

HASOMED[®]

Hardware and Software for Medicine

Operation Manual RehaStim 2, RehaMove 2

Version 2.4 / 2016-10 Hasomed GmbH

User Guide



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1 General Description

1.1 Declaration of Conformity

QMS-Formblatt



EG-KONFORMITÄTSERKLÄRUNG

entsprechend Anhang II der Richtlinie 93/42/EWG über Medizinprodukte
sowie Anhang VI der Richtlinie 2011/65/EU (RoHS 2)

EC DECLARATION OF CONFORMITY

according to annex II of the Council Directive 93/42/EEC concerning medical devices
and annex VI of the directive 2011/65/EU (RoHS 2)

Wir: HASOMED Hard- und Software für Medizin Gesellschaft mbH Paul – Ecke – Straße 1 39114 Magdeburg	We: HASOMED Hard- and Software for Medicine limited liability company Paul – Ecke – Straße 1 39114 Magdeburg / Germany
erklären in alleiniger Verantwortung, dass das Produkt/die Produkte: RehaStim 2 der Klasse IIa (Regel 9 nach MDD 93/42/EWG, Anh. IX)	declare under our sole responsibility that the product/s: RehaStim 2 of class IIa (rule 9 of MDD 93/42/EWG, annex IX)
den einschlägigen Bestimmungen der Richtlinie 93/42/EWG über Medizinprodukte und der Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten entspricht.	meets the provisions of the Council Directive 93/42/EEC concerning medical devices and the Directive 2011/65/EU on the restriction of hazardous substances in electrical and electronic equipment which apply to them.
Diese Konformitätserklärung ist gültig bis zur Ausstellung einer revidierten Konformitätserklärung nach Änderung des Produkts.	This declaration of conformity is valid until a revised declaration of conformity after product changes is issued.
 0482 Die Zertifizierung bezüglich Medizinprodukterichtlinie 93/42/EWG wird überwacht von: MEDCERT GmbH Pilatuspool 2 20355 Hamburg	 0482 Certification regarding medical device directive 93/42/EEC is observed by: MEDCERT GmbH Pilatuspool 2 D - 20355 Hamburg / Germany

Magdeburg, den 2017-04-20


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1.2 Description of the RehaStim2

The RehaStim2 is a portable electrical stimulation device that generates impulses, on up to 8 channels simultaneously, to activate paralysed 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 **RehaMove2**. 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 rotary switch.

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 **RehaMove2** using a motion trainer.

The RehaStim2 stimulator is certified according to the international standards EN 60601-1 and EN 60601-2-10 for medical technical devices and systems.

1.3 Warnings and Precautions

Executive Safety Summary

I. CONTRAINDICATION

1. Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

II. WARNINGS

1. The long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. Stimulation should 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 in breathing.
4. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied transcerebrally.
6. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
7. Stimulation should not be applied over, or in proximity to, cancerous lesions.

III. Further Warnings

1. Do not use when user is simultaneously connected to a highfrequency surgical unit, because this may lead to burns underneath the electrodes.
2. Do not use near (within 1 m) devices with high frequency (HF) range or micro- and short-wave devices or welding units.
3. Do not exceed 0,1 watts/cm². Current densities at the electrodes exceeding 2 mA/cm² may require the special attention of the OPERATOR.
4. Adjust the stimulator according to the user manual or/and the instructions of your clinician.
5. No modification of this equipment is allowed. Unexpected hazards (for instance electrical shock, unintended misuse, mechanical hazards) can result from unauthorized modification.

IV. PRECAUTIONS

1. Safety of powered muscle stimulators for use during pregnancy has not been established.
2. Caution should be used for patients with suspected or diagnosed heart problems.
3. Caution should be used for patients with suspected or diagnosed epilepsy.
4. 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.
5. 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.
6. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
7. Powered muscle stimulators should be kept out of the reach of children.
8. Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
9. [FOR PORTABLE DEVICES ONLY]: Portable powered 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.

V. ADVERSE REACTIONS

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

Read the manual carefully before using this device! The RehaStim2 is classified as a medical device type IIa.

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 by the manufacturer only!

CAUTION! The accumulator integrated in the device must only be replaced by the HASOMED service staff! If the accumulator is replaced without permission, no guarantee for a secure operation is given!

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.



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.

In the USA, Federal Law restricts the device to sale by, or on the order of, a physician or other practitioner licensed to use the device.

If the device is used in combination with the movement therapy machine as part of the RehaMove2 system, only the provided connection parts (cables, electrodes etc.) must be used.

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. If the patient begins to feel light-headed or bad, stop the treatment immediately.

- 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.
- If directed by the clinician, the client's blood pressure and heart rate should be monitored during the therapy session.
- 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. Children should only use this device under adult supervision. Never leave the RehaMove2 unattended when children are present.
The device presents a hazard to infants and small children, even if it is turned off. To prevent possible strangulation (e.g. with the cables) or suffocation (e.g. with small parts), ensure that children always stay under adult supervision when moving near the device.
- The arm crank should not be used unless continuous assistance is available as while using this device it may not be possible for the client to stop the therapy while their arm(s) / hand (s) are secured.



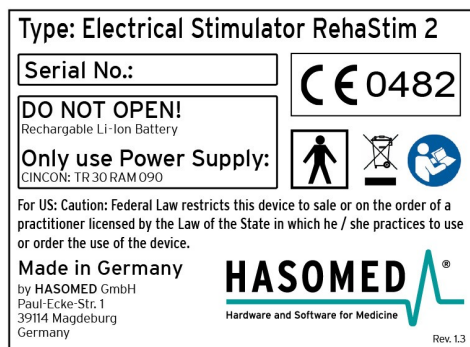
Safety instructions for electrode use:

Skin must always be clean, dry and free from lotion. When Electrodes begin losing adhesion, gently rubbing of one or two drops of water onto gel surface (Re-hydrate Gel) may extend usage. If not, replace with new electrodes.

Do not apply to open skin! Should a skin rash or a skin burn occur, discontinue use immediately and contact your clinician.

- Do not stimulate while driving or operating machinery!
- For your safety and comfort, turn off the stimulator before you attempt to remove electrodes from your skin.
- Always lift electrodes from the edge not the lead wire!
- Always replace electrodes to "ON" side of the storage liner.
- Always store the electrodes in the original package in a cool place.
- Never submerge electrodes.
- Using Hot or Cold packs for long periods of time can cause adhesive separation.
- Only one user per electrode (Single Patient Use).
- Replace electrodes when they show signs of wear or tear.

Following information can be found on the back of the stimulator:



CE 0482 - CE-certified



- Applied part: type BF



- Not to be disposed with domestic waste!



- Note operation manual!

1.4 Indications and Contra Indications

Functional electrical stimulation (FES) is an established method of electrotherapy and widely applied for impaired extremities due to diseases or accidents.

However, the RehaStim2 could also be used for therapeutic electrical stimulation. The RehaMove2 is a specialised system that has integrated the RehaStim2 specifically for therapy and exercise training.

Indications of use

Clients' interventions can have a variety of goal such as:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Maintaining or increasing of range of motion

During the course of the therapy, a physician or therapist must be consulted for improving exercising results, to set therapy goals and determine the further course of action. The physician or therapist supervises the course of therapy and adjusts parameters if necessary. Such close cooperation should be considered as precondition in order to achieve the best benefit for the client compared to conventional treatment methods.

The treatment should be carried out after an introduction by a doctor or therapist. The treating doctor must be kept informed about changes in the ailment/disability and of any new ailment.

Absolute contra indications

These contra indications absolutely exclude clients from applying the RehaStim2 or RehaMove2:

- Cardiac pacemakers: Functional electrical stimulation must not be used in people with cardiac pacemakers
- Pregnancy: Pregnant women must be excluded from stimulation treatment since possible adverse effects are unknown and have not been scientifically investigated yet.
- Fractures: Unhealed fractures in the following areas restrict the patient from using the RehaMove2 until the fracture is stable:
 - in the lower extremities, if you want to do leg training with the RehaMove2.
 - in the upper extremities, shoulder girdle or upper ribs, if you want to do arm training.
- Additional counter indications for Arm training:
 - inability to keep humeral head into glenohumeral joint utilizing electrically evoked contraction of the supraspinatus
 - grade 3 tear of either rotator cuff.

Relative contra indications

- Denervated muscles: The RehaMove can not be used to evoke contractions in denervated muscles in extremities.
- Severe Spasticity: In most cases, spasticity will not disqualify an individual from using the RehaMove. A stretching program may be necessary prior to therapy along with modified therapy settings to reduce the likelihood of spasms occurring.
- Limited Range of Motion/ Heterotopic Ossification:
 - for leg training: clients can be placed in their chair to accommodate for minor limitations in joint ranges. However, a minimum of 100 degrees of hip and knee flexion is recommended.
 - for arm training: clients can be placed in their chair to accommodate for minor limitations in joint ranges: However, a minimum of 90 degrees of shoulder flexion and 100 degrees of elbow flexion is recommended.
- Severe Osteoporosis: Mild to moderate osteoporosis is prevalent in the majority of the SCI population and in itself does not represent an immediate exclusion from the therapy. If the osteoporosis has progressed so that there is an increased risk of fractures, the therapy should be adjusted to account for the degree of osteoporosis.
- Dysaesthetic Pain Syndrome: In some cases, the pain syndrome may worsen during the stimulation and the therapy maybe too uncomfortable to continue.
- Pressure sores or open wounds in the area of treatment.
- Implants: Recently (< 3month) implanted plates, pins, screws and other hardware underneath or near the muscle groups which are to be stimulated.

- **Epilepsy:** Clients who suffer from epilepsy may have to be excluded from stimulation treatment since possible adverse effects are unknown and have not been scientifically investigated yet.
- **Additional relative contra indications for Arm training:**
 - Implanted stimulators such as vagus nerve, phrenic, cardiac, cochlear, diaphragmatic stimulators.
 - Malignancy.
- **Allergies to electrode gel:** If the client is aware to have an allergy to electrode gel, please consult your medical supplier for alternatives.

1.5 User Safety

Read the manual carefully before using this device!

The treatment may only be carried out after a consultation with a doctor or therapist. The treating doctor must be kept informed about changes in the ailment/ disability and of any new ailments.

Caution should be exercised during the treatment of individuals with the following preconditions:

- Patients with ANY implanted medical device
- Patients with suspected or diagnosed heart problems
- Patients with suspected or diagnosed epilepsy
- Patients with history of hip or knee dislocation/subluxation

Caution should be used under the following conditions:

- a. History of uncontrolled autonomic dysreflexia;
 - b. History of lower limb stress fractures;
 - c. History of severe spasticity or spastic response to application of electrical stimulation;
 - d. When there is a tendency to severe hemorrhage following acute trauma or fracture;
- and
- e. Following recent surgical procedures when muscle contraction may disrupt the healing process.

Additional Cautions for Upper Extremity Ergometry:

- A history of upper limb stress fractures.
- Uncontrolled hypertension



Clients with an implanted electrical device (e.g. cardiac pacemaker) must not be treated with electrical stimulation. In necessary cases, a doctor or a specialized medical engineer must be consulted in advance and carry out a risk analysis before making any decision.

Do not use when user is simultaneously connected to a high-frequency surgical unit, because this may lead to burns underneath the electrodes.

Do not use near (within 1.5m) devices with high frequency (HF) range or micro- and

short-wave devices or welding units.

Do not use near (<1m) working mobile phones or radio/ wireless transmitting sets.

For the correct operation, electrostatic loadings are to be avoided.

The treatment can influence electrical monitoring devices (e.g. ECG) if they are simultaneously connected to the client.

If the stimulator is to be used near the rib cage, consider and analyse the risk of ventricular fibrillation.

Electrodes must not be placed on excoriations or gashes.

Users should always be accompanied by an assistant.

Safety of powered muscle stimulators for use during pregnancy has not been established.

Caution in clients with suspected or diagnosed heart problems.

Caution in clients with with suspected or diagnosed epilepsy.

Caution should be used under the following conditions:

- a. When there is a tendency to severe hemorrhage following acute trauma or fracture
- b. Following recent surgical procedures when muscle contraction may disrupt the healing process
- c. When using above the uterus during menstruation or pregnancy
- d. When using in skin areas lacking sensitivity

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 instructions of the prescribing practitioner. Powered muscle stimulators should be kept out of the reach of children.

Electrical muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.

Portable 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.



All accessories which are not provided by HASOMED GmbH and which the user wants to connect to the interfaces of the unit, must verifiably meet the according EN specifications (e.g. EN 60601-1 for electrical medical devices and EN 6950 for data processing devices). Furthermore, all combinations must meet the system standards of EN 60601-1 chapter 16. For queries please contact the technical support at HASOMED GmbH (manufacturer).

Do not put electrode cables into AC mains power outlets.

Only use the provided battery charger (TR30M090) and plug to charge this device.

Safety and effectiveness of the treatment depend on the appropriate use of the device. Inappropriate use of this device is dangerous due to electrical currents.

Protect the device from water! If the device falls into water, do not use it any longer and contact the manufacturer for further instructions.

Store the device in the original packaging to protect it from damage and dirt.

Do not pass the device on to other people!

1.6 Adverse Reactions

Skin irritations or chemical burns may occur if there is insufficient contact between 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.

1.7 Default Values and Adjustment Ranges of Stimulation Parameters

1.7.1 Technical Specifications

	RehaStim2 (stand alone device)
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 Voltage Isolation	- TR 30M090 according to EN 60601-1 or battery powered by BMZ 18650V, Li-Ion, C=1600 mAh, 7.4 V - galvanically isolated to every applied part
Power connection	100-240 VAC 47-63 Hz
Power input	max. 30 W
Environmental conditions:	
· In use · Relative humidity	+5 °C to +40 °C RH 15% to 93%, non condensing
· Transporting/ storing · Relative humidity	-20 °C to +45 °C RH 0 to 80% , non condensing (recommended to assure life-time of battery)
Stimulator / Controller	
Display / Interface	LCD- 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 type	Biphasic rectangular impulses with balanced electric charge
Duration of the stimulation impulses (pulse width)	20 - 500 μ s in steps of 10 μ s
Stimulation frequency	10 - 50 Hz in steps of 5 Hz
Load impedance range	0 to 1000 ohm
Atmospheric pressure range for all conditions	700 to 1060 hPa
IP Code	IPX0
Protection class	II
Application part	Type BF
Medical device according to EU guidelines MDD 93/42/EWG	Ila
	RehaMove2 (consisting of RehaStim2 and motorized motion trainer)
	RehaStim2
	see above
IP Code	IPX0
	Motorized motion trainer MOTomed viva2
Size and Weight:	
Length	60 cm
Width	56 cm
Height	100cm
Shipping weight	leg trainer 31 kg leg and arm trainer 38 kg
Power Supply:	
Power connection	115V~, 50/60Hz 230V~, 50/60Hz
Power input	130VA 130VA
Protection class	II (since May 2012)
Application part	type BF (since May 2012)
Medical device according to EU guidelines MDD 93/42/EWG	Ila
Environmental conditions:	
· In use · Relative humidity	+5 °C to +40 °C RH 15% to 93%, non condensing
· Transporting/ storing · Relative humidity	-25 °C to +70 °C RH 70% to 93%, non condensing

	RehaMove2 for children (consisting of RehaStim2 and motorized motion trainer)
	RehaStim2
	see above
IP Code	IPX0
	Motorized motion trainer MOTomed gracile 12
Size and Weight:	
Length	45 cm
Width	63-85 cm
Height	76-100 cm
Shipping weight	leg trainer 24 kg leg and arm trainer 32 kg
Power Supply:	
Power connection	115V~, 50/60Hz 230V~, 50/60Hz
Power input	130VA 130VA
Protection class	II (since May 2012)
Application part	type BF (since May 2012)
Medical device according to EU guidelines MDD 93/42/EWG	Ila
Environmental conditions:	
· In use · Relative humidity	+5 °C to +40 °C RH 15% to 93%, non condensing
· Transporting/ storing · Relative humidity	-25 °C to +70 °C RH 70% to 93%, non condensing

1.7.2 Default Values

(Default value = Default settings)

Parameter	Minimum	Maximum	Increment	Default value
Rpm	15 rpm	60 rpm	5 rpm	15 rpm
Pulse width	20 μ s	500 μ s	10 μ s	20 μ s
Zero angle	0°	360°	5°	90°
Ramp	3 Pulses	5 Pulses	1 Pulse	3 Pulses
Resistance Level	0	20	1	2

Default settings for angles and muscles

- for RehaMove2 leg training:

Start and stop angle	Muscle	Short cut
40° to 180°	M. quadriceps fem. - right	Qu_R
220° to 360°	M. biceps fem. (hamstrings) - right	BF_R
120° to 210°	M. gluteus maximus - right	Gl_R
330° to 90°	M. tibialis anterior - right	TA_R
180° to 280°	M. gastrocnemius - right	Ga_R
220° to 360°	M. quadriceps fem. - left	Qu_L
40° to 180°	M. biceps fem. (hamstrings) - left	BF_L
300° to 30°	M. gluteus maximus - left	Gl_L
150° to 270°	M. tibialis anterior - left	TA_L
0° to 100°	M. gastrocnemius - left	Ga_L
0° to 360°	individual	Ind1
0° to 360°	individual	Ind2
0° to 360°	individual	Ind3
0° to 360°	individual	Ind4

- for RehaMove2 arm training:

Start and stop angle	Muscle	Short cut
20° to 180°	triceps - right	TB_R
220° to 10°	biceps - right	BB_R
200° to 360°	triceps - left	TB_L
40° to 190°	biceps - left	BB_L
0° to 360°	individual	Ind1
0° to 360°	individual	Ind2
0° to 360°	individual	Ind3
0° to 360°	individual	Ind4

1.7.3 Features

Duration of the stimulation impulses (pulse width)	max. 500 μ s
Current	max. 130 mA
Number of channels	8
Stimulation frequency	max. 50 Hz
Operation time in battery mode	ca. 90 min
Charging time for integrated battery pack	ca. 180 min

- High user safety: Test of the applied electrodes for connectivity before stimulation starts
- Quick Stop for unexpected sudden danger

1.8 Maintenance and Service Instructions

Cleaning of the stimulator

Use normal detergent to clean the stimulator. Do not use a cleaning spray, but a semi-moist cleaning tissue.

Cleaning of the MOTomed

For cleaning the MOTomed viva2 or Gracile, please read the recommendation of the manufacturer in the user manual.

Maintaining the stimulator accumulator

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 accumulator is 500 charging cycles or 2 years, and depends strongly on the application and storage conditions.

Avoid high temperature and follow the storage recommendations (see chapter 4.2.1).

Maintaining the 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.

The service life for the stimulator is 5 years.

2 What's new in this Software Version?

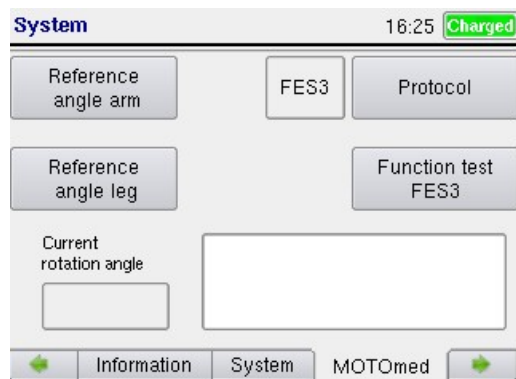
Enhanced parameter settings

For every 8 stimulation channels, starting from version 2.4, it is possible to set the parameter pulse width and frequency individually for the RehaMove training.



