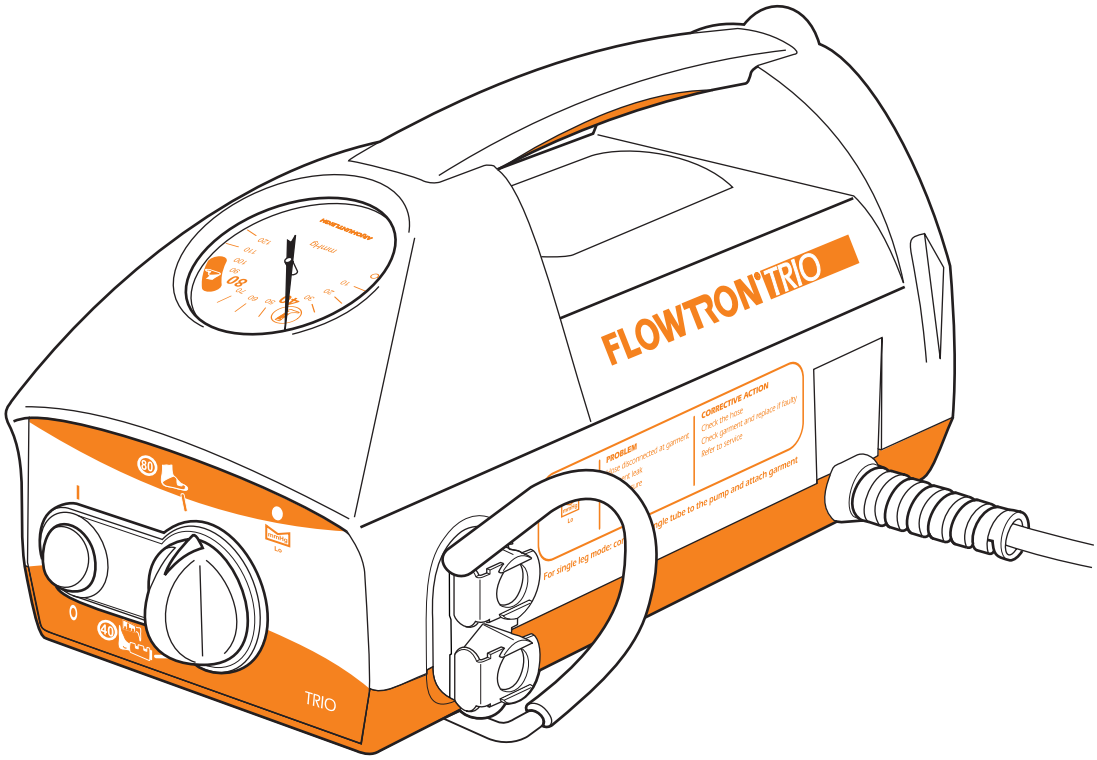
FLOWTRON® TRIO

Instructions For Use

ARJOHUNTLEIGH

GETINGE GROUP



Contents

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

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.**

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.

Service Information

ArjoHuntleigh recommend that this system should be serviced every 12 calendar months or, where applicable, when the service indicator is illuminated.

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

1. Description and Operating Principle

The **Flowtron Trio** system is a non-invasive prophylaxis system for reducing the incidence of deep vein thrombosis (DVT). The application of intermittent pneumatic compression has two effects:

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

The **Flowtron Trio** system consists of:

- A pump.
- A tube assembly.
- A pair of Calf / Thigh or foot, single patient garments.

The pump provides intermittent cycles of compressed air which alternately inflate the single-chambered air garments. The compression applied on the extremity augments venous blood flow velocity and stimulates fibrinolysis.

The pump operates on a 60-second automatically timed cycle consisting of approximately 12 seconds of inflation followed by approximately 48 seconds of deflation.

The **Flowtron Trio** system may be used on patients at risk of developing deep vein thrombosis and in conjunction with systemic interventions (e.g. anticoagulation drugs) for patients at risk.

Caution

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

2. Clinical Applications

The primary application of the **Flowtron Trio** system is for the prevention of DVT. Depending on the garment type used, other clinical applications may also be appropriate.

