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Cl\_bed18e\_India September 24, 2007

### **Admitted assessory:**

**Point detector PS3 + Connecting cable** 

Lightning cable bent (Dental top)

Power reducing tip

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** 

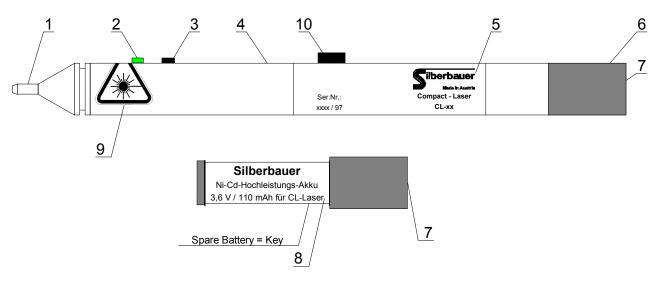
NiCd - high capacity battery 3.6V / 120mAh f. CL-Laser

Quick charging station for Silberbauer Laser

Special Medical Mains- Adapter for CL- Laser

# 1. Compact - Laser system CL: Views

### 1.1. Laser, Version with Quick-charging-station and 2 Accus:



1	Laser point	7	Socket for point detector
2	Light-diode yellow	8	Type plate of battery
3	Push-button	9	Laser-warning plate
4	Body	10	Standby-ready-switch
5	Type plate and details CL – Laser		
6	Mains adapter or battery		

The Silberbauer - Compact - Laser of series CL consists of the basic instrument as represented above with the following accessories:

2 batteries,

1 quick-charging-station,

1 laser casket.

As optional accessories are proffered optic fibre and power-reducing-tips, see chapter 1.3.

1.2.	Charging sta	ation			
1.3.	Special acce	essory			
Optio	Fibre, bent:				
					_
Powe	r loss with optic	fibre: 25 % a	almost!		
Powe	r-reducing-tip	:			
				(Enlarged illustration)	
				(Enlarged illustration)	
Transm	ission 50%: e.ş	g.: for CL50	- Output Power app	prox 25 mW	

# Mains Adaptor for PL- and CL- Laser:

Insert adaptor instead of battery.



# 2. <u>Safety precautions to be observed during the use of therapy-laser</u>

The appropriate legal security precautions are to be observed!

•Attention! The use of the operating facilities or installation contingencies in any methods other than mentioned in these user instructions can lead to dangerous irradiation!



• All therapy-lasers must be used and stored within the following temperature-range:

Case Temperature: CL 24-635: 10 to 35 °C!

all other models operating 10 to 40 °C, Storage 5 to 50 °C!

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 %<sub>rel</sub>,

The humidity should not condense on the case/body (no dew-drops)!

- Direct irradiation of the opened eye should be avoided at any cost!
- With a power of over 10 mW even the closed eye should not be irradiated!
- The model CL 80 808 is a class 3B laser; here the battery and the mains adapter are a safety key, however they may not be stored together with the laser for safety reasons, otherwise an unauthorized start-up of the laser cannot be shut off!
- 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	
22 mW	65,4 mm	78,3 mm	0,93 mm	
24 mW	68,4 mm	82 mm	1,14 mm	
36 mW 84,7 mm		101,2 mm	2,23 mm	
50 mW 100,5 mm		120 mm	3,3 mm	
80 mW IR	128,1 mm	152,7 mm	3,2 mm	
90 mW	136 mm	162,2 mm	5,7 mm	

- Eyes should remain closed at all times during irradiation to the face.
- Laser therapy should be conducted by trained personnel only!
- 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 disposition 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:

The danger sign of the laser must be displayed at the entrance of the treatment room. Therapy duration for babies being treated at the cranial region should be short!

### 2.1. Alignement Laser Spectacles (Therapist's Spectacles):

At the use of lasers of the laser-protection-class 2M the therapist should wear the laser adjust spectacles as in accordance with the current edition of international standard EN208, for class 3B lasers he MUST wear these glasses!

