Instructions for use

Compact - Laser

CL plus

Types:

60 – 638
100 – 638
60 – 405

CE 0044

Medical Electronics, Vienna, Austria, EU

Content:

Scope of delivery:

- 2 ea. NiMH – Batteries „Green" 2600 mAh
- *Nitecore* Intelligent Charger for NiMH- Batteries
- Luxury Leather Case "*Nabuka*"
- lockable Casket, Aluminum
- Instructions for use
- Applications of the Soft–Laser
- Measurement template for wounds
- Instruments book
- Laser sign board (Attention Laser Beam)

Optional accessories:

Tripod for Compact Laser CL plus

Irradiator for area

Mirror

Adapter for Light tube

Light tube, bent (Dental top)

Optional protection goggles:

Laserlands Laser goggles (same glasses for the patient and therapist) [2])

Noir Comfort Laser protection goggles (glasses for the patient) [1])

Noir Comfort Laser adjustment glasses (glasses for the therapist) [1])

Permitted device in connection with the CL plus Laser:

Point Detector PS3, with Safety- Connection Cable

[1]) for red laser only (638 + 658 nm)! [2]) for all kinds of Silberbauer - lasers!

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. 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 ^{O}C (50 to 104 ^{O}F),
  Storage temp. 0 bis 50 ^{O}C (40 to 122 ^{O}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 (N_2O) 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 open eye at all costs and do not irradiate the closed eye!
- Put laser safety goggles on the patient when irradiating the facial area!

Attention! Colour identification is disturbed by the glasses!

3.1 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! Sopme 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 photosensibility, 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%)!

3.2 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

3.3 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

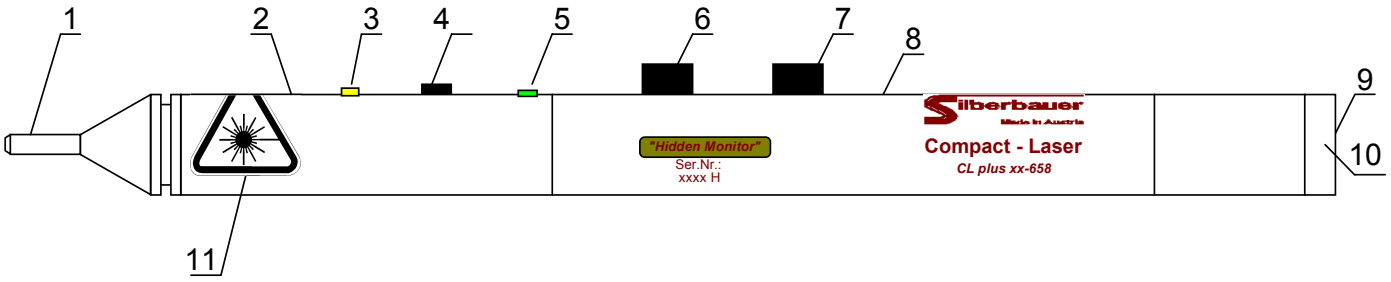
All other persons:
- Basic knowledge of the human body,
- the names of body parts, joints, organs,
- Names of diseases treated with laser,
- Basic knowledge of wound management

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 Optional approved accessories

Adapter and Light tube, bent:

Direction of the Laser Beam

Power loss with light tube: aprox. 24% [1]) or aprox. 28% [2])

Laserlands laser goggles:

Mirror:

Irradiator for area:

Power loss of mirror or irradiator for area: aprox. 18% [1]) or 14% [2])

Noir goggles for therapists:

Noir goggles for patient:

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 conterclockwise 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

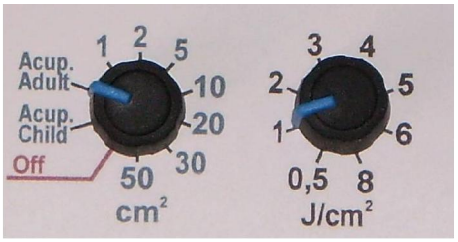
After treatment:

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



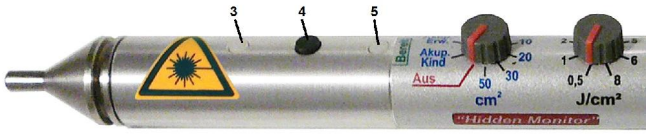
The **left rotary knob** is used to switch the unit **on and off** and to select the function: acupuncture or surface irradiation.

Acupuncture: in position "Acup. Child", the laser power is set to ¼ of the type power and the irradiation time is set to 5 seconds; in the "Acup.Adult" to ½ 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/cm^2 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.

