user manual

claros

ENGLISH V4.8 / 2022-06

elexxion
dental laser

Device-type:	**claros**
Manufacturer:	elexxion AG Otto-Hahn-Str. 7 78224 Singen Germany Tel. +49 (0) 7731 – 907330 Fax +49 (0) 7731 – 9073355 E-Mail: info@elexxion.com
Serial-No.:	01-
Software-Version:	Laser: Grafik:
Release / Date:	V4.8 /2022-06

CE 2797

CE

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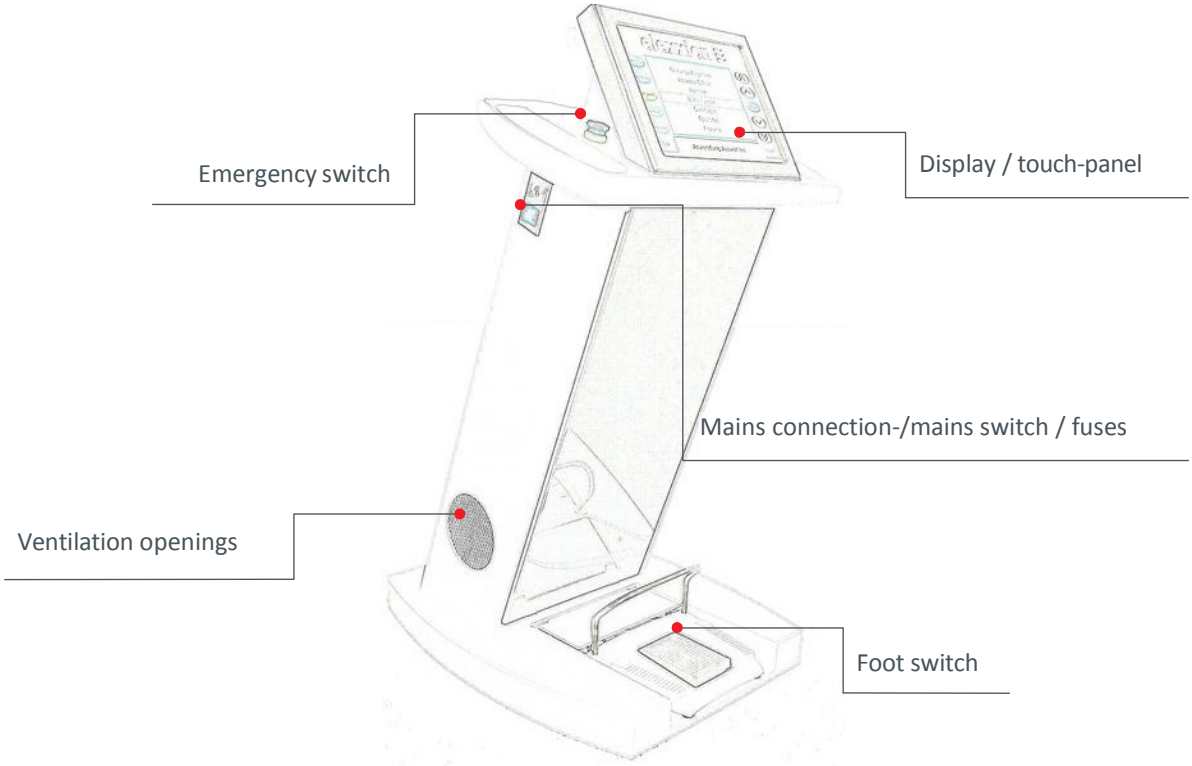
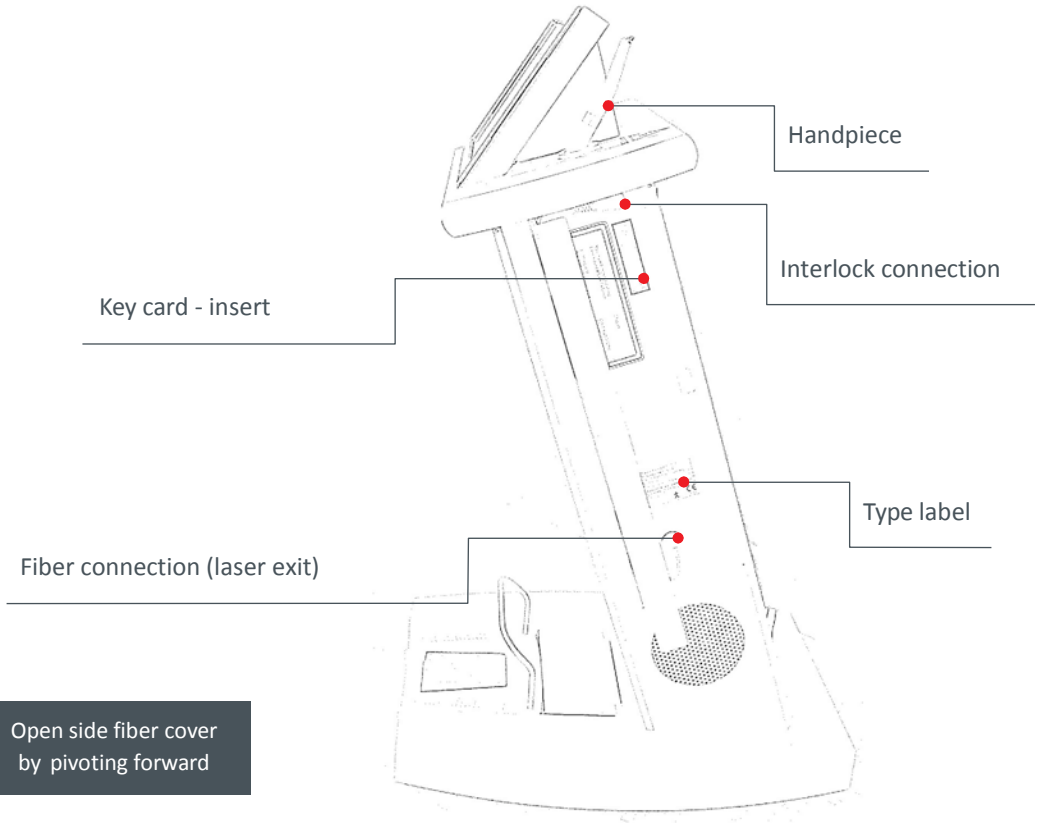
1. General information





Open side fiber cover by pivoting forward

2. Labelling and warning notices

2.1.Labels/ signs on the device

Type label:

Film label, on the right-hand side of the device under the side flap:

Symbol	Description
	Manufacturer
	Date of Manufacture
SN	Serialnumber
REF	Partnumber
	Application Part Type B
	Do not dispose with household waste
	Genral warning sign
	Follow instructions for use
	Laser warning sign, laser radiation
	Avoid eye exposure to direct or scattered radiation
	Avoid skin exposure to direct or scattered radiation
	Laser transmission part

