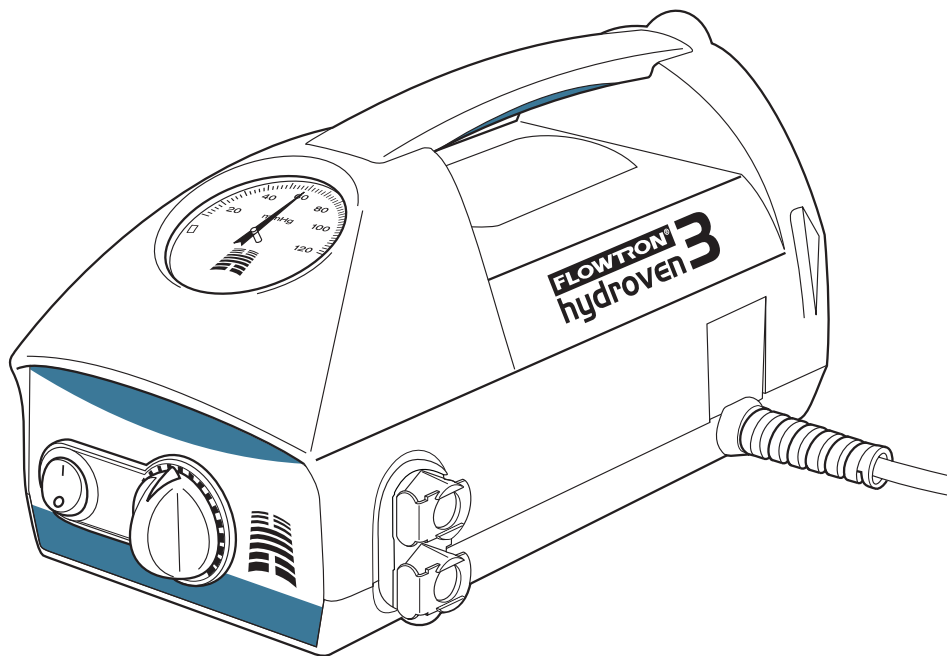




Huntleigh
HEALTHCARE

FLOWTRON HYDROVEN™ 3



User Manual

Intermittent Pneumatic Compression System

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General Safety

Before you connect the system pump to a main power supply, read carefully all the installation instructions in Section 4, “Garment and Insert Information” and Section 5, “Operation”. The system has been designed to comply with regulatory safety standards including UL60601-1 1st Edition, CAN/CSA C22.2 No 601.1-M90.

Safety Warnings

- Electrical equipment may be hazardous if misused. The pump's rear case should only be removed by authorized technical personnel.
- Do not use the pump in the presence of flammable gases such as anesthetic agents.

Precautions

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

- Regularly check the system when in use for pump operation and garment fit.
- Keep the pump away from sources of liquids and do not immerse in water.
- Do not expose the system, especially the garments, to open flames, such as cigarettes, etc.
- Do not store the system in direct sunlight.
- Switch off the power supply to the pump by disconnecting the pump from the power outlet before cleaning and inspecting.
- Do not use phenol-based solutions to clean the system.
- Ensure the system is clean and dry prior to storage.
- Never use sharp objects on the system.
- Only the pump and garment/insert combination manufactured by Huntleigh Healthcare should be used. The correct functioning of the product cannot be guaranteed if the incorrect pump and garment combinations are used.

Caution

Electromagnetic compatibility (EMC). This product complies with the requirements of applicable EMC Standards. The use of accessories not specified by the manufacturer may result in increased emissions by, or decreased immunity of, the equipment, affecting its performance

1. Introduction

The **Flowtron Hydroven™ 3** system is an intermittent pneumatic compression system designed to be used as part of a management program for the following clinical conditions:

- Dependent or traumatic edema
- Lymphedema in the upper or lower limbs
- Chronic venous insufficiency
- Post-phlebitic syndrome
- Acute and chronic wounds (including venous leg ulcers and post-surgical wounds)

The system is comprised of a pump and either single or three chamber arm or leg garments. Optional garment inserts can be applied to increase the circumference of the standard arm and leg garments.

The pump supplies air via connecting tubes to an inflatable garment allowing the application of controlled pressure to gently compress the limb. This action assists in increasing the return of blood, excess fluids, improves venous stasis and encourages the reabsorption of waste products.

