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CHEESEII DEN10B

Medical Diode Laser Systems Operating Manual



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1.Model	DEN10B, 980nm±10nm ,10W
2.Serial number	
3.Software version	
4.Date of sale	
5.Manufacturer	<p>Wuhan Gigaa Optronics Technology Co., Ltd.</p> <p>Add.: 5, 6/F, Unit A, B, Building B8, Hi-Tech Medical Device Industrial Park, #818 Gaoxin Avenue, East Lake Development Zone, Wuhan 430206,China</p> <p>Tel.:+86-27-6784 8871</p> <p>Fax:+86-27-6784 8873</p> <p>Email: info@gigaalaser.com</p> <p>Web: www.gigaalaser.com</p>
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Medical Device: CHEESEII, DEN10B, 980nm±10nm, 10W, 200µm

We herewith declare that the above mentioned product meet the essential requirements of the Annex II of the **Directive 93/42/EEC** and is classified subject to **Annex IX rule 9** as a medical device of Class **Ib**.

The product is designed in conjunction with the following safety standards:

EN 60825-1:2007 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests.

EN 60601-1:2006 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance.

EN 60601-1-2:2007 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests.

EN 60601-1-6: 2010 Medical electrical equipment-Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability

EN 60601-2-22:1996 Medical electrical equipment. Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

This declaration is based upon a Quality System meeting the requirements of EN ISO 13485:2012, EN ISO 13485:2012/AC: 2012.

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

CE 0197

Our expected sales countries are the European Union. This manual is only for EU-English speaking countries. We will prepare the local language for the non-English speaking countries.

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GA/QRCE-M-DEN10B

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Content

1	Warnings and safety precautions	1
2	Vigilance	3
3	Product description	4
4	Technical Specifications	6
5	Panels and Labels	7
5.1	Panel	7
5.1.1	General Overview	7
5.1.2	Front.....	7
5.1.3	Back	8
5.2	Labels.....	9
6	Operating instructions	11
6.1	Preparing unit before operation	11
6.2	Starting of the unit	11
6.3	password.....	12
6.4	Wireless Footswitch Configuration	13
6.5	Main Menu	14
6.5	Set Parameter	15
6.5.1	Set laser output power.....	15
6.5.2	Select laser emission mode.....	16
6.5.3	Set laser Ton time	16
6.5.4	Set laser Toff time	16
6.5.5	Adjust aiming beam	17
6.5.5	Standby and Ready	17
6.5.6	Menu and Proposal.....	17
6.6	Menu interface	18
6.6.1	System settings	18
6.6.2	System information.....	18
6.6.3	Test laser power.....	19
6.6.4	Calibrate laser power.....	21
6.7	Proposal	22
6.8	Laser emission	24
6.9	System Shutdown	24
7	Accessories	25
7.1	Safety goggles	25
7.2	Power supply.....	25
7.3	Footswitch	25
7.4	Handpiece	25
8	Failure Detection	26
9	Application systems and light delivery systems	28
8.1	Application systems	28
8.2	Handling and use of application and light delivery systems.....	28



Medical Laser Professional

- 10 Safety.....30**
 - 10.1 Safety elements 30
 - 10.2 Possible risk..... 30
- 11 Maintenance.....31**
 - 11.1 Routine maintenance 31
 - 11.2 Cleaning 31
 - 11.3 Planned preventative maintenance..... 32
- 12 Service policy33**
- 13 Environmental protection34**
- 14 Warranty policy.....35**
- 15 Attachment.....36**
 - 15.1 Device Master Record 36
 - 15.2 Training Protocol 36
 - 15.3 Annual Maintenance 37

1 Warnings and safety precautions

The CHEESE II Medical Diode Laser Systems should only be operated by the physician who with professional qualification certificate and has been trained and qualified in the use of the instrument.

The intended use of the CHEESE II is to cut, excise, vaporize, and coagulate tissues in various dental applications such as oral soft-tissue surgery, gingivectomy, diminish inflammation and oral therapy.

The CHEESE II is classified as class 4 laser according to Directives IEC 60825-1:2007. A class 4 laser is hazardous to the eye from both direct beam and diffuse reflection of the beam. It also represents significant skin and fire hazards. Always be extremely careful!



Attention!

Visible and invisible Laser Radiation, avoid eye or skin exposure to direct or scattered Radiation. Always wear safety goggles when using this unit.



Danger!

Do not use in the presence of flammable anesthetics or other flammable substances due to the risk of explosion.

Near infrared light (980nm) from the CHEESE II passes through the transparent components of the eye and is focused on the retina at the back of the eye. This can cause an accidental retinal burn.

Only protective glasses designed for protection from cw-diode laser radiation at a wavelength of 980nm +/-10nm with an optical density of OD \geq 4 should be used. Glasses not designed to this specification are not suitable for eye protection. Suitable glasses are available from your Gigaa Laser representative

Nominal Ocular Hazard Distance (NOHD) is 10.5m from the distal end of the fiber.



Attention!

Do not stare into the aiming beam or view the aiming beam directly through optical instruments. Avoid direct exposure to the aiming beam.

Avoid placing reflective material, such as metal and glass, into the beam.



Attention!

Accidental irradiation to other than the target tissue may result in laser burn.



Attention!

The CHEESE II laser is only to be used in combination with a footswitch and specified application and light delivery systems appendant to the device.



Attention!

Please avoid touching the patient and the foot switch / door contact /service connector socket simultaneously.

NOTE:

A minimum distance of 25 cm should be maintained between the ventilation slots and the walls.

To prevent the risk of electrical shock, do not remove the cover. All servicing should be done by Gigaa Laser or by qualified personnel authorized by Gigaa Laser. After the end of guarantee period servicing can also be done by sufficiently qualified persons.

The equipment should be routinely inspected and maintained in accordance with the instructions given in the maintenance section of this manual.

Separate the unit from power supply before cleaning and disinfecting.



Caution!

Use controls or adjustments or performing procedures other than those specified in this manual may result in hazardous radiation exposure.



Caution!

Laser equipment not in use should be protected against unqualified use by turning off the main power switch.

2 Vigilance

Gigaa Laser maintains a procedure to review the experience gained from devices in the post-production phase and to implement any necessary corrective action. This medical device vigilance system is designed to improve the protection of the health and safety of patients, users, and others by reducing the likelihood of the same type of adverse incident recurring. This will be achieved by the evaluation of reported incidents, and where appropriate, the dissemination of information to prevent repetitions, and/or alleviate the consequences.

Organizations and individuals involved in the purchasing of medical devices and in the provision of health-care should be aware that their co-operation is vital in providing the first link in the Vigilance chain. This includes organizations and individuals responsible for providing calibration and maintenance of medical devices.

