



miha-bodytec II
↓ **Operating instructions**

US

Read this manual prior to performing any task!

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Conscientious handling of the miha bodytec II

Conscientious handling is the prerequisite for successful and safe use. The trainer must take part in a training session held by the manufacturer to be able to safely operate the EMS training device, hereinafter referred to as "device".

Before starting with the workout, the trainer instructs the athlete/patient in the basic operating functions and displays on this device for the workout. The trainer points out consequences caused by misuse.

Information about this manual

This manual enables safe and efficient handling of the device. This manual is an integral part of the device and must be kept in the immediate vicinity of the device and accessible to the trainer at any time.

The trainer must be able to read and understand this manual. The trainer must have carefully read and understood this manual before handling the device. The prerequisite for safe training is compliance with all safety instructions and procedural instructions specified in this manual. The local regulations for the prevention of accidents and the general safety regulations for the location in which the device is used also apply.

The illustrations in this manual are provided for basic understanding and can be different from the actual design.

Safety instructions

Safety instructions in this manual are identified by symbols. The safety instructions are introduced by signal words which express the extent of the hazard.

DANGER

DANGER indicates a hazardous situation which, if not avoided, will result in death or serious injury.

WARNING

WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

CAUTION indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE

NOTICE indicates important, non-safety-related information, such as property and environmental damage.

Safety instructions in procedural instructions

Safety instructions can refer to specific, individual procedural instructions. Such safety instructions are embedded in the procedural instructions so that they do not interrupt the reading flow when performing the activity. The signal words described above are used.

Example:

→ **⚠ WARNING! Risk of injury if detaching the electrodes while the training program is running!**

Make sure that no training program is active. To do so, switch to the main menu.

Tips and recommendations



This symbol highlights useful tips and recommendations, as well as useful information for efficient and fault-free operation.

Identifiers in this manual

To highlight procedural instructions, results, lists, references, and other elements, the following identifiers are used in this manual:

Identifier	Explanation
→	Step-by-step procedural instructions
⇒	Results of procedural steps
☞	References to sections of this manual and to other applicable documents
■	Lists without a defined sequence
[Button]	Controls (e.g., buttons, switches), display elements (e.g., signal lamps)
“Display”	Screen elements (e.g., buttons, assignment of function keys)

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1 Overview and scope of delivery

1.1 Scope of delivery

miha bodytec II

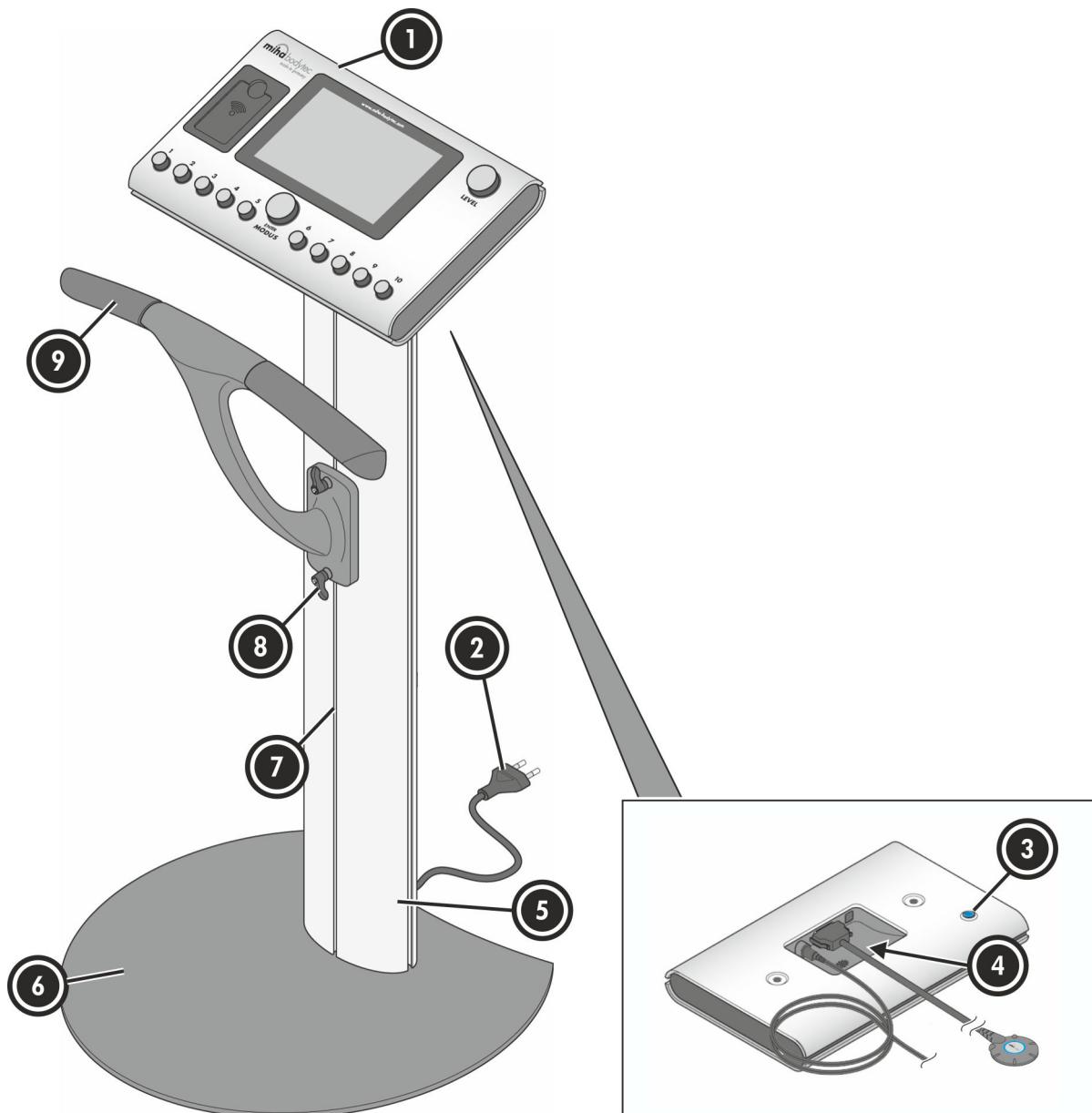


Fig. 1: Overview of miha bodytec II

1	Control unit (↳ "Control unit (top side)" on page 9)	5	Column
2	Power cable	6	Base plate
3	On/off switch	7	Guide rail
4	Connections and speaker	8	Clamping screw

Overview and scope of delivery

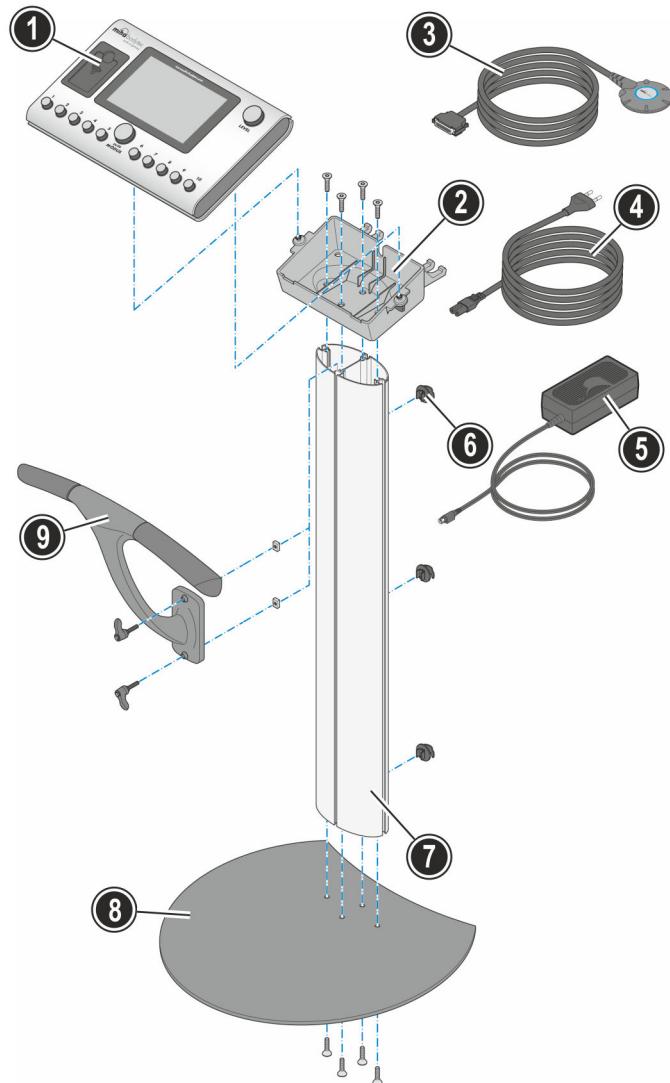


Fig. 2: Scope of delivery

1 Control unit	6 Cable clip
2 Support plate	7 Column
3 Connection cable to the control unit	8 Base plate
4 Power cable	9 Grab handle
5 Power supply	

What is EMS training?

EMS stands for **ElectroMyoStimulation**. This means that the muscles are stimulated by electrical pulses. Complete body training which addresses all muscle groups is possible with up to 10 pairs of electrodes.

During conventional training, electrical signals from the brain initiate contractions and thus movement of the muscles. With EMS, electrical pulses from outside activate the muscles. It makes no difference to the muscle whether electrical stimuli are sent from the brain or from electrodes: It reacts by contracting.

Special features and benefits:

- All muscle groups can be activated using an electrode system with up to 10 pairs of electrodes.
- Static and dynamic training with interaction of deliberate muscle contraction and EMS.
- Exercise postures increase the contraction of the deliberately stimulated muscles.
- Positive and negative electrodes are not on the same muscle.
- Agonist and antagonist are stimulated simultaneously.
- EMS training can cause more intense muscle contractions than classic strength training. At the same time, there is comparatively very little stress on the joints.
- Deeper muscle groups can be easily reached.
- The training is very intense and thus short (10 – 20 minutes).

Control unit (top side)



Fig. 3: Control unit (top side)

- 1 Level controller for legs
- 2 Level controller for buttocks
- 3 Level controller for lower back
- 4 Level controller for upper back
- 5 Level controller for side back
- 6 Level controller for abdomen
- 7 Level controller for chest
- 8 Level controller for arms
- 9 Level controller for channel 9
- 10 Level controller for channel 10
- 11 LC display
- 12 Transponder card contact surface
- 13 Multi-function button for start/stop and for setting the programs and the program parameters
- 14 Main controller for setting the pulse strength

All controls with the exception of the on/off switch, which is located on the underside (1), are located on the top side of the control unit.

Overview and scope of delivery

The main controller (Fig. 3/14) enables the athlete to regulate pulse strength of all outputs simultaneously. A connected pair of electrodes is considered an output in this context.

The pulse strength of individual outputs can be regulated using the relevant level controllers (Fig. 3/1 – 8). The image above each of these rotary switches shows the relevant part of the body for which the pulse strength is regulated. For example, using the level controller for legs (Fig. 3/1), the pulse strength sent to the legs is regulated using the i-body® straps flex.

The two level controllers without any assigned body parts (Fig. 3/9, 10) will only have a function if additional electrodes are used. In this case, the pulse strength can be adjusted using the additional electrodes on the respective level controller.

If a transponder card is placed on the transponder card contact surface (Fig. 3/12), the settings stored on this card can be edited or loaded automatically (☞ *Chapter 11.6 “Transponder system” on page 95*).

The multi-function button (Fig. 3/13) is used for navigating the menus and for activating programs. The multi-function button is also used for starting and stopping workouts.

The LC display (Fig. 3/11) shows menus and provides status information on the device. A virtual person, an avatar, is shown on the LC display during training. The athlete can use the movements of the avatar, in addition to the instructions of the trainer, as an orientation.

Control unit (underside)

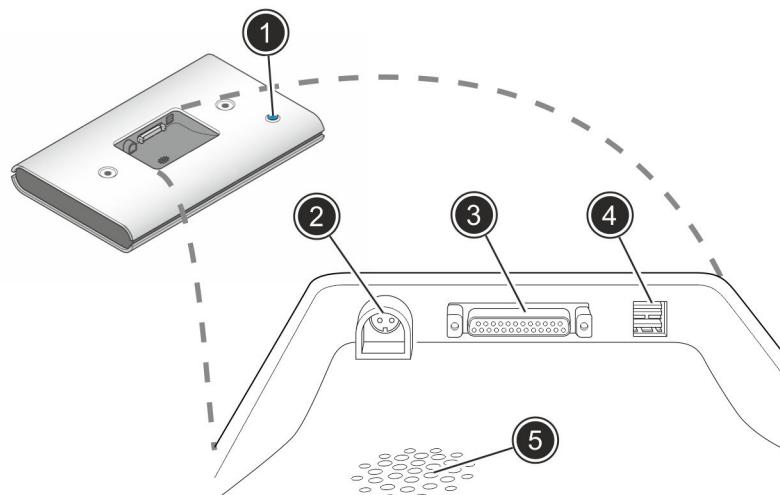


Fig. 4: Control unit (underside)

- 1 On/off switch
- 2 Connection to power supply unit
- 3 Connection to cable socket
- 4 USB port
- 5 Speaker

The on/off switch (Fig. 4/1) is embedded in the case on the underside of the control unit. A built-in terminal strip is located in a depression on the underside.

The supply cable of the power supply unit is connected to the power supply connection (Fig. 4/2) by means of a safety plug connector with a detent mechanism. To disconnect, the detent mechanism must be released by pulling back the plug grip.

The socket of the connection cable (Fig. 4/3) is used to attach the connection cable of the electrode vest, hereinafter referred to as "i-body®". The miha bodytec USB flash drive can be inserted into the USB port (Fig. 4/4) for performing updates and for saving device settings.

A speaker (Fig. 4/5) is located behind the perforations in the case. The device uses the speaker to output acoustic signals that provide information on inputs and device status

1.2 Equipment

Safety thanks to genuine miha bodytec equipment



Using equipment not obtained from miha bodytec or authorized dealers represents an increased safety risk. Only use genuine miha bodytec equipment.



Additional parts not mentioned in this manual must not be connected to the device, the electrodes or the cables.

Transponder card



Transponder card for storing the last values, individual time specification, and individually adjusted program.

Fig. 5: Transponder card

Overview and scope of delivery

i-body® connect wireless



Fig. 6: i-body® connect wireless

Wireless stimulation unit that can be attached to the body of the athlete for wireless training via a Bluetooth® connection.

See the “i-body® connect wireless” manual for further information.

i-body® connect charger



Fig. 7: i-body® connect charger

Charger for i-body® connect wireless.

See the “i-body® connect wireless” manual for further information.

i-body®



Fig. 8: i-body®

The i-body® electrode vest for applying electrodes to the upper body.

Table 1: Electrode sizes for each vest size

Vest size	Size 1 and size V1	Size 2, size 3 and size V2 in in ²
2 electrodes for abdomen	22.85 in ²	27.56 in ²
2 electrodes for chest	10.31 in ²	12.81 in ²
2 electrodes for upper back	16.25 in ²	20.98 in ²

Vest size	Size 1 and size V1	Size 2, size 3 and size V2 in in ²
2 electrodes for sides of back	9.75 in ²	11.85 in ²
2 electrodes for lower back	14.4 in ²	19.47 in ²

i-body® straps flex



Fig. 9: i-body® strap flex

Electrodes for applying to arms and legs.

Table 2: Electrode sizes for each i-body®straps flex size:

Size of the i-body®straps flex	Electrode size
Size 1 (pair)	16.74 in ² each
Size 2 (pair)	20.77 in ² each
Size 3 (pair)	29.14 in ² each

i-body® belt



Fig. 10: i-body® belt

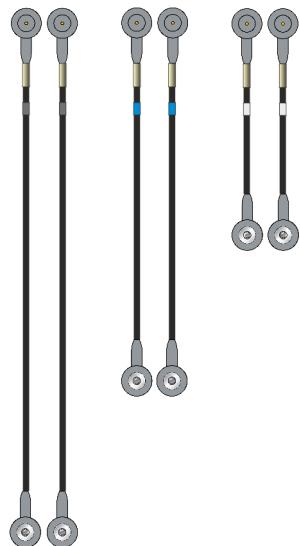
Buttocks electrode, hereinafter referred to as “i-body® belt”, for applying to the buttocks.

Table 3: Electrode sizes for each i-body®belt size:

Size of the i-body®belt	Electrode size
Size 1: 2 buttocks electrodes	each 14.7 in ²
Size 2: 2 buttocks electrodes	each 18.34 in ²

Overview and scope of delivery

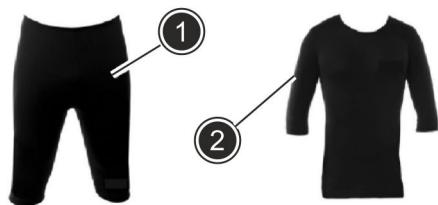
i-body® cable



External cables, hereinafter referred to as "i-body® cables" for connecting the "i-body®" to the external "i-body® straps flex" and "i-body® belt" electrodes.

Fig. 11: i-body® cable

Undergarments



- 1 Pants
- 2 Top

Undergarments for wearing under all electrodes to be applied.

Fig. 12: Undergarments

Pump spray bottle

Pump spray bottle for moistening the electrodes.



Fig. 13: Pump spray bottle

miha bodytec USB flash drive

The miha bodytec USB flash drive is delivered with the device and serves as a data carrier for performing updates as well as saving and transferring settings.



In the event of important updates, a miha bodytec USB flash drive will be sent to users of the device who perform the update themselves or have it performed on the device by the trainers.

Customer service

For technical information, please contact us at our headquarters:

Address	miha bodytec Inc. 2171 Executive Drive Suite 200 Addison, Illinois 60101 USA
Telephone	+1 833 367 6442
E-mail	usa@miha-bodytec.com
Website	www.miha-bodytec.us

We are also always interested in information and experience arising from the use of the device which can be valuable for the improvement of our product.

2 Safety

2.1 Intended use

miha bodytec II is a device which performs electronic muscle stimulation based on EMS technology. The device is specifically designed as an addition to other sports and for training muscles.

miha bodytec II is intended to stimulate muscles in order to improve or facilitate muscle performance. In addition it is indicated for the following conditions:

- Re-educating muscles
- Relaxation of muscle spasm
- Retarding or preventing disuse muscle atrophy

The miha bodytec II electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work.

Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.

miha bodytec II may only be used by persons above the age of 21.

2.2 Misuse

⚠ WARNING

Danger in the event of misuse!