Mains connection / fuses:

Film label, on the left-hand side of the housing:

I / O	220 – 240 VAC 50/60 Hz	Fuse: 5x20mm, 250V/1,6A Time lag, breaking capacity 35A Corresponding to IEC 60127-2-3

Foot switch:
Film label, on the foot switch connection in the device base:

Foot switch

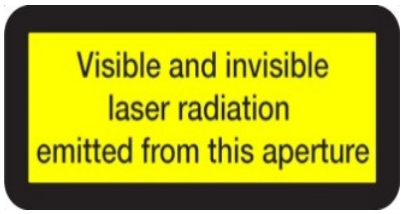
Interlock connection:
Film label, on interlock connection, right-hand side of the housing under the side flap:

Interlock

Laser stop:

Laser stop

Warning Labels:
Film label, yellow / black, above the handpiece holder:



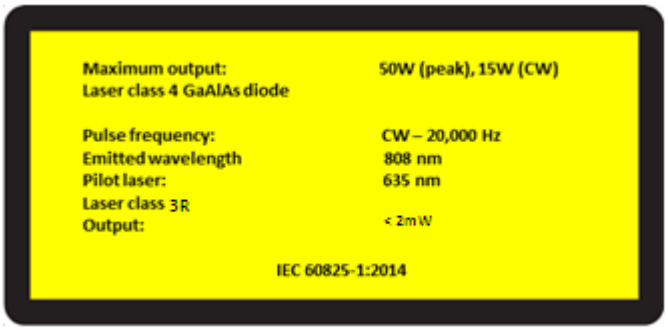
At the laser aperture and next to the handpiece holder

Follow operating instructions!

At the laser aperture:

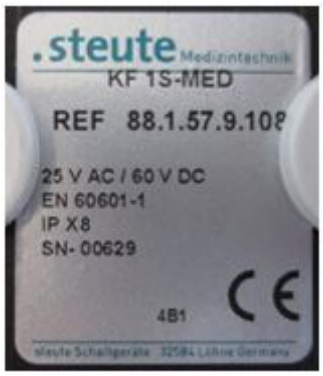
Laser output opening for visible and invisible laser radiation

Laser type:
Film label, yellow / black, right-hand side of the housing under the side flap:



2.2.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: Labeling / Instructions from manufacturer

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

3. Warning notices

3.1. 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. The power of the laser light is above the compatibility threshold of the eye and can therefore lead to irreversible eye damage. To prevent eye damage, the prescribed safety glasses must be worn by all people in the room. CE-designated safety glasses as per EN 207:1998 with scale number 5 or higher are to be used, as supplied by elexxion AG under the name “elexxion claros protect“. The separate Laser Safety Glasses operating instructions are to be followed when using laser safety glasses.
2. The room in which the device is being operated must be fitted out as per current legal provisions with respect to radiation protection and electrical safety. This is the responsibility of the operator, or of the laser protection officer, if one is appointed by the operator. Use is only permitted in rooms designed for medical purposes and which meet the above requirements. Use anywhere else is not allowed.
3. Visible and invisible laser radiation. Laser class 4. Avoid unintended radiation of skin and eyes.
4. Only those accessories specified by elexxion AG may be used. A listing of all such parts is detailed in section 6 of these operating instructions. If unsure, ask your medical product consultant.
5. Only those operating devices specified in these operating instructions may be used. Note: Using operating devices other than as described here can result in dangerous radiation.
6. The device may not be operated in an explosive atmosphere, irrespective of how these are created.
7. User, patients and all people in the room must wear the laser safety glasses as specified in item 1 during operation.
8. The operator must ensure that the treatment room is labelled as per legal provisions and that no person enters the room when the laser is being used without wearing corresponding protective glasses.
9. It is not permitted to look into the laser beam either directly or with optical devices and instruments.
10. When the device is not in use, the key-card must be removed from the device.
11. In the event of intentional or unintentional actuation of the emission switch, unprotected laser radiation can be emitted at the fiber end.
12. Caution, as laser fumes may contain viable tissue particles. Use an exhaust mechanism.
13. In therapy programs, only corresponding elexxion claros ergo-T applicators may be used. If another method is used, this can result in an incorrect application dose. The condition of the applicators must be checked prior to use. If they indicate damage, there is the risk of injury and they may not be used.
14. No explosive or flammable materials are to be stored nearby.
15. The use of flammable anaesthetic gases or oxydising gases such as nitrogen or oxygen should be avoided. Some materials such as cotton saturated with oxygen can be ignited at high temperatures, as may occur with correct use of the device. Solvents, for example of adhesives and flammable solutions used for cleaning or disinfection, are to be allowed time to evaporate before the laser device is operated.
16. Even body gases can be inflammable!
17. Prior to initial commissioning and before and after each application, applicators and handpieces are to be decontaminated via autoclaving or spray/wipe disinfection.
18. Ensure that any disinfection/cleaning agents used have a bactericide (incl. TbB), fungicide and virucide (incl. HBV) effect.
19. Exposure times of disinfection/cleaning solutions are to be observed as per manufacturer specifications.
20. Service and maintenance tasks are to be performed exclusively by authorised specialist (except for changing fuses).
21. The device is to be disconnected from the mains when fuses are being changed (plug pulled out).
22. No objects may be inserted through housing openings.
23. The device is to be disconnected from the mains for cleaning/disinfection. Also ensure that no liquids enter the housing openings.
24. If the system is damaged or if there are any signs that the system is not functioning properly, operation is to be discontinued immediately and the manufacturer is to be informed.
25. The laser system may not be used to remove hard tissue.
26. If the pedefined programs are modified the following principle applies: “Begin initially with the lowest possible power and increase it later, if needed“.
27. The red flashing underscore of the “elexxion“-logo in all monitor menus is a sign of correct operation of the software. If the underscore of the “elexxion“-logo is not flashing, operation is to be discontinued immediately and the manufacturer is to be informed.
28. To avoid the risk of electrical shock, this equipment must only be connected to a mains supply with protective earth
29. Do not modify this equipment without authorization of the manufacturer.

3.2.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.

30. The ventilation grilles of the device may not be obstructed.
31. If the device is taken from a cold environment to a warm environment, there must be an adequate waiting period (at least 30 minutes) before switching on to ensure that the device has reached the ambient temperature.
32. Discontinue using application fibers if less than 5 mm of fibers remains.
33. Handle applicators carefully; do not press, overload or twist.
34. Flexibility of the fibers is limited. Excessive pressure, bending, stretching or compression can lead to fiber breakage.
35. In the event of non-compliance, the transmission system can be damaged and/or the patient or user injured.
36. The applicator may be exchanged in any operating state. It must however be ensured that the foot switch is not actuated.
37. During operation, it should be ensured that a minimum distance of 20 cm be kept between the side ventilation slits and walls.
38. Use a spray bottle or soft cloth for surface disinfection/cleaning of the device, foot switch, fibers and handpieces. The membrane keyboard and display can be treated the same way.

