

RehaStim, RehaMove - Operating Manual -

Version 1.3 / December 2009 HASOMED GmbH



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Part VII Address of manufacturer

1 General Description

1.1 Declaration of Conformity

EG-KONFORMITÄTSERKLÄRUNG

entsprechend Anhang II der Richtlinie 93/42/EWG über Medizinprodukte

EC DECLARATION OF CONFORMITY

according to annex II of the Council Directive 93/42/EEC concerning medical devices

Wir:

HASOMED GmbH

Paul – Ecke –Straße 1

39114 Magdeburg

erklären in alleiniger Verantwortung,

daß das Produkt / die Produkte:

funktioneller Elektrostimulator

Typ

RehaStim

RehaMove

den einschlägigen Bestimmungen der Richtlinie 93/42/ EWG über Medizinprodukte entsprechen. We:

HASOMED GmbH

Paul – Ecke – Straße 1

39114 Magdeburg

declare under our sole

responsibility that the product/s:

functional electrical stimulator

type

RehaStim

RehaMove

meet the provisions of the Council Directive 93/42/EEC concerning medical devices

which apply to them.

Magdeburg, Sept. 1st 2005

Dr. P. Weber Managing Director of HASOMED GmbH

1.2 Description of the RehaStim

The RehaStim is a portable electrical stimulation device that generates impulses, on up to 8 channels simultaneously, to activate paralysed muscles via surface electrodes. The RehaStim 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 conjunction with a motion trainer as **RehaMove**. Numerous parameters for the power and time related progression of the stimulation can be adjusted individually for each channel.

The parameters and operational conditions are presented on a graphical touch display screen which makes interaction with the device easy.

The stimulator can 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 **RehaMove** using a movement exerciser.

The RehaStim stimulator is certified according to the EU guidelines EN60601-2-10 for medical technical devices and systems.

1.3 Indications and Counter Indications

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

However, the RehaStim could also be used for therapeutical electrical stimulation. The RehaMove is a specialised system that has integrated the RehaStim specifically for exercise training.

Indications of use

Clients interventions can have a variety of goals such as:

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

Absolute counter indications

These counter indications absolute exclude clients from applying the RehaMove:

- 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 yet been scientifically investigated.
- Fractures: Unhealed fractures in the following areas restrict the patient from using the RehaMove until the fracture is stable:
 - in the lower extremities, if you want to do leg training with the RehaMove.
 - in the upper extremities, shoulder girdle or upper ribs, if you want to do arm training.
- Additional counter indications for Arm training:
- unability to keep humeral head into glenohumeral joint utilizing electrically evoked contraction of the supraspinatus
 - grade 3 tear of either rotator cuff.

Relative counter 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 positioned 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: the client can be positioned in their chair to accommodate for minor limitations in joint ranges: However, a minimum of 90 degrees of shoulder flexion and 100 degree 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 making the stimulation and the therapy may be too uncomfortable to continue.
- Pressure sores or open wounds in 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 yet been scientifically investigated.
- Additional relative counter indications for Arm training:
- Implanted stimulators such as vegus 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.

1.4 Adverse Effects

Skin irritations or chemical burns may occur if there is insufficient contact between the skin and electrodes or if the parameters have been adjusted incorrectly. Therefore when using stimulation for the first time, **check the area underneath the electrodes after 2 minutes!** If you find that there is bad electronic contact, please use contact gel available from medical suppliers.

In known allergies against electrode material, be careful when making your choice. Electrodes must not be placed on excoriations or gashes.

1.5 User Safety

Please read the manual carefully before using this device!

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

- 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 in the presence of the following:
 - 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 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



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

The treatment must only 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 ailments.



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. EN60601-1 for electrical medical devices and EN6950 for data processing devices). Furthermore all combinations must meet the system standard EN60601-1-1. For queries please contact the technical support at HASOMED GmbH (manufacturer).

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

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 (within1.5m) devices with high frequency (HF) range electromagnetic radiation, such as micro- and short-wave devices or welding units.

Do not put electrode cables into AC mains power outlets.

Only the provided charger (TR 30RAM090) and plug must be used to charge this device.

The safety and effectiveness of the treatment depend on the appropriate use of the device. Inappropriate use of this device is dangerous.

1.6 Warning Notices



If the documentation is not clear about the use of this device in a particular way or on the connection of this device to another device then the manufacturer or an expert is to be contacted to ensure that the users safety is not put at risk.

If the device is used in conjunction with the movement therapy machine as part of the **RehaMove** 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 nauseated, 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 patient's blood pressure and heart rate should be monitored during the therapy session.
- The long-term effects of chronic electrical stimulation are unknown.
- The long term effects of electrical stimulation on a pregnant individual (mother and baby) are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in clients with a known sensitivity to the carotid sinus reflex.
- 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.
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied transcerebrally.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous diseases.
- 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 RehaMove unattended when children are present.
- The arm crank should not be used unless continuous assistance is available as while using this device it may not be possible for the patient 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 one or two drops of water onto gel surface (Re-hydrate Gel) may extend usage. If not, replace with new Electrodes.

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.

Do not apply to broken skin. Should a skin rash or a skin burn occur, immediately discontinue use and contact your clinican

Do not stimulate while driving or operating machinery.

Do not exceed 0.1 watts/cm².

Adjust stimulator according to stimulator or/and clinician instructions for your treatment. For your safety an comfort, turn off the stimulator before you attempt to remove electrodes from your skin.

Always lift Electrodes from the edge – not the leadwire.

Always replace Electrodes to "ON" side of the storage liner.

Always store and seal 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 driver per Electrode (Single Patient Use).

Replace Electrodes when they show wear or tear.

1.7 Precautionary Measures



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

If the stimulator is to be used near the ribcage, consider and analyse the risk of cardiac fibrillation.

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

Electrodes must not be placed on excoriations or gashes.

Do not use near (e.g. <1.5m) an HF-range or micro-wave device because that may cause variations of the initial values of the stimulator.

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

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

Protect the device from water. If the device falls into water do not use it any longer and contact 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.

Users should be always accompanied by an assistant.

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

Caution should be used for patients with suspected or diagnosed heart problems.

Caution should be used for patients with suspected or diagnosed epilepsy.

