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SIROLaser Advance

Operating Instructions

English



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1 General information

1.1 Dear Customer

We are pleased that you have equipped your practice with the SIROLaser Advance.

You now possess a therapy device that features diode laser technology. This device is characterized by a wide range of application. It can be used as rather pain-free therapy or as an extension to the conventional treatment. A high number of therapies are already preset. According to your approach you can change settings or put on also own treatment programs. The activation of the laser can occur alternatively about the finger switch at the handpiece or optional wireless foot switch.

These Operating Instructions are designed to assist you prior to initial use and whenever you require information later on. It is important to observe all safety information to prevent personal injury and material damage. Please perform maintenance and cleaning based on the corresponding instructions.

We wish you much success and pleasure with the SIROLaser Advance.
Your SIROLaser Advance Team

1.2 Contact data

Customer Service Center

Our German and English speaking Product Service staff are ready to answer your technical questions by telephone from 7:30 a.m. to 5:30 p.m. CET. Outside of these hours you can always contact us by fax or e-mail.

Phone: +49 (0) 6251/16-1670
Fax: +49 (0) 6251/16-1818
E-mail: product.service@sirona.de

To ensure that your correspondence is processed immediately, please specify the "Instruments Division" in the subject line of your e-mail or fax.

Manufacturer's address

Sirona Dental Systems GmbH
Fabrikstrasse 31
64625 Bensheim
Germany

Phone: +49 (0) 6251/16-0
Fax: +49 (0) 6251/16-2591
E-mail: contact@sirona.com
www.sirona.com

1.3 General information on the Operating Instructions

Observe the Operating Instructions

Please familiarize yourself with the SIROLaser Advance by reading through these Operating Instructions before putting it into operation. It is essential that you comply with the specified warning and safety information.

Keep documents safe

Always keep the Operating Instructions handy in case you or another user require(s) information at a later point of time. To this product belong even more documentations.

In case you sell the unit, make sure that the Operating Instructions and all other technical documents are attached to it so that its new owner can familiarize himself with its functioning and the specified warning and safety information. The technical documents are a component of the product.

Help

If you reach an impasse despite having thoroughly studied the Operating Instructions, please contact your dental depot.

1.4 Intended use

The SIROLaser Advance is developed as a table top laser device for:

- surgery and coagulating of soft oral tissue
- germ reduction in endodontics
- germ reduction in periodontics, incl. periimplantitis
- desensitization of tooth neck

All patients coming to a dental office or clinic and needing a treatment that can be done or supported by the use of a diode laser can be treated with the SIROLaser Advance. For indications for use refer to chapter "Indications, contraindications and medical precautions".

The use of the SIROLaser Advance is not appropriate in an OT.

1.5 Formats and symbols used

The symbols and character formats used in the present manual have the following meaning:

Instructions for action

✓ Prerequisite 1. First action step 2. Second action step or > Alternative action ↪ Result, reaction of SIROLaser Advance	Prompts you to do something.
--	------------------------------

References

See "General information".	Identifies a reference to another text passage.
[→ 8]	Indicates the page being referred to.

Lists

• List	Designates a list.
--------	--------------------

Designations

'Designation'	Denotes key and button
---------------	------------------------

2 Safety information

2.1 Identification of danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in this document. Such information is highlighted as follows:



WARNING

Warning of bodily injury

For an possible danger that could result in light to serious bodily injury or death.



CAUTION

Caution against damage

For a possibly harmful situation which could lead to damage of the product or an object in its environment.

NOTICE

Information to make work easier

For application information and other useful information.

2.2 Standards and regulations

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

- compliance with IEC 60825-1 and its amendments,
- compliance to CAN/CSA-Z386-92 "Laser safety in health care facilities" (only for Canada) as well as
- observance of any supplemental national laws and regulations.

Public legal requirements may include special safety regulations concerning protection against laser radiation. These requirements must be fulfilled.

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

National directives regarding electrical installations must be observed.

2.3 Operating personnel

Qualification/education

The SIROLaser Advance may only be operated by educated and qualified personnel (dentist, assistant, dental hygienist). The applicable occupational safety regulations and accident prevention measures, the current operating instructions and national requirements concerning education must be complied with.

Know-how

Know-how and expertise about laser therapy as well as the skilled use of the laser and the applied indications are required. Please refer to applicable country-specific requirements.

Experience

Sirona recommends to gain practical experience in laser dentistry before first use of the SIROLaser Advance by attending an appropriate training. Amongst others Sirona offers trainings. Please see the Sirona homepage (www.sirona.com).

Obligation of the user

Users are obliged to use only faultless materials, to ensure correct application and to protect themselves, the patient and other persons against hazards.

Unauthorized access

In order to prevent false or improper use, the SIROLaser Advance must not be used by unauthorized persons. Therefore the SIROLaser Advance equipment must be protected against unauthorized access when not in use. This can be achieved, for example, by switching the SIROLaser Advance off following use so that the electronic access key (pin code) must be entered before using it again.



WARNING

The SIROLaser Advance may only be used and maintained by thoroughly trained personnel.

2.4 Physical working principle

The 970 nm laser radiation of the SIROLaser Advance is generated via a laser diode inside the control unit and guided to the treatment region via quartz fibers. The laser radiation is absorbed by the tissue and converted to heat used for cutting, coagulation, germ reduction and desensitization.

2.5 Laser radiation hazards

Never direct the laser or aiming beam toward a person's eye! All persons present in the room (patient, dentist and assistant) must always wear the laser protective goggles.

Observe all labels on the SIROLaser Advance.

Master switch of the practice

Note that after switching off the master switch of the practice the SIROLaser Advance will still be switched on. Then it is energized by the rechargeable battery.

Emergency stop

In case of an emergency press the "Laser Stop" button below the touch screen on the front side of the SIROLaser Advance control unit.

Settings

Failure to use the settings specified in this manual or perform the actions described here may lead to a dangerous exposure to radiation.

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.

Flammable materials

Never direct the laser beam toward paper, plastics or objects with dark surfaces. They could catch fire due to the high temperatures produced by the laser beam.

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

Oxygen-saturated materials such as cotton wool can catch fire owing to the high temperature that the unit reaches during operation. Label removers and flammable solutions used for cleaning and disinfecting the SIROLaser Advance should be allowed to evaporate before using the device. Observe fire hazards caused by flammable gases.

Reducing the risk of burns

If any tissue is unintentionally irradiated, this may lead to burns. This risk can be reduced by surrounding the target area with moistened sterile drapes or gauze doused in salt. These covering materials must meet the requirements of laser surgery.

A extractor or a filter should be used. The operating personnel should be aware that biologically active material could get into the environment. It may contain particles of viable tissue.

2.6 Nominal ocular hazard distance

The nominal ocular hazard distance (NOHD) from the distal end of the optical fiber is 1.5 m.

2.7 Laser protective goggles

All persons present in the room (patient, dentist and assistant) must always wear the laser protective goggles delivered along with the SIROLaser Advance.

Check before use

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. Make sure that the laser protective goggles:

- are not damaged
- conform to standard EN 207 with protection level L5
- 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 Advance.

Optical instruments

Never use optical instruments such as microscopes, eye loupes or magnifiers together with the original protective goggles. Otherwise sufficient eye protection can no longer be ensured.

2.8 Optical fiber and single-use tip

Optical fiber and connection socket

Make sure that no dust, dirt and foreign particles can enter the optical fiber socket or the optical system. Never place your finger or any other objects in the optical connectors. Otherwise the unit may be permanently damaged.

When disconnecting the optical fiber from the SIROLaser Advance, always cover the connection socket with the special protection cap supplied. Make sure that the optical system is clean before connecting the optical fiber.

The optical fiber must not be twisted. There is a risk of breakage.

Single-use tips

Switch the SIROLaser Advance off immediately if the optical fiber is broken. Otherwise the single-use tips may become hot.

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

2.9 Contamination

Accessories

Danger of (cross) contamination. Pay attention not to hurt or stick yourself or any other person with the laser fiber or the tip. This applies also, if the handpiece is placed in the holder.

Prior to each use, the handpiece sleeve and the optical fibers must be sterilized.

Tissue particles

By cutting and coagulation of tissue, tissue particles could get into the air. Always wear a face mask, because a risk of infection exists.

A extractor or a filter should be used. The operating personnel should be aware that biologically active material could get into the environment. It may contain particles of viable tissue.

2.10 Installation

Location

The SIROLaser Advance is to be protected against the intrusion of liquids.

The SIROLaser Advance must not be used in areas, in which the appearance of liquids is probable.

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

Do not place the unit near heat sources. Do not cover the convection openings for air cooling on the sides of the unit.

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

Avoid interference between the laser emission and any optical sensors of devices operated in the vicinity of the SIROLaser Advance.

National directives regarding electrical installations must be observed.

Set up

Set up the SIROLaser Advance unit properly and completely before putting it into operation, see chapter "Installation" [→ 23].

Functional Check

The system owner is obliged to use only technically faultless products. Please check the unit for proper functioning before putting it into operation. In case of unusual noises, check both the unit and the handpiece. If the unit has fallen down, have it checked by qualified technical personnel.

To prevent the unit being accidentally pulled from the table, the handpiece hose should never be under tension. Please always ensure that ca. 40 cm of the handpiece hose hangs.

If there is any doubt about the correct function of the switching power supply or the correct electric power supply (wall outlet) the unit may only be used with internal electric power supply (battery).

Do not use the SIROLaser Advance if a visual inspection shows that it has been damaged.

2.11 Modifications

General product safety

As manufacturers of dental medical equipment and in the interest of the operational safety of your system, we stress the importance of having maintenance and repair of this product performed only by Sirona Dental Systems GmbH or by agencies expressly authorized by us. Furthermore components must always be replaced with original Sirona spare parts upon failure. When having such work done, we suggest that you request a certificate stating the type and extent of work performed, including information about any modifications of the rated parameters or of the operating ranges (if applicable), as well as the date, name of organization and signature. Please use a fault circuit interrupter to connect this system to the electrical line power supply. Modifications to this system which might affect the safety of the system owner, patients or other persons are prohibited by law! For reasons of product safety, this product may be operated only with original Sirona accessories or third-party accessories expressly approved by Sirona. The user is responsible for any damage resulting from the use of non-approved accessories.

It is not permitted to modify the design or construction of the unit.

Maintenance

The unit must be checked and maintained at regular intervals, as described in chapter "Maintenance and service".

Damages

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

Never under any circumstances try to disassemble the SIROLaser Advance. This is limited exclusively to trained and authorized personnel.

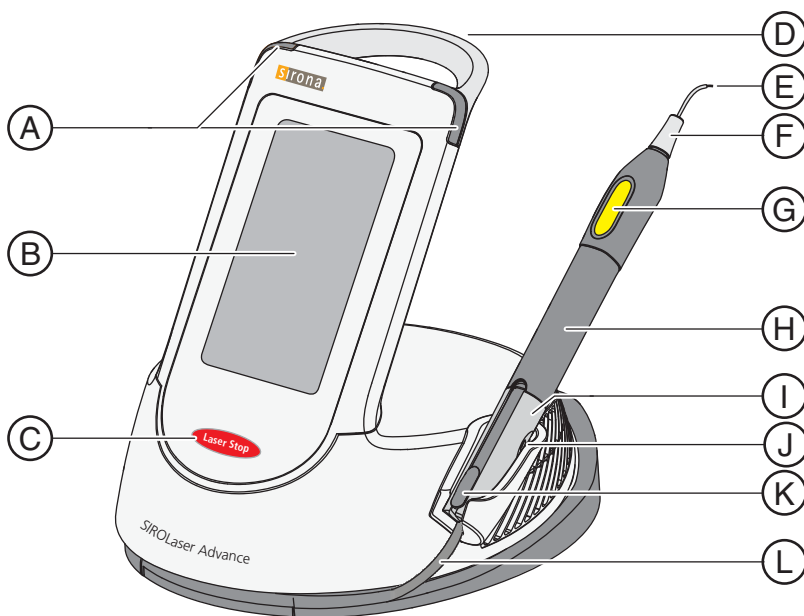
2.12 Cellular phones

Portable and mobile RF communications equipment may interfere with medical electrical equipment. Therefore, the use of mobile wireless phones in medical office or hospital environments must be prohibited.

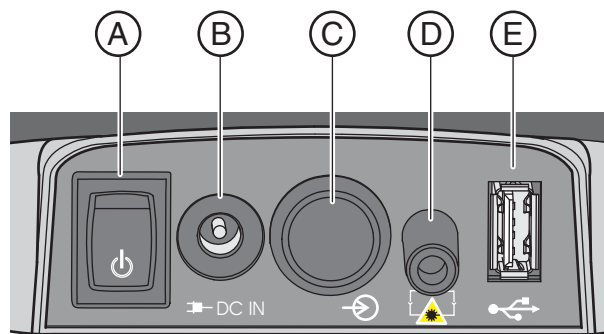
3 System description

3.1 System overview

SIROLaser Advance (Control unit)

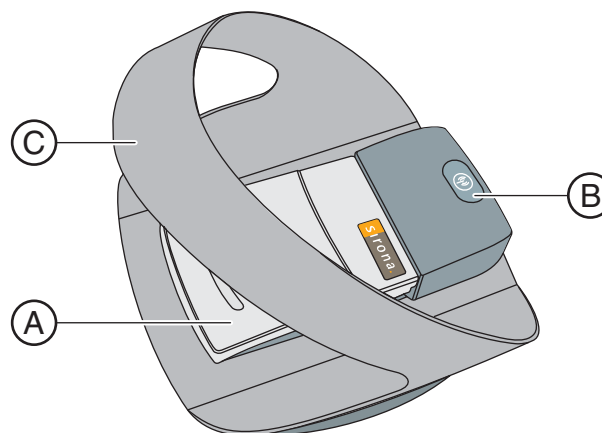


A	LED lights
B	Touch screen
C	Laser Stop key
D	Carry handle
E	Optical fiber
F	Single-use tip
G	Finger switch
H	Handpiece sleeve
I	Handpiece back-sleeve
J	Snap tabs
K	Fiber length adjustment
L	Cable for optical fiber and wires



A	ON/OFF switch
B	Power supply socket
C	Input for energy and signals
D	Interlock connector including interlock connector bridge
E	USB port

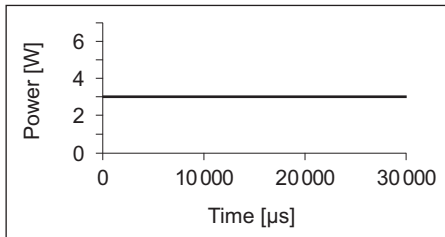
Wireless foot control – optional



A	Foot switch
B	Registration key
C	Safety and positioning bar

3.2 Laser operation modes

Continuous wave mode (CW)

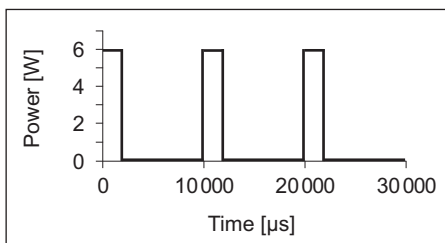


CW implies a continuous, uninterrupted laser beam as long as the laser is activated (and determined by a time set). This means a very good power control since the maximum power equals the average power.

