INSTRUCTIONS FOR USE

Auralis

Alternating pressure system

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arjo
EMPOWERING MOVEMENT

⚠ WARNING

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

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Foreword

Thank you for purchasing Arjo equipment.

Customer contact information

For questions regarding this product, supplies, maintenance, or additional information about Arjo products and service, please contact Arjo or an Arjo authorized representative, or visit www.arjo.com.

Please read and fully understand the Instructions for Use (IFU) before using the Auralis™ system

Information in this IFU is necessary to perform the proper operation and maintenance of the equipment. It will help to protect your product and make sure that the equipment performs to your satisfaction. The information in this IFU is important for your safety and must be read and understood to help prevent possible injury. Unauthorized modifications on any Arjo equipment can affect safety. Arjo will not be held responsible for any accidents, incidents or lack of performance that occur as a result of any unauthorized modification to its products.

Support

Routine maintenance must be performed on the Auralis system before every use or every week (if for long term use) to maintain safety and reliability of the equipment. See section Care and preventive maintenance for more information. If you require further information, please contact Arjo for comprehensive support and maintenance to maximize the long-term safety, reliability and value of the product. Contact your local Arjo representative for spare parts. The telephone numbers appear on the last page of this IFU.

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.

Definitions in this IFU

⚠ **WARNING**	Warning means: Safety warning. Failure to understand and obey this warning may result in injury to you or to others.
CAUTION	Caution means: Failure to follow these instructions may cause damage to all or parts of the system or equipment.
NOTE	Note means: This is important information for the correct use of this system or equipment.

Intended use for Auralis

The Auralis System is intended for use by caregivers[1] in acute and post-acute care facilities including, long-term care, home care facilities and private homes.

The system is indicated for the prevention and/or management of all categories of pressure injuries (pressure ulcer) when combined with an individualised, comprehensive pressure ulcer protocol; for example, repositioning, nutritional support, skin care.

The system represents one aspect of a pressure injury (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 system provides two modes of therapy: 'reactive pressure redistribution' and 'active (alternating) pressure redistribution'.

The system should only be used for the purpose specified in these Instructions for Use.

Any other use is prohibited.

Patient assessment

- We recommend that facilities establish regular assessment routines. Caregivers should assess each patient according to the following criteria prior to use:
- For the Auralis mattress, the patient weight must not exceed 250 kg (550 lb) for the standard and narrow mattresses
- For the Auralis Seat Cushion, the patient weight must not exceed 200 kg (440 lb).
- For the Auralis Plus mattress, the patient is within the weight range of 100 kg (220 lb) to 454 kg (1000 lb).
- For the Auralis Plus mattress, the patient Body Mass Index (BMI) is >30

Contraindications

Do not use with patients with unstable cervical, thoracic and/or lumbar fracture, cervical traction, and skeletal traction.

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 Standard and Narrow Auralis mattress 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 system with a higher weight limit such as Auralis Plus mattress.

Expected service life

The expected service life of the Auralis pump is seven (7) years, subject to preventive maintenance being carried out in accordance with the instructions for care and maintenance found in the Instructions for Use.

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

Safety instructions

WARNING
To avoid serious injury or death, the CPR rapid deflation unit must be visible and accessible at all times.

WARNING
To avoid strangulation, always use the cable management for the power cable.

WARNING
To avoid injury, the mains power socket and plug must be accessible at all times. To disconnect the Auralis pump completely from the electricity supply, remove the plug from the mains power socket.

WARNING
To avoid entanglement hazard, never leave children or vulnerable persons unattended with the Auralis system at any time.

WARNING
To avoid pressure injury, make sure the Auralis system is assembled correctly.

WARNING
To avoid bodily injury, never use the Auralis mattress as a movement device.

WARNING
To avoid suffocation, always attach the Auralis mattress cover and *Auralis* seat cushion cover when in use.

WARNING
To avoid severe burn injury, do not use the Auralis pump in the presence of uncontained flammable liquids or gases.

WARNING
To avoid falling and injury, make sure that cables and the tube-set are positioned correctly and are clear of moving bed mechanisms or other possible entrapment areas.

WARNING
To avoid pressure injury the patient must not wear clothing which may cause areas of localised high pressure due to creases, seams, etc. Placing objects in pockets must be avoided for the same reason.

WARNING
To avoid reduced benefits from the Auralis mattress, do not place extra layers between the patient and the Auralis mattress.

WARNING
To avoid injury to the patient, keep children and pets away from the equipment.

WARNING
To avoid suffocation, keep the bags supplied with this equipment away from babies and small children.

⚠ WARNING
Electrical equipment may be hazardous if misused. Do not use unapproved accessories or attempt to modify, disassemble or otherwise misuse the Auralis system

⚠ WARNING
To avoid choking, never leave children unattended near the equipment. The equipment includes small parts that may present a choking hazard to small children, vulnerable persons and pets if inhaled or swallowed.

⚠ WARNING
Do not attempt to service or maintain the Auralis pump while it is in use.

⚠ WARNING
To avoid discomfort or injury for the patient, ALWAYS set the comfort level at maximum for patients weighing over 360 kg (793 lb).

CAUTION
To avoid equipment damage, pets and children must be supervised in the vicinity of the Auralis system.

CAUTION
To avoid equipment damage, never use the Auralis pump close to heat sources.

CAUTION
To avoid equipment damage, never use sharp objects or electrically heated under blankets on or under the Auralis system.

CAUTION
To avoid equipment damage, do not expose the Auralis system, especially the mattress, to naked flames, such as cigarettes. A leak in the Auralis mattress or Auralis seat cushion could propagate the fire.

Home care

Use the Auralis system

Before using the Auralis system in home environment make sure that all caregivers, including relatives, have read and understood the instructions in this IFU.

When the Auralis system is in use, make sure:

- The Auralis system is kept away from sources of heat and moisture, and protected from dust, lint and dirt.
- The Auralis system is not covered.
- The operational environment fulfils the requirements specified in section “Operating conditions” on page 51.

When the Auralis system is not in use, make sure:

- No children can access the Auralis system.
- No pets can come in contact with the Auralis system.
- The storage environment fulfils the requirements specified in section “Transport and storage conditions” on page 52.

⚠ WARNING

To avoid injury to the patient when operating the Auralis system as a caregiver and as a lay person:

- **Make sure the system is operating according to sections “Product description - Auralis pump” on page 17, “Product description - Auralis mattresses” on page 21, and “Product description - Auralis seat cushion” on page 24.**
- **If the system is not operating correctly, see section “Troubleshooting and alarms” on page 48.**
- **If the system is still not operating correctly, or if you have concerns,contact the patient’s doctor or nursing staff for advice.**

Preparations

Bed frame recommendation

The Auralis Plus mattress is designed to be used with the Arjo Citadel Plus bed frame.

The Auralis mattress range (narrow, standard and Plus) may also be used with other bed frames (Arjo or non-Arjo). An assessment should be made by clinician or caregiver to determine which mattress and bed frame combination to use. See respective bed frame IFU for compatible mattress sizes and page 52 (within this IFU) for dimensions of all Auralis mattresses.

Actions before first use

(5 steps)

1. Check the package for damage. If the product looks damaged during transport, contact the transport agency.
   Do NOT use the product.
2. Check that the items are complete:
   - Auralis pump with power cable and hanging brackets,
   - Auralis 110 mattress overlay, Auralis 175, 200 or Plus mattress replacement or Auralis seat cushion, all with integrated tube-sets, labels and covers.
3. Recycle the packaging according to local regulations.
4. Read this IFU.
5. Store the IFU in a designated area, where it is easily accessible at all times.

Actions before every use

(2 steps)

1. Inspect the Auralis system, according to section “Care and preventive maintenance Schedule” on page 45.
2. If any item is damaged - do NOT use the product.

After each patient

Clean and disinfect the product after each patient according to section “Cleaning and disinfection instructions” on page 40.

The position of the caregiver

The caregiver should be positioned in front of the pump during operation. See Figure 1

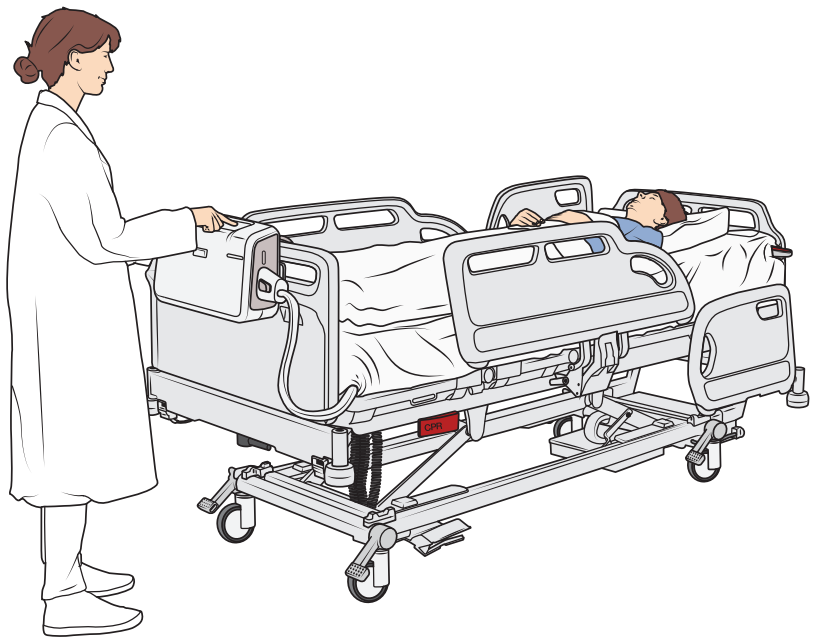
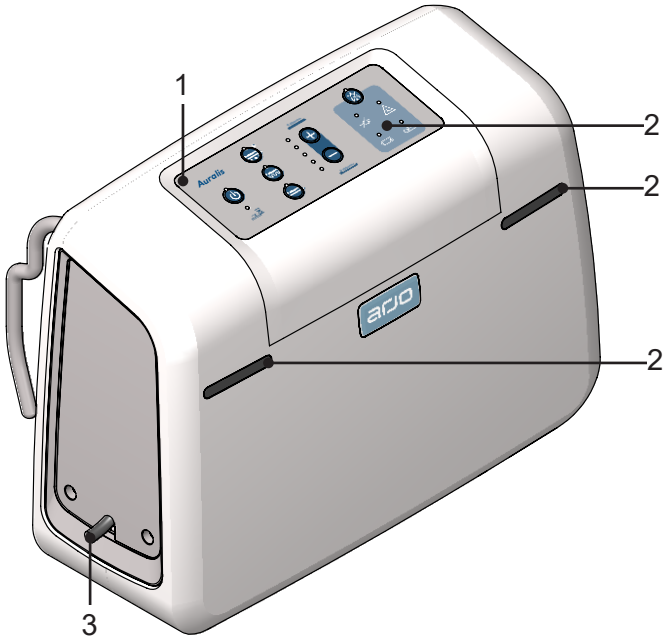
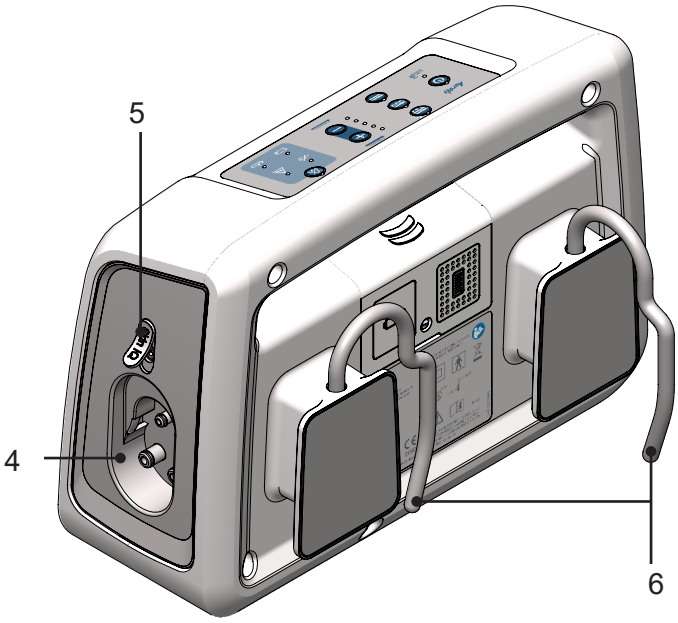


