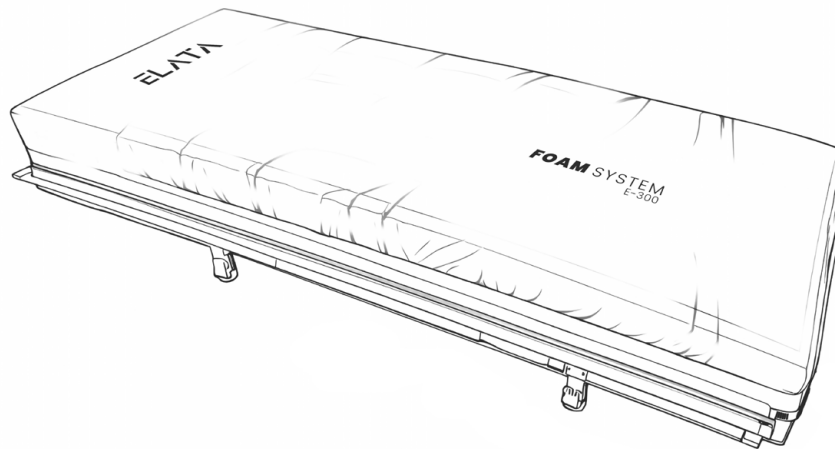




User Manual

ELATA® CLINICAL FOAM SYSTEM E300S | E300KS



CONTENTS

	Pg.
Welcome	3
Notice to User	3
Design Policy & Copyright	3
1. Introduction	4
1.1 Intended Use	4
1.2 Indications for Use	4
2. Product Information	5
2.1 Mattress at a Glance	5
3. Installation	6
3.1 Unpacking & Inspection	6
3.2 Mattress Installation	6
4. Using the Mattress	6
4.1 Recommended Linen	6
4.2 Patient Positioning & Comfort	7
5. Cleaning, Storage & Maintenance	8
5.1 General Cleaning & Disinfection Precautions	8
5.2 Cleaning the Mattress	8
5.3 Storing the Mattress	10
5.4 Shelf Life	10

	Pg.
6. Technical Information	10
6.1 Mattress Specifications	10
7. Additional Information	11
7.1 Disposal	11
7.2 Service & Support	11
7.3 Manufacturer & Sponsor Contact	11
7.4 Expected Service Life	11
7.5 Warranty	11
7.6 Table of Symbols	12
7.7 Warnings & Precautions	13

Welcome

Dear customer, thank you for purchasing an Enable Lifecare product. Before setting up and using the Elata® System, you must read and understand all the instructions in this manual. All actions and handling of the product must be performed in accordance with the instructions in this manual.

Please ensure that this manual is available to users and operators throughout the product service life. If you need further information, please contact us.

Notice to User

If a serious incident occurs in relation to this medical device affecting the user or patient, please report it to

Enable Lifecare Pty Ltd.

2 Selgar Avenue, Tonsley SA 5042

phone: **1300 370 370**

email: **support@enablelifecare.com.au**

Design Policy & Copyright

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1. Introduction

1.1 Intended Use

The Elata® Clinical Foam System is intended for the prevention and management of pressure injuries when used as part of a comprehensive pressure care program and based on clinical assessment. It supports up to Stage 2 pressure injury management.

NOTE: There are many factors which influence the risk of developing pressure damage, and a pressure care mattress is just one possible intervention. A holistic approach must be used when assessing the pressure care needs of a patient. The guidance in this document should be used in conjunction with regular monitoring of the patient's pressure care requirements.

