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Admitted Assessory:

Lightning cable bent (Dental top)

Power reducing tip

Admitted Protection Goggles:

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

Mini-Soft-Caps Laser goggles for children

Comfort Laser goggles (=glasses for the patient)

Comfort Laser adjust glasses (=glasses for the therapist)

Comfort Laser goggles for children

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

Point Detector PS3, with Connection Cable

1 Intended Use

The Compact – Laser *mini* is a Soft Laser (Low Level Laser) for radiation of skin, mucous membrane and dental applications in human and veterinary medicine.

It is a "Medical Product" in accordance with the EU Medical Product Law and 93/42 EWG.

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



The appropriate legal security precautions are to be observed!



Direct irradiation of the opened eye should be avoided at all costs! Irreparable damage can be expected!

- ^ With a power of over 10 mW even the closed eye should not be irradiated!
- ^ During radiation to the face use Soft Caps!
- For third persons is the observance of following security measures in terms of distance is required (NOHD). The safety-distance parameter for the eye also depends on the time of viewing.

Power of laser	Eye / 15 s	Eye / 60 s	Skin
8 mW	96 mm	114 mm	2,3 mm
20 mW	153 mm	183 mm	6,2 mm
30 mW	189 mm	225 mm	8,6 mm

- ^ Laser therapy should be conducted by trained personnel only!
- 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. 5 bis 50 °C (40 to 122 °F)!
Being the maximum temperature of the crystal, it is required!
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)!
- 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%)!

2.1 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 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.

2.2 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 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.

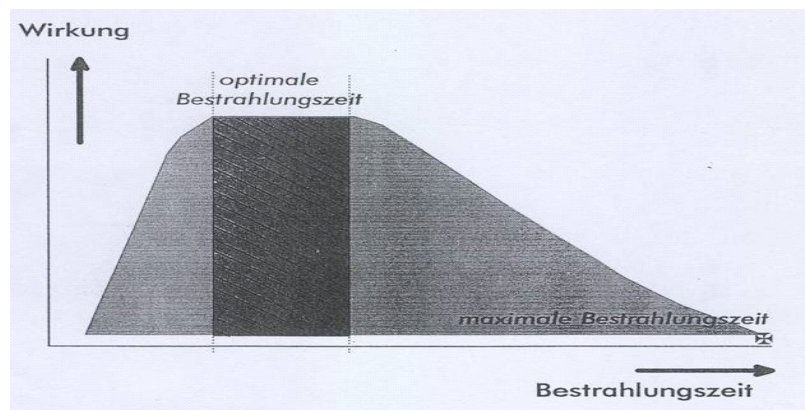
2.3. Indications

See scientific literature and soft laser courses!

2.4 Contraindications

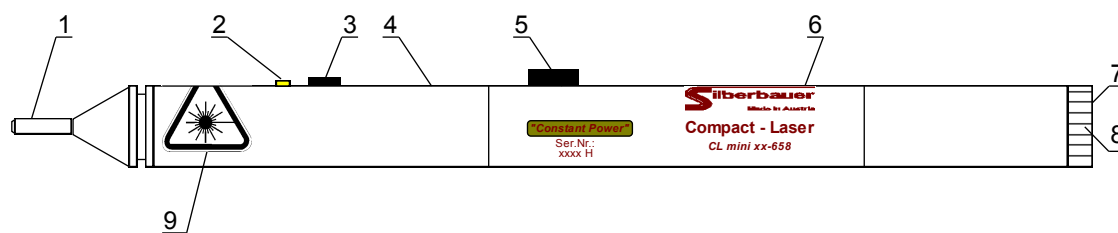
The laser treatment has a low risk only. Different authors have controversial positions because the laser is especially successful in applications where you for forensic reasons might have concerns. However, if no sufficient tests are available, some contraindications should be observed:

- **Direct irradiation of the open eye, it is essential to avoid!**
- 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 the literature, there are notes at the one side that tumors and malignant skin diseases should not be treated, at the other side tumor pains and damages due to radiation are a successful field of application. In the veterinary medicine there are good results after laser penetration of tumors because the lymphatic jam and the pain eases back.
- In case of 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.



