

## RehaMove3

# Instructions for Use



Read the Instructions for use (IFU) before you use the device

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HASOMED GmbH  
Paul-Ecke-Str. 1  
39114 Magdeburg  
Germany

Phone: +49 (0) 391 - 61 07 650

E-Mail: [info@rehamove.de](mailto:info@rehamove.de)

Webpage: [www.hasomed.de](http://www.hasomed.de)

Subject to Modifications

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# 1 Safety Notes

## 1.1 Basic details

Before you start using the device in any way at all, read this user manual in full and pay particular attention to the safety measures.

The RehaMove3 is classified as a medical device class 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 RehaMove3 must be performed only by the manufacturer.

This user manual describes the safe and correct use of RehaMove3. The safety measures contained herein must be strictly observed. Accident prevention regulations that apply in the country where the device is being used, as well as general safety and hygiene regulations, must also be complied with.



### Caution !

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

## 1.2 Symbols and Labels

The following symbols and labels are used on the RehaMove3. The rating plate stating the exact model name, CE mark and corresponding number of the notified body, date of manufacture, and power supply details are located on the head of the stimulator.



General warning sign



Information sign

Type BF application parts



Applied parts which are in contact with the user during standard use and which are therefore subject to special safety criteria. The following accessories (type BF) must be maintained on a regular basis:

- RehaMove3 Stimulator
- electrodes



Refer to the user manual



Do not dispose of in the same way as normal domestic waste. Contact HASOMED for further information.

**CE 0482**

The RehaMove3 meets the medical device 93/42/EWG standards.

### 1.3 Dangers

**Danger indicates a hazardous situation that, if not avoided, will result in death or serious injury.**



Disregarding the proper use will result in serious injury. Follow the Instructions specified in Part3 carefully.



Do not stimulate opposite site of the body with the same stimulation channel. This will result in serious injuries.



Do not insert the electrode cables into live sockets!



The device is a great hazard for small children, even if it's turned off. To prevent strangulation (e.g. with cables) or suffocation (e.g. on small parts), children are not allowed to be in the area of the device without a supervision by adults.



Users of RehaMove3 have to consider the risk of strangulation when using electrode cables.



Prevent the equipment from immersion in water or other liquids. The RehaMove3 is not waterproof. If water or foreign substances enter the interior, immediately turn OFF the stimulator. Continued use of the device may result in fire or electrical shock. Please contact the producer.

## 1.4 Warnings

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



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



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



If directed by the clinician, the patient's blood pressure and heart rate should be monitored during the therapy session.



Some medical conditions can be aggravated by physical activity. If symptoms of a medical condition occur during or after a therapy session, consult your clinician immediately.



Do not connect the patient simultaneously to high-frequency surgical equipment, as this may cause burns under the electrodes.



The therapy can interfere with electrical monitoring devices (e.g. ECG) that are connected to the patient.



Electrical muscle stimulators shall be used exclusively with the electrodes and cables recommended by the manufacturer. Use only the connection systems that have been tested for compatibility with RehaMove3.





The long-term effects of chronic electrical stimulation are unknown.



The long-term effects of chronic electrical stimulation on pregnant women and unborn children are unknown.



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.



Improper connection of system components could result in serious injury.

The safety of patients, users, third parties and equipment cannot be guaranteed if components of the RehaMove3 are not connected directly to the mains power supply. Therefore, do not connect the RehaMove3 to the mains power supply using an extension cable or a multiple socket outlet.



Prevent the equipment from immersion in water or other liquids. The RehaMove3 is not waterproof. If water or foreign substances enter the interior, immediately turn OFF the stimulator. Continued use of the device may result in fire or electrical shock. Please contact the producer.



Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is

ary, this equipment and the other equipment should be observed to verify that they are operating normally.



Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



If the patient's blood pressure or heart rate reaches a level that the clinician considers a compromise to safety or if the patient feels faint or nauseated, the session should be stopped immediately and appropriate medical action should be taken.



Referring to patient safety the power density (amount of energy in the electrode area) of 0,1W/ cm<sup>2</sup> may not be exceeded.

The maximum value of current density may not exceed 2mA/ cm<sup>2</sup>.



Plugs and connectors of RehaMove3 electrode cables, external trigger and quick stop/emergency off are color coded and form-locked. Inverting the connections can damage the stimulator and cause unwanted reactions.



Place the RehaMove3 in such a way that it is easy to disconnect it from the mains power supply, but make sure that the power supply cord cannot be accidentally disconnected by a person or object (no trip hazards). Check that the power cord is safely plugged in. Keep it away from hot surfaces and sharp edges



Do not use the stimulator if an accident could result through the loss of function.

## 1.5 Cautions

**CAUTION** indicates a hazardous situation that, if not avoided, could result in minor or moderate injury or damage the equipment.



**If the battery or battery charger is exchanged without permission, no guarantee for a secure operation is given!**

The battery built into the device must only be exchanged by the HASOMED service staff! The separate battery charger is part of the system and must not be replaced with a different type. It is recommended that the system undergoes a routinely checkup and is replaced where required.



Do not pull on cables to unplug electrodes.

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

HASOMED gives no warranty for obvious misuse.



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

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



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



The device and its surfaces can get warm during a stimulation session. Areas with longer direct contact to the device should be covered with clothing to prevent skin irritations.



Avoid electrostatic charges (generated by clothing, flooring and friction)!

## 1.6 Electromagnetism

### 1.6.1 Electromagnetic Emission

The RehaMove3 is intended for use in the electromagnetic environment specified below. The user of the RehaMove3 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The RehaMove3 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The RehaMove3 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

### 1.6.2 Electromagnetic Immunity


The RehaMove3 is intended for use in the electromagnetic environment specified below. The user of the RehaMove3 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 610004-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % $U_T$ for 0.5 cycle at 8 phase angles from 0° to 315° 0 % $U_T$ for 1 cycle at 0° 70 % $U_T$ for 25/30 cycles at 0° 0 % $U_T$ for 250/300 cycles 0°	0 % $U_T$ for 0.5 cycle at 8 phase angles from 0° to 315° 0 % $U_T$ for 1 cycle at 0° 70 % $U_T$ for 25/30 cycles at 0° 0 % $U_T$ for 250/300 cycles 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RehaMove3 requires continued operation during power mains interruptions, it is recommended that the RehaMove3 is powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
<b>NOTE: <math>U_T</math> is the a.c. mains voltage prior to application of the test level.</b>			

### 1.6.3 Guidance and manufacturer’s declaration

The RehaMove3 is intended for use in the electromagnetic environment specified below. The user of the RehaMove3 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p>	<p>3 and 6 Vrms 150 kHz to 80 MHz</p>	<p>6 Vrms</p>	<p>Portable and mobile RF communications equipment should not be used closer to any part of the RehaMove3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$
<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V/m</p>	$d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			
<p><b>NOTE 1</b> At 80 MHz and 800 MHz, the higher frequency range applies</p>			
<p><b>NOTE 2</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>a Field strengths from fixed transmitters such as base stations for radio (cellular/cordless) telephones, land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters an electromagnetic site survey should be considered. If the measured field strength in the location in which the RehaMove3 is used, exceeds the applicable RF compliance level above, the RehaMove3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be</p> <p>ary, such as reorienting or relocating the RehaMove3.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.</p>			

### 1.6.4 Recommended separation distances

The RehaMove3 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of the RehaMove3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RehaMove3 as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

**NOTE 4** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



## 2 General Information

### 2.1 RehaMove3 at a glance

The RehaMove3 is a portable electrical stimulation device that generates impulses, on up to 4 channels nearly simultaneously, to activate paralyzed muscles via surface electrodes. The RehaMove3 can be used for training and rehabilitation applications. Numerous parameters concerning power and temporal sequence of the impulses can be adjusted individually for each channel.



## 2.2 Responsible Organisation

### 2.2.1 Accountability

The user shall ensure that:

- Only people with the mandatory training are authorized to install, operate, use and maintain the medical device
- Every person using the device has read and fully understood the Instructions for Use
- The device shall only be operated if beforehand the manufacturer or an authorized person acting in agreement with the manufacturer has put the medical device through a functional test at the operating location
- Designated person is instructed based on the instructions for use
- The proper handling, use and operation of the medical device together with the permitted use in combination with other medical devices, equipment and accessoires is guaranteed
- The obligation to notify as well as other obligations for both the manufacturer and the users in connection with the European Medical Device Vigilance System met the German Medical Devices Safety Plan Ordinance. The completion of the functional test and the instruction of the person designated by the responsible organization shall be documented in a medical device log
- Every person using the device has read and fully understood the Instructions for Use
- The user manual shall at all times be kept near the device and made available to the people working with and on the device. However, there is no guarantee that anyone who has read it is qualified to operate, inspect, test, calibrate or troubleshoot the device
- Any person standing close to device shall fully comply with the safety measures described in this user manual
- The device is only used when it has no technical faults and is safe to operate. The device must be checked before every use to ensure that it is in good condition
- Only authorized people can have access to the device. A list of authorized users is kept for the device. Make sure that unauthorized people do not tamper with the device
- The information in this user manual shall be strictly observed in full and without restriction

### 2.2.2 Declaration of Conformity

HASOMED confirms that RehaMove3 is appropriate to the essential requirements for safety and health of all relevant European guidelines. The declaration of conformity is based on the CE-Mark of RehaMove3.

HASOMED declares the compliance to follow the 'ElektroStoffV' of 09.05.2013 and to consider the RoHS (Restriction of Hazardous Substances).

QMS-Formblatt



### EG-KONFORMITÄTSERKLÄRUNG

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

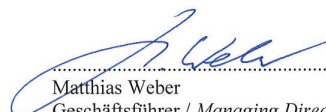
### EC DECLARATION OF CONFORMITY

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

<p>Wir:</p> <p>HASOMED GmbH          Hard- und Software für Medizin          Paul – Ecke – Straße 1          39114 Magdeburg</p>	<p>We:</p> <p><i>HASOMED GmbH          Hard- and Software for Medicine          Paul – Ecke – Straße 1          39114 Magdeburg / Germany</i></p>
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<p>erklären in alleiniger Verantwortung, dass das Produkt/die Produkte:</p> <p><b>RehaMove 3 - Science</b></p> <p>der Klasse II a          (Regel 9 nach MDD 93/42/EWG, Anh. IX)</p>	<p><i>declare under our sole responsibility that the product/s:</i></p> <p><b>RehaMove 3 - Science</b></p> <p><i>of class II a          (rule 9 of MDD 93/42/EWG, annex IX)</i></p>
<p>den einschlägigen Bestimmungen der Richtlinie 93/42/EWG über Medizinprodukte entsprechen.</p>	<p><i>meet the provisions of the Council Directive 93/42/EEC concerning medical devices which apply to them.</i></p>
<p>Diese Konformitätserklärung ist gültig bis zur Ausstellung einer revidierten Konformitätserklärung nach Änderung des Produkts.</p>	<p><i>This declaration of conformity is valid until a revised declaration of conformity after product changes is issued.</i></p>
<p style="text-align: center;"><b>CE</b> 0482</p> <p>Die Zertifizierung wird überwacht von:</p> <p>MEDCERT GmbH          Pilatuspool 2          20355 Hamburg</p>	<p style="text-align: center;"><b>CE</b> 0482</p> <p><i>Certification is observed by:</i></p> <p><i>MEDCERT GmbH          Pilatuspool 2          D - 20355 Hamburg / Germany</i></p>

Magdeburg, den 2017-07-05

  
 Matthias Weber  
 Geschäftsführer / Managing Director

## 3 Correct Usage

### 3.1 Proper Use

#### 3.1.1 Intended Use

RehaMove3 - Science provides functional electrical stimulation for patients with paralyzed muscles after neurological disorders. Low intensity electric current generates action potentials in the stimulated motoric nerves which produces muscle contractions. RehaMove3 can be used for the following purposes in a clinical environment:

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

#### 3.1.2 Environment of usage

Use the device only inside a professional healthcare facility or supervised by healthcare professional.

#### 3.1.3 Description of function

The stimulator RehaMove3 is a device for functional electrical stimulation and generates electrical pulses in order to stimulate muscles via surface electrodes on up to 4 channels simultaneously. The stimulator is battery operated, so it can be used network-independent and mobile. The stimulator needs to be controlled externally by compatible devices. The individual adjustment to the needs of the respective user or his muscles concerning intensity and temporal sequence of pulses is possible by using different parameters.

The user is responsible for the intensity of stimulation. We recommend to increase the amplitude in discrete steps of not more than 1 mA per increment.

