INSTRUCTIONS FOR USE

Flowtron ACS900

526933EN_G • 06/2019

arjo
with people in mind

WARNING

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

Mandatory to read the Instructions for Use

Contents

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GENERAL SAFETY

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

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

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

Safety Warnings

- **It is the responsibility of the caregiver to ensure that the user can use this product safely.**
- **Make sure that the mains power cable and tubeset or air hoses are positioned to avoid causing a trip or other hazard, and are clear of moving bed mechanisms or other possible entrapment areas.**
- **Electrical equipment may be hazardous if misused. There are no user-serviceable parts inside the pump. The pump's case must only be removed by authorised technical personnel. No modification of this equipment is allowed.**
- **The mains power socket/plug must be accessible at all times. To disconnect the pump completely from the electricity supply, remove the plug from the mains power socket.**
- **Disconnect the pump from the mains power socket before cleaning and inspecting.**
- **Keep the pump away from sources of liquids and do not immerse in water.**
- **Do not use the pump in the presence of uncontained flammable liquids or gasses.**
- **Only the pump and garment combination as indicated by Arjo should be used. The correct function of the product cannot be guaranteed if incorrect pump and garment combinations are used.**
- **The Flowtron® ACS900 system is NOT intended for use in the home healthcare environment (for example private dwellings).**

Caution (applicable to the USA market only)

- **US Federal law restricts this device to sale by or on the order of a physician.**

Precautions

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

- Do not expose the system to open flames, such as cigarettes, etc.
- Do not store the system in direct sunlight.
- Do not use phenol-based solutions to clean the system.
- Make sure the system is clean and dry prior to use or storage.
- 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.

Electromagnetic Compatibility (EMC)

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

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

Expected Service Life

The pump has an expected service life of seven years. To maintain the condition of the pump have the pump serviced regularly according to the schedule recommended by your Arjo distributor.

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

End of Life Disposal

- Garment material or any other textiles, polymers or plastic materials etc. should be sorted as combustible waste.
- Pump units have electrical and electronic components should be disassembled and recycled per Waste of Electrical and Electronic Equipment (WEEE) or in accordance with local or national regulation.

1. Introduction

About this Manual

This manual is your introduction to the *Flowtron* ACS900 system.

You must read and fully understand this manual before using the system.

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

If you have any difficulties in setting-up or using the *Flowtron* ACS900 system, contact your local Arjo sales office, listed at the end of this manual.

Intended Use

The intended use of this product is to help prevent Deep Vein Thrombosis (DVT). The garments are single patient use - do not re-use. It is not for use in the home healthcare environment.

The *Flowtron* ACS900 system should be used as part of a prescribed plan of care (refer to “Indications” on page 3).

About the *Flowtron* ACS900 System

The application of external pneumatic compression has two effects:

- Augments venous blood flow velocity, thereby reducing stasis.
- Enhances fibrinolytic activity to reduce the risk of early clot formation.

The system is comprised of a pump that can be used in conjunction with an extensive range of Arjo inflatable uniform (DVT), sequential (Tri Pulse) and foot garments. Refer to “Accessories” on page 28 for a complete list of the calf, calf & thigh and foot garments which can be used with the *Flowtron* ACS900 pump.

The pump automatically adjusts to the correct therapy profile depending upon which garment type is connected.

The tubeset is integral to the system and cannot be disconnected from the pump.

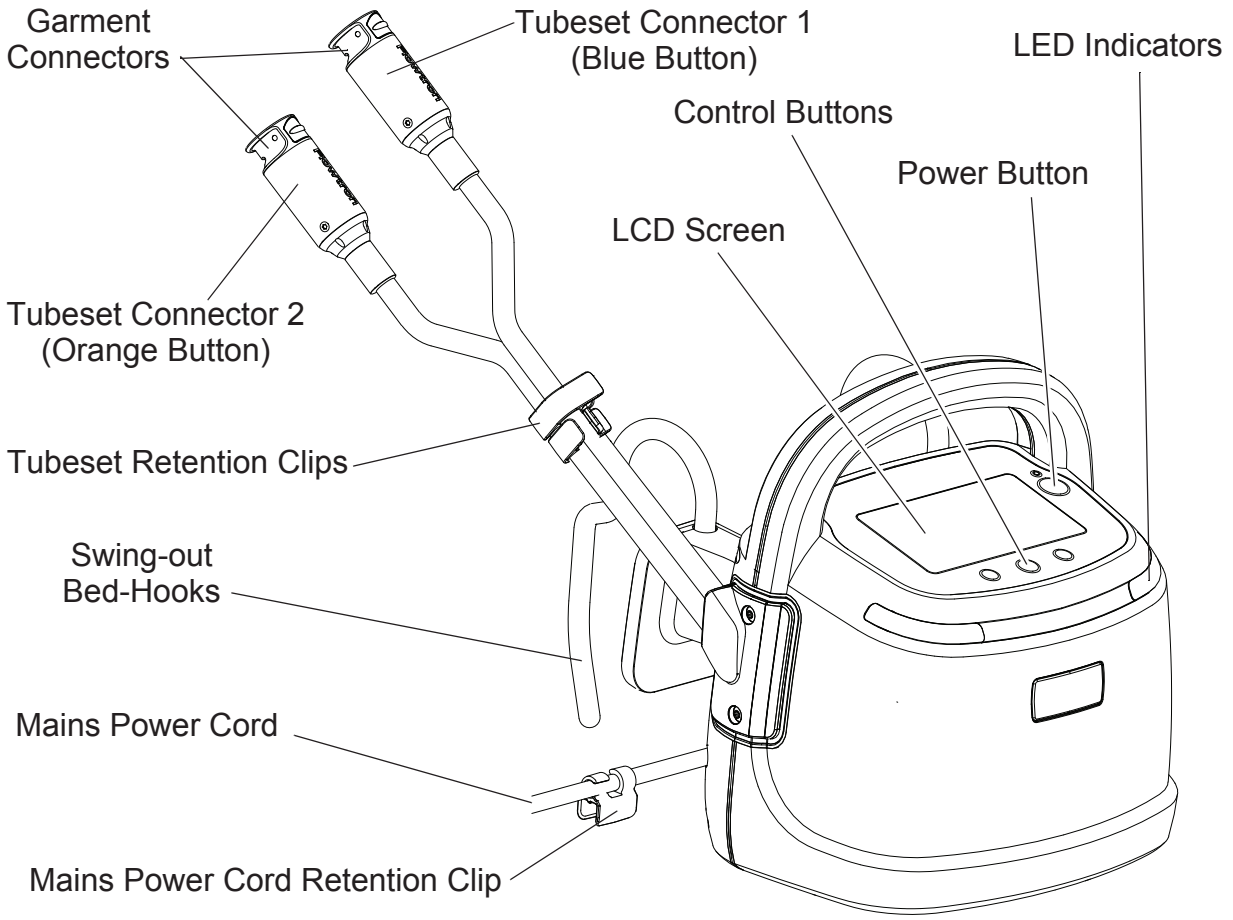
The mains power supply is the primary power source for the pump. The pump incorporates an internal battery, which is a secondary power source to back up the pump in the event of failure of or disconnection from (accidental or deliberate) the mains power supply.