Cessation of FES3 - Interface

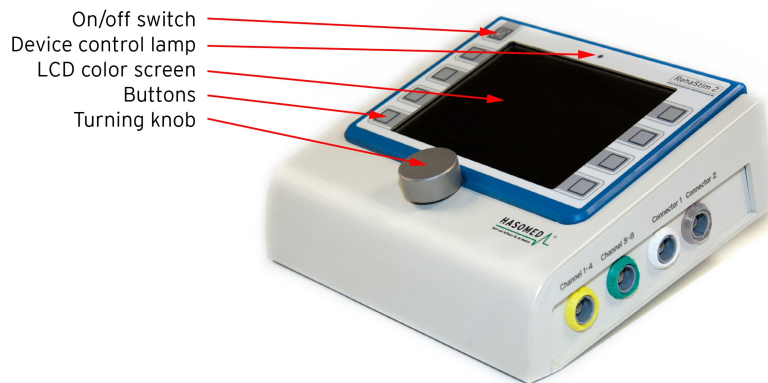
Starting from version 2.4, the connection to MOTomed motion trainer is only possible via FES3-Interface. Separate operation of RehaStim2 and MOTomed is no longer possible. All settings during FES-training are carried via the RehaStim2.



3 Device Controls and Accessories

3.1 Controls

With the on/off switch, the stimulator is turned on and off. The device is operated with nine buttons and one turning knob. All readouts and graphics are shown on a big LCD color screen.



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

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

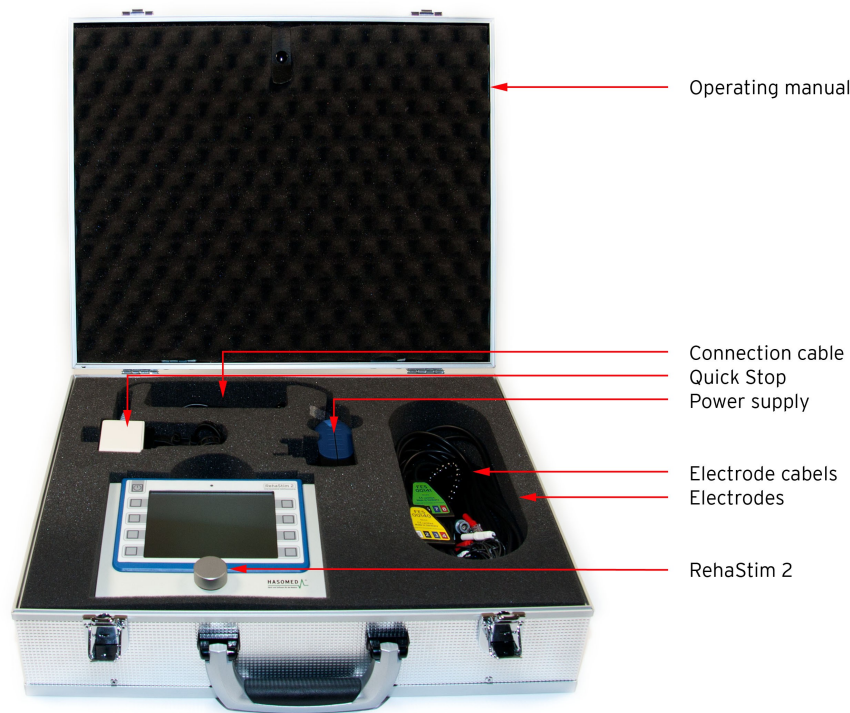
On the right side of the stimulator, the following connections can be found:

- The grey connector is used for the Quick Stop
- The white connector is used for the connection cable to the MOTomed or for the external trigger in sequence mode.
- The yellow and green connectors are used for corresponding electrode cables.



3.2 Accessories

The stimulator and its accessories are delivered in a transport case. It is recommended to keep the stimulator and its accessories in the transport case when it is not used.



The transport case includes:

- 1 stimulator
- optional: 1 Quick Stop
- 2 electrode cables
- 1 power supply unit for the stimulator
- 1 Power Supply Holder
- 4 sets of electrodes
- 1 operating manual

For RehaMove2:

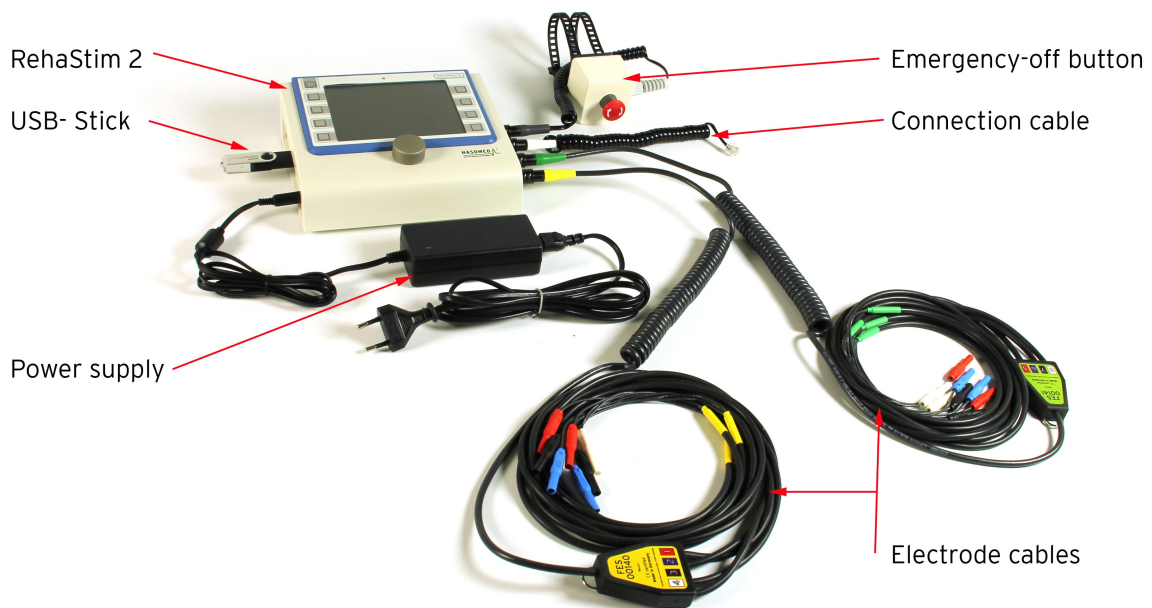
- 1 cable to connect the movement exerciser and RehaStim2
- Separately: bracket with screws to fix the stimulator onto the motion trainer

For sequence training/ general stimulation, if requested:

- an external trigger

For ScienceMode2:

- 1 USB connection cable to PC



Stimulator

See chapter "Controls"

Quick Stop



With this button the user can immediately stop the stimulation. Use the quick release fastener to fix the quick stop within reach of the user, which could be for example on the handlebar - as shown in the picture -, at the wheelchair frame or a similar suitable position. Connect it to the designated connector on the right side of the stimulator. For testing the functionality of the button, push the quick stop button while the stimulation is active. The stimulation should stop immediately. In FES 3 protocol, both stimulator and MOTomed stop immediately.

To reactivate the stimulator after the quick stop has been pressed, loosen the locking of the button and turn it until it is unlocked and moved upwards. In the meantime, the stimulator went into pause mode and can now restart where it was stopped.

Electrode cables

The electrode cables connect the stimulator to the surface electrodes. Each electrode cable is divided into 4 channels with 2 electrodes each. The channels are color coded and thus mix-up proof.

Power supply unit for the stimulator



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 at the RehaMove2 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.

Cable to connect movement therapy trainer and stimulator

This cable allows the communication between stimulator and motion trainer. Connect it to the stimulator interface on its right side. The interface at the movement trainer can be found on the bottom side of the operating panel.

Electrodes

The adhesive surface electrodes provided are applied to the skin above relevant muscles. Via these electrodes, electrical impulses from the stimulator go to the relevant muscles and cause their contraction. Relevant muscle groups for stimulation applications are shown in chapter 5.6.6: "Electrode Placement for Common Muscle Combinations". Since the exact application of electrodes varies between users, please consult your doctor or physiotherapist about where and how to apply the electrodes in order to generate an effective muscle contraction.



*Warning! Use recommended **RehaTrobe** electrodes only! The manufacturer HASOMED guarantees for the safe use of the RehaMove2 only with these electrodes. The RehaTrobe is tailored to the operation with the stimulator RehaStim2. Due to the technical data of the RehaStim2, an overload of the RehaTrobe by the initial values of the RehaStim2 is not possible. The electrodes have a gel layer and therefore no further conductive medium is needed.*

A patented two-layer adhesive gel prevents problems in quality as known from single-layer gels.

Hasomed Item Number	Description
FES00200 RehaTrode	2.0" x 3.5", 5cm x 9 cm, rectangle
FES00201 RehaTrode	3.0" x 5.0", 7,5cm x 13 cm, rectangle
FES00202 RehaTrode	1.5" x 2.5", 4cm x 6,4cm, oval

The electrodes are designed to be re-used several times on the same patient. The life span/ service life of the electrodes depends on how often they are used and how well the user takes care of them. With proper care, the electrodes can last for 30 sessions.

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.

Please note the safety instructions for the application of electrodes on page 4!

- Do not stimulate while driving or operating machinery.
- Do not exceed 0.1 watts/cm².
- Adjust the stimulator according to the user manual or/and the instructions of your clinician.
- For your safety and comfort, turn off the stimulator before you remove the electrodes from your skin.
- Always lift the electrodes from the edge- do not pull on the cable.
- Always store the electrodes on the "ON" side of the storage liner.
- Always keep the electrodes well sealed in the original package and store them in a cool place.
- Never let the electrodes get wet.
- Using hot or cold packs over a longer period of time can cause adhesive separation.
- Use each electrode for only one patient (single patient use).
- Replace electrodes once they show signs of wear.

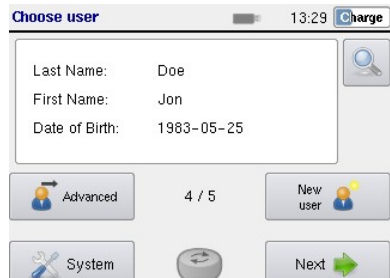
Bracket for mounting the stimulator at the movement trainer

The bracket allows the stimulator to be mounted onto the movement trainer in a position that allows easy access for the user. It is mounted when the RehaMove2 is delivered. See chapter 4.4: "Mounting instruction for arm and leg bracket".


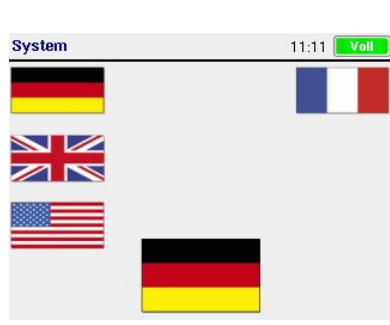
4 General Settings and Service Information

Switch on the stimulator by pressing the **on/off button**. The device control lamp indicates with a green light that the stimulator is switched on.

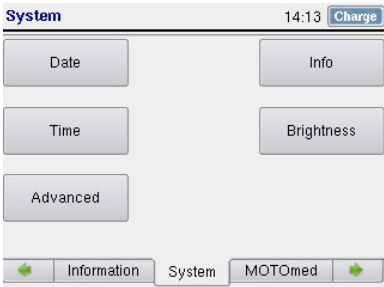


The HASOMED RehaMove2 logo appears on the LCD color screen. The stimulator starts loading the program and a few seconds later the window "Choose user" appears.

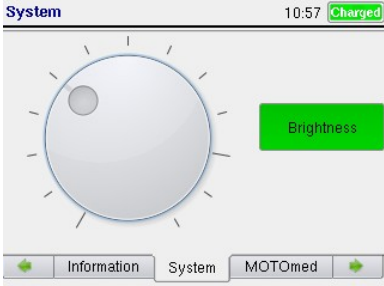
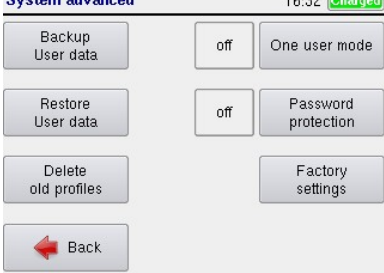
	<p>Press System in the window "Choose user".</p>
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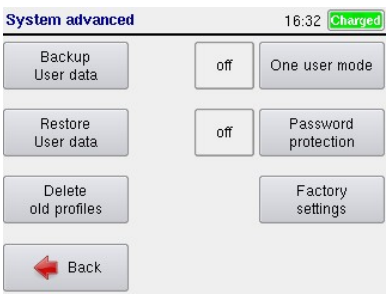
4.1 Information: Licence & Firmware, Memory, Language



	<p><u>Import Licence, Firmware update, free Memory</u></p> <p>The tab "Information" shows following information:</p> <ul style="list-style-type: none"> • The software version • The serial number of the stimulator • The checksum • The current date • The amount of occupied and vacant memory <p>Apart from that following settings can be chosen:</p> <ul style="list-style-type: none"> • A new software update respectively upgrade can be uploaded with the button Import licence. Further information about this feature is given by the manufacturer upon request. • Upload a firmware update • Language settings can be adjusted with the button Language
	<p><u>Language</u></p> <p>After the button Language is pressed, this window opens up. The country flag of the currently activated language can be found above the turning knob. To select a different language, press the button next to the flag of favored language. After the language has been set, the stimulator restarts with the new language.</p>

4.2 System: Device Settings, Backup & Restore, Password

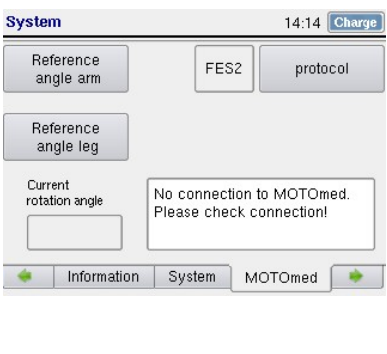
	<p>In the tab "System" following settings can be chosen:</p> <ul style="list-style-type: none"> • View copyright details and manufacturer address • Change the current date • Change the current time • Change the brightness of the screen • Advanced leads you to database settings (backup and restore) and password de/activation
	<p><u>Date</u></p> <p>The date can be changed by pressing the button next to the field Date.</p> <p>A window with the current date in YYYY-MM-DD pops up. Settings in the blue field are executed with the turning knob. If the knob is turned, entries are changed. If the knob is pressed, entries are confirmed and the next field is ready to be set.</p> <p>After the last field is set, the stimulator restarts with the date updated.</p>
	<p><u>Time</u></p> <p>The time can be changed by pressing the button next to the field Time.</p> <p>A window with the current time in hh:mm pops up. Settings in the blue field are executed with the turning knob. If the knob is turned, entries are changed. If the knob is pressed, entries are confirmed and the next field is ready to be set.</p> <p>After the last field is set, the stimulator restarts with the time updated.</p>

	<h3>Brightness</h3> <p>The light intensity of the screen can be changed by pressing the button Brightness.</p> <p>A window where the light intensity can be adjusted pops up. Settings in the blue field are executed with the turning knob. If the knob is turned, the light intensity of the screen changes. If the knob is pressed, entries are confirmed.</p>
	<h3>Advanced options</h3> <h4>Backup and Restore User data</h4> <ul style="list-style-type: none"> • Use Backup to export all user data, profiles and history data stored on the stimulator onto a USB flash drive <p><i>Note: All data on your USB stick stored in the file "reastim2" are overwritten! The directory "reastim2" is automatically created.</i></p> <ul style="list-style-type: none"> • Use Restore to import user data, profiles and history data stored on USB flash drive onto the stimulator <p><i>Note: Data on the stimulator are updated. User data without any changes remain unchanged!</i></p> <h4>Delete old profiles</h4> <p>The button enables you to delete those user profiles (Firmware version <1.5) and their session history which you did not assign to a user. How and when to assign profiles to users: see chapter Create new Users and new User Profiles</p> <h4>One user mode</h4> <p>Activate one user mode for home users. Deactivate it for clinical /multiple users.</p> <p>There is no password protection in one user mode!</p>

 <p>The screenshot shows the 'System advanced' menu with the following options:</p> <ul style="list-style-type: none"> Backup User data Restore User data Delete old profiles Back off One user mode Password protection Factory settings 	<p><u>Extended password protection</u></p> <p>3-Level-password protection The password protection secures user data and profiles.</p> <p>If the password protection is activated, the user can see the parameter settings. Due to safety reasons the patient is not allowed to make any changes. Only the therapist is allowed to make changes in the settings.</p> <p>There are three levels of password protection:</p> <p>Level 1 "Master password" Activates/deactivates password protection: Password is assigned only once.</p> <p>Level 2 "Therapist password" This individual password is entered when a new user is created. This password entry is only active if the master password has been activated.</p> <p>Level 3.1 "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.</p> <p>Level 3.2 "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.</p> <p><i>Only the therapist is allowed to activate and deactivate the password protection.</i></p> <p>There is no password protection in one user mode! Should the password be lost or forgotten contact the manufacturer.</p>
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	<p><u>Factory settings</u></p> <p>By pushing this button you restore the factory defaults of the stimulator.</p> <p><i>Warning: Data already stored will be deleted!</i></p> <p>The one user mode and password protection are deactivated.</p>
	<p><u>Copyright</u></p> <p>This window shows the copyright details and libraries used in programming.</p>

4.3 MOTomed: Reference Angle, FES3 Protocol, FES3 Test

	<p>In the tab "MOTomed" following applications can be chosen:</p> <ul style="list-style-type: none"> • Check/ change the reference angle to the MOTomed arm exerciser • Check/ change the reference angle to the MOTomed leg exerciser • Change the protocol for the communication between movement exerciser and stimulator • Carry out an FES3 function test <p>As they may be safety relevant, these changes must be done only</p> <ul style="list-style-type: none"> • by qualified personal, or • by the manufacturer, or • after consultation with the manufacturer.
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Reference angle


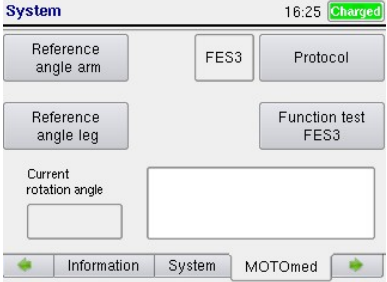
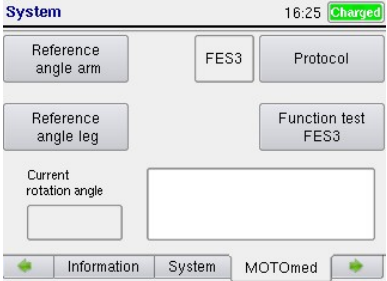
The reference angle (zero angle) is the RehaMove 2 calibration off-set value used to shift the actual physical zero point of the pedal angle sensor. The standard zero angle is defined as the sensor angle in a certain position.

