Enhancing Lives,
Delivering Comfort

OPERA® RELIEVE OVERLAY

MATTRESS SYSTEM

Instructions and Technical Specifications

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Contents

Indications

This air alternating mattress system is designed for patients who endure pressure ulcer and potential patients who wish to reduce the likelihood of pressure ulcer. This device is intended to treat and prevent pressure ulcers by facilitating blood circulation and decreasing pressure of each tissues contact area. Always consult a physician or healthcare professional before using this mattress system. This anti-decubitus mattress system is mainly for medium risk patient group.

Contradictions

Certain patient conditions are not suitable for using this type of device such as fracture of unstable vertebrae and illness of unstable 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.

Thank you for purchasing this anti-decubitus mattress replacement system. Please read these instructions carefully before setting up and using the device. Pay special attention to the warnings and other safety information. Use of genuine components is essential for optimal performance. If you do not fully understand all the instructions, safety precautions, and warnings, do not use this device. If you have questions, please contact Opera on 0333 222 8584.

1. Explanation of Symbols

Read information with this symbol carefully and urgently follow instructions. This information is safety-relevant.

This symbol indicates general hazards. There is danger to life and health.

Conformity mark in accordance with the Medical Device Directives 93/42 EEC.

IPX0 Do not immerse power unit in liquid or spray liquids directly on power unit.

Double Insulated (Class II) equipment.

Symbol for type B device according to DIN EN 60601-1.

Indoor use only.

This product must be disposed of in a separate refuse collection in the European Union. Do not dispose of as normal domestic waste.

Read instructions.

Manufacturer.

Date of Manufacture.

2. Safety Precautions

2.1 Proper Operation

To ensure proper operation, please inspect and verify that all parts are set up properly and are anchored securely to the bed system. Verify that the mattress replacement system does not interfere with the bed frame function. Do not place anything on top of the power unit. Make sure power cord set is underneath the bed frame and does not pose a hazard.

2.2 Use of Linens

It is recommended to limit bed linens to a single layer in order to allow moisture to escape efficiently through the coverlet. Breathable incontinent pads are recommended for use with this mattress system.

2.3 Flammability Hazard

Avoid using this device near open flames, lighters, or cigarettes. Flammability hazard exists. This device draws air from the surrounding environment. Thus, cigarette smoking may damage internal components.

2.4 Disinfection Between Patients

This system should be disinfected thoroughly between patients in order to avoid cross contamination.

2.5 Weight Capacity

Verify that the patient's weight, accessories, and this mattress replacement system, do not exceed the bed frame's manufacturer's recommended weight capacity.

3. Warnings

3.1 Side Rails

Use this mattress with side rails that meet bed rail regulations (BS EN 60601-2-52:2010) to ensure that the gap between the side rail and the top of the mattress is not large enough to pose risk of head or neck entrapment. Failure to do so could result in serious patient injury or death. If applicable, adhere to facility or local guidelines regarding entrapment regulations.

3.2 Do Not Disassemble

Do not disassemble the power unit if you are not a qualified technician. Please contact Opera on 0333 222 8584.

3.3 AP/APG Protection

This product is not AP/APG protected.

3.4 Periodic Repositioning

It is recommended that the patient be repositioned periodically while using this mattress.

3.5 Maintenance

If the equipment needs maintenance, contact Opera on 0333 222 8584 as soon as possible. For equipment that is no longer functional, make sure to follow national, state, and/or facility requirements for disposal of the unit.

3.6 Maximum Operating Temperature

The air mattress operates at a maximum temperature of 100 °F (37.7 °C).

3.7 Sharp Protrusions

Ensure that there are no protruding objects, sharp points, or bed springs under the mattress as these could puncture the air cells.

3.8 Disposal of Waste

This device must not be disposed of as normal household waste after the end of its service life. Contact your local waste recycling facility for further instructions.

4. System Package

4.1 Power Unit Package

Power Unit x 1

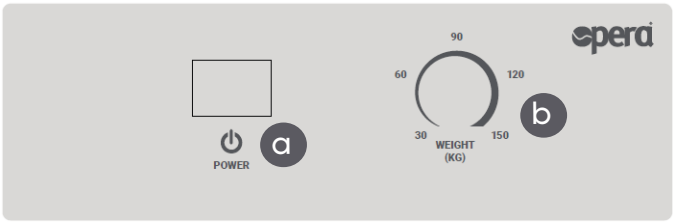
Power Cord x 1

Instructions For Use x 1

4.2 Mattress Package

Mattress replacement unit with coverlet x 1.