In adjacent example the laser is in CW mode with a power of 3 W.

Chopped mode

in literature sometimes also called "pulse mode"

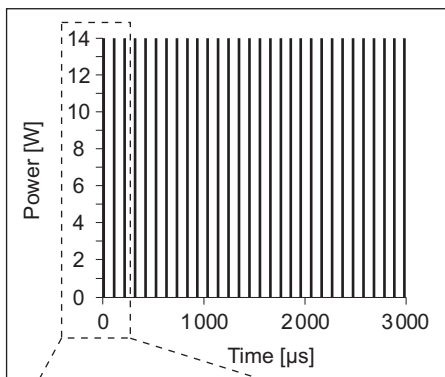


The laser beam is interrupted at regular intervals (e.g. 50% ON and 50% OFF) which can be adjusted via the duty cycle. The average power is the product of power and duty cycle.

The result is a better thermal control due to the fact that the OFF periods are used for thermal relaxation of the tissue.

In adjacent example the laser is in chopped mode with a power of 6 W and a duty cycle of 20%. The average power is 1.2 W.

Peak-pulse mode

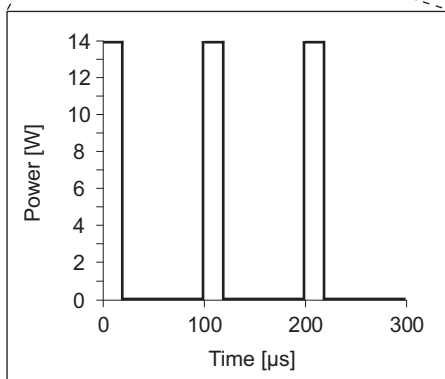


The laser beam is pulsed with a high peak (14 W) for a very short treatment puls (20 μs) at a very high frequency (20 kHz) to achieve a longer cooling time. So the duty cycles are reduced.

In adjacent example the laser is in peak-pulse mode with a power of 14 W and a duty cycle of 20%. The average power is 2.8 W.

NOTICE

The average power may not exceed 6 W in peak-pulse mode.



3.3 Symbols and abbreviations

3.3.1 Symbols



Type B applied part according to IEC 60601-1



CE mark in accordance with Council Directive 93/42/EEC, stating the manufacturer's Notified Body. Verifies the compliance of the SIROLaser Advance

USA ONLY
Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50 dated June 24, 2007

This label stands for device compliance with FDA laser product performance standard



This label stands for device compliance with FDA laser product performance standard



This label stands for meeting the requirements of the Canadian Standards Association (CSA)



This label stands for certification of the device according to GOST R. Thereby it fulfills the statutory regulations for Russia.



Date of manufacture: month-year



Best before date – Do not use after: month-year



Batch number: consecutive number / month / year

SN

Serial Number

REF

Reference number



Please refer to manual first (IEC 60601-1 3rd ed.)



Please refer to manual first (IEC 60601-1 2nd ed.)



Power switch (on the backside of the control unit)



On/Off (on the switching power supply)



Connection socket for DC input from Sinpro MPU100-106 power supply



Input for energy and signals (reserved, not used yet)



Connection socket for interlock



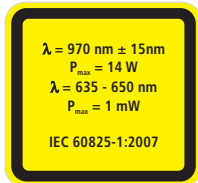
Connection socket for USB



Interference is possible in the vicinity of the device



Laser radiation warning



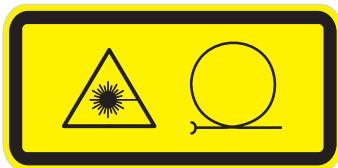
Specification of laser output power and wavelength of IR and aiming beam, see also chapter "Technical data" [→ 20].



Warns of potential laser radiation hazards when opening the laser unit.



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



Warns of laser radiation emission at the distal tip of the handpiece.



Warns of laser radiation hazards when the fiber connector is unscrewed.



"Laser Stop" key: press this button in case of an emergency



Operate the unit exclusively with the Sinpro MPU100-106 power supply



The disassembled handpiece sleeves and the fibers may be sterilized only in autoclaves with saturated water vapor at minimum sterilization values of 134°C (273.2°F), 3 min. holding time and 2.04 bar (29,59 psi) overpressure.



Single use only for the bendable tip



Refers to directive 2002/96/EC and EN 50419
 Do not dispose with domestic waste

3.3.2 Abbreviations

NOHD	Nominal ocular hazard distance	kV	Kilovolt
CW	Continuous Wave	VA	Volt-ampere
PF	Pulsed Frequency or Chopped Mode	V _{eff}	Effective voltage
PP	Peak-Pulse	U _T	Threshold voltage
cont.	continuous	V/m	Volt per meter
approx.	approximately	mA	Milliampere
IR	Infrared diode	A/m	Ampere per meter
g	Gram	mW	Milliwatt
kg	Kilogram	W	Watt
µs	Microseconds	P	Power
ms	Milliseconds	P _{max}	Maximum power
s	Seconds	J	Joule
µm	Micrometer	RF	Radiofrequency
nm	Nanometer	Hz	Hertz
mm	Millimeter	kHz	Kilohertz
cm	Centimeter	MHz	Megahertz
m	Meter	GHz	Gigahertz
WxLxH	Width x length x height	hPa	Hectopascal
DC	Direct current voltage	kpsi	Kilo-pound-force per square inch
AC	Alternating current voltage	db/km	Decibels per kilometer
mV	Millivolt	°C	Degree Celsius
V	Volt	°F	Degree Fahrenheit

3.4 Technical Data

General

Beam guide:	Flexible quartz glass fiber
Display:	Full color, graphical LCD touch screen
Cooling:	Internal air cooling controlled by output
Temperature switch:	Software temperature switch at 48° C
Door contact connection:	Potential-free contact 5 VDC/20 mA (TTL)
Dimensions (W x L x H):	182 x 197 x 189 mm
Weight:	approx. 1300 g (incl. handpiece and rechargeable battery)

SIROLaser Advance specification

Laser type:	Diode laser
Wavelength:	970 nm ± 15 nm
Laser system:	Class IV (according to IEC 60825-1)
Device classification:	Class IIb (according to Council Directive 93/42/EEC)
Optical power:	approx. 0.5 - 7.0 W (CW)
Optical peak power:	approx. 14 W (diode)
Emission modes:	CW (continuous wave), chopped 1 Hz to 10 kHz, peak-pulse approx. 1.5 kHz - 20 kHz
Pulse:	repeated pulse
Pulse duration:	Chopped mode: 10 µs - 0,99 sec. Peak-pulse: 23 µs fixed
IP degree of protection:	Laser unit: IP20; wireless foot control: IPX5 (according to EN IEC 60601-1)
Aiming beam:	635 - 650 nm, max. 1 mW
NOHD:	From the distal end of the optical fiber: 1.5 m
Optical fiber thickness:	200 and 320 µm
Operation:	Electrical wireless foot control or finger switch, with electronic access key
Nominal power input:	15 V DC 6.66 A max. 100 VA MPU100-106
Insulation class:	Class I, type B (according to IEC 60601-1)
Adapter:	External, 100 - 240 VAC, 50 - 60 Hz
Power supply:	The SIROLaser Advance may only be operated with the Sinpro MPU100-106 power supply.

Optical fibers specification

Optical fiber diameters:	200 µm fiber	320 µm fiber
Core diameter:	200 µm	320 µm
Cladding diameter:	240 µm	385 µm
Coating diameter:	270 µm	408 µm
All diameters \pm 20%		

Optical fiber length:	200 µm fiber: 170 \pm 30 mm 320 µm fiber: 160 \pm 30 mm
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Minimum transmission efficiency at related wavelength:	The optical fiber material has an attenuation of around 1 dB/km @970 nm
--	---

Maximum transmission power:	100 kW/mm ² (Nd:YAG, cw at 1060 nm)
-----------------------------	--

Numerical aperture:	\geq 0.22
---------------------	-------------

Tensile strength:	70 kpsi
-------------------	---------

Wireless foot control

Frequency:	2.4 GHz - 2.4835 GHz (ISM band)
Transmitting power:	< 2 mW (short-range device)
Modulation type:	Multi-dimensional Multi Access (MDMA)
Battery:	Type AAA, 1.5 V

Transport and storage

The SIROLaser Advance comes in a cardboard box that ensures proper and easy transport.

CAUTION

Do not leave the SIROLaser Advance in a vehicle parked in the sun. The inside temperature of the car could thus heat up to a point where individual components may be damaged.

To ensure appropriate storage, the device must always be kept in the box supplied by Sirona Dental Systems.

Thus stored, the SIROLaser Advance can withstand the following ambient conditions:

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

NOTICE

The rechargeable battery must be fully charged regularly. After six months of no charging (storage) the rechargeable battery might lose its loading capacity and might not be rechargeable anymore.

In its original transport packaging, the SIROLaser Advance can withstand the following ambient transport conditions:

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

Operating conditions

The SIROLaser Advance may be operated in the following environmental conditions:

- Temperatures from +10° C to +33° C
- Relative humidity from 10% to 95%
- Atmospheric pressure from 800 hPa to 1060 hPa



CAUTION

Following transport and storage, let the SIROLaser Advance adapt to room temperature for about one hour prior to operation to reduce the risk of malfunctions caused by condensation.

4 Installation

Any national or local regulations stipulating that the SIROLaser Advance may be installed only by trained personnel must be strictly observed.

4.1 Scope of supply

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

	Order-No
SIROLaser Advance	see below
1 x SIROLaser Advance control unit including handpiece with integrated finger switch	
1 x Additional handpiece sleeve for alternating operation	
1 x Set of fibers, 5 x 200 µm and 5 x 320 µm	
1 x Fiber cutter	
100 x Single-use tips including 1 x Bending tool	
1 x Rechargeable battery (already mounted)	
2 x Laser protective goggles for operator and assistant	
1 x Laser protective goggles for patients	
1 x Switching power supply	
1 x Transport packaging	
Language-specific documentation set, e.g. User Manual	
Country-specific power cable	see „Spare parts“ [→ 24]
Option: Wireless foot control	62 56 841

SIROLaser Advance Order-No for the following countries:

	Order-No
Germany, Austria	62 56 783
Switzerland	62 58 441
Netherlands, Belgium	62 58 425
France	62 58 482
England	62 58 490
Denmark	62 58 458
Finland, Norway, Sweden	62 58 474
Italy	62 58 508
Spain	62 58 466
Portugal	62 58 516
Australia	62 58 417

Russia	62 58 532
Canada	62 58 433

Further countries on request.

4.2 Spare parts

	Order-No
Handpiece sleeve for alternating operation	62 56 767
Handpiece back-sleeve, stainless steel	62 56 817
Set of fibers, 5 x 320 µm	62 56 759
Set of fibers, 5 x 200 µm	62 56 742
Package of single-use tips (100 pcs.) incl. bending tool	62 56 692
Fiber cutter	60 91 669
Laser protective goggles, transparent	61 81 585
Laser protective goggles for spectacle wearers, transparent	61 81 593
Laser protective goggles for patients, transparent	60 47 745
Rechargeable battery	62 56 833
Switching power supply	62 56 718
Power cord EU	62 58 581
Power cord IT	62 58 607
Power cord GB	62 58 599
Power cord US	62 58 615
Power cord AUS	62 58 565
Power cord DK	62 58 573
Power cord CH	62 69 554

4.3 Labels

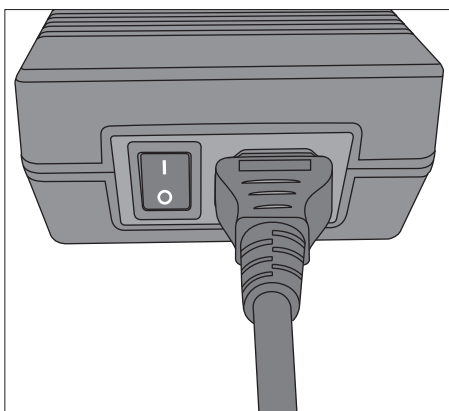
Attach the appropriate language-specific labels (1 and 2) to your laser unit. For more information on the labels and their position, refer to "Appendix B - Label positions" [→ 77].

4.4 Initial start-up – procedure for proper assembly

Any national or local regulations stipulating that the SIROLaser Advance may be installed only by trained personnel must be strictly observed.

1. Install power supply
2. Assemble handpiece, optical fiber and single-use tip
3. Install wireless foot control – optional
4. Install remote interlock – optional
5. Start SIROLaser Advance for the first time

4.4.1 Install power supply



1. Connect the power cable to the DC IN socket at the back of the SIROLaser Advance.
2. Please make sure to switch on the switching power supply.
↳ The green LED on the power supply lights up.

CAUTION

The SIROLaser Advance may only be operated with the Sinpro MPU100-106 power supply. Operation with other power supplies may result in failure or destruction of the laser unit. If any power supply other than the one recommended is used, the approval of the entire unit automatically becomes void and the warranty granted by Sirona Dental Systems GmbH expires.

The use of any power supplies other than the one recommended may cause overheating and failure of the laser unit or damage of batteries.

The SIROLaser Advance is supplied with a rechargeable battery and therefore can be used without connected power cable. The status of the rechargeable battery and whether the power cable is actually connected will be always displayed on the touch screen.

NOTICE

There will be a warning if the rechargeable battery will reach a low level of capacity.

The SIROLaser Advance is fully functional and can be run while charging the battery.

- Charge the battery completely.

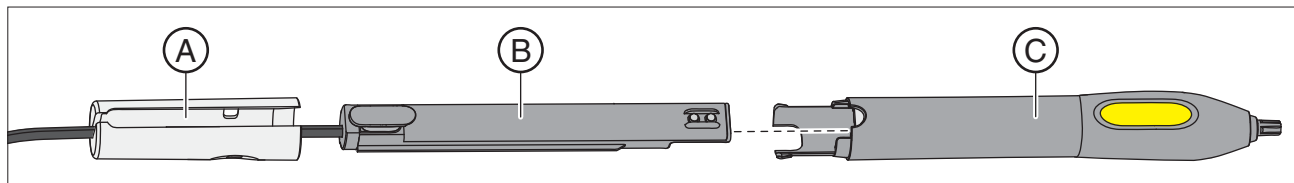
NOTICE

The rechargeable battery must be fully charged regularly. After six months of non-charging the rechargeable battery might reduce its loading capacity.

4.4.2 Handpiece, single-use tip usage and assembly of optical fiber

4.4.2.1 Handpiece

The handpiece consists of three parts:



A	Stainless steel handpiece back-sleeve
B	Handpiece body with tube
C	Handpiece sleeve

4.4.2.2 Single-use tip usage

1. Please sterilize the single-use tip before use.
2. Attach the single-use tip firmly on the handpiece prior to mounting the optical fiber.
3. After having mounted the optical fiber bend the single-use tip with the bending tool to the angle that you need for best handling and depending on the treatment.

WARNING

Do not move the fiber in the single use tip after having bent the tip, risk of fiber damage!

Always use the tip with the fiber and check for the correct fixation.

If the optical fiber does not protrude at least 1 cm out of the single-use tip, there is a risk that the single-use tip will heat up.

Do not move the fiber in the tip.

Do not resterilize the single use tips.

To avoid the risk of damaging optical fibers use only Sirona single-use tips. Also make sure that the single-use tips are only bent with the bending tool when the optical fiber is already mounted.

