



Lympha Press® Optimal Plus Model 912

Sequential Compression Therapy System
User Manual



C€₀₃₄₄



Table of Contents

Important - Before you Start	iii
Indications	iii
Contraindications	iii
Symbols used in this Manual	iv
Safety Warnings and Precautions	
Labels and Symbols on the Console, Garments, and/or Packaging	
1. Introduction - The Lympha Press [®] Optimal Plus System	
1.1. For Patients - What to Expect from Treatment	
1.2. How it Works	
1.3. Modes of Operation	
1.3.1. The Sequential Mode	
1.3.2. The Wave Mode	
.1.3.3 Pretherapy™	
1.3.4. Post-therapy	
1.4. Calibrated Gradient Pressure	4
2. System Components	5
2.1. Console and Accessories	
2.2. Compression Garments	
3. Setting up the System	8
3.1. Setting up the Console	8
3.2. Preparing for Treatment	8
3.3. Putting on the Compression Garment	9
3.3.1. Arm-Shoulder Garment	9
3.3.2. FL Leg Garment	
3.3.3. ComfySleeve Leg Garment	
3.3.4. Lympha Pants [®]	
3.3.5. Lympha Jacket™	
3.3.6. ComfySleeve™ 1-75	
3.3.7. LymphaPod [®]	
3.4. Connecting the Hose Bundle to the Console	
3.5. Disconnecting the Hose Bundle from the Console	15
4. Operating the Console	16
4.1. The Console Controls	16
4.2. The Console Display Screen	17
4.2.1. Home Screen	
4.2.2. Status Icons	18
4.2.3. Treatment Parameters Screens	
4.2.4. Setting Treatment Parameters	21
5. Setting Treatment Parameters	23
6. Starting the Treatment Session	29
7. Ending the Treatment Session	
7.1. Automatic Deflation of Garment	
7.1. Automatic Denation of Garmellt	,



	7.2.	User-initiated Deflation of Garment	30
8.	Us	ing the Lympha Press [®] Mobile Application	31
	8.1.	Download and Install the Lympha Press® Mobile Application	31
	8.2.	Connect to a Lympha Press® Optimal Plus Console	
	8.3.	Main screen	
	8.3.	1. Menu	38
	8.3.	2. Naming your Console	42
	8.3.	3. Setting Treatment Parameters	42
	8.3.		
	8.3.		
	8.3.	<u> </u>	
	8.3.		
	8.3.	8	
	8.4.	Starting Treatment	
	8.5.	Troubleshooting Wireless Communication Problems	54
9.	Ma	aintenance & Storage	55
	9.1.	Cleaning the Console	55
	9.2.	Cleaning the Compression Garment	55
	9.3.	Storage	56
	9.4.	Travel	56
	9.5.	Disposal	56
	9.6.	Retrieving Operation Log from the Console	
	9.7.	Firmware Upgrade	
4.0		. 9	
		oubleshooting	
		Repairs and Technical Support	
		Authorized Representative in Europe	
	10.3.	Manufacturer	59
	10.4.	Lympha Press [®] Optimal Plus Service Life	59
Αŗ	pen	dix I - Specifications	60
Αr	pen	dix II - EMC Manufacturer's Declarations	61

Copyright © 2024 by Mego Afek AC Ltd. All rights reserved.

No part of this manual may be reproduced or copied in any form by any means including graphic, electronic, or mechanical media, photocopying, typing, or other information retrieval systems, without the written permission of Mego Afek AC Ltd.



Important - Before you Start

- 1. Read this entire manual before setting up and operating the Lympha Press® Optimal Plus system. Keep the manual for future reference.
- 2. Keep all packing materials in case you need to transport the console.

 The packing materials have been designed to protect the system from damage during shipment.

Indications

Lympha Press® Optimal Plus is intended for use by medical professionals, and patients who are under medical supervision, in treating many conditions such as:

- Primary lymphedema
- Secondary lymphedema
- Chronic venous insufficiency
- Chronic edema
- Venous stasis ulcers
- Post mastectomy edema
- Traumatic edema
- Lipedema

The device is intended for hospital, home, and clinic use



Note:

Lympha Press® Optimal Plus may be operated by patients or their caregivers. If a patient is incapable of understanding the instructions, operating the system, or monitoring treatment, a caregiver must apply and supervise the treatment.

Contraindications

Lympha Press® Optimal Plus system should not be used in the presence of one or more of the following conditions:

- Known or suspected deep vein thrombosis (DVT) or pulmonary embolism
- During the inflammatory phlebitis process
- Active skin or limb infection/inflammatory disease (acute cellulitis, other uncontrolled skin or untreated inflammatory skin disease)
- Decompensated cardiac failure (acute pulmonary edema, decompensated heart failure)
- Severe arteriosclerosis or other ischemic vascular disease
- Any circumstance where increased venous and lymphatic return is undesirable

Due to movement of fluids in the body when using the system, exercise caution when using on patients with heart disease. High pressure is not recommended for patients who have peripheral occlusion disease.

The abdominal area should not be treated during pregnancy.



Caution:

This device is for sale and use by, or on the order of, a licensed medical practitioner.

L98008C4-P iii



Symbols used in this Manual

Symbol	Description
	Note : Describes how the system functions or provides a note on how best to use it.
Δ	Caution : Refers to the safe operation of the system and provides cautions where the possibility of loss of data or damage to the equipment exists.
	Warning : Indicates a situation in which the operator or the patient may be in danger of injury or death.

Safety Warnings and Precautions



Note:

This device complies with safety performance standards which applies to electro-medical devices:

Electrical safety: IEC 60601-1 Ed. 3.2

Electromagnetic compatibility: IEC 60601-1-2 Ed. 4.1

Home use devices: IEC 60601-1-11 Ed. 2.1



Warning: Electric Shock Hazard

To prevent electric shock, do not open the console or the DC power adapter. Do not attempt to service the console yourself. All maintenance tasks should be performed only by trained and authorized service personnel. Service by unauthorized personnel shall void any warranty.



Warning:

Do not immerse in liquid or allow liquid to enter any part of the Lympha Press® Optimal Plus console.

Do not use Lympha Press® Optimal Plus console, or any parts or accessories thereof, if they have become wet or have been exposed to liquids.



Warning:

Do not use the Lympha Press® Optimal Plus if you notice a change in operating system performance, the system is damaged, or any of its components are worn or frayed.



Warning:

Do not attempt to clean the console while it is operating. Unplug from mains power before cleaning.



Caution:

To prevent any damage to the Lympha Press® Optimal Plus system, keep it away from dust, lint, and dirt. Keep away from sources of heat or moisture. Keep away from pets.



Warning:

Do not modify any part of the Lympha Press® Optimal Plus system.





Warning:

To prevent any damage to equipment, use only accessories, detachable parts and materials described in this user manual.



Caution:

Do not use the Lympha Press® Optimal Plus system beyond the specified temperature range: 10 to 30°C (50 to 86°F).



Caution:

Do not use the Lympha Press® Optimal Plus system beyond the specified humidity range: 30%-85%, non-condensing



Caution:

Do not store or transport the Lympha Press® Optimal Plus system beyond the specified temperature range (see Section 9.3 - Storage).



Caution:

Use the Lympha Press® Optimal Plus system up to 3000m above mean sea level.



Caution:

While in use, place the console on a horizontal firm surface only. Do not place the console on bed, blanket, mattress, pillow, or soft furniture. Do not cover the console.



Caution:

Disconnect the console from electrical outlet before cleaning. Let it dry completely before reconnecting it to the electrical outlet.



Note:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



Labels and Symbols on the Console, Garments, and/or Packaging

Label	Description	Location
MD	Indicates the item is a medical device	On console package, and garment bag and package
IP21	Degree of protection against ingress of water	On console base
	Read instructions before use	On console base
<u></u>	Indicates the need for the user to consult instructions before use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself	On console base
[i]	Consult instructions before use	On garment labels
†	Level of protection type BF applied part	On console base
	Double insulation	On console base
===	Direct current	On console base
MR	MR Unsafe - keep away from Magnetic Resonance Imaging (MRI) equipment	On console base
Mego Afek AC Ltd. Kibbutz Afek 3004200, Israel	Manufacturer's name and address	On console base and console packaging label On garment and all garments packaging labels
EC REP	Authorized representative established within the Union who has received and accepted a written mandate from Mego Afek AC Ltd., to act on the Mego Afek AC Ltd.'s behalf in relation to specified tasks with regard to the latter's obligations under EU 2017/745 Medical Device Regulation	On Console package, and garment bag and package
YYYY-MM-DD IL REF LXXXXXXX	Date and Country of Manufacture and Reference of Console Part Number	On console base
UDI	Indicates a carrier that contains Unique Device Identifier information	On Console package, and garment bag and package

vi L98008C4-P



Label	Description	Location
(01) 0 7290105 87909 7 (11) 200325 (21) 999999	Unique Device Identification (UDI)	On console base and package, and package and package
	Separate collection for waste electrical and electronic equipment Note: For more information about disposal of equipment, its parts and accessories, contact your local distributor.	On console base
# 912 SN XXXXXX	Serial number of the console	On console base
C E 0344	CE label showing compliance with European Directive 2007/47/EC amending Directive 93/42/EEC, concerning medical devices.	On console base
Rx Only	For use by or on the order of a licensed medical practitioner	On console base and package, and garment bag and package
Contains Transmitter Module FCC ID: ASTBM70ABCDEFGH. This device compiles with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.	FCC CFR 47 Telecommunications, Part 15 statement	On console base
Scan and Download the Lympha Priss* Mobile Application Lympha Project App Store	Download LP Mobile App. QR label	On console top
	Fragile, handle with care	On package
	Keep dry	On package
<u>††</u>	This side Up	On package
类	Keep away from sunlight	On package
93%rH %	Transportation & storage humidity limitation	On package
10 <u>60h</u> Pa	Transportation & storage atmospheric pressure limitation	On package

L98008C4-P vii



Label	Description	Location
-20°C	Transportation & storage temperature limitation	On package
	"ON" (power)	On power switch
	"OFF" (power)	On power switch
***	Do Not Wash	On garment tag
\otimes	Do Not Dry-clean	On garment tag
	Do Not Tumble Dry	On garment tag
*	Do Not Bleach	On garment tag
\geq	Do Not Iron	On garment tag

viii L98008C4-P



Introduction - The Lympha Press® Optimal Plus System

The Lympha Press® Optimal Plus system is a multi-zone calibrated gradient pneumatic compression therapy system for treatment of lymphedema, chronic venous insufficiency, venous stasis ulcers and lipedema.

