

Compact - Laser

CL mini

Instructions for use

Type: CL mini xx -658



CE 0044



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Content:

page:

Contents:	0
Permitted Accessories:	0
Permitted Protection Goggles:	0
Permitted Device in connection with the CL <i>mini</i> Laser:	0
1 Description of the Compact Laser CL <i>mini</i>	1
2 Intended Use and Indications	1
3 Safety precautions to be observed during the use of therapy lasers	2
3.1 Alignment Laser Spectacles (Therapist's Spectacles):	3
3.2 Laser Protection Spectacles (Patient's Spectacles):	3
3.3 Contraindications	4
3.4 Requirements for patients	4
3.5 Requirements for user	5
4 Compact - Laser CL <i>mini</i> : View	6
4.1 Accessory	6
4.2 Initial use	6
5 Use of the Compact – Lasers CL <i>mini</i>	7
5.1 Commissioning	7
5.2 Laser-point and distance of irradiation	8
5.3 Irradiation Angle	9
5.4 Use of the accessories	9
5.5 Location of Acupuncture points with the Compact – Laser <i>mini</i> :	10
5.5.1. Preparation of the assembly	10
5.5.2. Acupuncture point detection on the body	10
5.5.3. Detection of ear- and skull acupuncture points	11
5.6 Irradiation period and Absorption Doses	11
5.6.1 Formule	11
5.6.2 Measuring units	11
5.6.3 Calculation of the correct dose	12
5.7 Control of Use of Lasers	14
5.8 Charge of the NiMH- Battery	14
6 Possible dysfunctions of the laser	15
7 Cleaning, disinfection and maintenance	16
7.1 Laser, Laser Tip and Adapter for Light tube	16
7.2 Power Reducing Tip	16
7.3 Bent Light Tube	16
7.4 Maintenance	16
8 Waste management of laser and accessory	17
9 Warranty	17
10 Laser inspection	18
10.1 Scope of inspection:	18
10.2 Inspection Certificate	19
11 Laser dispatch	19
12 Warning advices and Label Information :	20
13 Technical Data:	21
Appendix A: Declaration of Conformity	22
Appendix B: Declaration of Conformity Australia	23
Appendix C: Application of Microbac [®] Tissues	24

Contents:

- 2 ea. AAA size NiMH – Batteries „Green“
- Intelligent Charger for NiMH- Batteries
- Luxury Leather Case
- lockable Casket, Aluminum
- Instructions for use
- Applications of the Soft-Laser
- Laser goggles "Soft-Caps"
- Measurement template for wounds (for mini 30 only)
- Instruments book
- Laser sign board (Attention Laser Beam)

Permitted Accessories:

Adapter for Light tube

Light tube, bent (Dental top)

Power reducing tip

Laser storage

Permitted Protection Goggles:

Soft-Caps Laser goggles (=glasses for the patient)

Comfort Laser goggles (=glasses for the patient)

Comfort Laser adjust glasses (=glasses for the therapist)

Comfort Laser goggles for children

Permitted Device in connection with the CL *mini* Laser:

Point Detector PS3, with Safety Connection Cable

1 Description of the Compact Laser CL mini

The CL mini is a soft - laser (Low Level Laser) which you can hold in your hand. It is powered by one standard NiMH battery (size AAA).

The laser light is red and divergent, so that the device complies with the Laser Class 2M.

The light at the slender tip is almost point-like, so you very well may irradiate punctiform. If you penetrate with a distance of a few centimeters between tip and skin, the irradiation is circular, wherein the diameter of the circle becomes larger with increasing distance.

The irradiation time can be adjusted in two stages. In addition, it can also be selected manually as desired.

2 Intended Use and Indications

The Intended Use of the Compact - Laser *CL mini* is: radiation of skin, mucous membrane and dental applications.

It is a "Medical Product" in accordance with the EU Medical Product Law and with the Essential Requirements 93/42 EWG and 2007/47 EC.

This unit is approved by TGA.

The main applications are divided into the sections

- Accelerating of wound healing and improvement of local defense in the wound area, especially in older patients, diabetics and impaired wound healing,
- Reduction of pain, i.a. after trauma, surgery and chronic degenerative diseases,
- for Acupuncture (instead of needling).

3 Safety precautions to be observed during the use of therapy lasers

The appropriate legal security precautions are to be observed!

- Open wounds may NOT be touched with the laser or its accessory! Risk of infection!
- Upon insertion of the laser tip or of the accessory part "optical fiber bent" in body openings there is the risk of introducing contaminants into the body – danger of infection!
- When printing with the laser tip on non-intact skin or mucous membrane that could be pierced – danger of bodily injury and infection!
- Laser therapy should be conducted by trained personnel only (= according to the list of trained persons enrolled in the Instruments Book)!
- The use of the operating facilities or installation contingencies in any methods other than mentioned in these user instructions can lead to dangerous irradiation!
- *CL mini*- Laser must be used and stored within the following temperature range:
Case Temperature: during use 10 to 40 °C (50 to 104 °F),
Storage temp. 0 bis 50 °C (40 to 122 °F)!
Caution is recommended during its transport by car in the summer!
Permissible humidity: 30 till 95 %_{rel},
The humidity should not condense on the case/body (no dew-drops)!
Air pressure: not critically
- No modification of this equipment is allowed!
- Portable and mobile HF communication systems may interfere with this instrument!
- The use of inflammable anaesthetic gases or oxidized gases like nitrogen (N₂O) and oxygen should be avoided. Some materials like cotton, that are saturated with oxygen, could be set on fire at these high temperatures, created at the because of the laser's direction. Before the laser is put into operation, there should be a specific period for evaporation of solvents in adhesives and inflammable solvents, which are used for cleaning and disinfection. Attention should be drawn to the fact that the body's gases too can set on fire.
- It is further recommended that:
Therapy duration for babies being treated at the cranial region should be short (approx. 50%)!