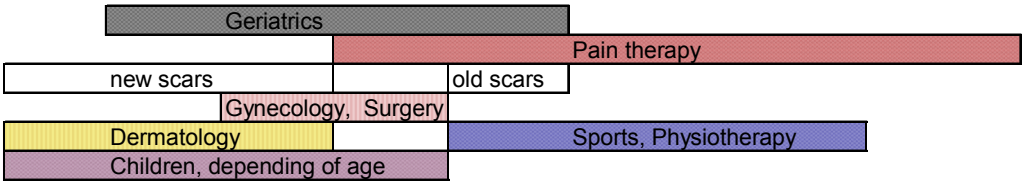
* At the end of each session, the **left rotary switch** must be turned back to the "Off" position.

For your information only – unit calculates automatically:

Therapy time depending of the position of the switches (in minutes : seconds):
and recommended dose for different applications:

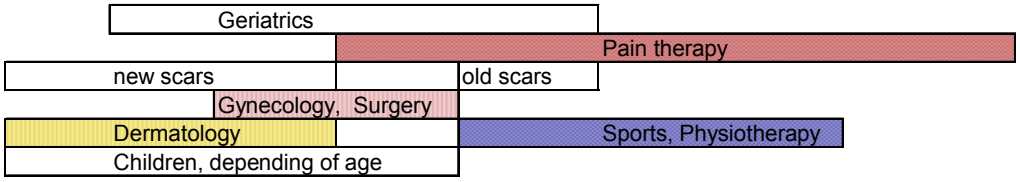
(for longer therapy time it is recommended to use a Silberbauer Laser Tripod!))

60-638 (red):



Dose (J/cm²): ▶	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 cm²	8s	17s	33s	50s	1m:7s	1m:23s	1m:40s	2m:13s	100%
2 cm²	17s	33s	1m:7s	1m:40s	2m:13s	2m:47s	3m:20s	4m:27s	100%
5 cm²	42s	1m:23s	2m:47s	4m:10s	5m:33s	6:57s	8m:20s	11m:7s	100%
10 cm²	1m:23s	2m:47s	5m:33s	8m:20s	11m:7s	13m:53s	16m:40s	22m:13s	100%
20 cm²	2m:47s	5m:33s	11m:7s	16m:40s	22m:13s	27m:47s	33m:20s	44m:27s	100%
30 cm²	4m:10s	8m:20s	16m:40s	25min	33m:20s	41m:40s	50 min	66m:40s	100%
50 cm²	6m:57s	13m:53s	27m:47s	41m:40s	55m:33s	1h:9m:27s	1h:23m:20s	1h:51m:7s	100%

100-638 (red):



Dose (J/cm²): ▶	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 cm²	5s	10s	20s	30s	40s	50s	1min	1m:20s	100%
2 cm²	10s	20s	40s	1min	1m:20s	1m:40s	2min	2m40s	100%
5 cm²	25s	50s	1m:40s	2m:30s	3m:20s	4m:10s	5min	6m:40s	100%
10 cm²	50s	1m:40s	3m:20s	5min	6m:40s	8m:20s	10min	13m:20s	100%
20 cm²	1m:40s	3m:20s	6m:40s	10min	13m:20s	16m:40s	20min	26m:40s	100%
30 cm²	2m:30s	5min	10min	15min	20min	25min	30min	40min	100%
50 cm²	4m:10s	8m:20s	16m:40s	25min	33m:20s	41m:40s	50min	1h:6m:40s	100%

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

60-405 (blue):

Dose (J/cm²): ▶	0,5	1	2	3	4	5	6	8
1 cm²	8s	17s	33s	50s	1m:7s	1m:23s	1m:40s	2m:13s
2 cm²	17s	33s	1m:7s	1m:40s	2m:13s	2m:47s	3m:20s	4m:27s
3 cm²	25s	50s	1m:40s	2m:30s	3m:20s	4m:10s	5min	6m:40s
5 cm²	42s	1m:23s	2m:47s	4m:10s	5m:33s	6:57s	8m:20s	11m:7s
8 cm²	1m:7s	2m:13s	4m:27s	6m:40s	8m:53s	11m:7s	13m:20s	17:47s
12 cm²	1m:40s	3m:20s	6m:40s	10min	13m:20s	16m:40s	20min	26m:40s
20 cm²	2m:47s	5m:33s	11m:7s	16m:40s	22m:13s	27m:47s	33m:20s	44m:27s
30 cm²	4m:10s	8m:20s	16m:40s	25min	33m:20s	41m:40s	50 min	66m:40s
50 cm²	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 stops 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:

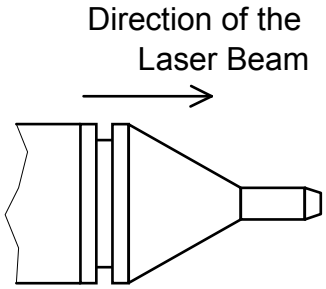
Back lamp	green	dark	If the laser is turned off or if the battery is wholly empty
	green	blinks slowly	If the device is turned on and the battery is ok
	green	blinks fast	If the battery is charged poor
Front lamp	orange	blinks	During the safety delay of 2 secounds
	yellow	glows	Laser is working and power 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 alterna ting	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 becames 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.

