

# Flowtron Universal

## Instructions for Use

**ARJOHUNTLEIGH**  
GETINGE GROUP





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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.**
- **The Flowtron® Universal system is NOT intended for use in the Home Healthcare Environment (e.g. private dwellings or nursing homes).**

### Caution (applicable to the USA market only)

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

### Safety Warnings - Battery Pack (Optional)

The following instructions are important for the safe use of the battery pack and to keep the user (resident/care giver) from harm:

- **The battery pack BBP600 for the *Flowtron* Universal is rechargeable.**
- **Only use the battery pack designed for use with the pump. If unsure, do not use the battery pack. Make sure the battery pack belongs to the pump by comparing the battery pack label with the "Technical Specification" on page 20. If the battery pack type cannot be confirmed, contact your local ArjoHuntleigh office.**
- **Do not expose the battery pack or charger to open flames.**
- **Do not expose the battery pack connector to water.**
- **To avoid bodily injury, do not crush, puncture, open, dismantle or otherwise mechanically interfere with the battery pack.**
- **Should the battery pack casing crack and cause contents to come in contact with skin or clothing, rinse immediately with plenty of water.**

- **If contents come in contact with the eyes, rinse immediately with plenty of water and seek medical attention.**
- **Inhalation of the contents can cause respiratory irritation. Provide fresh air and medical attention.**
- **Stop using the battery pack if any damage or deformation is noted. Contact your local ArjoHuntleigh office before further use.**
- **Refer to the “Battery Storage and Disposal” on page 13 for the correct disposal and recycling of the battery pack.**

### **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.

### **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* Universal 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* Universal 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.

### **Design Policy and Copyright**

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## 1. Introduction

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- About this Manual** This manual is your introduction to the Flowtron® Universal.  
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* Universal system, contact your local ArjoHuntleigh sales representative, listed at the end of this manual.
- Intended Use** The intended use of this product is to prevent Deep Vein Thrombosis (DVT). The garments are single patient use only. It is not for use in the home healthcare environment.  
  
The *Flowtron* Universal system should be used as part of a prescribed plan of care (refer to “Indications” on page 2).
- About *Flowtron* Universal** The pump automatically adjusts to the correct therapy profile depending upon which garment type (foot, calf or thigh length) is connected.  
An optional battery pack is available which allows the pump to be used independently of a mains power outlet.  
**The *Flowtron* Universal is intended for use ONLY in Professional Healthcare Facilities (e.g. hospitals or physicians’ offices).**  
A full technical description of the *Flowtron* Universal system can be found in the Service Manual, part number SER0009, available from your local ArjoHuntleigh sales representative.

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## 2. Clinical Applications

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**Indications** The primary application of the *Flowtron* Universal system is for the prevention of Deep Vein Thrombosis (DVT), when 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 FG 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

#### ***DVT Calf / Thigh Garments***

The *Flowtron* Universal system, when used with the DVT Calf / Thigh Garments, should **not** be used in the following conditions:


1. Severe arteriosclerosis or other ischaemic 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 *Flowtron* Universal 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. Additional care should be taken when placing the garments on any deformed leg or foot, or on legs with significant oedema.
3. Garments should be removed immediately if the patient experiences tingling, numbness, or pain, and the physician notified.
4. When used for DVT prevention, continuous external pneumatic compression is recommended until the patient is fully ambulatory. Uninterrupted use of the *Flowtron* Universal system is encouraged.
5. The *Flowtron* Universal 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:**

- While using the system, the patient's limbs should be checked during every shift, and more often if the patient has known circulatory or skin problems, or is diabetic.

- Note: 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 proper skin care.
- Clinical judgment should be used to determine if the patient's skin condition requires additional measures, or if the treatment should be discontinued and alternative modalities used.
- ArjoHuntleigh does not recommend the use of compression stockings with its system. If these 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.