CAUTION

Check whether the single-use tip is damaged before attaching it. Replace it if necessary.

Please check that the single-use tip is firmly attached prior to each use.

4.4.2.3 Optical fiber assembly

4.4.2.3.1 Area of application

The SIROLaser Advance is provided with two types of optical fibers of different diameter so that it can be used for a variety of different dental procedures and indications:

- Optical fiber, 200 µm
- Optical fiber, 320 µm

The optical fiber is delivered in a special transport and sterilization tube which also assists the mounting of the optical fiber.

The optical fibers can be used only with the SIROLaser Advance in the spectral range of 970 nm ± 15 nm.

If optical fibers from other manufacturers are used, physical properties such as load carrying capacity and transmission behavior may vary. Sirona Dental Systems GmbH therefore assumes no liability in such cases.

Therefore, use only Sirona optical fibers.

4.4.2.3.2 Initial use of an optical fiber

Initial check

Before using an optical fiber for the first time, check its best-before date. An 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 capacity and transmission behavior, may change, thus posing a hazard to the health of the patient, the dentist and the dental assistant.

Do not use the optical fiber if its packaging is damaged or the best-before month has been exceeded.

After taking the optical fibers out of the transport and sterilization tube, perform a visual check to make sure that they were not damaged during shipment.

Initial startup

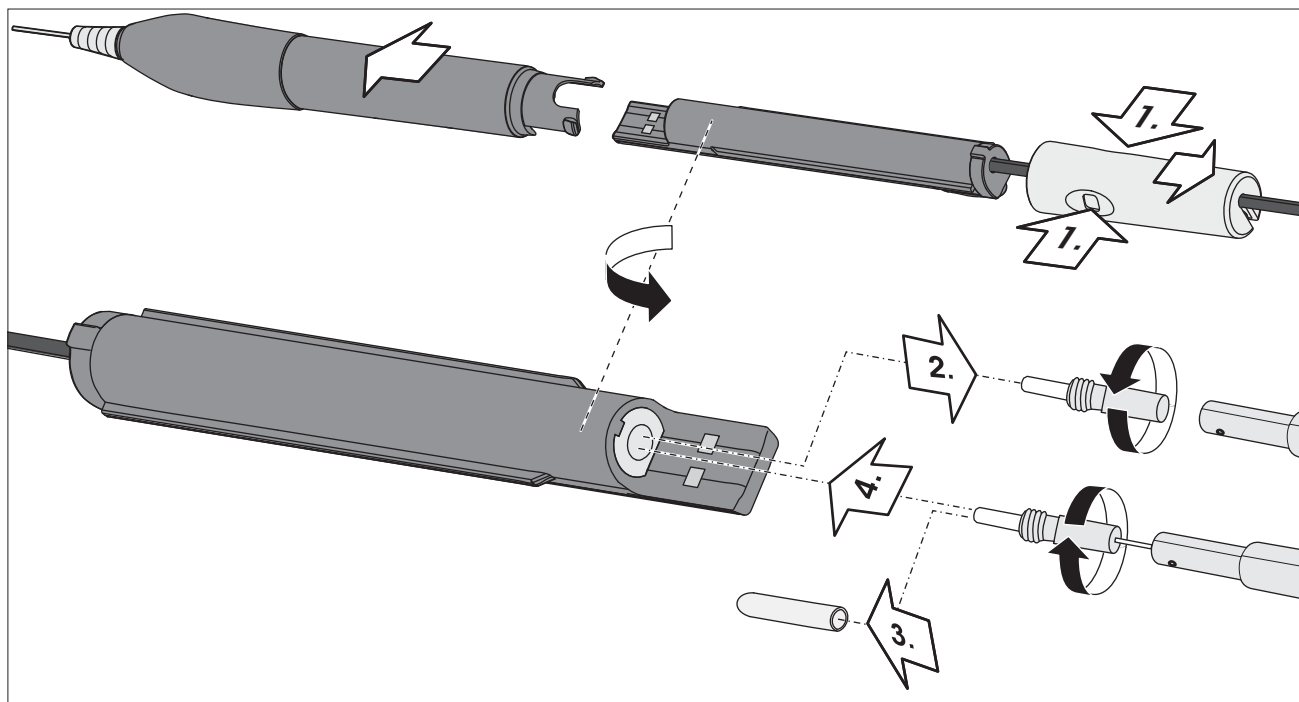
The optical fibers are supplied in non-sterile condition.



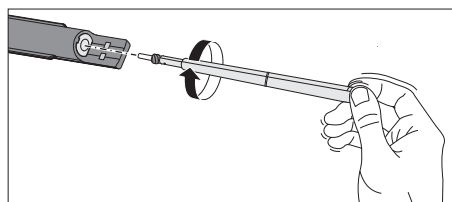
WARNING

The optical fiber must be disinfected and sterilized prior to initial use.

Screwing on the optical fiber

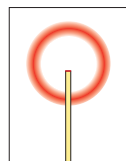


1. Open handpiece by pressing both snap tabs and pull apart the handpiece sleeve from the handpiece body.
2. Remove the protection screw from the handpiece body by using an empty transport and sterilization tube.
3. Remove the protective cap from the optical fiber.
4. Insert the optical fiber into the handpiece and screw it on. Tighten the optical fiber only slightly so that it can be loosened with the transport and sterilization tube again with ease. Make sure not to overwind the transport and sterilization tube!
5. Remove the transport and sterilization tube from the optical fiber.
6. Put the laser into operation by choosing any preset treatment. A corresponding description is provided in chapter "Operation".

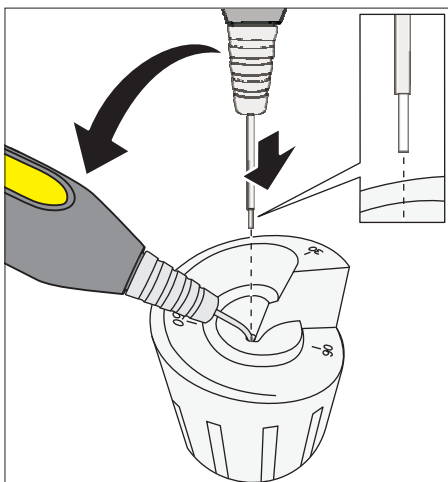
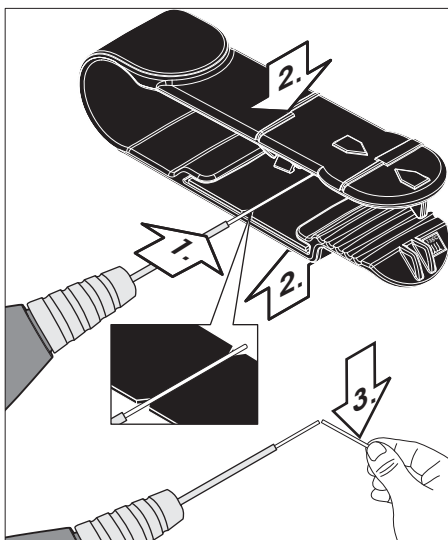


WARNING

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



7. As soon as the SIROLaser Advance is ready you can check to make sure that the aiming beam illuminates evenly, i.e. projects a circular light pattern (see adjacent picture). To do this, aim the optical fiber vertically at a white background located approx. 5 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 optical fiber to your dental depot so that it can be replaced under warranty. Do not use any defective optical fibers.**



8. If the aiming beam projects a uniform circular beam pattern, remove the distal seal with the fiber cutter, see chapter „Adjusting the optical fiber with the fiber cutter“ [→ 31]. Any liability of the manufacturer regarding mechanical damage to the optical fiber is thereby canceled.
9. Insert the handpiece body back into the handpiece sleeve making sure that the optical fiber slides easily through the single-use tip. Also check if the snap tabs have clicked into their rests.
10. Now you can insert the single-use tip and the optical fiber into the bending tool and bend the single-use tip to the angle that you need for best handling.

After treatment

Please bend back the single-use tip as straight as possible before moving the fiber within the single-use tip.

As soon as you disassemble the optical fiber after treatment make sure to protect the optical fiber socket and the optical fiber with the protective caps provided for this purpose.

For cleaning, disinfecting and sterilizing the optical fiber please refer to chapter "Cleaning, disinfection and sterilization" [→ 62].



CAUTION

Cover the optical fiber socket and the optical fiber with the special protective caps provided for this purpose after every treatment. Prevent dust, dirt and foreign particles from entering the optical fiber socket. Make sure that the optical system is clean before connecting the optical fiber.

Make sure that no dust or dirt can enter the optical fiber socket or the optical system. Otherwise the unit may be permanently damaged.

If the optical fiber is moved in a bent single-use tip the surface of the optical fiber may be destroyed (danger of optical fiber breakage).

4.4.2.3.3 Preparation for clinical application

1. Select the required optical fiber (200 µm or 320 µm), see chapter „List of preset indications“.
2. Make sure that the optical fiber is clean and sterile. Handpiece sleeve and the stainless steel handpiece back-sleeve can be cleaned in the autoclave (high-pressure sterilizer), see chapter "Cleaning, disinfection and sterilization" [→ 62].



WARNING

Use of the laser unit when the aiming beam is not functioning properly may cause injuries to operating personnel, assistants or patients. If you cannot see the red aiming beam after switching the laser on or during treatment refer to chapter "Troubleshooting of simple defects" [→ 66].

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 optical fiber must be cleaned, disinfected and sterilized prior to every treatment.

Remove the protection caps for treatment only.

Never touch the proximal end of the ferrule and protect them against damage and dirt.

Never use the laser without fiber, check for correct fixation.

Never bend, fold or jam the optical fiber, as this might cause it to break.

The single-use tip must never be bent without the bending tool.

Never pull on the optical fiber.

Bear in mind the maximum bending radius of the optical fiber:

- Short-term (during treatment): 100 x radius of optical fiber
- Long-term (during storage): 600 x radius of optical fiber

Mounting the optical fiber:

1. Open handpiece by pressing both snap tabs and pull apart the handpiece sleeve from the handpiece body.
2. Remove the protection screw from handpiece body by using the transport and sterilization tube.
3. Remove the protective cap from the optical fiber.
4. Insert the optical fiber into the handpiece and screw it on. Tighten the optical fiber only slightly so that it can be loosened with the transport and sterilization tube again with ease. Make sure not to overwind the transport and sterilization tube!
5. Remove the transport and sterilization tube from the optical fiber prior to mounting the handpiece sleeve on the handpiece body.
6. Attach a single-use tip on the handpiece sleeve.



CAUTION

Check whether the single-use tip is damaged before attaching it. Replace it if necessary.

Please check that the single-use tip is firmly attached prior to each use.

7. Insert the handpiece body back into the handpiece sleeve making sure that the optical fiber slides easily through the single-use tip. Also check if the snap tabs have clicked into their rests.
8. Trim the end of the optical fiber with the fibercutter until the light of the aiming beam projects an uniform circular pattern, see chapter „Adjusting the optical fiber with the fiber cutter“ [→ 31]. To do this, aim the optical fiber vertically at a white background located approx. 5 cm away. If the probe projects no pattern at all or only an uneven pattern, cut off one to two millimeters. Always make the notch perpendicular to the optical fiber.



WARNING

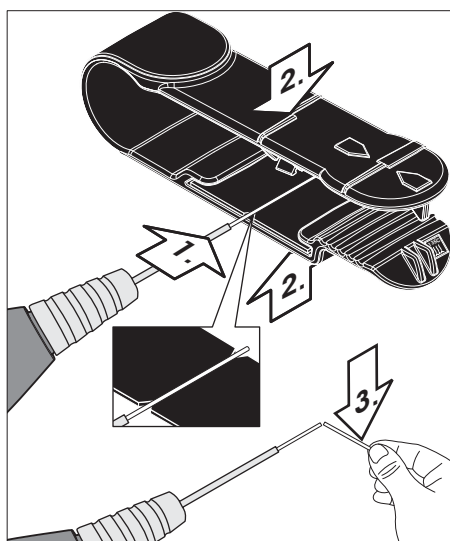
If the optical fiber does not protrude at least 1 cm out of the single-use tip, there is a risk that the single-use tip will heat up.

4.4.2.3.4

Adjusting the optical fiber with the fiber cutter

1. Place the optical fiber in the fiber cutter at the notched mark.
2. Press the fiber cutter together.
3. Bend the optical fiber at the notched location.
 - ↳ The optical fiber breaks at the notched location with a smooth, perpendicular fracture surface.

Check to see if the light of the aiming beam projects a uniform circular pattern. To do this, aim the optical fiber vertically at a white background located approx. 5 cm away. If the probe projects no pattern at all or only an uneven pattern, cut off another one to two millimeters.



NOTICE

Press firmly but do not squeeze the optical fiber. You just need a little notch to receive a perfect result when breaking the fiber at the notch.

4.4.3

Install wireless foot control – optional

The SIROLaser Advance can be operated using the finger switch (which is integrated in the handpiece) as well as by using the optional wireless foot control.

NOTICE

The foot switch has an IPX5 degree of protection. Therefore this foot switch must not be used in hospital operating rooms.

Technical data of the wireless foot control, see chapter Technical Data, "Wireless foot control".

The wireless foot control must be assigned to the SIROLaser Advance via a registration. This prevents malfunctions caused by neighboring wireless controls.



- ✓ The SIROLaser Advance control unit and the wireless foot control are ready for operation.
- 1. Choose in main home screen the item "Set-up".
- 2. Choose there the item "Activation device".
- 3. Choose the "Wireless registration".
- 4. Follow the instructions in the note window and press first the foot switch for three seconds.
- 5. After this press the registration key on the top of the wireless foot control radio box for three seconds.
 - ✎ After release of the registration key the note window disappears.
This means the wireless foot control is activated.
- 6. To use the wireless foot control, choose in submenu "Set-up" in "Activation device" the wireless foot control.

NOTICE

The finger switch is pre-set.

4.4.4 Install remote interlock – optional

Explanation

The interlock is a safety device that stops laser radiation whenever the door of the treatment room is opened. The interlock circuit must be connected to a switch that is located near the door of the treatment room in order to ensure automatic interruption of the laser emission.

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 Advance is connected.

NOTICE

Additional or different safety precautions required by the applicable national or local regulations for the protection of dentists, assistant personnel, or patients must also be observed.

Installation of an interlock with door switch

1. Prepare the interlock plug by connecting the interlock cable with the interlock plug and by opening the bridge. Please find the technical data sheet with circuit diagram for the installation of the interlock circuit in "Appendix C" [→ 79].
2. Mount the prepared interlock plug into the interlock socket on the backside of the SIROLaser Advance.

5 Operation

5.1 Start the device for the first time

NOTICE

Touch screen functionality: When the touch screen is touched by the finger the touch field is highlighted. As soon as the finger leaves the touch screen the action will be started.



