

Instruction Manual

PhysioCare



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1 General information

This operating and user manual applies to the PhysioCare 904 nm Laser by SYMBYX. This laser device is manufactured for SYMBYX Pty Ltd of Australia by Spectro Analytic Irradia AB of Sweden. (Note: Irradia also manufacture an identical product called the MIDCARE 904 nm).

Please read this manual before using the product. The reader is advised to keep the manual at hand for future reference when necessary. MEDICAL ELECTRICAL EQUIPMENT requires special precautions regarding EMC and need 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 the PhysioCare 904 nm Laser by SYMBYX, 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, HAND-HELD and INTERNALLY POWERED MEDICAL ELECTRICAL EQUIPMENT that is a NON-INVASIVE CLASS IIa ACTIVE THERAPEUTIC DEVICE, with which the OPERATOR administers TRANSIENT PULSED CLASS 1 INFRARED A (IRA) (model 904) LASER radiation to a PATIENT. The HAND-HELD device is classified as a TYPE BF APPLIED PART, and IP22. The equipment is classified for CONTINUOUS OPERATION in NORMAL USE.

1.2 Separate power supply source (mains supply transformer)

Not used.

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 condition and in accordance with normal and intended use.

1.4 Temperature range for use

Discharge of batteries: 10 - 90 % atmospheric humidity at temperatures ranging from +5 - 30° C and air pressure of 700 - 1060 hPa.

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 safety precautions and instructions for use may lead to a potentially dangerous exposure of the eyes (by intra-beam viewing at close range). To prevent these situations from occurring, as well as to ensure safe use of the device, the safety 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.

2 Device description and use

This device is a transportable, hand-held, super-pulsed, near infrared, battery-operated medical laser product, with which the operator administers non-invasive laser radiation to promote tissue repair. This device is intended to be used as a supplementary treatment

modality intended to be operated by the patient for HOME CARE. The treatment modality of medical laser devices is commonly called Low Level Laser Therapy (LLLT), photobiomodulation, or cold (non-thermal) laser therapy, when used for reducing pain and inflammation, as well as to promote tissue repair and recovery.

2.1 Operation description of laser treatment (general)

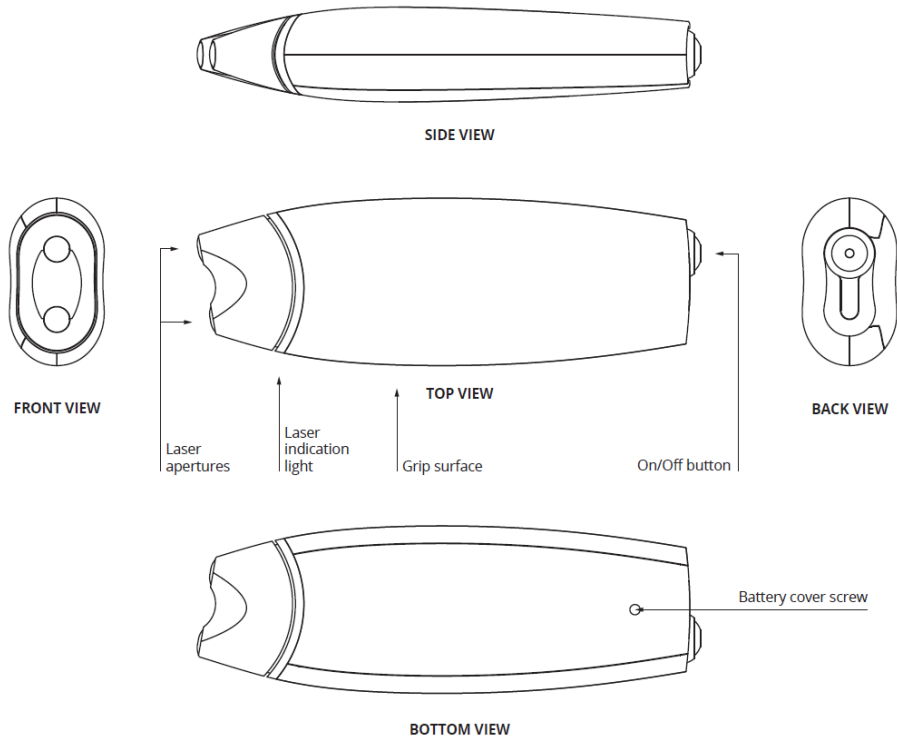
Treatment is performed by applying a generally optimal dose of laser energy in contact mode onto and around a condition, using a point-by-point application procedure by holding the device in position, and switching application point at each signal. An audible and visible signal informs the operator when to switch application point. At each signal, the laser aperture is moved approximately 1.5 cm until the whole condition area has been covered. Treatment shall only be performed onto and in contact with intact normal skin and skin conditions.

