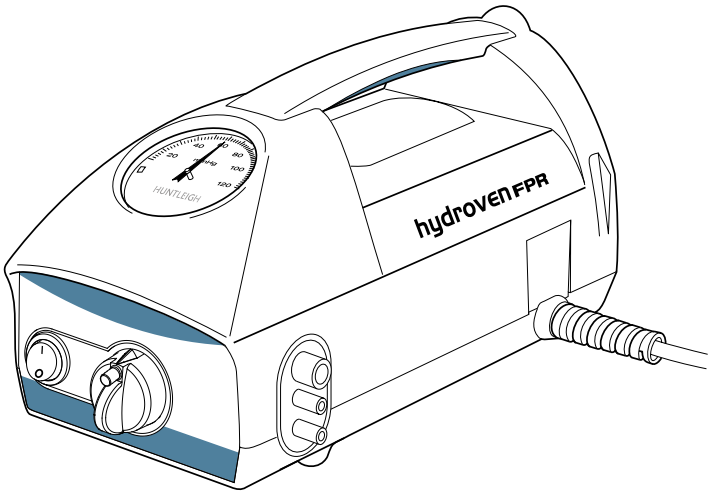
INSTRUCTIONS FOR USE

Hydroven FPR



516933EN-8 05/2023

HUNTLEIGH
A MEMBER OF THE ARJO FAMILY

Contents

1. Safety

Before using this equipment, please study this manual carefully and familiarise yourself with the controls, display features and operation. Ensure that each user fully understands the safety and operation of the unit, as mis-use may cause harm to the user or patient, or damage to the product.

Please keep these Instructions for Use to hand for future reference.

Symbols

General Warning/Cautions	Follow Instructions for Use

1.1 Warnings

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

WARNING: A possible explosion hazard exists if used in the presence of flammable anaesthetics.

WARNING: Do not mount the unit directly above the patient. Locate the unit so that it will not cause harm should it fall.

WARNING: Do not operate the unit from the mains supply if the mains cable is damaged.

WARNING: Do not immerse any portion of the unit in water or other liquids.

WARNING: Use only recommended accessories listed in this manual.

WARNING: If this product is connected to another item of electrical equipment, it is important that the system is fully compliant with EN60601-1.

WARNING: It is the responsibility of the care giver to ensure that the user can use this product safely.

WARNING: 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.

WARNING: 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.

WARNING: 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.

WARNING: Disconnect the pump from the mains power socket before cleaning and inspecting.

WARNING: Only the pump and garment/insert combination as indicated by Huntleigh should be used. The correct function of the product cannot be guaranteed if incorrect pump and garment combinations are used.

WARNING: Bags supplied with this equipment may present a suffocation risk; to avoid the risk of suffocation, keep the bags away from babies and small children.

CAUTION: Do not expose the system to naked flames, such as cigarettes, etc.

CAUTION: Do not store the system in direct sunlight.

CAUTION: Do not use phenol-based solutions to clean the system.

CAUTION: Make sure the system is clean and dry prior to use or storage.

CAUTION: Pets and children must be supervised in the vicinity of the system.

Caution (applicable to the USA market only)
US Federal law restricts this device to sale by or on the order of a physician.

Service Life

This has been defined as the minimum time period during which the device is expected to remain safe and suitable to meet its intended use, and all risk control measures remain effective.
Huntleigh Healthcare Ltd's commitment is that the expected service life for this Device has been defined as 7 years.

2. Electromagnetic Compatibility

Make sure the environment in which Hydroven FPR is installed is not subject to strong sources of electromagnetic interference (e.g. radio transmitters, mobile phones).

This equipment generates and uses radio frequency energy. If not installed and used properly, in strict accordance with the manufacturer's instructions, it may cause or be subject to interference. Type-tested in a fully configured system, complies with EN60601-1-2, the standard intended to provide reasonable protection against such interference. Whether the equipment causes interference may be determined by turning the equipment off and on. If it does cause or is affected by interference, one or more of the following measures may correct the interference:

- Reorienting the equipment
- Relocating the equipment with respect to the source of interference
- Moving the equipment away from the device with which it is interfering
- Plugging the equipment into a different outlet so that the devices are on different branch circuits

If this equipment needs to be used adjacent to other electrical equipment, normal operation must be checked before use.

