INSTRUCTIONS FOR USE

Alpha Active 4

648936EN_08 • 05/2019

arjo
with people in mind

WARNING

To avoid injury, always read this Instructions for Use and accompanied documents before using the product.

Mandatory to read the Instructions for Use

Contents

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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:

- EN60601-1:2006/A1:2013 and IEC 60601-1:2005/A1:2012
- EN60601-1-11:2010; IEC 60601-1-11:2010 and IEC60601-1-8:2012
- ANSI/AAMI ES 60601-1(2005)+AMD(2012) and CAN/CSA C22.2 No.60601-1(2008)+(2014).

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, safety sides should be used 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. Where cable management flaps are provided along the sides of the mattress, these should be used to cover the mains power cable.**
- **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.**
- **Only the pump and mattress combination as indicated by Arjo should be used. The correct function of the product cannot be guaranteed if incorrect pump and mattress combinations are used.**
- **If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor. In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.**

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.
- Do not 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.
- When the pump is in use the operator should remain in area in case the system alarms.

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 Arjo 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 Arjo for information on correct disposal.

Expected Service Life

The Alpha Active® 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 Arjo.

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

End of Life Disposal

- Fabric material used on the mattresses or any other textiles, polymers or plastic materials etc. should be sorted as combustible waste.
- Mattresses at the end of life should be disposed of as waste according to the national or local requirements which may be landfill or combustion.
- Pump units have electrical and electronic components should be disassembled and recycled per Waste of Electrical and Electronic Equipment (WEEE) or in accordance with local or national regulation.

1. Introduction

About this Manual

This manual is your introduction to the *Alpha Active*® *4.* You must read and fully understand this manual before using the system.

Use this manual to initially set up the system, and keep it as a reference for day-to-day routines and as a guide to maintenance.

If you have any difficulties in setting-up or using the *Alpha Active 4* system, contact your local Arjo 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 200 kg (440 lb).

