Instruction Manual
DuoCare 904

www.symbyxbiome.com

SYMBYX BIOME

Contents

1 General information

This operating and user manual applies to the DuoCare 904 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 MID-Lite Laser.

Pease read the ACCOMPANYING DOCUMENTS before the product is used. The reader is advised to keep the manual on hand for future reference, when necessary. MEDICAL ELECTRICAL EQUIPMENT requires special precautions regarding ELECTRO MAGNETIC COMPATABILITY (EMC) that need to be put into action. According to the EMC information provided in the ACCOMPANYING DOCUMENTS, portable and mobile RF communication equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

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 EMC 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 IIIb ACTIVE THERAPEUTIC DEVICE, with which the OPERATOR administers TRANSIENT PULSED CLASS 3B INFRARED A (IRA) LASER radiation to a PATIENT. The equipment consists of two parts, the INTERNALLY POWERED HAND-HELD device 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 PWER 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.

1.2 Separate power supply source (mains supply transformer)

This device is specified to be connected only to the Lithium-Ion battery charger, Model 2241Li 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 condition, and in accordance with its normal use and intended use.

1.4 Temperature range for use indoors/outdoors:

Charge of batteries: 0^{o}C to 35^{o}C $\pm 3^{o}$C (The device is connected to the battery charger but not used on a patient)

Discharge of batteries: 0^{o}C to 28^{o}C (The device is used on a patient whether connected to or disconnected from the battery charger)

Storage: -20^{o}C to 50^{o}C (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 EMC 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 laser.**

2 Device description and use

This device is a transportable, hand-held and battery-operated medical laser product, with which the operator administers non-invasive transient class 3B infrared 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 colors 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.

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)

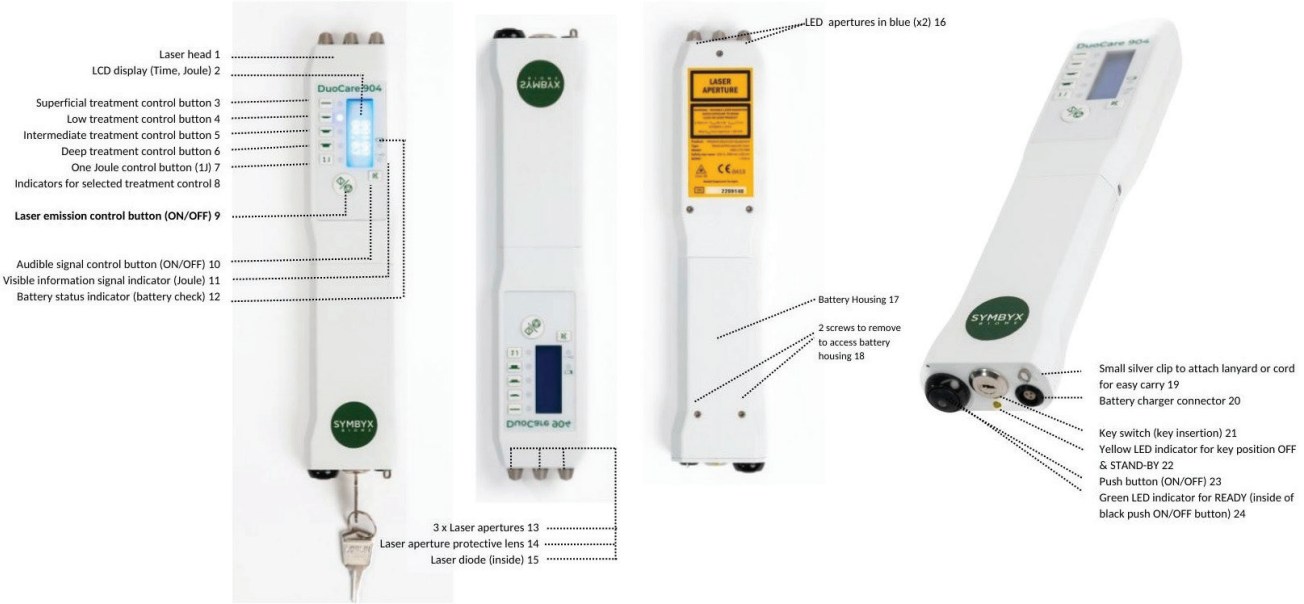
Treatment is performed by applying a generally optimal dose of laser energy onto and around a condition, using a point-by-point application procedure. An audible and visible signal informs the operator when to switch application point. At each signal, the laser aperture is moved ~ 1. 5 cm until the whole 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 respective treatment control button and places the laser apertures in contact with intact normal skin, or in non-contact (~ 2 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 medical lasers

