Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K050036 - 636 pages
COMPANY:	RESTORATIVE THERAPIES INC. (RESTTHER)
PRODUCT:	STIMULATOR, NEUROMUSCULAR, EXTERNAL FUNCTIONAL (GZI)
SUMMARY:	Product: FES CYCLE ERGOMETER, MODEL RT300-S
DATE REQUESTED:	Oct 21, 2015
DATE PRINTED:	Oct 21, 2015
Note:	Printed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

K 050036

JUN 27 2005

RT300-S Summary of Safety and Effectiveness

(1) Submitter's name, address, telephone number, a contact person, and the date the summary was prepared:

Andrew Barriskill
Restorative Therapies Inc
2363 Boston St
Baltimore, MD 21224

Phone: 310 691-5467

Prepared on June 24th 2005.

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

Proprietary name: RT300-S, RT300-SP (FES cycle ergometer)
Common name: Powered Muscle Stimulator
Classification name: Powered Muscle Stimulator

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

THERAPEUTIC ALLIANCES, INC. product: "ERGYS", K841112, a class 2 device

(4) A description of the device that is the subject of the premarket notification submission.

The RT300-S is a Functional Electrical Stimulation (FES) cycle ergometer which is composed of:

1. a motorized cycle ergometer (RTI part number SA100047 for adults and SA100044 for children)
2. an FES controller / stimulator (RTI part number SA100090)
3. a stimulation cable which connects the controller / stimulator to cutaneous electrodes (RTI part number SA100091)
4. cutaneous electrodes (12 electrodes for 6 stimulation channels, RTI part number FA100015)

This system allows a person with impaired lower extremity movement to undertake cycle ergometry both actively (utilizing FES evoked lower extremity muscle contractions) and passively (utilizing power developed by the ergometer's motor).

(5) Statement of the intended use of the device:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The RT300-S (adult version) and RT300-SP (pediatric version) 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

The RT300-SP (pediatric version), is intended for population ages 4 to 12 years.

(6) Technological Characteristics
The function of the RT300-S is the same as the predicate device however there are certain technological similarities and differences as described below:

Technology	RT300-S	Predicate
Power source (energy used)	Mains power	Mains power
Controller	Based on Pocket PC running custom software.	Uses custom controller running custom software.
Stimulator (energy delivered)	0-140mA charge balanced stimulator	0-140mA charge balanced stimulator
Flywheel	Uses motor to create flywheel effect with reduced weight and space.	Uses heavy mechanical flywheel.
Seating	Allows user to remain in their own seating, e.g wheelchair eliminating the need for transfer.	Includes a dedicated seating arrangement.
Passive cycling	Utilizes motor to provide assistance during passive cycling.	Requires manual assistance to provide power during passive cycling.

(b) Performance data

Non clinical testing to determine equivalence has been primarily composed of the following tests:

Test or procedure	Description
Review of user documentation for predicate device	Ensure that equivalent functionality is specified and implemented in the new device.
Review of 510(k) submission for	Confirm technical specifications for

predicate device	completion of predicate details in comparison tables
Output characteristic measurement of new device	Confirm technical specifications for completion of new device details in comparison tables
Conduct of system testing	Conduct system testing to verify performance to specification.

Clinical Test	Description
Testing with able bodied subjects	The RT300-S was tested on able bodied subjects to confirm correct operation of the system including correct detection of electrode off conditions with varying skin impedances.
Testing with spinal cord injured subjects	The RT300-S is being utilized in clinical studies involving spinal cord injured subjects.

RTI concludes that:

The RT300-S has the same intended use as the predicate device.

The RT300-S has 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 motor to simulate the predicate device's mechanical flywheel and provide passive cycling assistance has been extensively demonstrated in particular by the ongoing clinical use of the motorized ergometer without the stimulation component both in the European Union and in the U.S.A. The safety and effectiveness of the controller has been demonstrated over the development period of the RT300-S.

In conclusion, RTI's clinical and non clinical testing has demonstrated that the RT300-S is as safe and effective as the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2005

Mr. Andrew Barriskill
Restorative Therapies Incorporated
2263 Boston Street
Baltimore, Maryland 21224

Re: K050036
Trade/Device Name: RT300-S and RT300-SP
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: II
Product Code: GZI
Dated: April 26, 2005
Received: April 26, 2005

Dear Ms. Barriskill:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

Indications for Use

510(k) Number (if known): K050036

Device Name: RT300-S and RT300-SP

Indications For Use:

The RT300-S (adult version) and RT300-SP (pediatric version) are intended for general rehabilitation for:

a. Relaxation of muscle spasms
b. Prevention or retardation of disuse atrophy
c. Increasing local blood circulation
d. Maintaining or increasing range of motion

The RT300-SP (pediatric version), is intended for population ages 4 to 12 years.

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

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K050036

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2005

Mr. Andrew Barriskill
Restorative Therapies Incorporated
2263 Boston Street
Baltimore, Maryland 21224

Re: K050036
Trade/Device Name: RT300-S and RT300-SP
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: II
Product Code: GZI
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Sincerely yours,

Miriam C. Provost

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Acting Director
Division of General, Restorative
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510(k) Number (if known): K050036

Device Name: RT300-S and RT300-SP

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K050036

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DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
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5200 Corporate Boulevard
Rockville MD 20850

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2005

Mr. Andrew Barriskill
Restorative Therapies Incorporated
2263 Boston Street
Baltimore, Maryland 21224

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Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: II
Product Code: GZI
Dated: April 26, 2005
Received: April 26, 2005

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Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
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Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K050036

Device Name: RT300-S and RT300-SP

Indications For Use:

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a. Relaxation of muscle spasms
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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K050036

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-3118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 28, 2005

RESTORATIVE THERAPIES INC.
2363 BOSTON ST.
BALTIMORE, MD 21224
ATTN: ANDREW BARRISKILL

510(k) Number: K050036
Product: FES CYCLE ERGOMETER, MODEL RT300-S

Extended Until: 16-MAY-2005

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

March 25th 2005

RTI

Restorative Therapies Inc
2363 Boston St
Baltimore, MD 21224

Phone: (310) 691-5467
Fax: (410) 534-6263

www.restorative-therapies.com

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Pre-market Notification K050036

Thank you for your letter of March 15th advising your questions in relation to our pre-market notification for the RT300-S.

I would like to request an extension of time to respond to your questions. We believe that we will be able to fully respond by May 15th 2005.

Thank you for considering this request.

Kind Regards,

Andrew Barriskill
CEO

5049

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 15, 2005

RESTORATIVE THERAPIES INC.
2363 BOSTON ST.
BALTIMORE, MD 21224
ATTN: ANDREW BARRISKILL

510(k) Number: K050036
Product: FES CYCLE ERGOMETER, MODEL RT300-S

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified 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

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 #36

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 07, 2005

RESTORATIVE THERAPIES INC.
2363 BOSTON ST.
BALTIMORE, MD 21224
ATTN: ANDREW BARRISKILL

510(k) Number: K050036
Received: 07-JAN-2005
Product: FES CYCLE ERGOMETER, MODEL RT300-S

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Company Confidential K050036

January 6th 2005

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Restorative Therapies Inc
2363 Boston St
Baltimore, MD 21224

Phone: (310) 691-5467
Fax: (410) 534-6263

Abbreviated 510(k) submission

Please find attached our abbreviated 510(k) submission in relation to our RT300-S Functional Electrical Stimulation cycle ergometer.

This submission was prepared in accordance with FDA's **Guidance Document for Powered Muscle Stimulator 510(k)s** issued on June 9, 1999.

The required **cover sheet information** commences on page 5 of the submission.

Kind Regards,

Andrew Barriskill
CEO

Attached:
1. Medical device user fee cover sheet
2. 510(k) submission

FDA/CDRH/OCE/PMD
2005 JAN -7 A 9:03

SK 1
PM
II

RTI	Draft UR	Approved:	AB	Title:	RT300-S 510(k) Application				RV100243	PM100041
		Date:	12-22-04	Page:	1	of	61	Project: RT300	Version:	1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved:OMB No. 0910-0511 Expiration Date: August 31, 2006. 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. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

RESTORATIVE THERAPIES, INC
2363 BOSTON ST
BALTIMORE, MD 21224

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
201210361

2. CONTACT NAME
ANDREW BARRISKILL

2.1 E-MAIL ADDRESS
abarriskill@restorative-therapies.com

2.2 TELEPHONE NUMBER (Include Area Code)
310-691-5467

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
410-534-6263

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:
- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ Biologics License Application (BLA)
- ☐ Premarket Approval Application (PMA)
- ☐ Modular PMA
- ☐ Product Development Protocol (PDP)
- ☐ Premarket Report (PMR)

3.1 Select one of the types below:
- ☑ Original Application

Supplement Types:
- ☐ Efficacy (BLA)
- ☐ Panel Track (PMA, PMR, PDP)
- ☐ Real-Time (PMA, PMR, PDP)
- ☐ 180-day (PMA, PMR, PDP)

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

- ☐ 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:

5. 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, parents, and partner firms
- ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- ☐ The sole purpose of the application is to support conditions of use for a pediatric population
- ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. 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 ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)

(b)(4) [redacted]

Form FDA 3601 (08/2003)

453 30

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RT300-S Abbreviated 510(k) Application

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Administrative and General Information

Device Manufacturer and 510(k) Sponsor
Restorative Therapies Inc
2363 Boston St
Baltimore, MD 21224

Phone: 310 691-5467
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Contact Person
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Email: abarriskill@restorative-therapies.com
Cell: 410 241-0452

FDA Establishment Registration Number
3004733458

Proprietary Name of Device
RT300-S

Generic Name of Device
Powered Muscle Stimulator

Panel and Product Codes
89 IPF

Proposed Regulatory Class
Class 2

Predicate Devices
K841112
THERAPEUTIC ALLIANCES, INC. product: "ERGYS", a class 2 device

FDA History

a. The RT300-S has **not been** previously submitted to the FDA for identical or different indications

b. The RT300-S **is not** currently being reviewed for different indications by the same or different branch within ODE

c. The RT300-S **has not** been previously cleared by the FDA for different indications

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Performance Standards
Performance standard for electrode lead wires and patient cables: please see "Lead Wires" on page 28.

510(k) Summary
Please see exhibit A.

Financial Certification
Clinical studies have not been sponsored by RTI.

Truthful and Accurate
RTI believes, to the best of its knowledge, all data and information submitted in the pre-market notification are truthful and accurate and that no material fact has been omitted.

Indications for Use
Please see exhibit B.

Descriptive Information

Intended Use and Indications for Use
The RT300-S is intended for people with impaired movement or muscle paralysis arising from Spinal Cord Injury, muscular dystrophies, motor neuron diseases, stroke, multiple sclerosis and cerebral palsy.

The indications for use are:
1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

Labeling

1. Product Data Plate
See exhibit C

2. Promotional Brochure
See exhibit D

3. User Guide
See exhibit E

4. Package Labels
See exhibit F

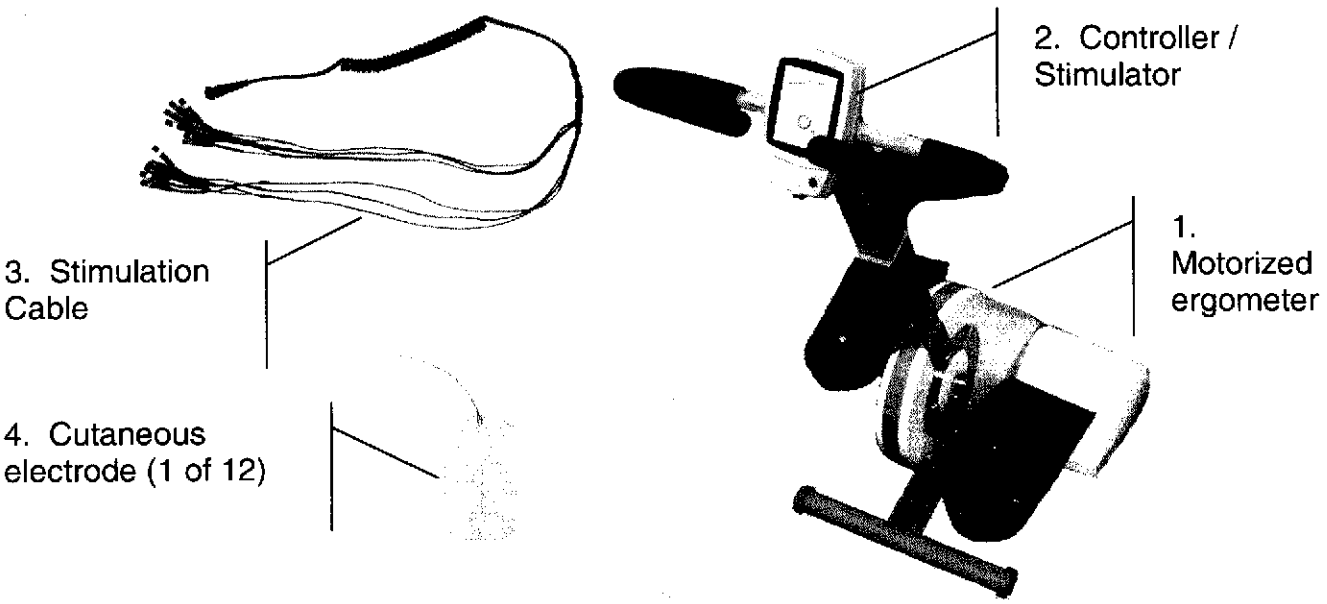
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Device Description

Description of device
The RT300-S is a Functional Electrical Stimulation (FES) cycle ergometer which is composed of:

1 a motorized cycle ergometer (RTI part number SA100047 for adults and SA100044 for children)
2 an FES controller / stimulator (RTI part number SA100090)
3 a stimulation cable which connects the controller / stimulator to cutaneous electrodes (RTI part number SA100091)
4 cutaneous electrodes (12 electrodes for 6 stimulation channels, RTI part number FA100015)

Note: The motorized ergometer is currently marketed with a different controller which does not provide any electrical stimulation, as the RT100 (Class 1, 89BXB, listed device E193605).



RT300-S

The RT300-S will also be produced in a pediatric version, the RT300-SP. This version will include:

1. pediatric pedal set
2. height adjustment platform

See "Section 4 - Description of Accessories", on page 23 for details on these pediatric options.

Dimensions and weight

Length 54cm 21.3"
Width 46cm 18.1"
Height 46cm 18.1" (without safety handle)
Weight 40 kg (90 lbs)

User controls, displays and functions
All user controls are incorporated into a touch sensitive display shown in Figure 1 below.

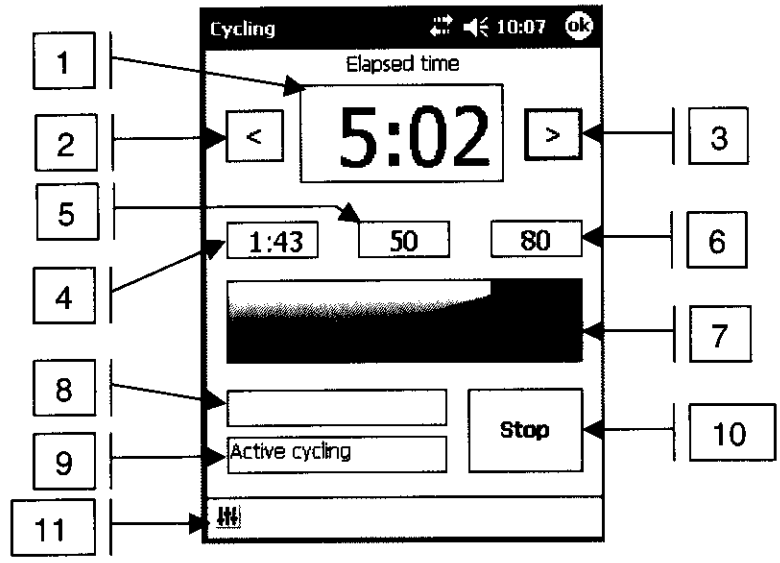


Figure 1 User display and controls

1. Main display window shows one of
   a. Elapsed time
   b. Remaining time
   c. Cycling velocity
   d. Stimulation level

2. Cycles the main display data left

3. Cycles the main display data right

4. Secondary display window (shows time remaining in Figure 1)

5. Secondary display window (shows cycle velocity in Figure 1)

6. Secondary display window (shows stimulation level in Figure 1)

7. Graphical display of data
    a. Green is stimulation level history
    b. Blue is time remaining

8. User advisory in the format <Therapy State> in 5,4,3,2,1 seconds

9 Therapy State:
    a. Ready
    b. Warm up (initial passive cycling)
    c. Active cycling (stimulation operating)
    d. Passive cycling
    e. Cool down
    f. Finished

10. Start and Stop button shows "Start" when the system is stopped and "Stop" when the system is operating.

11. Menu button
This provides clinician only (password protected) to the following two displays.

a. Therapy display

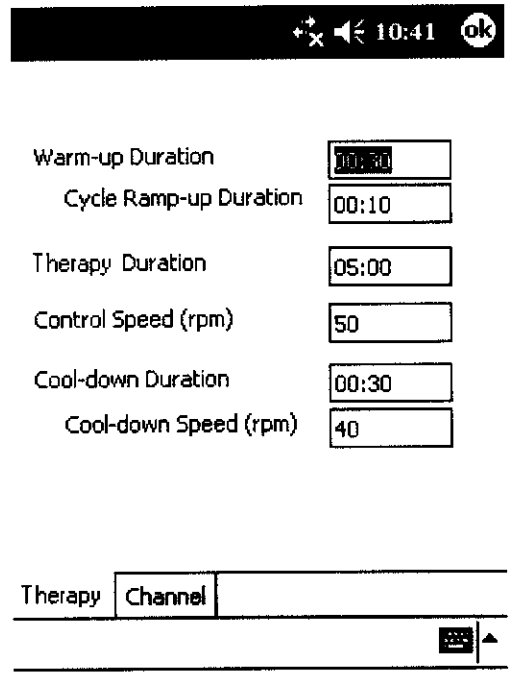


Figure 2 Clinician's therapy menu

i. Warm-up Duration
Time of passive cycling before active cycling starts
ii. Cycle Ramp-up Duration

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Duration of time during which the ergometer's motor ramps down and stimulation ramps up.

iii. Control Speed (rpm)
The target speed of active cycling. The system works to maintain this speed by controlling the level of stimulation applied.

iv. Cool-down Duration
The duration of passive cycling following completion of the active cycling phase.

v. Cool-down Speed (rpm)
The target speed of the cool down cycling. The system maintains this by utilizing ergometer motor assist.

(b)(4)

[redacted]

Device Interconnections

The device does not interconnect with any other devices or systems.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Engineering drawings
See exhibit G.

Comparison table
See comparison tables in sections "Section 2 - Basic Unit Characteristics" and "Section 3 - Output Specifications".

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Technological Characteristics

Section 1 - Output waveforms

Each output waveform was measured with a differential probe (GE 8100, Elditest, France) and a digital storage oscilloscope (GDS-820C, Instek, USA) in the configuration shown in Figure 4.

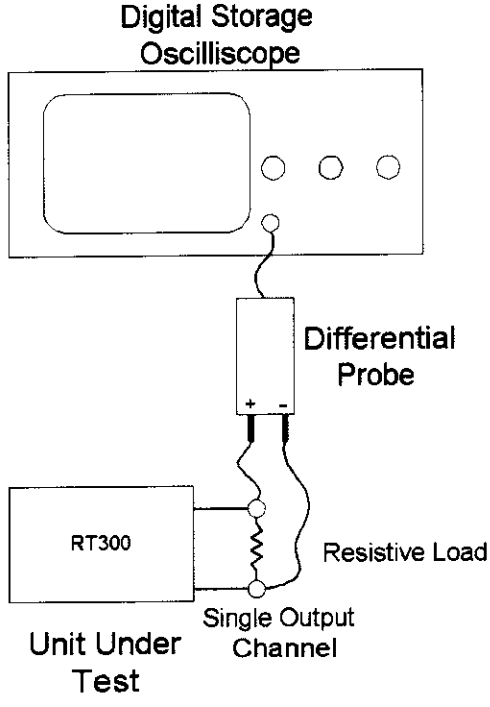
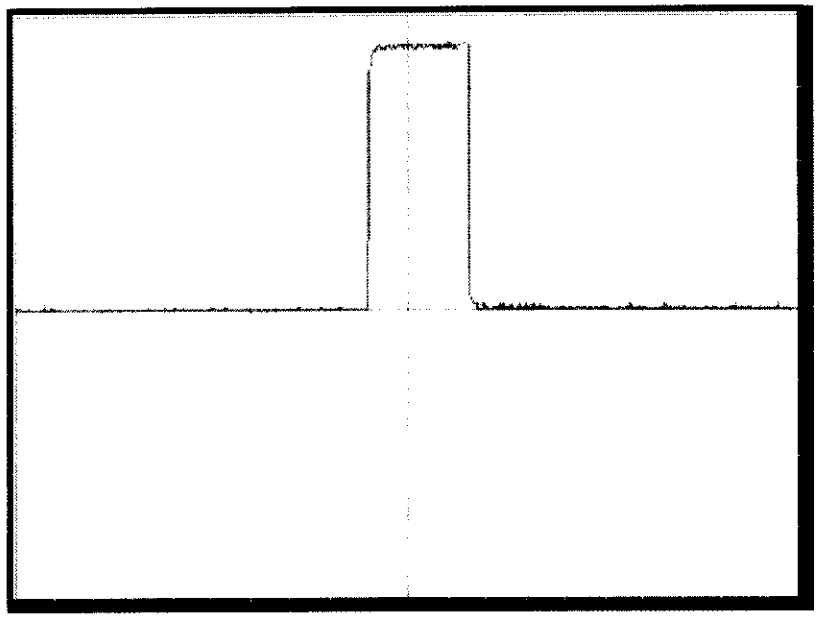


Figure 4 Test setup for trace measurements

The differential probe attenuates the measured signal by a factor of 20, therefore each trace must be multiplied 20 times to get its actual output voltage reading.

Output Mode – Alternating Monophasic (see Section 3 - Output Specifications for description)



Positive Pulse
Current = 140mA
Pulse Width = 250µs
Frequency = 33Hz
Load = 1000Ω

Vertical Scale = 2V/div
Horizontal Scale = 100µs/div

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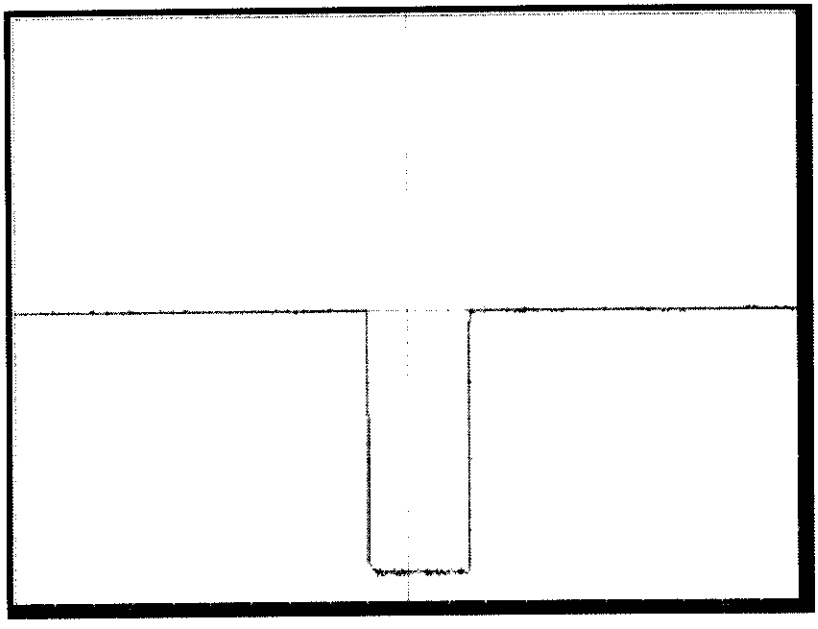
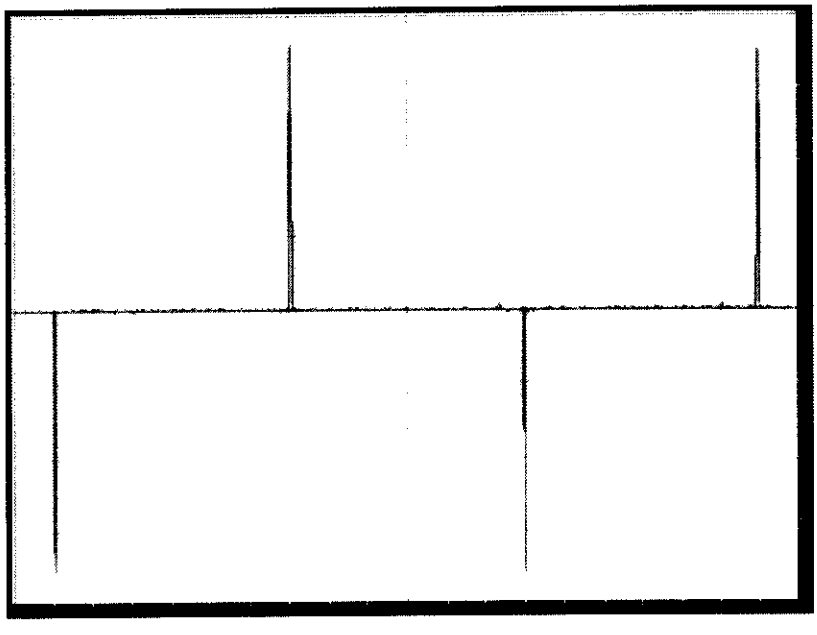


Negative Pulse
Current = 140mA
Pulse Width = 250µs
Frequency = 33Hz
Load = 1000Ω

Vertical Scale = 2V/div
Horizontal Scale = 100µs/div



Pulse Train
Current = 140mA
Pulse Width = 250µs
Frequency = 33Hz
Load = 1000Ω

Vertical Scale = 2V/div
Horizontal Scale = 5ms/div

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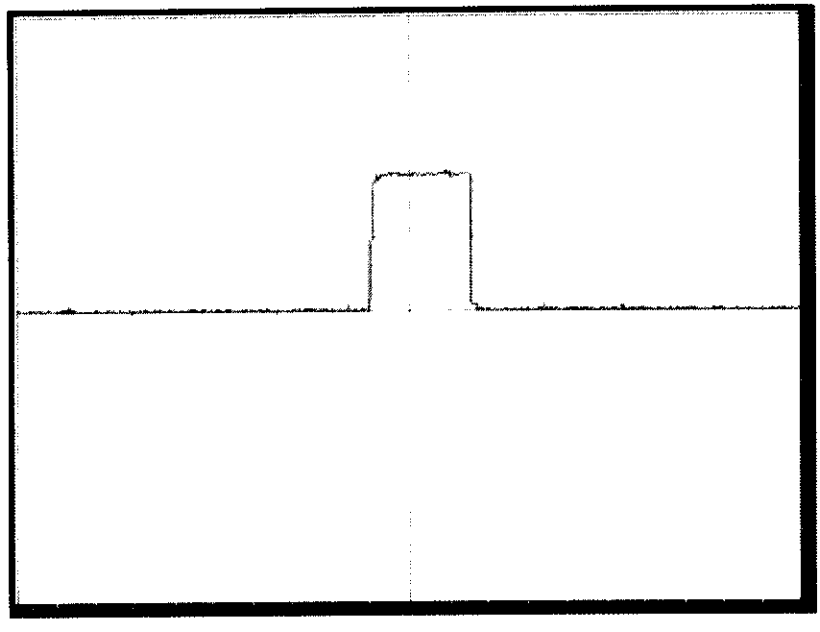
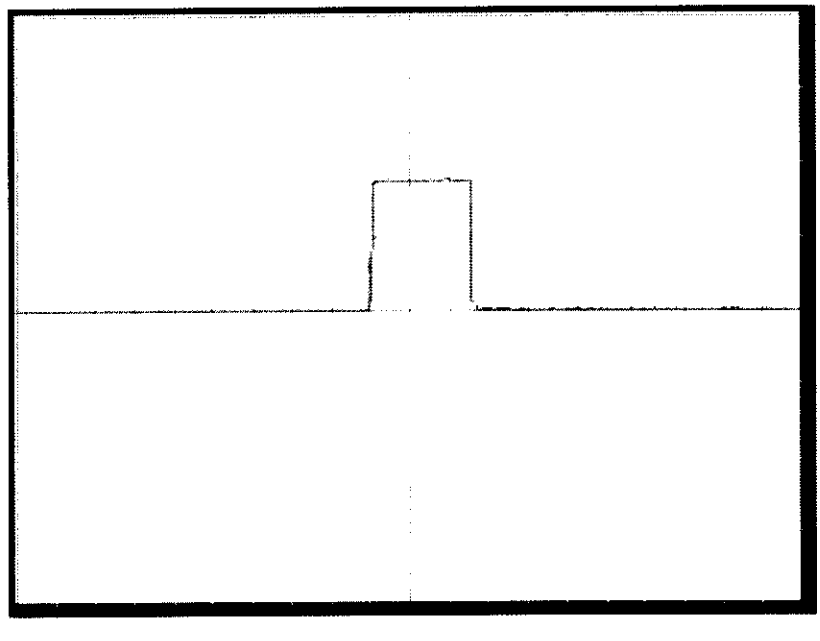


Positive Pulse
Current = 140mA
Pulse Width = 250µs
Frequency = 33Hz
Load = 500Ω

Vertical Scale = 2V/div
Horizontal Scale = 100µs/div



Positive Pulse
Current = 140mA
Pulse Width = 250µs
Frequency = 33Hz
Load = 2000Ω

Vertical Scale = 2V/div
Horizontal Scale = 100µs/div

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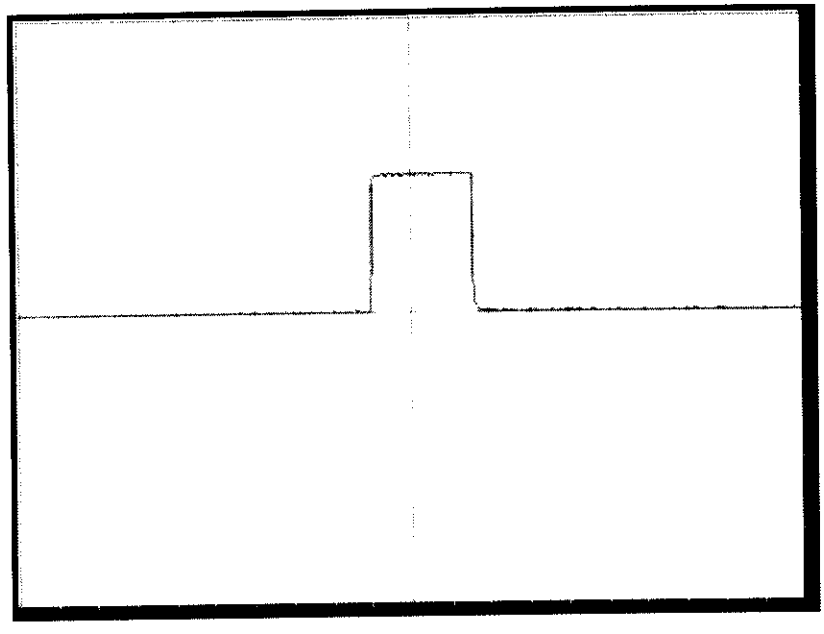
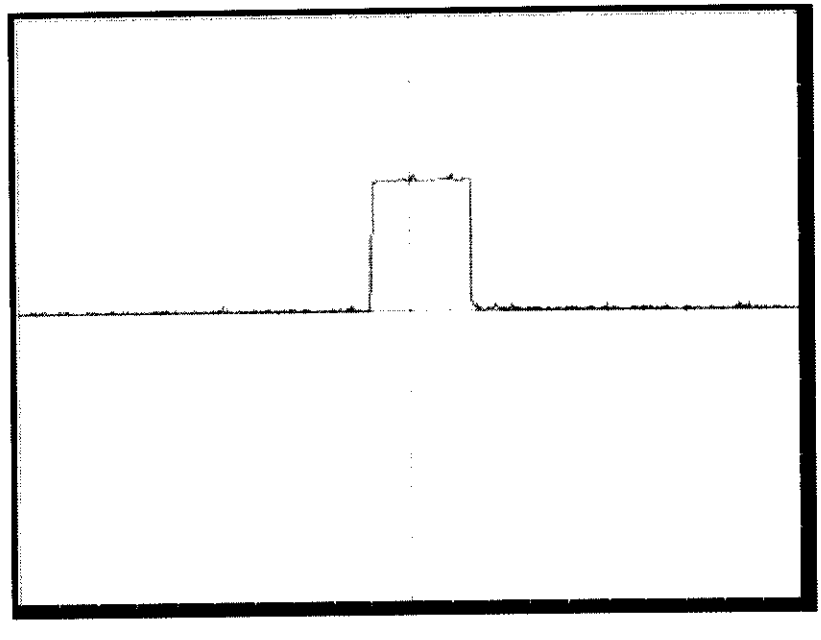


Positive Pulse
Current = 140mA
Pulse Width = 250µs
Frequency = 33Hz
Load = 10000Ω

Vertical Scale = 2V/div
Horizontal Scale = 100µs/div



Positive Pulse
Current = 70mA
Pulse Width = 250µs
Frequency = 33Hz
Load = 500Ω

Vertical Scale = 2V/div
Horizontal Scale = 100µs/div

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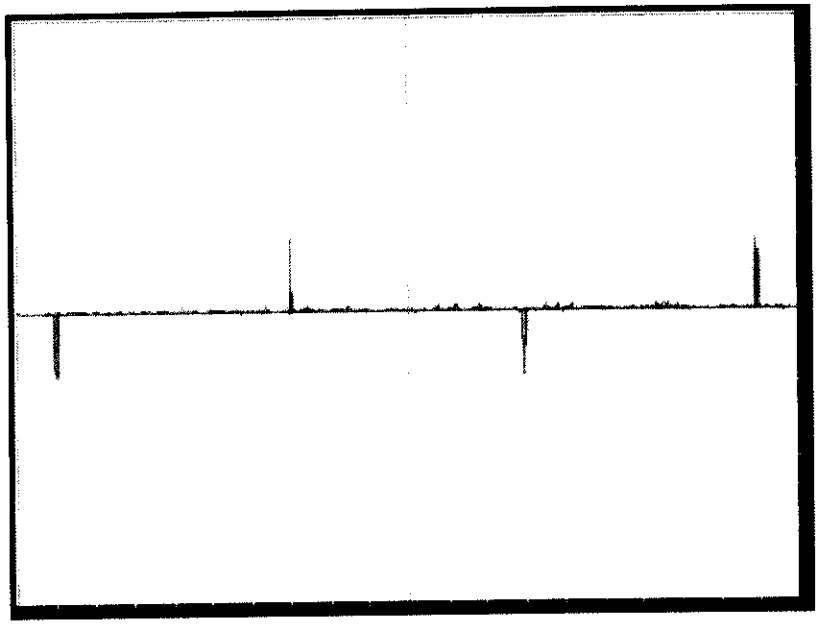
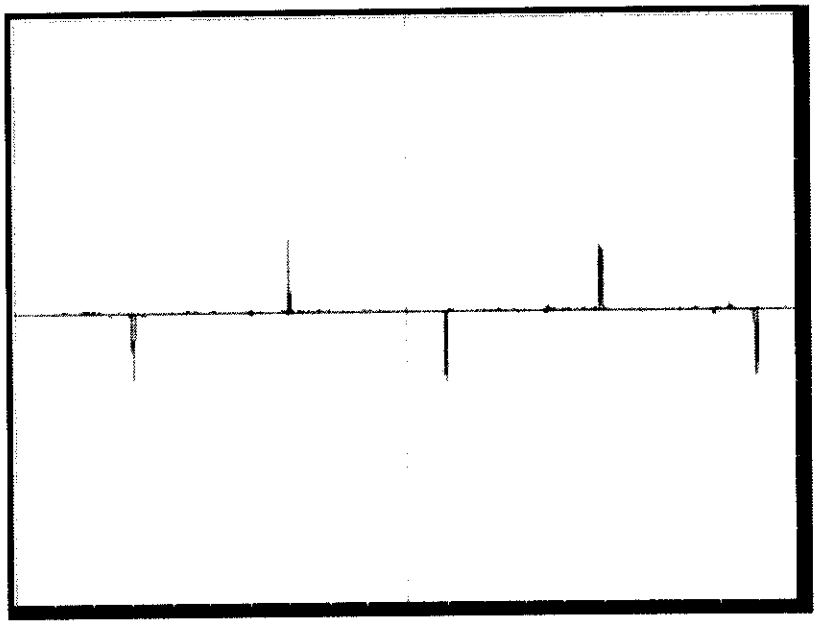


Pulse Train
Current = 70mA
Pulse Width = 250µs
Frequency = 33Hz
Load = 500Ω

Vertical Scale = 2V/div
Horizontal Scale = 5ms/div



Pulse Train
Current = 70mA
Pulse Width = 250µs
Frequency = 50Hz
Load = 500Ω

Vertical Scale = 2V/div
Horizontal Scale = 5ms/div

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 2 - Basic Unit Characteristics

Please also see notes following the table.

	Feature	RT300-S	Ergys predicate device
1	510(k)	To be assigned	TTI REHABILITATION GYM SYSTEM, REGYS, ERGYS I, SPECTRA STIM K841112
2	Device name & model	RT300-S	ERGYS
3	Manufacturer	Restorative Therapies, Inc	Therapeutic Alliances Inc
4	Power sources	110-120 V.A.C., 60Hz	110-120 V.A.C., 60Hz
	Method of line current isolation	See below, Method of line current isolation	Unknown
	Patient leakage current		
	Normal	0.6μA	<100μA
	Single fault	0.17μA (neutral open) 0.15μA (gnd open)	Unknown
5	Number of output modes	1	1
6	Number of output channels	6	6
	Synchronous or Alternating	Alternating	Alternating
	Method of isolation	See below, Method of Isolation	Unknown
7	Regulated current or voltage	Constant current	Constant current
8	Software/Firmware	Yes	Yes
9	Auto overload trip	Yes	Unknown
10	Auto no-load trip	Yes	Unknown
11	Auto shut off	Yes	Unknown
12	Patient override control	Yes	Yes
13	Indicator display	Yes	Yes
	On / off status	Yes	Yes
	Low battery	NA – no batteries	NA – no batteries
	Voltage / current level	Yes	Yes
14	Timer range	1 – 60 minutes	1 – 30 minutes
15	Compliance with voluntary standards	IEC 60601-1, sub-clause 57.10	Unknown
16	Compliance with 21CFR898	See page 28, Lead Wires	Unknown
17	Weight	40kg	107kg
18	Dimensions	54cm x 46cm x 46cm	269cm x 91cm x 122cm
19	Housing material and construction	Stimulator/Controller: Injection Molded Plastic Cycle Ergometer: Molded and extruded plastic, steel	Unknown

Table 1 Basic Unit Characteristics

Power source(s)

Method of Line Current Isolation

Electrical isolation of the RT300-S is shown in Figure 5. The connection from the mains is directly into the ergometer, which has CB certification (Report Number: 052-080353-000) that conforms to IEC60601-1/A2:1995 (see Exhibit P Ergometer Component CB Certificate). The secondary source is isolated from the patient circuit with an isolation transformer and optical isolation which meets the double insulation requirements of IEC60601-1, sub-clause 57.10, Table XVI for DC voltages of <=300V of 5mm of air clearance and 8mm of creepage distance.

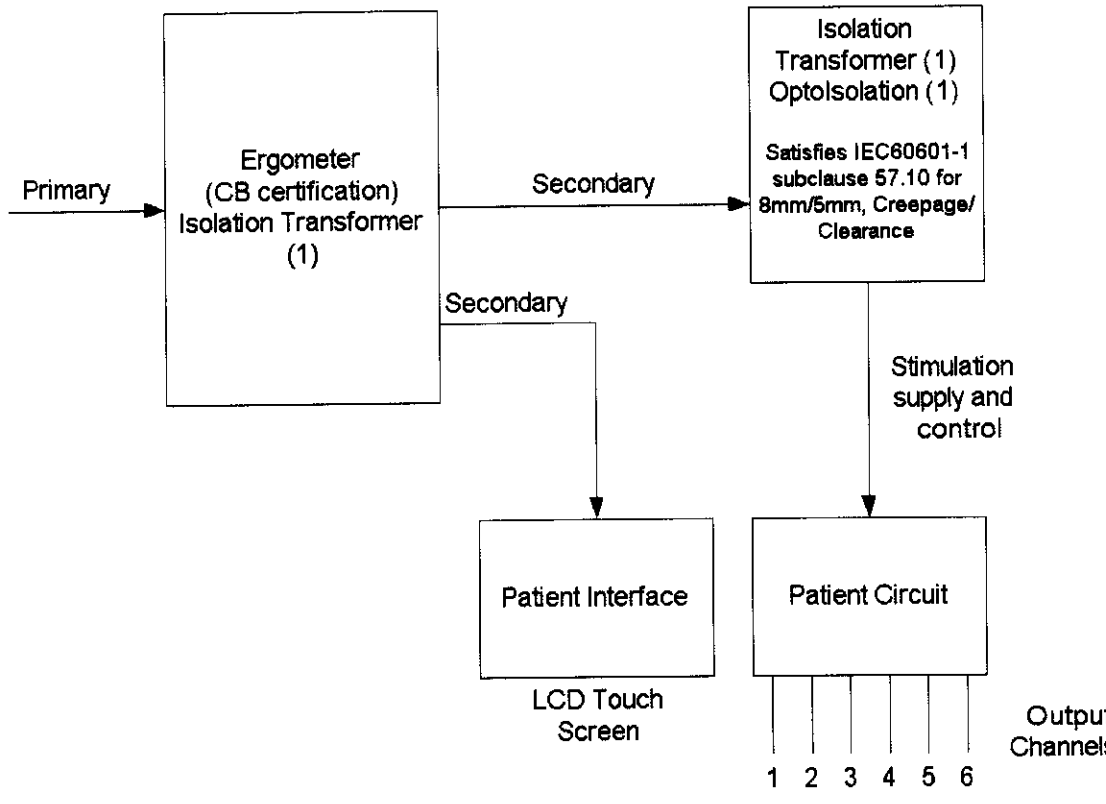


Figure 5. Isolation scheme for the RT300

Number of output channels

- **Synchronous or alternating**

The channel outputs are stimulated in an alternating fashion. Starting with the channel 1 each output is phase shifted by the stimulating period (ms) / # of stimulating channels, as shown in Figure 6. For example, if 6 channels are "simultaneously" stimulating at a period of 30ms after the first channel delivers a stimulation pulse the second channel will stimulate 5ms (30ms/6) later, and so on.

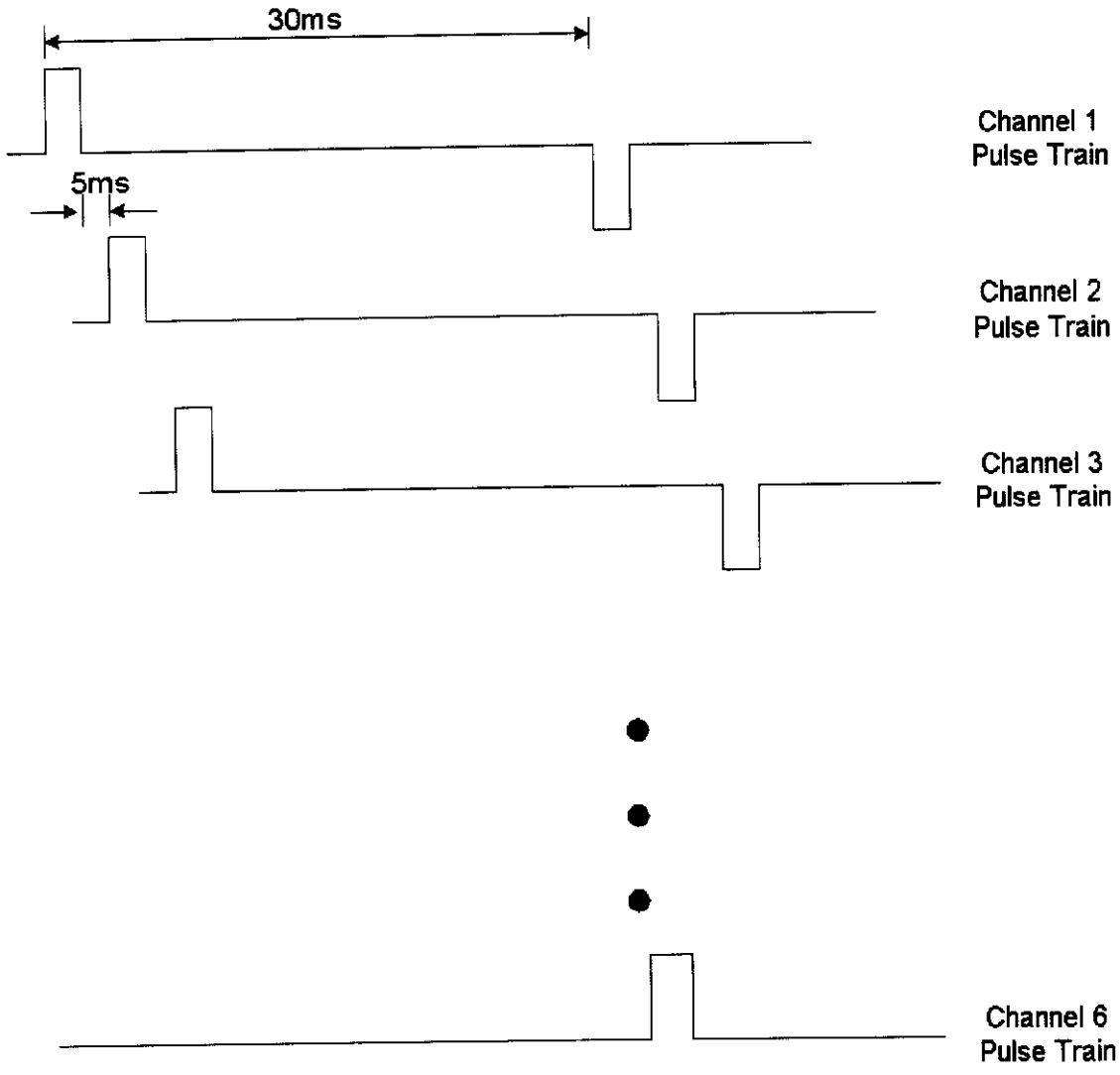


Figure 6. Display of alternating output of all 6 channels "simultaneously" simulating

Method of Isolation

The output channels are multiplexed through two 8-channel high-voltage analog switch integrated circuits (HV20720PJ, Supertex) with channel isolation characteristics outlined in Table 2.

Characteristic	Sym	Min	Typ	Max	Units	Description
Switch OFF leakage per switch	I_{SOL}		1.0	10	µA	
OFF isolation	KO	-45	-58		dB	
Switch crosstalk	K_{CR}	-60			dB	KO = K_{CR} = 20 log (Vout/Vin)

Table 2. Description of channel isolation characteristics for HV20720PJ

Section 3 - Output Specifications

	Feature	RT300	Ergys predicate device
1	Waveform	Alternating Monophasic (see comments below)	Monophasic
2	Shape	Rectangular	Rectangular
3	Maximum output voltage	200V@ 500Ω	Unknown @ 500Ω
		200V@ 2kΩ	Unknown @ 2kΩ
		200V@ 10kΩ	Unknown @ 10kΩ
4	Maximum output current	140mA@ 500Ω	140mA @ 500Ω
		100mA@ 2kΩ but auto switch off due to electrode off detection will occur	Unknown @ 2kΩ
		20mA@ 10kΩ but auto switch off due to electrode off detection will occur	Unknown @ 10kΩ
5	Pulse width	Adjustable, 100 - 250μs	Adjustable, 100 - 600μs
6	Frequency (Hz)	Adjustable, 7 – 60Hz	Adjustable, 7 – 60Hz
7	For interferential only: Beat frequency (Hz)	NA	NA
8	For multiphase only: Symmetrical phases	Yes	Yes
	Phase duration	Adjustable, 100 - 250μs	Adjustable 200-500μs
9	Net charge	0@ 500Ω	Unknown @ 500Ω
10	Max. phase charge	35uC@ 500Ω	70uC@ 500Ω
11	Max. current density	3.1mA.cm^{-2}@ 500Ω	Unknown @ 500Ω
12	Max. power density	0.01W. cm^{-2}@ 500Ω	Unknown @ 500Ω
13	Burst mode		
	a. pulses per burst	NA	Unknown
	b. bursts / sec	NA	Unknown
	c. burst duration	NA	Unknown
	d. duty cycle	NA	Unknown
14	ON time (seconds)	Adjustable, 0.250 – 2.2s. See comments below.	Adjustable, 6 – 12s (time allowed for one complete lift) for leg and arm rehabilitation Adjustable, 305 – 458ms (for each muscle group that is stimulated) during one pedaling cycle (one cycle = 1.2 seconds or 50 rpm) for rehabilitation bicycling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

	Feature	RT300	Ergys predicate device
15	OFF time (seconds)	Adjustable, 0.95 – 5s	Adjustable, 3 – 30s (rest time between lifts) for leg and arm rehabilitation Adjustable, 694 – 1041ms (each muscle group that is stimulated) during one pedaling cycle for rehabilitation cycling
16	Additional features:	N/A	N/A

Table 3 Basic Unit Characteristics

Waveform

An alternating monophasic waveform is one which alternates the polarity of the pulse through the stimulating electrodes once per period as shown in Figure 7.

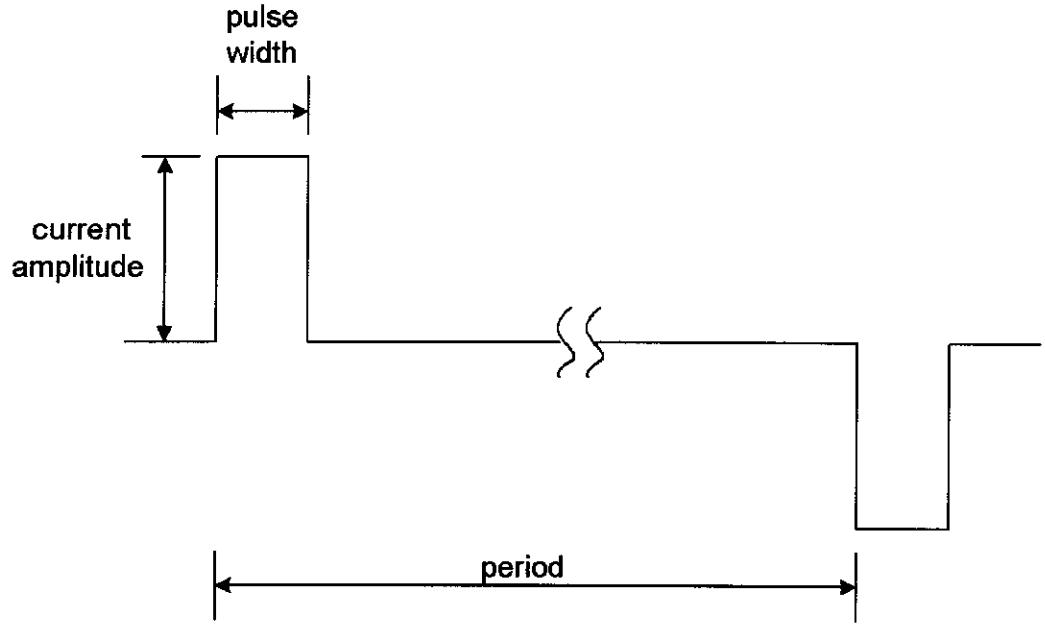


Figure 7. Diagram of Alternating Monophasic stimulation pulse

ON time (seconds)

ON Time for stimulation of any of the 6 muscle groups (Right and Left Quadriceps, Right and Left Hamstrings, and Right and Left Gluteals) depends on the velocity of the cycle ergometer and the crank position of pedals. Max cycling velocity is 50 rpm and minimum cycling velocity is 10 rpm.

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 4 - Description of Accessories

1. Electrodes
The device is supplied with electrodes manufactured by AxelGaard Manufacturing Co., Ltd (FDA registration number 2025066), manufacturer part number 895240. These electrodes are:

- 2.0" x 3.5" conductive stainless steel fabric electrodes
- FDA listed as "VARIOUS TYPES OF ELECTRODES, CUTANEOUS", product code GXY regulation 882.132
- recommended as the replacement electrodes

2. Electrode Conductive Medium
The electrodes are not intended to be used with an additional conductive medium.

3. Electrode Lead Wires and Patient Cables
The stimulation cable this connects the stimulator to the electrodes is shown in Exhibit G Engineering Drawings,
Stimulation Cable on page 43.

Also for performance standard for electrode lead wires and patient cables: please see "Lead Wires" on page 28.

4. Batteries
No batteries are required. The stimulation system is powered from the motorized ergometer.

5. Battery Charger
No battery charger is used.

6. Pediatric pedal accessory
The pediatric pedals, Figure 8, allow greater adjustability to deal with greater size variation among children. Please see Exhibit G Engineering Drawings, on page 47 for details.

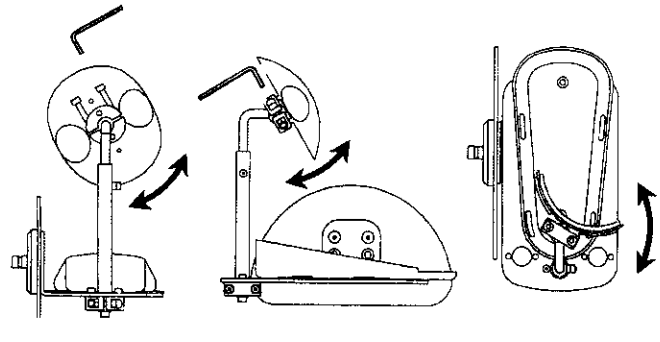

Figure 8 Pediatric pedal assembly

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7. Ergometer Platform

The ergometer platform will allow the RT300-S to be raised to match the higher seating position of many children in wheelchairs. Please see Exhibit G Engineering Drawings, Ergometer Platform on page 49 for details.

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Section 5 - Description of Software/ Firmware / Microprocessor Control

1. Determination of level of concern

i. Does the device software control a life supporting or life-sustaining device?
Answer: No.

ii. Does the device software control the delivery of potentially harmful energy, which could result in death or serious injury, such as radiation treatment systems, defibrillators, and so forth?
Answer: No. The amount of stimulation energy generated by the hardware system is not reasonably capable of causing death or serious injury. The maximum continuous deliverable current is only 12mA (2.4W).

iii. Does the device software control treatment delivery, such that an error or malfunction with the delivery could result in death or serious injury?
Answer: No. Refer to Hazard Analysis, EN100106, Adverse Events, which documents that we have not been able to identify any reported instances of death or serious injury arising from FES cycle ergometry.

iv. Does the device software provide diagnostic information on which treatment or therapy is based, such that if misapplied it could result in serious injury or death?
Answer: No.

v. Does the device software provide vital signs monitoring and alarms for potentially life threatening situations in which intervention is necessary?
Answer: No.

vi Does the software directly affect the patient so that failures or latent design flaws could result in minor to moderate injury to the patient, or does it indirectly affect the patient such that incorrect or delayed information could result in non-serious injury to the patient?
Answer: Yes.

Determination of level of concern: **MODERATE.**

2. Description of device functions controlled by the software

See also: Exhibit I System Specification and Exhibit K Software Specification.

i. What is the role of the software in the RT300 ?

The RT300 software has two primary functions:

a. provide a user feedback and control interface
b. implement active and passive therapy by:
    i. controlling the operation of the ergometer's motor
    ii. controlling the operation of the stimulator

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ii. What does the software do, and as important, what does the software NOT do ?

(b)(4)

[redacted]

iii. How does the user interact with the software ?

The user's direct interaction with the software is limited to pressing the start / stop button on the touch sensitive display. In addition the software provides graphical feedback on the progress of the session including phase (active, passive, cool down), stimulation level, time remaining, cycling velocity and any error conditions.

The clinician is provided with access to two additional screens which can be utilized to customize the stimulation and therapy to a particular user (please see "User controls, displays and functions" on page 8 for details).

iv. What software functions can be controlled or modified by the user, and which are unchangeable ?

The user cannot modify any software functionality. Only a clinician can modify stimulation or therapy parameters via password protected menus.

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iv. Which, if any, of the software features have hardware over-rides or backups ?
The following safety features have been implemented outside of or in addition to the RT300 software:

a. the ergometer's motor will stop if communications is lost with the controller for more than 2 seconds
b. the stimulator will stop stimulation at the end of the stimulation burst if communications is lost with the controller
c. the stimulator incorporates a hardware current limit of 200mA in addition to the software controlled 140mA limit
d. the stimulator implements a hardware high voltage cut off if the stimulation cable is not inserted or removed

3. Hazard Analysis
Please see
Exhibit H Hazard Analysis.

4. Software functional requirements
Please see
Exhibit K Software Specification

5. Software design chart
Please see Exhibit L Software Design Chart

6. Software test protocol
Please see Exhibit K Software Specification. Each requirement has been matched with a verification test.

7. Summary of test results
Please see Exhibit J System Test Results.

8. Other
i. Development
Please see
Exhibit M Software Development Procedure and Coding Guidelines.

ii. Traceability Analysis
Please see Exhibit K Software Specification. This document incorporates a verification step for each software requirement.

iii . Revision Level History
Please see Exhibit N Software Release History.

iv. Release Version Number
The released device will utilize software release 1.00.

Additional Information

1. Lead wires

The distal end of the Stimulation cable is required to meet the requirements for IEC601-1 subclause 56.3(c) which requires that its conductive connection be constructed such that :

1. The conductive connection cannot come into contact with a conductive surface of not less than 100mm diameter.

The conductive connection is recessed12mm within a rigid insulating tube with inner diameter of 6.4mm.

Result: **PASS**

2. The standard test finger does not make connection when applied to the end of the socket with 10N of force.

Tested utilizing a test probe smaller than the specified test finger.

Result: **PASS**

3. Creepage distance if the socket can be plugged into a mains socket.

The socket cannot be plugged into a mains socket.

Result: **PASS**

2. How the Guidance Document was used to address risks

We utilized FDA's Guidance Document for Powered Muscle Stimulator 510(k)s to assist in addressing risks as follows:

i. The Guidance document provided standard indications for use, a contraindication and a set of warnings and precautions which we have adopted

ii. The Guidance document provided guidance on device labeling which we have followed.

iii. The Guidance document provided guidance on the preparation of the User Manual which we have followed

iv. The Guidance document provided a list of key technological parameters which we considered when preparing the device's specification and during verification in order to ensure equivalence to the predicate device or to an accepted standard (e.g. patient leakage current).

v. The Guidance document called up a mandatory performance standard with respect to safety of the device's stimulation cable. This standard was considered during the design phase of the cable and compliance was verified during preparation of this submission.

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Exhibit A 510(k) Summary (CFR 807.92)

(1) Submitter's name, address, telephone number, a contact person, and the date the summary was prepared:

Andrew Barriskill
Restorative Therapies Inc
2363 Boston St
Baltimore, MD 21224

Phone: 310 691-5467

Prepared on December 22nd 2004.

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

Proprietary name: RT300-S (FES cycle ergometer)
Common name: Powered Muscle Stimulator
Classification name: Powered Muscle Stimulator

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

THERAPEUTIC ALLIANCES, INC. product: "ERGYS", K841112, a class 2 device

(4) A description of the device that is the subject of the premarket notification submission.

The RT300-S is a Functional Electrical Stimulation (FES) cycle ergometer which is composed of:

1. a motorized cycle ergometer (RTI part number SA100047 for adults and SA100044 for children)
2. an FES controller / stimulator (RTI part number SA100090)
3. a stimulation cable which connects the controller / stimulator to cutaneous electrodes (RTI part number SA100091)
4. cutaneous electrodes (12 electrodes for 6 stimulation channels, RTI part number FA100015)

This systems allows a person with impaired lower extremity movement to undertake cycle ergometry both actively (utilizing FES evoked lower extremity muscle contractions) and passively (utilizing power developed by the ergometer's motor). The controller is based on a Pocket PC core executing dedicated cycling software under Windows Mobile 2003 operating system. This software controls

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and co-ordinates the operation of both the ergometer's motor and the in built 0 to 140mA biphasic stimulator.

(5) Statement of the intended use of the device:
The RT300-S is intended for people with impaired movement or muscle paralysis arising from Spinal Cord Injury, muscular dystrophies, motor neuron diseases, stroke, multiple sclerosis and cerebral palsy.

The indications for use are:
1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

(6) Technological Characteristics
The function of the RT300-S is the same as the predicate device however there are certain technological similarities and differences as described below:

Technology	RT300-S	Predicate
Power source (energy used)	Mains power	Mains power
Controller	Based on Pocket PC running custom software.	Uses custom controller running custom software.
Stimulator (energy delivered)	0-140mA charge balanced stimulator	0-140mA charge balanced stimulator
Flywheel	Uses motor to create flywheel effect with reduced weight and space.	Uses heavy mechanical flywheel.
Seating	Allows user to remain in their own seating, e.g wheelchair eliminating the need for transfer.	Includes a dedicated seating arrangement.
Passive cycling	Utilizes motor to provide assistance during passive cycling.	Requires manual assistance to provide power during passive cycling.

Table 4 Technology comparison

(b) Performance data

(1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence;

Non clinical testing to determine equivalence has been primarily composed of the following tests:

Test or procedure	Description
Review of user documentation for predicate device	Ensure that equivalent functionality is specified and implemented in the new device.
Review of 510(k) submission for predicate device	Confirm technical specifications for completion of predicate details in comparison tables (see pages 17 and 20)
Output characteristic measurement of new device	Confirm technical specifications for completion of new device details in comparison tables (see pages 17 and 20)
Conduct of system testing as per Exhibit J System Test Results	Conduct system testing to verify performance to specification

(2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence.

Ergometer Background
The motorized ergometer used in the RT300-S system has undergone extensive clinical application:

a. Outside the U.S.A, medica MedizinTechnik, the manufacturer of the ergometer, has sold over 700 of these ergometers primarily within the European Union since their introduction in January 2004. medica MedizinTechnik advises that it has not received any adverse event reports relating to this device or to their previous model.
b. Within the U.S.A, Restorative Therapies Inc has listed the device (E193605) and currently markets it as the RT-100 motorized ergometer. To date 13 of these systems have been delivered with no adverse events reported to RTI.

Stimulator Background
The RT300-S system was developed from a muscle stimulation system licensed by RTI from Cochlear Ltd (Sydney, NSW, Australia) see Exhibit O A portable, 8-channel transcutaneous stimulator for paraplegic muscle training and mobility—A technical note.

The RT300-S project upgraded the original Cochlear system from a separate Pocket PC controller linked by cable to a battery powered belt worn stimulator TO a system which integrated the controller and stimulator within a single housing suitable for mounting directing on the motorized ergometer.

The Cochlear Ltd muscle stimulator system on which the RT300-S is based has been utilized by the Shriners Hospital for Children, Philadelphia in an IRB approved clinical study (protocol 4333 approved 5/22/2004) since June 2004. Shriners have been collecting the following data:

1) bone density (knee and hip)
2) MRI of the thigh for muscle cross sectional area
3) VO2 and HR during arm ergometry with increasing resistance
4) VO2 and HR during FES LE ergometry with increasing resistance
5) ASIA test
6) Blood work: lipid and immunological profile, CBC and WBC
7) Spasticity measures using Ashworth, spasm scale, and passive movement on the KinCom dynamometer
8) Stimulated force of quadriceps and hamstrings
9) Pressure in sitting

RTI has so far supplied 10 RT300-S systems for use in this study. The study randomly assigns children to one of 3 groups: FES ergometry, passive cycling, or electrical stimulation exercises. Each will receive the therapy 3 times per week for one year with testing after 6 months and 1 year.

Their current subject is an 11 year old male with a T1T2 ASIA A thoracic SCI, sustained at age 6.5 years in a motor vehicle accident. The subject began cycling with FES in August of 2004, cycling 3 times per week at home with the assistance of his mother. There have been no complications with this subject. He currently is working on increasing the amount of resistance of the cycle and has been doing this without any problems.

Recent Clinical testing
More recently we have conducted clinical testing of the RT300-S system on both able bodied testers and continued the testing at the Shriners Hospital as part of the previously mentioned IRB approved study.

Clinical Test	Description
Testing with able bodied subjects	The RT300-S was tested on 5 able bodied subjects to confirm correct operation of the system including correct detection of electrode off conditions with varying skin impedances. This testing uncovered one significant anomaly (RTI case #39) which resulted in an over-stimulation due to a manufacturing defect. This anomaly was corrected. Testing demonstrated correct system operation with appropriate, coordinated control of motor and stimulation power.

(3) The conclusions drawn from the non clinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.

RTI concludes that:

The RT300-S has the same intended use as the predicate device (please refer to Indications for Use on page 6).

The RT300-S has the same output characteristics as the predicate device (please refer to comparison tables on pages 17 and 21). The different technological characteristics described in Table 4 on page 30 do not raise new questions of safety and effectiveness. The safety and effectiveness of using a motor to simulate the predicate device's mechanical flywheel and provide passive cycling assistance has been extensively demonstrated in particular by the ongoing clinical use of the motorized ergometer without the stimulation component both in the European Union and in the U.S.A. The safety and effectiveness of a Pocket PC based controller has been demonstrated over the development period of the RT300-S in addition to the past clinical experience obtained by Cochlear Ltd (the technology licensee) in utilizing Pocket PC based controllers for muscle stimulation.

In conclusion, RTI's clinical and non clinical testing has demonstrated that the RT300-S is as safe and effective as the predicate device.

Exhibit B Indications for Use

The RT300-S is intended for people with impaired movement or muscle paralysis arising from Spinal Cord Injury, muscular dystrophies, motor neuron diseases, stroke, multiple sclerosis and cerebral palsy.

The indications for use are:
1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

Exhibit C Product data plate

The data plate shown in Figure 9 is attached to the RT300-S base unit:

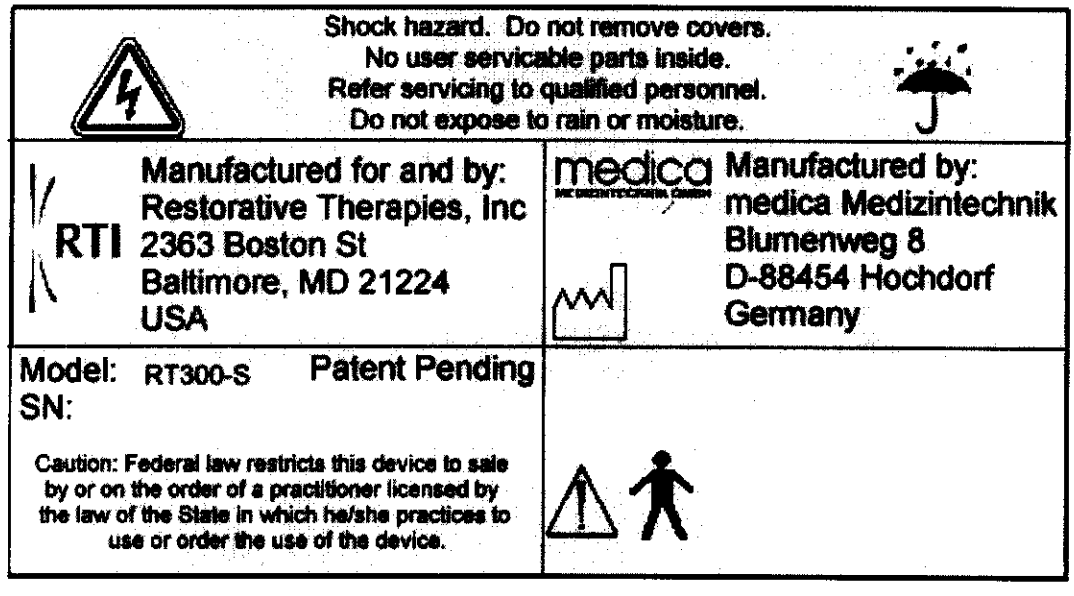

Figure 9 RT300-S data plate

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Exhibit D RT300-S brochure

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RTI
Restorative Therapies Inc.
Baltimore, MD USA
Ph: 310 691-5467
www.restorative-therapies.com

Restorative Therapy™ *RT300-S*

motorized FES ergometer for people with *Spinal Cord Injury*

Restorative Therapies Inc
2363 Boston St
Baltimore, MD 21224

Phone: 310 691-5467
Fax: 410 598-6263
www.restorative-therapies.com

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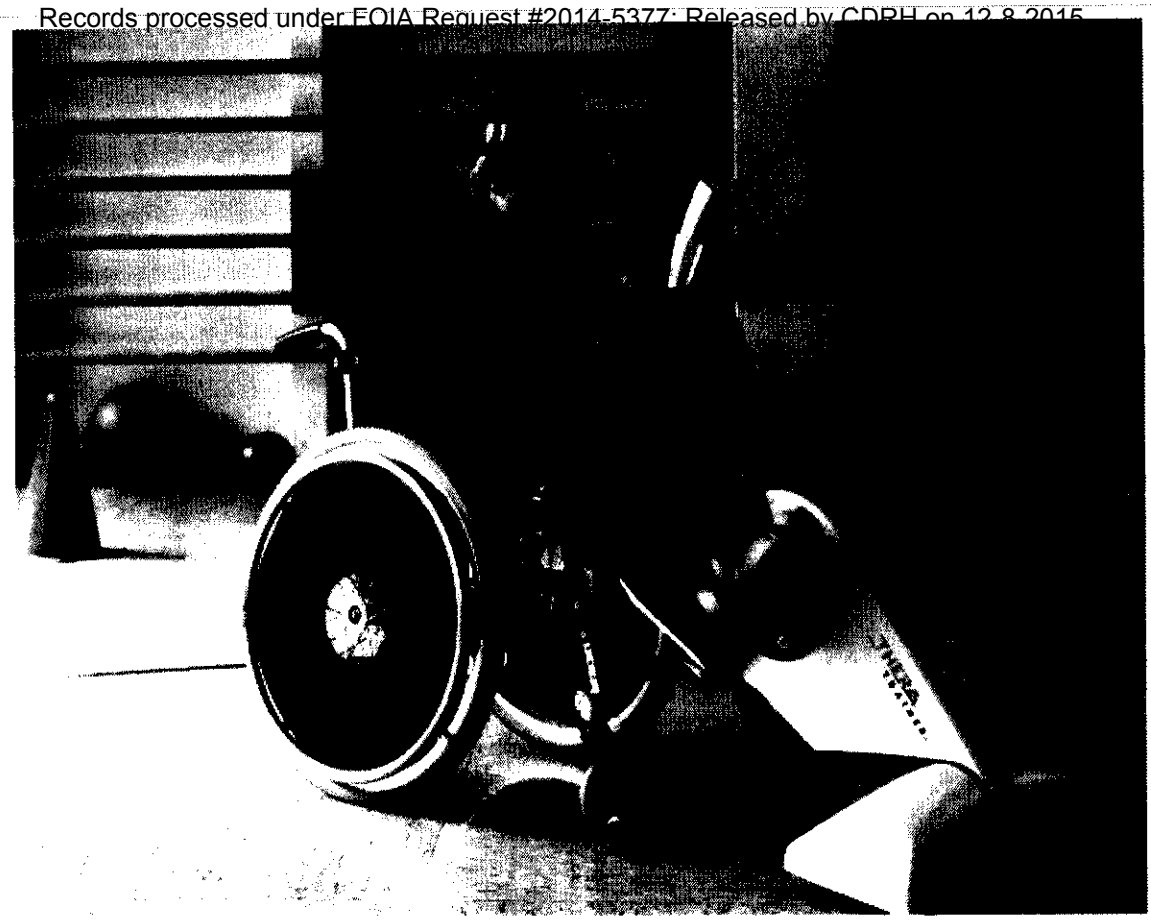

Spinal Cord Injury

Current accepted theory is that most individuals with a spinal cord injury (SCI) have little prospect of recovering function.

