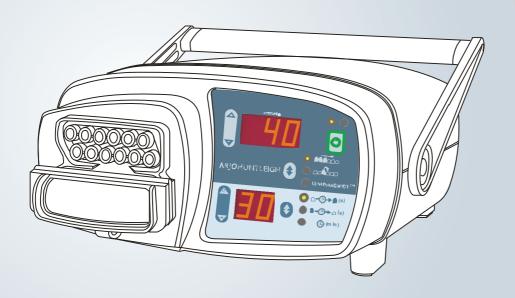
ARJOHUNTLEIGH

FLOWTRON HYDROVEN 12

Instructions for Use





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...with people in mind

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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:

- EN60601-1:1990/A13:1996 and IEC 60601-1:1988/A2:1995
- UL60601-1, UL2601-1 and CAN/CSA C22.2 No. 601.1-M90
- EN60601-1:2006 and IEC 60601-1:2005
- AAMI/ANSI ES60601-1:2006 and CAN/CSA C22.2 No.60601.1(2008)

Safety Warnings

- It is the responsibility of the care giver 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/insert combination as indicated by ArjoHuntleigh should be used. The correct function of the product cannot be guaranteed if incorrect pump and garment combinations are used.

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 naked flames, such as cigarettes, etc.
- Do not store the system in direct sunlight.
- Do not use phenol-based solutions to clean the system.
- Make sure the system is clean and dry prior to use or storage.
- Pets and children must be supervised in the vicinity of the system.

Electromagnetic Compatibility (EMC)

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

- The use of accessories not specified by the manufacturer may result in increased emissions by, or decreased immunity of, the equipment, affecting its performance.
- Portable and mobile radio frequency (RF) communications equipment (e.g. mobile/cell phones) can affect medical electrical equipment.

- If this equipment needs to be used adjacent to other electrical equipment, normal operation must be checked before use.
- For detailed EMC information contact ArjoHuntleigh service personnel.

Expected Service Life

The Flowtron® Hydroven 12 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 ArjoHuntleigh distributor.

Do NOT use unapproved accessories or attempt to modify, disassemble or otherwise misuse the **Flowtron Hydroven 12** system. Failure to observe this caution could result in injury, or in extreme cases, death.

Environmental Protection

Incorrect disposal of this equipment and its component parts, particularly batteries or other electrical components, may produce substances that are hazardous to the environment. To minimise these hazards, contact ArjoHuntleigh for information on correct disposal.

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1. Introduction

About this Manual

This manual is your introduction to the **Flowtron**[®] **Hydroven 12** 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 Hydroven 12** system, contact your local ArjoHuntleigh sales representative, listed at the end of this manual.

Intended Use

The intended use of this product is to manage the list of clinical conditions detailed in the "Indications" (refer to page 10).

The **Flowtron Hydroven 12** system should be used as part of a prescribed plan of care detailed in the "Indications" (refer to page 10).

About the Flowtron Hydroven 12 System

The system comprises a pump and multi-chamber arm or leg garments. Optional multi-chamber garment inserts can be used to increase the circumference of the arm and leg garments.

The pump supplies air to inflate the chambers in the garments via connecting tubes, allowing the application of controlled pressure to gently compress and/or massage the limb.

The pump has three inflation modes:

- Sequential.
- Wave.
- LymphAssist[®].

Sequential and **Wave** inflation are used for the treatment of wounds, chronic venous insufficiency, and venous or dependency oedema. The gentle compression of the limb increases the return of blood and excess fluids, improves venous stasis and encourages the reabsorption of waste products.

LymphAssist inflation is used where there is a requirement to move lymph away from malfunctioning lymphatics. The gentle, rhythmic massage of the limb throughout the **LymphAssist** cycle moves the skin in the direction of the lymph flow and stimulates the lymphatic vessels, which carry proteins and waste products.

The pump can also be set to "link" **LymphAssist** cycles with **Sequential** or **Wave** cycles to treat patients with lympho-venous oedema.

A full technical description of the **Flowtron Hydroven 12** system can be found in the Service Manual, part number SER0010, available from your local ArjoHuntleigh sales representative.

Pump

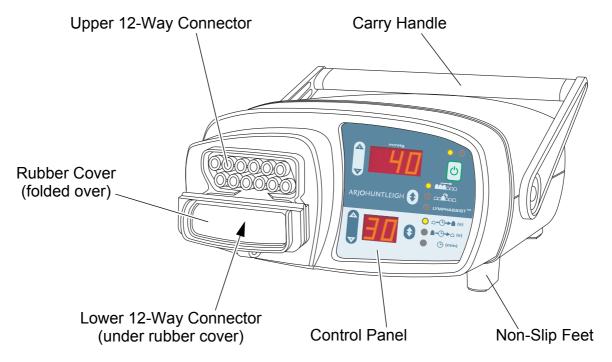
The **Flowtron Hydroven 12** pump is designed for tabletop use, with the controls situated at the front of the pump. It comprises a moulded case with non-slip feet on the base and rear cover, and an integral carry handle.

Garment Connections

There are two 12-way connectors on the front of the pump. They are covered by a 2-part, hinged, rubber cover, which is secured to the pump by a strap. The cover is fitted over both connectors when the pump is being cleaned to prevent ingress of fluids.

