expected service life.

1.4.4 Safety Caution Statement

- A warning indicating that replacement by inadequately trained personnel could result in hazard.
- Do not expose the Home Healthcare System to the sunlight or the dusty environment.
- Keep the Home Healthcare System out of reach of children.
- Skin irritation due to prolonged exposure to mattress or other accessories.
- No modification of this system is allowed.
- For cleaning & disinfection processes of ME equipment being performed by a Lay Operator shall be investigated by the Usability Engineering Process.
- Burn wound with severe exudate with the high risk of infection.

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1 Important Notes for Safe Use

Warranty terms and conditions

1.5 Warranty

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

- The device is used for the intended purpose and maintained only in accordance with the information provided by these Instructions for Use.
- Only original spare parts or accessories approved by the Manufacturer are used.
- No structural changes are made to the device.
- Inspections and maintenance work are carried out by certified personnel according to specified time intervals.

1.6 Safety Information and Symbols of These Instructions for Use

The safety instructions in this Instructions for Use are marked with symbols and key words. Signal words like WARNING, CAUTION or ATTENTION designate the classification of the risk.

1.6.1 Identification of Risks of Injury

WARNING

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

CAUTION

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

1.6.2 Identification of Material Damage

ATTENTION!

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

1.6.3 Identification of Additional Information

NOTE!

Means application tips and useful information.

1 Important Notes for Safe Use

1.6.4 Additional Symbols to the Safety Information

Additional symbols to the safety information are those listed below

	Manufacturer		Country and date of manufacture
	Authorized Representative in the European Community		Unique Device Identifier
	Catalogue Number		Model Number
	Serial Number		Medical Device
	Follow Instructions for Use		Caution (ISO 7000-0434A)
	Declaration of Conformity to MDR 2017/745		Type BF Applied Part
	Double Insulated, Class II Equipment		Waste Electrical and Electronic Equipment (WEEE Logo)
IP21	Protected against ingress of solid foreign objects ≥12.5mm diameter. Protected against vertically falling water drops.		Machine Wash Warm : Max. 60°C
			Machine Wash Warm : Max. 71°C
	Do Not Bleach		Do Not Iron
	Do Not Dry Clean		Tumble Dry Medium - Gentle Cycle
	Do Not Wash		Hang Dry
	Humidity Low and High Limits		Consult Instructions for Use
	This Way Up		Fragile, Handle with Care
	Use No Hooks		Keep Away from Rain

2 Security Norms

2.1 Correct Use of the System

(1) In order to guarantee the correct operation, ensure that the system is perfectly assembled and securely fasten the mattress with the specific straps to the bedframe. Make sure that the straps do not interfere with the bed movements.
(2) Hang the power unit to the bed footboard using the specific hanger hooks and do not place any objects onto the power unit.
(3) A single layer bed linen separates the patient from air mattress to avoid direct contact with the air mattress coverlet. Ensure that the bed linen fits properly and not too tight to prevent from hammocking.
(4) Do not use the system in presence of live flame or sources of heat. The 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) Never use the product if the power cable, plug of the control unit or power supply housing is defective, if the control unit housing is damaged, or if it is not functioning properly. Contact an authorized service technician for examination and repair.

Lay Operator Briefing Information

The equipment and accompanying Operation Manual should be simple to understand and straightforward to use for the Lay Operator, according to IEC60601-1-11 regulation, a Lay Operator needs to have at least 8 years of education. The healthcare professional should brief the Lay Operator on the use of the equipment and any precautions to be taken, including:

- Precautions to be taken in the event of changes in the performance of the equipment.
- Precautions to be taken regarding the exposure of the equipment to reasonably foreseeable environmental conditions.(e.g. magnetic and electromagnetic fields, external electrical influences, electrostatic discharge, variations in pressure etc.)
- Information about medicinal substances that the equipment is designed for, including any that the equipment is NOT designed for.
- Information about medicinal substances or blood products incorporated into the equipment as an essential part.
- The accuracy of equipment with a measuring function.

2 Security Norms

2.2 Advice

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

CAUTION

- DO NOT expose the DualFlex System to the sunlight or the dusty environment.
- May experience potential allergic reactions to accessible material used in the DualFlex System.
- Keep the DualFlex System out of reach of children.
- Skin irritation due to prolonged exposure to matress or other accessories.