Lasers with an average output power of 500mW or less can potentially cause eye injuries. If the beam is focused in order 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 up to 60Hz may trigger photosensitive epilepsy.

2.4 Device overview



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 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 both the key pad and at the laser apertures are lit in sequence, and a number of 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 ~2cm 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 (→○-LED indicator).
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, etc.).
o) Press and release the laser emission control button to stop laser emission (Stop of action).
p) Two audible signals indicate 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., locking the device).
u) Remove the key.
v) Clean the device with disinfectants.
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 – 28 ^{o}C, and charged within the temperature range of 0 – 35 ^{o}C ± 3 ^{o}C. When the temperature of the battery exceeds 35 ^{o}C ± 3 ^{o}C, 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 35 ^{o}C ± 3 ^{o}C.

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 color orange/red indicates charging of 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 form the mains supply (wall socket).
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 35 ^{o}C ± 3 ^{o}C, but not lower than 0 ^{o}C.
- Failure of charger, battery or the 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 SYMBYX customer service for support via info@symbyxbiome.com.

Note: The device can be used when connected to the charger, as well as during charging. Connect the Li-Ion charger to the device, then to the mains supply, and follow the primary operating functions. Remove the charger from the mains supply after use and disconnect the charger from the device.

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) are 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

If the device is switched on, 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.

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 they find most suitable or which corresponds best to the condition being treated. The following controls are guidelines only.

Treatment Parameters per application point

Treatment control	Depth of conditions being treated (in cm from skin surface)	Treatment example	Allotted time before beeping (s=seconds)	Joules emitted per laser aperture	Total delivered amount of laser energy (Joule) per treatment point	Maximum number of treatment points	Total delivered amount of energy (Joule) per treatment site
Superficial	0 - 1 cm	Swelling, open wounds (non-direct contact), sensitive skin	15 s	0.9	2.7	10	27
Low 	0 – 3 cm	Elbow, wrist, hand, foot, Achilles pain	30 s	1.8	5.4	10	54
Intermediate 	0.5 - 5 cm	Muscles or joints such as neck, knee, shoulder, abdominals, hamstring, calf, back	60 s	3.6	10.8	20	216
Deep 	3 - 5 cm	Deep situated muscles, such as in the hip, buttocks, groin, low back	120 s	7.2	21.6	15	324

IMPORTANT! New patients using laser treatment for the first time should commence at a lower dose and/or treatment time to evaluate reaction. For some patients suffering complex pain conditions, the laser treatment may cause in rare cases a transient increased pain. SYMBYX recommends a maximum of 30 seconds per treatment point and a total treatment time of 5 minutes in treatment of these patients with complex pain problems/disorder.

4.2 Treatment examples

The apertures of the device cover a surface area of 4-5 cm², and are moved approximately 1.5-2 cm at each signal. A treatment area of 10 cm² is covered after 1-2 signals. 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, sizes or body fat.

