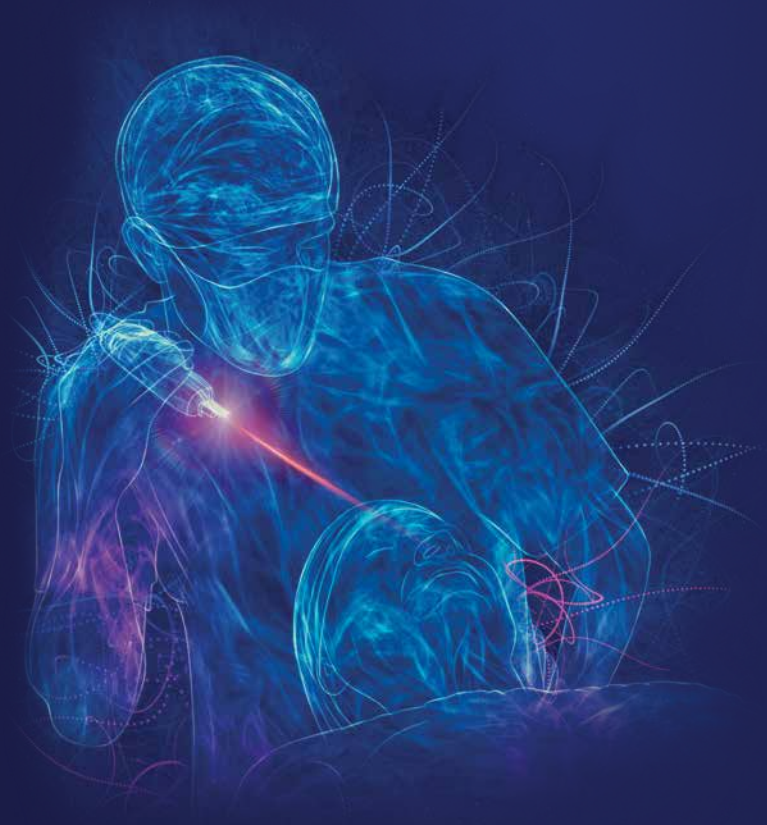
modulight

ML6710i Laser Device

INSTRUCTIONS FOR USE



Document ID: 35569
Document revision: ML6710i-IFU-Rev.9-2020-08-03-CA
ELM artwork number: X

Preface

Professional clinical information

Intended use

The intended use for the ML6710i laser is photoactivation of a light-activated drug used in photodynamic therapy (PDT) for the treatment of patients with disorders of the retina and choroid.

Please consult the prescribing information of the drug for additional information on intended use, recommended drug and light dose, administration instructions, contraindications, warnings and precautions, and side effects of the treatment.

Contraindications

Patients with cloudy cornea or extreme haze of the aqueous humor of the anterior chamber which prevent visualization of target tissue are contraindicated for laser treatment.

Precautions

The aiming beam, while low power, is an intense light source so that retinal exposure must be limited to the minimum required for target acquisition.

Adverse effects

The adverse effects of the ML6710i laser could be related to inappropriate dosages or improper use of the device that could result in incomplete treatment due to partial photoactivation of the drug, overtreatment due to over-activation of the drug, or damage to surrounding normal tissue.

Operator profile

ML6710i laser is intended for use only by qualified physicians and other licensed medical professionals.

1. Contents

1. Information for safety

This section describes how to operate the ML6710i safely and which precautions to take into account when preparing the ML6710i and use environment into use.

This section includes the general information for safety. More specific information related to detailed use of the device are given are in other section within the corresponding description of the functionality.

Please read the information for safety carefully and follow the given safety instructions. Should you have any questions regarding the information for safety or this document, please contact the manufacturer.

1.1 Symbols used

Prohibited action

Indicates prohibition of certain action in order to operate the device safely.

Mandatory action

Indicates mandatory actions required from the user to operate the device safely.

Warning

Indicates a hazardous situation that, if not avoided, could result in death or life-threatening injury.

Caution

Indicates

- Either a hazardous situation that, if not avoided, could result in temporary injury or impairment that may require professional medical intervention
- or a hazardous situation that, if not avoided, could damage the device or reduce its operating lifetime.

1.2 General safety notices and warnings

WARNING: No modification of this equipment is allowed. The unauthorized modification or alteration of the equipment, or the use of non-approved accessories, or parts with the equipment, or unauthorized service personnel are prohibited and shall relieve the manufacturer/distributor from any warranty, service obligation or other liability for damages to, or failure of, the equipment caused by such unauthorized acts. Furthermore, in order to reduce the risk of electrical shock, detaching the rear panel and exterior cover of the system is strictly prohibited. There are no serviceable parts inside.

Do not store or use the device in room exceeding the specified ambient conditions. Do not expose the device to water splashes, dripping or sprayed water.

Do not place any fluid-filled containers on top of the device.

Disregarding information for safety may subject the user or patient to a risk.

Follow Instructions For Use. Do not use the device before thoroughly reading and understanding these Instructions For Use.

See the drug prescribing information for determining patient suitability for the treatment. Use the device only for the indications addressed in these Instructions For Use.

Risk of explosion exists if used in presence of flammable anesthetics, or other flammable gases or liquids.

Only instructed, trained and authorized personnel should operate the ML6710i. The device owner/user is responsible to have the operating personnel trained and instructed appropriately.

Extravasation of the photosensitizer may cause burns and other severe reactions in the tissue, especially if the affected area is exposed to light. Please refer to the prescribing information of the drug for instructions.

ML6710i is a combination equipment utilizing a photochemical reaction between laser light and a photosensitive drug. Patient exposure to laser light elsewhere than the tissue planned to be treated should be avoided to minimize unnecessary drug activation. Please pay attention to laser safety precautions described in these Instructions For Use to avoid laser hazards. Please refer to prescribing information of the drug for possible contraindications and side effects from using the drug.

Follow the recommended light dose instructed in the prescribing information when setting the treatment parameters for the ML6710i.

Patient shall be instructed to avoid exposure to direct sunlight or bright indoor light according to the prescribing information of the drug.

ML6710i shall not be used when the intended use or the indication for use of ML6710i do not coincide with the intended use or the indication for use of the photosensitizer.

The device is not meant to be in contact with human tissue and unnecessary contact should be avoided.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

Federal law restricts this device to sale by or on the order of a physician.

1.3 Ventilation holes

The ventilation holes in the rear panel and bottom side of the device should not be blocked in any way to ensure sufficient airflow and therefore to avoid excess heating of the device. To emphasize this, the device has been marked with the text "DO NOT BLOCK VENTILATION HOLES".

Please note that ventilation holes are not protected against harmful ingress of water from splashes, dripping or sprayed water. Such exposure must be avoided.

Do not cover any ventilation holes of the device.

Make sure that there is at least 2 inches clearance around the device for cooling purposes.

1.4 Laser light safety

The output power of the laser goes up to 400 mW. As such, the device is classified as a class 3B laser product, which is indicated with the warning label in section 5.

By definition, a class 3B laser is normally hazardous when direct or reflected ocular exposure occurs, including accidental short time exposure. These lasers may produce minor skin injuries or even ignite combustible materials, and thus may represent a fire risk. The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided. Some materials, for example cotton wool when saturated with oxygen may be ignited by the high temperatures produced in normal use of the laser equipment. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases.

As a class 3B laser device, ML6710i is equipped with a key switch and a safety interlock. Laser equipment not in use should be protected against unqualified use, for example by removal of the key from the key switch. The laser design allows using a separate remote interlock prohibiting laser emission when a door to the laser room is opened, for example.

The device control electronics are designed to prevent any unintended laser emission in the event of single fault failures.

The device is equipped with protective fuses, which are not user replaceable.

Make sure to follow laser safety regulations and principles and ensure that there is no possibility of scattered or direct laser light being transmitted outside the application areas.

Laser safety eyewear (689 nm, OD 4+) is mandatory for all personnel (physician giving the treatment may be excluded when the SLA is equipped with a safety filter) within the reach of emitted direct or scattered light. Limit the number of persons in the laser hazard area to as few as possible. Nominal ocular hazard distance (NOHD) is 1.7 m calculated with 0.4 W at 689 nm wavelength.

Clearly protect and mark the laser hazard area during laser operation. Place the laser warning sign provided with the delivery package prominently at the entrance of the laser hazard area.

A remote interlock may be used for switching the laser emission off automatically should the laser hazard area be entered during operation. Contact the manufacturer for further instructions on installation of a remote interlock. Other laser safety precautions should be clarified with local authorities or your laser safety officer.

It is vital to take laser safety precautions when using the aiming and/or treatment beams of the device. The visible laser light emitted by the device is hazardous to the human eye and skin if misused. Exposure from direct light beam or induction of scattered light from highly reflective surfaces such as metal, watches, jewelry and other shiny objects shall be avoided. Beam divergence (full angle) after the SLA focal point is 130 mrad.

All personnel working with the ML6710i and/or in the laser hazard area, must be familiarized with these Instructions For Use and receive formalized training on current applicable laser safety regulations.

Use of incorrect treatment parameters, controls, adjustments or performance of procedures other than those specified in these Instructions For Use, or operation with improper or out of calibration device may result in hazardous laser light exposure or adverse health effects.

This page intentionally left blank.

2. The ML6710i

2.1 Description

This section describes the ML6710i. This section is not meant to describe every operating feature in detail. It is simply a guide to become familiar with the essential components of the laser device. Operating the laser device is described in more detail in sections 3 and 4.

ML6710i is a medical electrical (ME) device consisting of:

- ML6710i main unit accompanied by a key switch and an interlock (suitable for implementing remote interlock)
- Power supply and power cord
- Foot switch
- iPad for operating the graphical user interface (GUI), not part of standard delivery. ML6710i only operates with specific iPad models, please see section 4.2.2 for supported models.
- Slit lamp adapter

The treatment procedure is to be performed only by medical professionals trained and knowledgeable about using lasers. The process should be performed in a clinical setting, e.g.,, hospital, physician's office.

The output of the device is continuously operated (continuous wave, CW, i.e., laser is operated at constant power, not pulsed), designed for output power range up to 400 mW. The actual operating power depends on the device configuration, such as the treated area and irradiance.

The laser device configuration described here is for use with ML-SLA. The ML6710i output power range is measured at the output of the ML-SLA.

The output power does not need to be calibrated by the user as it is monitored internally. The device automatically checks the ML-SLA power based on the treatment configuration.

The GUI run on an iPad controls all the relevant parameters related to the treatment and functionality of the laser device. The device is operated with sequential screens guiding the user to perform required tasks before the actual treatment.

ML-SLA is equipped with a safety filter blocking the treatment light from entering the user's eyes when viewing through the ML-SLA mirror. The safety filter also prevents viewing the treatment beam in the patient's eye. Therefore, the laser is equipped with a low power aiming beam for targeting the intended laser irradiation to the target area in the tissue. The aiming beam is concentric with the treatment beam and is similar in size. Once the treatment is configured and treatment beam is targeted as intended, a foot switch is required for enabling the actual laser emission.

2.1.1 Essential performance

The essential performance of ML6710i is defined as follows:

- Capability of producing a specified wavelength of light within a specified spectral range
- Capability of producing a specified optical output irradiance from an SLA

The following radio field/electromagnetic disturbances may affect the essential performance of ML6710i:

- Communication loss between main unit and GUI may occur in case of a strong disturbance at 2.4 GHz
- Major mains supply voltage dips and interruptions may cause the main unit to shut down or reboot

2.2 Approved beam delivery systems

The ML6710i is designed for PDT treatments of the retina and to be used together with a slit lamp. For delivering the laser light into the treated eye, only compatible slit lamp adapters are allowed to be used together with the device. The Instructions For Use describe use with, Modulight Slit Lamp Adapter, part number ML-SLA.