The pump operates on an automatically timed cycle of 3 minutes, 90 seconds inflation followed by 90 seconds deflation. Variable pressure output ranges from 30-100 mmHg. The garments are inflated alternately.

The **Flowtron Hydroven 3** system operates two types of garments:

- **Hydroven™ 1** garments have a single chamber and provide uniform compression.
- **Hydroven™ 3** garments have three chambers providing gradient segmental compression, inflating distally to proximally.



We would recommend that this manual be read thoroughly before proceeding with treatment.

2. Clinical Applications

Indications Intermittent pneumatic compression (IPC) is effective in the treatment of the following clinical conditions:

- Edema
 - Dependent (including secondary to cerebrovascular incident, pregnancy or paralysis)
 - Traumatic (post-surgical or post-injury)
- Lymphedema
 - Primary and secondary (including post-surgery, radiation 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
- Lipedema

Contraindications IPC should NOT be used in the following circumstances:

- Known or suspected deep vein thrombosis (DVT), pulmonary embolism, thrombophlebitis
- Acute infections of the skin such as cellulitis
- Untreated, infected wounds
- Decompensated / severe congestive cardiac failure or pulmonary edema associated with significant limb edema, or any condition where an increase of fluid to the heart may be detrimental
- Severe arteriosclerosis or other ischemic vascular disease
- Active metastatic disease affecting the limb



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

Warning


- Therapy should be interrupted and physician notified 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, remove the garment
- Patients must not walk or stand when wearing leg garments

3. Clinical Treatment Guide

An initial pressure setting of 40 mmHg is suggested at the commencement of treatment. It may be necessary to start at a lower level of pressure dependant on the patient's tolerance.

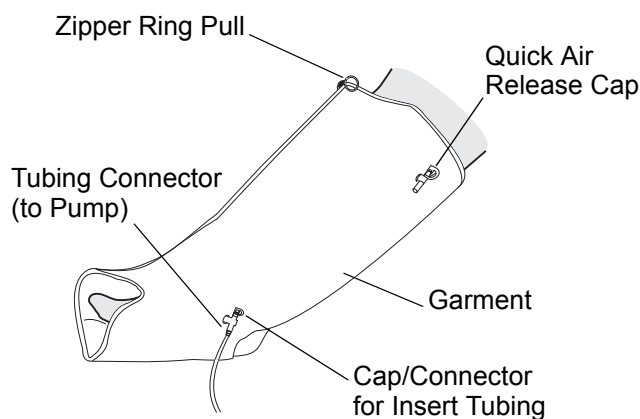
The pressure can be gradually increased over time, until the required pressure is reached. The upper treatment pressure range is generally 60-70 mmHg.

A single treatment session is usually 20-30 minutes.

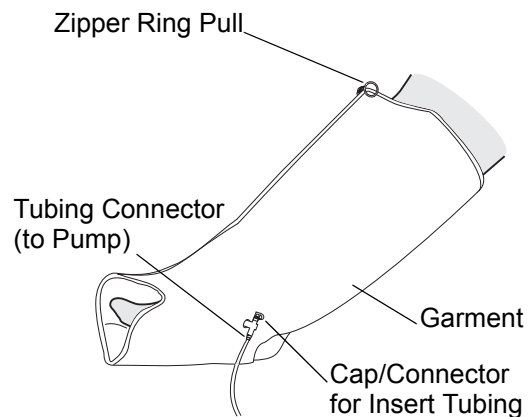
 *The above settings and timings are recommended guidelines, and should not be used as a substitute for clinical judgement and experience.*

4. Garment and Insert Information


Garment Description



Hydroven 3 Garment

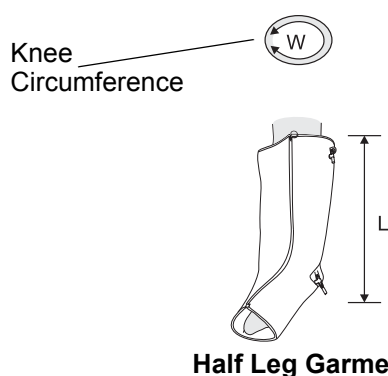


Hydroven 1 Garment

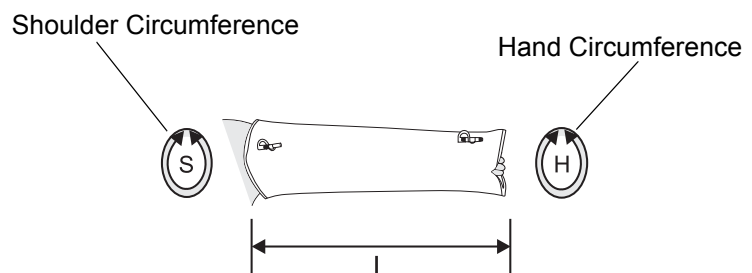
 For Hydroven 1 garments, when an insert is **not** in use, the cap can be used as a quick air release.

