New as of: 12.2017

Dentsply Sirona

Sculpt I.Q.

Operating Instructions

English

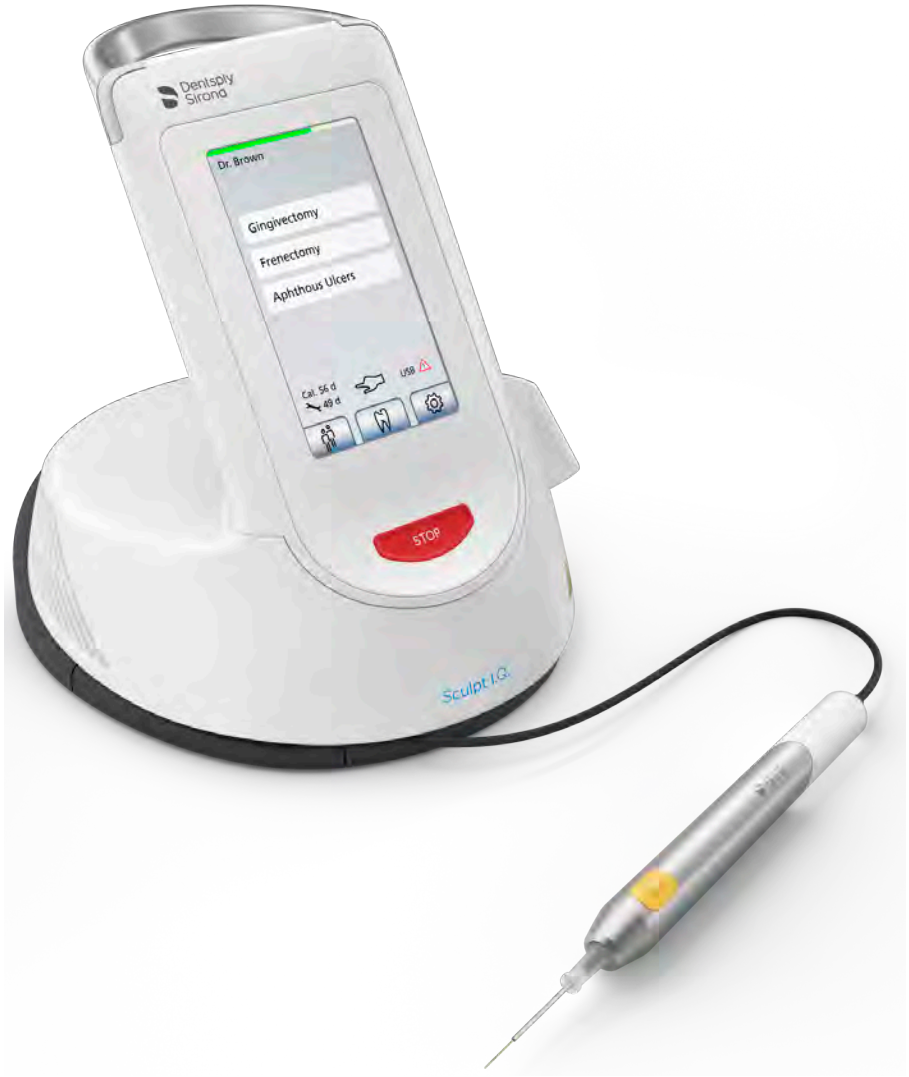


Table of contents

1 General information

1.1 Dear Customer

We are pleased that you have equipped your practice with the Sculpt I.Q..

The Sculpt I.Q. features diode laser technology. This device is characterized by a wide range of applications. A number of output settings are preset in the unit. Manual setting changes can be made and custom presets may also be introduced. The laser can alternatively be activated by the finger switch on the handpiece or by the optional wireless foot switch.

The 660 nm wavelength is not part of the standard device factory setup but can be unlocked with a specific code when purchasing the 660 nm upgrade. The code is unique for every single device and must be generated.

The upgrade is described in chapter Unlock of the 660nm wavelength (optional) [→ 34].

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 Sculpt I.Q..

Your Sculpt I.Q. Team

1.2 Contact data

Customer service center

For technical questions, use the contact form on the internet at the following address:
http://srvcontact.sirona.com

Local customer service - USA

Tel.: +1-800-883-8733

e-Mail: sales@essix.com

Manufacturer's address

Sirona Dental Systems GmbH
Fabrikstrasse 31
64625 Bensheim
Germany

Tel.: +49 (0) 6251/16-0
Fax: +49 (0) 6251/16-2591
e-Mail: contact@dentsplysirona.com
www.dentsplysirona.com

1.3 General information on the Operating Instructions

Observe the Operating Instructions

Please familiarize yourself with the Sculpt I.Q. 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

Retain these Operating Instructions in case you or another user require(s) information at a later point in time.

Make sure that the Operating Instructions and all other technical documents remain with the unit. 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 dealer.

1.4 Intended use

The Sculpt I.Q. is developed as a table top laser device intended for:

- intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and is indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.
- Whitening: For light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.
- Low Level Laser Therapy: To emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.

The use of the Sculpt I.Q. is not appropriate in an operating theater.

1.5 Formats and symbols used

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

Instructions for action

Prerequisite **1.** First action step **2.** Second action step or ➢ Alternative action ↳ Result, reaction of Sculpt I.Q.	Prompts you to do something.

References

See "General information [→ 5]"	Identifies a reference to another text passage.
[→ 7]	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 a 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 Sculpt I.Q., 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 Sculpt I.Q. 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 Sculpt I.Q. may only be operated by educated and qualified personnel (dentist, assistent, 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.

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 Sculpt I.Q. must not be used by unauthorized persons. Therefore the Sculpt I.Q. equipment must be protected against unauthorized access when not in use. This can be achieved, for example, by switching the Sculpt I.Q. off after usage so that the electronic access key (pin code) must be entered before using it again.

⚠ WARNING

The Sculpt I.Q. may only be used and maintained by thoroughly trained personnel.

2.4 Physical working principle

The 970 nm and 660 nm (optional, unlock via upgrade code) laser radiation of the Sculpt I.Q. is generated via laser diodes 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 and heating.

2.5 Laser radiation hazards

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

Observe all labels on the Sculpt I.Q..

Master switch of the practice

Note that after switching off the master switch of the practice the Sculpt I.Q. will still remain switched on. It is then 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 Sculpt I.Q. 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.

⚠ CAUTION

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

Flammable materials

Never direct the laser beam towards any flammable material, e.g. paper or plastics. 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 due to high temperature that the unit reaches during operation. Label removers and flammable solutions used for cleaning and disinfecting the Sculpt I.Q. should be allowed to evaporate before using the device. Observe fire hazards caused by flammable gases.

Reducing the risk of burns

Unintentional exposure to the laser radiation may lead to burns. This risk can be reduced by surrounding the target area with moistened sterile drapes or moistened gauze. These materials must meet the requirements of laser surgery.

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 e.g. patient, dentist, assistant must always wear the appropriate laser protective goggles which are delivered along with the Sculpt I.Q..

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:

These instructions apply particularly when using goggles supplied from an outside source that are not included with the Sculpt I.Q..

Optical instruments

Never use optical instruments such as microscopes, eye loupes or magnifiers together with the original protective goggles. Use of these instruments with the protective goggles will no longer ensure sufficient eye protection.

2.8 EasyTips and MultiTips

Optical fiber tips 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 EasyTip or MultiTip from the Sculpt I.Q., always cover the connection socket at the handpiece with the special protection cap supplied. Make sure that the optical system is clean before connecting the EasyTip or MultiTip.

The optical fiber must not be twisted inside the tube of the single-use fiber tip (EasyTip). There is a risk of breakage of the tip.

Stop the laser activation of the Sculpt I.Q. immediately if the EasyTip or MultiTip is broken. Otherwise the tips may become hot.

EasyTips and MultTips must be checked for proper seating prior to each use.

⚠ WARNING

Single-use fiber tips (EasyTip) must not be sterilized after usage. They are disposable products and are not for re-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 tip. This applies also if the handpiece is placed in the holder.

Prior to each use, the handpiece sleeve and the optical light guide (MultiTip) must be sterilized. The single-use fiber tips are delivered sterile and must be used only once and disposed after use.

Tissue particles

During cutting and coagulation of tissue, tissue particles could become aerosolized. 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.

⚠ WARNING

Single-use fiber tips (EasyTip) must not be sterilized again after usage. They are disposable products and are not for re-use.

➢ Never reuse the single-use fiber tips as they can also damage the handpiece optics if used more than one time.

2.10 Installation

Location

The Sculpt I.Q. is to be protected against the intrusion of liquids.

The Sculpt I.Q. must not be used in areas in which the presence 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.

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 Sculpt I.Q..

National directives regarding electrical installations must be observed.

Set up

Set up the Sculpt I.Q. unit properly and completely before putting it into operation, see chapter "Installation [→ 25]".

Functional Check

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 dropped or has fallen to the floor, 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 approximately 40 cm of the handpiece hose hangs and is not under tension.

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 Sculpt I.Q. if a visual inspection shows that it has been damaged in any way.

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 service performed, 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 ownerr / user, 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 [→ 63]".

Damages

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

Never, under any circumstances, try to disassemble the Sculpt I.Q.. Doing so is limited exclusively to trained and authorized personnel.

2.12 Radiotelephones

Mobile RF communications equipment can affect electro-medical equipment. Therefore, the use of mobile wireless phones in medical office or hospital environments must be prohibited.

2.13 Transferring data with USB stick

To guarantee the correct data transfer for software update, storage of the history file or user profiles use always an USB stick with the following specification:

- USB class 2.0 or above
- Minimum capacity of 512 MB and maximum 2 GB
- Filesystem FAT32 or NTFS

Always perform the data transfer according to the instructions of the manual. Never disconnect the USB stick during data transfer while you perform a software update.

