POWER TWIN 21 XP5



Operating Instructions

2025-09

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 XP5 (hereafter PowerTwin) 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 XP5	Item-Code 010213
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 (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	Item-Code 030207



Fig. 1: PowerTwin (casing, top side)

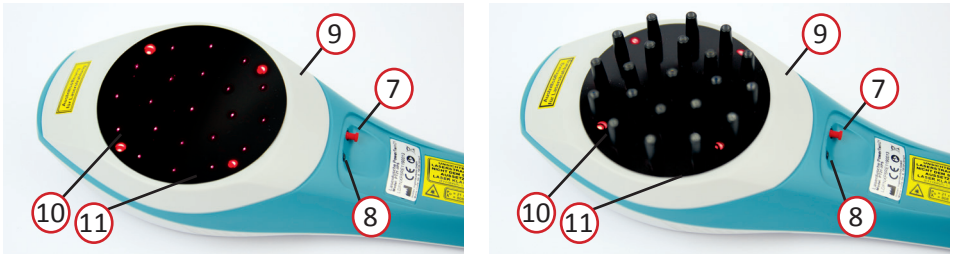


Fig. 2: shower adapter (left), comb adapter (right, optional)



Fig. 3: AC adapter for PowerTwin

1. Function keys and display elements

1		The PowerTwin 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	6a: Two red LED: On as error indication of LED diode operation, please contact customer service. 6b: Two yellow LED: On when laser output active
7	red connector	Connector for the key pin - operation of PowerTwin is only possible when the key pin is in correct position.
8	black connector	Storage for key pin when lasershower is off.
9	Adapter	Two adapter are available: • Adapter laser shower with protective glass (standard) • Adapter comb with comb tips (optional accessory)
10		Laser beam outlet
11	LEDs	4 red LEDs at the bottom indicate active laser output.

2. Intended purpose

2.1 General description of the product

The laser shower is a therapy device for low level laser therapy. Low level laser therapy belongs to the field of complementary therapy.

The application/therapy with the laser shower is carried out by emitting laser light to the skin via 21 laser diodes at the same time. Due to the arrangement of the laser diodes of the laser shower, a larger area of the body can be treated with one application.

The laser shower is moved slowly and evenly over the patient's skin surface.

2.2 Medical purpose

The PowerTwin 21 XP5 is a therapy device for low level laser therapy (LLLT) and can be used for wound healing, pain reduction and inflammation reduction.

2.3 Medical indications

The following indications are mentioned in the specialist literature. These also apply to the PowerTwin21 laser shower.

- Wound healing
- Pain reduction
- Inflammation reduction

2.4 Contraindications and exclusions

The following contraindications and treatment exclusions are mentioned in the specialist literature. These also apply to the PowerTwin21 laser shower.

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

Side-effects/ complications

- Skin irritation
- Thermal injury to skin (temperature rise exceeding 45°C)
- Damage to eyes of operator, patient or other near the device
- Skin sensitization
- Irritation of the skin or intracutaneous reactivity
- Fatigue / Dizziness

2.5 Charakterization of Patients

Patient selection

- Male, female
- Adults (greater than 18 years of age)
- Child (greater than 3 years to 18 years of age)

Patient and user contact

The application/therapy is carried out by emitting laser light to the skin via 21 laser diodes.

The laser shower is moved slowly and evenly over the patient's skin surface.

The distance to the skin should be only a few mm when doing it.

The device is not in contact with mucosal membranes, is not invasive nor an implantable device. However, depending on the body site the mucosal membrane may be treated indirectly via the skin surface.

The laser shower is a hand held device, so for the user there is a direct skin contact (hands) during the treatment to the housing.

2.6 Characterization of users

- General practitioners
- Dermatologists
- Orthopedists
- physiotherapists
- clinical specialists such as nurses according to the instructions of a physician

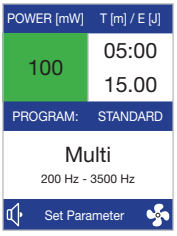
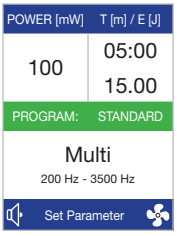
2.7 Use Environment

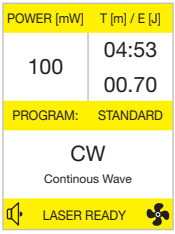
The use of the laser shower is in medical care facilities (professional healthcare).