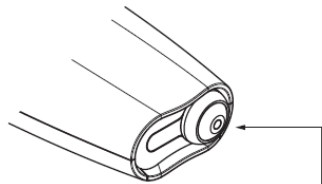
WARNING! Do NOT use the device in contact with sensitive and broken skin or open wounds. Do NOT use the device in contact with eyelids. Do NOT view the divergent beam with magnifiers.

2.2 General risks and hazards with class 1 lasers (IEC60825-1:2014)

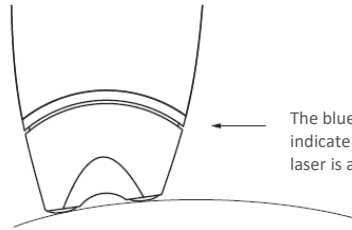
Laser products that are safe to use, still hold risks associated with misuse, such as long-term direct intra-beam viewing. Class 1 laser products which emit visible radiant energy may still produce dazzling visual effects, particularly in low ambient light.

2.3 Device overview



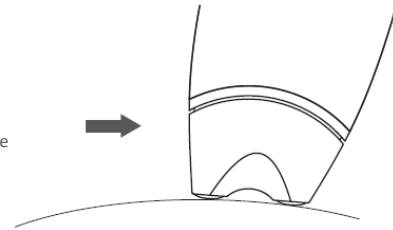


Press On/Off button to turn on the device. The green light indicates that the device is ready to use.



Press against the skin to activate the laser.

The blue light indicate that the laser is active.



After 60 seconds of treatment the device's front light will blink and a sound will be heard, indicating that you should move the laser device to a new treatment point.

3 Primary operating functions

- a) Press and release the push-button switch to put the device in operational mode (unlocking the device for use). The device enters a 2.5 seconds STAND-BY state. A green light emitting diode on the push-button switch indicates the device enters to a ready state.
- b) After pressing the push-button switch, the LEDs at the laser apertures are lit repeatably, and several audible signals inform the operator that the device is ready for use. The device is now in a READY to use state.
- c) Place the laser apertures in contact with dry intact skin at the location for treatment.
- d) Press gently to start laser emission (start of action).
- e) An audible signal indicates the start of laser emission. The laser aperture LED is lit, indicating laser emission.
- f) Hold the device in position.
- g) An audible and visual information signal informs the operator when a generally optimal laser energy dose per application point has been delivered.
- h) Move the applied part (laser apertures) approximately 1.5 cm.
- i) NOTE. During the movement to the next application point (when the device is no longer in contact with skin) the laser emission stops as well as the light indicators. Audible signals are given to indicate the stop of laser emission.
- j) Place in contact and press gently to start emission again, hold in position and wait for the next audio/visual information signal.
- k) Repeat until the entire area on and around the condition or disorder has been covered (i.e. a shoulder, knee, an elbow, etc.).
- l) Press and release the push-button switch to turn off and off the device.
- m) When the green LED on the push-button no longer is lit (switched off) the device is turned off. Note, failure to turn the device off, out of standby mode, will result in poor battery duration.
- n) Clean the device with disinfectants.
- o) Place the device in a safe and dry location (storing).

3.1 Replacement of batteries

See Chapter 7.4.

4 Treatment controls

4.1 Overview parameters of the treatment protocol for medical recording

Model/ Type	Laser Wavelength	No. of laser diodes	Laser output power per diode	Total Output Power	Time between each signal	Emitted laser energy per diode between each signal	Total emitted energy between each signal	Laser energy dosage per diode and point
PhysioCare Laser by SYMBYX	904 nm	2	30 mW	60 mW (2 x 30 mW)	60 s	1.8 J	3.6 J	1.8 J/cm ²

NOTE. Contact pressure of 1 to 5 N (Newton) is recommended for the operator when pressing 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 Medical recording

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

- Date of treatment/s
- Used treatment protocol (i.e. wavelength, output power and Joules per point/cm²).
- Application area (i.e. where the laser radiation has been applied).
- Total treatment time or Joules delivered.
- Patient response to treatment.

