



User Manual

ELATA® HYBRID SYSTEM E400S | E400KS



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Welcome

Dear Customer, thank you for purchasing an Enable Lifecare product. Before setting up and using the Elata® Hybrid 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 the manual is available to users and operators throughout the product service life. If you need further information, please contact us.

1. 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 | 1300 370 370 | support@enablelifecare.com.au

2. Design Policy and Copyright

Elata® and Elata™ are trademarks belonging to Enable Lifecare Pty Ltd unless otherwise stated.

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3. Intended use

The Elata® E400 is a pressure relieving mattress suitable for use with patients at very high risk of pressure injury damage. Supports Stage 2 pressure injury management without the pump and up to Stage 4 with the Elata® pump.

Offering high levels of patient comfort, this unique system has the facility to “step up” to that of a dynamic mattress when clinically required. Similarly, the mattress’s function can be downgraded as the patient’s condition improves. These features make it particularly beneficial for use within the patient’s home or palliative care environment and help reduce logistic and decontamination costs. The clinical benefits of a single system are equally applicable to those of a modern hospital setting.

Note that there are many factors which influence the risk of developing pressure damage, and a pressure care mattress is just one possible intervention. A holistic

Selector symbol:



DEEP WITH PUMP

4. Indication for use

The Elata® hybrid mattress system is recommended for patient weight up to 230 kg.

When the Elata® pump is used to provide additional support, it can support up patient weight up to 250 kg.

5. Contraindications

The Elata® Pressure Mattress system is contraindicated for patients:
with cervical traction, or unstable spinal fractures, spinal cord injury, fractures at risk of complication by a moving surface, or trauma patients where spinal injuries have not been excluded or cleared individuals with severe burns or motion intolerances due to factors such as nausea/ pain or gross oedema.

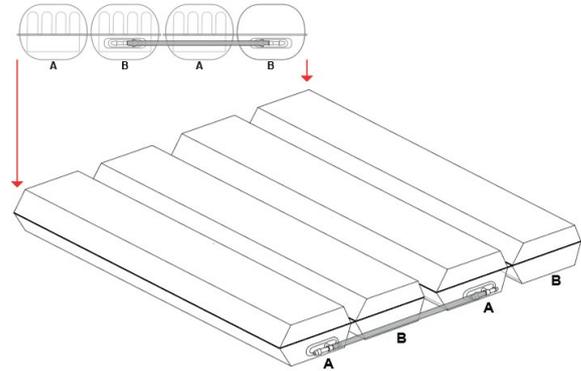
Always consult a physician prior to using this device.

6. General

The Elata® hybrid mattress consists of a foam head cell and series of transverse air cells, each containing a unique foam profiled insert, which are in turn held within a foam core, all protected by a vapour permeable waterproof cover. The single pillow end consists of foam only. The transverse cells are arranged into alternate pairs of A and B cells which are filled and emptied in sequence.

In Static Mode, the mattress attains the pressure reducing properties of the Elata® foam mattress (details available on request), whilst in Alternating Mode the mattress can offer similar properties to a pressure relieving dynamic system.

The digitally controlled Power Unit controls the Elata® pump that allows air to flow into, or out of the air cells as required according to the operating mode selected. It also maintains the air pressure within the mattress at the required level and controls the action of the audible/visual Audible Warning system in the event of mains supply failure or over or under inflation pressure.



NOTE: Please ensure that all securing straps on the base of the mattress are secured onto the NON-MOVING PARTS of the bed frame.

