LYMPHATOUCH®

INSTRUCTION MANUAL

Ver. LT01 SW rev 1.x.x.x

The manual contains instructions for use, maintenance and handling of the device, as well as safety precautions and warnings. Read through carefully before using the device, to ensure safety and efficiency for you. Keep for future reference.

TABLE OF CONTENTS

FDA device Class I, 510 (k) exempt, Quality 13485:2016
The information in this document is subject to change without prior notice. In a conflict situation the English version prevails.

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Safety and EMC certificate

LymphaTouch is CLASS 1 LASER PRODUCT
INVISIBLE LASER RADIATION
LymphaTouch® LT01 conforms with:
Medical Device Directive 93/42/EEC
RoHS Directive 2011/65/EU

1. SAFETY

In this User Manual, safety precautions and warnings are indicated with the following signal words. Make sure to read and understand all safety precautions and warnings before starting to use the device.

Caution – potentially hazardous situation which, if not avoided, may cause minor to moderate injuries, or damage to the device.

Warning – potentially hazardous situation which can cause injuries or damage the device, if instructions are not followed.

Danger – potentially hazardous situation which can result in serious injury or death, if instructions are not followed.

1.1 SAFETY INSTRUCTIONS AND SAFETY PRECAUTIONS

USER RELATED WARNINGS AND PRECAUTIONS

Warning - *Do not use the device while doing maintenance.*
Warning - *Choking resulting from child swallowing a filter.*
Warning - *Strangulation resulting from baby or child becoming entangled by the cable*

- Never use the unit for purposes other than those recommended by LymphaTouch Inc. LymphaTouch Inc. will not be liable for any inappropriate use of the equipment.
- Do not leave the device in proximity of pets, pests or children.
- Avoid situations where the cable can be wrap around the neck.
- Do not use the device without having had device specific training.
- Be careful with negative pressure values when treating with medication (corticosteroids, anticoagulants, NSAIDS, blood thinners) in order to avoid bruising and other tissue damages.
- Do not pull the device from the cable between the main unit and Treatment Handle.

TREATMENT RELATED WARNINGS AND PRECAUTIONS

Warning - *Skin irritation due to prolonged exposure to Treatment cups.*
Warning - *Do not treat directly over skin with open wounds. / Do not treat over open wounds or fistulas.*
Warning - *Make sure the filter in the treatment cup is in place before attaching it to the Treatment Handle, to avoid dust and debris from being sucked into the device.*
Warning - *Be careful when applying/treating on fragile skin and around the neck and throat area.*
Warning - Wipe the treatment cups carefully using a mild disinfectant or mild detergent after each use to prevent transfer of bacteria or other impurities from one patient to another. When cleaning the treatment cup, be careful not to touch the filter, as the detergent may also cause clogging of the filter. See chapter 10 for more information.

- Clean the device and accessories regularly following the instructions and the regulations of your institution, to ensure safe and hygienic use.
- Use treatment cups and treatment settings that are best suited to the anatomy and skin type you are treating.
- Change filters after every treatment to ensure better hygiene.

DEVICE RELATED WARNINGS AND PRECAUTIONS

***Warning** - Unauthorized modification of the equipment is strictly prohibited.*
***Warning** - LymphaTouch LT01 is not intended for field repair. Opening the device without authorization from LymphaTouch Inc. will void the Responsibility of the Manufacturer. Only trained service personel is allowed to change the lithium ion battery.*
***Warning** - Comply device usage, transport and storage environmental specifications Chapter 15. Device may otherwise malfunction.*

- Don't use the device near moist conditions for example nebuliser, steam kettle.
- Don't use the device near heated surfaces for example fireplace, radiant heater.
- Use, store and transport the system only under the conditions described in this manual. Not following the conditions of use, storage and transport may adversely affect the performance of the system, cause electronics to malfunction or the accessories to degrade.
- Handle the device with care and follow the maintenance instructions.
- Use only accessories and mounting provided by or approved by LymphaTouch Inc.
- Avoid situations where the unit might fall or collide with a heavy object.
- Inspect the device for visible damage or malfunctions and inspect the related accessories for cracks or other signs of overuse, and replace accessories as required.
- Keep dry. The device contains electronic components that, if subjected to liquids, may malfunction and cause incorrect device output.
- Keep out of direct sunlight. Prolonged exposure to direct sunlight may cause high temperatures that damage the system. Ensure that storage conditions shown in section 15 are met.
- Do not use the device in the bag.
- When the device is taken from minimum or maximum storage temperatures, let it rest two hours in normal room temperature before usage
- This device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Chapter 16
- Use original packaging when transporting the device via postal services.
- Store the device in its original packaging when not in use.
- Don't interconnect the device with other devices.
- If you experience performance degradation and troubleshoot Chapter 11 doesn't help, contact your local dealer.

2. APPLICATION SPECIFICATION

Intended use:
LymphaTouch is a negative pressure-based therapy device for health care professionals and for at-home users.
It is intended to be used by persons who are knowledgeable about the treatment method and e.g. read the user manual or under supervision of those persons.
The device is designed to be used as an assisting tool for manual therapy. The device helps to move excess fluid from an impaired body part to healthy regions of the body, where fluid can be absorbed and processed naturally by your body.
Intended conditions of use:
The environment, where this device is typically used are; physiotherapy setting including hospitals, physiotherapy centres and home use.