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

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

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

3. Cautions and Contraindications

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 edema.
3. Garments should be removed immediately if the patient experiences tingling, numbness or pain.
4. When used for DVT prophylaxis, continuous use is recommended and any interruption of therapy for a substantial length of time should be at the discretion of the physician.
5. Patients should be instructed not to stand or walk with foot garments on.
6. The **Flowtron Trio** system (foot compression) 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.*

Contraindications

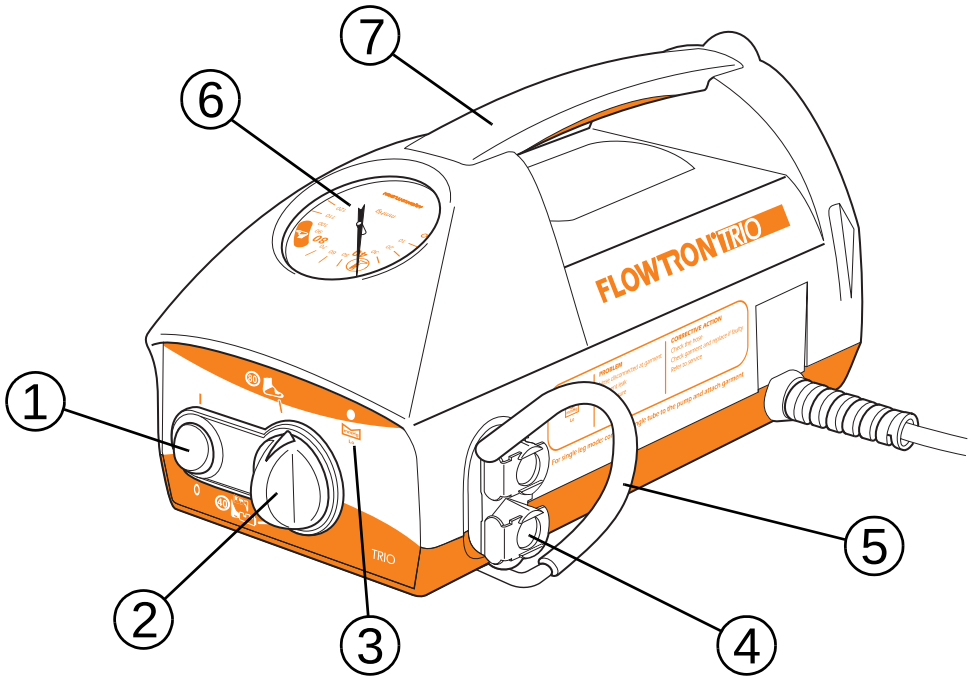
The **Flowtron Trio** system should not be used in the following conditions:

1. Severe arteriosclerosis or other ischemic vascular diseases.
2. Known or suspected acute DVT, thrombophlebitis or pulmonary embolism.
3. Severe congestive cardiac failure or any condition where an increase of fluid to the heart may be detrimental.

4. Any local condition in which the garments would interfere, including gangrene, recent skin graft, dermatitis or untreated, infected leg wounds.

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

4. System Set Up



Item	Description	Function
1	On (**I**) / Off (**O**) Switch	Operation of this switch starts or stops the system.
2	Pressure Control Knob	Rotates clockwise to increase and counterclockwise to decrease pressure (user range 40 - 100 mmHg)
3	Low Pressure Warning LED	An audible alarm will sound and a flashing red LED will remain on the display until corrective action is taken.
4	Tube Connectors	For garment attachment (snap-lock)
5	Hanging Bracket	To hang the pump on the end of a bedframe
6	Pressure Gauge	Indicates delivery pressure to garment (mmHg)
7	Carry Handle	For easy handling of pump
8	Fuse/Holder (Located on base)	Circuit breaker

Garment Application

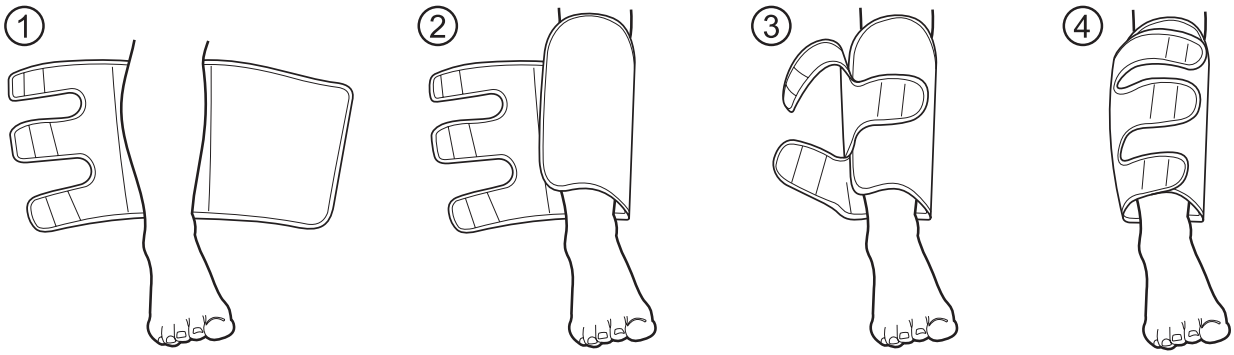
Check that the power switch on the pump is off (**O**). Remove the garments from the packaging and unfold.