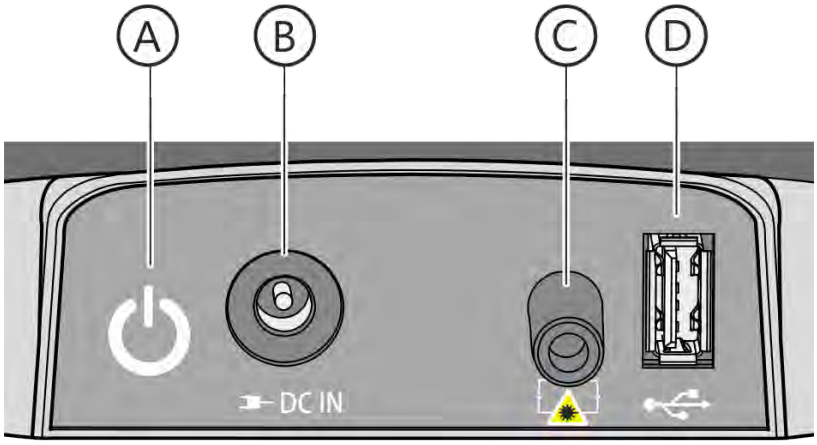
The connection of the Sculpt I.Q. to other USB devices could result in previously unidentified risks for your patients, yourself or others.

3 System description

3.1 System overview

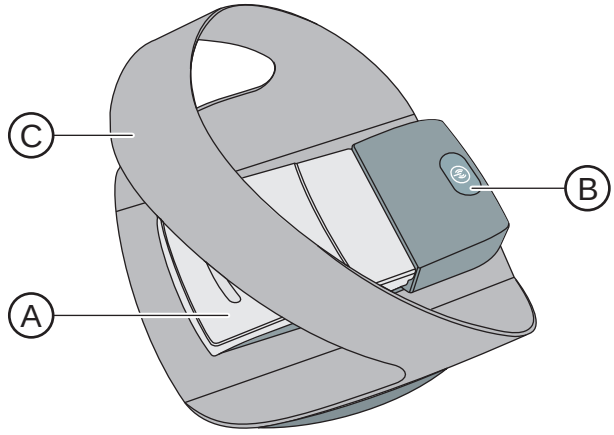
Sculpt I.Q. (Control unit)

A	LED lights
B	Touch screen
C	Handpiece holder
D	Laser Stop key
E	Cable for optical fiber and wires
F	Snap tab
G	Metal handpiece sleeve
H	Single-use fiber tips (EasyTip)
I	Finger switch with exchangeable keypad
J	Carry handle



A	ON/OFF switch
B	Power supply socket
C	Interlock connector including interlock connector
D	USB port

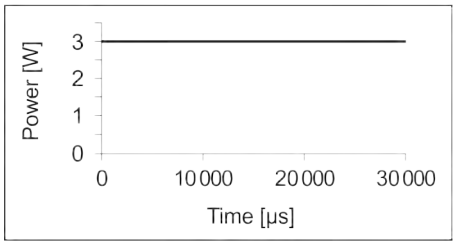
Wireless foot control – optional



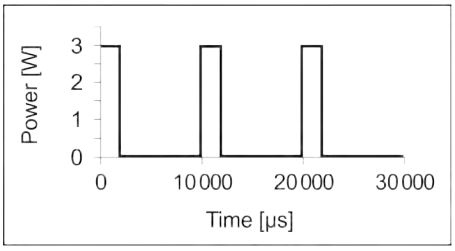
A	Foot switch
B	Registration key
C	Safety and positioning bar

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 mode presents a stable output power control since the maximum power equals the average power.



Chopped mode

In literature sometimes referred to as "pulse mode".

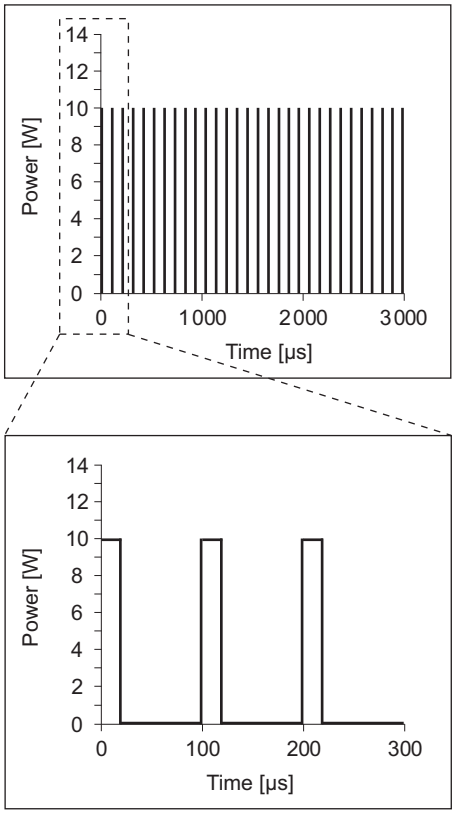
The laser beam is interrupted at regular intervals (e.g. 50% ON and 50% OFF) which can be adjusted via the duty cycle. The average power is the product of power and duty cycle.

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

⚠ CAUTION

The metal part on the back side of the handpiece can get warm. It serves as a passive cooling element for the laser source. However, an automatic control interrupts the laser emission when the temperature limit is reached.

Peak pulse mode



The laser beam is pulsed with a high peak (10 W) for a very short treatment pulse (20 µs) at a very high frequency (20 kHz) to achieve a longer cooling time. Therefore the duty cycles are reduced.

In adjacent example the laser is in peak-pulse mode with a power of 10 W and a duty cycle of 20%. The average power is 2.0 W.

NOTICE

The average power may not exceed 5 W in peak-pulse mode.

3.3 Symbols and abbreviations

3.3.1 Symbols

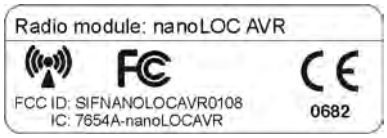
Type B applied part according to IEC 60601-1

CE 0123

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

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 of the wireless foot pedal

c SP® US

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

AE68

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

20XX-XX-XX

Date of manufacture: yyyy-mm-dd

20XX-XX

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

LOT XXXX / XX / XX

Batch number

STERILE EO

Single-use fiber tip is sterile, sterilized with gas (ethylene oxide)

NON STERILE

Single-use fiber tip is not sterile

Steripoint® as evidence of sterilization process
Filled with green dot: EO processed

SN

Serial Number

REF

Reference number

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

Please observe the user manual of the laser unit

Do not use when packaging is damaged

Temperature limitations, transport and storage

Protect against moisture, keep dry

Fragile, Handle with care

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

Power switch (on the backside of the control unit). Indicates the on and off position of the power switch

On/Off (on the switching power supply)

Class II unit according to EN 60601-1:2006

Connection socket for DC input from FRIWO FW8030M/18 power supply

Connection socket for interlock

Connection socket for USB

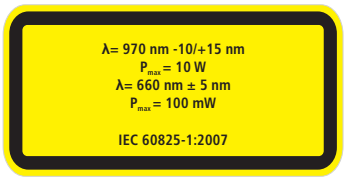
Interference is possible in the vicinity of the device

The disassembled handpiece sleeves may be sterilized only in autoclaves with saturated water vapor at minimum sterilization values of 135°C (275°F), 3 min. holding time and 2.04 bar (29,59 psi) overpressure.

Single-use only for sterile delivered fiber tips, no reuse

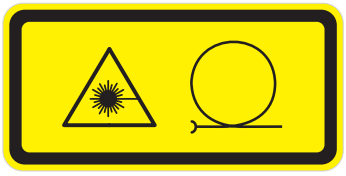
Refers to directive 2002/96/EC and EN 50419
Do not dispose with domestic waste

Laser radiation warning

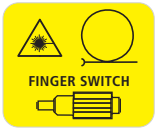


Specification of laser output power and wavelength of blue and aiming beam, see also chapter "Technical Data [→ 21]".

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



Warns of laser radiation emission at the distal tip of the handpiece. It also indicates the socket for the handpiece cable.



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 MPU101-106 power supply

3.3.2 Abbreviations

NOHD	Nominal ocular hazard distance	VA	Volt-ampere
CW	Continuous Wave	V_{eff}	Effective voltage
PF	Pulsed Frequency or Chopped Mode	V_{th}	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	kPa	Kilopascal
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
kV	Kilovolt		

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)

Sculpt I.Q. specification

Laser type:	Diode laser
Wavelengths & optical power:	970 -10/+15 nm / approx. 0.2 - 5.0 W (CW), optical peak power approx. 10 W 660 ± 5 nm / approx. 25, 50, 100 mW (CW), optional upgrade via code
Laser system:	970 nm: Class IV 660 nm: Class II(according to IEC 60825-1)
Device classification:	Class IIb (according to Council Directive 93/42/EEC)
Emission modes:	CW (continuous wave), chopped 1 Hz to 1000 Hz 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:	660 ± 5 nm, max. 1 mW
NOHD:	From the distal end of the optical fiber: 1.5 m
Optical fiber thickness:	200 and 320 µm (single-use fiber tips) 8 mm (glass rod
Operation:	Electrical wireless foot control or finger switch, with electronic access key
Nominal power input:	15 V DC 6.66 A max. 100 VA MPU101-106
Insulation class:	Class I, type B (according to IEC 60601-1) **Warning:** To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Type of protection against electric shock:	SIROLaser handpiece applied part type B 
Power supply:	The Sculpt I.Q. may only be operated with the Sinpro MPU101-106 power supply. Input voltage: 100 - 240 VAC Input current: 1.25 - 0.5 A Input frequence: 47 - 63 Hz
Separation of mains:	The separation of the mains of Sculpt I.Q. is conducted by unplugging the plug of the power supply on the backside of the unit's housing.

Optical fibers specification

Type of optical fiber:	EasyTip 320	EasyTip Endo
Core diameter:	320 µm	200 µm
Cladding diameter:	385 µm	240 µm
Coating diameter:	408 µm	270 µm
All diameters ± 20%		
Optical fiber length:	13 ± 1 mm	27 ± 1 mm
Tube length:	~ 25 mm	~ 25 mm

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/mm² (Nd:YAG, cw at 1060 nm)
Numerical aperture:	≥ 0.22
Tensile strength:	70 kpsi

Transport and storage

The Sculpt I.Q. comes in a cardboard box that ensures proper and easy transport.

⚠ CAUTION

Do not leave the Sculpt I.Q. 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.

