INSTRUCTIONS FOR USE

# Alpha Trancell Deluxe


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EMPOWERING MOVEMENT

## 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

## 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 caregiver[1] 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. 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 power switch must be accessible at all times. Use the power switch to disconnect the pump completely from the power supply.**
- **The Rapid Deflate 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.**
- **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 facility on the Alpha Trancell® Deluxe seat cushion.**
- **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.**

1. Caregiver may be a healthcare professional or a lay person who operates this medical device.

## 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 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 Trancell* Deluxe pump has an expected service life of seven years. To maintain the condition of the pump, observe the service information.

Do NOT use unapproved accessories or attempt to modify, disassemble or otherwise misuse the *Alpha Trancell* Deluxe 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 Trancell® Deluxe systems. 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 Trancell* Deluxe 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 120 kg (264 lb).

The *Alpha Trancell* Deluxe system should be used as part of a prescribed plan of care (refer to “Indications” on page 5).

## About *Alpha Trancell* Deluxe

The *Alpha Trancell* Deluxe is a pressure relief system which consists of a pump and a choice of mattresses or a seat cushion:

- *Alpha Trancell* Deluxe mattress overlay
- *Alpha Trancell* Deluxe mattress replacement
- *Alpha Trancell* Deluxe seat cushion
- *Alpha PREVENT*™ mattress overlay
- *Trancell*® II mattress overlay

Depending on the choice of mattress, the system is indicated for patients who are at risk of developing pressure ulcers.

The *Alpha Trancell* Deluxe system can be used in acute care, long-term care and home care environments, including private homes.

A full technical description of the *Alpha Trancell* Deluxe system can be found in the Service Manual, part numbers SER0004 (pump) and SER0005 (mattresses), available from Arjo.