The Lympha Press® Optimal Plus system consists of:

- The console (sometimes called "compressor" or "pump") supplies air at regulated pressures to a compression garment that is worn over the area to be treated.
- Hoses transfer the air from the console to each of the chambers in the compression garment.
- The compression garment is fastened around the area to be treated.
 Each garment contains overlapping air chambers. These air chambers are filled with air from the console in sequence, applying a compressive massage. Once the entire area has been compressed, the console releases the pressure, and there is a brief pause. Then the process starts over again and is repeated until the treatment session is complete.

The compress-and-release massage action stimulates lymphatic vessels in the treated area to take up and transport lymphatic fluid. The directional massage action encourages transport of the fluid towards the torso for collection by healthy lymphatics and return to the blood circulation.

The directional compressive massage also helps reduce venous edema and stimulates venous return.

1.1. For Patients - What to Expect from Treatment

Lympha Press® systems have been clinically proven to stimulate the lymphatic system and to increase lymph fluid uptake in lymphedema affected extremities. Studies have shown that, statistically over groups of patients, Lympha Press® treatment reduces edema volume and reduces discomfort/pain. Individual results may vary, and you may need to use additional treatments as part of a home treatment program. An example of adjunctive treatments are compression stockings or garments, which your practitioner may have you wear during waking hours in between Lympha Press® treatment sessions.

Treatment settings are to be prescribed by your licensed medical practitioner. Changing treatment settings may cause inadequate therapy, or could cause discomfort that could affect your ability to tolerate the therapy. Discontinuing treatment or using it less than prescribed could cause your symptoms to return. Adherence to the treatment program can help you manage your condition and improve your quality of life.

Adverse effects associated with pneumatic compression therapy include pain/discomfort which may be alleviated by reducing the pressure or altering other treatment settings. Discontinue treatment and consult your licensed medical practitioner if there is onset of pain or numbness during treatment, or if there is pain, bruising, or irritation after treatment.

If you have questions about your medical condition or your home treatment program, please consult your medical practitioner.

1.2. How it Works

The Lympha Press® Optimal Plus console supplies air at regulated pressure to the compression garment.

The compression garment is fastened around the area to be treated. Compression is applied sequentially, alternating with deflation and intermission to the treated area.

1.3. Modes of Operation

Lympha Press® Optimal Plus has four different treatment modes:

Sequential

Wave

Pretherapy™

Post-therapy

These modes are described in the following sections.





Note:

Your licensed medical practitioner selects the appropriate treatment mode for your condition. Treatment pressure, time, and frequency must be prescribed by your licensed medical practitioner.



Figure 1 - The Lympha Press® Optimal Plus Model 912 Console

1.3.1. The Sequential Mode

This mode is generally used as the main treatment cycle, either by itself or after Pretherapy™. The sequential mode applies a directional massage that starts at the base of the treated limb (the "distal" area), over the foot or hand, and progresses upwards towards the torso until the entire area is compressed (see Figure 2).

This gradual, directional compression assists the flow of lymphatic fluid out of the swollen area and towards the lymphatic collectors in the torso. It prevents reflux ("wrong-way flow") of lymphatic fluid that could occur if distal compression is not maintained. When the compression wave reaches the top of the garment, the pressure is released for a brief intermission, allowing for lymphatic and venous refill.

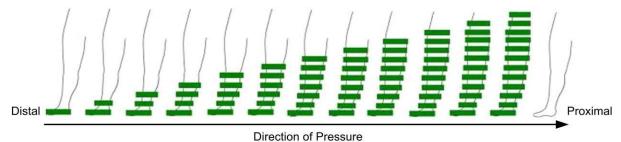


Figure 2 - Sequential Mode



1.3.2. The Wave Mode

This mode is an alternative to the Sequential mode and is also used as a main treatment cycle, on its own, after Pretherapy $^{\text{TM}}$, or during the last two minutes of Post-therapy. The Wave mode starts at the base of the limb, over the foot or hand. As the chamber at the front of the wave inflates, the chamber at the back of the wave starts to deflate, so at any one time a small area is being compressed (see Figure 3).

The inflated chamber in the middle prevents reflux (wrong way flow) as the wave moves up the limb. Because this mode releases the air in the distal chambers as it moves up the limb, it may be selected for patients with distal discomfort.

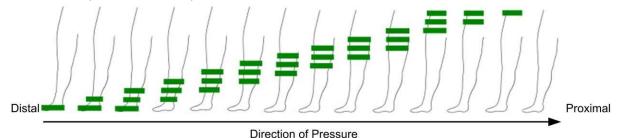


Figure 3 - Wave Mode

1.3.3. Pretherapy™



Note:

This Mode is not applicable for LymphaPOD garments

Pretherapy can be added to the beginning of the Sequential or Wave cycles. Pretherapy treats the proximal areas first, decongesting them so that they can receive the lymph fluid that is mobilized during the Sequential or Wave cycles. A specific pattern is applied, and the duration varies according to garment size, lasting between 5-12 minutes, with preselected pressure of 30 mmHg.

Figure 4 shows how the cycle starts by massaging the top of the leg/abdomen. The massage then continues from a lower point on the limb and progresses proximally. This pattern continues until the entire area has been treated.

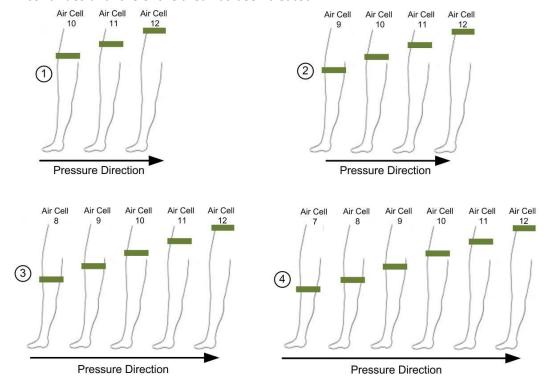


Figure 4 - Pretherapy™ Mode





Note:

The Pretherapy mode is a "priming" cycle that prepares the area for further treatment, and never used by itself. It is always followed by either the **Sequential** or **Wave** modes.

1.3.4. Post-therapy



Note:

This Mode is not applicable for LymphaPOD garments

You can add Post-therapy after the Sequential or Wave cycles. Post-therapy provides "focused" treatment for the proximal, medial, or distal areas according to user selection, and then follows with Wave mode over the entire garment, according to the principles of manual lymph drainage.

Post-therapy duration is 5 minutes, at the zone pressure that has been selected for the Sequential or Wave cycles.

1.4. Calibrated Gradient Pressure

Pressure in the Lympha Press® Optimal Plus can be selected individually on the console for four zones on the garment, or for each chamber individually, according to the patient's licensed medical practitioner's instructions. The system prevents setting a reverse gradient (in which the pressure is higher proximally), as a reverse gradient could cause wrong way flow (reflux).

The minimum pressure that can be set proximally (at chamber 12) is 20 mmHg.

The maximum pressure that can be set distally (at chamber 1) is 90 mmHg.



Note:

Pressure can be selected on the console for four zones of pressure, or for each chamber individually, to accommodate special circumstances. The system does not allow setting a reverse gradient.



2. System Components

The system consists of the console, compression garment(s), and hoses that deliver the air from the console to the garment.

2.1. Console and Accessories

Table 1 - Console and Accessories

Component	Illustration
The Console supplies air to the compression garments. There are two air outlets on the front of the unit.	typeshe Pear Cyclescalina Copyright Copyri
12-prong Plug : when using only one garment or hose, you must seal the second air outlet located on the front of the console to keep air from escaping. Use this 12-prong Plug to seal the unused outlet on the front of the console.	
DC Power Adapter The DC power adapter receives 100-240 VAC, 50-60 Hz power and supplies 12 VDC 7A to the console.	
Caution: For indoor use only. Use only the DC power adapter (UE Electronics) provided with the Lympha Press® Optimal Plus console.	



2.2. Compression Garments

Your local distributor will select the appropriate size and type of compression garment for you, according to your licensed medical practitioner's instructions.

If any standard garment size does not fit you, your local distributor can consult with Mego Afek AC Ltd. for solution.

Some garments have pressure limitations, which are indicated in Table 2 below.



Caution:

Do not exceed the pressure limitations listed for your garment in Table 2 below. If your licensed medical practitioner prescribes pressures higher than the limits for your garment, consult your local distributor.

Table 2 - Lympha Press® Garments

Garment Area Treated Pressure Limit Figure				
Arm-Shoulder	Arm	According to licensed medical practitioner's orders	riguie	
Garment	Arm	Can be used at full range of pressure		
FL Garment	Leg	According to licensed medical practitioner's orders Can be used at full range of pressure		
ComfySleeve	Leg	According to licensed medical practitioner's orders Can be used at full range of pressure		
LymphaPod®	Legs, abdomen, groin	According to licensed medical practitioner's orders Legs - can be used at full range of pressure Abdomen - do not exceed 40 mmHg	THE RESERVE OF THE PARTY OF THE	



Garment	Area Treated	Pressure Limit	Figure
Lympha Pants®	Both legs, groin, hips, buttocks, and abdomen	According to licensed medical practitioner's orders Legs can be used at full range of pressure Abdomen - do not exceed 40 mmHg	Sompho peaks Sompho peaks
Lympha Jacket™	Both arms, torso, chest, back, shoulders, abdomen	According to licensed medical practitioner's orders Arms - can be used at full range of pressure Abdomen - do not exceed 40 mmHg	
ComfySleeve™ 1-75	Arm, torso, chest, back, shoulders, abdomen	According to licensed medical practitioner's orders Arm - can be used at full range of pressure Abdomen - do not exceed 40 mmHg	Orania Maria
Expander Inserts	Used with all garments, to increase circumference. Various types are available		



3. Setting up the System

Before using the Lympha Press® Optimal Plus system for the first time, arrange the treatment area so that the patient can reach the console at any time during treatment.