The *Flowtron* ACS900 system is intended for use ONLY in professional healthcare facilities. It is not

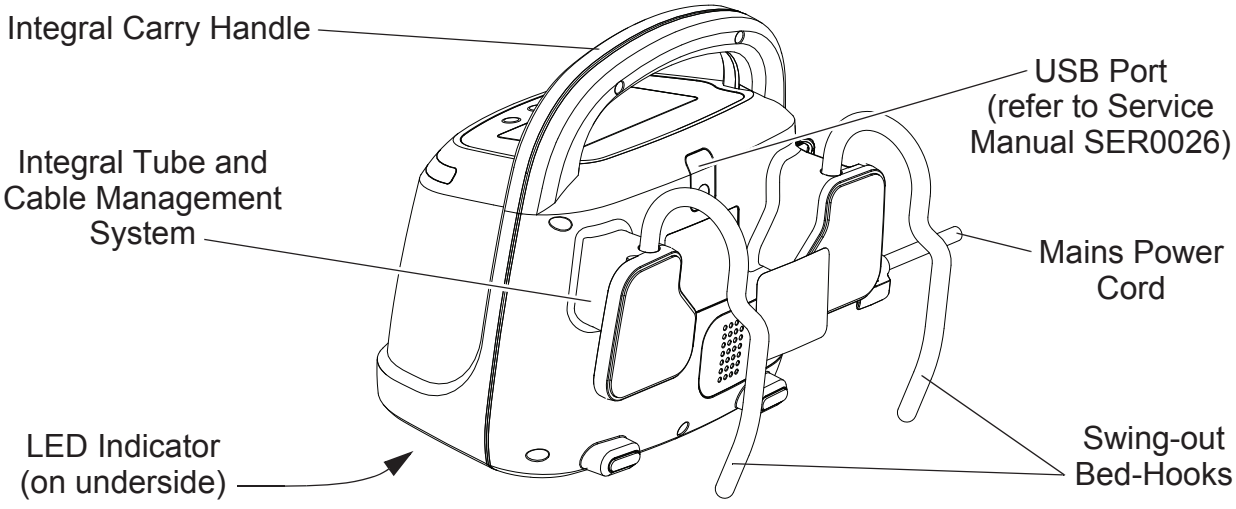
intended for use in the home healthcare environment (for example private dwellings).

A full technical description of the *Flowtron* ACS900 system can be found in the *Flowtron* ACS900 Service Manual, part number SER0026, available from your local Arjo sales office.

Pump: Front View



Pump: Rear View



2. Clinical Applications

Indications

The intended use of the *Flowtron* ACS900 system is to help prevent Deep Vein Thrombosis (DVT).

The system should be combined with an individualised monitoring programme.

This system represents one aspect of a DVT strategy; if the patient's condition changes, the overall therapy regimen should be reviewed by the prescribing clinician.

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

Depending on the garment type used, other clinical applications are also appropriate.

The foot garment, in particular, has a wide range of clinical applications.

Full details for clinical applications are included in the packaging of every garment.

The type of garment used on an individual patient must be specified by a physician.

Contraindications

Uniform & Sequential Calf and Calf & Thigh Garments

The system, when used with calf or calf & thigh garments, should **not** be used in the following conditions:

1. Severe arteriosclerosis or other ischemic vascular diseases.
2. Severe congestive cardiac failure or any condition where an increase of fluid to the heart may be detrimental.
3. Known or suspected acute deep vein thrombosis, thrombophlebitis or pulmonary embolism.
4. Any local condition in which the garments would interfere, including:
   - Gangrene
   - Recent skin graft
   - Dermatitis
   - On untreated, infected leg wounds.

Foot Garments

The system, when used with the foot garments, should **not** be used in the following conditions:

1. Severe congestive cardiac failure or any condition where an increase of fluid to the heart may be detrimental.
2. Known or suspected acute deep vein thrombosis, thrombophlebitis or pulmonary embolism.

3. Any local condition in which the garments would interfere, including:
   - Gangrene
   - Recent skin graft
   - Dermatitis
   - On untreated, infected leg wounds

+ *If you are unsure of any contraindications refer to the patient's physician before using the device.*

Cautions

1. Proper garment application and connection to the pump is essential.
2. Garments should be positioned in such a way that they do not create any potential for constant pressure points on the patient's limb. If using apparatus with straps or securing devices, for example lithotomy stirrups, make sure that the tubing is not placed inside the strap next to the patient's skin, and regularly check the patient's skin for signs of redness or pressure points. The garment is most effective in preventing venous stasis when the garment air bladders are located in the posterior position. If the air bladders cannot be placed at the posterior, the garment can be rotated around the calf to alternative positions all of which will still help to prevent venous stasis.
3. Lower limb positioning in relation to the garment and tubing should also be considered particularly in a patient that is unconscious, cannot feel or has reduced sensation and/or ability to move their leg(s).
4. The patient's skin should be inspected frequently during every shift.

+ *Many patients are at risk for pressure ulcers on the heel. Use of the foot garments does not negate the necessity for heel protection and appropriate skin care.*

5. Clinical judgement is required to determine if the patient's skin condition requires additional protective measures, or if the therapy should be discontinued and an alternative modality used.
6. Garments should be removed immediately if the patient experiences tingling, numbness, or pain, and the physician notified.

7. When used for DVT prevention, continuous external pneumatic compression is recommended until the patient is fully ambulatory. Uninterrupted use of the system is encouraged.
8. The system should be **USED WITH CAUTION** on patients with:
   - Insensitive extremities.
   - Diabetes.
   - Impaired circulation.
   - Fragile or impaired skin.

+ *These are guidelines only and should not replace clinical judgement and experience.*

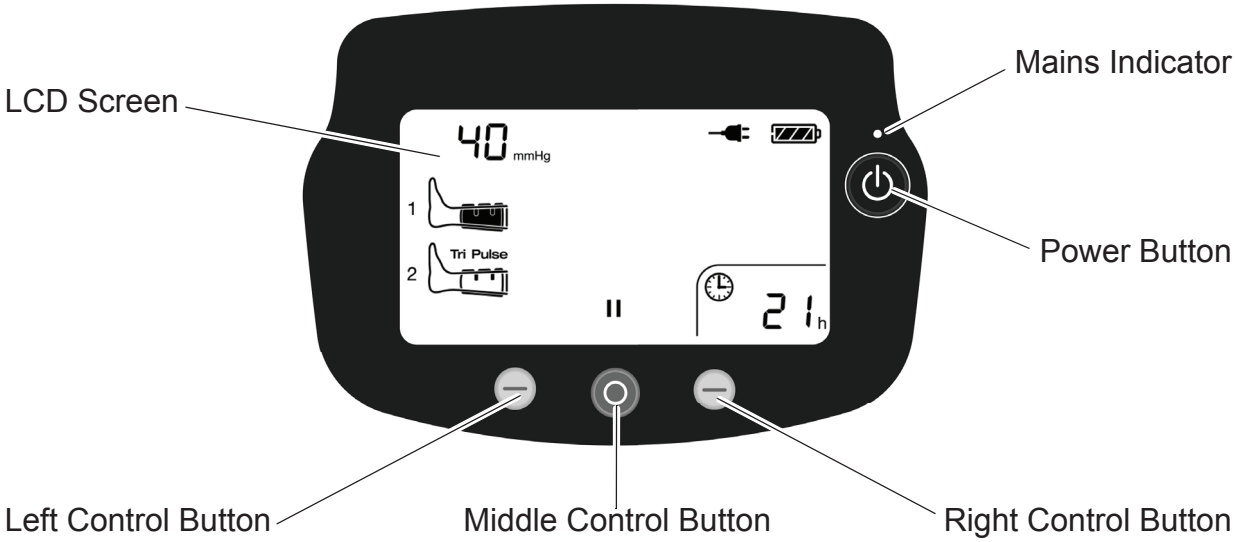
Guidelines and Recommendations

General Recommendations

- The system should be initiated immediately once the risk of DVT formation is identified and the plan of care has been prescribed.
- If compression stockings are ordered by the physician, the clinician should ensure that the compression stockings are properly measured, applied and worn by the patient. Any compression stocking used should be routinely checked to ensure continued proper fit and application, in addition to assessing the condition of the skin.
- Where appropriate, patients should be instructed in the proper use of the system, the purpose of therapy and that any problems should be reported to the nursing staff.
- For surgical patients, the system should be applied to the patient preoperatively, prior to the induction of anaesthesia.
- The system should be used continuously for no less than 72 hours post-operatively or until the patient becomes fully ambulatory.
- If the garment cannot be applied to the operative limb during surgery, it may be applied to the limb once the patient reaches the recovery unit.