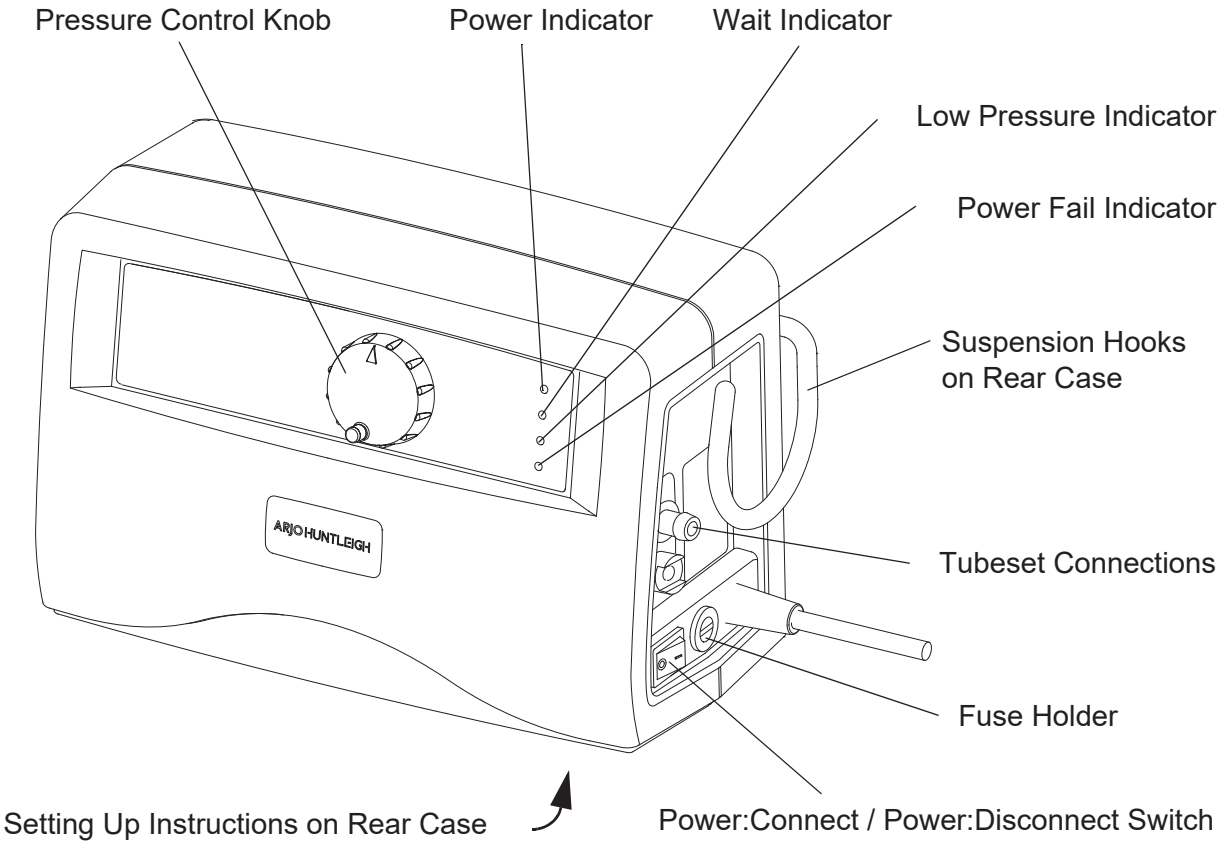
**WARNING**

**To avoid injury to the patient when operating the Alpha Trancell Deluxe system as a caregiver and as a lay person:**

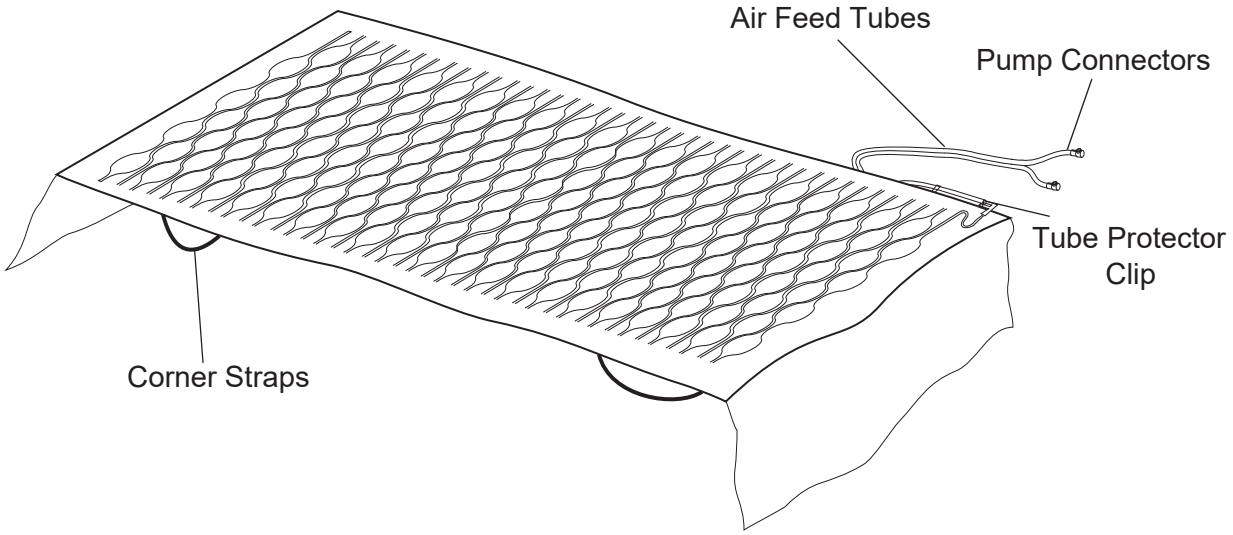
- **Make sure the system is operating according to section “Operation” on page 10.**
- **If the system is not operating correctly, see section “Troubleshooting Guide” on page 16.**
- **If the system is still not operating correctly, or if you have concerns, contact the patient’s doctor or nursing staff for advice.**