User and patient must always wear laser protection glasses.

It must be ensured that no mirrors or other reflecting surfaces are located within the safety distance NOHD (nominal ocular hazard distance) from the laser shower (reflection of laser light).

3. Display

	Once the laser is turned on and the unit has booted up, this picture appears. The active sound output is shown by the loudspeaker symbol. Sx.x.x / My.y.y: Software status of the unit
	Default setting: Here the therapy parameters output, time, energy, and programme selection are always displayed. The status line shows the status of volume, operating status of the laser unit, and fan.
	A value shown in green can be changed with the “+” and “–” keys. On this screen the laser power level can be altered. Pressing the arrow key saves the respective value. The parameters Output, Therapy Programs, Energy Dose Rate, and/or Therapy Time can be edited.
	Specifying the settings for the therapy program – for optional settings, see p. 14.
	Setting the treatment duration.

	Setting the energy dose rate.
	This screen appears when the laser is activated. Laser power level, remaining therapy time and discharged energy dose rate in joules (J) are shown.
	This picture appears when the laser discharge is interrupted with the Laser key. Laser discharge can be continued with the Laser key. You can cancel the operation and return to the default setting by pressing the arrow key.

4. Starting Operation

4.1 Unlocking the unit

Insert the key pin into the red socket on the housing bottom of the laser shower PowerTwin (● page 5, fig. 2/7). The adapter ring for the laser shower or the laser comb must be plugged in (● Chapter 8 “Replacing the Adapters”, page 21, figs. 2/10+11).

The PowerTwin cannot be operated without the adapter ring.

4.2 Connect the power supply unit and the adapter plug

Power supply unit and PowerTwin are connected by an adapter plug. To disconnect the power supply unit from the laser shower PowerTwin, please note the following:

- Slightly push back the locking device at the plug (black sleeve = connection to the PowerTwin) and pull the two plugs apart.



Please note!

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

- If you reconnect the PowerTwin with the power supply unit, make sure you observe the direction of the arrows on the plugs.

4.3 Connecting the power supply unit to the mains

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

Please note!

Always use the original power supply unit 12V/1.25A with protection class II and CE symbols which has been provided.

4.4 Basic settings after the unit has been turned on

Once the unit has been turned on, the output data of your laser system (wavelength and maximum power) are displayed under the product name after a few seconds.

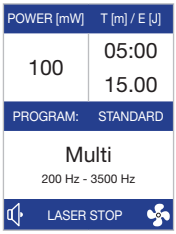


4.5 Further basic settings

You can deactivate the sound signal with the “–” key (page 5, fig. 1/3). By pressing the Laser key you can deactivate the fan (we recommend to always activate the fan).

4.6 Display of the stored therapy parameters

Subsequently the current parameter settings are shown by pressing the arrow key (page 5, fig. 1/2). When the unit is operated for the first time, the default settings are:



These are the maximum output of 100 mW, an energy dose rate of 15 J/LD (LD = laser diode) and the Multi mode of operation.

Subsequently, the values for the laser power, the therapy program and the therapy dose last set and saved will be displayed.

Changing the laser parameters

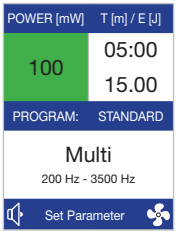
● Chapter 5.0 “Changing the Laser Parameters” (starting on page 14)

Laser activation

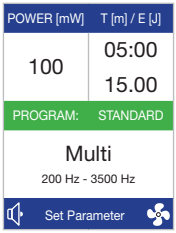
● Chapter 6.0 “Laser Application” (starting on page 19)

5. Changing the Laser Parameters

After pressing the arrow key, the POWER field turns green and can be changed by pressing the “+” and “–” keys (page 5, fig. 1/3). Possible settings are between 10 mW and 100 mW (in relation to the maximum value) in 10 mW increments.