- Never operate the device on an uneven base. The base plate must be level.
- Keep the device out of the reach of children.
- Never apply electrodes to positions other than those described in this manual.
- Never use the electrical stimulation treatment in the following areas of the body:
 - On or through the head
 - Directly on the eyes
 - In areas around the mouth
 - On the front of the neck (especially the carotid artery)
 - With electrode surfaces applied to the chest and the upper back or across the heart
 - Over the menstruating or pregnant uterus
 - Over areas of the skin with a lack of normal sensation.
- Stimulation must not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- Stimulation must not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty breathing.
- Stimulation shall not be applied transthoracically. The introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation must not be applied transcerebrally.
- Stimulation must not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombo-phlebitis, varicose veins, etc.
- Stimulation must not be applied over, or in proximity to, cancerous lesions.
- Whenever using the device, start with an intensity level of “0” and increase slowly.
- Ensure basic tension in the muscle group you are exercising for each pulse to prevent uncontrolled muscle contractions.
- In case of skin irritation and signs of burns beneath the electrodes, stop using the device immediately.
- If you are feeling unwell, dizzy, or have heart pain *↳ Chapter 2.3 “Risks due to physical condition: Contraindications” on page 18*, stop using the device immediately.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by alternate electrode placement using an alternate conductive medium.
- Electrode placement and stimulation settings must follow guidance of the prescribing practitioner.

- The long-term effects of repeated electrical stimulation are unknown.
- Only use genuine miha bodytec equipment and spare parts.

Misuse of the device can cause hazardous situations. The device is exclusively intended for use as an electronic muscle stimulator for the usecases described in this manual and must only be used in a dry environment. Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

2.3 Risks due to physical condition: Contraindications

EMS training in the event of existing contraindications

⚠ WARNING

Risk of fatal injury in the event of use despite presence of contraindications for specified persons!

All persons training with the device must ensure that none of the following contraindications are present:

- Before each further training session the trainer must check if the health condition of the athletes/patients has changed and/or if they are under influence of alcohol, drugs, narcotics, and/or painkillers.
- In the event of doubts whether any contraindication is present, do not use the device.
- In the event of doubts, consult a doctor before the first or any further trainings.
- If you are taking medication, consult a doctor before the first or any further trainings.

The presence of certain physical conditions can result in a risk of injuries or even death. The existence of such a physical condition is referred to as contraindication.

Never exercise if ...

The device must not be used if the following contraindications are present:

- Acute influence of alcohol, drugs, narcotics, and/or painkillers
- Recent operations
- Cardiac arrhythmias
- Active medical implants
- Epilepsy
- Seizures
- Pregnancy or suspected pregnancy
- Severe circulatory disorders
- Arterial circulatory disorders
- Strong bleeding tendencies (hemophilia)
- Bleeding
- Abdominal wall hernia
- Inguinal hernia
- Tuberculosis

- Tumor diseases
- Arteriosclerosis in advanced stage
- Severe neurological disorders
- Diabetes mellitus
- Febrile diseases
- Acute bacterial or viral infections
- Liver diseases
- Kidney diseases
- Cardiovascular diseases
- Coronary heart diseases
- Infected or wounded areas of the skin
- Skin cancer
- Rhabdomyolysis

2.4 A team for your safety

Acting responsibly

This section describes the requirements for people involved in training with this device. To ensure safe EMS training, the actions described in this manual may only be performed when the relevant person meets the specified requirements.

Athlete/Patient

Athletes/patients use the device actively for EMS training. They make sure that they are instructed by a qualified trainer of the training-relevant control elements and displays and notified of the consequences caused by misuse. They also make sure that they are guided through the training session by the trainer. Athletes/patients must provide the trainer responsible for them with truthful information on current health restrictions (e.g., fever).

Athletes/patients make sure that none of the listed contraindications (☞ *Chapter 2.3 “Risks due to physical condition: Contraindications” on page 18*) apply to them before they start with the training.

Trainer

The trainer must have taken part in a basic miha bodytec training session and can prove their qualification by presenting a certificate issued in their name. The participation in an additional higher-level EMS training session is recommended. This following information was taught during this training session:

- Effects and special characteristics of EMS training
- Adjustable parameters of the device and their impact
- Identifying and avoiding risks:
 - Function-related residual risks
 - Settings-related residual risks
 - Residual risks due to the condition of the athlete/patient
- Available equipment and its correct usage
- Applying the electrodes

- Function, operation, and programming of the control unit
- Performing updates

The trainer applies the information they learned in the basic miha bodytec training session so that everyone training with the device has a safe EMS workout. In particular, the trainer is responsible for the following:

- Ensuring that updates are integrated promptly following release.
- Ensuring that athletes/patients are healthy enough for EMS training in advance of each training session.
- Ensuring that defective parts are replaced when problems become known.
- Having the equipment properly cleaned after the EMS training session or cleaning it.

The trainer must be qualified in accordance with the local specifications to administer first aid and has a basic knowledge in anatomy, physiology, training theory and training planning.

During a workout, the trainer must focus exclusively on the needs of the athlete(s)/patient(s). They do not actively participate in the workout and are not hooked up to the device, but inform and monitor the athletes/patients. A maximum of 2 athletes/patients per 1 trainer is allowed. Before, during, and after the workout, the trainer enquires about the physical condition of the athletes/patients and checks them so risks can be eliminated.

During a workout, the trainer and the athletes/patients must have unimpeded access to the device's control elements. They must be able to use and regulate the device easily, quickly, and with precision.

The full attention of the trainer is required at all times during the workout. If this cannot be ensured, the trainer must reduce the main intensity level of the device/athlete/patient by at least 50 percent.

The trainer must ensure that all requirements above are met.

Private use of the device

The EMS training with the device must be supervised by a qualified trainer. This also applies to private use of the device. Even if the athlete/patient has qualified as a trainer, they may not use the device without qualified supervision.

Only the mandatory basic miha bodytec training by the manufacturer and an optional additional higher-level EMS training qualify a person as a trainer as described above.

2.5 Warnings

Getting to know the residual risks

The following section specifies risks which can arise from the device even when it is used as intended.

Comply with the safety instructions listed here and with the safety instructions in the other sections of this manual to reduce risks of personal injury and material damage and to avoid dangerous situations.

Interactions

⚠ DANGER**Risk of fatal injury from interactions!**

Do not connect athletes/patients to a high-frequency surgical appliance simultaneously. This can result in burns under the stimulation current electrodes.

- Keep a minimum distance of 3 ft / 1 m between the device and a short-wave or microwave therapy appliance. Otherwise, this can cause fluctuations in the output values of the stimulation current device.
- Never use the device on people who are fitted with active (e.g., electronic) medical implants.

Interactions with the device can be dangerous and cause injuries including death. Applying the electrode surfaces in the vicinity of the chest can increase the risk of ventricular fibrillation.

Cardiac arrhythmias

**⚠ WARNING**

So far, there has been no known event of cardiac arrhythmia that can be attributed to training with the device. Since a theoretical residual risk remains, strictly observe the instructions below.

Persons affected will lose consciousness after a brief period of time.

Health risk due to cardiac arrhythmia!

- Never exercise by yourself. Always ensure that a qualified trainer is paying attention and can intervene in the event of an emergency.
- Act immediately if the athlete/patient loses consciousness:
 - Disconnect the cables from the electrodes. To do so, unplug the connector plug from the vest.
 - Notify emergency medical services.
 - Administer CPR until emergency medical services arrive.
 - If you have access to a defibrillator, defibrillate the athlete/patient.

The EMS training involves a residual risk which may lead to cardiac arrhythmia. If untreated, cardiac arrhythmia may result in death.

Electrical voltage

DANGER

Risk of fatal injury from power supply!

- Only use the device in a dry environment.
- Never open the control unit and power supply.
- Always inform Customer Service (↳ “Customer service” on page 15) in the event of problems with the device.
- In the event of damage to the insulation, switch off the power supply immediately and unplug the mains plug.
- Observe the safety rules:
 - Unplug the mains plug.
 - Ensure that nobody reconnects the mains plug to the power supply.
- Never connect the power supply to any voltage other than 100 – 230 V ~ 47 – 63 Hz.
- Only use the genuine power supply and the genuine power supply cable of the manufacturer. Both are available from Customer Service.
If the power supply must be replaced, only use the genuine power supply (GlobTek Medical/ITE Power Supply; Model No.: GTM91099-6024-6.0-T2).

There is an immediate risk of fatal injury due to electrocution in the event of contact with live parts. Damage to the insulation or individual components can be fatal. There is a risk of fatal injury in the event of liquid penetrating the case!

DANGER

Risk of fatal injury from improper exposure of the electrodes to moisture!

- When moistening and putting on the electrodes, ensure that there is a sufficient distance to the control unit. No water must penetrate the case.

There is a risk of fatal injury due to electrocution in the event of liquid penetrating the case of the control unit!

WARNING

Damage to the cables and the connections!

- Do not place any heavy objects on the power supply cable.
- Never kink or pinch the power supply cable.
- Always keep the wall outlet accessible.
- Unplug the mains plug before cleaning and maintenance.

There is a risk of material damage and injuries in the event of damage to the cables or the connections.

WARNING

Risk of injury from improper routing of connection cables!

- Always route the connection cables along the column secure with clips.
- If the device is set up to be stationary, secure the connection cable between the device and the wall connection with a cable bridge.

Improper routing of connection cables can lead to trip hazards or strangulation of babies and toddlers/children as well as handicapped persons.

⚠ WARNING

Risk of injury if detaching or connecting electrode cables during operation!

- Start by making sure that no training program is active (↳ “Main menu” on page 54), then connect or detach the electrodes.
- Never detach electrode cables while training.
- Never connect electrode cables while training.

Detachment or connection of electrode cables can result in injuries that depend on the settings, such as torn muscle fibers or shoulder dislocations.

Hygiene

⚠ WARNING

Risk of injury from improper hygienic cleaning of the control elements of the device and equipment!

- Properly clean the control elements of the device and the equipment used after training.
- Before placing the device into intermediate storage, mark the components with the date and name of the last trainer.

In the event of improper hygienic cleaning of the control elements of the device and equipment, bodily fluids can lead to skin reactions and injure athletes/patients with skin problems!

Inhaling or swallowing

⚠ WARNING

Risk of injury due to inhaling or swallowing cable clips!

- Keep cable clips in a safe place out of the reach of babies, infants/children, and handicapped persons.

Inhaling or swallowing cable clips can lead to injuries.

Allergic reaction



There are currently no known allergic reactions to materials used by miha bodytec.

Safety

What trainers and athletes/patients have to know

WARNING

Danger due to insufficient level of knowledge!

- miha bodytec II may only be used by persons above 21 years.
- Electrodes may only be connected and detached by the trainer or under their supervision.
- Only work out under the supervision of a qualified trainer.
- Only work out under the supervision of a physician or therapist when using the device for the following indications:
 - Re-educating muscles
 - Relaxation of muscle spasm
 - Retarding of preventing disuse muscle atrophy
- Only train with the device if you have been instructed on how to handle it.
- Never allow other persons to operate the device without previous training.
- The manual must have been read completely and fully understood.
- The operating principle of EMS and the effects on the body must be known.
- Children are not allowed to train or play with the device or perform cleaning or maintenance tasks.

Handling the device without training/instruction can result in dangerous situations that can be fatal. Each trainer must take part in a training session held by the manufacturer before using the device and each athlete/patient must have been instructed by the trainer.

Individual adjustment



The individual adjustment of the device is required to guarantee and support correct training techniques, training positions, and training processes.

Slippery floor

CAUTION

Danger of injury from slipping!

- Clean up accumulations of liquid, such as water and perspiration immediately.
- Wear slip-resistant training shoes.

Floors can be slippery due to perspiration or water. Slipping and falling can result in injuries.

Pre-existing conditions

⚠ CAUTION**Caution must be exercised in the presence of the following:**

- When there is a tendency to hemorrhage following acute trauma or fracture.
- Following recent surgical procedures where muscle contraction may disrupt the healing process.
- Over areas of the skin which lack normal sensation.

Improper maintenance or repair

⚠ WARNING**Risk of injury from improper maintenance or repair!**

- Never perform unauthorized repairs of the device.
- In case of defects on the device, contact Customer Service (☞ “Customer service” on page 15).
- Only perform the maintenance tasks described in this manual.

If maintenance or repair is performed improperly, there is a risk of injury during training and operation. Additionally, mistakes during maintenance or repair can cause permanent damage to the device.

Interrupting the update

NOTICE**Interrupting the update process can result in material damage!**

- Do not disconnect it from the power source during an update.
- Do not turn off the device during an update.
- Wait for the update to finish and do not input anything.

The device can be permanently damaged if it is turned off during the update process or if the power supply is interrupted

 *If the update is interrupted due to an interruption of power, contact Customer Service (☞ “Customer service” on page 15).*

Condensation

NOTICE**Risk of damage to the device from condensation!**

- Only use the device in a dry environment.
- Never store the device in damp places.
- Let the device acclimatize in the event of location changes.
- In the event of faults, immediately disconnect the device from the power supply and notify Customer Service (☞ “Customer service” on page 15).
- Never switch on the device if condensation is visible.

Condensation can form in the event of changes in humidity and temperature. Moisture in the control unit can result in damage or even total destruction.

2.6 Reporting of adverse events

MedWatch (FDA)

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is not required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting adverse event reports to the FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

- MedWatch Online Voluntary Reporting Form:
[http://www.accessdata.fda.gov/scripts/medwatch/index.cfm?
action=reporting.home](http://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)
- Consumer Reporting Form FDA 3500B:
[http://www.fda.gov/downloads/AboutFDA/
ReportsManualsForms/Forms/UCM349464.pdf](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf)
Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn:
<http://www.accessdata.fda.gov/scripts/MedWatchLearn/>
- Call FDA at 1-800-FDA-1088 to report by telephone.

2.7 Symbols on the miha bodytec II

2.7.1 Symbols on the front



Fig. 14: Symbols on the front of the miha bodytec II

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 7010 Second Edition 2011-06-01, P007	Graphical Symbols – Safety Colours And Safety Signs – Registered Safety Signs [Including AMENDMENT 1 (2012) Through AMENDMENT 7 (2016)]	Not for persons with pacemakers or implanted defibrillators	The device must never be used by persons with cardiac pacemakers or other active medical implants. In this context, also observe the contraindications.
	ES60601-1:2005/(R)2012 And A1:2012, Table D.2, Symbol 10	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Follow instructions for use	Read and observe this manual carefully before start-up and use.

2.7.2 Symbols on the back



Fig. 15: Symbols on the back of the miha bodytec II

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ES60601-1:2005/ (R)2012 And A1:2012, Table D.2, Symbol 2	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	General warning sign	General warning sign
	ES60601-1:2005/ (R)2012 And A1:2012, Table D.1, Symbol 20	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Type BF applied part	Identifies a type BF applied part complying with IEC 60601-1.

2.7.3 Rating plates

Rating plate miha bodytec II



(01)04260646650007(11)210519(21)52119004769

Fig. 16: Rating plate miha bodytec II, example

The rating plate is located on the underside of the control unit and contains the following information:

- Manufacturer
- Type
- Model year
- Barcode
- Serial number
- Supply connection (control unit)
- Current consumption (control unit)
- Protection class
- Protection type
- Device type
- UDI number
- FCC IDs
- IC IDs
- Hardware version identification number (HVIN)
- Mandatory sign: Read manual
- Mandatory sign: Prohibited for persons fitted with cardiac pacemakers
- Mandatory sign: Waste of electrical and electronic equipment (WEEE)
- Mandatory sign: CE marking: Sign of European technical conformity
- Mandatory sign: IEC protection Class II
- Mandatory sign: RX only
- Mandatory sign: CAN ICES-3 (B)/NMB-3(B): Compliance with Canadian ICES-3 Rules.
- Mandatory sign: FCC marking: Compliance with part 15 of the FCC Rules

NOTICE

Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Rating plate equipment



Fig. 17: Rating Plate equipment (example: i-body strap flex)

The rating plate of the equipment contains the following information:

- Manufacturer
- Type
- Model year
- Serial number
- Device type
- Cleaning symbols

Safety

Symbols on rating plates

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1 Third Edition 2016-11-01 Clause 5.1.1	Medical Devices – Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied – Part 1: General Requirements	Manufacturer	Indicates the device manufacturer.
	ISO 15223-1 Third Edition 2016-11-01 Clause 5.1.3	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied – Part 1: General Requirements	Date of manufacture	Indicates the date when the device was manufactured.
	ES60601-1:2005/ (R)2012 And A1:2012, Table D.1, Symbol 11	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Consult instructions for use	Indicates the need for the user to read this manual for use.
	ISO 15223-1 Third Edition 2016-11-01 Clause 5.1.7	Medical Devices – Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied – Part 1: General Requirements	Serial number	Indicates the manufacturer's serial number so that a specific device can be identified.
	ES60601-1:2005/ (R)2012 And A1:2012, Table D.1, Symbol 4	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Direct current	Indicates direct current.
	ES60601-1:2005/ (R)2012 And A1:2012, Table D.1, Symbol 9	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Insulation protection Class II	Identifies an IEC Class II Insulation Protection.
	ES60601-1:2005/ (R)2012 And A1:2012, Table D.1, Symbol 20	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Type BF applied part	Identifies a type BF applied part complying with IEC 60601-1.

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 7010 Second Edition 2011-06-01, P007	Graphical Symbols – Safety Colours And Safety Signs – Registered Safety Signs [Including AMENDMENT 1 (2012) Through AMENDMENT 7 (2016)]	Not for persons with pacemakers or implanted defibrillators	The device must never be used by persons with cardiac pacemakers or other active medical implants. In this context, also observe the contraindications.
	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II)	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive.	CE marking	Signifies European technical conformity.
	21 CFR 801.109	Labeling-Prescription devices.	Prescription only	Requires prescription in the United States.
	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	Recycle: Electronic Equipment	Waste of electrical and electronic equipment (WEEE). Electrical and electronic parts may contain toxic materials. These parts must be collected separately and turned in at communal collection points, or disposed of by a specialist company.
	ISO 15223-1 Third Edition 2016-11-01 Clause 5.1.5	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied – Part 1: General Requirements	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ES60601-1:2005/ (R)2012 And A1:2012, Table D.3, Symbol 2	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Degree of Ingress Protection Provided by Enclosure	Manufacturer-determined degree of particle and water ingress protection, where... N1 = degree of protection from particulates (scale of 0 – 6); and N2 = degree of protection from water (scale of 0 – 8)

Safety

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	N/A	N/A	Compliance with US and Canadian electrical safety standards	Indicates the compliance with the minimum requirements of US and Canadian electrical safety standards tested by accredited certification body "TÜV Rheinland"
	47 CFR Part 15	Code of Federal Regulations, Title 47: Telecommunication, Part 15 - Radio Frequency Devices	Compliance with US electromagnetic interference standards	Indicates the compliance with part 15 of the FCC Rules for Class B digital devices.
CAN ICES-3 (B)/NMB-3(B)	CAN ICES-3 (B)/NMB-3(B)	Interference-causing Equipment Standard: "Digital Apparatus," ICES-003 of the Canadian Department of Communications	Compliance with Canadian electromagnetic interference standards	Indicates the compliance with the exemption from the routine evaluation limits in section 2.5 of RSS 102 and with RSS-102 RF exposure for Class B digital devices.

