HASOMED

RehaStim2 User Manual

Part 1: Instructions for Use

Read the Instructions for use (IFU) and Operating Instructions (OI) before you use the device

Content

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Subject to modifications

1. Safety notes

1.1 Before you start

Before you start using the device, read the user manual (part I & part II) completely and pay particular attention to the safety measures.

An **inspection** of the device must be carried out by the **HASOMED service staff only**.

You are not allowed to open the device. The repair of the RehaStim2 must be performed only by the manufacturer.

This user manual consists of **instructions for use** (part I) and **operating instructions** (part II). They describe the safe and correct use of RehaStim2. The safety measures contained herein must be strictly observed. Accident prevention regulations that apply in the country where the device is being used, as well as general safety and hygiene regulations, must also be complied with.

Caution !

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.

1.2 Symbols and Labels

The following symbols and labels are used on the RehaStim2. The rating plate stating the exact model name, date of manufacture and power supply details is located on the head of the stimulator.

	General warning sign
	Information sign
	Type BF applied part in accordance with EN 60601-1: RehaStim2 FES Stimulator, electrodes
	Refer to the user manual
	Do not dispose of in the same way as normal domestic waste. Contact HASOMED for further information.

1.3 Warnings

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

	If the documentation is not clear about the use of this device in a particular way or the connection of this device to another device, please contact the manufacturer or an expert to ensure that the user's safety is not put at risk.
	The treatment may only be carried out after a consultation and training by a healthcare professional (e.g. a doctor or a therapist). The treating doctor must be kept informed about changes in the ailment / disability and of any new ailments.
	Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
	Some medical conditions can be aggravated by physical activity. If symptoms of a medical condition occur during or after a therapy session, consult your clinician immediately.
	Do not connect the patient simultaneously to high-frequency surgical equipment, as this may cause burns under the electrodes.
	The therapy can interfere with electrical monitoring devices (e.g. ECG) that are connected to the patient
	The electrical muscle stimulator is only allowed to be used with the electrodes and cables specified by the manufacturer (see part 2.3).

	The long-term effects of chronic electrostimulation are not known.
	Muscle stimulators should not be used while driving, operating machinery or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
	Stimulation should not be applied transcerebrally.
	Improper connection of system components could result in serious injury. The safety of patients, users, third parties and equipment cannot be guaranteed if components of the RehaStim2 are not connected directly to the mains power supply. Therefore, do not connect the RehaStim2 to the mains power supply using an extension cable or a multiple socket outlet.
	Prevent the equipment from immersion in water or other liquids. RehaStim2 is not waterproof. If water or foreign substances enter the interior, immediately turn OFF the stimulator. Continued use of the device may result in fire or electrical shock. Please contact the manufacturer.
	Use of this unit in addition to or in conjunction with other equipment should be avoided as this may result in malfunction. If such use is required, this device and the other devices should be observed to ensure that they function normally.
	Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
	If the patient's blood pressure or heart rate reaches a level that the clinician considers a compromise to safety or if the patient feels faint or nauseated, the session should be stopped immediately and appropriate medical action should be taken.

	Referring to patient safety the power density (amount of energy in the electrode area) of 0,1W/ cm² may not be exceeded. The maximum value of current density may not exceed 2mA/ cm2.
	Plugs and connectors of RehaStim2 electrode cables, external trigger And quick stop are color coded and form-locked. Inverting the connections can damage the stimulator and cause unwanted reactions.
	Stimulation should not be applied over, or in proximity to, cancerous lesions.
	Do not use the stimulator if the loss of function could lead to an accident.
	Do not use devices with high frequency (HF) range or micro and short-wave devices or welding units in immediate vicinity of 1m. This may leads to the instability stimulator output.
	Stimulation should not be done transthoracically, because the insertion of electrical current into the heart can cause cardiac arrhythmia.
	Stimulation should not be applied to neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles can occur and the contractions may be strong enough to close the airway or cause difficulty in breathing. Do not stimulate at the neck or mouth!
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any parts of the RehaStim2, including cables and electrodes specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result among other things.

	Risk of suffocation due to small parts that can be swallowed (e.g. screws).
	Improper use of the cables belonging to the RehaStim2 can lead to unwanted strangulation. Do not wrap the cables around the neck or other parts of the body.
	RehaStim2 stimulator must be kept out of reach of children and young people under 18 years of age. RehaStim2 stimulator must be kept out of reach of pets.
	The use of accessories, converters and cables not specified or provided by the manufacturer of this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and may lead to incorrect operation.

1.4 Precautions

The term precaution is used for a statement of a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage the equipment or other property.

	If the accumulator or battery charger is exchanged without permission, no guarantee for a secure operation is given! The accumulator built into the device must only be exchanged by the HASOMED service staff! The separate battery charger is part of the system and must not be replaced with a different type. It is recommended that the system undergoes a routinely check up and is replaced where required.
	To unlink electrode cables and electrodes it may only be grasped the plug to excerpt. Pulling the cable can damage the plug connection. Also using other electrode types can cause a too strong connection between electrode and electrode cable and can damage or breakaway the cable. HASOMED gives no warranty for obvious usability faults.
	The stimulation parameter setting should be made only after consultation with healthcare professionals. An incorrect setting of incorrect values can cause that expected therapeutic effect does not occur, or that unexpected side effects occur due to incorrect or excessive currents.

	RehaStim2 instructions for use (IFU) do not contain RehaStim2 operation instructions (OI) for FES training modes (RehaStim2, Sequence and Sequence Extended). Attendant user guides must be read prior to the first application!
	IP21 (protection against objects the size of a finger and vertically falling dripping water.) When placed on a horizontal table or attached to a HASOMED GmbH RehaStim2 holder.
	Safety of powered muscle stimulators for use during pregnancy has not been established.
	Caution should be used for patients with suspected or diagnosed heart problems.
	Caution should be used for patients with suspected or diagnosed epilepsy.
	Caution should be used in the presence of the following: a. When there is a tendency to hemorrhage following acute trauma or fracture; b. Following recent surgical procedures when muscle contraction may disrupt the healing process; c. Over the menstruating or pregnant uterus; and d. Over areas of the skin which lack normal sensation
	Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
	Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

	Powered muscle stimulators should be kept out of the reach of children.
	Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
	Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity

1.5 Electromagenetism

1.5.1 Electromagnetic emission

The RehaStim2 is intended for use in the electromagnetic environment specified below. The customer or the user of the RehaStim2 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The RehaStim2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The RehaStim2 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

