ARJOHUNTLEIGH

GETINGE GROUP

# ALPHA RESPONSE

## INSTRUCTIONS FOR USE


CE 0086

...with people in mind

# Contents

## GENERAL SAFETY

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

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

- EN60601-1:1990/A13:1996 and IEC 60601-1:1988/A2:1995.
- UL60601-1, UL2601-1 and CAN/CSA C22.2 No. 601.1-M90.
- EN60601-1:2006, EN60601-1-11:2010 and IEC 60601-1:2005.
- AAMI/ANSI ES60601-1:2006 and CAN/CSA C22.2 No.60601.1(2008).

### Safety Warnings

- **It is the responsibility of the care giver to ensure that the user can use this product safely.**
- **Whilst the patient is unattended, the decision to use safety sides should be based on clinical assessment and in line with local policy.**
- **Alignment of the bed frame, safety sides and the mattress should leave no gap wide enough to entrap a patient's head or body, or to allow egress to occur in a hazardous manner where entanglement with the mains power cable and tubeset or air hoses may result. Care should be exercised to prevent occurrence of gaps by compression or movement of the mattress. Death or serious injury may occur.**
- **Make sure that the mains power cable and tubeset or air hoses are positioned to avoid causing a trip or other hazard, and are clear of moving bed mechanisms or other possible entrapment areas. The mains power cable of this pump is designed to allow movement of the bed, and should be fitted into the cable management flaps along the sides of the mattress, as described in this manual.**
- **When using a seat cushion, the tubeset may be a trip hazard; position the tubeset so that it does not create a trip hazard, and always supervise babies and small children when the product is in use.**
- **Electrical equipment may be hazardous if misused. There are no user-serviceable parts inside the pump. The pump's case must only be removed by authorised technical personnel. No modification of this equipment is allowed.**
- **The mains power socket/plug must be accessible at all times. To disconnect the pump completely from the electricity supply, remove the plug from the mains power socket.**
- **The CPR control and/or the CPR indicator tag must be visible and accessible at all times.**
- **Disconnect the pump from the mains power socket before cleaning and inspecting.**
- **Keep the pump away from sources of liquids and do not immerse in water.**
- **Do not use the pump in the presence of uncontained flammable liquids or gasses.**
- **The cover of this product is vapour permeable but not air permeable and may present a suffocation risk.**
- **Do not use the mattress without a cover, it provides a protective barrier.**
- **Bags supplied with this equipment may present a suffocation risk; to avoid the risk of suffocation keep the bags away from babies and small children.**
- **There is no transport mode on the seat cushion.**
- **Only the pump and mattress or seat combination as indicated by ArjoHuntleigh should be used. The correct function of the product cannot be guaranteed if incorrect pump and mattress or seat combinations are used.**

## Precautions

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

- Placing extra layers between the patient and the mattress potentially reduces the benefits provided by the mattress and should be avoided or kept to a minimum. As part of sensible pressure area care, it is advisable to avoid wearing clothing which may cause areas of localised high pressure due to creases, seams, etc. Placing objects in pockets should be avoided for the same reason.
- Do not expose the system, especially the mattress, to naked flames, such as cigarettes, etc.
- In the event of a fire, a leak in the seat or mattress could propagate the fire.
- Do not use or store the system in direct sunlight.
- Do not use phenol-based solutions to clean the system.
- Make sure the system is clean and dry prior to use or storage.
- Never use sharp objects or electrically heated under blankets on or under the system.
- Store the pump and mattress in the protective bags supplied.
- Pets and children must be supervised in the vicinity of the system.

## Electromagnetic Compatibility (EMC)

This product complies with the requirements of applicable EMC Standards. Medical electrical equipment needs special precautions regarding EMC and needs to be installed in accordance with the following instructions:

- The use of accessories not specified by the manufacturer may result in increased emissions by, or decreased immunity of, the equipment, affecting its performance.
- Portable and mobile radio frequency (RF) communications equipment (e.g. mobile/cell phones) can affect medical electrical equipment.
- If this equipment needs to be used adjacent to other electrical equipment, normal operation must be checked before use.
- For detailed EMC information contact ArjoHuntleigh service personnel.

## Environmental Protection

Incorrect disposal of this equipment and its component parts, particularly batteries or other electrical components, may produce substances that are hazardous to the environment. To minimise these hazards, contact ArjoHuntleigh for information on correct disposal.

## Expected Service Life

The Alpha Response™ pump has an expected service life of seven years. To maintain the condition of the pump, have the pump serviced regularly according to the schedule recommended by ArjoHuntleigh.

Do NOT use unapproved accessories or attempt to modify, disassemble or otherwise misuse the *Alpha Response* system. Failure to observe this caution could result in injury, or in extreme cases, death.

## Design Policy and Copyright

# 1. Introduction

## About this Manual

This manual is your introduction to the Alpha Response™ system. Use it to initially set up the system and keep it as a reference for day-to-day routines and as a guide to maintenance. You must read and fully understand this manual before using the system.

If you have any difficulties in setting-up or using the *Alpha Response* system, contact your ArjoHuntleigh sales office, listed at the end of this manual.

## Intended Use

The intended use of this product is to prevent and/or manage pressure ulcers for patients up to 160 kg (352 lb).

The *Alpha Response* system should be used as part of a prescribed plan of care (refer to “Indications” on page 4).

## About *Alpha Response*

The *Alpha Response* system is a pressure redistributing mattress replacement, mattress overlay or seat cushion system designed to complement pressure ulcer treatment and prevention protocols. The product offers two therapeutic modes:

- Active[1] (Alternating) mode which periodically redistributes pressure away from vulnerable areas by inflating and deflating the cells beneath the body every 10 minutes.
- Reactive[1] (Constant Lower Pressure or CLP) mode where the cell pressure is reduced and held constant across the surface in order to lower the pressure exerted on the body.

The product also offers an additional option, Transport Mode, where therapy is interrupted and the mattress cells become static in order to assist with patient transport.

The mattresses can be used on standard hospital and normal domestic beds. Beds with divided sections for independent elevation of a patient's head and/or knees can be adjusted with these mattresses in position. The seat cushion can be used on standard hospital and normal domestic chairs.

1. *International Pressure Ulcer Prevention and Treatment Guideline (2009). www.epuap.org*

The pump has three settings for the patient weight range:

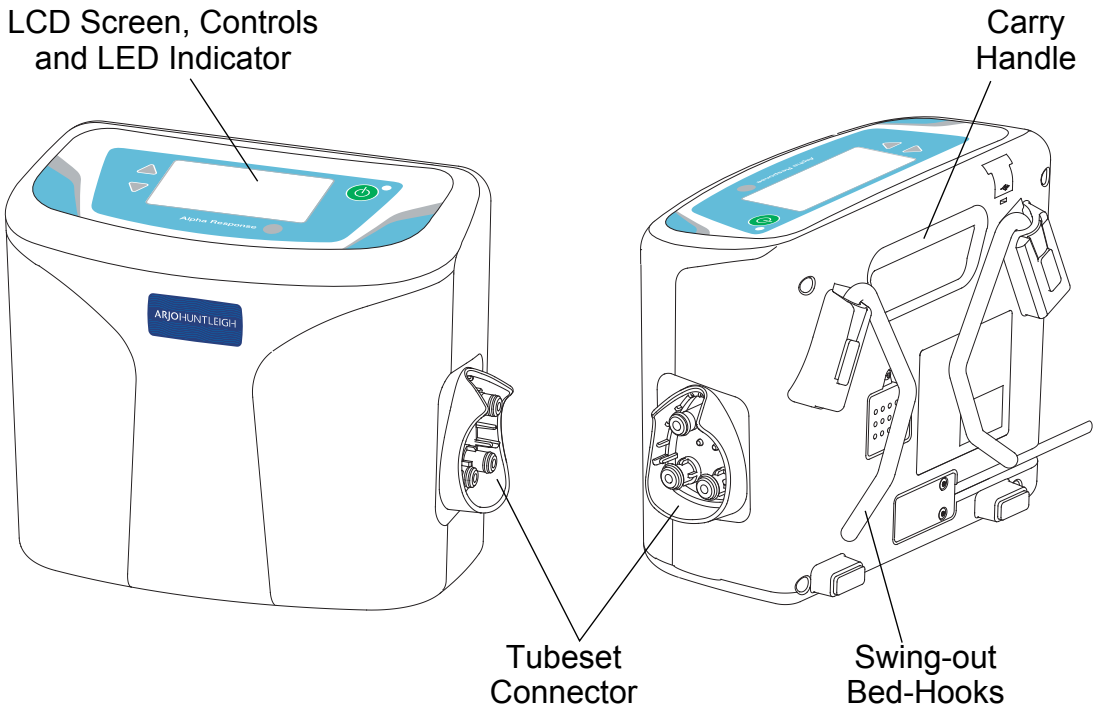
- Light: 40-70 kg
- Normal: 70-120 kg
- Heavy: 120-160 kg

The pump will automatically detect whether a mattress or seat cushion is connected.