The following incidents should be reported to Gigaa Laser immediately upon them becoming known:

Any malfunction or deterioration in the characteristics and/or performance of a device, or inadequacy in the labeling or instructions for use, which led to or might have led to:

- Death of a patient or user
- Serious deterioration in the state of health of a patient or user

Reports should be made to the following:

5, 6/F, Unit A, B, Building B8, Hi-Tech Medical Device Industrial Park, #818 Gaoxin Avenue, East Lake Development Zone, Wuhan 430206, China

TEL.:+86-27-6784 8871

FAX:+86-27-6784 8873

EMAIL: info@gigaa.com

3 Product description

The CHEESE II Medical Diode Laser System is a compact, air-cooled unit. It is a complete self-contained instrument, which includes a high efficiency power supply, a microprocessor controlled, adjustable light output with automatic power stabilization, (fan cooled), as well as a switch panel and LCD screen display panel designed to be user friendly. The system includes high power lasers, safety features and an SMA fiber output connector.

The diodes are made from GaAlAs semiconductor material for high output and superior reliability. The diode lasers are enclosed in a rugged, factory-aligned, replaceable, environmentally protective module. High-capacity fans eliminate the need for water-cooling, and assure low maintenance and reliable laser operation. The diodes convert electric energy into coherent laser radiation with a wavelength of 980nm+/-10nm (pilot beam: 650nm+/-10nm).



Attention!

The energy of the laser light lies above the compatibility of the eye and leads to irreversible eye damage. In order to avoid eye damage, all persons in the area have to carry the safety goggles.

The DEN10B has a maximum optical output power of 10W.

The CHEESE II laser meets the intent of Directive EN 60601-1-2:2007: Electromagnetic Compatibility Requirements and Tests. Compliance was demonstrated to the following specifications as listed: CISPR 11 (1990), IEC 801-2 (1991-04), IEC 801-3(1993), IEC 801-4 (1988) and IEC 801-5 (1992-07).

CHEESE II laser can therefore only be used in environment not intended for living. Any operating and servicing is only to be done by qualified personnel.

Potential electromagnetic or other influences between the equipment and other devices can be not completely excluded despite appropriate design precautions. Please inform Gigaa Laser in such a case. Accidental irradiation of tissue other than the target tissue may result in a burn or vaporization, regardless of the wavelength. Surrounding the target area with moist drapes or saline-soaked cottoning will keep it moist and greatly reduce this hazard. Care and precision in aiming and applying laser energy is of paramount importance.



Warnings!

Never secure a fiber optic using a clamp as doing so can result in an unsafe use condition. Use of a clamp can result in the fiber optic being bent at sharp angles or

Medical Laser Professional

fiber damage which, in turn, can also result in an unsafe use condition. The fiber optic can break causing a burn in the protective jacket and the release of laser energy. If undetected, this condition can result in a burn or ignition of flammable materials.

When using the fiber with the laser, the fiber device connector should never be allowed to touch the floor or any wet or non-sterile surface. If the fiber connector does come into contact with a surface other than the laser device port, dispose of the fiber in accordance with hospital safety regulations.

Must keep the fiber with SMA905 connector clean, otherwise the diode laser module will be destroy.

4 Technical Specifications

Laser Type	GaAIAs-Semiconductor laser
Model	DEN10B
Wavelength	980nm±10nm
Output power	0.1W-10W
Operation mode	CW, Single, Repeat
Pulse width	1ms-1000ms or continuous
Application / Light delivery system	Core Size (Use only approved systems)≥200µm
Numerical Aperture	NA = 0.22 – 0.48
Fiber Connector	SMA 905
Aiming Beam	Diode laser of 650nm±10nm, 4mW (max), adjustable brightness.
Laser Class	4
Operation interface	Color LCD touch screen
Power Supply	Model: WDY-15007000 input: 100-240Vac 47-63HZ 2.0A output: 15V $\overline{\text{---}}$ 7A
Cooling	Air cooling
Safety classification	Class I Type B
Dimensions	265 mm x 200 mm x 210 mm (HxWxD)
Weight	3 kg
Operating Temperature	10°C~40°C (In order to better heat dissipation, it is recommended to use temperature of 10-35 °C)
Storage/Transport Temperature	-10°C to +50°C
Humidity	Storage/Transport : 10% - 80%, Operating: 30% - 60%
Waterproof level	IPX1
Footswitch Waterproof level	IPX8
Safety Compliance	CE 0197

5 Panels and Labels

5.1 Panel

5.1.1 General Overview

The “CHEESE II” consists of five main components

- (1) Laser system
- (2) Color touch screen
- (3) Fiber and the handpiece
- (4) Foot switch
- (5) Power detector

The laser system consists of the fiber-coupled diode laser module, power supply, control panel, safety shutter and the embedded computer control system.

5.1.2 Front



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- (1) Color touch screen— show all system and laser information.
- (2) Power indicator (GREEN) — the power indicator will be green if the power supply of the laser is normal.
- (3) Laser emission indicator (YELLOW) — when laser emitting, the indicator is light.
- (4) Alarm indicator (RED) — when alarm, the indicator is light.
- (5) Handpiece bracket — when system is not in use, you can put the handpiece in it.
- (6) Handpiece — for 200 μ m and 400 μ m fiber.

5.1.3 Back

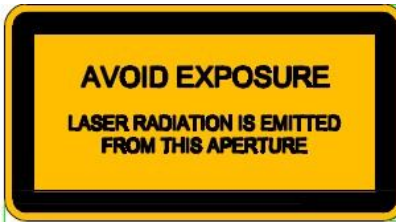


- (7) Displayer
- (8) FAN-
- (9) Foot switch socket.

Medical Laser Professional

- (10) Remote interlock — can be connected to the treatment room door. If the interlocked door is opened, the system will not emit laser.
- (11) Power plug-in — DC 15V/7A.
- (12) Main Power switch — make system power on or off.
- (13) Emergency stop — stop laser when in case of emergency.



5.2 Labels



Laser aperture



Pay attention to the fiber connector

Wuhan Gigaa Optronics Technology Co., Ltd.					
Name	MEDICAL DIODE LASER SYSTEMS				
Model	DEN10B	SN	GAXX-CXXX	Manufactured	YYYY.MM
Max Laser Output Power	10 W	Laser Wavelength	980nm/10W(MAX)		
		Aiming Beam	650nm/4mW(MAX)		
Mode of Operation: Continuous operation with intermittent loading					
Safety Classification		Notify Body		 0197	
Laser Classification	Class 4				
Rated Voltage	DC25.7V/3.89A(MAX)	Rated Power Input	100W		

Certification and power rating label



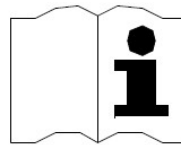
Danger and laser warning



Laser warning



Type B Equipment



Refer to operate manual



Protective earth conductor



Safety mark

	<p>Lotus Global Co., Ltd. Address: 1 Four Seasons Terrace, West Drayton, Middlesex, London, UB7 9GG United Kingdom Tel: +0044-20-78568010, +0044-20-70961611 FAX: +0044-20-79006187</p>
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European Representative

6 Operating instructions



Attention!

CHEESE II can be continuous use but must intermittent loading.
When laser worked continuously for more than 2 minutes, 1 minute must be intermittent.



Attention!

All personnel must wear safety goggles to eliminate the risk of eye damage when operating the laser system.



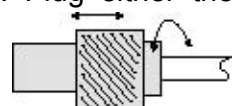
Caution!

