



INSTRUCTIONS FOR USE



LymphFlow
GO 

BEFORE YOU START

The device is intended for adult patients (18 years and over). No special skills are required to operate it. However, before each use, it is essential to follow a few steps to ensure the device functions safely and effectively:

1. Device Inspection

Prior to using the device, carefully inspect it for any visible defects or damage. This includes:

- a. Checking for deformities in the device.
- b. Inspecting the device for frays or wear.
- c. Inspecting the device for any visible marks such as stains.
- d. Ensuring all buttons and other components are intact and functioning properly.

2. Power supply

Verify that the batteries are fully charged. For instructions on charging the device please refer to “Charging Your Device” Section.

3. Device Setup

Place the device on a stable, flat surface close to where the therapy will be performed. Ensure there is enough space for the device to operate without obstruction.

4. Environment Check

Make sure the environment in which the device will be used is clean, dry, and free from dust. Avoid operating the device near water or in humid conditions to reduce the risk of electrical issues.

5. Readiness for Use

Once the inspection is complete, you are ready to operate the device. Refer to the operating instructions for details on starting the device and setting up the treatment parameters based on your needs.

Remember: Regular maintenance and preventive inspection are critical to the safe and effective operation of the device. Re-calibration is not required for this device. However, if any issues are found during inspection, do not use the device and contact manufacturer for assistance.

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Please ensure you read the entirety of this document before attempting to connect or operate the device.

INTRODUCTION

The Haddenham LymphFlow Go is a preprogrammed pneumatic compression device used to aid in the reduction of swelling related to primary and secondary lymphoedema, by moving excess fluid from an impaired lymphatic region toward healthier areas of the body where fluid can be naturally absorbed and processed.

The device consists of one garment with a fully integrated pump module, a separate charger and instruction booklet. The device provides two distinct treatment modes, as well as three separate pressure intensity settings.

INTENDED PURPOSE

LymphFlow Go is intended to promote lymphatic flow and reduce limb swelling by applying intermittent pneumatic compression to the lower limb. The device is intended for use by adult patients, under medical supervision, in home or clinical environments. The therapeutic effect is achieved exclusively through mechanical displacement of interstitial and lymphatic fluid. No pharmacological, metabolic, or immunological mechanism is involved.

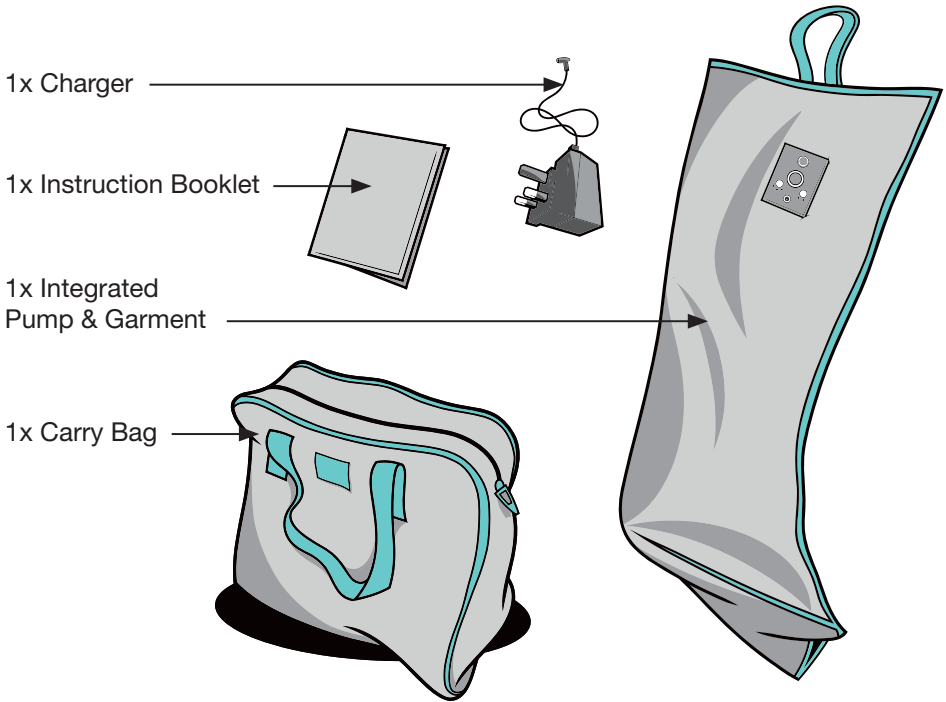
Intended Users:

- Adult patients diagnosed with primary and secondary lymphoedema of the lower limb.
- Non-professional caregivers assisting adult patients at home.
- Healthcare professionals supervising or prescribing intermittent pneumatic compression therapy.

