

LASERDUSCHE
POWER**21+**
TWIN



Operating Instructions

Last revised: February 28th, 2019



CE 0197

Preface

The Operating Instructions are directed at healthcare professionals physicians, who are familiar with the handling and of low level laser systems.

The laser shower PowerTwin21+ is a therapy device for the low level laser therapy of large body areas. Low level laser therapy belongs to the field of complementary therapy.



Advice

Please read the Operating Instructions carefully before using the device. The Operating Instructions should always be kept at the place where the low level laser system is employed.

Users must be able to reduce the risks and complications that are associated with the use of low level laser systems by taking the appropriate action.

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Scope of Delivery

MKW Low-Level Laser unit PowerTwin21 (Item-Code 010212)
adapter laser shower (Item-Code 021101)
adapter comb [optional] (Item-Code 021102)
AC adapter 230V (Item-Code 021005)
Laser safety goggles for therapist (Additional periphery, optional)
(Item-Code 020102)
Laser safety goggles for patient *Softcaps* (Additional periphery, optional)
(Item-Code 020103)
Device case (Additional periphery, optional) (Item-Code 020301)
Acrylic tray (Additional periphery, optional) (Item-Code 020405)
User Manual in English

1. 1. Function keys and display elements



1		The PowerTwin21+ is switched on and off with this key.
2	 = SET	The values can be selected and stored with this key.
3	+/-	Use Plus and Minus keys to change the values previously selected with the SET-key
4	LASER	Activate/Deactivate laser output
5	DISPLAY	Display screen (menu-driven) of selected laser power, operating mode, indication of therapy time as well as dose.
6	LEDs	<u>6a: Two red LED:</u> On as error indication of LED diode operation, please contact customer service. <u>6b: Two yellow LED:</u> On when laser output active
7	red connector	Connector for the key pin - operation of PowerTwin21+ is only possible when the key pin is in correct position.
8	black connector	Storage for key pin when lasershower is off.
9	Adapter-ring	An adapter is available for PowerTwin21+ laser shower (with protective glass) and a laser comb adapter (with comb tips, optional accessory).
10		Laser beam outlet
11	LEDs	4 red LEDs at the bottom indicate active laser output.

fig.1:
PowerTwin21+ (casing, top side)



fig.2:
shower adapter (top fig.)
comb adapter (lower fig.)

fig.3:
AC adapter for PowerTwin21+



2. Intended Use

The laser shower PowerTwin 21+ is a device to apply low level laser (laser with low energy) for the treatment of large body areas.

The laser shower PowerTwin21+ is a therapy device and can be used for wound healing and relief of pain and inflammation.

3. Contraindications

The professional literature lists the following contraindications. They also apply to the laser shower PowerTwin21+.

Absolute contraindications:

- Irradiation of the eyes
- Photo sensitivity
- Tumour patients
- Open fontanelles and epiphyseal plates in children
- Hyperthyroidis



Relative contraindications:

- Pacemaker patients (thorax)
- Epilepsy (head)
- Pregnancy (abdomen and back region)
- Endocrine organs (thyroid, testicles, ovaries)

Obstacles to therapy:

- Deep X-ray therapy
- Long-term medication
- Chemotherapy

4. Display and LED indicators

<p>Software V.x.x EU</p>	<p>This screen appears during the booting process after the laser unit has been turned on. The second line indicates the software status of the unit.</p>
<p> PowerTwin21+  808nm 21x100mW</p>	<p>This screen appears after the laser unit has been turned on once the booting process is finished. The second line shows the wavelength and the maximum CW output. The loudspeaker icon indicates the sound is activated.</p>
<p>100mW 15 J/LD MULTI</p>	<p>Initial setting. The settings which were used last and the current therapy parameters (laser power, therapy program, energy dose rate) are displayed. Factory setting when delivering is: 50 mW * Multi * 10 min (15 J/LD)</p>
<p>100 mW 30 J/LD CW</p>	<p>A value that appears inverted can be changed with the “+” and “-” keys. On this screen the laser power level can be altered. Pressing the SET key saves the respective value. Editing possible for: ◆ Therapy program ◆ Energy dose ◆ and/or therapy time.</p>
<p>100 mW 30 J/LD CW</p>	<p>Setting the therapy program</p>
<p>100mW 30 J/LD CW</p>	<p>Setting the energy dose</p>
<p>100mW 10:00 CW</p>	<p>Setting the therapy time: Maximum treatment time is 15 minutes.</p>
<p>21x... mW/Mode 10:00 - 0,0 J/LD</p>	<p>This screen appears when the laser is activated. Laser power level, remaining therapy time and discharged energy dose rate in Joule (J) are shown.</p>

5. Operation

5.1 Unlocking

Insert the key pin into the red connector at the bottom of the housing of the laser shower PowerTwin21+ (● page 4, fig. 1/7). The adapter ring for the laser shower or laser comb must be plugged in (● section 9, “Replacing the Adapters”, page 15, resp. page 4, fig. 2/10+11).

The PowerTwin21+ cannot be operated without the adapter ring. Only the power supply unit AC/DC adapter type FW7555M/12 which was shipped with the unit must be used.

Connect AC adapter with adapter plug

The power supply unit (AC adapter) and the PowerTwin21+ are connected with an intermediate plug. Should you wish to remove the power supply unit from the laser shower PowerTwin21+, please proceed as follows:

- Slightly push back the locking device (black sleeve) at the plug, and pull the two plugs apart.



Attention!

The plug-in connection is a push-pull locking system. Hold the plug-in connection only by the sleeves with the arrows, as illustrated. Never twist the plugs or pull at the back ends of the plug.

- If you reconnect the PowerTwin21+ with the AC adapter, make sure you observe the direction of the arrows on the plugs.

5.2 Connect AC Adapter to the power supply

Connect the AC adapter to the mains (100–240 V~). A correct connection is indicated by a green control light at the AC adapter.

5.3 Initial settings after booting

After switching the device on, the output data of your lasersystem (wavelength and max. output) are indicated in the second line.



5.4 Further initial settings

You can turn the display (right-handed/left-handed users) with the “+”key (page 4, fig. 1/3).

5.5 Display of saved therapy parameters

By pressing the “SET” key, the currently set parameters (initial setting) of the unit are displayed. With first use you'll be indicated the following initial settings:



100mW 60 J/LD
MULTI

The maximum output of 100 mW, the operation mode Multi and an energy dose of 15 J/LD (LD = laser diode) are preset when operated for the first time.

Following this the laser power values selected and stored previously will be displayed, as well as the therapy program and therapy dose used the last time.

Changing the laser parameters:

- Chapter 6.0 “Changing of laser parameters” (pages 10ff)

Activating the laser:

- Chapter 7.0 “Using the Laser” (pages 14ff)

6. Changing of laser parameters

Having pressed the SET key, the output value is blinking as highlighted in below figure. Changes can be made by pressing “+/-“-keys accordingly. Settings can be done from 10% to 100 % (in regard to the maximum value) in increments of 10%.



100 mW 30 J/LD
CW

By pressing the SET key again, the selected value is confirmed and stored. The display changes, showing the following information.



100mW 30 J/LD
CW

The therapy program can be changed with the “+” and “-” (page 5, fig. 1/3) keys and saved with the SET key.

The setting options are:

- CW ● Multifrequency ● Alphafrequency ● Nogier-Frequencies A-G, L
- Nogier-Frequencies pot. A'-G' ● Bahr-Frequencies 1-7 ● Reininger-Frequencies ● free programmable frequencies 1-9,999 Hz.