Caution

When the system has been stored in extreme temperature conditions of -20°C (-4°F) or 70°C (158°F) between uses, wait for two (2) hours before using the system.

3.1. Setting up the Console

- 1. Place the console on a flat stable surface from where it would not slip or fall. The front of the console must be at least six inches from the edge of the surface.
- 2. Position the console so that the patient can easily reach the controls during treatment. Make sure is in the O position (see Figure 11).
- 3. Insert the DC power adapter cable into the DC adapter socket on the console (see **Figure 11**), and then insert the power cord into an appropriate 100-240 Volt wall outlet.



Note:

The console is "multi-voltage" and can be used for travel.

An appropriate socket adapter must be used in countries with incompatible wall outlets.



Note:

The console does not include backup battery, thus cannot be used when unplugged from Mains power.

3.2. Preparing for Treatment

Always wear clothing under the compression garments, to prevent irritation and for hygienic reasons. Wear clean cotton socks and light cotton unrestrictive pants (such as sweatpants) under the leg garments. Wear a long-garment cotton T-shirt under the arm garments. Stockinette may also be used. Clothing worn underneath the compression garment should be free of buttons, zippers and decorations that may rub against the skin. Remove any jewelry or wristwatches before putting on garments that cover the arm.

Treatment Positions

Ask your licensed medical practitioner for specific recommendations on treatment position. Always make sure the console and hoses can be reached easily from the treatment position.

Use leg garments while sitting or lying down. When using leg garments while sitting, it is preferable to elevate the feet by supporting them on an ottoman or in a recliner.

Use Pants-type garments lying down face up, on a bed or couch.

Using these garments in a seated position causes folds in the garment that can block air flow and disrupt the massage cycle.

Use Arm and jacket-type garments (Lympha Jacket, ComfySleeve 1-75) in a seated position or lying comfortably on a bed or couch, with the arm elevated or at horizontal.



3.3. Putting on the Compression Garment

Your local distributor will select a garment for you according to your measurements and licensed medical practitioner's instructions. The garment should not fit tightly.

Find your garment on the list below and follow the instructions.

If the garment you receive is supplied with a separate hose, follow instructions from your local distributor to assemble the hoses to the garment.



Caution:

Do not inflate the garment without wearing it over the intended body area. Do not inflate the garment "on empty" or with open zippers. Doing so can damage the garment.

3.3.1. Arm-Shoulder Garment

The garment can be used on the right or the left arm.

- A. Close the garment zipper, using the inner zipper or outer zipper. The garment should not fit tightly around the arm at any point.
- B. The padded strap has two plastic clips (left and right). The strap through the right clip has a pull loop.
- C. Insert the left clip into the left buckle that will be located on the user's upper back.
- D. Open the garment zipper over the hand. Extend the padded strap.
- E. Insert the arm into the garment and pull the garment over the shoulder. Ensure the garment zipper is closed at the armpit.
- F. Pass the padded strap under the untreated arm, and then Insert the right clip into the buckle at the chest.
- G. Tighten the strap to comfort and position the padding under the untreated arm to prevent chafing.
- H. Close the zipper over the hand.
- I. When treatment is complete, open the garment zipper over the hand, disconnect the clip from the buckle at the chest, and remove the garment.

3.3.2. FL Leg Garment

FL Leg garments fasten with hook-and-loop fasteners that can be adjusted for individual fit.

- A. Insert the foot into the boot, pulling up on the garment to straighten it to its full length.
- B. Close the fasteners around the leg, starting from the foot.
 The fit should be snug but not tight. If the garment is too small, an expander can be added to increase the circumference.

3.3.3. ComfySleeve Leg Garment

- A. Open the zipper all the way. Insert your foot into the boot, and then pull up on the garment to straighten it out to its full length.
- B. Zip the garment closed. If the circumference is too small, an expander can be added.



3.3.4. Lympha Pants®

Lympha Pants[®] is available in two configurations:

Hose bundle inlets on garment sides (hips) - see Figure 5.

Hose bundle inlets on garment lower areas (heels) - see Figure 6.

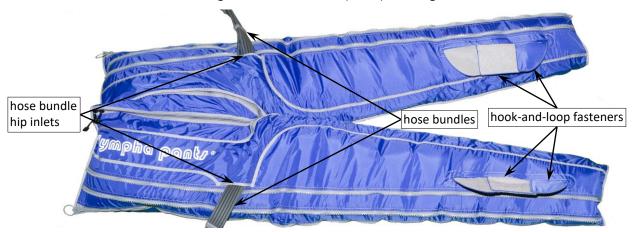


Figure 5 - Lympha Pants® Hose Bundle Hip Inlets Configuration



Figure 6 - Lympha Pants® Hose Bundle Heel Inlets Configuration



Caution:

Do not inflate the garment without wearing it over the intended body area.

Do not inflate the garment "on empty" or with open zippers.

Doing so can damage the garment.

- A. Use Lympha Pants® in a supine position (lying face up on a bed or couch).
- B. Wear clean cotton socks and light cotton unrestrictive pants (such as sweatpants) under Lympha Pants® to absorb perspiration, prevent irritation, and keep Lympha Pants® clean. Stockinette may also be used. Clothing worn underneath Lympha Pants® should be free of buttons, zippers and decorations that may rub against the skin.
- C. Lay Lympha Pants® flat on a bed or couch, with logo side up.
- D. Open the zippers on both sides halfway. Put on the pants and close the zippers all the way to the top. Lympha Pants® should not fit tightly at any point. Expander inserts are available to increase circumference.



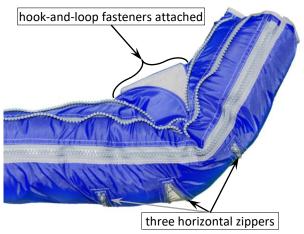


Figure 7 - Forming a Customized "Boot"

Using the Hook-and-Loop Fasteners

Use the hook-and-loop fasteners to form a customized "boot" for your foot (see Figure 7). Lympha Pants® has three horizontal zippers at the bottom, on the rear side (see Figure 7).

- E. After putting on Lympha Pants®, open the horizontal zipper nearest your heel.
- F. To initially adjust the boot angle, bend the boot at the heel, and then attach the lower hook-and-loop fasteners to the upper hook-and-loop fasteners (see Figure 7).
- G. After a few inflation cycles, adjust the boots angle by readjusting the hook-and-loop fasteners.



Note:

- If a caregiver assists, the caregiver can readjust the boot angle using the hook-and-loop fasteners.
- If you are on your own, pause the treatment, allow the pants to deflate, and then readjust the boot angle using the hook-and-loop fasteners.
- H. After use, leave the hook-and-loop fasteners attached for next treatment.



Caution:

Do not use pressure over 40 mmHg over the abdominal area. See your system user manual for pressure setting instructions.

- Do not use Lympha Pants® if you are pregnant.
- Do not use while standing or sitting. Use in a reclined or supine (lying face up) position.
- Do not use the hook-and-loop fasteners or other features other than described above. Excessive force and misuse shall void the manufacturer's warranty.



3.3.5. Lympha Jacket™

Lympha Jacket is a unique treatment system for the entire upper body.

Lympha Jacket covers both arms, thus inhibits your mobility.

Follow these instructions:

- A. Make sure you are sitting within easy reach of the console controls.
- B. Open the jacket at the front zipper and put it on.
- C. Open one arm zipper just above the wrist to free one hand to operate the console. If you cannot operate the console, you need someone with you during treatment to help you turn o to the O position if necessary.
- D. Close the front zipper. Adjust the front fasteners for a comfortably snug fit across your chest and abdomen. If the jacket is too small, add expanders at the arm or at the back zipper.



Caution:

If you cannot operate the console yourself, you need someone with you during treatment to help you turn to the **O** position if necessary.



Caution:

Using pressure over 40 mmHg on the abdominal area is not recommended. Do not treat the abdominal area during pregnancy.

3.3.6. ComfySleeve™ 1-75

Use ComfySleeve 1-75 lying down or in a seated position.

During treatment, position the arm at approximately 90 degrees (straight out) from the torso, allowing full contact of the garment with the armpit and shoulder.

Make sure the console is located where you can reach it easily during treatment.

- A. Lay the garment on a flat surface.
- B. Open the zipper at the front side. Then open the zipper at the wrist of the garment.
- C. Loosen the side straps until reaching almost their full length to allow grasping them after you put on the garment.
- D. Put on the garment, as you would a jacket. Make sure the armpit chamber is tucked into the arm garment, and not folded into the torso.
- Pull the inner padded section of the side fastener around your torso and lightly fasten the hook-and-loop tabs at the top and bottom.
 This allows you to let go of the garment and grasp the side fastener.
- F. Find the zipper of the side fastener (attached to the straps), and zip the garment closed around your torso. Zip the wrist zipper closed.
- G. Tighten the straps at the side for a comfortable fit. It does not need to be fastened tightly; you may feel the massage better if the fit is not too snug. If you experience discomfort during treatment, adjust the buckles at the side to loosen the garment.
- H. Fasteners can be changed to increase or decrease the circumference. When changing fasteners, note that the fasteners are sided LEFT and RIGHT. Select the LEFT fastener when treating the LEFT arm. Select the RIGHT fastener when treating the RIGHT arm.



Caution:

Using pressure over 40 mmHg on the abdominal area is not recommended. Do not treat the abdominal area during pregnancy.



3.3.7. LymphaPod®



Note:

LymphaPod® is a unique garment that treats the entire lower body. Follow these important instructions for use.



Note:

Pretherapy and Post-therapy modes are not applicable for LymphaPOD garments When garment type is set to LymphPOD, Pretherapy and Pos-Therapy modes are Unavailable.



Caution:

Do not treat the abdominal area during pregnancy.