## Product Description

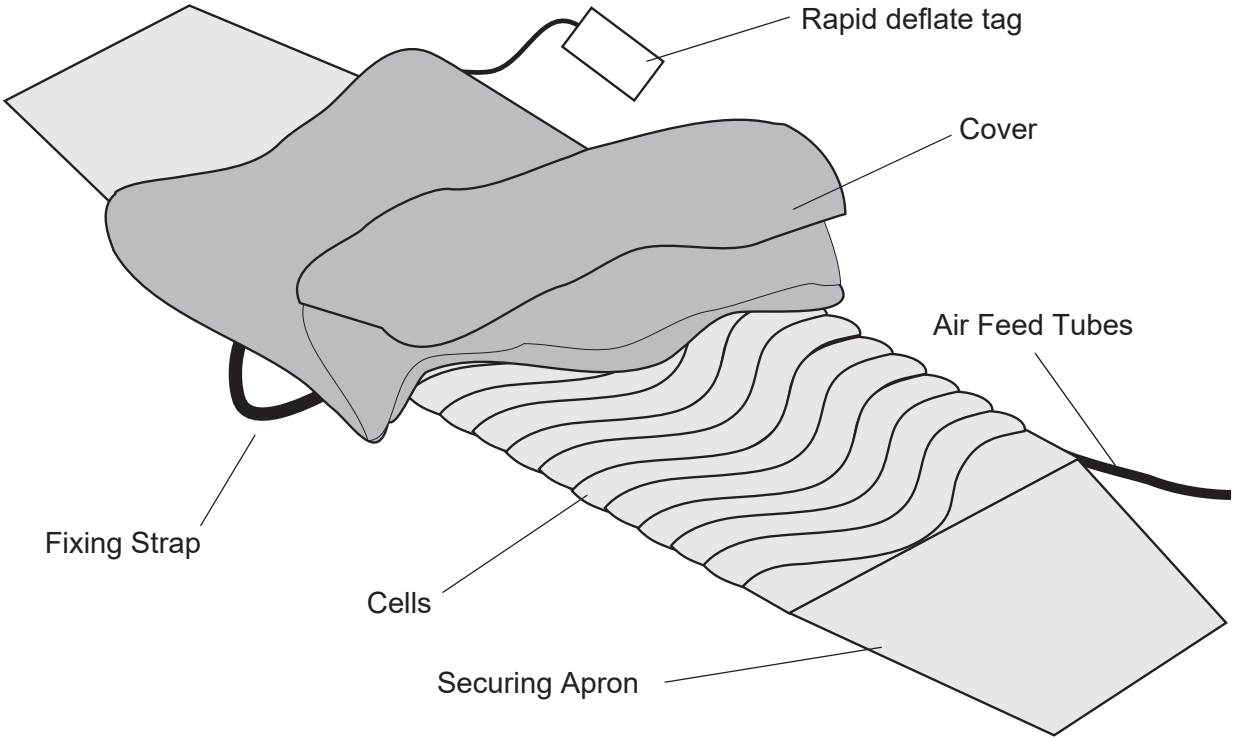
### *Pump Unit*



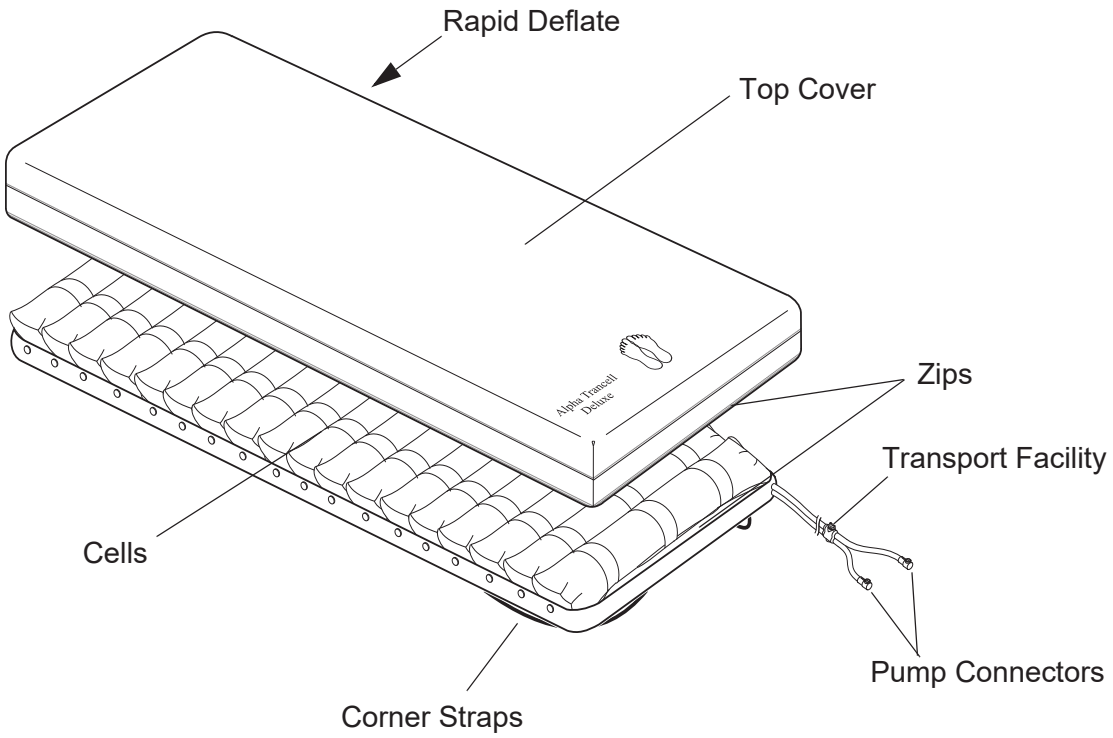

### *Alpha PREVENT Overlay*



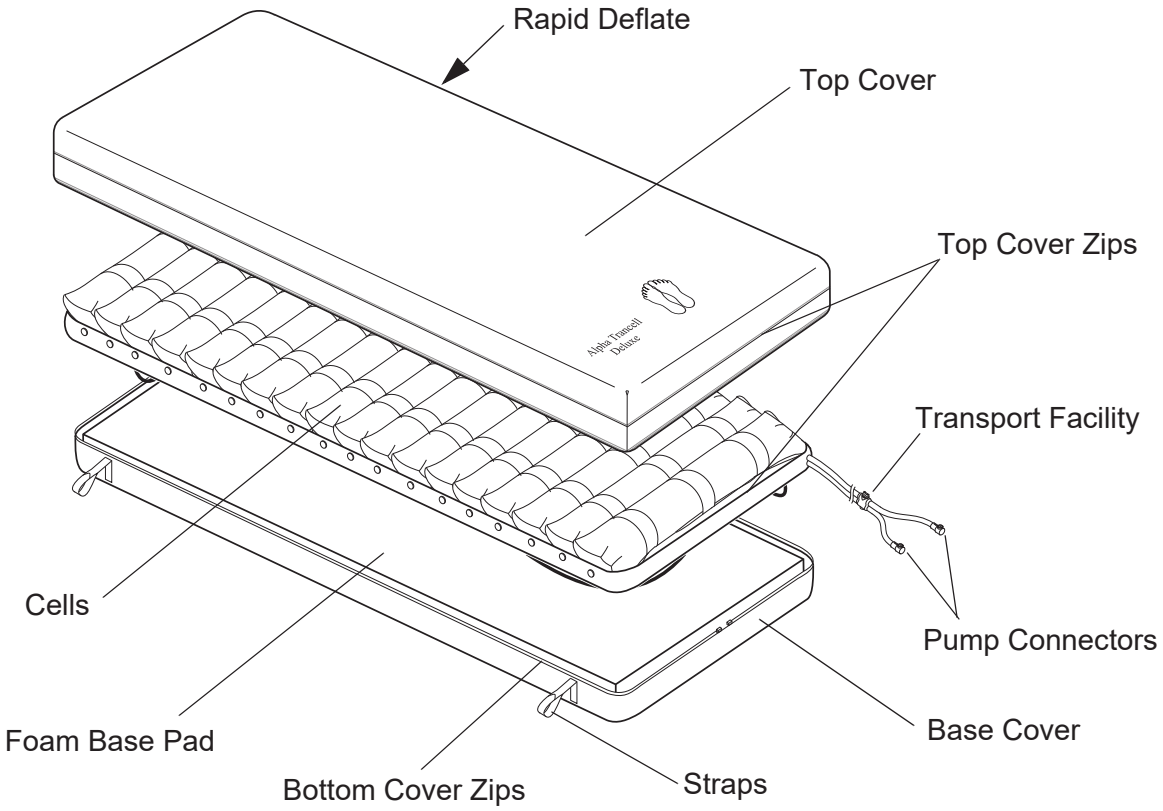
### *Trancell II Overlay*



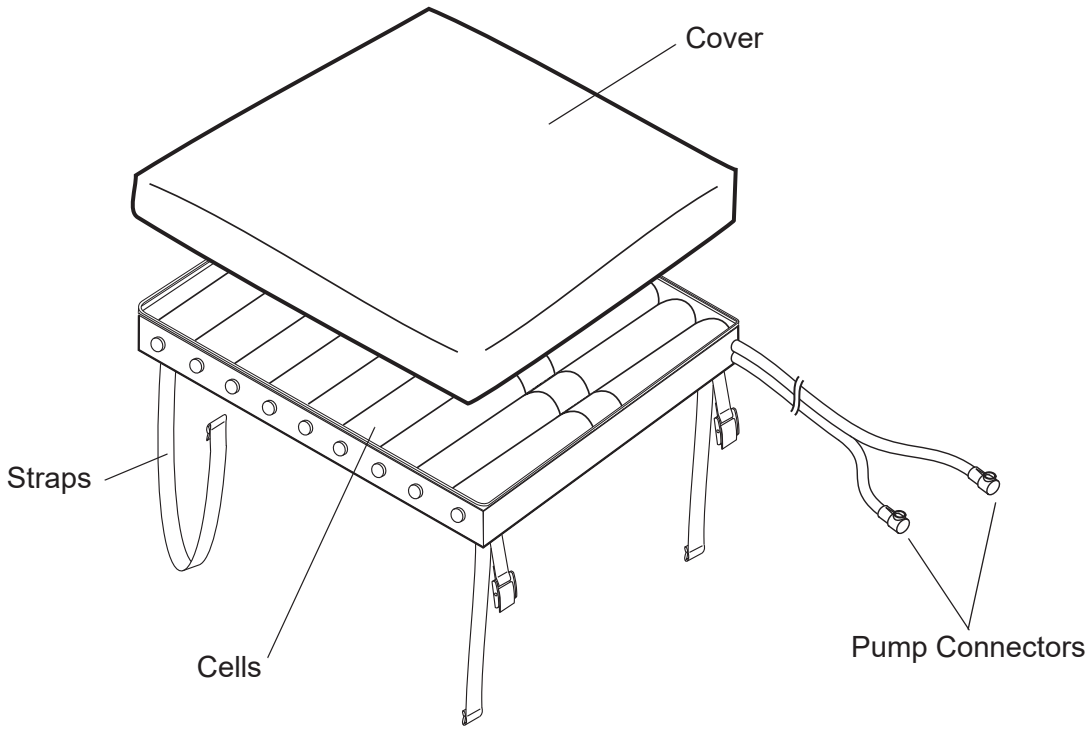

### *Alpha Trancell Deluxe Overlay*



## *Alpha Trancell Deluxe Mattress Replacement*




## *Alpha Trancell Deluxe Seat Cushion*



# 2. Clinical Applications

**Indications**

The *Alpha Trancell* Deluxe systems are indicated for the prevention and/or management of pressure ulcers, 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.

***Alpha PREVENT***

Indicated for prevention and/or management of pressure ulcers up to category 2[1]. Maximum patient weight 90 kg.

***Alpha Trancell Deluxe/ Trancell II***

Indicated for prevention and/or management of all categories of pressure ulcer. Maximum patient weight 120 kg.

***Alpha Trancell Deluxe Seat Cushion***

Indicated for prevention and/or management of all categories of pressure ulcer for patients weighing between 40 to 90 kg.

**Contraindications**

Do not use these 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 these 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.

NOTE

*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, 2014.*

# 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.**

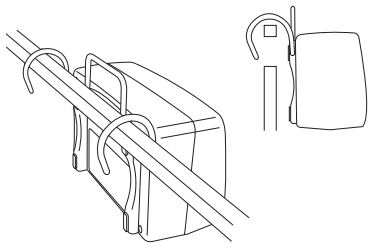
## Preparing the System for Use

The system is simple to set up using the following guidelines.

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

- *Alpha Trancell* Deluxe pump with integral mains power cord and hanging bracket.
- Mattress overlay, mattress replacement or a seat cushion.

### Installing the Pump



1. The pump should be placed feet down on any convenient surface or alternatively suspended from the bed foot rail by means of the swing out hooks.
2. Plug the pump power cable into wall socket. Leave the Power:connect / Power:disconnect switch in the Power:disconnect position.