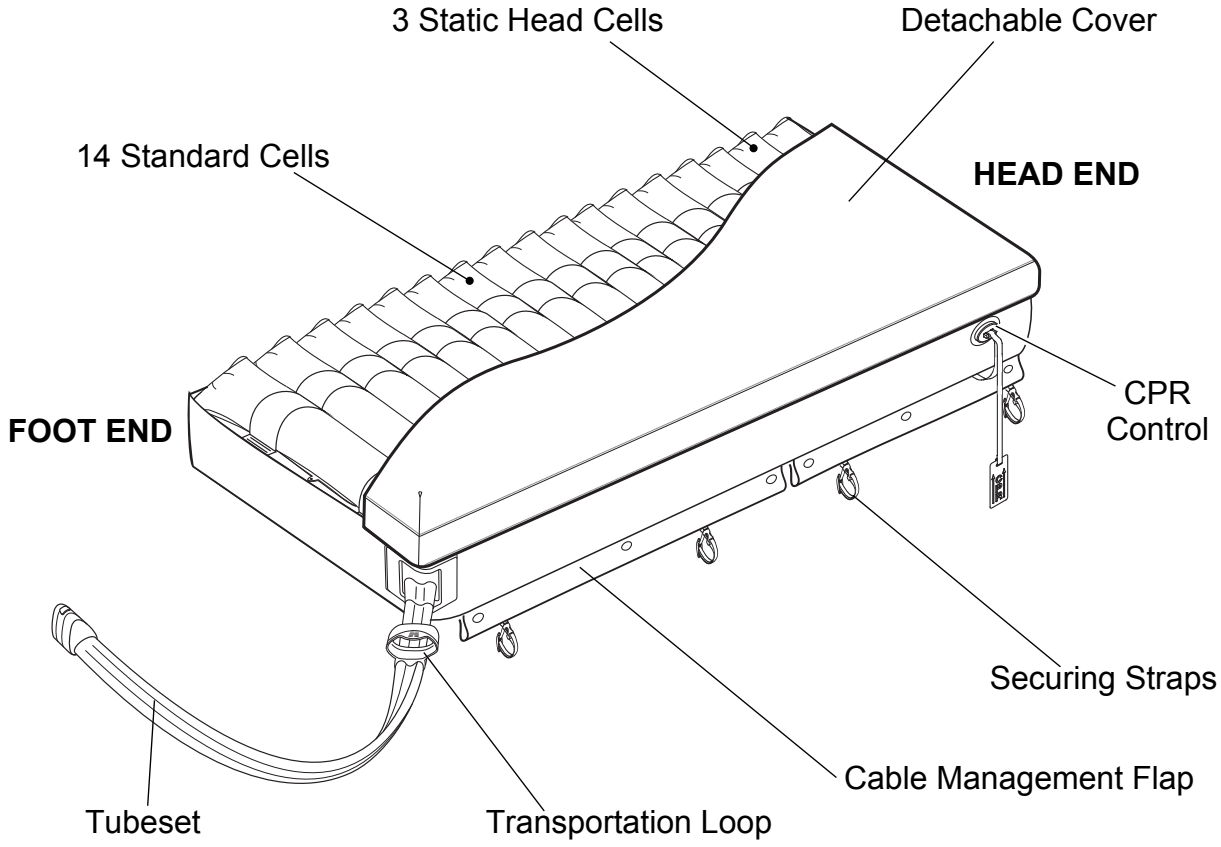
If the backrest on the bed is raised (the patient is in a semi-recumbent position), the system detects the new position and automatically increases the pressure in the mattress cells to provide optimal pressure redistribution to the patient.

A full technical description of the *Alpha Response* system can be found in the Service Manual, part number SER0021, available from your ArjoHuntleigh sales office.

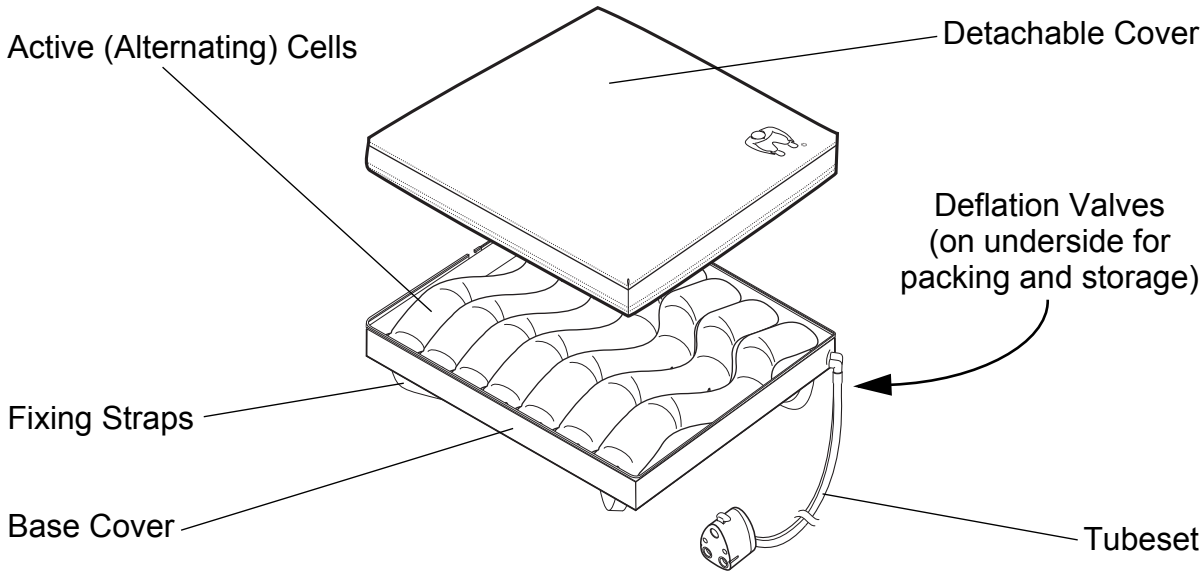
## Pump



## Mattress: Overlay and Replacement




## Seat Cushion



## 2. Clinical Applications

**Indications**

The *Alpha Response* systems are indicated for the prevention and/or management of all categories[1] of pressure ulcer, when combined with an individualised, comprehensive pressure ulcer protocol: for example, repositioning, nutritional support, skin care. Selection should be based upon a holistic assessment of the patient's individual care needs.

These systems represent one aspect of a pressure ulcer management protocol; all other aspects of care should be considered by the prescribing clinician.

If existing wounds do not improve or the patient's condition changes the overall therapy regimen should be reviewed by the prescribing clinician.

The above are guidelines only and should not replace clinical judgement.

The *Alpha Response* mattress and cushion are designed for patients weighing up to 160 kg (352 lb).

**Contraindications**

Do not use *Alpha Response* systems for patients with unstable spinal fractures.

**Cautions**

If patients have other unstable fractures, or conditions which may be complicated by a soft or moving surface, advice should be sought from an appropriate clinician before use.

While the *Alpha Response* systems have been designed to manage patients up to the weight limits indicated above, those approaching this upper limit are likely to have additional care and mobility needs and may be better suited to a specialist bariatric system.

Active therapy (alternating) cushions may be unsuitable for patients with poor sitting posture or pelvic deformity; advice from a seating specialist should be sought.

**Care of the patient when sitting**

Seated patients are at increased risk of pressure ulcers particularly if they are immobile or have wounds over the seating area. For optimal outcome, provide a pressure redistributing seat cushion in a chair which promotes a good sitting posture and has a level base seat to support the cushion, in addition to an individualised repositioning programme.

☞ *Mattress and cushion combinations may have different upper weight limits.*

☞ *Cushions should be used in combination with pressure-redistributing mattresses to provide 24-hour therapy.*

1. *NPUAP/EPUAP International Pressure Ulcer Guideline, 2009.*

# 3. Installation

**WARNING**

**Bags supplied with this equipment may present a suffocation risk; to avoid the risk of suffocation keep the bags away from babies and small children.**

**Preparing the Systems for Use**

Remove the system from the packaging. You should have the following items:

- *Alpha Response* pump including mains power cable.
- *Alpha Response* mattress overlay, *Alpha Response* mattress replacement or *Alpha Response* seat cushion, which all have integral tubesets and top covers.