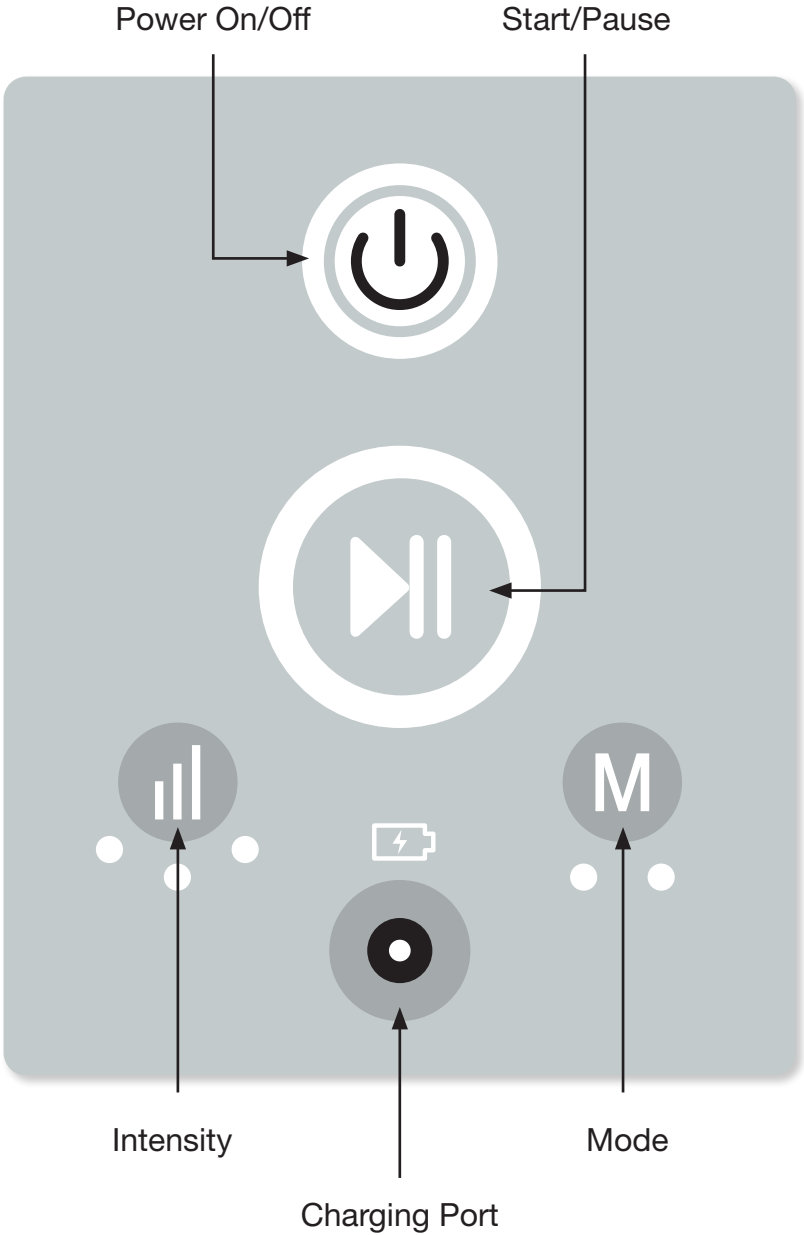
The device is not intended for paediatric patients.

WHAT'S INCLUDED

The device is supplied as a complete system. Components such as garments, tubing and power supply are not currently placed on the market separately by the manufacturer.



THE CONTROL PANEL



HOW TO OPERATE

Press the power button to turn on the device. The LED ring that surrounds the power button will then light up, signalling that the device is ready to begin a treatment cycle.

