

# USER MANUAL

## LASERNEEDLE Touch

LASERNEEDLE GmbH

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# 1 INTRODUCTION

You purchased a high-quality medical device for photo biomodulation. Congratulations!

This manual describes the correct use and maintenance of the LASERNEEDLE Touch device and points out the risks related to its operation.

The user manual is an integral part of the LASERNEEDLE Touch device.

The device may only be operated by individuals who are qualified in the operation and instructed in the risks of associated with laser radiation according to the international standards IEC 60601 and IEC 60825.

Please ensure further information if additional national standards or regulations have to be observed. For some countries a license to operate a laser is mandatory. Furthermore, in some countries registration of the device and/or the assignment of a laser protection advisor (LPA) or laser safety officer (LSO) is requested.

Please make sure to study the user manual carefully before operating the LASERNEEDLE Touch device.

## User assistance information

For any information about the device or any assistance regarding its use, please contact your local reseller or dealer. You are also welcome to contact the LASERNEEDLE GmbH directly, via email, telephone, or by post:

LASERNEEDLE GmbH

Ludolfingerplatz 5  
13465 Berlin  
Germany

Phone: +49 (0)30 2091395 - 0  
Fax: +49 (0)30 2091395 - 11  
Email: [info@laserneedle.eu](mailto:info@laserneedle.eu)

## 2 GENERAL SAFETY INSTRUCTIONS



Make sure to follow the instructions in this manual before and while setting up the device.



### Attention

This is a class 3R therapeutic laser device emitting laser radiation that can be hazardous for the human eye. Make sure to carefully follow the instructions in this manual, to protect the eyes of all persons present during operation of this device and to avoid any direct laser irradiation into the eyes.



Make sure that all persons present are wearing appropriate protective laser goggles during operation of the device, such as the provided Laserneedle laser goggles. The provided laser goggles are perfectly suitable for the Laserneedle device and are designed to protect against laser light.

The protective lens of the laser goggles has a light transmittance of 20%. Even when wearing laser goggles, beware not to look directly into the laser beam. The laser goggles as provided are intended to give protection against accidental radiation only. Laser resistance is tested on the basis of a maximum irradiation period of 5 seconds.

### Further general safety instructions:

- Specific safety instructions are found in the related chapters of this document.
- Make sure that the device is in proper condition, without visible defects and functionally safe before usage.
- Don't use the device if it has defects, which could endanger the user, patient or third parties.
- In case of an emergency, press the "Stop" button in the front or the on-/off button in the back of the device. This will shut down the device's operation immediately.
- Stop using the device if there is any risk of direct laser exposure to the eyes of any person near the device.
- Only authorized professionals with appropriate training are allowed to operate the device.
- The optical fibers are fragile and should be handled with care. Do not tear, bend or fold them. They should be cleaned regularly in order to maintain proper function.
- Protective laser goggles are sensitive to direct sunlight irradiation and scratches which might reduce laser impedance. Handle with care and store in the provided laser goggle boxes in order to preserve impedance level. Regular performance testing is recommended. The recommended useful life for laser safety goggles is approximately 3 years.
- Periodic technical and laser control of the device is recommended on a yearly basis.

### 3 DEVICE DESCRIPTION

The LASERNEEDLE medical device allows for simultaneous application of up to ten lasers that can be preconfigured individually with violet, red or infrared laser diodes, delivering up to 40 mW of output power for the realization of diverse treatment protocols. Red and infrared laser light can promote the activation of the immune system, increase the blood circulation and enhance cellular energy metabolism and cell proliferation. Violet laser light can have a strong anti-microbial effect.

#### Purpose

The LASERNEEDLE Touch device is used for non-invasive low-level laser therapy to treat traumatic, inflammatory and degenerative conditions, regenerative support, and applications treated with acupuncture or trigger point therapy.



#### Attention

The protocol for each treatment is to be determined by the attending doctor. Specific recommendations for the treatment of relevant indications in orthopedics and sports medicine are given in the “Treatment recommendations for the therapy with LASERNEEDLE Touch”.

#### Indications

- Traumatic, inflammatory and degenerative diseases of the
  - Joints,
  - Bones,
  - Muscular system,
  - Tendons and ligaments,
- Regeneration of nerve cells
- Further indications, e.g.
  - Acute and chronic wounds,
  - Burns,
  - Foot or leg ulcers, etc.



#### Attention

Laser therapy of dark pigmented skin or skin tattoos should be approached with caution. In order to avoid a heat sensation on the irradiated tissue lower power (optional function) or pulsed mode might be set.

## Contraindications

The following areas should not be exposed to the laser:

- Eyes
- Openings in the skull, such as fontanel in babies
- Belly area of pregnant women
- Endocrine glands and the thyroid gland
- Tumors of any kind.

## 4 SCOPE OF DELIVERY

The following LASERNEEDLE Touch device configurations (laser configuration) are available:

- LASERNEEDLE Touch OrthoPhys: configured with 5 red and 5 infrared lasers
- LASERNEEDLE Touch Solution: configured with 10 red lasers
- LASERNEEDLE Touch Allround: configured with 2 violet, 4 red, 4 infrared and lasers
- LASERNEEDLE Touch Dental: configured with 1 violet, 7 red, 2 infrared and lasers
- LASERNEEDLE Touch Individual: laser configuration according to customer requirements

For additional information and individual laser pre-configuration, please consult the manufacturer or direct dealer / reseller respectively.



Figure 1: LASERNEEDLE Touch device (front)

All versions are delivered with power adapter, optical fibers, silicone applicators, perforated tape, 2 pairs of laser protection goggles, mounting material and laser warning sign.

## Trolley Version

The above-described versions of the LASERNEEDLE Touch device are available mounted on a mobile trolley designed for the organization of the optical fibers and to allow optimal positioning of the device towards the patient.

The trolley is equipped with an adjustable device holder and a support tray for the organization of the optical fibers. In all trolley packages the power adapter is already built-in inside the trolley (Fig. 2).



Figure 2: Trolley version

## Special Trolley Version (for LASERNEEDLE Touch Dental)

The special trolley version for the Touch Dental (Fig. 3) includes the LASERNEEDLE Touch, the trolley with adjustable device holder, the tabletop with the slots for the optical fibers, as well as the mounting fixture for the dental handpieces (Fig. 4).



Figure 3: Dental version with special tabletop

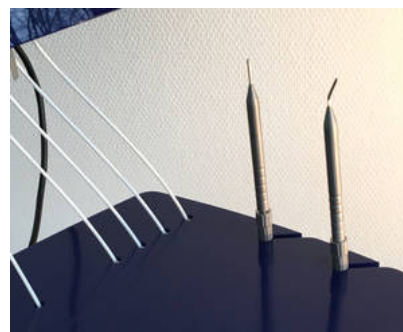


Figure 4: Dental handpieces in the suspension of the trolley



## Accessories

- Silicone applicator (blue silicone)
- Perforated tape (disposable)
- Laser protection goggle
- Optical fibers





			
The silicone applicators with the perforated tape are used to attach the optical fiber distal tip to the skin of the patient. After disinfection they can be used multiple times.	The perforated tape fixes the optical fiber with the help of the silicone applicators during	The laser goggle protects the patient and the therapist during treatment.	The optical fibers guide the laser light from the LASERNEEDLE Touch to the patient.

Figure 5: Accessories

## Optional Accessories

- Self-adhesive applicators
- Laser shower
- Treatment flex-arm
- Silicone pads




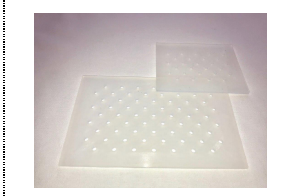
			
The self-adhesive applicators are used to attach the optical fiber distal tip to the patient. They are disposable.	The laser shower is used for surface irradiation of larger areas.	The treatment flex-arm is used in combination with the laser shower to enable surface irradiation and/or support the optical fibers	Silicone pads are suitable to attach the optical fibers for the treatment of muscles or other larger areas.

Figure 6: Optional accessories

## 5 SETUP INSTRUCTIONS

### Warnings related to setup



#### Attention

- Only trained professional personnel should assemble the device.
- Carefully unpack the unit, making sure that all the accessories are included in the package.
- Be careful not to damage the device or accessories while assembling the device.
- Handle the optical fibers with extra care during setup. Do not bend or fold them during the device assembly. Make sure they are not pressed or squeezed by any object during the setup process or after it.
- Do not turn on the device before the completion of all setup steps. Operating the device before that could lead to uncontrolled laser emission and may result in direct eye exposure to laser light.
- Do not operate the device unless you are certain that the setup process was accomplished correctly.
- Don't use the device if it has defects which could endanger the user, the patient, or third parties.
- For detailed setup instructions of the accessories please refer to the accessories section.
- The trolley version of the device is classified electrical protection class I. Connect the device only to a mains supply with protective earthing. For disconnection unplug the plug from the mains supply.

In case of damaged components, any problems or difficulties during the setup process, please contact the manufacturer, device reseller or dealer immediately for assistance.

### Combination with other products



#### Attention

Do not use any other parts, applicators or accessories other than those described in this manual.

