

3B LASER PEN 500



Operating Instructions

Last revised September 26th, 2017

Function Keys and Display Elements	5
Display and LED Displays.....	6
Operation	7
Changing the Laser Parameters.....	8
Using the Laser.....	10
Searching for acupuncture points	11
Application	12
Use	14
Adjunctive Use	14
Contraindications	14
Maintenance and Care	15
Installing and Charging the Batteries	15
Safety Information	15
Manufacturer's Labels and Warning Signs.....	16-17
Accessories	18
Technical Data for 3B LASER PEN 500	19
Appendix 1: Therapy Frequencies / Therapy programs.....	20

Scope of Delivery

The following units are included in the delivery:

- 3B LASER PEN 500
- Charging station incl. power supply unit
- Key pin
- Rechargeable batteries (2)
- Laser protection glasses for therapist
- Laser protection glasses for patient – SoftCap
- Case
- Operating instructions

Dear User,

We are glad that you have selected an ultra-modern, quality medical product in the 3B LASER PEN, and would like to thank you for placing your trust in us.

In order to achieve the success you are looking for and to ensure that you have many years of use from your 3B LASER PEN, we would ask you to read the following usage information carefully.




If you have any questions, please feel free to contact us via e-mail: Acupuncture@3bscientific.com.

Specific therapy advice can be obtained from specialist publications or by attending user courses and workshops

This manual has been written for the operators of the 3B LASER PEN. It contains general instructions for operation, precautionary instructions, and maintenance recommendations. In order to obtain maximum life and efficiency from your 3B LASER PEN, and to assist in the proper operation of the unit, read and understand this manual thoroughly.

Precautionary instructions

The precautionary instructions found throughout this manual are indicated by specific symbols. Understand this symbols and their definitions before operating this equipment. The definition of these symbols are as follows:

 CAUTION	= CAUTION	Text with "CAUTION" indicator will explain possible safety infractions that could have the potential to cause minor to moderate injury or damage to equipment.
 WARNING	= WARNING	Text with a "WARNING" indicator will explain possible safety infractions that will potentially cause serious injury and equipment damage.
 DANGER	= DANGER	Text with a "DANGER" indicator will explain possible safety infractions that are imminently hazardous situations that would results in death or serious injury.

- Read, understand, and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any laser light device. Observe the precautionary and operational decals placed on the unit.
- Do not operate this unit in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- Handle the unit with care and in accordance with the instructions outlined in the manual. Inappropriate handling of the unit may adversely affect its characteristics.
- This unit should be operated in temperatures between 50 to 86 °F (10 to 30 °C), and transported and stored in temperature between 32 to 122°F (0 to 50 °C), with relative humidity ranging from 30 % to 75 %.
- Do not disassemble, modify, or remodel the unit or accessories. This may cause unit damage, malfunction, electrical shock, fire, or personal injury.
- Failure to use and maintain the 3B LASER PEN and its accessories in accordance with the instructions outlined in this manual will invalidate your warranty.
- Do not open the housing. This may cause unit damage, malfunction, electrical shock, fire, or personal injury. If a malfunction occurs, discontinue use immediately and consult the dealer for repair service.
- Do not permit any foreign materials or liquids to enter the unit. Take care to prevent any foreign materials including, but not limited to, inflammables, water, and metallic objects from entering the unit. These may cause unit damage, malfunction, electrical shock, fire, or personal injury.
- If you have difficulty operating the unit after carefully reviewing this user manual, contact your dealer for assistance.
- U.S. federal law restricts this device to sale by, or on the order of, a physician or licensed practitioner.
- This unit generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this unit on and off.
- You must only connect original 3B parts due to the scope of delivery. Other parts or materials can degrade minimum safety.

