

User & Full Service Manual



Pressure Relieving / Alternating Air Mattress & Pump

Pump Model: HH/P09 Mattress Model: HH/T06

NB: Please ensure this document is fully read & understood by the Clinician / Carer / Service Engineer prior to use.



Lothian II™ User/Service Manual

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SAFETY

Before you connect the system pump to a mains socket, read carefully all the installation instructions.

This system has been designed to comply with regulatory safety standards including:

- EN 60601-1 / Class I Medical Device

For your own safety and the safety of the equipment always take the following precautions:

- Keep the pump away from sources of liquids.
- Do not expose the system, especially the mattress, to naked flames, such as cigarettes etc.
- Do not store the system in direct sunlight.
- Do not use phenolic based cleaning solutions.
- Keep sharp objects away from the mattress.
- Ensure that the system is clean and dry prior to storage.
- Store the pump and mattress in the protective bags supplied.
- We recommend the use of cot sides on the bed while the system is in use and the patient is positioned on top. Local policies regarding the use of cot sides should be taken into account.
- Keep these instructions handy for reference.

WARNING

Electrical equipment may be hazardous if misused or damaged. Ensure the power is isolated to the system before any repairs or maintenance is carried out & these should only be carried out by suitably trained & authorised personnel.

For further advice please call Herida Healthcare on Freephone 0800 193 6030.

Parts and Accessories:

- Mattress (1PC) / Pump (1PC) / Air tube (1PC) / Mattress cover (1PC)

INTRODUCTION

Product Description

The Lothian II™ has been designed to ensure ease of use, whilst high clinical delivery is achieved in a single mattress. Specifically designed for use in long term care environments or equally at home in a residential setting, this product provides high to very high risk solution (reference: clinical case study M. Hughes 2017), when used as part of a complete care package. The cyclical cells operate and deflate in a ten-minute alternating pattern, with a 1.5 minute equaling of cells in between the complete cycle, therefore providing direct pressure relief and patient stability throughout the whole dynamic process. The multi-stretch, vapor permeable cover, comprises of a high-level coating of polyurethane, which makes it easy to clean, whilst complying with strict infection control procedures. The rapid cell deflation system is unique in the sense that pressure relief happens much quicker than on a standard dynamic mattress system. This prompt deflation physically ventilates, thus allowing immediate relief between cycles, rather than awaiting deflation under patient weight as is often the case.

Application

This product is to be used for those patients who have existing tissue damage or pressure ulcers. It can also be used as a high-risk preventative item.

Contra indications

Patients with severe spinal injuries / fractures should not be using this product.

Do not attach the mattress to the fixed part of the bed frame. It should be secured to the moving / working parts to ensure the bed can be profiled as required.

Patients requiring a deep cell mattress should not be considered for this particular product without a prior clinical assessment.

This product forms part of a holistic care package and should only be used by trained personnel. For training or further advice contact Herida Healthcare on Freephone +44 800 193 6030.

Working Principle

The dynamic mattress system consists of a dynamic air pump and an alternating air mattress. The air mattress has three distinct airway chambers:

1. Pillow Chambers – Air tubes 1,2 & 3. These remain static throughout as to avoid head movement, sickness to the user.
2. Group A Chambers – Air tubes 4,6,8,10,12,14,16 & 18.
3. Group B Chambers – Air tubes 5,7,9,11,13,15 & 17.

OPERATION

A and B chambers alternate inflating and deflating by using the pump connected. This air alternating, mattress system enhances the blood circulation to treat and prevent pressure ulcers, when part of a holistic care package. Initialisation can take up to 50 minutes to achieve & it is recommended that a Rapid Inflator is used, where possible, to reduce the inflation time.

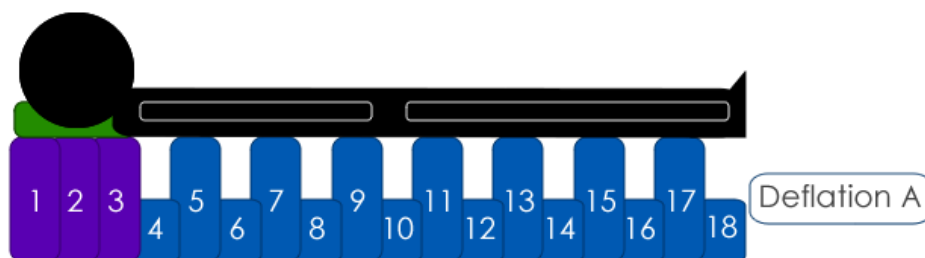
Static Mode

When the pump is adjusted to the static mode, air chambers A & B are both fully inflated until 52mmHg / 180 Kg is achieved. This mode is used for seating or patient transfer.



