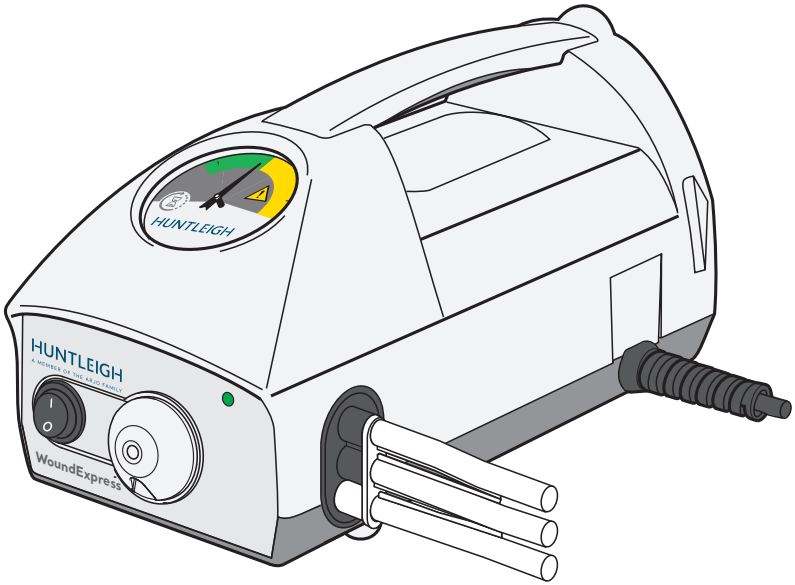
INSTRUCTIONS FOR USE

WoundExpress™

WoundExpress Therapy Device



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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 misuse 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**	 **Follow Instructions for Use**

1.1 Warnings

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

 **A possible explosion hazard exists if used in the presence of flammable gases.**	 **Do not operate the unit from the mains supply if the mains cable is damaged.**
 **Do not immerse any portion of the unit in water or other liquids.**	 **Use only recommended accessories listed in this manual.**
 **If this product is connected to another item of electrical equipment, it is important that the system is fully compliant with IEC60601-1.**	 **It is the responsibility of the care giver to ensure that the user can use this product safely.**
 **Only the pump and garment 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.**	 **Ensure that all cables and tubesets or air hoses are positioned so that they do not present a trip, strangulation or other hazard and they 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.

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.

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.

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

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

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.

This device must not be modified.

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

The garment must not be cleaned.

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
The WoundExpress Therapy Device garment has an expected service life of 16 weeks.

2. Introduction

The WoundExpress Therapy Device is a system consisting of a pump and garment which operates by using low pressure air to deliver a compression therapy.

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 WoundExpress Therapy Device, contact your local Huntleigh representative.

2.1 Intended Use

The intended use of this product is to manage the list of clinical conditions detailed in the “Indications” (section 3.1).
The WoundExpress Therapy Device should be used as part of a prescribed plan of care detailed in the “Indications” section.

2.2 About the WoundExpress Therapy Device

The pump operates on a 4 minute automatically timed cycle, consisting of a 2 minute venous emptying phase and a 2 minute rest phase. The venous emptying phase consists of six 20 second compression cycles, while no compression takes place during the rest phase. Each 20 second compression cycle is characterised by overlapping synchronous inflations and deflations of the distal (lower), central (middle)and proximal (upper) chamber.

Compression Cycle	Delay to cycle start	Inflated state	Deflated state
Chamber 1 (lower)	0s	15s	5s
Chamber 2 (middle)	5s	10s	10s
Chamber 3 (upper)	12s	10s	10s

The maximum pressure in each chamber is 60mmHg.

The segments within the garments are designed to prevent ridging and ensure high patient comfort and concordance.

A full technical description of the WoundExpress Therapy Device can be found in the Service Manual, part No. 785345, available from your local Huntleigh Service dept.

2.3 Use Environment

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

3. Clinical Applications

3.1 Indications

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

- Chronic wounds including leg ulcers (venous leg ulcers and mixed aetiology leg ulcers).