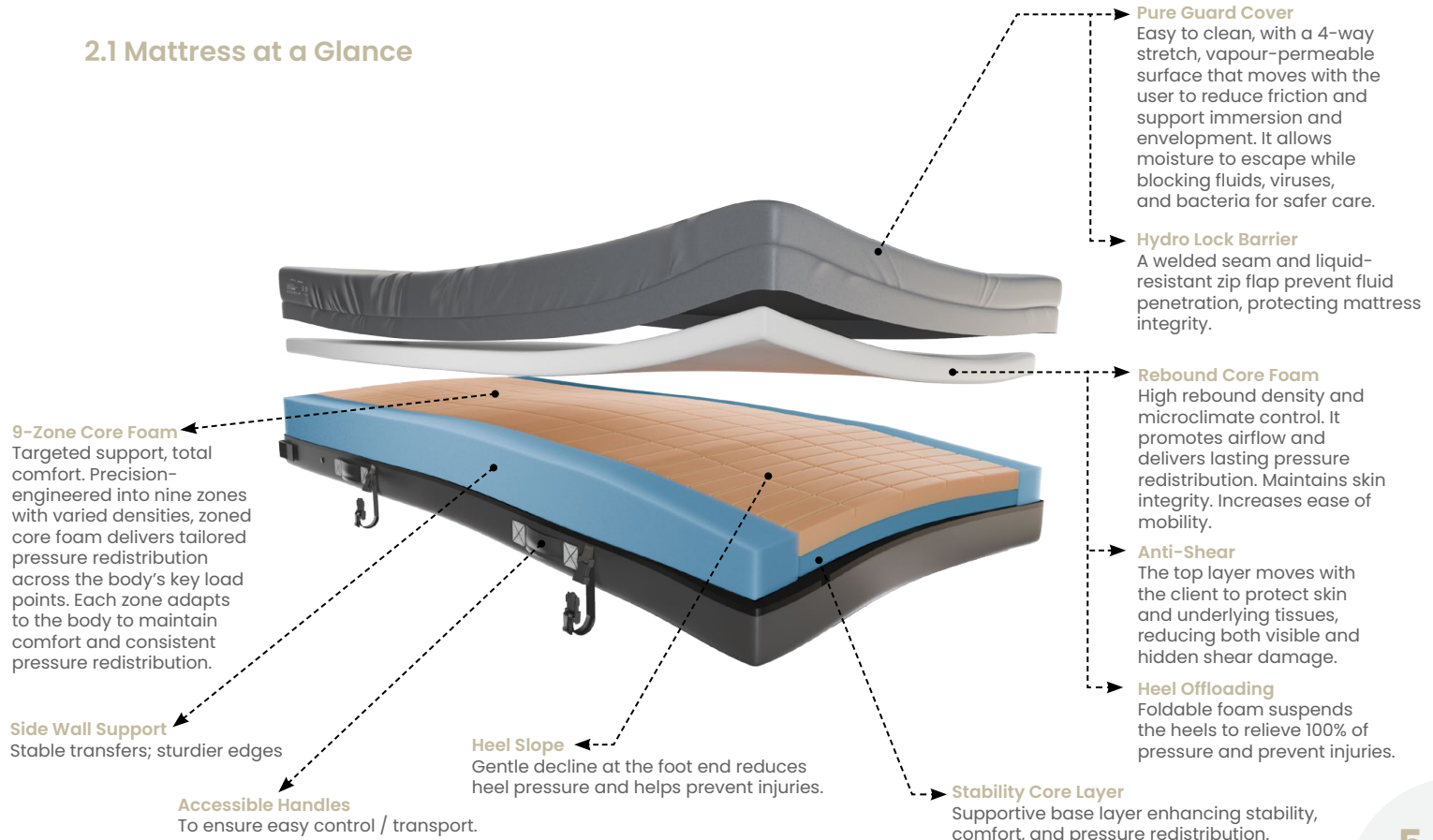
1.2 Indications for Use

The Elata® Clinical Foam System is recommended for patient weight up to 160 kg.

Always consult a physician prior to using this device.

2. Product Information

2.1 Mattress at a Glance



3. Installation

3.1 Unpacking & Inspection

Carefully remove the mattress from its packaging. To avoid damaging the product do not use sharp blades or objects when unpacking. To avoid danger of suffocation, keep packaging bags away from babies and children. These bags are not toys. Dispose of plastic bags immediately.

Inspect all items for any damage that may have occurred during shipping. If damage is found, contact Enable Lifecare or your local distributor before using the product.

3.2 Mattress Installation

- Place the mattress on the bed base. Secure the mattress to the bed using the fastening straps on the sides of the mattress. Ensure that the flexible Pure Guard Cover is facing upwards (printed side up) and that the heel slope is located at the foot end of the bed. If the mattress is used on an adjustable bed, the straps at the head end must be fastened at the moving part of the bed's head end. The straps at the foot end of the bed must be fastened at the moving part of the foot end.

- Confirm that the bed frame is appropriate for use with the mattress, and that the length and width of the mattress are appropriate for the frame.

Leave the mattress for 1 hour before use. This will allow the foam to recover its shape after being compressed by the packaging.



4. Using the Mattress

4.1 Recommended Linen

Based on the patient's specific needs, the following items of bed linen may be utilised:

- Draw or slide sheet to aid in positioning and to further minimise friction and shearing.
- 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.

Use minimal padding between the patient and the mattress surface to provide optimum performance.

4.2 Patient Positioning & Comfort

General Repositioning

Patients should be turned and repositioned as per facility policy. If it is not contraindicated, it is desirable to keep the back section of the bed in the flat position to provide optimal pressure redistribution and minimise the risk of shearing injuries.

Elevating Patient into Sitting Position

The special properties of the Elata® Mattress reduce the opportunity for shear and friction that may occur when raising the back section of other bed systems. As with any surface, sliding can be expected; therefore, patients should be repositioned after elevation. The knee gatch or knee section of the bed may be elevated first, to help prevent the patient from sliding when the back section is elevated.