The value is confirmed and stored with the arrow key. The field is now white again and you can set the programs (now on a green background).



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

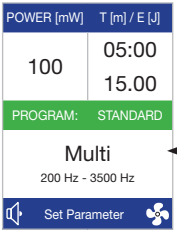
The setting options are:

● Standard programs (CW, Multifrequency, Alpha frequency) ● Nogier frequencies A–G, L ● Nogier frequencies pot. A‘–F‘ ● Bahr frequencies 1–7 ● Bahr+ ● Reininger frequencies • Reininger+ ● Solfeggio frequencies • Special frequencies ● Frequency bands (FI: Regeneration, Pain, Interference, Trauma, Inner Center, Detox, Infection, Bones, Nerve, Transcranium, Psyche / Autonomic Nervous System, Lymph, Trigger Points, Vagus, Stem Cells, Laser Blood) ● Sweeps (Sweep: Alpha, Purr, Beta, Theta, Delta) ● Cranio ● 20 freely programmable frequencies

Please note: Therapy programs and frequencies (● pages 30–32: Appendix 1)

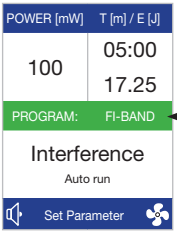
The standard programs CW, Multi or Alpha frequency can be set as follows:

Use the arrow key to go into the Program: STANDARD program mode and the +/– keys to search for the program you want. Select it by pressing the arrow key.

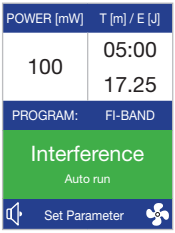


The +/– keys take you to the standard programs CW – Multi – Alpha. You can confirm the program with the arrow key.

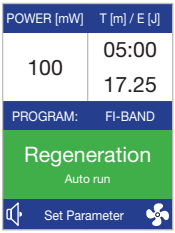
A frequency from a frequency series or an FI band or sweep can be set as follows. Always go to the respective program and press the arrow key. Example: FI band regeneration



Use the arrow key to go into Program: XXXX and chose the Program: FI-BAND by using the +/- keys. Then press the arrow key again.



In this picture you can select the desired program – Regeneration – with the +/– keys.

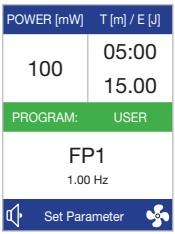


This display will then appear.

You can save the program with the arrow key.

Setting a freely programmable frequency:

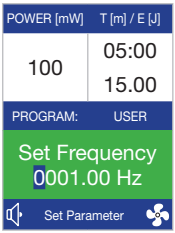
Twenty memory locations (FP1 to FP20) are available for freely programmable frequencies. Use the arrow key to get to PROGRAM: XXXX (now on a green background) and use the +/– keys to go to PROGRAM: USER.



Pressing the arrow key will take you to a storage space FP x. Use the +/– keys to select a free storage space. FP1–FP20

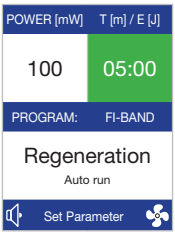


Press and hold the arrow key for 2–3 seconds to enter the programming mode (Set Frequency). You can set the desired frequency with the +/– and arrow keys (1–9,999 Hz): first set the thousands digit, then the hundreds digit, etc. Once you have set the desired frequency, confirm your choice with the arrow key. The frequency is now transferred to the treatment display.



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

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



The therapy time can be changed with the +/– keys. The arrow key confirms the selected value. Now the dose rate is shown in joules.



Press the arrow key to confirm the value.

Please note: If you change the dosage with the "+/–" key, the therapy time will also change in relation to the selected power setting.

Possible therapy time settings are:
10 seconds to 1 minute in 10-second increments
1 minute, 1:30, 2 minutes to 10 minutes in increments of 1 minute

Possible dose settings are:
0,5 J to 60 J max.