6 Device application specification

6.1 Description

The device is a transportable, hand-held and battery powered medical laser with which the operator administers non-invasive laser light/radiation to a patient.

6.1.1 Expected life before service required

Three to four years.

6.2 Medical purpose/intended use

Intended to reduce pain and inflammation, as well as to promote tissue repair.

6.3 Patient

Human.

6.4 Operator

Ordinary and patient operators:

- An ordinary operator is a medically trained practitioner who uses medical lasers in his or her day-to-day practice; and
- A patient operator uses the device according to the accompanying documents (this manual) for home care self-treatment with guidance or instruction from a non-present ordinary operator.

6.5 Application

Contact application on intact skin and skin around orifices.

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

6.6 Environment

Indoors, 10 - 90 % atmospheric humidity at temperatures ranging from +5 - 30° 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.

Do not use the device in ambient light or when performing safety-critical work due to the lasers potential to cause dazzle effect or flash blindness.

6.6.1 Home healthcare environment

Dust, lint and dirt may cause discomfort due to a thermal effect of light absorption in the dirt. Clean lenses before use (Chapter 9.1). Damaged or deformed parts of the enclosure or the applied part and lenses caused by pets or children may cause discomfort or negligible skin injury. Inspect the device before use (see chapter 9.2). Keep the device stored in a location not accessible to pets, pests and children.

6.7 Frequency of device use

Chronic conditions: 1 - 3 treatment a week.

Acute conditions: 3 - 5 treatments a week.

6.8 Treatment/application time per patient

Treatment time varies by specific physical ailment but is usually between 1 - 15 minutes per treatment (see table below). Move the laser approximately 1.5 - 2 cm after each minute of laser treatment (i.e., the time between beeps) on or around the Treatment Area of Body, until Total Minutes of Treatment is completed.

Treatment Area of Body	Number of Treatment Points per Area	Total Minutes of Treatment
Achilles tendon	6	6
Heel	6	6
Ankle	4	4
Top of foot	3	3
Shin	6	6
Knee	6	6
Glute or quad	6	6
Hips/Hip flexor	6	6
Back pain or spine	12 - 15	12 - 15
Finger (or toe)	1	1
Wrist	4	4
Elbow	4	4
Shoulder	6	6
Neck	10	10

Please read the above table in conjunction with **Chapter 6.14 Patient potential reaction** for first time users.

6.9 Treatment interval

Approximately every 48 hours, depending if condition is chronic or acute.

6.10 Number of treatments per patient/sessions per patient

Approximately 3 treatments per week are recommended.

6.11 Treatment session interval

Continuously.

6.12 Contraindications

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

6.13 Side effects

No known side effects.

6.14 Patient potential reaction

When treating acute conditions, the pain relief 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 for the first treatment.

6.15 Patient population

- a) Age: > 18 to geriatric.
- b) Weight: Not relevant.
- c) Height: Not relevant.
- d) Gender: Not relevant.
- e) Pregnancy: Not recommended. Avoid treatment of the abdominal region. There is, however, no evidence of any known risks for either the mother or fetus.
- f) Nationality: Not relevant.
- g) Skin color: Light or slightly pigmented. Absorption of light in dark/black pigmented skin can result in less effective treatments. Absorption of light in dark/black pigmented skin, hair and tattoos can cause discomfort by heat absorption.
- h) Hair color: High power (> 300 mW) may cause discomfort on dark/black hair. See Note 1.
- i) Implants, prosthesis, artificial limbs: Not relevant.
- j) Reduced sight or blindness: Not relevant.
- k) Reduced hearing or deafness: Not relevant.
- l) Reduced mobility or paraplegic: Not relevant.
- m) Psychological or intellectual disorders and conditions: Caution should be taken when treating patients potentially unable to respond to pain. See Note 1.
- n) Alcohol or tobacco user: Not relevant.
- o) Part of body to be treated: The gut/belly or abdomen area, as well as the back of the neck.
- p) Body modifications/changes: Tattoos can absorb light and result in less effective treatments. Dark colors can absorb enough light to cause discomfort. See Note 1.
- q) State of the patient: Awake and conscious. The patient should be able to respond to pain. See Note 1.
- r) Medications, drugs, anesthetics: Caution should be taken when treating patients on drugs, medications or anesthetics reducing skin sensitivity or ability to respond to pain. See Note 1.
- s) 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 discomfort. See Note 1.

