sirona
The Dental Company

SIROLaser

Operating Instructions

English

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CE
0123

SIROLaser is manufactured in compliance with the provisions of Council Directive 93/42/EEC concerning medical devices (MDD).
Its compliance is based on the following standards: IEC 60601-1: 1998, IEC 60601-1/A2: 1998 and IEC 60601-2-22: 1997.

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1 Warning and safety information

1.1 Highlighting of warning and safety information

To prevent any personal injury or material damage, please observe the warning and safety information provided in the present operating instructions. All such information is highlighted as follows:

NOTICE

For additional information.

CAUTION

If there is any risk of damage to the laser unit.

WARNING

If there is any hazard to the life or health of persons.

➢ This symbol indicates that you have to take action.

↳ This symbol indicates that a certain result will occur.

1.2 Intended use

NOTICE

The user should read and be thoroughly familiar with this manual before operating the laser. The equipment should be routinely inspected and maintained in accordance with the instructions given in the maintenance section of this manual. Accidental irradiation to other than the target tissue may result in laser burn. Surrounding the target area with moist drapes or saline-soaked gauze pads and keeping them moist will greatly reduce this hazards. Be sure the draping is appropriate for laser surgery. It is recommended that a smoke evacuator or in-line filter be used to capture the plume whenever possible. The plum should be regarded as a source of active biological material by the operating room personnel; it may contain viable tissue particulates.

NOTICE

Nominal Ocular Hazards Distance (NOHD) is 1.5 m from the distal end of the fibre.

NOTICE

For the installation and use of the SIROLaser, Sirona Dental Systems GmbH requires :

- *compliance with IEC 60825-1 and its amendments*
- *compliance with any additional national laws and ordinances.*

NOTICE

SIROLaser is intended for surgery and coagulation of oral soft tissue as well. This laser unit must only be used by trained personnel in compliance with the applicable occupational safety regulations and accident prevention measures as well as the present operating instructions.

NOTICE

The user is obliged to use only faultless materials, to observe the correct application as well as to protect himself or herself, the patient and other persons against hazards.

WARNING

This laser unit is not intended for operation in areas subject to explosion hazards or in the vicinity of flammable materials or substances.

WARNING

Public legal provisions may include special safety regulations for the protection of persons against laser radiation. These regulations must be complied with.

WARNING

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

1.3 Instructions on use of the laser protective goggles

Before using the laser protective goggles, please read and observe the instructions for use provided by the manufacturer and attached to the goggles in the case.

Before using the laser protective goggles, please make sure:

- that the laser protective goggles are not damaged,
- that the laser protective goggles conform to **standard EN 207** with **protection level L5**,
- and that the laser protective goggles are suitable for the **correct wavelength** (labeled on the goggles).

These instructions apply particularly when using goggles supplied from an outside source that are not included in the scope of delivery of the SIROLaser.

1.4 Wireless phone interference

CAUTION

To ensure the operational safety of medical electrical equipment, the use of mobile wireless phones in practice or hospital environments must be prohibited.

1.5 Disposal

If you plan to discontinue the use of your SIROLaser and intend to dispose of the unit, make sure to observe the applicable legal provisions. Please contact your local dental distributor or authorized service center for the disposal of the SIROLaser.

2 Glossary, symbols and abbreviations

2.1 Symbols on the SIROLaser

CE 0123

CE mark in accordance with Council Directive 93/42/EEC, stating the manufacturer's Notified Body

01-2005

Date of manufacture (January 2005)

01-2007

Best-before date: Do not use after January 2007

LOT 0123 / 12 / 05

Batch number (consecutive number/month/year)

Type B applied part according to IEC 60601-1

Please refer to manual first

Refers to directive 2002/96/EC and EN 50419

Do not dispose with domestic waste

DC IN

Socket for DC input from Sinpro MPU50–105 switching power supply

Optical fiber

Socket for optical fiber

INTERLOCK/ SWITCH

Socket for Y-connector

Laser radiation warning

λ 970 +/-15 nm
PMAX 7 Watt CW
λ 635-650 nm
PMAX 1 mW CW

Specification of laser output power and wavelength of IR and aiming beam (see also chapter "Technical data")

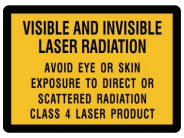
IEC 60825-1 (ed. 1.2)

States the compliance of the SIROLaser with IEC 60825-1, edition 1.2

CAUTION
CLASS 4 VISIBLE AND INVISIBLE LASER RADIATION WHEN OPEN.
AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION

Warns of potential laser radiation hazards when opening the laser unit

English



Warns of class 4 laser radiation hazards when using the laser unit.

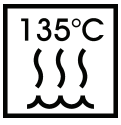
"LASER STOP" button: Press this button in case of an emergency.

CU

Operate the laser unit exclusively with the Sinpro MPU50-105 power supply.[1]

NU

SA



The disassembled handpiece and the tips must be sterilized only in autoclaves with saturated water vapor at 135 °C (275 °F), 3 min. holding time (2.13 bar; 30.89 psi overpressure)

1. *Software extention (CU, NU, SA)*

2.2 Glossary

CONTINUOUS EMISSION	Continuous laser emission
PULSED EMISSION	Pulsed laser emission (chopped mode)
FREQUENCY	Number of laser pulses per second
HERTZ	Measuring unit for frequency
INTERLOCK	Safety device that stops laser radiation when the door of the treatment room is opened
JOULE	Unit of measure for emitted energy
WATT	Unit of measure for laser power
STOP	End of treatment or treatment break
TIME	Treatment time setting mode

2.3 Abbreviations

cm^2	Square centimeter
Hz	Hertz
s	Seconds
W	Watt
mW	Milliwatt (one thousandth of a Watt)
J	Joule
nm	Nanometer
V	Volt
IR	Infrared diode
NOHD	Nominal Ocular Hazard Distance according to IEC 60825-1: 1993 + A1:1997 + A2:2001

3 Introduction

3.1 Classification

According to the applicable standards, the SIROLaser is classified as follows:

- Class I Type B according to EN IEC 60601-1:1990 + A1:1993 + A2:1 1995
- Class IIb according to Council Directive 93/42/EEC
- Class IV laser product according to IEC 60825-1: 1993 + A1:1997 + A2:2001
- Degree of protection according to EN IEC 60601-1:1990 + A1:1993 + A2:1 1995 medical unit: IP 20 (enclosure not water-proof); foot switch: IPX5

CAUTION

The laser unit itself cannot be sterilized. However, some accessories must be sterilized when used for contact applications.

WARNING

The laser unit is not suitable for use in the presence of anesthetics that are flammable when in contact with air, oxygen or nitrogen monoxide.

3.2 Safety precautions

SIROLaser is manufactured in compliance with the provisions of Council Directive 93/42/EEC concerning medical devices (MDD).

Always observe the following precautions:

WARNING

Always cover the optical fiber connection with the special protection caps provided, if the fiber is disconnected from the laser

CAUTION

Use of the operating controls or adjustment options in a way other than described herein can lead to dangerous radiation.

CAUTION

Never insert your fingers or any objects into the exit ports. This is important in order to avoid damage to the optical system.

CAUTION

In case of an emergency, switch the laser unit OFF immediately. To do this, press the "LASER STOP" button on the control panel.

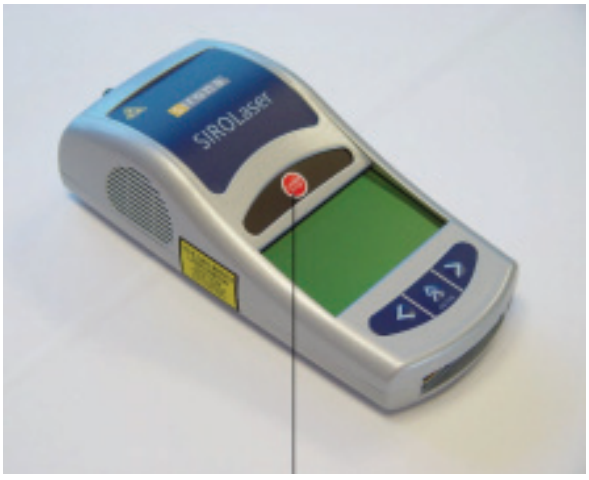


Figure 1: "LASER STOP" button

Observe all labels on the laser unit.

WARNING

Operation of this laser unit by unauthorized persons must be prohibited in order to prevent incorrect or improper use.

WARNING

Never direct the laser beam or the aiming beam toward the eyes or the thyroid gland of a person. All persons present in the room (patient, dentist and assistant) must always wear the laser protective goggles delivered along with the laser unit.

WARNING

Never use optical instruments such as microscopes, eye loupes or magnifiers together with the original protective goggles. Adequate eye protection is no longer ensured in this case.

CAUTION

Always cover the optical fiber connection with the special protection caps provided.

WARNING

The unit is not suitable for use in the presence of anesthetics that are flammable when in contact with air, oxygen or protoxide.