Recommendation to avoid claims for damages by patients who believe that they are now see worse after irradiation with the laser light:

- Avoid direct irradiation of the opened eye!
- Do not irradiate the closed eye with a power of over 10 mW!
- During radiation to the face use Soft Caps!

3.1 Alignment Laser Spectacles (Therapist's Spectacles):

At the use of lasers of the laser-protection-class 2M the therapist can wear the laser alignment spectacles as in accordance with the current edition of international standard EN208.

Minimal specifications of these spectacles for the *CL mini* corresponding to EN208:

Protection level at 658 nm: for *CL mini 8*: R 1
for all other *CL mini* lasers: R 2
and admitted for laser mode D (continuous operation)



- Silberbauer - laser alignment spectacles offer only protection against accidental irradiation through laser up to these levels!
- They are - according to EN208 - NOT ALLOWED to be used for the deliberate view of beam!
- They are only protection against casual irradiation, when the eye lid closure reflex is not suppressed or slowed down (medical treatment, illness ...); and thus repeated irradiations of the eye have to be reduced.

Attention! Colour identification is disturbed by the glasses!

- Clean glasses only with a glasses-cleaning-cloth or cloth and windows-detergent.

3.2 Laser Protection Spectacles (Patient's Spectacles):



The patient should wear laser-goggles. As per the international standard EN 207 in its current edition.

Minimal Specification of laser protection spectacles correspond to EN 207:

Protection level at 658nm : L3;
Laser mode: D (continuous operation)

- The Silberbauer laser protection spectacles offer only protection against accidental irradiation through laser up to these powers!
- They are - according to EN207 - NOT ALLOWED to be used for the deliberated view into the beam!
- They protect only then against casual irradiation, when the eye lid closure reflex is not suppressed or slowed down (medical treatment, illness ...); and thus repeated irradiations of the eye have to be reduced.

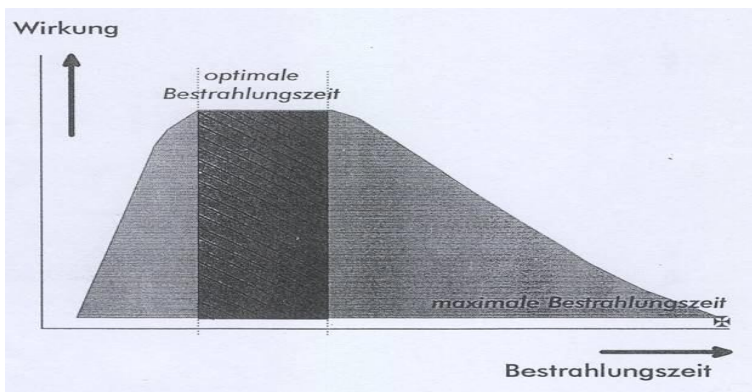
Attention! Colour identification is disturbed by the glasses!

- Clean glasses only with a glasses-cleaning-cloth or cloth and windows-detergent.

3.3 Contraindications

The laser treatment with a Class 2M laser has according to EN60825 no risk. However, different authors have controversial positions because the laser is especially successful in applications where you might have concerns **for forensic reasons**. So some contraindications should be observed:

- Avoid direct irradiation of the open eye!
- In the area of open fontanelles or open skullcaps, as well as growth gaps in childhood and adolescence should not be irradiated.
- During pregnancy, the penetration of the abdominal area is to be avoided. Attention! Some acupuncture points can trigger labour (Bl31, Bl32, Bl60, Bl67, Di4, Di5, Gbl21, Gbl34, LG20, MP6)
- Endocrine organs may not be treated!
- For epileptics, the scalp region may not be treated.
- In case of light dermatoses or higher photosensitivity, it is not allowed to penetrate (for all kinds of dermatoses which react with formation of erythems or vesicles to small doses of light).
- Pacemakers cannot be affected by penetration with the cw- laser, so there are no contraindications.
- Too long therapy time does not give better results, but also no harmful side effects. Exceptions are penetrations in the scalp region (more minutes), which can cause headache, and daily penetration with high doses which can cause that pain comes again.
- It is further recommended that: Therapy duration for babies being treated at the cranial region should be short (approx. 50%)!



3.4 Requirements for patients

- a) Age: Newborn to geriatric patients
- b) Weight: >2 kg
- c) State of health: not relevant
- d) Nationality: all
- e) Patient condition: not relevant

3.5 Requirements for user

a) Education: at least school leaving certificate, no upper limit

b) Knowledge:

Minimum:

- Reading and understanding of Western Arabic numbers and letters in a language of the country where the laser is used
- Mathematical knowledge (basic arithmetic, use of a simple formula) to determine the settings for area and dose per cm²
- Contraindications according to instructions for use
- Basic hygiene knowledge for cleaning and disinfection in the medical sector
- for acupuncture, position of the acupuncture points
- Training on the device (names of the persons registered as trained in the device book)

no upper limit

c) Experience:

Minimum:

Medical personnel:

- no additional requirements

All other persons:

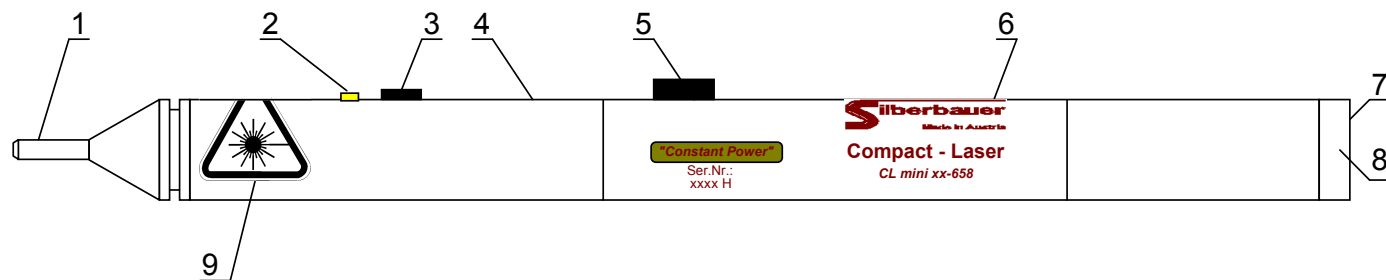
- Basic knowledge of the human body,
- the names of body parts, joints, organs,
- Names of diseases treated with laser,
- Basic knowledge of wound management

no upper limit

d) permissible impairments:

- slight impairment of reading ability or vision, but Arial 8 must be readable
- 60% reduction of normal hearing ability
- Impairment by hand, but must be able to grip and hold pipes with 20mm diameter securely

4 Compact - Laser *CL mini* : View



1	Laser point	6	Type plate and details
2	Light Emitting Diode, yellow	7	Socket for Silberbauer Point Detector PS3
3	Push-button	8	Battery Cap
4	Aluminium Body	9	Laser warning label
5	Rotary switch		

4.1 Accessory

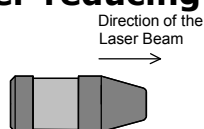
Adapter and Light tube, bent:



Power loss with optic fibre: 25 % almost!

Direction of the
Laser Beam

Power-reducing-tip:



Transmission 50%:

e.g.: for *CL mini 30* – Output Power reduces to approx. 15 mW

4.2 Initial use

The Silberbauer Compact - Laser *mini* is delivered with rechargeable NiMH- Batteries in Size AAA and with a charger for these batteries and can be used also with Alkali-Mangan-Batteries, Type AAA.

Open battery cap (8) at the end of the laser and insert battery with positive end pointing into the tube; close the cap and turn it clockwise until it stops.

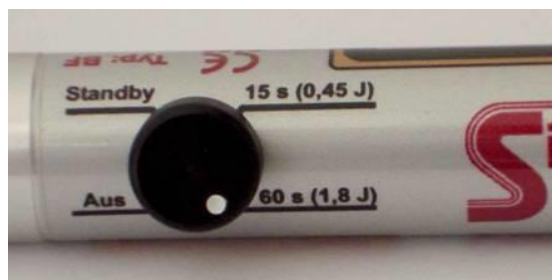


Now your Silberbauer Compact - Laser *mini* is ready to use!

5 Use of the Compact – Lasers CL *mini*

5.1 Commissioning

The **rotary switch (5)** is for switching the device on and off and to select the dose time of penetration.



In "Off" – position the device is switched off completely, no waste of battery power.

Nevertheless the battery should be removed from the laser if it is not used for a longer period because there is the risk of the battery leaking and then the risk of oxidation of the contacts. This causes a defect of the device!

Before and after each treatment the device should be disinfected, see Chapter 7!

In "Standby" position the laser is powered up and waits for selection of the necessary dose (time).

After selection of the dose the laser cannot be started promptly, but only after a security delay of 2 sec.

Now the laser can be started by pressing the **button (3)**. This button must be hold down during the whole penetration time because of security. After releasing, the laser will stop suddenly.

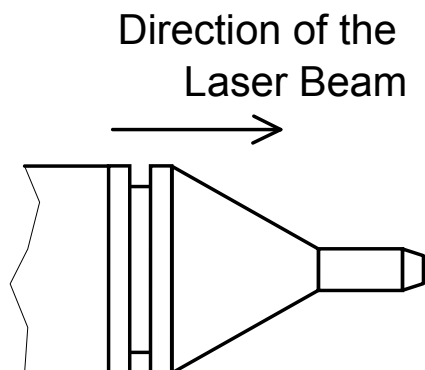
- Place the laser perpendicular to the area to be irradiated (see heading "Possibilities for use of Compact-Laser"),
- At the end of every therapy session the rotary switch must turned again into OFF-position.

The integrated timer starts promptly after pressing the button, the control LED glows yellow and indicates that the output power has the correct value and that the battery is OK. The timer stops the laser automatically after the chosen time for therapy and the LED becomes dark.

Shorter times of irradiation than the shortest selectable time of 15 seconds: Release the push-button early and the laser stops immediately.

Longer times of irradiation than the longest selectable time of 60 seconds: at the end of the therapy time, release the laser button (3) and start the therapy by pressing it again – and the next dose of selected time will start.

5.2 Laser-point and distance of irradiation



The point of the Silberbauer - CL-Laser is created in the shape of a small tube that follows the cone. The point is easily found through it – the point, where the laser-radiation radiates on the skin. Normally, nearly inaccessible points, like behind the ear are easily radiated with no problems.

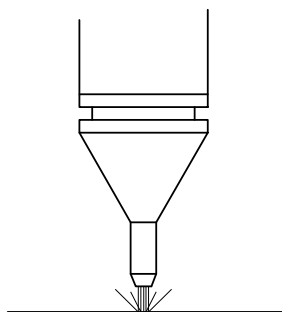
At the point there is a short light conductor. This light conductor serves among other things as mechanical protection for the heart of your therapy equipment, the laser diode. The impact point or the areas of operation are specified by this laser point. With all models the light emerges, whereby the size of points can be changed according to requirements through the choice of the distance from the skin.

The irradiation distance can be selected at will! Therefore the laser is allowed to be set on the skin's surface. The skin can also be pressed in with smooth pressure by the laser-point, to reduce the distance between deeper-set areas needing to be irradiated (e.g. area of abdomen).