Individuals discharged from rehabilitation facilities are counseled to adjust their lifestyle to accommodate their disability which often includes muscle paralysis, inability to control bladder and bowel functions, sexual dysfunction, loss of muscle and bone mass, and skin breakdown.

The lack of hope, the lack of effective alternatives and the lack of ongoing outpatient programs are the dominant contributing factors why individuals are unable to continue with life-long therapeutic rehabilitation.

It is time for a new approach to SCI rehabilitation.

There are now doable, time-efficient, life-long therapies designed to maximize function in individuals with chronic SCI.

About RTI...

As the designer and supplier of Restorative Therapy™ medical devices, RTI's mission is to help people with a neurological impairment achieve their *full* recovery potential.

Restorative Therapies Inc was founded in 2004 by John McDonald M.D., Ph.D., in order to design, manufacture and market new Restorative Therapy medical devices for people with neurological impairments by providing near-term solutions for maximizing function even long after injury.

RTI 's team has over 35 years of experience in medical device development. Its close relationship with leading clinical and research institutions is a key element of the team's success

RTI's high quality medical devices, leading edge technologies and patented therapy set a new benchmark in the treatment of neurological impairments.

At RTI we understand your impairment, your need for effective, time-efficient therapy compatible with your injury and environment. Our aim is to help you *achieve and maintain* your physical, psychological, social and vocational potential.

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Scientific background ...

Important advances in medical, surgical and rehabilitative care of SCI have taken place in the past two decades. Traditional rehabilitation is short in duration and focuses on the acute injury hospital based approach. This approach aims to limit the damage from secondary injury and promotes adaptation to disabilities via rehabilitation.

Paralleling these efforts are exciting advances that focus on neural restoration via application of new aggressive therapeutic interventions. Options include tendon transfers, functional electrical stimulation, adaptive equipment and environmental control devices. These approaches aim to make the most of existing function and reintegrate individuals into everyday life.

Significant research is also currently underway to promote cell regeneration and replace lost cells. However transition of this promising science into human trials is very slow.

Dr. John McDonald is a leader in this new era of scientific advances. One of his key discoveries is that neurological restoration and functional recovery can occur even long after the nervous system is damaged[10]. Scientists have also found that small anatomical improvements can produce significantly greater functional benefits such as improvement in bowel and bladder function, hand grasp or limb mobility.

It is important to recognize that future cure of SCI is likely to need multiple therapies to keep damage to a minimum, preserve and enhance residual function and promote regeneration.

What is FES ?

Functional Electrical Stimulation is a rehabilitation technique where low-level electrical current is applied to an individual with a disability to enhance that person's ability to function and live independently.

In the case of the RT300-S, FES is used to stimulate patterned movement of the legs. This enables the muscles to perform cycling work even though the user has lost voluntary control of the muscles.

Passive & Active Therapy

Passive therapy is when your arms or legs are moved mechanically, e.g. by the motor of a cycle or by a physical therapist's manipulations.

Active therapy is when your muscles are doing the work to complete a movement under your own control or activated by FES.

These future techniques will probably be most effective when applied to well-maintained human bodies – those who have minimized their medical complications and maximized their own restoration.

But what can I do now ?

RTI was founded to respond to this new knowledge based on the pioneering research of Dr. McDonald. His basic science research suggests that repetitive neural activity utilizing functional electrical stimulation (FES) stimulates the central nervous system to become more functional and to promote nerve cell growth[11]. This patented activity based process is known as Restorative Therapy.

Restorative Therapy adds to existing hospital-based treatment of acute injury by providing pragmatic home-based programs designed to promote ongoing restoration.

The RT300-S

The RT300-S system empowers you to undertake Restorative Therapy sessions in your own home that will assist you in maintaining your body by:

- **Relaxing muscle spasms**
- **Minimizing muscle atrophy**
- **Improving blood circulation**
- **Maintaining or increasing range of motion**

The RT300-S does this by utilizing a computer controlled motorized cycle ergometer with an integrated functional electrical stimulation system (FES). This enables you to cycle using your own muscles.

What is a cycle ergometer ?

An ergometer is a device for measuring the amount of work done by a muscle or group of muscles. In the case of the RT300-S, the ergometer is the machine that allows the user to conduct both passive and active therapy.

How does the RT300-S motor help you ?

The RT300-S motor is an essential component of the system. The motor can provide both assistance and resistance depending upon the phase of a therapy session. When you first start using the RT300-S, your muscles will tire quickly.

The motor on the RT300-S will allow you to complete a full duration therapy session (one hour) in your home from day one in spite of this early muscle fatigue. As you progress with your therapy and your muscles strengthen the motor will provide resistance against which your muscles can work.

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Key RT300-S features

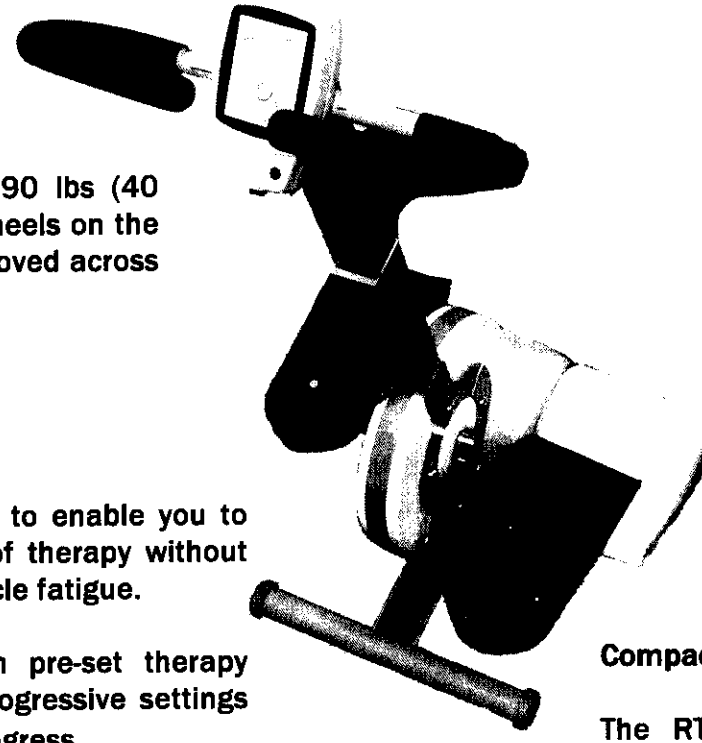
You use the RT300-S while sitting in your wheelchair with your feet secured in the footrests and your legs supported by the leg guides.

Surface electrodes placed on your skin over leg muscle groups are connected by a set of cables.

A computer controls the stimulation patterns sent to your legs producing a smooth pedaling motion. You then perform a therapy session. One hour three times per week is sufficient.

No transfer from your wheelchair

You will not have to leave your wheelchair to use the RT300-S. Transfer can be time consuming, uncomfortable and requires assistance.



Portable

The RT300-S weighs only 90 lbs (40 kg). A strap in front and wheels on the back allow it to be easily moved across a room.

Fully automatic therapies

The RT300-S is motorized to enable you to complete a full duration of therapy without assistance, even with muscle fatigue.

The RT300-S comes with pre-set therapy settings and automatic progressive settings based on your personal progress.

Compact size

The RT300-S takes up very little floor space. The dimension of the base is less than 2 feet wide by 2 feet long (54 cm X 46 cm). The height of the handle is adjustable to fit the user. The RT300-S has a sleek, durable design intended for home use.

Fast simple set up.

The touch sensitive controller screen and software defaults mean that initial set up is fast and simple. You will be able to commence your therapy session within minutes.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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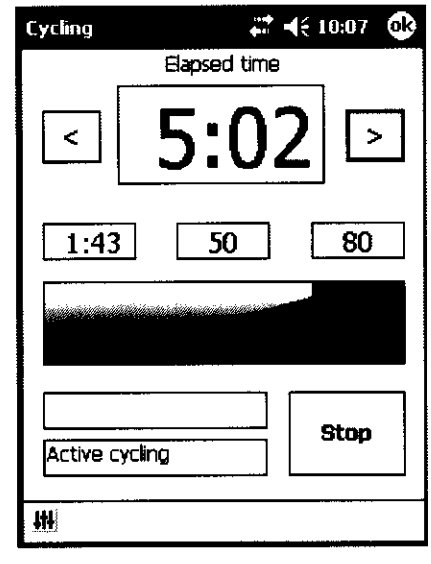
Inbuilt Safety Measures

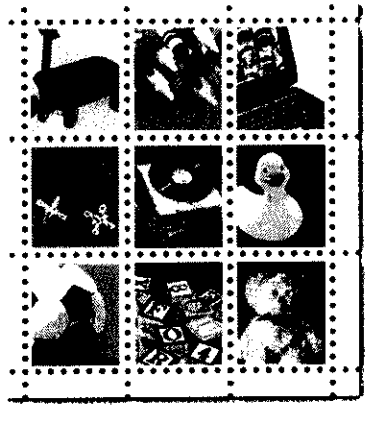
- ✓ spasm detection and control
- ✓ automatic speed control
- ✓ automatic stimulation control
- ✓ fatigue detection
- ✓ electrode monitoring system
- ✓ fault detecting electronic circuitry



Touch-sensitive controller screen

The controller screen lets you control all aspects of your therapy session. Graphically view your progress:

- ✓ distance
- ✓ speed
- ✓ duration
- ✓ calories



Pediatric model available

The RT300-SP is the pediatric model of the Cycle Ergometer for use by children as young as five under adult supervision. It differs from the adult model with:

- ✓ handles which can be adjusted to a lower height
- ✓ a different pedal system that is adjustable for smaller feet and limbs
- ✓ an Ergometer Platform to allow adjustment of the height of the whole Cycle Ergometer.

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Spasticity

Spasticity is a common accompaniment to paralysis that occurs with upper motor lesions.

.any patients report strong anti-spasms effects from FES[1]. A study of 79 SCI patients, 44 of whom utilized FES, revealed a long lasting reduction in spasticity and an increased range of passive movements in the individuals with a SCI who utilized FES[2].

Disuse atrophy

It is well documented that following a spinal cord injury paralysis results in severe muscle disuse atrophy[3]. FES leg therapy has almost universally demonstrated either an increase in muscle bulk or prevention / reversal of muscle atrophy following a spinal cord injury.

Increased muscle bulk is associated with improved cosmetic appearance, decreased total body fat, and more favorable muscle morphological and histochemical profiles. In addition a number of studies have suggested a decreased incidence of pressure sores.[4,5]

ɔcent work at the Washington University in St ʟouis has shown that maintaining or rebuilding muscle bulk with FES in SCI does not result in stronger muscle spasms.

Blood circulation

The physiological effects of FES have been investigated in numerous studies. FES therapy that stimulates rapid rhythmical muscle contractions can lead to an increase in circulation[6], reduced venous pooling[7] and increased leg blood flow[8] for its users.

Cardio respiratory fitness is usually increased when used three times per week for at least 30 minutes over a minimum of 8 to 10 weeks. Although there are some studies that have shown equivocal results, the majority of studies employing sufficient duration of FES (greater than 30 minutes) document improved leg power output, augmented aerobic power and changes to resting heart rate, ᵉtroke volume and myocardial dynamics.

Range of motion

Studies have documented an increased knee joint range of motion from FES evoked activity[7,8].

"The recovery has given me the security of knowing that I run minimal risk of infection, minimal risk of hospitalization" [10]

"The impact on my daily life has been increased mobility and respiratory benefits" [10]

"I look on building muscle mass as a preparation for recovery, which is the long term goal"[10]

"The economics of my life has been very strongly impacted because I have stayed out of hospital"[10]

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Activity is key...

. RTI we understand your impairment and your need for effective therapy compatible with your injury and environment.

Nervous system damage from diseases and injuries such as spinal cord injury, MS or stroke almost always reduces neural activity. Over time this loss can impair your general health and self-esteem, which can undermine your attempts to improve your situation, decrease your quality of life and increase demands on medical and social services.

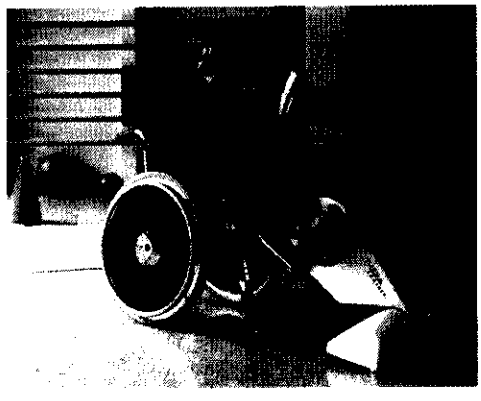
Up to 30% of individuals with SCI experience medical complications that lead them to be admitted to hospital yearly[9]. This increases already staggering medical costs and puts more pressure on you and your family.

At RTI we believe that regular activity is an important component in maintaining function and quality of life.

creasing your activity level can improve overall ıealth, cardiovascular fitness, range of motion, and flexibility. It can raise energy levels, improve balance, manage spasticity, decrease muscle atrophy, and allow you to better perform activities of daily living.

Feeling predictably better brings many rewards: economic rewards of more gainful employment days; psychological rewards of greater self-esteem and confidence.

"My recovery so far has helped my family worry less about me. They know I am healthier, stronger."



Return to work is an appropriate goal for all individuals with spinal-cord injury.

"It has greatly increased my productivity by increasing my daily endurance, reducing the number of sick or hospitalized days, and providing confidence that I will fulfill commitments. Recovery has given me the freedom to assure employers that I am ready, willing and able to work" [10]

"My recovery means everything to me because while some people are able to accept living with a disability, I am not one of them"[10]

At RTI our aim is to help you achieve and maintain your physiological, psychological, social and vocational potential - your *full* recovery potential.

How much effort will be required by me?

A therapy program needs to be designed specifically for you by your Doctor and Physical Therapist. Dr McDonald's work suggests that at least one hour of therapy three times per week is sufficient to achieve significant benefit.

Is the RT300-S reimbursed?

RTI works in collaboration with a successful insurance claims processing company to help maximize your reimbursement. Availability of insurance coverage for this therapy will depend upon several factors including the insurance that you hold. Please call RTI or see the web site for further details.

Is financing available?

RTI has established a collaboration with a leading medical finance provider to ensure access for customers to finance on attractive terms. Please call RTI or see the web site for further details.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RTI
Restorative Therapies Inc.
Baltimore, MD USA
Ph: 310 691-5467
www.restorative-therapies.com

Restorative Therapy™ *RT300-S* motorized FES ergometer for people with *Spinal Cord Injury*

Is the RT300-S system right for me?

The RT300-S is indicated for people with an upper motor neuron spinal cord injury (typically from a C2 level to a T11-12 level injury) and for some other neurological conditions.

This device is contraindicated (inappropriate) if you have a cardiac demand pacemaker.

Because of the individual differences in spinal cord injuries including level of injury, completeness and secondary complications such as autonomic dysreflexia and pressure sores, consultation with your physician is important to determine if the RT300-S is suitable for you to use.

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle mulators. This is a rare issue.

The benefits of RT300-S therapy are:

1. Relaxing muscle spasms
2. Minimizing muscle atrophy
3. Improving blood circulation
4. Maintaining or increasing range of motion

Technical Specifications

6 channels of electrical stimulation
Fully automatic therapy sessions
Touch sensitive, color display
Shows energy, distance, calories etc
Displays left and right leg stimulation levels
Spasticity control
Motorized with virtual motor flywheel
Wheels for portability
Torque 0 – 15Nm
Speed 0 – 60rpm
Noise Lpa ≤ 70dB (A)
Length 54cm 21.3"
Width 46cm 18.1"
Height 46cm 18.1" (without safety handle)
Weight 40 kg (90 lbs)

Pediatric edition

Minimum body height 120 cm or 3'
Torque 0 – 9Nm
Multi adjustable pedal system
Height adjustable platform
Reduced height safety handle

Description	Part number
RT300-S Adult FES cycle ergometer	FA100052
RT300-SP Pediatric	FA100053

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

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Exhibit E RT300-S User's Guide

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Exhibit E RT300-S User's Guide

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RT300-S System™

User Guide

RTI

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RT300-S System

User Guide

Caution:

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Part Number: LB100108 RV100083 Issue 1
[November 2004]

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Introduction

About this Guide

This guide explains how to use the RT300-S System in your own home. It contains information about how to:

- apply proper safety measures when you use the system
- set up and use the equipment
- fix any basic problems that may occur

What You Need to Know Before You Start

Before you start using the RT300-S System:

- read this guide – in particular, check the *Indications for Use, Contraindication,* and *Warnings, Precautions and Safety Measures* sections of this guide
- talk to your clinician who will provide training to help you get started and explain how the *Warnings, Precautions and Safety Measures* relate to you.

Indications for Use

The RT300-S is **indicated** for people with an upper motor neuron spinal cord injury (typically from a C2 level to a T11-12 level injury) and for some other neurological conditions where there is reduced lower extremity movement and sensation.

The benefits of RT300-S therapy are:

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

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Contraindication

Powered muscle stimulators should not be used on patients with other implanted devices (including cardiac demand pacemakers or electronic Baclofen pumps).

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RTI Technical Support

Restorative Therapies Inc (RTI) offers a technical support service to provide troubleshooting help when:

- you have read this guide but are experiencing difficulties with the RT300-S System
- the system is due for a maintenance service
- you need to order replacement parts

Contact RTI Technical Support:

- via the web at www.restorative-therapies.com or
- by phoning **1-310-691-5467 or 1-888-489-0695**

Terms used in this guide

Term	What it Means
Bluetooth WiFi	A wireless, automatic means by which electronic devices connect to each other. Bluetooth devices communicate with each other on a standard band or range of radio frequency called the ISM (industrial, scientific and medical) devices band. WiFi stands for **wi**reless **fi**delity. WiFi enabled devices can communicate with each other even if they are from different manufacturers.
controller	A computerized panel used to control the RT300-S System.
FES	Functional Electrical Stimulation
GSM	Global System for Mobile Communications, a standard mobile communications system used in many countries.
ℹ	Important information or help.
RTI	Restorative Therapies, Inc
calf or leg	The limb segment between the knee and ankle.
surface electrode	An electrode (pad) that is attached to the skin surface to stimulate a group of muscles. Each surface electrode connects to the RT300-S System via a set of stimulation cables.
Thigh	The limb segment between the hip and knee.
Torso	The part of the body from the shoulders to the waist.
Type B Applied Part	This term is used in the "IEC 60601-1" electrical safety standard. It applies to the parts of a medical device that must physically touch a person to carry out the device's intended function. Applied Parts are Type B, or Type BF, or Type CF depending on the nature of the device and the type of contact. Each type has different requirements for protecting people against electrical shock. Type B is used for Applied Parts that generally do not carry electricity and can be immediately taken off the person.
V	Volts

Table 1: Terms used in this guide

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RT300-S System

What is the RT300-S System used for?

The RT300-S System is a motorized therapy system, which you use for:
- **passive therapy** – with motor power, and
- **active therapy** – with electrical stimulation applied to your muscles

The system is designed to provide a therapy routine prescribed by your clinician.

Parts of the RT300-S System

Table 2 shows a list of the RT300-S System's parts:

Part		Part Number
RT300-S system	RT300-S	FA100052
	RT300-SP (Pediatric)	FA100053
Ergometer platform		FA100019
Controller / Stimulator		SA100090
Controller / Stimulator mounting plate		PP100207
Controller / Stimulator power cable		PP100206
US power cord		SA100110
Stimulation cable		SA100091
Rectangle surface electrodes 2"x3.5" Qty 4		FA100015
Velcro pedal straps		PP100124
Velcro calf support straps		PP100125
RT300-S System User Guide		LB100108
Warranty		LB100109

Table 2: RT300-S System parts and part numbers

If a part is damaged or lost, use the **part number** to order a new one from Restorative Therapies Inc. Please call or use our web store.

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Surface Electrodes

You should replace your surface electrodes after approximately 15 uses to ensure good adhesion and connectivity. **Be especially careful to monitor the condition of the electrodes that you use on your gluteal muscles as these are subject to more wear and skin burns are reported to be more likely here.**

Table 3 shows the description and part number for ordering the recommended surface electrodes. Order new electrodes from Restorative Therapies Inc via the web at www.restorative-therapies.com.

Part	Part Number
Size: 5cm x 9cm (2″ x 3.5″)	FA100015

Table 3: Recommended surface electrode details

Warnings, Precautions and Safety Measures

Read this section carefully so you understand how to use the RT300-S System safely.

Before you start using the RT300-S System, talk to your clinician about the information in this chapter.

Warnings

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

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Precautions

1. Safety of powered muscle stimulators for use during pregnancy has not been established.
2. Caution should be used for patients with suspected or diagnosed heart problems.
3. Caution should be used for patients with suspected or diagnosed epilepsy.
4. Caution should be used in the presence of the following:
   a. when there is a tendency to hemorrhage following acute trauma or fracture;
   b. following recent surgical procedures when muscle contraction may disrupt the healing process;
   c. over the menstruating or pregnant uterus;
   d. over areas of the skin which lack normal sensation;
   e. history of uncontrolled autonomic dysreflexia;
   f. history of lower limb stress fractures and
   g. history of severe spasticity or spastic response to application of electrical stimulation.
5. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
6. Some patients may be prone to thermal dysregulation. Episodes of thermal dysregulation are usually less pronounced when exercising in an environment controlled for temperature and humidity. Attention should be paid to hydration and limiting the duration and intensity of exercise in intemperate environments.
7. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
8. Powered muscle stimulators should be kept out of the reach of children. Children should only use this device under adult supervision. Never leave the RT300-S unattended when children are present.
9. Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.

Adverse Reactions

Autonomic Dysreflexia

Individuals with an injury at or above the T6 level are prone to episodes of autonomic dysreflexia. These episodes may be triggered by electrical stimulation. It is important that you discuss this with your clinician and understand how autonomic dysreflexia may impact you:

- know how to recognize the signs of autonomic dysreflexia
- know how to react if it occurs, including stopping electrical stimulation

Skin irritation and burns

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

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Safety Measures

Electrical Safety

- **Avoid flammable anesthetics:** Never use the equipment where there is a flammable anesthetic mixture containing air, oxygen or nitrous oxide.
- **Connecting the system:** Connect the system parts only in the way described in this guide. Do not try to connect or disconnect any parts while the system is turned on.
- **Other equipment:** Do not use the system with any equipment not supplied by Restorative Therapies Inc as doing so could affect the electrical safety of the system.
- **System parts:** The system contains complex electronic parts. The casings must not be opened by anyone other than qualified service personnel or the warranty will no longer apply. Also, if you attempt to make repairs yourself, you might be seriously injured.

Environment

- **Use a stable surface:** Position the motorized ergometer on an even, anti-slip surface so the equipment is stable and does not move during use.
- **Use an anti-slip device:** As an added precaution, you may wish to use an anti-slip device (e.g. mat, etc) to make sure your wheelchair does not slip backwards during very active therapy.
- **Avoid wet areas:** Never use the RT300-SCycle Ergometer in wet or damp areas.
- **Avoid heat sources:** Place the RT300-SCycle Ergometer equipment away from heat sources such as radiators, stoves, etc, or other objects that produce heat.
- **Arrange the power cord carefully:** Arrange the power cord so it will not be walked or tripped on, or damaged by objects being placed on it.
- **Use the correct line voltage:** Make sure you connect the RT300-SCycle Ergometer to a grounded (earthed) power outlet that uses the voltage shown on the product label.
- **Follow extension cord ratings:** If you plan to use an extension cord, make sure the plug has three pins (i.e. the plug includes a third, protective earth pin).

Parts and Operation

- **Do not use the controller for other purposes:** Do not use the controller for any other purposes – for example, to store documents or images as it may alter how the controller works.
- **Do not use other controllers:** Do not use another person's controller as each controller is specifically programmed to suit an individual's requirements. Using another person's controller may lead to incorrect or excessive stimulation.
- **Always empty your bladder** before starting a therapy session to minimize the risk of autonomic dysreflexia occurring. If you have any concerns, talk to your clinician.
- **Before use**: before using the RT300-SCycle Ergometer for the first time or after it has been transported over a long distance, allow it to stand for about 1 hour at room temperature.
- **After a long absence:** If you do not use the RT300-SCycle Ergometer system for a prolonged period (e.g. a few months), you may find your progress is affected. If this occurs, it is important to see your clinician for re-evaluation and, perhaps, re-training before you start using the system again.

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- **Handle with care:** Handle the various parts of the RT300-SCycle Ergometer system with care to reduce the risk of dropping and damaging the equipment. Do not stand on the footrests or the device's plastic motor covers.
- **Check for wear and tear:** Each time you use the RT300-SCycle Ergometer, carefully inspect all the parts first. If you notice any damage – such as cracks or breaks in the covering of a cable – stop using the system and contact RTI Technical Support.
- **Do not handle or adjust the pedals** when the RT300-SCycle Ergometer system is switched on.
- **Moving parts:** Keep hands well away from the pedals while the machine is in operation.
- **Report changes:** If you find any changes occur in how the RT300-S Cycle Ergometer operates, stop using the system and contact your clinician or RTI Technical Support.
  - Repairs to the RT300-S must only be carried out by properly trained specialists.
  - If the RT300-S is damaged or faulty or if it produces abnormal noises or smells, stop the therapy session immediately, unplug the power cord and contact your service technician.
- **Wheelchairs:** If it is not possible to be absolutely certain that the wheelchair will not tip over backwards (e.g. with very active patients), a wheelchair bracing/stabilizing device must be used.
- **Clothing:** Dress comfortably to allow for the appropriate range of motion in the legs and / or arms. Avoid wearing clothing that may catch on the moving parts of the system.
- **Velcro straps:** Patients secured to the RT300-Sby the Velcro straps must not be left unattended.

Electrostatic Discharge

A discharge of static electricity could damage:

- electrical parts of the system
- software programs on the controller

If static electricity is present, touch a metal part of the ergometer before fitting any parts or touching the controller. Examples of where static electricity might occur are:

- putting clothes on over your head
- in very low humidity

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Setting Up the Equipment

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RT300-S System Overview

Standard RT300-S Equipment

Standard RT300-S equipment is:

- motorized cycle ergometer
- controller / stimulator
- 12 skin surface electrodes
- stimulation cable for connecting the skin surface electrodes to the controller / stimulator
- power cord

Figure 1 shows the standard equipment and features.

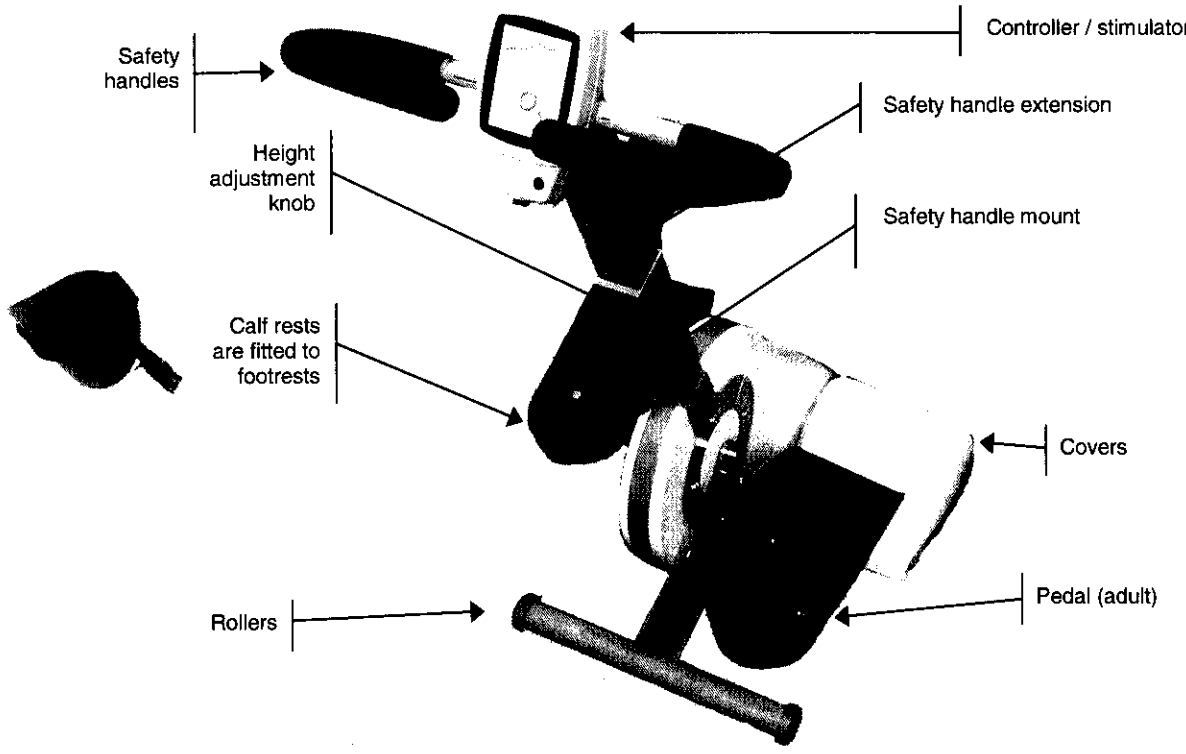

Figure 1: RT300-S system components

You use the RT300-S System from your wheelchair, with your feet secured in the footrests and your legs supported by the calf rests.

Surface electrodes placed on your skin over particular muscle groups are connected to the ergometer by a set of cables.

Software on the controller controls the stimulation patterns sent to your legs, producing a smooth pedaling motion.

It is recommended you always wear shoes (e.g. running shoes) when using the RT300-S System.

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Optional RT300-S Equipment

You can add the ergometer platform if you need to raise the height of the whole ergometer.

Contact RTI for more information on purchasing the ergometer platform or visit the store at www.restorative-therapies.com.

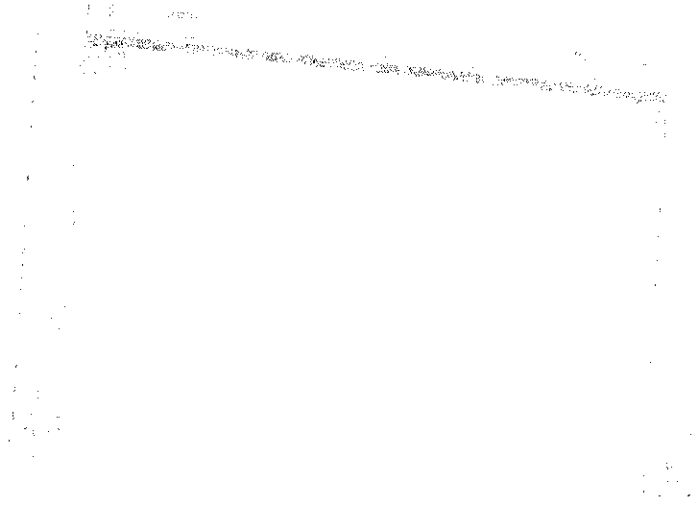

Figure 2 Ergometer platform with adjustable height legs, FA 100019

RT300-SP Ergometer for Pediatrics

The RT300-SP is the pediatric version of the RT300-S. It includes as standard equipment:

- handles which can be adjusted to a lower height than the handles on the adult ergometer
- a different pedal system that is adjustable for smaller feet and limbs
- reduced motor power settings

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Assembling the RT300-S

Checking the Parts

Before you start assembling the ergometer, unpack **all** of the parts and:

1. Check to make sure none of the parts are damaged or missing. See page 7 for a details on all parts.

If any of parts are damaged, missing contact RTI Technical Support immediately. Do not use the system.

Fitting the Support Arm

To fit the support arm:

1. Place the base unit of the ergometer on a flat, even surface.

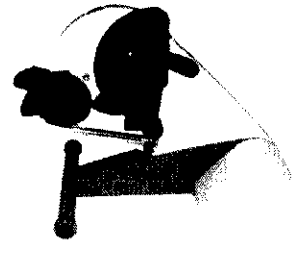

Figure 3: Base unit of the ergometer

2. Hold the safety handle mount with the height adjustment knob facing you.
3. Thread the Controller power cable that protrudes from the ergometer base unit up through the safety handle mount as shown in Figure 4.

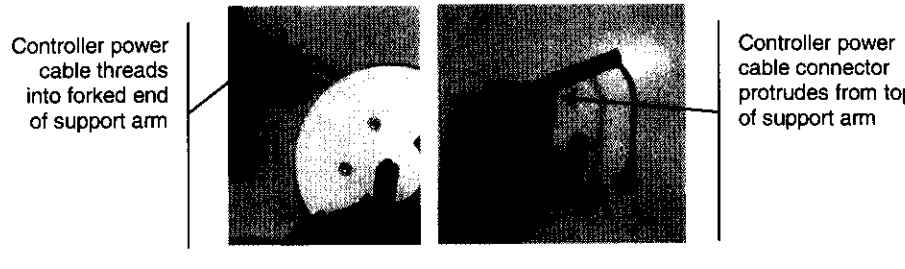

Figure 4: Threading PCS cable through the safety handle mount

4. Slide the safety handle mount forks over the encased sheave being careful not to trap the Controller power cable.

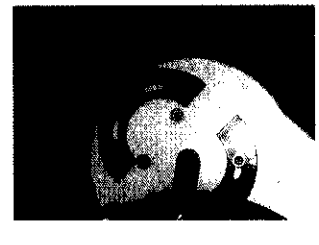

Figure 5: Forks fitting over the encased sheave

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5. Slide the support arm down until the bolt holes on the forks align with the bolt holes on the sheave casing.

There are two bolt holes on each fork and two corresponding bolt holes on each side of the sheave casing.

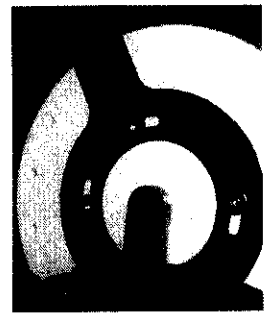

Figure 6: Bolt holes aligned

6. Screw the bolts into the bolt holes and tighten each bolt using the Allen (Hex) Key provided.

Figure 7 Allen (Hex) key

It is recommended you fit all four bolts **before** tightening any of them.

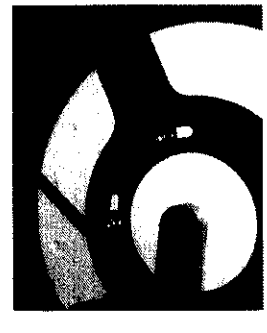

Figure 8: Tightening a bolt with the Allen (Hex) Key

Fitting the safety handle extension

To fit the safety handle extension:

1. Slide the Controller power cable extension down the safety handle extension starting from the top as shown in Figure 9.

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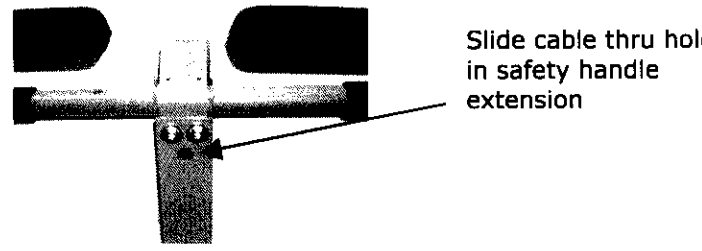

Figure 9 Slide the Controller power cable extension down the safety handle extension

2. Hold the extension with the safety handle's mounting slot facing towards you.

3. Connect the PCS connector at the bottom of the safety handle extension section to the PCS connector at the top of the support arm.

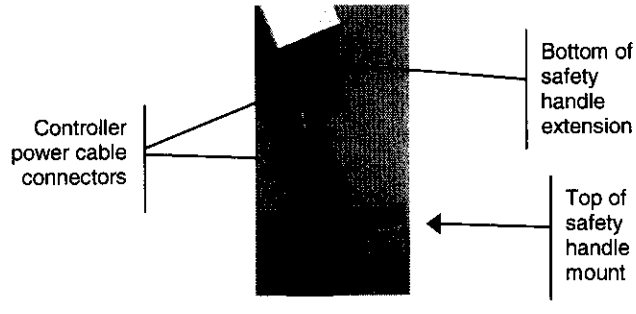

Figure 10: PCS connection

4. Slide the handle extension section into the support arm.

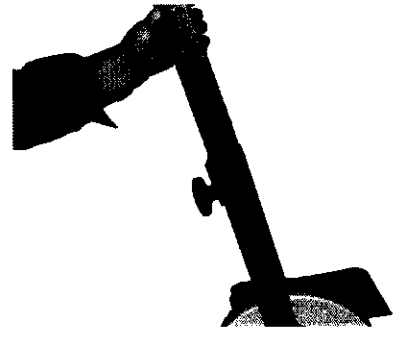

Figure 11: Handle extension section sliding into support arm

5. Turn the height adjustment knob clockwise until the safety handle extension section locks into place.

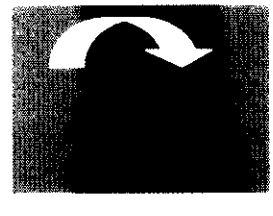

Figure 12: Height adjustment knob

Fitting the safety handle

1. Fit the safety handle to the safety handle extension using the two bolts supplied.

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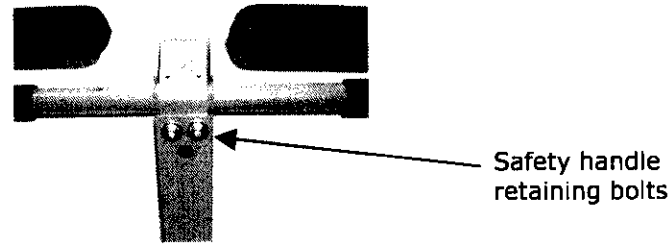

Figure 13: Fitting the safety handle

Fitting the controller / stimulator

1. Fit the Controller mounting plate to the safety handle assembly using the hex bolts supplied as shown in Figure 14.

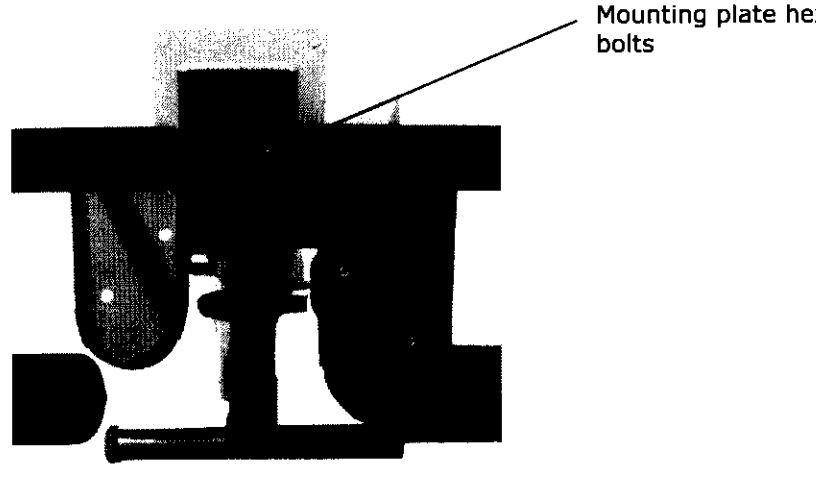

Figure 14 Controller Mounting Plate

2. Fit the Controller to the Controller mounting plate using the three screws supplied.

3. Plug the Controller power cable into the back of the Controller.

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Adjust the height of the safety handles

When you use the RT300-S System, you need to sit upright, and be able to comfortably reach and use the handles and controller.

The safety handle's extension section can be moved up or down to a height that suits you.

To adjust the height of the safety handles:

1. Turn the height adjustment knob counter-clockwise until the handle extension section is loose.

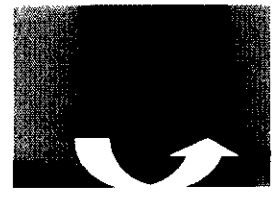

Figure 15: Adjusting the height

2. Slide the handle extension section to the height you require.
3. Turn the height adjustment knob clockwise until the handle extension section locks into place.

Adjusting the pedal crank radius

Standard crank radius system

The RT300-Scomes with a pedal crank which can be adjusted in 2 steps. Use a cone wrench (size 13) to set the optimal crank radius.

Figure 16 Cone wrench

Note that the right crank has a right-hand thread (turn it anticlockwise) and the left crank a left-hand thread (turn it clockwise). Please tighten the screws again firmly.

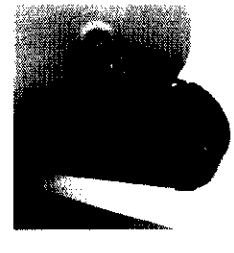

Figure 17 Standard crank radius adjustment

Make sure that the crank lengths on both sides are equal. Depending on the nature of the patient's condition, asymmetrical crank lengths may sometimes be of benefit. With an amputated leg it can be necessary to remove one pedal completely.

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Hand adjustable crank radius system

The pediatric version of the RT300-Sincludes as standard a hand adjustable crank radius system (no spanner is required). This is an option on the adult RT300.

The hand adjustable crank radius can be adjusted as shown in Figure 18

1. Open the locking pin
2. Move the footrest to the desired position on the crank and **tighten the locking pin firmly!**
3. Adjust the opposite pedal in the same way.

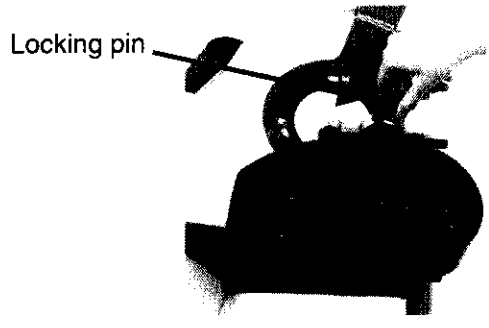

Figure 18 Pedal crank radius adjustment

Make sure that the crank lengths on both sides are equal. Depending on the nature of the patient's condition, asymmetrical crank lengths may sometimes be of benefit. With an amputated leg it can be necessary to remove one pedal completely.

Adjusting pediatric pedals

Two hex wrenches are provided for adjusting the pediatric pedals.

Figure 19 Pediatric pedal adjustment tools

The angle of the calf rest can be adjusted in three dimensions as shown in **Figure 20**.

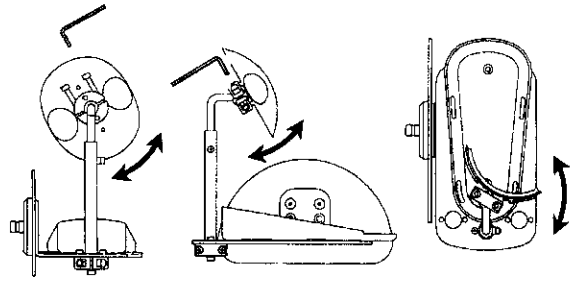

Figure 20 Calf support angle adjustment

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The plastic foot plate can be removed by detaching it from the retaining Velcro. The angle of the plastic foot plate can be adjusted by reattaching it at the required angle using the retaining Velcro provided.

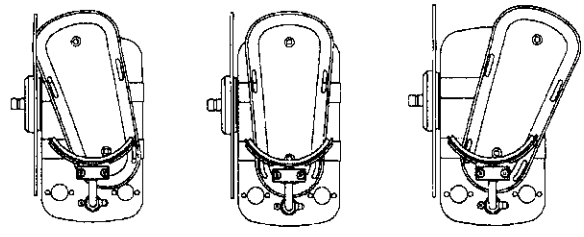

Figure 21 Foot plate angle adjustment

Make sure that the plastic foot plate is firmly attached by the Velcro. Press firmly!

The position of the calf rest on the foot plate assembly can be adjusted as shown in (inner, middle and outer positions).

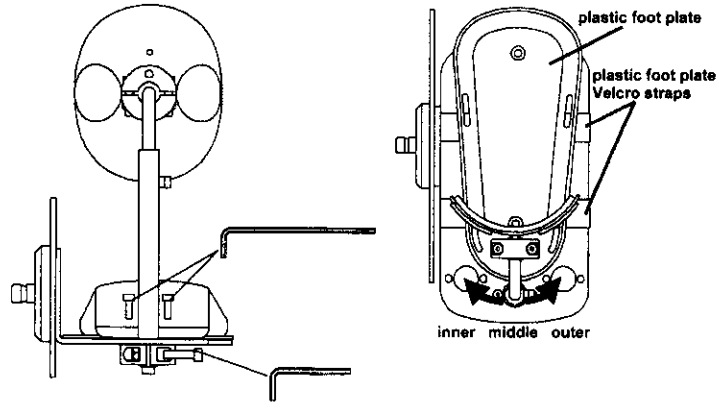

Figure 22 Calf rest position adjustment

The height of the calf rest can be adjusted as shown in Figure 23.

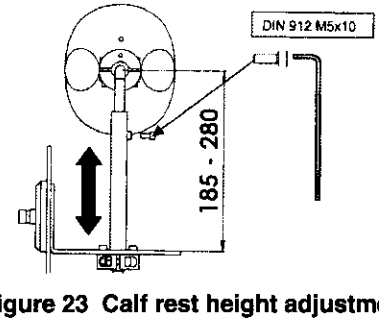

Figure 23 Calf rest height adjustment

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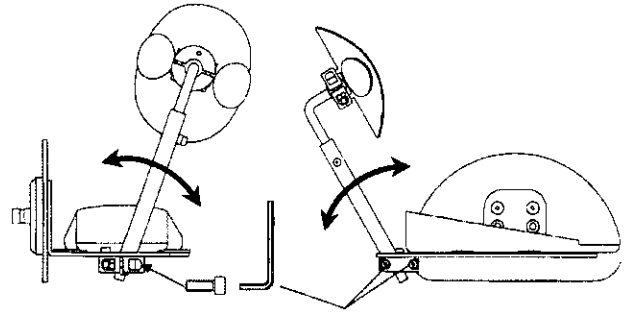

Figure 24 Calf rest angle adjustment

The height of the foot rest assembly can be adjusted as shown in figure Figure 25.

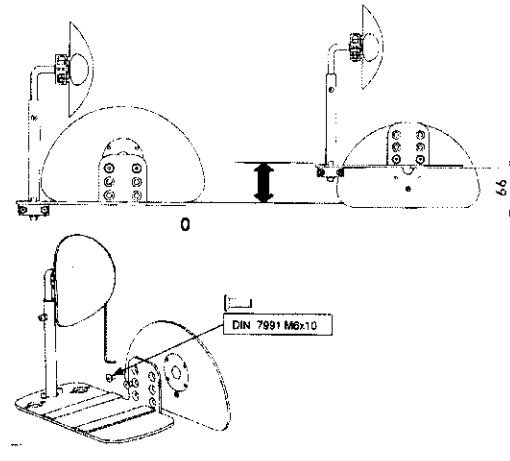

Figure 25 Foot plate assembly height adjustment

The feet must be strapped into place within the plastic foot rests using the Velcro straps shown in Figure 26.

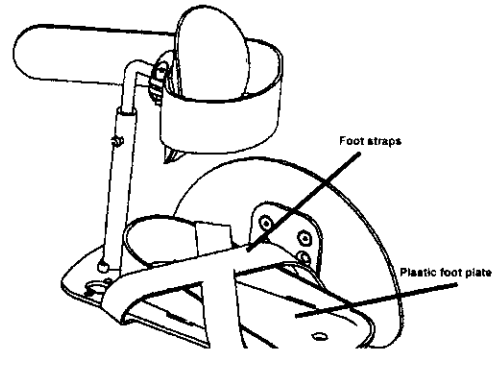

Figure 26 Foot straps

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Base of support

The stability of the RT300-Scan be increased by extending the stability bracket. This is especially useful when the upper extremity crank is to be used.

To extend the base of support:
1. Tip the RT300-Sup over on its castors
2. Loosen the two hex bolts with the hex key provided
3. Pull out the cross bar as far as needed but do not extend it beyond the mark.

Figure 27 Hex bolts and cross bar for stability adjustment

Connecting the Power

To connect the power:

1. Use the power cord provided to connect the RT300-S System to a power outlet.

2. The system is intended to be left connected to a power outlet so that the Controller's internal battery remains charged. The system will automatically switch off shortly after a therapy session.

Figure 28: Power connection

Never pull on the power cord. Always grip and pull the plug to disconnect the power cord from the power outlet.

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Fitting the Equipment

Using Surface Electrodes

The RT300-S System provides stimulation through adhesive surface electrodes placed on the skin over the following muscle groups:

- right and left gluteals
- right and left hamstrings
- right and left quadriceps

An initial 6 month supply of surface electrodes is provided with the RT300-S.

Before you fit the surface electrodes to your body, **you must** read the *Warnings, Precautions and Safety Measures* section at the front of this guide. Also read the following sections – *Surface Electrode Placement Precautions* and *Caring for Surface Electrodes.*

Surface Electrode Placement Precautions

- If there is poor contact between your skin and an electrode, or an electrode does not adhere to your skin, you may need to trim hair from the electrode site. It is recommended you clip, not shave, the hair.
- Following each session, always check electrode sites for any redness or other adverse reactions. If your skin becomes irritated, move the electrode to a slightly different area until the irritation clears. If irritation persists, or you experience a burn, contact your clinician.
- Do not use any surface electrodes that are smaller than those provided with the RT300-S System.
- Renew electrodes after 10-15 uses. See page 8 for re-ordering information.
- Periodically check the electrodes are in full contact with your skin. You can use an elastic strap to help secure an electrode, however, if an electrode repeatedly fails to adhere properly, replace it with a new one.
- Rough edges on a surface electrode may also cause electrical burns so replace the electrode if this occurs.
- Be especially careful to check the condition of the electrodes that you use on your gluteal muscles as these are subject to more wear.

Caring for Surface Electrodes

- Use the self-adhering surface electrodes supplied by Restorative Therapies Inc. See the details in Table 3 for ordering new electrodes.
- A surface electrode is expected to last for 10 to 15 applications with normal use. Throw a surface electrode away if it adheres poorly or shows signs of wear and tear (e.g. rough edges).
- Gently remove a surface electrode by lifting it from one corner. Do not pull on the connecting lead as this may damage the connection.
- Replace surface electrodes on the plastic carriers when they are not in use.

See the surface electrode pack for more instructions on use, care and storage.

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Fitting the Surface Electrodes

To use the RT300-S System, you must have all 12 surface electrodes correctly fitted to your body, as shown in Figure 29.

To fit the surface electrodes:

1. Make sure the skin where the electrodes are to be placed is clean and dry. Remove any lotion with an alcohol wipe.
2. Peel the plastic carrier off a pair of surface electrodes.
3. Place the two surface electrodes on your body at the correct location. (See Figure 29).
4. Apply light finger pressure to the entire surface of each surface electrode to make sure it is in full contact with your skin.
5. Repeat steps 2 to 4 for the remaining five pairs of surface electrodes.

Where to Place Surface Electrodes

Figure 29 indicates the sites for electrode placement. However, as placement varies slightly between individuals, your clinician will determine the locations that provide the most effective stimulation for you.

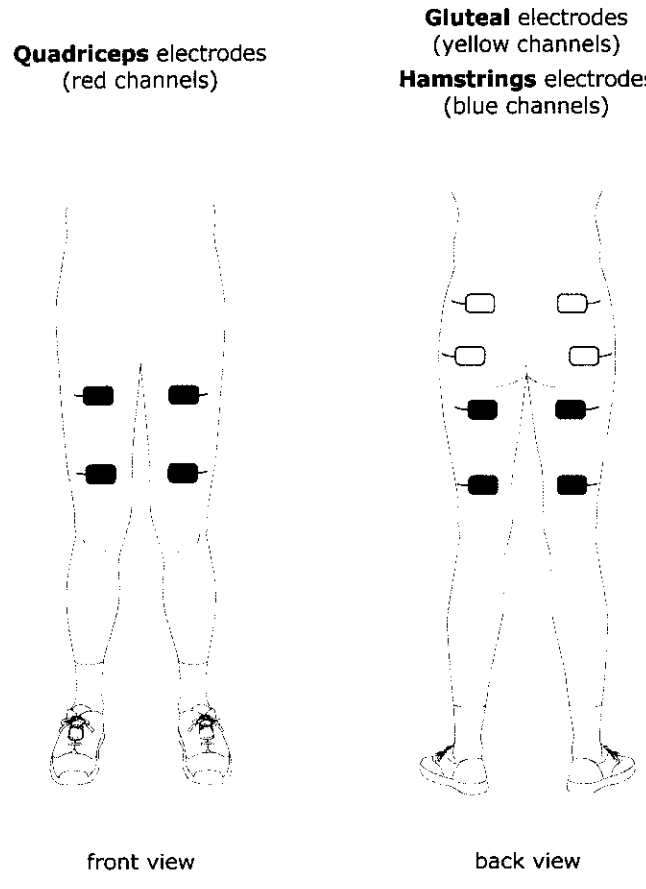

Figure 29: Surface electrode sites

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Connecting the surface electrodes to the ergometer

Simulation Cable Set

Once you have fitted all 12 surface electrodes, connect them to the stimulation cable.

One end of the stimulation cable splits into 12 leads. Six leads for the left side of your body and 6 leads for the right side. Each lead is color coded and labeled with two letters.

Figure 30: Color-coded, marked leads

Table 4 shows how the color and letters on a lead represents a particular muscle group.

Letters	Color code	Muscle Group
LG	Yellow	Left Gluteals
LH	Blue	Left Hamstrings
LQ	Red	Left Quadriceps
RG	Yellow	Left Gluteals
RH	Blue	Left Hamstrings
RQ	Red	Left Quadriceps

Table 4: Color-code/letter on stimulation cable leads

Each lead must be fitted to the corresponding surface electrode according to the color and letter.

Leads with an "R" on the label are for the right side of your body. Leads with an "L" on the label are for the left side of your body.

Examples

A surface electrode fitted to your **right** quadriceps connects to a **red** lead marked **RQ**.

A surface electrode fitted to your **left** gluteals connects to a **yellow** lead marked **LG**.

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Connecting the Surface Electrodes

To connect the stimulation cables:

1. Using the color-coding and letters on each lead as a guide:
   - connect the leads from the stimulation cable to the electrodes placed on your body.

Make sure all lead pins are fully inserted (see Figure 31). Press your finger tip across the top of the socket to be sure.

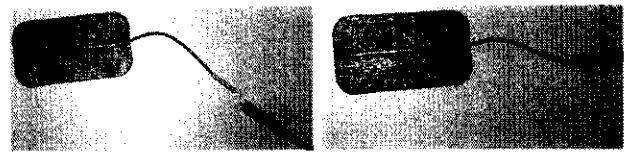

Figure 31: Connecting a lead to an electrode

2. Plug the stimulation cable into the outlet on the ergometer – it will click into place.

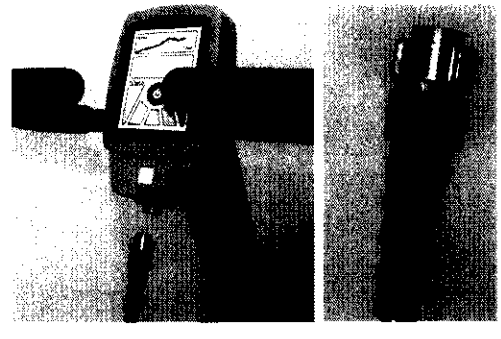

Figure 32: Connecting the cable set to the ergometer

The cable set can only be plugged into the ergometer one way. A square notch on the end of the plug helps you identify the right way up.

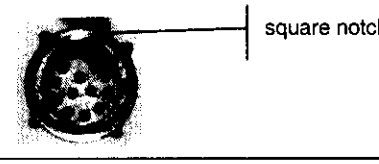

Figure 33: End of plug – right way up

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Using the RT300-S System

Using the RT300-S System involves:

- initial software installation
- correctly positioning yourself on the ergometer and making any necessary adjustments
- fixing your feet in the footrests and your legs in the calf rests
- understanding what happens during a typical therapy session
- understanding the functions of the RT300-S controller / stimulator
- starting and stopping a session
- knowing what happens if muscle spasm occurs
- being aware of the possibility of autonomic dysreflexia

Initial software installation

When you first power on the RT300-S it is necessary to:

- calibrate the Controller's touch screen
- install the software from the "flash disk"

The procedure to do this is described below.

Once you have installed the software you should leave the RT300-S connected to mains power. This will ensure that the RT300-S controller's back up battery remains charged.

If you disconnect your system from mains power for more than an hour you will need to repeat this installation procedure.

Calibrate the touch screen

1. Follow the instructions provided by the Controller
   - Using the Stylus touch the screen in the positions requested by the controller.
   - Cut and paste the demonstration appointment
   - Select your time zone

Install the software

Follow the 8 steps listed overleaf:

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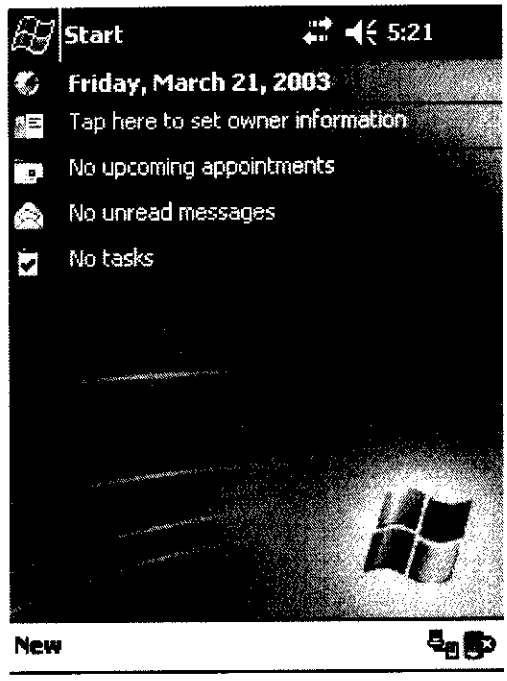
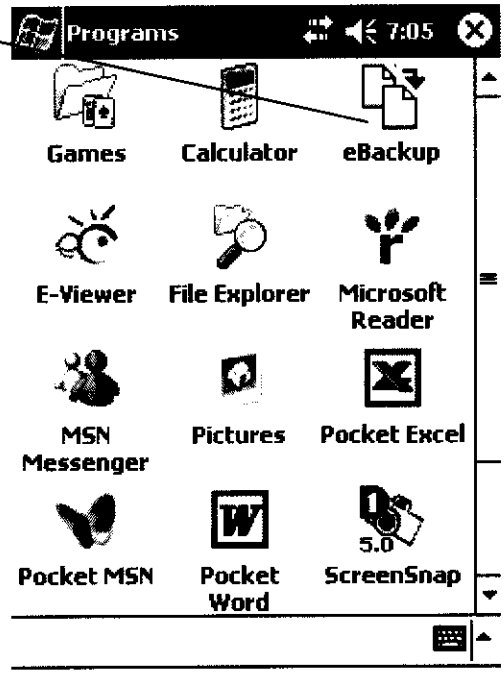
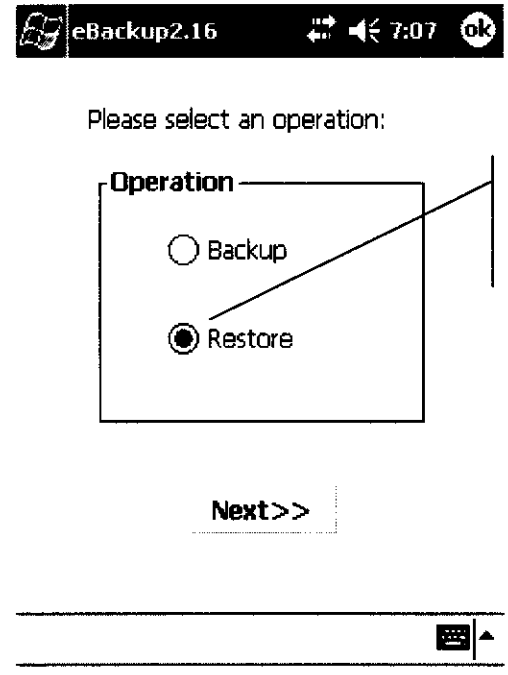
1. Press the flag



2. Press "Programs"

3. Press "eBackup"





4. Select "Restore"

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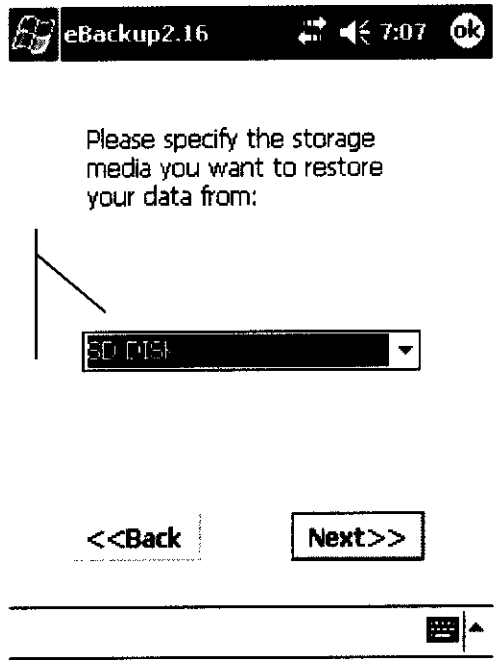
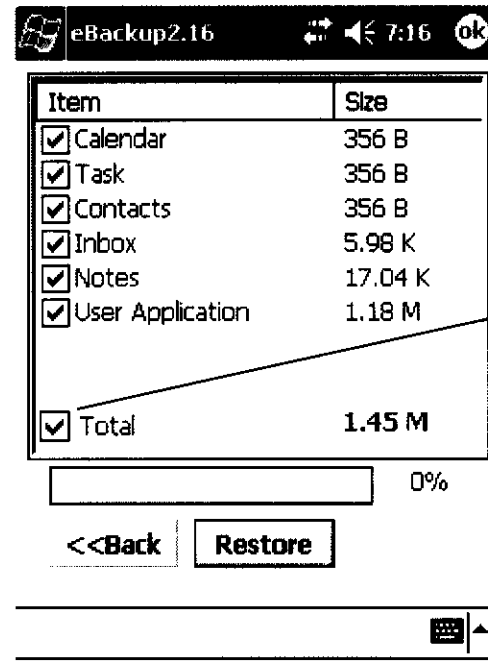
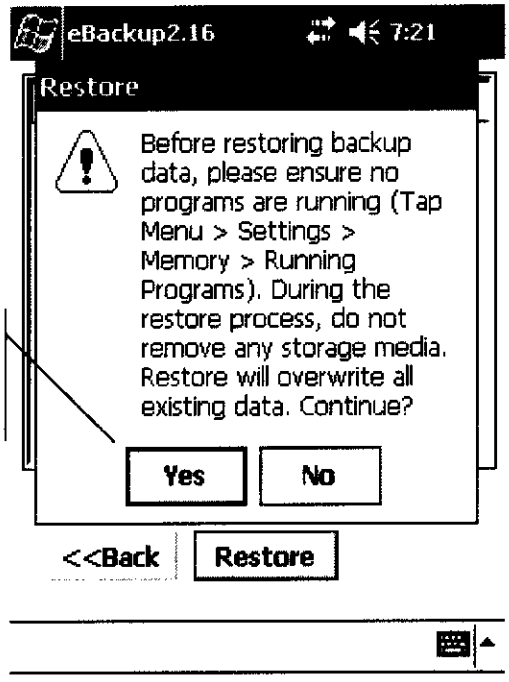


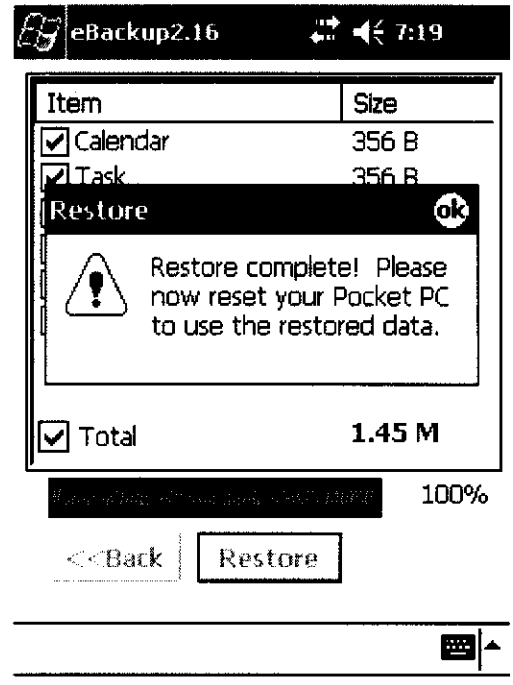
5. Select "SD DISK"



6. Select "Total"



7. Press "Yes"



8. Press the Reset button on the back of the controller

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Positioning on the Ergometer

Getting into the correct position on the ergometer involves:

- setting the distance between your wheelchair and the ergometer
- strapping your feet into the footrests and legs against the calf rests

Setting the distance

The distance you should set between your wheelchair and the ergometer is affected by:

- the type of wheelchair you use
- the length of your legs
- your height

The most effective way to check you are correctly positioned is to check the angle of your knee joint when your foot is in the footrest and your leg is fully extended.

To set the correct distance:

1. Place your foot in a footrest, resting your leg in the leg guide.
2. Move your wheelchair slowly back or forward until your knee joint reaches a 45° angle, as shown in Figure 34.

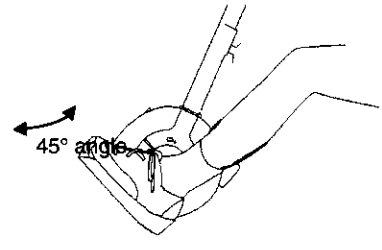

Figure 34: Knee joint at 45° angle

Using the Calf Rests and Footrests

It is recommended you always wear shoes (e.g. running shoes) when using the RT300-S System. The footrests are designed to accommodate shoes, while the calf rests help support the legs.

Both the footrests and calf rests have straps for added support and safety.

The RT300-S System provides help by automatically positioning the pedals ready for you to place your feet in the footrests.

Do not put your whole body weight on the pedals when you place your feet in the footrests.

To use the footrests and calf rests:

1. Open the straps on the footrests and calf rests.

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2. Touch the controller screen to turn the system on.

3. Keep your hands clear of the pedals and tap Start. The left pedal automatically moves into position and the controller displays the following message.

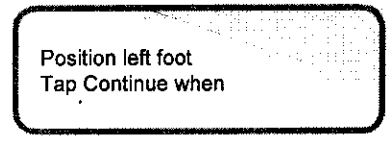

Figure 35: Message to position foot

4. Place your left foot in the footrest, resting your leg against the leg guide.

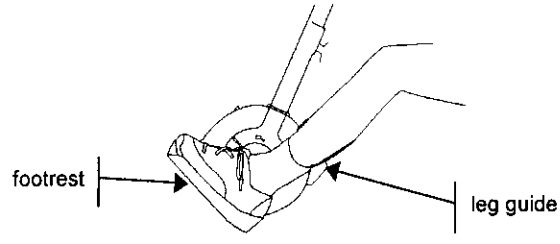

Figure 36: Foot and leg position

5. When you are correctly positioned, fasten the straps on the footrest and leg guide.

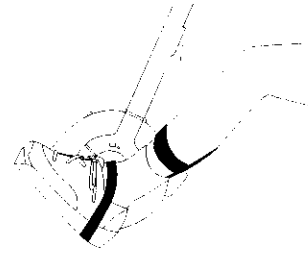

Figure 37: Straps fastened on footrest and leg guide

6. Keep your hands clear of the pedals and tap Continue. The right pedal automatically moves into position and the controller displays the following message.

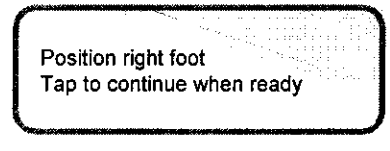

Figure 38: Message to position foot

7. Repeat steps 4 to 5 for your right foot.

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Therapy Sessions

RT300-S System therapy sessions help you to pedal using your own muscle power, providing the opportunity to make continual progress over the course of your therapy plan.

The RT300-S System is designed with pre-set (default) therapy settings. Your clinician may also make adjustments to settings like the:

- length of your therapy session
- amount of pedal resistance you experience during a therapy session

Inbuilt Safety Measures

At the end of each session, the RT300-S System automatically switches off. There are also inbuilt safety measures to help protect you during therapy. You should be aware that:

- if the system registers muscle fatigue, the ergometer's motor takes over for the remainder of the session. You will see that the display swaps from displaying "Active cycling" to "Passive cycling".
- if an electrode falls off, the system immediately pauses by ceasing stimulation and switching off the motor. An error message is displayed on the controller Therapy Session screen to let you know what has happened. After you fix the problem, tap Start to resume the session.

Starting and Stopping a Therapy Session

Before every therapy session, always empty your bladder to minimize the risk of autonomic dysreflexia occurring. If you have any concerns, talk to your clinician.

A therapy session involves:

- tapping Start on the controller to start the session
- knowing how to stop a session early if needed
- knowing what happens during muscle spasm

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Starting a Session

To start a therapy session:

1. Touch the controller screen to turn the system on.
2. Tap Start. The ergometer starts operating and your therapy session begins.

Stopping a Session Early

The RT300-S System automatically stops once the end of the session is reached. However, you can stop the system mid-session if you wish.

To stop a therapy session early:

1. Tap Stop. The session is ended.
2. When you want to start again, tap Start. If you restart within 5 minutes the therapy session will resume from where you left off. If you stop for longer than this, the system re-starts the session from the beginning.

Handling Muscle Spasm

The RT300-S System recognizes when muscle spasm occurs and pauses by stopping the motor and muscle stimulation.

Once the muscle spasm passes:

1. Tap Start to resume the session.

If you tap Start after 5 minutes have passed, the system re-starts the session from the beginning.

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Using the Controller

The controller's Therapy Session screen shows what is happening at any particular time during a therapy session. The controller's touch-sensitive screen allows you to:

- start and stop a session
- see any warnings or errors that occur
- check how your therapy session is going

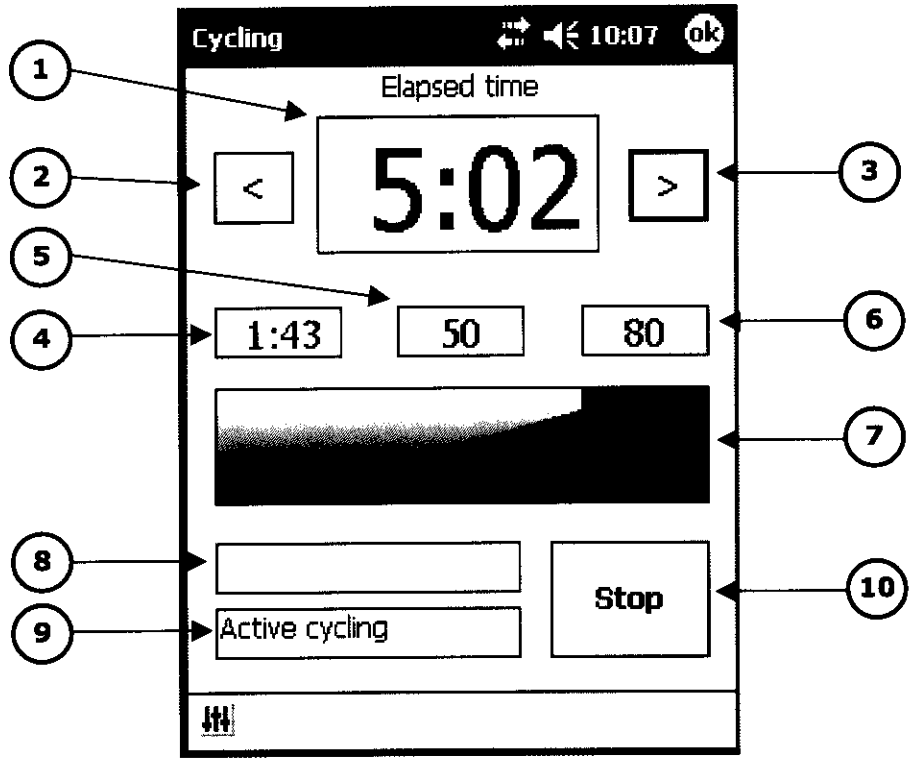

Figure 39: Controller - Therapy Session screen

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1. Main display window shows one of:
   - Elapsed time
   - Remaining time
   - Cycling velocity
   - Stimulation level
2. Cycles the display data to the left
3. Cycles the display data to the right
4. Secondary display window (shows time remaining in Figure 39). Tap this window to transfer the data to the main display window.
5. Secondary display window (shows cycle velocity in Figure 39). Tap this window to transfer the data to the main display window.
6. Secondary display window (shows stimulation level in Figure 39). Tap this window to transfer the data to the main display window.
7. Graphical display of data
   - The green tracing shows your stimulation level history
   - The blue area represents time remaining
8. User advisory in the format <State> in 54321 seconds
9. Therapy State:
   - Ready
   - Warm up (initial passive cycling)
   - Active cycling (stimulation operating)
   - Passive cycling (fatigue has been detected)
   - Cool down
   - Finished
10. Start and Stop button shows "Start" when the system is stopped and "Stop" when the system is operating.