Figure 1

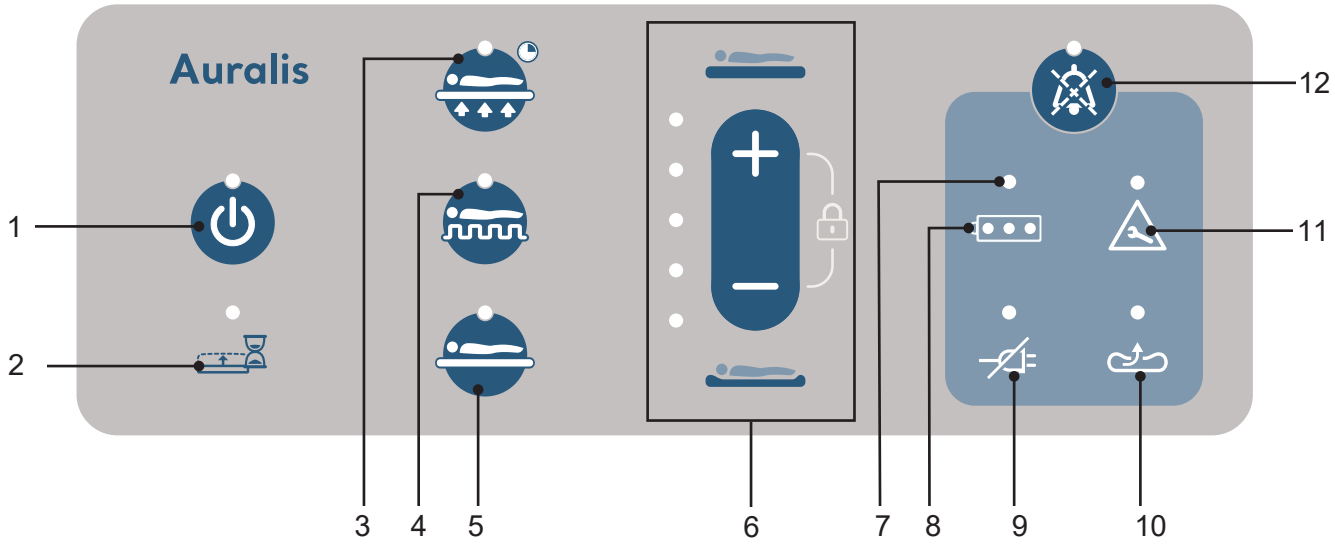
Parts designation - Auralis pump





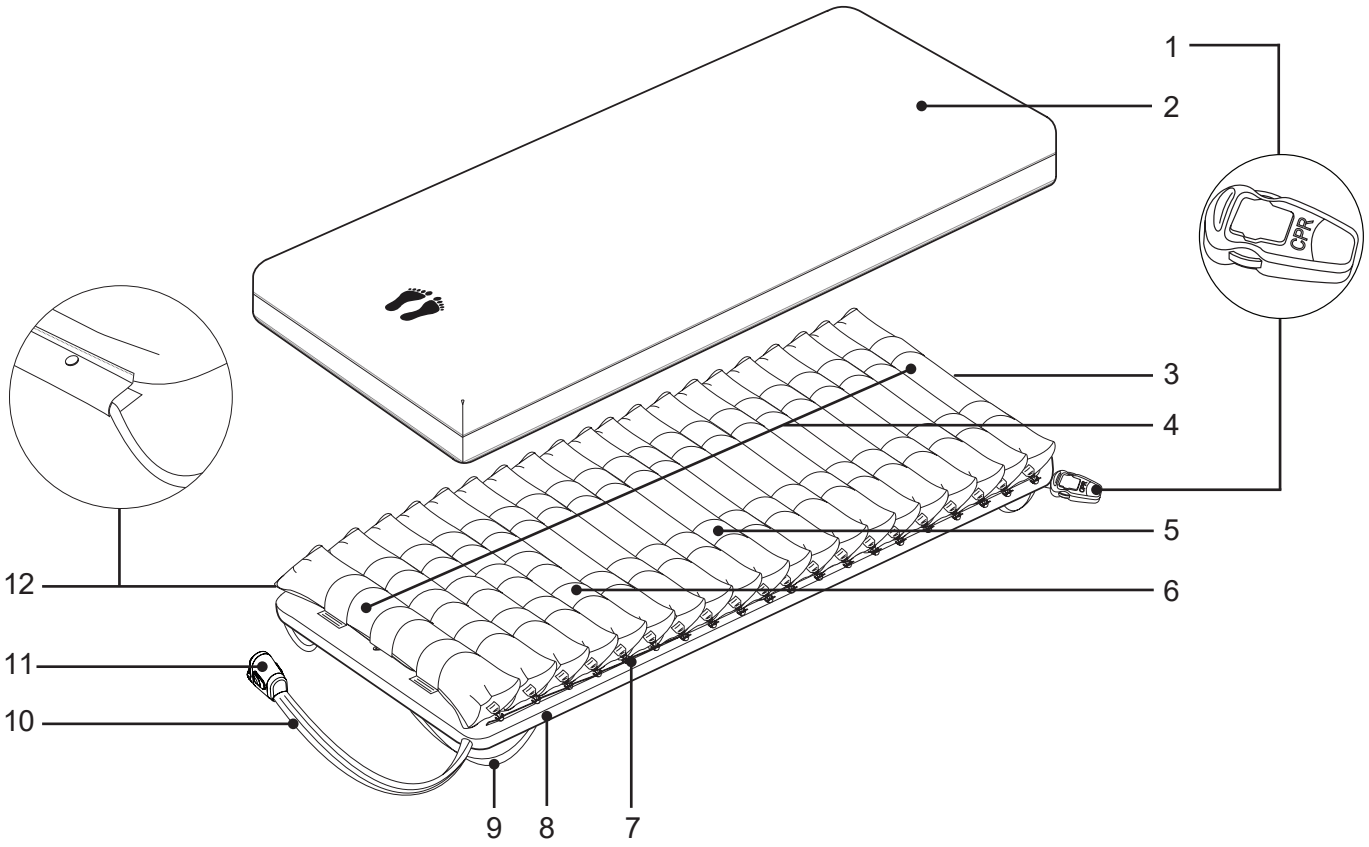
1. Control panel (with indicators)
2. Alarm indicators
3. Power cable
4. Connector socket
5. Skin IQ port
6. Hanging brackets

Control panel - buttons and indicators



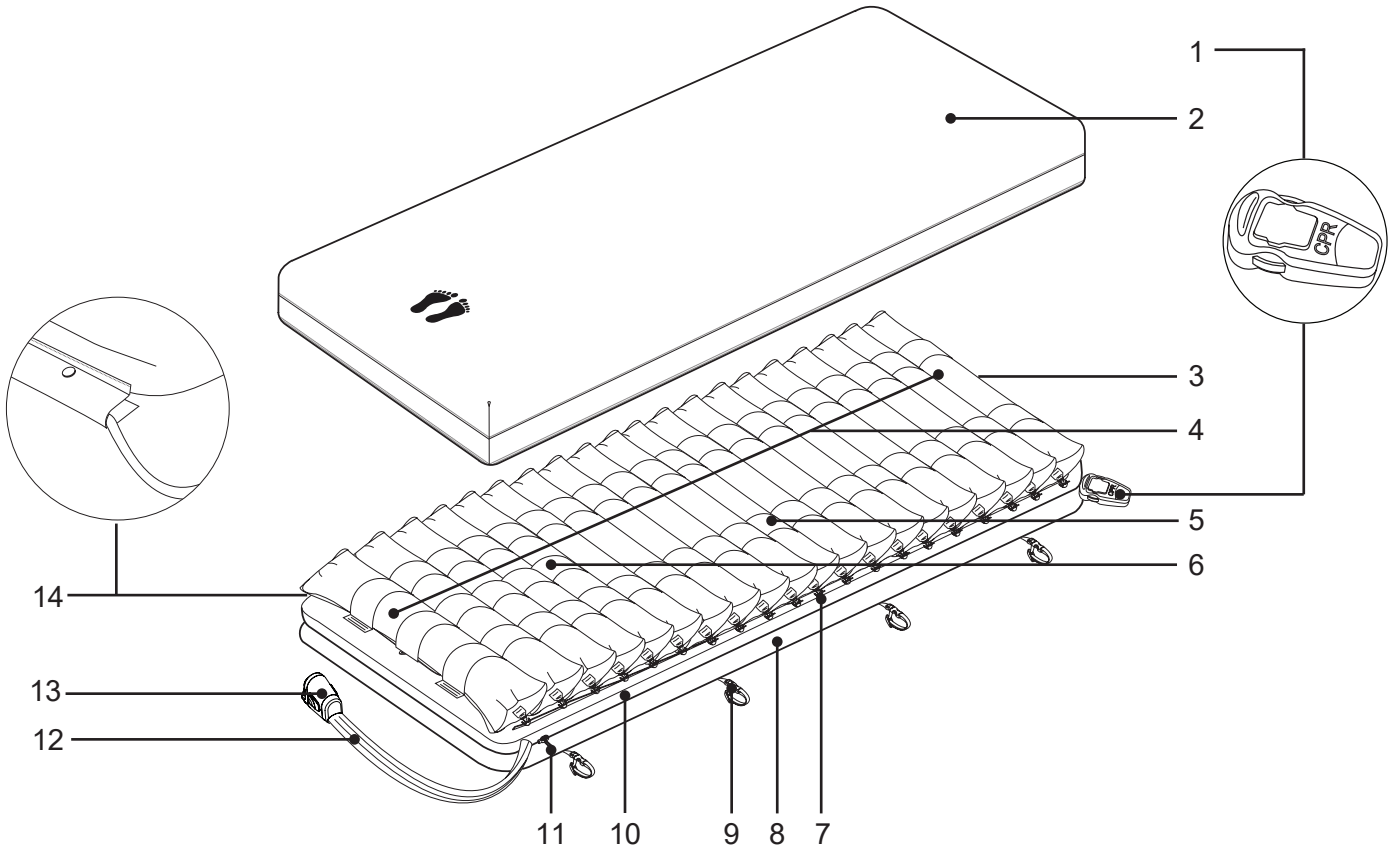
1. Run/Standby button and indicator
2. Wait indicator
3. Autofirm mode button
4. Alternating mode button
5. Reactive CLP mode button
6. Comfort control buttons/indicators
   Lock out buttons/indicators
7. Low battery indicator
8. Battery charge indicators
9. Mains power failure indicator
10. Low pressure indicator
11. Service indicator
12. Alarm mute button and indicator

Parts designation - Auralis 110 mattress overlay



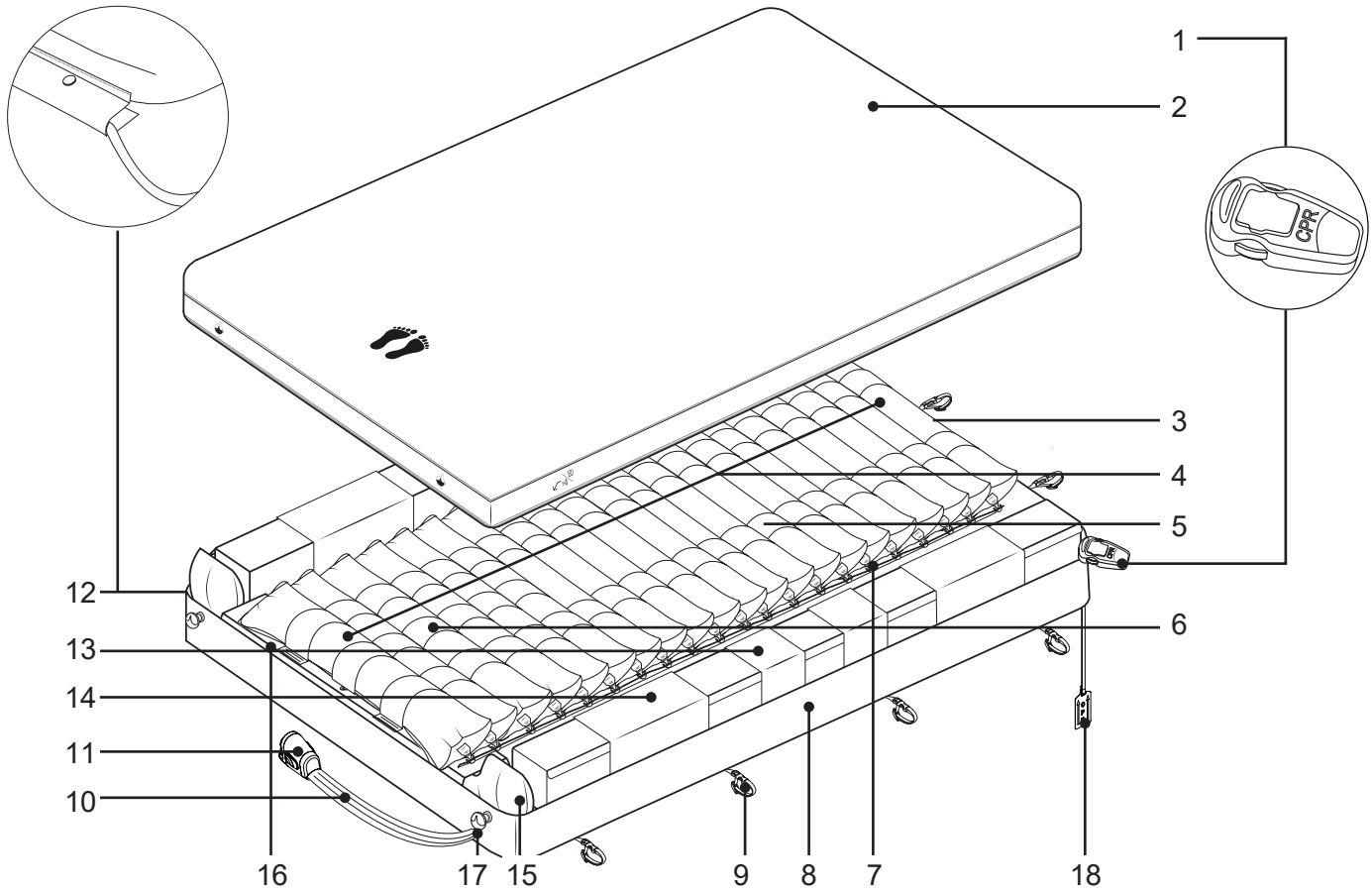
1. CPR rapid deflation unit
2. Detachable cover
3. Cover attachment zip
4. Cells (quantity)
   - Head cells (3)
   - Torso cells (12)
   - Heelguard™ cells (5)
5. Loop straps
6. Heelguard™ cell straps
7. Cell hooks
8. Overlay base cover (including micro air loss system)
9. Fixing straps
10. Tube-set
11. Connector
12. Cable management

Parts designation - Auralis 175 and 200 mattress replacement



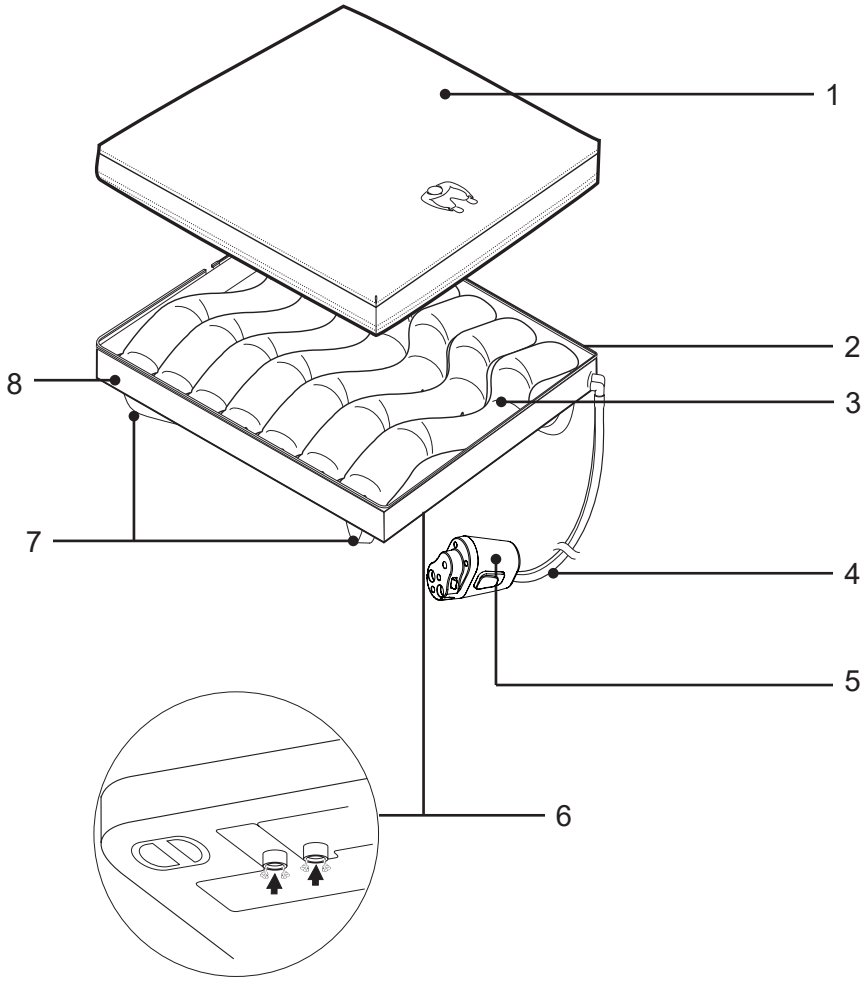
1. CPR rapid deflation unit
2. Detachable cover
3. Cover attachment zip
4. Cells (quantity)
   - Head cells (3)
   - Torso cells (12)
   - Heelguard™ cells (5)
5. Loop straps
6. Heelguard™ cell straps
7. Cell hooks
8. Non-slip base with:
   Foam underlay (mattress 175)
   Air filled zoned sub-mattress (mattress 200)
9. Securing straps (four on each side)
10. Overlay base (including micro air loss system)
11. Overlay zip
12. Tube-set
13. Connector
14. Cable management

Parts designation - Auralis Plus mattress replacement



1. CPR rapid deflation unit
2. Detachable cover
3. Cover attachment zip
4. Cells (quantity)
   - Head cells (3)
   - Torso cells (12)
   - Heelguard™ cells (6)
5. Loop straps
6. Heelguard™ cell straps
7. Cell hooks
8. Non-slip base with air filled zoned sub-mattress
9. Securing straps (four on each side and three at head end)
10. Tube-set
11. Connector
12. Cable management
13. Bolster (x2)
14. Bolster sleeve (x2)
15. Air channel
16. Foot extension sleeve
17. Bolster Valve (under valve symbol x2)
18. CPR Tag

Parts designation - Auralis seat cushion



1. Detachable cover
2. Cover attachment zip
3. Alternating cells
4. Tube-set
5. Connector
6. Deflation valves
7. Fixing straps
8. Non-slip base

Product description - Auralis pump

NOTE
There are three different indicator colours:

- Green indicators are functions
- Yellow indicators are information signals or alarms
- Blue indicators are battery charging

Control panel

Figure 2

Run/Standby button

The Run/Standby button (see Figure 2) switches the Auralis pump between run mode and standby mode. Run mode - press the button once. The indicator changes from flashing to constant.
Standby mode - press the button for two seconds.The indicator changes from constant to flashing.

NOTE
To turn the Auralis pump off during power failure or battery operation, press the Run/Standby button for four seconds.

Figure 3

Wait indicator

The Wait indicator (see Figure 3) is shown when the Auralis mattress or seat cushion is being inflated. The indicator remains on for approximately 15 minutes until the Auralis mattress or Auralis seat cushion is fully inflated and ready for use. The Auralis Plus mattress takes approximately 17 minutes to reach full inflation.

