

User Manual

AER Fusion

Alternating Hybrid Mattress

TABLE OF CONTENTS

IMPORTANT SAFEGUARDS	3
STATEMENTS	4
INTRODUCTION	4
PACKAGE CONTENTS	6
PRODUCT DESCRIPTION	7-8
Pump	7
Mattress	8
PUMP FUNCTION	9-10
SYSTEM INSTALLATION	11
OPERATION	12-14
Mattress	12
CPR function	13
Transport Mode	13
Pressure set up	14
Low pressure warning	14
CLEANING	14-15
HANDLING AND STORAGE	16
MAINTENANCE	16
TROUBLESHOOTING	17
SPECIFICATIONS	18
CONTACT	19

IMPORTANT SAFEGUARDS

When using electrical products, especially when children are present, basic safety precautions should always be followed.

Danger

To reduce the risk of electrocution:

- ▶ Always unplug this product immediately after use.
- ▶ Do not place or store this product where it can fall or be pulled into water.
- ▶ Do not submerge the pump unit in water.
- ▶ Do not reach for a product that has fallen into water. Unplug immediately.

Warning

To reduce the risk of burns, electrocution, fire, or injury to persons:

- ▶ Close supervision is necessary when this product is used by, on, or near children.
- ▶ Use this product only for its intended use as described in this manual.
- ▶ Do not use attachments not recommended by the manufacturer.
- ▶ If the product has a damaged cord or plug, if it is not working properly, if it has been dropped/damaged or dropped into water, it should be returned to your dealer/service centre for examination and repair. Do not try to operate the product under any of the above circumstances.
- ▶ Keep the cord away from heated surfaces.
- ▶ Never block the air openings of the product or place it on a soft surface, such as a bed, where the air openings may be blocked. Keep the air openings free of debris such as lint or hair.
- ▶ Never drop or insert any object into openings or the hose.
- ▶ Do not use outdoors or operate where aerosol (spray) products are being used.
- ▶ Connect this product to a properly grounded outlet only.

Grounding

Before any connection is made, make certain that this product shall be connected to a protective earth conductor via the three-wire power cord; the plug shall be inserted only into a socket outlet that provides a protective earth contact.

STATEMENTS

Note

Indicates some tips or some information users should be aware of.

Caution

Indicates correct operating or maintenance procedure to prevent damage to or destruction of the equipment or other property.

INTRODUCTION

This manual should be used for the initial set up of the system and for reference purposes. Always read this manual before using this product.

General

- ▶ The AER *Fusion* alternating hybrid mattress is designed for patients who suffer from or are at a high to very high risk of developing pressure ulcers.
- ▶ The AER *Fusion* is a foam mattress with a 16 cell alternating inner core.
- ▶ The AER *Fusion* can operate in powered and non-powered modes to facilitate step-up and step-down care for patients.
- ▶ The system can support patients weighing up to 254kg.
- ▶ The mattress may be used by adults, the elderly and children, subject to a clinician's guidance. The mattress is not intended to be used by young children or babies.
- ▶ The AER *Fusion* is suitable for use in a variety of hospital environments, care homes, community and home care.
- ▶ The mattress can be used in conjunction with profiling beds.
- ▶ This system is made with the highest quality material, which is durable and reliable.

The AER *Fusion* has been tested and certified for the following standards:

EMC & Safety Certified Standard
EN 60601-1:2006 / A1:2013_V3.1
IEC 60601-1:2005 / A1:2012_V3.1
IEC 60601-1-2:2014 / EN60601-1-2:2015

- ❖ CE
- ❖ UL

Mattress

The AER *Fusion* mattress cells are manufactured using a combination of Nylon and TPU. Please refer to the specifications section on page 15 for details.

CLASSIFICATION

- Medical Device Regulation (MDR) Class IIa
- Class II Medical electrical equipment (Protection against electric shock).
- CRIB Rating - BS7177:2008 Crib 5 (Ignition source 5) for medium hazard.
- Type BF Applied Part (The mattress is applied part).
- IP21.
- Continuous Operation

The mattress meets the required standard EN ISO10993-1 for biocompatibility.

The mattress meets the requirements of the Furniture & Furnishings (Fire Safety) Regulations 1988.

Intended Use

The AER *Fusion* alternating hybrid mattress is intended to reduce the incidence of pressure ulcers while optimising patient comfort.

Contraindication

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.