1.5.2 Electromagnetic immunity

The RehaStim2 is intended for use in the electromagnetic environment specified below. The customer or the user of the RehaStim2 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Proximity fields form RF wireless communi-cations equipment (IEC 61000-4-3)	385 MHz; Pulse Modulation: 18 Hz; 27 V/m 450 MHz, FM + 5 Hz	385 MHz; Pulse Modulation: 18 Hz; 27 V/m 450 MHz, FM + 5 Hz deviation: 1	
	deviation: 1 kHz sine; 28 V/m 710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/ m 810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/ m 1720, 1845, 1970 MHz; Pulse Modulation: 217 Hz; 28 V/m 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m; 5240, 5500, 5785 MHz; Pulse Modulation:217 Hz; 9 V/m	kHz sine; 28 V/m 710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse Modulation: 217 Hz; 28 V/ m 2450 MHz; Pulse Modulation: 217 Hz; 28 V/ m; 5240, 5500, 5785 MHz; Pulse Modulation: 217 Hz; 9 V/m	

Electrical fast transient/ burst IEC 610004-4	± 2 kV for power supply lines ± 1 kV for input/output lines 100kHz	± 2 kV for power supply lines 100kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT for 0.5 cycle at 8 phase angles from 0° to 315° 0 % UT for 1 cycle at 0° 70 % UT for 25/30 cycles at 0° 0 % UT for 250/300 cycles 0°	0 % UT for 0.5 cycle at 8 phase angles from 0° to 315° 0 % UT for 1 cycle at 0° 70 % UT for 25/30 cycles at 0° 0 % UT for 250/300 cycles 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RehaStim2 requires continued operation during power mains interruptions, it is recommended that the RehaStim2 is powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

1.5.3 Guidance and manufacturer's declaration

The RehaStim2 is intended for use in the electromagnetic environment specified below. The customer or the user of the RehaStim2 should assure that it is used in such an environment.

<table>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td rowspan="2">Conducted RF IEC 61000-4-6</td><td rowspan="2">3 V
0,15 MHz - 80 MHz
6 V m in ISM- and Frequency bands between 0,15 MHz and 80 MHz
80 % AM at 1 kHz</td><td rowspan="2">3 V
0,15 MHz - 80 MHz
6 V m in ISM- and Frequency bands between 0,15 MHz and 80 MHz
80 % AM at 1 kHz</td><td>Portable and mobile RF communications equipment should not be used no closer to any part of the RehaStim2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance</td></tr>
<tr><td>$d = 1.2\sqrt{P}$</td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>10 V/m
80 MHz to 2.7 GHz</td><td>10 V/m
80 MHz to 2.7 GHz</td><td>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</td></tr>
</table>

			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

a. Field strengths from fixed transmitters such as base stations for radio (cellular/cordless) telephones, land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters an electromagnetic site survey should be considered. If the measured field strength in the location in which the RehaStim2 is used, exceeds the applicable RF compliance level above, the RehaStim2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RehaStim2.

b. Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

1.5.4 Recommended separation distances

The RehaStim2 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RehaStim2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RehaStim2 as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 3

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 4

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

2 General information

2.1 RehaStim2 at a glance

The RehaStim2 is a portable electrical stimulation device that generates impulses, on up to 8 channels simultaneously, to activate paralyzed muscles via surface electrodes. The RehaStim2 can be used as a portable (contains a battery) or stationary device for training and rehabilitation applications. It can be used on its own or in combination with a motion trainer as RehaStim2. Numerous parameters concerning power and temporal sequence of the impulses can be adjusted individually for each channel. The parameters and operational conditions are presented on a big graphical display making it easy to interact with the device. The operation of the device happens via pressure-sensitive buttons and a control knob.

The stimulator can generally be applied to functional electrical stimulation tasks of all kinds. In addition, the stimulator software and hardware have been especially prepared for a specific rehabilitation system as RehaStim2 using a motion trainer.

The RehaStim2 stimulator is certified according to the international standards EN 60601-1 and EN 60601-2-10.

2.2 Responsible organization

The user shall ensure that:

- Only people with the necessary training are authorized to install, operate, use and maintain the device. The responsible organization shall assign the installation and operation of the device only to people with the appropriate expertise. The responsible organization shall only operate the device if beforehand the manufacturer or an authorized person acting in agreement with the manufacturer has put the device through a functional test at the operating location, and has instructed the person designated by the responsible organization, based on the Instructions for Use and Operating Instructions as well as enclosed safety-relevant information and maintenance instructions, in the proper handling, use and operation of the device as well as the permitted use in combination with other devices, equipment and accessories.

- Every person using the device has read and fully understood the Instructions for Use and Operating Instructions contained in this user manual.

- The user manual shall at all times be kept near the device and made available to the people working with and on the device. However, there is no guarantee that anyone who has read it is qualified to operate, inspect, test, calibrate or troubleshoot the device.

- Any person standing close to device shall fully comply with the safety measures described in this user manual.

- The device is only used when it has no technical faults and is safe to operate. The device must be checked before every use to ensure that it is in good condition.

- Only authorized people can have access to the device. A list of authorized users is kept for the device. Make sure that unauthorized people do not tamper with the device.

- The information in this user manual shall be strictly observed in full and without restriction.

2.3 Recommended Electrode cables and Electrodes

The electrical muscle stimulator is only allowed to be used with the electrodes:

- FES00200 RehaTrode 5 x 9 cm
- FES00201 RehaTrode 7.5 x 13 cm
- FES00202 RehaTrode 4 x 6.4 cm

and cables:

- FES 01191 – Electrode cable left (green 2-Channel)
- FES 01189 – Electrode cable left (green 4-Channel)
- FES 01187 – Electrode cable left (green 4-Channel) Special length

- FES 01190 – Electrode cable right (yellow 2-Channel)
- FES 01188 – Electrode cable right (yellow 4-Channel)
- FES 01186 – Electrode cable right (yellow 4-Channel) Special length

specified by the manufacturer.

3 Correct usage

3.1 Intended use

Purpose, applicable and valid in the United States of America.

- Muscle spasms are relieved
- Prevent or avoid atrophy due to immobilisation
- Increase local blood flow
- Range of motion is increased or maintained

Intended use, applicable and valid in the European Economic Area and the rest of the world (except USA)

- To relieve muscle spasms
- Atrophy due to immobilisation is prevented or avoided
- Increase of local blood circulation
- Range of motion is increased or maintained
- Relearning muscle control
- Relearning of movement sequences
- Building up of muscle cells
- Improvement of muscle coordination
- Stimulation of the cardiovascular system

3.2 Description of Function

The stimulator RehaStim2 is a device for functional electrical stimulation and generates electrical pulses in order to stimulate muscles via surface electrodes on up to 8 channels simultaneously. The stimulator is battery operated, so it can be used network-independent and mobile, as single unit or combined with a motion trainer as RehaStim2. The individual adjustment to the needs of the respective user or his muscles concerning intensity and temporal sequence of pulses is possible by using different parameters. The large user- friendly display allows a clearly structured view of stimulation parameters. The device is operated by pressure sensitive buttons and a control knob.

