

LYMPHATOUCH®



USER MANUAL

Model: LymphaTouch Pro LT02

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

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FDA device Class I, 510 (k) exempt, Quality 13485:2016. User manual applies for SW version 1.x.x.x. The information in this document is subject to change without prior notice. In a conflict situation the English version prevails.



LymphaTouch Inc.

Valimotie 13 A, FI-00380 Helsinki, Finland

web: lymphatouch.com

email: contact@lymphatouch.com

Safety and EMC certificate

LymphaTouch Pro® is CLASS 1 LASER PRODUCT
INVISIBLE LASER RADIATION



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NOTICE: Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State.

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 wrapped 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 over open wounds, fistulas, the eye intra-cavity areas, mucous membranes or the genital area.

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. 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 Pro is not intended for field repair. Opening the device without authorization from LymphaTouch Inc. will void the responsibility of the manufacturer. Only trained service personnel is allowed to change the lithium ion battery.

Warning Comply to device usage, transport and storage environmental specifications in Chapter 15. Device may otherwise malfunction.

- Do not use the device near moist conditions, for example nebuliser, steam kettle.
- Do not 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 Chapter 15 are met.
- When the device is taken from minimum or maximum storage temperatures, let it rest for two (2) 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.
- Do not interconnect the device with other devices.
- If you experience performance degradation and troubleshoot in Chapter 11 doesn't help, contact your local re-seller.
- Use treatment cups and treatment setting that are best suited to the anatomy and skin type of the patient you are treating.
- The device is intended to be used only by persons who are knowledgeable about the treatment methods or under supervision of those persons.

2 APPLICATION SPECIFICATION

Intended use:

LymphaTouch Pro is a negative pressure-based therapy device. The device is intended to be used as a tool for manual therapy. The intended user is a healthcare professional with appropriate knowledge of manual therapy.

Intended conditions of use:

The environment, where this device is typically used is; physiotherapy setting, including hospitals and physiotherapy centers.

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 blood and lymphatic circulation and reduction of edema, for example postoperative edema and lymphedema in treated area, and soft tissue mobilization.

Device is used on any one deemed to be appropriate for a physical treatment.

The person using the device should be aged and have enough knowledge to be able to understand and follow the instructions for the treatment and understand the operation of the device.

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. 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. Vertical stretching of the fascial (connective tissue) structures is accomplished at the same time, expanding the space for circulation of blood and lymph and mobilizing soft tissue.

3 PACKAGE CONTENTS

- LT02 LymphaTouch Pro therapy device (LT-2002)
- User manual
- Country specific adapter

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 60 mm 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. Mains power
2. USB 
3. Power on / off
4. Cable input



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 on the device or the package.

SYMBOL	DESCRIPTION
	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.
	Serial number of the device.
	Unique device identification code.

SYMBOL	DESCRIPTION
	Do not use sharp instrument to open the package
	Fragile. Handle with care.
	Humidity limitation. See more from table, page 26.
	Keep dry.
	Temperature limitation. See more from table, page 26.
	Atmospheric limitation. See more from table, page 26.
	A healthcare professional will provide the instructions on how to use the device.

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 Pro has an internal battery that should be fully charged before first use. When device is used via battery and the device is on, the power button light is green. Also when battery is recharging, the light is green.

7.3 Connecting treatment cable to main unit

Connect the cable to the round connector on the left side of the main unit. Make sure the cable is tightly connected. Do not use excessive force or rotate the connector. To disconnect, pull the connector straight.



7.4 Connecting a treatment cup to the treatment handle

Select the appropriate treatment cup for the body area in question. Please refer to the Chapter 8.4 "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.



7.5 Using filters in the treatment cup

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



7.6 Connecting removable soft part to the treatment cup

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



7.7 Using the 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 loosely from the device. User can use the device in any position.

Attach the treatment cup to the treatment handle. Place the treatment cup against the skin. The device will automatically start suction, when getting skin contact.



To terminate the operation quickly, press on/off button for one (1) second or back button, when in treatment screen. It is safe to stop treatment at anytime.