Figure 4

Autofirm mode button

The Autofirm mode (see Figure 4) inflates the Auralis mattress to a temporary firm surface allowing the nursing procedures to be performed. The Autofirm mode lasts for 15 minutes but may be increased in 5 minute steps to a maximum of 30 minutes. When activated the indicator is shown. The Auralis seat cushion does not have Autofirm mode.

Figure 5

Alternating mode button

The Alternating mode (see Figure 5) is set by default. The Alternating mode inflates/deflates different cells to create a fluctuating surface. When activated the indicator is shown.

Figure 6

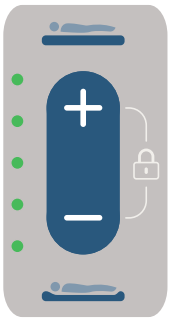


Figure 7

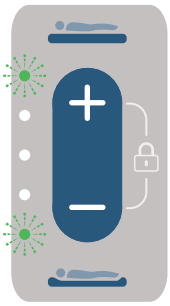


Figure 8

Figure 9

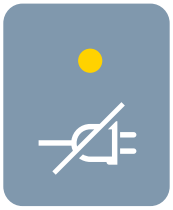


Figure 10

Reactive CLP (Constant Lower Pressure) mode button

The Reactive CLP mode (see Figure 6) maintains a constant lower pressure in all the cells. When activated the indicator is shown. The Auralis seat cushion does not have Reactive CLP mode.

Comfort control buttons and indicators

The Comfort control buttons (see Figure 7) set the comfort level by adjusting the pressure within the support surface. The Comfort control indicators indicate the comfort setting. When the system is first switched on, the default is set to the middle comfort setting.

- Press the + button to increase pressure in the cells to make the mattress firmer.
- Press the – button to reduce pressure in the cells to make the mattress softer.

Lock out mode

The Lock out mode sets the pump in a locked state to prevent unintentional changing of settings.

When the pump is in Lock out mode, pushing any button will result in a negative tone and the top and bottom Comfort control indicators flashing simultaneously to indicate the pump is in Lock out mode. See Figure 8.

Mute alarm button

When the Mute alarm button (see Figure 9) is activated the indicator is shown and the audible alarm is silenced for 15 minutes.

The alarm is cancelled when the alarm condition has been corrected.

Mains power failure indicator

The Mains power failure indicator (see Figure 10) is activated when a mains power failure has been detected. The indicator is shown for information only. The pump continues to operate normally by using the battery. There is no audible alarm.

Continue on the next page.

Figure 11

Service indicator

The Service indicator (see Figure 11) indicates two states:

- When the Auralis pump is ready for service, the Service indicator shows yellow and the front panel alarm indicators show green. This is an information signal and not an alarm condition.
- If the Auralis pump has an internal fault, the Service indicator shows yellow, the front panel alarm indicators show yellow and there is an audible alarm. The Service indicator may take up to 22 minutes to show. The alarm can be muted (see Mute alarm button).

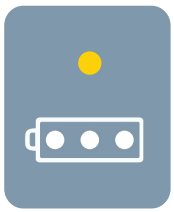


Figure 12

Low battery indicator

The single (top) indicator (see Figure 12) is shown and an audible alarm sounds when there is a minimum of 1 hour battery life left. The alarm can be muted (see Mute alarm button). When there is less than 15 minutes of battery life left, the Auralis pump enters the Reactive CLP mode. At this point, the audible alarm cannot be muted.

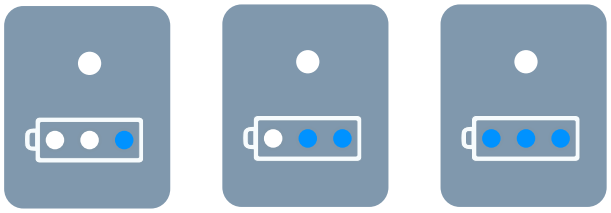


Figure 13

Battery charge indicators

The three indicators (blue) (see Figure 13) indicate the charge level of the battery. When an indicator is flashing it indicates that charging is taking place. When charged the indicator is constantly on. Each indicator represents a 1/3 of the full charge of the battery.

Figure 14

Low pressure indicator

The Low Pressure indicator (see Figure 14) is shown within 30 minutes if the Auralis pump detects low pressure within the Auralis mattress or Auralis seat cushion. For the mattress, there is a repeated audible alarm, which can be muted (see Mute Alarm button), but the visual alarm indicator will remain ‘on’ until the low pressure problem is rectified. If a facility requires a non-repeated audible alarm then the settings of the audible alarm only (not the visual indication), can be configured by a qualified personnel. For the seat cushion, there is no repeated audible alarm, there is a single warning tone.

If the mattress or seat cushion is disconnected while in use, the Low Pressure indicator is shown after 30 seconds. When the indicator is shown, there is a repeated audible alarm. The alarm can be muted (see Mute alarm button).

Continue on the next page.

If the pump detects that a mattress is not connected when the pump starts, the Low Pressure indicator is shown and there is a single warning tone.

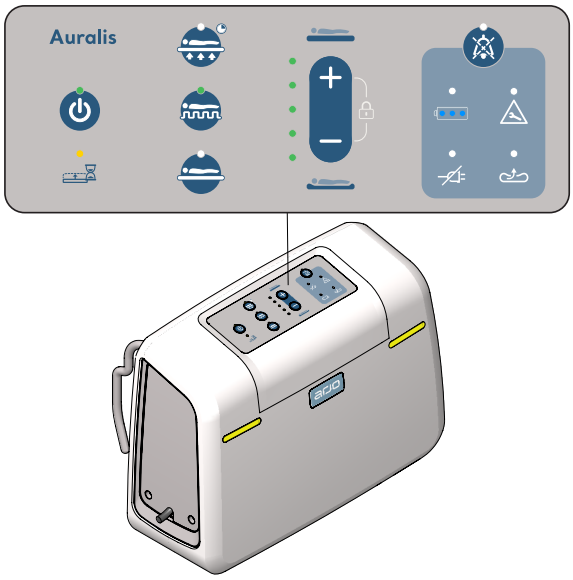


Figure 15

Alarm indicators

The power and alarm indicators are located on the top (the control panel) and front of the Auralis pump. The alarm indicators shown on the front of the pump are green when the pump is operating normally and yellow when there is an alarm condition. See Figure 15.

Hanging brackets

The hanging brackets are used to hang the Auralis pump at the foot end of the bed. See Figure 16

Power cable

The power cable must be positioned in the cable management on the left side of the Auralis mattress. See section “Cable management” on page 22.

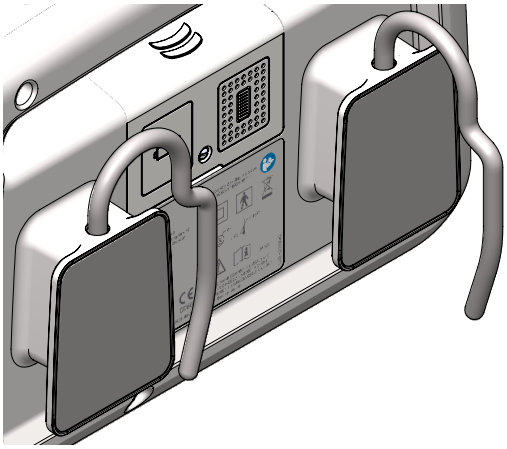


Figure 16

Skin IQ port

This port is only to be used with Skin IQ.
See Figure 17
To power *Skin IQ* directly from the pump, a coiled *Skin IQ* power cable is needed. See “Parts and accessories” on page 64
For instructions how to use Skin IQ, see respective *Skin IQ IFU*.

Figure 17

Product description - Auralis mattresses

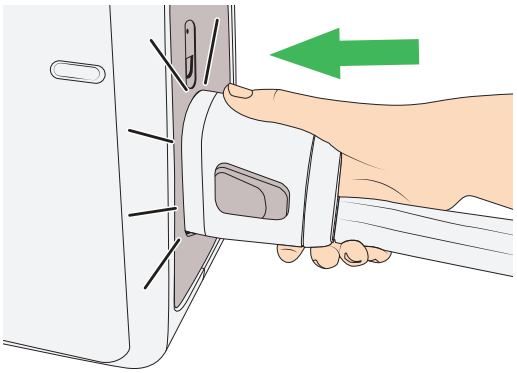


Figure 18

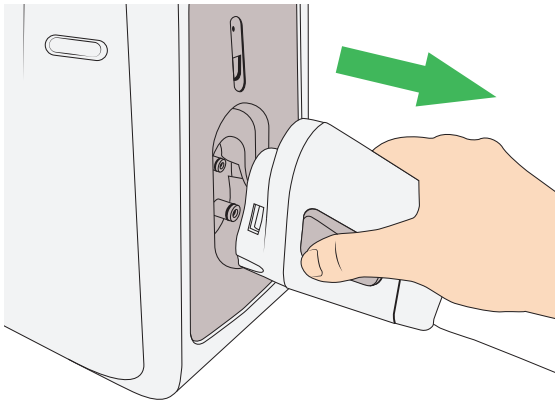


Figure 19

CPR rapid deflation unit

In case of a cardiac arrest, use the CPR rapid deflation unit positioned at the head end on the right side of the mattress. For how to use the CPR rapid deflation unit see section “CPR rapid deflation unit” on page 25.
The CPR rapid deflation unit is also used for deflating the Auralis mattress before storing.

Detachable cover

The detachable cover is attached by zip.

Cells

The Auralis mattress cells provide alternating or static support to the patient, depending on selected therapy mode.

- 3 head cells, static only
- 12 torso cells, alternating/CLP
- 5 foot cells with Heelguard™, alternating/CLP (Auralis)
- 6 foot cells with Heelguard™, alternating/CLP (Auralis Plus)

Loop straps

The loop straps keep the cells aligned and in place.

Heelguard™ cells

The Heelguard™ cells help to keep the pressure in the heel area lower for longer.

Cell hooks

The cell hooks attach the cells to the Auralis mattress base.

Tube-set

The tube-set is anti-kink and not removable from the Auralis mattresses.

Connector

The connector is clicked in to place in to the connector socket. See Figure 18

The connector is removed by pressing the two side buttons simultaneously. See Figure 19

Continue on the next page.

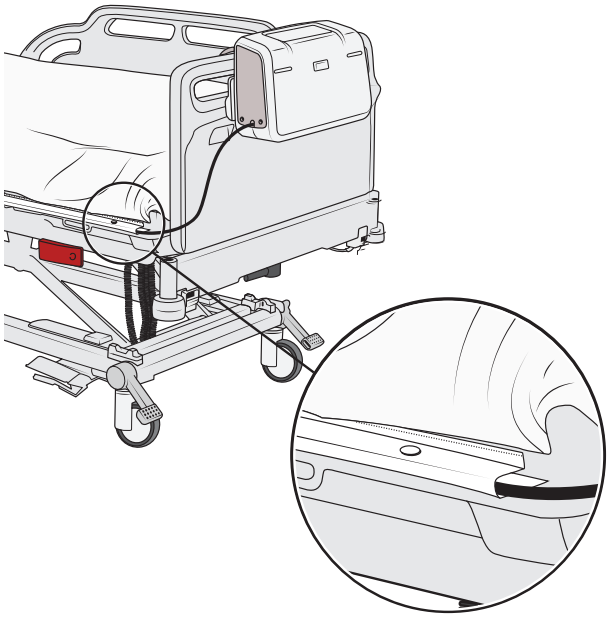


Figure 20

Cable management

Position the cable (3 steps)

1. Open the cable management on the opposite side to the tube-set and CPR rapid deflation unit.
2. Place the cable in the cable management.
3. Close the flap around the cable with the press studs. See Figure 20.

Micro air loss system

A micro air loss system is incorporated into the base cover which dehumidifies the air surrounding the cells to reduce heat build up within the mattress and to make sure that the patient is comfortable. This system is separate from the cell inflation to enable both micro air loss and patient transport modes to be incorporated into the mattress.

Auralis 110 mattress overlay

The Auralis 110 mattress is an overlay and is placed on top of an existing bed mattress.

Fixing straps (Auralis 110 mattress overlay)

The four fixing straps are to be placed under the four corners of an existing bed mattress and prevent the Auralis 110 mattress overlay from sliding off.

Auralis 175, 200 and Plus mattress replacement

The Auralis 175, 200 and Plus mattresses are replacements to existing bed mattresses. They all have a non slip base.

- Auralis 175 mattress has a foam underlay.
- Both Auralis 200 and Plus mattresses have an air filled zoned sub-mattress.

Continue on the next page.

Securing straps

The Auralis 175, 200 and Plus mattress replacements have eight securing straps that can be moved to any of the ten anchor points on the base of the mattress. This allows the mattress replacements to be attached to different types of bed frames. In addition, Auralis Plus has three fixed securing straps at the head end to avoid mattress movement due to the increased patient weight.

Overlay and overlay zip

The Auralis 175 and 200 mattress replacements can all be converted to an overlay. Use the overlay zip to remove the base. See Figure 21
The overlay can then placed on top of an existing bed mattress.

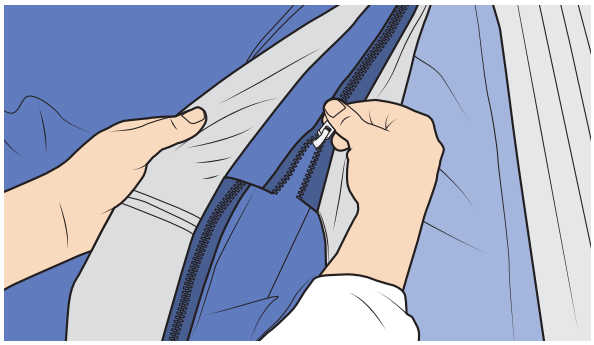


Figure 21

Bolsters (Auralis Plus mattress only)

Bolsters are located on either side of the core of the mattress in order to fit beds with different width positions. They can be inflated/deflated using the valves at the foot end, to achieve one of the following configurations:

- One bolster inflated (left or right)
- Both bolsters inflated (left and right)
- Both bolsters deflated (left and right)

Foot extension (Auralis Plus mattress only)

This consists of both an extra Heelguard™ cell and an air channel contained in a sleeve. The air channel feeds each bolster.

Mattress extensions (Auralis Plus mattress only)

Two sizes of mattress extensions are available as accessories, see section “Parts and accessories” on page 64. They can be placed at the foot of the bed. See section “Auralis Plus mattress extensions (accessory only)” on page 29.

Product description - Auralis seat cushion

Detachable cover

The detachable cover is attached by a zip.

Alternating cells

The seat cushion cells provide alternating support to the patient. The Auralis seat cushion can only be used with Alternating mode.

Fixing straps

The four fixing straps prevent the Auralis seat cushion from falling off a chair with an open construction or removable seat cushion.

Non-slip base

The non-slip base prevents the Auralis seat cushion fromslipping when the fixing straps cannot be used.

Deflation valves

The 2 deflation valves are located underneath the Auralis seat cushion. See Figure 22

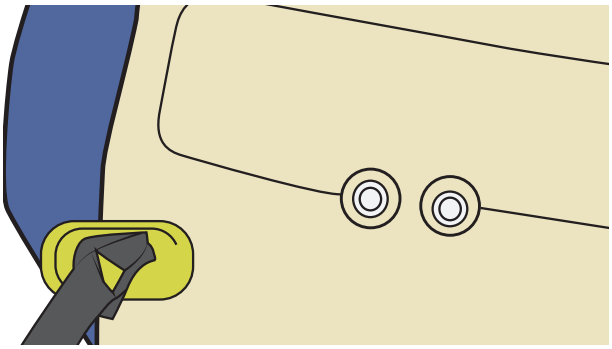


Figure 22

Tube-set

The tube-set is anti-kink and not removable from the seat cushion.