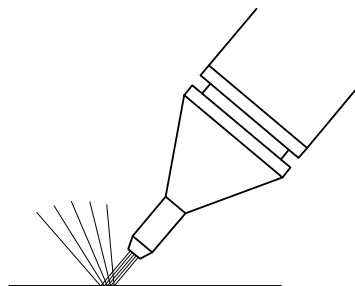
Apart from this the laser-point is conductive and is connected with the socket at the rear end of the laser battery. The point-searcher PS3 can be connected to this socket with a connecting cable. Herewith the laser-point can be used at the same time as searching point-peak for acupuncture points.

5.3 Irradiation Angle

To obtain optimal success during treatment, the laser must be positioned perpendicular to the skin's surface.



Low reflection,
Optimal penetration depth
= optimal success

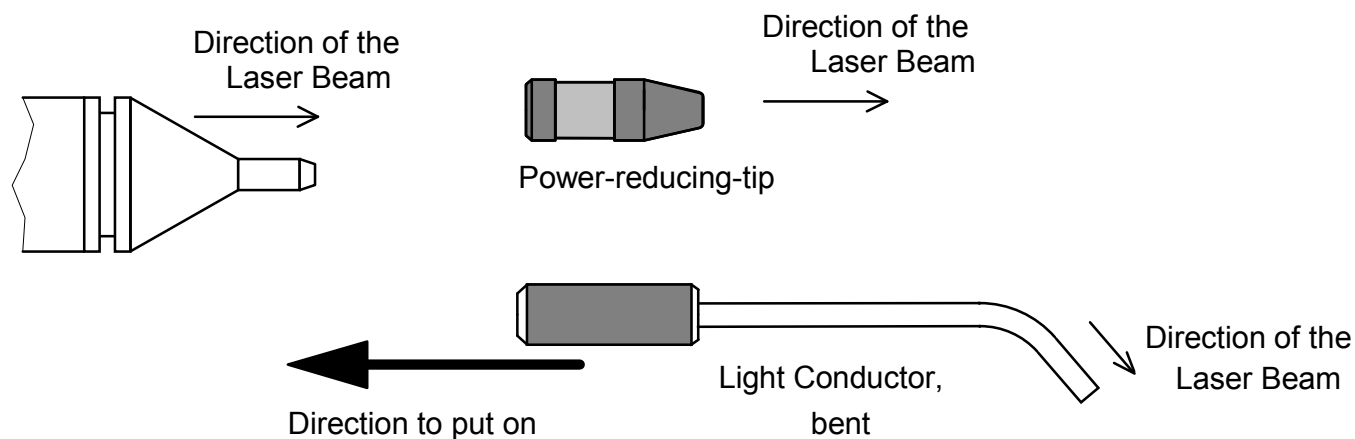


wide reflection,
lower penetration depth
= less success

5.4 Use of the accessories

To reduce power, push the power reduction tip onto the laser tip as far as it will go (see drawing). (Not possible in conjunction with the light conductors!)

When using the bent light tube, first push the adapter onto the laser tip up to the stop and then push a light tube into the adapter up to the stop; after use, simply pull off the light guide.



5.5 Location of Acupuncture points with the Compact – Laser *mini*:

5.5.1. Preparation of the assembly

As well as the Silberbauer Compact - Laser *mini* (without power reducing tip!) a Silberbauer Point Detector PS3 and a connection cable is required.

Put one plug of the connecting cable into the rear socket of the laser. The other cable plug is required to be inserted into the golden socket of the Silberbauer PS3 instead of the point-search-tip.

The point finder Silberbauer Punktsucher PS 3 must now be handed over into the hand of the patient. The laser-tip can now serve now as a point finder.

5.5.2. Acupuncture point detection on the body

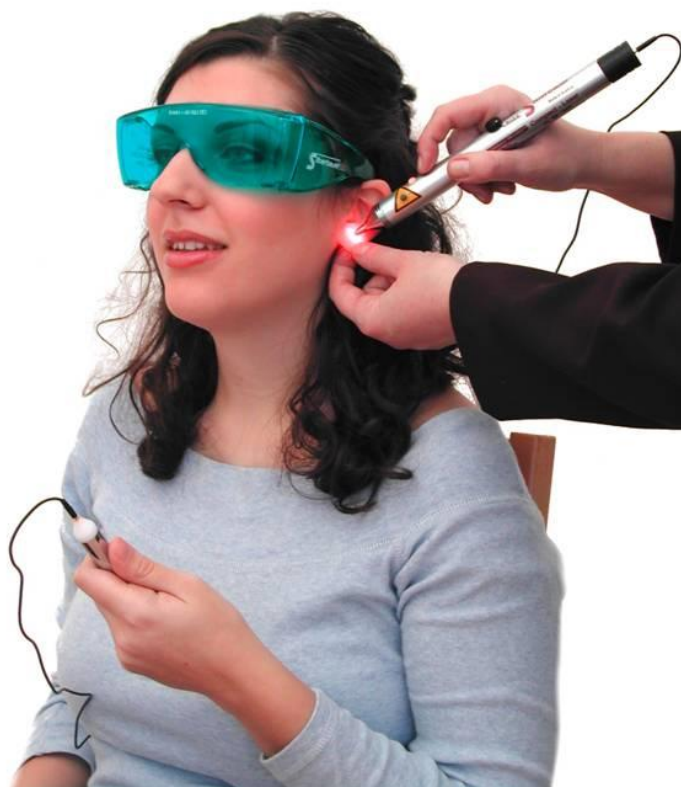
The Silberbauer Point Detector PS 3 indicates the electrical conductivity of the skin both optically (with higher or lower frequency of the installed light-diode) and acoustically (with a varying tone pitch). The latter can be heard by the doctor while focussing his eyes on the acupuncture point.