3.3.Warning notices – EMC

39. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally".
40. The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
41. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the claros, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
42. When the AC input voltage is interrupted, this equipment will shut down and if the power supply restored, it should be recovered by operator manually, this degradation could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance.

3.4.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.

43. Actuating (pressing) of the EMERGENCY OFF switch fully separates the device from the mains and stops all functions. Once the EMERGENCY OFF switch has been released, the device is ready for operation again within a few seconds and the desired mode can be selected.
44. Do not operate the touch panel using sharp instruments.
45. Since the aiming beam takes the same way through the laser transmission system as the working beam, it represents a good way of checking the integrity of the laser transmission system: to check this, point the aiming beam at a white surface (paper). A filled-in circular light spot should be visible. If the aiming beam does not appear, its intensity is visibly reduced or the beam is diffused, this is a possible indication of a damaged or incorrectly working laser transmission system.
46. The claros system is fitted with high-precision optics in the handpiece. Foreign bodies such as dust or moisture can therefore result in reduced output performance. For this reason a protective cap or a handpiece front part must be placed on the laser aperture during cleaning of the handpiece. We also recommend using a protective cap or a handpiece front part whenever the laser is not in use in order to prevent the entry of dust.
47. The claros system complies with the applicable provisions for electromagnetic compatibility, both with regard to background radiation interference and the emission of electromagnetic interference. However, it is strongly recommended not to operate any powerful electromagnetic transmitters such as mobile phones, radio remote controls or similar near the laser system. If electromagnetic influence / disturbance is suspected, the system may not be operated until the cause has been clarified and eliminated.
48. When opening and closing the side housing cover and the foot switch cover, ensure that lines do not get caught.

4. Electromagnetic compatibility (EMC):

4.1.General information

claros is a class A device in accordance with CISPR 11 and is intended for use by medical specialists only. claros is intended for use in settings other than residential settings. This equipment with no ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment, such as a hospital, clinic or doctor's surgery.

4.2.Installation and operation

Device installation and maintenance should be carried out by personnel with corresponding EMC expertise; the operation should be performed by trained personnel. Particular attention must be paid to proper cabling with specified cable types and lengths as well as firm assembly of the plug-in connectors and their locking mechanisms. The device should be used in a controlled electromagnetic environment that is characterised by perception and control of the EMC loads by the user.

Electromagnetic emissions from the device are below the standardised interference emission limit values.

In special cases, if for example highly sensitive operating equipment is used in the immediate vicinity, additional remedial measures may have to be taken so that the electromagnetic interference emission is reduced further below the specified limit values.

Electronic devices are sensitive to electrostatic discharge. In order to prevent malfunctions in the claros 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 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 system together with other devices may result in interference in the claros system or other devices. Care should therefore be taken to ensure that the claros system is not positioned directly next to or above another electronic device.
If it is impossible to avoid positioning the claros 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.

4.3. Guidelines and manufacturer declarations

Table 1: Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class A	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

Table 2: Enclosure port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3: Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m

870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Table 4: Input a.c. power Port

Phenomenon	**Basic EMC standard**	**Immunity test levels** **Professional healthcare facility environment**
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0º
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

Table 5: Signal input/output parts Port

Phenomenon	**Basic EMC standard**	**Immunity test levels** **Professional healthcare facility environment**
Electrical fast transients/burst	IEC 61000-4-4	±1 kV 100kHz repetition frequency
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz

Table 6: Cable information

Cable	Max calbe length Shielded/ unshielded		Number	Cable classification
AC power line	2.5m	Shielded	1 set	AC- Power
Foot switch line	2m	Unshielded	1 set	SIGNAL INPUT/OUTPUT PORT
Hand piece line	1.7m	Unshielded	1 set	PATIENT-Coupled Cable

5. Intended use

Elexxion Claros 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

- **Snoring (Application accessory is not implemented in standard set)**

Non invasive anti snoring therapy, a diode laser application to tighten and lift the soft palate.

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.

6. Protection and safety regulations

The device may be operated only after internal briefing of the operator and in compliance with the provisions and safety regulations. The separate operating instructions for the laser safety glasses are to be followed when using the 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.

6.1.Side-effects

» Carbonization / necrosis zones (surgery only):

Irreversible damage to tissue in the above form can occur with high outputs and/or exposure of one area over a longer peiod of time. Measures: move the fiber in a controlled manner, avoid excessive outputs!

» Unpleasant development of odour (surgery only):

Vaporization of tissue caused by intended photothermal effect. Measures: use suction!.

» Noise generation (surgery only):

Cutting noise caused by vaporization of tissue. Measures: none, noise unavoidable

» Warming of hard tissue, possibly destruction (surgery only):

If using outside of intended use, possible side-effect by damaging warming of dental enamel (tooth, bone) at high outputs and long exposure time. Measures: use surgery programs as per intended use and operating instructions, process hard tissue only as per the intended programs!

6.2.Risks of mutual interference

There are no risks of mutual interference during operation.

6.3.Residual risks / assessment

» 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.

6.4.Contraindications:

There are no known contraindications.

6.5.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 system in accordance with its intended use.

Users (laser protection officers) who intended ongoing education events, as offered by elexxion AG, are instructed on the dangers of laser radiation and trained in how to handle the laser device (see also “Intended Use“).

Users are briefed on how to handle and operate the laser by a function test of the device onsite and subsequent briefing.

7. Operation

7.1. Commissioning

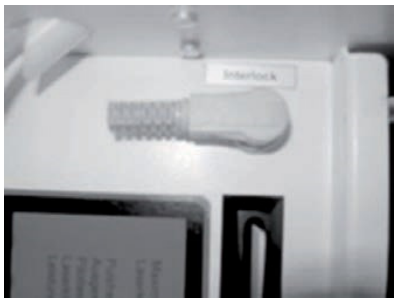
Please wait at least 30 minutes after moving from a cold environment to a warm environment before switching the device on to prevent condensation forming on electronic components.

If needed, release the EMERGENCY OFF switch by turning it.

1. Plug the mains cable into the socket provided on the left-hand side of the device. Plug the protective contact plug into the mains socket. Lay the mains cable so that nobody can stumble or fall over it.

2. Insert the foot switch plug into the connection socket in the unit base and secure it by turning the union nut clockwise.

3. Insert the interlock plug into the “Interlock“ connection socket behind the side housing cover and secure it by turning the union nut clockwise.



4. Insert the “All Applications“- or “Therapy“-key-card into the insertion slot behind the side housing cover.

5. Switch on the device at the main switch. The green pilot light of the mains switch lights up and the noise of the fans is audible.