3 Delivery and Storage

3.1 Packaging

DualFlex 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

DualFlex System is delivered with the following components:

- Power unit
  Including: Power unit x 1
  Instruction for Use x 1
- Mattress
  Including: Mattress x 1
  Coverlet x 1

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

3.3 Storage and Transport

Recommended environmental conditions for storage and transport:

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

⚠ ATTENTION

Storage of the mattress

- Do not fold.
- Do not bend
- Not more than two layers should be stacked on top of each other.
- 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

Principle of operation

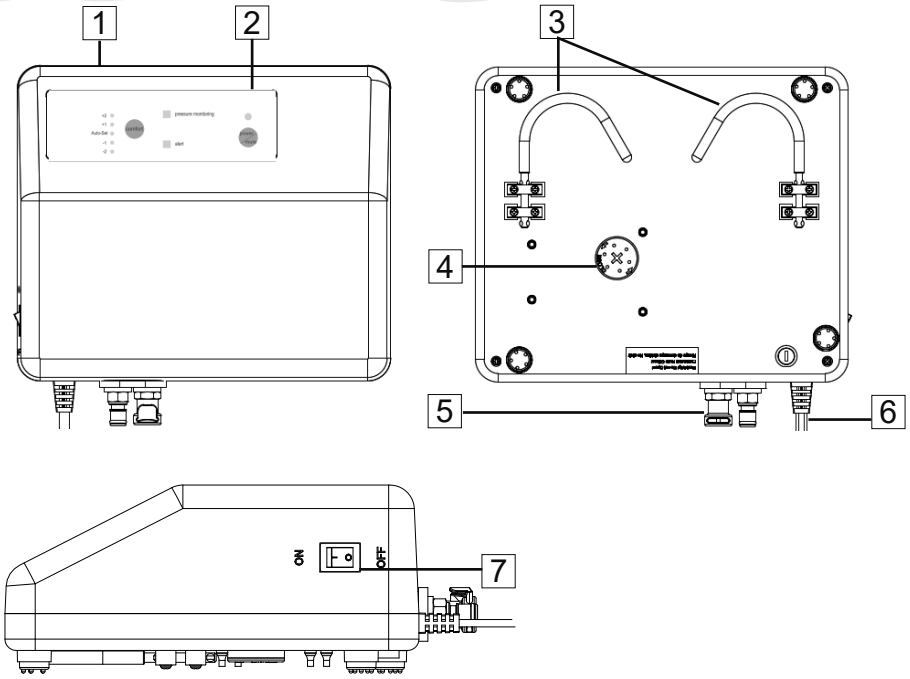
The power unit generates air by compressor then the rotor valve delivers the air into the mattress through air tube inside the power unit then pass through the air outlet.

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

Power unit

The power unit 1 is used as the housing for the air source as well as control features:

- A control panel 2 with buttons and lights to adjust the air system.
- Two hooks 3 on the back to hang the power unit to a bedframe.
- A receptacle for an air filter 4 on the rear panel.
- Two air outlets 5 for quick coupling.
- A power cable 6 with a plug to connect the device into a wall socket.
- A rocker switch 7 for main power.