Selecting the Correct Garment

1. Select the type of garment depending on treatment type:
 - **Hydroven 1** garments have a single chamber and provide uniform compression.
 - **Hydroven 3** garments have three chambers providing gradient segmental compression, inflating distally to proximally.
2. Measure the circumference of the largest part of the limb, and the length in inches from the heel to the inseam of thigh for a full leg garment, heel to knee for half leg garment, from shoulder to finger tips for full arm garment, and from elbow to finger tips for half arm garment. Refer to “Ordering Information” on page 15 to order the correct size garment.

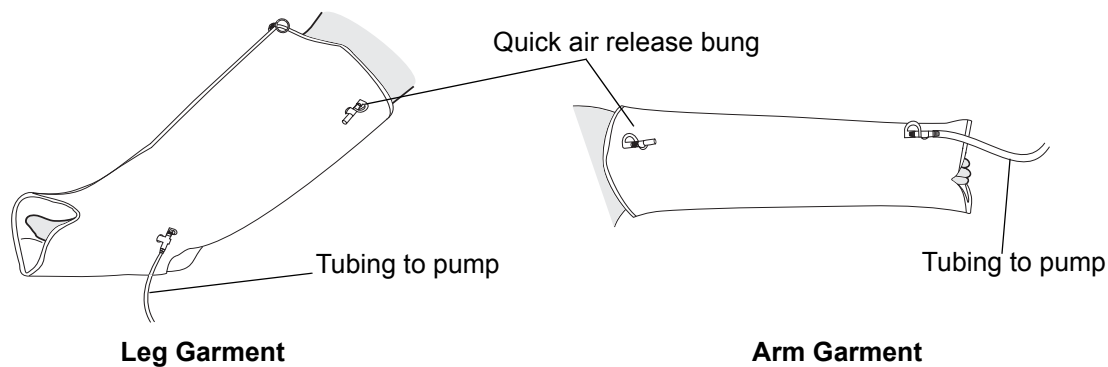



Half Leg Garment




Full Arm Garment

Applying the Garment



 *Before fitting the garment ensure all quick air release caps are closed, as this will effect the efficiency of the garment.*

1. Place the limb into the garment and zip up carefully, ensuring that the patient is in a comfortable position with the limb supported or elevated as necessary. If appropriate, a primary dressing or stockinet may be used underneath the garment(s)
2. Ensure that the zipper is fully secured at the top edge and that the quick air release caps are secured.
3. Attach the garment tubing to the pump ensuring a “click” is heard from each snap-lock connector.
4. If only one garment is to be used, attach the garment to either port on the pump. The system will automatically identify that only one garment is to be used.

 *Ensure that the all zippers are fully closed on the garment before switching the pump on.*

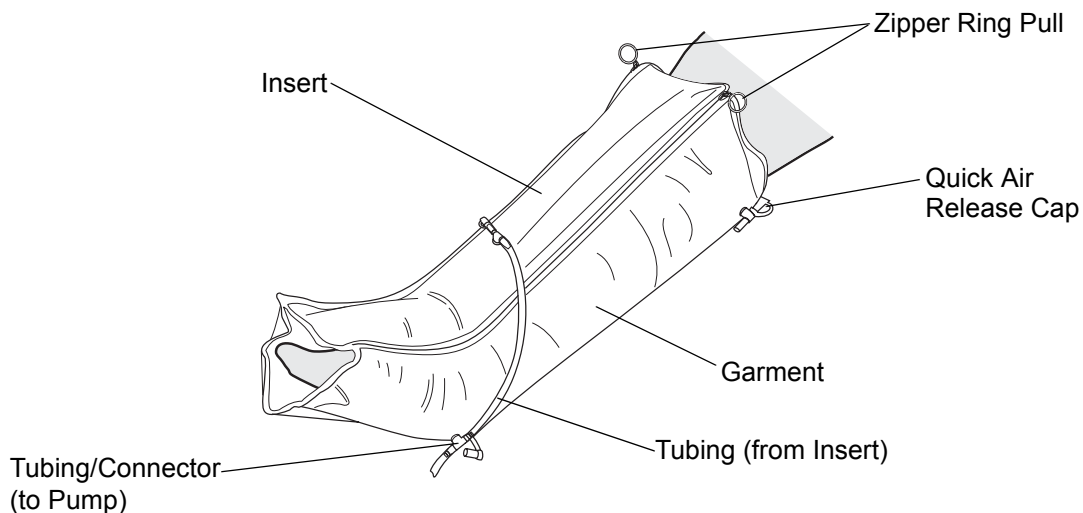
5. Switch on the pump and adjust the pressure control accordingly.

