medstrom aria® flex

Semi-Dynamic Mattress System
USER MANUAL

PRO00035
Revision 1.3

medstrom+
Improved Patient Outcomes

About this Document

Important:

The equipment must be installed and operated in the manner for which it is intended as outlined in this User Manual. The caregiver/user is responsible for reading and understanding the User Manual as it contains instructions for safe installation and use of the device. If instructions in this manual are unclear, please contact Medstrom Ltd customer support (see section '21. Manufacturer's Details' for contact details).

Medstrom Ltd will not be responsible for any injuries resulting from failure to comply with the instructions and precautions in this manual.

Read the User Manual carefully before use and retain for future reference.

Warning:

No modification to the Aria Flex Mattress System is allowed.

Note: Information in this User Manual is subject to change without notice and does not represent commitment on the part of Medstrom Ltd. No part of this manual may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying and recording for any purpose without the written permission of Medstrom Ltd.

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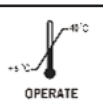
1. Conventions used in the Manual

	**Warning:** **A Warning is a statement that alerts the user to the possibility of injury, death or other serious adverse reactions associated with the use or misuse of the device.**
	**Caution:** A Caution is a statement that alerts the user to the possibility of a problem with the device associated with its use or misuse.
	**Important:** Indicates a harmful situation that could result in damage to the product or something around it.
Note:	Indicates to explain or amplify a procedure or condition.

2. Explanation of Label Symbols

	Warning		Caution		Important
	Refer to User Manual		Consult Operating Instructions		Start/Stop Button
	Manufacturer		Date of Manufacture	**Note:**	Note
	Catalogue Number		Serial Number	IP21	Protection from Ingress of Fluids
	Safe Working Load		Class II Electrical Device (Double Insulated)		Type BF Applied Part
	Possible Electric Shock Hazard		Not Suitable for use in presence flammable anaesthetic mixture with oxygen or nitrous oxide		Use 0.1% chlorine solution diluted to 1,000ppm
	Machine Wash Max Temperature		Tumble Dry Medium		Do Not Dry Clean
	Do Not Iron		Do Not Use Sharp Instructions		No Smoking
	Fragile, Handle with Care		Keep Dry		Protect from Heat and Radioactive Sources
	Operating Temperature Limitation		Humidity Limitation		Atmospheric Pressure Limitation
	Storage Temperature Limitation -10°C to +40°C		Medical Device under EU MDR 2017/745		Authorised Representative in Europe

CH REP	Authorised Switzerland Representative		Foot End
	Disposal of electric and electronic equipment in compliance with WEEE regulations. This product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment.		
CE 0197	Conformitè Europëenne (CE) Mark indicates conformity in accordance with EU Medical Device Regulations 2017/745.		

3. Introduction

Thank you for choosing to use the Medstrom Aria Flex Semi-Dynamic Mattress System. The product is a pressure redistributing mattress with an optional control unit intended to reduce the risk of pressure related tissue injuries.

The Aria Flex Mattress System features include:

- Innovative cell-in-cell design and valve system to allow the patient to be effectively immersed at all times.
- Self-adjusting for all patient morphologies and positions.
- Zoned for specific pressure redistribution and protection to vulnerable areas.
- Super-soft comfort layer on top of the core mattress.
- Firm surrounding perimeter for easier patient mobilisation.
- Multi-stretch, breathable cover to contour to the patient and assist with microclimate, moisture build-up.
- Control unit that can 'step' up the patient's therapy to continuous low pressure and alternating low pressure therapy modes and offer additional bespoke options such as comfort adjust.

Medstrom Ltd regularly pursues the goal of manufacturing products that are durable and of a superior quality. All required functions are tested prior to delivering products to customers. All our devices are tested before leaving our warehouse.

4. Intended Use and Contraindications

⚠ Warning:

Always consult a physician or health professional before using the Aria Flex Mattress System. The use of this system does not replace the regular repositioning, monitoring, and nursing of the patient.

4.1. Intended Use

The Aria Flex Mattress System is intended to treat and prevent pressure ulcers by achieving low contact pressures through immersion, therefore increasing the surface area and redistributing pressure. With the addition of the control unit, it converts the system into constant immersion (continuous low pressure therapy) or alternating low pressure therapy.

