

Compact - Laser

CL plus

Instructions for use

Edition: CL plus xx – 638



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Scope of delivery:

- 2 ea. NiMH – Batteries „Green“
- Intelligent Charger for NiMH- Batteries
- Luxury Leather Case
- lockable Casket, Aluminum
- Instructions for use
- Applications of the Soft-Laser ¹⁾
- Laser goggles „Comfort“ (for the patient) ¹⁾
- Laser adjustment goggles “Comfort” (for the therapist) ¹⁾
- 2 ea. Laser goggles for blue laser ²⁾
- Measurement template for wounds
- Instruments book
- Laser sign board (Attention Laser Beam)

Permitted Accessories:

Tripod for Compact Laser CL plus

Irradiator for area

Adapter for Light tube

Light tube, bent (Dental top)

Power reducing tip

Permitted Protection Goggles:

See also page 2 – 3!

Soft-Caps Laser goggles (glasses for the patient) ¹⁾

Comfort Laser goggles (glasses for the patient) ¹⁾

Comfort Laser adjust glasses (glasses for the therapist) ¹⁾

Comfort Laser goggles for children ¹⁾

Laser goggles for blue laser (same glasses for the patient and therapist)²⁾

Permitted Device in connection with the CL plus Laser:

Point Detector PS3, with Connection Cable

¹⁾ for red laser only (638 + 658 nm)! ²⁾ for blue laser only (405 nm)!

1 Description of the Compact Laser CL plus

The CL plus is a Soft – Laser. It can be hold by hand or fixed into a tripod. It is powered by an usual NiMH- battery (size AA).

The laser beam is visible and divergent. So the device complies with laser Class 2M.

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

The necessary treatment time is calculated from a built-in microcontroller. Therefore 2 rotary switches have to be set: the area of the region to be treated and the dosage per cm². For Acupuncture at children or at adults there are 2 additional switch positions.

2 Intended Use

The Compact – Laser *plus* is a Soft Laser (Low Level Laser) for radiation of skin, mucous membrane and dental applications (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.

It may be used by medical personnel only. They must have basic knowledge of hygiene in the medical field.

It may be used on all patients of any age.

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 ¹⁾,
- Reduction of pain e.g. after traumata and post surgery and at chronic-degenerative diseases ¹⁾,
- Acupuncture instead of needles,
- Reduction of number of germs at the skin surface, e.g. region of wounds ²⁾

¹⁾ for red laser only (638 + 658 nm)! ²⁾ for blue laser only (405 nm)!

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

The appropriate legal security precautions are to be observed!

- Open wounds may NOT be touched with the laser or its accessory parts! Risk of infection!
- Upon insertion of the laser tip or of the accessory part "optical fiber bent" in body openings there is the risk of introducing contaminants into the body – danger of infection!
- When printing with the laser tip on non-intact skin or mucous membrane that could be pierced – danger of bodily injury and infection!
- Laser therapy should be conducted by trained personnel only!
- 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 40 °C (50 to 104 °F),
 - Storage temp. 0 bis 50 °C (40 to 122 °F)!
 - Caution is recommended during its transport by car in the summer!
 - Permissible humidity: 30 till 95 %_{rel},
 - The humidity should not condense on the case/body (no dew-drops)!
 - Air pressure: not critically
- No modification of this equipment is allowed!
- Portable and mobile HF communication systems may interfere with this instrument!
- The use of inflammable anaesthetic gases or oxidized gases like nitrogen (N₂O) and oxygen should be avoided. Some materials like cotton, that are saturated with oxygen, could be set on fire at these high temperatures, created at the because of the laser's direction. Before the laser is put into operation, there should be a specific period for evaporation of solvents in adhesives and inflammable solvents, which are used for cleaning and disinfection. Attention should be drawn to the fact that the body's gases too can set on fire.
- It is further recommended that: Therapy dose for babies being treated at the cranial region should be lower (0,5 J max.)!

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

- Avoid direct irradiation of the opened eye!
- Do not irradiate the closed eye!
- During radiation to the face use Soft Caps!