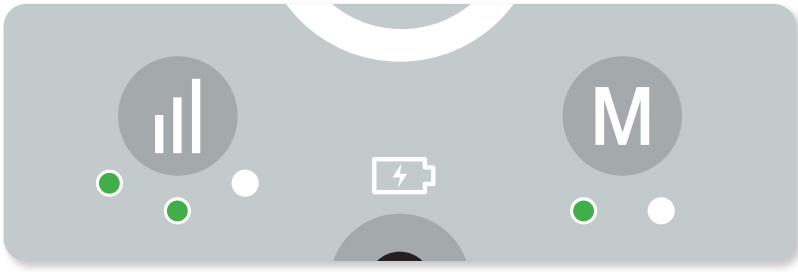
Mode:

Select one of the two available treatment modes, by pressing the mode button. The surrounding LEDs will alternate in colour depending on which mode is selected: green light indicates 'Lymphatic Mode', whereas blue light indicates 'Sequential Mode'.

- **Lymphatic Mode** is designed for use where the lymphatic drainage pathway has been disrupted, such as following lymph node removal or radiotherapy to the proximal/regional nodes. Delivers proximal-clearance-first sequencing, followed by a distal-to-proximal flush, lasting approximately 20-35 minutes on a medium intensity setting.
- **Sequential Mode** is designed for use where the proximal/regional lymph node drainage is intact, including primary lymphoedema and secondary lymphoedema without nodal disruption. Delivers multi-chamber, distal-to-proximal sequential compression, lasting approximately 30-45 minutes on a medium intensity setting.

Higher pressures/smaller limb sizes will increase treatment times.

Please note: the mode setting **cannot** be adjusted mid-treatment. If you wish to switch treatment modes after the treatment has begun you can reset the device by pressing the start/pause button, before then turning the device off and waiting for 10 seconds. Once this time has passed, power the device back on and adjust the settings accordingly before beginning a new treatment cycle.



Intensity:

The pressure intensity can be adjusted by pressing the intensity button. The surrounding LEDs will illuminate depending on the intensity level selected.

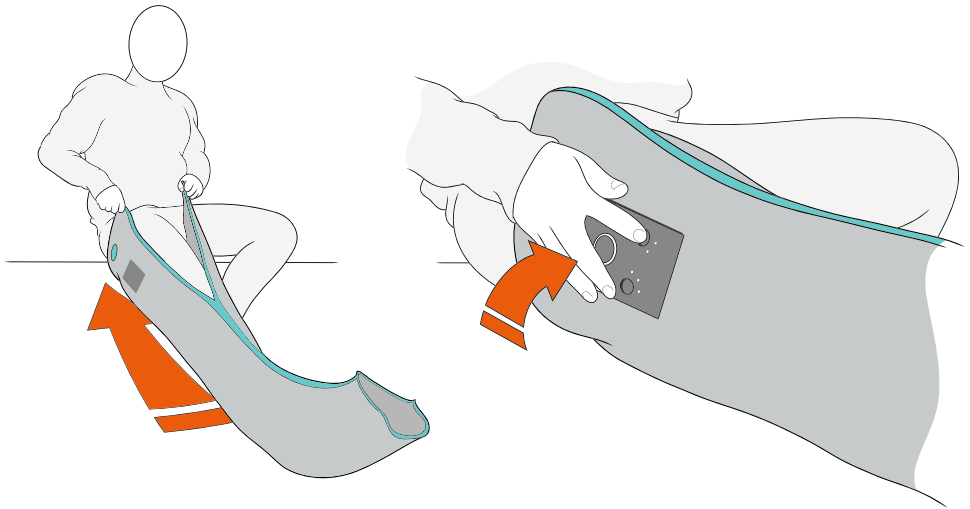
- **Low:** 40mmHg (*1x LED light will illuminate*)
- **Medium:** 60mmHg (*2x LED light will illuminate*)
- **High:** 80mmHg (*3x LED light will illuminate*)

The appropriate intensity setting (Low, Medium or High) is determined by the prescribing clinician, based on the patient's presentation, tolerability, and any relevant contraindications or precautions (Page 14). Treatment should begin at Low intensity. Where Low intensity is well tolerated, intensity may be increased to Medium, and subsequently to High, based on the patient's response and tolerability, up to the maximum intensity prescribed by the clinician. Patients should not exceed the maximum intensity prescribed by their clinician without first seeking medical advice.