2.7.4 Cleaning symbols

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	7000 Fifth Edition 2014-01-15, 3125	Graphical Symbols For Use On Equipment - Registered Symbols	Wash by hand	Hand wash only.
	7000 Fifth Edition 2014-01-15, 3114	Graphical Symbols For Use On Equipment - Registered Symbols	Do not dry clean	Do not dry clean.
	7000 Fifth Edition 2014-01-15, 3113	Graphical Symbols For Use On Equipment - Registered Symbols	Do not iron	Do not iron.
	7000 Fifth Edition 2014-01-15, 3109	Graphical Symbols For Use On Equipment - Registered Symbols	Do not tumble dry	Do not tumble dry.
	7000 Fifth Edition 2014-01-15, 3124	Graphical Symbols For Use On Equipment - Registered Symbols	Do not bleach	Do not bleach.

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	7000 Fifth Edition 2014-01-15, 3089	Graphical Symbols For Use On Equipment - Registered Symbols	Washing, normal process, max- imum 40 °C	Wash using normal cycle at 105 °F.

2.8 Environmental protection

Disposal

NOTICE

Environmental hazard from incorrect disposal!

- Arrange for disposal of electrical scrap and electronic components by locally authorized specialist companies.
- In case of doubt, obtain information about disposal in accordance with environmental regulations from local municipal authorities or specialized disposal companies.

Environmental hazards can be caused by incorrect disposal.

The device must not be disposed of via domestic waste. Recycle dismantled components:

- Have metals turned into scrap.
- Recycle plastic elements.
- Sort and dispose of all other components according to material condition.

Electronic components

Electronic components, such as liquid crystal display, printed circuit boards and cabling, can contain toxic substances. These must not get into the environment. Disposal must be carried out by a specialized disposal company.

3 Technical data

Table 4: Device information

Name	miha bodytec II
Manufacturer	miha bodytec GmbH Siemensstr. 1 86368 Gersthofen Germany
Initial importer	miha bodytec Inc. 2171 Executive Drive Suite 200 Addison, Illinois 60101 USA
Intended use	<p>miha bodytec II is a device for electronic muscle stimulation based on EMS technology. Regarding its use, the device is specifically designed as an addition to other sports and for training muscles.</p> <p>miha bodytec II is intended to stimulate muscles in order to improve or facilitate muscle performance. In addition, it is indicated for the following conditions:</p> <ul style="list-style-type: none"> ■ Re-educating muscles ■ Relaxation of muscle spasm ■ Retarding or preventing disuse muscle atrophy <p>The miha bodytec II electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.</p>
Dimensions (control unit)	16.73 × 10.63 × 2.76 (W × D × H in inches) 42,5 × 27 × 7 (W × D × H in cm)
Dimensions (complete)	21.26 × 20.28 × 46.65 (W × D × H in inches) 54 × 51,5 × 118,5 (W × D × H in cm)
Weight (Control unit)	10.3 lb 4,7 kg
Weight (complete)	45.2 lb 20,5 kg
Weight (i-body® with cable set)	3.3 lb 1,5 kg
Weight (i-body® belt)	0.9 lb 0,4 kg
Weight (i-body® strap flex)	0.5 lb 0,4 kg

Size of the electrodes	9.75 – 29.14 in ² 62,93 – 188 cm ²
Connection to the network (power supply)	100 – 240 V ~ 50 – 60 Hz
Connection to the network (control unit)	15 V – 19 V ===
Current consumption (control unit)	1.7 A at 15 V; 1.4 A at 19 V
Important performance characteristics:	(at 500 ohm) < 300 mJ
Output power	< 50 mA
Effective current	< 500 mJ
Output voltage	
Permissible ambient temperature (operation)	+40 °F – +105 °F +5 °C – +40 °C
Time for warming up the device from the lowest storage temperature (-13 °F / -25 °C) to the operating temperature for intended use of +68 °F (+20 °C) ambient temperature	10 hours
Time for cooling down the device from the maximum permissible storage temperature (+158 °F / +70 °C) to the operating temperature for intended use of +68 °F (+20 °C) ambient temperature	10 hours

Technical data

Permissible humidity (operation)	15% – 90%, non-condensing Note: Do not expose the device to the maximum humidity of 90% for more than 96 hours.
Maximum operating altitude above sea level	10,000 ft (20.67 hPa) 3000 m (700 hPa)
Number of fixed programs	6
Number of fixed training plans	5
Number of program memories	Up to 200
Number of channels	10 output pulses in multiplex mode
Maximum peak level of the output voltage	150 V The maximum peak level of the output voltage decreases due to the internal resistance of the end stages with decreasing load impedance.
Pulse width setting	50 µs – 400 µs in steps of 25 µs
Pulse rise setting	0.0 s – 1.0 s in steps of 0.1
Frequency setting	2.0 Hz – 10.0 Hz in steps of 0.5; 10.0 Hz – 150.0 Hz in steps of 1.0
Pulse pause setting	0.0 s – 1.0 s in steps of 1.0; 1.0 s – 10.0 in steps of 0.1
Pulse time setting	1.0 s – 10.0 s in steps of 0.1
Time specification setting	0.5 min – 5.0 min in steps of 0.5; 5.0 min – 30.0 min in steps of 1.0; 30.0 min – 90.0 min in steps of 2.0
Effective current density per cm ² of electrode area	≤ 0.48 mA r.m.s./cm ² (at 500 ohm)
Effective output value	Ueff = 15 V at 500 ohm (30 mA) Assuming a load impedance of 500 ohm, this produces a current intensity level of 30 mA r.m.s. The output voltage does not contain any DC component.
Output waveform – bipolar	

Protection type	IP21 <ul style="list-style-type: none"> ■ The device is protected against solid foreign objects with a diameter of ≥ 0.5 in (12.5 mm). ■ The device is protected against dripping water. 		
Device type	Type BF 		
Protection class	Protective insulation II  <p>Protection class II equipment has an increased or dual insulation at the level of the rated insulation voltage between active and touchable parts. In most cases, they are not connected to the protective conductor.</p>		
RFID reader/ writer	Operating frequency	Electric field strength	Modulation
	125 kHz	$\leq 60 \text{ dB}\mu\text{V/m} @ 3 \text{ m (Peak)}$	ASK
	134.2 kHz	$\leq 60 \text{ dB}\mu\text{V/m} @ 3 \text{ m (Peak)}$	ASK
	13.56 MHz	$\leq 55 \text{ dB}\mu\text{V/m} @ 3 \text{ m (Peak)}$	ASK
Transponder card	RFID (13.56 MHz), as per ISO/IEC 14443 Mifare Classic 4k, can be formatted on the device		
Synchronized start	2.4 GHz M2M wireless mesh network		
Number of persons training with synchronized start, maximum	2		
Cloud service	5 GHz Wi-Fi (Can only be used with an access point that is available upon request)		
Bluetooth®	2.4 GHz		
Power supply	GlobTek Medical/ITE Power Supply Model No.: GTM91099-6024-6.0-T2		
Expected service life of the device	The device is designed for a 10-year service life. With continuous product monitoring and regular maintenance, the service life can be significantly longer.		
Expected service life of equipment (contact points, Velcro fasteners, etc.)	The service life of the equipment depends on the functionality during training sessions. As soon as the functionality is no longer ensured or the hygienic requirements are no longer met, the equipment must be replaced.		

Compliances

miha bodytec II medical complies with the applicable requirements of the following international and national standards:

- IEC 60601-2-10:2012 – Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-1-2:2014 – Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- AAMI ANSI ES 60601-1_2005/(R)2012 And A1:2012 – Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2010 – Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62304:2015 – Medical device software - Software life cycle processes
- ISO 14971:2007 – Medical devices - Application of risk management to medical devices
- IEC 62366-1:2015 – Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 10993-1:2009 – Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 – Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 – Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

FCC Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that no interference will occur in a particular installation.

If this equipment causes harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

IC Caution

The device meets the exemption from the routine evaluation limits in section 2.5 of RSS 102 and compliance with RSS-102 RF exposure, users can obtain Canadian information on RF exposure and compliance. This device contains licence-exempt transmitter(s)/ receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s).

Operation is subject to the following two conditions:

- (1) This device may not cause interference.
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

Le dispositif rencontre l'exemption des limites courantes d'évaluation dans la section 2.5 de RSS 102 et la conformité à l'exposition de RSS-102 rf, utilisateurs peut obtenir l'information canadienne sur l'exposition et la conformité de rf. L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence.

L'exploitation est autorisée aux deux conditions suivantes:

- (1) L'appareil ne doit pas produire de brouillage;
- (2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Environment

The miha bodytec II medical is designed for use in domestic environments and professional health facilities but not near active systems of high-frequency surgery devices or in high-frequency shielding rooms used for magnetic resonance imaging where high-intensity electromagnetic interferences occur.

Open source software

This product also contains open source software among other things that was developed by third parties. Specifically, they include AFL, AGPL, Artistic, Beerware, BSD, Combined_OpenSSL +SSLeay, copyleft-next, eCos, FSLA, FTL, Google-BSD, GPL, IBM-pibs, IETF, IJG, ISC, LGPL, Libpng, MIT, MPL, OpenSSL, RHeCos, Sun, WebM, X11, Zlib.

Technical data

The open source software is provided free of charge. You can request the source code of the software for up to three years from the purchase date of the device, if provided in the relevant open source software license terms. Any liability for the use of the open source software beyond the program cycle provided by us for the product as well as any liability for defects caused by changes to the open source software is excluded. We do not provide technical support for this product if this was changed.

4 Electromagnetic compatibility

4.1 Compliance details

As noted in section 3, the miha-bodytec II EMS training device complies with IEC 60601-1-2:2014 and IEC 60601-2-10:2012. According to these standards, the requirements apply as listed in the tables below.

Guidance and manufacturer's declaration - electromagnetic emissions

The miha bodytec II EMS training device has been designed for use in electromagnetic environments as outlined below.

The buyer or user of the miha bodytec II device must make sure that the device is used under such conditions.

Emission tests	Compatibility	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The miha bodytec II EMS training device uses low RF power for internal operation. Generating very low RF interference emissions, it is not likely to interfere with electronic equipment in its vicinity.
RF emissions CISPR 11	Class B	
Harmonic distortion. IEC 61000-3-2	Class A	
Voltage fluctuations and flicker. IEC 61000-3-3	Complies	The miha bodytec II device is suitable for usage in any building, including residential buildings and those connected directly to low-voltage power supply networks installed for residential buildings.

Guidance and manufacturer's declaration - electromagnetic immunity

The miha bodytec II EMS training device has been designed for use in electromagnetic environments as outlined below.

The buyer or user of the miha bodytec II device must make sure that the device is used under such conditions.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV on contact discharge ±2 kV ±4 kV, ±8 kV, ±15 kV air discharge	±8 kV contact discharge ±2 kV ±4 kV, ±8 kV, ±15 kV air discharge	The miha-bodytec II EMS training device can be used in rooms without humidity control. Floors can be covered with synthetic material. If so, the relative humidity must be at least 5 %.

Electromagnetic compatibility

Guidance and manufacturer's declaration - electromagnetic immunity

The miha bodytec II EMS training device has been designed for use in electromagnetic environments as outlined below.

The buyer or user of the miha bodytec II device must make sure that the device is used under such conditions.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz Modulation 80 % AM at 1 kHz	10 V/m	The minimum separation distance d in m to a RF emitting device with a maximum power P in W not operating in a frequency band covered by the proximity fields test can be calculated using the equation in clause 8.10 of IEC 60601-1-2 with E as the field strength in V/m taken from the compliance level: $E = 6 / d \cdot \sqrt{P}$
Proximity fields from RF wireless communications equipment IEC 61000-4-3	385 MHz: 27 V/m 450 MHz: 28 V/m 710 MHz: 9 V/m 745 MHz: 9 V/m 780 MHz: 9 V/m 810 MHz: 28 V/m 870 MHz: 28 V/m 930 MHz: 28 V/m 1720 MHz: 28 V/m 1845 MHz: 28 V/m 1970 MHz: 28 V/m 2450 MHz: 28 V/m 5240 MHz: 9 V/m 5500 MHz: 9 V/m 5785 MHz: 9 V/m	385 MHz: 27 V/m 450 MHz: 28 V/m 710 MHz: 9 V/m 745 MHz: 9 V/m 780 MHz: 9 V/m 810 MHz: 28 V/m 870 MHz: 28 V/m 930 MHz: 28 V/m 1720 MHz: 28 V/m 1845 MHz: 28 V/m 1970 MHz: 28 V/m 2450 MHz: 28 V/m 5240 MHz: 9 V/m 5500 MHz: 9 V/m 5785 MHz: 9 V/m	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) must be used no closer than 30 cm (12 inches) to any part of the miha-bodytec II EMS training device, including cables specified by the manufacturer. The field strength test levels are calculated using the equation in clause 8.10 of IEC 60601-1-2: $E = 6 / d \cdot \sqrt{P}$ with E as the field strength in V/m, the maximum power P in W of and the minimum separation distance d in m to the RF.

Guidance and manufacturer's declaration - electromagnetic immunity

Mains-frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields must be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical fast transients/bursts IEC 61000-4-4	Input a.c. power port: ± 2 kV Input d.c. power port: ± 2 kV Signal input/output parts port: ± 1 kV (with 100 kHz repetition frequency)	Input a.c. power port: ± 2 kV Input d.c. power port: ± 2 kV Signal input/output parts port: ± 1 kV (with 100 kHz repetition frequency)	Mains power quality must equal that of usual commercial or hospital environments. Note: The miha-bodytec II EMS training device has no input d.c. port and no signal input/output parts ports with a maximum cable length of 3 meters or more

Guidance and manufacturer's declaration - electromagnetic immunity

The miha bodytec II EMS training device has been designed for use in electromagnetic environments as outlined below.

The buyer or user of the miha bodytec II device must make sure that the device is used under such conditions.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Surges IEC 61000-4-5	Input a.c. power port: ± 0.5 kV, ± 1 kV, ± 2 kV line-to-ground ± 0.5 kV, ± 1 kV, line to line Input d.c. power port: ± 0.5 kV, ± 1 kV, ± 2 kV line-to-ground ± 0.5 kV, ± 1 kV, line to line Signal output parts port: ± 2 kV	Input a.c. power port: ± 0.5 kV, ± 1 kV, ± 2 kV line-to-ground ± 0.5 kV, ± 1 kV, line to line Input d.c. power port: ± 0.5 kV, ± 1 kV, ± 2 kV line-to-ground ± 0.5 kV, ± 1 kV, line to line Signal output parts port: ± 2 kV	Mains power quality must equal that of usual commercial or hospital environments

Electromagnetic compatibility

Guidance and manufacturer's declaration - electromagnetic immunity

Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz Modulation 80 % AM at 1 kHz	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz Modulation 80 % AM at 1 kHz	As described in annex A.3 of IEC 60601-1-2, the voltage induced on a cable in the frequency range 150 kHz to 80 MHz from a field strength of 10 V/m is unlikely to exceed 6 V r.m.s. Therefore, assuming a field strength E of 10 V/m in the ISM and amateur radio bands between 0.15 MHz and 80 MHz (see note 2), the minimum separation distance d in m to a RF communications equipment with a maximum power P in W can be calculated using the equation in clause 8.10 of IEC 60601-1-2: $d = 6 / E \cdot \sqrt{P}$
Voltage dips IEC 61000-4-11	0 % U_T ; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle; 70 % U_T ; 25/30 cycles; Single phase: at 0°	0 % U_T ; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle; 70 % U_T ; 25/30 cycles; Single phase: at 0°	Mains power quality must be that of a typical commercial or hospital environment. If the use of the miha-bodytec II EMS training device requires continued operation during power mains interruptions, an uninterruptible power supply (UPS) sufficiently fast and powerful to provide the energy needed must be used.
Voltage interruptions IEC 61000-4-11	0 % U_T ; 250/300 cycles	0 % U_T ; 250/300 cycles	

Guidance and manufacturer's declaration - electromagnetic immunity

Electrical transient conduction along supply lines (input d.c. power port)	Not applicable	Not applicable	The miha-bodytec II EMS training device is not intended to be installed in passenger cars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems
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Note 1: U_T is the a.c. mains voltage prior to application of the test level.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz. The amateur radio bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Replaceable parts:

All cables and equipment must be obtained from miha bodytec or authorized dealers. For replaceable parts available, see [Chapter 1.2 "Equipment" on page 11](#). Using other cables or equipment can void the authority to operate the equipment.

Essential performance:

In the presence of an electromagnetic disturbance, the electronic muscle stimulation (EMS) operates as intended.

In case of voltage interruptions, continuous operation is not guaranteed. If continuous operation is required, an uninterruptible power supply (UPS) sufficiently fast and powerful to provide the energy needed must be used.

4.2 EMC Warnings

⚠ WARNING

Risk of injury if other equipment is used!
Use of miha bodytec adjacent to or stacked with other equipment must be avoided because it can result in improper operation. If such use is necessary, this equipment and the other equipment shall be observed to verify that they are operating normally.

NOTICE

Risk of damage due to the use of third-party equipment!
Use of equipment, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

NOTICE

Risk of damage due to portable RF communications equipment!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) must be used no closer than 30 cm (12 inches) to any part of the miha-bodytec II EMS training device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment can result.

5 Basic information on EMS training

5.1 Safety first

Increase loads slowly



Fig. 18: Control unit 0 position

Safety and controlled training take priority over experimentation and hurried and uncontrolled increase of the stress parameters! For every training session, start at "0" with the stress for the main level and then increase slowly using the main controller.

5.2 EMS training

What is EMS training?

EMS stands for **ElectroMyoStimulation**. This means the muscles are stimulated by electrical pulses. Complete body training which addresses all muscle groups is possible with up to 10 pairs of electrodes.

During conventional training, the muscles are controlled via electrical signals from the brain to initiate a contraction and thus movement of the muscles. With EMS, electrical pulses from outside activate the muscles. It makes no difference to the muscle whether electrical stimulations are sent from the brain or from electrodes: It reacts by contracting!