 *Loss of mains power will halt therapy.*

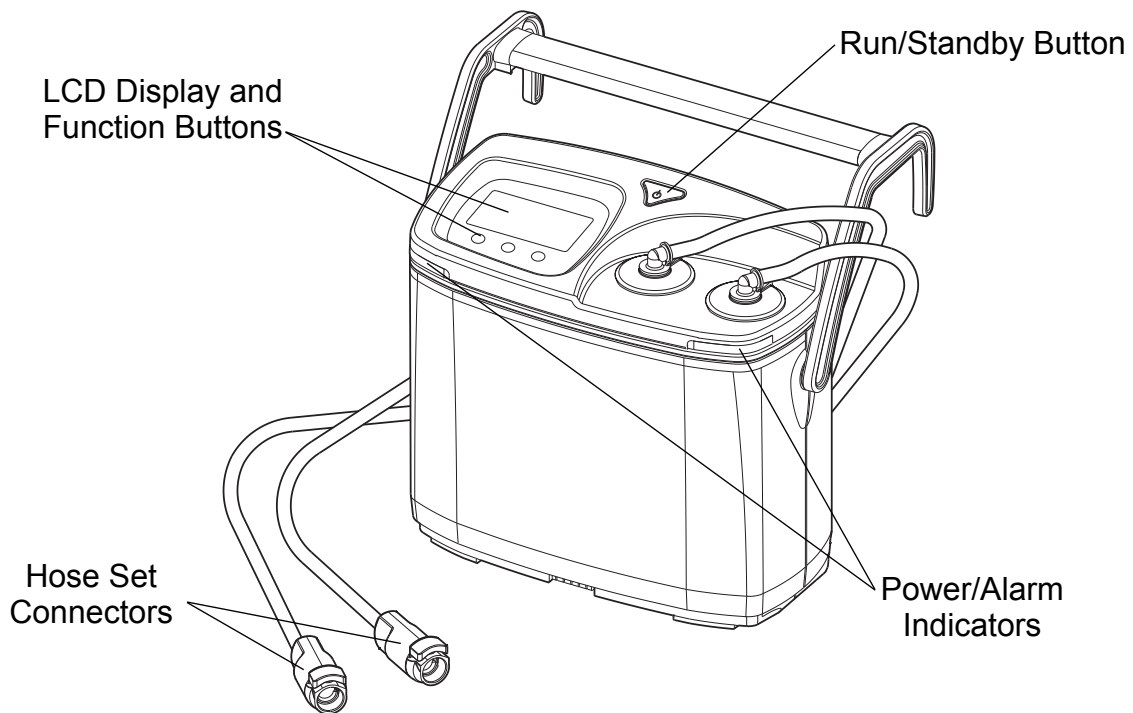
### **DVT prophylaxis**

- The *Flowtron* Universal system should be applied to the patient pre-operatively, 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.
- In the non-surgical patient, the system should be initiated immediately the risk of DVT formation is identified.


### 3. Operation

The *Flowtron* Universal system does not require any setting or adjustment of controls before use. It automatically senses the type of garment connected and adjusts the therapy cycle and pressure profile accordingly.

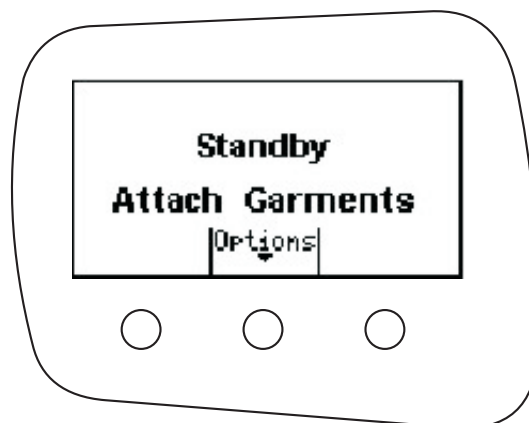
 *If the operation or performance of the pump changes during use, Refer to “Troubleshooting” on page 18 of this IFU before calling a service engineer or contacting your local ArjoHuntleigh sales office.*



Plug the pump into an electrical outlet.

 *Make sure system has been arranged so that the power cable and garment hoses do not pose a trip or strangulation hazard.*

**Standby Mode** The pump will first go through a self-test routine and then remain in **Standby** until required for use.



**Garment Application** Use the correct garment type as ordered by the patient's physician.

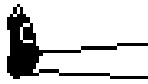

For detailed instructions on correct fitting and use, carefully read and follow the instruction provided with every garment set.


Connect the garments to the pump hose set connectors and ensure the connectors click into place.

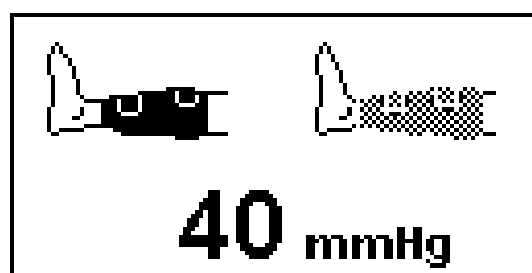
Check that the connection and garment type are confirmed correctly on the display.




**Typical garment options and therapy parameters**


Garment Type/ LCD Display	Inflation Pressure (mmHg)	Inflation Hold (seconds)	Cycle (seconds)
 Foot garments e.g., FG100-200	130	3	30
 Single chamber garments e.g., DVT10-40,60	40	12½	60

TO START, press and hold the green RUN  button on the pump. The green power indicators will illuminate and therapy will begin.



*This example shows the pump running and the left garment inflated to 40 mmHg.*

 Refer to “Battery Operation” on page 12 when operating the pump under battery power.

TO STOP press and hold the green RUN  button a second time. The green power indicators will go out and therapy will stop.