Alternating Mode

When started, both chambers A & B are initially inflated to 52mmHg / 180 Kg. Group A chambers deflate for 5 minutes followed by both A & B inflating for 1.5 minutes. This is followed by Group B chambers deflating for 5 minutes. This is one complete cycle.



Profiled Bed & Mattress - Clinical & Carer Considerations

If the bed is in the profiled position & the patient is touching the foam base, ensure that the pump pressure is increased accordingly to appropriately accommodate (*see below). Unless the clinical condition dictates, it is not advised to adjust the bed profile beyond 45°. The Lothian II™ will continue to operate beyond this but may cause increased pressure points on the patient. A fist or hand test to ensure patient clearance under the sacral area is a best practice guide (see image 1DA and diagram of profiled mattress 2DA or visit our website (www.heridahealthcare.co.uk) under "Education" tab section and select Dynamic Best Practice from the drop-down menu). If you are dealing with heavier or more complex patients that require a deeper cell mattress, then please contact your provider or seek assistance via Herida Healthcare Customer Services. The clinician must select the correct mattress type at prescription point / patients individual circumstances.

OPERATION



Image 1DA

(NB: use hand to check ensure appropriate clearance when profiled as below. Add more pressure on the pump if required in order to achieve this. NB: Weight setting is a guide only and cell pressure must also be taken into consideration for individual patients). Clinical judgement must always overrule user guidance.

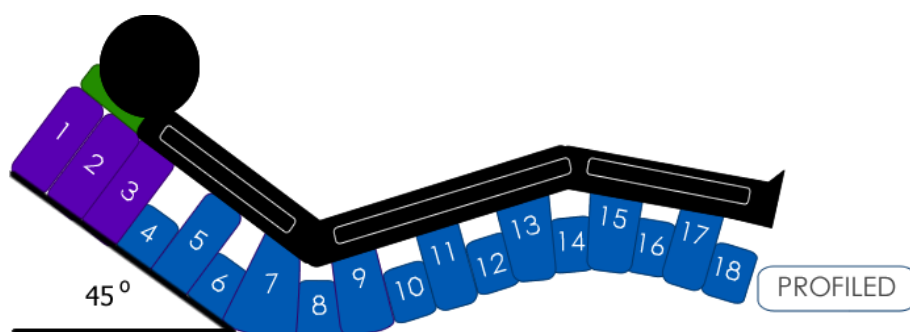


Image 2DA

Installation

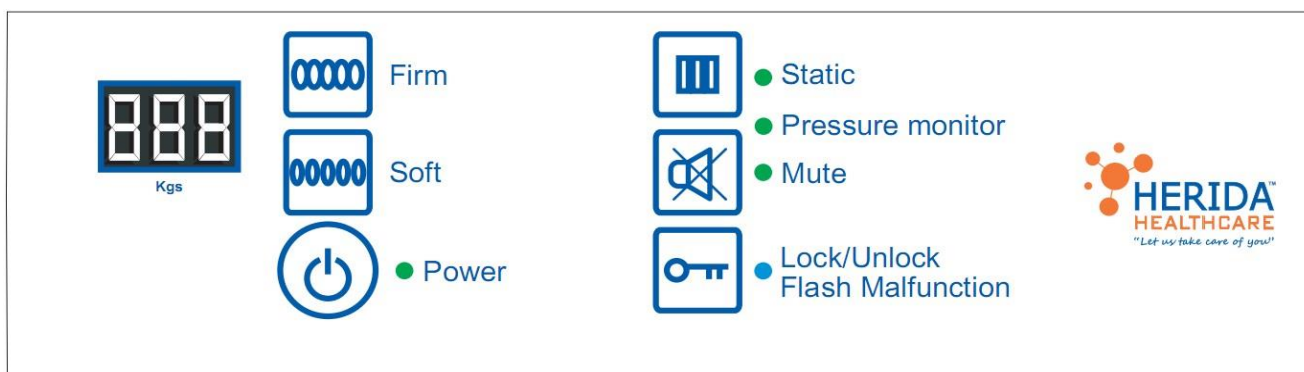
1. Remove all packaging & place the pump either at the end of the bed on its hooks or on a flat surface.
2. Ensure that there are no sharp or hard objects on the bed before unfolding the mattress & laying out flat. The air inlet should be located at the feet side of the bed.
3. Use the Rapid Inflator (if available) to inflate the mattress before connecting the air tubes to the pump. The tubes should be connected securely in place without any signs of leakage. If a Rapid Inflator is not available, the mattress will take approximately 50 minutes to inflate.
4. Connect the pump to the socket & switch on.
5. Adjust the mode & pressure by the users condition & weight to suit.
6. In order for the alarm to activate, the system must be switched on & powered up for at least 5 minutes. This should give the internal battery on the PCB sufficient time to charge.