### Result of incorrect setup



#### Warning

Incorrect setup results in:

- Risk to the patient, therapists or third parties
- Damage to the device and/or the accessories

### Environmental conditions



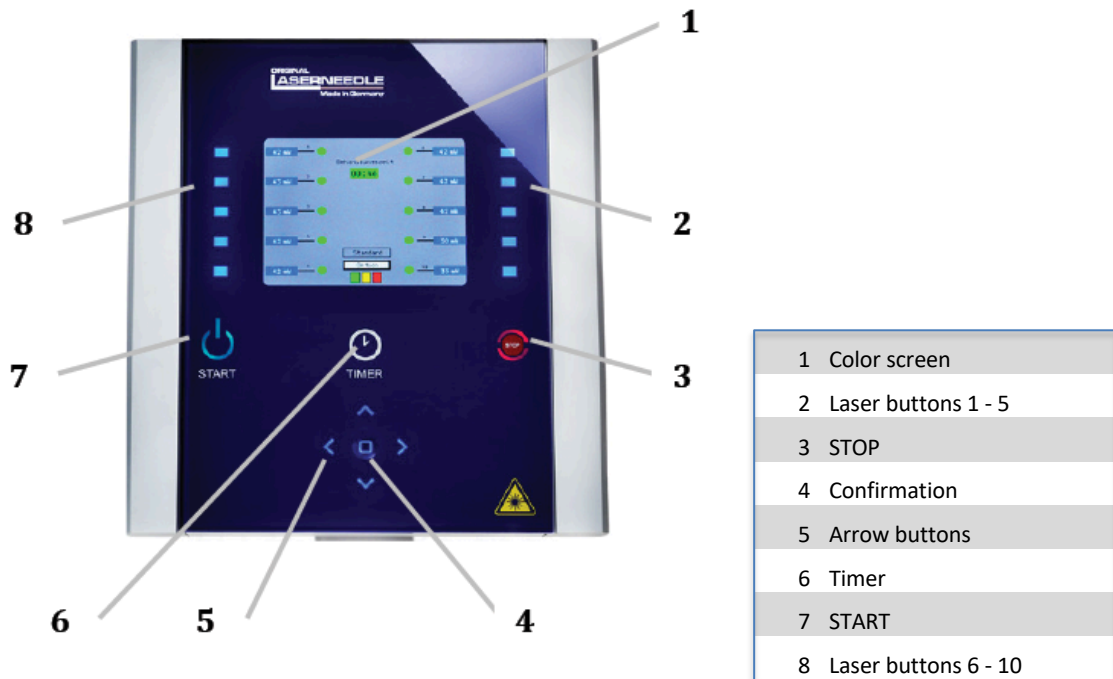
#### Attention

- The LASERNEEDLE Touch device is intended for indoor use in a professional healthcare facility environment only. The device should be used only in rooms with a temperature between 0°– 40°C.
- Do not use the device in oxygen-rich environments or in the presence of flammable anesthetics.
- The ideal treatment room is a separated closed room, to which the access can be controlled during the duration of the treatment.

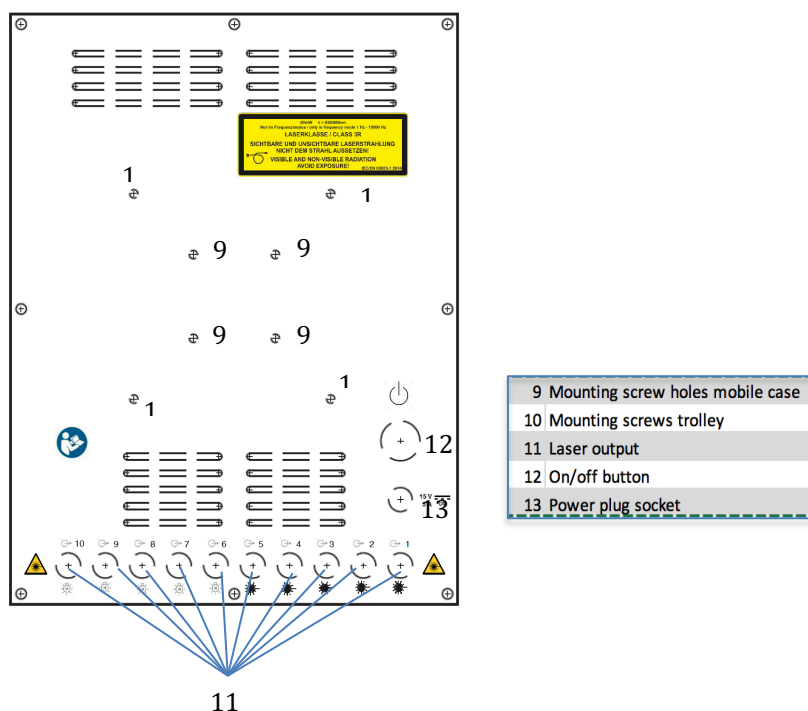
- During treatments, all people in treatment area should use laser protection goggles, in order to protect their eyes from an accidental direct eye exposure to the laser light.
- The patient should sit or lie for the duration of the treatment, and refrain from any big movements to avoid accidental detachment of the optical fibers from the patient body. Such detachments during the treatment will expose the laser light and may lead to direct eye exposure which could damage the eye.

## Device description of the LASERNEEDLE Touch

Front of the LASERNEEDLE Touch device (Fig. 7)



Back of the LASERNEEDLE Touch device (Fig. 8)



## 1. Assembly of the device on the LASERNEEDLE trolley

- i. Make sure that there is enough space between the trolley support tray and the LASERNEEDLE Touch device (at least 15 cm). This is to ensure that the optical fibers can be mounted correctly and will not be bent too strongly. If necessary, adjust the height of the tray holder using the knobs at the back of the column (see below: Trolley adjustment).
- ii. Position the LASERNEEDLE Touch device, so the grooves of the mounting plate (on back) fit into the trolley's mounting screws.
- iii. Use all four wing nuts to secure the device to the trolley. Turn the wing nuts clockwise to tighten them (Fig. 9).

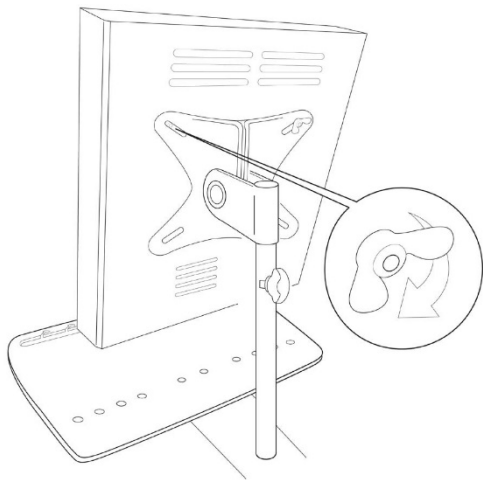


Figure 9: Mounting the LASERNEEDLE Touch device on the trolley

## 2. Installing the optical fibers



### Attention

- Infrared and violet lasers should be installed with quartz optical fibers only.
- Red lasers can be installed with regular or quartz optical fibers.

The regular and quartz optical fibers are packaged separately and are supplied with the device. Make sure to connect the optical fibers to the right laser. The laser output sockets on the rear-side of the device are labeled with the number of the lasers (1 to 10). Connect the optical fibers to the device one by one. This helps to keep the optical fibers organized, avoids entanglement and prevents potential damage. Install the optical fiber labeled with no. 1 to the laser socket no. 1, optical fiber no. 2 with laser socket no. 2 and so on. The type of radiation of the lasers is displayed with the following symbols on the rear-side of the device.

red	
violet	
infrared	

The installation of regular and quartz optical fibers is identical.

### Pre-mounting of the optical fibers

- i. Pass the distal tip of the optical fiber through the respective hole at the back of the trolley's support tray corresponding to the number of the laser.

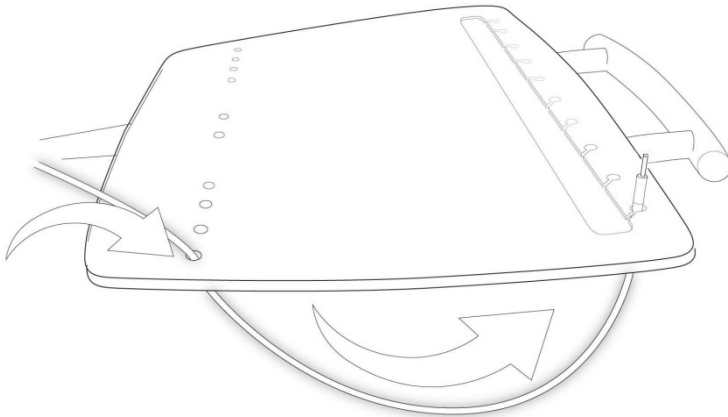


Figure 10: Passing optical fibers through the trolley's support tray

- ii. Secure the optical fibers in its corresponding groove at the front of the tray (Fig. 10).
- iii. Remove the protective cap from the plug. Screw the proximal end of the optical fiber with the plug to its corresponding laser output at the back of the device. Turn the screw cap clockwise to tighten the plug (Fig. 11).



### Attention

Pay attention while attaching the optical fibers that these are not snapped and the radius of bend is not too tight (see chapter 10: Storage, transport, and disposal).

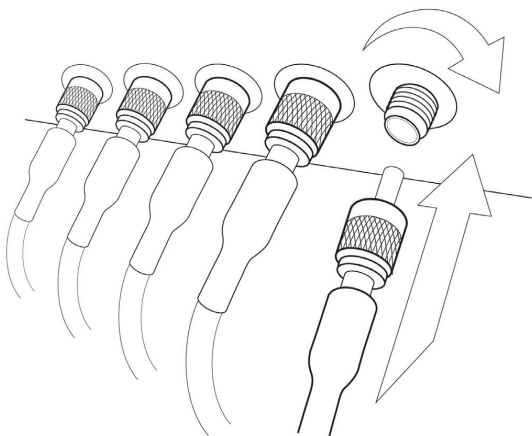


Figure 11: Connecting the plug of the optical fibers with the socket in the LASERNEEDLE Touch device

### 3. Connecting the power supply

The power adapter plug comes out of the top of the trolley's column. Plug in the power adapter plug into the power adaptor socket on the back of the device (Fig. 12).