Note 1) The discomfort a patient may experience is similar to that of a needle prick. Either stop the treatment or constantly move the device a little between two points. Treatment with the device should always be pain free.

6.16 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.

PATIENT operator

- An OPERATOR who is instructed by, and under the guidance of, an ordinary OPERATOR in how to perform self-treatment. The ordinary operator shall ensure that the patient operator applies the device in accordance with its intended use and the accompanying documents. The PATIENT becomes the OPERATOR.

ORDINARY operator education and knowledge:

- Medically trained in a relevant profession (physiotherapist, chiropractor, osteopath, 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; and
- Understands hygiene and sanitary control procedures.

PATIENT operator education and knowledge:

- Able to follow the instructions and guidance from an ORDINARY operator;
- Literate;
- Able to follow the instructions for use and the accompanying documents; and
- Understands hygiene and sanitary control procedures.

6.17 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 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 PATIENT operator.
- Be responsible for the use of correct eye protection wear (if necessary).
- 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; and
- 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

6.18 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; and
- Medically or clinically trained to guide a PATIENT operator.

In addition, the responsibilities incorporate;

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

6.19 Patient position

The patient should be 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 hyperthyroidism;** 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; and
- **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.

6.20 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/support 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.

7 General battery safety information

Do not use rechargeable batteries such as NiCd, NiMH, Li-Ion. This product is intended for non-rechargeable LR03 AAA 1.5 V batteries. The batteries are placed inside the device and only accessible by use of a tool. To ensure safety when removing or replacing the batteries the device must be turned off, i.e. the push-button switch is turned off and the green LED is not lit. To safely replace or remove the batteries follow the instructions described in this manual. The operator must not touch the patient while removing or replacing the batteries, unless the patient is the operator.

7.1 Battery safety

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.

7.2 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 of or on top of heaters. This may cause battery fluid leakage, impaired performance, and a shortening of the battery service life.
- 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.
- Keep the device and batteries out of the reach of children. Avoid situations where children may chew on or lick the batteries or device.
- Do not dispose of the device or the batteries in fire or heat. Doing so can melt the insulation and damage sealed parts or protective safeguards, cause battery fluid leakage, explosion or fire.

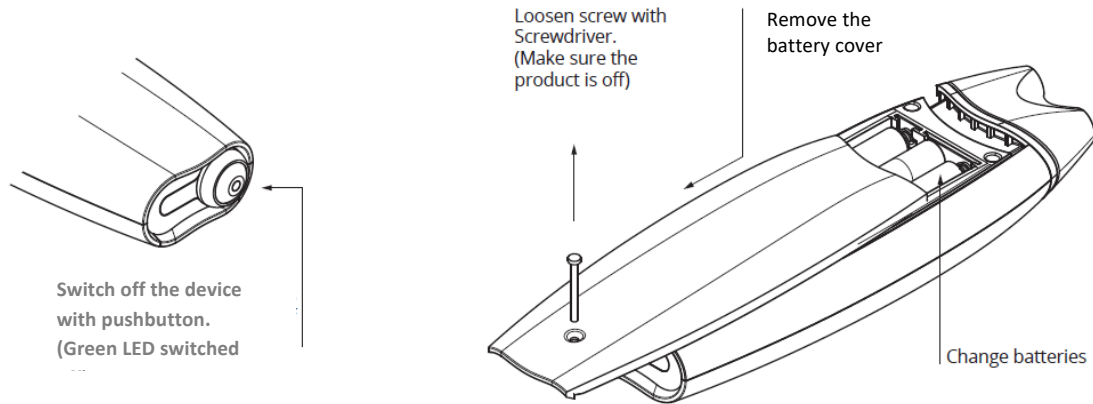
- Do not strike or throw the device containing batteries. The impact may cause battery fluid leakage, explosion or fire.
- Do not use the device if the enclosure is damaged or deformed. A damaged enclosure may have caused damage to the batteries, which could result in battery fluid leakage, explosion 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 disassemble the device or parts other than what is intended for removal or replacement of batteries. Doing so may cause short circuit, battery fluid leakage, heat generation, explosion or fire.