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Troubleshooting

Resetting the Controller

You may need to reset the RT300-S System controller in some situations, for example, if the controller does not respond when you tap the screen.

To reset the controller:

1. Press the Reset button on the back of the controller.

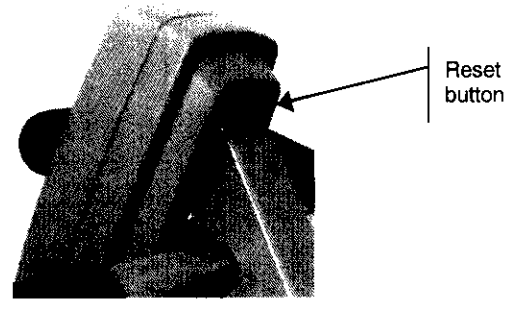

Figure 40: Reset button on controller

2. Wait until the controller displays the Therapy Session screen.

Reinstall the RT300-S software

If you remove power from the RT300-S for over an hour you will need to re-initialize the system as described in "Initial software installation" on page 28.

Controller Sounds and Messages

The controller notifies you about particular events or errors by:
- playing a sound
- displaying a message

Sounds

Table 5 describes the sounds the controller makes and their meaning.

Condition	Sound
Warning message	Short beep
Error message	Long beep
Tap	Click

Table 5: Controller sounds

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Care of the RT300-S System

Cleaning and Maintenance

Regularly cleaning the equipment prevents a build-up of dirt.

Always unplug the power cord from the power outlet before you start cleaning.

- Never use solvent-based or corrosive on the RT300-S System.
- Wipe the controller screen with a dry clean cloth. Don't use any water - make sure no moisture gets into the controller.
- Use a damp, soft cloth to clean the RT300-S System surfaces.
- Take care not to damage or remove labels during cleaning.
- After 2 years (or 2,000 hours) of use, the controller displays a message to let you know that it is time for a maintenance check. Contact RTI Technical Support to arrange the service.

Storing the RT300-S

When you are not using the RT300-S System:

- store the RT300-S System equipment in temperatures between −20°C (−4°F) and +50°C (+122°F)

Moving the RT300-S System

Always unplug the power cord from the power outlet and the RT300-S System before moving the device.

The RT300-S System is fitted with castors and a handle to facilitate moving the RT300-S System short distances over a smooth surface. Hold the handle with one hand and place the other hand under the power unit.

To move the RT300-S System, tilt it backwards as shown in figure and push it in front of you.

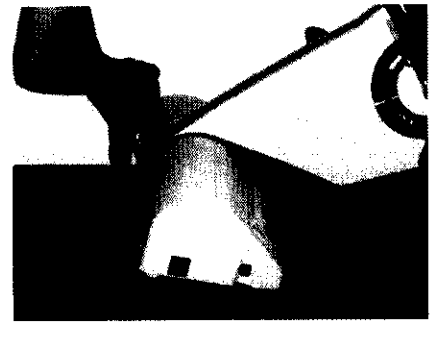

Figure 41 Moving the RT300-S System

The castors are not suitable for the transport on uneven or rough surfaces.
Two people are required to carry the RT300-S System up or down stairs.

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Shipping Instructions

The RT300-SCycle Ergometer should be shipped in its original packaging.

The package dimensions are: 27″ x 23.5″ x 19″

The package weight is: 80lbs

Symbols

Symbol	Meaning
	Fragile
	See instructions for use
2004-05-30	Date of manufacture
+50°C (+122°F) -20°C (-4°F)	Temperature limit
LOT 12345	Lot number or Batch number
REF 12345	Reference number or Part number
IN 123456	Serial Number
Model FA100052	Model Number
	Type B Applied Part

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Technical Specifications

	230V	115V
Motorized Ergometer		
Length	31.5" or 80cm	
Width	19.3" or 49cm	
Height	36.2" - 40.6" or 92 - 103cm	
Weight	RT100 80lbs or 36kg RT100-A 110lbs or 50kg	
Length of pedal: • RT300-S • RT300-S-P (pediatric)	 4.3" or 110mm 4.3" or 110mm	
Speed range	0 - 60 rev/min	
Torque range	Approximately 0 - 12Nm	
Power connection	230V~, 5/60Hz	115V~, 50/60Hz
Power input	160VA	
Fuses	2 x 1,6 A slow	2 x 2,5 A slow
Materials	Aluminum, Steel, Polystyrol, Polyurethane, etc	
Protective type	I	
Degree of protection	Type B	
Safety rating	I PXO	
Noise emission	Lpa ≤ 70dB (A)	
Noise emission value	According to DIN 45635-19-01-KL2	
Conditions: • In use • Transporting/storing	 5°C (41°F) to 40°C (104°F) 0 to 90% Rh 970 to 1030hPa -20°C (-4°F) to +50C (+122°F) 0 to 90% Rh 970 to 1030hPa	 5°C (41°F) to 40°C (104°F) 0 to 90% Rh 970 to 1030hPa -20°C (-4°F) to +50C (+122°F) 0 to 90% Rh 970 to 1030hPa
Controller		
Display / interface	Touch-sensitive LCD	
Communications	Wireless enabled (Bluetooth WiFi)	
Operating system	Windows CE 2003	
Inbuilt stimulator		
Maximum voltage output	200V	
Number of channels	6	
Current output per channel	0 - 140mA across a nominal 1 kΩ	
Waveform type	Biphasic, charged balanced	
Pulse frequency	1 - 100Hz	
Phase width	0 - 500μs	

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Printed in USA
LB100108 ISS1 RV100083 OCT2004

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Exhibit F Package label

The package label overleaf is placed on the outside of the RT300-S system shipping carton (Figure 12).

The package labeling for the Controller / Stimulator box is shown below.

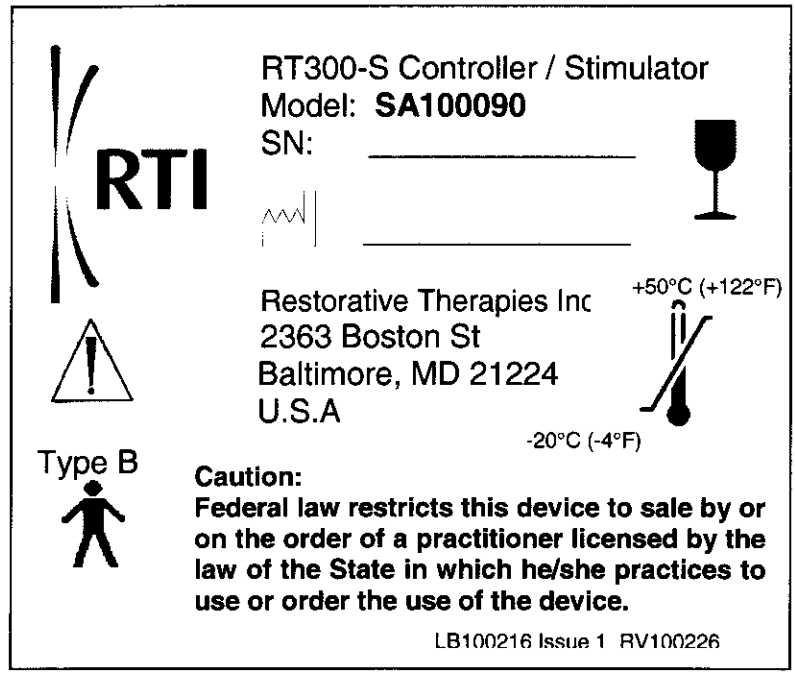

Figure 10 Controller Stimulator package labeling

The package labeling for the electrodes is shown below.

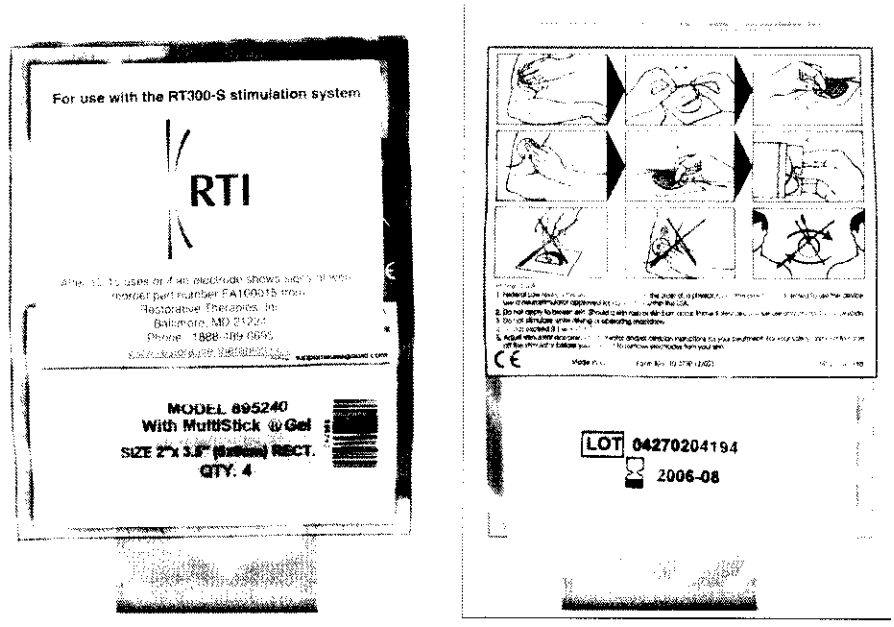

Figure 11 Electrode package labeling

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<Customer name> <Customer address>	3 +50°C (+122°F) -20°C (-4°F)
Model: RT300-S Quantity: one (1) SN: IN Manufactured in Germany and USA 2004	Voltage 115V 50-60Hz Type B
RTI Manufactured by and for: Restorative Therapies Inc. 2363 Boston St Baltimore MD 21442 U.S.A.	medica Ergometer manufactured by: medica Medizintechnik Blumenweg 8 D-88454 Hochdorf Germany
☐ Documents ☐ Accessories Packed by: __	**Caution:** Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Figure 12 RT300-S system shipping carton label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Exhibit G Engineering Drawings

Ergometer Component

Item	Description
2	Electronics cover
4	Right foot rest / pedal
5	Left foot rest / pedal
7	Crank radius
10	Controller stimulator connection
11	Lower safety arm support bracket
12	Upper safety arm support bracket
14	Carnk bolt cover
19	Crank retaining bolt
20	Crank washer
21	Safety arm adjustment bolts

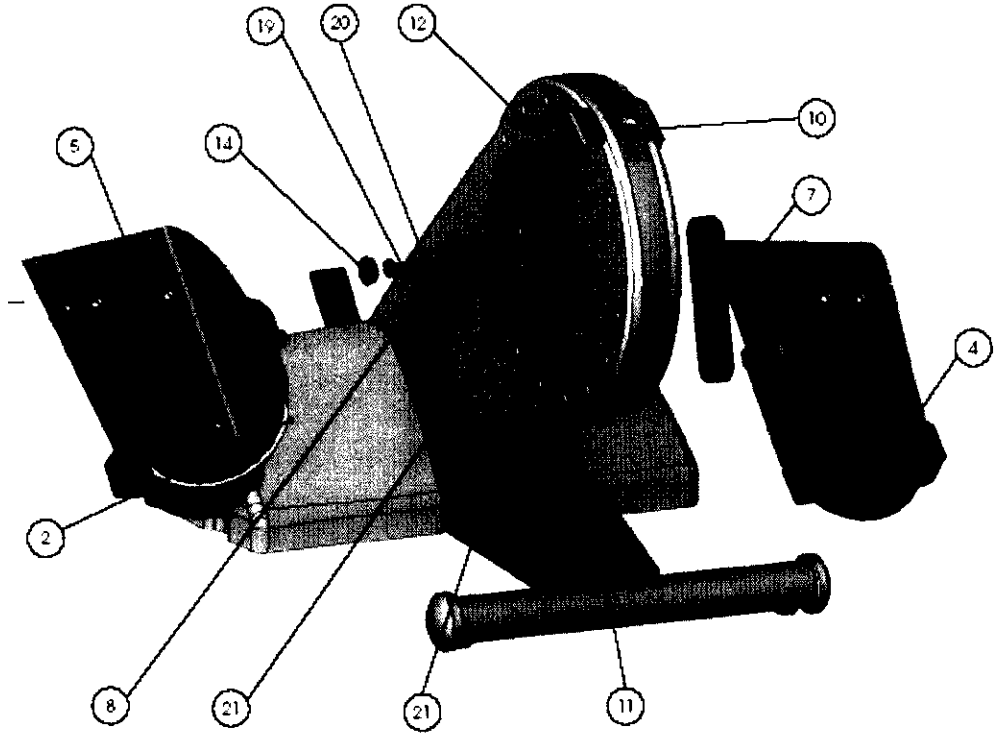

Figure 13 Ergometer component base unit

Item	Description
2	Safety handle support arm
3	Safety handle extension
4	Controller stimulator mounting plate
6	Safety handle
7	Safety handle height adjustment knob
8	Hex key
10	Safety handle retaining bolts

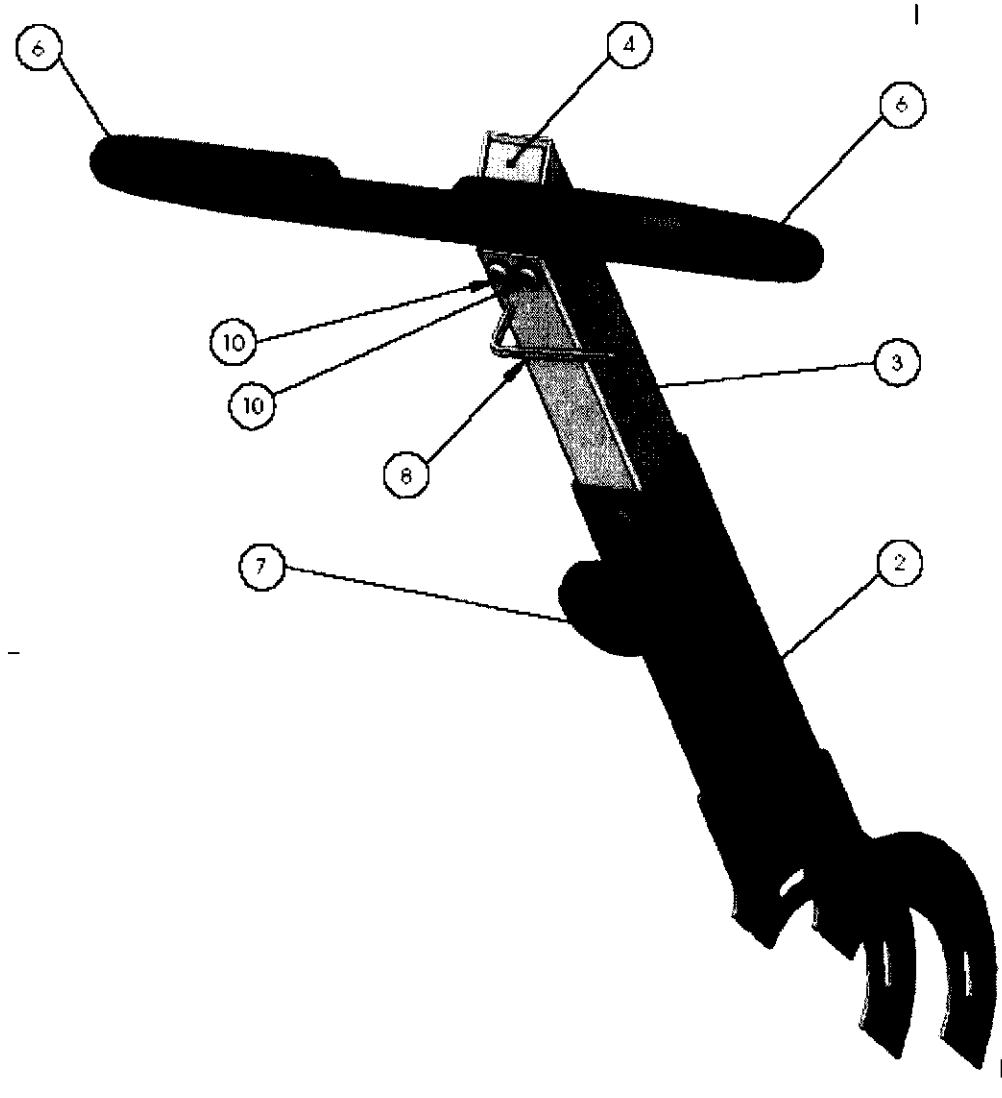

Figure 14 Ergometer comonent safety handle assembly

Item	Description
2	Controller stimulator mount plate
3	Motor cover
6	Left pedal (pediatric)
7	Right pedal (pediatric)
17	Safety arm retaining bolts

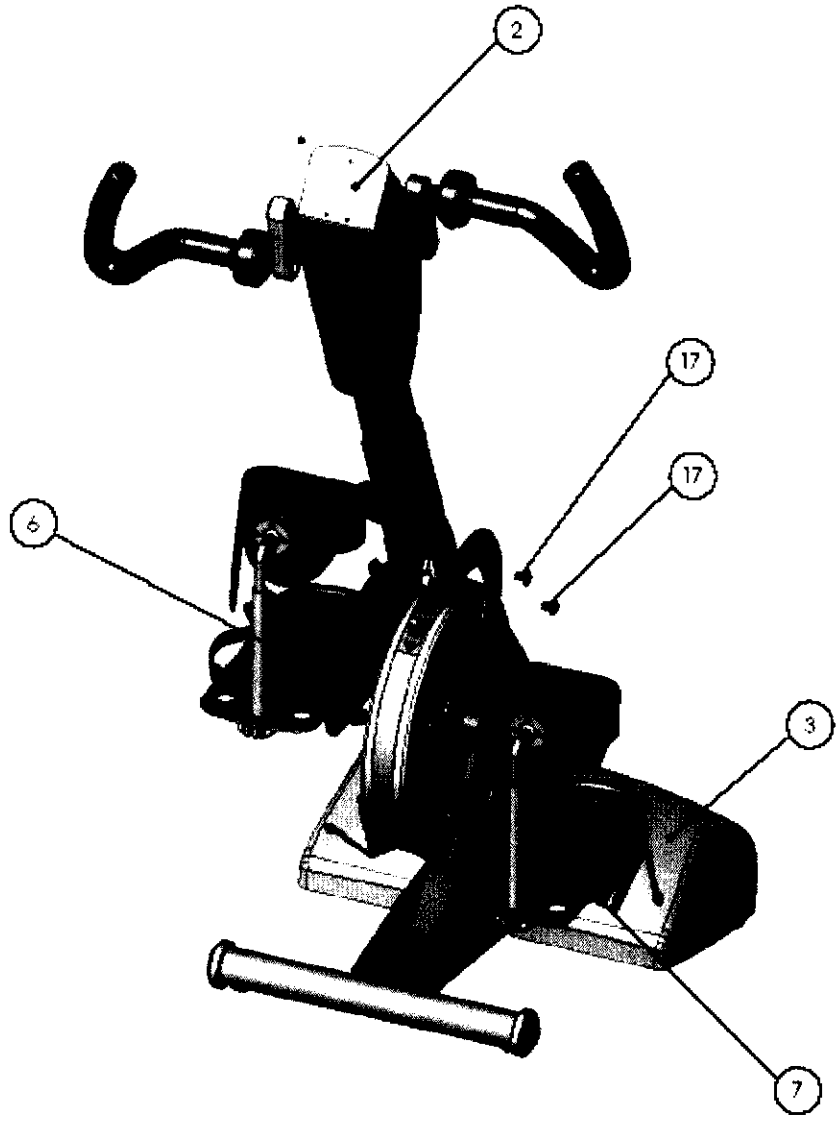

Figure 15 Ergometer component assembly

Controller / Stimulator Component

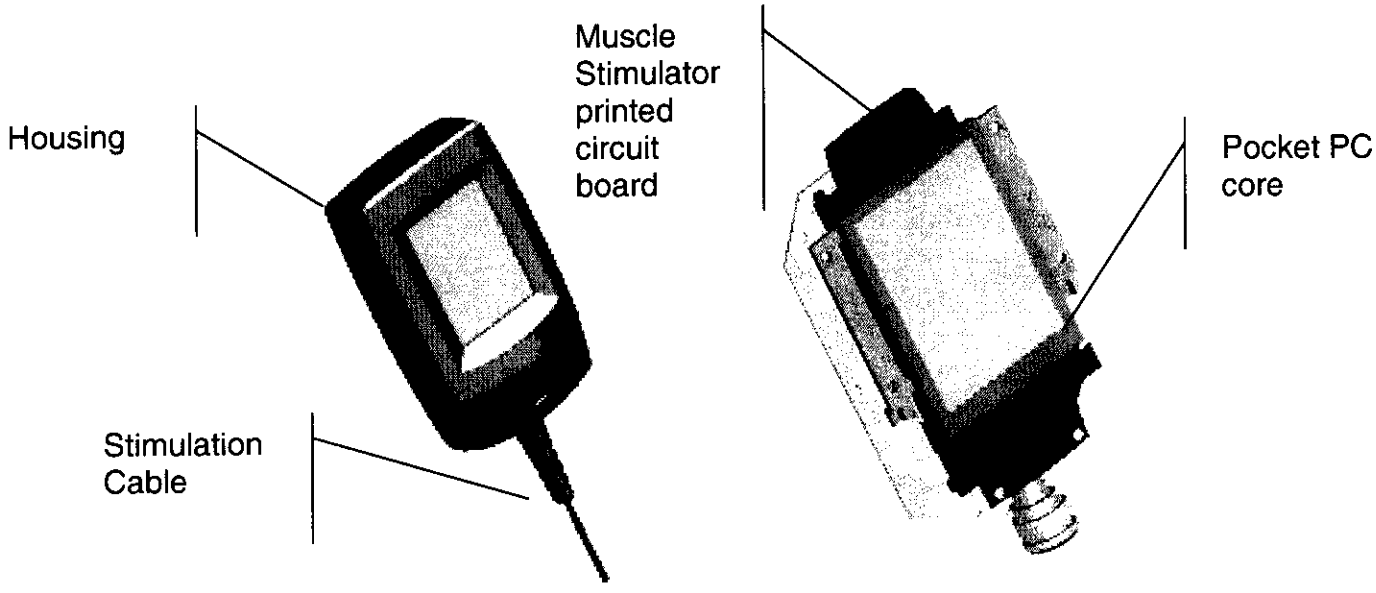

Figure 16 RT300-S Controller-Stimulator with Stimulation cable

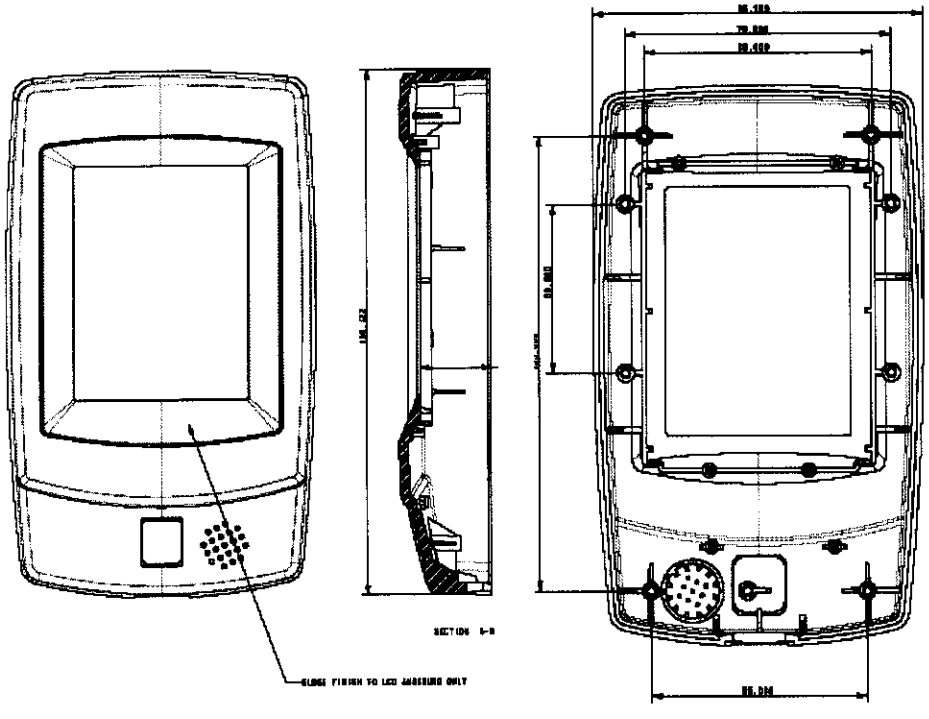

Figure 17 RT300-S Housing design detail

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[redacted]

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Stimulation Cable Component

The stimulation cable (part number FA100091) is used to connect the cutaneous electrodes to the controller / stimulator.

A circular "Lemo" snap fit connector is used at the controller / stimulator end

- Two independent loop back connections in the connector are used by the stimulator to confirm stimulation cable connection prior to enabling stimulation

Two millimeter pins are provided at the electrode end

- The pins are recessed within a shield to prevent the possibility of contact by a finger
- Each shield is color coded and labeled to aid in correct fitting

A 270mm long coil section is provided to provide controlled cable slack during use.

The voltage rating of all stimulation cable components exceeds 300V. The maximum system output voltage is 200V.

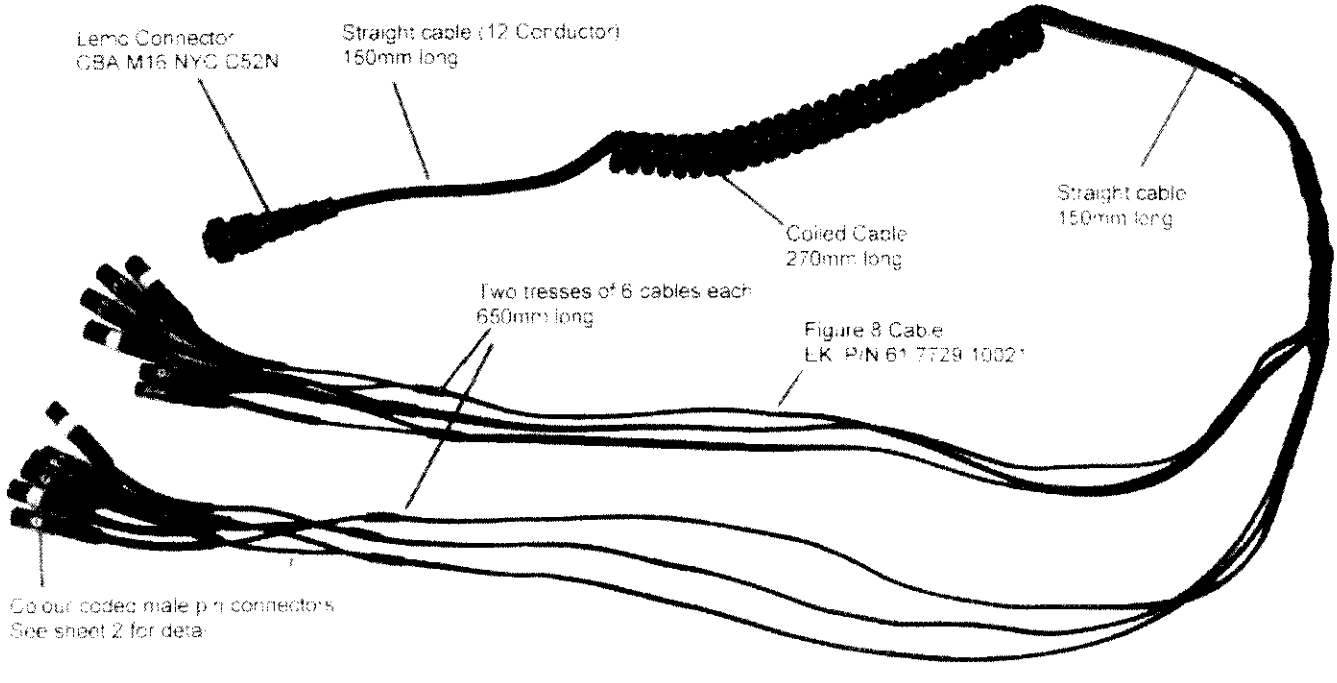

Figure 20 Stimulation cable assembly, part number SA100091

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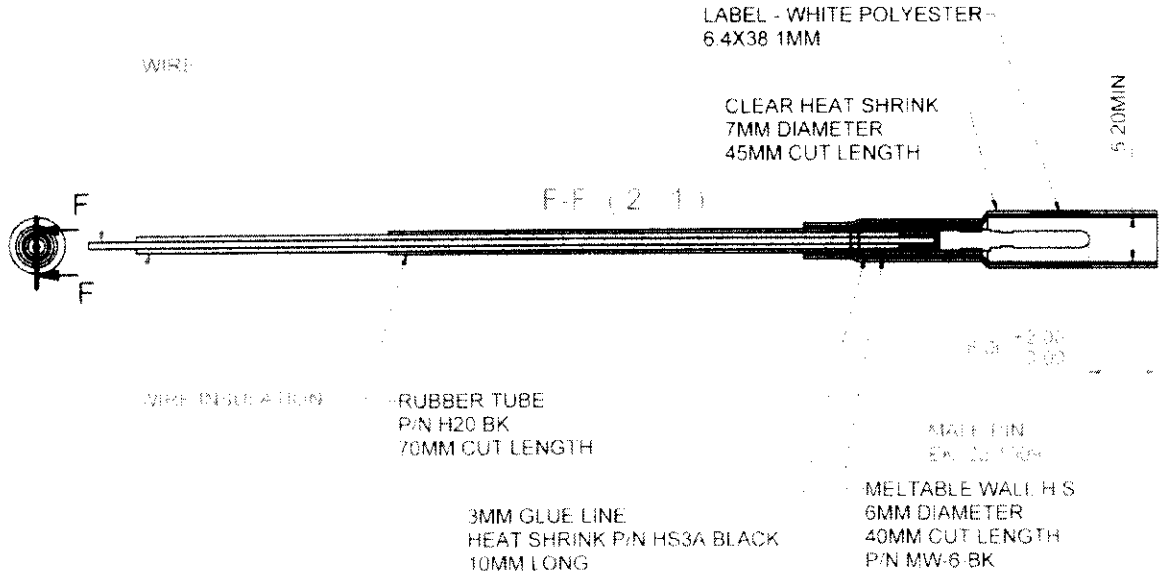

Figure 21 Stimulation cable distal end assembly detail

Pin Number	Label	Colour/Comment
1	LQ	Red
2	LG	Yellow
3	LH	Blue
4	LQ	Red
5	LG	Yellow
6	LH	Blue
7		S/C TO 8
8		S/C TO 7
9		S/C TO 10
10		S/C TO 9
11	RQ	Red
12	RG	Yellow
13	RH	Blue
14	RQ	Red
15	RG	Yellow
16	RH	Blue

NOTE:
PINS 7 AND 8 ARE SHORTCIRCUITED
PINS 9 AND 10 ARE SHORTCIRCUITED

Figure 22 Stimulation cable pin out details

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Pediatric Pedals

The pediatric pedals allow increased adjustment flexibility. This is fully described in Exhibit E RT300-S User's Guide, page 20. The images below illustrate the range of adjustments that are provided.

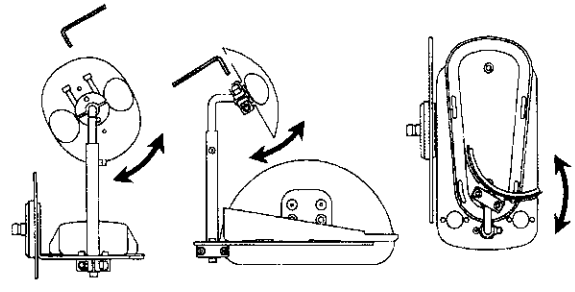

Figure 23 Calf support angle adjustment

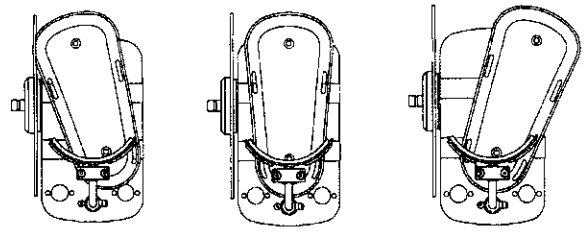

Figure 24 Foot plate angle adjustment

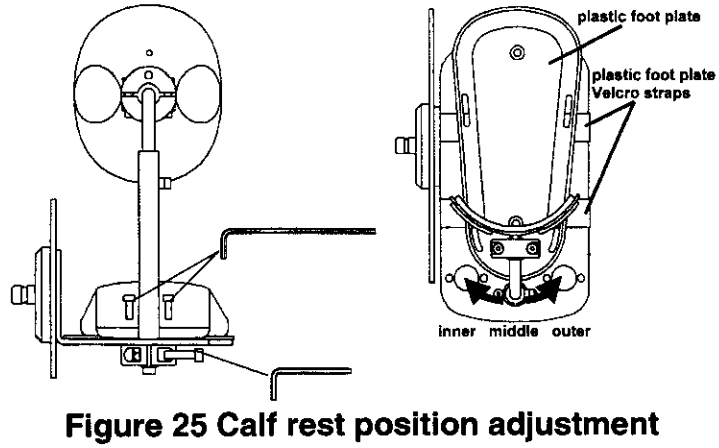

Figure 25 Calf rest position adjustment

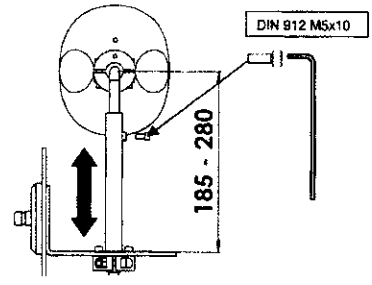

Figure 26 Calf rest height adjustment

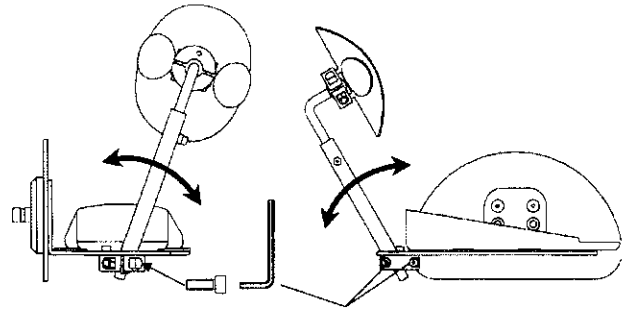

Figure 27 Calf rest angle adjustment

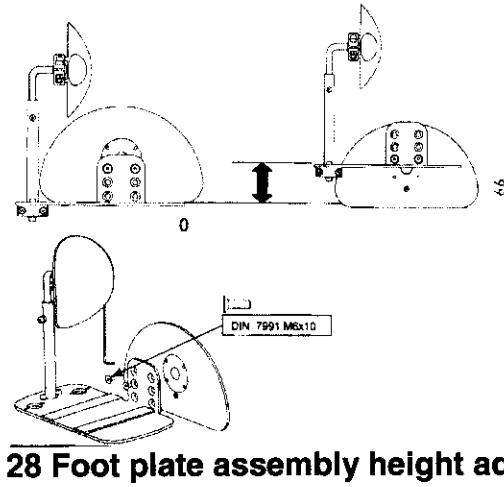

Figure 28 Foot plate assembly height adjustment

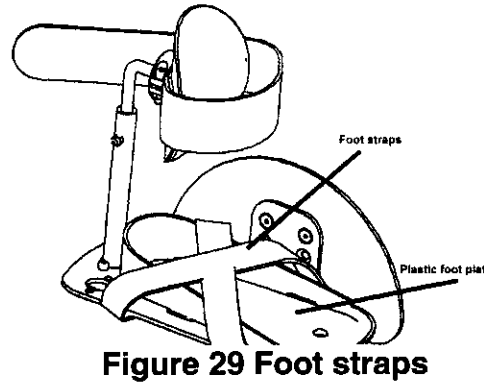

Figure 29 Foot straps

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Ergometer Platform

The ergometer platform (part number FA100091) is designed to provide a means to raise the Ergometer to facilitate better user placement. The platform is usually only required with pediatric wheelchairs which tend to be higher.

The Ergometer platform includes:

- Adjustable height legs
- Notches which mate with the bottom of the Ergometer to hold the Ergometer in place.

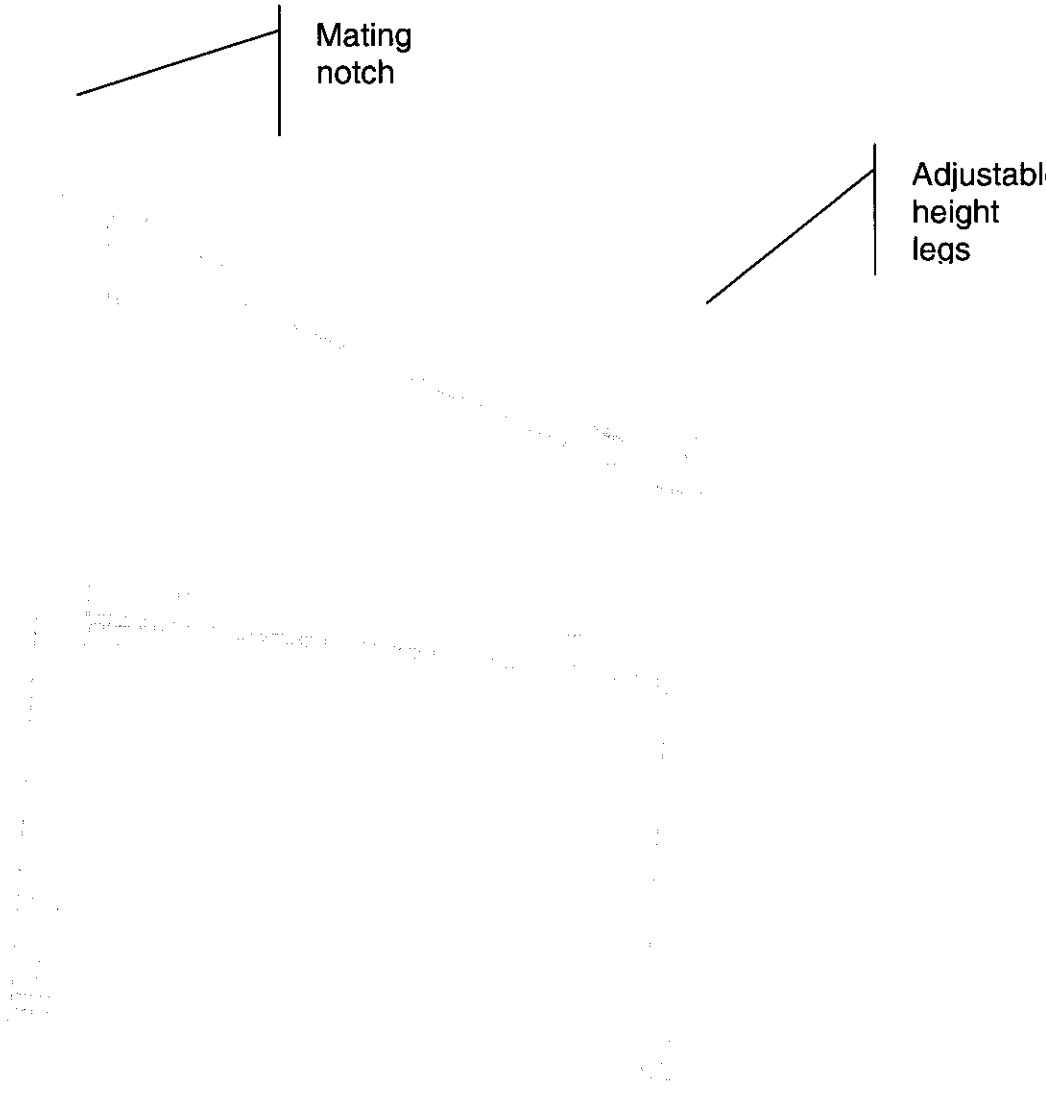

Figure 30 Ergometer platform, part number FA100019

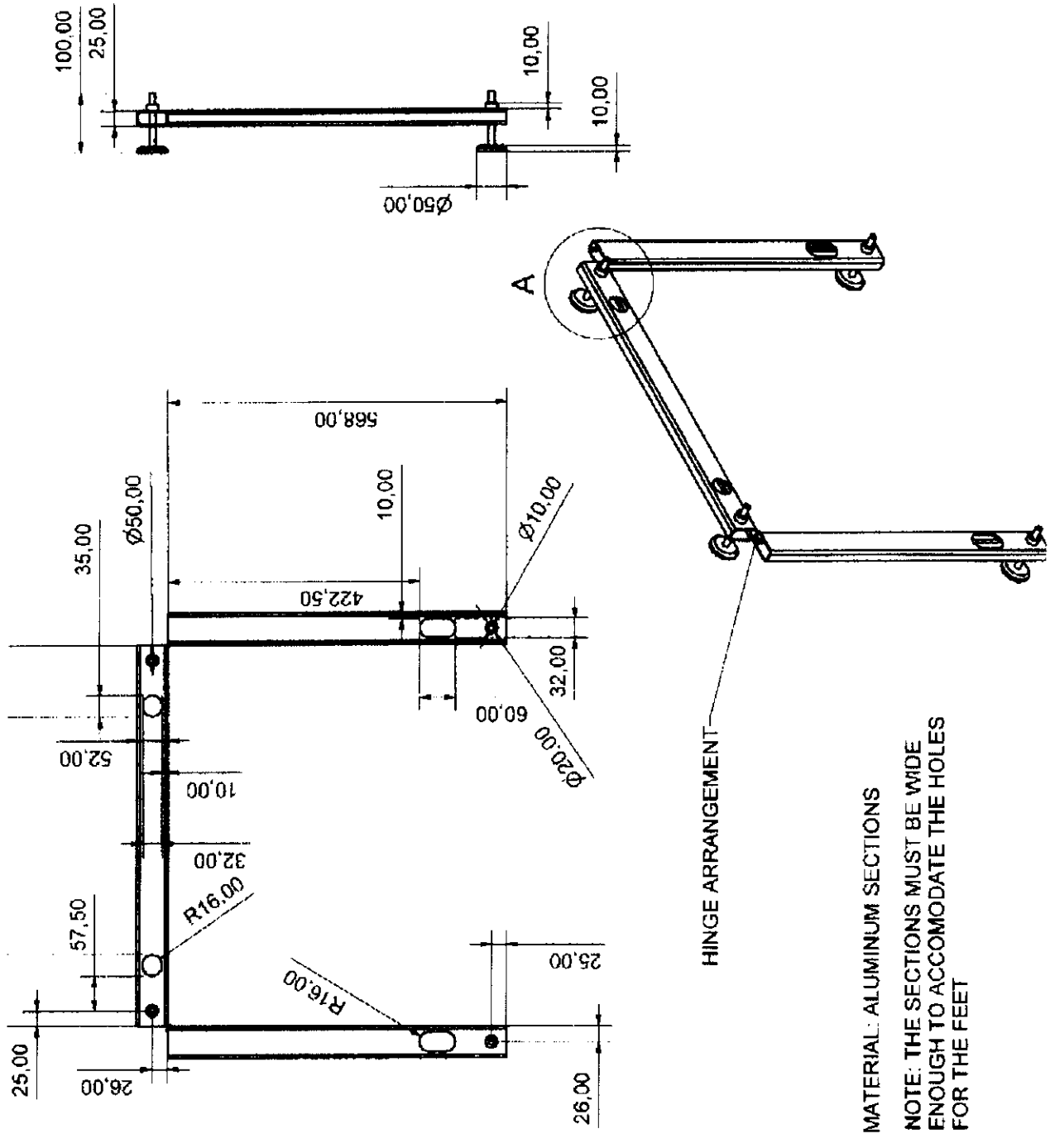

Figure 31 Ergometer platform design detail

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Exhibit H Hazard Analysis

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(b)(4) Hazard Analysis

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Exhibit I System Specification

Questions? Contact FDA/CDRH/OCE/DID at CDRHDFOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Software Specification

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Exhibit J System Test Results

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(b)(4) Software Requirement Specification

(b)(4) Software Requirement Specification

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Exhibit K Software Specification

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(b)(4) Software Design Document

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GUI (Graphical User Interface)
The GUI function is to allow the user to start and stop the therapy session and providing feedback information to the user during a therapy session.

In addition, the GUI allows the clinician to set certain therapy parameters under password protection.

Controller
The role of the Controller is to control:

- state changes (see States below)
- Stimulator component errors passed from the Stimulator Interface
- Ergometer component status information (velocity, crank angle) from the Ergometer Interface
- Send Stimulation commands to the Stimulator Interface
- Send Ergometer commands to the Ergometer Interface
- Maintain cycling velocity during active cycling by varying the stimulation to the users lower extremities.

States

Connecting
During the connecting state the software finds and connects to the two Bluetooth devices that provide a communications link with the cycle ergometer component and the muscle stimulator component.

Ready
This is the idle state for the therapy session. After the software has been initiated and the Connecting state has finished, the software will remain in the Ready state until the user presses the "start" button. Also, when the therapy session has timed out the software returns to the Ready state.

Warm-up
During the Warm-up state the controller sends a command to the Ergometer to initiate cycling at the set velocity for the prescribed warm-up duration.

Active Therapy
Upon completion of the warm-up state the software will transition to the Active Therapy state whereby the torque provided by the ergometer motor will ramp down while the stimulation to the user's lower extremities ramps up so as to maintain the target cycling velocity. During Active Therapy the Controller regulates the amount of stimulation current to maintain the target velocity. If the target velocity cannot be maintained and the stimulation is at the maximum level then Active Therapy will determine the muscles are fatigued and transition back to the Passive Therapy state. However, if the therapy duration expires and fatigue is not reached then the software will transition to the Cool Down state.

Passive Therapy

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If the legs fatigue the software enters the Passive Therapy state. During the Passive Therapy state there is no stimulation and the cycling velocity is maintained under motor power for the remainder of the therapy session. When the therapy session duration expires the software transitions to the Cool Down state.

Cool Down

During the Cool Down state the ergometer maintains cycling at the set velocity for the prescribed cool down duration.

Finished

When the Cool Down duration has elapsed, the software sends a command to the ergometer to turn off the motor and go to the Ready State.

Stimulator Interface

The Stimulator Interface provides the communications link between the controller and the Muscle Stimulator component's Bluetooth device. The interface receives commands from the controller to set stimulation parameters, turn on or off high voltage and converts these into packets to be transmitted to the muscle stimulator component. The interface also receives error packets from the muscle stimulator component.

Ergometer Interface

The primary function of the Ergometer Interface is to provide a communications link with the the ergometer component via Bluetooth. Commands and data are sent and received form the ergometer through this interface.

BlueRadios Transport

The BlueRadios Transport handles all the front-end Bluetooth connectivity, which involves searching, inquiring and discovering the devices to establishing a secure connection with each of them.

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Exhibit M Software Development Procedure and Coding Guidelines

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(b)(4) Software Development Procedure and Coding Guidelines

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Exhibit O A portable, 8-channel transcutaneous stimulator for paraplegic muscle training and mobility—A technical note

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JRRD Volume 41, Number 1, Pages 41–52
January/February 2004
Journal of Rehabilitation Research & Development

A portable, 8-channel transcutaneous stimulator for paraplegic muscle training and mobility—A technical note

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Abstract—This paper introduces an 8-channel transcutaneous neuromuscular stimulator, called ExoStim, which was designed and developed to provide stimulation to the lower-limb muscles of spinal cord injured individuals. The intended purposes of the ExoStim were to act as a skin-surface precursor to an implantable neuromuscular stimulator for the specific tasks of increasing paralyzed leg strength and endurance, enabling the performance of basic lower-limb functional tasks, and familiarizing patients with functional electrical stimulation training. The initial design specifications included portability (~500 g), battery-powered output, constant current control (0–300 mA), 8 channels of biphasic stimulation (charge-balanced, constant current), and microprocessor control of all stimulation parameters. Various tests, including output power characteristics, environmental, mechanical, and battery life, were performed on three prototype units to validate our design specifications. Having successfully passed all tests, the ExoStim is now ready to be deployed to clinical trial sites for further evaluation with spinal cord injured subjects.

Key words: functional electrical stimulation, neuromuscular stimulator, paraplegia.

INTRODUCTION

Functional electrical stimulation (FES) has been used to enhance the mobility of individuals with paraplegia for over 25 years [1,2]. Stimulation technologies have also evolved from the early developments, with transcutaneous stimulators by Bajd et al. [3] and Kralj et al. [4], to multifunctional implantable devices that restore control to the bladder and bowel, as well as various levels of functional mobility.

In 1991, a 22-channel FES system was surgically implanted into an individual with thoracic-lesion-level paraplegia to restore lower-limb movements [5], and in later years development had begun on new multifunction FES neuroprosthesis (the Praxis FES System, Neopraxis Pty. Ltd., Sydney, Australia) that included an implantable stimulator, controller, and external limb-orientation sensors [6]. Before this multifunction FES neuroprosthesis entered clinical trials, we hypothesized that a simpler, transcutaneous stimulator (later called the ExoStim), employing a shared controller with the implantable system,

Abbreviations: ADC = analog-to-digital converter, CF = compact flash, DAC = digital-to-analog converter, FES = functional electrical stimulation, HV = high voltage, IC = integrated circuit, I/O = input/output, SPI = serial peripheral interface.

This material was based on work supported by Neopraxis Pty. Ltd., Lane Cove, Sydney, NSW, Australia.

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would benefit prospective candidates by providing basic exercise and mobility functions prior to surgical implantation. In addition, a transcutaneous FES system, in its own right, could aid researchers and clinicians with a broad range of FES research interests.

Previous stimulator designs described in the literature portray devices that have successfully enabled standing [7], stepping [8], and lower-limb exercise [9,10] in persons with paraplegia. While standing can be achieved with only two channels of transcutaneous stimulation, four or more channels are necessary for reciprocal gait [11]. Other researchers have employed 6- [10] to 8-channel stimulators to achieve stepping, using the extra channels for better control of the gait cycle [12]. However, despite the inevitable development of improved stimulator technology and the abundance of research projects involving FES systems, there are still only a handful of commercially available skin surface stimulators for home use by paraplegic individuals [13].

Most of the aforementioned FES systems were designed for a particular research application and were not intended for clinical deployment. However, recent attempts have been made to develop clinical stimulators for a broad range of FES applications [14,15]. We considered it vital to incorporate into the ExoStim principles of FES system design appropriate for clinical devices, in an effort to overcome the negative attributes that previously led to poor end-user acceptance, such as—

- Lack of portability: Most stimulators reported in the literature are not portable because they derive their power from a mains connection [16] or, although portable, they rely on direct connection to a computer for programming of stimulation patterns or implementation of closed-loop control [8,12].
- Size: In the past, portable stimulators were large and cumbersome [10,17] and required a large number of batteries for a relatively limited amount of stimulating time.
- Clinician intervention: Most stimulators require input from a PC or other control device to program the operation of the stimulator before deployment, and thus require intervention by a trained professional. Even then, the stimulator cannot act autonomously to modify its stimulation parameters in real time with a user-friendly, robust control interface.

An important design objective of the ExoStim was to overcome some cosmetic and functional limitations apparent in previous neuromuscular stimulators, without compromising any of the criteria necessary for a multipurpose device suitable for a variety of FES tasks.

Therefore, the purpose of this project was to apply recent technological advances in the areas of electronics, microcontrollers, and software design to develop a transcutaneous neuromuscular stimulator that was small, lightweight, and portable, with multiple independent output channels and broad flexibility in the control of the stimulating pulse train (**Table 1**). Additionally, it was necessary for the design to provide some degree of backward hardware and software compatibility with an established, implantable FES system (the Praxis FES System, which comprises a Pocket PC controller, implantable stimulator, and orientation sensors) under worldwide clinical trials. Since the Praxis implant system already had an established serial communications protocol between the controller and the sensors, the ExoStim required compatibility with this communications protocol as well. We also wanted to keep system software changes within the controller to a minimum to accommodate the new stimulator, and the ExoStim's firmware had to be compatible with the existing implantable stimulator's software drivers.

This article describes the hardware and software of the ExoStim, and the components of the controller software as they relate to the command interface between the two devices. To verify the hardware design, we compared the calculated maximum power output of the stimulator to experimental results from a manufactured prototype. In preparation for eventual commercialization environmental and mechanical stress testing, we followed Australia Standards guidelines, and also determined the battery life during normal and extreme operating conditions.

METHODS

System Overview

The FES surface system consists of a stimulator, called the ExoStim, limb or trunk orientation sensors, and a controller. The stimulator is enclosed in a 9 × 6 × 3 cm portable case outfitted with two belt clips. The case meets International Electrical Code 60601-1 electrical safety requirements, including prevention of contact with interior electronics. The unit's power is supplied by 4 AA alkaline batteries enclosed within the case. The ExoStim, with batteries, weighs approximately 500 g. There are a total of six input/output (I/O) connectors: two stimulation

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Table 1.
Stimulation parameter ranges and technical specifications of ExoStim.

Stimulation Parameter	Range (Resolution)
Number of Channels	8
Current Output per Channel	0–216 mA (1 mA)
Waveform Type	Biphasic, square wave, charged balanced
Pulse Frequencies	17, 20, 25, 33, 50, 100 Hz
Pulse Width	25–500 μs (2 μs)
Interpulse Phase Interval	10 μs
Channel Parameter Update Schedule	Per period
Technical Specifications	
Maximum Electrode Voltage	200 V
Output Characteristics	Constant current
Power Source	4 AA alkaline batteries
Low-Battery Notification	3.6 V

channel connectors (modified RJ45 connectors) for the eight stimulation channels, and four serial peripheral interface (SPI) (Motorola, USA) communication ports. The stimulation channel connectors were specifically designed to accept a 4-channel, custom-made cable, which features no exposed terminal electrodes. The four communication ports provide a direct link to the controller, as well as additional links for body-worn position feedback sensors via the ExoStim communication ports. A low-power LED, visible on the side of the enclosure, continuously flashes at a rate of 1 Hz when the ExoStim is powered and executing its embedded software. To alert the user during stimulation of any of the output channels, the flash rate increases to 2 Hz.

The controller consists of a separate, hand-held PC (8.5 × 13.49 × 2.54 cm) (Cassiopeia EG-800STG, Casio, Japan) with a custom-designed compact flash (CF) interface card, which together weigh ~300 g. The CF card provides the SPI to all the external components (ExoStim or sensors) on the communications bus via three ports. The controller has been modified with two belt clips, so the entire FES system consists of body-worn devices, as shown in **Figure 1**.

Stimulator Hardware

A block diagram of the stimulator hardware is given in **Figure 2**. Descriptions follow of key components, including the microcontroller, high-voltage (HV) power supply, stimulation current control, and the stimulation pulse width and frequency generator.

Microcontroller

The microcontroller chosen for our portable stimulator was a 4 MHz, low-power, 8-bit RISC chip with 128 kB of programmable flash and 4 kB of EEPROM (ATmega103L, ATMEL, California). This microcontroller also includes an on-board, 8-channel, 10-bit, analog-to-digital converter (ADC); 32 programmable I/O lines; master/slave SPI; and two 8-bit and one 16-bit counter.

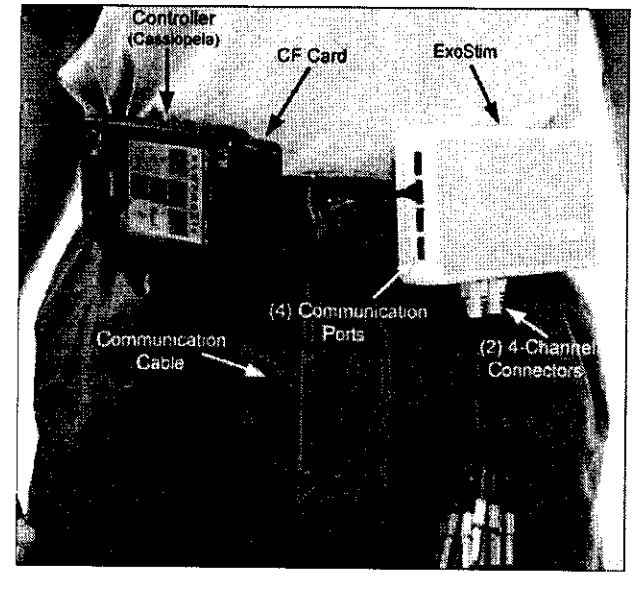

Figure 1.
ExoStim neuromuscular stimulator with its channel electrodes linked to handheld computer controller mounted on belt of user.

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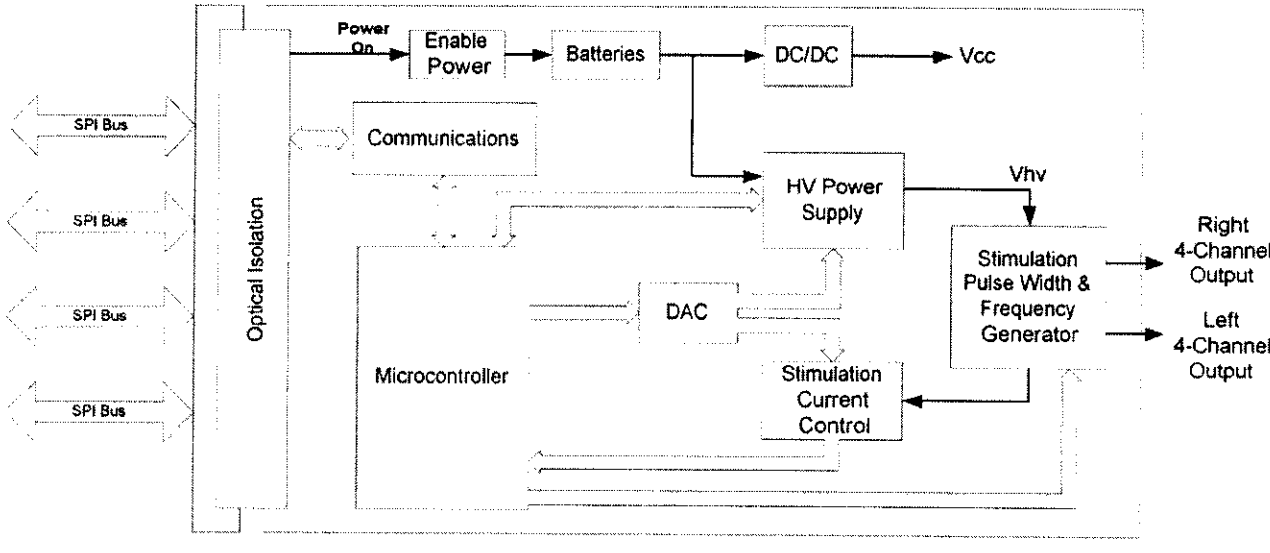

Figure 2.
Block diagram of stimulator components. Outlined arrows represent digital information flow and solid arrows represent power flow. Vcc is supply voltage for stimulator electronics and is maintained at +5 V. Vhv is high-voltage supply for stimulation channels and is maintained at +200 V.

Signals from the current control module, HV power supply module, and batteries are continuously sampled by the ADC and monitored for errors to ensure that the stimulator is safely operating within predefined parameters. Eight I/O lines to the digital-to-analog converter (DAC) (MAX505ACAG, Dallas Semiconductor, California) provide the analog signals that set the stimulation current and the HV threshold, and an additional nine lines are used to control the stimulation pulse width and frequency generator.

Communications

The communications module within the ExoStim is optically isolated from the controller to shield the user from potential grounding problems that could occur by touching the exterior casing of the controller while stimulating. This module includes a programmable logic device that facilitates the SPI with the controller and provides the means to shut down the microcontroller safely if the stimulator's battery output cannot maintain a nominal voltage for the microcontroller.

HV Power Supply

The HV power supply (5A200S, Pico Electronic, NY) of the HV power supply module is enabled by software control and maintained at 200 V with feedback control circuitry, as shown in **Figure 3**.

Stimulation Current Control

The stimulation current setting is derived from eight digital lines of the microcontroller feeding into a DAC. The generated analog signal provides the reference point for the operational amplifier (OP162, Analog Devices, Massachusetts) controlled current source. Output stimulation occurs in a time-interleaved manner, meaning that in a given period of stimulation, the eight channels are alternately stimulated in 2 ms intervals. For example, if the stimulating period is set at 40 ms for all eight channels, the software would stimulate channel 1, then 2 ms later stimulate channel 2, etc., until all active channels have been stimulated. The stimulator is then idle for the remaining 26 ms until the sequence is repeated. Therefore, the DAC only has to provide a single analog voltage every 2 ms to control the current for a particular channel, which is easily achievable by the 4 MHz microcontroller.

Stimulation Pulse Width and Frequency Generator

The biphasic output timing characteristics (stimulation pulse width and frequency) of each channel are generated by 3 HV switch ICs (HV20720, Supertex, California) connected in an H-bridge configuration. The

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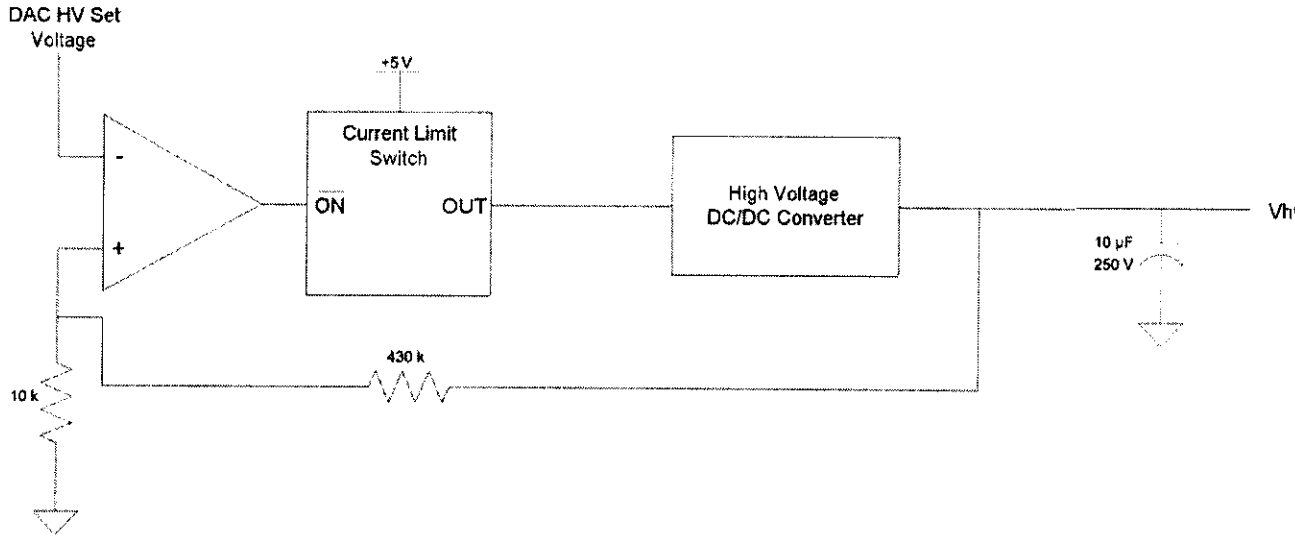

Figure 3.
Schematic of HV power supply module.

three digital inputs (A, B, and CLR) for each IC shown in **Figure 4** control up to 8 HV output switches that operate in tandem (SW1a & SW1b, SW2a & SW2b, etc.). It should be noted that when the CLR line is pulled high, all switches on the IC are open circuit; this is the state the switches are in upon start-up and when no channels are stimulating. Precise control of the switches, and therefore accurate stimulation pulse width and frequency of each channel, is achieved through interrupt-driven timers running in the embedded microcontroller software.

Controller Software

The controller software, Clinix, consists of a graphical user interface driven by C++ embedded software that runs on a Windows CE 3.0™ (MIPS) operating system. Functions are displayed as icons on the touch screen of the controller and represent various FES-related operations and tasks, such as a user-specific "stimulation parameter settings" function, lower-limb exercise (e.g., cycling), sit-to-stand, and stepping tasks. Each function consists of a "strategy," or multiple strategies, comprising software routines that control the pattern and timing of the electrical stimulation pulses that carry out the FES task; these are configured by a clinician to suit the user.

A set of the strategies is provided with the complete FES system; however, third-party development of strategies is possible and controller software provides interfaces for the stimulator and peripheral devices.

Stimulator Interface

The stimulator interface processes the information from the strategy and sends appropriate commands to the stimulator via the SPI bus. Since the controller may use either the ExoStim or an implanted stimulator, the function calls from the strategy to the interface are identical for either device. This feature allows for a strategy to be developed initially for the ExoStim and subsequently used with a Praxis-implanted stimulator, without the need to reprogram the controller.

Peripheral Device Interface

Communication between the controller and the ExoStim is handled by a multi-layered bidirectional protocol capable of simultaneous communication to multiple peripheral devices on the SPI bus. Commands are concatenated to uniquely identifiable packets, depending on their intended receiving device—multiple orientation sensors or the ExoStim. To prevent transmission errors, a "checksum" is carried out on each packet; if an error is detected, the packet is resent.

Stimulator Software

The ExoStim's microcontroller executes embedded software written in C language. Its operation can be described in three modes: communications, background, and stimulation.

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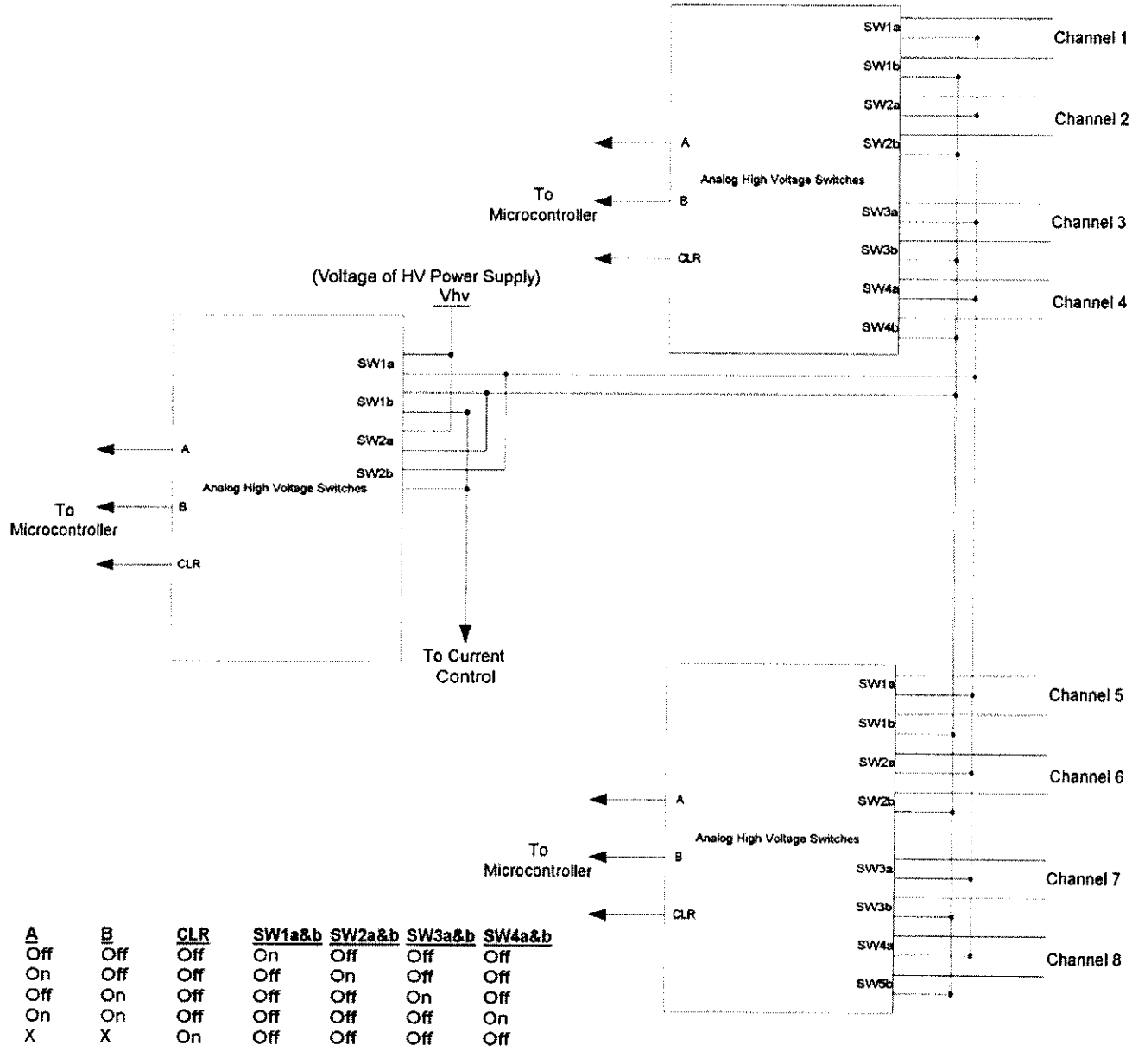

A	B	CLR	SW1a&b	SW2a&b	SW3a&b	SW4a&b
Off	Off	Off	On	Off	Off	Off
On	Off	Off	Off	On	Off	Off
Off	On	Off	Off	Off	On	Off
On	On	Off	Off	Off	Off	On
X	X	On	Off	Off	Off	Off

Figure 4.
Schematic of stimulation pulse width and frequency generator module. Inset truth table demonstrates how logic inputs (A, B, and CLR) control tandem switches (SW1a&b, SW2a&b, SW3a&b, and SW4a&b) of high-voltage ICs.

In communications mode, commands are sent from the controller as packets that trigger SPI interrupts on the stimulator's microcontroller when the receive buffer contains a "send" packet. The command is then stripped from the packet and processed. There are more than 20 different commands that deliver and retrieve information to and from the stimulator. For example, the SET_STIMULATION_PARAMETER command provides the waveform information for the stimulation output for each channel, such as stimulation period, amplitude, pulse width, pulse width and amplitude slope, and duration of stimulation.

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The stimulator enters the stimulation mode immediately after a stimulation command is received. Two software interrupt counters are enabled, one that regulates the stimulation pulse frequency and the other the pulse width of each channel, which execute a routine that opens or closes the appropriate HV switches to accurately establish the requested pulse width and frequency for each channel.

While in background mode, the microcontroller samples various ADC channels to conduct error checks on the stimulation output, batteries, and other electronic components. Data from each stimulation channel are analyzed per period for errors, such as significant impedance changes (open- or short-circuit conditions) and output compliance of the stimulation parameters (channels maintain the requested current level). A single ADC channel is all that is required to collect the output channel impedance data for all 8 channels. Also monitored, but on a less frequent schedule, are low battery voltage (V_{batt} < 3.6 V) and over voltage of the HV power supply (V_{hv} > 220 V). When an error condition arises, the stimulator software autonomously handles the error. For example, if a stimulation pad is removed from the user while stimulating, the software will detect the impedance change and deactivate that channel. All detected errors are written to an error register that is transmitted to the controller in the "return" packet after a command is sent to the stimulator. The controller alerts the user of the error condition and subsequently sends a command back to the stimulator to clear the error.

The ExoStim software can also be updated by the controller. If a software update is required, a controller utility can be executed that places the stimulator's microprocessor in programming mode and then transmits the new software to its flash memory. Software modifications can be downloaded from a PC to the controller or directly from the Internet, thus eliminating the need to return the stimulator to the manufacturer for software updates.

Design Specification and Validation Testing

Power Compliance

The limitations of the stimulator power output were calculated based on the capabilities of the HV power supply and the duty cycle of the stimulation parameters. The maximum available power (P_{max}) provided by the power supply is

$$P_{max} = VI_i = (200\text{ V})(18.75\text{ mA}) = 3.75\text{W}\ , \quad (1)$$

where V is the constant power supply voltage and I_i is the total output current of the power supplies.

The total output power (P_o) of the stimulators channels is related to the current amplitude of each channel and the pulse train duty cycle:

$$P_o = (V)\sum_{n=1}^{m}(I_n)(\text{PW}_n/\tau_n)\ , \quad (2)$$

where m is the number of stimulating channels, I_n is the current amplitude of channel n, PW_n is the pulse width of channel n, and τ_n is the period of channel n.

To maintain voltage compliance the requested power to the stimulation channels cannot exceed the available power of the HV power supply's output. Therefore, the duty cycles of the pulse train and current amplitude are bounded in order to sustain the desired power output of the stimulator.

To experimentally measure the power compliance of the ExoStim, we stimulated all eight channels through a 1 kΩ resistive load at set pulse amplitude and period. The pulse width was then increased from 50 μs in 2 μs intervals until the output voltage of the HV power supply decreased 5 percent from its regulated value of 200 V. This procedure was repeated for pulse amplitude/period combinations of 175 mA/20 ms, 125 mA/20 ms, 100 mA/20 ms, and 175 mA/30 ms.

Stress Tests

Three ExoStim units were evaluated under environmental and mechanical stress conditions according to specifications outlined by Australia Standards 1099 (1990), for basic environmental testing procedures for electrotechnology. The environmental testing was limited to the ability of components to be used or stored at the environmental extremes described in each test. All environmental tests were conducted in an environmental chamber (1020S, TestEquity, California) programmed to conditions specified in **Table 2**. At least 20 min were allowed for the test units to stabilize to ambient temperature (23 ± 3 °C) before an operational electrical test, described in **Table 2**, was conducted on each unit. An external testing facility conducted the shock and random vibration mechanical tests. The free-fall test was conducted in our laboratory. Following mechanical testing, an operational electrical test was again carried out on all units.

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Table 2.
Results and test conditions of ExoStim stress and battery tests.

Test	Condition	Referenced Australia Standard	Result
	Environmental		
Cold Temperature	5 ± 2 °C for 16 h	AS1099.2.1 Aa	Pass
Dry Heat	55 ± 2 °C for 16 h	AS1099.2.2 Ba	Pass
Thermal Cycling	60 ± 2 °C to –20 ± 2 °C for 30 min in each of 5 cycles	AS1099.2.14 Na	Pass
Cyclic Damp Heat	95% relative humidity 55 ± 2 °C for 12 hr, then 25 ± 2 °C for 12 h	AS1099.2.30 Db	Pass
	Mechanical		
Random Vibration	10–150 Hz @ 0.1 g^2/Hz 30 min/axis on 3 orthogonal axis	AS1099.2.34 Fd	Pass
Shock	15 g for 11 ms, half sine, 3 shocks per face on all 6 faces	AS1099.2.27 Ea	Pass
Free Fall	1.0 m drop per face onto all faces	AS1099.2.32 Ed	Pass
	Battery		
Idle	0.45 W, continuous	N/A	>12 h
Medium	1.25 W, continuous	N/A	4 h
Heavy	3.75 W, continuous	N/A	45 min

Note: Three stimulator units were tested under each test condition. A "pass" result was given if all test units successfully performed an operational electrical test that consisted of these tasks: established communications with controller, enabled and maintained high voltage, and stimulated a 100 µs pulse width, 100 mA amplitude, and 33 Hz frequency pulse train on all 8 channels.
N/A = not applicable

Battery Life Tests

Three ExoStims were used to measure the battery life during three operating conditions; idle, medium, and heavy stimulation. Software running on the controller recorded the time elapsed before a low battery (V_{batt} < 3.6 V) was detected while an ExoStim was operating in one of three selectable states: idle, no channels stimulating and HV power supply is off = 0.45 W; medium stimulation, power output = 1.25 W; and maximum stimulation, power output = 3.75 W. The output power from the batteries was measured with a digital voltmeter. For each condition the power output was continuous. For each test, fully charged, off-the-shelf alkaline batteries were used.

Waveform Traces

To illustrate the output characteristics of the ExoStim driving a real load, a single channel was applied to the leg of a healthy, able-bodied volunteer. Self-adhesive gel electrodes (Oval, 2.75 × 5 in., 6000 Series, Empi, MN) were placed across the rectus femoris while a stimulation waveform of 100 mA, 100 µs, and 25 Hz was applied. The voltage was measured by an oscilloscope (Tektronix, Beaverton, OR) with the probes connected directly across the electrodes, while the current was measured as the voltage across a small (100 Ω) series resistor.

RESULTS

The experimentally measured points of compliance limit corresponded well with the calculated compliance curves, as portrayed in **Figure 5**. Empirically derived points of compliance failure for 125, 150, and 175 mA at a 20 ms stimulation period, and 175 mA at a 30 ms stimulation period, were all on or slightly below their respective calculated parameter limits.

Table 2 displays the results of the environmental, mechanical, and battery tests. All three units satisfactorily passed environmental and mechanical stress testing. It should be noted that there was negligible cosmetic damage as a result of the free-fall test; however, this did not affect the normal mechanical or electrical operation of the stimulator. The battery test demonstrated the ExoStim battery life to be greater than 12 h for idle, 4 h at medium load, and 45 min at maximum load.

The current and voltage characteristics of a pulse train of stimulation applied to the quadriceps of an able-bodied

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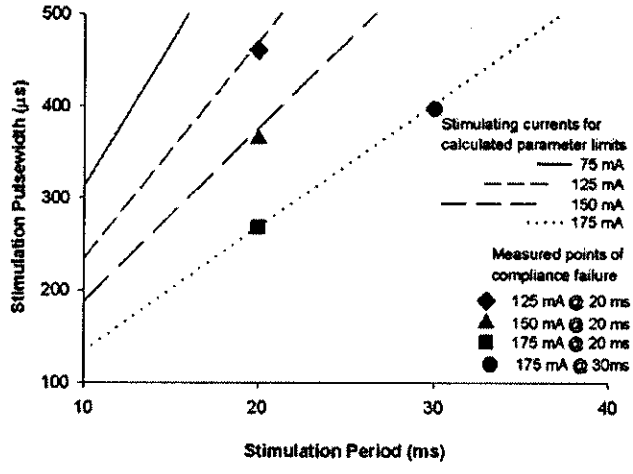

Figure 5.
Stimulator power output capabilities of 8 channels simultaneously stimulating 1 kΩ resistive load. Line plots represent theoretical power output of stimulator at various stimulating currents. Solid symbols represent measured stimulator output parameters that cause 5-percent decrease in power supply output.

volunteer are shown in **Figure 6**. The current trace demonstrates the ability of the stimulator to maintain balanced, rectangular pulses while driving a transcutaneous load.

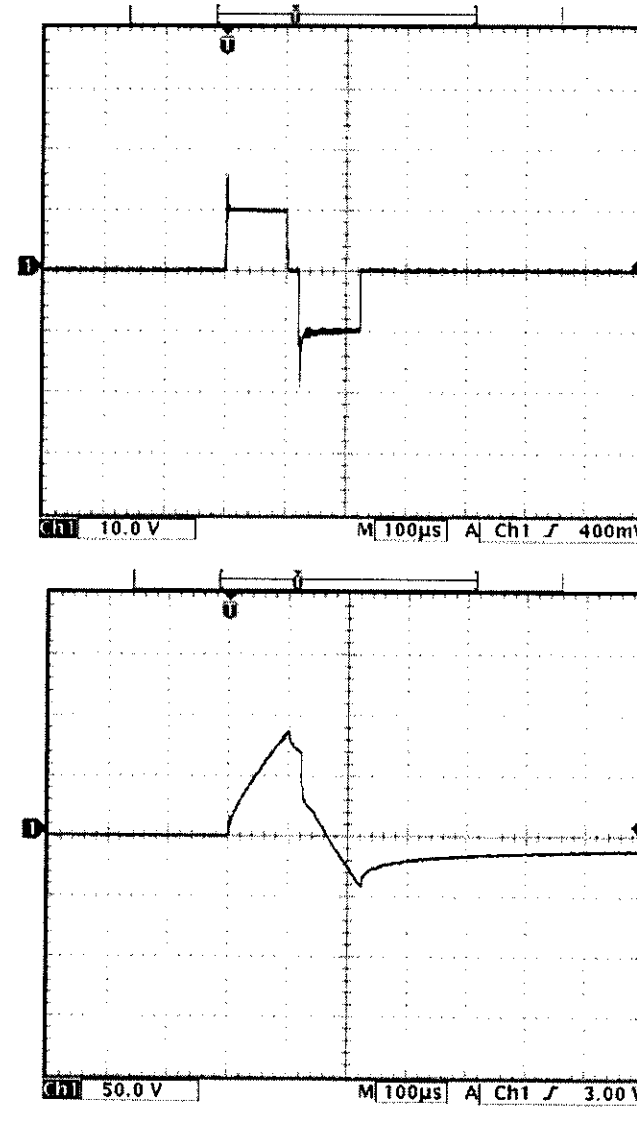

Figure 6.
Upper trace is single biphasic current pulse across single channel applied to real transcutaneous load. Lower trace is voltage through same load.

CONCLUSIONS

This article describes the design, development, and validation of a new, portable, eight-channel transcutaneous FES system intended for a wide variety of clinical and research functions and eventual commercial deployment. During the design stage, we relied on input from FES researchers and investigation of the current state of surface FES stimulator technologies found in the literature. Although similar in many characteristics to earlier presented FES systems, the ExoStim FES system incorporates several unique features. First, its portability allows the stimulator to be used outside the laboratory without the need for a PC or large battery pack. Both the ExoStim and controller are belt-worn devices, and this enhances their cosmesis for clinical or home use by clients. Second, the ability to modify stimulus parameters (e.g., pulse amplitude, width, frequency, and duty cycle) in real time on a period-by-period basis across all eight channels may be used to optimize muscle performance during a movement task. For example, in performing a sit-to-stand maneuver, the pulse frequency and duration might be altered in real time to recruit new muscles or change muscle performance near the end range of movement (e.g., near full-stance position). Third, the ExoStim's firmware was capable of acting autonomously to accomplish a multitude of stimulation and error-handling tasks, such as identifying batteries installed with

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reversed polarity, low battery voltage, and "open circuit" electrode impedance, all without the need to communicate with the controller.

The ExoStim's electrical performance behaved as expected. The results of the power compliance tests demonstrate that the theoretical expectations closely matched the experimental findings. Also encouraging are the results of the stress testing, demonstrating that our design and manufacturing processes meet independent standards for electronic devices, which is a basic requirement for future commercialization.

As with any device, certain compromises were necessary to maintain the design specifications that had been established at the onset of the project. One such compromise was the size of the stimulator versus its battery capabilities. To condense the size of the stimulator, the number and size of the batteries were reduced, with the knowledge that this would also reduce the time between battery supply changes, especially during heavy stimulation workloads. Nonetheless, a vital attribute of the stimulator was its cosmesis and portability, and these considerations were more important then the alternative of carrying unwieldy battery packs. Additionally, a battery pack of 4 AA alkalines was adequate to carry out a number of FES functional mobility or exercise tasks across multiple sessions. For example, the stimulator's power output, at its maximum of 3.75 W, yielded a battery life of 45 min. However, under normal operating conditions, where the stimulator's power output was only 1.25 W, the battery life was shown to be approximately 4 h. Well-trained individuals who perform FES-induced leg cycling have been shown to maintain 30 min of exercise involving 6 muscle groups at power outputs of 12 to 18 W [18], which translates to 8 to 10 training sessions per set of batteries.

Another design compromise was limiting the number of available stimulation frequencies to 100, 50, 33, 25, and 20 Hz (or 10, 20, 30, 40 and 50 ms stimulation periods) per channel, while gaining the advantage of having each channel individually stimulating at any of these frequencies. A contrasting approach would have allowed the stimulation of all channels at any frequency between 10 and 100 Hz (with a 1 Hz resolution); however, all channels would then be constrained to the same frequency. To justify the former design, most transcutaneous FES tasks involving the lower-limb use stimulation frequencies of 20 to 50 Hz, and for the control of fatigue it is desirable to individually modify the period of stimulation for various muscle groups [19]. So, for prolonged FES activities, muscle fatigue might be reduced by dynamically changing the stimulation frequency to certain stimulating channels to recruit fatigue-resistant muscle fibers. This approach will soon be deployed in a strategy using the ExoStim for prolonged leg-cycling exercise.

Currently, the ExoStim is undergoing final hardware validation and preliminary human trials before it is deployed as a complementary device to the implantable Praxis FES system. The stimulator is also being repackaged into a smaller, custom-designed housing, providing enhanced cosmesis. Future research with the system is also under way at several research sites to deploy it for FES-evoked leg-cycling exercise (using fatigue-minimization strategies) and for stepping, using six channels of FES muscle contractions (with the 2 additional channels stimulating erector spinae for trunk stabilization). Long-term uses of the ExoStim may involve reducing "foot-drop syndrome" in hemiplegic stroke patients and assisting with arm cranking for C7–C8 lesion-level tetraplegic individuals who desire to undertake upper-body exercise.

ACKNOWLEDGMENT

This research was completed as a component of a PhD degree for Scott Simcox. Neopraxis Pty. Ltd. sponsored the research during the design of the system and subsequently undertook further development and commercialization of the neuromuscular stimulator as the Neopraxis ExoStim ™.

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Submitted for publication May 28, 2002. Accepted in revised form August 12, 2003.

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Exhibit P Ergometer Component CB Certificate

IECEE CB-Scheme

Ref. Certif. No.

DE 3 - 4147

CB TEST CERTIFICATE
CERTIFICAT D'ESSAI OC

Product Produit	Medical Electrical Systems Therapeutic Exerciser
Name and address of the applicant Nom et adresse du demandeur	medica-Medizintechnik GmbH Blumenweg 8 88454 Hochdorf, GERMANY
Name and address of the manufacturer Nom et adresse du fabricant	medica-Medizintechnik GmbH, Blumenweg 8, 88454 Hochdorf, GERMANY
Name and address of the factory Nom et adresse de l'usine	medica-Medizintechnik GmbH, Blumenweg 8, 88454 Hochdorf, GERMANY
Rating and principal characteristics Valeurs nominales et caractéristiques principales	Rated voltage: 115 VAC 230 VAC Rated power: 130 VA Rated frequency: 50/60 Hz Protection class: I Degree of protection against electric shock: Type B
Model/type Ref. Ref. de type	THERA-live
Additional information (if necessary) Information complémentaire (si nécessaire)	(with the exception of: Clause 52.1 - Programmable Electronic Systems)
A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	IEC 60601-1/A2:1995
as shown in the Test Report Ref. No. which form part of this certificate comme indiqué dans le Rapport d'essais numéro de référence qui constitue une partie de ce certificat	TÜV Product Service 052-080353-000

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme **National de Certification**

Department: MGE
Date, 2004-11-11
CB 04 11 17939 001

TÜV PRODUCT SERVICE

TÜV PRODUCT SERVICE GMBH · Certification Body · Ridlerstrasse 65 · D-80339 München

Page 1 of 1

Draft UR	Approved:	AB	Title:	RT300-S 510(k) Application					RV100243	PM100041
	Date:	12-22-04	Page:	61	of	61	Project:	RT300	Version:	1

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) JEFFREY ALLEN ROSSI

Subject: 510(k) Number K050036/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.).

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☒ YES	☐ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☐ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 84 GZT CLASS II 882.5810

Additional Product Code(s) with panel (optional): ISD

Review: (Branch Chief) (Branch Code) LCDB (Date) 6/24/05

Final Review: (Division Director) Miriam C Rosario (Date) 6/24/05

Revised:4/2/03

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510 K PRIMARY REVIEW MEMORANDUM

DEVICE NAME: FES CYCLE ERGOMETER, MODEL RT300-S
COMMON NAME: FES CYCLE ERGOMETER
APPLICANT: RESTORATIVE THERAPIES, INC.
REVIEWER: ANDREW BARRISKILL
PHONE/ FAX: 310-691-5467 / 410-534-6263

DEVICE DESCRIPTION

The FES CYCLE ERGOMETER, MODEL RT300-S is a Functional Electrical Stimulator combined with a motorized cycle ergometer to provide stimulated biking motion from a person suffering from spinal cord injury. A wheelchair is moved proximally to the RT300 and the users feet are strapped into the cycle type rotational apparatus. The system operates by sequentially stimulating quadriceps, hamstrings, and gluteales in both legs to create a rotational motion. The system operates in phases that use a varying amount of motor assist:

i. Warm-up (passive cycling)
ii. Active Cycling (stimulation active)
iii. Passive Cycling
iv. Cool Down

The device is best described with reference to a photo of the unit:

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The Sponsor describes two versions of the device, a full size version and a pediatric version. The Sponsor further describes a pediatric pedal accessory. It is unclear how the pediatric accessory relates to the two versions of the device, i.e., does the accessory convert the full sized version to the pediatric version.

It is unclear which photos and components refer to the full version and which refer to the pediatric version. For example, there is a pediatric pedal assembly. Does this assembly convert the regular version of the device to the pediatric version? All versions of the device must be fully described, preferably separately, if you want clearance for all versions of the device. Currently, the reviewer is left to guess which photos and diagrams refer to which version of the device.

Applicant's response in Supplement 1: The pediatric version has been sufficiently characterized in the response. The pediatric version has a shorter handle extension and a pediatric pedal. See also clinical comments, attached.

The Sponsor has characterized the electrical output of their device in the table on page 3 (no page numbers provided). This comparative chart is incorporated herein by reference. The source is a voltage controlled source with a maximum current of 140 mA at 500 ohms. Based on the 510(k) records, the predicate appears to be a current controlled source of 130 mA at 500 and 1000 ohms.

INDICATIONS FOR USE UPDATED

Table 1 Comparison of Indications for Use

IRT300-S	ERGYS K011117
~~i. spinal cord injured patients,~~ ~~ii. people with muscular dystrophy,~~ ~~iii. with motor neuron disease,~~ ~~iv. stroke survivors,~~ ~~v. with MS, and~~ ~~vi. with cerebral palsy~~ ~~a) relaxation of muscle spasms~~ ~~b) prevention or retardation of disuse atrophy~~ ~~c) increasing local blood circulation~~ d) ~~maintaining or increasing range of motion~~[1]	General rehabilitation

[1] I am unsure how range of motion is intended to be defined for the clinically paralyzed patient. Ususally range of motion refers to the motion possible under voluntary muscle control.

The RT 300S (adult version) and the RT 300-SP (pediatric version) are intended for: a) relaxation of muscle spasms b) prevention and retardation of disuse atrophy c) increasing local blood circulation d) Maintaining or increasing range of motion	

2(a) You have provided a predicate K841112 which is cleared for general rehabilitation use only, and not for you intended patient population (*i.e.*, spinal cord injured patients, people with muscular dystrophy, with motor neuron disease, stroke survivors, with MS, and with cerebral palsy.) The office has researched the internal database to the extent possible and was unable to uncover a predicate for these indications. Please inform the office if there is a cleared predicate for your indications, and please provide a technological comparison to the newly cited predicate, if one exists. Substantial equivalence can be made to K841112, however a new predicate may reduce the amount of information needed to support your device.

Applicant's response in Supplement 1: Sponsor has revised indications for use to ge general indications for use. See also clinical comments, attached.

Questions 2(b) and 2(c) are fully addressed in the attached clinical comments.

(3) In your indications for use, please define range of motion as measured in the clinically paralyzed patient.

Applicant's response in Supplement 1: Sponsor has revised indications for use to recite general indications for use. The issue is thus moot. See also clinical comments, attached.

(4) In your intended use, please include reference to the pediatric population. This should be worded like "The [pediatric version of the device] RT300-P (?) is intended for a population ages __ to __."

Applicant's response in Supplement 1: Sponsor has revised indications for use as suggested. See also clinical comments, attached.

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PREDICATE COMPARISON

The Sponsor compares their system to the ERGYS system described in K841112. The ERGYS system is a rehabilitative gym which includes a cycling function with electrical stimulation. The ERGYS system is indicated generally for rehabilitation, but has not been cleared of record for the sub populations described by the Sponsor: spinal cord injured, persons affected with muscular dystrophies, with motor neuron diseases, with stroke, with multiple sclerosis, and with cerebral palsy. There is no mention in the predicate 510(k) of use of this device in a pediatric population.

Although the principle of operation of the RT3000-S is similar, the two devices have some important differences in design. The ERGYS system has a seat which is in mechanical attachment to the chair which is used by the patient. As seen in the photo above, the RTS-3000 is intended to be used with a wheelchair. No mention is given as to how the device was tested for compatibility with the numerous models of wheelchairs on the market, nor how the device maintains alignment with the chair.

The safety of mechanical devices of this type are difficult for the office to evaluate. Ultimately, the safety of the RTS-30000 will depend on the quality of the design, which is difficult to assess without some sort of clinical study of the device.

ELECTRICAL SAFETY

The electrical stimulation parameters appear to be within the range of predicate parameters which is not specifically indicated for the pediatric population. The 140 mA maximum current is software controlled, with a 200 mA hardware limit. Given that the maximum software controlled current is sufficient cause electrocution, I am concerned that the device has not been hardware controlled at the same current.

The maximum charge per pulse is 35μC. The TENS Guidance (now withdrawn) referred to data that FDA was aware of which indicated a risk of electrocution for charges per pulse greater than 25μC.

(8) **Your device output is sufficient to cause electrocution if used improperly. Please warn the user that the device provides currents sufficient to cause electrocution in the device labeling. This warning should be prominent and conspicuous.**

<u>Applicant's response in Supplement 1</u>: Sponsor has updated the labeling to warn the user as requested.

(9) **You have reported values for maximum phase charge, maximum current density, and maximum power density at 500 ohms. However, it is not clear that the**

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maximum of these values occurs at 500 ohms. Please report these maximum values at any impedance greater than 0 for which a current is delivered.

Applicant's response in Supplement 1: Sponsor has limited stimulation to a maximum of 1500 ohms which limits power transfer in the case of high impedance. The maximum power density thus will occur at 1500 ohms and is 0.0049 W/ cm 2. This is safe based on data currently available to FDA (citing prior published TENS guidance)

(10) You have provided a "CB certificate" certificate which indicates that a "therapeutic exerciser" was tested to IEC 60601-1. However, this appears to have been for the marketed exerciser only. The testing would be invalid for the device used in combination with the electrical stimulation component. Please provide evidence of electrical safety testing of the entire device as a unit to IEC 60601-1 or equivalent. Because this device is directed to a neurologically compromised population, we are requesting that you include testing to standards specifically directed to powered muscle stimulators such as IEC 60601-1-10.

Applicant's response via e-mail: This testing has been done and the sponsor has provided a statement of conformity to UL 60601-1, and EN 60601-2-10.

(11) Please provide evidence of electromagnetic compatibility testing to IEC 60601-1-2 or equivalent.

Applicant's response via e-mail: This testing has been done and the sponsor has provided a report by e-mail. This testing is acceptable in addition to the "ad hoc" wireless testing provided (reviewed by S. Seidman, OSEL, attached)

(5) **It is unclear that the stimulation parameters used for adults (predicate) are suitable for pediatric use. Please provide a basis, for example in clinical literature, of your stimulation parameters in a pediatric population.**

Applicant's response in Supplement 1: Sponsor has modified the output of the device for pediatric use and provided a clinical basis for pediatric use. Results of clinical studies to date have been provided and summarized in the attached clinical review. This is discussed in detail in the clinical review memorandum, attached.

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ISSUES ASSOCIATED WITH WIRELESS COMMAND AND CONTROL

This device is a moderate risk device capable of causing injury in case of a software failure. The Pocket PC used with the stimulator appears to use a wireless controller at the interface between the cycle and the controller.

(6) You have described a BLUETOOTH interface, but have not given details as to what information is passing through the wireless link. It appears from your photos and diagram that the stimulator is exchanging data with the cycle through the wireless link. We are concerned about command and control information being sent over a BLUETOOTH wireless link. Specifically, we are concerned about the following aspects fo the wireless connection:

- **Wireless coexistence, and data latency and throughput, and any limitations or restrictions for proper device operation and wireless communications.**
- **How users will interact with the system.**
- **Protections against unauthorized wireless access to device control or data (e.g., encryption, data access controls).**
- **For wireless devices that use computer programs ("software"), the program's ability to handle the device responses and or failures under EMI conditions.**

The wireless link itself should be characterized with respect to the following:

- **All functions that the RF wireless device will perform, and all safety-related requirements, specifications, features, and functions that will be implemented wirelessly.**
- **Wireless protocol specification name or designation (e.g., WMTS, IEEE 802.11b) for all wireless technologies incorporated into the device.**
- **Wireless transmitter/receiver parameters such as operating frequency, RF output power, etc.**
- **If RF wireless is specified for operation in the presence of other in-band transmitters, restrictions on the number or characteristics of other in-band transmitters.**
- **All coexistence, data integrity (e.g., data throughput, latency) and security features and performance requirements that the wireless system will meet.**

Data security features to prevent unauthorized access to data or networks

Testing should explicitly address the issues cited above, including the limitation of the number and type of wireless transmitters that can be present and still insure proper operation. Please contact the lead reviewer directly if you need assistance in formulating a wireless testing protocol that will satisfy FDA's concerns about your wireless link. This testing may or may not be included in the IEC 60601-

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1-2 EMC standard testing. If IEC 60601-1-2 testing is used to address some of these issues, a complete report (not summary) should be submitted.

Applicant's response in Supplement 1 and via e-mail: Sponsor has performed testing. FDA has worked interactively with the sponsor to assure that these questions were answered. The sponsor has performed EMC testing of their wireless link which is acceptable based in the information available to FDA to date. The detailed analysis is contained in the attached memorandum by Seth Seidman, OSEL.

RISK/ HAZARD ANALYSIS

The Sponsor has relied heavily on the risk hazard analysis to establish the safety of the RT3000. It is especially critical for this device since there are so few manufacturers and models of predicate devices to rely on for information regarding the safety considerations of this device. Furthermore, much of the mechanical safety will be a result of good design/ materials, and is consequently difficult to assess with standardized test protocols. It is thus difficult for the reviewer to assess all of these considerations, and there are no standards that might cover the safety issues specific to these devices.

The sponsor has referred to an article from Nash to assess the risks associated with stimulation patients with spinal cord injury. The Sponsor indicates that this article is explicitly directed to FES cycling. This reference should be provided.

You discuss an article by Nash in Sports Medicine, volume 11, 2004 on which you base your assessment of the risks associated with your device. Please provide a copy of the article and a description of the differences between your device and the device studied by Nash.

Applicant's response in Supplement 1: NASH clearly is directed to the general risks of functional electrical stimulation in spinal cord injured populations. This appears to be an adequate basis for assessing the risks of the FES Cycle ergometer.

Autonomic dysreflexia

Sponsor suggests that the user should discuss this condition with their physician and know how to recognize the symptoms and how to react.

(14) **You have mitigated the risk of autonomic dysreflexia by warning the spinal cord injured patient to discuss the condition with their physician and know how to recognize symptoms and how to react. Please explain how this adequately mitigates, for example, a child's risk of this life threatening condition. It is unlikely that a spinal cord injured patient, especially a child, will be able to identify the condition**

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and react appropriately. Please explain in further detail how this condition is supposed to be avoided by the patient, and what actions the patient should take. Assessment and mitigation of this risk by the suggested labeling is currently deemed insufficient.

Applicant's response in Supplement 1: The clinical reviewer, CAPT Schroeder, and I have discussed this at length with each other and the sponsor. We have encouraged the sponsor to mitigate these risks, and the labeling provided along with the clinical experience document appears adequate. Please see CAPT Schroeder's memorandum, attached, for a detailed discussion of this topic.

Musculoskeletal injury

Sponsor has mitigated this risk by advising the patient to use cautions if he has a history of lower limb stress fractures, and or history of severe spasticity. However, it is believed that the device should be designed to minimize these injuries. Further clarification is needed on how these risks were assessed.

You have indicated that risk of musculoskeletal injuries is acceptable because you have excluded patients with a history of lower limb stress fractures and/ or severe spasticity. However, we believe that these risks should also be mitigated by the device design. We are concerned that your device uses a wheelchair which does not appear to be well mechanically fixed into position with respect to the device. This is unlike the predicate you have cited which has a seat integral to the device, and was not specifically indicated for a neurologically compromised population. We are concerned that rotational movement between the chair and the device may cause problems in this population. Please provide more information on how the risk of musculoskeletal injury with you device was assessed for your patient population. It is understood that the device is currently associated with ongoing clinical trials. Perhaps a summary of those trials and a specific list of adverse events from those trials could help satisfy these concerns. If not, perhaps more literature could be used to help assess the risk of injury with your device (a detailed description of how the literature applies to your device would be needed). However, at this point in time it is believed that a clinical study of your device and adverse events associated with your device may be required in the absence of further safety data.

(S1) Sponsor's response is acceptable. Please see CAPT Schroeder's memorandum, attached, for a detailed discussion of this topic

Hypotension

Sponsor has mitigated this risk through labeling. It is my understanding that the risk of hypotension is related to the risk of autonomic dysreflexia. This issue may be re-visited upon evaluation of sponsor's response and review of the Nash article.

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(S1) See clinical review, attached.

Thermal Dysregulation

The mitigation of this risk through labeling appears to be acceptable.

SOFTWARE REVIEW

The Sponsor has provided a description of two experimental versions of the software and a beta version culminating in the beta version released on December 22, 2004. The cycling algorithm has been modified as recently as December 8, 2004 (version 0.01). This device should not be cleared until the final version of the software has been tested and a list of remaining bugs has been evaluated by the office.

The User Interfaces have not been adequately described in your software description. Please provide a screen-shot of all of your user interfaces. Each function described should be readily understandable from the software description.

(S1) Sponsor's has provided the requested screen shots and they are consistent with the written software description and are acceptable.

Your software is apparently still in a beta version as of filing. Please provide software documentation for MODERATE level of concern as described in the Guidance Document, including the traceability matrix and list of remaining bugs suggested in the guidance document, for your final software version.

(S1) Sponsor's has provided the software testing suggested in the Guidance Document and the level of testing is adequate.

Your software description does not describe in enough detail the "cycling algorithm". Please describe in detail all of the algorithms used for the following:

Adjusting motor speed and torque other than by user interface "speed control"

(S1) The sponsor has described the algorithm in detail. This is a part of an automatic "passive" cycling stage used to warm the patient up. The protocol is identical to K841112.

Automatic stimulation control

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(S1) The stimulation is increased in order to match cycling speed with the control speed in a fashion similar to the predicate device.

Fatigue detection

(S1) If the stimulator is at maximum stimulation (set-able for the patient) and the crank speed drops below the fatigue threshold, stimulation ceases and passive cycling begins.

Electrode monitoring system

(S1) Electrode impedance is constantly monitored.

Please ensure that your testing includes testing of these algorithms. It is anticipated that a clinical study is needed to demonstrate the safety of these algorithms absent a basis in clinical literature.

(S1) Sponsor has provided results of clinical studies of this device adequate to reasonably ensure safety and effectiveness of these features.

It is unclear if this device is able to be connected to an external PC. It is recommended that you disable any control from an external PC of the stimulation parameters. If the external PC is used for downloading data only (no control) it is conceivable that this is acceptable if it can be shown that the interface is isolated from the function of the device. Furthermore, any software provided for the PC with the device must be described in detail (per Guidance Document). Specifically, this software would be considered part of the device labeling even if it does not control any of the device function.

(S1) There is no external PC.

Your device software testing is minimal. Your testing should include testing of all user set-able parameters, and verification that the device output (stimulation, motor speed, and torque) is as specified. These parameters should be varied through their intended ranges, and the device output measured. Your testing should include ample verification that the cycling algorithms perform as specified in your algorithm description. Finally, testing of the final version of the software should be provided.

(S1) Sponsor has provided results of significant software testing including clinical trials. This testing is at an appropriate level for this type of device.

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LABELING

The Sponsor has followed the Guidance Document for powered muscle stimulators.

Labeling claims have been commented upon extensively by CAPT Marie Schroeder, physical therapist, attached.

Please add the following warning: "The long term effects of electrical stimulation on a pregnant individual (mother and baby) are unknown"

(S1) This statement has been added.

MISC

Please explain why the Simcox et al. article was provided. Please explain what concept was intended to be supported by inclusion of this paper.

CONCLUSION

I would like to adopt a "least burdensome" approach to resolving the safety issues associated with this device which does not require clinical data. However, I do not see how this can be done. The fact that the Sponsor alludes to algorithm adjustments to the software and ongoing clinical trials corroborates my thoughts that clinical studies are needed to collect adverse information on patients using this device to ensure that the Sponsor's design is as safe as the predicated device in the intended population.

(S1) The sponsor has modified indications for use and provided significantly more information, including clinical data as described in detail in the attached clinical review memorandum. The data is adequate for the reasons stated above.

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RECCOMMENDATION: Substantially Equivalent K811112
PRODUCT CODE: 84GZI (Stimulator, Neuromuscular, External, Functional)
ISD (Measuring Exercise Equipment)
CLASS: **II**

6/24/2005
Jeffrey Allen Rossi, Scientific Reviewer Date
General Surgical Devices Branch

Ted Stevens Date
Chief, Restorative Devices Branch/ Concur

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Rossi, Jeffrey

From: Andrew Barriskill [abarriskill@restorative-therapies.com]
Sent: Friday, June 10, 2005 10:26 AM
To: JRR@CDRH.FDA.GOV; MAS@CDRH.FDA.GOV
Subject: Answers to lastest clinical questions

Hi Jeff & Marie,

Below are Shriners answers to Marie's questions from yesterday.

Kind Regards, Andrew

(b) (4)

[redacted]

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Rossi, Jeffrey

Hi Jeff,

Below are our responses to Marie's questions this morning. The revised documents are attached.

Please let me know if any further clarification is required.

Kind Regards, Andrew

(b) (4)

[redacted]

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motorized FES ergometer

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Activity is key...

.ervous system damage from diseases or accidents almost always reduces activity levels. Over time this loss of activity can impair your general health, decrease your quality of life and increase demands on medical and social services.

Increasing your activity level can improve cardiovascular fitness and range of motion. It can raise energy levels and decrease muscle atrophy allowing you to better perform activities of daily living.

Predictably better health can bring other rewards: economic rewards of more gainful employment days; psychological rewards of greater self-esteem and confidence.

At Restorative Therapies we understand your need for effective, time-efficient therapy compatible with your rehabilitation goals and your environment.

The RT300-S

The RT300-S system empowers you to undertake rehabilitation sessions in your own home that will assist you by:

- Relaxing muscle spasms
- Minimizing muscle atrophy
- Improving blood circulation
- Maintaining or increasing range of motion

The RT300-S does this by utilizing a computer controlled motorized cycle ergometer with an integrated functional electrical stimulation system (FES). This enables you to cycle using your own muscles.

What is FES ?

Functional Electrical Stimulation is a rehabilitation technique where low-level electrical current is applied to an individual with a disability to enhance that person's health and ability to live independently.

In the case of the RT300-S, FES is used to stimulate patterned movement of the legs. This enables the muscles to perform cycling work even though the user has lost voluntary control of the muscles.

Passive & Active Therapy

Passive therapy is when your arms or legs are moved mechanically, e.g. by the motor of a cycle or by a physical therapist's manipulations.

Active therapy is when your muscles are doing the ›rk to complete a movement under your own ›ontrol or activated by FES.

What is a cycle ergometer ?

An ergometer is a device for measuring the amount of work done by a muscle or group of muscles. In the case of the RT300-S, the ergometer is the machine that allows the user to conduct both passive and active therapy.

How does the RT300-S motor help you ?

The RT300-S motor is an essential component of the system. The motor can provide both assistance and resistance depending upon the phase of a therapy session. When you first start using the RT300-S, your muscles will tire quickly.

The motor on the RT300-S will allow you to complete a full duration therapy session (one hour) in your home from day one in spite of this early muscle fatigue. As you progress with your therapy and your muscles strengthen the motor will provide resistance against which your muscles can work.

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Using the RT300-S

› transfer from your wheelchair is required. You sit in your wheelchair with your feet secured in the ›otrests and your legs supported by the leg guides.

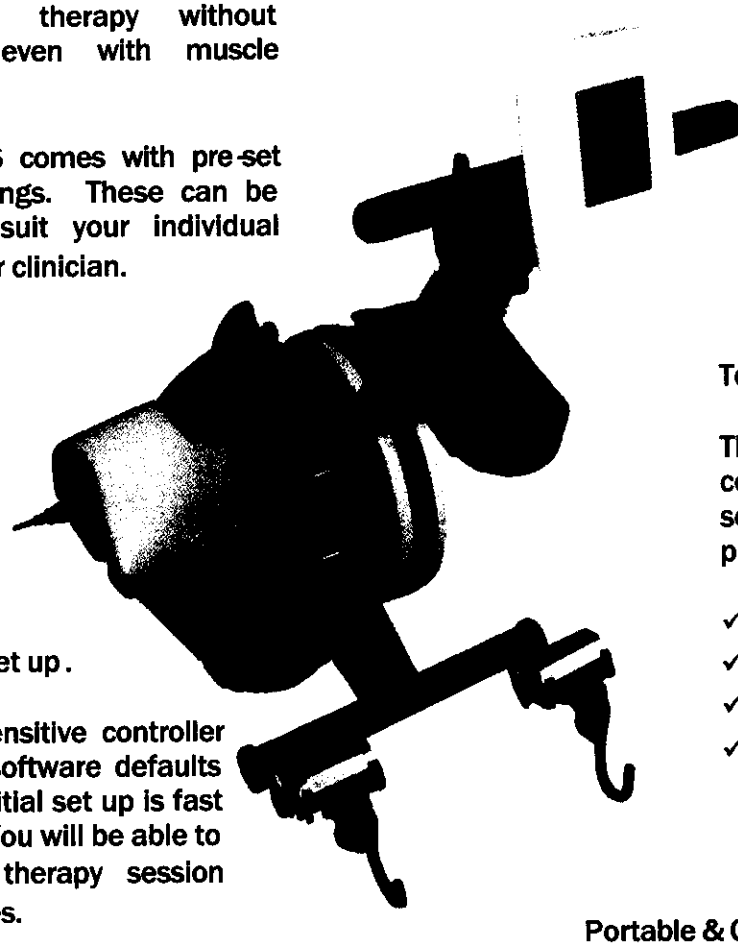
Surface electrodes placed on your skin over leg muscle groups are connected by a set of cables.

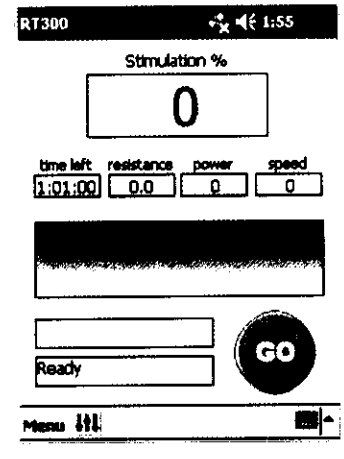
A computer controls the stimulation patterns sent to your legs producing a smooth pedaling motion. You then perform a therapy session.

Fully automatic therapies

The RT300-S is motorized to enable you to complete a full duration of therapy without assistance, even with muscle fatigue.

The RT300-S comes with pre-set therapy settings. These can be tailored to suit your individual needs by your clinician.





Touch-sensitive controller screen

The controller screen lets you control all aspects of your therapy session. Graphically view your progress:

- ✓ stimulation level
- ✓ speed
- ✓ time remaining
- ✓ resistance

Fast simple set up.

The touch sensitive controller screen and software defaults mean that initial set up is fast and simple. You will be able to begin your therapy session within minutes.

Portable & Compact

A strap in front and wheels on the back allow it to be easily moved across a room.

The RT300-S takes up very little floor space. The dimension of the base is less than 2 feet wide by 2 feet long (54 cm X 46 cm). The height of the handle is adjustable to fit the user. The RT300-S has a sleek, durable design intended for home use.

Inbuilt Safety Measures

- ✓ automatic speed control
- ✓ automatic stimulation control
- ✓ fatigue detection
- ✓ electrode monitoring system
- ✓ wheelchair restraints

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RT300-S
motorized FES ergometer

Is the RT300-S system right for me?

The RT300-S is indicated for

1. Relaxing muscle spasms
2. Minimizing muscle atrophy
3. Improving blood circulation
4. Maintaining or increasing range of motion

This device is contraindicated (inappropriate) if you have a cardiac demand pacemaker.

Consultation with your physician is *required* to determine if the RT300-S is suitable for you to use.

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

Is the RT300-S reimbursed?

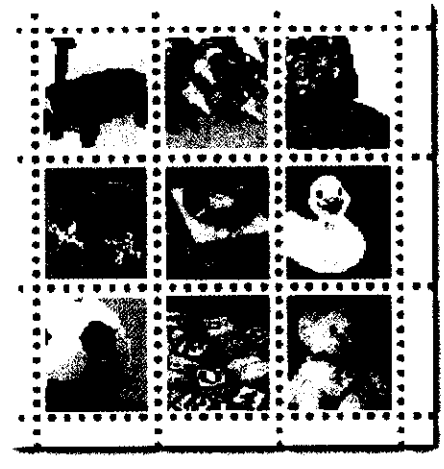
RTI works in collaboration with an insurance claims processing company to help maximize your reimbursement. Availability of insurance coverage for this therapy will depend upon several factors including the insurance that you hold. Please call RTI or see the web site for further details.

Is financing available?

RTI is able to refer you to medical finance providers who will assist you to finance the RT300-S on attractive terms. Please call RTI or see the web site for further details.

Pediatric version

The pediatric version, the RT300-SP, is intended for a population ages 4 to 12 years. It has a multi adjustable pedal system and reduced height handles.



Technical Specifications

6 channels of electrical stimulation

- 140mA (± 2mA) with 200V compliance

Motorized with virtual motor flywheel

- Torque 0 – 15Nm (± 1Nm)
- Speed 0 – 55rpm (± 2rpm)
- Noise Lpa ≤ 70dB (A)

Length 21.3" (54 cm)
Width 18.1" (46 cm)
Height 18.1" (46 cm) (without handles)
Weight 75 lbs (34 kg)

Description	Part Number
RT300-S Adult FES cycle ergometer	FA100052
RT300-SP Pediatric FES cycle ergometer	FA100053

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

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RT300-S™ system

User Guide

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RT300-S System

User Guide

Caution:

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

Part Number: LB100108 RV100578 Issue 6
[April 2005]

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Introduction

About this Guide

This guide explains how to use the RT300-S System in your own home. It contains information about how to:

- apply proper safety measures when you use the system
- set up and use the equipment
- fix any basic problems that may occur

What You Need to Know Before You Start

Before you start using the RT300-S System:

- read this guide – in particular, check the *Indications for Use, Contraindication,* and *Warnings, Precautions and Safety Measures* sections of this guide
- talk to your clinician who will provide training to help you get started and explain how the *Warnings, Precautions and Safety Measures* relate to you.

Indications for Use

The RT300-S is **indicated** 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**

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Contraindication

Powered muscle stimulators should not be used on patients with other implanted devices (including cardiac demand pacemakers or electronic baclofen pumps).

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Warnings, Precautions and Safety Measures

Read this section carefully so you understand how to use the RT300-S System safely.

Before you start using the RT300-S System, talk to your clinician about the information in this chapter.

The RT300-S generates currents sufficient to cause electrocution if used improperly.

Warnings

If the patient's blood pressure or heart rate reaches a level that the clinician considers to be 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.

1. 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.
2. If directed by the clinician, the patient's blood pressure and heart rate should be monitored during the therapy session.
3. The long-term effects of chronic electrical stimulation are unknown.
4. The long term effects of electrical stimulation on a pregnant individual (mother and baby) are unknown.
5. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
6. 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.
7. Stimulation should not be applied trans-thoracically (across the upper body) in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
8. Stimulation should not be applied trans-cerebrally (to the head).
9. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
10. Stimulation should not be applied over, or in proximity to, cancerous lesions.

Precautions

1. Safety of powered muscle stimulators for use during pregnancy has not been established.
2. Caution should be used for patients with suspected or diagnosed heart problems.
3. Caution should be used for patients with suspected or diagnosed epilepsy.
4. Caution should be used in the presence of the following:
   a. when there is a tendency to hemorrhage following acute trauma or fracture;

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b. following recent surgical procedures when muscle contraction may disrupt the healing process;

c. over the menstruating or pregnant uterus;

d. history of uncontrolled autonomic dysreflexia;

e. history of lower limb stress fractures and

f. history of severe spasticity or spastic response to application of electrical stimulation.

5. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel). The irritation can usually be reduced by using a sensitive skin electrode or an alternative electrode placement.

6. Some patients may be prone to thermal dysregulation. Episodes of thermal dysregulation are usually less pronounced when exercising in an environment controlled for temperature and humidity. Attention should be paid to hydration and limiting the duration and intensity of exercise in intemperate environments.

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

8. Powered muscle stimulators should be kept out of the reach of children. Children should only use this device under adult supervision. Never leave the RT300-S unattended when children are present.

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

Adverse Reactions

Autonomic Dysreflexia

Individuals with a spinal cord injury at or above the T6 level are prone to episodes of autonomic dysreflexia. These episodes may be triggered by electrical stimulation. If you have a spinal cord injury, it is important that you discuss this with your clinician and understand how autonomic dysreflexia may impact you:

- know how to recognize the signs of autonomic dysreflexia
- know how to react if it occurs, including stopping electrical stimulation

To reduce the chances of experiencing autonomic dysreflexia the following precautions should be followed:

- Empty bladder and bowels before commencing a therapy session with the RT300-S.
- Do **NOT** use the RT300-S if you have a bladder infection or fever.

IMPORTANT NOTE: Care in noting any symptoms of Autonomic Dysreflexia should be taken due every therapy session. Autonomic Dysreflxia could occur during any session even if you have not experienced it recently or in prior therapy sessions.

IMPORTANT NOTE TO PARENTS: The most common signs of dysreflexia in children include headache, dizziness, blurred vision, redness of the face, neck, and/or ears, and feeling hot. Sometimes individuals will also report goose bumps, an upset stomach, or tingling feelings. Consult your child's physician for more information on how to recognize these symptoms.

If any of these symptoms occur stop the therapy session immediately.

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Skin irritation and burns

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

Safety Measures

Electrical Safety

- **Avoid flammable anesthetics:** Never use the equipment where there is a flammable anesthetic mixture containing air, oxygen or nitrous oxide.
- **Connecting the system:** Connect the system parts only in the way described in this guide. Do not try to connect or disconnect any parts while the system is turned on.
- **Other equipment:** Do not use the system with any equipment not supplied by Restorative Therapies Inc as doing so could affect the electrical safety of the system.
- **System parts:** The system contains complex electronic parts. The casings ***must not*** be opened by anyone other than qualified service personnel or the warranty will no longer apply. Also, if you attempt to make repairs yourself, you might be seriously injured.

Environment

- **Use a stable surface:** Position the motorized ergometer on an even, anti-slip surface so the equipment is stable and does not move during use.
- **Use an anti-slip device:** As an added precaution, you may wish to use an anti-slip device (e.g. mat, etc) to make sure your wheelchair does not slip backwards during very active therapy.
- **Avoid wet areas:** Never use the RT300-S Cycle Ergometer in wet or damp areas.
- **Avoid heat sources:** Place the RT300-S Cycle Ergometer equipment away from heat sources such as radiators, stoves, etc, or other objects that produce heat.
- **Arrange the power cord carefully:** Arrange the power cord so it will not be walked or tripped on, or damaged by objects being placed on it.
- **Use the correct line voltage:** Make sure you connect the RT300-S Cycle Ergometer to a grounded (earthed) power outlet that uses the voltage shown on the product label.
- **Follow extension cord ratings:** If you plan to use an extension cord, make sure the plug has three pins (i.e. the plug includes a third, protective earth pin).

Parts and Operation

- **Isolation from supply mains:** The RT300-S Cycle Ergometer can be disconnected from the mains power supply by disconnecting the power supply cord from the RT300-S
- **Do not use the controller for other purposes:** Do not use the controller for any other purposes – for example, to store documents or images as it may alter how the controller works.
- **Do not use other controllers:** Do not use another person's controller as each controller is specifically programmed to suit an individual's requirements. Using another person's controller may lead to incorrect or excessive stimulation.
- **Before use** : before using the RT300-S Cycle Ergometer for the first time or after it has been transported over a long distance, allow it to stand for about 1 hour at room temperature.
- **After a long absence:** If you do not use the RT300-S Cycle Ergometer system for a prolonged period (e.g. a few months), you may find your progress is affected. If this occurs, it is important to see your clinician for re-evaluation and, perhaps, re-training before you start using the system again.

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- **Handle with care:** Handle the various parts of the RT300-S Cycle Ergometer system with care to reduce the risk of dropping and damaging the equipment. Do not stand on the footrests or the device's plastic motor covers.
- **Check for wear and tear:** Each time you use the RT300-S Cycle Ergometer, carefully inspect all the parts first. If you notice any damage – such as cracks or breaks in the covering of a cable – stop using the system and contact RTI Technical Support.
- **Do not handle or adjust the pedals** when the RT300-S Cycle Ergometer system is switched on.
- **Moving parts:** Keep hands well away from the pedals while the machine is in operation.
- **Report changes:** If you find any changes occur in how the RT300-S Cycle Ergometer operates, stop using the system and contact your clinician or RTI Technical Support.
  - Repairs to the RT300-S must only be carried out by properly trained specialists.
  - If the RT300-S is damaged or faulty or if it produces abnormal noises or smells, stop the therapy session immediately, unplug the power cord and contact your service technician.
- **Clothing:** Dress comfortably to allow for the appropriate range of motion in the legs and / or arms. Avoid wearing clothing that may catch on the moving parts of the system.

Electrostatic Discharge

A discharge of static electricity could damage:

- electrical parts of the system
- software programs on the controller

If static electricity is present, touch a metal part of the ergometer before fitting any parts or touching the controller. Examples of where static electricity might occur are:

- putting clothes on over your head
- in very low humidity

Electromagnetic Interference

The RT300-S needs special precautions regarding EMC and needs to be installed and put in service according to the EMC information provided in the User Guide.

The use of accessories and cables other than those specified with the exception of accessories and cables sold by the manufacturer of the RT300-S as replacement parts for internal components, may result in increased emissions or decreased immunity of the RT300-S.

Electromagnetic interference (EMI) from sources such as radio and TV stations, amateur radio (HAM) transmitters, two-way radios, and cellular phones can affect the RT300-S Cycle Ergometer.

a. Portable and mobile RF communications equipment can affect the RT300-S

b. Do not operate handheld transceivers such as citizens band (CB) radios while operating the RT300-S

c. Be aware of nearby transmitters, such as radio or TV stations

d. Keep the RT300-S at least 20ft away from microwave ovens

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RTI Technical Support

Restorative Therapies Inc (RTI) offers a technical support service to provide troubleshooting help when:

- you have read this guide but are experiencing difficulties with the RT300-S System
- the system is due for a maintenance service
- you need to order replacement parts

Contact RTI Technical Support:

- via email to **support@restorative-therapies.com**
- by calling **1-800-609-9166**

Terms used in this guide

Term	What it Means
BlueTooth	A wireless, automatic means by which electronic devices connect to each other. BlueTooth devices communicate with each other on a standard band or range of radio frequency called the ISM (industrial, scientific and medical) devices band.
controller	A computerized panel used to control the RT300-S System.
FES	Functional Electrical Stimulation
ⓘ	Important information or help.
RTI	Restorative Therapies, Inc
Calf or leg	The limb segment between the knee and ankle.
surface electrode	An electrode (adhesive pad) that is attached to the skin surface to stimulate a group of muscles. Each surface electrode connects to the RT300-S System via the stimulation cable.
Thigh	The limb segment between the hip and knee.
Torso	The part of the body from the shoulders to the waist.
Type BF Applied Part	This term is used in the "IEC 60601-1" electrical safety standard. It applies to the parts of a medical device that must physically touch a person to carry out the device's intended function. Applied Parts are Type B, or Type BF, or Type CF depending on the nature of the device and the type of contact. Each type has different requirements for protecting people against electrical shock.

Table 1: Terms used in this guide

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RT300-S System

What is the RT300-S System used for?

The RT300-S System is a motorized therapy system, which you use for:

- **passive therapy** – with motor power, and
- **active therapy** – with electrical stimulation applied to your muscles

The system is designed to provide a therapy routine prescribed by your clinician.

Parts of the RT300-S System

Table 2 shows a list of the RT300-S System's parts:

Part		Part Number
RT300-S system	RT300-S	FA100052
	RT300-SP (Pediatric)	FA100053
Controller / Stimulator		SA100090
Controller / Stimulator mounting plate		PP100271
Controller / Stimulator power cable		PP100206
Power cord (USA)		SA100110
Stimulation cable		SA100091
Rectangle surface electrodes 2"x3.5" Qty 4		FA100015
Velcro pedal straps		PP100124
Velcro calf support straps		PP100125
Wheelchair restraint strap		PP100458
RT300-S System User Guide (this document)		LB100108
Warranty card		LB100109

Table 2: RT300-S System parts and part numbers

If a part is damaged or lost, use the **part number** to order a new one from Restorative Therapies Inc. Please call or use our web store at www.restorative-therapies.com

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Surface Electrodes

You should replace your surface electrodes after approximately 15 uses to ensure good adhesion and connectivity. **Be especially careful to monitor the condition of the electrodes that you use on your gluteal muscles as these are subject to more wear and skin burns are reported to be more likely here.**

Table 3 shows the description and part number for ordering surface electrodes from RTI. Contact RTI to order new electrodes or via the web at www.restorative-therapies.com.

Part	RTI Part Number
Size: 2" x 2"	PP100418
Standard electrode: Size: 2" x 3.5"	FA100015
Size: 3" x 4"	PP100419
Size: 3" x 5" oval	PP100420
Size 2" x 2" (sensitive skin)	PP100421

Table 3: Recommended surface electrode details

Selecting the right electrodes

Electrodes need to be selected that best fits the size of your muscles - your clinician will assist you in selecting the correct electrodes for your body.

The quadriceps and hamstrings typically require larger electrodes than the gluteals. Usually your clinician will try to cover a good portion of the muscle without allowing the electrodes to touch and without covering other muscles that are not to be stimulated.

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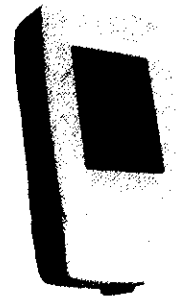
Setting Up the Equipment

Safety handle



Controller / stimulator

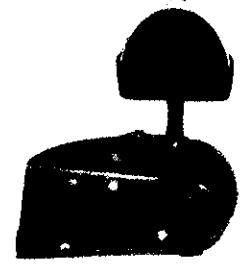
Stimulation cable

Safety handle extension with cable

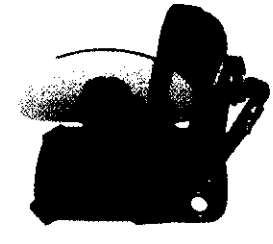
Surface electrode

Toolkit

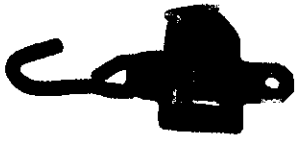
Safety handle mount



Adult pedal (1of 2)

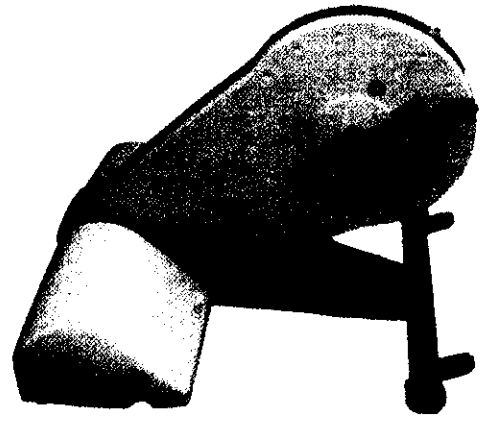


or Pediatric pedal (1 of 2)



Wheelchair restraint (1 of 2)

Base unit



Power cord (USA)

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RT300-S System Overview

Standard RT300-S Equipment

Standard RT300-S equipment is:

- motorized cycle ergometer
- controller / stimulator and mounting plate
- 12 skin surfac e electrodes
- stimulation cable for connecting the skin surface electrodes to the controller / stimulator
- wheelchair restraints for securing the wheelchair to the RT300-S
- power cord

Figure 1 shows the standard equipment and features.

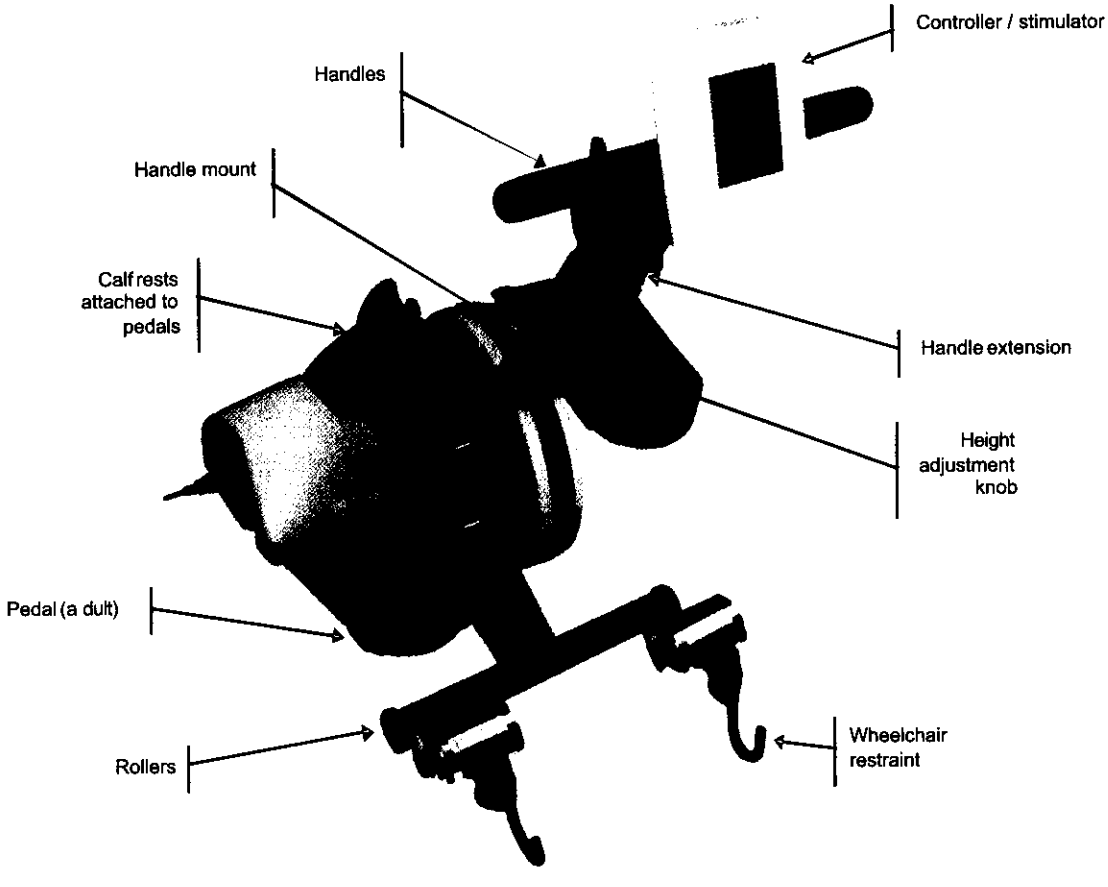

Figure 1: RT300-S system components

You use the RT300-S System from your wheelchair, with your feet secured in the pedals and your legs supported by the calf rests.

Surface electrodes placed on your skin over particu lar muscle groups are connected to the ergometer by a set of cables.

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Software on the controller controls the stimulation patterns sent to your legs, producing a smooth pedaling motion.

It is recommended you always wear shoes (e.g. running shoes) when usi ng the RT300-S System.

Optional RT300-S Equipment

You can add the ergometer platform if you need to raise the height of the whole ergometer.

Contact RTI for more information on purchasing the ergometer platform or visit the store at

www.restorative-therapies.com.

Figure 2 Ergometer platform with adjustable height legs, FA 100019

RT300-SP Ergometer for Pediatrics

The RT300-SP is the pediatric version of the RT300-S. It includes as standard equipment:

- handles which can be adjusted to a lower height than the handles on the adult ergometer
- a different pedal system that is adjustable for smaller feet and limbs

This system is intended for children aged from 4 to 12 years old.

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Assembling the RT300-S

Checking the Parts

Before you start assembling the ergometer, unpack **all** of the parts and:

1. Check to make sure none of the parts are damaged or missing. See page 11 for details on all parts.

If any of parts are damaged, missing contact RTI Technical Support immediately. Do not use the system.

Fitting the safety handle mount and extension

To fit the support arm:

1. Place the base unit of the ergometer on a flat, even surface.

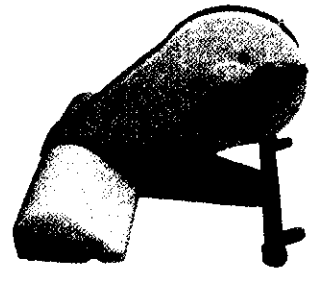

Figure 3: Base unit of the ergometer

2. Slide the safety handle extension into the safety handle mount as shown in Figure 4. Ensure that the Controller power cable also passes completely through.

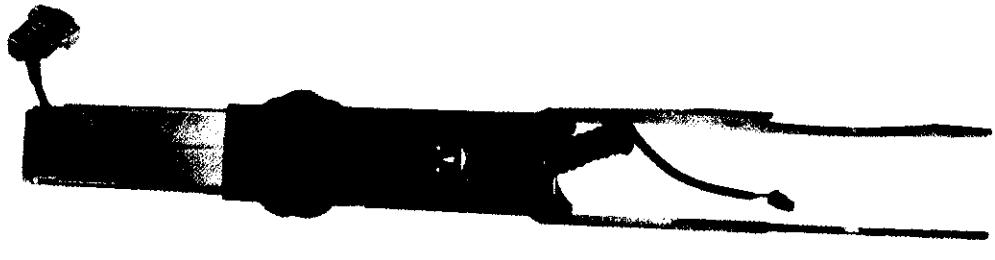

Figure 4 Slide the safety handle extension into the safety handle mount

3. Hold the safety handle mount with the height adjustment knob facing you.
4. Slide the safety handle mount forks over the encased sheave being careful not to trap the Controller power cable.
5. Connect the Controller power cable to the cable protruding from the base unit.
6. Slide the support arm down until the bolt holes on the forks align with the bolt holes on the sheave casing being careful not to trap or cut the Controller power cable.

There are two bolt holes on each fork and two corresponding bolt holes on each side of the sheave casing.

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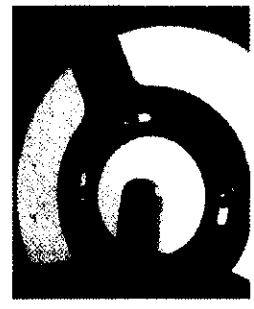

Figure 5: Bolt holes aligned

7. Screw the bolts into the bolt holes and tighten each bolt using the Allen (Hex) Key provided.

Figure 6 Allen (Hex) key

It may be necessary to loosen the lower bolts and rotate the whole assembly.

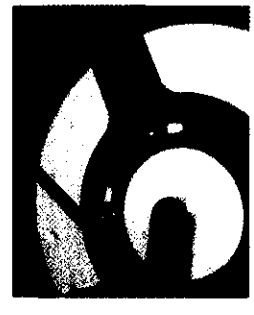

Figure 7: Tightening a bolt with the Allen (Hex) Key

Fitting the safety handle

1. Fit the safety handle to the safety handle extension using the two bolts supplied.

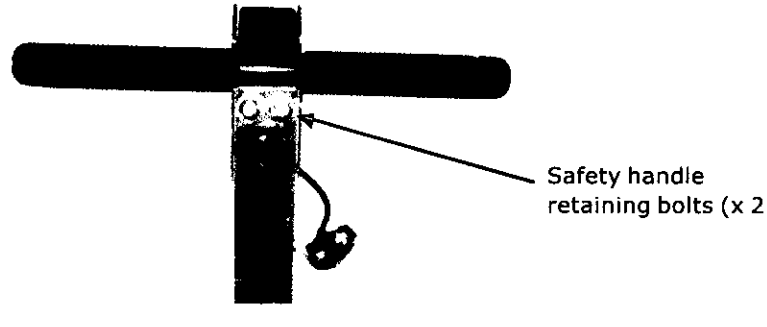

Figure 8: Fitting the safety handle

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Fitting the controller / stimulator

1. Fit the Controller mounting plate to the safety handle assembly using the hex bolts supplied as shown in Figure 9.

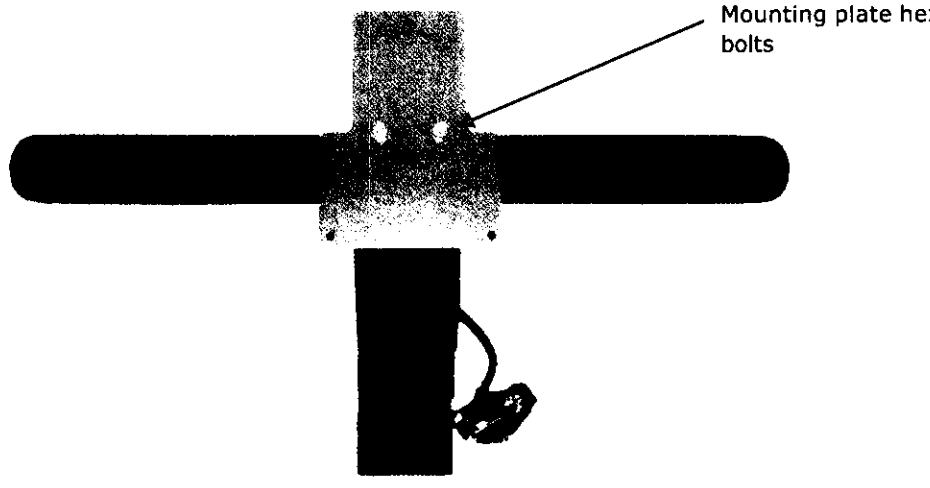

Figure 9 Controller Mounting Plate

2. Fit the Controller to the Controller mounting plate using the three screws supplied.

3. Plug the Controller power cable into the back of the Controller.

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Adjust the height of the safety handles

When you use the RT300-S System, you need to sit upright, and be able to comfortably reach and use the handles and controller.

The safety handle's extension section can be moved up or down to a height that suits you.

To adjust the height of the safety handles:

1. Turn the height adjustment knob counter-clockwise until the handle extension section is loose.

Figure 10: Adjusting the height

2. Slide the handle extension section to the height you require.
3. Turn the height adjustment knob clockwise until the handle extension section locks into place.

Adjusting the pedal crank radius

The pedal crank radius can be adjusted as shown in Figure 11

1. Open the locking pin
2. Move the footrest to the desired position on the crank and **tighten the locking pin firmly**!
3. Adjust the opposite pedal in the same way.

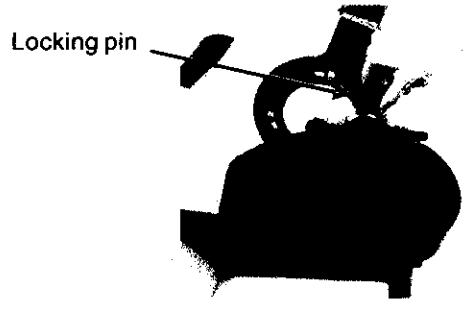

Figure 11 Pedal crank radius adjustment

Make sure that the crank lengths on both sides are equal. Depending on the nature of the patient's condition, asymmetrical crank lengths may sometimes be of benefit. With an amputated leg it can be necessary to remove one pedal completely.

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Adjusting pediatric pedals

Two hex wrenches are provided for adjusting the pediatric pedals.

Figure 12 Pediatric pedal adjustment tools

The angle of the calf rest can be adjusted in three dimensions as shown in **Figure 13**.

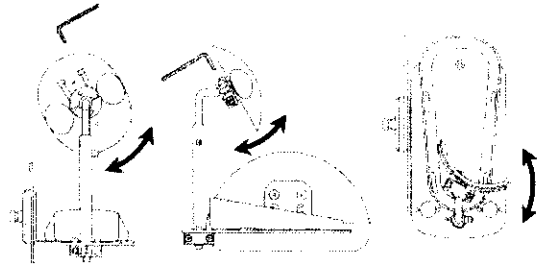

Figure 13 Calf support angle adjustment

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The plastic foot plate can be removed by detaching it from the retaining Velcro. The angle of the plastic foot plate can be adjusted by reattaching it at the required angle using the retaining Velcro provided.

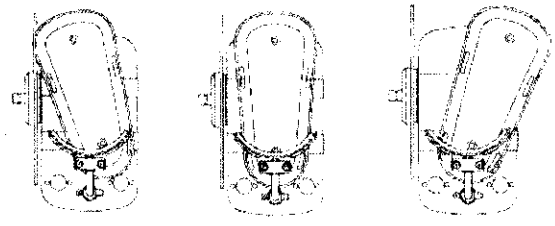

Figure 14 Foot plate angle adjustment

Make sure that the plastic foot plate is firmly attached by the Velcro. Press firmly!

The position of the calf rest on the foot plate assembly can be adjusted as shown in Figure 15 (inner, middle and outer positions).

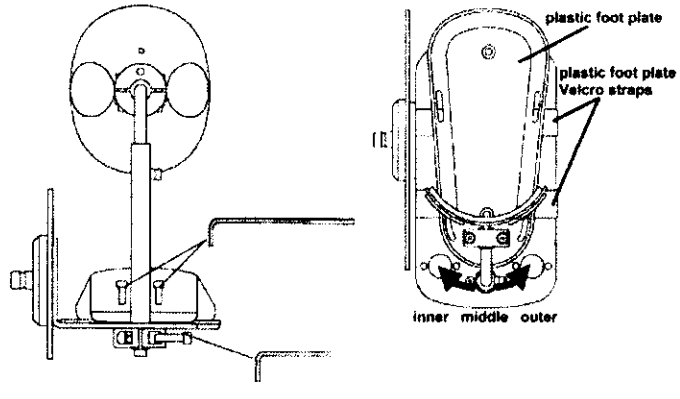

Figure 15 Calf rest position adjustment

The height of the calf rest can be adjusted as shown in Figure 16.

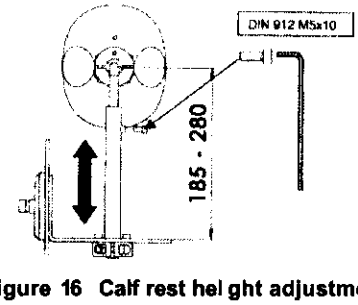

Figure 16 Calf rest height adjustment

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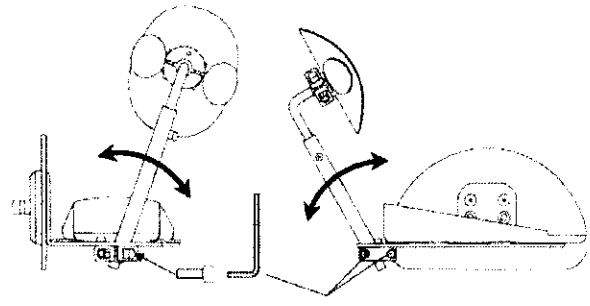

Figure 17 Calf rest angle adjustment

The height of the foot rest assembly can be adjusted as shown in Figure 18.

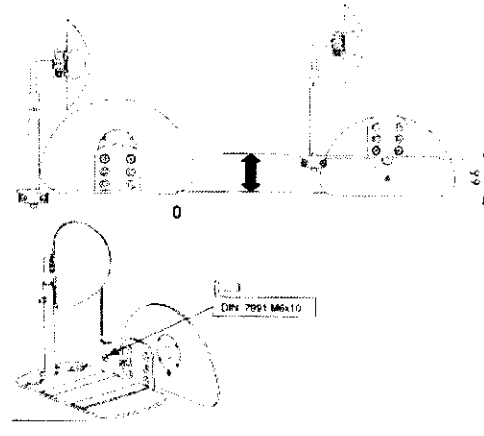

Figure 18 Foot plate assembly height adjustment

The feet must be strapped into place within the plastic foot rests using the Velcro straps shown in Figure 19.

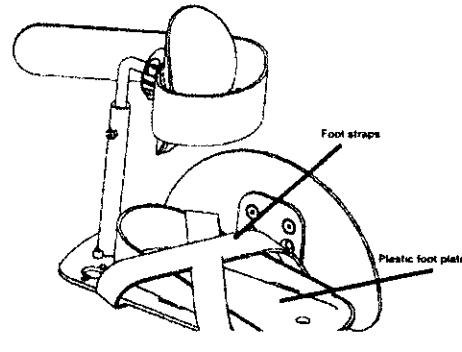

Figure 19 Foot straps

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Base of support

The stability of the RT300-S can be increased by extending the base of support.

To extend the base of support:
1. Tip the RT300-S up over on its castors
2. Loosen the two hex bolts with the hex key provided
3. Pull out the cross bar as far as needed but do not extend it beyond the mark.

Figure 20 Hex bolts and cross bar for stability adjustment

Fitting the wheelchair restraints

To fit the wheelchair restraints:

1. Place nylon washer over wheelchair restraint attachment point on crossbar

2. Bolt the wheelchair restraint to the crossbar and tighten

3. Repeat for the other side of the crossbar

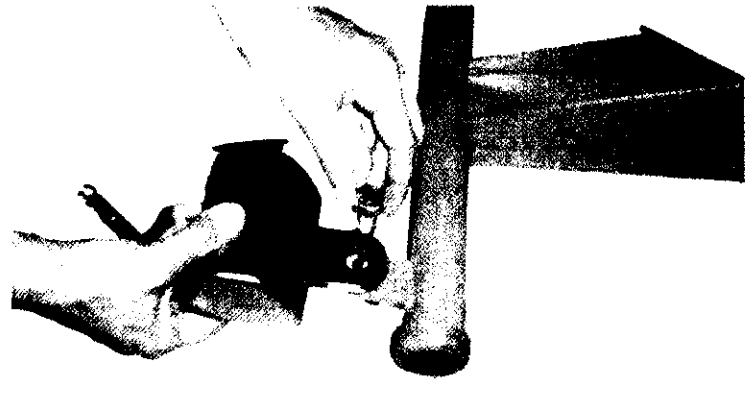

Figure 21 Fitting wheelchair restraint

Connecting the Power

To connect the power:

1. Use the power cord provided to connect the RT300-S System to a power outlet.

2. The system is intended to be left connected to a power outlet so that the Controller's internal battery remains charged. The system will automatically switch off shortly after a therapy session so it is not necessary to disconnect the power.

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Figure 22: Power connection

Never pull on the power cord. Always grip and pull the plug to disconnect the power cord from the power outlet.

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Fitting the equipment

Using Surface Electrodes

The RT300-S System provides stimulation through adhesive surface electrodes placed on the skin over the following muscle groups:

- right and left gluteals
- right and left hamstrings
- right and left quadriceps

Your clinician will advise you on which size electrodes are most suitable for you.

Before you fit the surface electrodes to your body, **you must** read the *Warnings, Precautions and Safety Measures* section at the front of this guide. Also read the following sections – *Surface Electrode Placement Precautions* and *Caring for Surface Electrodes.*

Surface Electrode Placement Precautions

- If there is poor contact between your skin and an electrode, or an electrode does not adhere to your skin, you may need to trim hair from the electrode site. It is recommended you clip, not shave, the hair.
- Following each session, always check electrode sites for any redness or other adverse reactions. If your skin becomes irritated, move the electrode to a slightly different area until the irritation clears. If irritation persists, or you experience a burn, contact your clinician.
- Do not use any surface electrodes that are smaller than those provided with the RT300-S System.
- Renew electrodes after 10-15 uses. See page 12 for re-ordering information.
- Periodically check the electrodes are in full contact with your skin. If an electrode repeatedly fails to adhere properly, replace it with a new one.
- Rough edges on a surface electrode may also cause electrical burns so replace the electrode if this occurs.
- Be especially careful to check the condition of the electrodes that you use on your gluteal muscles as these are subject to more wear.

Caring for Surface Electrodes

- Use the self-adhering surface electrodes supplied by Restorative Therapies Inc. See the details in Table 3 for ordering new electrodes.
- A surface electrode is expected to last for 10 to 15 applications with normal use. Throw a surface electrode away if it adheres poorly or shows signs of wear and tear (e.g. rough edges).
- Gently remove a surface electrode by lifting it from one corner. Do not pull on the connecting lead as this may damage the connection.
- Replace surface electrodes on the plastic carriers when they are not in use.

See the surface electrode pack for more instructions on use, care and storage.

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Fitting the Surface Electrodes

To use the RT300-S System, you must have all 12 surface electrodes correctly fitted to your body, as shown in Figure 23.

To fit the surface electrodes:

1. Make sure the skin where the electrodes are to be placed is clean and dry. Remove any lotion with an alcohol wipe.
2. Peel the plastic carrier off a pair of surface electrodes.
3. Place the two surface electrodes on your body at the correct location. (See Figure 23).
4. Apply light finger pressure to the entire surface of each surface electrode to make sure it is in full contact with your skin.
5. Repeat steps 2 to 4 for the remaining five pairs of surface electrodes.

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Where to Place Surface Electrodes

Figure 23 indicates the sites for electrode placement. However, as placement varies slightly between individuals, your clinician will determine the locations that provide the most effective stimulation for you.

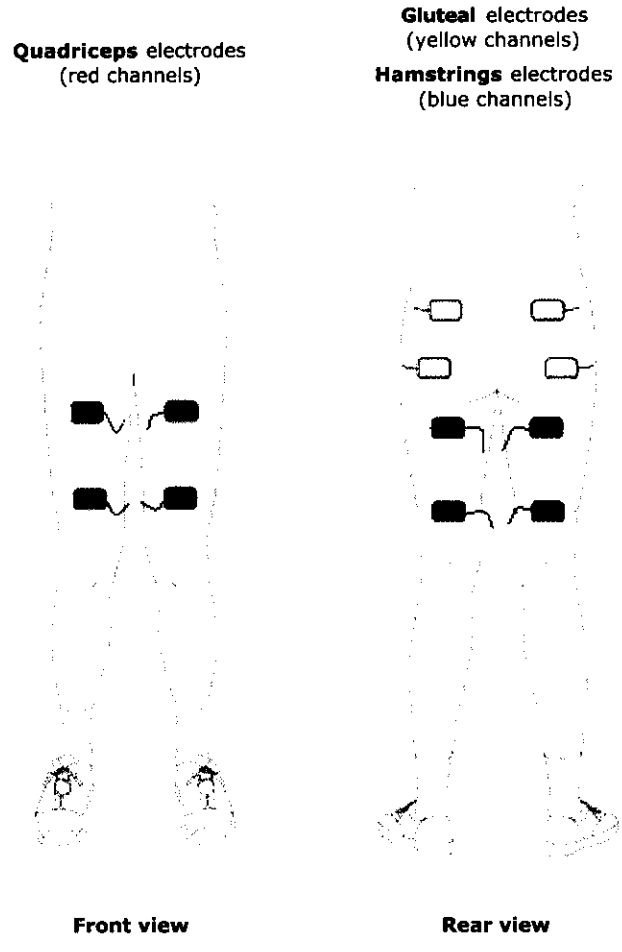

Figure 23: Surface electrode sites

The Gluteal electrode leads should face outward (lateral). It is often easiest to attach the stimulation cable to the Gluteal electrodes before placing them on your skin. All other electrode leads should face inwards (medial) as shown in Figure 23.

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Connecting the surface electrodes to the ergometer

Stimulation Cable Set

Once you ha ve fitted the surface electrodes, connect them to the stimulation cable.

One end of the stimulation cable splits into 12 leads. Six leads for the left side of your body and 6 leads for the right side. Each lead is color coded and labeled with two letters .

Figure 24: Color-coded, marked leads

Table 4 shows how the color and letters on a lead represents a particular muscle group.

Letters	Color code	Muscle Group
LG	Yellow	Left Gluteals
LH	Blue	Left Hamstrings
LQ	Red	Left Quadriceps
RG	Yellow	Right Gluteals
RH	Blue	Right Hamstrings
RQ	Red	Right Quadriceps

Table 4: Color-code/letter on stimulation cable leads

Each lead must be fitted to the corresponding surface electrode according to the color and letter.

Leads with an "R" on the label are for the right side of your body. Leads with an "L" on the label are for the left side of your body.

Examples

A surface electrode fitted to your **right** quadriceps connects to a **red** lead marked **RQ**.

A surface electrode fitted to your **left** gluteals connects to a **yellow** lead marked **LG**.

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Connecting the Surface Electrodes

To connect the stimulation cables:

1. Using the color-coding and letters on each lead as a guide:

   - connect the leads from the stimulation cable to the electrodes placed on your body.

Make sure all lead pins are fully inserted (see Figure 25). Press your finger tip across the top of the socket to be sure.

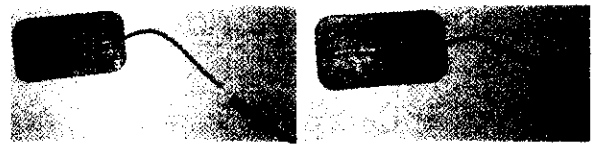

Figure 25: Connecting a lead to an electrode

2. Plug the stimulation cable into the outlet on the bottom of the Controller / stimulator – it will only fit in one way (vertical arrow on the connector to the front) and it will click into place.

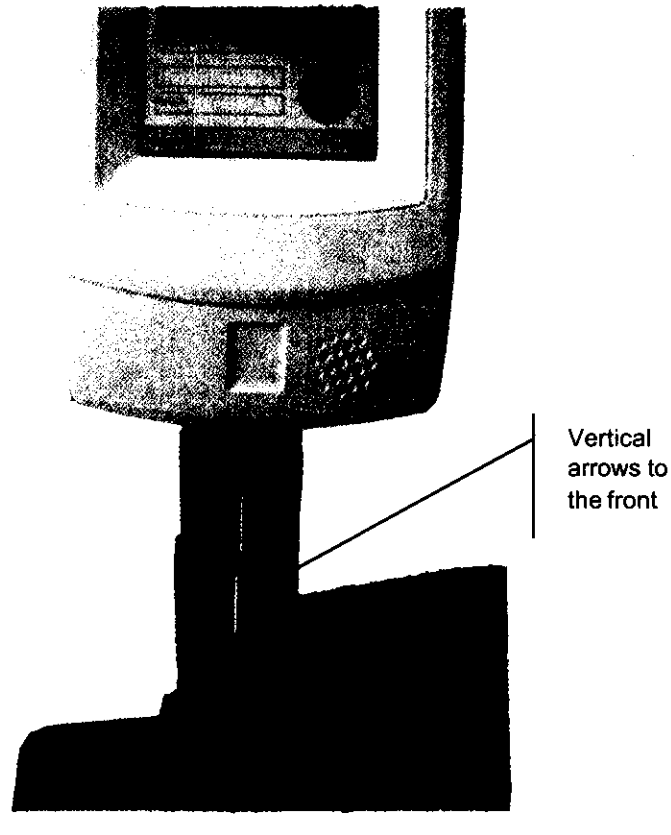

Figure 26 Attaching the stimulation cable

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Using the RT300-S System

Using the RT300-S System involves:

- initial setup
- correctly positioning yourself on the ergometer and making any necessary adjustments
- fixing your feet in the footrests and your legs in the calf rests
- restraining your wheelchair so that it does not move during the therapy session
- understanding what happens during a typical therapy session
- understanding the functions of the RT300-S controller / stimulator
- starting and stopping a session
- knowing what happens if muscle spasm occurs
- being aware of the possibility of autonomic dysreflexia

Initial setup

When you first power on the RT300-S it is necessary to calibrate the Controller's touch screen.

The procedure to do this is described below.

Once you have calibrated your controller's touch screen you should leave the RT300-S connected to a power outlet. This will ensure that the RT300-S controller's back up battery remains charged.

If you disconnect your system from a power outlet you will need to repeat this calibration procedure.

Calibrate the touch screen

1. Follow the instructions provided by the Controller
   - Using the Stylus touch the screen in the positions requested by the controller.
   - Cut and paste the demonstration appointment
   - Select your time zone

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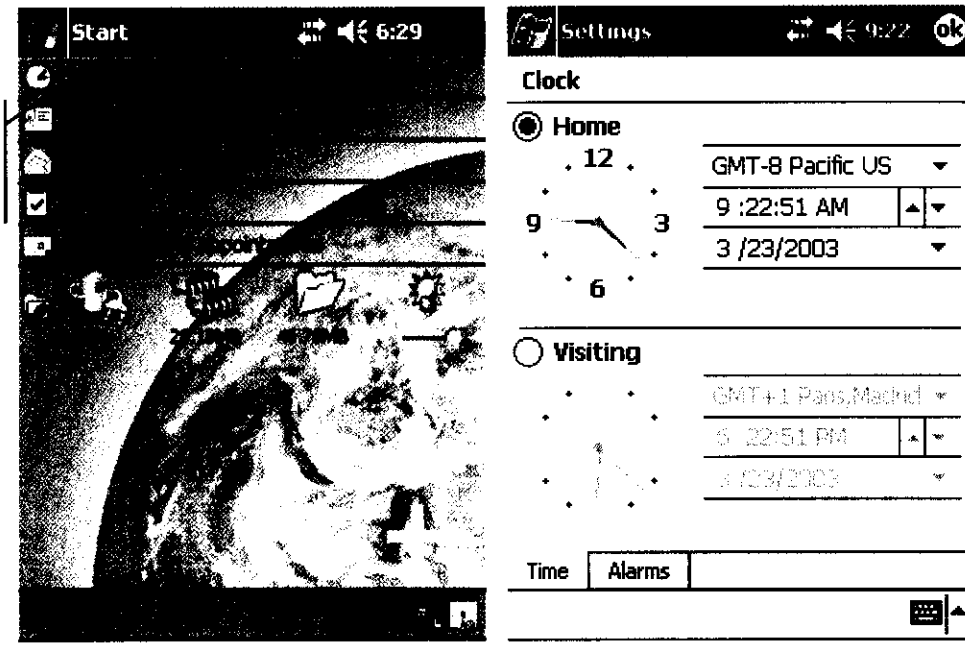
Set the time and date

1. Set the Home time on the system as shown below:

1. Press the date



2. Enter the correct time and date here

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Positioning on the Ergometer

Getting into the correct position on the ergometer involves:

- setting the distance between your wheelchair and the ergometer
- strapping your feet into the footrests and legs against the calf rests

Setting the distance

The distance you should set between your wheelchair and the ergometer is affected by:

- the type of wheelchair you use
- the length of your legs
- your height

The most effective way to check you are correctly positioned is to check the angle of your knee joint when your foot is in the footrest and your leg is fully extended.

To set the correct distance:

1. Place your foot in a footrest, resting your leg in the leg guide.
2. Move your wheelchair slowly back or forward until your knee joint reaches a 45 ° angle, as shown in Figure 27.

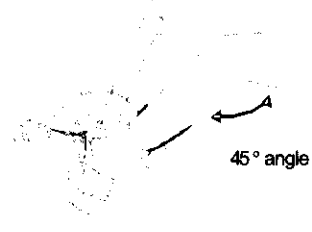

Figure 27: Knee joint at 45° angle

Using the Calf Rests and Footrests

It is recommended you always wear shoes (e.g. running shoes) when using the RT300-S System. The footrests are designed to accommodate shoes, while the calf rests help support the legs.

Both the footrests and calf rests have straps for added support and safety.

Do not put your whole body weight on the pedals when you place your feet in the footrests.

To use the footrests and calf rests:

1. Open the straps on the footrests and calf rests.
2. Place your left foot in the footrest, resting your leg against the leg guide.

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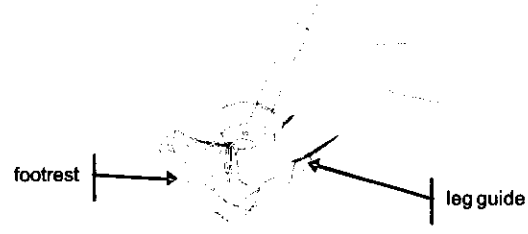

Figure 28: Foot and leg position

3. When you are correctly positioned, fasten the straps on the footrest and leg guide.

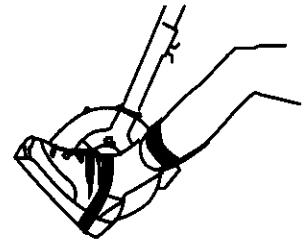

Figure 29: Straps fastened on footrest and leg guide

4. Repeat steps 2 and 3 for your right foot.

Using the wheelchair restraints

Once you have correctly positioned your wheelchair you should use the restraining straps provided to ensure that your wheelchair does not move during your therapy session.

1. Hold down the red lever on the front of one of the restraining straps and pull out the strap
2. Hook the strap to a secure point on your wheelchair beneath the level of your seat.
3. If necessary turn the tightening knob to take up any slack
4. Repeat for the other restraining strap

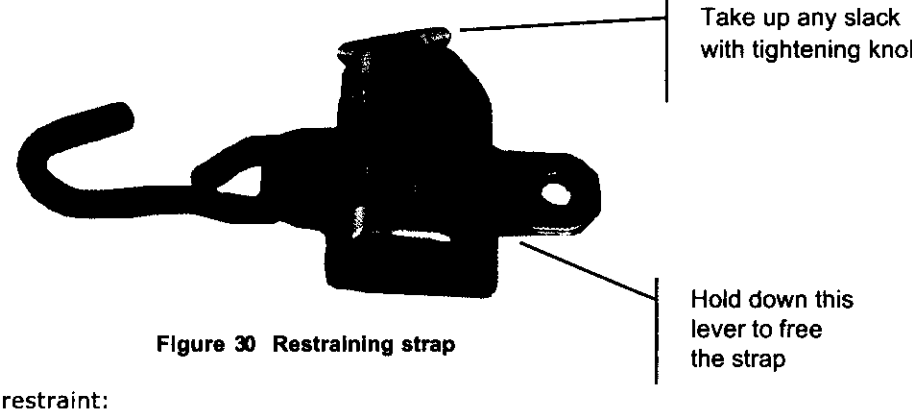

Figure 30 Restraining strap

To remove the wheelchair restraint:

1. Hold down the red lever on the front of one of the restraining strap and pull out enough slack to allow you to unhook the strap from your wheelchair
2. Release the strap and it will retract back into the restraint system.

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Using the Controller

The controller's Therapy Session screen shows what is happening at any particular time during a therapy session. The controller's touch-sensitive screen allows you to:

- Start and stop your therapy session
- Monitor the progress of your therapy session
- See any warnings or errors that occur
- Update your stimulation parameters

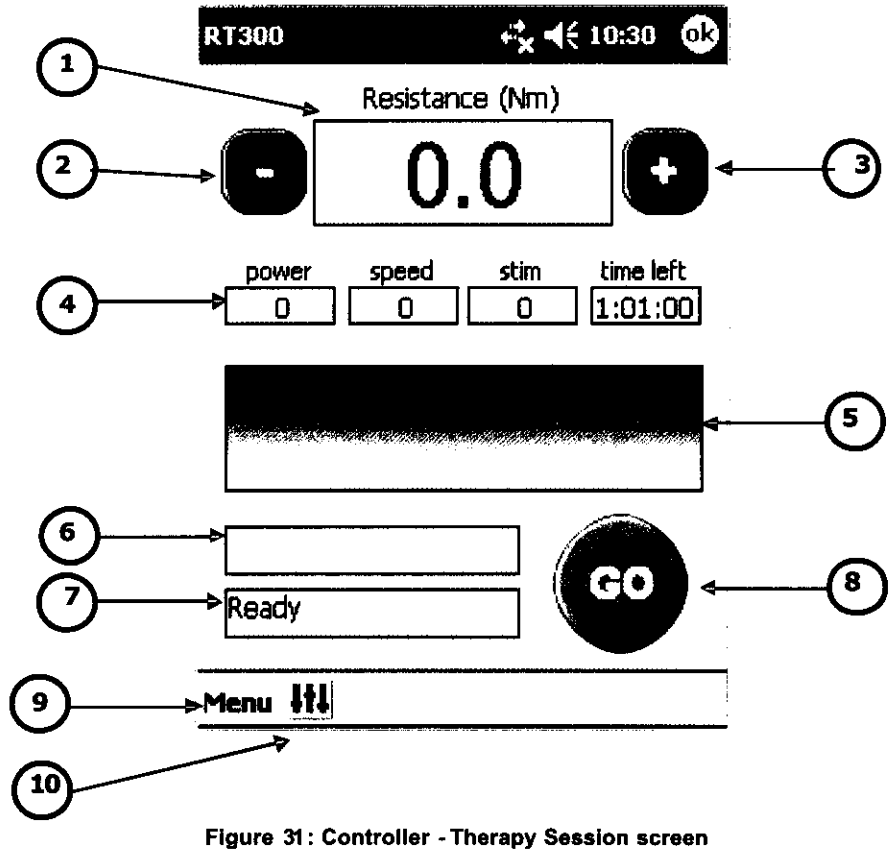

Figure 31: Controller - Therapy Session screen

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1. Main display window shows one of:
   - Time left
   - Cycling speed
   - Stimulation level (by default)
   - Resistance
   - Power

   Tap this window to cycle the displayed data.

2. Decrease button
   This button is only shown if Resistance is being displayed in the main display window AND patient adjustment has been enabled by the Clinician (see note below). Tap this button to reduce your resistance level during active therapy.

3. Increase button
   This is only shown if Resistance is being displayed in the main display window AND patient adjustment has been enabled by the Clinician (see note below). Tap this button to increase your resistance level during active therapy.

4. Secondary display windows.
   Tap these windows to transfer their data to the main display window.

5. Graphical display of data as your therapy session progresses
   - The green tracing shows your stimulation level history
   - The blue area represents time and stimulation level remaining

6. Notifies of a pending change in the phase of your therapy session (see page 36)

7. Therapy State:
   - Ready
   - Warm up (initial passive cycling)
   - Active cycling (stimulation operating)
   - Passive cycling (fatigue has been detected)
   - Cool down
   - Finished

8. Start and Stop button
   "Start" when the system is stopped and "Stop" when the system is operating.
   - Press "Start" to commence your therapy session.
   - Press "Stop" if you want to stop your therapy session early.

9. Menu bar allows for
   - About RT300... displays the version of the RT300 software
   - Log in... allows your clinician to log in to the system to adjust therapy parameters

10. Configuration button
    See page 40 for how to adjust your stimulation settings

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Clinician note: To enable or disable patient control of resistance tap on " Resistance" and enter the Clinician code when prompted.

Therapy Sessions

Once your are correctly positioned (page 32) and your wheelchair is restrained (page 33) you are ready to begin a therapy s ession.

RT300-S System therapy sessions help you to pedal using your own muscle power, providing the opportunity to make continual progress over the course of your therapy plan.

The RT300-S System is designed with pre-set (default) therapy settings. Your clinician may also make adjustments to settings like the:

- length of your therapy session
- amount of power your muscles generate during a therapy session

How the therapy session progresses

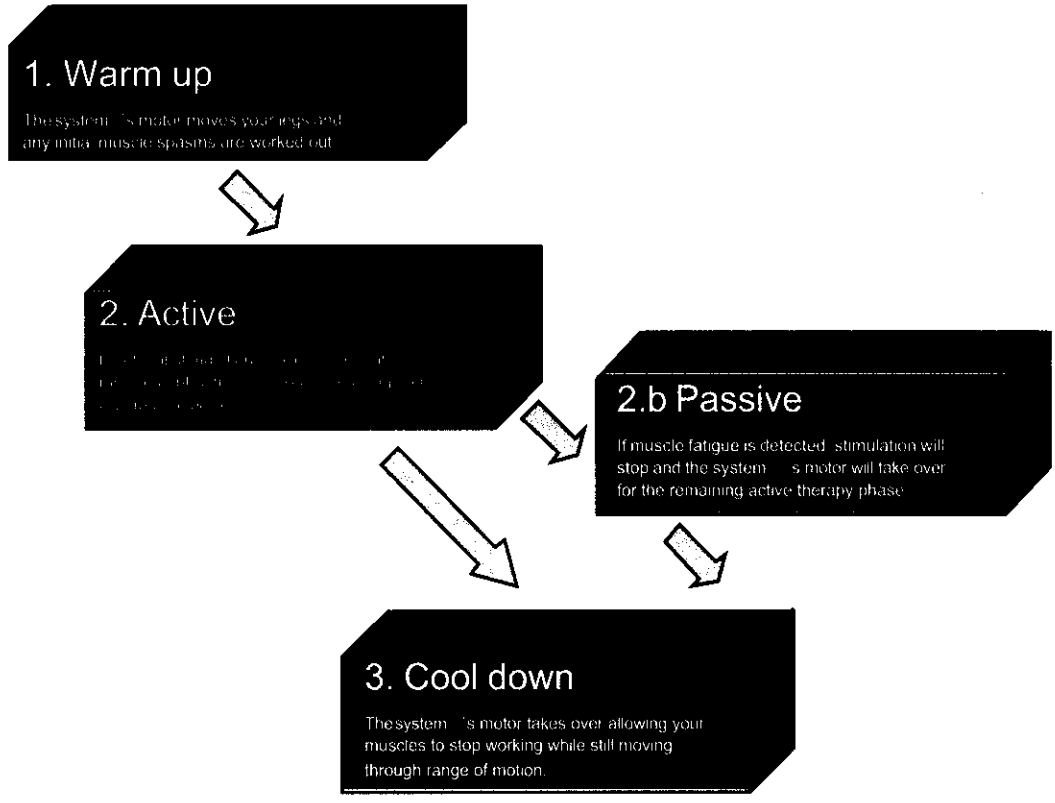

Figure 32 Phases of your therapy session

Inbuilt Safety Measures

At the end of each session, the RT300-S System automatically switches off. There are also inbuilt safety measures to help protect you during therapy. You should be aware that:

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- if the system registers muscle fatigue, the ergometer's motor takes over for the remainder of the session. You will see that the display swaps from displaying "Active cycling" to "Passive cycling".
- if an electrode falls off, the system immediately pauses by ceasing stimulation and switching off the motor. An error message is displayed on the controller Therapy Session screen to let you know what has happened. After you fix the problem, tap Go to restart the session.

Handling Muscle Spasm

At the beginning of the Warm Up phase, muscle spasms may occur. These usually subside before the Warm Up period ends.

If the spasms persist, wait approximately 5 minutes and then begin the therapy session again. If the spasms still do not subside, the therapy session should be postponed.

Starting and Stopping a Therapy Se ssion

Before every therapy session, always empty your bladder to minimize the risk of autonomic dysreflexia occurring. If you have any concerns, talk to your clinician.

Starting a Session

To start a therapy session:

1. If the screen is dark, touch the controller screen to turn the system on.
2. Tap Go. The ergometer starts operating and your therapy session begins.

Tapping...
You can tap the screen using the stylus provided or your fingernail. If your fingernails are short, simply use the back of your finger to allow your fingernail to contact the screen.

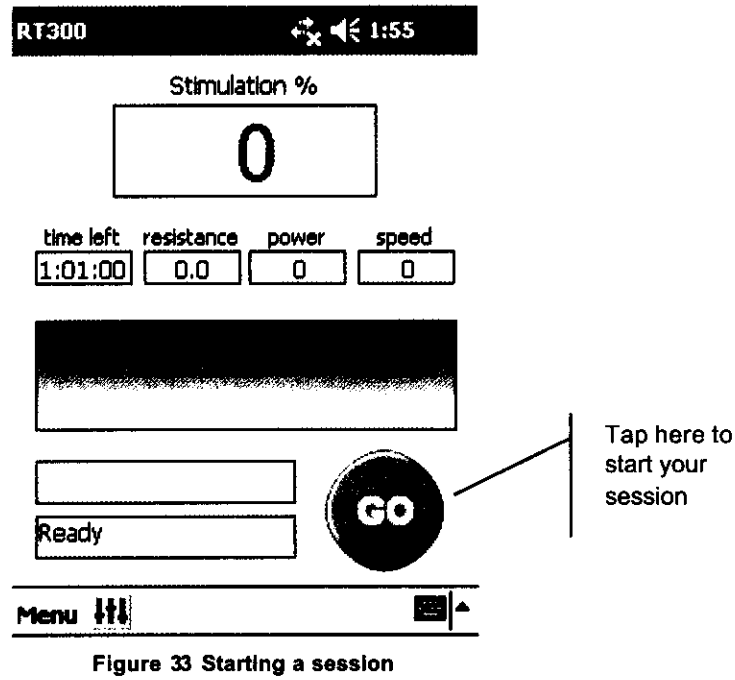

Figure 33 Starting a session

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Stopping a Session Early

The RT300-S System automatically stops once the end of the session is reached. However, you can stop the session at any tim e if you wish.

To stop a therapy session early:

1. Tap Stop. The session is ended.

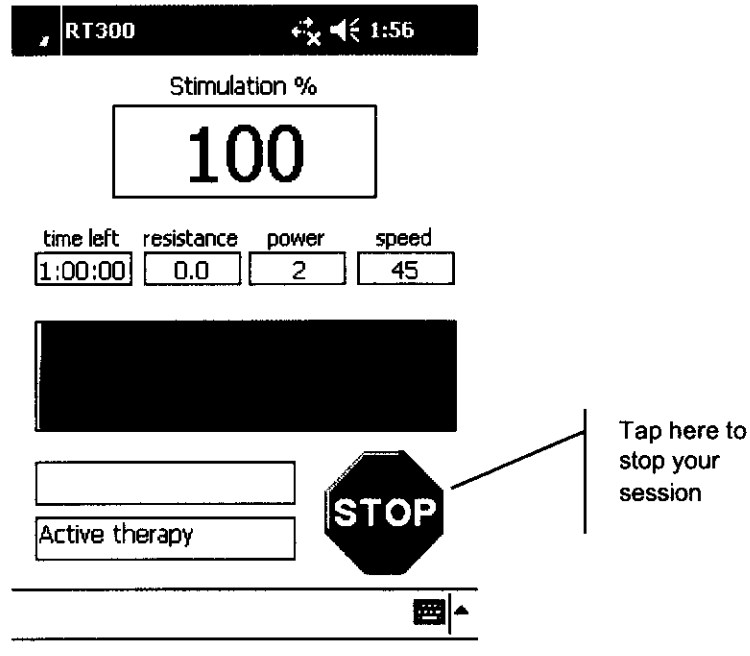

Figure 34 Stopping a session early

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Data display graph

The figure below illustrates the meaning of the data display graph which shows you how your session is progressing.

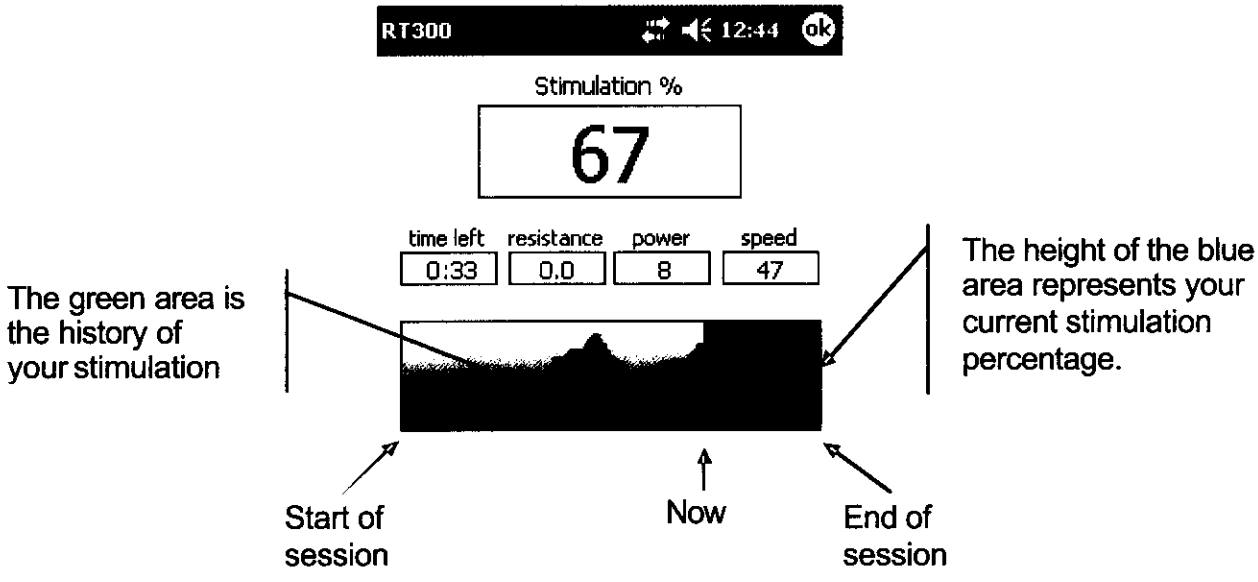

Figure 35 Data display

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Adjusting stimulation parameters

Clinicians should be cautious in setting initial maximum stimulation levels. Children in particular may require initial levels to be set lower than the default level.

You should only adjust these parameters after consulting with you clinician.

The stimulation parameter page is accessed via button 10

Enter the password when prompted. This password can be requested from your Clinician; it is designed to prevent unintended access to the stimulation parameters by children.

This page allows you to change the pulse width, minimum current and maximum current that is delivered by the RT300-S system to each of your muscle groups. This page will default to initial appropriate levels depending on whether you have an adult or pediatric RT300-S system.

During active therapy the RT300-S system will use as much electrical stimulation as is required to keep you cycling at the set cycling velocity. However, the stimulation amplitude on any channel will never exceed the maximum (Max) that has been set for that channel (see Figure 36).

Normally, if sensation to stimulus is not an issue, the maximum (Max) stimulation levels should be left at 140 mA for adults or 80mA for children.

The minimum (Min) stimulation is the amplitude in milliamps (mA) where a muscle first begins to contract as a result of surface electrical stimulation.

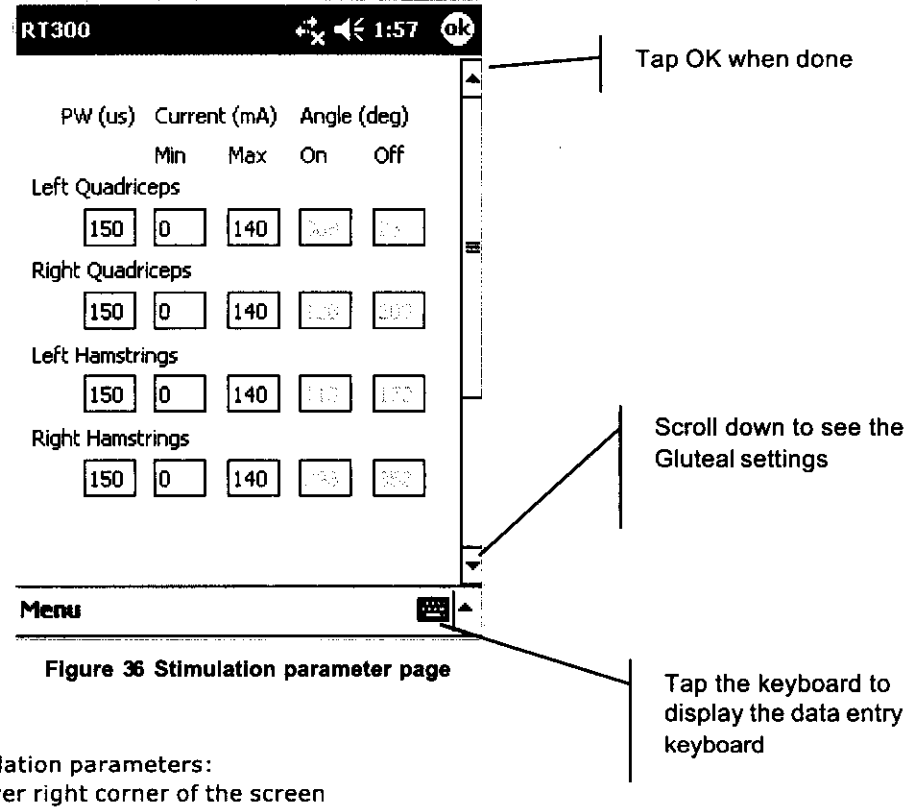

Figure 36 Stimulation parameter page

Making changes

To make a change to the stimulation parameters:

1. Tap the keyboard in the lower right corner of the screen
2. Highlight the number to be changed
3. Enter the new number using the displayed keyboard
4. Tap OK in the top right of the display

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Troubleshooting

Resetting the Controller

You may need to reset the RT300-S System controller in some situations, for example, if the controller does not respond when you tap the screen.

To reset the controller:

1. Press the Reset button on the back of the controller using the stylus or a pen.

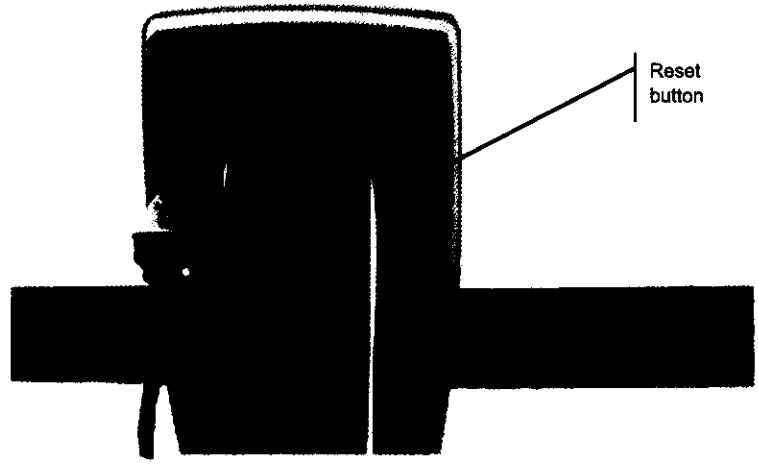

Figure 37: Reset button on controller

2. Wait until the controller displays the Therapy Session screen.

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Care of the RT300-S System

Cleaning and Maintenance

Regularly cleaning the equipment prevents a build-up of dirt.

Always unplug the power cord from the power outlet before you start cleaning.

- Never use solvent-based or corrosive on the RT300-S System.
- Wipe the controller screen with a dry clean cloth. Don't use any water - make sure no moisture gets into the controller.
- Use a damp, soft cloth to clean the RT300-S System surfaces.
- Take care not to damage or remove labels during cleaning.
- After 2 years (or 2,000 hours) of use, the controller displays a message to let you know that it is time for a maintenance check. Contact RTI Technical Support to arrange the service.

Storing the RT300-S

When you are not using the RT300-S System:

- store the RT300-S System equipment in temperatures between −20 °C (−4 °F) and +50 °C (+122 °F)

Moving the RT300-S System

Always unplug the power cord from the power outlet and the RT300-S System before moving the device.

The RT300-S System is fitted with castors and a handle to facilitate moving the RT300-S System short distances over a smooth surface. Hold the handle with one hand and place the other hand under the power unit.

To move the RT300-S System, tilt it backwards as shown in Figure 38 and push it in front of you.

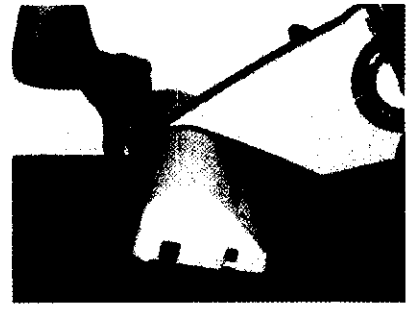

Figure 38 Moving the RT300-S System

The castors are not suitable for the transport on uneven or rough surfaces. Two people are required to carry the RT300-S System up or down stairs.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Shipping Instructions

The RT300-S Cycle Ergometer should be shipped in its o riginal packaging.

The package dimensions are: 27" x 23" x 20"

The package weight is: 90lbs

Symbols

Symbol	Meaning
	Fragile
	See instructions for use
2004-05-30	Date of manufacture
+50°C (+122°F) -20°C(-4°F)	Temperature limit
LOT 12345	Lot number or Batch number
REF 12345	Reference number or Part number
IN 123456	RTI's Serial Number
Model FA100052	Model Number
	Type BF Part

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

Technical Specifications

	115V	230V
Motorized Ergometer		
Length	31.5" or 80cm	
Width	19.3" or 49cm	
Height	36.2" - 40.6" or 92 - 103cm	
Shipping weight	90lbs or 41kg	
Length of pedal:		
• RT300-S	4.3" or 110mm	
• RT300-S-P (pediatric)	4.3" or 110mm	
Speed range	0 - 55 rev/min (± 2 rev/min)	
Torque range	0 - 16Nm (± 1N)	
Power connection	115V~, 50/60Hz	230V~, 5/60Hz
Power input	160VA	160VA
Fuses	2 x 1.6 A 250V slow	2 x 1.6 A slow
Key materials	Aluminum, Steel, Polystyrol, Polyurethane	
Protective type	I	
Degree of protection	Type BF Applied Part	
Noise emission	Lpa ≤ 70dB (A)	
Noise emission value	According to DIN 45635-19-01-KL2	
Mode of operation	This device is for continuous use.	
Conditions:		
• In use	5°C (41 °F) to 40 °C (104°F) 0 to 90% Rh 970 to 1030hPa	
• Transporting/storing	-20°C (-4°F) to +50C (+122°F) 0 to 90% Rh 970 to 1030hPa	
Controller		
Display / interface	Touch-sensitive LCD	
Communications	Wireless (BlueTooth)	
Operating system	Windows CE 2003	
Inbuilt stimulator		
Maximum voltage output	200V	
Number of channels	6	
Current output per channel	0 - 140mA (± 2mA) with 0 to 1500 Ω load	
Waveform type	Biphasic, charged balanced	
Pulse frequency	20Hz	
Phase width	0 - 250 µs	

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

RT300-S Ergometer Limited Warranty (USA)

This document is important. It contains your Limited Warranty for each of the product(s) identified below that you purchase (the "*Product*") and register with Restorative Therapies Inc. The terms and conditions of your Warranty, including important limitations on how the *Product* should be used, are set out below.

Product	Part Number	Warranty Period
RT300-S	FA100052	1 year
RT300-S-P	FA100053	1 year
Ergometer platform	FA100019	1 year

Limited Warranty, Terms and Conditions

A. Introduction

Words which appear in italics, *like this,* are given defined meanings in clause D below. This Limited Warranty gives you specific legal rights, and you may also have other rights which vary from State to State. This Limited Warranty applies in all jurisdictions.

B. Enquiries and Warranty Service

If you have an enquiry about this Limited Warranty or you want to have a *Product* repaired, please contact Restorative Therapies Inc. Do not ship *Product* to us without first obtaining a Return Material Authorization Number.

2363 Boston St
Baltimore, MD 21224
USA

Phone: (800) 609-9166
Fax: (410) 534-6263
Email: warranty@restorative-therapies.com

C. Your Warranties and Rights

3. We, Restorative Therapies Inc ("we"), warrant to you, the *owner* of the *Product* ("you"), that:

   a. each *Product* is reasonably fit for the purpose or purposes for which it is supplied by us; and

   b. each *Product* will be free from defects in workmanship and materials for the *Warranty Period* listed above.

4. If your *Product* is found not to be reasonably fit for the purpose or purposes for which it was supplied, or if it has defects in workmanship or materials during the *Warranty Period*, we will at our choice either:

   a. repair the *Product* at your home or clinic; or

   b. ship the *Product* to our facility for repair or replacement

5. Unless otherwise required by *local laws*, where a *Product* is replaced under clause 2 in this Section of the Warranty, the warranties set out in the table above will continue to apply for the unexpired portion of the *Warranty Period* of the original *Product*.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

D. Warranty limitations

6. We will not be liable to you or any other person under any circumstances for any incidental or consequential loss or damage, including without limitation, any liability for third party claims against you for damages or for *Product* not being available for use. Our liability will be no more than the amount you paid for the *Product* that is the subject of a claim. Some States do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

7. Any implied warranties of merchantability and fitness for a particular purpose are limited to the *Warranty Period*. Some States do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

8. All terms, warranties and conditions which are not set out in this Warranty as to the state, quality, fitness or otherwise for purpose, merchantability are expressly excluded and will not apply to the *Product* except where such terms, conditions and warranties are implied by applicable *local laws* and cannot be excluded or modified.

E. Restrictions on product use

9. The *Product* is designed and manufactured to operate according to the specifications contained in the RT300-S Ergometer User Manual.

10. The *Product* is designed and manufactured to operate within the temperature range of +5 °C (+41 °F) to +40 °C (+104 °F) and the *Product* should not be subject at any time to temperatures below -20 °C (-4 °F) or above +50 °C (+122 °F) otherwise this Warranty will be void for the *Product*.

11. The *Product* is supplied to you/your clinic/your clinician subject to our Standard Conditions of Sale. In the event of any inconsistency between the terms of this Warranty and our Standard Conditions of Sale, our Standard Conditions of Sale will prevail.

12. This Warranty will be void should we find evidence of alteration or repair of the *Product* or by anyone other than personnel authorised by us.

13. This Warranty will be void should we find evidence of any misuse, negligence or accident in respect of the *Product* by you or any other person.

F. Keywords

Local laws means applicable statutes and other laws of the jurisdiction in which the *Product* is supplied to you.

Owner means the person who originally purchased the *Product* or a person who later acquires it.

Product means an item of equipment manufactured or supplied by us to you, which has been identified on the first page of this Warranty.

Warranty Period in relation to a *Product,* means the period set out opposite the *Product* on the first page of this Warranty commencing from the date we ship the *Product* to the purchaser.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

Restorative Therapies Inc
2363 Boston St
Baltimore, MD 21224
USA

Telephone: 1-800-609-9166
Fax: 1-410-534-6263

www.restorative-therapies. com

RT300-S is a trademark of Restorative Therapies Inc

Printed in USA
LB100108 Issue 6 (2110) RV100578 May 2005

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number (if known): K050036

Device Name: RT300-S and RT300-SP

Indications For Use:

The RT300-S (adult version) and RT300-SP (pediatric version) are intended for general rehabilitation for:

a. Relaxation of muscle spasms
b. Prevention or retardation of disuse atrophy
c. Increasing local blood circulation
d. Maintaining or increasing range of motion

The RT300-SP (pediatric version), is intended for population ages 4 to 12 years.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Contents

PURPOSE 1
TEST ITEMS 1
TEST RESULTS 2
OVERALL RESULT 5

Purpose

The RT300-S utilizes BlueTooth wireless links to communicate between its controller and the ergometer and its controller and the stimulator.

The purpose of this verification is to demonstrate that multiple RT300 systems can operate in an environment where there may be other devices utilizing the 2.4 GHz industrial, scientific and medical (ISM) band. This band is 83.5 MHz wide, beginning at 2.4 GHz and ending at 2.4835 GHz. Both wireless Ethernet (802.11b), otherwise known as Wi-Fi, and BlueTooth, as utilized by the RT300, operate in this band. Other potential sources of interference in this band are 2.4GHz wireless phone handsets and microwave ovens.

This is considered to be a worst case clinic implementation because:
a. the number of systems operating concurrently in one room exceeds any probable real implementation
b. the systems were spaced around the room as closely as possible while remaining functional for wheelchair access
c. the room contained a variety of operating potential sources of interference.

Deleted: ¶

Test Items

Description	Part Number
RT300-S	100373
RT300-S	100371
RT300-S	100376
RT300-S	TT004465067
RT300-S	100231
RT300-S	100233
RT300-S	100232
RT300-S	100370
RT300-S	100368
RT300-S	100369
RT300-S	100367
Microwave oven	Magic Chef 1.5kW MCD1311ST
Wireless phone	Uniden 2.4GHz EXI7246

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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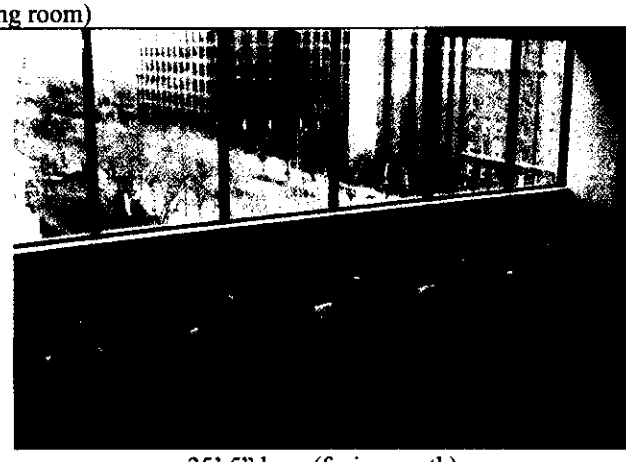
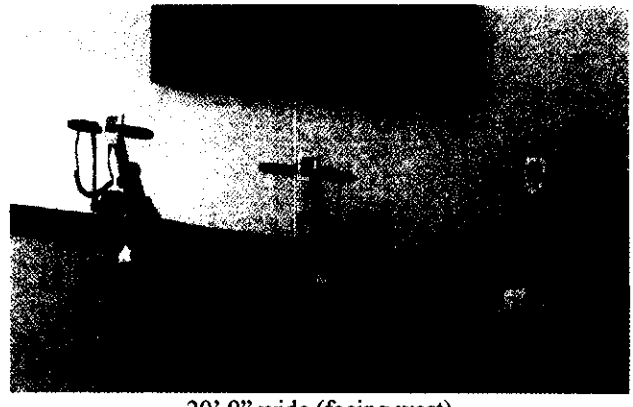
Laptop with Linksys WiFi G card	IBM T30
Laptop with Excel WiFi card	IBM T21
Laptop with Excel WiFi card	Compaq Presario 80XL200

Test Results

Protocol procedure number	Results
2	Room size was 20' 9" x 25' 5" (Kennedy Krieger Institute 5th Floor meeting room)
	 25' 5" long (facing south)  20' 9" wide (facing west)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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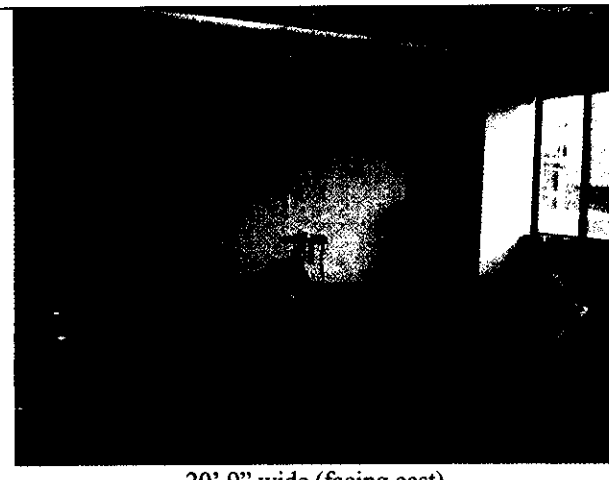
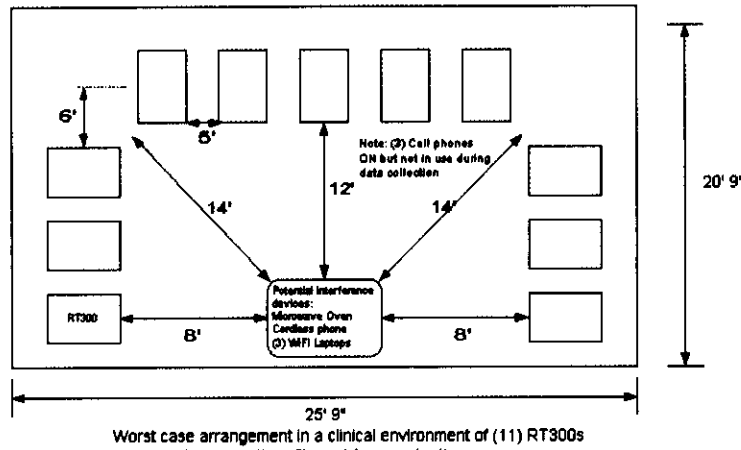
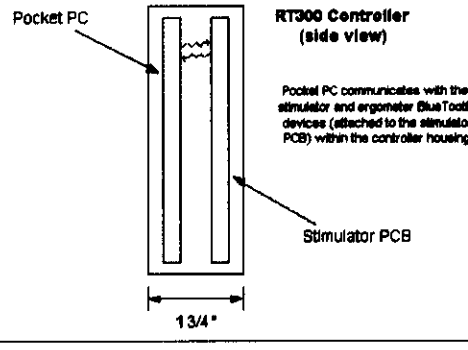


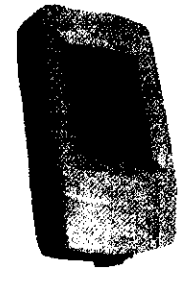
20' 9" wide (facing east)

Test environment



Worst case arrangement in a clinical environment of (11) RT300s positioned no more than 6' apart from each other





Actual RT300 Controller

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3	RT300-S software versions: controller 0.06 build 60 stimulator 0.06 build 51
5	**One RT300-S operating, all other equipment off** Back ground BlueTooth latency was 102 msec.
6	No lost communications packets
8	**All RT300-S system operating, interfering devices off** BlueTooth Latency with all RT300-S operating (order as per equipment list) 103 msec 114 msec 122 msec 105 msec 117msec 105msec 117msec 106 msec 117msec 104 msec 106msec Average 110.5
9	No lost communications packets
15	**All RT300-S system operating, interfering devices all on** a. Three laptop computers linked to a LAN via a WiFi access point (G) all generating traffic. b. One microwave oven operating on high power. c. One 2.4GHz wireless phone handset operating. d. Three cell phones switched on but not in use BlueTooth Latency with all RT300-S operating (order as per equipment list) 101 msec 115 msec 123 msec 105 msec 120 msec 105 msec 120msec 107 msec 120msec 105 msec 105msec Average 111.5
16	No lost communications packets

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Overall result

The performance of the BlueTooth communications as measured by average communications latency and lost communications packets was not significantly impacted by increasing the number of RT300-S systems operating in the room from 1 to 11; the average communications latency increased by less than 8% (success criteria < 20%).

Similarly, performance of the systems was not impacted by simultaneous operation of a microwave oven, wireless phone and WiFi traffic; the average communications latency increased by less than 1%.

All RT300-S systems operated normally throughout all phases of the test.

Overall result: **PASS**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) T. Rossi

Subject: 510(k) Number K050036

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☒ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☒ YES	☐ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☐ NO
Special 510(k)?	☐ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☐ NO

Truthful and Accurate Statement ☒ Requested ☐ Enclosed

☐ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☐ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 891PF class II, ISD class II

Additional Product Code(s) with panel (optional): (GEI)

Review: [signature] (Branch Chief) RSDB (Branch Code) 3/15/05 (Date)

Final Review: _____ (Division Director) (Date)

Revised:4/2/03

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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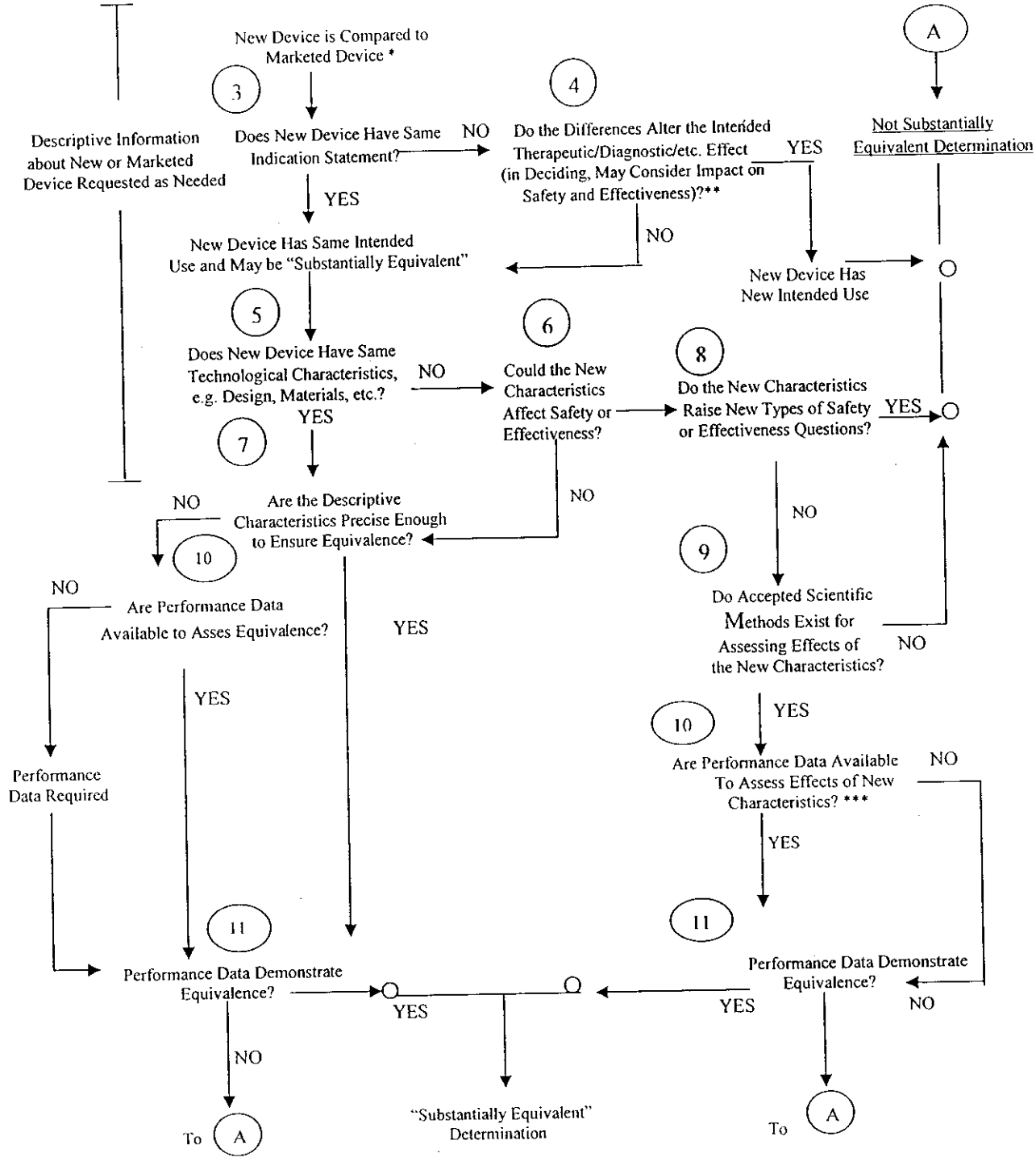
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?		
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 050037

Reviewer: J. Rossi

Division/Branch: DERND / RDB

Device Name: RT 300S CYCLE ERGOMETER

Product To Which Compared (510(K) Number If Known):

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K050036

Reviewer: J ROSSI

Division/Branch: DGRND/REDB

Device Name: FES CYCLE ERGOMETER RT 300-S

Product To Which Compared (510(K) Number If Known): K811112

	YES	NO	
1. Is Product A Device	✓		If **NO** = Stop
2. Is Device Subject To 510(k)?	✓		If **NO** = Stop
3. Same Indication Statement?	✓		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?		✓	If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?	✓		If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 ***If YES = Stop SE***
8. New Types Of Safety Or Effectiveness Questions?		✓	If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?	✓		If **NO** = Stop **NE**
10. Performance Data Available?	✓		If **NO** = Request Data
11. Data Demonstrate Equivalence?	✓		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PREVIOUS PAGE AS NEEDED

1. Explain why not a device: N/A
2. Explain why not subject to 510(k): N/A
3. How does the new indication differ from the predicate device's indication: N/A
4. Explain why there is or is not a new effect or safety or effectiveness issue: See attached memorandum
5. Describe the new technological characteristics: See attached memorandum
6. Explain how new characteristics could or could not affect safety or effectiveness: See attached memorandum
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new: See attached memorandum
9. Explain why existing scientific methods can not be used: N/A
10. Explain what performance data is needed: See attached memorandum
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: See attached memorandum

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8158

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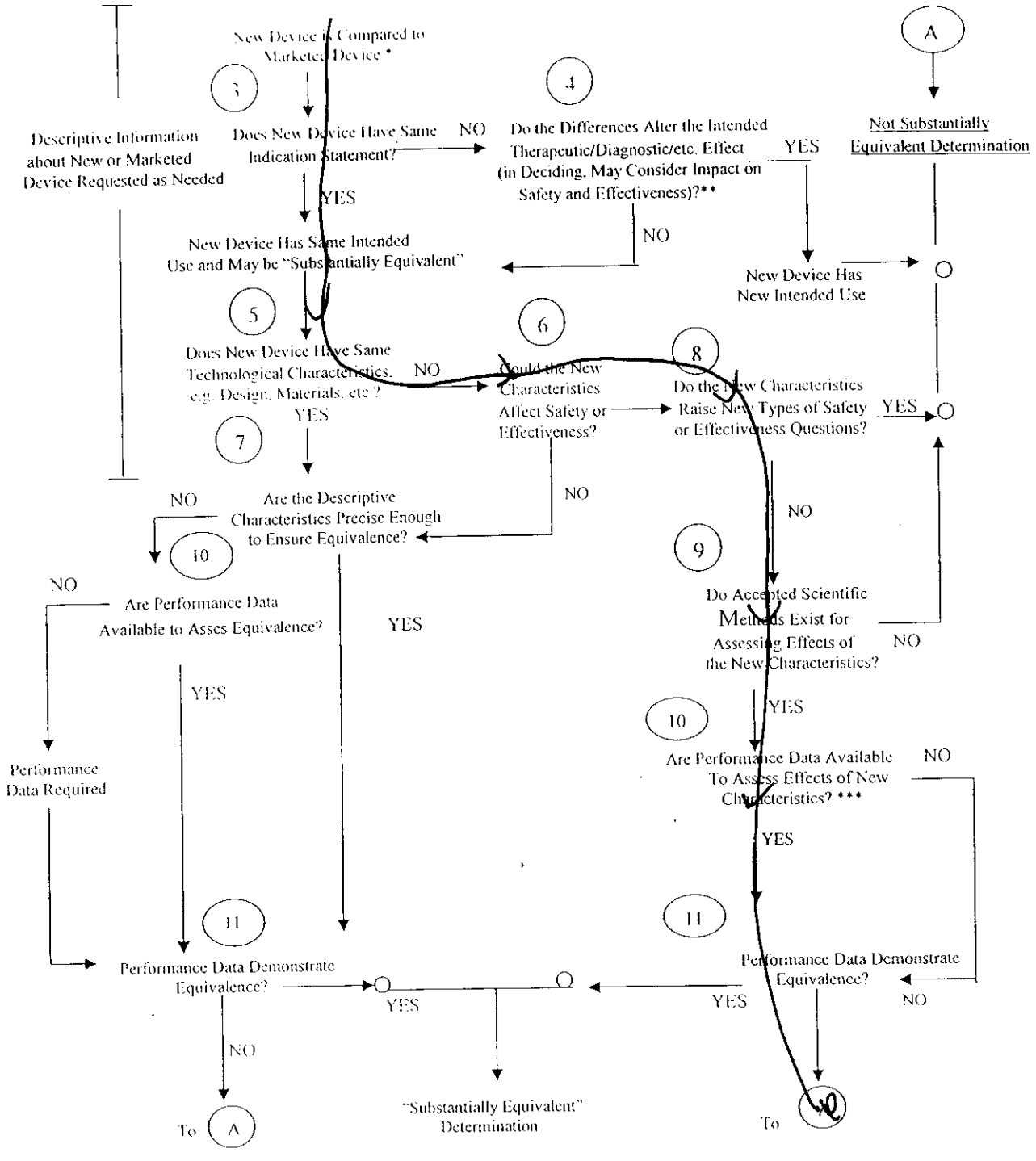
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 27, 2005

RESTORATIVE THERAPIES INC.
2363 BOSTON ST.
BALTIMORE, MD 21224
ATTN: ANDREW BARRISKILL

510(k) Number: K050036
Product: FES CYCLE ERGOMETER, MODEL RT300-S

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K050036/S1

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April 26th 2005

RTI

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RT300-S Pre-market Notification Supplement 1 (K050036)

Please find attached a **supplement** to our pre-market notification, K050036, for the RT300-S Functional Electrical Stimulation cycle ergometer.

This supplement was prepared in response to questions received from FDA on March 14th, 2005.

RTI believes, to the best of its knowledge, all data and information submitted in this supplement are truthful and accurate and that no material fact has been omitted.

Kind Regards,

Andrew Barriskill
CEO

Attached:
Supplement #1 to RT300-S pre-market notification, K050036

SK40

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RT300-S Pre-market Notification K050036 Supplement 1

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Answers to FDA Questions

Device Description

FDA Question:

1. It is unclear which photos and components refer to the full version and which refer to the pediatric version. For example, there is a pediatric pedal assembly. Does this assembly convert the regular version of the device to the pediatric version? All versions of the device must be fully described, preferably separately, if you wish to obtain clearance for all versions of the device. Currently, the reviewer is left to guess at which photos and diagrams refer to which version of the device.

RTI Answer:

The differences between the pediatric and adult versions of the device are:

a. the pediatric version is supplied with a shorter safety handle extension, see Figure 1.

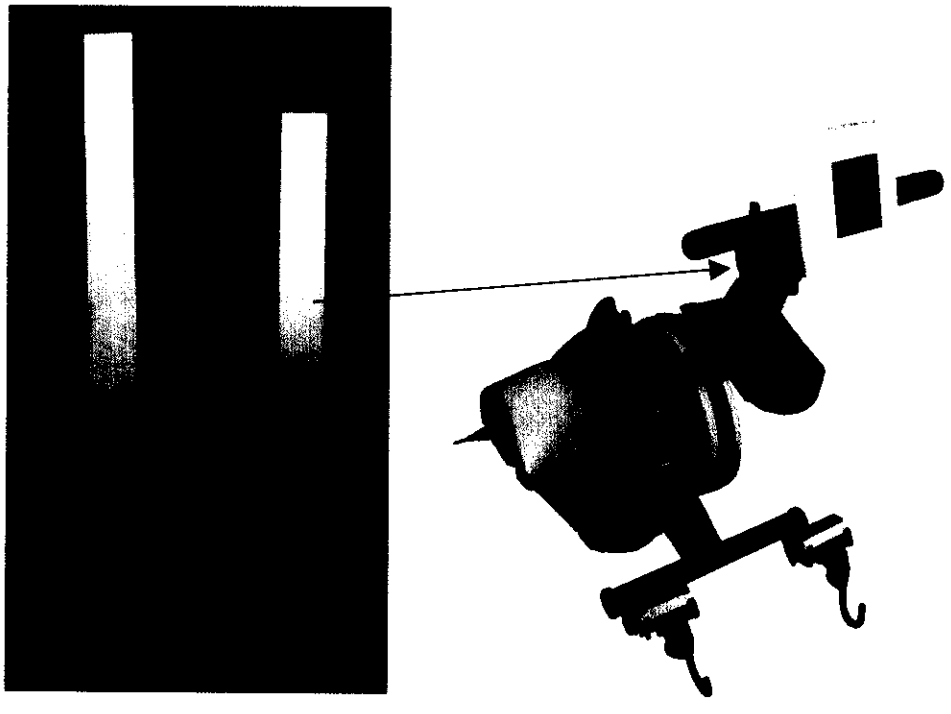

Figure 1 Adult and Pediatric Safety Handle Extensions

b. the pediatric version is supplied with pediatric pedals designed to accommodate the greater orthopaedic issues sometimes exhibited by children, see Figure 2. These pedals offer extra configurability allowing a clinician to better fit the patient.
   - Foot plate can be rotated and is smaller
   - Calf support can be attached to foot rest medially, laterally or mid line
   - Calf support has lockable ball joint at top and bottom of shaft

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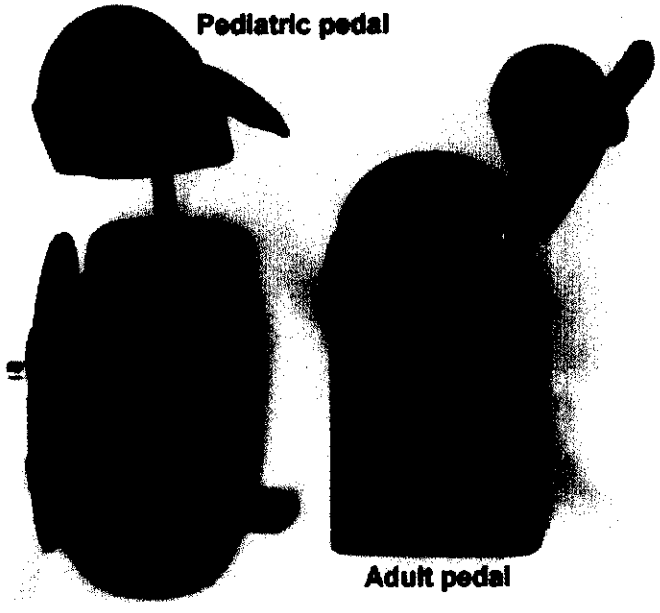

Figure 2 Adult and Pediatric Pedal assemblies

c. the pediatric version will be supplied with the software configured for pediatric use as per our response to question 5 below. This will set a default maximum stimulation current of 80mA compared to the adult maximum of 140mA (note that 140mA is also the maximum that can be delivered by the electronics).

FDA Question:
2a. You have provided a predicate K841112 which is cleared for general rehabilitation use only, and not for you intended patient population (i.e., spinal cord injured patients, people with muscular dystrophy, with motor neuron disease, stroke survivors, with MS, and with cerebral palsy.) The office has researched the internal database to the extent possible and was unable to uncover a predicate for these indications. Please inform the office if there is a cleared predicate for your indications, and please provide a technological comparison to the newly cited predicate, if one exists. Substantial equivalence can be made to K841112, however a new predicate may reduce the amount of information needed to support your device.

RTI Answer:
RTI intends to make our device available for general rehabilitation use only – as per the predicate device K84112.

FDA Question:
2b. It is not clear whether your device has a component that attaches to a user's wheelchair to secure the device to avoid inadvertent twisting of the wheelchair with respect to the ergometer which potentially could cause injury, e.g., fracture, if excessive stress is applied to the patient's lower extremity while the device is passively forcing the legs through the range of motion. Please clarify how such a scenario is avoided to assure safe use.

