



Improved Patient Outcomes

Mattress Bolsters USER MANUAL

PRO00064
Revision 1.1





This User Manual contains safety information and operating instructions.
Please retain for future reference.

Contents

1.	Notifications used in the Manual	5
2.	Identification of Labels and Symbols	5
3.	Intended Use of the Mattress Bolster	6
4.	General Information	6
5.	Precautions for Use	7
5.1.	General Precautions	7
5.2.	Bed Frame Compatibility	8
5.3.	Contraindications	8
6.	Transport and Storage	8
7.	Mattress Bolster Features	9
8.	Instructions for Use	10
9.	Operational Maintenance	11
9.1.	Cleaning	11
9.2.	High Temperature Laundering	11
9.3.	Low Temperature Ozone Laundering	11
9.4.	Drying Post-Laundry	11
9.5.	Medstrom Laundry Disinfection Service	12
10.	Preventive Maintenance	12
11.	Disposal	12
12.	Warranty	12
13.	Manufacturer's Details	13

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 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.

Medstrom Ltd will not be responsible for any damage or 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 mattress bolster is allowed.

Note: Information in this manual is subject to change without notice. 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.

1. Notifications used in the Manual



	Warning / Danger There is a risk to safety. Please read this safety instruction and note any warning labels on the mattress bolster.
	Caution There is a risk of damage to equipment. Please read this instruction.
Important:	Important information that provides further details for a procedure or condition.
Note:	A note that provides further explanation or advice.

2. Identification of Labels and Symbols











Label affixed to mattress bolsters:



Manufacturing and device information label (screen printed label).

	Dynamic data entry label displaying the manufacture date and the UDI for each batch of mattress bolsters manufactured. Part of screen-printed label.
	Mattress bolster orientation (this features on both bolsters). Part of screen-printed label.

Reference symbols used on the mattress or in the manual:

	Caution	There is a risk of damage to the equipment.
	Catalogue Number	Indicates Medstrom's catalogue number to identify the medical device.
	Medical Device	Identifies the equipment as a medical device.
	Operating Instructions	The manual contains the safety information and operating instructions for the equipment.
	Refer to User Manual	Refer to this manual before use.
	Maximum Patient Weight	The maximum weight the product is designed for.
	Manufacturer	The manufacturer of the equipment and their address.
	Date of Manufacture	The date that the equipment was manufactured.
	Authorised Representative in Europe	The name of the European Union representative company.
	CE Mark	Conformité Européenne (CE) Mark indicates conformity in accordance with EU Medical Device Regulations 2017/745.

3. Intended Use of the Mattress Bolster

The Medstrom Mattress Bolsters are designed to be partnered with any compatible mattress and bed combination within a hospital, nursing home or community environment in order to support plus-size patients with a wider body morphology on a wider platform.

The mattress bolster is intended to be used in:

- application environment 1 (intensive/critical care),
- application environment 2 (hospital/medical facility, acute and medical supervision),
- application environment 3 (medical area, long term care), and,
- application environment 4 (domestic care),
- application environment 5 (outpatient, ambulatory care).

4. General Information

Important:

Read this manual carefully before use and retain for future reference.



Images of the mattress bolsters in use.

5. Precautions for Use

Important:

Read this manual carefully before first use of the mattress bolsters and any subsequent maintenance.

5.1. General Precautions

The following is a list of general precautions which should be followed when using the mattress bolster:

Avoid Sharp Objects

Caution:

Do not place sharp objects such as scissors, needles, syringes, scalpels or other sharps or equipment with sharp corners or edges, on the mattress bolsters as these may damage the cover.

- Take extra care when using medical equipment such as monitors, drip stands, side rails, and transfer boards.
- When using slings and slide sheets take care to ensure that buckles do not scratch or snag the mattress bolster cover during use.
- Where the mattress and bed combination is not supplied by Medstrom, the compatibility with the mattress bolsters should be assessed independently.
- You should not change the combination of the Medstrom mattress bolsters, without the written permission of the manufacturer.
- Orientation of the Medstrom mattress bolsters is key when mobilising due to the higher density foam material in the centre, enabling greater and stability for patients when egressing from the side of the bed.
- Using detergent / disinfectant products does involve some risk. Always wear Personal Protective Equipment (PPE), follow the instructions and avoid mixing different products.