Caution should be used in the presence of the following:

- a. When there is a tendency to hemorrhage following acute trauma or fracture;
- b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
 - c. Over the menstruating or pregnant uterus; and
 - d. Over areas of the skin which lack normal sensation.

Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.

Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

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

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

Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

1.8 Indications and Counter-indications

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However, the RehaStim could also be used for therapeutical electrical stimulation. The RehaMove is a specialised system that has integrated the RehaStim specifically for exercise training.

Indications of use

- Incomplete and complete paraplegia after spinal cord injury: to prevent or retard disuse atrophy and to strengthen the cardio-pulmonary system, to relax muscle spasms, increase local blood circulation and maintain or increase range of motion
- Stroke: to relax muscle spasms and to maintain or increase range of motion

In order to achieve full therapy success, always an experienced doctor or therapist must be consulted to decide on therapy goals and interventions. The doctor or therapist must supervise the therapy and adjust parameters if necessary. This close cooperation is the key precondition for obtaining more benefit for the patient than with conventional methods.

Absolute counter indications

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• 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 yet been scientifically investigated.
- Fractures: Unhealed fractures in the following areas restrict the patient from using the RehaMove until the fracture is stable:
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The treatment can influence electrical monitoring devices (e.g. ECG) if they are simultaneously connected to the client.

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 (within1.5m) devices with high frequency (HF) range electromagnetic radiation, such as micro- and short-wave devices or welding units.

Do not put electrode cables into AC mains power outlets.

Only the provided charger ("mascot" type 9920/ 9V) and plug must be used to charge this device.

The safety and effectiveness of the treatment depend on the appropriate use of the device. Inappropriate use of this device is dangerous.

1.10 Default Values and Adjustment Ranges of Stimulation Parameters

1.10.1 Features

duration of the stimulation impulses (pulse width):	20μs to 500μs incremented in steps of 10μs	
current:	20mA to 130 mA incremented in steps of 5 mA	
number of channels:	2 modules with 4 channels each (running parallel constantly)	
Stimulation frequency:	10 to 50 Hz in steps of 5 Hz	
voltage reserve:	150V	
operation time:	about 2 to 2.5 hours with medium stimulation parameters (with a load of 1100Ohm and 100nF)	
charging time for integrated battery	about 3.5 hours	

- High user safety: Electrode connections are tested before stimulation starts
- Emergency stop button for unexpected sudden danger

1.11 Technical Specifications

RehaStim(stand	
alone device)	
Size and Weight:	
Length	13,5 cm
Width	15 cm
Height	7 cm
Shipping weight	5 kg
Power Supply:	
Power Source(s):	AC and/or Akku
Method of Line Current Isolation	- TR 30RAM090 nach EN60601-1, - SANYO, NiMh, C= 2700 mAh,
Power connection	100-240 VAC 50-60 Hz
Power input	max. 150 W
Environment conditions:	
· In use	0 °C to 40 °C
·Transporting/storing	-20 °C to +60 °C
· Relative humidity	0 to 85% Rh, not condensating

Stimulator / Controller	
Display / interface	Touch-sensitive LCD
Communications	USB / RS232
Operating system	custom software
Maximum voltage output	154 V
Maximum number of channels	8
Current output per channel	20 – 130mA incremented in steps of 5 mA
Waveform type	Biphasic, charged balanced
Duration of the stimulation impulses (pulse width):	20 – 500μs incremented in steps of 10μs
Stimulation frequency:	10 to 50 Hz in steps of 5 Hz
Degree of protection	Type BF Applied Part

RehaMove (consists of RehaStim and Motorized Ergometer)		
RehaStim		
	see above	
Motorized Ergometer		
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∼, 5/60Hz
Power input	130VA	130VA
Protective type	IPXO	
Classification	protection class I, Type B	
Medical device according to German Act on Medical devices	Па	
Environment conditions:		

· In use	0 °C to 40 °C
·Transporting/storing	-20 °C to +60 °C
·Relative humidity	0 to 85% Rh, not condensating

1.12 Maintenance and Service Instructions

Cleaning the stimulator

To clean the stimulator use normal detergent. Do not use spray cleaners. Use a semi-moist cleaning tissue.

For cleaning the MOTOmed viva2, please refer to its user manual.

Maintaining the Stimulator accumulator

To maintain the stimulator accumulator, please every three months

- let it discharge completely until the stimulator turns off automatically
- then recharge it fully.

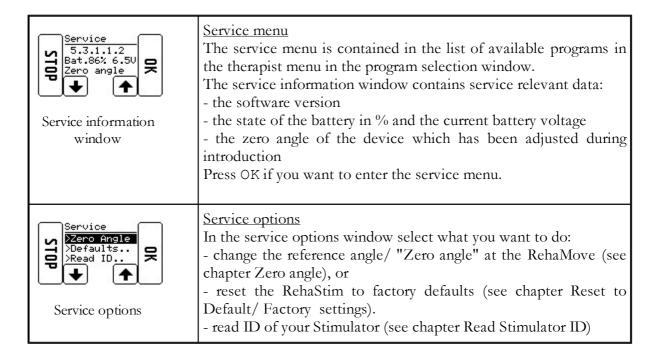
Maintaining the technical safety

The manufacturer recommends for the stimulator RehaStim a maintenance interval of 2 years in order to guarantee the safety standards for further use. For this please send your RehaStim to the manufacturer at your own account.

HASOMED will examine the adherence to the technical parameters and the function of the monitoring elements.

1.13 Service Information

At the end of the list of programmes in the therapist menu you find the service information.



- upgrade your stimulator software under "Prog. Update" (see chapter Program Update).
Use the arrow keys to scroll up and down between options and press OK to select one.

1.13.1 "Zero angle"

The "zero angle" is the RehaMove 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.