Note: The Aria Flex Mattress System is designed for patients who have existing pressure ulcers and patients who are at risk of developing a pressure ulcer.

4.2. Deviations from Intended Use

Any deviations from the intended use may result in reduced performance of the Aria Flex Mattress System and is excluded from warranty and liability.

4.3. Environment of Use

The Aria Flex Mattress System is intended to be used in the following environments:

- Hospitals / medical facility.
- Professional healthcare facilities.
- Domestic healthcare.

4.4. Contraindications

The Aria Flex Mattress System, in alternating low-pressure mode, is not suitable for unstable spines.

The Aria Flex Mattress System would be indicated for use for patients with unstable spinal injuries when used in the non-powered mode without control unit attached and with standard of care practices for such patients.

5. Warnings, Cautions and General Information

⚠ Warning:

The Aria Flex Mattress System is intended for use as a mattress replacement system. The risk of entrapment may occur when it is used on an inappropriate bed frame that leave gaps between the mattress and head panel, foot panel, and side rails. The Aria Flex Mattress System is NOT to be used when such gaps are present.

Where the Aria Flex Mattress System is used on bed frames, compatibility should be assessed independently, and it is the caregiver/users responsibility to ensure it fits the bed frame correctly.

Note: Medstrom Ltd is NOT responsible for the placement of the mattress and the head panel, foot panel, or side rail which presents a risk of harm to patients.

⚠ Warning:

When using the Aria Flex Mattress System, always ensure that the patient is positioned properly within the confines of the bed. Do not let any parts of the body stick out over the side or between the bed rails when the mattress is being used.

The medical professional is responsible for applying their best medical judgment when using this system. There are orthopaedic and neurological patients that require body positioning to be maintained in specific alignment. The use of the Aria Flex Mattress System for these patients should be considered on an individual basis and discussed with the attending physician.

- Suitable for continuous use.
- The materials used in the manufacture of all components of the mattress comply with the required fire safety regulations.
- Do not allow sharp objects to penetrate the mattress material.
- Do not store in damp conditions.

Medstrom Ltd advise against smoking to prevent the accidental secondary ignition of associated items which may be flammable, such as bed linen. Keep ignition sources away from the mattress and adhere to the following:

- Not suitable for use with oxygen or in an oxygen enriched environment, e.g. an oxygen tent.
- Do not use the system in the presence of flammable anaesthetic mixture with oxygen or nitrous oxide. Unplug the control unit when using oxygen administering devices other than the nasal mask.
- Do not smoke in bed/on the mattress.
- Do not burn candles in the same room as the bed/mattress.
- Do not use matches or lighters in the vicinity of the bed/mattress.
- Do not have electrical equipment in the vicinity of the bed/mattress e.g. a TV over the bed.
- Do not use electric blankets in combination with the bed/mattress.
- Do not have fires and heaters in the vicinity of the bed/mattress.
- Do not place hot items such as hairdryers or heated appliances on the bed/mattress.
- If you use a mobility aid, keep it within reach of your bed/mattress.
- Do not use in an outdoor environment.
- No part of the medical system should be maintained while it is in use by the patient.
- Not suitable for sterilisation.
- The mattress must be properly set up as directed.
- Do not use abrasive cleaners, e.g., Clearsol, Hycolin, Lyorthol, Sekural Soft and Turbo break, as these may destroy the cover materials (see section '13. Care and Maintenance').

To reduce the risk of electric shock, adhere to the following. Failure to do so could result in injury or equipment damage.

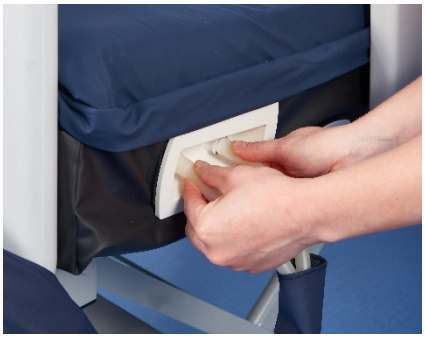
- Immediately after using the Aria Flex control unit, unplug it from its power source.
- Do not place or store the control unit where it can fall or be pulled into a sink or bath.
- Do not place or drop the control unit into water or other liquid.
- Do not remove the back of the control unit, this could result in potential electric shock hazard.