3. Controls, Alarms and Indicators

Control Panel with Typical LCD Screen View in Run Mode



Power Button and Mains Indicator

To switch the pump on:

- Connect the pump to mains power and the pump will run its internal diagnostic tests and go to Standby (refer to "Standby Screens" on page 12).
- If the pump is already connected to mains power, press and hold the Power button for approximately 2 seconds, and the pump will go directly to Standby.
- If the pump is not connected to mains power, press and hold the Power button for approximately 2 seconds, and the pump will run its internal diagnostic tests and go to Standby.

The Mains indicator above the Power button shows the mains power status of the pump:

- Extinguished: mains power is disconnected.
- Illuminated green: mains power is connected to the pump.

To switch off the pump, press and hold the Power button for approximately 2 seconds. Then,

- If the pump is connected to mains power, the LCD screen backlight will be extinguished and only the mains power and battery indication icons will be displayed. Release the button.
- If the pump is not connected to mains power, the pump will power down and the LCD screen will be blank. Release the button.

Middle Control Button

When the pump is in Standby and one or two garments are connected, press this button to put the pump into the Run mode and start therapy; the LED indicators on the front and underside of the case will be illuminated green.

To stop the therapy and put the pump into Standby, press and hold this button for approximately 2 seconds until the Standby screen is displayed and then release the button. The LED indicators on the front case will be extinguished.

Left Control Button

If an audible alarm sounds during therapy, press this button to mute the audible alarm.

+ *Only certain alarms can be muted.*
+ *Refer to "Troubleshooting" on page 22 for details of the various alarm conditions and possible corrective actions to rectify the faults.*

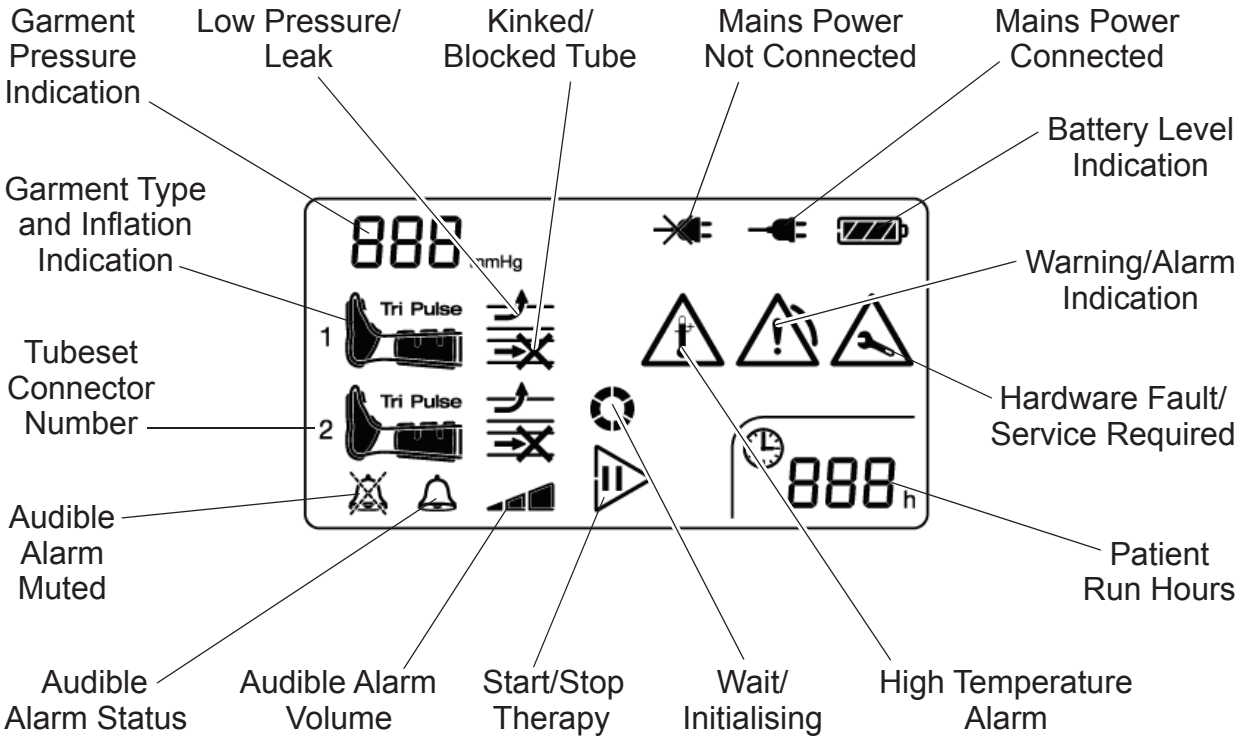
When the pump is in Standby, press this button to change the alarm volume (refer to "To Change the Audible Alarm Volume Setting" on page 18).

Right Control Button

Press this button to reset the patient run hours. This can be done either at power up, after the pump has initialised or if the therapy is stopped and the pump is in Standby (refer to "Resetting the Patient Run Hours" on page 19).

LCD Screen Icons

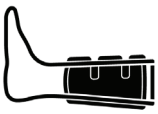
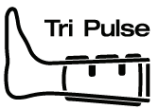
This screen shows the position and description of all possible icons which can be displayed. The actual icons which will be displayed will depend on the pump status, patient therapy and whether a fault has been detected.



Garment Type and Inflation Indication

These show which garment type is connected to each tubeset and when each garment is being inflated.

+ *A garment connected but not inflated is shown as an outline on the leg icon. When it is inflated, the garment outline is filled in black.*

Garment	Connected and Not Inflated	Connected and Inflated
Foot		
Uniform (DVT) Calf (or Calf & Thigh)		
Sequential (Tri Pulse) Calf (or Calf & Thigh)		

Tubeset Connector Number

The garment connector on the end of each tubeset has a push button which is colour-coded and has a number marked on it: blue “1” or orange “2”. The numbers correspond with the “1” and “2” on the left side of the LCD screen adjacent to the leg icons.

Start/Stop Therapy

The icon above the Middle Control button changes between Run and Standby modes, as follows.

	Start Therapy icon. In normal operation, this icon is displayed when the pump is in Standby and at least one garment is connected. Press the button to start therapy.
	Stop Therapy icon. In normal operation, this icon is displayed when the pump is in Run mode. Press the button to stop therapy.

Garment Pressure Indication

The default target inflation pressure for each garment is as follows:

- Foot: 130 mmHg.
- Uniform calf and calf & thigh: 40 mmHg.
- Sequential calf and calf & thigh: 45 mmHg.

Mains Power Indication

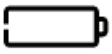
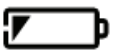
	The pump is connected to the mains power supply.
	The pump is NOT connected to the mains power supply.

Battery Indication

When the pump is connected to the mains power supply:

- If the battery is fully charged, the indicator will be static and show “full”.
- If the battery is not fully charged, the indicator will scroll from “Battery Empty” to the current battery capacity for example “Battery ½ Full”, to indicate that the pump is being charged.

When the pump is NOT connected to the mains power supply, the indicator is static and shows the approximate charge remaining in the battery.

	Battery Empty		Battery ¼ Full
	Battery ½ Full		Battery ¾ Full
	Battery Full		

+ *If the pump is not connected to the mains power supply and the battery is fully charged and in good condition, the pump will continue to operate normally for approximately 12 hours for calf and calf and thigh garments, and for approximately 6 hours for foot garments.*
+ *The battery has a service life of 5 years (approximately 600 charge cycles). It is not user replaceable and must be replaced as part of the service procedure.*

Wait/Initialising

This is a rotating 6-segment circular icon, which indicates that the pump is initialising after power up.

Patient Run Hours

This shows the total pump run time in hours. Refer to “Resetting the Patient Run Hours” on page 19 to clear the patient run hours.

+ *This is the pump run time since the patient run hours was last reset.*

Audible Alarm Status

When an alarm which is able to be muted is shown on the LCD screen, this icon is shown to indicate that the alarm can now be muted.

