INSTRUCTIONS FOR USE

Caylis Pro

Low air loss system

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arjo
EMPOWERING MOVEMENT

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Foreword

Thank you for choosing the Caylis® Pro low air loss system.

Customer contact information

For questions regarding this product, supplies, maintenance, or other Arjo products and services, contact Arjo, an Arjo authorised representative or visit www.arjo.com.

Read and fully understand this IFU before using the product

The information in this Instructions For Use (IFU) is necessary for the proper operation and maintenance of your product. It helps to protect your product and make sure that it performs to your satisfaction. The information in this IFU is important for your safety. You must read and understand the IFU to help prevent possible injury. Unauthorised modifications on any Arjo product can affect its safety and performance. Arjo cannot be held responsible for any accidents or incidents resulting from such modifications to its products.

Service and support

Routine maintenance is necessary to maintain the safety and reliability of the product. See the Care and preventive maintenance section for more information. Contact your local Arjo representative for spare parts. Find Customer contact information on the last page of this IFU.

Serious incident

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 others.

CAUTION

Caution means: Failure to follow these instructions may cause damage to all or parts of the system or product.

NOTE

Note means: This is important information for the correct use of this system or product.

Pre-sale information

GENERAL	
Intended use, the intended user group and the intended environment; including any contraindications.	See Intended use on page 7
Maintenance requirements	See Care and preventive maintenance on page 43
Cleaning requirements	See Cleaning and disinfection on page 38
Disinfection requirements	See Cleaning and disinfection on page 38
Operator controls	See Product description - Touchscreen on page 20
Storage and transporting when not in use.	See Turn-off and store the low air loss system on page 37
Accessories	See Parts and accessories on page 62
Detachable parts	See Measurements and compatibility on page 51
Compatible products	See Allowed combinations on page 51
The A-weighted sound power level	

DIMENSIONS	
Pump weight	5.2 kg (11.4 lb)
Mattress weight (max and min)	Max: 13.1 kg (28.9 lb) Min: 12.6 kg (27.8 lb)
Detachable parts above 20 kg (44lb)	None
Overall dimensions - surfaces	See Measurements and compatibility on page 51
Dimensions when packed	See Measurements and compatibility on page 51

Intended use

The Low Air Loss system is intended for use by caregivers[1] in acute care and long-term care facilities.

The Low Air Loss system is indicated for the prevention and management of pressure injuries. It should be used as part of an individualised, comprehensive pressure injury protocol. This typically includes: repositioning, nutritional support and skin care.

The Low Air Loss system represents one aspect of a pressure injury management protocol. All other aspects of care should be considered by the healthcare professional. If existing wounds do not improve, or the patient's condition changes the overall therapy regimen should be reviewed by the healthcare professional.

The Low Air Loss system also benefits the microclimate of the patient.

By definition this is climate of a small or restricted area that differs from the climate of it's surrounding area. It often occurs under bony prominences where pressure and shearing forces are at a peak. Heat and humidity build up may cause increased moisture on the skin surface.

As guidance, the system is indicated for all patients risk types, including those who are at 'Very High Risk' of pressure injuries including those individuals where there is a need to influence microclimate control and shear reduction.

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

The Low Air Loss system is for patients within the weight range of 23 kg (50 lb) to 200 kg (440 lb).

The Low Air Loss system should only be used for the purpose specified in this Instructions for Use. Any other use is prohibited

Contraindications

Do not use the Low Air Loss system with patients with an unstable cervical, thoracic and/or lumbar fracture, cervical traction, and skeletal traction. For any other unstable fractures, a medical examination is necessary to determine whether the use of the Low Air Loss system is suitable. For any other conditions that may be complicated by a moving surface, do not use the Low Air Loss system.

Patient assessment

Facilities should establish regular assessment routines. Caregivers should assess each patient before using the product. The patient weight must not exceed 200 kg (440 lb).

Expected service life

The expected service life of the Caylis Pro Low Air Loss pump is 7 Years.

The expected service life of this product is subject to preventative maintenance being carried out in accordance with the instructions for care and maintenance found in this Instructions for Use.

1 Caregiver will be a healthcare professional who operates this medical device.

Safety instructions

WARNING

To avoid injury, always read this Instructions for use before using the product.

WARNING

To avoid injury, side rails should be used when the patient is left unattended based on an accepted patient assessment.

WARNING

To avoid serious injury, do not use the pump near uncontained flammable liquids/ gases or any other sources of liquids.

WARNING

To avoid tripping, keep cables away from moving bed parts or other possible entrapment areas.

WARNING

To avoid tripping or strangulation, make sure that the tube-set is positioned correctly.

WARNING

To avoid injury, keep the mains power socket and plug accessible at all times. To safely cut off the pump's power supply, remove the plug from the mains outlet.

WARNING

To avoid injury, never use the mattress as a patient transfer device.

WARNING

To avoid injury and/or unsafe product, do not use unapproved accessories or attempt to modify, disassemble or misuse the low air loss system.

WARNING

To avoid injury and risk of fire hazard or explosion, make sure to unplug and do not use pump when using oxygen-administering equipment. Allowed are nasal, mask or half-bed length tent type. The pump is not suitable for use close to a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

WARNING

To avoid electric shock, do not service or maintain the pump while it is in use.

WARNING

To avoid pressure injury, make sure that the low air loss system is assembled correctly.

WARNING

To avoid pressure injury, do not let the patient wear clothing that may cause areas of localized high pressure due to creases, seams, etc. Objects in pockets must be avoided for the same reason.

CAUTION

To avoid damage, do not use sharp objects or electrically heated blankets on or under the low air loss system.

CAUTION

To avoid damage, do not expose the product to naked flames, such as cigarettes. This is especially important for the mattress. A leak in the mattress may increase the fire.

CAUTION

To avoid damage to the screen, the control screen should only be operated by finger.

Preparation

Bed frame recommendation

The mattress range is designed to be used on Arjo bed frames. See Measurements and compatibility on page 51

The mattress range may also be used with other bed frames (non-Arjo). The clinician or caregiver should assess the patient needs and determine which mattress and bed frame to use. See the bed frame IFU for compatible mattress sizes. For available mattress dimensions see section Measurements and compatibility on page 51.

WARNING

To avoid injury by entrapment, always select the correct mattress size for the bed.

Actions before first use

1. Visually check the product packaging for damage. If the packaging is damaged, contact the transport agency. Do NOT use the product.
2. Read this IFU.
3. Check that all parts of the product are supplied. Compare with the Parts designation sections. If any part is missing or damaged – do NOT use the product.
4. Recycle the packaging according to local regulations.
5. Choose a designated area where this IFU should be kept. The IFU should be accessible at all times.

Actions before every use

Inspect the low air loss system according to section Care and preventive maintenance on page 43. If any item is damaged - do NOT use the product.

Action after each patient

Clean and disinfect the product after each patient according to section Cleaning and disinfection on page 38.

Patient positioning guide

WARNING

To avoid occlusion or device related pressure injury, make sure any lines or tubing are not pressed against the patients skin.

The Low air loss system allows the patient to be placed in supine (face up) or Prone (face down) position.

Supine position

Make sure that the patient is centred on the mattress.

Prone position

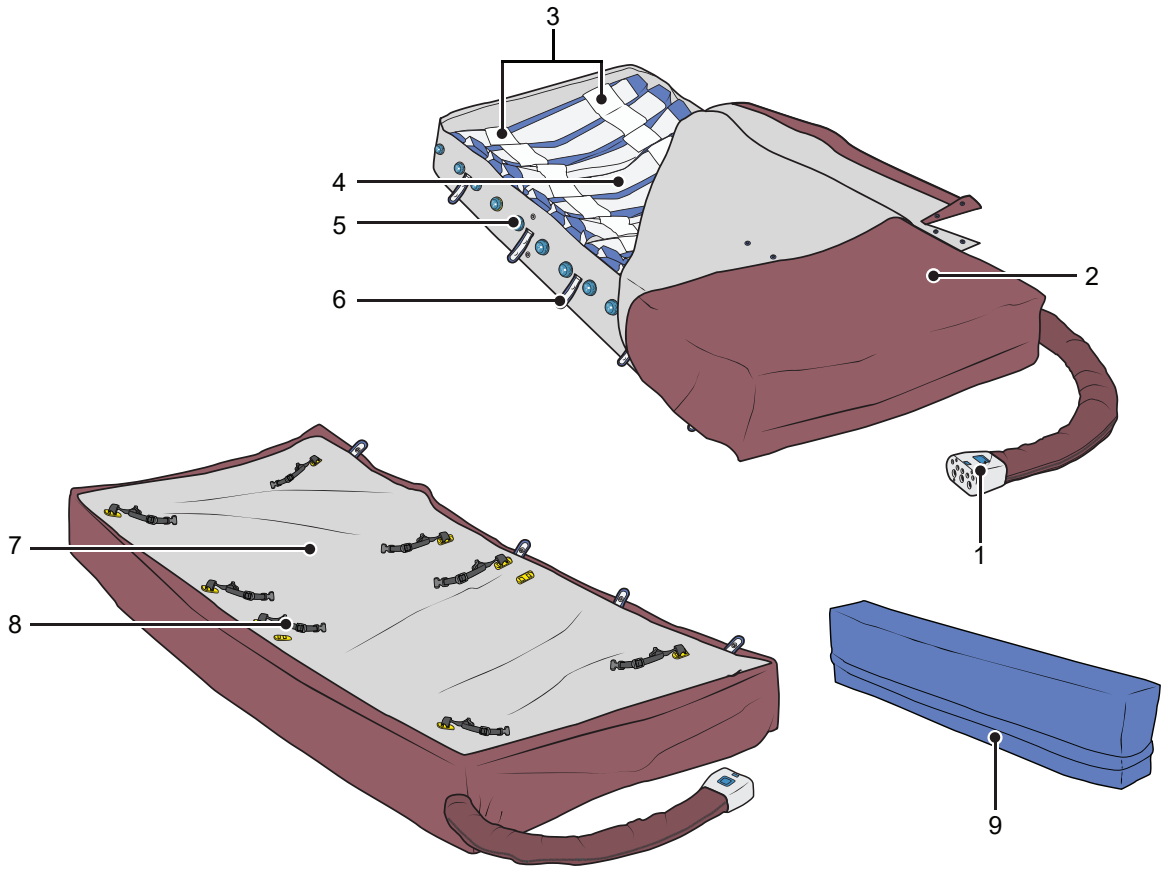
To place the patient in Prone position, see Proning on page 31.

Bed egress

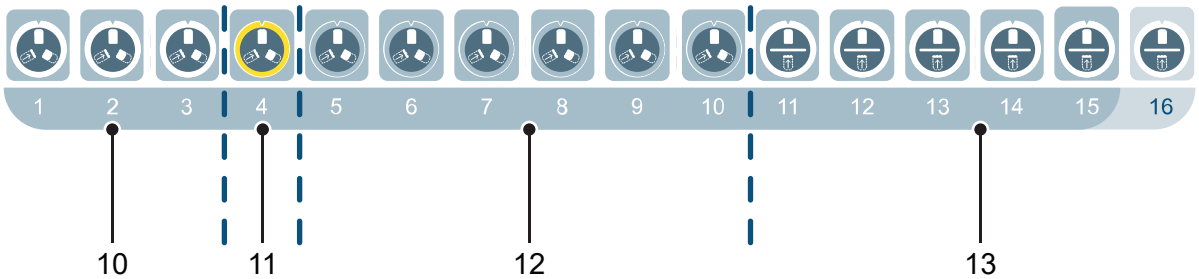
It is recommended that the patient exits the bed on the non-valve side. If this is not possible there is a cover panel to improve comfort and interference form the valves.

The Autofirm feature can be used to create a firmer surface to assist the patient to egress from the mattress.