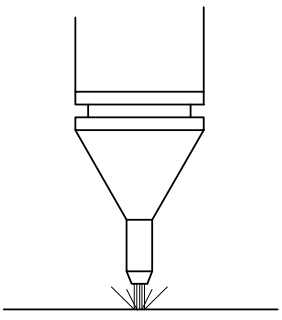
At the point there is a short light conductor. This light conductor serves among other things as mechanical protection for the heart of your therapy equipment, the laser diode. The impact point or the areas of operation are specified by this laser point. With all models the light emerges, whereby the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

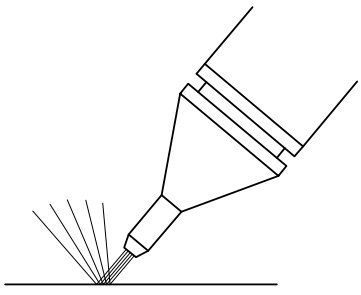
Apart from this the laser-point is conductive and is connected with the socket at the rear end of the laser battery. The point-searcher PS3 can be connected to this socket with a connecting cable. Herewith the laser-point can be used at the same time as searching point-peak for acupuncture points.

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

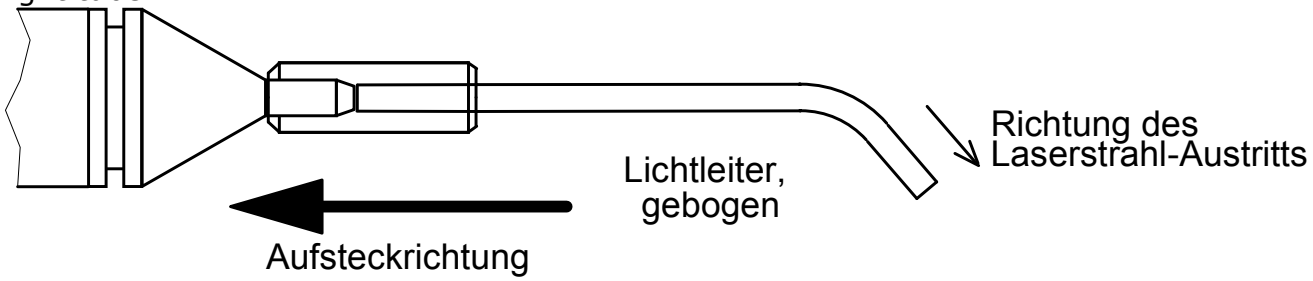


wide reflection,
lower penetration depth
= less success

5.4 Use of the accessory

5.4.1. Bent light tube:

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.



You only need one adapter, you should have several of the light guides in stock because of the preparation.

5.4.2. Mirror

In many cases, the laser can be held much more comfortably if the mirror is used. This is placed on the laser tip as far as it will go and can be turned on the tip so that the laser can be held comfortably.

5.4.3. Irradiator for area

To irradiate large areas, the laser beam can also be widened using the area attachment. This is attached to the laser tip as far as it will go.

5.4.4. Tripod

For longer irradiation times, it is advantageous to place the laser in the stand.

See also chapter 4.2.2 on setting up and handling the stand!

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 *plus* a Silberbauer Point Detector PS3 and a safety connection cable is required.

Put one plug of the safety- 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 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 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 .