Guidance and Manufacturer's declaration - electromagnetic emissions		
The Hydroven FPR is intended for use in the electromagnetic environment specified below. The customer or the user of the Hydroven FPR should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	The Hydroven FPR 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.
RF emissions CISPR 11	Class B	The Hydroven FPR is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's declaration - electromagnetic immunity			
The Hydroven FPR is intended for use in the electromagnetic environment specified below. The customer or the user of the Hydroven FPR 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 Hydroven FPR, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vrms 80MHz to 2.5MHz	3V/m	$d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d 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 the equipment marked with the following symbol: 
NOTE 1 At 80MHz and 800MHz, the higher frequency range applies. NOTE 2 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 Hydroven FPR is used exceeds the applicable RF compliance level above, the Hydroven FPR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Hydroven FPR. [b] Over the frequency range 150kHz to 80kHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Hydroven FPR

The Hydroven FPR is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Hydroven FPR can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Hydroven FPR 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		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	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 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

3. Introduction

3.1 About this Manual

This manual is your introduction to the Hydroven® FPR 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 Hydroven FPR system, contact your local Huntleigh sales representative, listed at the end of this manual.

3.2 Intended Use

The intended use of this product is to manage the list of clinical conditions detailed in the “Indications” section.
The Hydroven FPR system should be used as part of a prescribed plan of care detailed in the “Indications” section.

3.3 About the Hydroven FPR system

The pump operates on a 3 minute automatically timed cycle, which sequentially inflates the three chambered garment, distally to proximally followed by one minute of deflation.

Compression Cycle:

Chamber 1 (lower)	= 114 sec
Chamber 2 (middle)	= 76 sec
Chamber 3 (upper)	= 38 sec
Deflation	= 66 sec
Overall Cycle	= 180 sec

Variable pressure output ranges from 30 - 100mmHg.
The segments within the garments are designed to prevent ridging and ensure high patient comfort and compliance.
A full technical description of the Hydroven FPR system can be found in the Service Manual, part No. SER0022, available from your local Huntleigh sales office.

3.4 Use Environment

Hydroven FPR is suitable for use in hospital, primary care and community settings. It must not be used outdoors, or in any environment where it may come into contact with water.

4. Clinical Applications

4.1 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.
- Lower limb pain due to trauma or surgery.
- Lipoedema.

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

Note:	**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.**

Note:	**The above are guidelines only and should not replace clinical judgement**

4.2 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.

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

CAUTION: 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 if pain, tingling or numbness of the limb occurs during or as a result of therapy.

WARNING: 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).

WARNING: Patients must not walk or stand when wearing leg garments.

5. Preliminary Checks

Contents (supplied with each system)

Item	Item
1 x Hydroven FPR	1 x Instructions for Use

Delivery Inspection

Huntleigh takes every precaution to ensure that goods reach you in perfect condition. However, accidental damage can occur in transit and storage. For this reason we recommend that a thorough visual inspection is made immediately the unit is received. Should any damage be evident or any parts missing, ensure that Huntleigh is informed at once.

Storage

If the unit not be required for immediate use, it should be re-sealed into its original packing after carrying out the initial delivery inspection, and stored under covered conditions at a temperature between -20°C to +50°C, and relative humidity of 20% to 95% non-condensing.

After exposure to extreme temperatures during storage, the pump must be allowed to adjust to normal operating temperatures for a minimum of 12 hours before use. Failure to do this may result in accelerated wear of mechanical components.

6. Clinical Treatment Guide

An initial pressure setting of 40 mmHg, (30 mmHg for management of lymphoedema), is suggested at the commencement of treatment. It may be necessary to start at a lower level of pressure, dependent 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.