Parts designation - Pro mattress

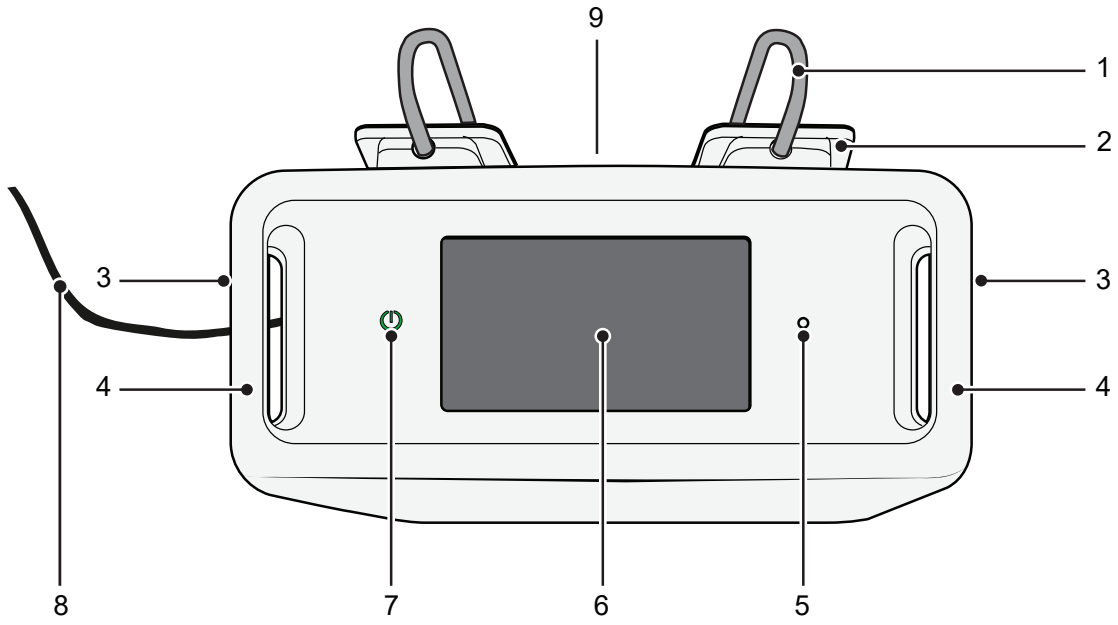


Cell types



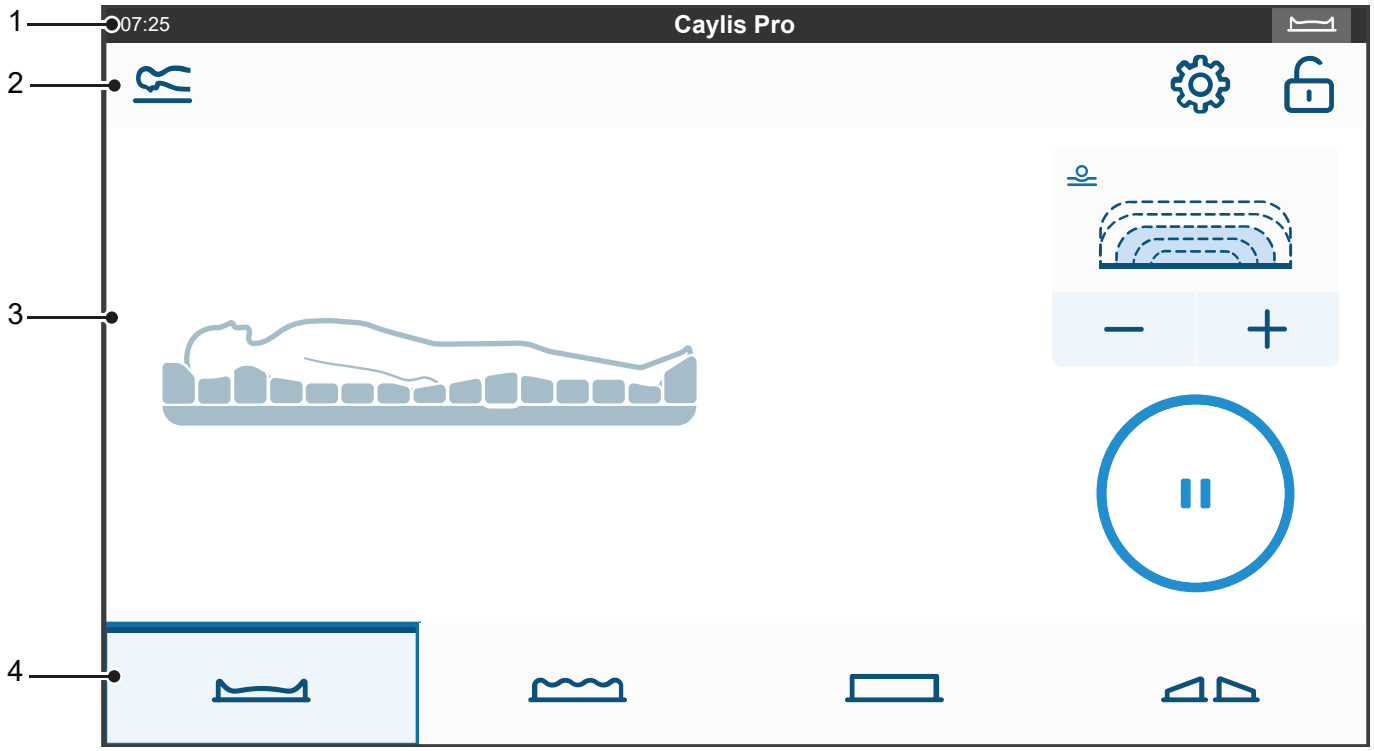
1. Mattress and CPR connector with tube-set (Mattress connector)
2. Top cover with valve cover panel
3. Cell holding sheet with loop straps
4. Cells
5. Cell valves
6. Cable management loops (five loops)
7. Bottom cover with Non-slip base
8. Securing straps (four on each side) and Anchor points (five on each side)
9. Mattress extension (Accessory)
10. Head cells
11. Shoulder support cell
12. Torso cells
13. Foot cells (cell 16 long mattress only)

Parts designation - Pump



1. Bed hooks
2. Pump cable management
3. Repeater lights (underneath the handles)
4. Handles
5. Light sensor
6. Touchscreen
7. Run/Standby button
8. Power cable
9. Air inlet (on bottom of pump)

Parts designation - Touchscreen



The Touchscreen is divided into four different information areas.

1. Status bar:
   Shows Time, active therapy mode, alarms and audio status.
2. Secondary mode bar:
   Shows Proning icon, Settings icon, Locked/Unlocked icon and any active alarm conditions.
3. Therapy detail area:
   Shows the main interaction point for each mode and the Start/Pause icon. Allows the user to adjust controls.
4. Mode bar:
   Shows available Therapy and Nurse assist modes.

Icon explanation

ICON	DESCRIPTION	ICON	DESCRIPTION	ICON	DESCRIPTION
	Continuous low pressure		Start		Settings
	Pulsation		Pause		About / info
	Autofirm		Confirm prompt		Bed exit alarm
	Patient turn		Decline prompt		Service settings
	Proning		Back icon		General prompt
	Comfort control		Locked		Safety prompt
	Cycle period		Unlocked		Low pressure alarm
	Timer		Locked, insert PIN		Service alarm
	Pulsation intensity		Audio OFF		Bed exit alarm - alarming
	Wait to inflate		Audio alarm pause control		High temperature alarm
			Audio alarm pause activated		Connector disconnected alarm

Product description - Pro mattress

WARNING

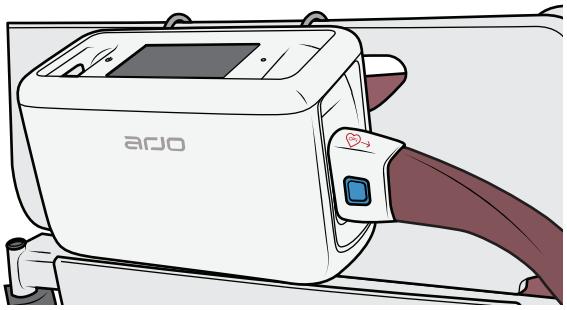
To avoid injury, never use the mattress as a patient transfer device.

Mattress connector with tube-set

WARNING

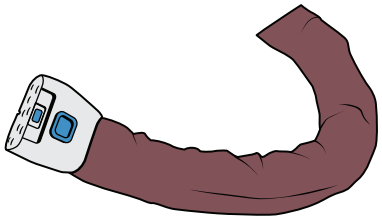
To avoid serious injury or death, the Mattress and CPR connector must be visible and accessible at all times.

The Mattress connector attaches the mattress to the pump.



In the event of a cardiac arrest, see section CPR rapid deflation on page 18.

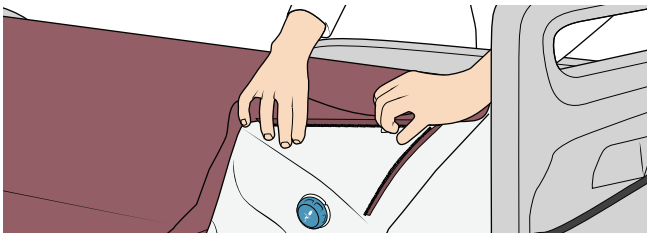
The Mattress connector tube-set is protected by a cover.



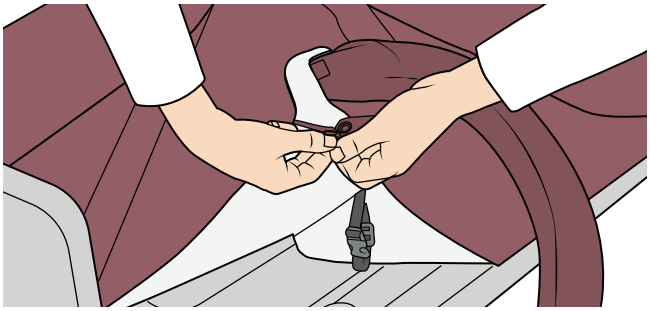
Before storing the mattress, deflate it by removing the connector from the pump.

Top cover (detachable)

The cover is attached by two zips.

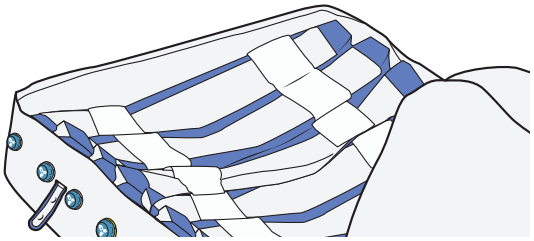


The cover is clipped around the Mattress connector using two fasteners.



Cell holding sheet with loop straps

The cell holding sheet with loop straps maintains cell position and alignment.



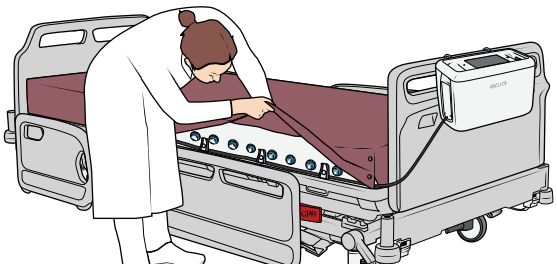
Cells

The cells provide the low air loss performance.

For cell positions see Cell types on page 11.

Cell valves

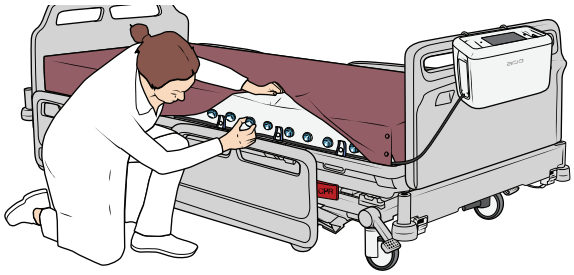
The valves are located on the opposite side to the mattress connector underneath the valve cover panel. Unfasten the panel to access the cell valves.



The inflation level is selected by turning the valve manually so that the desired icon is in the uppermost position.

3-way valves

The head and torso cells have individual valves that can fully or partially deflate.



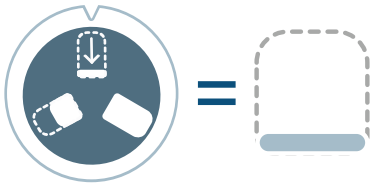
The torso cells are used to optimise patient support and comfort when in prone position.

The head cells should only be deflated during prone position.

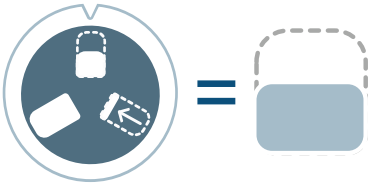
For more information on Prone position see section Proning on page 31

Cell valve settings

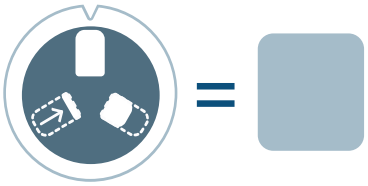
Setting for fully deflated cell.



Setting for partially deflated cell.

