Instruction Manual
ProSeries

Contents

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1. GENERAL INFORMATION

This instruction manual applies to the ProSeries Medical Laser by SYMBYX. This laser device is manufactured by Spectro Analytic Irradia AB of Sweden and is the result of a product collaboration between the two companies. (Note: Irradia also manufacture an identical product called the MID 2.5 Laser). Please read this manual before using the product and keep the manual at hand for future reference when necessary. MEDICAL ELECTRICAL EQUIPMENT requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS. Portable and mobile RF communication equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

“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 this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.”

The use of accessories, cables, and transducers other than those specified herein as replacement parts for internal components, with the exemption of transducers and cables sold by the manufacturer of the EQUIPMENT, may result in increased EMISSIONS or decreased IMMUNITY of the EQUIPMENT. The EQUIPMENT should not be used adjacent to or stacked on top of, other equipment. If it is necessary to use the EQUIPMENT under those circumstances, the EQUIPMENT should be continuously observed in order to verify normal operation in the configuration in which it is used. The RESPONSIBLE ORGANIZATIONS are advised to carry out all adjustments and cleaning and disinfection PROCEDURES as specified herein. The RESPONSIBLE ORGANIZATIONS are reminded that the assembly of ME SYSTEMS, as well as modifications during the actual service life, is evaluated as regards to the requirements of IEC60601-1.

Many countries have regulations, laws, requirements, and standards for personal protective equipment and the installation and use of lasers, including their clinical use. Contact the appropriate national agency for the correct user requirements.

1.1 Product Description

This product is a TRANSPORTABLE INTERNALLY POWERED MEDICAL ELECTRICAL EQUIPMENT that is a NON-INVASIVE CLASS IIIb ACTIVE THERAPEUTIC DEVICE, with which the OPERATOR administers TRANSIENT PULSED CLASS 3B INFRARED A (IRA) or visible LASER radiation to a PATIENT. The equipment consists of two parts, the INTERNALLY POWERED Base Unit and the HAND-HELD devices which emits LASER light through the APPLIED PART (or laser APERTURE), and the Lithium-Ion battery charger which can charge and power the device through the MAINS SUPPLY. The HAND-HELD device is classified as a TYPE B APPLIED PART and is considered to be a CLASS II electrical equipment when connected to the MAINS

SUPPLY through the Lithium-Ion battery charger, and INTERNALLY POWERED when not. The MAXIMUM MAINS VOLTAGE is 250 V.

The ENCLOSURE of the MAINS SUPPLY TRANSFORMER and the HAND-HELD device are classified as IP20. The equipment is classified for CONTINUOUS OPERATION in NORMAL USE. The SECONDARY CIRCUIT of the equipment, i.e., its INTERNAL POWER SOURCE, is only RATED suitable for connections to the MAINS SUPPLY at primary voltages of 100-240 VAC ± 10% by using the accompanying Lithium-Ion battery charger. The INTERNAL POWER SOURCE is a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS, which consists of a Lithium-Ion battery pack containing two 3.7 VDC Li-Ion cells in series.

1.1.1 Accessories

The cable connecting the hand-held devices with the base unit.

1.2 Separate Power Supply Source (Mains Supply Transformer)

This device is specified to be connected only to the Lithium-Ion battery charger, Model 2241P 2-cell Li-Ion from Mascot.

1.3 Essential Performance and Basic Safety

The device does not have an essential performance, the absence of which may result in an unacceptable risk. Basic safety is maintained when the device is stored, handled, and operated in normal conditions, and in accordance with its normal use and intended use.

1.4 Temperature Range for Use Indoors:

Charge of batteries: 0ºC to 35ºC ±5ºC (The device is connected to the battery charger but not used on a patient).

Discharge of batteries: 0ºC to 28ºC (The device is used on a patient whether connected to or disconnected from the battery charger).

Storage: -20ºC to +50ºC (Short or long-term transportation and storage when not using the device).

1.5 User Restrictions

Various safety features have been included and built into the design of the device. Failure to follow the instructions for the use, transport and storage of the device can lead to battery fluid leakage, heat generation, fire or battery explosion. Failure to follow the security precautions and instructions for use may lead to a potentially dangerous exposure of the eyes (by intra beam viewing at close range), or thermal skin injury (by applying high output power on dark pigmented skin).

To prevent these situations from occurring, as well as to ensure safe use of the device, the security precautions mentioned in this manual should be strictly observed.

1.6 General Caution and Warning Statements

“WARNING: The use of controls, adjustments to the device, or performance of procedures other than those specified herein may result in hazardous situations.”

This warning intends to inform the operator that BASIC SAFETY may be compromised by not using the device in its normal condition and in accordance with its normal use and intended use.

“WARNING: No modification of this equipment is allowed.” This statement addresses the HAZARDS that can follow an unauthorized modification of the ME EQUIPMENT, e.g., BASIC SAFETY may be compromised by a modification or an alteration of the normal condition of the device.

This device is a Class 3B laser product. Warning: Do not look at direct and non-diffuse reflections and avoid intra-beam viewing. **Safety glasses are provided with every ProSeries purchase**.

1.7 Licensing

The use of the device may require you to be licensed (subject to the jurisdiction you are located in). You should make your own inquiries regarding any license, or any other form of registration.

2. DEVICE DESCRIPTION AND USE

This device is a transportable, battery-operated medical laser product, with which the operator administers non-invasive transient class 3B infrared or visible laser light to reduce pain and inflammation, as well as to promote tissue repair and recovery. This device is intended to be used as a supplementary treatment modality intended to be operated by a variety of practitioners, e.g., doctors, nurses, veterinaries, dentists, physiotherapists, dermatologists, chiropractors, and massage therapists. The treatment modality of medical laser devices is commonly called Low Level Laser Therapy (LLLT), or laser therapy.

Laser is an acronym for Light Amplification by Stimulated Emission of Radiation and emits light with unique properties, which combined cannot be found in any other light source. These properties can be described briefly as monochromatic, coherent and, generally, highly polarized. Light consists of oscillating electric and magnetic waves, and our vision interprets colours on the basis of the wavelength content of the light as it enters the pupil and hits the retina.

The wavelength is described as the distance between repeating units of these waves and is measured in nanometers (nm). Light with wavelengths shorter than about 400 nm (ultraviolet) and longer than 800 nm (infrared) are not perceived as visible to the human eye. Visible light, when described in nm, are as follows: violet 420 nm, blue 470 nm, green 530 nm, yellow 580 nm, orange 610 nm, and red 700 nm. The light intensity (output power) of lasers is measured in Watts (W). Laser light can be pulsed or continuous, and the beam can be focused, divergent or collimated. A wide range of lasers are used in laser therapy, and the characteristics and parameters vary depending on their intended use.

Given the magnitude of treatment parameters, e.g., peak power, average output power, power density, spot size, wavelength, pulse frequency, duty cycle, aperture design, beam formation, exposure time, treatment procedure, number of sessions and treatment intervals, etc., it may be difficult for the clinical practitioner to know how to administer effective treatments without a properly designed device and the assistance of a user manual.

2.1 Device Design

Laser light applied to the skin or tissue may be absorbed, reflected, transmitted, or scattered. In order to perform the most efficient treatments, the laser light has to be able to penetrate and reach the area intended to be treated. Superficially situated conditions, such as open wounds, therefore require a lower dose, power and transmittance compared to those that are situated deep down within the tissue, for example in muscles and joint disorders.

This device is designed to enable the operator to administer efficient and safe laser treatments with ease. Generally recommended parameters, which are considered optimal for each treatment point on the basis of studies and clinical practice, have been built into the design and the controls of the device. The parameters and the dosages are automatically set by the treatment controls. The laser and the aperture design ensure practicable contact application and improved transmission of light through the tissue. Treatment intervals, number of sessions, application specification and use are described in this manual. The device complies with regulatory requirements, harmonized standards, and the medical device directive in order to ensure safe use and a high-quality standard. The device has been third-party tested (CB scheme) to ensure compliance with regulatory requirements.

2.2 Operation Description of Laser Treatment (General)

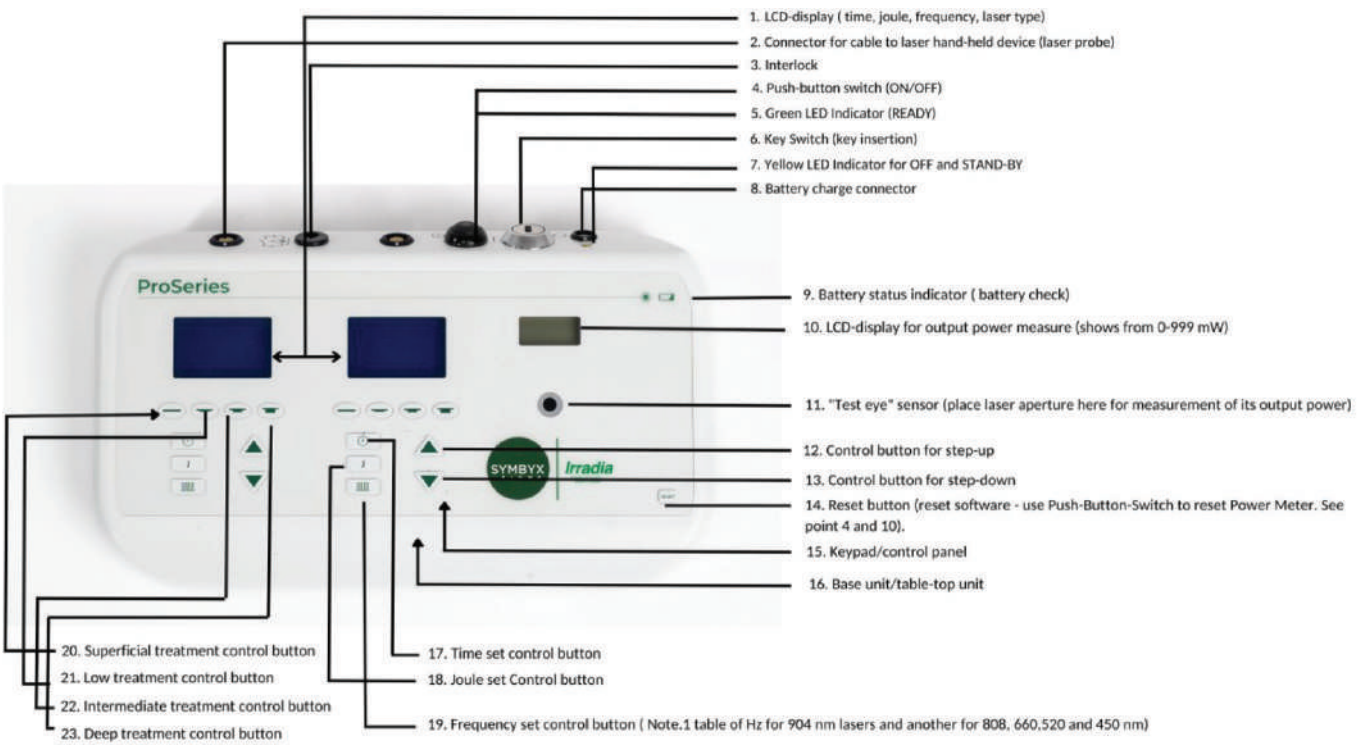
Treatment is performed by applying a generally optimal dose of laser energy onto and around a condition, using a point-by-point application procedure. An audible and visible signal informs the operator when to switch the application point. At each signal, the laser aperture is moved approximately 1,5 cm until the whole condition area has been covered.