Calf and thigh Garments

Fit the calf or thigh garments as follows:

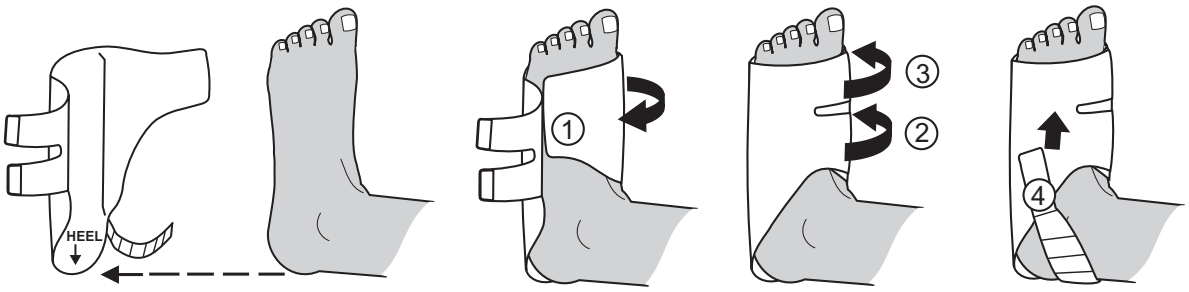
1. Place the back of the patient's leg in the centre section of the garment (1) with the connector tubing pointing downwards towards the foot.

2. Starting with the side that does not have the Velcro[1] tabs, wrap securely against the leg (2). While holding the garment snugly against the leg, wrap the tabs over the top, locating the centre tab first (3). Ensure that the garments are fitted snugly and are not ‘wrinkled’ or ‘tucked’. The connector tubing should be pointing towards the patient’s heel.



Foot Garments Fit the foot garments as follows:

1. Place the foot in the center of garment. Ensure the back of the garment is in line with the heel as indicated.
2. Bring flap (1) over the top of the foot and hold in place.
3. Bring flap (2) over the foot and secure.
4. Bring flap (3) over the foot and secure. The fit should be snug but comfortable.
5. Bring strap (4) around the back of the heel and fix in place as indicated.
6. Tension strap so garment is secure and comfortable.



1. *Velcro® is a registered trademark of VELCRO USA Inc.*

To Complete the system setup Snap-lock the garment connector to the tubing assembly. Ensure that a 'click' is heard. Pull lightly to confirm proper connection.

☞ *To disconnect the garments from the tubing, press the snap-lock connector and pull apart.*

Pre-Use Check

Before using the **Flowtron Trio** system on the patient, ensure that:

- The pump has been set to the correct setting (80mmHg for foot garments or 40mmHg for calf/ thigh garments).
- Garments have been applied to patient's feet / legs correctly, snugly and without wrinkles.
- There are no kinks in the tubing.
- The pump is connected to an electrical outlet.
- All tubing connections are secure.

Operation

Turn the power switch on (**I**). The pump proceeds directly to the inflation cycle.

If using 2 garments, the garments will inflate alternately. The first garment inflates for approximately 12 seconds and is deflated for approximately 48 seconds.

The second garment inflates 30 seconds after the inflation of the first garment and follows the same inflation/deflation cycle.

Verify that the pressure gauge is indicating the desired output pressure. Refer to "Pressure Adjustment" on page 8 for specific pressure setting instructions.

5. Pressure Adjustment

The **Flowtron Trio** pump pressure gauge indicates the actual pressure that is delivered to the garments, and gives continuous feedback for pump performance.

The pressure control mechanism is located on the front of the pump and ranges from 40-100 mmHg. The pressure exerted by the garments on the leg/foot can be adjusted by turning this knob. Turning the knob clockwise increases the pressure; counterclockwise decreases the pressure.

