Rakuten Aspyrian Europe GmbH

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Change	Date	Description
Sampsa Kuusiluoma	**14.6.2018**	**Updated ETL authorization mark to labeling section, unified nomenclature (light diffuser, power check).**
Sampsa Kuusiluoma	**16.11.2018**	**Updated company logos, included Rakuten Aspyrian Inc. review conclusions.**

Rakuten Aspyrian

Rakuten Aspyrian PIT Laser

Instructions for Use

Model: PIT690.4-2500

Software-Version: 2.15-1.45-0.53-1.4 Rev.F-0.6

Contents

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1. Product description

1.1 Intended use and indication

The PIT690.4-2500 (abbreviated PIT690) device is to be used only for clinical trials based on separate approvals by relevant local regulatory authorities and investigational review boards, and the intended use is studied during those clinical trials. The product bears an „investigational use only" label as a mark of the nature of investigational use of the device. The system should only be used by trained professionals and only for the purpose described in and based on instructions given in the relevant clinical protocol.

1.2 Mode of operation

The laser system PIT690.4-2500 (hereafter referred to as PIT690) is an active device that is only intended to administer energy (in form of light) and that does not contain, carry or deliver any drug to the human body. The system might have adverse health effects on its own, if the laser operation parameters are not correctly set. The radiation generated by the device is directed to the target tissues via one or more optical fibers and associated light diffusers. The device has no essential performance criteria other than those relevant for its basic safety.

1.3 Contraindications

The contraindications are studied during the clinical trial. The device is not designed to be used for any surgical or thermally induced therapy or for ophthalmic applications. The device is not designed for use for any application in the central circulatory system or in the central nervous system.

1.4 Potential side effects

The potential side effects are studied during the clinical trial. It is expected that too large a dose of laser radiation may lead to burning or swelling in the irradiated tissue during laser irradiation.

1.5 Intended user

The final intended user will be defined based on the clinical trial. The device is designed to be used by trained medical personnel, such as oncologists and trained nurses, only. The doctors or trained nurses operate the device and the surgeons or doctors handle the light diffusers. The user selects

the indication (head and neck cancer), number and the diffuser type, and specifies the assignment of ports 1 to 4. All ports are equivalent. The training on the use of the device will be performed by the manufacturer's (Aspyrian) medical product advisors and will cover the use of this Instruction for Use Manual and the Instructions for Use of the Accessories.

The device is designed to only be used in a professional healthcare environment, for example private practice, hospital setting, or private clinic. The device is stationary during treatment. The irradiance and the fluence rate can only be modified in the Study Manager mode, which are not available to the user. Treatment data can only be read out in the Study Manager mode.

The device is not designed to be used by the patient.

1.6 Environmental conditions

Operating conditions:

Ambient temperature	15 °C to 30 °C
Relative air humidity	20% to 85% absolute maximum rating Non-condensing humidity.
Max. operating altitude	3000 m
Ambient air pressure	70 kPa (3000 m) to 110 kPa (sea level)

The device is not intended to be used in the presence of strong magnetic fields e.g. near MRI systems.

Regarding electromagnetic compatibility (EMC), please refer to appendix, technical data, section 1.4.

Before operation the device must be allowed to reach the normal operating conditions after storage.

The device is not intended to be used with any liquids nor does it contain any tank or reservoir for liquids.

Storage and transportation conditions:

Ambient temperature	-20…50°C, absolute maximum rating No direct exposure to sun
Relative air humidity	20% to 85% absolute maximum rating Non-condensing humidity

2. Safety instructions and labeling

The following symbols are used in this document to describe the hazard levels for avoiding personal and property damage.

Caution:

Indicates a hazardous situation that can lead to property damage or minor to moderate injury.

Warning:

Indicates a hazardous situation that can lead to serious injury or death.

Warning:

Visible laser radiation. Avoid exposure to direct or scattered radiation.

2.1 General safety instructions

Warning:

The Nominal Ocular Hazard Distance (NOHD) depends on the numerical aperture of the diffuser.

The lensed light diffuser, cf. chapter 6.3, has a numerical aperture of 0.3 and a NOHD of 93 cm.

If that diffuser is broken, its Numerical Aperture may be 0.37 and thus its NOHD is about 74 cm.

Warning:

Laser Safety: Laser goggles must be worn during treatment by all present patients and operators, see chapter 4.5.4. and chapter 6.1.

Warning:

A risk of fire and/or explosion exists when the laser outout is used in the presence of inflammable materials, solutions or gases or in an oxygen enriched environment.

The laser must not be used in combination with narcotic gases when the laser radiation must be emitted close to the inhalation tubing.

Caution:

If generated: Laser fume and/or plume may contain viable tissue particles.

Warning:

To avoid risk of electric shock, the laser must only be connected to a mains supply with protective earth.

Caution:

Use of controls or adjustments for performance of procedures other than those specified herein may result in hazardous radiation exposure.

Warning:

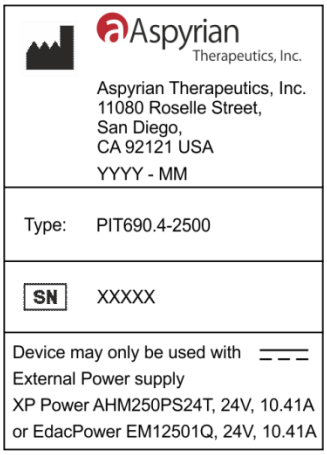
In case of incorrect diffuser type used during power check, the diffuser tip may no longer be sterile; for example, if a cylindrical diffuser was used in combination with a frontal diffuser calibration port insert to check the output power.

Handling precaution:

Do not bend the diffuser extremely. For the minimum bending radius, please refer to instructions for use for compatible diffuser types listed in chapter 6.3.

2.2 Product labels

2.2.1 Identification plate labels



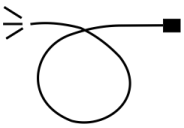
provides the manufacturer and the manufacturing date of the device

provides the serial number of the device

2.2.2 Laser warning label

Laser hazard warning

2.2.3 Light diffuser output label



Warning:

Laser aperture is at the end of the light diffuser

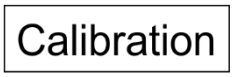
2.2.4 Emergency laser stop label

Emergency laser stop location

2.2.5 Next calibration date label

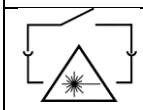
Sate of the last calibration of the device and the due date of the next calibration

2.2.6 Calibration port label



Location for inserting the calibration port insert and the distal diffuser end for power check

2.2.7 Backpanel labels

	Read these instructions for use
	Remote interlock (RI) connector
 Footswitch	Footswitch (FS) connector
 USB	USB connector The USB connector is only used to connect the device to an external computer in the study manager or in the maintenance mode.  The use of the USB connector by connecting it to an external computer USB port might result in unidentified risks for the patient, user or technician, induced by the external computer and its power supply. It is not allowed to use the USB connector during laser operation. The use of the USB port is allowed for the study manager and service personnel only. The potentially new risks should be identified, analyzed, evaluated and controlled by the responsible organization.

	Do not use the USB connector during laser operation. The use of the USB port is allowed for the Study Manager and service personnel only.
DC-IN	DC-input connector, 24V DC
FOR TEST EVALUATION ONLY **-CAUTION-** **INVESTIGATIONAL DEVICE!** **LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE**	**Caution:** The labels are fixed to the device to identify the device as an investigational device

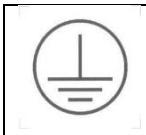
2.2.8 Laser safety labels

LASER RADIATION AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION CLASS 4 LASER PRODUCT P_0 = 2,5W λ = 680 - 700 nm IEC60825-1:2007	Explanatory and warning label for the visible (treatment) laser radiation
LASER RADIATION AVOID DIRECT EYE EXPOSURE CLASS 3R LASER PRODUCT $P_0 \leq$ 5mW λ = 520 - 540 nm IEC60825-1:2007	Explanatory and warning label for the visible (aiming) laser radiation
Complies with FDA performace standards for laser products except for deviations pursuant to Laser Notice No 50, dated June 24, 2007	Explanatory label, laser device is designed as a laser class 3R and class 4 laser product for the above wavelength ranges. It complies with the rules of the IEC 60825-1 and with FDA performance standards for laser products except for deviations pursuant to Laser Notice No 50, dated June 24, 2007.

2.2.9 Key switch labels

	Device is in power-standby.
	The device is ready for normal operation.

2.2.10 **Internal earth point label**

	Functional earth terminal identification label of the device.

2.2.11 **ETL mark label**

5011530

Conforms to

ANSI/AAMI ES60601-1

Certified to CAN/CSA

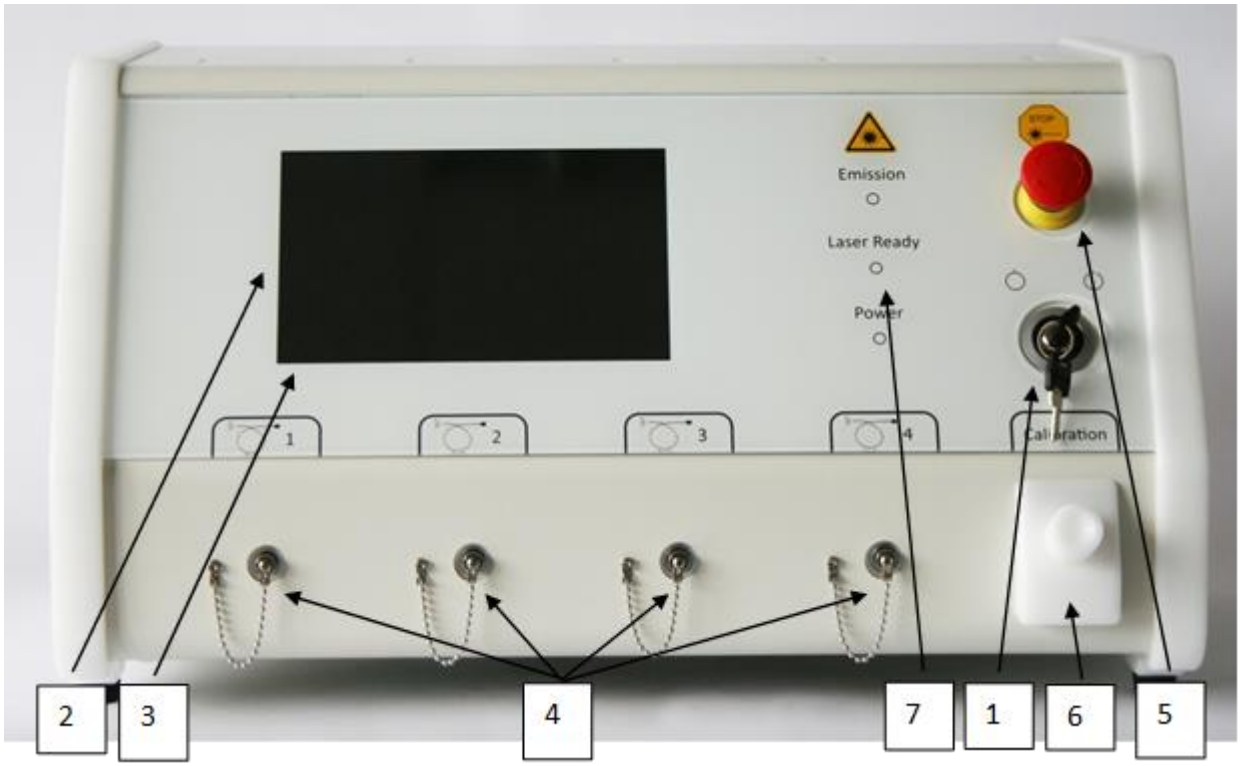
Std. C22.2 No.60601-1

ETL authorization to mark label

3. Description of the device

The following controls and displays are located at the front panel.