7.8 Power supply with country adapters

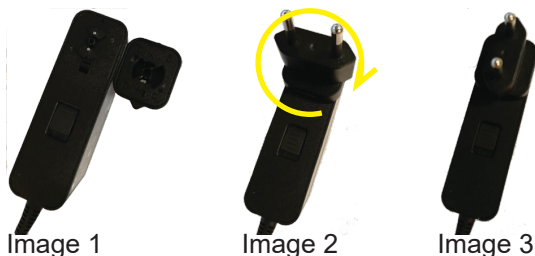
LymphaTouch Pro package contains country-specific adapter.

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.

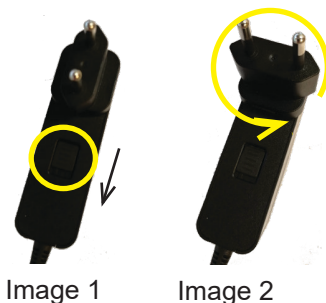
Image 3: After connecting the plug, it should look like this.



Disconnecting country adapter from the power supply:

Image 1: Move the release switch in to the direction of the arrow

Image 2: While holding the switch, turn the adapter anti-clockwise.



For safety purposes, do not position the device so 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.

8 USING THE LYMPHATOUCH PRO 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 ten (10) seconds. To turn off the device, press the on/off switch and hold it two (2) seconds. The device will also shutdown automatically after 20 minutes of inactivity, while on battery power.

8.2 *Treatment preparation*

LymphaTouch treatment does not require special preparation. The treatment is applied to bare skin.

Application of massage cream is recommended to reduce friction between skin and the treatment cup, the treatment cup will glide more smoothly on the skin.

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.

8.3 *Treatment handle lens and sensors*

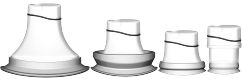
LymphaTouch Pro treatment handle has a lens inside. Avoid scratching the lens and keep the lens clean for best performance. If the lens gets scratchy, this may cause sensors performance to degrade.

8.4 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 soft part	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

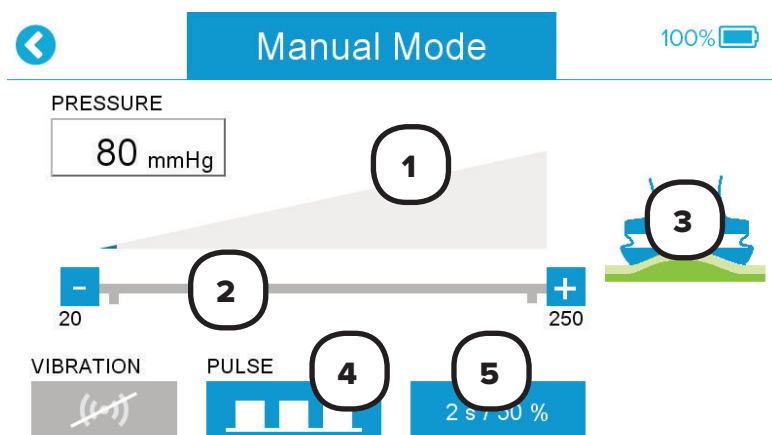
8.5 Accessories

Code	Accessory	Image
LT-1004-10	Treatment cup 10 mm, 4 pcs	
LT-1004-35	Treatment cup 35 mm, 4 pcs	
LT-1004-50	Treatment cup 50 mm, 4 pcs	
LT-1004-60	Treatment cup 60 mm, 4 pcs	
LT-1004-80	Treatment cup 80 mm, 4 pcs	
LT-1004-mix	Treatment cups 1x35 mm, 1x50 mm, 1x60 mm, 1x80 mm	
LT-1315-5	Filters for treatment cups, 500 pcs	

Use these codes to order accessories from your re-seller.