☞ *The recommended pressure settings are 40mmHg for calf/thigh garments and 80mmHg for foot garments, or as prescribed by the physician.*

6. Troubleshooting

The **Flowtron Trio** system features an audible and visual alarm. If a problem occurs, the system will sense the fault. If a fault occurs, the audible alarm will sound and a flashing red LED will remain on the display until corrective action is taken.

The following table provides a troubleshooting guide for the **Flowtron Trio** system in the event of malfunction:

Indicator	Possible Cause	Corrective Action
Low Pressure  	1. Hose disconnected at garment. 2. Garment leak. 3. Low pressure - Pump fault.	1. Check the hose connection at garment end. 2. Check garment and replace if faulty. 3. Call service engineer.
No indicators, no operation	1. No power. 2. Fuse blown.	1. Check plug and power cable. Check for power cut. 2. Call service engineer.

Alarm Cancel After a fault has been corrected, switch the pump off, then on again, using the on/off switch. This will reset the pump.

7. General Recommendations

- While using the system, the patient's skin should be checked at least every shift, and more often if the patient has known circulatory or skin problems, or is diabetic.
- Clinical judgment should be used to determine if the patient's skin condition requires additional measures, such as use of a stockinette or padding, or if the treatment should be discontinued and alternative modalities used.
- If compression stockings are ordered by the physician, the clinician should ensure that they 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.

8. 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 **Flowtron Trio** 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.

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, rinse and dry thoroughly.

Alcohol based disinfectants (maximum 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.

9. Garment Information

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

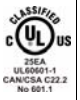
Calf Garments		
Order Code	Type	Calf Circumference
DVT10	DVT10 Standard Calf Garment	up to 17"
DVT10S	DVT10S Standard Calf Garment (Sterile)	up to 17"
L501-M	L501-M Standard Calf Garment	up to 17"
DVT20	DVT20 Large Calf Garment	up to 23"
DVT60	DVT60 Extra Large Calf Garment	up to 28"

Thigh Garments		
Order Code	Type	Thigh Circumference
DVT30	DVT30 Standard Thigh Garment	up to 28"
DVT30S	DVT30S Standard Thigh Garment (Sterile)	up to 28"
L503-M	L503-M Standard Thigh Garment	up to 28"
DVT40	DVT40 Large Thigh Garment	up to 35"

Foot Garments		
Order Code	Type	Shoe Size
FG100	Foot Garment - Regular	Women up to size 9 Men up to size 7
FG100S	Foot Garment - Regular (Sterile)	Women up to size 9 Men up to size 7
FG200	Foot Garment - Large	Women 9½ or above Men 7½ or above
FG200S	Foot Garment - Large (Sterile)	Women 9½ or above Men 7½ or above

10. Technical Description

PUMP	
Model:	Flowtron Trio
Part Numbers:	512001
Pressure Range:	30 - 100 mmHg ± 5%
Supply Voltage:	120 V
Supply Frequency:	60 Hz
Power Input:	14 VA
Size:	10.6 x 5.9 x 4.1” (270 x 150 x 105 mm)
Weight:	5.3 lb (2.4 kg)
Case Material:	ABS Plastic
Pump Fuse Rating:	T1AL 250V
Degree of protection against electric shock:	Class II, Double Insulated with Functional Earth Type BF
Degree of protection against liquid ingress:	IPX0
Mode of operation:	Continuous

SYMBOLS							
O (Off)	Power Disconnects from the mains supply		Do not dispose of in domestic refuse		Alternating Current		Double Insulated
I (On)	Power Connects to the mains supply		Refer to accompanying documents		Type BF		Refer to the User Manual
	Fuse		Dangerous voltage	**SN:**	Serial number	**Ref:**	Model Number
	With respect to electric shock, fire and mechanical hazards only in accordance with UL60601-1 and CAN/CSA C22.2 No. 601.1 MEDICAL EQUIPENT						

ENVIRONMENTAL INFORMATION			
Condition	**Temperature Range**	**Relative Humidity**	**Atmospheric Pressure**
Operating	+50°F to +104°F (+10°C to +40°C)	30% to 75%	700hPa to 1060 hPa
Storage and Transport	-40°F to +158°F (-40°C to +70°C)	10% to 95% (non-condensing)	500 hPa to 1060 hPa

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