Title: 0013-User Manual Personal Laser		Version: 7.1 Approved: 02.12.2020
Modifier: Iza Tobolska	Reviewer: Oskar Sawa	Approver: Leif Pedersen

Purpose

User Manual is a document created in purpose of correct use of laser by users to ensure high level of security. It covers risks connected with medical device and its use which have been defined in Risk Management Documentation.

Scope

Personal Laser L200
Personal Laser L400

Responsibilities

Activity	Responsible
Prepare User Manual	D&D Manager
Verify User Manual's clarity and actuality	Management Representative
Accept User Manual for publishing	President of the board

Definitions

Term	Definition
User Manual	Instruction for use

Content of the document

User Manual
PERSONAL-LASER™

Model: L200 – 200 mW / 660 nm

Model: L400 – 400 mW / 808 nm

Low Level Laser Therapy – LLLT

PhotoBioModulation - PBM

***NOTE**: Please read this User Manual thoroughly before use. For further assistance & advice please contact Akeda Sp. z o.o. or your local dealer direct!*

English

Table of Contents

This manual applies only to the laser model, as it is delivered with!

This manual is subject to change by Akeda Sp. z o.o. as and when required!

Dear customer
Congratulations on your excellent choice to acquire the powerful PERSONAL-LASER™

Before operating your PERSONAL-LASER™ - please read the user manual.

Familiarization with the operating instructions is equivalent to training in the use of the medical device.

PERSONAL-LASER™ is the latest generation of powerful LLLT / PBM lasers with the latest technology, for the benefit of both therapist and patient.

PERSONAL-LASER™ is developed and designed for home use but is also suitable for the professional clinicians for clinic use, for example with chiropractors, physiotherapists, wound clinics, and others.

PERSONAL-LASER™ is designed for the treatment of pain, muscle, and joint disorders, and for wounds.

PERSONAL-LASER™ provides a painless treatment and quick results.

PERSONAL-LASER™ is designed for battery operation, with Li-Ion battery technology, which has a large capacity of energy, up to 3 hours of treatment per fully charged battery.

PERSONAL-LASER™ is with electronic control for overheating.

PERSONAL-LASER™ provides a whole new range of opportunities to work effectively with laser light in pain, joint and tissue treatment

Energy for Life – Laser therapy for wounds and pain

Indications for laser treatment includes:

- Musculoskeletal disorders (Pain intensity)
- Chronic nonspecific low back pain (Pain reduction)
- Shoulder tendinopathy (pain relief)
- Knee osteoarthritis (pain reduction
- Temporomandibular myofascial pain (pain intensity)
- Fixed orthodontic therapy (pain reduction)
- Complication after mandibular third molar surgery (pain reduction
- Recurrent aphthous stomatitis (pain and wound healing)

DID YOU KNOW?
The word "LASER" is an acronym for "Light Amplification by Stimulated Emission of Radiation."
Lasers for therapeutic use are called Low Level Laser Therapy (LLLT) or PhotoBioModulation (PBM).

Certifications

PERSONAL-LASER™ is approved as a medical laser device used for LLLT/PBM treatment. The laser system complies with the rules in the EU Directive 93/42.

PERSONAL-LASER™ is Medical CE certified – **CE 2274**

GMDN – Classification (Global Medical Device Nomenclature) Code 60410 - Musculoskeletal/physical therapy laser, home-use

Definition

An electrically powered diode laser intended to provide noninvasive laser therapy [e.g., infrared phototherapy, low-level laser therapy (LLLT)] for localized treatment, improving blood circulation in the treated areas to facilitate healing. It typically consists of a hand-held applicator designed for transcutaneous delivery of visible red/infrared laser light energy. It is intended to be operated by a healthcare provider in both a clinical setting and in the home.

PERSONAL-LASER™ is designed and manufactured in accordance with all current standards:

PN-EN ISO 13485:2016	Quality Management Systems
PN-EN ISO 14971:2012	Risk Management Medical Equipment
PN-EN 60601-1:2011	Safety of Medical Electrical Equipment
PN-EN 60601-1-2:2015-11	Safety of Medical Electrical Equipment (EMC)
PN-EN 60601-2-22:2013-07	Medical electrical equipment - Specific requirements for laser equipment
PN-EN 60601-1-11:2015-09	Medical devices for Home Healthcare environment
PN-EN 60825-1:2014-11	Laser Safety
PN-EN 62133-2:2017-08	Li-Ion battery
PN-EN ISO 15223-1:2017-02	Symbols and labeling of medical devices (Graphical symbols)

Akeda Sp. z o.o. products are continuously in development and thus reserves the right to make changes and/or improvements to the products described in this manual without prior notice. We also reserve the right to revise or recall this document at any time without prior notice.
Akeda Sp. z o.o. products are covered by the liabilities and warranties stated by EU law.

Warnings & Precautions

Laser Classification
Laser classification provides the operator with knowledge about the laser and how they should protect themselves and others in order to avoid harm or injury. Equipment and devices that emit visible or invisible laser light is classified according to EU standard EN 60825-1 (Safety of Laser Products) by laser class: 1, 1M, 2, 2M, 3R, 3B and 4.

The most common laser in use for Laser therapy is class 3B lasers. In some cases, LLLT/PBM systems the laser is categorized as Class 4, but the actual energy being delivered equates to Class 3B. This is due to the use of optics to *scatter the laser light* which spreads the energy over a larger area.

***PERSONAL-LASER*™ are all Class 3B lasers!**

This laser class exceeds the power of Class 3R (5 mW), but not exceeding 500 mW. If exposed directly to Class 3B the laser beam produced may cause eye damage and, in some cases, cause skin damage. Consequently, eye protection should always be worn when there is a risk of the eyes being exposed.

It is the responsibility of the manufacturer to comply in accordance with the current rules of EU standards and the CE directive. Both manufacturers and vendors must ensure that the end user of the laser has received sufficient and necessary information enabling the safe and proper use of the equipment / device sold or provided.

Contraindications- Contraindications – General Precautions LLLT/PBM laser treatment

- Never aim at or attempt to treat the eyes! This can in unfortunate cases result in the lens gathering the laser light at a single point on the retina resulting serious damage!
- Do not treat the abdominal area if the patient is pregnant!
- Do not treat tumors and/or cancerous tissue!
- Do not treat areas in contact with hormone producing glands such as the Thyroid!
- Do not treat areas in contact with organs – this also applies to transplanted organs!
- Do not treat areas in contact with any kind of metal or plastic implants!
- Do not treat tissues in contact on or near a pacemaker!
- Do not treat patients on medication that increases light sensitivity!
- Do not treat patients with epilepsy!
- Do not treat patients with fever!
- Do not use laser light directly onto freckles, birthmarks and tattoos!
- Dark and tanned skinned patients have a higher risk of overheating and possibly burning-take extra care!

Contraindications and points of attention when using laser therapy

The amount of indications for the use of laser therapy is great, but there are also simple contraindications and points of attention you as a user of laser therapy should familiarize with. However, the individual contraindications and points of attention should always, like

other types of treatment (therapy and medication) assessed academically in relation to the patient, so that accidental side effects are avoided.

Old literature on lasers often contains certain alleged contraindications to laser treatment. There is in fact no absolute contraindication to LLLT/PBM, but some relative contraindications and common-sense warnings. However, direct illumination of the eye should be stated as an absolute contraindication though.

Eyes:

A laser class tells you how to protect yourself and others against the laser light, so you do not get an eye injury or a possible skin damage. Lasers whose power exceeds Class 3R (5 mW) and does not exceed 500 mW is referred to as Class 3B lasers. In case of direct exposure, Class 3B laser radiation may cause eye damage and in certain cases skin damage. Therefore, eye protection should always be used if there is a risk of direct illumination of the eye.

The power of an electric bulb (W) indicates it´s total power consumption. A 60W electric bulb emits only 1 – 2W visible light. This means that the rest of it´s power (58-59 W) turns into warm and invisible infrared light. At 1-meter distance from an electric bulb, the pupil of the eye will receive approx. 1 millionth of total light energy. A laser emitting light as a beam (collimated) will hit the eye with 100% of the light energy, even at a very long distance. A laser emitting the light scattered (divergent) at a distance of 1 meter will hit the eye with approx. 0.1% of light energy. At a distance of 20 cm, approx. 10% of the light energy hits the eye. This means that the risk of eye damage from the laser light depends primarily on the beam's parallelism and it´s diameter.