Connector

The connector is clicked in to place in to the connector socket. See Figure 23

The connector is removed by pressing the two side buttons simultaneously. See Figure 24

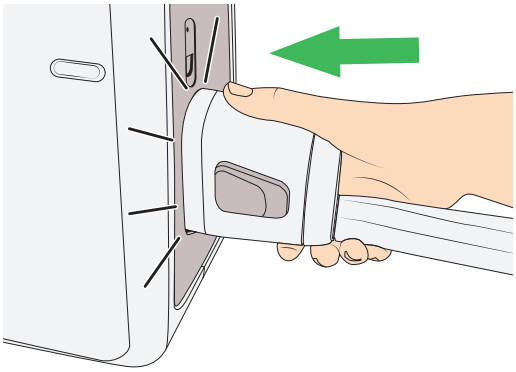


Figure 23

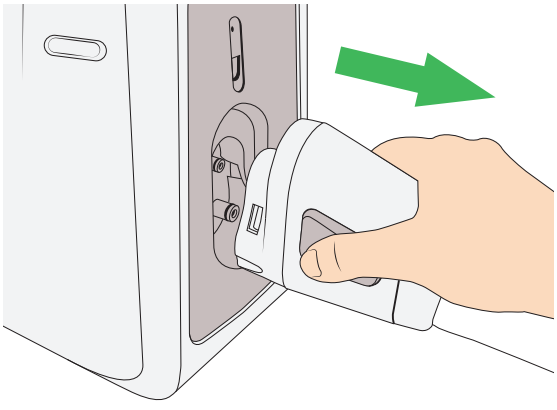


Figure 24

CPR rapid deflation unit

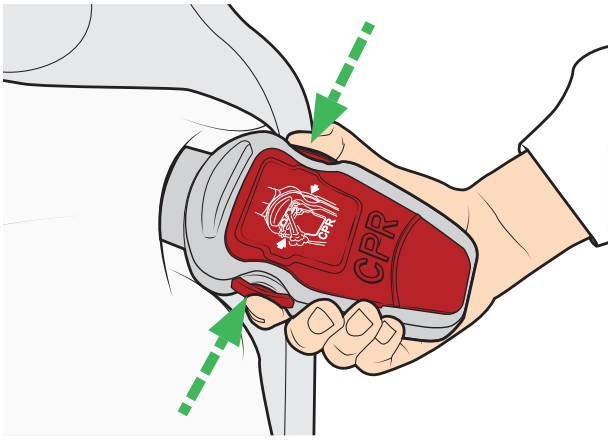


Figure 25

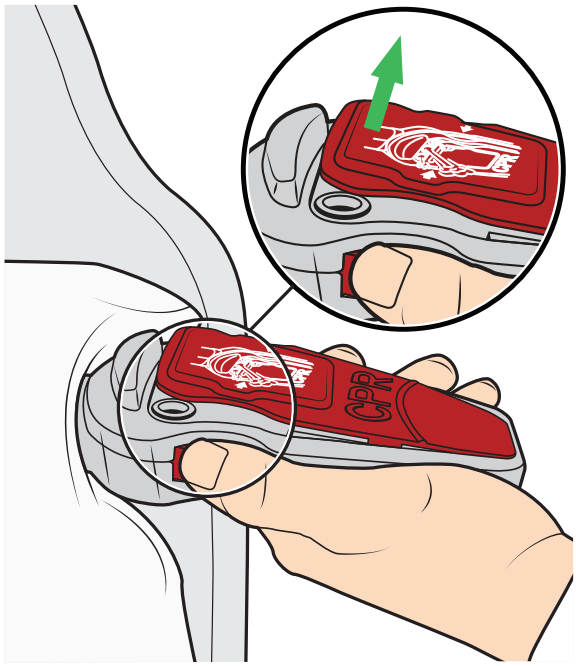


Figure 26

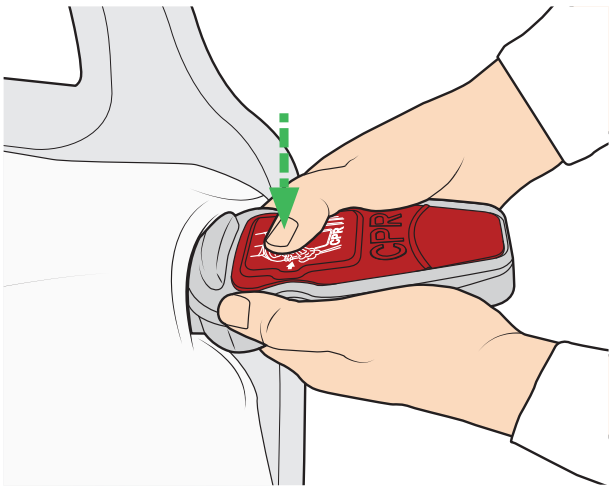


Figure 27

In the event of the patient suffering a cardiac arrest, the CPR rapid deflation unit can be activated:

Activate the CPR rapid deflation unit

Deflate the Auralis mattress to activate the CPR rapid deflation unit (2 steps)

1. Press both the CPR rapid deflation unit release buttons simultaneously. See Figure 25
2. Make sure the front part of the CPR rapid deflation unit is open. See Figure 26

The CPR rapid deflation unit evacuates the air from the main body of the mattress rapidly.

Deactivate the CPR rapid deflation unit

Press down the open part of the CPR rapid deflation unit until it clicks into place. See Figure 27

Assemble the Auralis system

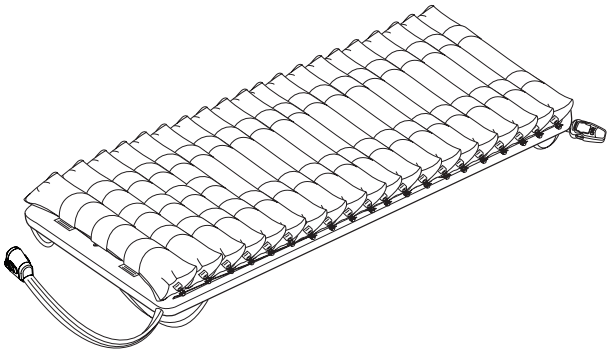


Figure 28

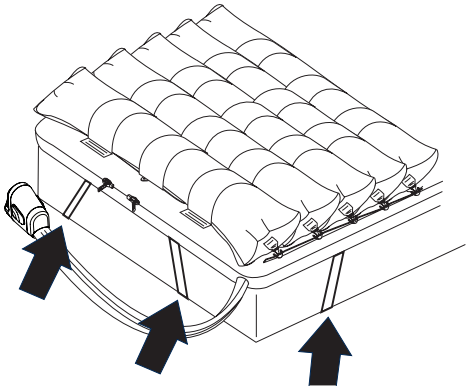


Figure 29

Auralis 110 mattress overlay

(6 steps)

1. **WARNING**
   To avoid death or serious injury by entrapment, always select the correct Auralis mattress size for the bed.

   Select the correct Auralis mattress overlay size for the bed. Make sure there are no gaps to entrap a patient's head or body. For mattress sizes see section "Auralis mattresses and seat cushion measurements" on page 52.

2. **WARNING**
   To avoid pressure injury, do not use the Auralis mattress overlay directly on the bed frame.

   Position the Auralis mattress overlay on top of the existing mattress. Make sure that:
   - the CPR rapid deflation unit is located at the head end
   - the tube-set is located at the foot end
   - the cells of the mattress are facing up.

   See Figure 28

3. **WARNING**
   To avoid falling, make sure the *Auralis* mattress overlay is secured to the bed.

   Secure the Auralis mattress overlay by placing and tightening the four fixing straps under the corners of an existing mattress.
   See Figure 29

4. **CAUTION**
   To avoid damage to the cells, always use the Auralis mattress with the protective top cover.

   Place the detachable cover over the Auralis mattress overlay with the Arjo logo visible and located at the foot end of the Auralis mattress.

Continue with steps on the next page.

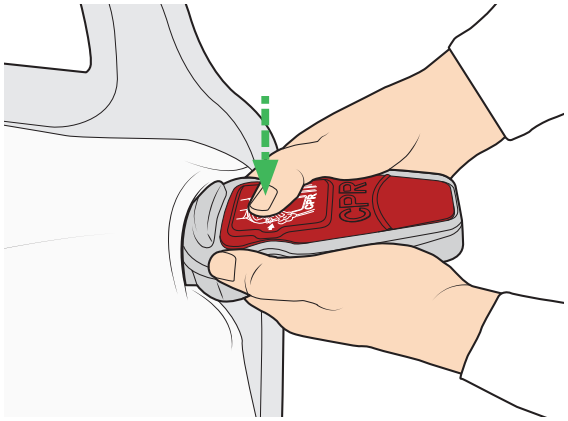


Figure 30

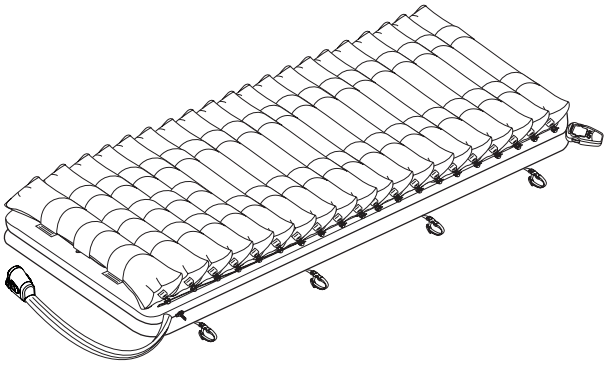


Figure 31

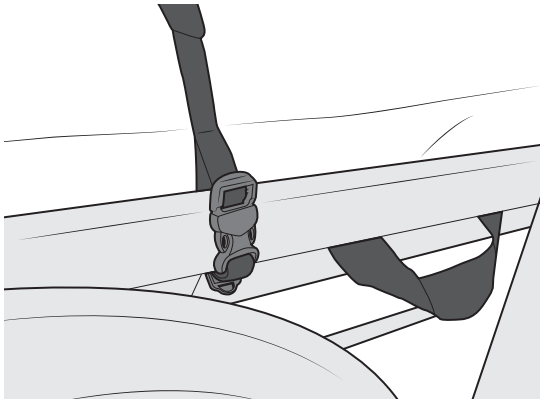


Figure 32

5. Zip the cover onto the Auralis mattress overlay, start from the head end. Do not trap any material in the zip. Make sure the zip is fully closed.
6. Make sure that the CPR rapid deflation unit is in closed position. (See Figure 30.) The CPR rapid deflation unit must be accessible at all times.

Auralis 175, 200 and Plus mattress replacement

(9 steps + 2 steps for Auralis Plus only)

1. Remove any existing mattress from the bed frame.
2. Check that there are no protruding sharp objects on the bed frame surface.
3. **WARNING**
   To avoid death or serious injury by entrapment, always select the correct Auralis mattress size for the bed.

   Select the correct Auralis mattress replacement size for the bed. Make sure there are no gaps to entrap a patient's head or body. For mattress sizes see section "Auralis mattresses and seat cushion measurements" on page 52.
4. Position the Auralis mattress replacement on the bed frame. Make sure that:
   - the CPR rapid deflation unit is located at the head end
   - check that the tube-set is positioned correctly
   - the mattress cells are facing up.

   See Figure 31
5. **WARNING**
   To avoid falling, make sure the *Auralis* mattress is secured to the bed.

   Secure the Auralis mattress replacement by attaching the eight securing straps to the bed frame. See Figure 32

   If the bed can be raised or lowered, attach the Auralis mattress replacement to the movable parts of the bed only.
6. Attach the three fixed securing straps at the head end (Auralis Plus only).

Continue with steps on the next page.

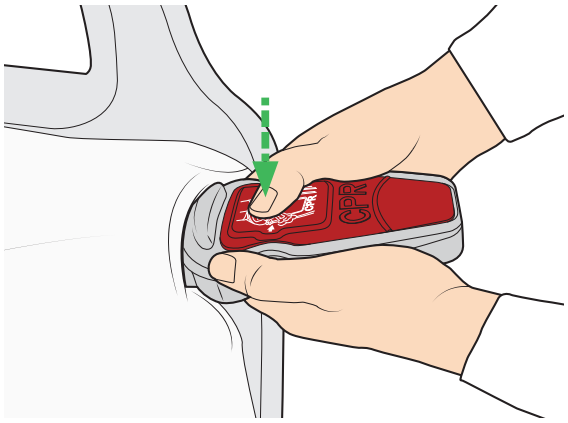


Figure 33

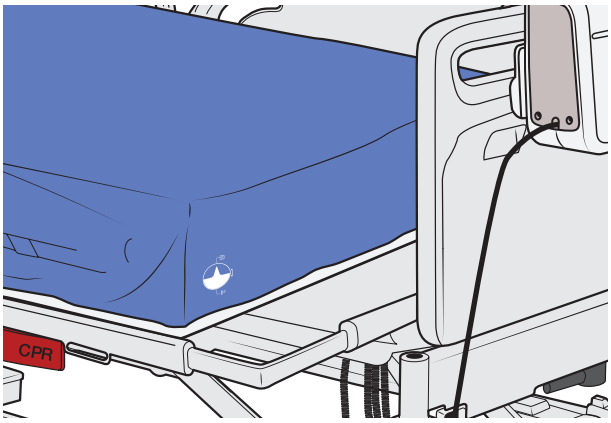


Figure 34

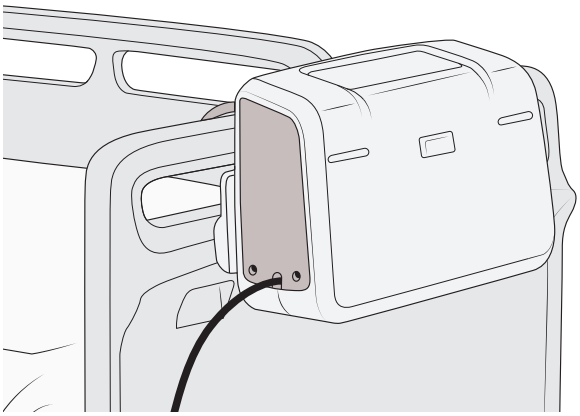


Figure 35

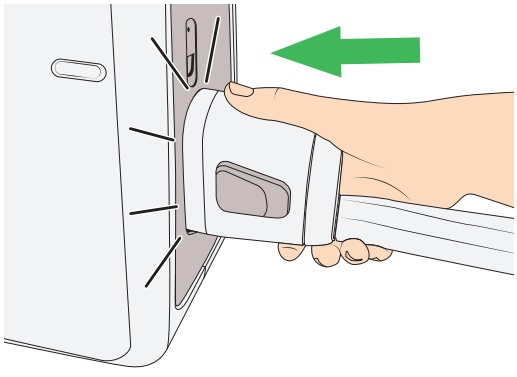


Figure 36

7. **CAUTION**
   To avoid damage to the cells, always use the Auralis mattress with the protective top cover.

   Place the detachable cover over the Auralis mattress replacement with the Arjo logo visible at the foot end of the Auralis mattress.
8. Zip the cover onto the Auralis mattress replacement, start from the head end. Do not trap any material in the zip. Make sure the zip is fully closed.
9. Make sure that the CPR rapid deflation unit is in closed position (see Figure 33). The CPR rapid deflation unit must be accessible at all times.
10. Make sure that the bolsters are positioned in the extended part of either side of the bed. (Auralis Plus mattress only.)
11. Make sure that the bolster valves are positioned in the extended part of either side of the bed. (Auralis Plus mattress only.) See Figure 34.

Auralis pump

(7 steps)

1. Hang the Auralis pump at the foot end of the bed. See Figure 35
   Make sure the pump is not:
   - near a heat source
   - in the sun
   - covered up
2. Check that the tube-set is not twisted.
3. Connect the tube-set to the Auralis pump. Make sure the tube-set clicks into place. See Figure 36
4. **⚠ WARNING**
   To avoid falling and injury, make sure that cables and the tube-set are positioned correctly and are clear of moving bed mechanisms or other possible entrapment areas.

   Open the cable management on the opposite side to the tube-set and CPR rapid deflation unit.

Continue with steps on the next page.

