



Improved Patient Outcomes

Protecta Luxe Foam Mattress USER MANUAL

PRO00045
Revision 1.1



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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 Protecta Luxe foam mattress 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 Protecta Luxe foam mattress. |
|  | 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

Labels affixed to mattress:

| | |
|---|---|
|  | Departmental identification and audit record sheet. |
|  | Cleaning, care and storage notes. Maximum weight guide. CE mark and user instruction. |
|  | Mattress orientation indicating the foot end of the mattress. |
|  | Mattress fire resistance rating. |

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. |
|  | EU Representative / | The name of the European Union representative company / |
|  | CH Representative | The name of the Switzerland representative company. |
|  | CE Mark | Signifies that this product meets the General Safety and Performance Requirements (GSPR) of the European Device Regulations. |

3. Intended Use of the Mattress

The Protecta Luxe foam mattress has been designed for comfort and the prevention of pressure ulcers in patients of all risk and the treatment of up to category I and II pressure ulcers. It is intended for use with hospital bed frames, with a patient weight guide of up to 250 kg.

The Protecta Luxe foam mattress is intended to be used in:

- application environment 2 (hospital/medical facility, acute and medical supervision),
- application environment 3 (medical area, long term care), and,
- application environment 4 (domestic care).

4. General Information

Important:

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

5. Precautions for Use

Important:

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

5.1. General Precautions

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

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 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 cover during use.

Avoid Ignition Sources

- Don't smoke in bed/on the mattress.
- Don't burn candles in the same room as the bed/mattress.
- Don't use matches or lighters in the vicinity of the bed/mattress.
- Don't have electrical equipment in the vicinity of the bed/mattress, e.g. a TV over the bed.
- Don't use electric blankets in combination with the bed/mattress.
- Don't have fires and heaters in the vicinity of the bed/mattress.
- Don't 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 device.

5.2. Bed Frame Compatibility

Caution:

Where the Protecta Luxe foam mattress is used on bed frames not supplied by Medstrom, the compatibility with the bed frame 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 flat.

Caution:

Do not fold.

Caution:

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

- Keep the mattress clean.
- Regularly inspect the exterior and interior of the mattress.
- 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 Features

The following is a list of features of the Protecta Luxe foam mattress:

Construction

- Two foam layers.
- Firm base and walls with side to side profiled head, sacral zones and Geltex® heel zone.
- Platilon® inner cover.
- Profiled base hinges.
- Printed X-treme® HF welded, moisture vapour permeable, multi-stretch cover.



Dimensions

- 910 mm (W) x 2060 mm (L) x 140 mm (D).

Medical Device Classification

- Class I.

Flammability

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

Maximum Patient Weight

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

8. Instructions for Use

Caution:

Should any serious incident occur in relation to the mattress 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.
- Ensure that the 'foot' symbol is oriented at the foot end of the bed facing upwards.
- 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.
- The mattress is now ready for use.

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 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 covers should be completely removed. Where required, mattress 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-Laundry

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

- The cover must be dried before refitting to the mattress inner 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 cover for signs of tearing and/or punctures.
2. Check the Platilon® inner cover for signs of tearing and/or punctures.

Note: If the Platilon inner cover is damaged but the mattress outer cover and inner foam core is still intact, the Protecta Luxe foam mattress can still be used, however replacement is advised as soon as possible.

3. Check the seams for any signs of splitting.
4. Check the zip(s) if applicable for any sign of damage.
5. Check for any signs of permanent staining.

Note: If any of the indicators in steps 1-5 are present, check the condition of the mattress 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 Protecta Luxe foam mattress should not be disposed of through the general waste stream. Refer to local guidance or contact Medstrom.

12. Warranty

The Protecta Luxe foam mattress is 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 not following the precautions and recommendations, including maximum patient weight, resulting in degradation of the mattress 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:



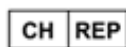
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