user manual

claros pico

ENGLISH / V3.0 / 2022-06

image subject to model

elexxion
dental laser

Device / type:	**claros pico**
Manufacturer:	elexxion AG Otto-Hahn-Str. 7 78224 Singen Germany Tel. 0049-(0)7731-90733-0 Fax 0049-(0)7731-90733-55 E-mail: info@elexxion.com
Serial no.:	-
Version:	V: 2.0
Release / date:	V 3.0/ 2022-06

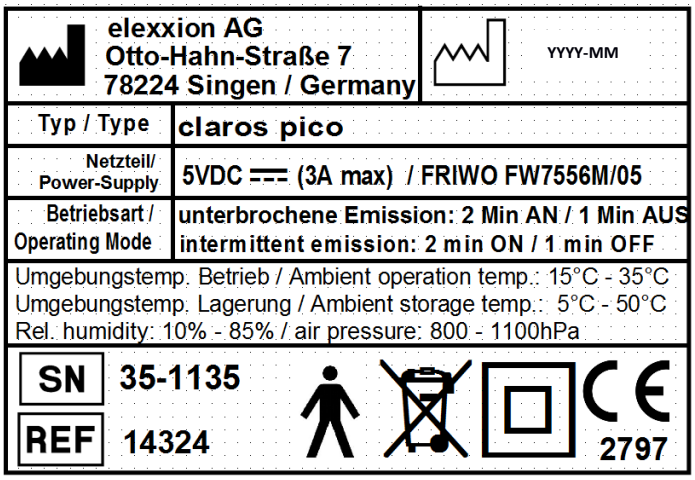
CE2797

Content

1 Labelling

1.1 Labels on the device

Information plate: Foil label on bottom of device:



Symbol	Description
	Manufacturer
	Date of Manufacture
SN	Serialnumber
REF	Partnumber
	Application Part Type B
	Do not dispose with household waste
	Protection class II - Protectionisolation

Power supply: Foil label on side of the unit:

5 V DC 3A max
⎓
FRIWO W7556M/05

On the transmission fiber, below application part type B

On side of casing: Please read operating instructions before use.

Applications: Foil label on the left side of the unit:

Progr.	Parameter	Progr.	Parameter
	1,0W - CW		1,0W - CW
	1,5W-12kHz; 5,0W;26µs	-	0,1W-2kHz; 1,0W; 50µs
	2,0W-16kHz; 5,0W;26µs	-	0,3W-2kHz; 1,0W; 150µs
	2,5W-20kHz; 5,0W;26µs		

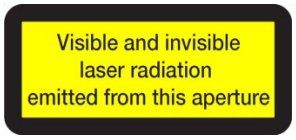
Warning labels:

Foil label, yellow/black, on back of device:

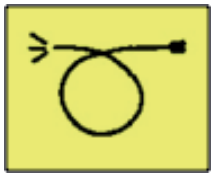
Laser aperture!

Please consult instructions for use!

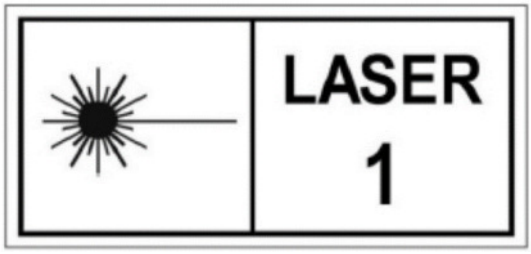
At fiber output on side of the unit:



Maximum bending radius of fiber optic cable:

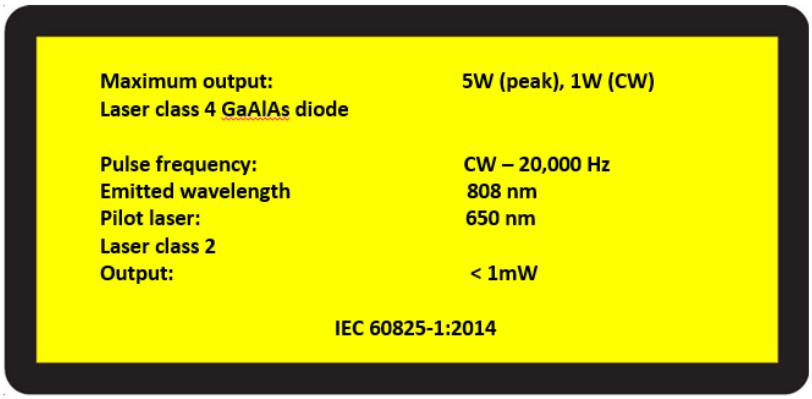


Pilot laser:



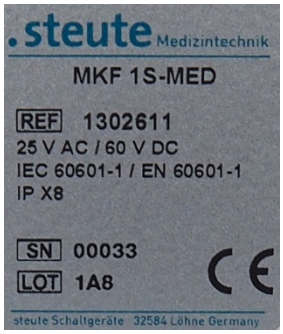
(This label is not applied to the device due to lack of space)

Laser type: Foil label, yellow/black, on back of base unit:



1.2 Labels on accessories

Foot-switch: Foil label on bottom of device



application-fibers: Foil label on bottom of storage-box:

Manufacturer:	elexxion AG Otto-Hahn-Straße 7 78224 Singen / Germany
Type:	starterkit fibers longlife
Lot-no.:	19-064
Application	Application fibers for elexxion pico/nano/claros/delos dental Laser, 2*200µm, 2*300µm, 3*400µm, 2*600µm
Item no.:	11056

Manufacturer:	elexxion AG Otto-Hahn-Str. 7 78224 Singen / Germany
Type:	ergo T8
Application	Therapie applicator 8mm for elexxion dental laser
Item no.:	10650

Manufacturer:	elexxion AG Otto-Hahn-Strasse 7 78224 Singen / Germany
Type:	elexxion 200 longlife
Lot-no.:	19-063
Application	Application fibers 200µm for elexxion dental Laser pico/nano/claros/delos
Item no.:	10063

Manufacturer:	elexxion AG Otto-Hahn-Strasse 7 78224 Singen / Germany
Type:	elexxion 300 longlife
Lot-no.:	19-065
Application	Application fibers 300 µm for elexxion dental Laser pico/nano/claros/delos
Item no.:	10391

Manufacturer:	elexxion AG Otto-Hahn-Strasse 7 78224 Singen / Germany
Type:	elexxion 400 longlife
Lot-no.:	19-066
Application	Application fibers 400µm for elexxion dental Laser pico/nano/claros/delos
item no.:	10112

Manufacturer:	elexxion AG Otto-Hahn-Strasse 7 78224 Singen / Germany
Type:	elexxion 600 longlife
Lot-no.:	19-062
Application	Application fibers 600 m for elexxion dental Laser pico/nano/claros/delos
item no.:	10120

Handpieces: Foil label on bottom of the storage box

Manufacturer:	elexxion AG Otto-Hahn-Strasse 7 78224 Singen / Germany
Type:	ergoflex plus
Application	handpiece ergoflex plus for elexxion dental laser pico / nano / claros / delos
Content	Soft metal tips (green & pink) & Bending tool
item no.:	11317-01

Manufacturer:	elexxion AG Otto-Hahn-Straße 7 78224 Singen / Germany
Type:	ergo T
Application	Therapy handpiece for elexxion dental lasers pico / nano / claros / delos
item no.:	10638

Laser safety glasses: Labelling / Instructions from manufacturer

Manufacturer:	elexxion AG Otto-Hahn-Str. 7 78224 Singen / Germany
Type:	claros protect
Application:	Laser safety glasses for elexxion lasers Wavelength 800-820 nm
Item no.:	14475

2 Warning notices

2.1 Warning notices – personal hazard

If the following instructions are ignored or not followed correctly, this may result in endangerment of the patient, operator or support staff.