Specifications of laser-protection-spectacles corresponding to EN208:

- a) Wave-length, at which the goggles give protection: due to CL-type:
  - 635 nm or 660 nm or 808 nm
- b) Protection Level: For laser over 10 mW to 100 mW output power R2
- c) Laser Control Mode: D (continuous operation)
- The Silberbauer laser alignement spectacles offer only protection against accidental irradiation through laser up to these levels!
- They are NOT ALLOWED to be used for the deliberated 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 if a class 2M laser is used; for 3B lasers he MUST wear these glasses. As per the international standard EN 207 in its current edition.

Specification of laser protection spectacles correspond to EN 207:

- a) Wave-length, at which the spectacles provide protection: due to CL-type:
  - 635nm or 660nm or 808 nm
- b) Protection Level: L3
- c) Laser Control Mode: D (continuous operation)
- The Siberbauer 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. Contra-indications and secondary-effects

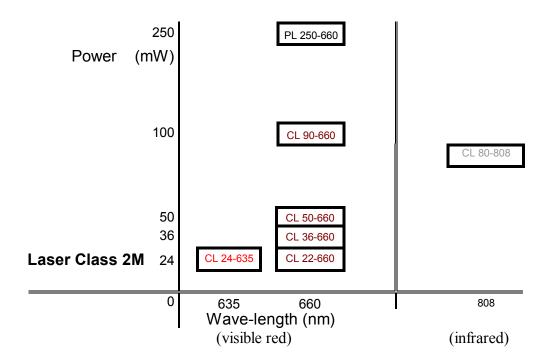
- Direct irradiation of the opened eye must be completely avoided!
- In the region of open fontanel's or open skullcaps treatment with rays is not permitted.
- Very long therapy-durations will not result in better outcomes but will not lead to any dangerous side effects either. Exceptions would be irradiations in the cranial region (more minutes), which can lead to headaches.

### 3. Types of CL-lasers

Presently we distinguish with 3 different wave-lengths of laser radiation at therapy-lasers:

- **635 nm**, consequently red laser-light, which corresponds quite exactly to the wave-length of the He-Ne-laser (632,8 nm). This wave-length is used in medicine, e.g. acceleration of wound-healing, for more than 30 years successfully. Not available in India!
- **660 nm,** consequently dark-red laser-light. With equal effectivity for acupuncture, but a little lesser than 635 nm for other applications with the same power. But with that wavelength higher power is available at a low price too.
- **808 nm**, that is unvisible Infrared light. Goes better into the depth of tissue, but poorer biological effects; used for large joints, Orthopedics, large animals.

Accordingly you have as well to regard for the qualities of the described wave-lengths for the different applications and at the therapy-times.



The **S**ilberbauer - lasers are lasers of the classe 2M.

# 4. Starting

• After each therapy execution the standby-ready-switch should be turned into the "Standby" mode again and the mains-adapter or the battery must be taken out to be kept safely away from unauthorised hands!

### The first starting, Version with Quick-charging-station and 2 Accus:

The Siberbauer Compact - Laser is delivered together with a Siberbauer loading unit which has to be connected to a socket with the power-plug and it should stay connected permanently.

### **Charging** (for this see chapter 5.2.):

First insert the high-power battery with the charging-socket at into the loading unit. The monitoring circuit in the loading unit determines the battery plugged in and initiates charging accordingly: initially the battery is recharged, and then the unit switches over to a trickle charge mode, thereby leaving a completely charged high-power battery at your disposal.

For usage take the battery out of the loading unit and insert it into your laser. Do not press the laser button during this. As soon as the battery is inserted completely, the laser is ready for use after 3 seconds delay.

### Point Search (see chapter 5.7.!):

For a point search with the laser tip affix the connecting cable at the end of the battery and place the other end of the cable into the plug of the Siberbauer point-searcher PS 3 instead of the tip. Place the point-searcher in the hand of the patient and detect the acupuncture points with the CL-tip in the same way as with the PS3.

Attention: If you use the mains adapter or the power reducing tip or the lightning cable bent you cannot use the laser tip for point detection!

### 5. Application of Compact - Lasers

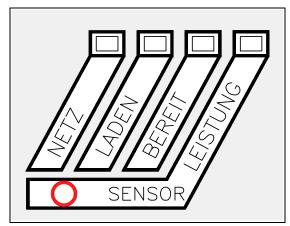
### 5.1. Mains Adapter or battery

The high-power interchangeable batteries utilise special cells with the latest technology. These have next to no memory-effect, even when they are not completely discharged. They also have the capacity to charge quickly. Depending upon the laser model the attainable therapy period for each battery charge is different, see chapter 8 for additional technical data!