Please note: the pressure intensity **can** be adjusted mid-treatment. To adjust the intensity during treatment, first press the play/pause button. Once the treatment has been temporarily halted, you can reselect the desired pressure levels from the options listed above before pressing the start/pause again to resume the treatment under the newly adjusted pressure.

PUTTING ON YOUR DEVICE

- Unfold and place the device on a flat surface, with the zip fastened as far as the ankle bend.
- While seated, slide the garment over one leg and pull the zip all the way toward the top, securely fastening the product before beginning a treatment cycle.
- Assume a comfortable seating position preferably with your leg raised, ensuring the device's control panel is visible and accessible before beginning a treatment cycle.



Please note: Prior to usage ensure that you have emptied your bladder, removed any jewellery from the part of the body to be treated, covered any open wounds with an occlusive/absorbent dressing, and removed any compression garments or bandages that will be covered by the device. Wear light, loose clothing and ensure your pockets are empty before beginning a treatment cycle.

TAKING OFF YOUR DEVICE

- Once the treatment has finished the light around the LED ring will stop blinking, and the device will make a beeping sound.
- Switch off the device by pressing the power on/off button.
- Unzip the garment down to the ankle bend, and gently slide your leg out of the garment.
- Once you have removed the garment, ensure the device is powered off and the product is stored safely out of harm's way for future usage.

Please note: You should only attempt to remove the garment from your leg once the treatment cycle has finished. If you need to take off the device mid-cycle, please ensure you temporarily halt the treatment by pressing the start/pause button before attempting to unzip the garment.



Once your treatment is complete or has stopped, ensure that the garment is fully deflated before starting your next treatment, or performing any maintenance activities.

CHARGING YOUR DEVICE

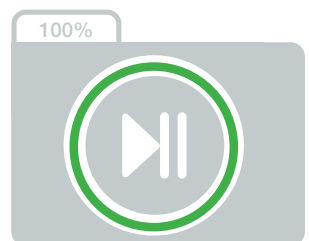
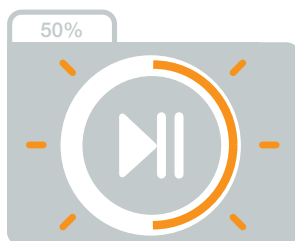
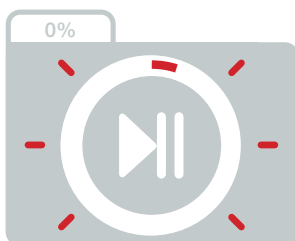
A fully charged regular device is capable of delivering five complete treatment cycles per charge, whereas a fully charged large device is capable of delivering three. In order to check the current charge level of the device, press and hold the start/pause button.

- When the battery of the device is running low/depleted, the first segment of the LED ring surrounding the start/pause button will flash red, as shown below (0%).
- To begin charging the device, plug the charger into the charging port located at the bottom of the control panel.
- The LED ring will flash while charging. The number of illuminated segments and overall colour of the LED ring indicates the level of charge, as shown below (50%, 100%).

Please note: Do not operate the device while the battery is charging. If the low battery indicator is shown, allow the device to fully recharge before beginning another treatment cycle.



Only use the provided charger or a charger provided directly from the manufacturer to charge the device.



CLEANING YOUR DEVICE

- Before cleaning the garment section of the device, ensure the control panel is powered off, and unplugged from the charger.
- Use a lint brush or roller to remove any excess dust or particles from the garment's surface.
- After dry-wiping, spot clean any areas that require further attention with isopropyl alcohol or a damp cloth soaked in a mild detergent.
- Allow the garment to dry thoroughly prior to any further usage.

Please note: do not spray water or any cleaning products directly onto the device, instead wipe the garment gently with a damp cloth as instructed above. It is recommended that the device be cleaned after each treatment cycle.



Do not expose charging port to water or any liquid. Users should only use recommended cleaning solutions and methods. Using other cleaning methods or solutions may damage the device.



INDICATIONS

The LymphFlow Go is indicated for use by medical professionals and adult patients under medical supervision, to increase lymphatic flow in the treatment or management of:

- Primary and secondary lymphoedema of the lower limb.

The expected clinical benefits of the device include reduction of limb swelling, promotion of lymphatic drainage and improvement in symptoms associated with lymphoedema.