5.6.1 Formulae

Energy = Laser power x irradiation period

Irradiation dose = Energy /unit area

5.6.2 Measuring units

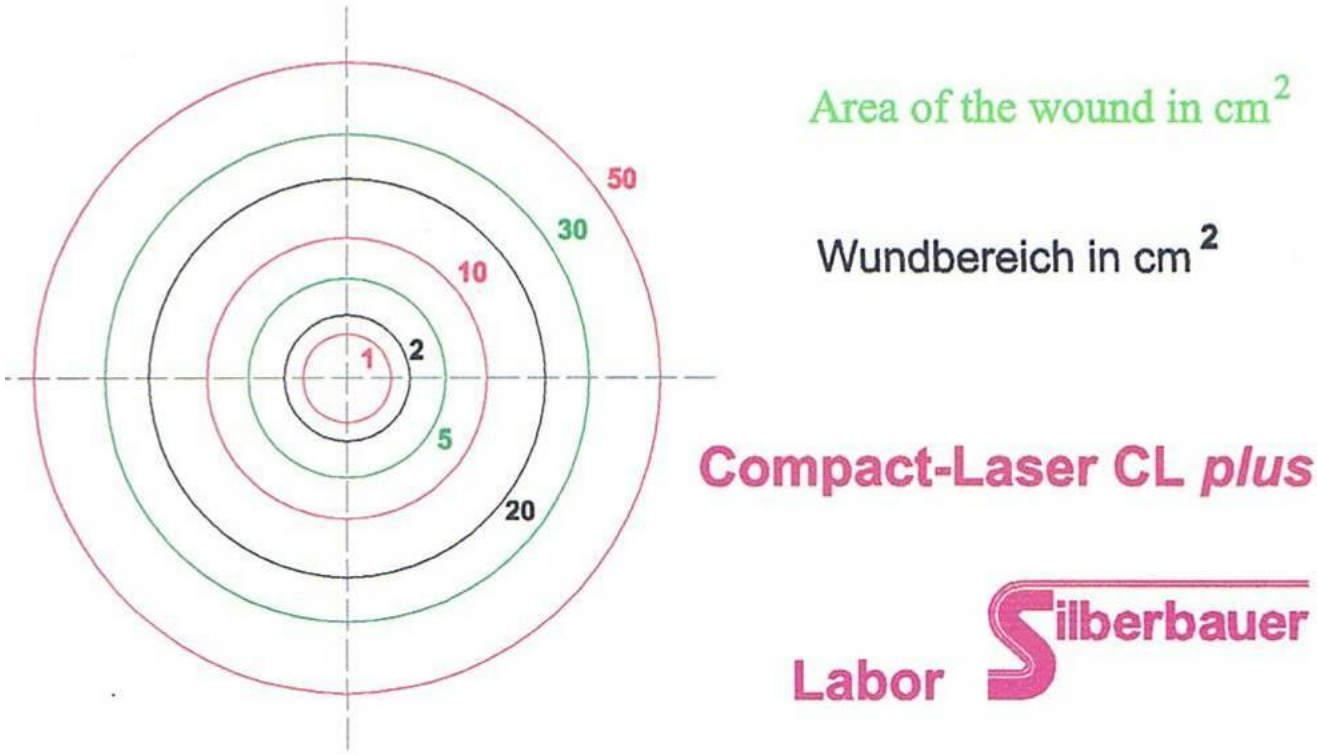
Energy: in **Joules (J)** = Watt-seconds (Ws)
Power: in **milli-watt (mW)** 1 mW = 0,001 W
Time: in seconds (s)
Unit area: in cm²
Irradiation-doses: in Joule / cm²

5.6.3 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.



5.7 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.

5.8 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) diesn't glow after pressing the start buttom, 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).

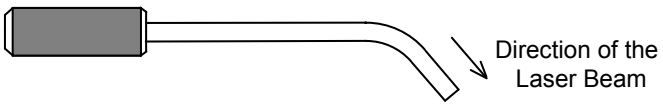
The **laser head** itself, the **irradiator for area** and also the **adapter for light conductors** and the **tripod** can also be cleaned and sanitized in this way.

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 maintainance 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 corrspond 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 then 2 secounds)
No laser radiation has to emerge out of the instrument.
Suddenly after you have turned the rotary switch into ist position the front lamp (3) must flash for 2 secounds in orange colour.

Press button again after more than 2 secounds.
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 readible!

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!

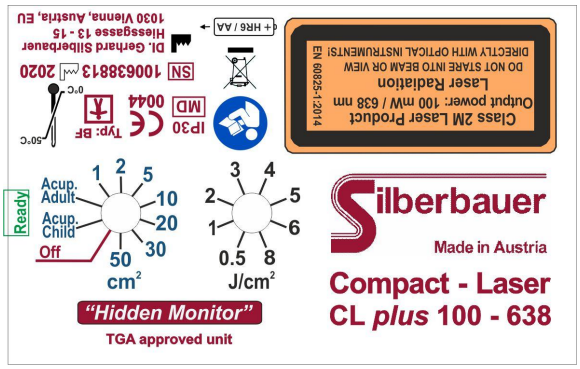
Please, for all checks or repairs to this equipment, send the Instruments Book also them along!

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 casket 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 ≥ 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

Consult Instructions for use!