IPC may also be beneficial in the management of:

- Lower limb pain

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.

3.2 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.
- Severe peripheral artery disease (ABI ≤ 0.6).
- Known malignancy

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.**

CAUTION
For patients with an ABI < 0.8: WoundExpress therapy should only be instigated and thereafter supervised by an appropriate physician or specialist nurse who has deemed that the arterial and venous status of the limb are suitable for IPC therapy.

WARNING
The garment must not be applied to open wounds or non-intact skin.

WARNING
If the user feels any numbness, tingling or has any other concerns, switch off the pump and remove the garment.

WARNING
In the event of a power failure or fault whereby the garment remains inflated, remove the garment(s) from the patient's limbs.

4. Preliminary Checks

Contents (supplied with each system)

Item	Item
1 x WoundExpress Therapy Device	1 x Instructions for Use
1 x Quick Reference Guide	1 x WoundExpress Diary

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.

5. Clinical Treatment Guide

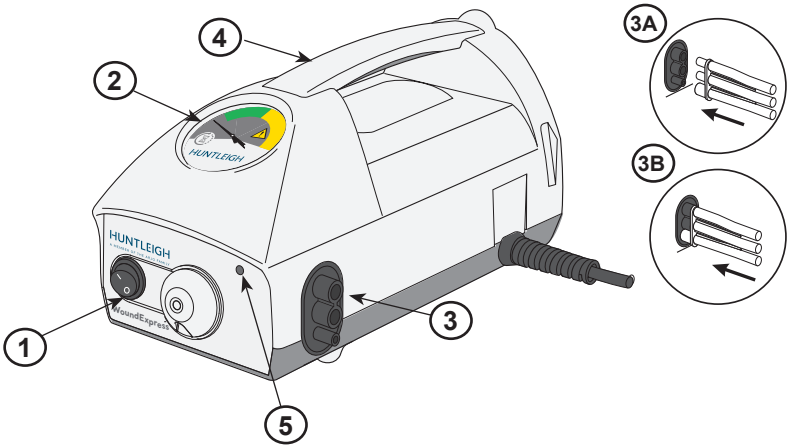
The WoundExpress Therapy Device has a preset pressure of 60mmHg.

The recommended therapy time is 2 continuous hours per day.

A diary is included with the pump for the patient to complete, to monitor concordance with the therapy.

Note
Loss of mains power will halt therapy.

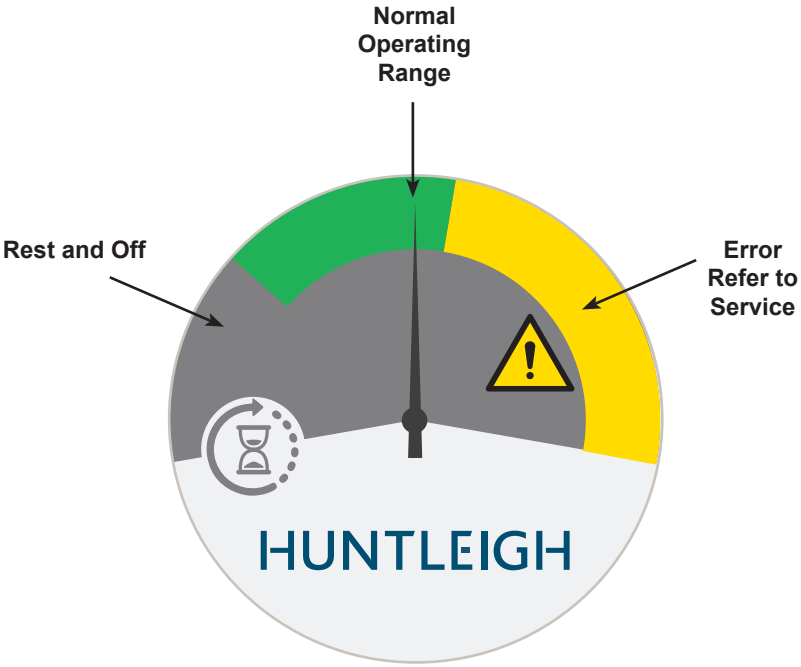
6. Pump Description



Item No.	Description	Function
1	On/Off Switch	Operation of this switch Starts or Stops the system
2	Status Indicator	Indicates the pressure in the garment
3	Tube connectors	For garment attachment (3A and 3B)
4	Carry Handle	For easy handling of the pump
5	Power status LED	Indicates the power status of the pump