### Installing a Mattress Overlay

If you have an *Alpha Trancell* Deluxe, *Trancell* II or *Alpha PREVENT*, mattress overlay, it should be installed as follows:

1. Place overlay on top of the normal mattress surface with the air feed tubes located near the pump at the foot end of the bed.

**WARNING**

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

2. Secure the mattress overlay by tucking the securing aprons under each end of the mattress and/or securing the corner straps under each corner of the bed mattress.
3. When using the *Trancell* II or *Alpha Trancell* Deluxe mattresses, ensure that the Rapid Deflate stopper at the head end of the bed is securely fitted.

NOTE

*Trancell II overlays are supplied with separate connector adaptors to suit the Alpha Trancell Deluxe pump. Ensure these are fitted to the overlay pump connectors before use.*

4. When using the *Trancell* II mattress overlays, place protective cover over the mattress overlay and adjust fixing strap around overlay or bed mattress. Make sure the cover is fitted loosely around mattress to prevent hammocking.

### *Alpha Trancell Deluxe Mattress Replacement*

If you have the *Alpha Trancell* Deluxe mattress replacement system, it 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. Place the mattress onto the bed frame and ensure that the tubeset is located at the foot end of the bed. The cells of the mattress must be uppermost.
3. Ensure the mattress has been secured to the bed frame using the straps provided.
4. Ensure that the Rapid Deflate stopper at the head end of the bed is securely fitted.

### *Alpha Trancell Deluxe Seat Cushion*

The seat cushion should be installed as follows:

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. From a standing position in front of the chair and facing it, ensure that:
   - The cells are uppermost.
   - The tube-set appears from the front right corner of the cushion.