New frequencies: ● Bahr+, ● Solfeggio-frequencies ● FI-Bands (FI: Regeneration, Pain, Interference, Trauma, Inner Center, Detox, Infection, Bones, Nerve, Transcranium, Psyche/Vegetativum, Lymph, Trigger Points) ● Sweeps (Sweep: Alpha, Purr, Beta, Theta, Delta) ● Cranio

Please note: therapy programs and frequencies on pages 22-23, appendix 1

An individual frequency can be set like this

When the value is flashing on the display, use the “+” or “-” keys to select the frequency program you want and press the key SET for 2-3 seconds. This is how you get to the setting mode for individual frequencies. With the +/- keys you then can select the desired frequency and confirm with pressing the SET key again. Further pressing the SET key will transfer the selected frequency to the treatment display.

Example: you want to select the „Nogier E“ frequency:

1. After booting is finished, use the arrow-key to select the program mode *Therapy program*.
2. The mode currently selected shows a black background and is flashing.
3. Select the Nogier-Frequency using the „+/-“ key. The display now shows: *Nogier xxxxx*
4. Press the arrow-key for 2-3 seconds. The display now shows in the first line the frequency *Nogier* and in the 2nd line the currently selected program.
5. Select *Nogier* by means of „+/-“ key. The display now shows a black background and the value is flashing.
6. Press the arrow-key twice, the 2nd line of the display now shows *Nogier E*. The value is not flashing any more and you're being forwarded to the setting mode *dose/time*.

The frequencies Bahr and Reininger can be selected accordingly.

The newly programmed frequencies Bahr+ and Solfeggio can be set analogous to the Nogier frequencies.

Setting a freely programmable frequency:

Twenty memory locations (FP1 to FP20) are available for freely programmable frequencies. When the value flashes, press the “+” or “-” key to enter the frequency program FP. Keep the SET key pressed for 2–3 sec. to get to the “Programmable” screen on the display.



**Programmable
FP1:xxx Hz**

Keep the SET-key pressed for 2–3 sec. to enter the frequency setting mode.

**Frequency x
xxxx.xx Hz**

You can set the desired frequency (1 - 9,999 Hz) with the “+/-” and SET-keys. First the thousands digit, then the hundreds digit, etc. Once the desired frequency has been set, confirm with the SET-key (keep pressed for 2–3 sec.). The frequency is now transferred to the treatment screen on the display (at first as a flashing value). The frequency is stored with the SET-key and displayed on the screen.

A set value remains in the memory until it is overwritten by another frequency.

**100mW 30 J/LD
CW**

After the treatment mode has been set, the display changes to the following screen:

The energy dose rate can be changed with the “+/-” keys. The SET key confirms the selected value. The selected dose automatically is being converted into the corresponding therapy time required for the selected output.

**100mW 10:00
CW**

Press the SET key to confirm the value. Now the required therapy time is flashing. It can be confirmed with the SET key.

Please note: Changing the therapy time with the „+/-“-key also changes the dose needed for said therapy time depending on the selected output.

Possible settings for the therapy time are:

10 seconds to 1 minute in increments of 10 seconds

1 minute to 15 minutes in increments of 1 minute

Possible settings for the dose are:

1 J to max. 60 J

Once all laser parameters have been set, this is shown in the display. The individual values are no longer flashing and you may start with the laser treatment (● section 7.0 *Using the laser*, pages 14ff).

Please note:

The maximum energy dose rate that can be selected is determined by the maximum therapy time and the maximum laser power level of the laser shower PowerTwin21+.

Example: Maximum therapy time for the laser shower PowerTwin21+ (100 mW) is 10 minutes and maximum laser power is 100 mW. The maximum energy dose rate that can be set is therefore $100 \text{ mW} \times 10 \text{ minutes} \times 60 \text{ s} = 60 \text{ J/LD}$. The minimum dose that can be selected is 1 J.

Note:

Please note that since energy and therapy time are correlated, changing either one of the two parameters will impact the other parameter. The other value will be adjusted automatically.

The selected value for the therapy time is confirmed and stored by pressing the SET key again. You can now start using the laser (● section 7: *Using the laser*). Please note that the settings for the parameters are retained when the unit is turned off and on again.