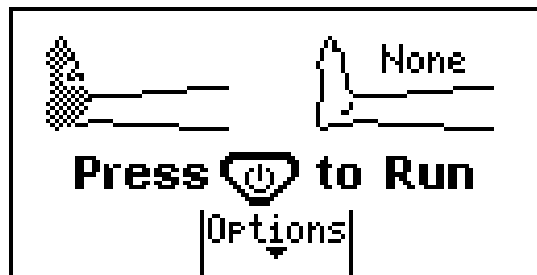
**Recommended Checks:**




- Check display symbols to confirm that the correct type of garment has been connected.
- During garment inflation, check the display to confirm that the correct pressure is being applied and that there are no fault messages appearing.
- Check that there are no kinks in the pump hoses and garment tubing.
- Check that the pump hoses and connectors do not cause the patient any discomfort.
- Regularly check that the garments remain correctly fitted to the patient.

**To Use One Garment**

When the pump is in standby (see “Standby Mode” on page 5) connect one garment to either pump hose connector.

The display will confirm that only one garment is connected.



 *If a garment is disconnected while the pump is running, the system will alarm **Lo**. If the single garment option is still required, press the RUN  button to reset the system and press RUN  again to restart therapy.*

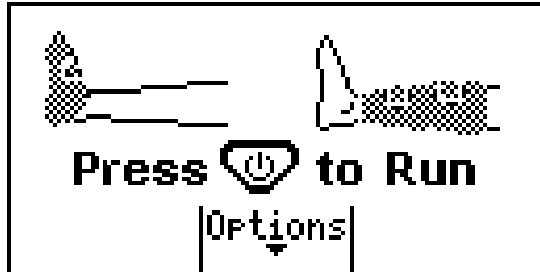
*If, at any time, a second garment is connected while the pump is running, the pump will automatically change to two garment operation.*


**To Use Different  
Garments on Each  
Limb**

It is possible to use different garment types on each limb (if prescribed by the patient's physician).

Connect the garments to either tubing outlet and the correct therapy cycle will be administered.

Check on the display panel to confirm the garment types connected.



 *The system is not designed to be used with different garment types (e.g. foot and calf/thigh) on the same limb.*

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## **4. Settings Adjustment**

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

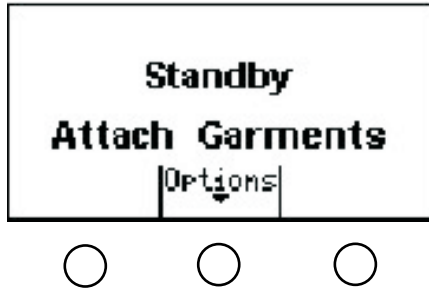
If the physician requires different therapy settings, limited changes can be made through a service link. Contact your local ArjoHuntleigh Sales Representative for details.

## 5. Options

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Pressing the option button will bring up a multi-choice menu of options.



The option can be set using a combination of the three function buttons on the display.





To return to the previous menu at any time, highlight **Back** using the arrow buttons and press the ✓ button to confirm.

To exit the options menu at any time, highlight **Exit** using the arrow buttons and press the ✓ button to confirm.



### **Audio Alarm Volume**

1. Press the function button adjacent to **Options**.
2. Use the arrow buttons   to highlight **Audio Alarm Volume**.
3. Press the ✓ button to display the volume setting controls.
4. Use buttons to select either **high** or **low** volume setting.
5. Press the ✓ button to confirm.
6. The selected volume setting will remain in place, during subsequent uses of the pump.

### **Patient Hours Meter**

1. Press the function button adjacent to **Options**.
2. Use the arrow buttons   to highlight **Patient Hours Meter**.
3. Press the ✓ button to display the total hours run.

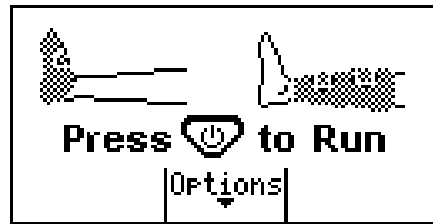
### **Clear the Patient Hours Meter**

1. In the **Patient Hours Meter** menu use the arrow buttons   to select **Clear Patient Hours**.
2. Press the ✓ button to clear the hours to 0.

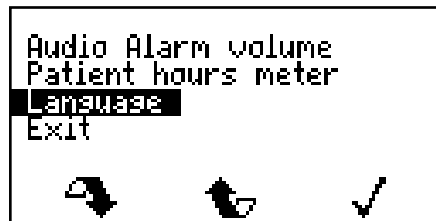
### **Change The Language Shown on The Pump**

1. Press the function button adjacent to “Options”.





2. Use the arrow buttons to highlight 'Language'.



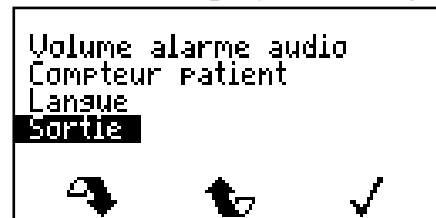
3. Press the ✓ button to confirm.
4. Use the arrow buttons to scroll through the available languages.