In summary, if one does not look directly at the laser light from a Class 3B laser, you do not need to use eye protection as practitioner. The patient should always be protected or wear eye protection when there is the slightest risk of direct exposure to the eyes.

Pregnancy:

Pregnancy is another alleged contraindication. Large doses above the abdomen should be avoided. It is completely safe to treat pregnant women, for both mother and child, but should complications arise in connection with the laser treatment or shortly afterwards, it is easy to blame the laser therapy and the therapist subsequently has the burden of proof.

Pacemakers, implants, and screws

In people with implanted pacemakers, implants or screws, laser therapy is not contra-indicated. Pacemakers are electronic and encapsulated in metal and therefore cannot be affected by light. Therefore, it is a misunderstanding when pacemakers are listed as a contraindication. The misconception is probably because ultrasound or other mechanical therapy contraindications have been directly transferred to laser therapy.

Epilepsy:

Epileptic seizures can be caused by certain types of light effects (pulsed visible light in the range 5-10 Hz). One must therefore be careful with instruments with visible flashing lights. There is nothing in the literature that indicates that invisible pulsating light should cause epileptic seizures. However, from anecdotal evidence it is recommended to be cautious in laser treatment of patients with epilepsy.

Thyroid gland:

It has not been reported that LLLT / PBM can cause irreversible damage and because the thyroid is sensitive to light, the gland is an interesting subject for research on hypo- and hyperthyroidism. Laser therapy of the thyroid gland is often warned against, but no clinical studies or clinical experience support this warning.

Children:

The dose should be adjusted to the weight of the child, but there is no indication in the literature that children, including babies, should not benefit from laser therapy. Illumination of epiphysis discs in children is also not contraindicated.

Cancer:

People with cancer or suspected cancer should never be treated by someone who is not a specialist. It is not because laser therapy will not have a stimulating effect, but because the law, in fairness, only allows specialists to treat cancer. Cancer patients can therefore not be treated with laser therapy without a written consent and in collaboration with the doctor responsible for the treatment. As a palliative treatment of patients in the terminal phase, laser therapy can act as an analgesic and stimulant treatment.

Hemophilia:

Patients with hemophilia and other blood and clotting diseases should not be treated with laser therapy at this time, as we don´t know enough about the effect it has on coagulation ability. However, it is more a warning than a real contraindication.

Irradiation of the brain:

It can be postulated that brain damage will not occur when areas of the brain are treated. Targeted therapy with laser light of the brain is not recommended so far due to inadequate documentation.

Radiation treatment:

Patients receiving radiation therapy have previously been considered counter-indicative of laser therapy. It is not obvious why since the radiation they are exposed to has a different characteristic than LLLT/PBM. Laboratory studies on animals receiving X-rays have shown that they made greater progress if they received laser therapy first. Several

studies have shown local effects on the immune system. More and more studies on laser treatment of circulating blood are being published. Changes in blood components in relation to the immune system after laser treatment can obviously lead to effects in many

other parts of the body, such as e.g. increased defence against cancer. In fact, LLLT/PBM seems to have a radioprotective effect on tissues.

Diabetes:

Diabetes has been suggested as a contraindication. However, there is no evidence that laser therapy can exacerbate the symptoms. Laser treatment increases blood flow and is effectively for wound healing. Therefore, laser therapy can be recommended as an extra treatment modality for diabetic foot problems.

Tattoos, moles, and dark skin:

Tattoos, moles, and dark skin (Type 5 and 6 - The Fitzpatrick Chart) contain another pigmentation and even low energy levels of laser light will be absorbed into these pigments. Depending on the type of pigment, the patient may experience heat or even pain when a therapeutic laser is used over an area of darker pigment. Therefore, it is recommended to start treatment remotely. Listen to patient feedback and adjust the laser power (mW) if necessary. Tattoos, moles and dark skin do not constitute a contraindication, but high intensities will cause high absorption and may cause a pain reaction.

Sensitivity:

Light sensitivity is often listed as a contraindication for LLLT/PBM. However, there is not much evidence in the literature that confirms the correlation between LLLT/PBM and light sensitivity. On the contrary, several studies show that LLLT/PBM before radiation therapy has a preventive effect. On the other hand, it is known that ultraviolet light can cause photosensitivity. Further research is needed if this alleged contraindication is to be confirmed.

General Warnings LLLT/PBM laser treatment

WARNING NOTICE!

- Never look directly into the laser light!
- The sight may be permanently damaged!
- When treating the face with laser light, always use laser safety goggles!

WARNING!
Do not point the laser at reflective or polished surfaces (especially mirrors).
If the laser light hits such a surface, the laser light will reflect and would pose a serious threat to safety.

WARNING!
Application part of lasers might rise to 45,6 °C during treatment! When Patient's or Operator feel too much heat, treatment should be stopped immediately!

WARNING!
The lasers are EMC tested according to: PN-EN 60601-1-2:2015-11 Safety of Medical Electrical Equipment (EMC). Without exclusions. All requirements are applicable.

WARNING!
When the laser device is not connected to the battery, there are no precautions for EMC! The Laser during work or in standby mode (laser probe with battery in) cannot be placed or used close to (less than 50 cm) other electrical equipment which emits electromagnetic energy and its cables or electricity connections. Other electrical equipment which emits electromagnetic energy used in close area might negatively influence on the laser and might cause a damage of electronics. To avoid any damage of the laser and use it properly keeping high quality of work and effectivity of the device do not use nearby other electronic equipment and its cables

WARNING!
A Patient's pain level and general discomfort should be monitored and noted throughout the treatment process.
If discomfort or pain is experienced, treatment should be stopped immediately.

WARNING!
If the lens / laser optics is getting hot, pause of treatment has to be conducted and laser has to be turned off. So it will feel very uncomfortable when the laser is held directly on the skin, and it can be so hot that it can damage the skin!

The lasers are designed for a treatment time of 5 minutes and max. 2 x 5 minutes.

Every 10 second the position of contact point of lens and patient/operator skin should be changed. There is a beep every 10 seconds for signalization of changing position.
The person who treats / or is treated, also quickly discover that something is wrong with the laser and stop the treatment!

WARNING!
If the laser is placed directly upon the skin during treatment the laser energy can sometimes become too concentrated. The treatment area is in high risk of being overheated and potentially being burned! Especially dark and tanned skinned patients have a higher risk of overheating and burns!

TIP!
The laser can be moved slowly back and forth over the treatment area to avoid built up of local heat!

WARNING!
Avoid infection! Always clean the laser and optics before and after use with the recommended disinfection method!

Safety in General

- Do not use the laser with, under, or near water, explosive or flammable materials, flammable anesthetics or oxidizing gases (oxygen, nitrous oxide etc.). Flammable liquids such as propyl alcohol used for cleaning and disinfection should have completely evaporated before the laser is turned on. See the environmental conditions described in the specifications section.
- Protect the laser against unauthorized use. Always separate the laser probe and battery after use. The laser must be placed out of the reach of children.
- Check the laser and its optics thoroughly before beginning treatment! Carry out a "fire" test on the Laser Test Card. Stop using the laser if any defects are found, the laser does not perform as expected and/or if there is any doubt about the proper and secure function and contact Akeda Sp. z o.o. or your local dealer.
- Before beginning treatment ensure sure that the desired settings are programmed to be used.
- The patient must always wear eye protection if there is risk of direct illumination of the eyes! Only the supplied goggles that came with the laser should be used!

- Periodically check the goggles for any damage. The eye googles should not be worn if they are damaged. In this case you should obtain a new pair directly from Akeda Sp. z o.o. or your local dealer.
- Never look directly into the beam when it is turned on, nor should you point the laser in the direction of any shiny or reflective surfaces!
- Do not use or place the laser in direct sunlight. It should also not be stored near strong electromagnetic fields so that mutual disruptive effects are avoided (thermal and EMC).
- The laser does not include medications, creams, gels or other substances. It does not emit toxic substances when used, stored or transported under the specified conditions.
- Do not attempt to open/disassemble the laser or the battery.
- The warranty is void if it can be proven that the any part of the laser has been tampered with by an unapproved individual.
- The user is responsible for the use of cleaning products that come in direct contact with the patient's body. The user must ensure that the products are in accordance with applicable standards. This includes irritants, allergens and toxins (ISO 10993-1).
- Only use original accessories provided by Akeda Sp. z o.o. or by your dealer!
- If the laser, batteries or accessories are to be disposed of they should be returned to the Akeda Sp. z o.o. or your local dealer!
- In case of the laser being used in a way that is not in accordance with this manual, or for a purpose that differs from that which is described in this manual, then Akeda Sp. z o.o. cannot be held responsible for any damage caused by operation of the laser.