Once all laser parameters have been set, this is shown in the display. The different values are no longer on a green background, and the footer says "LASER STOP" and you can start with the laser treatment (● chapter 6.0 "Using the Laser").

Please note:

The maximum possible setting of the energy dose rate is determined by the maximum therapy time and the maximum laser power of the laser shower PowerTwin.

Example: The maximum therapy time for the laser shower PowerTwin21 XP5 is 10 minutes, and the maximum laser power is 100 mW.

The maximum energy dose rate that can be set is therefore 100 mW * 10 minutes = 100 mW * 10 * 60 seconds = 60 J/LD. The minimum dose that can be set is 1 J.

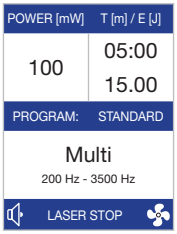
> ***Note***:
> Please keep in mind that since energy and therapy time are connected, changing one of the two parameters will also affect the other parameter.
>
> The respective other value will be adjusted automatically.

The selected value for the therapy time is confirmed and stored by pressing the arrow key again. You can now start using the laser.

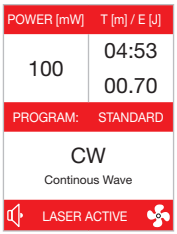
Please note that the parameters settings are retained even when the unit is turned off and on again.

6. Using the Laser

The laser application can only be activated if the parameter settings are shown on the display. Not a single field may be green.



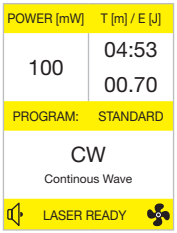
Pressing the LASER (fig. 1/4) key activates the laser after a 2-second warm-up period. The LED (fig. 1/6a) lights up yellow and the screen changes, e.g., to this display:



The screen shows the remaining therapy time and the emitted energy dose rate in Joule. The selected therapy time is now counted backwards and the energy dose rate changes in relation to the selected laser power and the elapsed therapy time according to the formula “Energy dose rate (Joule) = Laser power (mW) * Therapy time (sec.)”. A signal sounds during the energy discharge.

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 interrupted manually at any time by pressing the LASER key (fig. 1/4). An interrupted therapy is indicated on the screen.



Pressing the LASER key again will continue the therapy. Pressing the arrow key terminates the current therapy.

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

Note: If the laser is not activated, the unit will automatically turn off after 10 minutes (AUTO OFF).

7. 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 PowerTwin 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 sucession (only short pauses), rising temperature of the laser diodes take place. Reaching an internal temperature of <55° the mode is switched automatically to multi-frequency mode. The temperature symbol on the display will inform you (page 25)
- 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 PowerTwin slowly and evenly across the surface of the skin. The distance to the skin should be only a few mm when doing it.
- **Warning:** Do not activate the unit until you are in the treatment position.
- Apply ointments, lotions and creams only after a laser treatment.
- Avoid irradiating skin areas with tattoos, highly pigmented skin or moles with powers > 50mW CW to avoid the risk of thermal injury to the skin.

8. Replacing the adapters

The laser shower adapters may be replaced depending on their application. Two adapters are available. The adapter laser shower (with protection glass) is the standard adapter on the laser shower and is already mounted on every device on delivery. All treatments can be carried out with this adapter. The adapter comb is an optional accessory and can be used if the patient is very hair-covered in the area to be treated. A change may also be necessary, if one needed cleaning.

- Disconnect the lasershower PowerTwin from the mains.
- Put the PowerTwin on a flat surface, as illustrated here, and press the adapter gently against the housing with both hands (fig. 8.1).
- Turn the adapter just slightly counter-clockwise until it is in the position shown in the next illustration (fig. 8/2).
- In this position you can remove the adapter (fig. 8.3).
- When attaching the adapter, make sure that the detents are inserted into the proper recesses. Press the adapter gently against the housing with both hands and turn clockwise. The detents are now back in their initial position (fig. 8/4).
- Reconnect the PowerTwin with the mains.