Use of the Gigaa Laser CHEESE II laser in any way other than described in the operating instructions can lead to dangerous radiation exposure.

The operator must care that the operating room is properly labeled and that nobody can enter the operating room without wearing safety goggles.

6.1 Preparing unit before operation

Plug in the footswitch cable into the 4-PIN-interlock-connector at the back of the unit. The red mark on the socket is to correspond to the red one on the nut. Plug either the interlock-plug or the door-interlock-cable in the 2-PIN-interlock-connector at the back of the unit. Connect a Gigaa Laser delivery system or a laser probe approved by Gigaa Laser for the use with the system to the SMA connector located at the rear panel.



Built up the power supply like described in section: “Power supply”. Connect an approved light delivery system by the SMA connector. Screw the cup nut till the end. The light delivery System is complete connected, if there is no axial and radial clearance and no turn of fiber is possible.



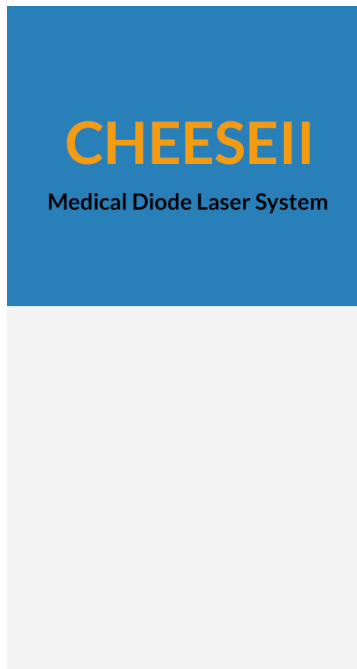
Caution!

CHEESE II must be placed vertically, the bottom must be level.

6.2 Starting of the unit

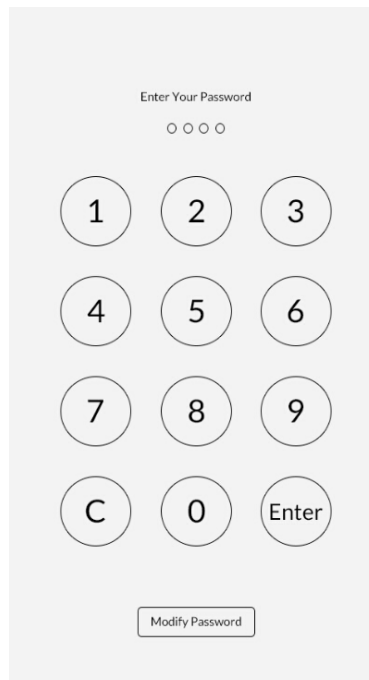
To start the laser unit, turn the main power switch ON. Immediately the power indicator will

be green with the system fans working. At the same time, the LCD screen lights up as the picture shows below.



After this interface, the system will perform a self-check. If there are problems during startup, the system will inform you at the display about the problems. System needs about 8 seconds to setup.

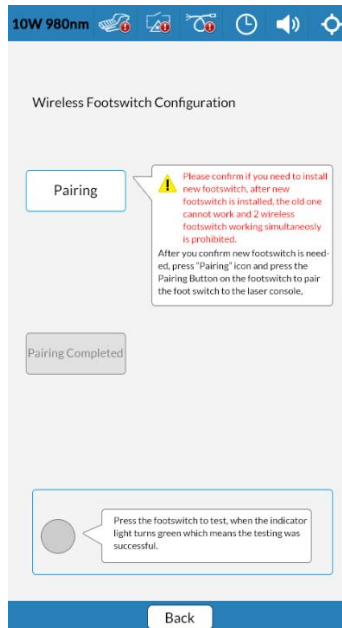
6.3 password



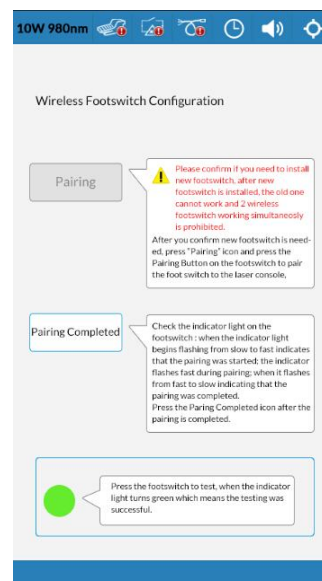
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You must input password before entering into the system. There are two sets of password, one initial password is “55555” entering into Wireless Footswitch Configuration while the other is “0000” entering into the laser system. By pressing the “modify password” button you can modify the laser system password from 0 to 9 (The Wireless Footswitch Configuration password cannot be modified).

6.4 Wireless Footswitch Configuration



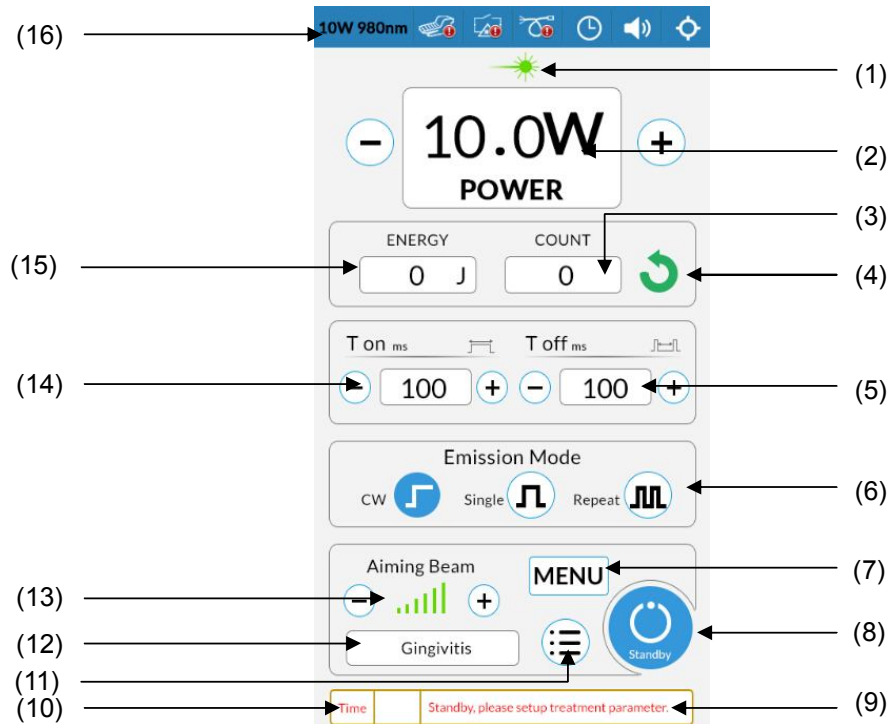
After inputting the password “55555”, the system turns into Wireless Footswitch Configuration interface. Carefully read the information on the screen, Install your new footswitch then press “Pairing” icon on the screen and the Pairing Button on the footswitch to start the pairing of footswitch and laser console.



After the pairing complete, press the footswitch to test, when the indicator light turns green, it means the pairing is successful.