Hygiene

IMPORTANT NOTICE!
To avoid infection, always clean the laser and optics before and after use, with the recommended disinfection method!

Disinfection of laser probe, battery and optics:

Wipe with isopropyl alcohol or pure (100% ethanol) alcohol and then wipe afterwards with chlorhexidine.

Chlorhexidine is a chemical antiseptic substance and is a strong antibacterial agent.

It is both bactericidal and bacteriostatic.

The laser probe and the battery must <u>not</u> be boiled or autoclaved!

Laser and optics are provided non-sterile!

TIP!
Clear plastic wrap (cling film) can be used as a protective layer on the laser and/or optics as to avoid contaminating the laser with biohazardous materials!

Device Description *PERSONAL-LASER™*

1. *Laser Optics*
2. *Laser cooling piece*
3. *Laser probe*
4. *LED DISPLAY (green / yellow / red)*
5. *Bottom laser section*
6. *Li-Ion battery*

LED DISPLAY:

ERROR = RED

STANDBY = YELLOW

LASER ON = GREEN

Laser Startup Guide

1. Use a fully charged battery (6.) and twist it clockwise onto the laser probe. Keep twisting until the laser switches on. 3 short beeps will sound followed by 1 long beep before the laser starts up. → **MODE:** LASER ON. When the laser is on the LED light is continuously green (4.)

2. The LED light (4.) will be continuously green
   Short beep every 10 sec.
   The lasers effect = 100%
   The laser is active for 300 sec. (5 min) after which the laser stops automatically while giving off a long beep followed by a high / low beep. This indicates that the laser has automatically gone into
   → **MODE:** STANDBY. The indicator LED light will change from a continuous green (4.) to flashing a yellow light.

3. To turn the laser off simply unscrew the battery (6.) with a counter-clockwise motion
   → **MODE:** LASER OFF.
   If you wish to restart the laser reattach the battery to the laser → **MODE:** LASER ON.

Treatment- Personal Laser dosage schedule

Model:	Power mW:	Joule/ Sec.:	Joule/10 Sec.:	Joule/min.:	Joule/ 5 min.:
	100	0,1	1	6	30
L200	**200**	**0,2**	**2**	**12**	**60**
	300	0,3	3	18	90
L400	**400**	**0,4**	**4**	**24**	**120**

1 Joule = 1 W per sec. / 1000 mW per sec.

PERSONAL-LASER gives beep for every 10 seconds.
Each point is considered 1 cm ²

Treatment guidelines

General instructions for pain point:
Pain radiating from a small area or point should be treated directly at the pain point until pain relief is achieved!
The laser must have skin contact and you can press hard on the spot!

General instructions for diffuse pain and inflammation in the area:
Diffuse pain and area affected by inflammation, point should be treated outside the area and subsequent point treatment in the inner area.
The laser must have skin contact, with light pressure!

General instructions for wounds and edema area:
Wounds and edema, point should be treated around the area in the border up to the wound or edema and subsequently in the inner area with reduced energy. This means that the laser is kept approx. 5 cm above the wound or edema area and moved point by point.
The laser must have skin contact in the area up to the wound border or edema and in the inner area the laser must be held over the skin!

The larger the injury area, the more treatment points must be used!

When treating the hairline, it may be necessary to keep the laser in motion (back and forth), to avoid heating in the hair follicle!

Treatment frequency:

Daily or 2 - 3 days intervals, to a maximum of one week between each treatment

New damage may conveniently be treated with one day interval.

Treatment Dose:

Wound and skin	2 - 5 joules per cm ²
Tendons, joints and muscles	5 - 10 Joules per cm ²
Pain points	10 - 150 Joule or until pain relief is achieved.

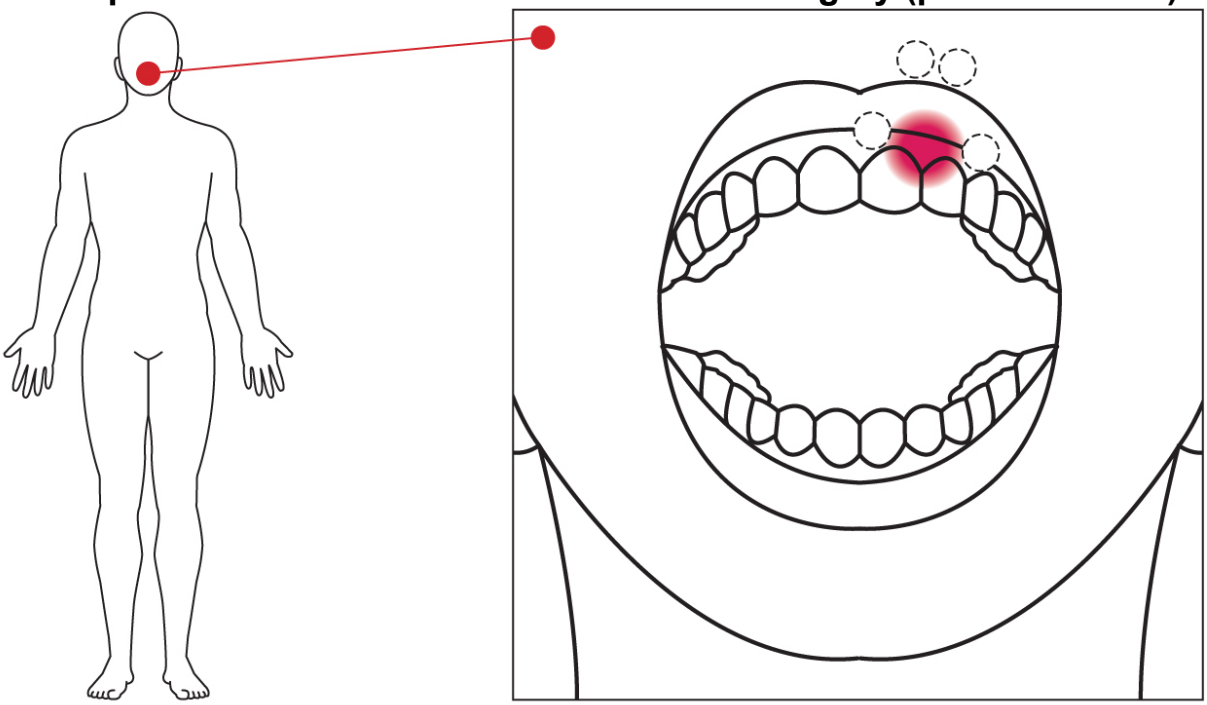
In case of overreaction, the dose should be reduced by 30 - 50%

In case of no reaction after several treatments, the dose can be increased by 30 - 50%

When recovery or healing is achieved, the frequency of treatments can be reduced and phased out!

Instructions are general and dose is the minimum recommendation!

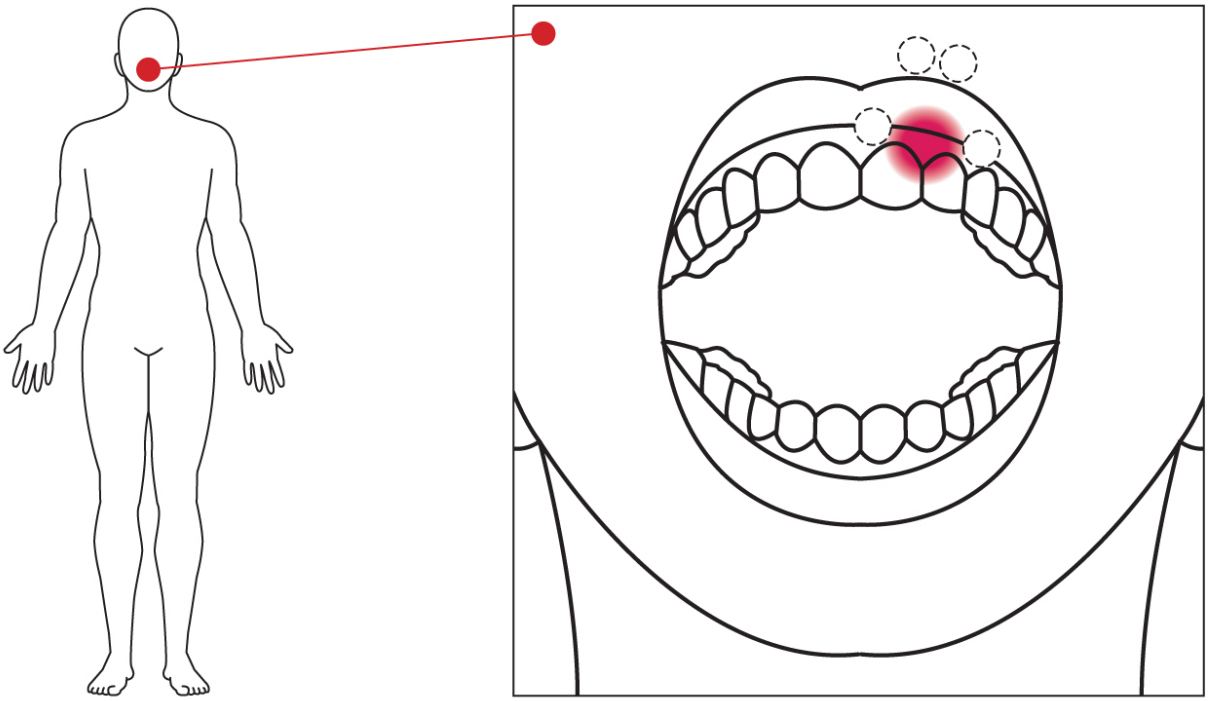
Complication after mandibular third molar surgery (pain reduction)