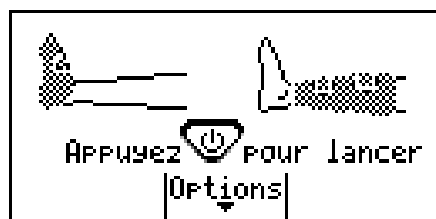
5. Press the ✓ button to confirm.



6. Press the ✓ button again to confirm.
7. Use the arrow buttons to highlight 'Exit'. Note the word 'Exit' will be displayed in language selected.



8. Press the ✓ button to confirm.



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## 6. Battery Operation

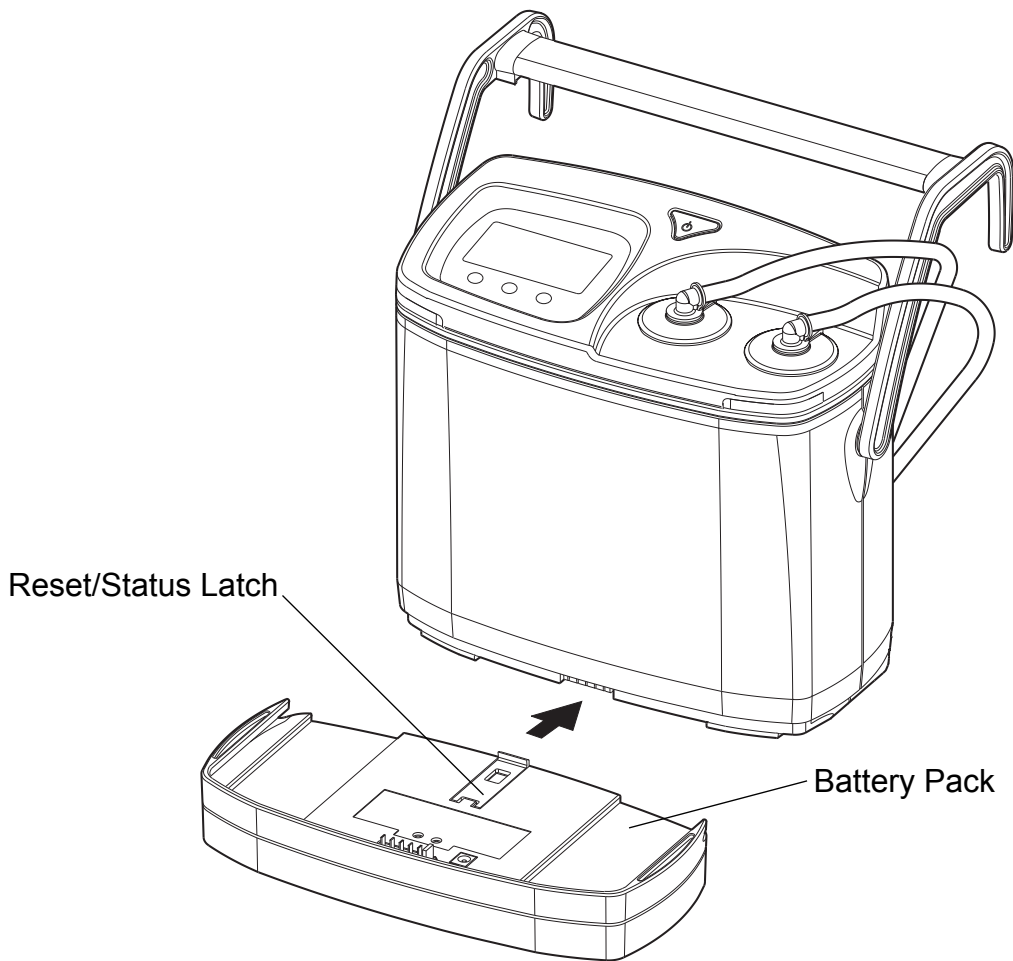
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When used with the optional battery pack, the system can be run independently of the mains power supply. Typically, 6-8 hours of operation can be expected from a fully charged battery pack.

### Connecting the Battery Pack

From the front of the pump, engage the pack on the runners and slide into place until a click is heard.

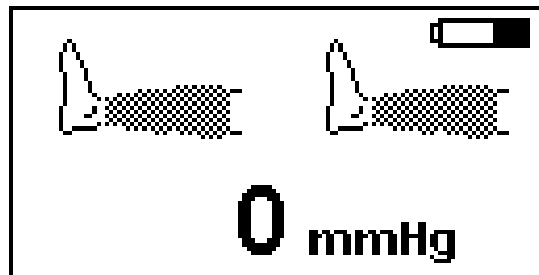
To remove the pack, depress the latch at the rear of the unit and slide pack forward and out.




### Battery Pack in Use

The battery pack will automatically take over powering the pump whenever the mains power cord is removed from the wall outlet.