☞ *Do not use the mattress or seat cushion without a cover.*

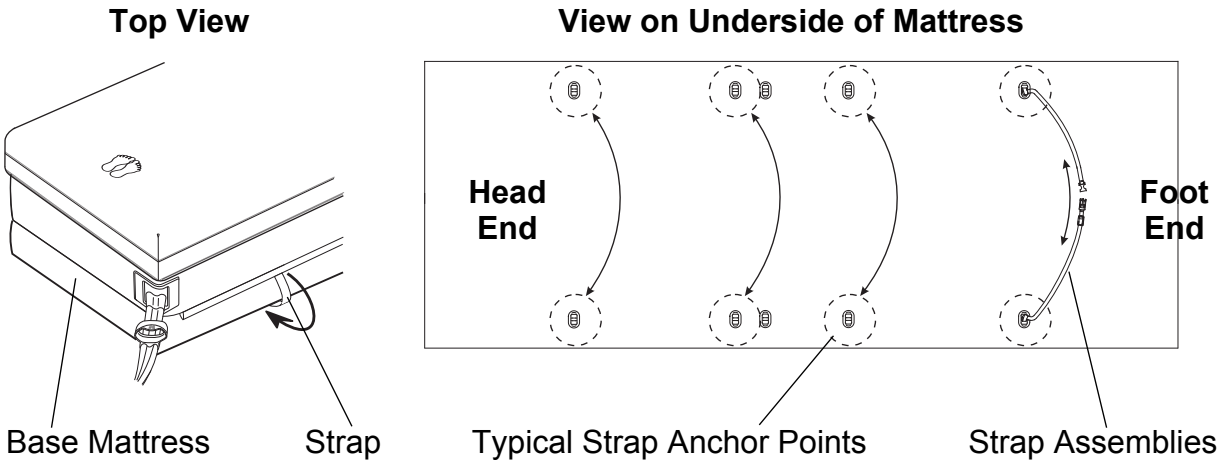
## Installing the Mattress

**Caution**

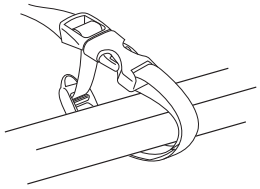
**Do not use the mattress overlay directly on the bed frame.**

***Mattress Overlay***

1. Place the overlay on top of the base mattress, with the tubeset located near the foot end of the bed and the CPR at the head end. The mattress cover must be uppermost.
2. Attach the mattress to the bed frame using the four strap assemblies on the underside of the mattress replacement:
   - The strap assemblies are attached to four of the five pairs of anchor points, their position depending on the type of bed frame. One strap assembly must be at the head end of the mattress and a second must be at the foot end. The remaining two can be attached to any of the three pairs of anchor points in the middle of the mattress.
   - Pass each half of the strap assembly under the base mattress, connect them together and pull the strap assembly tight.




***Mattress Replacement***



1. Remove the existing mattress from the bed frame and check that there are no protruding bed springs or sharp objects on the bed frame surface.
2. Unroll the mattress onto the bed frame and ensure that the tubeset is located at the foot end of the bed and the CPR at the head end.
3. Attach the mattress to the bed frame using the eight fastener straps. The eight fastener straps can be moved to any of the ten anchor points on the bottom of the mattress replacement. This allows for attaching the mattress to different types of bed frame.

☞ *If the bed has divided sections for independent elevation of a patient's head and/or knees, attach the mattress to the movable parts of the bed frame only.*

☞ *One strap assembly must be at the head end of the mattress and a second must be at the foot end.*

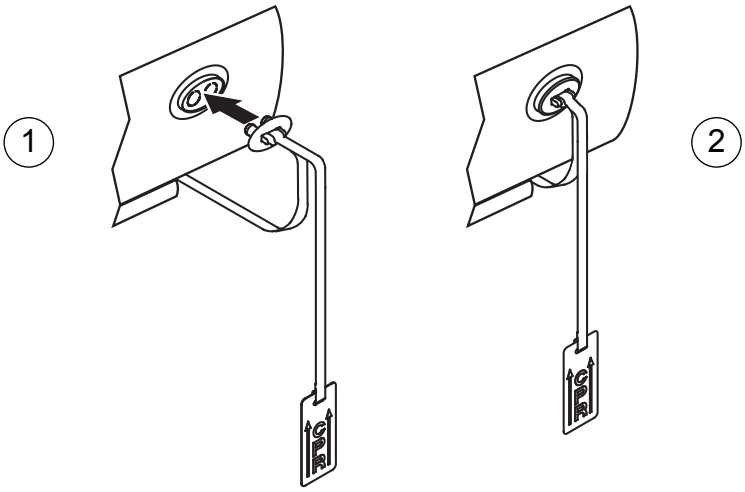
**WARNING**

**The CPR control and CPR indicator tag must be visible and accessible at all times.**

***Closing the CPR Control***

On the mattress overlay or mattress replacement, make sure the CPR control is closed:

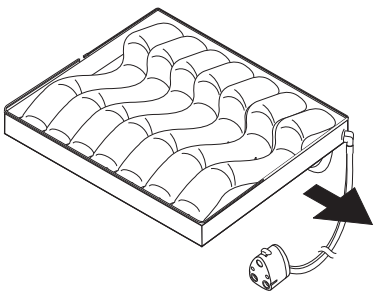
- The CPR control consists of a connector in the side of the mattress with a removable plug fitted.
- Make sure the CPR plug is fully pushed into the connector on the mattress.




## Installing the Seat Cushion

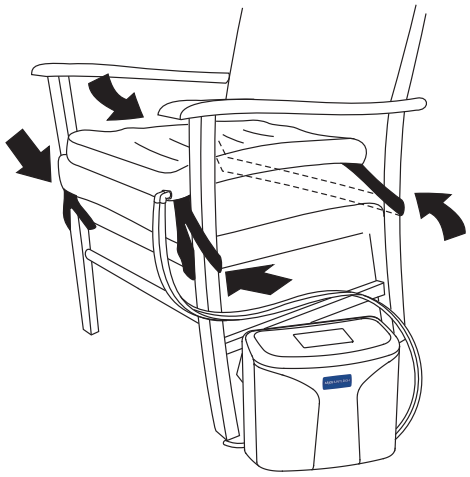
**Cautions**

- **Do not use the seat cushion without a foam cushion beneath it.**
- **Always use the seat cushion with the protective top cover.**
- **Always use the seat cushion in the correct orientation.**
- **Avoid trailing cables - make sure that cables and tubes are positioned beneath the chair to avoid causing a hazard.**
- **Position the tubeset so it does not create a trip hazard and always supervise babies and small children when the product is in use.**

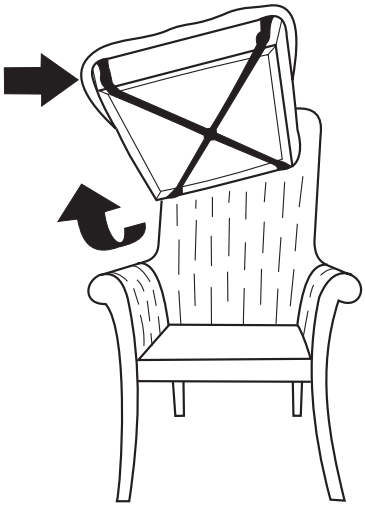


1. Check that there are no sharp objects on the chair which may puncture the cushion.
2. Place the cushion on top of the chair surface. Stand in front of the chair and look towards it. Make sure that:
   - The cells are uppermost.
   - The tubeset appears from the front right corner of the cushion.
   - The cells in the seat cushion are in a horizontal position across the chair, with the “V” shape pointing towards the front.