PACKAGE CONTENTS

Check inside the package. If any of the following items should be missing or damaged, please contact your local dealer or service center for replacement immediately.

Pump unit with power cord

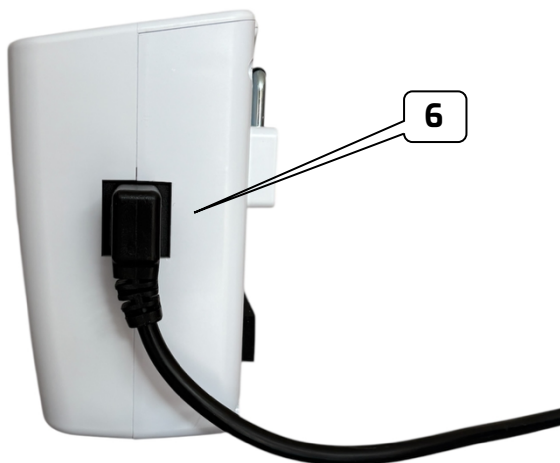
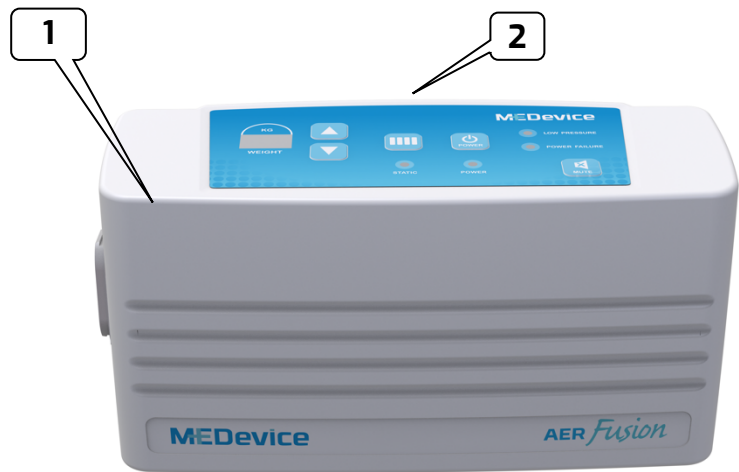