6.5 Main Menu

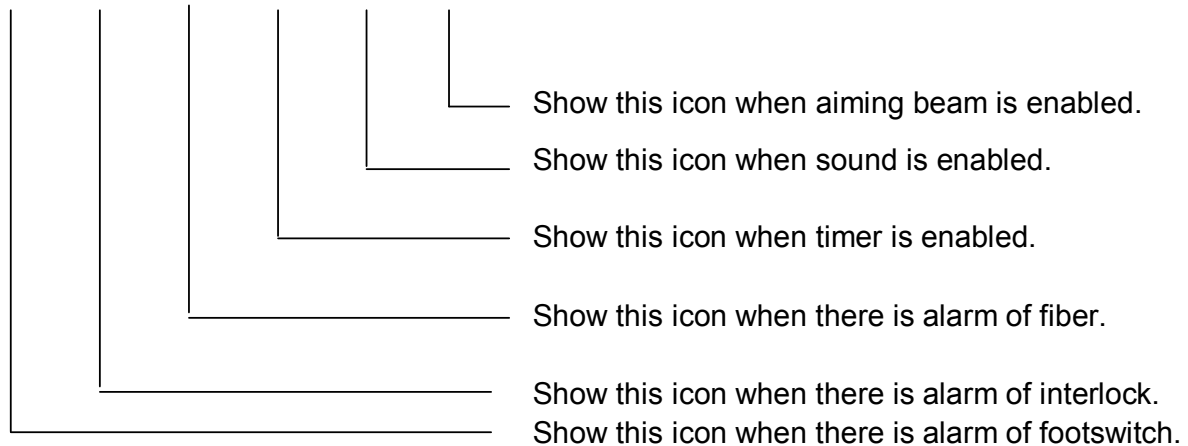
Inputting the laser system password, you will get into the laser system as the main menu interface shows up.



- (1) Laser output sign –when Laser emitting, It turns to red.
- (2) Set power – Set laser power, from 0.1W to 7W, step is 0.1W.
- (3) Laser pulse count – Show total laser pulse count.
- (4) Reset the energy
- (5) Laser off time – In pulse mode, the time is laser stop time in one pulse.
- (6) Laser emission mode
 - CW - continuous laser output
 - Single - press the footswitch, only one pulse laser out
 - Repeat - press the footswitch, multiple pulses laser out
- (7) Menu
- (8) Standby/Ready
- (9) Message and status –show system message, alarm and other information.
- (10) Timer –When the timer is active, the time is countdown, otherwise the time is add.

Medical Laser Professional

- (11) Preset proposals
- (12) The selected proposal
- (13) Aiming beam intensity
- (14) Laser on time – In pulse mode, the time is laser emit time in one pulse.
- (15) Laser energy –Show total laser energy.
- (16)Laser Wavelength –DEN10B is 980nm.
- (17) State bar – Show the option status.



6.5 Set Parameter

NOTE:

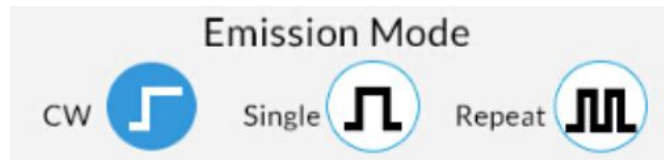
When you change the value, the value will be saved into the selected proposal.

6.5.1 Set laser output power



The peak power is the output MAX power when laser emitting and the range is 0.1W to 10W. By pressing the “+” and “-” button, you can set the laser output power conveniently. When finishing adjusting, the system will save the parameter into the selected proposal.

6.5.2 Select laser emission mode



There are 3 emission modes. When selected, the corresponding button will turn green:

(1) CW

In this mode, the laser will continue emitting unless you release the footswitch.



Attention!

For safety in this mode, after emitting 5 minutes (when peak power is above 12W), the laser should be stopped 1 minute at least.

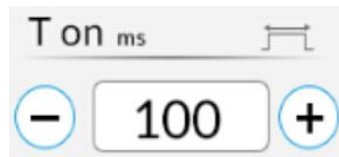
(2) Single

In this mode, the laser will emit one pulse when you don't release the footswitch.

(3) Repeat

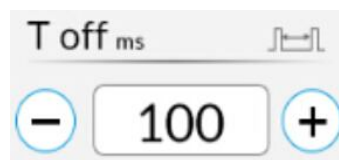
In this mode, the laser will emit by pulse when you don't release the footswitch.

6.5.3 Set laser Ton time



The Ton time is the laser emission time during one pulse period. It ranges from 1ms to 1000ms. By pressing the "+" and "-" button, you can adjust the value conveniently. When finishing, system will save the parameter into the selected proposal.

6.5.4 Set laser Toff time



The Toff time is the laser off time during one pulse period. It ranges from 1ms to 1000ms. By pressing the "+" and "-" button, you can adjust the value conveniently. When finishing, system will save the parameter into the selected proposal.

6.5.5 Adjust aiming beam



Adjust density of the aiming beam. [+] is increase and [-] is decrease.

There are 7 levels of the aiming beam from 0 to 6. When the level is selected, it turns green, otherwise it is grey. If the aiming beam level is 0, it means that the aiming beam is closed.

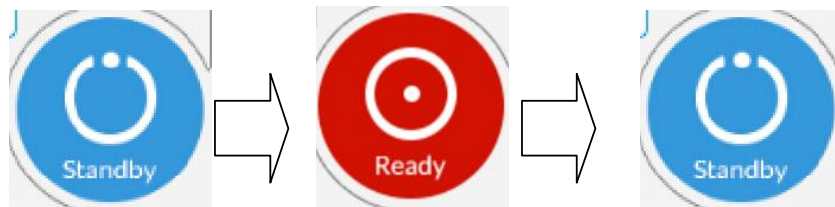
At the main menu, the item 6 is active only when the value is more than 0.



Attention!

Only in Ready status, you can see the density of the aiming beam. In standby status you can adjust the density, but can't see it.

6.5.5 Standby and Ready



When you press the Ready/Standby button, it changes from a status to another status.

Standby: in this status, the laser power supply is disabled. When you press the footswitch, it can't send out laser.

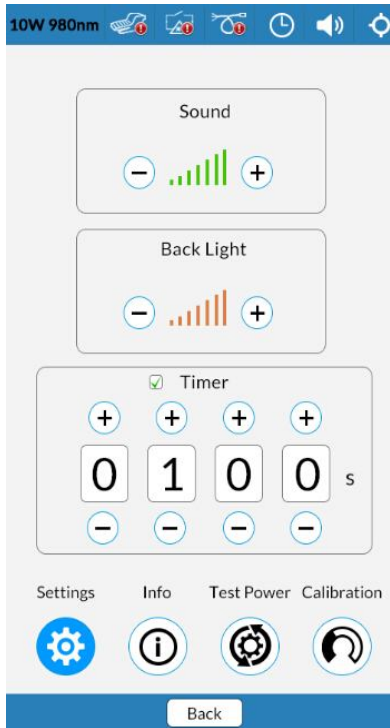
Ready: in this status, the laser power supply is enabled. When you press the footswitch, it can send out laser.