3. Secure the seat cushion to the chair by using the fixing straps as shown in the following illustrations.
4. If the chair is of the open sided construction, then fix the cushion as shown below:



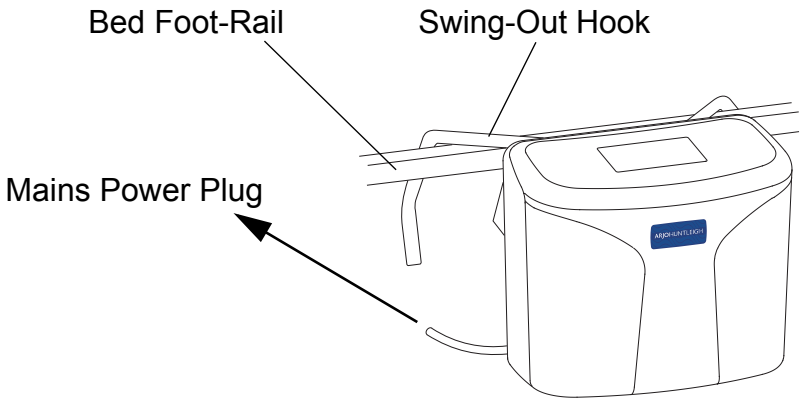
5. If the chair is of the closed side type with a removable seat cushion, fix the seat cushion as shown below:



6. If the chair is of the closed side type with a non-removable seat cushion, then security will rely on the anti-slip base material of the seat cushion.
7. Place the protective cover over the seat cushion and ensure that the logo and the orientation icon, printed on the cover, are uppermost and at the front of the seat.
8. Zip the cover onto the seat cushion, taking care not to trap any material in the zip.

## Installing the Pump

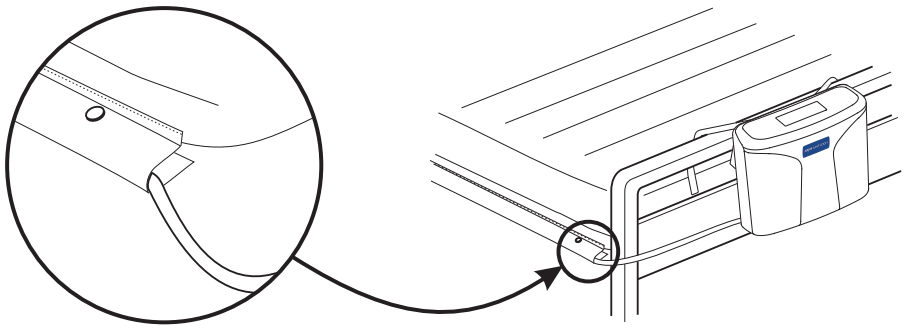
1. Position the pump, feet down, on any convenient horizontal surface or alternatively suspend from the bed foot-rail by means of the swing-out hooks.
2. Insert the mains power plug into a suitable mains power socket.




### *Cable Management in Mattresses*

The mains power cable should be put through one of the cable management flaps which are on each side of the mattress, as follows:

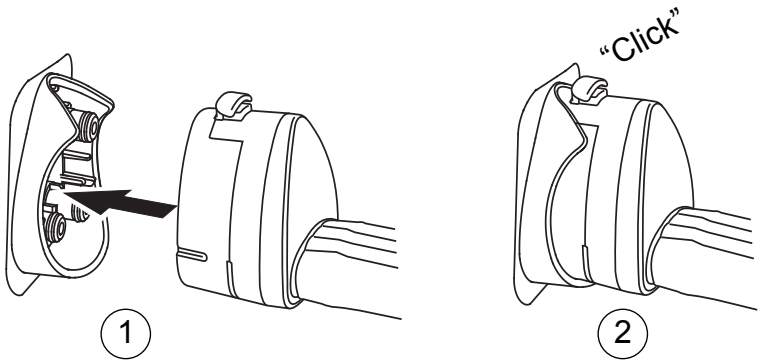
1. Locate one of the cable management flaps.
2. If necessary, open the press studs along the flap.
3. Run the mains power cable along the side of the mattress securing the flap round the cable using the press studs.



### *Connecting the Tubeset*

Make sure the mattress/seat tubeset is not “kinked” or twisted, and push the tubeset connector firmly onto the pump until it clicks into place.

☞ *Make sure that the tubeset is securely connected to the pump.*

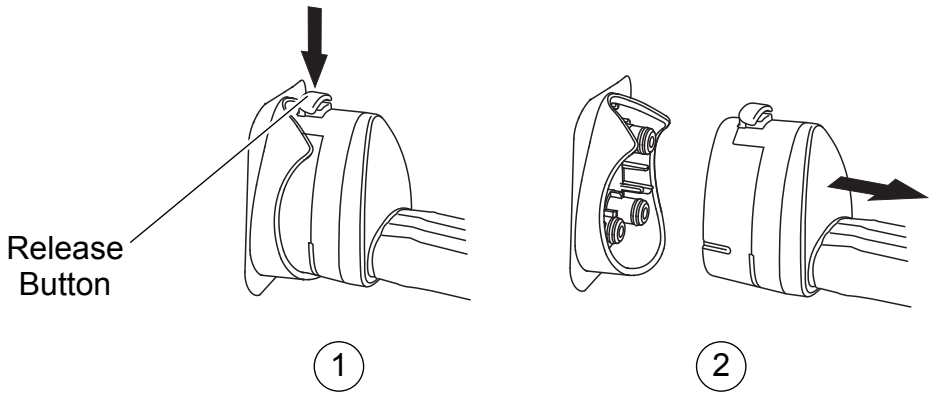



***Disconnecting the Tubeset***

To disconnect the tubeset at any time, push down the release button on the top of the tubeset connector and pull the tubeset connector away from the pump.

This will put the mattress into Transport Mode and will not deflate the mattress. To deflate the mattress, refer to "To Deflate the Mattress" on page 18.

☞ *There is no transport mode on the Alpha Response seat cushion.*

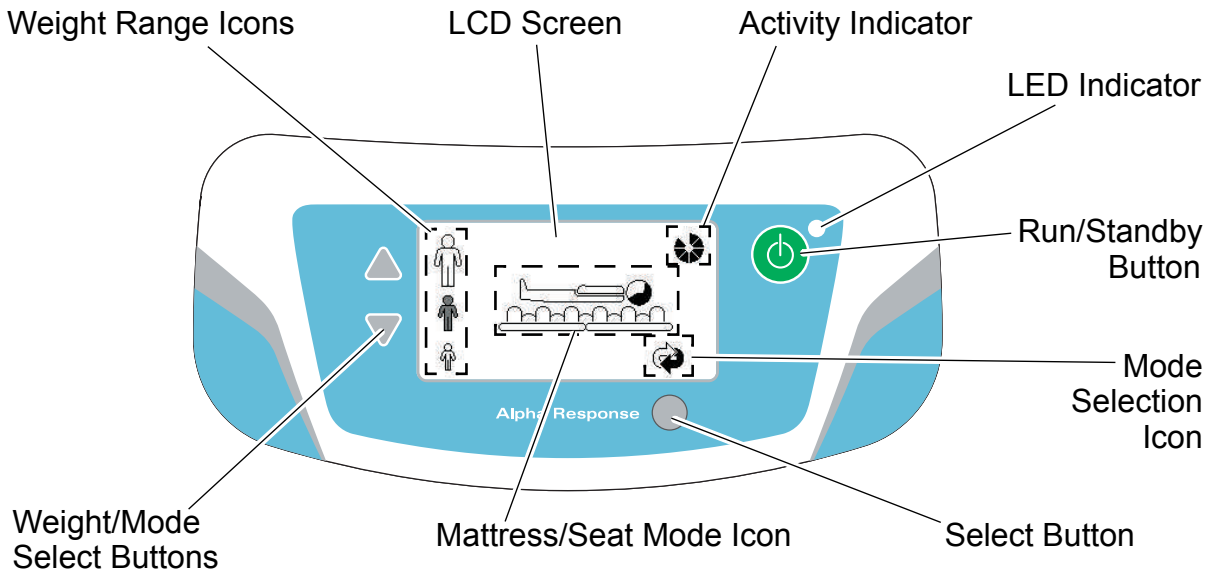



***System Operation***

The system is now ready for use. Refer to "Controls, Alarms and Indicators" on page 11 and "Mattress - Pump Operation" on page 16 for day-to-day operating instructions.

# 4. Controls, Alarms and Indicators

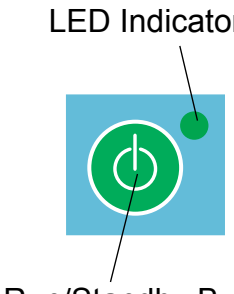
## Control Panel




***LCD Screen*** This displays the operating mode and status of the pump, as follows:

- Mattress/Seat Status.
- Weight Range (or Mattress Mode, if selected by the Mode Selection).
- Mode Selection.
- Activity Indicator.

***Run/Standby Button*** Press the Run/Standby button to put the pump into the Run mode; the LED indicator changes to green.