7.3 Recycling of batteries

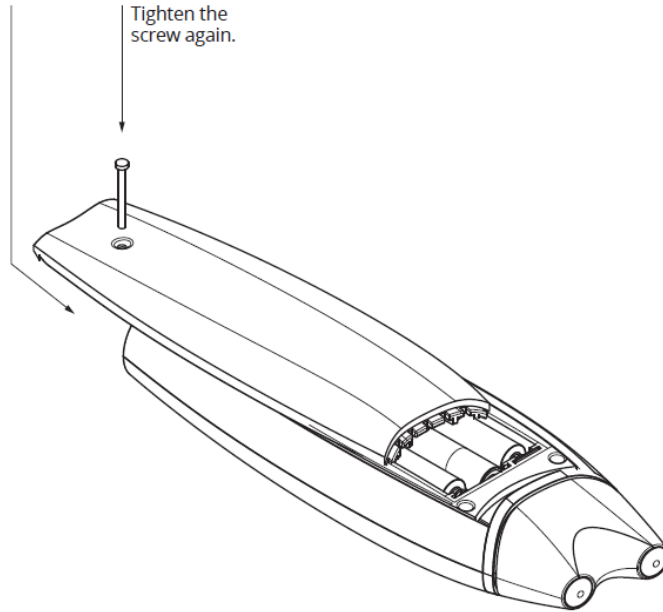
The batteries should be disposed of in a proper and environmentally safe way. Batteries that are no longer usable should be returned to the manufacturer or sent to a company specialized in the disposal of hazardous electrical materials and batteries.

7.4 Replacement of batteries

The operator should not touch the patient while removing the batteries, unless the operator is the patient. Use LR03 AAA 1.5 V batteries. Do not use rechargeable batteries such as NiCd, NiMH, Li-Ion. If the screw is missing, contact the manufacturer/supplier for replacement/spare screw, and do not use the device until the screw is in position.



After changing batteries
attach the cover



7.5 Transport and storage of the device

Ensure that the push-button (ON/OFF) is switched off. Do not carry or store removed batteries together with metal necklaces, hairpins, or other electrically conductive materials. This may short circuit the battery, which could result in excessive current flow and possibly battery fluid leakage, heat generation, explosion or fire. See Chapter 17 for instructions for packaging and transporting.

8 Laser safety

8.1 General laser safety information

These instructions for use are intended to minimize hazardous situations and the risk of potential harm. They include such things as:

- Safe handling and use of the device;
- Safe storage and transportation of the device;
- 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; and
- 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 must 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 $\pm 20\%$. 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); and
- Dirty laser apertures (protective lenses); decreases the emission.

The equipment should be protected against unauthorized use, for example by storing the device at a controlled and inaccessible location and permanently turned off.

The device is equipped with a stand-by/ready function. The device enters stand-by when the push-button switch is pressed to “ON” position. In the “ON” position, the green LED on the push-button switch is activated. The transition to “ready” is clearly indicated by repeated audible signals and the flashing of the LEDs at the laser aperture. 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 (i.e placed onto skin); however, no emission of laser radiation will occur.

Laser emission is started by the laser emission start/stop control button (i.e. placed in contact with the skin). 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 continuous emission by repeatable signals.

8.2 General risks with Class 1 Lasers (see Chapter 2.2) IEC 60825-1

8.3 Maintenance and control of emitted output power

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 NOHD is increased. If the operator wants to check the output power, the operator should send the device to 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 laser should be measured in those cases where a patient experiences discomfort under recommended use conditions. For further questions, considerations or need of technical service, please contact the supplier or the manufacturer.

Important notes regarding periodic measurements of the output power:

The power meter must be able to:

- Measure the wavelengths that the laser emits; and
- 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 very close to the laser aperture to ensure that the whole beam is fitted onto the part measuring the output power; and
- Measurements should be performed on all apertures.

How to check if the device emits laser radiation

- The 904 nm laser radiation is almost invisible to the eye but can be seen if photographed with some cell phone cameras when the aperture is placed close to a non-reflective material, for example, the palm of the hand. 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.

WARNING: Do not look at direct or non-diffuse reflections and avoid intra-beam viewing. The operator/patient may choose to 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.

8.4 Protective eyewear. Personal protective equipment (optional requirement)

If the responsible organization/operator or home patient wants to use protective eye safety wear the recommendations for protective eye wear are as follows:

- 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 0.05 W laser is reduced to 0.05 mW by using protective eyewear with OD+3
- The eye safety wear shall protect the wavelength the laser emits

Example of protective eyewear for a 904 nm 0.03 W laser. Wavelength range = 880 - 920 nm

NOTE: Many countries have regulations and standards for personal protective wear/equipment. Contact the appropriate national agency for those requirements.