Please note:

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

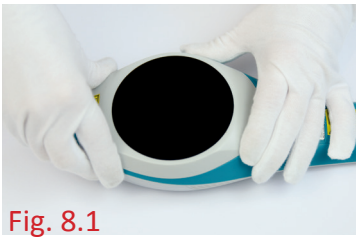


Fig. 8.1



Fig. 8.2



Fig. 8.3

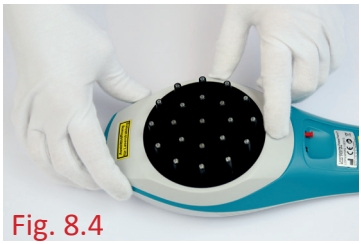


Fig. 8.4

9. Care and Maintenance

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

- To protect the PowerTwin, 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.

The service and safety checks for this laser system must be carried out every 24 months by the manufacturer or by partners authorised by him.

Scope of the inspection according to the Medical Devices Operator Ordinance (MPBetreibV):

1. visual inspection
2. check of the functional capability
3. testing of the necessary monitoring, safety, display and signalling devices
4. measurement of the safety-relevant output parameters and special technical tests. As part of the safety inspection, the output laser power is also calibrated using calibrated laser power meters.
5. test protocol and evaluation of the safety-related control

10. Safety information

Please follow the instructions given in the instructions for use and observe all warnings.

- The laser shower must be protected from unauthorised users by using the key pin.
- **Warning:** The PowerTwin may only be operated by trained medical personnel in medical practices. Treatment must be carried out under constant supervision.
- The laser radiation is not visible or only very faintly visible due to its wavelength.
- **Warning:** Do not look into the laser beam outlet and do not shine into the eyes of other persons. **Do not irradiate the closed eye either.**
- The safety distance NOHD (nominal ocular hazard distance) when looking directly into the beam is 100 cm (laser range) at the highest possible power (21 x 100 mW - CW).

  Lasers can cause damage to the eyes if used improperly, especially if the distance between the eye and the laser exit aperture is less than the safety distance NOHD (nominal ocular hazard distance). Please make sure that there are no mirrors or other reflecting surfaces within the safety distance to the PowerTwin (back reflection of laser light). **Warning: Laser safety goggles must always be worn by the user and patient.**
- Laser safety goggles must comply with EU standard EN 207 and be suitable for the laser diodes used (protection level = L3).
- **Warning:** Check the laser safety goggles for sufficient protection level before use.
- During laser treatment of patients with highly pigmented skin, moles, tattoos, unintentional heating of the irradiated skin surface may occur. Avoid direct irradiation with skin contact or at a distance <2cm from the treatment area. Minimum distance to skin >2 cm, keep applicator moving.

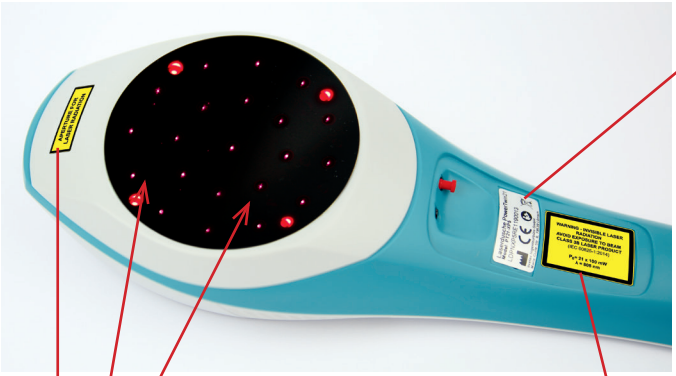
  Warning: Switch off CW-Mode on skin areas with highly pigmented skin, moles or tattoos.
- Do not use CW operation at powers >50 mW.
- Also observe the Technical Rules on Artificial Optical Radiation (TROS Laserstrahlung) as well as the Ordinance on the Protection of Employees against the Hazards of Artificial Optical Radiation (OstrV) when handling this laser product.
- **Warning:** The laser shower shall only be switched on in the treatment position. Before changing the treatment position, the laser shower must be switched off and may only be switched on again in the new treatment position.
- After treatment, the PowerTwin is switched off and the key pin is pulled out (page 5, Fig. 1).