Thus stored, the Sculpt I.Q. can withstand the following ambient conditions:

- Temperatures from -40 °C to +70 °C
- Relative humidity from 10 % to 95 %
- Atmospheric pressure from 50 kPa to 106 kPa

In its original transport packaging, the Sculpt I.Q. can withstand the following ambient transport conditions:

- Temperatures from -40 °C to +70 °C
- Relative humidity from 10 % to 95 %
- Atmospheric pressure from 50 kPa to 106 kPa

Operating conditions

The Sculpt I.Q. may be operated in the following environmental conditions:

- Temperatures from 50 °F (10 °C) to 91 °F (33 °C)
- Relative humidity from 10 % to 95 %
- Atmospheric pressure from 80 kPa to 106 kPa

⚠ CAUTION

Following transport and storage, allow the Sculpt I.Q. adapt to room temperature for one hour prior to operation to reduce the risk of malfunctions caused by condensation.

Sterile delivered single-use fiber tips

Labeling

Each tip is sterilized with gas (ethylene oxide). A label on the outer packing of each set of 25 single-use fiber tips indicates the sterilization procedure (see 3.3.1 symbols).

A green dot on the label of the outer packing serves as a process indicator for a correct sterilization process (see 3.3.1 symbols).

⚠ WARNING

Do not use the single-use fiber tips if there is no green dot on the label of the outer packaging.

Storage

To ensure the proper storage and therefore the sterility of the tips, the following environmental factors have to be considered in terms of storage:

- Protection from moisture
- Protection from pollution
- Mechanical stress
- Exposure to direct solar or UV radiation
- Exposure to temperature fluxuations
- In a closed storage system (e.g. cupboard, drawer), or
- in shelves or rooms of the room class II according to DIN 1946-4: 2008 -12
- From 15 °C to 25 °C (room temperature)
- Under relative humidity from 40% to 60% (dry conditions)

Only store the single-use fiber tips in the outer packaging, which serves as the safety packaging (carton).

Use the oldest tips first according to their best-before month. This date is labeled on each packaging tube of the tips and on the outer packaging of the tip set. The remaining quantity should be stored in the closed outer packaging (carton).

Do not refill an outer packaging (carton) of the single-use fiber tip sets with new tips.

4 Installation

Any national or local regulations stipulating that the Sculpt I.Q. 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 Sculpt I.Q.:

		Order-No
Sculpt I.Q.		66 59 101
1 x	Sculpt I.Q. control unit including handpiece with integrated finger switch	
1 x	Fiber cutter	
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	
5 x	Optic protection cap (package)	
Language-specific documentation set, e.g. User Manual		
Country-specific power cable		see "Spare parts [→ 25]"
Option: Wireless foot control		66 59 556
Option: 660 nm upgrade*		66 61 420

*For instruction how to perform the unlock see chapter Unlock of the 660nm wavelength (optional) [→ 34].

4.2 Spare parts

	Order-No
Handpiece sleeve with keypad	66 59 184
EasyTip 320 (25 pieces)	66 59 283
EasyTip Endo (25 pieces)	66 59 291
MultiTip 8 mm, therapy light guide	66 59 309
Optic protection cap for handpiece (5 pieces)	66 59 192
EasyBend - Bending tool (2 pieces)	66 59 200

Fibercutter	66 59 218
Laser protective goggles	66 59 226
Laser protective goggles for spectacle wearers	66 59 234
Laser protective goggles for patients	66 59 242
Battery Pack	66 59 259
Switching power supply	66 59 267
Power cord US	66 59 275

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 [→ 76]".

4.4 Initial start-up – procedure for proper assembly

4.4.1 Install power supply

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

⚠ CAUTION

The Sculpt I.Q. may only be operated with the Sinpro MPU101-106 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 Sculpt I.Q. 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 reaches a low level of capacity.

This is indicated by the red LED bar on the top of the control unit.

The Sculpt I.Q. 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 and assembly of single-use fiber tips and therapy rods

4.4.2.1 Handpiece

A	Handpiece body with tube
B	Snap tab
C	Stainless steel handpiece sleeve
D	Keypad for finger switch

4.4.2.2 Assembly of sterile single-use optical fiber tips

4.4.2.2.1 Area of application

The Sculpt I.Q. is provided with three types of sterile single-use optical fiber tips of different diameter so that it can be used for a variety of different dental procedures and indications:

- Single-use optical fiber tip, EasyTip 320 (sterile)
- Single-use optical fiber tip, EasyTip Endo (sterile)

For the specification of each type of EasyTip see chapter „Technical Data [→ 21]“.

EasyTips are delivered sterile in a special packaging tube, which also assists the mounting of the fiber tips.The single-use fiber tips can be used only with the Sculpt I.Q. in the spectral range of 970 nm ± 15 nm.

⚠ WARNING

If optical fiber tips 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 single-use optical fiber tips.

⚠ WARNING

The fiber tips from the demo set of single-use fiber tips in the scope of supply serve only as test fibers for first familarisation with the unit. They are not sterile, as shown on their label. Do not use them for clinical treatments of patients.

⚠ WARNING

Do not sterilize the single-use fiber tips (EasyTips) again after usage. Re-sterilization would severely affect the characteristics of the single-use fiber tips (laser power output, form, accuracy,…).

4.4.2.2.2 Preparation for clinical application

1. The EasyTips are delivered sterile. The metal handpiece sleeve can be sterilized in the autoclave (high-pressure sterilizer), see chapter "Cleaning, disinfection and sterilization [→ 60]".
2. Select the required sterile EasyTip (320 or Endo), see chapter "List of preset indications".

⚠ 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 [→ 64]".

The optical fiber of the EasyTip may be damaged if it is seriously bent. This may constitute a health hazard for patients, dentists and dental assistants.

Remove the protection cap for treatment only. Never touch the proximal end of the cap and protect it against damage and dirt.

Never use the laser without optical fiber. Verify correct fixation of the fiber. Never bend, fold or jam the EasyTip, as this might cause it to break. The EasyTip cannula must never be bent without the bending tool.

Never pull on the optical fiber of the EasyTip.

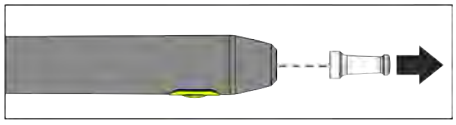
Mounting of the EasyTip:

Do not use the EasyTip if its packaging tube is damaged or the best-before date has expired. The best-before date is printed on the product label of the packaging tube.

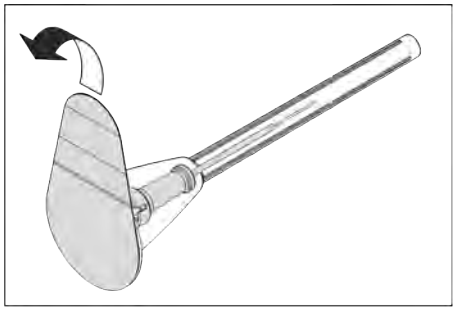
⚠ WARNING

If the EasyTip is used after the best-before date, the required sterile conditions of the EasyTip can not be guaranteed. Moreover, 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.

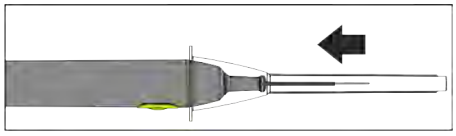
After removal of a tip, immediately lose the outer packaging.



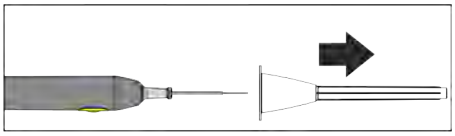
1. Remove the protective cap from the connection socket at the handpiece



2. Open the sterile transport packaging tube of the EasyTip by tearing off the seal label from the top of the packaging.



3. Position the packaging tube with the EasyTip on the connection socket by placing the funnel-shaped end of the packaging on the handpiece.
4. Press the packaging tube with the EasyTip against the handpieceusing light pressure until the EasyTip perceptibly clicks into place and is firmly seated.



5. Remove the packaging tube from the handpiece and the connected EasyTip.
6. Please check whether the EasyTip is firmly seated on the handpiece and perform a visual check to make sure that it has not been damaged during shipment.
7. Put the laser into operation by choosing any preset treatment. A corresponding description is provided in chapter "Operation [→ 35]".

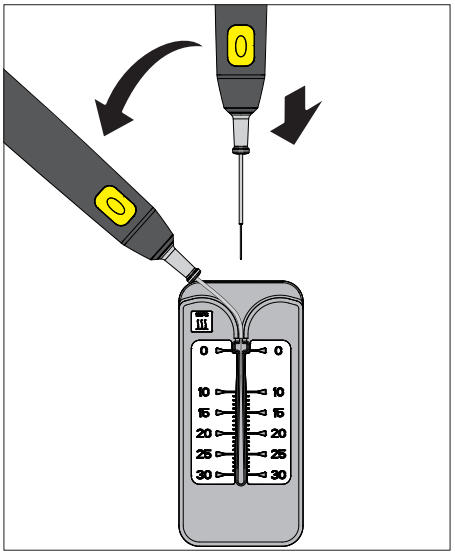
⚠ WARNING

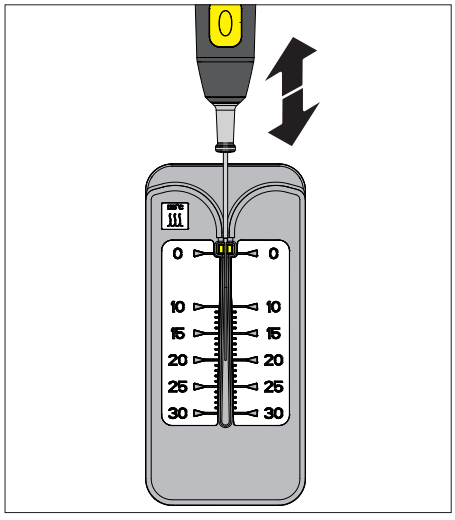
The aiming beam must not be aimed toward a person‘s eye. It consists of an intensive light source even when set to a low power level. Always wear protective goggles.

8. As soon as the Sculpt I.Q. 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 EasyTip vertically at a white background. If the beam shows no pattern or the beam pattern is not illuminated evenly, the EasyTip may be damaged or defective. In this case, return the EasyTip to your dental dealer so that it can be replaced under warranty. Do not use any defective EasyTips.

Bending of the EasyTip

1. Please sterilize the bending tool prior to each use in order to keep the sterile conditions of the EasyTip, see chapter "Cleaning, disinfection and sterilization [→ 60]"
2. After sterilizing the bending tool, you can insert the EasyTip into the bending tool and bend the EasyTip to the angle that you need for best handling.