The garments are connected to these two 12-way connectors, which are push-fit and polarised to prevent incorrect orientation of the connectors. The following pump/garment connections are possible:

- If two garments are used (either two arm garments, two leg garments, or one arm/leg garment and one garment insert), one will be connected to the upper connector and the other connected to the lower connector. The two connections are interchangeable both garments will inflate at the same time and to the same pressure.
- If only one garment is used, it must be connected to the upper connector and the rubber cover must be securely fitted to the lower connector (folded as shown below).



All garments (arm garments, leg garments and garment inserts) have multiple chambers. The chambers are inflated in a pre-determined sequence, according to the inflation modes detailed below (refer to "Inflation Modes" on page 4).

The inflation of the chambers follows a preset pressure gradient, but the deflation of the chambers is effectively instantaneous.

Operating Modes

Refer to Section 3, Page 12 "Controls, Indicators and Alarms" for a description of the controls and indicators on the pump.

The pump has the following three operating modes:

Standby

After the mains power supply has been switched on to the pump, the pump will perform a short self-test and then go into **Standby**.

In Standby:

- The **Run** and **Sleep** mode indicators are extinguished.
- The pump shows the previously selected therapy settings.
- The pump is ready to start therapy. Press the **Run/ Standby** button to start therapy.

Sleep Mode

If the pump has been in **Standby** for 10 minutes without any of the buttons being pressed, it then goes into **Sleep** mode to conserve power.

The pump can be left in **Sleep** mode for long periods without disconnecting the mains power.

In **Sleep** mode:

- Only the **Sleep** mode indicator on the control panel is illuminated.
- All other displays and indicators are extinguished.
- Press the Run/Standby button to put the pump into Standby.

Run Mode

The pump is in **Run** mode for the duration of the therapy session, while it is inflating and deflating the garments.

In **Run** mode:

- The **Run** mode indicator will be illuminated.
- The pump automatically stops at the end of the selected therapy time and the garments are deflated.
- The pump can be stopped during the therapy by pressing the **Run/Standby** button.
- Loss of mains power will halt therapy.

Inflation Modes

The pump has the following three inflation modes:

Sequential Inflation

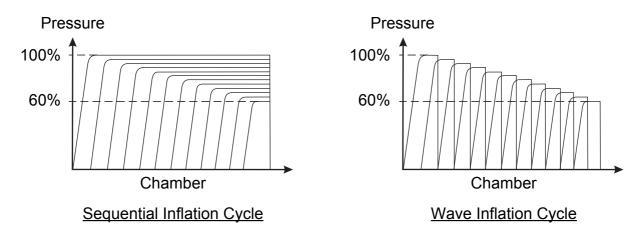
- 1. The first garment chamber starts to inflate.
- 2. When the first chamber has been inflated to the correct pressure, the second chamber starts to inflate.
- 3. This sequence continues for all 12 chambers.
- In Sequential mode, all chambers are kept fully inflated while subsequent chambers are inflated.
 - 4. After the final chamber has been inflated, all chambers are then deflated simultaneously.
 - 5. The pressure in each chamber is less than the pressure in the preceding chamber, and the pressure in the final chamber is set to 60% of the pressure in the first chamber.

Wave Inflation

- 1. The first garment chamber starts to inflate.
- 2. When the first chamber has been inflated to the correct pressure, the second chamber starts to inflate.
- 3. When the second chamber has been inflated to the correct pressure, the first chamber starts to deflate and the third chamber starts to inflate.
- This may feel to the patient that more than one chamber is inflated at any one time.
 - 4. This sequence continues for all 12 chambers.

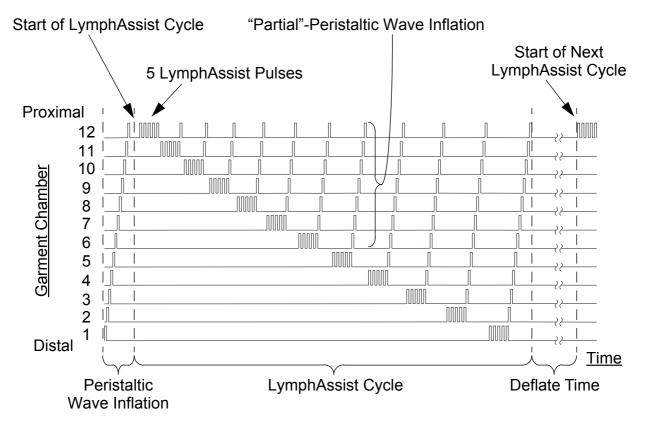
5. The pressure in each chamber is less than the pressure in the preceding chamber, and the pressure in the final chamber is set to 60% of the pressure in the first chamber.

Wave inflation is also known as "peristaltic" inflation.



LymphAssist Inflation Refer to the diagram below for the **LymphAssist** cycle.

- Chamber 1 is at the distal (foot/hand) end and chamber 12 is at the proximal (thigh/shoulder) end.
 - 1. On initial application, the **LymphAssist** therapy starts with a *single* peristaltic **Wave** inflation from chamber 1 to chamber 12.
 - 2. A **LymphAssist** cycle is comprised of the following sequence of inflations/deflations, starting at chamber 12, then 11, 10, etc., down to chamber 1:
 - There are 5 pulses where the chamber is inflated and deflated. These are referred to as LymphAssist pulses.
 - This is followed by a single "partial"-peristaltic **Wave** inflation of part of the garment between the *next* chamber and chamber 12.
- For example, at chamber 5, the 5 LymphAssist pulses are followed by a partial-peristaltic Wave inflation from chamber 6 to chamber 12.