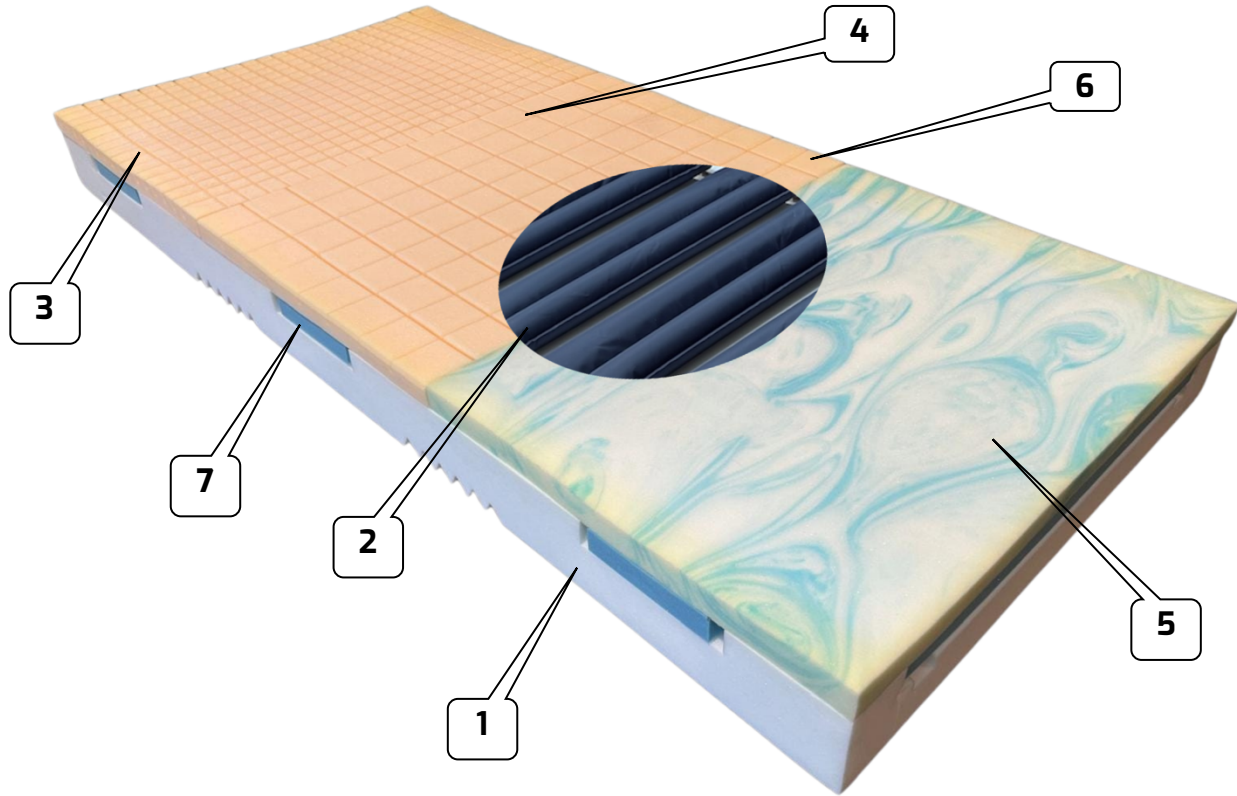
Mattress with cover



PRODUCT DESCRIPTION

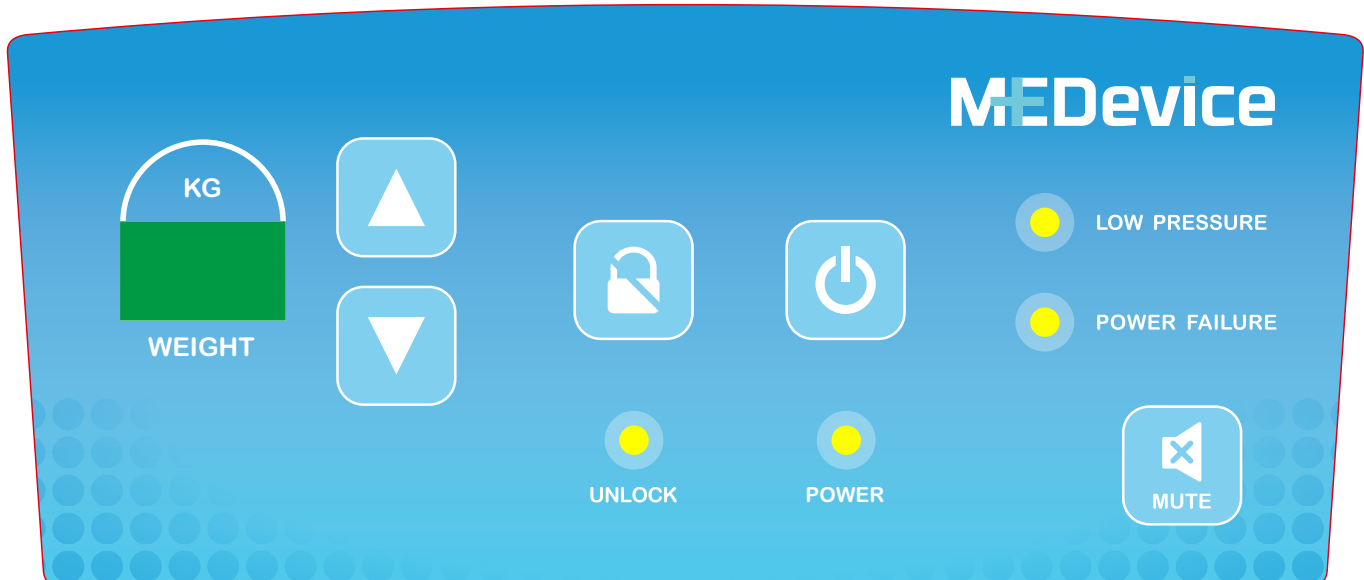
1. Pump unit which houses the compressed air system.
2. Control panel with buttons and lights to adjust the compressed air system.
3. Two hooks on the back to mount the pump unit to a bedframe.
4. Quick connectors for the mattress air tube.
5. CPR.
6. Power cable with plug.





1. Foam base with side walls for stability.
2. Inner core of 16 air cells alternating on a 1 in 2 cell cycle.
3. Top foam layer designed with optimal density to provide pressure redistribution for patients.
4. Head and sacrum zones. Engineered castellations to provide extra support for vulnerable areas.
5. Gel infused heel zone supporting the calf muscles and elevating the heels to reduce pressure damage in these vulnerable areas.
6. Hinge cuts at the knee break and sacrum zone to reduce movement, shear and friction for the patient when the bed is profiling.
7. Key cuts to lock the foam layers in position

PUMP FUNCTION



Pump Unit

The functions of the pump for the AER Fusion alternating hybrid mattress are described below.