Caution

Do not apply or remove the garment while it is attached to the pump and while the pump is in operation, as you may damage the garment zipper.

Do not stand or walk while leg garments are on.

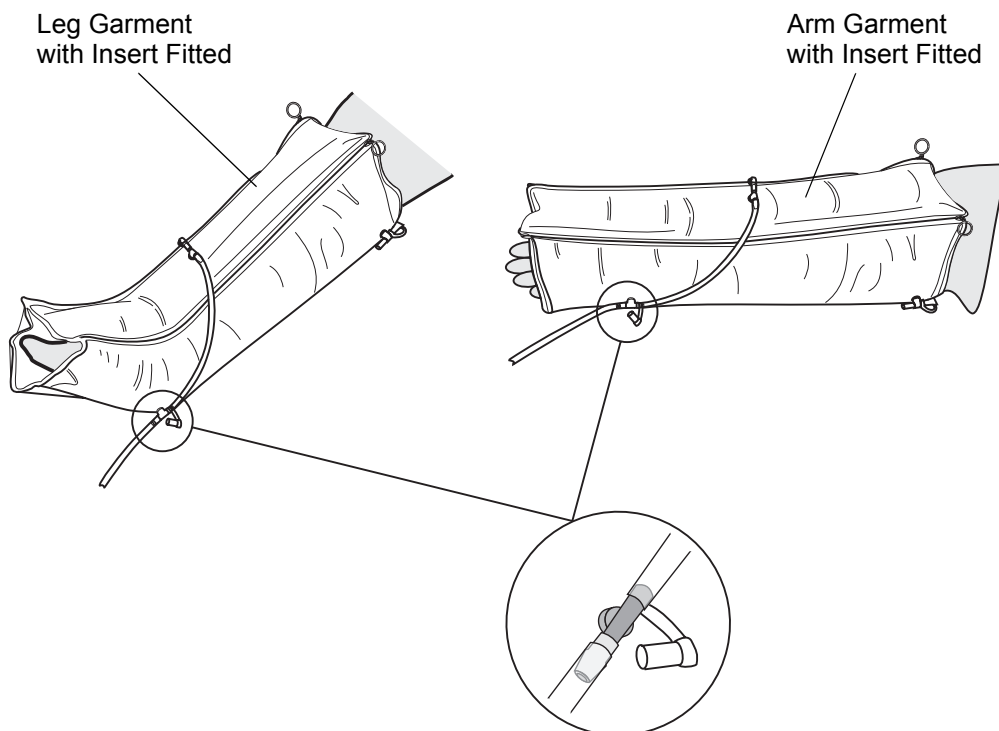
Garment with Insert



Applying an Insert

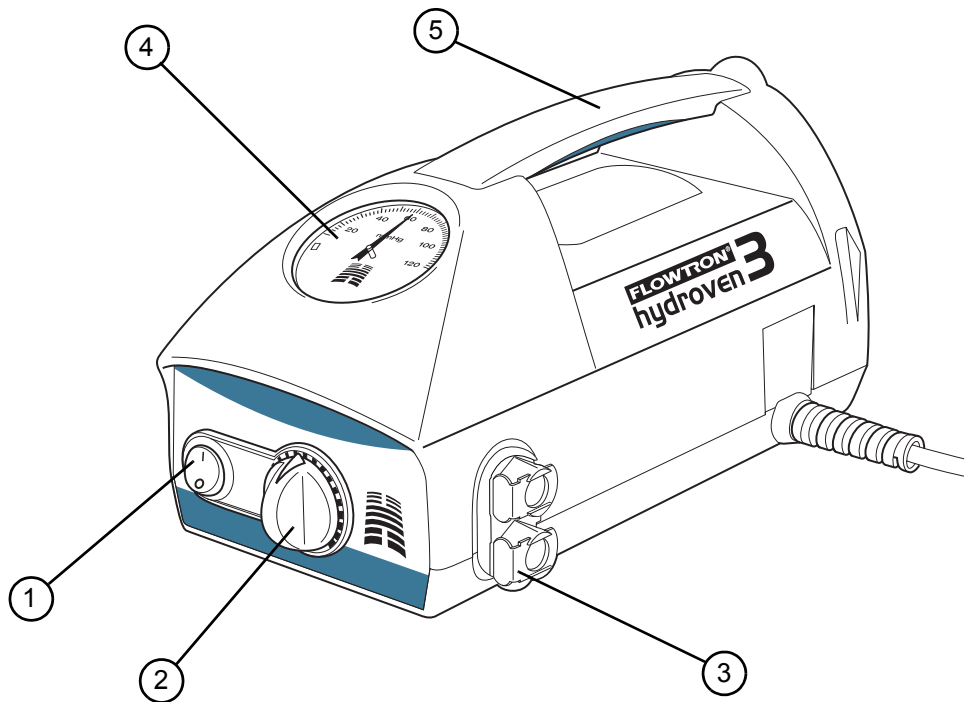
If a larger circumference garment is required, a matching length insert may be used. Before applying the garment to the limb, zip the insert along the length of the garment, as shown.

Check that the insert connecting tube is not kinked and is attached to the garment using the lower outlet cap as shown below.



5. Operation

Pump Description



Flowtron Hydroven 3 Pump

Control Number	Description	Function
1	On/Off Switch	Operation of this switch starts or stops the system
2	Pressure Control Knob	Rotates clockwise to increase and counterclockwise to decrease pressure (pressure range 30 - 100 mmHg)
3	Tube Connectors	For garment attachment (snap-lock)
4	Pressure Gauge	Indicates delivery pressure to garment (mmHg)
5	Carry Handle	For easy handling of pump

Caution

Do not apply or remove the garment while it is attached to the pump and the pump is in operation, as you may damage the garment zip.

Operation The pump should be placed securely on a flat surface.


Before starting the pump ensure that the garments are properly applied, the zippers are secured and the garment connecting tubes are attached to the pump outlet ports via snap-lock connectors.

Ensure that the pressure level is set at minimum (i.e. the knob (2) is fully rotated in a counterclockwise direction).

Switch On Press the ON/OFF switch.

To Set the Garment Pressure While the garment is inflating, rotate the pressure control knob (2) slowly clockwise until the required pressure is displayed on the gauge (4).