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

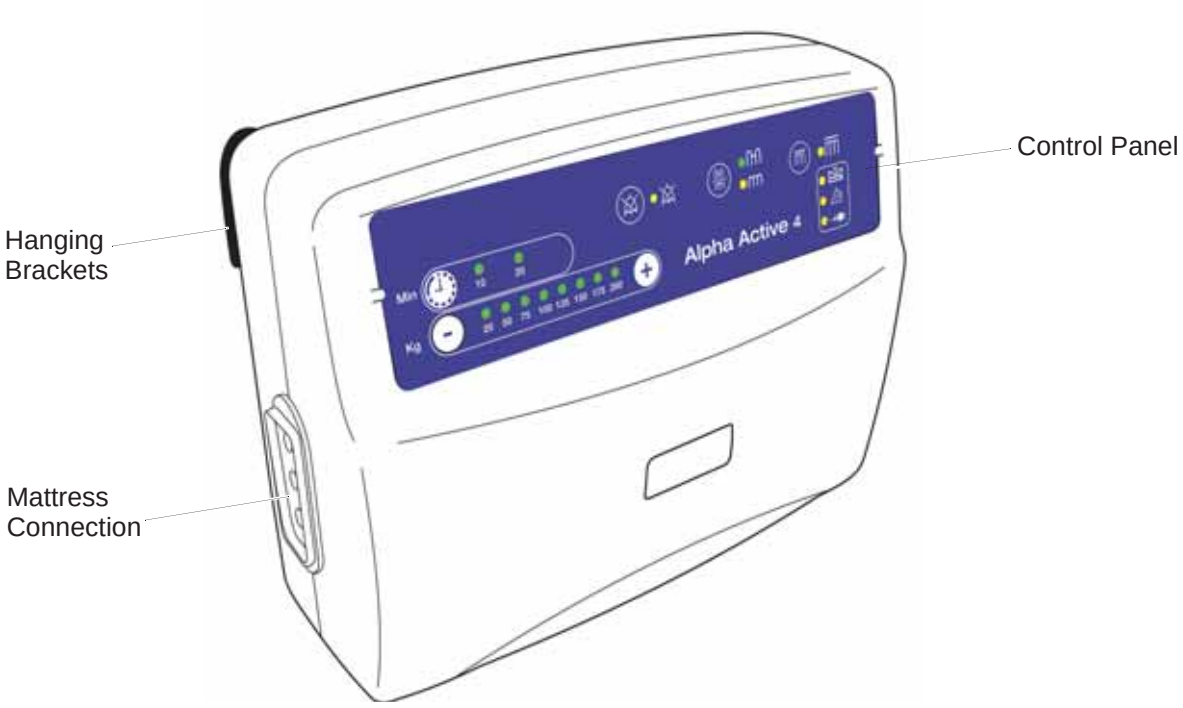
About *Alpha Active* 4

The *Alpha Active 4* systems comprise of a mattress replacement and pump. The support system can be used on hospital and domestic beds in acute care, long-term care and homecare environments, including private homes.

Alpha Active 4 Pump

The *Alpha Active 4* pump comprises of a moulded case with non slip feet on the base and integral hanging brackets.

The controls are situated on the front of the pump and a sophisticated alarm system differentiates between normal operation and genuine system faults. If an alarm situation is detected an indicator will illuminate on the front of the pump and an audible warning will sound.



Alpha Active 4 Mattress Replacement

The *Alpha Active 4* mattress replacement comprises the following components:

Detachable Cover

The standard cover comprises of a 2-way stretch PU (polyurethane) coated knitted fabric zipped to a durable nylon base. The zips are protected by flaps to prevent ingress of contaminants and allow easy removal of the cover for cleaning.

Cells

The mattress comprises of 19 PU cells, 16 providing support to the user in either Alternating (Active) or Static (Reactive) mode and 3 Static head cells.

> NOTE
>
> *The head cells are not involved for alternating, so these cells don't provide pressure ulcer management function.Check patient head area on a regular basis and be vigilant to skin issue are necessary to patient care.*

CPR function

A CPR (Cardio-Pulmonary Resuscitation) control is positioned at the head end of the mattress to allow rapid deflation of the mattress.

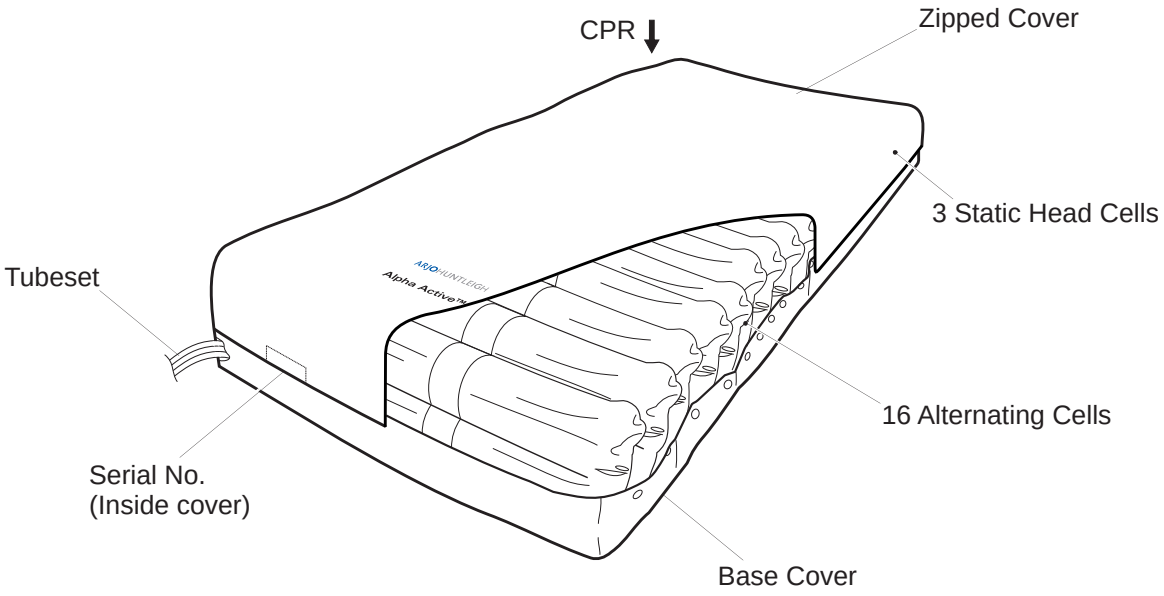
Tubeset

The tubeset has a 3-way pneumatic connection which incorporates a flexible, compact anti-kink tube that is resistant to crushing and any subsequent obstruction of air flow.