Note
If the operation of performance of the pump changes during use, refer to "Trouble Shooting" section of this IFU before contacting your local Huntleigh service department.

6.1 Status Indicator Description



Status Indicator

1. The sand timer symbol indicates that the device is not currently delivering a compression cycle. This can be during the 2 minute rest phase, or when the device is turned off.
2. The green zone indicates the proper functioning of the device. The needle will fluctuate within this area during a compression cycle.
3. The yellow zone indicates that the device is operating above the recommended pressure setting. Turn off the pump and consult the Troubleshooting section of this IFU.

7. Operation

7.1 Garment Description

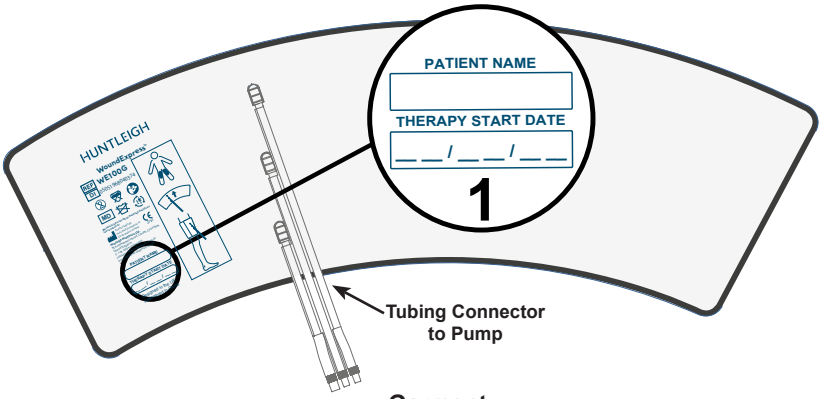
The garment Inner and Outer panels are made from a laminate of brushed polyester and Polyurethane foam.

The outer edges of the garment are ‘finished’ with a sewn nylon binding with a nylon thread.

The garment has a hook and loop fastener to enable adjustable fitting.

Air is delivered to the 3 bladder chambers through PU tubing connector via grommets in the bladders.

The patient name and therapy start date can be written onto the garment in the area provided, (1 - shown in diagram below), using a ball point pen.