It is recommended to check the reference angle

- if the MOTomed viva2 cockpit/controller has been exchanged or
- if the stimulator was moved to a different MOTomed viva2.

Warning! The zero angle is a device specific parameter and not part of the individual parameters.

This means that any changes to this variable will affect other parameter sets too:
 -Changing the zero angle affects the start and stop times of the stimulation for all RehaMove2 user programs.
 -Changing the zero angle for RehaMove arm/leg training affects all RehaMove arm/leg training programs.

	<p><u>Reference position</u></p> <p>In the RehaMove arm training at the MOTomed viva2: the right hand grip is in horizontal position and points towards the user (= backwards).</p> <p>The RehaMove leg training at the MOTomed viva2: the right foot pedal is in horizontal position and points towards the user (= backwards).</p>
	<p><u>Reference angle arm or leg</u></p> <p>Change the reference angle of the stimulator by pressing the button next to the field reference angle arm respectively leg. A window pops up with the current reference angle.</p> <p>Start the MOTomed viva2 arm/leg trainer, choose a speed of 0 or 1 rpm. In the left corner the current value from the sensor is constantly written. In the center top field, the set reference angle is displayed. Let the MOTomed viva 2 run and watch how the current angle value in the left corner changes. Read the value the MOTomed viva 2 tells you in the reference position (see above). If this value is not the same as the set reference angle at the center field, change the value of the center field accordingly by turning the knob.</p> <p>The reference angle is adjusted correctly once both values are the same the very moment the pedal/arm crank is in the reference position. Press the turning knob to confirm entries.</p> <p><i>Caution! Please be aware that changing the zero angle affects all programs. Save only when you are sure. Otherwise please contact the manufacturer.</i></p>
	<p><u>FES3 Function test</u></p> <p>Press the test button in order to run a test of the successful communication between stim and MOTomed in FES3 mode. The test lasts about 5 minutes!</p> <p>If there are issues, a popup window hints you how to solve these.</p>

4.4 Mounting Instruction for Stimulation Bracket

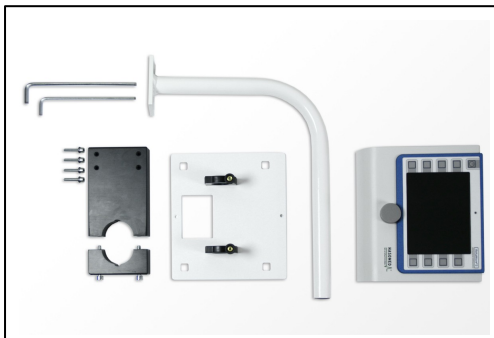
Mounting the RehaMove2 Control's Bracket to the MOTomed Viva2 Leg Trainer

	<p>Scope of delivery:</p> <ul style="list-style-type: none">• Bracket tube• PVC part for bracket tube (black)• Stimulator plate• Jaw spanner (size 10)• 2 screws• 2 cap nuts
	<p>Mount the black PVC part to the supporting module/ the front leg, approx. 15 cm/6 inches below the operating panel with the two enclosed screws. Do not tighten the cap nuts yet.</p>
	<p>Place the bracket tube to the fixed black PVC part. Now tighten the cap nuts with the enclosed jaw spanner.</p>
	<p>Put the stimulator plate onto in the bracket tube. Make sure that the bevelled edge points downward.</p>



Remove the two knurled screws from the back of the stimulator. Mount the stimulator with the two knurled screws onto the stimulator plate. The stimulator and the stimulator plate must line up precisely with each other.

Mounting the RehaMove2 Control's Bracket to the MOTomed Viva2 Arm and Leg Trainer



Scope of delivery:



- Bracket tube
- PVC part for bracket tube (black)
- Stimulator plate
- 2 allen keys (size 4 and 5)
- 6 screws (4 units size M5x25, 2 units size M6x55)





Mount the black PVC part to the MOTomed's cockpit standpipe with the two enclosed screws size M6x55. To fix them use the allen key size 5.






Fix the bracket tube to the black PVC part with the four remaining screws. To fix them use the allen key size 4.

	<p>Put the stimulator plate onto in the bracket tube. Make sure that the bevelled edge points downward.</p>
	<p>Remove the two knurled screws from the back of the stimulator. Mount the stimulator with the two knurled screws onto the stimulator plate. The stimulator and the stimulator plate must line up precisely with each other.</p>





Montageanleitung RehaMove2 Control an MOTOMed gracile

	<p>Scope of delivery:</p> <ul style="list-style-type: none"> • Bracket tube • PVC part for bracket tube (black) • Stimulator plate • 2 allen keys (size 4 and 5), 1 Jaw spanner (size 10) • 6 screws • 2 cap nuts
	<p>Mount the black PVC part to the MOTOMed's gracile cockpit standpipe with the two enclosed screws and the cap nuts. To fix them use the allen key size 5 and the Jaw spanner size 10.</p>

	<p>Fix the bracket tube to the black PVC part with the four remaining screws. To fix them use the allen key size 4.</p>
	<p>Put the stimulator plate onto in the bracket tube. Make sure that the bevelled edge points downward.</p>
	<p>Remove the two knurled screws from the back of the stimulator. Mount the stimulator with the two knurled screws onto the stimulator plate. The stimulator and the stimulator plate must line up precisely with each other.</p>

Connect the stimulator and the accessories as described in chapter "Device Controls and Accessories"

4.5 Mounting Instruction for Power Supply Holder

	<p>The power supply holder is used to fix the RehaMove/stimulator power supply to the MOTomed. This fixation is part of the RehaMove system.</p>
	<p>Remove the two lower Velcro strips on the back of the fixation and place them at the MOTomed. The position of the fixation should not disturb the RehaMove training.</p>
	<p>The RehaMove power supply exactly fits in this fixation. Push the power adaptor into the fixation through the upper opening until the power supply is completely placed. Therefore it is not necessary to remove the power cord.</p>
	<p>It is recommended to place the fixation on the back of the MOTomed. Push the fixation on the Velcro strips, which have been fixed before.</p> <p>Note: The power adaptor cables must be out of exercising area.</p> <p>Do not remove the fixation if you like to disconnect the power supply from the power source. Only disconnect the power cord which connects the power supply with the power source.</p>

5 RehaMove2-FES Cycling

RehaMove2 is the combination of RehaStim2 and motion trainer MOTomed viva2. The stimulator generates impulses depending on the crank position and rotating speed. Motion trainer and stimulator communicate via connection cable.

The following chapters introduce you to the therapy of upper and lower extremities with stimulation programs in FES3. Please make sure that at your stimulator (see MOTomed: Reference Angle, FES3 Protocol, FES3 Test) and at the MOTomed, the FES3 protocol is activated for an integrated operation.

5.1 Notes on the Therapy with RehaMove2

General notes

Before the first session, the user must consult a doctor or physiotherapist

- to find out how he/she can benefit from the system
- to show how to use the device
- to set ideal parameters

It is recommend that the RehaMove2 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.

Therapy and exercise program planning

The frequency and duration of sessions on the RehaMove2 should be individually planned and prescribed by a doctor or therapist. Therefore, only general guidelines on therapy program planning can be given at this point. Regular exercising with the RehaMove2 is extremely important if improvements in mobility and particularly in muscle strength are to be achieved. Short but frequent sessions are better than long strenuous ones. It is always recommended to consult with a doctor or therapist and to create a therapy plan together. It starts with sessions of not more than 15 minutes continuous exercising, starting with a period of gentle passive exercising and then the progression to light, active exercising with low resistance setting. The length of the session, the speed, the amount of active exercising and the resistance can be gradually increased in small steps at a time. It is possible to schedule several therapy sessions a day always providing that no negative symptoms of illness occur and the physical capabilities of the client are not exceeded. The intensity of the therapy is correct if strength, endurance and mobility gradually improve and the client feels well.

Course of a session

Generally a session starts with a slow "warm up" phase without or with stimulation. User's muscles can slowly warm up to be prepared for the session. A stimulation phase follows where the user's muscles are stimulated and work actively.

The session should finish with a cool down phase.

The RehaMove programs realize this course automatically, the duration of these three phases can be adapted user individually.

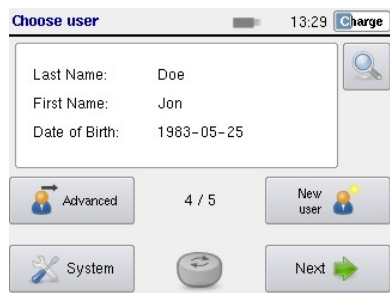

5.2 Safety Measures before you start

Before you start:

- Check that the supply voltage of the unit matches with your main current. Only connect the RehaMove2 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 walking by could get caught in the cables and these cannot get into the rotating pedals and be damaged.
- Mount the unit on even and non-slippery surface in order to ensure stability. If the device has just been delivered, leave it at room temperature for an hour.
- Never grab into rotating pieces (e.g. pedals).

5.3 Clinical Use

Use the RehaMove2 multi user mode in hospitals or other facilities where numerous patients train with the device.


	<p><u>Choose user</u> by</p> <ul style="list-style-type: none"> • first name • last name • date of birth (visible only if password protection is disabled) <p>Scroll through the list of users with the turning knob.</p>
	<p><u>Choose user profile</u> The number of user profiles/ training programs with individual settings is not limited per user.</p> <p>Picture: For user J. Doe (top line) 7 profiles (at the bottom "1 / 7") are available. Scroll through the user's profiles with the turning knob.</p>

Use client individual USB memory sticks if multiple RehaMove2 systems are accessible
see chapter 5.3.2: Using 2 or more RehaMove2

An optional password protection with three levels for increased data safety:

- client password: client achieves access to choose a training out of his/ her user profiles and start the session
- therapist password: therapist achieves full access to all features

5.3.1 Recommended Adjustments

<p>System advanced 16:32 Charged</p> <p>Backup User data off One user mode</p> <p>Restore User data off Password protection</p> <p>Delete old profiles Factory settings</p> <p> Back</p>	<p><u>3 level password protection</u></p> <p>The password protection ensures the safety of user data and profiles. See chapter 4.2: System: Device Settings, Backup & Restore, Password</p>
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For an integrated operation, please make sure that the FES3 protocol is activated at your stimulator (see chapter 4.3: MOTomed: Reference Angle and Communication Protocol) and the MOTomed.

5.3.2 Using 2 or more RehaMove2: Client individual USB Flash Drive

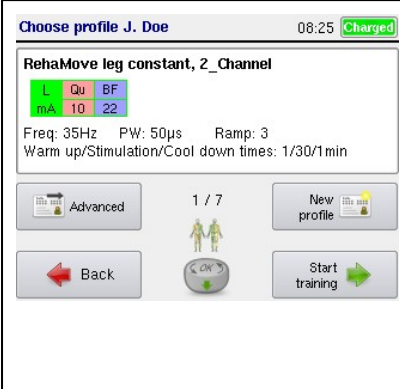
If you use several RehaMove2 units in a facility and clients may use different RehaMove2 systems, clients can move their settings and session results via a user individual RehaMove2 USB flash drive.

Each user keeps his/ her own "RehaMove2 USB flash drive" which contains only his or her data. The USB flash drive is connected to the stimulator before starting the session. The session continues where the last session was finished. Each available RehaMove2 unit may be used. The USB flash drive is kept by the user or it is suitably stored in the therapy department. With the USB, the therapist can make changes to the clients` settings and track progress (session/ training history).

The use of a client individual USB simplifies the operation, as the client will only see his/ her own profiles. After the session, the training history is automatically stored in the stimulator as well as on the USB.


5.4 Home Use

Use the RehaMove2 one user mode in home environments or facilities where only one client trains with the device.

	<p><u>Direct access to the user profiles of that single client only</u></p> <p>The number of user profiles/ training programs with individual settings is not limited per user.</p> <p>Picture: For user J. Doe (top line) 7 profiles (at the bottom "1 / 7") are available.</p> <p>Scroll through the user's profiles with the turning knob. See the corresponding templates by pressing the knob.</p>
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The client can access all functions of the device, as there is no password protection.

5.4.1 Recommended Adjustments

	<p>Start in window "Choose user". Press button "System" / go to tab "System" / press button "Advanced".</p> <p><u>One user mode</u> Activate one user mode. I.e. One user mode should be ON.</p> <p><u>Password protection</u> Turn the password protection to OFF.</p>
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5.5 Data Storage in the Stimulator

The FES therapy system "RehaMove2" stores therapy relevant files:

- In the data base of the stimulator RehaStim2 and/or
- Onto user USB flash drive and/or
- In the data base of the Windows PC program.

The stored files contain

- User data
- Training parameters (settings) and
- History data

These data can be exported to the PC via USB flash drive for documentation of the therapy session results. The PC software reads out the USB flash drive. FES data can be added to the database optionally.

Using ONE FES RehaMove2 system only in a clinic, it is recommended to store the data in the data base of the stimulator RehaStim2 (from version 1.5). Using SEVERAL FES RehaMove units in a clinic, it is recommended to store the data onto a RehaMove USB Flash Drive from Hasomed.

Each user receives a USB flash drive which includes only his/her personal data. The USB flash drive must be connected to the stimulator before starting a therapy session. This allows to train with the stored parameters. The results are stored on the USB flash drive after finishing the therapy session. The user may train on each RehaMove in the clinic.

The data of ONE user only can be stored onto the USB flash drive. If you try to store data from a second user to the USB flash drive via Windows Explorer, an error message will be displayed.

Note: In this case it is no longer possible to store or import user data with that USB flash drive!

Each user file is automatically generated. It consists of parts of the user name which is complemented by a unique identification (GUID). Each user file includes at least one user profile. The profile file contains the training parameters and the results of the performed therapy sessions. The number of the profile files per user is not limited.

Note: Do not change file names manually to avoid data loss!

Only the Hasomed RehaMove USB flash drive may be used to store data.

Backup and Restore User data via USB

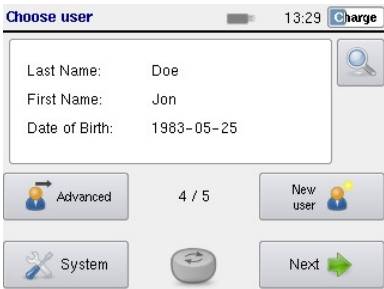

- Create a **Backup** from the stimulator onto your USB flash drive.
This function copies all users and all their profiles with all their session history from your stimulator onto your USB flash drive. For moving these to the PC, see chapter 5.6.11: "RehaMove PC Software". To see how much memory is available in the stimulator, see memory availability in chapter 4.1: "Information: Licence & Firmware, free Memory, Language". If a USB flash drive is connected, a symbol comes up in the start screen.

- **Restore** user data from your USB flash drive.

This feature copies numerous users, their profiles and their session history from the USB flash drive onto your stimulator. If the stimulator contains user data, the new data are added.

5.6 RehaMove Training - Integrated Operation (FES 3-Interface)

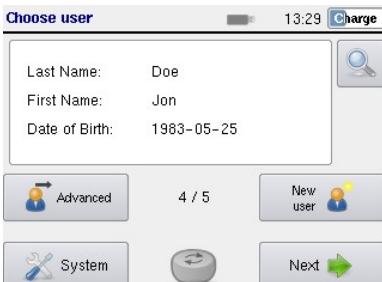
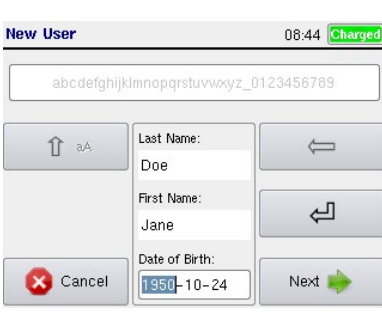

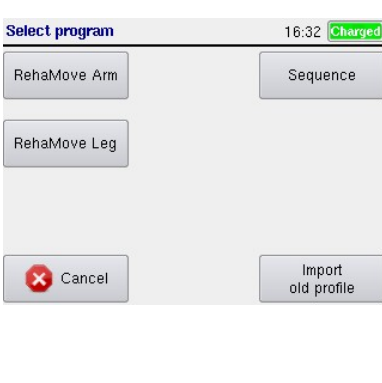
Switch on the stimulator by using the **On/Off** button.

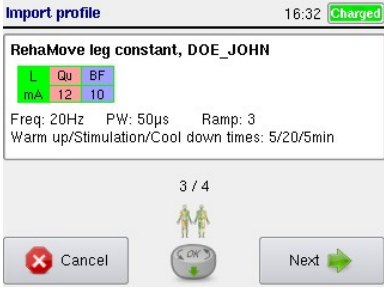

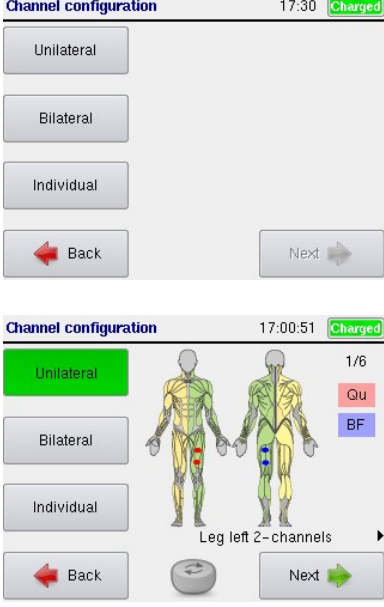
	<p><u>Choose user</u></p> <p>The screen lists all clients of the stimulator database, sorted by their last name. Scroll through the list by turning the knob. Once your database contains more than 3 users, a search icon appears in the upper right corner. Here you can enter the first letter of the client's last name for faster searches. If you connect a USB device, a USB flash drive icon appears in the upper bar.</p> <p>If the desired client is displayed in the white field, confirm with Next.</p> <p><i>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 RehaMove USB.</i></p>
	<p><u>Choose profile</u></p> <p>The white field above the turning knob shows the user`s profile with its parameters:</p> <ul style="list-style-type: none"> • Therapy mode (e.g. RehaMove Leg constant), individual name of the profile • Stimulated muscle groups with corresponding current and channels (in color) in table format • Frequency (Hz), pulse width (μs) and ramp • Times for warm up, stimulation and cool down in minutes <p>Scroll through the profiles by turning the knob. Above the turning knob you see two numbers, they display the number of the current profile and the number of all the profiles assigned to this user. E.g. "1/7" means that the user has 7 profiles, the one displayed in the white field is profile 1.</p> <p>Futhermore you see a small figure above the turning knob. If you press the knob, a pop up will display the template of the selected profile with the electrode positioning. This option is not available in individual electrode placements.</p>

	<p>Once the desired profile is displayed in the white field, press Start training in order to start the session.</p> <p>Use buttons: Advanced: see advanced options New profile: Create a new user profile Back: Go back to the window "Choose user"</p>
--	---

5.6.1 Create new Users and new User Profiles, import old Profiles

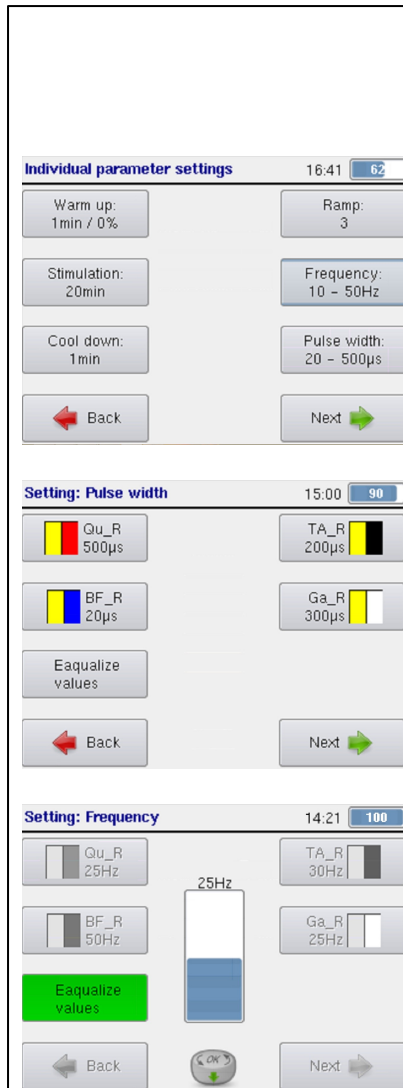
Switch on the stimulator by using the **On/Off** button.