6.5.6 Menu and Proposal

When you press the proposal button, you will enter into the proposal interface, and the "Menu" button is to the menu interface.

6.6 Menu interface

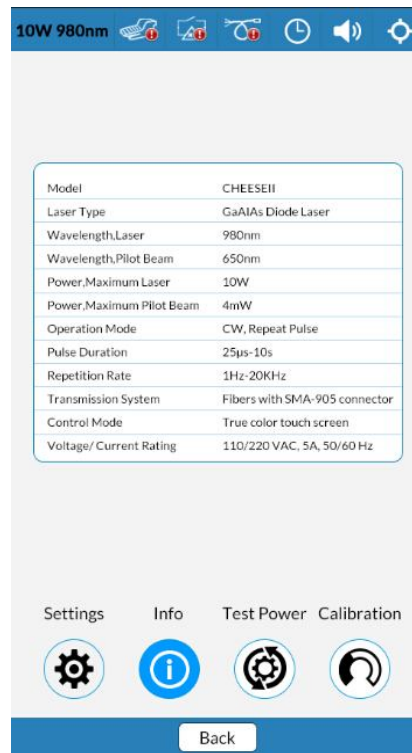
6.6.1 System settings



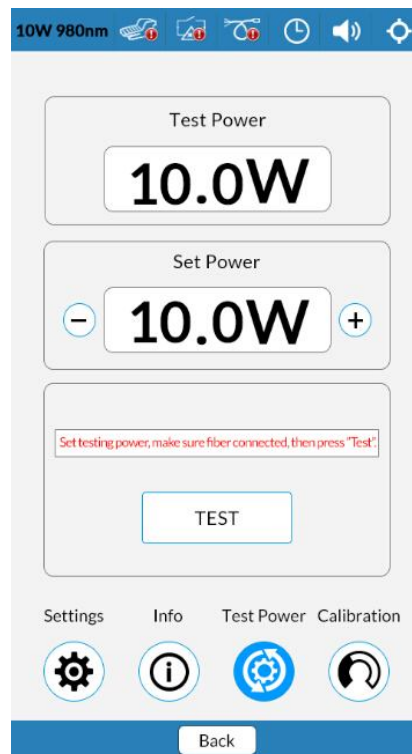
In menu interface pressing “Settings” icon, you will go into user setting interface. In this interface, you can set the speaker sound, LCD back light. And you can enable/disable the timer. When timer is on you can set the timer value. In this interface by pressing “Back” icon, you can back to the main menu.

6.6.2 System information

If you want to learn about the system information please press the “Info” icon in menu interface.



6.6.3 Test laser power



By pressing the "Test Power" button, you will enter into the test power interface.

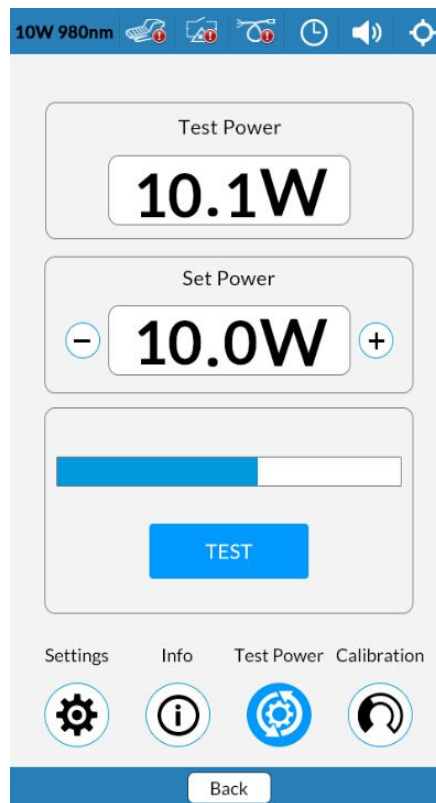
Medical Laser Professional

Set Power: the power you want to test.

Test Power: the value of the tested power.

Testing step:

- (1) Open the laser power detect aperture;
- (2) Fix the fiber;
- (3) Wear the safety goggles;
- (4) Press the “Test” button, the button will turn yellow meanwhile the aiming beam will be on;
- (5) Press the footswitch, and hold it.



(6) When the process bar is over, the power detect is finished. And then you can release the footswitch and read the value of the laser power.

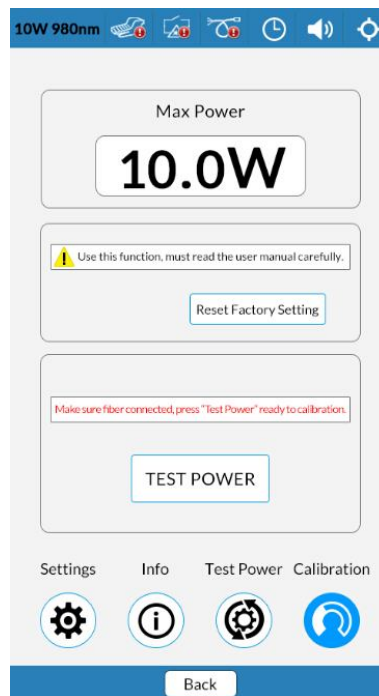
The footswitch and read the value of the laser power.



Attention!

The test value may be different to the set value, if the difference is in 20%, this is normal.

6.6.4 Calibrate laser power



Attention!

Before calibration, please make sure that there is an accurate power meter. Only when the CHEESE II testing result is near to the power meter testing power, can you begin to calibrate.

If you press the “Calibration” button, the calibration interface will show above.

Test Power: Before laser test, this power is the MAX power of the CHEESE II .

Max Power: the value of the tested power.

Save: After you make sure the CHEESE II testing power is near to the power meter testing result, save the result to the memory and finish the calibration.

Reset factory setting: Restore the laser power setting as the factory setting, don't keep the calibration result.

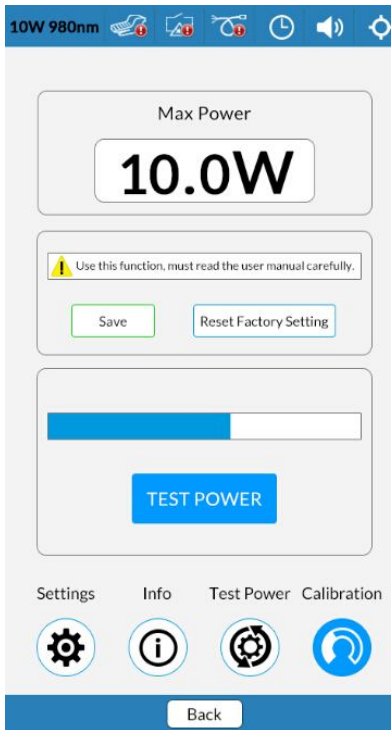
Calibration step:

- (1) Open the laser power detect aperture.
- (2) Fix the fiber.
- (3) Wear the safety goggles.

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(4) Press “Test Power” button, the button will turn yellow meanwhile the aiming beam will be on.

(5) Press the footswitch, and hold it.



(6) When the process bar is over, the power detect is finished. And then you can release the footswitch and read the value of the laser power.