Model:	Beeb per spot:	Joule tot. per spot:	Frequency* of treatment 1. week:	2. and 3. week:	4.- week:
L200	4	8	7	2 - 3	1 - 2
L400	2	8	7	2 - 3	1 - 2

***Frequency of treatment = Total number of treatments per week**

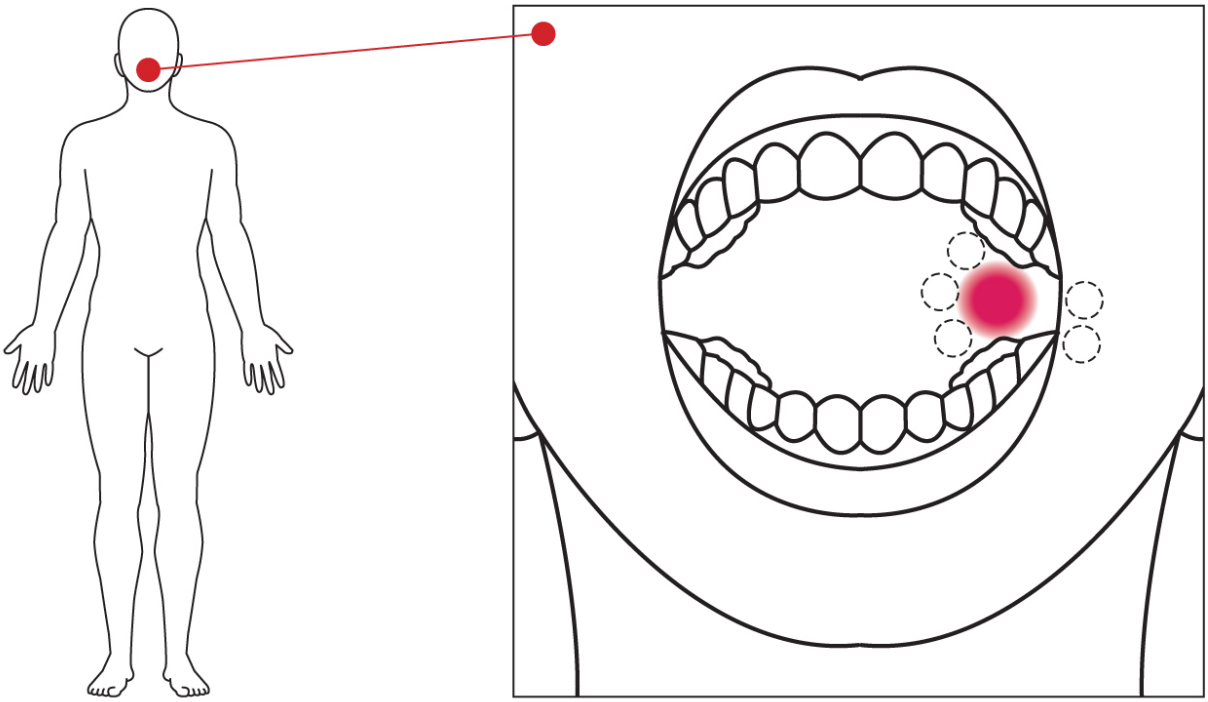
Fixed orthodontic therapy (pain reduction)



Model:	Beeb per spot:	Joule tot. per spot:	Frequency* of treatment 1. week:	2. and 3. week:	4.- week:
L200	8	8	7	2 - 3	1 - 2
L400	2	8	7	2 - 3	1 - 2

***Frequency of treatment = Total number of treatments per week**

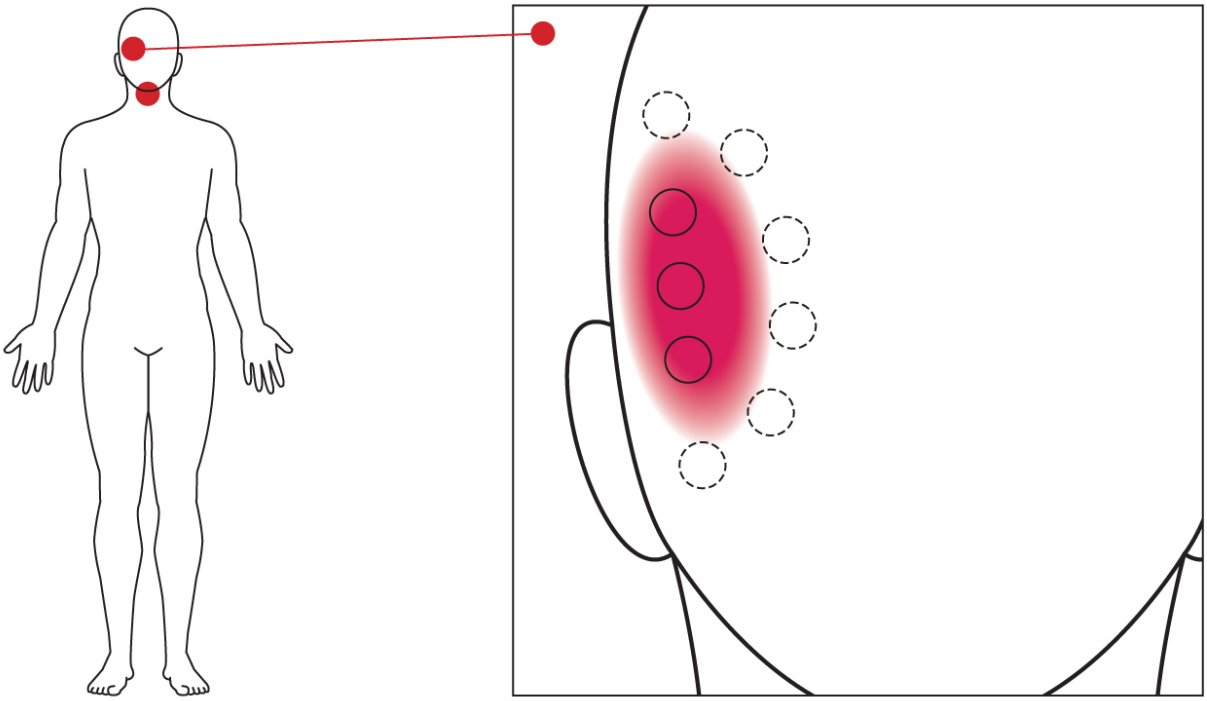
Recurrent aphthous stomatitis (pain and wound healing)



Model:	Beeb per spot:	Joule tot. per spot:	Frequency* of treatment 1. week:	2. and 3. week:	4.- week:
L200	2	4	7	2 - 3	1 - 2
L400	1	4	7	2 - 3	1 - 2