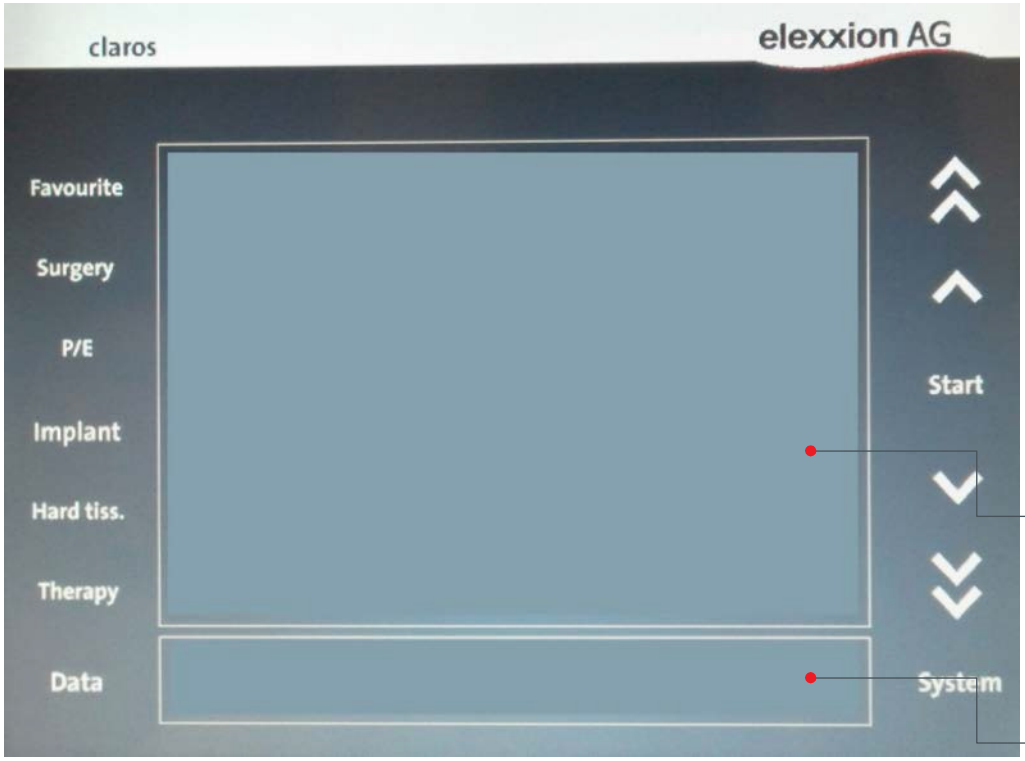
During the start phase, a completely white screen appears in the display for 3 seconds. If the display is damaged, individual dots or larger areas appear in black or colour. If this is the case, the system may no longer be used.

The claros system is delivered with two different key-cards:

“All Programs“: key-card for highly qualified, trained; medical or dental personnel. All applications and settings in the system menu. Access to “Data“ menu for modifying application programs.

“Therapy“: key-card for trained medical or dental assistans. Only therapy programs and no settings in the System and Data menus.

After the display test the basic menu appears:



The info window shows warnings or instructions on the currently selected treatment.
The main window shows the application programs for selection or the current operating parameters

7.2.Selection of application programs

Light pressure on one of the key fields

Surgery	Programs on surgery
P / E	Programs on periodontology / endodontics
Implant	Programs on implantology
Hard tiss.	Programs on hard tissue preparation
Therapy	programs on therapy (non-thermal)

selects the application. The main window now shows 7 programs for selection. With more than 7 application programs, the arrow keys on the right-hand side of the screen can be used to scroll up or down.

Tapping the “Start“ key selects the application program in the selection frame.

7.3.Favourites list

Pressing the“Favourites” selection button shows the editable list of favourite programs.

Adding or removing a program from here is done via the Data menu of the application programs via the row “Favourites X“. The meaning is as follows:

X=0	The program is not in the favourite list
X=1	The program is in the favourite list

This menu row can be changed between 0 and 1 by pressing Edit via the arrow keys on the right-hand side of the menu. After saving, the selected program is added to or removed from the Favourites list.

7.4.Laser operation

After an application program is selected, a warning message initially appears for 2 seconds as a reminder to use the prescribed safety glasses. Then the standby menu appears:

Note: From here on actuating the foot switch results in emission of laser radiation! The application name is shown in the upper frame. In the middle of the main windows, a flashing warning symbol appears during laser emission. An alert signal also sounds.

The parameters of the selected application program are shown in the lower part of the main window. The output of the

selected application program can be increased or decreased using the appropriate arrow keys (up to the maximum limit of 15 W of mean power). The increases / decreases (10%, 30%) always relate to the original values. Information related to applications is displayed in the info window. The program can be terminated at any time, even during laser emission, by pressing the “Stop“ key or one of the keys to select the application (Surgery, P/E, Implant, Hard tiss., Therapy). Laser emission is immediately switched off.

7.5.Modifying the application programs

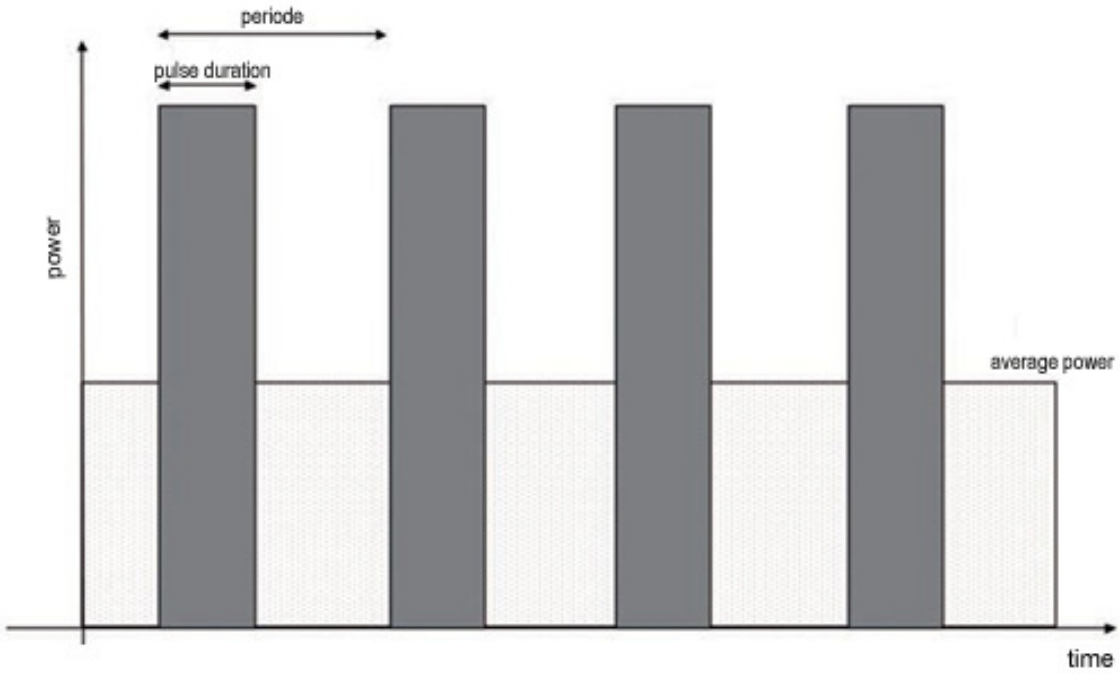
The predefined application programs can be modified individually (within certain performace limits). For this, select an application area. Using the arrow keys, mark the application to be modified and actuate the “Data“-key. The parameters of the selected application program are now shown:

» Pulse output (power of a pulse in watts)

» Frequency (number of pulses per second)

» Pulse duration (duration of pulse)

» Power (mean output power calculated from the three previous parameters based on the formula:
Pulse power x Pulse frequency x Pulse duration)



INFO

» The pulse duration cannot be set to more than the period duration (1/pulse frequency). Otherwise, permanent operation (CW) would be set.

» The mean power is derived from the product of pulse power x pulse frequency x pulse duration. The mean power is limited to 15 W for safety reasons.

» The maximum pulse power is 50 W

» The maximum pulse frequency is 20.000 Hz.

» The minimum pulse duration is 2.5 µs

» For safety reasons, the parameters in the application areaes of “Surgery“, “P/E“, “Implant“ and “Hard tiss.“ can be modified only such that the mean power deviates by a maximum of 30% from the factory setting. The permissible limits are shown in the lower monitor area (max. and min.).

To modify the parameters, mark the desired parameter using the arrow keys. Actuating the “Edit“ key activates Edit mode. The selected parameter can be varied using the arrow keys. Actuating the “Save“key saves the modified parameter. If

individual parameters are set such that the safety limits are exceeded, these parameters cannot be saved. The last-saved parameters are applied again.

For therapy programs, the pulse power can be modified in the range between 10 mW and 100 mW, and the pulse frequency in the range between 12 and 20.000 Hz. The procedure is similar to the process described above.
Parameters that deviate from the factory settings are marked by a " * ".
After parameters have been modified, the original factory parameters can be reset in the Data menu.

Reset Application:	For the selcted application all parameters are reset to factory settings
Range:	For all applications in the selected range the parameters are reset to factory setting
All:	For all applications in all ranges the parameters are reset to factory settings

Actuate the "Edit"key to perform the modification. Set the "1" value with the arrow key. Actuate the "Save" key.

7.6.Settings in the System menu

Some individual settings can be made in the System menu ("System" key). The following options can be selected:

7.6.1. Settings

» **Volume of key beep**

Can be adjusted from 0 (quiet) to 5 (loud). The change can be heard immediately.

» **Volume of emission beep**

Can be adjusted from 0 (quiet) to 5 (loud). The change can be heard on the next emission.

» **Therapy fee factor**

The proposed fee shown in the Standby menu is calculated via this factor. Specify the value here in EUR per second, that you would like to calculate for therapeutical services. Possible values from EUR 0 to EUR 655.

» **Fee factor**

The proposed fee shown in the Standby menu is calculated via this factor. Specify the value here in EUR per second, that you would like to calculate for hard laser treatments. Possible values from EUR 0 to 655 EUR.

All parameters can be modified by selecting with the arrow keys and pressing the "Edit" key. The current settings are saved using the "Save" key.

7.6.2. Touchscreen calibration

If the position of the keys on the display does not match those on the touch-sensitive touch panel (i.e. you have to press next to an indicated key to activate it), the touchpanel can be calibrated. After the "Calibrate Touchscreen" function is selected, press the "Start" key. You are now prompted to touch 4 points on the screen in succession. If all 4 points were touched correctly, the new setting can be applied by selecting the "Surgery" key and then the "System" key.

If not all 4 points were touched, wait 10 seconds. The old settings are then automatically retained.

7.6.3. System status

The “System Status“ function involves a function for calling in a service technician in the event of a fault. You will only need this function if a service technician asks you to activate it.

8. Handling of handpieces and fibers

8.1.ergoflex plus

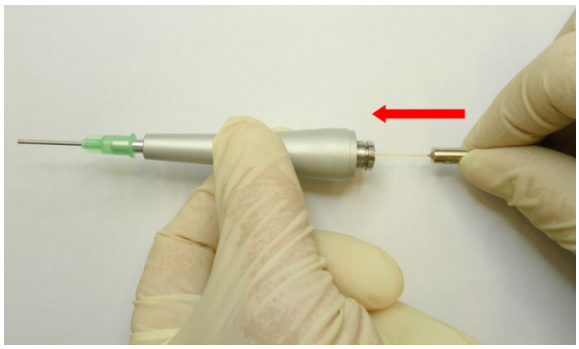
8.1.1. Introducing the application fibers

The claros 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.

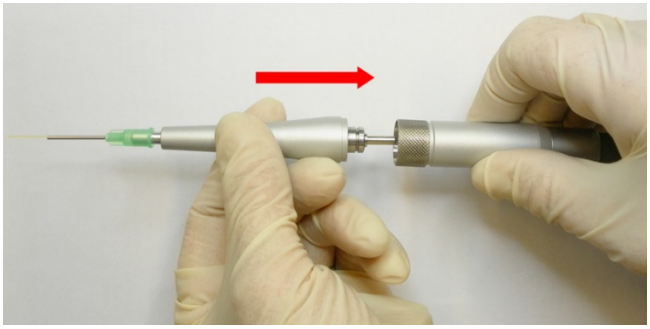
Depending on the diameter of the application fibers, various soft metal tips must be attached before introducing the application fibers:

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

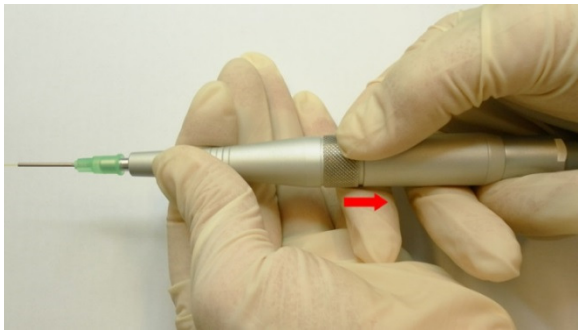
Push application fibers carefully into the handpiece front part from behind as far they will go. (Caution: glass fibers can break)



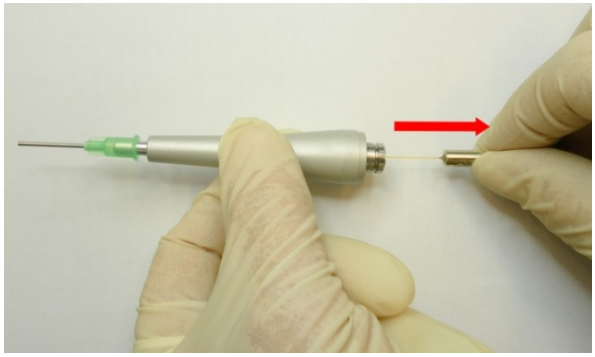
After this, place the handpiece front part centrally on the rear handpiece part. Then press both parts together in the handpiece longitudinal direction until the interlock ring can be heard to engage.