7. Using the laser

The laser application can only be activated, if the initial setting (display of the parameters) is shown on the screen.



100mW 30 J/LD
CW

Pressing the LASER key (fig. 1/4) activates the laser after a 2-sec. warm-up period. The LED (fig. 1/6) lights up green and the display changes to the following screen:



21x100 mW
10:00 - 0,0 J/LD

The display (page 5, fig. 1/5) shows the remaining therapy time and the emitted energy dose rate in Joule. The end of the first line displays the mode selected. The selected therapy time now counts backwards and the energy dose rate changes in line with the selected laser power and the elapsed therapy time, according to the formula “Energy dose rate (Joule) = Laser power (mW) x Therapy time (sec.)”.

An audible signal sounds while the laser output is active.

Treatment ends automatically after the selected therapy time has elapsed or when the selected energy dose has been achieved. The end of the therapy is indicated by a short triple sound signal.

Treatment can be terminated manually at any time by pressing the LASER key (page 4, fig. 1/4).

Once the therapy has ended, the screen changes back to the “Initial settings” display.

Note: When no laser application is taking place, the unit turns “OFF” automatically if it is not operated for a continuous period of ≥ 10 minutes (AUTO OFF).

8. Application

To achieve optimum therapeutic success, please observe the following:



- To keep reflection losses as small as possible, the skin must be free of grease and the laser shower PowerTwin21+ must be applied vertically to the skin.
- A general rule that applies to all treatments is the principle of gradually increasing the dosage. Initial treatments should last no longer than 2 minutes.
- Maximum treatment time per patient is 10 min. After 10 min. irradiation, the unit turns off automatically.
- When doing laser treatments are done in CW-Mode in quick succession (only short pauses), rising temperature of the laser diodes take place. Reaching an internal temperature of $< 55^{\circ}$ the mode is switched automatically to multi-frequency mode. The temperature symbol on the display will inform you (page 22)
- During laser emission mini fans will see to an improved removal of heat. The fans shut off when the laser emission is terminated.
- When doing continuous laser treatments in CW mode at maximum output, or treatments close together, the internal temperature may increase above 60°C . The device will then switch off automatically. This will be indicated in the display by “temperature auto off”. The device can only be switched on again, after the diodes were able to cool down.
- Move the laser shower PowerTwin21+ slowly and evenly across the surface of the skin. The distance to the skin should be only a few mm when doing it.
- Do not activate the unit until you are in the treatment position.
- Apply ointments, lotions and creams only after a laser treatment.

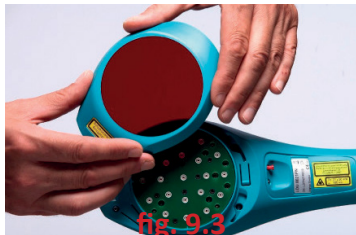
9. Replacing the adapters

The laser shower adapters may be replaced depending on their application. Two adapters are available. A change may also be necessary, if one needed cleaning.

- Disconnect the lasershower PowerTwin21+ from the mains.
- Put the PowerTwin21+ on a flat surface, as illustrated here, and press the adapter ring gently against the housing with both hands (page5, Abb. 9.1).
- Turn the adapter ring just slightly counter-clockwise until it is in the position shown in the next illustration (fig. 9/2).
- In this position you can remove the adapter ring (fig. 9.3).
- When attaching the adapter ring, make sure that the detents are inserted into the proper recesses. Press the adapter ring gently against the housing with both hands and turn clockwise. The detents are now back in their initial position (fig. 9/4).
- Reconnect the PowerTwin21+with the mains.

Please note:

- Do not touch the green circuit board with the green laser diodes.
- Don't store the laser shower PowerTwin21+ without the adapter being attached.
- Touch, press and turn the adapter ring only at the green housing. Avoid putting pressure on the comb tips.
- Do not replace the adapter in a dusty, dirty or wet environment.