3.3 Indications

- Stroke
- Spinal cord injuries

- Multiple sclerosis
- Parkinson‘s disease
- Cerebral palsy
- Traumatic brain injury

3.4 Contraindications

- Active implant, e.g. pacemaker
- Pregnancy
- Cancer lesions close to stimulation area
- Swollen, infected or inflamed areas close to stimulation area
- Skin rashes, skin injuries (e.g. open wounds), thrombophlebitis or varicose veins close to stimulation area,
- Unhealed fractures in the body areas to be stimulated Implants such as plates, nails, screws or other metal parts implanted less than 3 months ago under or near the muscle group to be stimulated

3.5 Risk factors

In addition to the above list of contraindications, there are several risk factors that do not have to exclude a patient from training but require increased attention from the person in charge of using the system with respect to the applicable risk factors.

Particular attention should be carried out in patients with:

- Suspected or diagnosed heart problems
- A history of knee or hip dislocation/subluxation
- A history of uncontrolled autonomic dysreflexia
- A history of lower extremity stress fractures
- A history of severe spasticity or spastic reaction to electrical stimulation
- A severe hemorrhage tendency following trauma or fracture
- Recent surgery, when muscle contraction may disrupt the healing process
- Loss of normal skin sensation in the stimulation area
- ANY implanted medical device (please note: cardiac pacemakers are contraindicated)
- Suspected or diagnosed epilepsy

The RehaStim2 stimulation should be stopped immediately as a consequence of any potentially dangerous situation arising from any of the following risk factors:

- **Denervated limb muscles** (lack of contraction).
- **Severe spasticity**: in most cases spasticity is not an exclusion criterion; stretching exercises prior to training with the RehaStim2 combined with individual training adjustments may however be necessary to reduce the likelihood of spasticity occurring.
- **Severe osteoporosis**: in the case of an increased risk of fractures, training with the RehaStim2 must be adapted accordingly (milder forms in patients with spinal cord injuries do not necessarily constitute exclusion criteria).
- **Dysesthetic pain syndrome**: in some cases the pain can become so unpleasant that it is necessary to interrupt the training session.
- **Skin lesions or open wounds** at the electrode application sites.
- **Implantable medical devices**: plates, nails, screws or other metal parts implanted less than 3 months ago underneath or near the group of muscles to be stimulated
- **Epilepsy**: this disorder can constitute an exclusion criterion under certain circumstances, since possible adverse reactions are still unknown.
- **Allergic reaction** to the gel used in the electrodes (ask your medical supplier).

3.6 Electrode application

To ensure **best performance, low impedance and lifespan of the RehaTrode,** please take care of the following aspects:

- The skin must always be clean, dry, and free of any lotions.
- When the electrodes start losing adherence, you can prolong their lifespan by applying one or two drops of water on the gel surface. If this does not work, replace the electrodes.
- Always remove the electrodes by lifting up one of the edges and peeling off. Do not pull on the cable!
- After use, always stick the electrodes back onto the “ON” side of the storage liner.
- Store the electrodes in their original packaging in a dry and cool place.
- Never let the electrodes get wet.
- Using hot or cold packs over a long period of time can diminish the electrodes’ adhesive performance.
- Do not use the same electrodes on different patients – each patient must have his own set.
- Replace the electrodes upon any sign of wear and tear.
- Using bigger electrodes can influence the sensation of current density. **The user has to replace the electrodes:**
- not later than after 30 sessions,
- after a maximum utilization time of 3 months,
- if a problem occurs during the product specific use,
- if skin irritations occur or
- the electrodes exceeded the use-by date indicated on the package.

3.7 Side effects

Skin irritations or chemical burns may occur if there is insufficient contact between the skin and electrodes or if the parameters have been adjusted incorrectly. Therefore when using stimulation for the first time, check the area underneath the electrodes after 2 minutes! If you find that there is bad electronic contact, please use contact gel available from medical suppliers. In known allergies against electrode material, be careful when making your choice. Electrodes must not be placed on excoriations or gashes.

Using the RehaStim2 can cause additional adverse reactions:

- **Allergies to electrodes** must be taken into consideration when choosing them.
- **Skin irritation or lesions** can result from poor electrode contact with the skin or incorrectly set electrical parameters. After the first stimulation session, wait two minutes then check the electrode application sites.
- **Muscle fatigue.**
- **Redness** in the area of stimulation due to increased local blood circulation or warmth of the skin.

These lists do not claim to be exhaustive.

WARNING!

If the documentation is not clear about the use of this device in a particular way or the connection of this device to another device, please contact the manufacturer or an expert to ensure that the user´s safety is not put at risk.

4. Device description

4.1 Technical specifications

RehaStim2	
Size and Weight	
Length	17,0 cm
Width	19,0 cm
Height	6,0 cm
Weight	0,950 kg
Power supply	
Power source(s)	AC and/or storage battery
Method of line current isolation	- Power supply: Cincon Electronics Co., Ltd TR36M090 - Power supply: GlobTek, Inc. GTM96300 - Battery usage:JK Electronics, Inc. PA-IEC-LNB76.R001 - Galvanic isolated to every applied part
Power connection	100-240 VAC, 47-63 Hz
Power input	max. 30 W
Enviroment conditions	
In use	+5 °C to +40 °C; RH 15% bis 93%, not condensating
Transporting/storing	-20°C bis +45°C; RH 0% - 80%, not condensating (recommended to ensure battery life cycle)

Stimulator/Controller	
Display/Interface	LCD color display / keypad, turning knob
Communications	USB / ODU Medi-Snap
Operation system	Special software
Maximum voltage output	154 V
Maximum number of channels	8
Current output per channel	0-130 mA in 65 steps
Waveform	Biphasic rectangle impulses with balanced electric charge
Duration of the stimulation impulses (pulse width)	20-500 µs in steps of 10 µs
Stimulation frequency	10 – 50 Hz in steps of 5 Hz
Load impedance	1000 ohm
Range of atmospheric pressure	700 to 1060 hPa
IP classification	IP21
Protection class	II
Application part	Typ BF
RehaStim2 system building	
RehaStim2 can be connected with selected motion trainer for motion synchronized functional electrical stimulation by receiving external stimulation trigger values Please contact HASOMED for more information regarding the compatibility of RehaStim2. Read the relative user manual / instructions for use.	
8 channel stimulator for functional electrical stimulation (FES). Individual programmable channels, several trigger modes of stimulation sequences.	