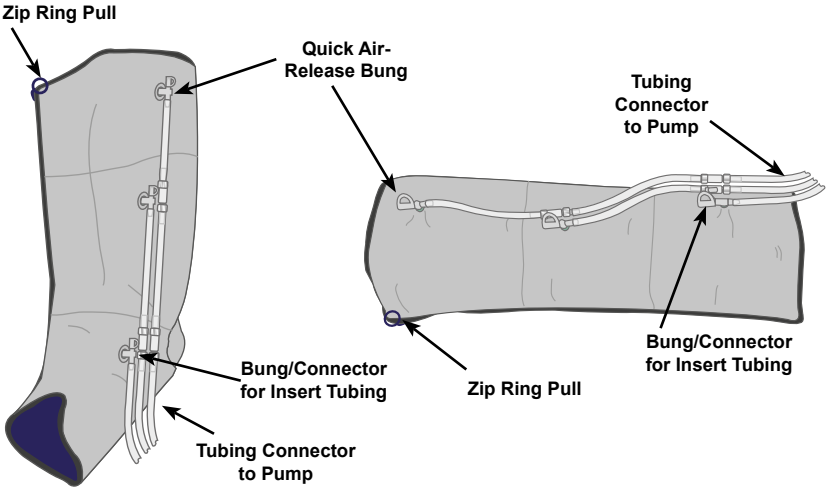
A single treatment session is usually 20-60 minutes.

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

Note: Loss of mains power will halt therapy.

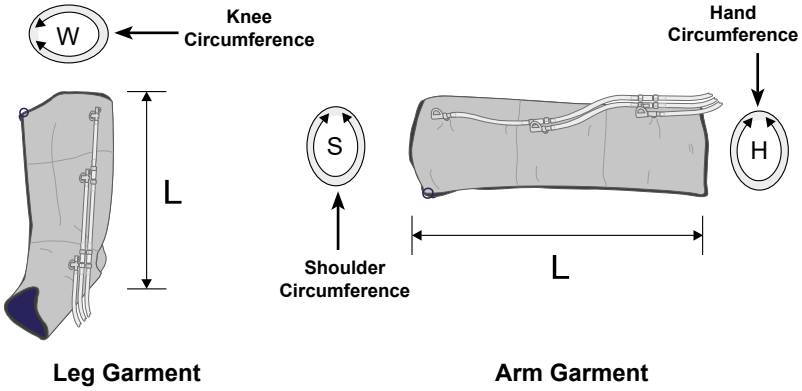
7. Garment and Insert Information

7.1 Garment Description



7.2 Selecting the correct Garment

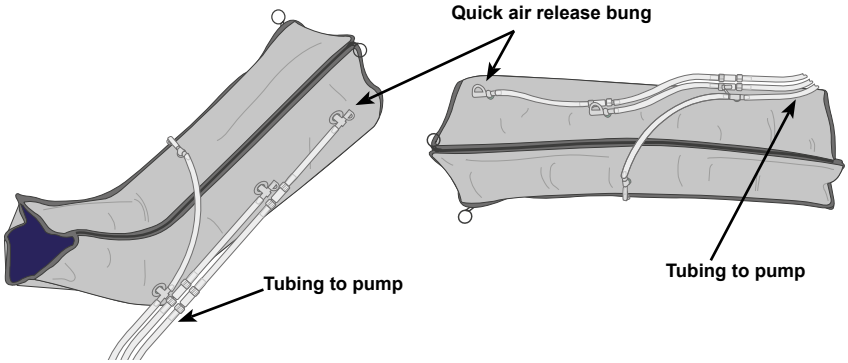
1. Check the type, and the length of the garment required.
2. Measure the circumference of the largest part of the limb, and the length in cm/ inch from the heel to the upper thigh for a full leg garment (at least 3cm from groin), fingertips to axilla (at least 3cm from axilla) for full arm garment (see below). Refer to “Accessories” section to order the correct size garment.



7.3 Applying the Garment

WARNING: Bags supplied with this equipment may present a suffocation risk; to avoid the risk of suffocation, keep the bags away from babies and small children.

1. If a larger circumference is required, fit a matching length insert piece before applying to the limb. If appropriate, a primary dressing or stockinette may be used underneath the garments.