To put the pump into Standby, press the Run/Standby button for approximately three seconds; this prevents accidental operation. The LCD screen goes blank and the LED indicator changes to amber.

After you put the pump in Standby, if you press the Run/Standby button within approximately 15 seconds the pump goes straight to the Run mode and continues the previous therapy; if you wait more than 15 seconds the pump re-initialises and restarts the initial mattress/seat cushion inflation sequence.

If the mains power is disconnected from the pump while the pump is operating, the pump enters the Power Fail Alarm mode (refer to “Alarms” on page 15). Press and hold the Run/Standby button; the alarm stops and the pump switches off completely.

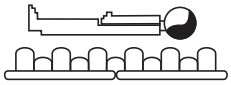
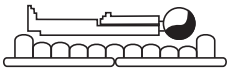
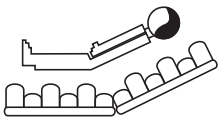
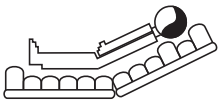
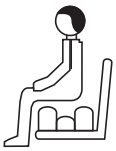
### *LED Indicator*

The multicolour LED adjacent to the Run/Standby button indicates the status of the pump, as follows:

| | |
|---|---|
| Amber (Constant) | External power is applied to the pump, but the pump is in Standby. |
| Green (Constant) | The pump is in Run mode and operating. |
| Red (Flashing) | The pump has detected an alarm condition. |

### *Mattress/Seat Status*

There are five mattress/seat mode icons which can be displayed, as follows:

| | |
|---|---|
|  | Mattress<br>Backrest Horizontal<br>Active (Alternating) Mode |
|  | Mattress<br>Backrest Horizontal<br>Reactive (CLP) Mode |
|  | Mattress<br>Backrest Raised<br>Active (Alternating) Mode |
|  | Mattress<br>Backrest Raised<br>Reactive (CLP) Mode |
|  | Seat<br>Active (Alternating) Mode |

### *Select Button*

The function of the Select button depends on the pump control change being carried out and the icon that is displayed on the LCD screen directly above the button.

### *Mode Selection Icon*

This “double-arrow” icon indicates that the pump is in normal therapy mode, and pressing the Select button below it will select either the Weight Range icons or the Mode icons.

When the Weight Range or Mode is being changed, the Mode Selection icon changes to a “tick” and flash. Pressing the Select button under the “tick” confirms the new selection.

☞ *If the Select button is not pressed for five seconds when the flashing “tick” is displayed, the requested pump status change is ignored, the “tick” reverts back to the Mode Selection icon and the pump continues in its current state.*

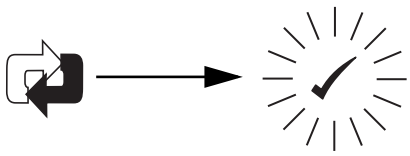
***Weight Range*** There are three Weight Range icons displayed on the LCD screen, the relative size of each "person" icon corresponding to the patient weight range. The selected weight range is indicated by the corresponding icon being solid and the other two icons as outlines.

☞ *Patient comfort and clinical judgement should be used to select the correct weight range setting.*

| | |
|---|---|
|  | Light Weight<br>Weight Range: 40-70 kg |
|  | Normal Weight<br>Weight Range: 70-120 kg |
|  | Heavy Weight<br>Weight Range: 120-160 kg |

To change the Weight Range, do the following:

1. Press the Weight/Mode Select buttons to highlight the new Weight Range icon; the new icon is solid and flashing.
2. The Mode Selection icon changes:



3. Press the Select button to confirm the new Weight Range setting.

**Mode**

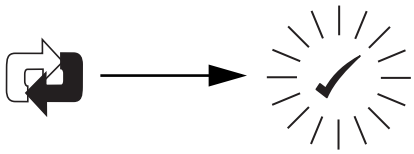
If the Select button is pressed during therapy when the Mode Selection icon is displayed, then the Weight Range icons are replaced by two Mode icons. The selected Mode is indicated by the corresponding icon being solid and surrounded by a square and the remaining icon as an outline:

| | |
|---|---|
|  | Active (Alternating) Mode<br>Backrest Horizontal |
|  | Reactive (CLP) Mode<br>Backrest Horizontal |

To change the Mode, do the following:

1. Make sure the Mode Selection icon is displayed.
2. Press the Select button, and the two Mode icons are then displayed.

3. Press the Weight/Mode Select buttons to highlight the new Mode icon. The new Mode icon is solid with a square border.
4. The new Mode icon and square flashes and the Mode Selection icon changes:



5. Press the Select button to confirm the new Mode.
6. Press the Select button again and the two Mode icons are replaced by the Weight Range icons.

**Activity Indicator**

After the mattress has inflated and the system is in the normal operating mode, an Activity Indicator icon is displayed in the top right corner of the LCD screen:

- The Activity Indicator rotates in a clockwise direction to show that the pump is operating normally.
- The Activity Indicator stops rotating and starts flashing if the pressure changes dramatically e.g. if the patient moves heavily on the mattress or if the Weight Range is changed. Once the pump pressure has stabilised around its target pressure the Activity Indicator stops flashing and starts rotating again.

**Alarms**

1. When the pump detects an alarm condition:
   - The corresponding visual alarm is displayed on the LCD screen, as detailed below.
   - The LED indicator on the control panel flashes alternately red and green.
   - An audible alarm is sounded, which increases in pitch if the alarm is ignored.
2. Press the Run/Standby button to stop the alarm.
3. Refer to Section 9, Page 26 “Troubleshooting” for the alarms, their possible causes and their remedies.

☞ *If the operation of the pump changes during use, refer to Troubleshooting procedures on page 26 of this IFU before calling a service engineer or contacting your local ArjoHuntleigh sales office.*

## 5. Mattress - Pump Operation

These instructions cover the day-to-day operation of the system. Other operations, such as maintenance and repair, should only be carried out by suitably qualified personnel.

☞ *Refer to Section 4, Page 11 "Controls, Alarms and Indicators" for a comprehensive description of the controls and indicators on the pump.*

**WARNING**

**Do not place the patient on the mattress until it is fully inflated**

### Installing the System

Before using the *Alpha Response* system make sure the system has been installed correctly in accordance with Section 3, Page 5 "Installation".

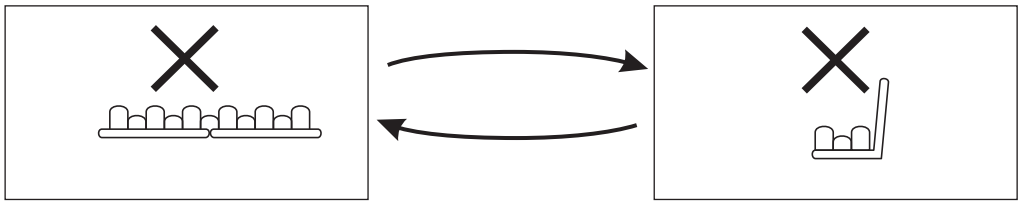
### Initial Inflation

1. Connect the pump to the mains power supply using the supplied cable and switch on the pump.
2. When mains power is first connected to the pump:
   - The LED indicator is illuminated amber to indicate that external power is applied to the pump but the pump is still in Standby.
   - The LCD screen is blank.



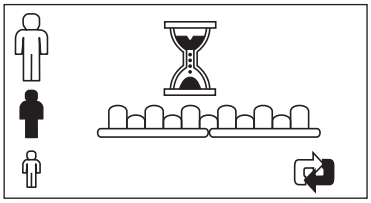
3. Press the Run/Standby button to put the pump into the Run mode:
   - The LED indicator changes to green.
   - The LCD screen displays the ArjoHuntleigh logo for 5 seconds, followed by the *Alpha Response* animated logo for five seconds.
   - The pump carries out a self-test routine and initialises itself.
4. At the end of this start-up sequence, the pump starts to inflate the mattress system.

☞ *If no tubeset is connected to the pump, or the tubeset is not connected securely, the LCD screen displays a No Connection alarm, which alternates the No Mattress and No Seat screens, and an audible alarm is sounded. To clear the alarm, connect a mattress or seat tubeset to the pump.*



## Mattress Operation

1. Make sure the CPR control on the mattress is closed.
2. At the start of the inflation sequence, the default mattress-inflation screen is displayed.