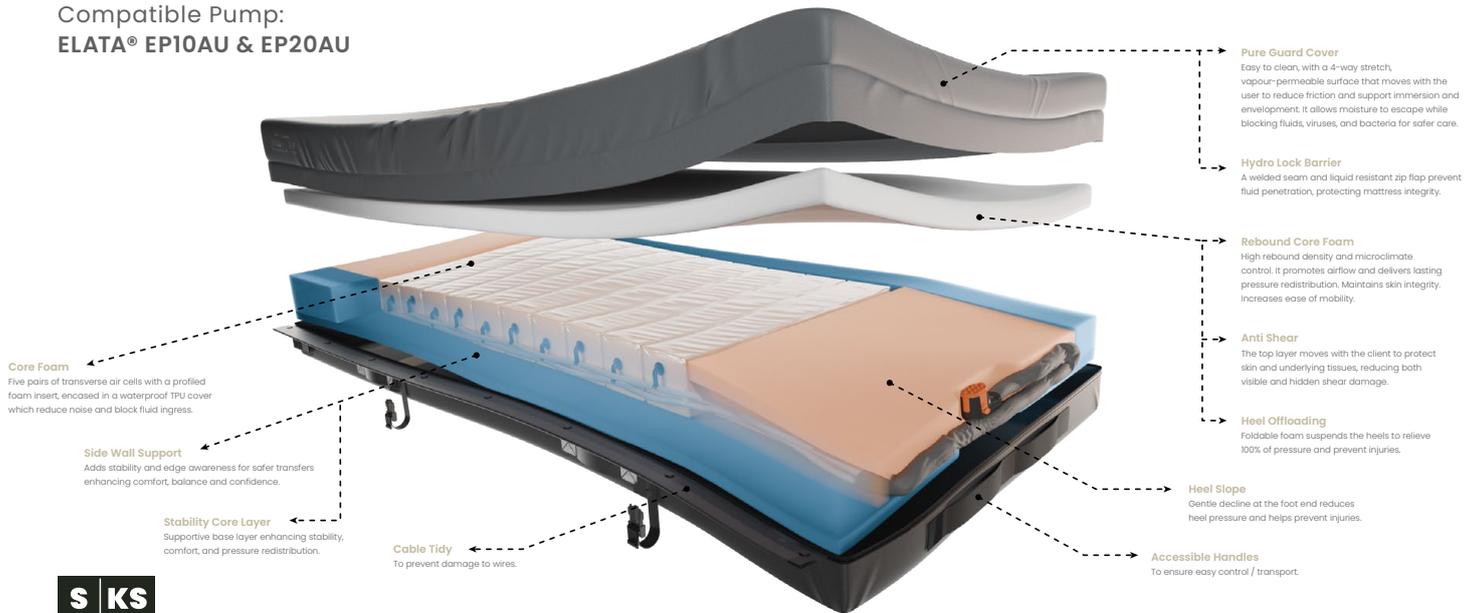
7. Model Information

MODEL REF	DESCRIPTION
E400S	Elata Hybrid mattress (Single: 88cm X 200cm X 19.5cm) Mattress weight: 20kg
E400KS	Elata Hybrid mattress (King Single: 107cm X 200cm X 19.5cm) Mattress weight: 25kg

Mattress at a Glance

STEP UP. STEP DOWN. STAY IN CONTROL.
ONE MATTRESS FOR CHANGING NEEDS.

Compatible Pump:
ELATA® EP10AU & EP20AU



Can be used with or without the pump
230kg SWL

8. Use Instructions

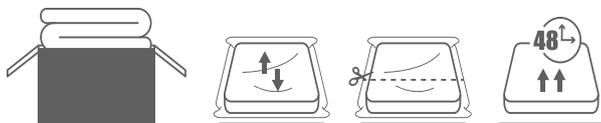
UNPACKING THE MATTRESS

Please ensure the packaging is not damaged upon arrival. Avoid using a knife when opening the packaging and any other protective material as this could damage the mattress and/or cover.

Place the Elata® Hybrid Mattress on to the bed platform ensuring that the grey multi-stretch waterproof cover is on top and that the umbilical hose is located at the left-hand corner at the foot end of the bed.

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. Cover the Mattress with a loose-fitting sheet.

Place directly on a healthcare bedframe only, never on top of another mattress. Leave for a few minutes before using.



STATIC MATTRESS USE

Elata® Hybrid system can be used as a pressure reducing mattress for patients at High Risk of pressure injury without the need to attach the pump.

ALTERNATING MATTRESS USE

If/when required, the Elata® hybrid system can be used as an alternating mattress system by attaching the Elata pump. No other system should be attached to the mattress as the design settings and internal air pressure properties of the Elata® pump are specific to this mattress only.

The start up time from static to dynamic mode is immediate.