See also scientific literature!

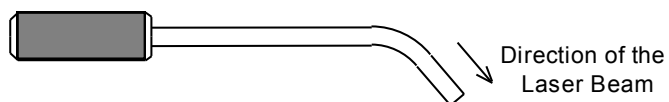
3 Compact - Laser *CL mini* : View



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		

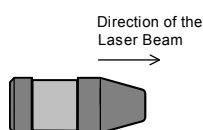
3.1 Accessory

Optic Fibre, bent:



Power loss with optic fibre: 25 % almost!

Power-reducing-tip:



Transmission 50%:

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

3.2 Initial use

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

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.



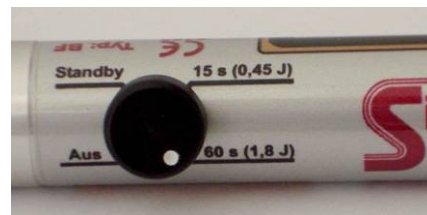
Now your Silberbauer Compact - Laser *mini* is ready to use!

4 Use of the Compact – Lasers CL *mini*

4.1 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!

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.

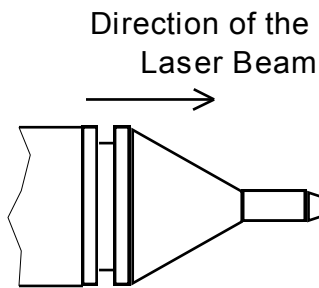
The integrated timer starts promptly after pressing the button, the control LED glows yellow and indicates that the output power has the correct value and that the battery is OK. The timer stops the laser automatically after the chosen time for therapy and the LED becomes dark.

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.

4.2 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.

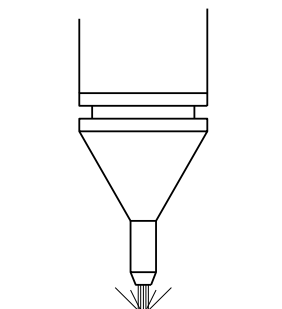
At the point there is a short light conductor. This light conductor serves among other things as mechanical protection for the heart of your therapy equipment, the laser diode. The impact point or the areas of operation are specified by this laser point. With all models the light emerges, whereby the 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).

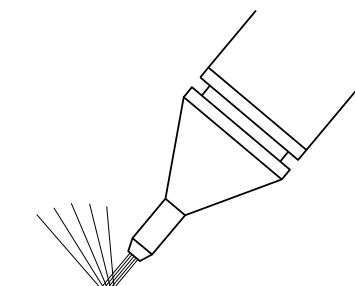
Apart from this the laser-point is conductive and is connected with the socket at the rear end of the laser battery. The point-searcher PS3 can be connected to this socket with a connecting cable. Herewith the laser-point can be used at the same time as searching point-peak for acupuncture points.

4.3 Irradiation Angle

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



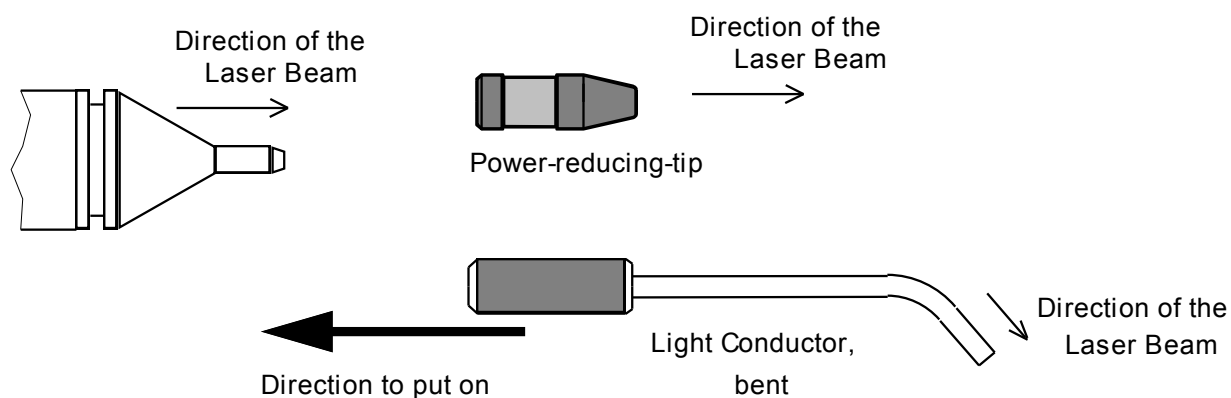
Low reflection,
Optimal penetration depth
= **optimal success**



wide reflection,
lower penetration depth
= **less success**

4.4 Use of the accessory

If necessary put the bent light conductor or the power reducing tip onto the point until a limit is reached (see drawing):