Contractures

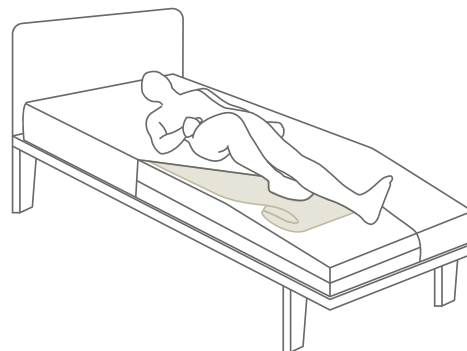
Contractures and foot drop are a concern for all bed-bound and immobilised patients. Physical therapy and any prescribed exercises may be performed on the Elata® Mattress as is done on any traditional hospital bed.

Incontinence

Moisture against the skin surface leads to maceration or softening of the tissues. To prevent maceration, we recommend you use an incontinence barrier pad to absorb the excess moisture. In the event of incontinence or excess drainage, you should wipe off the excess fluid from the bed surface.

Heel Offloading

The rebound core foam layer can be folded under itself to alleviate heel pressure.



5. Cleaning, Storage & Maintenance

5.1 General Cleaning & Disinfection Precautions

Infection control and routine cleaning must be carried out in accordance with your local infection control policy. It is suggested that all disinfection should be performed with a high-grade disinfectant in accordance with Enable Lifecare's instructions.

Reusable components that contact the patient must:

- Be cleaned and disinfected after each patient use.
- Be inspected for damage before reuse.
- Be replaced if fluid ingress or material degradation is identified.

If contamination with blood or other potentially infectious material occurs:

- Follow local infection control procedures.
- Use appropriate personal protective equipment during cleaning.
- Replace components if decontamination cannot be assured.

Do not use the system if cleaning or disinfection has not been completed.

5.2 Cleaning the Mattress

Please read the following warnings before cleaning the mattress:

- Do not use phenolic, biological or abrasive cleaning agents for cleaning.
- If alternative cleaning methods are used, the user must ensure they are compatible with the materials of the mattress and comply with institutional infection control policies.
- Do not use any steam cleaning device on the mattress.
- Excessive moisture can damage elements of the mattress.

Mattress Top Cover

- Polyurethane coatings need to be treated with care when cleaning the surface. Many industrial cleaning agents are extremely harsh on the coating and can cause the coating to break down.
- Regularly check the inside of the cover for any signs of leakage. If the cover leaks then the waterproof barrier has been damaged and a replacement cover should be purchased from Enable Lifecare.
- For superficial dirt use a disposable wipe and a warm solution of neutral detergent. Do not use abrasive cleaners.

- If there are visible signs of body fluids and/or substances present, the top cover should be washed. Top covers can be machine washed (up to 95°C) using authorised cleaning and disinfection solutions.
- To establish the amount of disinfectant to use, determine the amount of water in the washer and then follow the manufacturer's instructions for dilution.
- Soak the top cover in the disinfectant during the wash cycle. Rinse well in clean water and dry thoroughly before use.
- Spin and tumble dry on a low heat setting only (not more than 95°C). Some surface wrinkling may result from cleaning procedures. This should have no adverse effect on the fabric's properties.
- Do not iron.
- For in situ disinfection of the top cover, disinfect using 0.1% sodium hypochlorite solution (1000ppm available chlorine). Wipe off any residue with clean water.

Mattress Base and Internal Components

- Wipe down the outside of the mattress base with authorised cleaning and disinfection solutions, ensuring that all surfaces come into contact with the disinfectant. Use a cloth that is damp and not wet to ensure that no free liquid can enter the mattress. Wipe surfaces well with a clean damp cloth and air dry.
- Do not disassemble the mattress unless cleaning is required.
- Do not iron, machine wash or machine dry the foam or mattress base.
- The mattress includes foam components and these cannot be washed. Contact Enable Lifecare for replacement foam.

5.3 Storing the Mattress

- Store the mattress on a flat surface with the zip closed.
- Always store at room temperature in a dry area.
- Make sure the mattress is stored where it will not be exposed to impact, abrasion or other forms of damage. Do not place any heavy objects on top of the mattress.
- Avoid direct exposure to sunlight.

5.4 Shelf Life

Elata® products may be stored for the following periods if maintained in original packaging and stored under the environmental conditions specified in this document:

- Mattresses: 2 years prior to first use.

If any product is stored for a longer period, it must be inspected and approved for use by an authorised service agent.