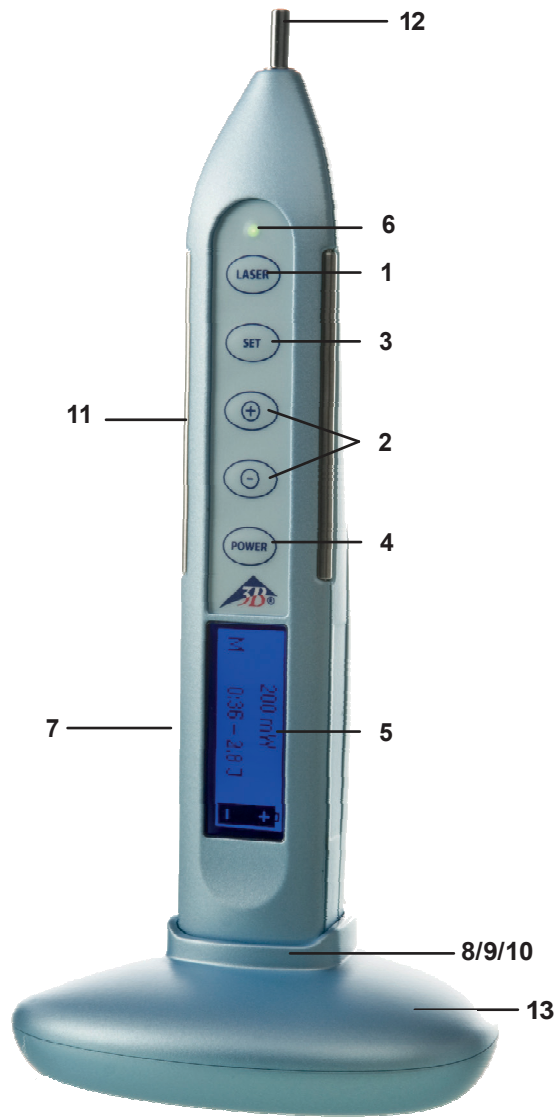
WARNING

- Be sure to read all instructions for operation before treating a patient. Observe the regulations for handling the 3B LASER PEN.
- Do not drop the unit, accessories on hard surfaces. Do not submerge the unit, accessories in water. All of these conditions will damage the unit. Damage resulting from these conditions is not covered under the warranty.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to laser light energy.
- This device should be kept out of the reach of children.
- This device should be used only under the continued supervision of a licensed practitioner.
- Dispose of all products in accordance with local and national regulations.
- This equipment is not designed to prevent the ingress of water or liquids. Ingress of water or liquids could cause malfunction of internal components of the system and therefore create a risk of injury to the patient.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous conditions causing damage to the unit and applicator.
- Care must be taken when operating this unit adjacent to or stacked with other equipment. Potential electromagnetic or other interference could occur to this or other equipment. Try to minimize this interference by not using other equipment (i. e. cell phones, etc.) in conjunction with it.
- Use only accessories that are specially designed for this unit. Do not use accessories manufactured by other companies.
- Use of other accessories other than those specified may result in increased emissions and decreased immunity.
- If laser is not in use, shut of the unit with key „Power“.
- Laser equipment not in use should be protected against unqualified use.
- Some patients are more sensitive to laser output (i. e., patients taking medications that increase sensitivity to light) and may experience a reaction similar to a heat rash.

DANGER














- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the unit is used.
- Avoid direct eye exposure. Laser protective eyewear should be worn by the operator and patient to block infrared light energy from the eyes during treatment.
- Do not point the laser light beam directly into human or animal eyes.
- Observe the safety information.









Function Keys and Display Elements



1	LASER	The laser is activated/deactivated with this key.
2	+ / -	The values selected with the SET key can be changed with these keys.
3	SET	The values can be selected and stored with this key.
4	POWER	The 3B LASER PEN is switched on and off with this key.
5	Display	The selected laser power level, operation mode, point search mode, therapy time, and dose rate as well as information about the battery charge are shown on the display screen.
6	LED	This LED above the LASER key indicates whether the laser has been activated. An error in the laser diode operation is indicated by a red light. When this happens, please contact our technical service.
7	Battery compartment	Battery compartment is at the bottom of the housing.
8	Red connector	Red connector connector for the key pin
9	Charging contacts	Charging contacts for the charging station
10	Black connector	Connector for storing the key pin
11	Contact surface	For the point search
12	waveguide	Laser beam outlet
13	Charging station with power supply unit	For charging the batteries

Display and LED Displays

<p>3BLASERPEN V.....</p>	<p>This screen appears during the booting process after the laser unit has been turned on. The first line shows the specific model, and the second line the software status of the unit.</p>
<p> 3BLASER PEN 808nm 500mW </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 of the specific model. The battery charge status is shown on every screen. The loudspeaker icon indicates whether the sound is activated. If the sound is deactivated, the loudspeaker icon is crossed out.</p>
<p>300mW 60.0J A CW </p>	<p>Base setting. The current therapy parameters (laser power, point search program, therapy program, energy dose rate) and the battery charge status are displayed.</p>
<p>100mW 60.0J M CW </p>	<p>A value that appears highlighted can be changed with the + and - keys. On this screen the laser power can be altered. Pressing the SET key saves the selected value. The parameters output, point search mode, therapy programs, energy dose rate, and/or therapy time can be altered.</p>
<p>500mW 60.0J M CW </p>	<p>Setting the point search mode and starting the laser unit manually or automatically. M = manual point searching, A = automatic point searching, 0 = point searching not activated</p>
<p>100mW 60.0J M CW </p>	<p>Setting the therapy program.</p>
<p>100mW 60.0J M CW </p>	<p>Setting the energy dose rate. Max. = 60 J</p>
<p>100mW 10:00 M CW </p>	<p>Setting the therapy time. Max. = 10 min.</p>
<p> M 63 LW </p>	<p>In point search mode M, the conductance of the skin is indicated by a bar chart and shown as a digital value (0–99).</p>
<p> A 00 LW </p>	<p>In point search mode A, the stored skin conductance value is shown as a hatched bar and as a digital value in the second line.</p>
<p>100mW M 4:43 -8.5J </p>	<p>This screen appears when the laser is activated. Laser power level, point search program, as well as the remaining therapy time and the discharged energy dose rate in J are shown.</p>