The device has four different treatment controls that adjust the dosage and power according to whether the condition intended to be treated is situated superficially, low, intermediate or deep within the tissue. The operator selects and presses the respective treatment control button and places the laser apertures in contact with intact normal skin, or in non-contact (approximately 2 to 5 cm air distance) with sensitive and broken skin or open wounds. The operator then presses the laser emission control button to start the laser treatment, holds the device in position, and switches application point at each signal. When the area surrounding the condition has been covered, the operator presses the laser emission control button to stop the laser emission and reads the LCD display for medical record keeping.

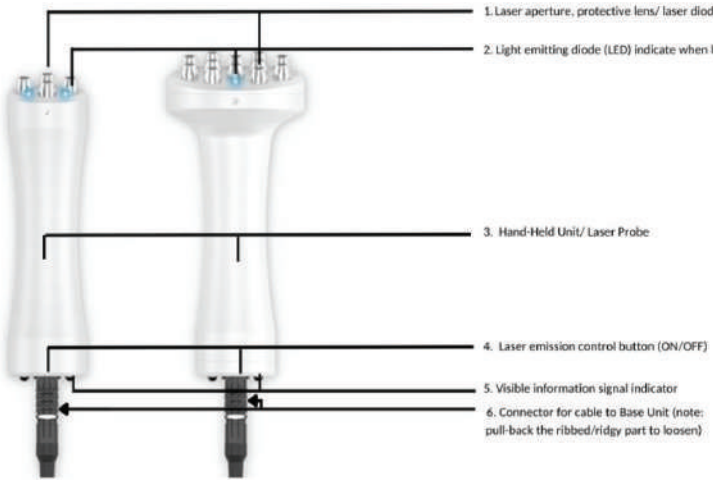
2.3 General Risks and Hazards with Class 3B Lasers

Class 3B lasers with an average output power of 500mW or less can potentially cause eye injuries. If the beam is focused to deliver a high-power density treatment, it can cause skin injuries when absorbed into dark pigmentation. Blue light lasers can cause photochemical injuries to the eye if one looks at the light for a prolonged period of time. Lasers with wavelengths close to the UV spectrum (400 nm) should be used with caution on patients that are light sensitive or who are using herbs or drugs causing sensitivity to light. Pulsed visible laser light with a pulse frequency of up to 60Hz may trigger photosensitive epilepsy.

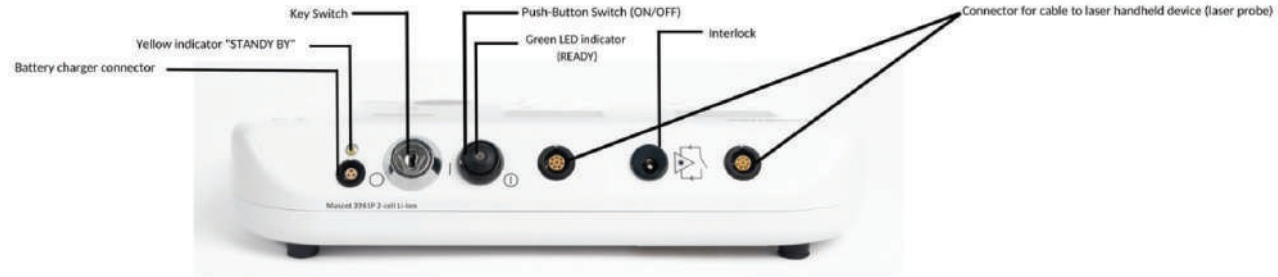
2.4 Device Overview Base Unit / Table-Top Unit



2.5 Device Overview Hand-Held Units (Laser Probe)



Back Side of Base Unit



3. PRIMARY OPERATING FUNCTIONS

a) Use the key switch to put the device in operational mode (unlocking the device for use). The device enters a STAND-BY state.

b) A yellow Light Emitting Diode (LED) is lit when the key switch is turned, indicating STAND-BY.

c) Press and release the push button to turn on the device (activate the device). The device enters a READY state.

d) A green LED on the push-button indicates that the device is in READY state.

e) LEDs on the keypad are lit in sequence, and several audible signals inform the operator that the device is ready for use.

f) The operator selects a treatment control according to the location and depth of the condition or disorder. The symbols of the controls are superficial ▬, low ▬, intermediate ▬ and deep ▬.

g) When a treatment control button is pressed, the adjacent LED is lit for verification.

h) Place the laser apertures either in contact with dry intact skin at the location for treatment or in non-contact (with approximately 2 to 5cm air distance between the laser apertures and the patient) if the skin is broken and sensitive, as well as over open wounds.

i) Press and release the laser emission control button to start laser emission ⚠/⊘ (start of action).

j) An audible signal indicates the start of laser emission. The laser aperture LED(s) is lit, indicating laser emission.

k) Hold the device in position.

l) An audible and visual information signal informs the operator when a generally optimal laser energy dose per application point has been delivered.

m) Move the applied part (or laser apertures) approximately 1, 5 cm and wait for the next audio/visual information signal.

n) Repeat until the entire area on and around the condition or disorder has been covered (i.e., a shoulder, knee, an elbow).

o) Press and release the laser emission control button to stop laser emission ⚠/⊘ (stop of action).

p) Two audible signals indicate the stop of laser emission. The laser aperture LED(s) is switched off, indicating that no laser radiation is emitted.

q) Remove the device from the patient.

r) Read the LCD display for medical record keeping (treatment time and dosage in Joules).

s) Press and release the push-button (ON/OFF) to turn off the device (the device enters STAND-BY).

t) Use the key switch to deactivate the device (i.e., lock the device).

u) Remove the key.
v) Clean the device with disinfectants (see 10.1).
w) Place the device in a safe and dry location (storing).
x) Make sure that the Li-Ion charger is unplugged from the mains supply (wall socket or similar).

3.1 Charging of The Battery

The device is intended to be used within the temperature range of 0 – 28ºC, and charged within the temperature range of 0 – 35ºC ± 5ºC. When the temperature of the battery exceeds 35ºC ±5ºC, the charging is automatically stopped by a thermal switch. Charging will not be possible again until the temperature of the battery has returned to a temperature of lower than 35ºC ± 5ºC.

1. Turn off the device with the key switch and remove the key.
2. Connect the cable connector of the Li-Ion charger to the battery charger on the device.
3. Connect the charger to the mains supply (wall socket).
4. Check that the Light Emitting Diode on the Li-Ion charger is lit (the colour orange/red indicates the charging of the battery).
5. If the orange Light Emitting Diode is not lit, remove the charger from the mains supply and wait until the green Light Emitting Diode is switched off. Connect the charger to the mains supply and retry.
6. Charge the battery under supervision (do not leave the device unattended).
7. The battery is fully charged when the Light Emitting Diode on the charger turns green.
8. Remove the charger from the mains supply (wall socket) when the device is not used or is unattended to.
9. Disconnect the charger from the device by removing the cable connector.
10. Store the Li-Ion charger in a safe and dry location.

If the Light Emitting Diode on the charger blinks between green and orange/red it might be caused by either:

- The temperature of the battery may be too high. Make sure that the device is cooled down to a temperature lower than 35ºC ± 5ºC, but not lower than 0ºC.
- Failure of charger, battery or connector. Contact service for support.

If the Light Emitting Diode on the charger is not lit – neither green nor orange – then the charger is not functioning as intended. Contact service for support.

Note: The device can be used without a connection to the charger. When used without connection to charger, the battery time before the need to recharge will vary depending on which hand-held laser devices (laser probes) are used. When used only on battery, the thermal switch protecting the battery charge/use may be overheated which will result in a shut-down mode of the Base Unit. In this mode, the LCD-displays will no longer be lit and the Base Unit cannot be used until the thermal switch has returned to a temperature of lower than 35ºC ± 5ºC, which may take up to 15-20 minutes.

4. TREATMENT CONTROLS

The treatment controls are indicated by the following symbols: — — — — When a control button is pressed, the device sets automatically the parameters required for delivering a generally optimal dose per application point onto and around a condition. When pressed, the Light Emitting Diode (LED) next to the control button is lit and the output power (in mW) and dose (in Joules) and time set signal per application point is shown on the LCD display.

The operator identifies at which approximate tissue depth, from the skin surface down, the condition or disorder is located. The corresponding treatment control button is then selected and pressed.

The operator presses and releases the laser emission control button to start the laser treatment, holds the device in position and switches application point at each signal by moving the device approximately 1,5 cm to a new application point adjacent to the one before. Treatment is ended when the area surrounding the condition or disorder has been covered.

Caution

By using the treatment control (—), the hand-held device (laser probe) can become hot after 10 minutes. If the device is switched on with this setting, but not used for more than 10 minutes, the applied part (the nut that holds the lens at the laser aperture) may become 51°C. If placed in skin contact and with pressure in this condition, it may initially be uncomfortable for the patient. The temperature of the applied part will, however, drop within a few seconds due to heat dissipation in tissue and become the same as the skin +2.5°C. The skin temperature will not be elevated by more than +2.5°C.

Recommended Use From The Manufacturer

When the applied part becomes hot by using the setting (—), switch to (—) and use it for two signals per point instead of one. By using a lower treatment setting, the temperature of the applied part will drop much faster. Once the applied part has cooled, one can switch back to the original setting (—).

4.1 Overview Chart of The Treatment Controls

The treatment controls overlap each other. There is no risk of harm using one control instead of another. The operator is advised to use the control he or she finds most suitable or which corresponds best to the condition or disorder to be treated. The use of the following controls is to be regarded as guidelines.