# 5.2. Charge of Silberbauer high-power alternating batteries

Charging is only possible with the given loading unit. This is to be connected to mains and should stay connected permanently, thereby allowing the battery to be monitored and can be recharged in its state of disposition.

The battery must be charged from the loading unit. Therefore insert the battery with its charging socket first into the loading unit.



The loading unit will detect the insertion of the battery will begin with an advanced loading process. LED "CHARGE" shines besides the LED "NET", that always glows so long as the system voltage exists

After a while it goes out only to be followed by "READY", signifying that the process has now changed to the disposition charging mode.

However, the battery can be removed and put into use at **anytime!** 

Normally the battery remains in the loading unit, for e.g. over the weekend, since the recharging is controlled automatically and is optimized. Therefore overloading the battery is effectively prevented. The system voltage can however be switched of overnight or over the weekend as well. When switched on again an automatic recharge takes place.

When to be put into function remove the battery out of the loading unit and insert it into the laser.

If you have more CL-batteries, they can be alternatingly charged in the loading unit thereby enabling the capacity of a completely charged battery.

# Service of laser Remove the battery from the loading unit and insert it with the charging socket into the laser first

- Remove the battery from the loading unit and insert it with the charging socket into the laser first till it reaches its limit, or insert the adapter part of the mains adapter. (Attention! **Do not press** the laser button (3) while inserting!)
- In case the need arises place the bent light conductor or the power-reducing-tip onto the laser-point until a limit is reached. (See picture).

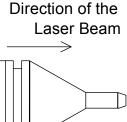
- Turn the rotary switch (10) from standby to one of two ready-positions. You can choose between times for irradiation of 15 seconds or 60 seconds. This would require about 3 seconds before the laser can be initiated with the press of a button (3).
- Place the laser perpendicular to the area to be irradiated (see chapter 6 "Possibilities for use of Compact-Laser"),
- Press the button (3) on the laser and keep it pressed.
- At the end of every therapy session the standby-ready-switch (10) must be switched back to the "Standby" mode. The mains adapter or the battery must be removed from the laser and kept in a safe place, where unauthorised personnel are prohibited to enter.

The integrated timer sends a short buzzer signal once pressed, the controlling LED glows yellow and indicates that the output power of the laser is all right. The timer stops the laser automatically after the chosen time for therapy, by which the LED goes out and a permanent buzzer signal arises until the button (3) is released.

**Shorter times of irradiation** as the shortest adjustable time of 15 seconds: Release the push-button simply and the laser stops immediately.

**Longer times of irradiation** as the longest adjustable time of 60 seconds: After arising of the permanent buzzer signal at the end of the therapy time, release the laser button (3) and start the therapy after 1 second by pressing it again.

### 5.4. Laser-point and distance of irradiation



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

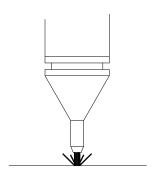
A short light conductor is fit into the tip. This light conductor serves among other things as mechanical protection for the heart of your therapy equipment, the laser diode. The impact point or the areas of operation are specified by this laser point. With all models the light emerges, whereby the size 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 Siberbauer 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 required to be irradiated (e.g. area of abdomen).

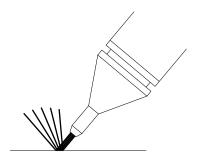
Apart from this the laser-point is conductive and is connected with the socket at the rear end of the laser battery. The point-searcher PS3 can be connected to this socket with a connecting cable. Herewith the laser-point can be used at the same time as searching point-peak for acupuncture points, see chapter 4.

### 5.5. 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

### 5.6. Irradiation period and Absorption Doses

The times for irradiations and absorption-doses indicated in the content can either be reduced distinctly by choice to the correct wave-length of laser (635 nm) or by combination with laser-acupuncture!