***Frequency of treatment = Total number of treatments per week**

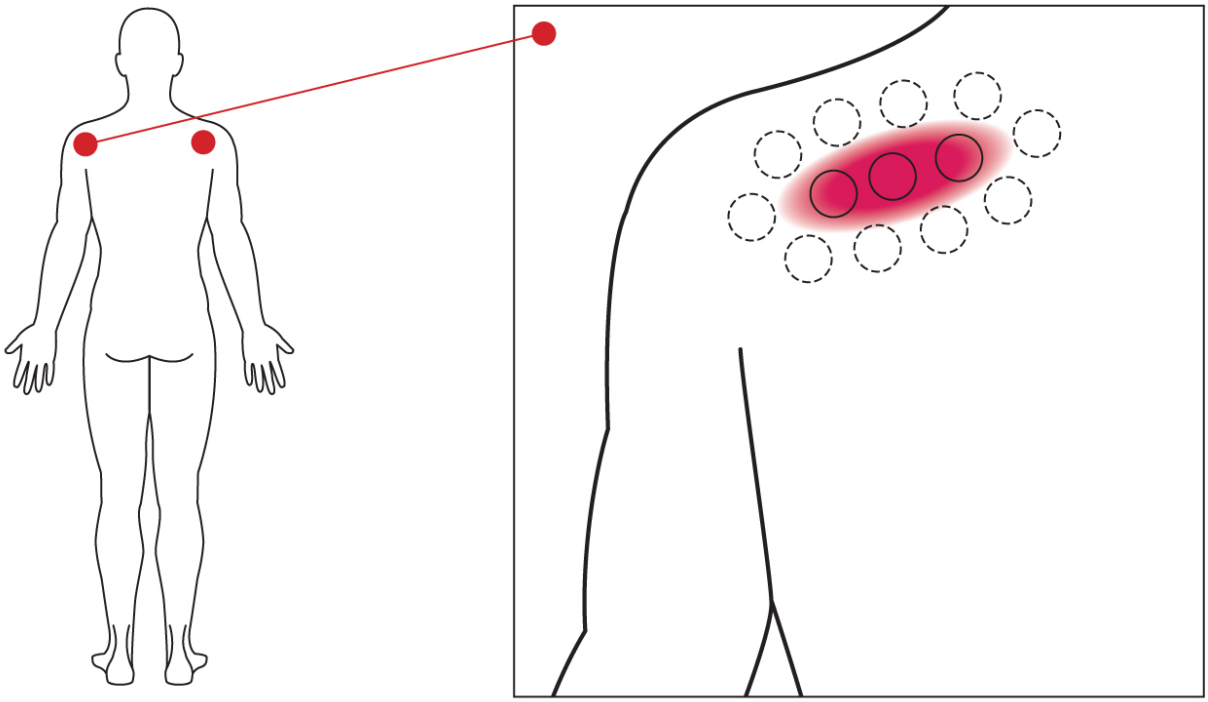
Temporomandibular myofascial pain / Neck pain (pain intensity)



Model:	Beeb per spot:	Joule tot. per spot:	Frequency* of treatment 1. week:	2. and 3. week:	4.- week:
L200	10	20	7	2 - 3	1 - 2
L400	3	12	7	2 - 3	1 - 2

***Frequency of treatment = Total number of treatments per week**

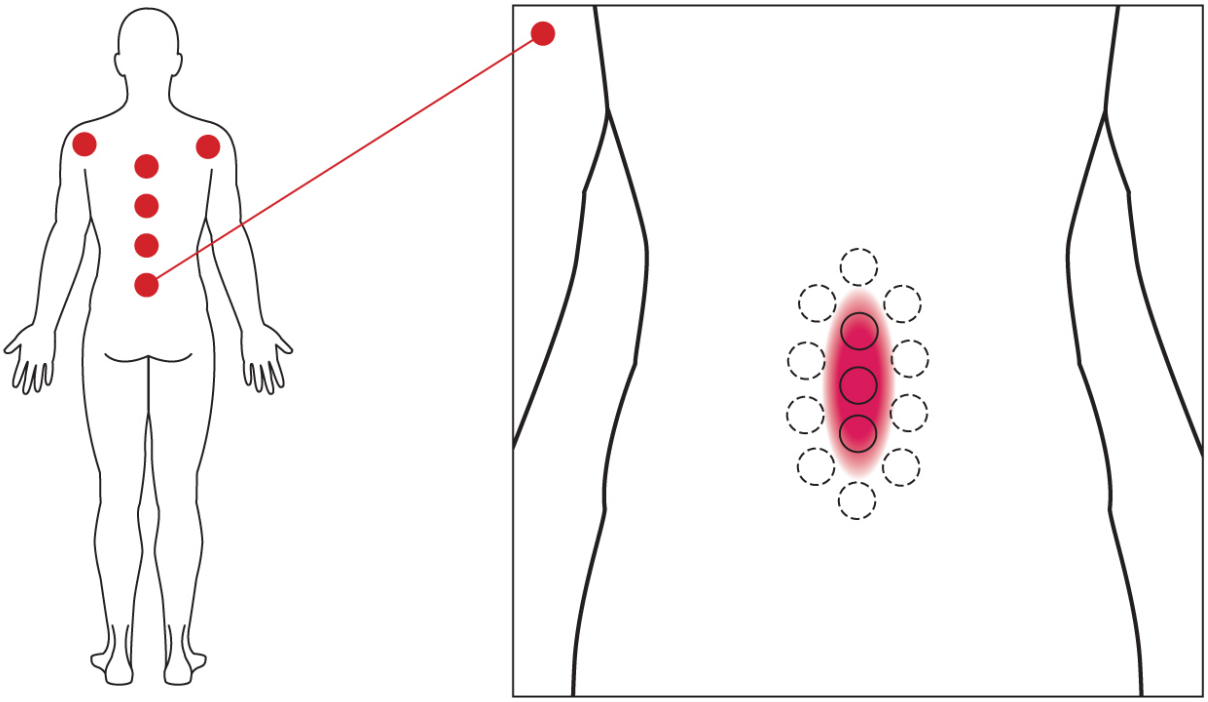
Shoulder tendinopathy (pain relief)



Model:	Beeb per spot:	Joule tot. per spot:	Frequency* of treatment 1. week:	2. and 3. week:	4.- week:
L200	10	20	7	2 - 3	1 - 2
L400	3	12	7	2 - 3	1 - 2

***Frequency of treatment = Total number of treatments per week**

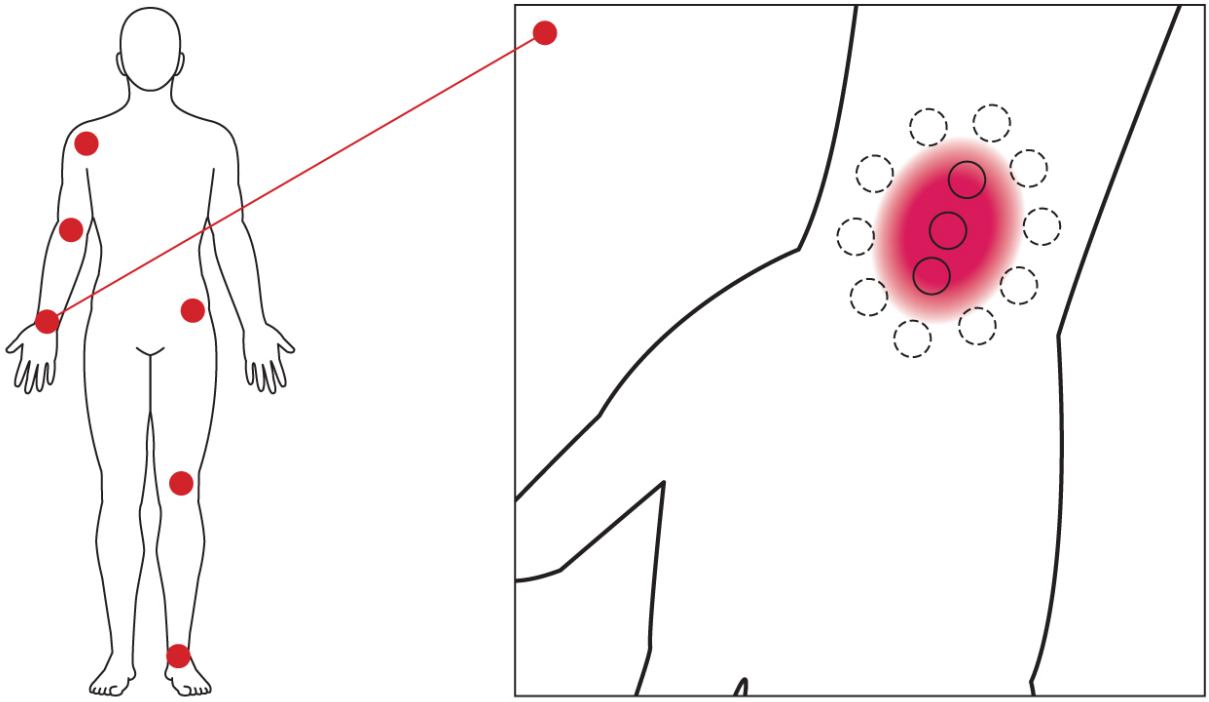
Chronic nonspecific low back pain (pain reduction)