OPERATION

Safety Instructions

1. Ensure that there are no sharp objects, fire or abrasive materials in the vicinity. If the mattress is damaged. Remove the patient & transfer to an alternative mode of pressure relief. A foam underlay is provided as standard at the base of the mattress to ensure pressure relief is maintained (to an extent) in the event of a power failure. **NB** This is not to be considered as a long-term pressure relief option.
2. If there is an issue with the pump, remove the patient & transfer to another mode of pressure relief.

Pump Operation



Power: Power On / Off

Soft / Firm: Pressure adjustment. Each single push adjusts ± 5 KG. Longer push adjusts ± 5 KG rapidly.

Static: All tubes will inflate up to 52mmHg / 180 Kg. No alternating takes place & the digital display will show " - - - ". The pump will revert back to the previous alternating cycle after 30 minutes.

Pressure Monitor: The light is illuminated when pressure is normal & extinguished when pressure is abnormal. The light will continuously flash during the alternating cycle change-over.

Mute: When pushed, the audible alarm is silenced.

Lock/Unlock/Malfunction:

- Push the key for 2-3 seconds to lock / unlock the panel.
- The light will continuously flash on the following occasions: when the mattress has not yet reached pressure during alternating cycles; the mattress has an air leak or the pressure has dropped lower than 6mmHg.
- When the panel is unlocked, it will automatically lock itself after a period of time.
- The lock / unlock facility will be unavailable if the system cannot reach pressure.

Alarm Activation: In order for the alarm to activate, the system must be switched on & powered up for at least 5 minutes. This should give the internal battery on the PCB sufficient time to charge.

OPERATION

Air Leakage / Low Pressure Alarm

- After working for 50 minutes and the pressure is lower than 15mmHg, the pump will alarm indicating an initialisation failure.
- During normal operation, when the pressure is lower than 6mmHg for 6 minutes, the pump will alarm indicating possible air leakage from the mattress.
- Pushing the mute key will silence the pump alarm.
- If the alarm sounds consistently and all attempts to remedy have failed, seek engineer assistance to rectify.

Power Off Alarm

The alarm will sound if power is lost to the pump.

Pump Characteristics

Power	AC220V / AC110V
Pressure Range	10 – 52 mmHg
Internal Fuse	F0.5A 250V
Plug Fuse	3A
Frequency	50Hz / 60 Hz
Power	8W
Noise	≤45dB
Alternating Time	1 complete cycle is 11 ½ minutes which is 2 x 5 minute periods of alternative cell inflation with a change over time of 1 ½ minutes.

Pump Pressures

Weight (Kg)	Pressure (mmHg)	Weight (Kg)	Pressure (mmHg)
30	10	110	26
40	12	120	28
50	14	130	30
60	16	140	32
70	18	150	34
80	20	160	40
90	22	170	46
100	24	180	52
This is subject to a tolerance of ±20%			

Mattress Characteristics

Model	T06 Lothian II™
Layers	2 including the foam base.
CPR	1
Max Loading Weight	180 Kg

MAINTENANCE

Cleaning

Regular cleaning of the mattress is required as per the below instructions. Failure to follow these instructions may result in a void warranty situation.