Caution:

Do not use pressures exceeding 40 mmHg over the abdomen. Determine where the patient's abdomen is located inside the garment before setting pressures in the chambers over the abdomen to ensure these maximum settings are not exceeded.

Using Pretherapy mode is not recommended.

Treatment must be conducted with the patient lying face up on a suitably sized bed. Provide pillows to support the patient's head and shoulders comfortably during treatment.

If the patient cannot independently put on, remove the LymphaPod® garment, or cannot independently rise to a standing position from the treatment position at the end of the treatment session, or cannot independently access and operate the console, a caregiver must assist the patient during treatment and must assist in putting on, removing, and exiting the garment.



Figure 8 - LymphaPod® Garment Front View



- A. Spread the LymphaPod® garment on the bed. Place it face up (with printed **LymphaPod** logo on front).
- B. If the patient has very large hips or buttocks, open the adjustment zippers in the back of the garment.
- C. FOR FIRST USE: If patient has a crotch-to-floor inseam of less than 65 cm, or needs more space to accommodate a pendulous abdomen, you may remove the top two chambers from the inner ridge between the legs and cap the four open air inlets with the cushioned plugs provided (located at the storage compartment at the foot of the garment). Make sure the plugs are inserted firmly to prevent air leakage. Contact your distributor for details on how to perform this adjustment.
- D. Straps can be used to attach the garment to the bed to prevent it from slipping down during donning. If you wish to use these, fasten straps through loops at top of the garment and around the treatment bed.
- E. Open the LymphaPod® completely from both sides and fold over the top down to the crotch to expose the inner surface. Fold up the sides along the center ridge, so that the patient can put their legs into the garment. The patient should be lying comfortably on the back, with the center ridge located between the legs.
- F. The patient should position him/herself so that the heels of the feet are on the printed **HEEL** mark at the base of the garment. However, if the patient is short in stature, the patient should not attempt to reach the **HEEL** mark. The garment should not cover the chest and should not impede arm movements.



Note:

Do not get too far inside the garment. The garment should not cover the chest and should not impede arm movements. Tall or medium height patients should locate their heels at the printed **HEEL** mark at the base of the garment. Shorter patients will not reach this point with their feet.

- G. Open or close front adjustment zippers if needed to increase or decrease circumference of the garment. If the middle front zipper is closed, pull the strap closed to support the zipper.
- H. Close the white side zippers. These must be closed completely.
- I. The fit should be comfortably loose. If the garment is too tight, expanders may be added to increase garment circumference. Contact your distributor.
- J. If treatment over the abdomen is uncomfortable, the hoses leading to the top chambers may be disconnected and capped with plugs provided with the garment. The hoses may be accessed through the side zipper compartment.
- K. Connect the hoses to the console and start treatment. Follow the instructions in Chapter 4 below for operating the console. Initial fill may take three to five minutes.
- L. At the end of treatment, wait for the garment to finish deflating before opening the zippers and exiting the garment.



Note:

Wait for the garment to deflate completely before exiting the garment. Allowing the garment to deflate makes it easier to get out of the garment. It also makes it easy to fold and store.



3.4. Connecting the Hose Bundle to the Console

- 1. Locate the big gray connector at the other end of the hose bundle. All twelve hoses join at this gray connector. Note the snap tooth on the top of the connector.
 - Also, note the two air outlets on the front of the console. You can insert the connector into either outlet.
- 2. Insert the hose bundle connector into one of the two air outlets at the front of the console, making sure the snap tooth is facing **UP**.
 - The hose bundle connector "clicks" into place. If you do not hear a click, move it gently to make sure it is secure.



Note:

When only one air outlet is in use, insert the 12-prong Plug to seal the second, unused air outlet. If you do not plug this outlet, the console shall not operate!

3.5. Disconnecting the Hose Bundle from the Console

To disconnect the hose bundle from the console, push down the snap tooth to release it and gently pull out the bundle from the console (see Figure 9).

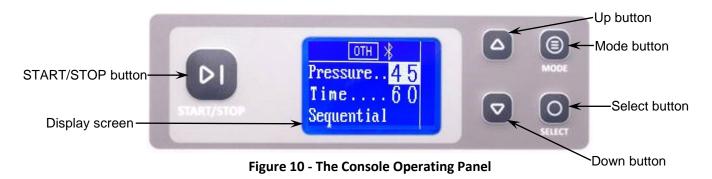


Figure 9 - Disconnecting the Hose Bundle



4. Operating the Console

Following is a description of the console operating panel. Read this section before operating the console for the first time.



4.1. The Console Controls

Table 3 - Console Controls

Control	Function
	Mode button: Used for selecting treatment pressure, treatment time, cycle mode, pause time, and hold time.
	Up & Down buttons: Used for adjusting treatment pressure, treatment time, cycle mode, pause time, and hold time.
DI	START/STOP button: Used for starting or stopping treatment.
0	Select button: Used for confirming selection or changing settings.
0 -	Power Switch: Used for console powerup (see Figure 11)
	DC Adapter Socket: Used for connecting the DC power adapter (see Figure 11)
	USB Socket: Used for connecting the console to PC and connecting USB drive to console (see Figure 11)





Figure 11 - Console USB Socket, Power Switch & DC Adapter Socket

4.2. The Console Display Screen

4.2.1. Home Screen

Table 4 - Home and Treatment Screen

Displayed Screen	Function
	 Icon bar (Top horizontal field) displays icons which reflect status of communication (Bluetooth), selected garment and treatment status (Run, Pause, Lock), Error, Disabled cells
► OTH ¾\$ Pressure45	 Pressure – Displays pressure setting at the most distal pressure zone. Pressure may be increased or decreased from the HOME screen (see instructions below).
Time15	 Time - Displays treatment time setting, which decreases during treatment.
1	 Sequential - Displays the selected cycle mode.
	 Progress bars (in vertical field at the right) - Display the progress of inflation only when treatment is in progress (each bar represents a chamber in the garment).



4.2.2. Status Icons

The status icons are displayed at the top of the screen.

Table 5 - Status Icons

Displayed Icon	Function
	General Warning (displayed when the console detects internal problem)
	Air Leak (displayed when the console detects an air leak)
)	Treatment in progress
a	Lock (displayed when Lock ON option selected)
*	Bluetooth connected from smartphone (console selected by Mobile App)
Φŧ	Bluetooth connection between console and smartphone approved
Φ÷	Note: When neither Bluetooth icon is displayed, a Bluetooth error occurred.
\times	displayed (blinking) continuously during treatment when chamber(s) bypassed
ARM	Arm garment is used
175	Comfy 1-75 garment is used
LEG	Comfy Sleeve – Leg garment is used
FL	FL garment is used
JACK	Jacket garment is used
PANT	Pants garment is used
POD	Pod garment is used
ОТН	Other garment is used



4.2.3. Treatment Parameters Screens

Table 6 - Treatment Parameters Screens

Displayed Screen	Function
Optimal Plus Model 912 Version 2.2.1	Welcome screen: Displaying the installed Firmware revision. Displayed for 2 seconds when turning or to the I position.
OTH \$ Pressure45 Time60 Sequential	Pressure setting. The selected pressure is highlighted.
LEG ≯ Pressure45 Time60 Sequential	Time setting. The selected time is highlighted.
3. Cycle Mode settings.	User can select a cycle mode from the following options:
ARM ∦ Pressure46 Time60 Sequential	■ Sequential
ARM ∦ Pressure4 6 Time6 0 PRE+Sequential	■ Pretherapy + Sequential
ARM ∦ Pressure4 6 Time6 0 Sequential+POS	■ Sequential + Post-therapy
ARM	■ Pretherapy + Sequential + Post-therapy
Pressure46 Time60 Mave	■ Wave



Displayed Screen	Function
Pressure46 Time60 PRE+Wave	■ Pretherapy + Wave
ARM ∦ Pressure46 Time60 Wave+POST	■ Wave + Post-therapy
Pressure46 Time60 PRE+Wave+POST	■ Pretherapy + Wave + Post-therapy



4.2.4. Setting Treatment Parameters

M. Press (a) continuously, until the following screen appears.

Settings To scroll, press MODE

N. Press (a)

Settings To return, press START

O. Press (a)

The Advanced Settings Screens appear.

Table 7 - Advanced Settings Screens

Displayed Screen	Function	
Set Pressure Select Option By Zone By Chamber	Set Pressure screen (see the following two screens) By Zone (4 zones) By Chamber (12 chambers)	
Set Pressure Distal Proximal 50 57 54 47 By Zone	Set Pressure By Zone screen Setting pressure in each zone according to the gradient settings.	
Set Pressure 45 44 43 42 41 40 39 38 37 36 35 34 By Chamber	Set Pressure By Chamber screen Setting pressure in each chamber according to the gradient settings.	
Set PreTherapy Pressure	Pretherapy Pressure - This display enables selecting Pretherapy cycle pressure of 30 or 40 mmHg (displayed only when a pretherapy cycle mode combination is selected)	
Set PreTherapy Duration SHORT	Pretherapy Duration - This display enables selection of one of the following options: SHORT: One Pretherapy cycle LONG: Two Pretherapy cycles (displayed only when a pretherapy cycle mode combination is selected)	



Displayed Screen	Function
Set PostTherapy Post Focus Area DISTAL	Post Focus Area - This display enables selection of the area to receive focused treatment during the Post-therapy cycle. You can select DISTAL, MEDIAL, or PROXIMAL areas for Post-therapy focus. (displayed only when a post-therapy cycle combination is selected)
Set Pause Time 15 Sec.	Pause Time - This display enables selection of Pause Time.
Set Hold Time 4 Sec.	Hold Time - This display enables selection of Hold Time.
Set Lock OFF	Lock - This display enables locking / unlocking the console settings, to prevent tampering.
Set Garment Arm & Shoulder	Garment Selection - This display enables selection of Garment. You can select: Arm & Shoulder, Comfy Sleeve 1-75, Comfy Sleeve Leg, FL, Lympha Jacket, Lympha Pod, Lympha Pants and Others.
Deflation Mode Automatic Deflation ON	Enable Automatic Deflation - allows deflating and quick emptying of the connected garment. Default: ON
Device Defaults Reset to Default Cancel	Reset to Default - This display enables resetting the console to factory default settings. Default: Cancel If user selects OK, and then presses the confirm screen is displayed.
Confirm Reset Reset to Default Cancel	Confirm Reset to Default - This display enables confirming reset to factory default settings. If user selects OK, the console resets to factory default settings.
Set Time 17 : 10 30 / 01 / 2024	Set Time - This display allows user to set time and date Time format: hh: mm Date format: dd / mm / yyyyy Use or to navigate, to enable edit and confirm, to exit.