CONTRAINDICATIONS

The device must not be used in patients with any of the following conditions:

- Heart failure (congestive cardiac failure or acute pulmonary oedema)
- Acute venous disease (including acute deep vein thrombosis or acute thrombophlebitis)
- Severe peripheral artery disease
- Active skin or limb infection or active inflammatory disease of the limb (including cellulitis without appropriate antibiotic coverage)
- Any circumstance in which increased lymphatic or venous return is clinically undesirable
- During pregnancy

Haddenham Healthcare assumes no liability as a result of any contra-indicated use of this device.

STORAGE

Haddenham LymphFlow Go should be stored in a cool, dry, dark place without any exposure to direct sunlight.

When storing the device ensure the control panel is turned off, facing up, and the garment is kept on a stable flat surface.



Make sure to charge the device at least once every six months if the product is not in use. If not charged once every six months the battery may be damaged and the device may not work.



Store the device away from children and pets.

The device can be transported/stored for short periods of time within:

- Temperature range of -25°C to 70°C
- Humidity range of 10% to 93% RH non-condensing
- Atmospheric pressure range of 70kPa to 106kPa
- Allow the pump to reach a reasonable room temperature of 10°C to 30°C before operating.
- When the system has been stored in extreme temperature conditions of -25°C or 70°C between uses, wait for two (2) hours before using again.

WARRANTY

The expected service life of the LymphFlow Go is a minimum of 1 year of daily use from the date of manufacture, subject to the device being used and maintained in accordance with IFU-LFG-001.

Your warranty does not cover:

- Accidental damage, for example if your device has been dropped, or has liquid damage.
- Repair costs caused by external factors, fire, theft, and weather.
- Repair costs caused by the failure to follow the manufacturer's general safety, cleaning instructions and other guidelines.
- Failure due to an incorrect or abnormal electrical supply or signal lead connection, defects in external wiring or in the electrical connection not forming part of the product covered.
- Cosmetic damage such as scratches, dents, corrosion or colour, where the function of the product is unaffected.
- Servicing, inspecting or prohibited cleaning of the product, and failure to follow the manufacturer's instructions and guidelines.
- Deliberate damage or neglect of the device.

DEVICE SAFETY/DAMAGE WARNINGS

Caution: the following can damage your device: Ointments, Petrol, Oils, Dry cleaning fluid, Turpentine. Direct heat – ironing, radiators, tumble driers, etc. Long, sharp or jagged toenails/fingernails/objects. Rings, bracelets and other jewellery. Storing in direct sunlight. Incorrect application. Loose threads or loops must never be pulled out or cut off. ***Do not attempt to disassemble the device. No modification of this equipment is allowed.***

Never block the ventilation openings on the sides of the garment; keep free of lint and hair. Do not operate the device with ventilation openings blocked (e.g. under a blanket or duvet). Do not drop or insert objects into any opening of the device. Do not use sharp objects such as pins or scissors on or near the device. Do not use heat sources such as irons, blow dryers, radiators, or tumble dryers on or near the device.

Very rarely, pneumatic compression devices can cause allergic reactions. If acute limb pain or skin irritations should occur whilst the device is being worn, remove the device and consult your doctor or healthcare professional immediately.

The software update port is for manufacturer use only; users must not access this port.

The DC Jack is for charging only and cannot be used for information transfer.

TROUBLESHOOTING

In the event of an error, the light ring around the play/pause button will blink red, signalling a malfunction. If such an error occurs turn the device off and wait 30 seconds before turning it back on. If the error persists after rebooting, please contact the manufacturer.

In the event that your device does not turn on, please contact your manufacturer.

If when charging, the charging indicator does not turn on, user should check the connections on the charger. If connections are secure, user should contact manufacturer.

In the event that the device does not inflate during a treatment, please contact your manufacturer.

Example of red blinking LED



GENERAL SAFETY

 Risk of Electric Shock	- Do not attempt to service the device. Such attempts could result in injury or damage to the product and will void any warranty. - Do not disassemble the device. - Only use the charging cable provided with the device. - Turn off the device when not in use. - The device is to be used indoors only. - Do not use the device near water or while bathing. - Do not use the device if it is wet. Dry it off before use or wait until it dries.
 Risk of Personal Injury	- Use the device only for its intended purpose, as directed in this guide. - Use accessories only if recommended or supplied by Haddenham Healthcare. - Never operate the device if the device has been dropped into water. Return the device to Haddenham Healthcare for inspection or repair. - Never smoke while wearing the product or while operating the product. - Do not attempt to replace batteries. Please contact the manufacturer.
 Risk of Device Damage	- Never block the ventilation openings on the sides of the garment. Keep the ventilation openings free of debris such as lint and hair. - Never operate the device in a situation where the ventilation openings may be blocked, such as under a blanket or duvet. - Never drop or insert any object into any opening of the device. - Never use sharp objects, such as pins, scissors on or near the device. - Never use hot devices such as irons or blow dryers, on or near the device. - No modification of this equipment is allowed. - This device contains no replaceable parts. Do not attempt to service or repair.
 CAUTION	- To avoid skin irritation that may result from contact with the nylon material, wear lightweight, loose-fitting (non-elastic) cotton clothing (example: scrubs, stockinette); for head and neck garments a face mask or balaclava. If skin irritation develops, consult with your doctor. - Lymph fluid is moved through the vessels in the skin. It is important to avoid wearing anything during therapy that may hamper the lymph flow. These items include belts, jewellery, restrictive clothing such as elastic-banded underwear, compression bandaging, elastic-banded socks, compression garments, bras. - The software update port is only utilized by the manufacturer for software maintenance purposes. Do not attempt to access this port, as this could damage the device. - Ensure that the ME equipment is positioned to allow easy access to the disconnection mechanism. The equipment must not be installed in a manner that impedes the user's ability to quickly and safely disconnect the device from its power source. - The DC Jack is only used for charging and cannot be used for information transfer. - The device should not be placed in direct contact with an open wound. It is recommended that wounds be properly dressed before the garment is applied. Contact your healthcare provider if you have any questions. Take care to avoid overheating when donning or doffing garments. - To achieve maximum benefit from your session it should be completed without interruption. RISK OF ELECTRICAL SHOCK: Unplug the device from the charger before cleaning it. Allow the device to dry completely prior to start a treatment. - The power adaptor provides means isolation from the mains supply. - Do not submerge. - Do not machine wash. - Do not disassemble. - Do not dry clean. - Do not machine dry. - Do not autoclave. - Do not iron.

TECHNICAL SPECIFICATION

Brand Name	LymphFlow Go
Product Description	Portable Pneumatic Full Leg Compression Device
Model Number	LFG3 (Regular) / LFG4 (Large)
Charger AC Input	100 - 240V AC, 50/60Hz, 1.5A AC
Input Power	12.6 VDC / 1A
Battery Type & Specification	Lithium Ion Battery, 12.6V Charge Voltage, 5,000mAh Capacity
Device Weight	1.75kg (Regular) / 2.12kg (Large)
Modes of Operation	2
Intensity Levels	3
Pressure Range	0 - 80 mmHg
Pressure Accuracy	±5 mmHg
Number of treatments on a full charge (Regular)	5
Number of treatments on a full charge (Large)	3
Chambers (Max)	12
Inner Fabric (Applied Part)	PU coated nylon
Outer Fabric	PU coated polyester
Calibration	Recalibration Not Required
Operating Atmospheric Pressure	70 kPa to 106 kPa
Device Transport & Storage Temperature Limits	-25°C to 70°C
Device Operating Temperature Limits	5°C to 40°C
Device Operating & Storage Humidity Limits	10% - 93% (non-condensing)
Charging Time	Approximately 5 hours

SYMBOL KEY

	Serial Number
	Unique Device Identifier
	Batch/Lot Number
	Type BF Applied Part
	Caution Symbol
	Manufacturer
	Medical Device
	Do Not Wash
	Do Not Bleach
	Do Not Wring
	Do Not Line Dry In The Shade
	Do Not Iron
	Do Not Dry Clean
	Do Not Tumble Dry
	Refer to Instruction Manual/Booklet
	Atmospheric Pressure
	Humidity Limitation
	Keep Away From Rain
	Temperature Limit
	Manufacturing Date
	Waste Electronics and Electrical Equipment
IP22	Protected from touch by fingers and objects greater than 12mm. Protected from water spray less than 15 degrees from vertical.

	European Union Declaration of Conformity (Conformité Européenne)
	Reference Number
	This Way Up
	Fragile
	Keep Away From Direct Sunlight
	European Authorised Representative

END OF LIFE

Please dispose of the device in an environmentally responsible manner, in accordance with your local regulations.