⚠ Warning:
Water or other liquids can cause corrosion and the control unit may not operate as intended and can result in a potential hazard for the user.

The above warnings, cautions and any safety considerations should be observed on a routine and regular basis, not only upon installation.

6. Installing the Mattress and Control Unit

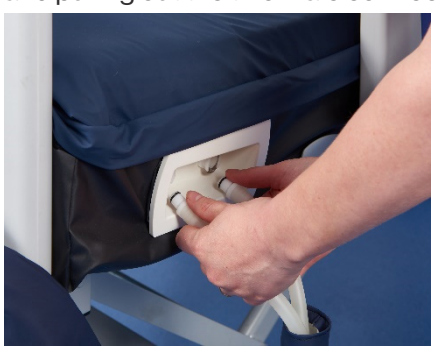
1. Remove the existing mattress from the bed frame and store in a safe place.
2. Place the mattress on to the bed frame, ensuring the foot symbol is at the foot end and uppermost.
3. Fit the mattress on the bed frame.
4. Place linen, if required, on the mattress. (see section '6.2. Recommended Linen').
5. If the control unit is required, secure the control unit on to the footboard of the bed frame using the securing hooks.
6. Locate the mattress connections on the right foot end of the mattress.
7. Insert the two male connectors at the end of the hose set into the mattress as shown in the images below:



8. Ensure the mains cable is connected to the control unit and plugged in to a suitable mains power outlet.
9. Press the Power ON button to turn the control unit on (see section '9. Control Unit Functions' for further control unit instructions).
10. Place the patient on the mattress.

6.1. Disconnecting the Aria Flex Control Unit

1. To disconnect the control unit from the mattress, locate the connections at the foot end of the mattress. Disconnect the hose set by pressing down on the buttons and pulling out the two male connectors.



2. Turn off the control unit (see section '9. Control Unit Functions').
3. Unplug the control unit from the mains power outlet.

Note: If the Aria Flex Mattress System is being used in non-powered mode, it is essential that the control unit is disconnected. If the Aria Flex Mattress System is being used in powered mode, it is essential that the control unit is connected correctly and switched on.

6.2. Recommended Linen

Based upon the patient's specific needs, the following may be utilised:

- Incontinence barrier pad for patients incontinent of urine and/or stool, and patients with heavily draining wounds.
- Top sheet, blanket and/or bedspread as needed for patient comfort, however these should not be fitted tightly or tucked into the mattress as hammocking may occur and the therapeutic benefits of the Aria Flex mattress may be compromised.
- Minimal padding between the patient and the surface to provide optimum performance.

7. Transport

The Aria Flex Mattress System should be transported in the non-powered mode of operation (i.e. no control unit).

8. Cardiopulmonary Resuscitation (CPR)

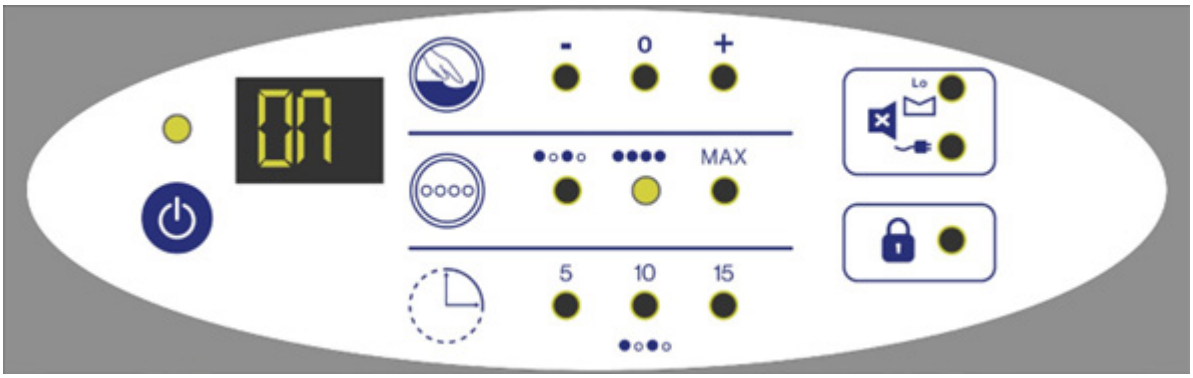
If the Aria Flex Mattress System is in non-powered mode, no action is necessary as the surface is stable enough to perform cardiopulmonary resuscitation (CPR).