When running under battery power, a battery symbol appears in the top right hand corner of the display.



 *In order to maximize battery life, the power alarm indicators will not illuminate when operating the Flowtron Universal under battery power. You may verify therapy is, or is not, being provided via the LCD screen.*

The amount of charge remaining in the battery pack is indicated by the black block inside the battery symbol.



When the battery has only 5% of the charge remaining, the battery symbol will flash and the remaining charge will be displayed as a percentage. Recharge the battery as soon as possible.

Then, when the battery has 1% charge, the audible alarm will sound and the pump will stop running. Recharge the battery.

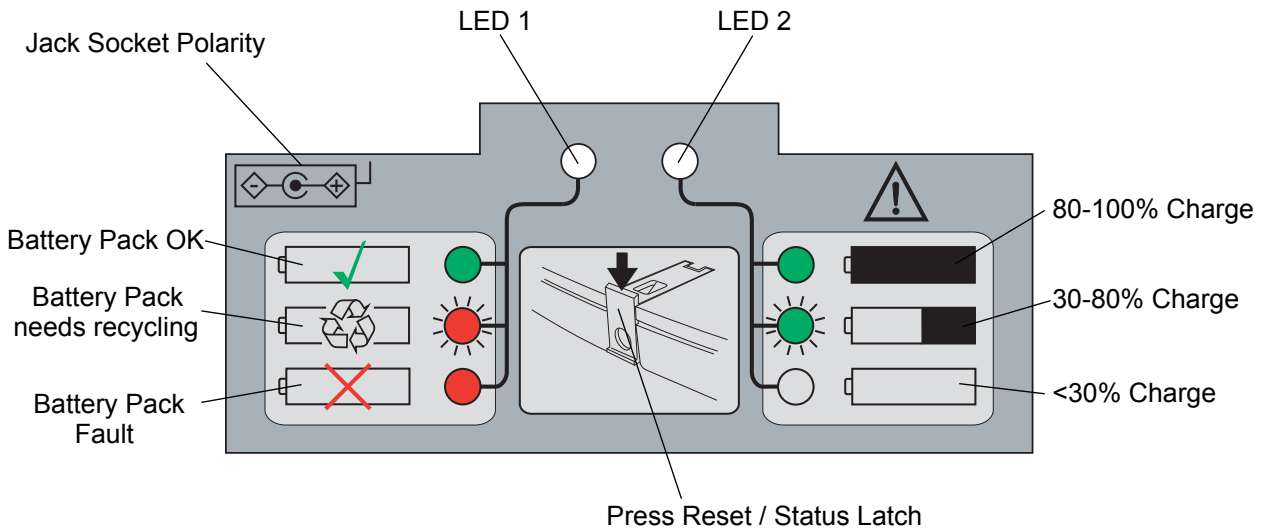
### **Battery Storage and Disposal**

If the device is not to be used for an extended period, charge (refer to “Recharging the Battery Pack” on page 15), remove and store the battery pack. If the battery pack is to be put into long term storage it should be recharged at least once every three to six months.

A faulty battery pack should be sent back to ArjoHuntleigh for recycling or correct disposal.

## Checking the Status of the Battery

### Battery Label



### To Check the Battery Status:







1. Remove the battery from the pump unit.
2. Press the Reset/Status Latch which will activate the 2 LEDs on the top of the battery.

If the battery pack is not on charge, the LEDs will display one of the following conditions:

LED 1	LED 2	Battery Status
Green ●	Green ●	The Battery Pack is OK. It has > 80% charge.
Green ●	Green ☀	The Battery Pack is OK. It has between 30-80% charge.
Green ●	○	The Battery Pack is OK. It has < 30% charge.
Red ☀	Green ☀	The Battery Pack needs recycling*. It has between 30-80% charge.
Red ☀	○	The Battery Pack needs recycling*. It has < 30% charge.
Red ●	○	The Battery Pack has an error. Press Reset/Status Latch.
○	○	The Battery Pack has an error. Try recharging.

If the battery pack is on charge via the optional battery charger, the LEDs will display one of the following conditions:

LED 1	LED 2	Battery Status
Green ●	Green ●	The Battery Pack is OK. It is fully charged.
○	Green ☀	The Battery Pack is charging.

Red 	Green 	The Battery Pack needs recycling*. The Battery is charging.
Red 		The Battery has a fault.
		The Battery has a fault.

\*Once the Battery Pack has entered the 'recycling' mode, it will never show that the battery is fully charged (Note: This does not indicate a fault condition).