	<p><u>Create new User</u></p> <p>Select button "new User" in the window "Choose user".</p>
	<p><u>Enter details of new user</u></p> <p>Enter the family and first name and date of birth.</p> <p><i>Note: These details are irreversibly entered and cannot be changed again after you pressed the button "next".</i></p> <p><i>By activating the NEXT button all of the information is required.</i></p>
	<p><u>Enter user individual password</u></p> <p>If the password protection is activated, the client is now requested to enter his/ her individual password. Minimum 3 digits length.</p> <p>Now the creation of the user is finished and you begin to create a new user profile.</p>
	<p><u>Select program for new user profile</u></p> <p>Select desired application by pressing the button next to the displayed application button. Transparent buttons are not active and cannot be pressed.</p> <p>Use buttons:</p> <p>RehaMove Arm: Arm training with RehaMove RehaMove Leg: Leg training with RehaMove Sequence: sequence mode with RehaStim as stand-alone</p>

	<p>Import old profile: Import profiles (firmware version < 1.5)</p> <p><u>Import old profile</u></p> <ul style="list-style-type: none"> • Select favored profile from the list → confirm with Next • Give new profile and user name → save <p><i>Old profiles can only be imported as new profile once!</i></p> <p>If all needed old profiles are imported go to system advanced and delete old profiles.</p>
	<p><u>Choose program extension</u></p> <p>The window "Choose program extension" allows for choosing between constant and adaptive training. Information about different program extensions can be found in the following chapters.</p> <p>Use buttons:</p> <p>adaptive: To select the adaptive RehaMove program extension</p> <p>constant: To select the constant RehaMove program extension</p>
	<p><u>Channel configuration</u></p> <p>In the window "Channel configuration" templates for unilateral or bilateral stimulation can be selected. These templates cover most frequently used combinations of muscle groups. The button Individual allows an individual channel configuration.</p> <p>Use buttons:</p> <p>Unilateral: to select unilateral stimulation templates</p> <p>Bilateral: to select bilateral stimulation templates</p> <p>Individual: to define individual stimulation patterns (see "Activate muscles")</p> <p>If the buttons Unilateral and Bilateral respectively are activated, a number of template pictures show up above the turning knob. These templates show selected channels from the front side and back side.</p> <p>Choose whether 2, 3 or 4 channels - or 4, 6 or 8 in a bilateral template - shall be used for stimulation.</p> <p>Use the turning knob in order to select one template. Press Next to confirm your entries.</p>

	<p><u>Activate Muscles individually</u></p> <p>This window allows the user to assign individual muscle/channel combinations. Muscle groups are chosen for the stimulation and colors are matched.</p> <p>Select a channel by pressing the corresponding button. The active channel is tagged green. A window with available muscle groups pops up in the middle of the screen. Abbreviations are used to indicate each muscle (see chapter "Default values").</p> <p>RehaMove arm and leg training (adaptive and constant) provides 4 individual muscles on each side. On the right side, the channels Ind_1 to Ind_4 are available. On the left, channels Ind_5 to Ind_8 are available. This allows a stimulation up to 8 channels without changing any template.</p> <p><i>Note: If at least 1 muscle "Ind_x" has been selected and no angle has been defined, a window pops up asking to define an angle for this individual muscle.</i></p> <p>Use the turning knob:</p> <ul style="list-style-type: none"> • In order to select muscle groups, turn the knob • In order to confirm entries, press the turning knob <p>Use buttons:</p> <p>Angles: to see/ change angles for the program</p> <p>Back: to cancel the process / go back to the previous window</p> <p>Next: to activate further muscle groups or adjust parameters</p>

 <p>Define angles 1/2 10:34 Charged</p> <p>Qu_R Not used</p> <p>BF_R Not used</p> <p>Default angles</p> <p>Muscle Next</p> <p>Define angles 1/2 10:35 Charged</p> <p>Qu_R 40° Not used</p> <p>180°</p> <p>BF_R Not used</p> <p>Default angles</p> <p>Muscle Next</p>	<p><u>Define angles individually</u></p> <p>In this window the activated muscle groups are shown and activation angles can be defined. In order to change the angles for one activated muscle, press the corresponding button. An overview of standard angles can be found in chapter "Default Values". Start and stop angles can be changed by the user. The button of the activated channel is tagged green.</p> <p>Use the turning knob:</p> <ul style="list-style-type: none"> • In order to change angles, turn the knob • In order to confirm entries, press the turning knob <p>Use button:</p> <p>Default angles: Default angles are reactivated, changes are overwritten, all settings for the angles are deactivated again.</p>												
 <p>Select parameter templates 16:28 Charged</p> <p>SCI</p> <p>Stroke</p> <p>Others Individual</p> <p>Back Next</p> <p>Select parameter templates 16:42 Charged</p> <p>SCI Endurance motor complete</p> <table border="1"> <tr> <td>Warm Up</td> <td>1 min</td> <td>Freq.</td> <td>25 Hz</td> </tr> <tr> <td>Stimulation</td> <td>30 min</td> <td>PW</td> <td>300 µs</td> </tr> <tr> <td>Cool Down</td> <td>1 min</td> <td>Ramp</td> <td>0</td> </tr> </table> <p>Stroke</p> <p>Others 2 / 6 Individual</p> <p>Back Next</p>	Warm Up	1 min	Freq.	25 Hz	Stimulation	30 min	PW	300 µs	Cool Down	1 min	Ramp	0	<p><u>Select parameter template</u></p> <p>Select standard settings from typical fields of application:</p> <ul style="list-style-type: none"> • choose a client group: stroke, SCI or other • choose a therapy goal, e.g. endurance, muscles strengthening <p>The table which appears on the right shows the typical settings used in hospitals for</p> <ul style="list-style-type: none"> • duration for warm up, stimulation and cool down, • frequency, • pulse width, and • ramp <p>Use the turning knob in order to select one template. Press Next to confirm your entries.</p> <p>Press Individual to make changes to the standard settings.</p>
Warm Up	1 min	Freq.	25 Hz										
Stimulation	30 min	PW	300 µs										
Cool Down	1 min	Ramp	0										
 <p>Define parameters 10:36 Charged</p> <p>Warm up: 1min Ramp: 3</p> <p>Stimulation: 30min Frequency: 35Hz</p> <p>Cool down: 1min Pulse width: 50µs</p> <p>1min</p> <p>Back Next</p>	<p><u>Individual parameter settings</u></p> <p>Warm up, Stimulation, Cool down</p> <p>This window allows for adjusting parameters that apply to all channels.</p> <p>Press the button Warm up in order to change the duration of the warm up. A field above the turning knob pops up with the present value in minutes.</p> <p>Use the turning knob:</p>												



- In order to change minutes, turn the knob
- In order to confirm entries, press the turning knob

The same procedure applies to change the duration of Stimulation and Cool down phase.

Ramp

The ramp is the number of gradual stimulation impulses before the pre-set pulse width is reached. The ramp is carried out every time the crank arm angle of the movement therapy device enters the active angle range for a stimulation channel.

Press the button **Ramp** in order to change the ramp. A field above the turning knob pops up with the present value.

Use the turning knob:

- In order to change minutes, turn the knob
- In order to confirm entries, press the turning knob

Frequency and pulse width

On the button for frequency and pulse width, current set values are displayed. If different values are set for different channels, the smallest and largest value will be displayed on the button. To change the values for frequency and pulse width, press the respective button to enter the appropriate input screen.

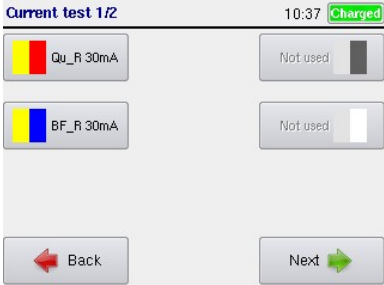
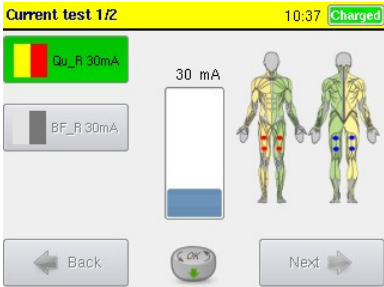
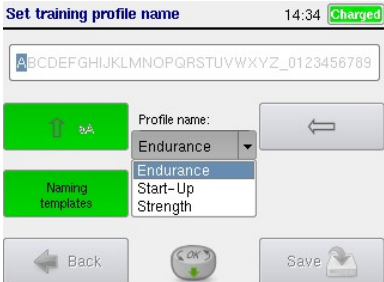
In the screen **setting: frequency** or **setting: pulse width**, the activated channels are displayed. If you want to set or change the value of a particular channel, press the corresponding button. Press the button next to the field for the channel or muscle you want to change. A pop up window opens in the middle of the screen, where pulse width or frequency is displayed in form of a bar.

Use the turning knob:

In order to change current, turn the knob
In order to confirm entries, press the turning knob


There is no stimulation during Settings. Use current test to verify the stimulation parameters.



The activated key will be deactivated by pressing the button next to the green marked field. The next

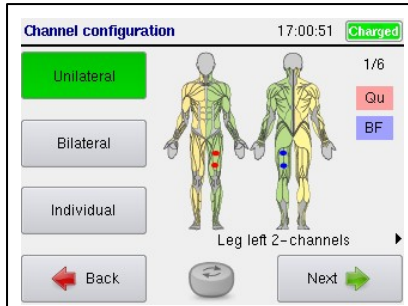
	<p>channel to be tested can now be selected.</p> <p>Next: to set values for further activated channels.</p>
 	<p><u>Current test</u></p> <p>This window shows all activated channels. If you want to test the current for one specific channel respectively muscle, press the corresponding button.</p> <p>A window in the middle of the screen pops up which shows the present current, displayed with a bar. By pressing the green tagged button once more, the activated button is deactivated again. The next channel can be selected and tested.</p> <p><i>If the stimulation is active, the status indication line is colored in yellow.</i></p> <p>Use the turning knob:</p> <ul style="list-style-type: none"> • In order to change current, turn the knob • In order to confirm entries, press the turning knob <p>Next: Test current for further channels if activated.</p>
	<p><u>Set training profile name</u></p> <p>The final step of the profile creation is to enter a name for the profile. You are free to use naming templates or choose your own wording.</p>

5.6.2 Edit or delete a User Profile

Switch on the stimulator by using the **On/Off** button.

	<p><u>Choose user</u></p> <p>The screen lists all users of the stimulator database, sorted by their last name. Scroll through the list by turning the knob. Once the desired client is displayed in the white field, confirm with Next.</p> <p><i>Note: This screen does neither appear in one user mode nor while using the patient USB.</i></p>
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	<h3>Choose profile to edit</h3> <p>The white field above the turning knob shows the user`s profile with its parameters:</p> <ul style="list-style-type: none"> • Therapy mode (e.g. RehaMove Leg constant), individual name of the profile • Stimulated muscle groups with corresponding current and channels (in color) in table format • Frequency (Hz), pulse width (μs) and ramp • Times for warm up, stimulation and cool down in minutes <p>Scroll through the profiles by turning the knob. Above the turning knob you see two numbers, they display the number of the current profile and the number of all the profiles assigned to this user. E.g. "1/7" means that the user has 7 profiles, the one displayed in the white field is profile 1.</p> <p>Futhermore you see a small figure above the turning knob. If you press the knob, a pop up will display the template of the selected profile with the electrode positioning.</p> <p><i>Note: This option is not available in individual electrode placements.</i></p> <p>Once the desired profile is displayed in the white field, press Start training in order to start the session.</p> <p>Use buttons: Advanced: to see advanced options and Edit profile Back: Go back to the window "Choose user"</p>
	<h3>Advanced options</h3> <p>Press Edit profile to change settings. Press Delete profile to delete it. Press History data to access the training history of the selected profile. Button is greyed out if there are no session history data available, i.e. if the profile has not been used before.</p> <p><i>Note: The user will be automatically deleted on the USB flash drive, if the user is deleted on the stimulator and the USB is connected to it at this time.</i></p>



Channel configuration 17:00:51 **Charged**

Unilateral 1/6

Bilateral

Individual

Leg left 2-channels

Back Next

Qu

BF

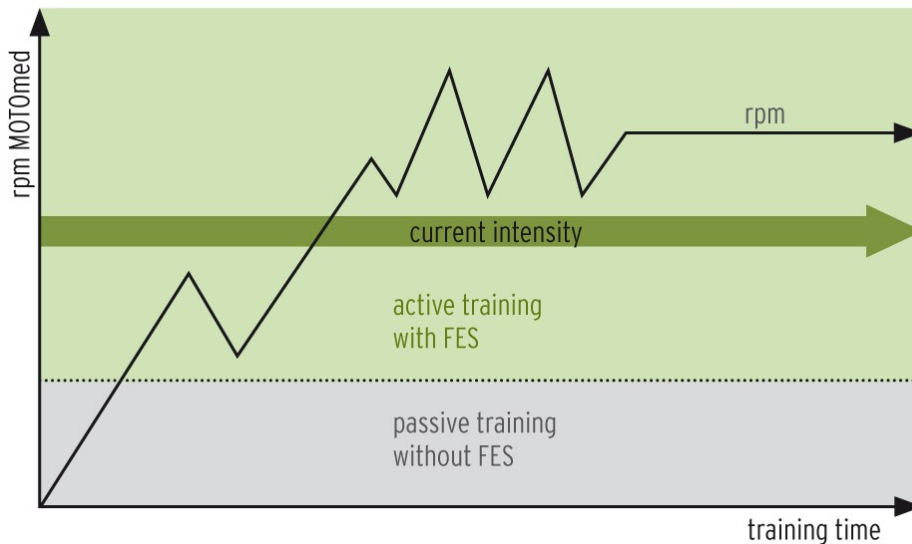
For editing the profile

You enter the profile creation in the window "channel configuration" .

Continue as described in chapter "Create a new user program".

5.6.3 Constant Stimulation Training

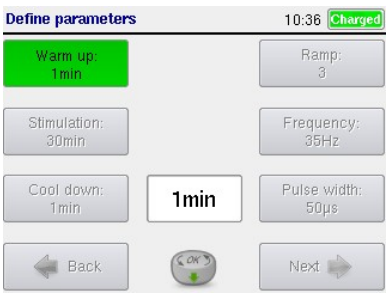



This training mode works with constant parameters. The pulse width remains the same regardless of the user's performance. By using the buttons of the stimulator you can change the resistance level as well as the speed of the MOTomed viva 2 (at least 10 rpm).


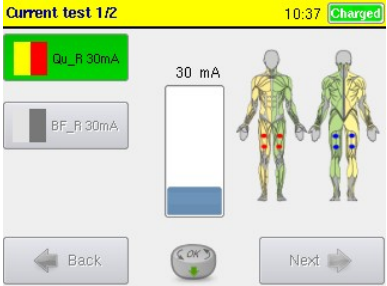


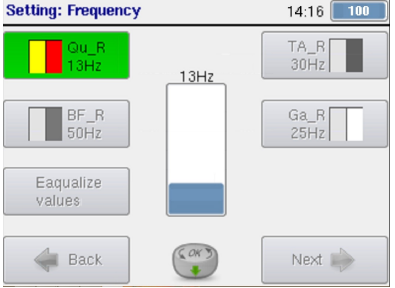
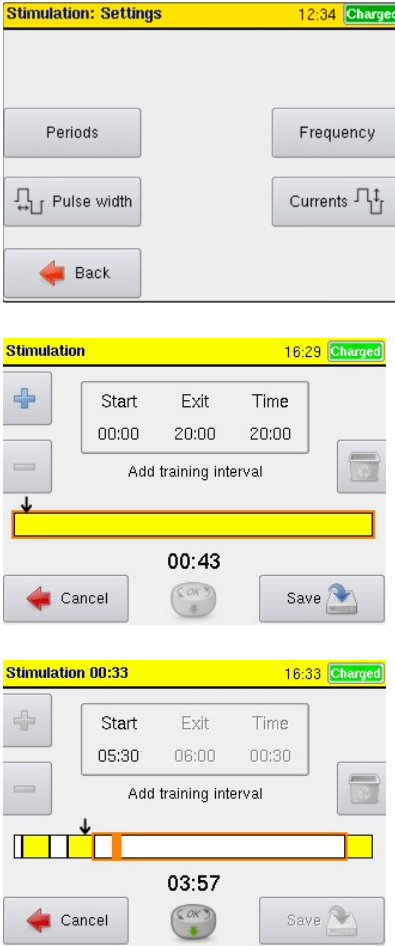
Turn the movement exerciser on and leave it in the start screen. Turn on stimulator and start training.


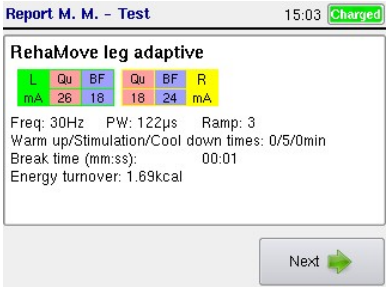
NOTE! For safety reasons the stimulation is automatically deactivated below 10rpm.