Contraindications:
ABSOLUTE
- Acute deep vein thrombosis
- Acute infection
- Congestive heart failure
- Cardiac Edema
- Kidney dysfunction
- Conditions in which increased venous and lymphatic return is undesirable

RELATIVE
- Active cancer, seek advice from home healthcare in advance
- Pregnancy, seek advice from home healthcare in advance

In addition, all contraindication for manual lymphatic drainage and physiotherapy apply. If you are uncertain of the suitability of the device for treatment, seek advice from healthcare professional prior to starting the treatment. As this list is not exhaustive, always seek advice from healthcare professional in the event of doubt.

Intended medical indication:
Improvement of lymphatic circulation in the treated area, improvement of secondary lymphedema and reduction of secondary lymphedema of the Arm (SLA) Post Mastectomy.
Device is used on any one deemed to be appropriate for a physical treatment.
The person using the device should be aged enough and knowledged enough to be able to understand and follow the instructions for the treatment and understand the operation of the device.
Patient weight is not limited as an own indicator for LymphaTouch treatment. If you are uncertain of the suitability of the treatment consult your healthcare provider to find out the underlying issue for your weight problem before starting the treatment.
Patient is the intended operator.

Operating principle

The mechanism of action is based on the effects of negative pressure in tissues. Negative pressure created by the treatment device stretches the skin and the tissue underneath, pulling on anchoring filaments to dilate the endothelial openings of lymph vessels. Vertical stretching of the fascial (connective tissue) structures is accomplished at the same time, expanding the space for circulation of blood and lymph. Lymph and the metabolic waste products that impede the healing process can then flow more easily from the interstitial space into lymph vessels, and excess fluid is carried away by the body's own lymph transport mechanisms to re-join the venous circulation.

3. PACKAGE CONTENTS

- LT-1001 Model LT01 LymphaTouch device
- LT-0035,LT-0050, LT-0060 and LT-0080 treatment cups
- LT-1601 LymphaTouch Bag
- LT-1315, 100pcs Filters for treatment cups
- Instructions for use

4. PARTS OF THE LYMPHATOUCH

1. Main unit
2. On / Off switch
3. Touch screen
4. Treatment Handle
5. Different sizes of treatment cups for the Treatment Handle
6. Soft covers for the treatment cup (detachable on 60mm treatment cup)
7. Treatment cup filter
8. DC-power, country adapter included. *Caution*: Power supply is specified as a part of the equipment.

The whole device is considered as applied part excluding the DC-power supply.

5. CONNECTORS

1. Device's serial number
2. Mains power
3. USB
4. Power ON / OFF

Use max. 32GB USB flash drives. These should be formatted to FAT32.
Warning – Do not use USB connectors while treatment is in progress.
Warning – Do not connect other connectable USB devices to the port.

6. SYMBOLS AND PRODUCT MARKINGS

In addition to the connector markers described above, you may find the following symbols and markings in the device or the package:

Symbol	Description
CE 0537	The product is CE marked and the number indicates the notified body.
	Read the User Manual before using the device.
	The device is classified as Type BF Applied part, according to the standard IEC 60601.
	Special instructions are needed to dispose device properly.
Li-ion	Lithium-ion battery must be disposed properly.
	The carton package of the device can be recycled.
	This side up.
	Manufacturer.
IP21	Enclosure is protected from touch by fingers and objects greater than 12 millimetres. Protected from dripping water.
SN	Serial number of the device.
FC	FCC declaration of conformity. Device includes BlueTooth and WLAN module.

Symbol	Description
	Do not use sharp instrument to open the package
	Fragile. Handle with care.
	Humidity limitation. See more from the table page 25.
	Keep dry.
	Temperature limitation. See more from the table page 25.
	Atmospheric limitation. See more from the table page 25.
Rx only	A healthcare professional will provide the instructions on how to use the device.
TÜV SÜD C US	Device is tested by TÜV and fulfils NRTL.

7. Installation

7.1 Unpacking

Carefully unpack all parts of the device and confirm that all parts are included and intact.

Caution - We recommend you to keep the box in case you need to return the device or send the device for service – the safest way to transport the device is to use the box it was originally shipping in.

7.2 Internal Battery

LymphaTouch® has an internal battery that should be fully charged before first use. When battery is recharging, the power button light turns orange. When battery is fully charged power button light turns to green and is constant. When device is used via battery and the device is on, the light is green.

7.3 Connecting a treatment cup to the Treatment Handle

Select the appropriate treatment cup for the body area in question. Please refer to the Chapter 8.5 ”Selecting a treatment cup”. Connect the treatment cup to the Treatment Handle as indicated in the figure.

Caution - Make sure that the treatment cup is connected in right orientation, as indicated by the guiding rail.

7.4 *Using filters in the treatment cup*

Attach the filter to the treatment cup as indicated in the figure below. Filters are changed for every treatment for ensuring better hygiene.

