



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® 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® Hybrid System is intended for the prevention and management of pressure injuries up to Stage 4 when used as part of a comprehensive pressure care program and based on clinical assessment.

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® Hybrid System is recommended for patient weight up to 230 kg.

Pressure Redistribution

The selection of a pressure redistribution surface should be based on each individual patient's clinical condition or diagnosis and co-morbidities.

Pain Management

For patients experiencing severe pain and discomfort due to pressure and/or positioning limitations, consider the Elata® Hybrid System as an adjunct to pain management interventions.

1.3 Contraindications

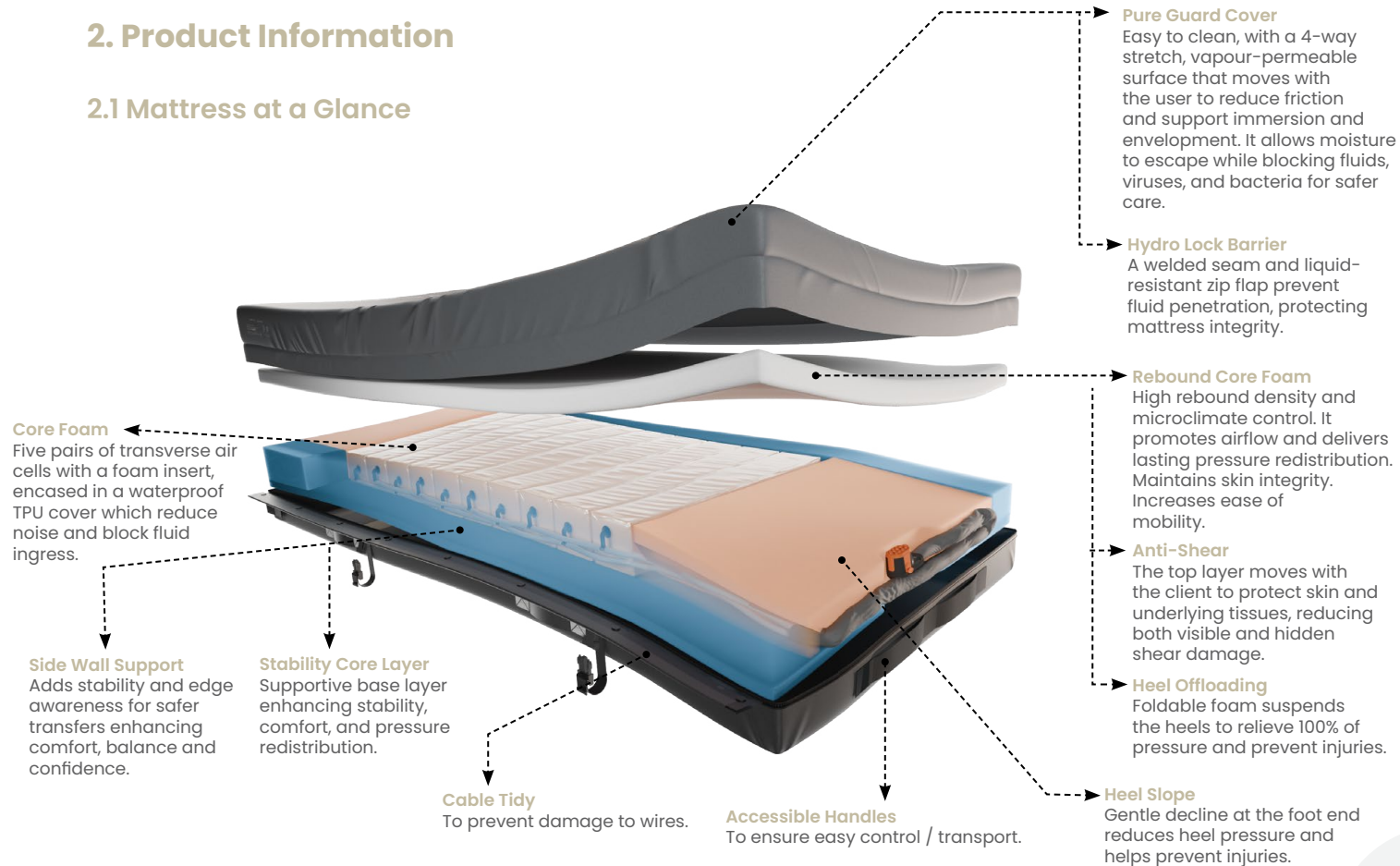
The Elata® Hybrid system is contraindicated for patients including but not limited to:

- with cervical traction,
- unstable spinal fractures,
- spinal cord injury,
- fractures at risk of complication by a moving surface,
- 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.