Overview per laser diode			
Treatment control button	**Adjustment/setting**	**Laser type/output power**	**Signal**
	Lowest output power Lowest dose/time per point	904 nm 60 mW	10 seconds / 0.6 J
		808 nm 80 mW	30 seconds / 2.4 J
		660 nm 25 mW	30 seconds / 0.75 J
		635 nm 25 mW	30 seconds / 0.75 J
		520 nm 25 mW	30 seconds / 0.75 J
		450 nm 25 mW	30 seconds / 0.75 J
	Low output power Low dose/time per point	904 nm 60 mW	30 seconds / 1.8 J
		808 nm 150 mW	30 seconds / 4.5 J
		660 nm 50 mW	30 seconds / 1.5 J
		635 nm 50 mW	30 seconds / 1.5 J
		520 nm 50 mW	30 seconds / 1.5 J
		450 nm 50 mW	30 seconds / 1.5 J
	Intermediate output power Intermediate dose/time per point	904 nm 60 mW	60 seconds / 3.6 J
		808 nm 300 mW	30 seconds / 9.0 J
		660 nm 75 mW	30 seconds / 2.25 J
		635 nm 75 mW	30 seconds / 2.25 J
		520 nm 75 mW	30 seconds / 2.25 J
		450 nm 75 mW	30 seconds / 2.25 J

	Highest output power Highest dose/time per point	904 nm 60 mW	120 seconds / 7.2 J
		808 nm 500 mW (808-1)	30 seconds / 15.0 J
		808 nm 400 mW (808-3)	30 seconds / 12.0 J
		660 nm 100 mW	30 seconds / 3.0 J
		635 nm 100 mW	30 seconds / 3.0 J
		520 nm 100 mW	30 seconds / 3.0 J
		450 nm 100 mW	30 seconds / 3 J
NOTE: The hand-held laser probes may contain more than one laser diode. The table above shows the values for one laser aperture applied to one treatment point.			

4.2 Treatment Application

The examples in the chart below are general guidelines based on patients with normal height and body fat, and with skin phototype I-III. Adjustments may be necessary for patients with other skin phototypes or with dissimilar heights and sizes and amounts of body fat.

Application	Laser type/ Wavelength	Treatment setting/ Energy/power per diode	Treatment time per application point	Application technique
Intact skin	904 nm	0.6 J to 18.0 J	10 s to 5 min	Contact with skin
Intact skin	808 nm	80 to 500 mW	10 s to 5 min	Contact with skin
Intact skin	660 nm / 635 nm	25 to 100 mW	10 s to 5 min	Contact with skin
Intact skin	520 nm	25 to 100 mW	10 s to 5 min	Contact with skin
Intact skin	450 nm	25 to 100 mW	10 s to 5 min	Contact with skin

Broken or sensitive skin, wounds	904 nm	0.6 J to 7.2 J	10 s to 2 min	Non-contact, at air distance of 2 to 5 cm, Hold still or Sweep over the surface
Broken or sensitive skin, wounds	808 nm	80 to 150 mW	10 s to 2 min	
Broken or sensitive skin, wounds	660 nm / 635 nm	25 to 100 mW	10 s to 2 min	
Broken or sensitive skin, wounds	520 nm	25 to 100 mW	10 s to 2 min	
Broken or sensitive skin, wounds	450 nm	25 to 100 mW	10 s to 2 min	
NOTE: Contact pressure of 1 to 5 N (Newton) is when the operator presses the device against the skin to remove blood from the tissue (in the same way as when a finger is pressed onto the skin creating a paler spot), which thereby increases the transmission or penetration of the laser light. **CAUTION!** Be careful when applying the device in contact pressure on elderly people or people with conditions causing them to bruise easily.				

5. TREATMENT ADJUSTMENTS

5.1 Skin Phototypes, Hair Colours

Different skin pigmentation is due to the amount of melanin pigment in the skin and is assessed on a scale from I-VI. The skin phototype is determined by complexion (white, brown or black skin) and the result of exposure to ultraviolet radiation (tanning). In connection with laser treatments, brown and black skin and hair are more easily burned due to the absorption of light in melanin. Caution should be exercised when using the device on dark pigmented skin, dark hair and tattoos, and on moles and nevus, since output power of the laser may cause discomfort and, possibly, cause burns if the patient is unable to respond.

5.2 Skin Types, Body Modifications, Tattoo Colours

The skin phototype scale can be used as a guideline for treatment on or over tattoos of various colours. See chapter 4.1 for reference to output power and treatment setting mentioned in the table.

Skin phototypes, hair type	Typical features	Potential risk of burns by the laser device	Treatment solution
I	Pale white skin, white or light grey hair	Never burns, unless the laser is pointed at a dark nevus or mole, etc.	Use the lower treatment settings or output powers on dark moles, nevus, etc. Alternatively, perform treatment in a non-contact mode.
II	Fair skin, blond/red hair	Never burns, unless the laser is pointed at a dark nevus or mole, etc.	Use the lower treatment settings or output powers on dark moles, nevus, etc. Alternatively, perform treatment in a non-contact mode.
III	Darker white skin, darker blond/red hair	Rarely burns, unless the laser is pointed at a dark nevus or mole, etc.	Use the lower treatment settings or output powers on dark moles, nevus, etc. Alternatively, perform treatment in a non-contact mode.

IV	Light brown skin, light brown hair	May cause an uncomfortable sting if higher output powers are used on darker spots.	Use the lower treatment settings or output powers if it is uncomfortable for the patient. Alternatively, perform treatment in a non-contact mode. Generally, due to the light absorption of the skin, the treatment time should be doubled (i.e., two information signals per treatment point instead of one).
V	Brown skin, brown hair	May cause an uncomfortable sting when higher output powers are used on darker pigmentation.	Use the lower treatment settings or output powers if it is uncomfortable for the patient. Alternatively, perform treatment in a non-contact mode. Generally, due to the light absorption of the skin, the treatment time should be doubled or tripled (i.e., two to three information signals per treatment point instead of one).
VI	Black skin, black hair	The highest output power or settings should generally not be used on these patients, since it can cause an uncomfortable sting. If the patient is unable to respond to pain, it can cause burns.	Use the lower treatment settings or output powers. Alternatively, perform treatment in a non-contact mode. Generally, due to the light absorption of the skin, the treatment time should be at least tripled (i.e., three information signals per treatment point instead of one).

5.3 Body Constitution

The patient's body constitution may influence the dose of laser energy needed to achieve the most efficient results. In the chart below, general guidelines are described for adjusting the treatment. This chart only applies when treating conditions or disorders that are not superficially or externally situated, such as wounds.

Body size	Patient example	General adjustment and treatment advice
Very thin or very low muscle mass	Elderly people, teenagers	Reduce the power and dose by selecting another treatment control for the treatment than normal. And/or avoid using pressure when performing treatment application.

High amount of body fat or extreme muscle mass	Large people, body builders	Increase the power and dose by selecting another treatment control for the treatment than normal. And/or double the treatment time per application point. Use contact pressure when performing treatment application.
NOTE 1. Patients with a low amount of body fat and/or muscle mass or smaller bodies require less application points to cover the area on and around a condition. **NOTE 2.** Patients with a high amount of body fat and/or muscle mass or larger bodies may require more application points to cover the area on and around a condition. In addition, the amount of body fat or muscles surrounding, for instance, a shoulder joint may require a larger dose and longer treatment time to compensate for the absorption and loss of transmission of laser radiation. Contact pressure removes circulating blood and physically places the aperture closer to the target area or condition intended to be treated.		

6. MEDICAL RECORDING

It is recommended that the medical record contains the following information:

- Diagnose, description of condition.
- Used treatment control (i.e., output power(s) and Joules per point).
- Application area (i.e., where the laser radiation has been applied).
- Application method (i.e., non-contact, contact, or contact pressure).
- Total treatment time and Joules delivered.
- Patient response to treatment.

7. DEVICE APPLICATION SPECIFICATION

7.1 Description

The device is a transportable, hand-held and battery powered medical laser with which the operator administers non-invasive class 3B laser infrared or visible laser radiation to a patient.

7.1.1 Expected Service Life

Three years, assuming high usage levels.

7.2 Medical Purpose / Intended Use

Reduce acute and chronic pain and inflammation, as well as to promote tissue repair.

7.3 Patients

Humans and animals.

7.4 Operator

Ordinary and temporary operators.

- An ordinary operator is a medically trained practitioner who uses the device in his or her day-to-day practice.
- A temporary operator uses the device for self-treatment for a limited period of time under the supervision and instruction of an ordinary operator.

7.5 Application

Contact application on intact skin and skin around orifices.

Non-contact application on broken or sensitive skin, as well as on wounds and natural or artificial orifices.

Caution: Never to be applied on eyes or used for treatments through the lens of the eye, including intra-beam viewing.

7.6 Environment

Indoors, 10-90% atmospheric humidity at temperatures ranging from 0 to 28°C and at air pressure of 700-1060 hPa.

Do not use the device at locations or environments with a high atmospheric humidity, such as saunas, swimming baths and shower rooms, etc.

7.7 Frequency of Device Use

Up to 20 times a day.

7.8 Treatment / Application Time Per Patient

10 seconds to 30 minutes; normally 5 - 20 minutes per treatment.

7.9 Treatment Interval

Normally once every 24-72 hours. The treatment interval can be longer, such as once every week or month. Chronic conditions 1 to 3 times a week. Acute conditions 3-5 times a week.

7.10 Number of Treatments / Sessions Per Patient

1-20 treatments; normally 2-4 treatments on acute conditions, while chronic generally require more treatments 5-20.

7.11 Treatment Session Interval

The first cycle lasts for three weeks, followed by a pause of two to three weeks before the next three-week cycle starts.

7.12 Contraindications

Treatment of the eye through the lens; intra-beam viewing.

7.13 Side Effects

No known side effects.

7.14 Patient Reaction

When treating acute conditions, the pain may cause stress or damage if the patient returns to normal activities before the condition has fully recovered. Also with chronic conditions, the patient may experience an increased transitional pain within 48 hours of treatment due to either the commencement of the healing process, the chronic condition turning to acute, or the relaxation of tense muscles. The patient may become tired or sleep longer than normal after treatment due to pain relief and muscle relaxation. Patients should not, in these cases, perform any activities that require a high level of concentration or alertness.

IMPORTANT! When treating a patient for the first time a lower dose and treatment time shall be applied for evaluating the reaction of the treatment. The treatment can cause transient increased pain for some patients and therefore it is recommended that the first treatment should be limited in dose and time. The manufacturer recommends maximum 30 seconds per treatment point and a maximal treatment time of 5 minutes.

7.15 Patient Population

Age: > 8 years to geriatric.

Weight: Not relevant.

Height: Not relevant.

Gender: Not relevant.

Pregnancy: Not recommended. Avoid treatment of the abdominal region.
There is, however, no evidence of any known risks for either the mother or foetus.

Nationality: Not relevant.

Skin colour: All. Absorption of light in very dark/black pigmented skin can result in less effective treatments. High output power may cause insignificant burns (discomfort) on dark skin (skin phototype V and VI). See Note 1.