1. By law, the device may only be sold to or on behalf of a dentist.
2. The energy emitted by the laser light exceeds the tolerance threshold of the eye and can therefore lead to irreversible damage to the eye. The prescribed safety glasses must be worn by all persons in the treatment room in order to prevent eye damage. The pilot laser (target beam) is automatically switched on when an application program is started. Do not look into the beam.
3. Safety glasses with filter level 5 or higher at 808 nm bearing the CE marking in accordance with EN207:1998 must be worn; these are available from elexxion AG with the name "claros protect". The separate instructions for use for the laser safety glasses must be observed when using laser safety glasses.
4. The laser danger zone (referred to as the 'treatment room' in the following) is the entire area located within the range of the laser beam. Warning! As reflections from instruments and equipment introduced into the beam path are possible, the laser danger zone is only delimited by obstacles around the laser system that are not transparent with regard to laser radiation (e.g. walls, ceiling, floor, closed doors) . An NOHD value (distance from which the laser can be observed safely) is not given due to the high mobility of the laser aperture. The entire room in which the laser is operated must be treated as the laser protection area.
5. The room in which the device is operated must be equipped in accordance with the BGV B2 accident prevention regulations. The electrical installation must comply with DIN VDE 0100 Part 710. This is the responsibility of the operator or a laser safety officer appointed by the operator. The BGV B2 accident prevention regulations can be obtained from elexxion AG upon request.
6. The operator of the laser system must ensure that the treatment room is clearly marked and that nobody enters the treatment room without safety glasses (see item 2) while the laser is being used.
7. Use is only permitted in rooms designed for medical purposes and which meet the above requirements. Use anywhere else is not allowed.
8. Only accessories specified by elexxion AG may be used. A list of all accessories can be found in Section 6 of these instructions for use. In case of doubt, please consult your medical product consultant.
9. Use of the operating equipment in any way other than that described here may result in dangerous irradiation.
10. The device may not be used in explosive atmospheres, irrespective of how these are created.
11. People must not look into the laser beam directly or through optical devices or instruments.
12. Please make sure that the position of the device during charging ensures that the mains adapter can be easily unplugged from the power supply.
13. Fully disconnect the charger from the power supply when it is not in use for a long period of time.
14. If the emission switch is accidentally activated, an unprotected laser beam may be emitted from the fiber end depending on the operating status. Please protect the emission switch from accidental activation.
15. Caution: laser smoke may contain viable tissue particles. Please use an extraction system.
16. Please check the condition of the applicator before use. If it is damaged, there is a risk that this may cause cuts – do not use damaged applicators.
17. The use of flammable anaesthetic gases and oxidising gases such as nitrogen and oxygen must be avoided. Some materials such as cotton wool that are saturated with oxygen can ignite at high temperatures, as can arise when the device is used in accordance with its intended use. Solvents, e.g. as contained in adhesives and flammable solutions that are used for cleaning or disinfection purposes, need time to evaporate before the laser device is operated.
18. Gases produced by the body can also be flammable!
19. Applicators and handpieces must be disinfected/sterilised using an autoclave or by spraying/wiping with disinfectant before they are first brought into service and before and after each use.
20. It must be ensured that the disinfectant/cleaning agents used have a bactericidal (including TbB), fungicidal and virucidal (including HBV) effect.
21. The exposure times for disinfectant/cleaning solutions given by the manufacturer must be observed.
22. Do not modify this equipment without authorization of the manufacturer.
23. Servicing and maintenance must be performed by authorized specialist personnel only. A technical safety

inspection must be performed on the laser system at least once a year to maintain safe operation of the system and to check its performance parameters. (see Section 7.3).

24. The device must be disconnected from the charger before cleaning/disinfecting.
25. If the system is damaged or there are signs that the system is not working properly, operation must be suspended immediately and the manufacturer notified, as there may be the risk that laser radiation could be emitted at unforeseeable parts of the device. The therapeutic effect is also no longer ensured.
26. The laser system must not be used to remove tooth hard tissue as this can lead to warming of the tooth tissue and damage to the dental pulp.
27. When using the surgery programs, the following rule applies: "Start with the lowest power possible and then increase it later if necessary".

2.2 Warning notices – system hazard

If the following instructions are ignored or not followed correctly, this may result in damage to the system. It may not be possible to continue with ongoing treatment or this may only be possible with some delay.

28. Please ensure that the device is placed in a secure and stable position on the stand supplied.
29. If the device is brought from a cold environment into a warm environment, please wait a sufficient amount of time (at least 30 minutes) until the device has reached the ambient temperature before switching it on.
30. Please stop using application fibers if there is less than 1 mm of fiber left (visual check before use).
31. Please handle applicators with care and do not squeeze, twist or apply a heavy load on them.
32. The flexibility of the fibers is limited. Pressing, bending, stretching or compressing the fibers too heavily can cause them to break.
33. Applicators must not be replaced while the device is ready for use and a program activated, as the emission switch may be activated by accident.
34. The battery may only be replaced by authorized elexxion AG service personnel. Replacing the battery, yourself may leave the device in a dangerous condition. Caution: risk of fire and explosion!

2.3 Warning notices – additional information

Refers to important and useful additional information. If this information is ignored, this may result in a device malfunction such as reduced power output or complete loss of function.

35. Do not use pointed objects to operate the membrane keypad.
36. If the intensity of the pilot beam is visibly reduced, a reduction in power output is to be expected, which will result in the loss of or a reduction in the therapeutic effect. elexxion AG's service centre should be contacted in this event.
37. The claros pico system is equipped with high-precision optics in the handpiece. Foreign bodies such as dust and moisture can therefore result in a reduction in power output (loss of or reduction in therapeutic effect). For this reason, a protective cap or applicator must be placed on the laser aperture when cleaning the handpiece. We also recommend using a protective cap or applicator when the laser is not in use in order to prevent penetration of dust.
38. The claros pico system complies with applicable electromagnetic compatibility regulations, both with regard to background radiation interference and the emission of electromagnetic interference. However, it is strongly recommended that no strong electromagnetic transmitters such as mobile phones, radio remote controls, etc. be used in the vicinity of the laser system. If an electromagnetic effect / interference is suspected, the system may no longer be operated until the cause is determined and remedied. Non-compliance may result in risks during use.

3 Electromagnetic compatibility (EMC)

3.1 General information

claros pico is a class A device in accordance with CISPR 11 and is intended for use by medical specialists only. claros pico is intended for use in settings other than residential settings; the typical electromagnetic environment is that of a hospital, clinic or doctor's surgery.