- **Warning:** In case the laser cannot be switched off by the keys or the display fails during application, remove key pin or pull out power plug and return the device to the manufacturer.
- Medical indications may only be treated professionally with a permit.
- **Warning:** The PowerTwin may not be used when damaged
- If there is any external damage to the PowerTwin, the mains cable, the connecting plug or the mains plug, the PowerTwin laser shower must no longer be operated and must be returned to the factory.
- As the AIMING BEAM passes down the same delivery system as the WORKING BEAM, it provides a good means of checking the integrity of the delivery system. If the AIMING BEAM is not present at the distal end of the BEAM DELIVERY SYSTEM, its intensity is reduced or it looks diffused, this is a possible indication of a damaged or malfunctioning BEAM DELIVERY SYSTEM.
- Magnetic and electric fields and ionising radiation can affect the function of the unit. Therefore, do not operate the laser system in the vicinity of devices that generate large electromagnetic fields or ionising radiation - such as X-ray or diathermy devices.
- In hospitals, use is not permitted in the vicinity of active facilities with RF surgical equipment or in RF screening rooms used for magnetic resonance imaging where high intensity electromagnetic interference may occur.
- **Warning:** Do not operate the unit in rooms where there is a risk of explosion. A risk of fire and/or explosion exists when the LASER OUTPUT is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environment". The temperatures produced in NORMAL USE of the laser equipment may ignite some materials, for example cotton wool when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases.
- The PowerTwin is subject to the WEEE Directive (waste of electrical and electronic equipment) 2012/19/EU and must not be disposed of with household waste.

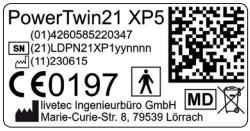


- If you take the PowerTwin out of service for good, please inform us. The manufacturer is only responsible for safety and reliability if the laser device is used in accordance with the instructions for use.
- Please note that serious incidents occurring during operation of the unit must be reported immediately to the manufacturer and the competent authorities of the country in which the unit is operated.

11. Manufacturer's labels and warning signs



Manufacturer's nameplate



APERTURE FOR LASER RADIATION

This warning sign marks the laser beam outlet of the unit. Do not look into the laser beam outlet.

WARNING - INVISIBLE LASER RADIATION
AVOID EXPOSURE TO BEAM
CLASS 3B LASER PRODUCT
(IEC 60825-1:2014)

P_0= 21 x 100 mW
λ = 808 nm

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.





Warning label laser

11.1 Definition of symbols of laser shower PowerTwin

CE 0197	CE marking. Conformity with the European Regulation (EU) 2017/745 for medical devices.
	Follow user's manual
	Application type BF
	Manufacturer
MD	Medical Device
	Date of manufacture
SN	Serial number
	Meets WEEE guideline (waste of electrical and electronic equipment) 2012/19/EU and must not be disposed of in the domestic waste.
	Warning: Laser beam
GS1 Application Labelling (AI)	(01) Global Trade Item Number (GTIN, UDI-DI) (11) Production date (YYMMDD) (21) Serial number

11.2 Definition of symbols on AC adapter

	Date of manufacture (only AC adapter) in form YY-MM
	Device of laser protection class II (only AC adapter)
AC ~	Alternating current (only AC adapter)
DC ⎓	Direct current (only AC adapter)
	Caution (only AC adapter)

11.3 Transport-/storage symbols

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

12. Error messages and safety information

⚠ Adapter ⚠ Not detected	Adapter not attached, or not attached correctly. Rectify error by attaching missing adapter, resp. attaching it correctly.
	Temperature at laser diodes > 55 °C. If CW-mode is active, the mode will be switched automatically to „multi frequency“.
Temperature Auto Off 	Temperature at laser diodes > 60 °C. The area laser will be switched off automatically.“.
⚠ WARNING ⚠ High Laser Power	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.
⚠ WARNING ⚠ Low Laser Power	Error in Laserdiode activation (Laser output too low). Should this message be displayed repeatedly, most likely a laser diode is defective. Please contact our service.