7.5 *Connecting removable soft part to the treatment cup*

60mm treatment cups has separate soft parts. Connect the treatment cup soft part to treatment cup as indicated in the figure.

7.6 *Using equipment*

Place the device on a flat surface, such as a table. Make sure the cable is not pressed against anything or twisted from anywhere and it hangs relaxed from the device. User can use the device in any position.
Press the treatment cup attached to the treatment handle to the skin. The device automatically starts suction when getting close to the skin.
To terminate the operation quickly Press On / Off button for one second or back button when in treatment screen.
It is safe to stop treatment at anytime.
Lay operator and operator can use every function of the device.

7.7 *Power supply with country adapters*

Choose proper country adapter suitable for your mains system from the LymphaTouch package.

Connecting country adapter to power supply
Image 1: See that the plug and power adapter are aligned. See from the plug information which way to connect the plug to the power adapter.
Image 2: Insert the plug to the power adapter. Turn clockwise and hear the click.
Image 3. After connecting the plug, the final result should look like this.

Image 1

Image 2

Image 3

Disconnecting country adapter from the power supply

Image1: Move the release switch in to the direction of the arrow
Image2: While holding the switch, turn the adapter anti-clockwise.

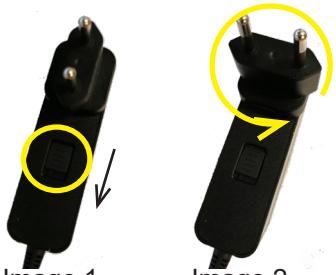


Image 1 Image 2

For safety purposes do not position the device that the access AC/DC power adapter is blocked. To disconnect the device from mains, disconnect the DC-plug from the device and disconnect the power supply from the mains.

7.8 Fully assembled device

Device comes fully assembled. The only actions needed are to attach filters to treatment cups (Chapter 7.4) and to connect country adapter to the power adapter.

8. USING THE LYMPHATOUCH® DEVICE

8.1 Turning the device on and off

Turn the device on by pressing the on/off switch on the left side of the device. Device starts in 10 seconds. To turn off the device, press the on/off switch and hold it two seconds. The device will also shut down automatically after an 20 minutes of inactivity, while on battery power.

8.2 Screen saver

The display will shut down and the device will enter a power saving mode when the device has not been used for 10 minutes. Reactivate the unit by touching the screen.

8.3 Treatment preparation

LymphaTouch®–treatment does not require special preparation for the treatment. The treatment is applied to bare skin.

Moderate application of oil or massage cream may allow the treatment cup to glide more smoothly on the skin. Avoid excessive use of oil or massage cream.

If the treated skin is very dry and producing dandruff, the filter in the treatment cup may get clogged faster than normal. This will result in difficulty achieving the set pressure. Replace the filter in order to continue an efficient treatment. Do not use talcum powder or other powdery top agents on the skin.

8.4 Treatment Handle lens and sensors

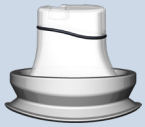
LymphaTouch®–treatment handle has a lens inside. Avoid scratching the lens and keep the lens clean for the best performance. If the lens gets scratchy this may cause sensors performance to degrade.

8.5 Selecting a treatment cup

Select the proper size treatment cup for each treatment situation. Please refer to the table below for general guidance, while using your own clinical judgment as to what is an appropriate size for each situation.

Treatment cup	Size	Removable rubber ring	Body areas
 LT-0010	10 mm		• Local scars • Small joints • Face • Head and neck
 LT-0035	35 mm		• Local scars • Small joints • Face • Head and neck
 LT-0050	50 mm		• Local scars • Joint areas • Face • Head and neck • Palm area
 LT-0060	60 mm	X	• Whole body
 LT-0080	80 mm		• Torso • Upper and lower limbs

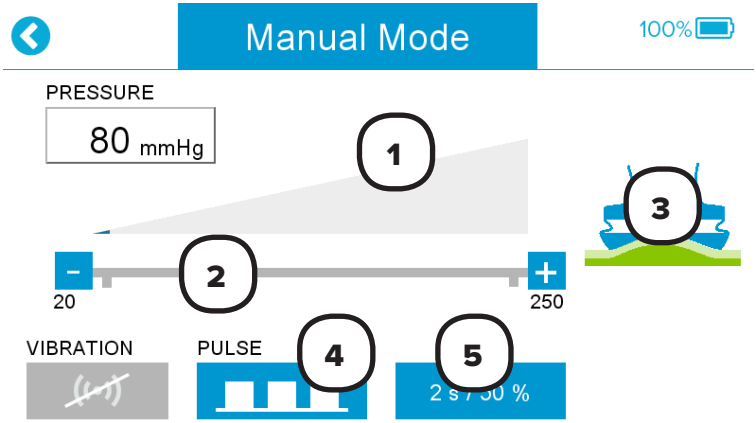
8.6 Accessories

Code	Accessory	
LT-1901	Roll Stand	
LT-1020-10 LT-1004-10	Treatment cup 10mm, 20pcs Treatment cup 10mm, 4pcs	
LT-1020-35 LT-1004-35	Treatment cup 35mm, 20pcs Treatment cup 35mm, 4pcs	
LT-1020-50 LT-1004-50	Treatment cup 50mm, 20pcs Treatment cup 50mm, 4pcs	
LT-1020-60 LT-1004-60	Treatment cup 60mm, 20pcs Treatment cup 60mm, 4pcs	
LT-1020-80 LT-1004-80	Treatment cup 80mm, 20pcs Treatment cup 80mm, 4pcs	
LT-1601	LymphaTouch® carrying bag	

Use these codes to order accessories from the nearest distributor.