Figure 37

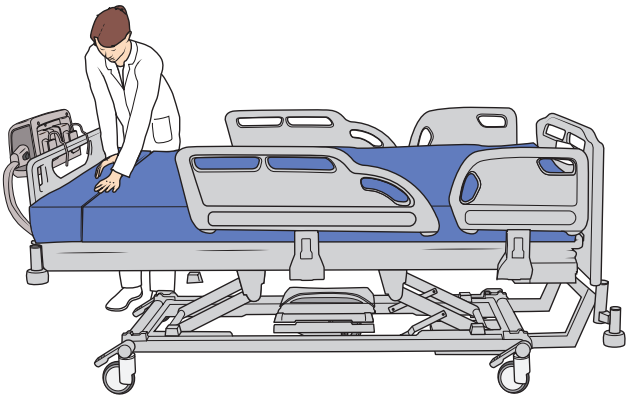


Figure 38

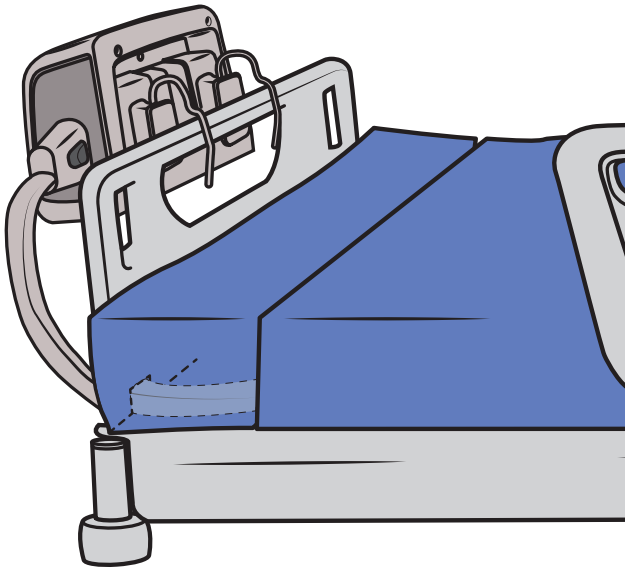


Figure 39

5. Place the cable in the cable management.
6. Close the flap around the cable with the press studs. See Figure 37
7. Connect the power cable to a power source.

Auralis Plus mattress extensions (accessory only)

(5 steps)

The mattress extensions are intended to be used when the bed frame is operated in fully extended length mode.

NOTE
These are guidelines only and should not replace clinical experience or judgement. If there is no improvement in the patient's condition, specialist advice should be sought.

1. Select the correct size mattress extension for the width of bed extension.
2. Remove all packaging.
3. Make sure that the mattress extension is fitted with its cover.
4. Place the mattress extension with the zip nearest the bottom into the space between the mattress and the footboard (see Figure 38). Make sure that there are no sharp edges which may rip the cover.
5. Make sure that the tube-set passes underneath the indentation in the mattress extension (see Figure 39).

CAUTION
Do not use the mattress extension without its cover. It provides a protective barrier against biological contamination of the foam.

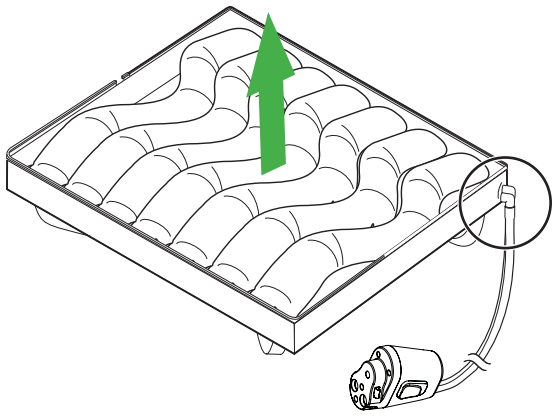


Figure 40

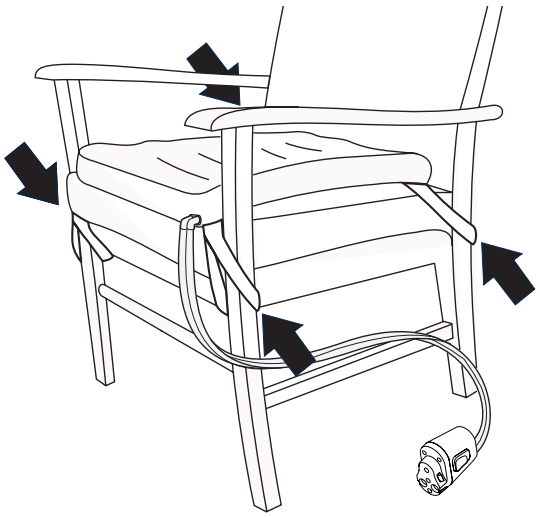


Figure 41

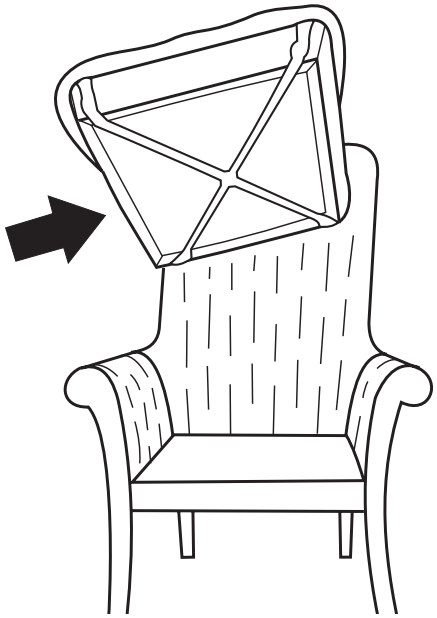


Figure 42

Auralis seat cushion

(7 steps)

1. **CAUTION**
To avoid inadequate pressure redistribution, always use the Auralis seat cushion in the correct orientation.

CAUTION
Check that there are no sharp objects on the chair which may puncture the seat cushion.

Place the Auralis seat cushion on top of the chair seat. From a position of standing and facing the front of the chair, make sure:

- the cells are facing up.
- the tube-set 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.
  See Figure 40

2. **CAUTION**
To avoid inadequate pressure redistribution, do not use the Auralis seat cushion without a foam cushion beneath it.

Secure the Auralis seat cushion to the chair as described below.

- **Open sided chair**
  Attach the fixing straps around the frame of the chair. See Figure 41
- **Closed chair with removable seat cushion**
  Attach the fixing straps crosswise underneath the removable seat cushion. See Figure 42

Continue with the steps on next page

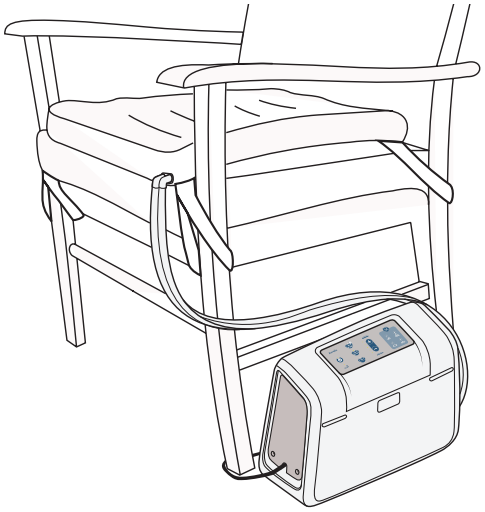


Figure 43

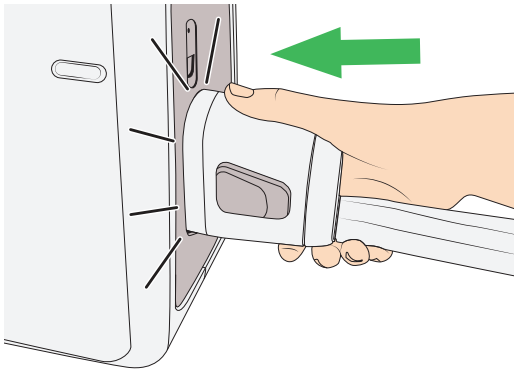


Figure 44

NOTE
If the chair is of the closed side type with a non-removable seat cushion, then security relies only on the non-slip base material of the seat cushion.

- **Closed chair with non-removable seat cushion**
  Position the Auralis cushion on the chair.

3. **CAUTION**
   To avoid damage to the cells, always use the Auralis seat cushion with the protective top cover.

   Place the protective cover over the Auralis seat cushion. Make sure the Arjo logo is visible at the front part of the seat.
4. Zip the cover onto the Auralis seat cushion. Do not trap any material in the zip. Make sure the zip is fully closed.
5. **WARNING**
   To avoid falling, position the Auralis pump, the cable and the tube-set so that they do not create a trip hazard.

   Place the Auralis pump on the floor next to the chair. Make sure:
   - the cable is under the chair.
   - the tube-set is placed along the side of the chair.
     See Figure 43
6. Check that the tube-set is not twisted.
7. Connect the tube-set to the Auralis pump. Make sure the tube-set clicks into place. See Figure 44

Start the Auralis system

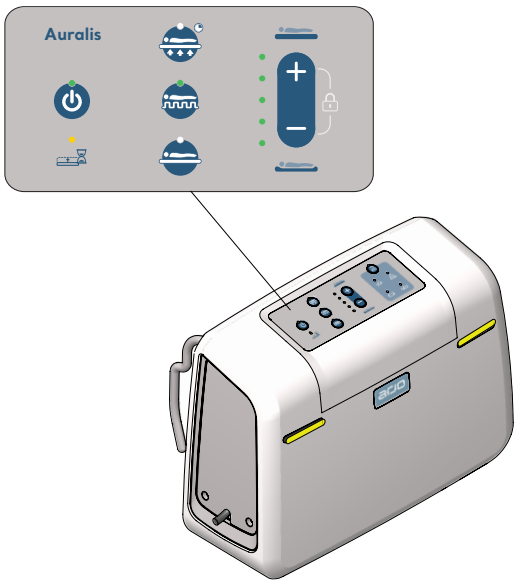


Figure 45

Figure 46

Before using any of the Auralis mattress or Auralis seat cushion systems make sure:

- The Auralis system is assembled correctly in accordance with section “Assemble the Auralis system” on page 26.
- The CPR rapid deflation unit on the mattress is in closed position.

Auralis system start-up

(5 steps)

When the Auralis pump power cable is connected to a power source, the Auralis pump sounds with a start-up tone and a self-diagnostic check runs for 10 seconds. Once the check is completed the Auralis pump beeps twice and is ready for use.

1. Press the Run/Standby button on the control panel for 2 seconds.
   The following indicators are shown:
   - Run/Standby
   - Wait indicator
   - Alternating mode button
   - Comfort control indicator
   - Battery charge indicator
   - Green indicators on the front of the pump
   See Figure 45

The Auralis mattress is fully inflated when the Wait indicator is off, after approximately 15 minutes.

The Auralis Plus mattress takes approximately 17 minutes to reach full inflation.

2. When the Auralis mattress is fully inflated, if a bed sheet is fitted, tuck it in loosely. Make sure that the CPR rapid deflation unit is clearly visible at the head end of the bed.
3. Place the patient on the Auralis mattress with the head at the head end and the feet at the foot end.
   See Figure 46

NOTE
The Auralis pump automatically adjusts the pressure in the mattress to support the patient.

Continue with steps on the next page.

4. The Alternating mode is set by default. If needed, select another mode (see “Select mode” on page 34):

- Autofirm mode: for nursing procedures
- Reactive CLP mode: for constant low pressure
- Transport mode: for transport of the patient

5. For patient comfort, use the Comfort control buttons to adjust the pressure. The level of comfort is indicated by a light.

Auralis 110, 175, 200 and Plus mattresses

The default comfort setting is in the middle. The pressure can be adjusted by two increments higher or lower than the default setting.

See Figure 47

⚠ WARNING
To avoid discomfort or injury for the patient, ALWAYS set the comfort level at maximum for patients weighing over 360 kg (793 lb). (Auralis Plus only)

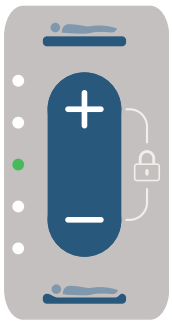


Figure 47

If there is a power failure, the Auralis pump enters Battery mode. If the Auralis pump is fully charged the Auralis pump offers a minimum of 3 hours operational use.

⚠ WARNING
If a patient is to be left unattended whilst using the device, the risk of falling and injury should be clinically assessed, in line with local policy.

Select mode

Figure 48

Autofirm mode

Activate (1 step)

The Autofirm mode (see Figure 48) only applies to the Auralis mattresses.

- Press the Autofirm button for 2 seconds.

The Autofirm mode and the Comfort control indicators start to flash and the mattress cells start to inflate to Autofirm pressure.

When the Autofirm and Comfort control indicators turn to constant, the mattress has reached Autofirm pressure.

Autofirm mode lasts for 15 minutes. If not extended, the pump goes back to the previous mode by default.

During the last minute of Autofirm mode, all Comfort control indicators flash and an audibe alarm sounds. During this alert period the Autofirm mode can be extended.

Extend (1 step)

- Press the Autofirm button to extend the Autofirm mode by 5 minutes.

The Autofirm can be extended up to a maximum of 3 times. For further extension repeat step 1.

If not extended, the Auralis pump goes back to the previous mode by default.

Deactivate

To deactivate the Autofirm mode, press and hold down the Autofirm button for 2 seconds or select any of the other modes.

Figure 49

Alternating mode, default setting

Activate (1 step)

- Press the Alternating mode (see Figure 49) button, the Alternating mode indicator is shown.

The Auralis mattress enters alternating mode. In this mode adjacent cells inflate and deflate on a 10 minute cycle.

Deactivate

To deactivate alternating mode, select either Reactive CLP or Autofirm mode. If no further therapy is required, remove patient from the surface and turn off the Auralis pump.

Continue on the next page

Figure 50

Reactive CLP mode

Activate

Press the Reactive CLP (see Figure 50) button for 2 seconds. The Reactive CLP mode indicator is shown.

Deactivate

To deactivate Reactive CLP mode, select either Alternating mode or Autofirm mode. If no further therapy is required, remove patient from the surface and turn off the Auralis pump.

Lock out mode

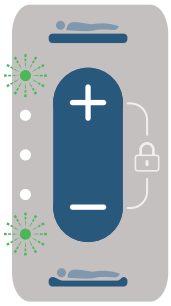


Figure 51

Locking

- Push and hold Comfort control Positive (+) and Comfort control Negative (–) buttons at the same time for at least 2 seconds.

The top and bottom Comfort control indicators will flash simultaneously. See Figure 51. Pump is now in Lock out mode and will not accept any more inputs until unlocked.

Unlocking from Lock out mode

- Push and hold Comfort control Positive (+) and Comfort control Negative (–) buttons at the same time for at least 2 seconds.

The top and bottom Comfort control indicators will flash simultaneously. Pump is now unlocked.

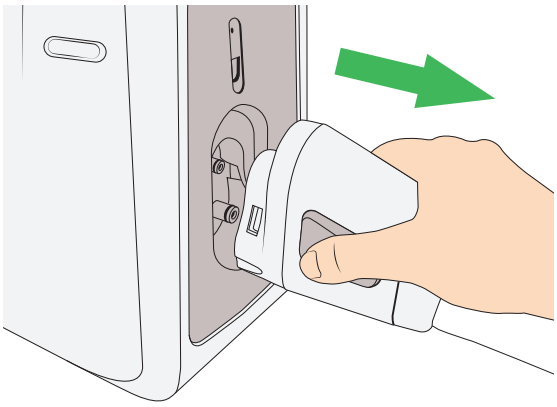


Figure 52

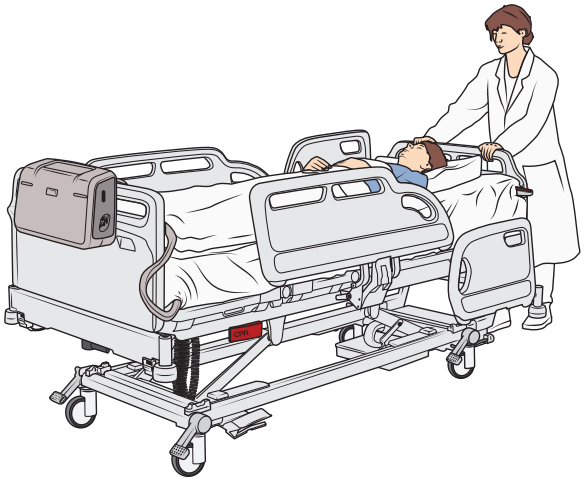


Figure 53

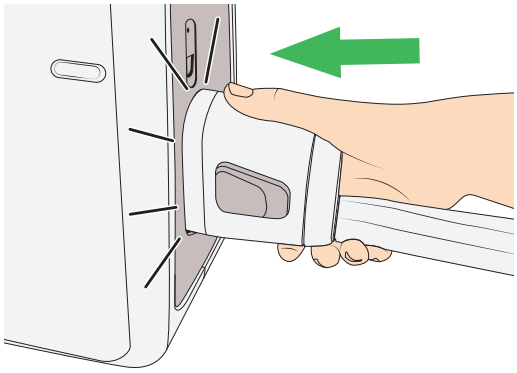


Figure 54

Transport mode

Activate (1 step)

To activate the Transport mode, disconnect the tube set during use.