Battery state

Information concerning the remaining battery power



Connected/charging battery

Battery is connected to power supply and charging



Activate Laser

Laser is being activated



Back

User goes back one screen



Home

User goes directly back to home screen



OK

User agrees to settings, confirms and activates action



Save

Settings of application will be saved in My Settings



Delete

Settings of application will be deleted from My Settings



Save as favorite

Application is added to Favorites



Delete favorite

Application is removed from Favorites



Peak-pulse

Laser is being set for peak-pulse mode



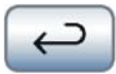
Continuous wave

Laser is being set for continuous wave mode



C (clear button)

User clears letters or digits (going backwards)



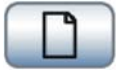
Cancel

User does not want to agree to action. Step back one screen



Help

User wants to open additional help information to this application



New

User wants to generate a new application within My Settings or to add a new user within User parameters.



'Plus' and 'Minus'

User is able to count up and down respectively can move cursor to the right or left side



'Forward' and 'Backward'

User is able to scroll forward and backwards (if there is more than one page of this screen)



'checked'



'disabled'



'defective' or 'missing'

NOTICE

Alphabetic and numeric letters, limitation to data input:

- Numbers are displayed with English decimals '.' for all languages/ regions.
- The power is displayed with one decimal place. Unit is watt (W).
- The time can be set-up as continuous or 1 to 9999 seconds. If continuous is selected it counts up to maximum 9999 seconds after activating application. If time is fixed it counts down. Unit is seconds (s). If 9999 is exceeded treatment will stop and display jumps back to treatment screen.
- The duty cycle is displayed in 1% steps, from 1% to 100% without unit. 100% is displayed as CW.
- The frequency can be entered by typing in the numbers or by moving higher or lower by using 'plus' or 'minus'. If using 'plus' or 'minus' the frequency will be set from 1 Hz -10 Hz in increments of 1 Hz, from 10 Hz -100 Hz in increments of 10 Hz, from 100 Hz -1 kHz in increments of 100 Hz and from 1 kHz -10 kHz in increments of 1 kHz. If 0 Hz is set, CW is displayed. Unit is hertz (Hz).
- Between 1 kHz -10 kHz the duty cycle cannot be below 10% and above 90% due to physical limits. So, at 1 kHz -10 kHz any input below 10% will automatically be displayed and used as 10% for the treatment as well as any input above 90% will automatically turn into 90%.
- The energy will automatically be calculated and displayed with no decimal place. Unit is joule (J). Before starting the application the to be attained total energy will be calculated and displayed if time is set. As soon as application is started and time running the energy will be accumulated as long as the laser is active.
- The average power will automatically be calculated and displayed with one decimal place. Unit is watt (W).

Clear screen before entering new parameters or data. Existing entries will not be overwritten.

Newly generated applications or changed parameters of preset applications will appear in red.

5.2 Switch on power

After starting the SIROLaser Advance by switching on the on/off button on the backside of the control unit the yellow LEDs will be blinking on.

While the SIROLaser Advance is booting information about the software version and the set language as well as the advice to read the user manual will be displayed.

When starting the SIROLaser Advance for the very first time you will automatically be asked to set-up the unit. Please proceed as requested:

1. Country setting

For all users except US users: Change the pre-set country setting to Non-US and confirm the selection.

Enter the pin code **3 3 3 4** and press 'OK'.

See also chapter "Country setting" [→ 50].

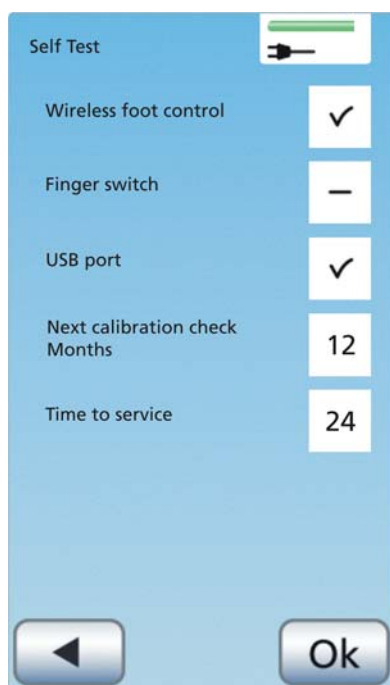
👉 Now you will have access to the full range of pre-set indications.

WARNING

It's forbidden to change the country setting to Non US if you belong to US legal regulations. The use of the country setting Non US is not authorised by the FDA.

2. Date & time
Please enter the appropriate date & time and press 'OK'. See also chapter "Date & time" [→ 50].
3. User parameters
If requested please change your profile or enter new profiles or leave the first set-up by pressing the 'back' or 'home' button. See also chapter "User parameters" [→ 48].

5.3 Self Test



After booting the SIROLaser Advance will automatically perform a self test including a status check of the following matters:

- Wireless foot control vs. finger switch
- USB port

In addition, you will be informed when the next calibration check or when the next servicing is due.

Foot control

If the wireless foot control is selected in the set-up the self test may result in:

The wireless foot control is selected and the appropriate box will be marked with a 'tick' for selected. If the wireless foot control is not selected appears a 'minus'.

NOTICE

If the wireless foot control is not detected and marked 'minus' please perform the registry of the wireless foot control and/or check the battery, see chapter "Install wireless foot control - optional" [→ 31].

If the wireless foot control remains not selectable please contact your local dental depot or an authorized Customer Service Department for technical support.

Finger switch

If the finger switch is selected in set-up the self test may result into:

The finger switch is connected and the appropriate box will be marked with a 'tick' for checked.

The finger switch is disconnected and the appropriate box will be marked with a 'cross' for defect/missing.

If the finger switch is not selected appears in the appropriate box a 'minus'.

NOTICE

If the finger switch is marked 'cross' for defective/missing please check if the handpiece sleeve is properly connected to the handpiece body. If the problem remains please check the cable connection to the SIROLaser Advance control unit, see chapter "Troubleshooting of simple defects". If the finger switch remains marked 'cross' for defective/missing please contact your local dental depot or an authorized Customer Service Department for technical support.

In general: If any switch is defective laser will be blocked.

USB port

To make sure that the USB port is available it is checked within the self test.

The USB port can be 'tick' for checked or 'cross' for defective.

NOTICE

If the USB port is marked 'cross' for defective please contact your local dental depot or an authorized Customer Service Department for technical support.

The SIROLaser Advance will remain functional but the download of the history file is not possible.

Calibration check

Sirona Dental Systems recommends a calibration check with external powermeter to be performed every twelve months, see chapter "Calibration check" [→ 46].

'Next calibration check' counts down from twelve to zero and will be highlighted if zero is reached. The laser remains fully functional. Unit is month.

Time to service

The safety test is a mandatory test for all medical devices. The SIROLaser Advance needs to be tested once every two years. "Time to service" counts down from 24 to zero and will be highlighted if zero is reached. The laser remains fully functional. Unit is month.

NOTICE

Legal regulations require a regular safety test of the performance of a laser device. The SIROLaser Advance needs to be tested once every two years. Please contact your local dental depot or an authorized Customer Service Department for technical support.

If internal or external calibration check failed after last calibration a warning screen pops up after self test. The laser remains fully functional.

NOTICE

Please contact your local dental depot or an authorized Customer Service Department for technical support.



1. To redo the self test press the 'back' button.
2. To quit the self test press 'OK'.

5.4 Enter pin code

The SIROLaser Advance may be operated only by authorized personnel and has an electronic key for security purposes.

1. Enter the key user pin code **2 9 7 4**.
2. To enter the pin code press 'OK'.



WARNING

Do not give the access code to unauthorized third parties. Risk of misuse of the laser by unauthorized persons!

This pin code is changeable in the set-up menu.

NOTICE

In case the key user forgets his/her pin code please enter the super pin code **2 8 7 7**. The super pin code is never changeable.

5.5 Main home screen



The following section describes the main home screen. The main home screen allows you to enter one of seven submenus:

- **Favorites**
In this submenu you will be able to save all your favorite applications.
- **Endodontics, Periodontology, Surgery and Miscellaneous**
After opening the submenu, you will be able to select among different indications with preset treatment parameters. All submenus are structured the same way.
- **My Settings**
In this submenu you will be able to save applications that you have newly programmed and applications that you have changed (and renamed).
- **Set-up**
Within this submenu you will be able to configure the SIROLaser Advance to your needs as well as you will find all necessary set-up and service programs.

5.5.1 Favorites

Twelve applications from pre-set applications within the preset submenus Endodontics, Periodontology, Surgery and Miscellaneous or self-defined applications from My Settings can be entered to Favorites.

- To save your entered settings as favorite press the 'save as favorite' button.
- To remove the selected application from Favorites press the 'delete favorite' button.
- If selected application is not an original preset application: To remove it completely from Favorites and My Settings press the 'delete' button.



NOTICE

If Favorites are full and you try to add another favorite a warning screen will signal to remove another application from Favorites else the chosen application cannot be saved to Favorites.

Favorites cannot be changed. To do so you have to move to the appropriate submenu.

Before starting a laser treatment in battery operation please reconfirm the battery status.

The treatment room must be protected by suitable measures (in compliance with IEC 60825-1), e.g. by closing the doors.

5.5.2 Submenus for endodontics, periodontology, surgery and miscellaneous

The submenus of the endodontics, periodontology, surgery and miscellaneous areas are arranged in the same way. After opening the submenus, you can select among different indications with preset treatment parameters.

Endodontics

Endo. Germ Reduction
Pulpotomy
Gangrene Germ Reduction

Miscellaneous

Aphthous Ulcers
Desensitization
Herpes

Periodontology

Periimplantitis (Germ Reduction)
Perio. Germ Reduction
Sulcular Debridement

Surgery

Abscess
Epulis
Fibroma
Fistula
Frenectomy
Gingivectomy
Gingivoplastic

Haemostasis
Implant Uncovery
Incisions/Excisions
Operculectomy
Gingival Troughing



1. Select the desired indication.
 - ↳ The pre-set parameters will be displayed.
2. Now you can activate the laser: Press the 'Activate Laser' button.
 - ↳ You will be advised to wear protective goggles before the aiming beam is activated.
3. Acknowledging the advice.
 - ↳ The green LEDs start flashing. After a delay of 2 seconds, the aiming beam is switched on.
 - ↳ The laser is now ready for operation.

WARNING

All persons present in the room (operator, assistants and patient) must wear the laser protective goggles as soon as it is advised to wear laser protective goggles and whenever the green LEDs are lit.

Any actuation of the finger or wireless foot control activates the laser unit.

Wrong settings may result in severe damage of the patient's soft or hard tissue or may result in no treatment efficacy. So any user is supposed to have sufficient knowledge and training in laser therapy.

The treatment room must be protected by suitable measures (in compliance with IEC 60825-1), e.g. by closing the doors.

NOTICE

Before starting a laser treatment in battery operation please reconfirm the battery status.

When you activate the finger or wireless foot control, the laser begins emitting. At the same time, two yellow LEDs at the upper right and left end of the SIROLaser Advance control unit light up as well as the laser active bar on the touch screen and the audible alarm sounds. When you release the finger or wireless foot control to interrupt treatment, the laser is deactivated, but remains ready for operation.



The following is a typical example of a treatment submenu.

1. Selected program

in this example Frenectomy

2. Laser power

in our example, 3.0 W power. By pushing on the power touch field you will be transferred to another screen where you will be able to adjust the emitted power between 0.5 W and 7 W in 0.1 W increments either by typing in the numbers or by moving higher or lower by using 'plus' or 'minus'.

WARNING

The preset power levels are considered to be safe for patients. Increasing the power levels entails the risk of overheating the patient's soft or hard tissue. Setting the power to excessively low levels may result in reduced treatment efficacy.

3. Time

in our example, continuous. The laser will be activated as long as the finger or wireless foot control is pressed. By pushing on the time touch field you will be transferred to another screen where you will be able to adjust the time between continuous or 1 to 9999 seconds either by typing in the numbers or by moving higher or lower by using 'plus' or 'minus'.

4. Duty cycle

in our example, CW (continuous wave mode). The duty cycle is defined as the ratio between the pulse duration (when the laser beam is actually actuated) and the total period of time (which is the time from the beginning of a pulse to the beginning of the next pulse). By pushing on the duty cycle touch field you will be transferred to another screen where you will be able to adjust the duty cycle between 1 to 100% (which equals continuous wave CW) by typing in the numbers or by moving higher or lower by using 'plus' or 'minus'. If set to zero, CW (for continuous wave mode) is displayed.

NOTICE

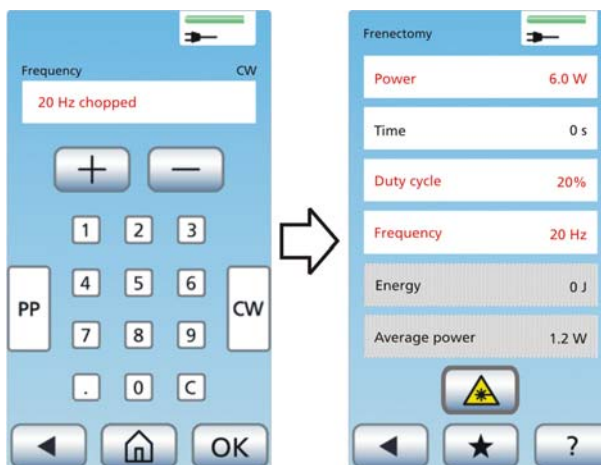
If the frequency is set CW the duty cycle will not be changeable.

5. Frequency

in our example, CW (continuous wave mode). This is the modulation frequency of the laser unit. By pushing frequency touch screen you will be transferred to another screen where you will be able to enter the laser operation mode. For more informations about the operation modes, see chapter „Laser operation modes“ [→ 16].

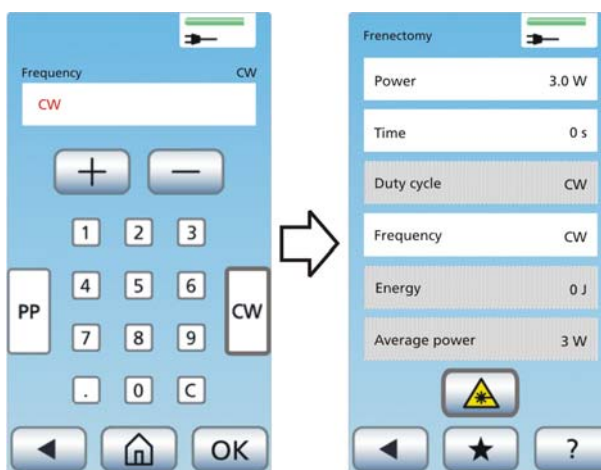
Chopped mode

When entering a frequency in the range from 1 to 10,000 Hz by typing in the numbers or by moving higher or lower by using 'plus' or 'minus'. The result is the chopped mode which will be also displayed in the control field above: e.g. "20 Hz chopped". Via 'OK' you will be proceeded back to the treatment submenu in which you can further adjust the power, time and duty cycle.



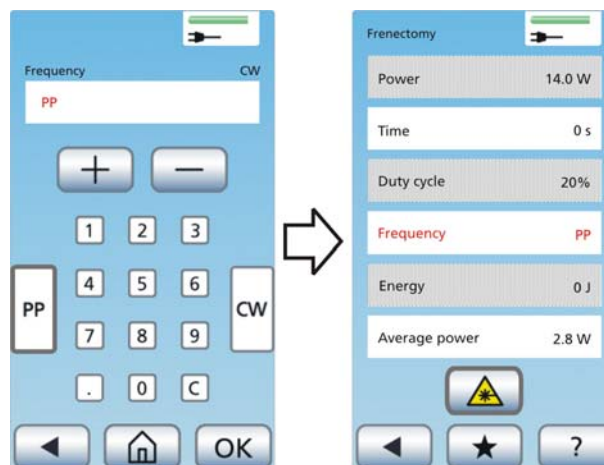
Continuous wave

When pushing the 'CW' button the continuous wave mode is set and in the control field appears "CW". Via 'OK' you will be proceeded back to the treatment submenu in which you can further adjust the power and time.