The garments will take approximately three cycles to fully inflate. Check and adjust as necessary after three inflation cycles.

 *It might be necessary to start at a lower pressure level dependant on the patient's tolerance. Compression should not cause any discomfort or pain to the patient.*

To Remove the Garment Switch off the pump (1), disconnect the tubing from the pump by releasing the snap-lock connectors (3), and release the quick air release cap on the garment.

Only open the zipper after the garment is completely deflated.

6. Cleaning, Care, Maintenance, and Service

The following cleaning guidelines for the **Flowtron Hydroven 3** system have been established in accordance with good infection control practice. Should you have any questions regarding cleaning or if you require further information please contact your Huntleigh Healthcare Service Department.

WARNING

Switch off the electrical supply to the pump and disconnect the power cord from the power supply before inspecting and cleaning.

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

Caution



Never use phenolic, hypocarbonate-based disinfectants containing cationic surfactants, ammonia-based compounds, or antiseptic solutions such as Steriscol or Hibiscrub. These will damage the surface coating.

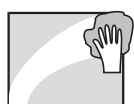
Do not spray cleaning solutions directly onto the pump. Avoid immersing electrical parts in water during the cleaning process.

The pump cannot be sterilized.

System It is recommended that, where practicable, all parts of the system (pump, garments and tubing) should be cleaned weekly.

Pump

To Clean



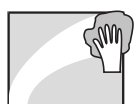
Wipe down using a soft cloth dampened with a mild detergent.