Main functions:

- 1-8-channels for FES
- Stimulation of motor nerves

  Biphasic rectangle impulse
- Free programming of all stimulation channels
- Pre-defined stimulation sequences and programs
- Automatic or manual trigger of stimulation sequences
- Patient library for individual stimulation profiles
- Integrated therapy storage
- Import-/Export function of training data
- Quick Stop for immediate interrupting

4.2 Product contents

4.2.1 Components

- 1x **Stimulator**
- 1x **Quick Stop Button**
- 2x **Electrode cables** (left/green & right/yellow)
- 1x **Power supply unit** with country-specific adapter
- 4x Sets of **electrodes** (size: 5x9cm)
- 1x **Operating manual** (consits of Part 1 - Instructions for use and Part 2 - Operating Instructions)

Transport case is not used as packaging and is not included as product content

1 = 4x Sets of **electrodes** (size: 5x9cm)

2 = 1x **USB flash drive**

3 = 1x **Power supply** with country-specific adapter

4 = 1x **Quick Stop**

5 = 1x **RehaMove2**

6 = 2x **Electrode cables** (left/green & right/yelow)

Transport case is not used as packaging and is not included as product content

For RehaStim2 units:

- 1 connection cable to connect MOTOmed ergometers and RehaStim2
- Separately: bracket with screws to fix the stimulator onto the motion trainer

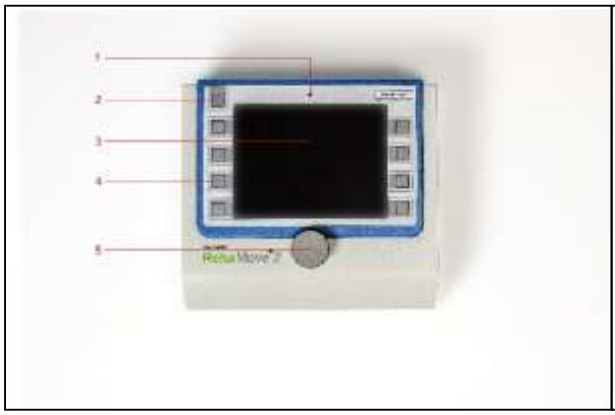
For Sequence Training:

- an external double trigger and/or bag for mobile use of the RehaStim2

For ScienceMode2 or External Trigger Device (ETD):

- 1 USB connection cable to PC

4.2.1.1 RehaStim2



1 = **Device control lamp**

2 = **On/Off button**

3 = **LCD color screen**

4 = **Operating buttons**

5 = **Control knob**

RehaStim2 provides 9 buttons and one control knob for operation. The software menu is displayed on a colored LCD screen.
On the **left side of the stimulator**, the following connections can be found:

- One USB output to connect the stimulator with an external trigger device or PC.
- Two USB ports which can serve to update software via USB flash drive.
- One connection for the power supply unit.

On the **right side of the stimulator**, the following connections can be found:

- The grey connector is used for the Quick Stop Button or for the external double trigger.
- The white connector is used for the connection cable to the MOTOmed.
- The green and the yellow connectors are used for color-coded electrode cables.

The yellow and green connectors can only be used for corresponding color-coded electrode cables.

	1 = **USB out** 2 = **USB in** 3 = **Power supply**
	1 = **Quick stop button or external double trigger** 2 = **Connection cable** for MOTOmed ergometer 3 = **Electrode cables** (left/green & right/yellow)

WARNING!

Plugs and connectors of RehaStim2 electrode cables, external trigger and quick stop are color-coded and form-locked. Inverting the connections can damage the stimulator and cause unwanted reactions.

4.2.1.2 Electrode cables

RehaStim2 provides two (left and right side) main electrode cables with 4 channels per side.

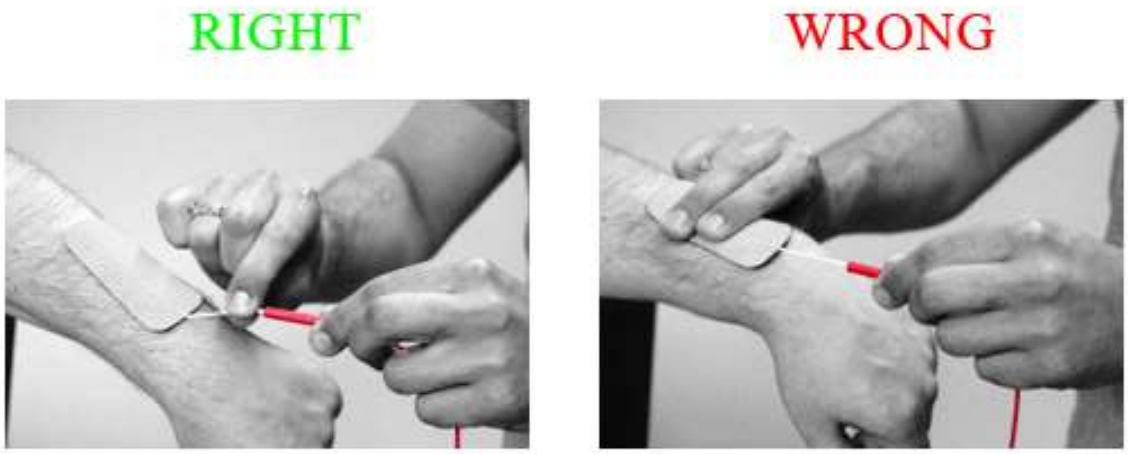
All cables are color-coded to avoid wrong application.

CAUTION!

To unlink electrode cables and electrodes it may only be grasped the plug to excerpt.

Pulling the cable can damage the plug connection. Also using other electrode types can cause a too strong connection between electrode and electrode cable and can damage or breakaway the cable.

HASOMED gives no warranty for obvious usability faults.



Please pay attention to the correct disconnecting procedure for electrodes!

4.2.1.3 Quick Stop button

WARNING!

Excessively physical and sensory stress, spasticity or other interruption of the training.

A defective Quick stop could result in serious injury.

Test every six months that the Quick stop is functioning properly without a patient on the device.