13. Technical Data – Laser shower PowerTwin21 XP5

Power supply	Power supply (medical 12V plug-in power supply FRIWO NEO018.0-1-X-12) / 110-240 VAC, 50-60 Hz, 400-200 mA Output: 12 VDC, 1.5 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 (absolut)	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	483 g (without AC adapter)
Classification	Application unit BF according to EN 60601-1 Without moisture protection (IPX0) Laser class 3B according to IEC60825-1:2014
Type of laser	Seminconductor laser 808 nm ± 5 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)
NOHD (nominal ocular hazard distance)	100 cm

Laser safety goggles for therapist (Additional periphery, optional)	Filter thickness: 3.1 mm, filter colour: yellowish-green, VLT: c. 60% Suitable for the following wavelengths: 750–785 DIR LB2 >785–805 DIR LB3 >805–825 DIR LB4 >825–855 DIR LB5 >855–10710 D LB5 + IR LB6 1064 D LB5 + IR LB7 >1070–1080 DIR LB5 >1080–1090 DIR LB4 >1090–1100 DIR LB3 The laser safety glasses meet the EU regulations for the use of class 3B medical lasers. The laser safety glasses satisfy the requirements of Directive 89/686/EEC (DIN EN 207). CE certificated.
Laser safety goggles for patient *Softcaps* (Additional periphery, optional)	Suitable for UV and diode lasers, compliant with DIN EN 207. For UV-A, UV-B, and UV-C protection when using UV lamps. Suitable for applications with 560 nm – >830 nm DI LB3, 830–880 DI LB2, VLT: 0.2%. CE certificated.
Beam divergence	x-direction 6,5°, y-direction 28°
Conformity	CE 0197
Manufacturer	livetec Ingenieurbüro GmbH, Marie-Curie-Str. 8, D-79539 Lörrach

14. Appendix: Definition of frequencies

Display	Frequenz
PROGRAM: STANDARD	
CW	Continuous Wave
Multi-Frequenz	200 Hz to 3,5 kHz – random siginal derrived from the quartz oscilliator, impulse duration max. 0,25 msec
Alpha-Frequenz	10 Hz
PROGRAM: NOGIER	
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
PROGRAM: NOGIER'	
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
PROGRAM: BAHR	
Bahr1	599,5 Hz
Bahr2	1199 Hz
Bahr3	2398 Hz
Bahr4	4796 Hz
Bahr5	9592 Hz
Bahr6	149,9 Hz
Bahr7	299,8 Hz

PROGRAM: BAHR+	
Bahr+ Self Heal	4625 Hz
Bahr+ Qi	7695 Hz
Bahr+ Serotonin	9637 Hz
Bahr+ Cortison	5743 Hz
Bahr+ ADHD	547 Hz
Bahr+ Allergy	1927 Hz
Bahr+ Interferon	699 Hz
PROGRAM: REININGER	
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
PROGRAM: REININGER+	
Reininger+ Minus-Stagnation	168 Hz
Reininger+ Interference	222 Hz
Reininger+ Degeneration	3632 Hz
Reininger+ ANS	3665 Hz
Reininger+ Pain	3894 Hz
Reininger+ Psyche	4221 Hz
PROGRAM: SOLFEGGIO	
Solfgeggio 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
PROGRAM: SPECIAL	
SF: Fasciae	20 Hz
SF: Purr M-Frequency	25 Hz
SF: Nerves	200 Hz
SF: Spleen-Kidney	440 Hz
SF: Staphylococci	728 Hz
SF: Osteitis	770 Hz
SF: Inflammation	787 Hz
SF: Streptococci	880 Hz
SF: Bones	2720 Hz
SF: Lymph	3176 Hz
SF: Pain	5000 Hz
PROGRAM: FI BAND	
FI-Band	Regeneration, Pain, Interference, Trauma, Inner Center, Detox, Infection, Bones, Nerve, Transcranium, Psyche/Vegetativum, Lymph, Trigger Points, Vagus, Stem Cells, Laser Blood
PROGRAM: SWEEP	
Sweep	Alpha, Purr, Beta, Theta, Delta
PROGRAM: CRANIO	
Cranio	
PROGRAM: USER	
FP1 to FP 20	20 freely programmable frequencies: 1,00–99,99 Hz, 100,0–999,9 Hz and 1000–9999 Hz.