9. TREATMENT SETTINGS

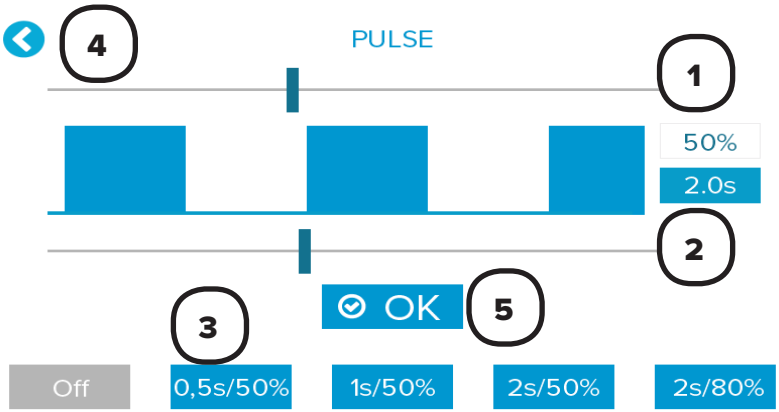
Turn on the device. LymphaTouch® main screen will appear (see picture).
The default setting is 80 mmHg with 2 s. pulsations. The unit will start operation automatically when the treatment cup is put close to the treated target.



1. The setting is indicated on the main screen on the top left, as well as graphically in the form of a wedge. During treatment a blue wedge appears which indicates the current vacuum in the treatment cup.
2. The negative pressure is adjusted with the touch screen by moving the slider at the desired location.
3. The image on the right hand side of the screen indicates when the device has good suction.
4. During treatment, it is possible to choose either pulsating or continuous treatment. By pressing this button pulse can be set on / off.
5. To modify the pulsation setting, touch the pulse button on the main screen, and the pulsation setting screen will appear

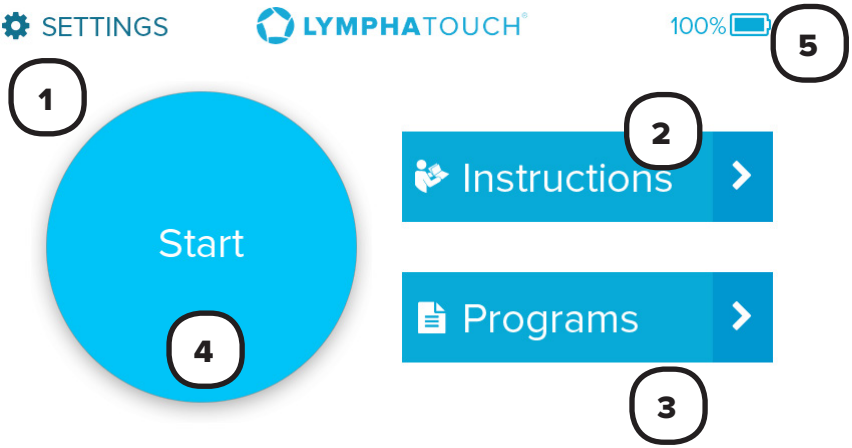
If the desired negative pressure is not achieved make sure that the treatment cup selected is suitable to the affected area of the body. If necessary replace the treatment cup with a more appropriate size, or reposition the treatment cup on the skin carefully. Also, the body hair may cause air leakage from the treatment cup. Refer to the section "Troubleshooting."

9.1 Pulsation screen



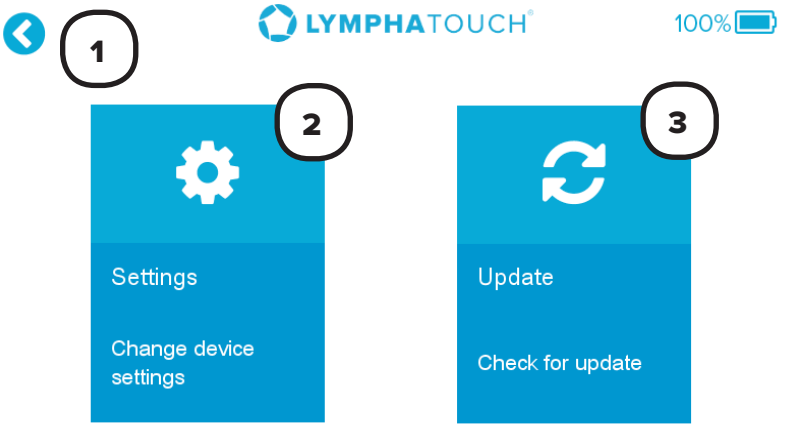
1. Set work/rest ratio by sliding the slider at the top of the screen between 30 – 90%.
2. Set pulse length by sliding the lower slider.
3. Quick settings
4. Return to previous screen
5. Save settings and return to previous screen.