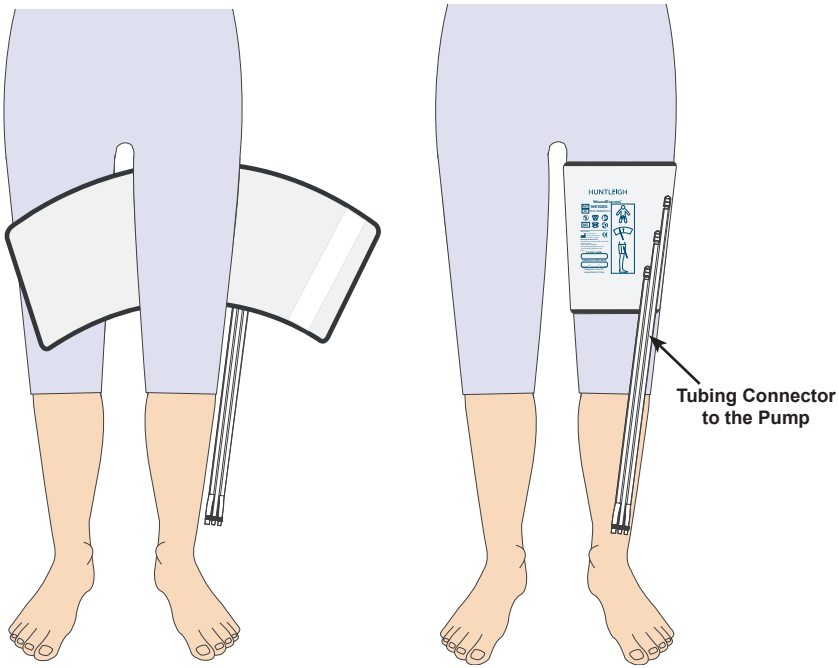


Garment

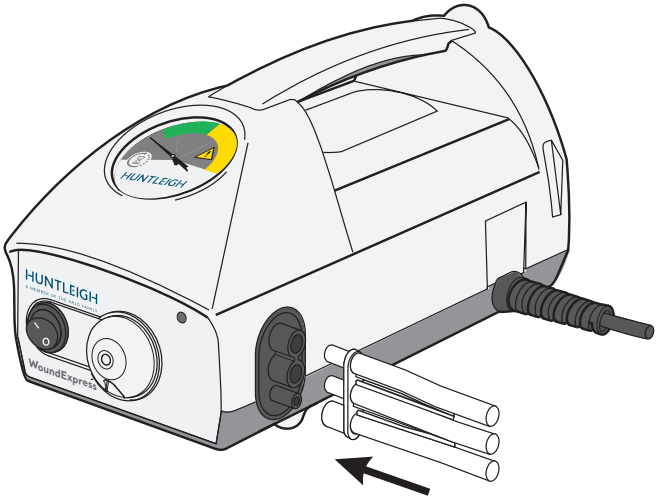
7.2 Applying the Garment

Note
Optimal therapy is performed over thin clothing, Any sharp or hard objects must be removed from clothing before applying the garment.

Fit the garment to the thigh (left or right) of the limb affected by the chronic wound. Ensure it is a snug fit and fasten using the velcro strip.



Attach the garment tubing to the pump.



Note
Ensure that the garment is applied correctly before switching the pump on.

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.

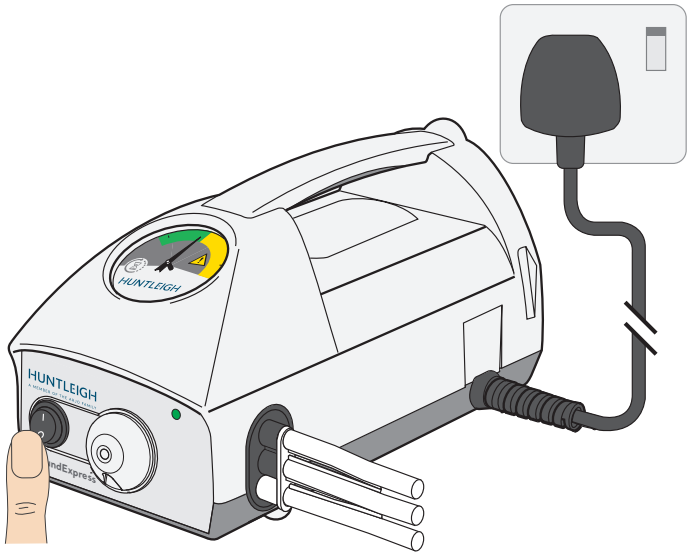
WARNING
Patients must not walk or stand when wearing leg garments.

7.3 Switching On

The pump should be placed securely on a flat surface.

Placing the pump on a flat surface at least 1m away from the patient's head ensures that any noise experienced is at a comfortably low level.