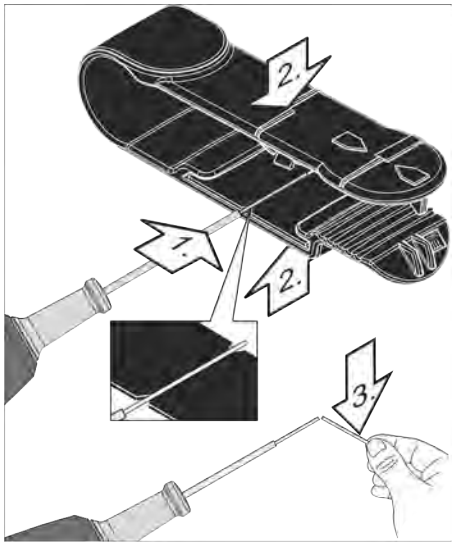




Adjusting the position of the endo stopper

The single-use fiber tip for endodontic applications (EasyTip Endo) is provided with a pre-mounted endo stopper, which serves as a stop collar for the length of the root canal. The endo stopper can be moved on the optical fiber.

1. To guarantee the sterile conditions of the fiber tip, please use the sterilized bending tool to adjust the position of the endo stopper.
2. Place the EasyTip in the bending tool so that the endo stopper positions itself in the notch for the stopper in the bending tool.
3. Adjust the position of the endo stopper by moving the handpiece up and down so that the end of the fiber tip has the needed distance to the stopper (indicated by the mm scale on the bending tool).



Adjusting the fiber length with the fiber cutter

Generally, all types of sterile delivered single-use fiber tips have the proper fiber length in order to start working immediately without the need of adjusting the length prior to application. However, in some cases it will be necessary to adjust the length of the fiber.

Please sterilize the fiber cutter prior to each use to keep the sterile conditions of the EasyTip, see chapter "Cleaning, disinfection and sterilization [→ 60]".

1. Place the optical fiber of the EasyTip in the fiber cutter at the notched mark.
2. Press the fiber cutter together and release it again.
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. 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. It is only necessary to create small notch to produce a clean break when breaking the fiber at the notch.

⚠ WARNING

If the optical fiber of the EasyTip does not protrude at least 5 mm out of its metal tube, there is a risk that the tube will heat up.

After treatment

The easiest and safest way to disconnect the EasyTip from the handpiece after treatment is to use a disposable container.

1. Open the lid of the disposable container and connect the plastic grip of the tip to the suitable recess inside the container.

2. Remove the EasyTip from the handpiece by pulling the container away from the handpiece.
3. The EasyTip falls into the disposable container.
4. Close the disposal container.

⚠ CAUTION

As soon as you disassemble the EasyTip after treatment make sure to protect the optical fiber socket with the protective cap provided for this purpose. Make sure that no dust or dirt enters the optical system. Otherwise the unit may be permanently damaged.

4.4.2.3 Assembly of therapy light guides

4.4.2.3.1 Area of application

There is one reusable therapy light guide that can be used for additional dental procedures with the Sculpt I.Q.:

- Light guide (MultiTip 8 mm), diameter: 8 mm

The light guides are delivered non-sterile.

⚠ WARNING

After 2,000 sterilization cycles or 2 years which marks the end of the service period, the MultiTips will have reached their wear limit. Please check the usage period based on the LOT number (definition of LOT = week year e.g. 0215 for calendar week 2, 2015). Please replace the light guide accordingly. The optical output can be reduced.

The MultiTips can be used only with the Sculpt I.Q. in the spectral range of 660 nm ± 5 nm and 970 nm ± 15 nm.

⚠ WARNING

If light guide rods 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 light guide rods.

4.4.2.3.2 Preparation for clinical application

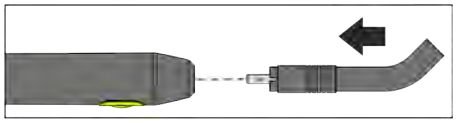
⚠ WARNING

For safety reasons it is necessary to use the 8 mm light guide (MultiTip) if wavelength of 660 nm is chosen

IMPORTANT

If the optional 660 nm wavelength should be used this optional feature must be unlocked with a unique code purchasable with the 660 nm upgrade package. Procedure to unlock the 660 nm option is described in chapter Unlock of the 660nm wavelength (optional) [→ 34]

1. The MultiTips are delivered non-sterile. Make sure that the rod is clean and sterile. The metal handpiece sleeve can be cleaned in the autoclave (high-pressure sterilizer), see chapter "Cleaning, disinfection and sterilization [→ 60]".
2. Select the required MultiTip light guide (diameter 4 mm), see chapter „List of preset indications”.



3. Please perform a visual check to make sure that the MultiTip is not damaged or has not reached its wear limit.
4. Connect the optical connection of the MultiTip to the optical socket of the handpiece. Press the MultiTip with light pressure against the handpiece, until the MultiTip perceptibly clicks into place and is firmly seated.
5. Put the laser into operation by choosing any preset treatment destined for the light guide. A corresponding description is provided in chapter "Operation [→ 35]".

⚠ 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 [→ 64]".

Only use the MultiTips for treatments appropriate for them. EasyTips and MultiTips have completely different optical characteristics.

Remove the protective cap of the handpiece only for treatment.

Never touch the proximal end of the cap and protect it against damage and dirt.

Never use the laser without optical fiber or MultiTip light guide, check for correct fixation.

After treatment

Disconnect the MultiTip from the handpiece by removing it carefully from the optical socket of the handpiece.

⚠ CAUTION

As soon as you disassemble the MultiTip after treatment make sure to protect the optical fiber socket with the protective cap provided for this purpose. Make sure that no dust or dirt can enter the optical system. Otherwise the unit may be permanently damaged.

For cleaning, disinfecting and sterilizing the MultiTip please refer to chapter "Cleaning, disinfection and sterilization [→ 60]".

4.4.3 Install wireless foot control – optional

The Sculpt I.Q. 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 is not suitable for use in hospital operating rooms.

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

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

✓ The Sculpt I.Q. control unit and the wireless foot control are ready for operation.

1. Choose "Settings" from the main home screen.
2. Choose "Activation device".
3. Choose "Wireless registration".
4. Press the foot pedal for 3 seconds and follow the instructions on the screen.
5. After this, press the registration key on the top of the wireless foot control radio box for three seconds.
   - ↳ After this the device shows a mac address of the pedal and asks to confirm the pairing within 20 sec.
   - ↳ Confirm via 'OK'.
6. To use the wireless foot control, choose the wireless foot control from the "Settings" submenu in "Activation device" .

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 Sculpt I.Q. 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 – Safety circuit (interlock) [→ 78]".
2. Mount the prepared interlock plug into the interlock socket on the backside of the Sculpt I.Q..

4.4.5 Unlock of the 660nm wavelength (optional)

The 660 nm wavelength is an optional feature which can be unlocked with a unique code purchasable with the related 660 nm upgrade package (Order No. 66 61 420).

For unlocking this feature please contact the local customer service:

Tel.: +1-800-883-8733

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 Applications

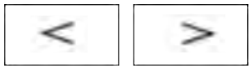
Delete
Settings of application will be deleted from My Applications. Defined users will be deleted from the user list.

Continuous wave
Laser is being set for continuous wave mode

C (clear button)
User clears letters or digits (going backwards)

Help
User wants to open additional help information to this application

'Plus' and 'Minus'
User is able to count up and down respectively and 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)

User Change
Change the user by entering the password dialog

Settings
User is able to do all the necessary settings, e.g. language settings

All applications
User is able to select an application from all applications or to define a customized application

NOTICE

Alphabetic and numeric letters, limitation to data input:

- Numbers are displayed with English decimals '.' for all languages/ regions.
- The power for 970 nm is displayed with one decimal place. Unit is watt (W).
- The power for 660 nm is displayed with no decimal place. Unit is milliwatt (mW).
- 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 H. If 0 Hz is set, CW is displayed. Unit is hertz (Hz).
- The average power will automatically be calculated and displayed with one decimal place for 970 nm, with no decimal place for 660 nm. Unit is watt (W) for 970 nm, milliwatt (mW) for 660 nm.
  The peak-pulse mode is not possible with an average power below 0.2 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 0.2 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%.

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/off power

Switch on the laser device

The LEDs will blink after starting the Sculpt I.Q. by switching on the on/off button on the backside of the control unit.

While the Sculpt I.Q. is booting, information about the software version and the set language as well as the note to read the user manual will be displayed.

IMPORTANT

In some cases when the laser has been switched off for a longer time, it may be necessary to press the on/off button two times to start the unit.

When starting the Sculpt I.Q. for the very first time, you will automatically be asked to set-up the unit. Please proceed as requested:

1. Language and 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 "Language and country settings".
   ↳ 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 authorized by the FDA.

2. Date & time
   Please enter the appropriate date & time and press 'OK'. See also chapter "Date & time [→ 46]".
3. User management
   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 management [→ 46]".

Switch off the laser device

To switch off the laser device press the on/off button on the backside of the control unit. The unit will ask you then to confirm switching off by pressing the “OK“ button on the screen.

NOTICE

After switching off the laser device, it is not possible to immediately restart the unit due to the shutdown process of the unit. Please wait a few seconds until the shutdown is completed.

⚠ WARNING

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

In any unpredicted case, the laser device can also be switched off by pressing the on/off button on the backside of the control unit for longer than 5 seconds.

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.

5.3 Enter pin code

The Sculpt I.Q. may be operated only by authorized personnel and has an electronic key for security purposes.

5.4 Sleep Mode

After 10 minutes, the unit falls into the sleep mode. During the sleep mode, the LEDs will be blinking in blue color. After touching the display, the unit will immediately wake up and jumps into the password screen.

5.5 Main home screen

The following section describes the main home screen. The main home screen includes the following options and information:

- **Favorites**
  Use, define or change three favorite applications directly on the home screen.
- **All applications**
  After opening the submenu, you will be able to select among different preset treatment parameters: Surgery, Periodontology, Endodontics, Miscellaneous, and My Applications. All submenus are structured the same way.
- **Settings**
  Within this submenu you will be able to configure the Sculpt I.Q. to your needs as well as you will find all necessary settings and service programs.
- **User Change**
  By pressing the 'user change button' you will jump back to the screen 'enter pin code'.
- **Self Test**
  After booting the Sculpt I.Q. will automatically perform a self test. The information will be shown in the main home screen.