3.2 Installation and operation

Electronic devices are sensitive to electrostatic discharge. In order to prevent malfunctions in the claros pico system, electrostatic charges created by the operator should be prevented by means of ESD protective measures (use of anti-static materials).

In order to prevent disruptions due to electrostatic discharges, the floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic materials, the relative humidity must be no lower than 40%.

Operators should be familiar with the basic physical processes behind electrostatic charges and how to prevent them.

The claros pico system uses RF energy for its own operation only. The amount of radio frequency interference emitted is therefore very low and is unlikely to disturb other devices being operated in the vicinity. Nevertheless, it should be noted that simultaneous operation of the claros pico system together with other devices may result in interference in the claros pico system or other devices. Care should therefore be taken to ensure that the claros pico system is not positioned directly next to or above another electronic device.

If it is impossible to avoid positioning the claros pico system in the immediate vicinity of analogue medical measurement devices, the user of these measurement devices must be made aware that device results should be observed in order to monitor intended device use in the position selected.

3.3 Guidelines and manufacturer declarations

Table 1: Electromagnetic emissions

Emission measurements	Compliance
Radiated RF emissions according to CISPR 11	Group 1 class A
Conducted RF emissions according to CISPR 11	Group 1 class B
Harmonics according to IEC 61000-3-2	Not applicable
Voltage flucuations / flicker according to IEC 61000-3-3	

Table 2: electromagnetic immunity

Immunity tests	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) according to IEC 61000-4-2	+/- 6 kV contact discharge +/- 8 kV air discharge	+/- 4 kV contact discharge +/- 8 kV air discharge
Radiated RF fields according to IEC 61000-4-3	80 MHz-2.5 GHz: 10V/m; not life-supporting	80 MHz-2.5 GHz: 10V/m
Electrical fast transient interference (burst) according to IEC 61000-4-4	Not applicable	N/A
Conducted radio frequency according to IEC 61000-4-6	3V/m	3V/m
Magnetic field at frequency of supply voltage according to IEC 61000-4-8	3A/m	3A/m
Voltage dips an short interruptions according to EN 61000-4-11	<5 % U / 10 msec 40 % U / 0.1 sec 70 % U / 0.5 sec	<5 % U / 10 msec 40 % U / 0.1 sec 70 % U / 0.5 sec

Table 3: Recommended safety distances between portable and mobile telecommunication devices and the claros pico system

The claros pico system is designed for use in an electromagnetic environment in which RF interference is controlled. The user of the claros pico system can help to prevent electromagnetic interference by complying with the minimum distance between portable and mobile RF telecommunication devices and the claros pico system, depending on the power output. [distances given in meters]

Rated output of transmitter [W]	Safety distance 150 kHz – 80 MHz	Subject to 80 MHz – 800 MHz	Transmitted frequency 800 MHz – 2.5 GHz
0.01	0.01	0.01	0.02
0.1	0.03	0.03	0.06
2	0.14	0.14	**0.3**
10	0.32	0.32	0.64
100	1	1	2

This results in a safety distance of approximately 14 cm for mobile phones (the transmitted power of which is limited to around 2 watts) in the D1 and D2 band and 0.3 m in the E band. (assumption: 10V/m compliance level; tested item not life-supporting)

Table 4: Cable information

Cable	Max calbe length Shielded/ unshielded		Number	Cable classification
DC power line	1.8m	Unshielded	1 set	DC- Power
Foot switch line	2m	Unshielded	1 set	DC- Power
Cable of handpiece	1.7m	Unshielded	1 set	Optical fiber

4 Intended use

Elexxion Claros pico is a class 4 diode laser system for use in dental medicine and that can be used in the following fields:

- **Surgery and Haemostasis**
  Applications in the field of surgical incision to cut soft tissue in the mouth and stop bleeding
- **Endodontology**
  Application to reduce bacteria by decontaminating root canals
- **Periodontology**
  Application to reduce bacteria by decontaminating hard and soft tissue surfaces
- **Implantology**
  Application to reduce bacteria by decontaminating implant surfaces
- **Bleaching (not for medical purpose)**
  Whitening of teeth and depigmentation of lips and gingiva
- **Low laser therapy**
  Non thermal treatment for pain reduction, biostimulation and prophylaxis

Dentists are the users of this laser device. They must be instructed in the risks of laser radiation and they must be trained in working with the laser equipment (Laser Safety Representative). Operate the laser only in a laser protection area; every person in this area (user, patient, assistant, etc.) must wear protective eyewear that complies with the requirements in section 2.

The base device is used to select the parameters and to generate the laser light which can be emitted using the switch at the footswitch. An optical applicator (fiber or glass rod) inside a handpiece is used to transmit the laser light. The laser beam is emitted at the distal end of the applicator after choosing mode, parameter and actuating the foot switch. This laser beam can be used to address the above mentioned fields of applications by irradiating.

5 Protection and safety regulations

The device may only be commissioned after the operator has received instruction from a laser specialist approved by elexxion, and in accordance with requirements and safety regulations. The separate instructions for use for the laser safety glasses must be observed when using laser safety glasses. laser equipment should be protected against unauthorized use.
Caution - Laser fume and/or plume may contain viable tissue particulates
What is a laser plume? Lasers and electrocautery are used for surgery to vaporize, coagulate, and cut tissue. The vapours, smoke, and particulate debris produced during these surgical procedures are called laser plumes.

5.1 Side-effects

- Carbonization / necrosis zones:
High outputs (> 1 W) and/or exposure of one area over a longer period of time can result in irreversible tissue damage due to carbonization and necrosis exceeding the desired level. Measures: move the fiber in a controlled manner; select a weaker output program!

- Unpleasant odour formation:
Vaporization of tissue caused by intended photothermal effect. Measures: use suction!

- Noise levels (surgery only):
Cutting noise caused by vaporization of tissue. Measures: none, noise unavoidable

- Warming of hard tissue, destruction in some cases (surgery only):
Side-effect that may arise when employing the device outside its intended use caused by harmful warming of hard tissue (tooth, bone) at high power outputs and over a long duration. Measures: use surgery programs in accordance with intended use and operating instructions; process hard tissue according to the intended program only!

5.2 Mutual interference risks

No mutual interference risks arise during use because combination with other medical products is not envisaged.