4 Device and Functional Description

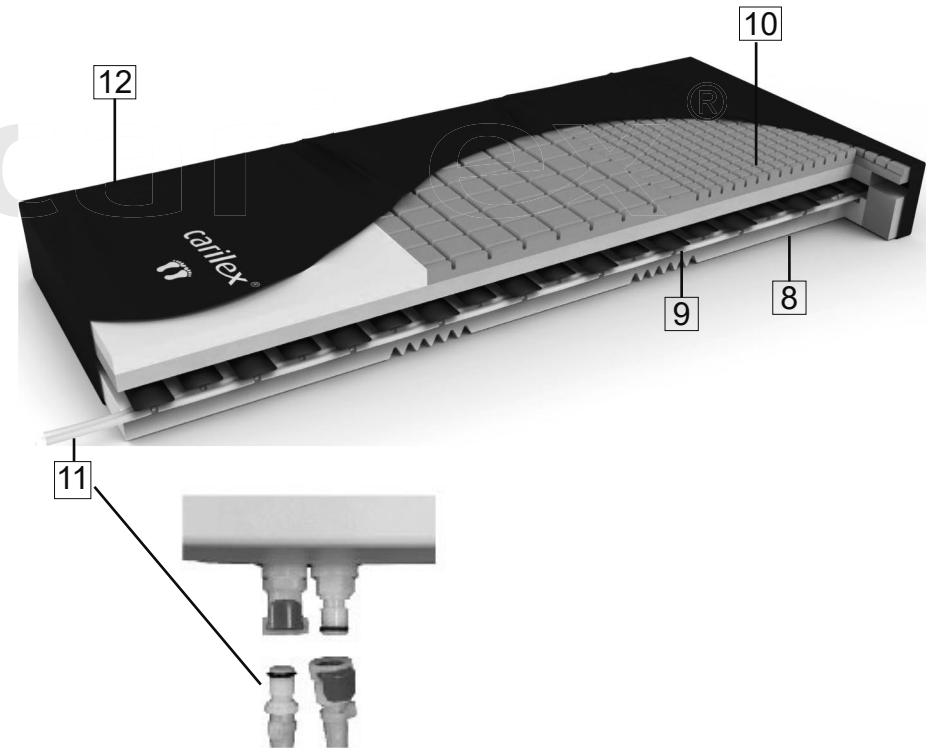
Mattress

The Mattress Replacement constructed in three different layers, a lower foam base [8], central air cells [9] and the top foam layer [10]. The lower foam base provide stability of the mattress, the central air cells consists of 19 individual cells which provide alternating pressure to relief pressure from patient's tissue. Top foam layer design with optimal density to provide pressure re-distribution to the patients.

In the top layer foam, a special density design in the heal section as a heal guard.

Two separate air hoses [11] feed the connected air cells with compressed air from the power unit. Both pressure hoses are equipped with a male or female coupling, which cannot be confused.

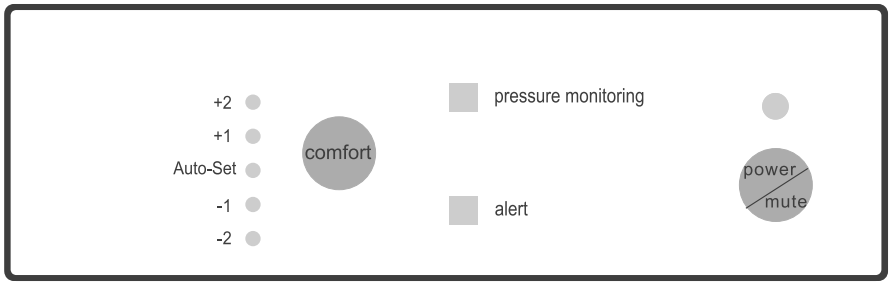
The coverlet [12] is made from a two way strech material.



4 Device and Functional Description

4.2 Functional Description

4.2.1 Control Panel



power/mute

This button would work for two functions. For Power function, user could use the 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 up. The LED will change to yellow when there is an abnormal power outage, or when power cable is removed without switching the system off by the rocker switch. It will also have audible beeping to notify caregivers. 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 indicator. After mute, the audible indicator will not re-start again and only have visual LED to notify the caregivers until the problem is solved.

comfort

Press this button to adjust the comfort setting of patient sensation. The system ‘s default comfort is “auto-set ”, +1 harder, +2 hardest. -1 softer, -2 softest. 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.

The system operates in 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. Dynamic mode will take 10 minutes to finish a complete cycle.

4 Device and Functional Description

pressure monitoring LED

DualFlex System is features with an intelligent pressure sensing technology which could monitor the mattress' pressure 24 hours to achieve optimal pressure and to ensure maximum pressure relief. The yellow LED indicates that the system is monitoring the mattress' pressure.

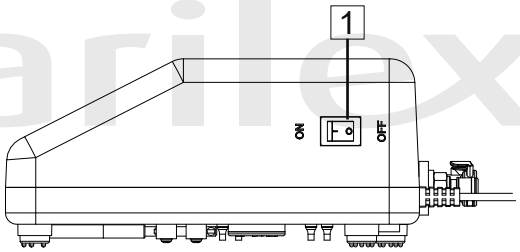
alert LED

This yellow LED is to indicate that the mattress has insufficient pressure. There will be both audible beeping and visual LED indicators. Audible indicator will be turned off after pressing the power/mute button and it will not start beeping again, to avoid acoustic pollution, but the LED will stay flashing until the problem has been solved.

Main Power off

Press the button power/mute and then switching off the rocker switch on the right side panel.