Peak-pulse

When pushing the 'PP' button the peak-pulse mode is set and in the control field appears "PP". Via 'OK' you will be proceeded back to the treatment submenu in which you can further adjust the time and average power. The power will be preset to 14 W peak-pulse. The duty cycle will be calculated. To vary the applied power you will now be able to adjust the average power.



To return from peak-pulse to any other laser operation mode please enter the frequency screen and choose either 'CW' (for continuous wave mode) or a certain frequency (for chopped mode).

NOTICE

Between 1 kHz -10 kHz the duty cycle cannot be below 10% and above 90% due to physical limits. So at 1 kHz -10 kHz any input below 10% will result in an error message. Values below 10% have to be increased to at least 10% and values above 90% have to be decreased to at most 90%.

Also due to physical limits the chopped mode is not possible with an average power below 0.05 W. If the user wants to set the chopped mode below this value an error message appears: "Chopped mode available only with an average power above 0.05 W."

The peak-pulse mode is not possible with an average power below 0.3 W. If the user wants to set the peak-pulse mode below this value an error message appears: "Peak Pulse available only with an average power above 0.3 W."

When returning from peak-pulse mode to chopped mode note that the average power will remain and the power will be calculated regarding a preset duty cycle of 50%.

6. Energy

in our example, 0 J (joule). The system calculates the energy used during treatment (in J) from the power values and the laser activation time. So as soon as application is started and time running the energy will be calculated and accumulated as long as the laser is active.

7. Average power

in our example, 3 W (watt). The system calculates the average power (in W) from the power values and the selected duty cycle.

Further more the example here shows:

8. Back button

By pushing the back button you will jump back one screen.



9. Favorite button

By pushing the 'save as favorite' button this program will be linked to the favorite submenu.



This is the 'delete favorite' button to delete the link from the favorite submenu.



10. Help button

By pushing the 'help' button the help menu will be opened and you can read additional information about this treatment.



11. Laser button

By pushing the 'Activate Laser' button the laser will be made ready for operation.



5.5.3 My Settings

Up to 24 applications can be generated and saved to My Settings.

NOTICE

If My Settings are full and you try to add another application a warning screen will signal to remove another application from My Settings else the chosen application cannot be saved to My Settings.



1. If you press on the My Settings screen the 'new' button a blank input mask is opened.
2. Name the new application by touching the empty description field on the top left corner of the screen.
↳ A keyboard field is shown.
3. Confirm your text input with 'OK'.
↳ The keyboard field is hidden.
4. Enter your desired parameters.
5. The new input will be confirmed by pressing the 'save' button.



Selected application can be deleted from My Settings by pressing the 'delete' button.



WARNING

Wrong settings may result in severe damage of the patient's soft or hard tissue or may result in no treatment efficacy. So any user is supposed to have sufficient knowledge and training of laser therapy.

NOTICE

Before starting a laser treatment in battery operation please reconfirm the battery status.

The treatment room must be protected by suitable measures (in compliance with IEC 60825-1), e.g. by closing the doors.

5.5.4 Set-up

5.5.4.1 Activation device

In case you have purchased your SIROLaser Advance with the optional wireless foot control you have the choice to use either the finger switch or the wireless foot control. Select one and confirm by pressing 'OK'.

NOTICE

The finger switch is pre-set.

To be able to use the wireless foot control please see chapter "Install wireless foot control – optional" [→ 31] for further instructions.

5.5.4.2 History file

After having finished a treatment all parameters will be saved and documented in the history file - i.e. user name, application, date & time as well as power, laser activation time, energy, and average power of this treatment.

NOTICE

A maximum of 50 treatments is possible to be stored. If the maximum is reached the 51st treatment will replace the 1st treatment.

When downloading the history file the data will be deleted from the control unit.

CAUTION

Use only USB Class 2.0 memory sticks.

- To download the history file please insert an USB mass storage (class version 2.0) and press the 'save' button.
 - ↳ Proceed as instructed on the screen.

5.5.4.3 Calibration check

WARNING

You must wear the supplied laser protective goggles during the entire calibration check.

The following section describes the procedure to check the calibration of the SIROLaser Advance.

We recommend performing this check at least once a week.

In order to enable exact inspection of the performance and flawless functioning of your SIROLaser Advance, we recommend performing calibration check at four different power levels:

- 1 W
- 3 W



- 5 W
- 7 W

The SIROLaser Advance performs a self-calibration. During this procedure, the system checks that the laser emission parameters are correct. We recommend that you check these values using a suitable external measuring instrument at least every twelve months. If the measurement readings indicate a wavelength of 970 nm +/- 15 nm, a power of 0.5 to 7 W and a resolution of 5% or higher, the calibration is correct.

Select one of three test procedures to check the calibration:

5.5.4.3.1 Calibration check without an external power meter

➤ Select w/o power meter.

Please read the operating instructions and wear protection goggles before proceeding the calibration check.

Now the calibration check starts! Direct the correctly mounted handpiece with correctly installed fiber to a beam dump, i.e. a non flammable object which does not reflect the laser beam.



WARNING

The calibration check takes place with laser power. Danger for skin and eyes!

Do not direct the laser beam to flammable objects or use the laser with flammable substances or gases around.

Do not direct the laser to reflective (metallic) surfaces. Danger for skin and eyes!

The menu asks you to press the finger switch for 3 seconds.

1. Press the finger switch for at least 3 seconds, the laser will stop emission automatically.
2. Press 'OK'.
3. Repeat the procedure for 3, 5 and 7 watt.

If the calibration check is passed successfully, the message "Calibration Test passed" will appear.

➤ Acknowledge with 'OK'.

If the laser shows an error message, please contact your local service.

5.5.4.3.2 Calibration check using an external power meter

Required power meter: Calibrated power meter capable of measuring a power level of at least 10 watts at a wavelength of 970 nm with an accuracy of better than 10%.

➤ Select with external power meter.

Please read the operating instructions and wear protection goggles before proceeding the calibration check.

Now the calibration check starts! Direct the correctly mounted handpiece with correctly installed fiber to the head of your power meter.



WARNING

The calibration check takes place with laser power. Danger for skin and eyes!

Do not direct the laser beam to flammable objects or use the laser with flammable substances or gases around.

Do not direct the laser to reflective (metallic) surfaces. Danger for skin and eyes!

The menu asks you to press the finger switch for 3 seconds.

1. Press the finger switch for at least 3 seconds, while directing the laser to the head of the power meter.
2. Readout the measured power from the display of your power meter.
3. Press 'OK'. Enter the measured power into the laser by using the keyboard and press 'OK'.
4. Repeat the procedure for 3, 5 and 7 watt.

If the calibration check is passed successfully, the message "Calibration Test passed" will appear.

➤ Acknowledge with 'OK'.

If the laser shows an error message, please contact your local service.

5.5.4.3.3 Calibration check with SIROLaser power meter

To be implemented in a later software version.

5.5.4.4 Sound volume

1. Select volume level of warning sound and press button sound by using 'plus' or 'minus'.
 - ✎ Level of warning and press button sound will immediately be applied.
2. Save with 'OK'.

5.5.4.5 Display settings

1. Select level of display brightness by using 'plus' or 'minus'.
 - ✎ Level of display brightness will immediately be applied.
2. Save with 'OK'.

5.5.4.6 User parameters

When entering the user parameters menu, the key user is already configured, similar to a computer administrator. This administrator has the possibility to enter five additional users (via new button).



NOTICE

The set-up of the key user is fixed and not changeable, but to give him a user name (e.g. SMITH instead key user) and to change the pin code 2 9 7 4.

The key user is the administrator of the SIROLaser Advance and has all rights to create and configure five new users as well as to remove them from the list of users.

The additional users will have access only to limited parts of the Set-up: Language, display setting, sound volume, history file, finger or foot switch, battery calibration.

The configuration for the selection finger or foot switch, and the screen and volume settings are not stored individually.

If key user presses the 'new' button on user parameters screen a blank file is opened.

- To enter the name, pin code and other settings of the new user press the appropriate buttons.

The key user decides if this user will be allowed to change preset applications.

NOTICE

If 'no' is entered there will be no My Settings screen for this user.

The key user decides if this user will have a power limit for treatments. If yes is entered the key user also enters the power limit in watt.

NOTICE

The power limit directly influences the number of applications that can be used by this user.

For example, when you choose a power limit of 2 W the user can not choose preset indication with more than 2 W. If the power limit 0.5 W (default) so the user has no access to preset indications.

The key user is able to select the applications this user is allowed to use.

NOTICE

The non-usable applications due to the direct selection or the power limit appear shaded and are disabled.

5.5.4.7 Software update

If a software update of the SIROLaser Advance is needed please proceed as follows:

1. Choose in main menu the item "Set-up".
2. Choose there the item "Software update" (these can be found on the second sheet).
3. Follow the instructions in the note message and insert the USB stick.

NOTICE

Please bear in mind that the system requires approx. 5 seconds to detect the USB stick.

4. Press "OK".

- ↳ It appears the note message with the information that the software update is in progress.
- ↳ The note message disappears, the start screen appears and the self test is in progress.



CAUTION

Leave the USB stick and the power cable plugged in until the completion of software update.

The Software update may take up to five minutes.

5. Please now, like when you turn on the device, press 'OK'.

- ↳ The software update was successfully performed. The USB stick can be removed.

5.5.4.8 Service Menu

NOTICE

Only authorized persons are allowed to enter the service menu. To avoid misuse it is necessary to enter the eight-digit pin code.

5.5.4.9 Language

Language is only available if "Country Settings" are set for NON-US else English is preset and fixed for the US (the button is grayed-out).

- You have the choice of twelve languages. Select one and confirm by pressing 'OK'.
 - ↳ Language will be applied after confirmation.

5.5.4.10 Date & time

Format for date: ddmmyy

Format for time (24hours notation): hhmm

- Enter date & time and save.

5.5.4.11 Country setting

NOTICE

The country setting for the US is pre-set.



WARNING

It's forbidden to change the country setting to Non US if you belong to US legal regulations. The use of the country setting Non US is not authorised by the FDA.

For all users except US users:

- Change the pre-set country setting to Non-US and confirm the selection.
Enter the pin code **3 3 3 4** and press 'OK '.
- ☞ Now you will have access to the full range of pre-set indications.

5.5.4.12 Battery calibration

For perfect battery performance a battery calibration must be proceeded in any case of having removed and again mounted or completely replaced the battery pack, see chapter „Replacing the rechargeable battery of the control unit“ [→ 68].

1. Switch on the laser without having connected the power supply.
2. Choose "Battery calibration" in the set-up menu.
 - ☞ The following message will appear. "Unplug the laser and press OK for battery calibration. For further steps refer to the user manual."
3. Press 'OK'.
 - ☞ The battery will now be discharged automatically until the device switches off due to lack of power. You will also be informed that "Battery calibration may take several hours."
4. When the device has been switched off automatically plug in the power supply and charge the battery for at least 2 hours (best over night).
 - ☞ Now the battery is calibrated.

5.5.5 Error messages, warnings and instructions

5.5.5.1 Error messages and warnings



Error
Internal calibration error

Contact technical support

OK

There occurred an error during the internal calibration check which could not be handled. Please contact Sirona Dental Systems GmbH, your local dental depot or your authorized service center. Confirmation via 'OK'.



Error
Calibration

Contact technical support

OK


There occurred an error during the external calibration check which could not be handled. Please contact Sirona Dental Systems GmbH, your local dental depot or your authorized service center. Confirmation via 'OK'.



Error
Wrong USB device!

OK

Software update or history file download procedure: The USB device was not accepted. Please plug it in again or try another USB device (Version 2.0). Confirmation via 'OK'.



Error
Battery malfunction

Contact technical support

OK

The battery is malfunctioning. Please contact Sirona Dental Systems GmbH, your local dental depot or your authorized service center. Confirmation via 'OK'.



Error
Finger switch

OK

There occurred an error about the finger switch. Please contact Sirona Dental Systems GmbH, your local dental depot or your authorized service center. Confirmation via 'OK'.



Error
Missing finger switch

OK

The finger switch could not be detected. See chapter "Troubleshooting ..." [→ 66]. Confirmation via 'OK'.



Error
Wireless foot switch

OK

There occurred an error about the wireless foot control. Please contact Sirona Dental Systems GmbH, your local dental depot or your authorized service center. Confirmation via 'OK'.



Error
Missing foot switch

OK

The wireless foot control could not be detected. See chapter "Troubleshooting ..." [→ 66]. Confirmation via 'OK'.



Error
Foot or finger switch
defective

Contact technical support

OK

There occurred an error due to a defective finger switch or wireless foot control which could not be handled. Please contact Sirona Dental Systems GmbH, your local dental depot or your authorized service center. Confirmation via 'OK'.




Error
EEPROM not initialized

Contact technical support

OK

There occurred an error about the initialization of the EEPROM which could not be handled. Please contact Sirona Dental Systems GmbH, your local dental depot or your authorized service center. Confirmation via 'OK'.



Error
EEPROM communication

Contact technical support

OK


There occurred an error about the EEPROM communication which could not be handled. Please contact Sirona Dental Systems GmbH, your local dental depot or your authorized service center. Confirmation via 'OK'.



Error
Fan not working

Power off the device

Cooling fan is not working. To avoid damage please switch off the SIROLaser Advance and let it cool down for a while. See chapter "Troubleshooting ..." [→ 66].



Error
Thermal sensor

Contact technical support

OK

There occurred an error due to overheating which could not be handled. Please contact Sirona Dental Systems GmbH, your local dental depot or your authorized service center. Confirmation via 'OK'.



Error
Photodiode

Contact technical support

OK


There occurred an error to the photo diode inside the handpiece which could not be handled. Please contact Sirona Dental Systems GmbH, your local dental depot or your authorized service center. Confirmation via 'OK'.



Error
Missing fiber

OK

The fiber could not be detected. See chapter "Troubleshooting ..." [→ 66]. Confirmation via 'OK'.



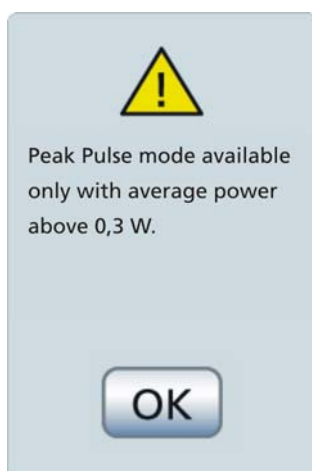
Duty cycle 10% ... 90%

OK

There occurred an error because the user wants to set the duty cycle below 10% or above 90% at a frequency above 1 kHz. Due to physical limits, this is not possible. Confirmation via 'OK'.



There occurred an error because the user wants to set the average power below 0.05 W in the chopped mode. Due to physical limits, this is not possible. Confirmation via 'OK'.



There occurred an error because the user wants to set the average power below 0.3 W in the peak-pulse mode. Due to physical limits, this is not possible. Confirmation via 'OK'.

5.5.5.2 Instructions



Internal calibration check: 1 Watt level is being checked when finger switch is pressed for three seconds. Confirmation via 'OK'.

For informations of the calibration check, see chapter "Calibration check" [→ 46].



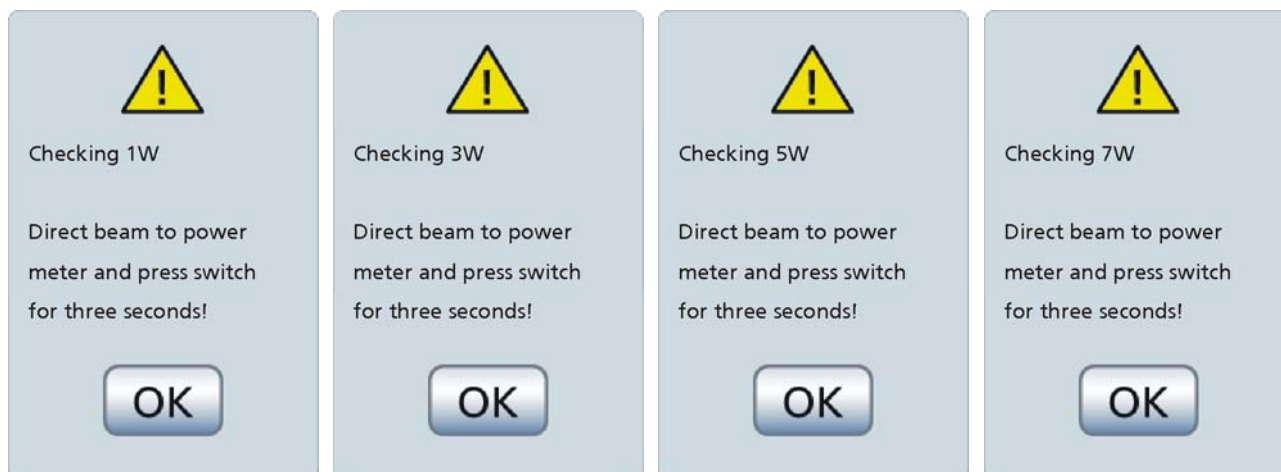
Internal calibration check: 3 Watts level is being checked when finger switch is pressed for three seconds. Confirmation via 'OK'.



Internal calibration check: 5 Watts level is being checked when finger switch is pressed for three seconds. Confirmation via 'OK'.



Internal calibration check: 7 Watts level is being checked when finger switch is pressed for three seconds. Confirmation via 'OK'.

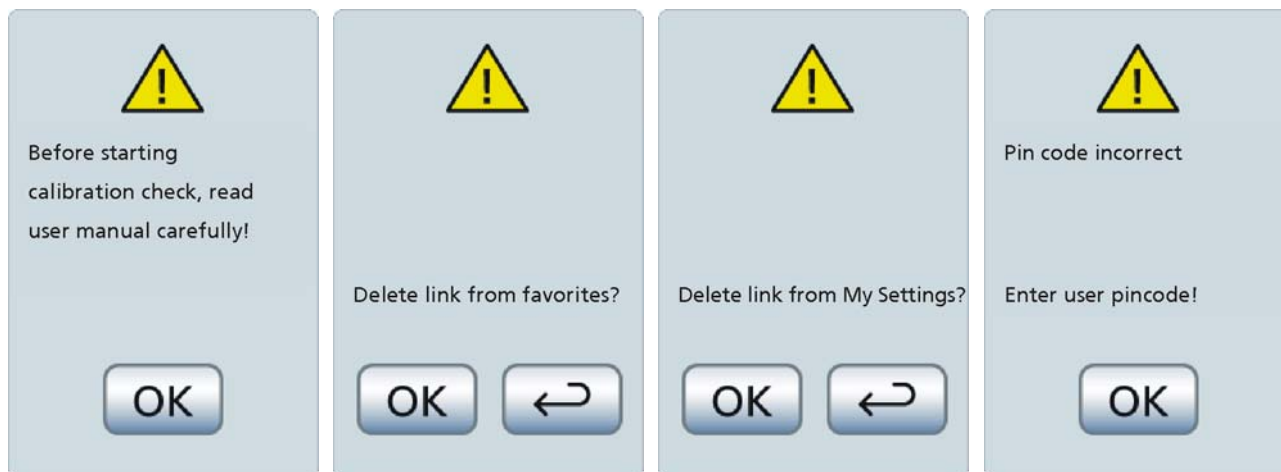


External calibration check:
1 Watt level is being
checked when laser beam
is directed to the power
meter and finger switch is
pressed for three seconds.
Confirmation via 'OK'.

External calibration check:
3 Watt level is being
checked when laser beam
is directed to the power
meter and finger switch is
pressed for three seconds.
Confirmation via 'OK'.

External calibration check:
5 Watt level is being
checked when laser beam
is directed to the power
meter and finger switch is
pressed for three seconds.
Confirmation via 'OK'.

External calibration check:
7 Watt level is being
checked when laser beam
is directed to the power
meter and finger switch is
pressed for three seconds.
Confirmation via 'OK'.



To perform any calibration
check it is advised to read
the user manual carefully.
Confirmation via 'OK'.

For informations of the
calibration check, see
chapter "Calibration check"
[→ 46].

Confirmation if link shall be
deleted from 'Favorites'. To
be confirmed via 'OK' or
returned to previous screen
via 'Cancel'.

Confirmation if link shall be
deleted from 'My
Settings'. To be confirmed
via 'OK' or returned to
previous screen via
'Cancel'.

Wrong pin code was
entered. Please try again
after confirmation via 'OK'.



Before proceeding it is advised to take on the laser safety goggles. Then confirm with 'OK'.



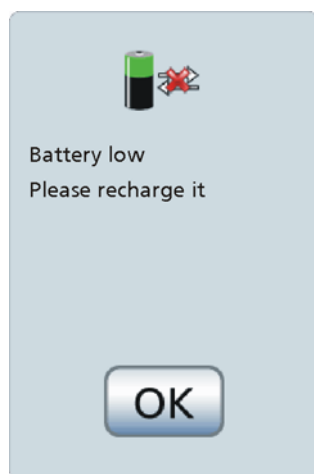
Software update procedure: Before going on please plug the USB device into USB port. Confirmation via 'OK'.



History file download procedure: Before going on please plug the USB device into USB port. Confirmation via 'OK'.



Software update procedure is in progress. Please wait.



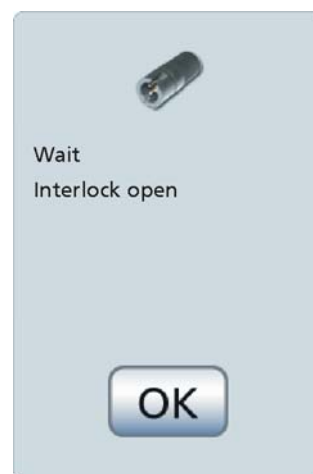
The battery level is low and needs to be charged. Confirmation via 'OK'.



Please release finger switch or wireless foot control. Confirmation via 'OK'.

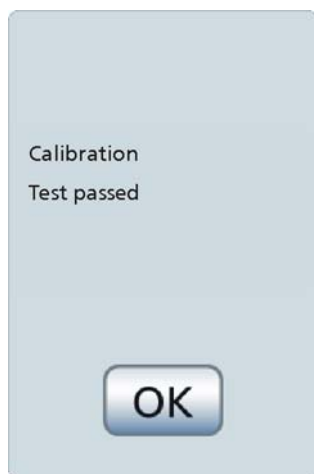


To avoid damage of the laser source please wait and let the SIROLaser Advance cool down. Confirmation via 'OK'.

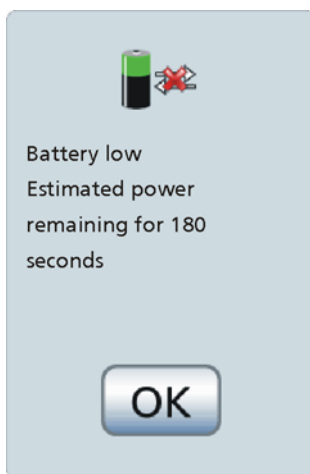


Please wait until the interlock is open. See chapter "Troubleshooting ..." [→ 66]. Confirmation via 'OK'.

5.5.5.3 Information messages



The calibration check was successfully performed. Confirmation via 'OK'.
For informations of the calibration check, see chapter "Calibration check" [→ 46].



The battery level is very low (remaining power for 180 seconds) and needs to be charged. Confirmation via 'OK'.



The laser has been deactivated by pressing "Laser Stop" button. Confirmation via 'OK'.

5.6 Switching off the laser device

Laser stop

In case of emergency press the laser stop button. Note, that the laser is interrupted and deactivated, but not switched off. If you want to continue, enter the pin code.

Main switch

During or after treatment the laser can be switched off by switching the main switch at the rear of the unit. Here the laser diode is permanently disconnected from power supply.

NOTICE

The laser main switch does not disconnect the battery loading circuit, i.e. the batteries are loaded even if the laser is switched off.

6 Indications, contraindications and medical precautions

6.1 Indications

Compared to conventional dental surgery, treatment with the SIROLaser Advance offers the following advantages: less invasive, minimum cell destruction, less bleeding, better coagulation, and negligible post-operative edema. Treatment with the laser is low-pain and not pain-free. We recommend using anesthetics if necessary. The SIROLaser Advance may be operated only by trained and qualified personnel.

6.2 List of preset indications

Application	Power [W]	Modus	Duty Cycle [%]	Frequency [Hz]	Fiber [µm]	Help Menu
Endodontics						
Endo. Germ Reduction	1,5	PF	50	15	200	Carefully insert the fiber into the root canal, ca. 1 mm from the apex, start laser and retract fiber slowly in circular motion from the canal (1-2 mm/s). Repeat procedure 4 times in 60-seconds-intervals. Caution: Do not stay at the apex after laser activation!
Pulpotomy	3,0	PF	50	5	200	After conventional pulp removal, residual pulp tissue can be removed with the laser.
Gangrene Germ Reduction	3,0	PF	50	20	200	Carefully insert the fiber into the root canal, directly to the apex, start laser and after maximum 2 seconds at the apex, retract fiber slowly in circular motion from the canal (1-2 mm/s). Repeat procedure 4 times in 60-seconds-intervals. Caution: Stay maximum 2 seconds at the apex after laser activation!
Miscellaneous						
Aphthous Ulcers	2,0	PF	50	10	320	Anesthetics not needed! Apply laser 1-3 mm away from lesion for a few seconds - semicontact, wave the laser fiber over the entire lesion. Interrupt treatment briefly, if pain sensations occurs.
Desensitization	1,0	CW			320	Apply tin fluoride solution as described in scientific diode-laser studies on the sensitive tooth areas, apply laser 2-4 mm away from these regions - semicontact, total time per area: 60 seconds. Caution: Avoid contact to dentine, keep laser tip always in motion!
Herpes	2,0	PF	50	10	320	Anesthetics not needed! Apply laser 1-3 mm away from lesion for a few seconds - semicontact, wave the laser fiber over the entire lesion. Interrupt treatment briefly, if pain sensations occurs.

Periodontology						
Periimplantitis (Germ Reduction)	1,5	PF	50	12	320	Move the fiber tip around the implant gently up and down with a sinuous movement, covering the wall of the tissue. Caution: Keep the laser tip always in motion!
Perio. Germ Reduction	1,5	PF	50	10	320	Irradiate the whole pocket starting from the deepest position using a meandering course to cover all contaminated regions. Reduce power, if pain sensations appear.
Sulcular Debridement	2,0	PF	33	10	320	Move the fiber tip around the tooth gently up and down with a sinuous movement, covering the wall of the tissue. Reduce power, if pain sensations appear. Caution: Keep the laser tip always in motion!
Surgery						
Abscess	6,0	PF	50	10	320	Point directly with fiber towards the tissue where the drainage canal is planned. Start laser and perform the drainage. Eject infected material. Perform laser treatment again to remove residual infected material. Caution: Avoid bone contact during treatment!
Epulis	6,0	PF	50	10	320	Stretch the tissue and use laser tip like an scalpel to excise the tissue.
Fibroma	6,0	PF	50	10	320	Stretch the tissue and use laser tip like an scalpel to excise the tissue. Depending on the size of the fibroma energy can be adjusted until desired cutting is achieved.
Fistula	2,0	PF	33	15	320	Carefully insert the fiber into the fistula canal, start laser and retract fiber slowly from the canal (1 mm/s). At bone contact retract the fiber 1-2 mm before laser is activated.
Frenectomy	3,0	CW			320	Stretch the frenulum and stay in contact with the fiber. Use brush stroke at the base to cut through fibrous attachment. Caution: For the tongue, protect the salivary glands! Avoid bone contact during treatment!
Gingivectomy	3,0	CW			320	Gently shape the gingival tissue in contact with the fiber. Caution: Work in parallel to the tooth surface!
Gingivoplastic	3,0	PF	50	10	320	Gently shape the gingival tissue in contact with the fiber. Caution: Work parallel to the tooth surface!
Haemostasis	3,0	CW			320	Seal small blood vessel with gentle contact to the tissue. Permeate larger vessels with fiber, start laser and retract the fiber slowly. To coagulate larger vessel perform multiple treatments.
Implant Uncovery	3,0	CW			320	Stretch the tissue and use laser tip like an scalpel to excise the tissue. Caution: Avoid contact to implant and bone!
Incisions/ Excisions	3,0	CW			320	Stretch the tissue and use laser tip like an scalpel to excise the tissue.
Operculectomy	3,0	CW			320	Stretch the tissue and use laser tip like an scalpel to excise the mucosa hood.
Gingival Troughing	2,0	PF	50	20	320	Gently shape the gingival tissue in contact with the fiber. Caution: Work parallel to the tooth surface!

6.3 Further non-preset indications

Further non-preset applications which you may define individually and medicate according to scientific publications in My Settings:

- Frenotomy
- Biopsy
- Laser assisted flap surgery
- Incisions and draining of abscesses
- Papillectomy
- Vestibuloplasty
- Excision of lesions
- Excision of hyperplasias
- Leukoplakia
- Corona extension
- Set hidden teeth free

6.4 Examples of treatment risk

Surgery area

Risk: Soft and hard tissue necrosis or overheating of the tooth.

Countermeasure: Use the laser beam like a scalpel, holding it perpendicular to the surface under treatment, and never aim it at a single point for a longer period of time. Do not select excessively high power levels for the laser.



WARNING

Never treat perpendicular to any bone surface.

Endodontics area

Root canal germ reduction

Risk: Contractions in the apical region, small fusions and microfractures.

Countermeasure: Measure the depth and stop 1 mm above the root apex. Never aim the optical fiber at a single point in the root apex for a longer period of time. The optical fiber must be moved constantly during treatment. Start in the apical region and work your way up to the crown.

Gangrenous canals

Risk: Contraction, fusion and bone necrosis.

Countermeasure: Measure the depth and stop 1 mm above the root apex. Never aim the optical fiber at a single point in the root apex for a longer period of time. The optical fiber must be moved constantly during treatment. Start in the apical region and work your way up to the crown.