- Hazard due to energy: caused by electricity, heat, mech. force, non-ionising radiation, electromagnetic fields, moving parts and acoustic pressure
- Minimal risk [1]

- Hazards when inserting, sharply bending, or improperly securing the fiber optics, indicating failure to follow manufacturer's recommendations may lead to damage to the fiber or delivery system and/or harm to the patient or laser operator
- Minimal risk [1]

- Biological hazards: caused by bio-burden, bio-incompatibility, incorrect supply (substance, energy), toxicity, infection, pyrogenicity and decomposition of material
- Minimal risk [1] (when appropriate suction is used)

- Environmental hazards: caused by electromagnetic interference, inadequate energy supply (excess voltage or undervoltage), limited cooling, operation outside prescribed environmental conditions, incompatibility with other devices, accidental mechanical damage and contamination with waste products
- Minimal risk [1]

- Hazards associated with device use: caused by inadequate labelling, insufficient instructions for use, insufficient accessory specifications, over-complicated instructions for use, instructions for use that are not available or have become separated, untrained staff, insufficient warning of side-effects, incorrect measurements and other technical measurement aspects, misdiagnosis, incorrect data transfer, misinterpretation of results and incompatibility with consumables and other products
- Low risk [1]

- Hazards due to malfunctions, maintenance and ageing: caused by insufficient performance features for planned use, inadequate maintenance, lack of appropriate assessment as to when the device's service life will expire, loss of mechanical integrity, substandard packaging (contamination) and unsuitable reuse
- Low risk [2]

1. Definition of "minimal risk":
   Risks of identified hazards are assessed as "small" when, if one or more of the hazards specified arises, the extent of injuries caused by the product to the user, patient or individuals in the immediate vicinity, both during intended use and in the event of error, is so small that it is not expected to result in health impairment and/or physical harm or detriment of any sort to the above individuals.
2. Definition of "low risk":
   Risks of identified hazards are assessed as "low" when, if one or more of the hazards specified arises, the extent of injuries caused by the product to the user, patient or individuals in the immediate vicinity, both during intended use and in the event of error, is so low that it is not expected to result in any permanent or long-term health impairment and/or physical harm or detriment of any sort to the above individuals.

Vasoconstrictors do not need to be used when administering local anaesthetic for invasive procedures. This is particularly the case when treating pregnant patients or those with pre-existing cardiac problems.

5.3 Contraindications

There are no known contraindications.

5.4 Summary assessment of residual risks

With due regard to the side-effects that may arise, the resulting residual risks in terms of hazards are deemed acceptable in due consideration of the intended application and use of the laser system and accessories. As a result, no restrictions have been specified for use of the **claros pico** system in accordance with its intended use.
Users (laser safety officers) who participate in operation courses as offered by elexxion AG are taught about the risks of laser radiation and trained in how to handle the laser device (see also "Intended use").

5.5 Handling rechargeable batteries

claros pico is fitted with a modern lithium-ion battery. This rechargeable battery is permanently installed in the device and may only be replaced by an authorised service company. The battery cell has a service life of around 2 years or 500 charging cycles.

5.5.1 Replacing the battery

The battery may only be replaced by authorised elexxion AG service personnel. Replacing the battery yourself may leave the device in a dangerous condition. Caution: risk of fire and explosion!

5.5.2 Charging the battery

The battery must be fully charged using the charger supplied before being used for the first time. A charging cycle takes up to 3.5 hours.
The battery display will show permanent chase lights while charging. All sections of the battery display will flash when the battery is fully charged. **The device cannot be used during charging! Only the charger supplied, model FW7556M/05, may be used.**

5.5.3 Operating time

The actual operating time depends on the power output used. A laser time of around 45 minutes can be achieved when subject to average use. A flashing light appears on the battery display when around 20% of capacity is left. It is possible to use the laser for up to a maximum of 5 minutes after this point in time (depending on the power output selected).

5.5.4 Disposal

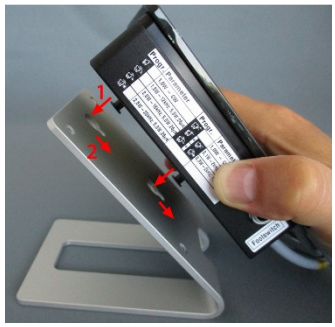
Batteries and the claros pico device containing batteries must not be disposed of in household waste. They should instead be taken to or sent to an authorised service company.

6 Operation

6.1 Commissioning

Please wait at least 30 minutes after moving from a cold environment to a warm environment before switching the device on to prevent condensation forming on electronic components.

1. Please ensure that the device is placed in a secure and stable position on the stand supplied. The max. load of the stand is 500 g. Do not use the pico without the stand.

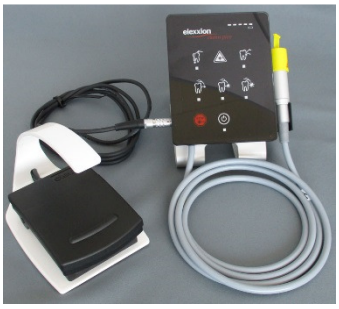
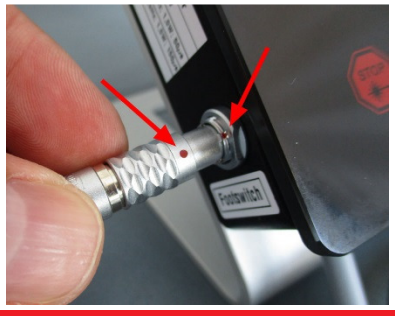
2. claros pico is fitted with rechargeable batteries. The batteries must be charged before the device is first brought into service. A full charging cycle takes up to 3.5 hours. In order to charge the device, connect the mains adapter plug supplied to the socket on the lower front side of the claros pico device.

3 The charging level is displayed in the top right-hand corner of the display. The indicator will flash during charging. The battery charging level is permanently displayed after charging is complete.

4 A visual warning is displayed when only a limited amount of battery charge is left. The charging level indicator will flash rapidly. Active operation of the laser is possible for a maximum of 5 minutes after this time.

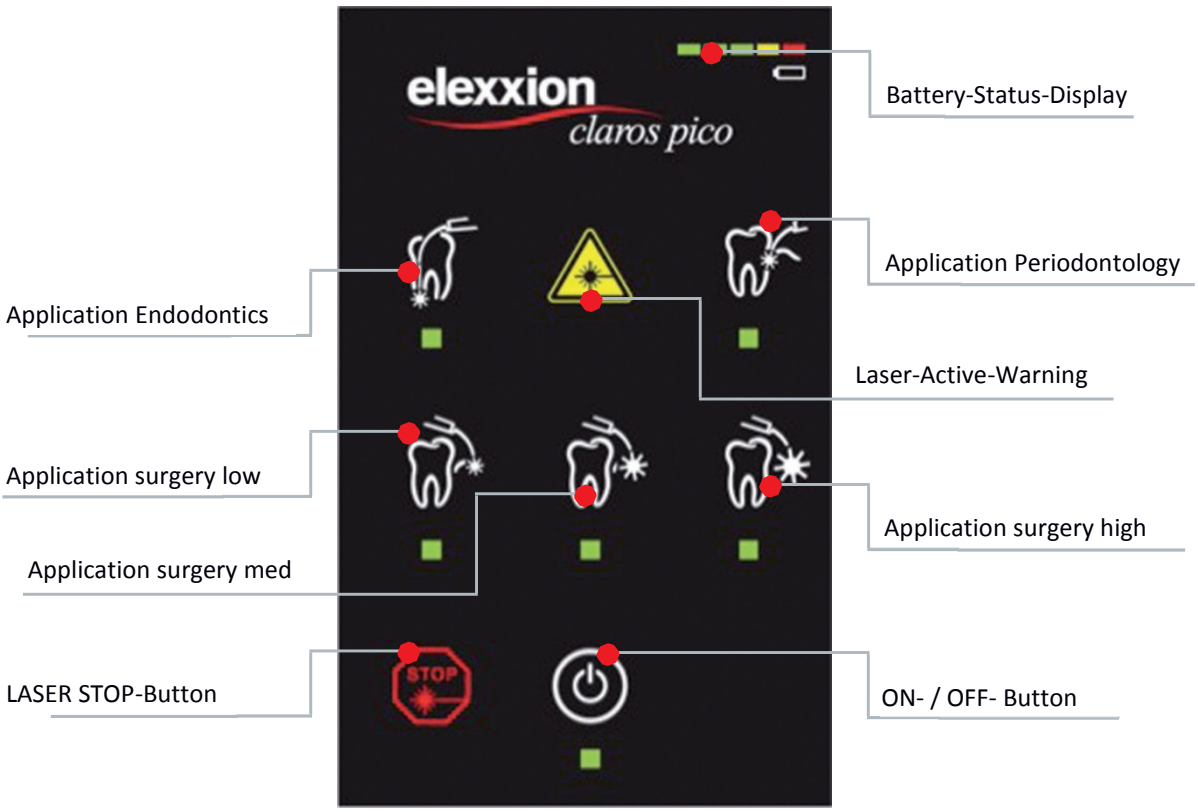
5 The operating time of the device when fully charged depends on the power output used. When all programs are used evenly, it is possible to operate the device for around 45 minutes.