 <p>WARNING</p>	<p>This screen appears when the batteries are empty and must be charged. In this condition it is not possible to activate the laser pen.</p>
 <p>3B LASER PEN 808nm 500mW</p>	<p>The charging process is indicated with this screen.</p>
 <p>WARNING</p>	<p>When this appears, insert key pin into red connector.</p>
 <p>WARNING</p> <p>High Laser Power</p>	<p>Warning: laser power error. This message appears when the laser power level may be outside the tolerance range. In most cases, however, this is due to reflections on reflecting surfaces (wet and/or white surfaces). Please notify our Service Department if you see this error message repeatedly.</p>
 <p>WARNING</p> <p>Low Laser Power</p>	<p>Error in the laser diode operation (laser power too low). If you see this message repeatedly, the laser diode is most likely defective. In this case please notify our Service Department.</p>
	<p>LED display of laser power level: The green LED indicates that the laser is activated.</p>
	<p>LED display says "Error": The red LED indicates that an error has occurred. In this case always check the message on the display.</p>
	<p>Laser pen can only be operated when the key pin has been inserted into the red connector. To insert the key pin in the black connector will lock the unit.</p>

Operation

You may only use the 3B LASER PEN with inserted wave guide. Never use the 3B LASER PEN without wave guide. Insert the red key pin into the red connector on the left (8) and turn on by pressing the POWER key (4). The display now shows the following message:



The output data of the specific laser system (wavelength and max. output) are indicated in the second line.

You can turn around the display (right-handed/left-handed users) with the “+” key (2). The sound (which is issued every 20 s during laser discharge) can be turned on and off with the “-” key (2). When the loudspeaker icon is crossed out, the sound is turned off.

By pressing the “SET” key you can then have the current parameters (initial setting) of the unit shown as follows:



The display always shows the values for laser power, point search mode, therapy program, and energy dose rate that were selected last (stored).

When the unit is operated for the first time, the maximum output (500 mW), the operation mode CW, point search mode OFF (0) and the energy dose rate 60 J (Therapy time 5 min.) are always preset.

The parameters can be modified as explained in the chapter “Changing the Laser Parameters”.

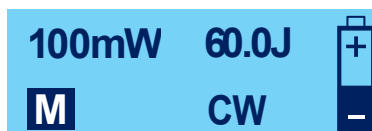
The laser discharge is started as explained in the chapter “Using the Laser”.

Changing the Laser Parameters

When the SET key (3) is pressed, the output value flashes as in the illustration below and can be changed with the “+” and “-” keys (2). The settings can be 100 / 200 / 300 / 400 / 500 mW.



By pressing the SET key (3) again, the selected value is confirmed and stored. The display changes to the following screen. The point search mode can now be altered with the “+” and “-” keys (2).



The setting options for the point search mode are “0” (point search off), “M” (manual point search) and “A” (automatic point search). (See the chapter “Point Search”. By pressing the SET key (3), the selected value is confirmed and stored.

The information on the screen changes into the following display.



The therapy program can be changed with the “+” and “-” (2) keys and saved with the SET key.

The setting options are:

CW – Multifrequency – Alpha frequency – Nogier frequencies A–G – Bahr frequencies 1–7 – Reiningger frequencies 18 – Nogier frequencies pot. A’–G’ – freely programmable frequencies between 1 and 9999,99 Hz.

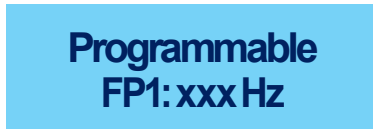
For therapy programs and frequencies, see Appendix 1 (page 20)

A single frequency can be selected as follows:

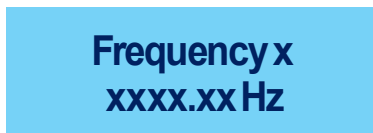
When the value on the display flashes, go to the respective frequency program by pressing the “+” or “-” key. Then press the SET key for 2–3 sec. This gets you into the setting mode for the specific frequency. Use the “+/-” key to select the desired frequency and confirm it with the SET key. When you press SET again, the selected frequency is shown on the display (now the value frequency is stored and now more flashing).

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 “Pro-grammable” screen on the display.



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



You can set the desired frequency (1 – 9999 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 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 energy dose rate can be changed with the “+/-” keys. The SET key confirms the selected value. Depending on the selected laser power the LASER PEN calculates automatically the therapy time required.