Model:	Beeb per spot:	Joule tot. per spot:	Frequency* of treatment 1. week:	2. and 3. week:	4.- week:
L200	10	20	7	2 - 3	1 - 2
L400	3	12	7	2 - 3	1 - 2

***Frequency of treatment = Total number of treatments per week**

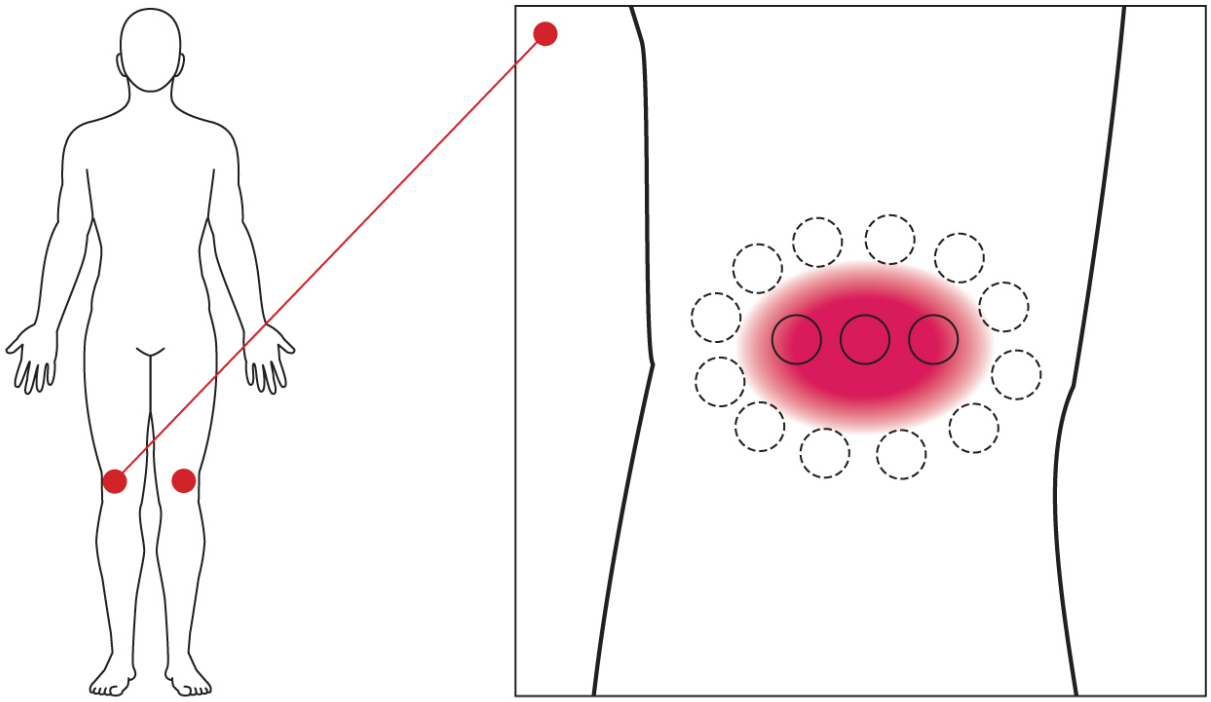
Musculoskeletal disorders (pain intensity)



Model:	Beeb per spot:	Joule tot. per spot:	Frequency* of treatment 1. week:	2. and 3. week:	4.- week:
L200	10	20	7	2 - 3	1 - 2
L400	3	12	7	2 - 3	1 - 2

***Frequency of treatment = Total number of treatments per week**

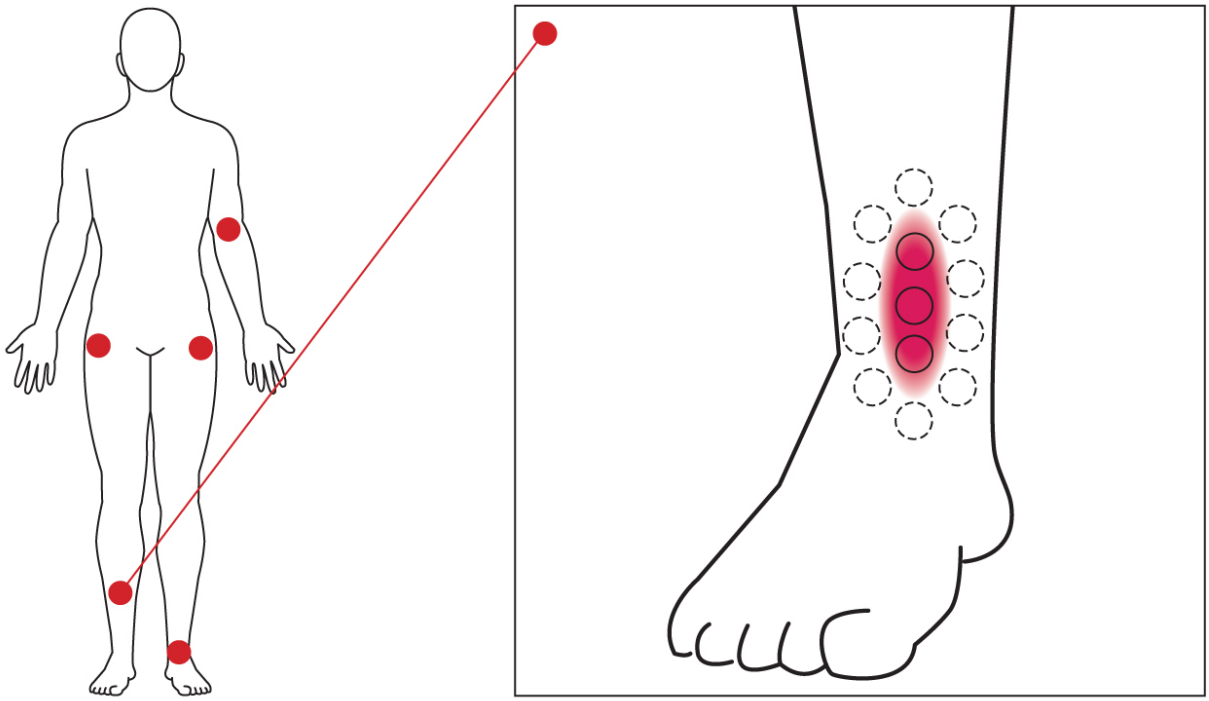
Knee osteoarthritis (pain reduction)



Model:	Beeb per spot:	Joule tot. per spot:	Frequency* of treatment 1. week:	2. and 3. week:	4.- week:
L200	10	20	7	2 - 3	1 - 2
L400	4	16	7	2 - 3	1 - 2

***Frequency of treatment = Total number of treatments per week**

Wounds and edema area



Model:	Beeb per spot:	Joule tot. per spot:	Frequency* of treatment 1. week:	2. and 3. week:	4.- week:
L200	3	6	7	2 - 3	1 - 2
L400	1	4	7	2 - 3	1 - 2

***Frequency of treatment = Total number of treatments per week**

IMPORTANT NOTICE!

- Do not fasten the battery (6.) too tightly!
- Only hold onto the bottom laser section (5.), when the battery (6.) is being screwed on or off!
- Never hold the laser by the cooling piece (2.) when the laser is ON!
- Always remove the battery (6.) from the laser probe (3.) after use!

The ***PERSONAL-LASER™*** is preprogrammed with the following settings:

Laser:	**Laser Power mW:** (+0-10%)	**Timer:** (300 sec.)	**Joule tot.:** (+0-10%)
L200	200 mW	5 min.	60 Joule - (10 sec. = 2 J)
L400	400 mW	5 min.	120 Joule - (10 sec. = 4 J)

IMPORTANT NOTICE!

- Always remove the battery (6.) from the laser device (3.) after use!

Error Messages

Low battery
Yellow LED light (4.) flashing slowly → **MODE:** Low battery. Battery must be charged soon.
Yellow LED light (4.) flashing quickly and then switches off → **MODE:** No battery. Battery must be charged.
.