To Disinfect

After cleaning, wipe down with an EPA-approved, hospital grade disinfectant, as per an appropriate protocol.

Garments and Washing

To Clean



Wipe down using a neutral detergent or soap powder at 104°F (40°C).



Do not tumble dry.



Do not iron.



Do not dry clean.

Do not machine wash.

Do not immerse tubeset in water.

Air dry thoroughly.

To Disinfect



After cleaning, wipe complete garment over using 70% isopropyl alcohol wipe or a chlorine-releasing agent at 1000 p.p.m. available chlorine.



Do not use phenol or phenol-derivative disinfectant.

Rinse with clean water to remove any residue.

Air dry thoroughly.

To Sterilize

After cleaning, gas sterilization is possible.

Do not exceed 120°F (51°C).

Do not autoclave.

7. Troubleshooting

If you should encounter a problem, please follow the fault finding guide below. If the fault cannot be rectified, please refer to Service.

Fault	Check	Remedy
Pump dead	Is power switch on?	Check switch.
	Is power cord plugged in correctly?	Check connections.
Pump operates but garment will not inflate.	Blockage in garment supply tubing.	Ensure that the tubing airway is clear.

Service Returns If for any reason your **Flowtron Hydroven 3** is being returned, please:

1. Clean the product following the instructions in section 6.
2. Contact Huntleigh Healthcare (X 157) for a Return Goods Authorization number (RGA) prior to returning your system. Note the RGA number on the outside of packaging.
3. Enclose a covering letter explaining the reasons for the return, with documentation (including an appropriate decontamination certificate if possible).
4. To prevent damage in transport, please pack the pump in a suitably robust box.

8. Warranty

Warranty:

All Huntleigh Healthcare products shall conform to applicable specifications in effect from the invoice date to the end of the Warranty Period, and Huntleigh Healthcare reserves the right to change such specifications at any time with or without notice. The Warranty Period for Huntleigh Healthcare products shall be as follows, calculated from the date of invoice:

- a. The **Flowtron Hydroven 3** pump is guaranteed for 12 months;
- b. The **Flowtron Hydroven 1 and 3** garments are guaranteed for 6 months.

Huntleigh Healthcare's sole liability to the Customer for nonconformity of any Products to the specifications therefore, for any claim arising out of or in any way connected with the manufacture, sale, handling, or use of the Products, or for any other reasons, shall be, at Huntleigh Healthcare's sole option, limited to (i) the refund of the full purchase price for such Products, plus the invoice shipping charges, or (ii) replacement thereof, free of charge to the Customer, with Products conforming to the then current specifications, thereof. The parties agree that these remedies shall be exclusive. HUNTLEIGH HEALTHCARE, AND ITS AFFILIATES, SHALL HAVE NO LIABILITY FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND OR, EXCEPT AS PROVIDED ABOVE, FOR ANY CAUSE ARISING OUT OF OR IN ANY WAY CONNECTED WITH THE MANUFACTURE, SALE, HANDLING OR USE OF SUCH PRODUCTS. EXCEPT AS SPECIFICALLY SET FORTH IN THIS PARAGRAPH, THERE ARE NO EXPRESS OR IMPLIED WARRANTIES, INCLUDING THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND THE FOREGOING PROVISIONS OF THIS PARAGRAPH ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED.

The customer is solely responsible for the proper use of the Products. Huntleigh Healthcare Products should not be used in conjunction with those of any other manufacturers.

Service:

The **Flowtron Hydroven 3** system should be routinely inspected (at least once every 24 months) by a qualified biomedical service technician to assure proper operation of the pump and garment system. Inspection should verify that pressure output and timing cycles are within listed specifications, and that the audible and visual alarms function properly.

The **Flowtron Hydroven 3** pump should receive annual preventative maintenance.

All required servicing should be performed by Huntleigh Healthcare service personnel:

Please obtain a “Returned Goods Authorization” from the Customer Service Department prior to returning the product to Huntleigh Healthcare. Display the RGA number prominently on the side of the package used to return the product. This will insure prompt and accurate servicing of your product.


Return to:

Service Department
Huntleigh Healthcare L.L.C.
40 Christopher Way
Eatontown, NJ 07724-3327

Telephone: (800)-223-1218

9. Ordering Information

To order garments, please contact your distributor quoting the appropriate codes as shown below:

 Refer to diagrams on page 5 of this manual.