If the Aria Flex Mattress System is in powered mode (with control unit), disconnect the control unit from the mattress (see section '6.1. Disconnecting the Aria Flex Control Unit') before performing cardiopulmonary resuscitation (CPR).

9. Control Unit Functions

9.1. Powered Mode (Control Unit)

The Aria Flex Mattress System can be converted to powered therapy with the addition of a control unit. This converts the system into constant immersion (continuous low pressure therapy) or alternating low pressure therapy.



9.1.1. Power

Press the **power** button to turn the control unit on. When the control unit is on, the LED will display the word 'ON'. To turn the control unit off, press the **power** button. When the control unit is off, no LEDs will display.

9.1.2. Mode Button

The Aria Flex has the option of two therapy modes:

- Constant Immersion (Continuous Low Pressure).
- Alternating Low Pressure Therapy.

9.1.3. Constant Immersion (Continuous Low Pressure) ●●●●

For powered immersion where the cells maintain constant pressure to maximise patient contact area, press the **mode** button until an LED is visible under the **continuous low pressure** icon.

Note: When the control unit is powered on, the system will default to Constant Immersion mode.

9.1.4. Alternating Low Pressure ●○●○

The Aria Flex Mattress System can be placed in alternating low pressure therapy mode. This alternates the pressure between the cells in a 1-in-2 cycle to provide periodic off-loading. For this therapy mode, press the **mode** button until an LED is visible under the **alternating low pressure** icon.

9.1.5. Max Inflate MAX

This function will rapidly inflate the cells to maximum pressure (i.e. maximum inflation) to allow for a stable surface for repositioning, nursing procedures or entry/exit from the bed. This is an untherapeutic mode, therefore as a safety feature and to avoid accidental use, max inflate is locked out. To use max inflate press and hold the **mode** button until an LED is visible under the **max inflate** icon.

Note: As an additional safety feature, max inflate will automatically switch off and default to the last used therapy mode after 20 minutes.

9.1.6. Cycle Times

When the control unit is operating in alternating low pressure therapy mode, it is possible to adjust the cycle times (how often the cells alternate) between 5 minutes (faster cycle), 10 minutes (default cycle) or 15 minutes (slower cycle).

Altering the cycle time allows bespoke therapy to be selected dependent on patient preference or tolerance.

By selecting a 15 minute cycle, this may also be beneficial as you are 'stepping down' the patient to non-powered therapy. To adjust the cycle times, press the **cycle** button until an LED is visible under the required cycle time.

9.1.7. Comfort Adjust

The softness/firmness of the mattress may be adjusted to suit individual patient preference. To make the mattress softer, press the **comfort** icon until a LED is visible under the softer icon (-). To make the mattress firmer, press the **comfort** icon until a LED is visible under the firmer icon (+).

Note: When first switched on, the control unit will default to medium comfort (0). All comfort settings are within a therapeutic window and will not alter the therapeutic benefits for the patient.

9.1.8. Lock/Unlock

The control unit will automatically lock-out after 30 seconds of inactivity. When the control unit is locked out, no functions can be altered to prevent unauthorised changes of the therapy settings chosen. When the control unit is locked, an LED will be visible adjacent to the **lock** button. To unlock the control unit, press and hold the **lock** button until the LED disappears.

9.1.9. Alarm Functions

The control unit has both a visual and an audible power failure and low pressure alarm.

- If the alarm sounds and the **power failure** LED is illuminated , ensure the mains cable is still connected and plugged in to a wall socket.
- If the alarm sounds and the **low pressure** LED is illuminated Lo, ensure the mattress hoses are securely connected to both the control unit and the mattress.
- To silence the alarm, press the **silence** button .

If the fault cannot be resolved, contact Medstrom Ltd or your medical Engineering Team.

10. Cleaning

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

Warning:
Contact with contaminated cleaning fluids can cause infections. Disinfectants can contain harmful substances.