### 3.1.4 Contraindications

These contraindications absolutely exclude clients from applying the RehaMove3:

- Cardiac pacemakers: Functional electrical stimulation must not be used in clients with cardiac pacemakers
- Pregnancy: Pregnant women must be excluded from stimulation since possible side effects are unknown and have not been investigated yet
- Fractures: Unhealed fractures exclude the application of the RehaMove3 until they are healed
- Wounds: Unhealed wounds exclude the application of the RehaMove3 until they are healed
- Additional contraindications for arm training:
  - Possibility of luxation of the shoulder joint
  - Deep tears in rotator cuff damaging more than half of the tendons
- Do not use over or in proximity to cancerous growth
- Do not use over swollen, infected or inflamed areas or skin eruptions such as phlebitis, thrombophlebitis or varicose veins

This list does not claim to be complete. The physician in charge has the sole medical responsibility for a rehabilitation therapy and decides whether a patient is fit for a specific treatment. In particular, the physician must weigh in each individual case possible risks and side effects against expected benefits. In addition, the patient's individual situation plays just as important role as the basic risk assessment for specific patient groups. As the patient's therapist you are responsible for adapting the training sessions and the course of therapy to the patient's abilities.

Due to the constant advances in medical knowledge and treatment, the physician in charge must continually keep up-to-date by reading the latest scientific literature and being informed of changes in treatment recommendations.

### 3.1.5 Risk factors

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

Particular attention should be carried out in patients with:

- Suspected or diagnosed heart problems

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

The RehaMove3 stimulation should be stopped immediately as a consequence of any potentially dangerous situation arising from any of the following risk factors:

- Denervated muscles (lack of contraction)
- Severe spasticity: stretching exercises prior to training with the RehaMove3 combined with individual training adjustments may however be necessary to reduce the likelihood of spasticity occurring
- Severe osteoporosis: in the case of an increased risk of fractures, training with the RehaMove3 must be adapted accordingly (milder forms in patients with spinal cord injuries do not necessarily constitute exclusion criteria)
- Dysesthetic pain syndrome: in some cases the pain can become so unpleasant that it is necessary to interrupt the training session
- Implantable medical devices: plates, nails, screws or other metal parts implanted less than 3 months ago underneath or near the group of muscles to be stimulated
- Epilepsy: this disorder can constitute an exclusion criterion under certain circumstances, since possible adverse reactions are still unknown
- Allergic reaction to the gel used in the electrodes (ask your medical supplier)

The stimulation can be interrupted immediately by press and holding the on/off-button of RehaMove3 or by disconnecting of an electrode or electrode cable. The electrode detection ensures that stimulation stops due to the interrupted connection of RehaMove3 and the electrode.

### 3.1.6 Electrode Application

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

- The electrodes have to be placed centrally on the muscle belly.
- Electrodes of one stimulation channel may not be placed on two different body sides.
- Ensure that the stimulated muscle/applied electrodes correspond to the muscle-channel configuration.
- For a higher therapeutic effect, the electrodes have to be placed with a handbreadth between them.
- The skin must always be clean, dry, and free of any lotions.
- When the electrodes start losing adherence, you can prolong their lifespan by applying one or two drops of water on the gel surface. If this does not work, replace the electrodes.
- Always remove the electrodes by lifting up one of the edges and peeling off. Do not pull on the cable!
- After use, always stick the electrodes back onto the "ON" side of the storage liner.
- Store the electrodes in their original packaging in a dry and cool place.
- Never let the electrodes get wet.
- Using hot or cold packs over a long period of time can diminish the electrodes' adhesive performance.
- Do not use the same electrodes on different patients – each patient must have his own set.
- Replace the electrodes upon any sign of wear and tear.
- Using bigger electrodes can influence the sensation of current density.

The user has to replace the electrodes:

- Not later than after 30 sessions,
- After a maximum utilization time of 3 months,
- If a problem occurs during the product specific use,
- If skin irritations occur or
- The electrodes exceeded the use-by date indicated on the package.

Please note that different muscles require different electrode positioning appropriate to their muscle fiber direction and other muscles close with antagonistic functions.

For instance a wrong electrode application for muscle Tibialis Anterior could affect an unwanted stimulation of the antagonistic Soleus muscle.

### 3.1.7 Side Effects

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

Using the RehaMove3 can cause additional adverse reactions:

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

These lists do not claim to be complete..