When the pump is in Standby, this icon indicates that the alarm volume can be changed (refer to "To Change the Audible Alarm Volume Setting" on page 18).

Audible Alarm Muted

This icon indicates that the audible alarm has been muted.

Warning and Alarm Indications

The following five icons indicate that a fault has been detected in the system. Refer to "Troubleshooting" on page 22) for a list of fault conditions, the corresponding warning and alarm indications, and possible corrective actions to rectify the faults.

	Alarm detected which may cause an interruption in therapy.
	Low pressure or garment leak.
	Kinked or blocked tubeset.
	High temperature.
	Hardware fault detected or periodic service required.

LED Indicators on the Pump Case

There are additional LED indicators on the pump to show pump status and alarms:

- Two sets on the front of the pump.
- One set on the underside of the pump.

Their status is as follows:

LED Colours	Pump Status	Warnings/Alarms
Extinguished	Off or Standby	- -
Green	Run	• No fault detected. • Warning only detected.
Yellow	Run	Fault detected with full audible and visual alarm.

4. Operation

General

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

Refer to "Controls, Alarms and Indicators" on page 6 for a description of the controls, indicators and LCD screen.

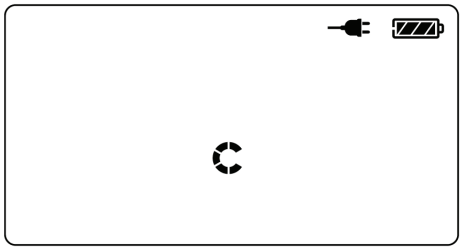
+ *If the operation or performance of the pump changes during use, refer to "Troubleshooting" on page 22 of this IFU before calling a service engineer or contacting your local Arjo sales office.*

Installing the Pump

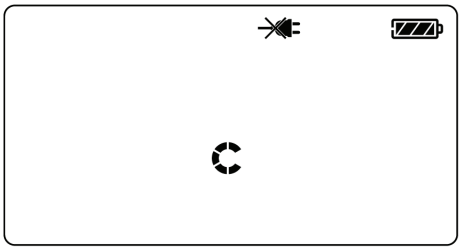
1. The pump should be placed feet down on any convenient horizontal surface or alternatively suspend the unit with the use of bed hooks (integral hanging brackets).
2. Beyond placing the pump on the bed frame or on the floor, the use of IV Pole Bracket or Wall Bracket should be considered.
3. Depending on the therapy environment, the pump may also be secured with the use of alternative solutions, such as the additional bracket mounted to the bed frame. The appropriate solution should be chosen to ensure patient safety.

Start Up

1. To switch on the pump, do one of the following:
   - Connect the pump to the mains power supply using the power cable provided.
   - If operating on battery (the pump is disconnected from the mains power supply), press the Power button.
2. The pump will power up automatically and start running a diagnostic test and initialising the pump. One of the following screens will be displayed, with a rotating 6-segment circular icon:



Mains Power Connected

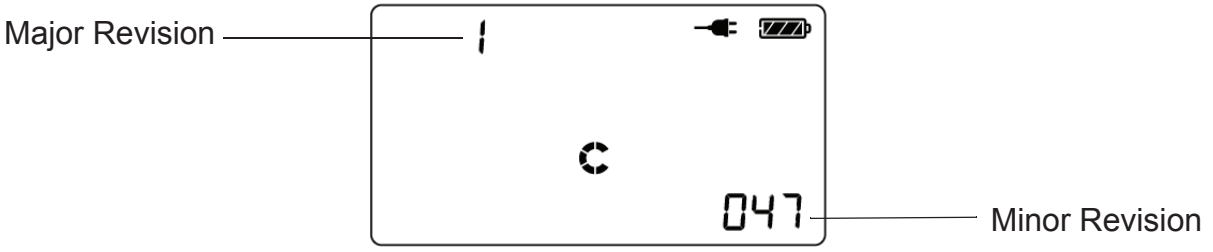


Mains Power Disconnected

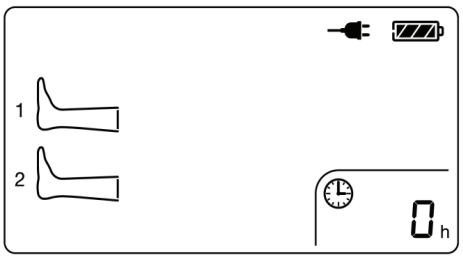
3. During the last part of the initialisation process, the software version will be displayed, comprised of:

- Major revision in top left.
- Minor revision in bottom right.

This screen shows software version “V1.047”.



4. At the end of the successful diagnostic test, the “No Garments” Standby screen is displayed.



5. The Patient Run Hours value can now be reset by pressing the Right Control button (refer to “Resetting the Patient Run Hours” on page 19).
6. The alarm volume can also be set by pressing the Left Control button (refer to “To Change the Audible Alarm Volume Setting” on page 18).

Standby Screens

The “No Garments” Standby screen (above) shows two leg icons on the left side of the LCD screen with no garment outlines on them, indicating that no garments are currently connected to either tubeset.

+ *The Start Therapy icon does not appear until at least one garment is connected to a tubeset connector.*

Apply the prescribed Arjo garment(s) to the patient by following the instructions included in the garment packaging.

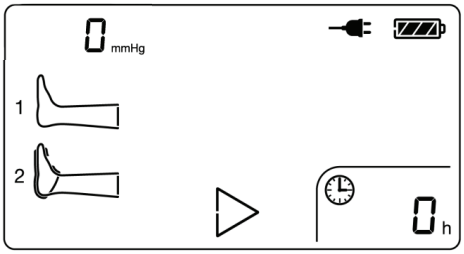
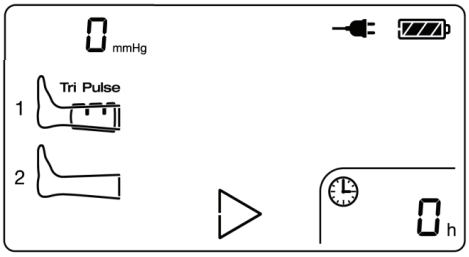
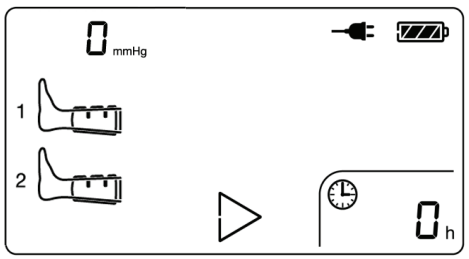
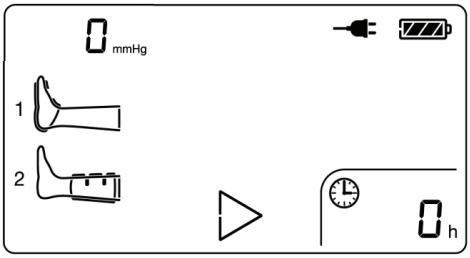
+ *Do not re-use the garments. Do not use the garments on multiple patients.*

Connect the garment(s) to the pump by pushing the garment connector firmly into the pump tubeset connector until it “clicks”.

The pump LCD screen will show which garments are connected to each tubeset connector: the garment connector with the blue push button is “1” and the one with the orange push button is “2” (refer to “Garment Type and Inflation Indication” on page 8).

The following four screens show typical Standby screens with different garment configurations.

+ *A garment connected but not inflated is shown as an outline on the leg icon. When it is inflated, the garment outline is filled in black.*
+ *The same garment outline is used for both calf and calf & thigh garments.*

	Tubeset Connector 1 Tubeset Connector 2	No garment connected Foot garment
	Tubeset Connector 1 Tubeset Connector 2	Sequential (Tri Pulse) calf or calf & thigh garment No garment connected
	Tubeset Connector 1 Tubeset Connector 2	Uniform (DVT) calf or calf & thigh garment Uniform (DVT) calf or calf & thigh garment
	Tubeset Connector 1 Tubeset Connector 2	Foot garment Uniform (DVT) calf or calf & thigh garment

Starting Therapy

Make sure the garment(s) are fitted correctly to the patient and the pump.