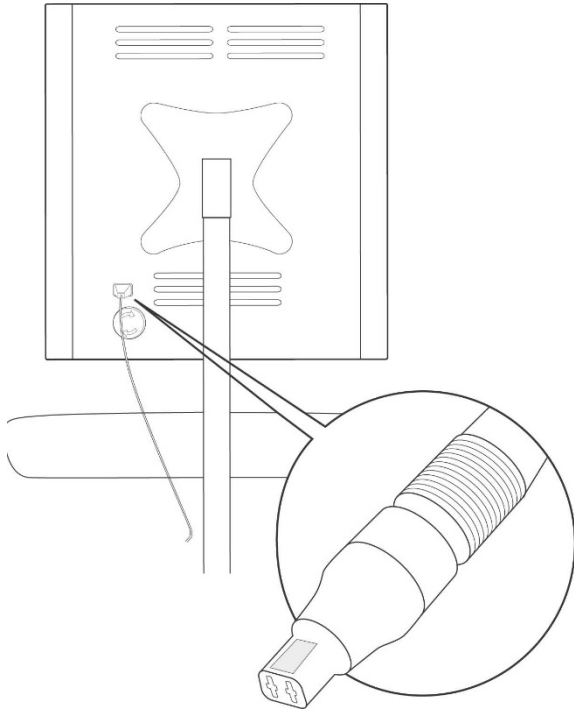


Figure 12: Connecting the power supply unit

### 4. Trolley adjustment

The LASERNEEDLE Touch device can be adjusted in height, rotation and tilt. The trolley support tray can be adjusted in height and rotation.

#### Adjustment of LASERNEEDLE Touch device on trolley (Fig. 13)

- i. LASERNEEDLE Touch device tilt – you can adjust the tilt of the device by hand along the axis through point A.
- ii. LASERNEEDLE Touch device rotation – use the knob B to adjust the device's horizontal angle in a range of approx. 120° relative to the trolley. Adjust the rotation manually by hand. Turn the knob clockwise and counter clockwise to lock and unlock the device's rotation.
- iii. LASERNEEDLE Touch device height – use the knob D at the back of the trolley to adjust the device's height. Adjust the height manually by hand. Turn the knob clockwise and counter clockwise to lock and unlock the height of the device.
- iv. Support tray rotation and height – use the knob C at the back of the tray to adjust the tray's horizontal angle relative to the trolley and the height. Adjust the rotation and height manually by hand. Turn the knob clockwise and counter clockwise to lock and unlock the tray's rotation.

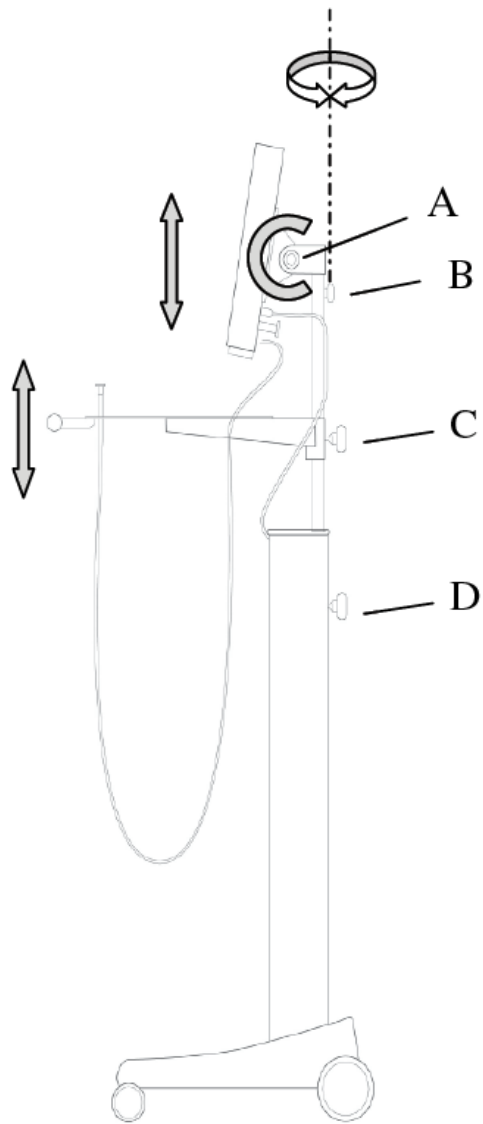


Figure 13: Device and trolley adjustments



**Attention**

Please note: A minimum distance of more than 15 cm, from the trolley support tray to the lower edge of the LASERNEEDLE Touch device, is necessary to prevent buckling and damage to the optical fibers (Fig. 14).

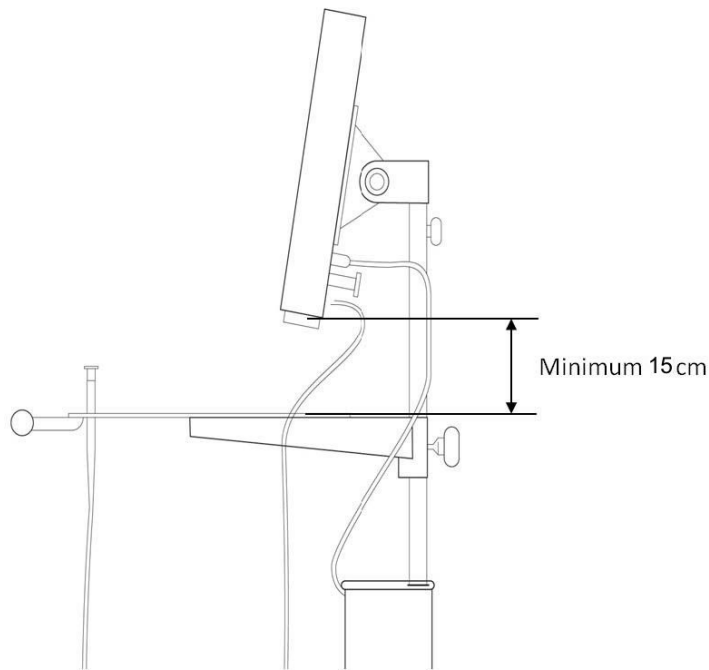


Figure 14: Minimum distance between support tray and frame of the LASERNEEDLE Touch

## 6. Initial cleaning

Please refer to section 8 “Cleaning and disinfection” for the description and instruction of the required cleaning procedure.

## Device placement



### Attention

- The entrance to the room should be marked with a laser warning sign (Fig. 18) according to ISO 7010-W004. An appropriate laser warning sign sticker is supplied with the package.
- The device should be placed close to the patient’s bed or chair, where the treatment will take place.
- The device should be placed within reasonable distance to the patient, so that the optical fibers are not stretched or bent during the treatment.
- The placement of the device should ensure that the optical fibers are not in the way of anyone or anything, to prevent damage at all times.
- The power supply cable should be positioned in a manner that it prevents risk to all people present and/or the device itself.
- Move the device carefully to prevent damage to people or to the device itself.
- Do not lean on or cling anything to the trolley.
- Do not place any foods or drinks on the device tray (trolley version). The device tray should not be loaded with more than 1 kg working load.



Figure 15: Warning sign of potentially visible and invisible hazardous laser radiation



## 6 LASERNEEDLE TOUCH DEVICE OPERATION



### Attention

- Only authorized health professionals with appropriate training (handling of the device, low-level laser therapy, laser safety) are allowed to operate the LASERNEEDLE device; appropriate training can be obtained directly from LASERNEEDLE or from a qualified dealer / reseller.
- Make sure that the device is in a proper condition and functionally safe before using it.
- Don't use the device if it has defects, which could endanger users, patients or third parties.
- Make sure that the ventilation slots are not covered or blocked.
- Make sure to operate the device only in appropriate environments. Please refer to the "environmental conditions for use of the LASERNEEDLE Touch device" section.
- Make sure that all laser outputs are connected to optical fibers before you turn on the device.



### Warning

Incorrect operation might result in:

- Direct eye exposure (associated with risk for patients, therapists, and all other people present).
- Inefficient therapy with partial or no results.
- Damage to one or more of the LASERNEEDLE system components.



### Attention

Emergency stop

In any case of emergency – quickly push the red "STOP" button in the front or the main On-/Off switch in the back of the device to shut down all operations of the LASERNEEDLE Touch device.

## Basic device operation

### Turning the LASERNEEDLE Touch device on and off

- i. Connect the power adaptor to a network power socket in the treatment room.
- ii. For the trolley version make sure that the main switch underneath the trolley is turned on.
- iii. Switch on the device at the main On-/Off-button in the back of the device. Switching the device on does not put any of the lasers into operation.
- iv. After self-testing the device lights up, loads, and shows the main overview screen (Fig. 15)
- v. Using the main ON-/Off-button in the back of the device will cut off the LASERNEEDLE Touch device again.



Figure 15: LASERNEEDLE Touch device with main overview screen

### Using the device controls

The device controls of the LASERNEEDLE Touch device are touch buttons (Fig. 16). No actual pressing is necessary, the user should simply touch the buttons.