3.1 Alignment Laser Spectacles (Therapist's Spectacles): ¹⁾

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

Attention! Colour identification is disturbed by the glasses!

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

Appropriate Protection eyewear from the Silberbauer – Programme:

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

for all other red and IR models until 500 mW: Comfort-Schutzbrille for Patient and Therapist (dark blue),



for blue lasers: laser goggles for blue lasers ²⁾.



¹⁾ for red laser only (638 + 658 nm)! ²⁾ for blue laser only (405 nm)!

3.2 Laser Protection Spectacles (Patient's Spectacles): ¹⁾ ²⁾

During 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 – according to EN207 - NOT ALLOWED to be used for the deliberated view into the beam!
- They protect only then against casual irradiation, when the eye lid closure reflex is not suppressed or slowed down (medical treatment, illness ...); and thus repeated irradiations of the eye have to be reduced.

Attention! Colour identification is disturbed by the glasses!

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

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),

for blue lasers: laser goggles for blue lasers ²⁾.

Children:

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

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

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

for blue lasers: laser goggles for blue lasers ²⁾.

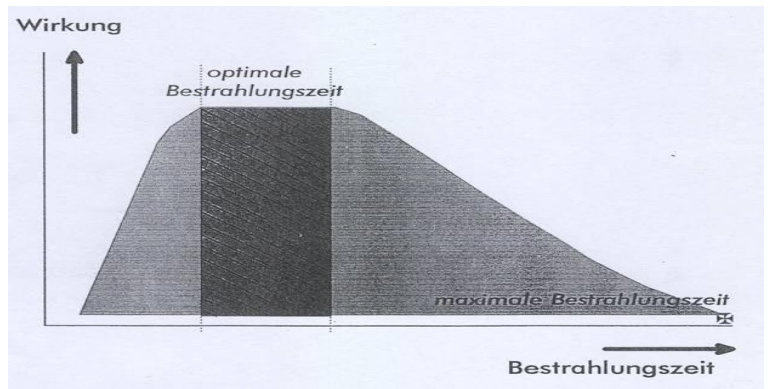


¹⁾ for red laser only (638 + 658 nm)! ²⁾ for blue laser only (405 nm)!

3.3 Contraindications

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

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



- It is further recommended that:
Therapy duration for babies being treated at the cranial region should be short (approx. 50%)!

3.4 Requirements for patients

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

3.5 Requirements for user

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

b) Knowledge:

Minimum:

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

no upper limit

c) Experience:

Minimum:

Medical personnel:

- no additional requirements

All other persons:

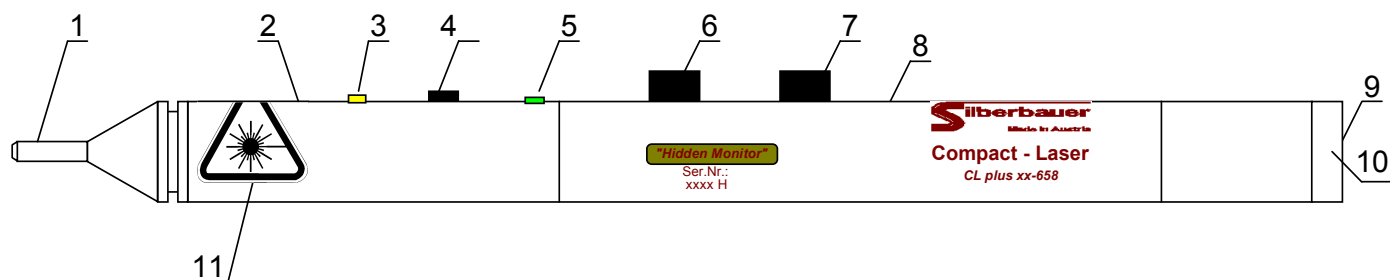
- Basic knowledge of the human body,
- the names of body parts, joints, organs,
- Names of diseases treated with laser,
- Basic knowledge of wound management

no upper limit

d) permissible impairments:

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

4 Compact - Laser *CL 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)		

4.1 Accessories

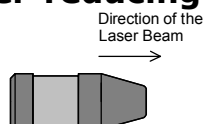
Adapter and Light tube, bent:



Power loss with light tube: approx. 24% ¹⁾ or approx. 28% ²⁾

Direction of the
Laser Beam

Power-reducing-tip 50%:



Irradiator for area:



Power loss: approx. 18% ¹⁾ or 14% ²⁾

Tripod for Compact Laser:



¹⁾ for red laser only (638 + 658 nm)! ²⁾ for blue laser only (405 nm)!