While the pump is in Standby, the LED indicators on the front and underside of the pump remain extinguished.

Press the Middle Control button below the Start Therapy icon to start the therapy. The LEDs on the front and underside of the pump change to green.

+ *If the pump is switched on and one or more garments are connected to the pump, but therapy is not started within 15 minutes, an alarm will occur. If no action is taken to start therapy or silence the alarm, then 15 minutes after the alarm starts, the pump will go into an "Off" state (refer to "Troubleshooting" on page 22).*

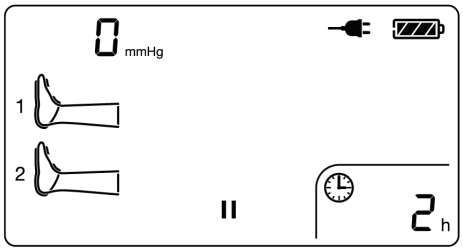
It is recommended that the following checks are carried out at the start of, and throughout, the therapy:

- Check the LCD screen icons to confirm that the correct type of garment(s) have been connected.
- During garment inflation, check the LCD screen to confirm that there are no fault indicators displayed and that the correct pressure is being supplied. The default target inflation pressures for the different garments are:
  - Foot garment: 130 mmHg.
  - Uniform calf and calf & thigh garments: 40 mmHg.
  - Sequential calf and calf & thigh garments: 45 mmHg.
- Check that there are no kinks in the tubeset.
- Check that the tubeset and connectors do not cause the patient any discomfort.
- Regularly check that the garments remain correctly fitted to the patient.

The pump will inflate and deflate each garment in turn, as follows, starting with the garment connected to tubeset connector 1. The garment pressure is displayed in the top left side of the screen. The Patient Run Hours are displayed in the bottom right of the screen.

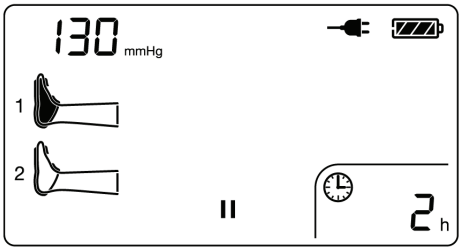
+ *The following example shows two foot garments fitted to the pump.*

1. Both garments are initially deflated, and the garment icons are shown as outlines.

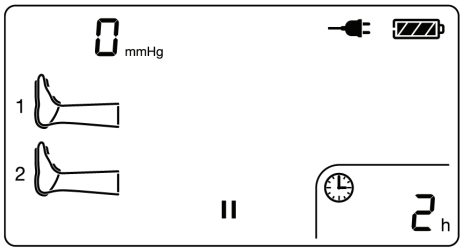


2. Foot garment 1 is inflated to the target pressure, with an inflate time of 3 seconds and a deflate time

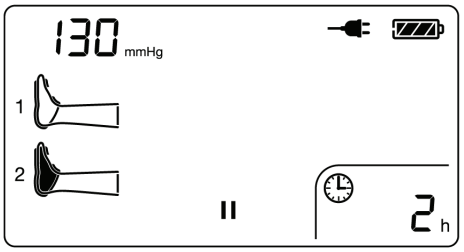
of 27 seconds. The foot garment icon is black while it is inflated.



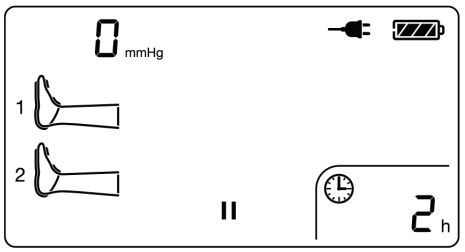
3. The foot garment is deflated to zero. Both garment icons are outlines.



4. Foot garment 2 is then inflated to the target pressure, with an inflate time of 3 seconds and a deflate time of 27 seconds. The foot garment icon is black while it is inflated.



5. The foot garment is deflated to zero. Both garment icons are outlines.



6. This cycle of alternate garment inflations repeats from step 2 (above) until the therapy is stopped.

If calf (or calf & thigh) garments are attached to the pump, then each of these garments is inflated to the target pressure, with an inflate time of 12 seconds and a deflate time of 48 seconds.

If a foot garment and a calf (or calf & thigh) garment are attached to the pump, then since the inflate and hold times for a foot garment are shorter than for a calf (or calf & thigh) garment, there is a modified inflation

sequence: the foot garment is always inflated twice in succession and then the calf (or calf & thigh) garment is inflated, as follows.

1. Inflate the foot garment.
2. Deflate the foot garment.
3. Repeat the inflation of the foot garment.
4. Deflate the foot garment.
5. Inflate the calf (or calf & thigh) garment.
6. Deflate the calf (or calf & thigh) garment.
7. This cycle of garment inflations repeats from step 1 until the therapy is stopped.

Stopping Therapy

To stop the therapy and put the pump into Standby, press and hold the Middle Control button for approximately 2 seconds until the Standby screen is displayed (refer to “Standby Screens” on page 12) and then release it.

The LEDs on the front and underside of the pump are extinguished.

If the pump stays in Standby, then:

1. After 5 minutes the LCD display backlight is dimmed.
2. After a further 10 minutes (15 minutes total) the pump automatically goes into an “Off” state:
   - On mains power, the LCD screen backlight will be extinguished and only the mains power and battery indication icons will be displayed.
   - On battery power, the pump will power down and the screen will be blank.

+ *The Mains indicator above the Power button will remain green if the pump is connected to the mains power and extinguished if the mains power is disconnected.*

To switch off the pump, press and hold the Power button for approximately 2 seconds. Then,

- On mains power, the LCD screen backlight will be extinguished and only the mains power and battery indication icons will be displayed.
- On battery power, the pump will power down and the screen will be blank.

Switching Off the Pump

1. Make sure the therapy is stopped and the pump is in Standby (refer to “Stopping Therapy” on page 16).
2. If connected, disconnect the mains power.
3. Press and hold the Power button for approximately 2 seconds until the LCD screen goes blank.

+ *The Mains indicator above the Power button will remain green if the pump is connected to the mains power and extinguished if the mains power is disconnected.*

Warnings/Alarms

On detection of a fault condition, the pump provides a visual-only warning followed by an audible and visual alarm if the fault is not cleared.

1. The visual-only warning is a fault icon on the LCD screen. The LED indicators remain unchanged and there is no audible alarm.
2. If the fault is not cleared then the warning is replaced by an audible and visual alarm, which consists of:
   - A fault icon on the LCD screen.
   - The LED indicators on the front and underside of the pump change to yellow.
   - An audible alarm will sound.

The warning and alarm can be cleared by either:

- Rectifying the fault on the system, or
- Pressing the Middle Control button to put the pump into Standby.

Refer to Section 7, Page 22 “Troubleshooting” for the alarms, their possible causes and their remedies.

To Change the Audible Alarm Volume Setting

1. When the pump is in Standby, press the Left Control button for 2 seconds to enter Audible Alarm Volume Setting mode.
2. The Audible Alarm Volume and Audible Alarm Status icons will be displayed in the bottom left of the screen.

	Audible Alarm Volume		Audible Alarm Status

3. Each time the Middle Control button is pressed the volume setting increases; if the volume setting is at maximum, pressing the button again will cycle back to the minimum setting.
4. The pump will save the selected volume setting when the Left Control button is pressed.

+ *If the Left Control button is not pressed for more than 2 minutes, the selected setting will be stored, the Volume and Audible icons will be removed and the pump will exit the Audible Alarm Volume Setting mode.*

	Minimum Volume		Medium Volume		Maximum Volume

Resetting the Patient Run Hours

1. When the pump is in Standby, press and hold the Right Control button for 2 seconds. The Patient Run Hours value will flash for 2 minutes. Press and hold the Middle Control button for 3 seconds to reset the Patient Run Hours to zero.