High temperature (+ 45C)
Red and yellow LED light (4.) flashes alternatingly → **MODE:** Laser's temperature is too high. The laser is programmed to switch off automatically. The laser should stay switched off and cool down fully before restarting the laser.

Photodiode (Laser Power test)
Red LED light (4.) continuously lit. This indicates that a laser diode error → **MODE:** ERROR.
Contact Customer support: info@akeda.com.pl

Battery and charger

The Li-Ion batteries are supplied uncharged and should therefore first be charged before use!

1. Connect the AC Adapter to the charger with the USB cable.
   The Li-Ion battery is placed with the threaded part down with a little pressure into the charger's battery holder.

2. Plug the charger into a 130/230 V outlet. This will light up the LED on the charger with red, but when fully charged the LED light will switch to a light green (or blue).

Li-Ion Charger

MINI Li-Ion battery
3,7V / 650 mAh

IMPORTANT NOTICE!
Make sure the small micro USB connector is properly seated and gently insert the plug, without twisting or breaking the plug!

The charging times are approx.:

MINI Li-Ion battery	3,7V / 650 mAh	1½ h

The charging system automatically ensures that the Li-Ion battery is fully charged.
If the Li-Ion battery is connected to the charger, the system will ensure that the Li-Ion battery will not be overcharged.

A fully charged battery will last approx.:		**L200**	**L400**
MINI Li-Ion battery	3,7V / 650 mAh	3 h	2 h

WARNING NOTICE!
Do not under any circumstances use a different USB adapter or charger other than is supplied by the manufacturer.
The Li-Ion battery can be seriously damaged if charged incorrectly!

IMPORTANT NOTICE!
Li-Ion batteries should never be exposed to environmental temperature lower than -5°C!
Li-Ion batteries should never be exposed to excessive heat or open flame!
Li-Ion batteries should never be exposed to water!
Li-Ion batteries should never be exposed to short circuiting!
Li-Ion batteries should never be exposed to excessive shock or vibration!
Li-Ion batteries which are defective should not be used, thrown away or disposed of!
Li-Ion batteries that are defective should not be used!
Li-Ion batteries that are defective should be returned for recycling or returned to the dealer!

Maintenance of *PERSONAL-LASER*™

Always keep the laser probe, battery, and lens clean!

Avoid storing lasers in a dusty environment!

Never expose laser a probe or battery to liquid of any kind!

Before use, always check that the laser probe and lens is not damaged in any way!

Do not use the laser probe, battery or lens if it is damaged.

Laser Optics

Dirt and oil on laser optics inhibit the laser's operational efficiency significantly!

Always keep the laser optics 100% clean!

Dirt and oils should be removed using propyl alcohol. (Rubbing alcohol)

Moisten a cotton swab with isopropyl alcohol and gently wipe down the surfaces of the laser optics after each use.

Wipe dry with a clean, lint free cloth.

IMPORTANT NOTICE!
The laser should not be turned on when the lens is being cleaned! The laser cannot be used without the optics attached as dirt and particles can burn into the laser diode and thereby destroying it. In case of such damage, the warranty does NOT apply!

TIP!
Clear plastic wrap (cling film) can be used as a protective layer on the laser and/or optics as to avoid contaminating the laser with biohazardous materials!

The laser probe, batteries, and charger

Wipe clean with a slightly damp cloth and/or with a cloth dampened with isopropyl alcohol and wipe chlorhexidine.

See also the section on hygiene!

Troubleshooting

Low battery
Yellow LED light (4.) flashing slowly → **MODE:** Low battery. Battery must be charged soon.
Yellow LED light (4.) flashing quickly and then switches off → **MODE:** Flat battery. Battery must be charged.

SOLUTION:
Battery should be charged.

High temperature (+ 45C)
Red and yellow LED light (4.) flashes alternatingly → **MODE:** Laser's temperature is too high. The laser is programmed to switch off automatically. The laser should stay switched off and cool down fully before restarting the laser.

SOLUTION:
The laser should be refrigerated and cannot be restarted until the temperature has returned to normal.

Photodiode (Laser Power test)
Red LED light (4.) continuously lit. This indicates a laser diode error → **MODE:** ERROR.

SOLUTION:
Try to restart the laser with a new, fully charged battery. Check if the laser optics are clean and that there are no impurities in the laser diode window.

WARNING!
If the laser diode doesn't emission light, it's the information, that laser diode is not fulfilling it's function (Life time of laser diode is 10 000 hours of lighting).

If the above does not solve the problem, please contact Customer support:
info@akeda.com.pl

Service and maintenance

PERSONAL LASER must be recalibrated annually. It is recommended that all Akeda's laser products be returned to the manufacturer or an authorized servicing dealer for repairs or recalibration. Recalibration is also recommended after the replacement or repair of any major component. Should the Akeda's Laser unit require service, contact the selling dealer or Akeda Service Department. The confirmation of the calibration will be the receipt of the calibration certificate.

NOTE!
Personal Laser unit was calibrated during the manufacturing process.
The unit is ready to be placed into service upon delivery.

All units returned to the manufacturer for service must include the following:

WARRANTY REPAIR/OUT OF WARRANTY REPAIR

1. Written statement containing the following information:
   - Unit Model Number
   - Unit Serial Number

- Contact person with Phone and Email
- Billing Address (for Out of Warranty Repair)
- Shipping Address (Where to Ship Unit after Repair)
- Detailed Description of Problem or Symptoms