Literature: e.g. Baxter: Therapeutic Lasers – Theory and Practice

Bahn/Küblböck:Laserstrahlen in der AkupunkturDanhof:Laser in der Zahnheilkunde,Iliev:Laser in der Dermatologie

Pöntinen/Pothmann: Laser in der Akupunktur,

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

### 5.6.1 Formulae:

Energy = laser power x irradiation period

Irradiation dose = Energy / unit area

### **5.6.2** Measuring units:

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

**Power:** in milli-watt (mW) 1 mW = 0.001 W

Time: in seconds (s)

Unit area: in cm<sup>2</sup>

Irradiation-doses: in J / cm<sup>2</sup>

### 5.6.3 Calculation of the correct dosage for treatment of areas

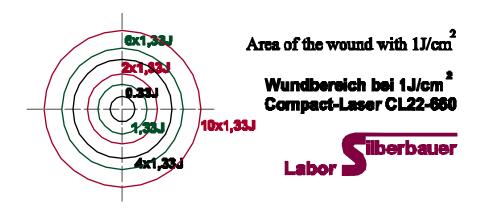
with the card:

Place the card close to the wound and check which circle has the same area like the wound (e.g. 4x1,33J).

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. 1,33J).

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 card for model CL 22 – 660

The card is made for a dose of 1 J/cm<sup>2</sup>. For higher or lower doses the showed number of how often you have to press the button has to be multiplicated or divided proportionate.

In the literature we find recommended values between 0,54 and 3 J/cm<sup>2</sup>.

Precalibrated dosage in Joule for different Siberbauer models:

Model:	at 15 Sec:	at 1 Min:				
CL 22 - 660	0,33 J	1,32 J				
CL 24 - 635	0,36 J	1,44 J				
CL 36 - 660	0,54 J	2,16 J				
CL 50 - 660	0,75 J	3,0 J				
CL 80 - 808	1,2 J	4,8 J				
CL 90 - 660	1,35 J	5,4 J				
Comparison: the <i>Profi</i> — Laser has						
PL 250 - 660	3,75 J	15 J				

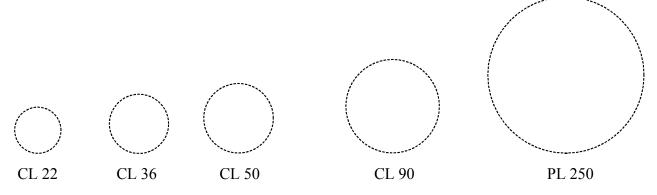
Comparison of different output power:

for penetration of this small wound (1cm²) wirh 1 J/cm² (common dose) you need the following time:

Model:	Sec:
CL 22 - 660	45,4
CL 24 - 635	41,7
CL 36 - 660	27,8
CL 50 - 660	20
CL 80 - 808	12,5
CL 90 - 660	11,1
PL 250 - 660	4

Or:

per minute you can penetrate the following area:



### 5.7. Acupuncture point search with the Compact-Laser

### 5.7.1. Assembly preparation

Apart from the Silberbauer Compact - Laser a Silberbauer point searcher PS3 and a connecting cable is also required.

Place a high-power battery into the Silberbauer Compact – Laser, put the black connecting cable plug into its rear socket. 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 searcher Siberbauer PS3 must now be handed over into the hand of the patient. The laser-tip can serve now as the point search.

### 5.7.2. Acupuncture point detection on the body

The **S**iberbauer point-searcher PS3 indicates the electric conductivity of the skin both optically (with more or less quick light-frequency in 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; you then search the area, where you suppose the acupuncture point, without lifting the tip from the skin. The pressure of the tip should be light and of consistent pressure while searching.

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

The push-button must be pressed on the laser above the acupuncture point thus beginning the irradiation. The time of therapy programmed in the Siberbauer Compact-Laser is optimised for this kind of application required in every model. See chapter 6.1.3. Acupuncture!

### 5.7.3. Acupressure point detection of the ear and cranium

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

### **5.8.** Laser Power Monitoring

The Siberbauer Compact - Laser has 2 mechanisms each independent from another control for laser radiation

- 1. The yellow lighting LED on the laser glows when the laser works with almost 90 % of its rated power at least, and
- 2. One sensor in the loading unit that switches on the LED "Sensor Power" during laser-radiation.