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.



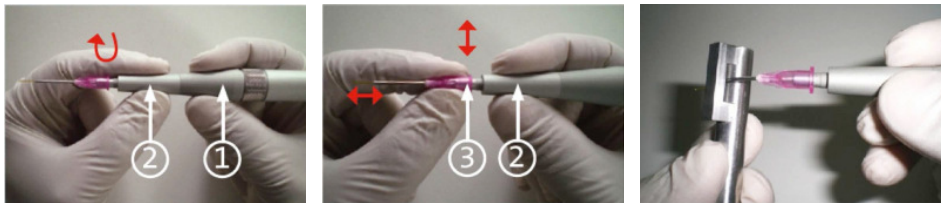
The fibers can be changed during operation with the device switched on. Fibers must not be replaced during laser emission under any circumstances!
Fibers have a limited service life depending on the power output used and the fiber diameter. Fibers can typically be used up to 15 times. Disinfected fibers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

8.1.2. 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.

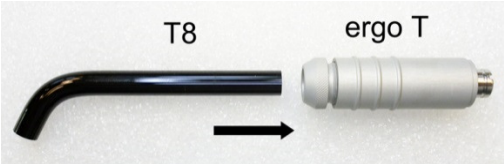
When you have reached the desired fiber length, lock the handpiece by twisting parts 1 and 2 clockwise. Bend the thin metal tube of the soft metal tip into the desired position using the bending tool.
Straighten the tube after use. Then separate the handpiece from the fiber cable and pull the fiber out of the handpiece.
Do not adjust the fiber length when the tube is bent!



8.2.ergo T

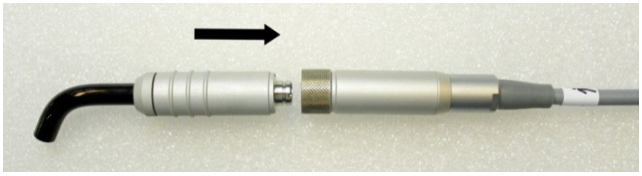
The ergoT handpiece can be used with the two glass rods T4 (optional) and T8. The glass rods are used in all therapy programs. The application information on the list of applikations shows which glass rod is used in the relevant program.

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.

9. Accessories

claros is a diode laser system for dental use. It comprises a base unit in which laser radiation is generated, and a set of accessory parts:

Article No.	Article	
14584	claros: 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 oder 600 (green)
	11257	Soft metal tips: single-use tips for Elexxion longlife 200 oder 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	
10003	claros step: foot switch	
10077	Main cable	
10052	Key-card: “All applications“	
10073	Key-card: “Therapy only“	
10765	“Laser“ wall sign english	
11005	elexxion claros comfort: storage tray for storing accessory parts	

Not in standard accessory:

14088	Glass rod Snore 3
14090	Key card: „Snore 3“

Use of accessory parts other than those specified here is not permitted.

9.1.Installation and handling of elexxion claros comfort

elexxion claros comfort is an optional storage tray that can be attached to the housing of the claros. To install, insert the studs of the storage tray frame into the guide bushings on the rear of the claros device (beneath the display) until these click in audibly.

Then place the sterilisable norm-tray-box in the frame. The norm-tray-box can be used to transport contaminated accessory parts for autoclaving or to transport sterile accessory parts to the device. The norm-tray-box must be sterilised prior to initial application!

Maximum load capacity of elexxion claros comfort: 5 N (approx. 500 g)

10. 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).

10.1. 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).

10.2. 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.

10.3. 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 Vacuum	-	-	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.).

11. 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. Protective conductor testing as per VDE 0751
5. Replacement unit leakage currents as per VDE 0751
6. Testing of the safety concept as per applicable “claros testing“ work instructions

! 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.

Authorized 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

12. Service life

The claros 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.

! 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.

13. Disposal

13.1. 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.

13.2. 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.

14. Technical data

14.1. 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.

14.2. 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.

14.3. Technical data of claros:

Mains:	220-240 V, 50/60 Hz Hz
Power consumption:	1,5 A
Fuses:	1,6 A T as per IEC 60127-2/III (2 x)
Operating type:	short-term operation: laser emission 2 min ON / 1 min OFF Protection class: I application part type B, IP X0
Electromagnetic compatibility:	Class A
Wavelength:	808 nm +/- 10 nm
Max. output: (pulse)	50 W +/- 10 W
Max. output: (CW operation)	15 W +/- 3 W
Pulse frequency:	CW – 20.000 Hz
Pulse duration:	2,5 µs – CW
Aiming beam	635 nm +/- 5 nm, < 2 mW
Dimensions:	85x40x50 cm (HxWxD)
Weight:	35kg

14.4. Precision of displayed operating data:

Output power:	+/- 20 % of display value
Frequency:	+/- 3 % of display value
Time:	+/- 3 % of display value
Temperatures:	+/- 5 % of display value
Operating conditions:	Temp. 15°C – 35°C Rel. humidity 20 % - 85 % Air pressure: 800 hPA – 1100 hPa
Storage / transport conditions:	Temp. 15°C – 50°C rel. Luftfeuchte 10 – 85 % Luftdruck: 800 – 1100 hPa

15. Error messages

Error message	Possible cause	Measure
“Close housing“	Housing cover opened or damaged	Close housing (rear cover)
“Check fiber contact“	Fiber not connected to device	Screw fiber finger-tight to stop
“Shutter does not open“	Malfunction of the beam attenuator	If this recurs, contact elexxion service
“Shutter does not close“	Malfunction of the beam attenuator	If this recurs, contact elexxion service
“Check interlock“	Open door with connected interlock Missing interlock plug	Close door, screw in supplied plug
“Laser temperature is too low“	Device temperature of under 15°C	Switch on device with sufficiently high room temperature and wait for device to reach room temperature.
“Laser temperature is too high“	Temperature on laser diode too high	Leave device switched on and wait for internal cooling system to set the target temperature.
“Cooling element temperature is too low“	Temperature on cooling element too low	Switch on device when room tem-perature is high enough and wait for device to reach room temperature.
“Cooling element temperature is too high“	Temperature on cooling element too high	Leave device switched on and wait for internal cooling system to set the target temperature. Check on correct environmental conditions if needed
“Board temperature is too low“	Temperature on power electronics too low	Switch on device when room tem perature is high enough and wait for device to reach room temperature.
“Board temperature is too high“	Temperature on power electronics too high	Leave device switched on and wait for internal cooling system to set the target temperature. Check on correct environmental conditions if needed
“Output difference“	Severe deviation between target power and actual power	If this persists, contact elexxion service
“Insert key-card“	Key-Card not in card reader	Insert card
“Invalid key-card“	Damaged key-card. Key-card wrongly inserted	Request new key-card from elexxion. Insert key-card as per section 5 of these operating instructions
“Check foot switch“	Foot switch already activated prior to laser readiness. Foot switch defect	Foot switch may only be activated. After warning message. Replace foot Switch
“Check connection to CPU“	Missing data connection between display and power electronics	Contact elexxion service
“Check setup“	Missing calibration data in internal storage	Contact elexxion service
“elexxion“ logo not flashing“	Software failure	Contact elexxion service
“Value not in range, not saved“	Settings in DATA menu exceed or fall below permitted values	Change values so that the mean power limits are kept to