6 The foot switch is brought into service by plugging the foot switch connection lead into the socket provided on the left-hand side of the claros pico casing. Push the foot switch plug in until it reaches the stop of the device socket. Take care, that the red dots are facing each other.

Attention! Activating the foot switch while the unit is activated emits class 4 laser radiation.

6.2 Display and display elements



The ON/OFF button is pressed first of all in order to activate the device.
All indicators light up to confirm that the device is functioning. A code should then be entered. The code consists of the following key combinations:

1. Periodontology key
2. "Med" surgery key
3. Endodontics key
4. "High" surgery key

The 5 program keys will turn off after a program has been activated.

6.3 Program selection and laser operation

6.3.1 Standby Mode

The device will go into standby mode automatically following 5 minutes of inactivity. The device is switched on by pressing the ON/OFF button. The activation code should then be entered.

6.3.2 Program selection mode

The five program keys will light up. The following options are available:

Endontics 

Periodontology 

surgery low 

surgery med 

surgery high 

Soft laser therapy  +  (at the same time)

perio green® program  +  (at the same time)

Appropriate applications together with the appropriate parameters in line with the programs are given in the application table page 26.

 Laser stop button. Stops radiation emission immediately in any operating status.

6.3.3 Laser warning mode

After confirming the specific program, the device displays a flashing laser warning symbol. This mode lasts 2 seconds. From this point in time, everyone in the laser protection area must wear suitable safety glasses.

Attention! From this point in time, activating the foot switch will result in emission of laser radiation.

6.3.4 Laser ready mode

Following the laser warning mode, the laser is ready for use. The selected program symbol is displayed.

Laser emission is activated by pressing the foot switch. The laser warning symbol on the device flashes while the foot switch is activated. A periodic warning sound beeps and laser radiation is emitted.

The device switches off automatically after 10 minutes without activity

6.4 Handling handpieces and fibers

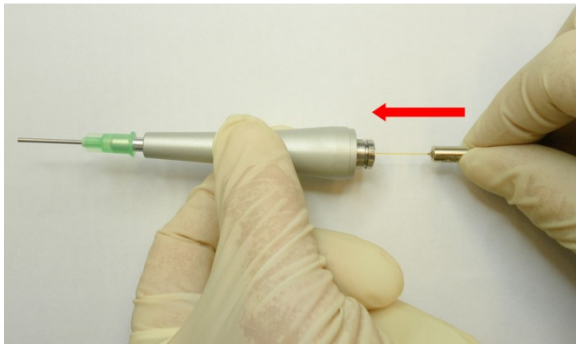
6.4.1 ergoflex plus

6.4.1.1 Introducing the application fibers

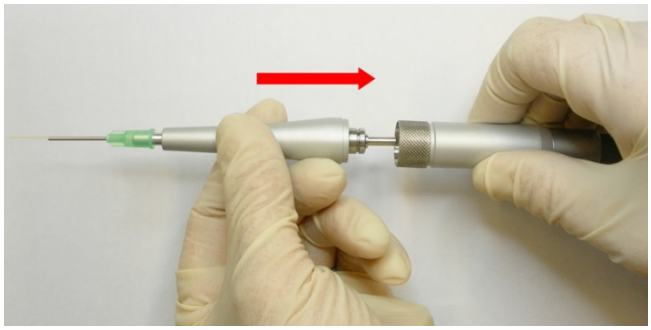
The claros pico system is fitted with an innovative application system, which keeps subsequent costs as low as possible and ensures a high level of hygiene capability at the same time.
Depending on the diameter of the application fibers, various soft metal tips must be attached before introducing the application fibers:

Pink for 200 µm/300 µm fibers	Green for 400 µm/600 µm fibers
	

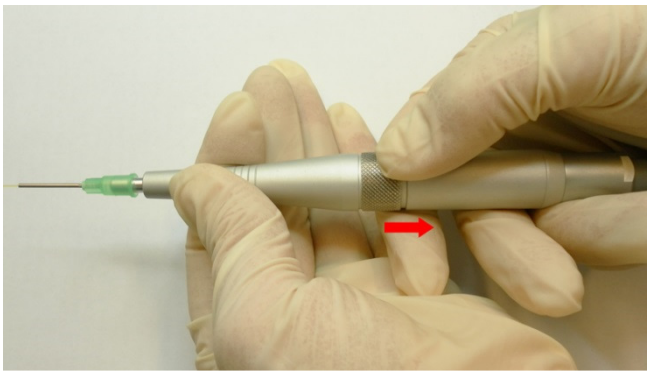
Push application fibers carefully into the handpiece front part from behind as far they will go. (Caution: glass fibers can break)



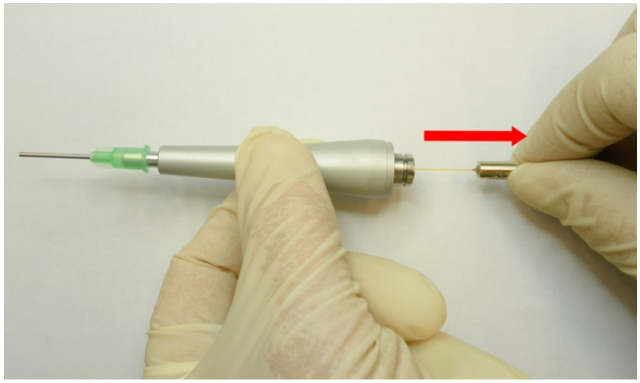
After this, place the handpiece front part centrally on the rear handpiece part. Then press both parts together in the handpiece longitudinal direction until the interlock ring can be heard to engage.



The fiber can be removed after use. (To do so, ensure that the soft metal tip has been bent straight again or removed beforehand.) To remove the handpiece front part, the interlock ring must be pulled to the rear. The handpiece front part can now be removed.



Carefully pull the fiber out of the handpiece front part and have it be disinfected.



The fibers can be changed during operation with the device switched on. Fibers must not be replaced during laser emission under any circumstances!
Fibers have a limited service life depending on the power output used and the fiber diameter. Fibers can typically be used up to 15 times. Disinfected fibers can be disposed of in household waste.

