

Compact - Laser

CL plus

Instructions for use

Type: CL plus 60-660 L

CE₀₁₂₀

Serial number: 60660 L 601 J

assembled by

Silberbauer India



with the European know how of
Silberbauer Medical Electronics, Vienna,
Austria, Europe

Content:

Page:

1	Intended Use.....	4
2	Safety precautions to be observed during the use of therapy lasers	4
	2.1 Alignment Laser Spectacles (Therapist's Spectacles):.....	5
	2.2 Laser Protection Spectacles (Patient's Spectacles):	6
	2.3 Indications	6
	2.4 Contraindications.....	7
3	Compact - Laser <i>CL plus</i> : View	8
	3.1 Accessory	8
	3.2 Initial use	9
4	Use of the Compact – Lasers CL plus	9
	4.1 Commissioning.....	9
	4.2 Laser-point and distance of irradiation.....	13
	4.3 Irradiation Angle.....	14
	4.4 Use of the assessor.....	14
	4.5 Location of Acupuncture points with the Compact – Laser <i>plus</i> :.....	15
	4.5.1 Preparation of the assembly	15
	4.5.2 Acupuncture point detection on the body	15
	4.5.3 Detection of ear- and skull acupuncture points.....	16
	4.6 Irradiation period and Absorption Doses	16
	4.6.1 Formule	16
	4.6.2 Measuring units.....	16
	4.6.3 Calculation of the correct dose	17
	4.7 Checking the output power of the laser.....	17
	4.8 Charge of the NiMH- Battery	18
5	Possible dysfunctions of the laser	19
6	Cleaning and maintenance.....	20
7	Waste management of laser and accessory.....	20
8	Warranty	21
9	Laser inspection.....	22
	9.1 Scope of inspection:	22
	9.2 Inspection Certificate.....	23
10	Laser dispatch.....	23
11	Warning advices and Label Information :	24
12	Technical Data:	25
	Declaration of Conformity 23	
	Calibration Certificate	24

Delivery :

- 2 ea. NiMH – Batteries „Green“, 2050mAh,
- Charger for NiMH- Batteries,
- Laser – Storage, Acrylic Glass,
- lockable Casket, Aluminum,
- Instructions for use
- Applications of the Soft-Laser
- Laser goggles „Comfort“ (= for the patient),
- Laser goggles „Mini-Soft-Caps“ (= for children),
- Laser adjustment goggles „Comfort“ (=for the therapist),
- Measurement templet for wounds
- Instruments book
- Laser sign board (Attention Laser Beam)

Admitted Assesory:

Lightning cable bent (Dental top)

Power reducing tip

Admitted Protection Goggles:

see also page 2 – 3!

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 plus Laser:

Point Detector PS3, with Connection Cable

1 Intended Use

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

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 also approved by TGA.

The main applications are divided into the parts

- Acceleration of wound healing and to avoid obstructions in healing, especially for older patients, for diabetics and patients with wound healing complications,
- Reduction of pain e.g. after traumata and post surgery and at chronic-degenerative diseases,
- Acupuncture instead of needles.

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!

- even the closed eye should not be irradiated!
- During radiation to the face use Soft Caps!
- 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 plus*- Laser must be used and stored within the following temperature range:
 - Case Temperature: during use 10 to 45 °C (50 to 112 °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.

For class 3B lasers and especially for infrared lasers the therapist MUST wear those spectacles.

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

for *CL plus* until 100 mW: R 2

for all other *CL plus* models: R 3

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.

Appropriate Protection eyewear from the Silberbauer – Programme:

For all RED lasers until 200 mW: Comfort Justierbrille (green);

for all other models (IR also) until 500 mW: Comfort- Schutzbrille for Patient and Therapeut (dark blue).



2.2 Laser Protection Spectacles (Patient's Spectacles):

At the use of lasers of the laser-protection-class 2M the patient can wear the laser protection spectacles.

For class 3B lasers and especially for infrared lasers the patient **MUST wear those spectacles.**

Minimal Specification of laser protection spectacles correspond to EN 207 for Model *CL plus*:

Protection level at the wavelength of the laser : 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.

Appropriate Protection eyewear from the Silberbauer – Programme:

Adults:

for all Laser models (IR also) until 500 mW: Soft-Caps;

for red Lasers until 500 mW: Comfort-Schutzbrille (blue);

for infrared Lasers until 1000 mW: Comfort-Schutzbrille IR (pink coloured).



Children:

for all Laser models (IR also) until 400 mW: Mini-Soft-Caps;

for red Lasers until 500 mW: Comfort-Schutzbrille for Children;

for infrared Lasers until 1000 mW: Comfort-Schutzbrille IR for children (pink).



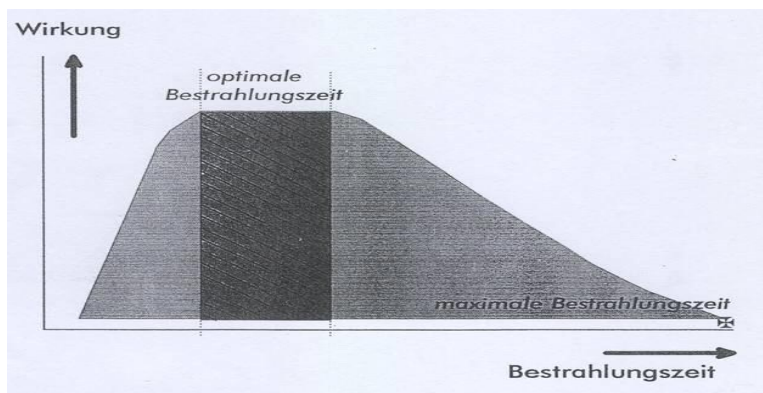
2.3 Indications

See scientific literature and soft laser courses!

2.4 Contraindications

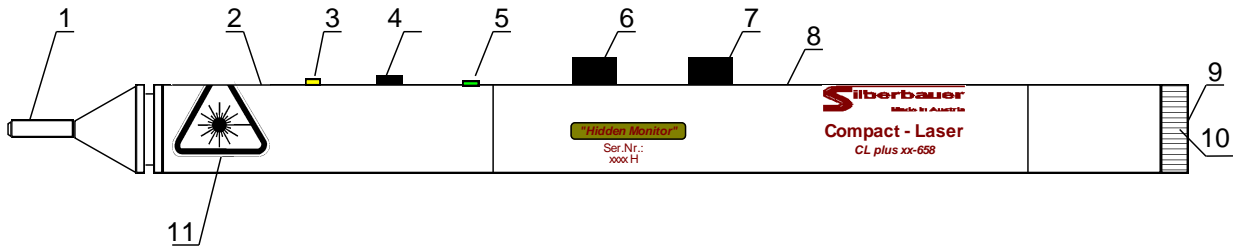
The laser treatment has a low risk only. Different authors have controversial positions because the laser is especially successful in applications where you for forensic reasons might have concerns. However, if no sufficient tests are available, some contraindications should be observed:

- **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!

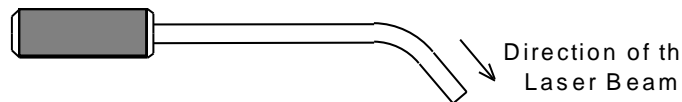
3 Compact - Laser *CL plus* : View



1	Laser Point	7	Rotary Switch 2 (Dose)
2	Aluminium Body	8	Type Plate and Details
3	Lamp multi colour (performance monitoring)	9	Socket for Silberbauer Point Detector PS3
4	Push-button (Start / Stop)	10	Battery Cap
5	Lamp (ready / battery low)	11	Laser Warning Label
6	Rotary Switch 1 (Function / Area)		

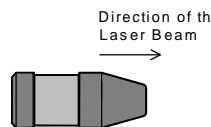
3.1 Accessory

Optic Fibre, bent:



Power loss with optic fibre: 25 % almost!

Power-reducing-tip:



Transmission 50%

3.2 Initial use

The Silberbauer Compact - Laser *plus* is delivered together with NiMH- Batteries in size AA and with a charger. These batteries have a very low self discharge rate: after ONE year, yet 85% of the initial charge are available!



Turn **Rotary Switch 1 (6)** into „Off“ position. Open **Battery Cap (10)** at the end of the laser and insert battery with negative end pointing into the tube; close the cap and turn it clockwise until it stops.

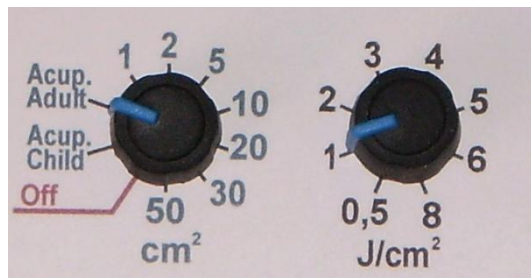
Now your Silberbauer Compact - Laser *mini* is ready to use!

4 Use of the Compact – Lasers *CL plus*

4.1 Commissioning

The left **Rotary Switch 1 (6)** is for switching the device on and off and to select the function or the area.

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 position „Acup. Child“ the laser power will be set to ¼ of the nominal output power and the penetration time to 5 sec., in position „Acup. Adult“ to ½ of output power and to 15 sec.

The other positions of this Rotary Switch are for setting the area which should be penetrated if the laser is used to penetrate larger areas.

The right **Rotary Switch 2 (7)** is used to adjust the Dose in Joule/cm².

After switching in the laser cannot be started promptly, but only after a security delay of 2 sec. During this time there sounds a warning signal and the **lamp (3)** blinks in orange colour. The **green lamp (5)** flashes slowly and shows that the device is switched on and the battery is charged enough. If this lamp flashes fast the charge will soon come to an end.

Now the laser can be started by shortly pressing the **Push Button (4)**. The laser can be stopped suddenly by pressing this Push Button again during penetration.

- Place the laser perpendicular to the area to be irradiated (see chapters 4.2 and 4.3).

The built-in timer will start immediately after pressing the start button. The **Lamp (3)** will lit yellow and shows that the laser power has the desired value. A short warning tone resounds. The Timer will automatically switch off the laser after the necessary therapy time, the yellow lamp extinguishes and again a short tone is audible.

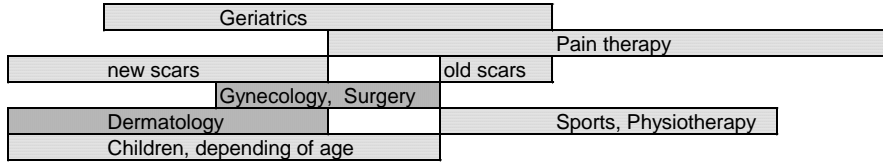
Shorter Treatment Times than choosed: press Push-Button during treatment and the laser will stop immediately.

- **At the end of every session** the **Rotary Switch 1** must be turned again into "Off" position.

For your information only – it calculates automatically:

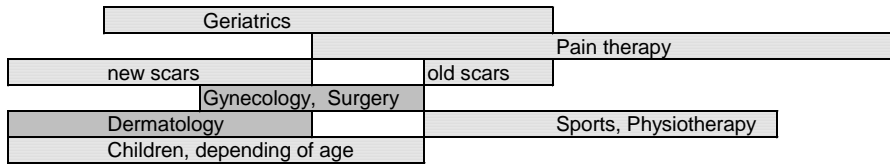
Therapy time depending of the position of the switches (in minutes : seconds):
 (for blank cells, time is over 1 hour)

60 mW- Model:



Dose (J/cm ²): ►	0,5	1	2	3	4	5	6	8	
									Power:
Acup. Child	5s	5s	5s	5s	5s	5s	5s	5s	25%
Acup. Adult	15s	15s	15s	15s	15s	15s	15s	15s	50%
1 cm ²	8s	17s	33s	50s	1m:7s	1m:23s	1m:40s	2m:13s	100%
2 cm ²	17s	33s	1m:7s	1m:40s	2m:13s	2m:47s	3m:20s	4m:27s	100%
5 cm ²	42s	1m:23s	2m:47s	4m:10s	5m:33s	6:57s	8m:20s	11m:7s	100%
10 cm ²	1m:23s	2m:47s	5m:33s	8m:20s	11m:7s	13m:53s	16m:40s	22m:13s	100%
20 cm ²	2m:47s	5m:33s	11m:7s	16m:40s	22m:13s	27m:47s	33m:20s	44m:27s	100%
30 cm ²	4m:10s	8m:20s	16m:40s	25min	33m:20s	41m:40s	50 min		100%
50 cm ²	6m:57s	13m:53s	27m:47s	41m:40s	55m:33s				100%

100 mW- Model:



Dose (J/cm ²): ►	0,5	1	2	3	4	5	6	8	
									Power:
Acup. Child	5s	5s	5s	5s	5s	5s	5s	5s	25%
Acup. Adult	15s	15s	15s	15s	15s	15s	15s	15s	50%
1 cm ²	5s	10s	20s	30s	40s	50s	1min	1m:20s	100%
2 cm ²	10s	20s	40s	1min	1m:20s	1m:40s	2min	2m40s	100%
5 cm ²	25s	50s	1m:40s	2m:30s	3m:20s	4m:10s	5min	6m:40s	100%
10 cm ²	50s	1m:40s	3m:20s	5min	6m:40s	8m:20s	10min	13m:20s	100%
20 cm ²	1m:40s	3m:20s	6m:40s	10min	13m:20s	16m:40s	20min	26m:40s	100%
30 cm ²	2m:30s	5min	10min	15min	20min	25min	30min	40min	100%
50 cm ²	4m:10s	8m:20s	16m:40s	25min	33m:20s	41m:40s	50min		100%

For long treatments you can fix the laser into a tripod.

Kind of operation of the indicator lamps:



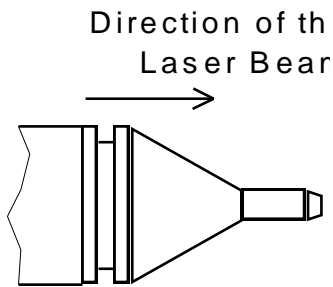
Back lamp	green	dark	If the laser is turned off or if the battery is wholly empty
	green	blinks slowly	If the device is turned on and the battery is ok
	green	blinks fast	If the battery is charged poor
Front lamp	orange	blinks	During the safety delay of 2 seconds
	yellow	glows	Laser is working and power is ok
	red	blinks	Power too low
	red	glows	Power was too high (Laser switches off in this case) or temperature is still too high (Laser cannot be switched on)

Buzzer:

sounds

- At startup of the laser,
- At stopping (at the end of the penetration time);
- If the output power is too high and the laser has switched off because of security.

4.2 Laser-point and distance of irradiation



The point of the Silberbauer - CL-plus Laser is made of stainless steel. It is created in the shape of a small tube that follows the cone. So it is easy to watch the point where the laser beam comes to the skin. Normally, nearly inaccessible points, like behind the ear are easily radiated with no problems.

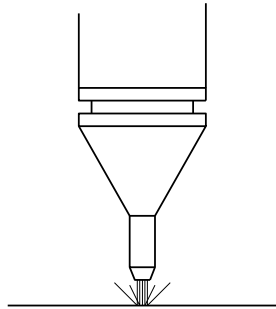
At the point there is a short light conductor. This light conductor serves among other things as mechanical protection for the heart of your therapy equipment, the laser diode. The impact point or the areas of operation are specified by this laser point. With all models the light emerges, whereby the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

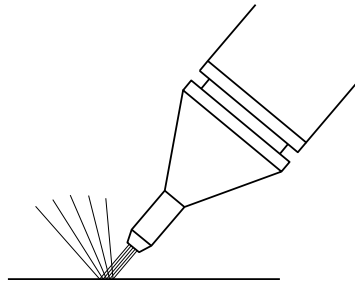
Apart from this the laser-point is conductive and is connected with the socket at the rear end of the laser battery. The point-searcher PS3 can be connected to this socket with a connecting cable. Herewith the laser-point can be used at the same time as searching point-peak for acupuncture points.

4.3 Irradiation Angle

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



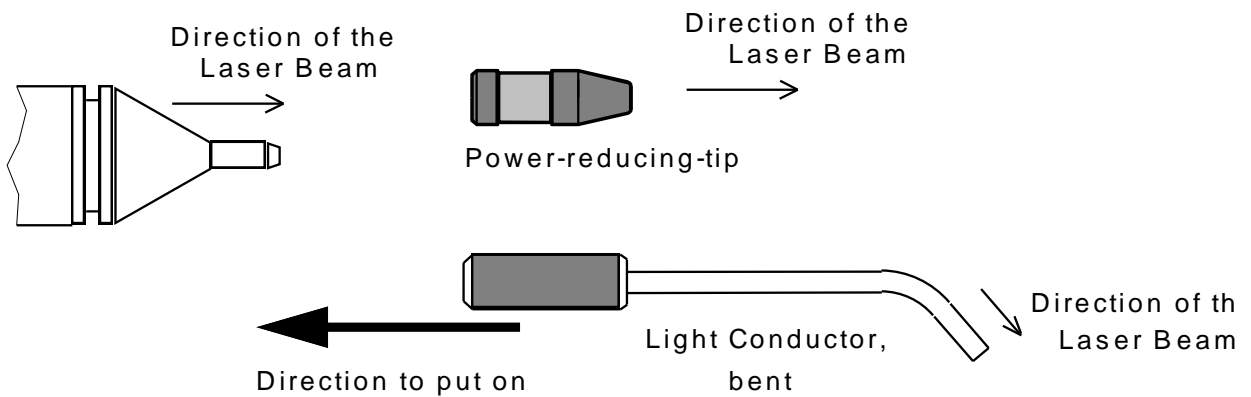
Low reflection,
Optimal penetration depth
= **optimal success**



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

4.4 Use of the assessor

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 *plus*:

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.

Turn **Rotary Switch 1** in position „Acup. Child“ or „Acup. Adult“. Set the laser point close to the acupuncture point which you want to seek, slightly diagonally onto the skins 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 *plus* is optimised for this kind of application required in every model.

4.5.3 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.

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

A large number of scientific papers, books, announcements of exhibitions and congresses about Soft Lasers you will find at www.laser.nu .

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

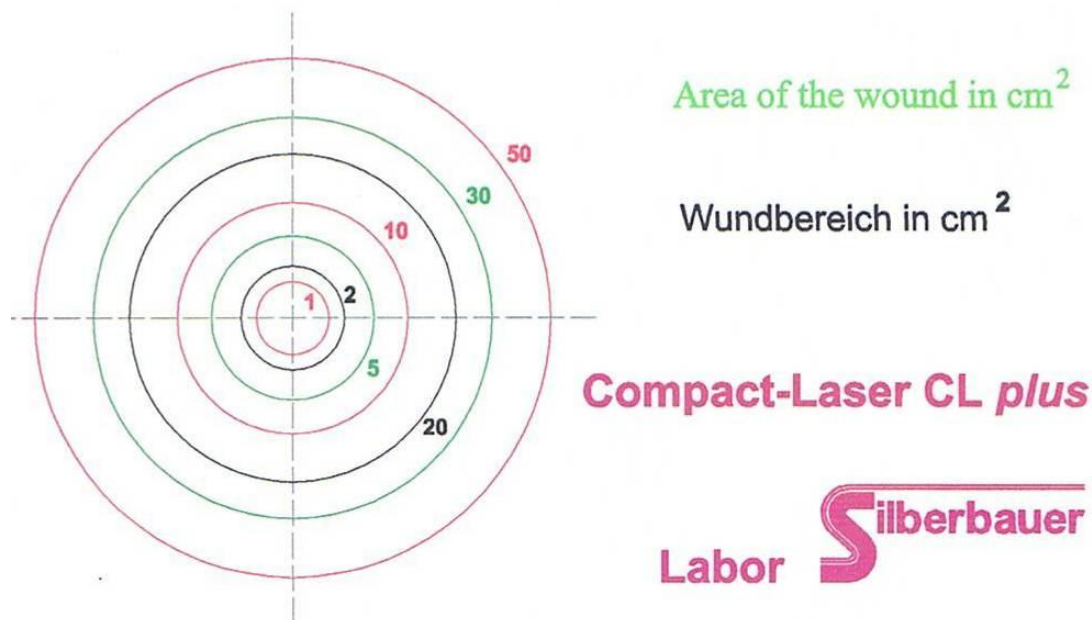
Irradiation-doses: in Joule / cm²

4.6.3 Calculation of the correct dose

Checking the area of a wound with the card:

Place the card close to the wound. Seek a circle which has approximately the same area like the wound.

Close to this circle you will find a number which shows the size of this area in cm². Set the size switch at the laser in this position.



4.7 Checking the output power of the laser

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

A yellow lamp which glows only if the laser works between 90% und 110% of ist nominal output power, and a red one which will blink 2x per second if the power is too low, and which will glow permanently together with a 5 second long warning

tone if the power is too high. In this case the laser will switched off automatically and can be switched in after the Rotary Switch 1 is turned into ist off- position.

4.8 Charge of the NiMH- Battery

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 green lamp (5) doesn't glow after switching in the laser:

- Battery is totally empty; turn out battery cap, put out battery and replace it by a charged one; close battery cap.

If the yellow lamp (3) doesn't glow after pressing the start button, then release button and check:

- are there several seconds since you switched in the device? (it will last 2 seconds delay time until the laser can be started)
- is the green lamp (5) blinking?

It is enough to charge the empty battery for several minutes to make a short treatment!

If the lamp (3) blinks red, so the laser power is too low for any reason. If this lamp glows permanently, either the laser power was too high or the case was too hot; the device has made a security switchoff. You have to turn the rotary switch 1 (6) into its off- position to reset the device. (Only after switching off respectively after cooling the device may be used again. **If the red lamp glows again please bring or send the device to our service station!**

If the laser doesn't work although the battery is charged, so please do not use the device and do not make any further attempts, but bring or send the laser and the battery to our service station for checking!

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

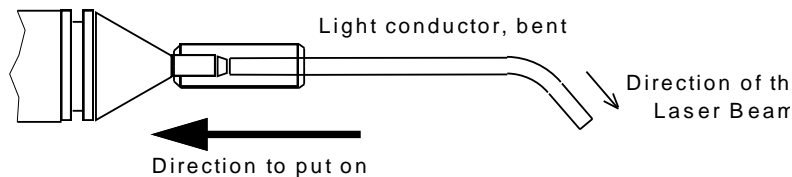
To avoid any danger of infection, the laser point must be disinfected before and after each treatment (and the power-reducing-tip and the bent light conductor).

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.



Cleaning of the Laser storage:

As this storage is made from acrylic it must be cleaned with lukewarm water with some dishwashing or soap added. Take the best with a soft cloth or with the water sucked sponge.

Regard! Do not use disinfectants, abrasive cleaners, glass cleaners or cleaners containing alcohol, because they attack the material! As a result, the formation of hairline cracks and breaks the clipboard!

There is no additional maintenance necessary by the user.

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

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.

The inspection will be made in Vienna by Labor Silberbauer. Please, send the Laser with all accessories and Instruments book!

If you want to get a spare device during the time of inspection, please contact us.



9.1 Scope of inspection:

1. Examination of controlling elements

Due to danger of mechanical abrasion, the laser-button (4) must be checked and also the rotary switches (6+7).

Scope of examination:

a) Control of strokes of rotary switch: The switch must be turned to its intended positions. The blue lines at the top of the knobs must correspond to the labeling.

b) Procedure for monitoring function of the rotary switches (6+7) and laser-button (4):

Turn the rotary switch (6) into its off position.

Insert battery.

Press the laser-button.

No laser radiation has to emerge out of the instrument.

Turn rotary switch (6) in position "Acup. Child" and immediately press the laser-button (4) (within less than 2 seconds)

No laser radiation has to emerge out of the instrument.

Suddenly after you have turned the rotary switch into its position the front lamp (3) must flash for 2 seconds in orange colour.

Press button again after more than 2 seconds.

The laser must work for 5 s (check this time), at the beginning and at the end of the time the warning signal must be audible.

2. 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 held perpendicular to the laser beam.

The output power should be: in position „Acup. Child“ 25% of the nominal output power, in Position „Acup. Adult“ 50% and in all other positions 100% of the nominal output power.

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.

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.

9.2 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.

10 Laser dispatch

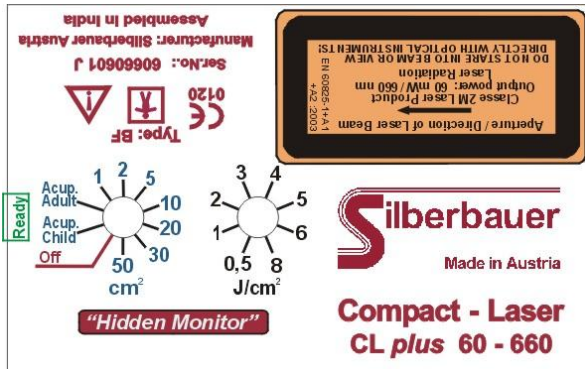
The laser is delivered in its original packing, devoid of any defects by post as bulk goods. Pull the battery out of the laser during transport!

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 plus* 100 - 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:

Laser device, Series Compact - Laser *CL plus xx - xxx* :

Manufacturer and distributor: Prof. Dipl.Ing. Gerhard Silberbauer
 Medizinische und physikalische Elektronik
 Hießgasse 15, 1030 Wien, Österreich

CE 0120

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 AA = LR 6

Classification: -protection level against electr. shock: Internal el. 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 or laughing-gas!

-Kind of operation: Permanent operation

-due to EC – directive 93 / 42 / EWG: II A

- Laser class: 2 M

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

Therapy time: depending of position of rotary switches and model
 automatically, +/-2%

Battery current: max. 1 A

Weight: **without / with battery:** 145 g / 173 g

Dimensions: 20 x 220 mm (D x L)

Model:	<i>CL plus 60-658</i>	<i>CL plus 100-658</i>	
Nominal laser power +/-10% (mW):	60	100	
Wavelength (nm):	658	658	
Beam diameter at output (mm):	3,2	3,2	
Admitted case temperature (operation):	10 bis 45 °C	10 bis 45 °C	
Laser class:	2M	2M	
Operating time with Alkali-Mangan-Batt. (hours):	3,5	2,5	
Operating time with 2050 mAh- NiMH-Batt. (hours):	5,5	4,5	

Interval for periodical inspection: 2 years

Rights for technical changes reserved! CL_plus_BED2_e.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 plus 60 - 658; CL plus 100 - 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 60825-1:2007
EN 60601-1-2:2007

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 9001:2008 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


Dipl. Ing. Gerhard Silberbauer
Med. u. physikal. Elektronik
A-1030 Wien, Hiessgasse 15

Vienna, July 8th, 2011

Dipl. Ing. Gerhard Silberbauer

Calibration - Certificate

Device: Compact - Laser
Model: *CL plus*
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