4.2 Initial use

4.2.1 Laser

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, 85% of the initial charge is available!



Turn **Rotary Switch 1 (6)** into „Off“ position. Open **Battery Cap (10)** at the end of the laser and insert battery with positive end pointing **OUT** of the tube. Insert battery. Close the cap by turning it clockwise until it stops. See above.

Now your Silberbauer Compact - Laser is ready to use!

4.2.2 Tripod

Before use of tripod:

- Lock the locking screw at the 3 bases
- Hike up the perpendicular rod
- Fix the locking screw
- Unfold the 3 feet until they stop
- Take tripod at its trivel by the hand, loose twist grip by turning counterclockwise and adjust desired height, then fix twist grip by turning clockwise
- Fold up movable rod as necessary
- Place tripod next to the patient horizontally
- Clamp laser into the clip at the end of the movable rod
- Hold the laser with one hand, lock the locking screw at the ball head approx. ½ turn, swivel the laser by turning the swivel and the ball head so that the laser shows into the desired position and height; fix the locking screw of the ball head



After treatment:

Take out the laser!

Then fold down the movable rod. If necessary, fold down the stand bases, unlock the locking screws at the bases and tie up and lock the screws again.

Warnings:

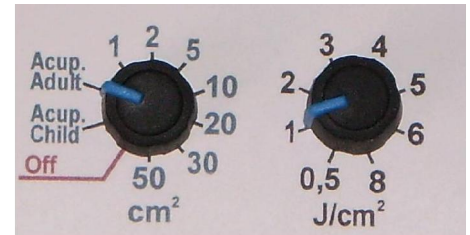
It is NOT allowed for the user to unlock the other screws at the tripod!

In case that the rubber brake at the upper end of the perpendicular rod will become loose so that the movable rod will be adjustable too loose or if it moves even itself, the tripod must be decommissioned immediately and our service department must be informed!

5 Use of the Compact – Lasers CL plus

5.1 Commissioning

The **left rotary knob** is used to switch the unit **on and off** and to select the function: acupuncture or surface irradiation.

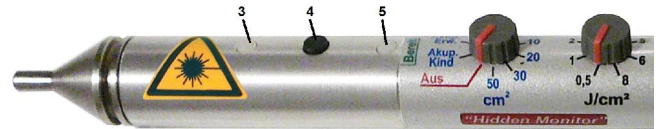


Acupuncture: in position "Acup. Child", the laser power is set to $\frac{1}{4}$ of the type power and the irradiation time is set to 5 seconds; in the "Acup. Adult" to $\frac{1}{2}$ of the power and to 15 seconds.

Area irradiation: the other switch positions are used to set the area to be irradiated.

The **right rotary knob** is used to set the desired dose in joules/cm² depending on the application, see medical literature.

After switching on, the laser cannot be started immediately, but only after a safety delay of 2 seconds, during which a warning signal sounds and the **front LED (3)** flashes orange. The **rear LED (5)** flashes green slowly and indicates that the device is switched on and the battery is sufficiently charged. If this LED flashes quickly, the charge will soon run out.



Now the laser can be started by briefly pressing the **key (4)**. If the key is pressed again during irradiation, the laser stops immediately.

* Aim the laser vertically at the surface to be irradiated (see chapters 5.2 and 5.3).

The built-in timer starts the laser immediately after pressing, the **LED (3)** lights up yellow and shows that the laser power has the desired value. A short warning tone sounds. The timer automatically switches the laser off again after the set therapy time, whereby the yellow light-emitting diode goes out and a short tone is heard again.