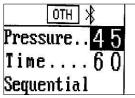


5. Setting Treatment Parameters

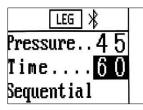


Note:

Select treatment parameters according to your licensed medical practitioner's instructions.



- 1. To set the **Pressure**, press \triangle or ∇ .
- 2. Press to select **Time**.



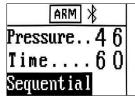
3. To set the **Time**, press \triangle or ∇



Note:

The minimum treatment time setting is 15 minutes. The maximum treatment time setting is 90 minutes. Add-ons are included in the total treatment time. When using Pretherapy or Post-therapy Add-ons, select a treatment time of at least 30 minutes duration.

4. Press to select the **Cycle Mode**.



5. To set the **Cycle Mode**, press \bigcirc or \bigcirc .



Note:

You can select one of the following Cycle Mode combinations:

- Sequential
- Pretherapy + Sequential
- Sequential + Post-therapy
- Pretherapy + Sequential + Post-therapy
- Wave
- Pretherapy + Wave
- Wave + Post-therapy
- Pretherapy + Wave + Post-therapy
- 6. Press continuously, until the following screen appears.



7. Press (a).



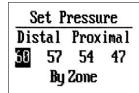
Settings To return, press START

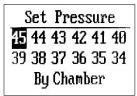
8. Press

The **Set Pressure** screen is displayed. The currently selected option is highlighted.



- 9. To select an option, press \triangle or ∇
- 10. To confirm **By Zone** or **By Chamber** press O
- 11. Depending on your selection, either the **Set Pressure By Zone** screen or the **Set Pressure By Chamber** screen is displayed with zone/chamber #1 highlighted (the most distal zone/chamber over the hand or foot):





To select a zone/chamber pressure, press (Δ) or (∇) .

- 12. Press **O**.
- 13. The highlighted zone/chamber #1 blinks.
- 14. To change zone/chamber #1 pressure, press \triangle or ∇
- 15. To confirm the change, press O.
- 16. To proceed to the next zone/chamber pressure, press ♠ or ♥.
- 17. To proceed to next setting, press (3).
- 18. Repeat Step 0 through Step 15 until you have selected the pressure in each zone/chamber.



Note:

The minimum pressure setting is 20 mmHg (proximal). The maximum pressure setting is 90 mmHg (distal).



Note:

The console does not allow setting a reverse gradient of pressure (higher proximal pressure). Decreasing distal pressure lowers the pressure in the more proximal zones.

To increase proximal pressures, you may need to increase the pressure in the more distal zones first, verifying that proximal chamber pressures do not exceed distal chamber pressures.



Alternative method for setting pressure:

You can increase or decrease pressure on the HOME screen using \triangle or ∇ before starting

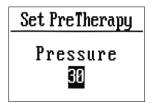
Doing so increases or decreases pressure in all zones/chambers according to the gradient.

During treatment, you can increase or decrease pressure by pressing \triangle or ∇ .

During treatment in **Lock** state, pressure cannot be increased above the preset pressure.

- If you have selected Pretherapy or Post-therapy cycle mode combination, proceed to Step 19.
- If not, proceed to Step 25.
- 19. To set the Pretherapy Pressure, press (a)

The **Pretherapy Pressure** screen is displayed:



- 20. To select **30 mmHg** or **40 mmHg**, press \triangle or ∇ .
- 21. To set the **Pretherapy Duration**, press 3. The **Pretherapy Duration** screen is displayed:

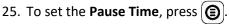


- 22. To select **SHORT** (one Pretherapy cycle) or **LONG** (two Pretherapy cycles), press \triangle or ∇ .
- 23. To set the **Post Focus Area**, press (a). One of following Post Focus Area screens is displayed:

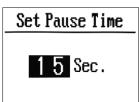
Displayed Screen	Focus Area
Set PostTherapy	
Post Focus Area DISTAL	Chambers 1-4
Set PostTherapy Post Focus Area MEDIAL	Chambers 5-8
Set PostTherapy	
Post Focus Area PROXIMAL	Chambers 9-12



24. To select the area for focused Post-therapy treatment, press \triangle or ∇ .



The Pause Time screen is displayed:



26. To set the **Pause Time**, press **A** or **V**



Note:

Pause time is the duration between compression cycles and can be set between 10-70 seconds. When the selected pause time is insufficient for garment deflation between compression cycles, the console automatically increases the pause time.

27. To set the **Hold Time**, press The **Hold Time** screen is displayed:



28. To set the **Hold Time**, press \triangle or ∇

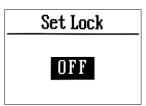


Note:

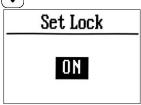
Hold time is the duration during which compression is maintained in the garment at the end of each compression cycle and can be set between 0-10 seconds.

29. To set the **Lock** state, press (a).

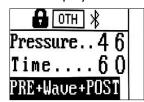
The **Lock** screen is displayed:



30. To select **ON** or **OFF**, press \triangle or ∇ .



31. When you select **ON**, the padlock icon is displayed on the Home screen.







Note:

In Lock state:

- Before treatment you cannot change any parameter.
- During treatment you can decrease or increase pressure up to the programmed pressure. When turning of to O and then to I, the pressure setting reverts to the programmed pressure. If the console beeps when you try to increase the pressure, and the padlock icon appears on the HOME screen, it means the console is in Lock state.
- 32. To set garment type press

The **Set Garment** screen is displayed.

Use \triangle or ∇ buttons to browse.

Press button (a) to set the garment and continue to next function setting.



33. To Enable Automatic deflation mode press (a).

Use \triangle or ∇ to toggle between automatic **ON** or **OFF** states.

Press button (a) to set the deflation mode and continue to next function setting.



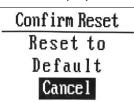
34. To reset to factory default settings, press (3).

The Reset to Default screen is displayed:



35. To select **Cancel** or **OK**, press \triangle or ∇ .

When you select **OK**, the **confirm** screen is displayed:



36. To select **Cancel** or **OK**, press ♠ or ♥.



When you select **OK**, the console resets to factory default settings.



37. To set the date and time in the console memory, press [3]. The **Set Time** screen is displayed:

Set Time				
17 : 10				
30 / 01 / 2024				

- 38. To set the hour, press \triangle or ∇ .
- 39. Press **O**. The highlighted hour blinks.
- 40. To change the hour, press \triangle or \bigcirc
- 41. To confirm the change, press .42. To proceed to the next data for change, press .
- 43. Repeat Step 38 through Step 42 until you have completed changing time and date.
- 44. To exit Advanced Settings and return to the HOME screen, press Lympha Press® Optimal Plus is now ready for operation.



6. Starting the Treatment Session

Now you are ready to operate the console and begin your treatment.

- 1. Ensure that all hoses are properly connected to the garment and that the hose bundle is securely attached to the console.
- 2. Verify that or is in the **O** position (see **Figure 11**).
- 3. Connect the DC power adapter cable to the DC adapter socket (see Figure 11).
- 4. Connect the power cord to the power adapter and to the wall electrical outlet.
- Get into a comfortable seated, reclining, or lying position from where you can easily reach the
 console controls. Put on the garment, following the directions in 3.3 Putting on the
 Compression Garment.
- 6. Turn o to the I position.
- 7. When you are ready to begin treatment, press Treatment begins.

Continue the treatment for the time ordered by your licensed medical practitioner.



Note

At the start of treatment, the inflation time may be longer as the garment must be filled from a completely empty state.

7. Ending the Treatment Session

- 1. When treatment time is complete, treatment stops. At the end of treatment, turn or to the oposition.
- 2. If you need to stop treatment in the middle, pres $\boxed{\triangleright 1}$.

The **Resume Treatment** screen is displayed for 10 minutes:

Resume Treatment Yes: Press START No: Press MODE Time Left:15

- ➤ To continue treatment, press .

 The remaining treatment time is displayed at the bottom of the screen.
- ➤ To stop treatment, press ⓐ

If you do not select either on the **Resume Treatment** screen, treatment is stopped after 10 minutes.

7.1. Automatic Deflation of Garment

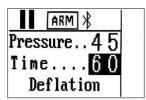
When treatment is finished or stopped in the middle, the console automatically drops the pressure and deflates air from the connected garment within 30 seconds to allow easy removal of the garment.



7.2. User-initiated Deflation of Garment

To deflate and quickly empty the connected garment for easy storage, press and hold for 3 seconds. Deflation runs for 3 minutes.

The **Deflation** screen is displayed:



- 1. To stop deflation, press \[\bigsit{\bigsit} \].
- 2. To repeat deflation, press and hold | for 3 seconds again.
- 3. At the end of treatment, turn o to the **O** position.



Caution:

Discontinue treatment and consult your licensed medical practitioner if there is onset of pain or numbness during treatment, of if there is pain, bruising, or irritation after treatment.



Note:

When immediate garment deflation is necessary, disconnect the hose bundle from the console to immediately deflate the air pressure in the garment.



8. Using the Lympha Press® Mobile Application

The Lympha Press® Mobile Application allows:

- Modifying treatment parameters:
 - > Cycle mode
 - > Treatment time
 - > Treatment pressure
- Retrieving operational log (usage history) from the console
- Starting or stopping the device using your smartphone
- The Advanced Settings allow modifying the unique Pretherapy and Post-therapy treatment cycles.



Note:

The Lympha Press® Mobile Application can be used for configuring the Lympha Press® Optimal Plus console only if installed with integrated Bluetooth module.



