



## **Semi-Dynamic Mattress Instructions for Use**

**medstrom<sup>+</sup>**  
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 product 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 17 for contact details).

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



**READ THE USER MANUAL CAREFULLY BEFORE USE AND RETAIN FOR FUTURE REFERENCE.**



**NO MODIFICATION TO THIS EQUIPMENT IS ALLOWED.**



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# 1

## Convention Used in This Manual

This manual includes information essential to the safety of the patient, personnel and equipment during normal operation of the Aria Flex Mattress. The safety information is displayed in this user manual by using the following conventions.



**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.



Indicates to explain or amplify a procedure or condition.

## 2 Explanation of Label Symbols

	Warning		Machine Wash 60°C Max
	Caution		Tumble Dry Medium
	Important		Do Not Dry Clean
<b>NOTE</b>	Note		Do Not Iron
	Manufacturer		Do Not Bleach
	Date of Manufacture		Do Not Use Phenol
	Authorised Representative in the European Community		Do Not Use Sharp Instruments
	Medical Device Under 2017/745		No Smoking
	Catalogue Number		Fragile, Handle with Care
	Serial Number		Keep Dry
	Consult Instructions for Use		Protect from Heat and Radioactive Sources
	Foot End		Temperature Limitation
	Min-Max Patient Weight		Humidity Limitation
	Medical Device Directive 93/42/EEC		Atmospheric Pressure Limitation
	Safe Working Load		

Thank you for choosing to use a Medstrom Aria Flex mattress. The product is a non-powered, pressure redistributing mattress intended to reduce the risk of pressure related tissue injuries.

The Aria Flex Mattress 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.

**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 mattresses are tested before leaving our warehouse.**

## 4 Intended Use and Contraindications



**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.**

### 4. Intended Use

The device is intended to treat and prevent pressure ulcers by achieving low contact pressures through immersion, therefore increasing the surface area and redistributing pressure.

#### NOTE

**The Aria Flex system is designed for patients who have existing pressure ulcers and patients who are at risk of developing a pressure ulcer.**

### 4.1 Deviations from Intended Use

Any deviations from intended use may result in poor performance of the mattress and is excluded from warranty and liability.

### 4.2 Environment of Use

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

- Hospitals
- Professional Healthcare Facilities
- Domestic Healthcare

### 4.3 Contraindications

Aria Flex is not suitable for patients with unstable spines.

## 5 Warning, Cautions and General Information

### 5.1 Warnings, Cautions and General Information



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

Where Aria Flex is used on bed frames, not supplied by Medstrom Ltd, compatibility should be assessed independently and it is the caregiver/user's responsibility to ensure the Aria Flex 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.**



When using the mattress system, always ensure that the patient is positioned properly within the confines of the bed. Do not let any extremities protrude over the side or between the bed rails when the mattress is being used.

The medical professional is responsible for applying his/her best medical judgment when using this system.

- Suitable for continuous use
- Do not allow sharp objects to penetrate the mattress material
- Do not store in damp conditions

Medstrom Ltd advises 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:

- Do not smoke in bed/on the 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 or mattress
- Do not use in an outdoor environment
- No part of the medical device should be serviced while it is in use by the patient



## 5 Warning, Cautions and General Information

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- Not suitable for sterilisation
- The mattress must be properly set up as directed
- Do not use abrasive cleaners, phenol disinfectants, solvents or alcohol-based cleansers, e.g. Dettol, Phenicol, Clearsol, Stericol, Hycoline, as these may destroy the cover materials. (see Care and Maintenance on page 14).

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

## 6,7&8 Installation, Transport and Clinical Procedure

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### 6. Installing the Mattress

1. Remove the existing mattress from the bed frame and store in a safe place.
2. Place the Aria Flex Mattress on to the bed frame, ensuring the foot symbol and Medstrom logo is at the foot end and uppermost.
3. Fit the Aria Flex on the bed frame.
4. Place linen on top of the Aria Flex Mattress (see section 6.1 for recommended linen).
5. Place the patient on the Aria Flex Mattress.

#### 6.1. 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 should not be fitted tightly or tucked into the mattress as hammocking may occur and the therapeutic benefits of the Aria Flex may be compromised.
- Minimal padding between the patient and the surface to provide optimum performance.

### 7. Transport

The Aria Flex (non-powered) is suitable for transport.

### 8. Cardiopulmonary Resuscitation (CPR)

The Aria Flex (non-powered) is suitable for CPR.

## 9&10 Cleaning, Disinfection and Inspection

### 9. Cleaning

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



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

Please follow these instructions carefully and wear personal protective equipment if necessary:

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



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

#### 9.1. General Cleaning

Mattress top covers should be cleaned regularly including between patients.

- Wipe the mattress top cover with soap and water, rinse with clean water and dry.
- If a disinfectant wipe is applied to the mattress top cover, any residue should be rinsed with clean water after the dwell time phase (normally less than 10 minutes).
- Allow time for the cover to dry (normally less than 10 minutes) or dry with clean paper towels.
- Do not use abrasive or phenolic based cleaners.

#### 9.2. 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.**

## 9&10 Cleaning, Disinfection and Inspection

- 9.2. 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 cloth.
  - Wipe the mattress top cover using a single-use wipe and a 0.1% chlorine solution (1,000ppm) and cold water.
  - If required, a 1% chlorine solution (10,000ppm) and cold water may be applied. Residual chlorine salts should be rinsed with clean water after the chlorine activation phase (normally less than 10 minutes).
  - Allow time for the cover to dry (normally less than 10 min) or dry with clean paper towels.