Use of a Slit Lamp Adapter other than verified for compatibility is strictly forbidden to avoid incorrect beam characteristics, wrong dose and other hazards.

Use only a Slit Lamp Adapter (SLA) compatible with the laser device.

2.3 General classifications

Table 1. *General ML6710i classification.*

Description	Classification	Applied standard
Medical device	Class III	21CFR860.3
Protection against electric shock	Class II	IEC 60601-1
Protection against harmful ingress of water or particulate matter	Laser unit: IP 2X Foot switch: IP X6	IEC 60529
Laser safety	Treatment beam: Class 3B [1] Aiming beam: Class 2	IEC 60825-1
Electromagnetic emissions	Class A, Group 1	CISPR 11
Applied part (SLA)	Type B	IEC 60601-1

[1] Complies with 21 CFR 1040.10 and 1040.11 except for conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1, as described in Laser Notice No. 56, dated May 8, 2019.

2.4 Specification

2.4.1 Electro-optical and electrical performance

The ML6710i has a specific usable output power range, which limits the available spot size depending on the selected contact lens magnification and irradiance. Spot diameter is limited by the SLA properties. Settings outside these ranges are indicated on the GUI.

Table 2. *Electro-optical characteristics at 59–86 °F (15–30 °C).*

Parameter	Symbol	Unit	Min	Typ	Max	Comment
Target wavelength [1]	λ	nm		689		90% power within 689 ± 3 nm
SLA output power [2]	P_{SLA}	mW			400	ML-SLA output power being within 20 % of set value
Stability [2]		%		±10		At maximum power over one treatment cycle, from 5 s after start
Aiming beam power	P_{AB}	mW	0.02		2.5	Class 2 Laser @ 635 ± 10 nm wavelength
Spot diameter [3]		mm	1.0		5.0	Without contact lens. All values full width at half maximum (FWHM) with ±10% accuracy
Contact lens magnification			0.5		2.5	Multiplied with Spot diameter to achieve actual spot at retina
Irradiance	E	mW/cm²	50	600	800	Depends on indication. Limited by selected contact lens.
Dose	$H_{e,o}$	J/cm²	5	50	95	Please consult the prescribing information of the drug for recommended light dose

[1] The wavelength is fixed by the manufacturer and is automatically controlled by the laser device

[2] The output power is automatically adjusted and stabilized by the device based on the set treatment parameters

[3] In focus after SLA

Table 3. *Electrical characteristics for ML6710i.*

Parameter	Range	Unit	Comment
Input voltage	15	V	± 5%
Input power	≤ 60	W	
Current consumption	≤ 4	A	
Input voltage of power supply	100–240	VAC	
Input frequency of power supply	50–60	Hz	
Max current consumption	1.5 0.7	A	115 VAC 230 VAC
Bluetooth Low Energy frequency of reception & transmission	2400–2483.5	MHz	Bandwidth 2 MHz
Effective radiated power	6	dBm	Nominal

2.4.2 Ambient conditions

The device is designed to be operated in typical hospital or clinic environments, with the ambient environment characteristics specified in Table 4. Exclusions regarding electromagnetic compatibility is listed in chapter 5.

The device should be allowed to return to normal operating conditions after transportation or storage prior to use.

Table 4. *Ambient conditions for ML6710i.*

Parameter	Unit	Min	Max	Comment
Operating temperature	°C	15	30	
Operating humidity	%RH	0	70	Non-condensing operating environment required
Operating atmospheric pressure	kPa	70	106	
Storage and transportation temperature	°C	-20	+50	
Storage and transportation humidity	%RH	0	90	Non-condensing environment required
Storage and transportation atmospheric pressure	kPa	70	106	

3. Product delivery package and installation

MANDATORY

Follow the device installation and setup protocol defined in these Instructions For Use.

3.1 Product delivery package

The ML6710i is delivered in a transport case shown in Figure 1. The transport case is equipped with a handle and wheels for temporary movement. Leave the case in a position as instructed by the labels whenever ML6710i is stored inside it.

Figure 1. *ML6710i transport case..*

3.1.1 Post-shipment inspection protocol

Follow the instructions in this section to ensure the device has not damaged during transit.

Transport case

- Inspect the transport case for cracks, dents and big scratches. They typically indicate a major impact on the transport case possibly harmful for the device
- Inspect the shock indicator attached on the transport case side
- In case any of the steps above give rise to concerns of the device condition, please follow instructions in the next section

ML6710i

- Inspect that all items are in their respective positions inside the transport case
- Inspect that the items supplied and accessories listed in section 3.2 are visually intact
- Take the main unit from the transport case and carefully turn it from vertical to horizontal position to listen that there is no movement or clinks inside the device
- In case any of the steps above give rise to concerns of the device condition, please contact the manufacturer

WARNING

ML6710i transport case is equipped with a shock indicator (Figure 2). When receiving the unit, check that the shock indicator has not activated. Activation of the indicator means that the device has been exposed to a potentially damaging impact during transit. A service person authorized by the manufacturer needs to verify the device functionality.

Figure 2. *Intact and activated shock indicator. The red indicator on the right side indicates that the ML6710i has been exposed to a potentially damaging impact during transit.*

3.2 Items supplied

Table 5. *The items supplied together with ML6710i.*

Item	Description	Part number (if spare parts needed)
Main unit	ML6710i main unit	-
Power supply	Medical power supply	AP0201, rev. 1
Power cord	Power cord provided with US plug	AP0307, rev. 1
Instructions For Use	Instructions for use and safety	ML6710i-IFU-Rev.6-2020-03-19
Foot switch	1-pedal foot switch integrated LASER STOP button	AP1130, rev. 1
Power key	Key for enabling/disabling device mains power. 2 pcs included	AP1236, rev. 1
Laser safety interlock	Allows implementation of remote interlock	Key only: AP1192, rev. 1 Remote interlock cable (5 m): AP1192, rev. 2
Laser warning sign	Laser warning sign that can be hanged e.g., on the handle of the laser hazard area door	AP0980 rev. 2
Velcro	For securing the optical fiber	AP1207
Slit Lamp Adapter (SLA)	Laser spot delivery into the patient's eye through a contact lens	ML-SLA, rev. 1
SLA mounting adapter	Attaches ML-SLA on the slit lamp	ML-SLA ADAPTER, slit lamp model dependent
Certificate of Conformance	A statement that the laser device is released by Modulight and meets the appropriate requirements	N/A

3.2.1 Unpacking and re-packing the device

Carefully unpack all parts from the transport case before setting up the device and inspect them visually to be intact

When receiving the product, unpack all parts carefully. Pay special attention to handling of the ML-SLA cable that incorporates an optical fiber sensitive to bending. For later use, place all plastic bags and similar supplies back to the transport case after all functional items have been unpacked.

Should the device setup need to be decommissioned e.g., for temporary storage, pack all items as they were when received. See Figure 3 for reference.

Follow the packing instructions when dismantling the setup for storage

Figure 3. *ML6710i items. 1: Main unit, 2: ML-SLA, 3: ML-SLA ADAPTER 4: Foot switch, 5: Power supply in a cardboard box, 6: Wind up ML-SLA fiber, 7: Various supplies in a bag.*

3.3 Product installation and setup

ML6710i is not a permanently installed device i.e. it doesn't require permanent (detachable by the use of a tool only) electrical connection to supply mains. The device does not have or require a separate supply mains switch and is isolated from the supply mains simply by pulling the plug from the mains socket.

Setup of the ML6710i is to be done at the treatment site by personnel authorized by the manufacturer (Figure 4).

MANDATORY

In case a calibrated treatment set-up (including laser, SLA and slit lamp) is disassembled or transported to another location the treatment station should be re-calibrated by service personnel authorized by the manufacturer. Please contact the manufacturer for further instructions or agreeing a service visit.

WARNING

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

Figure 4. *Example setup of ML6710i on an ophthalmic treatment station.*

Left: Illustration of a physician (person on right) directing the laser treatment beam into the eye of the patient (person on left) via a slit lamp and a contact lens on an ophthalmic table.

Right: A typical treatment station setup with ML6710i. 1: ML6710i laser device, 2: iPad (GUI) with wireless connection to ML6710i, 3: Modulight cloud service accessed via GUI, 4: Foot switch for activating laser emission, 5: ML-SLA accessory for shaping the treatment beam, 6: Slit lamp/ophthalmic microscope, 7: Ophthalmic contact lens to deliver treatment beam into the retina of the patient, 8: Ophthalmic table.

3.3.1 Treatment station

The ML6710i is installed on top of a separate ophthalmic treatment table equipped with a separate slit lamp.

When operating the slit lamp, follow manufacturer's instructions provided with the slit lamp.

When operating the ophthalmic table, follow manufacturer's instructions provided with the table.

3.3.2 Mounting SLA on a slit lamp (tower illumination model)

The ML-SLA is mounted on the slit lamp following the procedure:

- Placing the SLA on the slit lamp (Figure 5)
  - Make sure the slit lamp is equipped with a tonometer mounting base
  - Secure the ML-SLA ADAPTER to the ML-SLA
  - Place the ML-SLA ADAPTER to the tonometer mounting base
  - Secure the ML-SLA ADAPTER position with the finger screw

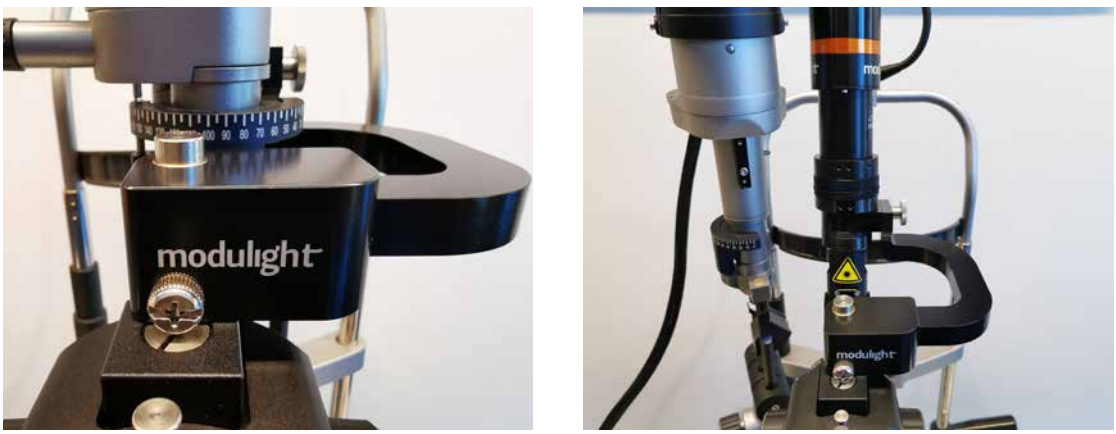


Figure 5. *Mounting the ML-SLA to the slit lamp tonometer base.*

- Supporting the SLA cable to the slit lamp (to avoid tight bends and breakage of the optical fiber)
  - Fold a velcro around the ML-SLA cable and place the cable next to the slit lamp headrest so that the velcro is between the cable and the headrest (Figure 6)
  - Wrap the velcro around the headrest and tighten to fix the ML-SLA cable position (Figure 6)
  - Support the cable from two positions (Figure 7)

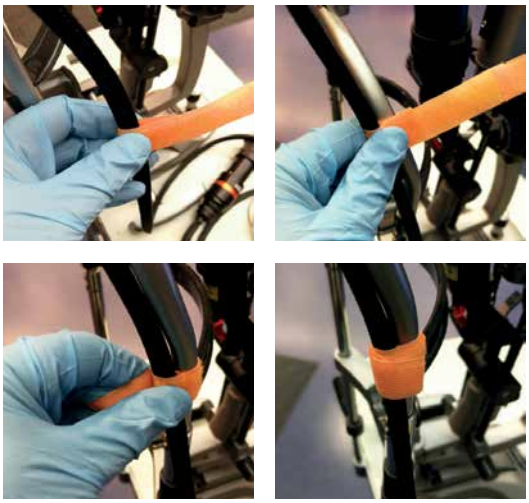


Figure 6. *Securing the ML-SLA fiber to the slit lamp headrest using velcros.*

Figure 7. *ML-SLA and its cable mounted on a slit lamp.*

WARNING

Precautions must be followed when handling the SLA fiber to avoid fiber breakage resulting e.g., from sharp bends or improper securing to the slit lamp. Not following these recommendations may lead to incorrect light dose and hazardous laser light exiting the SLA fiber.