Periodontics area

Risk: Minor necrosis or scarring of the radicular area.

Countermeasure: When working in periodontal pockets, always aim the laser parallel to, i.e. never perpendicular to, the roots. Run the distal end of the optical fiber over the entire inner surface of the periodontal pocket.

6.5 Contraindications

All clinical procedures performed with the SIROLaser Advance must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, cancer, pregnancy, heart disease, lung disease, bleeding disorders, sleep apnea, and immune system deficiency, or any medical conditions or medications that may contraindicate use of certain light/laser type sources associated with this device. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

7 Cleaning, disinfection and sterilization

Following treatment, switch off the SIROLaser Advance and disconnect the power cable from the power supply.

NOTICE

When following these instructions wear gloves.

Control unit, handpiece body, handpiece tube and foot control are supposed to be cleaned and wipe-disinfected.

Dispose the single-use tip.

The removable Handpiece sleeve, stainless steel back-sleeve, optical fibers, fibercutter and bending tool are supposed to be cleaned and sterilized.



CAUTION

Do not clean and disinfect the parts using a washer-disinfector! The parts may be seriously damaged.

For the number of sterilization cycles, see chapter "Replacement of parts subject to wear and tear" [→ 69].

7.1 Cleaning

NOTICE

Manual cleaning must always be combined with disinfection.

All tissue residues must be removed from the optical fiber before it is detached from the handpiece.

Optical fiber and handpiece sleeve

Before disassembly the optical fiber must be cleaned from residual tissue and disinfected.

1. Please bend back the single-use tip as straight as possible before moving the fiber within the single-use tip.



CAUTION

If the optical fiber is moved in a bent single-use tip the surface of the optical fiber may be destroyed (danger of optical fiber breakage).

2. Notch the optical fiber approx. 4 mm from its distal end. The notch must be made perpendicular to the axis of the optical fiber.
3. Remove the single-use tip from the handpiece and dispose it.
4. Remove the handpiece sleeve from the handpiece body by pressing both snap tabs.
5. After removal of the optical fiber from the handpiece, the optical fiber can be cleaned with a suitable cloth under running water (of at least drinking water quality).



CAUTION

Danger of damage to the optical system

Reattach immediately after dismounting the fiber the protective caps to the optical system of the handpiece and to the proximal end of the ferrule of the fiber. Do this before taking any hygienic measures.

6. Clean the handpiece sleeve with a suitable brush under running water.

Fibercutter

- Clean the fiber cutter in the ultrasonic bath or with a suitable brush under running water.

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.

7.2 Disinfection

Disinfect the upper mentioned parts by wipe disinfection:

SIROLaser Advance (wipe disinfection only)

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.

Sirona recommends the use of MinuteWipes from Alpro. In the USA: 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 optical fiber 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

Optical fiber and handpiece sleeve must be sterilized prior to initial use and before each subsequent use.

Before use the single-use tips must be sterilized.

NOTICE

Remove any possible water residues.

The parts must be sterilized only in an autoclave with saturated water vapor at minimum sterilization values of 134°C (273.2°F), 3 min. holding time and 2.04 bar (29,59 psi) overpressure.

Steam sterilizers are approved for sterilization that fulfill the requirements of EN 13060 class B or validated steam sterilizer (EN 13060 class S) which are employing three, separate initial vacuum air-purges being suitable for the sterilization of dental handpieces. For example SIRONA DAC PROFESSIONAL.

Please use the transport and sterilization tube for sterilizing the optical fiber.



CAUTION

Always protect the optical fiber with the transportation and sterilization tube as well as the sterilization cap.

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 optical fiber is 4.5 cm (diameter: 9 cm). Be careful not to pinch or tear the optical fiber when inserting or cleaning it.

7.4 Cleaning the control unit

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

NOTICE

Please proceed careful not to scratch and damage the foil on the touch screen.

You can wipe-disinfect the SIROLaser Advance using any of the products that are commonly used to disinfect medical electrical equipment, e.g. MinuteWipes, Caviwipes.



CAUTION

Spray disinfection may allow liquids to penetrate into the SIROLaser Advance!

The SIROLaser Advance may be disinfected **only by wiping** it. Do never spraydisinfect the SIROLaser Advance.

Observe the instructions provided by the manufacturers of these disinfectants.

MinuteWipes Fa. Alpro.

In USA: Caviwipes™.

8 Maintenance and service

8.1 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 visual and audible indicators
- NC and SFC earth leakage current acc. to IEC 60601
- NC and SFC housing leakage current acc. to IEC 60601
- NC and SFC patient leakage current acc. to IEC 60601
- Laser power measurement with a calibrated measuring instrument in the range between 0.5 W and 7 W

8.2 Maintenance

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

Action	Frequency	Conducting personnel
Check of the optical fiber, see "Optical fiber assembly" [→ 27]	Before each treatment session	System owner
Calibration check of the laser, see "Calibration check" [→ 46]	Weekly	System owner
Recommended check of the optical power at the tip of the fiber with an external power meter, see "Calibration check" [→ 46]	Every twelve months	System owner
Safety checks (required by law in some European countries)	Every 2 years	Sirona Dental Systems GmbH, local Dental Sales or qualified service engineer.

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 requirements are fulfilled:

- Modifications of the laser unit or repair work may be performed only by authorized personnel.
- The electrical installations in the rooms where the SIROLaser Advance is used must fulfill the applicable legal requirements.
- The unit must be used in compliance with the instructions provided in the present manual.

8.3 Troubleshooting of simple defects

In case of malfunctioning, proceed as follows:

General

First general directions in case of malfunctioning:

- Check if power supply is connected properly and/or rechargeable battery is loaded.
- Check if fiber is installed correctly.
- Be sure that all operational steps have been carried out correctly.
- Check the functioning of the finger switch and/or wireless foot control by pressing several times.

The touch screen of the SIROLaser Advance remains dark after switching it on.

- Check the connection of the power cable and/or check the rechargeable battery.
- Make sure that the switch on the switching power supply is switched on.
- Check the connection of the interlock device.

Finger switch

The finger switch is claimed to be missing.

- Check if the finger switch is chosen in the set-up submenu.
- Check if the plug of the cable is properly connected to the control unit.

Foot control

The foot control is not working or claimed to be missing.

- Check if the foot control is chosen in the set-up submenu.
- Check the battery of the wireless foot control.
- Register the wireless foot control again.

Optical fiber

The fiber is claimed to be missing.

- Make a visual check of the optical fiber and its connector. If you see any damage (e.g. scratches) replace the optical fiber with a new one.
- Check the connection of the optical fiber.
- Check the proper assembly of the handpiece sleeve.
- Be sure that all operational steps have been carried out correctly.

Aiming beam

There is no aiming beam.

- Check to see if the optical fiber or its connector is damaged. If the optical fiber is damaged, replace it with a new one.
- Check the connection of the optical fiber.
- Check the proper assembly of the handpiece sleeve.
- Be sure that all operational steps have been carried out correctly.

The light of the aiming beam does not project a uniform circular pattern.

- Trim the end of the optical fiber with the fiber cutter again. Always make the notch perpendicular to the optical fiber.

Interlock

The interlock is claimed to be open.

Interlock is used:

- Check the connection of the interlock.
- Check if the door is open.

Interlock is not being used:

- Check if the interlock bridge is connected properly.

Overheating

The laser source is claimed to overheat.

- Check if all convection openings for air cooling on the sides of the unit are uncovered.
- Check if unit is placed near heat sources. If so, place the unit somewhere else and let it cool down.

Accoustic signal

There is no accoustic signal for activating the laser and/or pushing the buttons.

- Check the settings for the accoustic signals in the set-up submenu.

If you cannot solve the malfunctioning, switch off the laser and contact Sirona Dental Systems GmbH, your local dental depot or your authorized service center.

8.4 Technical support, repair and testing

Sirona provides technical information on the repair of individual components only to authorized dealers and only after conducting an advanced training course for their technical personnel. Please contact your local dental depot or an authorized Customer Service Department for technical support.

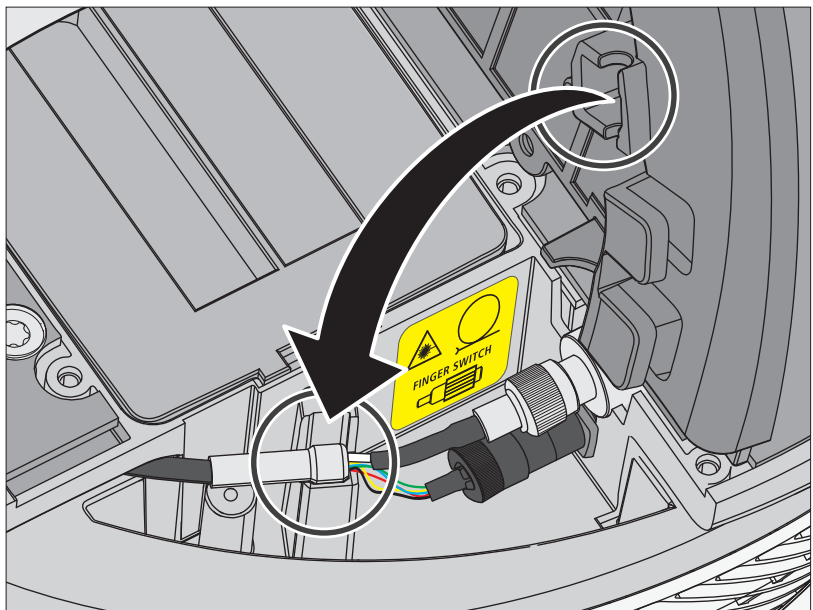
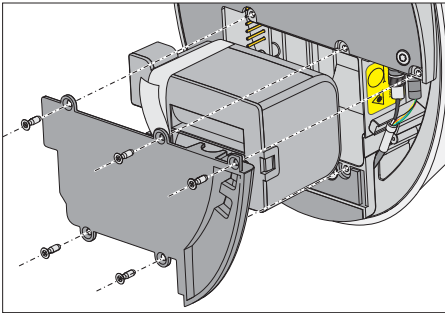
The SIROLaser Advance may be sent in for repair or for safety inspection only in its original packaging, including all accessories. Disinfect the SIROLaser Advance and sterilize the accessories according to the relevant instructions for use before shipping them.

Sirona requests that you provide written confirmation that the goods have been disinfected and sterilized respectively according to this user manual before sending them back to service.

8.5 Replacing the rechargeable battery of the control unit

If the rechargeable battery does not load more than 30% even by charging it overnight, the battery should be replaced.

1. Disconnect the power supply.
2. Take the handpiece out of the holder and unwind the tube completely.
3. Remove the battery cover.
4. Pull out the battery with the strips applied to the battery.
5. Mount the new battery.
6. Closing the battery cover. Make sure that the small metal cylinder of the cable is properly placed in the anti-pull protection! Otherwise, the handpiece is damaged.



7. Switch on the laser (use power supply if necessary).
8. Choose "Battery calibration" in the set-up menu.
 - ✎ The following message will appear: "Unplug the laser and press OK for battery calibration. For further steps refer to user manual."
9. Unplug laser and press 'OK'.
 - ✎ The battery will now discharged automatically until the device switches off due to lack of power.
10. Plug in the power supply, switch on the laser device and charge the battery for at least 2 h (best over night).

For perfect battery performance a battery calibration must be proceeded in any case of having removed and again mounted or completely replaced the battery pack, see chapter "Battery calibration" [→ 51].

CAUTION

Make sure that the small metal cylinder of the cable is properly placed in the anti-pull protection. Fiber in cable may break if not correctly mounted resulting in high repair costs.

Only use the Sirona Dental Systems battery pack, see "Spare parts" [→ 24].

8.6 Replacing the batteries of the wireless foot control

The wireless foot control is powered by two (2) AAA batteries (commercially available).

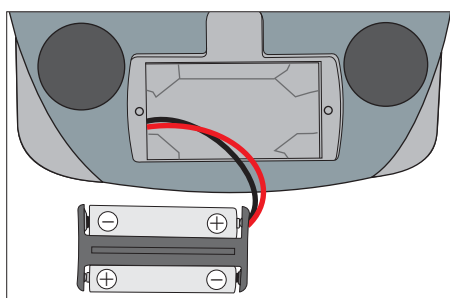
When the battery is empty, an error code is output, see "Error messages and warnings". In this case select the finger switch in the set-up submenu "Activation device" [→ 46] for further operation of the SIROLaser Advance.

The batteries can be changed by the user.

The housing of the wireless foot control must be opened to change the battery. Touch a grounded metal part before opening the housing to prevent damage to the PC board due to electrostatic discharge.

CAUTION

Prior to changing the batteries, switch the SIROLaser Advance off at the main switch. This prevents accidental triggering.



Removing and replacing the batteries

1. Remove the screws from the bottom of the foot control.
2. Remove the cover and open the battery compartment.
3. Pull the battery holder out of the battery compartment and replace the batteries with new ones. Be careful to insert it with the correct polarity (minus pole facing spring).

Assembling the foot control

1. Place the battery holder back again in the battery compartment.
2. Close the battery compartment with the cover.
3. Screw tight the screws at the bottom of the foot control.

NOTICE

After changing the batteries, start the SIROLaser Advance and check the complete functionality of the foot control. In case the finger switch was selected as preliminary activation device it is necessary to re-select the wireless foot control. It is not necessary to reregister the foot control again at the SIROLaser Advance after changing batteries.

8.7 Replacement of parts subject to wear and tear

Check the following parts subject to wear and tear and replace where applicable:

- Optical fibers (change after 10 treatments/sterilizations)
- Single-use tips (change after every treatment)
- Handpiece sleeve incl. plastic body and silicone switch coat (change after 400 treatments/sterilizations)
- Bending tool for single-use tips (change after 100 treatments/sterilizations)

- Fiber cutter (change after 400 treatments/sterilizations or every two years)
- Rechargeable battery (change after 1000 charging cycles or every two years)
- Batteries in wireless foot control (change after 1 year)

For further informations, see chapter "Cleaning, disinfection and sterilization" [→ 62].



CAUTION

Only use parts from Sirona Dental Systems, see "Spare parts" [→ 24].

9 Electromagnetic compatibility

NOTICE

The SIROLaser Advance complies with all requirements for electromagnetic compatibility according to IEC 60601-1-2: 2007

Definitions:

Emission (electromagnetic)

When electromagnetic energy is emitted by a source.

Interference immunity

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

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.

9.1 Electromagnetic emission

The **UNIT** is intended for operation in the electromagnetic environment specified below.

The customer or user of the **UNIT** should make sure that it is used in such an environment.


Emission measurement	Conformity	Electromagnetic environment – guidance
RF emissions according to CISPR 11	Group 1	The UNIT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions according to CISPR 11	Class B	The 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.
Harmonics according to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker according to IEC 61000-3-3	Complies	

9.2 Interference immunity

The **UNIT** is intended for operation in the electromagnetic environment specified below.

The customer or user of the **UNIT** should make sure that it is used in such an environment.