WARNING

Oxygen-saturated materials such as cotton wool can catch fire due to the high temperature that the unit reaches during operation. Label removers and flammable solutions used for cleaning and disinfecting the laser unit should be allowed to evaporate before using the device. Be aware of the fire risk caused by flamable gases.

English

WARNING

Never direct the laser beam toward paper, plastics or dark surfaces. They may catch fire or be damaged due to the high temperatures produced by the laser beam.

WARNING

Laser plume must contain tissue particles. There is a risk of contamination! Always wear a face mask.

Observe the following in addition:

NOTICE

The unit must only be operated in rooms that comply with the requirements of Council Directive 89/336/EEC. The applicable national or local legal regulations must be complied with.

CAUTION

Avoid interference of the laser emission with optical sensors of devices operated in the vicinity of the SIROLaser.

3.3 Transport and storage

3.3.1 Transport and storage

The SIROLaser is supplied in a case that ensures proper and easy transport.

However, please observe the following:

CAUTION

Do not leave the laser unit in a car parked in the sun. The temperature inside the car can reach levels that may damage its components.

To ensure appropriate storage, the laser unit must always be kept in the case supplied.

When stored in the case provided by Sirona Dental Systems, the SIROLaser withstands the following environmental conditions:

- Temperatures from -40° C (-40° F) to +70° C (+158° F)
- Relative humidity from 10 % to 90 %
- Atmospheric pressure from 800 hPa to 1060 hPa

When stored in its original transport packing, the SIROLaser withstands the following environmental conditions:

- Temperatures from -40° C (-40° F) to +70 °C (+158° F)
- Relative humidity from 10 % to 95 %
- Atmospheric pressure from 800 hPa to 1060 hPa

3.3.2 Operating conditions

The SIROLaser may be operated in the following environmental conditions:

- Temperatures from +10° C (+50° F) to +33° C (+92° F)
- Relative humidity from 10 % to 95 %
- Atmospheric pressure from 800 hPa to 1060 hPa

CAUTION
Following transport and storage, allow the laser unit to acclimate for about 1 hour in order to reduce the risk of malfunction due to condensation.

3.4 Precautions

Using controls or settings or performing functional tests other than those specified in this manual may result in hazardous radiation exposure.

Sirona Dental Systems GmbH cannot be held liable for any damage caused by improper use or non-compliance with the instructions and information provided in this manual.

Please remember the following:

CAUTION
SIROLaser may only be operated by trained and qualified personnel.

CAUTION
Laser equipment not in use must be protected against unauthorized access. This can be achieved for example by switching off the laser unit after use, so that the electronic access key must be entered prior to further operation.

Set up the SIROLaser laser unit properly and completely before putting it into operation (see chapter 4).

Make sure that the electrical system is equipped with the required devices for protection against direct and indirect contact (thermomagnetic switches, residual current circuit-breaker) and has been set up by a qualified electrician in compliance with the applicable standards.

National regulations concerning electrical installations shall be obeyed.

Verify that the line voltage corresponds to the voltage indicated on the rating plate of the switching power supply or in the technical specifications.

WARNING
Do not use the laser unit if a visual inspection reveals damage.

WARNING
Do not use the laser unit in the presence of flammable materials.

If you accidentally spill liquid on the unit, immediately stop treatment, disconnect the power supply cable and contact your local dental distributor or authorized service center for assistance.

CAUTION
Do not attempt to disassemble the laser unit in any case. This is limited exclusively to trained and authorized personnel.

Do not place the laser unit near heat sources.

Do not cover the convection openings for air cooling on the sides of the unit.

English

CAUTION

Never allow dust or dirt to enter the optical fiber socket and the optical system. Otherwise, the unit may be permanently damaged

CAUTION

Always protect the optical fiber socket as well as the optical fiber itself with the special protection caps. Do not allow dust, dirt or other foreign bodies to enter the optical fiber socket. Always make sure that the optical system is clean before connecting the optical fiber.

WARNING

Prior to each treatment, the handpieces must be sterilized and the optical fibers must be wipe disinfected.

CAUTION

Switch the laser off immediately if the optical fiber is broken. Otherwise the tips may become hot.

NOTICE

The tips must be checked for sure seating prior to each use.

4 Installation

If national or local legal regulations require that the installation of the SIROLaser be performed by specialized personnel, these regulations must be complied with.

WARNING

The handpieces and the tips are supplied non-sterile, you must clean, disinfect and sterilize these products prior to first use and prior to each subsequent use.

4.1 Packaging contents

The following components are included in the scope of supply of the **SIROLaser**:

Qty	Designation
1	SIROLaser unit
1	Transport case
	Power cord [1]
1	Switching power supply
1	Interlock connector
1	Y-connector
1	Interlock jumper
2	Laser protective goggles (for operator and assistant)
1	Laser protective goggles (for patients)
1	Take-up reel incl. 200µm optic fiber L, 3 m long (9' 10")
1	Take-up reel incl. 320µm optic fiber L, 3 m long (9' 10")
2	Handpieces
1	Finger switch
1	Foot switch
1	Ceramic-coated scissors for optical fiber trimming
1	Set of tips (30°, 45°, 60°, sterilizable)
1	User Manual
1	Set of warning labels (country-specific)
2	Optical fiber connectors with magnet

1. *Dependent on the SIROLaser version*

4.2 Spare parts

Qty	Designation	Order Number
1	Laser protective goggles (for operator and assistant)	60 47 737
1	Laser protective goggles (for patient)	60 47 745
1	Switching power supply	60 47 778
1	Power cord EU	60 56 613
1	Power cord AUS	61 29 741
1	Power cord DK	61 30 012
1	Interlock connector	60 56 472
1	Y-connector	60 56 506
1	Interlock jumper	61 47 024
1	Take-up reel incl. 200µm optic fiber, 3 m long (9' 10")	60 47 786
1	Take-up reel incl. 320µm optic fiber, 3 m long (9' 10")	60 53 578
1	Handpiece	60 47 695
1	Finger switch	60 47 760
1	foot switch	60 47 752
1	Ceramic-coated scissors for optical fiber trimming	60 56 480
1	Set of tips (30°, 45°, 60°, sterilizable)	60 47 794
1	User Manual	60 50 092
1	Set of warning labels (country-specific)	60 56 498
1	Optical fiber connector with magnet	60 56 647
50	SIROLaser patient information brochures	
	German	60 85 695
	English	60 85 711
	French	60 85 737
	Spanish	60 85 703
	Italian	60 85 729

4.2.1 Accessories

Upon request, the **SIROLaser** can be delivered with the following accessories:

	Laser protective goggles for wearers of glasses (nontransparent)	60 56 514
	Take-up reel incl. 400 µm optic fiber 3 m long	60 53 586

4.3 Labels

Attach the appropriate country-specific labels to your laser unit. For more information regarding the labels and label positions, see Appendix B – Label positions.

- Attach country-specific label 1 on the opposite side of English label 1.
- Attach country-specific label 2 below English label 2.

4.4 Interlock

4.4.1 Explanation

The interlock is a safety device that stops laser radiation whenever the door of the treatment room is opened. It is essential to connect the interlock device to a switch that is located near the door of the treatment room in order to ensure automatic interruption of the laser radiation.

NOTICE

The installation must be performed by a qualified electrician who is also responsible for the installation and maintenance of the electrical system to which the SIROLaser is connected.

Please request the technical data sheet with wiring diagram for installation of the interlock device.

NOTICE

If national or local legal regulations require additional or different measures to be taken for the safety of dentist, assistant or patient, these regulations must be complied with.

4.4.2 Installation of an interlock with door switch

Figure 2: Plugging the Y-connector into the laser unit

➢ Plug the Y-connector into the „INTERLOCK/SWITCH“ socket.

Figure 3: Plugging the interlock connector into the Y-connector

➢ As soon as a cable is connected to the interlock connector, connect the interlock connector to the Y connector.

English

4.4.3 Installation of an interlock jumper (without door switch)

Figure 4: Connection of the interlock jumper to the interlock socket

If you have protected the treatment room via suitable measures, however, have not installed the interlock with the door switch, you can replace the Y-connector with the space-saving interlock jumper.

➢ Plug the interlock jumper into the interlock socket.

4.5 Connection of the foot switch

Figure 5: Foot switch

Figure 6: Connection of the foot switch

➢ Plug the foot switch cable into the socket of the Y connector or into the interlock jumper.

NOTICE

The degree of protection of the foot switch is IPX5. Therefore, this foot switch may not be used in hospital operating rooms. Please contact Sirona Dental Systems LLC or your local dental distributor if you want to use the laser unit together with the foot switch in a hospital OR operation theatre.

4.6 Connection of the finger switch

Figure 7: Distal part of the handpiece

➢ Unscrew the distal part of the handpiece.

Figure 8: Distal part with finger switch

➢ Mount the finger switch.

Figure 9: Finger switch mounted on handpiece

➢ Screw the distal part of the handpiece back onto the rest of the handpiece.