- Press the side buttons on the connector simultaneously and remove the tube-set. See Figure 52

When the tube-set is disconnected from the Auralis pump during use, the Auralis mattress supports the patient for 12 hours without deflating.
See Figure 53

⚠ WARNING
To avoid injury, disconnect the power cable from the power source before moving the bed.

CAUTION
To avoid entanglement when the Auralis pump is in Transport mode, make sure that the tube-set connector is stowed appropriately.

NOTE
There is no Transport mode on the Auralis seat cushion.

Deactivate

To deactivate the Transport mode, connect the tube-set. The Auralis pump goes back to the previous mode by default. See Figure 54

Continue on the next page

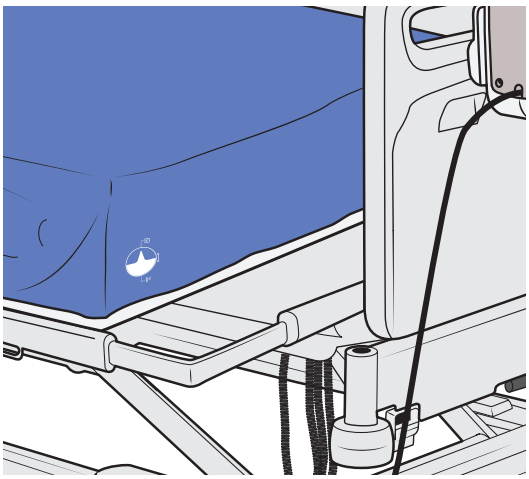


Figure 55

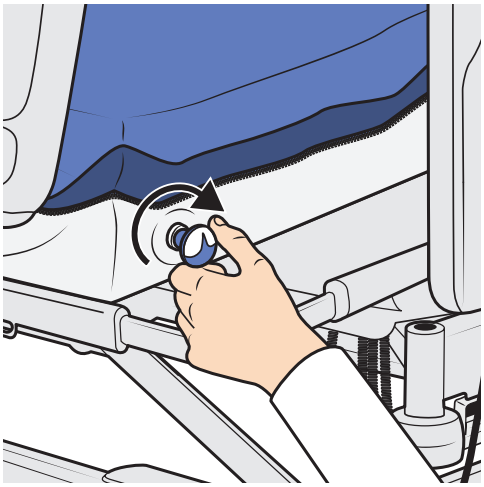


Figure 56

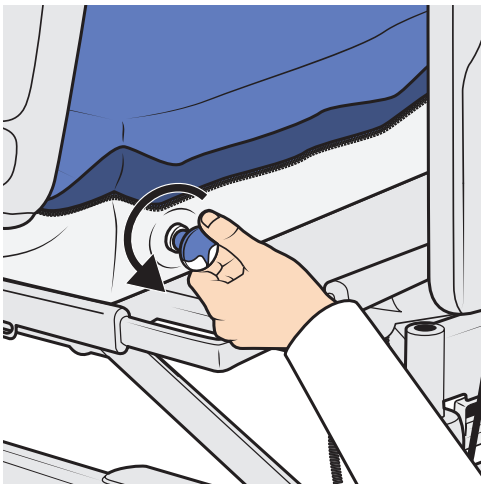


Figure 57

Bolster deflation, Auralis Plus only (4 steps)

The bolsters can be deflated to facilitate transport through narrow openings.

1. Locate the valve symbol on the bottom of the mattress. See Figure 55
2. Turn the valve (under the valve symbol) on the bolster fully clockwise. See Figure 56
3. Repeat on the other bolster, if required.
4. Leave to deflate for 5 minutes.

NOTE
Bolsters should be deflated before reducing the bed frame width.

Bolster inflation, Auralis Plus only (4 steps)

1. **⚠ WARNING**
   To avoid discomfort or injury for the patient, deactivate transport mode before inflating the bolsters.

   Locate the valve symbol on the bottom of the mattress. See Figure 55
2. Turn the valve (under the valve symbol) on the bolster fully anti-clockwise. See figure 57
3. Repeat on the other bolster, if required.
4. Leave to inflate for 8 minutes.

NOTE
The bed frame width should be extended before inflating the bolsters.

Turn off and store the Auralis system

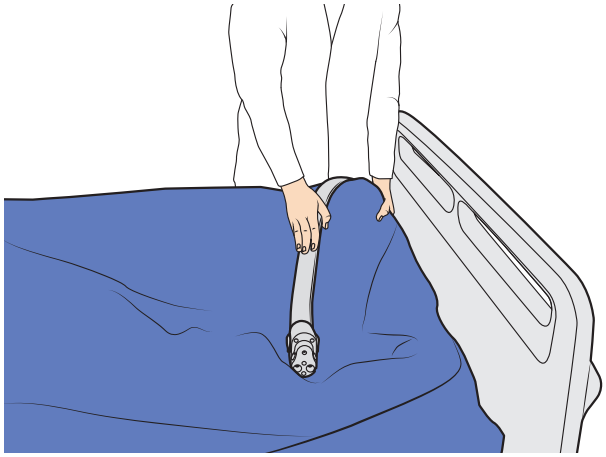


Figure 58

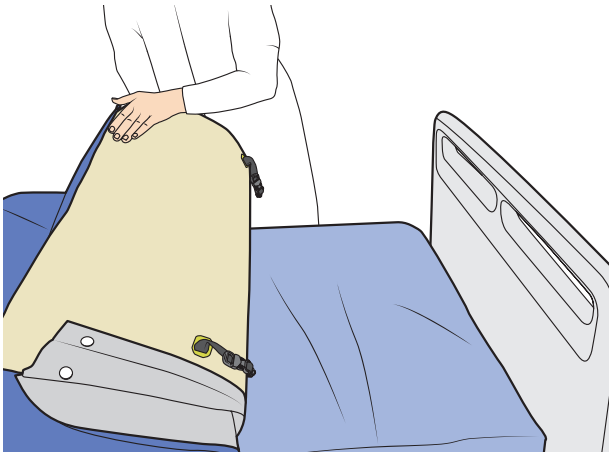


Figure 59

Figure 60

Turn off the Auralis pump

(3 steps)

1. Press the Run/Standby button for 2 seconds. The Auralis pump enters Standby mode.
2. Disconnect the power cable from the power source.
3. To turn off the Auralis pump completely, press the Run/Standby button for 4 seconds until a double beep is heard.

Deflate and store the Auralis mattress

(6 steps)

> **WARNING**
> **To avoid cross-contamination, always clean and disinfect the Auralis system after each patient.**

1. Clean and disinfect the mattress according to section “Cleaning and disinfection instructions” on page 40.
2. Activate the CPR rapid deflation unit to deflate the Auralis mattress.
3. Place the tube-set over the Auralis mattress parallel to the foot end. See Figure 58
4. Roll the Auralis mattress tightly, allowing it to deflate so it fits into the bag. See Figure 59 Start from the foot end and continue up to the CPR rapid deflation unit at the head end. For Auralis Plus only, deflate bolsters before rolling.
5. Place the Auralis mattress in the protective bag. See Figure 60
   The inside of the storage bag should be dry, clean and free from contamination and sharp objects.
6. Store the Auralis mattress in a designated area, in line with storage requirements, see “Transport and storage conditions” on page 52.

Deflate and store the Auralis seat cushion

(5 steps)

1. Clean and disinfect the Auralis seat cushion according to “Cleaning and disinfection instructions” on page 40.
2. Turn the Auralis seat cushion upside-down.
3. Push in the centre of the 2 valves to deflate the Auralis seat cushion. See Figure 61
4. Place the Auralis seat cushion in the protective bag. The inside of storage bag should be dry, clean and free from contamination and sharp objects.
5. Store the Auralis seat cushion in a designated area, in line with storage requirements, see “Transport and storage conditions” on page 52.

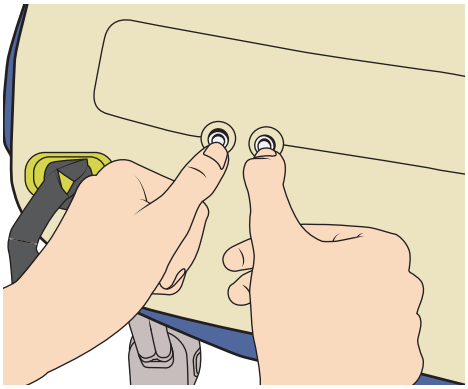


Figure 61

Store the Auralis pump

(3 steps)

1. Clean and disinfect the Auralis pump according to section “Cleaning and disinfection instructions” on page 40.
2. Wrap the power cable around the hanging brackets. See Figure 62
3. Store the Auralis pump in a designated area, in line with storage requirements, see “Transport and storage conditions” on page 52.

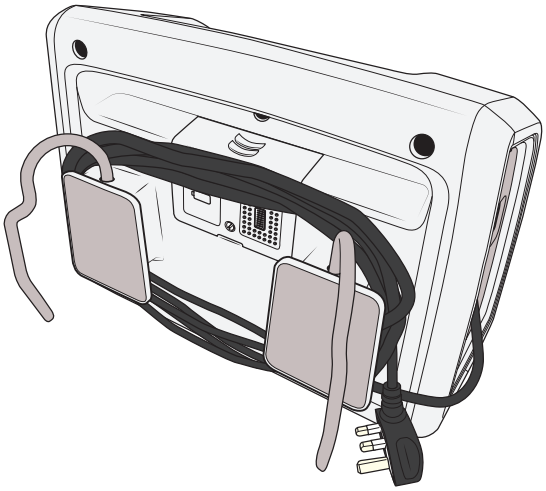


Figure 62

Cleaning and disinfection instructions

The Auralis system should be routinely cleaned and disinfected after each patient and at regular intervals while in use, as local practice for all reusable medical devices.

If there are any questions regarding cleaning and disinfecting the equipment contact Arjo Customer Service. Make sure the Safety Data Sheets (SDS) are available for the disinfectants being used.

WARNING
Always read the instructions for use and the safety data sheet of the disinfectant.

WARNING
To avoid electrical shock, always disconnect the *Auralis* pump from the power source before cleaning and inspecting.

WARNING
To prevent cross-contamination, always follow the disinfection instructions in this *Instructions for Use*.

WARNING
To avoid eye or skin irritation, never disinfect in the presence of a patient.

CAUTION
To avoid equipment damage:

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

Accessories needed for cleaning/ disinfection

- Spray bottle with disinfectant solution (either 70 % alcohol solution or chlorine solution up to 10,000 ppm)
- Neutral detergent (cleaning solution)
- Spray bottle with water
- Cloths

Cleaning and disinfection

(28 steps)

Always follow these steps for proper cleaning and disinfection procedure after each patient

Preparation

1. Disconnect the Auralis pump from the mattress / seat cushion.
2. Switch off the Auralis pump unit and disconnect the Auralis pump from the power source.

Clean the Auralis pump

3. Use a clean cloth and cleaning solution to wipe down the main enclosure, membrane, labels and hanging brackets to remove any deposits or visible dirt on the Auralis pump.
4. Any areas where residual dirt has been left should be cleaned again with the cleaning solution before continuing with the cleaning and disinfectant process.
5. Use water and a new cloth to wipe off all traces of cleaning solution, followed by a dry cloth to remove any excess moisture from the Auralis pump.

Disinfect the Auralis pump

6. Spray disinfectant solution on to a dry cloth and spread the solution onto all areas of the Auralis pump.
7. Allow time for disinfection according to the instructions provided by the disinfectant manufacturer.
8. After disinfecting the Auralis pump, use water and a new cloth to wipe off all traces of disinfectant solution from the Auralis pump.
9. Remove any excess moisture by wiping over with a dry cloth.
10. Allow the Auralis pump to air dry before reuse.

Clean the Auralis mattress / seat cushion

11. Spray all external areas of the Auralis mattress/ Auralis seat cushion top covers with the cleaning solution and wipe off any dirt with a clean cloth

Continue with steps on the next page.

12. Any areas where residual dirt has been left should be cleaned again with the cleaning solution before continuing with the cleaning and disinfectant process.
13. Use water and a new cloth to wipe off all traces of cleaning solution, followed by a dry cloth to remove any excess moisture.
14. If it is necessary to clean the inside of the Auralis mattress/ Auralis seat cushion, unzip the top cover to access the internal components.
15. Spray the cleaning solution on to a dry cloth to wipe down the cells, bottom cover and straps (mattress only) of the Auralis mattress/ Auralis seat cushion. Make sure the solution fully covers all the cells while wiping down.
16. Use water and a new cloth to wipe off all traces of cleaning solution, followed by a dry cloth to remove any excess moisture from the internal components.

Disinfect the Auralis mattress / seat cushion

17. Spray disinfectant solution on to a dry cloth and spread the solution onto all external areas of the Auralis mattress/ Auralis seat cushion top covers.
18. Allow time for disinfection according to the instructions provided by the disinfectant manufacturer.
19. After disinfecting the top cover, use water and a new cloth to wipe off all traces of disinfectant solution from the top cover.
20. Remove any remaining moisture by wiping over with a dry cloth.
21. Allow the Auralis mattress/ Auralis seat cushion top cover to air dry.
22. If it is necessary to disinfect the inside of the Auralis mattress/ Auralis seat cushion, unzip the top cover to access the internal components.
23. Spray disinfectant solution on to a dry cloth and spread the solution onto all internal components.
24. Allow time for disinfection according to the instructions provided by the disinfectant manufacturer.
25. After disinfecting the internal components, use water and a new cloth to wipe off all traces of disinfectant solution on the components.

Continue with steps on the next page.

26. Remove any remaining moisture by wiping over with a dry cloth.
27. Allow the internal components to air dry before reattaching the top cover of the mattress.
28. If required, the straps and base of the Auralis mattress/seat cushion can also be cleaned using the same method as above. Unclip the straps before cleaning for ease of access.

Care and preventive maintenance

The Auralis system is subject to wear and tear, and the following actions must be performed when specified to make sure that the product remains within its original manufacturing specification.

⚠ WARNING
To avoid malfunction resulting in injury, make sure to conduct regular inspections and follow the recommended maintenance schedule.

⚠ WARNING
Electrical equipment may be hazardous if misused. There are no user-serviceable parts inside the Auralis pump, Auralis mattress or Auralis seat cushion. The Auralis pump's case must only be removed by qualified service personnel. No modification of this equipment is allowed.

⚠ WARNING
To avoid injury and/or unsafe product, the maintenance activities must be carried out at the correct frequency by qualified service personnel using correct tools, parts and knowledge of procedures. Qualified service personnel must have documented training in maintenance of this device.

Expected service life

The Auralis pump has an expected service life of 7 years. To maintain the condition of the Auralis pump, the Auralis pump must be serviced regularly according to the schedule recommended by Arjo.

CARE AND PREVENTIVE MAINTENANCE SCHEDULE Caregiver obligations action/check	Before every use or every week (if for long term use)	After each patient	After 24 months use
Clean and disinfect		x	
Auralis pump			
Visually check the control panel	x		
Visually check all electrical connections and power cord	x		
Visually check the connector socket	x		
Auralis mattresses and seat cushion			
Visually check the tube-set and connector	x		
Visually check the top cover	x		
Visually check all zips		x	
Visually check the fixing and securing straps		x	
Visually check all loop straps and Heelguard™ cell straps		x	
Visually check all cell hooks		x	
Auralis system			
Visually check all labels		x	
Perform a full functionality test on the Auralis system	x		
Checks by qualified service personnel only.			x
Auralis Plus mattress extension (accessory only)			
Visually check the top cover	x		
Visually check the foam core	x		
Visually check all labels		x	

Caregiver obligations - before every use or every week (if in long-term use)

Visually check the Auralis pump for damage

- Check that the control panel is firmly affixed, is undamaged and legible.
- Check all electrical connections and power cable for signs of excessive wear or damage.
- Check the connector socket for signs of excessive wear or damage.