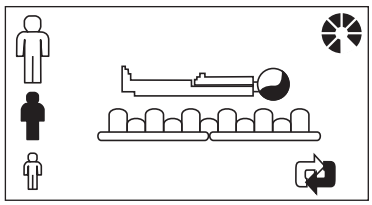


- The default patient weight range setting is Normal, as indicated by the three Weight Range icons.
- The default cell inflation mode is Active (Alternating) and the default setting for the bed frame is with the backrest horizontal, as indicated by the Mattress/Seat Mode icon.
- For the duration of the inflation sequence, the patient body is replaced by an “egg timer” icon.

3. The pump may take up to 40 minutes to inflate a mattress to operating pressure.

☞ *Failure to fully inflate the mattress will result in a low pressure alarm.*

4. When the mattress inflation is complete, the default mattress-operating screen is displayed:
   - The “egg timer” is replaced by the patient body icon.
   - The Activity Indicator is displayed and starts rotating to indicate that the pump is in the Run mode.



5. The patient can now be put onto the mattress.
6. To change the Weight Range setting or put the mattress into Reactive (CLP) mode, refer to Section 4, Page 11 “Controls, Alarms and Indicators”.

☞ *These settings can also be changed while the mattress is being inflated.*

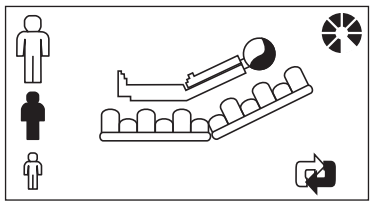
☞ *When changing between operating modes, patient's monitoring and repositioning program should be reviewed.*

☞ *If the operation or performance of the pump changes during use, stop using the system and refer to Section 9, Page 26 "Troubleshooting".*

***Raising the Backrest on the Bed Frame***

1. If the backrest on the bed is raised (the patient is in a semi-recumbent position), the system detects the new position and automatically does the following:
   - Increases the air pressure in the mattress cells to provide optimal pressure redistribution to the patient.
   - Changes the mattress icon from a "backrest horizontal" icon to a "backrest raised" icon.

☞ *The screen below shows the mattress in Active (Alternating) mode when the backrest is raised.*



2. When the bed frame is put back to the "backrest horizontal" position, the system detects this and automatically does the following:
   - Decreases the air pressure in the mattress cells to the value before the backrest was raised.
   - Changes the mattress icon back to the "backrest horizontal" icon.

## Stopping Therapy

To stop the therapy, press and hold the Run/Standby button for three seconds to put the pump into Standby.

- The LED indicator changes to amber.
- the LCD screen goes blank.
- If the pump is to be completely isolated from the mains, remove the plug from the mains power socket.

## To Deflate the Mattress

To deflate the mattress:

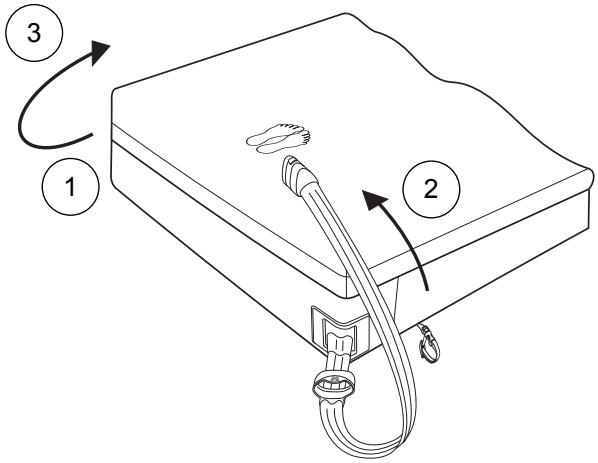
1. Stop the therapy and put the pump into Standby.
2. Disconnect the tubeset from the pump (refer to "Disconnecting the Tubeset" on page 10).
3. Activate the CPR control at the head end of the mattress to deflate it (refer to "To Activate the CPR Control" on page 20)

**To Store the Mattress**

Following deflation:

1. Start rolling the mattress from the foot end towards the head end; stop after ONE turn of the mattress.
2. Bring the tubeset connector over the mattress and secure.
3. Continue to roll the mattress from the foot end towards the head end.

☞ *Make sure the mattress is dry before rolling it up.*



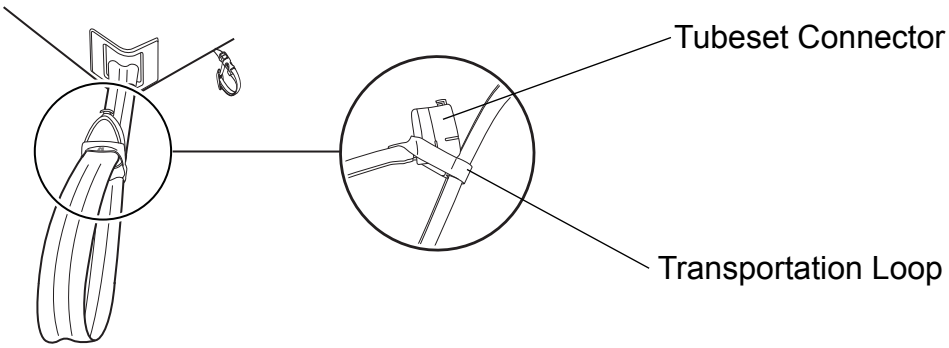

**Transport Mode**

To transport a patient who is lying on the *Alpha Response* mattress:

1. Stop the therapy and put the pump into Standby.
2. Disconnect the tubeset from the pump (refer to "Disconnecting the Tubeset" on page 10). This will automatically put the mattress into transport mode.
3. Put the tubeset connector through the transportation loop to prevent any damage to the tubeset while the bed is being moved.

☞ *The patient will remain supported for up to eight hours on the mattress.*

4. To resume normal operation, reconnect the tubeset to the pump and restart the therapy.



**IMPORTANT**

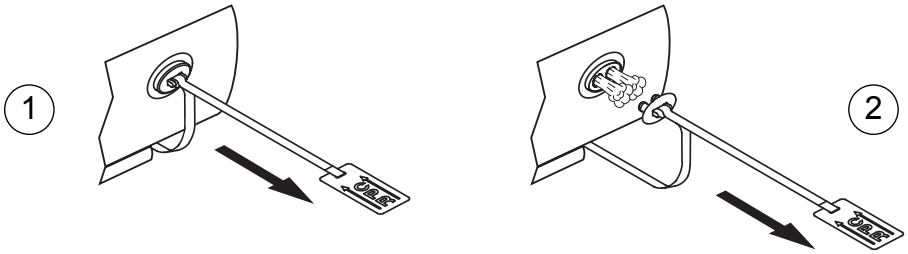
**IN THE EVENT OF CARDIAC ARREST**

**CPR Control** In the event of a patient suffering cardiac arrest and CPR (Cardio-Pulmonary Resuscitation) needing to be administered, activate the CPR control to rapidly deflate the mattress:

***To Activate the CPR Control*** Use a quick, firm pull on the CPR tag to remove the CPR plug. The air is rapidly evacuated from the mattress.

☞ *The plug is fastened to the mattress by a strap.*

☞ *If the pump is operating when the CPR is activated, the Low Pressure alarm may be activated.*

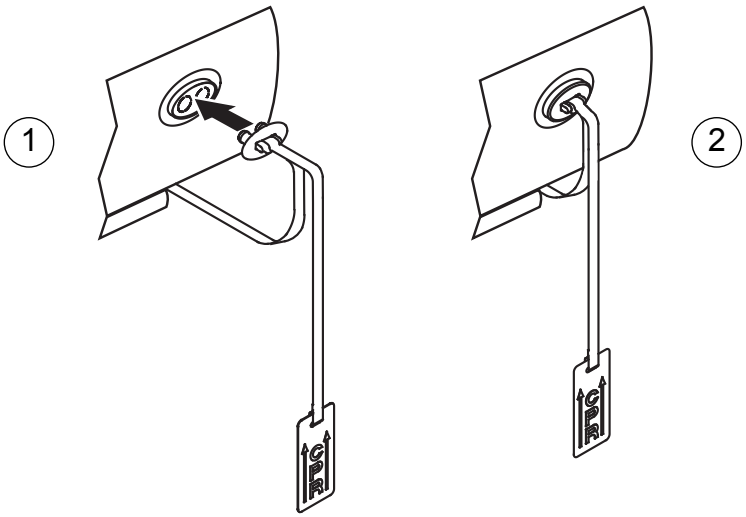



**WARNING**

**The CPR control and CPR indicator tag must be visible and accessible at all times.**

***To Close the CPR Control*** Push the CPR plug into the connector on the mattress.

☞ *Make sure the plug is securely fitted.*



## 6. Seat Cushion - Pump Operation

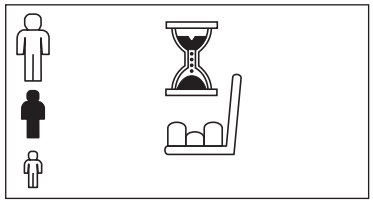
**General** Refer to the "Initial Inflation" section in Section 5, Page 16 “Mattress - Pump Operation”.