#### **Warning!**

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



## 4 Device description

### 4.1 Technical specifications

RehaMove3	
Size and Weight	
Lenght	50 mm
Width	73 mm
Height	32 mm
Weight	280 g
Power supply	
Power source(s)	AC and/or storage battery
Method of line current isolation	<ul style="list-style-type: none"> <li>- TR 30M090 nach EN60601-1</li> <li>- Battery usage: 2S1PCGA103450, Li-Ion</li> <li>- Galvanic isolated to every applied part</li> </ul>
Power connection	100-240 VAC, 47-63 Hz
Power input	max. 30 W
Enviroment conditions	
In use	+5 °C to +34 °C; RH 15% to 93%, not condensating
Transporting/storing	-20°C bis +45°C; RH 0% - 80%, not condensating (recommended to ensure battery life cycle)
Stimulator/Controller	
Display/Interface	keypad

Communications	USB
Operation system	Special software
Maximum voltage output	150 V
Maximale number of channels	4
Current output per channel	0-150 mA in 0,5 mA steps (at 1 k $\Omega$ )
Waveform	Variable, adjustable using 16 characteristic points
Duration of the stimulation impulses (pulse width)	10-65536 $\mu$ s in steps of 1 $\mu$ s
Stimulation frequency	10 - 500 Hz (period in steps of 0,5 ms; depending on waveform and number of active stimulation channels)
Range of atmospheric pressure	700 to 1060 hPa
IP classification	IP X0
Protection class	II
Application part	Typ BF
Medical device according to EU guidelines MDD 93/42/EWG	IIa

## 4.2 System components

### 4.2.1 Scope of Delivery

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 mandatory includes:**

- 1 stimulator
- 3 electrode cables
- 1 power supply unit for the stimulator
- 4 sets of electrodes
- 1 Instructions for Use



4.2.1.1 RehaMove3



RehaMove3 provides 4 operation buttons. The back of the stimulator shows the type label. A belt clip can be added optionally. On the right side of the stimulator, the following connections can be found:

- One USB output to connect the stimulator with an external Trigger device or PC
- One connection for the power supply unit



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

- The red connector is used for stimulation channel 1
- The blue connector is used for stimulation channel 2
- The grey connector is used for stimulation channel 3 and 4

**WARNING!**

Plugs and connectors of RehaMove3 electrode cables are color coded and form-locked. Inverting the connections can damage the stimulator and cause unwanted reactions.

**4.2.1.2 Electrode Cables**

RehaMove3 provides three electrode cables with 1 or 2 channels each. All cables are color coded to avoid wrong application.

**CAUTION!**

Do not pull on cables to unplug electrodes.

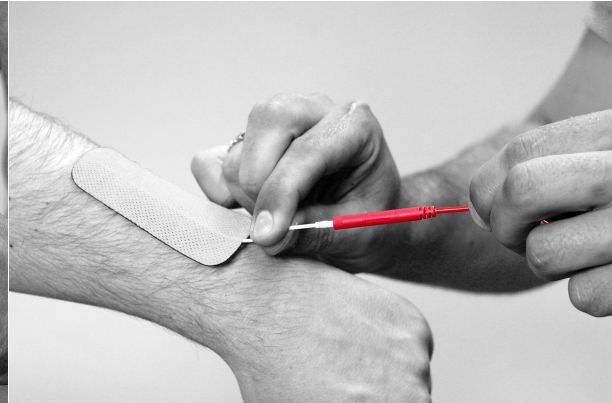
Pulling the cable can damage the plug connection. Also using other electrode types can cause a too strong connection between electrode and electrode cable and can damage or breakaway the cable.

HASOMED gives no warranty for obvious usability faults.

**Right**



**WRONG**



#### 4.2.1.3 Type label

**RehaMove3  
Electrical Stimulator**

**HASOMED**<sup>®</sup>  
HARDWARE AND SOFTWARE FOR MEDICINE

**SN**

**DO NOT OPEN!**

Rechargeable Li-Ion Battery

**Only use Power Supply:**

CINCON: TR30-M090,  
Output: 9V / 3A

**CE** 0482



HASOMED GmbH  
Paul-Ecke-Str. 1  
39114 Magdeburg  
Germany

**For US:  
Caution Rx Only  
Made in Germany**

#### 4.2.2 Science Mode

##### 4.2.2.1 Science Mode

The RehaMove3 includes an interface for scientific application, called ScienceMode. The ScienceMode gives opportunities for a wide range of research applications leaving full freedom to your creativity. It can be used to create complex stimulation patterns and training scenarios by controlling the RehaMove3 using an external device (e.g. PC or similar devices).