NOTE

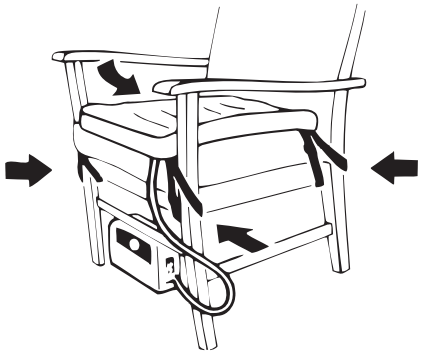
*The cells are in a horizontal position across the chair, not from front to back.*

3. Secure the seat cushion to the chair by using the fixing straps as shown in the following illustrations.

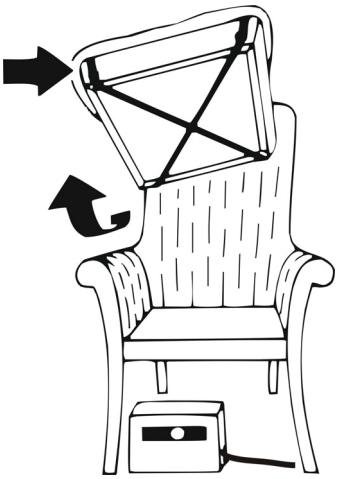
## Cautions

- **Do not use the *Alpha Trancell* Deluxe seat cushion without a foam cushion beneath it.**
- **Always use the *Alpha Trancell* Deluxe seat cushion with the protective top cover.**
- **Always use the *Alpha Trancell* Deluxe seat cushion in the correct orientation.**
- **Avoid trailing cables - ensure that cables and tubing are positioned beneath the chair to avoid causing a hazard.**

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. Position the protective cover over the seat cushion and ensure that the *Alpha Trancell* Deluxe logo is uppermost and at the front of the seat.

### *To complete the system installation*

Complete the installation of the system as follows:

1. If not already fitted, place the protective cover over the mattress. Ensure that the *Alpha Trancell* Deluxe logo is uppermost and at the foot end of the mattress.
2. Connect tubeset to pump ensuring that the tubes are not kinked or twisted.
3. The system is now ready for use. Refer to “Controls and Indicators” on page 9 and “Operation” on page 10 for day-to-day operating instructions.

# 4. Controls and Indicators

## Controls

***Pressure Control***

This is situated on the front panel and is adjusted by the carer to suit the weight of the patient.

***Power:Connect/ Power:Disconnect Switch***

| (Power:Connect)

◯ (Power:Disconnect)

This is situated on the side panel of the pump and is used to activate the unit and reset alarms. Mains isolation should be performed with the pump disconnected from power.
To isolate the pump from the mains power, switch the pump to Power: disconnect (◯) and then remove the plug from the mains power socket.

## Indicators

***Power On***

A light on the front panel indicates that the pump is running.

***Wait***

When the overlay is being inflated the amber Wait indicator remains illuminated until the overlay is correctly inflated.

***Low Pressure***


In the event of low pressure in the overlay, the yellow Low Pressure alarm indicator starts flashing and an audible alarm sounds.

***Power Fail***

In the event of mains power failure, the yellow alarm indicator starts flashing and an audible alarm sounds. If the power supply is returned the audible alarm stops, but the alarm light remains illuminated until the system is reset (UK only).

## Alarm

***Alarm Priority***

All the alarm conditions are low priority, compliance with 60601-1-8.

***Alarm Reset***

When the cause of the alarm has been resolved, the pump needs to be reset. This can be achieved by switching the pump to Power:disconnect and back to Power:connect using the Power:connect / Power:disconnect switch on the side panel.

***Self Test***

Every time the pump is switched on all indicator lights illuminate for approximately two seconds. During this period, the system self tests its circuits.

# 5. 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 Section 4, Page 9 “Controls and Indicators” for a comprehensive description of the controls and indicators on the pump.*

NOTE

*If the operation of the pump changes during use, refer to “Troubleshooting Guide” on page 16 of this manual before calling a service engineer or contacting your local Arjo sales office.*

**WARNING**

**Make sure that the mains power cable and mattress tubeset are positioned to avoid causing a trip or strangulation hazard, and are clear of moving bed mechanisms or other possible entrapment areas.**
**Do not place the patient on the mattress or seat cushion until it is fully inflated, when the Wait indicator is extinguished.**

## Installing the System

Before using the *Alpha Trancell* Deluxe system make sure that it has been installed correctly in accordance with Section 3, Page 6 “Installation”.

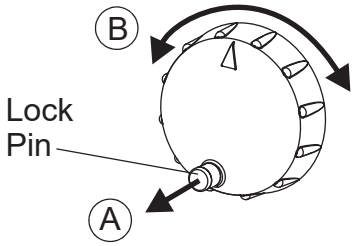
Where fitted, make sure:

- The rapid deflate stopper on the mattress is securely fitted.
- The Transport control on the mattress is set to Normal.

## Inflating the Mattress

1. Connect the pump to the mains power supply using the supplied cable.
2. Set the Power:connect / Power:disconnect switch to Power:connect ( | ). The pump performs a diagnostic self test, illuminating all four indicators and sounding the audible alarm.
3. At the end of this start-up sequence, the pump starts to inflate the mattress or seat cushion.
   - The green Power indicator and amber Wait indicator are illuminated while the mattress or seat cushion is inflating.
   - The pump may take up to 10-15 minutes to fully inflate a mattress or 2-3 minutes for the seat cushion. The amber Wait indicator extinguishes when the system is fully inflated.