Shorter irradiation times than the set therapy time: Press the key briefly during irradiation and the laser switches off immediately.

* **At the end of each session**, the **left rotary switch** must be turned back to the "Off" position.

60-405 (blue):

Dose (J/cm ²): ►	0,5	1	2	3	4	5	6	8
1 cm ²	8s	17s	33s	50s	1m:7s	1m:23s	1m:40s	2m:13s
2 cm ²	17s	33s	1m:7s	1m:40s	2m:13s	2m:47s	3m:20s	4m:27s
3 cm ²	25s	50s	1m:40s	2m:30s	3m:20s	4m:10s	5min	6m:40s
5 cm ²	42s	1m:23s	2m:47s	4m:10s	5m:33s	6:57s	8m:20s	11m:7s
8 cm ²	1m:7s	2m:13s	4m:27s	6m:40s	8m:53s	11m:7s	13m:20s	17:47s
12 cm ²	1m:40s	3m:20s	6m:40s	10min	13m:20s	16m:40s	20min	26m:40s
20 cm ²	2m:47s	5m:33s	11m:7s	16m:40s	22m:13s	27m:47s	33m:20s	44m:27s
30 cm ²	4m:10s	8m:20s	16m:40s	25min	33m:20s	41m:40s	50 min	66m:40s
50 cm ²	6m:57s	13m:53s	27m:47s	41m:40s	55m:33s	1h:9m:27s	1h:23m:20s	1h:51m:7s

Caution! If you set very long treatment times, please put a fully charged battery into the lasers! Otherwise, the laser would stop prematurely and you would lose track of what dose has been administered!

For long treatments you can fix the laser into a Silberbauer Laser Tripod.

Operation of the indicator lamps:



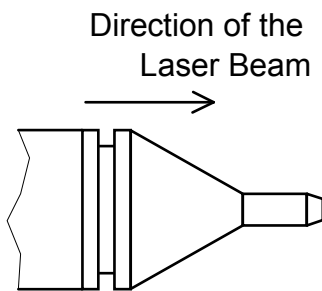
Back lamp	green	dark	If the laser is turned off or if the battery is wholly empty
	green	blinks slowly	If the device is turned on and the battery is ok
	green	blinks fast	If the battery is charged poor
Front lamp	orange	blinks	During the safety delay of 2 seconds
	yellow	glows	Laser is working and power 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)
	red and yellow alternating	blinking	shows that battery voltage became too low during treatment, so the laser switched off automatically! It cannot be started again, but must be switched off!

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;
- 8 times if the battery voltage becomes too low during treatment and the laser must stop untimely.

5.2 Laser-point and distance of irradiation



The point of the Silberbauer - CL-plus Laser is made of stainless steel. It is made 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.

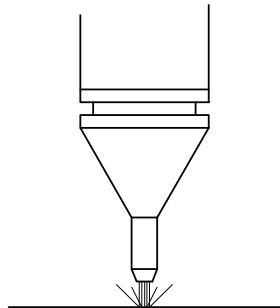
At the point there is a short light conductor. This light conductor serves among other things as mechanical protection for the heart of your therapy equipment, the laser diode. The impact point or the areas of operation are specified by this laser point. With all models the light emerges, whereby the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

The irradiation distance can be selected up to a few cm, but don't use too much distance because the energy density will be small! Therefore the laser is allowed to be set on the intact skin's surface. The skin can also be pressed in with smooth pressure by the laser-point, to reduce the distance between deeper-set areas needing to be irradiated (e.g. area of abdomen).

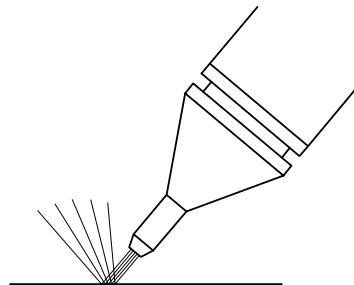
Apart from this the laser-point is conductive and is connected with the socket at the rear end of the laser battery. The point-searcher PS3 can be connected to this socket with a connecting cable. Herewith the laser-point can be used at the same time as searching point-peak for acupuncture points.