Treatment example	**Treatment control** (control button to be used)	**Laser output power & dose (per application point)**	**Application method**	**Time per application point** (and distance to a new adjacent application point	**Total application points** (number of information signals)	**Total treatment time**	**Total application dose** (Joules delivered)
Open wound		3 x 60 mW 3 x 0.9 J	Non-contact; over the wound	15 seconds per point, then move the aperture 1.5-2 cm	1 - 2	15 – 30 seconds	2.7 - 5.4 J
Achilles tendon		3 x 60 mW 3 x 1.8 J	Contact without pressure; over the tendon	30 seconds per point, then move the aperture 1.5-2 cm	2 - 4	1 - 2 min	10.8 - 21.6 J
Neck		3 x 60 mW 3 x 1.8 J	Contact, or contact pressure	30 seconds per point, then move the aperture 1.5-2 cm	7 - 15	7- 15 min	75.6 - 162 J
Knee, Back		3 x 60 mW 3 x 3.6 J	Contact, or contact pressure	60 seconds per point, then move the aperture 1.5-2 cm	10 – 20	10 - 20 min	108 - 216 J
Hip, groin		3 x 60 mW 3 x 7.2 J	Contact, or contact pressure	120 seconds per point, then move the aperture 1.5-2 cm	10 – 15	20 - 30 min	216 - 324 J

CAUTION! Be careful when applying the device in contact pressure on elderly people or people with conditions causing them to bruise easily. For the latest update on general dosage recommendations please visit www.symbyxbiome.com.

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 which thereby increases the transmission or penetration of the laser light.

5 Treatment adjustments

5.1 Skin phototype, hair colors

Skin pigmentation varies with the amount of melanin 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, darker brown and black skin and hair are more easily burned due to the absorption of light in melanin. Caution should therefore be exercised when using the device on dark pigmented skin, dark hair and tattoos, and on moles and nevus, since output powers of 300-500 mW may cause discomfort and, possibly, burns.

The skin phototype scale can be used as a guideline for treatment on or over tattoos of various colors.

Skin photo-type, hair type	Typical features	Potential risk of burns by the laser device	Treatment solution
I	Pale white skin	Never burns, unless the laser is pointed at a dark nevus or mole, etc.	Move the laser aperture back and forth between different treatment points faster than the preset treatment signaling times (example every 5 seconds). Alternatively, perform treatment in a non-contact mode.
II	Fair skin	Never burns, unless the laser is pointed at a dark nevus or mole, etc.	Move the laser aperture back and forth between different treatment points faster than the preset treatment signaling times (example every 5 seconds). Alternatively, perform treatment in a non-contact mode.
III	Darker white skin	Rarely burns, unless the laser is pointed at a dark nevus or mole, etc.	Move the laser aperture back and forth between different treatment points faster than the preset treatment signaling times (example every 5 seconds). Alternatively, perform treatment in a non-contact mode.
IV	Light brown skin	May cause an uncomfortable sting on darker spots.	Move the laser aperture back and forth between different treatment points faster than the preset treatment signaling times (example every 5 seconds). Alternatively, perform treatment in a non-contact mode.
V	Brown skin	May cause an uncomfortable sting on darker spots.	Move the laser aperture back and forth between different treatment points faster than the preset treatment signaling times (example every 5 seconds). Alternatively, perform treatment in a non-contact mode. This skin type absorbs more laser light/radiation more than paler skin. It is therefore recommended to double the treatment time given per point.
VI	Black skin	The laser should be used with supervision and caution should be taken. May cause an uncomfortable sting. If patient cannot respond to pain, burn injury may occur.	Move the laser aperture back and forth between different treatment points faster than the preset treatment signaling times (example every 5 seconds). Alternatively, perform treatment in a non-contact mode. This skin type absorbs more laser light/radiation more than paler skin. It is therefore recommended to double the treatment time given per point.

5.2 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 dose per treatment point by selecting another treatment (e.g., 3.6 J instead of 7.2 J). And/or avoid using pressure when performing treatment application.
High amount of body fat or extreme muscle mass	Large people, body builders	Increase the dose per treatment point by selecting another treatment (e.g.,7.2 J instead of 3.6 J). 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 radiation to a patient.