Visually check the Auralis mattresses and Auralis seat cushion for damage

- Check that the tubing is not damaged and that there are no obvious cracks or breaks to the connector.
- Remove the top cover and check for signs of wear or any tears.

Visually check the Auralis mattress extensions for damage

- Remove the top cover and check for signs of wear or any tears.
- Inspect the foam core for any signs of damage, soiling or staining.

If any part is damaged or missing DO NOT use the product.

Perform a full functionality test on the Auralis system (6 steps)

1. Connect the tube-set to the Auralis pump. Make sure the tube-set clicks into place.
2. Connect the power cable to a power source.

The Auralis pump sounds with a start-up tone and a self-diagnostic check runs for 10 seconds. Once the check is completed the Auralis pump beeps twice and is ready for use.

3. Press the Run/standby button to start the Auralis pump.
4. To check the alarm functionality, disconnect the tube-set from the pump while the system is switched on. After 30 seconds, two green alarm panel indicators on the front of the pump turn yellow, the Low pressure indicator turns yellow and an audible alarm sounds.
5. Reconnect the tube-set to the pump to deactivate the alarm.
6. If the functionality test is not completed, call qualified service personnel.

Caregiver obligations - after each patient

Clean and disinfect

- The Auralis system has to be cleaned and disinfected after each patient, see section “Cleaning and disinfection instructions” on page 40.

Visually check the Auralis mattresses and Auralis seat cushion for damage

- Check that all seams and the zips are undamaged and not loose. Check that the zip puller is not missing.
- Check that the fixing and securing straps are secure and not damaged
- Check that all cell fasteners, loop straps and Heelguard™ cell straps, are correctly connected to the Auralis mattress base and are not loose or damaged.
- Check that all cell hooks are attached.
  See Figure 63

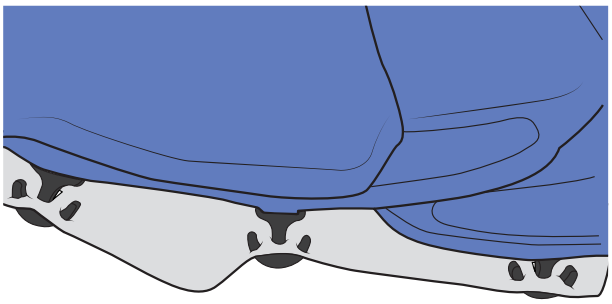


Figure 63

If any part is damaged or missing DO NOT use the product.

Visually check all labels

Check that all labels are attached on the Auralis system according to section Labels on page 54 and Labels on Auralis mattresses, Auralis seat cushion and Auralis mattress extensions (accessory only) Labels on Auralis mattresses, Auralis seat cushion and Auralis mattress extensions on page 56. If any label is missing, contact Arjo Customer Service.

After 24 months use check by qualified personnel only

The Auralis system must be serviced after 24 months use in accordance with the Maintenance and Repair Manual.

Troubleshooting and alarms

The following table provides a troubleshooting guide for alarms.

The WAIT, POWER FAILURE and READY FOR SERVICE indicators are information signals. All other alarms are low priority alarms.

INDICATOR	POSSIBLE CAUSE	SOLUTION	ALARM ACTIVATION DELAY
WAIT 	Mattress is inflating. This does not indicate a fault provided that the Low pressure alarm is off.	Wait for mattress to reach operating pressure (typically 15 minutes for mattress and 5 minutes for seat cushion, depending on state of inflation)	250 ms
LOW PRESSURE  and WAIT 	1. The Auralis pump is inflating the Auralis mattress or the Auralis seat cushion. 2. The CPR rapid deflation unit on the Auralis mattress is not closed. 3. The valves on the Auralis seat cushion are not closed. 4. The tube-set is not connected properly.	1. Both indicators turn off when operating pressure is reached. 2. Close CPR rapid deflation unit. 3. Check the valves on the seat cushion. 4. Check that the tube-set connector is correctly connected to the Auralis pump - an audible click should be heard when correctly connected.	Maximum 20 minutes for mattress Maximum 5 minutes for seat cushion
LOW PRESSURE 	1. The tube-set is not connected properly. 2. The CPR rapid deflation unit on the Auralis mattress is not closed. 3. The valves on the Auralis seat cushion are not closed. 4. There is a leak in the system. 5. System below optimum pressure whilst re-inflating bolsters (Auralis Plus only).	1. Check that the tube-set connector is correctly connected to the Auralis pump - an audible click should be heard when correctly connected. 2. Close CPR rapid deflation unit. 3. Check the valves on the Auralis seat cushion. 4. Contact qualified service personnel. 5. Wait for bolsters to fully inflate.	Up to 30 minutes in Alternating mode Up to 20 minutes in Reactive CLP mode 30 seconds following removal of connector Immediate if no connector is in place on startup

Continue on the next page.

INDICATOR	POSSIBLE CAUSE	SOLUTION	ALARM ACTIVATION DELAY
POWER FAILURE 	Power source failure.	Check if power is available and check the power cable. When the battery is fully charged the Auralis pump works for a minimum of 3 hours.	Less than 2 seconds
BATTERY LOW 	Less than 1 hour left on the battery.	Charge the battery by using mains power supply to run the Auralis pump.	500 ms
READY FOR SERVICE  and Front panel alarms show green	The Auralis pump needs service.	Contact qualified service personnel, quoting the serial number. To find the serial numbers for the Auralis pump, mattress or seat cushion see sections “Labels” on page 54 and “Labels on Auralis mattresses, Auralis seat cushion and Auralis mattress extensions” on page 56.	Immediate upon expiry of service timer
INTERNAL FAULT  and Front panel alarms show yellow	The Auralis pump has detected an internal fault.	Switch the Auralis pump off and restart it. If alarm persists, contact qualified service personnel.	Maximum 22 minutes
AUTOFIRM does not activate 	1. The Auralis seat cushion is in use. 2. The Auralis mattress is in use.	1. Disconnect the Auralis seat cushion. The Autofirm mode only applies to the Auralis mattresses. 2. To activate Autofirm mode press and hold the Autofirm button for 2 seconds.	Not applicable

Continue on the next page.

INDICATOR	POSSIBLE CAUSE	SOLUTION	ALARM ACTIVATION DELAY
LOCK OUT MODE 	The pump has been put into Lock out mode.	Push and hold Comfort control Positive (+) and Comfort control Negative (–) buttons at the same time for at least 2 seconds. The top and bottom Comfort control indicators will flash simultaneously. Pump is now unlocked.	Not applicable
OVER TEMPERATURE 	The Auralis pump is operating outside its temperature range and has entered the transport mode. There is an audible alarm and the indicators turn yellow before the Auralis pump shuts down.	1. Turn off the Auralis pump. 2. Disconnect the power cable. 3. Check the position of the Auralis pump: • is it near a heat source? • is it in the sun? • is it covered up? 4. If any of above apply, move or uncover the Auralis pump. 5. Wait for 5 minutes. 6. Reconnect the power cable to the power source. 7. Turn on the Auralis pump. 8. If the alarm is still present, contact qualified service personnel.	10 seconds

Technical specifications

AURALIS PUMP	
Model:	Auralis
Case material:	PC ABS
Part number:	636xxx (xxx is determined by the type of mains lead fitted. Please refer to rear label for actual part number)
Size:	385 x 290 x 170 mm (15.2 x 11.4 x 6.7 in)
Weight:	5 kg (11 lb)
Plug Fuse Rating:	5A to BS1362 (UK only)
Degree of protection against electric shock:	Mains Connected: Class II, Double Insulated without Functional Earth Type BF
Degree of protection against liquid ingress:	IP21 Protection against ingress of solid objects more than 12.5 mm diameter and water droplets falling vertically.
Mode of operation:	Continuous
Alternating Mode Cycle Time:	10 minutes (Alternate 10 minutes, Autofirm 15-30 minutes, CLP continuous.)

BATTERY	
Battery type:	Li-ion, non-removable
Voltage:	14.4 V
Capacity:	2200 mAh
Battery life:	300 cycles minimum

ELECTRICAL	
Supply voltage:	100-230 V
Supply frequency:	50-60 Hz
Power input:	4-58 VA

OPERATING CONDITIONS	
Temperature (Ambient):	5 °C to 40 °C (41 °F to 104 °F)
Relative humidity range:	15 % to 90 % (non-condensing)
Atmospheric pressure:	700 hPa to 1060 hPa
If the Auralis pump is stored in conditions outside the operating ranges, allow time for its temperature to stabilise to normal before use. Allow a minimum of 8 hours if the Auralis pump is stored at -20 °C or 60 °C.	

TRANSPORT AND STORAGE CONDITIONS	
Short term (Up to 30 days):	
Temperature (Ambient)	-20 °C to 60 °C (-4 °F to 140 °F)
Relative humidity range	0 % to 95 %
Long term (> 30 days):	
Temperature (Ambient)	0 °C to 40 °C (32 °F to 104 °F)
Relative humidity range	0 % to 95 % (non-condensing)

CAUTION

To avoid damage to the Auralis system:

- Do not store the Auralis system in direct sunlight.
- Store the Auralis pump and Auralis mattress in the protective bags supplied.
- Do not store the Auralis pump at high temperatures for extended periods. This may cause potential battery damage.
- Do not store the Auralis pump longer than 5 months without recharging the battery.

AURALIS MATTRESSES AND SEAT CUSHION MEASUREMENTS			
Part no	Description	Size mm (in)	Weight kg (lb) (Including transport bag of weight 0.46kg)
636T01S	Standard 110	2030 x 860 x 115 (80 x 34 x 4.5)	7.9 (17.4)
636T01N	Narrow 110	2030 x 780 x 115 (80 x 30 x 4.5)	7.7 (16.9)
636M05S	Standard 175	2030 x 860 x 175 (80 x 34 x 7)	13.8 (30.4)
636M05N	Narrow 175	2030 x 780 x 175 (80 x 30 x 7)	12.7 (27.9)
636M02S	Standard 200	2030 x 860 x 205 (80 x 34 x 8)	11.3 (24.9)
636M02N	Narrow 200	2030 x 780 x 205 (80 x 30 x 8)	11 (24.2)
636C01S	Seat cushion	470 x 455 x 105 (18.5 x 17.9 x 4)	1.2 (2.6)
636B02	Plus	2140 x 1220 x 205 (84 x 48 x 8)	16 (35.3)
Cover material		Premium fabric	

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.

ALLOWED COMBINATIONS	
Auralis	• Skin IQ® MCM, Coverlet Only • Skin IQ® 365, Coverlet Only
Auralis Plus	• Skin IQ® 1000, Coverlet Only

EXPECTED SERVICE LIFE	
Auralis pump	7 years

SOUND LEVELS	
Sound level during audible alarm	55 dBA at 1.8 m (1 m horizontal, 1.5 m vertical)

END OF LIFE DISPOSAL	
Package	Corrugated cardboard, recyclable.
Product	• 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 and should be disassembled and recycled per Waste of Electrical and Electronic Equipment (WEEE) or in accordance with local or national regulation.

COVER SPECIFICATION	
Feature	Premium Cover
Removable Cover	Yes
Moisture Vapour Permeable	Low
Water Resistant/Repellent	Yes
Polyurethane coating includes an antimicrobial agent to control microbial deterioration of fabric	Yes
Fire Retardant[1]	BS 7175: 0, 1 & 5
Material stretch properties	4-way
Recommended Wash Temperatures	60 °C (140 °F) 15 minutes
Maximum Wash Temperatures	Max 95 °C (203 °F) 15 minutes
Recommended Drying Temperatures	60 °C (140 °F) or air dry
Maximum Drying Temperatures	Max 80 °C (176 °F)
Wipedown Chemicals[2]	Chlorine at strength of 1000 ppm or Alcohol at 70 % concentration; no phenol; make sure product is dry before storage

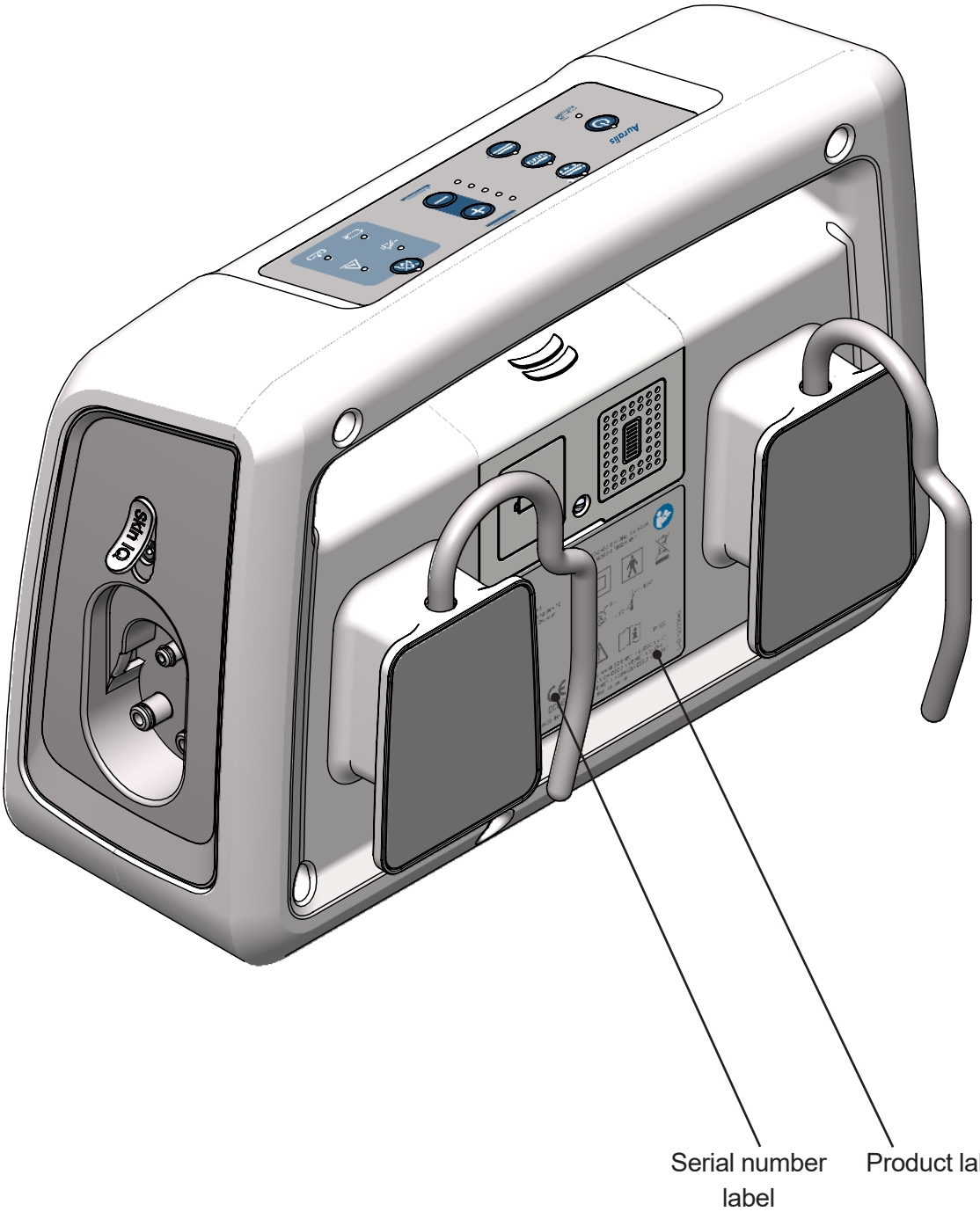
[1] For additional flammability testing standards, refer to individual product law tags, if applicable.