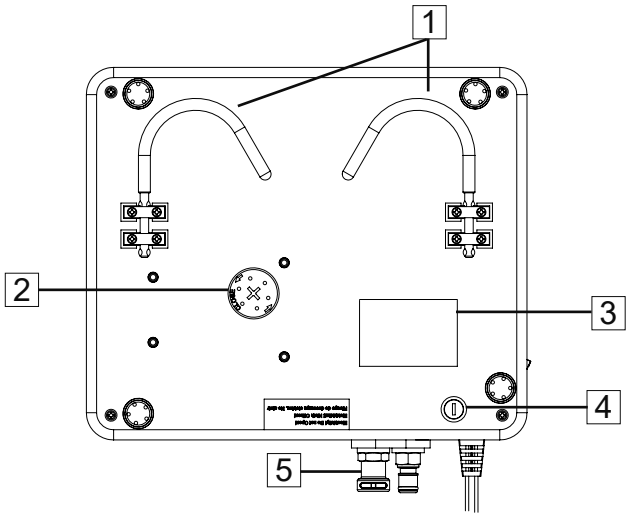
4.2.2 Right Side Panel



Rocker Switch (1)

Main power switch of power unit.

4.2.3 Real Panel



4 Device and Functional Description

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

Air Filter and Filter Cap(2)
We recommend inspecting and cleaning this filter monthly or more often, depending on the environment the unit is being used. Failure to keep the filter clean will result in shorter life span of the unit and/or unit failure. When replacing, be sure to use Carilex standard filter to optimize the performance of the power unit.

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

Fuse Holder (4)
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.

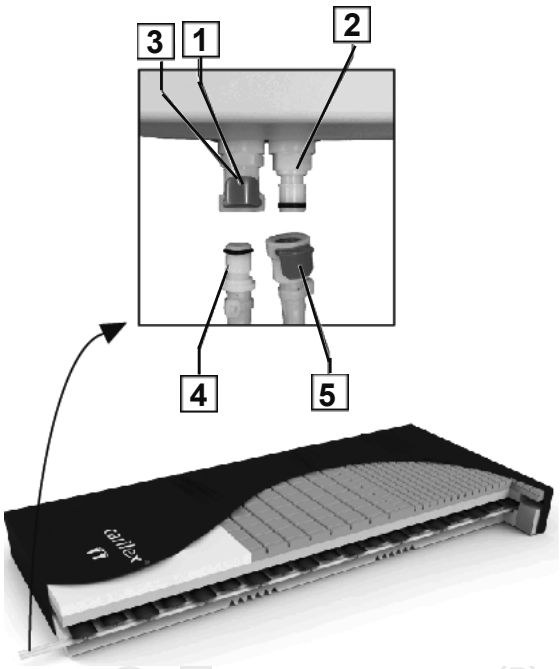
Air Outlet (5)
Quick couplings enable a rapid and firm connection between the mattress and the power unit.

4.3 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 4 and 5 must be able to move easily without any kinks or pressure points.
- Insert the compressed air hose 5 into the connecting piece 2 ,Insert the compressed air hose 4 into the connecting piece 3.
- To disconnect a compressed air hose from the connecting piece: Press the release 1.
- For function test details, please refer to Chapter 4.2, and make sure all functions work normally before use.

4 Device and Functional Description



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 plug and the main power cable of the power unit before connecting.

- Damaged components may not be used for connection!

5 System Installation, Operation and Transport of Patient

5.1 System Installation

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

(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) CAUTION!

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

(4) CAUTION!

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

(5) Hang the power unit at the foot of the bedframe with aid of the hanger hooks.

(6) Push the quick coupling of the mattress firmly into the air outlet of the power unit.

(7) Insert the power cable into a wall outlet. Ensure that the ppower cable is not in the way of the operators and the movement of the bedframe.

(8) CAUTION!

Patient hit against the bedframe/floor that may increase the risk associated with injury or bone fracture. Please follow the section 8.1 Inspection, to check the strut force of mattress after install the system.

(9) CAUTION!

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

5 System Installation, Operation and Transport of Patient

5.2 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.

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

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

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

5 System Installation, Operation and Transport of Patient

5.3 Transport of Patient

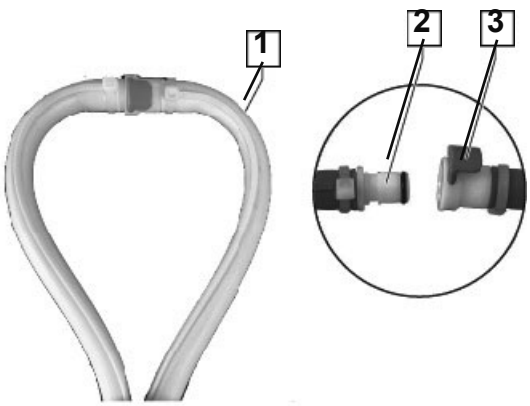
If the patient needs to be transported together with the alternating pressure mattress system, then the compressed air supply hoses must be disconnected from the controller and connected to close the tubing circuitry 1.