+ *This is the pump run time since the patient run hours was last reset.*

2. Press the Right Control button again to save the new setting. If there is no action within the 2 minutes of flashing, the selected setting will be saved.

Settings Adjustment

The pump is configured to give the recommended therapy for each garment type and does not require any direct setting by the clinician or nurse.

If the physician requires different therapy settings for uniform calf and/or calf & thigh garments, then limited changes can be made to the pump pressure setting. These changes, and returning the pump to the default settings, can only be made either:

- By contacting service personnel through your local Arjo sales office, or
- By trained authorised technical personnel at the facility.

+ *The pump pressures for foot garments and sequential calf and calf & thigh garments are fixed and cannot be changed.*

+ *The pressure range and factory default pressure for the uniform calf and calf & thigh garments are detailed in the Pressure Range on page 30.*

5. Cleaning and Disinfection

The following processes are recommended, but should be adapted to comply with the local or national guidelines (Decontamination of Medical Devices) which may apply within the healthcare facility or the country of use. If you are uncertain, you should seek advice from your local infection control specialist.

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

WARNING

Remove the electrical supply to the pump by disconnecting the mains power cable from the mains power supply before cleaning.

Protective clothing should always be worn when carrying out decontamination procedures.

Caution

Do not use Phenol-based solutions or abrasive compounds or pads during the decontamination process as these will damage the surface coating.

Avoid immersing electrical parts in water during the cleaning process.

Do not spray cleaning solutions directly onto the pump.

Do not immerse the tubeset in water.

Garments are single patient use and hence cannot be cleaned or reused.

To Clean

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

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

Do not use anything abrasive to clean the LCD window on the pump.

Chemical Disinfection

Arjo recommends a chlorine-releasing agent, such as sodium hypochlorite, at a strength of 1,000ppm available chlorine (this may vary from 250ppm to 10,000ppm depending on local policy and contamination status).

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

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

Make sure the product is dry before storage.

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

6. Routine Maintenance

Flowtron ACS900 System

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

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

Service Manual The *Flowtron* ACS900 Service Manual, part number SER0026, is available from your local Arjo sales office.

Service Period Arjo recommend that the pump is serviced every 12 months by an Arjo authorised service agent.

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

Check the tubeset and connectors for any damage.

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

Serial Labels The serial number for the pump is on the label on the rear of the pump case.

Quote this serial number when requesting service.

7. Troubleshooting

General

On detection of a fault condition, the pump provides a visual-only warning followed by an audible and visual alarm if the fault is not cleared.

Warning Conditions

The visual-only warning is a fault icon on the LCD screen. The LED indicators remain unchanged and there is no audible alarm.

The warning can be cleared by either:

- Rectifying the fault on the system, or
- Pressing the Middle Control button to put the pump into Standby.

Alarm Conditions

If the fault is not cleared then the warning is replaced by an audible and visual alarm, which consists of:

- A fault icon on the LCD screen.
- The LED indicators on the front and underside of the pump change to yellow.
- An audible alarm will sound.
- All the alarm conditions are low priority.

The alarm can be cleared by either:

- Rectifying the fault on the system, or
- Pressing the Middle Control button to put the pump into Standby.

+ *For simplicity, the following screens (except Battery Low, Hardware Fail and High Temperature) show a fault detected on garment 1; similar fault messages are displayed if the fault is detected on garment 2 (or both garments).*

+ *If the trouble shooting procedures do not return the system to normal performance, stop using the system immediately and call the service engineer.*

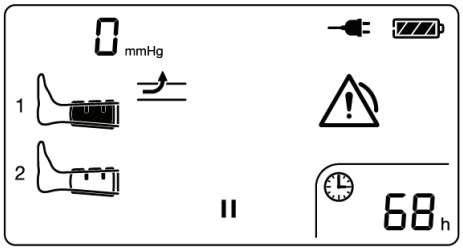
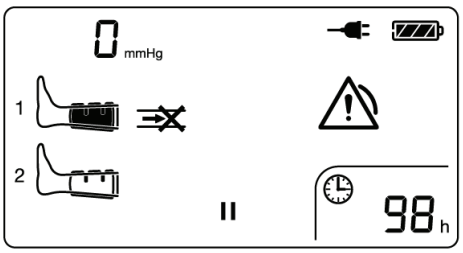
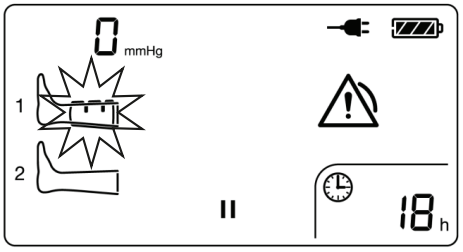
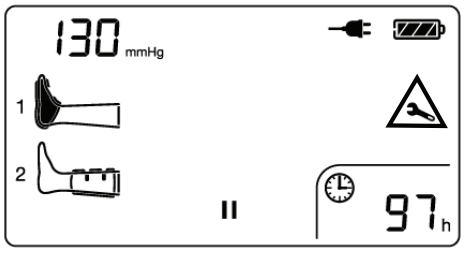
Service Manual

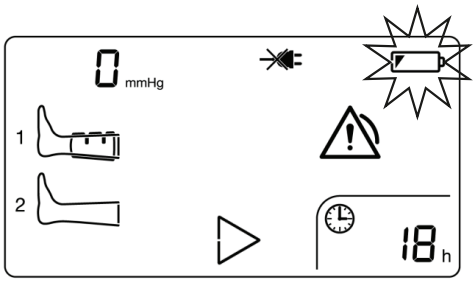
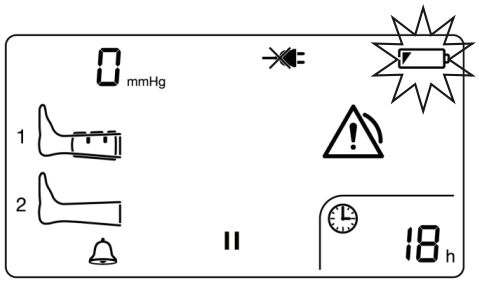
Where reference is made in the following Troubleshooting table to the *Flowtron* ACS900 Service Manual, this is part number SER0026 and is available from your local Arjo sales office.

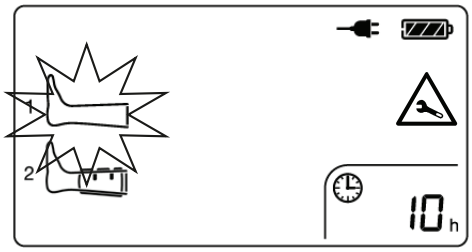
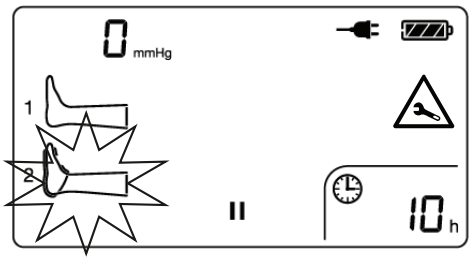
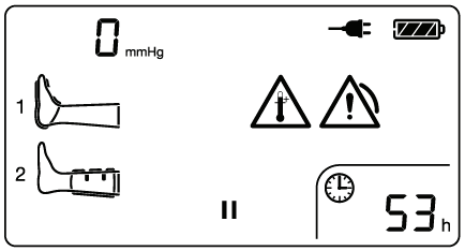
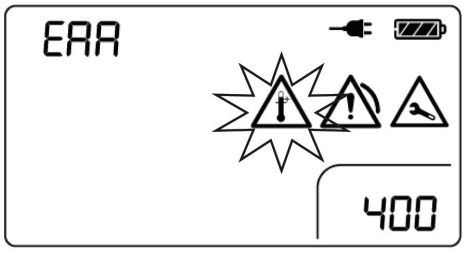
Troubleshooting Table

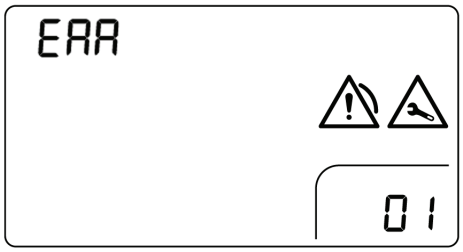
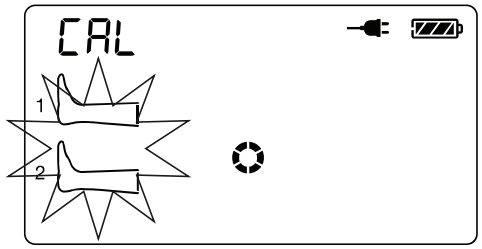
The following table provides typical warning and alarm conditions shown on the LCD screen.