#### **Arrow buttons (5):**

⇒ are used to navigate between the options presented on the screen

#### **Confirmation button (4):**

⇒ is used to choose a highlighted option or to set a chosen value

#### **Start button (7):**

⇒ after programming the device according to the chosen parameter:

- a) A first touch confirms the parameters. As feedback, the start button and the attendance-time will blink in green color and an acoustic signal will be given.
- b) A second touch on it starts the treatment / the laser irradiation.

#### **Timer button (6):**

⇒ is used to change the treatment time

#### **Stop button (3):**

⇒ stops the treatment / the laser irradiation and the menu returns to the original setting.

#### **Laser buttons (2) and (8):**

⇒ are used to separately control each

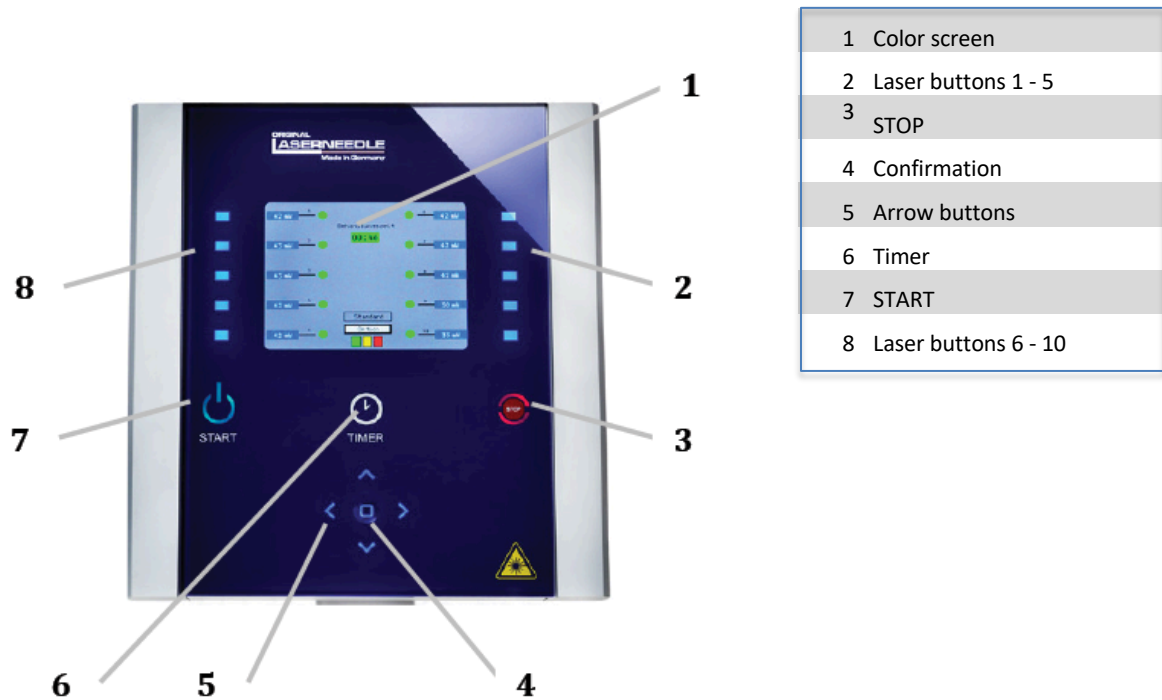


Figure 16: Overview device controls

### Main overview screen

The main overview screen is the default display of the device. It is displayed during the treatment (Fig. 17). The screen contains information on all ten lasers and on the treatment time.

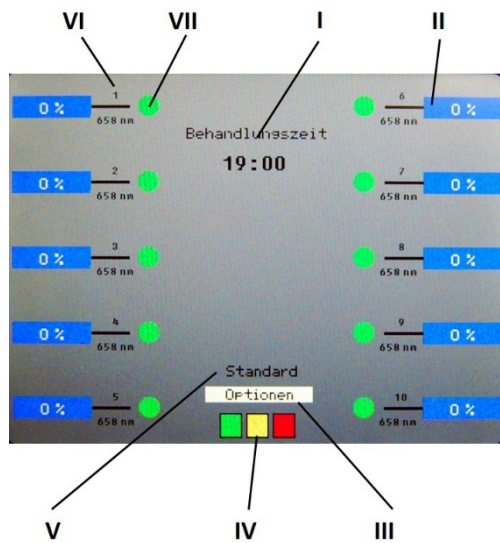


Figure 17: Main overview screen

The middle part of the screen shows the treatment time (I) and the different main control options (III, IV, V). The color dots (VII) next to the laser numbers (VI), indicate the irradiation mode of the specific lasers:

- Green – continuous wave (CW)
- Yellow – pulsed mode (PM)
- Red – laser deactivated (Off mode)

Beside the color dots the number of the laser is displayed above the line and below the wavelength of the laser.

The blue square (II) provides additional information on the laser's activity:

- CW mode (green) – the blue square (II) contains the status of the laser
  - 0% laser inactive
  - 100% laser active, maximum laser radiation
  - i.e. 75% laser active, laser radiation 75% of maximum laser radiation\*

\*Please note that the modification of the „Laser output power“ is an optional property and does not necessarily appear in all devices.

- Frequency mode (yellow) – the blue square contains the irradiation frequency of the laser.
- Off mode (red) – the blue square is empty.

### Manual setup of the treatment parameters

Most of the treatment parameters can be set using the main overview screen. The lasers can be controlled individually or simultaneously (all lasers at once).

- Individual laser control** - is done by touching any of the laser buttons. By touching a button, it can be chosen between three modes of each laser (CW, Frequency and Off mode). In frequency mode the irradiation frequency is chosen using the up and down arrow buttons and then setting the desired frequency by pressing the confirmation button.
- Simultaneous control** - (all lasers at once) is done using the main control options (III, IV, V) on the main overview screen. To choose between them, use the arrow buttons and the confirmation button (Fig. 17).
  - Standard (V):  
All lasers are in CW mode. The treatment time and the laser output power (if available) is identical to the last performed treatment.
  - Option (III):  
Enters the device menu, which allows choosing treatment programs from the database, saving and loading of customized treatment programs, and the advanced controls of the device (for using the device's menu please refer to the advanced operation section).
  - Colored squares (IV):
    - Green set – sets all lasers to CW mode
    - Yellow set – sets all lasers to frequency mode
    - Red set – sets all lasers to Off mode
- Treatment time (I)  
To choose the treatment time:
  - Touch the “Timer” button.
  - Adjust the treatment duration using the up and down arrow buttons (resolution: 1 minute). The maximum treatment duration is 60 minutes.
  - Confirm the new treatment time by touching the confirmation button.

## Advanced operation

The advanced operation section explains the use of advanced options of the LASERNEEDLE Touch device. To navigate in the menu use the arrow keys. To open a lower level of the menu or to choose a function touch the confirmation button. To exit a menu and to return to the previous level use the arrow key to highlight “back” on the screen and confirm by touching the confirmation button.

To enter the LASERNEEDLE Touch device menu choose the “Options” section on the main overview screen (Fig. 18). Use the arrow keys to highlight the “Options” section and the confirmation button to enter.

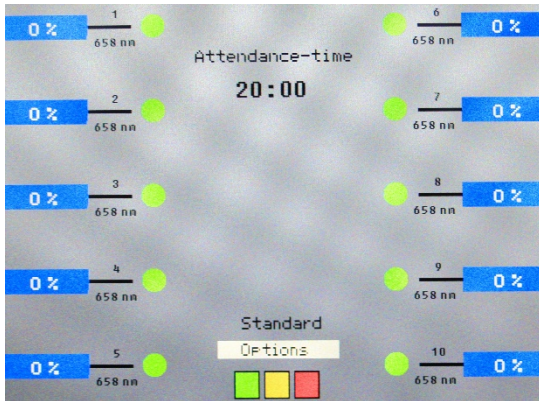


Figure 18: Main overview screen with highlighted “Options”

The following screen appears:

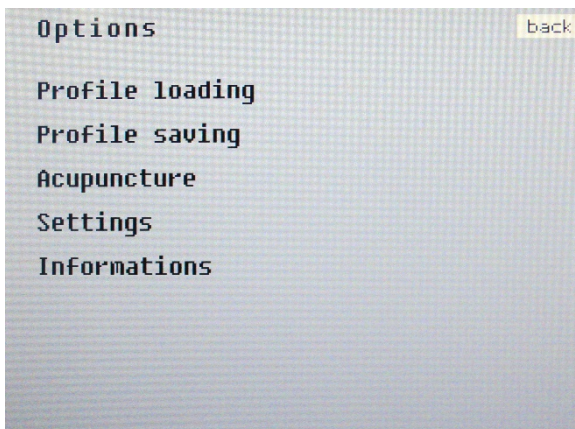


Figure 19: LASERNEEDLE Touch device menu “Options”

The following options are available:

- Profile loading
- Profile saving
- Acupuncture\*
- Settings
- Information

\*The menu item “Acupuncture” is optional and not available in all devices.

## Loading and saving of customized treatment profiles

### Profile loading

1. Choose „Profile loading“ in the main menu to load a customized treatment profile.

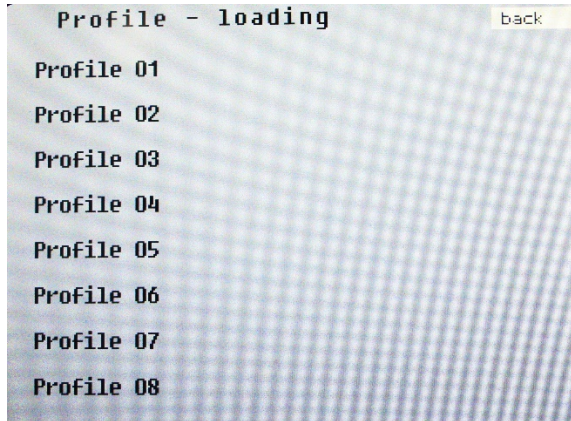


Figure 20: Profile loading – Loading a customized treatment profile

2. Choose the desired profile you wish to load and touch the confirmation button. The memory provides for up to 20 different customized treatment profiles.
3. The display automatically returns to the main menu. The chosen profile is loaded and the number of the profile is displayed.
4. The device is ready for operation
5. Press the Start button twice in order to start the treatment. Should you wish to interrupt the treatment before it ends, press the Stop button.
6. At the end of the chosen treatment time the treatment is stopped automatically with a double acoustic signal.

### Profile saving

The LASERNEEDLE Touch memory allows for up to 20 customized treatment profiles. The device stores the different laser settings for each customized profile. This spares the need to reprogram the device again and again with frequently used treatment profiles. The device stores the laser parameters and the power adjustment (if available) in the device memory. The treatment time will not be stored.

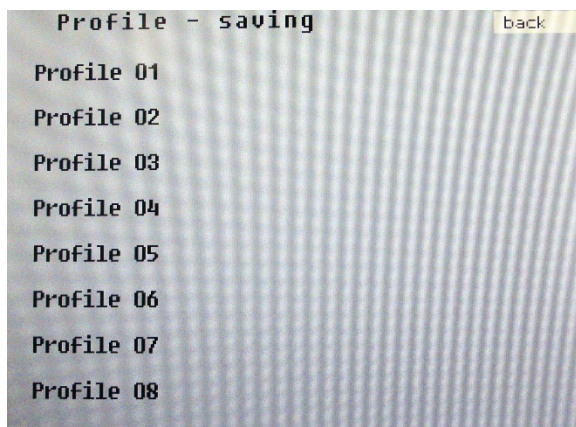


Figure 21: Profile saving – Saving customized treatment profiles

### Saving a treatment profile

1. In the main overview screen (Fig. 18) set all treatment parameters manually according to the desired treatment plan. Do not forget to confirm by touching the confirmation button.
2. Before starting the treatment – go to „Options“ > “Profile saving”, select under which profile the current settings should be saved by using the up and down arrow keys and confirm again.
3. The display automatically returns to the main menu. The number of the saved profile will be displayed below the treatment time.
4. The device is ready for operation now.
5. Touch the “Start” button and after the tone confirm by touching the “Start” button again in order to start the treatment. Should you wish to interrupt the treatment before it ends automatically, touch the “Stop” button.
6. The last treatment time selected will remain, the laser configuration returns to the default setting automatically.

### Acupuncture\*: pre-programmed treatment plans

\*The menu item “Acupuncture” is optional and not available in all devices.

The menu „Acupuncture“ contains the subsections „Frequencies“ and „Diagnostic“ (Fig. 22).

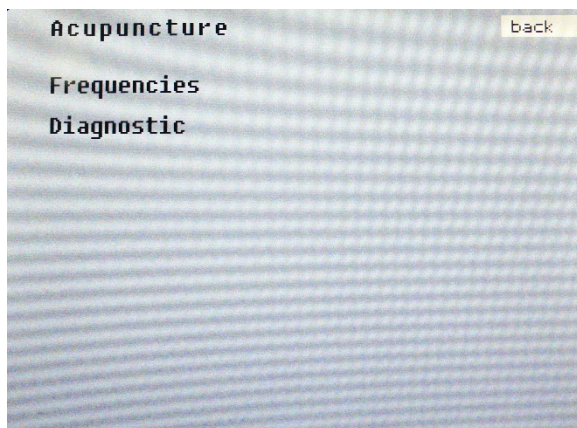


Figure 22: Menu „Acupuncture“

The device provides pre-programmed frequency mode therapy plans related to Traditional Chinese Medicine (TCM) therapy techniques. The frequencies database contains treatment plans that follow the “Bahr”, “Chakra”, “Nogier”, “Reininger” and “TONS” schools (Fig. 23).

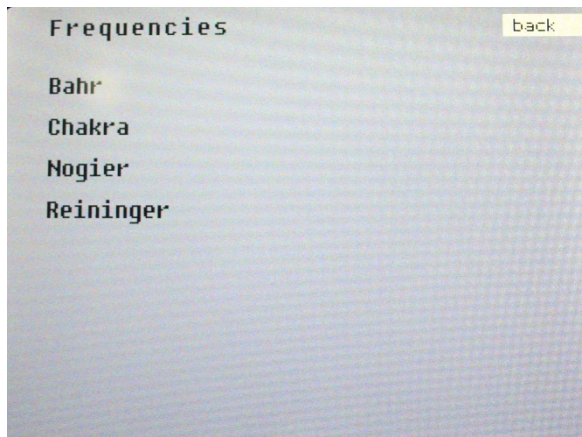


Figure 23: Menu „Frequencies“

### Frequencies

- The frequency database is accessible in the menu through Options > Acupuncture > Frequencies. Navigate within the single frequencies and treatment plans using the arrow keys and the confirmation button.
- Choose a highlighted frequency by touching the confirmation button. The treatment overview screen will appear and all lasers will be set at the chosen frequency. In the middle of the screen, below the treatment time, the name and the frequency will be displayed.



#### Attention:

If you do not need every laser, do not forget to deactivate the non-used ones.

- Select the desired treatment time using the timer button and the up or down arrow keys.
- Touch the Start button twice in order to start the treatment.

When the treatment is over, the default overview screen will appear automatically.

### Diagnostics

The diagnostic database is accessible through Options > Acupuncture > Diagnostics and contains 51 pre-programmed frequencies. The frequency can be chosen just for laser 1. By pressing the confirmation button, the treatment overview screen appears and the diagnosis can be started. All other lasers (2-10) are switched off and deactivated.

Choose one frequency by pressing the confirmation button, the treatment overview screen will appear and the diagnosis can be started by touching the Start button twice.

To change the selected frequency during the diagnosis, choose another one without interrupting the operation of the device. Use the up and down arrow keys to select the desired frequency. The value and the name of the frequency will be displayed. After touching the confirmation button, the laser will adopt the changed frequency. This may be useful when trying different frequencies in the course of the diagnosis.

### Settings

#### Language

The LASERNEEDLE Touch device supports several languages (Fig. 24). To select a language, go to the language menu in Options > Settings > Language. In addition to English the following languages are available: German, French, and Portuguese.



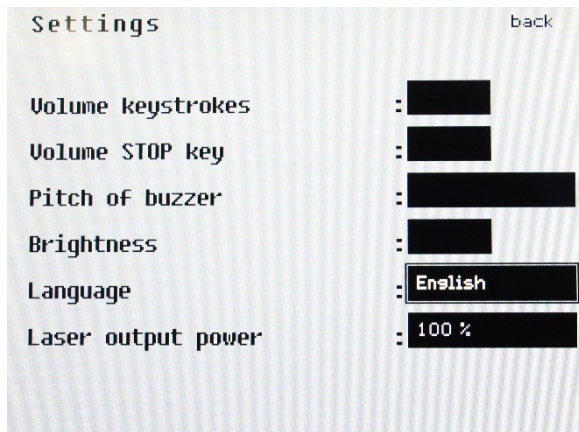


Figure 24: settings menu

### Further settings

Further settings (Fig. 24) can be selected by the user via Options > Settings. Use the „up” and “down” arrow keys to select the property you wish to adjust. The “right” and “left” arrow buttons change the value of the property and the confirmation button sets the chosen value.

### Note:

Please note that the modulation of irradiance power „Laser output power“ is an optional property and does not necessarily appear in all devices.

### Information

Information on the device itself and on the usage of the different lasers (Fig. 25) can be found on the main menu in the “Information” section.

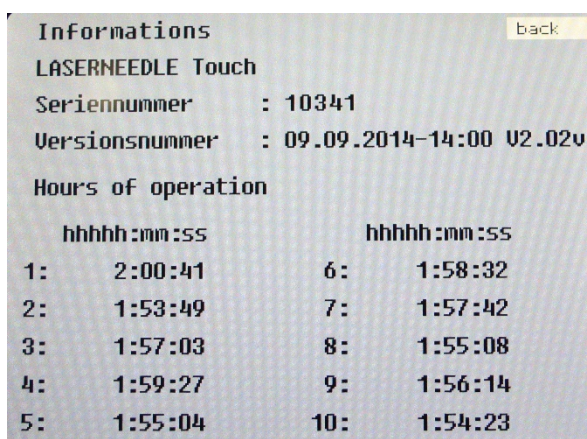


Figure 25: Information menu

## 7 TREATMENT WITH THE LASERNEEDLE TOUCH DEVICE



### Attention

- Only authorized professionals with appropriate training are allowed to operate the LASERNEEDLE device.
- Make sure that the patient is suitable for laser therapy and that no contraindication applies.
- A treatment plan should be designed by an attending doctor only.
- Make sure that all safety measures are available for use.
- Only use the provided safety goggles for laser protection and use only original LASERNEEDLE accessories.

### Treatment planning

Every treatment should be planned before starting any of the operational steps. Make sure to consider all of the following.

- Treatment goal,
- Treatment protocol / plan and number of treatments,
- Laser parameters,
- Type of irradiation: precise irradiation or surface irradiation,
- Location of the irradiation on the patient's body.

### Treatment course

After completion of the treatment planning, each treatment session has to be performed following the subsequent steps:

1. Preparing the lasers for treatment:  
Prepare the optical fibers and applicators for the treatment: place the self-adhesive applicators in the correct positions on the patient and attach the lasers; alternatively prepare the perforated tape with the silicone applicators and place them accordingly.
2. Setting the chosen treatment parameters:  
Turn on the LASERNEEDLE Touch by using the main On-/Off-button in the back of the device. After self-testing of the device the main overview screen is displayed. Set the planned parameters of treatment
3. Safety check:
  - Is everyone in the room wearing laser protection goggles?
  - Is the laser warning sign attached on the door?
4. Turning on the laser by touching the "Start" button twice.
5. During the treatment:
  - Patient should stay calm and relaxed, either sitting or lying.
  - Nevertheless, minor movements even of the treated area do not affect the treatment.
  - If a problem should occur during the therapy / treatment, shut down the device by pressing the "Stop" button in the front or the main On-/Off-button in the back."
6. End of treatment:
  - The device will shut down automatically after the end of the treatment time.
  - To finish the irradiation before the end of the preset treatment time, touch the "Stop" button.
  - Place all the optical fibers back in their grooves in front of the tray
  - If no further treatment is planned, cut off the device by pressing the main On-/Off-button in the back

## 7. Cleaning the optical fibers:

- Please refer to chapter 8 “Cleaning and disinfection”

## Treatment protocol and laser parameters

The LASERNEEDLE Touch device is a versatile device that can be used for the treatment of many different medical indications. The actual parameters for each patient should be determined by a trained professional after close examination and consideration of the patient’s condition.

Nevertheless, treatment protocols usually follow a common structure:

- Two or three treatment sessions a week over a period of several weeks.
- The duration of a treatment session is usually between several and thirty minutes.

The major laser parameters are laser color (or wavelength) and irradiation time. The total treatment energy is the product of power and time.

Specific recommendations for the treatment of relevant indications are given in the brochure „Treatment recommendations for the therapy with the LASERNEEDLE Touch“.

## Preparing the patient for the treatment

1. Inform the patient about possible contraindications of the LASERNEEDLE therapy and explain all possible risks and side effects of the treatment.
2. Make sure that the patient is suitable for treatment.
3. Instruct the patient to sit or lie calmly and avoid sudden or big movements during the treatment.
4. Make sure that the chosen skin areas for irradiation are exposed and accessible.
5. Remove excessive body hair, makeup, creams, etc. that might interfere with the laser irradiation and reduce the grip of the applicators.
6. Clean the target skin areas.

## Preparing the lasers for the treatment



### Attention

- Make sure to follow the instructions in this manual in the preparation the device.
- Pay attention not to harm the patient in any way during the application of the optical fibers.
- Be careful not to damage the device or accessories while connecting the optical fibers to the patient.
- Do not use any other applicators or accessories other than those described in this manual in order to assure a safe and effective treatment.
- Make sure that all applicators and accessories are clean and disinfected before use.

The lasers have to be applied differently, depending on the types of irradiation during treatment (precise irradiation or surface irradiation):

## Precise irradiation

During precise irradiation, the optical fibers are attached to the patient's body in skin contact at the desired treatment points. The attachment is done either using the blue silicone applicators with the perforated tape or the self-adhesive applicators.

### Using the silicone applicators and the perforated tape

For every laser to be used in the treatment (Fig. 26):

1. **Preparing the perforated tape:**  
Cut an appropriate size of the perforated tape for the desired treatment points. Make sure that you include at least one complete hole in the tape.
2. **Attaching the perforated tape to the silicone applicator:**  
If the silicone applicator is already positioned on the end of the optical fiber, remove it first. Stick the silicone applicator through the tape opening in the way that the wider (flat) end of the applicator (its bottom) is attached to the sticky side of the tape.
3. **Attachment to the patient:**  
Tightly fix the applicator-tape structure at the desired treatment point on the patient's body.
4. **Attaching the optical fiber:**  
Connect the distal tip of the optical fiber to the silicone applicator by inserting it into to the applicator from its narrow end.

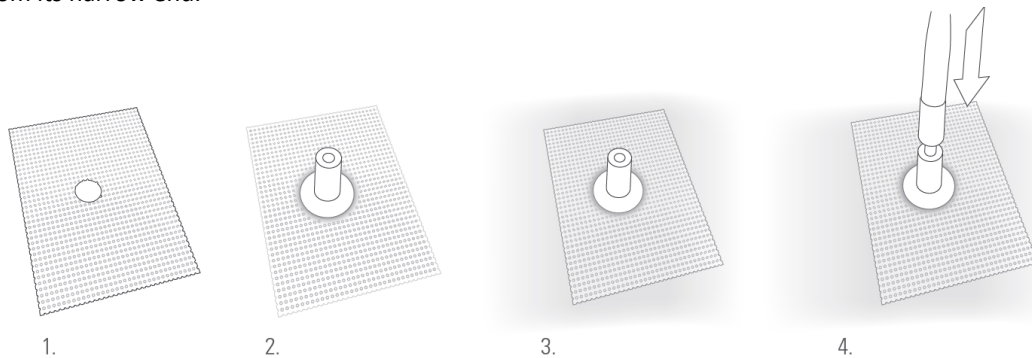
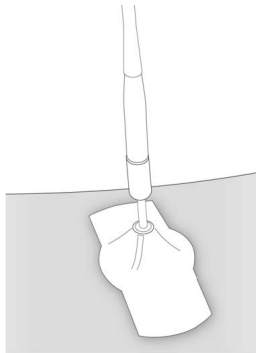


Figure 26: Attaching silicone applicators with perforated tape to the skin

### Using the white self-adhesive applicators

For every laser to be used in the treatment (Fig. 27):



**1. Attachment to the patient:**

Remove the self-adhesive applicator from the sheet and fix it to the patient's skin at the desired location.

**2. Connect the optical fiber:**

Connect the distal tip of the optical fiber to the self-adhesive applicator. Carefully insert the distal end of the optical fiber until it touches the skin of the patient while softly turning the tip of the optical fiber back and forth by about half a turn.

Figure 27: Attachment of the self-adhesive applicator to the patient

### Surface irradiation

The laser shower bundles the lasers for larger surface irradiation. The laser shower can be used in combination with the flexible treatment arm.

#### Laser shower

The laser shower is provided with drillings for the insertion of the optical fibers. The laser shower can be mounted on the treatment arm (Fig. 6 and Fig. 30). When the treatment arm is directed to the specified body region, unattended use is possible. Alternatively, the laser shower can be applied by using a handpiece.

The bundling of different lasers with different wavelengths in the laser shower allows for polychromatic treatment. Apart from that, the frequency of each laser can be also chosen independently.

To avoid the risk of an infection, the laser shower is equipped with a removable translucent cap. The cap can be autoclaved after use.



#### Attention

To minimize the risk of an infection do not use the laser shower directly on the patient's skin. You should allow a safety distance of at least 5mm.

#### Attaching the optical fibers to the laser shower

- Insert the distal ends of the optical fibers one by one into the drillings of the laser shower. Insert the optical fiber to the point where the tip of the fiber and the bottom of the laser shower are even. (Fig. 28).
- Set the laser parameters according to the chosen treatment plan.
- Treat the affected surface of the patient (Fig. 29).

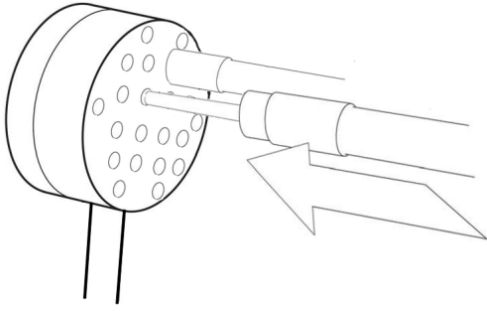


Figure 28: Inserting the distal tip of the optical fibers into the laser shower

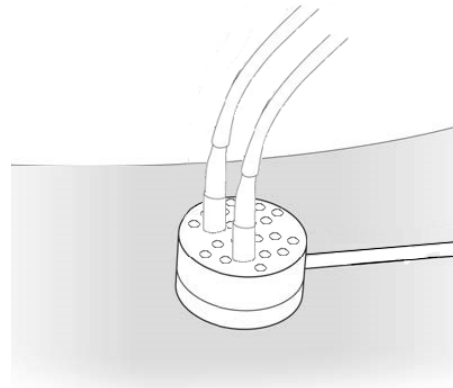


Figure 29: Surface irradiation with the laser shower

### Treatment flex-arm

The treatment flex-arm is used in combination with the trolley. The trolley is equipped with two openings at the top of the column covered by a protective cap each. Remove one of the caps on the desired side of the column and insert the bottom end of the treatment flex-arm (Fig. 30).

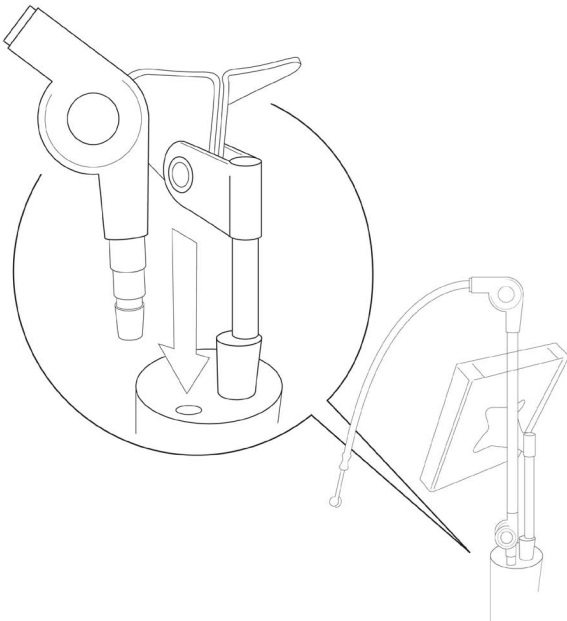


Figure 30: Treatment flex-arm

## 8 CLEANING AND DISINFECTION

The LASERNEEDLE Touch and the accessories should be cleaned and disinfected regularly in order to maintain proper function of the system. The touch buttons on the glass panel of the LASERNEEDLE Touch are serving as the device's keyboard. Dirt and grease on the glass panel could have a negative impact on the function of the touch panel. The distal tips of the optical fibers and the reusable applicators are in direct skin contact with the patient. Dirt and grease could affect the treatment efficacy.



### Attention

- Make sure the device is turned off and disconnected from mains supply before cleaning / disinfecting it.
- Follow the specific cleaning and disinfection procedure as described below.
- Only use the recommended agents to clean / disinfect the device. Other substances may damage the device or lead to insufficient cleaning and disinfection.
- Only authorized professionals with appropriate training are allowed to clean the device.
- Follow the cleaning / disinfection agent safety instruction.
- Make sure the device is completely dry before using it after the cleaning / disinfection procedure.
- Make sure to dispose the cleaning agent according to the manufacturer's instructions.
- Spray disinfection is not permitted.

### Initial cleaning / disinfection

Cleaning and disinfection agent:

For cleaning and disinfection we recommend Incidin™ Rapid manufactured by ECOLAB® Healthcare.

Procedure:

- Wiping disinfection according to the recommendations of the Robert Koch Institute (RKI).<sup>(1,2)</sup>
- Use a soft cloth or towel, moistened with the cleaning agent for wiping.

### Cleaning / disinfection of the device (LN Touch, laser shower, treatment flex-arm)

Frequency:

- Clean the LASERNEEDLE Touch, the laser shower, and the flexible treatment arm at least once a month or if any dirt is visible.

Cleaning agent:

- Incidin™ Rapid manufactured by ECOLAB® Healthcare.

Procedure:

- Wiping disinfection according to RKI recommendation<sup>(1,2)</sup>.
- Use a soft cloth or towel, moistened with the cleaning agent for wiping.

## Cleaning / disinfection of the distal ends of the optical fibers, reusable applicators

### Frequency:

- Clean / disinfect the distal tips of the optical fibers and the blue silicone applicators after each treatment.

### Cleaning agent:

- Incidin™ Rapid manufactured by ECOLAB® Healthcare.

### Procedure:

- Wiping disinfection according to RKI recommendations.<sup>(1,2)</sup>
- Use a soft cloth or towel, moistened with the cleaning agent for wiping the distal tips of the optical fibers.
- Remove the reusable blue applicators from the distal tips and clean them separately with the cleaning agent. Let them dry on an absorbent cloth.

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<sup>(1)</sup> Recommendation of the commission for hospital hygiene and infection prevention at the Robert Koch Institute (RKI): "Hygiene Requirements for Cleaning and Disinfecting Surfaces" (Bundesgesundheitsbl (2004) 47:51-61; article in German)

<sup>(2)</sup> List of disinfectants and disinfection procedures tested and approved by the Robert Koch Institute (Bundesgesundheitsbl (2013) 56:1706-1728; Bundesgesundheitsbl (2016) 59:814-817; articles in German)



## 9 MAINTENANCE

The device and all its accessories have to be cleaned and disinfected regularly. The only maintenance needed for the LASERNEEDLE Touch is to periodically reassess its efficiency and safety. This procedure requires special measurement equipment and should be done by the LASERNEEDLE company or by an authorized dealer or reseller only.

The assurance of the device effectiveness is done by the laser output power validation. Optical fiber damage is the most common cause for insufficient power output. The optical fibers wear out mostly due to improper handling as for example lack of cleaning or small fractures caused by bending or tearing. Other causes are rare and relate to technical problems in the internal structures of the device. In these cases the device should be sent to the manufacturer or an authorized dealer for repair.

The electrical safety also has to be verified once a year. In addition, we recommend to verify the laser output power at least once a year.

In case of broken fuses of the trolley replace the broken fuse with an appropriate new one (T1AH / 250V; 5 x 20 mm). If you have to replace the fuse disconnect the power adapter plug from the mains supply. Carefully lay down the device attached to the trolley on the floor without bending or crushing the optical fibers. The fuses can be accessed from the bottom side of the trolley. Replacement of fuses should be done by authorized personal only.

In case of maintenance or repair contact your local dealer or reseller. Alternatively, you can also contact the service of the LASERNEEDLE company directly:

LASERNEEDLE GmbH  
Ludolfingerplatz 5  
13465 Berlin  
Germany

Phone: +49 (0)30 2091395 - 0  
Fax: +49 (0)30 2091395 - 11  
Email: info@laserneedle.eu

Under normal conditions of use, the LASERNEEDLE Touch device has a service life of about 7 years. Premised a proper and careful usage the regular optical fibers have a life span of around 150 hours; quartz optical fibers about 200 hours.

### Overview service and maintenance schedule:

Activity	Exercised by ...	Recommended interval
control of correct installation of optical fibers	authorized dealer / user	after set up and every installation of optical fiber(s)
control of deactivation of unused lasers	user	prior to every treatment before starting the laser system
Cleaning / disinfection of tip of optical fiber	user	after every treatment
Visual control of optical fibers for damages	user	daily
Technical control of electrical safety	authorized dealer	annually
Technical control of laser safety	authorized dealer	annually
Exchange of optical fibers	authorized dealer / user	after 150 / 200 hours of operation for synthetic / glass fibers respectively

## 10 STORAGE, TRANSPORT AND DISPOSAL

### Storage

When the device is not in use, the LASERNEEDLE Touch should be stored in a cool and dry place. When not in use for extended periods, cover the unit. The optical fibers should be disconnected and kept in closed containers for the storage period.



#### Attention

Please pay extra attention to the optical fibers:

- If necessary, please roll up the optical fibers. Bends and very tight radii will damage the optical fibers.
- The regular optical fibers, which are used for the red lasers, should be rolled up to diameter no smaller than 5 cm.
- The quartz optical fibers, which are used for infrared and violet lasers, should be rolled up to a diameter no smaller than 17 cm.

### Transport

For transport disassemble the device from the trolley or from the stand of the case unit (see chapter 5 “Setup instructions”). Protect the device against transport damages by appropriate padding and packing material. When shipping the device to the manufacturer or distributor please use the original packaging. If this should not be available any more, appropriate packaging can be supplied by the manufacturer.



#### Attention

When shipping the device to the manufacturer, please include all the following:

- all 10 optical fibers,
- the power adapter (case unit version only)

### Disposal

Electrical and electronic equipment placed on the market as from 13<sup>th</sup> of August 2005 will be marked with the following symbol. The symbol notes that the device must be disposed correctly.

Symbol:



Separate collection of waste electrical and electronic equipment (WEEE)

(Currently, this symbol is only mandatory for the EU countries)

To guarantee the requirements of a proper disposal of the device, you have the possibility to return your old device free of charge to the LASERNEEDLE GmbH.

#### **Please note that you have to disinfect the device before shipping!**

Optical fibers and non-radiation-emitting accessories can be disposed safely according to the local regulations. Consumables and polluted parts should be disposed as medical waste.

## 11 TROUBLESHOOTING

The table below shows a list of operational problems, which can often be fixed by the user. If the suggested corrective actions do not help to solve the issue, please contact customer service.

Situation	Possible cause	Corrective action
The unit does not switch on.	1. Power adapter plug is not connected	1. Make sure that the power adapter is connected to both – the device and the mains supply.
	2. ON-/Off-button is not turned on	2. Turn on the ON-/Off-button in the back of the device
	3. Main switch of trolley is not turned on	3. Make sure that the main switch below the trolley is turned to the position “I”.
	4. Fuse of the trolley main switch is broken	4. Replace fuse.
The laser irradiation does not start	1. The start button was not pressed twice	1. The start button should be blinking and an acoustic signal occurs. Press the start button again. The acoustic signal is cancelled and the laser irradiation starts.
No light emission on the tip of the optical fiber	1. The laser might be infrared. Check the symbol on the respective socket (backside of the LN Touch device)	1. Infrared radiation is invisible – no visible light should come out of this laser.
	2. The output power might be set too low* *if device function is available	2. Set the power output to the desired level.* *if device function is available
	3. The optical fiber may be disconnected	3. Make sure that the optical fibers are connected to the back of the device.
	4. The distal tip of the optical fiber may be too dirty	4. Make sure that the distal tips of the optical fibers are clean.
	5. The optical fiber may be defect	5. Try to change optical fibers between two lasers and see whether the situation persists. The second laser must be a laser that does emit light! If the situation resolves replace the optical fiber, otherwise contact service. Beware not to use synthetic fibers on infrared or violet lasers.