Please note: Changing the therapy time with the “+/-” keys also changes the dose required for this therapy time depending on the selected output.

Possible settings for the therapy time are:

10 sec.–1 min. in 20-sec. increments

1 min.–10 min. in 1-min. increments

Possible settings for the dose are depending on the specific model and are :

3B LASER 500 / 1 J–60 J max.

Once all laser parameters have been set, this is shown in the display. The different values are now no longer flashing and you can start with the laser treatment – see the chapter “Using the Laser.”

Please note:

The maximum energy dose rate that can be selected is 60 J.

Example: If the setting is 60 J (dose), laser/power 500 mW and mode CW set, the therapy time is 2 minutes, and for frequency modes it's 4 minutes.

Note: Please understand that due to the correlation between energy and therapy time, changing one of the two parameters will also impact the other parameter. The respective other value will be automatically adjusted accordingly.

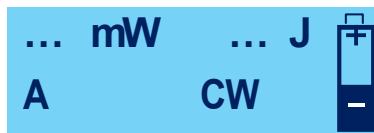
The selected value for the therapy time is confirmed and stored by pressing the SET key (3) again. You can now start using the laser (see the chapter “Using the Laser”).

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

Using the Laser

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

Please note: It is not possible to activate the laser, if a parameter is still flashing.



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



The display (5) now shows the remaining therapy time and the emitted energy dose rate in Joule as well as the selected point search mode. 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.)”.

If the loudspeaker has been turned on, a signal will sound every 20 sec.

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 short triple sound signal.

Treatment can be terminated manually at any time by pressing the LASER key (1).

Once the therapy has ended, the screen changes back to the “Base setting” display.

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

1. The 3B LASER PEN must only be operated with inserted laser tip.

2. **Risk of burns:**

When the laser output is >300 mW, especially in CW mode, the skin is heated. Please alert the patient to this fact. Terminate the therapy session immediately when the patient finds the laser therapy too hot.

No direct irradiation of tattoos, moles, highly pigmented skin or from a distance to the treatment area less than 2 cm.

When applying a laser output of more than 300 mW, please note:

No irradiation with direct contact.

Distance to the skin approx. 2 cm.

Move the applicator slowly over the treatment area making circular or linear motions.

Max. dosage in treatments per patient: 60 Joule.

Please double-check on the monitor that the correct dosage has been set before starting treatment. The therapy time is calculated automatically on the basis of the selected laser power and programme.

Maximum treatment time per patient is 10 min.

3. **Risk of infection:**

When treating injured skin and wounds, avoid direct contact with the skin to prevent contamination with germs.

In the presence of wounds and injuries, keep a distance of approx. 1 cm to the skin.

4. Please replace the tip after each treatment. A second tip has been provided.

Disinfect the laser tip after each treatment.

The tip may be disinfected in an autoclave or via spray-and-wipe disinfection with a 70% alcohol .

The 3B LASER PEN works with a maximum laser output of 500 mW. At maximum power (500 mW in CW mode) and a fully charged battery, the battery time is approx. 1 h.

If the battery time becomes significantly shorter, replace the batteries with new ones.

As a general rule, the unit should be placed in the charger station after every application. But note that the laser pen must be charged whenever the battery level indicator is $<50\%$.

Charge the unit as long as possible, preferably until the charge symbol “disappears” (4 h).

Always keep a fully charged replacement battery at hand. Please note the user manual for the charger that has been supplied.

Use only batteries of the same kind (AA – NiMH 1.2 V – min. 2,450 mAh). How to replace the batteries is explained on p. 15 of the User Manual.

Searching for acupuncture points

Acupuncture points exhibit a different electronic response compared to the immediately adjacent areas of skin which appear visibly identical. These points can be detected as zones with an increased skin conductivity (equivalent to a reduced electric resistance of skin).

This fact is the basis when working with a point searching unit. To activate the point searching device you need to change into the modus M. From the starting position press the key SET twice. Now you can change the modus with keys + or -. The following modus are possible:

- 0 = point searching off, M = manual point searching, A = automatic point searching

Modus M (manual point searching)

By touching one of the metallic contact surfaces and simultaneously tou-ching the skin of the patient the point searching is active.

(See picture) The skin conductance is displayed both as a bar image and as a digital value (0-99). A sound signal shows if the value of the skin's conductance is getting higher or lower.

Gently press the 3B LASER PEN perpendicularly onto the skin in the vicinity of the expected acupuncture point. You can search for acupuncture points by moving the 3B LASER PEN over the skin.

Skin zones exist where the conductivity value is below the measuring range (display indicates a value of 0). In this case you must press the 3B LASER PEN more firmly onto the skin or slightly moisten the area. In the modus M (manual point searching) you can activate the 3B LASER PEN by pressing the key LASER key at the highest measured value.



Modus A (automatic point searching)

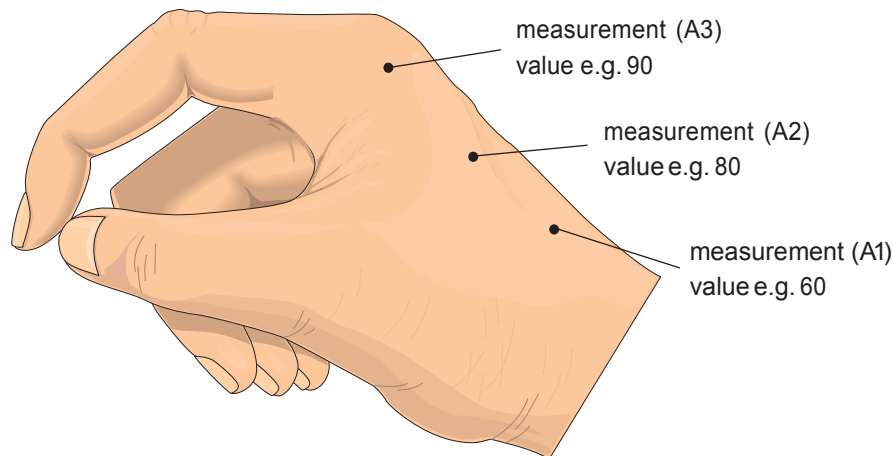
If you stay in modus M (manual point searching) and you briefly press the SET key you can store the actual skin conductance. The stored value is shown on the display as a digital value and as a hatched bar. The point searching modus in the display changes to A. The automatic laser function has now been activated.

While point searching there is always a continuous comparison between the actual skin conductivity and the stored value. If you find a point with a higher conductivity as the stored value then this is seen in the bar-display. If the 3B LASER PEN is not moved, and the actual measured value is stable for 2 seconds and greater than the stored value, the 3B LASER PEN automatically switches on. Now the display indicates the therapy time and the treatment dose.

Measurement

For example, if you store the skin's conductivity value at point A1 and then move the 3B LASER PEN in the direction of A2, the displayed conductivity values will be greater than 60 in this example.

If you carry out the measurement at A2, conductivity values will only be displayed where the compared value is greater than 80. Any points below 80 will not be displayed, etc.



This method allows you to locate the acupuncture point relatively accurately.

To search for another point, first remove the 3B LASER PEN from the skin. The laser switches to the automatic status again, the measured value remains stored.

To delete the stored value you have to press the SET key. After doing that you are back in the basic setting and the point search modus is OFF.

The complete procedure as described must be repeated each time you search for a new point.

Please note:

Switching-on the laser does not necessarily mean that you have found an acupuncture point. It only means that the current conductivity value is higher than the stored value. It may well be the case that you have to carry out several measurements before you find the point.

Working with the 3B LASER PEN does not replace knowledge of the positions of acupuncture points. Extremely moist, dry or hairy skin, or also an extremely high atmospheric humidity in the room, may lead to faulty results.

Acupuncture points can possibly lie very deep under the skin and are extremely difficult to find. The same applies to points which are not active. It is extremely difficult, and sometimes even impossible, to find such points using a point searcher. A measurement is very accurate if the acupuncture points are located relatively far apart. It is understandable that point searchers will have difficulties if the acupuncture points are situated very closely together.

Application

The following must be observed if you wish to achieve optimum success with the therapy.

- To keep reflection losses as low as possible, skin must be grease-free, and the 3B LASER PEN must be held perpendicular to the skin.
- A general rule that applies to all treatments is the principle of tapering dosage. Initial treatments should last no longer than 5 minutes.
- Maximum treatment time per patient is 10 min. After this time the unit turns off automatically.
- The distance between the applicator and the skin should be no more than a few mm, or direct contact.



- Move the 3B LASER PEN over the skin slowly and uniformly, and only activate it when it is in treatment position.
- Only apply creams or lotions after the laser treatment has been finished. Clean the laser beam outlet using 70 % ethanol following each contact with skin and for each new patient.