Hence the laser tip is positioned slightly diagonally above the acupuncture point, which should be localized on the skin's surface. The area assumed to be an acupuncture point is sought out; then search the area, where you suppose the acupuncture point is, without lifting the tip from the skin. The pressure of the tip should be light and consistent while searching.

Continue the search in the direction of a higher tone or a quicker signal. The tone pitch reaches its maximum light and maximum pitch or frequency at the centre of the acupuncture point.

The push-button must be pressed on the laser above the acupuncture point thus beginning the irradiation. The time of therapy programmed in the Silberbauer Compact-Laser *mini* is optimised for this kind of application required in every model.

5.5.3. Detection of ear- and skull acupuncture points



The acupuncture points at the cranial zone because of Yamamoto and at the ear are "silent" -in contrast to acupuncture points for the rest of the body. This indicates that the electrical conductivity of the skin is very low there. However if a disturbance in the organism is projected to the reflexion zones, the electric conductivity of the skin changes at the relevant acupuncture points and zones. These points can be located like with the body's acupuncture. Very high tones appear at points with strong disturbances which should be irradiated.

5.6 Irradiation period and Absorption Doses

Suggested references: e.g.:

Baxter: Therapeutic Lasers – Theory and Practice

Füchtenbusch/Bringmann: Laser Therapy and Laser Acupuncture, Treatment tables

Tunér/Hode: Laser Therapy – Clinical Practice and Scientific Background

Tunér/Hode: The Laser Therapy Handbook

5.6.1 Formule

$$\text{Energy} = \text{Laser power} \times \text{irradiation period}$$

$$\text{Irradiation dose} = \text{Energy} / \text{unit area}$$

5.6.2 Measuring units

Energy: in **Joules (J)** = Watt-seconds (Ws)

Power: in **milli-watt (mW)** 1 mW = 0,001 W

Time: in seconds (s)

Unit area: in cm²

Irradiation doses: in J / cm²

Recommended dose for different applications

Necessary irradiation period in seconds/cm²

for different laser models (upper line):

This table shows how more power saves time!

The area to be irradiated is 50 x 10 mm large and should be irradiated with a 8 mW-laser with 1 Joule per cm².

1 Joule /cm² = 125 seconds /cm² with the 8 mW-laser.

For $50 \times 10 \text{ mm} = 5 \text{ cm}^2$ would it be $5 \times 125 = \mathbf{625}$ seconds for time for, that are more than 10 minutes!

Or:

for treatment of areas with help of the card (for mini 30 only!):

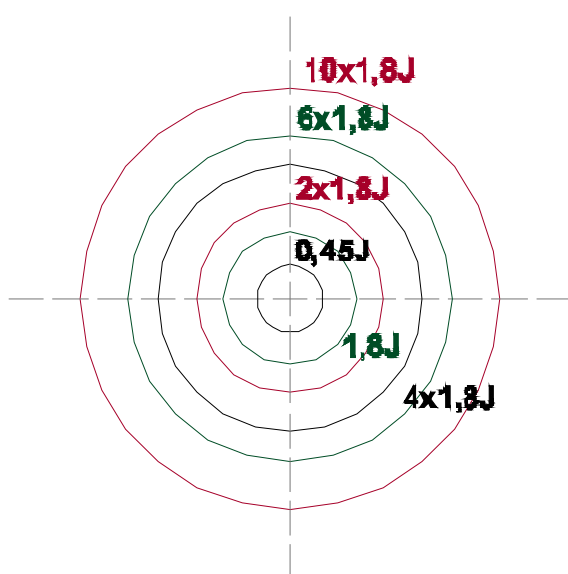
Place the card close to the wound and check which circle has the same area like the wound (e.g. 4x1,8J).

At this circle you find the number how often this dose has to be applied at once (e.g. 4x) and the dose setting of your laser (e.g. 1,8J).

Set your laser to this dose setting. Place the laser tip close to the rim of the wound, press the start button and remain pressing until the laser switches off.

Now release the button and press it again. Repeat this corresponding to the number.

Example for model CL mini 30 – 658:



Area of the wound with $1\text{J}/\text{cm}^2$

Wundbereich bei $1\text{J}/\text{cm}^2$

**Compact-Laser
CL mini 30-658**

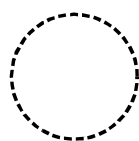
Labor Silberbauer

In the literature there are values between 0,54 and 3 J/cm^2 recommended.

Preset duration time in Joule at Silberbauer *CL mini* models:

model:	at 15 seconds:	at 1 minute:
CL mini 8 - 658	0,12 J	0,5 J
CL mini 20 - 658	0,3 J	1,2 J
CL mini 30 - 658	0,45 J	1,8 J

For comparison between different Silberbauer laser models:



For penetration of this small **wound (1cm²)** with 1 J/cm² (usual dose) you will need following **times**:

Model:	Seconds:
<i>CL mini 8 - 658</i>	125
<i>CL mini 20 - 658</i>	50
<i>CL mini 30 - 658</i>	33

5.7 Control of Use of Lasers

The Silberbauer Compact - Laser *mini* has a mechanism for control of the laser output power:

The yellow light emitting diode (2) glows when the laser works with 90% of its rated power at least.

5.8 Charge of the NiMH- Battery

See manual of the battery charger!

Attention! Don't try to charge normal one use batteries!

6 Possible dysfunctions of the laser

Attention must be paid to the existing danger involved in meddling with a damaged instrument and being exposed to dangerous laser-radiations!

If the yellow lighting LED does not glow once the start-button is pressed, then please leave the button and observe whether

- A few seconds have passed after the rotary switch was switched on?
(It takes about 2 seconds till the laser can be switched on)
- Could the battery be flat?

It is enough to recharge the flat battery for a few minutes and irradiation can begin for a short time!

If the laser does not work in spite of a correct battery or fully charged battery, please do not make any further attempts, but send or bring the laser together with the battery for monitoring purposes to our service!