Special features and benefits:

- All muscle groups can be activated using an electrode system with up to 10 pairs of electrodes.
- Static and dynamic training with interaction of deliberate muscle contraction and EMS.
- Exercise postures increase the contraction of the deliberately stimulated muscles.
- Positive and negative electrodes are not on the same muscle.
- Agonist and antagonist are stimulated simultaneously.
- EMS training can cause more intense muscle contractions than classic strength training. At the same time, there is comparatively very little stress on the joints.

- Deeper muscle groups can be easily reached.
- The training is very intense and thus accordingly short (10 – 20 minutes).

To be observed during EMS training

On the one hand, EMS training can be used on a large part of the body. On the other hand, EMS training permits athletes/patients to attain a training intensity level that is substantially higher than that of conventional workout methods. This is why a few special considerations must be observed during the training process. Regardless of the athletic background and physical condition, the instructions on the training frequency and regeneration – in particular for EMS beginners – must be observed [↳ Chapter 5.3 “Training frequency and regeneration” on page 48](#).

5.3 Training frequency and regeneration

Overtraining

⚠ WARNING

Risk from overtraining!

- Always give your body sufficient regeneration time.
- Do not train if suffering from continued severe muscle ache.
- In the event of overload, do cyclical alternating intensive and regenerative workouts on different days.

Overtraining can result in physical weakness, sleep disorders, headaches, increased resting and active pulse rate, muscle and tendon pains, and also depression among other things.

The recommended training frequency is 1 – 2 times per week. Do not train when feeling unwell, in the event of severe muscle ache or other contraindications ([↳ Chapter 2.3 “Risks due to physical condition: Contraindications” on page 18](#)).

Training if fatigued

⚠ WARNING

Danger to health from EMS training if performed while ill or otherwise fatigued!

- If ill, only train after consulting with your doctor.
- Always eat and drink sufficiently before training [↳ “Always eat and drink sufficiently” on page 49](#). Never train on an empty stomach.
- Follow the instructions on training frequency and regeneration [↳ Chapter 5.3 “Training frequency and regeneration” on page 48](#).

EMS training is an intense workout that challenges the body. If the athlete/patient is ill or otherwise fatigued due to health reasons, their body is unable to cope with the exertion and their illness may become worse as a result

Illness and training

Just as with intense conventional workouts, EMS training may only be performed if the body is in adequate physical condition.

Persons suffering from fever in particular are not permitted to train with the device.

The first workout

Do not let the first workout exceed 15 minutes in length, and use the following programs:

- Program 1: Pulse familiarization for 3 approx. minutes
- Program 6: Test workout for 12 minutes

Training in the first 10 weeks

In the first 10 weeks, do not exceed a training frequency of one training session per week.

Do not exceed a training time of 20 minutes.

Training after the first 10 weeks

After an acclimatization period of 10 weeks, workouts must still be separated by a regeneration phase of at least 4 days. Depending on the athlete's/patient's physical condition and fitness level, the regeneration phase may have to be longer.

Do not exceed a training time of 20 minutes.



If clarification is necessary, sports physicians can provide information about the optimum regeneration phase for optimum training results.

Always eat and drink sufficiently

EMS training is an intense workout and stimulates a large number of muscles simultaneously. This is why the athlete's/patient's body has elevated energy requirements during training. Before an intense workout, ensure that the athlete/patient replenishes his/her body's reserve of carbohydrates. This can be done by eating a meal high in carbohydrates (but not heavy) 2 – 3 hours before a workout.

The athlete's/patient's body also requires adequate fluids. The athlete/patient shall drink 17 fl oz (500 ml) before and after a workout to replenish his/her hydration levels.

Effect of training on blood count

Training close to your physical limit can initially lead to extremely elevated levels of creatine kinase and myoglobin, especially during the first training sessions. Even in healthy people, this is connected with stress on the kidneys.

EMS beginners in particular must therefore proceed carefully and increase this particular stress factor slowly. On the one hand, this particular stress factor must be increased slowly. Athletes/patients must ensure sufficient regeneration between individual workouts.

After an acclimatization phase of 8 – 10 weeks with one workout per week, the body has adjusted to the situation. This means that the effects of EMS training on the body's creatine kinase and myoglobin levels are comparable to the effect of a very intense conventional muscular workout

Regeneration



Muscle growth takes place in the resting phase between workouts. Therefore, always allow your body the necessary rest.

You should drink a high-protein energy drink such as a protein shake for better regeneration and for stimulation of muscle building. Take a break after the workout and do not complete any further workouts to guarantee best possible regeneration and to avoid overtraining.

6 Understanding the device

6.1 Explanation of terms

Programs

Programs are defined as settings that are based on various parameters such as the pulse time, pulse width, pause time, etc., which generate a pulse within the desired intensity range that is specific to the selected workout. While the program is running, the desired pulse will be output for the previously selected duration. This makes it possible to engage in “freestyle” training.

Training plan

A training plan is the combination of a program and a sequence of different exercises which are demonstrated on the display by an avatar (male or female). You can select from different training plans, each composed of different exercises and sequences.

Loading the level



“Load level” is only available in combination with the transponder card. The function must be enabled in the device settings and under card management. The function is also only available for training plans and training programs that are defined on the customer card.

“Load level” is a function that automatically sets the intensity for the level controller.

When you complete a workout, the intensity levels currently set for the level controller are stored on the transponder card. These intensity levels can be automatically accessed on the transponder card during future workouts.

For this to work, the “Load level” function must be active in the device settings. In addition, this option must also be set on the transponder card of the athlete/patient.

When a workout is started with a transponder card in place, level controllers 1 – 10 are automatically set to the saved levels.

To increase safety for the athlete/patient, there are threshold values for the main controller if the “Load level” function is active. If the intensity level is increased using the main controller, the device automatically stops this increase at the value levels of 30, 40, and 50. To increase the intensity level above these thresholds, the main controller must be pressed once (each time).

Favorites menu

The favorites menu is the first menu tab. It enables the trainer to create a customized choice of workout options.

The favorites menu can be used for storing frequently used programs and/or training plans. This lets trainers restrict the range of choices available to the athlete/patient and therefore select the programs and training plans to be used. Creating a summary in the favorites menu also makes it possible to speed up the selection process, which facilitates the use of transponder cards.

Understanding the device



If favorites have been selected, only these favorite workouts will be displayed in the card management menu.

Data backup/restoration

The backup function is used to create a backup of the device settings and programs as well as training plans on an external device (USB flash drive). The “Restore” function can then be used to load device settings and/or programs and training plans (depending on your selection) to other devices.



Only use original USB flash drives supplied by the manufacturer on the USB port.

Master device/managed device

With synchronized start, one device is assigned a managing function. This device controls the training procedure for all other devices involved and is referred to as the master device. Devices participating in the synchronized start that are not master devices are referred to as managed devices.

The athlete/patient must strictly adhere to the instructions of the trainer. If physical or device-specific problems arise during training, notify the trainer immediately and follow the trainer's instructions.



To ensure the trainer and persons training can communicate as required, the managed devices must be oriented towards the master device to allow the trainer to monitor each person training. To ensure that training with synchronized start is effective and safe, a maximum of 2 persons training per trainer is recommended.

Brand code

The brand code (parameterization) is used for selecting or adding default factory settings such as color settings, graphics settings, and network functions. This option may only be used by miha bodytec service employees or under their supervision.

WARNING

Risk of injury from improperly entering brand codes!

- Never enter brand codes by yourself.
- If you want to use brand codes, contact Customer Service („Customer service“ on page 15).

If brand codes are entered without adequate background knowledge, athletes/patients can be injured due to malfunctions or incorrect parameterization and the device can be damaged.

System status

The system status can be used for identifying different device parameters. It is an important source of information for our service employees in the event of a defect. Provide service employees with system status information if asked.

Export log

“Export log” is a function that allows relevant device information to be exported to a USB flash drive in the event of an error.



The “Export log” function must be used only under the guidance of miha bodytec service personnel.

Symbolic level controller assignment

The individual connections of the electrodes are assigned to the level controllers using symbols. The strength for the area is adjusted using the respective level controller.

Symbol	Channels/application area
 1	Channel 1 – legs
 2	Channel 2 – buttocks
 3	Channel 3 – lower back
 4	Channel 4 – upper back
 5	Channel 5 – side back
 6	Channel 6 – abdomen
 7	Channel 7 – chest
 8	Channel 8 – arms
 9	Channel 9
 10	Channel 10

6.2 Opening menu tabs

Main menu



Fig. 19: Main menu

The menu level where the menu tabs are displayed (Fig. 19/1) is the main menu. When the main menu shows, the device is in a safe condition. In this context, “safe condition” means that the electrode connections are voltage-free. Electrodes may be attached and detached from the device only when they are in this safe condition.

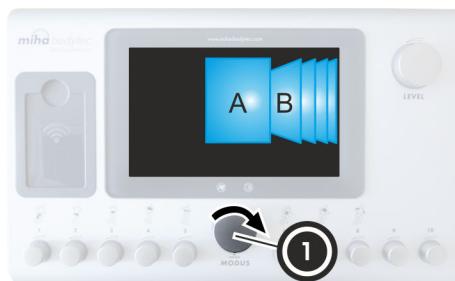


Fig. 20: Selecting a menu tab



Fig. 21: Selected menu tab

i *Menu tabs (Fig. 19/1) offer a convenient way to access various settings options and special types of workouts. You can start navigating the available options with the help of menu tabs. After selecting a menu tab, you will be shown the associated menus or secondary menu tabs.*

1. ➔ Turn the multi-function button (Fig. 20/1) clockwise.

⇒ The following menu tab (Fig. 21/B) has been selected.

2. ➔ Press the multi-function button (Fig. 20/1).

⇒ The selected menu tab opens.

i *Turn the multi-function button counterclockwise to select the menu tab that is displayed to the left of the selected menu tab. In the example shown, this would be tab “A” (Fig. 21/A).*

6.3 Opening menus

Menu structure

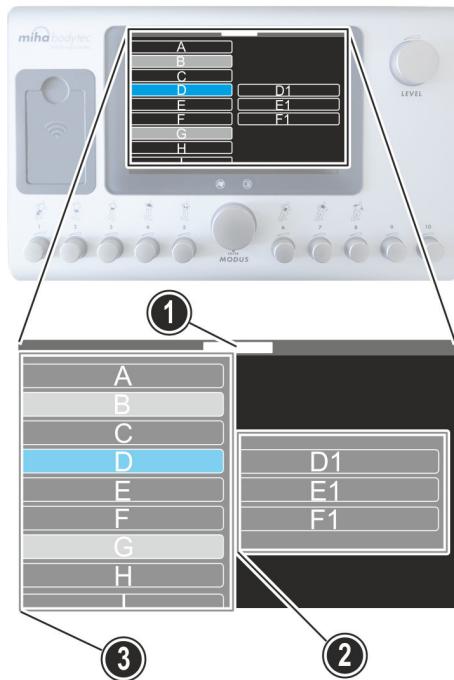


Fig. 22: Menu structure



If a menu contains more items than can be shown on the display at one time, the menu items will only be displayed partially. In the example shown, the menu item on the very bottom is the one that is only displayed partially (Fig. 22/1).

The right half of the display shows the current settings (Fig. 22/2) defined for the respective items in the menu. The current settings are always displayed next to the associated menu items.

Menu colors

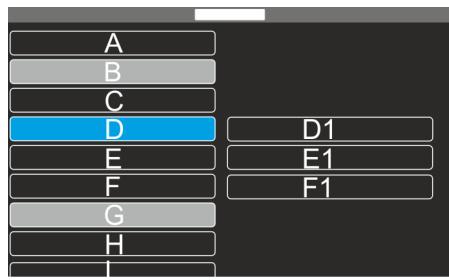


Fig. 23: Example menu

Menus are labelled with different colors. The color of a menu item indicates whether the menus are locked or can be selected using the multi-function button. The device also uses the color of the menu items to provide feedback on which menu is currently selected:

Color	Example	Meaning
Black background	A	Menu can be selected.
Gray background	B	Menu is locked. Locked menus cannot be opened.
Colored background*	D	Menu is currently selected.

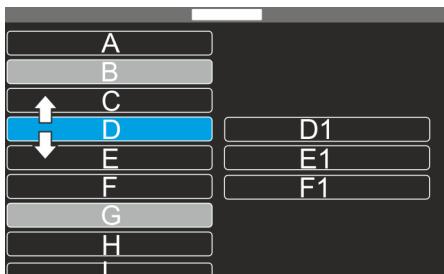
Understanding the device

Color	Example	Meaning
Gray background and colored frame*	G	Locked menu is currently selected**.

* The indicated color corresponds to the color selected in the “Device color” menu item.

** By turning the multi-function button, only the position is shown.

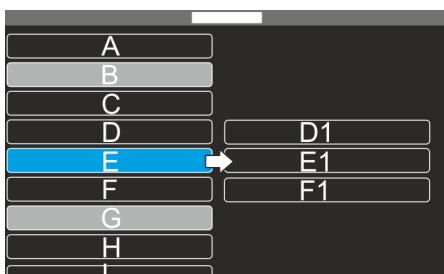
Selecting and opening menus



1. Turn the multi-function button until the desired menu item is displayed against a colored background.
 - ⇒ Menu item with colored background has been selected.
2. Press the multi-function button.
 - ⇒ The menu opens and the submenu associated with the menu item is selected.

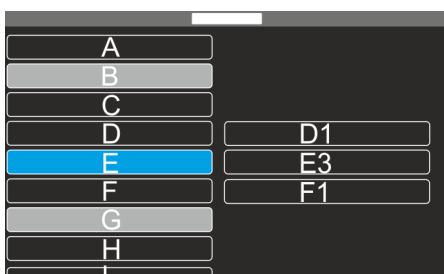
Fig. 24: Selecting a menu

Settings in submenus



1. Open the desired menu item containing a submenu
 - ⇒ “Selecting and opening menus” on page 56.
2. Press the multi-function button.
 - ⇒ Submenu has been selected (Fig. 25/white arrow).
3. Turn the multi-function button.
 - ⇒ The settings options available for the submenu are displayed one at a time (example here “E1 → E2 → E3”).
4. Press the multi-function button.

Fig. 25: Setting has been selected



- ⇒ The displayed submenu setting (here Fig. 26/E3) is applied.

Fig. 26: Setting has been changed

Opening main menu



How the main menu opens depends on the current status of the device. The following situations are possible:

- Opening the main menu while a menu is displayed ↗ “From a menu” on page 57.
- Opening the main menu while a workout is active ↗ “During workout” on page 57.

1. ➔ Turn the multi-function button to select the top or bottom menu item.
2. ➔ Press the multi-function button to open the top or bottom menu item.
3. ➔ Repeat steps 1 and 2 until you see the “Main menu” menu item.
4. ➔ Select the “Main menu” menu item.
⇒ The main menu is displayed.



Fig. 27: Main menu

During workout

1. ➔ Press the multi-function button.
⇒ The workout is cancelled or ended. Training screen remains open.
2. ➔ Press the multi-function button again.
⇒ Without transponder card: The main menu is displayed.
With transponder card: Data is written on the card and the programs or training plans saved on the card are displayed. The main menu is only displayed when the card is removed from the device.



Fig. 28: Main menu

6.4 Entering text

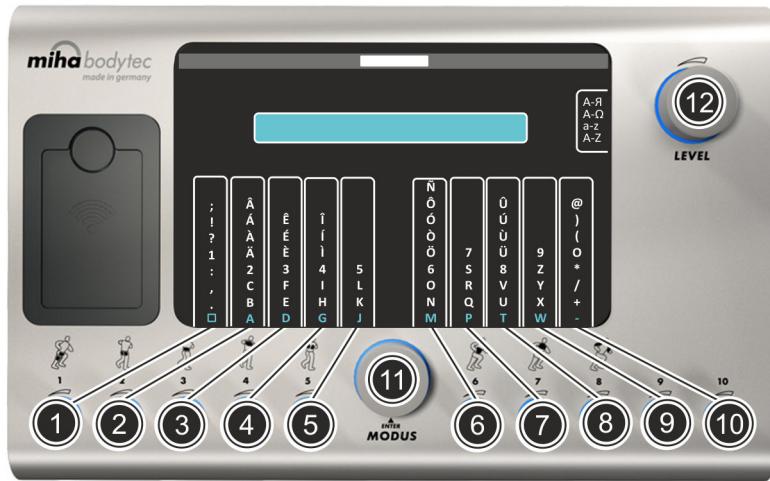


Fig. 29: Entering text

When creating custom settings or person-specific data, there is the option of storing information in text form (e.g., "Create customer card" → "Name").

When selecting these text boxes with the multi-function button (Fig. 29/11), there are the following input options:

- Turn the main controller (Fig. 29/12) to select between different types of letters and upper and lower case letters.
- Briefly press the main controller (Fig. 29/12) to delete the last letter from the text box. Pressing and holding the controller for longer will clear the text box completely.
- Select the letters by turning the individual level controllers (Fig. 29/1 – 10) (channels 1 – 10) and copy them into the respective text boxes by pressing the corresponding controllers.
- Copy the entered text by pressing the multi-function button (Fig. 29/11).

7 Customization and setup

7.1 Adjusting the device setup

Displaying device settings

Personnel: Trainer

1. ➔ Open the “Setup” menu tab.
2. ➔ Open the “Device settings” menu item.
⇒ The “Device settings” menu opens.

Menu items device settings

You can set the following parameters in the “Device settings” menu:

- **Load level:** Enables or disables the option “Load level” in general, but requires additional activation for each customer on the customer card.
- **Device color:** Lets you adjust the color of all LED lights in the device.
- **Active color:** Sets the color of the decreasing LED strip in the display and on the rear while a pulse is being output.
- **Pause color:** Sets the color of the increasing LED strip in the display and on the rear while no pulse is being output.
- **Pause transition color:** Specifies the color of the LED strip in the display and on the rear if a pause transition of more than 0 LEDs was selected.
- **Pause transition:** Specifies how many LEDs are supposed to change color at the beginning of the pulse.
- **Brightness:** Specifies the brightness of the display in the device.
- **Language:** Specifies the language to be used for display texts.
- **Gender of avatar:** Specifies the gender of the avatar for work-outs without a transponder card.

Changing controller colors



Any change of the controller color will not take effect until you exit the “Setup” menu. Pause transitions can be used for instance to demonstrate to the athlete/patient when they have to contract their muscles.

7.2 Selecting the language



The device lets you choose from the following menu language options:

- German
- English
- French
- Spanish
- Italian

- Russian
- Greek
- Polish
- Portuguese
- Dutch
- Hungarian
- Romanian
- Turkish
- Chinese
- Czech

Selecting the default language for display texts



The selected default language is the default option applying to all athletes/patients.