	<p><u>Warm up</u></p> <p>The warm up window shows the remaining time for the warm up phase.</p> <p>Use buttons:</p> <p>Resistance: adjust the resistance level of the MOTomed viva 2</p> <p>Speed (rpm): adjust the speed of the MOTomed viva 2</p> <p>Break: Pause the warm up</p> <p>Stimulation: Stop the warm up and start the stimulation</p>
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	<p><u>Warm up: Adjust stimulation during warm up:</u></p> <p>Stimulation during warm up is set in minutes. Intensity is expressed as a percentage (%) and refers to the defined pulse width (respectively max. pulse width in adaptive mode). Intensity settings are changed in 5 % periods. The defined stimulation intensity is shown on the warm up screen. After warm up, the stimulation increases gradually until the defined pulse width has been reached.</p>
	<p><u>Warm up: Adjust MOTomed speed</u></p> <p>In order to change the speed of the MOTomed during session, press the button Speed (rpm). A bar displaying the chosen speed in rpm then appears in the middle of the screen. In order to change the speed, use the turning knob. Press the turning knob to confirm your choice.</p> <p><i>Note: In the stimulation phase the speed remains as high as during warm up.</i></p>
	<p><u>Warm up: Adjust the MOTomed resistance level</u></p> <p>In order to regulate the resistance level of the MOTomed during session, press the button Resistance. A bar displaying the resistance level chosen appears in the middle of the screen. To change the resistance level, use the turning knob. Press the turning knob to confirm your choice. For more support by the motor, choose a lower resistance level. To achieve more resistance during session, choose a higher resistance level.</p> <p><i>Note: In the stimulation phase the resistance level remains as high as during warm up.</i></p>
	<p><u>Stimulation</u></p> <p>If the stimulation is active, the status indication line is colored in yellow.</p> <p>There are five different feedback screens within the stimulation. For more information please see chapter Feedback Screens</p> <p>Use buttons: Pin/Arrow: The pin symbol is shown in the top left. The current feedback screen stops by pushing the pin button. The pin symbol is replaced by the arrow symbol. The next feedback screen appears if the user taps the button within 5s again. The user gets back into switch</p>

	<p>mode if the button is pushed after 5s.</p> <p>Settings: The parameters pulse width, frequency and current can be changed during the session (see below)</p> <p>Stimulation break: The button, placed at lower left above the button "break", deactivates the stimulation only. The indication line is then colored in grey and the word "Stimulation" is set to "Stimulation break". The MOTomed and the therapy time continue.</p> <p>Break: Stimulation, therapy time and MOTomed are stopped. The screen shows the word "Break" and the break time. Push "Cancel" to finish the therapy session. Push "Next" to get back to stimulation screen and continue the therapy session.</p> <p>Bicycle: Is shown if the user cycles actively</p> <p>Resistance: Adjust the resistance level of the MOTomed viva 2 (see Warm Up in this chapter)</p> <p>Speed (rpm): Adjust the speed of the MOTomed viva 2 (see Warm Up in this chapter)</p> <p>Cool down: Cancel the stimulation and start the cool down phase (see below)</p>
	<p><u>Stimulation: Pulse width settings</u></p> <p>To adjust the pulse width during the session, press the button Pulse width in this window.</p> <p>If you want to set or change the value of a particular channel, press the corresponding button.</p> <p>Press the button next to the field for the channel or muscle you want to change.</p> <p>A bar with adjustable pulse width in μS pops up in the middle of the screen.</p> <p>In order to change the pulse width, use the turning knob.</p> <p>Press the turning knob to confirm the setting.</p>
	<p><u>Stimulation: Current settings</u></p> <p>To adjust the current during the session, press the button Current in this window. Thereupon a new window pops up which shows all active channels with corresponding muscle groups as well as the present current. To select more than 4 channels, press Next. In order to select a channel, press the button next to the associated picture on the screen.</p> <p>If one channel is selected, it is marked green and a bar with set current in mA pops up in the middle of the screen.</p> <p>Use the turning knob:</p> <ul style="list-style-type: none"> • Change the current by turning the knob

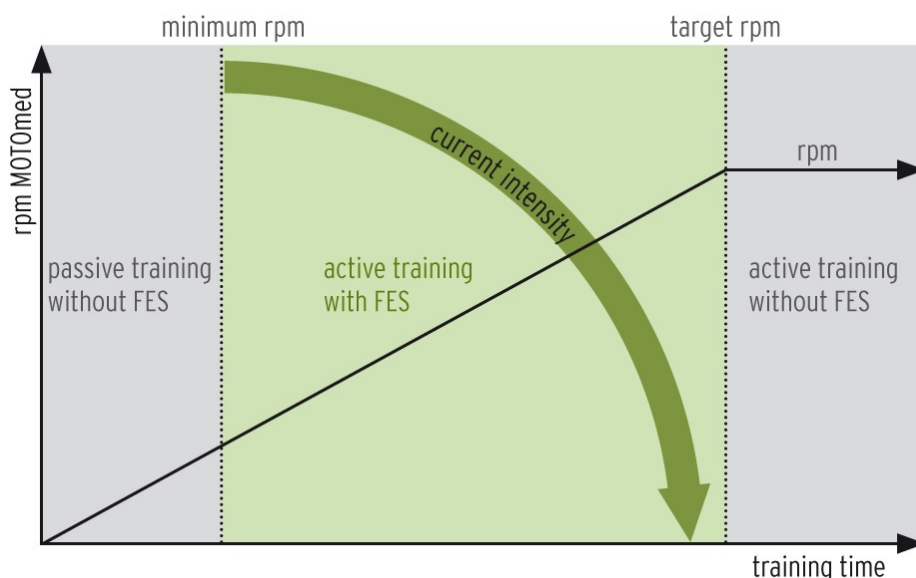
	<ul style="list-style-type: none"> • Confirm the current by pressing the knob <p>After having adjusted the parameters, the channel is not marked green anymore. Now, the current of another channel can be changed.</p>
	<p><u>Stimulation: Frequency settings</u></p> <p>To adjust the frequency during the session, press the button Frequency in this window. If you want to set or change the value of a particular channel, press the corresponding button. Press the button next to the field for the channel or muscle you want to change. A bar with adjustable frequency in Hz pops up in the middle of the screen. In order to change the frequency, use the turning knob. Press the turning knob to confirm the setting.</p>
	<p><u>Stimulation - Adjust intervals</u></p> <p>Press button periods to adjust intervals during training. Stimulation time can be adjusted in several intervals. Stimulation is active when the upper bar on the screen is marked yellow. Pauses may adjusted during stimulation to enable a break within the training.</p> <p>Use buttons:</p> <p>Plus: Add stimulation times by pressing the plus button. Stimulation times are adjusted in periods of 0.5 minutes by turning the knob. Confirm the stimulation period by pressing the knob.</p> <p>Minus: Added pause times will be deleted.</p> <p>Recycle bin: Complete interval will be deleted.</p> <p>Start shows the time when the pause starts. End shows the end of pause intervals. Duration/Period shows pause in minutes.</p> <p>Press button Save to store the adjustments.</p> <p>These adjustments allow a reaction on clients' individual muscle fatigue during stimulation and helps to complete a whole therapy session.</p>

	<p><u>Cool down</u></p> <p>The Cool down window shows the remaining time for the Cool down phase.</p> <p>Use buttons:</p> <p>Speed (rpm): adjust the speed of the MOTomed viva 2</p> <p>Resistance: adjust the resistance level of the MOTomed viva 2</p> <p>Break: Pause the Cool down</p> <p>Exit: Cancel the Cool down and continue with the report window</p>
	<p><u>Report</u></p> <p>The report shows the times for warm up, stimulation and cool down as well as the entire duration of breaks during the session, and the energy consumption in kcal.</p> <p>Use buttons:</p> <p>Next : Close the report and go to window "Select application"</p>

5.6.4 Adaptive Stimulation Training

This training program automatically adapts to the clients' physical condition.

The user starts session at a low base speed. The goal is to achieve a certain speed fixed prior to session (target speed). The program recognizes the difference between the current and the fixed target speed. Based on this, it automatically regulates the stimulation intensity by changing the pulse width.



When the user approaches the target speed, the pulse width decreases. The maximum value can be adjusted. During the automatic regulation the pulse width is likely to change, especially when it is close to the target speed. Little deviations in the speed may occur as well. How easily the user manages to reach the predetermined target speed can be varied with the resistance level selected, meaning that a lower resistance level requires less power than a higher resistance level. The rate of speed (rpm) is displayed on a graph on the screen of the stimulator. The target speed is shown as vertical line. Adjust the resistance level as follows: Increase resistance level if the speed is always at the vertical line (target speed) and decrease in reverse case.

The optimal setting for an automatic adaption of the stimulation intensity is a minimum pulse width that complies with about half of the maximum pulse width. For example: A minimum pulse width of 200 μs and a maximum pulse width of 400 μs .

The resistance level of the MOTOmed viva 2 can be adapted individually from the stimulator. If the pulse width reaches the upper part of the bar, the resistance level should be decreased. If it reaches the lower part of the bar, it needs to be increased.

Recommended start values (independent of the user's individual stimulation conditions):

- at the MOTOmed: speed and resistance level are set from stimulator
- at the stimulator: base speed at 20 rpm, resistance level: 0 (zero)

Start the movement exerciser and leave it in the start screen. No further operation is allowed! Turn on the stimulator and start training. **Speed of the MOTOmed must be at least 10 rpm.**

NOTE! The stimulation is deactivated below 10 rpm for safety reasons.

For information about settings and feedback screens see chapter 5.6.3: „RehaMove Arm and Leg Training - Integrated Operation (FES 3-Interface) - Constant Stimulation“

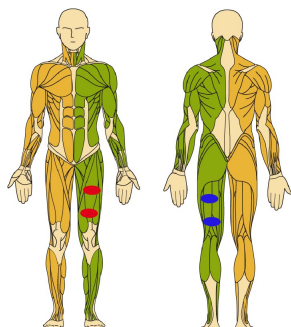
5.6.5 Templates for common Muscle Combinations in Leg Training

This list contains a number of common muscle combinations being stimulated in a session. Apart from these templates the combination of any other muscle group is possible.

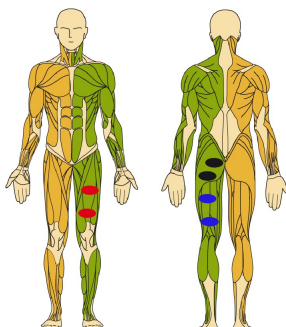
For further request please contact the manufacturer.

5.6.5.1 Unilateral stimulation: left leg

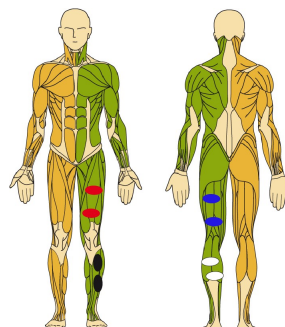
Leg left 2 Channels



Leg left 3 Channels

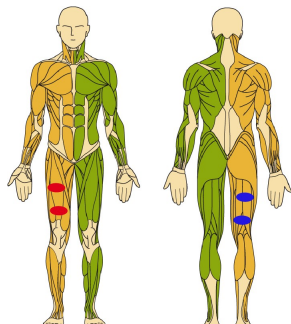


Leg left 4 Channels

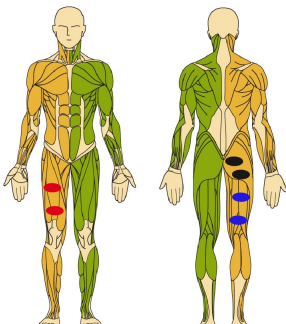


5.6.5.2 Unilateral stimulation: right leg

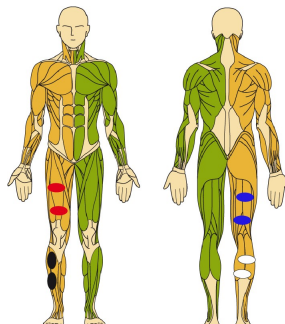
Leg right 2 Channels



Leg right 3 Channels

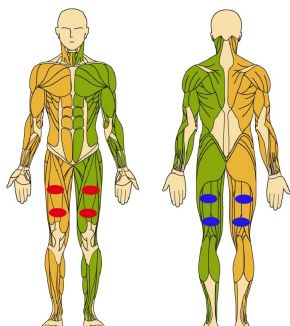


Leg right 4 Channels

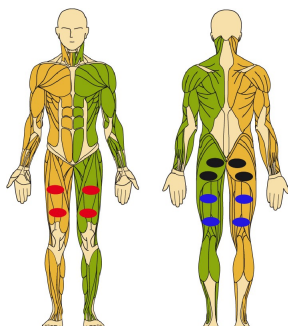


5.6.5.3 Bilateral stimulation of legs

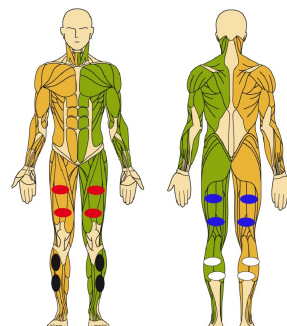
Leg bilateral 4 Channels



Leg bilateral 6 Channels



Leg bilateral 8 Channels



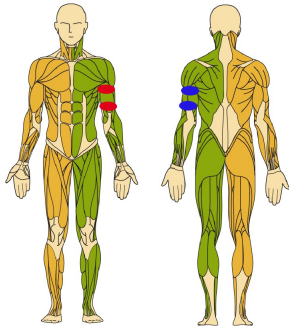
5.6.6 Templates for common Muscle Combinations in Arm Training

The list includes a number of common muscle combinations being stimulated in a session. Apart from these templates the combination of any other muscle group is possible.

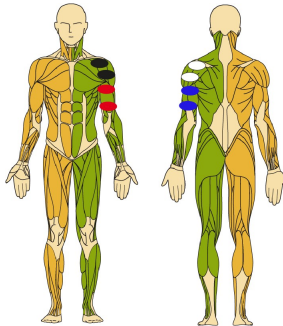
For further request please contact the manufacturer.

5.6.6.1 Unilateral stimulation: left arm

Arm left 2 Channels

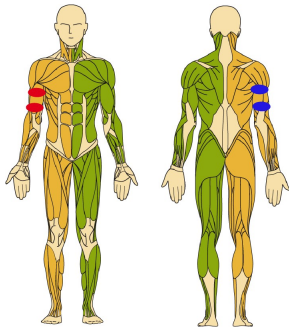


Arm left 4 Channels

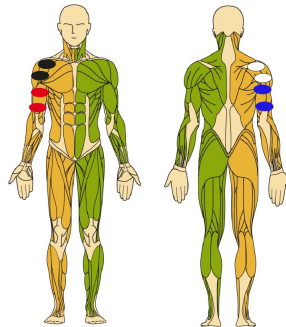


5.6.6.2 Unilateral stimulation: right arm

Arm right 2 Channels

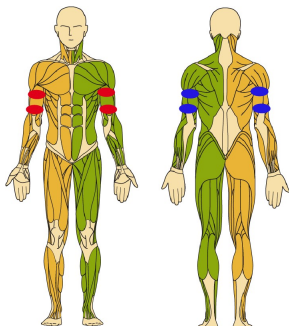


Arm right 4 Channels

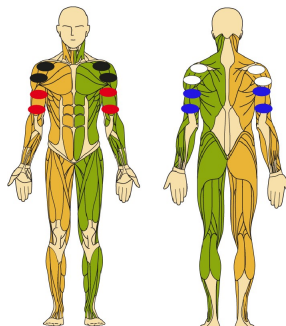


5.6.6.3 Bilateral stimulation of arms

Arm bilateral 4 Channels



Arm bilateral 8 Channels

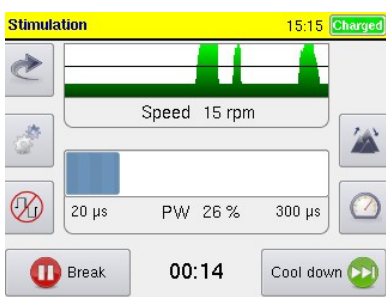
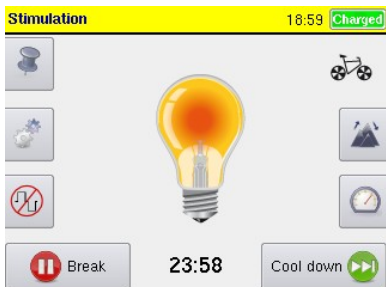
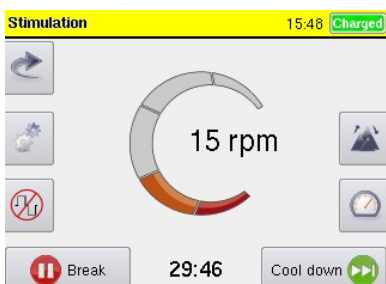


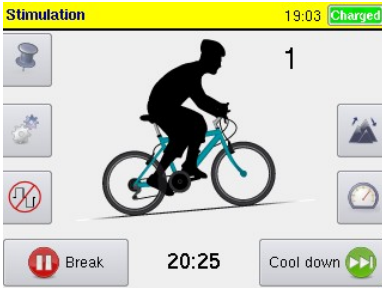
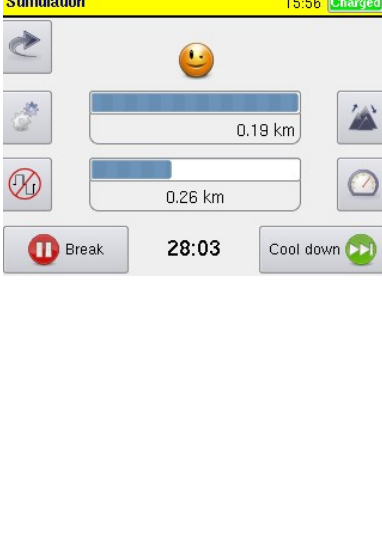
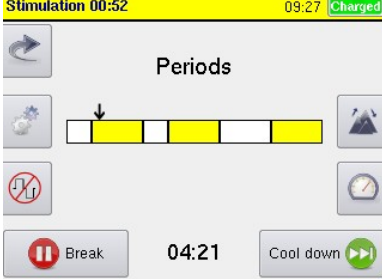

5.6.7 Details about the Feedback Screens

The motivation of the patient to perform with the MOTomed is essential to reach the therapy goal. The feedback screens help the patient to work concentrated and to perform correctly. The graphics on the feedback screens inform about the session progress and session settings. Further, the therapist is informed about the current parameter settings and the patient's active performance.

The feedback screens appear during the stimulation only if the protocol is set to integrated operation, so-called FES3 (see chapter 5.6: RehaMove Training - Integrated Operation (FES 3-Interface)).

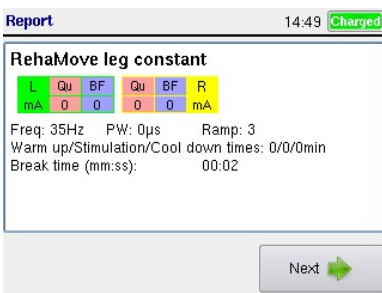
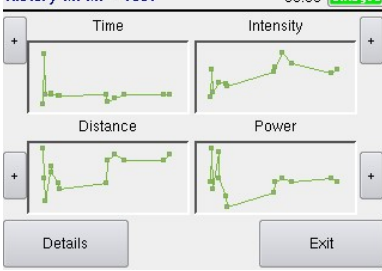
The header of all feedback screens shows the time and the battery charge status.
During current output the header is marked in yellow.