10. Care and Maintenance

To ensure safe and hygienic operation, please observe the following:

To ensure safe and hygienic operation, please observe the following:

- To protect the PowerTwin21+, in particular to avoid damage to the protective glass/the comb tips, store it e.g. in the case that can be purchased optionally. For temporary storage, it may also be placed on a matching acrylic plate.
- The laser beam outlet must be cleaned with a soft cloth/cotton using 70 % ethanol (medical alcohol) every time it has come in contact with skin or when changing patients.
- Do not expose the unit to direct sunlight.
- The housing may be cleaned with a mild detergent. Before you start cleaning, disconnect from the mains.
- Unauthorized repairs or modifications of the unit may put users or patients in jeopardy. Therefore repairs may only be performed by the manufacturer or by persons who have been authorized by him. Illicit opening will void the warranty. When repair is required, please contact the Service Department.
- The laser shower should only be used in indoors at moderate temperature.

11. Safety information

Please strictly observe the instructions in the operating manual and heed the warnings.

- The laser shower must be protected against unauthorized users with the key pin
- The lasershower PowerTwin21+ must only be operated by specialized medical of the medical staff in doctors' offices, that have been trained in handling the unit. Treatment must be supervised at all times
- Due to its wavelength, laser radiation is not or only very weakly visible. **Do not look into the laser beam outlet and do not point the laser beam into the eyes of other persons, even if the eyes are closed.**
- The safety distance when looking straight into the beam at maximum output (21 x 50 mW – cw) is 80 inches (200 cm). If used incorrectly, lasers can damage the eyes, especially if the distance between the eye and the laser beam outlet is shorter than the safety distance.
- Please make sure that no mirrors or other reflecting surfaces are located within the safety distance from the PowerTwin21+ (reflection of laser light).

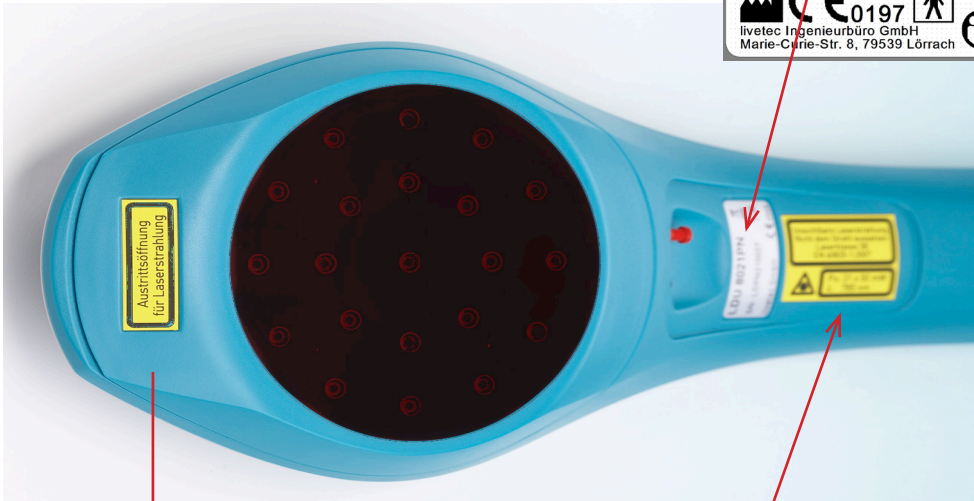
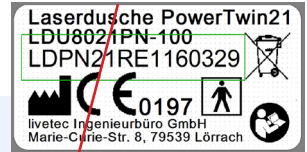
- **User and patient must always wear laser protection glasses!** The protection level >805-825 DIR LB4)
- **When treating patients with highly pigmented skin, moles or tattoos, the treated skin area may be heated unintentionally. Absolutely avoid a direct irradiation with skin contact or from a distance of less than 2 cm (0.8 inch) to the treated area. Minimum distance to skin >2 cm (0.8 inch), keep the applicator in motion. When using an output of >50mW, do not use CW mode.**
- The PowerTwin21+ must only be switched on when it is in the treatment position. When the treatment position is changed, the area laser must be turned off and only be turned on again when it is in the new treatment position. Turn off the PowerTwin21+ after the treatment and pull the key pin (page 4, fig. 1).
- If the PowerTwin21+, the power cord, the connecting or power plug show any signs of external damage, the laser shower PowerTwin21+ may no longer be operated and must be returned to the manufacturer.
- In case the PowerTwin21+ cannot be switched off, or the display fails, please remove the power supply immediately and contact the service department.
- Magnetic and electric fields as well as ionizing radiation may influence the functioning of the unit. For this reason you should not operate near devices which generate large electromagnetic fields or ionizing radiation, such as X-ray machines or diathermy equipment.
- Don't use the PowerTwin21+ in hospitals near active HF surgical equipment and RF shielded rooms with magnetic resonance imaging systems, where the intensity of electromagnetic disturbances is high.
- Do not operate the unit in rooms which are subject to the risk of explosion.
- The manufacturer is only responsible for the safety and reliability of the product, if the laser unit is used in accordance with the operating instructions. The PowerTwin21+ is subject to the WEEE Directive (Waste of Electrical and Electronic Equipment) 2012/19/EU and must not be disposed of in domestic waste.
- If you put the PowerTwin21+ permanently out of operation, please let us know. The manufacturer only is reliable for safety and reliability if the laser device is being used in accordance with the user's manual.