LymphAssist Inflation Cycle

- 3. When the partial-peristaltic **Wave** inflation gets to chamber 12, there is a short delay, and then the sequence of 5 **LymphAssist** pulses followed by a partial-peristaltic **Wave** inflation is repeated for the next chamber.
- 4. The **LymphAssist** cycle is complete after the 5 **LymphAssist** pulses at chamber 1 and the partial-peristaltic **Wave** inflation from chamber 2 to chamber 12.
- 5. The next **LymphAssist** cycle will start after the **Deflate** time set on the pump control panel.
- The maximum pump pressure that can be set in LymphAssist mode is 40 mmHg.

Linking LymphAssist with other Therapy Cycles

The **LymphAssist** cycle can be "linked" with **Wave** or **Sequential** cycles.

In this mode of operation, a *single* **LymphAssist** cycle is followed by continuous **Wave** or **Sequential** cycles until the **Treatment** time has elapsed or the pump is turned off (refer to "Inflation Modes" on page 4).

Controls, Indicators and Alarms

The controls and indicators are located on the control panel, and a sophisticated alarm system differentiates between normal operation and genuine system faults.

If an alarm situation is detected, an alarm message will be displayed on the control panel and an audible warning will sound.

Garments

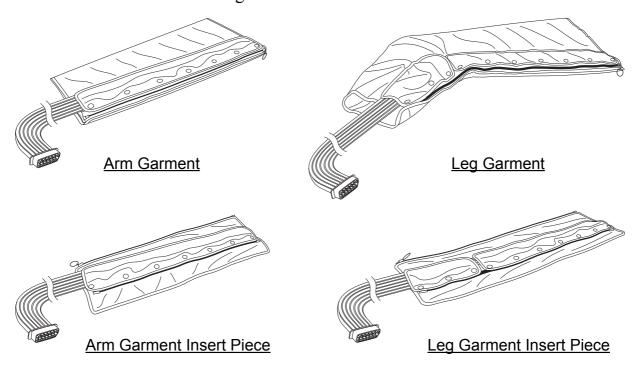
The Flowtron Hydroven 12 pump is designed to be used with Hydroven™ 12 garments, which are available in two sizes for arms and four sizes for legs. Each length arm and leg garment has a corresponding Hydroven 12 insert piece which increases its circumference by 17 cm for arm garments and 19 cm for leg garments.

The length of the tubeset is 140 cm from the pump connector to the foot/hand end of the garment.

All garments (arm garments, leg garments and garment inserts) have multiple chambers. Each chamber overlaps the adjacent chamber to provide smooth and seamless pressure application, and prevent pressure voids or ridging to the limbs. All garments have zip closures. When closed, the inflating chamber section overlaps underneath the zip around the whole circumference of the limb to prevent pressure voids and ridging of the skin underneath the zip section.

The leg garment (and leg garment insert) has a unique 5-chamber foot section which provides fine application of pressure to the foot, promoting blood and lymph movement.

Garment inserts are available for arm and leg garments to fit larger limbs. Once connected to the garment and pump they are designed to inflate in sequence with the garment to provide unique inflation capabilities for larger limbs.



Garment Dimensions

Limbs should be measured and the correct garment(s) chosen using the following measuring guides and tables of dimensions.

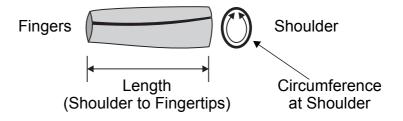
When determining the correct garment size:

- Remove any bandages, stockings and/or any bulky dressings.
- Measure the circumference of the limb where stated.
- When measuring, do not pull the tape measure tight.
- Make sure the garment extends above the level of the swelling/trauma, whilst maintaining the level of comfort.

Garments should not feel tight-fitting when deflated.

1. Arm Garments:

- The length of the garment is measured from the fingertips to 5 cm below the armpit, with the arm straight.
- The circumference of the garment is measured at the shoulder.

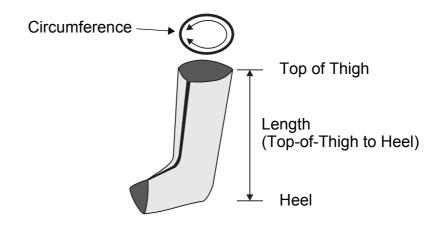


Arm Garment Dimensions					
Garment Part No.	316A68	316A78			
Length (Shoulder to Fingertips)	68 cm	78 cm			
Circumference (at Shoulder):					
Arm Garment	62 cm	62 cm			
With Garment Insert	79 cm	79 cm			
Corresponding Insert Piece Part No.	316AI68	316AI78			
Width of Insert (at Shoulder)	17 cm	17 cm			

The **Hydroven 12** arm garment insert piece adds 17 cm to the shoulder-end circumference of the garment.