5.5.1 Self Test

After booting, the Sculpt I.Q. will automatically perform a self test including a status check of the following functions:

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

The statuses are displayed on the home screen.

Finger switch

NOTICE

If the finger switch is defective/missing the unit shows an error message after booting. In this case please check the cable connection to the Sculpt I.Q. control unit, see chapter "Troubleshooting of simple defects". If the finger switch remains defective/missing, please contact your local dental dealer or an authorized Customer Service Department for technical support.

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

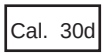
USB port

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

If the appropriate symbol for USB port error is not displayed on the home screen, the USB port works properly.

If the symbol is displayed on the home screen, the USB port is defective.

Calibration check



The information for 'next calibration check' is only displayed on the home screen for the first time after restart or log-in (in month).

For the last 30 days it is displayed continuously on the home screen. After excess of the service interval the days are displayed with a minus [-] and red coloured.

The laser remains fully functional during this time.

Time to service

The safety test is a mandatory test for all medical devices. The Sculpt I.Q. needs to be tested once every two years.
The information for 'time to service' is only displayed on the home screen for the first time after restart or log-in (in month).

For the last 30 days it is displayed continuously on the home screen. After excess of the service interval the days are displayed with a minus [-] and red coloured. The laser remains fully functional.

NOTICE

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

5.5.2 Favorites

Three applications from pre-sets within the submenus: Surgery, Periodontology, Endodontics, Miscellaneous and / or self-defined applications from My Applications can be defined as favorite applications directly accessible from the home screen.

5.5.2.1 Change a favorite

➢ If a favorite button is already assigned to an application, please press and hold the favorite button for longer than 2 seconds.

↳ The screen will automatically jump to the screen 'All Applications'.

↳ You will be now able to select another application from the different submenus as a favorite: Surgery, Periodontology, Endodontics, Miscellaneous, and My Applications.

5.5.3 Submenu: All applications

The submenus of the surgery, periodontology, endodontics, soft laser therapy and miscellaneous areas as well as the area of own applications are arranged in the same way. After opening the submenus, you can select among different indications with preset treatment parameters.

Endodontics

- Pulpotomy
- Pulpotomy as adjunct to root canal ther

Miscellaneous

- Aphthous Ulcers

Periodontology

- Sulcular debridement
- Gingival incisions of granulation tissue

Surgery

- Frenectomy
- Gingivectomy
- Gingivoplasty
- Hemostasis
- Implant uncovery
- Operculectomy

Putting the laser in ready mode

1. Select the desired preset.
   ↳ The pre-set parameters will be displayed.

⚠ WARNING

Check the set parameters before activating the treatment.

2. Now you can activate the laser: Press the 'Activate Laser' button.
   ↳ You will be notified to wear the correct protective goggles before the aiming beam is activated.
3. Acknowledging the notification.
   ↳ The green LEDs start flashing. After a delay of 2 seconds, the aiming beam is switched on.
   ↳ The laser is now ready for operation.

NOTICE

If the finger switch or foot switch is actuated during the 2 second period before the laser is in ready mode, an error message will be displayed.

⚠ WARNING

All persons present in the room (operator, assistants and patient) must wear the proper laser protective goggles as soon as the laser unit's notification to wear laser protective goggles appears and whenever the green LEDs are lit.

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

Incorrect settings may result in severe damage of the patient's soft or hard tissue or may result in lack of treatment efficacy. Users of this device must have proper 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 using battery power, please reconfirm the battery status.

When you actuate the finger or wireless foot control, the laser output is activated. At the same time, two yellow LEDs at the upper right and left end of the Sculpt I.Q. control unit light up, as does 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 output is deactivated, but the laser 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 this example, the power output setting is 3.0 W. 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 0.2 W and 5.0 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, the output duration (time) is set to continuous (00 s). In this mode, the laser is 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 to durations from 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, the duty cycle is set to CW (continuous wave mode). The duty cycle is defined as the ratio between the pulse duration (the duration that the laser beam is actually activated) 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 10% and 90% by typing in the numbers or by moving higher or lower by using 'plus' (+) or 'minus' (-).

NOTICE

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

5. Frequency

In our example, the frequency is set to 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 [→ 15]".

Continuous wave

When pushing the ’CW’ button, the continuous wave mode is set and "CW" appears in the control field. Selecting ’OK’ returns you to the treatment submenu in which you can further adjust the power and time.

Chopped mode

When a frequency setting in the range from 1 to 1,000 Hz is entered, the "chopped" mode set. Selecting ’OK’ returns you to the treatment submenu in which you can further adjust the power, time and duty cycle.

NOTICE

The chopped mode is not available with an average power below 0.05 W. If a power setting below this value is set in chopped mode, the following error message appears: "Chopped mode available only with an average power above 0.05 W."

Peak-pulse

When pushing the ’PP’ button, the peak-pulse mode is set. Selecting ’OK’ returns you to the treatment submenu in which you can further adjust the time and average power. The power peak-pulse mode is preset to 10 W peak-pulse. The duty cycle is calculated. Applied power in peak-pulse mode is adjusted by changing the average power.

6. Average power

Further more the example here shows:

7. Home button

By pushing the home button you will jump directly to the home screen.

8. Back button

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

9. Help button

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

10. Laser button

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

5.5.3.1 My Applications

Up to 12 applications can be generated and saved to My Applications.

NOTICE

If My Applications are full and the addition of another application is attempted, a warning screen will signal that remove an application must be removed or the chosen application will not be saved.

1. If you press the 'plus' button on the My Applications screen, a blank input screen is opened.
2. Name the new application by touching the field ‘name‘.
   ↳ 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 'OK' button.

Applications can be deleted from My Applications by pressing the 'delete' button.

⚠ WARNING

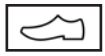
Incorrect settings may result in severe damage of the patient's soft or hard tissue or may result in lack of treatment efficacy. Users of this device must have proper knowledge and training of laser therapy.

5.5.3.2 Settings

After pressing the ‘settings‘ button on the home screen, the screen jumps into the settings menu

5.5.3.2.1 Activation device

If you have purchased the Sculpt I.Q. 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 [→ 33]" for further instructions.

It is also possible to check the functionality of the finger switch and the foot control (only if it is registered) in this menu:

➢ Press the finger switch or the foot control.

↳ If the pressed activation device works properly, the unit indicates it by beeping of the warning sound. No laser beam is activated during this functionality check.

5.5.3.2.2 Date & time

Format for date: dd/mm/yyyy
Format for time (24hours notation): hh/mm

➢ Enter date & time and save by pressing 'OK'.

5.5.3.2.3 Sound volume and display settings

Sound volume

1. Select volume level of warning sound and push button sound by using 'plus' (+) or 'minus' (-).
   ↳ Level of warning and push button sound will immediately be applied.
2. Save with 'OK'.

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'.

5.5.3.2.4 User management

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

NOTICE

The set-up of the key user is fixed and not changeable, but it is possible to edit the key user name (e.g. SMITH instead key user) and to change the default PIN code 2 9 7 4.

The key user is the administrator of the Sculpt I.Q. and has all rights to create and configure one adittional user as well as to remove the user.

The additional user will have access only to limited parts of the settings: Language, display setting, sound volume, finger or foot switch, and battery calibration.

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

Create a new user

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

➢ To enter the name, pin code and other settings for the new user, press the appropriate buttons shown on the screen.

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

NOTICE

If 'no' is entered, there will be no My Applications 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 watts.

NOTICE

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

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

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

NOTICE

Non-usable applications due to direct selection or power limit restriction appear shaded and are disabled.

Load & save the addditional user profile

It is possible to either upload the additional user profile including their own applications and favorites (for example from other devices) from a USB stick to the unit or to download an existing user profile from the unit to an USB stick.

Profile upload:

1. Insert the USB stick.
2. Press the "load configuration" button.
3. The user profile stored on the USB stick will be uploaded to the device.

NOTICE

The previous user profile on the unit will be overwritten by the profile from the USB stick.

Profile download:

1. Insert the USB stick.
2. Press the "save configuration" button.
3. The user profile on the device will be copied to USB stick.

⚠ CAUTION

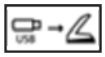
Use a USB class 2.0 (or above) memory stick.

Specify the USB configuration that is FAT32 and NTFS.

NOTICE

The system requires approx. 5 seconds to detect the USB stick.

5.5.3.2.5 Software update



If a software update of the Sculpt I.Q. is needed, please proceed as follows:

⚠ CAUTION

Use a USB class 2.0 (or above) memory stick.
To perform the software download, use a USB stick with a minimum capacity of 512 MB.
Specify the USB configuration that is FAT32 and NTFS.

1. Choose the "Settings" item in the main menu.
2. Choose "Software update".
3. Follow the instructions and insert the USB stick.

NOTICE

The system requires approx. 5 seconds to detect the USB stick.

- ↳ The message "updating software..." and an hour glass appears which indicates that the software update is in progress.
- ↳ After this, the unit automatically reboots with the 2 LEDs lighting orange and a white screen.

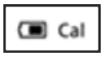
⚠ CAUTION

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.

4. Enter the pin code.
   - ↳ The software update was successfully performed. The USB stick can be removed.

5.5.3.2.6 Battery calibration



For optimum battery performance, a battery calibration must be performed whenever the battery has been removed and reconnected or when a new battery pack is installed. See chapter "Replacing the rechargeable battery of the control unit [→ 66]".

1. Switch on the laser without having connected the power supply.
2. Choose "Battery calibration" in the settings menu.
   - ↳ The following message will appear: "Battery calibration may take several hours."
3. Press 'OK'.
   - ↳ The battery will now be discharged automatically until the device switches off due to lack of power.
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).
   - ↳ The battery is now calibrated.

5.5.3.2.7 Laser calibration check

⚠ WARNING

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

The following section describes the procedure to check the laser calibration of the Sculpt I.Q..

We recommend performing this check at least once a week.

In order to verify proper functioning of the Sculpt I.Q., we recommend performing calibration check at the following stages:

- 1 W (970 nm)
- 100 mW (660 nm)

The Sculpt I.Q. 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 the following values, the calibration is correct:

- wavelength: 970 ±15 nm
  power: 1 W
  resolution: 5 % or higher
- wavelength: 660 ±5 nm
  power: 100 mW
  resolution: 5 % or higher

Select one of two test procedures to check the calibration:

5.5.3.2.7.1 Calibration check without an external power meter

➢ Select "w/o power meter".