When disconnecting the tubeset, place the attached cover over the end to place the mattress in transport mode.

Mattress Replacement Base Cover

The base cover for the mattress replacement is PU coated nylon on the underside. There are six straps located on the underside of the mattress replacement to secure the mattress to the bedframe.



A full technical description of the *Alpha Active 4* system can be found in the Service Manual, part number SER0018, available from your Arjo sales office.

2. Clinical Applications

Indications

The *Alpha Active 4* system is 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.

The 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 Active 4* mattress is designed for patients weighting up to 200 kg (440lb).

Contraindications

Do not use *Alpha Active 4* system 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 Active 4* system has 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.

NOTE

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

1. *NPUAP/EPUAP International Pressure Ulcer Guideline, 2014.*

3. Installation

Preparing the system for use

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

- *Alpha Active 4* pump including mains power cord and hanging brackets.
- *Alpha Active 4* mattress replacement with integral tubeset.
- Cover.

Installing the Mattress

The *Alpha Active 4* mattress replacement system should be installed as follows:

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 near the foot end of the bed and the CPR at the head end. The cells of the mattress must be uppermost.
3. Secure the mattress to the bed frame using the 6 fastener straps.

NOTE

If the bed can be profiled to any position (i.e. raised or lowered), attach the mattress to the movable parts of the bed only.

To Complete the Mattress Installation

Complete the installation of the mattress replacement as follows:

1. If not already fitted, place the protective cover over the mattress. Ensure that the logo is uppermost and at the foot end of the mattress.
2. Zip the cover onto the mattress starting from the head end and taking care not to trap any material in the zip.
3. Ensure that the CPR unit is secured in it's closed position.

NOTE

The CPR must be accessible at all times.

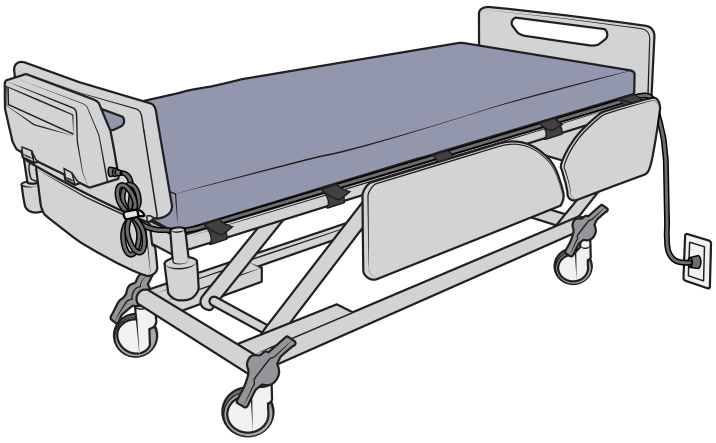
WARNING

Make sure that the mains power cable is positioned to avoid causing a hazard and is clear of moving bed mechanisms or other possible entrapment areas.

Installing the Pump

The pump should be installed as follows:

1. Position the pump, feet down, on any convenient horizontal surface or alternatively suspend from the bed foot rail by means of the integral hanging brackets.
2. Ensure that the mattress tubeset is not “kinked” or twisted and connect it to the pump until it clicks into place. Ensure that the tubeset is securely connected to the pump.
3. Insert the mains power plug into a suitable mains power socket.
4. Put the mains cable under the mattress using the three mattress cable ties. The magic cable tie can be used to manage the surplus cable by the bed foot rail.