5. Power Unit Features

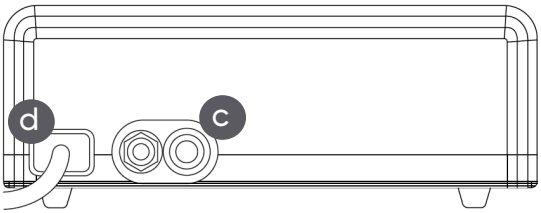


a. Power Switch

The green power LED will light when the main power rocker switch on the panel is turned on.

b. Lockable Patient Weight Knob

Patient Weight Knob is used to adjust the internal pressure of the mattress according to patient weight. Simply turn the knob to adjust the pressure setting if the mattress is too soft or firm to suit each patient's needs. Caregivers should always perform a hand check by placing their hands underneath the patient's pelvis area to check if there is sufficient air support to ensure that the patient is not bottoming out.



c. Couplers

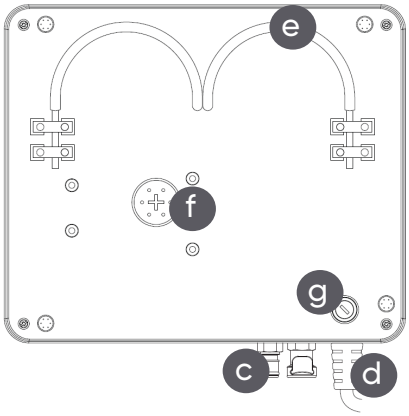
Quick release female couplers are used to secure mattress air hoses to the power unit.

d. Strain Relief of Power Cord

Provided with a moulded-on anti-kink bushing held in place by integral slot in bottom enclosure.

e. Hanging Hooks

Hanging hooks are designed to hang the power unit on almost any foot board.



f. Air Filter and Cap

We recommend that the filter is kept clean to ensure optimal performance of the power unit.

g. Fuse

Fuse Holder

6. Mattress and Power Unit Installations

6.1 Secure Mattress Overlay

Place mattress overlay on top of the original mattress with the logo at the foot end. Secure the mattress using the elastic straps at four corners. Please verify all bed functions are working properly without interference before proceeding to the next step. Also, check the combined height of the Overlay and Mattress meets bed rail regulations (BS EN 60601-2-52:2010).

6.2 Secure Power Unit

Secure the power unit on to the foot board using hanging hooks.

6.3 Connect Hose Couplers

Firmly connect the air hose couplers to the couplers on the power unit.

6.4 Power Up Unit

Plug the power unit into an electrical outlet, and turn on the main power rocker switch on the control panel.

6.5 Set Patient Weight

Turn the lockable patient weight knob on the power unit's control panel to maximum setting to shorten the initial inflation time if needed.

6.6 Wait for Inflation

Wait approximately 30 minutes for the mattress to inflate fully before allowing the patient to lie down on the mattress.

7. Program Settings

7.1 Adjusting Firmness

Place the patient in the centre of the mattress. Adjust the mattress' internal pressure according to the patient weight by using the lockable patient weight knob on the control panel of the power unit. If the mattress is too soft or too firm, increase or decrease the mattress' internal pressure one increment at a time and wait for the system to stabilise before making another change. Continue this process until comfort is achieved.

7.2 Perform Hand Check

Caregivers should always perform a hand check by placing their hands underneath the patient's pelvis area to check if there is sufficient air support to ensure the patient is not bottoming out.

Tucking the bed sheet in too tightly may reduce the effectiveness of the system.

8. Patient Transfer and Transport

8.1 Transfer

It is recommended to have the mattress system fully inflated during the transfer process. Make sure the bed is secured before proceeding.

8.2 Transport

In the event of a patient transport, two options are available.

1. Detach the mattress' air hose couplers from the power unit's quick release couplers and connect the two air hose couplers together to retain air in the mattress. The mattress will stay inflated for approximately 2 hours, depending on the patient's weight.

2. Unplug the power unit's power cord from the wall outlet and the mattress should stay inflated for approximately 40 - 50 minutes. This mattress system also has a safety foam base underneath the air cells to support the patient for a short period of time in case of deflation. To resume normal operation, please follow the instructions beginning in Section 6.1.

9. Emergency CPR Deflation

In the case of emergency, pull on the air hose couplers from the control unit and turn off the power unit by pressing the power/mute button on the control panel at the same time for emergency deflation. The air will discharge from the mattress with the patient's own weight. To resume normal operation, simply re-insert the air hose couplers, press the power/mute button again and reset the patient weight. See instructions in Section 6.1.

10. Cleaning Instruction

The air mattress and power unit must be cleaned thoroughly between patients to avoid cross contamination. The following is a suggested guideline. Be sure to follow local infection control policies.

Regular cleaning can be performed at bedside with a disinfectant followed by drying with a clean dry cloth. Use only mild detergents to clean the coverlet and the mattress. Any appropriate non-phenolic cleaning agent may be used for heavy soiling from urine, blood or other bodily fluids. Please ensure that the air mattress and coverlet are completely dry before letting the patient lie on the surface again.