Avoid Ignition Sources

- Don't smoke in bed/on the mattress/bolsters.
- Don't burn candles in the same room as the bed/mattress/bolsters.
- Don't use matches or lighters in the vicinity of the bed/mattress/bolsters.
- Don't have electrical equipment in the vicinity of the bed/mattress/bolsters, e.g. a TV over the bed.
- Don't use electric blankets in combination with the bed/mattress/bolsters.
- Don't have fires and heaters in the vicinity of the bed/mattress/bolsters.
- Don't place hot items such as hairdryers or heated appliances on the bed/mattress/bolsters.
- If you use a mobility aid keep it within reach of your bed or device.

5.2. Bed Frame Compatibility

Compatibility testing has only been completed with the Medstrom Aria Flex mattress and the Versatech 1100 bed frame.

Caution:

Where the Medstrom foam mattress bolsters are used with bed frames and mattresses not supplied by Medstrom, the compatibility with the bed frame and mattress should be assessed independently.

5.3. Contraindications

There are no recognised contraindications with regard to the use of this product.

Caution:

Do not use the product without a cover. The cover provides a protective barrier against biological contamination of the foam.

6. Transport and Storage

- Store the mattress bolster flat.

Caution:

Do not fold.

Caution:

Do not place heavy objects on the mattress bolster surface when not in use.

- Keep the mattress bolster clean.
- Regularly inspect the exterior and interior of the mattress bolster.
- Store in a cool dry place.
- Maximum and minimum storage temperatures are between +50°C and -5°C.
- Maximum and minimum storage humidity limits are between 90% and 10%.

Caution:

Do not store in damp conditions.

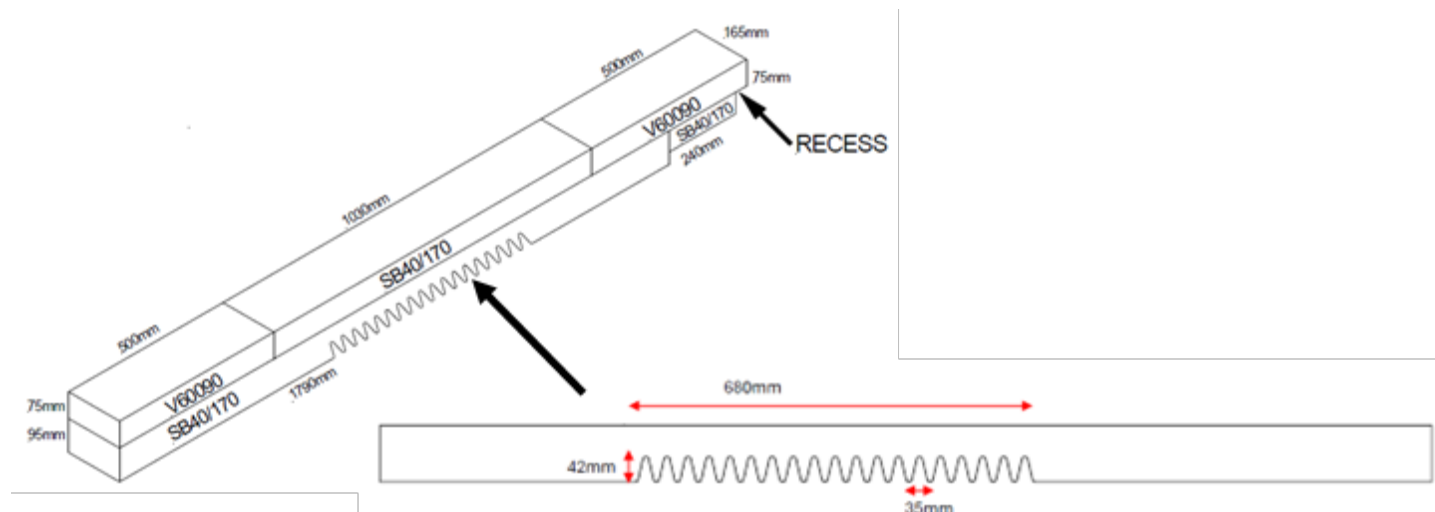
7. Mattress Bolster Features

The following is a list of features of the foam mattress bolster:

Construction

- Two foam layers with supportive heel zone compositions .
- Firm base with recessed wall for air hose access.
- Profiled base hinges.
- Printed HF welded, moisture vapour permeable, multi-stretch cover with zip access.
- Two bolsters in a set, connected by four woven fabric straps with adjustable buckles.

Dimensions



- Each bolster measures 2030 mm (L) x 165 mm (W) x 170 mm (D).

Medical Device Classification

- Class I.

Flammability

- The foam mattress bolsters meet the requirements of BS7177:2008 for medium hazard.
- The interior materials meet the requirements of The Furniture & Furnishings (Fire) (Safety) Regulations 1988.

Maximum Patient Weight

- The mattress bolsters are designed for a patient of maximum weight of 250 kg (39 stone).
- Check the mattress bolsters are suitable for the intended patient in terms of pressure care risk assessment and are appropriate to the safe working load of the bed.

8. Instructions for Use

Caution:

Should any serious incident occur in relation to the mattress bolster, it should be reported to Medstrom and the competent authority of the Member State in which the user and/or patient is established.

Healthcare establishments are divided into sectors in terms of the risk of infection.

Frequency and methods of cleaning and disinfection are adapted according to the evaluated risk.

The level of infection risk in one room with a patient being cared for is moderate. It is much higher if the patient presents an identifiable infection risk.

- Remove the outer protective polythene bag. It is recommended that you retain this for future storage of the mattress bolster.
- Ensure the compatible bed platform is at the correct and desired width, with the bed extended if necessary to meet these requirements (119cm).
- On the Versatech 1100, this is denoted by the red labels on the sleep deck extensions.
- Place the mattress bolsters onto the bed with the connecting straps in the middle and the symbol on the side of the bolsters reading "Use This Way Up".
- Place the compatible mattress (Aria Flex) on top of the mattress straps, ensuring that it fits safely against the bolsters at the right level.
- Locate the buckles on the straps and tighten to ensure that the bolsters remain as close to the mattress as possible.
- Wipe clean the top surface with soap and water or a wipe suitable for cleaning soft surfaces.
- Allow to dry.
- Place a standard sheet over the mattress and mattress bolsters.
- The device is now ready for use.

Caution:

Ensure that the mattress bolsters remain together at all times. If you need to remove one bolster in order to gain access during transport, this is possible, however it should be returned and connected again when the bed is stationary.

If the mattress bolsters are being used with a mattress which has a control unit, follow these additional instructions:

- To ensure a safe fit when installing with a mattress and a control unit, the bolsters have a neat recess design on the inside.
- Ensure that the air hose can be connected to the control unit and the mattress without squashing or affecting air flow.
- Incorporated on both sides, this enables the mattress bolsters to be used in either orientation with the recess always located at the right foot end.

9. Operational Maintenance

9.1. Cleaning

Non removable covers can only be cleaned in situ. Thoroughly clean and dry the cover before re-use or storage.

9.1.1. General Cleaning and Cleaning Between Patients

General cleaning of the mattress bolster should be carried out after each patient use:

- For general cleaning and superficial dirt, use a disposable wipe with a solution of warm water and neutral detergent.



Caution:

Do not use abrasive or phenolic-based cleaners.

9.1.2. Thorough Cleaning and Disinfection

If the 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, in line with Trust protocols.