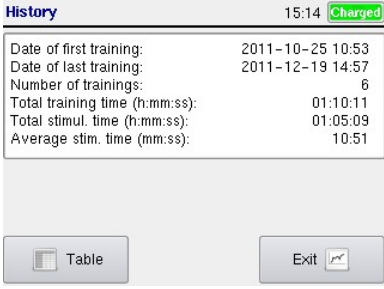
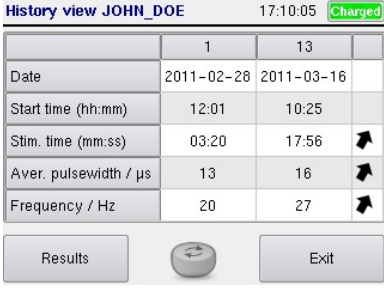
	<p><u>In adaptive training: speed and target speed</u></p> <p>The window shows</p> <ul style="list-style-type: none"> • the current speed / rpm of the client (green graph, number below the upper picture) • the target rpms (black line in the upper picture) • the amount of pulse width used as share of the overall pulse width in the lower bar • lower and upper limits as set: values of min and max pulse width • percentage of max pulse width currently used
	<p><u>Active performance</u></p> <p>The graphic shows the current active performance of the user in form of a light bulb. The harder the client pedals actively, the brighter the bulb will shine. There are five different active power levels/intensity levels.</p>
	<p><u>Speed/ rpm</u></p> <p>In the center of the graphic the current speed in rpm is shown. The speed display is updated every two seconds.</p>

	<p><u>Resistance level</u></p> <p>There is a bicycle in the center of the graphic. The bicycle incline changes according to the chosen resistance level. There are five different graphics for incline levels. The current resistance value is shown in the upper right corner.</p>
	<p><u>Active distance</u></p> <p>The graphic shows the patient's active distance covered in form of a progress bar. The distance is displayed in km. The distance of the last session is shown at the end of the progress bar.</p> <p>If the user reaches the end of the progress bar, a second progress bar will be shown below the first one and a smiley is displayed in the center above the bar. Kilo meters are doubled at the end of the first progress bar and are placed at the end of the second progress bar. If also the second progress bar reaches the end, it will be set back.</p> <p>This graphic is not shown in the very first session of the user or as long as the user has not cycled actively at all.</p>
	<p><u>Intervals</u></p> <p>The progress bar displays the stimulation time including pauses. Stimulation time is shown in minutes. Stimulation is active when the bar is marked yellow. Stimulation is paused when the bar is marked white.</p>
	<p><u>Overview/ Therapists screen</u></p> <p>All parameters on this graphic refer to the ongoing therapy session:</p> <ol style="list-style-type: none"> 1. Active distance = distance covered while the user cycled actively. The user is "active" if the current speed is at least 2rpm faster than the set passive speed. 2. Active performance of the user is specified in watt (W). 3. Average active performance results from the

	<p>values of the active performance since start of the therapy session. It is specified in calories (cal).</p> <ol style="list-style-type: none"> 4. Speed is the current MOTomed speed in revolutions per minute (rpm). 5. Pulse width values depend on the training mode. During adaptive mode, the current pulse width is calculated dynamically between [min] and [max] pw. During constant mode, the set pulse width value is shown . 6. Resistance level as set for the MOTomed
--	---

5.6.8 Access Training History after Session is finished

	<p><u>Report</u></p> <p>The report at the end of your session shows the times for warm up, stimulation and cool down as well as the entire duration of breaks during the session.</p> <p>Use buttons: Parameters/ Save changes (active if parameters were changed): to save parameter changes as start settings for the next session. Next: Go to "History"</p>
	<p><u>History: graphic display</u></p> <p>This window shows the progression of the therapy by means of a graphic display. The history for each parameter is shown in a table.</p> <p>Use buttons next to the graphic display to see for each therapy session in chronological order: Time: the stimulation time Intensity: the stimulation intensity Distance: the active distance Power: the power created</p> <p>Use buttons: Table: For an overview about the progression of each stimulation parameter Exit: Go back to the start window</p>

	<p><u>History: graphic display in detail</u></p> <p>Once one parameter from the graphic display is selected, a new window comes up where each parameter is shown in detail using a coordinate system. The y-axis indicates the unit of each parameter whereas the x-axis gives the timeline.</p> <p>NOTE: Values of the x-axis do not exactly relate to the date display. The space between for instance March 8th and March 9th can be interpreted as 24 hours time span. Depending on the time of the therapy session, the value of the parameter shifts on the x-axis.</p> <p>Use buttons:</p> <p>Next: To switch between graphic displays for each parameter</p> <p>Overview: To go back to the general overview of parameters</p>																								
	<p><u>History: Overview</u></p> <p>This window shows details of the entire training course of the selected user program.</p> <ul style="list-style-type: none"> • The date and time of the first and last session • The number of therapy sessions • The total duration of training • The total duration of stimulation • The average stimulation time per session <p>Use button:</p> <p>Table: To show details of individual therapy sessions</p>																								
 <table border="1" data-bbox="199 1368 584 1563"> <thead> <tr> <th></th> <th>1</th> <th>13</th> <th></th> </tr> </thead> <tbody> <tr> <td>Date</td> <td>2011-02-28</td> <td>2011-03-16</td> <td></td> </tr> <tr> <td>Start time (hh:mm)</td> <td>12:01</td> <td>10:25</td> <td></td> </tr> <tr> <td>Stim. time (mm:ss)</td> <td>03:20</td> <td>17:56</td> <td>↗</td> </tr> <tr> <td>Aver. pulsewidth / μs</td> <td>13</td> <td>16</td> <td>↗</td> </tr> <tr> <td>Frequency / Hz</td> <td>20</td> <td>27</td> <td>↗</td> </tr> </tbody> </table>		1	13		Date	2011-02-28	2011-03-16		Start time (hh:mm)	12:01	10:25		Stim. time (mm:ss)	03:20	17:56	↗	Aver. pulsewidth / μ s	13	16	↗	Frequency / Hz	20	27	↗	<p><u>History: Table</u></p> <p>This window shows parameters for each therapy session. To select one session, scroll in the second column. The right column shows the final session. The last column indicates a tendency/ trend, starting with the selected until the last session by using an arrow.</p> <p>Following information is shown:</p> <ul style="list-style-type: none"> • The number of the therapy session • The date • The start time • The stimulation time • The average pulse width during the session • The frequency <p>Use button:</p> <p>Results: To see further parameters (not included in FES2)</p> <ul style="list-style-type: none"> • The active training time
	1	13																							
Date	2011-02-28	2011-03-16																							
Start time (hh:mm)	12:01	10:25																							
Stim. time (mm:ss)	03:20	17:56	↗																						
Aver. pulsewidth / μ s	13	16	↗																						
Frequency / Hz	20	27	↗																						

History view M. M. – Test 17:01 Charged			
	1	2	
Time active / s	59	47	↘
Distance active / m	310	270	↘
Aver. Power / W	12	17	↗
Symmetry L / R	53% / 47%	51% / 49%	
Energy / kcal	1.69	1.91	↗
<div style="display: flex; justify-content: space-between; align-items: center;"> Currents L Exit </div>			

- The active distance (m)
- The average performance (W)
- The symmetry L/ R in % per side
- The energy / kcal

Use the turning knob to page through sessions.

Use button:
Current L: To access the window "Details of training course/ Current" for the left side of the body

History view JOHN_DOE 17:10:20 Charged			
	1	13	
Qu_L / mA	---	30	
TA_L / mA	---	30	
BF_L / mA	---	30	
Ga_L / mA	---	---	
GL_L / mA	---	50	
<div style="display: flex; justify-content: space-between; align-items: center;"> Currents R Exit </div>			

History: Details of the Training Course / Current

Following information is shown:

- The current for each muscle on the left and right side

Use the **turning knob** to page through sessions.

Use button:
Current R: To access the window "Current details" for the right side of the body

5.6.9 Access Training History

Choose profile J. Doe 08:25 Charged							
<p>RehaMove leg constant, 2_Channel</p> <table border="1" style="width: 100%; text-align: center;"> <tr> <td style="background-color: #90EE90;">L</td> <td style="background-color: #FFB6C1;">Qu</td> <td style="background-color: #ADD8E6;">BF</td> </tr> <tr> <td>mA</td> <td>10</td> <td>22</td> </tr> </table> <p>Freq: 35Hz PW: 50µs Ramp: 3 Warm up/Stimulation/Cool down times: 1/30/1min</p> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="display: flex; gap: 10px;"> Advanced 1 / 7 New profile </div> <div style="display: flex; gap: 10px;"> Back Start training </div> </div>		L	Qu	BF	mA	10	22
L	Qu	BF					
mA	10	22					


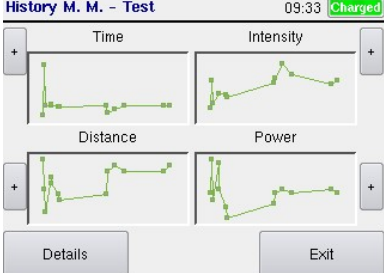
Choose profile to see history of trainings of

The white field above the turning knob shows the user`s profile with its parameters:

- Therapy mode (e.g. RehaMove Leg constant), individual name of the profile
- Stimulated muscle groups with corresponding current and channels (in color) in table format
- Frequency (Hz), pulse width (µs) and ramp
- Times for warm up, stimulation and cool down in minutes

Scroll through the profiles by **turning the knob**. Above the turning knob you see two numbers, they display the number of the current profile and the number of all the profiles assigned to this user. E.g. "1/7" means that the user has 7 profiles, the one displayed in the white field is profile 1.

Use buttons:
 Press **Advanced:** to see advanced options and **Access Training history data** of the selected profile
Back: Go back to the window "Choose user"

	<p><u>Advanced options</u></p> <p>Press History data to access the session history of the selected profile. Button is greyed out if there are no training history data available, i.e. if the profile has not been used before.</p>
	<p><u>History: graphic display</u></p> <p>Continue as described in chapter Access Training History after Session is finished</p>

5.6.10 Finishing a Stimulation Session

1. Stop stimulation, switch off stimulator
2. Stop the movement trainer
3. Disconnect electrodes from cables and detach from the skin
4. Take the feet or arms of the client out of the pedals and arm rests, remove the tilt protection

5.6.11 RehaMove PC Software

5.6.11.1 General Information

5.6.11.1.1 About RehaMove-PC

The PC program "RehaMove2 PC" extends the management of data for the RehaMove2. The PC program easily:

- evaluates/ analyzes
- documents/ prints
- modifies and complements files from stimulator RehaStim2.

The PC program "RehaMove2 PC" contains the following menu items:

- Read USB flash drive and store data: Data are read after connecting the user USB flash drive to the USB port of the PC. Modified data can be saved onto USB flash drive.
- User data: Details describing the user can be evaluated, details of a new user can be entered.
- Training parameters: The PC program manages the parameters set for therapy with the RehaMove2. Parameters can be modified and extended.
- History data: The therapy parameters and the output performed by the user during the session are exported to USB flash drive. This allows the analysis of the session with the target to optimize the parameter settings. The results can be visualized in a table and be printed.
- Backup of data: Data of **all** users of one stimulator or in the PC data base are stored in one specific data backup file in one step. Thereby data can be traced back in case of data loss.
- Settings: The program surface can be applied to the individual needs of the user. System language included.

5.6.11.1.2 Read USB Flash Drive and Store Data

The data on the **user USB flash drive** are transferred to the RehaMove data base on the PC and back. For this purpose connect the user USB flash drive to the USB port of the PC.

Click "Apply" to transfer data from USB flash drive into PC data base.

Confirm "Read USB flash drive" in the menu. Data are compared with the data base of the PC while reading the USB flash drive. Data are synchronized at once. If the therapy parameters have been modified on the stimulator or on the PC, a message is displayed

on the screen asking if the current parameters shall be continued to use.

A parameter different on the memory stick and in the PC data base is shown. Confirm to store the latest therapy parameters changed on the PC data base. New results from therapy sessions are automatically added to former data records in the history data. The stimulator RehaStim2 generates and stores exactly one history data record for each therapy session. History data document therapy development and cannot be changed.

Store data onto user's USB flash drive to continue using therapy parameters changed on PC. Click menu item "Save to USB flash drive". All data of the current selected user from the user list is transferred to USB flash drive. The current user and training profile are always displayed in the upper screen. Before storing to USB flash drive it is verified if the memory stick is empty or contains data of the same user. If data of another user exist the system asks if these should be deleted and be overwritten by data of the current user.

Please Note: Only data of ONE user can be stored onto user's USB flash drive. Reading of the USB flash drive occurs analog to the user's memory stick procedure, if **backup USB flash drive** is used instead of user's USB flash drive. Indeed, the list of backup memory stick contains data of all users. Click "Data"/ "Save backup on USB flash drive" in the upper window bar to store data on backup USB flash drive.

Click "Eject USB flash drive" to disconnect the memory stick from the PC. This conforms the Windows function to remove external devices from the PC.

Please do always use this option before removing the memory stick from PC to prevent data loss.

5.6.11.1.3 Settings

Click menu "File/Options" to select following items:

- Language
- Show or hide the time - additionally to the date - in the **table** or graphic of the **training parameters** and **history data**
- Type of **graphic**

5.6.11.2 User Management

5.6.11.2.1 User List

Activate the menu item "users and profiles" to see the user list consisting of two tables. The left table displays the user's last name, first name and the date of birth. After choosing a user by clicking the mouse button, all existing training profiles of this user appear in the right table.

The first column displays the name of the training profile which is given while creating a new profile. Training program and program extension describe basic performance of a training profile. Total number of the user's previous performances are shown in the column "training sessions". Date of the last session is displayed in the right column. The chosen current user as well as the chosen profile are always displayed in the upper screen. All further activities to check **training parameters** and to analyze **history data** refer to this user and profile.

Click "New user" to enter a new patient in the PC data base. Click "Delete user" to delete the patient and all existing training profiles from the PC data base. Click "New configuration", "Edit configuration" or "Delete configuration" to add, modify or remove a profile.

The user's data (last name, first name and date of birth) cannot be modified.

5.6.11.2.2 Create New User

Enter last name, first name and date of birth of the new user (mandatory fields). Click "Save" to import data to the data base. It is not possible to store users with the same last name, first name or date of birth. The maximum length of name or first name is 12 characters.

5.6.11.3 Therapy and Training Parameters

5.6.11.3.1 Training Parameters

The screen displays the training parameters. Amongst others, this includes settings for the stimulation and for the motion trainer MOTomed. These **training parameters** and the user's **history data** form the **training profile**.

Defining a new group of training parameters and therewith a new training profile requires a unique profile name with a length of a maximum of 12 digits. An already existing profile name cannot be used for another profile. Trying this an error message is displayed. Profile name, training program and program extension may not be modified afterwards.

Only experienced therapists or persons trained on the RehaMove2 system are allowed to modify the training parameters. Improper settings may endanger the user.

Placing of electrodes on the body is chosen by template arrow keys. Click into the table "channel" to see a drop down box which contains predefined muscles. There, another muscle can be selected for stimulation. Start and stop angles for stimulation with RehaMove are modified in the table directly. A modification of the angles may significantly influence the performance of the user. Due to this a special care is required. The arrangement of the electrodes on the body is selected by the cursor keys.

Click "Save parameters" to store data after creating a new profile or rather modification. Click "Save to USB flash drive" to import data directly to USB flash drive. Click "Print" to carry out documentation of training parameters.

5.6.11.4 History Data

5.6.11.4.1 Overview History Data

Activate the menu item "History data" to see the data of the chosen user and profile.

5.6.11.4.2 Table

The table demonstrates the chosen user including user's profile, **training parameters** and - if available - the **history data** saved after each therapy session. The table can be

printed. In case that a value remains unchanged compared to last therapy session, the print of the table shows the character "...". This enables better visualization.

5.6.11.4.3 Graphic

Among the tabular listing of the training parameters and the history data, graphics often give clear information. The graphic demonstrates the chosen user including user's profile, **training parameters** used for each therapy session and - if available - the **history data** saved after each performance.

As needed, curves can be displayed in one graphic (same unit of measure) or in up to four graphics positioned on top of each other (different unit of measure). This allows the time based comparison of history data. This option is realized by configuration.

Click "Group of history data" in the drop-down list to select configurations. Click "New configuration" to create a new configuration. Click "Edit configuration" to modify existing configurations. This is realized by clicking the window "Group of history data".

Click "Print" to print the graphic. Therewith the health insurance, the therapist or the user receive clearly represented information to results of the sessions in combination with, e.g. the parameters of stimulation.

Activate menu item "**File/Options**" to modify the graphic presentation additionally.

5.6.11.4.4 Configuring Graphic

Click "Edit configuration" in the **graphic** display to modify predefined graphic configurations as well as configurations created by the user. The configuration name is displayed in the upper screen. Create individual configurations by modifying the therapy parameters and history data of an existing training profile.

Click "OK" to store individual configurations.

Click "Delete Group" to delete a configuration.

Up to four single graphics positioned on top of each other can be shown in a general survey. These graphics are time based. Please note that each graphic documents data with the same measurement unit.


5.7 RehaMove Letto2

The RehaMove Letto2 may help to balance lack of movement in patients confined to bed. Patients can train actively, from a hospital bed or a therapy chair. The RehaMove Letto2 provides a well-rounded therapy to patients in stationary care. It can also be effectively applied in home care.

Ask the manufacturer Hasomed for a RehaMove Letto2 license.

The RehaMove Letto2 menu navigation corresponds to the settings of the RehaMove leg training. Settings of FES 3 Interface, see chapter: "RehaMove Arm and Leg Training - Integrated Operation (FES 3-Interface)"

Due to the patient's lying position, the angles of the corresponding muscles change by minus 20% compared to the training with the motion trainer MOTomed viva2. These angles are included in the RehaMove Letto2 adjustments. No further settings are necessary.

	<h3>RehaMove Letto2</h3> <p>The window "Choose program" contains the following training options:</p> <ul style="list-style-type: none"> • RehaMove Leg • RehaMove Arm • RehaMove Letto • Sequence <p>Choose appropriate training by pressing the corresponding button.</p> <p>For further menu navigation see selected protocol FES3.</p>
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5.8 RehaMove2 for Children: RehaMove2 Gracile

The RehaMove for children offers the little patients all the advantages of Functional Electrical Stimulation combined with a movement therapy on the MOTomed Gracile of the company Reck.

The leg training with the RehaMove Gracile is carried out exactly the same way as the RehaMove leg training. The arm training with the RehaMove Gracile is carried out exactly the same way as the RehaMove arm training. How to set up the bracket, please see chapter Preparations and Setup of Stimulator Bracket.

Children should never use the RehaMove without supervision.

For additional safety considerations, as e.g. correct seating, use of special accessories, please refer to the MOTomed Gracile user manual available from the MOTomed manufacturer Reck MOTomed/ Germany.

6 General Stimulation/ Sequence Mode

With programs for general stimulation, the stimulator can be used as a free standing device for a wide range of applications.

In the so-called sequence mode, movements can be generated in individual stimulation sequences (e.g. hand flexion/ extension). Thus, the stimulator can be used as stand-alone device in order to increase training intensity, selectivity or complexity. A cyclic, automatically repetitive stimulation can be generated and adjusted according to the requirements of the user. Each channel is activated once per rotation or sequence. The session runs with constant current and pulse width.

The RehaStim2 sequence mode provides **templates** for a variety of movement patterns for arms, legs or torso. The respective percentages or seconds are predefined in the configuration and can be adjusted individually.