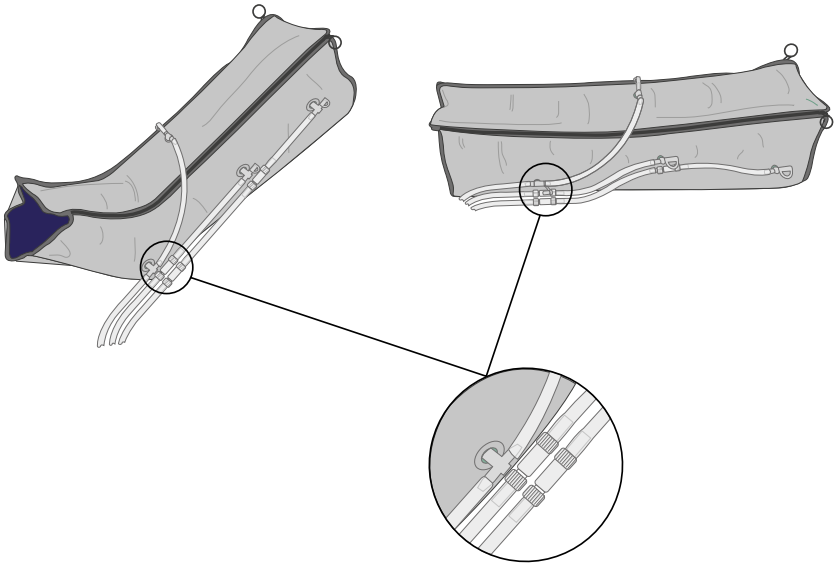


Leg Garment with Insert **Arm Garment with Insert**

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

Note: **Garments are designed to be worn over thin clothing and not in direct contact with the patients skin.**

2. Undo the zip on the garment.
3. If a garment insert is fitted to the garment, fully fasten one of the zips between the garment and insert, leaving the other unfastened.
4. 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. Make sure that the quick air release bung is secured.
5. Make sure the patient is in a comfortable position with the limb supported or elevated as necessary.
6. Check that the connecting tubes are not kinked and are attached correctly to the insert garment (See below), and pump outlet ports - refer to Pump Description.



7. Attach the garment tubing to the pump.

Note: Ensure that the zip is fully done up on the garment before switching the pump on.

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

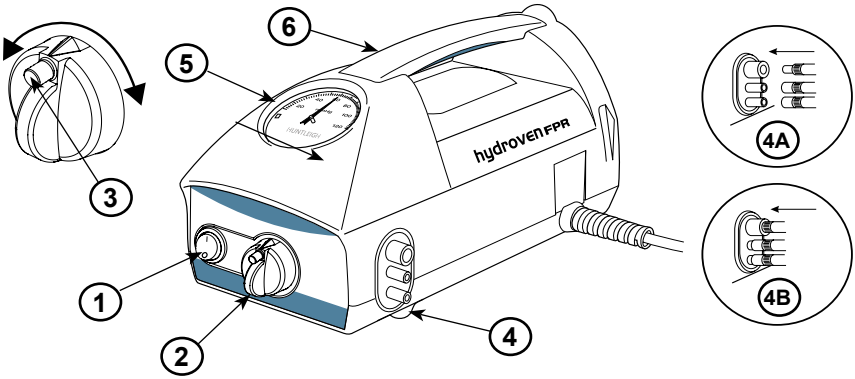
CAUTION: Do not apply the garment to the limb unless it is partially zipped, as you may damage the garment zip.

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.

CAUTION: Do not stand or walk while leg garments are fitted.

8. Operation

8.1 Pump Description



Item No.	Description	Function
1	On/Off Switch	Operation of this switch Starts or Stops the system
2	Pressure Control Knob / Lock Pin* (* If fitted)	Rotate clockwise to increase pressure or counter-clockwise to decrease pressure (pressure range 30 ~ 100 mmHg). The pressure control knob is locked in position, (if Lock Pin is fitted), to prevent accidental movement. Refer to “To Adjust the Pressure Control Knob Position” .
3	Lock Pin	Locks the Pressure Control Knob position
4	Tube Connectors	For garment attachment (4A and 4B)
5	Pressure Gauge	Indicates delivery pressure to garment
6	Carry Handle	For easy handling of the pump

Note: If the operation of performance of the pump changes during use, refer to “Trouble Shooting” section of this IFU before calling a service engineer or contacting your local Huntleigh sales office.

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.

8.2 Operation

It is the responsibility of the care giver to ensure that the user can use this product safely.