3.4 Rear panel

The ML6710i is powered by connecting the AP0201 medical power supply to a wall socket with an AP0307 power cord. The power supply is then connected to the inlet at the right side on rear panel of the device. The power supply automatically detects 100–240 V operating voltage and is protected against short circuiting and overloading.

Do not use power inlet outside the nominal ratings specified in these Instructions For Use and marked on the rear panel of the device.

Only supply voltage 100–240 VAC with frequency 50–60 Hz for the power supply that supplies 15 VDC for the device.

Figure 8. *ML6710i rear panel and connections.*

The rear panel is presented in Figure 8.

The input ports for the foot switch and interlock connectors are located at the middle of the rear panel. Laser emission can be turned on and a treatment can be performed only when the foot switch and the interlock are connected.

Fiber and SLA connector are located at the left side. The key switch at the right side is for switching device power on and off.

Bluetooth pairing button is located at the top-right corner and is marked CONNECT. It has an integrated LED which shows blue when the device is connected to the iPad.

3.4.1 Connection and disconnection of SLA, interlock and foot switch

The SLA, foot switch and the interlock are connected to the rear panel of the ML6710i with push-pull type connectors (Figure 9).

Connection

While connecting the push-pull connectors to rear panel, please keep the red dot on the connector to upwards direction. Push gently until the connector is all the way in its place.

Disconnection

To disconnect the SLA, interlock or foot switch from the ML6710i rear panel:

- Hold the connector by the grid-surfaced barrel only (Figure 10)
- Gently pull the barrel away from the ML6710i rear panel to disconnect

Figure 9. *Attach the SLA, interlock and foot switch connectors red dot upwards.*

PROHIBITED

Do not use excessive force while disconnecting the push-pull connectors on the rear panel. Do not twist the push-pull connectors.

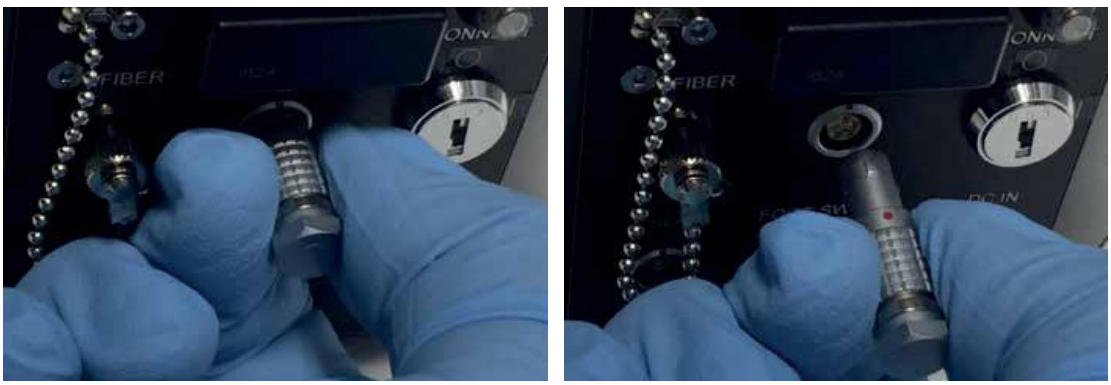


Figure 10. *Hold the connector by the grid-surfaced barrel only.*

Before running a treatment, please inspect functionality of the interlock by removing the interlock connector or by releasing the remote interlock. The change of the interlock state must be visible on the GUI (see Figure 21). After confirming the functionality, place the interlock connector/remote interlock back to the original position. It is recommended to repeat this procedure each time when starting the main unit.

If any of the cable connectors seems damaged or does not connect properly, disable the device from use and contact the manufacturer for service.

Connecting SLA fiber

Always place a dust cap to the optical fiber connector when the fiber is disconnected.

If a fiber is damaged or seems twisted, contact customer service (see rear cover page of these Instructions For Use). The fiber must be replaced and device recalibrated by a manufacturer authorized personnel.

Avoid unnecessary disconnection of the SLA optical fiber or the SLA electrical cable from the ML6710i as it may result in changed calibration and incorrect treatment parameters that can cause harm to the patient.

It is recommended to use dust-free gloves when handling optical fibers. The SLA fiber is attached to the rear panel connector as follows (presented in Figure 11):

- Pay attention not to touch/contaminate the tip of the fiber
- Remove the fiber connector dust cap from the rear panel by twisting it anti-clockwise
- Remove the dust cap from the SLA fiber and gently push the connector inside the port in the rear panel
- Twist the fiber connector nut clockwise until tightened

Disconnecting the fiber is done in a reversed order. Make sure to reattach the dust caps to the fiber tip and the rear panel port.

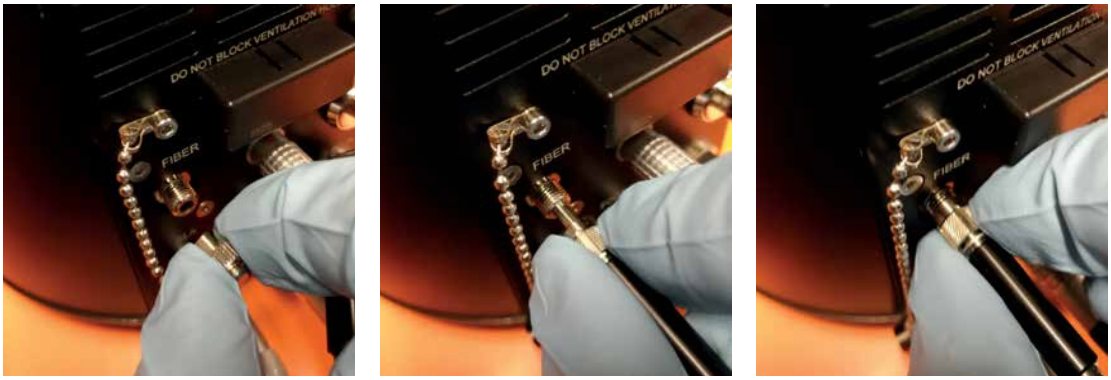


Figure 11. *Connecting the optical fiber of the SLA to the ML6710i rear panel.*

3.4.2 Connecting power supply to DC IN

The power supply's DC cable is attached to the DC IN inlet as presented in Figure 12.

In order to reduce of damaging of the power supply of the power cord by overstepping or overrunning, they shall be placed so that they are not on isles or on typical floor areas where people or equipment move frequently. Should the device e.g., be taken temporarily out of use, please follow re-packing instructions in section 3.2.1.

Figure 12. *Connecting the power supply cable to the DC IN jack on the ML6710i rear panel.*

Do not use other than the original power supply provided with the device or specified by the manufacturer.

In case of worn-out electric power cord or other event possibly leading to weakening of insulation and danger of electric shock, contact the manufacturer for service and disable device from use.

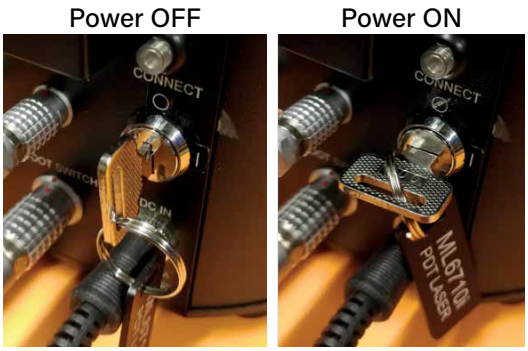


Figure 13. *Connecting the power key to the ML6710i rear panel.*

3.4.3 Connecting power key

The power key is symmetrical and can be inserted either way into the power switch. Figure 13 shows how the key is used for switching device power on (|) and off (O).

3.5 Disposal

At the end of the device's lifetime, the device should be returned to manufacturer for disassembly and partitioning of material belonging to different waste groups and possible recycling of material.

4. Operating the laser device

This section contains instructions on how to operate the ML6710i. The examples cover the normal operation of the device as well as various error situations.

Figure 14. *Laser status indicators.*

4.1 User interface on the main unit

4.1.1 ML6710i chassis

On the main unit chassis upper edge there are LED's indicating laser and device status.

READY shows green when the device is ready for use. This means that the treatment parameters have been confirmed and the laser emission can be turned on (see subsection 4.3.2) provided that status LED is in normal state.

EMISSION shows blue whenever the laser emission is on (treatment running).

The middle LED is for indicating device status as explained in Table 6.

Please note that the green READY indicator remains on also in the case of an error during treatment. This is to say that also in the special case of a disconnected iPad (see section 4.3.4), the treatment is still configured to the device, but the error situation indicated by the Yellow LED needs to be cleared before continuing treatment is possible.

Table 6. *Device status indicator.*

LED state	Description
White ON	Device is powered on and functioning normally.
White BLINK	iPad (GUI) is disconnected and only limited features are available. If a treatment has been started, it can be continued with the foot switch (treatment automatically ends after the planned duration).
Yellow ON	Warning – please see instructions given by the GUI and troubleshooting section in these Instructions for Use in order to solve the issue.
Yellow BLINK	Unrecoverable internal error. Device power needs to be cycled off and on to continue.
Red ON	LASER STOP button has been pushed. Treatment cannot be continued before LASER STOP has been reset by pushing LASER STOP button again or rebooting device (power off and back on).
Red BLINK	Unrecoverable internal error. Device power needs to be cycled off and on to continue.

4.1.2 Foot switch

The foot switch in Figure 15 is used for starting treatment i.e. enabling laser emission with the orange pedal. The LASER STOP button is designed to disable all lasers rapidly in case of an emergency and is integrated on the foot switch.

Figure 15. *Foot switch for enabling laser emission. Laser stop button is integrated into the foot switch.*

MANDATORY

Before running a treatment, please inspect functionality of the LASER STOP button by pushing it when in Treatment planning screen. The button activation must be visible on the GUI. After confirming the functionality, deactivate the LASER STOP button by pushing it again. It is recommended to repeat this procedure each time when starting the main unit.

CAUTION

The LASER STOP switch only turns the laser emission off, it does not shut down the device itself.

4.2 Graphical user interface (GUI)

The user interface of the ML6710i is an iOS application called ML6710i. The application requires access to the internet for user authentication.

4.2.1 Network Requirements

You must provide a Wi-Fi connection that can be configured to the iPad device. It is recommended to use a Wi-Fi network secured with WPA2 encryption, and to configure the IP address using DHCP.

The ML6710i iOS application makes an HTTPS connection to cloud.modulight.com, port 443. The port should be opened in your firewall, if necessary.

Should you require assistance, please contact your local IT network administrator.

4.2.2 iPad requirements

Operating system requirements

The ML6710i application is compatible only with specific versions of the iPad operating system. The Compatibility details are found in App Store under Information section of the ML6710i application.