### *To Adjust the Pressure Control Knob Position*




The pressure control knob (2) is locked in position to prevent accidental rotation.

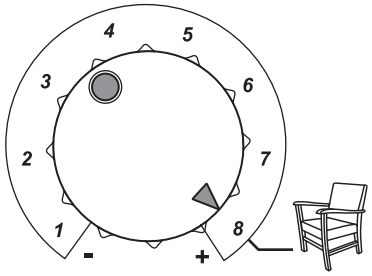
To adjust the position of the pressure control knob:

1. Lift the lock pin (A) to release the control knob.
2. Rotate the control knob (B) whilst the lock pin is raised.
3. Release the lock pin when the pressure control knob is in the desired position to lock the control knob.

NOTE

*Rotate the pressure control knob clockwise to increase and counterclockwise to decrease pressure.*

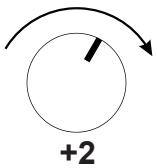
### *Initial Pressure Setting*




4. If you are using the *Alpha Trancell* Deluxe seat cushion, set the pressure control to the maximum position (8).
5. If you are using a mattress, adjust the pressure for the appropriate patient weight. Refer to the patient weight guide on the back of the pump for the correct setting. In the case of a patient sitting in bed, increase the pressure control knob by two settings.

**WARNING**

**The weight guide is only an indication and should not replace clinical judgement.**

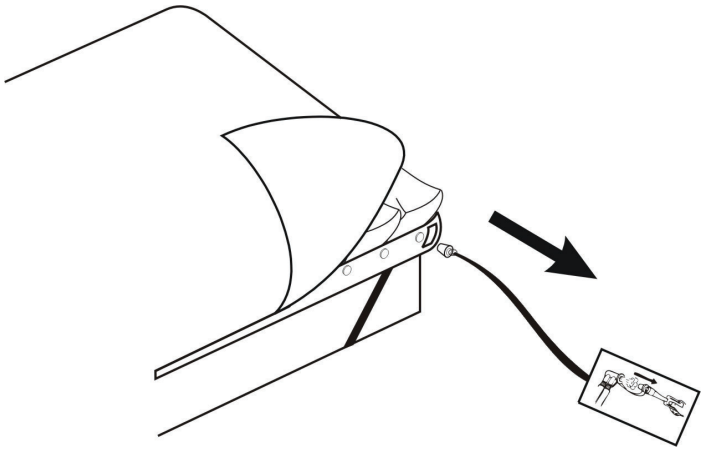
| kg | lbs | Alpha PREVENT | *Trancell* II | *Alpha Trancell* Deluxe | If Patient Sitting in Bed |
|---|---|---|---|---|---|
| 40 | 88 | 2 | 1 | 1 |  |
| 60 | 132 | 2-4 | 1-2 | 2-3 | |
| 80 | 176 | 4-5 | 2-3 | 4 | |
| 100 | 220 | ***Trancell II*** | 3+ | 5-6 | **+2** |

**IMPORTANT**

- **The Rapid Deflate facility is fitted to the *Trancell* II and *Alpha Trancell* Deluxe mattresses only.**
- **In the event of a cardiac arrest, pull the Rapid Deflate tag firmly at the head end of the mattress and disconnect the tubeset connectors at the pump.**

## Rapid Deflate

Located at the head end of the mattress (on the same side as the tubeset) is a tag with a Rapid Deflate picture. In the event of cardiac arrest, pull this tag for rapid mattress deflation.



To reinflate the mattress, simply replace the stopper securely into the manifold and ensure secure connection of the mattress to the pump.

NOTE

*When the Rapid Deflate stopper is removed, the low pressure alarm will activate on the pump. To cancel the alarm, switch the pump OFF then ON again.*
*Ensure that the pump is connected to the power supply and switched on.*

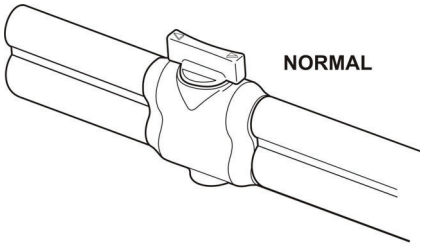
## IMPORTANT

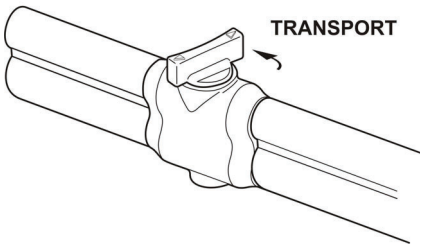
- **The Transport facility is fitted to the *Alpha Trancell* Deluxe mattress replacement and the mattress overlay only.**
- **There is no Transport facility on the *Alpha Trancell* Deluxe seat cushion.**

### *Transport Mode*

The transport facility is located on the tubeset near the pump. The patient may be transported on the *Alpha Trancell* Deluxe systems as follows:

1. Turn the control knob 90 degrees as shown below.
2. Remove the tubeset from the pump.
3. Switch the pump to Power:disconnect.




The pressure in the two sets of cells will equalise and the patient continues to be supported (with the mattress static) for 1 - 2 hours with the patient in the supine (lying) position.

### *Normal Mode*

To return to normal alternating mode, push the tubeset onto the pump, make sure the pump is switched on and then turn the control knob 90 degrees counter-clockwise so that the arrows align with the tubeset.

NOTE

*To obtain the maximum use of the transport facility ensure that the patient remains in the supine position and the mattress is put in transport mode when all cells are inflated.*

### Stopping Therapy

To stop the therapy, switch the pump to the Power:disconnect (◯) position.

- To completely isolate the pump from the mains, remove the plug from the mains power socket.