Note:

- RF emitters near the console may disturb the communication between the console and the Smartphone.
- In case of communication failures between the Lympha Press® Mobile Application and the console, see Section 8.5 - Troubleshooting Wireless Communication Problems.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- o Reorient or relocate the receiving antenna.
- o Increase the separation between the equipment and receiver.
- o Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- o Consult the local distributor or an experienced radio/TV technician for help.

Download and Install the Lympha Press® Mobile Application

The Lympha Press® Mobile Application can be used after installing from either Google Play or App Store.

- https://play.google.com/store/apps/

App Store - https://www.apple.com/itunes/

Internet access is required for installing the Lympha Press® Mobile Application.

The last version of the application must be downloaded.

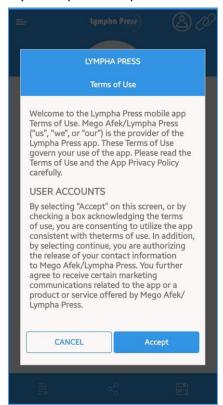


8.2. Connect to a Lympha Press® Optimal Plus Console

- Pairing the Mobile with the console (connecting for the first time)
 - 1. Turn o to the I position.
 - To open the application, tap on your Smartphone screen.
 The Splash screen is displayed for 3 seconds.



The Terms of Use window opens.
 Read the Terms carefully and tap the Accept button.



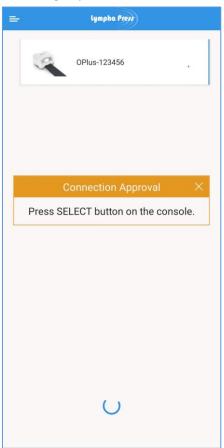


4. It is followed by the Search Screen.



- 5. Turn **On** Bluetooth on your Smartphone.
- 6. To refresh the list, tap .
- 7. To select your device, tap the device on the Search Screen.

 The Connection Approval message opens on the Search Screen:

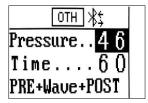




8. The screen with the Smartphone name opens on the console:



9. To approve connection, press on the console. The following screen opens on the console:



10. The Connection Approval message disappears from the Search Screen. The Main Screen opens (see Section 0 -



).

- Connecting the Mobile with the Console (other than for the first time)
 - 1. Turn to the I position.
 - 2. To open the application, tap on your Smartphone screen. The Splash screen is displayed for 3 seconds.





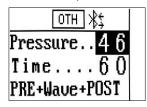
3. Followed by the Search Screen.



- 4. Turn On Bluetooth on your Smartphone.
- 5. To refresh the list, tap .
- 6. To select your device, tap the device on the Search Screen.
- 7. The devices connect automatically.
- 8. The Main Screen opens (see Section 0 -



- 10.).
- 11. The following screen opens on the console (Bluetooth icon with bidirectional arrows):



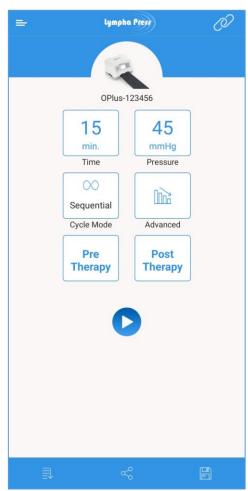


8.3. Main screen

Following is a description of the Main Screen, which includes all operations of the Mobile App. Read this section before operating the Mobile App for the first time.

The Main Screen comprises the following operations:

- ➤ Menu (see Section 0)
- ➤ Naming your console (see Section 0)
- > Setting treatment parameters (see Section 8.3.3)
- ➤ Advanced settings (see Section 0)
- ➤ Loading a treatment program (see Section 0)
- ➤ Sharing a treatment program (see Section 8.3.6)
- ➤ Saving a treatment program created from current settings (see Section 8.3.7)



Main Screen



Main Screen Buttons

Control	Function				
	Menu button				
50 min. Time	Time button: Used for setting treatment time				
90 mmHg Pressure	Pressure button: Used for setting treatment pressure				
\sim	Cycle Mode toggle button: Used for selecting:				
Sequential	Sequential mode				
Cycle Mode					
	or				
Wave					
Cycle Mode	Wave mode				
	Advanced buttons used for selecting:				
Advanced	Advanced settings with gradient pressures				
	or				
Advanced	Advanced settings without gradient pressures				
Pre Therapy Pre Therapy Pre Therapy	Pretherapy button: Used for Pretherapy settings Button is: Blue – When Pretherapy is Disabled (or when the mobile app is offline) Orange – When Pretherapy is Enabled Grey - When Pretherapy is Unavailable (if LymphaPod garment is in use)				
Post Therapy Post Therapy Pre Therapy	Post-therapy button: Used for Post-therapy settings Button is: Blue – When Post-Therapy is Disabled (or when the mobile app is offline) Orange – When Post-Therapy is Enabled Grey - When Post-Therapy is Unavailable (if LymphaPod garment is in use)				
0	Play button: Used for: Updating setting in console Starting treatment				
	Resume button: Restart treatment after pausing				
0	Pause button: Pause treatment				



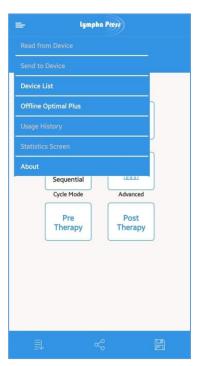
Control	Function
0	Stop button: Used for stopping treatment
$ \geqslant $	Load button: Used for loading a treatment program
80	Share button: Used for sharing a treatment program
=-	Save button: Used for saving a treatment program created from current settings

8.3.1. Menu

To open the menu, tap = or swipe the Main Screen to the right.

The menu opens:





Online Mode Menu

Offline Mode Menu

The **Read from Device**, **Send to Device**, **Usage History**, options, and are available only in Online mode (i.e., only when the Mobile App is connected to a Lympha Press® Optimal Plus console).

Note that (only) when the device is online, the **Connected** icon \mathcal{O} is shown at the top right corner of the screen.

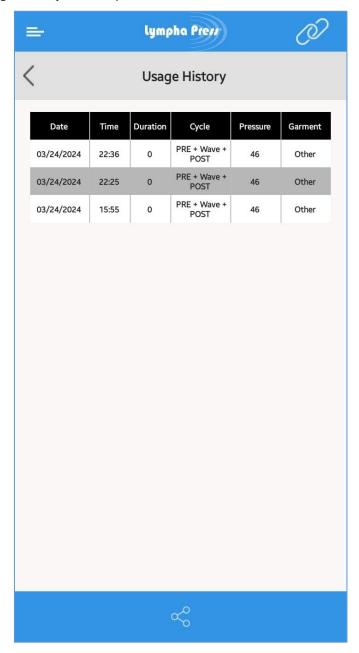
Menu Options:

- Read from Device Mobile App settings updated with connected-device settings
- Send to Device Connected-device settings updated with Mobile App settings
- Device List Return to device list screen e.g., connect to a different device or re-connect to the pervious device (if the app was used offline)
- Offline Optimal Plus Opens Main Screen for unconnected Optimal Plus console



 Usage History - Read treatment log from console Tap Usage History.

The **Usage History** screen opens:

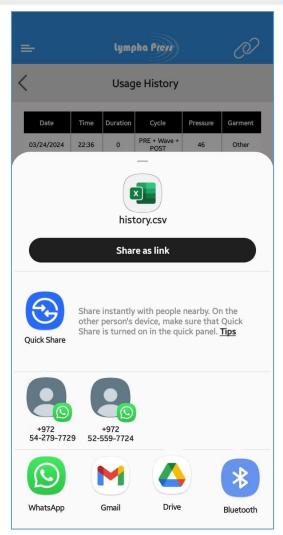


You can share the Usage History log as follows:

a. Tap 🗬.

A standard Share-via-Application screen opens (different depending on devices and operating systems).





b. Select the application used for sharing (e.g., Outlook, Gmail, WhatsApp).

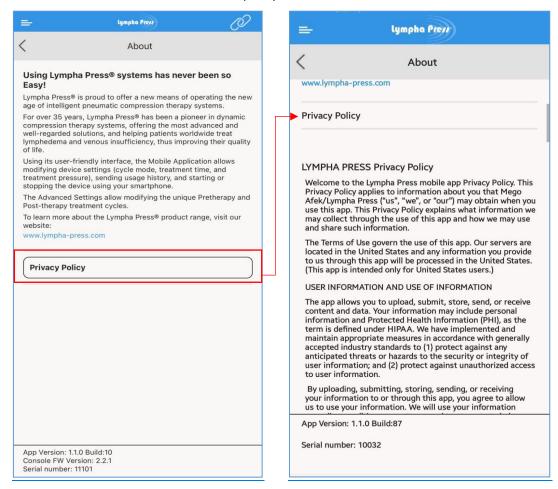


About - Opens the Mobile App About page

The About screen leads to the privacy policy.

Tap on the **Privacy Policy** button to view it.

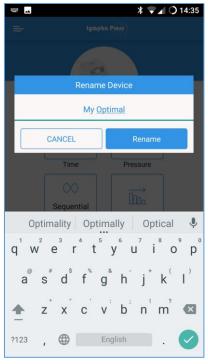
Scroll down to view the entire policy.





8.3.2. Naming your Console

A. Tap and hold the device icon on the **Main Screen** for about 2 seconds, until the **Rename Device** dialog box with virtual keyboard opens.



- B. Tap the new name using the virtual keyboard.
- C. To approve the new name, tap **Rename** or tap **CANCEL** to cancel and return to the Main Screen.

8.3.3. Setting Treatment Parameters

- Selecting Treatment Time
 - a. Tap the **Time** button.

The **Time** screen opens:



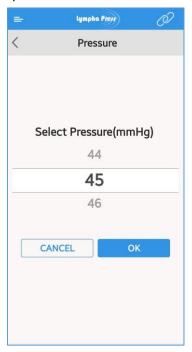


- b. To set the required treatment time, swipe up/down the time values.
- c. To approve the set treatment time, tap **OK.** Tap **CANCEL** to cancel selection and return to the Main Screen.