“Maximum permitted output reached“		Further output increase not possible
“Minimum permitted output reached“		Further output reduction not possible
“Selection blocked“	Wrong key-card	Insert “All Programs“ key-card

16. Repair service

If the device or a accessory part needs to be sent to elexxion AG to repair, please visit our web site at easc.elexxion.com (RMA) to announce shipping. Please send only disinfected devices or accessory parts to elexxion AG. Contaminated devices or accessory parts cannot be accepted! For transportation (carrying), lift the device on both sides by the handles and carry in an upright position.

17. Calibration

Output calibration is done during the annual safety check. Normally, no output calibration is required outside these times. But if output calibration is necessary, it should be done as follows:

17.1. Required tools:

Power meter	Ophir Orion / TH with measuring head 50 (150) A-BB-SH-26 with valid calibration
Key-Card	Factory card

17.2. Procedure:

» Remove the handpiece front part and use the rear handpiece part to measure the power.
» Point the rear part at the measuring field of the power meter
»Insert technician card
» Select “SYSTEM“ menu
» Select “Calibration DPL“ menu item
» Press “Start“ key
» Set “Limit“ menu item from “1” to “0”(with the up/down-button) and press “Save”
» Move to “DAC off”, press “Edit”.
»Activate the Laser, change the value until the measured power is between 25mW an 35mW. Then press “Save”.
» Select “DAC value 1 W“ menu item, Press “Edit“ key
» Activate the Laser, change the value until the measured power is between 0.8w and 1.2w. Then press “Save”.
» Move to “DAC 28W”, press “Edit”,
» Activate the Laser, change the value until the measured power is between 28,0W and 28,3W. Then press “Save”
» Move to “DAC Max.”, press “Edit”
» Activate the Laser, change the value until the measured power is between 43,0W and 44,0W and the current is not higher then 57,5 Ampere. Then press “Save”.
» Assemble the transmission fibre, the handpiece and the applications fibres and measure the power in the following applications:

Application	fibre-type	Value
surgery- surgery general	600µm	13,5W - 16,5W
surgery – curettage	600µm	3,35W – 4,15W
implant – Decontaminate implant	400µm	0,8W – 1,2W
therapy – allergies to metal	T8	17mW – 23mW
therapy – smooth scars	T8	85mW – 115mW

» If there is the message “power difference” in the Therapy-applications you have to play with the value for DAC Off. (Increase / decrease the value for 1 or 2 and do the application measurements again)
»Press “SYSTEM“ key
» Remove technician card
» Document calibration with measured values in medical products log

18. Application tables

18.1. Surgery

No.	Program name	Pulse output [W]	Pulse freq [Hz]	Pulse duration [µs]	Therapy	Time [sec]	Remarks	Average power [W]
S 1	Surgery, general	50	20000	15	-	-	High performance: Move 400 / 600 µm fiber relatively quickly	15,00
S 2	Puncture abscess	10	20000	20	L 6	-	200µm, selectively penetrate abscess as far as possible	4,00
S 3	Aphtha	30	10000	10	L 6	-	600 µm, move in a grid motion at a distance	3,00
S 4	Hemostasis	50	12000	10	-	-	600 µm, keep distance of approx. 2 mm	6,00
S 5	Curettage	25	15000	10	-	-	400/600 µm, remove granulation tissue	3,75
S 6	Epulides	30	13330	10	L 6	-	400µm,gigantocellularis,granulomat-osa,fibrosa,stretchtissue	4,00
S 7	Fibroma	40	12500	10	L 6	-	400/600µm,stretch tissue with surgical tweezers	5,00
S 8	Frenectomy	50	12000	10	L 6	-	600 µm, stretch tissue, detach parallel to alveolar ridge, no stitches	6,00
S 9	Gingivectomy bef. impression	25	15000	10	L 6	-	200/400/600 µm, advancing from front tooth to rear molars	3,75
S 10	Granuloma	40	12500	10	L 6	-	400 µm, stretch tissue with surgical tweezers	5,00
S 11	Gum depigmentation	50	12000	16	-	-	Only to be used with the protocol of Dr Kenneth Luk, Hong Kong	9,60
S 12	Hemangioma	25	15000	10	L 6	-	300 / 400 µm, detach in circular fashion, no stitches	3,75
S 13	Hyperplasia	50	12000	10	L 6	-	600 µm, move in a grid motion at a distancdof approx. 1 mm	6,00
S 14	Periimplantitis, surgical	25	15000	10	I 3	-	400/600 µm, to remove granulation tissue, assistant to provide	3,75
S 15	Specimen biopsy	30	13330	10	L 6	-	400µm,stretch tissue,segmentalablation	4,00
S 16	Retention cyst	30	13330	10	L 6	-	300 µm, remove cyst sac undamaged if possible	4,00
S 17	Expose impacted teeth	25	15000	10	L 6	-	400 µm, secure brackets as wound area is dry	3,75
S 18	Edentulous ridge	50	12000	10	L 6	-	600 µm, stretch tissue with surgical tweezers	6,00
S 19	Seeping hemorrhage	50	12000	10	L 6	-	600 µm, distance approx.2 mm, sloughing of bleeding	6,00
S 20	Sulcus preparations	30	13330	10	L 6	-	300 µm, for front teeth, 400/600 µm for molars	4,00
S 21	Verrucas	25	15000	10	L 6	-	300/400µm,stretchtissuewithsurgicaltweez ers	3,75
S 22	Vestibuloplasty	25	15000	10	L 6	-	400/600 µm, draw back lip or cheek and stretch tissue	3,75
S 23	Root end resection	25	15000	10	E 3	-	300/400 µm, remove granulation tissue, decontaminate with 200 µm	3,75
	Depigmentation of lips (special)	5W	16000	26	-	-	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 to improve the healing.	2,00
	Dentitio difficilis, surgical	5W	20000	26	-	-	Application fiber 300µm/400µm longlife	2,50