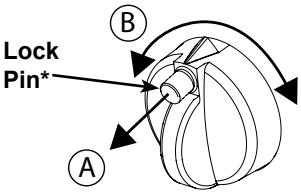
Note: Garments are designed to be worn over thin clothing and not in direct contact with the patients skin.

The pump should be placed securely on a flat surface.

8.2.1 To Adjust the Pressure Control Knob Position

The pressure control knob (2) is locked in position* to prevent accidental rotation.

To adjust the position of the pressure control knob:



1. Lift the lock pin* (A) to release the control knob.
2. Rotate the control knob (B) whilst the lock pin is raised.
3. Release the lock pin* when the pressure control knob is in the desired position to lock the control knob.

** If lock pin fitted.*

Note: Rotate the pressure control knob clockwise to increase and counterclockwise to decrease pressure

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 the tube connectors (4).

Make sure that the pressure control knob (2) is set to minimum i.e. rotated fully counterclockwise.

WARNING: Ensure that all cables and air hoses are positioned so that they do not present a trip hazard or strangulation.

WARNING: Bags supplied with this equipment may present a suffocation risk; to avoid the risk of suffocation keep the bags away from babies and small chidren.

8.2.2 Switch On

Connect the pump to the mains power supply using the power cable provided. Turn the mains power switch (1) to the On (I) position.

8.2.3 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 (5).
The garments will take approximately three cycles to fully inflate. Check and adjust as necessary after three inflation cycles.

Note: 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.

8.2.4 Shut Down

Turn the power switch (1) to the off (O) position. Turning the power off will stop the patient therapy.

Note: If it is required to completely isolate the pump from the mains power, remove the plug from the mains power socket.

8.2.5 To Remove the Garment

Make sure the pump power switch is in the off (O) position, disconnect the tubing from the pump by removing the tube connectors (4), and release the quick air release cap on the garment.

Only open the zip after the garment is completely deflated.

9. 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 FPR 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.

9.1 Cleaning

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.

9.2 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.

9.3 Cleaning and Sterilising Garments

Cleaning the Garment					
	Wipe down using a neutral detergent or soap powder at 51°C (120°F).				
	Do not iron		Do not dry clean		Do not tumble dry
Do not machine wash		Air dry thoroughly.		Do not autoclave	

Disinfecting the Garment		
	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.

Cleaning the Tubeset			
Use a soft brush.	Air dry only.	Do not immerse in water.	Do not machine wash.

Note: Always refer to local protocols and guidelines, as some protocols recommend single patient use outside of a clinically controlled environment, to avoid cross contamination.

Note: Garments are designed to be worn over thin clothing and not in direct contact with the patients skin.

10. Routine Maintenance

10.1 Hydroven FPR System

10.1.1 Maintenance

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

10.1.2 Servicing

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

10.1.3 Service Period

Huntleigh recommend that the Hydroven FPR pump is serviced every 24 months by an Huntleigh authorised service agent.

10.2 Hydroven FPR Pump

10.2.1 General Care, Maintenance and Inspection

Check all electrical connections and power cable for signs of excessive wear.

Check the tubeset and connectors for any damage.

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

10.2.2 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.

11. Trouble Shooting

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 does not operate.	Is power switch on? Is power cord plugged in correctly? Fuse blown?	Check switch. Check connections. Call service engineer.
Pump operates but garment will not inflate.	Blockage in garment supply tube. Garment not fitted correctly to pump. Pressure control set too low. Air leak in garment.	Ensure that the tube airway is clear. Check connections. Increase pressure control. Check garment. Replace if defective.

Note: If the trouble shooting procedures do not return the system to normal performance, stop using the system immediately and call the service engineer or return the unit to Huntleigh for service. Refer to "Warranty & Service"

12. Accessories

WARNING: Use only recommended accessories listed in this manual.