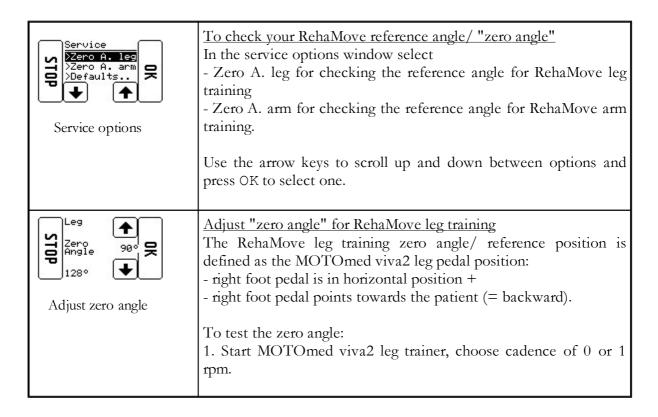
It is recommended to check the zero angle

- 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 for RehaMove arm training affects all RehaMove arm training programs.
- Changing the zero angle for RehaMove leg training affects all RehaMove leg training programs.



a Sign

Warning!

Zero angle affects ALL programs!



The window shows the default zero angle at the right side.

In the left corner the current value from the sensor is constantly written

2. Let the viva 2 run and watch the current angle value in the left corner change.

Read the value the viva 2 tells you in the reference position (see above).

If this value is not the same as the default zero angle at the right side, change the value at the right side to read value.

The zero angle is adjusted correctly when both values in this window are the same the very moment the pedal is in the reference position.

Confirm with OK.

3. Please be aware that changing the zero angle affects all programs. Save only when you are sure. If you are not sure, contact the manufacturer.

Then the zero angle test is finished.

Arm Zero Angle



Adjust zero angle

Adjust "zero angle" for RehaMove arm training

The RehaMove arm training zero angle/ reference position is defined as the MOTOmed viva2 arm handle position:

- right arm handle is in horizontal position +
- right arm handle points towards the patient (= backward).

To test the zero angle:

1. Start MOTOmed viva2 arm trainer, choose cadence of 0 or 1 rpm.

The window shows the default zero angle at the right side.

In the left corner the current value from the sensor is constantly written.

2. Let the viva 2 run and watch the current angle value in the left corner change.

Read the value the viva 2 tells you in the reference position (see above).

If this value is not the same as the default zero angle at the right side, change the value at the right side to read value.

The zero angle is adjusted correctly when both values in this window are the same the very moment the pedal is in the reference position.

Confirm with OK.

3. Please be aware that changing the zero angle affects all programs. Save only when you are sure. If you are not sure, contact the manufacturer.

Then the zero angle test is finished.

Warning!

Zero angle affects ALL programs!

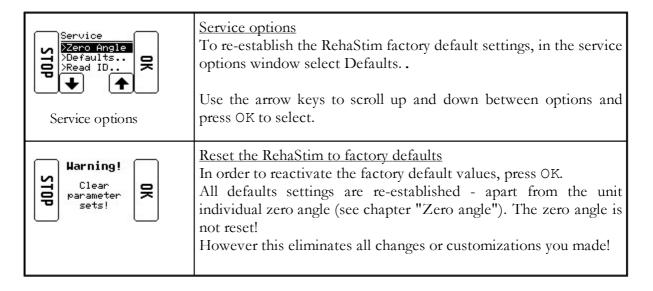


If you want to check the adjustments once more, use LED cables and start a program with few channels, e.g. Ri. 2 Ch.

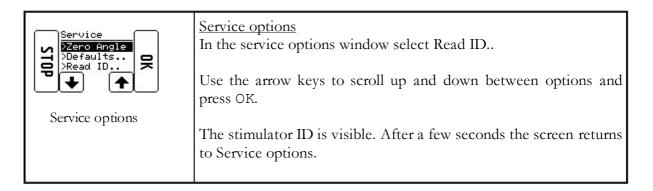
Test whether the lights shine at the correct positions.

Note: When you reset your stimulator to the default /factory settings (see chapter Reset to Default/ Factory settings), the zero angle is not reset!

1.13.2 Reset to Default/ Factory Settings



1.13.3 Read Stimulator ID



1.13.4 Program Update



Service options

Service options

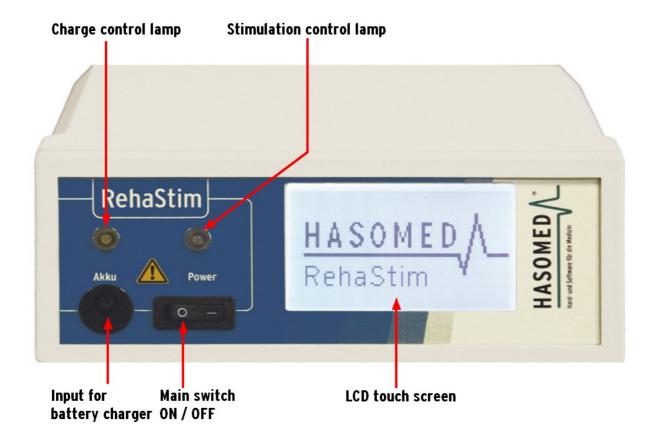
In the service options window upgrade your stimulator software under "Prog. Update".

Please contact manufacturer for a software upgrade and upgrade instructions.

Use the arrow keys to scroll up and down between options and press OK.

2 Control Elements and Accessories of the RehaStim

2.1 Operating and Connection Elements



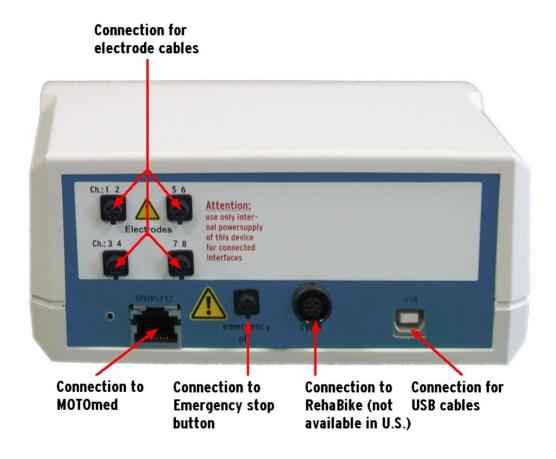
Picture1: Front view with control elements

With the main switch the stimulator is turned on and off.

The device is operated with a graphic LCD touch screen. Depending on task and status, the touch screen displays specific readouts and switch elements.