In case that the patient feels unwell or is about to lose consciousness during a training session stop the movement and stimulation immediately by tapping [Stop] on the Screen or pressing the

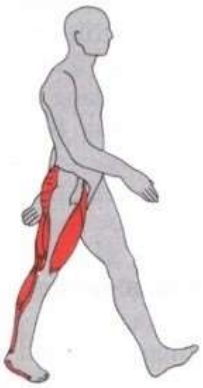
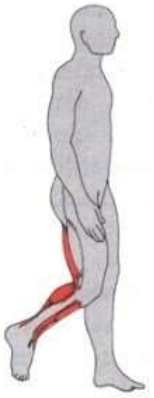
- **Quick Stop button**
  (grey connector RehaStim2/ red connector RehaStim2)

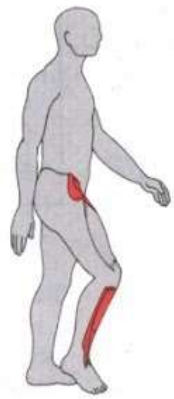
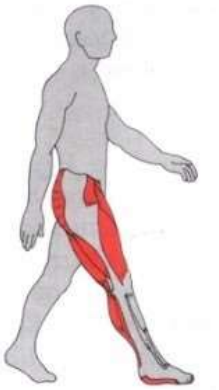
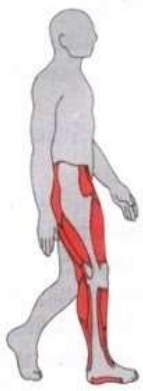
4.2.2 Sequence Extended Training

4.2.2.1 Basic information & trigger values

The RehaStim2 has the ability to receive trigger signals from an external device, represented by angle values. Both devices are connected via serial interface (USB, FTDI). The external device triggers the stimulation timing of RehaStim2, related to angle values of the external device. RehaStim2 provides Sequence Training gait values for gait related FES. The stimulation percentages are related to the gait phases defined by Perry (PERRY, Jacquelin; BURNFIELD, Judith M. Gaitanalysis: normal and pathological function. Second Edition. 2010.). The left leg is used as reference.

All Stimulation parameters must be set at RehaStim2 and are not influenced by the activity of the external device.

Muscles left	**%**	**Muscles right**	**%**	**Graphic**	**Gait event (left leg)**
Tibialis Anterior	5-62				Loading response
		Gastroc-nemius	10-50		Mid stance – pre-swing
		Gluteus	15-70		Mid stance – initial swing
Biceps femoris	30-63				Terminal stance – pre-swing
Quadriceps	40-65				Terminal stance – initial swing

		Tibialis Anterior	55-12		Pre-swing – loading response
Gastrocnemius	60-100				Initial swing – initial contact
Gluteus	65-20				Initial swing – mid stance
		Biceps femoris	80-13		Mid swing – mid stance
		Quadriceps	90-15		Terminal swing – mid stance

The external device has to fire trigger values convenient to RehaStim2 Sequence Gait training. Every gait event must be covered with one related angle value.

1. **Task: Correlate the device movement to gait phases**
2. **Task: Translation of percentages into angles**

A mute signal in any case of inactivity must be delivered to the stimulator to stop electrical stimulation. Every robotic device needs its own assessment coupling with RehaStim2. In case of any doubts or problems, **please contact HASOMED or external device manufacturer!**

5. Maintenance and service instructions

5.1 Cleaning and disinfection

Clean the RehaStim2 regularly for hygienic reasons. Use a dry or slightly moist cloth. If there are persistent stains, you can also soak the cloth in alcohol or a universal (BMF) cleaner. Never use strong detergents, soaps or solvents.

Contact HASOMED if there is any heavy-duty dirt that cannot be removed.

Disinfect the RehaStim2 before every patient treatment session, thus preventing cross-contamination between patients. Wipe the device's surfaces with disinfectant.

Clean and disinfect parts in direct contact with the patient's skin after each training session as described below.

We strongly recommend that you use detergents which feature in the list of disinfectants and disinfectant processes as tested and approved by the Robert Koch Institute.

5.2 Stimulator accumulator

5.2.1 Charging

Use the power supply to recharge the stimulator. Depending on the country/type of the power outlet, different plugs are available. The appropriate plug for your country is delivered by the manufacturer. The battery status is indicated in the upper part of the LCD color screen.

If the battery is charged with less than 20%, the battery status indicator is shown in red. Use the power supply unit to recharge the stimulator if the status indicator is shown in red.

If the battery is fully charged, the status indicator is filled completely and the symbol says "CHARGED". If the stimulator is in the process to be charged, the symbol says "CHARGE". The status of the battery is always shown in %. Shortly before the battery is fully discharged, the status indicator turns red, and then the stimulator switches off. It takes about 180 minutes to recharge the stimulator completely.

It is possible to recharge the stimulator during stimulation without risk for the user.

To recharge and stimulate simultaneously: turn stimulator off, connect power supply unit and turn stimulator on again. If it is necessary to recharge the stimulator during stimulation: pause stimulation, connect power supply unit and continue stimulation.

NOTE! Do not disconnect the power supply unit while stimulating! Only use the power supply unit provided by the manufacturer.

5.2.2 Maintaining

To maintain the stimulator battery, please follow these instructions every three months:

- Completely discharge the stimulator until it turns off automatically,
- Then recharge it fully.

The service life of the battery is 500 charging cycles or 2 years, and depends strongly on the application and storage conditions. Avoid high temperature and follow the storage recommendations.

5.3 Technical safety

The manufacturer recommends for the stimulator a maintenance interval of 2 years in order to guarantee the safety standards for further use. Hence, please send your RehaStim2 on your own account to the manufacturer. HASOMED will examine the adherence to technical parameters and the function of the monitoring elements.

Regular maintenance ensures that technical faults and discrepancies are identified and rectified at an early stage. The risk of a defect is reduced as a result.

The proper disposal of such device (LI-ION battery) involves certain risks. You can avoid these risks by returning the device to HASOMED GmbH. The separate battery charger is part of the system and must not be replaced with a different type. You are recommended that the charger undergoes a regular check-up and is replaced if necessary.

5.4 Service life

The service life for the stimulator is 5 years.

5.5 Declaration of warranty

HASOMED GmbH gives a warranty on the function of the equipment, with the extent according to above description.

- **For 1 year** after distribution in countries **outside of the European Union.**

The warranty voids:

- If damages arise from improper use, e.g. operation of screen with hard mechanical objects like a biro; damages of the device case or connectors, downfall.
- If you connect other electrical devices to the stimulator except devices that have been acknowledged by HASOMED.
- If the official seal for safety requirements was vandalized, or the device was opened by an unauthorized party.