Use

The 3B LASER PEN is intended to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of muscle and joint pain and stiffness, arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

Adjunctive Use

The 3B LASER PEN may be used adjunctively for the following:

- symptomatic relief of minor pain
- minor muscle and joint pain
- minor muscle
- spasms
- relief of associated minor stiffness and pain associated with arthritis - promoting relaxation of muscles

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Contraindications and Precautions

The following contraindications and precautions are referred to in the laser literature:

Absolute:

- Irradiation of eyes
- Photosensitivity
- No direct irradiation of cancerous tissue
- Open fontanelles and epiphyseal cartilage in children
- Thyroid gland hyperactivity

Relative:

- Pacemaker patients (thorax)
- Epilepsy (head)
- Pregnancy (stomach and back regions)
- Endocrine organs (Thyroid gland, testicles, ovaries)

Therapy hindrances:

- deep X-ray treatment
- permanent medication
- chemotherapy

Maintenance and Care

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

- The laser beam outlet must be cleaned with a cotton swab using 70 % ethanol (medical alcohol) every time it has come in contact with skin or for each new patient.
- Do not expose the unit to direct sunlight.
- The housing may be cleaned with a mild detergent and a damp cloth. The 3B LASER PEN must be disconnected from the charging station for cleaning. Disconnect the power cord before cleaning.
- Unauthorised repairs or modifications of the 3B LASER PEN may put users or patients in jeopardy. Therefore repairs may only be performed by the manufacturer or by persons who have been authorised by him. Unauthorised opening may result in the uncontrolled discharge of laser radiation and will void the warranty. Please contact the technical service if repair is necessary.
- Operate the 3B LASER PEN only in closed rooms at room temperature. The laser warning sign which has been supplied must be attached to the door.
- Please protect the unit against moisture.

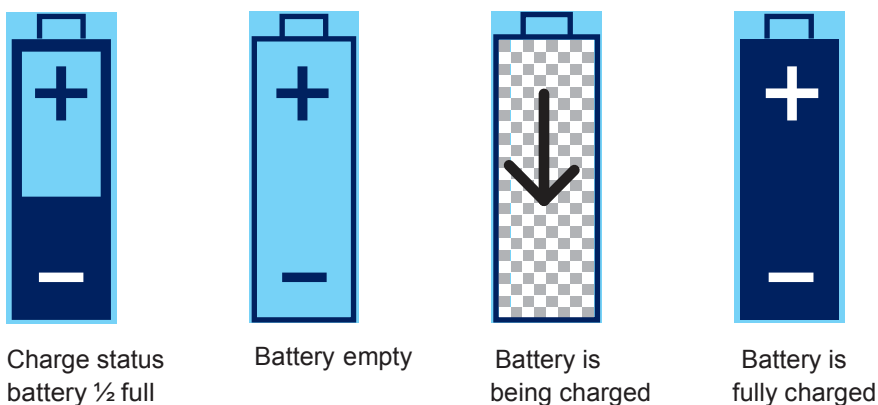
The mandatory safety controls must be performed every 24 months for this laser system.

Installing and Charging the Batteries

The laser pen 3B LASER PEN must be charged prior to first use. To do this open the battery compartment cover on the back of the 3B LASER PEN carefully with a pointed object or enclosed plastic part and insert the two rechargeable batteries supplied. Make sure to match the + and – symbols in the compartment. Replace the battery compartment cover firmly.

Use only the rechargeable batteries supplied or batteries that conform to the technical specifications indicated (see the chapter “Technical Data”). Never use normal batteries. Using the wrong rechargeable batteries or normal batteries may damage the unit.

Connect the charging station supplied to the power source (100 V–230 VAC) and insert the 3B LASER PEN vertically into the charging station. The battery charge status is always shown in the display (5).



When the charging process is complete (the batteries are fully charged) remove the 3B LASER PEN from the charging station.

Important: The 3B LASER PEN may not be stored with empty rechargeable batteries. We recommend removing the rechargeable batteries if you are not intending to operate the unit for a period of >1 month. Rechargeable batteries that have been removed must be charged at least every three months. The battery charge control takes the memory effect into account, so you can charge the device after each treatment without having to worry.

Safety Information

Please observe the instructions in the operating manual strictly and heed the warnings (see warning signs in the chapter “Manufacturer’s Labels and Warning Signs”). Using the operating elements, settings and procedures other than described in the operating instructions may result in hazardous laser radiation.

The 3B LASER PEN must be protected against unintentional operation by using the key pin.

To this end, insert the key pin into the black connector (10) after you are finished using the unit.

Also please observe the provisions of the pertaining national Accident and Prevention Insurance regulations on “Laser Radiation”.

The 3B LASER PEN may only be operated by specialised medical staff who have been trained in handling the unit. Treatment must be supervised at all times.

Portable and mobile HF communication devices can disrupt the proper functioning of the unit. This device is subject to special precautions regarding EMC and therefore may only be installed and operated in accordance with the instructions provided in the accompanying document entitled “Notes on Electromagnetic Compatibility”.

Do not look into the laser beam outlet and do not point into the eyes of other persons even if the eyes are closed. During laser applications near the eyes, the eyes require special protection.

The safety distance for the 3B LASER PEN is 500 cm (78.74 inch).

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 3B LASER PEN (reflection of laser light).

User and patient must always wear laser protection glasses. Laser protection glasses must meet the European EN 207 standard and be suitable for the laser diodes used (protection level = L3).