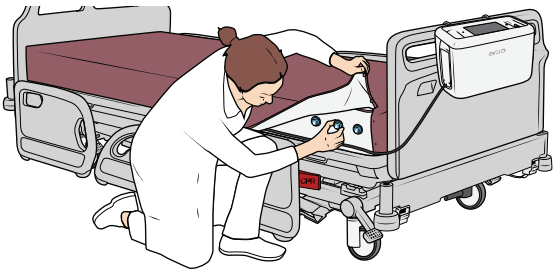


Setting for inflated cell.



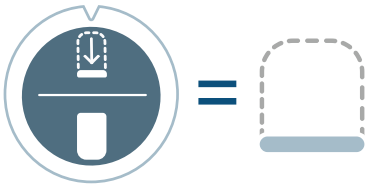
2-way valves

The foot cells have individual valves that can fully deflate. The foot cells assists with heel offloading.

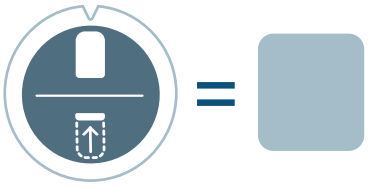


Cell valve settings

Setting for fully deflated cell.



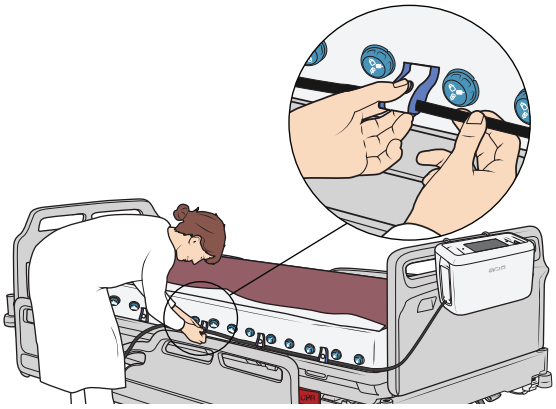
Setting for inflated cell.



Cable management loops

> **WARNING**
>
> **To avoid tripping or strangulation, always use the cable management loops for the power cable.**

The five cable management loops must be used to secure the power cable along the side of the mattress.

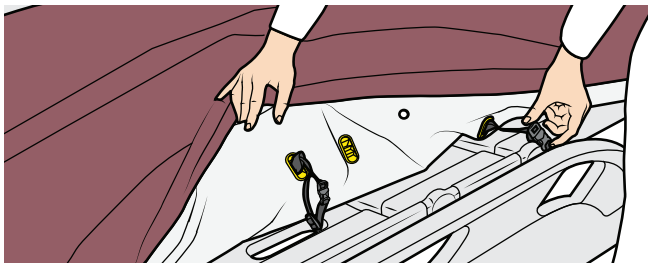


Bottom cover with non-slip base

The bottom cover with non-slip base prevents the mattress from slipping when on the bed frame.

Securing straps and anchor points

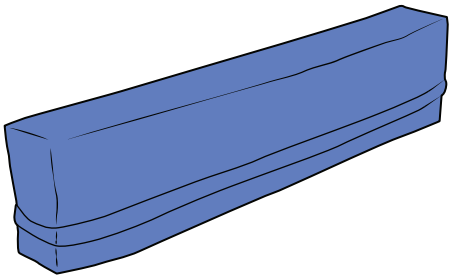
The mattress has eight securing straps. These can be used in any of the ten anchor points on the base of the mattress. This allows the mattress to be attached to different types of bed frames.



Mattress extension (Accessory)

The mattress extension is an optional accessory which can be used to extend the length of the support surface for taller patients.

See section Assemble mattress extension on page 25.



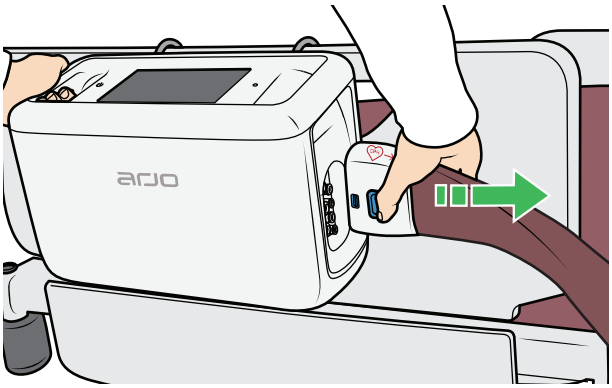
CPR rapid deflation

In the event of the patient suffering a cardiac arrest, the mattress can be rapidly deflated using the Mattress connector.

Activate the CPR rapid deflation

Deflate the mattress by activating the CPR function located on the pump mounted at the foot end of the bed.

1. Press both buttons on the Mattress connector simultaneously.
2. Pull the Mattress connector out and away from the pump.



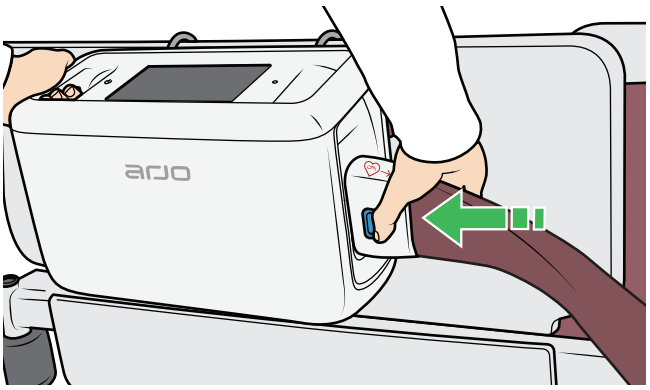
3. CPR can be performed after 10 seconds.

NOTE

If the Mattress connector is disconnected during therapy an alarm sounds and the following symbol appears:

Deactivate the CPR rapid deflation

Reconnect the Mattress connector to the pump. The mattress begins to inflate based on the active therapy mode.



Product description - Pump

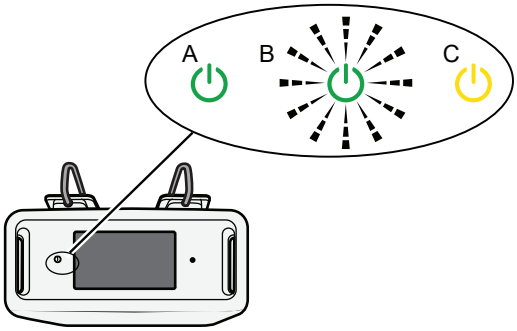
Run/standby button

The Run/Standby button switches the state of the pump between Run mode and Standby mode.

Touch and hold the button for two seconds to switch between Run and Standby mode.

> **NOTE**
>
> **The Run/Standby button is activated by touch and does not require any pushing force**

- In Run mode therapy is delivered and the button lights up green (A).
- In Standby mode no therapy is delivered and the button flashes green (B).
- In the event of a power failure, therapy stops, the touchscreen turns off and the button lights up yellow for up to 5 minutes (C).



> **NOTE**
>
> **To turn off the pump during power failure, touch and hold the Run/Standby button for two seconds.**

Touchscreen

The Touchscreen is the main interaction point for controlling the pump. See Icon explanation on page 14 and Product description - Touchscreen on page 20 for more details.

Light sensor

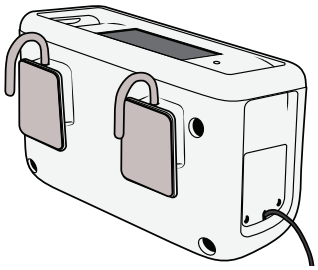
The light sensor automatically adjusts the brightness of the touchscreen and repeater lights dependent on ambient light level.

Repeater lights

- The repeater lights are Green during normal mode.
- The repeater lights are Yellow during an alarm condition.
- The repeater lights are Yellow and reduce in brightness during power fail mode.

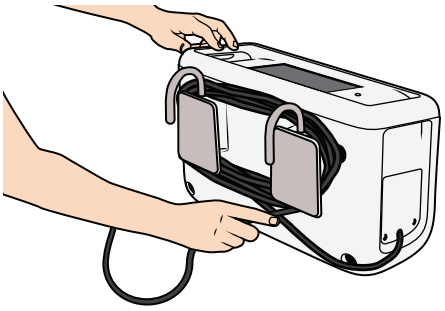
Bed hooks

Use the bed hooks to mount the pump at the foot end of the bed.



Pump cable management and power cable

When the pump is assembled, use the pump cable management to store any remaining power cable.



Product description - Touchscreen

General description

To operate the Touchscreen tap the desired icon with one finger to make a choice.

A light blue box surrounds the icon in the mode bar to indicate the mode displayed on the screen.

Tap to activate any mode.

A dark blue line shows above the activated mode icon when in use.

Mode types

Therapy Modes

- Continuous low pressure (CLP), see Cell levels - Supine/Semi-recumbent position on page 26
- Pulsation, see Pulsation on page 27

Nurse Assist Modes

- Autofirm, see Autofirm on page 28
- Patient turn, see Patient turn on page 29

Prone Mode

- Proning, see Proning on page 31

All modes can be reached from any screen.

Safety Prompt

Failure to follow the on screen prompt may pose a safety risk to the patient.

General Prompt

Failure to follow the on screen prompt may result in reduced efficacy of system features.

Locked/Unlocked icon

In therapy modes, the pump automatically locks if there is no interaction with the screen for 2 minutes.

The lock button icon in the secondary mode bar is used to activate / deactivate the lock. The icon also indicates the lock status.

The locked icon shows when the pump is locked.

The Unlocked icon shows when the pump is unlocked.

Touch and hold the icon for 2 seconds or more to lock / unlock.

Audio pause icon

The Audio pause icon shows if an Audio alarm sounds.

Tap to pause the alarm for 15 minutes. The icon changes to Audio Pause activated .

Alarm pause is cancelled if another alarm condition occurs in the 15 minute pause period.

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

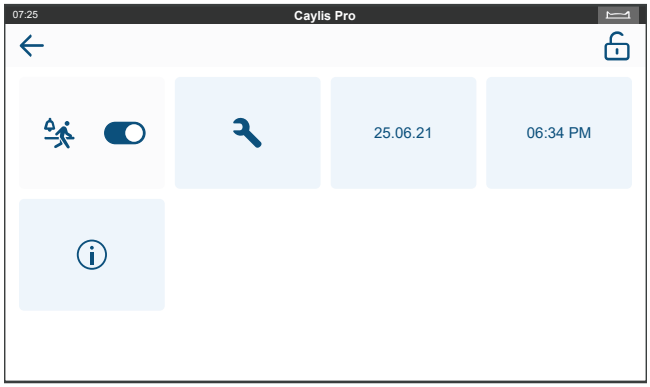
Audio ON/OFF

Audio ON/OFF disables all alarm sounds and notifications. It is for use when it has been determined that audio output could be distressing for the patient.

The Audio off icon shows in the status bar when the Audio notifications and alarms have been permanently disabled.

> **NOTE**
>
> **The Audio ON/OFF setting can only be changed by qualified service personnel under direction of the responsible organisation. It can be found within the service settings.**

Settings



Tap ⚙ to access the settings screen.

Activate Bed exit alarm

The Bed exit alarm is not intended to replace good nursing practice or regular patient assessments.

When activated, the Bed exit alarm provides an audible and visual indication that the patient has left the mattress.

When the pump is first switched on, the Bed exit alarm is disabled.

1. Make sure that the patient is positioned on the mattress according to section Supine position on page 10 before activating.
2. Tap the Bed exit alarm toggle.

> **NOTE**
>
> **When the Bed exit alarm sounds, it runs continuously until the alarm is paused.**

Access Service settings

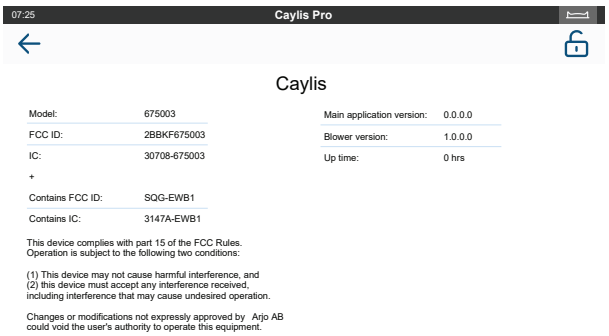
1. Tap 🔧.
2. Enter either default PIN or the PIN set by your organisation.