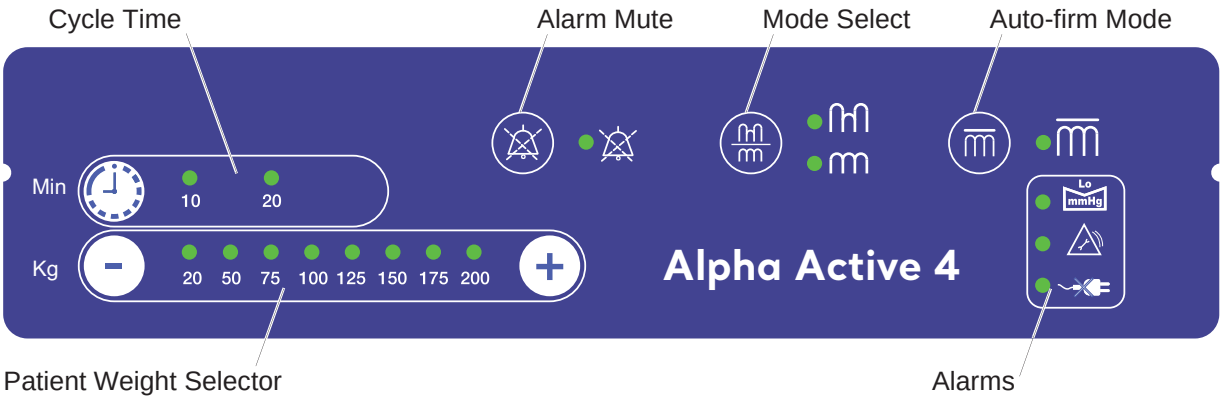


System Operation

The system is now ready for use. See “Mattress - Pump Operation” on page 9 for day-to-day operating instructions.

4. Controls, Alarms and Indicators

Controls



On/Off Button

Pressing the **On/Off** button will activate the pump.The pump will perform a self test during which all LEDs will illuminate, and audible beeps will sound.

Alarm Mute

During an alarm condition the sound of the alarm can be muted by pressing this button, and the audible alarm will be silenced for 15 minutes. The mute state can also be terminated manually by pressing this button again.

Mode Select

The mode selector allows the mode of operation to be selected. Two modes of operation are available, Alternating or Static (non-alternating). The indicator next to the respective icon indicates the currently selected mode.

Auto-firm Mode

Selects the **Auto-firm**, non-alternating mode. The orange indicator will illuminate when the pump is in this mode.

Auto-firm lasts 30 minutes, after which the pump will default back to the previous setting.

Patient Weight Selector

Two buttons (+ and -) are used to select the patient weight. This sets the pressure inside the mattress replacement and therefore the amount of support the patient receives. The patient weight setting may be affected by a power fail event. See **Power Fail** on page 8.

The pressure setting is indicated by the green indicator above the selected setting.

Cycle Time

A single button allows the cycle time to be selected for patient and/or clinician preference. The cycle time setting is indicated by the green indicator above the selected setting.

Alarms and Indicators

Low Pressure Indicator

The **Low Pressure** indicator is illuminated whenever the pump detects low pressure within the mattress replacement. An audible alarm will sound, but the audible alarm can be muted by the **mute** button.

The indicator will extinguish once normal pressure is reached.

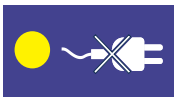
NOTE

See “Troubleshooting and Alarm Conditions” on page 15 for possible causes of Low Pressure.

Service Indicator/Pump Fault

The **Service/pump fault** indicator will illuminate and remain on if the pump has detected an internal fault. A service engineer should be called.

Power Fail Indicator



The **Power Fail** indicator will illuminate when a mains power failure has been detected. An audible alarm will sound until power is resumed or the pump is switched off using the on/off button.

NOTE

Weight settings are affected due to power fail. There are two variants of pump in the market as follows:

1. The pump will revert to a default patient weight setting of 125 kg
(275 pounds) once power is restored after a power outage or generator test.

2. The pump will revert to the last setting set by the caregiver once power is restored after a power outage or generator test.

To determine which pump is being used once the pump is operating, set the pump to 20 kg (44 pounds) and disconnect from the power supply. Reconnect power and if the pump reverts to 125 kg (275 pounds), you have pump 1, and if it reverts to 20 kg (44 pounds), you have pump 2.

5. Mattress - Pump Operation

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

NOTE

Refer to “Controls, Alarms and Indicators” on page 7 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.

Quick Start

Before using the *Alpha Active 4* mattress replacement make sure it has been installed correctly in accordance with “Installing the Mattress” on page 5, and ensure that the CPR unit on the mattress is clicked into the closed position.

1. Connect the pump to the mains power supply using the supplied cable and switch on the pump.
2. Press the On/Off button on the side of the pump.
3. Allow approximately 30 minutes for the mattress replacement to inflate fully.
4. Place a bed sheet loosely over the mattress without tucking, to gain maximum pressure redistribution.