Do not under any circumstance turn or pull the mains adapter or the battery out of the laser while it is switched on! In case of the tiniest loss of contact – possible after a dropped battery or laser – the laser-diode could be badly damaged!

Any changes in the device is NOT allowed!

Fluid traces or small colorless or white crystals at the battery or at contacts indicate that a battery or a rechargeable battery has leaked and the contacts do not work. In this case, please send the device to the service for professional cleaning!

7 Cleaning, disinfection and maintenance

To avoid any danger of infection, the laser point must be disinfected before and after each treatment (and the power-reducing-tip and the bent light conductor). Disinfection should be bactericidal, fungicidal, sporicidal and (limited) virucidal.

7.1 Laser, Laser Tip and Adapter for Light tube

The **laser** itself is NOT waterproof and should therefore not be placed in a bath! He must first be carefully pre-cleaned with a woven cloth moistened with a little tap water to remove any dirt. It is important to ensure that no water gets into the openings.

Then it can be wiped carefully with a certified practice non-alcoholic disinfectant for Medical Devices ¹ (its leaflet must be observed).

The **laser head** itself and also the **adapter for light tubes** can also be cleaned and sanitized in this way.

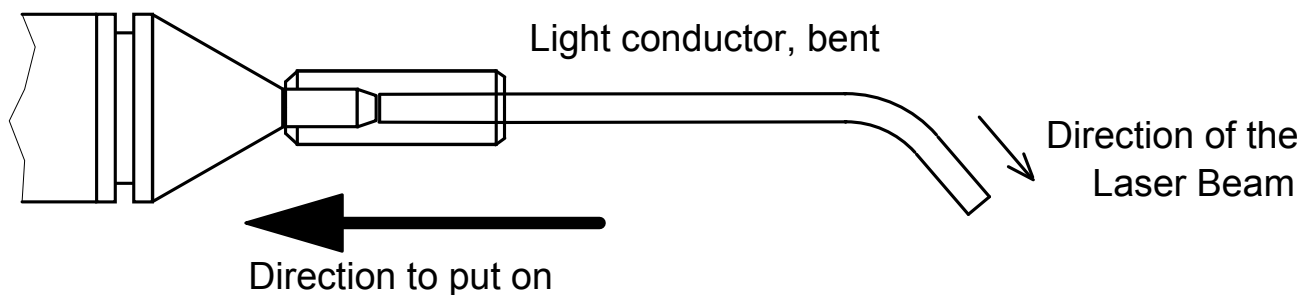
7.2 Power Reducing Tip

The **power reducing tip** must be deducted from the laser prior to cleaning. Its hole may for example be pre-cleaned using toothpicks, tap water and a cloth. Then it must be placed in a disinfectant for Medical Devices (its leaflet must be observed!).

7.3 Bent Light Tube

Also the **bent light tube** must be deducted from the laser prior to cleaning.

Now it can be pre-cleaned with tap water and a cloth. Then it can be placed into a non-alcoholic disinfectant for Medical Devices (observe leaflet of disinfection liquid before use!).



The light tube can also be cleaned chemo-technically with a disinfectant suitable for acrylic glass (80 °C max.!).

7.4 Maintenance

There is no additional maintenance necessary by the user.

¹ E.g. Microbac® Tissues from BODE; it must be **alcohol-free and suitable for acrylic glass!** Application see Appendix C.

8 Waste management of laser and accessory



For waste management please regard the valid legal regulations of each country/region!

Disposal of the device: Not like household waste, but in the nearest receiving depot for disposal of electric devices!

The batteries have to be brought to the next receiving depot for special waste disposal.

9 Warranty

Guarantee:

All recently manufactured Silberbauer products: 3 years after date of sales,

All used products: 1 year.

Within the scope of this guarantee we will provide free replacement of all parts which are defective because of material failure or mistake in production or we will repair them.

Excluded from the warranty are

batteries, accumulators and

damage by effect of mechanical force eg dropping or

by too high or too long working- or storage- temperature and

damage by inappropriate handling.

Also excluded from warranty are all damages at any device or accessory caused by leaked batteries.

After demounting of the device by non-authorized ones there is no more warranty!

10 Laser inspection

The **CL-Laser *mini*** must be inspected at regular intervals of **2 years**.



10.1 Scope of inspection:

1. Examination of Output Power:

Measuring Equipment required:

Measuring device for the laser output with a large Si-photo-diode (at least 10 x 10 mm) is well suited for the measurement of every monitoring phase of the laser output and the wave-length of the *CL mini* Laser.

Specification:

Measuring accuracy: +/- 5%

Measuring Process: The output power is measured when the laser is turned on and the sensor is hold perpendicular to the laser beam.

Range of tolerance of the measured power: Nominal Power +/- 5%

If the measured power is out of the mentioned range of tolerance, the laser must be calibrated or repaired.

2. Examination of controlling elements

Due to danger of mechanical abrasion, the laser-button (3) must be checked and also the rotary switch (5).

Scope of examination:

a) Control of strokes of rotary switch: The switch must be turned to its 3 intended positions. The white point at the knob must corrspond to the labeling.

b) Procedure for monitoring function of the rotary switch (5) and laser-button (3):

Turn the rotary switch into its off position.

Insert battery.

Press the laser-button.

No laser radiation has to emerge out of the instrument.

Turn the rotary switch into its standby position.

Press the laser-button.

No laser radiation has to emerge out of the instrument.

Turn the rotary switch into 15 s position.

Press the laser-button.

The instrument has to give laser-radiation for 15 s (control of time).

Turn the standby-ready-switch into the position of 60 s.

Press the laser-button.

The instrument must radiate for 60 s (control of time).

3. Checking the readability of all labels

All labels must be perfectly readable!