Set time or date

1. Tap **Time or Date**.
2. Set the time or date.
3. Tap **Confirm**, the system returns to settings.

Access Product information

1. Tap ⓘ.
2. The Regulatory Compliance information and Software information is displayed.

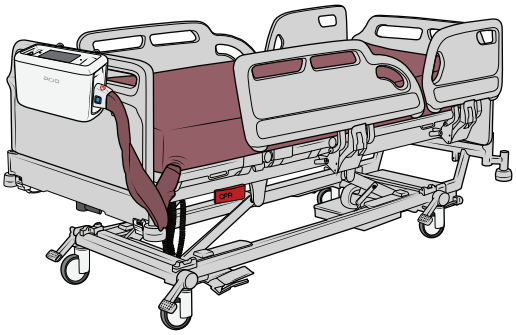


3. Tap ← to return to Settings.

Assemble the low air loss system

Assemble the mattress

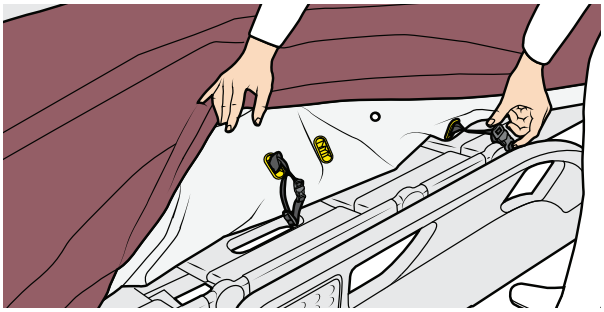
1. Remove any existing mattress from the bed frame.
2. Check that there are no protruding sharp objects on the bed frame surface.
3. Select the correct mattress size for the bed frame. See section Measurements and compatibility on page 51.
4. Position the mattress on the bed frame. Make sure that:
   - The purple mattress top cover is facing up. The silver base cover sits on the bedframe.
   - The tube-set is positioned so that it is exiting the mattress at the foot end, right hand corner.



5. If applicable, fit the mattress extension according to Assemble mattress extension on page 25
6. **WARNING**

   To avoid injury by displacement of the mattress from the bed frame, secure the mattress to the bed frame using all eight securing straps, adjusting the length of the straps to safely secure the mattress.

   Secure the mattress to the bed frame (8 securing straps).



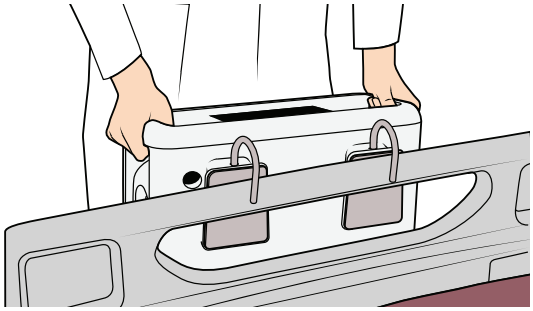
   If the bed can be raised or lowered, attach the mattress to the movable parts of the bed only.
7. **WARNING**

   To avoid suffocation and damage to the cells, always attach the mattress top cover to the base cover securely before use.

   Attach the top cover with the two zips.
8. Clip the cover around the Mattress connector using two fasteners. The Mattress connector must be accessible at all times.

Assemble the pump

1. Unwrap power cable from pump cable management.
2. Hang the pump at the foot end of the bed using the bed hooks.



> **CAUTION**
>
> **To avoid product damage, do not place the pump underneath the bed.**

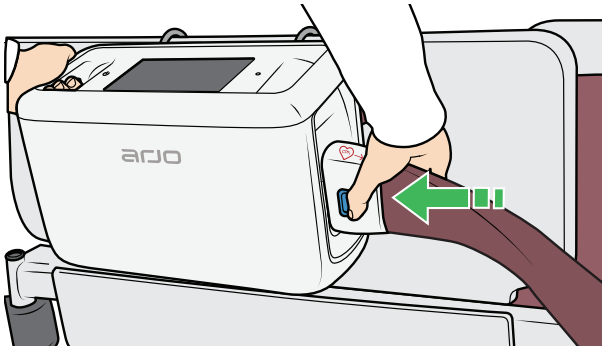
Make sure that the pump is not:

- Near a heat source.
- In the sun.
- Covered up.
- Placed on a soft surface that blocks the air inlet.

3. Check that the tube-set is not twisted or kinked.
4.

> **WARNING**
>
> **To avoid tripping or strangulation, make sure that the tube-set is positioned correctly.**

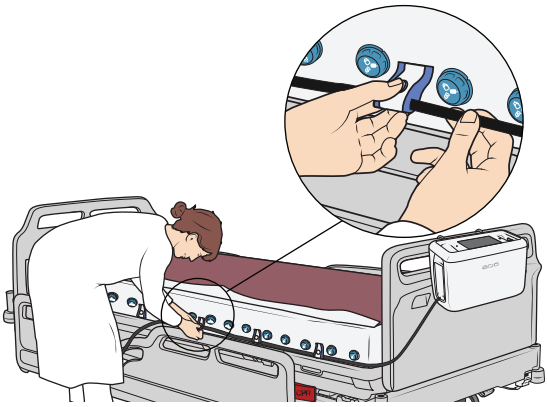
Connect the Mattress connector to the pump.



5.

> **WARNING**
>
> **To avoid tripping or strangulation, always use the cable management for the power cable.**

Unfasten the valve cover panel and place the power cable in the cable management loops. Secure the cable with the cable management loop fasteners.

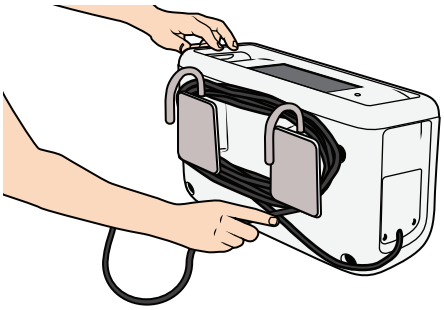


6.

WARNING

To avoid tripping keep cables away from moving bed parts or other possible entrapment areas.

Any remaining power cable can be stored on the pump cable management.



7.

WARNING

To avoid risks of injury, the power source should always be accessible.

Connect the power cable to a power source. The pump automatically powers up.

8. Reattach the valve cover panel to the base cover using the fasteners.

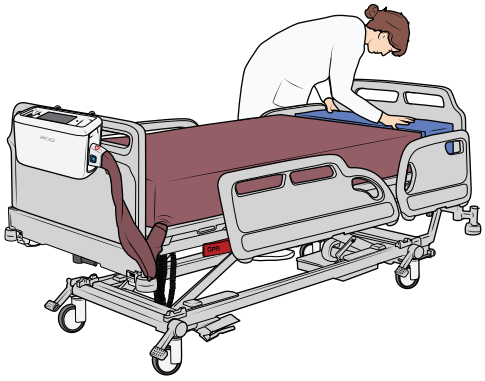
Assemble mattress extension

Use the mattress extension when the bed frame length is fully extended.

CAUTION

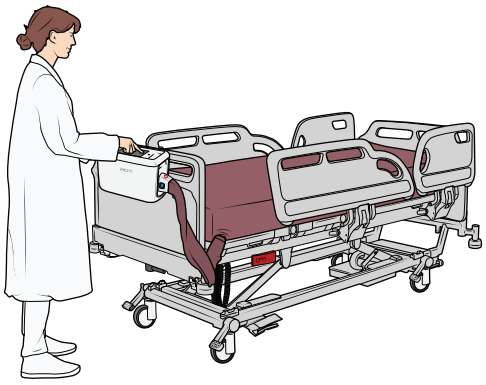
Do not use the mattress extension without its cover. It provides a protective barrier against biological contamination.

1. Remove all packaging.
2. Make sure that the mattress extension is fitted with its cover.
3. Check that there are no protruding sharp objects on the bed frame surface.
4. Place the mattress extension in the space between the mattress and the headboard.



Low air loss system

Caregiver position



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

Start-up

1. Make sure that the mattress is connected to the pump.
2. Connect the pump power cable to a power source. The pump makes a start up tone.
3. The system runs a short self-diagnostic test. During this test the touchscreen displays a loading screen.
4. The mattress automatically begins to inflate. This takes less than 90 seconds.
5. Place the bed sheet loosely over the mattress once inflated. Make sure that the Mattress connector is clearly visible at the foot end.
6. Place the patient on the mattress. See Patient positioning guide on page 10

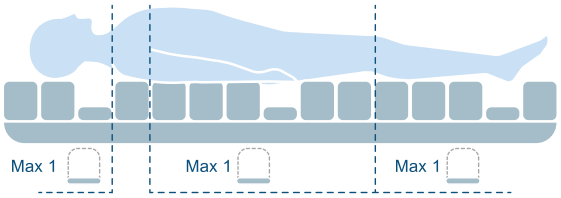
   NOTE

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

7. The default settings are Continuous low pressure with middle comfort setting.

Cell levels - Supine/Semi-recumbent position

1. For long term off-loading/pressure relief in the supine position:
   - Select only one cell in the head section.
   - Select only one cell in the torso section.
   - Select only one cell in the foot section.



NOTE

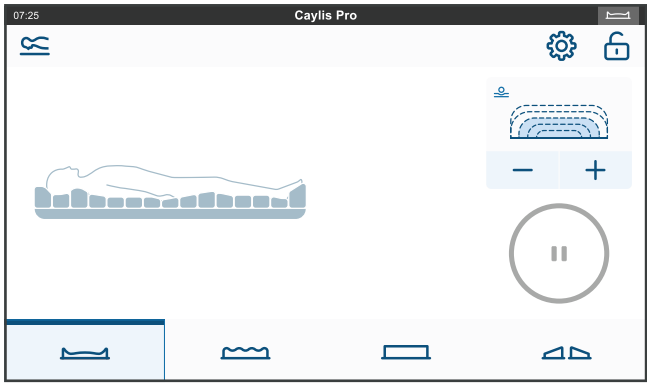
Do not deflate any more cells in each section or it may affect the support of the patient, especially in profiled positions.

2. For short term nursing procedures:
   - Select one or more adjacent cells and rotate valve to desired position.
   - Once the clinical/nursing procedure is complete, re-inflate the cell(s) by rotating the valve to the fully inflated position.

NOTE

Deflating more than one adjacent cell may affect the support of the patient it should therefore only be used for short-term procedures.

Continuous low pressure



Continuous low pressure is the default therapy mode.

This mode maintains optimum patient immersion and envelopment. A continuous flow of air out of the mattress helps manage the skin microclimate.

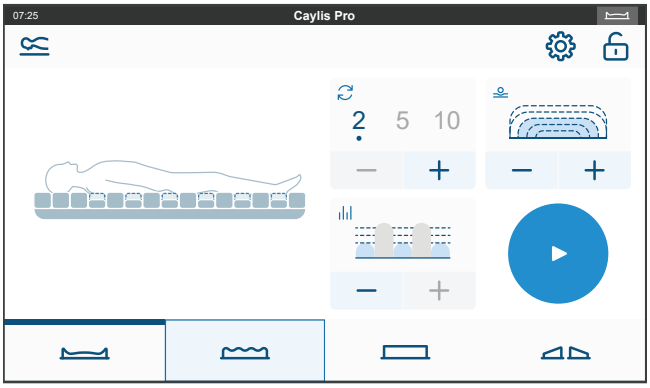
Activate Continuous low pressure

1. Tap
2. Tap to start Continuous low pressure.

Deactivate Continuous low pressure

Activate another mode to deactivate Continuous low pressure.

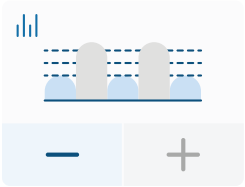
Pulsation



Pulsation is a therapy mode where the air cells inflate and deflate sequentially. The pulsation cycle time can be set to any of the available cycle times.

Intensity level

Available intensity levels are low, medium or high. Tap the + and - icons to select intensity level.



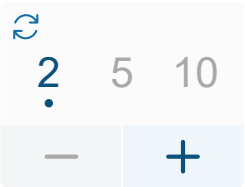
Intensity	Pressure target in increased cells (% of set pressure)	Pressure target in decreased cells (% of set pressure)
High	125%	42%
Medium	125%	55%
Low	125%	75%

NOTE

Intensity level and cycle time can be changed at any time.

Cycle time

Available cycle times are 2, 5 or 10 minutes. Tap the + and - icons to select cycle time.



Activate Pulsation

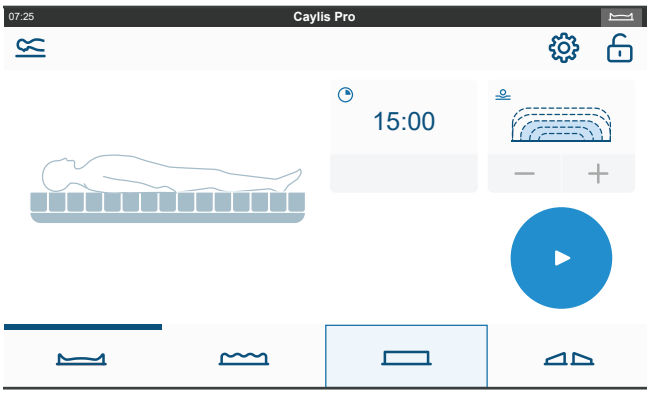
1. Tap
2. Tap to start Pulsation.