The manufacturer recommends for the stimulator a **maintenance rhythm of 2 years** in order to guarantee the safety standards for further use. The adherence to the technical parameters and the function of the monitoring elements are examined. For this please send back the stimulator to the manufacturer on your own account. HASOMED GmbH offers a security check with optional follow-up warranty of one year, including the exchange of wear parts and the accumulator.

6 Main functions

6.1 Operation

6.1.1 General notes

Read the user manual (part I & II) carefully before using this device!

Before the first session, the user must consult a doctor or physiotherapist to find out how he/she can benefit from the system and how to use the device to set ideal parameters.

It is recommended that the RehaStim2 is used as part of a therapy program prescribed by a doctor or therapist.

Begin the sessions slowly and then increase the level of intensity gradually according to the user's physical capabilities, being particularly careful to avoid over-exertion.

6.1.2 Before you start

Check that the supply voltage of the unit matches with your main current. Only connect the RehaStim2 with the main outlet if the values match. If they do not match or damages to the power supply occur, please contact the manufacturer HASOMED GmbH.

Use only properly earthed power outlets. Use only the original power supply delivered by the manufacturer HASOMED GmbH. If an electric cable has been damaged, stop session immediately and contact the manufacturer.

Connect cables in a way that no person who is walking by could get caught in the cables and these cannot get into the rotating pedals and be damaged.

Mount the unit on flat and non-slippery surface in order to ensure stability. If the device has just been delivered, leave it at room temperature for an hour.

6.1.3 Switch on the stimulator

- RehaStim2 is directly ready for usage after delivery.
- The **user manual** must be read prior to the first operation.
- In general, RehaStim2 is configured in the country-specific language.
- Switch on the stimulator by pressing the **on/off button** (2).
- The device control lamp (1) indicates with a green light that the stimulator is switched on.
- The HASOMED RehaStim2 logo appears on the LCD color screen (3).
- The stimulator starts loading the program and a few seconds later the starting screen appears.
- Please use the operating buttons (4) and the control knob (5) to create and select patient profiles and programs.

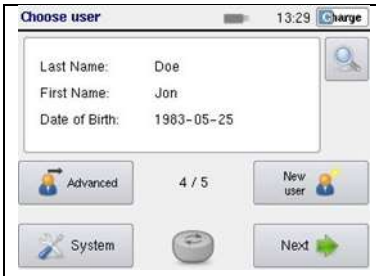
6.1.4 User and user profiles

6.1.4.1 Create a new user

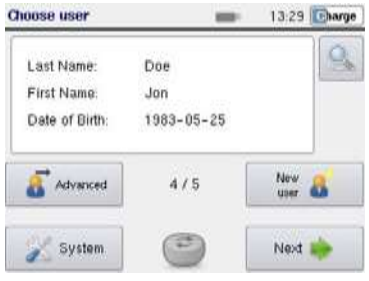
Creating a user is required to operate with RehaStim2 and create stimulation profiles. Privacy protection especially in hospitals or medical facilities require not to use real names or private data.

	Create a new User Select button "New user" in the window "Choose user". The user will be saved and added to the database. Use the turning knob to select still created user.
	New User Enter the family and first name and date of birth. Note: These details are irreversibly entered and cannot be changed again after you pressed the button "Next". To activate the Next button all of these inform actions are required.
	Enter user individual password If the password protection is activated, the client is now requested to enter his/ her individual password. Minimum 2 digits length. Now the creation of the user is finished and you begin to create a new user profile.
	Select program for new user profile Select desired application by pressing the button next to the displayed application button. Transparent buttons are not active and cannot be pressed. For Sequence Extended applications, this screen will be skipped automatically. Use buttons: - **Sequence**: sequence mode with RehaStim2 as stand- alone - **Arm**: FES Arm-Cycling - **Leg**: FES Leg-Cycling - **Letto2** : FES Cycling with bed ergometer

6.1.4.2 Select user or training profile

	<u>Choose user</u> The screen lists all clients of the stimulator database, sorted by their last name. Scroll through the list by turning the knob. Once your database contains more than 3 users, a search icon appears in the upper right corner. Here you can enter the first letter of the client's last name for faster searches. If you connect a USB device, a USB flash drive icon appears in the upper bar. If the desired client is displayed in the white field, confirm with Next. Note: this window is left out if only one single patient uses the device ("one user mode "), as in home setting or if the client uses a RehaStim2 USB.
	<u>Choose profile</u> The white field above the turning knob shows the user`s profile with its parameters. Scroll through the profiles by turning the knob. A small figure above the turning knob display the template of the selected profile with the electrode positioning. Press the knob to maximize the display. This option is not available in "Individual" settings.
	Press the "Next" button when you want to import an old profile or press the "Start training/Start therapy session" button.

6.1.4.3 User Import and User Export

	Connect a commercially available **USB stick** with the RehaStim2. Press the "Advanced" button to export the selected user or import a new user. **On a USB flash drive only data of a patient or one backup can be saved**. Is there already a backup or user profile on the USB flash drive available, you will get asked whether this should be deleted. Make sure that you have this data already stored or they can be overridden