(7) Use the power meter to test the laser power again.

(8) If the test results are very nearly, you can make sure the test result is correct. Press the “Save” button to save the test result.



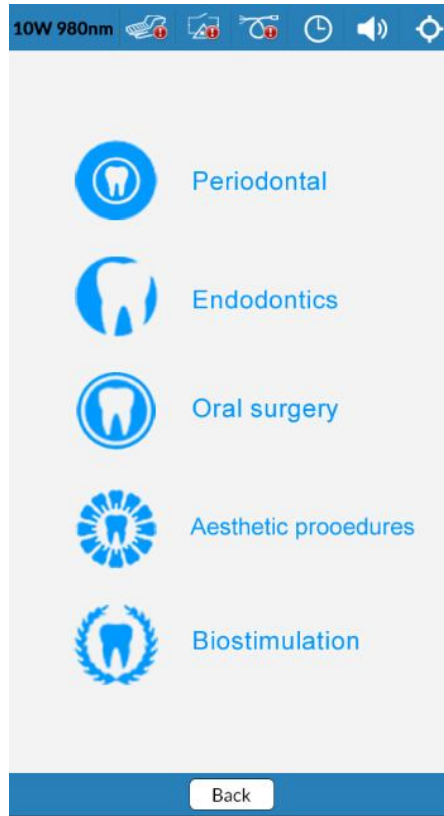
Attention!

(1) If the test power is too low (<50%), the calibration will not be going on.

(2) After calibration, the CHEESE II MAX power will be changed. If the calibration power is lower than the old MAX power, you can only save the lower as the MAX power.

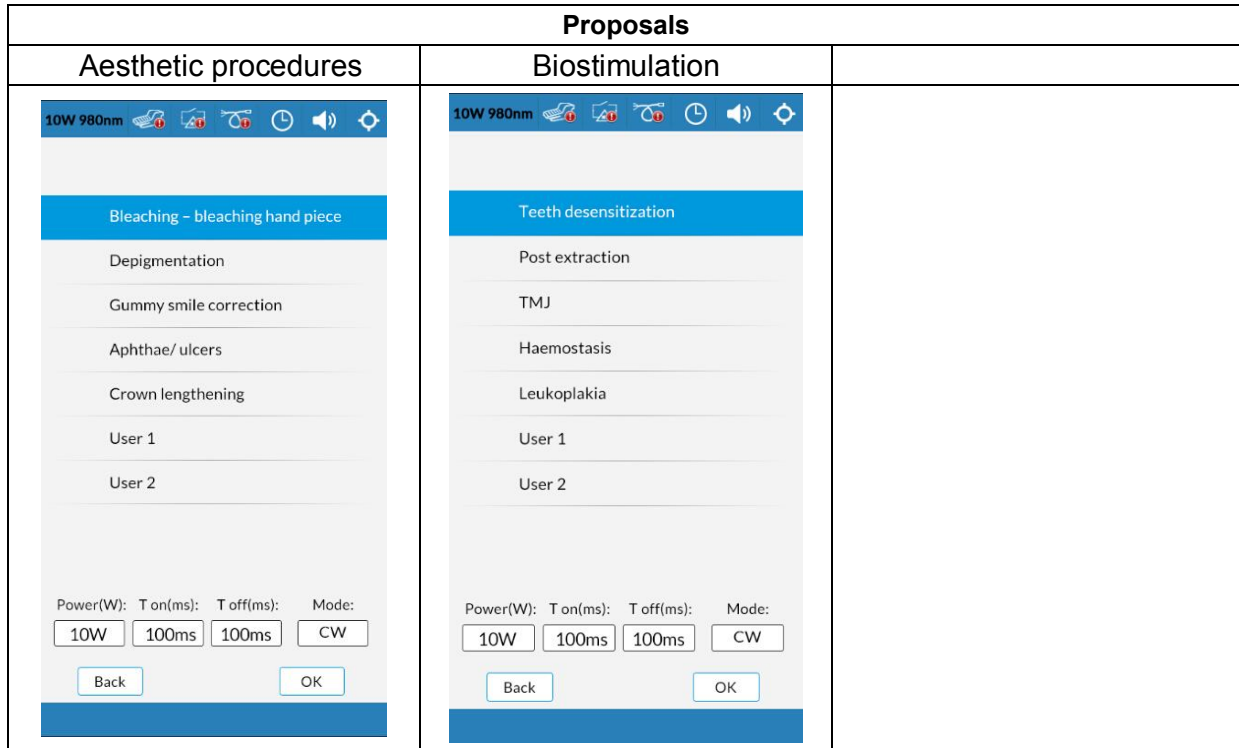
6.7 Proposal

The proposals are classified into “Periodontal”, “Endodontics”, “Oral surgery”, “Aesthetic procedures” and “Biostimulation”.



Proposals		
Periodontal	Endodontics	Oral surgery

Medical Laser Professional



When going into the proposal interface, you can change the proposal parameter as the following step:

- (1) Select the proposal you want to change.
- (2) See the old parameter at the bottom of the screen.
- (3) Press “OK” button return to the main menu.
- (4) Change the parameter in the main interface.

6.8 Laser emission

After finishing setting the parameters, press the “Ready” button and then the system will remind you to wear the safety goggles (protect wavelength from 800nm to 1100nm). At this time when you press down the footswitch, the laser will emit.

6.9 System Shutdown

You can turn off the laser by the main power switch.

NOTE:

To turn off the system correctly you first need to change the CHEESE II into “Standby” status.

7 Accessories

7.1 Safety goggles

NOTE:

Always wear safety goggles when operating the laser or working nearby.

Make sure only to use glasses with an effective optical density around the wavelength of 980 +/-10nm.

7.2 Power supply

Input: 100-240V 50/60Hz 2.0A

Output: 15V === 7A

Please use WDY-15007000 desktop power supply adapter.

7.3 Footswitch

Item	Type
Wireless Footswitch	MED-GF2

7.4 Handpiece

The CE Marked dental handpiece is applied.

NOTE:

When the handpiece not in use, need to handle the handpiece on the bracket, the handpiece must not be allowed to fly in order to avoid damage to optical fiber.