9 TREATMENT SETTINGS

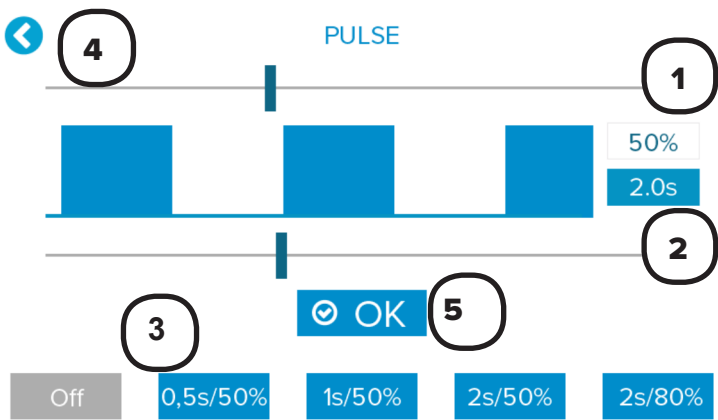
Turn on the device. LymphaTouch Pro main screen will appear (see picture). The default setting is 80 mmHg with two (2) seconds pulsation. The unit will start operating automatically when the treatment cup is put close to the treated target.



1. The setting is indicated on the main screen in 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 to 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

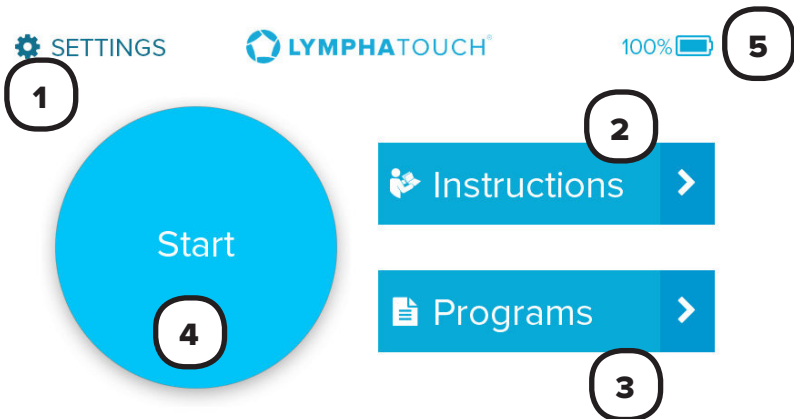
If the desired negative pressure is not achieved, make sure that the treatment cup selected is suitable for the treated area of the body. If necessary, replace the treatment cup with a more appropriate size, or re-position the treatment cup carefully on the skin. Also, the body hair may cause air leakage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

9.1 Pulsation screen



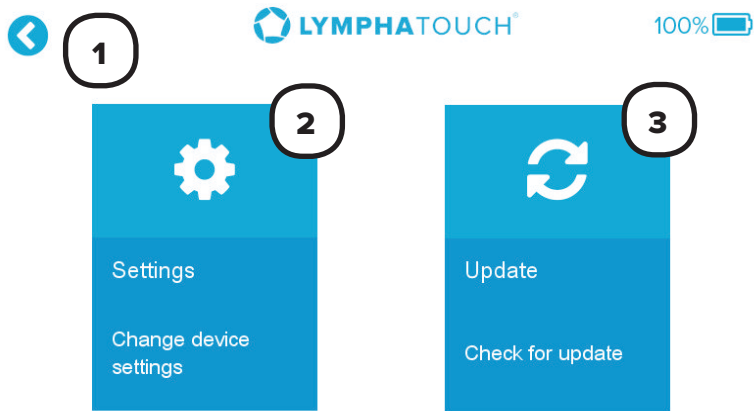
1. Set work/rest ratio by sliding the slider at the top of the screen between 30 – 90%.
2. Set pulse length by sliding the lower slider.
3. Quick settings
4. Return to previous screen
5. Save settings and return to previous screen.