Support Setting Procedure

It is important to follow the correct support setting procedure to ensure the patient receives adequate support (lift) while achieving maximum pressure redistribution and comfort.

1. Lie or sit the patient on the mattress.
2. Select appropriate cycle time.
3. Select patient weight on pump. This should serve as an approximate guide only. An independent clinical determination needs to confirm that the patient is properly supported.
4. Wait 10/20 minutes while the pump adjusts the pressures.
5. Ensure that the patient is not ‘bottoming out’. To do this, unfasten the cover and slide a hand beneath the patients sacral area to ensure at least 2.5cm clearance between the sacrum and bed base.
6. If the caregiver feels less than 2.5cm of support material, the patient has bottomed out and the support pressures should be adjusted accordingly.

Changes in Patient Position

When a patient is in the lying or supine position, their body weight is dispersed over a large area. When in the sitting position, their body weight is concentrated within a much smaller area and therefore will require more support than in the lying position.

Therefore, when the patient changes position, it may be necessary, in order to maximise the benefit of the support surface, to make adjustments to the setting of the patient weight selector.

From Lying to Sitting - Increase weight selector setting.

From Sitting to Lying - Decrease weight selector setting.

This adjustment should be in conjunction with independent clinical determination of appropriate support.

Static

Provides a stable, non-moving support surface for instances where active therapy is not indicated e.g. to carry out nursing procedures or for patients unable to tolerate a moving surface. In **Static** mode the support surface remains constant (all cells are equally inflated). Additional nursing assessment must be undertaken in order to direct an individualised repositioning programme.

When operating the system in **Static** mode it may be necessary, where possible, to reduce the pressure setting to increase patient comfort and safety.

Power Fail Condition

If a **Power Fail** condition arises disconnect the tubeset from the pump and place the attached cap over the end of the tubeset to put the mattress into transport mode. Once power is resumed, re-connect the tubeset to the pump and carry out the “Support Setting Procedure” on page 9 to continue therapy.

To Disconnect the Tubeset

To disconnect the tubeset at any time, depress the buttons on the top and bottom of the tubeset connector pull the tubeset connector away from the pump.

To deflate the mattress Refer to “To Deflate and Store the Alpha Active 4 Mattress” on page 11.

Transport Mode

To transport a patient using the *Alpha Active 4* mattress replacement, disconnect the tubeset from the pump and place the attached cap over the end of the tubeset to put the mattress into transport mode. This will automatically switch the mattress into transport mode.

The patient will remain supported by the mattress for up to 12 hours.

To resume normal operation, simply reconnect the tubeset and run the pump.

Caution

Transport mode is non-therapeutic offering support only for up to 12 hours. It is recommended that when in transport mode the patient is frequently monitored.

To Deflate and Store the *Alpha Active 4* Mattress

To deflate the mattress:

1. Disconnect the tubeset from the pump.
2. Activate the CPR control to deflate the mattress.

To store the mattress

Following deflation:

1. Bring the tubeset over the mattress to lie parallel to the foot end of the mattress.
2. Roll the mattress from the foot end toward the head end of the mattress.