- The device can be activated and deactivated by the key switch (1).
- The device has a display as a part of the user interface (2).
- The device has touch buttons as a part of the user interface, located in display area (3).
- The device has up to four diffuser output ports to connect the light diffusers (4).
  All ports can be controlled completely independently from each other. They can provide the same output power.
- The device has an emergency laser stop button to stop the laser emission in any operating state due to emergency reasons (5).
- The device has a calibration port to check the output power of the light diffusers (6).
- The device has three visible indicators. One for the power supply (blue), laser ready (green) and laser emission state (white) (7).



The following connectors and controls are located at the back panel.

- The device has a cooling air outlet. The cooling air outlet should not be blocked by additional equipment or any other item. (1).
- The device has a remote interlock connector for connecting the remote interlock or the remote interlock bridging connector (2).
- The device has a footswitch connector for connecting the footswitch (3).
- The device has an USB connector for connecting it to a PC for servicing (4).
- The device has a power supply connector for connecting the external power supply (5).
- The device has a functional earth terminal that can be used for example during electrical safety testing (6).

3.1 Packaging content

The packaging contains:

- 1 PIT laser device
- 1 Power supply
- 1 Footswitch
- 1 Mains power supply cord
- 2 Keys for the key switch
- 1 Bridging connector for the remote interlock
- 3 Laser protection goggles
- 2 Calibration port inserts (one for cylindrical and one for frontal light diffuser, packed in sterile pouch)
- 3 Class 4 laser warning signs
- These instructions for use

4. Handling, application and frequently used functions

4.1 Unpacking

When you receive the PIT690 Laser, please immediately inspect the packaging. If there is any damage (holes or crushing, etc.) insist that a representative of your local carrier is present while you unpack the contents.

Make sure the orientation of the packaging is the right way up before opening it (see labeling „This way up“).

The packaging is designed such that the device can be easily taken out of the packaging by using the handles on the right and the left side of the PIT690 Laser device. Carefully inspect your device as you unpack it. If any damage is evident, such as dents or scratches on the covers or broken parts

etc., immediately notify your carrier and your sales distributor. Please make sure that all components are present. The packaging should be kept for storing or returning the device. Chapter 6.2 provides ordering details in case a new packaging is needed.

4.2 Installation, setting up of the device

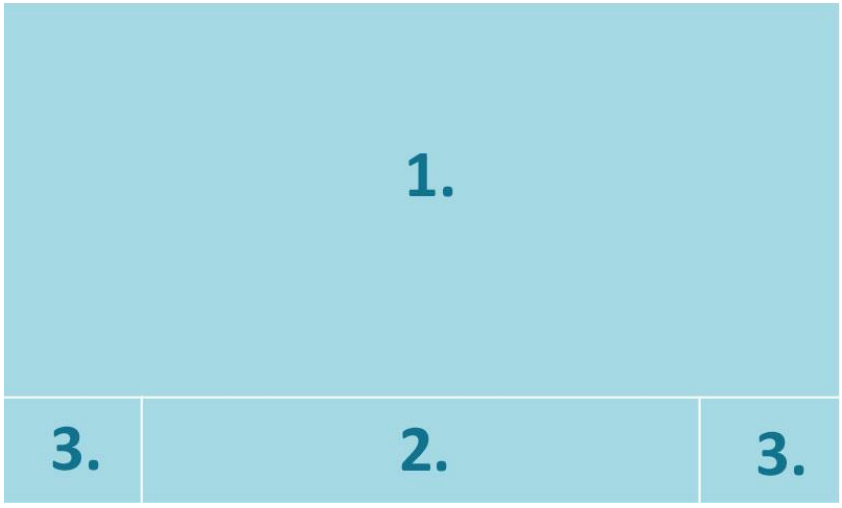
The PIT Laser Device is very easy to set up. But, please verify the ambient temperature and the device temperature before operating. If the housing temperature is out of the specified (Section 1.6) operating temperature, wait until the device has reached the specified temperature range.

After unpacking and inspection the PIT690 laser device has to be set up as follows:

1.) The PIT690 laser device must be placed in a stable and clean position, that the user interface is visible from the intended position of operating the system.
2.) Disconnection from mains is accomplished by pulling the mains plug. Make sure the device is placed such that the user can easily disconnect the device from mains by unplugging the mains power cord.
3.) The PIT690 laser cooling air flow direction goes from the bottom to the back of the device. It is important, that the airflow is not disturbed or blocked by placing the system on a soft underground or by placing the system too close to a wall.
4.) Connect the power supply, the remote interlock bridging connector, and the footswitch to the corresponding sockets on the rear side of the device.
5.) The device has the option to install a remote interlock circuit to prevent laser irradiation when the door is opened.
6.) Use only the provided power supply unit and mains power cord for connecting the PIT690 Laser device to the mains. (see chapter 6.2 for ordering information of spare parts and accessories).
7.) Insert the key into the key switch.
8.) The system is ready to be switched on.

4.3 The user interface

The user interface is divided in three areas, clearly separating between the main/icon area (1), the description and help area (2), and the main actions button area (3).



1. The main area shows actual parameter values or prominent state icons. If necessary it also displays warnings and error messages.
2. The description/help area shows a headline describing the actual state of operation plus anindication as to how to proceed.

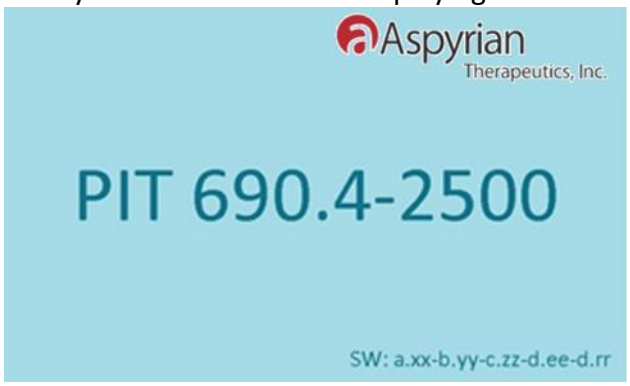
3. In the Main Actions button area state changing buttons are shown if relevant. For example next, “back”, “ok” or “cancel” buttons.

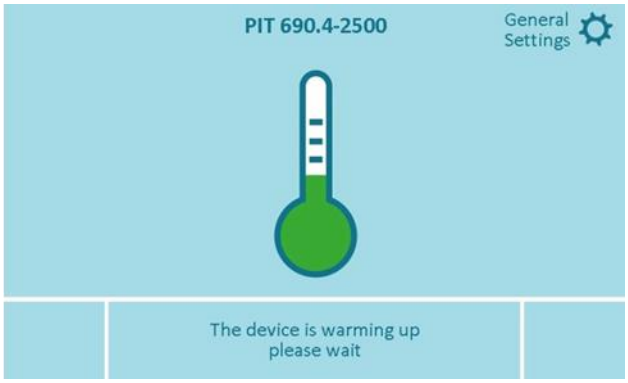
4.4 Switching on

To prevent the use by unauthorized personnel, the device has a key switch. If the device is not in use, remove the key(s). Make sure only authorized and instructed personnel has access to the keys for the key switch.

Turn the key clockwise to switch on the device.

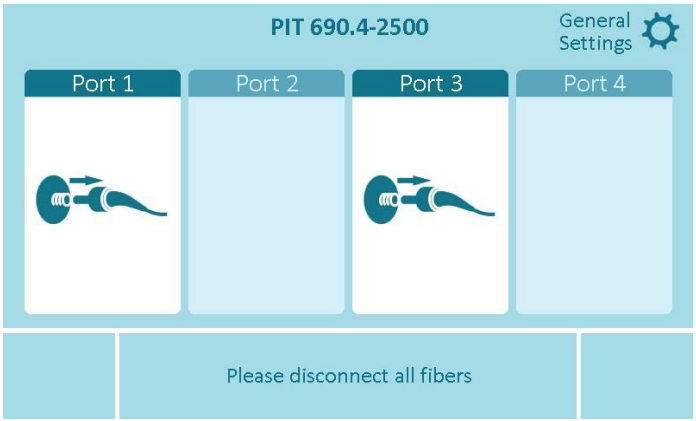
The system will boot while displaying the device name and the software version.





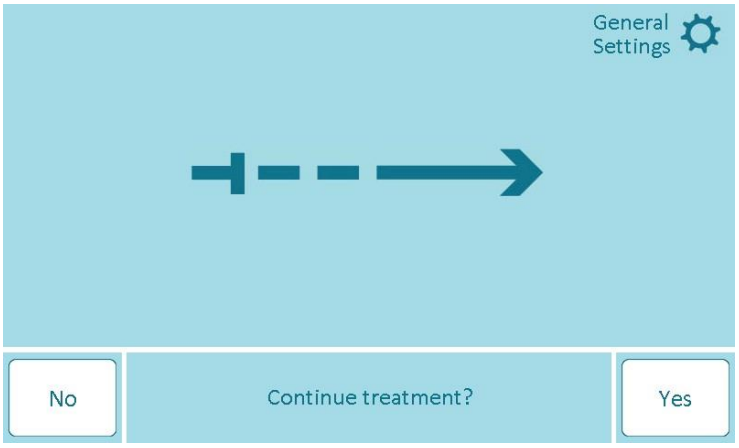
Depending on the environmental temperature, the system will warm up, or cool down the up to four lasers installed in the device. This procedure can take up to 120 seconds.

After a successful boot sequence, the device will display the following screens.



If there are still some light diffusers or a calibration port insert connected to the device for example from a previous treatment, please remove used diffusers and the calibration port insert completely.

If any unfinished treatment is pending after switching on the device, for example due to a previous power drop failure, the device will display the following screen.

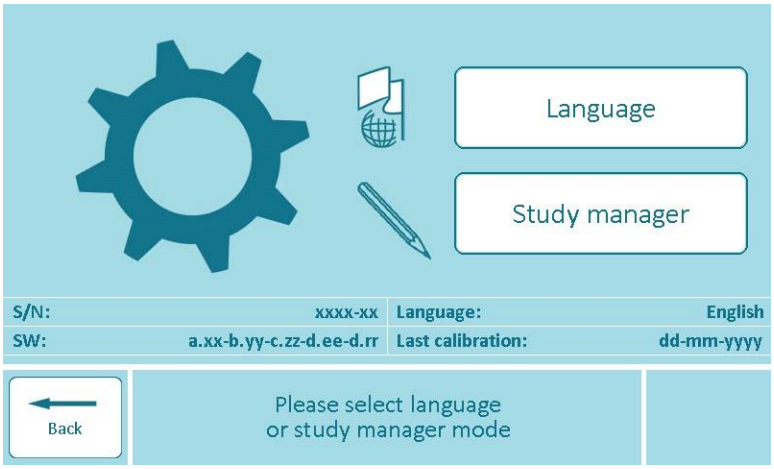


After the return of the electrical power, the user can choose to continue the interrupted treatment or to abort the treatment. The decision for continue treatment is made by the user. The user must consider the duration of the power drop, to decide if there is a higher benefit for the patient to stop or to continue the treatment.