ScienceMode enables the communication between a controlling device and the RehaMove3 via USB using a virtual serial interface (FTDI) to control all stimulation tasks. RehaMove3 with ScienceMode offers two advanced layers for high scientific FES performance.

The Mid-Level layer implements a command set for the most common stimulation applications. Each channel can be configured with an individual wave form and stimulation parameters (e.g. current, pulse width, frequency).

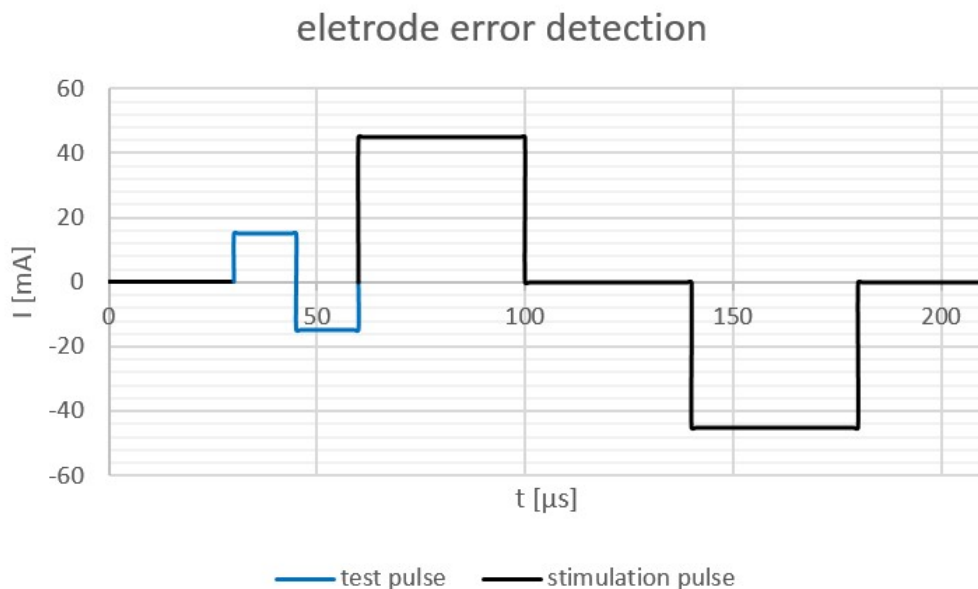
The Low-Level layer allows each stimulation impulse to be generated by the control program, which enables individual non-periodic stimulation patterns.

The ScienceMode pre-compiled C-library is available for several compilers and operating systems for easy integration into a wide range of control applications. For API documentation and library download, please visit the following website [www.rehamove.com](http://www.rehamove.com) (ScienceMode).

#### 4.2.3 Electrode error detection

To ensure that the electrodes are conductively connected the RehaMove3 uses a biphasic test pulse right in front of the stimulation pulse. The test pulse is applied independently of the communication protocol. The amplitude is 15 mA and the pulse duration is 15  $\mu$ s.

The following figure shows an exemplary signal path.



## 5 Maintenance and Service Instructions

### 5.1 Cleaning and Disinfection

Clean the RehaMove3 regularly for hygienic reasons. Use a dry or slightly moist cloth. If there are persistent stains, you can also soak the cloth in alcohol or a universal (BMF) cleaner. Never use strong detergents, soaps or solvents.

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

Disinfect the RehaMove3 before every patient treatment session, thus preventing cross-contamination between patients. Wipe the device's surfaces with disinfectant.

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

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

### 5.2 Stimulator Battery

#### 5.2.1 Charging

Use the power supply to recharge the stimulator. Depending on the country/type of the power outlet, different plugs are available. The appropriate plug for your country is delivered by the manufacturer.

For the status indicator (LED) see section 6.1.3.2 .

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

**NOTE! Only use the power supply unit provided by the manufacturer.**

#### 5.2.2 Maintaining

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

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

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



### 5.3 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 RehaMove3 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.

The proper disposal of RehaMove3 involves certain risks due to the integrated LI-ION battery. 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.

**General information on disposal:** Please contact HASOMED GmbH for the respective information on returning.

### 5.4 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. damages of the device case or connectors, downfall.
- If you connect other electrical devices to the stimulator except devices that have been acknowledged by HASOMED.
- If the official seal for safety requirements was vandalized, or the device was opened by an unauthorized party.