Selecting Treatment Pressure

a. Tap the **Pressure** button.

The **Pressure** screen opens:



- b. To set the required pressure, swipe up/down the pressure values.
- c. To approve the set pressure, tap **OK.** Tap **CANCEL** to cancel selection and return to the Main Screen.

Selecting Cycle Mode

Tap the **Cycle Mode** toggle button to select either **Sequential** or **Wave** mode.



8.3.4. Advanced Settings

Tap the **Advanced** button.

The **Advanced Treatment Settings** screen opens:



Setting Gradient Pressures

- a. To enable gradient pressures, swipe right the **Gradient Pressures** button or swipe left to disable gradient pressures.
- b. Tap **PRESSURE SETTINGS**.

The 12-chamber pressures screen opens (depending on Gradient Pressures setting):





- ◆ To increase/decrease pressure of each chamber, swipe right/left the pressure value.
- ◆ To bypass a chamber, swipe left the chamber button.
- ◆ To approve the selected pressures, tap **OK** (which brings you to Main Screen with values accepted) or tap **CANCEL** to cancel selection and return to the Main Screen.



Note:

Pressure can be selected for each chamber individually. The Mobile App prevents setting a reverse gradient (in which the pressure is higher proximally), as a reverse gradient could cause wrong way flow (reflux). Increasing/decreasing pressure in one chamber increases/decreases the pressure in the adjacent chambers when necessary, to prevent a reverse gradient.



Tip:

You can quickly decrease the overall pressure by swiping left chamber-1 pressure or quickly increase the overall pressure by swiping right chamber-12 pressure.

Selecting Hold Time

Swipe up/down the **Hold Time** value.

Setting Pause Time

Swipe up/down the **Pause Time** value.

- Lock Console Interface
 - a. Swipe right the **Lock Interface** button to lock the console interface or swipe left to unlock the console interface.

When locked, the **Advanced** button is displayed with a padlock at the top left corner:



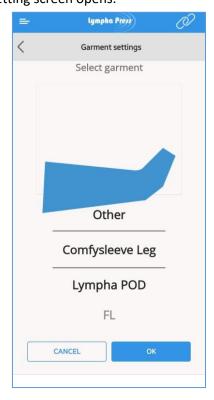


To approve the set **Hold Time**, **Pause Time**, and **Lock**, tap **OK**. Tap **CANCEL** to cancel these settings and return to the Main Screen.



Selecting Garment

a. Tap **GARMENT SETTINGS** in the Advanced treatment settings screen. The Garment setting screen opens.



- b. To select the required garment, swipe up/down the garment names.
- c. To approve the selected garment, tap OK (which brings you to Main Screen with selection accepted). Tap CANCEL to cancel selection and return to the Main Screen.
- Pretherapy settings (inactive when LymphaPOD is used)
 - a. Tap the **Pretherapy** button.

The **Pretherapy Settings** screen opens.





b. Tap Short for one Pretherapy cycle, tap Long for two Pretherapy cycles, or tap Disable for no Pretherapy cycle.

The radio button of the selected option turns .

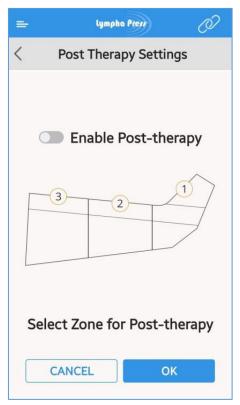
The Pretherapy button display changes as follows:



Disabled Enabled

- c. Swipe up/down the **Pressure** value to select 30 or 40 mmHg.
- d. To approve the Pretherapy settings, tap **OK** or tap **CANCEL** to cancel and return to the Main Screen.
- Post-therapy settings (inactive when LymphaPOD is used)
 - a. Tap the Post-therapy button.

The **Post-therapy Settings** screen opens. The map of the appropriate garment is shown on the screen.



b. Swipe right the **Enable Post-therapy** button.



c. To select a **Post-therapy** zone, tap one zone as follows:

	Zone 1 (distal)	Zone 2 (medial)	Zone 3 (proximal)
Comphysleeve Leg	3 2	3 2	3 2
Comfysleeve 1-75	1	2 1	2 1
Arm Shoulder	73 2 1	1	3 2 1
FL	3 2 1	3 2 1	3 2 1
Lympha Jacket	1 1	1 1	2 1
Other	3 2 1	3 2 1	3 2 1
PLympha Pants	3 2 1	3 2 1	3 2 1



Tip:

To select a **Post-therapy** zone, tap a Post-therapy zone directly without enabling Post-therapy first.

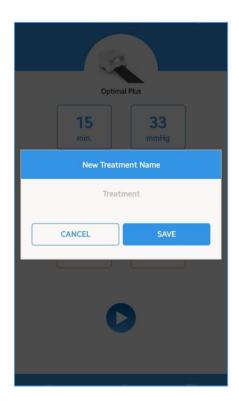
d. To approve the Post-therapy settings, tap **OK**, or tap **CANCEL** to cancel and return to the Main Screen.



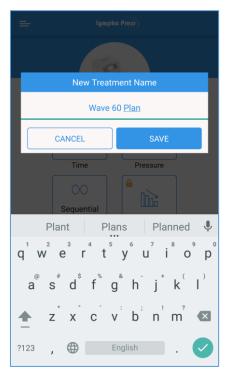
8.3.5. Saving a Treatment Program Created from Current Settings

А. Тар 🖺 .

The New Treatment Name dialog box opens on the Main Screen.



B. Tap the New Treatment Name field to assign a treatment name.
 The New Treatment Name dialog box with virtual keyboard opens on the Main Screen.



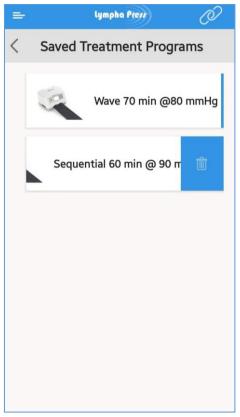
- C. Tap the treatment name using the virtual keyboard.
- D. To approve the treatment name, tap **SAVE** or tap **CANCEL** to cancel and return to the Main Screen.



8.3.6. Loading/Deleting a Treatment Program

A. To load a treatment program, tap

The **Saved Treatment Programs** screen opens.



B. To select a treatment program, Tap the program on the list (Wave 70 min @ 80 mmHg in the example above).

The selected treatment program is loaded.

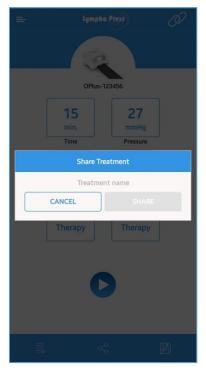
- C. To delete a saved treatment program, swipe left the program you wish to delete (**Sequential 60 min @ 90 mmHg** in the example above).
- D. Tap 🛗.

8.3.7. Sharing a Treatment Program

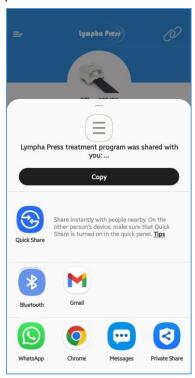
Settings that can be shared are those currently active in the mobile application:

- A current program whose settings are adjusted using the application
- Settings read from the connected console
- A saved program (requires loading the program first)
- А. Тар 🥰.
- B. Enter name of the shared treatment.





A standard Share-via-Application screen opens (May be different depending on devices and operating systems).



C. Select the application used for sharing (e.g., Outlook, Gmail, WhatsApp, etc.).

8.3.8. Handling a Shared Treatment Program

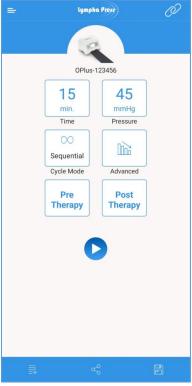
A. Open the received treatment program.

The Lympha Press® Mobile Application automatically updates the treatment parameters according to the received treatment program.

B. Start treatment or save the received treatment program for later use.

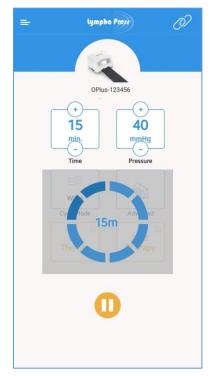


8.4. Starting Treatment



To start treatment, tap on the Main Screen.

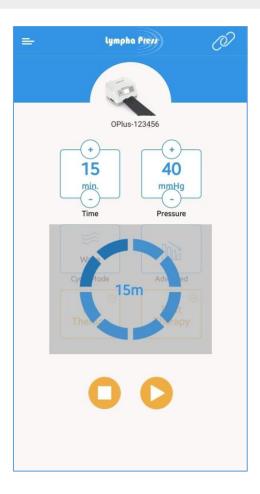
The **Treatment Screen** opens.



- To adjust **Time** and/or **Pressure**, tap (+) or (-).
- ➤ (50m) displays the remaining treatment time.

To pause treatment, tap 1 The treatment is paused and the following screen opens:





- To resume treatment, tap
- To stop treatment, tap .



8.5. Troubleshooting Wireless Communication Problems

Lympha Press® Mobile Application uses Bluetooth wireless technology for communication with the console. In most cases of temporary communication loss, communication resumes automatically.

To resume communication with the Lympha Press® Mobile Application in an unlikely event of communication loss, application failure, or console disturbances, user should restart the application.

Note that proximity to RF emitters like Wi-Fi access points, RFID anti-theft devices, or other wireless transmitting devices may cause communication disturbances.

Make sure the console is located at least 3 meters away from such emitters.

If disturbances continue, stop treatment, turn o — to the **O** position, and contact your local distributor for service.

When using the Lympha Press® Mobile Application to configure and monitor the console, make sure to remain within reach of the console allowing you to turn o - to the O position or change settings and start or stop treatment without using the Lympha Press® Mobile Application.



Note:

In an event of communication loss or failure of the Lympha Press® Mobile Application, the console is fully functional, thus continues operating normally without interruption.