 **NOTE**

**Medstrom Ltd provides laundry disinfection services. For further information, please call on +44 845 371 1717.**

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 spoiled mattress top cover will be not covered by the warranty. Please follow the hygiene control regulations of your local authority.



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

### 10. Disinfection

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

## 9&10 Cleaning, Disinfection and Inspection

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### 10.1. Disinfection Procedures

Please follow the procedure required by your local health authority.



**Please follow the hygiene control regulations of your local authority.**

### 10.2. Inspection

Prior to patient use, between patients, and at least yearly, the safe operating condition of the Aria Flex Mattress should be checked with regards to the following:

- Condition of the air hoses
- Condition of the air and foam cells
- Condition of the cover

# 11 Care and Maintenance

## 11.1. Mattress - Exterior Components

- Inspect 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 cover with objects such as needles, scalpels, pat slides, acrylic nails, etc.
- Always keep the 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 cover.
- Where high concentration disinfectants e.g. > 10,000ppm 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.
- Alternatively, disinfection may be achieved by laundering cover at temperatures not exceeding 60°C for 10 minutes.
- Do not use abrasive cleaners, phenol disinfectants, solvents or alcohol-based cleansers, e.g. Dettol, Phenicol, Clearsol, Stericol, Hycoline, as these may destroy the cover materials.
- Do not iron and do not bleach.
- Ensure that the cover is thoroughly dried before remaking the bed or placing in storage.

## Mattress - Interior Components

- 11.2.
- Check the air cells and the 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.

# 11 Care and Maintenance

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## 11.3. Servicing

To prevent an unacceptable risk, all information necessary for correct replacement of detachable or interchangeable parts will be available to qualified service personnel only.

## 12 Storage, Transport and Disposal

### 12.1. Storage and Transport

Thoroughly wipe down the outside of the support surface as described in the previous section 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.

Handle with care. Please report instances of damage or impact to Medstrom Ltd Service Personnel.

#### Operational and Storage Conditions

- A temperature range of 10°C to +40°C
- A temperature range for storage -15°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.

### 12.2. Disposal

The Aria Flex must be decontaminated before disposal.



**Mattress disposal should be in accordance with the local regulations.**



## 13 Product Conformance Standards

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The Aria Flex Mattress is developed in conformance with ISO 13485 Quality management system, ISO 14971 Risk Management, ISO 10993 Biocompatibility, Medical Device Directive (MDD 93/42/EEC) and Medical Device Regulations (MDR 2017/745).

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

## 14 Technical Specification

The Aria Flex System is suitable for continuous operation.

<b>Model Reference:</b>	APH401 Aria Flex Mattress
<b>Mattress Weight:</b>	14.5kg
<b>Mattress Dimension:</b>	203cm x 88cm x 17cm
<b>Min. Patient Weight:</b>	20kg
<b>Max. Patient Weight:</b>	227kg
<b>Cells Material:</b>	TPU
<b>Cover Material:</b>	Nylon/PU
<b>Fire Retardancy:</b>	BS 7177:2008+A1:2011
<b>Expected Service Life:</b>	Mattress and its accessories is 5 years.
<b>Specified Shelf Life:</b>	2 years.

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**Consumables and Accessories**

Catalogue Number	Description
ARIAAC00106BLU	Aria Flex Top Mattress Cover

 **NOTE**

**USE ONLY MEDSTOM LTD APPROVED CONSUMABLES AND ACCESSORIES.**

## 16 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.

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.

All warranties subject to terms and conditions of trading.

 **NOTE**

**Normal wear and tear is NOT included in the manufacturer's warranty.**

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 outer cover.

## 17 Contact Information

Medstrom Ltd customer service is available to answer questions 24/7 for business and upgrades. Our sales/clinical team is available for pricing, order processing and order status.

In the event of a complaints, questions regarding the product, service support or reporting of incidents, please contact the following:

### **Sales & Service:**

Medstrom Ltd  
2 Cygnus Court, Castle Donington,  
Derbyshire, DE74 2SA  
United Kingdom  
Tel: +44 845 371 1717  
Email: [info@medstrom.co.uk](mailto:info@medstrom.co.uk)

### **Complaints:**

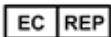
Medstrom Ltd  
2 Cygnus Court, Castle Donington,  
Derbyshire, DE74 2SA  
United Kingdom  
Tel: +44 845 371 1717  
Email: [info@medstrom.co.uk](mailto:info@medstrom.co.uk)

### **Distributor:**

Medstrom Ltd  
2 Cygnus Court, Castle Donington,  
Derbyshire, DE74 2SA  
United Kingdom  
Tel: +44 845 371 1717  
Email: [info@medstrom.co.uk](mailto:info@medstrom.co.uk)



APOLLO HEALTHCARE TECHNOLOGIES LTD.  
Holme Street, Liversedge, WF15 6JF, UK. Tel: +44 (0) 1924 614567  
Email: [sales@apollo-ht.co.uk](mailto:sales@apollo-ht.co.uk) Web: [www.apollo-ht.co.uk](http://www.apollo-ht.co.uk)



### **EU Representative:**

PaMed Consulting s.c. Tywonia 2, 37-500 Jaroslaw, Poland  
Tel: +48 509 778 660  
Email: [info@pamed-consulting.eu](mailto:info@pamed-consulting.eu)

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