9.2 Start screen

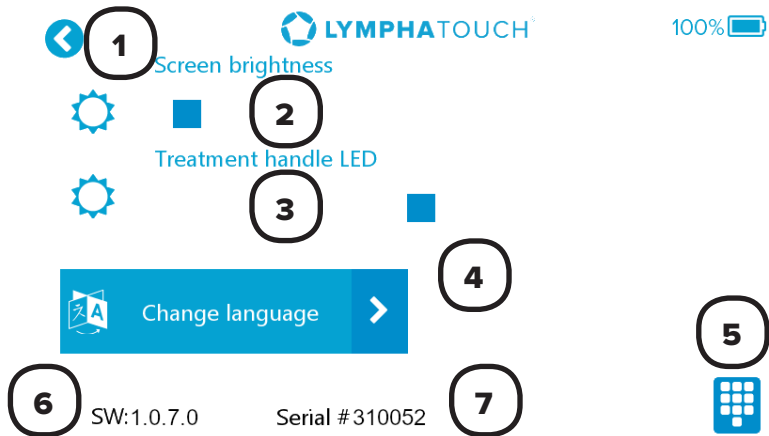


1. Go to Settings
2. Instructions how to use device
3. Treatment programs
4. Quick start to free mode
5. The battery icon indicates the battery charge level. When the device is connected to the mains, battery is charging, which is indicated by a flash icon.

9.3 Settings screen

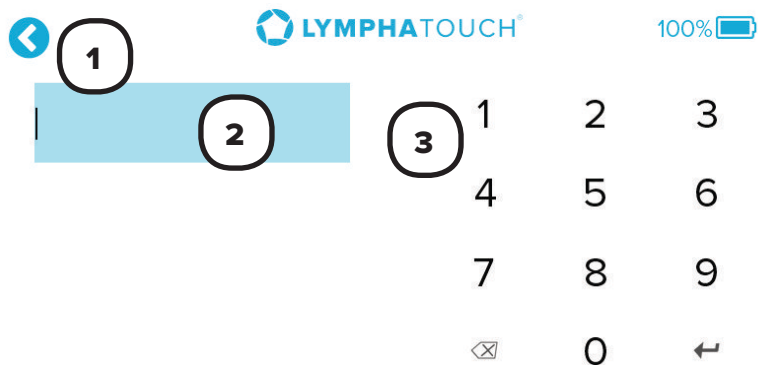


1. Go to previous screen
2. Set screen brightness, language and use numeric keypad to input codes
3. Guidance for the software upgrade



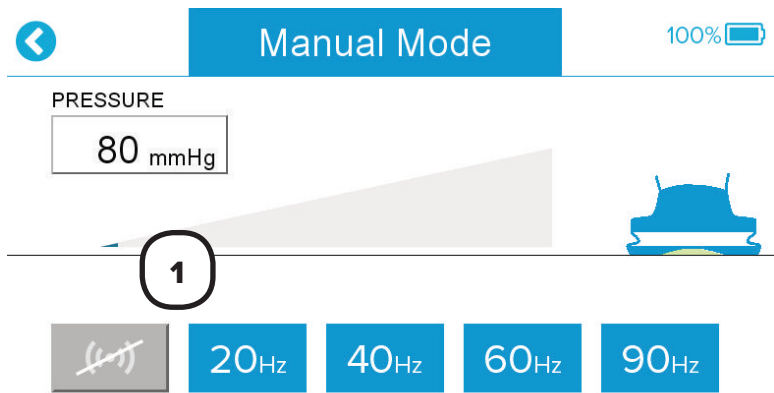
1. Go to previous screen
2. Adjust screen brightness
3. Adjust treatment handle LEDs
4. Change language
5. Enter numeric keypad screen.
6. Software version number
7. Device serial number