Figure 10: Optical fiber and guiding rings

➢ Run the optical fiber through the guiding rings on the finger switch supply cable.

English

Figure 11: Connection of the finger switch

➢ Plug the connector of the finger switch cable into the socket of the Y connector or into the interlock jumper.

4.7 Connecting the optical fiber

4.7.1 Field of application

For different dental procedures and indications, two SIROLaser optical fibers with different diameters are supplied with your SIROLaser: the 200 µm fiber (bend protection colored black) and the 320 µm fiber (bend protection colored yellow). The user will be prompted by the laser software to select the appropriate fiber for each indication.

The SIROLaser optical fibers have a standard SMA-905 connection and can be used only with the SIROLaser in the spectral range of 970 nm ± 15 nm.

If optical fibers from other manufacturers are used, physical properties such as tensile strength and transmission behavior may vary. For this reason, Sirona Dental Systems GmbH assumes no liability in such cases.

Use Sirona optical fibers only.

4.7.2 Initial use of an optical fiber

Initial check

➢ Before using an optical fiber for the first time, check its best-before date. A nonsterile optical fiber can be used maximally 4 years after its month of manufacture. This information is printed on the product label of the packaging.

WARNING

If the optical fiber is used after the best-before date, some of its physical properties, e.g. its load carrying strength and transmission behavior, will change, thus posing a hazard to the health of the patient, the dentist and the dental assistant.

➢ Do not use the laser probe if its packaging is damaged or the best-before month has been exceeded.

➢ After removing the optical fibers from their original packaging, perform a visual check to make sure that they were not damaged during shipment.

Initial startup

CAUTION

The optical fiber and the take-up reel must be disinfected prior to initial use.

The optical fibers are supplied in nonsterile condition and wound up on the take-up reel (see illustration below). The optical fiber can be wound onto the take-up reel either clockwise or counterclockwise.

- ➢ Remove the end of the optical fiber with the black protective cap from the fastening of the take-up reel.
- ➢ Remove the black protective cap **(A)** from the optical fiber.

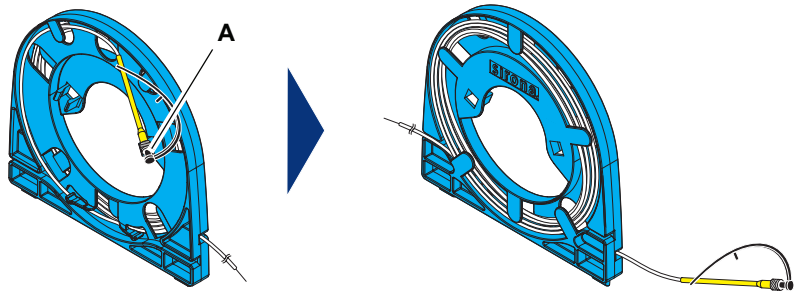


Figure 12: Take-up device

Screw on optical fiber connector with magnet.

The connector comprises 2 parts:

- Tapered part with slot
- Cylindrical part

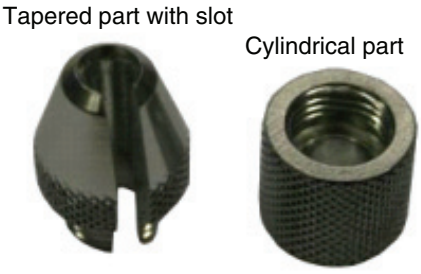


Figure 13: Connector

NOTICE

The SIROLaser detects that the optical fiber is also properly connected only if it is connected to the connector. If the connector or the optical fiber is missing, an error message is output.

- ➢ Attach the slotted optical fiber connector with magnet (see Fig. 13) to the optical fiber.
- ➢ The optical fiber must be laid in the slot of the tapered part (see Fig. 14).
- ➢ Screw on the tapered part from the rear up to the stop of the optical fiber (see Fig. 15).

You do not have to roll up the optical fiber. The optical fiber is thus protected against contamination.

- ↳ The optical fiber can now be connected to the SIROLaser (see Fig. 16).

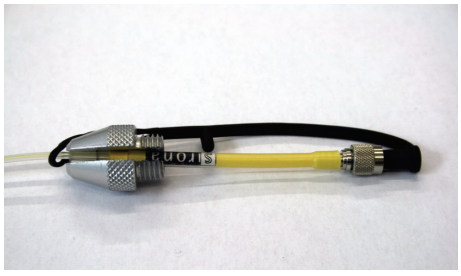


Figure 14: Optical fiber with protection caps

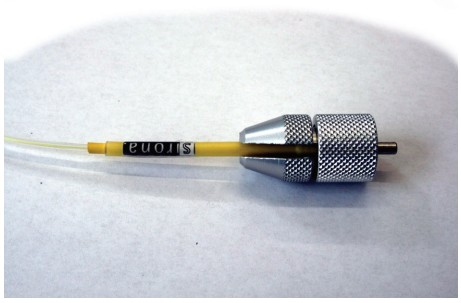


Figure 15: Optical fiber with magnet

English

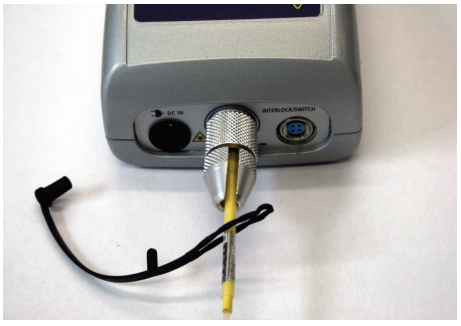


Figure 16: Connecting the optical fiber

- Screw the optical fiber onto the laser (See Fig. 16).
- Put the laser into operation. A corresponding description is provided in Chapter 5.

WARNING

The aiming beam must not be aimed at anyone's retina. It comprises an intensive light source even when set to a low power level. Always wear protective goggles.

- Check to make sure that the aiming beam illuminates evenly, i.e. projects a circular light pattern. To do this, aim the probe tip vertically at a white background located approx. 20 cm away. If the beam shows no pattern or the beam pattern is not illuminated evenly, the optical fiber may be damaged or defective. **In this case, return the laser to your dental depot so that it can be replaced under warranty. Do not use any defective optical fibers.**

Preparation

- If the aiming beam signal produces an evenly illuminated, circular beam pattern, remove the attached distal seal by cutting it off with a pair of scissors. This results in the expiration of Sirona Dental Systems GmbH's liability for any mechanical damage to the optical fiber.
- Protect the optical fiber socket *(see Fig. 17, page 24)* as well as the optical fiber *(see Fig. 14, page 23)* itself with the special protection caps .

Figure 17: Protection cap on the laser unit.

CAUTION

Always protect the optical fiber socket as well as the optical fiber itself with the special protection caps at the end of treatment. Do not allow dust, dirt or other foreign bodies to enter the optical fiber socket. Always make sure that the optical system is clean before connecting the optical fiber.

CAUTION

Never allow dust or dirt to enter the optical fiber socket and the optical system. Otherwise, the unit may be permanently damaged

- When necessary, hold the optic fiber approx. 10 cm below the distal end.
- Press the sheath and the optical fiber together.
- Pull off approximately 10 cm of the sheath with your thumbnail.
- Mount the dust cap to the fiber plug.
- Clean and disinfect the optical fiber.
  Descriped in chapter „Cleaning and sterilization“ on page 40.

4.7.3 Preparation for clinical use

- Select the optical fiber you need either 200 µm or 320 µm.
- Make sure that the optical fiber is clean and disinfected.

All handpieces are autoclavable (see chapter „Cleaning and sterilization“ on page 40).

CAUTION

Strong bending or improper routing of the optical fiber inside the handpiece may damage the optical fiber, creating a health hazard for patients, dentists and assistants.

CAUTION

If you switch on the laser unit and the signal of the red aiming laser is not visible or if you cannot see the aiming beam during treatment, proceed as follows:

- Check the optical fiber as well as the fiber connection for mechanical damage.

  If the optical fiber is damaged, replace it with a new one.
- Connect the fiber to the laser.
- Check the optical fiber whether the signal of the aimingbeam is visible
- If you cannot detect any damage on the optical fiber and the signal of the aiming laser is not visible with the new optical fiber either, turn off the laser and contact Sirona Dental Systems GmbH, your local dental distributor or your authorized service center.

WARNING

Using the laser unit without a properly working aiming beam may cause injuries to operators, assistants and patients.

CAUTION

The optical fiber must be cleaned and disinfected prior to the first treatment.

CAUTION

Remove the protection caps only for operation!

CAUTION

Do not touch the end surfaces of connectors and protect against damage!

CAUTION

Do not kink or pinch the optical fiber as this would cause breaking the optical fiber!

CAUTION

Do not pull on the optical fiber!

CAUTION

Note the maximum permissible bending radius of the optical fiber!
• Short-term (during use): 100 x radius of optical fiber
• Long-term (during storage): 600 x radius of optical fiber

NOTICE

Magnet is for recognizing the presence and absence of the fiber.