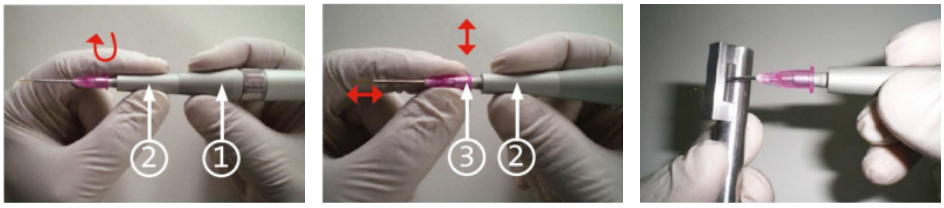
6.4.1.2 Adjusting the fiber length

Open the locking device by twisting parts 1 and 2 anticlockwise. A quarter turn is sufficient. Hold on to part 2 and twist part 3 to adjust the fiber length.

Turning clockwise => increases the fiber length;
Turning anticlockwise => shortens the fibe length.

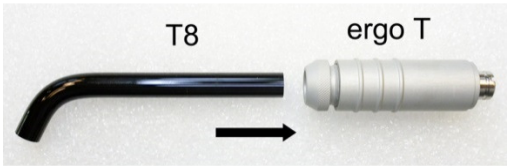
When you have reached the desired fiber length, lock the handpiece by twisting parts 1 and 2 clockwise. Bend the thin metal tube of the soft metal tip into the desired position using the bending tool.

Straighten the tube after use. Then separate the handpiece from the fiber cable and pull the fiber out of the handpiece. Do not adjust the fiber length when the tube is bent!



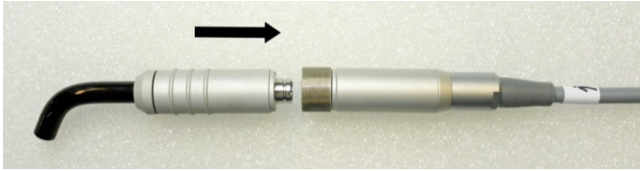
6.4.2 ergo T

The ergoT handpiece can be used with the two glass rods T4 (optional) and T8. The glass rods are used in all therapy programs. The application information on the list of applications shows which glass rod is used in the relevant program. To insert the glass rod, undo the fixing nut on the ergo T handpiece and introduce the glass rod into the handpiece as far as it will go.



After this, tighten the fixing nut by hand so that the glass rod sits firmly.

Remove the safety cap from transmission fiber, pull the interlock ring to the rear and press the handpiece into the handpiece holder until it can be heard to engage.



To undo the handpiece, the interlock ring must be pulled back.

7 Accessories

claros pico is a diode laser system developed for dental use. It consists of a base unit, which generates the laser radiation, and a range of accessories:

Article No.	Article	
14324	claros pico GP: base unit including transmission fiber	
11317-01	ergoflex plus: handpiece for use with application fibers includes	
	11256	Soft metal tips: single-use tips for Elexxion longlife 400 or 600 (green)
	11257	Soft metal tips: single-use tips for Elexxion longlife 200 or 300 (pink)
	12930	Bending tool: tool used to bend the soft metal tips
10638	ergo T: handpiece for use with glass rod T8	
11056	Starterset fibers longlife includes	
	10063	elexxion longlife 200: application tip 200 µm
	10391	elexxion longlife 300: application tip 300 µm
	10112	elexxion longlife 400: application tip 400 µm
	10120	elexxion longlife 600: application tip 600 µm
10650	Ergo T8: applicator, glass rod 8 mm in diameter	
14475	claros protect: laser safety glasses	
13973	claros pico step: foot switch	
11649	Mains adapter/charger	
11718	pico Europe primary adapter	
11856	pico UK primary adapter	
11841	Case pico	

The use of accessories other than those specified here is not permitted.

8 Cleaning and sterilisation

The base unit and transmission fiber are wiped with an appropriate cleaning/disinfectant agent. (DGHM- or VAH-listed/e.g. Dürr FD 322 or Mikrozid liquid)

Note: Unplug the mains adapter before cleaning the device!

Preparing the instruments generally involves cleaning followed by sterilisation.Place instruments (application fibers/glass rod) in a burr steriliser or instrument bath filled with a suitable cleaning/disinfectant agent (mild alkaline/aldehyde-free/alcohol-free/DGHM- or VAH-listed) immediately after use on patient. This prevents residues from drying (protein fixation). Instruments (application fibers/glass rod) should be transported to the preparation site in the burr steriliser, instrument bath or an appropriate container in accordance with accident prevention regulations (industrial safety/employer's liability insurance association).

8.1 Cleaning

Instruments in the "critical B" category (handpieces) should generally be cleaned by machine according to RKI guidelines. Manual pre-cleaning may be necessary for effective cleaning if the instruments are particularly dirty.

- Thoroughly clean and dry re-usable instruments immediately after use to minimise corrosion and possible cross-contamination.
- Validation of the cleaning, sterilisation and re-sterilisation processes and the correct setup of the corresponding devices must be checked regularly.
- Do not allow instruments to come into contact with any substances that contain chlorine or fluorine.
- Do not allow instruments that are made entirely or partly of plastic to come into contact with strong acids or bases, organic or ammonia-containing solvents, aromatic and/or halogen-containing hydrocarbons or oxidising chemicals.
- Do not allow aluminium or materials that contain aluminium to come into contact with any substances that contain mercury. Even the slightest trace of mercury can cause considerable corrosion. Instruments made from materials that contain aluminium may be wiped and cleaned only with (or placed only in) solvents or disinfectant agents with a pH value between 4.5 and 8.5. Higher or lower pH values cause the neutral coating of the aluminium-containing materials to detach, leading to corrosion.
- Do not let dirt dry on the instruments, as this may make later cleaning difficult.
- If corrosive substances, such as silver nitrate, iodine preparations, albothyl and mercury compounds are used during the operation, all residues of these substances must be removed from the instruments immediately.
- Instruments must not be placed in physiological saline solutions, as extended contact with these substances can result in corrosion and changes to the instrument surfaces.
- Do not use metal brushes or abrasive cleaners to clean the instruments. Subsequent rinsing with demineralised water is recommended to prevent water spots. The instruments must then be dried immediately. Sterile compressed air can be used for drying.
- Rinsing in demineralised water is recommended after cleaning.
- After cleaning, grease moving metal parts with a water-soluble lubricant approved for use with medical products. Reassemble and, if applicable, tighten screws.
- Submerge instruments entirely in the enzyme or alkaline solution (pH ≤ 12) and leave them to soak for ten minutes. Gently brush the product using a brush with soft nylon bristles until all visible dirt marks have been removed. Pay particular attention to the gaps, lumina, fitting surfaces, connections and other areas that are difficult to clean. Lumina should be cleaned with a long, thin brush with soft bristles (i.e. a pipe-cleaner).
- Note: Using a syringe or water jet can make it easier to rinse out areas that are difficult to access, as well as small fitting surfaces.
- Remove instruments from the cleaning solution and rinse them with clean water for at least a minute. Thoroughly rinse lumina, blind holes and other difficult-to-reach areas.
- Place the instruments in a suitable basket for the cleaning/disinfecting machine such that they can be reached unhindered by water and cleaning agents and undergo a standard cleaning cycle for instruments.
- The following minimum parameters are extremely important for thorough cleaning and disinfection:

Step	Description

1	Pre-rinse with cold water for at least one minute
2	Clean with 0.3% Neodisher MediClean cleaner at 55°C for at least five minutes
3	Rinsing 1: at least two minutes with water
4	Rinsing 2: at least one minute with water
5	Disinfection: 5 minutes, 15,5 l water (≤ 3µS / cm), 90° C
6	Drying: 15 minutes, 95° C air inlet temperature

The automated reprocessing of cannulated parts or hollow bodys (e.g. handpieces) is done by the specifications and with the tools of the manufacturer of the cleaning unit (e.g. Thermaldisinfectors). They are mandatory to adhere.