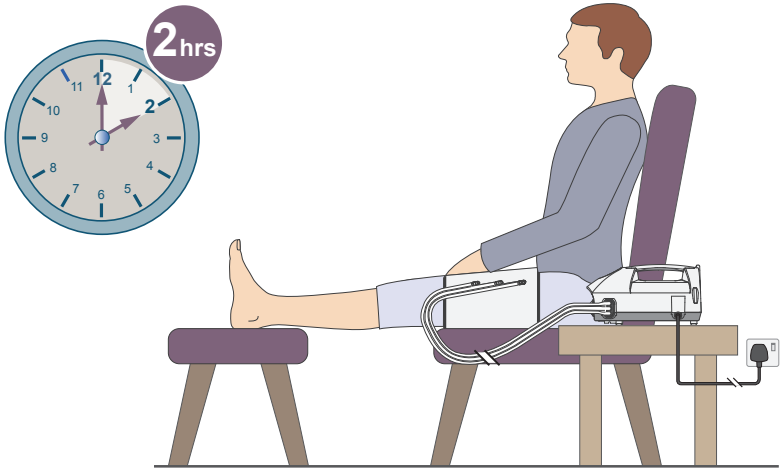
Connect the pump to the mains power supply using the power cable provided. Turn the mains power switch (1) to the On (I) position. The power status LED will illuminate.



7.4 Therapy

During therapy the user should lie down or sit with the leg elevated.

Check that the garment remains snugly in place and does not move down the leg, reposition as necessary.



Check occasionally to ensure the pump is running its normal cycle and is reaching a pressure in the green zone on the gauge on top of the pump.

The normal cycle is approximately 2min of inflation followed by 2min of deflation.

The recommended therapy time is 2 continuous hours per day.

A diary is included with the pump for the patient to complete, to monitor concordance with the therapy.

It is normal during the inflation phase for the pressure to vary within the green segment shown on the status indicator, and to drop to zero for 2 mins.

In use, the patient will feel a gentle massaging.

Compression should not cause any discomfort or pain to the patient.

WARNING
If the user feels any numbness, tingling or has any other concerns, switch off the pump and remove the garment.

WARNING
The garment is intended for single patient use only.

7.5 Switching Off

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.

7.6 Removing the Garment

Make sure the pump power switch (1) is in the off (O) position and disconnect the tubing from the pump by removing the tube connectors (3). This will allow removal of excess air from the garment. The garment can then be removed by undoing the velcro strip.

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 WoundExpress Therapy Device 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.

WARNING
Do not use Phenol-based solutions or abrasive compounds or pads during the cleaning or 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.

8.1 Cleaning

8.1.1 Wound Express Therapy Device

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.

8.1.2 Garments

Garments are single patient use and cannot be reprocessed or cleaned.
The garment should be treated as domestic waste and disposed of accordingly.

8.2 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. Routine Maintenance

9.1 WoundExpress Therapy Device

9.1.1 Maintenance

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

9.1.2 Servicing

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

9.1.3 Service Period

Huntleigh recommend that the WoundExpress Therapy Device pump is serviced every 24 months by an Huntleigh authorised service agent.

9.2 WoundExpress Therapy Device Pump

9.2.1 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.

9.2.2 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.

10. 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. Air leak in garment.	Ensure that the tube airway is clear. Check for kinked tubing. Check connections. Check garment. Replace if defective.
Needle on status indicator is in yellow zone		Contact Huntleigh service department.

Note
If the trouble shooting procedures do not return the system to normal performance, stop using the system immediately and contact Huntleigh service department. Refer to “Warranty & Service” .

11. Accessories

WARNING: Use only recommended accessories listed in this manual.

Accessory	Order Code
WoundExpress Therapy Device Garment	WE100G

12. Specifications

12.1 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.
Degree of safety of application in the presence of a flammable anaesthetic	Equipment not suitable for use in the presence of flammable gases or oxygen rich environments.

12.2 General

Model	WoundExpress™ Therapy Device
Part Numbers	WE100P
Pressure Range	60 mmHg ± 5mmHg
Supply voltage	230 V AC
Supply Frequency	50Hz
Pump Fuse Rating	F500 mA 250 V
Power input	14 VA
Case Material	Fire Retardant ABS Plastic
Size	270 x 130 x 150 mm (10.6 x 5.1 x 5.9”)
Weight	2.5 kg (5.5 lb)

12.3 Environmental

Condition	Temperature range	Relative Humidity	Atmospheric Pressure
Operating	5°C to 40°C (41°F to 104°F)	15% to 90% (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.