**WARNING**

**Do not place the patient on the seat cushion until it is fully inflated**

**Seat Cushion Operation**

1. At the start of the inflation sequence, the default seat-inflation screen is displayed.

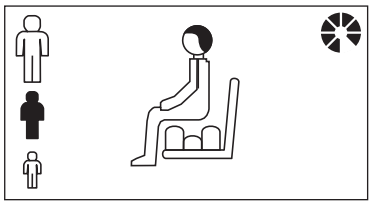


- The default patient weight range setting is Normal, as indicated by the three Weight Range icons.
- The only cell inflation mode is Active (Alternating), as indicated by the Mattress/Seat Mode icon.
- For the duration of the inflation sequence, the patient body is replaced by an “egg timer” icon.

2. The pump may take up to 5 minutes to inflate a seat cushion to operating pressure.

☞ *Failure to fully inflate the seat cushion will result in a low pressure alarm.*

3. When the seat cushion inflation is complete, the default seat-operating screen is displayed; the “egg timer” is replaced by the patient body icon.



4. The patient can now sit on the seat cushion.
5. To change the Weight Range setting, refer to Section 4, Page 11 “Controls, Alarms and Indicators”.

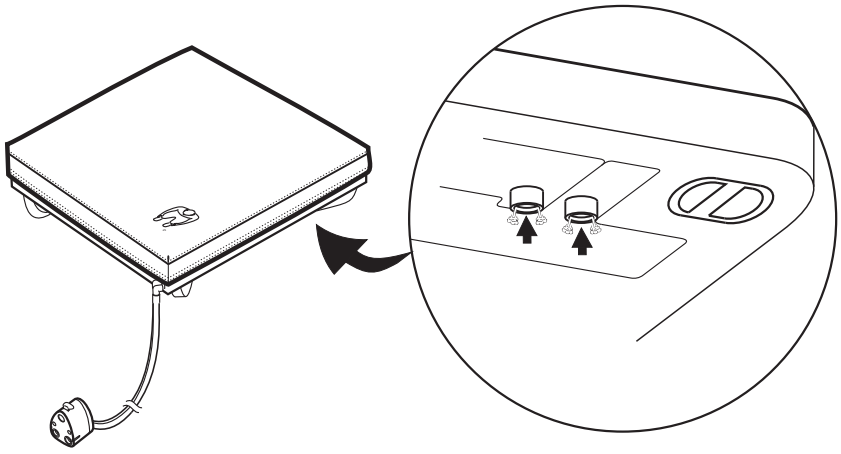
☞ *This setting can also be changed while the seat cushion is being inflated.*

### To Deflate the Seat Cushion

To deflate the seat cushion, do the following:

1. Press and hold the Run/Standby button for three seconds to put the pump into Standby.
   - The LED indicator changes to red.
   - The LCD screen goes blank.
   - If the pump is to be completely isolated from the mains, remove the plug from the mains power socket.
2. Disconnect the tubeset from the pump (refer to “Disconnecting the Tubeset” on page 10).
3. Depress the two valves on the underside of the seat cushion to release the remaining air from it.

☞ *There is no transport mode on the Alpha Response seat cushion.*



# 7. Decontamination

The following processes are recommended, but should be adapted to comply with the local or national guidelines (Decontamination of Medical Devices) which may apply within the Healthcare Facility or the country of use. If you are uncertain, you should seek advice from your local Infection Control Specialist.

The *Alpha Response* system should be routinely decontaminated between patients and at regular intervals while in use; as is good practice for all reusable medical devices.

**WARNING**

**Remove the electrical supply to the pump by disconnecting the mains power cord from the mains power supply before cleaning. Protective clothing should always be worn when carrying out decontamination procedures.**

**Caution**

**Do not use Phenol-based solutions or abrasive compounds or pads during the decontamination process as these will damage the surface coating. Do not boil or autoclave the cover.**
**Avoid immersing electrical parts in water during the cleaning process. Do not spray cleaning solutions directly onto the pump.**

***To Clean***

Clean all exposed surfaces and remove any organic debris by wiping with a cloth moistened with a simple (neutral) detergent and water. Dry thoroughly.

Do not allow water or cleaning solutions to collect on the surface of the pump.

***Chemical Disinfection***

To protect the integrity of the cover we recommend a chlorine-releasing agent, such as sodium hypochlorite, at a strength of 1,000ppm available chlorine (this may vary from 250ppm to 10,000ppm depending on local policy and contamination status).

Wipe all cleaned surfaces with the solution, then wipe with a cloth moistened in water and dry thoroughly.

Alcohol based disinfectants (strength 70%) may be used as an alternative.

Ensure the product is dry before storage.

If an alternative disinfectant is selected from the wide variety available we recommend that suitability for use is confirmed with the chemical supplier prior to use.

DO NOT WRING/MANGLE, AUTOCLAVE OR USE PHENOLIC BASED SOLUTIONS TO LAUNDER THE TOP COVER.

For information on the mattress top cover, including laundering guidelines, refer to “COVER SPECIFICATION” on page 29.

***Re-use with multiple patients***

Professional hygiene maintenance is required before re-use of the system with a different patient.

# 8. Routine Maintenance

## *Alpha Response* System

***Maintenance*** The equipment has been designed to be virtually maintenance-free between service periods.

***Servicing*** ArjoHuntleigh will make available on request service manuals, component parts lists and other information necessary for ArjoHuntleigh trained personnel to repair the system.

***Service Period*** ArjoHuntleigh recommend that the *Alpha Response* system should be serviced by an ArjoHuntleigh authorised service agent, after 12 months running time has elapsed.

The Service symbol illuminates to indicate that the pump is ready for a service (refer to “Alarms” on page 15).

### Pump

***General Care, Maintenance and Inspection*** Check all electrical connections and power cable for signs of excessive wear or damage.

If the pump has been subjected to abnormal treatment, e.g. immersed in water or dropped, the unit must be returned to an authorised service centre.

***Biofilter*** The internal biofilter can be run continuously for 12 months before it requires autoclaving or replacement. The biofilter can only be replaced by a service engineer.

## Mattress Replacement, Overlay and Seat Cushion

***General Care*** Remove the top cover and inspect for signs of wear or any tears.

Check all zips are secure.

Check integrity of all connectors, including cell to manifold connections.

Ensure all cell fasteners are correctly connected to the mattress base sheet and are not loose or damaged.

### Serial Labels

***Pump*** The serial number for the pump is on the label on the back of the pump case.

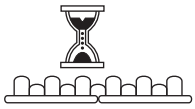
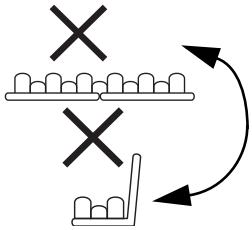
***Mattress*** The mattress serial label can be found just inside the base cover above the tubeset.

***Seat Cushion*** The seat cushion serial label can be found just inside the front of the base cover.

Quote these serial numbers when requesting service.