The stimulator is powered from an internal battery. When charging use only the provided battery charger! While the battery is being charged the charge light (LED) will shine yellow. Stimulation is still possible during charging.

When stimulation is carried out, the stimulation light (LED) shines yellow. If an error occurs, this light shines red (see chapter Fault Indication).



Picture 2: Back view with interface elements

There are 4 connection points for the electrode cables, each cable connecting two channels. The RehaMove interface (SPI/RS232) should be connected to the corresponding device. The emergency stop button must be connected to the corresponding interface. With it the user can immediately turn off the stimulation in the case of an emergency. The USB interface is used to connect the stimulator to a computer for software updates.

2.2 Accessories

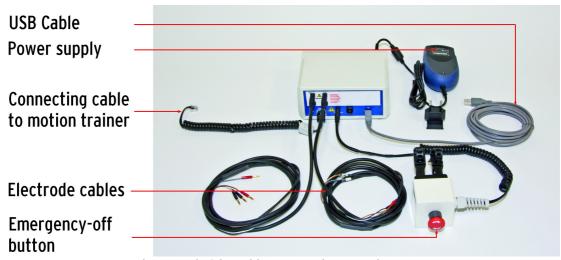
The stimulator and its accessories were delivered to you in a transport case.



Picture: RehaStim accessories

Its contents are described below:

- 1 stimulator RehaStim
- 1 emergency stop button
- 4 electrode cables
- 1 power supply for the stimulator
- 1 cable to connect the movement exerciser and RehaStim
- 1 USB connection cable to PC
- 4 sets of electrodes separately:
- bracket with bolt to fix the stimulator onto the movement therapy machine



Picture: RehaStim with connected accessories

a) The Stimulator RehaStim See chapter "Operating and Connection Elements"

b) Emergency stop button



Picture: How to connect the emergency stop button

With this button the user can immediately turn off the stimulation. Use the quick release fastener to fix the emergency stop button within easy access of the user, which could be for example on the handlebar - as shown in the picture -, at the wheelchair frame or a similarly suitable location.

The manufacturer recommends the use of the emergency stop button. Connect it to the designated socket on the back of the stimulator. The connected movement exerciser has to be stopped separately by pressing the STOP button.

To test the button, push the emergency stop button when stimulation is active. The stimulation should stop immediately.

To reactivate the stimulator after the emergency stop button has been pressed, first switch the stimulator off and then rotate the emergency button until it opens again. The stimulator can then be restarted as usual.

c) Electrode cables

Use the electrode cables as a connection from stimulator to the surface electrodes.

Each electrode cable separates into 2 channels and each channel splits into 2 electrodes. The channels are marked with the letters "A" and "B".

The channel A is always the channel with the lower number! So, for example, if you have put in your electrode cable into interface "1 2", the channel marked with an "A" is channel No. 1 and the channel marked with a "B" is channel No. 2.

When applying them, follow the explanations given in chapter "Preparations".

d) Power supply for the stimulator



Picture: How to connect the power supply

Use power supply to recharge stimulator.

Depending on country/type of power outlet different plugs are available. The right plug for your country is delivered by the manufacturer.

Use the power supply to recharge the stimulator when the battery is low as visible in the charge bar in the

menu:

Warning: To charge the battery, use only the battery charger/ power supply (TR30RAM090) and plug provided.

If the battery is fully charged, the bar is filled with 5 small boxes. If the battery is almost empty, the bar is empty and the outer line is dotted. When the battery becomes fully discharged there is an acoustic alarm and readout on the display for a few seconds before the stimulator turns off. Recharging will take 3 to 4 hours. In **RehaMove** simultaneous recharging and stimulating is possible with full user safety.

To recharge and stimulate simultaneously:

- turn RehaStim off, connect the power supply unit, turn RehaStim on again.
- if you need to recharge in the course of a stimulation: pause stimulation, connect power supply unit and continue stimulation; however do not disconnect during stimulation!

The yellow LED controls the charging process - it shines yellow when recharging is running and it turns off when recharging is finished.

e) Cable to connect movement therapy trainer and stimulator

This cable allows the communication between stimulator and movement exerciser.

Connect it to the RehaMove interface (SPI/RS232) at the back of the stimulator. The interface at the motion trainer can be found underside of the cockpit.

f) USB connection cable to PC

This cable allows the update of the RehaStim software from a PC.

If you need to do an update, please contact us and we will send you all details.

g) Electrodes

The surface electrodes provided are applied to the skin above the relevant muscles. Through them, the electric impulses from the stimulator go to the relevant muscles and cause their contraction.

The relevant muscles for stimulation are named in chapter "Preparations". Since the exact application of the electrodes varies between users, please consult you doctor or physiotherapist about where and how to apply the electrodes in order to generate an effective muscle reaction.



Picture: RehaTrode

Warning: Only use the recommended **RehaTrode** electrodes

•

The electrodes are pre-geled and no extra conductive medium is needed.

A patented two-layer adhesive gel eliminates performance problems associated with single layer gels.

Hasomed Part 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 on the same patient several times. The number of reapplications (the life of the electrodes) is dependent upon how well the patient takes care of the electrodes. With proper care, one should expect to get 30 applications.

The user has to replace the electrodes:

- not later than 30 applications
- or a maximum utilization time of 3 months or
- or when a problem with the product specific use (e.g. irritation) occurs.



Safety instructions for electrode use:

Skin must always be clean, dry and free from lotion.

When electrodes begin losing adhesion, gently rubbing one or two drops of water onto gel surface (Re-hydrate Gel) may extend usage. If not, replace with new electrodes.

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

Do not stimulate while driving or operating machinery.

Do not exceed 0.1 watts/cm².

Adjust stimulator according to stimulator or/and clinician instructions for your treatment. 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 leadwire.

Always replace electrodes to "ON" side of the storage liner.

Always store and seal 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 driver per electrode (Single Patient Use).

Replace electrodes when they show wear or tear.

g) Bracket with bolt to fix the stimulator at the movement therapy machine

The bracket allows the stimulator to be mounted on to the movement exerciser in a position that allows easy access for the user. It is is fixed to the RehaMove at delivery.

3 Software for General Stimulation

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

3.1 Therapy instructions for General Stimulation

Start the training with a passive warm-up phase without stimulation in order to prepare the muscles for the training. The stimulation phase follows. Thereby muscles are stimulated and they exercise actively. The training should end with a passive phase, the cool-down.

3.2 User Safety

Please check before starting a training session,

- whether supply voltage of device is conform to your line current. Connect the stimulator to the power outlet only if supply voltage of device and your line current correspond. If you notice damages, or details regarding the supply voltage do not correspond, please contact the manufacturer HASOMED GmbH immediately.
- Connect the stimulator only to a power outlet which is connected to a ground fault circuit interrupter. Please use the provided power cable from HASOMED GmbH only. If a power cable is damaged, stop the training immediately and contact the manufacturer!
- Connect cables safely so that nobody happens to stumble and the cables can not be damaged.
- Place the stimulator on a flat and skid proof ground (e.g. table) in order to secure stability. Leave the device standing at room temperature for one hour after delivery.

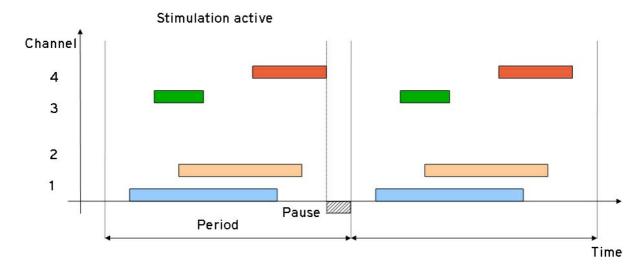
3.3 Sequence Stimulation-Operation by Client

Following program allows the training of sequential courses with the stimulator as a free standing device for a wide range of applications:

-to stimulate certain muscles/muscle groups in order to increase the intensity of training -application where the RehaMove could not be used before, i.g. re-initiation of complex motion sequences.

The stimulation takes place periodically, i.e. the chosen cycle is repeated as often as the user wishes. Each channel can be activated once per cycle respectively sequence. The training uses constant parameters as current and pulse width.

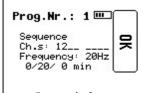
With an extension of the period a break glues in, start and stop time stay constant and do not change.



Scheme course of sequence training. With an extension of the duration of the sequence a break glues in, start and stop time stay constant and do not change.

Usage of an external trigger in order to actuate the sequence

Alternatively an external trigger respectively switch-key can be used in order to actuate a stimulation sequence - see chapter "Use External Trigger".



Start window

The start window displays the name of the current program and the main details of the program:

- program number
- training mode Sequence
- Ch.s = the active channels
- Frequency: the frequency used in the program in Hz
- The average time indicates the duration for the stimulation phase in min (minutes).

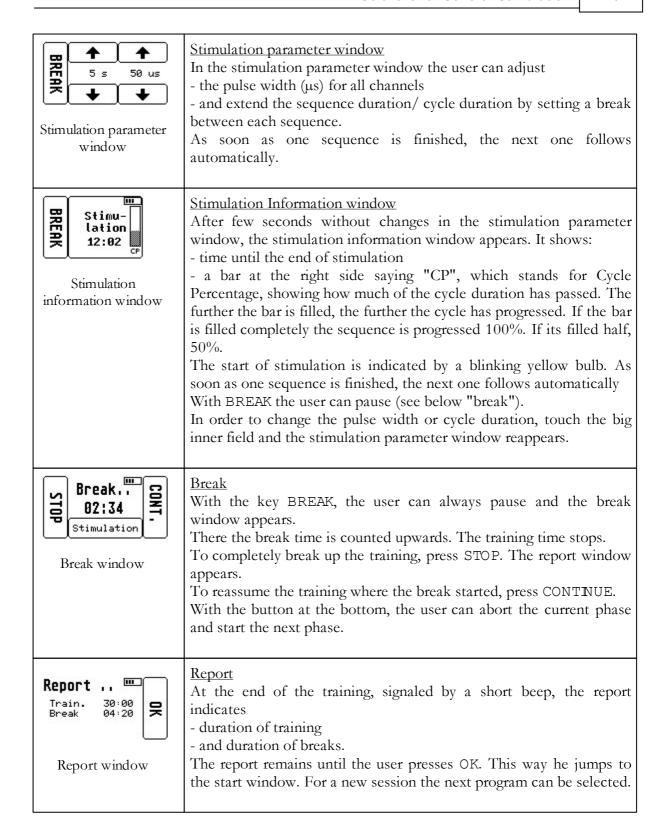
There are NO warm up and cool down phases (times = 0) for the general stimulation! Warm-up and cool down are to be carried out by the therapist if necessary!

Right above the charging status of the battery is indicated.

If the indicated program is the right one for the session, press OK.

If the indicated program is not the correct one, please call the therapist to change the program or to adjust parameters via therapist menu (see chapter "Customize program").

As soon as the user pushes OK, electrodes and cables are checked – invisibly for the user.



3.4 Use External Trigger

Optionally for applications of general stimulation, an external trigger respectively switch-key can be used in order to actuate a stimulation sequence. For doing so, you may use a 3,5 mm mono plug (1,8"mono plug) and to connect that, by means of an adapter of HASOMED

GmbH, with the simulator/ plug "Cycle".

Preparation

Please connect the external trigger before starting the training.

Do not disconnect the external trigger during the training.

Activation

After the start of the program a trigger-key-window appears where the client can choose to use an external trigger.

If you want to activate the external trigger, press it now.

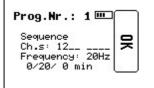
If you do not want to use it, press OK and sequences respectively steps are repeated automatically.

Safety first

With one key press exactly one cycle/step is activated.

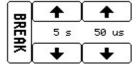
If the client unintentionally activates the trigger more than once, the software secures from risks:

Only if 50% of the cycle has been executed, the key press pushes exactly one new cycle after the ending of the current cycle. That means the software completes the current cycle/ step and starts exactly one new cycle afterwards.



Start window

The start window displays the name of the current program and the main details of the program. If the indicated program is the right one for the session, press OK. If the indicated program is not the correct one, please call the therapist to change the program or adjust parameters via therapist menu (see chapter "Customize a program").