1. Power Switch



- Connect the power lead then connect the mattress air hose to the pump.
- Turn ON/OFF by pressing the power button on the panel, the pump will start/stop operation.

2. Weight guide



- Press the arrow up to increase the weight guide.
- Press the arrow down to decrease the weight guide.

3. Alarm Mute



- The audible/visible alarm turns on when the pump unit detects low pressure or power failure.
- To mute the audible alarm, press the Alarm Mute button.
- Re-press the Alarm Mute button to reactivate the alarm.

4. Low Pressure

- When the pump detects low-pressure the audible alarm will sound, and the Low-Pressure indicator will flash after 30 minutes.

5. Power Failure

- Should there be a power failure, the audible alarm will be activated, and the Power Failure indicator will flash immediately.

6. Unlock button

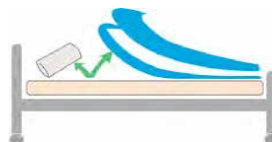


- The pump unit will automatically lock in 5 minutes without operation.
- Press the unlock button for 3 seconds to lock the panel, press again for 3 seconds to unlock the panel

System Installation

The following describes the procedures for setting up the system for the first time.

Remove all covers, sheets and mattress from the bed.



On a standard bed, position the mattress on top of the bed, printed top cover facing upwards and air hoses towards the base of the bed. Attach to the bed by securing the adjustable straps under each end of your bed. Ensure buckles are securely fastened and straps are pulled tight.

On a profiling bed, secure the side straps around the moveable sections of the bed base. **DO NOT SECURE TO THE SIDE RAILS - STRAPS WILL TEAR OFF.**



Confirm there are no sharp objects in the immediate area, which may risk damage to the mattress.

Important: Check that the attachment of the mattress does not interfere with the movement or operation of the bed.

Pump Unit Activation

Position pump unit by hanging hooks over foot board of the bed or place unit on the floor under the bed.



Attach the air hoses using the quick connector to the pump unit. Ensure air hoses do not kink between mattress, bed frame and pump unit.

Plug the power cord into an electrical outlet with grounded AC power.

NOTE: Before inserting the plug into the outlet, make sure the voltage is compatible. Also make sure this product is well grounded.

Switch the power button on. The mattress inner cells will inflate within 2 minutes and start alternating in a one in two cell cycle. Place the patient on the bed and select the correct weight setting.

Perform a test to ensure that the patient is properly supported (see hand check page 12). Secure sheets loosely enough to ensure they do not interfere with therapeutic performance.

OPERATION

NOTE: Always read the operating instructions before use.

General

This product is designed to provide maximum comfort to patients. Make sure that you operate this product in a proper way to optimise its value. Here are some general points to be aware of.

For products:

- DO NOT use another pump with different specifications unless instructed to do so by your local dealer. It is dangerous to use a pump with a greater pressure capacity. This may result in cell damage.
- DO NOT change any component by yourself. If there is need for replacement or repair, always contact your local dealer.

Hand check:

Check if the pressure is properly adjusted by sliding one hand between the air mattress and bed frame to feel the patient's buttock. Users should be able to feel the space in between, and the acceptable range is approximately 25 to 40 mm (1" to 1-1/2").

Using the mattress

- 1) If the mattress arrives rolled, carefully remove the plastic packaging and unroll. The mattress should be unrolled within 3 months of receipt.
- 2) Before using the mattress for the first time, ensure there is no damage to the mattress and cover, this includes cuts, tears and frayed edging. Make sure the two zips are fully closed.
- 3) If the mattress cover is compromised do not use it as this may result in infection. Take the mattress out of service and inform your local dealer.
- 4) For initial set up refer to System Installation on page 11 of this manual.
- 5) Once the mattress is on the bedframe, insert the mattress air hose into the pump using the quick connector. Insert the power lead into the pump and plug into a socket outlet that provides a protective earth contact.