Personnel: ■ Trainer

1. ➤ Open the “Setup” menu tab.
2. ➤ Open the “Device settings” menu item.
 - ⇒ The “Device settings” menu opens.
3. ➤ Open the “Language” menu item.
4. ➤ Select the desired language and confirm your selection by pressing the multi-function button.
 - ⇒ Display texts are shown in the language you have selected.



Every athlete/patient can customize the language settings and store these personalized settings on the transponder card
↳ *“Selecting individual language settings for the athletes/patients” on page 98.*

7.3 Program memory settings

Displaying the program memory

Personnel: ■ Trainer

1. ➤ Open the “Setup” menu tab.
2. ➤ Open the “Program memory settings” main menu item
↳ *Further information on page 58.*
 - ⇒ The “Program memory settings” opens.

Menu items

You can set the following parameters in the “*Program memory settings*” menu:

- **Name:** Defines a custom name for the training program. Instructions on how to write names ↗ *Further information on page 58*.
- **Training time:** Specifies the total training time.
- **Pulse time:** Specifies the duration for which pulses will be emitted. The pulse time is indicated in seconds.
- **Pause time:** Specifies the time in between pulses. Pause time is indicated in seconds.
- **Frequency:** The pulse frequency in Hz indicates how many individual pulses will be emitted per contraction phase.
- **Pulse width:** Specifies the length of an individual pulse. The longer the pulse width, the deeper the pulse will penetrate the muscle tissue. The pulse width is indicated in microseconds.
- **Rise time:** Specifies the time that will elapse between the beginning of the pulse to the pulse reaching its peak.
- **Save program:** Saves the program on the device. Once saved, a program can no longer be modified or deleted. It can only be deactivated. It will then only be displayed in the training plan memory settings and program memory settings. The program can be activated again in these settings.

The “*Program memory settings*” menu displays all training programs that have been created in numerical order.



While you can view the programs memory settings by selecting them, you will not be able to modify or delete them.

7.4 Setting up the training plan memory

Viewing/creating training plan memory

Personnel: ■ Trainer

1. ➔ Open the “*Setup*” menu tab.
⇒ The “*Setup*” menu tab opens.
2. ➔ Turn the multi-function button to the right to select the “*Set up training plan memory*” menu item.
⇒ The “*Set up training plan memory*” menu item is selected.
3. ➔ Confirm your selection by pressing the multi-function button.
⇒ The “*Set up training plan memory*” menu opens.
4. ➔ Turn the multi-function button to the right to select the “*Create training plan memory*” menu item.
⇒ The “*Create training plan*” menu item is selected.
5. ➔ Confirm your selection by pressing the multi-function button.
⇒ The “*training plan*” menu opens.

Menu items of the training plan memory

You can set the following parameters in the “Set up training plan memory” menu:

- **Name:** Defines a custom name for the training program. Instructions on how to write names ↗ *Further information on page 58*.
- **Program:** Specifies the training program including pulse width, rise time, etc., which will be stored for the training plan.
- **Training time:** Specifies the duration of the entire training plan.
- **Repetitions:** This screen shows the number of repetitions/exercises after selecting the exercise.
- **Exercises:** Allows you to select the individual exercises. “Pause” is an exercise.
- **Remaining repetitions/time:** Depending on the training time, this shows the number of repetitions which can still be completed during the remaining time.
- **Save training plan:** The training plan cannot be saved as long as the value of the remaining repetitions is not “0”.



- *The screen will only show training programs with 4 second cycles.*
- *While the athlete/patient is working out with the device, there will be a remaining time that elapses with no exercising if the training time cannot be divided by 8 seconds (4 second exercise/4 seconds pause).*
- *If a training plan is deactivated, it is no longer visible in the “Training plans” selection or in the favorites menu.*
- *After storing the training plan, you can change the exercises and the name, but you cannot alter the program associated with the training plan.*
- *If you select “Pause” as the exercise, the main controller is automatically set to 30. You can only change this setting during or after the pause if you press the main controller. The LED strip turns orange while the intensity level is being reduced.*

7.5 Setting up synchronized start

What is training with synchronized start?

During training with synchronized start, several devices are networked to form a training group. One device in the training group provides the start command and enables simultaneous training with several devices.



To ensure that the trainer and athletes/patients can communicate as specified, the managed devices must be oriented towards the master device so that the trainer can monitor each athlete/patient. A maximum of 2 athletes/patients per trainer are recommended to ensure that training with synchronized start is effective and safe.

Steps to set up synchronized start

2 steps are required to set up synchronized start:

- Setting up the master device ↗ “Setting up the master device” on page 63
- Setting up managed devices ↗ “Setting up a managed device” on page 63

Overview of synchronized start settings

You can set the following parameters in the “Synchronized start” menu:

- **Synchronized start:** Enables or disables the synchronized start option in general (if synchronized start is enabled, the synchronized start symbol lights up blue).
- **Master device:** Specifies whether the device is supposed to control the training as the master device or participate in the training as a managed device.
- **Group number:** Defines a group number for the training session.
- **Countdown:** Specifies the delay with which the training session will begin following the start command.
- **Flexible training:** When the flexible training option is activated, all participating devices only have to be set to the same cycle (e.g., 4 s of pulse and 4 s of pause). In addition, the users of all devices must use training plan or a program.

When the flexible training option is deactivated, a device can only participate in the training with synchronized start session if it is set to the same program or same training plan as the master device.

Setting up the master device

Personnel: ■ Trainer

1. ➔ Open the “Setup” menu tab.
⇒ The “Setup” menu tab opens.
2. ➔ Open the “Synchronized start” menu item.
3. ➔ Set the current “Synchronized start” setting to “YES”
↳ “Settings in submenus” on page 56.
4. ➔ Set the current “Master device” setting to “YES”.
5. ➔ Set the current “Group number” setting to the desired group number.

i *The selected group number must be between 1 and 16. The group number also needs to be set for all other managed devices participating in the training session.*

⇒ The device is ready to control the training session as the master device.

Setting up a managed device



All managed devices that are supposed to participate in the training session have to be set up as described below.

Personnel: ■ Trainer

1. ➔ Open the “Setup” menu tab.
⇒ The “Setup” menu tab opens.
2. ➔ Open the “Synchronized start” menu item.

3. ➤ Set the current “Synchronized start” setting to “YES”
↳ “Settings in submenus” on page 56.
4. ➤ Set the current “Master device” setting to “NO”.
5. ➤ Set the current “Group number” setting to the desired group number.

i *The selected group number must match the group number of the master device.*
⇒ The device is ready to participate in the training session as a managed device.



All patients/athletes also have to specify that they want to participate in the training with synchronized start session ↳ “Setting up the transponder card for training with synchronized start” on page 97.

7.6 Adjusting the favorites menu



The favorites menu allows trainers to store their preferred training plan selections. These selection options are called favorites and represent a preselection of training plans. Preselections can be stored on transponder cards. When a transponder card is inserted, an athlete/patient can only choose from the set preselections.

1. ➤ Open the “Setup” menu tab.
⇒ The “Setup” menu tab opens.
2. ➤ Open the “Favorites menu settings” menu item.
⇒ The “Favorites menu settings” menu item opens.
3. ➤ Use the multi-function button to select a workout of your choice and press the button to confirm your selection.

i *You can select all types of workouts (including all training programs and training plans you have created).*
⇒ The corresponding workout is selected.
4. ➤ Turn the multi-function button to set the “YES/NO” selection box to the “YES” option.
⇒ The corresponding workout has been assigned to the favorites.
5. ➤ Confirm the assignment by pressing the multi-function button.
6. ➤ Use the multi-function button to select the “Setup menu” menu item and press the button to confirm your selection.
⇒ The “Favorites menu settings” menu is closed.

7.7 Backing up data

Personnel: ■ Trainer
 Materials: ■ miha bodytec USB flash drive

i “Backup” will not be enabled until you insert the miha bodytec USB flash drive into the device before switching to the “Setup” menu tab!

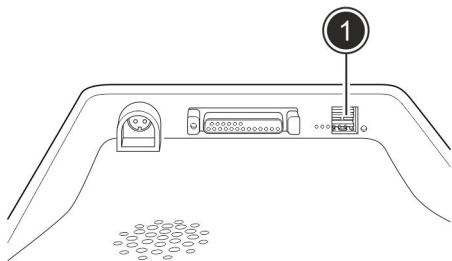


Fig. 30: USB port

1. ➤ Insert the miha bodytec USB flash drive into the USB port (Fig. 30/1).
2. ➤ Open the “Setup” menu tab.
 ⇒ The “Setup” menu tab opens.
3. ➤ Use the multi-function button to select the “Data backup” menu item and press the button to confirm your selection.
4. ➤ Turn the multi-function button to the left to set the selection box to “YES” and press the multi-function button to backup the data.

i The backup files written to the USB flash drive can only be copied or moved! Subsequently edited files will no longer be recognized by the device and can therefore no longer be used!

⇒ The device settings, the created workouts, and the device statistics are saved to the miha bodytec USB flash drive as backup files.

7.8 Restoring/importing data

Personnel: ■ Trainer
 Materials: ■ miha bodytec USB flash drive

i “Restore data” will not be enabled until you insert the miha bodytec USB flash drive containing the backup files into the device before switching to the “Setup” menu tab!

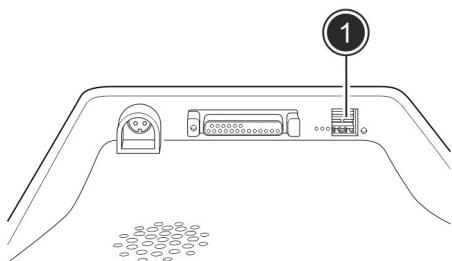


Fig. 31: USB port

Importing settings

4. ➤ Use the multi-function button to select the “Import settings” menu item and press the button to confirm your selection.

Importing training programs

5. ➤ *You can use the selection box to define whether the device settings stored in the backup files are supposed to be imported and applied.*

Use the multi-function button to select the “YES” or “NO” selection box and press the button to confirm your selection.

6. ➤ Use the multi-function button to select the “Import training programs” menu item and press the button to confirm your selection.

7. ➤ *You can use the selection box to define whether the training plans and programs stored in the backup files are supposed to be imported and applied.*

Use the multi-function button to select the “YES” or “NO” selection box and press the button to confirm your selection.

Starting data restoration

8. ➤ *After selecting the data packages you wish to import, you can start restoring the data stored on the miha bodytec USB flash drive.*

Use the multi-function button to select the “Start process” menu item and press the button to confirm your selection.

9. ➤ *All settings and training programs as well as all training plans stored on the device will be erased and replaced with the contents of the backup files.*

Use the multi-function button to select the “YES” selection box and press the button to confirm your selection.

⇒ Data restoration starts.

10. ➤ *Once the data has been restored/imported successfully, it is necessary to restart the device.*

Press the On/Off switch on the back of the device.

⇒ The device shuts down.

11. ➤ Remove the miha bodytec USB flash drive.

12. ➤ Press the On/Off switch on the rear of the device.

⇒ The device starts up. The data is restored.

7.9 Installing updates

Data errors due to computer viruses

 **WARNING**

Risk of injury due to data errors caused by computer viruses!

- Only use the specified download paths for update files provided in the miha bodytec newsletter.
- Only use computers with updated anti-virus software when handling update files
- Before copying the update file to the miha bodytec USB flash drive, scan the computer for viruses.

Computer viruses can change the update files. This can result in errors in the control unit that affect the electrical outputs.

Interrupting the update

 **NOTICE**

Interrupting the update process can result in material damage!

- Do not disconnect it from the power source during an update.
- Do not turn off the device during an update.
- Wait for the update to finish and do not input anything.

The device can be permanently damaged if it is turned off during the update process or if the power supply is interrupted



If the update is interrupted due to an interruption of power, contact Customer Service (↳ “Customer service” on page 15).

Receiving update files

miha bodytec can send important updates by mail on a miha bodytec USB flash drive. Important updates must be installed immediately.

Installing updates

Personnel:	■ Trainer
Materials:	■ Latest update file ■ miha bodytec USB flash drive



Keep the device updated at all times.

1. ➤ Save the relevant update file on the miha bodytec USB flash drive.
2. ➤ Insert the miha bodytec USB flash drive with the update file into the USB port on the underside of the device (Fig. 32/1).
3. ➤ Open the “Setup” menu tab.
⇒ The “Setup” menu tab opens.
4. ➤ Use the multi-function button to select the “Update” menu item and press the button to confirm your selection.
■ If the “Update” menu item has a grey background, the update file on the miha bodytec USB stick is defective, or the miha bodytec USB stick has not been fully inserted. Ensure that the update file is valid and that the miha bodytec USB flash drive is fully inserted.
⇒ A prompt appears asking if you want to perform an update.
5. ➤ Answer the prompt with “Yes”.
⇒ The update process starts. This can take several minutes.
6. ➤ Wait for the update to complete. Do not disconnect the device from the power supply. Do not turn off the device.
⇒ After the update process is complete, a prompt appears to manually turn the device off and on again.
7. ➤ Turn the device off.
8. ➤ Remove the miha bodytec USB flash drive.
9. ➤ Turn the device on.
⇒ The update is now complete and the device is ready for use.

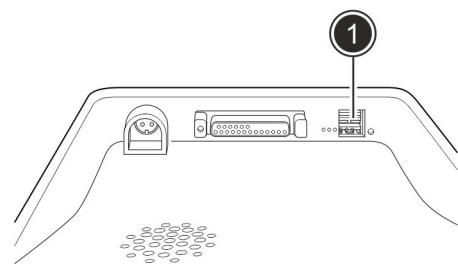


Fig. 32: USB port

7.10 Using networks

Wi-Fi

The device is fitted with a Wi-Fi module so it can exchange data with the miha bodytec LOGX portal.

It can only be used in networks with the designated and preconfigured Wi-Fi access point, which is available upon request from miha bodytec.

miha bodytec LOGX portal

The device's network capability is used for communicating with the miha bodytec LOGX portal. The miha bodytec LOGX portal is a control center for commercial use. It is provided by miha bodytec.

7.11 Resetting to factory settings

A security code can be used for resetting the device settings to the state they were in when it was delivered. This process deletes customized settings. If you want to reset the device, contact Customer Service ⇨ “Customer service” on page 15.

7.12 Displaying statistics

1. ➔ Open the “Setup” menu tab.
⇒ The “Setup” menu tab opens.
2. ➔ Use the multi-function button to select the “Statistics summary” menu item and press the button to confirm your selection.
⇒ The “Statistics summary” menu opens.

You can view the following statistics in the “Statistics summary” menu:

- Device runtime (operating hours counter)
- Programs (total runtime divided across the programs)
- Customers (total runtime divided across customer card numbers)



Example:

– 25:30 equals 25 hours and 30 minutes.

Statistics are displayed in hours and minutes.

8 Before the training

8.1 Eating and drinking

Nutrition

Eat a high-carbohydrate meal 2 – 3 hours before the training to achieve the best possible training effect.

Drink at least 17 fl oz (500 ml) of liquid 30 – 45 minutes beforehand. Lukewarm water is ideal. Avoid beverages containing caffeine and alcoholic drinks due to the increased fluid excretion.

Mineral drinks and energy drinks

Drink mineral drinks or high-carbohydrate energy drinks immediately before the training. Sufficient liquid supply with carbohydrate drinks must be guaranteed during as well as after the training to prevent hypoglycemia (low blood sugar).

8.2 Selecting undergarments and shoes

Wearing miha bodytec undergarments

The miha bodytec undergarments available as equipment have been specially developed for using the device with respect to material composition and strength. It is mandatory to wear the genuine miha bodytec undergarments (☞ *“Undergarments” on page 14*).

Ensuring that undergarments fit correctly

Always pay attention to the correct size. The undergarments must fit closely everywhere, but must not cut into the skin or be too tight. Pay attention that pants and shirt do not overlap under the electrode areas on the abdomen and back. Doubled fabric layers change pulse transfer, making the actual workout different from what was planned.

Choosing the correct undergarment size

The sizes of the undergarments correspond to the usual clothing sizes. In addition, the hip width can be used as a more detailed indication:

	XS	S	M	L	XL	XXL
Hip width men	2'11"	3', 3'1"	3'2", 3'3", 3'4"	3'5", 3'6"	3'7", 3'8"	3'9", 3'10", 3'11"
Hip width women	2'9 ", 2'10"	2'11", 3, 3'1"	3'2", 3'3", 3'4"	3'5", 3'6"	3'7", 3'8", 3'9", 3'10	3'11", 4', 4'1", 4'2", 4'3"

Wear slip-resistant training shoes.

Always wear sport shoes with slip-resistant soles during training.

8.3 Moistening and applying electrodes

Moistening and applying the electrodes



Electrodes may only be moistened and applied by the trainer or under their supervision.

Incorrectly attached cables



Risk of injury in the event of incorrectly attached cables!

- Electrodes may only be moistened and applied by the trainer or under their supervision.

Cables not attached to the correct electrodes present a risk.

Changing attachment during operation



Risk of injury if detaching or connecting electrode cables during operation!

- Start by making sure that no training program is active (↳ “Main menu” on page 54), then connect or detach the electrodes.
- Never detach electrode cables while training.
- Never connect electrode cables while training.

Detaching or connecting electrode cables can result in injuries.

Damages



Risk of injury due to damaged cables!

- Check the cables and electrodes for damage before every workout.
- Never use the device if cables or electrodes are damaged.

Training with damaged cables or damaged electrodes can lead to injuries.

Unsuitable accessories



Risk of injury from wearing accessories that are too small or too large!

- Select the i-body® in accordance with the instructions ↳ “Choosing the correct i-body® size” on page 72.
- Select i-body® straps flex and i-body® belt in accordance with the instructions ↳ “Selecting the size of the i-body® straps flex” on page 72.

Wearing accessories that are too small or too large (i-body®, i-body® straps flex, i-body® belt) can lead to contact injuries.

Before the training

Choosing the correct i-body® size



You can find the tag that specifies the size at the lower end of the zipper of the i-body®.

The i-body® is available in the following unisex sizes:

i-body® version	Size
1	Small
2	Medium
3	Large
V1	Small + additional adjustment options
V2	Large + additional adjustment options

Select the i-body® vest so that it fits snugly on your body and does not cut in anywhere. If the vest is loose, select a smaller size. If the vest is too tight, select a larger size.

Selecting the size of the i-body® straps flex

i-body® straps flex are available in 3 different versions:

i-body® strap flex version	Size
1	Small
2	Medium
3	Large

Select i-body® straps flex so that they fit your arms and legs closely and do not cut in anywhere when closed.