CPR Control

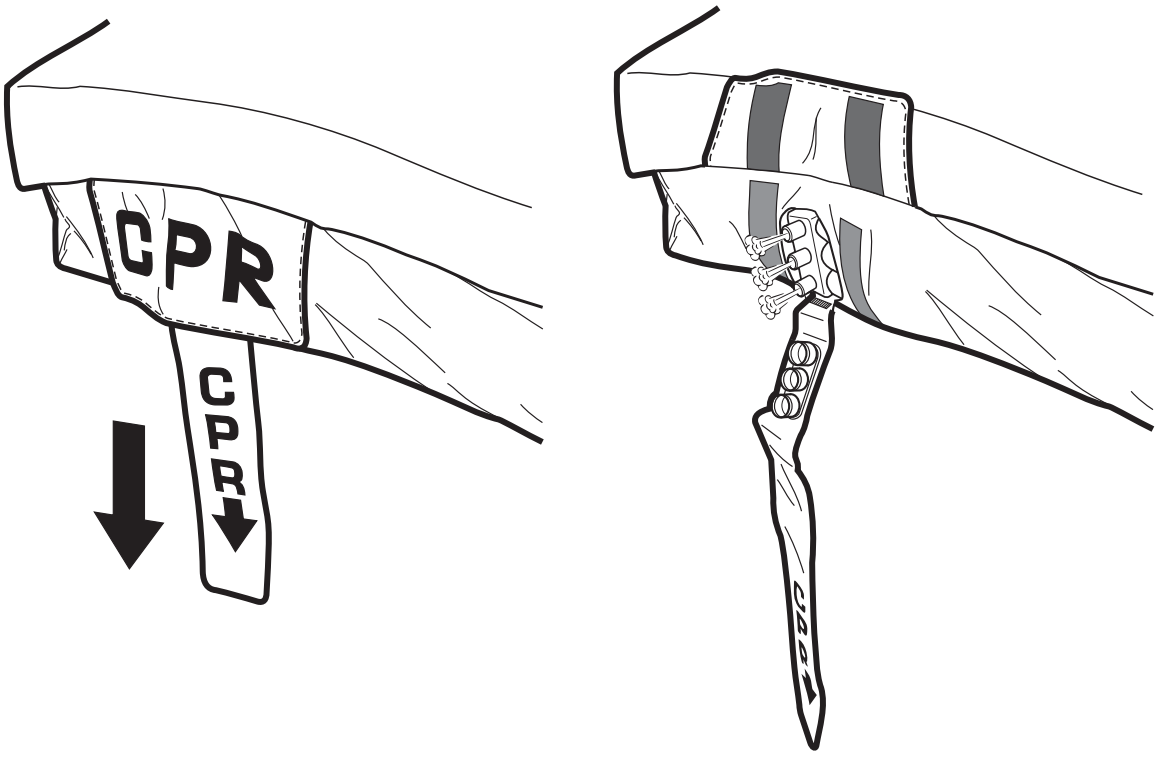
IMPORTANT

IN THE EVENT OF CARDIAC ARREST

In the event of a patient suffering cardiac arrest and CPR needing to be administered:

To activate CPR

Located at the head end of the mattress replacement (on the same side as the tubeset) is a red strap labelled CPR. In the event of a cardiac arrest pull this from the mattress to deflate.



To reset CPR

To re-inflate the mattress, simply replace the stopper securely into the manifold.

6. 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 Active 4* 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 wring/mangle, 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.

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, rinse 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.

Thermal Disinfection

For information for the mattress top cover, including laundering guidelines, refer to “Cover Specification” on page 19.

7. Routine Maintenance

Alpha Active 4 System

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

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

Service Period Arjo recommend that the *Alpha Active 4* system should be serviced by an Arjo 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 “Service Indicator/Pump Fault” on page 8).

Alpha Active 4 Pump

General Care, Maintenance and Inspection

Check all electrical connections and power cord for signs of excessive wear.

In the event of the pump being subjected to abnormal treatment, e.g. immersed in water or dropped, the unit must be returned to an authorised service centre.

Alpha Active 4 Mattress Replacement

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.

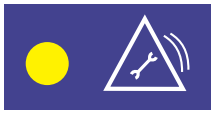
Serial Labels

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. Refer to “Alpha Active 4 Mattress Replacement” on page 2.

8. Troubleshooting and Alarm Conditions

The following table provides a troubleshooting and alarm condition guide for the *Alpha Active 4* system in the event of malfunction. These alarms do not cause any delay or interruption in therapy.

Indicator	Possible Cause	Remedy	
LOW PRESSURE 	The tubeset is not connected properly. CPR not fully closed. There is a leak in the system.	Check the tubeset connector and ensure it is securely fitted to the pump. Close CPR unit. Call service engineer.	Low priority according to IEC60601-1-8
POWER FAILURE 	Power has been removed from the pump.	Re-apply power or switch the pump off.	Low priority according to IEC60601-1-8
SERVICE 	Pump has detected an internal fault, such as the gearbox failure.	Switch the pump off and call service engineer.	Low priority according to IEC60601-1-8