- 6) Turn on the power. The LED light will illuminate.
- 7) The inner cells will inflate within 2 minutes.
- 8) On first use the pump will default to a weight setting of 70kg. To increase the weight, press the up arrow or to decrease the weight press the down arrow.
- 9) On future use the pump will default to last used setting.
- 10) On initial set up, if optimum pressure cannot be reached within the cells within 40 minutes the low-pressure alarm will sound, and the LED light will flash.
- 11) Press the Alarm Mute button to mute the alarm. The alarm LED will continue flashing until the problem is solved. Press the Alarm Mute button again to re-enable the audible alarm.
- 12) During normal operation, the pump will monitor pressure. If the mattress pressure is lower than the set pressure, the pump will automatically inflate the mattress to the set level and then stop.
- 13) Should there be an unstable connection of tubing or any air leakage from the mattress, the low-pressure LED indicator will light up and the low pressure alarm will activate within 30 minutes. Once the low-pressure problem is solved, the control unit will resume operating in the previous set mode.
- 14) Should there be a power failure the pump will alarm and the power failure LED will flash immediately. When power resumes, switch the control unit back on and it will revert to the previous set pressure.

CPR function

When there is an emergency requirement to perform CPR on the patient, disconnect the quick connector on the pump unit to release the air quickly from the mattress. The mattress will deflate in approximately 3 minutes. To deactivate CPR, reconnect the air hose to the control unit by using the quick connector.

Transport Mode

To put the mattress into transport mode, switch off the pump at the control panel, unclip the umbilical cord from the pump unit and close the lid labelled transport. Ensure the lid is fully fastened with the clips. The inner cells within the foam mattress will stay inflated for up to 12 hours.

NOTE: The AER *Fusion* is a hybrid mattress and therefore can support patients in non-powered mode when the pump is switched off or disconnected.

Pressure set up

If the patient requires a softer or firmer mattress, users can alter the comfort mode to the desired setting by pressing the weight arrows up or down.

Low pressure warning

If the Low Pressure audible and visible alarms are activated, check if the connections are secure and correctly installed according to the relevant instructions.

NOTE:

If the pressure is consistently low, open the zipper and confirm that all the hoses are properly connected. Then check for any noticeable leakage in any of the tubes. If necessary, contact your local dealer to replace any damaged tubes or hoses. See troubleshooting on page 10.

CLEANING

In this section are the procedures to clean and decontaminate the pump and mattress. It is important to follow these procedures before using the system again. This cleaning procedure should be followed at least once a week to maintain personal hygiene.

Pump Unit

- ▶ DO NOT immerse or soak the pump in any water or fluids.
- ▶ Check for external damage prior to cleaning.
- ▶ DO NOT use a solvent or phenolic based cleaning solution as this may cause damage to the case.
- ▶ DO NOT spray any cleaning solution directly on the surface of the pump.
- ▶ Wipe case with a clean cloth. Spray cloth with cleaning solution. Make sure all areas are clean (top and bottom, both sides).
- ▶ DO NOT allow excess cleaning solution on faceplate or control panel. (If solution gets inside, damage will occur.)
- ▶ Allow surface to thoroughly dry after cleaning.
- ▶ After the pump is thoroughly cleaned and dried, proceed to plug in the pump and test to see if it runs normally.
- ▶ Avoid long exposure to sunlight.

Mattress

- ▶ Inspect the mattress cover inside and outside, including the seams and zips. If the cover has any damage such as rips or tears replace immediately.
- ▶ Check for strike through by examining the white substrate on the inside of the cover. If the cover has been compromised do not use the mattress as it poses a significant risk of infection.

Cleaning

- ▶ Brush off or wipe down all surfaces of the cover sheet with soap and water before wetting with any liquid disinfectant. To disinfect in situ, use a 0.1% sodium hypochlorite solution (1,000ppm chlorine).
- ▶ Any blood spots or bodily fluid should be wiped first with a paper towel and then cleaned with 1% sodium hypochlorite solution (10,000ppm chlorine).
- ▶ Wash down with soap and water to remove disinfectant and allow to dry thoroughly.

Washing

- ▶ Unzip the top cover from the mattress.
- ▶ Brush or wipe down all surfaces with soap and water before applying any disinfectant.
- ▶ Covers are immersed and soaked in disinfectant for the required incubation time.
- ▶ After pre-soaking, the cover is laundered with mild detergent (wash temperature up to 95°C).
- ▶ Covers must be aerated/hung until they are fully dry or tumble up to 60°C.
- ▶ Remove the top layer of foam to access the air cells. To clean the air cells spray all sides with a disinfectant. Let it sit for the required incubation time and wipe down with a clean cloth.
- ▶ The base cover must be sprayed down with the disinfectant, inside and outside. Let it sit for the required incubation time and wipe down with a cloth.
- ▶ The carrying bag should be turned inside out and completely wiped down using the disinfectant solution. Allow it to thoroughly air dry. Once the inside is dry, turn it back, wipe down the outside of the bag with disinfectant.
- ▶ Avoid long exposure to sunlight.