8 Failure Detection

Problem	Eventually Cause	Problem Solving
When turn on the main switch, the unit does not start up, and the power indicator is off	1) “Emergency Stop” button is pressed 2) The fuse is burned	1) Turn the “Emergency Stop” button back to the normal position 2) Take off the power line to cut off the power, and check the fuse.
Alarm information on the screen	1) The fiber is not plugged in or plugged in an improper way 2) Safety interlock switch is on 3) Footswitch not connect 4) System is wrong	1) Plug in the fiber tightly 2) Connect the safety interlock switch. 3) Connect the footswitch 4) Write down the wrong code, and contact GIGAA.
TEMPERATURE is HIGH	Temperature more than 35°C	Stop the laser and wait for a few minutes
TEMPERATURE is LOW	Temperature less than 10°C	Make room temperature more higher
POWERSUPPLY ERROR	Laser current is high	Laser current is high
Remote INTERLOCK	The interlock is not connected	Connect the interlock
FIBER NOT CONNECTED	The fiber is not connected	Connect the fiber
Footswitch opened	The footswitch is not connected	Connect the footswitch
Fiber temperature is high	The fiber connector temperature is high	May be the fiber tip or the laser output lens is dirty, please check the fiber tip and the laser output lens
MOSFET temperature is high	MOSFET temperature is high	Stop the laser output
No electricity when starting up the laser	Not plug in the external power	Plug in the external power
No electricity when starting up the laser	Press down the emergency stop switch	Turn around clockwise, pop-up the emergency stop switch
No electricity when starting up the laser	The inner power supply has no output	Check the supplied voltage and the required voltage
No electricity when starting up the laser	The inner power supply has no output	The power supply have already destroyed, the laser system must be sent back to GIGAA
Can not start up, no display	The screen wire break off or the data wire fall off	Take apart the machine to check the screen wire and the data wire

Medical Laser Professional

Can not start up, no display	The control board cannot output	The control board broken, send back to GIGAA
No aiming beam	Didn't connect the fiber	Check if the fiber is connected or not
No aiming beam	The intensity is too low	The aiming beam is broken, send the laser back to GIGAA
No aiming beam	The laser is in standby situation	Only the laser is in the ready situation, it will has the aiming beam
No aiming beam	Caused by the fiber or optical parts	Change the fiber or the handpiece
No aiming beam	The diode laser problem	Contact GIGAA
No aiming beam	The aim beam status is "OFF"	Set aim beam status to "ON"
No aiming beam	The diode laser output lens in the SMA connector is destroyed	Contact GIGAA
Has aiming beam, no laser light	Foot switch didn't insert in	Check if the switch connected well
Has aiming beam, no laser light	Something wrong with the foot switch	Check the foot switch wire
No aiming beam, no laser light	The fiber didn't connect to the laser	Check if the fiber connected well
No aiming beam, no laser light	Something wrong with the fiber part	Contact GIGAA
No aiming beam, no laser light	Foot switch didn't insert in	Check if the switch connected well
No aiming beam, no laser light	Something wrong with the foot switch	Check the foot switch wire
Has aiming beam, but no laser light	Something wrong with the foot switch	Replace the foot switch of the same model
Has aiming beam, but no laser light	Diode laser module is destroyed	Contact GIGAA
The alarm info. appears	Checked the temporary failures	Restart the laser, if the failure still exist, read the info. description, analyze the reason or contact GIGAA

9 Application systems and light delivery systems

8.1 Application systems

The following application systems are approved for the use with CHEESE II laser:

The fiber parameter must satisfy the following:

- Fiber core diameter $\geq 200\mu\text{m}$
- NA ≥ 0.22
- With SMA905 connector
- Before use must sterile
- You can choose the fiber from our Product accessories list.

ITEM	TYPE	Manufacturer	Intended use
Fiber	FTIR364 /400ST-3/SL-F na=0.22	FiberTechGmbH	Transmission laser

8.2 Handling and use of application and light delivery systems



Attention!

The clinical rules concerning the use of sterile medical laser probes must be followed. Valid rules concerning the handling of sterile products must be considered. Gigaa Laser is not liable for accidents or damage on the laser system resulting from violations of the above-mentioned rules.

To ensure the proper and safe use of laser systems, only well trained doctors should use approved application and light delivery systems.



Warnings!

Pay attention to the application instruction for the application and light delivery systems.

Check the sterile packaging of the laser probe for possible damage. Laser probes delivered in damaged packaging are not sterile, and therefore should not be used.



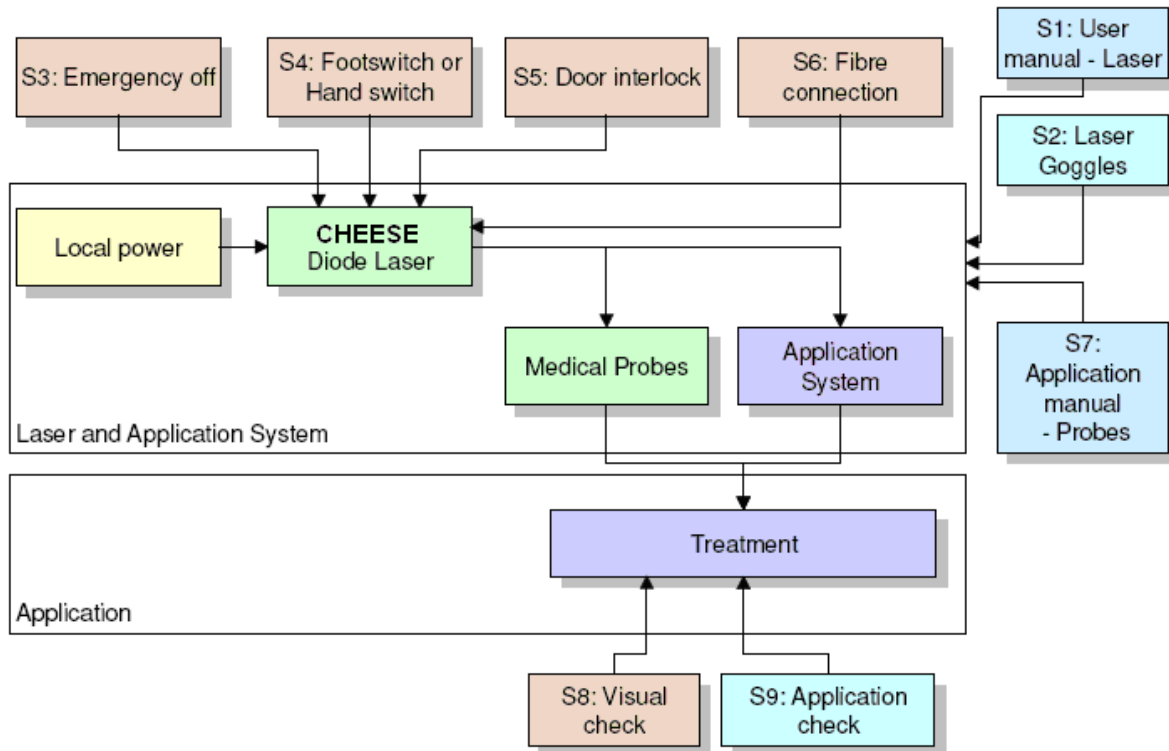
Warnings!

To avoid damage to the laser probe, do not hit on a hard surface or over bend.

- Check the sterile packaging for possible damage. Laser probes delivered in damaged packaging are not sterile, and therefore should not be used.
- Remove fiber from pouch.
- Make a visual check before using.
- Make sure laser is “Off” or in standby mode prior to inserting the fiber into the laser aperture port.
- Insert the fiber into laser aperture port until fully engaged. Make sure the laser probe is screwed in correctly otherwise the security switch in the SMA connector will not be activated and an error will be displayed.
- Handle the fiber with care as damage may occur if struck or bent sharply.
- Remove the protective covering at the distal end of the fiber if present. Examine the tip for any visual damage.

10 Safety

10.1 Safety elements



Attention!