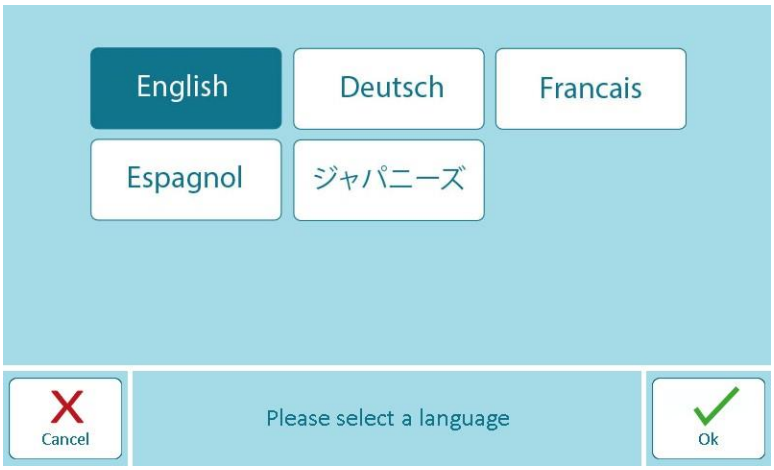
If the user decides to continue the treatment, the user has to confirm that the setup (diffuser types and treatment data) is still valid.

4.4.1 Selecting the language of the user interface

The language can be set via the “General Settings”-Menu.



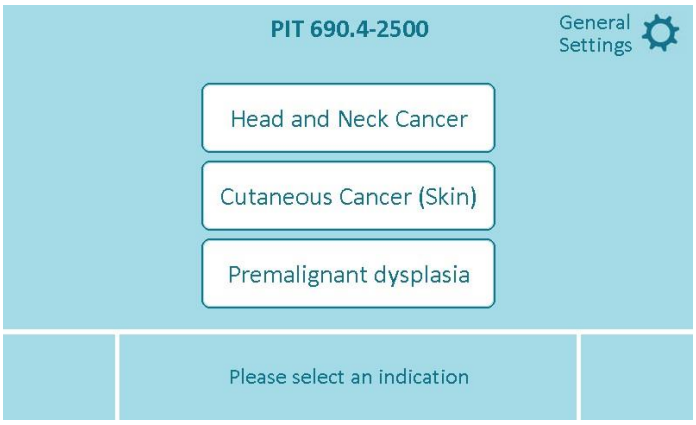
The languages can be chosen by pushing the “Language” button. Pushing the “Back”-button will switch the display back to the previous screen.



The only language available at this time is English. However, the screen and software have been set to allow other languages to be added in the future. They will be chosen by using the language buttons. The explanations will change to the selected language. The language setting has to be confirmed with the “OK” button. The display will switch back to the previous screen. Pushing the “Cancel”-button will discard the changes and also switch the display back to the previous screen.

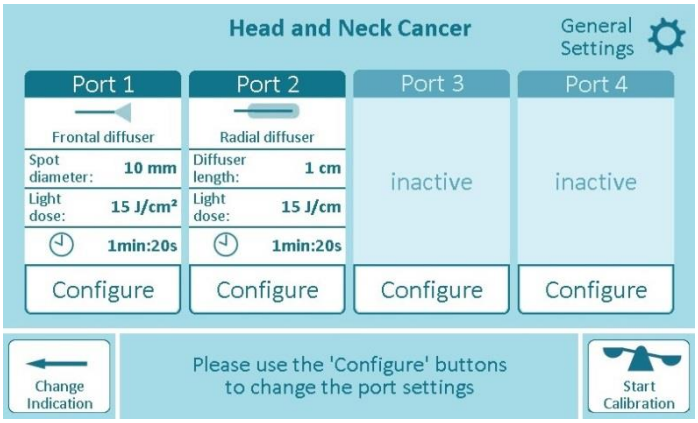
4.5 Preparing the device for a treatment

Preparing the device for the treatment of a new patient starts with the selection of the indication.



The only indication available for use at this time is Head and Neck Cancer. However, the screen and software have been set to allow other indications to be added in the future. They will be selected from this screen. After selecting an indication, the device loads the predefined treatment parameters and the allowed ranges. The physician can then select the parameters, e.g., the light dose or the spot diameter, appropriate for each patient's treatment from the options available.

The user has to prepare the treatment. The number of involved diffuser output ports is at least one and maximum four ports for the treatment. The number of used ports depends on the size and type of the tumor.



By pressing the configure button, the user has to adjust the treatment parameters for each port individually.

All ports have the same features and output characteristics. There is no restriction to start for example using port one.

The chosen indication is always displayed above the port settings. If the selection of the indication was wrong, please change the indication by pressing the "Change Indication" button. Attention: already configured port settings will be discarded and the ports will be set to inactive again. (For adjusting the treatment parameters, please see chapter 4.5.2).

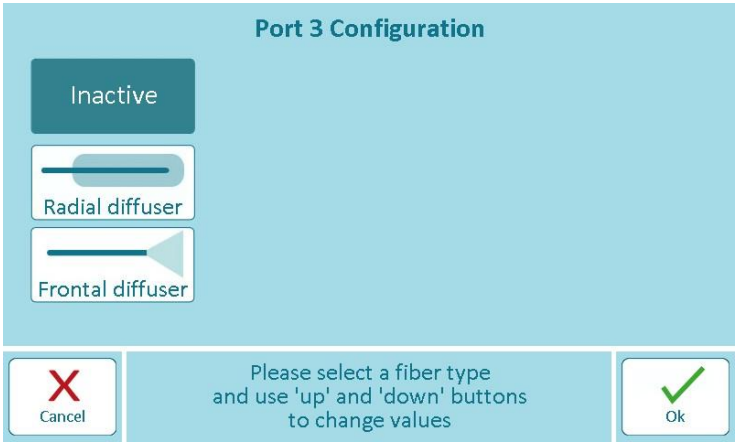
4.5.1 **Connecting the light diffusers and calibration port insert**

The frontal or cylindrical diffusers and the appropriate calibration port inserts for frontal or cylindrical light diffusers will be connected during the step by step power check process. The device guides the user through the power check process and requests the diffuser and the calibration port insert according to the port 1-4 configuration. For example, if there are two ports (1) and (3) configured for frontal and two ports (2) and (4) configured for cylindrical diffusers, the device will start using the configuration at the first active port for starting the power check process. The device will first check that all the ports assigned for the same diffuser type as configured under the configuration for port one. Then the device requests a change of the calibration port insert and it will continue checking the output power of the remaining diffuser outputs for the remaining port configurations.

Read the instructions provided with the light diffusers before connecting and using the light diffuser.

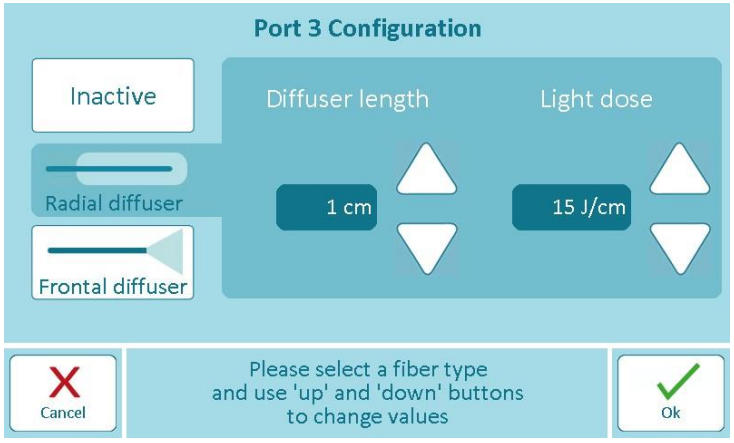
4.5.2 Setting the treatment parameters

The device will switch to the following screen after pressing the “Configure” button.



The user has to select the diffuser type, or leave the port inactive. If the cylindrical or frontal diffuser type was selected, the device switches to the following two possible screens. This example shows the Port 3 configuration.

Screen after selecting the cylindrical diffuser type:

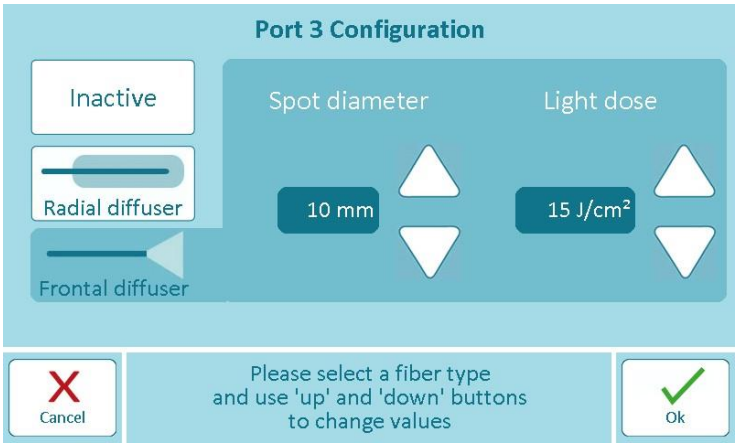


The user can enter the desired “Diffuser length” and “Light Dose” by pressing the corresponding touch buttons up and down.

The ranges for “Diffuser length” and “Light Dose” are limited by the pre-defined borders, set by the study manager and by the minimum diffuser transmission efficiency including the cylindrical diffuser and the device characteristics itself.

The light dose is set in Joule/cm, while the diffuser length is set in cm. The correct setting is confirmed by pressing the “OK”-button.

Screen after selecting the frontal diffuser type:



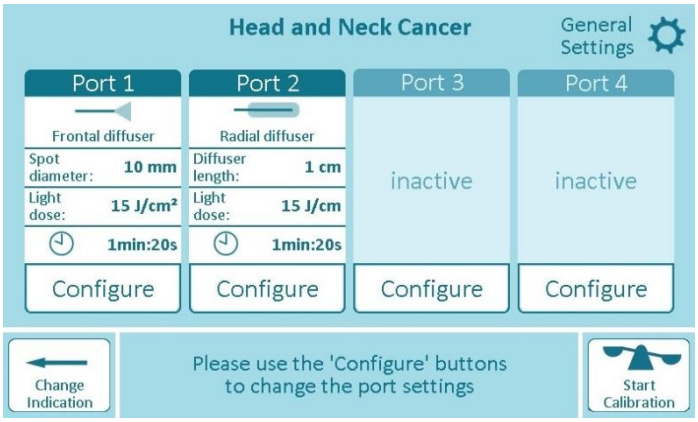
The user can enter the desired “Spot Diameter” and “Light Dose” by pressing the corresponding touch buttons up and down.

The ranges for “Spot Diameter” and “Light Dose” are limited by the pre-defined borders, set by the study manager and by the minimum overall diffuser transmission efficiency including the frontal diffuser and the device characteristics itself.

The light dose is set in Joule/cm², while the spot diameter is set in mm. The correct setting is confirmed by pressing the “OK”-button.

The PIT690 Laser calculates the corresponding laser settings and the treatment time from these parameters for each port. These are displayed upon power check of the light diffusers (see chapter 4.5.3).

To initiate the treatment, the configured ports of the device have to be calibrated to the output power of the connected light diffuser. To initiate the power check process, please press the “Start Calibration”-button.