Garments

Hydroven FPR Arm Garment				
Order Code	**Type**	**Length (L)**	**Circumference at hand (H)**	**Circumference at shoulder (S)**
5163A68	Full Arm	26.8” (68 cm)	17.3” (44 cm)	24.4” (62 cm)
5163A78	Full Arm	30.7” (78 cm)	17.3” (44 cm)	24.4” (62 cm)

Hydroven FPR Leg Garment			
Order Code	**Type**	**Length (L)**	**Circumference**
5163L50	Half Leg	19.7” (50 cm)	24” (61 cm)
5163L66	Full Leg	26” (66 cm)	25.2” (64 cm)
5163L71	Full Leg	28” (71 cm)	26” (66 cm)
5163L76	Full Leg	29.9” (76 cm)	28” (72 cm)
5163L84	Full Leg	33.1” (84 cm)	28” (72 cm)
5163L92	Full Leg	36.2 (92 cm)	28” (72 cm)

Inserts

Hydroven Arm Garment Insert Pieces				
Order Code	**Type**	**Length (L)**	**Circumference Wide End**	**Circumference Narrow End**
510AI68	Full Arm	24.4” (68 cm)	6.7” (17 cm)	4.7” (12 cm)
510AI78	Full Arm	30.7” (78 cm)	6.7” (17 cm)	4.7” (12 cm)

Hydroven Leg Garment Insert Pieces				
Order Code	**Type**	**Length (L)**	**Circumference Wide End**	**Circumference Narrow End**
510LI50	Half Leg	19.7” (50 cm)	7.5” (19 cm)	5.5” (14 cm)
510LI66	Full Leg	26” (66 cm)	7.5” (19 cm)	5.5” (14 cm)
510LI71	Full Leg	28” (71 cm)	7.5” (19 cm)	5.5” (14 cm)
510LI76	Full Leg	29.9” (76 cm)	7.5” (19 cm)	5.5” (14 cm)
510LI84	Full Leg	33.1” (84 cm)	7.5” (19 cm)	5.5” (14 cm)
510LI92	Full Leg	36.2 (92 cm)	7.5” (19 cm)	5.5” (14 cm)

13. Specifications

13.1 Equipment Classification

Type of protection against electric shock.	Class II, Double Insulated
Degree of protection against electric shock 	Type BF
Mode of operation.	Continuous
Degree of protection against solid and liquid ingress	IP21* - Protection against ingress of solid objects more than 12.5mm diameter and water droplets falling vertically. IPX0* - No Protection
Degree of safety of application in the presence of a flammable anaesthetic	Equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OXYGEN OR NITROUS OXIDE

** See product label for IP Rating*

13.2 General

Model	Hydroven FPR
Part Numbers	516003
Pressure Range	30 - 100 mmHg ± 5%
Supply voltage	120 V AC
Supply Frequency	60Hz
Pump Fuse Rating	F500 mAH 250 V
Power input	14 VA
Case Material	Fire Retardent ABS Plastic
Size	270 x 130 x 150 mm (10.6 x 5.1 x 5.9”)
Weight	2.5 kg (5.5 lb)

13.3 Environmental

Condition	Temperature range	Relative Humidity	Atmospheric Pressure
Operating	5°C to 40°C (41°F to 104°F)	30% to 75% (non condensing)	700 to 1060 hPa
Storage and transport (Long term)	10°C to 40°C (50°F to 104°F)	20% to 95% (non condensing)	700 to 1060 hPa
Storage and transport (short term)	-25°C to 70°C (-13°F to 158°F)	20% to 95%	500 to 1060 hPa

Note: When exposed to extreme temperature during storage, the pump must be allowed to adjust to normal temperatures for a minimum of 12 hours before use. Failure to do so may result in accelerated wear of mechanical components.

13.4 Standards Compliance

EN60601-1:1990/A13:1996 and IEC 60601-1:1988/A2:1995
EN60601-1-1:2001 and EN60601-1-2: 2001
UL60601-1, UL2601-1 and CAN/CSA C22.2 No. 601.1-M90
EN60601-1:2006, EN60601-1-11:2010* and IEC 60601-1:2005
AAMI/ANSI ES60601-1:2006 and CAN/CSA C22.2 No.60601.1(2008)
EN62366:2008
BS EN 980:2008