Hair colour: High output power may cause insignificant burns (discomfort) on dark hair (brown and black hair). See Note 1.

Implants, prosthesis, artificial limbs: Not relevant.

Reduced sight or blindness: Not relevant.

Reduced hearing or deafness: Not relevant.

Reduced mobility or paraplegic: Not relevant.

Mental, psychological or intellectual disorders: Caution should be taken when treating patients unable to respond to pain.
See Note 1.

Alcohol or tobacco user: Not relevant.

Part of body to be treated: The whole body, with the exception of the eyes.

Body modifications/changes: Tattoos can absorb light and result in less effective treatments. Dark colours can absorb enough light to cause insignificant burns (discomfort). See Note 1.

State of the patient: Awake and conscious. The patient should be able to respond to pain. See Note 1.

Medications, drugs, anaesthetics: Caution should be taken when treating patients on drugs, medications or anaesthetics reducing skin sensitivity or ability to respond to pain. See Note 1.

Cosmetic products: Skin care and cosmetic products, oils, creams and lotions that have been placed on the skin can reduce the effect of the treatment by the absorption of light, cause damage to electrical components, and render the hygienic handling and cleaning of the device more difficult. In addition, cosmetic products may also absorb enough light to possibly cause burns (discomfort). See Note 1.

Note 1. *Absorption of light in dark/black pigmented skin, hair and tattoos can cause burns if the patient is not able to respond to pain and inform the operator about the discomfort. The discomfort a patient may experience is similar to that of a needle prick. Either stop the treatment, use the same power at a distance of 1-2 cm, or reduce the power. Treatment with the device should always be pain free.*

7.16 Intended Operator

Ordinary operator

- An OPERATOR who is medically trained and instructed in the use of the device, and who uses the device in a day-to-day practice. The OPERATOR performs treatments on PATIENTS.

Temporary operator

- An OPERATOR who is instructed by, and under the surveillance of, an ordinary OPERATOR in how to perform a specific self-treatment procedure for a limited period of time. The ordinary operator shall ensure that the temporary operator applies the device in accordance with its intended use and the accompanying documents. The PATIENT becomes temporarily the OPERATOR.

Operator education and knowledge:

- Medically trained in a relevant profession (massage therapist, chiropractor, physic therapist, nurse, etc.).
- Educated in the use of the device and competent to make a diagnosis.
- Literate.
- Able to follow the instructions for use and the accompanying documents.
- Understands hygiene and sanitary control procedures.

7.17 Operator Responsibilities

It is recommended that every device is under the care of only one person/operator who is well acquainted with its use and functions.

The responsible person for the device should;

- read and understand the accompanying documents.
- keep or store the accompanying documents.
- make sure that the accompanying documents and instructions for use are easily accessible when needed.
- make sure that he/she is well acquainted with the device before use.
- ensure that the device is used in accordance with its intended use, as well as in accordance with the accompanying documents (user manual).
- be responsible for safe storage and transport of the device.
- be responsible for educating, instructing and surveying a temporary operator.
- be responsible for the use of correct eye protection wear.
- be responsible for contacting the manufacturer or its representative when further education or training is required, as well as with questions regarding service.

Operator contact with the device

- The operator sits or stands and uses at least one hand to control and operate the device.
- The operator manages the device with dry or normal hand skin condition or with protective gloves.
- Neither hands nor gloves should have been in contact with any oils, creams, lotions, balms, moisturizers, etc.
    - Oils and creams etc. might damage electrical or mechanical components.
    - Oils and creams etc. make the grip slippery. The operator might drop the device.

7.18 Responsible Organization

The responsible organization should designate the responsibility for the device to one person only (the operator). The responsibilities the responsible organization has include ensuring that the operator of the device is;

- Educated or trained in the use of the device.

- Well acquainted with the device.
- Familiar with the instructions for use and the accompanying documents.
- Medically trained.
- Trained in laser safety.

In addition, the responsibilities incorporate;

- Ensuring the supply of proper and correct eye protection wear.
- Ensuring means for technical service or support when needed.
- Using the device in accordance with local laws, regulations and requirements.

7.19 Patient Position

- Sitting, standing or lying down. The patient's skin must not have been in contact with any oils, creams, lotions, balms, moisturizers, etc. Oils and creams etc. might damage electrical or mechanical components Use **with caution in the following circumstances!**

Treatment should be avoided or performed under supervision and by medical professionals in the following circumstances:

- **In or around the neck region in hyperthyreosis;** it has not been observed that laser light can cause direct damage, but since the thyroid is sensitive to light, it is advised to avoid irradiation over the gland, especially with large doses.
- **Exposure of the abdomen during pregnancy;** treatment should be avoided due to legal reasons, i.e., that the operator could be accused should any complications arise.
- **Certain blood diseases;** haematological diseases include, on the one hand, mild hypochromic anaemia and, on the other hand, life-endangering myeloblastic leukaemia. Laser therapy does not affect the length of life of blood cells, and there is no basis for avoiding its application in any field, with the exception of irradiating hemopoietic bone marrow.
- **Heavy blood losses;** treatment should be avoided due to the vasodilating effect of the laser light.
- **Neuropathies;** the analgesic effect of laser therapy can potentially reduce the sensitivity of proprioceptors in the skin. Therefore, caution is necessary regarding neuropathies, since the application of laser therapy may reduce existing minimum sensitivity with a danger of damaging the given region. On the other hand, laser therapy can promote nerve and tissue repair, and such treatments should therefore be performed with correct patient information and under post treatment surveillance.

- **Irradiation in the region of the gonads;** the application of therapeutic laser in the region of the gonads cannot be considered as contraindicated, but it is recommended that the procedure is performed by specialists with sufficient experience.
- **Use of excessive treatment dosages of laser radiation on acute open wounds;** it has been observed in rats subjected to treatment that this has caused temporarily slower healing compared to a control group. Due to the results from these studies, dosages lower than 15-20 J/cm² are recommended in the treatment of acute open wounds on both humans and animals.

7.20 Training

Training: Application-specific and operator-orientated instruction or exercises are required for a safe and effective use of the equipment.

The use and operation of the equipment is assessed to be fairly simple, and the instructions for use (herein) cover all necessary information concerning the primary operating functions, as well as how to perform successful treatments in accordance with the INTENDED USE and BASIC SAFETY of the device. In addition, or as a complement to the manual, users of the device can be trained by the sales representative organization, which may also provide advice on the use of the equipment by telephone or via e-mail.

The responsible organization and the operator are both responsible for ensuring that they have sufficient knowledge and training in performing treatments with the device. The responsible organization or the operator should contact the manufacturer or its representative if further education or training is deemed necessary, as well as with questions regarding service.

8. GENERAL BATTERY SAFETY INFORMATION

This product contains a rechargeable lithium-ion battery. The lithium-ion battery pack is placed inside the device and only accessible by use of a tool. The battery inside the device shall only be replaced by service personnel authorized by or trained by the manufacturer. Change of battery by inadequately trained personnel may result in dangers such as excessive temperature, battery fluid leakage, explosion or fire. See 8.4 for more information.

A failure of the Lithium-ion battery could cause a hazardous situation. By following the instructions in this manual, and by using the battery in accordance with its specified ratings (charging, discharging, storage, environmental concerns, etc.), the risk of battery failure is reduced to a minimum. The connector on the Lithium-ion charger is a non-standard connector to ensure the risk of connecting the device to charger not suitable for the battery is minimized. The connector can only be connected in only one way, reducing the risk of reversed polarity.

The Lithium-ion battery has a predetermined service life. If the operating time shortens excessively, the battery life has expired. If this happens, the batteries should be replaced with new batteries. Contact the manufacturer or retailer. In general, the end of the cycle life of secondary batteries is defined as when the capacity falls below 60% of normal capacity and no longer recovers in subsequent cycles. Cycle life largely depends on the conditions of the cycle, such as charge, depth of discharge, current, and ambient temperature. Generally, 500 cycles (full discharge and charge) will leave the capacity at approximately 75%. Shallow charge and discharge cycles increase the cycle life. In the case of, for example, regular cycles of full charge and ~50% discharge, the cycle life is doubled to about 1000 cycles. Battery self-discharge is about 3% of the capacity per month. Therefore, if the battery is not used for long periods of time, the battery should be charged with about 10% every 6 months.

To ensure safety when removing or replacing the enclosure covering the battery (battery cover), the key switch must be turned off. The OFF status of the key switch is indicated by the yellow LED being switched off and that no other indicators are lit. To safely replace or remove the battery cover and/or the lithium-ion battery, follow the instructions described in this manual. The operator must not touch the patient while removing the cover or the battery.

The battery cover for the battery pack has holes for ventilation and pressure release. The battery is protected from movement and shock by a rubber/foam plastic coating, which holds the pack in position and reduces shock on impact. The wires connecting the battery to PC-boards and/or other components are isolated and placed in such a way that the wires cannot be damaged, thus preventing short-circuit. There is no warm-up state for the device. Charging mode is indicated by the battery status indicator and on the Li-Ion battery charger.

8.1 Battery Safety

Removal of the battery should only be performed by trained service personnel. The operator must not use the device if deformed or damaged, dropped in water, producing excessive heat, or smells strangely. In these cases, the operator should contact the supplier or the manufacturer for technical service or replacement of parts. The operator should contact the supplier or manufacturer for support or service in every case where there are changes in the performance of the device, or if one suspects any faults.

8.2 Warnings and Precautions

- Do not use or store the battery or the device at high temperatures, e.g., in strong direct sunlight, in cars during hot weather, or directly in front or on top of heaters. This may cause battery fluid leakage, impaired performance, and a shortening of the battery service life.
- Do not charge the device below 0ºC. This may cause impaired performance, a shortening of the battery service life, battery fluid leakage, explosion or fire.
- Do not splash any liquids on the device or allow the battery terminals to become damp. This may cause heat generation and formation of corrosion on the battery and its terminals, which in turn may cause electrical shocks, battery fluid leakage, explosion or fire.
- Do not use or store the device in locations with a high atmospheric humidity. This may cause heat generation and formation of corrosion on the battery and its terminals, which in turn may cause electrical shocks, battery fluid leakage, explosion or fire.
- Use the specified Li-Ion charger to charge the Lithium-ion batteries. Failure to follow proper charging procedures may cause excessive voltage, excessive current flow, loss of control during charging, battery fluid leakage, heat generation, explosion or fire.
- Do not connect various assembled batteries or battery housings in series. This may cause electrical shocks, battery fluid leakage, heat generation, explosion or fire.
- Do not use force to connect the battery or the device to the Li-Ion charger. Do not use the device or the battery if either generate heat or function in a non-standard way. Contact the distributor, sales representative or manufacturer.
- Keep the device and battery housing out of the reach of children. Avoid situations where children may chew on or lick the battery housing, Li-Ion charger or device.
- Do not dispose of the device or the battery housing in fire or heat. Doing so can melt the insulation and damage sealed parts or protective safeguards, cause battery fluid leakage, explosion or fire.

