

# *LymphaTouch*®

## User Manual

Ver. A01 SW rev. 1.1

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 and your patient.



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## Manufacturer

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## Safety and EMC certificate



HLD LymphaTouch® A01 conforms with Medical Device

Directive 93/42/ETY

HLD LymphaTouch A01 conforms with medical electrical equipment electromagnetic compatibility EN 60601-1-2 (2007)

## Safety

In this User Manual, safety precautions and warnings are indicated with the following symbols. Make sure to read and understand all safety precautions and warning 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.

## Safety precautions



- Clean the device and accessories regularly following the instructions and the regulations of your institution, to ensure safe and hygienic use.
- Use and store the device only under the environmental conditions specified.
- Handle the device with care, and follow the instructions for maintenance.
- Use only accessories and mounting provided by or approved by HLD.
- Use mouthpieces and treatment setting that are best suited to the anatomy and skin type of the patient you are treating.
- Avoid situations where the unit might fall or collide with a heavy object.
- Inspect the device and the related accessories for cracks or other signs of overuse, and replace accessories as required.
- Make sure the filter in the mouthpiece is in place before attaching it to the treatment head, to avoid dust and debris from being sucked into the device.
- Never use the unit for purposes other than those recommended by HLD. HLD will not be liable for any inappropriate use of the equipment.



## **Intended use:**

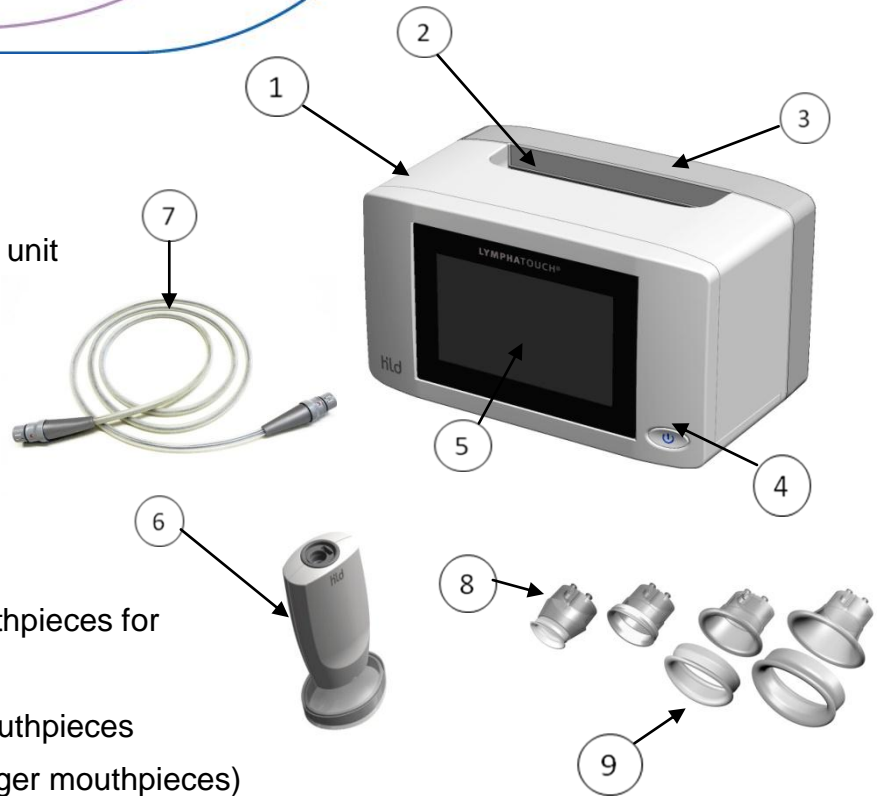
LymphaTouch® is a negative pressure-based therapy device and aid for physiotherapy and lymphatic drainage therapy. The device is meant to be used by persons who are knowledgeable about the treatment method or under supervision of those persons.