2. Leg Garments:

- There are two ranges of leg garments: standard and large.
- The length of the garment is measured from the heel to 5 cm below the groin.
- The circumference of the garment is measured at the top of the thigh.



Leg Garment Dimensions	Stan	dard	Large	
Garment Part No.	316L76S	316L84S	316L76W	316L84W
Length (Top-of-Thigh to Heel)	76 cm	84 cm	76 cm	84 cm
Circumference (at Top-of-Thigh):				
Leg Garment	71 cm	71 cm	79 cm	79 cm
With Garment Insert	90 cm	90 cm	98 cm	98 cm
Corresponding Insert Piece Part No.	316LI76	316LI84	316LI76	316LI84
Width of Insert (at Top-of-Thigh)	19 cm	19 cm	19 cm	19 cm

The **Hydroven 12** leg garment insert piece adds 19 cm to the top-of-thigh circumference of the garment.

For further information about garment sizing, please contact ArjoHuntleigh.

2. Clinical Applications

Indications

Intermittent Pneumatic Compression (IPC) is effective in the treatment of the following clinical conditions, when combined with an individualised monitoring programme:

- Oedema.
 - Dependent (including secondary to cerebrovascular incident, pregnancy or paralysis).
 - Traumatic (post-surgical or injury).
- Lymphoedema.
 - Primary and secondary (including post surgery, radio or chemotherapy).
- Chronic venous insufficiency.
- Post phlebotic syndrome.
- Acute and chronic wounds including venous leg ulcers and post-surgical wounds.

IPC may also be beneficial in the management of:

- Fixed flexion deformity.
- Arthritic conditions.
- Lower limb pain due to trauma or surgery.
- Lipoedema.

Selection should be based upon a holistic assessment of the patients' individual care needs.

- These systems represent one aspect of a treatment 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.

Contraindications

IPC should *NOT* be used in the following circumstances:

- Known or suspected deep vein thrombosis (DVT), pulmonary embolism, thrombophlebitis and acute infections of the skin, such as cellulitis.
- Decompensated/severe congestive cardiac failure, pulmonary oedema associated with significant limb

- oedema or any condition where an increase of fluid to the heart may be detrimental.
- Severe arteriosclerosis or other ischaemic vascular disease.
- Active metastatic disease affecting the limb.

PATIENT NOTE: if you are uncertain whether you have any of the above conditions please consult a physician before use.

Cautions

IPC should be used with care in patients with the following symptoms or conditions:

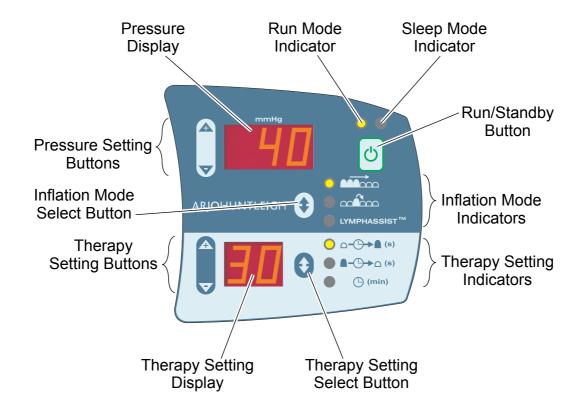
- Peripheral neuropathy, pain or numbness in the limb.
- Undiagnosed, untreated or infected wounds, fragile skin, grafts or dermatological conditions that may be aggravated by the garment.
- Extreme limb deformity which may practically impede the correct application of the garment.

Warnings

- Therapy should be interrupted if pain, tingling or numbness of the limb occurs during, or as a result of therapy.
- In the event of a power failure or fault whereby the garment remains inflated, disconnect the tubeset(s) in order to deflate the garment(s) and then remove the garment(s) from the limb(s).
- Patients must not walk or stand when wearing leg garments.

3. Controls, Indicators and Alarms

Typical Control Panel Display in Run Mode



Pump Controls and Indicators

The pump control panel has the following controls and indicators.

When a button on the pump control panel is pressed, the sounder will "beep" to confirm a valid selection.

Run/Standby Button, and Run and Sleep Mode Indicators



- When the pump is in **Standby**, both the **Run** and **Sleep** mode indicators are extinguished.
- Press the **Run/Standby** button to start the patient therapy. The **Run** mode indicator (the left one of the two indicators) is illuminated to show that the pump is in **Run** mode.
- At the end of the therapy, as set by the Treatment duration, the pump will stop. The pump can also be stopped during the therapy by pressing the Run/ Standby button. Press the Run/Standby button after the pump has stopped to reset it to Standby.
- If the pump has been in **Standby** for 10 minutes without any button being pressed, it then goes into **Sleep** mode to conserve power:

- Only the **Sleep** mode indicator (the right one of the two indicators) is illuminated in **Sleep** mode, everything else is effectively shut down.
- Press the Run/Standby button to put the pump from Sleep mode into Standby.



The pump can be left in **Sleep** mode for long periods without disconnecting the mains power.

Inflation Mode Select Button and Inflation Mode Indicators



The pump has three main inflation modes: **Sequential**, **Wave** and **LymphAssist**. In addition, **LymphAssist** cycles can be linked with **Sequential** or **Wave** cycles, offering a total of five treatment alternatives. These modes are described in "Inflation Modes" on page 4.