9.4 Numpad screen



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

9.5 Vibration setting screen

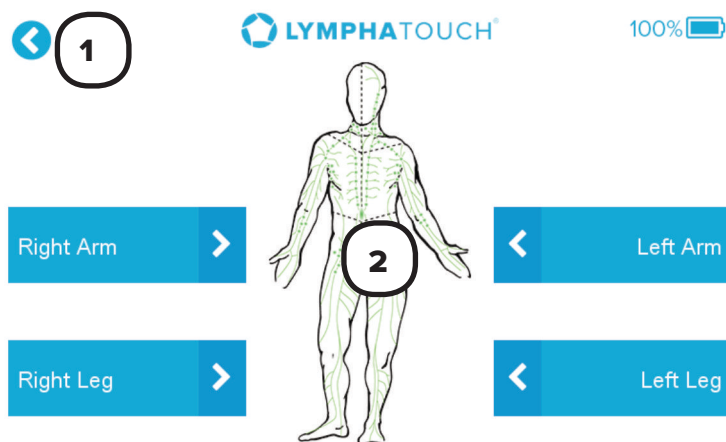


- 1. Set vibration value

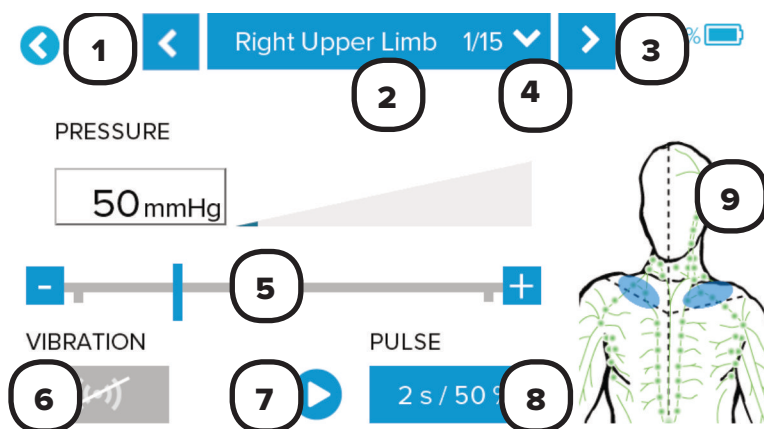
9.6 Programs screen



1. Go to previous screen
2. Select Lymphatic program
3. Select Pre- and Post-operative program



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. Dropdown list, where instructions for treated part are shown
3. Arrows for jumping forward or backward in treatment program
4. Arrow pointing down shows treatment settings panel
5. Adjust pressure
6. Adjust vibration
7. Start treatment
8. Adjust pulse settings
9. Treatment area

10 MAINTENANCE, CLEANING AND STORING THE DEVICE

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

10.1 Treatment cup maintenance and cleaning

Clean the treatment cups after every treatment session. Use a mild disinfectant to wipe the cups, for example Oxivir.

The elastomer ring should be removed from the 60 mm treatment cup when cleaning the cup. If the treatment cups are used heavily, the elastomer ring may become worn out and soften faster. In this case, replace the treatment cups more frequently to ensure a proper negative pressure treatment.

On the closed end of the treatment cup there is a small cavity for filter. Filters prevent dust and debris from entering the device. Filters are changed for every treatment, for ensuring better hygiene.

Manufacturer recommends that treatment cups are replaced with new ones regularly or latest when there is visible wear and tear.

Note:

- Avoid exposure to sun light or bright light from lamps.
- It is advisable to rub fingers along the o-ring with a small amount of massage cream.
- The treatment cups are not autoclavable.

10.2 Cleaning main unit and other parts

Clean the LymphaTouch Pro 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 display.
- 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 advice 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 re-seller 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 five (5) seconds to shutdown the device. Press start button to start the device.

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 for a long period of time in hot environment.
- Wait until the unit cools down and the error message disappears.

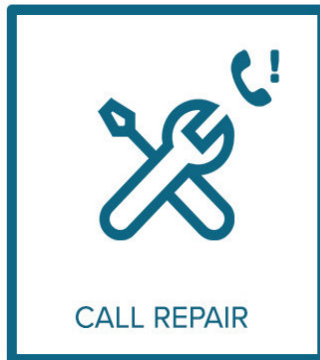


Problem: Suction initiates, but the set negative pressure is not achieved.

- 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 a 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 there is a malfunction or the error message below appears, first try to reset the device by pressing the on/off switch for five (5) seconds. If the error message reappears, contact the re-seller and inform the error code displayed on the lower right corner.