4. Checking of all accessories

Inspection of all accessories by visual inspection for breaks or wear should be done. Also goggles for deep scratches which disturb the view.

10.2 Inspection Certificate

To confirm the accurate functioning of the instrument the owner will receive an inspection certificate including its measured power. The results are given in the instruction book.

11 Laser dispatch

The laser is delivered in its original packing, devoid of any defects by post. Pull the battery out of the laser during transport!

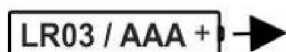
Attention! *The Instruments Book is a **Document!** Please, send it together with all kinds of inspections or repair together with the device and accessories!*

Storage temperature must not exceed 50 °C (122 °F) !

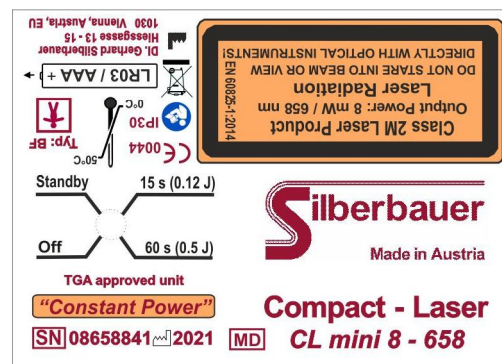
12 Warning advices and Label Information :

For the Laser there are used different warning labels depending of the model:
e.g. for the model *CL mini 8 - 658*:

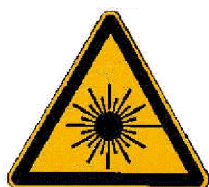
All other models have the same warning labels with other values for power and wavelength.



Battery type and direction for insertion



IP30 means: Protected against solid foreign parts with a diameter $\geq 2,5$ mm as well as against access with a tool, no protection against water



Caution! Laser radiation!



Permissible temperature range



Disposal of the device: Not like household waste, but in the nearest depot for disposal of electric devices! The batteries have to be brought to the nearest depot for special waste disposal.



Application part type BF



Serial number



Consult Instructions for use!



Manufacturer



Year of production



Medical Product

Label at outside of cases:



The manufacturer is only considered responsible to bearing on security, reliability and capacity of the instrument, if

- A. changes or repairs are made by personnel authorized by him,
- B. the electrical installation of the room is according to the regulations of ÖVE-EN 7,
- C. the instrument is used in accordance with the directions of use.

13 Technical Data:

Laser device, Series Compact - Laser CL mini xx - xxx :

CE 0044

Manufacturer and distributor: Prof. Dipl.Ing. Gerhard Silberbauer
Medical Electronics
Hiessgasse 13 - 15, 1030 Wien, Austria, European Union

Intended use: for laser radiation of skin, mucosa and dental applications

EMC Approval: Federal Institute of Technology, Electrical and Electronic Engineering, TGM, Vienna, Austria,
Ref. No. TGM-VA EE 38008 EMC

Accessory: see page 0

Internal power source: Alkali-Mangan- Battery or NiMH- battery, size AAA = LR03

This unit is approved by TGA

Classification: - protection level against electr. shock: Internal electric power source



Part of application type BF

- **ingress protection:** IP30
- **protection level during application together with explosive mixtures of anaesthetics with air or with oxygen or laughing-gas:**
Instrument is not to be used in an explosive atmosphere or with explosive mixtures from anaesthetics with oxygen to laughing-gas
- **Kind of operation:** Permanent operation
- **due to EU - direction 93 / 42 / EWG:** II A
- **Laser class:** 2 M

divergence of beam: 0,33 rad +/- 10%

therapy time: 15s or 60s (switchable) +/-3%

battery current: max. 0,25 A

weight: **without / with battery:** 78 g / 89 g

dimensions: 15 x 188 mm (D x L)

Model:	CL mini 8-658	CL mini 20-658	CL mini 30-658
nominal laser power +/-10% (mW):	8	20	30
wavelength (nm):	658	658	658
beam diameter at output (mm):	1,5	1,5	1,5
admitted case temperature (operating):	10 to 40 °C 50 to 122 °F	10 to 40 °C 50 to 122 °F	10 to 40 °C 50 to 122 °F
operating time of battery (Alkali-Mangan-Type):	16 h	12 h	10 h
operating time of battery (800 mAh- NiMH)	8 h	6 h	5 h

Interval for periodical inspection: 2 years

EMC (Reference required in accordance with EN 60601-1-2:2015):

The Silberbauer Compact Laser CL mini is tested according to the standard EN 60601-1-2:2015.

Result:

Emission: the limit values according to limit class B have not been exceeded!

Rights for technical changes reserved!

CL_mini_BED12_e.doc

Appendix A: Declaration of Conformity

EC – Declaration of Conformity

The company

DI. Gerhard Silberbauer
Hiessgasse 15, 1030 Vienna, Austria, EC,

declares its sole responsibility in development, production and sales of the medical products:

Compact - Laser

Models: CL mini 8 - 658; CL mini 20 - 658; CL mini 30 - 658;

Medical Products - Class: II A for laser-radiation of skin, mucosa and dental application
Laser Class 2M

according to EC- Medical Products Guideline 93 / 42 / EWG of the council of European Communities from June 14th, 1993, annex II (without 4).

The products meet all applicable requirements of the regulations in 93 / 42 / EWG annex I.

Involved Notified Body:

TÜV NORD CERT GmbH
Langemarckstrasse 20
45141 Essen
Deutschland (Germany)

Notified Body No. 0044, Certification Authority for Medical Products.

This Declaration of Conformity is valid
for all lasers listed above, produced until 2024-05-26.

Vienna, 2019-07-09



Dipl. Ing. Gerhard Silberbauer
CEO and QM Manager

Appendix B: Declaration of Conformity Australia



MANUFACTURERS DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

This declaration is made in accordance with the requirements of Clause 1.8 of schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the relevant devices in the attached schedule.