2. Product Information

2.1 Mattress at a Glance



2.2 Pump at a Glance



Battery Backup with **Elata PowerGuard™** for up to 12 hours*



Lock/Unlock user interface



Alarm Silence button



Elata AdaptiveMode™ for personalised responsive therapy



Constant Low Pressure (CLP) Mode*



Max Inflation Mode



Pressure Comfort Setting*



Service Required Alarm and Diagnostics



Pump/Mattress Disconnection Alarm



Low Pressure Alarm



Backrest Tilt Sensor auto support with **Elata TiltSense™***

Control Panel
(EP20AU model is shown - EP10AU model has a simplified control panel)

Power Switch

Umbilical
Connector

Umbilical Clip

Power Input Socket
(underneath)

*Available on EP20AU model only

2.3 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.

3. Installation

3.1 Unpacking & Inspection

Carefully remove the pump (optional) and mattress from their 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

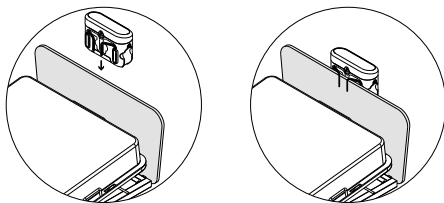
- Place the mattress on the bed base. Secure the mattress to the bed using the fastening straps on the sides of the mattress. Ensure that the flexible Pure Guard Cover is facing upwards (printed side up) and that the heel slope is located at the foot end of the bed. If the mattress is used on an adjustable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

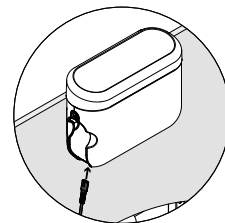


3.3 Pump Installation (if using a pump)

- 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).



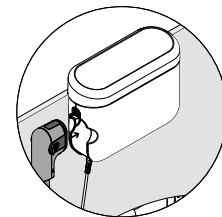
- Place the power cable in the cable holder by opening the studs or zipper, placing the cable in the gap and closing the studs or zipper. Check that the power cable is positioned to avoid any chance of tripping over it, running over it with the bed wheels, or getting it jammed when raising or lowering the bed.



- 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.

- The umbilical for the mattress is stowed inside the cover at the foot end of the mattress. Partially unzip the cover to retrieve the umbilical then re-zip the cover.

- 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.

3.4 Initial Inflation (if using a pump)

- 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. The mattress is now ready for use. Initial inflation can take up to 45 minutes if the mattress is completely deflated.

4. Using the Mattress & Pump

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.

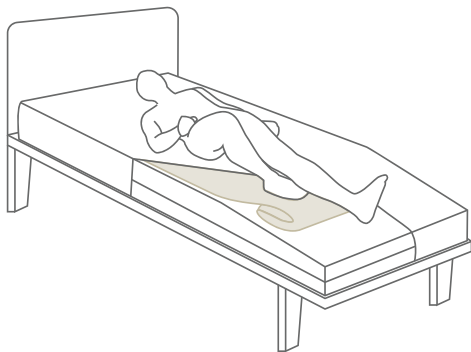
The 'MAX' mode can be used for periods where a more stable support surface is required for repositioning. The mattress will default to alternating air mode after 30 minutes as a safety measure.

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.



4.3 Pump Operation (Mode & Comfort Setting)

Use the mode buttons on the pump to select the preferred mattress operating mode. It may be necessary to unlock the control panel by pressing and holding the lock button before using the buttons.

Use the comfort level button to select the preferred mattress comfort level (EP20AU model only). Comfort level is saved and restored when the pump is switched off and back on.

Please see the 'Pump User Interface' section of this document for a full description of the user interface on the pump.

4.4 Transport Function (if using a pump)

To transport the bed and patient:

- Ensure that the pump is securely positioned on the bed and cannot slip off during relocation.
- Activate 'MAX' mode on the pump. Once inflation is complete switch off the pump (pressure will be maintained in the mattress).
- Switch off power at the wall socket then unplug the

power lead from the wall. Stow any excess cabling in such a way that it can't be damaged when relocating the bed.

- Relocate the bed. Ensure patient and operator safety and follow all instructions and warnings for the bed.
- Follow the installation instructions to reconnect the pump to the wall outlet and resume operation of the pump.

4.5 CPR

In an emergency where Cardiopulmonary Resuscitation (CPR) is necessary, disconnect the orange umbilical connector from the pump to allow the mattress to deflate. On Alternating Air (E600 & E700) mattresses a twist CPR valve is also located at the head end of the mattress to rapidly deflate the mattress.

4.6 After Use (if using a pump)

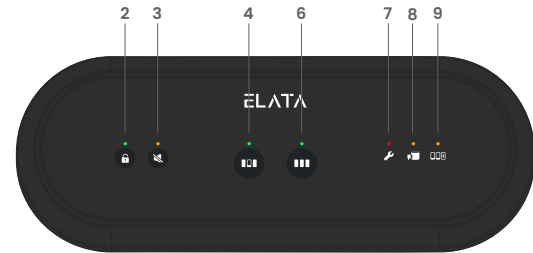
After use, flip the power switch on the pump to the off (O) position.