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

Begin the calibration: Assemble the handpiece with a properly 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. Potential danger exists for skin and eyes!

Do not direct the laser beam to flammable objects or use the laser in the vicinity of flammable substances or gases around.

Do not direct the laser to reflective (metallic) surfaces. Potential danger exists 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 all wavelengths.

For each value, the device compares the delivered current with the calibration value. If the value is inside the tolerance, the test is passed. If the measurement is out of the tolerance, the test is stopped.

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.

5.5.3.2.7.2 Calibration check using an external power meter

Required power meter: Calibrated power meter capable of measuring a power level of at least 1 watt at a wavelength of 970 nm and 100 mW at a wavelength of 660 nm with an accuracy of better than 10%.

➢ Select "with external power meter".

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

Begin the calibration: Direct the mounted handpiece with properly installed fiber to the head of your power meter.

⚠ WARNING

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

Do not direct the laser beam to flammable objects or use the laser in the vicinity of flammable substances or gases.

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

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

1. For each value, the device asks to perform a measurement and indicate if the measured value is within the tolerance (value -20% / value +20%).
2. Press the finger switch for at least 3 seconds while directing the laser to the head of the power meter.
3. Read the measured power from the display of your power meter.
4. The unit will ask you whether the measured value is within the tolerance of ±20%. Press 'Yes' on the screen if the measured value is within the tolerance of ±20% Press `No` if it is outside the tolerance.
5. Repeat the procedure for all wavelengths.

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.

5.5.3.2.8 Language and country settings

Language

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

➢ You have the choice of different languages. The currently set language is greyed out. Select one and confirm by pressing 'OK'.

↳ Language will be applied after confirmation.

NOTICE

The language will be changed for all users.

Country settings

NOTICE

The country setting for the US is pre-set.

⚠ WARNING

It's forbidden to change the country setting to Non US if you are subject to US legal regulations. The use of the country setting Non US is not authorized 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.

5.5.3.2.9 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 Error messages, warnings and instructions

5.5.4.1 Error messages and warnings

Pin not correct
Confirm via ‘OK’ to insert the pin code again.

The screen is displayed in case of anomaly. It avoids hazardous situation resulting from failure of the it-network: downgrade not allowed or corrupted package.
Confirm via ‘OK’.

Before battery calibration, this screen is displayed.
‘OK’ for confirmation, ‘arrow’ to go back to the current screen. No action occurs.

Warns the user that USB is missing. Please plug a suitable USB device (Version 2.0) into the slot.
Confirmation via ‘OK’.

"Laser not calibrated" if the calibration test was not successful.
Confirmation via ‘OK’.

Displayed when the temperature sensor of the laser module is defective.Please contact Sirona Dental Systems GmbH, your local dental dealer, or your authorized service center.
Confirmation via ‘OK’.

Displayed when the laser stop button has been pressed.
Confirmation via ‘OK’.

Displayed when there is a foot switch error.
Please contact Sirona Dental Systems GmbH, your local dental dealer, or your authorized service center.
Confirmation via ‘OK’.

Displayed when there is a finger switch error.
Please contact Sirona Dental Systems GmbH, your local dental dealer or your authorized service center.
Confirmation via ‘OK’.

Displayed when an error of the fan occurs (for example: the fan is blocked).
To avoid damage, please switch off the Sculpt I.Q. and allow it cool down. See chapter "Troubleshooting of simple defects [→ 64]".
Confirmation via ‘OK’.

Displayed when the interlock contact is open.
See chapter "Troubleshooting of simple defects [→ 64]".

Displayed when the diode current differs by more than the 20% tolerance compared to the calibrated current.
Please contact Sirona Dental Systems GmbH, your local dental dealer or your authorized service center.
Confirmation via ‘OK’.

Displayed in case when there is no fiber connected. See chapter "Troubleshooting of simple defects [→ 64]".
Confirmation via ‘OK’.

The battery level is low and needs to be connected to the power supply.
Confirmation via ‘OK’.

Device error has occurred. Please contact Sirona Dental Systems GmbH, your local dental dealer or your authorized service center.
Confirmation via ‘OK’.

An error occurred during calibration check (with or without power meter). which could not be handled. Please contact Sirona Dental Systems GmbH, your local dental dealer or your authorized service center.
Confirmation via 'OK'.

5.5.4.2 Instructions

This screen describes how to perform the pairing process of the wireless foot switch.

Prior to starting battery calibration, remove the power supply before.
Confirmation via ‘OK’

The device asks to insert the USB device to download the history file (USB 2.0, min. 512MB storage capacity).
‘OK’ for confirmation, ‘arrow’ to go back to the current screen. No action occurs.

The device asks to use the protective goggles.
‘OK’ for confirmation, ‘arrow’ to come back to the current screen. No action occurs.

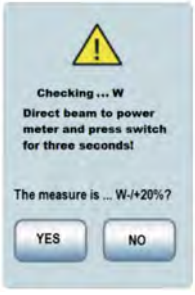
Displayed in case of overheating of the laser block. It is requested to wait for cooling.
Confirmation via ‘OK’

Release the activation device: footswitch or finger switch
Displayed when footswitch or finger switch is pressed before the laser is in ‘ready mode‘ (complete green bar).
Confirmation via ‘OK’.

The MultiTip must be used.
Confirmation via ‘OK’ to insert the pin code again.

To perform any calibration check it is advised to read the user manual carefully.
Confirmation via 'OK', ‘arrow’ to go back to the current screen. No action occurs.

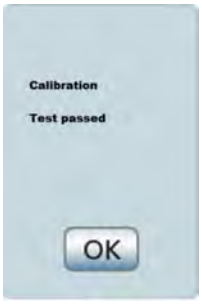
The unit asks that the finger switch is pressed for three seconds. This screen is displayed during laser calibration for the calibration process (without power meter)
Confirmation via ‘OK’



The unit asks to direct the laser beam to the power meter and to press the finger switch for three seconds.
This screen is displayed during laser calibration for the calibration process (with power meter).
The operator presses ‘Yes’ or ‘No’ if the measured value in inside the stated value or not.

5.5.4.3 Information messages

This screen occurs when the battery level is low and the external power supply is not connected.
The device displays the information that the battery charge is sufficient only for 180sec of treatment (with max power) and recommend to connect the power supply.



The calibration check was successfully performed.
Confirmation via 'OK'.

6 Indications, contraindications and medical precautions

6.1 Indications

The Sculpt I.Q. is intended for:

Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and interdental and epithelial lining of free gingiva and is indicated for:

frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.

Whitening: For light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.

Low Level Laser Therapy: To emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.

6.2 List of preset indications

Application	Power [W]	Modus	Time [sec]	Duty Cycle [%]	Fre-quency [Hz]	Fiber [µm]	Help Menu
Endodontics							
Pulpotomy	1.5	CW	20	0	0	200	After conventional pulp removal, residual pulp tissue can be removed with the laser.
Pulpotomy as adjunct to root canal therapy	1.5	CW	20	0	0	200	Removal of residual pulp tissue and hemostasis can be accomplished with the laser device.
Miscellaneous							

Application	Power [W]	Modus	Time [sec]	Duty Cycle [%]	Frequency [Hz]	Fiber [µm]	Help Menu
Aphthous Ulcers	2.0	CW	20	0	0	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							
Sulcular Debridement	2.5	PF	cont.	50	75	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!
Gingival incisions of granulation tissue	2.5	PF	cont.	50	75	320	Tighten the tissue, if possible, and use the laser tip like a scalpel to incise and excise the respective tissues.
Surgery							
Frenectomy	3.0	CW	cont.	0	0	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	4.0	CW	cont.	0	0	320	Gently shape the gingival tissue in contact with the fiber. Caution: Work in parallel to the tooth surface!
Gingivoplasty	4.0	CW	cont.	0	0	320	Gently shape the gingival tissue in contact with the fiber. Caution: Work in parallel to the tooth surface!
Hemostasis	6.0	CW	cont.	0	0	320	Seal small blood vessels 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	4.0	CW	cont.	0	0	320	Stretch the tissue and use laser tip like an scalpel to excise the tissue. Caution: Avoid contact to implant and bone!
Operculectomy	4.0	CW	cont.	0	0	320	Stretch the tissue and use laser tip like an scalpel to excise the mucosa hood.

6.3 Additional non-preset indications

Application	Power [W]	Modus	Time [sec]	Duty Cycle [%]	Frequency [Hz]	Fiber [µm]	Help Menu
Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket	2.5	PF	cont.	50	75	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!
Gingival incision and excision	2.5	PF	cont.	50	75	320	Tighten the tissue, if possible, and use the laser tip like a scalpel to incise and excise the respective tissues.
Treatment of canker sores	2.0	CW	cont.	0	0	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.

6.4 Creating a 660 nm program - optional

Once the 660 nm feature is unlocked (procedure described in chapter Unlock of the 660nm wavelength (optional) [→ 34]) it is possible to use the 660 nm wavelength. The device has no preset programs for 660 nm. To create a 660 nm program please create a new program in "my applications" as described in chapter My Applications [→ 45] and choose the 660 nm wavelength.

6.5 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 an excessive period of time. Do not select excessively high power levels for the laser.

⚠ WARNING

Never treat perpendicular to any bone surface.

Endodontics area

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.

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.

6.6 Contraindications

All clinical procedures performed with the Sculpt I.Q. 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.

Moreover, patients suffering from photodermatoses must not be treated as well as photosensitized patients (Photoallergy).

7 Cleaning, disinfection and sterilization

Following treatment, switch off the Sculpt I.Q. and disconnect the power cable from the power supply.

NOTICE

Wear gloves during these procedures.

Control unit, handpiece body, handpiece tube and foot control must be cleaned and wipe-disinfected.

Dispose the single-use fiber tips.

The removable stainless steal handpiece sleeve, therapy light guides, fibercutter and bending tool must 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 [→ 68]".

7.1 Cleaning

Handpiece sleeve

1. After disposing of the single-use fiber tip or removing the therapy light guide, remove the handpiece sleeve from the handpiece body by pressing the snap tab.