NOTE:

- ▶ The cover is not designed for frequent and multiple washes, damage from frequent and multiple washes are not covered by the warranty.
- ▶ If the cover is soiled or loses its water resistant properties, please purchase a new cover from your distributor.

Always follow your infection control policy.

HANDLING AND STORAGE

- ▶ Lay the mattress out flat.
- ▶ Do not fold, crease or stack the mattress.
- ▶ Store in dry conditions out of direct sunlight.
- ▶ Store away from sources of ignition and heat.
- ▶ Always clean the mattress before reuse.

DISPOSAL

Electronic and electrical waste must not be disposed of through general waste streams. Please contact an authorised disposal facility or your local dealer/service centre for further advice.

MAINTENANCE

General

- ▶ Check the power cord and plug to see if there are abrasions or excessive wear.
- ▶ Check the mattress cover for signs of wear or damage. Ensure the mattress cover and tubes are connected correctly.
- ▶ Plug in the pump unit and check the airflow from the hose connection port. The airflow should alternate between ports every half-cycle time.
- ▶ Check the air hoses to see if there are any kinks or breaks. For replacement, please contact your local agent or dealer.
- ▶ Make sure the mattress tube is well connected.

Low pressure

- ▶ Examine if there is any air leakage between the pump and the mattress connections or from the air mattress tubes.
- ▶ Check connectors between the air mattress and pump. If there is any disconnection, please reconnect it.
- ▶ Check the CPR Valves. Ensure their outlets are sealed.
- ▶ Check the air-connecting tubes. Ensure each single cell is not broken.
- ▶ Check if there is any air leakage from cells. Ensure no leakage occurs. If any leakage occurs, please contact your local agent or dealer.

TROUBLESHOOTING

Problems		Reasons	Maintenance
Mattress fails to inflate or does not inflate completely.	Pump issue	1. Pump does not work.	1. After power is on, check if visible LED light turns on. If not, please check the following issues: 1.1 Check if power cord is plugged into appropriate voltage AC outlet. 1.2 Check if fuse is loose or burned out. Make sure it connects well or replace it with new one. 1.3 If still not working contact your engineer/local dealer. 2. If the visible indicator light is on: 2.1 Contact your engineer/local dealer.
		3. Air pressure from pump is too low.	1. Contact your engineer/local dealer.
	Mattress issue	1. Quick connector on mattress does not connect well with pump. 2. Air tubes do not connect well. T connector and air valve are loose. 3. Air cell has leakage.	1. Make sure the quick connector on the mattress has a good connection with the pump. 2. Make sure T connector and air valve connect well, 3. Change air cell.
Pump is working but synchronous motor does not work; thus, mattress does not alternate.		1. Synchronous motor is out of order. 2. Wires inside synchronous motor do not connect well. 3. PCB is out of order.	1. Contact your engineer/local dealer. 2. Contact your engineer/local dealer. 3. Contact your engineer/local dealer.
Pump and motor keep working, but cycle time does not work correctly.		1. Micro switch on the exchanger is out of order. 2. PCB is out of order.	1. Contact your engineer/local dealer. 2. Contact your engineer/local dealer.
When power is on, compressor stops after working some time; but the exchanger keeps rotating.		1. Pressure detector is out of order.	4. Contact your engineer/local dealer.
Mattress pressure is low but alarm is not activated.		1. Pressure detector is out of order. 2. Buzzer on PCB is out of order.	1. Contact your engineer/local dealer.

Push button on panel does not operate well, LED indicator is not on, and LED segment display is not on.	1. Push button does not operate well. 2. LED is out of order. 3. LED segment display is out of order.	Contact your engineer/local dealer.
Mattress pressure is too high or too low.	1. Pressure sensor is out of order.	1. Contact your engineer/local dealer.