9. Technical Description

PUMP		
Model:	*Alpha Active 4*	
Supply Voltage:	230V	
Supply Frequency:	50Hz	
Power Input:	0.1A	
Size:	(L)280mm x (W)205mm x (H)112mm	
Weight:	2.5kg	
Case Material:	ABS Plastic	
Plug Fuse Rating:	5A to BS1362 (UK ONLY)	
Pump Fuse Rating:	2 x T1AL 250V	
Degree of protection against electric shock:	Class II Type BF	
Degree of protection against liquid ingress:	IP21	
Mode of operation:	Continuous	
Cycle Times:	**10 mins**	**20 mins**
	Inflate - 4.5 mins	Inflate - 9.5 mins
	Crossover - 30 secs	Crossover - 30 secs
	Deflate - 4.5 mins	Deflate - 9.5 mins
	Crossover - 30 secs	Crossover - 30 secs

PUMP SYMBOLS					
	The operator must read this document (Instructions for Use) before use. Note: This symbol is blue on the product label.	**O** (Off)	Power Disconnects from the mains	**I** (On)	Power Connects to the mains supply
	With respect to electric shock, fire and mechanical hazards only in accordance with CAN/CSA-C22.2 No. 60601.1 (2008) + (2014). ANSI/AAMI ES 60601-1 (2005) +AMD (2012) 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
CE 2797	CE marking indicating conformity with European Community harmonised legislation Figures indicate Notified Body supervision.		Do not dispose of in domestic refuse		Manufacturer: This symbol is accompanied by the name and the address of the manufacturer.
	Refer to this document (Instructions for Use) for a description of the product classification (2nd Edition).		Dangerous Voltage		Date of Manufacture
MD	Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745				

PUMP ENVIRONMENTAL INFORMATION			
Condition	**Temperature Range**	**Relative Humidity**	**Atmospheric Pressure**
Operating	+10°C to +40°C (+50°F to +104°F)	30% to 75% (non-condensing)	700hPa to 1060 hPa
Storage (Long Term)	+10°C to +40°C (+50°F to +104°F)	20% to 95% (non-condensing)	700 hPa to 1060 hPa
Storage (Short Term)	-20°C to +50°C (-4°F to +122°F)	20% to 95% (non-condensing)	500 hPa to 1060 hPa

NOTE

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

MATTRESS

Description	Cell Material	Base Pad Material
ALPHA ACTIVE 4 MR 90	Nylon PU Coated	Nylon PU Coated
ALPHA ACTIVE 4 MR 85	Nylon PU Coated	Nylon PU Coated
ALPHA ACTIVE 4 MR 85 (PU)	Polyurethane	Nylon PU Coated
ALPHA ACTIVE 4 MR 80 (PU)	Polyurethane	Nylon PU Coated
ALPHA ACTIVE 4 MR 90 (PU)	Polyurethane	Nylon PU Coated

MATTRESS SIZE INFORMATION

Part No.	Description	Spare Cover	Welded Spare Cover	Length mm	Width mm	Height mm
648322	*ALPHA ACTIVE* 4 MR 90	648437	NA	1911 (75 1/4")	857 (33 3/4")	200 (8")
648334	ALPHA ACTIVE 4 MR 90 PU		NA			
648324	*ALPHA ACTIVE* 4 MR 85	648461	NA		806 (31 3/4")	
648326	*ALPHA ACTIVE* 4 MR 85 PU		NA			
648333	*ALPHA ACTIVE* 4 MR 80 PU	648338	NA		800 (31 1/2")	
648322W	*ALPHA ACTIVE* 4 MR 90 welded	NA	648437W		857 (33 3/4")	
648334W	*ALPHA ACTIVE* 4 MR 90 PU welded	NA				
648324W	*ALPHA ACTIVE* 4 MR 85 welded	NA	648461W		806 (31 3/4")	
648326W	*ALPHA ACTIVE* 4 MR 85 PU welded	NA				
648333W	*ALPHA ACTIVE* 4 MR 80 welded	NA	648338W		800 (31 1/2")	

CLEANING SYMBOLS

 Max 95 15 Min	Recommended wash temperature: 15 min at 60°C (140°F). Maximum wash temperature: 15 min at 95°C (203°F)	 Max 80	Tumble dry at 60°C (140°F) Maximum drying temperature 80°C (176°F)
 Max 71 15 min	Recommended wash temperature: 15 min at 60°C (140°F). Maximum wash temperature: 15 min at 71°C (160°F)		Tumble dry at 60°C (140°F)
	Do not iron		Do Not Use Phenol-based cleaning Solutions
	Wipe all surfaces with cleaning solution, then wipe with a cloth moistened with water and dry thoroughly	 1000ppm NaOCl NaDCC	Use solution diluted to 1000 ppm of Available Chlorine