7.2 Medical purpose

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

Indoor and outdoor locations with dry and normal atmospheric humidity at temperatures ranging from 0 to 28 °C.
Do not use the device in indoor or outdoor locations or environments with a high atmospheric humidity, such as saunas, swimming baths and shower rooms, or in rain, fog, etc.

7.7 Frequency of device use

Up to 20 times a day.

7.8 Treatment/application time per patient

30 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 two to four weeks.
Chronic conditions 1 to 3 times a week. Acute conditions 3-5 times a week.

7.10 Number of treatments per patient

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

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 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.

7.15 Patient population

a) Age: > 8 years 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. High power (> 300 mW) may cause insignificant burns (discomfort) on dark skin (skin phototype V and VI). See Note 1
h) Hair color: High power (> 300 mW) may cause insignificant burns (discomfort) on dark hair (brown and black hair). See Note 1
h) Implants, prosthesis, artificial limbs: Not relevant
i) Reduced sight or blindness: Not relevant
j) Reduced hearing or deafness: Not relevant
k) Reduced mobility or paraplegic: Not relevant
l) Mental, psychological or intellectual disorders and conditions: Caution should be taken when treating patients unable to respond to pain. See Note 1
m) Alcohol or tobacco user: Not relevant
n) Part of body to be treated: The whole body, with the exception of the genitals, thyroid gland and eyes
o) Body modifications/changes: Tattoos can absorb light and result in less effective treatments. Dark colors can absorb enough light to cause insignificant burns (discomfort). See Note 1
p) State of the patient: Awake and conscious. The patient should be able to respond to pain. See Note 1
q) 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
r) 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 (applying 18 – 3.6 J) 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 move the laser aperture back and forth between different treatment points faster than the preset treatment signaling times (example every 5 seconds). 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 and 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 such that 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 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 anemia 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. 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 between the Lithium-ion charger and the hand-held device is

used as a MOP (Means of Protection). By using a specified non-standard connector, the risk of connecting the device to the wrong charger is greatly reduced. The connector selected can be connected in only one way, reducing the risk of reversed polarity. The charger used is in compliance with IEC60601-1.

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 battery housing, 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 housing containing the Li-Ion battery, follow the instructions described in this manual. The operator must not touch the patient while removing the battery.

The Li-Ion battery pack is placed within an enclosure/container (called battery housing) only accessible by using a tool. The battery inside the battery housing is intended to be changed only by service personnel authorized by the manufacturer. Replacement of the actual battery by inadequately trained personnel could result in hazardous situations, such as excessive temperatures, battery fluid leakage, explosion or fire. The operator is instructed to replace only the part containing the Li-Ion battery (i.e., the battery housing). The enclosure (battery housing) is designed to reduce incorrect replacements of this part.

The housing of 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 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 a battery when it is cold (below 0^{o}C) or outdoors at cold temperatures. 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.

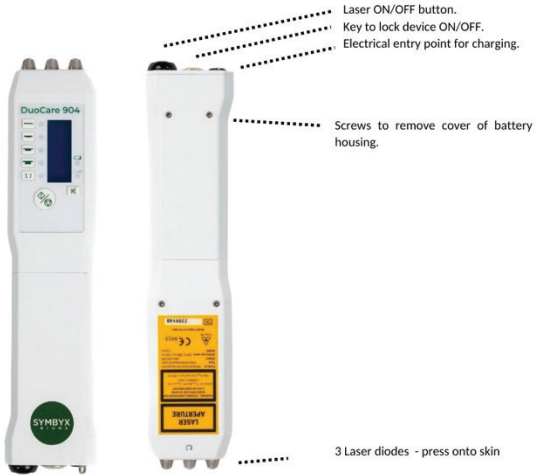
- Do not disassemble the Lithium-ion batteries. Doing so can damage the protection circuit or protective safeguards, which may cause an internal or external short circuit. It may also cause battery fluid leakage, heat generation, explosion or fire.
- Do not strike or throw the device containing the lithium-ion 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