12. Manufacturer's labels and warning signs

Information on serial number starting with LDU8021RE:
digits 1-4 starting from the right: continuous number in year of manufacture
digits 5-6 starting from the right: year of manufacture (18 = 2018)

Manufacturer's nameplate









This warning sign marks the laser beam outlet of the unit. Do not look into the laser beam outlet without laser protection glasses.








This warning sign indicates that the unit is a class 3B laser device which emits laser light of the specified wavelength and at the specified power output.







12.1 Definition of symbols of laser shower PowerTwin21 Laserdusche

	Conformity to European medical device directive 93/42/EWG
	Follow user's manual
	Application type BF
	Manufacturer
	Meets WEEE guideline (waste of electrical and electronic equipment) 2012/19/EU and must not be disposed of in the domestic waste.
	Distributor







12.2 Definition of symbols on AC adapter

	Manufacturer date (only AC adapter) in form YY-MM
	Device of laser protection class II (only AC-Adapter)
	Direct current (only AC Adapter)
	AC/DC (only AC Adapter)
	Attention (only AC Adapter)

12.3 Transport-/Lagersymbole

	Protect against moisture		Storage-/Transport temperature
	Protect against heat		Storage-/Transport humidity
	Recycling in general		Storage-/Transport air pressure

13. Error Messages and safety information

	<p>Error in Laser-Diode Control. If the error occurs repeatedly, please contact our service team.</p>
	<p>Adapter not attached, or not attached correctly. Rectify error by attaching missing adapter, resp. attaching it correctly.</p>
<p>21x100 mW 03:12 - 6.6 J</p> 	<p>Temperature at laser diodes > 55 °C. If CW-mode is active, the mode will be switched automatically to "multi frequency".</p>
<p>temperature auto off</p> 	<p>Temperature at laser diodes > 60 °C. The area laser will be switched off automatically."</p>
	<p>Error in laser diode activation (Laser output too high). When this message is displayed, the output emitted varies from the output selected. Laser output still can continue. This message may also occur due to reflection of laser light on wet, reflective or mirror surfaces (i.e. wet, sweaty, light or white skin or generally heavily reflecting surfaces like light-colored metal surfaces or glass). So it does not necessarily indicate an error of the device. Please make sure that no reflective surfaces are being hit with laser light. Should the error continue in spite of your precautions, please contact our service.</p>
	<p>Error in Laserdiode activation (Laser output too low). Should this message be displayed repeatedly, most likely a laser diode is defective.</p> <p>Please contact our service.</p>