# 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 Trancell* Deluxe 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.

***Thermal Disinfection***

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

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

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

# 7. Routine Maintenance

## *Alpha Trancell* Deluxe Systems

***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 Trancell* Deluxe systems should be serviced after 12 months continuous running time, by an Arjo authorised service agent.

## *Alpha Trancell* Deluxe Pump

***General Care, Maintenance and Inspection*** Check all electrical connections and the mains power cable for signs of 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.

## Mattresses and Seats

***General Care*** Remove the cover from the mattress or seat.

Inspect the cover for signs of wear or any tears, and check that all cover fasteners are secure.

Check the security of all internal connections, including:

- Between the cells and the manifold.
- To the rapid deflate control.

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

## Serial Number Labels

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

***Mattress and Seat*** The serial number label is on the base cover.

Quote these serial numbers when requesting service.

# 8. Troubleshooting Guide

**WARNING**

**Electrical equipment may be hazardous if misused. The pump's case back should only be removed by authorised technical personnel.**

| Problem | Possible Cause | Action |
|---|---|---|
| Mattress or seat not inflating. | 1. CPR stopper not inserted.<br>2. Tubes kinked.<br>3. Pump not switched on.<br>4. No pump output.<br>5. Tubes not correctly fitted.<br>6. Transport facility set to 90 degrees. (*Alpha Trancell* Deluxe only) | Check<br>Check<br>Check<br>Check. See Pump not operating below.<br>Check<br>Check. |
| Consistent Low Pressure Alarm. | 1. Rapid Deflate stopper not inserted.<br>2. Tubes not correctly fitted.<br>3. Leakage. | Check<br>Check<br>Check |
| The Wait indicator does not go off | 1. Rapid Deflate stopper not inserted.<br>2. Tubes not correctly fitted.<br>3. Leakages | Check<br>Check<br>Check |
| The Power Fail indicators (audible and visual) are active. | 1. A mains power failure has occurred.<br>2. The power cord has been removed from the wall socket | Check<br>Check |
| The Power Fail indicator remains constantly illuminated but there is no audible alarm (UK Only). | There has been a mains power failure but power has been restored (UK only). | Check if electrical plug is correctly fitted, and if pump is running correctly. |
| Pump makes a lot of noise and/ or is causing a lot of vibration. | System damaged or dirty. | Call Service Engineer for maintenance. |
| Pump not operating | 1. Pump Power:connect switch not on.<br>2. Plug not inserted correctly.<br>3. Fuse Blown.<br>4. Technical failure. | Switch on<br>Check<br>Call Service Engineer for maintenance.<br>Call Service Engineer for maintenance. |
| All indicators remain illuminated on initial switch-on. | Internal fault. | Call Service Engineer for maintenance. |

NOTE

*Ensure pump alarms are reset by operating the Power:connect / Power:disconnect switch after the fault has been corrected.*

NOTE

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

# 9. Technical Specification

| Pump | | | | |
|---|---|---|---|---|
| Model: | *Alpha Trancell* Deluxe | | | |
| | | KSA | | |
| Supply Voltage: | 230 V | 230 V | 120 V | 220-230 V |
| Supply Frequency: | 50 Hz | 60 Hz | 60 Hz | 50 Hz |
| Power Input: | 14 VA | 14 VA | 14 VA | 14 VA |
| Size: | 248 x 160 x 116 mm (9.8 x 6.3 x 4.6”) | | | |
| Weight: | 2.7 kg (6lb) | | | |
| Case Material: | ABS Plastic | | | |
| Plug Fuse Rating: | 5A to BS1362 (UK ONLY) | | | |
| Pump Fuse Rating: | 2 x T1AL 250 V | | | |
| 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 | | | |

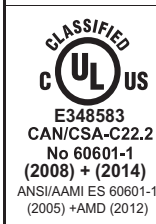
| Environmental Information | | | |
|---|---|---|---|
| **Condition** | **Temperature Range** | **Relative Humidity** | **Atmospheric Pressure** |
| **Operating** | +10°C to +40°C (+50°F to +104°F) | 30% to 75% (non-condensing) | 700hPa to 1060 hPa |
| **Storage (Long Term)** | +10°C to +40°C (+50°F to +104°F) | 20% to 95% (non-condensing) | 700 hPa to 1060 hPa |
| **Storage (Short Term)** | -20°C to +65°C (-4°F to 149°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.*

NOTE

*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.*

| Pump Symbols | | | |
|---|---|---|---|
|  | The operator must read this document (Instructions for Use) before use.<br>Note: This symbol is blue on the product label. |  | Refer to this document (Instructions for Use) for a description of the product classification (3rd Edition). |
|  | With respect to electric shock, fire and mechanical hazards<br>only in accordance with<br>CAN/CSA-C22.2 No. 60601.1 (2008) + (2014). ANSI/AAMI ES 60601-1 (2005) +AMD (2012)<br>MEDICAL EQUIPMENT |  | CE marking indicating conformity with European Community harmonised legislation<br>Figures indicate Notified Body supervision. |
|  | Refer to this document (Instructions for Use) for a description of the product classification (2nd Edition). |  | Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745. |
|  | Manufacturer: This symbol is accompanied by the name and the address of the manufacturer. |  | Double Insulated |
|  | Do not dispose of in domestic refuse |  | Serial Number |
|  | Type BF |  | Model number |
|  | Power:<br>disconnect |  | Power:<br>connect |
|  | Unique device identifier | | |

**UK Symbol explanation**

This section is only applicable to United Kingdom (UK) market when UK marking is applied to the Arjo medical device labelling.

| | |
|---|---|
|  | UK marking indicating conformity with UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended).<br>Figures indicate UK Approved Body supervision. |

**UK Responsible Person & UK Importer:**
**Arjo (UK) Ltd, ArjoHuntleigh House, Houghton Regis. LU5 5XF**
Is the appointed UK Responsible Person as defined in UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended).
For Northern Ireland (NI) CE marking will still apply until further amendment to applicable regulations.