- Do not use the battery for any other purpose than for which the product is intended. Do not connect it to any other electrical devices.
- Do not charge or use the lithium –ion batteries with the + (positive) and – (negative) terminals reversed. Charging the batteries with the terminals reversed may drain rather than charge the battery, as well as cause abnormal chemical reactions inside the battery, abnormal current flow during discharge, battery fluid leakage, heat generation, explosion or fire.
- Do not break open the housing of a battery or damage it. Doing so will risk short circuiting the battery and may cause battery fluid leakage, heat generation, explosion or fire.
- Do not disassemble the Lithium-ion batteries. Doing so can damage the protection circuit or protective safeguards, which may cause an internal or external short circuit. It may also cause battery fluid leakage, heat generation, explosion or fire.
- Do not strike or throw the device containing the lithium-ion battery or the battery housing. The impact may cause battery fluid leakage, explosion or fire.
- Do not use the device if the housing is damaged or deformed. A damaged housing may have caused damage to the batteries, which could result in battery fluid leakage, explosion or fire.
- If leaked electrolyte comes into contact with the eyes, flush the eyes immediately with clean water and seek medical attention. Leaked electrolyte can damage the eyes and lead to permanent loss of eyesight.
- If skin or clothing comes in contact with leaked electrolyte, wash the affected area immediately with clean water. Leaked electrolyte can cause skin damage.
- The device and the batteries should be disposed of in a proper and environmentally safe way. Batteries that are no longer usable should be returned to the manufacturer or sent to a company specialized in the disposal of hazardous electrical materials and batteries.
- Do not open or dissemble the device or the battery housing and/or replace or change the battery pack. Doing so may cause short circuit, battery fluid leakage, heat generation, explosion or fire.

8.3 Recycling of Batteries

- The batteries should be disposed of in a proper and environmentally safe way. Batteries that are no longer usable should be returned to the manufacturer or sent to a company specialized in the disposal of hazardous electrical materials and batteries.

8.4 Replacement of Battery

Contact the supplier SYMBYX Pty Ltd when need of replacement of battery arises, or if a screw is missing on the battery cover. Do not use device unless both screws are in place.

8.5 Transport and Packaging of The Device for Change of Battery

See chapter 18 transport and packaging of the device.

9. LASER SAFETY

9.1 General Laser Safety Information

These instructions for use are intended to minimize hazardous situations and the risk of harm due to laser radiation of Class 3B. They include such things as:

- Safe handling and use of the device.
- Safe storage and transportation of the device.
- NOHD distance.
- Use and descriptions of correct protective eyewear (i.e., wavelength range and optical density OD+).
- Information and warnings regarding direct intra-beam viewing and non-diffuse reflections.
- Appropriate maintenance instructions.
- Clear warnings and classifications.

Human access is necessary for the performance of the function(s) of the product. During its intended use, the patient is exposed to laser radiation; however, eye exposure should always be avoided. Dark, tattooed, or highly pigmented skin may absorb laser radiation and cause thermal heating and discomfort. The instructions herein describe how to use the device safely on such skin conditions. The instructions for use have been compiled and evaluated in accordance with usability safety standard IEC60601-1-6.

The laser emission from the device has been calibrated, tested and measured before product release. The actual laser output measured in the working area does not deviate from the set value by more than ±20%. An increase or a decrease of emission can occur due to the following reasons:

- An increased temperature of the laser/laser chip; may decrease the emission by 10 - 20%.
- Broken protection lenses; may increase the emission by 5%.
- Excessive increased temperature due to component failure, resulting in a change of the component characteristics; either no change or an increased or a decreased emission by 10 - 20%.
- Component failure; decreases the emission, or results in no emission at all (broken circuit).
- Dirty laser apertures (protective lenses); decreases the emission.
- Use of controls; decreases the emission from maximum values (intended by the use of the treatment controls).

The equipment should be protected against unauthorized use, for example by removing the key from the key switch to ensure that the equipment is permanently turned off. The laser apertures are indicated by a “LASER APERTURE” label placed in close proximity to the apertures.

The device is equipped with a stand-by/ready function. The device enters stand-by when the key switch is turned to the “ON” position. In the “ON” position, the yellow LED next to the key switched is activated. The transition to “ready” is clearly indicated by repeated audible signals and the flashing of the LEDs on the laser aperture and keypads. The transition from stand-by to ready takes about 2, 5 seconds. The transition from stand-by to ready is possible while the laser emission control button is pressed . Laser emission is only possible in the ready-state.

Laser emission is started by the laser emission start/stop control button . When the emission of laser radiation starts, the operator is informed by a clear audible signal and the lighting of the blue LEDs. The audible indicator indicates emission by repeatable signals.

There is a very low potential risk of fire or explosion when the laser output is used in close contact with flammable liquids, solutions or gases, or in an oxygen enriched environment. However, the laser beam is divergent and the intensity and temperatures produced in normal use with the laser equipment has shown that highly flammable solutions or solvents evaporate and, therefore, do not cause ignition.

9.2 General Risks with Class 3B Lasers According to IEC 60825-1

According to IEC60825-1:2007, the potential hazards with Class 3B lasers are as follows:

Normally hazardous when intra-beam ocular exposure occurs (i.e., within the NOHD), including accidental short time exposure. Viewing diffuse reflections is normally safe. Class 3B lasers which approach the AEL for Class 3B may cause minor skin injuries or even pose a risk of igniting flammable materials. However, this is only likely if the beam has a small diameter or is focused.

Note. *NOHD stands for nominal ocular hazard distance. NOHD is the distance at which the beam irradiance or radiant exposure equals the appropriate corneal maximum permissible exposure (MPE).*

9.3 Maintenance and Control of Emitted Output Power

The operator should regularly measure the actually emitted output power of the device. Operating this device with an output power

that is much lower than intended or what has been specified may result in poor or ineffective treatments. If the output power is much higher (+50%), the patient may experience discomfort depending on the treatment setting being used. In addition, the NOHD at maximum output power is increased. It is recommended to check the output power at least once per week to ensure that the device emits laser radiation within ± 20% of the intended output power. If the operator does not have access to a calibrated power meter, the operator should obtain one either from the supplier of the device or some other source in order to make certain that the device operates within specifications. If the output power deviates by more than ± 20 %, contact the supplier or the manufacturer for technical service and calibration of the device. The protective lenses on the aperture should be kept clean to ensure that the output power is measured correctly.

Important notes regarding periodic measurements of the output power: The power meter must be able to:

- Measure the wavelengths that the laser emits.
- Measure output powers of at least 1000 mW (or 1 w).

In addition, the following routines should be adhered to:

- Ensuring that the aperture lenses are clean before measuring the output power (dirty lenses may reduce the output power by absorption and cause discomfort due to the heat generated).
- The power meter should be placed in contact with, or very close to, the laser aperture to ensure that the whole beam is fitted onto the part measuring the output power.
- Measurements should be performed on all apertures.
- The output power depends on the treatment setting (superficial, low, intermediate, deep), where the superficial setting produces the lowest output power and deep the highest.
- Infrared laser radiation is almost invisible to the eye but can in some cases be seen if the aperture is placed close to a non-reflective material, for example the palm of the hand. The laser appears as a thin, red line. Or photographed with a cell phone camera that is sensitive enough. This method can be used to check that the laser emits laser radiation in those cases where there is no power meter available and the operator needs to ensure that the device is functioning.
- The laser should be measured in those cases where a patient experiences discomfort even though the device is applied onto skin or hair that is not dark (see chapter Treatment Adjustment for more information).
- For further questions, considerations or need of technical service, please contact the supplier or the manufacturer.

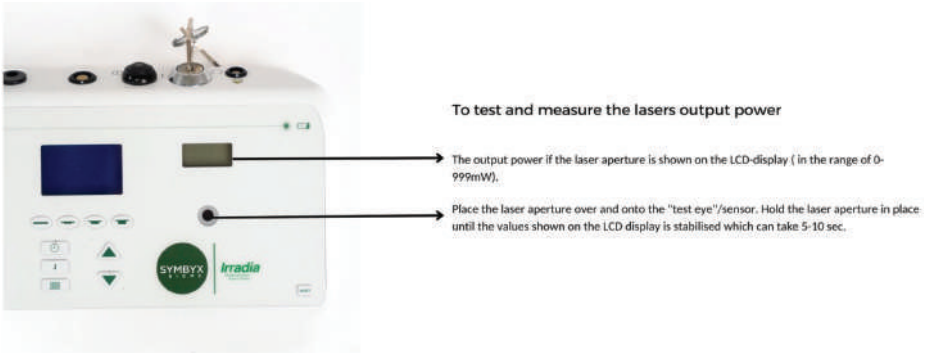
This device is a Class 3B laser product. Warning: Do not look at direct or non-diffuse reflections and avoid intra-beam viewing. Use correct protective eyewear to minimize unintentional exposure.

“Caution: Use of controls or adjustments or performances of procedures other than those specified herein may result in hazardous situations.” The intent of the warning is to inform the operator that BASIC SAFETY may be compromised by not using the device in its normal condition and in accordance with normal practice and intended use.

“WARNING: No modifications of this equipment are allowed.” This warning statement addresses the issue that HAZARDS can result from an unauthorized modification of the ME EQUIPMENT, e.g., BASIC SAFETY may be compromised by a modification or an alteration of the normal condition of the device.

9.3.1 The Power Meter / Power Tester

By using the power meter function, the laser diodes on the hand-held units (laser probes) can be measured to ensure the emit laser light or radiation. The power meter has an accuracy of 15%. The power meter measures the laser radiation in relation to its reference temperature. This may cause the power meters “zero-level” to change if the equipment temperature has changed. An example of this is when the room temperature changes, or if the device been in use for a certain amount of time. To reset the power meters “zero-level” restart the Base Unit by turning the key switch off then on or by repressing the push-button switch (off/on).



9.4 Protective Eyewear. Personal Protective Equipment

Optical density should be minimum +3 (OD+3), which means that 1/1000 of the light passes through the protective eyewear. The power of a 0.5 W laser is reduced to 0.5 mW by using protective eyewear with OD+3. Through the proper use of protective eyewear by both patients and operators, the possibility of eye injuries caused by laser radiation is reduced to a minimum. The responsible organization must ensure that proper protective eyewear is supplied and used in a correct manner.