14. Technical Data – Laser shower PowerTwin21+

Power supply	110-240 V AC, 50-60 Hz, 350-150 mA Output: 12 V DC, 1,25 A
Admissible temperature range	Operating temperature: +10 to +30° C Storage temperature: 0 to +50° C
Admissible relative humidity	Operating: 30-75 % Storage/transport: 10-90%
Admissible air pressure (absolute)	Operating: 80 -106 kPa Storage/transport: 70 to 110 kPa
Dimensions	L x B x H = approx. 310 x 105 x 47 mm
Total weight	430 g
Classification	Protection class II according to EN 60601-1 Application unit BF according to EN 60601-1 Without moisture protection (IPX0) Laser class 3B according to EN 60825-1:2014
Type of laser	Semiconductor laser 808 nm
Effective output	Max. 21 x 100 mW – CW operation Tolerance +/- 10% Max. 21 x 50 mW in frequency-mode
Max. duration of pulse	0,5 seconds (for the freely selectable programs)
Beam divergence	x-direction 7,5-12°, y-direction 30-40°
Conformity	CE 0197
WEEE-Reg.-No.	DE 59335168
Manufacturer	livetec Ingenieurbüro GmbH, Marie-Curie-Str. 8, D-79539 Lörrach, Germany
Distributed by	MKW Lasersystem GmbH Landstr. 67 D-76547 Sinzheim, Germany Phone: +49 7221 / 98 83 91 Fax: +49 7221 / 98 83 93 E-Mail: mkw@mkw-laser.de Internet: www.mkw-laser.de

15. Appendix: Definition of frequencies

Anzeige Display	Frequenz
CW	Continuous Wave
Multi-Frequenz	200 Hz to 3,5 kHz - random signal derived from the quartz oscillator, impulse duration max. 0,25 msec
Alpha-Frequenz	10 Hz
Nogier A	2,28 Hz
Nogier B	4,56 Hz
Nogier C	9,12 Hz
Nogier D	18,25 Hz
Nogier E	36,5 Hz
Nogier F	73 Hz
Nogier G	146 Hz
Nogier L	276 Hz
Nogier A' (potentiated Nogier-Frequency)	292 Hz
Nogier B'	584 Hz
Nogier C'	1168 Hz
Nogier D'	2336 Hz
Nogier E'	4672 Hz
Nogier F'	9344 Hz
Bahr 1	599,5 Hz
Bahr 2	1199 Hz
Bahr 3	2398 Hz
Bahr 4	4796 Hz
Bahr 5	9592 Hz
Bahr 6	149,87 Hz
Bahr 7	299,75 Hz
Bahr + Self Heal	4625 Hz
Bahr + Qi	7695 Hz

Bahr + Serotonin	9637 Hz
Bahr + Cortison	5743 Hz
Bahr + ADHS	547 Hz
Bahr + Allergy	1927 Hz
Bahr + Interferon	699 Hz
Reininger LIV/LE	442 Hz
Reininger ST/MA	471 Hz
Reininger HEA/HE	497 Hz
Reininger PC/KS	530 Hz
Reininger LI/DI	553 Hz
Reininger GBL	583 Hz
Reininger KI/NI	611 Hz
Reininger BL	667 Hz
Reininger SP/MP	702 Hz
Reininger 3W/3E	732 Hz
Reininger SI/DUE	791 Hz
Reininger LU	824 Hz
Solfeggio 1	174 Hz
Solfeggio 2	285 Hz
Solfeggio UT	396 Hz
Solfeggio RE	417 Hz
Solfeggio MI	528 Hz
Solfeggio FA	639 Hz
Solfeggio SOL	741 Hz
Solfeggio LA	852 HZ
Solfeggio 9	963 Hz
Fi-Band	Regeneration, Pain, Interference, Trauma, Inner Center, Detox, Infection, Bones, Nerve, Transcranium, Psyche/Vegatativum, Lymph, Trigger Points
Sweep	Alpha, Purr, Beta, Theta, Delta
Cranio	
FP1 bis FP 20	Freely programmable (see chapter • Free setting of frequencies)

16. Notes on Electromagnetic Compatibility

Medical electronic devices are subject to special precautions regarding their EMC and must be installed and operated in accordance with the EMC instructions in the accompanying documents.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the laser shower including the cable and plug-in power supply. Otherwise, degradation of the performance of this device could result.