5.3 Irradiation Angle

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



Low reflection,
Optimal penetration depth
= optimal success

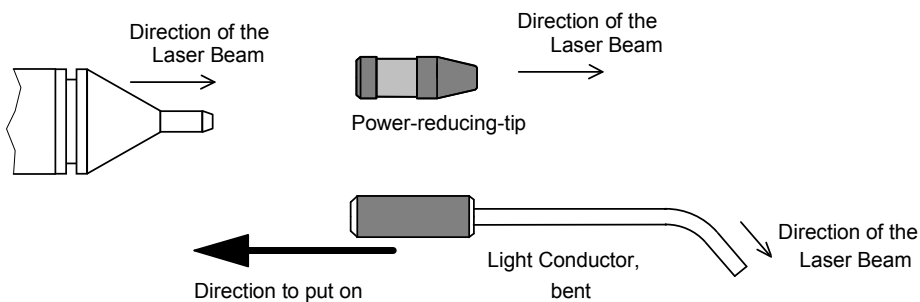


wide reflection,
lower penetration depth
= less success

5.4 Use of the accessory

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

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



5.5 Search of Acupuncture points with the Compact – Laser plus:

5.5.1. Preparation of the assembly

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

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

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

5.5.2. Acupuncture point detection on the body

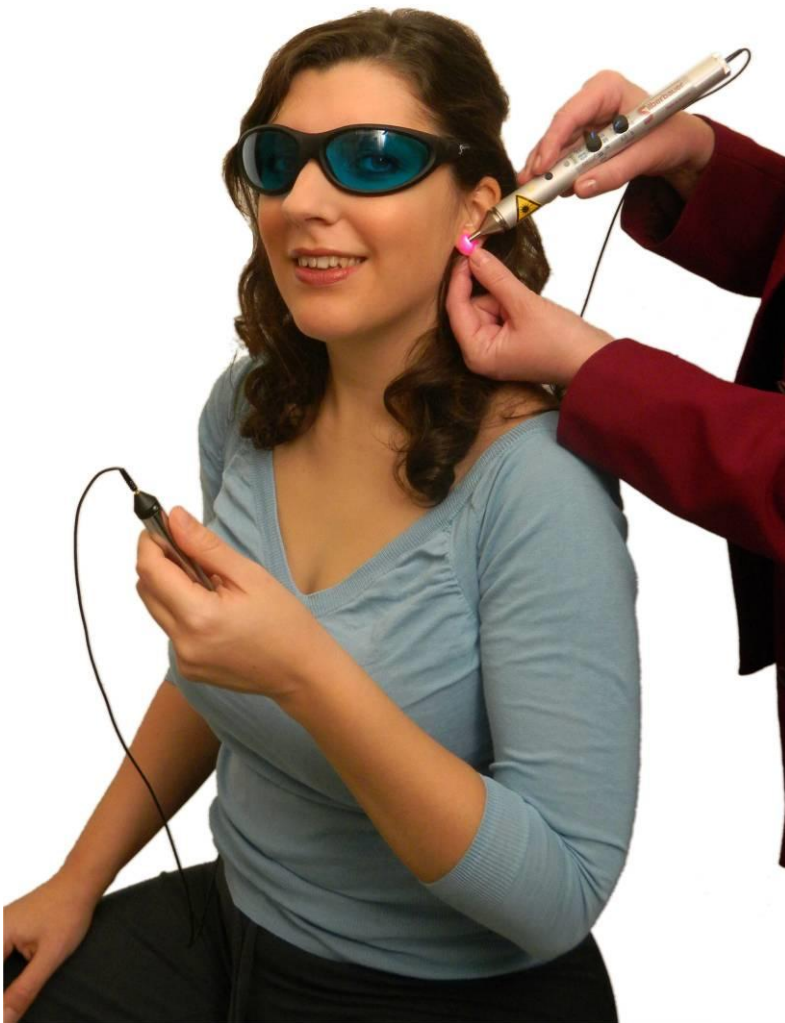
The Silberbauer Point Detector PS 3 indicates the electrical conductivity of the skin both optically (with higher or lower frequency of the installed light-diode) and acoustically (with a varying tone pitch). The latter can be heard by the doctor while focussing his eyes on the acupuncture point.