⚠ CAUTION

Danger of damage to the optical system

Reattach the protective cap to the optical system of the handpiece immediately after removing the EasyTip or MultiTip. Do this before conducting any cleaning process.

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

Therapy light guide (MultiTip)

➢ Clean the therapy light guide under running water (< 38 °C, water must be at least drinking water quality).

NOTICE

Never clean in an ultrasonic bath!

Fibercutter

➢ Clean the fiber cutter in an ultrasonic bath or with a suitable brush under running water (< 38 °C, water must be at least drinking water quality).

Laser protective goggles

➢ Before cleaning the laser protective goggles, please read and observe the instructions for use provided by the manufacturer.

7.2 Disinfection

Disinfect the previously mentioned parts by wipe disinfection:

Sculpt I.Q. laser unit: 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™ are recommended.

Observe the instructions provided by the manufacturer of these disinfectants.

7.3 Sterilization

⚠ WARNING

Therapy light guide (MultiTip), handpiece sleeve, fibercutter and bending tool must be sterilized prior to initial use and before each subsequent use.

⚠ WARNING

Single-use fiber tips (EasyTip) must not be sterilized again after usage. They are disposable components and must not be re-used.

NOTICE

Thoroughly dry the parts after cleaning.

Sterilizable components must be sterilized only in an autoclave with saturated water vapor at minimum sterilization values of 135 °C (275 °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 or DAC PREMIUM.

NOTICE

Sterilize the therapy light guides in a packing material suitable for sterilization and storage to prevent scratching or chipping the light guides inthe autoclave. Do not exceed a temperature of 140 °C (284 °F) during the drying cycle. Do not abort the drying cycle before it has ended. Do not try to accelerate the cool-down process by placing the MultiTips in cold water. This could cause the therapy light guide to crack.

⚠ CAUTION

Store all components so that they are protected against contamination.Sterilize again once the storage period has elapsed.

7.4 Cleaning the control unit

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

NOTICE

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

You can wipe-disinfect the Sculpt I.Q. 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 Sculpt I.Q.!

The Sculpt I.Q. may be disinfected **only by wiping** it. Do not spray disinfect the Sculpt I.Q. laser unit.

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 Cleaning the handpiece optics

⚠ CAUTION

From time to time the cleaning of the handpiece optics can be required because of soiled optics, for example due to a missing optic protection cap. Therefore, the handpiece optics should be cleaned after every 20 usages of the device.

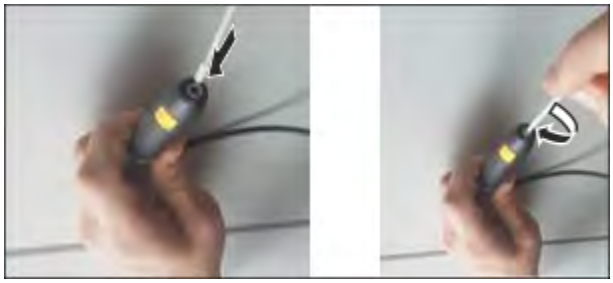
Please proceed as follows for cleaning the optics at the handpiece:

1. Switch off the control unit and unplug the handpiece from the control unit.

⚠ WARNING

Never inspect or clean the handpiece optics when the laser system is switched on.

2. Dismount the optical fiber/ glass rod/ optic protection cap from the handpiece optics.
3. Dismount the handpiece sleeve from the handpiece body.
4. Use a commercially available lint-free cleaning swab (for example for cleaning camera or CD player lenses) and moisten it with a little bit of isopropanol.



5. Insert the lint-free cleaning swab into the handpiece optics and clean the optics by gently rotating the swab.
6. Remove the lint-free cleaning swab from the handpiece optics after cleaning. Take a new dry lint-free cleaning swab to dry the

handpiece optics afterwards by gently rotating the dry swab inside the handpiece optics.

8.3 Maintenance

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

Action	Frequency	Conducting personnel
Check of the single-use fiber tips or therapy light guides, see "Assembly of sterile single-use optical fiber tips [→ 28]" and "Assembly of therapy light guides [→ 32]"	Before each treatment session	System owner
Calibration check of the laser, see "Laser calibration check [→ 48]"	Weekly	System owner
Recommended check of the optical power at the end of the single-use fiber tip with an external power meter, see "Laser calibration check [→ 48]"	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 Sculpt I.Q. is used must fulfill the applicable legal requirements.
- The unit must be used in compliance with the instructions provided in this instruction manual.

8.4 Troubleshooting of simple defects

In case of malfunctioning, proceed as follows:

General

Initial general directions in case of malfunctioning:

If the touch screen of the Sculpt I.Q. remains dark after switching it on:

Finger switch

If the "finger switch broken" error message is displayed:

Single-use fiber tip or therapy light guide

If the single-use fiber tip or therapy light guide missing error is displayed:

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

Aiming beam

If there is no aiming beam:

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

Iof the aiming beam does not project a uniform circular pattern.

- Trim the end of the single-use fiber tip with the fiber cutter. Always make the notch perpendicular to the optical fiber.

Interlock

If the interlock open error message is displayed:

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

If a laser source overheating message is displayed:

- Check if all convection openings for air cooling on the sides of the unit are uncovered.
- Check if the unit is placed near heat sources. If so, place the unit away from heat sources and allow it to cool.

Accustic signal

If there is no accustic signal when activating the laser and/or pushing the buttons:

- Check the settings for the accustic signals in the settings submenu.

8.5 Technical support, repair and testing

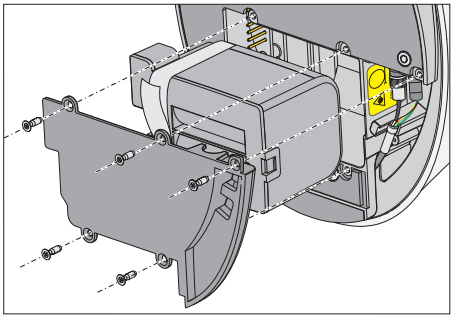
Sirona provides technical information on the repair of individual components only to authorized dealers and only after conducting an advanced training course for their technical personnel. Please contact your local dental dealer or an authorized Customer Service Department for technical support.

The Sculpt I.Q. may be sent in for repair or for safety inspection only in its original packaging, including all accessories. Disinfect the Sculpt I.Q.

and sterilize the accessories according to the relevant instructions for use before shipping them.

8.6 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 clamp! Otherwise, the handpiece may be damaged.
7. Switch on the laser (use power supply if necessary).
8. Choose "Battery calibration" in the settings 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 optimum battery performance, a battery calibration must be conducted whenever a battery is removed and replaced or when a new battery pack is installed, see chapter "Battery calibration [→ 48]".

⚠ CAUTION

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

Only use the Sirona Dental Systems battery pack, see "Spare parts [→ 25]".

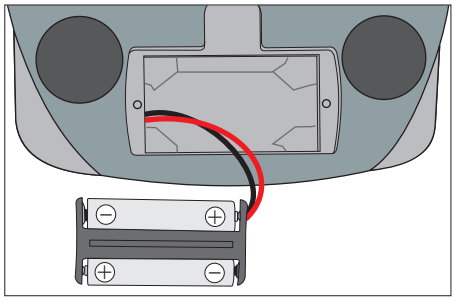
8.7 Replacing the batteries of the wireless foot control

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

When the battery is empty, select the finger switch in the settings submenu "Activation device [→ 45]" for further operation of the Sculpt I.Q..

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 Sculpt I.Q. 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 them 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 Sculpt I.Q. 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 re-register the foot control again at the Sculpt I.Q. after changing batteries.

8.8 Replacement of parts subject to wear and tear

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

- Therapy light guides (change after 2,000 sterilization cycles or every two years)
- Silicone key pad of the handpiece (change after 400 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 information, see chapter "Cleaning, disinfection and sterilization [→ 60]".

⚠ CAUTION

Only use parts from Sirona Dental Systems, see "Spare parts [→ 25]".

9 Electromagnetic compatibility

NOTICE

The Sculpt I.Q. 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 - guidelines
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**	coincides	

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:

Interference immunity tests	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF interference **IEC 61000-4-6**	3 V_{eff} 150 kHz to 80 MHz[1]	3 V_{eff}	d= [1.2] √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] √P at 80 MHz to 800 MHz d= [2.3] √P at 800 MHz to 2.5 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[2] should be less than the compliance level[3] in each frequency range. Interference is possible in the vicinity of equipment bearing the following graphic symbol. 

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 RF interference is checked. The customer or the user of the **UNIT** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **UNIT** - depending on the maximum output power of the communication device, as shown below.

Power rating of the transmitter [W]	Working clearance according to transmission frequency [m]		
	150 kHz - 80 MHz	80 MHz - 800 MHz	800 MHz - 2.5 GHz
	d= [1.2] √P	d= [1.2] √P	d= [2.3] √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

The recommended safety distance d in meters (m) can be determined for transmitters, whose maximum power rating is not specified in the above table, using the equation that belongs to the corresponding column, wherein P is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

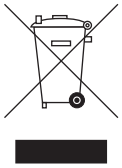
Note 1

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

Note 2

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

10 Disposal



In accordance with Directive 2012/19/EU and national disposal regulations regarding old electrical and electronic devices, please be advised that such items must be disposed of in a special way within the European Union (EU). These regulations require the environmentally friendly recycling/disposal of old electrical and electronic devices. Such items must not be disposed of as domestic refuse. This has been expressed using the icon of the “crossed out trash can”.

Disposal procedure

We feel responsible for our products from the first idea to their disposal. For this reason, we give you an option to return our old electronic and electrical devices.

If you wish to dispose of your devices, please proceed as follows:

In Germany

To initiate return of the electrical device, please send a disposal request to enretec GmbH. You have the following options here:

- Use the “Returning an electrical device” button under the “eom” menu item on the enretec GmbH homepage (www.enretec.de).
- Alternatively, you can also contact enretec GmbH directly.

  enretec GmbH
  Kanalstraße 17
  16727 Velten
  Tel.: +49 3304 3919-500
  E-mail: eom@enretec.de

In accordance with the national disposal regulations regarding old electrical and electronic devices (ElektroG), as the manufacturer, we assume the costs for disposing of the electrical and electronic devices in question. Disassembly, transport and packaging costs shall be borne by the owner/operator.

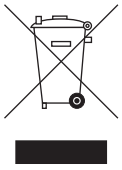
Prior to disassembly/disposal of the product, it must be fully prepared (cleaned/disinfected/sterilized).