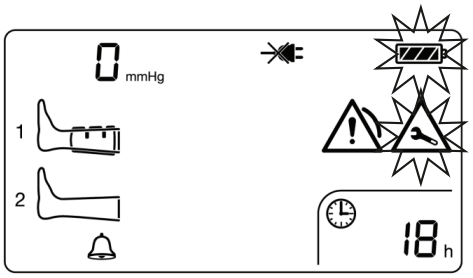
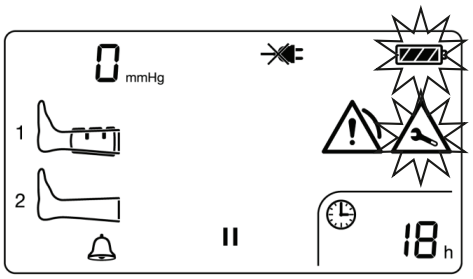
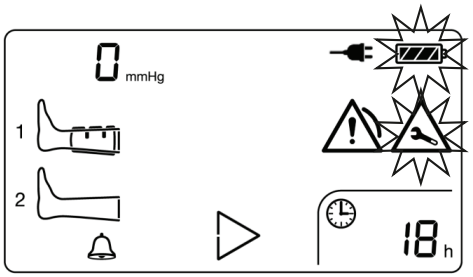
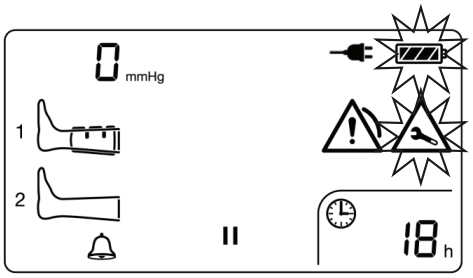
For each condition, there is a description and the relevant corrective action required.

Condition	Description and Corrective Action
Low Pressure/Leak 	The warning is activated after 4 minutes and shows a leak in garment 1 or its tubing. The warning changes to an alarm after an additional 6 minutes (10 minutes total). Examine the garment and tubing for leaks. The warning or alarm will be cleared if the leak is repaired. If the alarm continues, replace the affected garment.
Kinked/Blocked Tube 	The warning is activated after 4 minutes and shows garment 1 has a kinked or blocked tube. The warning changes to an alarm after an additional 6 minutes (10 minutes total). Examine the garment and tubing for kinks or blockages. The warning or alarm will be cleared if the kink or blockage is repaired. If the alarm continues, replace the affected garment.
Garment Disconnected 	This warning is activated after 1 minute if the pump detects that a garment has been disconnected while the pump is in the Run state; it shows that garment 1 has been disconnected. The “garment type” icon flashes. The warning changes to an alarm after an additional 9 minutes (10 minutes total) if the pump continues to detect that a garment has been disconnected while the pump is in the Run state; it shows that garment 1 has been disconnected. Reconnect or replace the garment. The warning or alarm will be cleared if the garment is reconnected.
Service Required 	The service “spanner” icon appears at the right side of the screen to indicate that the pump requires service attention. This will normally occur after the preset service interval has expired. The LED indicators on the front and underside of the pump remain green. Therapy can continue until service is available. **Call the service engineer.**

Condition	Description and Corrective Action
Battery Low   	The Battery Low warning and alarm will only be activated when the pump is operating from the battery (the mains power is disconnected). ***When any of these Battery Low warning or alarm screens are activated, connect the pump to the mains power supply to recharge the battery and continue therapy.*** If the pump is in Standby: • The warning will be activated when the remaining charge in the battery is less than 15%. The battery icon flashes. Therapy can be started. Connect to the mains power supply to clear the warning. • When the charge in the battery is less than 10%, therapy cannot be started. Connect to the mains power supply to clear the warning and start therapy. If the pump is in the Run state: • The alarm will be activated when the remaining charge in the battery is less than 10%. There is an audible tone and the battery icon flashes. The LED indicators on the front and underside of the pump change to yellow. Therapy can continue. Pressing the Left Control button will silence the audible tone. Connect to the mains power supply to clear the warning and continue therapy. • If the audible alarm is muted when the remaining charge in the battery is less than or equal to 7%, then an audible tone will sound and the LED indicator will change to yellow. The audible tone can no longer be silenced. The pump should be connected to the mains power supply immediately. • **When the remaining charge in the battery is less than 5%, the pump will shut down with no additional visible or audible indications.**

Condition	Description and Corrective Action
Faulty Tubeset   	The Faulty Tubeset warning and alarm are activated if the pump detects a fault in the tubeset. **For both conditions:** • **Switch off the pump.** • **Call the service engineer.** If the pump is in Standby when the faulty tubeset is detected: • A warning is activated. The leg icon and garment icon (if present) will flash, and show a faulty tubeset and affected connector. Therapy cannot be started. If the pump is in the Run state when the faulty tubeset is detected: • An alarm is activated. The leg icon and garment icon (if present) flash and show a faulty tubeset and affected connector. The LED indicators on the front and underside of the pump change to yellow. Therapy can continue as if the same garment(s) is attached. • When the operator next stops the pump and puts it into Standby, the alarm reverts back to the Standby warning screen above with the flashing leg icon and garment icon (if present). Therapy cannot be restarted.
High Temperature   	This warning occurs if the temperature inside the pump exceeds 55°C. The High Temperature icon is displayed and an audible alarm sounds. Therapy can continue. Make sure the pump is not close to a heat source, or covered by blankets. If the temperature inside the pump exceeds 60°C, this screen is shown. Therapy is stopped. Switch off the pump and allow pump to cool. Then switch back on and continue therapy. **If either alarm continues, switch off the pump and call the service engineer.**

Condition	Description and Corrective Action
Hardware Fail 	This alarm is activated if the pump detects an internal fault: • The “spanner” symbol is permanently displayed. • “ERR” is displayed in the top left of the screen. • A 2 or 3 digit fault code is displayed in the bottom right of the screen. Therapy is suspended. **Switch off the pump.** **Call the service engineer.** **The fault codes and their descriptions can be found in the *Flowtron* ACS900 Service Manual, part number SER0026.**
Tubeset Disconnected/ Calibration Required 	The Tubeset Disconnected alarm is activated if the pump detects that the tubeset has been disconnected from the pump: • An alarm is activated. • Both leg icons flash. • “CAL” is displayed in the top left. • Therapy is suspended. The pump must be recalibrated by Arjo authorised service personnel before therapy can continue. **Switch off the pump.** **Call the service engineer.**

Condition	Description and Corrective Action
Battery Fault  	The Battery Fault alarm is activated if the pump detects a fault in the internal battery. If the pump is in Standby, on battery power: • An alarm is activated which can be muted. • The battery icon flashes and shows the last known charge remaining in the battery. • The “spanner” symbol flashes. • Therapy cannot be started. • **Call the service engineer.**
 	If the pump is in the Run state, on battery power: • An alarm is activated which can be muted. • The battery icon flashes and shows the last known charge remaining in the battery. • The “spanner” symbol flashes. • Therapy can continue until the battery has expired. • **Call the service engineer.**
 	If the pump is in Standby, on mains power: • An alarm is activated which can be muted. • The battery icon flashes and shows the last known charge remaining in the battery. • The “spanner” symbol flashes. • Therapy can be started. • **Call the service engineer.**
 	If the pump is in the Run state, on mains power: • An alarm is activated which can be muted. • The battery icon flashes and shows the last known charge remaining in the battery. • The “spanner” symbol flashes. • Therapy can continue. • **Call the service engineer.**