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.

Press the push-button on the laser above the acupuncture point to start the irradiation. The time of therapy programmed in the Silberbauer Compact-Laser *plus* is optimised for this kind of application required in every model. See chapter 1.3. "Acupuncture" in the booklet Applications of the Soft - Laser!

5.5.3. Detection of ear- and skull acupuncture points



The acupuncture points at the cranial zone because of Yamamoto and at the ear are "silent" -in contrast to acupuncture points for the rest of the body. This indicates that the electrical conductivity of the skin is very low there. However if a disturbance in the organism is projected to the reflexion zones, the electric conductivity of the skin changes at the relevant acupuncture points and zones.

These points can be located like with the body's acupuncture. Very high tones appear at points with strong disturbances which should be irradiated.

5.6 Transmission of drugs:

For Australia, this option is not applicable.

5.7 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 .

5.7.1 Formulae

Energy = Laser power x irradiation period

Irradiation dose = Energy /unit area

5.7.2 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

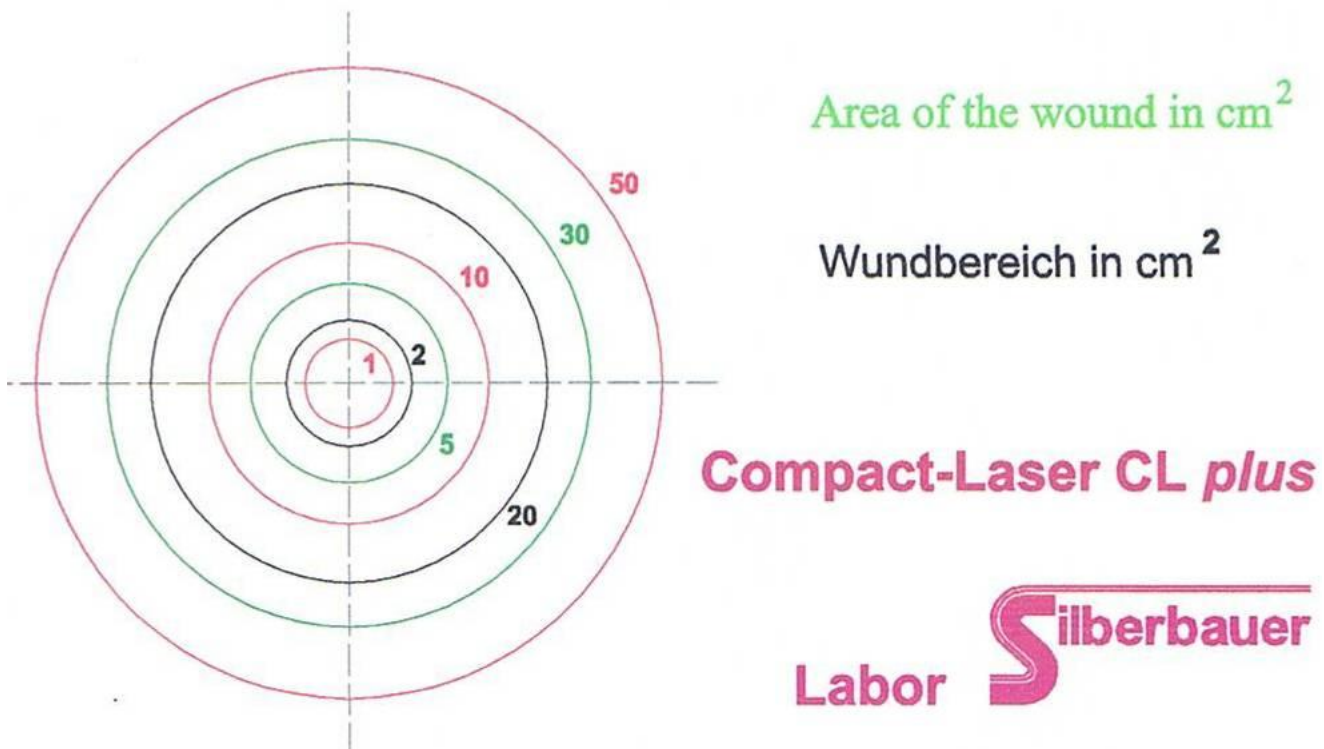
Irradiation-doses: in Joule / cm²

5.7.3 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 cm^2 . Set the size switch at the laser in this position.



5.8 Checking the output power of the laser

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

The yellow lamp will glow only if the laser is between 90% und 110% of nominal output power, and a red one which blinks at 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 switch off automatically and can be switched in after the Rotary Switch 1 is turned into off- position.

5.9 Charging of the NiMH- Battery

See manual of the battery charger!

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

6 Possible dysfunctions of the laser

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

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

- Battery is totally empty; unscrew battery cap, remove 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? (there is a 2 seconds delay time before 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 some 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 off- position to restart the device. (Only after switching off respectively and cooling can the device be used again. **If the red lamp glows again please bring or send the device for service !**

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

Any modification of the device is NOT ALLOWED!