When using disinfectant, follow the disinfectant manufacturer's Instructions for Use during cleaning and disinfection of the Aria Flex Mattress System. Wear personal protective equipment:

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

Warning:
Incompatible cleaning agents. The components of the Aria Flex Mattress System are made of thermoplastic polymers. Solvents can spoil synthetic material and coating. Strong acids or alkalis can cause damage.

10.1. General Cleaning

Mattress top covers should be cleaned regularly including between patients.

- Wipe the whole surface of the mattress with a neutral detergent e.g. soap and water, rinse with clean water and dry.
- If a disinfectant wipe is applied to the mattress cover, any residue should be wiped per the guidelines of the cleaning agent.
- Allow time for the cover to dry (normally less than 10 minutes) or dry with a clean cloth.
- Do not use abrasive cleaners.

10.2. Cleaning the Control Unit

Warning:

Remove the mains cable from the wall socket before cleaning the control unit. Do not spray any cleaning liquid directly on to the control unit.

- Turn off the control unit and unplug the mains cable from the mains power outlet (socket).
- Wet a soft cloth with water and mix it with approved or recommended disinfectant solution.
- Wipe off dirt and dust accumulations.
- Then dry the surfaces with a clean, soft cloth.

10.3. Contamination with Blood or Body Fluids

If the mattress top cover is not securely fixed onto the mattress, it could increase the risk of the inners of the mattress becoming contaminated.

- If the mattress top cover is heavily soiled or has been exposed to bodily fluids such as blood, urine or faeces it will require a more thorough cleaning and disinfection procedure.
- Large spillages of blood on the mattress top cover should first be disinfected by use of chlorine-releasing solutions instead of granules.
- Other body fluids should be removed with paper towels followed by use of chlorine-releasing solutions instead of granules.
- The mattress top cover should then be rinsed using clean water with a clean damp sponge.
- Wipe the Mattress Top Cover using a single-use wipe and a 0.1% chlorine solution (1,000ppm) with cold water.
- If required a 1% chlorine solution (10,000 ppm) and cold water may be used. Residual chlorine salts should be rinsed with clean water after the chlorine activation phase (normally less than 10 minutes).
- Allow time for the mattress top cover to dry (normally less than 10 min) or dry with a clean cloth.

Note: Medstrom Ltd provides laundry disinfection services. For further information, please call on +44 345 3711717.

If the mattress top cover is soiled or loses its water-resistant properties, it must be replaced. Any resulting damage of the mattress caused by a soiled top cover will be not covered by the warranty. Please follow the hygiene control regulations of your local authority.

Warning:

If the mattress top cover is not securely fixed onto the mattress, the cells and mattress top cover movement may be unstable and may cause risk of patient injury.

11. Disinfection

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

> ⚠ **Warning:**
> **Please follow the hygiene control regulations of your local authority.**

12. Inspection

The safe operating condition of the Aria Flex Mattress System has to be checked at each use by the operator or during use at least once in a year in particular with regards to the following:

- Condition of the air hoses.
- Condition of the air and foam cells.
- Condition of the cover.
- Check the mains cable and plug are not excessively worn or cut.
- Check the filter is not excessively dirty or clogged.

13. Care and Maintenance

13.1. Mattress - Exterior Components

- Inspect the mattress top cover for signs of damage or wear which could result in the contamination of the interior, e.g. tears, holes, damage to seams or zips, underside staining, etc. The frequency of these checks should be at each decontamination process, i.e. between patients or patient occupancy (or weekly for longer term patients).
- Care should be taken to avoid puncturing the mattress top cover with objects such as needles, scalpels, pat slides, acrylic nails, etc.
- Always keep the mattress top cover as clean as is practicable. The material is waterproof and vapour permeable.
- Frequent or prolonged exposure to high concentrations of aggressive disinfectant solutions will reduce the useful life of the mattress top cover.
- Where high concentration disinfectants e.g., > 10,000 ppm chlorine releasing agent (e.g., Haztab or bleach) or combined cleaning/chlorine releasing agent and detergent solutions are used to remove blood or other body fluids, covers should be thoroughly rinsed with clean water to remove any residues. This will help prevent any possible long term compatibility issues associated with disinfectant residues.
- Disinfection may also be achieved by laundering base cover at temperature not exceeding 60°C and top cover at a temperature not exceeding 95°C for 10 minutes each.
- Do not use abrasive cleaners such as Clearsol, Hycolin, Lyorthol, Sekural soft and Turbo Break, as these may destroy the cover materials (see section ‘10. Cleaning’).
- Do not iron.
- Ensure that the mattress top cover is thoroughly dried before remaking the bed or placing in storage.
- Approved disinfectants and cleaning agents:

Products	Concentration
Actichlor Plus	1,000 ppm
Anios Ddhs	Pure
Dürr Dental	Pure

Products	Concentration
Chlor-Clean Tablets	1,000 ppm
Dettol	5%
Dismozon Pur	4%
Ethanol	%70
Formaldehyde	%37
Germatol	5%
Hansamed (Spray)	Pure
Haz-Tabs	1,000 ppm
Hibicet	Pure
Incidin Active	2%
Incidin Extra N	2%
Incidin Foam	Pure
Incidin Plus	2%
Kodan Tinktur Forte	Pure
Medicarine	1,000 ppm
Mikrobac Forte	4%
Minudes	Pure
Natriumhypochlorite	0.1%
Octenisept (Spray)	Pure
Sagrotan (Spray)	Pure
Sagrotan Med (Spray)	Pure
Sanit P20	Pure
Softasept N (Spray)	Pure
Spring	Pure
Sprint 200	2%
Sterillium	Pure
Suma Bac D10	1%
Surfa'safe	Pure
Ultrasan	Pure
Virkon	10 G/L
Volvone	40%
Hydrogen Peroxide	1,000 ppm

13.2. Mattress - Interior Components

- Check air cells and mattress interior for signs of damage or contamination e.g. staining or evidence of fluid ingress. The frequency of these checks should be at each decontamination process, i.e. between patients or patient occupancy (or weekly for longer term patients).
- Care should be taken to avoid puncturing air cells with objects such as needles, scalpels, pat slides, acrylic nails, etc.
- All cells are replaceable and can be obtained easily from Medstrom Ltd.

13.3. Control Unit

- Inspect the condition of the mains cable and plug for signs of excessive wear or tears. If the mains cable is damaged, immediately remove the plug from the mains power outlet and replace the mains cable.
- Inspect the condition of the filter. Replacement filters can be purchased and used if filter is excessively dirty or damaged.
- Inspect the condition of the outer casing (including control panel) for signs of damage or cracking. If the outer casing is damaged in any way, immediately stop using the control unit, unplug from mains power outlet and contact Medstrom Ltd or your medical engineering team.

13.4. Recommended Checks

To prevent an unacceptable risk, all information necessary for correct replacement of detachable or interchangeable parts should be available and replaced by qualified personnel only. For full list of parts please refer to the Aria Flex Semi-Dynamic Mattress System Technical Manual.

14. Storage, Transport and Disposal

14.1. Storage and Transport

Thoroughly wipe down the outside of the support surface as described in section '10. Cleaning' and allow to air dry prior to storage.

Protect with suitable covering and return to storage area.

It is recommended not to fold the mattress and to avoid storage of the mattress other than in a flat format. The manufacturer does not recommend storing or stacking mattresses any more than 10 units high.

The control unit should be placed into the original packaging that it came with in order to fully protect it whilst in storage. If original packaging is not available, wrap in bubble wrap and place in a cardboard box.

Handle with care. Please report instances of damage or impact to Medstrom Ltd service personnel.

14.2. Operational and Storage Conditions

- An operating temperature range of +5°C to +40°C.
- A storage temperature range of -10°C to +40°C.
- A relative humidity range of 10% to 90%, non-condensing.

Suitable for all standard modes of transport when in the correct packaging.

14.3. Disposal

The mattress must be decontaminated before disposal.

The control unit must be disposed of observing the proper disposal of electrical and electronic equipment WEEE regulations.