To disconnect the umbilical mattress from the pump, press the two orange tabs on the sides of the umbilical connector to release the clips.

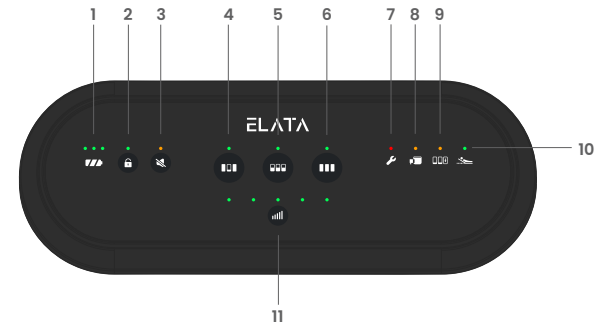
5. Pump User Interface

5.1 Control Panel

EP10AU control panel



EP20AU control panel



5.2 Pump Functions

REF	SYMBOL & FUNCTION	EP10AU	EP20AU
1	 Indicates level of battery charge.  Pulsing green (x3) Charging  Steady green (x3) High charge  Steady green (x2) Medium charge  Steady amber (x1) Low charge  Flashing red (x1) Critically low charge All three battery indicators may remain unlit for a few seconds when the unit is first powered on (until battery level is established).	-	✓

REF	SYMBOL & FUNCTION	EP10AU	EP20AU
2	 Lock and unlock the control panel. • Press and hold the button for 3 seconds to unlock the panel. • Press the button momentarily to lock the panel. 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. 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.	✓	✓
3	 Mute an audible alert. The mute button can be used to silence any audible alert for 30 minutes. Please note: • 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). The mute button is unaffected by panel lock (i.e. it can be pressed at any time). The indicator will flash when any alert is sounding and will be lit when an alert has been silenced.	✓	✓

REF	SYMBOL & FUNCTION	EP10AU	EP20AU
4	 Elata AdaptiveMode™ 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.	✓	✓
5	 Constant Low-Pressure (CLP) Mode 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.	-	✓
6	 Maximum (MAX) Pressure Mode. 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.	✓	✓

REF	SYMBOL & FUNCTION	EP10AU	EP20AU
7	 Indicates that service is required or a fault has occurred that may need repair. • 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). Servicing is due if the pump has run for 1 year or more since its last service (or initial use). Minor faults may sometimes be cleared by restarting the pump using the power switch. The service indicator and critical errors can only be reset by certified service personnel.	✓	✓
8	 Indicates that the mattress is disconnected from the pump unit. Lit when the mattress is disconnected. To reset the alert: • 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	 Indicates a failure to maintain pressure (typically due to a leak). A minor leak will trigger an alert tone and a major leak will trigger a continuous alert. To reset the alert try using the following procedures: • 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	 Elata TiltSense™ 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).	-	✓

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

5.3 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 button can be used to suppress active audio alerts for 30 minutes. Mains power failure and low battery alerts will remain muted until mains power is restored.

6. Cleaning, Storage & Maintenance

6.1 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.

6.2 Cleaning, Storing & Maintaining the 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 or storage.
- 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 on the EP20AU pump should be recharged every 6 months and stored at room temperature.
- Servicing is recommended every 12 months or sooner depending on usage conditions. The servicing alert will indicate when a scheduled 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 policy.

6.3 Cleaning the Mattress

Please read the following warnings before cleaning the mattress:

- The mattress base and umbilical connector contain electronic components that **MUST NOT** be exposed to or immersed in any liquid.
- 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, Umbilical and Internal Components

- Electronic components within the mattress and umbilical must not come into contact with any liquid.
- Wipe down the outside of the mattress base and umbilical 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 or umbilical connector. Wipe surfaces well with a clean damp cloth and air dry.
- Do not disassemble the umbilical.
- Do not disassemble the mattress unless cleaning is required.
- If cleaning or disinfecting of internal components within the mattress is required, do not disconnect the tubing connectors.
- Air cells can be swabbed with authorised cleaning and disinfection solutions. Dry thoroughly with a soft cloth.
- Do not iron, machine wash or machine dry the foam, air cells or mattress base.
- The mattress includes foam components and these cannot be washed. Contact Enable Lifecare for replacement foam.

6.4 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.
- If the mattress is to be stored for more than 3 months, we recommend storing it flat (not folded or rolled up) on a flat surface.

6.5 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.
- Pumps: 18 months prior to first use. Must remain in transport mode and be stored at a temperature not exceeding 30°C.