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

7 Cleaning, disinfection and maintenance

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

7.1 Laser, Laser Tip, Irradiator for area, Adapter for Light Tubes and Tripod

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

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

The **laser head** itself, the **irradiator for area** and also the **adapter for light conductors** and the **tripod** can also be cleaned and sanitized in this way.

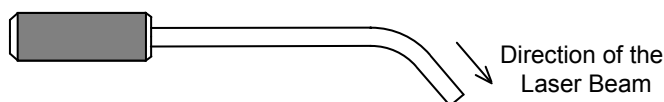
7.2 Power Reducing Tip

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

7.3 Bent Light Tube

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

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



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

7.4 Maintenance

There is no additional maintenance necessary by the user.

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

8 Waste management of laser and accessory



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

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

The batteries should be taken to a depot for special waste disposal.

9 Warranty

Guarantee:

All recently manufactured Silberbauer products: 3 years

All used products: 1 year.

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

Excluded from the warranty are

- batteries, accumulators and
- damage by effect of mechanical force eg dropping or
- by too high or too long working- or storage- temperature and damage by inappropriate handling.

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

After opening of the device by non-authorized person warranty is void!

10 Laser inspection

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

The inspection will be made in locally by Acupak or by 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.

10.1 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 hold 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.

10.2 Inspection Certificate

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

11 Laser dispatch

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

Please, for all checks or repairs to this equipment, send the Instruments Book also them along!

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

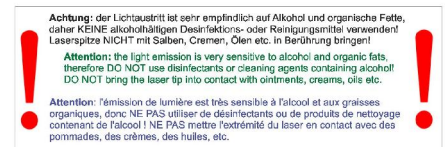
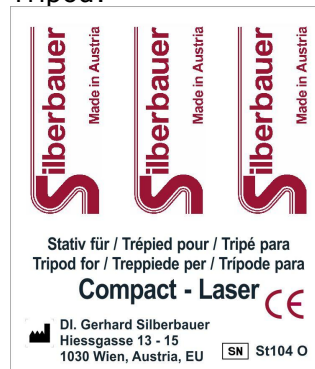
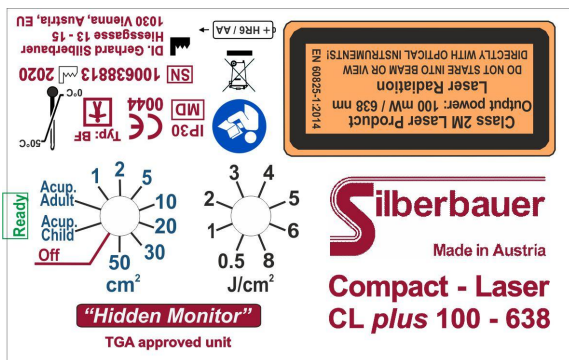
12 Warning advices and Label Information :

For the Laser there are used different warning labels depending of the model:

e.g. for the model *CL plus 100 - 638*:

Tripod:

Warning text basket inside:



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



Caution! Laser radiation!