# 9. Troubleshooting

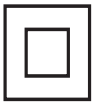
The following table provides a troubleshooting guide for the *Alpha Response* systems in the event of malfunction.

| LCD Screen | Possible Cause | Remedy |
|---|---|---|
|  **Mattress Inflating** | Pump is inflating the mattress replacement or mattress overlay. | The “egg timer” is replaced by the patient body icon when mattress inflation is complete. |
|  **Seat Inflating** | Pump is inflating the seat cushion. | The “egg timer” is replaced by the patient body icon when seat cushion inflation is complete. |
|  **No Mattress/Seat (graphics alternate)** | 1. No tubeset connected to pump.<br>2. Tubeset fitted but not connected securely. | 1. Connect a mattress or seat tubeset to the pump.<br>2. Remove and reconnect tubeset, making sure it is securely pushed onto the pump until a “click” is heard. |
|  **Lo Low Pressure** | 1. The tubeset is not connected properly.<br>2. CPR control not fully closed<br>3. There is a leak in the system. | 1. Remove and reconnect tubeset, making sure it is securely pushed onto the pump until a “click” is heard.<br>2. Make sure the CPR plug is fully pushed into the CPR grommet.<br>3. Call service engineer. |
|  **High Pressure** | 1. Tubeset is “kinked” or blocked.<br>2. Pump has detected an internal fault. | 1. Check and remove any “kinks” or blockages in the tubeset.<br>2. Disconnect the pump from the electrical supply and call service engineer. |
|  **Power Fail** | External mains power supply has been removed while the pump is operating. | Reconnect the mains power supply to the pump. |
|  **Hardware Fail** | Pump has detected an internal fault. | Disconnect the pump from the electrical supply and call service engineer. |
|  **Service Indicator (top right of LCD screen)** | Pump needs a service:<br>After 12 months run time, the spanner icon is illuminated.<br>After a further 3 months run time, the spanner icon starts flashing. | Call the service engineer. |

☞ *If correct operation or performance of the pump is not restored by troubleshooting procedures, stop using the system immediately and call the service engineer.*

# 10. Technical Specification

| PUMP | |
|---|---|
| **Model:** | *Alpha Response* |
| **Part Numbers:** | 464001 - UK<br>464009AU - AUS |
| **Supply Voltage:** | 100 - 230 V |
| **Supply Frequency:** | 50 - 60 Hz |
| **Power Input:** | 24 - 36 VA |
| **Size:** | 240 (L) x 210 (H) x 135 mm (D) [9.49 x 8.27 x 5.3”] |
| **Weight:** | 3.2 kg (7.05 lb) |
| **Case Material:** | ABS Plastic |
| **Plug Fuse Rating:** | 5A to BS1362 (UK ONLY) |
| **Degree of protection against electric shock:** | Mains Connected: Class II, Double Insulated with Functional Earth Type BF |
| **Degree of protection against liquid ingress:** | IP21 - Protection against ingress of solid objects more than 12.5mm diameter and water droplets falling vertically. |
| **Mode of operation:** | Continuous |

| PUMP SYMBOLS | | | | | |
|---|---|---|---|---|---|
|  | The operator must read this document (Instructions for Use) before use.<br>Note: This symbol is blue on the product label. |  | Run/Standby Button |  | Do not dispose of in domestic refuse |
|  <br>25EA<br>CAN/CSA-C22.2<br>No 60601-1<br>(2008) | With respect to electric shock, fire and mechanical hazards only in accordance with CAN/CSA-C22.2 No. 60601.1 (2008).<br>MEDICAL EQUIPMENT |  | Double Insulated |  | Type BF |
|  | Refer to this document (Instructions for Use) for a description of the product classification (3rd Edition). | **SN:** | Serial Number | **Ref:** | Model number |
|  | Refer to this document (Instructions for Use) for a description of the product classification (2nd Edition). | | |  | Manufacturer: This symbol is accompanied by the name and the address of the manufacturer. |

## PUMP ENVIRONMENTAL INFORMATION

| Condition | Temperature Range | Relative Humidity | Atmospheric Pressure |
|---|---|---|---|
| **Operating** | +5°C to +40°C (+41°F to +104°F) | 30% to 75% (non-condensing) | 700hPa to 1060 hPa |
| **Storage (Long Term)** | +5°C to +40°C (+41°F to +104°F) | 20% to 95% (non-condensing) | 700 hPa to 1060 hPa |
| **Storage (Short Term)** | -20°C to +65°C (-4°F to +149°F) | 20% to 95% (non-condensing) | 500 hPa to 1060 hPa |

☞ *If the pump is stored in conditions outside the "Operating" ranges, allow time for its temperature to stabilise to normal before use.*

☞ *One of the effects of prolonged exposure to high temperatures is to increase the self-discharge of the internal battery; this will reduce the duration of power fail alarms. The pump will fully charge the battery over a 24-hour period when the pump is connected to a mains power supply.*

## MATTRESS

| Description | Size (Height x Length) | Cell Material | Base Cover Material |
|---|---|---|---|
| Mattress Replacement (MR) | 205mm (H) x 2090mm (L) | Polyurethane | PU Laminate |
| Mattress Overlay (OL) | 115mm (H) x 2090mm (L) | Polyurethane | PU Laminate |

## MATTRESS SIZE INFORMATION

| Part No. | Description | Width (mm) |
|---|---|---|
| 465001ADV | *Alpha Response* Mattress Replacement (Advantex) | 886 |
| 465001DAR | *Alpha Response* Mattress Replacement (Dartex) | 886 |
| 465002ADV | *Alpha Response* Mattress Replacement, Narrow (Advantex) | 806 |
| 465002DAR | *Alpha Response* Mattress Replacement, Narrow (Dartex) | 806 |
| 465003ADV | *Alpha Response* Mattress Overlay (Advantex) | 886 |
| 465003DAR | *Alpha Response* Mattress Overlay (Dartex) | 886 |
| 465004ADV | *Alpha Response* Mattress Overlay, Narrow (Advantex) | 806 |
| 465004DAR | *Alpha Response* Mattress Overlay, Narrow (Dartex) | 806 |

## SEAT CUSHION

| **Part Number:** | **465005DAR** |
|---|---|
| Length: | 470mm |
| Width: | 455mm |
| Height: | 50mm |
| Cell Material: | Polyurethane |

## CLEANING SYMBOLS

| | | | |
|---|---|---|---|
|  | Do Not Use Phenol-based cleaning Solutions |  | Tumble dry at 130°C (266°F) |
|  | Do not iron |  | Tumble dry at 80-85°C |
|  | Use solution diluted to 1000 ppm of Available Chlorine |  | Wipe surface with damp cloth |
|  | Wash at 95°C (203°F) MAX | | |

## COVER SPECIFICATION

| Feature | Standard Cover (Dartex)® | Advantex® |
|---|---|---|
| **Removable Cover** | Yes | Yes |
| **Moisture Vapour Permeable** | Yes | Yes |
| **Air Permeable** | No | No |
| **Low Friction** | Yes | 18% lower |
| **Water Resistant / Repellent** | Yes | Yes |
| **Infection Control** | Material coating is Antimicrobial | Material coating is Antimicrobial |
| **Fire Retardant** | BS 7175: 0,1 & 5 | BS 7175: 0,1 & 5 |
| **2-Way Stretch** | Yes | Some |
| **Washing Conditions[a]** | MAX 95°C (203°F) | MAX 95°C (203°F) |
| **Drying Conditions** | Tumble Dry up to 130°C (266°F) or Air Dry[b] | Tumble Dry ONLY at 80-85°C (176°F-185°F)[c] |
| **Life Span** | 50 Wash Cycles (minimum) | 50 Wash Cycles (minimum) |
| **Application Area** | Acute and Homecare | Acute and Homecare |

a. The top cover may be washed. The temperature in the washing cycle may be up to 95°C (203°F); however it is recommended that you check your local policy to determine the time/ temperature ratio required to achieve thermal disinfection.
b. The top cover may be tumble dried or air dried. The temperature in the drying cycle may be up to 130°C (266°F); however it is recommended that you check your local policy to determine the time/temperature ratio required.
c. The top cover should be tumble dried only at a temperature of 80-85°C (176-185°F); however it is recommended that you check your local policy to determine the time/temperature ratio required.

## Guidance and manufacturer's declaration - electromagnetic emissions

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should assure that it is used in such an environment.

| Emissions Test | Compliance | Electromagnetic environment - guidance |
|---|---|---|
| RF emissions<br><br>CISPR - 11 | Group 1 | The pump uses RF energy only for its internal function. therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br><br>CISPR - 11 | Class B | The pump is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br><br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions<br><br>IEC 61000-3-3 | Complies | |

## Recommended separation distances between portable and mobile RF communications equipment and the pump

The pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pump as recommended below, according to the maximum output power of the communications equipment.

| **Rated maximum output power of transmitter W** | **Separation distance according to frequency of transmitter** m | | |
|---|---|---|---|
| | **150 kHz to 80 MHz**<br><br>$d = 1.2\sqrt{P}$ | **80 MHz to 800 MHz**<br><br>$d = 1.2\sqrt{P}$ | **800 MHz to 2.5 GHz**<br><br>$d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 2.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

***Note:*** *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

***Note:*** *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

## Guidance and manufacturer's declaration - electromagnetic immunity

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic environment - guidance |
|---|---|---|---|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance** |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 V | $d = 1.2\sqrt{P}$<br><br>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5GHz | 3 V/m | $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br><br>where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range.[b]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

***Note:*** *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

***Note:*** *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the pump is used exceeds the applicable RF compliance level above, the pump should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorientating or relocating the pump.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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