4.5.3 **Light diffuser power check**

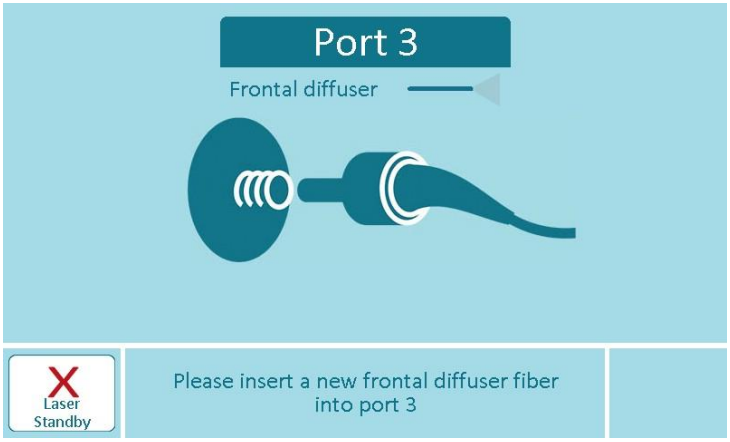
Once the power check process has been successfully performed, the aiming beam of the power-checked PIT690 laser device port is switched on. The aiming beam can be hazardous for the eye. The user can see the difference of the frontal- and cylindrical light dispersion by the illumination of the aiming beam.

During the power check process the distal end of each of the light diffusers, individually, has to be inserted into the correct calibration port insert. Once inserted, the light diffuser is detected in the

calibration port immediately before and after the power check process, thus, no laser light is emitted outside the system.

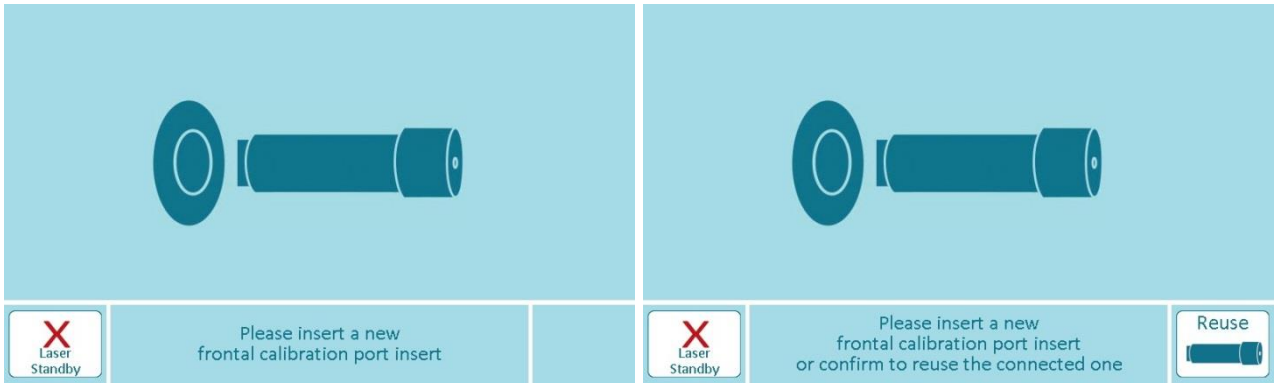
During the power check process of each diffuser, the calibration port lights up in the colour of the aiming and treatment beam.

The device starts the power check with the first configured port number requesting the connection of the configured light diffuser. If a frontal diffuser was configured, the device displays the following screen.

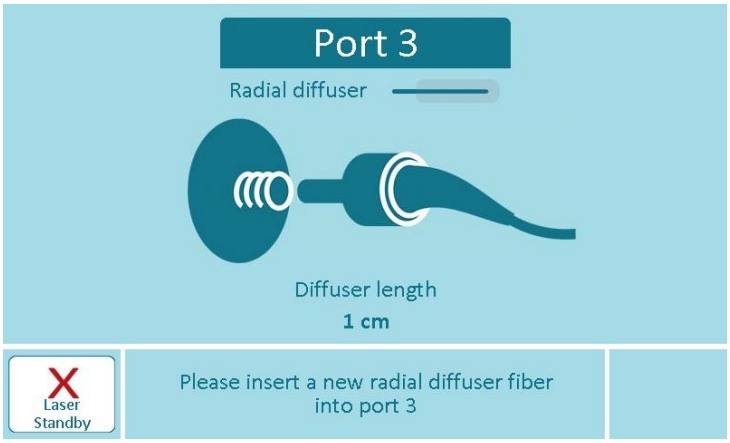


After connecting the frontal diffuser, the device requests the corresponding calibration port insert (CPI) be inserted for a frontal diffuser type. If there is no CPI inserted into the calibration port, the device does not move to the next step for checking the output power of the diffuser.

Important: If there is more than one frontal diffuser to calibrate for the actual patient treatment, the device allows reusing the CPI for the single patient.

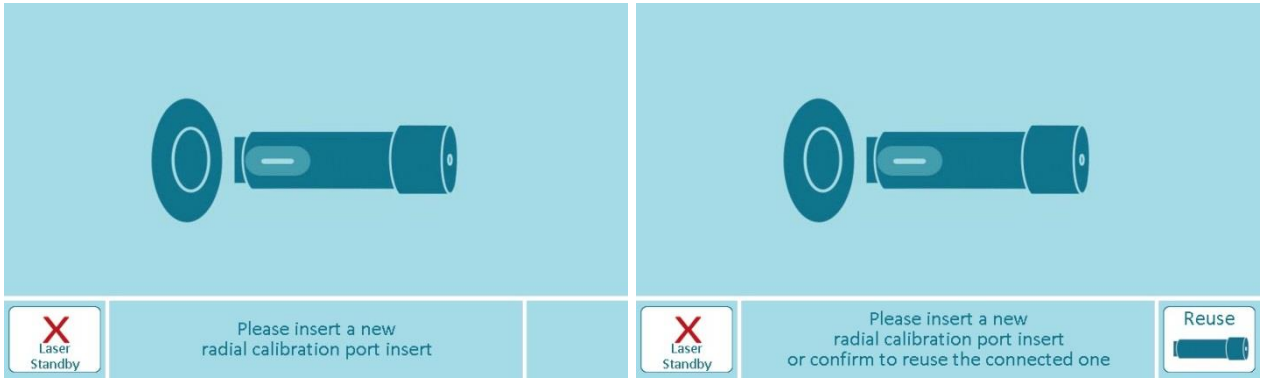


If a cylindrical (radial) diffuser was configured, the device displays the following screen and requests the right diffuser length. Please use the requested diffuser length. Otherwise the power check will not be successful and must be repeated.

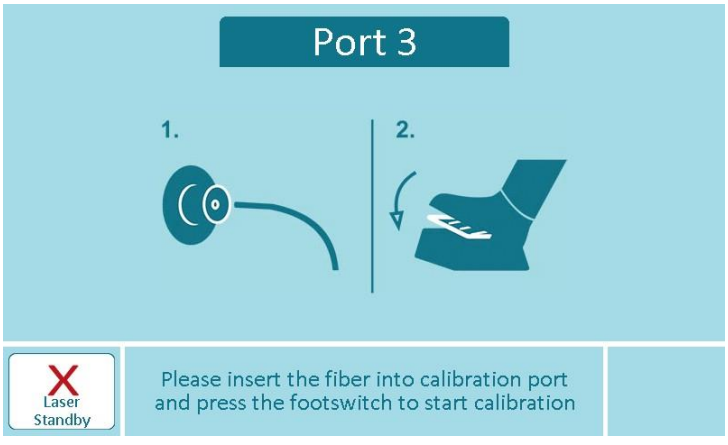


After connecting the cylindrical (radial) diffuser, the device requests the corresponding calibration port insert (CPI) be inserted for a cylindrical diffuser type. If there is no CPI inserted into the calibration port, the device does not move to the next step for power check of the diffuser.

Important: If there is more than one cylindrical diffuser to calibrate for the actual patient treatment, the device allows reusing the CPI for the single patient.

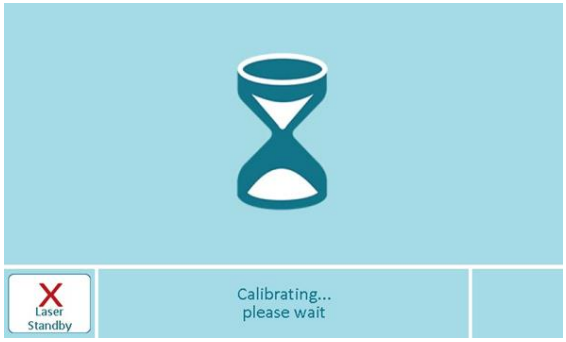


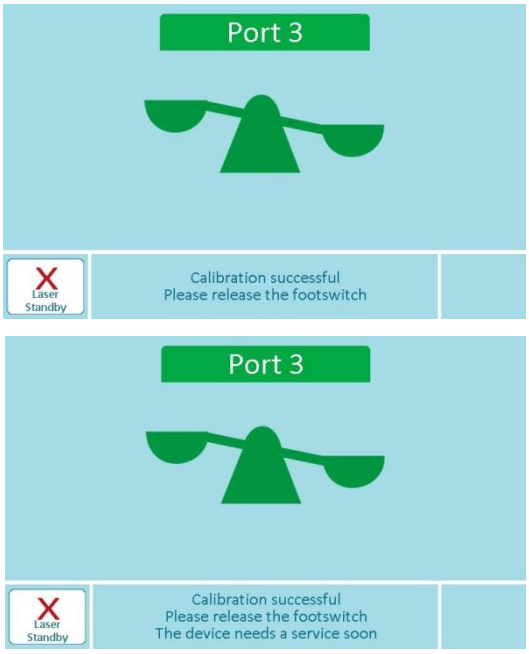
The instructions on the display will guide the user through the power check process.



1.) and 2.)

1.) Insert the distal end of the light diffuser into the calibration port insert.
2.) Press the footswitch.



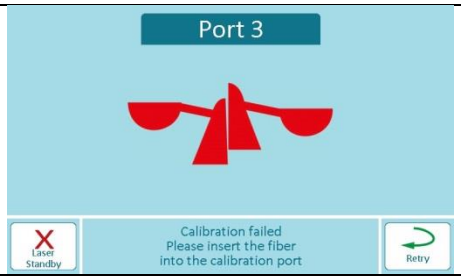
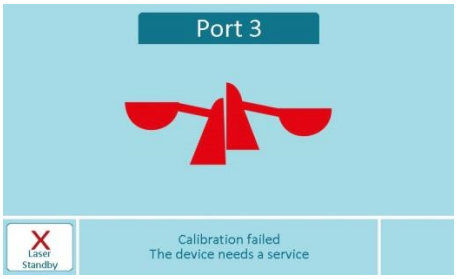
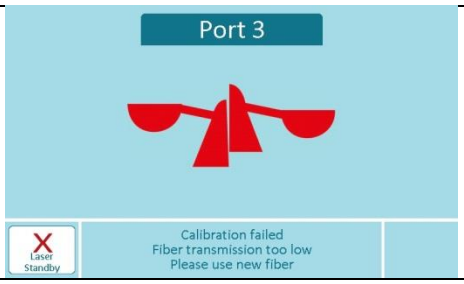


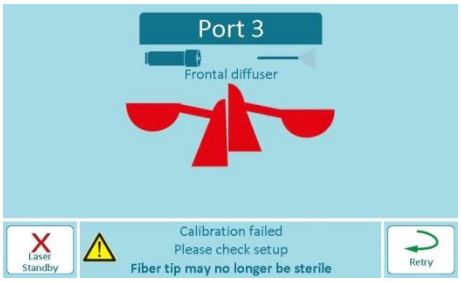
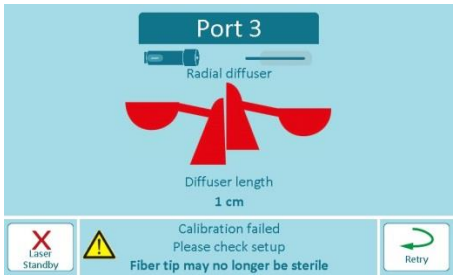
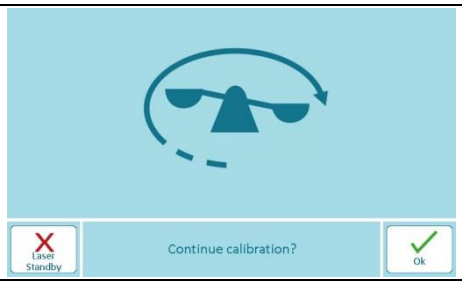
The power check process starts immediatelly.