ELECTROMAGNETIC INTERFERENCE

This device has been constructed and tested to comply with IEC 60601-1-2:2014. This equipment may generate and radiate radio frequency energy and, if not installed correctly may cause interference to radio communication. If the equipment does cause interference the user is encouraged to try to correct the interference by one or more of the following measures:

- Re-orient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment into an outlet on a circuit different to which the receiver is connected.
- Consult the device manufacturer.

EMC GUIDANCE & DECLARATION

This device complies with IEC 60601-1-2:2014.

- This device complies with IEC 60601-1-2:2014.
- The device must be installed and put into service in accordance with the EMC information provided in this document.
- Portable and mobile RF communications equipment can affect the behaviour of medical electrical equipment.
- The device complies with all applicable and required standards for electromagnetic interference.
- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is not safe to operate the device in the presence of high frequency equipment.
- It is good practice to avoid using the device in extremely close proximity to other equipment.

ELECTROMAGNETIC EMISSIONS

The LymphFlow Go Portable Full Leg Compression Device is intended for use in the electromagnetic environment specified below. The customer or user of the LymphFlow Go Portable Full Leg Compression Device should assure that it is used in such an environment.

Emissions	Compliance	Electromagnetic Environment Guidance
Radiated Emissions CISPR 11	Group 1	The LymphFlow Go Portable Full Leg Pneumatic Compression 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.
CISPR Emissions Classification	Class B	The LymphFlow Go Portable Full Leg Pneumatic Compression Device is suitable for use in all establishments, including domestic establishments and those connected to the public low-voltage power adapter network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/ Flicker IEC 61000-3-3	Complies	

ELECTROMAGNETIC IMMUNITY

The LymphFlow Go Portable Full Leg Compression Device is intended for use in the electromagnetic environment specified below. The customer or user of the LymphFlow Go Portable Full Leg Compression Device should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2:2014+A1:2020 Test Level	Compliance	Manufacturer Guidance
ESD Immunity IEC 61000-4-2	Direct Contact ± 8 kV Air Discharge ± 2 , ± 4 , ± 8 , ± 15 kV	Direct Contact ± 8 kV Air Discharge ± 2 , ± 4 , ± 8 , ± 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered in synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transients/Bursts IEC 61000-4-4	A.C. & DC Power supply line ± 2 kV (100 kHz repetition frequency)	A.C. & DC Power supply line ± 2 kV	Mains power quality should be that of a typical home healthcare or commercial environment.
Surge Immunity IEC 61000-4-5	AC Power Line to line ± 0.5 kV, ± 1 kV	AC Power Line to line ± 0.5 kV, ± 1 kV	Mains power quality should be that of a typical commercial, or home healthcare environment.
Voltage Dips and Interruptions EN 61000-4-11	50 Hz - 0 %UT, 0.5 (at 0° , 45° , 90° , 135° , 180° , 225° , 270° , and 315°), 0 %UT, 1 (at 0°), 70 %UT 25 (at 0°), 0 %UT 250 (at any angle)	50 Hz - 0 %UT, 0.5 (at 0° , 45° , 90° , 135° , 180° , 225° , 270° , and 315°), 0 %UT, 1 (at 0°), 70 %UT 25 (at 0°), 0 %UT 250 (at any angle)	Mains power quality should be that of a typical home healthcare or commercial environment.
Radiated Electromagnetic Field Immunity IEC 61000-4-3	10V/m (r.m.s) 80MHz – 2.7GHz 80% AM at 1kHz, 3s dwell time	10V/m (r.m.s) 80MHz – 2.7GHz 80% AM at 1kHz, 3s dwell time	This device is suitable for the electromagnetic environment of typical home healthcare environment.
Power Frequency Magnetic Field Immunity IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare or commercial environment.
Proximity Magnetic Fields Immunity IEC 61000-4-39	30 kHz (CW, 8 A/m), 134.2 kHz (Pulse modulation 2.1 kHz, 65 A/m), 13.56 MHz (Pulse modulation 50 kHz, 7.5 A/m)	30 kHz (CW, 8 A/m), 134.2 kHz (Pulse modulation 2.1 kHz, 65 A/m), 13.56 MHz (Pulse modulation 50 kHz, 7.5 A/m)	Equipment with high RF emissions should be kept at a distance to reduce the likelihood of interference.
Conducted Disturbance Immunity IEC 61000-4-6	A.C. Power Lines, 3V(r.m.s.) in 0.15MHz – 80MHz 80% AM at 1 kHz; 6V(r.m.s.) in ISM and amateur radio bands	A.C. Power Lines, 3V(r.m.s.) in 0.15MHz – 80MHz 80% AM at 1 kHz; 6V(r.m.s.) in ISM and amateur radio bands	This device is suitable for the electromagnetic environment of typical home healthcare environment.
Immunity to Proximity Fields From RF Wireless Communications Equipment IEC 61000-4-3	See Adjacent Table	Complies	