9 General electrical and mechanical safety

9.1 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, with isopropyl alcohol, in order to prevent the risk of contaminants impairing the optical path, as well as to minimize patient cross-contamination. Excessive use of cleaning or disinfectants will in time damage the coating and color on the product.

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, laser emission failure, battery fluid leakage, heat generation etc.

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.

9.2 Visual inspections

The operator should perform a visual inspection of the device before use and contact the distributor 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	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 cases, cause skin breakage or small cut wounds	Do not use the device. The battery may be damaged. Contact the distributor or manufacturer for technical service and replacement of part
2	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 distributor or manufacturer for technical service and replacement of part
3	Loose or lost screws	Loose or lost screws may cause the housing of the device to come apart	Reattach the screws. Contact the distributor or manufacturer for technical service and replacement of lost screws
4	Legible labels and markings	If symbols, text markings or labels have deteriorated, their meaning could be misunderstood. This might increase any potential usage risks	Contact the distributor or manufacturer for technical service and replacement of signs, labels and markings
5	Green LED is lit when the push button is pressed ON (ready state)	If not lit; failure of switch or LED. Batteries may be replaced in wrong direction	Check the positioning of batteries. Contact the distributor or manufacturer for technical service and replacement of part
6	Laser aperture LEDs are lit when the laser is activated	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	Control the output power with a power meter. Contact the distributor or manufacturer for technical service and replacement of part

9.3 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; and
- legible reproductions (color is optional) of required labels and hazard warnings.

The following can be supplied upon request: Wire schematic, wire schematic 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.

10 Description of controls, messages, and indicators

10.1 Laser emission control



When pressed into contact with surface (the skin), the laser diodes are activated and starts to emit laser radiation through the laser aperture. A single audible signal indicates “start of action” and laser emission. A laser aperture LED is illuminated to indicate emission of laser radiation

When lifted or moved from the surface contact (skin) the laser diodes stop emitting laser radiation through the laser aperture. Double audible signals indicate “stop of action”, and thus stop of laser emission. When laser radiation is stopped, the laser aperture LED is switched off

NOTE. If, by any reason, the laser emission is not stopped when the laser apertures are not in contact with the surface/skin, the operator can use the push-button on the rear end of the device to cut the power to the laser diodes and thereby stop the emission of laser radiation immediately

10.2 ON/OFF



Switch the device “ON” or “OFF”.
To indicate connection or disconnection. Each position, “ON” or “OFF”, is a stable position.
When the Green LED is switched on, the device is turned “ON”

11 Technical specifications (general)

Product	Medical electrical equipment
Type	Therapeutic laser/medical laser
Device type	Non-invasive active therapeutic
Model	PhysioCare 904 nm Medical Laser
Electrical classification	Type BF
Laser class	1
IP classification	IP22
Battery type	LR03 AAA 1.5 V non-rechargeable
Internal power source	6 pcs primary LR03 AAA 1.5 V battery
Current consumption	< 0.35 A
Working voltage	6 - 9 VDC
Typical power consumption	< 3 W
Battery time (before need of change to new batteries)	Approximately 3 hours
Materials (enclosure)	Powder painted aluminum. Plastic enclosure
Notified body nr. CE-mark	CE 0413 CE ₀₄₁₃

12 Technical specifications

12.1 PhysioCare Laser 904 nm by SYMBYX











Laser type	GaAs
Wavelength(s)	904 nm \pm 10 nm
Type of radiation	Infrared A, invisible
Beam type	Divergent
Beam divergence	9x25 deg (FWHM) or \sim 0,44 rad
Spot size (at contact application)	9 mm in diameter (63.5 mm ²)
Continuous or pulsed laser	Pulsed
Pulse frequency	70 Hz \pm maximum 20%
Pulse duration	7 μ s
Maximum average aperture output power (per laser diode)	30 mW \pm maximum 20%
Maximum aperture peak power output	25,000 mW
Number of laser diodes	2
Total average output power	60 mW
Aperture size	\varnothing 0.9 cm
NOHD (3R exposure)	< 0.4 m
Protective eyewear	Minimum OD+3 at 904 nm \pm 20 nm
MPE level at skin contact (W/m ²)	$0.03\text{W}/63.5\text{ mm}^2 = 0.000472\text{ W/mm}^2 = 472\text{ W/m}^2$
Laser class	1