9.2 Start screen

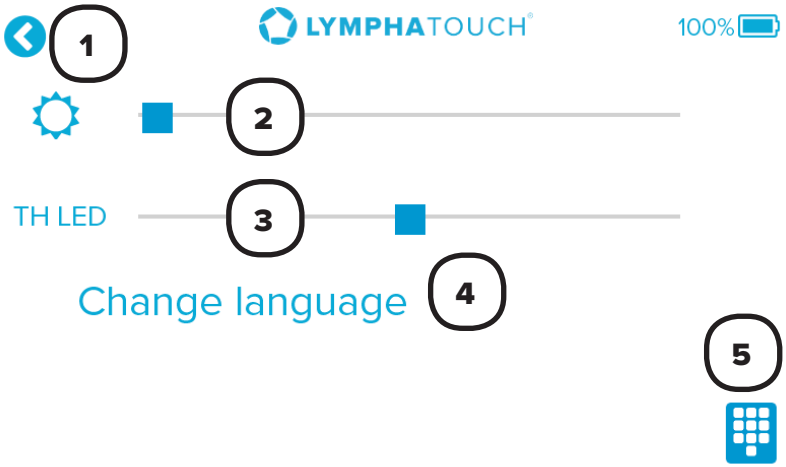


1. Go to Settings
2. Instructions how to use device
3. Pre-programmed treatment programs
4. Quick start to free mode
5. The battery icon indicates the battery charge level. When the device is connected to the mains, battery is charging which is indicated by a flash icon.

9.3 Settings screen

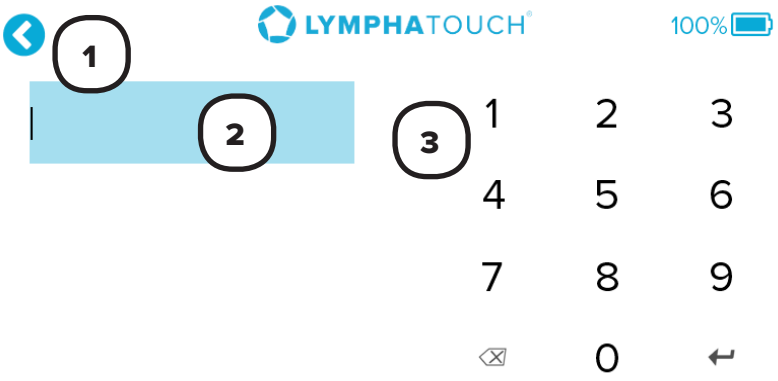


1. Go to previous screen
2. Set screen rightness, language and use numeric keypad to input codes
3. Guidance for the software upgrade



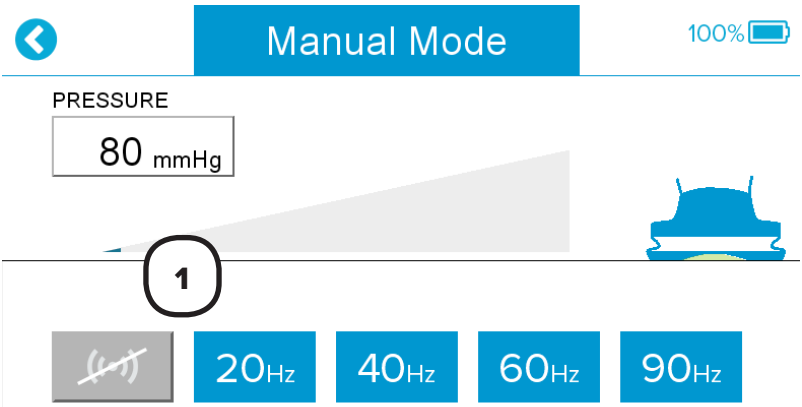
1. Go to previous screen
2. Adjust screen rightness
3. Adjust Treatment Handle LEDs
4. Change language
5. Enter numeric keypad screen.

9.5 Numpad screen



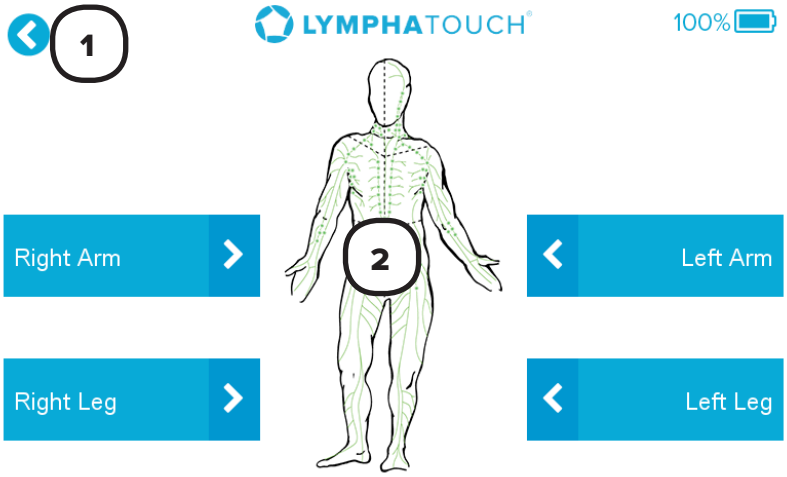
1. Go to previous screen
2. Code is shown here
3. Numeric keypad for entering code