The version information provides a guideline. If i-body® straps flex never fit snugly when closed, select a smaller size. If the hook and eye cannot be closed, select a larger size.

Selecting the size of the i-body® belt

i-body® belts are available in 2 different versions:

i-body® belt version	Size
1	Small
2	Large

Select the i-body® belt so that the buttocks belt fits snugly on your body and does not cut in anywhere. If the buttocks belt is loose, select a smaller size. If the buttocks belt is too tight, select a larger size or use an extension piece to enlarge it.

Moistening instructions

Personnel: Trainer

1. ➔ Spread out the opened i-body® and the i-body® straps flex on a level surface for moistening.
2. ➔ Moisten the electrode surfaces evenly using the pump spray bottle filled with water for a minimum of 3 seconds per electrode.



Fig. 33: Pump spray bottle

DANGER

Risk of fatal injury from improper exposure of the electrodes to moisture!

- When moistening and putting on the electrodes, ensure that there is a sufficient distance to the control unit. No water must penetrate the case.

There is a risk of fatal injury due to electrocution in the event of liquid penetrating the case of the control unit!



Do not use distilled water. Do not exceed a water temperature of +86 °F. Only fill the pump spray bottle up to the max. marking visible on the side. Otherwise, no pressure can be built up. Pump air into the bottle by moving the pumping piston up and down (Fig. 33/1).

Before the training

Moistening and applying electrodes



If the electrodes are not moistened correctly, the pulses cannot be transmitted correctly. If the electrodes are moved, always moisten them again.

Personnel:

- Athlete/Patient
- Trainer

Preparing the i-body®

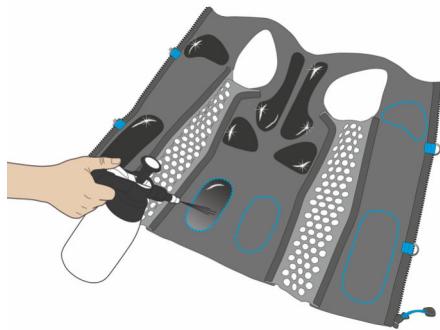


Fig. 34: Moistening the i-body®

Putting on the i-body®

3. ➤ Put on the i-body®.

ⓘ Close the “fitting aid” (hook and loop in the area of the chest and abdomen) in accordance with Fig. 35.

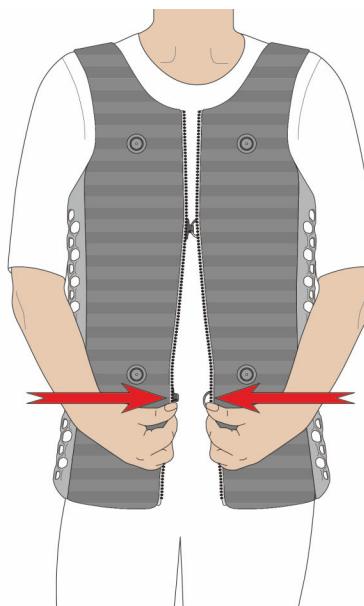


Fig. 35: Wearing the i-body®

4. ➔ Close the i-body® with the zipper (Fig. 36).



Fig. 36: Closing the i-body®

5. ➔ Smoothing out the i-body® (Fig. 37).

i For optimum fit of the i-body® and the electrodes, it can be pulled into place on the fabric in the front and rear. However, never pull on the silicone on the side to smooth out the i-body®.



Fig. 37: Smoothing out the i-body®

Putting on and closing the i-body® straps flex (arms)

Before the training

6. ➤ Moisten 2 i-body® straps flex (Fig. 38).



Fig. 38: i-body® straps flex

7. ➤ Pre-stretch one i-body® straps flex and straps it on the arm.

ⓘ The pushbutton and the loops (Fig. 39/1) on the i-body® straps flex must face outwards.

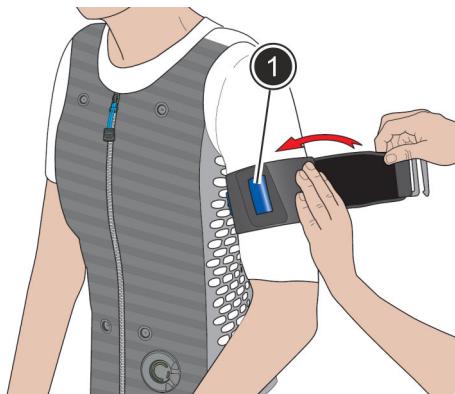


Fig. 39: Putting on the i-body® straps flex

8. ➤ Insert the hook into one of the loops (Fig. 40). Adjust the width so that it is comfortable for the athlete and at the same time provides enough contact pressure.

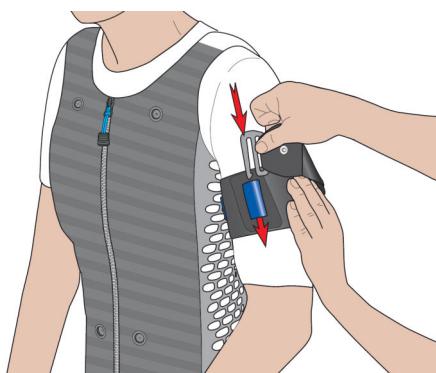


Fig. 40: Closing the i-body® straps flex



Fig. 41: Positioning the i-body® straps flex

9. ➤ Turn the i-body® straps flex so that the pushbutton faces outwards (Fig. 41).
10. ➤ If the i-body® straps flex does not fit properly, select a different loop to make it tighter or wider. If necessary, select a different i-body® straps flex size.
11. ➤ Put the i-body® straps flex on the right arm in the same way as on the left arm.

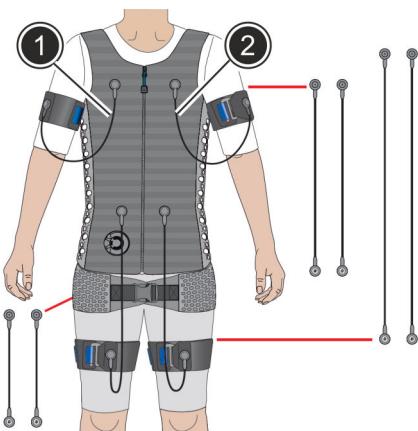


Fig. 42: Connecting the i-body® straps flex

12. ➤ Connect both i-body® straps flex to the i-body® (Fig. 42/1 and 2) with the i-body® cable.

i When connecting the i-body® straps flex, always ensure that the corresponding cables (medium length) are used in accordance with Fig. 42.

Putting on and closing the i-body® straps flex (legs)

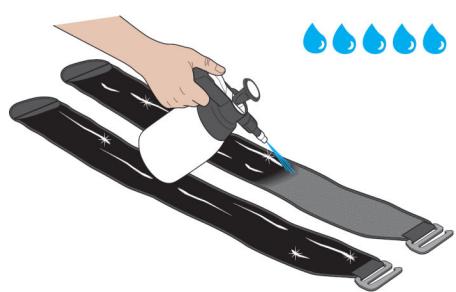


Fig. 43: i-body® straps flex

13. ➤ Moisten 2 more i-body® straps flex (Fig. 43).

Before the training

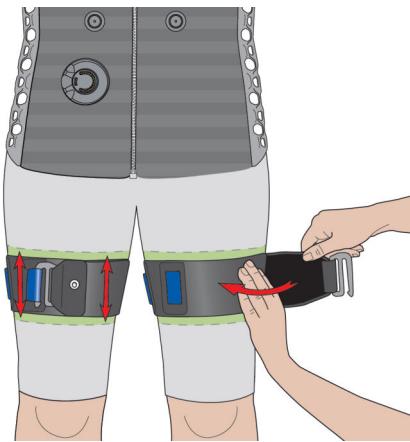


Fig. 44: Putting on the i-body® straps flex

14. Pre-stretch one i-body® straps flex and strap it on the leg (Fig. 44).

i The pushbutton and the loops on the i-body® straps flex must face outwards.

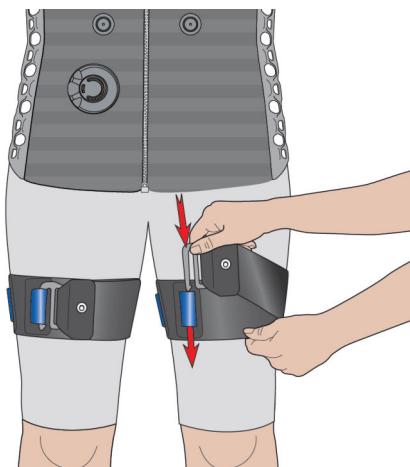


Fig. 45: Closing the i-body® straps flex

15. Insert the hook into one of the loops (Fig. 45). Adjust the width so that it is comfortable for the athlete and at the same time provides enough contact pressure.

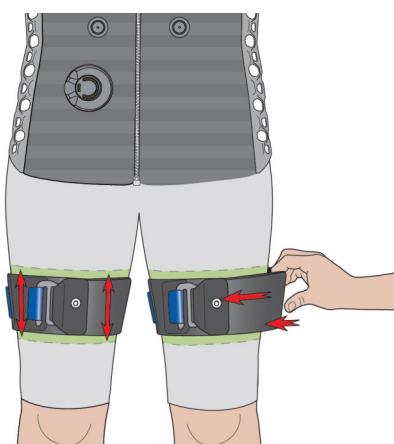


Fig. 46: Positioning the i-body® straps flex

16. Turn the i-body® straps flex so that the pushbutton faces forwards (Fig. 46).

17. If the i-body® straps flex does not fit properly, select a different loop to make it tighter or wider. If necessary, select a different i-body® straps flex size.

18. Put the i-body® straps flex on the right leg in the same way as described for the left leg.

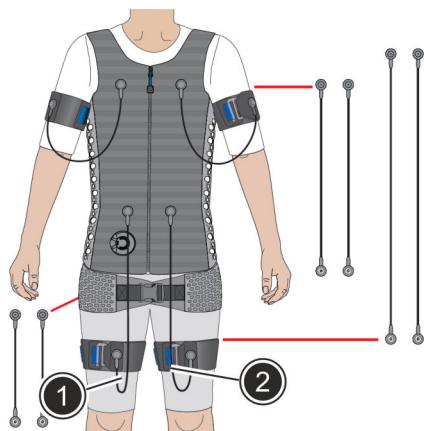


Fig. 47: Connecting the i-body® straps flex

19. ► Connect both i-body® straps flex to the i-body® (Fig. 47/1 and 2) with the i-body® cable.

i When connecting the i-body® straps flex, always ensure that the corresponding cables (longest length) are used in accordance with Fig. 47.

Putting on and connecting the i-body® belt

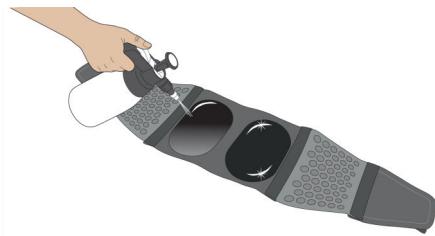


Fig. 48: i-body® belt with buttocks electrodes

20. ► Moisten the electrodes of the i-body® belt (Fig. 48).

i Connect the buttocks electrodes to the cables, then put on the i-body® belt.

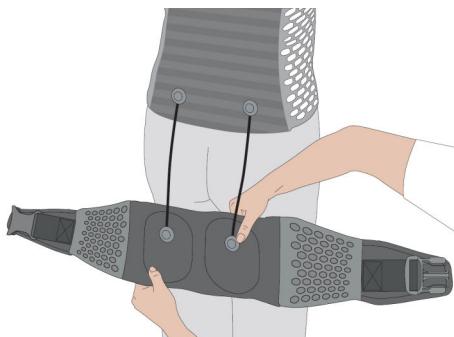
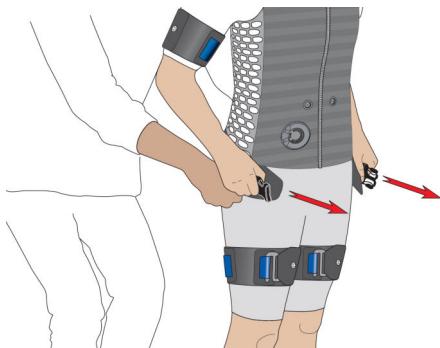


Fig. 49: Connecting the i-body® belt

21. ► Connect both electrodes of the i-body® belt to the i-body® (Fig. 49) with the i-body® cable.

i When connecting the i-body® belt, always ensure that the corresponding cables (shortest length) are used in accordance with Fig. 47.

Before the training



22. Securely fasten the i-body® belt (Fig. 50).

Fig. 50: Fastening the i-body® belt

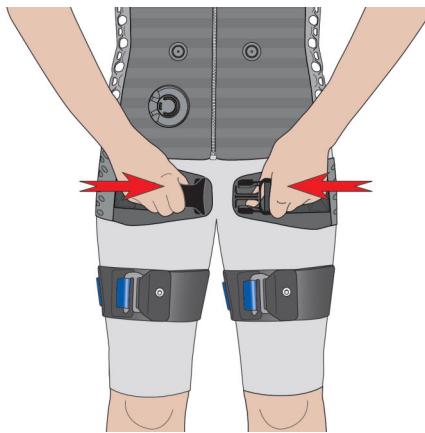


Fig. 51: Securing the i-body® belt

23. Secure the i-body® belt with the release buckle (Fig. 51).

24. **⚠ WARNING!** Risk of injury if connecting while the training program is running!

Make sure that no training program is active.

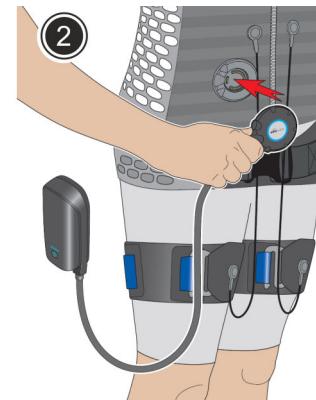
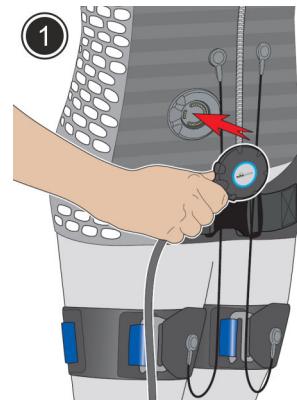


Fig. 52: Connecting

25. Connect the control unit connection cable to magnetic connector of the i-body® (Fig. 52/1).

Or:

Connect the i-body® connect wireless to the magnetic connector of the i-body® (Fig. 52/2). See the “i-body® connect wireless” manual for further information.

⇒ All electrodes are moistened, applied, and connected as instructed. The connection cable is securely connected to the control unit or the i-body® connect wireless. Training can now start.

9 Training with the device

9.1 Safety during training

Electrical voltage

 **DANGER**

Risk of fatal injury from power supply!

- Only use the device in a dry environment.
- Never open the control unit and power supply.
- Always inform Customer Service (☞ “Customer service” on page 15) in the event of problems with the device.
- In the event of damage to the insulation, switch off the power supply immediately and unplug the mains plug.
- Observe the safety rules:
 - Unplug the mains plug.
 - Ensure that nobody reconnects the mains plug to the power supply.
- Never connect the power supply to any voltage other than 100 – 230 V ~ 47 – 63 Hz.
- Only use the genuine power supply unit provided by the manufacturer

If the power supply must be replaced, only use the genuine power supply (GlobTek Medical/ITE Power Supply; Model No.: GTM91099-6024-6.0-T2).

There is an immediate risk of fatal injury due to electrocution in the event of contact with live parts. Damage to the insulation or individual components can be fatal. There is a risk of fatal injury in the event of liquid penetrating the case!

Operation without column

 **WARNING**

Risk of injury from operating the device without column!

- Only use the device if it is connected to the column as described in ☞ “Mounting the control unit on the column” on page 83.

If the device is not secured by the column, it can fall to the ground or be damaged by impacts. This can cause malfunctions injuring the athlete/patient.

Condensation

 **NOTICE**

Risk of damage to the device from condensation!

- Only use the device in a dry environment.
- Never store the device in damp places.
- In the event of location changes, let the device acclimatize.
- In the event of faults, immediately disconnect the device from the power supply and notify Customer Service (☞ “Customer service” on page 15).
- Never switch on the device if condensation is visible.

Condensation can form in the event of changes in humidity and temperature. Moisture in the control unit can result in damage or even total destruction.

Observing the operating temperatures

NOTICE

Risk of damage to the device from not observing the operating temperatures!

- Before the workout, ensure that the device is at the prescribed operating temperature \triangleleft Table 4 “Device information” on page 34.
- Observe the time needed to cool down or warm up the device \triangleleft Table 4 “Device information” on page 34.

9.2 Connecting the device

Connecting the control unit

Personnel: Trainer

1. \rightarrow Spread out a soft cloth on a level and firm base.
2. \rightarrow Set down the control unit upside down on the cloth.
3. \rightarrow Plug the connection cable into the control unit (Fig. 53/1).
4. \rightarrow Connect the power supply to the control unit (Fig. 53/2).
5. \rightarrow *i When connecting the power cable (Fig. 53/2), make sure that the safety plug connector is safely locked in place. To disconnect, the detent mechanism must be released by pulling back the plug grip.*
Connect the power cable to the power supply.
 \Rightarrow The control unit can be mounted on the column.

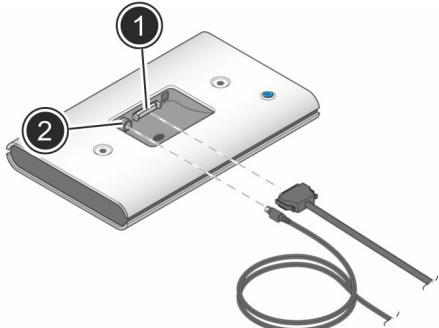
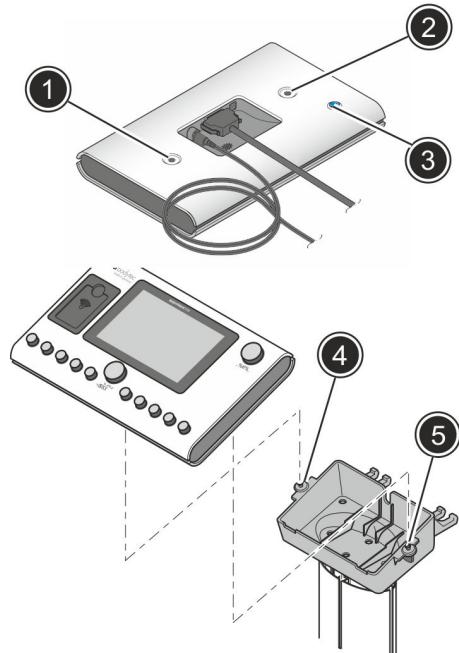


Fig. 53: Connecting the control unit

Mounting the control unit on the column



Personnel: ■ Trainer

1. ► Make sure that the control unit is connected as described in [“Connecting the control unit” on page 82](#).
2. ► Put the control unit onto the mounting screws of the column (Fig. 54/4, 5) using the threaded holes on its underside (Fig. 54/1, 2).
3. ► Tighten both mounting screws (Fig. 54/4, 5) by hand.
4. ► Make sure that the control unit sits firmly on the column.
⇒ The control unit is now firmly connected to the column.
5. ► Plug the mains plug of the power supply into the wall outlet.
6. ► Switch on the device with the on/off switch (Fig. 53/3).

i *It takes approx. 17 seconds after the device has been switched on before it is ready for use.*

7. ► Make sure that the main menu is displayed [“Main menu” on page 54](#).
⇒ You can now connect the electrodes to the device.