- Large spillages of blood on the mattress should first be disinfected by use of chlorine-releasing solutions instead of granules.
 - The surface should then be rinsed using clean water with a clean cloth.
 - Wipe the cover using a single-use wipe and a 0.1% chlorine solution (1,000 ppm) and cold water.
- Other body fluids should be removed with paper towels followed by use of chlorine-releasing solutions instead of granules.
 - The surface should then be rinsed using clean water with a clean cloth.
 - Wipe the cover using a single-use wipe and a 0.1% chlorine solution (1,000 ppm) and cold water.
- If required a 1% chlorine solution (10,000 ppm) and cold water may be applied.
 - Residual chlorine salts should be rinsed off with clean water after the chlorine activation phase (normally less than 10 minutes - see chlorine solution container label).
 - Allow time for the cover to dry (normally less than 10 minutes) or dry with clean paper towels.
- Non removable covers can only be cleaned in situ.
- Thoroughly rinse and dry the cover before re-use or storage.
- Store in a cool, dry area.

9.2. High Temperature Laundering

Before laundering, mattress bolster covers should be completely removed. Where required, mattress bolster covers can be laundered as follows:

- Wash at 65°C for 10 minutes or 73°C for at least three minutes, which may include a final concentration of 150 ppm available chlorine, which must be achieved for a minimum of five minutes exposure time.
- Follow with a cold rinse cycle.

9.3. Low Temperature Ozone Laundering

Alternatively, disinfection may be achieved at lower temperatures where ozone is continually fed and dissolved into the wash water throughout an automatic laundry wash cycle.

9.4. Drying Post-Laundering

Spin and tumble dry covers at less than 65°C.

- The cover must be dried before refitting to the mattress bolster or being stored.

9.5. Medstrom Laundry Disinfection Service

Medstrom provides a laundry disinfection service. For further information, please call 0345 371 1717.

10. Preventive Maintenance

1. Check the outer mattress bolster cover for signs of tearing and/or punctures.
2. Check the seams for any signs of splitting.
3. Check the zips for any sign of damage.
4. Check for any signs of permanent staining.

Note: If any of the indicators in steps 1 to 4 are present, check the condition of the mattress bolster using the Mount Vernon Test. This is available for reference in BHTA Protect Rinse and Dry guidelines at <https://www.bhta.net/content/beds-support-surfaces.html>.

11. Disposal

The foam mattress bolster should not be disposed of through the general waste stream. Refer to local guidance or contact Medstrom.

12. Warranty

The foam mattress bolsters are guaranteed against faulty manufacture and materials as replacement goods. Normal wear and tear is not included.

The manufacturer reserves the right to inspect and assess the faulty parts before validating guarantee rights. A technician team is at your service 24/7 and 365 days a year to advise you and decide on the appropriate response to any possible problem.

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

If no Medstrom-approved maintenance program is in place within the first year of purchase, the warranty will revert to two years only.

Warranty may lose its validity in the following cases:

- Degradation of coatings or materials from shock, friction and scratches.
- Abnormal use of mattress bolster not following the precautions and recommendations, including maximum patient weight, resulting in degradation of the mattress bolster or its environment.
- Use of unapproved disinfectants.
Note: Medstrom do not approve disinfectants. Disinfectants are locally approved by each establishment.
- Use of cleaning products without respecting appropriate dilution proportions.
- Washing with a water pressure jet.

13. Manufacturer's Details

UK:



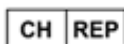
Medstrom Ltd
2 Cygnus Court, Beverley Road,
Pegasus Business Park, Castle Donington,
DE74 2SA
United Kingdom
Tel: +44 (0)345 371 1717
info@medstrom.co.uk

EC Representative:



BEING s.r.l.s.,
Saonara (PD) Via Vittorio Emanuele II,
53 CAP 35020
Italy

CH Representative:



CHRN-IM-20000224
Medstrom Healthcare Sàrl
Chemin des Quatre-Vents 7F, 1166 PERROY
Switzerland



GTIN Numbers:

UK 5060467210416

EU 5060467210423