9.4 Vibration setting screen

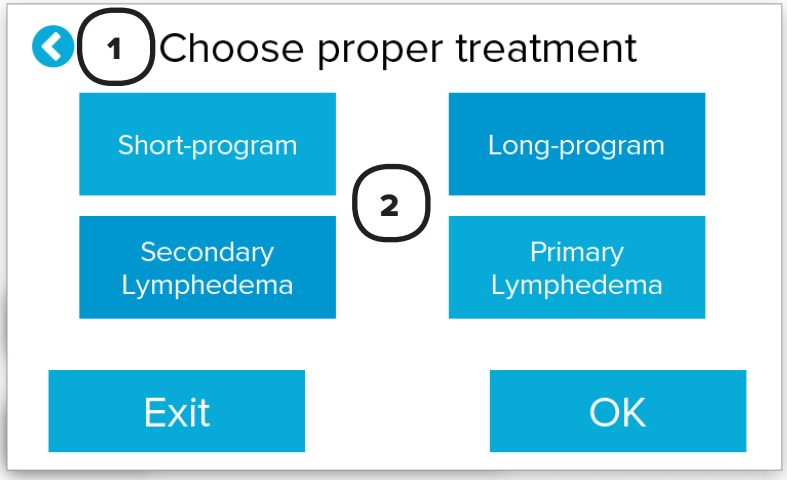


1. Set vibration value

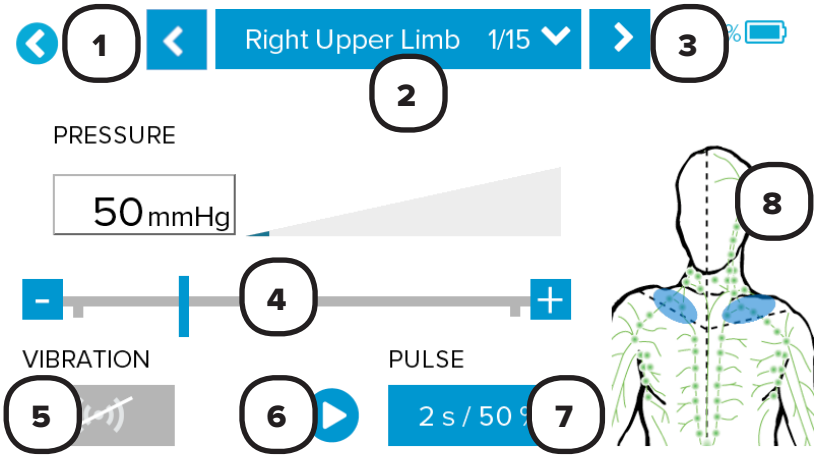
9.6 Programs screen



1. Go to previous screen
2. Select a suitable program for you with a healthcare professional and make sure you understand the contraindications before the treatment.



1. Go to previous screen
2. Select correct program



1. Go to previous screen
2. Dropdown list from which instructions for treated part are shown.
3. Arrows for jumping forward or backward in treatment program
4. Adjust pressure
5. Adjust vibration
6. Start treatment
7. Adjust pulse settings
8. Treatment area

10. Maintenance, cleaning and storing the device

Check the device for visible damage or malfunctions regularly, and replace accessories if required.

10.1 Treatment cup maintenance and cleaning

Wipe the treatment cups carefully using for example Oxivir after each use. Disconnect the soft covers from the 60 mm treatment cup during the cleaning process. The treatment cups are not autoclavable.

On the closed end of the treatment cup there is a small opening for filters. Filters prevents dust and debris from entering the device.
Manufacturer recommends that treatment cups are replaced with new ones regularly or latest when there is visible wear and tear. Filters are changed for every treatment for ensuring better hygiene.

10.2 Cleaning main unit and other parts

Clean the LymphaTouch® main unit, cable and Treatment Handle by wiping them with a cloth containing mild detergent, for example Oxivir. Do not autoclave any parts of the device.

Cleaning instructions for surfaces:

- Shut down the device.
- Dampen a soft cloth with for example Oxivir.
- Lightly wipe the surfaces with soft cloth.
- Be careful not to scratch the dis advice from home healthcare play.
- Dry the surfaces with a dry soft cloth.

10.3 Storing device between uses

See safety precautions Chapter #1.1 and technical data Chapter #15 for advises how to store the device.

11. TROUBLESHOOTING

The section below provides assistance in certain problem situations. If the suggested corrections do not fix the situation, contact device's retailer for more instructions, or return the device for service.