** Only applies to IP21 rated products (see product label for IP rating)*

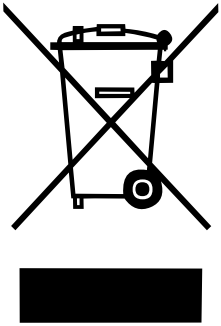
14. Product Labelling

Symbols			
	Hydroven FPR is Class II, double insulated according to the definitions in BS EN 60601-1:1990		
	Applied parts are type BF according to the definitions in BS EN 60601-1:1990		
	Refer to this document (Instructions for Use) for a description of the product classification (3rd Edition).		
	With respect to electric shock, fire and mechanical hazards only in accordance with CAN/CSA-C22.2 No. 60601.1 (2008). MEDICAL EQUIPMENT		
	This symbol signifies that this product, including its accessories and consumables is subject to the WEEE (Waste Electrical and Electronic Equipment) regulations and should be disposed of responsibly in accordance with local procedures.		
	Refer to this document (Instructions for Use) for a description of the product classification (2nd Edition).		
CE 2797	This symbol signifies that this product complies with the essential requirements of the Medical Device Directive (93/42/EEC) - Medical Device Regulation (EU/2017/745)		
Manufactured By:	**Huntleigh Healthcare Ltd.** 35 Portmanmoor Road, Cardiff, CF24 5HN, United Kingdom T: +44 (0)29 20485885 sales@huntleigh-diagnostics.co.uk www.huntleigh-diagnostics.com		
	Legal Manufacturer in association with the CE mark in Europe ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö, Sweden		
O	Power: Disconnects from the mains supply	I	Power: Connects to the mains supply
~	Alternating Current (AC)		Fuse
	Follow Instructions for Use	MD	Medical Device
SN	Serial Number	REF	Reference Number

	Legal Manufacturer		

Cleaning Symbols			
	Wipe surface with damp cloth		Use solution diluted to 1000 ppm of Available Chlorine
	Do not iron		Do Not Use Phenol-based cleaning Solutions
	Do not dry clean		Do not tumble dry

15. End of Life Disposal



This symbol signifies that this product, including its accessories and consumables is subject to the WEEE (Waste Electrical and Electronic Equipment) regulations and should be disposed of responsibly in accordance with local procedures.

16. Warranty & Service

a) ARJO INC. HEREBY DISCLAIMS ALL EXPRESS OR IMPLIED WARRANTIES (INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND ANY AGREEMENTS, REPRESENTATIONS, AFFIRMATIONS, OR WARRANTIES, WHETHER ORAL OR WRITTEN, MADE BY ANY AGENT, EMPLOYEE OR REPRESENTATIVE OF ARJO INC., UNLESS SPECIFICALLY SET FORTH IN THIS PARAGRAPH. ARJO INC. SHALL NOT BE LIABLE FOR BREACH OF CONTRACT ARISING FROM ANY DEFECT IN MATERIAL OR WORKMANSHIP OF THE GOODS. ALL LEGISLATION RELATING TO EXPRESS AND IMPLIED WARRANTIES OR OTHER OBLIGATIONS ON THE PART OF ARJO INC. THAT MAY BE LAWFULLY EXCLUDED ARE HEREBY EXCLUDED.

b) Notwithstanding the foregoing, Arjo Inc.'s sole warranty is that the Goods shall be free from defects in material and workmanship for a period of one (1) year, following delivery of such Goods to the original purchaser; provided that the Goods were used in an appropriate and reasonable manner during such period and provided further that Arjo Inc. shall be in no event be liable to Customer for defective Goods if: (i) the Goods are damaged in the course of shipping; (ii) any defect is caused wholly or to any material extent by customer's negligence, misuse, failure to use the Goods properly or use of the Goods in conjunction with any accessory not approved for use with the Goods by Arjo Inc.; (iii) the Goods are damaged as a result of improper maintenance, failure to follow manufacturer's instructions, including without limitation those on washing and cleaning, or failure to follow necessary routine maintenance procedures; or (iv) the Goods are altered, repaired or dismantled other than with manufacturer's written authorization using its approved procedures or by any party other than manufacturer's properly qualified and trained technicians.