Manufacturer

Year of production

Medical product

Label at outside of cases:

Label at Irradiator for area:

Label at the mirror:

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 Vienna, Austria, office@silberbauer.at

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 anaesthesias with air or with oxygen or laughing-gas:**

Instrument is not to be used in an explosive atmosphere or with explosive mixtures from anaesthesias with oxygen or laughing-gas!

- **Kind of operation:** Permanent operation
- **due to MDR2017/745:** 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)
Expected life time: 15 years

Model:	**CL *plus* 60-638**	**CL *plus* 100-638**	
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:	**CL *plus* 60-405**		
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 limits according to class B were not 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

BERLIN CERT AFNOR Group

Berlin Cert GmbH · Dovestraße 6 · 10587 Berlin
Dipl. Ing. Gerhard Silberbauer-Medizinische Elektronik
Hießgasse 13-15
1030 Vienna
Austria

Your contact person:
Martin Tettke
Tel: +49 30 5858216-0
Fax: +49 30 5858216-80
cert@berlincert.de
www.berlincert.de
Berlin,14.08.2024

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices
Reference number: 24-116-S

To whom it may concern,

This letter confirms that, Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0633 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the manufacturer listed above.

The devices covered by the formal application and the written agreement mentioned above are listed in Table 1 below.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer submitted the MDR application and signed the written agreement by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation/exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Digital unterschrieben von Martin Tettke
Datum: 2024.08.15 11:10:17 +02'00'

Dipl. Ing. Martin Tettke

Head of Certification Body and Notified Body

Tabelle 1: devices covered by this letter

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Punktsucher PS3	Class IIa	Punktsucher PS3	442321806247 NB Indentification: 0044
Compact Laser CL plus/mini	Class IIa	Compact Laser CL plus/mini	442321806247 NB Indentification: 0044

Tabelle 2: revision history

Date	action
14.08.2024	Initial Issue

Appendix B: Declaration of Conformity Australia

Silberbauer

MANUFACTURERS DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

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

Reference:	Not applicable
Manufacturers Name:	Dipl.Ing. Gerhard Silberbauer, Medizinische Elektronik
Business Address:	Hiessgasse 13-15, 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: 44 232 160627 EC Certificate / Directive 93/42/EEC Annex II (excluding section 4)

Standards Applied:

EN 10993-1:2021
EN 13485:2016
EN14971:2020
EN 60601-1:2007 +A1:2013 + ISH1:2021
EN 60825-1:2015
EN 60601-1-2:2015 + A1:2021
EN 60601-1-6:2016
EN62304:2016
EN62366:2015 +COR1:2016
RoHS2 Directive 2011/65/EU

Authorised by:

Prof. Dipl.Ing. Gerhard Silberbauer
Managing Director

Date: May 24th, 2022

Appendix C: Application of Microbac® Tissues

Mikrobac® Tissues

Proven efficacy

Mikrobac Tissues are a ready-to-use product.

Bacteria und Fungi		
EN Phase 2 / Step 1 Efficacy according to EN Norm Phase 2 / Step 1 (suspension tests), tested under clean / dirty conditions	Bactericidal (EN 13727) - dirty conditions	30 sec.
	Yeasticidal (EN 13624) - dirty conditions	30 sec.
EN Phase 1 / Basic tests Efficacy according to EN Phase 1 (Basic tests / suspension tests) without contamination; does not define the applicability of a product for a specific purpose	Bactericidal (EN 1040)	30 sec.
	Yeasticidal (EN 1275)	30 sec.
VAH 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)	Bactericidal/Yeasticidal - dirty conditions	5 min.
DGHM Rapid disinfection (in accordance with the German Society for Hygiene Microbiology [DGHM]); Based on suspension and practical tests; tested under clean / dirty conditions	Bactericidal/Yeasticidal - 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 Phase 2 / 2 Phase 2 / 1 Efficacy according to EN Norms (Phase 2 / 2 und Phase 2 / 1), tested under different conditions	Bactericidal (EN 13697 + 1276) - low contamination (20 °C)	1 min.
	- 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 + 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 Phase 2 / Step 2 Efficacy according to EN Phase 2 / Step 2 (practical tests), tested under different conditions	Bactericidal (EN 13697) - low contamination (20 °C)	1 min.
	- 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 Phase 2 / Step 1 Efficacy according to EN Phase 2 / Step 1 (suspension tests), tested under different conditions	Bactericidal (EN 1276) - low and high contamination (20 °C)	1 min.
	- 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/cm ^{3}
- pH-value (20 °C) approx. 8

All data refers to the wipe:

- Dimensions: 180 x 200 mm^2
  250 x 380 mm^2

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