To enable safe and efficient use of the device also when new operating system versions are released, remember to disable automatic software updates from your iPad as shown in Figure 16.

Figure 16. *Disabling automatic updates of iPadOs.*

This allows you to control that an incompatible iPadOS version is not automatically installed. The installation cannot be reverted so it is important to wait until a new, tested version of the ML6710i application is released in App Store. Additionally, do not install a new iPadOS version manually before confirming compatibility from App Store.

To make sure that patient safety is not compromised due to an untested operating system, ML6710i application prompts a warning when iPadOS version is not supported.

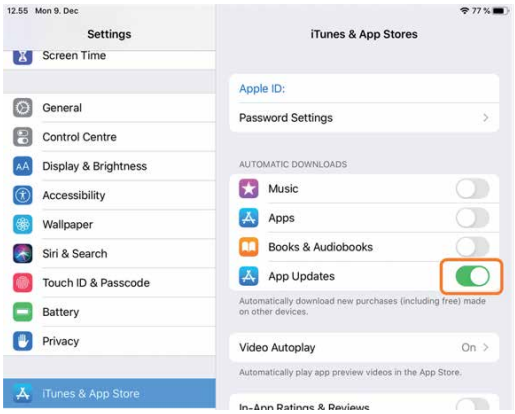


Figure 17. *Enabling automatic App Updates.*

Table 7. *Supported iPad models.*

Type	Model
iPad mini 4	A1538, A1550
iPad, 6th generation	A1893, A1954

This warning reappears until the ML6710i application and iPadOS version have been validated to be compatible with each other.

To enable automatic update of the ML6710i application (e.g., in case of the unsupported iPadOS, this setting allows automatic update of the app once the compatibility is confirmed), it is important to enable automatic App Updates in the iPad as shown in Figure 17.

Hardware requirements

The ML6710i application is compatible with the iPads listed in Table 7.

Figure 18. *Login form.*

4.2.3 Login

You first need to authenticate yourself. The login form in Figure 18 is shown when the ML6710i application is opened.

Fill in your valid Modulight user account credentials. Login name is typically your email address and password is your self-defined personal password. In case you don't have credentials for logging in, please contact Modulight for registration.

Invalid credentials or incorrect passwords are displayed with the error message shown in Figure 19.

The actual user interface of the ML6710i is shown after the user authentication is done successfully.

PROHIBITED

Do not share your personal credentials.

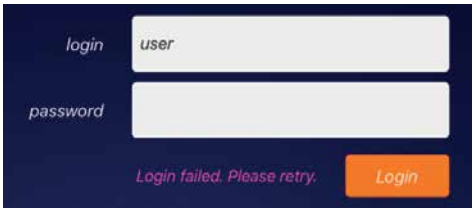


Figure 19. *Login failure e.g., due to incorrect password.*

4.2.4 Navigation and status bars

The ML6710i application is navigated via tabs with specific functionalities. Figure 20 shows the available tabs.

Various device status information is given on the status bar displayed at the screen bottom. Figure 21 shows some examples of the messages.

4.2.5 Laser tab

The main unit communicates with the iPad wirelessly via Bluetooth.

Laser tab consists of one screen (Figure 22) which identifies the connected ML6710i. The ML6710i application can control one ML6710i main unit at a time. If there are many ML6710i devices available nearby, you can select, which laser to connect to.

Figure 22. *Laser device is connected and ready for operation.*

Figure 20. *Tab ribbon on the ML6710i application.*

Figure 21. *Examples of status messages displayed at the screen bottom.*

The ML6710i application remembers the last ML6710i connected. If the application is opened while the same previously connected laser device is available nearby, the application reconnects with the device automatically.

Bluetooth pairing

There are cases when you need to pair the iPad with the main unit, such as:

- New iPad taken into use
- Operating system/software update
- Pairing forgotten for unknown reason

Should this happen, you may re-establish the pair by:

- First making sure Bluetooth is enabled in the iPad settings
- Pushing the CONNECT button in the main unit rear panel (Figure 8) for 5 seconds until it starts blinking in blue
- Waiting until the ML6710i is shown on the **Laser** tab and then selecting **connect** (status on GUI changes to connected)
- Confirming the Bluetooth Pairing Request shown on display by selecting Pair (see Figure 23).

Choose another laser

If the application is connected to an ML6710i but you wish to use another ML6710i (which is also available nearby), you can tap **disconnect** and the existing device connection is ended.

When the device is disconnected, the device scan is started and the application proposes another device to connect to (Figure 24).

If the device proposed is not the desired one, you can tap **choose another laser** and the next

Figure 23. *Confirmation pop-up when pairing a new main unit with the GUI.*

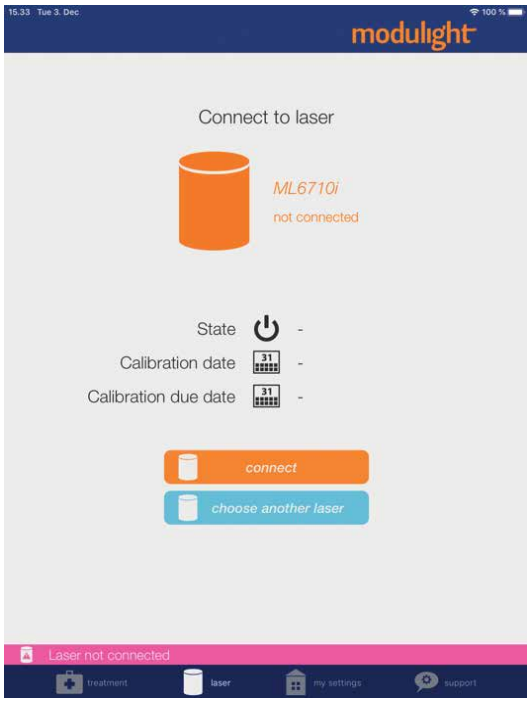


Figure 24. *Laser device is available and proposed for a connection.*

available ML6710i is proposed. You may do this as many times as is needed to find the right device. When the desired laser device is proposed, the connection is done by tapping **connect**. The ML6710i is ready for use when the connection is established (status **connected**) and device State is Ready for operation as in Figure 22.

4.2.6 Treatment tab

When you log in to the ML6710i application the **treatment** tab is selected by default.

The **treatment** tab shows either the treatment planning screen (Figure 33) or the treatment screen (Figure 37) depending of the device state (e.g., in case of an unfinished treatment).

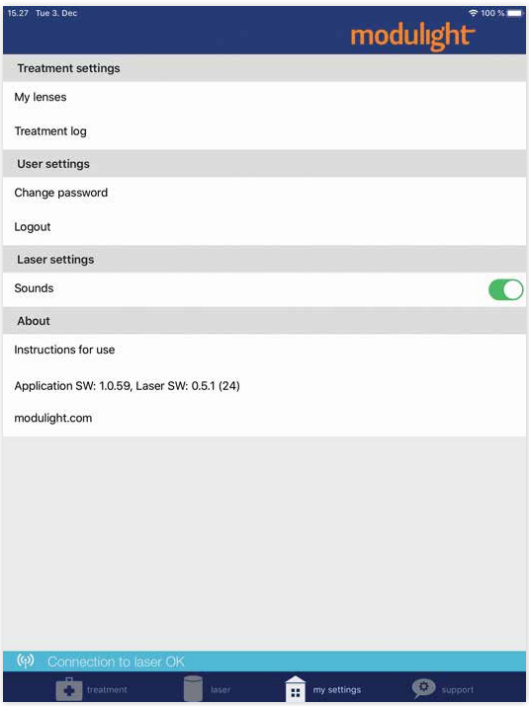


Figure 25. *My settings tab.*

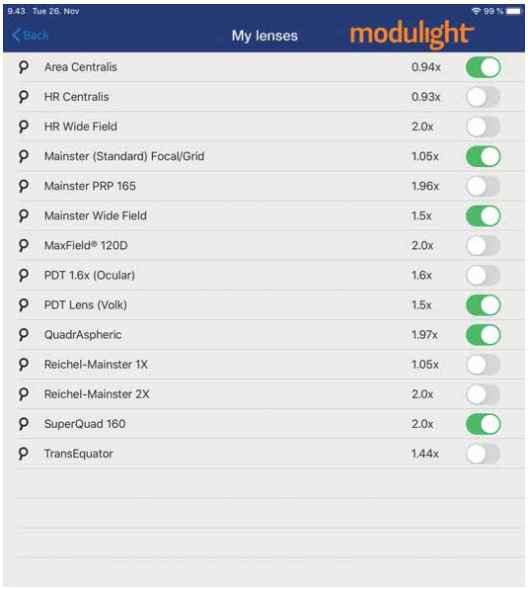


Figure 26. *My lenses view.*

4.2.7 My settings tab

My settings tab shown in Figure 25 contains several important features.

My lenses

My lenses option allows you to define the contact lenses available for selection in the Treatment planning screen (Figure 33).

Figure 26 shows how specific contact lenses may be activated or inactivated (only the activated lenses will be shown in treatment planning screen).

Using **My lenses** is not mandatory but it helps in treatment planning step since you can limit lens options only to those in your typical use.

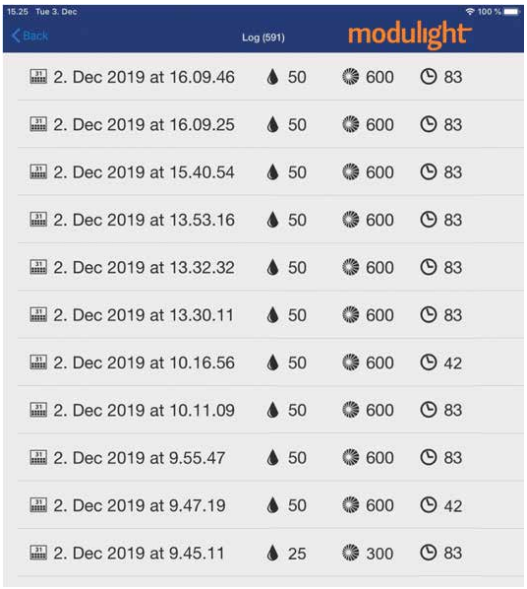


Figure 27. *Treatment log.*

Treatment log

Treatment log lists previous treatments that have been done with the ML6710i (Figure 27). Treatment list is sorted by the treatment date starting from the latest treatment. Scroll down the list to see the older treatments.

Tap a treatment in the list to see the detailed view of a treatment. As seen in Figure 28, the comments given after the treatment are displayed in the treatment details view. The comment can still be modified and can be opened for editing by tapping the comment text.

In case of an interrupted treatment (ended before planned time), the realized values of dose and duration are displayed while the planned settings are displayed in parentheses after the realized ones.

Figure 28. *Treatment log details.*

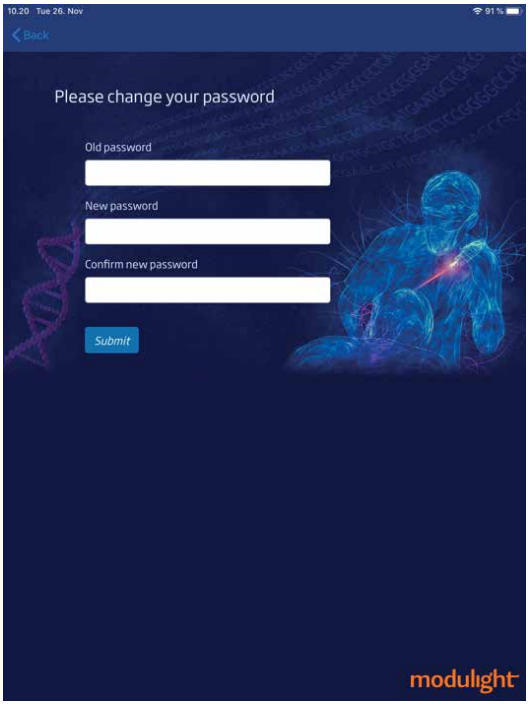


Figure 29. *Password change window.*

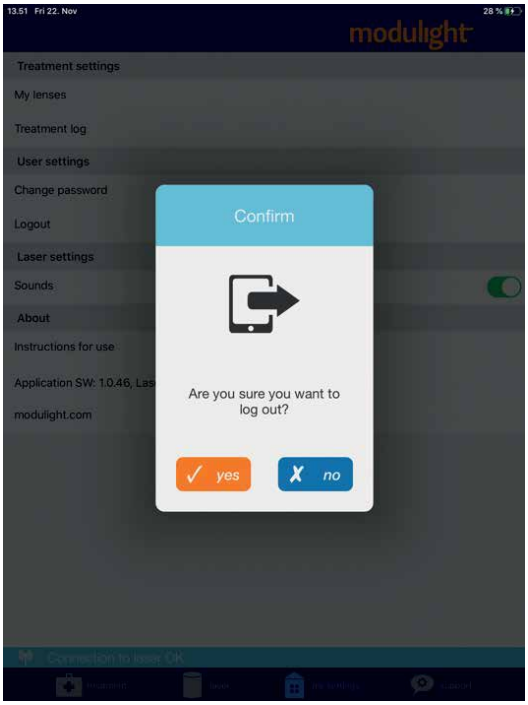


Figure 30. *Confirmation pop-up after selecting Logout.*

As internet connection is required for uploading treatment logs into the cloud service, it is not guaranteed that all executed treatments are successfully recorded in treatment history.

Change password

The **Change password** feature is meant for changing of the users' password. It is important to follow prevailing password recommendations. The tapping of **Change password** (Figure 25) opens a new page (Figure 29) where a new password for the ML6710i user account can be defined.

Please contact the manufacturer should you need to change password and

- There is reason to suspect that the current password has been stolen
- The password change feature does not work for some reason

Logout

It is recommended to log out from the GUI with the **Logout** button after each use of the iOS device to prevent unauthorized use. A confirmation screen as in Figure 30 is given. Logout is also done automatically after 30 minutes of inactivity.

Figure 31. *Support tab.*

4.2.8 Support tab

Support tab shown in Figure 31 provides means of contacting technical support and access to various instructions. This is a living feature with continuous updates.

4.3 Running a treatment

Treatment tab functionality is illustrated as a flow chart in Figure 32. Using ML6710i follows the same basic process:

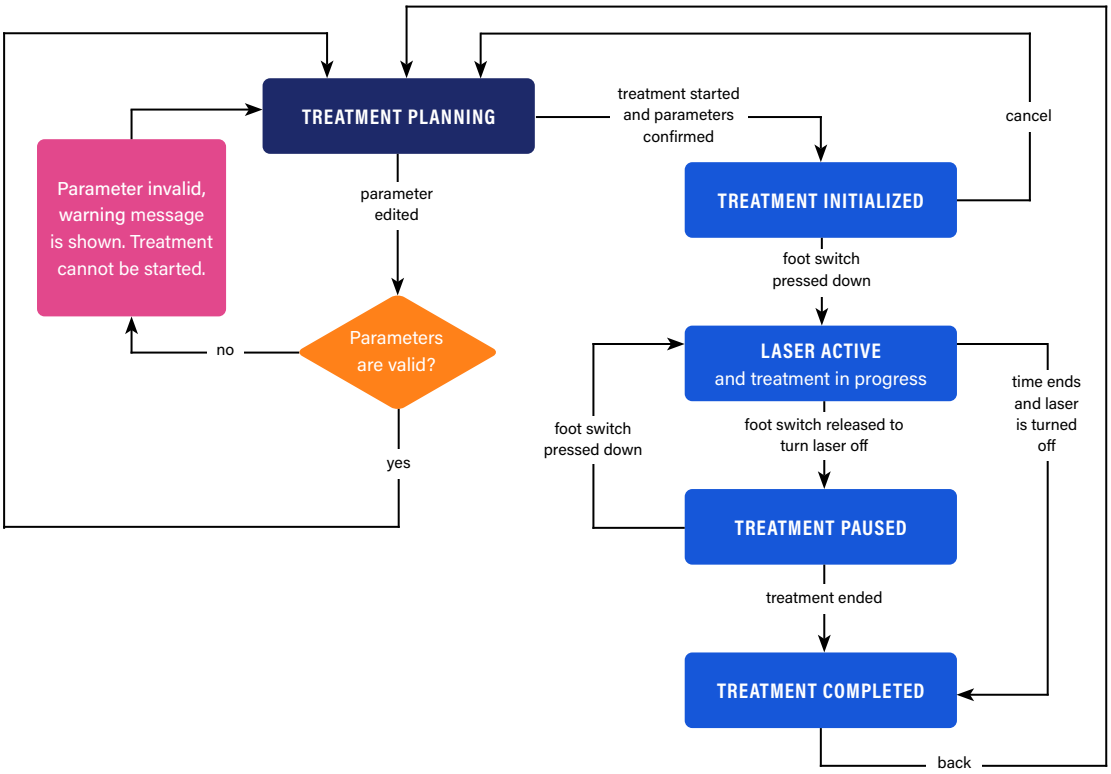


Figure 32. *Treatment tab flow.*

- Set the treatment parameters
- Adjust the spot size
- Start the treatment
- Control the laser by using the foot switch.

4.3.1 Treatment planning

Treatment planning screen in Figure 33 allows you to modify dose and irradiance values and set the correct contact lens specific to each patient. The available value range for each parameter is shown in Table 9.

Treatment duration is calculated automatically according to dose and irradiance values set.

The treatment parameters are saved per user. If you logout and re-login the previously set treatment parameters are restored.

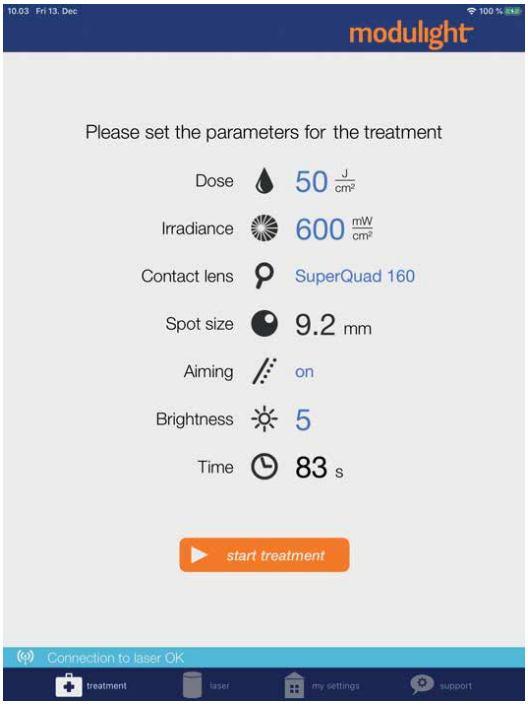


Figure 33. *Treatment planning screen. Interactive fields are identified by the blue text color.*

Table 8. *Available treatment settings.*

Parameter	Available values
Dose	5 – 95 J/cm2
Irradiance	50 – 800 mW/cm2
Contact lens	Selection from list
Aiming beam mode	On, Off or Pulse
Aiming beam brightness	1 – 10
Selected spot size	1.0 – 5.0 mm multiplied with the contact lens magnification

Figure 34. *The spot size is selected by rotating the grip wheel on the SLA.*

Spot size selection

Spot size is adjusted by turning the adjustment ring on the SLA (Figure 34). You may observe the spot size value from the GUI screen while adjusting the spot size from the SLA. The spot size value range depends on the magnification of the selected contact lens, often also referred to as Laser Magnification Factor.

Figure 35. *The spot size is selected by rotating the grip wheel on the SLA.*

Spot size view on GUI

As explained, the available spot size depends on selected parameters and maximum optical power of the laser. Figure 35 gives an example of the notification when spot size is adjusted too large and laser power limit is exceeded. In this case, the spot must be adjusted lower until the red warning message disappears and the treatment parameters can be confirmed.

Aiming beam

In addition, you can control the aiming beam by setting the aiming beam to on, off or pulsed mode. You can also set the aiming beam brightness to desired level. The aiming beam laser is a class 2 laser and corresponding laser safety precautions must be followed.

Please make sure the spot is properly in focus before starting a treatment. See section 4.4.4 for instructions.

WARNING

The spot size given by the Graphical User Interface (GUI) includes the contact lens magnification and indicates the diameter of the actual spot in the retina of the patient.

WARNING

In case the aiming beam is not visible, do not treat the patient. Disable the device from use and contact the manufacturer for service.

Preparing the patient for the treatment

Please consult the prescribing information for instructions regarding the drug administration before giving the laser dose.

Please consult the instructions for use of the contact lens for proper use and maintenance.

Please consult instructions for use of the slit lamp for proper use and maintenance.

It is not mandatory to have laser safety eyewear on the untreated eye of the patient. However, wearing an eye-patch or similar protection during laser administration is recommended.

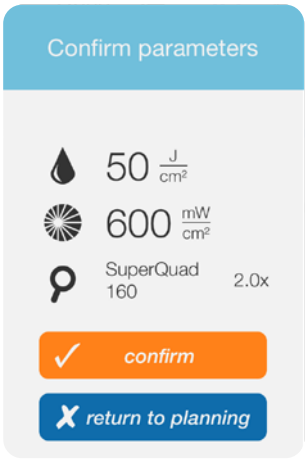


Figure 36. *Confirmation of the treatment parameters.*

4.3.2 Proceeding to treatment

After configuring the treatment parameters (Figure 33), you may proceed to treatment parameter confirmation by tapping the start treatment button, which leads to Figure 36 showing the treatment parameter confirmation window before the actual treatment can be started.

Check the treatment parameters. If some of the parameters are wrong, you need to tap **return to planning** and set correct treatment parameters.

If the parameters are correct, tapping **confirm** leads to the treatment screen shown in Figure 37.

Treatment screen shows the treatment status and guides you during the treatment. Please note that in the treatment screen the GUI navigation is disabled and transition between function tabs is possible only after ending a treatment.

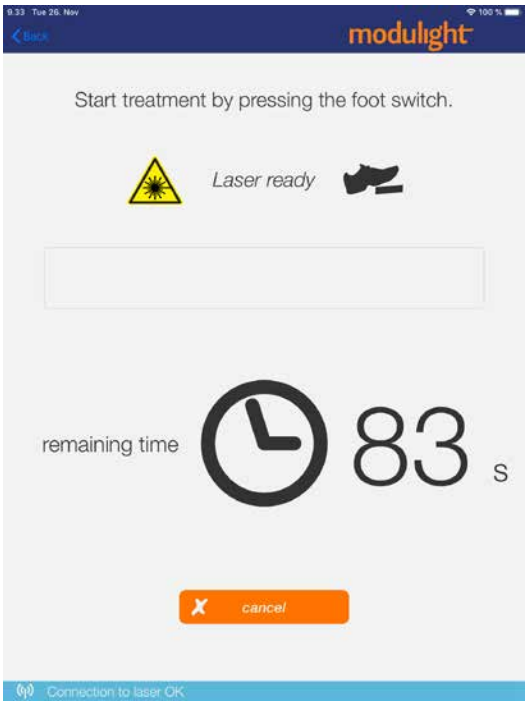


Figure 37. *Treatment screen when the treatment can be started by pressing the foot switch.*

You must press the orange pedal on the foot switch down to activate the laser. The laser is active as long as the foot switch pedal is pressed down and there is treatment time remaining.

The remaining time is counted down only when the laser is active (Figure 38).

Pausing a treatment

You may release the foot switch emission pedal at any time during the treatment if needed. If the emission pedal is released the laser is set off immediately and the treatment is paused (Figure 39). The pause length is not limited by the ML6710i and you may continue the treatment whenever ready.

The treatment is continued when the emission pedal on the foot switch is pressed down again.

WARNING

After pushing the laser emission switch (orange pedal) on the foot switch in treatment mode, the device emits laser light from the SLA. Releasing the emission switch during treatment will pause the treatment.

Figure 38. *Foot switch pedal is pressed down and laser is active.*

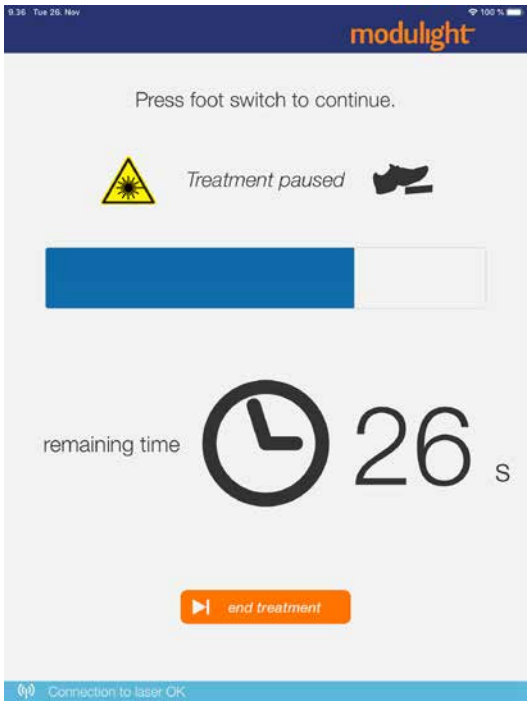


Figure 39. *Treatment is paused.*

Ending a treatment

You may also end the treatment early. If you need to end the treatment before the full time has elapsed, tap the **end treatment** button. Please note that the treatment cannot be continued after this even though there is treatment time remaining. A confirmation is required if the user decides to end the treatment before full time has elapsed (Figure 40).

The treatment is completed (Figure 41) either when the time set in treatment planning has elapsed or when ending the treatment explicitly using the **end treatment** option.

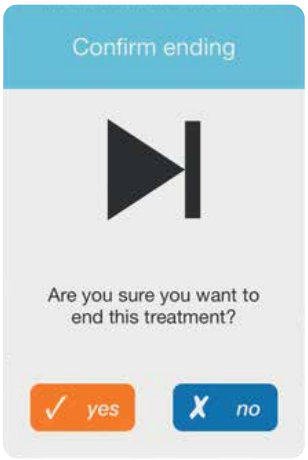


Figure 40. *Confirmation is required if treatment is ended before full time.*

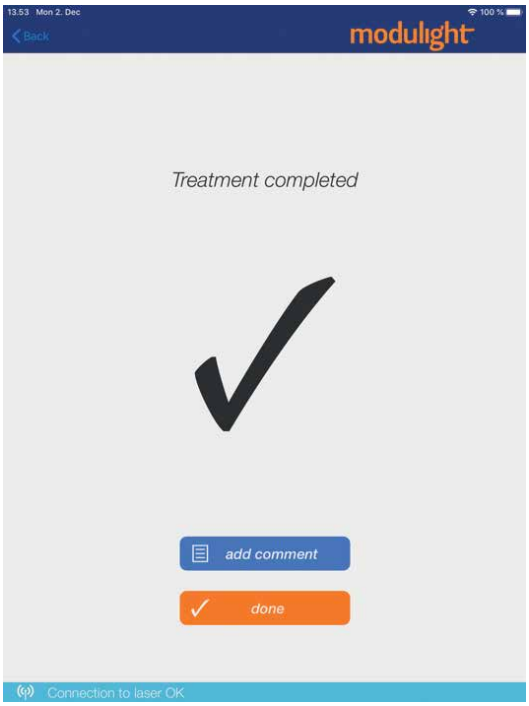


Figure 41. *Treatment is completed.*

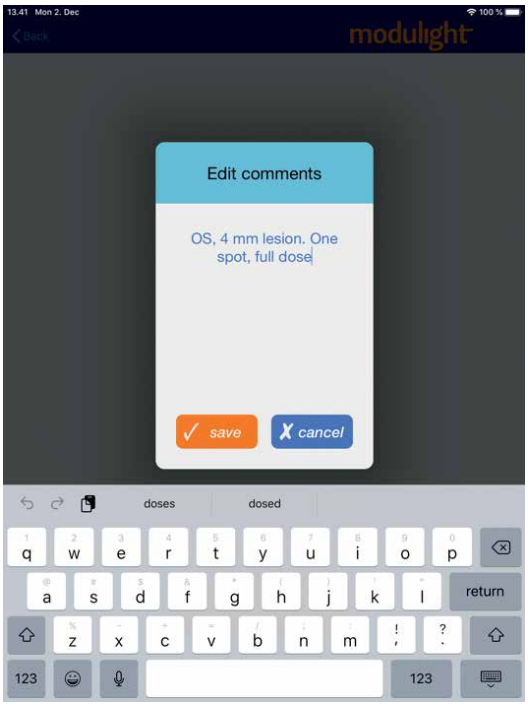


Figure 42. *Adding comments to a treatment.*

Commenting a treatment

You may add a comment after ending the treatment. When selecting **add comment**, the commenting pop-up in Figure 42 is displayed. Here you can record notes or any other useful information related to the given treatment.

After writing the comments and selecting **save**, the GUI returns to the treatment completed window. As shown in Figure 43, the **add comment** button has changed to display the recently fed comments.

The comment text may still be edited by tapping it, which opens the commenting pop-up again.

A completed treatment cannot be continued anymore.

You can navigate back to treatment planning screen by selecting **done** (Figure 43) and start a new treatment if needed.

PROHIBITED

Do not insert patient data into the treatment comment field. Patient data includes e.g., patient name, birth date, social security number or diagnosis.

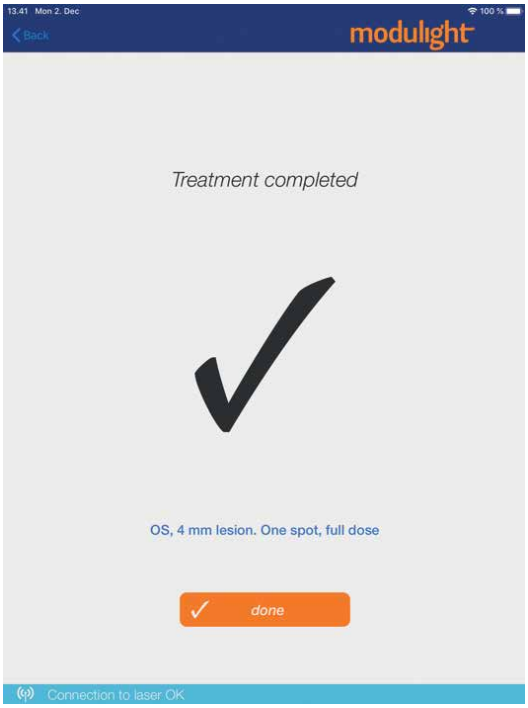


Figure 43. *Treatment is completed.*

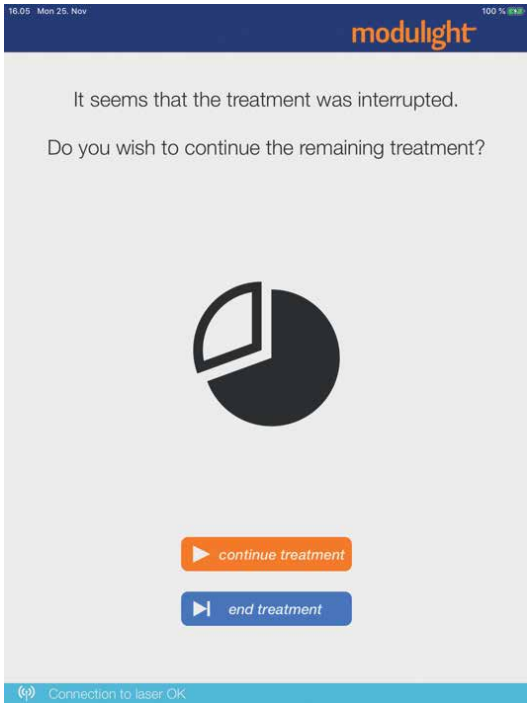


Figure 44. *Message given on the GUI in case of an interrupted treatment.*

4.3.3 Interrupted treatment

The ML6710i is able to continue an interrupted treatment e.g., in case of power failure in the building. When the device is again powered and the Bluetooth connection between the main unit and iPad is re-established, the GUI shows the message given in Figure 44.

After tapping **continue treatment**, the confirmation pop-up in Figure 45 is shown. All settings for the interrupted treatment are restored from device memory and dose value is based on the light dose remaining at the time of the interruption.

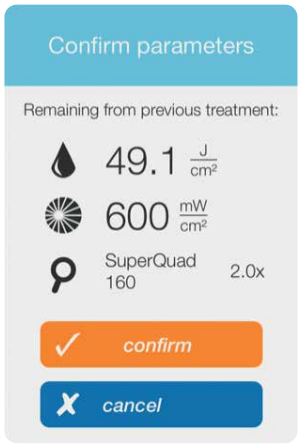


Figure 46. *Confirmation pop-up for continuing an interrupted treatment.*

4.3.4 Device warnings and errors

The device reports warnings whenever required. If a warning is displayed you should try to fix the problem. In case an error is detected during an active treatment, the treatment is automatically paused and a warning message is given on the GUI.

Figure 46 shows an example warning in case the connection to the GUI/iPad is lost after starting a treatment. Should this occur, you may continue the treatment normally by pushing the foot switch emission pedal as long as the green READY emission LED is on and status LED is white. An audio signal is given by the ML6710i main unit to indicate laser emission.

The blue EMISSION LED is also lit normally. The GUI automatically attempts to reconnect with the ML6710i.

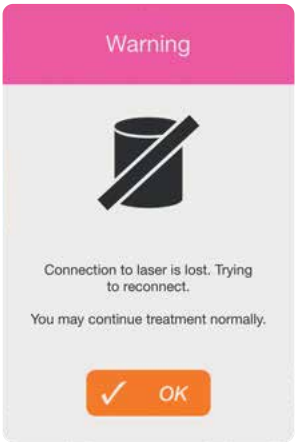


Figure 45. *Warning popup is displayed in case the connection between the GUI and laser device is lost during treatment. Treatment may be continued with the foot switch.*

MANDATORY

If after the instructed actions a problem/warning message reappears, please disable the device from use and contact the manufacturer for service. The functionality of the device may have been compromised due to an internal or external factor (e.g., electromagnetic disturbances).

CAUTION

Please note that when the GUI is disconnected some device features that are performed by the GUI will have limited availability. For example, error messages or elapsed time are not displayed and ending treatment early on the GUI is not possible. In the case of a disconnected GUI, treatment may be continued with the foot switch pedal until planned treatment time has elapsed or can be paused by releasing the foot switch pedal.

MANDATORY

In case of an unexpected software behaviour or error, see troubleshooting section in these Instructions For Use.

Please check the Troubleshooting section of this document for more information on how to proceed in various cases, also when experiencing unexpected behavior of the device (e.g., in the software).

4.4 Maintenance

There are no user serviceable parts inside ML6710i other than changing of the exterior power cord. Only power cords provided by the manufacturer (AP0307, length 1.83 m) can be used to prevent possible problems with electromagnetic compatibility (EMC). In addition, you may temporarily replace the protective dust cap mounted to the rear panel fiber output port should it become unattached. A spare piece of an unattached version is provided with the unit.

The GUI prompts when the due date for periodic maintenance is approaching. The reminder message in Figure 47 is given when due date is 60 days or less away. The message appears each time the GUI is connected to the device, and the displayed number of days remaining is updated automatically.

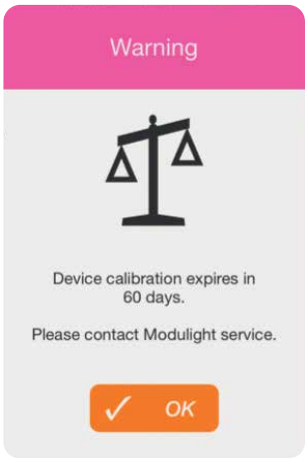


Figure 47. *Reminder of an approaching calibration due date.*

MANDATORY

Annual maintenance interval shall be followed. Only personnel authorized by the manufacturer are allowed to carry out maintenance or service on the device.

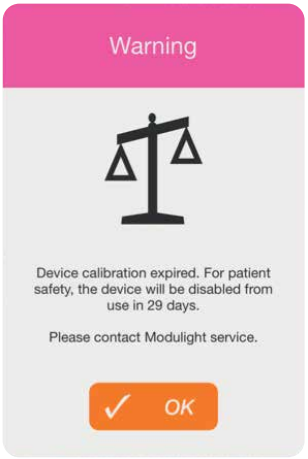


Figure 48. *Warning displayed when device calibration due date has passed and calibration has expired.*

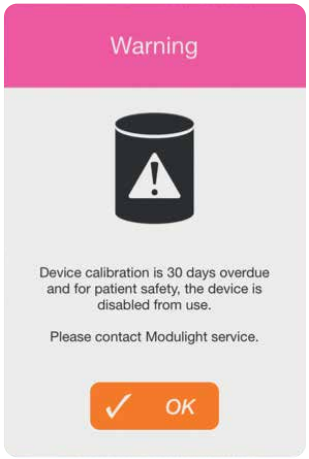


Figure 49. *Warning displayed when device calibration is overdue 30 days or more and device is disabled from use.*

After the due date has passed, a warning message of expired calibration (Figure 48) is given. Please note that the laser calibration cannot be guaranteed after calibration overdue. Therefore, for patient safety, the device is disabled from use and treatments cannot be executed after 30 days past the due date.

The remaining number of days before the disabling is displayed on the pop-up window.

Should the device calibration overdue pass 30 days or more, the warning message in Figure 49 is displayed.

4.4.1 Cleaning

Cleaning the main unit

The outer casing of the main unit can be wiped down periodically with a damp cloth. The device endures normal cleaning for the entire service life of the device.

Cleaning the SLA

It is recommended to inspect the SLA mirror regularly and clean when necessary as dust and other dirt may build up on the mirror surface.

CAUTION

No chemicals other than water or 70% ethanol shall be used for cleaning the device to avoid damage of the device surface and labeling. Do not pour or spray cleaning agents directly on the device.

MANDATORY

Follow the SLA inspection and cleaning protocol to avoid incorrect beam characteristics and wrong dose.

CAUTION

Do not touch the optical surfaces of the SLA with bare hands. If the SLA optics seem damaged or cannot be cleaned with the methods specified in these Instructions For Use, please contact the manufacturer.

For loose dirt, try an air duster first. For stains, wear rubber gloves and wipe the mirror with a dust-free cloth (e.g., lens tissue) lightly dampened with 70% ethanol or equivalent lens cleaning agent. Use gentle gestures from top to bottom; it is important to move the cloth only in one direction not to scratch the delicate optical surface with loose particles.

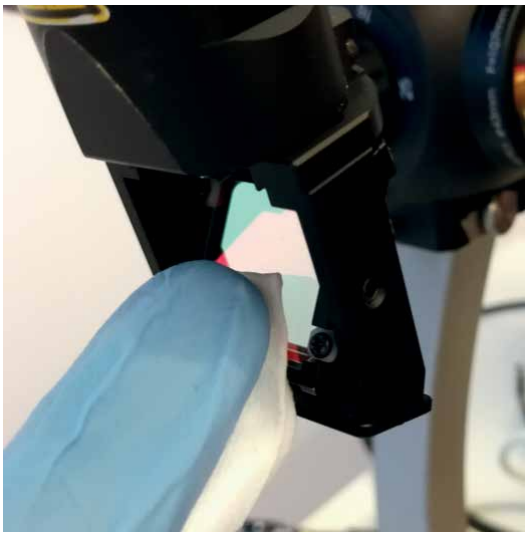


Figure 50. *Cleaning the SLA mirror.*

Cleaning the optical fiber connector

Unless the optical fiber is disconnected, regular cleaning of the fiber connector is not required. If you consider cleaning the fiber connector necessary, use a dust-free cloth lightly dampened with 70% ethanol or equivalent lens cleaning agent for cleaning the connector with one-direction, gentle wipes. It is recommended to inspect the fiber after cleaning with a suitable fiber microscope.

The fiber shall be reconnected immediately after cleaning and inspection to avoid contamination of the fiber connector. Pay attention to using the dust caps on the fiber connectors when disconnecting optical fibers.

Cleaning contact lenses

When using non-disposable contact lenses that are used from patient to patient, please pay attention to lens hygiene and maintenance in order to reduce the risk of cross-contamination via the contact lens surface in contact with the patient's eye.

4.4.2 Preventive and periodic maintenance

The ML6710i will show and alert for an approaching calibration/maintenance due date. Please contact the manufacturer authorized service personnel for ordering and scheduling of the preventive maintenance to avoid disabling of the calibration past-due device.

The device is disabled from use after 30 days overdue.

The service life of ML6710i is generally seven (7) years.

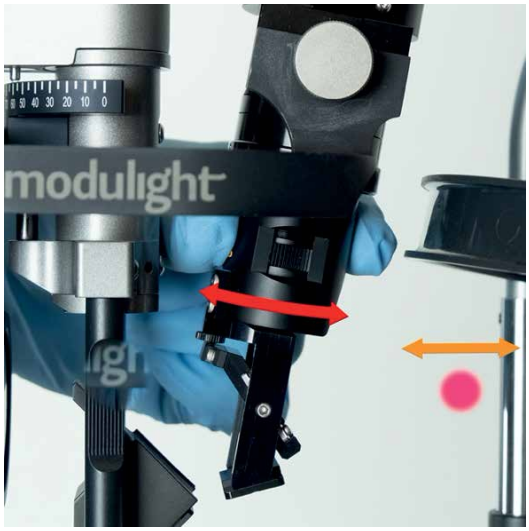


Figure 51. *Adjustment of the spot location horizontally by turning ML-SLA lower part.*

4.4.3 Adjusting the SLA spot location

The SLA spot location can be adjusted in XYZ directions i.e. in horizontal, vertical and focal planes.

Figure 51 shows how the horizontal location of the spot is adjusted by turning the lower part of the SLA.

The vertical location of the spot can be adjusted by turning the dial that tilts the mirror, as shown in Figure 52.

The spot is focused by turning the wheel located on the side of the lower part of the SLA (Figure 53). The re-focusing protocol in section 4.4.4 on page 65 must be followed. The working area (distance between spot focus and SLA mirror axis) is adjustable in the range 37.5–47.5 mm.

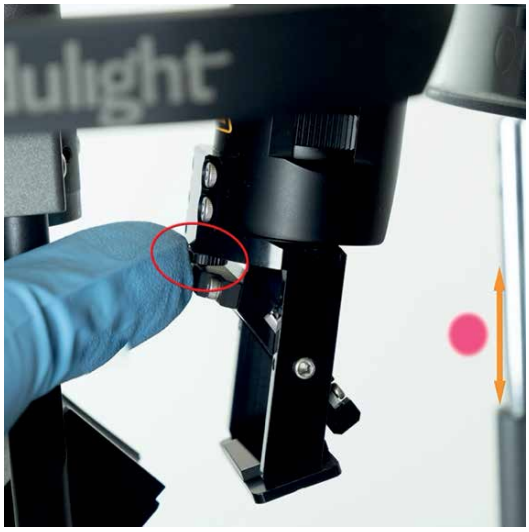


Figure 52. *Adjustment of the spot location vertically by tilting the mirror with a dial (highlighted with the circle).*

4.4.4 SLA output spot re-focus protocol

MANDATORY

In case of misaligned SLA output spot, follow the re-focus protocol below to avoid incorrect spot characteristics and wrong dose.

1. Make sure the laser emission is off.
2. Turn the slit lamp on and adjust a proper illumination brightness.
3. Place the object plane post provided with the slit lamp to its intended position. If the post is not available, follow these steps:
    a. Fix a piece of paper or carton to the headrest to a position where the slit lamp beam is projected onto it.
    b. Set the slit lamp eyepieces to 0.
    c. Set the slit lamp magnification to the highest setting.
    d. Move and lock the slit lamp to a position where the slit lamp beam is in focus (beam edges are sharp).
4. Set the slit lamp beam to a 3 mm round spot.
5. Turn the ML6710i aiming beam on in pulsed mode. Adjust brightness if needed.
6. Adjust the SLA native spot (in air, no lens) to 3 mm diameter. Note that the selected contact lens is included in the spot reading given on the screen. For instance, a spot reading of 6 mm with SuperQuad 160 lens equals 3 mm SLA native spot (Figure 33 for reference).
7. Make sure the SLA spot location matches that of the slit lamp spot. If needed, adjust the horizontal and vertical position of the SLA spot as shown in Figure 51 and Figure 52, respectively.
8. Make sure SLA focal plane (SLA spot has sharp edges on the target plane) matches that of the slit lamp spot. If needed, adjust the focal of the SLA spot as shown in Figure 53.

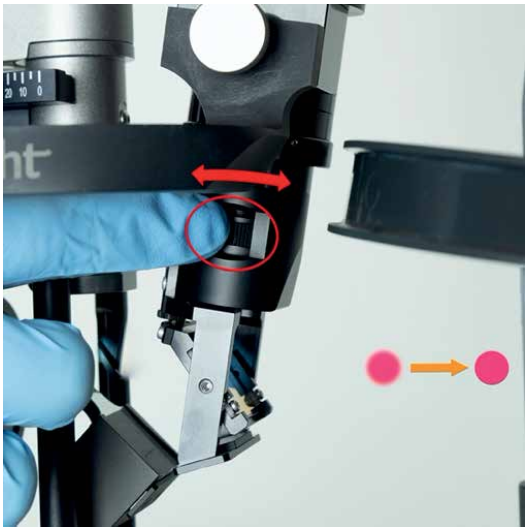


Figure 53. *Adjustment of the spot location vertically by tilting the mirror with a dial (highlighted with the circle).*

Beam focus reminder given in Figure 54 is displayed every now and then.

An example of a focused beam is given in Figure 55.

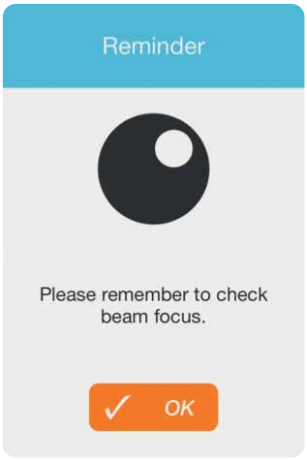


Figure 54. *Beam focus reminder.*

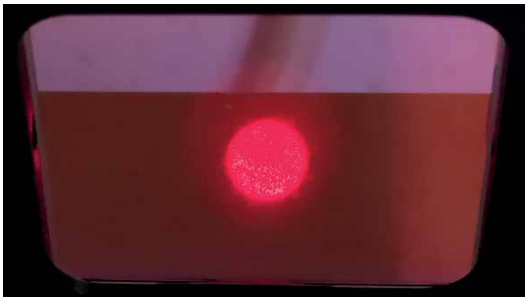
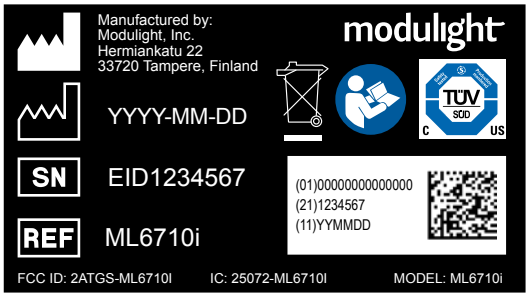


Figure 55. *Beam adjusted to focus.*

This page intentionally left blank.

5. Labels and markings

5.1 Device labels



The information about manufacturing facilities and device identity. It is mandatory to read the Instructions For Use before using this device.

Manufacturer identification and address.

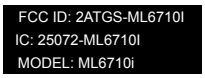
Date of manufacture.

Serial number of the product (entity ID).

Product code.

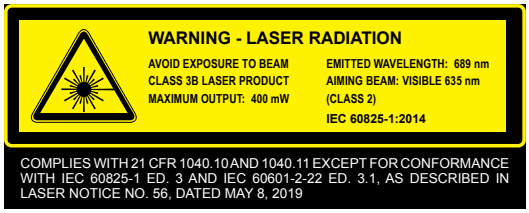
It is mandatory to read the Instructions For Use before using this device.

NRTL certification.



FCC ID/IC information.

Unique Device Identification (UDI) number.



Warning label emphasizing laser safety and giving details about laser output power and wavelength.

Explanatory warning text, notifying the user not to block the ventilation holes (located in the rear panel) of the device. IP classification of the device is IP2X.

Marking near the laser stop switch.

Laser READY indicator (green on left) and laser EMISSION indicator (blue on right). Located in the device chassis upper edge.

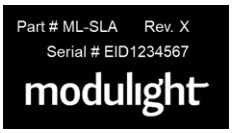
Identification label on the bottom of the foot switch. IP classification of the foot switch is IPX6.

Identification label on the power supply.

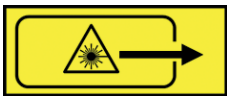
Identification label on the power cord.

Key chain.

Laser warning sign that can be hung e.g., on the handle of the laser hazard area door.



Identification label on the SLA.



Laser aperture label on the SLA.

SLA mounting adapter label.

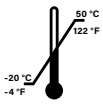
Mobile device (Apple iPad Mini) label.

Mobile device cover label.

Identification label on the laser safety goggles.

5.2 Storage and transportation markings

This side up.

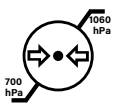


Acceptable temperature range of surroundings is -4° to 122° Fahrenheit (-20° to 50° Celcius).

Handle with care, fragile material inside.

Keep dry. Keep away from rain.

Acceptable relative humidity range.



Acceptable pressure range of surroundings.

6. Guidance and manufacturer's declaration – electromagnetic emissions

In order to prevent adverse events to the patient and yourself due to electromagnetic disturbances, please make sure all equipment in the room where this device is used are compliant with prevalent electromagnetic compatibility (EMC) standards and regulations and that the supply mains is suitable for this device.

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

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 ML6710i, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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.

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Guidance and manufacturer's declaration — electromagnetic emissions

The ML6710i is intended for use in the electromagnetic environment specified below. The owner/user of this device is responsible for assuring that it is used in such an environment.

In order to comply with FCC / ISED RF Exposure requirements, this device must be installed to provide at least 2 cm separation from the human body at all times.

Table 9. *Electromagnetic emissions – ML6710i device.*

Emission tests	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1 Class A	The laser system 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.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

CAN ICES-3 (A)/NMB-3(A) (Canada)

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

In order to comply with FCC / ISED RF Exposure requirements, this device must be installed to provide at least 2 cm separation from the human body at all times.

This device complies with Industry Canada's licence-exempt RSSs.
Operation is subject to the following two conditions:

1. This device may not cause interference; and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

Afin de se conformer aux exigences d'exposition RF FCC / ISED, cet appareil doit être installé pour fournir au moins 2 cm de séparation du corps humain en tout temps

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

3. l'appareil ne doit pas produire de brouillage;
4. l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Guidance and manufacturer's declaration — electromagnetic safety

The ML6710i is intended for use in the electromagnetic environment specified below. The owner/user of this device is responsible for assuring that it is used in such an environment.

Table 10. *Electromagnetic safety – ML6710i device.*

Immunity test	IEC 60601-1-2 test level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be conductive. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	AC mains line ±2 kV, 100 kHz repetition frequency Signal port ±1 kV, 100 kHz repetition frequency	Mains power quality should be that of a typical hospital environment.
Surge IEC 61000-4-5	±0,5 kV, ±1 kV line-to-line	Mains power quality should be that of a typical hospital environment.
Voltage dips IEC 61000-4-11	Single-phase mains: 0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical hospital environment. If the user of this laser system requires continued operation during power mains interruptions longer than 45 minutes, it is recommended that the laser system be powered from an uninterruptible power source.
Voltage interruptions IEC 61000-4-11	0 % UT ; 250/300 cycle	Mains power quality should be that of a typical hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.

Guidance and manufacturer's declaration — electromagnetic immunity

The ML6710i is intended for use in the electromagnetic environment specified below. The owner/user of this device is responsible for assuring that it is used in such an environment.

Table 11. *Electromagnetic immunity – ML6710i device.*

Immunity test	IEC 60601-1-2 test level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Electromagnetic environment should be that of a typical hospital environment except for near active HF surgical equipment and the RF shielded room for magnetic resonance imaging, or other special environments where the intensity of electromagnetic disturbance is high.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	

In case essential performance of ML6710i is lost or degraded due to electromagnetic disturbances the device will stop or pause ongoing treatment and starting a new treatment may not be possible until electromagnetic disturbance is removed.

Table 12. *Proximity fields from RF wireless communications equipment – IEC 61000-4-3.*

Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Test level immunity (V/m)
385	380 –390	TETRA 400	Pulse modulation 18 Hz 50 % square wave	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710, 745, 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz 50 % square wave	0.2	0.3	9
810, 870, 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz 50 % square wave	2	0.3	28
1720, 1945, 1970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz 50 % square wave	2	0.3	28
2 450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz 50 % square wave	2	0.3	28
5240, 5500, 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz 50 % square wave	0.2	0.3	9

7. Troubleshooting

7.1 Solving problem and error situations

Problems, warnings and notifications given by the GUI and ML6710i indicators are explained in Table 13. In case any of these events, follow the instructions given on the GUI and this table.

Table 13. *ML6710i warnings and notifications.*

Description	Required action
iPad doesn't connect to the main unit	Make sure main unit power is on (see section 3.4.5 and that Bluetooth is enabled in the iPad settings.
Yellow indicator light is blinking on the device.	Device internal error that prevents normal operation. You must restart the device by switching the device off and back on. If the problem persists, please contact technical support.
The device is not visible in the user interface and all main unit indicator LEDs are off .	Turn the key switch on the back panel from "O" option to "I". Make sure that power adapter is properly connected.
Error. Reboot laser warning message is displayed on the laser tab.	Device internal error that prevents normal operation. Error should disappear automatically after a short period and operation can then be continued. If error does not disappear you need to be reboot the ML6710i main unit (turn power off with the key, wait 10 seconds and turn power back on).
No internet connection warning is displayed in login screen	Internet connection is not available. Please check your iPad settings to ensure network connections are in use and make sure that there's internet connection available.
 Internet connection is required for running a new treatment.	Internet connection is not available. Please check your iPad settings to ensure network connections are in use and make sure that there's internet connection available.
 Device temperature stabilizing.	Device temperature is stabilizing. This is typical if the room temperature is higher or lower than normally. The message will disappear automatically when target temperature is reached; this may take a few minutes. If you push OK, the status bar continues to display the message until target temperature is reached.
 Device overheating.	Device temperature is too high. Laser can't be activated. You must wait until the device cools down. Make sure the ventilation holes are not blocked and that the ambient temperature does not exceed specified values.
Noticeable heating of the exterior of the device	Shutdown the device and wait until device cools down. Make sure the ventilation holes are not blocked and that the ambient temperature does not exceed specified values. If the problem persists, please contact technical support.
Dose or irradiance error is visible in Treatment planning and new treatment cannot be started.	Please set the dose and irradiance to values requested by the application. The editing is started by tapping the value.

If even after the instructed actions a problem/warning message reappears, please disable the device from use and contact the manufacturer for service. The functionality of the device may have been compromised due to an internal or external factor (e.g., electromagnetic disturbances).

Description		Required action
Desired lens is not available in treatment planning		Please go to my settings tab and tap My lenses row. All available lenses are listed and you can select which lenses you want to have visible in treatment planning. Unselect obsolete lenses and select desired lenses.
	Spot size altered	Warning is displayed if spot size is changed after a treatment is initialized. Warning popup displays the required spot size and current spot size. Adjust the SLA spot until the current spot size matches the required value and the warning is cleared. The treatment can then be continued.
	Unfortunately this version of the application is too old.	iPad software needs to be updated. Device cannot be used before the update is completed.
	You do not have access rights to device EIDXXXXXX.	The ML6710i is not defined under your user account. Please connect to a device you have access to.
	Device calibration expires in XX days	Calibration is about to expire. Please schedule maintenance with the manufacturer.
	Device calibration expired.	Calibration has expired. Please schedule maintenance with the manufacturer. Device is automatically disabled after 30 days calibration overdue.
	Connection to laser is lost.	iPad is not able to connect to laser. Please check your iPad settings to ensure Bluetooth connection is in use.
	Battery level low.	iPad battery is running low. Please recharge it.
	Laser stop pressed	LASER STOP button pressed. Please deactivate LASER STOP by pressing the laser stop button again.
	Interlock is disconnected.	Interlock is not detected. Please check that the interlock is properly plugged in. If the problem persists, please contact technical support.
	Optical fiber is disconnected .	SLA fiber is not detected. You must properly connect the SLA fiber to the device. If the fiber is connected and the error message still appears: Check that the fiber port on the back panel of the device appear clean i.e. no big particles inside the adapter, and also that the threading is clean so that the nut and the connector can be twisted to the end. If the problem persists, please contact technical support.

Description		Required action
	Foot switch is disconnected.	Foot switch is not detected. You must properly plug in the foot switch connector. If the problem persists, please contact technical support.
	SLA is not detected.	SLA is not detected. You must properly plug in the SLA connector. If the problem persists, please contact technical support.
	Interlock / optical fiber / foot switch / SLA are disconnected	Multiple items are not connected. You must properly plug in all the connectors listed (order is insignificant). If the problem persists, please contact technical support.

7.2 Customer service

You may contact **Technical support** by e-mail or phone:

support@modulight.com

(833) 829-3749

(US toll free)

This page intentionally left blank.

This page intentionally left blank.

This page intentionally left blank.

modulight

FINLAND

Modulight, Inc.
Hermiankatu 22
33720 Tampere, Finland
Tel. +358 20 743-9000
sales@modulight.com

USA

Modulight USA, Inc.
2033 Gateway Place
Suite 500
San Jose, CA 95110
Tel. (408) 573-6291