POWER UNIT (ELATA PUMP)

For instructions on operating the Elata® pump, refer to the Elata® Pump user Instructions section later in this manual.

9. Troubleshooting

For assistance (if needed) in setting up, using or maintaining the Elata® Hybrid System, or to report unexpected operation or events, please contact Enable Lifecare.

NOTE: Mattresses are reusable and may become contaminated through contact with:

Skin

Bodily fluids

Wounds

Perspiration

These accessories are supplied non-sterile and must be cleaned and disinfected between patients in accordance with **Section 18** and institutional infection control protocols.

Failure to adequately clean and disinfect reusable accessories may result in cross-contamination or infection.

ELATA® PUMP (EP10AU AND EP20AU)

10. Elata® Pump Introduction

The Elata® Pump is meant to be used with the Elata® range of alternating pressure mattresses for patients at risk of pressure injury damage.

Note that 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 needs of a patient.

11. Elata® Pump Technical Specifications

SPECIFICATION	EPI0AU	EP20AU
Dimensions (LxWxH)	308 x 119 x 228 mm	
Weight	3.5 kg	4.2 kg
Input Power	100–240V, 50/60Hz	
Input current	1.2 A max @ 230V AC	
Backup Time	Pump operation is not supported. The battery allows the pump to safely shut down and then alert for 3–4 hours	6–12 hours full operation
Batteries	4.8V (4x1.2V) NiMH, 2000 mAh	12V (10x1.2V) NiMH, 3500 mAh
Ingress protection	IP20. No protection against ingress of liquids. Use is restricted to controlled indoor environments away from direct liquid exposure.	
Rated Operation	The Elata Pump is designed for continuous operation (24 hours per day). It may be operated continuously in a clinical or home care setting.	
Electrical Protection Class	Class II	
Equipment Type	Stationary ME Equipment. Not intended to be moved or carried during operation	
Applied Part Classification	BF	
Degree of Safety in Presence of Inflammable Gases	Not for use in the presence of flammable liquids or gases (including anaesthetic mixtures with air or with oxygen or nitrous oxide)	

12. Operating Conditions

PARAMETER	OPERATING (NORMAL USE)	STORAGE (NON-OPERATING)	TRANSPORT (NON-OPERATING)
Ambient Temperature	+5 °C to +40 °C	0 °C to +40 °C	-20 °C to +60 °C
Relative Humidity	15% to 93% RH, non-condensing	0% to 93% RH, non-condensing	0% to 93% RH, non-condensing
Atmospheric Pressure / Altitude	70 kPa to 106 kPa (≈ up to 2,000 m above sea level)	70 kPa to 106 kPa (≈ up to 2,000 m)	11.6 kPa to 106 kPa

13. Compatible Components

Compatible mattresses	ELATA® PUMP MODEL	
	EP10AU	EP20AU
E400S	✓	✓
E400KS	✓	✓
E500S		✓
E500KS		✓
E600S	✓	✓
E600KS	✓	✓
E700S		✓
E700KS		✓

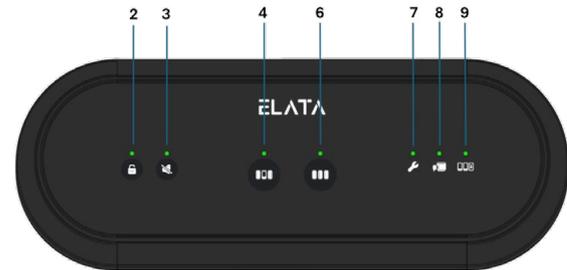
14. Operating Modes

The Elata® Pump provides the following operating modes:

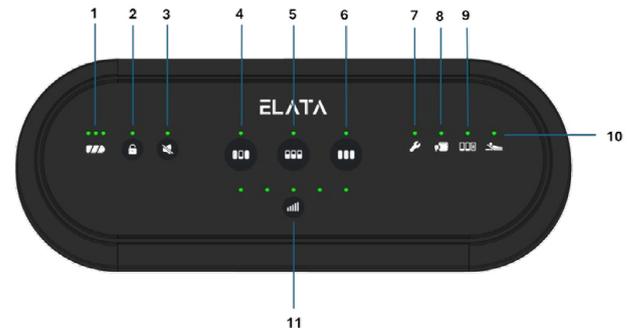
- Elata AdaptiveMode™ is the default mode and is available on all pump models. In this mode pressure is alternated across 2 cell or 4 cell cycles (depending on the mattress structure).
- Constant Low Pressure (CLP) mode is available on the EP20AU pump model. In this mode all air cells inflate to a single constant low pressure to allow the user to be immersed and enveloped by the support surface.
- Maximum Pressure (MAX) mode is available on all pump models. In this mode all air cells inflate to a high pressure to provide a firm and stable surface for nursing procedures. MAX mode will automatically timeout after 30 minutes and the pump will revert to Elata AdaptiveMode™. MAX mode is intended for occasional use only.

15. Control Panel

EP10AU control panel



EP20AU control panel



REF	SYMBOL & FUNCTION	EP10AU	EP20AU												
1	<div data-bbox="245 191 309 255" data-label="Image"> </div> <p data-bbox="239 266 555 314">Indicates level of battery charge. When connected to mains power:</p> <table border="1" data-bbox="272 344 1171 540"> <thead> <tr> <th data-bbox="272 344 459 423">INDICATOR BAR</th> <th data-bbox="459 344 1171 423">DESCRIPTION</th> </tr> </thead> <tbody> <tr> <td data-bbox="272 423 459 482">1</td> <td data-bbox="459 423 1171 482">pulsing green when charging steady green when fully charged</td> </tr> <tr> <td data-bbox="272 482 459 540">2</td> <td data-bbox="459 482 1171 540">pulsing green when charging steady green when fully charged</td> </tr> </tbody> </table> <p data-bbox="239 613 544 636">When running on battery power:</p> <table border="1" data-bbox="272 664 1171 865"> <thead> <tr> <th data-bbox="272 664 459 742">INDICATOR BAR</th> <th data-bbox="459 664 1171 742">DESCRIPTION</th> </tr> </thead> <tbody> <tr> <td data-bbox="272 742 459 809">1</td> <td data-bbox="459 742 1171 809">steady green when battery level is medium or high steady amber when level is low flashing red when level is critical</td> </tr> <tr> <td data-bbox="272 809 459 865">2</td> <td data-bbox="459 809 1171 865">steady green when battery level is medium or high</td> </tr> </tbody> </table> <p data-bbox="239 932 1171 983">All three battery indicator bars may remain unlit for a few seconds when the unit is first powered on (until battery level is established).</p>	INDICATOR BAR	DESCRIPTION	1	pulsing green when charging steady green when fully charged	2	pulsing green when charging steady green when fully charged	INDICATOR BAR	DESCRIPTION	1	steady green when battery level is medium or high steady amber when level is low flashing red when level is critical	2	steady green when battery level is medium or high	-	✓
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REF	SYMBOL & FUNCTION	EP10AU	EP20AU
2	 <p>Lock and unlock the control panel.</p> <ul style="list-style-type: none"> • Press and hold the button for 3 seconds to unlock the panel. • Press the button momentarily to lock the panel. <p>The control panel is locked by default to minimise unauthorised use. Once unlocked, the panel automatically re-locks itself if no other button is pressed for 3 minutes.</p> <p>The lock indicator will be lit when the control panel is locked. It will flash rapidly 3 times if any other button is pressed while the panel is locked.</p>	✓	✓
3	 <p>Mute an audible alert.</p> <p>The mute button can be used to silence any audible alert for 30 minutes. Please note:</p> <ul style="list-style-type: none"> • Mains power failure and low battery alerts will remain muted until mains power is restored. • Only the current alert is muted (any new alert that occurs during the 30 minute mute period will still sound an audible alert). <p>The mute button is unaffected by panel lock (i.e. it can be pressed at any time).</p> <p>The indicator will flash when any alert is sounding and will be lit when an alert has been silenced.</p>	✓	✓

REF	SYMBOL & FUNCTION	EP10AU	EP20AU
4	 <p>Elata AdaptiveMode™</p> <p>This button will activate AdaptiveMode™. When pressed the indicator will pulse slowly until the mattress has reached its new pressure condition, then it will become steady.</p>	✓	✓
5	 <p>Constant Low-Pressure (CLP) Mode</p> <p>This button will activate CLP mode. When pressed the indicator will pulse slowly until the mattress has reached its new pressure condition, then it will become steady.</p>		✓
6	 <p>Maximum (MAX) Pressure Mode.</p> <p>This button will activate MAX mode. When pressed the indicator will pulse slowly until the mattress has reached its new pressure condition, then it will become steady.</p>	✓	✓

REF	SYMBOL & FUNCTION	EP10AU	EP20AU
7	 <p>Indicates that service is required or a fault has occurred that may need repair.</p> <ul style="list-style-type: none"> • Lit amber to indicate that scheduled service is due. • Lit red to indicate the need for immediate service (minor fault). • Flashing red for a critical error (pump will become inoperable). <p>Servicing is due if the pump has run for 1 year or more since its last service (or initial use).</p> <p>Minor faults may sometimes be cleared by restarting the pump using the power switch.</p> <p>The service indicator and critical errors can only be reset by certified service personnel.</p>	✓	✓
8	 <p>Indicates that the mattress is disconnected from the pump unit.</p> <p>Lit when the mattress is disconnected.</p> <p>To reset the alert:</p> <ul style="list-style-type: none"> • Remove and re-fit the umbilical air connector (the mattress connector), and/or • Restart the pump using the power switch. 		✓

REF	SYMBOL & FUNCTION	EP10AU	EP20AU
9	 <p>Indicates a failure to maintain pressure (typically due to a leak).</p> <p>A minor leak will trigger an alert tone and a major leak will trigger a continuous alert.</p> <p>To reset the alert try using the following procedures:</p> <ul style="list-style-type: none"> • Remove and re-attach the umbilical air connector to the pump • Check the tubing in the umbilical and mattress for damage or leaks • Restart the pump using the power switch 	✓	✓
10	 <p>Elata TiltSense™</p> <p>Indicates that Elata TiltSense™ is active. This feature boosts the mattress pressure when the backrest of the bed is raised (only available when the pump is used with a compatible mattress equipped with a tilt sensor).</p>		✓

REF	SYMBOL & FUNCTION	EP10AU	EP20AU
11	 <p>Comfort Setting</p> <p>This button is used to toggle between 5 pressure settings. Setting 3 is the default pressure setting.</p> <p>The current pressure setting is indicated by lighting the corresponding number of indicator lights.</p> <p>When pressure settings are changed the indicators will pulse until the target pressure has been achieved.</p> <p>Comfort settings do not apply to MAX mode. When in MAX mode all indicators will be unlit.</p>		✓

16. Alerts & Indicators

Elata® pumps will provide alerts when the following conditions are encountered:

- Mains power failure (continuous alert on EP10AU, alert tone on EP20AU)
- Low pressure (leaks or failed pressurisation)
- Mattress disconnection
- Low battery (EP20AU only)
- Service required / critical fault

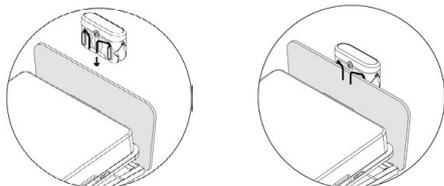
The alert mute function can be used to suppress active audio alerts for 30 minutes, except for continuous power/battery alerts.

17. Assembly and Installation

Check that no parts are damaged. If damage is found, contact Enable Lifecare or your local distributor before using the product. Do not use sharp objects when unpacking as it might damage the product.

Step 1 – Pump Setup

- Place the compatible mattress on the bed base. Secure the mattress to the bed using the fastening straps on the side of the mattress. If the mattress is used on an adjustable bed, the straps at the head end shall be fastened at the moving part of the bed's head end. The straps at the foot end of the bed shall be fastened at the moving part of the foot end.
- Fit the pump to the middle of the bed-end at the foot end of your bed using the integrated bed hooks. Ensure that the pump is securely attached to the bed end and cannot slip off. The pump should be positioned such that the top panel is facing away from the bed and readable by a person standing at the end of the bed. Check that the switch on the side of the control unit is set to '0' (off).



- If the mattress is equipped with a cable holder, place the power cable in the cable holder by opening the press studs, placing the cable in the gap and closing the press studs again. Otherwise, place the power cable so there is no risk of tripping over it, running over it with the bed wheels, or getting it jammed when raising or lowering the bed.

NOTE: On E400 mattresses, the umbilical connector can be stowed inside the mattress cover at the foot end of the mattress when not connected to the pump.

- Connect the ends of the power cable to the pump and a suitable wall outlet. The power outlet should be switched off at this point.



- Connect the mattress to the pump. Push the umbilical connector into the pump until the two orange clips 'click' into place.



- Switch the power on at the wall outlet.

Step 2 – Initial Inflation

- Flip the power switch on the left side of the pump (above the umbilical attachment point) to the 'on' (I) position.
- The pump will play a startup tune and briefly illuminate all indicators on the control panel before starting to inflate the mattress. During inflation the Elata AdaptiveMode™ indicator will pulse along with the comfort setting indicator (EP20AU model only).
- When inflation is complete the pump will play a short tune and the Elata AdaptiveMode™ indicator will become steady. Initial inflation can take several minutes if the mattress is completely deflated.

Step 3 – Mattress Use

The mattress system independently and without manual adjustment controls the inner pressure of the mattress according to the weight, length, and position of the patient. No manual action needs to be performed to adjust the inner pressure of the mattress. This function works as follows:

- The mattress is ready for use when initial inflation of the mattress is complete
- Use the mode buttons to select your preferred mattress operating mode. You may need to unlock the control panel by pressing and holding the lock button before using the buttons.
- Use the comfort level button to select your preferred mattress comfort level (EP20AU model only). Comfort level is saved and restored when the pump is switched off and back on.

Step 4 – After Use

- After use, flip the power switch on the pump to the 'off' (O) position.
- To disconnect the mattress umbilical from the pump, press the two orange tabs on the sides of the umbilical connector to release the clips.

18. Cleaning, Maintenance & Storage

Pump

- Switch the pump off and disconnect from mains power before cleaning.
- Wipe surfaces with neutral detergent using a damp (but not wet) cloth; do not allow liquid to pool on or run across the unit; do not allow any fluid ingress into the power, servicing/clinician log-in port and umbilical cord connection points.
- Abrasive cleaning agents should NOT be used.
- Ensure the pump is completely dry before use. Store in a cool, dry environment away from direct heat or sunlight. Always fully charge the battery before storing. To maximise battery life the battery should be recharged every 6 months and stored at room temperature.
- Regular servicing is required every 12 months. The servicing alert will indicate when service is required. All servicing must only be performed by authorised technicians.

NOTE: The Elata® Pump and accessories are supplied non-sterile. Accessories that may contact patients, such as mattresses and tubing, should be cleaned and disinfected according to the healthcare institutional procedure.

Mattress

Elata Alternating Air mattress covers are vapour permeable, so it is waterproof, but breathable to reduce sweating of patient. This outer barrier must not be penetrated. Even the smallest breach of this barrier will cause fluid to penetrate the mattress.

There are specific cleaning and care instructions that need to be strictly adhered to prolong the life of the product.

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.

WARNING: Unplug the Elata® pump, if in use, from its power source. Failure to do so could result in personal injury or equipment damage.

WARNING: Do not expose the mattress or control unit to excessive moisture that would allow for liquid pooling. Personal injury or equipment damage could occur.

- Abrasive cleaning agents should NOT be used.
- In addition, due to the range of cleaning chemicals and conditioners being used, customers should ascertain that any fabric performs as expected, without any adverse effect.
- Some surface wrinkling may result from cleaning procedures. This should have no adverse effect on the fabric's properties.
- If customers have their own cleaning methods that must be used and that are not covered in this article, they should consult Enable Lifecare for further direction and guidance.
- Do not use any steam cleaning device on the mattress. Excessive moisture can damage mechanisms in this mattress.

Washing of mattress covers

- All 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 it to break down.
- For superficial dirt use a disposable wipe and a warm solution of neutral detergent. Do not use abrasive cleaners.
- If the mattress is heavily soiled, it is recommended that the mattress is taken apart and cleaned. Remove the covers. Wipe off the cells, tubing and the CPR module with a cleaning agent according to local instructions and the instructions for use of the cleaning agent. If the foam is dirty or contaminated, replace with a new one from Enable Lifecare. The foam is not to be washed.
- When all parts are dry, assemble the mattress. If cells have become detached from the tubes, these must be put back according to the drawing on the '**Mattress at a Glance**' page.

Disinfection of mattresses

- Disinfect in situ using 0.1% sodium hypochlorite solution (1000ppm available chlorine). Wipe off any residue with clean water.

Drying of mattresses

- Spin and tumble dry on a low setting (not more than 130°C. The fabric surface may wrinkle but this will not impede function). The operator ensures it is removed as soon as all moisture is removed. The fabric must not be left sitting on the heated bowl of the drier when drying is complete.
- Do not mangle.
- Do not iron.

NOTE: Regularly check the inside of the cover for any signs of leakage. If the cover leaks, then the waterproof barrier has been broken and a new cover should be purchased from Enable Lifecare.

If the foam gets dirty or contaminated, purchase a new one from Enable Lifecare.

Check the cover, cells and hoses each time the product is cleaned. If damaged, it must be replaced or repaired. Also check the control unit, tube connectors and power cable during cleaning. Damaged parts must be replaced or repaired.

Storage of mattress

- Store the mattress on a flat surface or carefully rolled/folded 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 thrusts, hits or other things that can damage it. Do not place any heavy objects on top of it.
- Avoid direct exposure of sunlight.
- If the mattress is to be stored more than 3 months, we recommend it is stored on a flat surface (not folded or rolled up).

19. Warnings

NOTE: If any serious incident that has occurred in relation to 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 (e.g. pump and mattress), 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.
- Prolonged interruption of therapy may reduce pressure redistribution. Users should ensure appropriate alternative patient support is available if required.
- The pump poses an electric shock hazard if exposed to water ingress. Do not expose the pump to any liquid while it is plugged in.
 - Ensure the pump is disconnected from the mains electricity supply before cleaning.
 - Do not spray disinfectant directly on to the pump or immerse the pump in any type of liquid.
- Do not use the product in wet rooms or where there is a risk of the pump coming into contact with any liquid. Never handle a product that has come into contact with water/liquid. In this event, switch off the pump at the mains and then pull the plug out of the electrical socket immediately and send the product to an authorised service technician for servicing.
- Ensure the pump is correctly mounted on the foot end of a bed. Both bed hooks must be securely hooked over the bed end and the pump cannot slip off the bed end. If used on a bed without bed ends, ensure the pump is placed securely, upright, ensuring cables and umbilical cords are not kinked and where there is no risk of the pump being accidentally knocked over.
- Always provide clear access to the power switch, power cable inlet and umbilical connector on the pump and the power outlet to which the pump is connected.
- Regularly check product functionality by performing a hand check of alternating cell inflation and deflation.
- The product must be placed and used so that it does not become trapped or damaged. Ensure that the mattress is the correct size for the bed.

- If the product is used for individuals needing special supervision, such as children, continuous monitoring is required.
 - 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.
 - Caution with sharp objects to prevent damage to the Pure Guard cover.
 - Do not use the pump in the vicinity of or in contact with fire sources/hot surfaces, such as fire, burning cigarettes, hot lamps, fan heaters or heating stoves/open fires. Although the product has undergone fire testing, it could become damaged if it comes into contact with heat sources or naked flames.
 - Only use the power cord supplied with the product.
 - Never use the product if the pump power cord or plug is defective, the pump casing is damaged or the pump is not functioning properly. Contact an authorised service technician for examination and repair.
 - Cables, tubing, hoses and umbilical connectors may present a strangulation or entanglement hazard, particularly in home healthcare environments or where children or pets are present. To reduce risk:
 - Route all power cables and air tubing away from the patient's neck and head.
 - Ensure excess cable length is secured using available cable management features.
 - Do not allow cables or tubing to hang freely over the bed edge.
 - Inspect regularly to ensure cables are not twisted, looped or wrapped around bed components.
 - Supervision is required for patients at risk of agitation or involuntary movement.
 - Keep children and pets away from the equipment and associated cables.
- Failure to follow these instructions may result in serious injury or death.
- Exercise caution when there are children and pets in the environment around the equipment, as they may damage the product or pull out the power adaptor, which may interrupt the treatment.