Stimulation parameter window

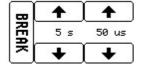
Activate trigger respectively switch-key

Alternatively it can be used an external trigger respectively switch-key in order to actuate a stimulation sequence. After the confirmation of the program the trigger-key-window appears.

In order to use an external trigger respectively switch-key, please press the external trigger **now**.

The user enters the stimulation parameter window automatically and starts with the first sequence.

For training without external trigger, i.e. with automatic repetition, press OK.



Stimulation parameter window

Stimulation parameter window

In the stimulation parameter window the user can adjust

- the pulse width (μs) for all channels
- and extend the sequence duration individually by taking a break between each

course of stimulation.

Without external trigger: As soon as one sequence ends, the next cycle starts automatically.

With external trigger: With a key press exactly one cycle is activated. If the client unintentionally activates the trigger more than once, the software secures from risks:

Only if 50% of the cycle has been executed, the key press is detected. The software then executes the current cycle completely and starts exactly one new cycle.

Continue with the training as used to.

3.5 Choose program in therapist menu



Enter the Therapist menu with two hidden keys in the lower line of the display - press the 1st and the 3rd button from the left side one after another.

Enter Therapist Menu



A security warning appears. This warning reminds the user that he/she does not have the medical background - and might have entered the therapist menu unintentionally - to change basic stimulation parameters.

Warning window at entry



Program selection window

List of available programs

The program selection window successively shows the programs available. The list contains 9 customizable programs. The details displayed for each program are: training mode, active channels, frequency.

Use the arrow keys to scroll up and down between programs. To select and start a program for a client, press OK. To customize a program for a client, press Editand continue as described in chapter "Customize a program". To create a completely new program for a client, scroll to Template and see chapter "Create a new Program from Template".

STOP = abort and go back to the start window.

3.6 Customize a Program



Enter the Therapist menu with two hidden keys in the lower line of the display - press the 1st and the 3rd button from the left side one after another.

Enter Therapist Menu



Program selection window
Choose the program to be

Choose the program to be edited from the list of available templates. The program selection window successively shows the programs available. The list contains 9 customizable programs. The details displayed for each program are: training mode, active channels, frequency.

Use the arrow keys to scroll up and down between programs. To select a program for a client, press OK.

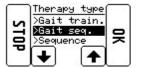
To customize a program for a client, scroll to the desired program and press Edit

STOP = abort and go back to the start window.



Program selection

window



Training modes

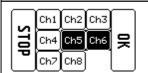
Choose the training mode/ therapy form

In this window select which therapy form you want to use for the client.

The therapy form currently used is marked with a black bar. Use the arrow keys in order to change the therapy form

- -Sequence
- -Gait sequence
- -Gait training

Press OK.



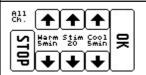
Channel selection

Select channels

Available channels are displayed. By pressing the desired channels, the therapist activates/deactivates them. Activated channels are inversely (black) represented.

To save changes, press OK.

With STOP you go back to the window Training modes.



Edit general parameters: frequency, ramp and duration of stimulation After the channels have been set, the parameters concerning all channels can be adjusted:

- times for the simulation phase in minutes
- the ramp: is the number of gradual stimulation impulses before the preset pulse width is reached.

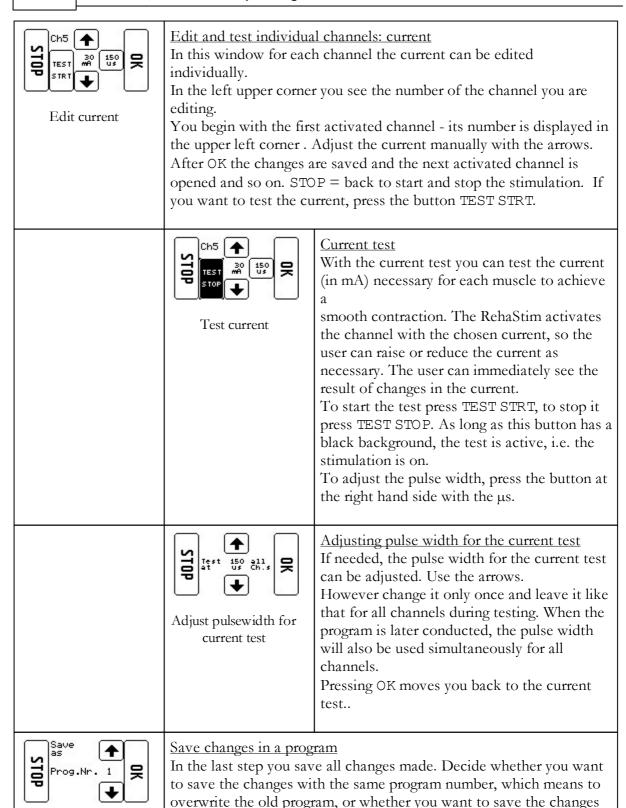
The ramp is carried out every time the stimulation starts:

- for every channel and sequence.
- and the frequency for all channels.

Edit duration of the phases

Edit frequency and ramp	With OK all changes are confirmed. This procedure takes place for all types of general stimulation. The next step varies when using different program types.		
	Edit start and stop seconds	Sequence: Edit individual channels: edit start and stop of stimulation in seconds In the left upper corner of the screen you see the number of the channel you are editing. Start and stop seconds refer to the start and stop of the stimulation for the current channel/muscle. The stop second can not be lower than the start second. The lower the starting second, the sooner the muscle will be activated. The bigger the difference between start and stop second, the longer the muscle will be stimulated. An overlapping at the end of the sequence training is not possible. Begin with the first activated channel. Adjust start and stop seconds with the arrows. After OK the changes are saved and the next activated channel is opened and so on.	
	Edit start and stop percentages	Gait training and gait sequence: Edit individual channels: edit start and stop of stimulation in percentage In the left upper corner of the screen you see the number of the channel you are editing. Start and stop percentages refer to the start and stop of the stimulation for the current channel/muscle. The lower the starting percentage, the sooner the muscle will be activated. The bigger the difference between start and stop percentage, the longer the muscle will be stimulated. An overlapping above 100% is possible. Begin with the first activated channel. Adjust start and stop percentages with the arrows. After OK the changes are saved and the next activated channel is opened and so on.	