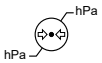
[2] Chlorine concentrations may vary from 250 ppm to 10,000 ppm depending on local policy and contamination status. If an alternative disinfectant is selected from the wide variety available, Arjo recommend that suitability for use is confirmed with the chemical supplier prior to use.

Labels

Labels on the Auralis Pump

LABEL EXPLANATION	
Product label	States technical performance and requirements, e.g. input power and input voltage.
Serial number label	States the product identification



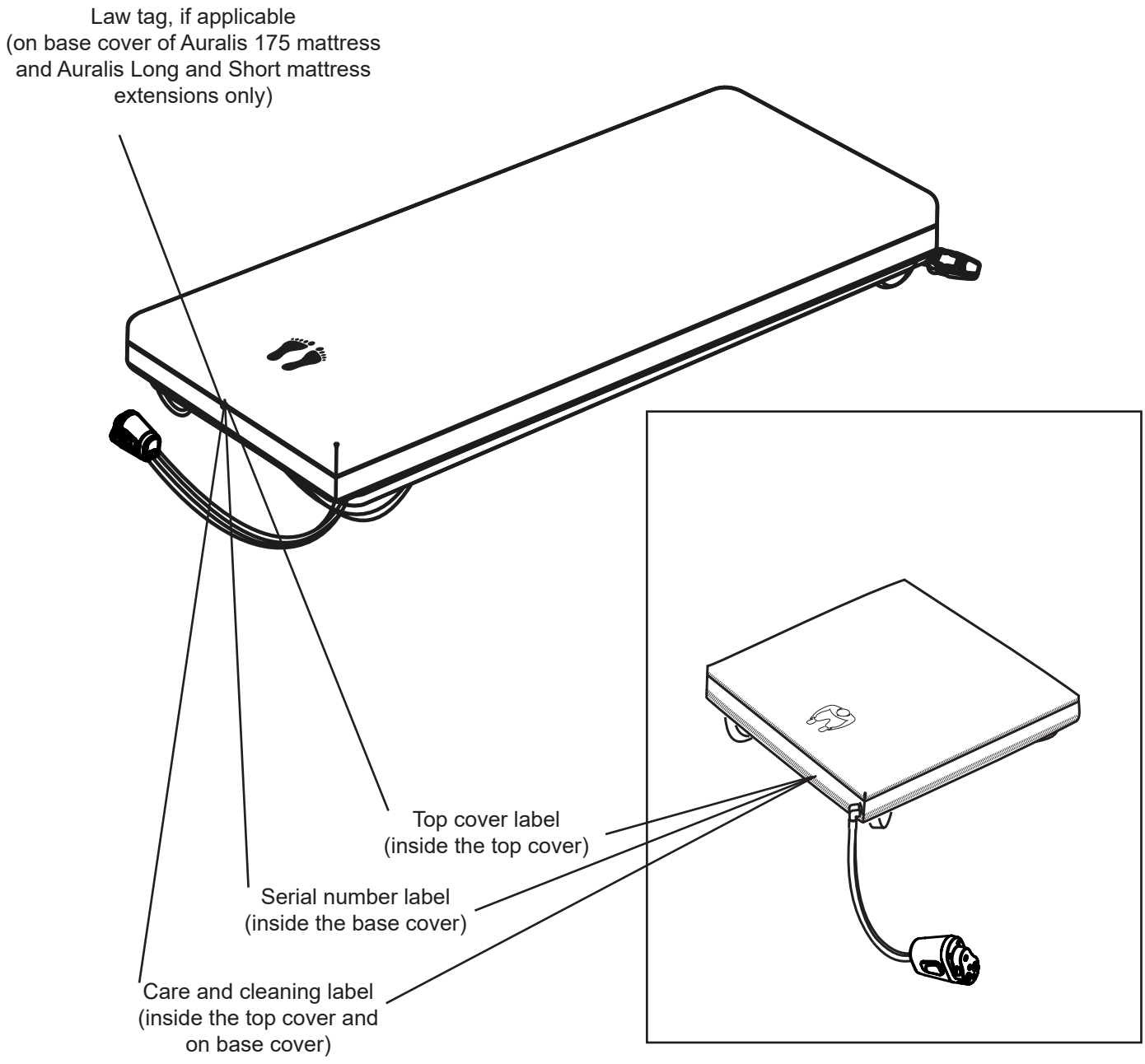
SYMBOL EXPLANATION	
	Read the Instructions for use before use.
CE 2797	CE marking indicating conformity with European Community harmonised legislation. Figures indicate Notified Body supervision.
MD	Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745.
CLASSIFIED C UL US E348583	With respect to electric shock, fire and mechanical hazards only in accordance with CAN/CSA-C22.2 No.60601.1 (2008) + (2014) and ANSI/ AAMI ES60601-1 (2005)+AMD(2012). MEDICAL EQUIPMENT
SN	Serial number
REF	Reference number
	Name and address of the manufacturer
	Manufacturing date
	Separate electrical and electronic components for recycling in accordance with the European Directive 2012/19/EU (WEEE)
	Type BF, Applied part: protection against electrical shock in accordance with IEC 60601-1.
	Double Insulated
	Temperature limitation. To indicate the temperature limitations for the product during usage
	Atmospheric pressure limitation. To indicate the acceptable upper and lower limits of atmospheric pressure for the product during usage
	Humidity limitation. To indicate the acceptable upper and lower limits of relative humidity for the product during usage
UDI	Unique device identifier.

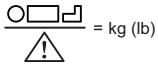
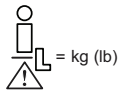
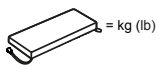
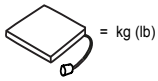
UK SYMBOL EXPLANATION	
This section is only applicable to United Kingdom (UK) market when UK marking is applied to the Arjo medical device labelling.	
UK CA 0086	UK marking indicating conformity with UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) Figures indicate UK Approved Body supervision.
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.	

Labels on Auralis mattresses, Auralis seat cushion and Auralis mattress extensions

LABEL EXPLANATION	
Serial number label	States the product identification and product weight
Top cover label	States the product identification and maximum patient weight
Care and cleaning label	States the washing conditions
Law tag (US and Canada only)	States certification of flammability test

Example of mattress



SYMBOL EXPLANATION	
	Read the Instructions for use before use.
CE	CE marking indicating conformity with European Community harmonised legislation.
MD	Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745.
LOT	Lot number
SN	Serial number
REF	Reference number
	Name and address of the manufacturer
	Manufacturing date
	Safe working load defines the maximum total load of the patient kg (lb) (mattresses)
	Safe working load defines the maximum total load of the patient kg (lb) (seat cushion)
	Product weight (Auralis mattresses)
	Product weight (Auralis seat cushion)
 Max 95°C 15 Min	Recommended wash temperature: 15 min at 60 °C (140 °F) Max wash temperature: 15 min at 95 °C (203 °F)
 Max 80°C	Tumble dry at 80 °C (176 °F) Maximum drying temperature: 80 °C (176 °F)
	Do not iron
	Wipe surfaces with cleaning solution, then wipe with a cloth moistened with water and dry
	Do not use Phenol-based cleaning solutions
	Use solution diluted to 1000 ppm of Available Chlorine
UDI	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.	
UKCA	UK marking indicating conformity with UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended)
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.	

Electromagnetic Compatibility (EMC)

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

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.

⚠ WARNING

Stacking or placing other electrical equipment next to this device is not recommended, it can interfere with the equipment's operation and safety. Portable and mobile radio frequency (RF) communications equipment can interfere with this equipment operation and safety.

⚠ WARNING

The equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take action, such as reorienting, relocating the equipment or shielding the location.

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC EMISSIONS (EMI)		
The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Auralis pump should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions	Group 1	The Auralis 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	Class B	This pump is suitable for use in all establishments including domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY

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

Immunity test	IEC 60601 test level	Compliance level	Electromagentic environment - guidance
Conducted RF IEC 61000-4-6	3Vrms 6Vrms ISM, 150KHz- 80MHz 80 % AM 1KHz	10Vrms 150KHz- 2300MHz	Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables,that the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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). 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] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	

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 Auralis pump is used exceeds the applicable RF compliance level above, the Auralis pump should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorientating or relocating the Auralis pump.

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

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE PUMP

The Auralis pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Auralis pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Auralis 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
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

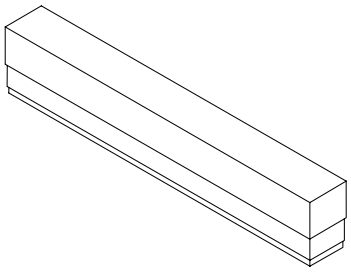
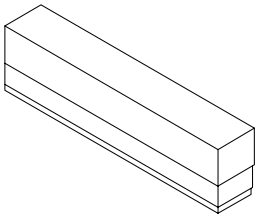
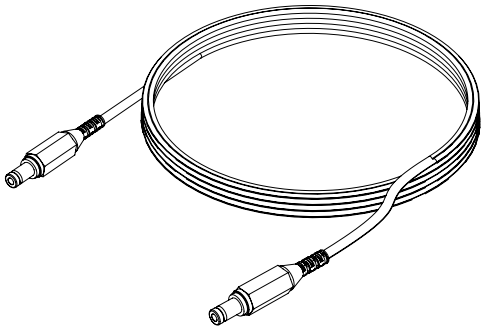
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter 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 Auralis pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Auralis pump should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines input/output lines not applicable	Mains power quality should be that of a typical domestic commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical domestic commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical domestic commercial or hospital environment. If the user of the Auralis pump requires continued operation during mains power interruptions, it is recommended that the Auralis pump is powered from an uninterrupted power supply or battery.
Power frequency (50/60 Hz) Magnetic field IEC 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 domestic commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level			

Parts and accessories

	
Auralis Plus Long mattress extension Accessory 636614	Auralis Plus Short mattress extension Accessory 636615
	
Coiled *Skin IQ* power cable 636377	

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AUSTRALIA
Arjo Australia
Building B, Level 3
11 Talavera Road
Macquarie Park, NSW, 2113,
Australia
Phone: 1800 072 040

BELGIQUE / BELGIË
Arjo Belgium
Evenbroekveld 16
9420 Erpe-Mere
Phone: +32 (0) 53 60 73 80
Fax: +32 (0) 53 60 73 81
E-mail: info.belgium@arjo.com

BRASIL
Arjo Brasil Equipamentos Médicos Ltda
Rua Marina Ciufuli Zanfelice, 329 PB02
Galpão - Lapa
São Paulo – SP – Brasil
CEP: 05040-000
Phone: 55-11-3588-5088
E-mail: vendas.latam@arjo.com
E-mail: servicios.latam@arjo.com

CANADA
Arjo Canada Inc.
90 Matheson Boulevard West
Suite 350
CA-MISSISSAUGA, ON, L5R 3R3
Tel/Tél: +1 (905) 238-7880
Free: +1 (800) 665-4831
Fax: +1 (905) 238-7881
E-mail: info.canada@arjo.com

ČESKÁ REPUBLIKA
Arjo Czech Republic s.r.o.
Na Strzi 1702/65
140 00 Praha
Czech Republic
Phone No: +420225092307
E-mail: info.cz@arjo.com

DANMARK
Arjo A/S
Vassingerødvej 52
DK-3540 LYNGE
Tel: +45 49 13 84 86
Fax: +45 49 13 84 87
E-mail: dk_kundeservice@arjo.com

DEUTSCHLAND
Arjo GmbH
Peter-Sander-Strasse 10
DE-55252 MAINZ-KASTEL
Tel: +49 (0) 6134 186 0
Fax: +49 (0) 6134 186 160
E-mail: info-de@arjo.com

ESPAÑA
ARJO IBERIA S.L.
Poligono Can Salvatella
c/ Cabanyes 1-7
08210 Barberà del Valles
Barcelona - Spain
Telefono 1: +34 900 921 850
Telefono 2: +34 931 315 999

FRANCE
Arjo SAS
2 Avenue Alcide de Gasperi
CS 70133
FR-59436 RONCQ CEDEX
Tél: +33 (0) 3 20 28 13 13
Fax: +33 (0) 3 20 28 13 14
E-mail: info.france@arjo.com

HONG KONG
Arjo Hong Kong Limited
Room 411-414, 4/F, Manhattan Centre,
8 Kwai Cheong Road, Kwai Chung, N.T.,
HONG KONG
Tel: +852 2960 7600
Fax: +852 2960 1711

ITALIA
Arjo Italia S.p.A.
Via Giacomo Peroni 400-402
IT-00131 ROMA
Tel: +39 (0) 6 87426211
Fax: +39 (0) 6 87426222
E-mail: Italy.promo@arjo.com

MIDDLE EAST
Arjo Middle East FZ-LLC
Office 908, 9th Floor,
HQ Building,North Tower,
Dubai Science Park,
Al Barsha South
P.O. Box 11488, Dubai,
United Arab Emirates
Direct +971 487 48053
Fax +971 487 48072
Email: Info.ME@arjo.com

NEDERLAND
Arjo Nederland BV
Biezenwei 21
4004 MB TIEL
Postbus 6116
4000 HC TIEL
Tel: +31 (0) 344 64 08 00
Fax: +31 (0) 344 64 08 85
E-mail: info.nl@arjo.com

NEW ZEALAND
Arjo Ltd
34 Vestey Drive
Mount Wellington
NZ-AUCKLAND 1060
Tel: +64 (0) 9 573 5344
Free Call: 0800 000 151
Fax: +64 (0) 9 573 5384
E-mail: nz.info@Arjo.com

NORGE
Arjo Norway AS
Olaf Helsets vei 5
N-0694 OSLO
Tel: +47 22 08 00 50
Faks: +47 22 08 00 51
E-mail: no.kundeservice@arjo.com

ÖSTERREICH
Arjo Austria GmbH
Lemböckgasse 49 / Stiege A / 4.OG
A-1230 Wien
Tel: +43 1 8 66 56
Fax: +43 1 866 56 7000

POLSKA
Arjo Polska Sp. z o.o.
ul. Ks Piotra Wawrzyniaka 2
PL-62-052 KOMORNIKI (Poznań)
Tel: +48 691 119 999
E-mail: arjo@arjo.com

PORTUGAL
Arjo em Portugal
MAQUET Portugal, Lda.
(Distribudor Exclusivo)
Rua Poeta Bocage n.º 2 - 2G
PT-1600-233 Lisboa
Tel: +351 214 189 815
Fax: +351 214 177 413
E-mail: Portugal@arjo.com

SUISSE / SCHWEIZ
Arjo Switzerland AG
Fabrikstrasse 8
Postfach
CH-4614 HÄGENDORF
Tél/Tel: +41 (0) 61 337 97 77
Fax: +41 (0) 61 311 97 42

SUOMI
Arjo Scandinavia AB
Riihitontuntie 7 C
02200 Espoo
Finland
Puh: +358 9 6824 1260
E-mail: Asiakaspalvelu.finland@arjo.com

SVERIGE
Arjo International HQ
Hans Michelsensgatan 10
SE-211 20 MALMÖ
Tel: +46 (0) 10 494 7760
Fax: +46 (0) 10 494 7761
E-mail: kundservice@arjo.com

UNITED KINGDOM
Arjo UK and Ireland
Houghton Hall Park
Houghton Regis
UK-DUNSTABLE LU5 5XF
Tel: +44 (0) 1582 745 700
Fax: +44 (0) 1582 745 745
E-mail: sales.admin@arjo.com

USA
Arjo Inc.
2349 W Lake Street Suite 250
US-Addison, IL 60101
Tel: +1 (630) 307-2756
Free: +1 (800) 323-1245
Fax: +1 (630) 307 6195
E-mail: us.info@arjo.com

JAPAN
Arjo Japan K.K.
東京都港区虎ノ門三丁目7 番8 号
ランディック第2 虎ノ門ビル9 階
Tel: +81 (0)3-6435-6401
Fax: +81 (0)3-6435-6402
E-mail: info.japan@arjo.com

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.

ArjoHuntleigh AB
Hans Michelsensgatan 10
211 20 Malmö, Sweden
www.arjo.com

arjo

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