Problem: Device will not turn on

- Battery may be empty. Connecting to mains will start charging the battery, and allow using the device with mains power immediately.
- There may be an internal error which has caused the system to halt. Press the on/off switch for 5 seconds to shutdown the device. Press again to start the device again

Problem: Treatment handle not available ERROR CODE 0411

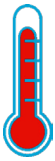
- See Chapter 12.

Problem: Suction will not start when the Treatment Handle is brought to near to the skin

- Attach the filter to the treatment cup if missing.
- If the treatment cup is not properly connected, the error message will be displayed.
- Verify that the treatment cup is properly connected to the Treatment Handle.
- Replace treatment cup if necessary.

Problem: Device is overheated

- Device is used with maximum performance long period of time in hot environment.
- Wait until the unit cools down and the error message disappears.

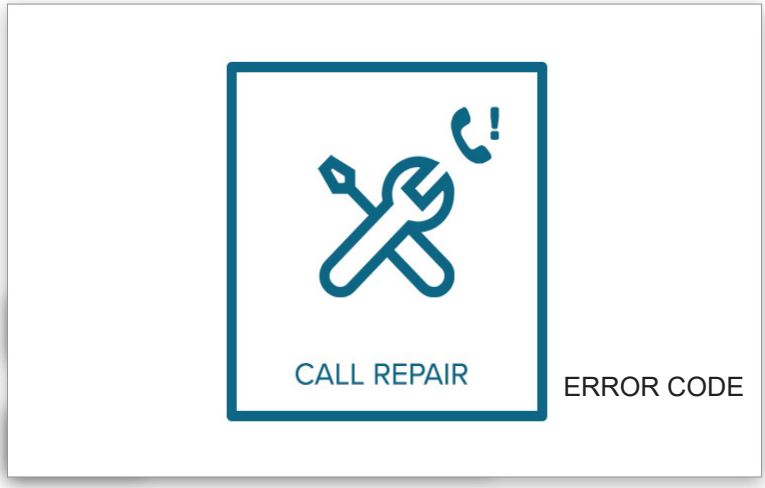


Problem: Suction initiates, but the set negative pressure is not achieved.

- Ensure that the treatment cup fits tightly on the area you are attempting to treat. Try to find a location where you can achieve an airtight connection or replace treatment cup with the size that fits better.
- The filter in the treatment cup may be clogged. Replace the filter.
- Verify that the treatment cup is properly connected to the Treatment Handle.
- Verify that the soft treatment cup cover is properly connected to the treatment cup and intact.
- Wear and tear of the treatment cup may result in leaks appearing. Verify and replace the treatment cup if necessary.

12. SERVICE

If the device malfunctions or the error message below appears, first try to reset the device by pressing the on/off switch for 10 seconds. If the error message reappears, contact the reseller and inform the error code displayed on the lower right corner.



Warning, Danger - Only persons certified by LymphaTouch Inc are authorized to perform servicing of the device. Opening the device or servicing the device without authorization will result in voiding the warranty and may lead to serious injury or damage to the equipment.

If you need assistance for setting up, using or maintaining the device or you need to report unexpected operation or events of the device, please contact to your local distributor or go to website: lymphatouch.com

13. SOFTWARE UPGRADE

LymphaTouch Inc. releases new software versions to the LymphaTouch® unit from time to time. Software can be easily upgraded by using a USB memory stick.

The software upgrade is provided either via email, internet, or directly on a USB stick. More detailed instructions on performing the software upgrade and detailed description of the new software features will be included with each software upgrade.

If you have received a software zip-file upgrade via email or downloaded it from them lymphatouch.com web site, unzip the file to the USB memory stick root folder. There should be the following file on the memory stick when the upgrade process is initiated: image.bin. Other files on the memory stick will not disturb the upgrade process.

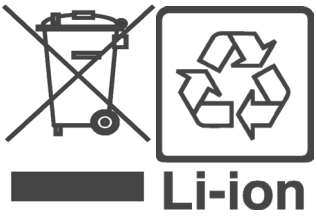
Proceed with the software upgrade according to the following steps:

- Keep the device connected to mains during the upgrading.
- Turn off the device.
- Connect the memory stick to the USB connector on the left side of the device.
- Turn on the device. The device will immediately start upgrading the software.
- Do not disconnect the memory stick until you see the LymphaTouch logo and device has restarted.
- Upgrading is complete and the device is ready for use.

If you have several LymphaTouch® treatment devices in use, it is recommended that all units are upgraded to the same software version.

14. Disposal

This is an electronic device containing a lithium-ion battery as an internal power source. Do not throw away the device with normal household waste at the end of its life. Consider the environment: deliver the device for recycling at an official collection point for electronic devices. Check with the appropriate recycling organization for local disposal information.