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

## 6 Main Functions

### 6.1 Operation

#### 6.1.1 General Notes

Read the manual carefully before using this device!

Before the first session, the user must consult a doctor or physiotherapist to find out how to set ideal parameters.

It is recommend that the RehaMove3 is used as part of a therapy program prescribed by a doctor or therapist.

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

#### 6.1.2 Before you start

Check that the supply voltage of the unit matches with your line voltage. Only connect the RehaMove3 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 the original power supply delivered by the manufacturer HASOMED GmbH. If an electric cable has been damaged, stop session immediately and contact the manufacturer.

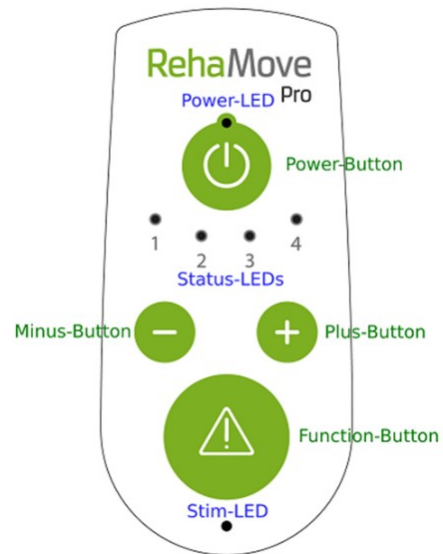
Connect cables in a way that no person walking by could get caught in the cables and these cannot get into the rotating pedals and be damaged.

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.

### 6.1.3 Button and LED Management

#### 6.1.3.1 Usage Buttons

- Power button
  - Press the button to switch on the RehaMove3.
  - The device can be switched off by pressing and holding the button for at least 5 seconds.
  - After the device has been switched off, a 5 seconds break is required before the RehaMove3 can be switched on again.
- Minus, plus, function button
  - These buttons have no function currently.



#### 6.1.3.2 Status LED

RehaMove3 status	Power supply	Battery	LED	Description
Off	No	-	Off	-
On	Yes	Device without battery	Orange – on	-
On	No	Not full	Green – slow blinking	-
On	No	Low battery	Orange – slow blinking	Low rechargeable battery (11-20%); Please connect power supply.
On	No	Very low battery	Red – slow blinking	Very low rechargeable Battery (<11%); Please connect power supply.