> ⚠ **Warning:**
> **Mattress disposal should be in accordance with the local regulations.**

15. Troubleshooting

Problem	Inspection Procedure	Possible Solution
Control unit does NOT operate	Check if the two ends of the mains cable are safely connected to both the control unit and the wall socket.	Confirm that the wall socket has power supply.
	Check if the fuse has burnt out or is not correctly installed.	Turn off the power and check/replace the fuse.
	Ensure the control unit is not locked out.	Press the **lock** button and ensure an LED is NOT visible adjacent to the **lock** button.
Control unit is working, but the mattress is NOT inflating	Check if air comes out of the control unit and ensure the hoses are properly connected.	If the unit operates normally, but no air comes out, it is possible that the control unit has a mechanical problem that needs repair.
	Check and ensure the mattress connector is correctly fitted and free from damage.	Repair or replacement is necessary if the connector is damaged and cannot be restored, or if the material shows signs of excessive wear.
	Check if the air hose is damaged or shows signs of excessive wear.	Repair or replace as necessary.
	Inspect the air cotton filter to ensure it is not clogged or showing signs of deterioration.	Replace the filter if required.
Mattress is bottoming out	Check the patient does not exceed maximum patient weight.	If the patient weighs more than 250 kg, place the patient on a different mattress.
	Check for air leaks from the mattress.	Replace the cells if damaged.
Other	Issues other than those mentioned above.	Contact Medstrom on +44 345 3711717 for further advice and/or investigation.

16. Electromagnetic Compatibility (EMC)

Warning:

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Aria Flex control unit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The purpose of this testing is to ensure the Aria Flex Mattress System is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the Aria Flex Mattress System.

Warning:

Normal operation of the Aria Flex Mattress System can be affected by using a cell phone or a microwave oven. HF surgical equipment, magnetic resonance imaging or other radio radiant equipment near this product may cause malfunction or lead to loss of essential performance.

Warning:

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Guidance and manufacture's declaration – electromagnetic emission		
The Aria Flex control unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Aria Flex Mattress System should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic environment – guidance**
Conducted and Radiated RF emissions CISPR 11	Group 1	The control unit 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.
Conducted RF emissions CISPR 11	Class B	The control unit is suitable for use in all establishments, including professional/domestic and those not directly connected to the public low-voltage power supply network that supplies buildings used for professional/domestic purposes except for near active HF surgical equipment and the RF shielded room for magnetic resonance imaging.
Radiated RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations and flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The Aria Flex control unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Aria Flex Mattress System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge 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 transients/ bursts IEC 61000-4-4	±2 kV AC power supply lines; ±1 kV DC power/Signal lines. 100 kHz repetition frequency	±2 kV for AC power supply lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	±0.5 kV, ±1kV lines to lines; ±0.5 kV, ±1kV, ±2 kV lines to earth	±0.5kV, ±1kV lines to lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips 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 Aria Flex Mattress System control unit requires continued operation during power mains interruptions, it is recommended that the control unit be powered from an uninterruptible power supply or a battery.
Voltage interruptions IEC 61000-4-11	0% UT, 250/300 cycle	0% UT, 250/300 cycle	

Guidance and manufacture's declaration – electromagnetic immunity			
The Aria Flex control unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Aria Flex Mattress System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Note:	U_T is the a.c. mains voltage prior to application of the test level. E.g.: 25/30 means 25 periods at 50 Hz or 30 periods at 60 Hz. 250/300 means 250 periods at 50 Hz or 300 periods at 60 Hz		
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms in 0.15 MHz – 80 MHz; 6 Vrms in ISM bands between 0.15 MHz and 80 MHz (Professional healthcare facility environment), 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80MHz (Home healthcare environment)	3 Vrms in 0.15 MHz – 80 MHz, 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz (Home healthcare environment)	Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer to any part of the Aria Flex Mattress System control unit including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
	80% AM at 1 kHz	80% AM at 1 kHz	
Radiated RF EM fields IEC 61000-4-3	3 V/m (Professional healthcare facility environment); 10 V/m (Home healthcare environment), 80 MHz – 2.7 GHz 80% AM at 1 kHz	10 V/m (Home healthcare environment) 80 MHz – 2.7 GHz 80% AM at 1 kHz	Recommended separation distance: $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 Hz to 800 MHz $d = 1{,}2\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter manufacturer and d is the recommended separation distance in metres(m). Interference may occur in the vicinity of equipment marked with the following symbol: 
Note:	The ISM (industrial, scientific and medical) bands between 0.5 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.		