### Recharging the Battery Pack

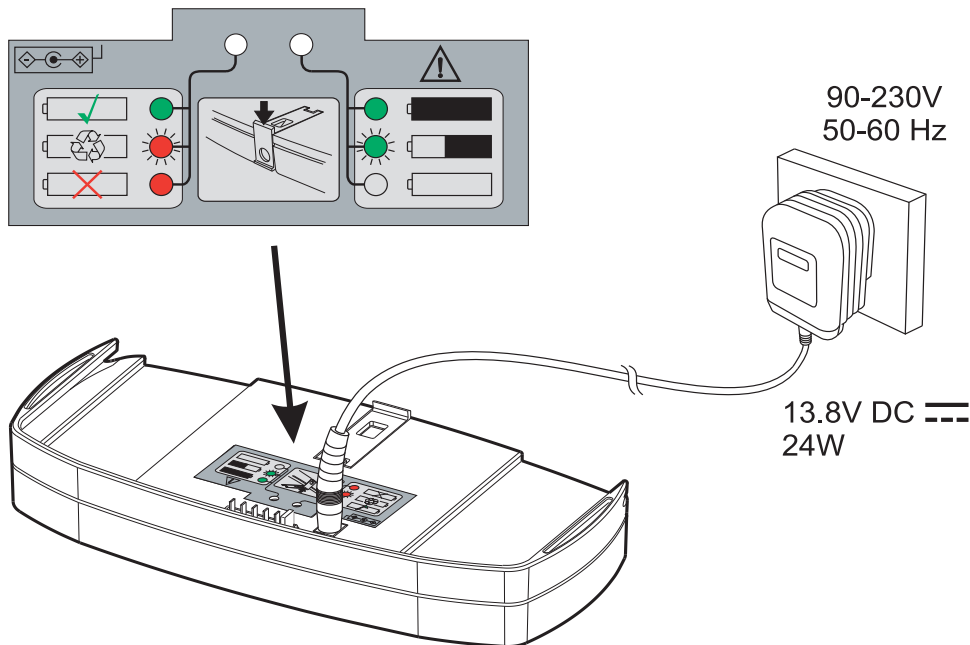
The battery pack is automatically recharged whenever the pump is connected to an AC outlet. On the display, the arrow confirms the pump is connected to AC power and the battery is charging.



### Alternative Method of Charging

Alternatively, the battery pack can be recharged away from the pump by plugging it into the battery charger as shown below.

 *Avoid charging the battery near source of heat or in direct sunlight.*



### Caution

**Only ArjoHuntleigh-approved battery chargers must be used. Use of a non-approved charger may result in damage to the battery pack or ineffective charging and therefore voids the warranty.**

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## 7. Decontamination

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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 *Flowtron* Universal 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.

### Caution

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

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## 8. Routine Maintenance

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### **Flowtron Universal System**

**Maintenance** The equipment has been designed to be 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* Universal pump is serviced every 12 months by an **ArjoHuntleigh** authorised service agent.

### **Flowtron Universal Pump**

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

**Inspection** Check the tubeset and connectors for any damage.

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.

**Serial Labels** The serial number for the pump is on the label on the back of the pump case. Quote this serial number when requesting service.

## 9. Troubleshooting


The *Flowtron* Universal pump features an audible and visual alarm. If a problem occurs, the system will sense the fault and briefly flash a message on the display.


If the same fault continues for 10 successive inflations (up to 10 minutes), the audible alarm will sound, the red alarm lights flash and a message will appear on the display until corrective action is completed. (The exception to this is an “F” fault, which will alarm immediately.)

Pump LCD Display	Problem	Corrective Action
<b>Lo</b> Garment leak	Garment Leak	Check garment and replace if faulty.
<b>Lo</b> Garment unplugged	Garment disconnected	Check and reconnect.
<b>Lo</b> Garment loosened	Foot garment has come off patient during use	Reapply foot garment to patient.
<b>HI</b> Tube kinked	Pump hose kinked causing a blocked tube	Check pump hoses for kinks and obstructions.
<b>F</b> Pump fault	Pump failure	Do not use pump, refer to service.

### Alarm Cancel:

After a fault has been corrected, the alarm can be cancelled by two methods:

Press the RUN  button twice, or until the green power indicators are lit and the pump is running.

 Refer to “Battery Operation” on page 12 when operating the pump under battery power.


With the exception of a pump failure (**F**), correct the fault and allow the pump to run until it senses a normal inflation; it will then reset itself.

### Recommended Checks:

To confirm that the fault has corrected, watch the display for approximately one minute. If the fault has not been corrected, a fault message will flash during that time.

In addition, the pump will refuse to start if it does not recognize the attached garment.

Pump Display	Problem	Corrective Action
“None” or “Standby Attach Garments”	Pump will not start due to no garments connected or a non-ArjoHuntleigh authorized garment connected.	Connect an authorized ArjoHuntleigh garment.