6. Technical Information

6.1 Mattress Specifications

SPECIFICATION	E300 MATTRESS
Dimensions	Single: 88cm X 200cm X 17cm. King Single: 107cm X 200cm X 17cm.
Weight	Single: 15kg. King Single: 17.5kg.
System Type	A multi-layer clinical foam mattress with 9-zone configuration for targeted pressure redistribution.
Clinical Use	Suitable for up to Stage 2 pressure injury management.
Safe Working Load	Supports patients up to 160 kg.
Construction	Precision 9-zone foam design; reinforced side walls; heel slope.

7. Additional Information

7.1 Disposal

Dispose of this product and its components according to local regulations. Contact Enable Lifecare for environmentally responsible recycling or disposal options.

7.2 Service & Support

There are no user serviceable parts. To arrange servicing or for technical support, please contact Enable Lifecare:

Email: support@enablelifecare.com.au

Phone: 1300 370 370

7.3 Manufacturer & Sponsor Contact

Enable Lifecare Pty Ltd.

2 Selgar Avenue, Tonsley SA 5042 Australia

email: support@enablelifecare.com.au

phone: 1300 370 370

www.enablelifecare.com.au

7.4 Expected Service Life

The Elata® Pressure Care System is designed for an expected service life as listed below under normal use conditions, and with appropriate maintenance.

Expected Life of Mattress: 7 years

Service life is dependent on proper cleaning and maintenance, environmental conditions, frequency of use and compliance with servicing requirements.

After the expected service life has been reached, performance and safety cannot be guaranteed. The device or component should be assessed and replaced if necessary.

7.5 Warranty








The ELATA® Pressure Care System is covered by a voluntary manufacturer's warranty provided by Enable Lifecare Pty Ltd.

- Mattress: 5-year warranty from date of purchase.

Warranty terms, conditions, exclusions, servicing requirements, and claim procedures are available at:

www.enablelifecare.com.au/pages/elata-warranty

7.6 Table of Symbols

SYMBOL	USE
	Catalogue Number
	Serial Number
	Manufacturer
	Date of Manufacture
	Medical Device
	Refer to User Manual before Use
	Machine wash at 95°C

SYMBOL	USE
	Drip dry
	<1% Chlorine
	Do not dry clean
	Wipe down
	Do not iron
	Tumble dry
	Resistant to ignition

7.7 Warnings & Precautions

NOTE: Any serious incident that occurs as a result of using the device should be reported to the manufacturer.

- The product must only be installed and used for its intended purpose according to the instructions in this manual and other documentation from Enable Lifecare. The product must not be combined, assembled or repaired with parts, accessories or spare parts other than those described in this manual. The product must not be modified in any way.
- Incorrect patient positioning or prolonged use without repositioning may reduce comfort and effectiveness of pressure redistribution. Follow clinical best practice for patient positioning and repositioning.
- The patient's head should always be positioned in the centre of the top section of the mattress. Always ensure that the patient is positioned properly within the confines of the bed. Do not allow extremities to protrude over the side of the mattress or between the bed rails when the mattress is in use.
- With any traction or unstable fractures, maintain physician-directed angle of articulation and guard against risks of patient migration or inadvertent deflation of patient surface.
- Monitor skin conditions regularly, particularly in areas where incontinence and drainage occur or collect. Early intervention may be essential to preventing serious skin breakdown.
- To minimise the risks of falls or injury, the mattress support platform should always be in the lowest practical position when the patient is unattended. Make sure areas under and around the frame are clear of objects, persons and parts of body before adjusting height.
- Mattresses are reusable and may become contaminated through contact with skin, bodily fluids, wounds, perspiration. Our products are supplied non-sterile and must be cleaned and disinfected between patients in accordance with the instructions provided in the 'Cleaning, Storage & Maintenance' section and institutional infection control protocols. Failure to adequately clean and disinfect reusable accessories may result in cross-contamination or infection.
- Always ensure that the mattress is the correct size for the bed.
- The mattress is protected by a Pure Guard cover that does not allow liquid or air to penetrate but is vapour permeable. Ensure the patient is positioned correctly to avoid the risk of suffocation. Avoid using multiple layers over the cover as it can affect the vapour

permeability of the mattress.

- Use caution with sharp objects to prevent damage to the Pure Guard cover.
- Side handles are only intended for managing or relocating the mattress. Do not use the handles to lift the mattress with the patient laying on it.
- Do not position the product in direct sunlight for extended periods as the elevated temperature and UV light may degrade the product.
- This device contains materials that may come into contact with skin during normal use, including:
 - Polyurethane-coated fabrics
 - Foam components

Patients with known sensitivities or allergies to synthetic polymers should be assessed prior to use. If signs of irritation, rash, redness or hypersensitivity occur:

- Discontinue use immediately.
- Remove the device from patient contact.
- Seek medical advice.

Enable Lifecare Pty Ltd

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