Inserting the optical fiber into a sterilized handpiece

- Loosen the proximal part of the handpiece.

Figure 18: Inserting the optical fiber into the handpiece

➢ Insert the optical fiber in to the handpiece.

Figure 19: Fitting the tip

➢ Insert the desired curved tip by applying pressure and twisting it.

CAUTION

Do not use the 320 µm fiber or one larger in combination with the 60° tip!

CAUTION

Check the tip for damage before inserting it. Replace it if necessary.

CAUTION

Check the tip to make sure it is firmly seated.

➢ Using the scissors, trim the end of the optical fiber millimeter by millimeter until it projects a well-defined circle. Always cut perpendicular to the fiber.

Check whether the aiming beam is evenly illuminated, ring-shaped pattern. To do this, please aim the tip of the probe vertically at a white background located approx. 20 cm away. If there is no beam pattern at all or the beam pattern of the laser probe is unevenly illuminated pls. cut off 1 - 2 mm again.

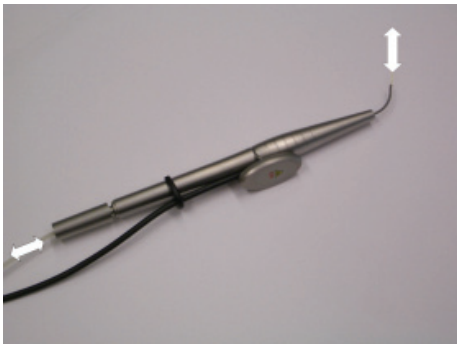


Figure 20: Adjusting the length of the optical fiber

➢ Loosen the proximal part of the handpiece that blocks the protective sheath.

➢ Adjust the length of the optical fiber so that the optical fiber projects out of the tip at least 1 cm.

CAUTION

If the optical fiber does not project out of the tip at least 1 centimeter, there is danger of the tip heating up.

4.7.4 Adjusting the sheath

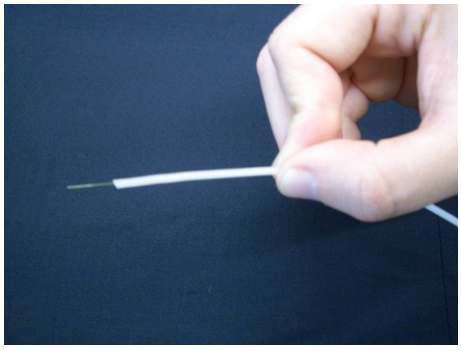


Figure 21: Sheath of the optical fiber is too long

The silicone sheath should be 5-10 cm shorter than the optical fiber itself. If the sheath is too short, the optical fiber may not be fastened properly in the handpiece. If the sheath is too long, the optical fiber cannot be inserted into the handpiece. To shorten the sheath to an appropriate length in relation to the optical fiber, proceed as follows:

- Hold the optic fiber approx. 10 cm below the distal end.
- Press the sheath and the optical fiber together.
- Pull off approximately 10cm of the sheath with your thumbnail.

NOTICE

After stripping the optical fiber, bend it back and forth to make sure it has not been damaged.

4.8 Power supply connection

- Connect the power cord to the DC IN socket at the back of the SIROLaser (see figure 22).

Figure 22: Power supply connection

CAUTION

The SIROLaser may only be operated with the Sinpro MPU50-105 power supply. Operation with other power supplies may result in failure or destruction of the laser unit. Using power supplies other than the recommended one results in invalidation of the approval of the entire unit and loss of the warranty granted by Sirona Dental Systems GmbH.

WARNING

Using power supplies other than the recommended one may cause the risk of overheating and malfunction of the laser unit.

English

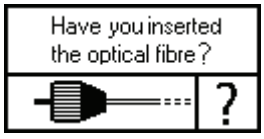
5 Operating Instructions

⚠ *CAUTION*

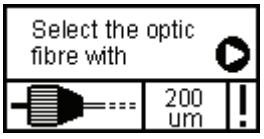
Always protect the optical fiber as well as its connector with the special protection caps at the end of treatment (see Fig. 17, page 24).

5.1 Warning and error messages

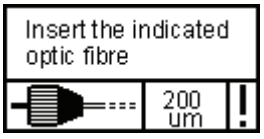
After selecting the indication, press the “ENTER” key. The laser unit is now ready for operation. The message “Wear protective goggles” appears on the display and four green LEDs start flashing.



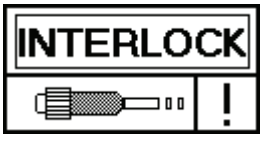
If this message is displayed, check whether the optical fiber is properly connected. Once the optical fiber is properly connected, the message will disappear automatically.



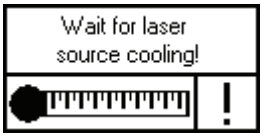
If this message is displayed, you must select an optical fiber diameter with the “RIGHT ARROW” key and then confirm your selection with the “ENTER” key.



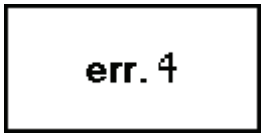
If this message is displayed, you must insert the specified optical fiber and then confirm your action with the “ENTER” key.



This message signals that the INTERLOCK safety device has responded. Either the door of the treatment room is open, or the INTERLOCK connector is not properly seated in its socket.



If this message is displayed, allow the laser unit to cool down for a few minutes.



The temperature of the laser diode is < 5 °C or > 90 °C; or the temperature sensor is defective.

Adapt the SIROLaser to room temperature over a period of 2 hours.

If this message nevertheless still appears, contact your dealer or an authorized Customer Service Department.

err. 5	This message indicates an error of the laser current output power. The SIROLaser output is out of the ± 20 % tolerance. Switch the laser unit off and switch it on again. If the error message is displayed again contact your local dealer or your authorized service center.
err. 6	This error message indicates that the foot switch or finger switch was pressed during menu selection or that you foot switch or finger switch is defective (short circuited). Please make sure that neither the finger switch nor the foot switch is pressed during menu selection. If the error message is still displayed, please contact your local dealer or your authorized service center.
err. 7	This error message indicates, that the fiber connection sensor is defective, or the fiber is not properly connected to your laser. Try to disconnect and connect the fiber again, if the error message is still displayed, please contact your local dealer or your authorized service center.

5.2 Switching the laser unit on and off

Once you have completed the installation procedure, press the “ENTER” key to switch on the laser unit.

After 2 minutes of inactivity, the SIROLaser enters the standby mode.
You can leave the unit in standby mode with the power cord connected.

➢ To switch off the laser unit, select “OFF AREA”, press the “ENTER” key and unplug the power cord.

5.3 Key panel

Figure 23: Key panel

“LEFT ARROW” key	Navigate to the left. Decrease parameter values. Quit certain menus.
“ENTER” key	Confirms, starts or stops a selected action following setup.
“RIGHT ARROW” key	Navigate to the right (in all menus). Increase parameter values.
“LASER STOP” button	The “LASER STOP” button acts as emergency stop for the laser.

5.4 Electronic access key

Only authorized personnel is allowed to operate the SIROLaser. Therefore, once the unit has completed its power-up and self-test routines, you will be prompted to enter an access code which works as an electronic key.
The access code consists of a sequence of four keys.

The code is: **6 2 5 1**

To enter the access code, press the following keys consecutively:

➢ Scroll to the given number by pressing the "RIGHT ARROW" key.

➢ Change from one number to the next by pressing the "ENTER" key.

WARNING

Do not give the access code to non authorized users. Risk of misuse of the laser by unqualified persons!

5.5 Setting up the software interface language

- Press the "RIGHT ARROW" key to select the treatment area.
- Press the “LEFT ARROW” key twice. The following screen appears on the display:

- Press the “ENTER” key.
- ↳ A new screen appears on the display.
- Press the “ENTER” key until the menu item “LANGUAGE EN” is highlighted.
- Press the “RIGHT ARROW” key until the desired language appears. The following abbreviations are used[1]:

	CU		NU		SA
EN	English	EN	English	EN	English
FR	French	DK	Danish	NL	Dutch
IT	Italian	SE	Swedish	FR	French
ESP	Spanish	FIN	Finnish	PT	Portuguese
DE	German	NO	Norwegian	ESP	Spanish

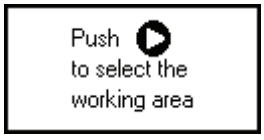
- Press the “ENTER” key.
- Press the “LEFT ARROW” key.
- ↳ You are now in the main menu.

5.6 Main menu

The following section describes the main menu. You will find an explanation of the different menu items and the steps that are required for accessing the submenus.

1. *Software extention (CU, NU, SA)*

English



➢ Press the “RIGHT ARROW” key to select the treatment area.

➢ Press the “ENTER” key to access the surgery area (SURGERY AREA). In this area you will find a number of surgical submenus with preset treatment parameters.

➢ Press the “ENTER” key to access the periodontics area (PERIODONTICS AREA).