9. Maintenance & Storage

9.1. Cleaning the Console

- 1. Ensure the power cord is unplugged before cleaning the console.
- 2. Wipe clean using a slightly damp cloth.
- 3. Do not allow any moisture or liquids to enter the console!

9.2. Cleaning the Compression Garment



Caution:

Wear protective gloves during garment cleaning.

Wash your hands thoroughly after garment cleaning.

- 4. Gently wipe the external and internal surfaces of the compression garment using a soft cloth, warm water not exceeding 100°F (40°C), and a mild detergent. Do not submerge in liquid!
- Do not allow liquid to enter the air inlets or hoses of the garment!
 Wipe with clear water to remove any detergent residue, again taking care that water does not enter the air inlets or hoses.
- 6. Wipe dry using a soft towel only.
- 7. When dry, the external and internal surfaces of the compression garment, as well as the hoses, may be wiped down with alcohol. When using alcohol, wear gloves and work in a well-ventilated area.
- 8. Allow the garment to air dry completely before using.

If you have questions about cleaning, please contact your local distributor.



Caution:

Do not hand or machine wash. Surface wipe only!

Do not allow liquid to get into the air inlets or hoses.

Do not use bleach.

Do not dry clean.

Do not wring, iron, tumble, or force heat dry.



9.3. Storage

Follow the storage instructions listed below:

- ➤ Keep the console, all components, and the garments away from direct sunlight.
- > Store in a dry, shaded place (see Caution below).
- > Do not twist or fold the hose bundle.
- > Store the DC power adapter lightly wrapped and secured.
- ➤ Avoid folding the garments during storage.



Caution:

The system can be transported or stored for short periods of time within:

Temperature range of -20°C to 70°C (-4°F to 158°F)

Relative humidity of 10% to 93% non-condensing

Atmospheric pressure of 190hPa to 1060hPa

Allow the system to reach reasonable room temperature range of 10° C to 30° C (50° F to 86° F) before operating.

When the system has been stored in extreme temperature conditions of -20°C (-4°F) or 70°C (158°F) between uses, wait for two (2) hours before using the system.

9.4. Travel

- ➤ Make sure to obtain the proper power adapter plug for the location you visit.
- ➤ Follow all storage guidelines when packing the console or garment.

9.5. Disposal

If the console, hose bundle and/or garment(s) is to be disposed of, follow the local country regulations taking environmental factors into consideration.

9.6. Retrieving Operation Log from the Console



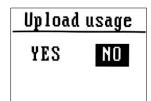
Note:

Retrieving operation log from the console should be done only when treatment is **not** running.

Operation log can be retrieved for analyzing console correct operation, and operation history, as follows:

- 1. Turn o to the I position but do not start treatment.
- 2. Insert an empty USB drive into the console USB port.

The following screen is displayed:



3. To select **YES**, press \bigcirc or \bigcirc and then press \bigcirc . The console operation log is copied to the USB drive.



9.7. Firmware Upgrade



Note:

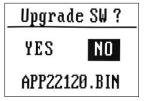
Only a certified technician should upgrade firmware.

Firmware can be upgraded only when treatment is not running.

You can upgrade firmware from USB drive as follows:

- 1. Copy the new firmware version to a USB drive.
- 2. Turn o to the I position but do not start treatment.
- 3. Insert the USB drive into a USB port.

The **Upgrade SW** screen is displayed.



4. To select **YES**, press or , and then press . The firmware in the console is upgraded.



10. Troubleshooting

Table 8 - Troubleshooting

Symptom	Possible Cause	Corrective Action	
	No electricity	Inspect the electrical wall outlet.	
The console is not working.	DC power adapter	Verify that the DC power adapter cable is connected to the DC adapter socket on the console, and the power cord is connected to an appropriate 100-240 Volt wall outlet.	
	DC power adapter cable	Examine the cable for any defects.	
The console starts working and stops immediately.	The air cannot move through the hose bundle.	Examine hose bundles for kinks, twists and folds.	
The console starts working but inflation continues for long time, and console enters error state.	Potential air leak in garment(s), hoses, or console.	 Examine garment(s) for air leak. Examine hose bundle connections to console garment(s). If no obvious air leak detected and fixed, and problem persists, contact your local distribute for service. 	
One garment inflates but the second one does not.	The second garment does not receive air.	Examine its hose bundle for kinks, twists, and folds.	
The console stops working, the air leak icon turns On, and the buzzer beeps.	Hose bundle is not connected properly to garment or console, or prong plug is not inserted into unused air outlet.	Examine and fasten all air connections. When treating only one limb, always plug the unused air outlet with the prong plug provided with the console. If all air connections are OK and problem persists, contact your local distributor for service.	
The console works at a very low	Defective garment.	Replace garment and check again.	
pressure, regardless of the pressure set by the user.	An internal problem.	Contact your local distributor for service.	
Irregular noise.	Transferring of vibrations to the table.	Make sure the console is standing firmly on all five of its bumpers.	
	An internal problem.	Contact your local distributor for service.	



10.1. Repairs and Technical Support

Contact your local distributor for repairs and/or technical support.

10.2. Authorized Representative in Europe

MedNet EC-REP GmbH

EC REP

Borkstrasse 10 48163 Muenster Germany

Tel: +49 251 32266-61 Fax: +49 251 32266-22

Web: http://www.mednet-eurep.com

10.3. Manufacturer

Mego Afek AC Ltd.

Kibbutz Afek, 3004200

Israel

Tel: 972-77-9084277 Fax: 972-4-8784148

E-mail: <u>info@megoafek.com</u>
Web: <u>www.megoafek.com</u>

10.4. Lympha Press® Optimal Plus Service Life

When used and maintained as instructed, the expected service life of the Lympha Press® Optimal Plus console is five (5) years.



Appendix I - Specifications

Model: 912, appliance coupler with adaptor, Non-transit-operable and portable, rated: 100-240 VAC, 50-60 Hz					
Type of protection against electric shock	Class II				
Degree of protection against electric shock	Type BF				
Degree of protection against ingress of water	IP21				
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide				
Mode of operation	Continuous				
Environmental Conditions	Normal: 10-30°C, 30-75% rH, 700-1060 hPa				
Pressure Range	20 mmHg to 90 mmHg				
Dimensions	34 cm × 24 cm × 19.8 cm (13.3" × 9.4" × 7.8")				
Weight	4.5 kg (9.92 lbs.)				



Appendix II - EMC Manufacturer's Declarations



Warning:

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally



Warning:

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



Warning:

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Optimal Plus model 912, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 1: Declaration - Electromagnetic Emission

Optimal Plus model 912 is intended for use in the electromagnetic environment specified below. The customer or the user of Optimal Plus model 912 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	Optimal Plus model 912 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	Optimal Plus model 912 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power
Harmonic emissions IEC 61000-3-2	Class A	supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Clause 5 of EN 61000-3-	



Table 2: Declaration - Electromagnetic Immunity

Optimal Plus model 912 is intended for use in the electromagnetic environment specified below. The customer or the user of Optimal Plus model 912 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 ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tie. 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 ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	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	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Optimal Plus model 912 requires continued operation during power mains interruptions, it is recommended that the Optimal Plus model 912 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) 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: UT is the AC mains voltage prior to application of the test level.



Table 3: Declaration - Electromagnetic Immunity

Optimal Plus model 912 is intended for use in the electromagnetic environment specified below. The customer or the user of Optimal Plus model 912 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80%, 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of Optimal Plus model 912, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m	$d = \left[\frac{3.5}{V_{\rm I}}\right] \sqrt{P}$ $150 \text{ kHz to } 80 \text{ MHz}$ $d = \left[\frac{3.5}{E_{\rm I}}\right] \sqrt{P}$ $80 \text{ MHz to } 2.7 \text{ GHz}$ 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 meters (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. Interference may occur in the vicinity of equipment marked with the following symbol: ((***)**)
Immunity to proximity magnetic fields in the frequency range	Immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56	See table 11 of standard Any one of its nominal input voltages and frequencies	

NOTE 1: At 80 MHz and 800 MHz, 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 RF 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 Optimal Plus model 912 is used exceeds the applicable RF compliance level above, Optimal Plus model 912 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Optimal Plus model 912.
- b. Over the frequency range 0.15 MHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4: Recommended Separation Distances between Portable and Mobile RF Communication Equipment and Optimal Plus model 912

Optimal Plus model 912 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of Optimal Plus model 912 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Optimal Plus model 912, as recommended below, according to the maximum output power of the communications equipment.

	Separation Distance according to Frequency of Transmitter (m)			
Rated Maximum Output Power of Transmitter (W)	0.15 MHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	80 MHz to 2.7 GHz $d = 2.3\sqrt{P}$	
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 meters (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 80 MHz and 800 MHz, 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.



Table 5: declaration - IMMUNITY to Proximity Fields from RF Wireless Communication Equipment

Optimal Plus model 912 is intended for use in an electromagnetic environment in which RF wireless communication equipment are controlled.

	IEC60601 Test Level					Electromagnetic
Immunity Test			Maximum Power	Immunity Level	Compliance Level	Environment - Guidance
Radiated RF	385 MHz	**Pulse Modulation: 18Hz	1.8 W	27 V/m	27 V/m	
IEC 61000-4-3	450 MHz	*FM+5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m	
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m	
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m	
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m	
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m	
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m	

Note * - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Note ** - The carrier shall be modulated using a 50 % duty cycle square wave signal.

The Lympha Press® Optimal Plus model 912 may include Bluetooth transmitter receiver, Microchip RN4870, FCC ID: A8TBM70ABCDEFGH, Operating frequencies: 2402.0 - 2480.0 MHz Inclusion of Bluetooth module is indicated on the front panel.



FCC compliance

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: 1. this device may not cause harmful interference, and 2. this device must accept any interference received, including interference that may cause undesired operation. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and may cause harmful interference to radio communications if not installed and used in accordance with the instruction. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Consult the dealer or an experienced radio/TV technician for help

Changes or modifications made to this equipment not expressly approved by Mego Afek AC Ltd. for compliance may void the FCC authorization to operate this equipment