> **NOTE**
>
> **Pulsation can be deactivated any time.**

Deactivate Pulsation

Activate another mode to deactivate Pulsation.

Autofirm



The mode inflates the mattress to a firm surface.

Autofirm can be used to assist some nursing procedures. It can also assist some patients with ingress or egress of the bed.

Activate Autofirm

1. Tap
2. Tap to start Autofirm mode.
3. A progress ring shows (2 minutes to fully activate).

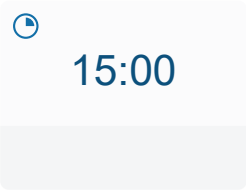
4. When the progress ring is full, the mattress has reached Autofirm pressure. Autofirm pressure lasts for 15 minutes.
5. A time out alert shows in the last minute of the cycle.

Extend Autofirm

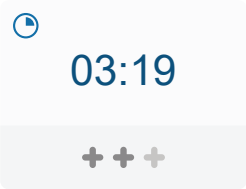
To extend Autofirm for 5 minutes, tap +5:00 .

This can only be done in the last minute of Autofirm. Until this point the option is unavailable.

It is possible to extend Autofirm up to 3 times.



The number of time extensions already used shows by plus symbols underneath the timer.



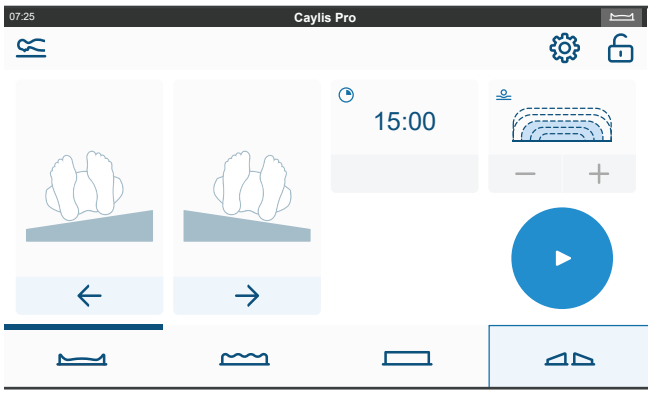
If Autofirm is not extended the system returns to the previous therapy mode.

Deactivate Autofirm

Tap on the Autofirm screen or start any other therapy mode.

If paused, the system returns to the previous therapy mode.

Patient turn



Patient turn is a nurse assist mode. It assists manual lateral repositioning of the patient to the left or right up to 30 degrees.

It can be used to help reduce the physical effort required by the caregiver.

NOTE

30° is the target turn angle, it may not be achieved by all patients. The actual angle is dependent on many factors including: patient weight, patient weight distribution, pressure settings and patient positioning on the mattress.

WARNING

To avoid patient injury, side rails should be raised before patient turn is activated.

During patient turn one side rail can be lowered temporarily if there is a caregiver present on that side of the bed.

Do not activate patient turn when patient restraints are in use.

WARNING

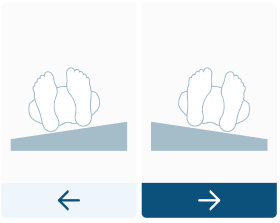
To avoid injury, make sure that tubes/lines/ drains are safely positioned during turning or repositioning.

WARNING

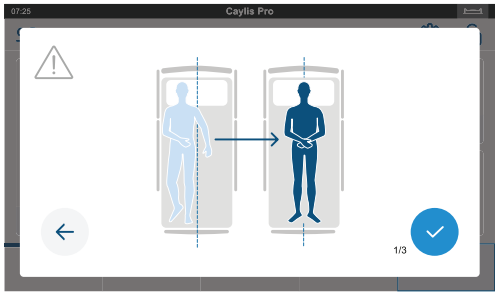
To avoid injury make sure the backrest is positioned between flat and 30 degrees prior to activating patient turn.

Activate Patient turn

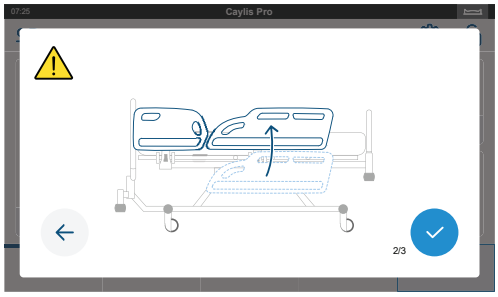
1. Tap
2. Choose left or right.



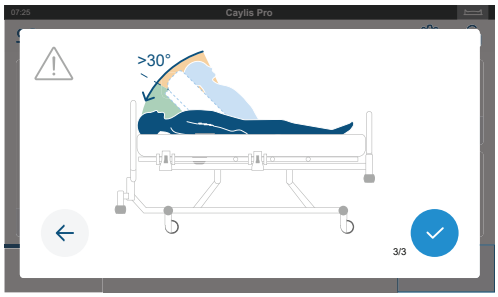
3. Tap
4. A confirmation screen is displayed. Tap to confirm:
   - The patient is centred on the mattress.



   - The bed rail is raised on the side the patient turns towards.



   - The head of bed angle is between 30° and flat. The maximum turn is achieved when the bed is flat.



5. The turning process starts and a progress ring shows.

The turning process takes around one minute.

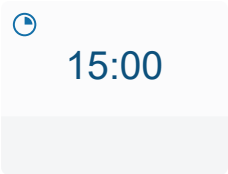
Once inflated the timer count down begins.

6. After 15 minutes, a time out alert advises that the turn angle returns to less than 3 degrees in 2 minutes. .

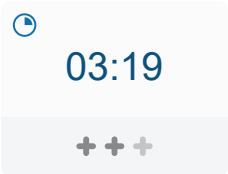
Extend Patient turn

To extend Patient turn for 5 minutes, tap +5:00 . This can only be done in the last minute of Patient Turn. Until this point the option is unavailable.

It is possible to extend Patient turn up to 3 times.



The number of time extensions already used shows by plus symbols underneath the timer.

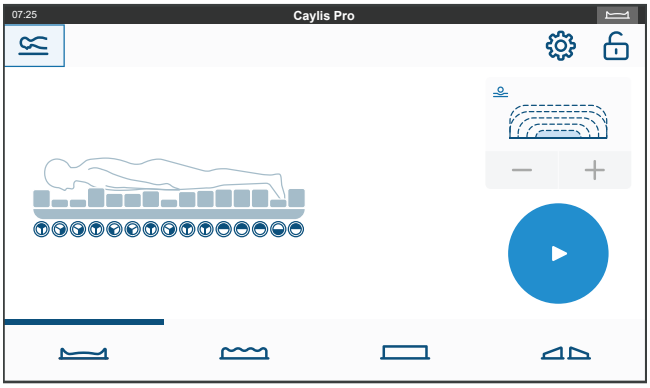


Deactivate Patient turn

Tap on the Patient turn screen or start any other therapy mode.

If paused, the system returns to the previous therapy mode within 2 minutes.

Proning



Proning is the process of turning a patient though a series of precise, safe motions from their back onto their abdomen so the patient is lying face down.

Prone position is used in medical settings to help patients who are compromised due to certain medical conditions with or without the need to be on mechanical ventilation.

Mattress cell valves

The cell valves enable individual cells to be inflated, deflated and/or partially deflated. For more details see Cell valves on page 16.

NOTE

The long Caylis mattress has an additional foot cell with a 2-way valve.

Set cell inflation levels

WARNING

To avoid serious injury it is important that the patients head, neck and shoulders are in the correct anatomical position.

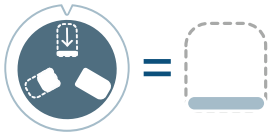
WARNING

To avoid serious injury monitor patients frequently to make sure there is no build of pressure on areas such as:

- **Head and face including eyes**
- **Top of the shoulders**
- **Sternum**
- **Breasts and genitals**
- **Knees and toes**

To set the desired inflation level for each cell, rotate the cell valve manually.

- Setting for fully deflated cell.



- Setting for partially deflated cell.

- Setting for inflated cell.

NOTE

Allow 5 minutes for the patient and the mattress to settle before making final adjustments of any supporting pillows

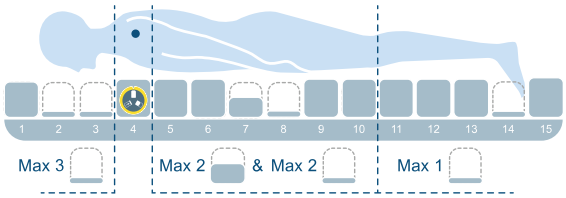
Cell levels - Prone position

WARNING

To avoid airway disruption, asphyxiation, and/or strangulation while patient is proned, make sure that all airways are viable and any tubing, or lines are not obstructing airways or entangled around the patient's neck or limbs.

For long term off-loading/pressure relief in Prone position:

- Up to three cells in the head section can be fully deflated.
- Up to two cells in the torso section can be fully deflated and an additional two partially deflated.
- No more than one cell in the foot section should be deflated.



NOTE

No more than 8 cells should be partially or fully deflated.

Prone position

These instructions are not guidelines or a substitute for hospital policies and procedures for prone positioning.

Refer to the individual facility policies and procedures for prone positioning to make sure the recommendations in these instructions are in line with local protocol.

The decision to initiate prone positioning must be authorised by the physician responsible for the patients care.

Turning a patient prone carries a degree of risk from a moving and handling perspective for both patient and clinical staff. Conduct a full assessment, in accordance with the facilities policies and procedures using positioning aids and bed side rails where necessary.

In addition, refer to the facilities pressure injury policies and procedures to ensure management of the patient's skin integrity whilst in the prone position is in line with local protocol.

NOTE

The anaesthetist or most senior member of the team responsible for the patients airway should be positioned at the head of the bed and coordinates the turning procedure. This person is also responsible for the safety of the patient's head, neck and ventilation tubing. The other members of the team helps safeguard all lines and assist with the turning procedure as directed.

NOTE

Before commencing the turn, it is recommended that all non-essential lines and monitoring equipment are disconnected in line with hospital protocol.

The Caylis mattress has features to help caregivers manage the patient in prone position.

The proning mode is activated from the screen on the pump and by manually adjust the cell valves located on the side of each mattress cell. The cells are designed to help off-load pressure when the patient is in prone position.

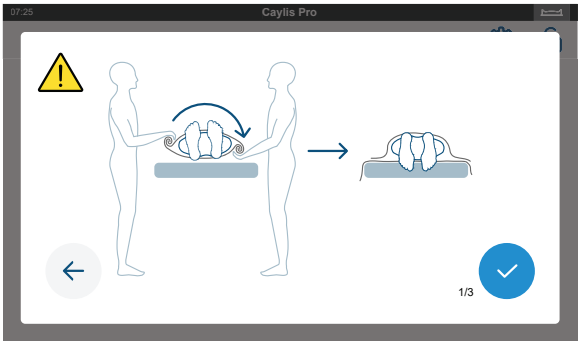
The most appropriate valves to select to off-load pressure depend on the patient's size and weight distribution.

Activate Proning

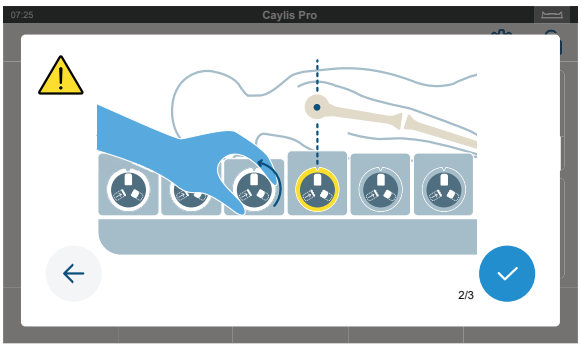
1. Optional - Tap and then tap to activate Autofirm. This provides a flat, firm surface to help facilitate repositioning into the prone position.
2. Tap .
3. Tap .

   A series of confirmation screens appears to guide the procedure. Tap to confirm each step.