Repeated presses of the **Inflation Mode** select button will cycle the pump through the five types of patient therapy, as follows:

- Sequential
- Wave ____
- LymphAssist
- LymphAssist plus Sequential (linked therapy cycles)
- LymphAssist plus Wave (linked therapy cycles)

For each of the three main inflation modes (**Sequential**, **Wave** and **LymphAssist**), the indicator adjacent to the selected **Inflation Mode** is illuminated.

With linked therapy cycles (LymphAssist plus Sequential and LymphAssist plus Wave):

- Initially, the two relevant **Inflation Mode** indicators are both illuminated.
- During the therapy, the Inflation Mode indicator will flash to show which cycle is currently operating. For example, if LymphAssist and Wave cycles are linked, then during the LymphAssist cycle the LymphAssist indicator will flash while the Wave indicator will be permanently illuminated. The indications will be reversed during the Wave cycle.

Pressure Display and Pressure Setting Buttons

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The value shown on the **Pressure** display is the set pressure for the first garment chamber to be inflated.

The pressure range for each inflation mode is:

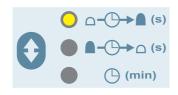
• Sequential: 15-120 mmHg.

• **Wave**: 15-100 mmHg.

• **LymphAssist**: 15-40 mmHg.

The pressure can be adjusted in 5 mmHg increments by pressing the **+** and **- Pressure** setting buttons.

Therapy Setting Select Button and Therapy Setting Indicators



Repeated presses of the **Therapy Setting** select button selects which parameter is shown on the **Therapy Setting** display:

- Inflate time in seconds □-□→■ (s)
- **Deflate** time in seconds **△**→ (s)
- Treatment duration in minutes () (min)

The indicator adjacent to the selected **Therapy Setting** is illuminated, to show which parameter can be adjusted.

The **Therapy Setting** select button is used to select

which parameter is shown on the Therapy Setting

Therapy Setting Display and Therapy Setting Buttons



display: **Inflate** time, **Deflate** time or **Treatment** duration.

The default setting is **Treatment** duration.

- 1. Inflate/Deflate times (in seconds).
 - To adjust the settings, press the **Therapy Setting** select button until the desired **Therapy Setting** indicator is illuminated, as follows:
 - Inflate time □-□→■ (s)
 - Deflate time ■-⊕→△ (s)

The Inflate and Deflate times can only be adjusted when the pump is in Standby.

• The **Inflate** time for each inflation mode can be set as follows:

Sequential:

30-95 seconds (15-80mmHg)

60-95 seconds (85-120mmHg)

Wave: 60-95 seconds.

LymphAssist: 60-95 seconds.

• The **Deflate** time for each inflation mode can be set as follows:

Sequential:

10-95 seconds (15-80mmHg)

60-95 seconds (85-120mmHg)

Wave:

15-60 seconds (15-60mmHg)

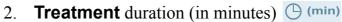
60-95 seconds (65-80mmHg)

95 Seconds

LymphAssist: 15-60 seconds.

 The Inflate and Deflate times can be adjusted in 5 second increments by pressing the + and – Therapy setting buttons.

If the + or - Therapy setting buttons are not pressed for 10 seconds, the pump reverts to the **Treatment** duration option.



- Make sure the Therapy Setting indicator adjacent to Treatment duration is illuminated. If not, press the Therapy Setting select button to select it.
- The **Treatment** duration can be adjusted in the range 10-99 minutes, in one minute increments, by pressing the **+** and **Therapy** setting buttons.
- If you continue to hold down the **+ Therapy** setting button when the **Treatment** duration gets to 99 minutes, **CO** will be shown on the **Therapy Setting** display to indicate continuous therapy.

The pump will automatically stop continuous therapy after two hours of continuous use.

- When the therapy starts, the **Treatment** duration shown on the **Therapy Setting** display will count down, indicating the time remaining (to the nearest full minute) unless **CO** is selected.
- The **Treatment** duration can be adjusted at any time, in **Run** or **Standby** modes.
- At the end of the therapy, as set by the **Treatment** duration, the pump will stop.



Storing New Therapy Settings

The last selected patient therapy is stored and used as the default setting for the next therapy session.

For each of the three main **Inflation Modes** (**Sequential**, **Wave** and **LymphAssist**), the pump will store a separate set of four therapy settings (**Pressure** setting, **Inflate** time, **Deflate** time and **Treatment** duration).

If any of these four therapy settings are adjusted, the new setting is stored and used as the default setting whenever that inflation mode is next selected.

Pump Alarm

System Fault

- 1. If a system fault is detected, the pump will stop operating.
- 2. An audible warning will sound, and an **F** alarm message will appear on the **Therapy Setting** display.
- 3. Immediately disconnect the garment from the pump.
- 4. Press the **Run/Standby** button to re-run the self-test on the pump.
- 5. If the fault condition can not be rectified, call a service engineer.

4. Operation

These instructions cover the day-to-day operation of the **Flowtron Hydroven 12** system. Other operations, such as maintenance and repair, should only be carried out by suitably qualified personnel.

Refer to Section 3, Page 12 "Controls, Indicators and Alarms" for a comprehensive description of the controls and indicators on the pump.