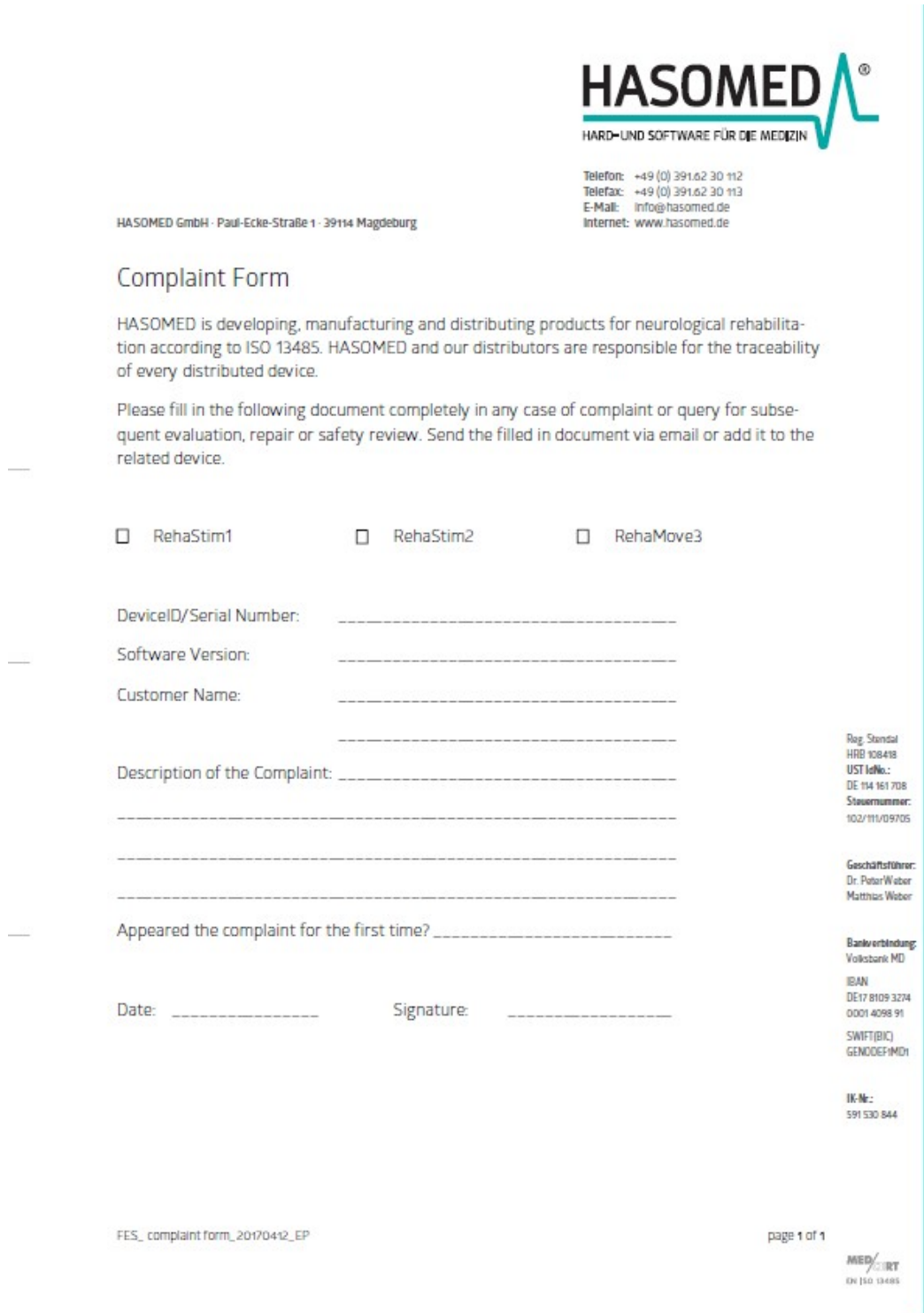
Off	Yes	-	Blue – on	-
On	Yes	Rechargeable battery is charging	Green – fast blinking	Rechargeable battery is charging
On	Yes	Completely charged	Green – on	-

### 6.1.3.3 Stimulation LED

Color	LED state	Description
Yellow	On, Off, blinking	After the first initialization, the LED is switched on during the stimulation (at least one channel is active).
Red	Fast blinking	Electrode error at least on one channel.

## 6.2 Complaint form for unwanted events

All devices must be monitored since the first placing on the market to ensure a highest level of usability and user safety. Appearing complaints must be reported, documented and evaluated immediately by HASOMED. Complete specifications of the user, device details and the complaint are mandatory. Please complete the following document in the event of an error.



The image shows a complaint form from HASOMED. At the top right is the HASOMED logo with the tagline 'HARD-UND SOFTWARE FÜR DIE MEDIZIN'. Below the logo are contact details: Telefon: +49 (0) 391.62 30 112, Telefax: +49 (0) 391.62 30 113, E-Mail: info@hasomed.de, and Internet: www.hasomed.de. The company address is HASOMED GmbH · Paul-Ecke-Straße 1 · 39114 Magdeburg. The form is titled 'Complaint Form' and explains that HASOMED is developing, manufacturing and distributing products for neurological rehabilitation according to ISO 13485. It asks the user to fill in the form completely in any case of complaint or query for subsequent evaluation, repair or safety review. The form includes three checkboxes for device types: RehaStim1, RehaStim2, and RehaMove3. There are several lines for entering 'DeviceID/Serial Number', 'Software Version', and 'Customer Name'. A 'Description of the Complaint' section follows with multiple lines for text entry. A question 'Appeared the complaint for the first time?' is followed by a line for a yes/no response. At the bottom, there are lines for 'Date' and 'Signature'. On the right side of the form, there is contact information for the Reg. Stempel (HRB 108418, UST IdNo.: DE 114 161 708, Steuernummer: 102/111/09705), Geschäftsführer (Dr. Peter Weber, Matthias Weber), Bankverbindung (Volksbank MD, IBAN: DE17 8109 3274 0001 4098 91, SWIFT(BIC): GENODEF1MD1), and IK-Nr.: 591 530 844. The footer contains the file name 'FES\_complaint form\_20170412\_EP', 'page 1 of 1', and the MED/ART logo with 'EN ISO 13485'.