10. GENERAL ELECTRICAL AND MECHANICAL SAFETY

10.1 Cleaning / Disinfection Procedures

The device is not intended to be sterilized. The equipment is intended for direct physical contact with the patient on clean and dry skin (normal skin conditions). Cleaning/disinfection should be performed before use. The operator is advised to clean the equipment with disinfectants on cotton pads, such as isopropyl, in order to prevent the risk of contaminants impairing the optical path, as well as to minimize patient cross contamination. Excessive use of disinfectants may cause damage to the coating, enclosure or colour of the product. ***Do not use chloride-containing preparations since such solvents or solutions may damage or deform the silicon keypads.***

Do not place the device under running water, splash solvents, or use soaked towels or cotton pads when cleaning the device. Liquid entering the device may damage electrical circuits or cause damage to the batteries, resulting in short-circuit, battery fluid leakage, heat generation, explosion or fire.

Dirty lenses or lenses containing a crack may absorb laser radiation, thereby creating a tiny heated spot on the lens. This may, when the aperture is placed in contact with the skin, cause discomfort to the patient. Patients may experience a sensation similar to that of a slight needle prick.

10.2 Visual Inspections

The operator should perform a visual inspection of the device before use and contact the supplier or manufacturer for support or service in any case where real or perceived changes in the performance of the device occur. To ensure a safe inspection, follow the instructions described below:

No.	*Inspection*	*Potential problem*	*Action to be taken*
1	*Connector and Li-Ion charger cable*	*A damaged cable or connector may cause short-circuit or electrical shock.*	*Do not connect the Li-Ion charger to the mains supply or the device. Contact the supplier or manufacturer for support and replacement of charger.*

2	*Inspection of the housing (overview of the device)*	*Damaged mechanical parts or a deformed shape, such as dents, may indicate that the device is no longer functioning normally. A deformed enclosure may be uncomfortable for the patient and could, in worst case, cause skin breakage or small cut wounds.*	*Do not use the device. The battery may be damaged. Contact the supplier or manufacturer for technical service and replacement of part.*
3	*Laser aperture protective lenses*	*Damaged lenses may cause cut wounds. Cleaning or using the device in this condition may cause electrical component failure.*	*Do not use or clean the device. Contact the supplier or manufacturer for technical service and replacement of part.*
4	*Laser aperture parts*	*The protective lens which covers the laser diode (at the laser aperture) must be in place and fastened. Using the device without this protective lens may damage the laser diode and cause discomfort for the patient (by high intensity at skin contact). Cleaning the aperture with the nut removed may damage electrical components.*	*Do not use or clean the device. Contact the supplier or manufacturer for technical service and replacement of part.*
5	*Loose or lost screws*	*Loose or lost screws may cause the housing of the device to come apart.*	*Reattach the screws. Contact the supplier or manufacturer for technical service and replacement of lost screws.*
6	*Legible labels and markings*	*If symbols, text markings or labels have deteriorated, their meaning could be misunderstood, which increases potential risks of class 3B hazards.*	*Contact the supplier or manufacturer for technical service and replacement of signs, labels and markings.*
7	*Yellow LED indicator is lit when the key-switch is turned to ON (Standby)*	*If not lit; battery failure or broken key-switch.*	*Contact the supplier or manufacturer for technical service and replacement of part.*

8	*Green LED is lit when the push button is pressed ON (Ready-state)*	*If not lit; failure of switch or LED.*	*Contact the supplier or manufacturer for technical service and replacement of part.*
9	*Laser aperture LEDs are lit when the laser is activated (one LED per aperture)*	*If not lit; the laser diode may not emit laser radiation, or the aperture LED is broken and does not indicate when the laser is emitting radiation. Do not look directly at the blue LEDs.*	*Control the output power with a power meter. Contact the supplier or manufacturer for technical service and replacement of part.*

10.3 Information for Service Technicians

Upon request by the servicing personnel, appropriate instructions for service adjustments and procedures for each laser model are only provided in a specified service manual. To ensure safe service and safe usage after service, as well as guaranteeing that the high-quality standard of the product remains intact, service of the device should only be performed by a service technician authorized by the manufacturer. The service manual includes:

- Clear warnings and precautions to be taken to avoid possible exposure to laser radiation above class 1 and similar hazards.
- A list of controls and procedures, implementable by persons other than the manufacturer or his or her agents, which increase the accessible emission levels of radiation.
- Clear warnings and precautions to be taken to avoid exposure to possible battery failure and similar hazards.
- A list of controls and procedures, implementable by persons other than the manufacturer or his or her agents, which increase the exposure to possible battery failure and similar hazards.
- Protective procedures for service personnel.
- Legible reproductions (colour is optional) of required labels and hazard warnings.

The following can be supplied upon request: circuit diagrams, component part lists, descriptions, calibration instructions or any other information that will assist in repairing the parts of the device that have been designated by the manufacturer as repairable by external service personnel. All parts will be supplied by the manufacturer to ensure that correct components are used by the service personnel.

Note: Service or maintenance of the equipment shall not be performed while the device is in use or in contact with patient.

11. DESCRIPTION OF CONTROLS, MESSAGES AND INDICATORS

11.1 LCD-display	The LCD display shows the treatment time and the number of joules applied on a condition. [Time] 00:00 [Joules] 00.0 J [Frequency] 250 Hz (700Hz for 904 nm lasers) [Laser type] _ _nm _ _mW The treatment time is displayed in hours, minutes and seconds. Every second that the laser(s) is activated is registered on the timer. When the laser emission is stopped, the timer pauses. The treatment dose is displayed in Joules (J), which is calculated by the laser output power (mW) multiplied by the time (seconds). For every second the lasers are activated, the number of joules increases. The joules delivered are displayed with one decimal precision (0, 1 J). The displayed treatment dosages always show the total treatment dosage, irrespective of the number of lasers being used, i.e., one or two. When the operator changes from one treatment control to another, e.g., from superficial to deep, or restarts the device, the values are reset to zero.
11.2 Treatment control "Superficial" 	Control button for lowest output power or lowest dose/time per treatment point. For more information see table in section 4.1 When the control button is pressed down, the information of the pre-set values for the connected laser are shown on the LCD display until the control is released.
11.3 Treatment control "Low" 	Control button for low output power or low dose/time per treatment point. For more information see table in section 4.1 When the control button is pressed down, the information of the pre-set values for the connected laser are shown on the LCD display until the control is released.
11.4 Treatment control "Intermediate" 	Control button for intermediate output power or intermediate dose/time per treatment point. For more information see table in section 4.1 When the control button is pressed down, the information of the pre-set values for the connected laser are shown on the LCD display until the control is released.

11.5 Treatment control "Deep" 	Control button for highest output power or highest dose/time per treatment point. For more information see table in section 4.1 When the control button is pressed down, the information of the pre-set values for the connected laser are shown on the LCD display until the control is released.
11.6 Joule Set control button "Joule" 	With this control function a specific number of Joules delivered per point can be set. This control function sets the time between the audible information signals by calculating the number of Joules (J) delivered and compare with the amount set by the operator. This control shall be kept pressed down and used together with the controls "Step-Up and Step-Down" ▽△ The time between the signals when setting the number of Joules is also shown on the LCD-display. The time may differ a little when moving back and forth depending on the calculation rounding up or down. The audible information signal informs each time the set number of Joules has been delivered.
11.7 Time Set control button "Time" 	With this control function a specific number of seconds or time between each signal can be set. This control shall be kept pressed down and used together with the controls "Step-Up and Step-Down" ▽△ The amount of energy or Joules delivered between is also shown on the LCD-display. The number of Joules may differ a little when moving back and forth depending on the calculation rounding up or down. The audible information signal informs each time the set amount of time has been passed.
11.8 Frequency Set control button "Hz" 	With this control function a specific frequency (Hz) of the laser light can be set. This control shall be kept pressed down and used together with the controls "Step-Up and Step-Down ▽△ For the lasers 808 nm, 660 nm, 520 nm and 450 nm the pre-set frequency is 250 Hz. The frequency of these lasers can be set in steps of 31.25 Hz rounded up or down to a whole number. The frequency table for these lasers are from 32 Hz to 1000 Hz. For the 904 nm lasers the pre-set frequency is 700 Hz and can be set from 5 Hz to 5000 Hz.

11.9 Battery status indicator  **“Battery check”**	This LED is lit when the battery is getting low and soon needs to be recharged. The remaining battery time depends on the output power (mW) used. A low output power increases the time before recharging is necessary. “LOW BATTERY” means that the battery capacity is getting low. Depending on the treatment control selected, the remaining battery time is at least 15 minutes. When the battery gets low, the battery check LED indicator is lit. The battery LED indicator blinks on/off before “LOW BATTERY” is shown on the LCD display. If the indicator is ignored, “RECHARGE BATTERY” will in time be shown on the LCD display, followed by repeated audible information signals. “RECHARGE BATTERY” indicates that the battery is about to get depleted. “RECHARGE BATTERY” means that the battery needs to be recharged before the lasers can be activated. The “RECHARGE BATTERY” indication is followed by a repeated audible signal informing the operator that the battery needs to be recharged before use. When “RECHARGE BATTERY” is shown, the emission from the lasers is automatically stopped. Switch off the device with the key switch and connect it to the Li-Ion charger before switching on the device again. The battery does not need to be fully recharged before use or activation of lasers.
11.10 Step-Up / Step-Down 	These control buttons are used in combination with Joule, Time and frequency setting. See chapter 11.6, 11.7 and 11.8.
11.11 Reset RESET	When this control is pressed and released the Base Unit software restarts and returns to all default values, except for the Power Meter.
11.12 INTERLOCK 	On the rear side of the Base Unit there is an outlet to which an interlock system can be connected using the accompanying interlock connector. With this connector/outlet interlock function the Base Unit will immediately interrupt the laser emission for instance if doors to the area were treatment is performed is opened.