18.2. Implantology

No.	Program name	Pulse output [W]	Pulse freq [Hz]	Pulse duration [µs]	Therapy	Time [sec]	Remarks	Average power [W]
I 1	Vestibuloplasty	25	15000	10	L 6	-	400/600 µm, draw back lip or cheek and stretch tissue	3,75
I 2	Gingivectomy bef. impression	25	15000	10	L 6	-	300/400/600µm,advancingfromfronttoothtor earmolars	3,75
I 3	Decontaminate implants	1	CW	CW	-	15	200 / 300 µm, move around to cover all areas if possible	1,00
I 4	Expose implant	15	15000	10	L 6	-	600µm,fromscrewcentreoutwards,impressio n immediately	2,25
I 5	Flap surgery	25	15000	10	L 6	-	200 / 300 µm, operation field stays clear and free ofbleeding	3,75
I 6	Periimplantitis, surgical	25	15000	10	I 3	-	400/600 µm for removal of granula- tion tissue, assistant to provide	3,75

18.3. Periodontology / Endodontology

No.	Program name	Pulse output [W]	Pulse freq [Hz]	Pulse duration [µs]	Therapy	Time [sec]	Remarks	Average power [W]
P1	Pocket treatment	1,5	1.500	444	L6	15	Glass rod, as near as possible to pockets, pain eases	1,00
P 2	Gingivectomies, extern	50	12.000	10	L 6	-	600 µm, if possible stretch tissue	6,00
P 3	Gingivectomies, intern	25	15.000	10	L 6	-	300 / 400 / 600 µm	3,75
P 4	Hyperplasias	50	12.000	10	L 6	-	600 µm, move in a grid motion at a distance of approx.	6,00
P 5	Bacterial reduction in pockets	1,0	CW	CW	-	15	300 µm, under motion, record all areas if possible	1,00
P 6	Decontaminate mem- branes	1,0	CW	CW	-	15	300 µm	1,00
P 7	Open curettage	25	15.000	10	-	-	300 / 400 / 600 µm	3,75
P 8	Pocket reductions	25	15.000	10	L 6	-	300 / 400 µm	3,75
P 9	Bacterial reduction of canals	1,5	CW	CW	-	15	200 µm, fiber if possible up to apex, rotating up and down	1,50
P 10	Retrogr. Bacterial reduction	1,5	CW	CW	-	15	200 µm, try to reach all areas	1,50
P 11	Perio Green	1,0	10.000	30	-	40	300 µm fiber, 40 sec from lingual and labial in the pocket	0,30
P 12	Pulp capping	5	10.000	20	-	-	Glass rod immediately haemostasis, anti inflammatory, promotes dentin formation	1,00
P 13	Sulcus preparations	30	13.330	10	L 6	-	200 µm, for front teeth, rising to 600µm for rear molars	4,00
	Removal of granulation tissue	1	20000	10	-	-	200 um if the dentist will do the treatment from inside the rootcanal 300 µm if the dentist will perform the	0,20
	Retraction of gingiva	1	12000	10	-	-	200 or 300 depends on the space between the gingiva and tooth surface	0,12

18.4. Hard Tissue

No.	Program name	Pulse output [W]	Pulse freq [Hz]	Pulse duration [µs]	Therapy	Time [sec]	Remarks	Average power [W]
H 1	Bleaching	2,0	CW	CW	-	15	glass rod; distribute gel evenly. Observe exposure time.	2,00
H 2	Decontamination of membranes	1,0	CW	CW	-	15	600 µm, if possible under contact	1,00
H 3	Cavity decontamination	1,0	CW	CW	-	15	600 µm, if possible under contact	1,00
H 4	Hypersitive teeth	1,5	CW	CW	-	15	glass rod, Elmex fluid, if possible completely cover tooth	1,50
H 5	Tooth surface irradiation	1,5	CW	CW	-	15	600 µm, if possible under contact	1,50
H 6	Tooth stump sensitivity	1,5	100	3000	-	10	Use glass rod, irradiate prior to setting crowns	0,45

18.5. Snoring

No.	Program name	Pulse output [W]	Pulse freq [Hz]	Pulse duration [µs]	Therapy	Time [sec]	Remarks	Average power [W]
	Snoring	10	15000	33	-	-	Use straight glass rod SNORE3	5,00

18.6. Therapy

No.	Program name	Pulse output [W]	Pulse freq [Hz]	Time [sec]	Remarks	Average power [mW]
L 1	Hypersentivity	1	3000	180	Glass rod, coat entire area, allergy dissipates, 3 treatments	20
L 2	Aphtha	1	1800	80	Glass rod, coat directly if possible aphtha melts down, 2-3 treatments.	60
L 3	Post-extraction pain	1	8800	100	Glass rod, immediately after extraction in wound area, quicker wound healing	60
L 4	Gingivitis	1	2500	70	Glass rod,coat gumseam,bleedingandpaincase2-3treatments.	60
L 5	Hematoma	1	3500	90	Glassrod,irradiate close distanceacceleratedabsorption,1-2treatments.	40
L 6	Herpes labialis	1	4000	90	Glass rod, dry blisters, tension eases, 2-3 treatments.	40
L 7	TMJ disorder	1	10000	60	Glassrod,painrelief,butdoesnotremedycause,2treatments.	100
L 8	Relief Lockjaw	1	10000	60	Glass rod, irradiate each side, hold directly on joints	100
L 9	Alveolar osteitis	1	8000	30	Glass rod, prevention of post-extraction pain, irradiate entire surgical area, 2 treatments.	90
L10	Neuralgiform pain	1	7000	120	Glass rod, position on suspected point pain, usually, helps immediately	60
L11	Oedema	1	4000	120	Glass rod, tension cases immediately,rapid absorption, 2-3 treatments.	60
L12	Peridontosis, initial	1	10000	120	glass rod,ir radiate affected gums, 2-3 treatments.	80
L13	Peridontitis, initial	1	6200	120	Glass rod, irradiate as close as possible to apex	60
L14	Pulpitis, initial	1	1000	80	Glass rod, directly on open pulp horn, soothespulpa	20
L15	General pain	1	9000	120	Glass rod, hold as close as possible to pain centre	50
L16	Acid trauma	1	10000	120	Glass rod,irradiategingivaon bothsides,completerelief from painfreedom	70
L17	Abrasion trauma	1	10000	120	Glass rod, after 2 min. haematosis, immediate	70
L18	Stomatitis	1	2200	90	Glass rod, rapid reduction in inflammation, 5 treatments.	20
L19	Healing of wounds	1	8000	120	Glass rod, ATP process is accelerated by a factor of around 4 times	75
L20	Suppress gag relfex	1	1800	70	Glass rod, irradiate KG24 and LG25 directly, helps for around 20 min.	60
L21	Root end resect./ wnd. Treat.	1	2000	90	Glass rod T8, apply directly in apex area, prevents oedema	10

Notes

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