13 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 (~1 cm ² per aperture)
Point size	The size within which the laser beam is applied (~1 cm ² per aperture)
Application point	Each place where the operator applies the device or laser
Treatment area	The area on and around the pain area of body
Contact pressure treatment	The apertures are placed in contact pressure with a force of approximately 1 - 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). $J = mW \times s$
Dose	The quantity of laser radiation energy applied to a certain area. Commonly measured in joules delivered per cm ² (J/cm ²)
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
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	Person undergoing treatment
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
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

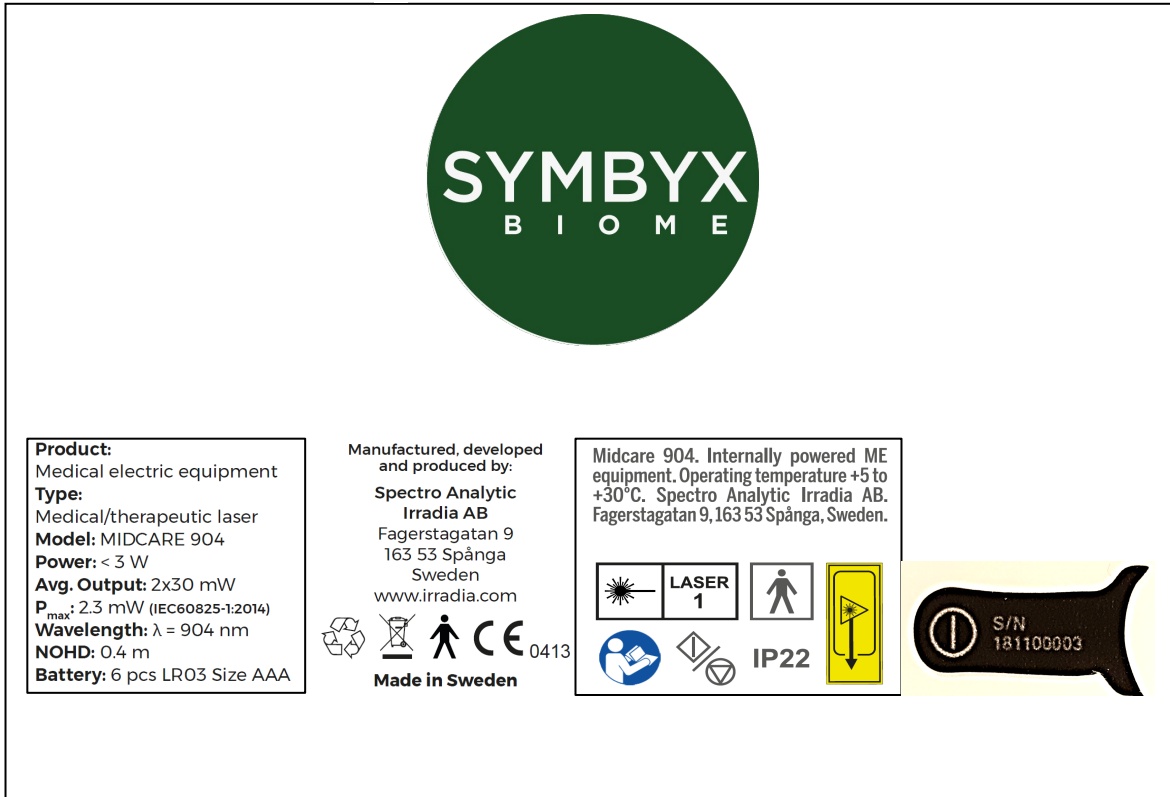
14 Labels and symbols

Symbol/label/sign	Description
	Avoid intra beam viewing. Do not look into the beam
	Laser aperture
	Warning: laser beam To warn of laser beam hazards
	Switch the device "ON" or "OFF" To indicate connection or disconnection. Each position, "ON" or "OFF", is a stable position
	Start (of action) To identify the control by means of which an action is started, i.e. start of laser emission (press aperture against surface)
	Stop (of action) To identify the control by means of which an action is stopped, i.e. stop of laser emission (remove aperture from surface)
	Type BF applied part
	Follow instructions for use. Consult the accompanying documents before use or action
	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
IP22	ENCLOSURES of ME EQUIPMENT and ME SYSTEMS designed to give a specified degree of protection against harmful ingress of water or particulate matter. IP22 means protection against vertically falling water drops when tilted 15° and objects 12.5 mm Ø and greater

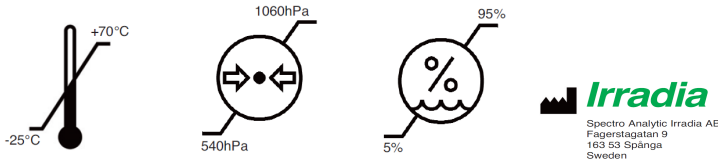
NOTE. Reference for symbols. IEC60825-1:2014, IEC60601-1:2005 and IEC60878:2003

14.1 Labels on the device

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



14.2 Symbols and marking on package label



15 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.