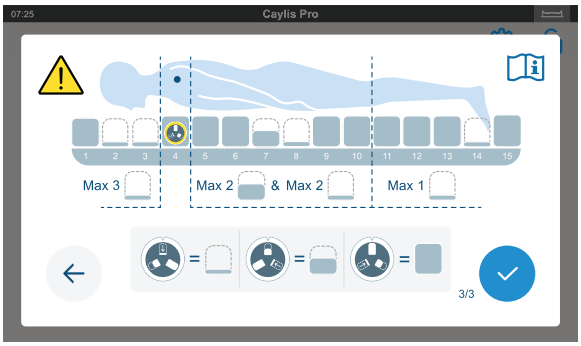
4. Make sure the patients shoulders are located on the fourth cell.
5. Optional - Rotate the cell valves to fully deflated position on all three head cells. Make sure the head is supported and airways protected during activation.
6. Follow your facility policies and procedure for prone position procedure to facilitate repositioning and managing the patient in prone position.



7. When the patient is turned to prone position make sure all lines, tubes, and drainage bottles etc. remain connected. Make sure patient's head, including Endo Tracheal (ET) tube is adequately supported.
8. Check that the shoulders are still in line with the fourth cell.



9. The cells can be adjusted to meet patient requirements. See Cell levels - Prone position on page 32 for details on how the cells can be adjusted. Once adjusted tap the ✓ to activate proning mode.



NOTE

While the patient is in prone position, the bed frame should be kept in either flat or Reverse Trendelenburg position.

Deactivate Proning

Proning can be deactivated at any time.

1. Tap either on the Proning screen or alternatively to exit prone.

   A pop up will appear on the screen to advise that all cells should be re-inflated to fully inflated position.

   > **NOTE**
   >
   > **If the head cells is deflated, make sure a clinician is responsible in ensuring the head is supported and airway protected when the cells are re-inflated.**

2. Make sure no body appendages are 'trapped' or 'pinched' as the cells re-inflate.
3. Optional - Tap if not already selected. Tap to activate Autofirm, to maximum inflate and firm the surface. This may help facilitate repositioning to the supine position.
4. Optional - Return the sleep deck to the flattened position to prepare for the repositioning of the patient from prone to supine.
5. Follow the facility's prone positioning procedure to facilitate repositioning of the patient from prone to supine.
6. After the patient is turned to supine position make sure all lines, tubes, and drainage bottles etc. remain connected. Make sure patient's head, including ET tube is adequately supported.

Conscious proning

Prone position for conscious patients can be considered on the Caylis Pro mattress. The decision to initiate conscious prone positioning must be authorised by the physician responsible for the patients care.

Refer to the individual facility policies and procedures for prone positioning to make sure the recommendations in these instructions are in line with local protocol.

Follow the same steps for conscious proning as the ones detailed for prone positioning.

> **NOTE**
>
> **The conscious patient is less likely to have an ET tube in place, requiring a different method of oxygen delivery. Attention to the patient's head, to make sure it is adequately supported remain a priority.**

Transport mode

The mode provides short term patient support when a power source is not available. For example when moving the bed between wards.

In transport mode the patient is supported by an air filled base layer.

> **NOTE**
>
> **The sub-mattress remains inflated for up to 12 hours, if the mattress remains connected to the pump.**

Activate Transport mode

> **WARNING**
>
> **To avoid injury, do not use the mattress as a patient transfer device**

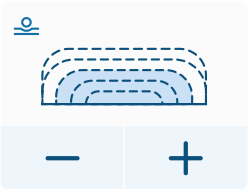
1. Touch and hold the button on the pump for 2 seconds to place it in standby mode.
2. Make sure the Mattress connector remains attached to the pump.
3. Unplug the pump power cable from the power source.

Deactivate Transport mode

1. Connect the pump power cable to the power source.
2. The pump starts normally with default settings.

> **NOTE**
>
> **It is good practice to connect the pump power cable at the destination as soon as possible. This to avoid long periods without the patient receiving full benefit of the therapeutic mattress.**

Comfort control



The comfort control allows a limited adjustment to the therapy pressure.

When the system is first switched on, the default is set to the middle comfort setting.

Adjust Comfort control

On the comfort control, tap the + and − icons to select comfort level.

- Tap + to increase the therapy pressure making the mattress firmer.
- Tap − to decrease the therapy pressure making the mattress softer.

> **NOTE**
>
> **Autofirm and Patient turn does not have comfort control. Comfort control can be selected in any other therapy mode.**

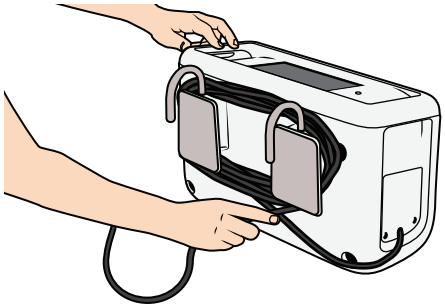
Turn-off and store the low air loss system

Turn-off the pump

1. Touch and hold the **Run/Standby** button for 2 seconds. The pump enters Standby mode.
2. Disconnect the power cable from the power source.
3. Disconnect the mattress connector.

Store the pump

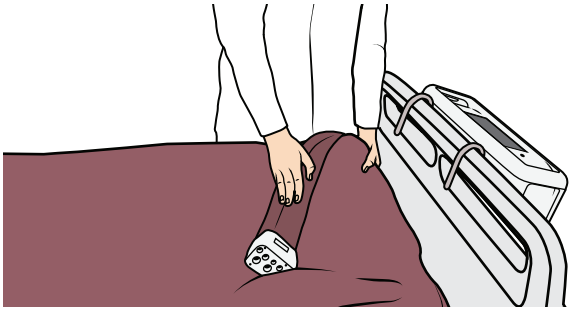
1. Clean and disinfect the pump. See section Cleaning and disinfection on page 38.
2. Wrap the power cable around the pump cable management.



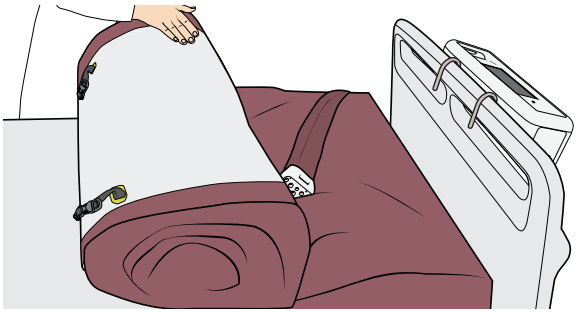
3. Store the pump in a designated area. For the storage requirements, see Transport and storage on page 50.

Deflate and store the mattress

1. Clean and disinfect the mattress according to section Cleaning and disinfection on page 38.
2. Release the mattress securing straps.
3. Place the tube-set over the mattress parallel to the foot end.



4. Roll the mattress tightly, to deflate it so it fits into the storage bag. Start at the head end and continue to the tube-set at the foot end.



5. Place the mattress in the storage bag.

The inside of the storage bag should be dry, clean and free from contamination and sharp objects.

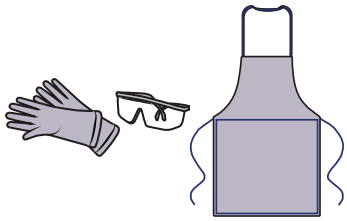
6. Store the bag in a designated area, in line with storage requirements. See Transport and storage on page 50.

Cleaning and disinfection

The product should be cleaned and disinfected at regular intervals and between patients.

Contact Arjo Customer Service for any questions regarding the cleaning and disinfection of the product.

WARNING



To avoid eye and skin injury, always use protective glasses, gloves and apron when handling disinfectant.
If contact occurs, rinse with plenty of water. If eyes or skin become irritated, contact a physician. Always read the IFU and the safety data sheet (SDS) of the disinfectant.

WARNING

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

WARNING

To avoid cross-contamination, always follow the disinfection instructions in this IFU.

WARNING

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

CAUTION

To avoid product damage:

- **Do not use Phenol-based solutions or abrasive compounds or pads during the disinfection process as these damage the surface coating.**
- **Do not autoclave or boil any part of the low air loss system.**
- **Do not immerse the pump in water.**

Equipment needed

- Protective equipment (protective glasses, gloves and apron)
- Neutral detergent (cleaning solution)
- A clean bowl with warm water
- Single use or washable clean cloths
- Detergent / disinfection wipes can be used as an alternative in line with the compatible chemical list provided.

Allowed disinfectants

DISINFECTANT	PUMP	TUBE-SET COVER	MATTRESS SYSTEM	TOP COVER	BOTTOM COVER
Isopropyl Alcohol (< 70%)	●	●	●	●	●
Chlorine (10,000 ppm[1])	●	●	●	●	●
Quaternary ammonium (1920ppm) Acceptable pH 7-10 only	●		●	●	●
Quaternary ammonium (3-10%)				●	
Hydrogen peroxide solution, <7% (pH<9)				●	

[1] Chlorine concentrations may vary from 250 ppm to 10,000 ppm depending on local policy and contamination status.

NOTE

Rinse and dry thoroughly with clean water to remove residual disinfectants after disinfecting with each disinfectant before storage

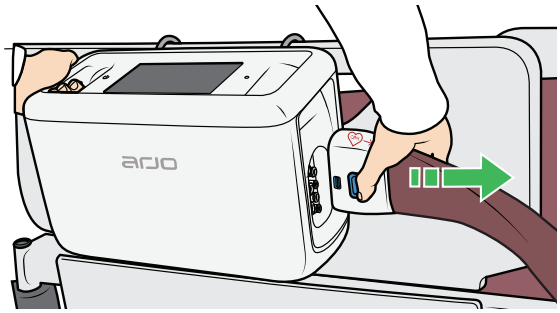
Clean and disinfect

(32 steps)

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

Prepare the pump

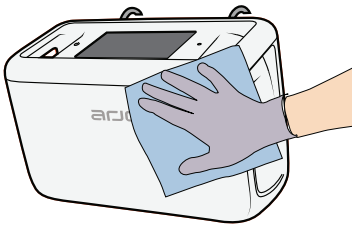
1. Disconnect the pump from the mattress.



2. Switch off the pump unit. Disconnect the pump from the power source.

Clean the pump

3. Put on protective glasses and gloves.
4. Use a clean cloth, warm water and neutral detergent (cleaning solution) to wipe down all areas of the pump, to remove any deposits or visible dirt on the pump and discard the cloth..



5. Clean any areas with residual dirt again before continuing with the cleaning and disinfectant process.

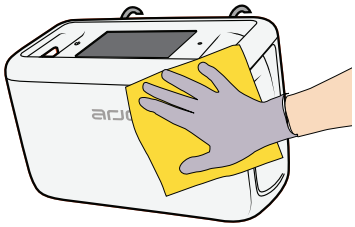
> **NOTE**
>
> **Do not use abrasive cleaning products or materials e.g. a scouring pad on the pump**

6. Use water and a clean cloth to wipe off all traces of cleaning solution.
7. Use a clean dry cloth to remove any excess moisture from the pump.

> **NOTE**
>
> **Never clean the pump by pouring water on it.**

Disinfect the pump

8. Add disinfectant solution onto a dry clean cloth. Spread the solution onto all areas of the pump.

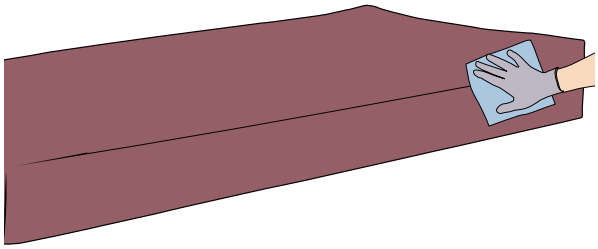


9. Allow time for disinfection according to the instructions provided by the disinfectant manufacturer.
10. Use water and a clean cloth to wipe off all traces of disinfectant solution from the pump.
11. Wipe with a clean dry cloth to remove any remaining moisture.
12. Allow the pump to air dry before reuse.

Continued on the next page

Clean the mattress

13. Use a clean cloth with warm water and neutral detergent (cleaning solution), clean off any visible soiling of the external mattress. Use a S shaped action, to avoid recontamination discard the cloth.

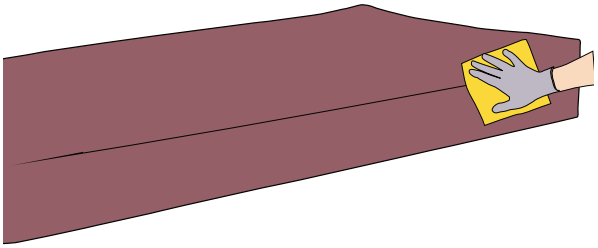


14. Clean any areas with residual dirt again before continuing with the cleaning and disinfectant process.
15. Use water and a clean cloth to wipe off all traces of cleaning solution. Followed by a clean dry cloth to remove any excess moisture.
16. If detergent wipes are used the manufacturers guidance should be followed.
17. Remove the top cover to inspect the internal components for any visual contamination and clean using the following steps.
18. Use a clean cloth with warm water and neutral detergent (cleaning solution) to wipe down the cells, bottom cover and securing straps of the mattress. Make sure the cleaning solution fully covers all the cells while wiping down.
19. Use water and a clean cloth to wipe off all traces of cleaning solution.
20. Use a clean dry cloth to remove any excess moisture from the internal components.