Save changes in a program



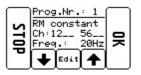
with a new program number (use arrows to choose different number).

3.7 Test or customize current



Enter the Therapist menu with two hidden keys in the lower line of the display - press the 1st and the 3rd button from the left side one after another.

Enter Therapist Menu



Program selection

window

Choose the program to be edited from the list.

The program selection window successively shows the programs available.

Use the arrow keys to scroll up and down between programs.

To customize the current of a program for a client, scroll to the desired program and press Edit

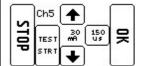
STOP = abort and go back to the start window.



Select current test

In order to select the current test, use the arrow keys to move the black bar and press OK.

Training modes



Edit and test individual channels: current

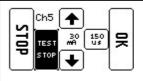
In this window for each channel the current can be edited individually. In the left upper corner you see the number of the channel you are editing.

You begin with the first activated channel. Adjust the current manually with the arrows.

After OK the changes are saved and the next activated channel is opened and so on.

If you want to test the current, press the button TEST STRT.





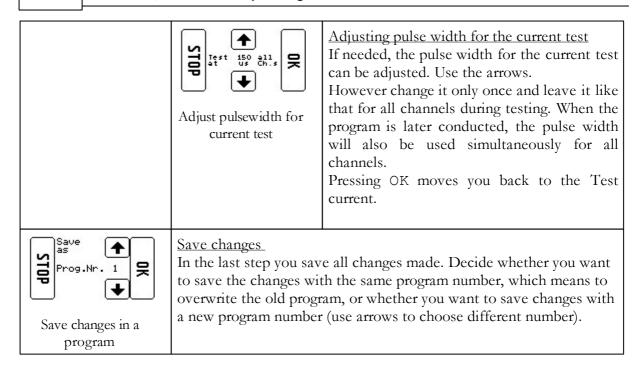
Test current

Current test

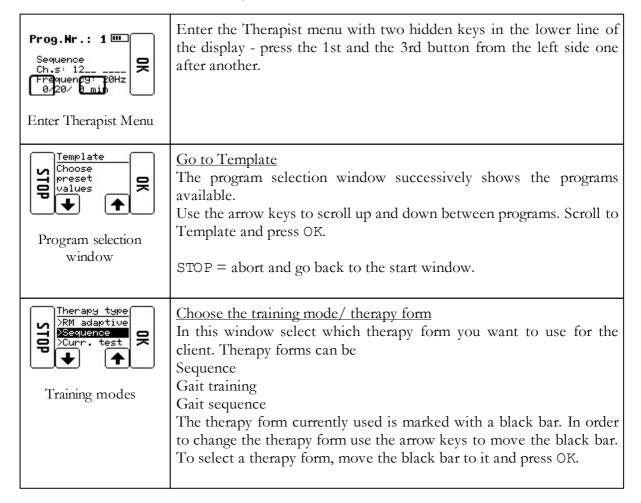
With the current test you can test the current (in mA) necessary for each muscle to achieve a smooth contraction. The RehaStim activates the channel with the chosen current, so the user can raise or reduce the current as necessary. The user can immediately see the result of changes in the current.

To start the test press TEST STRT, to stop it press TEST STOP. As long as this button has a black background, the test is active, i.e. the stimulation is on.

To adjust the pulse width, press the button at the right hand side with the µs.



3.8 Create a new Program from Template





List of available templates

Select a template

There are numerous templates available for the gait training and gait sequence (see chapter "Available Templates").

For gait training and gait sequence:

Left 2 Ch. = for left leg training with 2 channels

Left 3 Ch. = for left leg training with 3 channels

Left 4 Ch. = for left leg training with 4 channels

Right 2 Ch. = for right leg training with 2 channels

Right 3 Ch. = for right leg training with 3 channels

Right 4 Ch. = for right leg training with 4 channels

Le.Ri 4 Ch. = for right and left leg training with 4 channels

Le.Ri.6 Ch. = for right and left leg training with 6 channels

Le.Ri.8 Ch. = for right and left leg training with 8 channels

Press OK to select a template.



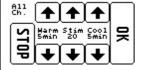
Channel selection

Select channels

By pressing the desired channels, the therapist activates/deactivates them. Activated channels are inversely (black) represented.

To save changes, press OK. After OK, the parameters of the activated channels are processed one after another.

With STOP you go back to the program selection window.



Edit duration of the phases



Edit frequency and ramp

Edit general parameters: frequency, ramp and duration of warm up, stimulation and cool down

After the channels have been set, the parameters concerning all channels can be adjusted:

- times for the simulation phase in minutes

- ramp: number of gradual stimulation impulses before the preset pulse width is reached.

The ramp is carried out every time the crank arm angle of the pedals of the movement therapy device enters the active angle range for a stimulation channel.

- and frequency for all channels.

With OK all changes are saved.

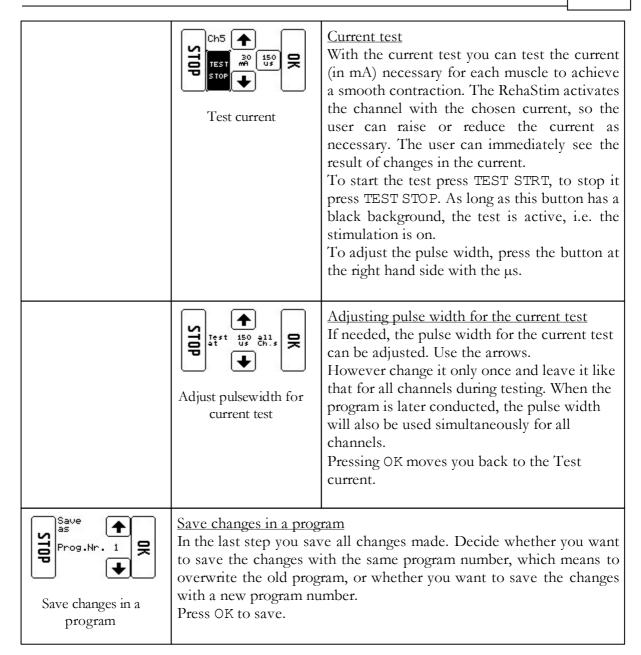


Edit start and stop seconds

Sequence: Edit individual channels: edit start and stop of stimulation in seconds In the left upper corner of the screen you see the number of the channel you are editing