12. TECHNICAL SPECIFICATIONS (GENERAL)

Product	Medical electrical equipment
Type	Therapeutic laser/medical laser
Device type	Non-invasive active therapeutic
Model	PROSERIES
Class	II
Electrical classification	Type B
Laser class	3B
IP classification	IP20
Battery type	Lithium-ion (Li-Ion)
Internal power source	Secondary Lithium-ion battery
Supply voltage	Li-Ion battery charger with a secondary nominal output voltage of 7.4 VDC ± 10%
Mains supply (for charger)	100-240 VAC 50-60Hz
Current consumption	< 1.5 A
Working voltage	8.4 VDC
Typical power consumption	< 12 W
Battery recharge time	< 2.5 hours
Battery time (before need to recharge)	>1.5 hours
Battery life time	> 750 treatment hours. Up to 7500 hours at lowest output power
Battery recharge cycle life	Minimum 500 cycles at full discharge/charge
Battery self-discharge	3% per month
Materials (enclosure)	Aluminium

Coating	Powder paint
Notified body nr. CE-mark CE 0413	CE 0413 The product is CE marked in accordance to the requirements of MDD 93/42/EEC

13. TECHNICAL SPECIFICATIONS (GENERAL)

13.1 Laser Diode for Laser Probe 904 nm

Laser type	GaAs
Wavelength(s)	904 nm ± 10 nm
Type of radiation	Infrared A, invisible
Beam type	Divergent
Beam divergence	9x25 deg (FWHM) or ~ 0.44 rad
Spot size (at contact application)	5 mm in diameter (19.5 mm²)
Continuous or pulsed laser	Pulsed
Pulse frequency pre-set	700 Hz
t(ms)	0.7 ms
Pmax (IEC60825-1) for 904 nm 60 mW (904-1)	53 mW
Pmax (IEC60825-1) for 904 nm 240 mW (904-4)	68 mW
Pmax (IEC60825-1) for 904 nm 720 mW (904-12)	58 mW
Maximum average aperture output power	60 mW
Maximum aperture peak power output	25 000 mW
No of laser diodes and output power model 904-1 (904 nm 60 mW)	1 x 60 mW
No of laser diodes and output power model 904-4 (904 nm 240 mW)	4 x 60 mW
No of laser diodes and output power model 904-12 (904 nm 720 mW)	12 x 60 mW
Adjustable average output power from aperture (per diode)	60 mW, fixed and not adjustable
Aperture size	Ø 0.5 cm

NOHD	<0.8 m
Protective eyewear	Minimum OD+3 at 904 nm ± 20 nm

13.2 Laser Diode for Laser Probe 635 nm 100 mW

Laser type	AlGaInP
Wavelength(s)	637 nm ± 5 nm
Type of radiation	Red, visible
Beam type	Divergent
Beam divergence	8.5 x 33 grader (FWHM) eller ~ 0.57 rad
Spot size (at contact application)	9 mm in diameter (63.5 mm²)
Continuous or pulsed laser	Pulsed
Pulse frequency	250 Hz
t(ms)	0.9 ms
Pmax (IEC60825-1)	63 mW
Maximum average aperture output power	100 mW
Maximum aperture peak power output	450 mW
Number of laser diodes model 635-1 (635 nm 100 mW)	1
Adjustable average output power from aperture (per diode)	25 mW, 50 mW, 75 mW, 100 mW
Aperture size	Ø 0.9 cm
NOHD	<0.8 m
Protective eyewear	Minimum OD+3 at 637 nm ± 20 nm

13.3 Laser Diode for Laser Probe 635 nm 400 mW

Laser type	AlGaInP
Wavelength(s)	637 nm ± 5 nm
Type of radiation	Red, visible
Beam type	Divergent
Beam divergence	8.5 x 33 grader (FWHM) eller ~ 0.57 rad
Spot size (at contact application)	9 mm in diameter (63.5 mm²)
Continuous or pulsed laser	Pulsed
Pulse frequency	250 Hz
t(ms)	0.75 ms
Pmax (IEC60825-1)	88 mW
Maximum average aperture output power	100 mW
Maximum aperture peak power output	450 mW
Number of laser diodes model 635-4 (635 nm 400 mW)	1
Adjustable average output power from aperture (per diode)	25 mW, 50 mW, 75 mW, 100 mW
Aperture size	Ø 0.9 cm
NOHD	<0.8 m
Protective eyewear	Minimum OD+3 at 637 nm ± 20 nm

13.4 Laser Diode for Laser Probe 808 nm

Laser type	GaAlAs
Wavelength(s)	808 nm ± 3nm
Type of radiation	Infrared A, invisible
Beam type	Divergent
Beam divergence	10x40 deg (FWHM) or ~ 0,7 rad
Spot size (at contact application)	9 mm in diameter (63,5 mm²)
Continuous or pulsed laser	Pulsed
Pulse frequency	250 Hz
t(ms)	1.8 ms
Pmax (IEC60825-1)	131 mW
Maximum average aperture output power	400 mW
Maximum aperture peak power output	1400 mW
Number of laser diodes model 808-3 (808 nm 1200 mW)	3
Adjustable average output power from aperture (per diode)	80 mW, 150 mW, 300 mW, 400 mW
Aperture size	Ø 0.9 cm
NOHD	<1.0 m
Protective eyewear	Minimum OD+3 at 808 nm ± 20 nm

14. DEFINITIONS

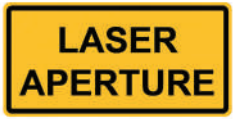
Terms	Description
Non-invasive treatment	A treatment procedure that does not break the skin or come in contact with mucosa or internal body cavities through any natural or artificial orifices.
Laser aperture	The opening from which laser radiation is emitted.
Laser diode	The component that produces and emits laser radiation.
Laser light	Laser radiation that is visible, i.e., that has a wavelength within the visible range of wavelengths.
Laser radiation	Laser radiation that is invisible, i.e., that has a wavelength outside the visible range of wavelengths.
Treatment point	The point where the laser aperture is applied and on which treatment is performed (~1cm² per aperture).
Point size	The size within which the laser beam is applied (~1cm² per aperture).
Application point	Each place where the operator applies the device or laser.
Treatment area	The area on and around a condition or problem area.
Non-contact treatment	The apertures are held approximately 2 cm from the patient (air distance between aperture and patient).
Contact treatment	The apertures are placed in contact with the skin, but without any specific pressure.
Contact pressure treatment	The apertures are placed in contact pressure with a force of approximately 1 to 5 Newtons.
Output power	The light intensity of the laser radiation, or the laser's "power".
mW	milliWatt. 1 mW = 0,001 W. The output power is measured in mW.
Joule	The energy of laser radiation delivered. The laser radiation is measured by the intensity of light (mW) multiplied by the time (seconds). J = mW x s
Dose	The quantity of laser radiation energy applied. Commonly measured in joules delivered per cm² (J/cm²).

LASER	Laser is an acronym for Light Amplification by Stimulated Emission of Radiation.
LED	LED is an acronym for Light Emitting Diode (used as indicators).

Terms	Description
Accompanying documents	Documents and information for the responsible organization or operator regarding the medical electrical equipment, particularly about basic safety and essential performance.
Active therapeutic device	The operation of the device depends on an electrical energy source, and is used for the treatment or alleviation of injuries and diseases.
Applied part	The part of the medical electrical equipment that in normal use comes into physical contact with the patient during treatment.
Basic safety	Freedom from unacceptable risks directly caused by physical hazards when the medical electrical equipment is used under normal conditions and in single fault condition.
Component with high-integrity characteristics	Component with one or more characteristics ensuring that the functions are fault-free in relation to the safety requirements during the expected service life of the medical electrical equipment, as well as in normal use and with reasonably predictable misuse.
Essential performance	Performance necessary to achieve freedom from unacceptable risks.
Hand-held	Term referring to electrical equipment that is intended to be managed by hand in normal use.
Hazard	Potential source of harm (harm is defined as physical injury or damage to the health of people or animals, as well as damage to property or the environment).
Intended use	Use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer.
Internally powered	Term referring to electrical equipment that is able to operate by means of an internal electrical power source.
Normal condition	Condition in which all provided means to prevent hazards are intact.
Normal use	Operation and use, including routine inspections and adjustments, in accordance with the instruction manual.

Operator	Person handling the equipment.
Patient	Living being (person or animal) undergoing a medical, surgical or dental procedure.
Responsible organization	Entity accountable for the use and maintenance of a medical electrical equipment or system. For example a hospital, an individual clinician or a layperson. For domestic use, the patient, operator and responsible organization can be one and the same person.
Risk	Combination of the degree or probability of harm and the severity of the harm caused.
Service personnel	Persons accountable to the responsible organization for installing, assembling, maintaining, and repairing the medical electrical equipment.
Supply mains	Source of electrical energy which is not part of the medical electrical equipment.
Tool	An instrument that can be used manually to secure or release fasteners/screws or to make adjustments.
Transient	Normally intended for less than 60 minutes of continuous use.

15. LABELS AND SYMBOLS

Symbol/label/sign	Description
	Warning sign close to the apertures through which laser radiation in excess of the AEL for Class 1 or Class 2 is emitted.
	Explanatory label. The name and publication date of the standard to which the product has been classified. The product is described on the explanatory label by a statement concerning the maximum output of laser radiation, the pulse duration (if applicable), and the emitted wavelength(s).
	Warning: laser beam. To warn of laser beam hazards.
 Li-Ion battery	Caution sign. Use caution when handling the Li-Ion battery. For safe use, consult the accompanying documents for further information.
	Type B applied part.
	Class II equipment.
	Reset. Restarts the equipment to default settings.
	Battery check. To identify the battery condition indicator. When lit, the battery is getting low.
	Start (of action). To identify the control by means of which an action is started, i.e., start of laser emission.