Ensure that the key switch has been removed and that the device is turned off (e.g., no LED indicators are lit).
Remove the two screws by using a matching screw driver. Pull out the battery housing from the laser head. The screws used are M2.5 countersunk. The operator should not touch the patient while removing the battery housing. The battery housing should be placed and stored in accordance with the warnings and cautions mentioned herein regarding the Li-Lion batteries. Insert the new battery into the laser head. The battery can be inserted in only one way. Fasten the battery housing to the laser head by using the screw driver and the screws previously removed. If a screw is missing, contact the manufacturer for replacement/spare screws, and do not use the device until both screws are in position. Insert the key into the key switch and turn on the device.



8.5 Transport and storage of the battery housing

Ensure that the push-button (ON/OFF) and the key switch are turned off and that the key has been removed. Do not carry or store a disconnected battery housing 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. The housing should be stored/transported at temperatures ranging from -20 to +50 ^{o}C, in normal atmospheric humidity, and placed in a dry package that protects the device from vibrations, impacts and shock.

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 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 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,  however, no emission of laser radiation will occur.

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 emitting a signal either after every thirty seconds or at each delivered one Joule.

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 Class 3B potential hazards

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 both 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
- The laser radiation is almost invisible to the eye, but can 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. 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, as supplied, 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 EMC EQUIPMENT, e.g., BASIC SAFETY may be compromised by a modification or an alteration of the normal condition of the device.

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.

Example of protective eyewear for a 904 nm 0.06 W laser:

Wavelength range = 880-920 nm Optical density = OD+3

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

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, for example alcohol, benzalkonium or isopropyl, in order to prevent the risk of contaminants impairing the optical path, as well as to minimize patient cross-contamination.

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 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 nut containing the lens which covers the laser diode (at the laser aperture) must be in place and fastened. Using the device without this nut 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 (Stand-by)*	*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:

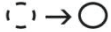
- clear warnings and precautions to be taken to avoid possible exposure to laser radiation above Class 1 and similar hazards
- a list of controls and procedures, implementable by persons other than the manufacturer or his or her agents, which increase the accessible emission levels of radiation
- clear 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 (color 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.

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 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. 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"	This treatment control is used to deliver a generally optimal dose of laser energy for superficial or external conditions. The output power of the laser diodes is set to 60 mW, delivering 0.9 J (joules) per aperture and treatment point. A signal is given each 15 seconds the laser has been emitting laser radiation. This device has three laser diodes and the output power for each laser diode is shown on the LCD-Display (i.e., 3x60 mW and 3x0.9 J) When the control button is pressed down, the information on the LCD display is shown until the control is released.
11.3 Treatment control "Low"	**This is the preset treatment control setting when the device starts up. It is generally recommended for the most types of treatments that are not superficially situated.** The output power of the laser diodes is set to 60 mW, delivering 1.8 J (joules) per aperture and treatment point. A signal is given each 30 seconds the laser has been emitting laser radiation. This device has three laser diodes and the output power for each laser diode is shown on the LCD-Display (i.e., 3x 60 mW and 3x 1.8 J) When the control button is pressed down, the information on the LCD display is shown until the control is released.