Start and stop seconds refer to the start and stop of the stimulation for the current channel/muscle. The stop second can not be lower than the start second. The lower

	1	
		the starting second, the sooner the muscle will be activated. The bigger the difference between start and stop second, the longer the muscle will be stimulated. An overlapping at the end of the sequence training is not possible. Begin with the first activated channel. Adjust start and stop seconds with the arrows. After OK changes are saved and the next activated channel is opened and so on.
	Edit start and stop percentages	Gait training and gait sequence: Edit individual channels: edit start and stop of stimulation in percentage In the left upper corner of the screen you see the number of the channel you are editing. Start and stop percentages refer to the start and stop of the stimulation for the current channel/muscle. The lower the starting percentage, the sooner the muscle will be activated. The bigger the difference between start and stop percentage, the longer the muscle will be stimulated. An overlapping above 100% is possible. Begin with the first activated channel. Adjust start and stop percentages with the arrows. After OK the changes are saved and the next activated channel is opened and so on.
Edit current	Edit and test individual channels: current In this window for each channel the current can be edited individually. In the left upper corner you see the number of the channel you are editing. You begin with the first activated channel. Adjust the current manually with the arrows. After OK the changes are saved and the next activated channel is opened and so on. If you want to test the current, press the button TEST STRT. If needed, the pulse width for the current test can be adjusted. Use the arrows. However change it only once and leave it like that for all channels during testing. When the program is later conducted, the pulse width will also be used simultaneously for all channels. Pressing OK moves you back to the Test current.	



3.9 Finishing a Stimulation Session

Actions at the end of a therapy:

- 1. stop stimulation, switch off stimulator
- 2. disconnect electrodes from cables and detach from client

4 Software Module ScienceMode

4.1 Description

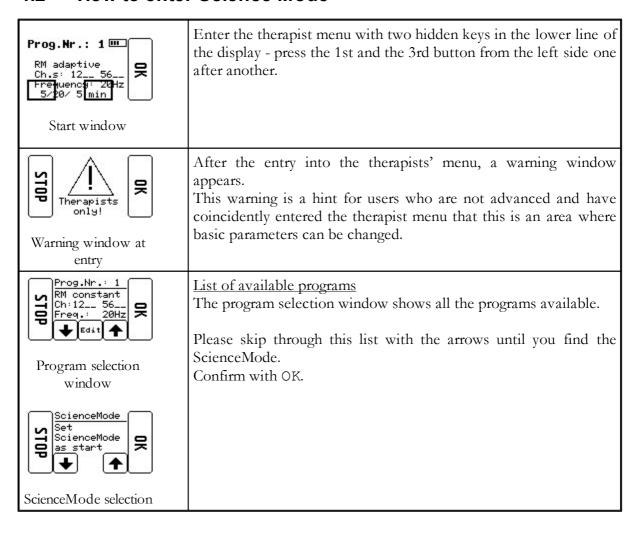
The versatility of the stimulator is extended by the option of a direct PC connection. Over the PC and the "ScienceMode" protocol any sequence of stimulation impulses can be programmed. The information handed over to the stimulator is processed in defined time intervals and transferred as stimulation impulse to the electrodes.

With access to the extensive periphery, highly complex stimulation surroundings and corresponding therapy places, which so far could only be realized laboriously and costly, can now be installed.

A survey on the ScienceMode is available through a third party: http://sciencestim.sourceforge.net/sciencemode.html

Further documents on the ScienceMode can be downloaded: http://sourceforge.net/projects/sciencestim/files/

4.2 How to enter Science Mode



ScienceMode Science Mode start window	ScienceMode start window This is the start window for the ScienceMode. With OK you start the ScienceMode
Science- Mode is active! Window "ScienceMode is active"	The ScienceMode is now activated. You can proceed communication with the RehaStim through your computer. In order to interrupt the ScienceMode, pres STOP. You will return to the ScienceMode start window.
ScienceMode Start with OK Return to therapist menu	Leave ScienceMode/ Return to therapist menu via start window In order to leave the ScienceMode, press STOP and go back to the ScienceMode start window. Enter the therapist menu by pressing the 2 hidden keys in the lower line as pictured.

5 Fault indication

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

5.1 Errors in the RehaStim

• LEDs on the RehaStim

Stimulation control light	Stimulator state	Possible cause	Fault repair
Not shining	Stand-by/no stimulation active		Turn device off and restart it. If the error is not fixed then please contact the HASOMED GmbH technical support.
Blinking red	Stimulation stopped	Operation fault: electrode has fallen off or has been connected incorrectly	connection, check channel
Red continuously	Stimulation is not started	(communication	Turn device off and restart it. If the error is not fixed then please contact the HASOMED GmbH technical support.

• RehaStim LCD touch screen

LCD screen	touch	Stimulator state	Possible cause	Fault repair
Unlighted		The screen is not lit up but the keys are still dimly visible		Touch an area on the screen where there is a button.
Dark		Internal turn off		Turn device off and then on again. If the error repeats please contact the technical support of the manufacturer HASOMED GmbH.

Dark	Internal turn off	Battery is empty	Recharge the battery with the charger provided.
Dark	Internal turn off		Turn device off and unbolt the button by twisting.

6 Declaration of Warranty

HASOMED GmbH gives a warranty on the function of the equipment, the extent according to the 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 void:

- -if damages arise from improper use, e.g. operation of touch screen with hard mechanical objects like a biro; damages at 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 has been interfered by a third 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 your RehaStim to the manufacturer at your own account.

HASOMED GmbH offers a security check with optional follow-up warranty of one year including exchange of wear parts and accumulators.

7 Address of manufacturer

Developer and manufacturer: HASOMED GmbH

Paul- Ecke- Str. 1 39114 Magdeburg GERMANY

Managing Director: Dr. Peter Weber

Telephone: +49 391 6230112

E- mail: info@hasomed.de

Service address: HASOMED GmbH

Service – FES Paul-Ecke-Str. 1 39114 Magdeburg GERMANY

Tel: +49 391 6107646