Note: The instructions from the manufacturer of the cleaning/disinfecting machine must be strictly observed. Use only cleaning agents recommended for this particular type of automatic cleaning/disinfecting machine. A cleaning/disinfecting machine with verified effectiveness must be used (e.g. CE marking and valid validation as per EN ISO 15883-1).

If residual contamination is still visible on the instrument following manual preparation, repeat cleaning and chemical disinfection process until contamination is no longer visible (a visual inspection using a magnifier is recommended according to the RKI).

8.1.1 Packaging

Packaging that is suitable for the instrument (application fibers/glass rod) and the sterilisation procedure should be selected. Instruments with restrictions in terms of their frequency of use should be labelled accordingly in order to ensure clear allocation for the purpose of the QM system. The packaging must be labelled, at the latest after their treatment in the steam steriliser, with usage-relevant markings. The following must be visible: the sterilisation date or sterile storage period, the contents, the sterilisation procedure and, if multiple sterilisers are used, the device used.

8.2 Sterilisation

For dental practices, devices with cycle B or cycle S are specifically prescribed. In order to ensure effective sterilisation, it is vital that steam can reach all parts of the product being sterilised, especially in the event of stricter preparation requirements (critical B / e.g. hollow parts, handpieces). Based on the risk assessment for the instruments (application fibers/glass rod = critical A) (handpiece= critical B), all detachable parts must be sterilised. The autoclave procedure using a fractioned pre-vacuum method is validated in accordance with DIN EN ISO 13060. The person preparing the instruments is responsible for ensuring that the reprocessing actually carried out using the equipment, materials and staff available in the reprocessing facility achieves the desired results.

Step	Description	Duration	Temperature	Pressure
1	Fractionated Vakuum	-	-	3x200 – 1500mbar
2	Hold time	5 min	134°C	Saturated steam 134°C
3	Drying	5 min	-	<100mbar

! PLEASE NOTE

We recommend that after repeated sterilisations a suitable optical inspection is carried out (for visual damage etc.).

9 Maintenance

The device must undergo a technical safety inspection once a year together with these instructions for use and the relevant medical products log. This may only be performed by individuals who are able to perform inspections correctly based on their training, knowledge and experience gained through practical application and who can perform inspections without supervision. Time period: once a year

1. Radiation output test in all application modes
2. General functional test
3. General visual inspection
4. Safety concept test in accordance with "claros pico testing" operating instructions in force

! PLEASE NOTE

If the device does not undergo this inspection on schedule, elexxion AG cannot guarantee unrestricted operating safety. Any warranty and liability claims on the part of the manufacturer shall also expire. All maintenance work must be performed by providers that have been authorized by elexxion AG to maintain the device type in question.

Authorised maintenance providers:

elexxion AG | Otto-Hahn-Straße 7 | 78224 Singen, Germany

Tel. +49 7731-90733-0 | Fax +49 7731-90733-55
E-mail: info@elexxion.com.
Contact information can also be found on the website at www.elexxion.com

10 Service life

The claros pico system and accessories have a service life of at least 10 years when used in accordance with their intended use, when subject to proper care and maintenance and when requirements with regard to technical safety inspections are observed. The rechargeable battery has a limited service life of up to 2 years or 500 charging cycles.

! ATTENTION

If you have any queries, please contact the manufacturer. If you identify any malfunctions or damage, stop using the device immediately and notify the manufacturer.

11 Disposal

11.1 Packaging

elexxion AG recommends retaining the unit's packaging so that it can be sent off correctly in the event of servicing. In order to dispose of packaging, please contact your elexxion AG representative or dispose of the packaging in accordance with applicable legal regulations.

11.2 Device

The system must be disposed of correctly at the end of its service life in order to prevent environmental damage and rule out the possibility of improper use. The device must be taken to or sent to an authorized service company. Where necessary, the system must be secured to prevent accidental reuse before disposal. The usual risks concerning the disposal of electronic devices apply.
Batteries and the claros pico device containing batteries must not be disposed of in household waste. They should instead be taken to or sent to an authorized service company.

12 Technical data

12.1 Description of the beam guiding system:

Laser diodes: Gallium Aluminium Arsenide (GaAlAs). The divergent beam is focused internally on a defined point in front of the laser aperture by a multiple-lens system. By inserting an optical fiber with NA (numerical aperture) = 0.22 or 0.37 and an SMA screw connection, the focal point is projected onto the fiber input (plug) and the beam is guided to the application end of the fiber with virtually no losses by means of total internal reflection and emitted at an angle of 13° (divergence).

Recommendation: As the aiming BEAM passes down the same beam guiding system as the working laser BEAM, it provides a good means of checking the integrity of the beam guiding system. If the aiming Beam is not present at the distal end of the beam guiding system, its intensity is reduced or it looks diffused, this is a possible indication of a damaged or malfunctioning beam guiding system.

12.2 Laser aperture:

The laser aperture is located at the distal end of the handpiece. This is where application parts are connected to the handpiece. When the applicator is connected, the distal end of the handpiece (application fiber or glass rod) forms the laser aperture. Laser emission may only commence when the applicator (application fiber or glass rod) is connected.

12.3 Disconnection from the mains (charging mode):

In order to disconnect the device from the mains, unplug the mains adapter plug.

Changes to the device and its accessories are not permitted and may result in dangerous operating conditions. **claros pico** technical data

12.4 Technical data power supply:

Mains supply:	100-240 VAC/60,50 Hz
Current consumption:	0.4 A max.

12.5 Technical data base unit:

Power supply:	5V/DC, < 3.0 A (with Friwo FW7556M/05 mains adapter supplied)
Fuses:	No accessible fuses
Operating mode:	Intermittent operation / 2 min ON / 1 min OFF
Protection class:	I application part type B / IP 00
Wavelength:	808 nm +/- 10 nm
Max power output (pulse):	5 W
Max. power output (CW):	1.0 W
Pulse frequency:	CW – 20.000 Hz
Pulse duration:	26 µs,50 µs, 150 µs
Aiming beam:	650 nm +/- 5 nm / < 1mW
Operating conditions:	Temp. 15°C – 35°C Rel. humidity 20 – 85 % Air pressure: 800 – 1100 hPa
Storage/transport conditions:	Temp. 5°C – 50 °C Rel. humidity 10 – 85 % Air pressure: 800 – 1100 hPa

12.6 Accuracy of values displayed:

output:	+/- 20 % from value specified

13 Error messages

Error message	Cause	Action
On/Off button flashing	Overtemperature	Leave the device to cool down or make the surrounding environment cooler. .
Symbol flashing rapidly	Power deviation	Charge the battery. If the error is still present after taking this action, please contact elexxion AG service center

Important note: If you send the device or accessories to elexxion AG, please go to our website at easc.elexxion.com (RMA) to register that they have been sent.