## Mattress Information

| Part No. | Description | Cell Material | Length mm | Width mm | Height mm |
|---|---|---|---|---|---|
| AB037 | Alpha Prevent | Polyurethane | 1850 | 750 | 60 |
| TRA04 | *Trancell* II Mattress Overlay | | 2006 | 840 | 90 |
| ATD002DAR | *Alpha Trancell* Deluxe OL | | 2040 | 860 | 114 |
| ATD001DAR | *Alpha Trancell* Deluxe MR | | 2040 | 860 | 210 |

For the dimension and weight specifications in this IFU, there could be some tolerance, not explicitly listed. Arjo is entitled to have the final explanation on these specifications.

## Product

| Mattress SKU | Product Description | Sewn Part Number | Welded Part Number |
|---|---|---|---|
| ATD002DAR | *Alpha Trancell* Deluxe (OL) | ATD082 | ATD082W |
| ATD001DAR | *Alpha Trancell* Deluxe (MR) | ATD082 | ATD082W |

## Cover Specification

| Feature | **Standard Cover (Reliant IS$^2$)** |
|---|---|
| Removable Cover | Yes |
| Moisture Vapour Permeable | Low |
| Low Friction | No |
| Water Resistant / Repellent | Yes |
| Polyurethane coating includes an antimicrobial agent to control microbial deterioration of fabric | Yes |
| Fire Retardant[a] | 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 |
| Max Drying Temperatures | Max 80°C (176°F) |
| Wipedown Chemicals[b] | Chlorine at strength of 1000ppm or Alcohol at 70% concentration; no phenol; ensure product is dry before storage |

a. For additional flammability testing standards, refer to individual product law tags, if applicable.
b. 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.

## Cleaning Symbols

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

## Seat Information

| *Alpha Trancell* Deluxe Seat | **ATD003DAR** |
|---|---|
| Length: | 470 mm |
| Width: | 455 mm |
| Height: | 50 mm ALT03 |
| Cell Material: | Polyurethane |

For the dimension and weight specifications in this IFU, there could be some tolerance, not explicitly listed. Arjo is entitled to have the final explanation on these specifications.

# 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 1.5m 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 emission** | | |
|---|---|---|
| **Emission 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.<br>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<br>IEC 61000-3-2 | ClassA | |
| Voltage fluctuations/ flicker emissions IEC61000-3-3 | Complies | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| **Immunity test** | **IEC 60601-1-2 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge (ESD)<br><br>EN 61000-4-2 | ±2kV, ±4kV, ±8kV, ±15kV air<br><br>±8kV contact | ±2kV, ±4kV, ±8kV, ±15kV air<br><br>±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<br><br>EN 61000-4-6 | 3V in 0,15 MHz to 80 MHz<br><br>6V in ISM and amateur radio bands between 0,15 MHz and 80 MHz<br><br>80% AM at 1 kHz | 3V in 0,15 MHz to 80 MHz<br><br>6V in ISM and amateur radio bands between 0,15 MHz and 80 MHz<br><br>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 1.0m, 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]<br>Interference may occur in the vicinity of equipment marked with this symbol:<br>  |
| Radiated RF electromagnetic field<br><br>EN 61000-4-3 | Home Healthcare environment<br>10 V/m<br><br>80 MHz to 2,7 GHz<br>80% AM at 1 kHz | Home Healthcare environment<br>10 V/m<br><br>80 MHz to 2,7 GHz<br>80% AM at 1 kHz | |
| Electrical fast transient/burst<br><br>EN 61000-4-4 | ±1kV SIP/SOP ports<br><br>±2kV AC port<br>100 kHz repetition frequency | ±1kV SIP/SOP ports<br><br>±2kV AC port<br>100kHz repetition frequency | Mains power supply should be that of a typical commercial or hospital environment. |
| Power frequency Magnetic field<br><br>EN 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| **Immunity test** | **IEC 60601-1-2 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Surge<br><br>IEC61000-4-5 | ±0.5kV, ±1kV, ±2kV, AC Mains Line to Ground<br><br>±0.5kV, ±1kV, AC Mains Line to Line | ±0.5kV, ±1kV, ±2kV, AC Mains Line to Ground<br><br>±0.5kV, ±1kV, AC Mains Line to Line | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>IEC 61000-4-11 | 0% $U_T$ ; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0% $U_T$ ; 1 cycle<br>and<br>70% $U_T$ ; 25/30 cycles<br>Single phase: at 0°<br><br>0% $U_T$ ; 250/300 cycle | 0% $U_T$ ; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0% $U_T$ ; 1 cycle<br>and<br>70% $U_T$ ; 25/30 cycles<br>Single phase: at 0°<br><br>0% $U_T$ ; 250/300 cycle | Mains power quality should be that of a typical commercial or hospital environment.<br>If the user of the pump requires continued operation during power mains interruption, it is recommended that the pump be powered from an uninterruptible power supply or battery. |
| NOTE: $U_T$ 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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At Arjo, we believe that empowering movement within healthcare environments is essential to quality care. Our products and solutions are designed to promote a safe and dignified experience through patient handling, medical beds, personal hygiene, disinfection, diagnostics, and the prevention of pressure injuries and venous thromboembolism. With over 6500 people worldwide and 65 years caring for patients and healthcare professionals, we are committed to driving healthier outcomes for people facing mobility challenges.

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