STANDARD CLEANING PROCEDURE

Wipe down cover with a soft, disposable cloth which has been moistened with warm water & detergent (advisory at 40°C).







SEVERE INFECTION CONTROL PROCEDURE

Use a diluted solution of Sodium Hypochlorite (or similar) & fresh water (up to 10,000 ppm) In the following circumstances:

- Blood or bodily fluids has soiled the mattress
- Between different patients

Directions for use:

- Apply a fresh water base to the cover with a soft cloth
- Apply the solution
- Thorough fresh water wash down
- Ensure the cover is dried thoroughly

Machine wash up to 85°C	Do not dry clean	Occasional tumble dry on low heat	Do not bleach	Do not iron	Do not use phenol based products such as 'Stericol' or Clearsol'
					

Maintenance & Repair

Maintenance & repair work should only be carried out by an appointed engineer who have been trained by Herida Healthcare Ltd. and only original manufacturers parts should be used. Failure to do so could result in a void warranty situation.

Service Interval & Instructions

This product must be serviced annually as a minimum (or as suggested upon patient return) to ensure ongoing safe, trouble free usage. The service must be conducted by a Herida trained / competent individual that has demonstrable training records. This training must be reviewed regularly. Only Herida Healthcare spare parts can be used to ensure warranty and safe use is achieved throughout.

MAINTENANCE – 12 months or as suggested upon patient return

At point of service the following aspects must be maintained to ensure that manufacturer's warranty remains intact. These can be done in a non-alphabetic way, if all areas are covered:

- Ensure the pump unit and mattress / cells are fully decontaminated prior to service and are cleaned in accordance with the schedule provided.
- Electrical safety checks / Pat Test – To be conducted annually or time of service. Please make sure the kettle lead and plug fuse is compliant at 3amp only.
- Filters must be changed at point of return / before patient handover / new client and at time of service.
- Rear pump fuse must be inspected and replaced if faulty – 0.5A only.
- Pump casing must be opened and vacuumed internally, if any dust or particles are evident. Never use any water / fluid internally to clean.
- Pump must achieve pressure within 20% tolerances as per page 9 of this manual – via calibrated sphygmometer and cell attachments. Kits available to purchase via manufacturer. Ensure that a rapid inflator is used at time of service to ensure that service and installation time is reduced to minutes.
- Pump low pressure function is evident at 6mmHG or lower for 15-20 minutes or more.
- Cells are to be fully inflated and tested for leakage. This should be done via a pressurised system, soak test over at least 3 cycles or under weights to replicate patient in situ.
- The tubing and connectors that run down the side of the mattress, must be clear of kinks / debris or must not be snapped in any way. These should be running freely with air distribution to each cell and have no leakage or deterioration of surface. A spring is situated at the head section of the mattress tubing at to avoid kink in the critical area.
- The non-return valve holding the 3 head cells must be functioning correctly. This is evident via 3 solid static head cells / none alternating during cycle.
- A functional "soak test", ensuring that the tactile panel / pump and mattress operates fully in synergy. This is done by attaching and inflating the mattress to full pressure and then increasing / decreasing both weight and other panel / button functions.
- The pump, if stored for a period of time, may require attaching to the mains electric for at least 30 minutes prior to use. This is to ensure the battery is sufficiently charged, ensuring the alarm function is fully functioning. Contact manufacture if a warranty item.
- Ensure the timer valve is rotating freely & a light application of grease should be applied if required. The manufacturer recommends Molykote 111 compound lubricant.
- The key lock button is effective by release / addition, holding 3 seconds or more to activate.
- CPR is to be checked functionally and deflated after all soak tests are completed.
- Mattress Cover and cells are to be inspected for puncture, tear, rip or excessive odour post cleaning and replaced accordingly if defective.

MAINTENANCE

Storage

- Good ventilation will be required when storing the product & it should always be kept dry & away from direct sunlight. Temperature should be maintained in the region of $22^{\circ}\text{C} \pm 3^{\circ}\text{C}$ when in use.
- Avoid repeat exposure to extreme temperatures.