If your unit is not permanently installed, it will be collected from the practice. If it is permanently installed, it will be picked up curbside at your address by appointment.

Other countries

For country-specific information on disposal, contact your local dental dealers.

10.1 Batteries



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

10.2 Accessories

MultiTips, handpiece sleeve incl. keypad for finger switch, bending tool for EasyTips and fiber cutter may be disposed in the domestic refuse. Please disinfect or sterilize the parts prior to disposal.

Please dispose the single-use fiber tips (EasyTips) in a biohazard medical waste/ sharps container.

11 Appendix

11.1 Appendix A – Certification

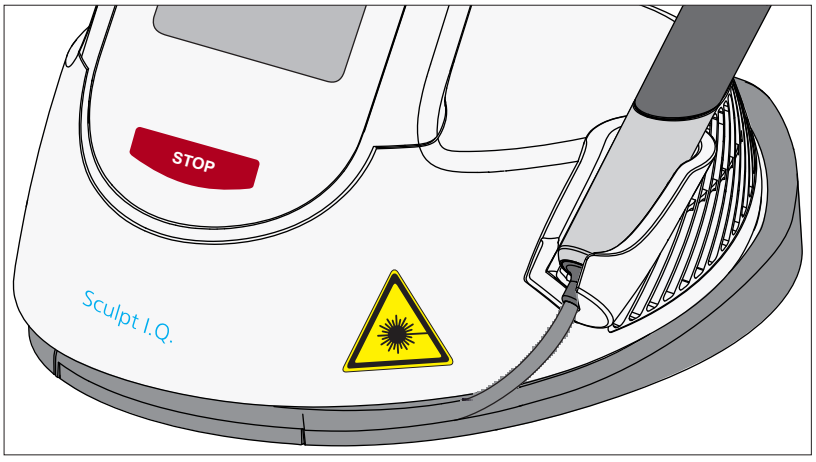
The unit is manufactured in compliance with the provisions of Council Directive 93/42/EEC concerning medical devices.

11.2 Appendix B -Label positions

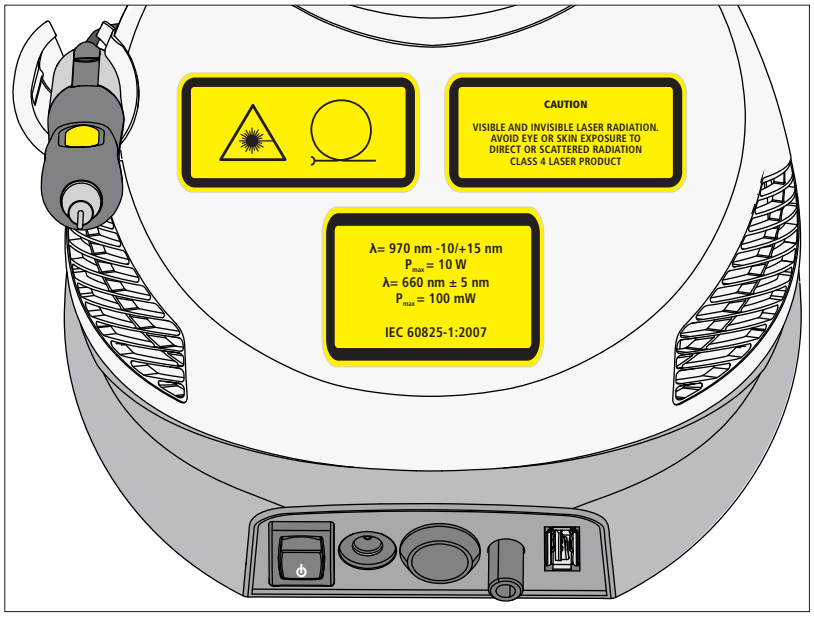
11.2.1 Control unit

The following figures show the positions of the labels on the Sculpt I.Q.:

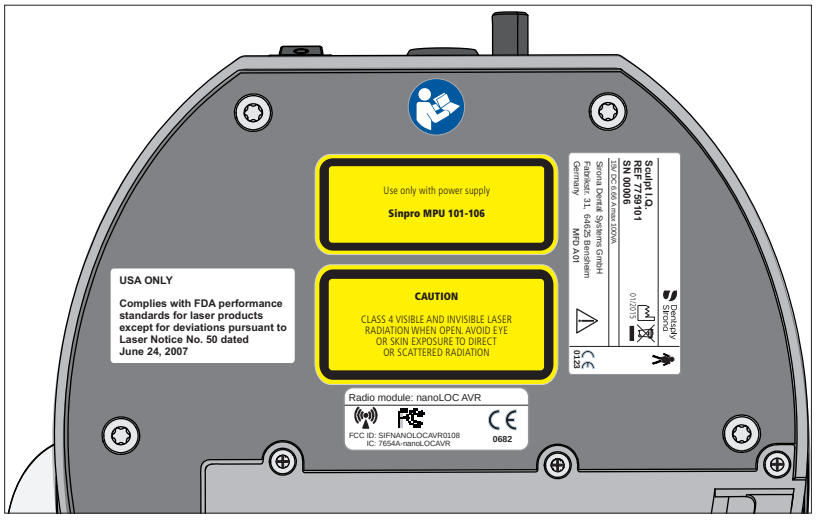
Front side



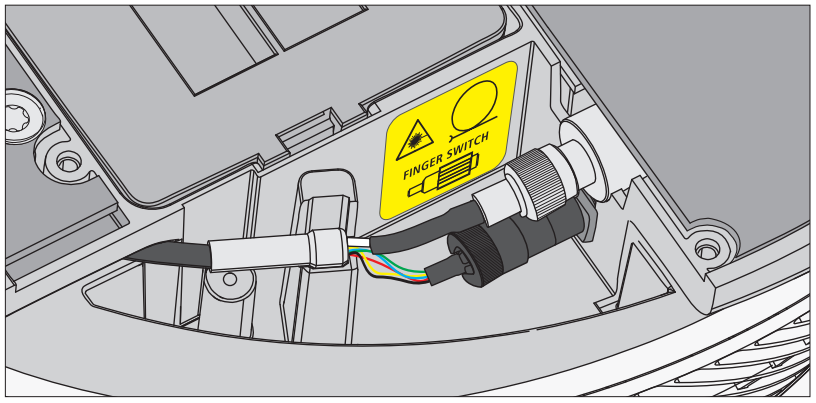
Rear side



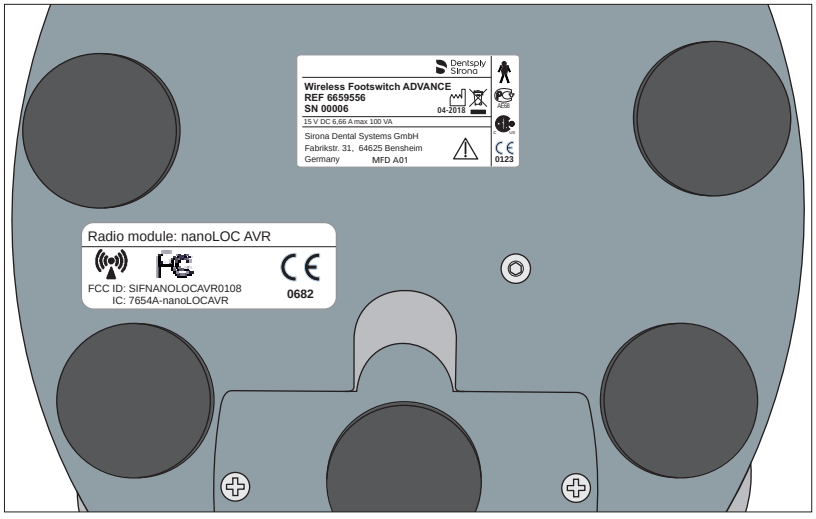
Bottom side



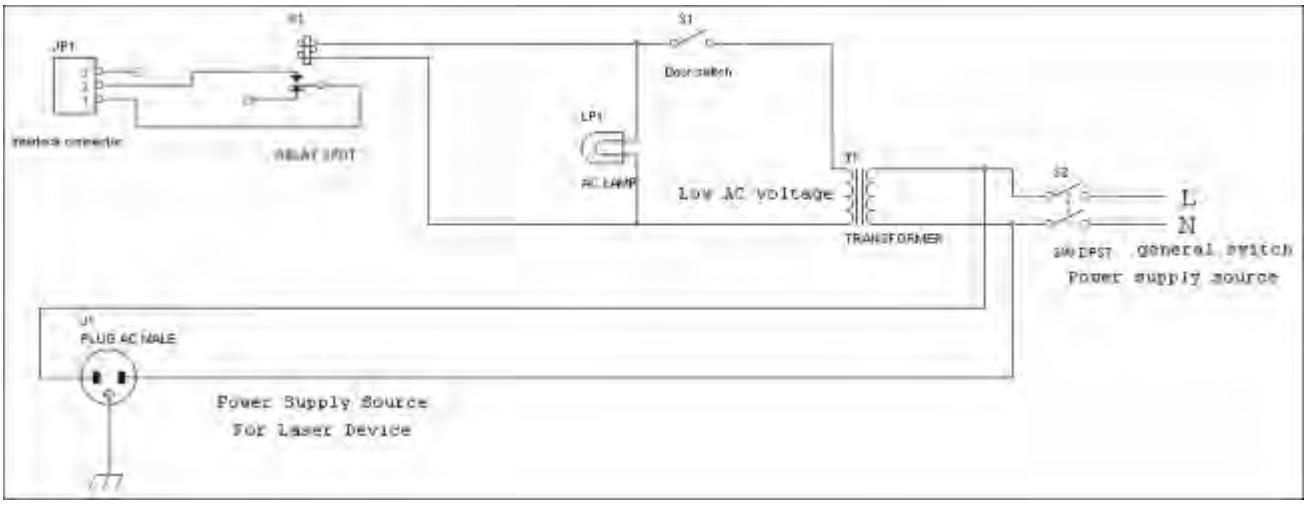
Under the battery cover



11.2.2 Wireless foot control – optional



11.3 Appendix C – Safety circuit (interlock)



JP1	Interlock connection supplied with the Sculpt I.Q. (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 Sculpt I.Q.

⚠ 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, they may be 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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