## 12 TECHNICAL SPECIFICATIONS

LASERNEEDLE Touch technical specifications	
Laser classification	3R (acc. to IEC/EN 60825-1)
Number of lasers	10
Maximum optical power (per laser)	max. 40mW
Wavelengths	Red light: 658nm Infrared light: 785nm / 808nm Violet light: 405nm
Beam divergence (parallel x perpendicular)	405nm: max. 12° x 23° 658nm: max. 12° x 20° 785nm: max. 9° x 16° 808nm: max. 12° x 40°
Operation modes	Continuous wave(CW) Pulsed mode (PM)
Pulsed mode	0-10,000 Hz, 1 Hz resolution; 50% duty cycle
Internal memory	20 customer treatment protocols
Power supply	Manufacturer: FRIWO Type: FW7405M/15 Input: 100-240V AC/50-60 Hz Output: 15VDC/3A
Fuses	Fuse type: 5 x 20 mm Voltage/Current: 250 V AC / 2 A Operating speed (s) and Breaking Capacity: T / H
Degree of protection against ingress of solids and water	IP 20
Medical devices applied part type	BF
Operating/ Storage/ Transport conditions	
Temperature	0°C-40°C
Relative humidity	20%-80% (not condensing)
Air pressure	785 - 1013 hPa
Device size	26cm x 28cm x 4.5cm
Device weight (without trolley)	4.5kg
Laser protection goggle	for 405nm OD>3, D LB3 for 658nm OD>4, D LB4 for 785nm OD>4, DIR LB4 for 808nm OD>4, DIR LB4

## 13 EMC / ESD-NOTES



### Attention

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by LASERNEEDLE could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 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 LASERNEEDLE Touch, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

### Essential performance

The LASERNEEDLE Touch is a class 3R laser for photo biomodulation. Its maximum laser power at the distal end of the optical fibers is 40 mW. Laser safety is achieved by acoustic and optical warning systems. Due to electromagnetic disturbance this essential performance might be lost or degraded. This can result in too high or too low laser power or in false positive or false negative laser warning. The color screen might be affected (“blinking”) and in the worst case the device will shut down by electromagnetic disturbance. In any case of malfunction press the “Stop” button or the main ON-/Off-button in the back of the device.

None of the above described situations will result in a risk for the patient or operator if laser safety goggles will be worn during the complete treatment session.

Guidance and manufacturer’s declaration – electromagnetic emissions		
The LASERNEEDLE Touch (LN Touch) is intended for use in the electromagnetic environment as specified below. The user of the LN Touch should assure that it is used in such an environment. <sup>(1)</sup>		
Emission test	Compliance	Electromagnetic environment - guidance
RF-emissions acc. to CISPR 11	Group 1	The LN Touch 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 acc. to CISPR 11	Class A	
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions acc. to IEC 61000-3-3	Complied	


## Guidance and manufacturer's declaration – electromagnetic immunity

The LASERNEEDLE Touch (LN Touch) is intended for use in the electromagnetic environment as specified below. The user of the LN Touch should assure that it is used in such an environment.<sup>(1)</sup>

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floor 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 acc. to IEC 61000-4-4	+/-2kV for power supply lines +/-1kV for input / output lines	+/-2kV for power supply lines +/-1kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge acc. to IEC 61000-4-5	+/-1kV differential mode +/-2kV common mode	+/-1kV differential mode +/-2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply acc. to IEC 61000-4-11	0% $U_T$ 0.5 different angles <sup>(3)</sup> 0% 1 cycle 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles 0% $>U_T$ for 5 sec	<5% $U_T$ 0.5 different angles <sup>(3)</sup> 0% 1 cycle 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles 0% $>U_T$ for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source.
Power frequency (50/60 Hz) magnetic field acc. to IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

## Guidance and manufacturer's declaration – electromagnetic immunity (cont.)

The LASERNEEDLE Touch (LN Touch) is intended for use in the electromagnetic environment specified below. The customer or the user of the LN Touch should assure that it is used in such environment.<sup>(1)</sup>

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF disturbances acc. to IEC 61000-4-6	3 V <sub>eff</sub> / 6 V ISM 150 kHz to 80 MHz	3V <sub>eff</sub> / 6 V ISM	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance: $d = [3.5/3] \sqrt{P}$ for 150kHz to 80MHz <sup>(4)</sup>
Radiated RF disturbances acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	$d = [3.5/3] \sqrt{P}$ for 80 MHz to 800 MHz <sup>(4)</sup> $d = [7/3] \sqrt{P}$ for 800 MHz to 2.7 GHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	9 V/m, 27 V/m, 28 V/m 385 MHz to 5.785 GHz Pulsed mode: 8 / 217 Hz	9 V/m to 28 V/m	$d = [6/E] \sqrt{P}$  where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the immunity test level in V/m.  Field strengths from fixed RF transmitters, as determined by electromagnetic site survey <sup>(5)</sup> should be less than the compliance level in each frequency range. <sup>(6)</sup>  Interference may occur in the environment of the devices marked with the following symbol: 

**Notes:**

<sup>(1)</sup> These guidelines may not be applicable in all cases. The electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>(2)</sup> 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 11 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.

<sup>(3)</sup>  $U_T$  is the AC mains voltage prior to application of the test level.

<sup>(4)</sup> At 80 MHz and 800 MHz, the higher frequency range applies.

<sup>(5)</sup> The 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

<sup>(6)</sup> Over the frequency range 150 kHz to 80 MHz field strengths should be less than 3 V/m.



## Recommended separation distance between portable and mobile RF wireless communications equipment and the LASERNEEDLE Touch

The LASERNEEDLE Touch is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled.<sup>(1)</sup> The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF wireless communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)<sup>(2)</sup>      Separation distance according to frequency of transmitter (m)

	150 kHz to 80 MHz $d = [35/3] \sqrt{P}$	80 MHz to 800 MHz $d = [3.5/3] \sqrt{P}^{(3)}$	800 MHz to 2.5 GHz $d = [7/3] \sqrt{P}^{(3)}$	385 MHz to 5.785 GHz $d = [6/E] \sqrt{P}^{(4)}$
0,1 W	0.37 m	0.37 m	0.74 m	0.21, 0.07, 0.07 m <sup>(4)</sup>
1 W	1.17 m	1.17 m	2.33 m	0.67, 0.22, 0.21 m <sup>(4)</sup>
10 W	3.70 m	3.70 m	7.37 m	2,12, 0,70, 0,68 m <sup>(4)</sup>
100 W	11.70 m	11.70 m	23.30 m	6.67, 2.22, 2.14 m <sup>(4)</sup>

### Notes:

<sup>(1)</sup> These guidelines may not be applicable in all cases. The electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>(2)</sup> For transmitter rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. If the maximum output power of the transmitter is not known keep a minimum distance of 0.3 m.

<sup>(3)</sup> At 80 MHz and 800 MHz, the higher frequency range applies.

<sup>(4)</sup> RF wireless communications equipment; distance refers to immunity test level of 9 V/m (service LTE Band 13/17, WLAN 802.11 a/n), 27 V/m (service TETRA 400), and 28 V/m (service GMRS 460, FRS 460, GSM 800/900/1800/1900, TETRA 800, iDEN 820, CDMA 850/1900, LTE Band 1/3/4/5/7/25, DECT, UMTS, Bluetooth, WLAN 802.11 b/g/n, RFID 2450), respectively.

## 14 LIMITATION OF LIABILITY

The LASERNEEDLE Touch device should only be used in accordance with the instructions given in this manual. Any other use of the device has to be refrained. The manufacturer cannot be held liable for any damage resulting from improper use of the device.

## 15 WARRANTY





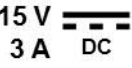










When bought as a new device directly from the manufacturer or from any official distributor or seller, the device has a limited 2-years international warranty.



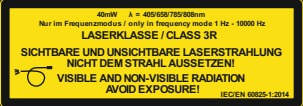







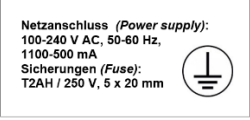




The warranty covers the entire device itself but not optical fibers, trolley or any of the accessories. To the extent of appropriate use – all malfunctions are included in the warranty. Damage or malfunction as a result of mishandling, improper use or accidents will not be covered).

The warranty is valid worldwide as long as the warranty claim is done by the original purchaser of the device and through the original distributor or reseller of the device.

Any repair or attempted repair by anyone other than the manufacturer will void the warranty immediately.

## 16 SYMBOL EXPLANATIONS

Symbol:	Explanation:
	Attention! Please note safety instructions and warning
	Note user manual
	“OFF” (position main button)
	“ON” (position main button)
	Warning of potentially hazardous visible and invisible laser radiation
	Current entry device (direct current incl. power input)
	Item number
	Serial number
	Year of manufacture
	Manufacturer symbol
	Degree of protection against ingress of solids and water (1. Code 2 = protected against solid foreign objects with diameter form 12.5 mm; protected against access with one finger) (2. Code 0 = no protection against water)
	Protect from moisture
	Protect from light
	Store, carry and operate product only in the specified temperature limits
	Laser output (optical fiber connection)
	Output laser radiation: red

	Output laser radiation: violet
	Output laser radiation: infrared
	Laser warning sign including maximum optical output and wavelengths of the lasers (depending on the device)
	Warning label invisible infrared laser (if applicable)
	Application part of type BF
	Insulation: device of protection class II (case unit version only)
	CE mark and number of notified body (MEDCERT)
	CE mark for medical devices class I
	Single use (disposable)
	Do not dispose the device with general household waste
	Current entry for power supply; specification of internal fuse
	Warning label on packaging: this side up
	Warning label on packaging: protect from moisture
	Warning label on packaging: caution fragile
	Warning label on packaging: caution fragile / keep dry

## 17 MANUFACTURER

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