3.)

3.) Once the power check is completed, release the footswitch. The following possible screens are displayed.

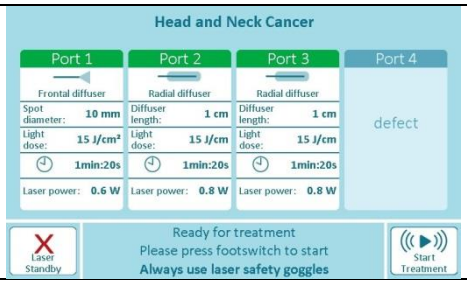
4.) If the power check process was not successful, the reason and further instructions are displayed on the screen:

	The light diffuser is not inserted into calibration port (for port 3). Please insert the light diffuser properly into the calibration port and push the “Retry”-button to continue.
	The laser power was not sufficient to complete the power check process. The device needs a service, refer to chapter 5.2. Push the “Laser Standby” button to change the port configuration or remove the diffuser and retry the power check. Power check with smaller values for “Spot Diameter” or “Diffuser Length” at this port may be successful.
	The transmission of the diffuser is insufficient or the calibration port is dirty. The diffuser may be dirty or broken. Connect a new diffuser to the device to proceed. Or possibly the calibration port insert or the calibration port itself is dirty. Use a new CPI.

	Frontal diffuser power check selected: Wrong setup for diffuser power check detected. Cylindrical diffuser type is possibly in use with CPI for cylindrical diffuser type, or possibly in use with CPI for frontal diffuser type. Please check setup and retry the diffuser power check. Warning! In case of cylindrical diffuser type in use with CPI for frontal diffuser type, the diffuser tip may no longer be sterile or contaminated. Connect a new diffuser and the corresponding new CPI into the device when requested to proceed.
	Cylindrical diffuser power check selected: Wrong setup for diffuser power check detected. Cylindrical diffuser type is possibly in use with CPI for frontal diffuser type or frontal diffuser type is possibly in use with CPI for frontal diffuser type. Please check setup and retry diffuser calibration. Warning! In case of cylindrical diffuser type in use with CPI for frontal diffuser type, the diffuser tip may no longer be sterile or contaminated. Connect a new diffuser and the corresponding new CPI into the device when requested to proceed.
	If the power check process was interrupted by a door-open interlock event, the device will ask the user to continue the power check process or to stop the power check process and return to laser standby state and abort the treatment. The user has to decide if there is a higher benefit for the patient to abort or to continue the power check process.

5.) If the power check was successful for each of the configured ports the device automatically transits into the ready-state after a 2 second delay together with an optical and acoustic indicator. During this 2 second period the footswitch must not be pressed or the device will transfer back to a safe state. If the additional message appears “The device needs a service soon”, the user can continue the treatment, but please refer to chapter 5.2.

	If the footswitch has been pressed during the 2 second delay period the system switches to a safe state. Please release the footswitch to continue to the ready-state or press the “Laser Standby” button to abort the treatment.

	If the footswitch has not been pressed during the 2 second delay period the system switches automatically to the Ready-state.

The user can test the frontal diffuser light diffuser by pointing the aiming beam of the frontal diffuser tip at a flat surface. The illuminated area should be circular (or other geometric shape according to the diffuser type) and homogeneous. If there are any flaws in the illuminated area or if the area is not perfectly in shape, the diffuser may be broken.

The user can test the cylindrical diffuser in a similar way. Watch the illuminated area of the cylindrical diffuser tip itself while the aiming beam is illuminated. The illuminated diffuser area should glow in a homogeneous pattern. If there are any flaws or hotspots visible on the illuminated diffuser tip area, the diffuser may be broken. Note that protective eyewear (i.e., goggles) should be worn while treatment beam is enabled. The treatment beam should never be used for these checks.

A broken or damaged diffuser must not be used. Replace the broken diffuser with a new one and check the power output of the new diffuser before proceeding.

After finishing the power check, please leave the calibration port insert in the calibration port as a dust protection.

4.5.4 **Treatment**

Laser radiation can only be initiated by an intended 4-step process with 3 different interactions (touch button, calibration port and footswitch or touch button):

1.) Performing the power check for each of the 1-4 output ports by pressing the “Start Calibration” button (see chapter 4.5.3).
2.) Inserting the diffuser to be calibrated into the calibration port and pressing the footswitch (see chapter 4.5.3)
3.) Releasing the footswitch such that the device may transit into the Ready-state (see chapter 4.5.3)

Once the device changes into the Ready-state, the aiming beam for all calibrated diffusers is switched on and the device warns optically that it is now in this state. Only then can the laser radiation be emitted by pressing the footswitch or the “Start-Treatment” button. The display shows the configured treatment parameters “Spot Diameter”, “Diffuser Length” and “Light Dose” as well as the calculated treatment parameters “Laser Power” and “Treatment Time”. The distal end of the diffusers 1-4 must be kept in position during the treatment period so that the marked area and measured spot diameter is illuminated by the aiming beam of the frontal light diffuser and the cylindrical diffuser is in treatment position, too.

Warning:

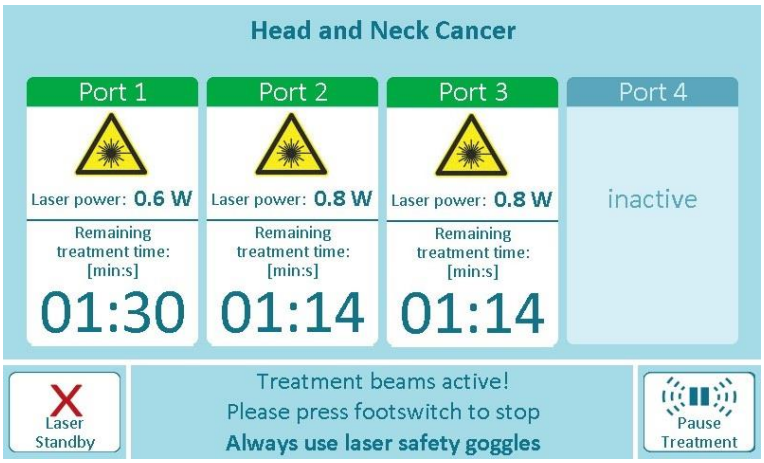
Pressing the footswitch or pressing the “Start-Treatment” button in this state leads to laser emission.

Make sure that everyone in the room is wearing appropriate laser safety goggles during treatment.

Specifications for suitable safety goggles and ordering information can be found in chapter 6.1.

The Nominal Ocular Hazard Distance (NOHD) is provided in chapter 2.1.

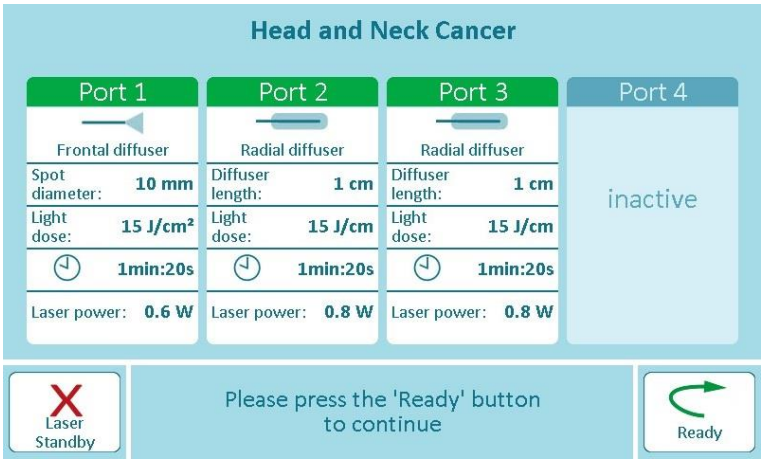
After the footswitch or the “Start-Treatment” button was pressed all the configured output treatment channels are switched on and the device displays the “Treatment Active” screen. The remaining treatment time is counting down on the screen for each port. The device emits an optical and acoustical warning signal while laser radiation is emitted.



When the footswitch is pressed again or the “Pause Treatment” button is pressed the device immediately ceases the treatment laser emission and switches back to the Ready-state. The timer is stopped until the footswitch or the “Start/Continue Treatment” button is pressed again and the treatment is resumed.

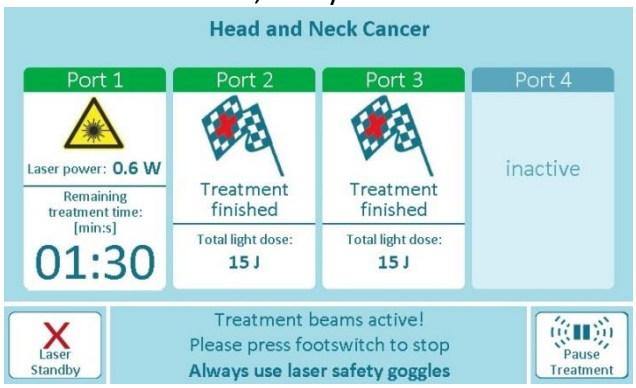
The treatment can be interrupted and resumed as often as necessary by pressing the footswitch or the “Pause/Continue Treatment” button again while the treatment time has not been completed.

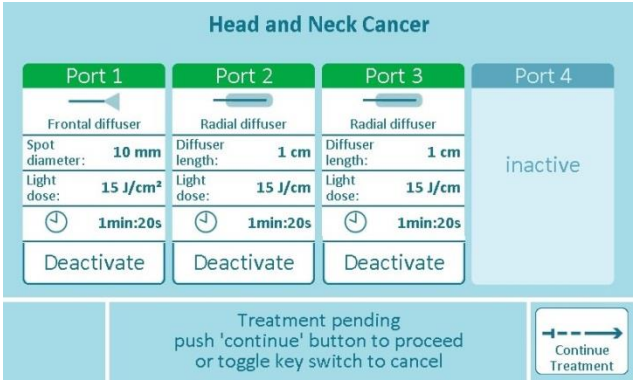
If the treatment is interrupted for more than 5 minutes the device automatically leaves the Ready-state and switches back into a safe state. Pressing the “Ready” button will bring the device back to the Ready-state.