The motion sequences can be adjusted either **in percentages or seconds**. A complete cycle of movement is defined as 100% or 4 seconds (the latter can be adjusted). In **percentage mode**, the 100% are classified according to the desired stimulation times and pause times. The **adjustment in seconds** makes it possible to define stimulation times and pause times by entering the desired second values. When extending the period, a pause is inserted; start time and stop time remain unchanged and absolute.

Different **types of triggers** are available:

- Automatic: sequence starts as soon as the last one is finished
- Manual: sequence starts when you press the **start** button on the screen
- External single Trigger: sequence starts after pressing an external trigger, see External single trigger
- External double Trigger: sequence starts after pressing an external trigger, see External double trigger

The operation follows the same principles as the RehaMove training as in RehaMove Leg Training and Arm Training.

Please note!

Starting from software version 2.4 the single trigger mode can be used via the external double trigger. The sequence in single trigger mode can be initiated by pressing button 1 on the external double trigger.

6.1 Notes on the Therapy with the Sequence Mode

The notes on the therapy with sequence mode correspond with the notes on therapy with RehaMove2. Please see chapter "Notes on therapy with RehaMove2".

6.2 Safety Measures

Before you start:

- Check that the supply voltage of the unit matches with your main current. Only connect the RehaMove2 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.


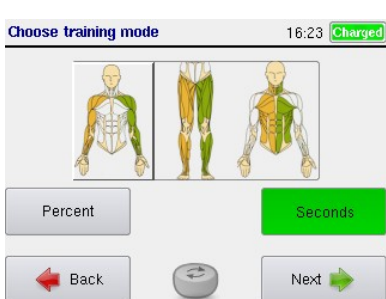
- Use only properly earthed power outlets. Use only the original power supply delivered by the manufacturer HASOMED GmbH. If an electric cable has been damaged, stop session immediately and contact the manufacturer.
- Connect cables in a way that no person walking by could get caught in the cables and these can not be damaged.
- Mount the unit on even and non-slippery surface in order to ensure stability. If the device has just been delivered, leave it for an hour at room temperature.

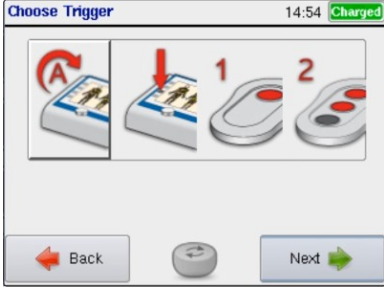


When using the sequence mode to initiate **steps**,

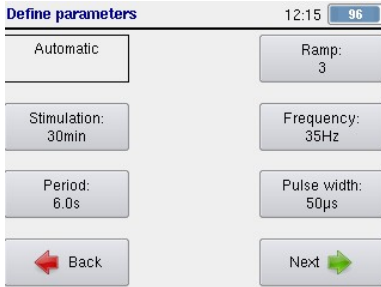
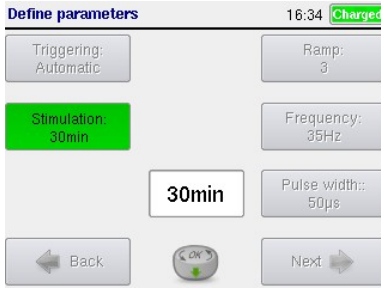
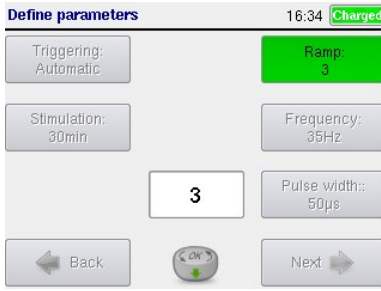
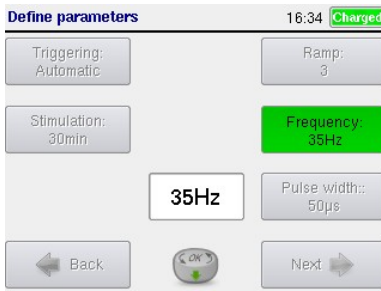
- take appropriate precaution measures to prevent risk of falls, e.g. handle bar support
- never train without supervision of a therapist or a suitable person at the discretion of the treating physiotherapist

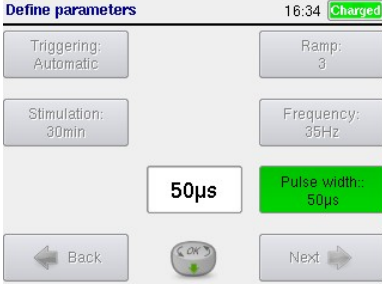
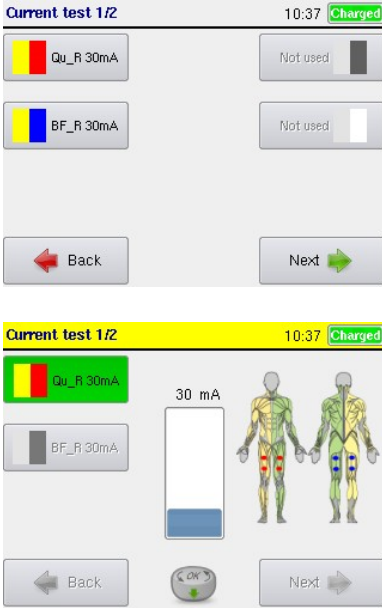
6.3 Create new Users and new Profiles

Please follow the instructions in chapter RehaMove Arm and Leg Training - Integrated Operation (FES 3-Interface) sub-chapter Create new users and new user profiles.

	<p><u>Select program for new user profile</u></p> <p>Select desired application by pressing the button next to the displayed application button. Transparent buttons are not active and cannot be pressed.</p> <p>Use buttons:</p> <p>RehaMove Arm: Arm training with RehaMove RehaMove Leg: Leg training with RehaMove Sequence: Sequence mode with RehaStim as stand-alone</p>
	<p><u>Choose training mode</u></p> <p>Select the area of application: arms, legs or torso. Select seconds or percentage.</p> <p>The motion sequences can be adjusted either in percentages or seconds. A complete cycle of movement is defined as 100% or 4 seconds (the latter can be adjusted).</p> <p>In percentage mode, the 100% are classified according to the desired stimulation times and pause times. The adjustment in seconds makes it possible to define stimulation times and pause times by entering the desired second values.</p> <p>For stepping training, the percentage option is recommended. Special stepping templates are then available.</p> <p>To select a type of trigger, please go to screen "Choose Trigger"</p>

	<ul style="list-style-type: none"> • Automatic: sequence starts immediately when as the last sequence is finished • Manual: sequence starts when client presses a button on the screen • External single or double trigger: sequence starts after pressing an external trigger (see chapter "External trigger") <p>Use the turning knob:</p> <ul style="list-style-type: none"> • In order to change selection, turn the knob • In order to confirm entries, press Next
	<p><u>Define activation seconds (in seconds training mode)</u></p> <p>In this window the activated muscle groups are shown and activation and deactivation seconds can be defined. In order to change the seconds for one activated muscle, press the corresponding button. An overview of standard seconds can be found in chapter "Electrode Placement for common muscle Combinations for Sequence Mode". Start and stop seconds can be changed by the user. The button of the activated channel is tagged green.</p> <p>Use the turning knob:</p> <ul style="list-style-type: none"> • In order to change seconds, turn the knob • In order to confirm entries, press the turning knob <p>If the button next to the green marked area is pressed, second settings will not be applied.</p>
	<p><u>Define percentages (in percentage training mode)</u></p> <p>In this window the activated muscle groups are shown and activation and deactivation percentages can be defined. In order to change them for one activated muscle, press the corresponding button.</p> <p>Example percentage mode: selected muscles QU_R + BF_R for knee extension/ flexion_R period 6 seconds= 100%</p> <ul style="list-style-type: none"> • QU_R: 5 - 45% = 0.3 - 2.7 Sek • BF_R: 55 - 100% = 3.3 - 6 Sek <p>An overview of standard values can be found in chapter "Electrode Placement for common muscle Combinations for Sequence Mode". Start and stop percentages can be changed by the user.</p>

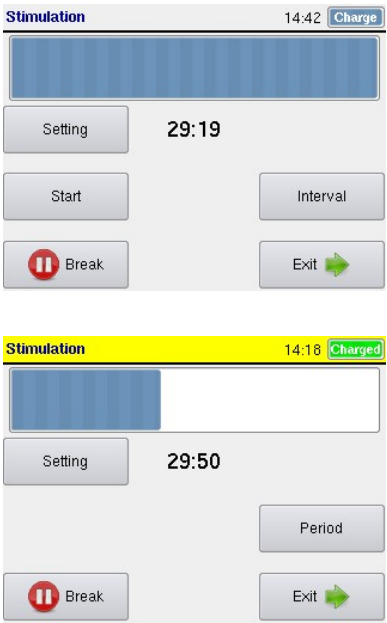
	<p>The button of the activated channel is marked green.</p> <p>Use the turning knob:</p> <ul style="list-style-type: none"> • In order to change value, turn the knob • In order to confirm entries, press the turning knob <p>If the button next to the green marked area is pressed, percentage settings will not be applied.</p>
	<p><u>Define parameters:</u> This window allows for adjusting parameters that apply to all channels.</p>
	<p><u>Define parameters: Duration of Stimulation</u></p> <p>Press the button Stimulation in order to change the duration of the phase. A field above the turning knob pops up with the present value in minutes.</p> <p>Use the turning knob:</p> <ul style="list-style-type: none"> • In order to change minutes, turn the knob • In order to confirm entries, press the turning knob
	<p><u>Define parameters: Ramp</u></p> <p>The ramp is the number of gradual stimulation impulses before the pre-set pulse width is reached. The ramp is carried out every time a sequence starts.</p> <p>Press the button Ramp in order to change the ramp. A field above the turning knob pops up with the present value.</p> <p>Use the turning knob:</p> <ul style="list-style-type: none"> • In order to change the number of reduced pulses, turn the knob • In order to confirm entries, press the turning knob
	<p><u>Define parameters: Frequency</u></p> <p>The frequency indicates the number of impulses per second.</p> <p>Press the button Frequency in order to change the frequency. A field above the turning knob pops up with the present value.</p>

	<p>Use the turning knob:</p> <ul style="list-style-type: none"> • In order to change frequency, turn the knob • In order to confirm entries, press the turning knob
	<p><u>Define parameters: Pulse width</u></p> <p>Press the button Pulse with in order to change the pulse width. A field above the turning knob pops up with the present value.</p> <p>Use the turning knob:</p> <ul style="list-style-type: none"> • In order to change pulse width, turn the knob • In order to confirm entries, press the turning knob
	<p><u>Current test</u></p> <p>This window shows all activated channels. To test the current for one specific channel respectively muscle, press the corresponding button. A window in the middle of the screen pops up which shows the present current, displayed with a bar. By pressing the green tagged button once more, the activated button is deactivated again. The next channel can be selected and tested.</p> <p><i>If the stimulation is active, the status indication line is coloured in yellow.</i></p> <p>Use the turning knob:</p> <ul style="list-style-type: none"> • In order to change current, turn the knob • In order to confirm entries, press the turning knob <p>Next: Test current for further channels if activated.</p>

6.4 Operation

Once the stimulation parameters have been set by a clinical specialist, users may be able to carry out sessions on their own. Depending on the desired type of trigger, the user is stimulated either automatically or as soon as he initiates a new stimulation cycle.

The stimulation is automatically finished when the set time has finished. For sequences longer than 60 minutes, please connect the power supply before the training to ensure energy for the full course. For sequences longer than 120 minutes, sequence time is set in 30 minutes periods.

	<p><u>Stimulation</u></p> <p>To initiate the sequence manually, press Start (manual trigger). If you select Automatic trigger, the stimulation starts autonomously. If you select External trigger, press the trigger. For more, read chapter "External trigger".</p> <p>In the upper part of the screen you find a bar picturing the course of the sequence running in seconds.</p> <p><i>If the stimulation is active, the status indication line is colored in yellow</i></p> <p>Use buttons:</p> <p>Interval: to set the pause time (in seconds) between the individual sequences (seconds mode only) Period: to set the duration of one course in seconds (percentage mode only) Setting: Adjust the pulse width and frequency (for all channels each) and current (for each channel separately) during the stimulation Start: to start each single sequence Exit: Cancel the stimulation</p>
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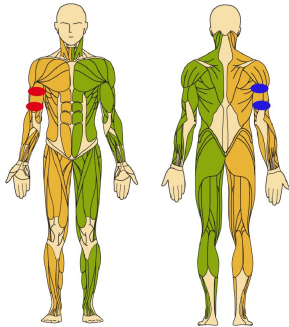
For settings of pulse width, frequency, current and interval please see the following chapters: RehaMove Arm and Leg Training - integrated operation (**FES 3 interface**) "Constant Stimulation Training".

6.5 Templates for common Muscle Combinations in Sequence Mode

The list contains a number of common muscle combinations being stimulated in a session. Apart from these templates the combination of any other muscle group is possible. Please contact the manufacturer for further questions.

6.5.1 Arms

The picture is a sample for the electrode placement. The table below explains the available templates including the abbreviations of the stimulated muscles.



Unilateral: for right or left arm

Program	Task	No of channels	Muscle(s)	Abbreviation	Seconds Start - Stop	Percent % Start-Stop
Wrist_Extension_1Ch L/R	extend wrist of left or right hand	1	M. Extensor carpi	EC	0-4.0	0-100
Thumb_Extension_1Ch L/R	extend thumb of left or right hand	1	M. Extensor pollicis longus	EP	0-4.0	0-100
Thumb_Radial abduction_1Ch L/R	radially abduct thumb of left or right hand	1	M. Abductor pollicis longus	AP	0-4.0	0-100
Elbow_Flect./Ext._2Ch L/R	alternatingly flex and extend elbow of left or right arm	2	M. Biceps brachii	BB	0-1.8	0-46
			M. Triceps brachii	TB	2.2-4.0	54-100
Finger_Flection/Extension_2Ch L/R	alternatingly flex and extend finger of left or right hand	2	M. Flexor digitorum	FD	0-1.8	0-46
			M. Extensor digitorum	ED	2.2-4.0	54-100
Shoulder stabilisation_2Ch L/R	simultaneously contract left or right	2	M. Deltoid anterior	DA	0-4.0	0-100

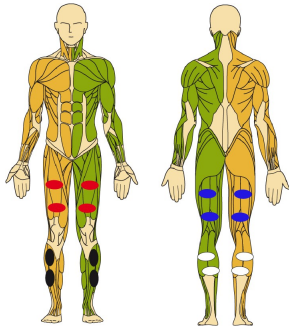
	shoulder		M. Supraspinatus	SU	0-4.0	0-100
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Bilateral: for right and left arm simultaneously

Program	Task	No of channels	Muscle(s)	Abbreviation	Seconds Start - Stop	Percent % Start-Stop
Wrist_Extension_2Ch	extend wrist of left or right hand	2	M. Extensor carpi	EC	0-4.0	0-100
Thumb_Extension_2Ch	extend thumb of left and right hand	2	M. Extensor pollicis longus	EP	0-4.0	0-100
Thumb_Radial abduction_2Ch	radially abduct thumb of left and right hand	2	M. Abductor pollicis longus	AP	0-4.0	0-100
Elbow_Flect./Ext._4Ch	alternatingly flex and extend elbow of left and right arm	4	M. Biceps brachii	BB	0-1.8	0-46
			M. Triceps brachii	TB	2.2-4.0	54-100
Finger_Flection/Extension_4Ch	alternatingly flex and extend finger of left and right hand	4	M. Flexor digitorum	FD	0-1.8	0-46
			M. Extensor digitorum	ED	2.2-4.0	54-100
Shoulder_Stabilisation_4Ch	simultaneously flex left and right shoulder	4	M. Deltoid anterior	DA	0-4.0	0-100
			M. Supraspinatus	SU	0-4.0	0-100

6.5.2 Legs

The picture is a sample for the electrode placement. The table below explains the available templates including the abbreviations of the stimulated muscles.



Unilateral: for right or left leg

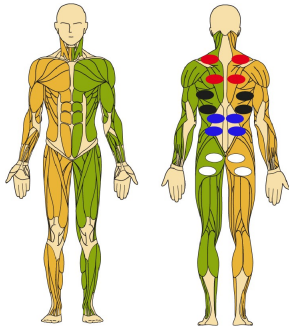
Program	Task	No of channels	Muscle(s)	Abbreviation	Seconds Start - Stop	Percent % Start-Stop
Knee_Flection_1Ch L/R	flex knee of right or left leg	1	M. Biceps femoris	BF	0-4.0	0-100
Knee_Extension_1Ch L/R	extend knee of right or left leg	1	M. Quadriceps femoris	QU	0-4.0	0-100
Foot_Dorsalexension_1Ch L/R	dorsally extend foot of right or left leg	1	M. Tibialis Anterior	TA	0-4.0	0-100
Knee_Flection/Extension_2Ch L/R	alternatingly flex and extend knee of right or left leg	2	M. Quadriceps	QU	0-1.8	0-46
			M. Biceps femoris	BF	2.2-4.0	54-100
Foot_Dorsalexext./Plantarflect._2Ch L/R	dorsally extend and plantarflex foot of right or left leg	2	M. Tibialis Anterior	TA	0-1.8	0-46
			M. Gastrocnemius	GA	2.2-4.0	54-100
Pressure sore_prevention_1Ch L/R	contraction of gluteal muscles	1	M. Gluteus	GL	0-4.0	0-100

Bilateral: for right and left leg simultaneously

Program	Task	No of channels	Muscle(s)	Abbreviation	Seconds Start - Stop	Percent % Start-Stop
Knee_Flection_2Ch L/R	flex knees of right and left leg	2	M. Biceps femoris	BF	0-4.0	0-100
Knee_Extension_2Ch L/R	extend knee of right and left leg	2	M. Quadriceps	QU	0-4.0	0-100
Foot_Dorsalextension_2Ch	dorsally extend feet of right and left leg	2	M. Tibialis Anterior	TA	0-4.0	0-100
Knee_Flection/Extension_4Ch	alternatingly flex and extend knees of right and left leg	4	M. Quadriceps	QU	0-1.8	0-46
			M. Biceps femoris	BF	2.2-4.0	54-100
Foot_Dorsalext./Plantarflect._4Ch	dorsally extend and plantarflex foot of right and left leg	4	M. Tibialis Anterior	TA	0-1.8	0-46
			M. Gastrocnemius	GA	2.2-4.0	54-100
Pressure sore_prevention_2Ch L/R	contraction of gluteal muscles	2	M. Gluteus	GL	0-4.0	0 - 100
Crawling_8Ch	hip and knee flexion right and extension left	8	M. Quadriceps	QU_L	0-2	0-40
			M. Gluteus	GL_L	0-2	0-40
			M. Biceps femoris	BF_R	0-2	0-40
			M. Iliopsoas	IO_R	0-2	0-40
Crawling_8Ch	hip and knee flexion left and extension right,	8	M. Quadriceps	QU_R	3-5	50-90
			M. Gluteus	GL_R	3-5	50-90
			M. Biceps femoris	BF_L	3-5	50-90
			M. Iliopsoas	IO_L	3-5	50-90

6.5.3 Torso

The picture is a sample for the electrode placement. The table below explains the available templates including the abbreviations of the stimulated muscles.