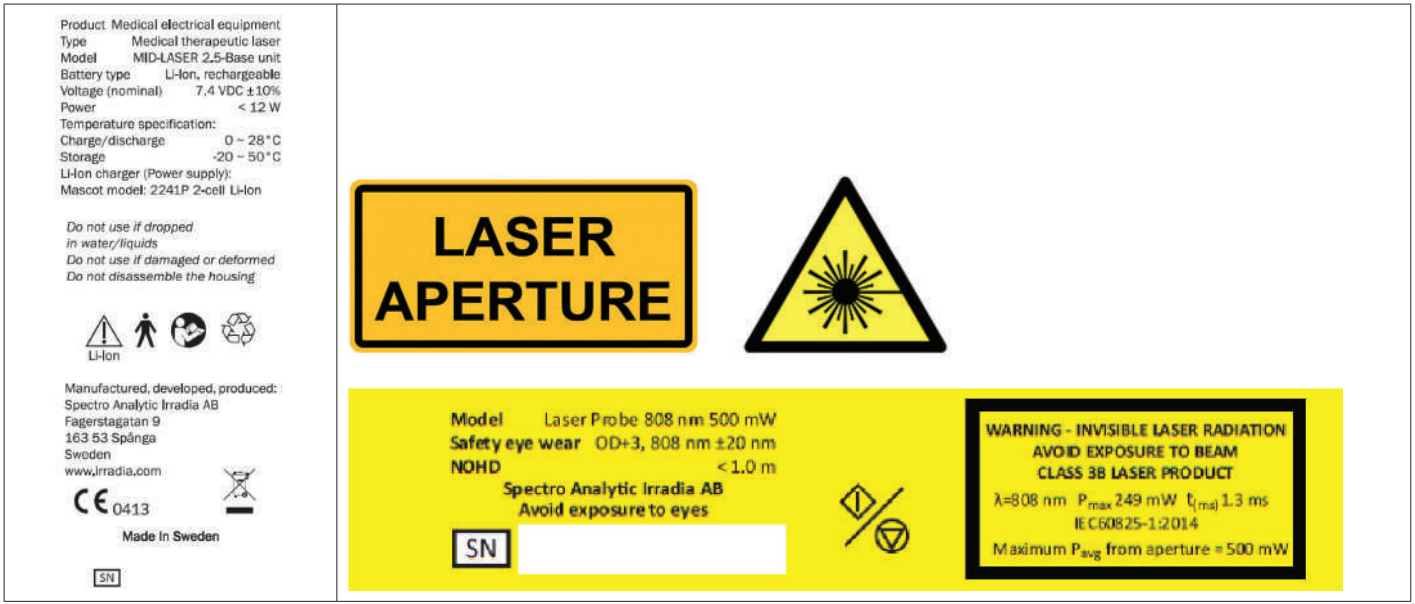
	Stop (of action). To identify the control by means of which an action is stopped, i.e., stop of laser emission.
	Follow instructions for use. Consult the accompanying documents before use or action.
	Step-Up / Step-Down control function symbols. Used together with Time Set, Joule Set, Frequency Set.
	Symbol for Joule Set. Identify control to set number of Joules delivered between each signal.
	Symbol for Time Set. Identify control to set number of seconds/minutes between each signal.
	Symbol for Frequency Set. Change or set the frequency (Hz) of laser light/radiation.
	General symbol for recovery/recycling. Indicating that the material can be part of a recovery/recycling process.
	The WEEE symbol. Indicating a separate collection for WEEE products, i.e., waste electrical and electronic equipment.
Superficial 	Control button for superficial treatment. Output power and joules are set for the above-mentioned tissue depth.
Low 	Control button for low treatment. Output power and joules are set for the above-mentioned tissue depth.
Intermediate 	Control button for intermediate treatment. Output power and joules are set for the above-mentioned tissue depth.
Deep 	Control button for deep treatment. Output power and joules are set for the above-mentioned tissue depth.
“Low battery”	Battery check status. Battery is getting low.

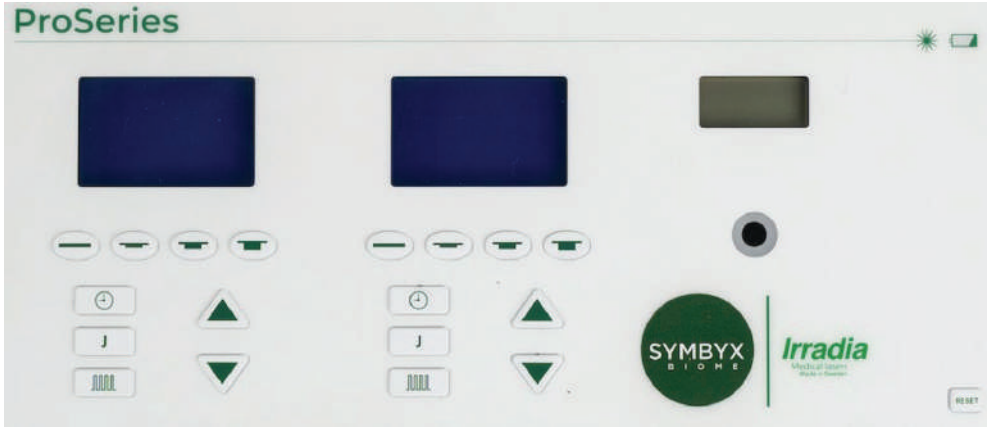
“Recharge battery”	Battery check status. Battery is about to become depleted. The operator is instructed to recharge the battery.
	Interlock.

NOTE. Reference for symbols. IEC60825-1:2014 and IEC60878:2003

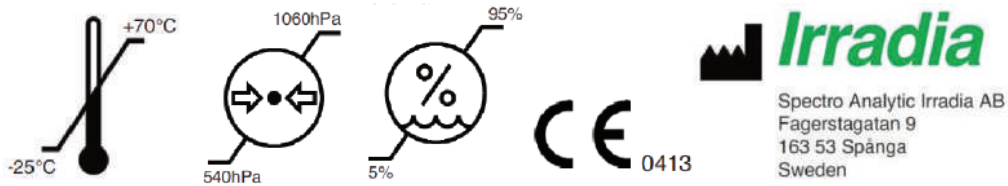
15.1 Labels and Markings on The Product

These are legible reproductions of the labels and hazard warnings affixed to the device.





15.2 Symbols and Marking on Package Label



16. LIMITATION OF LIABILITY

SYMBYX PTY LTD and Spectro Analytic Irradia AB disclaim any liability for personal injury or damages to property or possessions that occur as a consequence of the following circumstances:

- Use of the device that is not in accordance with its normal or intended use.
- Neglected maintenance and failure to take appropriate actions when cleaning, storing, transporting or using the device.
- Failure to follow the instructions in the accompanying documents.
- Use of the device that is not in accordance with laws, regulations or requirements.

17. DISPOSAL AND RECYCLING OF THE DEVICE

The device should be disposed of in a proper and environmentally safe way. The device and batteries that are no longer usable should be sent back to the supplier for proper disposal or to a company specialized in the disposal of hazardous electrical materials and batteries. Electrical components, PC-boards, and keypads should be sorted as electrical component disposal. The aluminium housing can be recycled or sorted into metal aluminium disposal. The laser diodes should be sorted as hazardous electrical components, or together with lamps, LEDs, etc.

18. TRANSPORT AND PACKAGING OF THE DEVICE AND/OR BATTERY HOUSING

Save and use the original package which the device was delivered in for transport and storage. During transport or storage, the key should be removed from the key switch of the device. The device should be stored/transported within the temperature range of -20 to + 50ºC, 5-95% humidity and 540-1060hPa air pressure, and placed in a dry package that protects the device from vibrations, impacts and shock. If the original package has been lost, the device should be packaged in a carton box with impact/vibration reducing materials such as air caps, towels or crumpled paper.

19. SUPPLIER CONTACT INFORMATION

SYMBYX Pty Ltd at 2/50 Yeo St, Neutral Bay NSW 2089 AUSTRALIA (www.symbyxbiome.com) in collaboration with Spectro Analytic Irradia AB, Fagerstagatan 9, 163 53 Spånga, Sweden. For technical service and support, contact SYMBYX AUSTRALIA on +61 2 8066 9966.

19.1 Reporting serious incidents

Any serious incident that has occurred in relation to the device should be reported by the user and/or patient to SYMBYX Pty Ltd (above) and the competent authority of the Member State in which the user and/or patient is established.

20. ELECTROMAGNETIC COMPATIBILITY (EMC)

The need for establishing the electromagnetic compatibility in standards is to ensure that the performance of Medical Electrical Equipment, under certain conditions, can be expected to be normal. Electromagnetic emission standards are essential for, inter alia, the **protection** of safety services and other Medical Electrical Equipment and Systems, as well as telecommunications. Electromagnetic Immunity Standards are used to ensure that the Medical Electrical Equipment performs satisfactorily within its intended environment. The electromagnetic disturbance environment can occur in the shape of ambient temperature, humidity, and atmospheric pressure. Medical Electrical Equipment and Systems may experience environmental conditions within the expected range of the interference environment at any time, and for extended periods of time, without the operator being aware of the ambient levels on a continuous basis.

It is the manufacturer's responsibility to design the product according to the necessary requirements, as well as to provide the Operator or Responsible Organization with information for creating and maintaining a compatible electrical environment so that the Medical Electrical Equipment or System can perform as intended.

List of ACCESSORIES with which compliance is met:

- Lithium-Ion battery charger from Mascot, Model 2241P 2-cell Li-Ion, cable connecting Hand-Held laser units (laser probes) to Base Unit.

The use of ACCESSORIES, transducers and cables other than those specified herein, or those sold by the manufacturer as replacement parts for internal components, may result in increased EMISSION or decreased IMMUNITY of the ME EQUIPMENT.

20.1 Electromagnetic Emissions – Guidance and Declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The ProSeries is intended for use in the electromagnetic environment specified below. The customer or the user of the ProSeries should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**

RF emissions CISPR 11	Group 1	The ProSeries 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 CISPR 11	Class B	The ProSeries 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

20.2 Electromagnetic Immunity – Guidance and Declaration

Guidance and manufacturer's declaration – electromagnetic immumity			
The ProSeries is intended for use in the electromagnetic environment specified below. The customer or the user of the ProSeries 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	±8 kV contact ±15 kV air	±8 kV contact ±15 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	+/- 2 kV for power supply lines n/a. for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode n/a. for common mode	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 % UT (>100 % dip in UT) for 0.5 periods <5 % UT (100% dip in UT) for 1 period 70 % UT (30 % dip in UT) for 25/30 periods <5 % UT (>100 % dip in UT) for 5 sec	<5 % UT (>100 % dip in UT) for 0,5 periods <5 % UT (100 % dip in UT) for 1 period 70 % UT (30 % dip in UT) for 25/30 periods <5 % UT (>100 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial hospital environment. If the user of the ProSeries requires continued operation during power mains interruptions, it is recommended that the ProSeries be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The ProSeries is intended for use in the electromagnetic environment specified below. The customer or the user of the ProSeries should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V + 6 V ISM and amateur radio bands 150 kHz to 80 MHz 3 V/m 80MHz to 2.7GHz Immunity to RF Wireless Communication Equipment, 385-5800 MHZ, 9-28V/m	3 V + 6 V ISM and amateur radio bands 150 kHz to 80 MHz 3 V/m 80MHz to 2.7GHz Immunity to RF Wireless Communication Equipment,385-5800 MHZ, 9-28V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ProSeries including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **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 2.7 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol.

NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflected from structures, objects and people.

[a] Field strengths 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 ProSeries is used exceeds the applicable RF compliance level above, the ProSeries should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ProSeries. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

20.3 Separation Distances – Portable and Mobile RF Communications

Recommended separation distances between portable and mobile RF communications equipment and the ProSeries

The ProSeries is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ProSeries can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ProSeries 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 transmitter** m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 2.7 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 meters (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.

21. APPLIED STANDARDS

IEC 60601-1:2005+A1, IEC 60601-2-22:2007+A1, IEC 60825-1:2014, IEC 60601-1-6:2010+A1, IEC 62366:2007+A1, IEC 62304:2006, IEC60601-1-2: 2007 & 2014, ANSI/AAMI ES60601-1:2005, CAN/CSA-C22.2 No. 60601-1:08. National differences for Korea and Japan. Other standards with which the device complies with: ISO14971:2019, ISO10993-5, ISO10993-10.