The laser system must only be switched on when it is in the treatment position (in direct contact with or a few mm distance from the treatment area). When the treatment position is changed, the laser must be turned off and only be turned on again when it is in the new treatment position. After the treatment the 3B LASER PEN must be switched off.

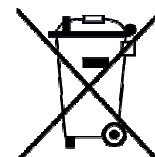
If the 3B LASER PEN or the charging station shows any signs of external damage, the device may no longer be operated and must be returned to the manufacturer.

Magnetic and electric fields as well as ionizing radiation may influence the functioning of the unit. For this reason you should not operate the laser system near devices which generate large electromagnetic fields or ionizing radiation, such as X-ray machines, diathermy equipment, and wireless telephones. Do not operate the unit in rooms which are subject to the risk of explosion.

The 3B LASER PEN and the rechargeable batteries are subject to the WEEE Directive (waste of electrical and electronic equipment) 2002/96/EC and must not be disposed of as normal household waste. This also applies to the rechargeable batteries that are part of the unit.

If you wish to discontinue using the 3B LASER PEN for good, please let the supplier or MKW Lasersystem GmbH know. The manufacturer is only responsible for safety and reliability if the laser device is used in accordance with the operating instructions.

Operate the 3B LASER PEN only in closed rooms at room temperature. The laser warning sign which has been supplied must be attached to the door.


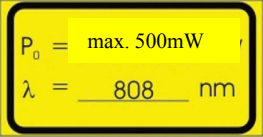




The manufacturer is only responsible for safety and reliability if the laser device is used in accordance with the operating instructions.

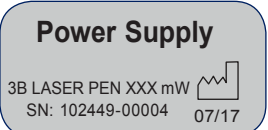
Operate the 3B LASER PEN only in closed rooms at room temperature. The laser warning sign which has been supplied must be attached to the door.

Manufacturer's Labels and Warning Signs



3B LASER PEN 500

	Laser warning sign, hazard symbol according to IEC 60825-1 and warning of laser radiation/power
	Warning label of the radiation / laser power emitted according to IEC 60825-1 LA-X 500 = P _o max. 500 mW / λ = 808 nm
	Label at the laser beam outlet
	Manufacturer's label Models 3B Laser 500






3B LASER PEN charging station

	Label for charging station
---	----------------------------

CAUTION • WARNING

	Federal law restricts this device to sale by or on the order of a physician.
	Use carefully. May cause serious burns. Do not use over sensitive skin areas or in presence of poor circulation. The unattended use of 3B Laser Pen by children or incapacitated persons may be dangerous.

Labels

	Observe the operating instructions
	Observe the disposal regulations
	Name of manufacturer
	Production date
	CE symbol
0197	Notified body

Accessories

- Protective Glasses – Therapist
- SoftCap Protective Glasses – Patient
- Rechargeable AA-size NiMH batteries min. 2.400 mAh
- Spare wave guide
- 2 pc. Spare rechargeable batteries

Technical Data for 3B LASER PEN

General	
Product name	3B Laser Pen
Device type	Low level laser therapy device
Proper use	Low-energy laser system for the treatment of pain, trigger and acupuncture points as well as small skin areas
Classification and standards	
Classification	Protection class II according to EN 60601-1 Application unit BF according to EN 60601-1 Class IIA according to RL 93/42 EEC Laser class 3B according to EN 60825-1: 2008 EN 60825-1: 2008 100 cm Without moisture protection (IPX0)
Standards	EN60601-1: 2006 Medical electrical devices EN60601-1: 2007 Medical devices, EMC standard IEC 60601-2-22: 2007 Medical devices, laser application standard EN60825-1: EN60825-1: 2007 Safety of laser devices
Laser Power	
Effective laser output, wavelength	500 mW/808 nm
Setting of laser power	From 10% to 100% of the effective output in increments of 10%
Type of laser	Semiconductor laser 808 nm
Therapy programmes	See Appendix 1
Therapy times	10 minutes max., max. dose 60 J
Beam divergence	808 nm: x-direction 8-11°, y-direction 39-48°
Operation	
Operating elements	“ON/OFF” key for switching the laser output on or off “Laser” key for switching the laser output on or off “SET”, “+”, “-” keys for setting the therapy parameters (programmes, power level, automatic operation)
Display elements	Green LED “POWER”: laser output is activated Red LED “ERROR”: error message concerning laser power monitoring LCD: 128x32 points to display the therapy parameters and error messages
Power supply	
Power supply	Via integrated rechargeable batteries (NiMH)
Rechargeable batteries	NiMH (2 cells) / 1.2 V, AA size, 2,600 mAh capacity Service life in battery-operated mode (when batteries are fully charged): >2h Charging time: approx. 3 h Manufacturer: e.g. Panasonic, HHR-3XRE, 2,600 mAh
Safety fuse	2A, power supply unit also short-circuit-proof
Mechanics and environment	
Permissible temperature range and relative humidity	Operating temperature: 10°C – 30°C Storage temperature: 0°C – 50°C Relative humidity: 30-75% Ambient air pressure: >80 kPa
Dimensions	Applicator: W x H x D = 34 x 36 x 225 mm Charging station: W x H x D = 107 x 35 x 106 mm
Weight	Applicator: approx. 200 g Charging station: approx. 230 g
Housing	Plastic/ABS
Manufacturer	
Name of manufacturer	Livetec GmbH, Marie-Curie-Str. 8, 79539 Lörrach, Germany
Conformity	CE 0197
WEEE reg. no.	FE 59335168
Sold by	American 3B Scientific, 2189 Flintstone Dr., Suite O, Tucker, GA 30084, USA phone 1.678.405.5807, cell 1.770.310.5886, fax 1.678.405.5728