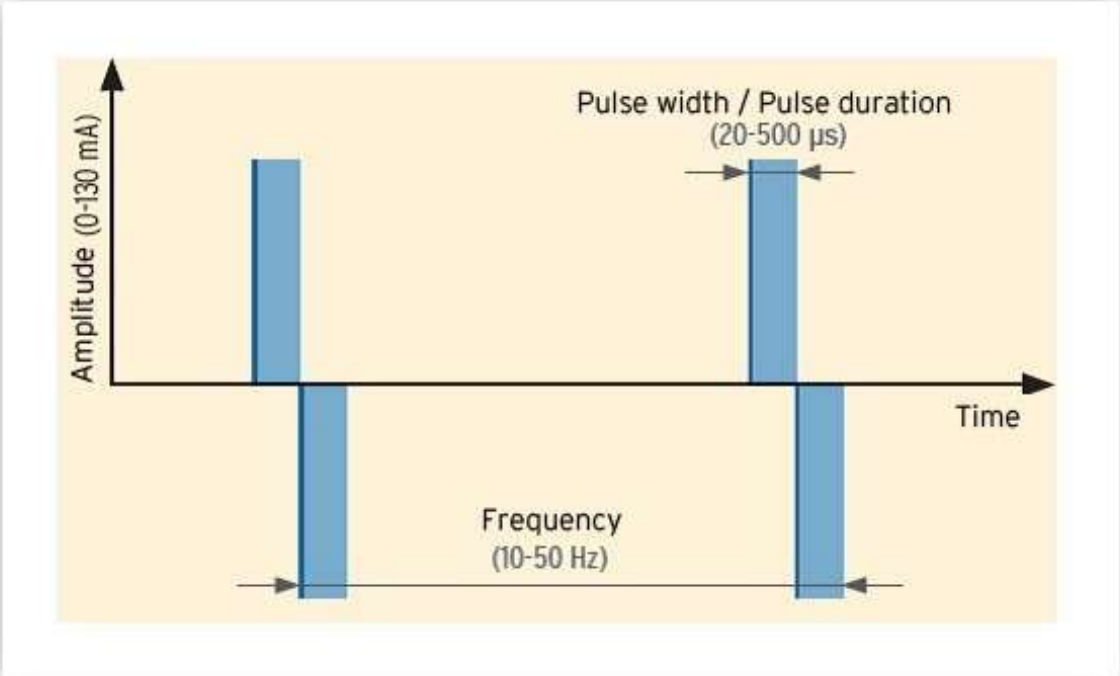
6.1.5 Stimulation parameter

Caution !

The stimulation parameter setting should be made only after consultation with healthcare professionals.

An incorrect setting of incorrect values can cause that expected therapeutic effect does not occur, or that unexpected side effects occur due to incorrect or excessive currents.

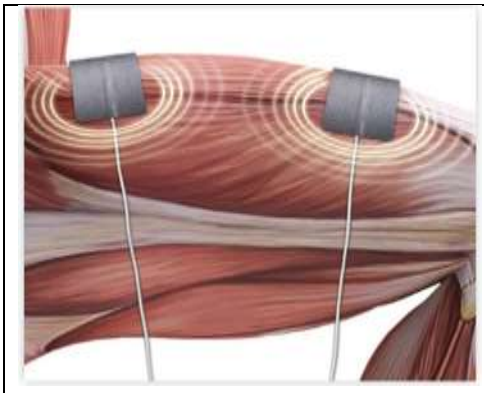
The following chapters will explain how to create user profiles according to the desired FES training. The software guides you intuitively through the menu. During creating a user profile, you are prompted to set workout-specific stimulation parameters. All parameters will be described in detail.



Parameter	Specification	Standard setting	Range
Amplitude (Current)	The amplitude (current value) has a direct impact on the intensity of the contraction. As with the pulse width the amplitude must be sufficient to reach the threshold of excitability of the stimulated sensory or motor nerve. Reduce the amplitude if the stimulation is uncomfortable. Increasing the amplitude generates a faster and stronger muscle fatigue. You can set the amplitude for each channel separately.	0mA	0-130mA
Pulse width	The pulse width has a direct impact on the stress of nerve fibers and thus the strength of contraction. The most effective contractions are generally achieved with a pulse duration of 300-400µs. Together with the amplitude value the pulse width is relevant for reaching the threshold of excitability of the stimulated nerve fibers. Use longer pulse widths for the stimulation of high volume muscles (e.g. M. Quadriceps) You can set the pulse width for each channel separately.	20µs for Sequence training 50-450µs for FES Cycling (depending on the therapy goal)	20-500µs
Frequency	The frequency is defined as the number of pulses per second. It impacts directly on the type of muscle contraction (muscle twitch brief to sustained tetanic contraction) and the strength of contraction. An increase of the frequency increases the generated muscle strength as well as increased muscle fatigue. You can set the frequency for each channel individually (applies only to FES Cycling).	0Hz for Sequence training 1-50Hz for FES Cycling (depending on the therapy goal)	1-50Hz
Ramp	The ramp is defined as a gradual increase of the pulse width with a series of impulses. A ramp of 3 corresponds to 3 impulses with escalating pulse widths up to the 4th impulse, were target pulse width will be reached.	3	5

6.1.6 Positioning of electrodes

FES does not stimulate the muscle directly. Action potentials were generated in the stimulated motor nerve and contract the innervated muscle fibers. The maximum effect is achieved with the stimulation of all (possible) motor nerves.

	Therefore electrodes should be applied **central on the muscle belly**. For maximum **effectiveness** both electrodes should have a distance of (minimum) one electrode size. Do not stimulate muscle with **antagonistic effect** at the same time. Use smaller electrodes if necessary. By the **depolarization** for biphasic stimulus pulses it is not necessary to distinguish in the electrode placement between anode and cathode.

6.2 System menu

In the system menu you can set the system adjustments of RehaStim2. Press the button “System” in the starting screen to change system settings or to update the stimulator with new software versions or licenses. After pressing the "System" button in the starting screen of the RehaStim2, please use the fourth button on the right and the fourth button on the left to navigate between the system menu tabs "Information", "System" and "Interface". Further information for these tabs you will find on the following pages.

6.2.1 Tab "Information"

6.2.2 Tab “System”

Information/Settings:

- **Information window**: Details of software version, serial number and occupied storage.
- **Import licence**: Reading a license to unlock features. Connect the USB flash drive with the RehaStim2. Make sure that it contains the appropriate license file. After pressing the button the license import starts automatically.
- **Firmware update**: Updates RehaStim2 firmware. Connect the USB flash drive with the RehaStim2. Make sure that it contains the appropriate firmware version. After pressing the button the update is carried out automatically and the RehaStim2 will restart.
- **Language**: Changing the system language. Following languages can be chosen: German, English (UK & US), French and Italian. After the change, RehaStim2 will restart automatically.

6.2.2.1 General settings

- **Date**: Change the actual system date. Use the turning knob to change and confirm the setting. After the change the stimulator will automatically perform a restart.
- **Time**: Change the actual system time. Use the turning knob to change and confirm the setting. After the change the stimulator will automatically perform a restart.
- **Advanced**: Please have a look through the following chapters backup/restore of user data, one user mode and password protection.
- **Info**: View copyright details and manufacturer address.
- **Brightness**: Change the light intensity of the screen. Use the turning knob to change and confirm the setting.

6.2.2.2 Backup/Restore of user data

Backup: Export all user data, profiles and history data stored on the stimulator onto a USB flash drive.

Note : All data on y our USB stick stored in the file "rehastim 2" are overwritten! The directory "rehastim 2" is automatically created.

Restore: Import user data, profiles and history data stored on USB flash drive onto the stimulator.

Note : Data on the s tim ula tor a reupdated. User data without any changes remain unchanged!

INFO

On a USB flash drive only data of one patient or one backup can be saved.