COVER SPECIFICATION

Feature	Reliant IS[2]
Removable Cover	Yes
Moisture Vapour Permeable	Low
Low Friction	No
Water Resistant / Repellent	Yes
Polyurethane coating includes an antifungal agent to control microbial deterioration of fabric	Yes
Fire Retardant*	BS 7175: 0,1 & 5
2-Way Stretch	Yes
Recommended Wash Temperatures	60°C (140°F) 15 min.
Maximum Wash Temperatures	Max 95°C (203°F) 15 min.
Recommended Drying Temperatures	60°C (140°F) or air dry
Maximum Drying Temperatures	Max 80°C (176°F)
Wipedown Chemicals**	Chlorine at strength of 1000ppm or Alcohol at 70% concentration; no phenol; ensure product is dry before storage

* For additional flammability testing standards, refer to individual product law tags

**Chlorine concentrations may vary from 250ppm to 10,000ppm depending on local policy and contamination status. If an alternative disinfectant is selected from the wide variety available, Arjo recommend that suitability for use is confirmed with the chemical supplier prior to use.

10.Electromagnetic Compatibility (EMC)

Product has been tested for compliance with current regulatory standards regarding its capacity to block EMI (electromagnetic interference) from external sources.
Some procedures can help reduce electromagnetic interferences:

- Use only Arjo cables and spare parts to avoid increased emissions or decreased immunity which can compromise the correct functioning of the equipment.
- Ensure that other devices in patient-monitoring and/or life-support areas comply to accepted emissions standards.

WARNING

Wireless communications equipment such as wireless computer network devices, mobile phones, cordless telephones and their base stations, walkie-talkies, etc. can affect this equipment and should be kept at least 1.5 m away from the equipment.

Intended Environment: Home Healthcare Environment and Professional Healthcare facility environment.
Exceptions: HF Surgical Equipment and the RF Shielded room of an ME SYSTEM for magnetic resonance imaging.

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Guidance and manufacturer's declaration - electromagnetic emissions

Emissions Test	Compliance	Guidance
RF emissions CISPR - 11	Group 1	This equipment uses RF energy only for its internal functions. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. This equipment 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.
RF emissions CISPR - 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
Immunity Test	**IEC 60601-1-2 test level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	±2kV, ±4kV, ±8kV, ±15kV air ±8kV contact	±2kV, ±4kV, ±8kV, ±15kV air ±8kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity level should be at least 30%
Conducted disturbances inducted by RF fields EN 61000-4-6	3V in 0,15 MHz to 80 MHz 6V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3V in 0,15 MHz to 80 MHz 6V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than 1.0 m, if the transmitter's output power rating exceeds 1W[(a)] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range[(b)] Interference may occur in the vicinity of equipment marked with this symbol: 
Radiated RF electromagnetic field EN 61000-4-3	Home Healthcare environment 10 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz	Home Healthcare environment 10 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz	
Electrical fast transient/burst EN 61000-4-4	±1kV SIP/SOP ports ±2kV AC port 100kHz repetition frequency	±1kV SIP/SOP ports ±2kV AC port 100kHz repetition frequency	Mains power supply should be that of a typical commercial or hospital environment.
Power frequency Magnetic field EN 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0,5kV ±1kV; ±2kV, AC Mains, Line to Ground ±0,5kV ±1kV, AC Mains, Line to Line	±0,5kV ±1kV; ±2kV, AC Mains, Line to Ground ±0,5kV ±1kV, AC Mains, Line to Line	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or a battery.
Note: *UT is the AC mains voltage prior to application of the test level.*			

[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 product is used exceeds the applicable RF compliance level above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary.

[b)] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

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Address page - REV 24: 04/2019

www.arjo.com

At Arjo, we are committed to improving the everyday lives of people affected by reduced mobility and age-related health challenges. With products and solutions that ensure ergonomic patient handling, personal hygiene, disinfection, diagnostics, and the effective prevention of pressure ulcers and venous thromboembolism, we help professionals across care environments to continually raise the standard of safe and dignified care. Everything we do, we do with people in mind.

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