15. TECHNICAL DATA

Dimensions (WxHxD)		19 x 10 x 11,5 cm
Weight		1.1 kg
Power requirements	Adapter, Delta Electronics Inc. Model: MDS-030AAC15	100-240 VAC, 50-60 Hz Output: 15Vdc, 2A, 30W Device input 15Vdc, 2A
Battery	Type	LT-1200 Lithium Ion 10,8V, 5.2Ah, 56Wh
	Replacement interval	~3 years (*)
	Duration time in use	~8 hours (*)
	Duration time in stand by	18 hours (*)
	Charging while in use	8 hours (*)
	Charging while in stand-by	6 hours (*)
CLASS 1 LASER PRODUCT	Standard	IEC 60825-1:2014
	Max output power	0.97 mW
	Pulse duration	t < Ti Ti = 10^-6s
	Wavelength	850 nm

(*) Estimated time. Time can vary due to the ambient and / or device temperature.
Note: Designed lifetime for the adapter is two years.

At maximum stress and ambient temperature being maximum allowed (35 °C) the temperatures of the device parts may reach as stated in the following table. Avoid exeeding the touching time (t) and keep short pauses after touching the parts.

Device part	**Temperature**	**Time allowed to touch the part**
Touchscreen	49.2°C	t <1 min
Enclosure top	42.5 °C	10 min ≤ t
Treatment Handle	42.5 °C	10 min ≤ t

In these conditions it is advisable not to load battery while patient is treated.

Environmental conditions	Use	+5°C ... +35°C, humidity 15% - 85% non-condensing, 700-1060 hPA
	Storage and transport	-25°C ... +60°C, humidity 15% - 95% non-condensing 700-1060 hPA
Classification		Medical device (CE-MDD), class 2a FDA Class 1, 510 (k) exempt
Conformity to standards		ISO 13485:2003 IEC 60601-1 IEC 60601-1-11
Performance specifications	Negative pressure adjustment	Range 20 - 350 mmHg Accuracy ± 10% + ± 10 mmHg
	Pulsation adjustment	Range 0.5s - 5 s Accuracy ± 10% + ± 0.05s
	Vibration adjustment	Range 20-90 Hz Accuracy ± 10%
Designed lifetime		2 years

16. EMC

16.1 Guidance and manufacturer's declaration – electromagnetic emissions

LymphaTouch® is intended for use in the electromagnetic environment specified below. The customer or the user of the LymphaTouch® should assure that it is used in such an environment.

Warning: Use of accessories and parts other than those specified, with the exception of accessories and parts sold by LymphaTouch Inc as replacement parts, may result in increased electromagnetic emissions or decreased immunity of the device to such emissions.

Warning: LymphaTouch® should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the LymphaTouch® should be observed to verify normal operation in the configuration in which it will be used.

Emission tests according to the test specification IEC 60601-1-2 ed.4.0

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The LymphaTouch® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The LymphaTouch® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable (low input power)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

16.2 Guidance and manufacturer's declaration – electromagnetic immunity

The LymphaTouch® is intended for use in the electromagnetic environment specified below. The customer or the user of the LymphaTouch® should assure that it is used in such an environment. Portable and mobile RF communications equipment can affect medical electrical equipment. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d (see tables on page 28) away from the any part of the LymphaTouch® including cables.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for IO-ports, 100kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for IO-ports, 100kHz repetition frequency	Mains power quality should be that of a typical professional healthcare facility environment and home healthcare environment
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical professional healthcare facility environment and home healthcare environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycle (1 phase) 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles (50/60 Hz) 0 % U_T for 250/300 cycles (50/60 Hz)	0 % U_T for 0.5 cycle (1 phase) 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles (50/60 Hz) 0 % U_T for 250/300 cycles (50/60 Hz)	Mains power quality should be that of a typical professional healthcare facility environment and home healthcare environment.
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 professional healthcare facility environment and home healthcare environment
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V 150kHz–80MHz 6V in ISM and amateur radio bands between 150kHz and 80MHz	3 V 150kHz–80MHz 6V in ISM and amateur radio bands between 150kHz and 80MHz	Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the any part of the LymphaTouch® including cables. The recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2*√(P) MHz to 800 MHz d=2.3*√(P)800 MHz to 2,5 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2.7GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2.7GHz 80 % AM at 1 kHz	
IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3	450 MHz, 50% PM at 18 Hz 810 MHz, 50% PM at 18 Hz 870 MHz, 50% PM at 18 Hz 930 MHz, 50% PM at 18 Hz 1720 MHz, 50% PM at 217 Hz 1845 MHz, 50% PM at 217 Hz 1970 MHz, 50% PM at 217 Hz 2450 MHz, 50% PM at 217 Hz	28 V/m	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3	385 MHz, 50% PM at 18 Hz	27 V/m	
	710 MHz, 50% PM at 217 Hz 745 MHz, 50% PM at 217 Hz 780 MHz, 50% PM at 217 Hz 5240 MHz, 50% PM at 217 Hz 5500 MHz, 50% PM at 217 Hz 5785 MHz, 50% PM at 217 Hz	9 V/m	

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 transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LymphaTouch is used exceeds the applicable RF compliance level above, the LymphaTouch should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the LymphaTouch
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 30 V/m.

17. TRAINING

All health care professionals, patients and caregivers should practice the use of the LymphaTouch with this instruction manual or the patient guide, training videos or receive training from a trained professional prior to performing LymphaTouch therapy.

LYMPHATOUCH®

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