Transportation

- Care should be taken when loading, unloading and during transportation & refrain from placing heavy objects on top of the mattresses.
- Do not expose to direct sunshine for any period of time when loading and unloading & ensure a cover is used to protect the mattress when raining or snowing.
- Do not open with a knife or sharp objects as this may damage the mattress cover.
- Always use the provided re-usable pump protector for all transportation methods. This plastic sleeve will need to be cleaned prior to re-use for infection control purposes.

Calibration

- During service intervals or between patients, it is recommended to check pressure tolerances (see the table on page 9) using a Herida Testing System. Calibration training must be conducted & applied by a Herida trained technician.

Other Considerations

- Original internal fuse is F0.5A 250V. When replacing the fuse, ensure a similar type is used and that the fuse is disposed of in the appropriate manner.
- During normal working, when the emergency deflation is needed, switch off the pump and pull out the CPR toggle quickly.
- The mattress should be away from sharp objects to avoid any scratches or punctures.
- Put bed cover sheet or blanket over the mattress before use. No plastic or rubber sheets should be used.
- Ensure that all the tubes remain flat & any twists / kinks are avoided.
- If any air leakage is found, check all the tube connectors and air tubes carefully to see if any are loose or damaged.
- If any major problems or issues are found or the product is not working, stop using immediately and ask the engineer / manufacturer / provider for assistance.
- Any discarded mattress or covers should be treated in accordance with local rules and guidance in accordance with contaminated products.
- The pump is factory set to 80Kg and is a guide only. This can be adjusted depending on the needs of the patient.