If the operation or performance of the pump changes during use, refer to "Troubleshooting" on page 25 of this IFU before calling a service engineer or contacting your local ArjoHuntleigh sales office.

Preparing the System

- 1. Remove the system from the packaging. You should have the following items:
 - Flowtron Hydroven 12 pump.
 - Flowtron Hydroven 12 garment (arm or leg).
 - Flowtron Hydroven 12 garment insert (optional).
- Make sure system has been arranged so that the power cable and garment hoses do not pose a trip or strangulation hazard.
 - 2. Make sure the garment is the correct size for the limb, and that a garment insert is used if necessary (refer to "Garment Dimensions" on page 8).
 - 3. Undo the zip on the garment.
 - 4. If a garment insert is to be fitted to the garment, do the following:
 - Put the garment insert in between the two halves of the garment zip. Make sure the orientation of the garment and insert are correct: the two tubesets should be at the same end and on the outside of the garment and insert.
 - Fully fasten one of the zips between the garment and insert, leaving the other unfastened.
 - 5. Before applying the garment (and insert, if fitted) to the limb, zip up the first 150 mm (6") of the unfastened garment zip. Put the garment (and insert) onto the limb and fully fasten the zip.
 - 6. Make sure the patient is in a comfortable position with the limb supported or elevated as necessary.
 - 7. Connect the garment(s) to the two 12-way connectors on the pump, as follows:
 - If two garments are used (either two arm garments, two leg garments, or one arm/leg

garment and one garment insert), one will be connected to the upper connector and the other connected to the lower connector. The two connections are interchangeable - both garments will inflate at the same time and to the same pressure.

• If only one garment is used, it must be connected to the upper connector and the rubber cover must be folded over and securely fitted to the lower connector.

The connectors are push-fit and polarised to prevent incorrect orientation.

- 8. If the patient is setting up or operating the system on his/her own, then make sure:
 - The pump is set up *before* garments are fitted.
 - The garments are connected to the pump *before* they are fitted to the limbs.
- 9. Insert the mains power plug into a suitable mains power socket.
- 10. Switch on the mains power supply to the pump.
- 11. The pump will perform a short self-test and then go into **Standby**.
- 12. The **Run** and **Sleep** mode indicators are extinguished.
- 13. The indicators and displays on the pump control panel will show the previously selected therapy settings (refer to "Storing New Therapy Settings" on page 15).
- 14. Check the therapy settings and make any changes (refer to "Checking the Therapy Settings" on page 17).

Checking the Therapy Settings

To check the therapy settings, do the following:

- 1. Press the **Inflation Mode** select button until the required inflation mode is selected, as follows:
 - Sequential
 - Wave
 - LymphAssist
 - LymphAssist plus Sequential
 - LymphAssist plus Wave

The indicator adjacent to the selected Inflation

Mode is illuminated. With linked therapy cycles,
both Inflation Mode indicators are illuminated.

- 2. Check the **Pressure** setting on the **Pressure** display.
- 3. Check the **Inflate** and **Deflate** times and **Treatment** duration on the **Therapy Setting** display. Press the **Therapy Setting** select button to select which parameter is shown on the **Therapy Setting** display, as follows:
 - Inflate time □-□-■ (s)
 - Deflate time ▲-ᢕ→△ (s)
 - Treatment duration () (min)
- The indicator adjacent to the selected **Therapy Setting** is illuminated.
 - 4. To change any of the four therapy settings, refer to "Changing the Therapy Settings" on page 18.
 - 5. When the therapy settings are correct, the therapy session can then be started (refer to "Starting Therapy" on page 19).

Changing the Therapy Settings

To change the four therapy settings (**Pressure** setting, **Inflate** time, **Deflate** time and **Treatment** duration), do the following:

Setting the Pressure

- 1. The value shown on the **Pressure** display is the set pressure for the first garment chamber to be inflated.
- 2. The pressure can be adjusted in 5 mmHg increments by pressing the + and **Pressure** setting buttons. If the + or button is held down, the display change increases in speed.
- For **Sequential** and **Wave**, the pump will not start inflating the next chamber in the garment until the set pressure is reached in the previous chamber. Therefore if the set pressure is greater than 80 mmHg, the **Inflate** and **Deflate** times may be longer than the selected values.

Setting the Inflate/ Deflate Times

For Sequential and Wave:

- The **Inflate** time is the total time to inflate all 12 chambers in the garment(s) during one cycle: from starting to inflate the first chamber to the last chamber being completely deflated.
- The **Deflate** time is the time between the end of one **Sequential** or **Wave** cycle and the start of the next cycle: from the last chamber being completely deflated in one cycle to starting to inflate the first chamber in the next cycle.

For LymphAssist:

- The **Inflate** time is the total time to inflate all 12 chambers in the garment during the single peristaltic **Wave** inflation at the start of the **LymphAssist** cycle.
- The **Deflate** time is the time between the end of one **LymphAssist** cycle and the start of the next cycle (refer to "LymphAssist Inflation" on page 5).

To set the **Inflate** or **Deflate** times, do the following:

- 1. Press the **Therapy Setting** select button until the desired **Inflate** or **Deflate** indicator is illuminated.
- 2. The **Inflate** and **Deflate** times can both be adjusted in 5 second increments, by pressing the + and **Therapy** setting buttons. If the + or button is held down, the display change increases in speed.