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



## 10. Accessories

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










<b>CALF GARMENTS</b>		
<b>Order Code</b>	<b>Type</b>	<b>Calf Circumference</b>
DVT10	DVT10 Standard Calf Garment	Up to 43 cm (17")
DVT10S	DVT10S Standard Calf Garment (Sterile)	Up to 43 cm (17")
L501-M	L501-M Standard Calf Garment	Up to 43 cm (17")
DVT20	DVT20 Large Calf Garment	Up to 58 cm (23")
DVT60L	DVT60L Extra Large Calf Garment	Up to 81 cm (32")

<b>THIGH GARMENTS</b>		
<b>Order Code</b>	<b>Type</b>	<b>Thigh Circumference</b>
DVT30	DVT30 Standard Thigh Garment	Up to 71cm (28")
DVT30S	DVT30S Standard Thigh Garment (Sterile)	Up to 71cm (28")
L503-M	L503-M Standard Thigh Garment	Up to 71cm (28")
DVT40	DVT40 Large Thigh Garment	Up to 89cm (35")

<b>FOOT GARMENTS</b>		
<b>Order Code</b>	<b>Type</b>	<b>Shoe Size</b>
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
FG100S	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
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
FG200S	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


# 11. Technical Specification


PUMP	
<b>Model:</b>	Flowtron Universal
<b>Part Numbers:</b>	507001 UK 507009AU Australia 507003 US 507003OR US Operating Room (longer tubeset) 507009ZA South Africa/India
<b>Pressure Range:</b>	Calf/Thigh: 40 mmHg ± 5 mmHg Foot: 130 mmHg ± 10 mmHg
<b>Supply Voltage:</b>	100-230 V
<b>Supply Frequency:</b>	50-60Hz
<b>Power Input:</b>	38-77 VA
<b>Size:</b>	230 x 270 x 150 mm
<b>Weight:</b>	3.9 kg
<b>Case Material:</b>	Fire Retardant ABS Plastic
<b>Plug Fuse Rating:</b>	5A to BS1362 (UK ONLY)
<b>Degree of protection against electric shock:</b>	<ul style="list-style-type: none"> <li>Mains Connected: Class II, Double Insulated with Functional Earth Type BF</li> <li>Mains Not Connected: Internally Powered</li> </ul>
<b>Degree of protection against liquid ingress:</b>	IPX0 - No protection
<b>Mode of operation:</b>	Continuous



PUMP SYMBOLS					
	The operator must read this document (Instructions for Use) before use. Note: This symbol is blue on the product label.		Run/Standby. Note: Unit is not isolated from mains supply.		Do not dispose of in domestic refuse
	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		Type BF
	Refer to this document (Instructions for Use) for a description of the product classification (3rd Edition).	<b>SN:</b>	Serial Number	<b>Ref:</b>	Model number
	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.		

**Table 1:**

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

 *Storage: products should be well packaged and stored in a dry, well-ventilated and non-corrosive environment.*

 *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.*


<b>ACCESSORIES</b>	
<b>Part:</b>	Battery Pack
<b>Part Number:</b>	BBP600
<b>Size:</b>	242 x 37 x 118 mm
<b>Weight:</b>	0.8 kg
<b>Electrical Rating:</b>	13.8V dc — — — 4Ah (NiMH)
<b>Symbols</b>	
	Do not dispose of in domestic refuse
	Recycle

<b>Guidance and manufacturer’s declaration - electromagnetic emissions</b>		
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.		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR - 11	Group 1	The pump uses RF energy only for its internal function. therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

<b>Guidance and manufacturer's declaration - electromagnetic emissions</b>		
RF emissions CISPR - 11	Class A	The pump is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

## Guidance and manufacturer's declaration - electromagnetic immunity

The 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
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> <p><math>d = 1.2\sqrt{P}</math></p> <p><math>d = 1.2\sqrt{P}</math>      80 MHz to 800 MHz</p> <p><math>d = 2.3\sqrt{P}</math>      800 MHz to 2.5 GHz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup>, should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

**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.

<sup>a</sup> 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.

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

### Recommended separation distances between portable and mobile RF communications equipment and the pump

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 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.

**AUSTRALIA**

ArjoHuntleigh Pty Ltd  
78, Forsyth Street  
O'Connor  
AU-6163 Western Australia  
Tel: +61 89337 4111  
Free: +1 800 072 040  
Fax: + 61 89337 9077

**BELGIQUE / BELGIË**

ArjoHuntleigh NV/SA  
Evenbroekveld 16  
BE-9420 ERPE-MERE  
Tél/Tel: +32 (0) 53 60 73 80  
Fax: +32 (0) 53 60 73 81  
E-mail: info.belgium@arjohuntleigh.be

**BRASIL**

Maquet do Brasil  
Equipamentos Médicos Ltda  
Rua Tenente Alberto Spicciati, 200  
Barra Funda, 01140-130  
SÃO PAULO, SP - BRASIL  
Fone: +55 (11) 2608-7400  
Fax: +55 (11) 2608-7410

**CANADA**

ArjoHuntleigh  
90 Matheson Boulevard West  
Suite 300  
CA-MISSISSAUGA, ON, L5R 3R3  
Tel/Tél: +1 905 238 7880  
Free: +1 800 665 4831 Institutional  
Free: +1 800 868 0441 Home Care  
Fax: +1 905 238 7881  
E-mail: info.canada@arjohuntleigh.com