(1) Press the release tabs and disconnect both quick plugs from the connections on the power unit.

(2) Connect the CPC connector 2 and 3 of the two compressed air hoses together.

(3) Turn off the power unit by pressing the power/mute button.

Once the transportation phase is complete, reconnect the mattress to the power unit and follow Section 5.2 to resume normal operation.It is not necessary to move the patient from mattress during the re-inflating maneuver.



6 Application

Mandatory bedframe size

It is mandatory to select proper bedframe size for the DualFlex System. Do not operate the DualFlex 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.

If the mattress cover is not fixed, the hybrid alternating presure mattress cells may move. For patients there is a risk that they may be injured if placed in an unstable position. Always use the DualFlex coverlet. Without the coverlet, there is a high risk of cross contamination.

6.1 Preparing the Application

(1) Place the bedframe in the supine (flat) position.
(2) Fix the mattress with the straps onto the bedframe.
(3) Hang the power unit with the two hooks on to the footboard of the bedframe and check that the fixing is stable.
(4) 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.

6.1.1 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 on the head end of the mattress.

CAUTION

Pressure points on protective body areas!

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

CAUTION

Loose power cable may cause tripping and serious injury.

7 Cleaning and Disinfection

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

⚠ WARNING

Check electrical components

Electric shock!

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

- Turn off the power unit.
- Unplug the power cable from the power socket.

⚠ CAUTION

Health hazard!

The contact with contaminated cleaning fluids can cause infections. Disinfectants can contain harmful substances.

Please follow the Instructions for Use of the manufacturer of the disinfectant and the hygiene of the operator during the cleaning and disinfection. Wear personal protective equipment:

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

⚠ ATTENTION

Incompatible cleaning agents!

The components of the DualFlex 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.

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7 Cleaning and Disinfection

7.1 Cleaning

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

⚠ WARNING

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

Cleaning of the coverlet

Cleaning the Coverlet

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

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

7 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.

7.2 Disinfection

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

Disinfection procedures

Disinfection procedure

Please follow the procedure required by your local health authority.

⚠ CAUTION

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

8 Care and Maintenance

8.1 Inspection

The safe operating condition of the DualFlex 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.
- Condition of the air hoses and quick coupling.
- Condition of the air cells.
- Condition of the coverlet.

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

⚠ CAUTION

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.

9 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.
2.) Low pressure indicator.	2.1) Check the air filter.	2.1) Clean or replace the air filter.
	2.2) Power unit is defective.	2.2) Contact the authorized distributor for technical service.
3.) The power unit cannot power on.	3.1) Verify that the power cable is plug into the proper socket.	3.1) Insert the power cable of power unit into an appropriate socket and turn the power on.
	3.3) Verify that the power cable is not damaged.	3.3) Replace with a functioning power cable.
	3.4) Verify that the fuses are not burned out.	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.

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.

10 Technical Data

The DualFlex System is suitable for continuous operation.

Power unit

Model SR353
Dimensions(W x H x D).....26 x 22 x 10cm
Weight.....2.5Kg
Electrical Rating.....220-240Vac 50/60Hz 0.2A
Power Consumption.....Max.15W (normal operation)
Fuse Rating.....T1A 250V
Electrical Class .....Class II with FE
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

Mattress

Min. Patient Weight 30Kg
Max. Patient Weight 250Kg
Material of Air Cells.....Nylon with TPU lamination material

The DualFlex 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.

10 Technical Data

Mattress	
Device Item	S2602 DualFlex
Article number	S2602-2040
Mattress size& Coverlet size	90x200cm
Coverlet material	VTX: 100% Polyester Jersey
Coverlet MVTR	500g/24H/M^2
Coverlet Wash Condition	Coverlet need to be water repellent- 3000mm/ H_2O after 1.5Hrs*40 wash
Base material	100%PVC with Webnet base
Air cell material	Nylon+PU
Air cell height/number	2.5”/19
Protection unit	Foam
CPR Time	N/A
Max Weight Capacity	250 kg
Weight of Mattress Set	19kg±2

11 EMC Declaration

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	

11 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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