- Do not open the pump housing due to the risk of electric shock. Servicing and maintenance must be performed by Enable Lifecare authorised service technicians.
- The product is only intended for indoor use and is not intended to be moved while in operation.
- 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.
- Ensure that the patient's feet do not come into sustained contact with the bed hooks for the pump.
- Do not position the product in direct sunlight for extended periods as the elevated temperature and UV light may degrade the product.
- If internal temperature limits are exceeded, the device will automatically shut down to protect the device. During shutdown, therapy will be unavailable. Allow the device to cool before restarting.
- Batteries can only be replaced by authorised service technicians.
- The backup battery (in the EP20AU model) is only intended to power the pump in the event of a power failure. For normal use always connect the pump to mains power.
- Always fully charge the battery before storage.
- Always switch the pump off during handling and transport. Use sturdy, impact-resistant packaging materials to protect the equipment from external forces.
- This device contains materials that may come into contact with skin during normal use, including:
 - Polyurethane-coated fabrics
 - Foam components
 - Plastic tubing and connectors
 - Patients with known sensitivities or allergies to synthetic polymers or medical-grade plastics 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.

20. Table of symbols

SYMBOL	USE
	Catalogue Number
	Serial Number
	Manufacturer
	Date of Manufacture
IP20	Protection against the intrusion of objects that are about the size of an adult finger (12.5mm in diameter) and no protection against the ingress of water.
	Do not dispose in bin
	Medical Device
	Refer to User Manual before Use
	Keep Dry
	Temperature limit
	Fragile

SYMBOL	USE
	Humidity limit
	Double insulated
	Type BF applied part
	Electric shock hazard
	Machine wash at 95
	Drip dry
	<1% Chlorine
	Do not dry clean
	Wipe down
	Do not iron
	Tumble dry
	Resistant to ignition

21. Electromagnetic Compatibility

This medical equipment complies with IEC 60601-1-2 EMC requirements. The device may be affected by strong electromagnetic fields (for example, near RF transmitters, mobile phones, or microwave ovens). Maintain at least 30cm distance between this device and portable RF communication devices.

Operation of this equipment during diagnostic or therapeutic procedures using high-frequency surgical equipment or defibrillators may cause reciprocal interference. Consult the responsible organisation before use in such environments.

22. Disposal

Dispose of this product and its components according to local regulations for electronic waste. Do not dispose of in general waste. Batteries must be removed and recycled. Contact Enable Lifecare for environmentally responsible recycling or disposal options.

23. Service & Support

The Elata® EP10AU and EP20AU pumps are designed for annual servicing by Enable Lifecare authorised service personnel only. 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

24. Manufacturer and Sponsor Contact

Enable Lifecare Pty Ltd
2 Selgar Avenue, Tonsley SA 5065 Australia
Email: support@enablelifecare.com.au
Phone: 1300 370 370
Website: www.enablelifecare.com.au

25. Expected Service Life

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

Expected Life of Pump: 10 years

Expected Life of Mattress: 7 Years

Service life is dependent upon 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.

Shelf Life

When stored in original packaging under specified environmental conditions:

Pump: To maximise battery life during prolonged storage we recommend storage at room temperature and charging of the battery every 6 months.

Mattress components: 2 years maximum prior to first use
If stored longer than this period, the device must be inspected by authorised personnel prior to clinical use.

26. Warranty

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

- Pump/Control Unit: 12-month standard warranty from date of purchase. An extended warranty of up to 10 years may apply subject to it meeting warranty terms and conditions.
- Mattress: 5-year warranty from date of purchase.

The Pump and Mattress are covered under separate warranty periods. Full warranty terms, conditions, exclusions, servicing requirements, and claim procedures are available at:

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

Enable Lifecare Pty Ltd

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