Safety-elements (S1 to S9) are part of the laser system. They must be used to increase the safety in using the CHEESE II with applications systems or light delivery systems/medical probes in a treatment. Check that the safety-elements are working well.

10.2 Possible risk

Swelling, bleeding, or an attack of fever occurs as a result of laser treatment. Burning of the target tissue can occur if the laser energy is too high.

All these complications can usually be avoided if the user is properly trained.

11 Maintenance

The **CHEESE II** has been designed to operate reliably, with a minimum of maintenance.

NOTE:

This unit contains no user serviceable parts. Any attempt to repair, adjust, or modify the system beyond those procedures outlined in this manual by any person not authorized by Gigaa Laser will invalidate the warranty. Gigaa Laser reserves the right, in its sole discretion, to decide on warranty voidance.

To prevent the risk of electric shock, do not remove the cover. All servicing should be performed by qualified personnel. If service is required, contact a factory service representative.

11.1 Routine maintenance

The following checks should be carried out regularly by the user:

- Check laser safety goggles (right type, mechanically undamaged).
- Check all labels are firmly in place.
- Check the emergency switch.
- Check that disconnection of remote interlock causes the laser to be inoperable and to indicate error message “interlock open”.
- Check audible signal is active when footswitch is depressed and laser emission is present.
- Check that display indicates error message “Fiber not connect”, laser goes into and remains in standby mode when removing fiber optical delivery system from fiber connector port.
- Check that when fiber is removed from laser aperture, laser goes into and remains in standby mode.

In case unit fails any of the aforementioned tests, do not use device for further treatments but call Gigaa Laser service immediately.

11.2 Cleaning



Warnings!

Before cleaning and disinfection of the unit, separate the equipment from the power supply. Do not splash water at it may penetrate the equipment.

Medical Laser Professional

The housing of the laser can be cleaned with a wet cloth. A mild antiseptic detergent or a mild cleaning agent may be used such as 75% medicinal alcohol. Chemical cleaning agents, strong cleaning agents, and rough cleaning cloths can damage the surface of the housing and therefore should not be used.

11.3 Planned preventative maintenance

The CHEESE II laser should be checked annually by a Gigaa Laser -accredited technician, the results of the maintenance should be recorded in the instrument log book. (See also the section Annual Maintenance) Failure to use a Gigaa Laser or other authorized Gigaa Laser technician during the guarantee period will result in the warranty being invalid.

12 Service policy

Gigaa Laser will make available on request schematic interaction diagrams, component part lists, descriptions and other information that will enable appropriately qualified technical personnel to carry out first line maintenance on the CHEESE II . When parts are deemed to be irreparable by Gigaa Laser or when special training/equipment are required to perform the repair or adjustments, the manufacturer reserves the right to withhold information on the grounds of safety.

In case of returning the CHEESE II to Gigaa Laser, use its original packaging and enclose a declaration ensuring the device being disinfected.

13 Environmental protection

The disposable sterile medical fiber when last used should be abandoned in accordance with the disposal of medical waste which Contact with the human body.

Warnings!

It is prohibited to reuse the disposable sterile medical fiber. It may become the important means of disease transmission.

“CHEESE II” will not generate any wastes during the normal use. When scrapped, the host can be disposed as the conventional electric products.

14 Warranty policy

Gigaa Laser warrants the CHEESE II laser system against defects in material and workmanship for a period of up to 1000 hours operating time but no longer than 12 months. Warranty extension plans will be made available during the warranty period, which will commence on the date of installation.

NOTE:

Any attempt to repair, adjust or modify the system beyond those procedures outlined in this manual by any person not authorized by Gigaa Laser will invalidate the warranty. The warranty will also void in case of:

- incorrect handling/ mishandling of the laser**
- using components not appending to the laser**
- using non-authorized application systems**

Prerequisite for warranty is giving a feedback by using the attached customer feedback card or internet: Web: <http://www.gigaa.com>

To make a warranty claim the purchaser shall, promptly, following discovery of the basis of claim, contact Gigaa Laser in writing or by telephone.

During the guarantee period Gigaa Laser, in its sole discretion, will repair or replace components which are verifiably damaged.

In no event shall Gigaa Laser be liable for direct, indirect, special, incidental or consequential damages whether based on contract, tort or any other legal theory.

15 Attachment

15.1 Device Master Record

DEVICE MASTER RECORD			
Model:		Operator:	
S/N:		Location:	
Inventory-No.:			

15.2 Training Protocol

Responsible: Name / Signature:	
Date:	
Checked:	
Name of person trained / signature:	

Medical Laser Professional

1.	Visual Inspection	Passed	Failed	comment
1.1	Laser labels/Laser warning (laser class, max. power, wavelength) cp. Section Labels			
1.2	All labels are firmly in place cp. Section Labels			
1.3	User manual			
1.4	Equipment complete			
1.5	Ports			
1.6	Outer device surface			
2.	Inspection of functional capability			
2.1	Foot switch			
2.2	Optical Input/ Output /Aiming Beam			
2.3	Interlocks			
2.4	Display and Key Pad			
3.	Inspection of Monitoring and Safety System			
3.1	Laser Safety Goggles			
3.2	Control LED			
3.3	Main power Switch			
3.4	Emergency stop			
4.	Electric Safety VDE 0750 / VDE 0751			
4.1	Insulation Resistance			
4.2	Earth Leakage Current			
4.3	Protective Conductor Continuity			
5	Measurement of Output Parameters Relevant to Safety			



Caution!

Always wear laser safety laser goggles when performing this procedure.

Medical Laser Professional

Laser Calibration Test:

Connect a new FiberTechGmbH Bare Fiber to the output port of the laser. Put the distal end of the delivery system into the specific power meter adapter. Enable the laser, fire the laser and record the values.

Put the laser into Continuous Mode. Fire the laser and verify with the power meter that the output is in the tolerances:				
Power selected only till the max Laser Power	Power selected Value (W) +/-20% Min / Nominal / Max	Actual Value	Passed	Failed
1 W	0.8~1.0~1.2			
2 W	1.6~2.0~2.4			
3 W	2.4~3.0~3.6			
4 W	3.2~4.0~4.8			
5 W	4.0~5.0~6.0			
6 W	4.8~6.0~7.2			
7 W	5.6~7.0~8.4			
8 W	6.4~8.0~9.6			
9 W	7.2~9.0~10.8			
10 W	8.0~10.0~12.0			

If the results fall within the expected 20% range then the laser is deemed recalibrated. No further action is needed.



Caution!

If the laser falls outside the 20% range than Gigaa Laser or an authorized representative should be contacted.

5.	Measurement of Output Parameters Relevant to Safety	Passed	Failed	Evaluation
5.1	Result according to 5.			
6.	Inspection of Internal Error Messages			
6.1	Interlock			
6.2	Excess Temperature Indication: Inspection via Software			



Warnings!

In case of any parameters relevant to safety failing the annual maintenance the device should be disused immediately.

Medical Laser Professional



Actions taken:			
Service informed on:		Device disused on:	
Device repaired on:		Entry in Instrument log book:	
Inspector:			
Notes:			
Status:	Date:	Inspector:	