SPECIFICATIONS

Technical Specifications

Pump	Mattress
Item: AER Fusion	Item: Alternating Hybrid Mattress
Power supply: 230V, 50Hz	Size: 200cm(L) x 90cm(W) x 18cm(H)
Air output: 9 litre/min	High/Very High Risk
Electrical classification : Class 1	Top cover: Four-way multi-stretch PU cover, fully welded, vapour permeable and water resistant. Concealed zipper with PU overhang.
Inflate time: 2 minutes	Foam - Castellated SB40/145 CMHR and SB38/200 CMHR foam
Case material: Flame Retardant ABS	BS7177:2008 - Crib 5 (Ignition source 5)
Therapy mode: Alternating	16 air cells: Nylon/TPU
Alarm: Low pressure/Power failure	Base : Durable Nylon / PVC 840D
Size: 27cm(L) x 10cm(W) x 15.5cm(H)	Quick connectors
Weight: 1.8kg	Safe workload: 254kg
Decibels: 30dB	Minimum workload: 30kg
CPR/Transport mode	Mattress foam weight: 12kg

Note:

The above specifications are also applicable to those areas operating with the same power supply range.

Warranty:

2 years for pump and mattress

Reference Label Symbols:

	Waste Electrical and Electronic Equipment (WEEE) Directive	Waste Electrical and Electronic Equipment must not be disposed of through general waste streams. Please contact an authorised disposal facility.
	Refer to User Manual	Refer to this manual before operating.
	Operating Instructions	Identifies the user manual that contains the safety information and operating instructions for the equipment.
	Protective Earth (Ground)	Terminal is intended for connection to an external conductor for protection against electrical shock in case of a fault, or is the terminal of a protective earth (ground) electrode.
	Equipotentiality (Equipotential Earth)	Identifies terminals which, when connected together, bring the various parts of the equipment to the same potential.
	Type B applied part	Identifies a type B applied part complying with IEC 60601-1. Classification of protection against electrical shock.
	Caution	There is a risk of damage to equipment.
	Ingress Protection (IP) Rating	IPX4: Water splashing against the equipment from any direction will have no harmful effect.
	CE Mark	Signifies that this product meets the General Safety and Performance Requirements (GSPR) of the European Medical Device Regulations.

CONTACT INFORMATION

MEDevice Limited

Tower House, Lucy Tower Street, Lincoln, LN1 1XW

www.medevice.uk

info@medevice.uk

Telephone UK +44 07340 512099

The UDI information can be found on the back of the pump housing and on the mattress cover.

REF AER Fusion Pump M-AFP
Alternating Pressure Pump with Hybrid Mattress, Input Rating: 220-240V~, 50Hz, Max.1A

   **CE0197 IP21** **MD** 

 Airflo (Xiamen) Medical Co., Ltd.
1F, 3F, 4F, No. 6, East Haijing Road, Haicang Xiamen, Fujian, China

 MEdDevice Ltd
Tower House, Lucy Tower Street, Lincoln, England, LN1 1XW

EU **REP** Share Info GmbH **UK** **REP** SHARE INFO LTD
Am Schulzentrum 12, 3rd Floor, Office C, Townend House,
41564 Kaarst, Germany Park Street, West Midlands, Walsall,
WS1 1NS, UK

 YYYY-MM **SN** XXXXXXXXXXXXX



(01)06972910603166(10)YYMM(21)XXXXXXXXXXXX

REF AER Fusion Hybrid Mattress - M-AF690200

 Airflo (xiamen) Medical Co., Ltd
1F, 3F, 4F, No. 6, East Haijing Rd,
Haicang Xiamen, Fujian, China

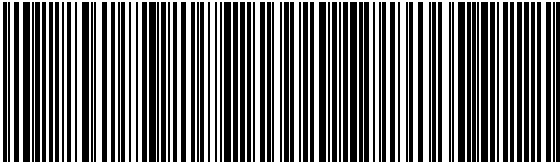
EU **REP** Share Info GmbH
Am Schulzentrum 12,
41564 Kaarst, Germany

UK **REP** SHARE INFO LTD
3rd Floor, Office C, Townend House,
Park Street, West Midlands, Walsall,
WS1 1NS, UK

 MEdDevice Ltd
Tower House, Lucy Tower Street,
Lincoln, England, LN1 1XW

 **254Kg** **CE0197** **MD**  

 YYYY-MM **SN** XXXXXXXXXXXXX



(01)06972910603173(10)YYMM(21)XXXXXXXXXXXX

IEC 60601-1-2