Appendix 1: Therapy Frequencies / Therapy programs

Program	Frequency
CW	Continuous wave
Multi-frequency:	200Hz bis 3,5 kHz
Alpha-frequency:	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:	73,0 Hz
Nogier G:	146,0 Hz
Nogier L:	276 Hz
Nogier A' (exponential Nogier-frequency)	292 Hz
Nogier B'	584 Hz
Nogier C'	1168 Hz
Nogier D'	2336 Hz
Nogier E'	4672 Hz
Nogier F'	9344 Hz
Nogier G'	146 Hz
Bahr 1	599,5 Hz
Bahr 2	1199,0 Hz
Bahr 3	2398,0 Hz
Bahr 4	4796,0 Hz
Bahr 5	9592,0 Hz
Bahr 6	149,87 Hz
Bahr 7	299,75 Hz
Reininger 1:	442,0 Hz
Reininger 2:	471,0 Hz
Reininger 3:	497,0 Hz
Reininger 4:	530,0 Hz
Reininger 5:	553,0 Hz
Reininger 6:	583,0 Hz
Reininger 7:	611,0 Hz
Reininger 8:	667,0 Hz
Reininger 9:	702,0 Hz
Reininger 10:	732,0 Hz
Reininger 11:	791,0 Hz
Reininger 12:	824,0 Hz
FP1 to FP 20	Freely programmable in the range between 1 Hz and 9,999 Hz

Laser system 3B Laser
Notes on Electromagnetic Compatibility

Medical electronic devices are subject o special precautions regarding their EMC and must be installed and operated in accordance with the EMC instructions in the accompanying documents. In particular, medical electronic equipment may be influenced by portable and mobile HF communication devices.

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.

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. 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.

Guidance and Manufacturer’s declaration - electromagnetic emissions

The 3B Laser is intended for use in the electromagnetic environment specified below. The customer or the user of the 3B Laser should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The 3B Laser uses RF energy only for is internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The 3B Laser 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 (< 75 W)	
Voltage fluctuations/flicker emissions IEC 61000-3-3 (*)	Not applicable (< 75 W)	
(*) Note: The requirement is only valid for equipment with power input between 75 and 1000 W		


Guidance and Manufacturer's declaration - electromagnetic immunity

The 3B Laser is intended for use in the electromagnetic environment specified below. The customer or the user of the 3B Laser should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment- guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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 for power supply lines ± 1 kV for input/output lines (not applicable, no input/output lines)	± 2 kV for power supply lines ± 1 kV for input/output lines (not applicable, no input/output lines)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth (not applicable, no earth connection)	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth (not applicable, no earth connection)	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	< 5% U _T for ½ cycle (> 95% dip in U _T) 40% U _T for 5 cycles (60% dip in U _T) 70% U _T for 25 cycles (30% dip in U _T) < 5% U _T for 5s (> 95% dip in U _T)	< 5% U _T for ½ cycle (> 95% dip in U _T) 40% U _T for 5 cycles (60% dip in U _T) 70% U _T for 25 cycles (30% dip in U _T) < 5% U _T for 5s (> 95% dip in U _T)	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruption, it is recommended that the device is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

The „3B Laser“ is intended for use in the electromagnetic environment specified below. The customer or the user of the “3B Laser” should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment- guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 V eff. 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3 V eff.</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the LDU8021PN laser system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strength from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b).</p> <p>Interference may occur in vicinity of equipment with the following symbol.  the marked</p>

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.

- (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 3B Laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the 3B Laser.
- (b) Over the frequency range 150kHz to 80 MHz, field strength should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the 3B Laser.

The 3B Laser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 3B Laser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 3B Laser as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of in m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.



...going one step further

American 3B Scientific
2189 Flintstone Dr, Suite O
Tucker, GA 30084
USA

Tel: +1.678.405.5807
Cell: +1.770.310.5886
Fax: +1.678.405.5728