8. Accessories

The *Flowtron* ACS900 pump should only be used with the following garments:

CALF GARMENTS			
Order Code	**Type**	**Calf Circumference**	**Therapy**
DVT5	DVT5 Small Calf Garment	Up to 36 cm (14")	Uniform
DVT10	DVT10 Standard Calf Garment	Up to 43 cm (17")	Uniform
DVT10S[a]	DVT10S Standard Calf Garment (Sterile)	Up to 43 cm (17")	Uniform
L501-M	L501-M Standard Calf Garment	Up to 43 cm (17")	Uniform
DVT20	DVT20 Large Calf Garment	Up to 58 cm (23")	Uniform
DVT60L	DVT60L Bariatric Calf Garment	Up to 81 cm (32")	Uniform
TRP10	Tri Pulse TRP10 Regular Calf Garment	Up to 43 cm (17")	Sequential
TRP20	Tri Pulse TRP20 Large Calf Garment	Up to 58 cm (23")	Sequential
TRP60L	Tri Pulse TRP60L Bariatric Calf Garment	Up to 81cm (32")	Sequential

CALF & THIGH GARMENTS			
Order Code	**Type**	**Thigh Circumference**	**Therapy**
DVT30	DVT30 Standard Thigh Garment	Up to 71cm (28")	Uniform
DVT30S[a]	DVT30S Standard Thigh Garment (Sterile)	Up to 71cm (28")	Uniform
L503-M	L503-M Standard Thigh Garment	Up to 71cm (28")	Uniform
DVT40	DVT40 Large Thigh Garment	Up to 89cm (35")	Uniform
TRP30	Tri Pulse TRP30 Regular Thigh Garment	Up to 71cm (28")	Sequential
TRP40	Tri Pulse TRP40 Large Thigh Garment	Up to 89cm (35")	Sequential

FOOT GARMENTS			
Order Code	**Type**	**Shoe Size**	**Therapy**
FG100	Foot Garment - Regular	UK Men/Women up to size 7 US Women up to size 9 US Men up to size 7 EURO up to size 40	Uniform
FG100S[a]	Foot Garment - Regular (Sterile)	UK Men/Women up to size 7 US Women up to size 9 US Men up to size 7 EURO up to size 40	Uniform
FG200	Foot Garment - Large	UK Men/Women size 7½ or above US Women size 9½ or above US Men size 7½ or above EURO size 41 or above	Uniform
FG200S[a]	Foot Garment - Large (Sterile)	UK Men/Women size 7½ or above US Women size 9½ or above US Men size 7½ or above EURO size 41 or above	Uniform

a. Please check with your local Arjo representative for availability of sterile garments.

9. Technical Specification

Pump Specification

PUMP	
Part numbers	526000-XX 526000-17/18 (KSA)
Supply Voltage (V)	100 - 230V 230V (KSA)
Supply Frequency (Hz)	50 - 60Hz 60Hz (KSA)
Power Input	10 - 40 VA
Size	230 x 228 x 190 mm (9.1 x 9.0 x 7.5 in.)
Weight	4.1 kg (9.0 lb)
a. Configuration: STD is the Standard pump which has a standard length tubeset (2.1 m / 7 ft). OR is the Operating Room pump which has a longer tubeset (4 m / 13 ft long).	
Case Material	Flame Retardant ABS Plastic
Mains Power Plug Fuse Rating	5A to BS1362 (UK ONLY)
Degree of protection against electric shock	Class II, Double Insulated Type BF
Degree of protection against liquid ingress	IPX3 - Protected against spraying water
Mode of operation	Continuous
Pressure Range	Foot Garment: 130 ± 10 mmHg Uniform (DVT) Calf and Calf & Thigh Garments: Range: 35 - 65 ± 5 mmHg Factory Default: 40 ± 5 mmHg Sequential (Tri Pulse) Calf and Calf & Thigh Garments: 45 ± 5 mmHg

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

If the pump is stored in conditions outside of the "Operating" ranges, it should be allowed time to stabilise at normal operating conditions before use.

Electromagnetic Compatibility

Product has been tested for compliance with current regulatory standards regarding its capacity to block EMI (electromagnetic interference) from external sources.

Some procedures can help reduce electromagnetic interferences:

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

WARNING

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

Intended Environment: Home Healthcare Environment and Professional Healthcare facility environment.

Exceptions: HF Surgical Equipment and the RF Shielded room of an ME SYSTEM for magnetic resonance imaging

WARNING

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

Guidance and manufacturer's declaration - electromagnetic emissions

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

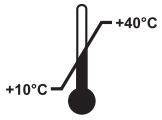
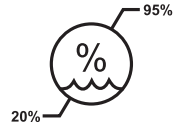
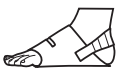
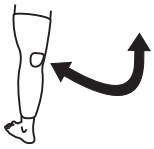
Guidance and manufacturer's declaration - electromagnetic immunity			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	±2kV, ±4kV, ±8kV, ±15kV air ±8kV contact	±2kV, ±4kV, ±8kV, ±15kV air ±8kV contact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

Guidance and manufacturer's declaration - electromagnetic immunity			
Surge IEC 61000-4-5	±0,5kV ±1kV; ±2 kV, AC Mains, Line to Ground ±0,5kV ±1kV, AC Mains, Line to Line	±0,5kV ±1kV; ±2 kV, AC Mains, Line to Ground ±0,5kV ±1kV, AC Mains, Line to Line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or a battery.
Note: *UT is the AC mains voltage prior to application of the test level.*			

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

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

Symbols

CE 2797	CE marking indicating conformity with European Community harmonised legislation Figures indicate Notified Body supervision.	CLASSIFIED C UL US E348583 CAN/CSA-C22.2 No 60601-1 (2008) + (2014) ANSI/AAMI ES 60601-1 (2005) +AMD (2012)	With respect to electric shock, fire and mechanical hazards only in accordance with CAN/CSA-C22.2 No. 60601.1 (2008) + (2014). ANSI/AAMI ES 60601-1 (2005) +AMD (2012) MEDICAL EQUIPMENT	SN	Serial Number
	The operator must read this document (Instructions for Use) before use. Note: This symbol is blue on the product label.		Refer to this document (Instructions for Use) for a description of the product classification (3rd Edition).	REF	Model Number
MD	Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745	IPX3	Degree of protection against liquid ingress: Protected against spraying water.		Type BF
	Refer to this document (Instructions for Use) for a description of the product classification (2nd Edition).		Power Note: Pump is not isolated from mains power supply.		Double Insulated[a]
	Manufacturer: This symbol is accompanied by the name and the address of the manufacturer.		Date of Manufacture in Year-Month-Day format.		Do not dispose of in the domestic refuse.
	Temperature Limits (Typically +10°C minimum to +40°C maximum).		Non-ionising electromagnetic radiation.		Alternating Current
	Humidity Limits (Typically 20% minimum to 95% maximum).		Do not use if package is damaged.	LOT	Batch code.
Rx Only	Caution: US Federal law restricts this device to sale by or on the order of a physician. Note: Applicable to the USA market only.	STERILE EO	Sterilised using ethylene oxide.		Do not stand or walk.
	When the garment is placed on the leg, the arrow must point to the heel.		Shows position on foot for garment size measurement.		Latex free
	Indicates that the cutout in the garment must be positioned behind the knee.		Shows position on thigh for garment size measurement.		Do not re-use.
	Shows position on calf for garment size measurement.		Use by date.		

a. Based on the UL mark, this pump is considered to be electrically safe. Double insulated products rely on two independent electrical insulation systems that are isolated from metal parts. Grounding is not required, and the pump shall not be modified to ground the pump.

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Address page - REV 24: 04/2019

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

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