RTI Answer:

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The ergometer component is currently marketed in Europe without the electrical stimulation component. The German manufacturer of the ergometer advises that approximately 90% of users of the ergometer use it from a wheelchair with the wheelchair held in position only by its brakes. The manufacturer also advises that no adverse events have been reported. Over 700 of this model have been sold.

In the US, in investigational use with electrical stimulation, we have taken the additional precaution of connecting the wheelchair to the ergometer with a Velcro strap (please see Appendix C). We have received no adverse events as a result.

To ensure reliable and repeatable wheelchair restraint we have incorporated two wheelchair restraint straps (QRT retractor series by Q'Straint USA, Ft. Lauderdale, Fl). We have trialed this enhanced arrangement and found it to securely hold the wheelchair in position with no tendency for a wheelchair to twist (please see Appendix C). The arrangement is shown in Appendix A.

We have updated the User Guide (Appendix B) and the product brochure (Appendix L) to incorporate this restraint system.

FDA Question:
2c. According to the controller picture on page 35 of the user manual, the controller has a number of unlabeled windows. Please revise the controller and the picture to label each window. Also, the controller pictures on pages 13 and 27 show a different display than that shown on page 35 of the user manual. The shape of the controller on page 12 is different from all of the other three pictures. Please resolve these discrepancies.

RTI Answer:
The User Guide has been updated as requested and is provided in Appendix B.

Indications for Use

FDA Question:
3. In your indications for use, please define range of motion as measured in the clinically paralyzed patient.

RTI Answer:
As discussed with the reviewers, RTI will now adopt general rehabilitation indications for use as follows:

The indications for use are:

a. Relaxation of muscle spasms
b. Prevention or retardation of disuse atrophy
c. Increasing local blood circulation
d. Maintaining or increasing range of motion

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The pediatric version of the device, the RT300-P, is intended for a population ages 4 to 12 years.

The age indication proposed is based on the following information provided by the researcher at Shriners Hospital in Philadelphia (please see the full report in Appendix C): The youngest child that has been positioned on the RT300-S ergometer is 4 years old. The smallest child is a 5 year old who is 106cm tall. Safe positioning for children shorter than 106 cm and younger than 4 years old would need to be determined on an individual basis for each child. A height of 106 cm has been reported to be approximately the 90th-95th percentile for a 3 year old, the 50th-70th percentile for a 4 year old, and the 5th-10th percentile for a 5 year old by the National Center for Health Statistics.

The upper age limit has been set based on average height. A child approximately 5ft tall or taller is likely to require the longer safety handle extension supplied with the adult version of the device.

FDA Question:
4. In your intended use, please include reference to the pediatric population. This should be worded like "The [pediatric version of the device] RT300-P (?) is intended for a population ages __ to __."

RTI Answer:
Please see question 3 above.

FDA Question:
5. It is unclear that the stimulation parameters used for adults (predicate) are suitable for pediatric use. Please provide a basis, for example in clinical literature, of your stimulation parameters in a pediatric population.

RTI Answer:
The researcher at Shriners Hospital in Philadelphia has advised:
"the clinician will need to use clinical judgment in selecting stimulation levels based upon the size of the child. Physical therapists are trained in the use of electrical stimulation and can select stimulation levels that will create the response based upon the size of the muscle and the ability of the muscle to contract with stimulation. No exact recommendation can be made regarding these levels. The smallest child in the study (106 cm) required current levels of 100 mA for the quadriceps and hamstring muscles while a taller child (130 cm) required 60 mA for the quadriceps and 50 mA for hamstring muscles."

After additional discussion with this researcher, RTI proposes to supply the pediatric version of the device, the RT300-P, with the default maximum stimulation level set to 80mA instead of the adult default of 140mA. This is a safe and conservative level of stimulation which can, for instance, be comfortably tolerated by most individuals with normal sensation.

FDA Question:

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6. Your device is indicated for new and specific populations, such as spinal cord injury, muscular dystrophies, motor neuron diseases, stroke, multiple sclerosis, and cerebral palsy, which raises questions of safety (e.g., risk of autonomic dysreflexia with a spinal cord population) as compared to indications for the legally marketed device to which you claim substantial equivalence. Please either delete these new populations from your indications for use statement and labeling or provide clinical data sufficient for demonstrating equivalent safety for use with these populations. We are willing to consider clinical literature or other materials in lieu of a study, as a "least burdensome approach", if such literature is available.

RTI Answer:
Please see the answer to question 3 above.

FDA Question:
7. You have specified that there is a pediatric version of the RT300-S but you have not clarified the minimum age and/or size for which the pediatric device should be used. A discussion and data ,demonstrating how you determined that the pediatric version is safe and effective for a pediatric population, have not been included in your premarket notification application. Additionally, you have not provided a technological description of the pediatric version that is precise enough to demonstrate that it is substantially equivalent to a legally marketed device. Please provide this information.

RTI Answer:
Please see question 1 for a discussion of the pediatric version of the device.

Please see the answer to question 3 above for a discussion on minimum child age.

Please see the answer to question 5 above for a discussion on stimulation levels for children.

Electrical Safety

FDA Question:
8. Your device output is sufficient to cause electrocution if used improperly. Please warn the user that the device provides currents sufficient to cause electrocution in the device labeling. This warning should be prominent and conspicuous.

RTI Answer:
The RT300-S User Guide has been updated to include the requested warning as a bolded note at the beginning of the Warnings, Precautions and Safety Measures. Please see Appendix B, page 6 of the User Guide.

FDA Question:
9. You have reported values for maximum phase charge, maximum current density, and maximum power density at 500 ohms. However, it is not clear that the maximum of these

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

values occurs at 500 ohms. Please report these maximum values at any impedance greater than 0 for which a current is delivered.

RTI Answer:
The RT300-S delivers current controlled pulses. Therefore the phase charge and current density are not effected by the load impedance.

Power density = $I^2 R d / 2A$ where d = duty cycle and A = electrode area

Maximum power density will occur at the highest possible impedance. This is set at 1500Ohms because the stimulator will cease stimulation if electrode impedance exceeds this level.

With a 2" x 3.5" electrode, surface area is 45.2cm^2
Maximum duty cycle = max pulse width * max stimulation rate = 500usec * 30 = 0.015

Therefore, maximum power density = 0.0049 W / cm^2

This is well below levels considered to be safe. For example the FDA Guidance document on TENS stimulators states: "Data derived from heated electrodes at 46°C and from RF current burns indicates that 0.25 W/cm^2 can produce a burn." The manufacturer of the transcutaneous electrodes used with the RT300-S system specifies that power density should not exceed 0.1 W/ cm^2.

FDA Question:
10. You have provided a "CB certificate" which indicates that a "therapeutic exerciser" was tested to IEC 60601-1. However, this appears to have been for the marketed exerciser only. The testing would be invalid for the device used in combination with the electrical stimulation component. Please provide evidence of electrical safety testing of the entire device as a unit to IEC 60601-1 or equivalent. Because this device is directed to a neurologically compromised population, we are requesting that you include testing to standards specifically directed to powered muscle stimulators such as IEC 60601-2-10 (*Note: corrected from originally requested 60601-1-10*).

RTI Answer:
RTI no longer proposes to label this device for a specific neurologically compromised population.

RTI is working with UL to complete testing of the RT300-S to IEC60601-1 and 60601-2-10 as requested above. A report will be supplied to FDA upon completion of this testing. RTI requests that FDA review this supplement and make a determination regarding substantial equivalence conditional upon successful completion of this testing.

FDA Question:
11. Please provide evidence of electromagnetic compatibility testing to IEC 60601-1-2 or equivalent.

RTI Answer:
RTI has completed testing the RT300-S to IEC60601-1-2 as requested above and is waiting on supply of the test report by UL. A report will be supplied to FDA once available. RTI requests that FDA review this supplement and make a determination regarding substantial equivalence conditional upon successful completion of this testing.

This EMC testing necessitated a change in the ergometer's handle bars. During susceptibility testing we discovered that the handle bars resonated at approximately 163MHz and this effected the operation of the device's controller. The problem was resolved by reducing the length of the handle bars as shown below.

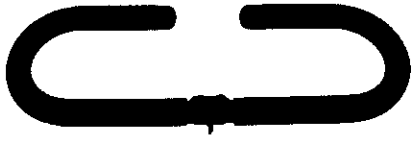

Figure 3 Handle bars prior to susceptibility testing

Figure 4 Handle bars after susceptibility testing

After consulting with clinicians we have confirmed that this change does ***not*** effect clinical use of the device as the handles are not required by patients to fully utilize the device and most patients actually do not touch them.

We have updated the User Guide (Appendix B) and the product brochure (Appendix L) to reflect this change.

Wireless

FDA Question:
12. You have described a BLUETOOTH interface, but have not given details as to what information is passing through the wireless link. It appears from your photos and diagram that the stimulator is exchanging data with the cycle through the wireless link. We are concerned about command and control information being sent over a BLUETOOTH wireless link. Specifically, we are concerned about the following aspects of the wireless connection:

12.a. Wireless coexistence, and data latency and throughput, and any limitations or restrictions for proper device operation and wireless communications.

RTI Answer:
Both wireless Ethernet (802.11b), otherwise known as Wi-Fi, and Bluetooth operate in the unlicensed 2.4 GHz industrial, scientific and medical (ISM) band. This band is 83.5 MHz wide, beginning at 2.4 GHz and ending at 2.4835 GHz. Bluetooth devices hop in a pseudo-random manner among 79 defined channels spaced at 1 MHz distances. Bluetooth uses very small data packets and hops to a new channel in the ISM band about 1,600 times a second so it is very immune to interference from 802.11 and other devices in the same

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frequency band. Additionally, the Bluetooth 1.1 specification includes a feature called adaptive hopping that detects 802.11b signals and adjusts Bluetooth's hopping pattern to avoid the existing signals. The frequency-hopping, spread-spectrum technology is highly tolerant of ambient radio-frequency (RF) noise and retains good bandwidth even in the presence of devices such as electrosurgical units and home appliances.

Several device manufacturers have already implemented Bluetooth technologies and received FDA approval.
Examples include (http://www.breaktech.com/content.php?article.60):

- Stryker Endoscopy Sidne – Effectively removes cabling from the control unit to devices at the operating table.
- Zoll M-Series Defribrillator/Monitor – Allows transmittal of vital sign reports to a PDA
- GE Medical Achilles DexterQUS – Enables data collection at floor level with data entry and printing at patient level without wires
- Nonin Pulse Oximeter – Offers patient mobility within 10 meters of monitoring device with 4 days of battery life
- RTX Healthcare Wireless TeleHealth – Used for monitoring patent weight and blood pressure in their homes. Data is transmitted to a home gateway for remote retrieval and review

In the RT300-S system, BlueTooth modules are use to implement a BlueTooth "piconet" for:
a. communications between the controller and the ergometer. This link carries data at no more than 115,200Baud.
b. communications between the controller and the stimulator. This link carries data at no more than 9,600Baud.

Hence the total data transfer requirements for the BlueTooth link for a single RT300-S system (a single BlueTooth "piconet") are only 124,800Baud out of a maximum total available of up to 723,200Baud.

Lin et al, An Improved Packet Collision Analysis for Multi-BlueTooth Piconets, IEEE J. Selected Areas in Comm., Vol 22, No 10, Dec 2004. See Appendix D) demonstrate that with small numbers of BlueTooth piconets, equivalent to the number of RT300-S systems co-located in a room there is only a minimal reduction in per-piconet data throughput, see Figure 5. In fact over 80 RT300-S piconets would need to be co-located to reduce the per piconet traffic below that required by the RT300-S (124,800 baud).

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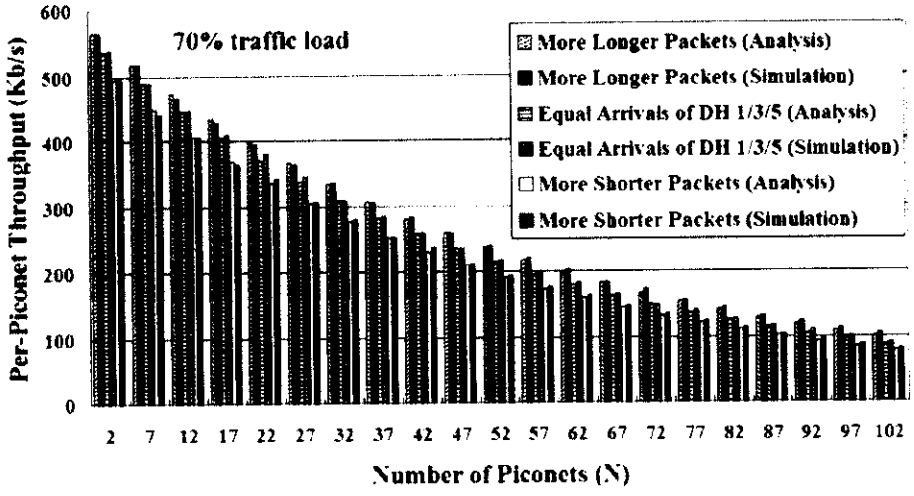

Figure 5 Piconet data capacity vs number of piconets

RTI has conducted a verification to confirm correct RT300-S operation under the most extreme operating conditions anticipated.

The protocol for this verification is provided in Appendix E.
The report describing the outcome of this verification is provided in Appendix F.

RTI has concluded that the BlueTooth wireless links utilized by the RT300-S provide a very reliable communications link between the RT300's controller and its ergometer and stimulator.

12.b. How users will interact with the system.

RTI Answer:
There is no user interaction with the BlueTooth system. The unique BlueTooth id addresses of the ergometer and stimulator are entered into Flash memory during manufacture. There is no further user interaction required.

12.c. Protections against unauthorized wireless access to device control or data (e.g., encryption, data access controls).

RTI Answer:
Each BlueTooth wireless link utilizes:
a. unique 12 digit hex key device address (i.e. the ergometer and stimulator each have a unique address)
b. proprietary communications protocol with independent checksums is utilized

These two features make the wireless link immune to accidental or inadvertent access.

The unique BlueTooth device address ensures that only the correct device will respond to a command while the proprietary protocol ensures that only commands originating in the RT300-S controller will be interpreted by the stimulator and ergometer.

The system may not resist a determined hacking effort. Please note however that the BlueTooth signals are very short range (10m). RTI does not consider this to be a relevant threat or risk for this product.

12.d. For wireless devices that use computer programs ("software"), the program's ability to handle the device responses and or failures under EMI conditions.

RTI Answer:
The RT300-S system is designed to fail safe in the case of communication failures:
a. the ergometer motor will stop if a valid command is not received from the controller within any 1 second period
b. the stimulator will cease stimulation if a valid command is not received in 1 second
c. the controller conducts "heart beat" transactions with the stimulator and ergometer; if a heart transaction fails the controller stops the therapy session and advises the user.

12.e. The wireless link itself should be characterized with respect to the following:

12.e.i. All functions that the RF wireless device will perform, and all safety-related requirements, specifications, features, and functions that will be implemented wirelessly.

RTI Answer:
The BlueTooth wireless link provides all device communications between the controller and the stimulator and the controller and the ergometer. Please see 12.d. for a description of the safety features implemented to mitigate the risk of a loss of communications between any of these devices.

12.e.ii. Wireless protocol specification name or designation (e.g., WMTS, IEEE 802.11b) for all wireless technologies incorporated into the device.

RTI Answer:
Bluetooth operates in the 2.4–2.485-GHz radio band. Its radio meets the power and spectral emissions specifications defined by ETSI ETS 300–328 in Europe and FCC under CFR 47 Part 15 in the United States using the following set of parameters:

- Frequency hopping, spread spectrum 79 channels, 1600 hops per second.
- Gaussian frequency shift keying modulation with a 1-m symbol-per-second rate or 1 Mb/sec data rate.
- 83.5 MHz of spectrum divided into 1-MHz channels.
- Symbol timing accuracy ±20 ppm timing (when synchronized).
- Power control based on received signal strength intensity feedback from the receiving device (Class 1 requirement).
- 4 dBm (10 mW) without power control (Class 2, 10-m range).

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- Bit error rate of 0.1%, receiver sensitivity of –70 dBm.

12.e.iii Wireless transmitter/receiver parameters such as operating frequency, RF output power, etc.

RTI Answer:
The ergometer and stimulator BlueTooth modules are BlueTooth Version 1.1 class 2 modules with a power output of 4 dBm (10 mW). The controller uses BlueTooth Version 1.2 class 2.

12.e.iv If RF wireless is specified for operation in the presence of other in-band transmitters, restrictions on the number or characteristics of other in-band transmitters.

RTI Answer:
RTI's testing (see Appendix E and F) has shown that multiple RT300-S systems will operate normally in close proximity to other transmitters.

12.e.v All coexistence, data integrity (e.g., data throughput, latency) and security features and performance requirements that the wireless system will meet.

RTI Answer:
Please see answers to questions 12.a and 12.c.

12.e.vi Data security features to prevent unauthorized access to data or networks

RTI Answer:
Please see answer to question 12.c.

12.e.vii Testing should explicitly address the issues cited above, including the limitation of the number and type of wireless transmitters that can be present and still insure proper operation. Please contact the lead reviewer directly if you need assistance in formulating a wireless testing protocol that will satisfy FDA's concerns about your wireless link. This testing may or may not be included in the IEC 60601-1-2 EMC standard testing. If IEC 60601-1-2 testing is used to address some of these issues, a complete report (not summary) should be submitted.

RTI Answer:
The verification conducted by RTI in EN10045 (Appendix E and F) has been supplemented by the electromagnetic susceptibility testing conducted as part of the IEC 60601-1-2 EMC standard testing. A full report shall be provided.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Risk Analysis

FDA Question:
13. You discuss an article by Nash in Sports Medicine, volume 11, 2004 on which you base your assessment of the risks associated with your device. Please provide a copy of the article and a description of the differences between your device and the device studied by Nash.

RTI Answer:
The Jacobs and Nash paper is a review article that covers the current recommendations for exercise in the SCI population. There is a section that discusses the risks of exercise performed by persons with SCI (section 5). This section does not indicate specifics with regard to the type of FES equipment used to illicit these risks; instead it outlines the potential risks of exercise to this population. Since FES ergometry is a form of exercise, as stated in section 4 of the article, it follows that these risks apply to users of the RT300-S. The description of leg FES cycling exercise given in section 4.2 is identical to the RT300-S and is as follows – "...electrically stimulated cycling uses electrically activated contractions of the bilateral quadriceps, hamstrings and gluteus muscles under computer microprocessor command. Control of pedal cadence and muscle stimulation intensity is exerted by feedback from position sensors placed in the pedal gear." Please find a copy of this article in Appendix G.

FDA Question:
14. You have mitigated the risk of autonomic dysreflexia by warning the spinal cord injured patient to discuss the condition with their physician and know how to recognize symptoms and how to react. Please explain how this adequately mitigates, for example, a child's risk of this life threatening condition. It is unlikely that a spinal cord injured patient, especially a child, will be able to identify the condition and react appropriately. Please explain in further detail how this condition is supposed to be avoided by the patient, and what actions the patient should take. Assessment and mitigation of this risk by the suggested labeling is currently deemed insufficient.

RTI Answer:
The RT300-S is a prescription-only device and will only be used by an individual after consulting with their physician; such consultation would include the risks of autonomic dysreflexia, signs of onset and how to react.

In the case of children, the user guide recommends the device is only to be used under adult supervision (RT300-S User Guide, page 9, item 8), in addition, we have added a note to parents describing typical symptoms indicating the onset of autonomic dysreflexia (RT300-S User Guide, page 10) and what to do if these symptoms become apparent. There is also a note in the same section that recommends to the user precautions for prevention of autonomic dysreflexia.

FDA Question

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15. You have indicated that risk of musculoskeletal injuries is acceptable because you have excluded patients with a history of lower limb stress fractures and/ or severe spasticity. However, we believe that these risks should also be mitigated by the device design. We are concerned that your device uses a wheelchair which does not appear to be well mechanically fixed into position with respect to the device. This is unlike the predicate you have cited which has a seat integral to the device, and was not specifically indicated for a neurologically compromised population. We are concerned that rotational movement between the chair and the device may cause problems in this population. Please provide more information on how the risk of musculoskeletal injury with you device was assessed for your patient population. It is understood that the device is currently associated with ongoing clinical trials. Perhaps a summary of those trials and a specific list of adverse events from those trials could help satisfy these concerns. If not, perhaps more literature could be used to help assess the risk of injury with your device (a detailed description of how the literature applies to your device would be needed). However, at this point in time it is believed that a clinical study of your device and adverse events associated with your device may be required in the absence of further safety data.

RTI Answer:
Please see answer to question 2b.

Software

FDA Question
16. The User Interfaces have not been adequately described in your software description. Please provide a screen-shot of all of your user interfaces. Each function described should be readily understandable from the software description.

RTI Answer:
Please see Software Design Description, Appendix H, for a complete description of the user interface.

FDA Question:
17. Your software is apparently still in a beta version as of filing. Please provide software documentation for MODERATE level of concern as described in the Guidance Document, including the traceability matrix and list of remaining bugs suggested in the guidance document, for your final software version.

RTI Answer:
The RT300-S software is now fully released as version 1.00. The following documents have been updated since the original pre-market notification and relate to version 1.00 of the software:

a. An updated software requirements specification has been provided in Appendix I.
b. A software design description has been provided in Appendix H.
c. A verification report has been provided in Appendix J.

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d. A traceability matrix has been provided in Appendix K.
e. There are no known software bugs described in our tracking database.

FDA Question:
18. Your software description does not describe in enough detail the "cycling algorithm". Please describe in detail all of the algorithms used for the following:
a. Adjusting motor speed and torque other than by user interface "speed control"
b. Automatic stimulation control
c. Fatigue detection
d. Electrode monitoring system
Please ensure that your testing includes testing of these algorithms. It is anticipated that a clinical study is needed to demonstrate the safety of these algorithms absent a basis in clinical literature.

RTI Answer:
Algorithms for automatic stimulation control and fatigue detection follow the same protocols as outlined in the predicate device's 510k submission (K841112), in particular the literature cited in K841112 appendix IV, pg. 234 (J. Petrofsky, C. Phillips, H. Heaton, and R. Glaser, "Bicycle ergometer for paralyzed muscle", J. Clin. Eng., vol. 9, pp. 13-19, 1984.), and the user manual for the predicate device. Additional demonstration of the safety of these algorithms can be surmised from the preliminary findings of a clinical study (Appendix C) which indicates no adverse events during the use of the RT300-S. Further explanation of these algorithms are provided below.

a. Adjusting motor speed and torque other than by user interface "speed control"
Motor speed and torque are only applicable during the passive cycling phase of the therapy session (see section 3.2.5 of the RT300 Software Design Description (SDD), Appendix H). During this phase the controller simply sends a command to the ergometer to set the motor speed and torque to the values for *control speed* and *passive drive torque*, respectively (section 4.1.7 SDD, Appendix H). These parameters ***are only*** applied during passive cycling (warm-up, passive and cool-down phases) and are not controlled during active cycling. During active cycling the motor provides no assistance (active motor speed and torque are 0) only resistance, if set above 0 on the Therapy Page (section 4.1.7 SDD, Appendix H).
b. Automatic stimulation control
The algorithm for stimulation control during active cycling was derived from the predicate device and clinical literature referenced in the predicate device's 510k submission (K841112), Appendix IV, pg. 234 – J. Petrofsky, C. Phillips, H. Heaton, and R. Glaser, "Bicycle ergometer for paralyzed muscle", J. Clin. Eng., vol. 9, pp. 13-19, 1984.
Applying the algorithm cited in the above reference, the RT300-S software incrementally changes the stimulation to all the muscle groups (quadriceps, hamstrings and gluteals) to maintain the *control speed.* The crank speed is continually monitored by the ergometer's sensors and this information is passed to the controller which will change the stimulation level by *stimulation control(%/s)* (default value is 5%/s) every second if the speed is not at the control speed – increasing the stimulation at this rate if pedaling slower than the *control speed* and vice versa if faster.

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c. Fatigue detection
Again the RT300-S detects fatigue in the same manner as the predicate device citing the same reference as for the stimulation control. Fatigue is detected if the stimulation levels are at maximum (settable parameters for the maximum stimulation for each muscle group are available to the user (section 4.1.7 SDD, Appendix H)) and the crank speed decreases below the *fatigue threshold* (settable parameter in the Controller Page with a default value of 35 rpm as per predicate device). When this condition occurs, stimulation ceases and the system continues with passive cycling for the remainder of the therapy session.

d. Electrode monitoring system
Both the predicate device and the RT300-S monitor the electrodes by measuring the impedance of the circuit. The RT300-S' stimulator microprocessor monitors each channel's impedance every 60ms by sampling each output channel when stimulation is applied. If the impedance of any channel exceeds 1500 ohms then an error is logged and sent to the controller. The controller will alert the user with a message on the GUI stating, for example, "Right Quadricep pad is off". Stimulation will cease and the therapy session will halt.

FDA Question:
19. It is unclear if this device is able to be connected to an external PC. It is recommended that you disable any control from an external PC of the stimulation parameters. If the external PC is used for downloading data only (no control) it is conceivable that this is acceptable if it can be shown that the interface is isolated from the function of the device. Furthermore, any software provided for the PC with the device must be described in detail (per Guidance Document). Specifically, this software would be considered part of the device labeling even if it does not control any of the device function.

RTI Answer:
The device is not intended to be connected to an external PC and the stimulation parameters can only be controlled from the user interface provided by the RT300-S software. No PC software is provided with the device.

FDA Question:
20. Your device software testing is minimal. Your testing should include testing of all user adjustable parameters, and verification that the device output (stimulation, motor speed, and torque) is as specified. These parameters should be varied through their intended ranges, and the device output measured. Your testing should include ample verification that the cycling algorithms perform as specified in your algorithm description. Finally, testing of the final version of the software should be provided.

RTI Answer:
Please see software verification report in Appendix J for test results on final version.

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Labeling

FDA Question:
21. Please add the following warning: "The long term effects of electrical stimulation on a pregnant individual (mother and baby) are unknown"

RTI Answer:
This statement has been added as the third warning in the User Guide (Appendix A).

FDA Question:
22. Please revise your labeling to include the warning, precautions and adverse effects immediately following the contraindications.

RTI Answer:
The User Guide has been modified such that the warning, precautions and adverse effects immediately follow the contraindications. Please see Appendix A.

FDA Question:
23. Please clarify all output stimulation programs available with this device and clarify whether all channels must operate with the same program or whether different programs can be simultaneously used with each channel.

RTI Answer:
Only one stimulation program is provided and this does apply to all channels. Please see question 18 for a full description of the cycling algorithm.

FDA Question:
24. The brochure appears misleading with respect to certain aspects that go beyond the indications for your device. For example, it implies spinal cord individuals can regain function such as walking and that the spinal cord injury may be healed by using the device. The brochure includes statements such as functional electrical stimulation stimulates the central nervous system to become more functional and to promote nerve cell growth. However, you have not provided sufficient data to substantiate these implications or statements. Therefore, please delete all potentially misleading information and all testimonials and revise the brochure to discuss and imply only those indications identified on your indication for use form. All references to "providing function" should be defined instead as an "electrically-induced pedaling motion". Furthermore, statements that these devices provide near-term solutions for maximizing function even long after injury may mislead individuals to believe that this device is safe and effective for patients who start treatment long after having the spinal cord injury. Such patients may have significant atrophy and/or osteoporosis which may make your device unsafe for use with this population. This statement may also potentially mislead patients to believe your device is safe and effective for providing maximum function over long term use. Since there are no data to substantiate long term outcome, please delete the statement or provide clinical data to substantiate this statement.

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RTI Answer:
The brochure has been revised and is provided in Appendix L.
Please note that the photograph on the front page shows the RT100 product instead of the RT300. This will be corrected prior to use of the brochure. A new similar photograph will be taken utilizing the RT300-S device.

FDA Question
25. You have indicated that clinical studies are currently being conducted with your device. Please summarize the adverse events documented in your ongoing clinical studies with this device.

RTI Answer
No adverse events have been reported.

FDA Question
26. The User's Manual does not provide adequate instructions for use, e.g., how to apply the device, including how to adjust output parameters. Please amend your instructions for use to provide adequate directions for safe and effective use.

RTI Answer:
Please see the updated User Guide in Appendix A. A section has been incorporated which described the adjustment of the stimulation output parameters. The material provided in this section now closely matches that provided by the predicate device.

FDA Question:
27. A number of features of your device have not been discussed, e.g.,
a. how the device automatically controls stimulation without burning patients or causing musculoskeletal injury;
b. how the device registers muscle fatigue and
c. detects spasm and how it reacts to these data;
d. how the device safely controls speed.
Please describe these features and compare to the legally marketed device to which you claim substantial equivalence.

RTI Answer:
a. Please see question 18 for a description of automatic stimulation control

b. Please see question 18 for a description of fatigue detection

c. The RT300-S does not detect spasm **and the predicate device does not detect spasm**. The User Guide carries the following warning:

"At the beginning of Warm Up, muscle spasms may occur. These usually subside before the Warm Up period ends. If the spasms persist, wait approximately 5 minutes and then begin the procedure again. If the spasms still do not subside, the

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session should be postponed."

d. Please see question 18 for a description of speed control

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Appendix A Wheelchair restraints

The RT300-S wheelchair restraint system incorporates two retractable restraint straps as shown in Figure 6.

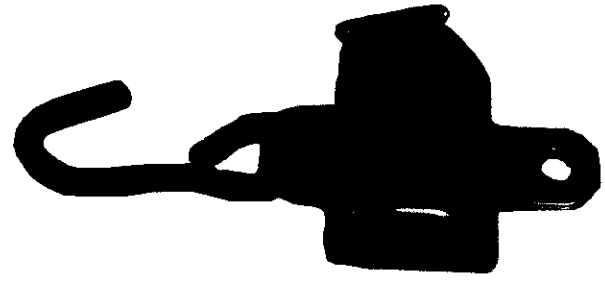

Figure 6 Wheelchair restraint (1 of 2 provided)

The RT300-S User Guide (Appendix B) provides instructions on attaching the restraints to either side of the ergometer crossbar as shown in Figure 7.

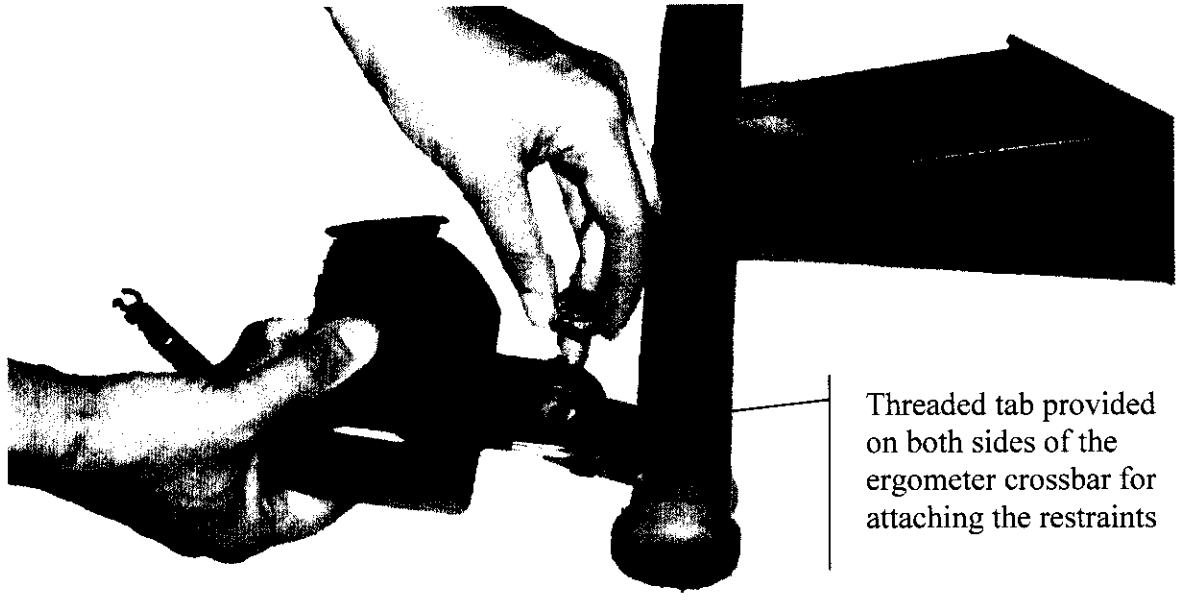

Figure 7 Fitting a restraint to the ergometer

The system restrains the wheelchair to the left and right sides of the ergometer as shown in Figure 8.

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Figure 8 Restraints fitted to the ergometer

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Appendix B RT300-S User Guide

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RT300-S™ system

User Guide

RTI

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RT300-S System

User Guide

Caution:

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

Part Number: LB100108 RV100459 Issue 5
[April 2005]

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Introduction

About this Guide

This guide explains how to use the RT300-S System in your own home. It contains information about how to:

- apply proper safety measures when you use the system
- set up and use the equipment
- fix any basic problems that may occur

What You Need to Know Before You Start

Before you start using the RT300-S System:

- read this guide – in particular, check the *Indications for Use, Contraindication,* and *Warnings, Precautions and Safety Measures* sections of this guide
- talk to your clinician who will provide training to help you get started and explain how the *Warnings, Precautions and Safety Measures* relate to you.

Indications for Use

The RT300-S is **indicated** 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**

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Contraindication

Powered muscle stimulators should not be used on patients with other implanted devices (including cardiac demand pacemakers or electronic baclofen pumps).

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Warnings, Precautions and Safety Measures

Read this section carefully so you understand how to use the RT300-S System safely.

Before you start using the RT300-S System, talk to your clinician about the information in this chapter.

The RT300-S generates currents sufficient to cause electrocution if used improperly.

Warnings

1. 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.

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

If the patient's blood pressure or heart rate reaches a level that the clinician considers to be 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.

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

4. The long term effects of electrical stimulation on a pregnant individual (mother and baby) are unknown.

5. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.

6. 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.

7. Stimulation should not be applied trans-thoracically (across the upper body) in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

8. Stimulation should not be applied trans-cerebrally (to the head).

9. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.

10. Stimulation should not be applied over, or in proximity to, cancerous lesions.

Precautions

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

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

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

4. Caution should be used in the presence of the following:

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a. when there is a tendency to hemorrhage following acute trauma or fracture;

b. following recent surgical procedures when muscle contraction may disrupt the healing process;

c. over the menstruating or pregnant uterus;

d. history of uncontrolled autonomic dysreflexia;

e. history of lower limb stress fractures and

f. history of severe spasticity or spastic response to application of electrical stimulation.

5. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel). The irritation can usually be reduced by using a sensitive skin electrode or an alternative electrode placement.

6. Some patients may be prone to thermal dysregulation. Episodes of thermal dysregulation are usually less pronounced when exercising in an environment controlled for temperature and humidity. Attention should be paid to hydration and limiting the duration and intensity of exercise in intemperate environments.

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

8. Powered muscle stimulators should be kept out of the reach of children. Children should only use this device under adult supervision. Never leave the RT300-S unattended when children are present.

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

Adverse Reactions

Autonomic Dysreflexia

Individuals with a spinal cord injury at or above the T6 level are prone to episodes of autonomic dysreflexia. These episodes may be triggered by electrical stimulation. If you have a spinal cord injury, it is important that you discuss this with your clinician and understand how autonomic dysreflexia may impact you:

- know how to recognize the signs of autonomic dysreflexia
- know how to react if it occurs, including stopping electrical stimulation

To reduce the chances of experiencing autonomic dysreflexia the following precautions should be followed:

- Empty bladder and bowels before commencing a therapy session with the RT300-S.
- Do **NOT** use the RT300-S if you have a bladder infection or fever.

IMPORTANT NOTE TO PARENTS:

The most common signs of dysreflexia in children include headache, dizziness, blurred vision, redness of the face, neck, and/or ears, and feeling hot. Sometimes individuals will also report goose bumps, an upset stomach, or tingling feelings. Consult your child's physician for more information on how to recognize these symptoms.

If any of these symptoms occur stop the therapy session immediately.

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Skin irritation and burns

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

Safety Measures

Electrical Safety

- **Avoid flammable anesthetics:** Never use the equipment where there is a flammable anesthetic mixture containing air, oxygen or nitrous oxide.
- **Connecting the system:** Connect the system parts only in the way described in this guide. Do not try to connect or disconnect any parts while the system is turned on.
- **Other equipment:** Do not use the system with any equipment not supplied by Restorative Therapies Inc as doing so could affect the electrical safety of the system.
- **System parts:** The system contains complex electronic parts. The casings ***must not*** be opened by anyone other than qualified service personnel or the warranty will no longer apply. Also, if you attempt to make repairs yourself, you might be seriously injured.

Environment

- **Use a stable surface:** Position the motorized ergometer on an even, anti-slip surface so the equipment is stable and does not move during use.
- **Use an anti-slip device:** As an added precaution, you may wish to use an anti-slip device (e.g. mat, etc) to make sure your wheelchair does not slip backwards during very active therapy.
- **Avoid wet areas:** Never use the RT300-S Cycle Ergometer in wet or damp areas.
- **Avoid heat sources:** Place the RT300-S Cycle Ergometer equipment away from heat sources such as radiators, stoves, etc, or other objects that produce heat.
- **Arrange the power cord carefully:** Arrange the power cord so it will not be walked or tripped on, or damaged by objects being placed on it.
- **Use the correct line voltage:** Make sure you connect the RT300-S Cycle Ergometer to a grounded (earthed) power outlet that uses the voltage shown on the product label.
- **Follow extension cord ratings:** If you plan to use an extension cord, make sure the plug has three pins (i.e. the plug includes a third, protective earth pin).

Parts and Operation

- **Isolation from supply mains:** The RT100 Cycle Ergometer can be disconnected from the mains power supply by disconnecting the power supply cord from the RT100
- **Do not use the controller for other purposes:** Do not use the controller for any other purposes – for example, to store documents or images as it may alter how the controller works.
- **Do not use other controllers:** Do not use another person's controller as each controller is specifically programmed to suit an individual's requirements. Using another person's controller may lead to incorrect or excessive stimulation.
- **Before use**: before using the RT300-S Cycle Ergometer for the first time or after it has been transported over a long distance, allow it to stand for about 1 hour at room temperature.
- **After a long absence:** If you do not use the RT300-S Cycle Ergometer system for a prolonged period (e.g. a few months), you may find your progress is affected. If this occurs, it is important to see your clinician for re-evaluation and, perhaps, re-training before you start using the system again.

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- **Handle with care:** Handle the various parts of the RT300-S Cycle Ergometer system with care to reduce the risk of dropping and damaging the equipment. Do not stand on the footrests or the device's plastic motor covers.
- **Check for wear and tear:** Each time you use the RT300-S Cycle Ergometer, carefully inspect all the parts first. If you notice any damage – such as cracks or breaks in the covering of a cable – stop using the system and contact RTI Technical Support.
- **Do not handle or adjust the pedals** when the RT300-S Cycle Ergometer system is switched on.
- **Moving parts:** Keep hands well away from the pedals while the machine is in operation.
- **Report changes:** If you find any changes occur in how the RT300-S Cycle Ergometer operates, stop using the system and contact your clinician or RTI Technical Support.
  - Repairs to the RT300-S must only be carried out by properly trained specialists.
  - If the RT300-S is damaged or faulty or if it produces abnormal noises or smells, stop the therapy session immediately, unplug the power cord and contact your service technician.
- **Clothing:** Dress comfortably to allow for the appropriate range of motion in the legs and / or arms. Avoid wearing clothing that may catch on the moving parts of the system.

Electrostatic Discharge

A discharge of static electricity could damage:

- electrical parts of the system
- software programs on the controller

If static electricity is present, touch a metal part of the ergometer before fitting any parts or touching the controller. Examples of where static electricity might occur are:

- putting clothes on over your head
- in very low humidity

Electromagnetic Interference

Electromagnetic interference (EMI) from sources such as radio and TV stations, amateur radio (HAM) transmitters, two-way radios, and cellular phones can affect the RT100 Cycle Ergometer.

a. Do not operate handheld transceivers such as citizens band (CB) radios while operating the RT100

b. Be aware of nearby transmitters, such as radio or TV stations

c. Keep the RT300-S at least 20ft away from microwave ovens

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RTI Technical Support

Restorative Therapies Inc (RTI) offers a technical support service to provide troubleshooting help when:

- you have read this guide but are experiencing difficulties with the RT300-S System
- the system is due for a maintenance service
- you need to order replacement parts

Contact RTI Technical Support:

- via email to **support@restorative-therapies.com**
- by calling **1-800-609-9166**

Terms used in this guide

Term	What it Means
BlueTooth	A wireless, automatic means by which electronic devices connect to each other. BlueTooth devices communicate with each other on a standard band or range of radio frequency called the ISM (industrial, scientific and medical) devices band.
controller	A computerized panel used to control the RT300-S System.
FES	Functional Electrical Stimulation
ⓘ	Important information or help.
RTI	Restorative Therapies, Inc
Calf or leg	The limb segment between the knee and ankle.
surface electrode	An electrode (adhesive pad) that is attached to the skin surface to stimulate a group of muscles. Each surface electrode connects to the RT300-S System via the stimulation cable.
Thigh	The limb segment between the hip and knee.
Torso	The part of the body from the shoulders to the waist.
Type BF Applied Part	This term is used in the "IEC 60601-1" electrical safety standard. It applies to the parts of a medical device that must physically touch a person to carry out the device's intended function. Applied Parts are Type B, or Type BF, or Type CF depending on the nature of the device and the type of contact. Each type has different requirements for protecting people against electrical shock.

Table 1: Terms used in this guide

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RT300-S System

What is the RT300-S System used for?

The RT300-S System is a motorized therapy system, which you use for:

- **passive therapy** – with motor power, and
- **active therapy** – with electrical stimulation applied to your muscles

The system is designed to provide a therapy routine prescribed by your clinician.

Parts of the RT300-S System

Table 2 shows a list of the RT300-S System's parts:

Part		Part Number
RT300-S system	RT300-S	FA100052
	RT300-SP (Pediatric)	FA100053
Controller / Stimulator		SA100090
Controller / Stimulator mounting plate		PP100271
Controller / Stimulator power cable		PP100206
Power cord (USA)		SA100110
Stimulation cable		SA100091
Rectangle surface electrodes 2"x3.5" Qty 4		FA100015
Velcro pedal straps		PP100124
Velcro calf support straps		PP100125
Wheelchair restraint strap		PP100458
RT300-S System User Guide (this document)		LB100108
Warranty card		LB100109

Table 2: RT300-S System parts and part numbers

If a part is damaged or lost, use the **part number** to order a new one from Restorative Therapies Inc. Please call or use our web store at www.restorative-therapies.com

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Surface Electrodes

You should replace your surface electrodes after approximately 15 uses to ensure good adhesion and connectivity. **Be especially careful to monitor the condition of the electrodes that you use on your gluteal muscles as these are subject to more wear and skin burns are reported to be more likely here.**

Table 3 shows the description and part number for ordering surface electrodes from RTI. Contact RTI to order new electrodes or via the web at www.restorative-therapies.com.

Part	RTI Part Number
Size: 2" x 2"	PP100418
Standard electrode: Size: 2" x 3.5"	FA100015
Size: 3" x 4"	PP100419
Size: 3" x 5" oval	PP100420
Size 2" x 2" (sensitive skin)	PP100421

Table 3: Recommended surface electrode details

Selecting the right electrodes

Electrodes need to be selected that best fits the size of your muscles - your clinician will assist you in selecting the correct electrodes for your body.

The quadriceps and hamstrings typically require larger electrodes than the gluteals. Usually your clinician will try to cover a good portion of the muscle without allowing the electrodes to touch and without covering other muscles that are not to be stimulated.

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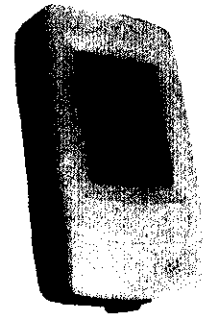
Setting Up the Equipment

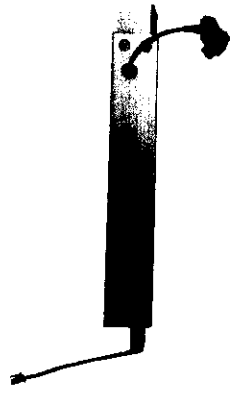
Safety handle



Controller / stimulator

Stimulation cable

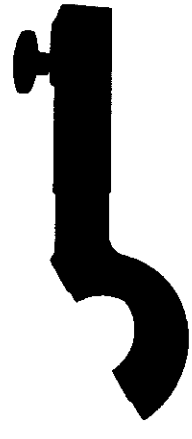
Safety handle extension with cable

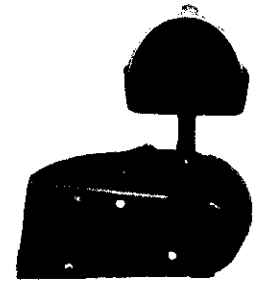


Surface electrode

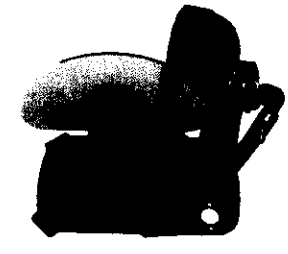
Toolkit

Safety handle mount





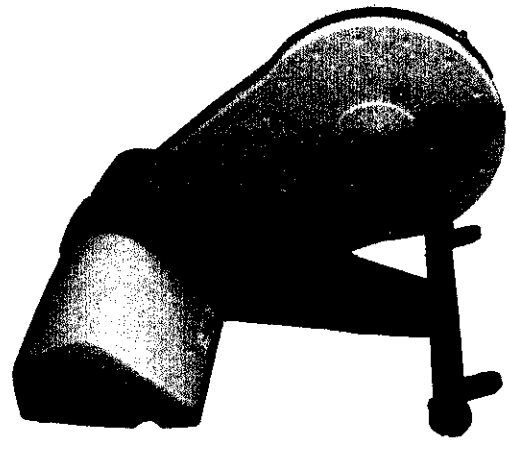
Adult pedal (1of 2)



or Pediatric pedal (1 of 2)

Wheelchair restraint (1 of 2)

Base unit



Power cord (USA)

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RT300-S System Overview

Standard RT300-S Equipment

Standard RT300-S equipment is:

- motorized cycle ergometer
- controller / stimulator and mounting plate
- 12 skin surface electrodes
- stimulation cable for connecting the skin surface electrodes to the controller / stimulator
- wheelchair restraints for securing the wheelchair to the RT300-S
- power cord

Figure 1 shows the standard equipment and features.

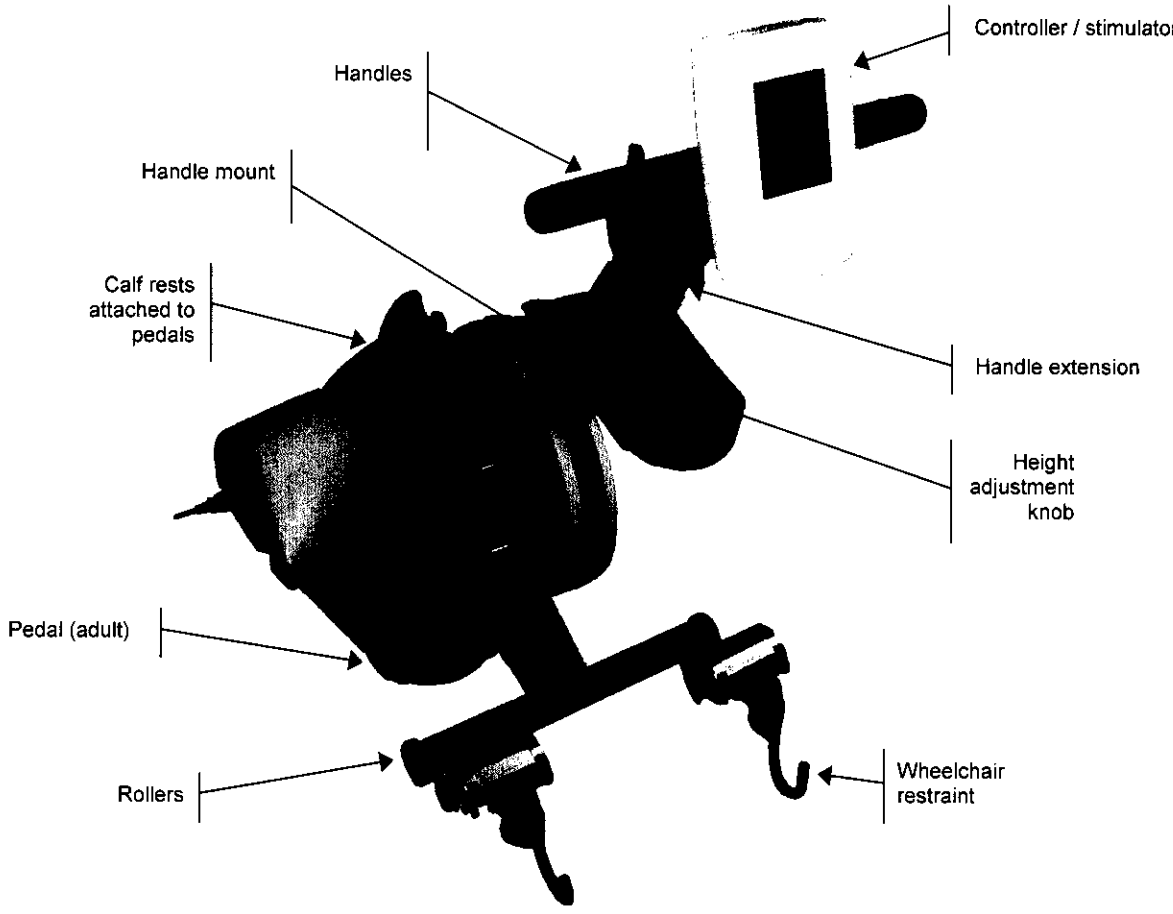

Figure 1: RT300-S system components

You use the RT300-S System from your wheelchair, with your feet secured in the pedals and your legs supported by the calf rests.

Surface electrodes placed on your skin over particular muscle groups are connected to the ergometer by a set of cables.

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Software on the controller controls the stimulation patterns sent to your legs, producing a smooth pedaling motion.

It is recommended you always wear shoes (e.g. running shoes) when using the RT300-S System.

Optional RT300-S Equipment

You can add the ergometer platform if you need to raise the height of the whole ergometer.

Contact RTI for more information on purchasing the ergometer platform or visit the store at www.restorative-therapies.com.

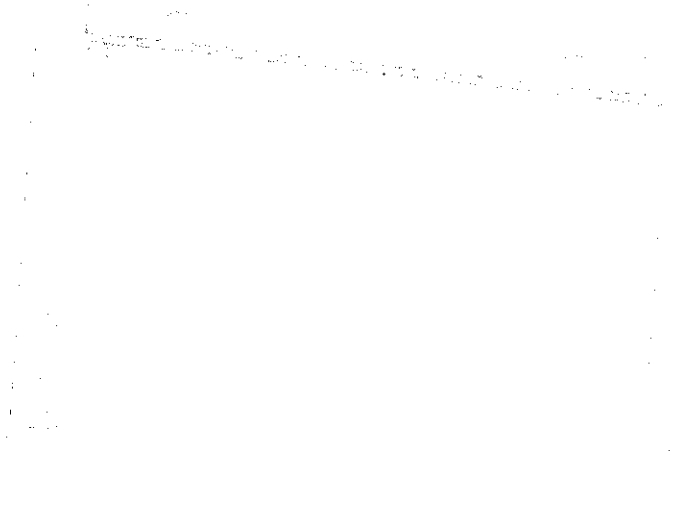

Figure 2 Ergometer platform with adjustable height legs, FA 100019

RT300-SP Ergometer for Pediatrics

The RT300-SP is the pediatric version of the RT300-S. It includes as standard equipment:

- handles which can be adjusted to a lower height than the handles on the adult ergometer
- a different pedal system that is adjustable for smaller feet and limbs

This system is intended for children aged from 4 to 12 years old.

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Assembling the RT300-S

Checking the Parts

Before you start assembling the ergometer, unpack **all** of the parts and:

1. Check to make sure none of the parts are damaged or missing. See page 11 for details on all parts.

If any of parts are damaged, missing contact RTI Technical Support immediately. Do not use the system.

Fitting the safety handle mount and extension

To fit the support arm:

1. Place the base unit of the ergometer on a flat, even surface.

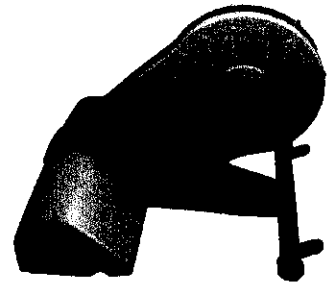

Figure 3: Base unit of the ergometer

2. Slide the safety handle extension into the safety handle mount as shown in Figure 4. Ensure that the Controller power cable also passes completely through.

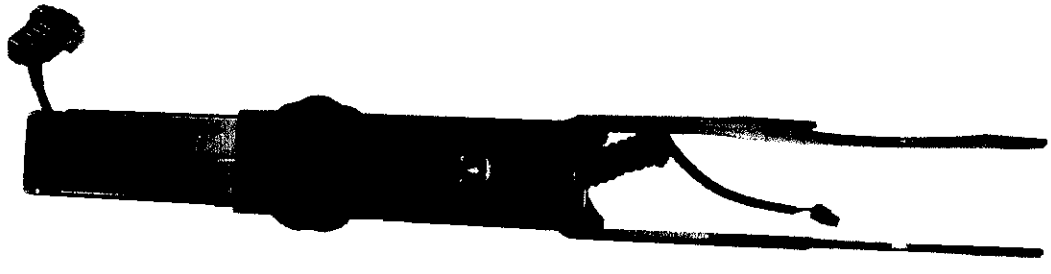

Figure 4 Slide the safety handle extension into the safety handle mount

3. Hold the safety handle mount with the height adjustment knob facing you.
4. Slide the safety handle mount forks over the encased sheave being careful not to trap the Controller power cable.
5. Connect the Controller power cable to the cable protruding from the base unit.
6. Slide the support arm down until the bolt holes on the forks align with the bolt holes on the sheave casing being careful not to trap or cut the Controller power cable.

There are two bolt holes on each fork and two corresponding bolt holes on each side of the sheave casing.

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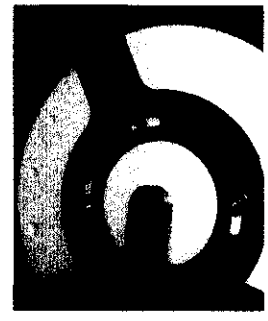

Figure 5: Bolt holes aligned

7. Screw the bolts into the bolt holes and tighten each bolt using the Allen (Hex) Key provided.

Figure 6 Allen (Hex) key

It may be necessary to loosen the lower bolts and rotate the whole assembly.

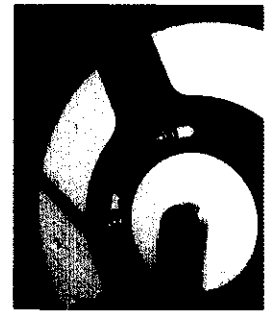

Figure 7: Tightening a bolt with the Allen (Hex) Key

Fitting the safety handle

1. Fit the safety handle to the safety handle extension using the two bolts supplied.

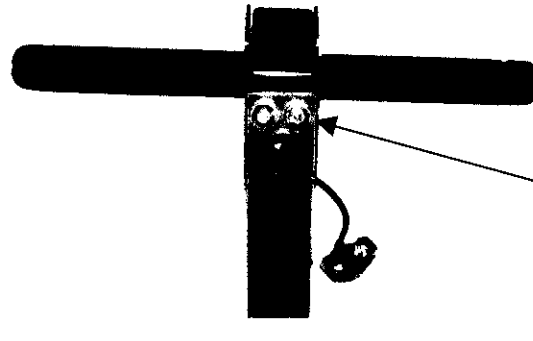

Figure 8: Fitting the safety handle

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Fitting the controller / stimulator

1. Fit the Controller mounting plate to the safety handle assembly using the hex bolts supplied as shown in Figure 9.

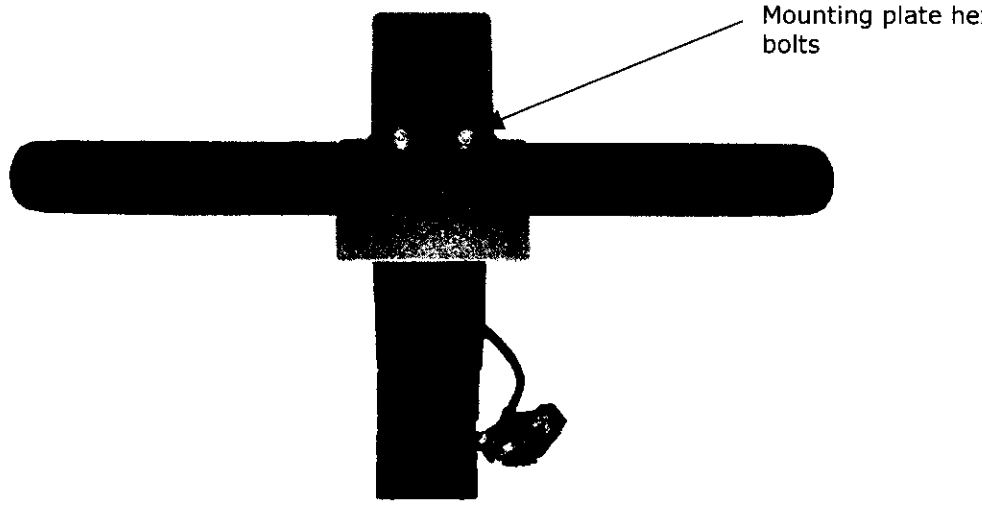

Figure 9 Controller Mounting Plate

2. Fit the Controller to the Controller mounting plate using the three screws supplied.

3. Plug the Controller power cable into the back of the Controller.

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Adjust the height of the safety handles

When you use the RT300-S System, you need to sit upright, and be able to comfortably reach and use the handles and controller.

The safety handle's extension section can be moved up or down to a height that suits you.

To adjust the height of the safety handles:

1. Turn the height adjustment knob counter-clockwise until the handle extension section is loose.

Figure 10: Adjusting the height

2. Slide the handle extension section to the height you require.
3. Turn the height adjustment knob clockwise until the handle extension section locks into place.

Adjusting the pedal crank radius

The pedal crank radius can be adjusted as shown in Figure 11

1. Open the locking pin
2. Move the footrest to the desired position on the crank and **tighten the locking pin firmly**!
3. Adjust the opposite pedal in the same way.

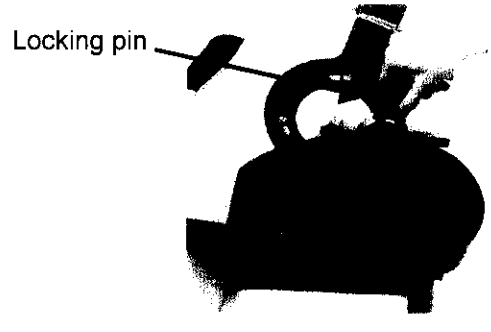

Figure 11 Pedal crank radius adjustment

Make sure that the crank lengths on both sides are equal. Depending on the nature of the patient's condition, asymmetrical crank lengths may sometimes be of benefit. With an amputated leg it can be necessary to remove one pedal completely.

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Adjusting pediatric pedals

Two hex wrenches are provided for adjusting the pediatric pedals.

Figure 12 Pediatric pedal adjustment tools

The angle of the calf rest can be adjusted in three dimensions as shown in **Figure 13**.

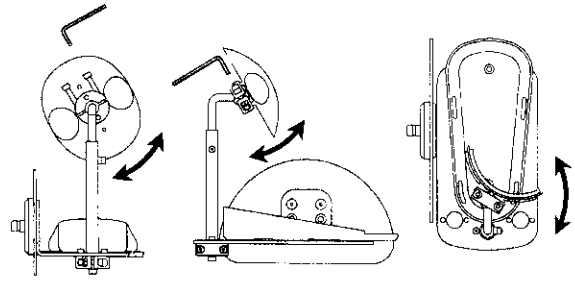

Figure 13 Calf support angle adjustment

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The plastic foot plate can be removed by detaching it from the retaining Velcro. The angle of the plastic foot plate can be adjusted by reattaching it at the required angle using the retaining Velcro provided.

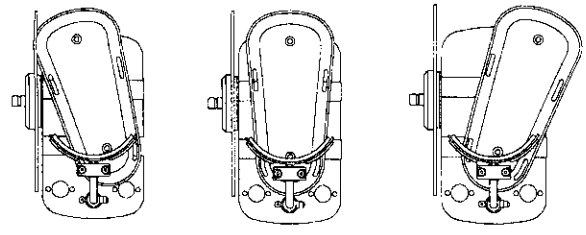

Figure 14 Foot plate angle adjustment

Make sure that the plastic foot plate is firmly attached by the Velcro. Press firmly!

The position of the calf rest on the foot plate assembly can be adjusted as shown in (inner, middle and outer positions).

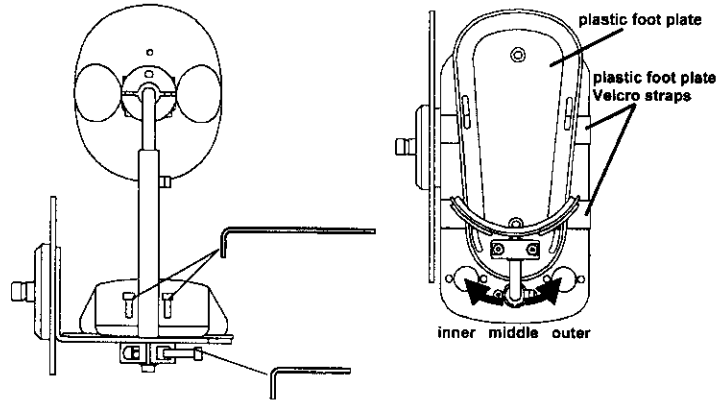

Figure 15 Calf rest position adjustment

The height of the calf rest can be adjusted as shown in Figure 16.

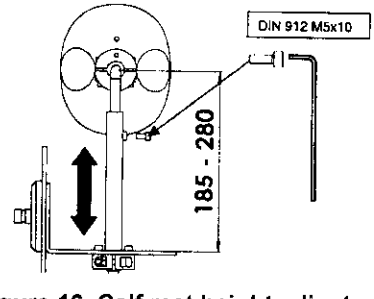

Figure 16 Calf rest height adjustment

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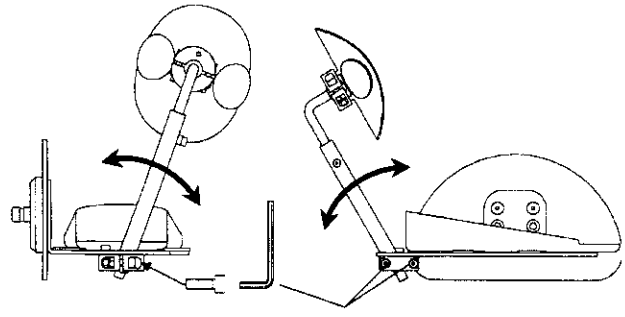

Figure 17 Calf rest angle adjustment

The height of the foot rest assembly can be adjusted as shown in Figure 18.

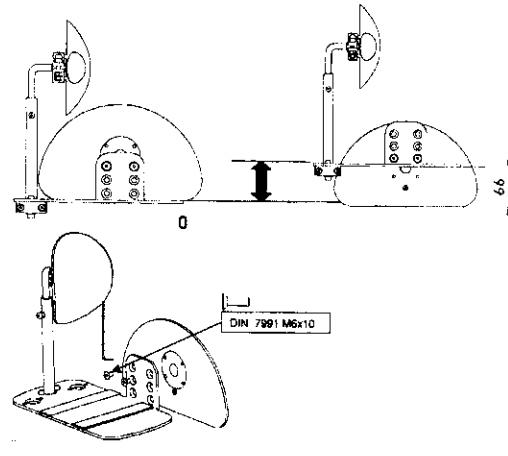

Figure 18 Foot plate assembly height adjustment

The feet <u>must</u> be strapped into place within the plastic foot rests using the Velcro straps shown in Figure 19.

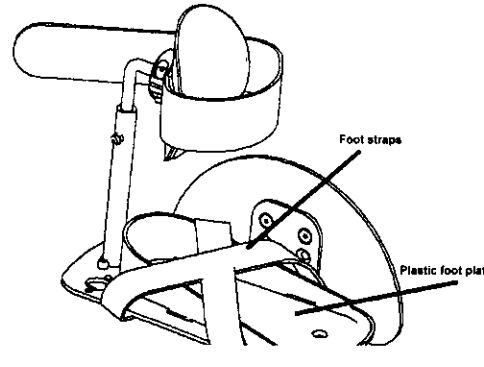

Figure 19 Foot straps

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Base of support

The stability of the RT300-S can be increased by extending the base of support.

To extend the base of support:
1. Tip the RT300-S up over on its castors
2. Loosen the two hex bolts with the hex key provided
3. Pull out the cross bar as far as needed but do not extend it beyond the mark.

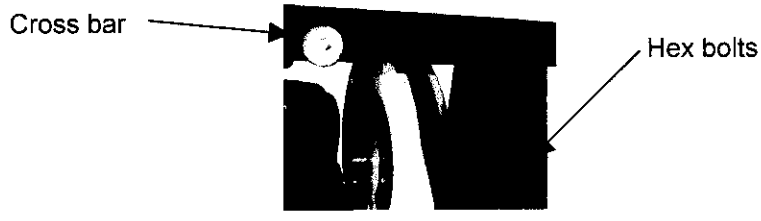

Figure 20 Hex bolts and cross bar for stability adjustment

Fitting the wheelchair restraints

To fit the wheelchair restraints:

1. Place nylon washer over wheelchair restraint attachment point on crossbar
2. Bolt the wheelchair restraint to the crossbar and tighten
3. Repeat for the other side of the crossbar

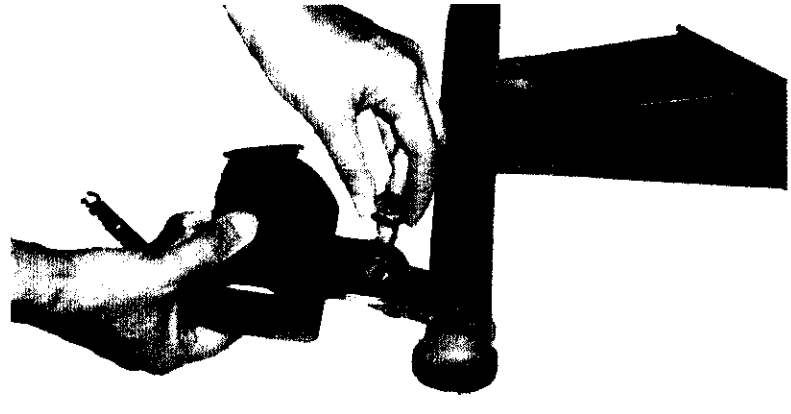

Figure 21 Fitting wheelchair restraint

Connecting the Power

To connect the power:

1. Use the power cord provided to connect the RT300-S System to a power outlet.
2. The system is intended to be left connected to a power outlet so that the Controller's internal battery remains charged. The system will automatically switch off shortly after a therapy session so it is not necessary to disconnect the power.

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Figure 22: Power connection

Never pull on the power cord. Always grip and pull the plug to disconnect the power cord from the power outlet.

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Fitting the equipment

Using Surface Electrodes

The RT300-S System provides stimulation through adhesive surface electrodes placed on the skin over the following muscle groups:
- right and left gluteals
- right and left hamstrings
- right and left quadriceps

Your clinician will advise you on which size electrodes are most suitable for you.

Before you fit the surface electrodes to your body, **you must** read the *Warnings, Precautions and Safety Measures* section at the front of this guide. Also read the following sections – *Surface Electrode Placement Precautions* and *Caring for Surface Electrodes.*

Surface Electrode Placement Precautions

- If there is poor contact between your skin and an electrode, or an electrode does not adhere to your skin, you may need to trim hair from the electrode site. It is recommended you clip, not shave, the hair.
- Following each session, always check electrode sites for any redness or other adverse reactions. If your skin becomes irritated, move the electrode to a slightly different area until the irritation clears. If irritation persists, or you experience a burn, contact your clinician.
- Do not use any surface electrodes that are smaller than those provided with the RT300-S System.
- Renew electrodes after 10-15 uses. See page 12 for re-ordering information.
- Periodically check the electrodes are in full contact with your skin. If an electrode repeatedly fails to adhere properly, replace it with a new one.
- Rough edges on a surface electrode may also cause electrical burns so replace the electrode if this occurs.
- Be especially careful to check the condition of the electrodes that you use on your gluteal muscles as these are subject to more wear.

Caring for Surface Electrodes

- Use the self-adhering surface electrodes supplied by Restorative Therapies Inc. See the details in Table 3 for ordering new electrodes.
- A surface electrode is expected to last for 10 to 15 applications with normal use. Throw a surface electrode away if it adheres poorly or shows signs of wear and tear (e.g. rough edges).
- Gently remove a surface electrode by lifting it from one corner. Do not pull on the connecting lead as this may damage the connection.
- Replace surface electrodes on the plastic carriers when they are not in use.

See the surface electrode pack for more instructions on use, care and storage.

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Fitting the Surface Electrodes

To use the RT300-S System, you must have all 12 surface electrodes correctly fitted to your body, as shown in Figure 23.

To fit the surface electrodes:

1. Make sure the skin where the electrodes are to be placed is clean and dry. Remove any lotion with an alcohol wipe.
2. Peel the plastic carrier off a pair of surface electrodes.
3. Place the two surface electrodes on your body at the correct location. (See Figure 23).
4. Apply light finger pressure to the entire surface of each surface electrode to make sure it is in full contact with your skin.
5. Repeat steps 2 to 4 for the remaining five pairs of surface electrodes.

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Where to Place Surface Electrodes

Figure 23 indicates the sites for electrode placement. However, as placement varies slightly between individuals, your clinician will determine the locations that provide the most effective stimulation for you.

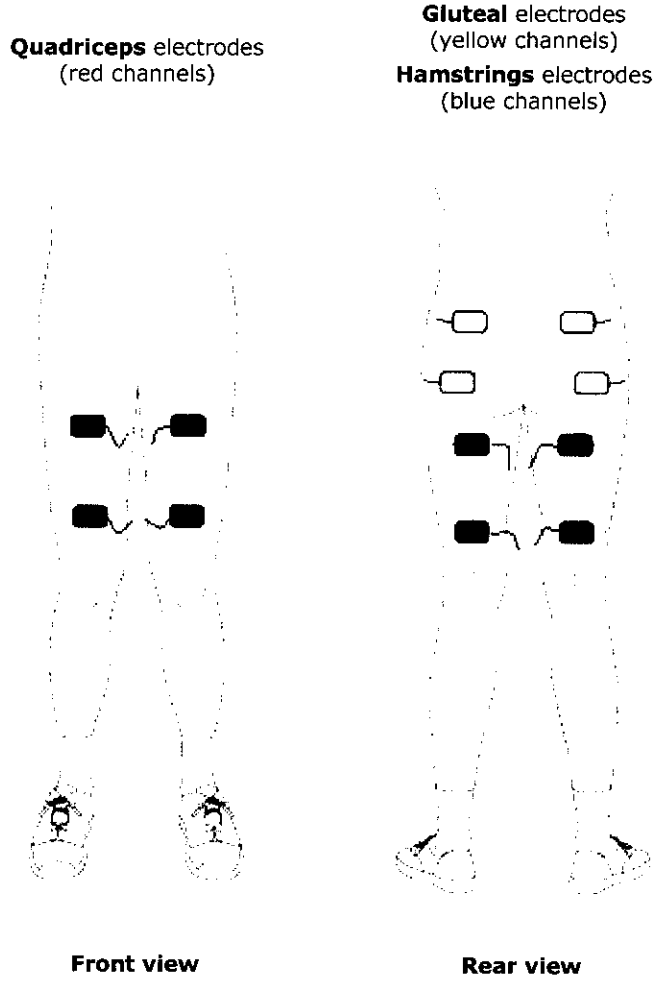

Figure 23: Surface electrode sites

The Gluteal electrode leads should face outward (lateral). It is often easiest to attach the stimulation cable to the Gluteal electrodes before placing them on your skin. All other electrode leads should face inwards (medial) as shown in Figure 23.