In case the backup or the user profile is already saved on the USB flash drive, you will be asked if the file should be deleted. Make sure that you have this data already stored.

6.2.2.3 One-user-mode

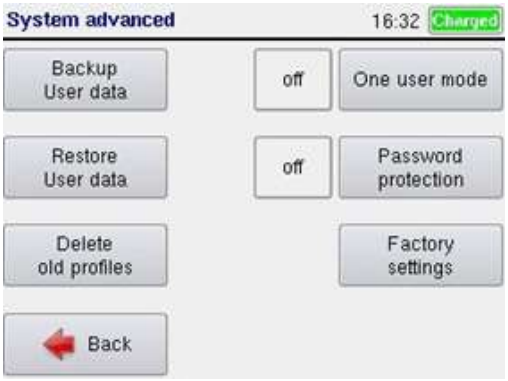
One user mode does not display a user library. **It cannot be activated if more than one user is created**. Activate one user mode for home users. Deactivate it for clinical /multiple users. There is no password protection in one user mode!

6.2.2.4 Password protection

Password protection allows you to protect user data and profiles as well as the assignment of privileges to different users. There are **three levels of password protection:**

- **Master password**

With the master password, the password protection is enabled. Only the master password can deactivate the password protection again. Like all other passwords, the master password must consist of at least 3 characters. The master password has all permissions.



- **Therapist password**

This individual password must be entered when a new user is created. This password entry is only active if the master password has been activated.

The therapist/level 2 password offers:

- Access to own created users and profiles
- Changing of parameters
- Deleting of users and profiles
- Start the 'authorized training'

Authorized training

Start an authorized training by pressing the 'Start' button twice. Within 1.5 seconds you are requested to enter the therapist password. The user is allowed to change the parameters during the therapy session.

Only the therapist is allowed to activate and deactivate the password protection.

Non-authorized training

Start a non-authorized training by pressing the start button. The user is not allowed to change the parameter during this therapy session.

INFO

Note assigned passwords well or write them on. If you reset the RehaStim2 to the factory settings, the password protection will be disabled. All created users and user profiles will be deleted. Therefore, perform regular backups.

6.2.3 Tab "Interface"

The stimulation timing of RehaStim2 can be triggered externally by connected devices (ETD's). Please press button:

"MOTOmed", to have access to MOTOmed/FES 3 interface settings for RehaStim2 **FES Cycling applications:**

- change reference angle arm
- change reference angle leg
- renew the MOTOmed calibration
- do a function test of FES3 protocol

Please note that you will only see the MOTOmed button, when you have a valid license activated on your RehaStim2.

"Sequence Extended", to have access to interface settings for Sequence Extended FES gait training.

- change the external trigger device offset value

Please note that you will only see the Sequence Extended button, when you have a valid license activated on your RehaStim2.

CAUTION!

RehaStim2 instructions for use (IFU) do not consist of the RehaStim2 operation instructions (OI) for FES training modes (RehaStim2 Sequence and Sequence Extended).

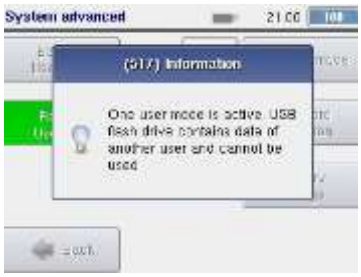
Attendant user guides must be read prior the first application!

6.3 Troubleshooting

If an error occurs, please examine possible causes and follow the instructions in this chapter.

6.3.1 General errors

Error	Cause	Troubleshooting
The stimulator don't react on any operation.	Temporary system crash.	Hold the switch on button longer than 5 seconds and switch on the stimulator again.
	To be able to use the stimulator properly, a software license must be uploaded by the manufacturer. The stimulator does not have a valid software license.	Please contact the manufacturer.
	During the session the electrodes are constantly checked. If the electrodes or electrode cables are not properly connected, this window comes up.	Check whether the electrodes are properly attached and connected. Press "Next".
	Stimulation module error. One of the two stimulation modules does not work correctly. The session has stopped.	Please contact the manufacturer!
	A quick stop can be connected to the RehaStim2 to interrupt the application for safety reasons. This window pops up if the connected quick stop is pressed/locked.	Connect the quick stop with the stimulator and press "Next".

	This note is displayed if the one user mode is active and the connected USB flash drive contains another user profile which is not the active one on the stimulator.	Delete the profile from the USB flash drive and switch off the one user mode in the stimulator system.
	This note is displayed if the user export to USB flash drive was not successful.	Repeat this operation. Please use another USB flash drive. If the error occurs again, contact the manufacturer!
	This note is displayed if no USB flash drive has been found to export user profiles.	Please connect USB flash drive.

6.3.2 Connection errors

Error	Cause	Troubleshooting
	The connection to the MOTOmed is checked before the session starts. This window pops up if - the connection to the MOTOmed does not work or has been disconnected (e.g. the cable has been loosened) - the MOTOmed is switched off or - the communication between stimulator and motion trainer does not work properly.	Check the cable from the RehaStim2 to the motion trainer and make sure that it is connected properly or not damaged. Please reset the MOTOmed on default settings and set up the FES Program as starting program. Please also set up FES3 as serial interface communication protocol. Please start the training again.
	The session cannot start when the MOTOmed does not show the start screen.	Please switch to the start screen of the MOTOmed.
	During the session the connection to MOTOmed or other external trigger devices are constantly checked. This window is displayed if, the connection does not exist or is interrupted (e.g. loose cable).	Check correct RehaStim2 connection and cable to connected devices. Check the correct interface of the connected device (FES3 for MOTOmed, Sequence extended for others). Please contact the manufacturer for instructions.

	The stimulation stops during the session if a spasm is detected or the speed of the external trigger device trainer is too low. RehaStim2 needs a minimum speed of 10 rpm/6 sec double step forward movement in order to activate the stimulation. Below this speed the stimulation is deactivated for safety.	If spasticity occurs, wait until the movement therapy device has calmed the spasticity. When the movement therapy machine starts normal exercise, let the movement go in a forward direction at minimum 10 rpm or 6 sec double step duration.
	This note is displayed if the stop button was pressed during FES3 arm or leg training. MOTOmed and stimulation stop. The training ends.	Restart the training.

6.4 Complaint form

To ensure a highest level of usability and user safety all products must be monitored since the first placing to market. Appearing complaints must be reported immediately and documented and evaluated by HASOMED. Complete specifications of the customer, device details and the complaint are necessary. Therefore please send over requested information plus serial number and software version of the device to export@hasomed.de.