Garments

HYDROVEN 1 LEG GARMENTS			
Order Code	Type	Length (L)	Circumference (W)
5101L50	Half Leg	19.7" (50cm)	24" (61cm)
5101L66	Full Leg	26" (66cm)	25.2" (64cm)
5101L71	Full Leg	28" (71cm)	26" (66cm)
5101L76	Full Leg	29.9" (76cm)	28" (72cm)
5101L84	Full Leg	33.1" (84cm)	28" (72cm)
5101L92	Full Leg	36.2" (92cm)	28" (72cm)

HYDROVEN 1 ARM GARMENTS				
Order Code	Type	Length (L)	Circumference Hand (H)	Circumference Shoulder (S)
5101A51	Half Arm	20.1" (51cm)	17.3" (44cm)	22" (56cm)
5101A68	Full Arm	26.8" (68cm)	17.3" (44cm)	24.4" (62cm)
5101A78	Full Arm	30.7" (78cm)	17.3" (44cm)	24.4" (62cm)

HYDROVEN 3 LEG GARMENTS			
Order Code	Type	Length (L)	Circumference (W)
5103L50	Half Leg	19.7" (50cm)	24" (61cm)
5103L66	Full Leg	26" (66cm)	25.2" (64cm)
5103L71	Full Leg	28" (71cm)	26" (66cm)
5103L76	Full Leg	29.9" (76cm)	28" (72cm)
5103L84	Full Leg	33.1" (84cm)	28" (72cm)
5103L92	Full Leg	36.2" (92cm)	28" (72cm)

HYDROVEN 3 ARM GARMENTS				
Order Code	Type	Length (L)	Circumference Hand (H)	Circumference Shoulder (S)
5103A68	Full Arm	26.8" (68cm)	17.3" (44cm)	24.4" (62cm)
5103A78	Full Arm	30.7" (78cm)	17.3" (44cm)	24.4" (62cm)

Inserts

HYDROVEN INSERT PIECES (To Fit Hydroven 1 and Hydroven 3 Garments)				
Order Code	Type	Length (L)	Added Circumference Wide End	Added Circumference Narrow End
510LI50	Half Leg	19.7" (50cm)	7.5" (19cm)	5.5" (14cm)
510LI66	Full Leg	26" (66cm)	7.5" (19cm)	5.5" (14cm)
510LI71	Full Leg	28" (71cm)	7.5" (19cm)	5.5" (14cm)
510LI76	Full Leg	29.9" (76cm)	7.5" (19cm)	5.5" (14cm)
510LI84	Full Leg	33.1" (84cm)	7.5" (19cm)	5.5" (14cm)
510LI92	Full Leg	36.2" (92cm)	7.5" (19cm)	5.5" (14cm)
510AI68	Full Arm	26.8" (68cm)	6.7" (17cm)	4.7" (12cm)
510AI78	Full Arm	30.7" (78cm)	6.7" (17cm)	4.7" (12cm)

10. Technical Description

Model No.:	510003
Supply Voltage:	120 V
Supply Frequency:	60 Hz
Electrical Rating:	14VA
Fuse Rating:	F500 mA 250V
Size:	Width: 10.6" (270 mm)
	Depth: 5.9" (150 mm)
	Height: 4.1" (105 mm)
Weight:	5.3lbs (2.4 kg)
Case Material	ABS Plastic
Electrical Safety Standards:	UL60601-1 1st Edition. CAN/CSA C22.2 No 601.1-M90
Degree of protection:	Class II Type BF with functional ground
Degree of protection against ingress of liquids:	Ordinary (not protected) IPX0
Mode of operation:	Continuous

Equipment Symbols:



Alternating Current

O (off)

Power disconnects from mains

I (on)

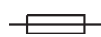
Power connects to the mains supply



Type BF



Double Insulated



Fuse

Operating

Temperature Range: +50°F to +104°F (+10°C to +40°C)

Relative humidity: 30% to 75%

Atmospheric pressure 700hPa to 1060 hPa

Storage

Storage temperature range: -40°F to +158°F (-40°C to +70°C)

Relative humidity: 10% to 100% (non-condensing)

Atmospheric pressure: 500 hPa to 1060 hPa

Environmental Protection: Please dispose of this unit in accordance with local regulations



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