Please only send disinfected devices or accessories to elexxion AG. Contaminated devices and accessories cannot be accepted.

14 Calibration

Power calibration takes place during the annual technical safety inspection. Power calibration is not normally necessary outside these periods. However, if power calibration is necessary because clear power deviations are observed, the following procedure should be used:

Please note that class 4 laser radiation is emitted during this procedure, as in normal laser operation.

Please observe the warnings given in Section 2. Warning notices.

Ophir Orion / TH with 30A-SH-V1 measuring head (with valid calibration)

Procedure:

Open casing.
Connect circuit board to claros pico setup controller.
Use terminal software to compare target values with actual values.

15 Table of applications /setting

Endodontology 	**Power: 1,0 W / Freq.: CW**	
Bacterial reduction in canals	Application fiber 200µm longlife, if possible up to apex, rotating up and down	max. 20 seconds
Retrograde bacterialreduction	Application fiber 200µm longlife, try to reach all areas	max. 20 seconds
Pulp capping	Application fiber 600µm longlife, irradiate with circular movements at short distance. Immediate haemostasis, anti-inflammatory, promotesdentineformation.	max. 20 seconds

Periodontology 	**Power: 1,0 W / Freq.: CW**	
Pocket bacterial reduction	Application fiber 300µm or 400µm longlife, move around to cover all	max. 20 seconds
Decontaminate membranes	Application fiber 600µm longlife, irradiate membrane extensively at short distance.	max. 20 seconds
Removal of granulation tissue	200 um if the dentist will do the treatment from inside the rootcanal 300 um if the dentist will perform the treatment after exposing the root by a flap surgery.	-
Retraction of gingiva	200 or 300 depends on the space between the gingiva and tooth surface	-

Surgery „low“ 	**Pulse-power: 5 W / Pulse-Length: 26µs / Freq.: 12 kHz Average-Output: 1,5 W**
Decontaminate implants	Application fiber 200µm/300µm longlife, move around to cover all areas if possible
Periimplantitis, surgical	Application Fiber 400µm/600µm longlife, to remove granulation tissue, assistant to provide suction

surgery „med“ 	**Pulse-power: 5 W / Pulse-Length: 26µs / Freq: 16 kHz Average-Output: 2,0 W**
Curettage	Application fiber 400 µm longlife, remove granulation tissue
Aphthae	Application fiber 600 µm longlife, move in a grid motion at a distance of around 1 mm

Gingivectomy before dental cast	Application fiber 400µm/600µm longlife, advancing from anterior teeth to rear molars
Sulcus preparations	Application fiber 300µm longlife, for anterior teeth, 400µm/600µm for molars
Depigmentation of lips (special)	400/600 and this treatment is very sensitive and dentist must be professional to do it. After using fibers the dentist has to use glass rod T8 to improve the healing.
Depigmentation of gingiva	Only to be used with the protocol of Dr Kenneth Luk, Hong Kong
Hemangioma treatment	300 / 400 µm, detach in circular fashion, no stitches
Fibroma removal	400/600µm,stretch tissue with surgical tweezers

Surgery „high“ 	**Pulse-power: 5 W / Pulse-Length: 26µs / Freq.: 20 kHz Average-Output: 2,5 W**
Abscess opening	Application fiber 200µm longlife, selectively penetrate as far as possible into abscess
Haemostasis	Application fiber 600 µm longlife, maintain distance of around 2 mm
Frenectomy	Application fiber 600 µm longlife, stretch tissue, detach parallel to alveolar ridge, no stitches
Expose implants	Application fiber 600µm longlife, from screw centre outwards, dental cast possible immediately
Sample biopsies	Application fiber 400µm longlife, stretch tissue, wedge excision
Retention cysts	Application fiber 300µm longlife, remove cyst sac undamaged if possible
Expose impacted teeth	Application fiber 400µm longlife, expose impacted teeth (soft tissue only)
Dentitio difficilis, surgical	Application fiber 300µm/400µm longlife

perio green®  **+** 	**Pulse-power: 1 W / Pulse-Length: 150µs / Freq.: 2 kHz Average-Output 0,3 W**	
Periodontitis therapy with perio green®	Application fiber 300µm longlife For details of treatment procedure, please see information on how to use elexxion perio green®	2 x 40 Seconds
Periimplantitis therapy with perio green®	Application fiber 300µm longlife For details of treatment procedure, please see informationon how to use elexxion perio green®	2 x 40 Seconds

Low-Level-Laser-Therapy 	**Pulse-power: 1 W / Pulse-Length: 50µs / Freq.: 2 kHz** **Average-Output: 0,1 W**	
Hypersentivity	Glass rod T8, coat entire area, allergy dissipates, 3 treatments	60 Seconds
Aphthae	Glass rod T8, coat directly if possible, aphtha melts down, 2 – 3 treatments	60 Seconds
Post-extraction pain	Glass rod T8, immediately after extraction in wound area, quicker wound healing	90 Seconds
Gingivitis	Glass rod T8, coat gum seam, bleeding an pain ease, 2 – 3 treatments	70 Seconds
Haematoms	Glass rod T8, irradiate at clos distance, acceleratied absorption, 1 – 2 treatments	45 Seconds
Herpes labialis	Glass rod T8, dry blisters, tension eases, 2 – 3 treatments	60 Seconds
Temporomandibular joint disorders	Glass rod T8, reliefs pain , but does not remedy the cause 2 treatments	60 Seconds
Relieve lockjaw	Glass rod T8, irradiate each side, hold directly on joints	60 Seconds
Alveolar osteitis	Glass rod T8, prevention of post-extraction pain, irradiate entire surgical area, 2 treatments	45 Seconds
Neuralgiform pain	Glass rod T8, position on suspected point of pain, usually helps immediately	90 Seconds
Oedema	Glass rod T8, tension eases immediately, rapid absorption, 2 – 3 treatments	90 Seconds
Pulpitis, initial	Glass rod T8, directly on open pulp horn, soothes pulp	30Seconds
Pain in general	Glass rod T8, hold as close as possible to pain epicenter	90Seconds
Acid trauma	Glass rod T8, irradiate gingiva on both sides, complete relief from pain	90Seconds
Abrasion trauma	Glass rod T8, after 2 min. haemostasis, immediate improvement	90Seconds
Stomatitis	Glass rod T8, rapid reduction in inflammation, 5 treatments	60Seconds
Wound healing	Glass rod T8, ATP process is accelerated by a factor of around 4	120Seconds

Low-Level-Laser-Therapy 	**Pulse-power: 1 W / Pulse-Length: 50µs / Freq.: 2 kHz** **Average-Output: 0,1 W**	
Suppress gag reflex	Glass rod T8, irraditate KG24 and LG25 directly, helps for around 20 minutes	60Seconds
Root end resection wound treatment	Glass rod T8, apply directly in apex area to prevent oedema	90Seconds
Bleaching	Glass rod T8.	30 seconds per tooth if vital and 60 seconds per tooth if non vital.