12.4 Standards Compliance

IEC 60601-1:2005 + A1:2012
IEC 60601-1-2: 2014
IEC 60601-1-11:2015
IEC62366:2015
BS EN 980:2008
ISO 14971:2012
ISO 10993-1:2018

13. Product Labelling

Symbols					
	WoundExpress Therapy Device 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				
	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.				
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)				
	Refer to this document (Instructions for Use) for a description of the product classification.				
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				
SN	Serial Number	REF	Reference Number	MD	Medical Device
	General Warning		Do Not Reuse		Fuse
~	Alternating Current (AC)				Date of Manufacture
O	Power: Disconnects from the mains supply			I	Power: Connects to the mains supply
	Follow Instructions for Use				Single Patient Use
LATEX	LATEX FREE Does not contain Latex				Cardboard packaging can be recycled.
Cleaning Symbols					
	Wipe surface with damp cloth			Cl 1000ppm NaOCl NaDCC	Use solution diluted to 1000 ppm of Available Chlorine
PHENOL	Do Not Use Phenol-based cleaning Solutions				Do Not Wash

14. Electromagnetic Compatibility

Make sure the environment in which WoundExpress Therapy Device 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

WARNING
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 WoundExpress Therapy Device is intended for use in the electromagnetic environment specified below. The customer or the user of the WoundExpress Therapy Device should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	The WoundExpress Therapy Device 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 WoundExpress Therapy Device 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 WoundExpress Therapy Device is intended for use in the electromagnetic environment specified below. The customer or the user of the WoundExpress Therapy Device 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 WoundExpress Therapy Device, 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	10 Vrms 80MHz to 2.5MHz	10V/m	$d = 0.35\sqrt{P}$ 80MHz to 800MHz $d = 0.7\sqrt{P}$ 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 WoundExpress Therapy Device is used exceeds the applicable RF compliance level above, the WoundExpress Therapy Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the WoundExpress Therapy Device.

[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 WoundExpress Therapy Device

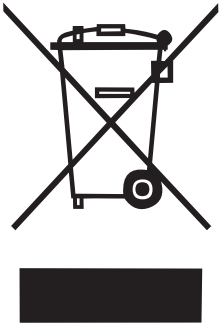
The WoundExpress Therapy Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the WoundExpress Therapy Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WoundExpress Therapy Device 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** $d = 0.35\sqrt{P}$	**800MHz to 2.5GHz** $d = 0.7\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.70
10	3.8	1.11	2.21
100	12	3.50	7.0

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.

Guidance and Manufacturer's declaration - electromagnetic immunity			
The WoundExpress Therapy Device is intended for use in the electromagnetic environment specified below. The customer or the user of the WoundExpress Therapy Device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_r (>95 % dip in U_r) for 0,5 cycles 70 % U_r (30 % dip in U_r) for 30 cycles <5 % U_r (>95 % dip in U_r) for 5 s	<5 % U_r (>95 % dip in U_r) for 0,5 cycles 70 % U_r (30 % dip in U_r) for 30 cycles <5 % U_r (>95 % dip in U_r) for 5 s	Mains power quality should be that of a typical commercial of hospital environment. If the user of the WoundExpress Therapy Device requires continued operation during power mains interruptions, it is recommended that the WoundExpress Therapy Device is powered from an uninterruptible power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_r is the a.c. mains voltage prior to the application of the test level.			

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

Huntleigh Healthcare Diagnostic Products Division standard terms and conditions apply to all sales. A copy is available on request. These contain full details of warranty terms and do not limit the statutory rights of the consumer.

Service Returns

If for any reason the WoundExpress Therapy Device 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 '

For further details, refer to NHS document HSG(93)26.

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

Service Department.
Huntleigh Healthcare, Diagnostic Products Division,
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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;

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A Member of the Arjo Family

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