Unilateral: for right or left side of torso

Program	Task	No of channels	Muscle(s)	Abbreviation	Seconds Start - Stop	Percent % Start-Stop
Lateral inclination_1Ch L/R	lateral inclination	1	M. Obliquus externus abdominis	OX	0-4.0	0-100
Left/Right rotation_2Ch L/R	left/ right rotation	2	M. Obliquus externus abdominis	OX	0-4.0	0-100
			M. Rhomboideus major	RM	0-4.0	0-100
Lateral inclination_2Ch L/R	lateral inclination	2	M. Obliquus externus abdominis	OX	0-4.0	0-100
			M. Pectoralis major	PM	0-4.0	0-100
Left/Right rotation_3Ch L/R	left/ right rotation	3	M. Obliquus externus abdominis	OX	0-4.0	0-100
			M. Rhomboideus major	RM	0-4.0	0-100
			M. Serratus anterior	SA	0-4.0	0-100
Lateral inclination_3Ch L/R	lateral inclination	3	M. Obliquus externus abdominis	OX	0-4.0	0-100
			M. Pectoralis major	PM	0-4.0	0-100
			M. Serratus anterior	SA	0-4.0	0-100

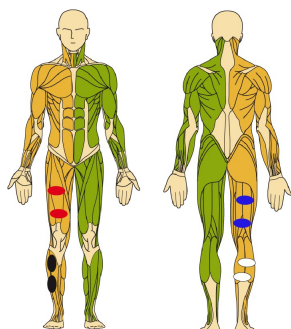
Bilateral: for right and left side of torso

Program	Task	No of channels	Muscle(s)	Abbreviation	Seconds Start - Stop	Percent % Start-Stop
LS_Flection_2Ch	flex lumbar spine	2	W. Rectus abdominis	RA	0-4.0	0-100
LS_Extension_2Ch	extend lumbar spine	2	M. Erector spina	ES	0-4.0	0-100
TS/ LS_Flection_4Ch	flex thoracic/ lumbar spine	4	W. Rectus abdominis	RA	0-4.0	0-100
			M. Pectoralis major	PM	0-4.0	0-100
TS/ LS_Extension_4Ch	extend thoracic/ lumbar spine	4	M. Trapezius	TZ	0-4.0	0-100
			M. Latissimus dorsi	LD	0-4.0	0-100
TS_Flection_4Ch	flex thoracic spine	4	M. Deltoideus anterior	DA	0-4.0	0-100
			M. Pectoralis major	PM	0-4.0	0-100
TS_Extension_4Ch	extend thoracic spine	4	M. Trapezius	TZ	0-4.0	0-100
			M. Deltoideus posterior	DP	0-4.0	0-100
LS_Flection/ Extension_4Ch	alternatingly flex and extend lumbar spine	4	W. Rectus abdominis	RA	0-1.8	0-46
			M. Erector spina	ES	2.2-4.0	54-100
LS_Flexion_6Ch	flex lumbar spine	6	W. Rectus abdominis	RA	0-4.0	0-100
			M. Obliquus externus abdominis	OX	0-4.0	0-100
			M. Iliacus	IL	0-4.0	0-100
LS_Extension_6Ch	extend lumbar spine	6	M. Trapezius	TZ	0-4.0	0-100
			M. Erector spina	ES	0-4.0	0-100
			M. Latissimus dorsi	LD	0-4.0	0-100
TS/ LS_Flection_8Ch	flex thoracic/ lumbar spine	8	W. Rectus abdominis	RA	0-4.0	0-100
			M. Obliquus	OX	0-4.0	0-100

			externus abdominis			
			M. Iliacus	IL	0-4.0	0-100
			M. Pectoralis major	PM	0-4,0	0-100
TS/ LS_Extension_8Ch	extend thoracic/ lumbar spine	8	M. Trapezius	TZ	0-4.0	0-100
			M. Erector spina	ES	0-4.0	0-100
			M. Latissimus dorsi	LD	0-4.0	0-100
			M. Gluteus maximus	GL	0-4.0	0-100
TS/LS_Flection/ Extension_8Ch	alternatingly flex and extend thoracic and lumbar spine	8	W. Rectus abdominis	RA	0-1.8	0-46
			M. Pectoralis major	PM	0-1.8	0-46
			M. Erector spina	ES	2.2-4.0	54-100
			M. Trapezius	TZ	2.2-4.0	54-100

6.5.4 Stepping

Regarding the initiation of steps with this program, please consider the special safety measures named in chapter "Safety".



Unilateral: for right or left leg

Program	Task	No of channels	Muscle(s)	Abbreviation	Percent % Start-Stop
Step_Thigh_2 Ch L	step with thigh activation in left leg	2	M. Quadriceps femoris	QU	40-65
			M. Biceps femoris	BF	30-63
Step_Thigh_2 Ch R	step with thigh activation in right leg	2	M. Quadriceps femoris	QU	90-15
			M. Biceps femoris	BF	80-13
Step_Shank_2 Ch L	step with lower leg activation in left leg	2	M. Tibialis Anterior	TA	5-62
			M. Gastrocnemius	GA	60-100
Step_Shank_2 Ch R	step with lower leg activation in right leg	2	M. Tibialis Anterior	TA	55-12
			M. Gastrocnemius	GA	10-50
Step_Leg_4C h L	step with lower and upper leg activation in left leg	4	M. Quadriceps femoris	QU	40-65
			M. Biceps femoris	BF	30-63
			M. Tibialis Anterior	TA	5-62
			M. Gastrocnemius	GA	60-100
Step_Leg_4C h R	step with lower and upper leg activation in right leg	4	M. Quadriceps femoris	QU	90-15
			M. Biceps femoris	BF	80-13
			M. Tibialis Anterior	TA	55-12
			M. Gastrocnemius	GA	10-50
Step_Leg_6C h L	step with lower and upper leg activation in left leg	6	M. Quadriceps femoris	QU	40-65
			M. Biceps femoris	BF	30-63
			M. Gluteus	GL	65-20
Step_Leg_6C	step with lower	6	M. Quadriceps femoris	QU	90-15

h R	and upper leg activation in right leg	M. Biceps femoris	BF	80-13
		M. Gluteus	GL	15-70

Bilateral: for left and right leg

Program	Task	No of channels	Muscle(s)	Abbreviation	Percent % Start-Stop
Step_Thigh_4Ch	alternating thigh activation in both legs	4	M. Quadriceps femoris	QU_L	40-65
			M. Biceps femoris	BF_L	30-63
			M. Quadriceps femoris	QU_R	90-15
			M. Biceps femoris	BF_R	80-13
Step_Shank_4Ch	alternating lower leg activation in both legs	4	M. Tibialis Anterior	TA_L	5-62
			M. Gastrocnemius	GA_L	60-100
			M. Tibialis Anterior	TA_R	55-12
			M. Gastrocnemius	GA_R	10-50
Step_Leg_6Ch	step with lower and upper leg activation in both legs	6	M. Quadriceps femoris	QU_L	40-65
			M. Biceps femoris	BF_L	30-63
			M. Gluteus	GL_L	65-20
			M. Quadriceps femoris	QU_R	90-15
			M. Biceps femoris	BF_R	80-13
			M. Gluteus	GL_R	15-70
Step_Leg_8Ch	alternating thigh and lower leg activation in both legs	8	M. Quadriceps femoris	QU_L	40-65
			M. Biceps femoris	BF_L	30-63
			M. Quadriceps femoris	QU_R	90-15
			M. Biceps femoris	BF_R	80-13
			M. Tibialis Anterior	TA_L	5-62
			M. Gastrocnemius	GA_L	60-100
			M. Tibialis Anterior	TA_R	55-12
			M. Gastrocnemius	GA_R	10-50

6.6 External Trigger

Stimulation sequences can be triggered by an external double trigger. Two different trigger options are available:

- single trigger: 1 sequence can be started by pressing the button once.
- double trigger: 2 sequences can be defined and be started separately (e.g. 1. button: knee flexion; 2. button: knee extension). The stop button allows to stop a sequence.

Please note!

Starting from software version 2.4 the single trigger mode can be used via the external double trigger. The sequence in single trigger mode can be initiated by pressing button 1 on the external double trigger.

Preparation for external trigger

Connect the external trigger before you start the session. Do not disconnect during the session!

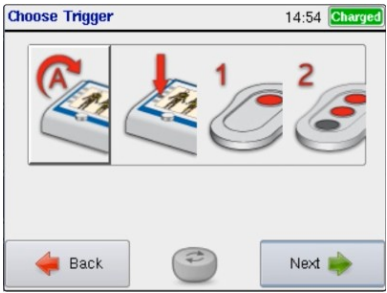
Safety


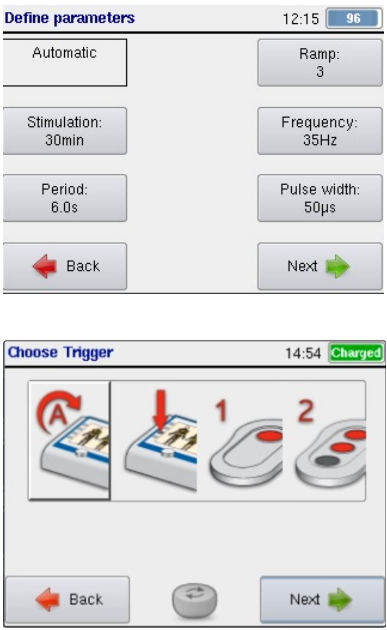
By pressing the external trigger, exactly one sequence/cycle will be initiated. Two sequences/cycles will be initiated with the double trigger. If the user accidentally happens to press the trigger several times, the device protects against risks: only if at least 50% of the running cycle are finished, the trigger will initiate the one next cycle, only after the running cycle is finished. This means the running sequence is finished, and afterwards exactly one new sequence is started.

Activation of the trigger

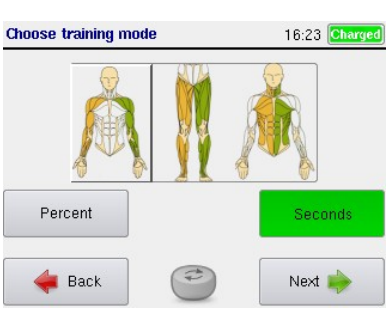


At the start of the program the hint "Press external trigger now!" will appear for 10 seconds in single trigger mode. Press the trigger once during this period. If not, the device automatically changes to manual trigger.

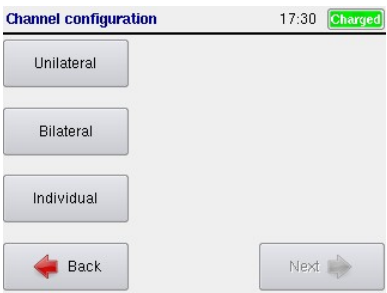
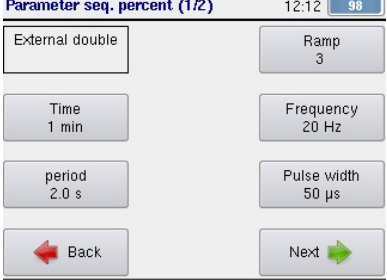
6.6.1 Adjusting the external single Trigger

<p><u>Adjusting the external single trigger when creating a new user program (advanced menu)</u></p>	
	<p>When creating a new user program, go to the window "Choose Trigger".</p> <p>Use the turning knob:</p> <ul style="list-style-type: none"> • In order to select a triggering type, turn the knob • In order to confirm entries, press the Next <p>Regarding further steps during the creation of a new user program, refer to chapter "Create a new User Program".</p> <p>Please note!</p>

	<p>Starting from software version 2.4 the single trigger mode can be used via the external double trigger. The sequence in single trigger mode can be initiated by pressing button 1 on the external double trigger.</p>
	<p>In order to change the adjustment for an existing user program, go to user advanced and press Edit profile.</p> <p>In the following window "Channel configuration" press Next.</p>
<p><u>Adjusting the external trigger for an existing user program (advanced menu)</u></p>	
	<p><u>Define parameters: Triggering</u></p> <p>This window allows for adjusting parameters that apply to all channels.</p> <p>To select a type of trigger, you have to create a new profile and in screen "Choose trigger" you are able to choose the trigger type.</p> <p>Use the turning knob:</p> <ul style="list-style-type: none"> • In order to change selection, turn the knob • In order to confirm entries, press the turning knob

6.6.2 Adjusting the external double Trigger

Adjusting the external trigger when creating a new user program (advanced menu)	
	<p><u>Choose training in sequence mode</u></p> <p>Choose a training by turning the knob:</p> <ul style="list-style-type: none"> • Arms • Legs • Torso <p>Confirm entries by pressing the turning knob. Press the corresponding button for a training in percent or second mode. Click Next to confirm selection.</p>
	<p><u>Choose the external double Trigger</u></p> <p>Choose a training type by turning the knob:</p> <ul style="list-style-type: none"> • single • double • automatic • manual <p>Confirm by pressing the turning knob. Click Next to define the stimulation channels.</p>
	<p><u>Channel configuration</u></p> <p>Channel configuration, definition of parameters and current test have to be done twice. Channels, current and parameters are determined per sequence.</p> <p>Please follow further explanations in chapter: Create new Users and new User Profiles, import old Profiles. In the window "Channel configuration" templates for unilateral or bilateral stimulation can be selected. The button Individual allows individual channel configuration.</p> <p>Use buttons: Unilateral: to select unilateral stimulation templates Bilateral: to select bilateral stimulation templates Individual: to define individual stimulation patterns</p> <p>If the buttons Unilateral and Bilateral respectively are activated, a number of template pictures above the turning knob come up. These templates show selected channels from the front side and back side.</p> <p>Use the turning knob in order to select one template. Press Next to confirm your entries.</p>

	<p><u>Channel Configuration: Individual</u></p> <p>Consider the following requirements to configure channels individually:</p> <p>Green and yellow channels can be used for a sequence. A maximum of 8 channels per sequence may be defined. If a muscle is allocated to a channel in the 1. sequence, the same channel in the 2. sequence must include the same muscle. All other muscles shall not be included in the drop-down list in that case.</p>
	<p><u>Define parameters: double trigger</u></p> <p>Please follow further explanations in chapter: "Create new Users and new User Profiles, import old Profiles".</p> <p>Consider the following requirements to define parameters:</p> <p>First, choose parameter settings for the 1. sequence. Press NEXT to proceed to the settings for the 2. sequence. The defined stimulation time is valid for both sequences. This also applies to settings in percentage mode.</p> <p>The current test follows after parameter settings have been performed.</p> <p><i>Note: If you choose green or yellow channels only, there is no current test for excluded channels.</i></p>

6.7 Edit or delete a User Profile, show Training History

Please follow the instructions in chapters "Edit or delete a User Profile" and "Show Training History" in analogy.

6.8 Finishing a Stimulation Session

1. Stop stimulation, switch off stimulator
2. Disconnect electrodes from cables and detach from the skin

7 Fault Indication

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

Error number	Error	Cause	Troubleshooting
541	Missing license!	To be able to use the stimulator properly, a software licence must be uploaded by the manufacturer. The stimulator does not have a valid software licence.	Please contact the manufacturer!
536	Quick stop pressed. Training is paused.	A quick stop can be connected to the RehaStim2 during the therapy 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 . Check whether the quick stop is pressed. If it is pressed, unlock the button by turning it. Press Next .
7	Check connection to MOTomed!	During the session the connection to MOTomed are constantly checked. This window is displayed if, <ul style="list-style-type: none"> • the connection to MOTomed does not exist or is interrupted (e.g. loose cable) • the MOTomed viva 2 is switched off • the communication between stimulator software and the MOTomed does not work correctly. 	Check correct RehaStim2 connection cable to MOTomed. Press Next . Check if the correct interface of MOTomed Cockpit is activated . Please contact the manufacturer for instructions.
6	Electrode error!	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 .

3	Stimulation module error! Training is paused.	One of the two stimulation modules does not work correctly. The session has stopped.	Please contact the manufacturer!
544	Check speed and direction. Stimulation active from 10 rpm forward.	<p>The stimulation stops during the session if:</p> <ul style="list-style-type: none"> • a spasm is detected or • the speed of the MOTomed motion trainer is too low. <p>The RehaMove 2 needs a minimum speed of 10 rpm forward movement in order to activate the stimulation. Below this speed the stimulation is deactivated for safety.</p>	<p>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</p> <ul style="list-style-type: none"> • in a forward direction • at minimum 10 rpm. <p>If the speed of the MOTomed is too low, raise the speed up to 10 rpm.</p>
524	<p>No connection!</p> <ul style="list-style-type: none"> - MOTomed switched on? - Cable connected? - Correct FES protocol? 	<p>The connection to the MOTomed is checked during session. This window pops up if</p> <ul style="list-style-type: none"> • the connection to the MOTomed does not work or has been disconnected (e.g. the cable has loosened) • the MOTomed viva2 is switched off or • the communication between stimulator and motion trainer does not work properly. <p>For safety reasons, the session has been finished.</p>	<p>Check the cable from the RehaStim2 to the motion trainer and make sure that it is connected properly or even damaged.</p> <p>Start the session again.</p>
523	Activate MOTomed start screen	The session cannot start as the MOTomed is not shown in the start screen.	Please switch to the start screen in the MOTomed.
520	MOTomed connection error! Training was finished.	The connection to the MOTomed is checked before the session starts. This window pops up if	Check the cable from the RehaStim2 to the motion trainer and make sure that it is connected properly.

		<ul style="list-style-type: none"> • the connection to the MOTomed does not work or has been disconnected (e.g. the cable has been loosened) • the MOTomed viva2 is switched off or • the communication between stimulator and motion trainer does not work properly. 	<p>Switch on the motion trainer.</p> <p>Check whether the right interface of the MOTomed cockpit is activated. Please contact the manufacturer for further instructions.</p>
522	Stimulation module error! Training is paused.	The stimulator cannot communicate to the stimulation module. The session was paused.	Reboot the stimulator. If the error occurs repeatedly, contact the manufacturer!
515	No USB flash drive found.	This note is displayed if no USB flash drive has been found to export user profiles.	Please connect USB flash drive.
516	An error occurred when exporting the user.	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!
517	One user mode is active. USB flash drive contains another user and cannot be used.	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.
521	Stop button at the MOTomed was pressed! Training was finished.	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.
538	Quick stop!	This note is displayed if the current output should be higher than 0mA and the quick stop is pressed. In this case there is no current output.	Release the quick stop button to activate the current output.

8 Declaration of Warranty

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

- for **2 years** after distribution within the **European Union**.
- 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 unauthorised 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 offer a security check with optional follow-up warranty of one year, including the exchange of wear parts and the accumulator.

We need your feedback to continuously optimize our products.

- Do you find the menu navigation intuitive?
- Does the device correspond to your ergonomic requirements?
- Can you or your patients easily operate the device?
- Do you have any concern that keeps you from using the device or its accessories?
- Do you have any comments regarding our device that might improve its ease of use?
- Does the device react in an unexpected way?

Thank you for your feedback!

9 Address of Manufacturer

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