16 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 manufacturer for proper disposal or to a company specialized in the disposal of hazardous electrical materials and batteries. Electrical components, PC-boards should be sorted as electrical component disposal. The aluminum housing can be recycled or sorted into metal aluminum disposal. The laser diodes should be sorted as hazardous electrical components, or together with lamps, LEDs, etc.

17 Transport and packaging of the device

Save and use the original package which the device was delivered in for transport and storage. During transport or storage, the device should be switched off. The device should be stored/transported within the temperature range of -25 to + 70° C, 5 - 95 % humidity and 540 - 1,060 hPa 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. Do not use the device if has been stored or transported at its minimum or maximum storage temperature. If stored or transported at -25 or 70° C let the device cool down or heat up, to reach its intended temperature range for use, in ambient room temperature of +20° C for 45 minutes, before use and application.

18 Distributor and manufacturer contact information

Distributor: SYMBYX Pty Ltd. ABN 29638049073 Suite 6, 110-114 Hampden Lane, Artarmon NSW 2064 Australia.
Tel +61 (0)2 8066 9966
Email: info@symbyxbiome.com.

Manufacturer: Spectro Analytic Irradia AB. Fagerstagatan 9, 163 53 Spånga, Sweden Phone: +46-8-7672700, www.irradia.se.

For technical service and support, please contact the Distributor.

18.1 Reporting serious incidents

Any serious incident that has occurred in relation to the device should be reported by the user and/or patient to the manufacturer and the competent authority of the Member State/Country in which the user and/or patient is established.

19 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, is 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:

- None, no accessories.

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.

19.1 Electromagnetic emissions – guidance and declaration

Guidance and manufacturer’s declaration – electromagnetic emissions		
The PhysioCare 904 nm Laser by SYMBYX is intended for use in the electromagnetic environment specified below. The customer or the user of this laser should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR 11	Group 1	The PhysioCare 904 nm Laser by SYMBYX 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

19.2 Electromagnetic immunity – guidance and declaration

Guidance and manufacturer’s declaration – electromagnetic immunity


The PhysioCare 904 nm Laser by SYMBYX is intended for use in the electromagnetic environment specified below. The customer or the user of this laser should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8kV 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 %
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 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: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The PhysioCare 904 nm Laser by SYMBYX is intended for use in the electromagnetic environment specified below. The customer or the user of this laser should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	10 V/m (Home Healthcare environment) Immunity to RF wireless communication equipment (Table 9) 385-5800 MHz 9-28 V/m	10 V/m (Home Healthcare environment) Immunity to RF wireless communication equipment (Table 9) 385-5800 MHz 9-28 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the PhysioCare 904 nm, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter</p> <p>Recommended separation distance</p> $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)</p> <p>Field 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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol</p> 

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

NOTE 2: 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 PhysioCare 904 nm Medical Laser is used exceeds the applicable RF compliance level above, the PhysioCare 904 nm laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PhysioCare 904 nm Laser by SYMBYX.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

19.3 Separation distances – portable and mobile RF communications

Recommended separation distances between portable and mobile RF communications equipment and the PhysioCare 904 nm Laser by SYMBYX			
The PhysioCare 904 nm Laser by SYMBYX is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the laser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the laser as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of 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 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in 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.			

20 Applied standards

IEC60601-1:2005:e.d 3.1, IEC60601-1-2:2014, IEC60825-1:2014, IEC60601-1-11:e.d 2, IEC62366:2014, e.d.1.1.1, IEC60601-1-6:2013, e.d 3.1, IEC 62304:2006 +A:2015, ANSI/AAMI ES60601-1:2005 and CAN/CSA-C22.2 No 60601-1:08
Other standards in which the device complies with: ISO14971:2012, IEC62304:2006, ISO10993-5, ISO10993-10.