Setting the Treatment Duration

- 1. The **Treatment** duration is the default setting for the **Therapy Setting** display.
- 2. Make sure the **Therapy Setting** indicator adjacent to **Treatment** duration is illuminated. If not, press the **Therapy Setting** select button to select it.
- 3. The **Treatment** duration can be adjusted in one minute increments by pressing the **+** and **Therapy** setting buttons. If the **+** or **-** button is held down, the display change increases in speed.
- 4. If you continue to hold down the **+ Therapy** setting button when the **Treatment** duration gets to 99 minutes, **CO** will be shown on the **Therapy Setting** display to indicate continuous therapy.

Starting Therapy

- 1. Make sure the pump is in **Standby**.
- Make sure that all garment zips are completely and securely fastened before starting the therapy.
 - 2. Press the **Run/Standby** button to start the patient therapy.
 - 3. The **Run** mode indicator will be illuminated and the **Therapy Setting** and **Pressure** displays will show the previously selected settings.
 - 4. The pump will run through an initialisation process (this initialisation may take up to 15 seconds).
 - 5. At the end of the initialisation process the pump compressor will start running and the garment(s) will start inflating.

- 6. When the therapy starts, the **Treatment** duration shown on the **Therapy Setting** display will count down, indicating the time remaining (to the nearest full minute).
- 7. The **Treatment** duration can be adjusted at any time during the treatment session (refer to "Setting the Treatment Duration" on page 19).

Caution

Do not apply the garment to the limb unless it is partially zipped, as you may damage the garment zip.

Do not undo the zips or attempt to remove the garments during the therapy session or you may damage the zips. Make sure the therapy session has stopped and the garments have deflated before you remove the garments.

Do not stand or walk during the therapy session if leg garments are fitted.

Stopping Therapy

- 1. There are two ways to stop the therapy, as follows:
 - The pump automatically stops at the end of the selected therapy time and the garments are deflated.
 - The pump can be stopped during the therapy by pressing the **Run/Standby** button. The pump will not stop immediately as it takes a few seconds to deflate the garment.
- 2. When the garments have been deflated, the **Therapy Setting** and **Pressure** displays both change to zero and the pump gives 5 beeps to confirm that the treatment session has been completed.
- 3. The **Run** indicator is extinguished.
- 4. Press the **Run/Standby** button to reset the pump to **Standby**.

Storing New Therapy Settings

- 1. If the Inflation Mode, Pressure setting, Inflate time, Deflate time or Treatment duration are adjusted, the new setting is stored and used as the default setting for the next therapy session.
- 2. The new setting is stored in the pump five seconds after the last function button has been pressed.
- 3. If the pump is switched off during this five second period after the last function button has been pressed, the new setting will **NOT** be saved.

Control Panel Lockout

The buttons on the pump control panel can be "locked" to prevent the patient from changing the therapy settings on the control panel.

Pressure Setting

- 1. To lock the **Pressure** setting, and prevent accidental alterations during the therapy session, press the following two buttons simultaneously:
 - The **+ Pressure** setting button.
 - The **Pressure** setting button.
- 2. To unlock the **Pressure** setting, press the following three buttons simultaneously:
 - The **+ Pressure** setting button.
 - The **Pressure** setting button.
 - The **Therapy Setting** select button.

Inflation Mode and Therapy Time Settings

- 1. To lock the **Inflation Mode**, **Inflate** time, **Deflate** time and **Treatment** duration settings, and prevent accidental alterations during the therapy session, press the following two buttons simultaneously:
 - The **+ Therapy** setting button.
 - The Therapy setting button.
- In the **Lockout** mode, the **Treatment** duration is set to the nearest 5 minutes (rounded down).
 - 2. To unlock the **Inflation Mode**, **Inflate** time, **Deflate** time and **Treatment** duration settings, press the following three buttons simultaneously:
 - The **+ Therapy** setting button.
 - The **Therapy** setting button.
 - The **Therapy Setting** select button.

5. Decontamination

The following processes are recommended, but should be adapted to comply with the local or national guidelines (Decontamination of Medical Devices) which may apply within the Healthcare Facility or the country of use. If you are uncertain, you should seek advice from your local Infection Control Specialist.

The **Hydroven 12** system should be routinely decontaminated between patients and at regular intervals while in use; as is good practice for all reusable medical devices.

WARNING

Remove the electrical supply to the pump by disconnecting the mains power cord from the mains power supply before cleaning. Protective clothing should always be worn when carrying out decontamination procedures.

Caution

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

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.

Chemical Disinfection

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

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

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

Ensure the product is dry before storage.

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

To Clean and Sterilise Garments

Wipe down garments using a neutral detergent or soap powder at 40°C. Dry thoroughly.

After cleaning gas sterilisation is possible, however:

- Do not exceed 51°C (120°F).
- Do not autoclave.

6. Routine Maintenance

Flowtron Hydroven 12 System

Maintenance The equipment has been designed to be virtually

maintenance-free between service periods.

Servicing ArjoHuntleigh will make available on request service

manuals, component parts lists and other information necessary for ArjoHuntleigh trained personnel to repair

the system.