In this area you will find a number of periodontic submenus with preset treatment parameters.

➢ Press the “ENTER” key to access the endodontics area.

In this area you will find a number of endodontic submenus with preset treatment parameters.

➢ Press the “ENTER” key to access the "MANUAL SETTING AREA".

In this area you can manually configure up to 10 different sets of treatment parameters. The sets are stored and will be available for use in future treatment sessions.

➢ Press the “ENTER” key to access the setup area.

In this submenu you can make basic settings such as interface language, sound, brightness. The service menu is also located in this area.

➢ Press the “ENTER” key to switch off the laser.

5.7 “SURGERY”, “PERIODONTICS” and “ENDODONTICS” submenus

The submenus of the surgery, periodontology and endodoncy area are arranged in the same way. After opening one of the submenus, you can choose among various indications with preset treatment parameters.

➢ Use the “RIGHT ARROW” key to scroll through the different indications.

➢ The “LEFT ARROW” key returns you to the main menu. The following submenus are available:

SURGERY AREA	
S1	Gingivectomy
S2	Exposing implantations

S3	Operculectomy
S4	Frenulectomy
S5	Hemostasis
S6	Gingival incisions
S7	Aphthae
S8	Herpes
PERIODONTICS AREAPERIODONTICS	
P1	Periodont. lesions
P2	Periodont. pockets
P3	Peri-implantitis
ENDODONTICS AREA	
E1	Endodont. germ reduction
E2	Gangrene germ reduction

After you have selected the desired indication with the “ENTER” key, the following happens:

- You are prompted to connect the specified fiber (200 µm/320 µm)!
- ➢ Confirm with "ENTER" once you have connected the right fiber.
- The green LEDs start flashing, indicating that the laser is in standby mode now.
- After a delay of 2 seconds, the aiming beam is switched on.
- The laser is now ready for operation.
- If aiming beam is on, please wear protective goggles.

WARNING

The operator, assistant and patient all must wear the special protective laser goggles supplied when the green LEDs are active!

WARNING

Any actuation of the foot switch or finger switch activates the laser unit!

Below you will find an example of a typical treatment submenu.

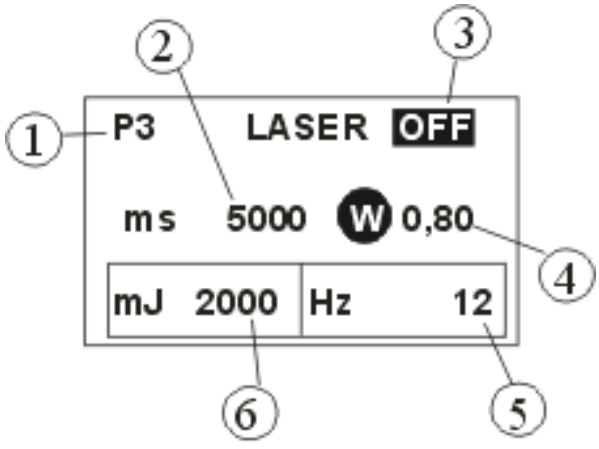


Figure 24: Example of a treatment submenu

1. **Selected program:** in our example P3:

2. **Pulse duration** in milliseconds: in single pulse or auto-repeat mode. If set to any time, laser radiation will stop after this time, even if you continue to press the foot switch or finger switch. If set to zero, "------" appears on the display, and the laser remains activated as long you press the foot switch or finger switch. In the autorepeat mode, the laser unit switches back on after two sec. if the finger-/foot switch is actuated.

NOTICE

In the preset menus, the laser unit activation time cannot be modified by the user.

3. **Laser radiation**:
   ON when the foot switch or finger switch is actuated,
   OFF when the laser is in standby mode.
4. **Selected laser power:** in our example 0.8 W peak power. Using the "LEFT ARROW" and "RIGHT ARROW" key, you can adjust the emitted power between 0.5 W and 7 W in 0.1W increments.

WARNING

The preset power levels are safe for the patient. Increasing the power levels entails the risk of overheating the patient's soft or hard tissue. Lowering the power levels may result in reduced treatment efficacy.

5. **Frequency**: Modulation frequency of the laser unit. The frequency range is from 1 to 10,000 Hz. If set to zero, CW (for continuous wave mode) is displayed.

NOTICE

In the preset menus, the frequency cannot be modified by the user.

6. **Treatment energy**: The system automatically calculates the energy (in mJ) applied during treatment from the power value and the selected laser activation time. If no activation time has been preset, the energy will not be calculated.

When you actuate the foot switch or finger switch, the message "LASER ON" appears. At the same time, 4 yellow LEDs light up, the audible alarm sounds and the laser starts emitting. When you release the foot switch or finger switch to interrupt treatment, the laser is deactivated, but remains ready for operation.

When you press the red "LASER STOP" emergency button, laser radiation (and thus also treatment) is terminated immediately.

➢ To quit the selected preset menu, press the "ENTER" key.

↳ A message confirming the end of the therapy appears on the display.

➢ The "LEFT ARROW" key returns you to the main menu.

5.8 "MANUAL SETTING AREA" submenu

After accessing the "MANUAL SETTING AREA", the illustrated screen appears on the display (see Fig. 25).

Here you can select from 10 programs with the arrow keys.

- Pressing the "ENTER" key takes you to the selected program (PP1 for program 1, PP2 for program 2,.....)
- Confirm the fiber you would like to have for your personal setting (200µm or 320 µm) with "ENTER" or change it with the "RIGHT ARROW" key.

After selected the submenu

- The green LEDs start flashing, indicating that the laser is in standby mode now.
- The laser is now ready for operation.
- If aiming beam is on, please wear protective goggles.

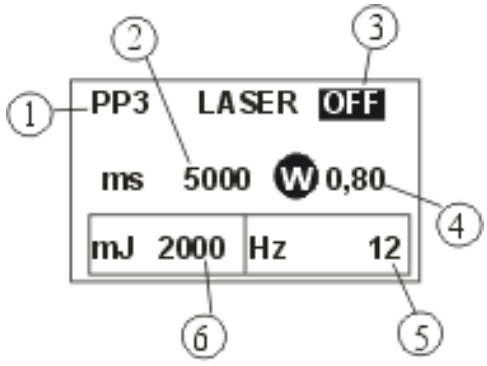


Figure 25: "MANUAL SETTING AREA" submenu

1. **Selected program:** in our example PP3:
2. **Laser activation time in milliseconds**: in single pulse or auto-repeat mode. In the autorepeat mode, the laser unit switches back on after two seconds if the foot switch is actuated. If set to any time, laser radiation will stop after this time, even if you continue to press the foot switch or finger switch. If set to zero, "------" appears on the display, and the laser remains activated as long you press the foot switch or finger switch. You can set a time between 100 ms and 60 s (60000 ms) in 50 ms intervals. When you press the key for more than 3 s , the value increases at a faster rate.
3. **Laser radiation:**
   ON when the foot switch or finger switch is actuated.
   OFF when the laser is in standby mode.
4. **Selected laser power**: in our example 0.8 W peak power. Using the "LEFT ARROW" and "RIGHT ARROW" key, you can adjust the emitted power between 0.5 W and 7 W in 0.1W increments.

WARNING

Setting the power to excessively high levels increases the risk of overheating the patient's soft or hard tissue. Setting the power to excessively low levels may result in reduced treatment efficacy.

5. **Frequency:** Modulation frequency of the laser. The frequency range is from 1 to 10,000 Hz. If set to zero, CW (for continuous wave mode) is displayed. Up to 100 Hz, the parameter value can be increased in 1 Hz increments. Between 100 Hz and 1,000 Hz, the parameter value can be increased in 100 Hz increments. Between 1,000 Hz and 10,000 Hz, the

English

parameter value can be increased in 1,000 Hz increments. When you press the “RIGHT ARROW” key for more than 3 s , the value increases at a faster rate.

6. **Treatment energy**: The laser unit automatically calculates the energy (in mJ) applied during treatment from the power value and the selected laser activation time. If no activation time has been preset, the energy will not be calculated.

WARNING

As soon as you have selected the program, the SIROLaser is in standby mode. As soon as you press the foot switch or finger switch, the laser unit is activated.

When you actuate the foot switch or finger switch, the message “LASER ON” appears. At the same time, 4 yellow LEDs light up, the audible alarm sounds and the laser starts emitting. When you release the foot switch or finger switch to interrupt treatment, the laser is deactivated, but remains ready for operation.

To change the output parameters, press the “ENTER” key. As soon as the area has been selected, you can change the parameters by pressing the "RIGHT ARROW" or "LEFT ARROW" key.

When you press the red “LASER STOP” emergency button, laser radiation (and thus also treatment) is terminated immediately.

To quit the selected menu or save your changes, press the “ENTER” key for more than 1 second. A message confirming the end of the therapy appears on the display.

➢ The “LEFT ARROW” key returns you to the main menu.

5.9 “SETUP AREA” submenu

After accessing the “SETUP AREA”, you can scroll through the available functions with the “ENTER” key. The following functions are available:

FUNCTION 1:	Adjustment of the display contrast.
FUNCTION 2:	Activation or deactivation of the key tones.
FUNCTION 3:	Activation or deactivation of the audible alarm during laser radiation (Sirona Dental Systems GmbH recommends activating this function).
FUNCTION 4:	Activation or deactivation of the auto-repeat function for the laser activation time in single pulse mode.
FUNCTION 5:	Selection of the interface language
FUNCTION 6:	Service program for laser calibration

A function is activated when it is highlighted. To save the changes made, press the “ENTER” key. Pressing the “ENTER” key again highlights the next function.

To quit the “SETUP AREA”, press the “LEFT ARROW” key while no functions are highlighted.

6 Indications, contraindications and medical precautions

6.1 Indications

Compared to conventional dental surgery, treatment with the SIROLaser offers the following advantages: less invasive, minimum cell destruction, less bleeding, better coagulation, negligible post-operative edema. The SIROLaser may only be operated by trained and qualified personnel.

At the end of this section, you will find an overview where some possible treatments with the SIROLaser as well as the power values to be used are listed.

6.2 List of indications

Indications	Optical fiber thickness	Mode	Power
SURGERY AREA			
Gingivectomy	320 µm	cw	4 - 6 W
Operculectomy	320 µm	cw	4 W
Frenectomy	320 µm	cw	3 - 4 W
Hemostasis	320 µm	cw	6 W
Gingival incisions	320 µm	cw	4 W
Aphthae	320 µm	cw	2 W (without contact)
Herpes	320 µm	cw	2 - 4 W (without contact)
PERIODONTICS AREA			
Periodont. lesions	see periodont. pockets	see periodont. pockets	see periodont. pockets
Periodont. pockets	320 µm	cw	1 W
Periodont. pockets	320 µm	chopped mode 75 - 100 Hz	2.5 W
Peri-implantitis	320 µm	cw	1 - 1.5 W
Peri-implantitis	320 µm	chopped mode	2.5 - 3 W
ENDODONTICS AREA			
Endodont. germ reduction	200 µm	cw	1.5 W
Gangrene germ reduction	200 µm	cw	1.5 W

6.2.1 Examples of treatment risks

SURGERY AREA

WARNING

***Risk**: Soft and hard tissue necrosis or overheating of the tooth.*
***Countermeasure**: Use the laser beam like a scalpel perpendicular to the treated area and never direct it to one single spot for too long. Do not set the laser power to excessively high levels.*

PERIODONTICS AREA

WARNING

Risk: *Minor necrosis or scarring of the radicular area:*
Countermeasure: *When working in periodontal pockets, always align the laser exactly parallel to the roots, never perpendicular. Brush over the entire interior of the pocket with the the distal end of the optical fiber.*

ENDODONTICS AREA

- **Root canal germ reduction**

WARNING

Risk*: Contraction at the apical level, small fusions and microfractures*
Countermeasure*: Measure the depth and stop 1mm above the apex. Never direct the optical fiber to one single spot in the root apex for too long. The optical fiber must be moved constantly during treatment. Start in the apical region and work upward toward the crown.*

- **Gangrenous canals**

WARNING

Risk*: Contraction, fusion and bone necrosis*
Countermeasure*: Measure the depth and stop 1 mm above the apex. Never direct the optical fiber to one single spot in the root apex for too long. The optical fiber must be moved constantly during treatment. Start in the apical region and work upwards toward the crown.*

6.3 Contraindications

At present, no contraindications are known for the use of therapeutic lasers in dentistry with devices of the same power and wavelength as the SIROLaser.

6.4 Precautions

WARNING

Never direct the laser beam or the aiming beam toward the eyes or the thyroid gland of a person.

WARNING

The eyes of patients, assistants and dentists must always be protected with the laser protective goggles provided with the unit, even when only the aiming beam is active.
Wearer of glasses should use the special offered protective goggles.

English

7 Cleaning and sterilization

After finishing treatment, switch off the laser and disconnect the power cord from the power supply.

WARNING

The handpieces and the tips are supplied non-sterile, you must sterilize these products prior to first use and prior to each subsequent use.

WARNING

Disinfect the finger switch and the fiber prior to the first use and prior to each subsequent use.

Laser protective goggles

Before cleaning the laser protective goggles, please read and observe the instructions for use provided by the manufacturer and attached to the goggles in the case.

7.1 Cleaning

NOTICE

Manual cleaning must always be combined with disinfection.

NOTICE

All tissue residues must be removed from the optical fiber before it is detached from the handpiece. This prevents internal contamination of the tip.

Following treatment:

Optical fiber

CAUTION

Reattach the black protective cap to the (laser) end of the connector before taking any hygienic measures.

- Remove the optical fiber from the handpiece.
- Cut off approx. 4 cm from the distal end of the optical fiber. The cut must be made perpendicular to the axis of the optical fiber.
- Remove approx. 4 cm of the sheath if necessary (see Chapter 4.7.4, page 27).
- The take-up reel and optical fiber must be disinfected first.
- After it is removed from the reel, the optical fiber can be cleaned with a suitable brush under running water (of at least drinking water quality).

Handpiece

- Remove the tip from the handpiece.
- Disassemble the handpiece by unscrewing the two threaded joints.
- Clean the handpiece and tip by scrubbing them with a suitable brush under running water. Clean the distal end of the optical fiber using a soft, damp cloth.
- If a finger switch is installed, remove it as described in Chapter 4.6 Installation (page 21).

7.2 Disinfection

- Disinfect the optical fiber and the take-up reel by spray or wipe disinfection.
- Disinfect the finger switch by spray or wipe disinfection.

NOTICE

Use only disinfectants that comply with the requirements of your national authorities and whose bactericidal, fungicidal and virucidal properties have been tested and properly certified.

You can use for instance: MinutenSpray classic from Alpro; MinutenWipes from Alpro. In the USA: Cavicide® and Caviwipes™.

Observe the instructions provided by the manufacturers of these disinfectants.

CAUTION

The optical fiber may be damaged if it is seriously bent or improperly routed inside the handpiece. This may constitute a health hazard for patients, dentists and dental assistants. The minimum bending radius of the light guide is 4.5 cm (diameter: 9 cm). Be careful not to pinch or tear the optical fiber when inserting or cleaning it.

7.3 Sterilization

WARNING

The handpiece and tips must be sterilized prior to initial use and before each subsequent use.

NOTICE

Remove any possible water residues from the handpiece and tips.

- The disassembled handpiece and the tips may be sterilized only in autoclaves with saturated water vapor at 135 °C (275 °F), 3 min. holding time and 2.13 bar (33.88 psi) overpressure.

CAUTION

The optical fiber may be damaged if it is seriously bent or improperly routed inside the handpiece. This may constitute a health hazard for patients, dentists and dental assistants. The minimum bending radius of the light guide is 4.5 cm (diameter: 9 cm). Be careful not to pinch or tear the optical fiber when inserting or cleaning it.

English

Approved for sterilization are steam sterilizers that fulfill the requirements of EN 13060 or at least use fractionated vacuum and are suitable for the sterilization of dental handpieces such as e.g. SIRONA DAC PROFESSIONAL.

7.4 Cleaning of the laser unit and finger switch

➢ Use a dry, soft cloth to remove dust from the SIROLaser. More stubborn spots can be removed with a damp cloth.

For disinfection, you can treat the SIROLaser with all products commonly used for medical electrical equipment, such as MinutenSpray classic, CAVICIDE® or Caviwipe.

Observe the instructions provided by the manufacturers of these disinfectants.

➢ Disinfect the finger switch by spray or wipe disinfection

You can use for instance: MinutenSpray classic from Alpro; MinutenWipes from Alpro. In the USA : cavicide® and caviwipes™.

Observe the instructions provided by the manufacturers of these disinfectants.

CAUTION

Take care that the fiber will not be damaged in case of disconnecting the finger switch.

WARNING

For further precautions, see chapter 1.3.

CAUTION

The SIROLaser unit cannot be sterilized.

CAUTION

The handpieces and tips must be sterilized after each treatment!

8 Maintenance and service

8.1 Calibration-Check

WARNING

You must wear the laser protective goggles supplied with the laser unit during the entire calibration procedure!

The following section explains how to calibrate the SIROLaser.

We recommend performing this check at least once a week.

To ensure precise control of the efficiency and perfect functioning of your SIROLaser unit, we recommend you to perform a calibration at three different power levels:

- 1 W
- 3 W
- 5 W

The SIROLaser performs a self-calibration, during which the system will check whether the parameters responsible for laser emission are correct. In addition, we recommend that you check these values at least once every six months with the help of a suitable external power meter, for power measurements at a wavelength of 970 nm +/–15 nm, a power between 0.5 W and 7 W and a resolution better than 5 % that has been properly calibrated.

8.1.1 Calibration-Check without use of an external power meter

WARNING

You must wear the laser protective goggles supplied with the laser unit during the entire calibration procedure!

- ➢ Connect an optical fiber to the SIROLaser.
- ➢ Make the optical fiber point in a controlled direction in the air.
- ➢ Wear the laser protective goggles and verify that the entrance to the room where the calibration is being performed is controlled by an INTERLOCK device or is locked.
- ➢ Switch on the SIROLaser and go to the “SETUP AREA”.
- ➢ Select “SERVICE”.

The first test (1W) is highlighted.

- ➢ Use the “RIGHT ARROW” key to select the test you want to perform (1 W, 3 W, 5 W). To quit the test area, press the “LEFT ARROW” key.

Test for 1 W

- ➢ Release laser radiation with the foot switch or finger switch until the message OK appears.

Test for 3 W

- ➢ Release laser radiation again until the message OK appears.

Test for 5 W

- ➢ Release laser radiation again until the message OK appears.
- ➢ Quit the calibration menu by pressing the “LEFT ARROW” key.

English

↳ If you did the test correctly and got an OK message on all three tests, the laser unit has been successfully calibrated.

8.1.2 Calibration-Check with use of an external power meter

Equipment Needed: Certified traceable power meter that can measure a minimum of 10 Watt.

WARNING

You must wear the laser protective goggles supplied with the laser unit during the entire calibration procedure!

- Connect an optical fiber to the SIROLaser.
- Make the optical fiber point to the measuring head of the power meter. Keep a minimum distance of 20 mm between the optical fiber and the surface of the measuring head. This will prevent damage to the measuring instrument due to the high energy density resulting from the small fiber diameter.
- Wear the laser protective goggles and verify that the entrance to the room where the calibration is being performed is controlled by an interlock device or is locked.
- Switch on the SIROLaser and go to the “SETUP AREA”.
- Select “SERVICE”.
- Check to see that the fiber is neatly cut, and that the laser beam projects a red circle. The circle must be as well defined as possible.

The first test (1 W) is highlighted.

- Use the “RIGHT ARROW” key to select the test you want to perform (1 W, 3 W, 5 W). To quit the test area, press the “LEFT ARROW” key.

Test for 1 W

- Release radiation with the foot switch or finger switch until the message OK appears. Check whether the power meter reading is within the permissible range of 1 W +/- 20 %.

Test for 3 W

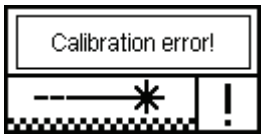
- Release radiation again until the message OK appears. Check whether the power meter reading is within the permissible range of 3 W +/- 20 %.

Test for 5 W

- Release radiation again until the message OK appears. Check whether the power meter reading is within the permissible range of 5 W +/- 20 %.
- Quit the calibration menu by pressing the “LEFT ARROW” key.

If the test procedure runs without errors, the message OK will appear for each test, and the values measured on the power meter will be within the permissible range. In this case, the unit has been successfully calibrated.

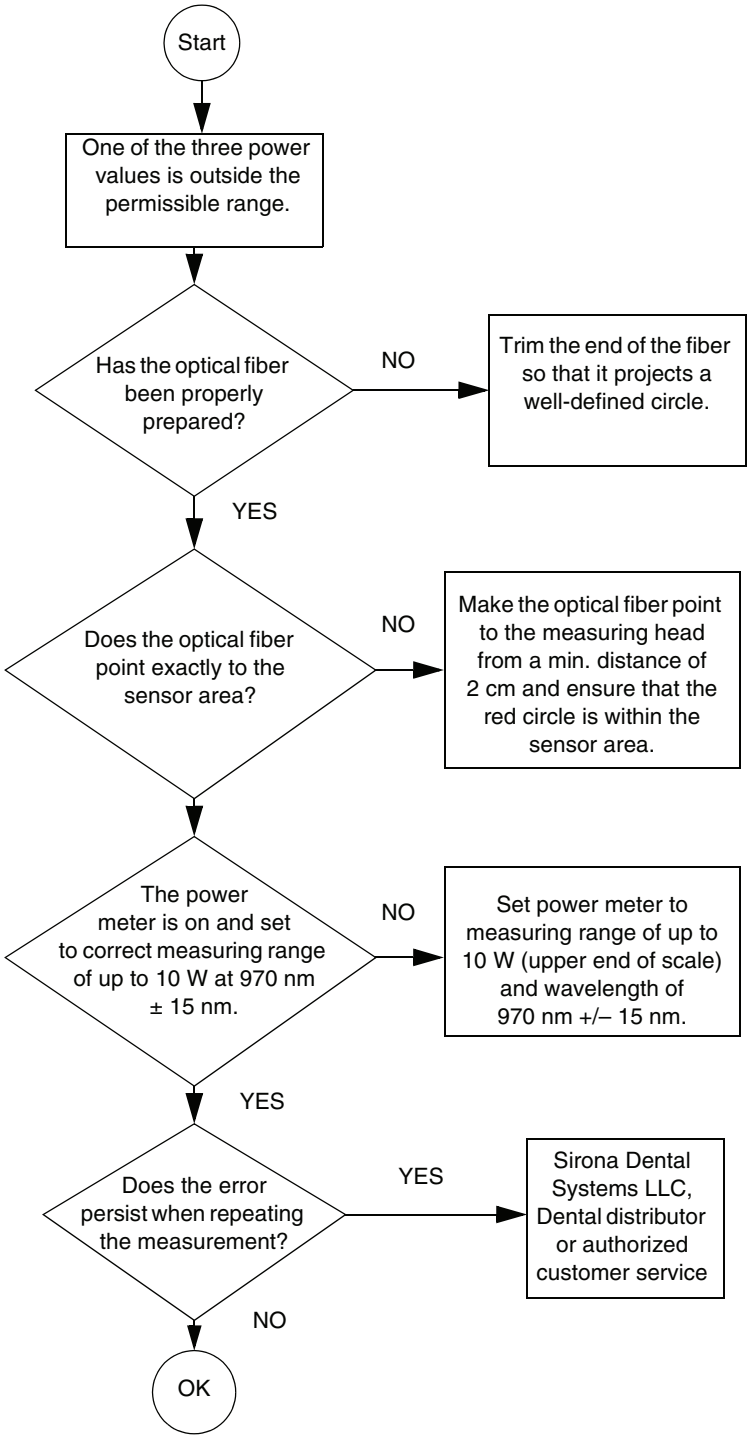
8.1.3 Error message and incorrect parameter values



If the following screen appears during one of the three calibration tests:

Repeat the test from the beginning. If the error persists, please contact your local dental distributor or your authorized service center. Do not, under any circumstances, continue to use the laser unit!

If the values measured by the power meter are outside the permissible range in each of the three calibration tests, please proceed according to the following flow chart:



English

8.2 Safety checks

The following safety checks must be performed every 24 months by a qualified service engineer:

- Visual inspection of the unit and its accessories for mechanical damage that might impair operation
- General function check
- Check of the audible and visual indicators
- Earth leakage current NC and SFC accd. to IEC 601
- Housing leakage current NC and SFC accd. to IEC 601
- Patient leakage current NC and SFC accd. to IEC 601
- Laser power measurement with calibrated measuring equipment in the range between 0.5 W and 7 W

8.3 Maintenance

The SIROLaser does not require special maintenance. In case of malfunctioning, see chapter Technical support, repair and testing. However, Sirona Dental Systems GmbH recommends the following actions to be taken at regular intervals:

Action	Interval	Person in charge
Check of the optical fiber (see chapter 4.7 “Connecting the optical fiber” on page 22)	before each treatment session	Operator
Calibration of the laser (see chapter 8.1 “Calibration-Check” on page 43)	weekly	Operator
Safety checks (required by law in some European countries)	every 2 years	Sirona Dental Systems GmbH, local dental distributor or authorized service center

NOTICE

If national or local legal regulations require additional safety checks for your laser unit, these regulations must be complied with and the corresponding checks must be performed.

The manufacturer accepts responsibility for the safety of the laser unit only if the following prerequisites are fulfilled:

- Modifications of the laser unit or repair work must be performed by authorized personnel.
- The electrical system at the premises where the SIROLaser is installed must comply with the applicable legal requirements for electrical installations.
- The laser unit must be used in compliance with the instructions provided in this manual.

8.4 Basic troubleshooting

In case of malfunctions, check the following first:

- ➢ Check the connection of the power cord.
- ➢ Check the connection of the INTERLOCK device.
- ➢ Check the connection of the optical fiber.
- ➢ Be sure that all operational steps have been executed correctly.

➢ Check the connection of the foot switch.

8.5 Technical support, repair and testing

Technical information concerning parts to be repaired may be supplied by Sirona only to authorized agents and after providing a training course to the technical personnel. Please contact your local dental distributor or authorized service center for technical support.

The laser unit may be sent in for repair or for safety inspection only in its original packaging, including all accessories. Disinfect and sterilize the laser unit according to the relevant instructions for use before shipping it.

9 Technical data

Laser system	Class IV (according to IEC 60825-1: 2003)
Equipment classification	Class IIb (according to Council Directive 93/42/EEC)
IP degree of protection	Laser unit: IP20; foot switch: IPX5
Wavelength	970 nm +/- 15 nm
Power max.	approx. 7 W CW (optical)
Aiming beam	635 or 650 nm, 1 mW max.
Emission mode	CW (continuous wave) or modulated 1 Hz to 10 kHz
Pulse (chopped mode)	Single or repeated pulse
Pulse duration	100 ms - 60 s in 50 ms intervals
Optical fiber thicknesses	200, 320 and 400 µm, NA > = 0.22
Start	Electrical foot switch/finger switch plus electronic access key
Adapter	External, 100 - 240 VAC, 50- 60 Hz
Rating	48 VA
Isolation class	Class 1, type B
Operation parameters	on graphical display
Dimensions	87 × 54 × 190 mm (3.43" × 2.1" × 7.48")
Weight	0.45 kg (1 lb.)
Power supply	The SIROLaser may only be operated with the Sinpro MPU50-105 power supply provided
NOHD (Nominal Ocular Hazard Distance)	approx. 1.5 m for 10 s radiation exposure of the unprotected eye (numerical aperture of the optical fiber NA = 0.22)

10 Manufacturer's declaration regarding electromagnetic compatibility

NOTICE

The SIROLaser complies with all requirements for electromagnetic compatibility according to IEC 60601-1-2: 2005

10.1 Definitions

10.1.1 Emission (electromagnetic)

When electromagnetic energy is emitted by a source.

10.1.2 Interference immunity

The ability of a device or system to work without errors even if there is electromagnetic interference.

10.1.3 Immunity level

The maximum level of a certain electromagnetic interference that affects a particular device or system, where the device or system remains operative with a certain level of performance.

ELECTROMAGNETIC EMISSION		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The **SIROLaser UNIT** uses HF energy only for its internal function. The HF emission is therefore very low, and it is improbable that nearby electronic devices might be disturbed.
RF emissions CISPR 11	Class B	The **SIROLaser UNIT** is intended for use in all facilities, including residential areas and in any facilities connected directly to a public power supply providing electricity to buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

10 Manufacturer's declaration regarding electromagnetic compatibility

Interference immunity			
The SIROLaser is intended for use in the electromagnetic environment specified below. The end user should ensure that it is used in such an environment.			
Immunity test	**EN 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	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 EN 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	The quality of the line power supply should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1 kV differential mode	±1 kV differential mode	The quality of the line power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 5 % U_T (> 95 % dip of U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip of U_T) for 5 seconds	< 5 % U_T (> 95 % dip of U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip of U_T) for 5 seconds	The quality of the line power supply should be that of a typical commercial or hospital environment. If the user of the **SIROLaser UNIT** requires continued operation during power mains interruptions, it is recommended that the **SIROLaser UNIT** be powered by an uninterruptible power supply or a battery.
Power frequency magnetic field EN 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.

RF immunity

The SIROLaser is intended for use in the electromagnetic environment specified below. The end user should ensure that it is used in such an environment.

Immunity test	EN 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF EN 61000-4-6	3 Vrms from 150 kHz to 80 MHz	3 Vrms from 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 1.2 \sqrt{P}$ from 150 kHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$ from 80 MHz to 800 MHz $d = 2.3 \cdot \sqrt{P}$ from 800 MHz to 2.5 GHz where "P" is the maximum output power rating of the transmitter in watt according to the transmitter manufacturer and "d" is the recommended separation distance in meters.
Radiated RF EN 61000-4-3	3 Vrms from 80 MHz to 2.5 GHz	3 Vrms from 80 MHz to 2.5 GHz	

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

English

10 Manufacturer's declaration regarding electromagnetic compatibility

Recommended separation distances between portable and mobile RF communications equipment and the SIROLaser

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

Rated maximum output power of transmitter (in watt)	**Separation distance according to frequency of transmitter (in meters)**		
	From 150 kHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$	From 80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$	From 800 MHz to 2 GHz $d = 2{,}3 \cdot \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance "d" in meters 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 watt according to the transmitter manufacturer.

Remarks:

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

11 Appendix

11.1 Appendix A – Approvals

The unit is manufactured in compliance with the provisions of Council Directive 93/42/EEC concerning medical devices.

11.2 Appendix B – Label positions

The following figures show the positions of the labels on the SIROLaser.

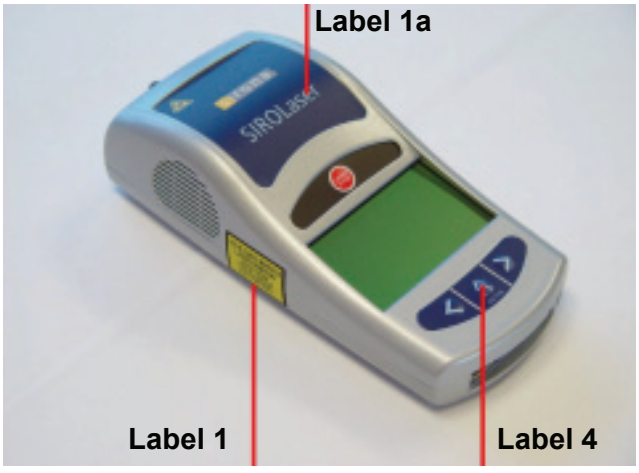


Figure 26: Label positions, top view

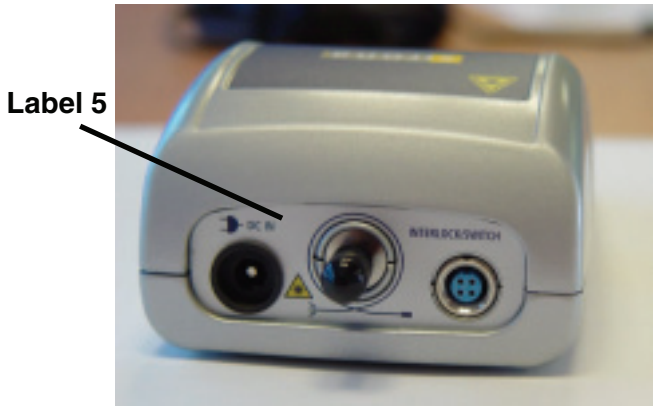


Figure 27: Label position, rear view

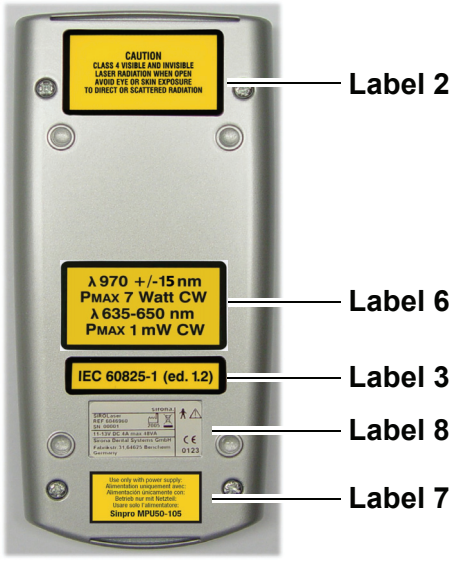
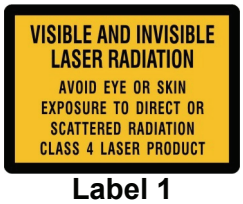


Figure 28: Label positions, bottom view

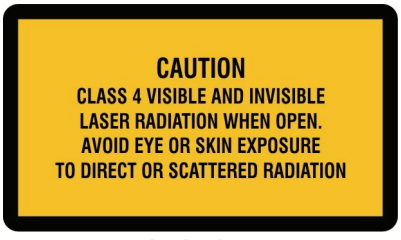
B2 – Label list

The following labels are attached to the SIROLaser:

Label 1a



Label 1



Label 2

Label 3

Label 4

Label 5

Label 6

CU[1]

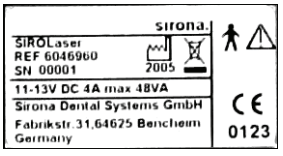
NU[1]

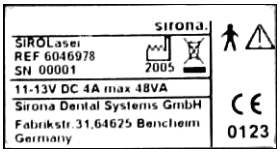
SA[1]

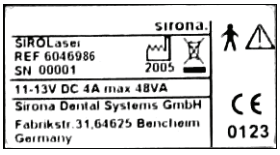
1. *Software extention (CU, NU, SA)*

Label 7

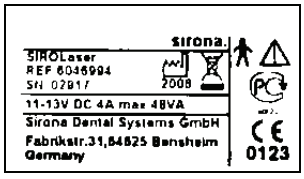
CU, NU, SA[1]







GUS[1]



1. *Software extention (CU, NU, SA)*

Label 8

We reserve the right to make any alterations which may be required due to technical improvements.

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