15. Notes on Electromagnetic Compatibility

The laser shower PowerTwin is intended for operation in the electromagnetic environment of medical care facilities.

The customer or user of the laser shower should make sure that it is operated in an appropriate electromagnetic environment in accordance with the EMC instructions contained 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 guarantees that the device complies with the EMC requirements only if the specified accessory parts are used. 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.

15.1 Guidance and Manufacturer's declaration electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The 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 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		

15.2 Manufacturer's Declaration Concerning Electromagnetic Immunity

Immunity test	Test level IEC 60601-1-2:2014/AMD1:2020	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% Uτ; 1 cycle and 70% Uτ; 25/30 cycle Single phase: at 0° 0% Uτ; 250/300 cycle	0% Uτ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% Uτ; 1 cycle and 70% Uτ; 25/30 cycle Single phase: at 0° 0% Uτ; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the "PowerTwin" laser shower requires continued operation during power mains interruption, it is recommended that the "PowerTwin" 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: Uτ is the a.c. mains voltage prior to application of the test level.			

Immunity test	Test level IEC 60601-1-2:2014/AMD1:2020	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Veff 0,15 bis 80 MHz 6 Veff in ISM bands between 0,15 and 80 MHz 80% AM at 1 kHz 3 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz 385MHz – 5,7GHz 9-28V/m	3 Veff 0,15 bis 80 MHz 6 Veff in ISM bands between 0,15 and 80 MHz 80% AM at 1 kHz 3 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz 385MHz – 5,7GHz 9-28V/m	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” laser shower, including cables.  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: for 80Mz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is affected by absorptions and reflections of buildings, objects and people. Note 3: Table 9 of IEC 60601-1-2:2014/AMD1:2020 contains all test frequencies and immunity levels for wireless RF communications equipment. Information is also given on the calculation of the minimum protective distances as a function of power, frequency band and immunity level.			

15.3 Interference Immunity in the Near Field of Wireless RF Communication Devices (IEC 60601-1-2:2014/AMD1:2020, Table 9):

Test Frequency	Band [1]	Service [1]	Modulation [2]	Maximum power	Distance	Immunity test level	compliance level
MHz	MHz			W	Meter	(V/m)	(V/m)
385	380-390	TETRA 400	Pulse modulation [2] 18 Hz	1,8	0,3	27	27
450	430-470	GMRS460, FRS 460	FM [3] ± 5 kHz deviation 1 kHz Sinus	2	0,3	28	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation [2] 217 Hz	0,2	0,3	9	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [2] 18 Hz	2	0,3	28	28
1720 1845 1970	1700-1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [2] 217 Hz	2	0,3	28	28
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [2] 217 Hz	2	0,3	28	28

5240 5500 5785	5100-5800	WLAN 802.11a/n	Pulse modulation [2] 217 Hz	0,2	0,3	9	9
Note: To achieve the immunity test level, the distance between the transmitting antenna and the PACE T20 may be reduced to 1 m if necessary. The test distance of 1 m is permissible according to IEC 61000-4-3.							
1) For some services, only the Uplink frequencies are included. 2) The carrier is modulated with a square wave signal with a duty cycle of 50%. 3) As an alternative to frequency modulation, 50% pulse modulation at 18 Hz can be used. Since this does not correspond to the current modulation, this would be the worst-case scenario.							

15.4 Insensitivity to magnetic near fields in the frequency range 9 kHz to 13,56 MHz (IEC60601-1-2:2014:AMD1:2020, Table 11)

Test frequency	Modulation	Immunity test level (A/m)
30 kHz [a]	CW [a]	8 [a]
134,2 kHz	Pulse modulation [b] 2,1 kHz	65 [c]
13,56 MHz	Pulse modulation [b] 50 kHz	7,5 [c]
a) This test applies only to ME equipment and ME systems intended for use in a domestic environment. b) The carrier shall be modulated with a square wave signal with 50% duty cycle. c) r.m.s. before applying the modulation.		



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