Machine wash warm water at maximum 71 °C.

Do not use electric or tumble dryers. Do not iron.

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

11. Routine Maintenance and Storage

Remove air filter from the rear panel of the power unit by opening up the filter cap. Inspect the filter for dirt or dust, and clean it with mild soap and water. Reinsert the dried air filter after cleaning and ensure that the cap is secure. If a replacement is needed, contact Opera on 0333 222 8584.

Only disinfected and dry systems should be stored. Disconnect the air hoses from the power unit. Roll up the mattress starting from the head end and working down toward the foot end. Use the straps to secure it and store in clean plastic or other storage bag. Store in a cool, dark place.

12. Troubleshooting

Fault	Inspection Procedure	Remedy
Power unit is not working	Check if power cord is firmly plugged into both the control unit and the electrical outlet.	Secure power cord into control unit and/or electrical outlet.
	Check if the power switch is in the on position.	Turn power switch to on position.
	Check if the power surge has shut down the power unit.	A power surge may overload the circuitry temporarily. Turn the unit off, and check the fuse for damage. Turn the unit on again with normal procedure.
	Make sure there is no power failure.	Turn on and operate the unit after power is restored to the facility or home.
	Power unit does not respond to possible solutions.	Please contact Opera on 0333 222 8584 for assistance.
Power unit is working, but mattress replacement is not inflating **and/or** Bottoming out is occurring **and/or** Patient leaves a deep indentation at the contact area which does not return back to its original shape.	Check CPR Pull Cord.	Unzip mattress cover and inspect CPR latch is fully inserted into socket.
	Check if mattress' air hose couplers are properly connected to power unit's quick release couplers.	Secure air hose couplers firmly into place.
	Verify that patient weight setting is correct.	Increase or decrease weight setting until appropriate pressure is reached.
	Inspect air filter for dust and dirt.	Clean or replace air filter.
	Lift mattress coverlet up to check if air cells are connected correctly.	Make sure all air cells are properly linked to air supply.
	Lift mattress coverlet up to check if air tubes are kinked or obstructed.	Check and adjust air tubes positions.
	Check if air cells are cut or cracked	Please contact Opera on 0333 222 8584 for assistance.
Patient's wounds are not responding to pressure relief (reddening of skin).		Contact your physician and/or nursing service immediately.

13. Return for Service

Service and repair must be performed by Opera authorised technicians or representatives. Please contact Opera on 0333 222 8584.

14. Warranty

We warrant the product to be free from defects from the date of purchase.

Please inspect all accessories when you purchase our product. If there is any damage or missing accessories when you receive the product, please ask for a replacement from Opera on 0333 222 8584 within three days of purchase.

The warranty period for the products are according to the regulations in your country, the minimum period is 2 years from date of purchase for the power unit and 2 years for the mattress and the coverlet. The warranty coverage of any product is contingent up on its purchase from Opera.

Warranty coverage will not be extended to any product on which the production lot number has been removed or defaced on which repair has been attempted by any person or agency not authorized by our company or if in the sole opinion of our company that the system shows evidence of tampering, abnormal or unreasonable abuse, negligence, accident or operation without regard for the restrictions specified in the instructions which accompany the system. This warranty does not cover normal maintenance such as cleaning, adjustment, lubrication, and updating of equipment or parts. If the damage is a result from improper operation, a reasonable service fee and part cost will be charged.

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

15. Product Specifications

System Name	RELIEVE Overlay Mattress System
Power Unit (Air Pump) Model	SR303
Mattress Dimension	2000 x 900 x 130mm (5" depth)
Number of Air Cells	16 Cells
Power Control Unit Dimension	260 x 220 x 90mm
Material	Power Unit - Plastic Case rated UL 94V-0 Mattress Cell - 100% nylon with TPU lamination Coverlet - Quilted Nylontaffeta Backing
Power Input	220 - 240Vac, 50Hz, 0.05A
Power Consumption	Normal Operation: Max 6W
Power Control Unit Weight	2.5 kg
Fuse Rating	T1A 250V
Electrical Classification	Class II Type B, double insulated. IPX0, do not immerse power unit in any liquid, or spray any liquids directly on the power unit. This system is not AP/APG Protected. Continuous operation.
Power Cord	H05VV-F or H05VVH2-F, 2 x Min. 075mm^2
Operating, Transportation & Storage Conditions	Temperature: 5°C - 40°C Humidity: 15% - 60% Atmospheric Pressure: 700 - 1060hPA
IEC/EN Test Standards	Safety: IEC/EN 60601-1_v3.0 EMC: IEC/EN 60601-1-2_v3
Maximum Weight Capacity	150 kg

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