Fig. 54: Putting on the control unit

9.3 Individual training settings

Specifying settings



The individual adjustment of the device is required to support correct training techniques, training positions, and training processes. This is why these settings must always be determined by a trainer.



Every person reacts differently to current intensity. Therefore, the current intensity must be regulated individually depending on the respective current sensitivity.

10 Adjusting the height of the grab handle

Using the handle properly

⚠ CAUTION

The grab handle is designed exclusively to provide a safe and secure standing position throughout the duration of the EMS training session (☞ *Chapter 11.5 "Training" on page 92*).

Risk of injury from using the grab handle in an inappropriate manner!

- Use the grab handle only for the purpose of holding on to while performing EMS training described in (☞ *Chapter 11.5 "Training" on page 92*).
- Never use the grab handle as a pull-up bar.
- Do not use the grab handle as a support for performing push-ups or other types of gymnastic exercises.

Using the grab handle for pull-ups or otherwise subjecting it to a large portion of your body weight (e.g. performing push-ups) involves the risk of the grab handle breaking off. Apart from material damage to the device, this may result in injuries from a fall.

Adjusting the handle height

Personnel: Athlete/Patient

The height of the grab handle can be individually adjusted. Proceed as follows to adjust the handle height:

1. ➤ Loosen the two clamping levers (Fig. 55/2), but do not unscrew them all the way. To do so, pull the clamping levers forwards and move them so that the clamping lever can be released counterclockwise.
⇒ The height of the grab handle can be adjusted when the clamping lever is released.
2. ➤ Adjust the height of the grab handle (Fig. 55/1) in the upper third of the guide rail (Fig. 55/3).
3. ➤ Tighten the clamping lever clockwise.

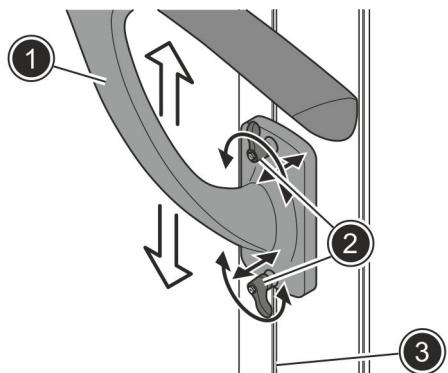


Fig. 55: Adjusting the handle height



The handle must not be loose after tightening and must sit firmly. Check to make sure that the screw connection is tight prior to every training session.

11 Overview of programs/training plans

11.1 Selecting individual training settings

Specifying settings

-  *The individual adjustment of the device is required to support correct training techniques, training positions, and training processes.*
-  *The individual adjustment of the device is required to support correct therapy techniques, therapy positions, and therapy processes.*
-  *Every person reacts differently to the current intensity. Therefore, the current intensity must be regulated individually depending on the respective current sensitivity.*

11.2 Stress standards

Pulse intensity

- Currents in the range of thousandths of an ampere (mA) are used in the EMS.
- The pulse intensity determines the degree to which the nerves and muscle fibers are stimulated.
- The stronger the pulse, the stronger the contraction.
- Every person reacts differently to current intensity. Therefore, the current intensity must be regulated individually depending on the respective current sensitivity.

Pulse duration

The pulse duration specifies the time in seconds (s) or milliseconds (ms) during which a current is output and the muscle is held in the shortened (contracted) condition.

Pulse frequency

The pulse frequency is displayed in Hertz (Hz). The pulse frequency specifies how many individual pulses per second act on the muscles during the contraction phase.

- Each pulse results in a muscle contraction.
- The number of muscle contractions is increased by increasing the pulse frequency.
 - 7 Hz: Improved circulation and metabolic stimulation
 - 85 Hz: Optimum stimulation of striated muscles
 - 100 Hz: Relaxation and pain relief

Pulse width

- The pulse width describes the time duration of a single pulse.
- The longer a single pulse lasts, the deeper it penetrates the tissue and increases the stimulation of the moving parts.

Pulse rise

- The pulse rise specifies in which time a current pulse increases to its maximum value.
- Rectangular pulses are preferred due to the rising slope of the pulse and the resulting effective stimulation.

Overview of programs/training plans

Pause time

- The pause time is the time in seconds (s) or milliseconds (ms) during which no current is flowing.
- The recommendations for an optimum pulse-pause ratio vary between 1:1 and 1:5.
- Guiding principles for general strength training:
 - A good recovery between the individual contractions.
 - High performance for each individual contraction.
- Similar principles for stress and recovery apply as for conventional strength training ( *Chapter 5.3 “Training frequency and regeneration” on page 48*).

11.3 Training programs

Overview of training programs

No.	Program	Duration	Frequency	Pulse duration	Pulse pause	Pulse rise	Pulse width
1	Impulse familiarization	5 min	85 Hz	Continuous	0 s	0 s	350 µs
2	Invigoration - Basic	20 min	85 Hz	4 s	4 s	0.4 s	350 µs
3	Invigoration - Advanced	20 min	85 Hz	4 s	4 s	0 s	350 µs
4	Muscular endurance	20 min	7 Hz	Continuous	0 s	0 s	350 µs
5	Body relax	10 min	100 Hz	1 s	1 s	0 s	150 µs
6	Test training	12 min	85 Hz	4 s	4 s	0.4 s	350 µs



The device uses bipolar pulses and supplies all channels equally during all programs.

Impulse familiarization (1)

Continuously emitted pulse to start off the workout.

Invigoration (2 and 3)

The invigoration programs are used for muscle building and tightening and strengthening the connective tissue and the skin. At the same time, the strengthening programs increase the basal metabolic rate (BMR), thus ensuring that a lot more calories are burnt.

The basic option (2) allows beginners to experience an adequate workout feeling by providing for a more gently rising pulse wave. When selecting the advanced option (3), users will experience an instantaneous pulse rise, resulting in an even stronger contraction of the muscles.

Muscular Endurance (4)

The muscular endurance program is intended to stimulate weight loss among other things. The requirement for this is a combination with the strengthening programs (2 and 3) to increase muscle mass and reduce body fat levels by building muscle and increasing muscular endurance. Activation and tightening of the connective tissue also takes place due to the pulse type used here.

Body Relax (5)

The "Body Relax" relaxation program provides body relaxation, stress reduction, and slightly improved blood circulation of the tissue for removal of metabolic waste products. The muscles function imperceptibly. The feeling the athlete/patient should experience is entirely pleasant.

Test training (6)

The test training program has the identical parameters like the invigoration-basic program. The only difference is the length of the program and is therefore not to be regarded as another output mode. It is ideal for starting EMS training thanks to its shorter length and gentle familiarization process. For EMS beginners in particular, it is important to follow the instructions on training frequency and regeneration [↳ Chapter 5.3 "Training frequency and regeneration" on page 48](#).

11.4 Training plans

Optimized sequences

The training plans provided by the device combine the training programs ([↳ Chapter 11.3 "Training programs" on page 86](#)) with specially designed exercises. The sequences perfectly complement the intended training targets.

Overview of programs/training plans

Training plan 1

Color	Red
Name	Fitness
Program	Invigoration – basic (2)
Time	20 min

Exercise sequence	Exercise	Number of repetitions
0	Basic position	18
1	Dynamic squats	12
2	Dynamic forward lunges, left	12
3	Dynamic forward lunges, right	12
4	Dynamic diagonal crunches, left	12
5	Dynamic diagonal crunches, right	12
6	Dynamic knee compression	12
7	Dynamic body rotation, left	12
8	Dynamic body rotation, right	12
9	Dynamic crunches	12
10	Dynamic forward fold	12
11	Dynamic biceps	12

Overview of programs/training plans

Training plan 2

Color	Green
Name	Invigoration back
Program	Invigoration – basic (2)
Time	20 min

Exercise sequence	Exercise	Number of repetitions
0	Basic position	18
1	Dynamic squats	15
2	Dynamic butterfly reverse diagonal, left	12
3	Dynamic butterfly reverse diagonal, right	12
4	Dynamic body rotation, left	12
5	Dynamic body rotation, right	12
6	Dynamic diagonal crunches, left	12
7	Dynamic diagonal crunches, right	12
8	Dynamic crunches	15
9	Dynamic overstretching	15
10	Dynamic forward fold	15

Overview of programs/training plans

Training plan 3

Color	Blue
Name	Sports performance
Program	Invigoration – advanced (3)
Time	20 min

Exercise sequence	Exercise	Number of repetitions
0	Basic position	18
1	Dynamic squats	15
2	Dynamic forward lunges, left	10
3	Dynamic forward lunges, right	10
4	Dynamic side lunges, left	10
5	Dynamic side lunges, right	10
6	Dynamic knee compression	13
7	Dynamic diagonal crunches, left	10
8	Dynamic diagonal crunches, right	10
9	Dynamic body rotation, left	10
10	Dynamic body rotation, right	10
11	Dynamic crunches	13
12	Dynamic forward fold	13

Overview of programs/training plans

Training plan 4

Color	Orange
Name	Body forming
Program	Invigoration – basic (2)
Time	20 min

Exercise sequence	Exercise	Number of repetitions
0	Basic position	18
1	Dynamic squats	13
2	Dynamic knee compression	13
3	Dynamic forward lunges, left	10
4	Dynamic forward lunges, right	10
5	Dynamic side lunges, left	10
6	Dynamic side lunges, right	10
7	Dynamic diagonal crunches, left	10
8	Dynamic diagonal crunches, right	10
9	Dynamic crunches	13
10	Dynamic body rotation, left	10
11	Dynamic body rotation, right	10
12	Dynamic forward fold	13

Overview of programs/training plans

Training plan 5

Color	Yellow
Name	Test training
Program	Test training (6)
Time	12 min

Exercise sequence	Exercise	Number of repetitions
0	Basic position	10
1	Dynamic butterfly reverse	8
2	Dynamic shoulder rotation	8
3	Static forward lunges, left	8
4	Static forward lunges, right	8
5	Static knee compression	8
6	Dynamic crunches	8
7	Static forward fold	8
8	Static single-leg stand, left	8
9	Static single-leg stand, right	8
10	Static broad squats	8

11.5 Training

Incorrect programming

⚠ WARNING

Risk of injury from incorrect program selection!

- Only perform pre-programming after extensive experience with EMS training.
- Always be careful with pre-programming.
- Always check the program parameters ↗ *Chapter 11 “Overview of programs/training plans” on page 85*.

Selecting an incorrect program can result in injuries.

When to interrupt the training?

Safety first!

Stop a workout immediately if the athlete/patient feels unwell, has muscle cramps, or is dizzy. The athlete/patient shall drink fluids and, if problems persist, see a doctor if necessary.

What to do in emergency situations?

A basic requirement of EMS training is that the athlete/patient is supervised by their trainer. The trainer can therefore intervene appropriately in the event of an emergency. The trainer must act immediately if the athlete/patient loses consciousness:

Personnel: ■ Trainer

1. ➔ Press the multi-function button.
⇒ The current workout stops.
2. ➔ Turn off the device via the on/off switch on its underside (Fig. 56/1).
⇒ The network connection is interrupted.
3. ➔ Disconnect the cable connections from the athlete/patient.
4. ➔ Initiate first aid measures.

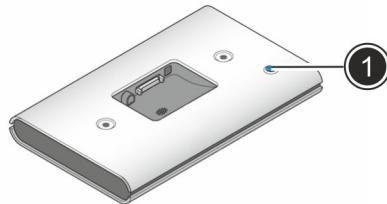


Fig. 56: On/off switch

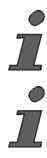
Stop button



Stop button

The multi-function button is not only used for choosing and confirming the programs, but also as a stop button. The training can be stopped at any time with the multi-function button.

Turning up the intensity



Turning up the intensity during the pulse pause is limited to 5 units both on the level controllers and the main controller.

Main controller

If the “Load level” function is enabled, the device is programmed such that the main controller cuts out at 30, 40, and 50 for safety reasons. Regardless of whether or not the “Load level” function is enabled, an additional cut-out is set for all programs and training plans when the device reaches a value of 85. Before the athlete can increase the intensity beyond this value, the main controller must be acknowledged by pressing it once.

Pausing the training session

Personnel: ■ Athlete/Patient
■ Trainer

The training session can be interrupted between individual exercises to pause or discuss the next exercise with the trainer.

1. ➔ Press and briefly hold the main controller (Fig. 3/14).
⇒ The main level jumps to “0” and all LEDs are flashing.
The training time continues running during the pause.
2. ➔ Turn the main controller to end the pause.
⇒ The training session continues as usual.

Overview of programs/training plans

Electrode detection/channel shutoff

- i** Before starting with the workout (countdown) and during the pulse phases, the electrodes connected via the channel outputs are detected.
- i** If a pair of electrodes is not detected before starting with the workout (countdown), the corresponding channel is shown in gray on the display and cannot be reactivated during the training session. If this happens even though something was connected to this channel, remove the transponder card again right away at the start of the workout. This ends the training session. Next, check to make sure that the contacts are properly connected and the electrodes are sufficiently moistened. Correct the problem, if necessary.
- i** If the contact of a channel is interrupted unexpectedly during the workout, the intensity of the channel drops to "0" and cannot be increased again afterwards. The channel is shown in gray on the display. The channel intensity can only be increased again once the electrode is properly reconnected.

Working out

Personnel:

- Athlete/Patient
- Trainer



Fig. 57: Control unit

1. ➤ Select the program by turning the multi-function button (Fig. 57/13).
2. ➤ Read and check the parameters of the selected program by turning the main controller (Fig. 57/14).
3. ➤ Confirm the desired program by pressing the multi-function button (Fig. 57/13).
4. ➤ Adjust the application time if necessary by turning the multi-function button.
5. ➤ Press the multi-function button to start the program.
⇒ The time at the top right in the display starts running.



Fig. 58: Basic position

11.6 Transponder system

Transponder card

⚠ WARNING

Risk of injury if transponder cards are mixed up!

- Always ensure that the correct transponder card is used.
- Always check the program parameters.
- Always start with a low level and then increase it slowly.

Incorrect program parameters can result in the respective settings being too high. This can cause injuries.

The device comes with a transponder card reader to maximize operation convenience. The following personalized data can be saved on the transponder card:

- Program and/or training plan
- Time specification
- Last value of the main controller
- Last value of the individual level controllers



The “Load level” function is not enabled unless the following criteria have been met:

- The “Load level” function on the corresponding customer card must be selected and confirmed with “YES” ↵ Chapter 11.6 “Transponder system” on page 95.
- The “Load level” function must be selected in the device settings and confirmed with “YES”.

The “Load level” function remains disabled until both of these criteria are have been met. The function also remains disabled if only one of the functions is confirmed.

First use of the transponder card

Personnel: ■ Trainer
Materials: ■ Transponder card



1. ➤ Place the new transponder card (Fig. 59) in the main menu on the designated contact surface.
2. ➤ If the transponder card is still unformatted, you are prompted to format the transponder card. Confirm the prompt by selecting “YES” using the multi-function button.
3. ➤ If the transponder card is empty, the following question is displayed: “Empty card. Create customer card?”. Confirm the prompt by selecting “YES” using the multi-function button.
 - ⇒ The system automatically switches to the “Card management” menu.
4. ➤ Use the multi-function button to set the different default parameters in the “Card management” menu and save them to the transponder card using the “Write card” function.
 - ⇒ The transponder card is now formatted with the defined values and ready for use.

Fig. 59: Transponder card

Using the transponder card

Personnel: ■ Athlete/Patient
Materials: ■ Transponder card

1. ➔ Place the transponder card in the main menu on the designated contact surface.
⇒ The system automatically switches to the selection of the workouts stored on the transponder card. The “*Card management*” menu shows the programs/training plans stored on the transponder card and allows you to select them using the multi-function button.
2. ➔ Press the multi-function button again to start the program/training plan (☞ *Chapter 11.5 “Training” on page 92*).
3. ➔ Complete your training or press the multi-function button again to terminate the workout prematurely.

Changing data on the transponder card

Personnel: ■ Trainer
Materials: ■ Transponder card

1. ➔ Remove the transponder card if a card is currently inserted in the device.
2. ➔ Use the multi-function button to select the “*Card management*” menu item.
3. ➔ Place the transponder card on the designated contact surface and change its settings as needed.
4. ➔ Use the multi-function button to select “*Write card*”.
⇒ The changes will be saved on the transponder card.
5. ➔ Remove the card from the designated contact surface.
⇒ The data on the transponder card has been changed.

Setting up the transponder card for training with synchronized start



After the device has been set up as a master or managed device, the user settings for every athlete have to be defined as well. These user settings are linked to the transponder card associated with the athlete. This ensures that athletes will only participate in the training with synchronized start if they wish to do so.

Overview of programs/training plans

Personnel: ■ Trainer
Materials: ■ Transponder card

1. ➤ Remove the transponder card if a card is currently inserted in the device.
2. ➤ Open the “Card management” menu tab.
⇒ The “Card management” menu opens.
3. ➤ Insert the transponder card.
4. ➤ Open the “Synchronized start” menu item.
5. ➤ Set the current “Synchronized start” setting to “YES”.
⇒ The transponder card stores the information that the athlete will participate in the training with synchronized start.
6. ➤ Use the multi-function button to select “Write card”.

i *If the synchronized start settings are correct and a transponder card is placed in position, the synchronized start symbol on the master device lights up blue on the outside and red on the inside, and the managed device lights up green on the outside and blue on the inside.*

Selecting individual language settings for the athletes/patients



Each athlete/patient has the option of selecting an individual language. Once an individual language has been selected, a customized language will automatically be used for all display texts as soon as an athlete/patient logs into the device.