ERROR CODE

Warning, Danger

Only persons certified by LymphaTouch Inc. are authorized to perform service 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 re-seller or go to website: lymphatouch.com

13 SOFTWARE UPGRADE

LymphaTouch Inc. releases new software versions for the LymphaTouch unit from time to time. Software can be easily upgraded by using a USB 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 the lymphatouch.com web site, unzip the file to the USB stick root folder. There should be the following file on the stick when the upgrade process is initiated: image.bin. Other files on the 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 upgrade.
- Turn off the device.
- Connect the 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 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 Pro 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 lifetime. 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)		230 x 180 x 178 mm
Weight		2.7 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	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	$t < T_i$ $T_i = 10^{-6}$ s
	Wavelength	850 nm

(*) Estimated time. Time can vary due to the ambient and / or device temperature.

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 exceeding 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	$10 \text{ min} \leq t$
Treatment handle	42.5 °C	$10 \text{ min} \leq t$

In these conditions, it is advisable not to charge the 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		FDA Class 1, 510 (k) exempt
Conformity to standards		ISO 13485:2016 IEC 60601-1 IEC 60601-1-11
Performance specifications	Negative pressure adjustment	Range 20 - 400 mmHg Accuracy $\pm 10\%$ + ± 10 mmHg
	Pulsation adjustment	Range 1.0 - 5 s Accuracy $\pm 10\%$ + $\pm 0.05s$
	Vibration adjustment	Range 20 - 90 Hz Accuracy $\pm 10\%$
Designed lifetime		2 years

16 EMC

16.1 Guidance and manufacturer's declaration – electromagnetic emissions

LymphaTouch Pro is intended for use in the electromagnetic environment specified below. The customer or the user of the LymphaTouch Pro 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 Pro 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 5.2.1.1. a).

Warning The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The LymphaTouch Pro 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 A	The LymphaTouch is suitable for use in all establishments other than domestic.
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 Pro is intended for use in the electromagnetic environment specified below. The customer or the user of the LymphaTouch Pro should assure, that it is used in such an environment.

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 LymphaTouch Pro, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact $\pm 2, \pm 4, \pm 8, \pm 15$ kV air	± 8 kV contact $\pm 2, \pm 4, \pm 8, \pm 15$ kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical professional healthcare facility environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical professional healthcare facility 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.
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.
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 radio bands between 150kHz and 80MHz	3 V 150kHz – 80MHz 6V in ISM and radio bands between 150kHz and 80MHz	Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations and walkie-talkies, can affect this equipment and should be kept at least a distance d away from 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 $d = 1.2 \cdot \sqrt{P}$ MHz to 800 MHz $d = 2.3 \cdot \sqrt{P}$ 800 MHz to 2,5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a. should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7GHz 80 % AM at 1 kHz	3 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 385 MHz, 50% PM at 18 Hz	28 V/m	
	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 Pro with this user manual or the treatment instructions, training videos or receive training from a trained professional prior to performing LymphaTouch therapy.

18 WARRANTY

LymphaTouch products must be purchased from an authorized LymphaTouch re-seller. Please keep your proof of purchase to validate your warranty.

LymphaTouch devices are warranted to be free of manufacturing defects (for the periods outlined below) from the date of purchase. This warranty is void if the product is modified or altered, is subject to misuse or abuse, damaged in transit or lack of responsible care, is dropped, if damage occurs by reason of failure to follow written instruction manual, or if product repairs are carried out without authority from LymphaTouch distributor.

Product warranty period:

- LymphaTouch Pro main unit 2 years
- LymphaTouch treatment handle 1 year
- Batteries 6 months
- Accessories are warranted to be free from defects in materials and workmanship appearing
- Accessories are not warranted for wear and tear

We will repair, or at our option replace free of charge, any parts necessary to correct material or workmanship, or replace the entire unit and return to you during the period of warranty. Otherwise, we will quote for any repair which will be carried out on acceptance of our quotation.



Lymphatouch Inc.

Valimotie 13 A, 00380 Helsinki, Finland

Tel. +358 (0)10 423 7300

contact@lymphatouch.com

www.lymphatouch.com

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