11.4 Treatment control "Intermediate " 	This treatment control is used to deliver a generally optimal dose of laser energy for conditions that are situated intermediately in the tissue. The output power of the laser diodes is set to 60 mW, delivering 3.6 J (joules) per aperture and treatment point. A signal is given each 60 seconds the laser has been emitting laser radiation. This device has three laser diodes and the output power for each laser diode is shown on the LCD-Display (i.e., 3x60 mW and 3x3.6 J) When the control button is pressed down, the information on the LCD display is shown until the control is released
11.5 Treatment control "Deep" 	This treatment control is used to deliver a generally optimal dose of laser energy for conditions that are situated deep down in the tissue The output power of the laser diodes is set to 60 mW, delivering 7.2 J (joules) per aperture and treatment point. A signal is given each 120 seconds the laser has been emitting laser radiation. This device has three laser diodes and the output power for each laser diode is shown on the LCD-Display (i.e., 3x60 mW and 3x7.2 J) When the control button is pressed down, the information on the LCD display is shown until the control is released.
11.6 One Joule control "1 J" 1 J	This control sets the visible and audible signal to indicate each time 1 J (joules) has been delivered per laser aperture. By selecting this control in combination with a treatment control, the operator receives an audible and visual indication for every 1 J delivered with the selected output power. The control is designed to make it easy for those used to other similar devices, as well as for professionals with their own treatment protocols for specific conditions. The control is also intended to be used when conducting scientific research or clinical studies, monitoring and controlling each Joule delivered, and for following/reproducing a certain treatment protocol. The output power (mW) and dosage (1J) are shown on the LCD display when the control button is pressed down. In short, the control sets the visible and audible indicator to signal for each delivered joule per laser aperture for the output power of 60 mW. When the control is set, both the LED next to the control and the LED for the treatment control are lit. The operator can, therefore, easily check the output power that is set to signal for every 1 joule that delivered. When the control button is pressed down, the information on the LCD display is shown until the control is released.

11.7 Audible information signal control **“sound mute”** 	This control allows the operator to mute the audible information signal both before and during laser emission. If pressed once, the audible signal is muted. When pressed again, the audible signal is reactivated. The audible signal is always reset to “ON” when the device is restarted by the push-button or the key switch. The audible indicator will “beep” when the selected dose for each application point has been reached. It also indicates for every 1 joule that is delivered when the “1 J” control is used. When the audible signal is muted, the English words “SOUND OFF” are shown on the LCD display. When the audible signal is reactivated, the English words “SOUND ON” are shown on the LCD display. These words are only shown before the laser emission is started. This control is designed to be used with patients who are extremely sensitive to sounds, as well as by operators who, by experience, no longer need or want the audible signal as a guide.
11.8 Visible information signal indicator 	The visible information signal indicator informs the operator when to switch treatment point, along with every 1 J delivered. The indicator is illuminated for a short moment (by a blink) when the selected dose for each application point has been reached, as well as for each one joule that is delivered when using the “1 J” control. When the audible signal is muted, the operator can check this indicator for verification.
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, 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 Laser emission control  **Start of action** **Stop of action**	When pressed and released once, the laser(s) is activated and starts to emit laser radiation through the laser aperture. A single audible signal indicates “start of action” and laser emission. A blue laser aperture LED is illuminated for each corresponding aperture emitting laser radiation. When pressed and released again, the laser(s) stops 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. The operator controls the start and stop of laser emission with this control. If, by any reason, the laser emission is not stopped when the control is used, the operator can use the push-button or key switch on the rear end of the device to cut the power to the laser(s) and thereby stop the emission of laser radiation.

12 Technical specifications (general)

Product	Medical electrical equipment
Type	Therapeutic laser/medical laser
Device type	Non-invasive active therapeutic
Model	DuoCare 904
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 50-60 Hz
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)	< 2.5 hours
Battery life time	Up to 1500 hours
Battery recharge cycle life	Minimum 500 cycles at full discharge/charge
Battery self-discharge	3 % per month
Materials (enclosure)	Aluminum (~ 1 mm thick)
Coating	Powder paint
Notified body nr. CE-mark	CE 0413 CE 0413