2. Copy of original invoice issued at purchase of the unit.
3. Ship the unit to address specified in this user manual.

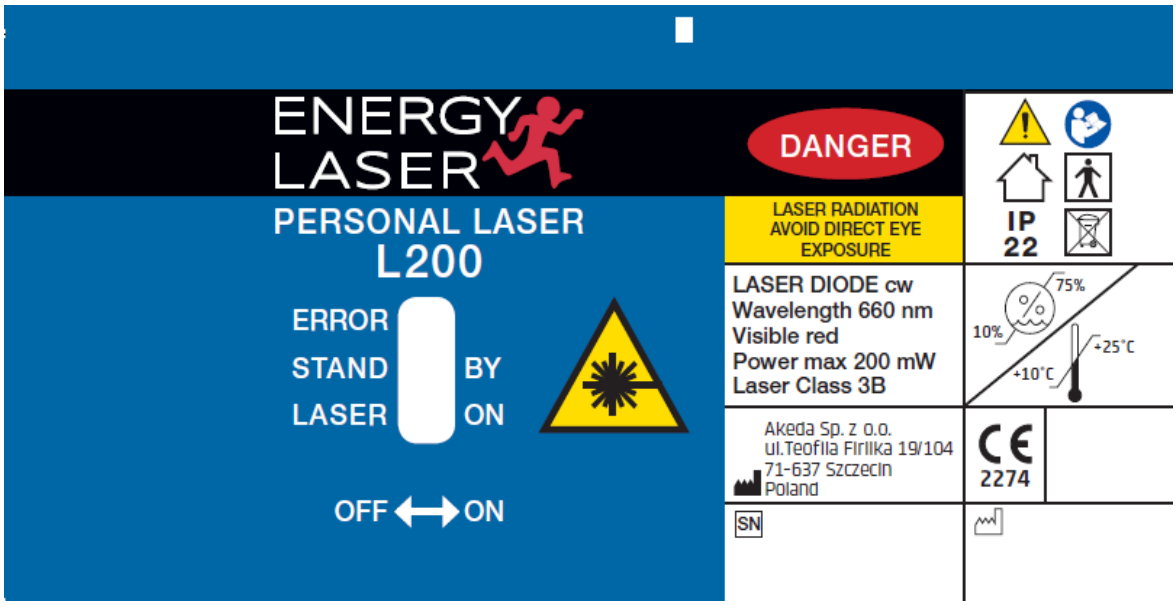
Transport and Storage

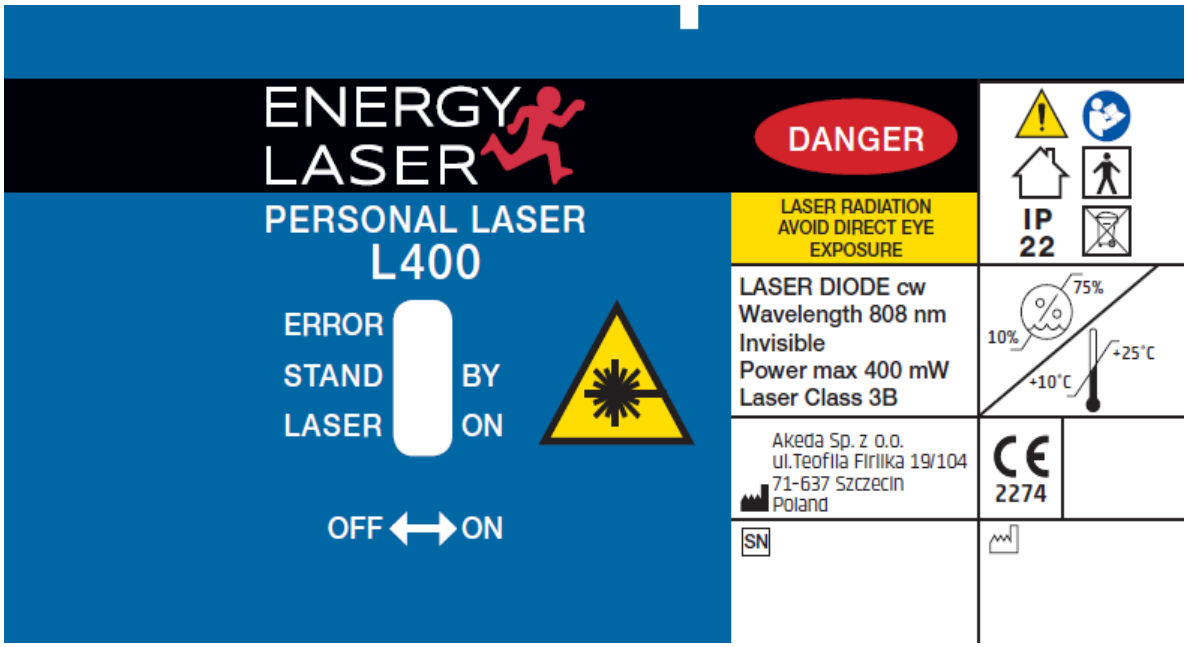
- Store the shipping box and always use the aluminum suitcase to store or transport the laser to ensure maximum protection.

- Make sure the laser is not exposed to dirt, excessive movement or shock during transport.

- The laser should only be transported and stored under conditions described in Technical Data.

PERSONAL-LASER label symbol information





Attention!
Follow the instructions when using this item.

Read the following documents.

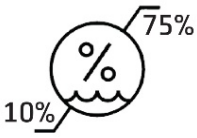
Indoor
For indoor use only.

Type BF
The part which is used to the treat the patient is elevated power supply. The device does not require grounding.

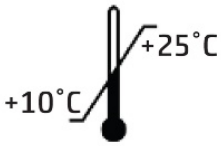
IP22

Dust and waterproof
IEC 60529

Environmental Information
The equipment should not be disposed of with household waste! To dispose of the equipment: return the equipment to your dealer or AKEDA Sp. z o.o.



Environmental conditions during normal use
Relative humidity: 75% or less (non-condensing)



Environmental conditions during normal use
Environmental temperature: +10 to 25 °C

Laser beam!
DANGER do not look at the laser light! (EN 60825).

Serial number
Indicates the manufacturers serial number so that a specific medical device can be identified.

Date of Manufacture
Indicates the date when the medical device was manufactured.

Manufacture
Indicates the medical device manufacturer.

CE mark
The device is a medical device and comply with the rules in the EU Directive 93/42

Technical data PERSONAL-LASER™

PERSONAL-LASER™
Following comes as standard in an aluminum carrying case:

1 pcs. Laser probe with built-in optics

1 pcs. Li-Ion battery

1 pcs. Li-Ion charger

1 pcs. USB cable

1 pcs. USB power adapter

1 pcs. Laser Test Card

1 pcs. Safety glasses

1 pcs. User manual

1 pcs. Treatment of LLLT

Product	PERSONAL-LASER™ L200	PERSONAL-LASER™ L400
Wavelength	660 nm	808 nm
Max power	200 mW	400 mW
Max total power	200 mW	400 mW
Operations mode (CW continus wave)	CW	CW
SPOT/BEAM (divergence), approx.	Spread 20˚x30˚	Spread 10˚x10˚
Guide LED red	No	No
Laser Class	3B	3B
Energy pr. 10 sec.	2 Joule	4 Joule
Laser Penetration, approx.	1-2 cm	3-4 cm
Cooling	No	No
Bluetooth	No	No
Battery Li-Ion	650 mAh	650 mAh
Treat. time per charging	3 h	2 h

Produced and registered as medical equipment CE 2274

Laser diode:

PERSONAL-LASER L200:	1 x TO18 - MM	200 mW / 660 nm / Visible red
PERSONAL-LASER L400:	1 x TO5 - MM	400 mW / 808 nm / Invisible IR

Charger:

AC adapter USB-A - Li-Ion Charger: 130/230V / DC 5V - 1A

Li-Ion Battery		**Hight:**	**Dia.:**	**Weight:**
MINI Li-Ion battery	3,7V / 650 mAh	65 mm	22/38 mm	45 grams

Dimensions laser device:	**Length:**	**Dia.:**	**Weight:**
PERSONAL-LASER L200	76 mm	27 mm	42 grams
PERSONAL-LASER L400:	76 mm	27 mm	42 grams

Important information about Li-Ion battery!

Li-Ion batteries should never be exposed to environmental temperature lower than -5°C!
Li-Ion batteries should never be exposed to high heat or open flame!
Li-Ion batteries should never be exposed to water!
Li-Ion batteries should never be exposed to short circuit!
Li-Ion batteries should never be exposed to excessive shock or vibration!
Li-Ion batteries which are defective, they must not be used, thrown away or disposed of!
Li-Ion batteries that are defective, must not be used!
Li-Ion batteries that are defective, must be returned for recycling or returned to the dealer!

Environmental conditions during transport and storage

Environmental temperature:	-5°C to +35°C
Relative humidity:	75% or less
Atmospheric pressure:	700-1060 hPa

Environmental conditions during normal use

Environmental temperature:	+10 to 25 °C*
Relative humidity:	75% or less (non-condensing)
Atmospheric pressure:	700-1060 hPa

** If the temperature exceeds +25 °C -air conditioning should be used in the room where the laser is used!*

Warranty

Akeda ("Company") warrants that the Personal Laser™ ("Product") is free of defects in material and workmanship.

This warranty shall remain in effect for two years (24 months)* from the date of original consumer purchase. If this Product fails to function during the two-year warranty period due to a defect in material or workmanship, at the Company's option, Company or the selling dealer will repair or replace this Product without charge
within a period of thirty (30) days from the date on which the Product is returned to the Company or the dealer. All repairs to the Product must be performed by a service center certified by the Company. Any modifications or repairs performed by unauthorized centers or groups will void this warranty.

* *The warranty does not cover damage caused by incorrect use and misuse of the equipment.*

This Warranty Does Not Cover:

- ANY MALFUNCTION OR FAILURE IN THE PRODUCT CAUSED BY PRODUCT MISUSE, INCLUDING, BUT NOT LIMITED TO, DROPPING THE UNIT OR APPLICATOR AND FAILURE TO PROVIDE REASONABLE AND NECESSARY MAINTENANCE OR ANY USE THAT IS INCONSISTENT WITH THE PRODUCT USER MANUAL.
- Replacement parts or labor furnished by anyone other than the Company, the selling dealer, or a certified Company service technician.
- Defects or damage caused by labor furnished by someone other than Company, the selling dealer, or a certified Company service technician.

COMPANY SHALL NOT BE LIABLE IN ANY EVENT FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES.

The Company does not authorize any person or representative to create for it any other obligation or liability in connection with the sale of the Product. Any representation or agreement not contained in the warranty shall be void and of no effect.
THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Manufacturer and service:

Akeda Sp. z o.o.
Ul. Teofila Firlika 19/104
71-637 Szczecin
Poland

Customer support: info@akeda.com.pl

Every serious incident connected with any Akeda's product shall be noticed and reported to Akeda Sp. z o.o. and to the competent authority of the Member State, according to place of living!

Accessories for PERSONAL-LASER™

Rechargeable Li-Ion Battery:

MINI Li-Ion battery 3,7V / 650 mAh

Li-Ion charger - DC 3,7V

AC Adapter 130/230 V - DC 5V – 1 A

If you have any further questions that you cannot find the answer to here, please do not hesitate to contact Akeda Sp. z o.o. or your local dealer!