Interference immunity tests	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) according to IEC 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 according to IEC 61000-4-4	± 1 kV for input and output lines ± 2 kV for power supply lines	± 1 kV for input and output 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 voltages according to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode voltage	± 1 kV differential mode ± 2 kV common mode voltage	The quality of the line power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and variations of the power supply according to IEC 61000-4-11	<5% U_T for ½ period (>95% dip of U_T) 40% U_T for 5 periods (60% dip of U_T) 70 % U_T for 25 periods (30% dip of U_T) <5% U_T for 5sec. (>95% dip of U_T)	<5% U_T for ½ period (>95% dip of U_T) 40% U_T for 5 periods (60% dip of U_T) 70 % U_T for 25 periods (30% dip of U_T) <5% U_T for 5sec. (>95% dip of U_T)	The quality of the line power supply should be that of a typical commercial or hospital environment. If the user of the UNIT requires it to continue functioning following interruptions of the power supply, it is recommended to have the UNIT powered by an uninterruptible power supply or a battery.
Magnetic field of power frequencies (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Remarks: U_T is the AC supply voltage prior to application of the test level.			
			Portable and mobile radio equipment must not be used within the recommended working clearance from the UNIT and its cables, which is calculated based on the equation suitable for the relevant transmission frequency. Recommended working clearance:

Conducted RF interference IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz ¹	3 V _{eff}	$d = [1.2] \sqrt{P}$
Radiated RF interference IEC 61000-4-3	3 V/m 80 MHz to 800 MHz ¹ 3 V/m 800 MHz to 2.5 GHz ¹	3 V _{eff} 3 V _{eff}	$d = [1.2] \sqrt{P}$ at 80 MHz to 800 MHz $d = [2.3] \sqrt{P}$ at 800 MHz to 2.5 GHz <p>where P is the nominal transmitter output in watts (W) specified by the transmitter manufacturer and d is the recommended working clearance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey² should be less than the compliance level³ in each frequency range.</p> <p>Interference is possible in the vicinity of equipment bearing the following</p>  <p>graphic symbol.</p>

1. The higher frequency range applies at 80 MHz and 800 MHz.
2. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. An investigation of the location is recommended to determine the electromagnetic environment resulting from stationary HF transmitters. If the measured field strength in the location in which the **UNIT** is used exceeds the applicable RF compliance level above, the **UNIT** should be observed to verify normal operation. If unusual performance characteristics are observed, it may be necessary to take additional measures such as reorientation or repositioning of the **UNIT**.
3. Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

9.3 Working clearances

Recommended working clearances between portable and mobile RF communication devices and the UNIT

The **UNIT** is intended for operation in an electromagnetic environment where radiated HF interference is checked. The customer or the user of the **UNIT** can help prevent electromagnetic interference by duly observing the minimum distances between portable and/or mobile RF communication devices (transmitters) and the **UNIT**. These values may vary according to the output power of the relevant communication device as specified below.

Rated maximum output power of transmitter [W]	Working clearance according to transmission frequency [m]		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = [1.2] \sqrt{P}$	$d = [1.2] \sqrt{P}$	$d = [2.3] \sqrt{P}$
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 whose maximum nominal output is not specified in the above table, the recommended working clearance d in meters (m) can be determined using the equation in the corresponding column, where P is the maximum nominal output of the transmitter in watts (W) specified by the transmitter manufacturer.

Remark 1

The higher frequency range applies at 80 MHz and 800 MHz.

Remark 2

These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and persons.

10 Disposal



Your product is marked with the adjacent symbol. Within the European Economic Area, this product is subject to Directive 2002/96/EC as well as the corresponding national laws. This directive requires environmentally sound recycling/disposal of the product. The product must not be disposed of as domestic refuse!

Please observe the disposal regulations applicable in your country.

Disposal procedure

We advise that this product is subject to the stipulations in the EC guideline 2002/96 governing waste electrical and electronic equipment and must be disposed of in line with these special requirements within the European Union (EU).

Prior to disassembly / disposal of the product, it must be fully prepared (cleaned / disinfected / sterilized).

When disposing of equipment permanently, please proceed as follows:

In Germany:

To initiate return of the electrical device, please send a disposal request to "enretec GmbH".



1. You will find a form for placing a disposal order on the company's homepage (www.enretec.de) under the menu item "Entsorgung elektrischer und elektronischer Geräte" (Disposal of electric and electronic devices). The form can either be downloaded or completed online.
 2. Fill out the form with the corresponding details and send it either as an online order or fax it to enretec GmbH at +49(0)3304 3919 590. You can also get in touch with the following contacts for disposal orders and any questions relating to this you may have:
Tel: +49(0)3304 3919 500;
By e-mail: pickup@eomRECYCLING.com
Mailing address: enretec GmbH, Geschäftsbereich eomRECYCLING
Kanalstraße 17, 16727 Velten
- ✎ Any fixed installation equipment will be collected from its installation location in the practice, while loose equipment will be collected at the street curb at your address at the agreed time and date.

All disassembly, transport and packaging costs are to be borne by the owner/operator of the equipment. The disposal itself is free of charge.

Worldwide (outside Germany):

Please contact your local dental equipment specialist for country-specific information on disposal.



10.1 Batteries

Please dispose the batteries according to the disposal regulations and legal requirements applicable in your country.

Prior to disposal, remove the following batteries:

- Batteries in the wireless foot control
- Lithium battery in the SIROLaser Advance

10.2 Accessories

Optical fibers, single-use tips, handpiece sleeve incl. plastic body and silicone switch coat, bending tool for single-use tips and fiber cutter may be disposed in the domestic refuse. Please disinfect or sterilize the parts prior to disposal.

11 Appendix

11.1 Appendix A – Certification

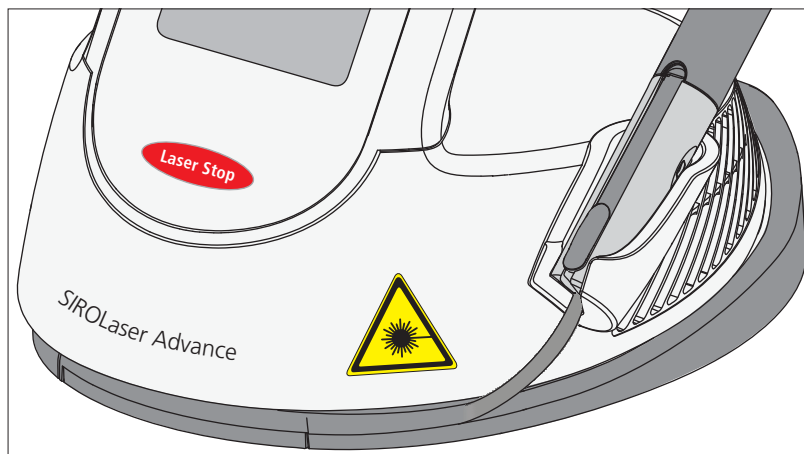
The unit is manufactured in compliance with the provisions of Council Directive 93/42/EEC concerning medical devices.

11.2 Appendix B – Label positions

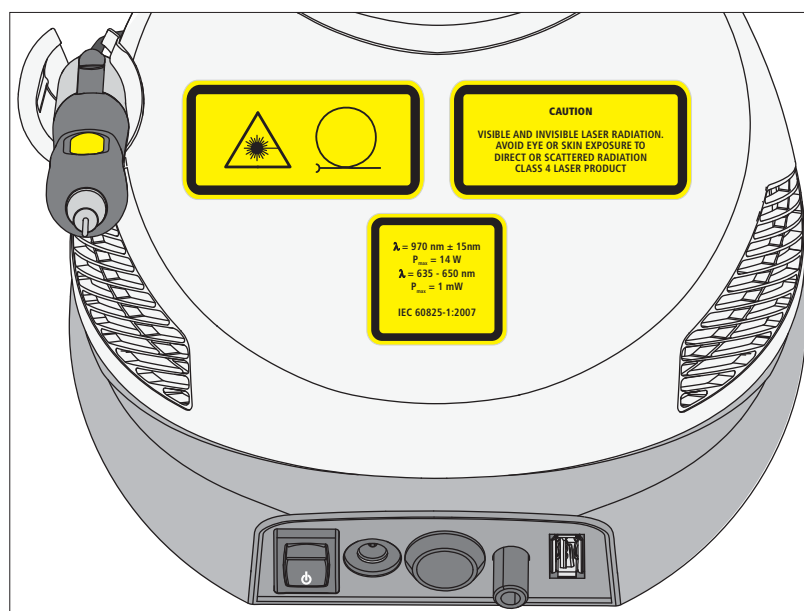
11.2.1 Control unit

The following figures show the positions of the labels on the SIROLaser Advance:

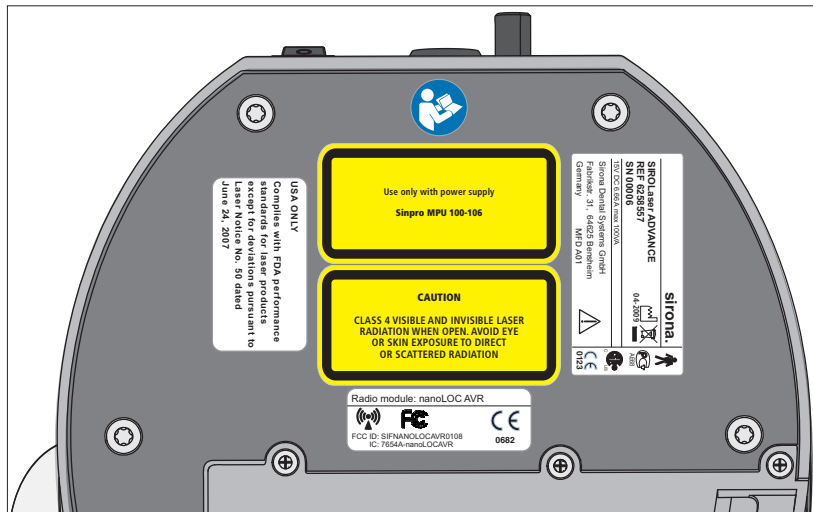
Front side



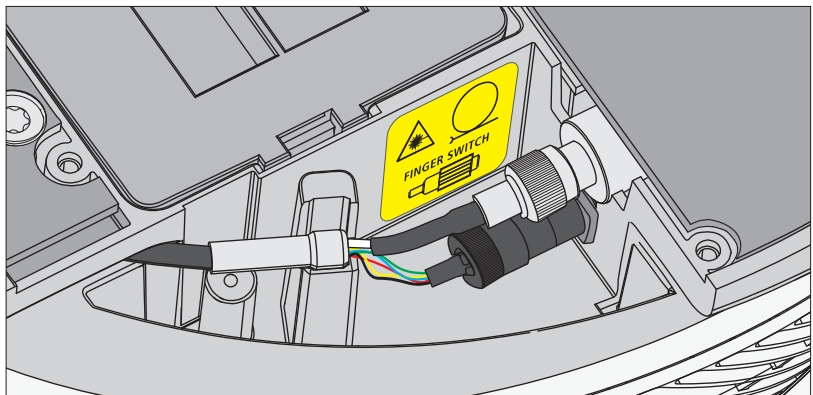
Rear side



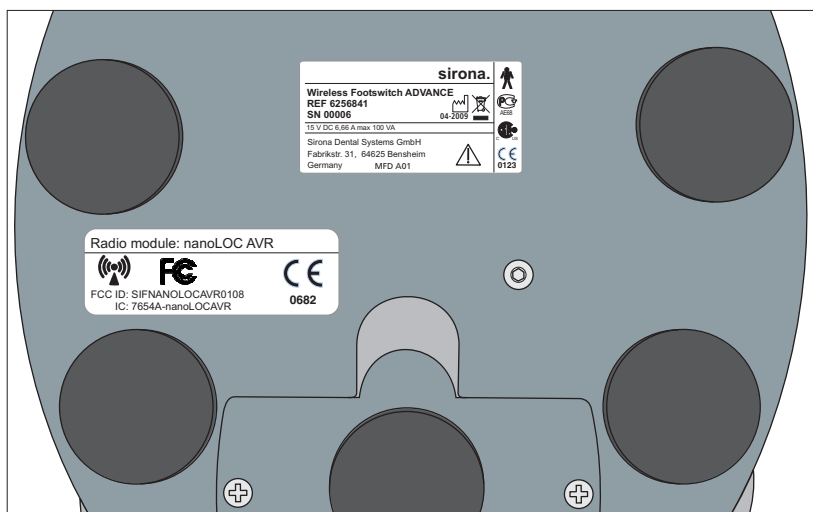
Bottom side



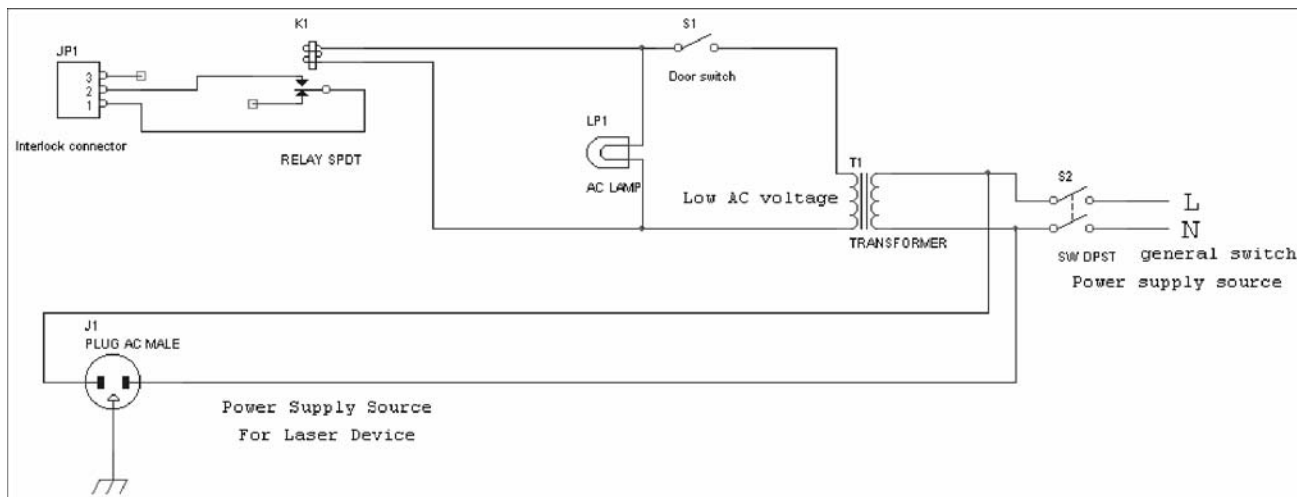
Under the battery cover



11.2.2 Wireless foot control – optional



11.3 Appendix C – Safety circuit (interlock)



JP1	Interlock connection supplied with the SIROLaser Advance (Insulate the jumper between pins 1 and 2; connect both of these pins to relay K1 with a two-core cable).
K1	Low-level relay (AC)
Door switch S1	Must close the interlock circuit when the treatment room door is closed.
Lp1	Optional low-level lamp used as an optical warning while the laser is in operation.
T1	Power transformer
S2	Main switch for power supply
J1	Possible power supply for the SIROLaser Advance

CAUTION

It is recommended to keep the distance between connector JP1 and relay K1 as short as possible.

Units designed for this purpose are already available from various companies, however, are also unreasonably expensive in some cases. We recommend having the installation performed by a qualified electrician who is also responsible for the electrical system.

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

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