13 Technical specifications (laser)

Laser type	GaAs (gallium arsenide)
Wavelength(s)	904 nm ± 10 nm
Spectral bandwidth	± 2nm
Type of radiation	Infrared A, invisible
Beam type	Divergent
Beam divergence	10x40 deg (FHWM) or ~ 0.7 rad
Source size	200 µm
Spot size (at contact application)	< 0.5 cm^2
Continuous or pulsed laser	Pulsed
Pulse frequency	250 Hz
tmax	3 ms
Pmax (*Maximum peak output power, IEC60825-1)*	23 mW
Maximum average output power, per aperture IEC60825-1	17 mW
Maximum average aperture output power	60 mW
Maximum aperture peak power output	25000 mW
Duty cycle	Maximum 25 %
Maximum pulse energy from aperture	0.002 J or less
Aperture size	Ø 0.5 cm
NOHD	<0.8 m
Protective eyewear	Minimum OD+3 at 904 nm ± 10 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 (~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 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 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
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 lay person. For domestic use, the patient, operator and responsible organization can be same
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
	Sound muting To identify the control for turning off the sound
	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
	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
1 J	Control button: 1 joule Audible and visible signals for each delivered joule per activated aperture
Superficial	Control button for superficial treatment Output power and joules are set for the abovementioned tissue depth
Low	Control button for low treatment Output power and joules are set for the abovementioned tissue depth
Intermediate	Control button for intermediate treatment Output power and joules are set for the abovementioned tissue depth
Deep	Control button for deep treatment Output power and joules are set for the abovementioned tissue depth
	LED indicator for change of application point Note: If the 1 J control button has been pressed, the indicator will be lit for every 1 joule delivered per activated aperture
“SOUND ON”	Audible information signal turned ON
“SOUND OFF”	Audible information signal turned OFF
“Low battery”	Check battery status. Battery is getting low
“Recharge battery”	Check battery status. Battery is about to become depleted. The operator is instructed to recharge the battery

NOTE. Reference for symbols. IEC60825-1:2007 and IEC60878:2003.

Labels on the device

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

16 Limitation of liability

SYMBYX Pty Ltd disclaims 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 manufacturer 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 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.

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 + 50 ^{o}C, in normal atmospheric humidity, 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 Manufacturer and Supplier Contact Information

Spectro Analytic Irradia AB Phone: +46-8-7672700, www.irradia.se is the manufacturer. For all questions, technical service and customer support, please contact the Authorised Exclusive Distributor, SYMBYX Pty Ltd, Suite 2, 50 Yeo Street, Neutral Bay NSW 2089 Australia. Phone: +61 8066 9966, www.symbyxbiome.com or email info@symbyxbiome.com .

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 2241Li. 2cell, 1.3 A

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 EMC EQUIPMENT.

20.1 Electromagnetic Emissions – guidance and declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The DuoCare 904 is intended for use in the electromagnetic environment specified below. The customer or the user of the DuoCare 904 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The DuoCare 904 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 DuoCare 904 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 immunity			
The DuoCare 904 is intended for use in the electromagnetic environment specified below. The customer/user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / Burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 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 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T)) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DuoCare 904 requires continued operation during power mains interruptions, it is recommended that the DuoCare 904 be powered from an uninterruptible power supply or battery.
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 DuoCare 904 is intended for use in the electromagnetic environment specified below. The customer or the user of the DuoCare 904 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the DuoCare 904, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 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 DuoCare 904 is used exceeds the applicable RF compliance level above, the DuoCare 904 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DuoCare 904.

[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 DuoCare 904

The DuoCare 904 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the DuoCare 904 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DuoCare 904 as recommended below.

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.

21 Applied standards

IEC60601-1:2005, IEC60601-1-2:2007, IEC60825-1:2007, IEC 60601-2-22:2007, IEC60601-1-6:2006, ANSI/AAMI ES60601-1:2005 and CAN/CSA-C22.2 No 60601-1:08

Other standards in which the device complies with: ISO14971:2007, IEC62304:2006, ISO10993-5, ISO10993-10