If the treatment time is elapsed for one or for all of the ports the treatment laser and the aiming beam of the elapsed ports are switched off. The display shows for example the following screen for

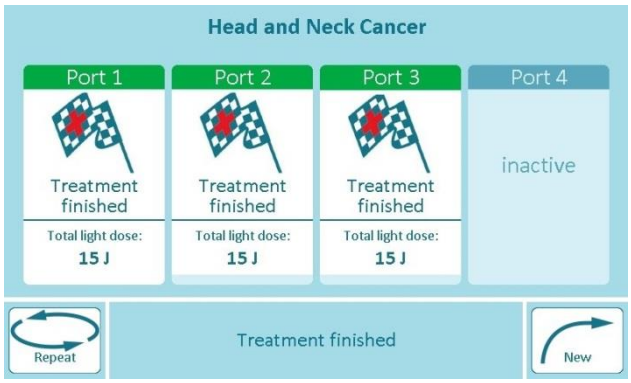
elapsed treatment of port 2 and port 3, while port 1 is still treating the patient for the remaining time of one minute, thirty seconds:

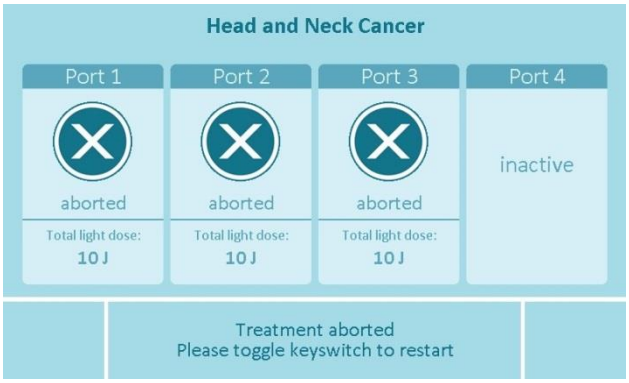




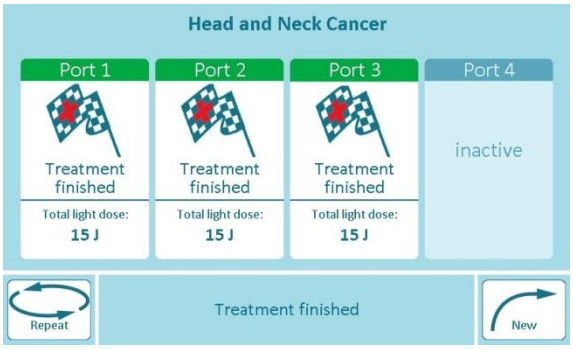
The user may abort the treatment at any time by pressing the “Laser Standby” button. To continue the treatment the user has to press the “Continue-Treatment” button. If one or all of the ports need to be deactivated because of any unforeseen event, it is the user’s decision to abort the treatment by toggling the key switch to deactivate one or more of the ports by first removing the diffuser and pressing the “Deactivate” button. If a treatment was aborted, the total delivered light dose is displayed as shown below for each port.

If all treatment timers elapsed, the device displays the message treatment finished.

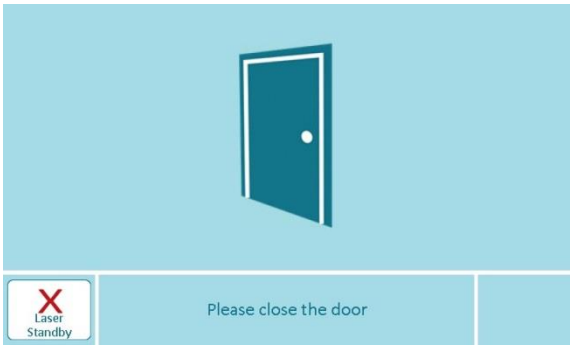




The user can continue treating the same patient by pressing the “Repeat” treatment button using the same treatment parameters as used in the previous treatment. Or the user can start a new treat by pressing the “New” treatment button.



To stop the laser emission in any operating state due to emergency reasons, please press the emergency laser stop button (see chapter 3). If the door is opened during treatment the laser emission stops immediately. In opposition to pressing the emergency stop button the treatment may be continued right after the door is closed again.



4.5.5 **Parameters set by the user for superficial photoimmunotherapy**

The frontal light diffusers are used for superficial photoimmunotherapy. The spot diameter is the diameter of the laser light spot at the skin of the patient. The default spot diameter and the boundaries are set by the study manager. It can be altered by the user if the boundaries allow a change of the parameter. If the study manger sets the boundaries to the same value as the default setting, the user cannot change the spot diameter anymore after choosing an indication.

Maximum spot diameter	40 mm depending on the set laser power density
Minimum spot diameter	10 mm depending on the set laser power density
Spot diameter step size	1 mm
Preset / default spot diameter	Minimum spot diameter

For the selection of an adequate light dose, refer to the clinical protocol. The default light dose and the boundaries are set by the study manager for each indication. It can be altered by the user if the boundaries allow a change of the parameter. If the study manager sets the boundaries to the same value as the default setting, the user cannot change the light dose anymore after choosing an indication.

Maximum Light Dose	500 J/cm^2
Minimum Light Dose	50 J/cm^2
Light Dose Step Size	10 J/cm^2
Preset / Default Light Dose	Minimum Light Dose

The laser power density or irradiance can be set by the study manager only.

Maximum Laser Power Density (Irradiance)	180mW/cm^2
Minimum Laser Power Density	50mW/cm^2
Laser Power Density Step Size	10mW/cm^2
Preset / Default Laser Power Density (Irradiance)	150mW/cm^2

For setting this parameter, please refer to the instructions for use of study manager software tool.

Example:

Name	Symbol	Unit
LIGHTDOSE	*D*	J/cm²
Total Light Dose (Energy)	$D_{total} = D * A$	J
SPOTDIAMETER	*d*	mm
Spot Area	$A = \pi * \left(\frac{d}{2}\right)^2$	cm²
Laser Power Density (Irradiance)	*I*	W/cm²
Total Power	*P*	W
Treatment Time	*t*	s

Spot diameter $d = 2cm$ Light dose $D = 5\frac{J}{cm^2}$ Laser power density $I = 130\frac{mW}{cm^2}$

$$A = \pi * \left(\frac{2cm}{2}\right)^2 = 3{,}14cm^2 \qquad D_{total} = 5\frac{J}{cm^2} * 3{,}14cm^2 = 15{,}7J$$

$$P = 0{,}13\frac{W}{cm^2} * 3{,}14cm^2 = 0{,}408W \qquad t = \frac{15{,}7J}{0{,}408W} = 38{,}46s$$

4.5.6 **Parameters set by the user for interstitial photoimmunotherapy**

The cylindrical light diffusers are used for interstitial photoimmunotherapy. The diffuser length is the active length of the cylindrical (radial) diffuser and it is selected according to the size of the tumor to be treated of the patient. The default diffuser length and the boundaries are set by the study manager for each indication. It can be altered by the user if the boundaries allow a change of the parameter. If the study manger sets the boundaries and the default parameter to the same value, the user cannot change the diffuser length anymore after choosing an indication.

Maximum diffuser length	4 cm
Minimum diffuser length	1 cm
Diffuser length Step Size	1 cm
Preset / Default diffuser length	Minimum Diffuser length

For the selection of an adequate light dose, refer to the clinical protocol. The default light dose and the boundaries are set by the study manager for each indication. It can be altered by the user if the boundaries allow a change of the parameter. If the study manger sets the boundaries and the parameter to the same value, the user cannot change the light dose anymore after choosing an indication.

Maximum Light Dose	500 J/cm
Minimum Light Dose	50 J/cm

Light Dose Step Size	10 J/cm
Preset / Default Light Dose	100J/cm

The laser power fluence rate can be set by the study manager only.

Maximum fluence rate	400mW/cm
Minimum fluence rate	40mW/cm
Fluence rate step size	10mW/cm
Preset / Default fluence rate	400mW/cm

For setting this parameter, please refer to the instructions for use of study manager software tool.

Example:

Name	**Symbol**	**Unit**
LIGHTDOSE	*D*	J/cm
Total Light Dose (Energy)	$D_{total} = D * l$	J
DIFFUSERLENGTH	l	cm
Fluence Rate	*I*	W/cm
Total Laser Power	*P*	W
Treatment Time	*t*	s

$\text{diffuser length } l = 4cm \qquad \text{Light dose } D = 200\frac{J}{cm} \qquad \text{Fluence Rate } I = 400\frac{mW}{cm}$

$$D_{total} = 200\frac{J}{cm} * 4{,}0cm = 800J$$

$$P = 0{,}4\frac{W}{cm} * 4cm = 1{,}6W \qquad t = \frac{800J}{1{,}6W} = 500s = 8\,\text{min}\,20s$$

Note: The device records the applied treatment parameter sets consisting of spot diameter, diffuser length, light dose, power density (irradiance), fluence rate and the resulting values for laser power and treatment time as well as the actually applied treatment time. Date and time of the treatment are purposely not recorded.

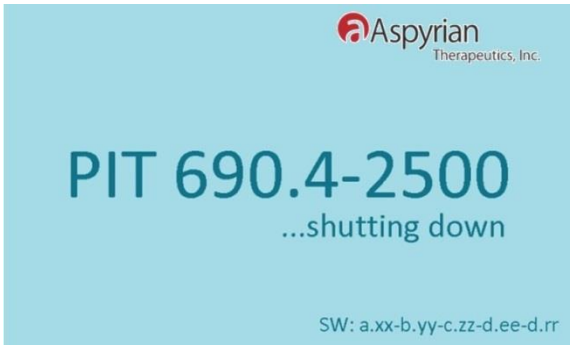
These parameters can be read out by the study manager.

4.5.7 **Switching off**

Turning the key counter clockwise causes defined switching off of the laser.

Turn the key counter clockwise to switch off the device.

The following screen is displayed:



5. Maintenance and device messages

5.1 Cleaning and disinfection of the device

The housing of the laser device, the footswitch and the power supply may be cleaned with a moist cloth. A mild antiseptic detergent or a mild cleaning agent may be used.

Caution:

Chemical cleaning agents, strong cleaning agents or rough cleaning clothes can damage the housing's surface and must therefore not be used.

Caution:

Separate the device and the power supply from mains before cleaning and disinfecting. No splashing water may penetrate the equipment.

A regular disinfection of the device's surface especially in the area of the touch display is recommended with high alcohol content cleaning solution.

5.2 Maintenance and calibration

There is no maintenance or service required by the user. An annual verification of the power and wavelength calibration is required to address the slight degradation of the laser diodes over time and usage.

If the device itself indicates the need for service soon, the user can continue the actual treatment, but a service is required to check the degradation level of the laser diodes. This verification cannot be conducted by the user, but by authorized service personnel only.

At the end of the annual verification of the power and wavelength calibration procedure the device must be safety-checked by authorized and trained service personnel according to EN (IEC) 62353.

The next service date is noted on a label at the rear side of the device. Contact your sales representative or the manufacturer for the annual service.

The laser device may be sent in for annual calibration service or for safety inspection only in its original packaging, including all accessories.

Disinfect the laser device and the accessories according to chapter 5.1 and relevant instructions for use of other connected devices (such as light diffusers) prior to shipment.

In order to keep and maintain the EMC requirements over the entire lifecycle of the device, no special maintenance is required for the PIT690 laser.