### 5.9. 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.

In case 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 standby-ready-switch was switched on? (It takes about 3 seconds till the laser is turned on again)
- Could the battery be empty?
- Has the loading unit been turned on?
- When was the battery been put onto the loading unit last?

It is enough to recharge the empty battery for a few minutes and irradiation can begin for a short time! However the batteries should normally be fully charged, otherwise they could be strained.

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!

### 5.10. 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, its loading unit and plug can be cleaned carefully with a cloth moistened with alcohol or surgical disinfection. During this process the loading unit must be disconnected from the network! 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 anyhow.

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.

### 5.10. Waste management of laser and accessory

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

The high-power-batteries are NiCd-batteries! They have to be brought to the next receiving office for special waste disposal.



### 5.12. Laser Inspection



The CL-Laser must be inspected periodically every year.

### **5.12.1.** Scope of inspection:

### 1. Examination of Output Power:

### **Measuring Equipment required:**

Specification:

Measuring device for the laser output with a Si-photo-diode is well suited for the measurement of every monitoring phase of the laser output and the wave-length of the CL-Laser.

Measuring accuracy:	+/- 3%	ŗ	

**Measuring Process:** The output power is measured when that the laser is turned on and the sensor is at an angle of 45 ° and the button depicted above (see picture), on the laser must be turned on.

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 or wave description, the laser-button (3) must be checked as the standby-ready-switch (10).

Scope of examination:

- a) Control of strokes of standby-ready-switch: The switch must be turned to its 3 intended positions. In case the switch could be turned further with acceptable torque, you have the indication of a defect and the instrument has to be repaired.
  - b) Procedure for monitoring function of the standby-ready-switch (10) and laser-button (3): Turn the standby-ready-switch into its standby position.

Attach the mains-adapter or the charged battery.

Press the laser-button.

No laser-radiation has to emerge out of the instrument.

Turn the standby-ready-switch to 15 s.

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. Examination of the labels

All labels have to be readable without any problems.

### 4. Examination of all assessories

Examination of the assessory in breaking, signs of wear, examination of glasses also in scratches which disturb the sight.

### **5.12.2.** Inspection Certificate

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

### 5.13. 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!

**Attention, also for transport!** The battery is also "key", which must not be stored with the laser for precautionary reasons, as an unauthorised use of the laser cannot be stopped!

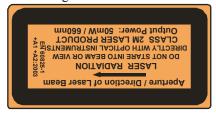
Storage temperature must not exceed 35  $^{\circ}$  C (model CL24-635) and 50  $^{\circ}$  C (all other models)!

### 6. Warning advices and Labels:

There are different quality indications on the loading plug, the inscription of which is advised by the quality board.

The following warning labels are valid for lasers of types mentioned below:

e.g. for the model CL50:



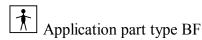
The other laser models have the same labels with according values for power and wavelength.

Attention! Laser radiation!





Don't dispose with the normal rubbish!



Year of production: 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 the given valid regulations the "Instructions to avoid explosive dangers in operational equipment" of BM for social administration Zl. 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.

### 8. Technical data:

### Laser-instrument, series Compact - Laser CL xx - xxx:

Manufacturer and distributor: Prof. Dipl.Ing. Gerhard Silberbauer

**C** € <sub>0120</sub>

Medizinische und physikalische Elektronik Hießgasse 15, A- 1030 Wien, Austria, EU

Assembled at Silberbauer India

Application as directed: Laser radiation of skin, mucous membrande and dental applications **Quality Mark:** VA f.Radiotechnik am TGM, Wien, Protokoll Nr. 713 / 4 / 95,

Examination of type at testing institute for medical technique, P.Z.Nr. 97274 / 172

Accessory: See directions for use, page 2

**Internal power source:** Accu able to be put on, with 3 pieces NiCd-cells SAFT VRE 1/3AA L3P or

mains adapter Friwo Type FW7333M/05

Classification -Protection against electrical shock: Internal electrical power source

> -Protection level against electr. shock: Part of application type BF

- Protection level against harmful water invasion: Common instrument

- Protection level during application together with explosive mixtures of anaethesias with air or with oxygen or laughing-gas:

Instrument is not to be used in an explosive atmosphere or with explosive mixtures from

naesthesias with oxygen to laughing-gas

-Kind of operation: Permanent operation

-due to EU - direction 93 / 42 / EWG:

Laser Classe: 2M (CL80-808: 3B)

Divergence of ray: 0.8 rad +/- 10%

Therapy Period: 15s or 60s (adjustable by user)+/-10%

**Input of current from battery:** max. 0,15 A without accu: Weight: 74 g, **accu:** 36 g

20,2 x 233 mm (D x L) Measures: with accu:

Model:	CL 22-660	CL 24-635	CL 36-660	CL 50-660	CL 90-660	CL 80-808
Nominal power +/-10% (mW):	22	24	36	50	90	80
Wave-length (nm):	660	635	660	660	660	660
Diameter of ray-output (mm)	3,0	3,0	3,0	3,0	3,0	3,0
Admitted temperature of case:	10 bis 40 °C	10 bis 35 °C	10 bis 40 °C			
Time of therapy per chargement (min.):	110	60	90	60	35	45

### Charging plug:

 $\epsilon$ Manufacturer: Ansmann

Assamstadt, Germany, EU

Type: AP 312

**System voltage:** 230 V, 50 to 60 Hz 12 V, 300 mA **Output:** 

Weight / Measures: 238 g / 75 x 43 x 52 mm (L x W x H)

### Loading unit:

Medizinische und physikalische Elektronik Hießgasse 15, 1030 Vienna, Austria, EU

Assembled in India at Silberbauer India Pvt. Ltd., Pune (MS)

Released Voltage:max. 12 VReleased Current:max. 460 mALaser-monitor: glows at2 mW almost

**Weight / Measures:** 615 g / 85 x 150 x 47 mm (W x D x H)

Charging period for discharged battery: 24 Minutes

### Mains adapter for PL- and CL- Laser:

Manufacturer: FRIWO Gerätebau GmbH,

Von-Liebig-Str. 11, 48346 Ostbevern, Germany, EU

**Mains voltage:** 100 - 240 V, 50 bis 60 Hz, 200 mA

Output voltage: 5 V (at the plug: 4,3V)
Output current: max. 1300 mA
Standards: meets class II SELV

for application parts type BF according to IEC 660601-1, UL 2601, VDE,  $\ \ \boldsymbol{\xi}$ 

Weight / Measures: 120 g incl. adapter u. cable / 29 x 74 x 79,3 mm (L x W x H)

Operating temp:  $0 \, ^{\circ}\text{C}$  to  $+40 \, ^{\circ}\text{C}$ Storage temp:  $-40 \, ^{\circ}\text{C}$  to  $+70 \, ^{\circ}\text{C}$ 

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Cl\_bed18e\_India

# EC – Declaration of Conformity

The company

### Dipl. Ing. Gerhard Silberbauer Medicinal and Physical Electronics

Hiessgasse 15, 1030 Vienna, Austria, EU,

explains his sole responsibility in development, production and sales of the medical products:

Compact - Laser

Models: CL22 - 660; CL24 - 635; CL36 - 660; CL50 - 660; CL80 - 808 x); CL90 - 660;

Medical Products - Class: II a for laser-radiation of skin, mucosa and dental application

Laser Class 2M (x): Class 3B)

according to EU- medical products direction 93 / 42 / EWG of the council of European Communities from June  $14^{th}$ , 1993, annex II. The products fullfill all the requirements of the regulations in 93 / 42 / EWG annex I.

These instruments correspond to 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. (Certified Body No. 0120), office for the certification of medical products, according to regulation 93 / 42 / EWG annex II, in agreement with the ISO 9001 and ISO 13485.

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

C€0120

Vienna, Sept 24th, 2007

Dipl.Ing. Gerhard Silberbauer

# **Certificate of Calibration**

Instrument: Model:	Compact - Laser
Serial number/Year of manufacture:	CL/
It is hereby confirmed that the instrumexamined and calibrated at its time of	· · · · · · · · · · · · · · · · · · ·
Measured output-capacity:, _ m\	V
The date of revisory examination of the planned at intervals of 1 year.	ne output power of the laser is
The test badge on the instrument serve	es as a recollection of this test.
Vienne en the	
Vienna, on the	
	Technical examiner