Permissible Temp. Range



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

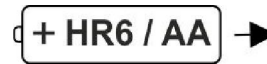
IP30 means: Protected against solid foreign parts with a diameter $\geq 2,5$ mm as well as against access with a tool, no protection against water



Application part type BF



Serial Number



Type and direction of inserting for NiMH battery

Year of manufacturing: coded for devices until summer 2020 at the end of the serial number: letter A for 2001, B for 2002, R for 2018, etc.



Consult Instructions for use!



Manufacturer



Year of production



Medical product

Label at outside of cases:

Label at Irradiator for area:



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

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

13 Technical Data:

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

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

CE 0044

Intended use: for laser radiation of skin, mucosa and dental applications
EMC Test Report: Federal Institute of Technology, Electrical and Electronic Engineering,
Ref. No. TGM-VA EE 38008 EMC

Accessory: see page 0

Internal power source: NiMH- battery, Size AA = LR 6

Classification: -protection level against electr. shock: Internal el. Power source



Part of application type BF

- **ingress protection:** IP30

- **protection level during application together with explosive mixtures of anaesthetics with air or with oxygen or laughing-gas:**

Instrument is not to be used in an explosive atmosphere or with explosive mixtures from anaesthetics with oxygen 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:** 88 g / 118 g

Dimensions: 20 x 217 mm (D x L)

Model:	<i>CL plus 60-638</i>	<i>CL plus 100-638</i>	
Nominal laser power +/-10% (mW):	60	100	
Wavelength (nm):	638	638	
Beam diameter at output (mm):	3,2	3,2	
Admitted case temperature (operation):	10 bis 40 °C	10 bis 40 °C	
Laser class:	2M	2M	
Operating time with NiMH-Batt. (hours):	4,5	2,5	

Model:	<i>CL plus 60-405</i>		
Nominal laser power +/-10% (mW):	60		
Wavelength (nm):	405 (blue)		
Beam diameter at output (mm):	3,2		
Admitted case temperature (operation):	10 bis 45 °C		
Laser class:	2M		
Operating time with NiMH-Batt. (hours):	4,5		

Interval for periodical inspection: 2 years

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

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

Result:

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

Rights for technical changes reserved!

Appendix A: Declaration of Conformity**EC – Declaration of Conformity**

The company

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

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

Compact - Laser

Models: CL plus 60 - 638; CL plus 100 - 638; CL plus 250 - 658 ; CL plus 60 – 405;

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

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

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

Involved Notified Body:

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

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

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

Vienna, 2019-07-09



Dipl. Ing. Gerhard Silberbauer
CEO and QM Manager

Appendix B: Declaration of Conformity Australia**MANUFACTURERS DECLARATION OF CONFORMITY**
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

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

Reference: Not applicable

Manufacturers Name: Dipl.Ing. Gerhard Silberbauer, Medical Devices

Business Address: Hiessgasse 13 – 15, 1030 Vienna, Austria, EU

Medical Devices: CL plus

Classification: Class IIa

GMDN Code: 36546 – Laser, diode

Scope: All

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

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

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

Authorized by:

Date:



Prof. Dipl.Ing. Gerhard Silberbauer
Managing Director

Sept 27, 2015

Appendix C: Application of Microbac® Tissues

Mikrobac® Tissues

Proven efficacy

Mikrobac Tissues are a ready-to-use product.

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

Listing

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

Chemical-physical data

All data refers to the Mikrobac Tissues use-solution:

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

All data refers to the wipe:

- Dimensions: 180 x 200 mm²
250 x 380 mm²

Reach

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

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

Stability

After opening

- in tightly closed flowpack: 3 months