5.3 Messages and possible causes

Message / display	Possible causes	Suggested action
Black display, no LED on	Device is not connected to the external power supply.	The external power supply should be connected to the device and to the mains.
Black display, blue 'LED on	The key switch is in position "Off": 	Turn the key switch off and on again for using the device: 
Device error, contact manufacturer, error code displayed (all error messages are displayed on the same screen).	Fatal error that stops operating the device for safety reasons.	Contact manufacturer for service. Please report the error code to the manufacturer. For an intermediate solution, please turn the device off by disconnecting the power supply and turn it on again as described in this instruction for use. If the power off-on reset solves the problem, the device might be used for the actual treatment. But please send the device to the manufacturer after finishing the actual treatment.
Error, please connect footswitch.	The footswitch is not connected, or it is defective.	Please connect the footswitch at the connector in the back of the device or replace the footswitch.
Release emergency laser stop	The emergency laser stop button is pressed	Release the emergency laser stop button by turning it clockwise and releasing it.
Temperature error, device too cold, wait for the device to acclimatize	The device is too cold.	Please wait while the device is warming up until it reaches the operating temperature
Temperature error, device too hot, please check cooling airflow	The device is too hot. Or the cooling air inlet, or fan outlet are blocked. The device might be placed on a soft surface.	Please wait while the device is cooling down until it reaches the operating temperature. Please check the cooling air inlet, outlet or fan if one of them is blocked. Please keep the device away from walls. Place the device on a solid and stable surface.
Please close the door	The remote interlock is connected to the door contact and the door is open.	Close the door and continue normal operation

Message / display	Possible causes	Suggested action
Calibration failed, Please insert fiber	The active light diffuser under power check is not inserted into the calibration port.	Please insert the light diffuser of the actual diffuser port under power check properly into the calibration port and push the “Retry”-button to continue.
Calibration failed, fiber transmission too low. Please use new fiber.	The light diffuser is broken or an incorrect diffuser was selected.	Please use an appropriate light diffuser. Refer to chapter Please detach the light diffuser from the device and replace the diffuser with a new one. Then insert a new CPI or push the “Reuse” button to confirm the sterility of the already inserted CPI.
Calibration failed, the device needs a service	The laser power was not sufficient to complete the power check process.	The laser power was not sufficient to complete the power check process. The device needs a service. Refer to chapter 5.2. Push the “Laser Standby” button to change the port configuration or remove the diffuser. Retry the power check. Power check with smaller values for “Spot Diameter” or “Diffuser Length” at this port may be successful.
Calibration failed. Transmission too low	The transmission of the diffuser is insufficient. Maybe the diffuser is contaminated or broken.	Connect a new diffuser to the device to proceed.
Calibration failed. Please check setup Fiber tip may no longer be sterile. Warning!	Wrong setup for diffuser power check detected. 1.) Cylindrical diffuser type is possibly in use with CPI for cylindrical diffuser type, or possibly in use with CPI for frontal diffuser type. 2.) Cylindrical diffuser type is possibly in use with CPI for frontal diffuser type or frontal diffuser type is possibly in use CPI for frontal diffuser type.	Please check setup and retry the diffuser power check. Cylindrical diffuser type must be calibrated with CPI for cylindrical diffuser type. Frontal diffuser type must be calibrated with CPI for frontal diffuser type. Connect a new diffuser and the corresponding new CPI into the device and retry the diffuser power check when requested to proceed.

Message / display	Possible causes	Suggested action
Calibration failed, the device needs a service	Calibration port is defective or dirty; power check was not possible	Use a new insert for the calibration port (CPI for cylindrical or frontal diffuser). Please check the calibration port for dirt inside the port. If necessary, please remove the dirt by wiping it with a clean and moist cloth. If the dirt is not removable, please contact the manufacturer. Turn the key switch off and on again. If this does not solve the problem please send the device to the manufacturer.
Error Code is displayed in laser standby state. Port n (n: 1 - 4) has a defect. It cannot be activated for treatments. Please confirm.	One of the four ouput ports has a defect.	Please press the “Confirm” button. The defective port cannot be used for treatments and will be displayed as “defective”. The device might be used for the next planned treatment by using the remaining diffuser ports. Please send the device to the manufacturer after finishing the treatment. Please report the error code to the manufacturer.
Error Code is displayed during an active treatment. An Error occurred at Port n (n: 1 - 4), it will be deactivated. Please confirm.	One of the four output ports has a defect.	Please press the “Confirm” button. The defective port cannot be used for the actual treatment and will be displayed as “defective”. The so far delivered light dose is displayed. The device might be used for the actual treatment by using the remaining output ports to finish the treatment. Please send the device to the manufacturer after finishing the actual treatment. Please report the error code to the manufacturer.
Study manager mode is displayed.	The device is in study manager mode.	Disconnect the USB-connection. Then press “Cancel”.
Maintenance mode is displayed.	The device is in maintenance mode.	Consult your service technician or the manufacturer whether the maintenance is completed. If so, disconnect the USB-connection, then press “Cancel”.

6. Accessories

6.1 Laser goggles

The laser goggles for the PIT690 laser must have an optical density of at least 6.0 to 7.0 in the wavelength range 680 – 700 nm and an optical density of less than 0.5 in the wavelength range of 520 – 540 nm and an L-rating of D LB4 + IR LB5 (RB2), DIR LB2 (RB3) for the wavelength range 680 – 700 nm.

Ordering number	Article numbers (REF)	Article description
PIT690.Safety Goggles	RB2, RB3	Laser goggles for PIT690.4-2500 laser with L-rating: RB2: >665-693 DIR LB2; optical density 685-705 nm 6+ RB3: >665-715 D LB4 + IR LB5; optical density 680-710 nm 6+

6.2 Accessories

Article number (REF)	Article description
MKF 2S-MED SK12	Footswitch with cable and plug
AHM250PS24	Power supply XP Power AHM250PS24, 24V, 250VA (IEC 60601-1 3rd Ed.)
EM12501Q	Power supply EdacPower EM12501Q, 24V, 250VA (IEC 60601-1 3rd Ed.)
Med.0016	Power cord EU Type (IEC 320)
Med.0017	Replacement key for key switch
Med.0018	Bridging connector for the remote interlock
Medsys-2011	Calibration port insert for cylindrical/cylindrical light distributor (REF: medsys-2011)
Medsys-2012	Calibration port insert for frontal light distributor (REF: medsys-2012)
PIT690.4.2500.IFU.EN	Instruction for use for PIT690.4.2500 laser (language English)
MED.Package.Size2	Replacement packaging for PIT690.4-2500 laser device

Warning:

Use of other parts or connecting other accessories than specified in the above table of accessories may result into unidentified risk or non-compliance according to the standard for electromagnetic compatibility.

6.3 Compatibility with third-party products

6.3.1 Light diffuser

This laser device may only be used in conjunction with the following diffusers:

Article number (REF)	Article description	
FD1	Medlight frontal light distributor, model FD1	For the intended use of the diffusers and for handling the different diffuser types, please refer to the specific instruction for use. The diffusers are not applied parts in the meaning of the EN (IEC) 60601-1 standard.
RD-ML-AS-10 (RD-ML-10)	Medlight cylindrical light diffuser, model RD-ML-AS-10, 10mm diffuser length	
RD-ML-AS-20 (RD-ML-20)	Medlight cylindrical light diffuser, model RD-ML-AS-20, 20mm diffuser length	
RD-ML-AS-30 (RD-ML-30)	Medlight cylindrical light diffuser, model RD-ML-AS-30, 30mm diffuser length	
RD-ML-AS-40 (RD-ML-40)	Medlight cylindrical light diffuser, model RD-ML-AS-40, 40mm diffuser length	
AFD-1	Rakuten Aspyrian frontal light diffuser	

7. Disposal

WEEE (Waste of Electrical and Electronic Equipment)

Recycling of Electronic Products, disposing of this product.

The WEEE Directives (2008/98/EC and 2012/19/EU) require all EU-based manufacturers and importers to recycle electronic products at the end of their useful life. Rakuten Aspyrian, Inc accepts its responsibility in accordance with the WEEE recycling requirements. PIT690 products that are marked with the WEEE symbol (see symbol on left) indicating that this product must NOT be disposed of with household waste. Instead, it is the user's responsibility to dispose of their waste electrical and electronic equipment by handing it over to an approved re-processor or by returning it to Rakuten Aspyrian, Inc. or their distributor for recycling.

8. Limited Warranty

The limited warranty by Rakuten Aspyrian, Inc. is applied to the physical product and accessories as described in this user manual, and it covers defects in material, any defects in workmanship under normal use, and shipment when the product is delivered to the customer.

The customer is required to inspect the product upon arrival and report any observed shipment damages or defects immediately and within 5 business days of receiving the product to Rakuten Aspyrian, Inc.

Upon a defect observed by the user after taking the device into use, the user is required to

- Notify Rakuten Aspyrian immediately and within 3 business days by e-mail (info@rakutenaspyrian.com), or by phone (858)-925-5619
- Provide Rakuten Aspyrian detailed description of the nature of the defect, users and patients involved, where the defect was observed, when, and possible harm(s) caused by the defect
- Provide Rakuten Aspyrian information about the use conditions of the product
- Allow Rakuten Aspyrian, Inc. to investigate the defect on-site or at Rakuten Aspyrian, Inc.
- Request a Return Material Authorization (RMA) prior to return of product and give assistance in shipping the product back to Rakuten Aspyrian
- Packaging the product in its original packaging materials if required to be returned to Rakuten Aspyrian
- Making sure that any documents or accessories that shipped with the product are included in the package
- Providing contact information to person that observed the defect
- Defining a contact for arranging any further communication

During the limited warranty period, Rakuten Aspyrian will repair any broken parts of a product using new or replacement parts or exchange with a new product, once verified that the defect is covered by the limited warranty.

The repair can be completed on-site or at Rakuten Aspyrian based on Rakuten Aspyrian's evaluation of the extent of repairs needed.

The Warranty Period for the product 2 years from the date of installation.

The products that have been repaired under warranty have no extension of total warranty period. If a new product has been provided as a replacement, the new product is covered by same coverage period as the original product, and the coverage period does not automatically re-start with delivery of a replacement.

The warranty does not cover damage of a product resulting from negligence, damage of a product resulting from unauthorized modification of the product, improper maintenance, or damage caused by natural disaster or theft or loss of the product.

9. Consumer Protection

Some states do not allow the exclusion or limitation of incidental or consequential damages, or allow limitations on how long an implied warranty lasts, so the above limitations or exclusions may not apply to you. This warranty gives you specific legal rights, and you may also have other rights that vary by state to state.

10.Trade marks

Rakuten Aspyrian

Rakuten Aspyrian, Inc.

11.Manufacturer information

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Images inside this manual may not be fully identical with the images showed by laser system.

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Rakuten Aspyrian

Technical Manual

1. Appendix: Technical data

1.1 General specifications for the PIT690.4-2500 laser model

The device shall only be used with the external power supply XP Power AHM250PS24 or EDAC/Neumüller EM12501Q (for ordering information see chapter 6.2).

External DC power supply rating	100 – 240 VAC;30 – 60 Hz
Power Consumption	up to 250 VA
Power Supply Cord	acc. to IEC 60320-C13
DC in of device	24 V, typ. max. 10.4 A
Dimensions (height, width, depth)	251mm, 444mm, 308mm
Weight including footswitch and power supply	approx. 15,2 kg
Electrical protection class	I, acc. to EN (IEC) 60601-1
Medical device class acc. to 93/42/EEC	IIb, rule 9

1.2 Model dependent specifications

1.2.1 **Model PIT690.4-2500**

Laser power	(4 x) 2.5 W ±0.075 W, laser class 4 acc. to EN (IEC) 60825-1
Wavelength: Wavelength stability and spectral width:	690 nm 90% of the emitted laser power are within ±4 nm centred around centre operating wavelength
Mode of operation	CW
Aiming laser wavelength	520-540 nm
Aiming laser power	< 5mW at output port; laser class 3R
Aiming beam power settings	automatically on/off
System light diffuser output connector	SMA 905
Diameter of diffuser core	min. 400 µm, typical 600 µm
Full angle of divergence at the distal end of diffuser (FD1, frontal diffuser)	34.7° (NA = 0.3, for air)

For cylindrical diffusers (RD-ML-AS-xx, cylindrical light diffuser, xx = length of active diffuser material)	The illumination field is a homogeneous and cylindrical illumination field around the diffuser. It starts at the end of the transmission fiber and it ends at the end of the diffuser material.

1.3 Applied standards

The laser device is developed, manufactured and tested in accordance with the appropriate regulations and standards for the European Economic Area (EEA) and the following countries:

- USA,
- Japan
- Canada
- Mexico
- Brazil
- Taiwan
- South Korea
- Singapore
- Australia
- Russia
- India

List of applied standards:

1.Medical Electrical Equipment - Part 1: General Requirements For Basic Safety AndEssential

Performance [IEC 60601-1:2005 Ed.3+C1;C2;A1]

RMF according to: Medical devices - Application of risk management to medical devices

[ISO 14971:2007-03 (German Version EN ISO 14971:2012, April 2013)]

2.Medical Device Software - Software Life Cycle Processes

[IEC 62304:2006 Ed.1]

3.Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety And

Essential Performance - Collateral Standard: Usability

[IEC 60601-1-6:2010 Ed.3 +A1]

Medical Devices - Application Of Usability Engineering To Medical Devices

[IEC 62366:2007 Ed.1 +A1]

4.Medical electrical equipment - Part 1-2: General requirements for basic safety andessential performance –

Collateral standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014

IEC 60601-1-2 ed. 4, IEC 60601-1-2 ed. 3 for Canadian deviations.

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5.Medical Electrical Equipment - Part 2-22: Particular Requirements For Basic SafetyAnd

Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment

[IEC 60601-2-22:2007 Ed.3+A1]

6.Safety of Laser Products - Part 1: Equipment Classification And Requirements

[IEC 60825-1:2007 Ed.2]

ETL approval and certificates according to ANSI/AAMI ES60601-1:2005/(R)2012/ CAN/CSA C22.2 No.

60601-1:2014 und UL/CAN/CSA-C22.2 NO. 60601-2-22 A-08 - Amendment 1:2014.

1.4 Manufacturer's declaration regarding electromagnetic compatibility according to 60601-1-2, 4 ed

The information in this paragraph provides the operator of the PIT690.4-2500 with the information necessary to determine whether the PIT690.4-2500 is suitable for the particular environment from the point of view of the electromagnetic compatibility.

The PIT690.4-2500 laser is a medical electrical device.

Therefore, in order to ensure the functions of the PIT690.4-2500 laser, precautions regarding electromagnetic compatibility must be observed and the PIT690.4-2500 laser must be set up and put into operation according to the following conditions.

Mobile RF communications equipment can affect medical electrical equipment.

For all electromagnetic immunity tests, four frontal diffusers were connected to the device. The device was operated at the smallest adjustable spot diameter to achieve the lowest output power.

The output power and the displayed power were monitored during the electromagnetic compatibility (EMC) test.

The output power was measured externally at the system output by a thermopile laser power sensor and meter.

The characteristics of the PIT690.4-2500 laser, determined by emissions, allow its use in the industrial sector and in professional healthcare environment (CISPR 11, Class A).

For use in the home healthcare environment (for which Class B is normally required according to CISPR 11), this device may not provide adequate protection for radio services. The user must take remedial measures such as implementation or reorientation of the device.

Warning:

Portable or mobile RF communications devices (e.g., mobile telephones) should not be used in a distance less than 30 cm from the parts and lines designated by the manufacturer of the PIT690.4-2500 laser.

Non - compliance may result in a reduction of the performance of the device.

Warning:

The PIT690.4-2500 laser should not be used in close proximity to other electronic devices or stacked during operation. If use is still required in the prescribed manner, this device and the other devices should be observed to ensure that they work properly

Warning:

If the PIT690.4-2500 laser is connected to other cable or accessory than specified (device or system), the requirements for EMC according to IEC 60601-1-2 must be met, otherwise the device function of the PIT690.4-2500 laser may be negatively

affected, as well as the electrical safety and EMC of the laser device are not guaranteed.

Note:
Due to electromagnetic interference, the device can be influenced. This can cause restrictions of the normal function of the PIT690.4-2500 (see chapter 5.3).

1.4.1 **Electromagnetic Emission:**

Guidelines and manufacturer 's declaration - Electromagnetic interference:		
The PIT690.4-2500 laser is intended for operation in an electromagnetic environment as specified below. The customer or user of the PIT690.4-2500 laser or the responsible organization should ensure that it is operated in such an environment (CISPR11, Group 1, Class A).		
Emitted interference measurements	Accordance	Electromagnetic Environment - Guidelines
RF emissions, CISPR 11	Group 1	The PIT690.4-2500 laser uses RF energy exclusively for its internal function. Therefore, RF transmission is very low and it is unlikely that adjacent electronic equipment will be disturbed.
RF emissions, CISPR 11	Class A	The PIT690.4-2500 laser is for use in professional healthcare facilities (CISPR11, Group 1, Class A).
Harmonics, IEC 61000-3-2	Class A	
Voltage fluctuations, IEC 61000-3-3	fulfilled	

1.4.2 **Electromagnetic Immunity:**

Guidelines and manufacturer 's declaration - Electromagnetic immunity			
The PIT690.4-2500 laser is intended for operation in an electromagnetic environment as specified below. The customer or user of the PIT690.4-2500 laser or the responsible organization should ensure that it is operated in such an environment.			
Immunity tests	Test levels, IEC 60601-1-2 4.ed	Accordance - Level	Electromagnetic Environment - Guidelines
Electrostatic discharge (ESD) by human or machine, IEC 61000-4-2, Electrostatic discharge by air	± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV (air)	± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV (air)	Floors should consist of wood or concrete or be provided with ceramic tiles. If the floor is provided with synthetic material, the relative humidity must be at least 30%.
IEC 61000-4-2, Electrostatic discharge by contact	± 8 kV (contact)	± 8 kV (contact)	
Fast transient electrical disturbances / bursts, conducted, IEC 61000-4-4	± 2 kV, 100 kHz	± 2 kV, 100 kHz	The quality of the supply voltage should correspond to a typical business or hospital environment.
Surges, conducted, IEC 61000-4-5	± 0,5 kV, ± 1 kV, surge, differential mode,	± 0,5 kV, ± 1 kV, surge, differential mode,	The quality of the supply voltage should correspond to a typical business or hospital environment.
	± 0,5 kV, ± 1 kV, ± 2 kV, surge, common mode	± 0,5 kV, ± 1 kV, ± 2 kV, surge, common mode	
Voltage Dips, IEC 61000-4-11	0% U-T; ½ periode at 0, 45, 90, 135, 180, 225, 270 and 315 degr.	0% U-T; ½ periode at 0, 45, 90, 135, 180, 225, 270 and 315 degr.	The quality of the supply voltage should correspond to a typical business or hospital environment.
	0% U-T; 1 periode and 70% U-T,	0% U-T; 1 periode and 70% U-T,	

	25/30 periodes, single phase at 0 degr.	25/30 periodes, single phase at 0 degr.	
Voltage interruptions, IEC 61000-4-11	0% U-T; 250/300 periode	0% U-T; 250/300 periode	
Note: U-T is the AC line voltage before applying the test level.			
Magnetic field at the supply frequency (50 - 60 Hz), IEC 61000-4-8	30 A/m	30 A/m	The intensity of magnetic fields at the mains frequency should correspond to the typical values found in the business and hospital environment.
Radiated electromagnetic field, low and high frequency phenomena: electric fields, magnetic fields, electromagnetic fields: continuous waves, single/repetitive transients, IEC 61000-4-3	3V/m, 80 MHz to 2.7 GHz, stepsize 1%, 80% AM at 1 kHz	3V/m, 80 MHz to 2.7 GHz, stepsize 1%, 80% AM at 1 kHz	Portable and mobile radios should be used at no closer distance to any part of the PIT690-4-2500 laser including the cabling, than the recommended 30 cm safety distance.
Conducted RF disturbances, IEC 61000-4-6	3 V 0,15 MHz to 80 MHz 6 V in ISM - frequency bands(a), between 0,15 MHz and 80 MHz 80% AM at 1kHz	3 V 0,15 MHz to 80 MHz 6 V in ISM - frequency bands(a), between 0,15 MHz and 80 MHz 80% AM at 1kHz	Portable and mobile radios should be used at no closer distance to any part of the PIT690-4-2500 laser including the cabling, than the recommended 30 cm safety distance.
(a): The ISM bands between 150kHz and 80MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz, and 40.66 MHz to 40.70 MHz.			

Electromagnetic Immunity, resistance of enclosures against high - frequency wireless communication devices:

Test procedure for the resistance of enclosures against high - frequency wireless communication devices						
Test frequency	Frequency band	Radio service	Modulation	Maximum power	Distance	Interference immunity test level
MHz	MHz			W	m	V/m
385	380 - 390	TETRA 400	Pulsmodulation, 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM, ± 5 k Hz swing/Hub, 1 kHz sine/Sinus	2	0,3	28
710, 745, 780	704 - 787	LTE Band 13	Pulsmodulation, 217 Hz	0,2	0,3	9

	810, 870, 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulsmodulation, 18 Hz	2	0,3	28
	1720, 1845, 1970	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulsmodulation, 217 Hz	2	0,3	28
	2450	2400 - 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulsmodulation, 217 Hz	2	0,3	28
	5240, 5500, 5785	5100 - 5800	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	WLAN 802.11 a/n	0,2	0,3	9

1.5 Manufacturer's declaration regarding electromagnetic compatibility according to 60601-1-2:2007

According to the Canadian standard deviations, the guidelines and manufacturer`s statements for electromagnetic emission and immunity are listed in the following sections.

1.5.1 Guidelines and manufacturers statement for electromagnetic emission
Table 1 according to 60601-1-2:2007, 5.2.2.1 c

The PIT690.4-2500 laser is intended for use in the electromagnetic environment specified below. The operator of the PIT690.4-2500 laser should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The PIT690.4-2500 laser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	

Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	The PIT690.4-2500 laser is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:  **Warning:** This equipment / system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the PIT690.4-2500 laser or shielding the location

1.5.2 Guidelines and manufacturers statement for electromagnetic immunity
Table 2 according to 60601-1-2:2007, 5.2.2.1 f

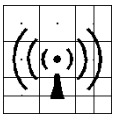
The PIT690.4-2500 laser is intended for use in the electromagnetic enviroment specified below. The customer or the user of the PIT690.4-2500 laser should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV 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 input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T)	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T)	Mains power quality should be that of a typical commercial or hospital environment. If the use of the PIT690.4-2500 laser requires continued operation during power mains interrupts, it is recommended that the PIT690.4-2500 laser be powered from an

	for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	uninterruptible power supply or a battery.
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE	U_T is the a.c. mains voltage prior to application of the test level.		

1.5.3 Guidelines and manufacturers statement for electromagnetic immunity

Table 4 according to 60601-1-2:2007, 5.2.2.2

The PIT690.4-2500 laser is intended for use in the electromagnetic enviroment specified below.
The customer or the user of the PIT690.4-2500 laser should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Portable and mobile RF communications equipment should be used no closer to any part of the PIT690.4-2500 laser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter: **Recommended separation distance can be calculated for conducted and radiated RF as follows:**			
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	$d = 1{,}17 * \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}17 * \sqrt{P}$ 80 MHz to 800 MHz
			$d = 2{,}3 * \sqrt{P}$ 800 MHz to 2,5 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 			
NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular /cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.

If the measured field strength in the location in which the PIT690.4-2500 laser is used exceeds the applicable RF compliance level above, the PIT690.4-2500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation the PIT690.4-2500 laser.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

1.5.4 Table 6 according to 60601-1-2:2007, 5.2.2.2

Recommended separation distances between portable and mobile RF communications equipment and the PIT690.4-2500 laser

The PIT690.4-2500 laser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PIT690.4-2500 laser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PIT690.4-2500 laser as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1{,}17 * \sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}17 * \sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3 * \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.