Warning: The manufacturer warrants that the device meets the EMC requirements only if the accessories are used which are listed in the EC Declaration of Conformity. Using other accessories may result in an increased emission of electromagnetic interference or reduced immunity against electromagnetic interference.

Warning: The device may not be placed directly next to or stacked with other devices. If such an arrangement is nonetheless necessary, the device must be observed to make sure that it operates properly in this arrangement.

Higher level of electromagnetic disturbance could degrade or abandon the laser output temporarily.

While respecting the hints to EMC and guidance to EMC of this user manual will, no restriction is expected to the essential performance of the medical device during its lifetime of 7 years.

Additional EMC recommendations can be found in the chapter “Safety Information” of the User Manual as well as the technical information below. Pursuant to the EMC regulations for medical products we are obligated by law to provide you the following information.

16.1 Guidance and Manufacturer’s declaration electromagnetic emissions

The Laser shower "PowerTwin 21+“ is intended for use in the electromagnetic environment specified below. The customer or the user of the “PowerTwin 21+“ laser shower should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The “powerTwin 21+“ laser shower uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions	Class B	The “powerTwin 21+“ laser shower is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2 (*)	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3 (*)	Not applicable	
(*) Note: The requirement is only valid for equipment with power input between 75 and 1000 W		


16.2 Guidance and Manufacturer’s declaration electromagnetic immunity

The Laser shower „PowerTwin 21+“ is intended for use in the electromagnetic environment specified below. The customer or the user of the “PowerTwin 21+” laser shower should assure that it is used in such an environment.

Immunity test	Test level IEC 60601-1-2:2014	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, 15 kV air discharge	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, 15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000- 4-4	± 2 kV, 100 kHz repetition frequency	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Harmonic emissions IEC 61000-3-2 (*)	+ 0,5 kV, + 1 kV	+ 0,5 kV, + 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycle Single phase: at 0°	0% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycle Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the “PowerTwin 21+” laser shower requires continued operation during power mains interruption, it is recommended that the “PowerTwin 21+” laser shower be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment. The area shower does not contain any sensitive parts or switch elements.
Note: Ut is the a.c. mains voltage prior to application of the test level.			

16.2 continued Guidance and Manufacturer's declaration electromagnetic immunity

The Laser shower „PowerTwin21+“ is intended for use in the electromagnetic environment specified below. The customer or the user of the “PowerTwin 21+” laser shower should assure that it is used in such an environment.

Immunity test	Test level IEC 60601-1-2:2014	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Veff 0,15 bis 80 MHz 6 Veff in ISM bands between 0,15 and 80 MHz 80% AM at 1 kHz	3 Veff 0,15 bis 80 MHz 6 Veff in ISM bands between 0,15 and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer than the recommended separation distance of 30 cm (12 inches) to any part of the “PowerTwin 21+” laser shower, including cables.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	 Interference may occur in the vicinity of equipment
Proximity fields from RF wireless communications equipment	385MHz – 5,7GHz 9-28V/m	385MHz – 5,7GHz 9-28V/m	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
NOTE 3: Table 9 of IEC 6100-2-1:2014 lists all frequencies and services based on RF communications equipment. It includes the immunity test level and specifications for the calculation of minimum separation distances depending on maximum power, frequency band and immunity test level.			
a) Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the “PowerTwin 21+” laser shower should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the “PowerTwin 21+” laser shower.			
b) Over the frequency range 150kHz to 80 MHz, field strength should be less than 3 V/m.			



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