c) Customer must provide written notice to Arjo Inc., within said warranty period of any defect in the Goods. Upon Arjo Inc.'s written request, Customer must return such Goods adequately packed (in their original packing) and fully insured to Arjo Inc.'s place of business and shall be responsible for all shipping costs incurred therein.
Customer's exclusive remedy and Arjo Inc.'s exclusive liability for any claim for loss, damage or destruction resulting from any defects in materials and workmanship shall be limited to repair, service, adjustment or replacement (at Arjo Inc.'s option) of any nonconforming or defective Goods. Arjo Inc. will have a reasonable time to repair, service or replace such Goods. Any Goods returned to Arjo Inc. which are found not to be defective in breach of the warranty in Subsection (b) above, shall be returned to the Customer in the manner described in this subsection.

d) IN NO EVENT SHALL ARJO INC. BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSSES OR DAMAGES (INCLUDING BUT NOT LIMITED TO ECONOMIC LOSS, LOSS OF PROFITS OR SPECIAL DAMAGES) ARISING OUT OF OR INCURRED BY CUSTOMER IN CONNECTION WITH THE PURCHASE OF ARJO INC.'S GOODS EVEN IF ARJO INC. HAS BEEN ADVISED OR HAS KNOWLEDGE OF THE POSSIBILITY OR EXTENT OF SUCH DAMAGES SUFFERED OR INCURRED BY CUSTOMER OR ANY END USER AS A RESULT OF OR IN CONNECTION WITH ANY BREACH OF THESE TERMS AND CONDITIONS BY ARJO INC. OR ANY TORT (INCLUDING BUT NOT LIMITED TO STRICT LIABILITY OR NEGLIGENCE) COMMITTED BY ARJO INC., ITS AGENTS OR REPRESENTATIVES IN CONNECTION WITH THESE TERMS AND CONDITIONS OR ANY CONTRACT WITH CUSTOMER FOR THE SUPPLY OF GOODS.

e) Customer shall not create, directly or indirectly, any warranty obligations on the part of Arjo Inc. to the customers of Customer, and in particular, without limiting the foregoing, Customer agrees not to pass on to its customers any warranties beyond or in addition to those given by Arjo Inc. to Customer hereunder. Where the Customer is a dealer in the Goods, it shall be responsible for the labor cost of all repairs and Arjo Inc. shall be responsible for providing all repair parts during said one (1) year. The dealer shall provide written verification of warranty repairs including the original invoice number, date of purchase, description of repairs, name of its customer and date of sale to such customer.

f) Customer shall be deemed to have full knowledge of the nature and properties of the Goods ordered and of any hazards they involve and the proper treatment, storage and handling thereof. Any technical advice furnished by Arjo Inc. or its representatives or agents is given only on the basis that it is followed at the Customer's own risk

16.1 Service Returns

If for any reason the Hydroven FPR has to be returned, please:

- Clean the product following the instructions in this manual.
- Pack it in suitable packing.
- Attach a decontamination certificate (or other statement declaring that the product has been cleaned) to the outside of the package.
- Mark the package 'Service Department '

Huntleigh Healthcare Ltd reserve the right to return product that does not contain a decontamination certificate.

For service, maintenance and any questions regarding this, or any other Huntleigh Healthcare product, please contact:

Service Department
Arjo Inc.
12625 Wetmore Road
Suite 308
San Antonio, Texas 78247
USA

Telephone: 1-800-343-0974 Option #3

Email: TechServiceParts.USADD@arjo.com

If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor.
In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

Manufactured for Huntleigh Healthcare Ltd on behalf of;

ArjoHuntleigh AB
Hans Michelsensgatan 10
211 20 Malmö, Sweden

CE 2797

Huntleigh Healthcare Ltd.
35 Portmanmoor Road, Cardiff, CF24 5HN, United Kingdom
T: +44 (0)29 20485885 sales@huntleigh-diagnostics.co.uk
www.huntleigh-diagnostics.com

Distributed in the USA by:
Arjo Inc.
2349 West Lake Street, Suite 250
Addison, IL 60101
T: 800-323-1245
www.huntleigh-healthcare.us

1001057-3

www.huntleigh-diagnostics.com/

www.huntleigh-healthcare.us/

A Member of the Arjo Family
As our policy is one of continuous improvement, we reserve the right to modify designs without prior notice.

HUNTLEIGH

AW 1001064-4