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

7. Technical Information

7.1 Mattress Specifications

SPECIFICATION	E400 MATTRESS
Dimensions	Single: 88cm X 200cm X 19.5cm. King Single: 107cm X 200cm X 19.5cm.
Weight	Single: 20kg. King Single: 25kg.
System Type	A foam + air hybrid mattress with 1-in-2 alternating air cell configuration.
Clinical Use	Suitable for up to Stage 2 pressure injury management when used without a pump and up to Stage 4 when used with the Elata® pump.
Safe Working Load	Supports patients up to 230 kg.
Construction	10 transverse air cells (profiled foam insert encased in a waterproof TPU cover) with 1-in-2 alternating air cell configuration; rebound foam layer for airflow and natural movement; heel slope.
Pump Compatibility	Compatible with the EP10AU pump and the EP20AU pump. May be used with or without a pump.

7.2 Pump Specifications

SPECIFICATION	EP10AU	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 3–4h	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)	

7.3 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

7.4 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.

7.5 Troubleshooting

PROBLEM	POSSIBLE SOLUTION(S)
Pump does not start	• Check that the power lead is connected to the wall outlet and the outlet is switched on. • Check that the power switch on the side of the pump is switched on (I). • Check that the mattress umbilical is securely clipped to the pump. • Restart the pump using the power switch.
Service light is lit amber 	• This indicates that scheduled service is due. Servicing is due if the pump has run for 1 year or more since its last service (or initial use). Contact certified service personnel to arrange servicing.
Service light is lit steady red 	• This indicates the need for immediate service (minor fault). • Minor faults may sometimes be cleared by restarting the pump using the power switch. • If the light stays lit after restarting the pump, contact certified service personnel to arrange servicing.
Service light is flashing red 	• Flashing red indicates a critical error and the pump will become inoperable. Contact certified service personnel to arrange immediate servicing.
Mattress disconnect indicator is lit 	• This indicates that the mattress is disconnected from the pump unit. • Try to remove and re-fit the umbilical air connector (the mattress connector), and/or restart the pump using the power switch.
Leak indicator is lit 	• This indicates a failure to maintain pressure (typically due to a leak). • Try removing and re-attaching 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.

PROBLEM	POSSIBLE SOLUTION(S)
The user is disturbed by noise or vibration from the pump	• Check that the pump is hanging securely on the end of the bed. • Try adjusting the position of the pump (using the bed hooks) to prevent resonance. • Try placing a vibration absorbing material such as a piece of foam rubber or thick fabric between the pump and the bed end.
The mattress slips on the bed frame	• Ensure that the mattress is correctly fastened to the frame with the straps.
The user is 'bottoming out' (insufficiently supported or feeling the bed frame through the mattress)	• Adjust the comfort level (EP20AU model only). • Restart the pump using the power switch. • Remove and re-attach the umbilical to the pump. • Check the mattress and umbilical for air leaks or disconnected air cells
Nothing changes when the bed backrest is raised	• The TiltSense™ feature is only supported on the EP20AU pump with compatible mattresses (incorporating a tilt sensor).
The pump starts but the mattress will not inflate	• Check that the mattress umbilical is securely clipped to the pump. • If the mattress includes a CPR valve (E600 & E700 models) check that it is closed. • Check the mattress and umbilical for air leaks or kinked tubing.
Tilt sensor light is flashing 	• This indicates a fault with the tilt sensor. • This fault may sometimes be cleared by restarting the pump using the power switch. • If the light continues flashing after restarting the pump, contact certified service personnel to arrange servicing.

Please contact Enable Lifecare at **1300 370 370** if the problem persists.

8. Additional Information

8.1 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.

8.2 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

8.3 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

8.4 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 Pump: 10 years

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.

8.5 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. Extended warranty options may be available subject to separate warranty terms and conditions.
- Mattress: 5-year warranty from date of purchase.

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

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

8.6 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°C
	Drip dry
	<1% Chlorine
	Do not dry clean
	Wipe down
	Do not iron
	Tumble dry
	Resistant to ignition

8.7 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 (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.
- 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.
- Prolonged interruption of therapy may reduce pressure redistribution. Users must ensure that an alternative pressure redistribution surface or support method is available if therapy is interrupted.
- As with any pressure redistribution surface, patient movement may occur. Appropriate bed rail configuration and patient monitoring should be used to reduce the risk of entrapment or unintended bed exit.
- 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 and pumps 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.

- The pump poses an electric shock hazard if exposed to liquid 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 so the pump cannot slip off the bed end.
- 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 mattress, umbilical hose and power lead must be positioned in such a manner that they cannot become trapped or damaged. Always 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.
- Use 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.
- 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 that attach the pump to the bed.
- 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 intended for emergency use during power failure only and must

not be used as the primary power source.

- Always fully charge the battery of the EP20AU pump 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 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.

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