## **Contraindications for LymphaTouch treatment:**

- Do not use on a pregnant patient without prior consultation with the attending doctor.
- Do not use on a patient with cancer without prior consultation with the attending doctor.
- Do not use on areas with inflammation.
- Be very careful when applying on fragile skin (e.g., due to cortisone treatments), and on the throat area.
- If you are uncertain of the suitability of LymphaTouch for treatment of your patient, consult with the attending doctor prior to starting the treatment.
- In addition, all contraindications of manual lymphatic drainage apply.

## Parts description

1. LymphaTouch® main unit
2. Handle
3. Battery module
4. On / Off switch
5. Touch screen
6. Treatment head
7. Cable
8. Different sizes of mouthpieces for the treatment head
9. Soft covers for the mouthpieces (detachable on the larger mouthpieces)



## Connectors

Mains power

Integrated air hose and cable



Local area network










USB



## Symbols and product markings

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

Symbol	Description
	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 Class BF, according to the standard EC 60601.
	The device has double insulation; connection to mains does not require a grounding pin.
	This symbol appears next to a connector enabling connecting a battery module expansion.
	The battery module contains a lithium-ion (Li-Ion) battery. A battery of this type must not be discarded in regular waste.
	Lithium-ion battery must be disposed of properly.

## Installation

### Unpacking

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



We recommend you keep the box in case you need to return the device or send the device for service – it is most safely transported in the box it was originally shipped in.

### Connecting the battery module

The main unit can be operated with or without the battery unit. Connect and disconnect the battery to the main unit using the two screws attached to the battery unit.

During battery recharge, a yellow light blinks in the power button.



Do NOT open the battery module. Only a qualified service engineer can open the battery module.

## **Connecting and disconnecting the cable**

Attach the integrated air hose and cable to the round connector on the left side of the unit. Make sure the cable is tightly connected, but do not use excessive force or rotate connector.

To disconnect, pull the connector in a straight angle.

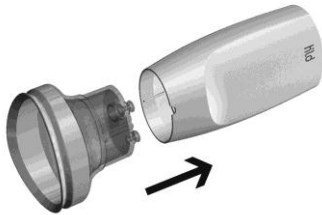
## **Connecting and disconnecting the treatment head**

Attach the integrated air hose and cable to the round connector on the left side of the unit. Make sure the cable is tightly connected, but do not use excessive force or rotate connector.

To disconnect, pull the connector in a straight angle.

## Connecting a mouthpiece to the treatment head

Select the appropriate mouthpiece for the patient and body area in question. Please refer to the section "Selecting a mouthpiece".



Connect the mouthpiece to the treatment head as indicated in the figure.

**!** Make sure the mouthpiece is connected in right orientation, as indicated by the guiding rails.

**!** **Push to ensure the treatment head is properly connected. If necessary lubricate rubber gaskets in a very small amount of massage oil.**

## Placing the LymphaTouch device for treatment use

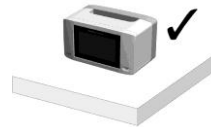
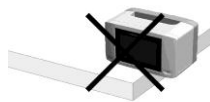


We recommend permanent fixture to the LymphaTouch® Roll Stand (see figure) when the device is used primarily in one location. The Roll Stand is designed for safe, efficient and ergonomic use.

Instructions for connecting the LymphaTouch® main unit to the Roll Stand are included in the Roll Stand package.



Use only mounting elements provided or recommended by HLD Healthy Life Devices Ltd to mount the device. If the device is not attached properly, it may fall and cause injury or damage to the equipment.



## Using the LymphaTouch device

### Turning the device on and off

Turn the device on by pressing the on/off switch in the lower right hand corner. Wait a while as the device starts. To turn off the device, press the on/off switch. The device will also shut down automatically after an hour of inactivity, while on battery power.



### Screen saver

The display will shut itself down and the device will enter a power-saving mode when the device has not been used for 30 minutes. Reactivate the unit by pressing the on/off switch or by touching the screen.

## **Patient preparation**





LymphaTouch® treatment does not require special preparation of the patient. The treatment is applied to bare skin. If needed, see separate application guides for different treatments.

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

If the patient's skin is very dry and producing dandruff, the filter in the mouthpiece may get clogged faster than normal. Do not use talcum powder or other powdery top agents on the skin.