Reference: Not applicable

Manufacturers Name: Dipl.Ing. Gerhard Silberbauer, Medizinische Elektronik

Business Address: Hiessgasse 13-15 Vienna A-1030 Austria

Medical Devices: CL mini

Classification: Class IIa

GMDN Code: 36546 – Laser, diode

Scope: All

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Verification Certificate: GB98/13629 EC Certificate / Directive 93/42/EEC Annex II (excluding section 4)

Standards Applied: ISO 13485:2012
EN 60601-1:2007 +A1:2013
EN 60825-1:2014
EN 60601-1-2:2007
EN 60601-1-6:2010
EN14971:2012
EN62366:2008 +A1:2014
RoHS2 Directive 2011/65/EU

Authorised by:



Prof. Dipl.Ing. Gerhard Silberbauer
Managing Director

Date:

Sept. 25th, 2015

Appendix C: Application of Microbac® Tissues

Mikrobac® Tissues

Proven efficacy

Mikrobac Tissues are a ready-to-use product.

Bacteria und Fungi		
EN	Bactericidal (EN 13727)	
Phase 2 / Step 1	- dirty conditions	30 sec.
Efficacy according to EN Norm	Yeasticidal (EN 13624)	
Phase 2 / Step 1 (suspension tests), tested under clean / dirty conditions	- dirty conditions	30 sec.
EN	Bactericidal (EN 1040)	30 sec.
Phase 1 / Basic tests	Yeasticidal (EN 1275)	30 sec.
Efficacy according to EN Phase 1 (Basic tests / suspension tests) without contamination; does not define the applicability of a product for a specific purpose		
VAH	Bactericidal/Yeasticidal	
Certified application recommendations for prophylactic wet-wipe disinfection from the Association for Applied Hygiene (VAH). Based on suspension and practical tests, tested under clean conditions (i.e. optically clean surfaces) / dirty conditions (i.e. visibly contaminated surfaces)	- dirty conditions	5 min.
DGHM	Bactericidal/Yeasticidal	
Rapid disinfection (in accordance with the German Society for Hygiene Microbiology (DGHM)); Based on suspension and practical tests; tested under clean / dirty conditions	- dirty conditions	1 min.
Viruses		
Efficacy against viruses (German Society for the Control of Viral Diseases (DVV))	Virucidal against enveloped viruses (incl. HBV, HIV, HCV)	30 sec.
Appraised efficacy against non-enveloped viruses (DVV)	Polyomavirus	1 min.
Appraised efficacy against non-enveloped viruses (in accordance with DVV)	Rotavirus	30 sec.
Appraised efficacy against non-enveloped viruses (in accordance with EN)	MNV (EN 14476)	
	- clean conditions	4 hrs.
	- dirty conditions	4 hrs.
(Food) Industry		
EN	Bactericidal (EN 13697 + 1276)	
Phase 2 / 2	- low contamination (20 °C)	1 min.
Phase 2 / 1	- high contamination (20 °C)	1 min.
Efficacy according to EN Norms (Phase 2 / 2 and Phase 2 / 1), tested under different conditions	- low contamination (10 °C)	1 min.
	- high contamination (10 °C)	5 min.
	- low contamination (4 °C)	1 min.
	- high contamination (4 °C)	5 min.
	Yeasticidal (EN 13697 + EN 1650)	
	- low contamination (20 °C)	1 min.
	- high contamination (20 °C)	5 min.
	- low contamination (10 °C)	1 min.
	- high contamination (10 °C)	5 min.
	- low contamination (4 °C)	1 min.
	- high contamination (4 °C)	5 min.
EN	Bactericidal (EN 13697)	
Phase 2 / Step 2	- low contamination (20 °C)	1 min.
Efficacy according to EN Phase 2 / Step 2 (practical tests), tested under different conditions	- high contamination (20 °C)	1 min.
	- low contamination (10 °C)	1 min.
	- high contamination (10 °C)	5 min.
	- low contamination (4 °C)	1 min.
	- high contamination (4 °C)	5 min.
	Yeasticidal (EN 13697)	
	- low contamination (20 °C)	1 min.
	- high contamination (20 °C)	5 min.
	- low contamination (10 °C)	1 min.
	- high contamination (10 °C)	5 min.
	- low contamination (4 °C)	1 min.
	- high contamination (4 °C)	5 min.
EN	Bactericidal (EN 1276)	
Phase 2 / Step 1	- low and high contamination (20 °C)	1 min.
Efficacy according to EN Phase 2 / Step 1 (suspension tests), tested under different conditions	- low and high contamination (10 °C)	1 min.
	- low and high contamination (4 °C)	1 min.
	Yeasticidal (EN 1650)	
	- low and high contamination (20 °C)	1 min.
	- low and high contamination (10 °C)	1 min.
	- low and high contamination (4 °C)	1 min.

Listing

- Certification/list issued by the Association for Applied Hygiene (VAH) (submitted, data referring to the Mikrobac Tissues solution)
- CE-labelling in accordance with the Medical Device Directive (MDD)

Chemical-physical data

All data refers to the Mikrobac Tissues use-solution:

- Density (20 °C) approx. 1 g/cm³
- pH-value (20 °C) approx. 8

All data refers to the wipe:

- Dimensions: 180 x 200 mm²
250 x 380 mm²

Reach

The reach of Mikrobac Tissues not only depends on their size, but also on further factors, for example, the ambient temperature and structure of the surface to be disinfected. Always make sure to completely cover the surface area.

- Tissue 180 x 200 mm²: approx. 1 m²
- Tissue 250 x 380 mm²: approx. 2 m²

Stability

After opening

- in tightly closed flowpack: 3 months