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

4.5.1. 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.

4.5.2. Acupuncture point detection on the body

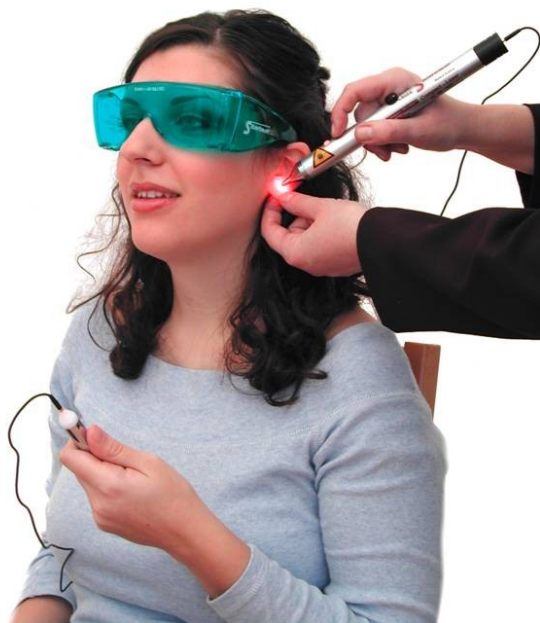
The Silberbauer Point Detector PS 3 indicates the electrical conductivity of the skin both optically (with higher or lower frequency of the installed light-diode) and acoustically (with a varying tone pitch). The latter can be heard by the doctor while focussing his eyes on the acupuncture point.

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. See chapter 1.3. "Acupuncture" in the booklet Applications of the Soft - Laser!

4.5.3. Detection of ear- and sculp 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.

4.6 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

4.6.1 Formule

Energy = Laser power x irradiation period

Irradiation dose = Energy /unit area

4.6.2 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 Joule / cm²

4.6.3 Calculation of the correct dose

Necessary irradiation period in seconds/cm²

to get a certain dose (left row)

for different laser models (upper line):

		CL mini			Compare:	
		8	20	30	CL 50	CL 90
Dose in Joule / cm ²	0,1	12	5	3	2	1,1
	0,2	25	10	7	4	2,2
	0,3	42	15	10	6	3,3
Region for skin:	0,5	62	25	17	10	5,5
	0,8	100	40	27	16	9
	1	125	50	33	20	11
in case of pain:	1,5	188	75	50	30	16,5
	2	250	100	67	40	22
	3	375	150	100	60	33
	4	500	200	133	80	44
	5	625	250	167	100	56
	6	750	300	200	120	67
	7	875	350	233	140	78
	8	1000	400	267	160	89
	9	1125	450	300	180	100
	10	1250	500	333	200	111
	12	1500	600	400	240	133
	14	1750	700	467	280	155
	16	2000	800	533	320	178
	18	2250	900	600	360	200
	20	2500	1000	666	400	222

This table shows how more power saves time!

Example:

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.

It is observed from the table that:

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

*For 50 x 10 mm = 5 cm² would it be 5 x 125 = **625** seconds for time for, that are more than 10 minutes!*

With a more powerful laser these times are much shorter:

*1 Joule /cm² = 20 secondes /cm² with the **CL 50** ,*

*for 50 x 10 mm = 5 cm² there are **100** second necessary..*

*With the **CL90** there are only **55** seconds to penetrate!*

Or:

for treatment of areas with help of the card:

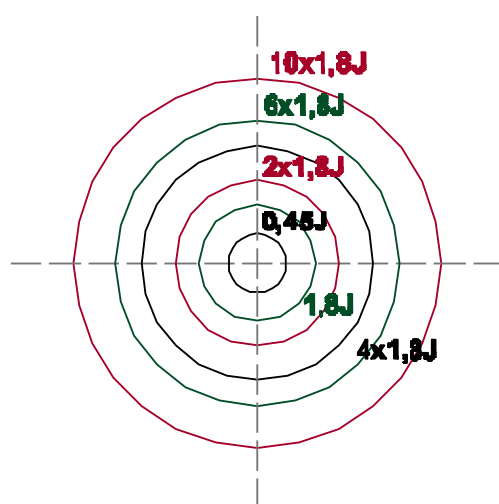
Place the card close to the wound and check which circle has the same area like the wound (e.g. 4x1,8J).

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 you hear the permanent warn tone and 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

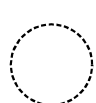
Labor Silberbauer

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: the CL – laser has		
CL 50 - 660	0,75 J	3,0 J
CL 90 - 660	1,35 J	5,4 J
the <i>Profi</i> — laser has		
PL 250 - 660	3,75 J	15 J

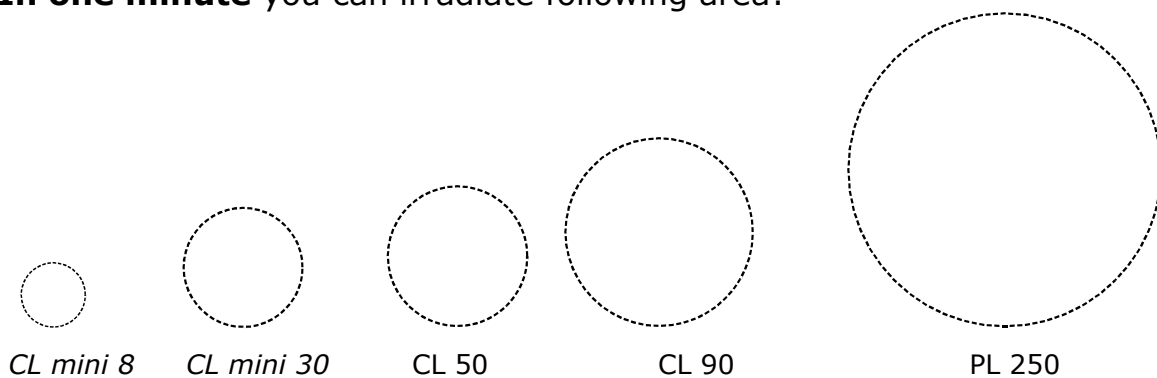
For comparison between different Silberbauer laser models:


 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
CL 50 - 660	20
CL 90 - 660	11,1
PL 250 - 660	4

Or:

In one minute you can irradiate following area:



4.7 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.

4.8 Charge of the NiMH- Battery

See manual of the battery charger!

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

5 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!

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!

6 Cleaning and maintenance

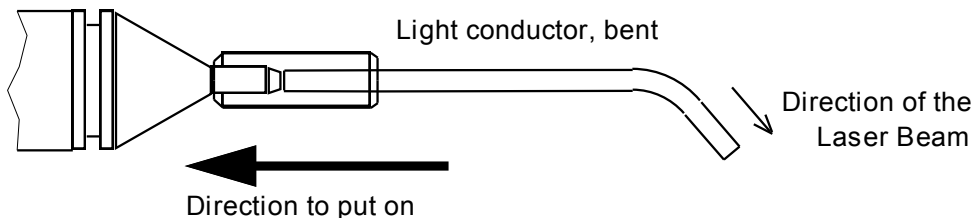
To avoid any danger of infection, the laser point must be disinfected before and after each treatment (and the power-reducing-tip and the bent light conductor).

The laser can be cleaned carefully with a cloth moistened with alcohol or surgical disinfection. No liquid should be allowed to enter the openings.

The laser point itself can be cleaned with a pad or cloth moistened with alcohol.

The drill of the "power-reducing-tip" can be cleaned with a toothpick and thereafter be washed with alcohol. For this, the power-reducing-tip must be pulled out of the laser always.