Personnel: ■ Trainer
Materials: ■ Transponder card

1. ➤ Open the “Card management” menu tab.
⇒ The “Card management” menu opens.
2. ➤ Insert the transponder card.
3. ➤ Open the “Language” main menu item.
4. ➤ Select the language by turning the multi-function button.
5. ➤ Confirm the selected language by pressing the multi-function button.
⇒ The transponder card of the athlete/patient is linked to an individual language setting. Display texts will be shown in the individually selected language when the transponder card has been inserted.
6. ➤ Use the multi-function button to select “Write card”.

Selecting training programs from favorites



If favorites have been specified, the athlete/patient can only access the training plans that have been set up as favorites (章 Chapter 7.6 “Adjusting the favorites menu” on page 64).

11.7 Training with synchronized start

Personnel: ■ Trainer

Materials: ■ Transponder card

Prerequisites

- A master device as well as at least one managed device must be set up correctly.
- Synchronized start must be activated on all participating transponder cards.

1. ➔ Place the transponder cards on the devices.
2. ➔ Select a workout on the master device by pressing the multi-function button once.

➔ If “Flexible training” is activated, the corresponding programs or training plans must be selected on the managed devices. If “Flexible training” is not activated, the managed devices immediately switch to the program selected on the master device.

3. ➔ Start the workout by pressing the multi-function button on the master device once.

⇒ The countdown begins on all the participating devices.
The synchronized start was successful.

12 After the training

12.1 Taking off electrodes

Taking off the electrodes



Electrodes must only be detached by the trainer or under their supervision.

Pulling on the cable

NOTICE

Damage due to pulling on the cable!

- Do not pull on the cable to detach the i-body® straps flex and the i-body® belt.
- Always detach the pushbutton connections directly at the closure.

Removing the i-body® straps flex and electrodes by pulling on the cable can cause damage to the cables and the material.

Taking off electrodes

Personnel:

- Athlete/Patient
- Trainer

Detach the electrodes from the cables one after another.

1. ➤ **⚠ WARNING! Risk of injury if detaching the electrodes while the training program is running!**

Make sure that no training program is active. To do so, switch to the main menu (↳ “Main menu” on page 54).

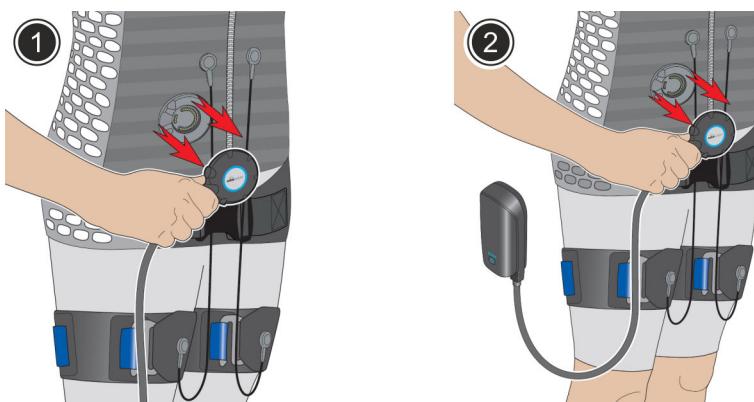


Fig. 60: Detaching the main connection

2. ➤ Disconnect the connection between the control unit and the i-body® (Fig. 60/1).

Or:

Disconnect the connection between the i-body® connect wireless and the i-body® (Fig. 60/2). See the “i-body® connect wireless” manual for further information.

3. ➔ Disconnect all i-body® straps flex on arms and legs from the i-body® connect wireless.
4. ➔ Disconnect and remove the i-body® belt from the i-body® connect wireless.
5. ➔ Open the zipper and the fitting aid and take off the i-body® (Fig. 61).

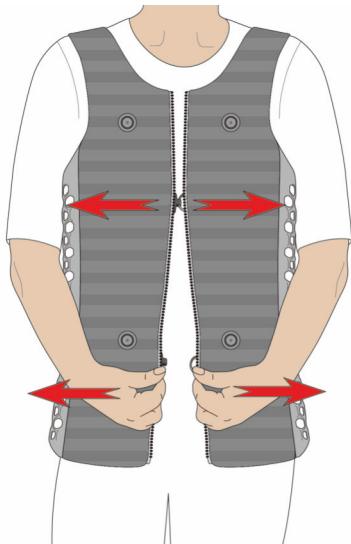


Fig. 61: Taking off the i-body®

12.2 Cleaning and storage

12.2.1 Cleaning the i-body® and the individual electrodes

Improper cleaning of electrodes

NOTICE

Danger of material damage!

- Remove cables.
- Never use the following cleaning agents:
 - Synthetic cleaning agents
 - Solvents
 - Chlorides
 - Polishing agents
 - Washing/polishing agents
 - Aerosol sprays
- Observe the cleaning symbols ↗ *Chapter 2.7.4 “Cleaning symbols” on page 32.*
- Do not dry clean the electrodes.
- Do not exceed a water temperature of 105 °F / 40 °C.
- Do not use any fabric softeners and bleach.
- Do not tumble dry.
- Do not iron or treat with steam.
- Do not spin-dry.
- Do not wring out.

Incorrect cleaning can cause material damage of the i-body® electrode vest and individual electrodes.

Observing the cleaning intervals

Interval	Component	Cleaning type
As necessary or after use.	Accessories: ■ i-body® ■ i-body® belt ■ i-body® straps flex	Disinfection ↳ <i>Chapter 12.2.1 “Cleaning the i-body® and the individual electrodes” on page 101</i>
If visibly dirty, but at least once a month.	Device	Wipe the control unit, surfaces, and grab handles with a moist cloth. ↳ <i>Chapter 12.2.3 “Cleaning the control unit” on page 104</i>
As necessary, but at least once a month.	Accessories: ■ i-body® ■ i-body® belt ■ i-body® straps flex	Cleaning ↳ <i>Chapter 12.2.1 “Cleaning the i-body® and the individual electrodes” on page 101</i>

Cleaning the i-body®, i-body® straps flex, and the i-body® belt



Use ISOPROPANOL 70% for disinfection.

The electrode surfaces have an anti-bacterial layer. If necessary, i-body® straps flex, i-body® belt, i-body®, and additional electrodes can be cleaned. To do so, proceed as follows:

Personnel: ■ Trainer

1. ➤ Wash the i-body® by hand at a maximum water temperature of 105 °F / 40 °C.

■ If a washer with a hand wash setting is available, you can also wash the i-body® in the washer using the supplied laundry net.

2. ➤ Hang the i-body® on a clothes hanger and let it dry in a well-ventilated place.

3. ➤ Wash the i-body® belt by hand at a maximum water temperature of 105 °F / 40 °C.

■ If a washer with a hand wash setting is available, you can also wash the i-body® belt in the washer using the supplied laundry net.

4. ➤ Let the i-body® belt dry in a well-ventilated place.

5. ➤ Wash the i-body® straps flex by hand at a maximum water temperature of 105 °F / 40 °C.

■ If a washer with a hand wash setting is available, you can also wash the i-body® straps flex in the washer using the supplied laundry net.

6. ➔ Let the i-body® straps flex dry in a well-ventilated place.

⇒ The washed electrodes are now clean and can dry. They can be reused once they are dry.

Storing the i-body®, i-body® straps flex and the i-body® belt



All parts except the control unit are subject to wear and must be inspected regularly and replaced if necessary. Only intact equipment guarantees optimal use of the device.

Ambient conditions for storing and safekeeping the accessories
↳ *"Storage of the packages" on page 106.*

- Hang the i-body® on a clothes hanger to dry.
- Always attach the wash protection to the i-body® straps flex for storing and drying.
- Sort the i-body® straps flex and the i-body® belts by size and lay them out open to dry in a well-ventilated place.
- Check the hygienic condition of the i-body®, the i-body® straps flex, and the i-body® belts regularly.
- Clean or replace accessories that are in inadequate hygienic condition.

12.2.2 Cleaning the external cables

Improper cleaning of external cables.

NOTICE

Danger of material damage!

- Disconnect cables from control unit and external electrodes
- Never use a washing machine or dryer for the external cables
- Never use the following cleaning agents:
 - Synthetic cleaning agent
 - Solvents
 - Chlorides
 - Polishing agents
 - Washing/polishing agents
 - Aerosol sprays
- Do not use any fabric softeners and bleach.

Incorrect cleaning can cause material damage of the cables.

Only use a soft, lightly moistened cloth for cleaning the control unit connection cable and the cables for the external electrodes. Never use abrasives or solvents.

Personnel: ■ Trainer

1. ➤ Clean all cables with a soft, slightly moist cloth.
2. ➤ Dry all cables surfaces with a soft, dry cloth.
⇒ All external cables are now dry and clean. This completes the cleaning of the external cables.

12.2.3 Cleaning the control unit

Incorrect cleaning of the control unit

NOTICE

Material damage from incorrect cleaning!

- Unplug the mains plug.
- Only clean with a moist cloth.
- Do not use any abrasives.
- Do not use any solvents.

Incorrect cleaning may cause material damage. The surface can become unsightly and the control unit can even be destroyed.

Cleaning the control unit

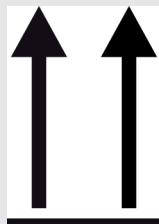
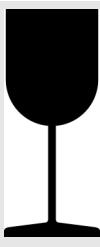
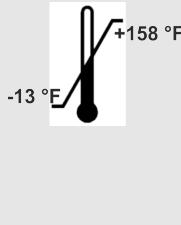
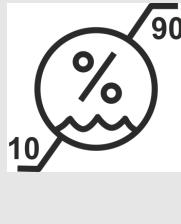
Only use a soft, lightly moistened cloth for cleaning the foil keyboard and the case parts. Never use abrasives or solvents.

Personnel: ■ Trainer

1. ➤ Clean all control unit surfaces with a soft, slightly moist cloth.
2. ➤ Dry all control unit surfaces with a soft, dry cloth.
3. ➤ Wipe the LC display with a soft polishing cloth.
⇒ All control unit surfaces are now dry and clean. This completes the cleaning of the control unit.

13 Packaging and storage

13.1 Symbols on the packaging

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 7000 Fifth Edition 2014-01-15, 0623	Graphical Symbols For Use On Equipment – Registered Symbols	This way up	The arrows of this symbol show which side of the package is up. Packages must be transported and stored with the arrows pointing upward.
	ISO 15223-1 Third Edition 2016-11-01 Clause 5.3.4	Medical Devices – Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied – Part 1: General Requirements	Keep dry	Packages with this symbol are sensitive to moisture. These packages must be protected from moisture (e.g., rain) when being transported and stored.
	ISO 15223-1 Third Edition 2016-11-01 Clause 5.3.1	Medical Devices – Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied – Part 1: General Requirements	Fragile, handle with care	This symbol indicates that the package contains fragile objects. These packages must be transported carefully and protected against shocks. Packages must not be thrown.
	ISO 15223-1 Third Edition 2016-11-01 Clause 5.3.7	Medical Devices – Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied – Part 1: General Requirements	Storage temperature range	This symbol on the packages shows the safe temperature limits a device may be exposed to for storage purposes.
	ISO 15223-1 Third Edition 2016-11-01 Clause 5.3.8	Medical Devices – Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied – Part 1: General Requirements	Storage humidity range	This symbol on the packages shows the safe limits for non-condensing relative humidity within the temperature limits a device may be exposed to for storage purposes  Chapter 13.2 “Transport and storage” on page 106.

13.2 Transport and storage

Transporting packages

The symbols listed in [Chapter 13.1 "Symbols on the packaging" on page 105](#) are attached to the packaging. Observe these symbols when handling packages.

Storage of the packages

Store the packages under the following conditions:

- Do not store outdoors.
- Store in a dry and dust-free location.
- Do not expose to aggressive media.
- Protect against direct sunlight.
- Avoid mechanical shocks.
- Storage temperature:
 - -13 °F – +95 °F (-25 °C – +35 °C)
 - +41 °F – +95 °F (+5 °C – +35 °C) at a relative humidity of up to 90%, non-condensing
 - +41 °F – +158 °F (+5 °C – +70 °C) at a water vapor pressure of up to 50 hPa
- Relative air humidity: max. 90%, non-condensing.
- Permissible air pressure: 10 psi – 15.5 psi.
- If storing for longer than 3 months, check the general condition of all parts and the packaging regularly. If necessary, renew or replace preserving agents.



Under certain circumstances, storage instructions may be affixed to packages that extend beyond the requirements specified here. Comply with these instructions accordingly.



The period of storage of the electrodes must not be longer than 24 months.

13.3 Environmental protection

Incorrect disposal of packaging.

ENVIRONMENT!

Incorrect disposal can be hazardous for the environment.

- Dispose of packaging materials in accordance with environmental regulations.
- Comply with local disposal regulations. If necessary, outsource the disposal to a specialist company.

Packaging materials are valuable raw materials. In many cases, they can be re-used or recycled for other uses. Environmental hazards can result from the incorrect disposal of packaging materials.

Disposal

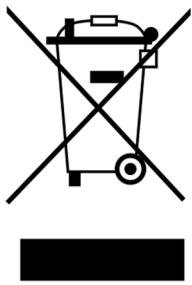
NOTICE

Environmental hazard from incorrect disposal!

- Return electronic scrap and electronic components to the manufacturer.
- Contact customer service in case of questions (↳ “Customer service” on page 15).

Environmental hazards can result from incorrect disposal.

The device must not be disposed of via domestic waste.



Battery disposal

The circuit board inside the control unit houses a CMOS battery which is used for storing the device settings when the device is unplugged. The following type of battery is installed:

- Lithium battery CR2032 (3 V, 220 mAh)

The installed battery must not be disposed of via domestic waste. Return to the manufacturer for proper disposal.

14 Ensuring optimum function

14.1 Maintaining the device

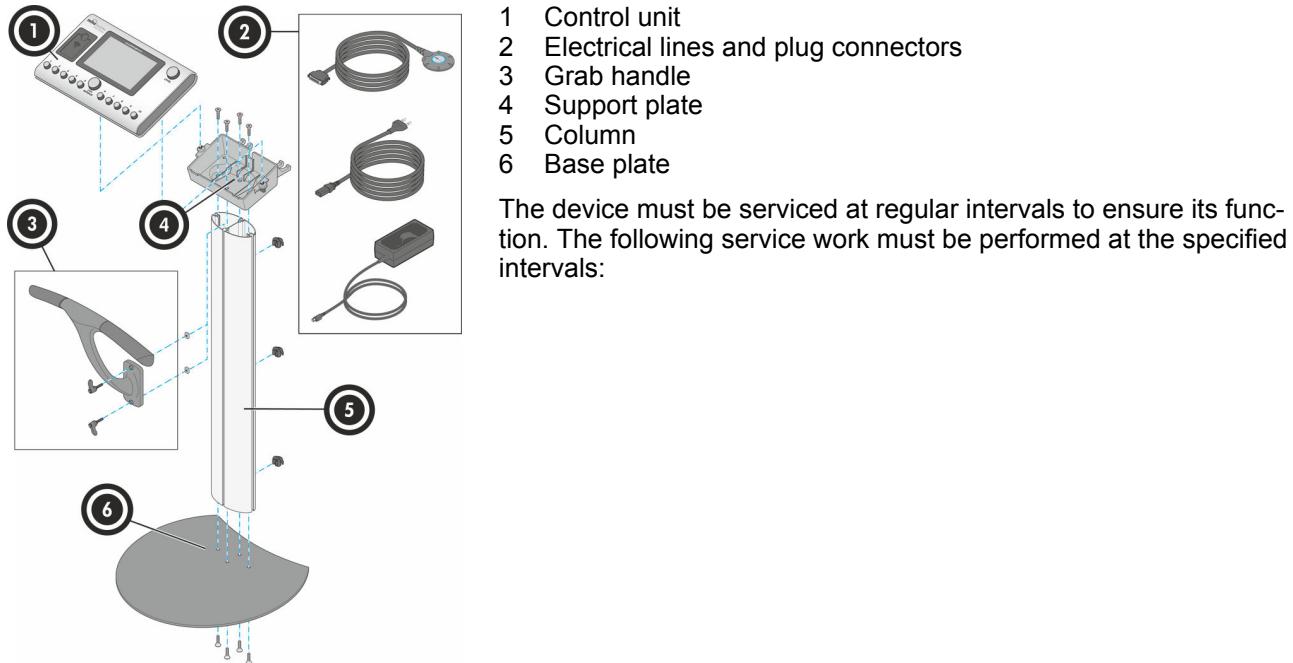


Fig. 62: Performing a visual inspection

When must the device be serviced?	What must be serviced?	Who must service the device?
Before every workout	<p>Check the device for signs of damage:</p> <ul style="list-style-type: none"> ■ Control unit Fig. 62/1) ■ Electrical lines and plug connectors (Fig. 62/2) ■ Support plate (Fig. 62/4) ■ Grab handle (Fig. 62/3), column (Fig. 62/5), and base plate (Fig. 62/6) ■ i-body® (☞ “i-body®” on page 12) <p>Replace damaged parts immediately with genuine replacement parts of the manufacturer ☞ “Customer service” on page 15.</p> <p>Do not use the device if there are signs of damage.</p> <p>Check to make sure the mounting screws of the grab handle are tight (☞ Chapter 10 “Adjusting the height of the grab handle” on page 84).</p>	Trainer
After all workouts	Check to make sure the mounting screws of the grab handle are tight (☞ Chapter 10 “Adjusting the height of the grab handle” on page 84).	Trainer
Monthly	Check to make sure the mounting screws between the base plate (Fig. 62/6) and the column (Fig. 62/5) are tight.	Trainer
Every 24 months	Check the electrical system	Licensed electrician

14.2 Maintaining the Electrodes

To ensure optimum function, it is recommended to replace the electrodes after 12 months of use.

14.3 Handling error messages

If a malfunction was identified that affects the operational readiness, the active training session (voltage generation) is blocked and an error code is displayed in the status line as well as in the LED line. Configurative operation functions remain enabled.



Notify the manufacturer and the relevant authority of the member state in which the operator is located of all major incidents that occur in connection with the device.

Proceed as follows to fix the error:

1. ➔ Remember or write down the error code.
2. ➔ Switch off the device with the on/off switch.
3. ➔ Switch on the device with the on/off switch.
➔ It takes approx. 17 seconds after the device has been switched on before it is ready for use.
4. ➔ Check whether the error is displayed again.
 - If the error is no longer displayed, continue with the workout.
 - If the error is displayed again or another error code is displayed, notify the manufacturer or Customer Service and report the error codes (↳ "Customer service" on page 15).

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