> **NOTE**
>
> **Never clean the mattress by pouring water on it.**

Disinfect the mattress

21. Add disinfectant solution onto a dry clean cloth. Spread the solution onto all external areas of the mattress top cover. Use a S shaped action, to avoid recontamination



22. Allow time for disinfection according to the instructions provided by the disinfectant manufacturer.
23. Use water and a clean cloth to wipe off all traces of disinfectant solution from the top cover.
24. Wipe with a clean dry cloth to remove any remaining moisture.
25. Allow the mattress top cover to air dry.
26. Remove the top cover to inspect the internal components for any visual contamination and disinfect using the following steps.

Continued on the next page

27. Add disinfectant solution onto a dry clean cloth. Wipe down the cells and bottom cover. Make sure that the solution fully covers all the cells while wiping down.
28. Allow time for disinfection according to the instructions provided by the disinfectant manufacturer.
29. Use water and a clean cloth to wipe off any remaining solution on the components.
30. Use a clean dry cloth to remove any excess moisture from the internal components.
31. Allow the internal components to air-dry before reattaching the top cover of the mattress.
32. If required, disinfect the securing straps and base of the mattress using the same method as above. The straps should be unclipped before cleaning for ease of access.

Launder

Launder the mattress top cover

1. Unfasten and remove the top cover from the mattress.
2. The top cover can be laundered at a maximum temperature of 60°C (140°F) with detergent.
3. After washing, allow the top cover to air dry (preferred) or tumble dry at 60°C (140°F) maximum.
4. Once dry refit the top cover to the mattress.

Care and preventive maintenance

Under normal use the product is subject to wear and tear. Perform the following actions when specified to make sure that the product remains within its original manufacturing specifications.

WARNING

To avoid malfunction resulting in injury, inspect your product regularly. Always follow the recommended maintenance schedule.

WARNING

To avoid injury and/or an unsafe product, the pump's case must only be removed by qualified service personnel. There are no user-serviceable parts inside the pump or the mattress.

Care and preventive maintenance schedule

CAREGIVER OBLIGATION	BEFORE EVERY USE OR EVERY WEEK	AFTER EACH PATIENT	EVERY YEAR
Perform a full functionality test on the low air loss system	●		
Visually check the Touchscreen	●		
Visually check all electrical connections and power cable	●		
Visually check the top and bottom covers	●		
Visually check the tube-set and Mattress connector	●		
Visually check the foam core (mattress extension accessory)	●		
Clean and disinfect		●	
Visually check all labels		●	
Visually check all fasteners		●	
Visually check the securing straps		●	
Visually check cell holding sheet with loop straps		●	
Yearly checks by qualified personnel only			●

Caregiver obligations - before every use or every week

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

Perform a full functionality test on the low air loss system

1. Connect the tube-set to the pump. Make sure the tube-set clicks into place.
2. Connect the power cable to a power source. The pump sounds with a start-up tone. A self-diagnostic check runs for 10 seconds.
3. Touch and hold the **Run/Standby** button to start the pump.
4. To check the alarm functionality:
    - Disconnect the tube-set from the pump while the system is switched on.
    - After 30 seconds, an alarm screen should show on the pump
    - The repeater lights should turn yellow.
5. Reconnect the tube-set to the pump to deactivate the alarm.
6. If the functionality test is not completed, call qualified service personnel.

> **NOTE**
>
> **If startup and alarm tones do not sound, check status bar to see if pump has been placed in Audio Off mode.**

Visually check the Touchscreen screen

Check that the Touchscreen is firmly affixed, undamaged and legible.

Visually check all electrical connections and power cable

- Check all electrical connections and power cable for signs of excessive wear or damage.
- Check the electrical socket for signs of excessive wear or damage.

Visually check the top and bottom covers

- Remove the top and bottom cover and check for signs of wear or any tears.
- Check that the zips are undamaged and not loose.
- Check that the zip puller is not missing.
- Look for signs of wear or any tears in the mattress extension top cover.

Visually check the tube-set and Mattress connector

- Check the tube-set for signs of excessive wear or damage.
- Check the Mattress connector for signs of excessive wear or damage.

Visually check the foam core (mattress extension accessory)

- Look for signs of wear or any tears in the foam core.

Caregiver obligations - after each patient

Clean and disinfect

The low air loss system must be cleaned and disinfected. See section Cleaning and disinfection on page 38.

Visually check all labels

Check that all labels are attached according to section Labels on page 52. If any label is missing, contact Arjo Customer Service.

Visually check all fasteners

Check that all

- Top cover fasteners are attached, undamaged and not loose.
- Cell fasteners are attached, undamaged and not loose.
- Bottom cover fasteners are attached, undamaged and not loose.

Visually check the securing straps

Check that the securing straps are secure and undamaged

Visually check cell holding sheet with loop straps

Check that:

- All loop straps are correctly connected to the cell holding sheet.
- No loop strap are loose or damaged.

Yearly Checks by Qualified Personnel only

WARNING

To avoid injury and/or an unsafe product, the product must be properly serviced at the correct frequency. All qualified service personnel must have documented training in the maintenance of this product and use the correct tools, parts and know-how.

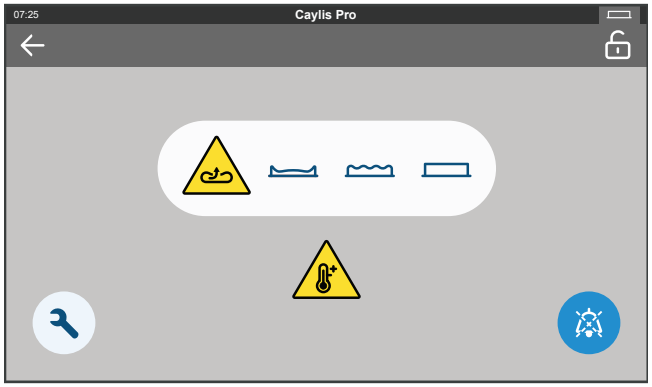
The low air loss system must be serviced once a year in accordance with the Maintenance and Repair Manual.

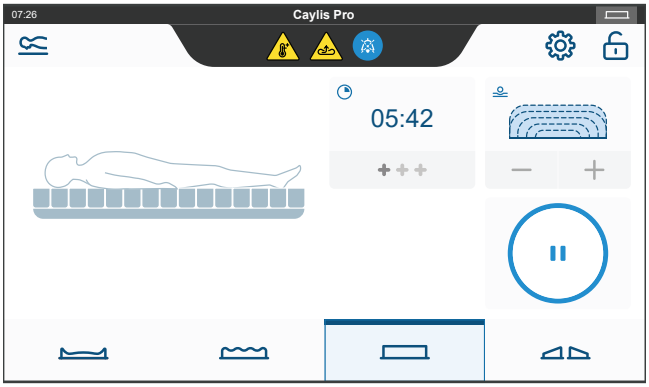
NOTE

All Caregiver Obligations are to be checked when performing the Qualified Personnel Service. For details, see separate service instructions.

Troubleshooting and alarms

When an alarm becomes active the screen displays which alarm condition has occurred on a full alarm screen. Audio can be paused by tapping the Audio Pause button in the bottom right corner. With some alarm conditions it is possible to return to the normal therapy screens by pressing the back arrow in the top left hand corner. All alarm conditions are low priority.





Once in normal therapy modes, pressing on the small alarm condition icons in the secondary mode bar brings up the full alarm screen again. After 10 minutes of no interaction with the screen, the pump also returns to the full alarm screen.

The service settings menu can be accessed from the lower left corner. Details of this can be found in the Maintenance and Repair Manual.

PROBLEM	POSSIBLE CAUSE	ACTION	ALARM ACTIVATION DELAY
Low pressure Low pressure Patient turn Low pressure automat	• The Mattress connector is not connected properly. • There is a leak in the system.	1. Tap Audio pause if required 2. Check that the Mattress connector is correctly connected to the pump (an audible click should be heard when correctly connected). 3. If alarm continues, contact qualified service personnel	5 minutes Low pressure Patient turn: 2 minutes Low Pressure automat: 1 minute
Connector disconnected alarm	The connector is loose or not connected to the side of the pump.	1. Push in the connector firmly to the side of the pump. See Assemble the pump on page 24 2. If alarm continues, contact qualified service personnel	Less than 1 second
Service alarm	The low air loss system has detected a fault. Pump is no longer in operation.	1. Switch the pump off and restart it. 2. If alarm continues, contact qualified service personnel	Less than 1 second

PROBLEM	POSSIBLE CAUSE	ACTION	ALARM ACTIVATION DELAY
Bed exit alarm	The patient weight is not detected on the mattress.	1. Aid the patient. 2. Tap pause bed exit alarm screen 3. Once patient is laying back on mattress re-activate the bed exit alarm if required.	Less than 5 seconds.
High temperature	The pump is operating outside its internal temperature range (40°C, 104°F).	1. Tap Audio pause if required 2. Turn off the pump. 3. Disconnect the power cable. 4. Check the position of the pump: • Is it near a heat source? • Is it in the sun? • Is it covered up? 5. If any of above apply, move or uncover the pump. 6. Wait for 5 minutes. 7. Reconnect the power cable to the power source. 8. Turn on the pump. 9. If the alarm continues, contact qualified service personnel.	Less than 5 seconds
Power fail Symbol relates to colour of Run/Standby button	• Pump has stopped working. • Plug has been taken out without tapping the run/ standby button	1. Check if power is available. Check the power cable for damage. Check that the cable is connected to wall outlet. **NOTE** **If power returns the pump will resume therapy, however if power fails during Autofirm or Patient turn, the pump will return to CLP therapy.** 2. If alarm continues, contact qualified service personnel.	Less than 1 seconds. The alarm can remain active for a minimum of 3 minutes when power is lost.
Blank screen	• Power Failure • Screen fault	1. Check if power outlet is working 2. If screen does not show image after checking power outlet contact qualified service personnel.	N/A

PROBLEM	POSSIBLE CAUSE	ACTION	ALARM ACTIVATION DELAY
Liquid spill on the therapy unit:	Accidental contact	1. Disconnect the unit from mains power 2. Clean fluid from the case 3. Make sure there is no moisture in or near the screen, power outlet, power switch and power plug before reconnecting the power supply 4. Check the operation of controls and other components in the area of the spill 5. Fluids remaining on the electronic controls can cause corrosion that may cause the electronic components to fail. Component failures may cause the unit to operate erratically, possibly producing potential hazards for patients or caregivers. 6. Prolonged contact with the therapy unit may result in hazard to the patient or caregiver.	N/A
Lock out mode	• The pump has been manually put into Lock out mode. • No interaction to pump detected for 60 seconds after completion of power up.	1. Touch and hold the unlock symbol for two seconds this unlocks the LCD screen	N/A
No audio	• Audio has been turned off by the responsible organisation. The Audio Off icon shows in the status bar. • System fault, speaker malfunction.	1. Contact responsible organisation to activate Audio On if required. **NOTE** **The Audio ON/OFF switch should only be used by qualified service personnel under direction of the responsible organisation.** 2. Contact qualified service personnel.	N/A

Technical specifications

LCD USER INTERFACE	
Display type	LED Backlit LCD touchscreen
Finish	Colour display
Size	Screen active area is 154 mm x 86 mm
Resolution	Minimum resolution of 1024 x 600
Viewing angle	160°

GENERAL - PUMP	
Model:	Caylis
Case material:	PC-ABS
Part number:	675XXX (xxx is determined by the type of power cable fitted. Please refer to rear label for actual part number)
Size:	Length 412 mm x Height 264 mm x Depth 210 mm
Weight (with mains cable):	5.2 kg (11.4 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:	IP22 Protection from touch by fingers and objects greater than 12 millimetres. Protected from water spray less than 15 degrees from vertical
Mode of operation:	Continuous
Pulsation Mode Cycle Time:	2, 5, 10 minutes

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 pump is stored in conditions outside the operating ranges, allow time for its temperature to stabilise at room temperature before use. Allow a minimum of 8 hours if the pump is stored at -20°C (-4°F) or 60°C (140°F).	