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Connecting the surface electrodes to the ergometer

Stimulation Cable Set

Once you have fitted the surface electrodes, connect them to the stimulation cable.

One end of the stimulation cable splits into 12 leads. Six leads for the left side of your body and 6 leads for the right side. Each lead is color coded and labeled with two letters.

Figure 24: Color-coded, marked leads

Table 4 shows how the color and letters on a lead represents a particular muscle group.

Letters	Color code	Muscle Group
LG	Yellow	Left Gluteals
LH	Blue	Left Hamstrings
LQ	Red	Left Quadriceps
RG	Yellow	Right Gluteals
RH	Blue	Right Hamstrings
RQ	Red	Right Quadriceps

Table 4: Color-code/letter on stimulation cable leads

Each lead must be fitted to the corresponding surface electrode according to the color and letter.

Leads with an "R" on the label are for the right side of your body. Leads with an "L" on the label are for the left side of your body.

Examples

A surface electrode fitted to your **right** quadriceps connects to a **red** lead marked **RQ**.

A surface electrode fitted to your **left** gluteals connects to a **yellow** lead marked **LG**.

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Connecting the Surface Electrodes

To connect the stimulation cables:

1. Using the color-coding and letters on each lead as a guide:
   - connect the leads from the stimulation cable to the electrodes placed on your body.

Make sure all lead pins are fully inserted (see Figure 25). Press your finger tip across the top of the socket to be sure.

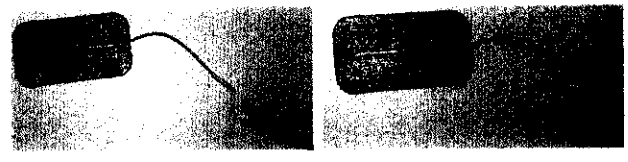

Figure 25: Connecting a lead to an electrode

2. Plug the stimulation cable into the outlet on the bottom of the Controller / stimulator – it will only fit in one way (vertical arrow on the connector to the front) and it will click into place.

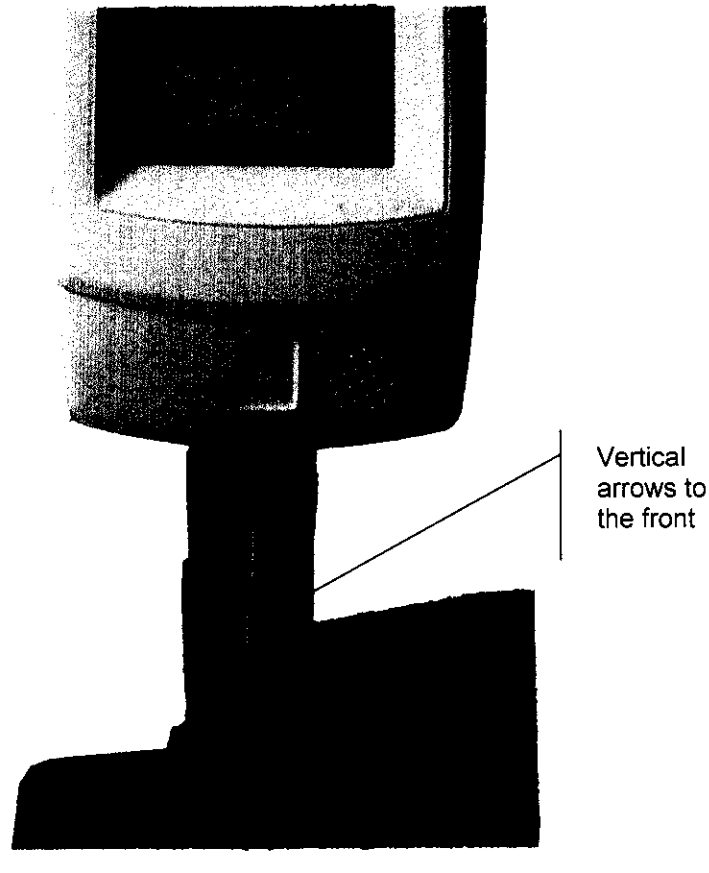

Figure 26 Attaching the stimulation cable

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Using the RT300-S System

Using the RT300-S System involves:

- initial setup
- correctly positioning yourself on the ergometer and making any necessary adjustments
- fixing your feet in the footrests and your legs in the calf rests
- restraining your wheelchair so that it does not move during the therapy session
- understanding what happens during a typical therapy session
- understanding the functions of the RT300-S controller / stimulator
- starting and stopping a session
- knowing what happens if muscle spasm occurs
- being aware of the possibility of autonomic dysreflexia

Initial setup

When you first power on the RT300-S it is necessary to calibrate the Controller's touch screen.

The procedure to do this is described below.

Once you have calibrated your controller's touch screen you should leave the RT300-S connected to a power outlet. This will ensure that the RT300-S controller's back up battery remains charged.

If you disconnect your system from a power outlet you will need to repeat this calibration procedure.

Calibrate the touch screen

1. Follow the instructions provided by the Controller
   - Using the Stylus touch the screen in the positions requested by the controller.
   - Cut and paste the demonstration appointment
   - Select your time zone

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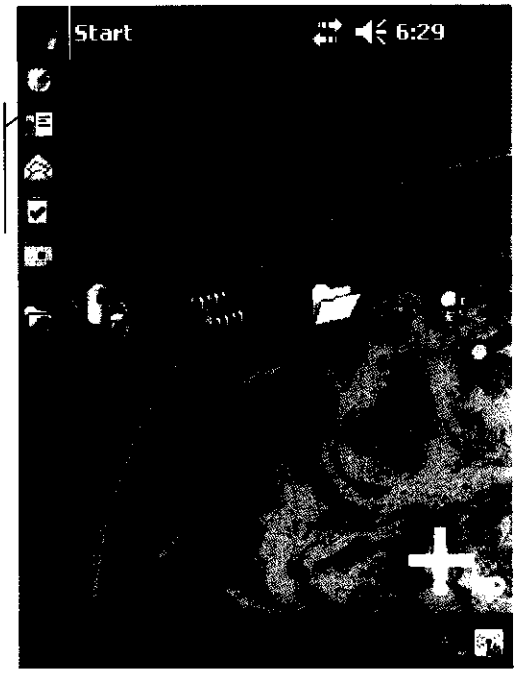
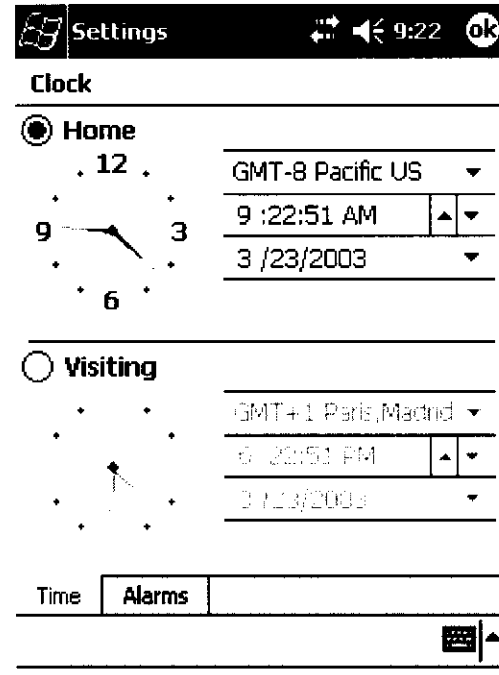
Set the time and date

1. Set the Home time on the system as shown below:

1. Press the date





2. Enter the correct time and date here

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Positioning on the Ergometer

Getting into the correct position on the ergometer involves:

- setting the distance between your wheelchair and the ergometer
- strapping your feet into the footrests and legs against the calf rests

Setting the distance

The distance you should set between your wheelchair and the ergometer is affected by:

- the type of wheelchair you use
- the length of your legs
- your height

The most effective way to check you are correctly positioned is to check the angle of your knee joint when your foot is in the footrest and your leg is fully extended.

To set the correct distance:

1. Place your foot in a footrest, resting your leg in the leg guide.
2. Move your wheelchair slowly back or forward until your knee joint reaches a 45° angle, as shown in Figure 27.

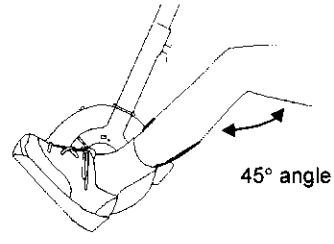

Figure 27: Knee joint at 45° angle

Using the Calf Rests and Footrests

It is recommended you always wear shoes (e.g. running shoes) when using the RT300-S System. The footrests are designed to accommodate shoes, while the calf rests help support the legs.

Both the footrests and calf rests have straps for added support and safety.

Do not put your whole body weight on the pedals when you place your feet in the footrests.

To use the footrests and calf rests:

1. Open the straps on the footrests and calf rests.
2. Place your left foot in the footrest, resting your leg against the leg guide.

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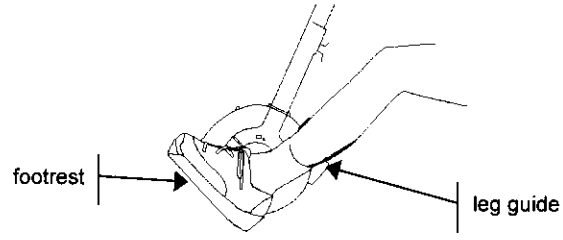

Figure 28: Foot and leg position

3. When you are correctly positioned, fasten the straps on the footrest and leg guide.

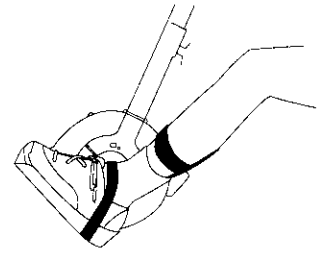

Figure 29: Straps fastened on footrest and leg guide

4. Repeat steps 2 and 3 for your right foot.

Using the wheelchair restraints

Once you have correctly positioned your wheelchair you should use the restraining straps provided to ensure that your wheelchair does not move during your therapy session.

1. Hold down the red lever on the front of one of the restraining straps and pull out the strap
2. Hook the strap to a secure point on your wheelchair beneath the level of your seat.
3. If necessary turn the tightening knob to take up any slack
4. Repeat for the other restraining strap

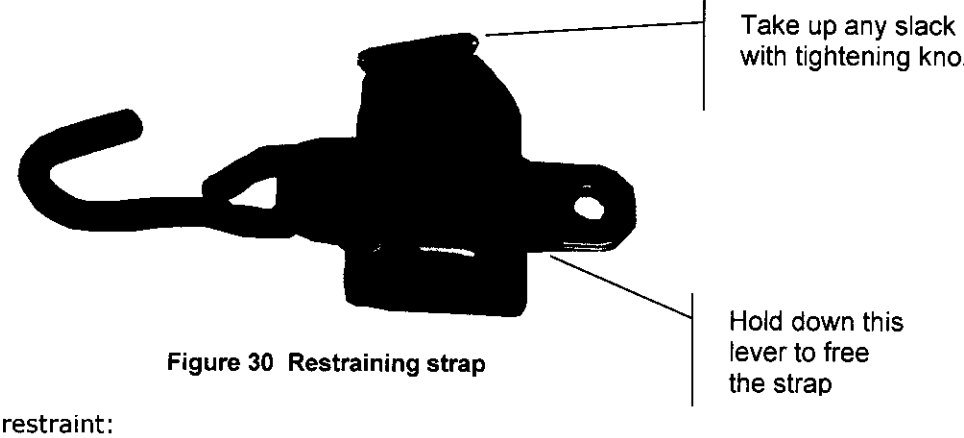

Figure 30 Restraining strap

To remove the wheelchair restraint:

1. Hold down the red lever on the front of one of the restraining strap and pull out enough slack to allow you to unhook the strap from your wheelchair
2. Release the strap and it will retract back into the restraint system.

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Using the Controller

The controller's Therapy Session screen shows what is happening at any particular time during a therapy session. The controller's touch-sensitive screen allows you to:

- Start and stop your therapy session
- Monitor the progress of your therapy session
- See any warnings or errors that occur
- Update your stimulation parameters

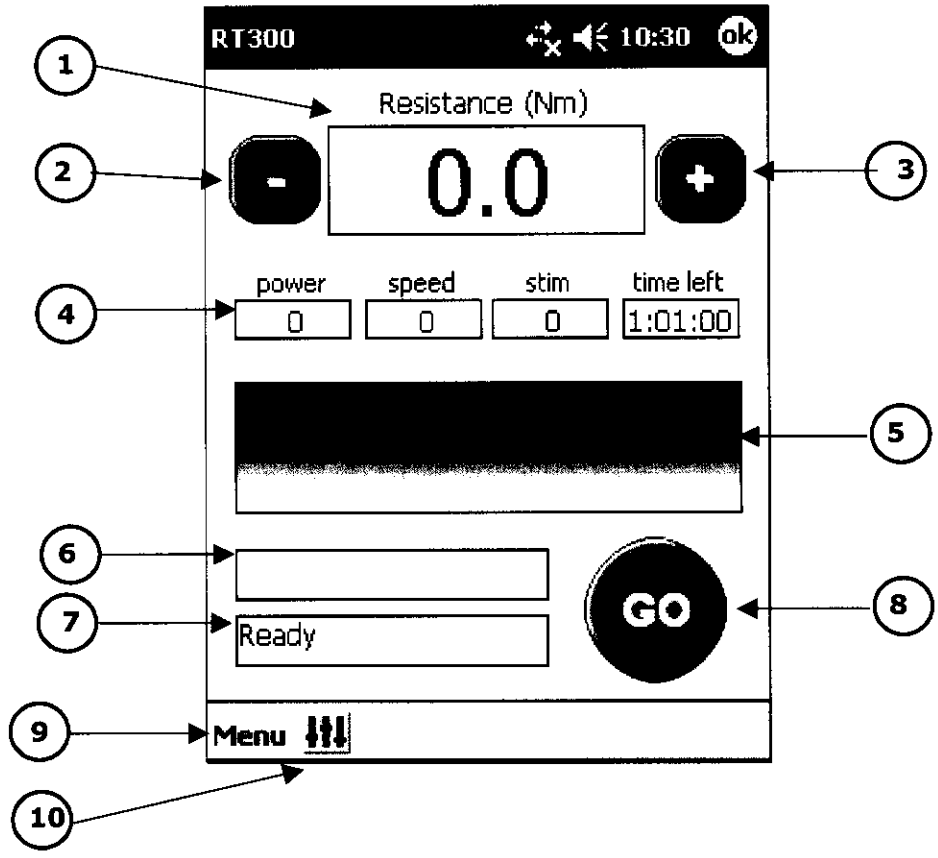

Figure 31: Controller - Therapy Session screen

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(1) Main display window shows one of:
- Time left
- Cycling speed
- Stimulation level (by default)
- Resistance
- Power

Tap this window to cycle the displayed data.

(2) Decrease button
This button is only shown if Resistance is being displayed in the main display window. Tap this button to reduce your resistance level during active therapy.

(3) Increase button
This is only shown if Resistance is being displayed in the main display window. Tap this button to increase your resistance level during active therapy.

(4) Secondary display windows.
Tap these windows to transfer their data to the main display window.

(5) Graphical display of data as your therapy session progresses
- The green tracing shows your stimulation level history
- The blue area represents time and stimulation level remaining

(6) Notifies of a pending change in the phase of your therapy session (see page 36)

(7) Therapy State:
- Ready
- Warm up (initial passive cycling)
- Active cycling (stimulation operating)
- Passive cycling (fatigue has been detected)
- Cool down
- Finished

(8) Start and Stop button
"Start" when the system is stopped and "Stop" when the system is operating.
- Press "Start" to commence your therapy session.
- Press "Stop" if you want to stop your therapy session early.

(9) Menu bar allows for
- About RT300... displays the version of the RT300 software
- Log in... allows your clinician to log in to the system to adjust therapy parameters

(10) Configuration button
See page 40 for how to adjust your stimulation settings

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Therapy Sessions

Once your are correctly positioned (page 32) and your wheelchair is restrained (page 33) you are ready to begin a therapy session.

RT300-S System therapy sessions help you to pedal using your own muscle power, providing the opportunity to make continual progress over the course of your therapy plan.

The RT300-S System is designed with pre-set (default) therapy settings. Your clinician may also make adjustments to settings like the:

- length of your therapy session
- amount of power your muscles generate during a therapy session

How the therapy session progresses

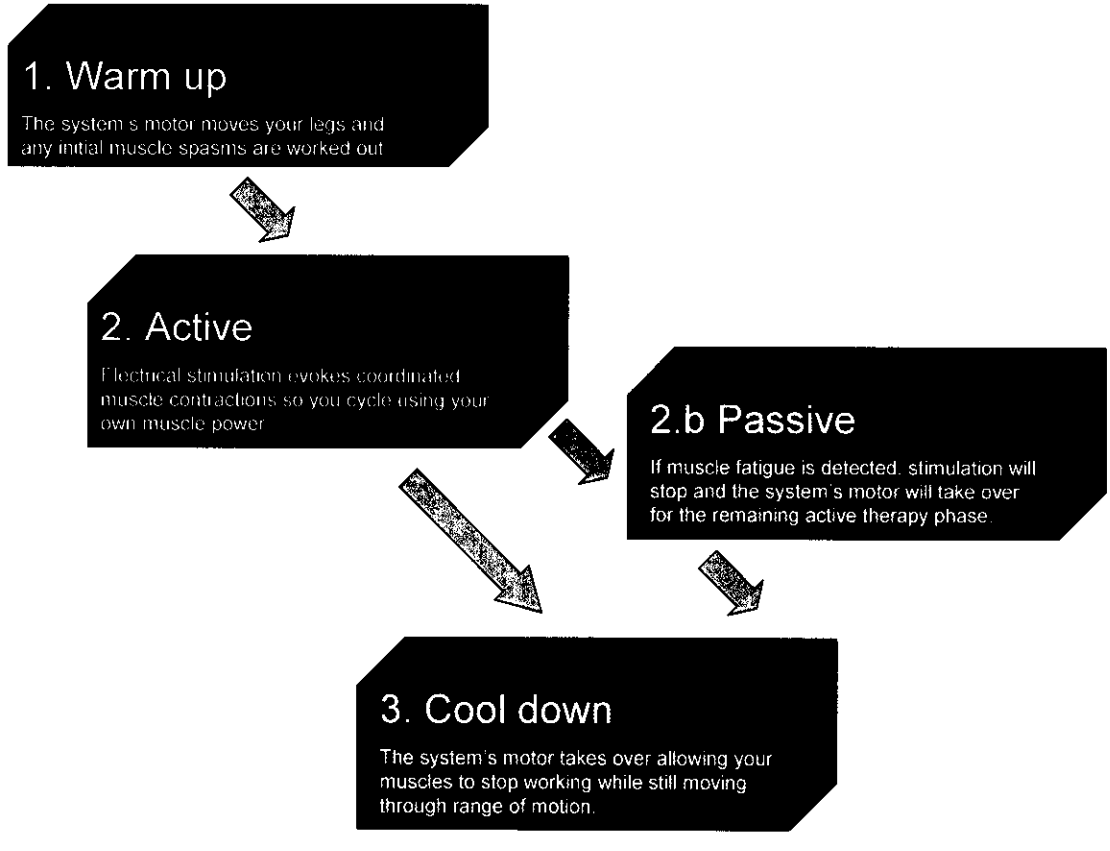

Figure 32 Phases of your therapy session

Inbuilt Safety Measures

At the end of each session, the RT300-S System automatically switches off. There are also inbuilt safety measures to help protect you during therapy. You should be aware that:

- if the system registers muscle fatigue, the ergometer's motor takes over for the remainder of the session. You will see that the display swaps from displaying "Active cycling" to "Passive cycling".

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- if an electrode falls off, the system immediately pauses by ceasing stimulation and switching off the motor. An error message is displayed on the controller Therapy Session screen to let you know what has happened. After you fix the problem, tap Go to restart the session.

Handling Muscle Spasm

At the beginning of the Warm Up phase, muscle spasms may occur. These usually subside before the Warm Up period ends.

If the spasms persist, wait approximately 5 minutes and then begin the therapy session again. If the spasms still do not subside, the therapy session should be postponed.

Starting and Stopping a Therapy Session

Before every therapy session, always empty your bladder to minimize the risk of autonomic dysreflexia occurring. If you have any concerns, talk to your clinician.

Starting a Session

To start a therapy session:

1. If the screen is dark, touch the controller screen to turn the system on.
2. Tap Go. The ergometer starts operating and your therapy session begins.

Tapping...
You can tap the screen using the stylus provided or your fingernail. If your fingernails are short, simply use the back of your finger to allow your fingernail to contact the screen.

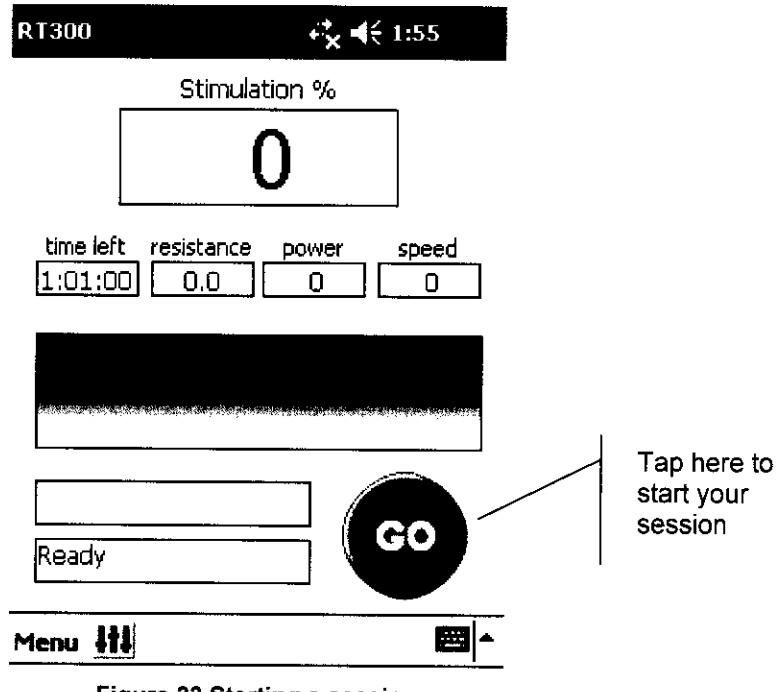

Figure 33 Starting a session

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Stopping a Session Early

The RT300-S System automatically stops once the end of the session is reached. However, you can stop the session at any time if you wish.

To stop a therapy session early:

1. Tap Stop. The session is ended.

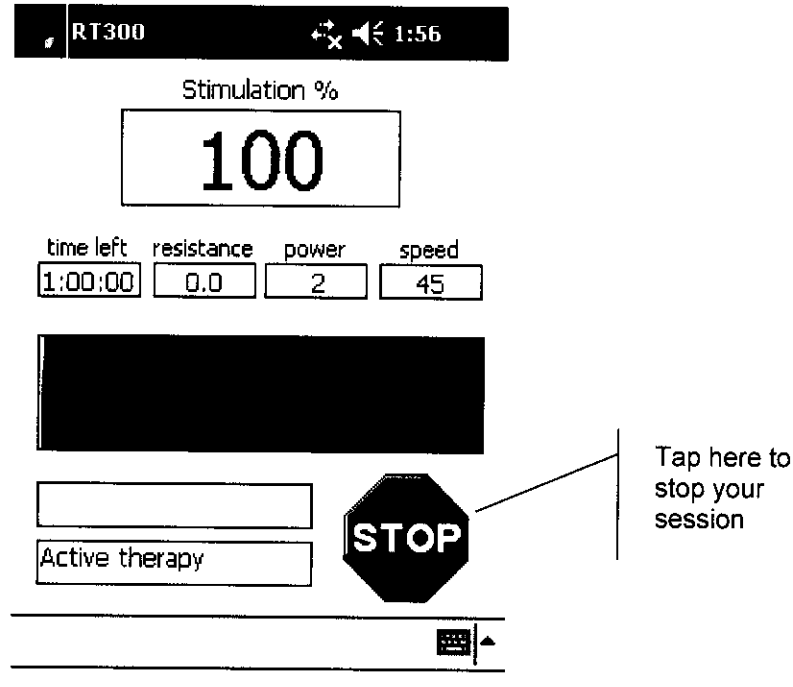

Figure 34 Stopping a session early

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Data display graph

The figure below illustrates the meaning of the data display graph which shows you how your session is progressing.

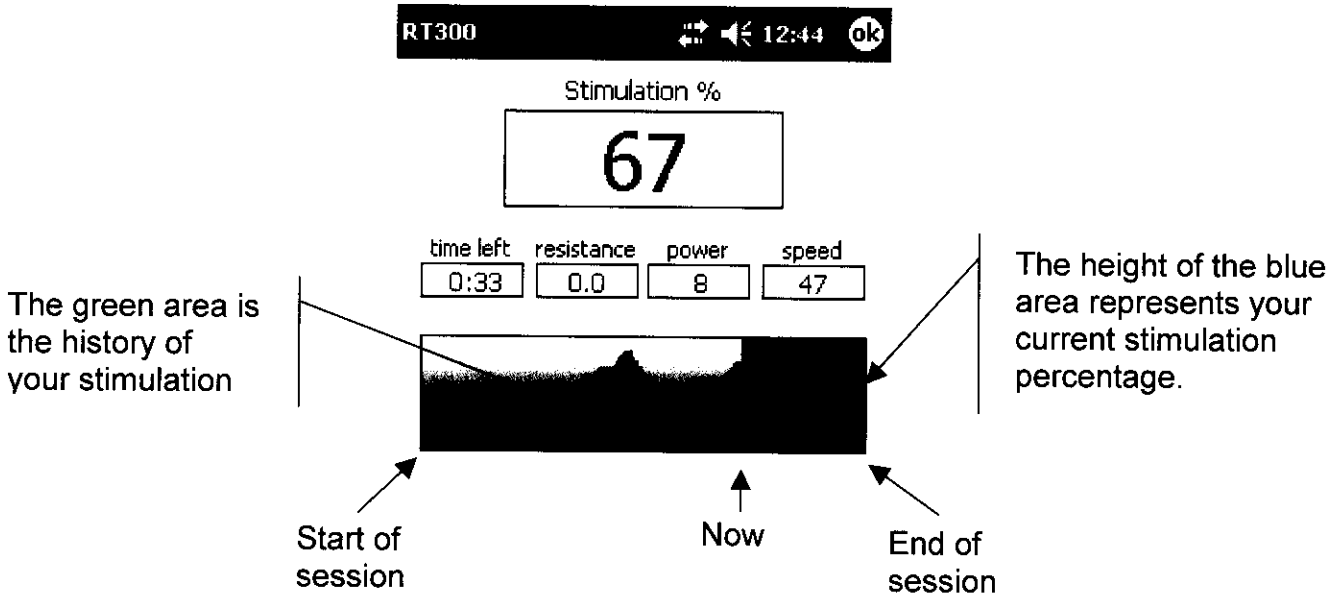

Figure 35 Data display

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Adjusting stimulation parameters

You should only adjust these parameters after consulting with you clinician.

The stimulation parameter page is accessed via button 10

This page allows you to change the pulse width, minimum current and maximum current that is delivered by the RT300-S system to each of your muscle groups. This page will default to initial appropriate levels depending on whether you have an adult or pediatric RT300-S system.

During active therapy the RT300-S system will use as much electrical stimulation as is required to keep you cycling at the set cycling velocity. However, the stimulation amplitude on any channel will never exceed the maximum (Max) that has been set for that channel (see Figure 36).

Normally, if sensation to stimulus is not an issue, the maximum (Max) stimulation levels should be left at 140 mA for adults or 80mA for children.

The minimum (Min) stimulation is the amplitude in milliamps (mA) where a muscle first begins to contract as a result of surface electrical stimulation.

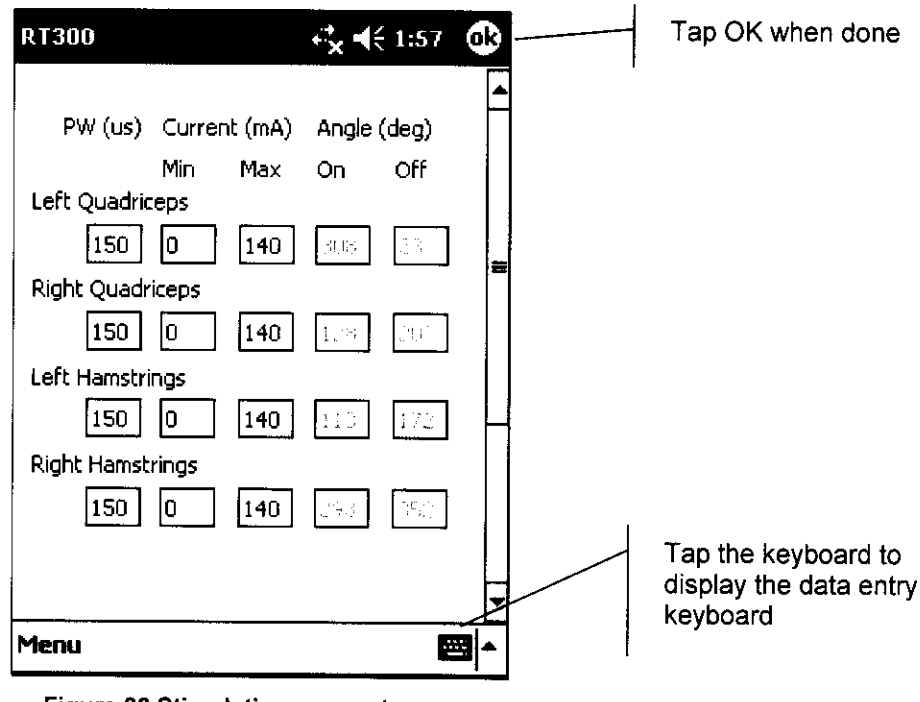

Figure 36 Stimulation parameter page

Making changes

To make a change to the stimulation parameters:

1. Tap the keyboard in the lower right corner of the screen
2. Highlight the number to be changed
3. Enter the new number using the displayed keyboard
4. Tap OK in the top right of the display

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Troubleshooting

Resetting the Controller

You may need to reset the RT300-S System controller in some situations, for example, if the controller does not respond when you tap the screen.

To reset the controller:

1. Press the Reset button on the back of the controller using the stylus or a pen.

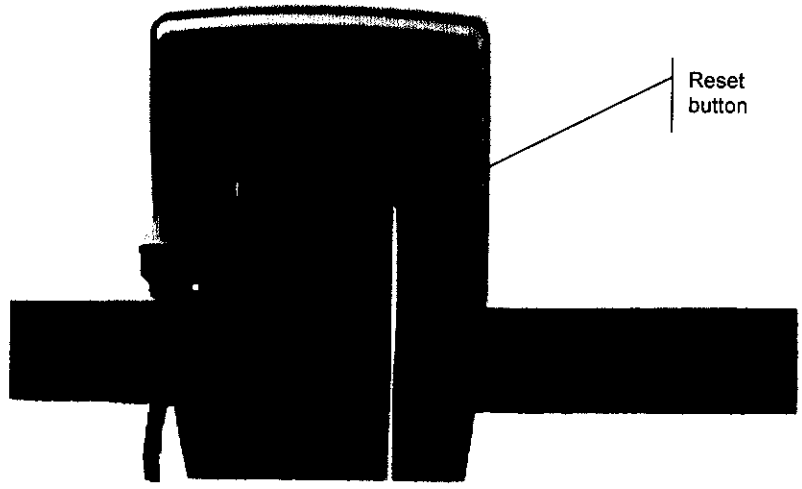

Figure 37: Reset button on controller

2. Wait until the controller displays the Therapy Session screen.

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Care of the RT300-S System

Cleaning and Maintenance

Regularly cleaning the equipment prevents a build-up of dirt.

Always unplug the power cord from the power outlet before you start cleaning.

- Never use solvent-based or corrosive on the RT300-S System.
- Wipe the controller screen with a dry clean cloth. Don't use any water - make sure no moisture gets into the controller.
- Use a damp, soft cloth to clean the RT300-S System surfaces.
- Take care not to damage or remove labels during cleaning.
- After 2 years (or 2,000 hours) of use, the controller displays a message to let you know that it is time for a maintenance check. Contact RTI Technical Support to arrange the service.

Storing the RT300-S

When you are not using the RT300-S System:

- store the RT300-S System equipment in temperatures between −20°C (−4°F) and +50°C (+122°F)

Moving the RT300-S System

Always unplug the power cord from the power outlet and the RT300-S System before moving the device.

The RT300-S System is fitted with castors and a handle to facilitate moving the RT300-S System short distances over a smooth surface. Hold the handle with one hand and place the other hand under the power unit.

To move the RT300-S System, tilt it backwards as shown in Figure 38 and push it in front of you.

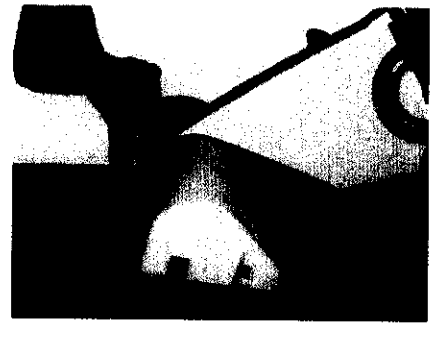

Figure 38 Moving the RT300-S System

The castors are not suitable for the transport on uneven or rough surfaces.
Two people are required to carry the RT300-S System up or down stairs.

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Shipping Instructions

The RT300-S Cycle Ergometer should be shipped in its original packaging.

The package dimensions are: 27″ x 23″ x 20″

The package weight is: 90lbs

Symbols

Symbol	Meaning
	Fragile
	See instructions for use
2004-05-30	Date of manufacture
+50°C (+122°F) -20°C (-4°F)	Temperature limit
LOT 12345	Lot number or Batch number
REF 12345	Reference number or Part number
IN 123456	RTI's Serial Number
Model FA100052	Model Number
	Type BF Part

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Technical Specifications

	115V	230V
Motorized Ergometer		
Length	31.5" or 80cm	
Width	19.3" or 49cm	
Height	36.2" – 40.6" or 92 – 103cm	
Shipping weight	90lbs or 41kg	
Length of pedal: • RT300-S • RT300-S-P (pediatric)	 4.3" or 110mm 4.3" or 110mm	
Speed range	0 – 55 rev/min (± 2 rev/min)	
Torque range	0 – 16Nm (± 1N)	
Power connection	115V~, 50/60Hz	230V~, 5/60Hz
Power input	160VA	160VA
Fuses	2 x 1.6 A 250V slow	2 x 1.6 A slow
Key materials	Aluminum, Steel, Polystyrol, Polyurethane	
Protective type	I	
Degree of protection	Type BF Applied Part	
Noise emission	Lpa ≤ 70dB (A)	
Noise emission value	According to DIN 45635-19-01-KL2	
Mode of operation	This device is for continuous use.	
Conditions: • In use • Transporting/storing	 5°C (41°F) to 40°C (104°F) 0 to 90% Rh 970 to 1030hPa -20°C (-4°F) to +50C (+122°F) 0 to 90% Rh 970 to 1030hPa	
Controller		
Display / interface	Touch-sensitive LCD	
Communications	Wireless (BlueTooth)	
Operating system	Windows CE 2003	
Inbuilt stimulator		
Maximum voltage output	200V	
Number of channels	6	
Current output per channel	0 – 140mA (± 2mA) with 0 to 1500Ω load	
Waveform type	Biphasic, charged balanced	
Pulse frequency	20Hz	
Phase width	0 – 250μs	

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Printed in USA
LB100108 Issue 5 (2110) RV100459 April 2005

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Appendix C Report on investigational use

Interim report on use of the RT300-S system at Shriner's Hospital for Children, Philadelphia

Eleven children with spinal cord injury (SCI) have experienced cycling with functional electrical stimulation (FES) using the RT300 cycle (Table 1) as part of a research study comparing three interventions. Four of these children were randomly assigned to the group in which they were provided with the FES cycle for home use. They were instructed to use the cycle for one hour, 3 times per week for one year. Two of these children have been using their cycles at home and two will begin using them in the near future. One child has been using the cycle at home since August of 2004 and the other since December 2004 without any difficulties. Their parents received written and verbal instructions on the use of the FES cycle and demonstrated that they could safely conduct an FES cycling session with their children before the FES cycle was sent home with them. Three sessions were sufficient to achieve this level of competence.

Table 1: Children enrolled in the study

Subject Age (yrs)	Level of Injury	Height (cm)	Weight (kg)
11	C7	144.5	29.1
6	T7T8	118	20.7
11	T1T2	138.5	27.5
7	T3	118.5	19.7
13	T5	171.4	70.2
7	T4T5	119	27.5
5	T10	106	16.2
8	T3T4	134.7	37
12	T7	161.3	72.6
8	C7	121.5	24.6
9	C7	130	23.7

All eleven children could be safely positioned on the FES cycle and were able to safely cycle from approximately 6 to 45 minutes without prior conditioning. All children with injuries at T6 and above were monitored for autonomic dysreflexia and stimulation levels were adjusted as needed to prevent blood pressure increases. Stimulation levels were able to be adjusted to prevent autonomic dysreflexia in every child, while still allowing the child to cycle successfully.

The smallest child, who was 5 years old, was 106 cm tall and weighed 16.2 kg. A child smaller than this may be difficult to position on the cycle but may be possible depending on the design of the child's wheelchair. This decision could be made by a clinician using clinical judgment to make this decision. The youngest child that was safely positioned on the FES cycle was 4 years old and not a part of the study. Stimulation was not attempted with this child but this was primarily done to determine if positioning could be achieved.

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This child's height was not formally measured but she was likely taller than the 5 year old who is in the study. Safe positioning for children shorter than 106 cm and younger than 4 years old would need to be determined on an individual basis for each child. A height of 106 cm has been reported to be approximately the 90th-95th percentile for a 3 year old, the 50th-70th percentile for a 4 year old, and the 5th-10th percentile for a 5 year old by the National Center for Health Statistics.[1]

As with the decision about the smallest and youngest child that can use the FES cycle, the clinician will need to use clinical judgment in selecting stimulation levels based upon the size of the child. Physical therapists are trained in the use of electrical stimulation and can select stimulation levels that will create the response based upon the size of the muscle and the ability of the muscle to contract with stimulation. No exact recommendation can be made regarding these levels. The smallest child in the study (106 cm) required current levels of 100 mA for the quadriceps and hamstring muscles while a taller child (130 cm) required 60 mA for the quadriceps and 50 mA for hamstring muscles.

At the current time, manual wheelchairs are attached to the RT300 via heavy fabric straps secured with a loop ring and Velcro. Wedges are placed behind the rear wheels of the wheelchair to further assist with security of the wheelchair for the larger adolescents using the cycle. Straps have not been needed to secure a power wheelchair to the RT300 due to the weight of power wheelchairs. There have been no issues with torqueing and no adverse events related to movement between the wheelchair and the RT300, even as resistance of the cycle is increased.

We have also recently tested the new Q'Straint restraining straps and found that they securely hold the wheelchair in place without the use of additional wheel wedges.

Subjects using the RT300 are encouraged to not lean on the handlebars on the RT300 when cycling as the preferred cycling position involves cycling with the trunk upright and/or slightly reclined. Subjects have been able to do this without stability issues. Subjects may use the handlebar for support when starting or stopping a session or making any permitted changes to the current cycling parameters.

Reference List

(1) Crawford SM. Anthropometry. In: Docherty D, editor. Measurement in Pediatric Exercise Science. Champaign, IL: Human Kinetics, 1996: 17-86.

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Appendix D BlueTooth Packet Collision Paper

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An Improved Packet Collision Analysis for Multi-Bluetooth Piconets Considering Frequency-Hopping Guard Time Effect

Ting-Yu Lin, *Member, IEEE*, Yen-Ku Liu, and Yu-Chee Tseng, *Senior Member, IEEE*

***Abstract*—Operating in the unlicensed 2.4-GHz ISM band, a Bluetooth piconet will inevitably encounter the interference problem from other piconets. With a special channel model and packet formats, one research issue is how to predict the packet collision effect in a multipiconet environment. In several earlier works, El-Hoiydi (2001), El-Hoiydi and Decotignie (2001), Lim *et al.* (2001), this problem is studied, but the results are still very limited in that packets are usually assumed to be uniform in lengths and in that time slots of each piconet are assumed to be fully occupied by packets. These assumptions have been successfully removed in the analytical results proposed in Lin and Tseng (2003). In this paper, we further improve the analytical results in Lin and Tseng (2003) by taking into account the frequency-hopping guard time effect in Bluetooth baseband. The result would offer a way to better estimate the network performance in a multipiconet environment.**

***Index Terms*—Bluetooth, collision analysis, frequency hopping (FH), piconet, wireless communication, wireless personal-area network (WPAN).**

I. Introduction

As a promising wireless personal-area network (WPAN) technology, Bluetooth is expected to be used in many applications, such as wireless earphones, keyboards, and wireless access points [5], [7], [14]. Operating in the unlicensed 2.4-GHz ISM band, multiple Bluetooth piconets are likely to coexist in a physical environment. By interconnecting existing piconets, we can form a larger-scale network called scatternet. Several papers have addressed the formation algorithms and routing strategies for Bluetooth scatternets [9], [12], [13], [15], [16]. We do not intend to discuss those scatternet-related issues in this paper. Instead, we focus on the packet collision problem due to co-channel interference in a multi-Bluetooth piconets environment (whether the piconets are interconnected or not).

With a frequency-hopping (FH) radio and without coordination among piconets, transmissions from different piconets will inevitably encounter the collision problem. In a previous work [2], the author investigates the co-channel interference between Bluetooth piconets and derives an upper bound on packet error rate. The analysis in [2] has two limitations. First, all packets are assumed to be single-slot ones. Second, it is assumed that each piconet is fully loaded, in the sense that packets are sent in a back-to-back manner. These constraints greatly limit the applicability of the result in [2]. The work in [3] further extends the result in [2] by considering the physical location relationship between piconets (however, the above two limitations remain the same). The analysis in [10] does allow one-, three-, and five-slot packets, but packets of different lengths cannot mix together and each piconet is still assumed to be fully loaded.

The above limitations have been successfully removed in the analytical results proposed in [11]. A more general analysis model is proposed, where all packet types (one-slot, three-slot, and five-slot) can coexist in the network, and the system is not necessarily fully loaded. More specifically, the latter is achieved by modeling idle slots as individual single slots with *no* traffic load. In this paper, we further improve the analytical results in [11] by taking into account the FH guard time effect in Bluetooth baseband. The result would offer a way to better estimate the network performance in a multipiconet environment.

As to other references, the work in [4] considers the interference between Bluetooth and 802.11 wireless local area network (LAN) on the 2.4-GHz unlicensed band. Performance analysis of the Bluetooth physical layer is addressed in [8], but the location relation between piconets is modeled by a probabilistic model. Reference [1] further improves [8] by considering real location relation of piconets.

II. Problem Statement

Bluetooth is a master-driven, time-division duplex (TDD), FH wireless radio system [6]. The smallest networking unit is a *piconet*, which consists of one master and no more than seven active slaves. Each picocell channel is represented by a pseudo-random hopping sequence comprised of 79 or 23 frequencies. In Bluetooth, the hopping sequence is determined by the master's ID and clock value. For each piconet, its channel is divided into time slots, each corresponding to one random frequency. In the following discussion, we assume 79 frequencies.

Manuscript received September 1, 2003; revised April 12, 2004. The work of Y. C. Tseng was supported in part by the MOE Program for Promoting Academic Excellence of Universities and in part by the NSC of Taiwan under Grant NSC92-2213-E009-076 and Grant NSC92-2219-E009-013, in part by the Computer and Communications Research Laboratory, ITRI, Taiwan, in part by Intel Inc., in part by the Institute for Information Industry and MOEA, R.O.C, under the Handheld Device Embedded System Software Technology Development Project, in part by the Lee and MTI Center of NCTU, and in part by the Chung-Shan Institute of Science and Technology under Contract BC93B12P.

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Digital Object Identifier 10.1109/JSAC.2004.836018

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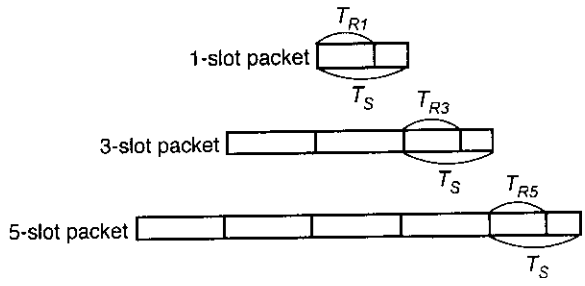

Fig. 1. Frequency-hopping guard time in Bluetooth.

In each piconet, the master and slaves take turns to exchange packets. While the master only transmits in even-numbered slots, slaves must reply in odd-numbered slots. Three packet sizes are available: one-slot, three-slot, and five-slot. For a multislot packet, its frequency is fully determined by the first slot and remains unchanged throughout.

Since Bluetooth takes a FH channel model, each packet has a guard time at the packet end. As Fig. 1 illustrates, an i-slot packet actually does not fully occupy all the i slot(s). Let T_S be the length of one time slot. For a one-slot packet, the data duration is T_{R1}. For three-slot and five-slot packets, the data durations at the last time slot are T_{R3} and T_{R5}, respectively. Those vacant periods without data transmission activities are designed mainly for radio transceiver turnover, preparing for stabilizing at the next frequency hop. Define r_i, $i = 1, 3, 5$, to be the corresponding *data occupancy ratio* for an i-slot packet at the ith time slot

$$r_1 = \frac{T_{R1}}{T_S}, \quad r_3 = \frac{T_{R3}}{T_S}, \quad r_5 = \frac{T_{R5}}{T_S}. \tag{1}$$

According to the Bluetooth specification, $r_1 = 366/625 = 0.586$, $r_3 = 372/625 = 0.595$, and $r_5 = 370/625 = 0.592$ for one-slot, three-slot, and five-slot data packets (without error correction capability), respectively. Since the differences between r_i's are very small in Bluetooth, below we will approximate them by a single value r for simplicity, i.e., $r = r_1 = r_3 = r_5$.

In this paper, we consider N piconets coexisting in a physically closed environment. Since no coordination is possible between piconets, each piconet has $N - 1$ potential competitors. In any time instance, if two piconets transmit with the same frequency, the corresponding two packets are considered damaged (note that during the guard time periods, a host is not considered transmitting). Our goal is to derive an analytic model to evaluate the impact of collisions in such a multipiconet environment.

We assume a Poisson traffic in each piconet, and let λ_1, λ_3, and λ_5 be the arrival rates of one-, three-, and five-slot packets per slot, respectively, to a piconet. Note that we do not model the link-layer automatic repeat requests (ARQs) mechanism. The given arrival rates account for both original and retransmitted packets. For a multislot packet, only the header slot counts as arrival. It is easy to see that $\lambda_1 + 3\lambda_3 + 5\lambda_5 \leq 1$. Further, we regard the remaining vacant slots as "dummy" single-slot packets. Thus, the arrival rate of such dummy (one-slot) packets is $\lambda_0 = 1 - (\lambda_1 + 3\lambda_3 + 5\lambda_5)$.

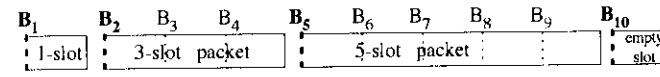

Fig. 2. Classification of slot delimiters.

III. Collision Analysis Without Considering Guard Time Effect

In this section, we review the collision analysis in [11], which does not consider the guard time effect. Specifically, when this effect is not considered, two packets are considered damaged if they are transmitted using the same frequency and they have nonempty overlapping in their slot time (including both transmission period and guard time period). The review would facilitate presenting our result in the next section, which considers guard time effect.

Let us consider a piconet X and another competitor piconet Y, which is regarded as the unique source of interference to X. We assume that the frequency hopping patterns of piconets are independent and random.[1] With the interference from Y, we first derive the success probability $P_S(i)$ of i-slot packets in X, where $i = 1, 3, 5$. We start by introducing the concept of "slot delimiter." A slot delimiter is the start of a slot. Consider any slot in X. One or two slot delimiters in Y may cross X's slot. However, since we are considering continuous probability, the possibility of two crossing slot delimiters can be ignored and, thus, we will deal with one crossing delimiter in the rest of the discussion. For example, for a one-slot packet in X, it succeeds only if there is no interference from the two slots before and after the delimiter, so the success probability of X's packet could be 1, 78/79, or $(78/79)^2$, depending on whether Y transmits or not (where 79 indicates the total number of possibly available frequencies for a 79-channel Bluetooth system). Below, we denote the constant factor 78/79 by P_0.

Depending on what packet(s) is divided by it, a delimiter is classified into ten types (refer to Fig. 2).

- B_1, B_2, B_5: the beginning of a one-, three-, and five-slot packet, respectively.
- B_3, B_4: the beginnings of the second and third slots of a three-slot packet, respectively.
- B_6, B_7, B_8, B_9: the beginnings of the second, third, fourth, and fifth slots of a five-slot packet, respectively.
- B_{10}: the beginning of a dummy slot.

The rate of B_1 is λ_1 per slot; the rate of each of B_2, B_3, and B_4 is λ_3, the rate of each of B_5, B_6, B_7, B_8, and B_9 is λ_5, and the rate of B_{10} is λ_0. We denote the arrival rate of B_j by $\lambda(B_j)$, $j = 1 \ldots 10$. Given any B_j, we also define $g(j)$ to be the number of slots that follows delimiter B_j and belong to the same packet. For example, $g(1) = 1$, $g(3) = 2$, $g(7) = 3$, and $g(10) = 1$.

Intuitively, when a packet in X is crossed by a delimiter of type $B_1/B_2/B_5$ in Y, there may exist two packets (of different frequencies) in both sides of the delimiter in Y, which are potential sources of interference to X's packet. On the other hand,

[1] In the Bluetooth specification, the hopping patterns are pseudorandom. However, without the randomness assumption, the analysis would be difficult. We will validate this assumption by generating pseudorandom hopping patterns in our simulations to verify the impact of such an assumption.

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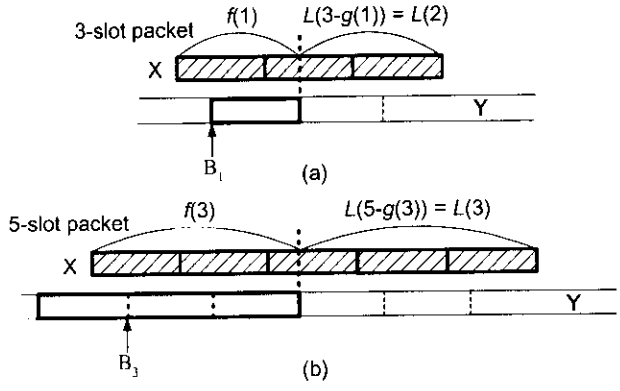

Fig. 3. Analysis of success probabilities for (a) three-slot and (b) five-slot packets.

when the delimiter is of the other types, the interference source reduces to one.

Definition 1: Given any i-slot packet in piconet X and any interference source piconet Y, define $L(k)$, $k < i$, to be the probability that the packet of X experiences no interference from Y starting from the delimiter of Y crossing the $(i-k+1)$th slot of the packet to the end of the packet, under the condition that the aforementioned delimiter is of type $B_1/B_2/B_5/B_{10}$. For $k \leq 0$ (in which case the above definition is not applicable), $L(k) = 1$.

The above probability function is introduced in [11]. Intuitively, $L(k)$ is the success probability of the last k slots of X's packet excluding the part before the first delimiter of Y crossing these k slots, given the above delimiter type constraint. With this definition, we can find $P_S(i)$ by repeatedly cutting off some slots from the head of X's packet, until there is no remaining slot

$$P_S(i) = \sum_{j=1}^{10} \lambda(B_j) \cdot f(j) \cdot L(i - g(j)) \tag{2}$$

where

$$f(j) = \begin{cases} (1-\lambda_0) \cdot P_0^2 + \lambda_0 \cdot P_0, & \text{if } j = 1, 2, 5 \\ (1-\lambda_0) \cdot P_0 + \lambda_0, & \text{if } j = 10 \\ P_0, & \text{otherwise} \end{cases}.$$

In the equation, we consider each type B_j, $j = 1, \ldots, 10$, of the first delimiter in Y crossing X's packet. The corresponding probability is $\lambda(B_j)$. Function $f(j)$ gives the probability that the packet(s) of Y on both sides of the first delimiter B_j does (do) not interfere with X's packet. It remains to consider the success probability of the last $i - g(j)$ slots of X's packet, excluding the part before the first delimiter of Y crossing these $i - g(j)$ slots (which must be of delimiter type $B_1/B_2/B_5/B_{10}$). This is reflected by the last factor $L(i - g(j))$.

For example, Fig. 3(a) illustrates a three-slot packet in X. The first delimiter in Y crossing the three-slot packet is of type B_1. The success probability of the first part in X is $f(1) = (1-\lambda_0) \cdot P_0^2 + \lambda_0 \cdot P_0$. Intuitively, if the packet of Y before the delimiter B_1 is a dummy packet (of probability λ_0), the success probability is simply P_0; otherwise, there are two packets which are potential interference sources, and the success probability is P_0^2. Then, we can move on to consider the success probability of the remaining part of X after the second delimiter in Y, which is given by $L(2)$. $L(2)$ computes the success probability of the last two slots excluding the part before the dotted line. By multiplying $f(1)$ with $L(2)$, we obtain the success probability of the whole packet. Another example of a five-slot packet is shown in Fig. 3(b). The first delimiter in Y crossing the five-slot packet is of type B_3. So the success probability from the beginning of the packet up to the third delimiter in Y crossing the packet is $f(3)$. For the remaining part, the success probability is $L(3)$. So the success probability of the five-slot packet is $f(3) \cdot L(3)$.

The remaining part of X's packet covered by $L(k)$ must start with a delimiter in Y of a restricted type of $B_1/B_2/B_5/B_{10}$. Since the packet in Y after the delimiter must be a complete packet, it can be solved recursively as follows ($k > 0$):

$$\begin{aligned} L(k) = & \frac{\lambda_0}{\lambda_0 + \lambda_1 + \lambda_3 + \lambda_5} \cdot L(k - g(10)) \\ & + \frac{\lambda_1}{\lambda_0 + \lambda_1 + \lambda_3 + \lambda_5} \cdot P_0 \cdot L(k - g(1)) \\ & + \frac{\lambda_3}{\lambda_0 + \lambda_1 + \lambda_3 + \lambda_5} \cdot P_0 \cdot L(k - g(2)) \\ & + \frac{\lambda_5}{\lambda_0 + \lambda_1 + \lambda_3 + \lambda_5} \cdot P_0 \cdot L(k - g(5)). \end{aligned} \tag{3}$$

In each term, the first part is the probability of the corresponding packet type in Y. As to the boundary conditions, $L(k) = 1$, for $k \leq 0$.

Next, we consider an N-piconet environment. For each piconet X, there are $N - 1$ piconets each serving as an interference source. Since these interferences are uncoordinated and independent, the success probability of an i-slot packet in X can be written as $P_S(i)^{N-1}$. So the network throughput of X is

$$\begin{aligned} T = \lambda_1 \cdot P_S(1)^{N-1} \cdot R_1 + 3 \cdot \lambda_3 \cdot P_S(3)^{N-1} \cdot R_3 \\ + 5 \cdot \lambda_5 \cdot P_S(5)^{N-1} \cdot R_5 \end{aligned} \tag{4}$$

where R_1, R_3, and R_5 are the per-slot data rates of one-, three-, and five-slot packets, respectively (for example, if DH1/DH3/DH5 are used, $R_1 = 216/1 = 216$, $R_3 = 1464/3 = 488$, and $R_5 = 2712/5 = 542.4$ bits per slot, where 216, 1464, and 2712 are the numbers of bits contained in DH1, DH3, and DH5 packets, respectively). Note that we will use "bits per slot" as our metric to calculate network throughput. This also explains why factors of three and five are multiplied to the second term and third term in (4) when calculating T. The aggregate network throughput of N piconets is $N \times T$.

IV. Enhanced Collision Analysis Considering Guard Time Effect

Next, we improve the collision analysis in [11] by considering the guard time effect. During guard time periods, hosts are considered not transmitting. Thus, collisions may only occur in real transmission periods. Again, we consider a piconet X and another competitor piconet Y, which is the interference source of

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X. With guard time effect, the probability $P_S(i)$ should be reformulated as follows:

$$P_S(i) = (1-r)\cdot\sum_{j=1}^{10}\lambda(B_j)\cdot\tilde{f}(j)\cdot L(i-g(j)) + (2r-1)\cdot\sum_{j=1}^{10}\lambda(B_j)\cdot f(j)\cdot L(i-g(j)) + (1-r)\cdot\sum_{j=1}^{10}\lambda(B_j)\cdot f(i,j)\cdot\tilde{L}(i-g(j)) \quad (5)$$

where

$$\tilde{f}(j) = \begin{cases} 1, & \text{if } j = 10 \\ P_0, & \text{otherwise} \end{cases}$$

and

$$f(i,j) = \begin{cases} (1-\lambda_0)\cdot P_0 + \lambda_0, & \text{if } i=1 \text{ and } j=1,2,5 \\ (1-\lambda_0)\cdot P_0^2 + \lambda_0\cdot P_0, & \text{if } i=3,5 \text{ and } j=1,2,5 \\ (1-\lambda_0)\cdot P_0 + \lambda_0, & \text{if } j=10 \\ P_0, & \text{otherwise} \end{cases}.$$

$\tilde{L}(k)$ can be derived in two cases. When $k > 1$

$$\tilde{L}(k) = \frac{\lambda_0}{\lambda_0+\lambda_1+\lambda_3+\lambda_5}\cdot\tilde{L}(k-g(10)) + \frac{\lambda_1}{\lambda_0+\lambda_1+\lambda_3+\lambda_5}\cdot P_0\cdot\tilde{L}(k-g(1)) + \frac{\lambda_3}{\lambda_0+\lambda_1+\lambda_3+\lambda_5}\cdot P_0\cdot\tilde{L}(k-g(2)) + \frac{\lambda_5}{\lambda_0+\lambda_1+\lambda_3+\lambda_5}\cdot P_0\cdot\tilde{L}(k-g(5)) \quad (6)$$

and when $k \le 1$, $\tilde{L}(k) = 1$.

In (5), the definitions of $\lambda(B_j)$, $f(j)$, and $g(j)$ remain the same as those in (2). Equation (6) differs from (3) in its boundary conditions. To explain the above formulations, we introduce the concept of *critical section* (CS) within a single time slot. Since guard time periods are interleaving real data packets, the position (or offset) of the first slot delimiter B_j in Y crossing X's packet does affect the packet success probability $P_S()$. So, we partition the first slot of any X's packet into three critical sections, CS1, CS2, and CS3, which occupy $1-r$, $2r-1$, and $1-r$ proportions of the first slot in this packet, respectively (recall that r is the approximated data occupancy ratio). An illustration is shown in Fig. 4.

Fig. 4 shows how the slot delimiter of Y may cross the above critical sections. In the first case, the delimiter B_j falls in X's CS1. If fortunately B_j equals B_1, B_2, B_5, or B_{10} (i.e., the beginning of a new packet), the darkened area before B_j in Y belongs to guard time. So the CS1 (before B_j) of X would experience no interference from Y. In this case, the packet success probability $P_S()$ will increase, and this effect is reflected in the new function $\tilde{f}(j)$ [compared to the function $f(j)$ in (2)].

In the second case of Fig. 4, the delimiter B_j falls in X's CS2. The aforementioned benefit would disappear because certain part in the beginning of CS1 will fall out of the range of

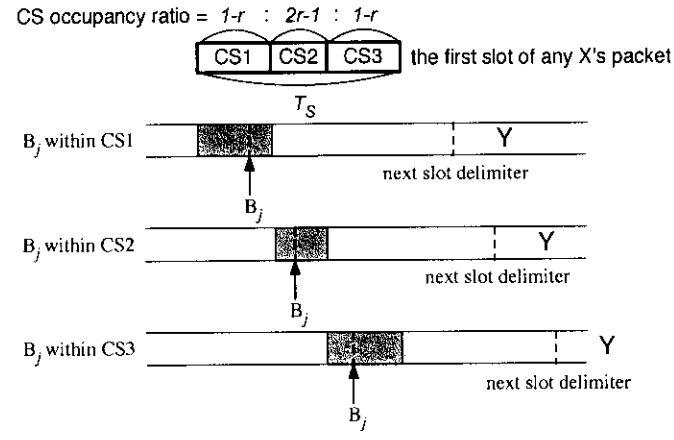

Fig. 4. Critical sections and collision analysis by considering guard time effect.

Y's guard time period. So $P_S()$ remains the same in this case [compared with (2)].

In the third case of Fig. 4, the delimiter B_j resides in X's CS3. If fortunately the packet in X is a single-slot packet, then CS3 of X would be guard time. If so, the darkened area after B_j in Y would not pose any interference to X's packet. Even if the packet in X is not a single-slot packet, this also means that the last slot delimiter of Y crossing X's packet would fall in a CS3 of X, a guard time period. If this last delimiter is the beginning of a packet, $P_S()$ can also benefit in this case. This is reflected by defining the new function $f(i,j)$, and by ending the recursive formula $\tilde{L}()$ at an earlier time (whenever k decreases to 1 or less).

Here, we give some examples for our analysis.

- **Case I—B_j within CS1 (with probability $1-r$).**
  Consider the example in Fig. 5(a). Benefiting from the guard time of Y's packet before B_1, the packet success probability of X's one-slot packet is P_0. In comparison, without considering the guard time effect, the formulation in [11] would suggest a lower success probability of P_0^2.
- **Case II—B_j within CS2 (with probability $2r-1$).**
  Consider the example in Fig. 5(b). The packet success probability of X's one-slot packet is P_0^2, which remains the same as that in the analysis of [11]. Guard time does not reduce the probability of interference from Y's packet(s) in this case.
- **Case III—B_j within CS3 (with probability $1-r$).**
  In Fig. 5(c), the packet in X under consideration is a three-slot packet. The CS3 in X's first slot does not represent a guarding period in this example. Hence, the two packets of Y right before and after the first delimiter B_1 still pose as a potential interference source to X's packet. However, since B_1 falls in CS3, the last slot delimiter of Y crossing X's packet (denoted by SD_{last} in the figure) must reside in a guarding period. As a result, no interference needs to be taken into account after SD_{last}. In this example, the success probability of X's packet is P_0^3 (compared with a success probability of P_0^4 in the analysis of [11] without considering guard time effect). These are reflected in the function $f(i,j)$ and in the boundary conditions for $\tilde{L}(k)$.

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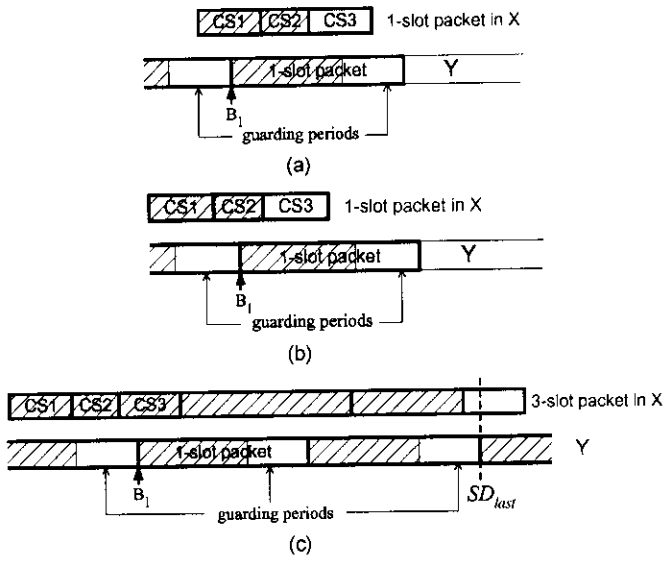

Fig. 5. Collision analysis examples. B_j falling in (a) CS1, (b) CS2, and (c) CS3.

Finally, for an N-piconet environment, the network throughput T of piconet X can be derived by the same equation (4). The aggregate network throughput of N piconets is, therefore, $N \times T$.

We remark that we use the uniform data occupancy ratio r to approximate r_1, r_3, and r_5. One concern is that the proposed analysis may have a certain level of bias. We examine this concern through simulation experiments in Section V.

V. Simulation and Experimental Results

This section presents our simulation and experimental results based on C++ programs. We test different numbers of piconets. Each simulation run lasts for 10 000 time slots. Frequency-hopping sequences are simulated by pseudorandom sequences as defined in Bluetooth (recall that in our analysis, the sequences are assumed to be random). For simulation results, we use the exact values of r_1, r_3, and r_5. For analytical results, we use the approximated r. Packets being simulated are DH1/3/5. We do not model the physical environment of the networks (such as relative locations of Bluetooth devices and their transmission power), so collisions are modeled only at the logical level.

Assuming $\lambda_1 = \lambda_3 = \lambda_5$, we inject traffic loads of 100% and 70% to each piconet (the load reflects the percentage of busy slots in a piconet, i.e., $\lambda_1 + 3\lambda_3 + 5\lambda_5 = 1$ and 0.7). Also, note that as mentioned earlier, the traffic loads are aggregated loads, which include both original and retransmitted traffics. Fig. 6(a) and (b) plots the error probabilities of DH1/3/5 packets from both analysis and simulation results under different N's. To verify our analysis results, Fig. 6(c) and (d) further plots the relative errors between simulation and analytical results. The relative error is calculated by [(packet error probability from analysis)-(packet error probability from simulation)]/(packet error probability from simulation). The packet error probability increases as the traffic load or the number of piconets grows. Smaller packets suffer less collisions than larger ones due to the formers' shorter transmission durations. However, larger packets are much more bandwidth-efficient than smaller ones (e.g., a DH5 carries 542.4/216 times more bits per slot than a DH1 does). This observation leads us to conduct the next experiment by using network throughput as the metric.

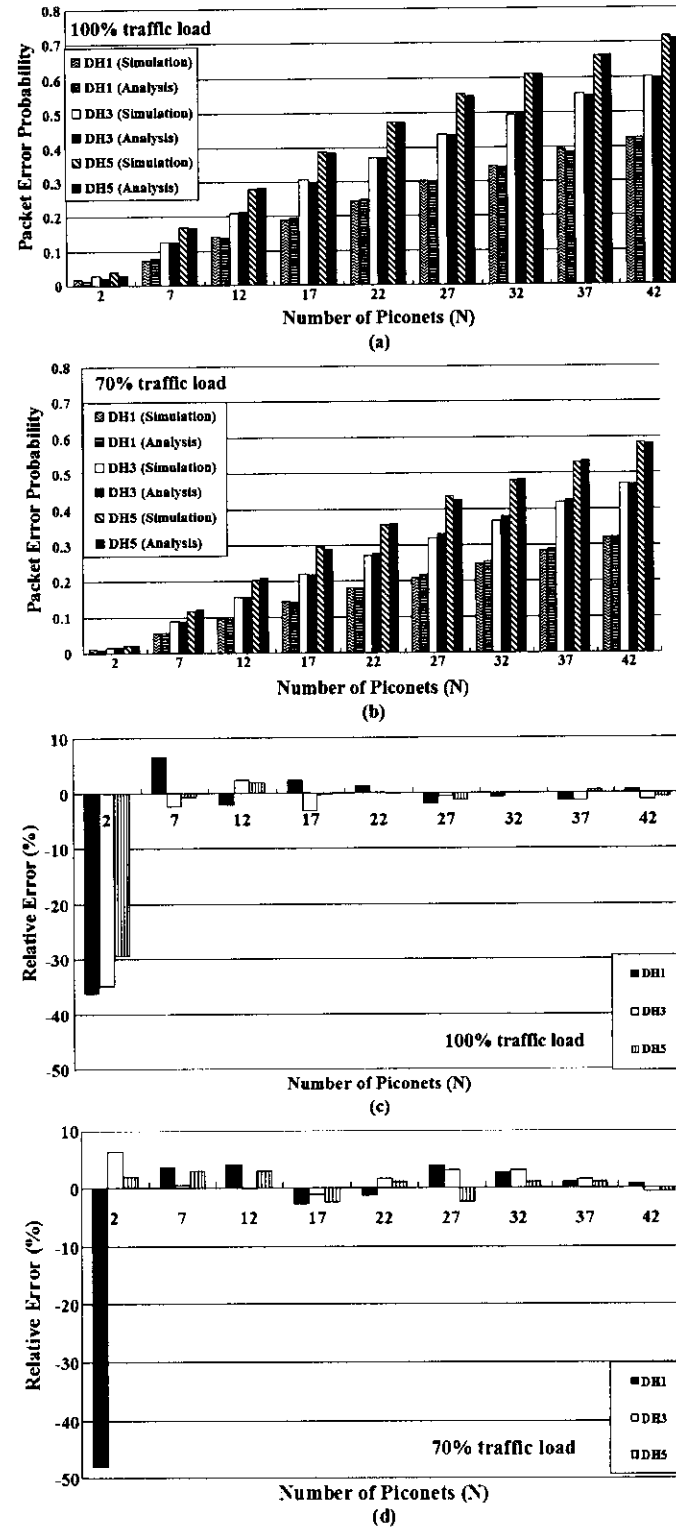

Fig. 6. Packet error probabilities under (a) 100% traffic load and (b) 70% traffic load, and relative errors between simulation and analytical results under (c) 100% traffic load and (d) 70% traffic load.

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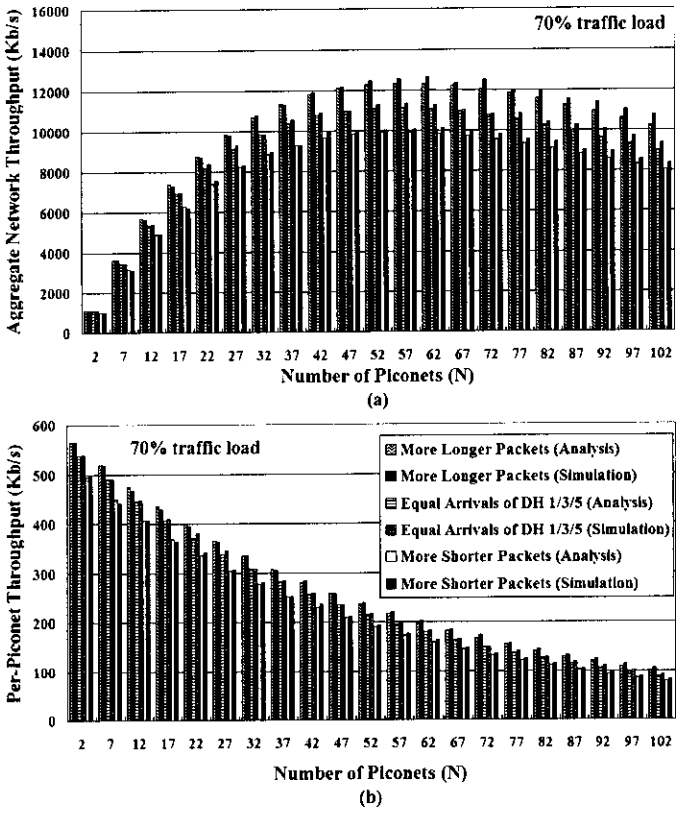

Fig. 7. (a) Aggregate network throughput under 70% traffic load. (b) Per-piconet throughput under 70% traffic load.