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Test Level (V/m)
385	380-390	TETRA 400	Pulse Modulation 18Hz	27
450	430-470	GMRS 460, FRS 460	FM±5 kHz deviation 1kHz sine	28
710	704-787	LTE Band 13, 17	Pulse Modulation 217Hz	9
745				
780				
810				
870	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA	Pulse Modulation 18Hz	28
930				
1720				
1845	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE	Pulse Modulation 217Hz	28
1970				
2450	2400-2570	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UTMS	Pulse Modulation 217Hz	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217Hz	28
5500				
5785				

CONTACT INFORMATION

If you have any questions or need assistance in setting up, using or maintaining your device, require service or need to report unexpected operation or events, please contact:

Haddenham Healthcare Ltd. (UK)

4D Drakes Drive,
Long Crendon,
HP18 9BA
United Kingdom
Tel: 01844 208842

Haddenham Healthcare Ltd. (AUS)

Unit 6, 3/4 Anzed Court,
Mulgrave,
VIC 3170
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Tel: 03 9544 5515

Haddenham LLC. (USA)

3300 International Airport Drive,
Suite 1100,
Charlotte, NC
28208
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The Netherlands,
Tel: +31 (0)70 345 8570
Email: EmergoVigilance@ul.com

If you have questions related to your health, please contact your clinician or the healthcare provider. Any serious incident that has occurred in relation to the device should be reported to Haddenham Healthcare Ltd and to the competent authority of the Member State in which the user and/or patient is established.

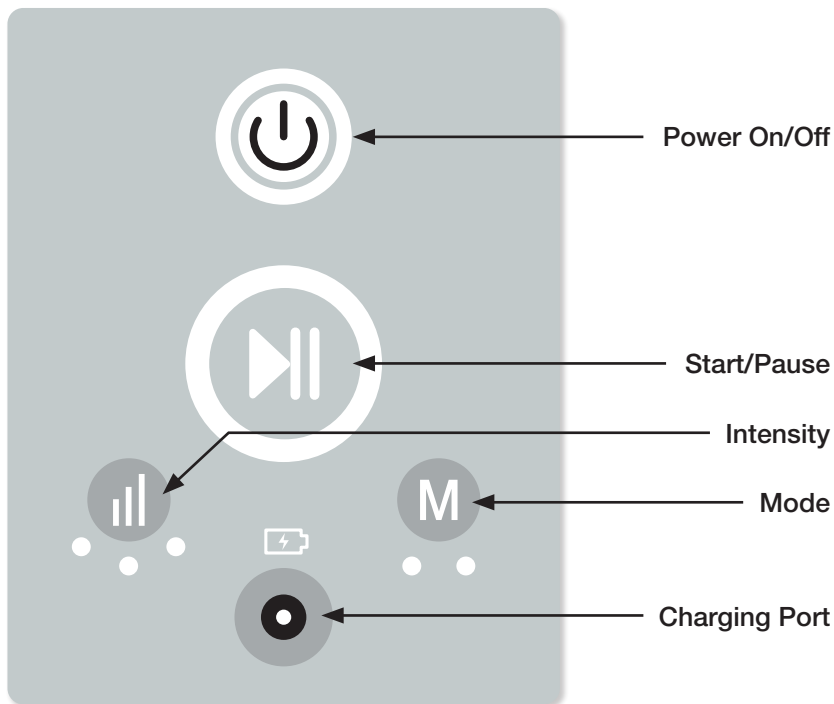
LEGAL MANUFACTURER

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QUICK-START GUIDE



Haddenham Healthcare Ltd.
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