TRANSPORT AND STORAGE	
Short term (Up to 30 days):	
Temperature (Ambient)	-20°C to 60°C (-4°F to 140°F)
Relative humidity range	10% to 85%
Long term (> 30 days):	
Temperature (Ambient)	0°C to 40°C (32°F to 104°F)
Relative humidity range	10% to 85% (non-condensing)
CAUTION **To avoid damage to the low air loss system:** • **Do not store in direct sunlight.** • **Store the pump and mattress in the protective bags supplied.**	

EXPECTED SERVICE LIFE	
Pump	7 years

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 (WEE) or in accordance with local or national regulation.

ALLOWED COMBINATIONS	
Caylis Pro mattress	Mattress extension

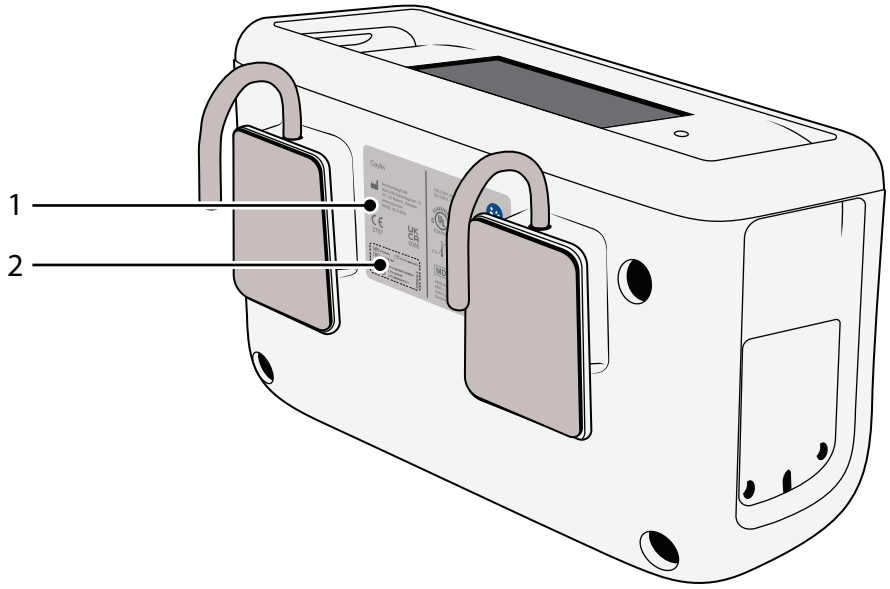
MEASUREMENTS AND COMPATIBILITY				
Part no	**Size mm (in)**	**Top cover material**	**Weight kg (lb)**	**Arjo bed frames**
675802	2020 x 880 x 200 (80 x 35 x 8)	Nylon 70D tricot 20D	12.6 (27.8)	Contoura C880, Enterprise 5000X, 8000X, 9000X (Standard), Citadel (Standard)
675803	2140 x 880 x 200 (84 x 35 x 8)	Nylon 70D tricot 20D	13.1 (28.9)	Enterprise 5000X, 8000X, 9000X (Extended), Citadel (Extended)
Weight includes storage bag of weight 0.46kg (1lb). Dimensions for storage bag when packed are: L=1500 mm (59 in) x W=500 mm (20 in) x H=440 mm (17 in). When the Patient turn mode is activated the max mattress height is 260 mm (10 in).				

TOP COVER SPECIFICATION	
Features	**Nylon 70D tricot 20D**
Removable Cover	Yes
Moisture Vapour Permeable MVTR - Index method BS3424-34	Yes
Polyurethane coating includes an antimicrobial agent to control microbial deterioration of fabric	Yes
Fire Retardant[1]	TBC
Material stretch properties	2- way
Recommended wash Temperatures	60°C (140°F)
Maximum wash Temperatures	60°C (140°F)
Recommended Drying Temperatures	Tumble dry 60°C (140°F) or air dry
Maximum Drying Temperatures	Max 60°C (140°F)

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

Labels

Labels on the Pump

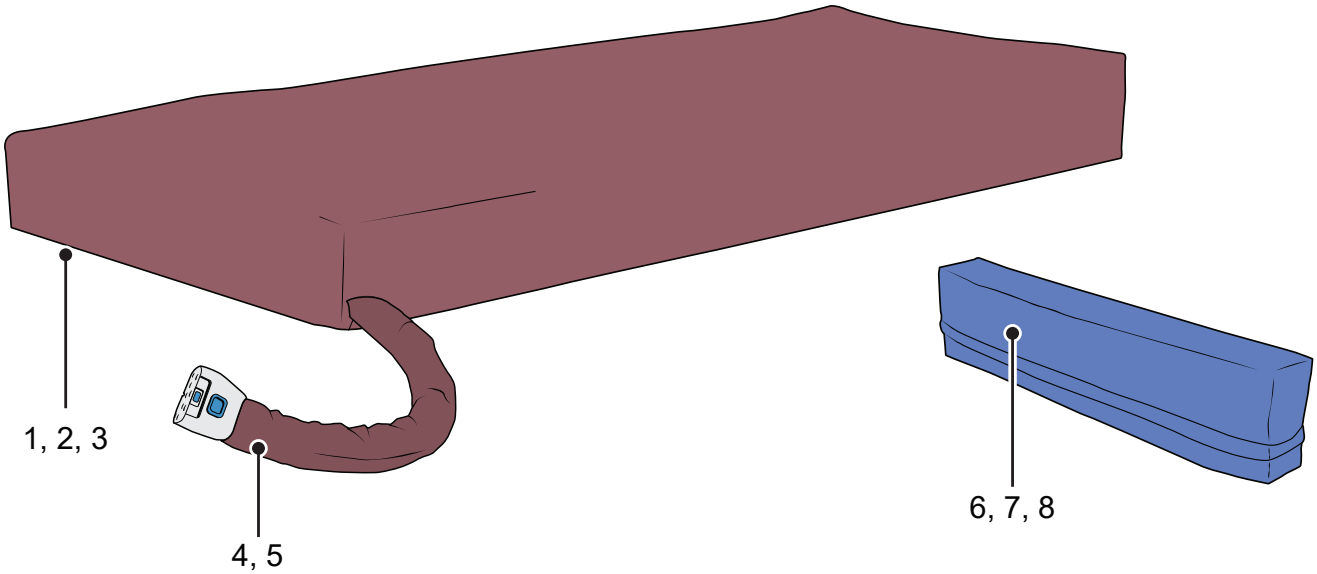


1. Product label - States technical performance and requirements, e.g. input power and input voltage. States storage requirements.
2. Serial number label -States the item identification

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.	

SYMBOL EXPLANATION	
	Refer to instruction manual/ booklet - Instructions for use should be read
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
˚C ˚C	Temperature limitation To indicate the temperature limitations for the product during usage
hPa hPa	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

Labels on the mattress



1. Mattress ID label (inside the bottom cover) - States the product identification and product weight
2. Top cover label (inside the top cover) - States the identification and maximum patient weight
3. Care and cleaning label
4. Connector Tube set Label
5. Cleaning label
6. US law tag (inside the mattress extension) - States certification of flammability test
7. Canadian law tag (inside the mattress extension)
8. Mattress extension ID label (inside the mattress extension) - States the product identification and product weight

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	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.	

SYMBOL EXPLANATION	
	Operating instructions - Consult Instructions for use
	CE marking indicating conformity with European Community harmonized 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
= kg (lb)	Safe working load defines the maximum total load of the patient kg (lb) (mattresses)
= kg (lb)	Product weight (surface)
60	Recommended wash temperature: 15 min at 60 °C (140 °F)
60°C	Tumble dry at 60 °C (140 °F)
	Do not iron
	Wipe surfaces with cleaning solution, then wipe with a cloth moistened with water and dry
H	Identifies the facility and ward where the surface is used
1	The date when the surface was fitted to current bed frame or seat.
Cl 1000 ppm NaOCl NaDCC	Use solution diluted to 1000 ppm of Available Chlorine
PHENOL	Do not use Phenol-based cleaning solutions
UDI	Unique Device Identifier

Electromagnetic compatibility

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

This product complies with the requirements of applicable electromagnetic compatibility (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 decreased immunity of the product, or increased emissions from the product. This would affect the products performance.
- Portable and mobile radio frequency (RF) communications equipment (e.g. mobile/cell phones) can affect medical electrical equipment.
- If this product 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 product is not recommended, it can interfere with the product's operation and safety. Portable and mobile radio frequency (RF) communications equipment can interfere with this product operation and safety.

WARNING

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

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSION		
The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions	Group 1	The pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions	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.
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 pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic 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, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 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 pump is used exceeds the applicable RF compliance level above, the pump should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as re-orientating or relocating the 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 COMMUNICATION EQUIPMENT AND THE PUMP

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

Rated maximum output power of transmitter - W	Separation distance according to frequency of transmitter - m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	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 pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should ensure 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 % µT (>95 % dip in µT) for 0.5 cycle 40 % µT (60 % dip in µT) for 5 cycle 70 % µT (30 % dip in µT) for 25 cycles <5 % µT (>95 % dip in µT) for 5 s	<5 % µT (>95 % dip in µT) for 0.5 cycle 40 % µT (60 % dip in µT) for 5 cycle 70 % µT (30 % dip in µT) for 25 cycles <5 % µT (>95 % dip in µT) for 5 s	Mains power quality should be that of a typical domestic commercial or hospital environment. If the user of the pump requires continued operation during mains power interruptions, it is recommended that the 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: µT is the a.c. mains voltage prior to application of the test level			

Regulatory compliances

REGULATORY COMPLIANCES:

FCC Conformity section

FCC ID: 2BBKF675003
IC: 30708-675003

Also contains radio module with the following approvals:

FCC ID: SQG-EWB1
IC: 3147A-EWB1

US FCC compliance statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications not expressly approved by ArjoHuntleigh AB could void the user's authority to operate this equipment.

This device complies with FCC RF exposure limits for general population / uncontrolled environments. A separation distance of at least 20 cm must be maintained between the antenna and all persons. This device must not be co-located with any other antenna or transmitter.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

ISED Conformity.

Canada ISED compliance statement

This device complies with ISED Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

This Class B digital apparatus complies with Canadian ICES-003.

Le présent appareil est conforme aux CNR d'ISDE Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Cet appareil numérique de la classe B est conforme à la normeNMB-003 du Canada

REGULATORY COMPLIANCES:

This device complies with ISED RF exposure limits for general population / uncontrolled environments. A separation distance of at least 20 cm must be maintained between the antenna and all persons. This device must not be co-located with any other antenna or transmitter.

Cet appareil se conforme aux normes ISED sur les limites d'exposition aux radiofréquences pour la population générale et environnements non controllés. Une distance minimale d'au moins 20cm doit être maintenue entre l'antenne et toute personne. Cet appareil ne doit pas être co-localisé avec toute autre antenne ou transmetteur.

EU and UK conformity section

Connectivity	Operating Frequency	Max Power Output
RFID	13.56 MHz	< 50 dBuV/m @ 3m
Wi-Fi	2.4 - 2.483.5 GHz	< 20.0 dBm EIRP
BT	2.4 - 2.483.5 GHz	< 10.0 dBm EIRP

This product complies with the following standards:

EN 301 489-1 v2.2.3, EN 301 489-17 v3.2.4, EN 300 328 v2.2.2, EN 300 330 v2.1.1

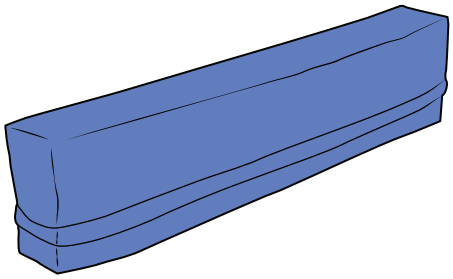
This product complies with the following safety standards:

EN 60601-1, EN 60601-1-2

ArjoHuntleigh AB as the manufacturer of this medical device, takes sole responsibility and declares conformity with the applicable provisions of EU Directive 2014/53/EU and the UK Radio Equipment Regulations 2017. Full Declarations can be found at: www.arjo.com

This device is intended for indoor use only.

Parts and accessories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At Arjo, we believe that empowering movement within healthcare environments is essential to quality care. Our products and solutions are designed to promote a safe and dignified experience through patient handling, medical beds, personal hygiene, disinfection, diagnostics, and the prevention of pressure injuries and venous thromboembolism. With over 6500 people worldwide and 65 years caring for patients and healthcare professionals, we are committed to driving healthier outcomes for people facing mobility challenges.

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