Recommended separation distance between Portable and mobile RF communications equipment and the Aria Flex Control Unit			
The Aria Flex control unit is intended for use in the electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the Aria Flex control unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Aria Flex control unit 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**		
	150kHz to 80 MHz d = 1,2√P	**80MHz to 800 MHz d = 1,2√P**	**800MHz to 2.7 GHz d = 1,2√P**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 Mhz, the separation distance for the higher frequency range applies.			
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and manufacture's declaration – electromagnetic immunity Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
The Aria Flex control unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Aria Flex control unit should assure that it is used in such an environment.							
Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**	**Compliancy Level (V/m)** (for home and professional healthcare)
385	380 – 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9	9
745							
780							

Guidance and manufacture's declaration – electromagnetic immunity Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
The Aria Flex control unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Aria Flex control unit should assure that it is used in such an environment.							
Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**	**Compliancy Level (V/m)** (for home and professional healthcare)
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28	28
870							
930							
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28	28
1845							
1970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9	9
5 500							
5 785							
Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
a. For some services, only the uplink frequencies are included. b. The carrier shall be modulated using a 50% duty cycle square wave signal. c. As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. while it does not represent actual modulation, it would be worst case.							

17. Technical Specification

The Aria Flex Semi-Dynamic Mattress System is suitable for continuous operation.

17.1. Mattress Specifications

Model reference:	APH401 Aria Flex Mattress
Mattress weight:	14.5 kg
Mattress dimension:	203 cm x 88 cm x 17 cm

Min. Patient Weight:	20 kg
Max. Patient Weight	250 kg
Cells Material:	TPU
Top Cover Material:	Polyurethane coated polyester
Base Cover Material:	PVC Coated Polyester Knitted Fabric 300DI FR Polyester PF FR PVC
Fire Retardancy:	BS 7177:2008+A1:2011
Expected service life:	Mattress and its accessories is 5 years
Specified shelf life:	2 years

17.2. Control Unit Specifications

Model Reference:	APH402 Aria Flex Control Unit
Control Unit Weight:	1.8 kg
Control Unit Dimension:	28 cm x 17 cm x 12 cm
Power Supply:	AC 220-240V 50 Hz, 0.09 A
Fuse Rating:	T1AH 250 V
Cycle Time:	5, 10, 15 minutes
Pressure Range:	10 – 32 mmHg
Flow Rate:	7 LPM
Expected service life:	5 years
Specified shelf life:	2 years

18. Consumables and Accessories

Catalogue No	Description
SP03499	Outer Mattress Cover
SP03500	Foam Base
SP03502	Foam Pillow
SP03501	Foam Topper
SP03503	Inner Foam Cover
SP03505	Inline Filter
SP03504	Individual Cell
SP04007	Control Unit Filter

Note: Use only Medstrom Ltd consumables and accessories.

19. Product Conformance Standards

The Aria Flex Semi-Dynamic Mattress System is developed in conformance with ISO 13485 Quality management system, ISO 14971 Risk Management, ISO 10993 Biocompatibility, Electrical Safety IEC 60601-1, Electro Magnetic Compatibility (EMC) 60601-1-2, UK Medical Device Regulation (2002) and Medical Device Regulations (MDR 2017/745).

The consumables and accessories section of this manual are in conformance with NICE guidelines.

20. Warranty

All internal mattress components are covered by a 24 months manufacturer's warranty. The mattress top cover is covered by a 12 months manufacturer's warranty. The control unit and electrical components are covered by a 24 months manufacturer's warranty. Damages arising from improper use will not be covered by this warranty. Improper use is defined as those caused by burns, chemicals, excessive loads, staining, cuts or abrasions, improper maintenance including handling and/or cleaning.

Note: All warranties subject to terms and conditions of trading.

In order to claim product under warranty refer to the batch number printed on the product label.

Summary user instructions are also printed on the mattress top cover.

21. Manufacturer's Details

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info@medstrom.co.uk

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EC REP
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CH REP CHRN-IM-20000224

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For further information relating to technical characteristics, maintenance or After Sales Service, please consult the Aria Flex Semi Dynamic Mattress System Technical Manual available on request.

CE 0197

GTIN Number: 5060467210195

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Improved Patient Outcomes

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