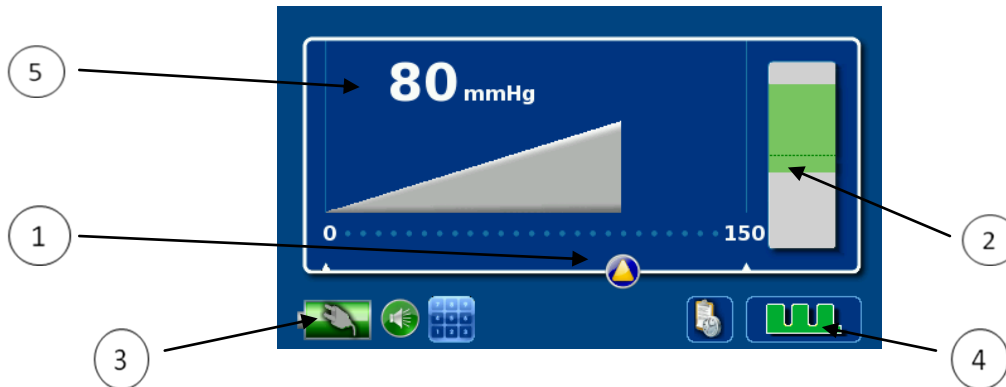
## Selecting a mouthpiece

Select the proper size mouthpiece 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.


Mouthpiece	Dimension	Body areas
 HLD0380	80 mm	<ul style="list-style-type: none"><li>- torso</li><li>- lower limbs</li></ul>
 HLD0360	60mm	<ul style="list-style-type: none"><li>- torso</li><li>- lower limbs</li></ul>
 HLD0350-2	50 mm	<ul style="list-style-type: none"><li>- upper chest</li><li>- upper limbs</li></ul>
 HLD0335-2	35 mm	<ul style="list-style-type: none"><li>- hands, fingers</li><li>- face</li><li>- feet</li></ul>

## 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 mouthpiece is put close to the treated target. The vacuum is adjusted with the touch screen by moving the slider (1) at the desired location. The



pressure range is determined by the size of the nozzle. The setting is indicated on the main screen on the top left (5), as well as graphically in the form of a wedge. During treatment a purple wedge appears which indicates the current vacuum in the mouthpiece.

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

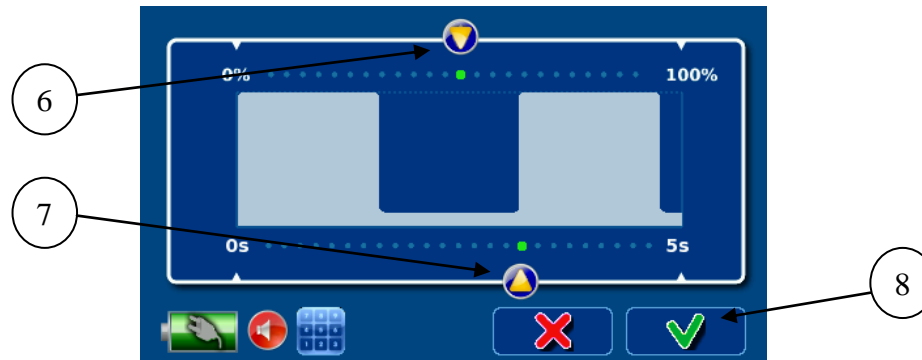
The bar (2) on the right hand side of the screen indicates the distension of the skin in the middle of the mouthpiece, as a result of the applied negative pressure.


The battery icon in the lower left hand corner (3) indicates the battery charge level. When the device is connected to the mains, the top of the battery icon is a power plug icon and when the battery is charging, a flash icon.

During treatment, it is possible to choose either pulsating or continuous treatment.

The pulsation button (4) at the bottom right is green when pulsation is activated. The button is white when the pulsation is inactive.

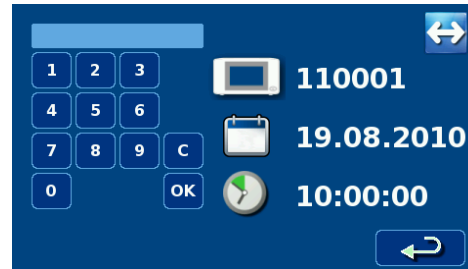
To modify the pulsation setting, touch the pulse symbol (5) on the main screen, and the pulsation setting screen will appear (see figure below).



- 
- Set pulse length by sliding the arrow, or by pressing the desired location on the axis on the lower part of the screen (7).
  - Set work/rest ratio by sliding the arrow at the top of the screen (6).
  - Confirm pulsation settings and return to main screen by touching the green “check” sign (3). Remove pulsation and return to main screen by pressing the red “cancel” symbol.

## Activation of additional features

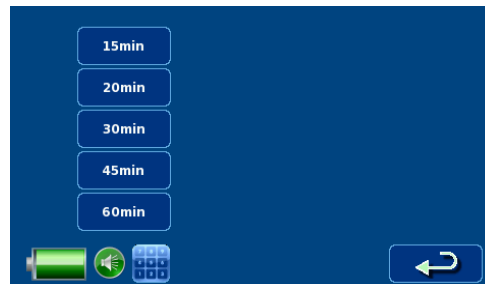
Press the keypad button to open additional features activation screen



An additional features activation code can be entered from this window. Also this window displays the serial number, current date, thumbnails of additional features and potential licensed 'tariff' time.

## Treatment timer

LymphaTouch has preset treatment times that can be selected from the timer display. Press the treatment button to open a display where you can select the desired duration of treatment.



Remaining duration of treatment is shown on the main display. See the picture below. When treatment time ends LymphaTouch will beep if the signal indicator is selected.



## Maintenance and cleaning

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

### Mouthpiece maintenance and cleaning

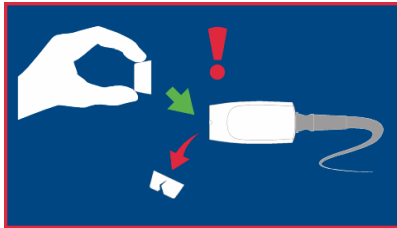


**Never use a mouthpiece without a filter in place, as this will result in dust and debris being transported inside the LympaTouch device and the device being damaged.**

Mouthpieces are intended for same patient use only. Wipe the mouthpieces using a mild detergent after each use. Disconnect the soft covers from the larger mouthpieces (80 mm and 60 mm) during the cleaning process. The mouthpieces are not autoclaveable.

Inside the mouthpiece is a small, white filter that prevents dust and debris from entering the device. When cleaning the mouthpiece, be careful not to touch the filter, as the detergent may also cause clogging of the filter.

Normally a mouthpiece filter will function for a whole patient treatment care series. In a very dusty environment, or if the patient's skin is releasing particles, the filter may get clogged. This will result in difficulty achieving the set pressure. Replace the mouthpiece in order to continue an efficient treatment. The error message below is displayed if filter is clogged.



### **Cleaning main unit and other parts**

Clean the LympaTouch main unit, cable and treatment head by wiping them with a cloth containing mild detergent. Be careful not to scratch the display. Do not autoclave any parts of the device.

## Troubleshooting

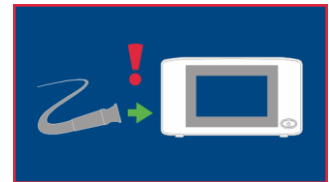
The section below provides assistance in certain problem situations. If the suggested remedies do not fix the situation, contact service for more instructions, or return the device for service.

**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 10 seconds to reset the device or temporarily remove battery.

**Problem:** Treatment cable disconnected

- Verify that the cable is properly connected both to the device and to the treatment head. Contact service if necessary.



**Problem:** Device is on stand-by but suction will not start when the treatment head is brought to the patient's skin.


- Verify that the mouthpiece is properly connected to the treatment head. Replace if necessary. If the mouthpiece is disconnected, the error message will be displayed.



**Problem:** Device is overheated

- Wait until the unit cools down and the error message disappears.



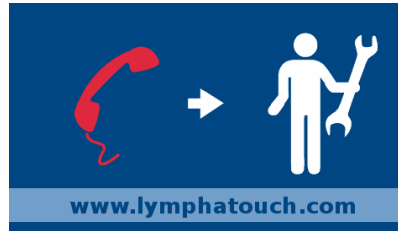


**Problem:** Suction initiates, but the set negative pressure is not achieved.

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

## 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 or a certified service company.



Only persons certified by HLD Healthy Life Devices Ltd 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.



## Software upgrade

HLD Healthy Life Devices Ltd release new software versions to the LymphaTouch unit from time to time. Software can be easily upgraded using a USB memory stick.

The software upgrade is provided either via email, or 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 [www.lymphatouch.com](http://www.lymphatouch.com) Web site, unzip the file to the USB memory stick root folder.

There should be the following two files on the memory stick when the upgrade process is initiated: targetfs\_vx.xx.bin and update.spec. Other files on the memory stick will not hamper the upgrade process.

Proceed with the software upgrade according to the following steps:

- If the device is operating on battery power, make sure there is at least 10% battery charge left when the upgrade process starts. If not, 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, and follow the instructions on the screen.
- Do not disconnect the memory stick, until instructed to do so.
- The device will restart and upgrade the treatment head if necessary. If the treatment head is not connected at the time, it will be upgraded the next time it is connected.
- 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 level.

## Technical data

Dimensions (w x h x d)	Without battery module	19 x 10 x 8,5 cm
	With battery module	19 x 10 x 11.5 cm
Weight	Without battery module	1.0 kg
	With battery module	1.7 kg
Power requirements		100-240 VAC, 50/60 Hz, 90 VA
Battery	Type	HLD-200 Litium Ion
	Replacement interval	~3 years
	Duration time in use	8 hours
	Duration time in stand by	24 hours
	Charging while in use	8 hours
	Charging while in stand-by	5 hours

Environmental conditions	Use	10° - 40° C, humidity 15 - 90 % non-condensing, altitude -170 - 3050 m
	Storage and transport	0° - 50° C, humidity 15 - 90 % non-condensing, altitude -170 - 3050 m
Classification		Medical device (CE-MDD), class 2a
Conformity to standards		ISO 13485:2008 EC 60601-1
Essential performance	Negative pressure	Range 10-250 mmHg Resolution 1 mmHg Accuracy ± 10% + ± 10 mmHg

# EMC

## Guidance and manufacturer's declaration – electromagnetic emissions

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.



Warning: Use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by HLD Healthy Life Devices as replacement parts for internal components, 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 EN 60601-1-2 (2007).

<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>
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	

## 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.

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 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.

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
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 commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	30 % / 25 periods 60 % / 5 periods 100 % / 0.5 periods > 95 % / 5000 ms (interruption)	30 % / 25 periods 60 % / 5 periods 100 % / 0.5 periods > 95 % / 5000 ms (interruption)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LymphaTouch requires continued operation during power mains interruptions, it is recommended that LymphaTouch be installed with battery option.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-6</p>	<p>3 Vrms 150 kHz - 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3 Vrms</p> <p>3 Vrms</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the LympaTouch including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> <p><math>d = 1.2 \cdot \sqrt{P}</math></p> <p><math>d = 1.2 \cdot \sqrt{P}</math></p> <p>MHz to 800 MHz</p> <p><math>d = 2.3 \cdot \sqrt{P}</math></p> <p>800 MHz to 2,5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>



## Recommended separation distances between portable and mobile RF communications equipment and the LymphaTouch

The LymphaTouch is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LymphaTouch can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LymphaTouch as recommended below, according to the maximum output power of the communications equipment..

<b>Max Output Power (Watts)</b>	<b>Separation (m)</b> 150kHz - 80MHz $d=(3.5/\sqrt{P})(\text{Sqrt } P)$	<b>Separation (m)</b> 80MHz - 800MHz $d=(3.5/\sqrt{E1})(\text{Sqrt } P)$	<b>Separation (m)</b> 800MHz - 2.5GHz $d=(7/\sqrt{E1})(\text{Sqrt } P)$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			



# *Lympha***Touch**<sup>®</sup>