ROUTINE CHECKS

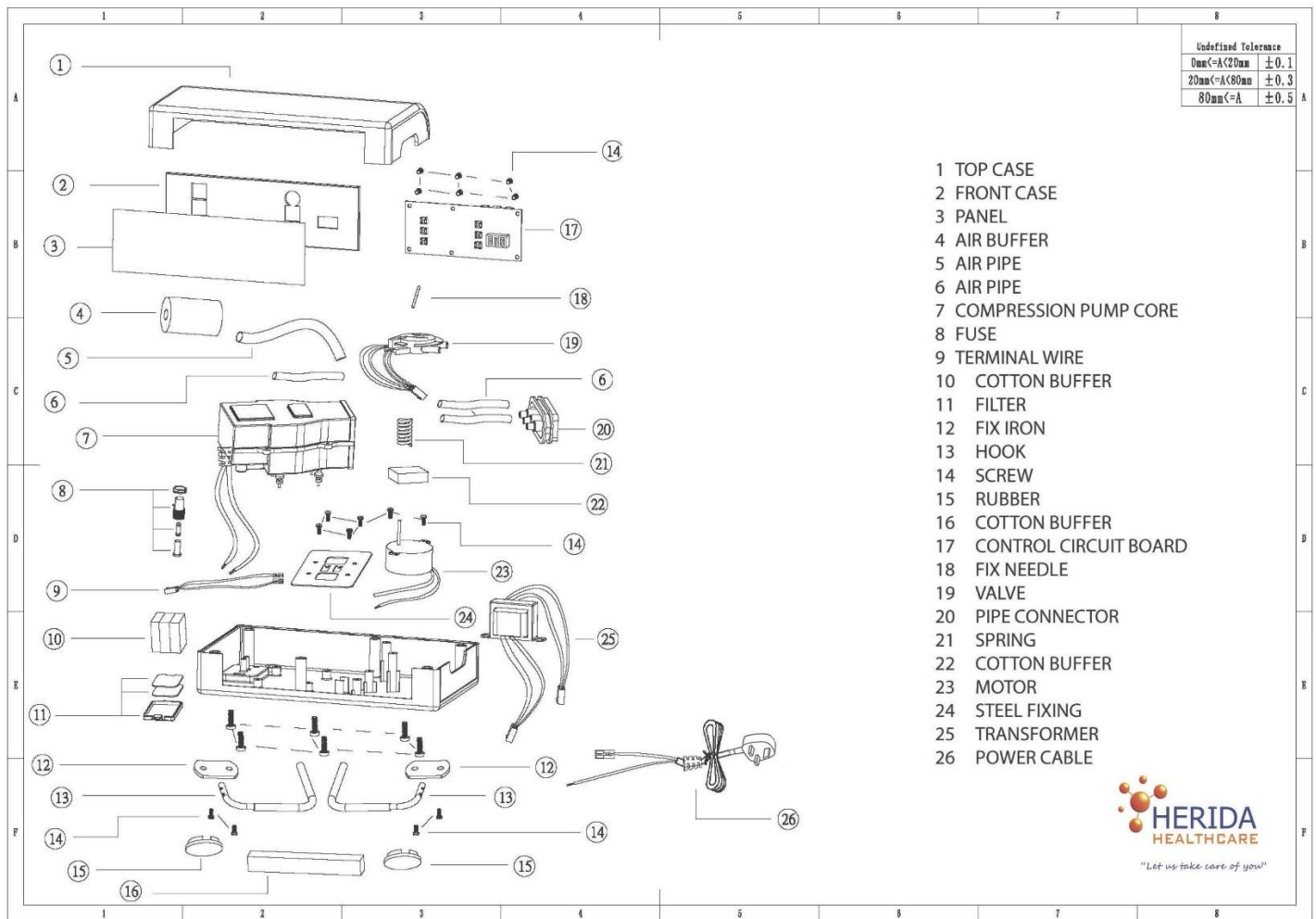
Mattress

- Remove top cover and inspect for signs of wear or any tears.
- Check zips are still operative & function as normal.
- Check integrity of all connectors including cells, tubing and CPR toggle.
- Ensure all cell fasteners are snapped to the mattress base and are not loose or faulty.
- Check that stitching which secures the straps to the base of the mattress is sound and no fraying or damage has occurred.



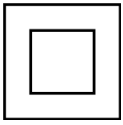





Pump

- Check the outer casing of the pump unit for damage.
- Examine the mains supply lead of the pump unit for signs of wear or damage & replace if necessary.
- Test power fail alarm system before use.

P09 Pump



WARNINGS & SYMBOLS

	<p>Warning – Follow guidance at all times as per the instructions within the user manual.</p>
	<p>BF application symbol – Provides a higher degree of protection against electric shock.</p>
	<p>Class II electrical appliance – Double insulated.</p>
	<p>Dispose of electrical equipment correctly (WEEE).</p>
	<p>Do not use broken or damaged electrical plugs or cables as this may lead to electric shocks.</p>
	<p>Ensure hands are dry before handling all electrical items.</p>
	<p>No exposure to water / splashing or it may cause electric shocks or fire.</p>
	<p>Only authorised / qualified personnel should dis-assemble, repair or rebuild this product.</p>

TROUBLE SHOOTING

No.	Issue	Possible Cause	Possible Resolution
1	No power	<ul style="list-style-type: none"> The plug is not properly connected. Power Cut. The fuse is broken. The machine / system is broken. 	<ul style="list-style-type: none"> Make sure the power is correctly connected and the voltage is normal. Await re-connection of power / look at generator. Check the fuse, replace if broken. Call the local distributor for repair or replacement.
2	Air mattress leakage / Alarm Sounding	<ul style="list-style-type: none"> The mattress is not connected to the pump correctly. Air tube is disconnected or damaged. CPR not attached properly 	<ul style="list-style-type: none"> Check the tube connectors. Repair the air tubes or call for replacement. Re-attach CPR plug
3	Mattress is too hard or too soft	<ul style="list-style-type: none"> The air pressure is not adjusting to required level. 	<ul style="list-style-type: none"> Adjust the pump pressure according to the user weight until suitable and comfortable.
4	No full inflation after long inflating	<ul style="list-style-type: none"> Air hoses are loose or not connect properly. CPR is loose or not connected. Air pump has not enough air pressure. 	<ul style="list-style-type: none"> Check all the air hoses and connectors. Connect the CPR tightly. Adjust the pressure on the pump. If it is showing maximum pressure full inflation has not been achieved, the pump has a problem. Ask for repair or replacement.
5	Pump has strong vibration	<ul style="list-style-type: none"> The pump is not located on a flat area or not hooked properly on the bedframe. 	<ul style="list-style-type: none"> Put the pump on flat area or hook it in a suitable position on the bedframe.

COMPANY INFORMATION

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Disclaimer

Please be aware that all products should be disposed of in an environmentally friendly & infection control manner in compliance with any local or national requirements. Contact Herida Healthcare Ltd. for responsible WEEE disposal methods.