The "bent light conductor" can be cleaned like the laser top. The rear surface is well protected with a black hull made out of synthetic material. If this surface does get soiled the hull must be taken off. The lighting cable can then be proceeded to be cleaned, see laser-point. Ensuing which the hull must remain attached to the lighting cable again, in such a way that the lighting cable just touches the front-surface of the laser point after the hull is pulled up, whereby the hull has to loom until the end of the cylindrical area of the laser point.



Additional maintenance by the user is not required.

7 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.

8 Warranty

According to the product liability law, general conditions apply to liability insurance (AHVB), supplementing general conditions for the liability insurance (EHVB) and the special conditions NR. 3401 valid in each case version. During the processing of our distributed devices the relevant legal safety regulations and editions in the valid in each case version are to be followed.

We will provide free replacement of all parts which are defective because of material failure or mistake in production or we will repair them.

Guarantee:

All recently manufactured Silberbauer products: 3 years

All used products: 1 year.

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!

9 Laser inspection

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



9.1 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 correspond 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.

9.1 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.

10 Laser dispatch

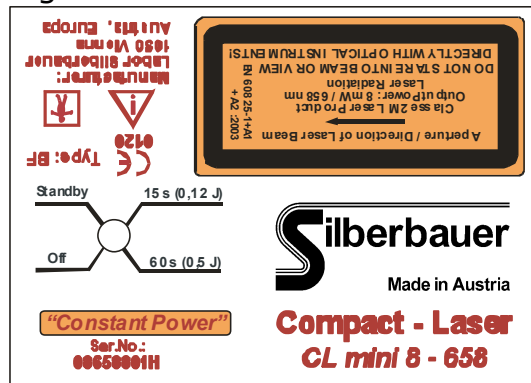
The laser is delivered in its original packing, devoid of any defects by post as bulk goods. Pull the battery out of the laser during transport!

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

11 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.



Caution! Laser radiation!



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

Year of manufacturing: coded at the end of the serial number:
letter A for 2001, B for 2002, etc.



Attention! The attached documents are to be noted!

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

- 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.

The instrument must not to be used with volatile gases or fumes during narcosis. This could cause sparks in the button or at the contacts. Apart from normal valid regulations the "Instructions to avoid explosive dangers in operational equipment" of BM for social administration ZI. V-88015-17 are to be considered in the advisory statement made by the medical experts from 03.02.1968 and ÖVE-EN 7 regarding the use of the instrument in an atmosphere enriched with oxygen.

12 Technical Data:

Lasengerät, Serie Compact - Laser *CL mini xx - xxx* :

 0120

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

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

Accessory: see page 0

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

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



Part of application type BF

- **protection level against harmful water invasion:** Common device
- **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:	<i>CL mini 8-658</i>	<i>CL mini 20-658</i>	<i>CL mini 30-658</i>
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	13 h	10 h
operating time of battery (800 mAh- NiMH)	9 h	7 h	5 h

Interval for periodical inspection: 2 years

Rights for technical changes reserved!

CL_mini_BED1.doc

EC – Declaration of Conformity

The company

Dipl. Ing. Gerhard Silberbauer

Medical Electronics

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

These instruments meet the following standards:

EN 60601-1:2007

EN 60601-2-22:1996

EN 60825-1 + A1 + A2:2003

EN 60601-1-2:2001

The company Silberbauer had been certified by SGS United Kingdom Ltd. (Notified Body No. 0120), office for the certification of medical products, according to regulation 93 / 42 / EWG annex II, in agreement with the ISO 9001:2000 and ISO 13485:2003.

The conformity of the product as in the conformity process according to annex II is confirmed by attaching the sign

CE 0120.

Vienna, Sept 2nd, 2008



Dipl.Ing. Gerhard Silberbauer

Calibration - Certificate

Device: Compact - Laser

Model: *CL mini*.....

Serial number:

It is hereby confirmed that the instrument mentioned above, has been examined and calibrated at its time of manufacturing.

Measured output-capacity: _ _ , _ mW

The date of examination of the output power of the laser is planned at intervals of 2 years.

The test badge on the instrument serves as a reminder of this test.

Vienna.....

Technical examiner

Change directory: