U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K112844 - 268 pages
COMPANY:	HASOMED GMBH (HASOMED)
PRODUCT:	STIMULATOR, NEUROMUSCULAR, EXTERNAL FUNCTIONAL (GZI)
SUMMARY:	Product: REHASTIM 2, REHAMOVE 2
DATE REQUESTED:	Oct 21, 2015
DATE PRINTED:	Oct 21, 2015
Note:	Printed

K112844

OCT 27 2011

Special 510(k) RehaStim 2 / RehaMove 2

05 510(k) summary

21CFR807.92 / special 510(k)

Name of the legally marketed (unmodified) device

Proprietary name:	RehaStim;
	RehaMove (RehaStim with movement exerciser)
510(k):	K073237
Device Class:	class 2 device
Classification:	Neurology

Submitter's / owner's name, address, Telephone number, a contact person, and the date the summary was prepared:

510k Submitter:	Hasomed GmbH
Contact person:	Matthias Weber
Address:	Paul-Ecke-Strasse 1
	39114 Magdeburg
	Germany
Phone:	+493916209190
Fax:	+493916230113

Prepared on September 26 2011

Name of device, including the trade or proprietary name if applicable, the common or usual name, and the classification name :

Proprietary name: "RehaStim 2" of HASOMED GmbH

"RehaMove 2" (movement exerciser with arm crank, includes RehaStim) of HASOMED GmbH

Common Name: Powered Muscle Stimulator

Classification Name: Powered Muscle Stimulator

Identification of the legally marketed device to which the submitter claims equivalence:

Manufacturer: HASOMED GmbH

Product: "RehaStim" ; "RehaMove" (Version 1)

K-number: K073237

Class: class 2 device

Product Code: GZI

A description of the device that is the subject of the premarket notification submission:

The RehaMove 2 is a portable Functional Electrical Stimulation (FES) system based on a cycle ergometer and a stimulator. It consists of: a motorized movement exerciser (MOTO Med viva II) produced by Reck-company and a stimulator unit (RehaStim 2) produced by Hasomed GmbH. For alternative training of upper extremities a motorized arm crank with same characteristics can be used. The stand-alone mode of RehaStim 2 allows training without movement exerciser.

The system RehaMove 2 allows training for person with impaired functions of lower and upper extremities in two modes:

active mode - using FES support for muscle contractions and if necessary motor power of movement exerciser

passive mode - only movement by motorized movement exerciser

The FES – stimulation controller RehaStim 2 generates impulses, on up to 8 channels simultaneously, to activate paralyzed muscles via surface electrodes. A connection cable enables the RehaStim to receive angle-parameters and to control the Reck Viva II movement exerciser. Two electrode cables (at maximum 16 cutaneous electrodes for 8 channels) connect the RehaStim 2 with the electrodes on the skin. A USB interface gives the possibility to connect the RehaStim 2 to the PC e.g. connect to patient database.

The RehaStim 2 can be used as a portable (contains a battery) or stationary device for training and rehabilitation applications.

Statement of the intended use of the device:

Both the RehaStim 2 and RehaMove 2 are intended for general rehabilitation for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

Technological Characteristics

The functions of the RehaMove 2 and RehaStim 2 are the same as the predicate device however there are certain technological similarities and differences as described below:

Technology	RehaStim 2 / RehaMove 2	RehaStim/RehaMove
Power Source	AC and/or storage battery: Power supply: cincon tr30m according to EN60601-1 Battery: BMZ18650 V, Li-Ion Mangan cells, 2S1P, C= 1600 mAh,	AC and/or storage battery: Power supply :mascot typ9920 according to EN60601-1 Battery: SANYO, NiMh, C= 2700 mAh
Controller	Uses custom processor, running LinuxOS ,running custom software	Uses custom controller running custom software
Stimulator (energy delivered)	0-130mA charge balanced stimulator with rectangular impulses	0-130mA charge balanced stimulator with rectangular impulses
patient part	Type: BF	Type: BF
movement exerciser	RehaMove 2: Uses motor to create flywheel effect with reduced weight and space	RehaMove: Uses motor to create flywheel effect with reduced weight and space
Arm crank	Arm crank gives same upper extremities training possibilities as with lower extremities Uses motor to create flywheel effect with reduced weight and space	Arm crank gives same upper extremities training possibilities as with lower extremities Uses motor to create flywheel effect with reduced weight and space

Seating	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer
Passive cycling	RehaMove 2: Utilizes motor to provide assistance during passive cycling	RehaMove: Utilizes motor to provide assistance during passive cycling
Database interface	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs

Table 5-1 Technological similarities and differences

Determination of substantial equivalence

Test or procedure	Task
Review of user documentation for predicate device	It was reviewed that equivalent function-nality was implemented in RehaMove 2.
Review of 510(K) submissions for predicate device	Confirm technical specifications for completion of predicate details in comparison tables
Output characteristic measurement of new device	The RehaMove 2 / RehaStim 2 device was tested and technically compared with the predicate device.
Control of system testing	The system testing was aligned to verify performance to specification.

Table 5-2 Performance data

It can be matched that there is a substantial equivalence in all important technical and medical characteristics to the premarket notification.

HASOMED concludes that:

Both the RehaMove 2 and RehaStim 2 have the same intended use and the same output characteristics as the predicate device. The different technological characteristics do not raise new questions of safety and effectiveness.

The safety and effectiveness of using a movement exerciser to simulate the predicate devices motor powered flywheel and provide passive cycling assistance has been extensively demonstrated in particular by the ongoing clinical use of the movement exerciser without the stimulation component both in the European Union and the U.S.A.

The safety and effectiveness of the controller has been demonstrated over the development period of the RehaStim 2 and RehaMove 2 and many clinical applications.

The remote database enhances the safety and effectiveness of the system by ensuring that patients always starts a therapy session with their latest, accurate device settings.

In conclusion, HASOMED´s clinical and non- clinical testing have demonstrated that the RehaStim 2 and RehaMove 2 are as safe and effective as the predicate device.

Product code: GZI

Common Name: Powered Muscle Stimulator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT 2 7 2011

Hasomed GMBH
% Mr Matthias Weber
HASOMED GmbH
Paul-Ecke-Strasse 1
39114 Magdeburg
Germany

Re: K112844
Trade/Device Name: RehaMove 2 & RehaStim 2
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: September 27, 2011
Received: September 29, 2011

Dear Mr. Weber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

04 Indications for Use

510k number if known: K112844

Device Name: RehaMove 2

RehaStim 2 (stand alone)

Indications for Use:

Both the RehaMove 2 and RehaStim 2 are intended for general rehabilitation for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112844

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT 2 7 2011

Hasomed GMBH
% Mr Matthias Weber
HASOMED GmbH
Paul-Ecke-Strasse 1
39114 Magdeburg
Germany

Re: K112844
Trade/Device Name: RehaMove 2 & RehaStim 2
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: Class II
Product Code: GZI
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related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

04 Indications for Use

510k number if known: K112844

Device Name: RehaMove 2

RehaStim 2 (stand alone)

Indications for Use:

Both the RehaMove 2 and RehaStim 2 are intended for general rehabilitation for:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K112844

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 29, 2011

HASOMED GMBH
PAUL-ECKE-STRASSE 1
MAGDEBURG
GERMANY 39114
ATTN: MATTHIAS WEBER

510k Number: K112844
Received: 9/29/2011
Product: REHASTIM 2, REHAMOVE 2

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

K112844

HASOMED®
Hard- und Software für die Medizin

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Telefax: +49 (0) 391.62 30 113
E-mail: info@hasomed.de
Internet: www.hasomed.de

HASOMED GmbH · Paul-Ecke-Straße 1 · 39114 Magdeburg

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
USA

Tuesday, September 27, 2011

Documents for application / registration
Organisation-Number: 170430

FDA CDRH DMC
SEP 29 2011
Received

Dear Madam or Sir,

enclosed we send you the documentation to the registration of our product RehaStim2 / RehaMove2 in duplicate.

We would be very grateful about a short intermediate message when the documents arrived at you.

Sincerely yours,

Sabine Hartmann
Personal Assistent

FDA CDRH DMC
SEP 29 2011
Received

Reg. Stendal
HRB 108418
UST IdNo.:
DE 114 161 708
Steuernummer:
102/111/09705

Geschäftsführer:
Dr. Peter Weber
Frank Schulze

Bankverbindung:
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BLZ 810 932 74
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140 98 91
IBAN
DE17 8109 3274
0001 4098 91
SWIFT(BIC)
GENODEF1MD1

IK-Nr.:
591 530 844

41

MED CERT
EN ISO 13485

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted] Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
HASOMED GMBH Paul-Ecke-Strasse 1 Magdeburg 39114 DE	Matthias Weber 2.1 E-MAIL ADDRESS matthias.weber@hasomed.de 2.2 TELEPHONE NUMBER (include Area code) 493916107653
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2.3 FACSIMILE (FAX) NUMBER (Include Area code) +493916230113

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD116241

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [redacted]

26-Sep-2011

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

HASOMED

Hard- und Software in der Medizin
Paul-Ecke-Straße 1
D-39114 Magdeburg
Tel. (+49)391-6230-112
Fax (+49)391-6230-113

09/26/2011

Online Payment

Step 3: Confirm Payment 1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

(b)(4)

[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
08/01/2011	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Hasomed GmbH	E662579		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	+49 3916230112		
Street Address	**FAX Number *(including area code)***		
Paul-Ecke-Straße 1	+49 3916230113		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Magdeburg	SA	39114	Germany
Contact Name			
Matthias Weber			
Contact Title	**Contact E-mail Address**		
Managing engineer	matthias.weber@hasomed.de		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Graphics (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:

newer version (update) of an existing device

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GZI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K073237	1	RehaStim/RehaMove	1	Hasomed GmbH
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

	Trade or Proprietary or Model Name for This Device		Model Number
1	RehaStim	1	2
2	RehaMove	2	2
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	D034390	2	K073237	3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GZI	882.5850	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Neurology

Indications *(from labeling)*

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
	3006141275	

Company / Institution Name	Establishment Registration Number
HASOMED GmbH	E662579
Division Name *(if applicable)*	Phone Number *(including area code)*
	+49 3916230112
Street Address	FAX Number *(including area code)*
Paul-Ecke-Straße 1	+49 3916230113

City	State / Province	ZIP Code	Country
Magdeburg	SA	39114	Germany

Contact Name	Contact Title	Contact E-mail Address
Matthias Weber	managing engineer	matthias.weber@hasomed.de

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*
Street Address	FAX Number *(including area code)*

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*
Street Address	FAX Number *(including area code)*

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	EN ISO	13485: 2009	Quality Management		
2	EN IEC	14971: 2009	Risk Management		
3	EN IEC	60601-1: 2006	Medical Electrical Equipment		
4	EN IEC	60601-1-2: 2007	EMC		
5	EN IEC	60601-1-6: 2007	Usability		
6	EN IEC	60601-2-10: 2000	Stimulators		
7	EN IEC	62304: 2006	Software		

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

HASOMED®
Hard- und Software für die Medizin
Paul-Ecke-Straße 1
D-39114 Magdeburg

09/20/2011

K112844

01 Cover letter

Type of 510(k) submission: special

Device Type: RehaMove 2: Movement exerciser with functional electrical stimulation (FES) - includes
RehaStim 2: Functional Electrical Stimulator

Submitter and holder
HASOMED GmbH
Paul-Ecke-Strasse 1
39114 Magdeburg
Germany

Phone: +493916230112
Fax: +493916230113

Facility registration number: FEI 3006141275
Establishment reg. number: E662579

Contact person: Matthias Weber
Managing engineer
HASOMED GmbH
Paul-Ecke-Strasse 1
39114 Magdeburg
Germany

Phone: +493916209190

Preference for continued confidentiality: „yes"

Device Class: class II device

Classification: Neurology

Product code: GZI

Common Name: Powered Muscle Stimulator

Proprietary name: RehaStim 2;
RehaMove 2 (RehaStim 2 with movement exerciser)

Basis for the Submission: modified device

Identification of the Legally marketed device to which the submitter claims equivalence: HASOMED product RehaStim / RehaMove

50

Regulation number: 21 CFR 882.5810

Class: class II device

Product Code: GZI

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	-	-
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

Table 1-1 Design and Use of the Device

02 Table of Contents

Content/Format of a Special 510(k)	
A Special 510(k) should be well organized and formatted in sections, with page numbering, and include the required elements:	Section
Medical Device User Fee Cover Sheet (Form FDA 3601)	Form FDA 3601
CDRH Premarket Review Submission Cover Sheet (FDA Form 3514)	Form FDA 3514
Certification of Compliance with ClinicalTrials.gov Data Bank, FDA-3674	N/A
Cover sheet FDA 3514	0
medical device cover sheet - final 2011-09-26	00
confirm payment - cover sheet 2011-09-26	00a
Cover Letter	01
Table of Contents	02
510(k) Screening Checklist	03
Statement of Indications for Use	04
510(k) Summary	05
Standards Data Report	06
Truthful and Accuracy Statement	07
Class III Certification and Summary (if applicable)	N/A 08
Unmodified device	09
Description of the modified device	10
Datasheet Lilly-912	10a
Product Safety Datasheet	10b
TR30M Datasheet	10c
Comparison of the devices	11
Intended use of the device	12
Proposed label and labeling	13a
Proposed advertisements	13b
Directions for use	13c
Summary of design control activities	14a
Risk analysis methods used	14b
Risk management report	14c
Identification of verification and validation activities	14d
Software documentation	15
Pruefprotokoll Software RS2 Nr06	15b
Pruefprotokoll Software RS2 Test	15c
SW docu annex Pruefprotokoll_Software_RS2_Nr06	15b
SW docu annex Pruefprotokoll_Software_RS2_Tests	15c
Hardware documentation	16
Test report_RehaStim 2_Rev1.5_11-02-23 pp1-10	16a
4082531_emc_hasomed_rehastim2 pp1-2	16b
Declaration of conformity with design controls	17
Information on sterilization, biocomp., exp. date, etc., if applicable.	18

03 Checklist

Content/Format of a Special 510(k)	
A Special 510(k) should be well organized and formatted in sections, with page numbering, and include the required elements:	Section
Medical Device User Fee Cover Sheet (Form FDA 3601[7]). See 510(k) Review Fees[8] for additional information on review fees.	Form FDA 3601
CDRH Premarket Review Submission Cover Sheet (FDA Form 3514[9]) [PDF]	Form FDA 3514
Certification of Compliance with ClinicalTrials.gov Data Bank, FDA-3674[10]* *Beginning December 26, 2007, all 510(k) submissions must include a completed copy of form FDA-3674. See Form FDA-3674, ClinicalTrials.gov Data Bank[11] for additional information.	Form FDA 3674 N/A
Cover Letter, clearly identifying the application as a "Special 510(k)." Include 510(k) holder name, address, and facility registration number, if available.	01
Table of Contents (recommended)	02
510(k) Screening Checklist (recommended)[12]	03
Statement of Indications for Use[13] Prepare a Statement of Indications for Use as a separate page. We recommend that you use the Indications for Use format. Use the ODE recommended format[15] for submissions to ODE and the OIVD[16] recommended format for submissions to OIVD. The statement should include specific indications, clinical settings, define the target population, anatomical sites, etc. This statement must be consistent with your labeling, advertising and instructions for use. Once the review is complete, FDA will include the Indications for Use Statement with the Substantial Equivalence (SE) letter to the applicant and make it available to the public on the Internet.	04
510(k) Summary[14] [21 CFR 807.92] or 510(k) Statement[15] [21 CFR 807.93]	05
Standards Data Report for 510(K)s - FDA 3654[16] [PDF] Submit this form if your 510(k) references a national or international standard.	06
Truthful and Accuracy Statement[17]	07
Class III Certification and Summary[18] (if applicable)	N/A 08
The name of the legally marketed (unmodified) device and the 510(k) number under which it was cleared. Include the trade or proprietary name, if any, and the common or usual name or classification name of the device. Provide the classification of the device, approprate panel (e.g. cardiovascular, dental, etc.), and product code, if known. • In cases where the referenced 510(k) was submitted under a different name than that of the submitter of the Special 510(k),	09

FDA recommends that a statement to this effect be included in the Special 510(k) and that the submitter maintain adequate information demonstrating his legal right to distribute the device. • When the legally marketed (unmodified) device is a preamendments device, the submitter should clearly state that the device is a preamendments device, is legally marketed, and has not been the subject of premarket notification clearance. (Refer to "Documentation Required for Preamendments Status[19]" for the procedures for demonstrating preamendments status.) Submitters should maintain this information in their files.	
Items required under §807.87 (Information required in a Premarket Notification submission), including description of the modified device; where applicable, photographs or engineering drawings should be supplied,	10
comparison to the cleared device indicating similarities and/or differences accompanied by data, as appropriate; this information may include an identification of materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.	11
intended use of the device,	12
proposed label, labeling, and advertisements for the device and directions for use. It is recommended that submitters of Special 510(k)s highlight, or otherwise prominently identify, all changes in the proposed labeling that may result from modifications to their legally marketed device. In addition, it should be clearly stated in the Special 510(k) that the intended use of the modified device, as described in its labeling, has not changed as a result of the modification(s). **Please note** that a labeling change from prescription use to over the counter use, or vice versa, is considered a change in intended use and, therefore, is not eligible for the Special 510(k) method.	13
A concise summary of the design control activities. FDA may consider the information generated from these activities to be "appropriate supporting data" within the meaning of §807.87(g). This summary should include the following:	14a
An identification of the Risk Analysis method(s) used to assess the impact of the modification on the device and its components as well as the results of the analysis;	14b
Risk management report - extract with reference to changes	14c
Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and the acceptance criteria applied; and	14d
Software documentation	15
Hardware documentation	16

A declaration of conformity with design controls. (See Attachment 2 of 510(k) Paradigm[20]) Please note that if a recent Quality System inspection has resulted in the issuance of a violative inspection report, the manufacturer should be prepared to describe those corrective actions taken, if needed, that form the basis for the declaration of conformity. The **declaration of conformity** should include: A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met; and A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. If a recent Quality System inspection has resulted in the issuance of a violative inspection report, the manufacturer should be prepared to describe those corrective actions taken, if needed, that form the basis for the declaration of conformity. The above two statements should be signed by the designated individual(s) responsible for those particular activities.	17
Information on sterilization, biocompatibility, expiration date, etc., if applicable.	18

Tabs may be used to separate each section but in any case each section should begin on a new page. The order in which required elements are presented is less important than completeness. In other words, it is not strictly required that labeling be presented as part of the device specifications, or in a separate section. For additional information, see Content of a 510(k)[21] and Format of a 510(k)[22]

The 510(k) summary must contain the information described below. Please make a copy of the following to use as a checklist and check off each item to make sure your summary is adequate and complete.

[ ]	The summary should be in a separate section of the submission. It should begin on a new page and end on a page not shared with any other part of the 510(k) submission. It is clearly identified as "510(k) Summary" as required by section 807.92(c).
[ ]	The summary contains on the first page, preferably on your letterhead paper, the 510(k) owner's name, address, phone and fax numbers, name of contact person, and date the summary was prepared [807.92(a)(1)].

[ ]	The summary includes the name of the device, including the trade or proprietary name, if applicable, the common or usual name, and the classification name, if known [807.92(a)(2)]. Example: • Trade name - DRAG@N LATEX EXAMINATION GLOVES • Common name - exam gloves • Classification name - patient examination glove (21 CFR 880.6250, Product Code FMC)
[ ]	The summary identifies the legally marketed device to which your firm is claiming equivalence [807.92(a)(3)].
[ ]	The summary includes a description of the device such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties; [807.92(a)(4)].
[ ]	The summary provides the intended use of the device including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the predicate device, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled [807.92(a)(5)].
[ ]	The 510(k) summary contains a summary of the technological characteristics of your device compared to the predicate device. If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device, a summary of the technological characteristics of the new device in comparison to those of the predicate device should be included. If your device has different technological characteristics from the predicate device, provide a summary of **how** the technological characteristics of your device compare to the predicate device. [807.92(a)(6)]
[ ]	If the determination of substantial equivalence is also based on an assessment of non-clinical performance data, the summary includes a brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence and how their results support a determination of substantial equivalence [807.92(b)(1)].
[ ]	If the determination of substantial equivalence is also based on an

	assessment of clinical performance data, the summary includes a brief discussion of clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence and how their results support a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence [807.92(b)(2)]. Please note: Clinical data is not needed for most devices cleared by the 510(k) process.
[ ]	The summary includes the conclusions drawn from the nonclinical and clinical tests (discussed above) that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device . 807.92(b)(3)
[ ]	The summary includes any other information reasonably deemed necessary by FDA. Such requests will be made directly to the applicant by FDA or the requirements will be published in guidance documents. Additional information requested by FDA during review of the 510(k) may include additional safety and effectiveness information which may necessitate an update of your summary if requested by FDA. 807.92(d)
[ ]	Please make sure you have included all of the information listed above and verify that the following criteria have been met. • " The summary includes only information that is also covered in the body of the 510(k). • " The summary does not contain any puffery or unsubstantiated labeling claims. • " The summary does not contain any raw data, i.e., contains only summary data. • " The summary does not contain any trade secret or confidential commercial information. • " The summary does not contain any patient identification information.

04 Indications for Use

510k number if known: _____

Device Name: RehaMove 2

RehaStim 2 (stand alone)

Indications for Use:

Both the RehaMove and RehaStim are intended for general rehabilitation for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

HASOMED®
Hard- und Software für die Medizin

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HASOMED GmbH · Paul-Ecke-Straße 1 · 39114 Magdeburg

05 510(k) summary

21CFR807.92 / special 510(k)

Name of the legally marketed (unmodified) device

Proprietary name:	RehaStim;
	RehaMove (RehaStim with movement exerciser)
510(k):	K073237
Device Class:	class 2 device
Classification:	Neurology

Submitter's / owner's name, address, Telephone number, a contact person, and the date the summary was prepared:

510k Submitter:	Hasomed GmbH
Contact person:	Matthias Weber
Address:	Paul-Ecke-Strasse 1
	39114 Magdeburg
	Germany
Phone:	+493916209190
Fax:	+493916230113

Prepared on September 26 2011

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DE 114 161 708
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IK-Nr.:
591 530 844

MED CERT
EN ISO 13485

Special 510(k) RehaStim 2 / RehaMove 2

Prepared on august 1th 2011

Name of device, including the trade or proprietary name if applicable, the common or usual name, and the classification name :

Proprietary name: "RehaStim 2" of HASOMED GmbH

"RehaMove 2" (movement exerciser with arm crank, includes RehaStim) of HASOMED GmbH

Common Name: Powered Muscle Stimulator

Classification Name: Powered Muscle Stimulator

Identification of the legally marketed device to which the submitter claims equivalence:

Manufacturer: HASOMED GmbH

Product: "RehaStim" ; "RehaMove" (Version 1)

K-number: K073237

Class: class 2 device

Product Code: GZI

A description of the device that is the subject of the premarket notification submission:

The RehaMove 2 is a portable Functional Electrical Stimulation (FES) system based on a cycle ergometer and a stimulator. It consists of: a motorized movement exerciser (MOTO Med viva II) produced by Reck-company and a stimulator unit (RehaStim 2) produced by Hasomed GmbH.

For alternative training of upper extremities a motorized arm crank with same characteristics can be used. The stand-alone mode of RehaStim 2 allows training without movement exerciser.

The system RehaMove 2 allows training for person with impaired functions of lower and upper extremities in two modes:

active mode - using FES support for muscle contractions and if necessary motor power of movement exerciser

passive mode - only movement by motorized movement exerciser

The FES – stimulation controller RehaStim 2 generates impulses, on up to 8 channels simultaneously, to activate paralyzed muscles via surface electrodes. A connection cable enables the RehaStim to receive angle-parameters and to control the Reck Viva II movement exerciser. Two electrode cables (at maximum 16 cutaneous electrodes for 8 channels) connect the RehaStim 2 with the electrodes on the skin. A USB interface gives the possibility to connect the RehaStim 2 to the PC e.g. connect to patient database.

The RehaStim 2 can be used as a portable (contains a battery) or stationary device for training and rehabilitation applications.

Statement of the intended use of the device:

Both the RehaStim 2 and RehaMove 2 are intended for general rehabilitation for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

Technological Characteristics

The functions of the RehaMove 2 and RehaStim 2 are the same as the predicate device however there are certain technological similarities and differences as described below:

Technology	RehaStim 2 / RehaMove 2	RehaStim/RehaMove
Power Source	AC and/or storage battery: Power supply: cincon tr30m according to EN60601-1 Battery: BMZ18650 V, Li-Ion Mangan cells, 2S1P, C= 1600 mAh,	AC and/or storage battery: Power supply :mascot typ9920 according to EN60601-1 Battery: SANYO, NiMh, C= 2700 mAh
Controller	Uses custom processor, running LinuxOS ,running custom software	Uses custom controller running custom software
Stimulator (energy delivered)	0-130mA charge balanced stimulator with rectangular impulses	0-130mA charge balanced stimulator with rectangular impulses
patient part	Type: BF	Type: BF
movement exerciser	RehaMove 2: Uses motor to create flywheel effect with reduced weight and space	RehaMove: Uses motor to create flywheel effect with reduced weight and space
Arm crank	Arm crank in the same possible like upper extremities	Arm crank in the same possible like upper extremities
Seating	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer
Passive cycling	RehaMove 2: Utilizes motor to provide assistance during	RehaMove: Utilizes motor to provide assistance during

	passive cycling	passive cycling
Database interface	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs

Table 5-1 Technological similarities and differences

Determination of substantial equivalence

Test or procedure	Task
Review of user documentation for predicate device	It was reviewed that equivalent function-nality was implemented in RehaMove 2.
Review of 510(K) submissions for predicate device	Confirm technical specifications for completion of predicate details in comparison tables
Output characteristic measurement of new device	The RehaMove 2 / RehaStim 2 device was tested and technically compared with the predicate device.
Control of system testing	The system testing was aligned to verify performance to specification.

Table 5-2 Performance data

It can be matched that there is a substantial equivalence in all important technical and medical characteristics to the premarket notification.

HASOMED concludes that:

Both the RehaMove 2 and RehaStim 2 have the same intended use and the same output characteristics as the predicate device. The different technological characteristics do not raise new questions of safety and effectiveness.

The safety and effectiveness of using a movement exerciser to simulate the predicate devices motor powered flywheel and provide passive cycling assistance has been extensively demonstrated in particular by the ongoing clinical use of the movement exerciser without the stimulation component both in the European Union and the U.S.A.

The safety and effectiveness of the controller has been demonstrated over the development period of the RehaStim 2 and RehaMove 2 and many clinical applications.

The remote database enhances the safety and effectiveness of the system by ensuring that patients always starts a therapy session with their latest, accurate device settings.

In conclusion, HASOMED´s clinical and non- clinical testing have demonstrated that the RehaStim 2 and RehaMove 2 are as safe and effective as the predicate device.

Product code: GZI

Common Name: Powered Muscle Stimulator

06 Standards data report

This section contains the following FORM FDA 3654 sheets:

- *IEC 60601-1-2*
- *IEC 60601-1*
- *IEC 60601-2-10*
- *IEC 62304*
- *IEC 62366*
- *ISO 13485*
- *ISO 14971*

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essen ... EMC

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-54	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: (not for stimulators)

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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Paperwork Reduction Act Statement

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety... 2005, THIRD EDITION

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
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If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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DESCRIPTION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-2-10 1987/Amendment 1 2001, Medical electrical equipment - Part 2-10: Particular requirem

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#17-5	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
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Title of guidance: Guidance Document for Powered Muscle Stimulator 510(k)s. Document issued on: June 9, 1999.

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
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STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62304 Ed. 1.0, Medical device software - Software life cycle processes

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#13-8	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62366:2007, Medical devices - Application of usability engineering to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#5-67	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Medical Device Use-Safety: Incorporating Human Factors into Risk Management

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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

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STANDARD TITLE [1]

ISO 13485: Quality management

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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Title of guidance: _____

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TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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JUSTIFICATION

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◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971:2007, Medical devices - Application of risk management to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-40:	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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07 Statement

Premarket Notification Truthful And Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as *managing engineer* of *HASOMED GmbH*, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____

(Signature)

M. Weber 2011/08/01

(Matthias Weber)

_____

(2011-08-01)

_____

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

80

07 Statement

Premarket Notification Truthful And Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as *managing engineer* of *HASOMED GmbH*, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature) M. Weber 2011/08/01

(Matthias Weber)

(2011-08-01)

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

08 Class III certification

This section does not apply.

The submitted device is class II.

09 Unmodified device

name of the legally marketed (unmodified) device

Proprietary name:	RehaStim; RehaMove (RehaStim with movement exerciser)
510(k):	K073237
Device Class:	class 2 device
Classification:	Neurology
Product code:	GZI
Common Name:	Powered Muscle Stimulator

[redacted]

10 Description of the modified device

(1) Description of the proposed device, including all device accessories, and new futures of the device

A detailed description of the device is given in section 13c Instructions for use, pp 2-18.

Here, we will describe the hardware background.

Our product RehaStim was updated to the new version 2. The main focus of the redesign was the special need for a better usability. So the conspicuous difference is the big screen and the new concept of using the device. For using the new man-machine interface a new central processor unit was necessary. For a better integration and replacement of components a modular organization was selected.

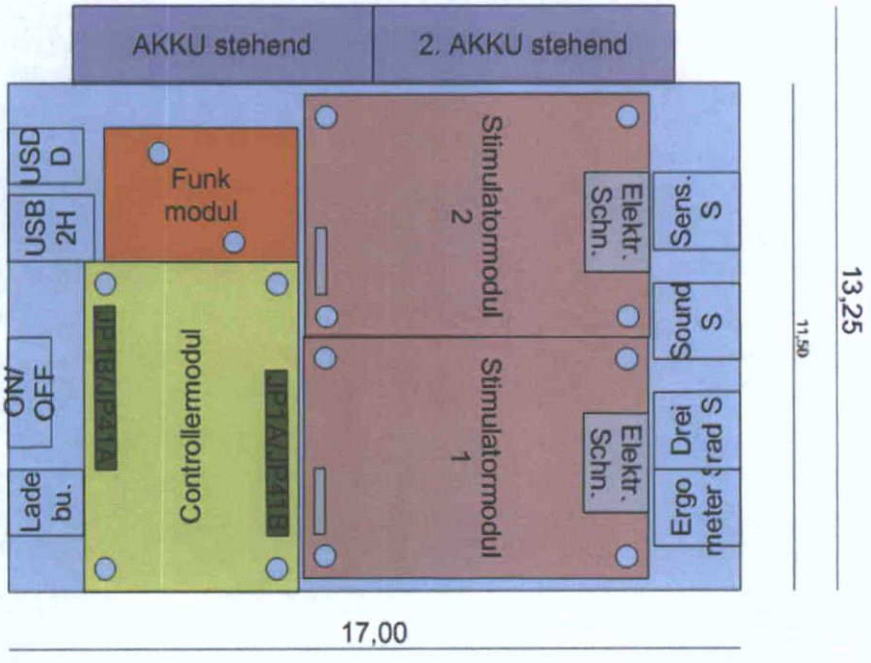

Figure 1

Fig. 10-1

On the picture Fig.1 you can see the main board (blue), the separate controller module (green) and the 2 stimulator modules (red).

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So the main processor a ARM9 microcontroller with peripheries (ram, flash, RTC, CPU power supply, interface controller,..) is located on a separate module. This module is external manufactured by incostartec. For detailed information please see: 10a *Datasheet Lilly-912.pdf*.

(2) Identification of the relevant dimensions and weight of the device and accessories

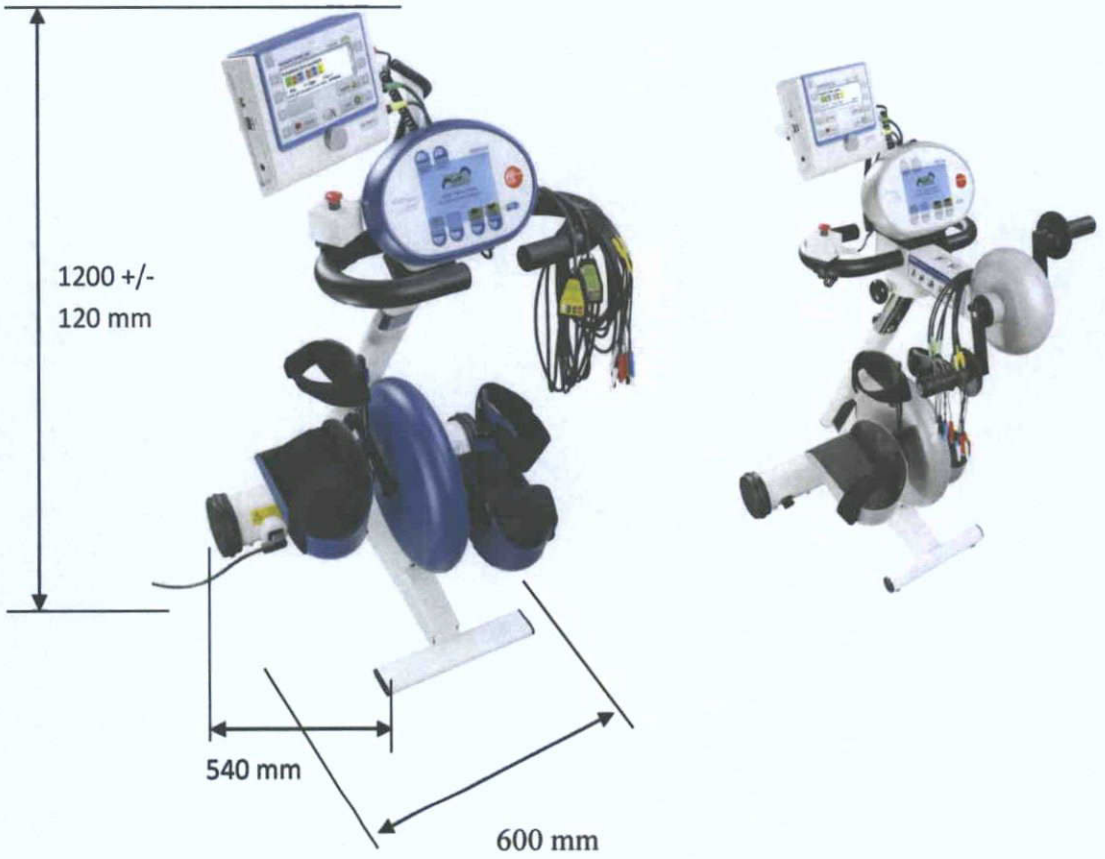

Figure 2 Size of RehaMove 2, right hand side with arm cranking (detailed values please look at manual)

weight:

- movement exerciser 31 Kg
- stimulator RehaStim 2 Kg
- arm cranking module 10 Kg

(3) A description of all user controls, displays, and functions

Please see Section 13: Proposed Labeling "User Manual"

(4) A description of how the device interconnects with other components

Please see Section 13: Proposed Labeling "User Manual" (Page 15 ff.)

The device interconnections are the same as the predicted device. Optionally a new communication-protocol FES3 was implemented. This protocol gives you the possibility to control the movement exerciser functionality by RehaStim 2. A bidirectional communication exchanges the information for angle, speed-parameters and so on.

Please see 13c *User manual* for more information.

(5) Engineering drawings and/or photographs of the device

The mainboard connects the modules and contains power supply and interfaces (USB host, USB device, flat panel display, foil keyboard).

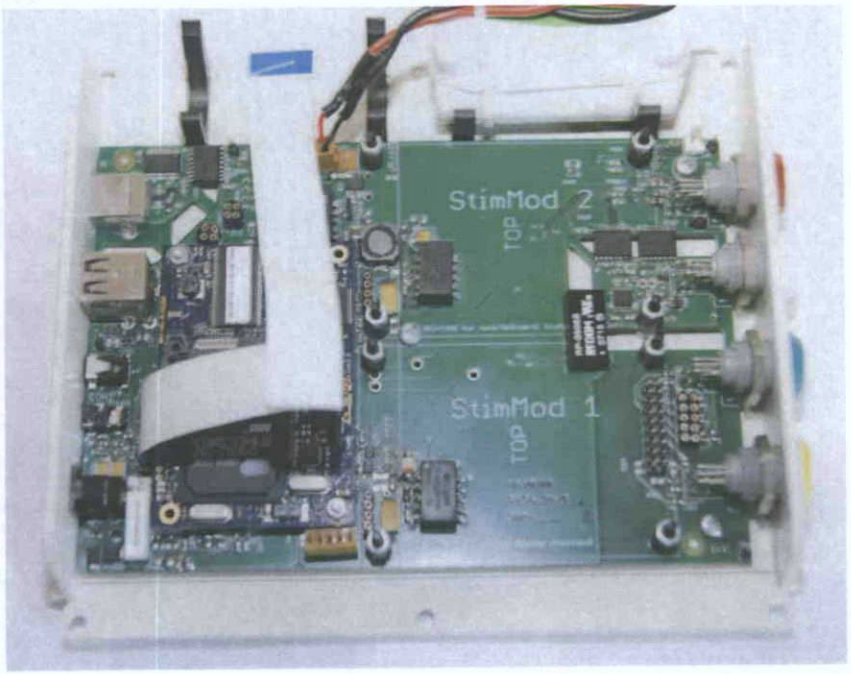

Figure 3

The stimulator modules StimMod 1 and StimMod 2 are the same as in the predecessor model RehaStim. So the stimulator-module hardware itself was not changed. The Output waveforms are the same.

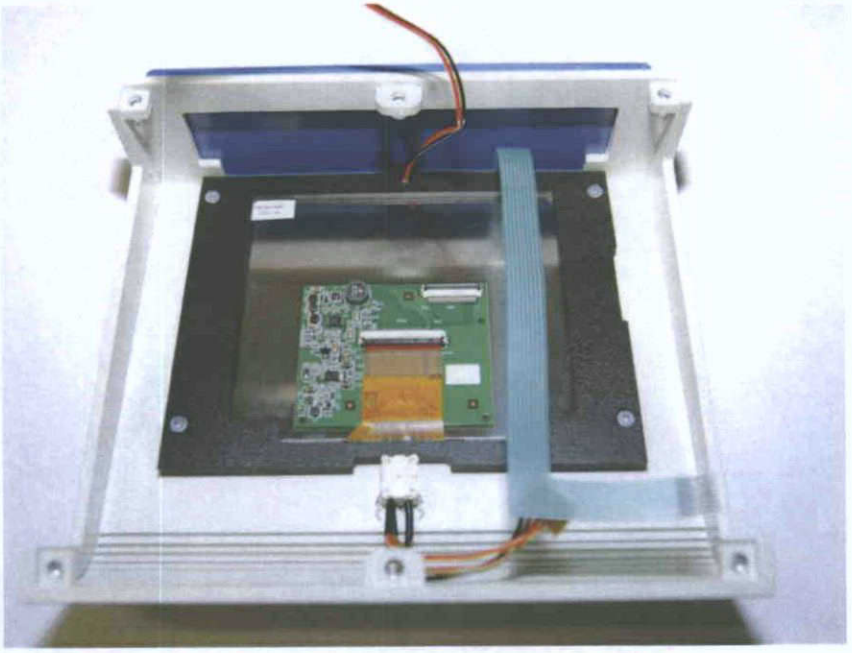

Figure 4 Upper port of RehaStim 2 shown from below

In Figure 4 the upper part of RehaStim 2 together with the wiring of the rotation knob and the flat cable for the display can be seen.

More technical details (e.g. insulation diagram) of the device are given in section 16 hardware documentation and section 15 software documentation.

(6) Output waveforms

The Output waveforms are the same as the predicted device.

Because of the same stimulator modules the high safety standard was not changed, but strictly checked.

(7) Basic Unit Characteristics

		New Device	Predicate Device
1.	510(k) Number	(To Be Assigned)	K073237
2.	Device Name, Model	RehaStim 2 RehaMove 2	RehaStim RehaMove
3.	Manufacturer	HASOMED GmbH	HASOMED GmbH
4.	Power Source(s)	AC and/or storage battery: Power supply: cincon tr30m090 according to EN60601-1 Battery: BMZ18650 V, Li-Ion Mangan cells, 2S1P, C= 1600 mAh,	AC and/or storage battery: Power supply: mascot typ9920 according to EN60601-1, Battery: SANYO, NiMh, C= 2700 mAh,
	- Patient Leakage Current		
	- Normal condition	6,4 µA	5 µA
	- Single fault condition (voltage isolation min = 2KV)	3,4 µA	30 µA
5.	Number of Output Modes	1	1
6.	Number of Output Channels	2 groups with 4 ch.	2 groups with 4 ch.
	- Synchronous or Alternating?	group in synchronous mode and channels alternate switched	group in synchro-nous mode and channels alternate switched

	- Method of Channel Isolation	- 2 KV isolation between 2 groups - isolation of	- 2 KV isolation between 2 groups - isolation of
7.	Regulated Current or Regulated Voltage?	regulated current	regulated current.
8.	Software/Firmware/Microprocessor Control?	Linux OS runs on ARM9 processor, customized Microprocessor and Software (Stim-Modul)	customized Microprocessor and Software
9.	Automatic Overload Trip?	Yes (Hardware!)	Yes (Hardware!)
10.	Automatic No-Load Trip?	Yes	Yes
11.	Automatic Shut Off? (by low battery)	Yes	Yes
12.	Patient Override Control?	Yes	Yes
13.	Indicator Display:		
	- On/Off Status?	Yes	Yes
	- Low Battery?	Yes	Yes
	- Voltage/Current Level?	Yes	No
14.	Timer Range (minutes)	Yes	Yes
15.	Compliance with Voluntary Standards?	Yes, IEC 60601-1,-2-10, ... Type BF Applied Part	Yes, IEC 60601-1,-2-10, ... Type BF Applied Part
16.	Compliance* with 21 CFR 898? (*Becomes mandatory beginning May 9, 2000)	Yes	Yes
17.	Weight (shipping)	~ 44 Kg	~ 40 Kg

18.	Dimensions (in.) [W x H x D]	1200 x 540 x 600	1100 x 540 x 600
19.	Housing Materials and Construction	PS (UL-94 HB)	ABS (UL 94 V-0)

(8) Output specifications

	New Device	Predicate Device
Waveform (e.g., pulsed monophasic, biphasic)	biphasic	Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	rectangular	rectangular
absolute maximum output voltage	154V	154V
Maximum Output Voltage (specify units)	63V @ 500 Ω	63V @ 500 Ω
(+/- 3 %)	154V @ 2 kΩ	154V @ 2 kΩ
	154V @ 10 kΩ	154V @ 10 kΩ
Maximum Output Current (specify units)	130mA @ 500 Ω	130mA @ 500 Ω
(+/- 3%)	77mA @ 2 kΩ	77mA @ 2 kΩ
	15mA @ 10 kΩ	15mA @ 10 kΩ
Pulse Width (specify units)	20µs ... 500µs	20µs ... 500µs
Frequency (Hz)	10Hz.... 50Hz	10Hz.... 50Hz
abs. Frequency max (Hz) (8 channels with 500µs)	143 Hz	143 Hz
For interferential modes only:		
- Beat Frequency (Hz)	-	-

For multiphasic waveforms only:		
- Symmetrical phases?	Yes	Yes
- Phase duration	1,5 ms (includes all)	1,5 ms (includes all)
Net Charge (µC per pulse) (If zero, state method of achieving zero net charge.)	zero, because negative impulse is inverted generated with same curve	zero, because negative impulse is inverted generated with same curve
Maximum Phase Charge, (mC)	63mC @ 500 Ω	63mC @ 500 Ω
Maximum Current Density, (mA/cm²) A= 45cm²	2.8mA/cm²@ 500 Ω	2.8mA/cm²@ 500 Ω
Maximum Power Density, (W/cm²) (using smallest electrode conductive surface area)	0,176W/cm² by 45cm² electrode area @ 500 Ω	0,176W/cm² by 45cm² electrode area @ 500 Ω
Burst Mode (i.e., pulse trains) a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	 1 20 (default) 0,05 s (default) 1000µs x 50	 1 20 (default) 0,05 s (default) 1000µs x 50
ON Time (seconds)	3.5s	3.5s
OFF Time (seconds)	0,9s	0,9s
Additional Features (if applicable)	%	%

8-1 Output specifications

(9) Description of Accessories

9.1. Electrodes

The electrodes are the same as the predicted device.

FES00200 RehaTrode	2.0" x 3.5", rectangle
FES00201 RehaTrode	3.0" x 5.0", rectangle
FES00202 RehaTrode	1.5" x 2.5" oval

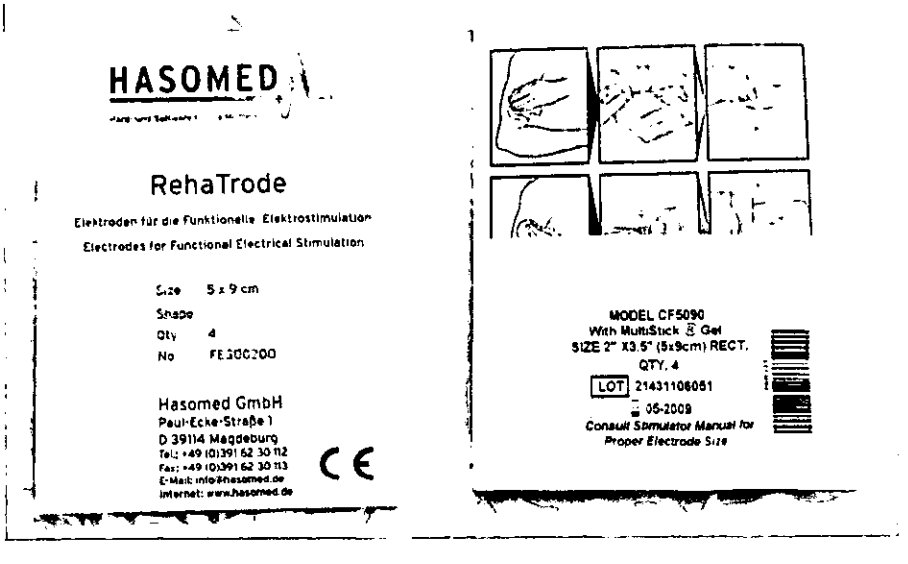

Figure 5 RehaTrode, front and back view

Type: RehaTrode

No: FES00200

9.2. Electrode Lead Wires and Patient Cables

The electrode lead wires are used to connect RehaMove 2/RehaStim 2 output and electrodes on skin. Every lead wire should connect to eight electrodes (4 channels). Every channel is labeled for non- reversible use.

9.3. Batteries

Cell: BMZ18650 V, C= 1600 mAh, 7,4V

Chemical composition: Li-Ion Mangan cells

Size: Ø17mm x 50 mm

Number: 2 batteries in one package with

Casing: 2S1P, Shrink hose package with integrated Protection Circuit Module (PCB / PCM) for Lithium Ion *Batteries*

Please also see product data safety sheet 10b *15815_2S1P BM18650Z1 mit PCB_PSDS.pdf.*

9.4. Power supply

Cincon power supply

Type : TR30M090

Please see 10c *TR30M Datasheet.pdf* for further information.

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11 Comparison of the devices

Both devices have identical intended use as well as identical operational principles. The printed circuit boards for the stimulator modules remained unchanged in comparison to the predecessor device.

The functions of the RehaMove 2 and RehaStim 2 are the same as the predicate devices RehaMove and RehaStim, however there are certain technological similarities and differences as described below:

Technology	**RehaStim 2 / RehaMove 2**	**RehaStim / RehaMove**
Power Source	AC and/or storage battery: Power supply: cincon tr30m according to EN60601-1 Battery: BMZ18650 V, Li-Ion Mangan cells, 2S1P, C= 1600 mAh,	AC and/or storage battery: Power supply: mascot typ9920 according to EN60601-1 Battery: SANYO, NiMh, C= 2700 mAh,
Power input (charging)	9V, 3A, max. 30 W	9V, 3A, max. 30W
Operation time	ca. 90 min	ca. 120 min
Charging time	ca. 180 min	ca. 210 min
Controller	uses custom controller using embedded Linux as basis operating system, running custom software	uses custom controller running custom software
Stimulator (energy delivered)	0-130mA charge balanced stimulator with rectangular impulses / same hardware	0-130 mA charge balanced stimulator with rectangular impulses
Pulse width	max. 500 µs	max. 500 µs

Stimulation frequency	max. 50 Hz	max. 50 Hz
Number of channels	8	8
Electrodes	HASOMED's RehaTrodes only	HASOMED's RehaTrodes only
FES00200 RehaTrode	2.0" x 3.5", rectangle	2.0" x 3.5", rectangle
FES00201 RehaTrode	3.0" x 5.0", rectangle	3.0" x 5.0", rectangle
FES00202 RehaTrode	1.5" x 2.5" oval	1.5" x 2.5" oval
Application part	Type BF	Type BF
Movement exerciser	RehaMove: Uses motor to create flywheel effect with reduced weight and space	RehaMove: Uses motor to create flywheel effect with reduced weight and space
Communication interface	FES 2 + FES 3; FES 3- bidirectional communication, controlling of movement exerciser functionality	FES 2 – unidirectional communication, transmission of basic angle parameter
Arm crank	Arm crank in the same possible like upper extremities	Arm crank in the same possible like upper extremities
Seating	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer
Passive cycling	RehaMove: Utilizes motor to provide assistance during passive cycling	RehaMove: Utilizes motor to provide assistance during passive cycling
Database interface	Utilizes database interface for storage and retrieval of patient	Utilizes database interface for storage and retrieval of

	therapy settings and storage of session logs	patient therapy settings and storage of session logs

Table 11-1 Technological similarities and differences

Determination of substantial equivalence

Test or procedure	Task
Review of user documentation for predicate device	It was reviewed that equivalent functionnality was implemented in RehaMove 2.
Review of 510(K) submissions for predicate device	Confirm technical specifications for completion of predicate details in comparison tables (see above)
Output characteristic measurement of new device	The RehaMove 2 / RehaStim 2 device was tested and technically compared with the predicate device.
Control of system testing	The system testing was aligned to verify performance to specification.

Table 11-2 Performance data

It can be matched that there is a substantial equivalence in all important technical and medical characteristics to the premarket notification.

HASOMED concludes that:

Both the RehaMove 2 and RehaStim 2 have the same intended use and the same output characteristics as the predicate device. The different technological characteristics do not raise new questions of safety and effectiveness.

The safety and effectiveness of using a movement exerciser to simulate the predicate devices motor powered flywheel and provide passive cycling assistance has been extensively demonstrated in particular by the ongoing clinical use of the movement exerciser without the stimulation component both in the European Union and the U.S.A.

The safety and effectiveness of the controller has been demonstrated over the development period of the RehaStim 2 and RehaMove 2 and many clinical applications in the European market.

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The remote database enhances the safety and effectiveness of the system by ensuring that patients always starts a therapy session with their latest, accurate device settings.

In conclusion, HASOMED's clinical and non-clinical testing has demonstrated that the RehaStim 2 and RehaMove 2 are as safe and effective as the predicate device.

12 Intended use

Both the RehaMove and RehaStim are intended for general rehabilitation for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

13a Proposed label and labeling

Intended use of predecessor device and this device are the same (see section 12). Labeling and advertisements of the new device are mainly the same as for the predecessor device. Changes were introduced to enhance clarity of usage and to make clear the new concept of usability. The proposed advertisement is more or less similar to the old one (see section 13b). The reworked sections in the instructions for use are the following (see section 13c Instructions for use):

Chapter	Changes
1.1	All => New device
1.3	All => New device
1.5	All => New User Interface
1.7.1	All => New User Interface
1.7.2	All => New User Interface
1.7.3	All => New User Interface
1.8	All => New device
2.1	All => New device
2.2	All => New device
3	All => New device
3.1	All => New device
3.2	All => New device
3.3	All => New User Interface
4	All => New User Interface
4.1	All => New User Interface
4.2	All => New User Interface
4.3	All => New User Interface
4.4	All => New User Interface
4.4.1	All => New User Interface
4.4.2	All => New User Interface
4.4.3	All => New User Interface
4.4.4	All => New User Interface
4.4.5	All => New User Interface
4.4.6	All => New User Interface
4.4.7	All => New User Interface
4.4.8	All => New User Interface
4.4.8.1	All => New User Interface
4.4.8.2	All => New User Interface
4.4.8.3	All => New User Interface
4.5	All => New device
4.5.1	All => New device
4.5.2	All => New User Interface
4.5.3	All => New User Interface
4.5.4	All => New User Interface

4.5.5	All => New User Interface
4.5.6	All => New User Interface
4.5.7	All => New User Interface
4.5.8	All => New User Interface
4.5.8.1	All => New User Interface
4.5.8.2	All => New User Interface
4.5.8.3	All => New User Interface
4.6	All => New User Interface
4.6.1	All => New User Interface
4.6.2	All => New User Interface
4.6.3	All => New User Interface
5	All => New User Interface
5.1	All => New User Interface
5.2	All => New User Interface
6	All => New User Interface

unchanged: 1.2 Description of the RehaStim
1.4 Indications and Contra Indications
1.6 Adverse Effects
7 Address of manufacturer

13b Proposed advertisements

The product flyer corresponds to the old one. The 510(k) number will be updated for the new product.

HASOMED
Hardware and Software for Medicine

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of medical technology
DIN/ISO 13485

In cooperation with:
Reck Medizintechnik

RI, LLC
6452 W. Crenshaw St., Suite 6
Tampa, FL 33634
www.ri-llc.com

New Therapy Options

- Fast adjustment with integrated current test and graphical templates
- Safe application with color coded cables for 8 channels and big push buttons
- Performance control: feedback during and after training on color screen
- Option to upgrade your viva 2 with stimulation

Indications of Use:

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

RehaMove2 actively improves and stabilizes your health and feelings of well-being. RehaMove helps to raise your quality of life.

RehaMove - Moves you through life!
Call us today and arrange for a trial session without obligation!

www.rehamove.com +49 (0) 391.61 07 645

HASOMED

RehaMove® 2

Movement Therapy with Electrical Stimulation

New!

Moves you

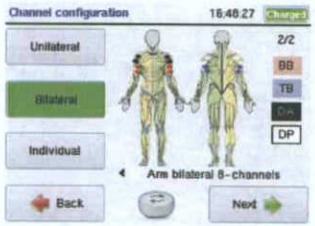
Upgrade your MOTOmed viva 2 with an activating Therapy

RehaMove unites a stimulation device, produced by Hasomed, and a motorized ergometer MOTOmed viva2, produced by the German company Reck. Thereby any viva2 can be easily retrofitted with the RehaMove therapy.

Eight channels, which is up to eight muscles start to contract and are stimulated in a way that they work synchronously to the crank movement of the MOTOmed. This way, your muscles can produce power despite paralysis.

New: More Features for your easy Handling

The new **stimulation templates** give the user an easy guideline of the right positioning and allocation of the stimulation channels.
The **History** shows the progression of the therapy by means of a graphic display. The users can analyze the improvement of their performance in the course of the therapy.
The **current test** allows the user to adjust the stimulation intensity before the beginning of the actual training.



Activate Muscles despite Paralysis

Paralyzed muscles are very often weak because active limb movements are limited or impossible.

Regular exercise with the RehaMove 2 rebuilds muscle strength and bulk, improves your feelings of well-being and helps to avoid secondary diseases, such as spasticity or pressure sores.

Avoid secondary Diseases when affected by Movement Disorders

Individuals with residual or no voluntary motor control as well as users with no conscious sensory function should exercise with the RehaMove 2 regularly 3-6 times per week for 30-60 minutes.

HASOMED

RehaMove2

Reactivate
paralysed Muscles

Reduce
Limb Spasticity

Regain
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ASC

HASOMED®

Hardware and Software for Medicine

Operation Manual RehaStim 2, RehaMove 2

Version 2.0 / 2011-09 HASOMED GmbH

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1.1 Declaration of Conformity

HASOMED

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:	*We:*
HASOMED GmbH Paul – Ecke – Straße 1 39114 Magdeburg	*HASOMED GmbH* *Paul – Ecke – Straße 1* *39114 Magdeburg* *Germany*

erklären in alleiniger Verantwortung, daß das Produkt/die Produkte:	*declare under our sole responsibility that the product/s:*
RehaStim **RehaStim2** **RehaMove** **RehaMove2**	**RehaStim** **RehaStim2** **RehaMove** **RehaMove2**
den einschlägigen Bestimmungen der Richtlinie 93/42/EWG über Medizinprodukte entsprechen.	*meet the provisions of the Council Directive 93/42/EEC concerning medical devices which apply to them.*
Diese Konformitätserklärung ist gültig bis zur Ausstellung einer revidierten Konformitätserklärung nach Änderung des Produkts.	*This declaration of conformity is valid until a revised declaration of conformity after product changes is issued.*
CE 0482 Die Zertifizierung wird überwacht von: MEDCERT GmbH Pilatuspool 2 20355 Hamburg	CE 0482 *Certification is observed by:* *MEDCERT GmbH* *Pilatuspool 2* *D - 20355 Hamburg / Germany*

Magdeburg, den 16.02.2011

.....

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1.2 Description of the RehaStim 2

The RehaStim2 is a portable electrical stimulation device that generates impulses, on up to 8 channels simultaneously, to activate paralysed muscles via surface electrodes. The RehaStim2 can be used as a portable (contains a battery) or stationary device for training and rehabilitation applications. It can be used on its own or in conjunction with a motion trainer as **RehaMove2**. 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 big graphical display screen which makes interaction with the device easy. The operation of the device happens via pressure-sensitive buttons and a turning knob.

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 **RehaMove2** using a movement exerciser.

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

1.3 Security notes

Please read the manual carefully before using this device!

The RehaStim 2 is classified as a medical device type IIa.

An inspection of the device must be carried out by the HASOMED service staff only. You are not allowed to open the device. The repair of the RehaStim2 must be performed only by the manufacturer.

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

The proper disposal of such device (LI-ION battery) involves certain risks. Avoid these risks and return the device to the manufacturer, 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 system undergoes a routinely check-up and is replaced where required.

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 contact the manufacturer or an expert to ensure that the users safety is not put at risk.

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

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

If the patient's blood pressure or heart rate reaches a level that the clinician considers a compromise to safety, or if the patient feels faint or nauseated, the session should be stopped immediately and appropriate medical action should be taken. If the patient begins to feel light-headed or 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 RehaMove2 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.

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 and comfort, turn off the stimulator before you attempt to remove electrodes from your skin.
Always lift electrodes from the edge not the lead wire.
Always replace electrodes to "ON" side of the storage liner.
Always store 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.

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

CE 0482 - CE-certified

- Applied part: type BF

- Not to be disposed with domestic waste!

- Note instruction manual!

1.4 Indications and Contra Indications

Functional electrical stimulation (FES) is an established method of electrotherapy and widely applied for impaired extremities due to diseases or accidents.
However, the RehaStim2 could also be used for therapeutic electrical stimulation. The RehaMove2 is a specialised system that has integrated the RehaStim2 specifically for 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

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

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

Absolute contra indications
These contra indications absolute exclude clients from applying the RehaStim2 or RehaMove2:
- Cardiac pacemakers: Functional electrical stimulation must not be used in people with cardiac pacemakers
- Pregnancy: Pregnant women must be excluded from stimulation treatment since possible adverse effects are unknown and have not yet been scientifically investigated.
- Fractures: Unhealed fractures in the following areas restrict the patient from using the RehaMove2 until the fracture is stable:

- in the lower extremities, if you want to do leg training with the RehaMove2.
- in the upper extremities, shoulder girdle or upper ribs, if you want to do arm training.

- Additional counter indications for Arm training:

- unability to keep humeral head into glenohumeral joint utilizing electrically evoked contraction of the supraspinatus
- grade 3 tear of either rotator cuff.

Relative contra indications
- Denervated muscles: The RehaMove can not be used to evoke contractions in denervated muscles in extremities.
- Severe Spasticity: In most cases, spasticity will not disqualify an individual from using the RehaMove. A stretching program may be necessary prior to therapy along with modified therapy settings to reduce the likelihood of spasms occurring.
- Limited Range of Motion/ Heterotopic Ossification:

- for leg training: clients can be placed in their chair to accommodate for minor limitations in joint ranges. However, a minimum of 100 degrees of hip and knee flexion is recommended.

- for arm training: clients can be placed in their chair to accommodate for minor limitations in joint ranges: However, a minimum of 90 degrees of shoulder flexion and 100 degrees of elbow flexion is recommended.
- Severe Osteoporosis: Mild to moderate osteoporosis is prevalent in the majority of the SCI population and in itself does not represent an immediate exclusion from the therapy. If the osteoporosis has progressed so that there is an increased risk of fractures, the therapy should be adjusted to account for the degree of osteoporosis.
- Dysaesthetic Pain Syndrome: In some cases the pain syndrome may worsen during the stimulation and the therapy maybe too uncomfortable to continue.
- Pressure sores or open wounds in the area of treatment.
- Implants: Recently (< 3month) implanted plates, pins, screws and other hardware underneath or near the muscle groups which are to be stimulated.
- Epilepsy: Clients who suffer from epilepsy may have to be excluded from stimulation treatment since possible adverse effects are unknown and have not yet been scientifically investigated.
- Additional relative contra 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.

1.5 User Safety

Please read the manual carefully before using this 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.

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

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.

Do not use when user is simultaneously connected to a high frequency surgical unit, because this may lead to burns underneath the electrodes.
Do not use near (within 1.5m) devices with high frequency (HF) range or micro- and short-wave devices or welding units.
Do not use near (<1m) working mobile phones or radio/ wireless transmitting sets.
For the correct operation, electrostatic loadings are to be avoided.
The treatment can influence electrical monitoring devices (e.g. ECG) if they are simultaneously connected to the client.
If the stimulator is to be used near the ribcage, consider and analyse the risk of cardiac fibrillation.
Electrodes must not be placed on excoriations or gashes.
Users should be always accompanied by an assistant.

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

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.

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 ISO specifications (e. g. ISO 60601-1 for electrical medical devices and IEC 6950 for data processing devices). Furthermore all combinations must meet the system standards. For queries please contact the technical support at HASOMED GmbH (manufacturer).

Do not put electrode cables into AC mains power outlets.
Only the provided charger (TR30M090) 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.
Protect the device from water. If the device falls into water do not use it any longer and contact the manufacturer for further instructions.
Store the device in the original packaging to protect it from damage and dirt.

Do not pass the device on to other people!

1.6 Adverse 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.

1.7 Default Values and Ajustment Ranges of Stimulation Parameters

1.7.1 Technical Specifications

	RehaStim 2 (stand alone device)
Size and Weight:	
Length	17,0 cm
Width	19,0 cm
Height	6,0 cm
Weight	0,950 kg
Power Supply:	
Power Source(s) :	AC and/ or storage battery
Method of Line Current Isolation	- TR30M090 to EN60601-1, - BMZ 18650V, Li-Ion, C= 1600 mAh, 7.4 V
Power connection	100-240 VAC 47-63 Hz
Power input	max. 30 W
Environment conditions:	
· In use · Transporting/ storing · Relative humidity	0 °C to 40 °C -20 °C to +60 °C 0 to 85% RH, not condensating
Stimulator / Controller	
Display / interface	LCD- Display/ keypad, Turning knob
Communications	USB / ODU Medi-Snap
Operation system	Special-Software
Maximum voltage output	154 V
Maximum number of channels	8
Currennt output per channel	0 - 130 mA in 65 steps
Waveform type	Biphasic rectangular impulses with balanced electric charge
Duration of the stimulation impulses (pulse width)	20 - 500 µs in steps of 10 µs
Stimulation frequency	10 - 50 Hz in steps of 5 Hz
IP-classification	IP00
Protection class	II
Application part	type BF
Medical device according to EU guidelines MDD 93/42/EWG	IIa

	RehaMove 2 (consists of RehaStim 2 and Motorized Ergometer)
	RehaStim 2
	see above
	Motorized Ergometer MOTOmed viva 2
Size and Weight:	
Length	60 cm
Width	56 cm
Height	100cm
Shipping weight	leg trainer 31 kg leg and arm trainer 38 kg
Power Supply:	
Power connection	115V~, 50/60Hz 230V~, 50/60Hz
Power input	130VA 130VA
Protection type	IPXO
Protection class	I
Application part	type B
Medical device according to EU guidelines MDD 93/42/EWG	IIa
Environment conditions:	
· In use · Transporting/ storing · Relative humidity	0 °C to 40 °C -20 °C to +60 °C 0 to 85% RH, not condensating

1.7.2 Default Values

(Default value = Default settings)

Parameter	Minimum	Maximum	Increment	Default value
Speed (in rpm)	15 rpm	60 rpm	5 rpm	40 rpm
Pulse width	20 µs	500 µs	10 µs	20 µs
Zero angle	0°	360°	5°	90°
Ramp	0 Pulse	21 Pulses	1 Pulse	3 Pulses

Default settings for angles and muscles
Following default settings are standard for the RehaMove leg training

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

Following default settings are standard for the RehaMove 2 arm training (if delivered)

Start and stop angle	Muscle	Short cut
40° to 180°	triceps - right	TB_R
220° to 360°	biceps - right	BB_R
220° to 360°	triceps - left	TB_L
40° to 180°	biceps - left	BB_L

1.7.3 Features

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

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

1.8 Maintenance and Service Instructions

Cleaning of the stimulator
Use normal detergent to clean the stimulator. Do not use spray cleaner. Use a semi-moist cleaning tissue. For cleaning the MOTOmed viva2, please refer to its user manual.

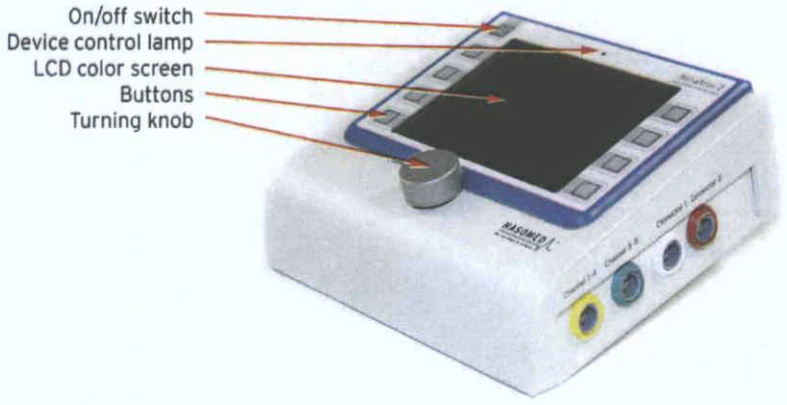
Maintaining the Stimulator accumulator
To maintain the stimulator accumulator, please follow the instructions every three months:
- let it discharge completely until the stimulator turns off automatically,
- then recharge it fully.

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

2 Control Elements and Accessories of the RehaStim 2

2.1 Operating and Connection Elements

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

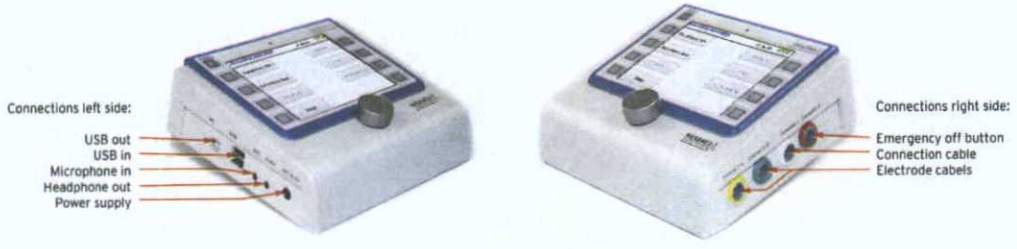


On the right side following connections can be found:

- One USB gate to connect the stimulator with an external PC.
- Two USB ports which can serve to update software via USB flash drive.
- One connection for the power supply unit
- Optionally one connection for a microphone and one for a headset.

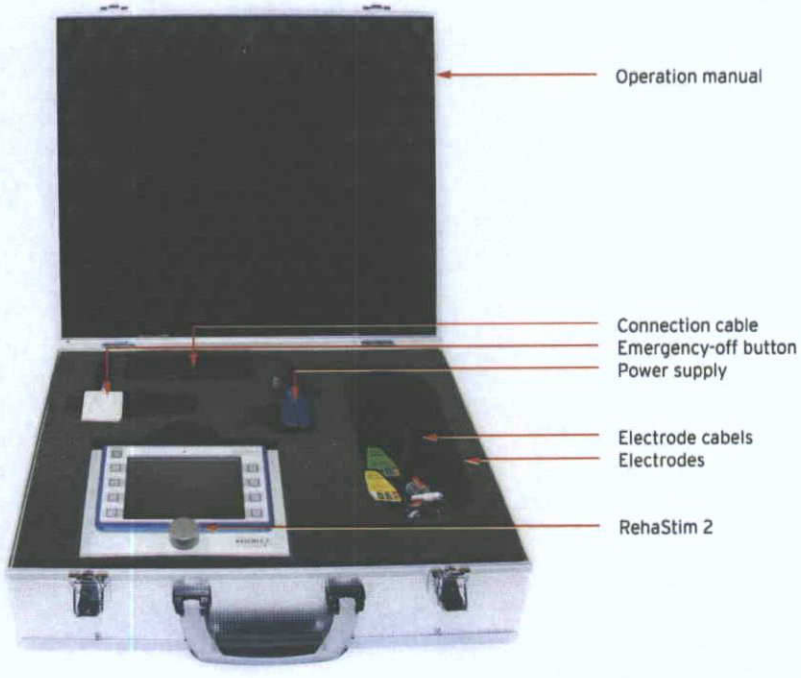
On the left side following connections can be found:

- The red connector is used for the emergency off button
- The white connector is used for the connection cable to the MOTOmed.
- The yellow and green connectors are used for corresponding electrode cables.



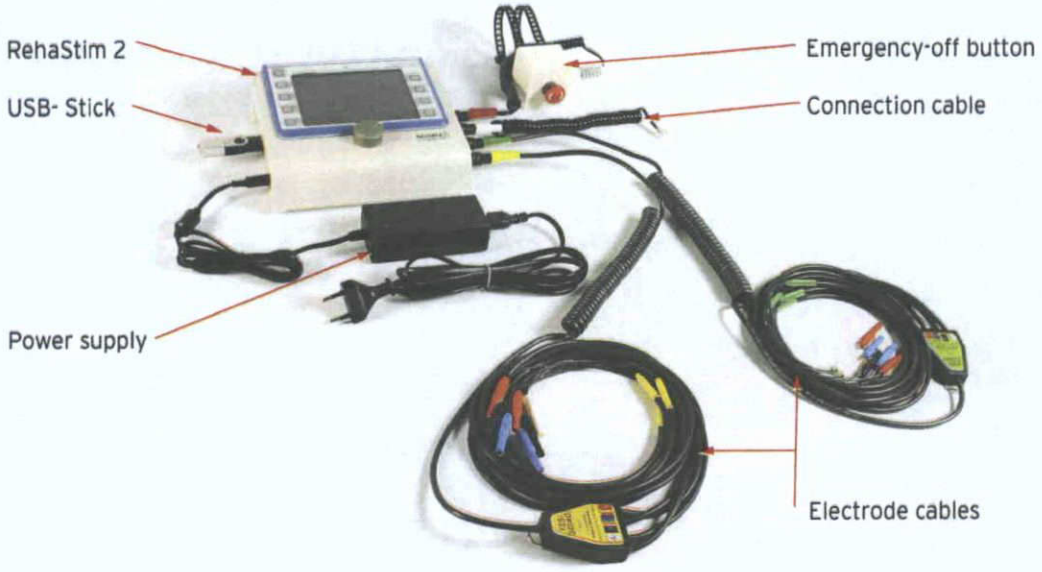
2.2 Accessories

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



The transport case includes:
- 1 stimulator RehaStim 2
- 1 emergency-off button
- 2 electrode cables
- 1 power supply unit for the stimulator
- 1 cable to connect the movement exerciser and RehaStim 2
- 1 USB connection cable to PC
- 4 sets of electrodes

Separately:
- bracket with bolt to fix the stimulator onto the movement therapy machine



Stimulator RehaStim 2

See chapter "Operating and Connection Elements"

Emergency-off button

With this button the user can immediately turn off the stimulation. Use the quick release fastener to fix the emergency-off button within easy access for the user which could be for example on the handlebar - as shown on the picture -, at the wheelchair frame or a similar suitable location.
Connect it to the designated socket on the right side of the stimulator. The connected movement exerciser has to be stopped separately by pressing the STOP button.

To test the button, push the emergency-off button while the stimulation is active. The stimulation should stop immediately.

To reactivate the stimulator after the emergency-off button has been pressed, first switch the stimulator off and then turn the emergency button until it is unlocked again. The stimulator can then be restarted as usual.

Electrode cables

The electrode cables connect the stimulator to the surface electrodes. Each electrode cable divides into 4 channels with 2 electrodes each. The channels are color coded and thus mix-up proof.
When you connect the electrode cables, follow the instructions given in chapter "Preparations".

Power supply unit for the stimulator

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

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

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

With the stimulator, the recharging process as well as the stimulation can happen simultaneously with full user safety.
To recharge and stimulate simultaneously:
- turn the stimulator off, connect the power supply unit, turn the stimulator on again.
- if it is necessary to recharge the stimulator in the course of the stimulation: pause stimulation, connect power supply unit and continue stimulation.

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

Cable to connect movement therapy trainer and stimulator

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

Electrodes

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

RehaTrode

Warning! Use recommended RehaTrode electrodes only! The manufacturer HASOMED can guarantee for the safe use of the RehaMove 2 only with this these electrodes.

The electrodes are pre-geled and no extra conductive medium is needed. A patented two-layer adhesive gel eliminates performance issues as known from 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 several times on the same patient. How often the electrodes can be re-used (life span) depends upon how well the patient takes care of it. With proper care the electrodes can last for 30 sessions.

The user has to replace the electrodes:

- not later than after 30 sessions,
- a maximum utilization time of 3 months,
- when a problem with the product specific use occurs,
- skin irritations occur or
- the electrodes past its sell-by as indicated on the package.

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

Do not stimulate while driving or operating machinery.
Do not exceed 0.1 watts/cm².

Adjust 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.

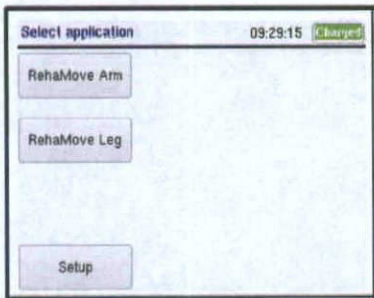
Always lift electrodes from the edge not the lead wire.
Always replace electrodes to "ON" side of the storage liner.
Always store and seal electrodes in the original package in a cool place.
Never submerge electrodes.

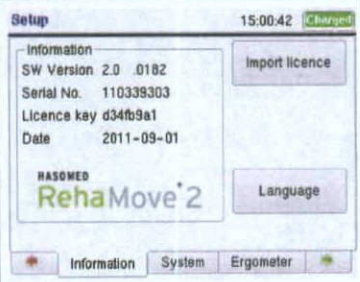
Using hot or cold packs for longer periods of time can cause adhesive separation.
Use each electrode for only one patient (single patient use).
Replace electrodes once these show wear or tear.

Bracket with bolt to fix the stimulator at the movement therapy machine
The bracket allows the stimulator to be mounted onto the movement exerciser in a position that allows easy access for the user.

3 Service Information and General Settings

Switch on the stimulator by pressing the on/off button. The device control lamp indicates with a green light that the stimulator is switched on. The HASOMED RehaMove logo appears on the LCD color screen. The stimulator starts loading the program and a few seconds later the window "Select application" appears.

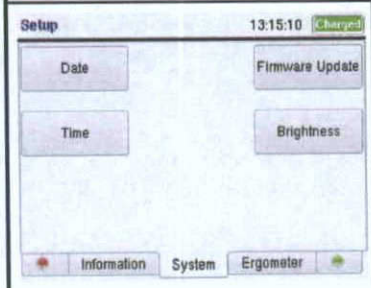
<table>
<tr>
<td> 
</td>
<td>Press Setup in the window "Select application"

After the button is pressed the window "Setup" opens up.
In this window following information and settings can be selected.</td>
</tr>
<tr>
<td> 

Setup-Menu / Information</td>
<td>The tab "Information" shows following information:

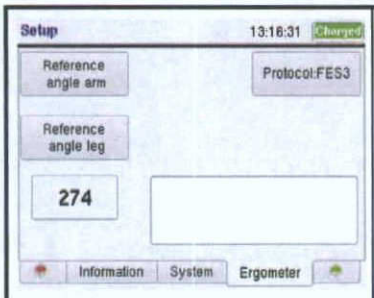
• The software version
• The serial number of the stimulator
• The licence key
• The current date

Apart from that following settings can be chosen:

• A new software update respectively upgrade can be uploaded with the button Import licence
• Language settings can be adjusted with the button Language</td>
</tr>
<tr>
<td> 

Setup-Menu / System</td>
<td>In the tab "System" following settings can be chosen:

• Change the current date
• Change the current time
• Upload a firmware update
• Change the light intensity of the screen</td>
</tr>
</table>

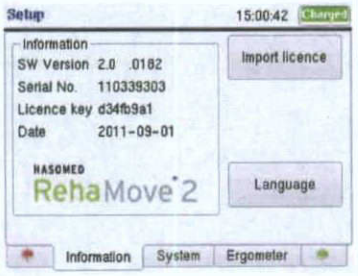


Setup-Menu / Ergometer

In the tab "Ergometer" following settings can be chosen:

- Change the reference angle to the MOTOmed arm exerciser
- Change the reference angle to the MOTOmed leg exerciser
- Change the protocol for the communication between movement exerciser and stimulator

3.1 Information: Import Licence, set Language



Setup-Menu / Information

Import Licence

The tab "Information" shows following information:

- The software version
- The serial number of the stimulator
- The licence key
- The current date

Apart from that following settings can be chosen:

- A new software update respectively upgrade can be uploaded with the button **Import licence**
  Further information about this feature is given by the manufacturer upon request.
- Language settings can be adjusted with the button **Language**

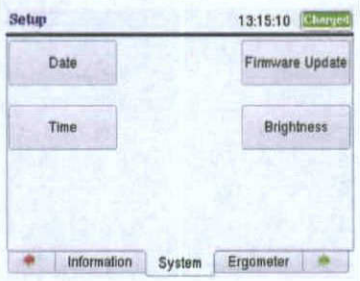
Change language

Language

After the button **Language** is pressed, the window for selecting the language opens up.

The country flag of the currently activated language can be found above the turning knob.
To select a different language, press the button next to the flag of favored language.
After the language has been set, the stimulator restarts with the new language.

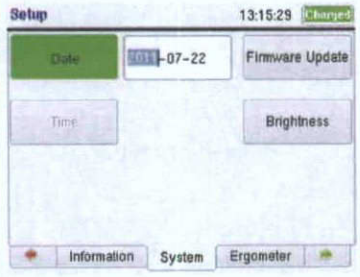
3.2 System: Change Date, Time, Light Intensity of the Screen and Firmware



Setup Menu / System

In the tab "System" following settings can be chosen:

- Change the current date
- Change the current time
- Upload a firmware update
- Change the light intensity of the screen

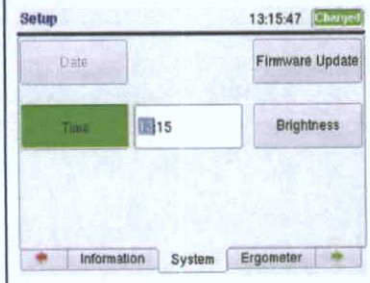


Date

The date can be changed by pressing the button next to the field **Date**.

A window with the current date in YYYY.MM.DD pops up. Settings in the blue field are executed with the **turning knob**. If the knob is turned, entries are changed. If the knob is pressed, entries are confirmed and the next field is ready to be set.

After the last field is set, the stimulator restarts with the date updated.



Time

The time can be changed by pressing the button next to the field **Time**.

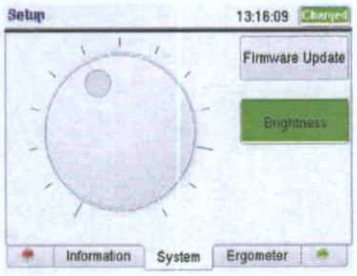
A window with the current time in HH.MM pops up. Settings in the blue field are executed with the **turning knob**. If the knob is turned, entries are changed. If the knob is pressed, entries are confirmed and the next field is ready to be set.

After the last field is set, the stimulator restarts with the time updated.

Firmware Update

Upload a firmware update with the button **Firmware Update**.

Further information is given by the manufacturer if required.



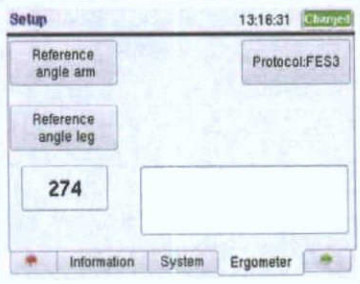
change Brightness

Brightness

The light intensity of the screen can be changed by pressing the button **Brightness**.

A window where the light intensity can be adjusted pops up. Settings in the blue field are executed with the **turning knob**. If the knob is turned, the light intensity of the screen changes. If the knob is pressed, entries are confirmed.

3.3 Ergometer: Check the Reference Angle



Setup-Menu / Ergometer

In the tab "Ergometer" following settings can be chosen:

- Change the reference angle to the MOTOmed arm exerciser
- Change the reference angle to the MOTOmed leg exerciser
- Change the protocol for the communication between movement exerciser and stimulator

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

It is recommended to check the reference angle
- if the MOTOmed viva2 cockpit/controller has been exchanged or
- if the stimulator was moved to a different MOTOmed viva2.

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

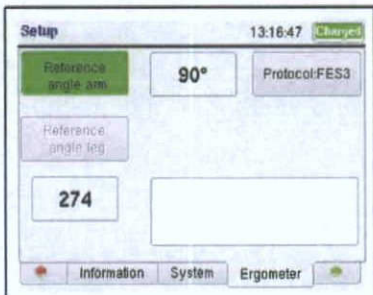
This means that any changes to this variable will affect other parameter sets too:
-Changing the zero angle affects the start and stop times of the stimulation for all RehaMove2 user programs.
- Changing the zero angle for RehaMove arm/leg training affects all RehaMove arm/leg training programs.

Reference position

The RehaMove arm training zero angle/ reference position is defined as the MOTOmed viva2 arm crank position: the right hand grip is in horizontal position and points towards the patient (= backward).

The RehaMove leg training zero angle/ reference position is defined as the MOTOmed

viva2 leg pedal position: the right foot pedal is in horizontal position and points towards the patient (= backward).

	Reference angle arm or leg Change the reference angle of the stimulator to be matched with the MOTOmed viva2 by pressing the button next to the field **reference angle arm** respectively **leg**. A window pops up with the current reference angle. Start the MOTOmed viva2 arm/leg trainer, choose a speed of 0 or 1 rpm. In the left corner the current value from the sensor is constantly written. In the center top field, the set reference angle is displayed. Let the MOTOmed viva 2 run and watch how the current angle value in the left corner changes. Read the value the MOTOmed viva 2 tells you in the reference position (see above). If this value is not the same as the set Reference angle at the center field, change the value of the center field accordingly by turning the **knob**. The reference angle is adjusted correctly once both values are the same the very moment the pedal/arm crank is in the reference position. Press the **turning knob** to confirm entries. *Caution! Please be aware that changing the zero angle affects all programs. Save only when you are absolutely sure. Otherwise please contact the manufacturer.*
	Protocol The field protocol shows the current protocol that is used to communicate data between the stimulator and MOTOmed viva2. The protocol is activated by an authorized assistant if necessary. Further information are given by the manufacturer if required.

4 RehaMove 2 - Motion Training with FES

As RehaMove, the stimulator is used in combination with a movement therapy machine. The stimulator generates stimulation impulses depending on the crank arm position / pedal position and the rotation speed of the movement exerciser. For this purpose, movement therapy machine and stimulator are connected with the provided cable.

Features of the RehaMove2

Two menu levels:

-A so-called **patient menu** where the user starts a pre-selected program. During the session the user can adjust certain parameters, e.g. the pulse width. However adjustable options are limited for the purpose of client safety.
-A so-called **therapist menu** for the therapist or for advanced users. Here a client individual setting of all parameters is possible.

Automatic correction of the stimulation angles depending on the rotation speed: At higher speed the angular range for stimulation slightly shifts forward in order to compensate for the delay of the muscle strength. Thereby the muscular strength always takes place at the right time regardless the speed.

2 Stimulation Modes

a) **Adaptive stimulation mode**
This training program automatically adapts to the client's physical abilities. The user starts with a base speed and aims to achieve an adjustable target speed [rpm] which is 20 rpm higher. In order to achieve the target speed, the stimulator automatically regulates the pulse width: as long as the user does not reach the target speed, the pulse width rises. Once the user exceeds the target speed the pulse width decreases. The limit of pulse width can be adjusted.
The intensity of the stimulation given is shown with a graph on the screen. This graph shows the proportion pulse width of the adjusted pulse width maximum. While the automatic regulation works the pulse width may fluctuate to some extent, particularly when it is close to the target speed. Also slight fluctuation of the speed may occur.
Reaching the target speed depends also on the chosen gear: A lower gear enables the user to reach the target speed with less power, whereas in a higher gear the user needs to generate more power.
The automatic adaptation of stimulation intensity works best if the effective pulse width is at about half of the maximum pulse width. Adjust the gear in order to reach that. If the effective pulse width is always at the upper end of the bar, decrease the gear; if the effective pulse width is always at the bottom of the bar, raise the gear.

b) **Constant stimulation mode**
This training mode uses stable parameters: the pulse width remains stable, regardless the users' performance. Gear and speed (minimum 10 rpm) can be selected as usual and do not influence the stimulation. The speed at the ergometer is shown in a graph on the screen of the stimulator.

4.1 Notes on Therapy with RehaMove

General notes
Before the first training, the client must consult a doctor or physiotherapist
- to find out how he/she can benefit from the system
- to show how to use the device
- to set ideal parameters
It is recommend that the RehaMove2 is used as part of an exercise program prescribed by a doctor or therapist.

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

Exercise program planning
The frequency and duration of exercise sessions on the RehaMove2 should be individually planned and prescribed by a doctor or therapist. Therefore, only general guidelines on exercise program planning can be given at this point.
Regular exercising with the RehaMove 2 is extremely important if improvements in mobility and particularly in muscle strength are to be achieved. Short but frequent sessions are better than long strenuous ones.
It is always recommended to consult with a doctor or therapist and to create a therapy plan together. It starts with sessions of not more than 15 minutes continuous exercising, starting with a period of gentle passive exercising and then the progression to light, active exercising with low resistance setting.
The length of the session, the speed, the amount of active exercising and the resistance can be gradually increased in small steps at a time. It is possible to schedule several exercise sessions a day always providing that no negative symptoms of illness occur and the physical capabilities of the client are not exceeded.
The intensity of the therapy is correct if strength, endurance and mobility gradually improve and the client feels well.

Course of a session
Generally a session starts with a slow "warm up" phase when no stimulation is active and the user's muscles can slowly warm up to prepare for the training. A stimulation phase follows where the user's muscles are stimulated and work actively.

The session should finish with a cool down phase.
The RehaMove programs realize this course automatically, the duration of these three phases can be adapted user individually.

4.2 Safety Measures

Before you start, please:
- Check that the supply voltage of the unit matches with your main current. Only connect the RehaMove2 with the main outlet if the values match. If they do not match or damages to the power supply occur, please contact the manufacturer HASOMED GmbH.
- Use only properly earthed power outlets. Use only the original power supply delivered by the manufacturer HASOMED GmbH. If an electric cable has been damaged, stop training immediately and contact the manufacturer.
- Connect cables in a way that no person walking by could get caught in the cables and these can not 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 for an hour at room temperature.
- Never grab into rotating pieces (e.g. pedals).

4.3 Preparations

Before the training:

1. Establish a tight connection between movement therapy device and wheel chair, use a tilt protection if necessary. Make absolutely certain that the wheelchair will not tip over backwards (e.g. with extreme spasms or extremely active muscle contractions).
2. Leave the stimulator and movement exerciser turned off. Connect them with the provided cable - see chapter "Accessories".
3. Attach electrode cables to the stimulator.
4. Place the client in front of the movement exerciser, fix the legs in the foot rests.
5. Clean the area of skin where the electrodes are to be placed, so it is conductive; if necessary shave the area and clean with alcohol.
6. Attach electrodes to the client and connect them with the electrode cables. Pay attention to the correct channels!

Numbering of the channels

On the right side of the stimulator the interfaces for the electrode cables can be found. There is one connector in green color and one connector in yellow color. Each electrode cable comprises 4 channels and each channel is separated into 2 electrodes.

> The cables have color matching codes. The green cable is meant for the left side of the body. The yellow cable is meant for the right side of the body!

7. Switch on the ergometer, adjust the speed up to at least 10rpm!
8. Switch on the stimulator and start the program.

4.4 RehaMove Leg Training

Following chapters introduce you to the exercise of lower extremities with stimulation programs being set by the therapist. There are two different training modes available with constant and adaptive parameters (see chapter: "RehaMove - Motion training with FES"). The window "parameters" at the beginning of the training shows which training mode is selected.

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

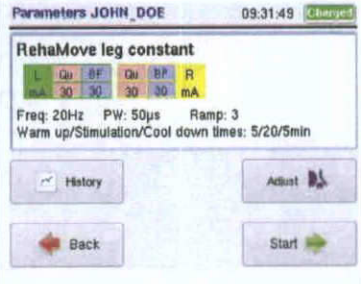
<table>
<tr>
<td> 
</td>
<td>Select application

Select desired application by pressing the button next to the displayed application.
Activate the RehaMove Leg training by pressing the button next to the displayed one on the screen.

Transparent buttons are not active and cannot be pressed.</td>
</tr>
<tr>
<td> 
</td>
<td>Choose user program

The field above the turning knob shows all user programs.
Choose a user program by turning the knob.
Press Next in order to start the training with a selected program.

Use buttons:

Delete: Delete a created user program (password protected)
New user: Create a new user program (password protected)
Back: Go back to the window "Select application"</td>
</tr>
<tr>
<td> 
</td>
<td>Parameters of user program

The parameter window shows saved program settings:

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

Use the turning knob to scroll up and down.
Use buttons:

History: Show the training course of the user program (password protected)</td>
</tr>
</table>

	Adjust: Change settings (password protected) **Start:** Start the training with the warm up

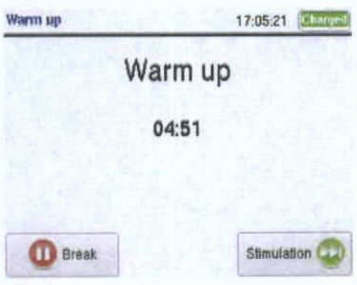
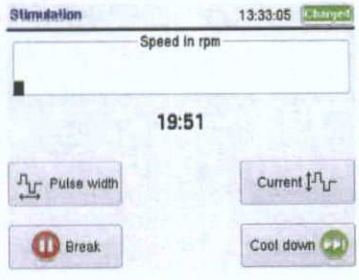
4.4.1 Constant Stimulation Leg Training - Operation by Client

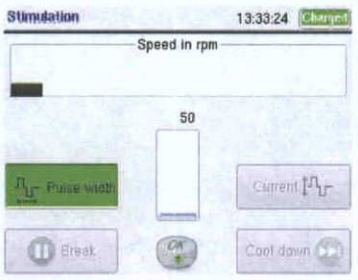
This training mode uses stable parameters: the pulse width remains stable, regardless the users' performance. Gears and speed can be selected as usual and do not influence the stimulation.

Start values (apart from the client individual stimulation settings): Gear and speed can be selected as without stimulation and do not influence the stimulation.

Start the movement exerciser and the stimulator.

NOTE! The movement therapy device needs a minimum speed of 10 rpm in order to activate the stimulation. The stimulation is deactivated below this speed and an error message pops up.

	Warm up The warm up window shows the remaining time for the warm up phase. Use buttons: **Break:** Pause the Warm up **Stimulation:** Abort the Warm up and start the stimulation
	Stimulation The display of the stimulation window changes depending on the selected therapy mode. Constant training: Speed in rpm is demonstrated through a graph *If the stimulation is active, the status indication line is colored in yellow.* Use buttons: **Pulse width:** Adjust the pulse width (for all channels) during the stimulation **Current:** Adjust the current (for each channel separately) during the stimulation **Cool down:** Abort the stimulation and start the cool down phase

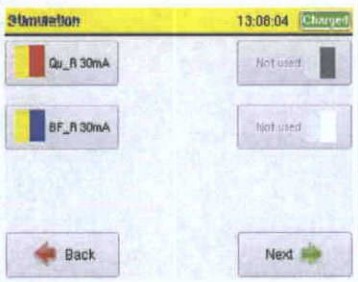


Pulse width adjustment

To adjust the pulse width during the training, press the button **Pulse width** in the stimulation window. The pulse width is changed for ALL muscles.

A bar with adjusted pulse width in µs pops up in the middle of the screen.

In order to change the pulse width, use the **turning knob** . Once the right pulse width is found, press the **turning knob** to confirm the setting.

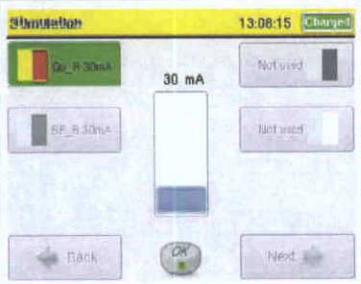


Current adjustment

To adjust the current during the training, press the button **Current** in the stimulation window.

Thereupon a new window pops up which shows all active channels with corresponding muscle groups as well as the present current.

To select more than 4 channels, press **Next**. In order to select a channel, press the button next to the associated picture on the screen.

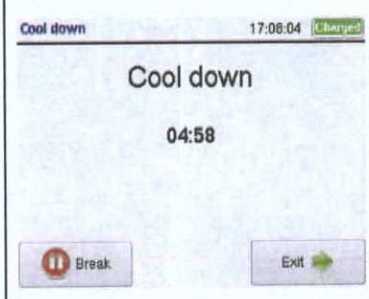


If one channel is selected, it is marked green and a bar with set current in mA pops up in the middle of the screen.

Use the **turning knob**:

- Change the current by turning the knob
- Confirm the current by pressing the knob

After having adjusted the parameters, the channel is not marked green anymore.
Now, the current of another channel can be changed.



Cool down

The Cool down window shows the remaining time for the Cool down phase.

Use buttons:

Break: Pause the Cool down
Exit: Abort the Cool down and continue with the report

Report

The report shows the times for warm up, stimulation and cool down as well as the entire duration of breaks during the training.

Use the button:

Parameters (active if parameters were changed): to save parameter changes as start settings for the next training.
Next: Close the report and go to window "Select application"

4.4.2 Adaptive Stimulation Leg Training - Operation by Client

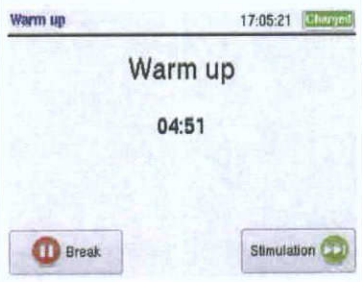
This training program automatically adapts to the client's physical abilities.

The user starts with a base speed and aims to achieve an adjustable target speed [rpm] which is at least 20 rpm higher. In order to achieve the target speed, the stimulator automatically regulates the pulse width: as long as the user does not reach the target speed, the pulse width rises. Once the user exceeds the target speed the pulse width decreases. The limit of pulse width can be adjusted.
The intensity of the stimulation given is shown with a graph on the screen. This graph shows the proportion pulse width of the adjusted pulse width maximum.
While the automatic regulation works the pulse width may fluctuate to some extent, particularly when it is close to the target speed. Also slight fluctuation of the speed may occur.
Reaching the target speed depends on the chosen gear: A lower gear enables the user to reach the target speed with less power, whereas in a higher gear the user needs to generate more power. The automatic adaptation of stimulation intensity works best if the effective pulse with is at about half of the maximum pulse width. Adjust the gear in order to reach that. If the effective pulse width is always at the upper end of the bar, decrease the gear; if the effective pulse width is always at the bottom of the bar, raise the gear.

Start values (apart from client individual stimulation settings):
- At the MOTOmed: Base speed: minimum: 10 rpm, maximum: 40 rpm
- Gear: 0 (zero) - adjust manually
- Optional: in the main menu/ "Basic adjustments": adjust the active/ passive- change to "direct": if patient can not achieve the target speed, the speed goes down to the base speed.

- At the stimulator: target speed (= "max. rpm"): 20 rpm higher than target speed at the MOTOmed, maximum: 60 rpm

Start the movement exerciser and then the stimulator.
NOTE! The movement therapy device needs a minimum speed of 10 rpm in order to activate the stimulation. The stimulation is deactivated below this speed and an error message pops up.

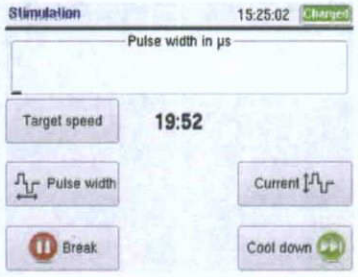


Warm up

The warm up window shows the remaining time for the warm up phase.

Use buttons:

Stimulation: Abort the warm up and start the stimulation



Stimulation

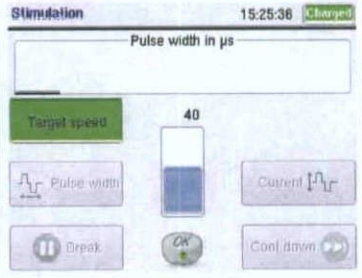
The display of the stimulation window changes depending on the selected therapy mode.

Adaptive training: Pulse width in µs is demonstrated through a bar.

If the stimulation is active, the status indication line is colored in yellow.

Use buttons:

Target speed: Adjust the target speed during the stimulation
Pulse width: Adjust the pulse width (for all channels) during the stimulation
Current: Adjust the current (for each channel separately) during the stimulation
Break: Pause the stimulation phase
Cool down: Abort the stimulation and start the cool down phase

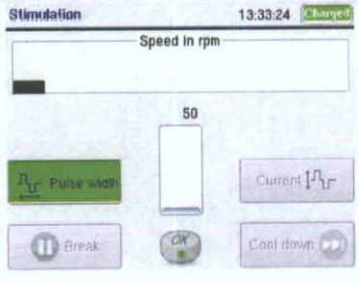


Target speed adjustment

To adjust the target speed during the training, press the button **Target speed** in the stimulation window.

A bar with adjusted target speed pops up in the middle of the screen.

In order to change the target speed, use the **turning knob**. Once the right target speed is set, press the **turning knob** to confirm the setting.



Pulse width adjustment

To adjust the pulse width during the training, press the button **Pulse width** in the stimulation window. The Pulse width is changed for ALL muscles.

A bar with adjusted pulse width in µs pops up in the middle of the screen.

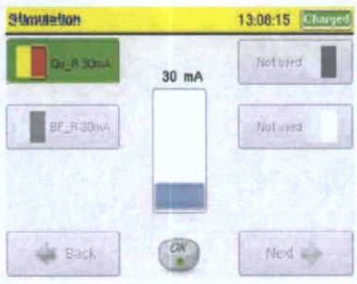
In order to change the pulse width, use the **turning knob** . Once the right pulse width is set, press the **turning knob** to confirm the setting.

Current adjustment

To adjust the current during the training for each channel, press the button **Current** in the stimulation window.

Thereupon a new window pops up which shows all active channels with corresponding muscle groups as well as the present current.

To select more than 4 channels, press **Next**. In order to select a channel, press the button next to the associated picture on the screen.

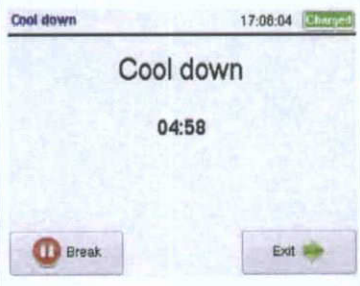


If one channel is selected, it is marked green and a bar with set current in mA pops up in the middle of the screen.

Use the **turning knob**:

- Change the current by turning the knob
- Confirm the current by pressing the knob

After having adjusted the parameters, the channel is not marked green anymore.
Now, the current of another channel can be changed.

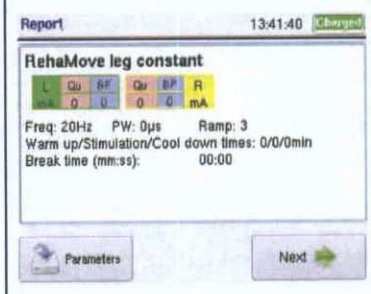


Cool down

The Cool down window shows the remaining time for the Cool down phase.

Use buttons:

Break: Pause the Cool down
Exit: Abort the Cool down and continue with the report window



Report

The report shows the times for warm up, stimulation and cool down as well as the entire duration of breaks during the training.

Use the button:

Parameters (active if parameters were changed): to save parameter changes as start settings for the next

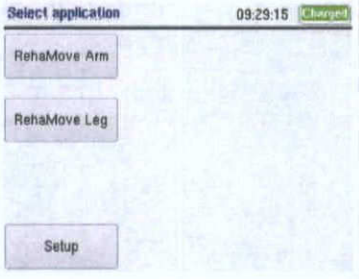
	training. **Exit:** Close the report and go to window "Select application"
	<u>Report/ save parameters</u> If the changed parameters are saved a confirmation message pops up. Now you will be forwarded directly to the window "Select application".

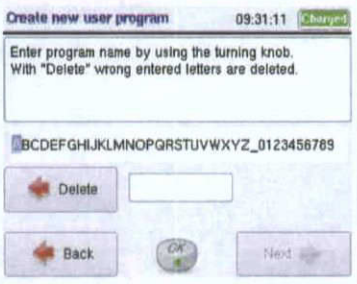
4.4.3 Create a New User Program

Several fields are password protected and tagged with a lock icon. For safety reasons there is a password protected area to be used by therapists/ advanced users only. Thereby wrong handling and operation by patients can be avoided. The password is a combination of buttons.

Following chapters introduce you to the operation of the RehaMove2 by therapists/ advanced users.

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

	Select application Select desired application by pressing the button next to the displayed application button. Transparent buttons are not active and cannot be pressed. Use buttons: **RehaMove Arm:** Arm training with RehaMove **RehaMove Leg:** Leg training with RehaMove **Setup:** To adjust device-specific settings
	Choose user program Create a new user program by pressing the button **New user .** Now you enter the password protected area.
	Password protected fields are tagged with a lock icon. After having pressed this button, the information window: "Enter password" comes up. You have 5 seconds to enter the password. The password is a combination of buttons: **press the first button on the right side, followed by the first button on the left side**, shortly one after another.



Create new user program

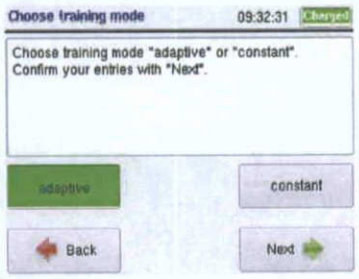
In the window "Create a new user program" a new program can be created for a client. Use the turning knob in order to enter a new program name.

Use the turning knob:

- turn the knob in order to select letters or numbers,
- press the turning knob in order to confirm entries,

Use button:

Delete: To delete letters or numbers

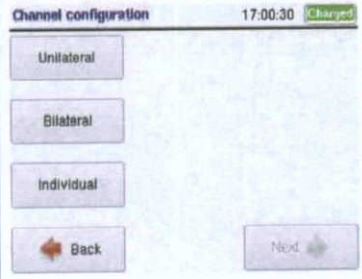


Choose training mode

The window "Choose training mode" allows for choosing between constant and adaptive training. Information about different training modes can be found in chapter: "RehaMove - Motion training with FES".

Use buttons:

adaptive: To select the adaptive RehaMove training mode
constant: To select the constant RehaMove training mode

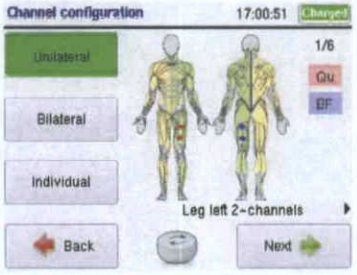
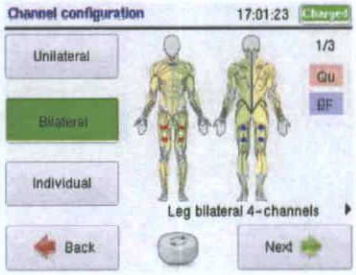
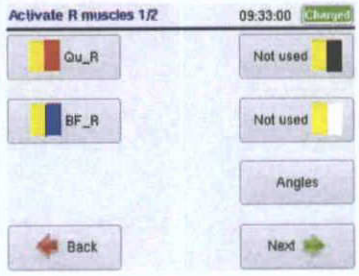


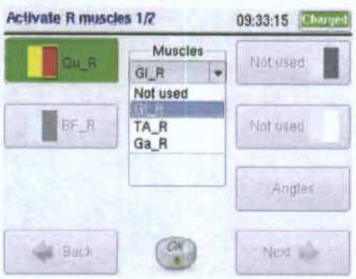
Channel configuration

In the window "Channel configuration" templates for unilateral or bilateral stimulation can be selected. The button **Individual** allows for individual channel configuration.

Use buttons:

Unilateral: to select unilateral stimulation templates

	Bilateral: to select bilateral stimulation templates **Individual:** to define individual stimulation patterns (see "Activate muscles")
	Channel configuration: unilateral If the button **Unilateral** is activated, a number of template pictures above the turning knob come up. These templates show selected channels from the front side and back side. Choose whether 2, 3 or 4 channels shall be activated to stimulate one side of the body. These templates cover most frequently used combinations of muscle groups. Use the turning knob in order to select one template. Press **Next** to confirm your entries.
	Channel configuration: bilateral If the button **Bilateral** is activated, a number of template pictures above the turning knob come up. These templates show selected channels from the front side and back side. Choose whether 4, 6 or 8 channels shall be activated to stimulate both sides of the body. These templates cover most frequently used combinations of muscle groups. Use the turning knob in order to select one template. Press **Next** to confirm your entries.
	Activate Muscles This window allows the client to assign individual muscle/ channel combinations. Muscle groups are chosen for the training and colors are matched. Select a channel by pressing the corresponding button. The active channel is tagged green. A window with available muscles groups pops up in the middle of the screen. Abbreviations are used to indicate each muscle (see chapter "Default values".) Use the turning knob:



- In order to select muscle groups, turn the knob.
- In order to confirm entries, press the turning knob

Use buttons:

Angles: to see/ change angles for the program
Back: to abort the process / go back to the previous window
Next: to activate further muscle groups or adjust parameters

Define angles

In this window the activated muscle groups are shown and activation angles can be defined.
In order to change the angles for one activated muscle, press the corresponding button.
An overview of standard angles can be found in chapter "Default values".
Start and stop angles can be changed by the user. The button of the activated channel is tagged green.

Use the turning knob:

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

Use button:

Default angles: Default angles are reactivated, changes are overwritten, all settings for the angles are deactivated again.

Define parameters: Warm up, Stimulation, Cool down

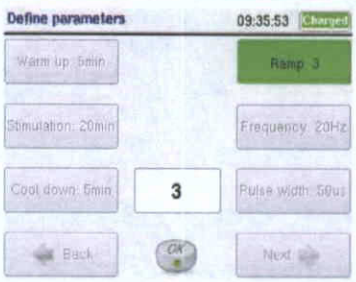
This window allows for adjusting parameters that apply to all channels.

Press the button **Warm up** in order to change the duration of the warm up. A field above the turning knob pops up with the present value in minutes.

Use the turning knob:

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

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



Define parameters: Ramp

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

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

Use the turning knob:

- In order to change the number of reduced pulses, turn the knob
- In order to confirm entries, press the turning knob

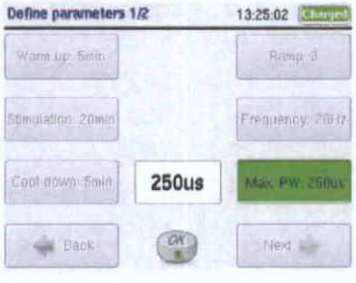
Define parameters: Frequency

The frequency indicates the number of impulses per second.

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

Use the turning knob:

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



Define parameters: Pulse width and Max. pulse width

Press the button **Pulse with** in order to change the pulse width (in constant training mode). When using the adaptive training mode, the **Max. PW** width is adjusted. A field above the turning knob pops up with the present value.

Use the turning knob:

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

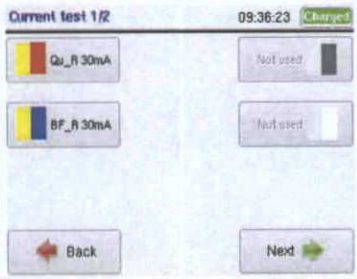
Define parameters: Target speed (adaptive training only)

The user starts to train with a basic speed and aims to reach the target speed in rpm. (see chapter: "Adaptive Stimulation - Operation by patient".

Press the button **Targ. speed** in order to change the target speed. A field above the turning knob pops up with the present value.

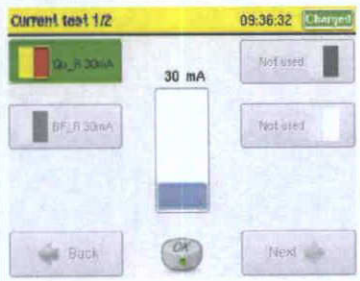
Use the turning knob:

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



Current test

This window shows all activated channels.
If you want to test the current for one specific channel respectively muscle, press the corresponding button.



Current test

A window in the middle of the screen pops up which shows the present current, displayed with a bar. By pressing the green tagged button once more, the activated button is deactivated again. The next channel can be selected and tested.

If the stimulation is active, the status indication line is colored in yellow.

Use the turning knob:

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

Next: Test current for further channels if activated.

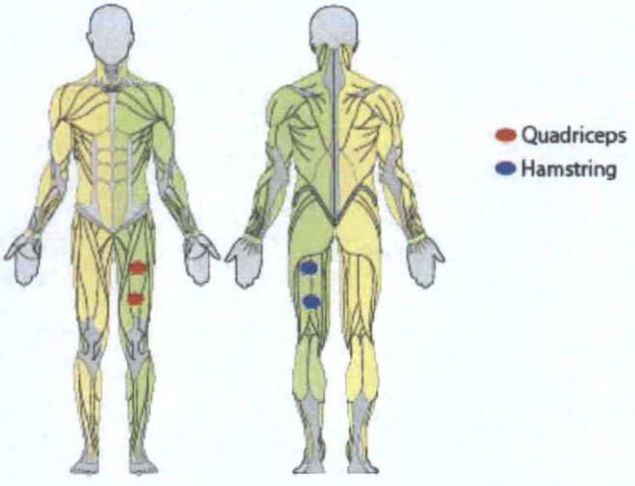
4.4.4 Electrode Placement for Common Muscle Combinations for Leg Training

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

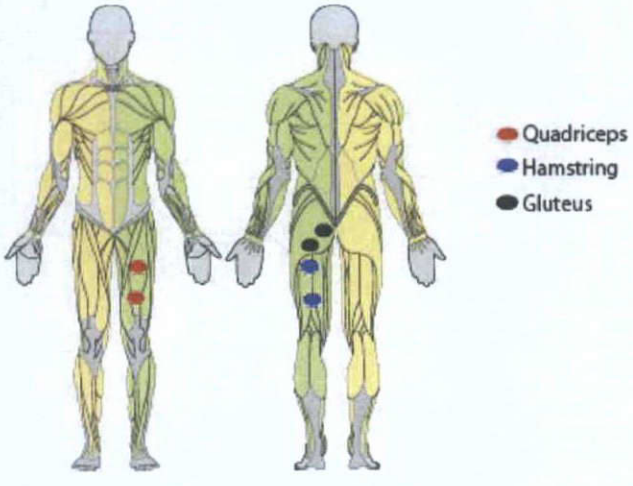
Please contact the manufacturer for further questions.

4.4.4.1 Unilateral stimulation: left leg

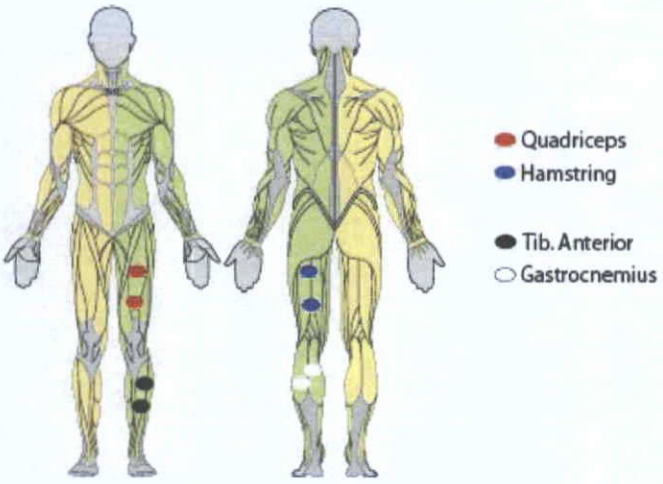
Leg left 2 Channels



Leg left 3 Channels

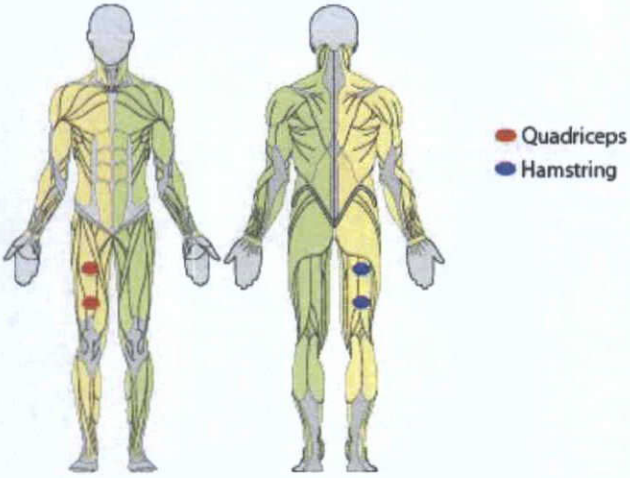


Leg left 4 Channels

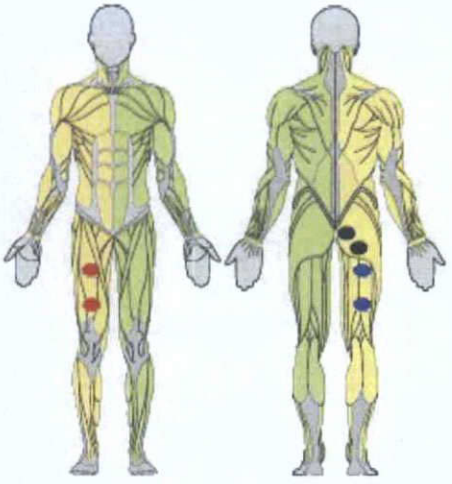


4.4.4.2 Unilateral stimulation: right leg

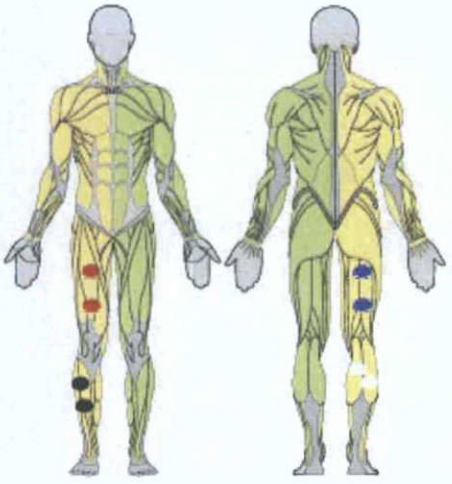
Leg right 2 Channels



Leg right 3 Channels

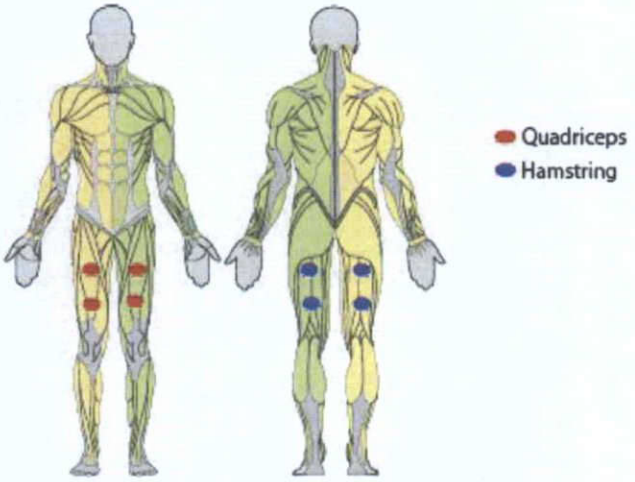


Leg right 4 Channels

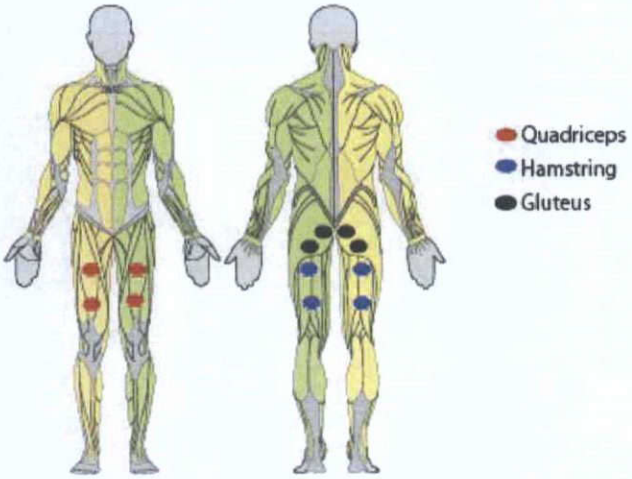


4.4.4.3 Bilateral stimulation of legs

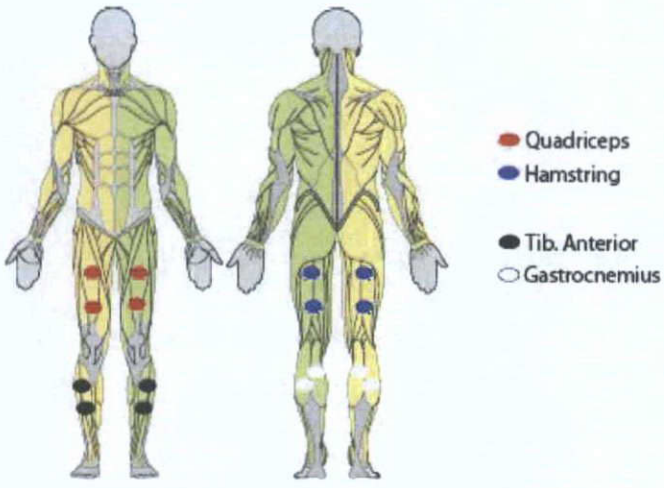
Leg bilateral 4 Channels



Leg bilateral 6 Channels

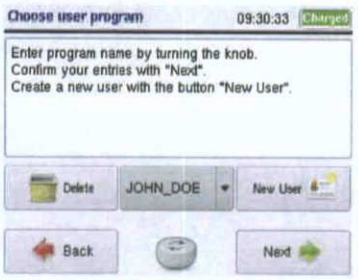
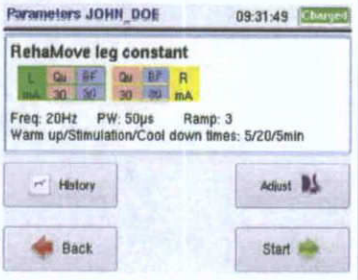


Leg bilateral 8 Channels

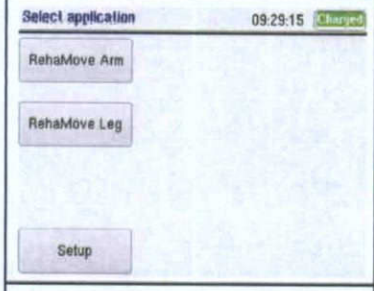


4.4.5 Adjust a User Program

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

	Select application Select desired application by pressing the button next to the displayed application button. Activate the **RehaMove leg** training. Transparent buttons are not active and cannot be pressed. Use buttons: **RehaMove Arm:** Arm training with RehaMove **RehaMove Leg:** Leg training with RehaMove **Setup:** To adjust device specific settings
	Choose user program The field above the turning knob shows all available user programs. Choose a user program by turning the **knob**. Press **Next** in order to start the training with the selected program.
	Parameters for user program The parameter window shows program settings: • Therapy mode (e.g. RehaMove Leg constant) • Stimulated muscle groups with corresponding current and cable color in table form • Frequency (Hz), pulse width (µs) and ramp • Times for warm up, stimulation and cool down in minutes Use the **turning knob** to scroll up and down. Press **Adjust** to changes settings (password protected area).
	The information window **"Enter password"** comes up. You have 5 seconds time to enter the password. The password is a combination of buttons: **press the first button on the right side, followed by the first button on the left side**, shortly one after another.

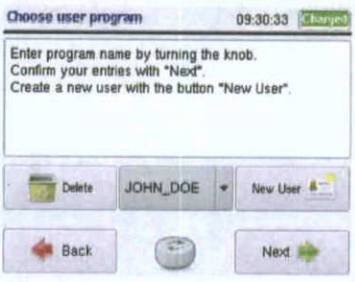
4.4.7 Show Training History



Select application

Use buttons:

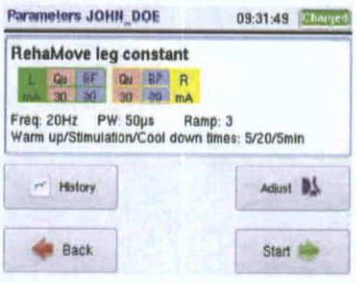
RehaMove Arm: Arm training with RehaMove
RehaMove Leg: Leg training with RehaMove



Choose user program

The field above the turning knob shows all available user programs.

Choose a user program by turning the **knob** and press **Next.**

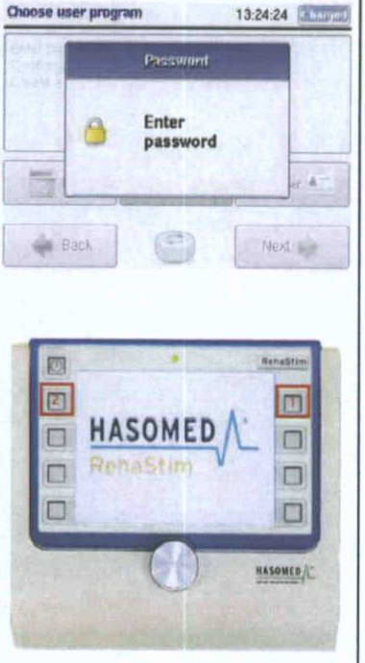


Parameters for user program

The parameter window shows saved program settings

Use button:

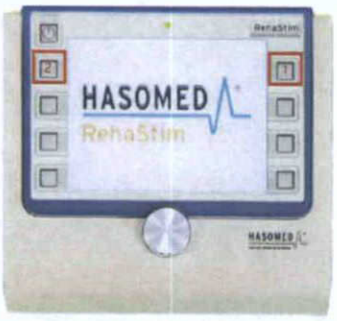
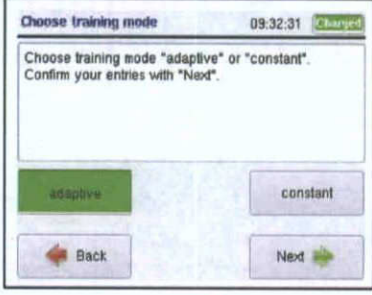
History: to show the training course of the user program (password protected)



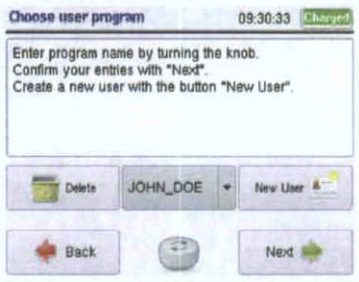
The information window "Enter password" comes up.

You have 5 seconds to enter the password.

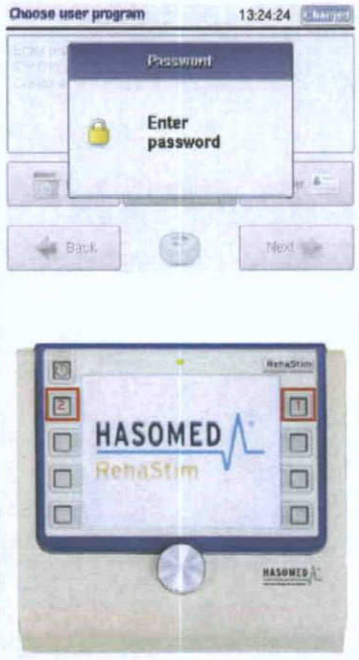
The password is a combination of buttons: **press the first button on the right side, followed by the first button on the left side**, shortly one after another.

	
	After the password is entered the window "Choose training mode" comes up. Further instructions can be found in chapter "Create a new user program".

4.4.6 Delete a User Program

<table>
<tr>
<td> 
</td>
<td><u>Choose user program</u>
The field above the turning knob shows all available user programs.

Choose a user program by turning the knob.

Press the button Delete in order to delete the program.
Now you enter the password protected area.</td>
</tr>
<tr>
<td> 
</td>
<td>"Enter password" comes up.

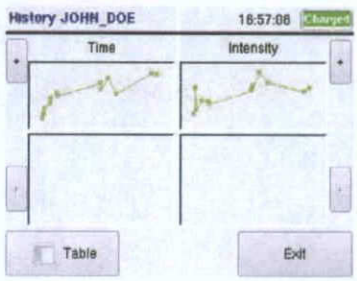
You have 5 seconds to enter the password.

The password is a combination of buttons: press the first button on the right side, followed by the first button on the left side, shortly one after another.</td>
</tr>
<tr>
<td> 
</td>
<td><u>Security query: Delete user program</u>

A query comes up which shows the name of the user program.
The program is deleted once this is confirmed.

Use the buttons:

Yes: to delete the user program with corresponding training course
No: to abort process and keep user program and training course</td>
</tr>
</table>



History: graphic display

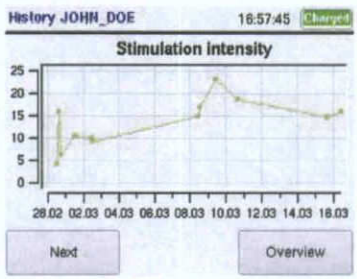
This window shows the progression of the therapy by means of a graphic display.
The history for each parameter is shown in a table.

Use buttons next to the graphic display:

Time: to show the stimulation time for each therapy session in chronological order
Intensity: to show the stimulation intensity for each therapy session in chronological order

Use buttons:

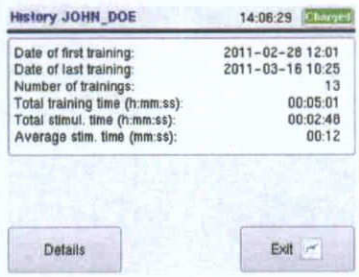
Table: for an overview about the progression of each stimulation parameter
Exit: to go back to the start window



History: graphic display in detail

Once one parameter from the graphic display is selected, a new window comes up where each parameter is shown in detail using a coordinate system. The y-axis indicates the unit of each parameter whereas the x-axis gives the timeline.
NOTE: Values of the x-axis do not exactly relate to the date display. The space between for instance March 8th and March 9th can be interpreted as 24 hours time span. Depending on the time of the therapy session, the value of the parameter shifts on the x-axis.

Use buttons:
Next: to switch between graphic displays for parameters
Overview: to go back to the general overview of parameters

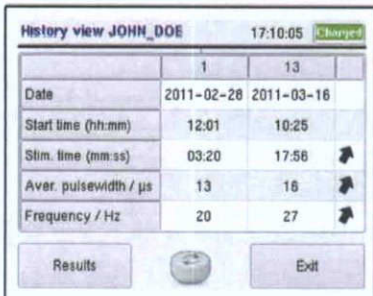


History: Overview

This window shows details of the entire training course of the selected user program.

- The date and time of the first and last training
- The number of exercise sessions
- The total duration of training
- The total duration of stimulation
- The average stimulation time per training session

Use button:
Details: to show details of individual exercise sessions



History: Details of training course

This window shows parameters for each exercise session. To select one session, scroll in the second column. The third column shows the last training session. The right column indicates a tendency/trend, starting with the selected until the last training session by using an arrow.

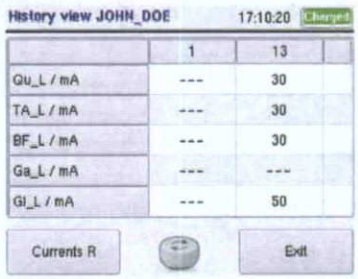
Following information is shown:

- The number of the exercise session
- The date
- The start time
- The stimulation time
- The average pulse width during the exercise session
- The frequency during the training

Use the turning knob to page through training sessions.

Use buttons:

Results: To see further parameters
Current L: To access the window "Details of training course: Current" for the left side of the body



History: Details of the Training Course : Current

Following information is shown:

- The current for each muscle on the left side

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

Use buttons:

Current R: To access current details for the right side of the body

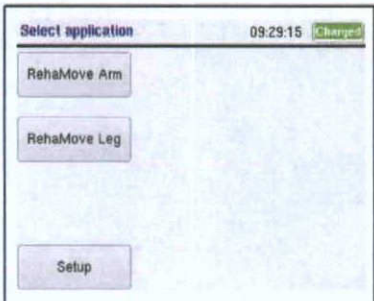
4.4.8

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

4.5 RehaMove Arm Training

Following chapters introduce you to the exercise of upper extremities with stimulation programs being set by the therapist. There are two different training modes available with constant and adaptive parameters (see chapter: "RehaMove - Motion training with FES"). The window "Parameters" at the beginning of the training shows which training mode is selected.

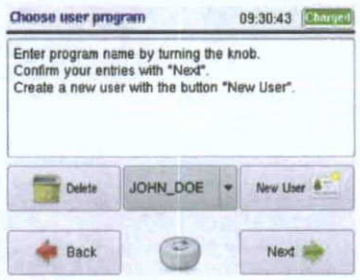
Switch on the stimulator by using the **On/Off** button.



Select application

Select desired application by pressing the button next to the displayed application.
Activate the **RehaMove Arm** training by pressing the button next to the displayed one on the screen.

Transparent buttons are not active and cannot be pressed.



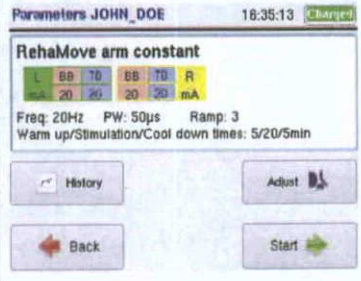
Choose user program

The field above the turning knob shows all user programs.

Choose a user program by turning the **knob**.
Press **Next** in order to start the training with a selected program.

Use buttons:

Delete: Delete a created user program (password protected)
New user: Create a new user program (password protected)
Back: Go back to the window "Select application"



Parameters of user program

The parameter window shows saved program settings:

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

Use the **turning knob** to scroll up and down.
Use buttons:

	History: Show the training course of the user program (password protected) **Adjust:** Change settings (password protected) **Start:** Start the training with the warm up

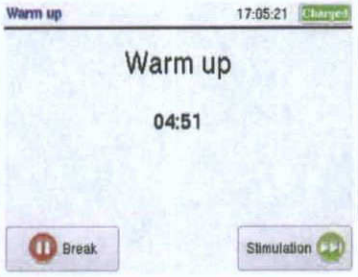
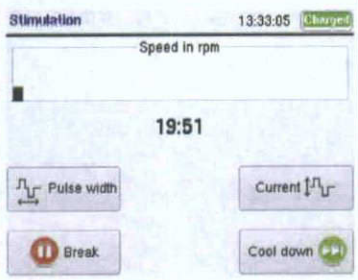
4.5.1 Constant Stimulation Arm Training - Operation by Client

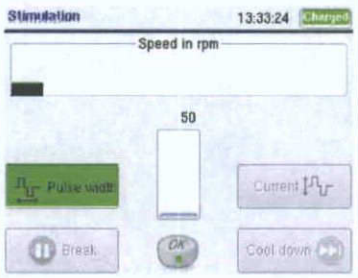
This training mode uses stable parameters: the pulse width remains stable, regardless the users' performance. Gears and speed can be selected as usual and do not influence the stimulation.

Start values (apart from the client individual stimulation settings): Gear and speed can be selected as without stimulation and do not influence the stimulation.

Start the movement exerciser and the stimulator.

NOTE! The movement therapy device needs a minimum speed of 10 rpm in order to activate the stimulation. The stimulation is deactivated below this speed and an error message pops up.

	Warm up The warm up window shows the remaining time for the warm up phase. Use buttons: **Break:** Pause the warm up **Stimulation:** Abort the warm up and start the stimulation
	Stimulation The display of the stimulation window changes depending on the selected therapy mode. Constant training: Speed in rpm is demonstrated through a graph *If the stimulation is active, the status indication line is colored in yellow.* Use buttons: **Pulse width:** Adjust the pulse width (for all channels) during the stimulation **Current:** Adjust the current (for each channel separately) during the stimulation **Cool down:** Abort the stimulation and start the cool down phase

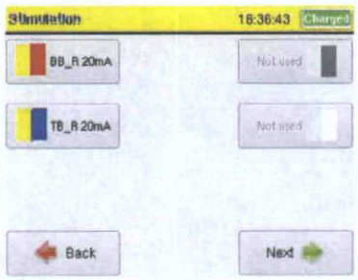


Pulse width adjustment

To adjust the pulse width during the training, press the button **Pulse width** in the stimulation window. The pulse width is changed for ALL muscles.

A bar with adjusted pulse width in µs pops up in the middle of the screen.

In order to change the pulse width, use the **turning knob** . Once the right pulse width is found, press the **turning knob** to confirm the setting.

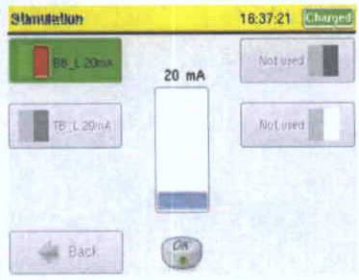


Current adjustment

To adjust the current during the training, press the button **current** in the stimulation window.

Thereupon a new window pops up which shows all active channels with corresponding muscle groups as well as the present current.

To select more than 4 channels, press **Next.** In order to select a channel, press the button next to the associated picture on the screen.



If one channel is selected, it is marked green and a bar with set current in mA pops up in the middle of the screen.

Use the turning knob:

- Change the current by turning the knob
- Confirm the current by pressing the knob

After having adjusted the parameters, the channel is not marked green anymore.
Now, the current of another channel can be changed.

Cool down

The Cool down window shows the remaining time for the Cool down phase.

Use buttons:

Break: Pause the Cool down
Exit: Stop the Cool down and continue with the report

Report

The report shows the times for warm up, stimulation and cool down as well as the entire duration of breaks during the training.

Use the button:

Parameters (active if parameters were changed): to save parameter changes as start settings for the next training.
Next: Close the report and go to window "Select application"

4.5.2 Adaptive Stimulation Arm Training - Operation by Client

This training program automatically adapts to the client's physical abilities.

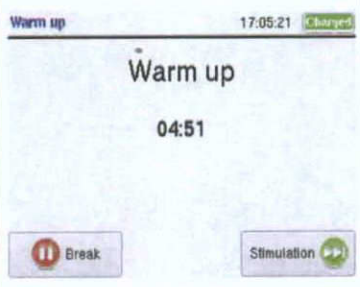
The user starts with a base speed and aims to achieve an adjustable target speed [rpm] which is 20 rpm higher. In order to achieve the target speed, the stimulator automatically regulates the pulse width: as long as the user does not reach the target speed, the pulse width rises. Once the user exceeds the target speed the pulse width decreases. The limit of pulse width can be adjusted.
The intensity of the stimulation given is shown with a graph on the screen. This graph shows the proportion pulse width of the adjusted pulse width maximum.
While the automatic regulation works the pulse width may fluctuate to some extent, particularly when it is close to the target speed. Also slight fluctuation of the speed may occur.
Reaching the target speed depends on the chosen gear: A lower gear enables the user to reach the target speed with less power, whereas in a higher gear the user needs to generate more power. The automatic adaptation of stimulation intensity works best if the effective pulse width is at about half of the maximum pulse width. Adjust the gear in order to reach that. If the effective pulse width is always at the upper end of the bar, decrease the gear; if the effective pulse width is always at the bottom of the bar, raise the gear.

Start values (apart from client individual stimulation settings):
- At the MOTOmed: Base speed: minimum: 10 rpm, maximum: 40 rpm
- Gear: 0 (zero) - adjust manually
- Optional: in the main menu/ "Basic adjustments": adjust the active/ passive- change to "direct": if patient can not achieve the target speed, the speed goes down to the base speed.

- At the stimulator: target speed (= "max. rpm"): 20 rpm higher than base speed at the MOTOmed, maximum: 60 rpm

Start the movement exerciser and then the stimulator.

NOTE! The movement therapy device needs a minimum speed of 10 rpm in order to activate the stimulation. The stimulation is deactivated below this speed and an error message pops up.

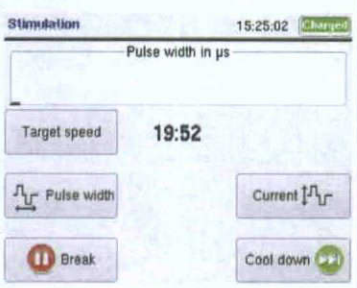


Warm up

The warm up window shows the remaining time for the warm up phase.

Use buttons:

Stimulation: Stop the warm up and start the stimulation



Stimulation

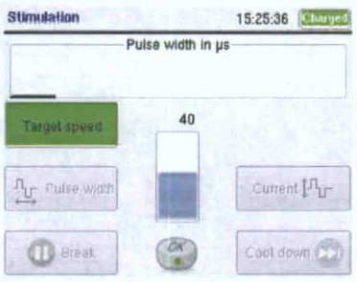
The display of the stimulation window changes depending on the selected therapy mode.

Adaptive training: Pulse width in µs is demonstrated through a bar.

If the stimulation is active, the status indication line is colored in yellow.

Use buttons:

Target speed: Adjust the target speed during the stimulation
Pulse width: Adjust the pulse width (for all channels) during the stimulation
Current: Adjust the current (for each channel separately) during the stimulation
Break: Pause the stimulation phase
Cool down: Abort the stimulation and start the cool down phase

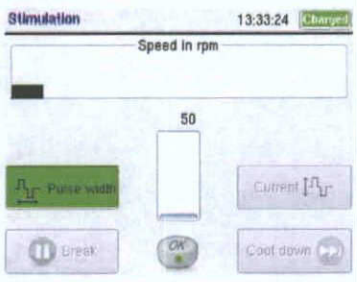


Target speed adjustment

To adjust the target speed during the training, press the button **Target speed** in the stimulation window.

A bar with adjusted target speed pops up in the middle of the screen.

In order to change the target speed, use the **turning knob**. Once the right target speed is set, press the **turning knob** to confirm the setting.



Pulse width online adjustment

To adjust the pulse width during the training, press the button **Pulse width** in the stimulation window. The **Pulse width** is changed for **ALL** muscles.

A bar with adjusted pulse width in µs pops up in the middle of the screen.

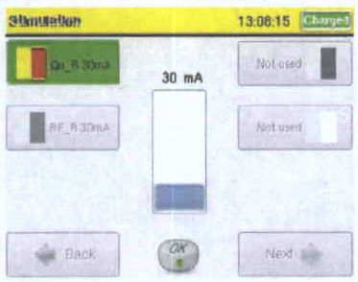
In order to change the pulse width, use the **turning knob** . Once the right pulse width is set, press the **turning knob** to confirm the setting.

Current adjustment

To adjust the electric current during the training for each channel, press the button **Current** in the stimulation window.

Thereupon a new window pops up which shows all active channels with corresponding muscle groups as well as the present current.

In order to select a channel, press the button Next to the associated picture on the screen.



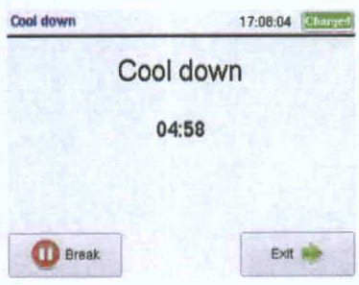
If one channel is selected, it is marked green and a bar with set current in mA pops up in the middle of the screen.

Use the turning knob:

- Change the current by turning the knob
- Confirm the current by pressing the knob

After having adjusted the parameters, the channel is not marked green anymore.
Now, the current of another channel can be changed.

To select more than 4 channels, press **Next**.

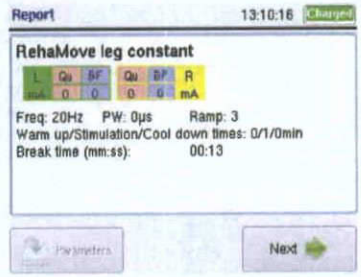


Cool down

The Cool down window shows the remaining time for the Cool down phase.

Use buttons:

Break: Pause the Cool down
Exit: Abort the Cool down and continue with the report window

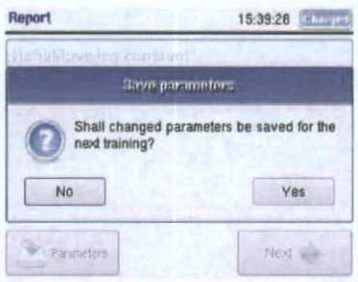


Report

The report shows the time for warm up, stimulation and cool down as well as the entire duration of breaks during the training.

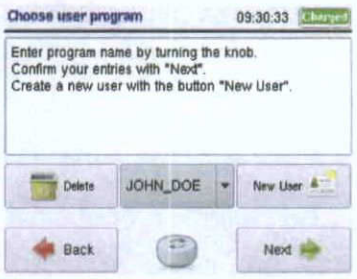
Use the button:

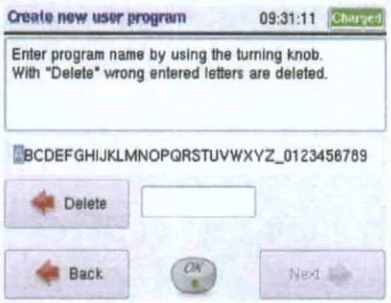
Parameters (active if parameters were changed): to save parameter changes start settings for the next training.

	Exit: Close the report window and go to window "select application"
	Report / save parameters If the changed parameters are saved a confirmation message pops up. Now you will be forwarded directly to the window "Select application".

4.5.3 Create a New User Program

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

	Select application Select desired application by pressing the button next to the displayed application button. Transparent buttons are not active and cannot be pressed. Use buttons: **RehaMove Arm:** Arm training with RehaMove **RehaMove Leg:** Leg training with RehaMove **Setup:** To adjust device specific settings
	Choose user program Create a new user program by pressing the button **New user.** Now you enter the password protected area.
 	After having pressed this button, the information window: "enter password" comes up. You have 5 seconds to enter the password. The password is a combination of buttons: **press the first button on the right side, followed by the first button on the left side**, shortly one after another.



Create new user program

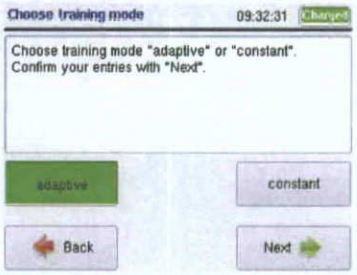
In the window "create a new user program" a new program can be created for a client. Use the turning knob in order to enter a new program name.

Use the **turning knob**:

- In order to select letters / numbers, turn the knob
- In order to confirm entries, press the turning knob

Use buttons:

Delete: to delete letters or numbers

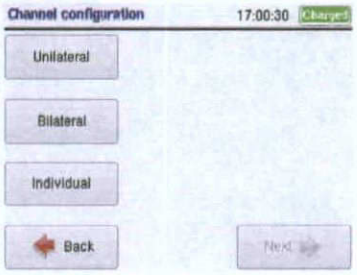


Choose training mode

The window "Choose training mode" allows for choosing between constant and adaptive training. Information about different training modes can be found in chapter: "RehaMove - Motion training with FES".

Use buttons:

Adaptive: To select the adaptive RehaMove training mode
Constant: To select the constant RehaMove training mode

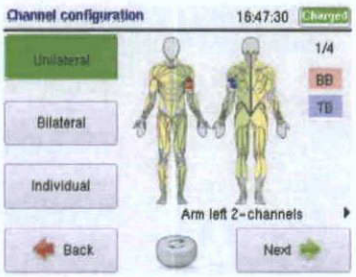


Channel configuration

In the window "Channel configuration" templates for unilateral or bilateral stimulation can be selected. The button **Individual** allows for individual channel configuration.

Use buttons:

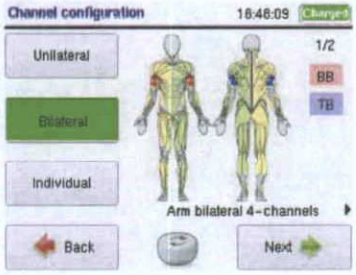
Unilateral: to select unilateral stimulation templates
Bilateral: to select bilateral stimulation templates
Individual: to define individual stimulation patterns (see "Activate muscles")



Channel configuration: Unilateral

If the button **Unilateral** is activated, a number of template pictures above the turning knob comes up. The templates show selected channels from the front side and back side. Choose whether 2, 3 or 4 channels shall be activated to stimulate one side of the body. These templates cover most frequently used combinations of muscle groups.

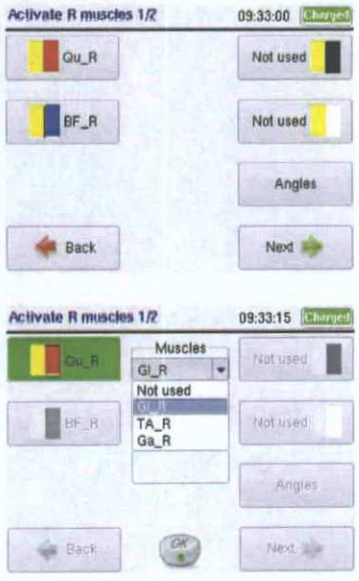
Use the turning knob in order to select one template. Press **Next** to confirm your entries.



Channel configuration: Bilateral

If the button **Bilateral** is activated, a number of template pictures above the turning knob comes up. The templates show selected channels from the front side and back side. Choose whether 4, 6 or 8 channels shall be activated to stimulate both sides of the body. These templates cover most frequently used combinations of muscle groups.

Use the turning knob in order to select one template. Press **Next** to confirm your entries.



Activate Muscles

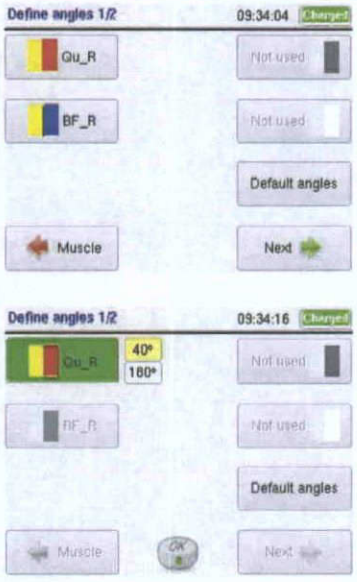
This window allows the client to assign **individual** muscle channel combinations. Muscle groups are chosen for the training and colors are matched.

Select a channel by pressing the corresponding button. The active channel is tagged green.
A window with available muscles groups pops up in the middle of the screen. Abbreviations are used to indicate each muscle (see chapter:"Default values").

Use the turning knob:

- In order to select muscle groups, turn the knob.
- In order to confirm entries, press the turning knob

Use buttons:
Angles: to see/change angles for the program
Back: abort the process / go back to the previous window
Next: to activate further muscle groups or Adjust parameters



Define angles

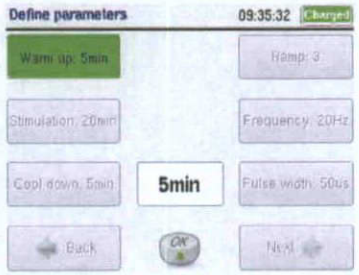
In this window the activated muscle groups are shown and activation angles can be defined.
In order to change the angles for one activated muscle, press the corresponding button.
An overview standard the angles can be found in chapter "Default values".
Start and stop angles can be changed by the user. The button of the activated channel is tagged green.

Use the turning knob:

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

Use button:

Default angles: Default angles are reactivated, changes are overwritten, all settings for the angles are deactivated again.



Define parameters: Warm up, Stimulation, Cool down

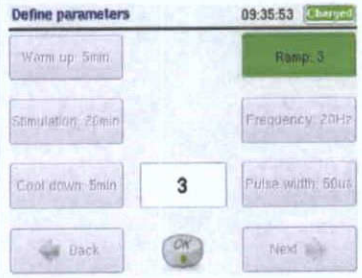
This window allows for adjusting parameters that apply to all channels.

Press the button **Warm up** in order to change the duration of the warm up.
A field above the turning knob pops up with the present value in minutes.

Use the turning knob:

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

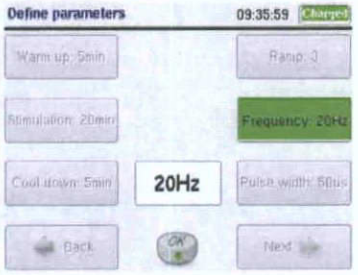
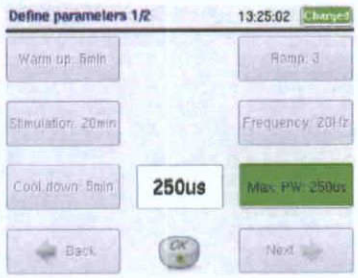
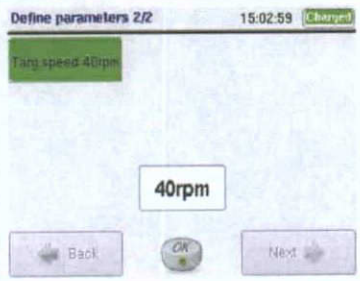
The same procedure applies to change the duration of stimulation and cool down phase

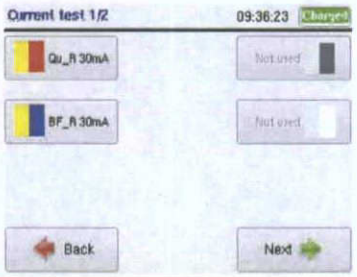
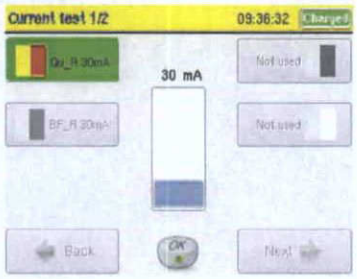


Define parameters: Ramp

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

Press the button **Ramp** in order to change the ramp.

	A field above the turning knob pops up with the present value. Use the turning knob: **Turning knob:** • In order to change number of reduced pulses, turn the knob • In order to confirm entries, press the turning knob
	<u>Define parameter: Frequency</u> The frequency indicates the number of impulses per second. Press the button **Frequency** in order to change the frequency. A field above the turning knob pops up with the present value. Use the turning knob: • In order to change the frequency, turn the knob • In order to confirm entries, press the turning knob
	<u>Define parameters: Pulse width and Max. pulse width</u> Press the button **Pulse with** in order to change the pulse width (in constant training mode). When using the adaptive training mode, the **Max. PW** width is adjusted. A field above the turning knob pops up with the present value. Use the turning knob: • In order to change pulse width, turn the knob • In order to confirm entries, press the turning knob
	<u>Define parameters: Target speed (in adaptive training only)</u> The user starts to train with a basic speed and aims to reach the target speed in rpm. (see chapter: "Adaptive Stimulation - Operation by patient".) Press the button **Targ. speed** in order to change the target speed. A field above the turning knob pops up with the present value.

	Use the turning knob: • In order to change speed, turn the knob • In order to confirm entries, press the turning knob
	Current test This window shows all activated channels. If you want to test the current for one specific channel respectively muscle, press the corresponding button.
	Current test A window in the middle of the screen pops up which shows the present current, displayed with a bar. *If the stimulation is active, the status indication line is colored in yellow.* By pressing the green tagged button once more, the activated button is deactivated again. The next channel can be selected and tested. Use the turning knob: • In order to change current, turn the knob • In order to confirm entries, press the turning knob Next: Test current for further channels, if activated

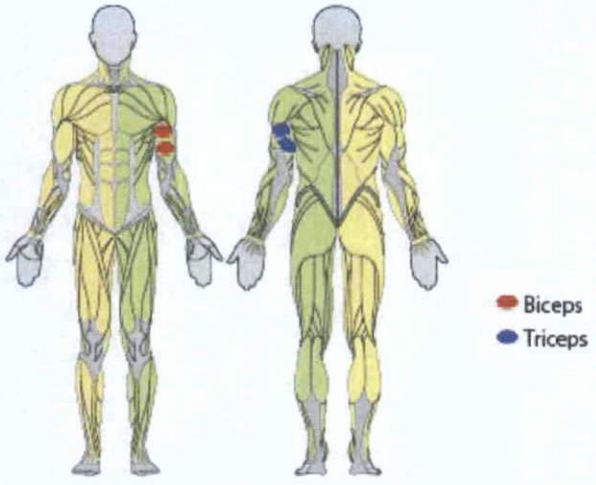
4.5.4 Electrode Placement for Common Muscle Combinations for Arm Training

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

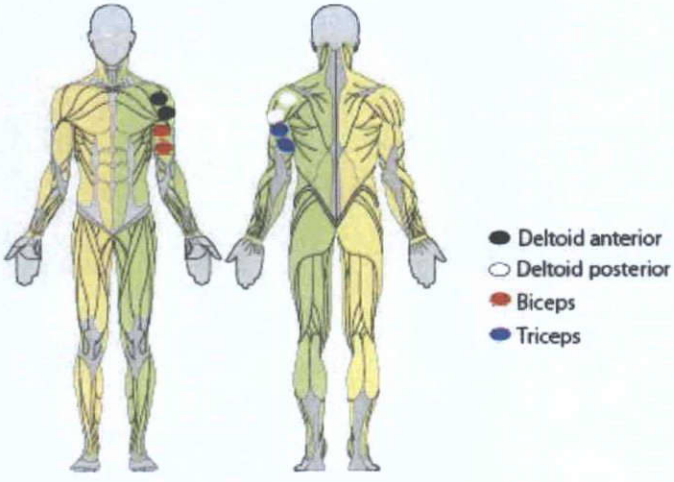
Please contact the manufacturer for further questions.

4.5.4.1 Unilateral stimulation: left arm

Arm left 2 Channels

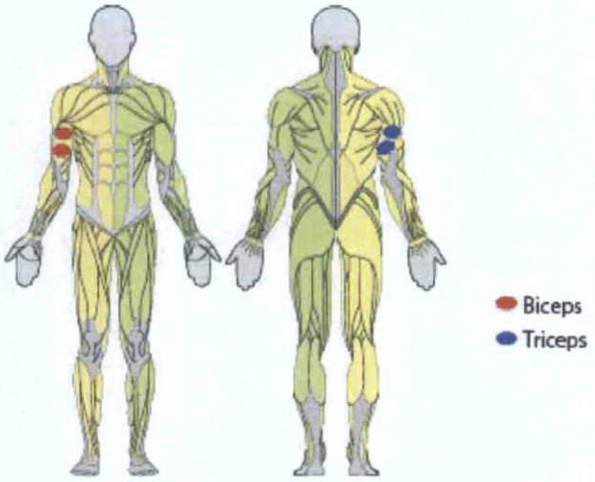


Arm left 4 Channels

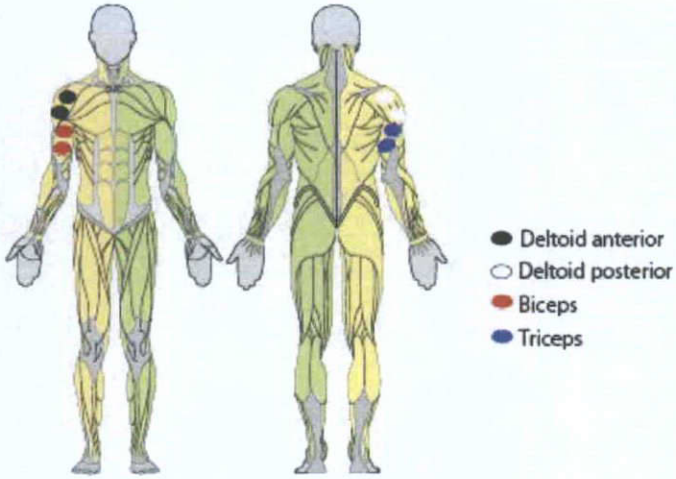


4.5.4.2 Unilateral stimulation: right arm

Arm right 2 Channels

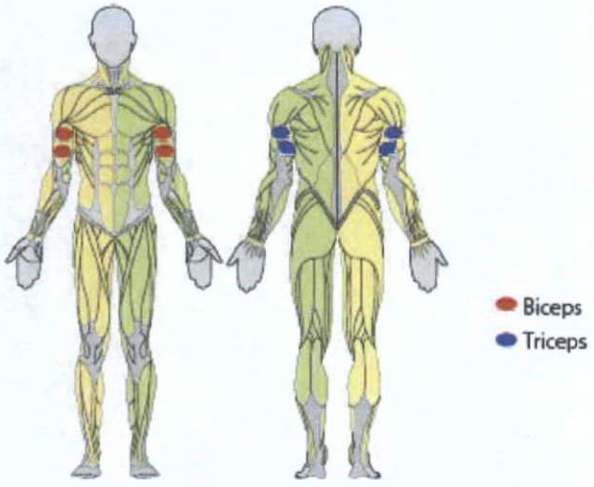


Arm right 4 Channels

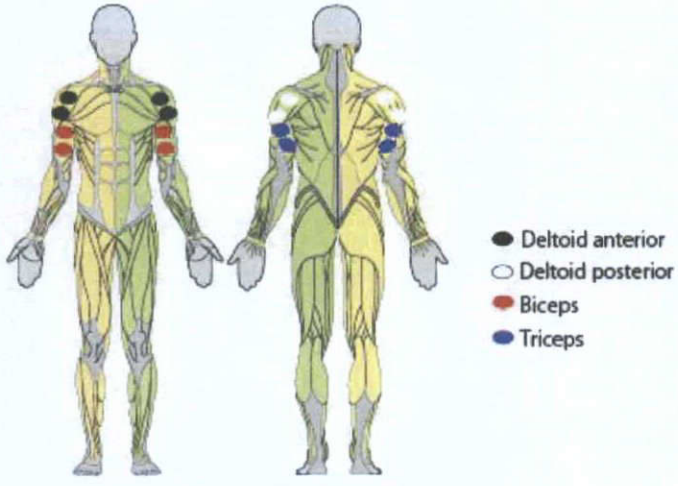


4.5.4.3 Bilateral stimulatation of arms

Arm bilateral 4 Channels

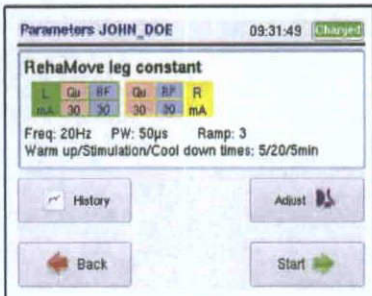


Arm bilateral 8 Channels



4.5.5 Adjust a User Programme

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



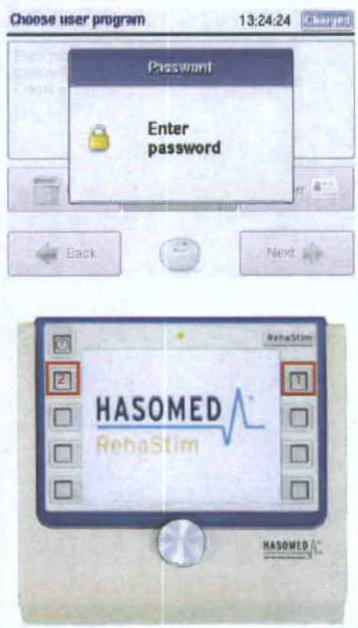
Parameters for user program

The parameter window shows program settings:

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

Use the **turning knob** to scroll up and down.

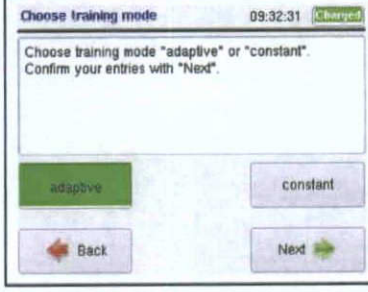
Press the button **Adjust** to changes settings (Password protected area).



The information window "Enter password" comes up.

You have 5 seconds to enter the password.

The password is a combination of buttons: **press the first button on the right side, followed by the first button on the left side,** shortly one after another.



After the password is entered the window "Choose training mode" comes up.

Further instructions can be found in chapter "Create a new user program".

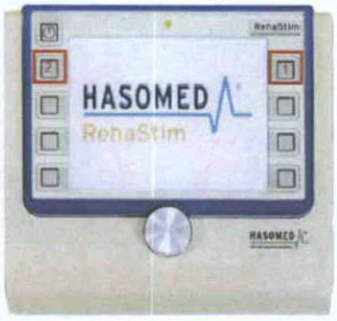
4.5.6 Delete a User Programme

Choose user program

The field above the turning knob shows all available programs.

Choose a user program by turning the knob.

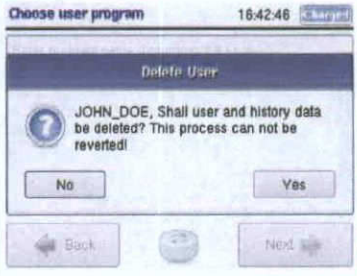
Press the button **Delete** in order to delete the program.
Now you enter the password protected area.



"Enter password" comes up.

You have 5 seconds to enter the password.

The password is a combination of buttons: **press the first button on the right side, followed by the first button on the left side**, shortly one after another.



Security query: Delete user program

A query comes up which shows the name of the user program.
The program is deleted once this is confirmed.

Use the buttons:

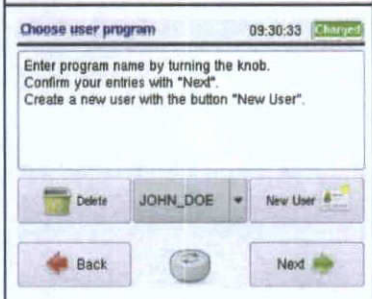
Yes: To delete the user program with corresponding training course
No: Abort process and keep user program and training course

4.5.7 Show Training History

Select application

Use buttons:

RehaMove Arm: Arm training with RehaMove
RehaMove Leg: Leg training with RehaMove



Choose user program

The field above the turning knob shows all available user programs.

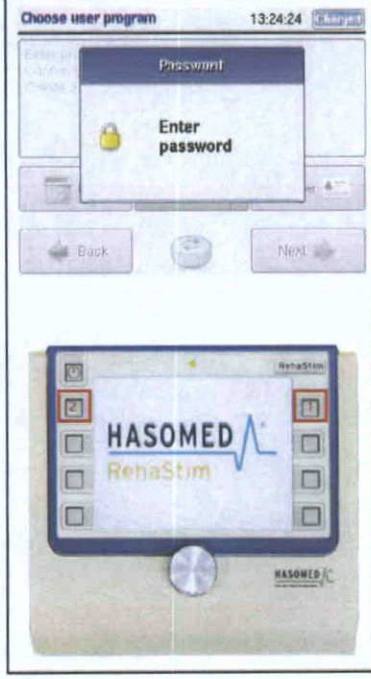
Choose a user program by turning the **knob** and press **Next.**

Parameters for user program

The parameter window shows saved program settings.

Use buttons:

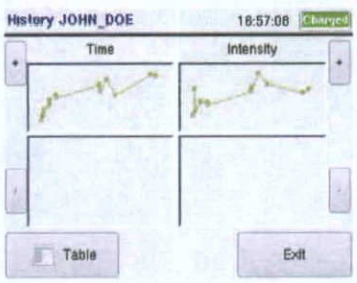
History: Show the training course of the user program (password protected)



"Enter password" comes up.

You have 5 seconds to enter the password.

The password is a combination of buttons: **press the first button on the right side, followed by the first button on the left side**, shortly one after another.



History: graphic display

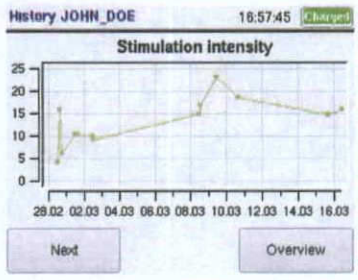
This window shows the progression of the therapy by means of a graphic display.
The history for each parameter is shown in a table.

Use buttons next to the graphic display:

Time: To show the stimulation time for each therapy session in chronological order
Intensity: To show the stimulation intensity for each therapy session in chronological order

Use buttons:

Table: For an overview about the progression of each stimulation parameter
Exit: Go back to the start window

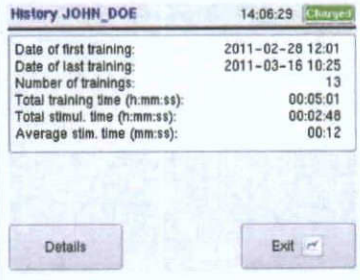


History: graphic display in detail

Once one parameter from the graphic display is selected, a new window comes up where each parameter is shown in detail using a coordinate system. The y-axis indicates the unit of each parameter whereas the x-axis gives the timeline.
NOTE: Values of the x-axis do not exactly relate to the date display. The space between for instance March 8th and March 9th can be interpreted as 24 hours time span. Depending on the time of the therapy session, the value of the parameter shifts on the x-axis.

Use buttons:

Next: To switch between graphic displays for each parameter
Overview: To go back to the general overview of parameters

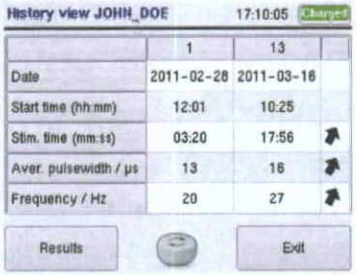
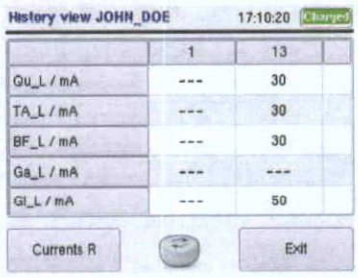


History: Overview

This window shows details of the entire training course of the selected user program.

- The date and time of the first and last training
- The number of exercise sessions
- The total duration of training
- The total duration of stimulation
- The average stimulation time per training session

Use button:

	Details: To show details of individual exercise sessions
	History: Details of training course This window shows parameters for each exercise session. To select one session, scroll in the second column. The right column shows the final training session. The last column indicates a tendency/trend, starting with the selected until the last training session by using an arrow. Following information is shown: • The number of the exercise session • The date • The start time • The stimulation time • The average pulse width during the exercise session • The frequency during the training Use the turning knob to page through training sessions. Use buttons: **Results:** To see further parameters **Current L:** To access the window "Details of training course current" for the left side of the body
	History: Details of the Training Course / Current Following information is shown: • The current for each muscle on the left and right side Use the **turning knob** to page through training sessions. Use buttons: **Current R:** To access the window "Current details" for the right side of the body

4.5.8 Finishing a Stimulation Session

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

4.6 RehaMove Training with One Surface Operation

The new one surface operation (so called FES 3 interface) insures the control of each parameter of the MOTOmed viva 2 directly from the stimulator. In the end of the training information to the parameters of distance and power are transmitted from the MOTOmed to the stimulator. Through that the progress of the most relevant therapy parameters can be directly documented and evaluated on the stimulator.

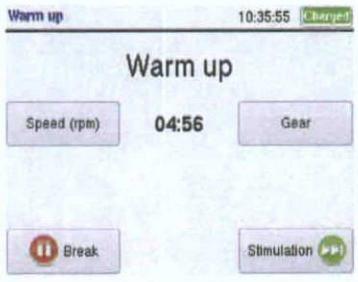
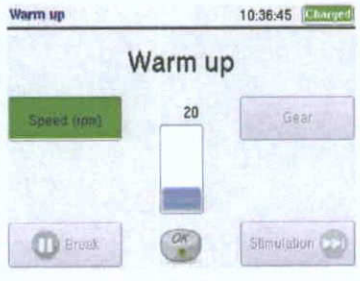
The chapters: "Create a new user program", "Adjust a User Program" and "Delete a User Program" correspond to the operation of RehaMove training with FES2 protocol.

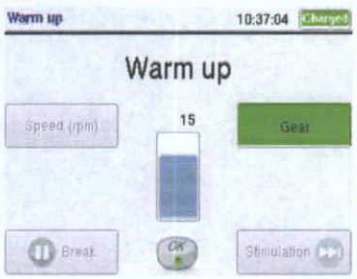
4.6.1 Constant Stimulation Training - Operation by Client

This training mode works with constant parameters. The pulse width remains the same regardless of the user's performance. By using the buttons of the stimulator you can change the brake resistance (gear) as well as the speed of the MOTOmed viva 2 (at least 10 rpm) since these factors do not have an impact on the stimulation.

Start the movement exerciser and the stimulator.

NOTE! The movement therapy device needs a minimum speed of 10 rpm in order to activate the stimulation. The stimulation is deactivated below this speed and an error message pops up.

	Warm up The warm up window shows the remaining time for the warm up phase. Use buttons: **Speed (rpm)**: adjust the speed of the MOTOmed viva 2 **Gear**: adjust the brake resistance of the MOTOmed viva 2 **Break**: Pause the warm up **Stimulation**: Stop the warm up and start the stimulation
	Warm up: Adjust MOTOmed speed In order to change the speed of the MOTOmed during training, press the button **Speed (rpm)**. A bar displaying the chosen speed in rpm then appears in the middle of the screen. In order to change the speed, please use the turning knob. Press the turning knob to confirm your choice. *Note: In the stimulation phase the speed remains as high as during warm up.*



Warm up: Adjust the MOTOmed brake resistance

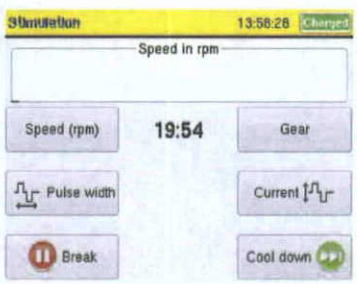
In order to regulate the brake resistance of the MOTOmed during training, press the button **Gear**.

For more support by the motor, choose a lower gear. To achieve more resistance during training, choose a higher gear.

A bar displaying the gear chosen appears in the middle of the screen.

To change the gear, use the turning knob. Press the turning knob to confirm your choice.

Note: In the stimulation phase the gear remains as high as during warm up.



Stimulation

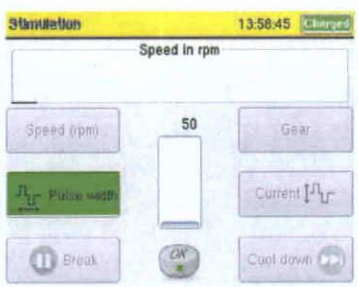
The display of the stimulation window changes depending on the selected therapy mode.

Constant training: speed in rpm is demonstrated through a bar

If the stimulation is active, the status indication line is colored in yellow.

Use buttons:

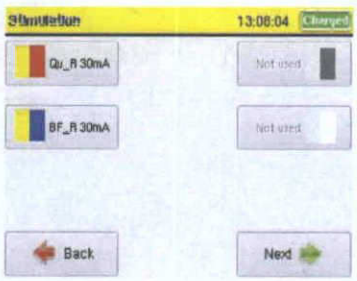
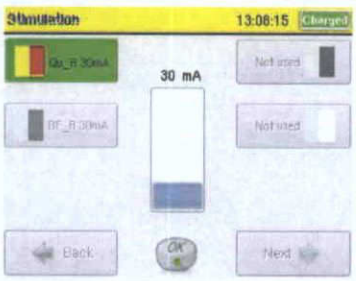
Speed (rpm): adjust the speed of the MOTOmed viva 2
Gear: adjust the brake resistance of the MOTOmed viva 2
Pulse width: Adjust the pulse width (for all channels) during the stimulation
Current: Adjust the current (for each channel separately) during the stimulation
Cool down: Abort the stimulation and start the cool down phase

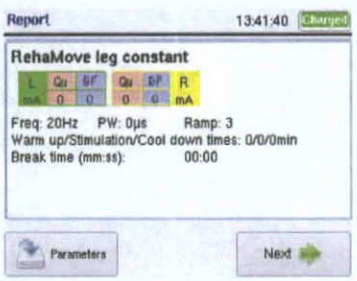


Stimulation: Pulse width adjustment

To adjust the pulse width during the training, press the button **Pulse width** in the stimulation window. The pulse width is changed for ALL muscles.

A bar with adjusted pulse width in µs pops up in the middle of the screen.

	In order to change the pulse width, use the turning knob. Press the **turning knob** to confirm the setting.
	Stimulation: Current adjustment To adjust the current during the training, press the button **Current** in the stimulation window. Thereupon a new window pops up which shows all active channels with corresponding muscle groups as well as the present current. To select more than 4 channels, press **Next**. In order to select a channel, press the button next to the associated picture on the screen.
	If one channel is selected, it is marked green and a bar with set current in mA pops up in the middle of the screen. Use the **turning knob**: • Change the current by turning the knob • Confirm the current by pressing the knob After having adjusted the parameters, the channel is not marked green anymore. Now, the current of another channel can be changed.
	Cool down The Cool down window shows the remaining time for the Cool down phase. Use buttons: **Speed (rpm):** adjust the speed of the MOTOmed viva 2 **Gear:** adjust the brake resistance of the MOTOmed viva 2 **Break:** Pause the Cool down **Exit:** Abort the Cool down and continue with the report window



Report

The report shows the times for warm up, stimulation and cool down as well as the entire duration of breaks during the training.

Use the buttons:
Parameters: (only active if parameters were changed): to save parameter changes as start settings for the next training.
Exit : Close the report and go to window "Select application"

4.6.2 Adaptive Stimulation Training - Operation by Client

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

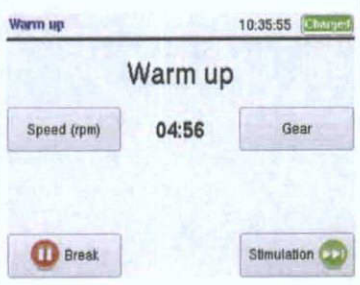
When the user approaches the target speed, the pulse width decreases.
How easily the user manages to reach the predetermined target speed can be varied with the gear selected, meaning that a lower gear requires less power than a higher gear.

The stimulation intensity is displayed on a graph on the screen of the stimulator. It consecutively shows the particular pulse width. During the automatic regulation the pulse width is likely to change, especially when it is close to the target speed. Little deviations in the speed may occur as well.
The best condition for an automatic adjustment of the stimulation intensity is a pulse width that complies with the half of the maximum pulse width. The brake resistance of the MOTOmed viva 2 can be adapted individually from the stimulator. If the pulse width reaches the upper part of the bar, the brake resistance should to be increased. If it reaches the lower part of the bar, it needs to be decreased.

Start values (independent of the user's individual stimulation conditions):
- at the MOTOmed: speed: set from stimulator, gear: set from stimualtor
- at the stimulator: base speed at least 10 rpm, gear: 0 (zero)

Start the movement exerciser by pressing the start button. No further operation is allowed! Turn on the stimulator.

NOTE! The movement therapy device needs a minimum speed of 10 rpm in order to activate the stimulation. The stimulation is deactivated below this speed and an error message pops up.

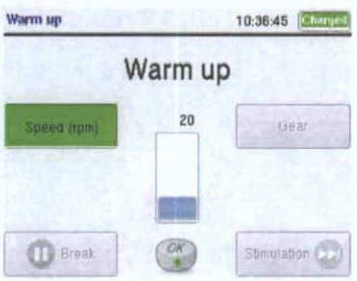


Warm up

The warm up window shows the remaining time for the warm up phase.

Use buttons:

Speed (rpm): adjust the speed of the MOTOmed
Gear: adjust the brake resistance of the MOTOmed
Break: Pause the Warm up
Stimulation: Abort the warm up and start the stimulation



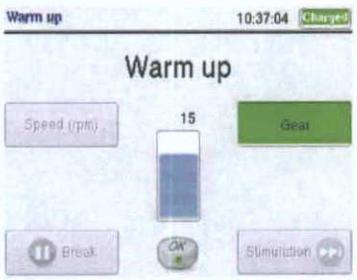
Warm up: Adjust MOTOmed speed

In order to change the speed of the MOTOmed during training, press the button **Speed (rpm)**.

A bar displaying the chosen speed in rpm then appears in the middle of the screen.

In order to change the speed, use the turning knob. Press the turning knob to confirm your choice.

Note: The speed determined during the warm up is not taken over to the stimulation phase. At the beginning of the stimulation of the MOTOmed viva 2 is always 15 rpm.



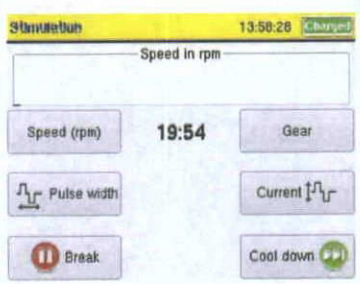
Warm up: Adjust the MOTOmed gear

In order to regulate the brake resistance (gear) of the MOTOmed during training, press the button **Gear**.

A bar displaying the gear chosen appears in the middle of the screen.

To change the gear, use the turning knob. Press the turning knob to confirm your choice. For more support by the motor, choose a lower gear. To achieve more resistance during training, choose a higher gear.

Note: The brake resistance determined during the warm up is not taken over to the stimulation phase. At the beginning of the stimulation the gear/ brake resistance of the MOTOmed viva 2 is always zero.



Stimulation

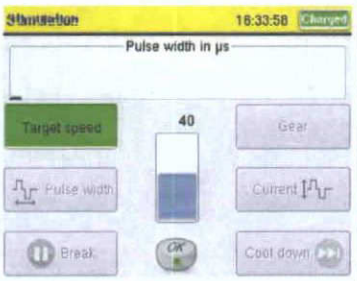
The display of the stimulation window changes depending on the selected therapy mode.

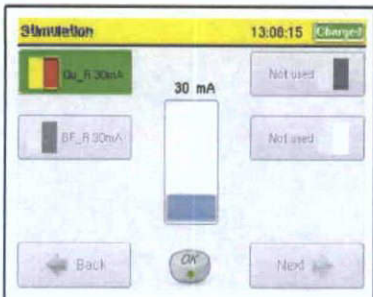
Adaptive training: Pulse width in µs is demonstrated through a graph.

If the stimulation is active, the status indication line is colored in yellow.

Use buttons:

Speed (rpm): adjust the speed of the MOTOmed
Gear: adjust the brake resistance of the MOTOmed
Pulse width: Adjust the pulse width (for all channels) during the stimulation

	Current: Adjust the current (for each channel separately) during the stimulation **Break:** Pause the stimulation phase **Cool down:** Abort the stimulation and start the cool down phase
	Stimulation: Target speed adjustment To adjust the target speed during the training, press the button **Target speed** in the stimulation window. A bar with adjusted target speed pops up in the middle of the screen. In order to change the target speed, use the **turning knob**. Press the turning knob to confirm the setting.
	Stimulation: Pulse width adjustment To adjust the pulse width during the training, press the button **Pulse width** in the stimulation window. The pulse width is changed for ALL muscles. A bar with adjusted pulse width in µs pops up in the middle of the screen. In order to change the pulse width, use the **turning knob** . Press the turning knob to confirm the setting.
	Stimulation: Current adjustment To adjust the current during the training for each channel, press the button **Current** in the stimulation window. Thereupon a new window pops up which shows all active channels with corresponding muscle groups as well as the present current. To select more than 4 channels, press **Next.** In order to select a channel, press the button next to the associated picture on the screen.



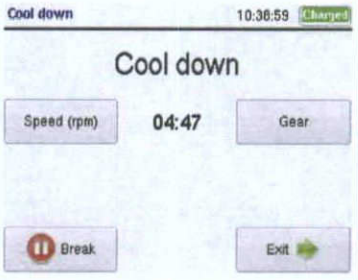
Stimulation: Current adjustment

If one channel is selected, it is marked green and a bar with set current in mA pops up in the middle of the screen.

Use the **turning knob**:

- Change the current by turning the knob
- Confirm the current by pressing the knob

After having adjusted the parameters, the channel is not marked green anymore.
Now, the current of another channel can be changed.

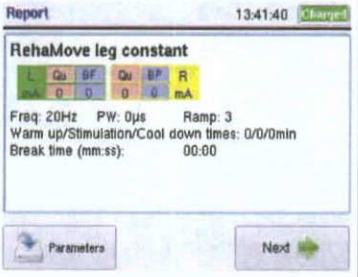


Cool down

The Cool down window shows the remaining time for the Cool down phase.

Use buttons:

Speed (rpm): adjust the speed of the MOTOmed
Gear: adjust the brake resistance of the MOTOmed
Exit: Abort the Cool down and continue with the report



Report

The report shows the times for warm up, stimulation and cool down as well as the entire duration of breaks during the training.

Use the button:

Parameters (only active if parameters were changed): to save parameter changes as start settings for the next training.
Exit : close the report window and go to window "Select application"

Report/ save parameters

If the changed parameters are saved a confirmation message pops up.
Now you will be forwarded directly to the window "Select application".

4.6.3 Show Training History

Select application

Use buttons:
RehaMove Arm: Arm training with RehaMove
RehaMove Leg: Leg training with RehaMove

Choose user program

The field above the turning knob shows all user programs available.

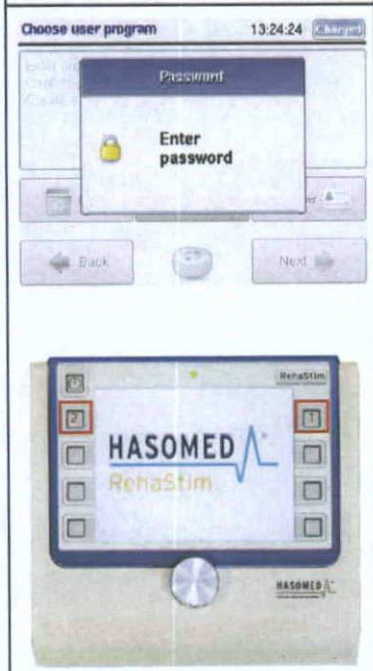
Choose a user program by turning the **knob** and press **Next.**

Parameters for user program

The parameter window shows saved program settings.

Use button:

History: Show the training course of the user program (password protected)



The information window: **"Enter password"** comes up.

You have 5 seconds to enter the password.

The password is a combination of buttons: **press the first button on the right side, followed by the first button on the left side**, shortly one after another.

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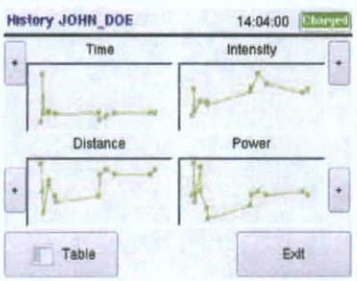


History: graphic display

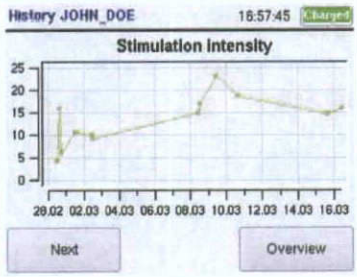
The window "History" shows the progression of the therapy by means of a graphic display.

Use buttons next to the graphic display:

Time: To show the stimulation time for each therapy session in chronological order
Intensity: To show the stimulation intensity for each therapy session in chronological order
Distance: To show the distance covered during each therapy session in chronological order
Power: To show the average power generated during each therapy session in chronological order.

Use buttons:

Table: To have an overview about the progression of each stimulation parameter
Exit: Go back to the start window



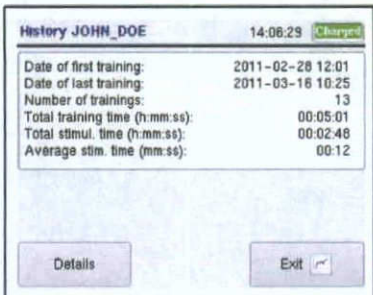
History: graphic display in detail

Once one parameter from graphic display is selected, a new window comes up where each parameter is shown in detail using a coordinate system. The y-axis indicates the unit of each parameter whereas the x-axis gives the timeline.

NOTE: Values of the x-axis do not exactly relate to the date display. The space between for instance March 8th and March 9th can be interpreted as 24 hours time span. Depending on the time of the therapy session, the value of the parameter shifts on the x-axis.

Use buttons:

Next: To switch between graphic displays for each parameter
Overview: To go back to the general overview of parameters



History: Overview

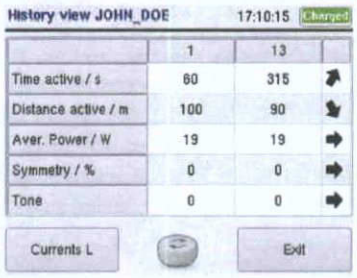
The window "History" shows an overview of the entire training course of the selected user program.

Following information are shown:

- The date and time of the first and last training
- The number of exercise sessions
- The total duration of training
- The total duration of stimulation
- The average stimulation time per training session

Use button:

Details: To show details of individual exercise sessions



History: View details

The window "History view" will show training details in tabular form.

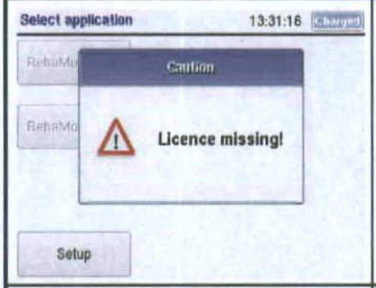
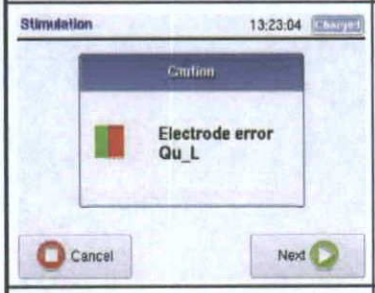
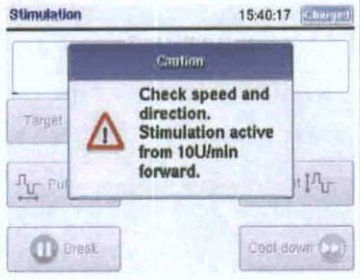
Use buttons:

Current L": to see the current of selected channels on the left body side. (same procedure for right leg)
Exit: to return to the window "History: Overview"

Use the turning knob to switch between all therapy sessions unit in the second column of the table. The third column with the last therapy unit remains the same as a reference. It can not be changed.

5 Fault indication

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

Error	Cause	Troubleshooting
The stimulator does not react to entries.		Press the **ON/OFF** button for more than 5 seconds. Switch on the stimulator again.
	To be able to use the stimulator properly, a software licence must be uploaded by the manufacturer. The stimulator does not have a valid software licence.	Please contact the manufacturer!
	The emergency-off button must be connected to the RehaStim2 during the therapy for safety reasons. This window pops up if no emergency-off button is connected or if the connected one is pressed/ locked.	Connect the emergency-off button with the stimulator and press **Next.** Check whether the emergency-off button is pressed. If it is pressed, unlock the button by turning it. Press **Next.**
	During the training the electrodes are constantly checked. If the electrodes or electrode cables are not properly connected, this window comes up.	Check whether the electrodes are properly attached and connected. Press **Next.**
	The stimulation stops during the training if: - a spasm is detected or - the speed of the MOTOmed motion trainer is too low. The RehaMove 2 needs a minimum speed of 10 rpm forward movement in order	If spasticity occurs, wait until the movement therapy device has calmed the spasticity. When the movement therapy machine starts normal exercise, let the movement go - in a forward direction - at minimum 10 rpm.

	to activate the stimulation. Below this speed the stimulation is deactivated for safety.	If the speed of the MOTOmed is too low, raise the speed up to 10 rpm.
	The connection to the MOTOmed is constantly checked. If the connection does not work, e.g. - the connecting cable has come out, - the MOTOmed viva2 is switched off or - the communication between the stimulator and motion trainer does not exist, this window pops up.	Check the cable from the RehaStim2 to the motion trainer and make sure it is connected properly. Press any key to close the pop up window and to continue. Check whether the right interface of the MOTOmed cockpit is activated. Please contact the manufacturer for further instructions.
	This screen comes up if the MOTOmed is not in start position and the Stimulator cannot take control of the MOTOmed. e.g. if a MOTOmed training session is running.	Stop the MOTOmed (press big red button start/ stop) and then "restart". The correct MOTOmed start screen says "Start screen FES programme". At the stimulator, press any key to close the pop up window and to continue operation.
	The connection to the MOTOmed is constantly checked also during the training. If the connection does not work during training, e.g. the connecting cable has come out or the MOTOmed viva2 is switched off, the training is finished and this window pops up.	Check the cable from the RehaStim2 to the motion trainer and make sure it is connected properly. Check that the MOTOmed is turned on. Press any key to close the pop up window and continue. Please contact the manufacturer for further instructions.

6 Declaration of Warranty

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

- for **2 years** after distribution within the **European Union.**
- for **1 year** after distribution in countries **outside of the European Union.**

The warranty voids:

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

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

We need your feedback to continuously optimize our products.

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

Thank you for your feedback!

7 Address of manufacturer

Developer and manufacturer:	HASOMED GmbH Paul- Ecke- Str. 1 39114 Magdeburg Germany
Managing Directors:	Dr. Peter Weber, Dipl.-Ing. Frank Schulze
Phone:	+49 (0) 391 62 30 112
Email:	info@hasomed.com
Service address:	HASOMED GmbH Service FES Paul-Ecke-Str. 1 DE-39114 Magdeburg Germany
Service hotline:	+49 (0) 391 61 07 646

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14d Identification of verification and validation activities

The development process used the results and market feed-back from the predecessor device RehaStim / RehaMove. Risk management is an important part of the HASOMED quality management system. On occasion of the development project, a summarizing hazard management report was compiled. It served as a basic document also for the verification and validation activities of the project. The risk analysis includes input from different international and FDA-recognized standards to the topic, including IEC 60601-1 for basic safety, IEC 60601-2-10 for electrostimulation , IEC 60601-1-6 for usability, IEC 62304 for software life cycle, and ISO 14971 for risk management.

During the development process there were several verification steps according to IEC 62304 for software life cycle. They were done by the development team and were approved by the product manager for functional electrostimulation devices as well as by the general manager of HASOMED.

On system level there were specific test procedures defined and fixed in form sheets. Testing on system level is described in section 15 (software documentation) in more detail. The testers were selected from non-development staff of HASOMED to make sure that testing is completely independent from the development coworkers.

Verification and validation activities include also hardware testing according to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6. These activities were done partly in-house and partly with third parties (e.g. EMC testing, usability feed-back from clinics).

Until now, we have also feed-back from the European market to the new device. Also this information is used regularly to get more independent results and information from practice relating clinical usability and risk management.

15 Software documentation

The software was developed under the conditions of the standard for software lifecycle of medical products IEC 62304. The requirements of the standard regarding documentation, reviewing, and approval procedures are realized in the HASOMED standard operating procedure and form "FB Software Lebenszyklus".

The following is in relation to the FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (issued on 2005-05-11)".

Minor and Serious Injuries

For the purposes of this document, we use the term minor injury to mean any injury that does not meet the definition of a serious injury as defined in 21 CFR 803.3(bb)(1). This regulation defines serious injury as an injury or illness that:

i. is life threatening;
ii. results in permanent impairment of a body function or permanent damage to a body structure; or
iii. necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

For the purposes of this document, the term permanent is defined as "irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage." 21 CFR 803.3(bb)(2).

Determination of Level of Concern

The level of concern was determined to be moderate.

Table 1 Major Level of Concern

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.	RehaStim 2 / RehaMove 2
1. Does the Software Device qualify as Blood Establishment Computer Software?	no

(Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)	
2. Is the Software Device intended to be used in combination with a drug or biologic?	no
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?	no
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:	no
a. Does the Software Device control a life supporting or life sustaining function?	no
b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	no
c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?	no
d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?	no
e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	no

Table 2 Moderate Level of Concern

If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.	

1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	yes
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	yes
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	yes

If the answers to all of the questions in Tables 1 and 2 above are No, the Level of Concern is Minor.

These questions resulted in "Moderate state" for level of concern for the device. This fact is caused by the operation procedure of functional electrical stimulation with transporting energy by skin electrodes to human body. We have implemented different and independent safety concerns to minimize risks.

Table 3. Documentation Based on Level of Concern

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN	documentation
Level of Concern	A statement indicating the Level of Concern and a description of the rationale for that level.			See above tables 1 & 2
Software Description	A summary overview of the features and software operating environment.			See section 13c instructions for use / and see below
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations.			See section 14c RMB risk management summary

Software Requirements Specification (SRS)	Summary of functional requirements from SRS.	The complete SRS document.	IEC 62304, see below
Architecture Design Chart	No documentation is necessary in the submission.	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.	IEC 62304, see below
Software Design Specification (SDS)	No documentation is necessary in the submission.	Software design specification document.	IEC 62304, see below
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.		See below

Software Development Environment Description	No documentation is necessary in the submission.	Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities.	Summary of software life cycle development plan. Annotated list of control documents generated during development process. Include the configuration management and maintenance plan documents.	IEC 62304, see below
Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results.	Description of V&V activities at the unit, integration, and system level. System level test protocol, including pass/fail criteria, and tests results.	Description of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.	IEC 62304, see below
Revision Level History	Revision history log, including release version number and date.			IEC 62304, see below

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Unresolved Anomalies (Bugs or Defects)	No documentation is necessary in the submission.	List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.	IEC 62304, see below

Software Description

Programming language

All programs are written in C++ language. For development a Linux based PC is used with GCC compiler and with Qt embedded libraries.

Hardware platform and functional units

The hardware platform remained comparable to the predecessor device.. The hardware consists of 2 different units, the main PCB with ARM920T processor and the two stimulation modules with MSP430F147. They are connected by serial communication. The main board controls all communication processes with peripheral units, calculates and generates the stimulation pattern. The stimulation modules receive these data and generate the stimulation impulses on electrodes on a separate ground level while observing the stimulation conditions. If there are observed any failure in a peripheral unit a message is sending to the main board.

The software for main PCB can be transferred to the RehaStim 2 device by USB-interface from PC.

Operating system

Embedded Linux is used as operating system on RehaStim 2.

Device Hazard Analysis

The main risk management principles are not changed with this device update. The results of the specific risk management activities are given in section 14.

(b)(4) Software Documentation

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16 Hardware documentation

A description of the device is given in section "13c Directions for use", pp. 2-18, and in section 10. The stimulator modules are not changed. The device contains the same stimulator boards as the predecessor device. The hardware-related measures for risk mitigation are equal to the predecessor device as well (as stated in section 14c).

The differences to the predecessor device are in the housing and in the main board. The development was managed according to IEC 60601-1, 3. Ed.. The device was tested according to the test procedure IEC/TR 62354:2005 with the additions according to IEC 60601-2-10.

On the following pages (section 16a test report pp1-10) the main topics are covered.

The results of EMC testing according to IEC 60601-1-2 are given in section 16b.

There is no deterioration of safety or effectiveness by the further development of the device.

Annexes

16a Test report_RehaStim 2_Rev1.5_11-02-23 pp1-10

16b 4082531_emc_hasomed_rehastim2 pp1-2

(b)(4) Testing

(b)(4) Testing

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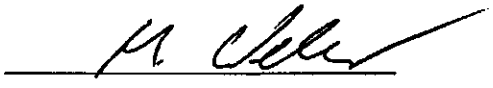
17 Declaration of conformity with design controls

I certify that, as required by the risk analysis, all verification and validation activities were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.



(Matthias Weber / managing engineer of HASOMED GmbH)

(2011-08-01)

I certify, that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

M. Ueltzen

(Dr. Matthias Ueltzen / quality consultant of HASOMED GmbH)

(2011-07-22)

S. Liedecke

(Sabine Liedecke / quality manager of HASOMED GmbH)

(2011-08-01)

18 Information on sterilization, biocomp., exp. date

The further development of the product did not influence the following topics:

- Sterilization
- Biocompatibility
- Expiration date

No additional information is required.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Andrew Yang

Subject: 510(k) Number K112844

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X X	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			X
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			X X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21		X	
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number	**Class***	**Product Code**
882.5810	2	GZI

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ ENTB 10/25/11
(Branch Chief) (Branch Code) (Date)

Final Review: _____ 10/27/11
(Division Director) (Date)

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		YES	NO
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			X
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			X
3. Does this device type require a PMA by regulation? (Please see management.)			X
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)			X
5. a. Did the firm request expedited review? (See management.)□			X
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		X
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		X
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			X

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K112844

(b) (4)

[redacted]

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
   n/a

2. Explain why there is or is not a new effect or safety or effectiveness issue:
   n/a

3. Describe the new technological characteristics:
   Power supply, battery, software

4. Explain how new characteristics could or could not affect safety or effectiveness:
   The fundamental technology is not affected by the changes.

5. Explain how descriptive characteristics are not precise enough:
   n/a

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
   n/a

7. Explain why existing scientific methods can not be used:
   n/a

8. Explain what performance data is needed:
   n/a

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
   The mechanical design and stimulation parameters are identical to the predicate. The device was validated to be as safe and effective as the predicate.

SCREENING CHECKLIST FOR SPECIAL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K112844

Section 1: Required Elements for a SPECIAL 510(k) submission:

	Present or Adequate	Missing or Inadequate
Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	X	
Cover Letter Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/cdrh/ode/guidance/1567.html	X	
Table of Contents	X	
Truthful and Accurate Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_9	X	
Form FDA 3654 - Standards Data Report for 510(k)s – http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf 1: No standard used? = No Standards Form Required 2: Declaration of Conformity? = Yes Standards Form Required 3: Standard but no declaration? = Yes Standards Form Required	3	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	X	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	X	
Proposed Labeling - Device Advice www.fda.gov/cdrh/devadvice/314312.html#link_10	X	
Indications for Use Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_6	X	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	X	
510(k) Summary or 510(k) Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_7	X	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	X	
Identification of legally marketed predicate device. *	X	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	X	
Class III Certification and Summary. **	N/A	

Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html.	N/A	
Kit Certification: Device Advice http://www.fda.gov/cdrh/ode/odecl874.html	N/A	

*- May not be applicable for Special 510(k)s.
**- Required for Class III devices, only.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present or Adequate	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	X	
A description of the modified device and a comparison to the sponsor's predicate device.	X	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	X	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.	X	
A Design Control Activities Summary that includes the following elements (a-c):	X	
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	X	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	X	
c. A Declaration of Conformity with design controls that includes the following statements:	X	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met.? This statement is signed by the individual responsible for those particular activities.	X	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	X	

Items with checks in the Present or Adequate column do not require additional information from the sponsor. Items with checks in the Missing or Inadequate column must be submitted before substantive review of the document.

Passed Screening ___(Yes)___ No - Reviewer: _____

Concurrence by Review Branch: _____ Date: 10/25/11

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving

these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the A Suggested Approach to Resolving Least Burdensome Issues document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification 510(k) Review
Special
K112844

Date: October 25, 2011
To: The Record
From: Andrew Yang

Office: ODE
Division: DONED

510(k) Holder: Hasomed GmbH
Device Name: RehaStim 2; RehaMove 2
Contact: Mr. Matthias Weber
Phone: +493916230112
Fax: +493916230113
Email: Matthias.Weber@hasomed.de

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce RehaStim 2 and RehaMove 2 into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

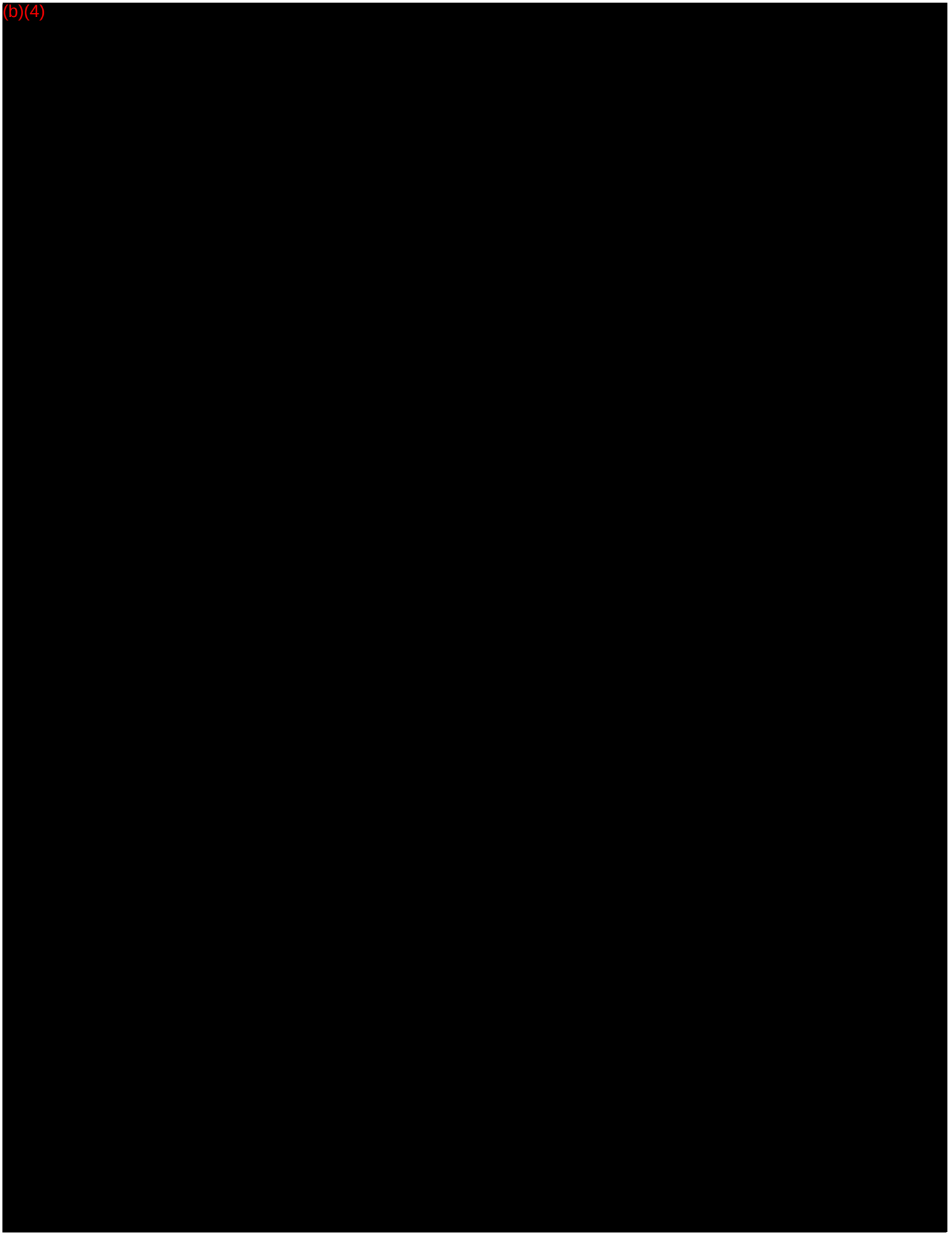
III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?	X	X	

(b) (4)

[redacted]

(b)(4)



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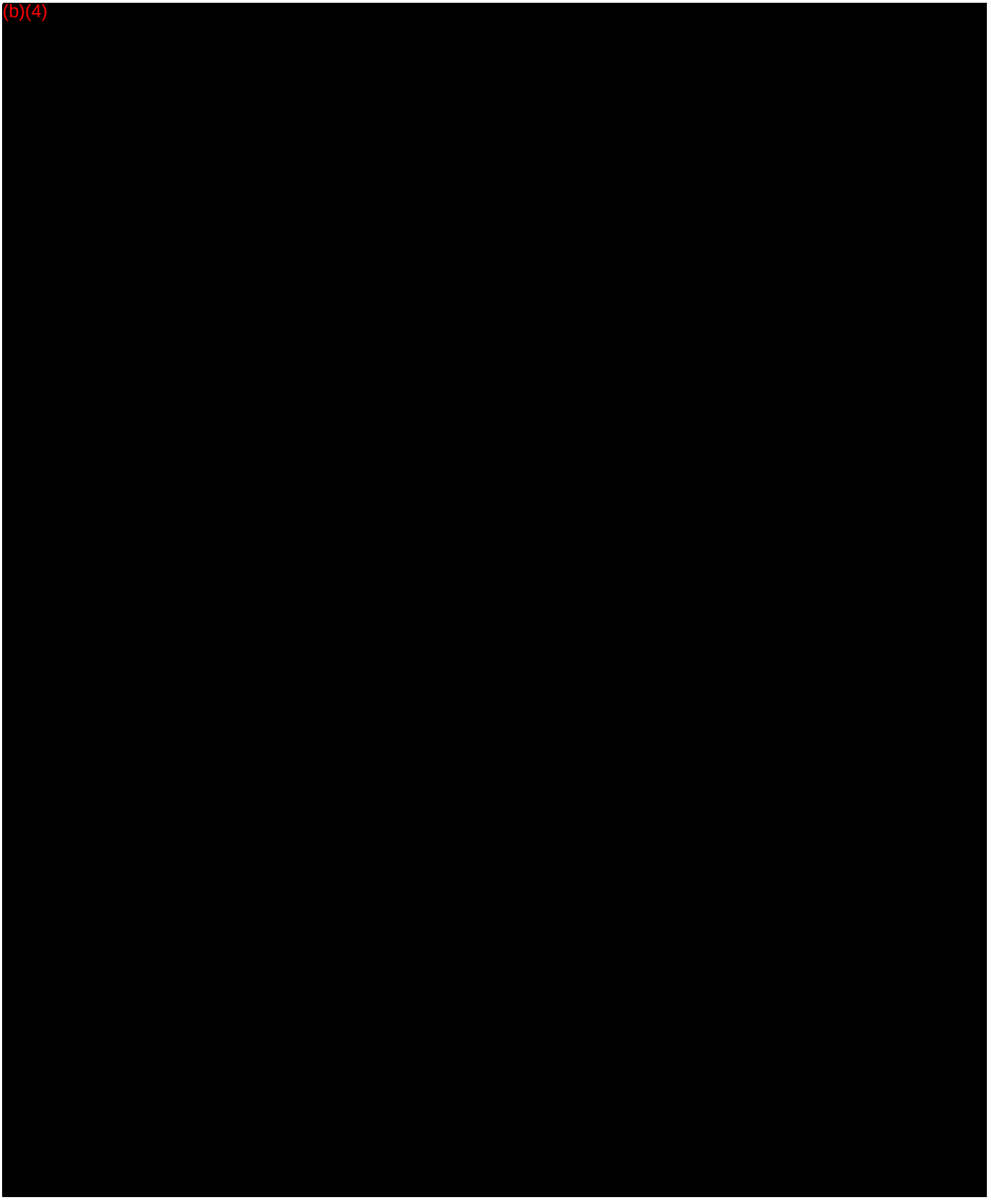

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16

(b)(4)

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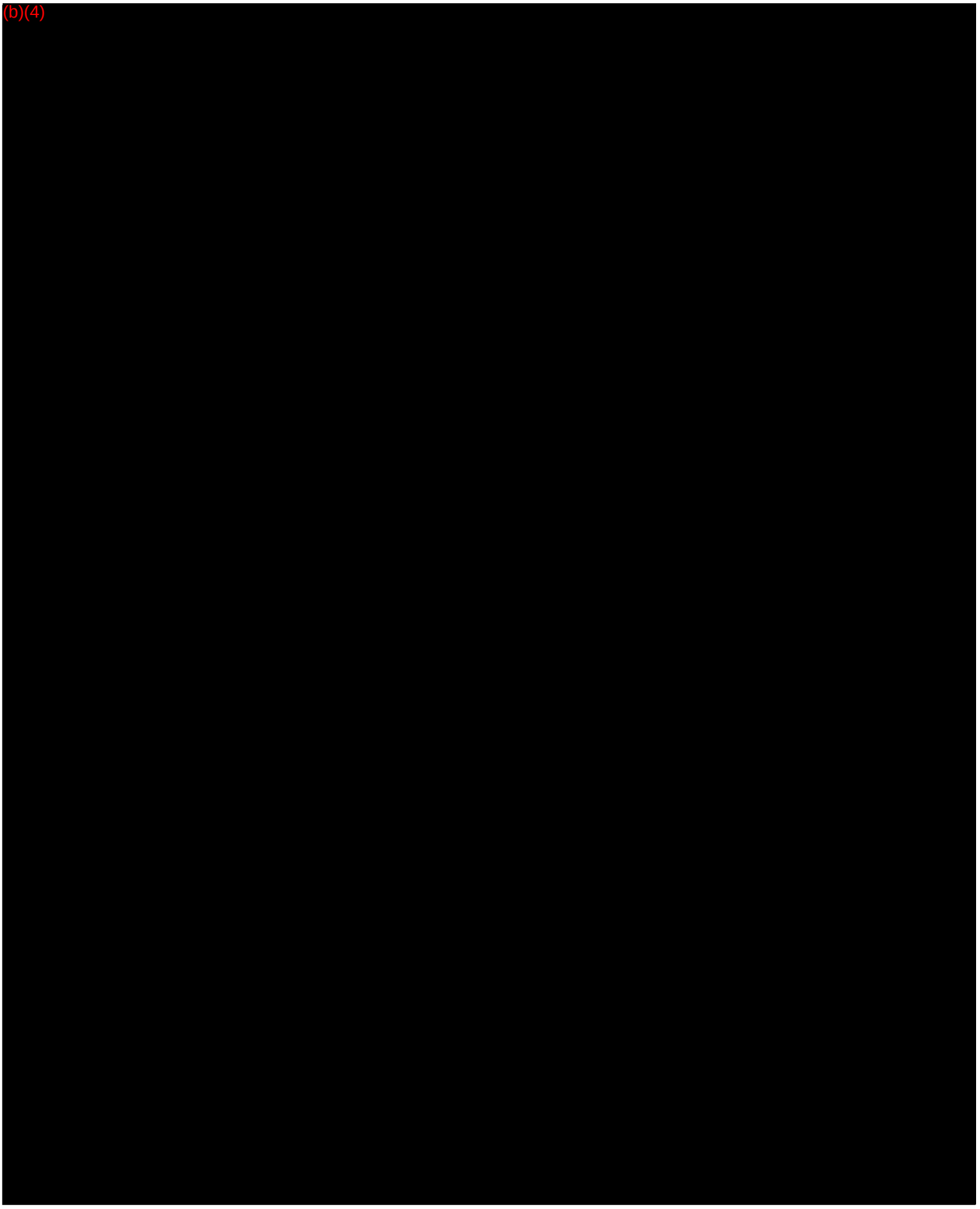

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[redacted]

20

(b)(4)

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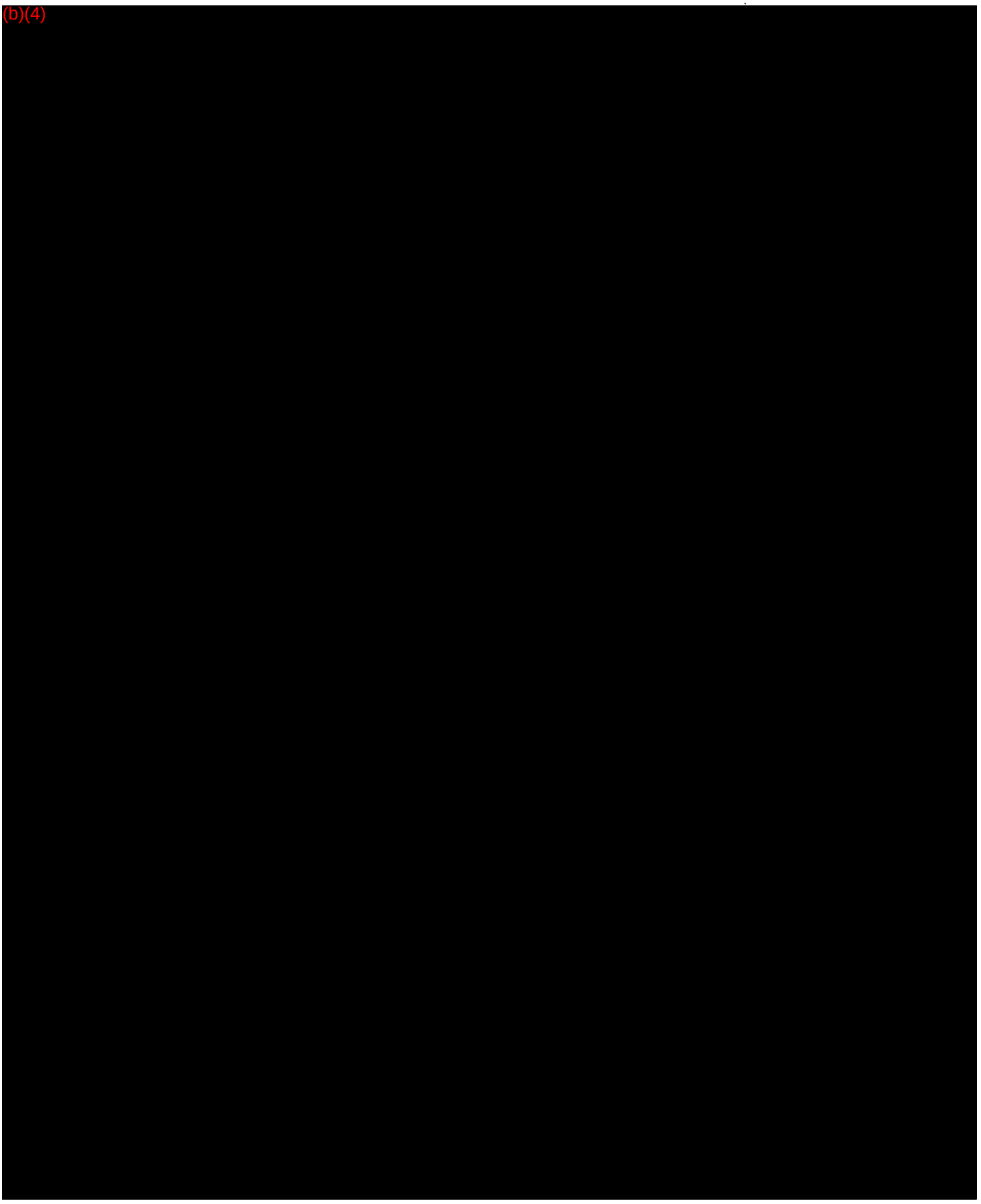
21

(b)(4)



XV. Deficiencies

n/a

XVI. Advisory

n/a

XVII. Recommendation

Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: Class II
Product Code: GZI

SE – Substantially Equivalent

Reviewer — Date 10/25/11

Branch Chief — Date 10/25/11

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(b)(4)

[redacted]

(b)(4)

(b)(4)

05 510(k) summary

21CFR807.92 / special 510(k)

Name of the legally marketed (unmodified) device

Proprietary name:	RehaStim;
	RehaMove (RehaStim with movement exerciser)
510(k):	K073237
Device Class:	class 2 device
Classification:	Neurology

Submitter's / owner's name, address, Telephone number, a contact person, and the date the summary was prepared:

510k Submitter:	Hasomed GmbH
Contact person:	Matthias Weber
Address:	Paul-Ecke-Strasse 1
	39114 Magdeburg
	Germany
Phone:	+493916209190
Fax:	+493916230113

Prepared on September 26 2011

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Name of device, including the trade or proprietary name if applicable, the common or usual name, and the classification name :

Proprietary name: "RehaStim 2" of HASOMED GmbH

"RehaMove 2" (movement exerciser with arm crank, includes RehaStim) of HASOMED GmbH

Common Name: Powered Muscle Stimulator

Classification Name: Powered Muscle Stimulator

Identification of the legally marketed device to which the submitter claims equivalence:

Manufacturer: HASOMED GmbH

Product: "RehaStim" ; "RehaMove" (Version 1)

K-number: K073237

Class: class 2 device

Product Code: GZI

A description of the device that is the subject of the premarket notification submission:

The RehaMove 2 is a portable Functional Electrical Stimulation (FES) system based on a cycle ergometer and a stimulator. It consists of: a motorized movement exerciser (MOTO Med viva II) produced by Reck-company and a stimulator unit (RehaStim 2) produced by Hasomed GmbH. For alternative training of upper extremities a motorized arm crank with same characteristics can be used. The stand-alone mode of RehaStim 2 allows training without movement exerciser.

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The system RehaMove 2 allows training for person with impaired functions of lower and upper extremities in two modes:

active mode - using FES support for muscle contractions and if necessary motor power of movement exerciser

passive mode - only movement by motorized movement exerciser

The FES – stimulation controller RehaStim 2 generates impulses, on up to 8 channels simultaneously, to activate paralyzed muscles via surface electrodes. A connection cable enables the RehaStim to receive angle-parameters and to control the Reck Viva II movement exerciser. Two electrode cables (at maximum 16 cutaneous electrodes for 8 channels) connect the RehaStim 2 with the electrodes on the skin. A USB interface gives the possibility to connect the RehaStim 2 to the PC e.g. connect to patient database.

The RehaStim 2 can be used as a portable (contains a battery) or stationary device for training and rehabilitation applications.

Statement of the intended use of the device:

Both the RehaStim 2 and RehaMove 2 are intended for general rehabilitation for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

Technological Characteristics

The functions of the RehaMove 2 and RehaStim 2 are the same as the predicate device however there are certain technological similarities and differences as described below:

Technology	RehaStim 2 / RehaMove 2	RehaStim/RehaMove
Power Source	AC and/or storage battery: Power supply: cincon tr30m according to EN60601-1 Battery: BMZ18650 V, Li-Ion Mangan cells, 2S1P, C= 1600 mAh,	AC and/or storage battery: Power supply :mascot typ9920 according to EN60601-1 Battery: SANYO, NiMh, C= 2700 mAh
Controller	Uses custom processor, running LinuxOS ,running custom software	Uses custom controller running custom software
Stimulator (energy delivered)	0-130mA charge balanced stimulator with rectangular impulses	0-130mA charge balanced stimulator with rectangular impulses
patient part	Type: BF	Type: BF
movement exerciser	RehaMove 2: Uses motor to create flywheel effect with reduced weight and space	RehaMove: Uses motor to create flywheel effect with reduced weight and space
Arm crank	Arm crank gives same upper extremities training possibilities as with lower extremities Uses motor to create flywheel effect with reduced weight and space	Arm crank gives same upper extremities training possibilities as with lower extremities Uses motor to create flywheel effect with reduced weight and space

Seating	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer
Passive cycling	RehaMove 2: Utilizes motor to provide assistance during passive cycling	RehaMove: Utilizes motor to provide assistance during passive cycling
Database interface	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs

Table 5-1 Technological similarities and differences

Determination of substantial equivalence

Test or procedure	Task
Review of user documentation for predicate device	It was reviewed that equivalent function-nality was implemented in RehaMove 2.
Review of 510(K) submissions for predicate device	Confirm technical specifications for completion of predicate details in comparison tables
Output characteristic measurement of new device	The RehaMove 2 / RehaStim 2 device was tested and technically compared with the predicate device.
Control of system testing	The system testing was aligned to verify performance to specification.

Table 5-2 Performance data

It can be matched that there is a substantial equivalence in all important technical and medical characteristics to the premarket notification.

HASOMED concludes that:

Both the RehaMove 2 and RehaStim 2 have the same intended use and the same output characteristics as the predicate device. The different technological characteristics do not raise new questions of safety and effectiveness.

The safety and effectiveness of using a movement exerciser to simulate the predicate devices motor powered flywheel and provide passive cycling assistance has been extensively demonstrated in particular by the ongoing clinical use of the movement exerciser without the stimulation component both in the European Union and the U.S.A.

The safety and effectiveness of the controller has been demonstrated over the development period of the RehaStim 2 and RehaMove 2 and many clinical applications.

The remote database enhances the safety and effectiveness of the system by ensuring that patients always starts a therapy session with their latest, accurate device settings.

In conclusion, HASOMED's clinical and non- clinical testing have demonstrated that the RehaStim 2 and RehaMove 2 are as safe and effective as the predicate device.

Product code: GZI

Common Name: Powered Muscle Stimulator

04 Indications for Use

510k number if known: K112844

Device Name: RehaMove 2

RehaStim 2 (stand alone)

Indications for Use:

Both the RehaMove 2 and RehaStim 2 are intended for general rehabilitation for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

11 Comparison of the devices

Both devices have identical intended use as well as identical operational principles. The printed circuit boards for the stimulator modules remained unchanged in comparison to the predecessor device.

The functions of the RehaMove 2 and RehaStim 2 are the same as the predicate devices RehaMove and RehaStim, however there are certain technological similarities and differences as described below:

Technology	**RehaStim 2 / RehaMove 2**	**RehaStim / RehaMove**
Power Source	AC and/or storage battery: Power supply: cincon tr30m according to EN60601-1 Battery: BMZ18650 V, Li-Ion Mangan cells, 2S1P, C= 1600 mAh,	AC and/or storage battery: Power supply: mascot typ9920 according to EN60601-1 Battery: SANYO, NiMh, C= 2700 mAh,
Power input (charging)	9V, 3A, max. 30 W	9V, 3A, max. 30W
Operation time	ca. 90 min	ca. 120 min
Charging time	ca. 180 min	ca. 210 min
Controller	uses custom controller using embedded Linux as basis operating system, running custom software	uses custom controller running custom software
Stimulator (energy delivered)	0-130mA charge balanced stimulator with rectangular impulses / same hardware	0-130 mA charge balanced stimulator with rectangular impulses
Pulse width	max. 500 µs	max. 500 µs

Stimulation frequency	max. 50 Hz	max. 50 Hz
Number of channels	8	8
Electrodes	HASOMED's RehaTrodes only	HASOMED's RehaTrodes only
FES00200 RehaTrode	2.0" x 3.5", rectangle	2.0" x 3.5", rectangle
FES00201 RehaTrode	3.0" x 5.0", rectangle	3.0" x 5.0", rectangle
FES00202 RehaTrode	1.5" x 2.5" oval	1.5" x 2.5" oval
Application part	Type BF	Type BF
Movement exerciser	RehaMove: Uses motor to create flywheel effect with reduced weight and space	RehaMove: Uses motor to create flywheel effect with reduced weight and space
Communication interface	FES 2 + FES 3; FES 3- bidirectional communication, controlling of movement exerciser functionality	FES 2 – unidirectional communication, transmission of basic angle parameter
Arm crank	Arm crank gives same upper extremities training possibilities as with lower extremities Uses motor to create flywheel effect with reduced weight and space	Arm crank gives same upper extremities training possibilities as with lower extremities Uses motor to create flywheel effect with reduced weight and space
Seating	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer

Passive cycling	RehaMove: Utilizes motor to provide assistance during passive cycling	RehaMove: Utilizes motor to provide assistance during passive cycling
Database interface	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs

Table 11-1 Technological similarities and differences

Determination of substantial equivalence

Test or procedure	Task
Review of user documentation for predicate device	It was reviewed that equivalent function-nality was implemented in RehaMove 2.
Review of 510(K) submissions for predicate device	Confirm technical specifications for completion of predicate details in comparison tables (see above)
Output characteristic measurement of new device	The RehaMove 2 / RehaStim 2 device was tested and technically compared with the predicate device.
Control of system testing	The system testing was aligned to verify performance to specification.

Table 11-2 Performance data

It can be matched that there is a substantial equivalence in all important technical and medical characteristics to the premarket notification.

HASOMED concludes that:

Both the RehaMove 2 and RehaStim 2 have the same intended use and the same output characteristics as the predicate device. The different technological characteristics do not raise new questions of safety and effectiveness.

The safety and effectiveness of using a movement exerciser to simulate the predicate devices motor powered flywheel and provide passive cycling assistance has been extensively demonstrated in particular by the ongoing clinical use of the movement exerciser without the stimulation component both in the European Union and the U.S.A.

The safety and effectiveness of the controller has been demonstrated over the development period of the RehaStim 2 and RehaMove 2 and many clinical applications in the European market.

The remote database enhances the safety and effectiveness of the system by ensuring that patients always starts a therapy session with their latest, accurate device settings.

In conclusion, HASOMED´s clinical and non-clinical testing has demonstrated that the RehaStim 2 and RehaMove 2 are as safe and effective as the predicate device.

Nichols, Karl *

From: Microsoft Exchange
To: 'matthias.weber@hasomed.de'
Sent: Thursday, September 29, 2011 1:34 PM
Subject: Relayed: K112844- ACK Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'matthias.weber@hasomed.de'

Subject: K112844- ACK Letter

Sent by Microsoft Exchange Server 2007