**ČESKÁ REPUBLIKA**

ArjoHuntleigh s.r.o.  
Hlinky 118  
CZ-603 00 BRNO  
Tel: +420 549 254 252  
Fax: +420 541 213 550

**DANMARK**

ArjoHuntleigh A/S  
Vassingerødvej 52  
DK-3540 LYNGE  
Tel: +45 49 13 84 86  
Fax: +45 49 13 84 87  
E-mail: dk\_kundeservice@arjohuntleigh.com

**DEUTSCHLAND**

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

**ESPAÑA**

ArjoHuntleigh Ibérica S.L.  
Ctra. de Rubí, 88 1ª planta - A1  
08173 Sant Cugat del Vallés  
ES- BARCELONA 08173  
Tel: +34 93 583 11 20  
Fax: +34 93 583 11 22  
E-mail: info.es@arjohuntleigh.com

**FRANCE**

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

**HONG KONG**

ArjoHuntleigh (Hong Kong) Ltd  
1510-17, 15/F, Tower 2  
Kowloon Commerce Centre  
51 Kwai Cheong Road  
Kwai Chung  
HONG KONG  
Tel: +852 2207 6363  
Fax: +852 2207 6368

**INTERNATIONAL**

ArjoHuntleigh International Ltd  
ArjoHuntleigh House  
Houghton Hall Park  
Houghton Regis  
UK-DUNSTABLE LU5 5XF  
Tel: +44 (0) 1582 745 800  
Fax: +44 (0) 1582 745 866  
E-mail: international@arjohuntleigh.com

**ITALIA**

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

**MIDDLE EAST**

ArjoHuntleigh ME  
Office G005 - Nucleotide Complex,  
Dubitech & Research Park,  
P.O.Box 214742, Dubai,  
United Arab Emirates  
Tel: +971 (0)4 447 0942  
E-mail: international@arjohuntleigh.com

**NEDERLAND**

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

**NEW ZEALAND**

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

**NORGE**

ArjoHuntleigh Norway AS  
Olaf Helsetts vei 5  
N-0694 OSLO  
Tel: +47 22 08 00 50  
Faks: +47 22 08 00 51  
E-mail: no.kundeservice@arjohuntleigh.com

**ÖSTERREICH**

ArjoHuntleigh GmbH  
Dörrstrasse 85  
AT-6020 INNSBRUCK  
Tel: +43 (0) 512 204 160 0  
Fax: +43 (0) 512 204 160 75

**POLSKA**

ArjoHuntleigh Polska Sp. z o.o.  
ul. Ks Piotra Wawrzyniaka 2  
PL-62-052 KOMORNIKI (Poznan)  
Tel: +48 61 662 15 50  
Fax: +48 61 662 15 90  
E-mail: arjo@arjohuntleigh.com

**PORTUGAL**

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

**SUISSE / SCHWEIZ**

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

**SUOMI**

Oy Vestek AB  
Martinkuja 4  
FI-02270 ESPOO  
Puh: +358 9 8870 120  
E-mail: info@vestek.fi

**SVERIGE**

ARJO Scandinavia AB  
Hans Michelsensgatan 10  
SE-211 20 MALMÖ  
Tel: +46 (0) 10 494 7760  
Fax: +46 (0) 10 494 7761  
E-mail: kundservice@arjohuntleigh.com

**UNITED KINGDOM**

ArjoHuntleigh UK  
ArjoHuntleigh House  
Houghton Hall Park  
Houghton Regis  
UK-DUNSTABLE LU5 5XF  
Tel: +44 (0) 1582 745 700  
Fax: +44 (0) 1582 745 745  
E-mail: sales.admin@arjohuntleigh.com

**USA**

ArjoHuntleigh Inc.  
2349 W Lake Street Suite 250  
US-Addison, IL 60101  
Tel: +1 630 307 2756  
Free: +1 800 323 1245 Institutional  
Free: +1 800 868 0441 Home Care  
Fax: +1 630 307 6195  
E-mail: us.info@arjohuntleigh.com

REV 17: 03/2016

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## GETINGE GROUP

**Getinge Group** is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of **ArjoHuntleigh**, **Getinge** and **Maquet**. **Getinge** provides solutions for infection control within healthcare and contamination prevention within life sciences. **Maquet** specializes in solutions, therapies and products for surgical interventions, interventional cardiology and intensive care.

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## ARJOHUNTLEIGH

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ArjoHuntleigh focuses on patient handling and hygiene, disinfection, DVT prevention, medical beds, therapeutic surfaces and diagnostics.



ArjoHuntleigh AB  
Hans Michelsensgatan 10  
211 20 Malmö, Sweden  
[www.arjohuntleigh.com](http://www.arjohuntleigh.com)

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