Service Period ArjoHuntleigh recommend that the Flowtron

Hydroven 12 pump is serviced every 12 months by an

ArjoHuntleigh authorised service agent.

Pump

General Care, Check all electrical connections and the mains power

Maintenance and cord for signs of excessive wear.

In the event of the pump being subjected to abnormal treatment, e.g. immersed in water or dropped, the unit

must be returned to an authorised service centre.

Garments

Inspection

General Care Inspect the garment for signs of wear or any tears, and

check that all zips and fasteners are secure.

Check the security of all internal pneumatic

connections.

Serial Number Labels

Pump The serial number label is secured to the rear case of the

pump. Quote this serial number when requesting

service.

Garment The serial number label is attached to the garment.

7. Troubleshooting

The following table provides a troubleshooting guide for the **Flowtron Hydroven 12** system in the event of malfunction.

Refer to Section 3, Page 12 "Controls, Indicators and Alarms" for a comprehensive description of the alarms and indicators on the pump.

Therapy Setting Display	Possible Cause	Corrective Action
(Pump Fault)	Internal pump fault.	Re-run the pump self-test. If still faulty, call service engineer.

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

8. Technical Specification

Pump			
Model:	Flowtron Hydroven 12 System		
Part Numbers:	316001 UK 316009AU Australia / New Zealand		
Pressure Range:	Sequential: 15 - 120 mmHg Wave: 15 - 100 mmHg LymphAssist: 15 - 40 mmHg all ± 5%		
Supply Voltage:	100-230 V		
Supply Frequency:	50-60 Hz		
Power Input:	38-77 VA		
Size:	250 x 130 x 290 mm		
Weight:	3.8 kg		
Case Material:	Fire Retardant ABS Plastic		
Plug Fuse Rating:	5A to BS1362 (UK ONLY)		
Degree of protection	Class II, Double Insulated		
against electric shock:	Type BF		
Degree of protection against liquid ingress:	IPX0 - No protection		
Mode of operation:	Continuous		

ENVIRONMENTAL INFORMATION					
Condition	Temperature Range	Relative Humidity	Atmospheric Pressure		
Operating	+10 °C to +40 °C (+50 °F to +104 °F)	30% to 75% (non-condensing)	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		

B

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.

Symbo	Symbols				
Ф	Standby. Note: Unit is not isolated from mains supply.	X	Do not dispose of in domestic refuse		The operator must read this document (Instructions for Use) before use. Note: This symbol is blue on the product label.
SN:	Serial Number	*	Type BF	25EA CAN/CSA-C22.2 No 60601-1 (2008)	With respect to electric shock, fire and mechanical hazards only in accordance with CAN/CSA-C22.2 No. 60601.1 (2008). MEDICAL EQUIPMENT
	Double Insulated	Ref:	Model number	i	Refer to this document (Instructions for Use) for a description of the product classification (3rd Edition).
				<u> </u>	Refer to this document (Instructions for Use) for a description of the product classification (2nd Edition).
					Manufacturer: This symbol is accompanied by the name and the address of the manufacturer.

GARMENTS AND GARMENT INSERTS						
Arm Garment Dimensions						
Garment Part No.	316	A68	316	A78		
Length (Shoulder to Fingertips)	68	cm	78	cm		
Circumference (at Shoulder):						
Arm Garment	62	cm	62	cm		
With Garment Insert	79	cm	79	cm		
Corresponding Insert Piece Part No.	316	A168	316	AI78		
Width of Insert (at Shoulder)	17	cm	17	17 cm		
Leg Garment Dimensions	Standard		Large			
Garment Part No.	316L76S	316L84S	316L76W	316L84W		
Length (Top-of-Thigh to Heel)	76 cm	84 cm	76 cm	84 cm		
Circumference (at Top-of-Thigh):	· · · · · · · · · · · · · · · · · · ·					
Leg Garment	71 cm	71 cm	79 cm	79 cm		
With Garment Insert	90 cm	90 cm	98 cm	98 cm		
Corresponding Insert Piece Part No.	316LI76	316LI84	316LI76	316LI84		
Width of Insert (at Top of thigh)	19 cm	19 cm	19 cm	19 cm		
Material						
Inner:	PU-coated, knitted nylon					
Outer:	Double PU-coa	ited, woven nylor	า			

CLEANING SYMBOLS				
(Aun)	Wipe surface with damp cloth		Do Not Tumble Dry	
PH BANO.	Do Not Use Phenol-based cleaning Solutions	\bowtie	Do not Iron	
\boxtimes	Do Not Dry Clean	1000ppm NaOCI NaDCC	Use solution diluted to 1000 ppm of Available Chlorine	

Guidance and manufacturer's declaration - electromagnetic emissions

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should assure 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
CISPR - 11		and are not likely to cause any interference in nearby electronic equipment.
RF emissions	Class A	The pump is suitable for use in all establishments other than domestic and those directly connected
CISPR - 11		to the public low-voltage power supply network
Harmonic emissions	Class A	that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions	Complies	
IEC 61000-3-2		

Recommended separation distances between portable and mobile RF communications 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	Separation dista	nce according to frequency of transmitter m			
output power of transmitter W	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 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 assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, that the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
			$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
IEC 01000-4-3	00 IVII 12 10 2.301 12		where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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:

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 reorientating or relocating the pump.

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

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