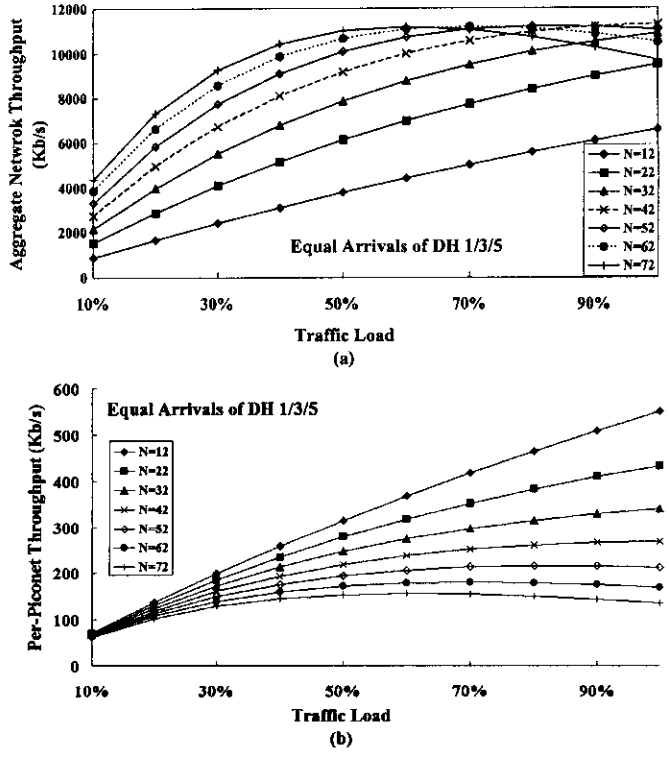

Fig. 8. (a) Aggregate network throughput versus traffic load. (b) Per-piconet throughput versus traffic load.

Next, we evaluate the aggregate network throughput ($N \times T$) and per-piconet throughput. We show the case of 70% traffic load. We consider three arrival models: one with equal arrivals of DH1/3/5 packets ($\lambda_1 = \lambda_3 = \lambda_5$), one with more shorter packets ($\lambda_1 : \lambda_3 : \lambda_5 = 3 : 2 : 1$), and one with more longer packets ($\lambda_1 : \lambda_3 : \lambda_5 = 1 : 2 : 3$). Both analytical and simulation results are shown in Fig. 7. The aggregate throughput saturates at a certain point as the number of piconets increases, and then drops. Different from the earlier observation, the result indicates that longer packets are more preferable in terms of

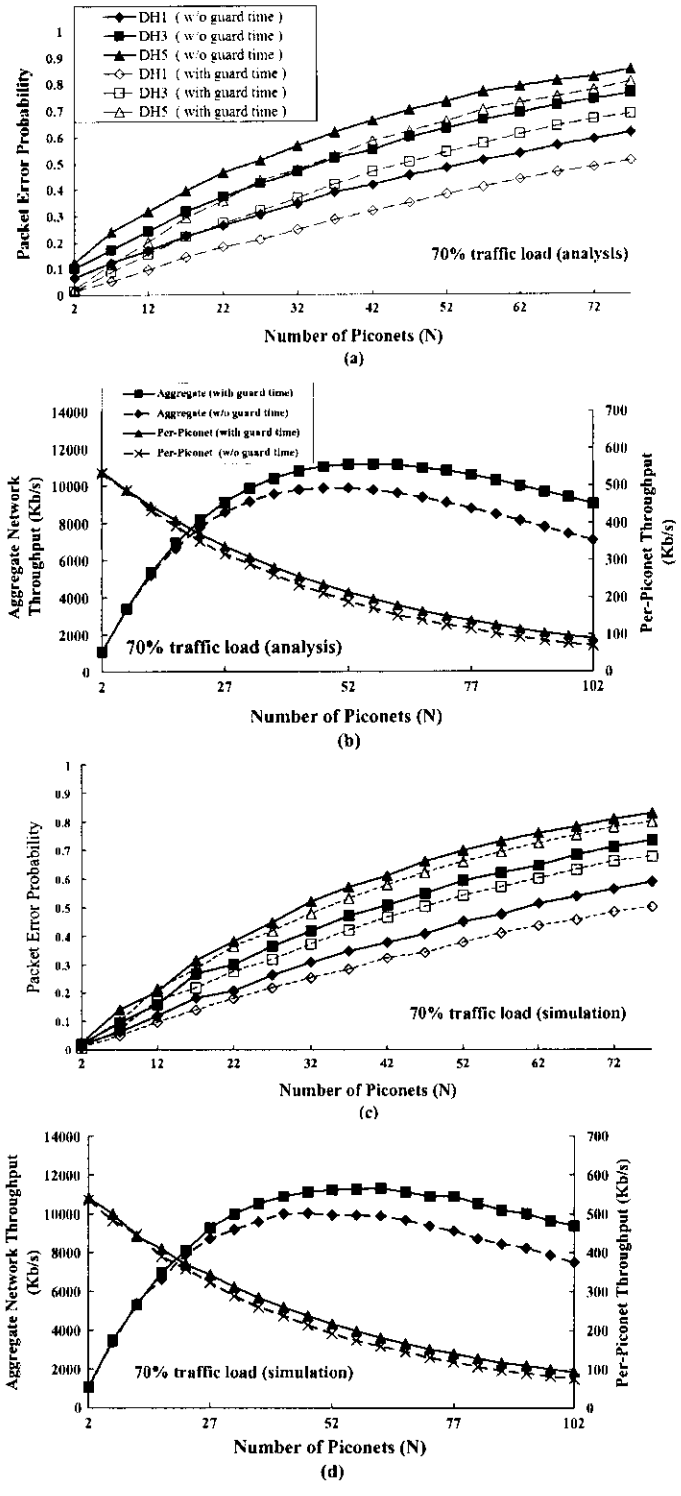

Fig. 9. Analytical results to evaluate the guard time effect on (a) packet error probability and (b) network throughput, and simulation results to evaluate the guard time effect on (c) packet error probability and (d) network throughput.

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throughput because the collision problem can be compensated by the benefit of higher bandwidth efficiency. Also, in terms of per-piconet throughput, the performance consistently degrades as N increases, which is reasonable due to the impact of increased packet error probability.

Fig. 8 plots the network throughputs vs. traffic loads under fixed values of N. It indicates that the throughput goes up steadily as traffic load increases when $N \leq 42$. However, for larger N's, throughputs saturate at certain points, due to more serious collisions. The results can be used to estimate the proper number of piconets to be deployed in a physical area, in terms of the aggregate network throughput and per-piconet throughput under our packet collision model.

Finally, we observe the guard time effect. Fig. 9 compares the packet error probability and network throughput when the guard time effect is considered and when the guard time effect is not considered (i.e., the case in [11]) under 70% traffic load with equal arrivals of DH1/3/5 packets. Both analytical and simulation results are shown, which do not exhibit much difference. From the figure, we observe that due to less stronger conditions for packet collision, at $N = 42$, when considering the guard time effect, the packet error probabilities for DH1/3/5 packets are reduced by about 0.1, 0.09, and 0.075, respectively, and the aggregate network throughput is improved by about 1000 kb/s. The difference of packet error probability for DH1 is more significant because guard time takes a relatively larger part in such packets. As to throughput, the improvement when considering guard time effect tends to increase as N increases.

VI. Conclusion

We have presented new collision analysis results for Bluetooth piconets by taking into account the guard time effect. The result improves earlier works by removing several unrealistic limitations. Our simulation results match quite well with our analytical results, which justify the correctness. In addition, the guard time effect, which influences system throughput as the number of piconets grows, has been proven to be noticeable. This further validates the usefulness of the proposed enhanced analysis in this work.

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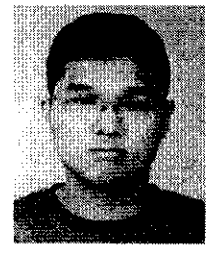

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Appendix E BlueTooth verification protocol

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ACCEPTANCE CRITERIA 2
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Purpose

The RT300-S utilizes BlueTooth wireless links to communicate between its controller and the ergometer and its controller and the stimulator.

The purpose of this verification is to demonstrate that multiple RT300 systems can operate in an environment where there may be other devices utilizing the 2.4 GHz industrial, scientific and medical (ISM) band. This band is 83.5 MHz wide, beginning at 2.4 GHz and ending at 2.4835 GHz. Both wireless Ethernet (802.11b), otherwise known as Wi-Fi, and BlueTooth, as utilized by the RT300, operate in this band. Other potential sources of interference in this band are 2.4GHz wireless phone handsets and microwave ovens.

Test Items

After discussions with clinicians it is unlikely that more than 10 RT300 systems would be set up in one clinic. This verification will therefore utilize 11 RT300 systems in order to exceed the maximum number in clinical use at any one clinic. Note that the results from Lin et al (1) indicate that there is not likely to be a significant reduction in bandwidth or RT300-S operation unless around 80 systems are co-located.

Three laptop computers linked to a LAN via a WiFi access point will be utilized to generate inband WiFi traffic.

One microwave oven will be utilized to generate additional potential interference.

One 2.4GHz wireless phone handset will be utilized to generate additional potential interference.

Test Procedure

This test will utilize the RT300-S' ability to record BlueTooth communications latency and log any lost BlueTooth communications packets in its diagnostic log as a means to evaluate the performance of the RT300-S' communications system during this test.

In addition the operation of all RT300-S will be visually monitored.

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1. Install all equipment in the test room
2. Record room size and equipment locations
3. Record software versions
4. Start a therapy session on a single RT300-S system and allow this to run for 10 minutes
5. Record the BlueTooth latency time from the system diagnostic log establishing the background latency
6. Examine the diagnostic log of the RT300-S and check for any instances of missed BlueTooth replies
7. Sequentially start a therapy session on all RT300-S systems and allow the systems to run for 10 minutes.
8. Record the BlueTooth latency measured by each RT-300-S from the system diagnostic logs
9. Examine the diagnostic log of each RT300-S and check for any instances of missed BlueTooth replies
10. Turn the microwave oven on high and allow it to run for the remainder of the test
11. Sequentially start a therapy session on each RT300-S
12. Operate the wireless phone for the remainder of the test
13. Browse the internet on the laptop computers for the remainder of the test
14. Continue for 10 minutes observing RT300-S systems for continued normal operation
15. Record the BlueTooth latency measured by each RT-300-S from the system diagnostic logs
16. Examine the diagnostic log of each RT300-S and check for any instances of missed BlueTooth replies

Acceptance Criteria

All RT300-S systems continue to operate normally throughout each test period.
No significant increase in BlueTooth latency (no more than 10-20% is expected, see reference).

References

	Title
1	Lin et al, An Improved Packet Collision Analysis for Multi-BlueTooth Piconets, IEEE J. Selected Areas in Comm., Vol 22, No 10, Dec 2004

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Appendix F BlueTooth verification report

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Purpose

The RT300-S utilizes BlueTooth wireless links to communicate between its controller and the ergometer and its controller and the stimulator.

The purpose of this verification is to demonstrate that multiple RT300 systems can operate in an environment where there may be other devices utilizing the 2.4 GHz industrial, scientific and medical (ISM) band. This band is 83.5 MHz wide, beginning at 2.4 GHz and ending at 2.4835 GHz. Both wireless Ethernet (802.11b), otherwise known as Wi-Fi, and BlueTooth, as utilized by the RT300, operate in this band. Other potential sources of interference in this band are 2.4GHz wireless phone handsets and microwave ovens.

Test Items

Description	Part Number
RT300-S	100373
RT300-S	100371
RT300-S	100376
RT300-S	TT004465067
RT300-S	100231
RT300-S	100233
RT300-S	100232
RT300-S	100370
RT300-S	100368
RT300-S	100369
RT300-S	100367
Microwave oven	Magic Chef 1.5kW MCD1311ST
Wireless phone	Uniden 2.4GHz EXI7246
Laptop with Linksys WiFi G card	IBM T30
Laptop with Excel WiFi card	IBM T21
Laptop with Excel WiFi card	Compaq Presario 80XL200

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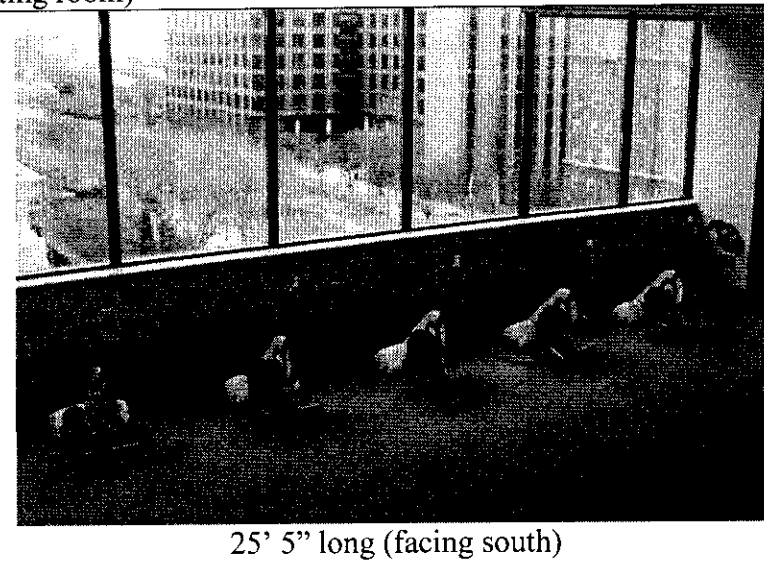
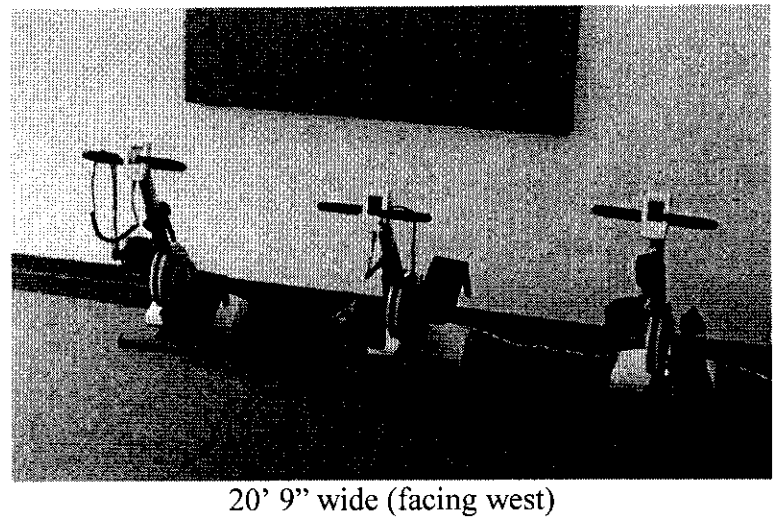
Test Results

Protocol procedure number	Results
2	Room size was 20' 9" x 25' 5" (Kennedy Krieger Institute 5th Floor meeting room)
	 25' 5" long (facing south)  20' 9" wide (facing west)

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	107 msec 120msec 105 msec 105msec Average 111.5
16	No lost communications packets

Overall result

The performance of the BlueTooth communications as measured by average communications latency and lost communications packets was not significantly impacted by increasing the number of RT300-S systems operating in the room from 1 to 11; the average communications latency increased by less than 8% (success criteria < 20%).

Similarly, performance of the systems was not impacted by simultaneous operation of a microwave oven, wireless phone and WiFi traffic; the average communications latency increased by less than 1%.

All RT300-S systems operated normally throughout the test.

Overall result: **PASS**.

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	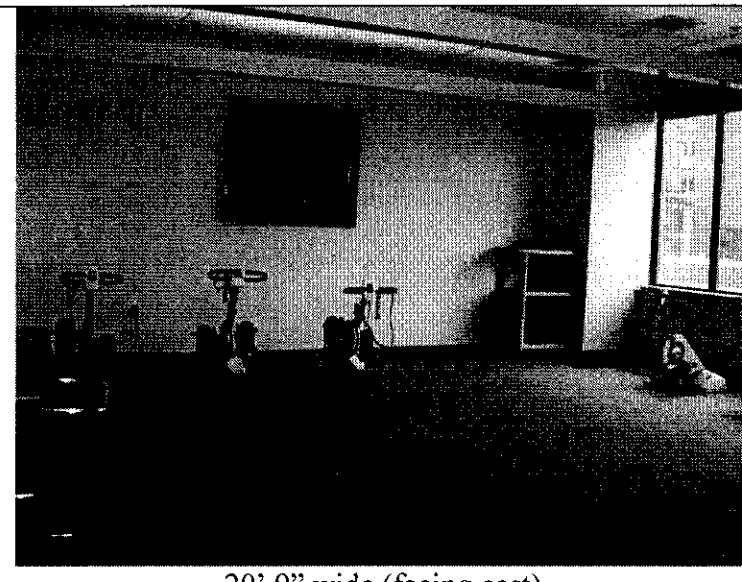 20' 9" wide (facing east)
3	RT300-S software versions: controller 0.06 build 60 stimulator 0.06 build 51
5	Back ground BlueTooth latency (one RT300-S operating, all other equipment off) was 102 msec.
6	No lost communications packets
8	BlueTooth Latency with all RT300-S operating (order as per equipment list) 103 msec 114 msec 122 msec 105 msec 117msec 105msec 117msec 106 msec 117msec 104 msec 106msec Average 110.5
9	No lost communications packets
15	BlueTooth Latency with all RT300-S operating (order as per equipment list) and all additional noise source equipment on 101 msec 115 msec 123 msec 105 msec 120 msec 105 msec 120msec

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Appendix G Nash paper

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REVIEW ARTICLE

Sports Med 2004; 34 (11): 727-751
0112-1642/04/0011-0727/$31.00/0

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Exercise Recommendations for Individuals with Spinal Cord Injury

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Abstract

Persons with spinal cord injury (SCI) exhibit deficits in volitional motor control and sensation that limit not only the performance of daily tasks but also the overall activity level of these persons. This population has been characterised as extremely sedentary with an increased incidence of secondary complications including diabetes mellitus, hypertension and atherogenic lipid profiles. As the daily lifestyle of the average person with SCI is without adequate stress for conditioning purposes, structured exercise activities must be added to the regular schedule if the individual is to reduce the likelihood of secondary complications and/or to enhance their physical capacity. The acute exercise responses and the capacity for exercise conditioning are directly related to the level and completeness of the spinal lesion. Appropriate exercise testing and training of persons with SCI should be based on the individual's exercise capacity as determined by accurate assessment of the spinal lesion. The standard means of classification of SCI is by application of the *International Standards for Classification of Spinal Cord Injury*, written by the Neurological Standards Committee of the American Spinal Injury Association. Individuals with complete spinal injuries at or above the fourth thoracic level generally exhibit dramatically diminished cardiac acceleration with maximal heart rates less than 130 beats/min. The work capacity of these persons will be limited by reductions in cardiac output and circulation to the exercising musculature.

Persons with complete spinal lesions below the T_{10} level will generally display injuries to the lower motor neurons within the lower extremities and, therefore, will not retain the capacity for neuromuscular activation by means of electrical stimulation. Persons with paraplegia also exhibit reduced exercise capacity and increased heart rate responses (compared with the non-disabled), which have been associated with circulatory limitations within the paralysed tissues. The recommendations for endurance and strength training in persons with SCI do not vary dramatically from the advice offered to the general population. Systems of functional electrical stimulation activate muscular contractions within the paralysed muscles of some persons with SCI. Coordinated patterns of stimulation allows purposeful exercise movements including recumbent cycling, rowing and upright ambulation. Exercise activity in persons with SCI is not without risks, with increased risks related to systemic dysfunction following the spinal injury. These individuals may exhibit an autonomic dysreflexia, significantly reduced bone density below the spinal lesion, joint contractures and/or thermal dysregulation. Persons with SCI can benefit greatly by participation in exercise activities, but those benefits can be enhanced and the relative risks may be reduced with accurate classification of the spinal injury.

The human spinal cord is a complex association of upper and lower motor neurons that functions as a bidirectional conduit between the brain and its motor, sensory and autonomic targets. It also serves as a site for reflex integration between body sensors and their motor and autonomic effectors. Because spinal cord functions differ by level and structure, injury to or disease of spinal tracts results in varying types and degrees of dysfunction depending upon the specific neural structures affected.

The interruption of spinal cord functions by trauma affects 10 000 Americans annually, with an estimated 179 000 persons having survived their initial injury.[1-4] Thereafter, these individuals experience

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unique physical, social and psychological changes throughout their lives, including diminished ability to perform and benefit from exercise conditioning.[5,6] The latter limitation is cause for concern as: (i) individuals with spinal cord injury (SCI) are usually young and physically active at the time of injury;[3] (ii) profound physical deconditioning is common after injury;[7-9] and (iii) physical deconditioning contributes to multisystem medical complications,[10-19] activity limitations[7,20,21] and accelerated aging.[6,7,22-26]

Many reviews and chapters published over the past decades have addressed the need for persons with SCI to adopt habitual exercise as part of a healthy lifestyle.[5,6,9,17,18,27-33] Exercise options contained in these reports have focused on use of muscle activities still under voluntary nervous system control, as well as sequenced contractions of muscles stimulated by electrical current. Outcomes of studies cited in these monographs provide credible evidence that exercise performed by persons with SCI enhances physical conditioning and reduces multisystem disease susceptibility. They further suggest that habitual exercise might reduce fatigue, pain, weakness, joint deterioration and incipient neurological deficits that appear as persons age with disability. As these deficits challenge the ability of those with SCI to perform essential daily activities first mastered after injury, their prevention will likely foster fullest health and life satisfaction for those aging with a disability.

Use of exercise as a healthy activity and lifestyle elective for those with SCI might appear fairly straightforward. To the contrary, exercise options available to those with SCI are more limited than those without disability,[33] their acute exercise and training responses less robust than those of persons without SCI,[28,34,35] and the risks of impudent activity greater and longer lasting.[33,36] This makes an understanding of neurological classification, exercise opportunities and risks of activity important if those with SCI are to benefit and not be harmed from exercise conditioning. This paper will review common medical problems experienced by persons with SCI that lend themselves to benefit from exercise conditioning, contemporary methods of injury classification, exercise options and established benefits of training, and risks imposed by inappropriate exercise recommendations for those with SCI.

1. Neurological Classification of Persons with Spinal Cord Injury (SCI)

If trauma to, or disease of, the spinal cord always resulted in its anatomical or physiological transection, classification of spinal cord dysfunctions following SCI would be relatively easy. However, the spinal cord is rarely severed unless penetrated by a bullet or severed by its bony covering during very high velocity impact. More often the cord remains anatomically intact but suffers contusion, infarction or mechanical deformation that interrupts its local or relay circuitry. It also can undergo secondary damage from inflammatory autodestruction, which explains the routine administration of high-dose corticosteroids within hours of an SCI.[37] Notwithstanding the cause of spinal damage, more than half of the survivors will experience varying degrees of motor, sensory or autonomic sparing at different spinal cord levels,[2,38,39] making classification of persons with SCI a challenging, yet important, science.[4]

To assist with accurate and consistent classification, uniform standards have been developed that allow persons with SCI to be systematically examined and classified, and to document changes in sensorimotor function that accompany the passage of time, clinical treatments or research interventions. The benchmark system used to classify persons with SCI is the *International Standards for Classification of Spinal Cord Injury* (revised 2000), which is written by the Neurological Standards Committee of the American Spinal Injury Association (ASIA), and endorsed as the recommended international standards by the International Spinal Cord Society (ISCoS; formerly the International Medical Society for Paraplegia, and hereinafter the 'ASIA Guidelines') [figure 1].[40] While a complete description of spinal column and spinal cord anatomy is beyond the scope of this review, the accurate description of an injury to a given spinal cord segment involves designation of a spinal column region

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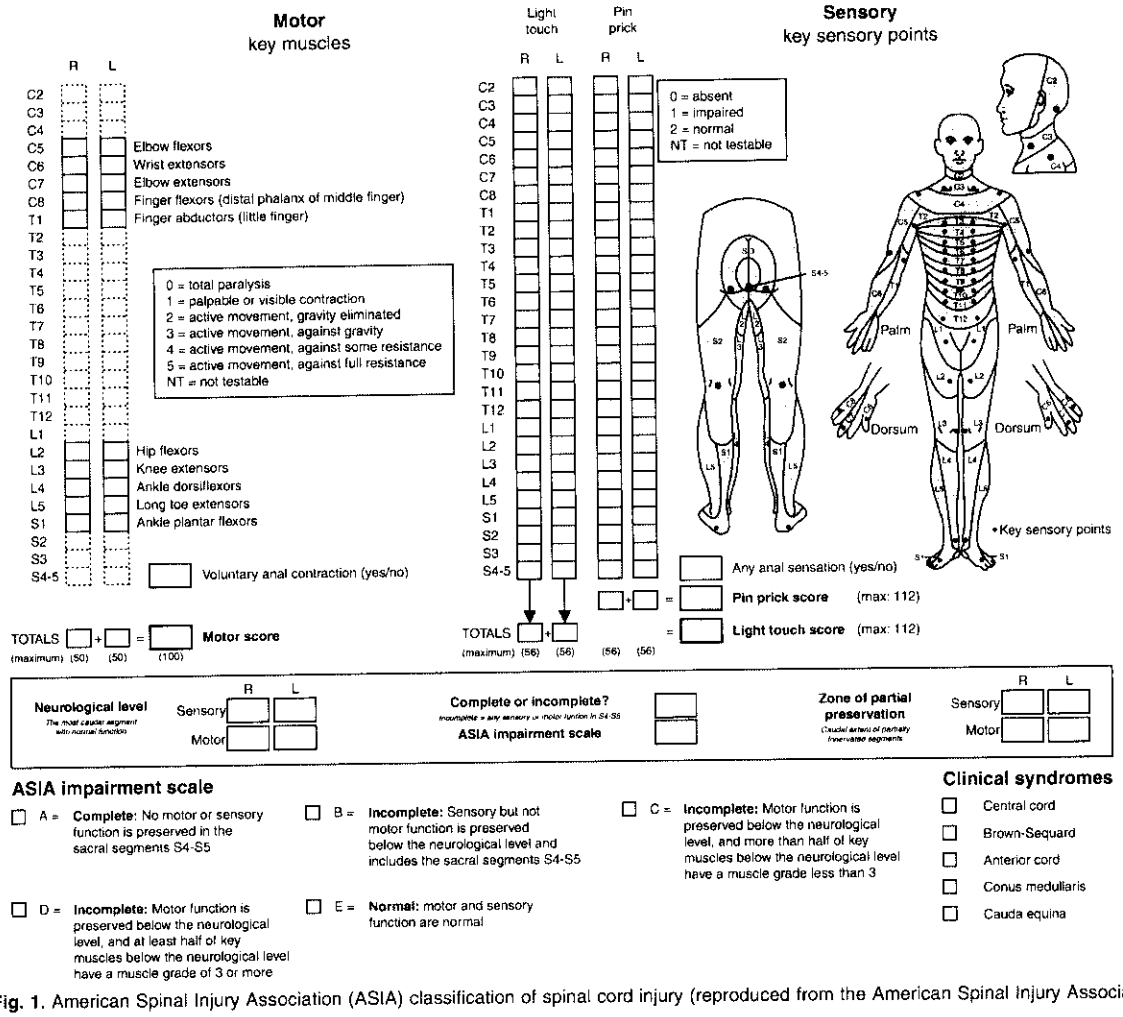

Fig. 1. American Spinal Injury Association (ASIA) classification of spinal cord injury (reproduced from the American Spinal Injury Association,[41] with permission).

(e.g. cervical, thoracic, lumber or sacral), a spinal nerve within that region, and the degree to which the injury is neurologically complete or incomplete. Should the injury result in a specific spinal cord syndrome this should also be designated.

1.1 Upper and Lower Motor Neuron Lesions

It is clinically important for those working with subjects having SCI to differentiate between upper and lower motor neuron injuries. The spinal cord is organised in such a way that either upper or lower motor neuron function, or both, can be disrupted by trauma or disease. The long tracts of the spinal cord are upper motor neurons. By convention, the lower motor neuron system begins in the anterior horn of the grey matter and exits the intervertebral foramen to join the returning sensory axons as a mixed nerve. The motor portion of this mixed nerve then travels to its target muscle(s). The returning sensory nerve fibres travel in this mixed nerve but, upon entry to the foramen, form a dorsal root that penetrates the cord in the dorsal root entry zone and synapses with the anterior horn cells of the anterior grey matter. This completes the motor-sensory reflex arc. Lesions of upper motor neurons result in 'decentralisa-

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tion' of the nervous system, spastic paralysis and exaggerated sensorimotor reflexes below the injury. This means that motor, sensory and autonomic reflex activities are preserved, but no longer under command of the brain. The contrasting injury is a lower motor neuron lesion, which often accompanies SCI at the T_{10} level or lower and almost always occurs at, or caudal to, T_{12}. Persons with these lesions lose central nervous system control of sensorimotor functions, as well as sensorimotor reflex activity, which causes flaccid paralysis and areflexia ('denervation'). This explains the greater loss of lower extremity muscle mass in individuals with flaccid rather than spastic paralysis. Otherwise, injury to the cord at any site resulting in damage to the reflex arc can leave a denervated (areflexic) segment among neighbouring segments that remain spastic.

It is important to note that while spastic muscles are capable of contracting upon stimulation with transcutaneous electrical alternating currents, generally, flaccid muscles are not. This provides a means of discriminating upper from lower motor neuron lesions and also determining subject or patient candidacy for use of electrical prostheses that provide exercise or ambulation in persons with SCI.

1.2 Defining Spinal Cord Lesions: Plegias

Individuals with SCI are described as having lesions affecting either sensorimotor function of all limbs or the upper extremities alone. The former are said to have tetraplegia (preferred to 'quadriplegia'), which is defined as: "A term referring to impairment or loss of motor and/or sensory function in the cervical segments of the spinal cord due to damage of neural elements within the spinal canal. Tetraplegia results in impairment of function in the arms as well as in the trunk, legs and pelvic organs. It does not include brachial plexus lesions or injury to peripheral nerves outside the neural canal."[42,43] Paraplegia is defined as: "A term referring to impairment or loss of motor and/or sensory function in the thoracic, lumbar or sacral (but not cervical) segments of the spinal cord, secondary to damage of neural elements within the spinal canal. With paraplegia, arm functioning is spared, but, depending on the level of injury, the trunk, legs and pelvic organs may be involved. The term is used when referring to cauda equina and conus medullaris injuries, but not to lumbosacral plexus lesions or injury to peripheral nerves outside the neural canal."[42,43]

1.3 Neurological, Sensory and Motor Levels

Neurological level refers to the most caudal segment of the spinal cord with normal sensory and motor function on both sides of the body. Because the results of sensorimotor testing often differ by side, up to four different segments may be identified in determining the neurological level, i.e. R-sensory, L-sensory, R-motor and L-motor. In such cases it is strongly recommended that each of these segments be separately recorded and that a single 'level' not be used, as this can be misleading. When the term 'sensory level' is used, it refers to the most caudal segment of the spinal cord with normal sensory function on both sides of the body; the 'motor level' is similarly defined with respect to motor function. These 'levels' are determined by neurological examination of: (i) a key sensory point within each of 28 dermatomes on the right and 28 dermatomes on the left side of the body;[42] and (ii) a key muscle within each of ten myotomes on the right and ten myotomes on the left side of the body. Assessment of sensory and motor level is key in those with paraplegia having injuries from T_1 through T_8, whereas motor function is the determining factor in classification of tetraplegia.

1.4 Complete and Incomplete Spinal Cord Lesions

Confusion and imprecise language surround the definitions of neurological completeness and incompleteness. Historically, the Functional Classification scale of Frankel et al.[44] was used to assign a grade of SCI from A to E. These grades were assigned on the basis of sensorimotor sparing below the level of SCI. In contrast, the ASIA scale uses 'sacral sparing' as the criterion for determining neurological completeness.[39,42,45] This requires a test of motor function examining the presence of voluntary contraction of the external anal sphincter upon digital

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examination. The ASIA definitions of complete and incomplete lesions are:

- 'Complete injury': a term describing absence of sensory and motor function in the lowest sacral segment.[42]
- 'Incomplete injury': a term describing partial preservation of sensory and/or motor functions below the neurological level *and* including the lowest sacral segment. Sacral sensation includes sensation at the anal mucocutaneous junction as well as deep anal sensation.[42]

Both ASIA and Frankel methods are useful for describing completeness of injuries, as an individual with infralesional sensory sparing (i.e. incomplete sensory loss; Frankel Grade B) can still be neurologically complete when using the ASIA guidelines. Also, the ASIA C classification is so broad as to sometimes limit useful classification of motor and functional abilities of patients with SCI that may be better understood when using Frankel grades.

Accurate descriptions of complete and incomplete lesions are often confounded by recovery of sensorimotor function within weeks or months after injury, which is not uncommon for some individuals initially presenting without preserved reflex or sensorimotor functions.[46] This recovery, however, will more likely occur in individuals with very low velocity injuries in which cord bleeding or anatomic disruption of neural elements are limited. Several mechanisms have been postulated to explain 'return of function' after SCI. The first involves a belief that a 'spinal shock' occurs immediately upon SCI in some individuals – a state of areflexia thought to result from hyperpolarisation of cord neurons accompanying injury-related loss of descending facilitation.[47] Thereafter, those with incomplete lesions often recover reflexes in a caudal to rostral sequence, although the extent of reflex recovery has questionable value in predicting eventual patterns or extent of motor recovery.[47] Otherwise, post-synaptic receptor up-regulation and synaptic growth have been postulated as explanations for neuronal recovery following SCI,[48,49] although the precise mechanisms promoting these changes remain incompletely understood. Notwithstanding the controversial explanations for resolution of 'spinal shock' and recovery of sensorimotor functions, the designation of 'neurological completeness' within the first year of injury leaves open the possibility for erroneous classification of a subject thereafter. This explains why many investigators use the first anniversary of injury as both a benchmark for neurological stability and a criterion for enrolment of subjects with SCI in research studies, especially when sensorimotor function is under study. Clearly, however, the use of the term 'complete' written on an initial trauma examination might ultimately have little bearing on whether recovery of reflexes or sensorimotor function might result. Thus, examination and classification at the beginning of exercise testing and training is needed.

1.5 SCI Syndromes

As the various spinal columns transmit different types of information, and because most persons surviving SCI do not experience complete severance of their cords, many different patterns of spared sensorimotor function are possible. The syndromes that ensue are usually described when defining the levels and completeness of injury. The major syndromes, their definitions and causations are listed in the following sections.

1.5.1 Anterior Cord Syndrome

An anterior cord syndrome is "a lesion that produces variable loss of motor function and of sensitivity to pain and temperature, while preserving proprioception".[42] An anterior cord syndrome results primarily in a profound motor loss below the level of injury. Destruction of the anterior portions of the white and grey matter of the spinal cord affects the corticospinal motor tracts and, to a lesser extent, sensory tracts that mediate light touch and pressure.

1.5.2 Central Cord Syndrome

A central cord syndrome is "a lesion occurring almost exclusively in the cervical region, that produces sacral sensory sparing and greater weakness in the upper limbs than in the lower limbs".[42] A person with a central cord syndrome often presents

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with greater motor impairment of the upper than lower extremities if the damage or disease is primarily limited to the central grey and white spinal cord matter. Because upper extremity motor function is primarily activated by the medial corticospinal tracts, sensorimotor functions of the lower extremities are usually affected to a lessor degree. Central cord injury is common among individuals having congenitally narrow spinal canals and in those, especially aging persons, whose osteoarthritic pathology results in spinal canal stenosis.

1.5.3 Brown-Sequard Syndrome

A Brown-Sequard syndrome is "a lesion that produces relatively greater ipsilateral proprioceptive and motor loss and contralateral loss of sensitivity to pain and temperature".[42] The Brown-Sequard syndrome results from an anterior-posterior hemisection of the spinal cord often accompanying a penetrating wound that severs the neural elements. When the elements of only one lateral portion of the spinal cord are destroyed, the injury results in an unusual pattern of sensorimotor function with a loss of infralesional motor function, proprioception, fine touch and vibration discrimination on the same side of injury, but loss of pain, temperature, crude touch and deep pressure on the opposite side of injury. The syndrome is explained by decussation of motor tracts in the brain stem before they descend in the cord. In contrast, ascending sensory tracts of the anterolateral systems cross to the opposite side at (or near) the level in which the dorsal roots enter the cord. This explains why 'same side' motor deficits are common in patients with Brown-Sequard syndrome, but sensory preservation is greater on the contralateral side of injury.

1.5.4 Conus Medullaris and Cauda Equina Syndrome

A conus medullaris syndrome involves an "injury of the sacral cord (conus) and lumbar nerve roots within the spinal canal, which usually results in an areflexic bladder, bowel and lower limbs".[42] Sacral segments may occasionally show preserved reflexes (e.g. bulbocavernosus and micturition reflexes). A cauda equina syndrome involves "injury to the lumbosacral nerve roots within the neural canal resulting in areflexic bladder, bowel and lower limbs".[42]

2. Medical and Health Consequences of SCI

Persons with SCI face unique health challenges throughout their lives, and their injuries dissociate the normally well integrated homoeostatic responses of body systems known to accompany physical activity. Nervous system damage disrupts to varying degrees the necessary signal integration among motor, sensory and autonomic targets, and thus has a profound effect on fitness, exercise capacities and health. Depending on the level and type of cord lesion, persons with SCI are among the most physically deconditioned of all humans.[7,50] Not surprisingly, young persons with chronic SCI experience accelerated pathological states and conditions normally associated with physical deconditioning and premature aging, including: dyslipidaemias and heart disease;[23,24,51,52] arterial circulatory insufficiency[53-57] and clotting disorders;[58,59] bone and joint diseases;[60-62] and pain of musculoskeletal and neuropathic origins.[63-68]

Notwithstanding their physical limitations, many persons with SCI can still undergo exercise reconditioning. Those who retain upper extremity function can participate in a wide variety of exercise activities and sports,[6,69] and ambulate with the assistance of orthoses and computer-controlled electrical neuroprostheses.[70-76] Individuals with upper motor neuron lesions can pedal cycle ergometers by surface electrical stimulation of selected lower extremity muscle groups under computer control.[30,31,33] Many body organs and tissues acutely respond to exercise despite their decentralised or denervated states, and because many survivors of SCI experience complete sensory loss or significantly diminished nociceptive responses, electrically stimulated muscle contractions can often be utilised without pain.

2.1 Physical Deconditioning

Persons with SCI usually live sedentary lives,[7,9,68,77] which explains their poor physical fit-

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ness and heightened risk of cardiovascular morbidity and mortality.[9,22,51,78] Nearly one in four healthy young persons with paraplegia fails to achieve levels of oxygen consumption ($\dot{V}O_2$) on an arm exercise test sufficient to perform many essential activities of daily living.[8] While those with paraplegia have far greater capacities for activity and more extensive choices for exercise participation than persons with tetraplegia, they are only marginally more fit.[7,11]

2.2 Musculoskeletal Decline

Altered structural and contractile properties of muscle after SCI limit the ability of totally paralysed and weakened muscle to sustained intense contractions for extended durations. Most studies of sublesional muscle after SCI in humans report fibres that:

- are smaller than those above the lesion and those of persons without SCI;[79-83]
- have less contractile protein;[84]
- produce lower peak contractile forces;[85,86]
- transform toward fast phenotypic protein expression;[81,87-90]
- increase myosin heavy chain isoforms;[90,91]
- decrease their resistance to fatigue.[19,79,84,92,93]

Muscle fibre cross-sectional area declines within 1 month of SCI,[80,89] while electrical stimulation of muscle paralysed for more than 1 year evokes forces only one-seventh to one-third those of subjects without SCI.[85,86,94] Physiological and contractile properties adopted after SCI further compromise the ability of muscle without motor sparing to optimally increase in size and metabolic activity after exercise reconditioning,[95] which has adverse consequences for cardiovascular, musculoskeletal and comorbid diseases to which those with SCI are highly susceptible.

Persons sustaining SCI develop muscles below the level of the lesion that are either hypertonic or atonic depending on the level and type of SCI. Hypertonia is the more common condition in which exaggerated rate-dependent stretch results in spastic contraction. This results from damage to the upper motor neurons alone, in which descending inhibition of reflex response in interrupted by cord injury. Hypertonia in these individuals can by worsened by a number of 'noxious' stimuli unrelated to muscle stretch, including urinary voiding, venous thrombosis, thermal dysregulation, occult fracture or infection.[96] In contrast, damage to lower motor neurons involving injury below T_{10} usually results in flaccid paralysis and loss of neuromuscular response to administration of alternating electrical currents.

Rapid bone demineralisation is expected during the first year after SCI, after which bone density levels continue to slowly decay. Increased urinary excretion of calcium and hydroxyproline,[97] and progressive rarefying of bone on radiographs are evident throughout this period. About one-third to one-half of bone mineral density is lost by 1 year after injury, with primary losses occurring in the supracondylar femur. The inevitable course of SCI leads to underhydroxylated and hypocalcific bone[98,99] with permanently heightened susceptibility to fracture, even following trivial or imperceptible trauma.[100] Joints experience similar deterioration[60] and heightened injury susceptibility brought on by cartilage atrophy[101] and joint space deformities.[102-104]

2.3 Cardiovascular Disease, Dyslipidaemia and Comorbidities

Epidemiological studies conducted in the early 1980s, and thereafter, reported emergence of cardiovascular disease as a major cause of death in persons with SCI.[1,3,24,105] While genitourinary complications accounted for 43% of deaths in the 1940s and 1950s, mortality from these causes were reduced to 10% of cases in the 1980s and 1990s.[24,106,107] Cardiovascular diseases currently represent the most frequent cause of death among persons surviving >30 years after injury (46% of deaths) and among persons >60 years of age (35% of deaths)[107,108]

Decline of cardiovascular function in persons aging with SCI mirrors that experienced by persons who age without SCI, although at an accelerated rate.[23] Asymptomatic cardiovascular disease also occurs at earlier ages after SCI[108,109] and its symptoms may be masked by interruption of ascending afferent pain fibres conveying warnings of impending heart damage or death.[108-110] Several major risk

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factors commonly reported in persons with SCI have been linked with their accelerated course of cardiovascular disease; these include dyslipidaemia[7,22,78] and a sedentary lifestyle imposed by muscle paralysis and limited exercise options.[8,9] The cardiovascular disease risks of individuals without SCI are worsened by hyperinsulinaemia[22,111,112] and elevated percentages of body fat,[113,114] which are common among persons with SCI.[24]

An atherogenic lipid profile is commonly reported in persons with chronic SCI.[22,78,112-115] This lipid profile satisfies criteria for designation as 'dyslipidaemic', i.e. elevated total cholesterol (TC), triglyceridaemia and plasma low density lipoprotein-cholesterol (LDL-C) or depressed high density lipoprotein-cholesterol (HDL-C).[116] All have all been reported in sedentary persons with SCI, although elevated TC is not observed in all of these studies,[115,117] and LDL-C concentrations, while sometimes elevated, show patterns of elevation typical of those reported in the general population.[115] The most consistent finding of reports examining the lipid profiles of persons with SCI is a depressed blood plasma concentration of the cardioprotective HDL-C[22,78,114,115,118,119] whose levels are inversely associated with cardiovascular risk.[120] More than 40% of persons with SCI have HDL-C levels below the earlier criterion score for high cardiovascular risk (HDL >35 mg/dL). When combined with other known risks factors for vascular disease in persons with SCI (e.g. prevalent truncal obesity,[114] elevated body mass indices,[113] physical inactivity[8,9] reduced lean body mass,[95,113,121-123] diabetes,[124,125] metabolic syndrome X[126] and advancing age),[18] the risks of abnormal lipid profile on disease progression become magnified.

Insulin resistance occurring in a high percentage of persons with SCI was first reported more than two decades ago.[125] Since that time, others have confirmed this finding and included insulin resistance among the cardiovascular risks sustained by persons aging with SCI.[22,111,112,114,127] Almost half the persons with SCI live in a state of carbohydrate intolerance or insulin resistance.[22,125] A reason for prevalent insulin resistance in persons with SCI have not been firmly identified, although physical inactivity,[127] truncal obesity[113,114] and sympathetic dysfunction[111,112] have been suggested as causes. An association may also exist between their abnormal lipid profiles and insulin resistance. Such an association has been identified in persons without SCI having depressed serum HDL-C, as they are also especially prone to insulin resistance.[128-130] This risk profile closely matches that of persons with SCI, in whom isolated low HDL-C and insulin resistance are often comorbid.[51]

2.4 Cardiac Structure and Function

Individuals with chronic SCI experience various types of circulatory dysregulation depending on the level of their cord lesion.[96] When injury occurs above the level of sympathetic outflow at the T_1 spinal level, resting hypotension with mean arterial pressures of 70mm Hg are common.[131] In addition to challenging effective orthostatic pressure regulation, low pressures also instigate altered heart structure and function observed after SCI.[132] As size and architecture of the human heart are known to be influenced by peripheral circulatory volume and systemic pressures, withdrawal from normal activity levels and altered circulatory dynamics transform the structure of the heart and alter its pumping efficiency.[133] For those with tetraplegia, a chronic reduction of cardiac preload and myocardial volume coupled with pressure underloading causes the left ventricle to atrophy.[132,134] In contrast, long-term survivors of paraplegia are normotensive and have normal left ventricular mass and resting cardiac output, but experience a cardiac output comprised of elevated resting heart rate (HR) and depressed resting stroke volume (SV).[28,134] This lowered SV is attributed to decreased venous return from the immobile lower extremities or frank venous insufficiency of the paralysed limbs.[135,136]

2.5 Vascular Structure and Function

The volume and velocity of lower extremity arterial circulation is significantly diminished after SCI, with volume flow of about half to two-thirds that reported in matched subjects without paraly-

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sis.[56,137] This circulatory 'hypokinesis'[138] results from loss of autonomic control of blood flow as well as diminished regulation of local blood flow by vascular endothelium.[56] The lowering of volume and velocity contribute to heightened thrombosis susceptibility commonly reported in those with acute and subacute SCI.[58] A contributing factor to thrombosis disposition appears to be a markedly hypofibrinolytic response to venous occlusion of the paralysed lower extremities,[139] a poor response likely attributable to low blood flow conditions in the paralysed lower extremities[54,56] or interruption of adrenergic pathways that regulate fibrinolysis in the intact neuraxis.[59]

2.6 Autonomic Dysregulation

Like those of the motor system, sympathetic nerve tracts descend in the spinal cord, albeit within the intermediolateral columns and not the corticospinal tracts, and exit with motor nerves in the thoracolumbar segments. As no sympathetic autonomic tracts exit the cord above the T_1 spinal level, individuals with cervical injuries often sustain decentralisation of their sympathetic nervous system. Loss of autonomic outflow to the adrenals is also observed in persons with paraplegia above the T_6 spinal level. Injury above the sacral cord segments abolishes central parasympathetic regulation of genitourinary organs (S2-4), which explains the common occurrences of neurogenic bowel and bladder after SCI, as well as erectile dysfunction in males.[140] Autonomic dysfunction that results from injury above the thoracolumbar levels of sympathetic nerve outflow is associated with cardiac and circulatory dysfunction,[34,132] clotting disorders,[58] altered insulin metabolism,[112,125] resting and exercise immunodysfunction,[65,141-151] orthostatic incompetence,[152] osteoporosis and joint deterioration,[60,153] and thermal dysregulation at rest and during exercise.[154-157] A blunted chronotropic response to exercise in persons with tetraplegia is well documented,[158-160] and usually yields peak HRs in the mid-120 beats/min range, similar in magnitude to persons without SCI who exercise under conditions of pharmacological adrenergic blockade. The absence of, or meagre catecholamine responses to, exercise in these individuals have been reported[161] and explains their suppressed HR responses to exercise. Thus, cardiac acceleration during exercise implies withdrawal of vagal tone and not increased sympathetic drive.

Few direct clinical comparisons can be made between persons having SCI above and below the highest level of sympathetic outflow at T_1 (i.e. between those persons whose motor status results in tetraplegia and paraplegia). Testing of subjects having inhomogeneous lesion levels usually leads to widely variable chronotropic, pressor, fuel, peripheral circulatory, thermal and work capacity responses. For those with paraplegia from T_2 to T_5 (or T_6), sparing of sympathetic efferents to the heart with resulting noradrenergic-mediated cardiac acceleration will be observed. A relatively normal response is observed below T_5 or T_6,[162] as central inhibitory control of the adrenals (normally innervated from T_6–T_9) is regained below these levels.[158]

3. Volitional Upper Extremity Exercise in Persons with SCI

3.1 Acute Physiological Responses to Exercise Stress

SCI blunt the expected physiological responses to exercise and diminish peak exercise capacity.[163] These limitations are associated with the level of SCI, and are explained by various factors. First, ascending levels of injury cause greater loss of muscle mass necessary to serve as prime movers and stabilisers of trunk position. This requires that the arms simultaneously generate propulsive forces and steady the trunk during exercise. Secondly, increasing levels of injury are associated with increasing adrenergic dysfunction, and at key spinal levels dissociate adrenal, cardiac and total sympathetic nervous system control from the brain. As the adrenergic and noradrenergic systems play key roles in cardiovascular regulation and fuel homeostasis during exercise, their loss attenuates the cardiovascular

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and metabolic efficiencies achieved in persons with an intact neuraxis.

Many studies have observed a direct association among level of injury, peak workload attained and peak oxygen uptake ($\dot{V}O_{2peak}$) reached during arm crank testing. This association serves as the basis for sports classification used during paralympic and other sports events for persons competing with physical disability. Exercise performance after SCI is limited by circulatory dysregulation accompanying thoracic injuries.[138,156,159,164-166] Individuals with injuries below the level of sympathetic outflow at T_6 have a significantly lower resting SV and higher resting HR than persons without paraplegia.[156,159,167] The significant elevation of resting and exercise HR is thought to compensate for a lower cardiac SV imposed by pooling of blood in the lower extremity venous circuits, diminished venous return and cardiac end-diastolic volumes, or frank circulatory insufficiency.[138,168] Adjustments to the adrenergic systems after SCI may also regulate the excessive chronotropic response to work, as higher resting catecholamine levels and exaggerated catecholamine responses to physical work have been reported in individuals with paraplegia with middle thoracic (T_5) cord injuries. These exceed resting and exercise levels of both high level paraplegics and healthy persons without SCI.[155,169] Hypersensitivity of the supralesional spinal cord is believed to regulate this atypical adrenergic state and dynamic, which contrasts the downregulation of adrenergic functions observed in persons with high thoracic and cervical cord lesions.[155,161]

An exaggerated HR response is experienced during physical activity by persons with paraplegia,[158] which may be performance delimiting. This belief is consistent with reports in which subjects with paraplegia require higher levels of $\dot{V}O_2$ to perform the same work intensity as subjects without SCI[32,138,156,170] and may represent a limiting factor in the performance of activities of daily living.[21,156,171] As the sympathetic nervous system regulates haemodynamic and metabolic changes accompanying exercise, the elevated $\dot{V}O_2$ and HR response to work in individuals with paraplegia with injuries below T_5 may be due to adrenergic overactivity accompanying their paraplegia.[158,161,169]

3.2 Cardiorespiratory Testing

Assessment of cardiorespiratory fitness in persons with SCI requires specialised knowledge of both exercise testing procedures and the unique physiology that ensues SCI. Exercise testing modalities for these individuals commonly employ overground wheelchair propulsion on a treadmill or wheelchair rollers, cyclical arm ergometry and variations of electrically stimulated exercise. Exercise testing by wheelchair propulsion offers the advantage of comparison to many wheelchair-based daily tasks. However, wheelchair propulsion testing generally requires specialised equipment. Also, it is not known whether testing is best when using a single standardised wheelchair, in which the usual wheelchair-used interface is compromised, or having subjects use their habitual chair, in which some individuals may be advantaged by better equipment. These factors limit use of wheelchair ergometry as a research and clinical testing tool.

The exercise test mode most commonly used in the cardiorespiratory testing of persons with SCI is the arm crank ergometer. The lack of task specificity to wheelchair mobility has been considered a limitation to their usefulness. However, as these devices are generally found in the rehabilitation environment and allow standardised application of testing stresses, it represents the most frequently used means for clinical or fitness assessment of wheelchair users. Reliable test results require consistent positioning of the test subject and the ergometer. The test subject and the cranking ergometer should be positioned so that the axis of the crank arm is horizontally aligned with the subject's shoulder joint and the elbows are slightly flexed at the point of furthest reach. To ensure enhanced reliability of test results, care should be taken to replicate subject positioning and to use the same wheelchair and cushion. The latter may affect seating stability and exercise efficiency.

Cardiorespiratory exercise testing of persons with SCI follows the same general protocols as

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testing in the general population. In most cases, the graded multi-stage tests proceed in 2- to 3-minute stages until volitional exhaustion. As $\dot{V}O_{2peak}$ is dependent on level of SCI, lower intensity loads are applied than those used in standard exercise testing. These workloads have been detailed in several publications,[172-175] although no particular advantage for a single testing strategy has been tested or established. However, accurate and valid results require that testing utilise metabolic monitoring to establish the $\dot{V}O_{2peak}$, as prediction equations normally used to estimate maximal responses in persons without disability have not been validated in those with SCI.

3.3 Endurance Training

In most cases, injury to the spinal cord renders the lower extremities without sufficient strength, endurance or motor control to support safe and effective physical training. This explains why most exercise training after SCI employs upper extremity exercise modes including arm crank ergometry, wheelchair ergometry and swimming. All of these training modes improve $\dot{V}O_{2peak}$ in those with SCI,[27,32,172,176-186] with the magnitude of improvement inversely proportional to level of spinal lesion. While it is possible for persons with low tetraplegia to train on an arm ergometer, special measures must be taken to affix the hands to an ergometer and their gains in $\dot{V}O_{2peak}$ fail to match those of their SCI counterparts with paraplegia.[187] Therefore, the level of injury is a key to predicting outcome from arm endurance training.[188,189] Guidelines for training after SCI have been published by several authorities,[32,52,172] although testing for superiority of training algorithms has not been performed. However, given that most persons with SCI are sedentary long after injury and the accepted dictum that training best benefits the most deconditioned individuals, these methods are nonetheless successful in achieving higher levels of fitness.

Benefits of arm conditioning are widely reported for persons with SCI, with many studies reporting significant increases in $\dot{V}O_{2peak}$ after training.[27,185-187,190,191] It is less clear whether the changes in $\dot{V}O_{2peak}$ result from central (HR, SV, cardiac output [$\dot{Q}$]) adaptations or increases in peripheral oxygen extraction (a-$\dot{V}O_2$ difference), or whether central adaptations take place at all. Only one endurance training study examining 16 weeks of intense arm exercise observed clear evidence of central cardiovascular benefit.[176] Notwithstanding the mechanisms contributing to increased $\dot{V}O_{2peak}$ after arm exercise training, many studies report individuals with paraplegia improve their $\dot{V}O_{2peak}$ by 10–20% following 8–12 weeks of training. These gains are inversely proportional to the level of SCI, as those with higher levels of injury attain lower peak exercise capacities on arm exercise test than those with lower-level SCI, and both groups lower than persons without disability tested by arm ergometry.

Endurance training recommendations for those with SCI do not vary dramatically from advice directed to the general population.[192-194] The American College of Sports Medicine recommended training frequencies, durations and intensities are contained in *Exercise Management for Persons with Chronic Diseases and Disabilities*.[192] Generally, three to five weekly exercise sessions of 20–60 minutes in duration and at an intensity of 50–80% $\dot{V}O_{2peak}$ is the recommended exercise prescription for persons with paraplegia using the following modes of exercise:

- arm cranking
- wheelchair propulsion
- swimming
- wheelchair sports
- circuit resistance training (CRT)
- electrically stimulated cycling
- electrically stimulated walking.

This reference suggests that target exercise intensities should produce HR responses equivalent to 50–80% of the individual's peak HR. As in the general population, excessive exercise volume has been associated with increase pain and injury. Thus, exercise frequency and duration should be carefully monitored and gradually increased with the input of certified exercise professionals familiar with the unique physiological responses of persons with SCI to exercise. As long-term compliance and injury

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avoidance are major goals of training, erring on the conservative side of selected exercise durations and intensities are prudent and more important for persons training with a disability than those without.

3.4 Resistance Training for Persons with SCI

Far less is known about effects of resistance than endurance training in persons with SCI. This might seem counterintuitive, as muscle weakness has been reported to precipitate pain and dysfunction as persons with SCI age with their disability. Moreover, the most commonly reported symptom of upper extremity physical dysfunction among persons with SCI is pain of the shoulder joint and girdle.[66,195-200] While a single cause for shoulder pain has not been identified, deterioration and injury resulting from insufficient shoulder strength is one commonly cited source.[63,199-202] Pain that accompanies wheelchair locomotion and other wheelchair activities reportedly interferes with functional activities including upper extremity weight bearing for transfers, high resistance muscular activity in extremes of range of motion, wheelchair propulsion up inclines and frequent overhead activity.[196,198-200] Onset of pain is common during body transfer activities and severity increases as time following injury lengthens.[196] Given evidence that wheelchair locomotion is a major source of pain and dysfunction for persons with SCI, incorporation of resistance training into the healthcare plan of those with SCI appears both justified and essential.

Several investigators have studied effects of resistance exercise in persons with paraplegia. In a study of Scandinavian men (most of whom had incomplete low thoracic lesions) a weight-training programme emphasising triceps strengthening for crutch walking was undertaken for 7 weeks with modest but significant increases in $\dot{V}O_{2peak}$ observed following training. These endurance gains were accompanied by increased strength of the triceps brachii.[203] Another study[204] examined the effects of arm ergometry in subjects assigned to high-intensity (70% of their $\dot{V}O_{2peak}$) or low-intensity training (40% of their $\dot{V}O_{2peak}$) for 20 or 40 minutes per session, respectively. Strength gains were limited to subjects assigned high-intensity training, and occurred only in the shoulder joint extensor and elbow flexor muscles. Otherwise, no changes in shoulder joint abduction or adduction strengths were reported, and none of the muscles that move or stabilise the scapulothoracic articulation or chest were stronger following training. These results suggest that arm crank exercise is ineffective as a training mode for upper extremity strengthening because it fails to target the muscles most involved in performance of daily activities.

Conditioning of five paraplegic and five tetraplegic subjects three times weekly for 9 weeks was reported using a hydraulic fitness machine.[205] Exercises were limited to two manoeuvres: (i) chest press/chest row; and (ii) shoulder press/latisimus pull.[205] Significant increases in peak values of $\dot{V}O_2$ and power output measured by arm ergometry testing were observed at the conclusion of the study, although no testing was conducted that directly measured strength gain in any muscle groups undergoing training. Another study focused their training on strengthening of the scapular muscles, although this study focused solely on the scapular retractor muscles when comparing seated rowing and a standardised scapular retraction exercise, and did so only for concentric actions.[206] The authors found that higher levels of retractor activation were obtained during backward compared with forward wheelchair locomotion and suggested that rowing was effective for improving scapular retractor activity and cardiorespiratory fitness. A recent study observed reduced shoulder pain following a series of shoulder resistance exercises using elastic bands.[63]

As both endurance and resistance exercise benefit those without SCI, the effects of CRT[207] on various attributes of fitness, dyslipidaemia and shoulder pain have been studied in young and middle-aged subjects with paraplegia. This exercise programme incorporates periods of low-intensity high-paced movements interposed within activities performed at a series of resistance training stations. The CRT exercise programme adapted for persons with paraplegia consisted of three circuits of six resistance stations encompassing three pairs of agonist/

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antagonist movements (e.g. overhead press and pull) and three 2-minute periods of free wheeling arm cranking performed between resistance manoeuvres. No true rest periods were allowed during the performance of CRT, with active recovery limited to the time necessary for the subject to propel the wheelchair to the next exercise station. Three weekly sessions were completed with each session lasting approximately 45 minutes. Young subjects undergoing 16 weeks of mixed resistance and endurance exercise increased their arm $\dot{V}O_{2peak}$ by an average of 29%, with accompanying strength gains of 13–40%, depending on the upper extremity site tested.[174] Subjects undergoing CRT lowered their total and LDL-C while increasing their HDL-C by nearly 10%.[175] Subjects aged over 40 years undergoing the same treatment for 12 weeks experienced significant gains in all of endurance, strength and anaerobic power, even though the latter was not specifically targeted by training (Nash MS, unpublished data). Shoulder pain present in these subjects before training was assessed by a pain instrument validated in the population and significantly reduced. Pain was eliminated in four of ten subjects.

In a separate study, the effects of circuit training performed on an adapted multi-exercise system could be replicated by use of elastic bands.[208] Evidence therefore supports health and fitness advantages of CRT over either endurance or resistance exercises alone for persons with paraplegia.

General recommendations for strength training exercise prescription include three sets of 8–12 repetitions per exercise movement for two sessions per week at moderate to high intensity using the following modes of exercise:

- free weights
- weight machines
- elastic tubing and bands.

4. Electrically Stimulated Exercise in Persons with SCI

4.1 Basis of Electrically Stimulated Movement

Many forms of electrically stimulated exercise are available for use by persons with SCI. These include site-specific stimulation of the lower extremities[82,209-212] and upper extremities,[65,213-218] leg cycling,[30,34,134,219-222] leg exercise with upper extremity assist,[222-225] lower body rowing,[50] electrically assisted arm ergometry,[226,227] electrically stimulated standing[76,217] and electrically stimulated bipedal ambulation either with[74-76,228,229] or without an orthosis.[55,70,72,173,230-232] Most forms of exercise require that the lower motor neuron system remain intact following injury, as direct activation of the peripheral nerve and not the muscle by electrical current ultimately results in muscle activation.[233] This reality excludes most individuals having cauda equina or conus medullaris syndromes from electrically stimulated exercise. It may also compromise the efficiency of a muscle having a denervated segment from injury to its anterior horn cells or spinal (Wallnerian) degeneration from injured adjacent spinal areas. Many applications of SCI target muscle strengthening of limb segments whose motor function is partially spared by injury,[76] while others use electrical current as a neuroprosthesis for the lower extremities[71,229] and upper extremities.[234-238]

Most electrical stimulation devices currently approved for use by the US FDA employ surface, not implanted, electrical stimulation. The most common uses of surface electrical stimulation for system exercise in those with SCI include electrically stimulated cycling, either with or without upper extremity assistive propulsion and electrically stimulated ambulation. Qualifications necessary to safely participate in exercise programmes have been described[71,72,233,239,240] and risks of participation are included in the section of this monograph addressing adverse events associated with exercise by those with SCI.

4.2 Leg Cycling Exercise

The simplest form of multi-limb segmental exercise for persons with SCI employs a cycling motion performed in a slightly recumbent seated position. This electrically stimulated cycling uses electrically activated contractions of the bilateral quadriceps, hamstrings and gluteus muscles under computer microprocessor command.[31] Control of pedal ca-

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dence and muscle stimulation intensity is exerted by feedback provided from position sensors placed in the pedal gear.[241]

Training with electrically stimulated cycling is often preceded with electrically stimulated strengthening of the quadriceps muscles, which is necessary in cases of severe muscle atrophy or diminished muscle endurance.[209,221] Responses to electrically stimulated exercise are variable, ranging from poor to robust. As noted, poor muscle strength and endurance and altered muscle contractile properties normally accompany SCI. In general, these factors will slow success in training, especially in those individuals with longstanding paralysis, absent spasticity and flexor patters of spasticity. Electrically stimulated strength training programmes are capable of altering the strength, resistance to fatigue and contractile properties of the muscles undergoing the training. Dudley and associates,[209] demonstrated the effectiveness of a simple programme of electrically induced knee extensions, performed twice weekly over an 8-week period, dramatically reversed muscular atrophy of the quadriceps muscles.

Notwithstanding poor levels of muscle strength and endurance early in most training programmes and despite limited ability to exercise against intense workloads, enhanced levels of fitness,[224,242,243] improved gas exchange kinetics[244,245] and increased muscle mass[218] have been reported following exercise training using electrically stimulated cycling. For those with neurologically incomplete injuries, gains in lower extremity mass, as well as isometric strength and endurance under conditions of voluntary and electrically stimulated cycling have been reported.[218] Reversal of the adaptive left ventricular atrophy reported in persons with tetraplegia has also been observed, with near normalisation of pretraining cardiac mass.[134] This change may be associated with significantly improved lower extremity circulation following training,[246,247] which is also accompanied by a more robust hyperaemic response to experimental occlusion ischaemia.[55,56]

Attenuation of paralytic osteopaenia has been observed by several investigators[248,249] and an increased rate of bone turnover by another,[110] although the sites benefiting from training are the lumbar spine and proximal tibia, not the proximal femur.[249] Not all studies have found a post-training increase in mineral density for bones located below the level of the lesion.[250] Those that fail to do so have usually studied subjects with longstanding paralysis, in which attenuation or reversal of osteopaenia by any treatment has yet to be reported. Notwithstanding, a study examining the appearance of lower extremity joints and joint surfaces using magnetic resonance imaging reported no degenerative changes induced by cycling, and less joint surface necrosis than previously reported in sedentary persons with SCI.[60] Improved body composition favouring increased lean mass and decreased fat mass[251] and an enhancement of whole-body insulin uptake, insulin-stimulated 3-0-methyl glucose transport and increased expression of GLUT4 transport protein in the quadriceps muscle have been reported.[252] In a recent report, this training has resulted in improved profiles of insulin resistance.[253] When combined with simultaneous upper extremity arm ergometry, the acute cardiovascular metabolic responses to electrically stimulated cycling are more intense and the gains in fitness greater than observed with lower extremity cycling alone.[224,253]

4.3 Bipedal Ambulation

Complex electrical stimulation to achieve bipedal ambulation has been used as a neuroprosthesis for those with motor-complete injuries[71,72,228,239,254] and an assistive neuroprosthesis for persons with incomplete SCI who lack necessary strength to support independent ambulation.[255-263] Surface and implantable neuroprostheses for those without spared motor function have both been fabricated,[76,264] although the sole method currently approved by the FDA (Parastep-1®)[1] uses surface electrical stimulation of the quadriceps and gluteus muscles.[72,230] Muscle activation is sequenced by a microprocessor worn on the belt, with activation of step initiated by a finger-sensitive control switch located on a rolling

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walker used by ambulating subjects. When pressed, the electrical stimulator sends a current to the stance limb that initiates contraction of the quadriceps and gluteus muscles. Contralateral hip flexion is then achieved by exploiting an ipsilateral flexor withdrawal reflex obtained by introducing a nociceptive electrical stimulus over the common peroneal nerve at the head of the fibula. This allows the hip, knee and ankle to move into flexion followed by extension of the knee joint by electrical stimulation to the quadriceps. As muscle fatigue occurs increasing levels of stimulation can be provided by a switch mounted on the handle of the rolling walker.

As in the case of electrically stimulated cycling, functional use of ambulation neuroprostheses by those with paraplegia are compromised by post-injury muscle weakness and poor endurance. These need to be addressed in subject preparation before ambulation training is initiated. Electrically activated knee extensions against progressively increased resistance (sandbag at ankle) is the standard training exercise. While not as commonly addressed, conditioning of the gluteal muscles with electrically produced hip bridging (in supine position) prior to bodyweight-supported gait training will enhance the response of the hip extensors to electrical stimulation. A single most effective protocol to satisfy requisite strength and endurance needs for upright ambulation training has not been reported. However, it is inadvisable to undertake electrically stimulated ambulation training until the ability to stand with electrical stimulation for at least 3–5 minutes has been demonstrated.

Once training is initiated, rates of ambulation are relatively slow and distances of ambulation relatively limited when using the system,[229] and the community use of these devices remains limited to a small percentage of training subjects. Despite the limitations of ambulation velocity and distance, ambulation distances of up to 1.6km (1 mile) have been reported after training in some subjects[229] and upper extremity fitness is enhanced following ambulation training.[71,173] Other adaptations to training include significantly increased lower extremity muscle mass,[265] improved resting blood flow[55] and an augmented hyperaemic response to an experimental ischaemic stimulus.[55] No change in lower extremity bone mineralisation following has been reported,[232] although most subjects participating in research trials of electrically stimulated exercise are beyond the duration of injury at which reversal of their neurogenic osteoporosis is expected.[232]

5. Risks of Exercise When Performed by Persons with SCI

Special attention is required when designing, instituting or performing exercise programmes for persons with SCI. Some of the risks encountered will be similar to those experienced by persons without paralysis, although complications such as general overuse may be exaggerated in persons with SCI, and their occurrence will likely compromise daily activities to a far greater extent than similar injuries arising in persons without SCI.

5.1 Autonomic Dysreflexia

Individuals having cord injuries at or above the T_6 spinal level are prone to episodes of autonomic hyperreflexia when exposed to noxious stimuli.[266] The neurological basis for these episodes involves loss of supralesional sympathetic inhibition that normally suppresses the unrestricted autonomic reflex accompanying such exposure. This allows the adrenals to release high concentrations of epinephrine (adrenaline) under reflex control and infralesional adrenergic targets to experience the full measure of reflex noradrenergic stimulation.[267] The most common stimuli evoking autonomic dysreflexia are bladder and bowl distention before their emptying. Other stimuli include venous thromboembolism, bone fracture, sudden temperature change, febrile episodes and exercise. The disposition to autonomic dysreflexia during exercise is especially heightened when an electrical current is used to generate muscle movement, or when exercising while febrile or during bladder emptying. Episodes of autonomic dysreflexia are characterised by hypertension and bradycardia, supralesional erythema, piloerection and headache. In some cases, hypertension can rise to the point where crisis headache results, and cere-

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bral haemorrhage and death might ensue. Recognition of these episodes, withdrawal of the offending stimulus, and the possible administration of a fast-acting peripheral vasodilator may be critical in preventing serious medical complications. Prophylaxis with a slow calcium channel antagonist or α_1-selective adrenergic antagonist may be needed prior to exercise.[268-270] It is known that wheelchair racers have intentionally induced dysreflexia as an ergogenic aid by restricting urine outflow through a Foley catheter,[271] which represents a dangerous and possibly life-threatening practice.

5.2 Musculoskeletal Injury

Fracture and joint dislocation of the lower extremities is a risk of participation in exercise by those with SCI, and may be caused by asynergistic movement of limbs against the force imposed by either electrical stimulation or the device used for exercise.[36] This explains why these activities are contraindicated for individuals with severe spasticity or spastic response to the introduction of electrical current. Precautions to prevent overuse injuries of the arms and shoulders must be taken for those participating in upper extremity exercise.[201,206,272] As the shoulder joints are mechanically ill-suited to perform locomotor activities, but must do so in individuals using a manual wheelchair for transportation, these injuries may ultimately compromise performance of essential daily activities including wheelchair propulsion, weight relief and depression transfers.[273,274]

5.3 Hypotension

Small risks of post-exercise hypotension[131,275] are associated with lost vasomotor responses to orthostatic repositioning,[276] although these episodes can abate after upper limb training.

5.4 Thermal Dysregulation

Individuals with SCI often lack sudomotor responses below their level of injury and are thus challenged to maintain thermal stability.[154,277-279] These responses are less pronounced as the level of SCI descends,[280,281] and when exercising in an environment controlled for temperature and humidity.[278,282] Thus, attention should be paid to hydration and, if possible, limiting the duration and intensity of activities performed in intemperate environments.

6. Conclusions

Multisystem organ dysfunction is common after SCI. Depending on the level of injury, alterations of cardiac function, peripheral circulation, autonomic function, skeletal integrity, muscle composition and genitourinary functions all accompany an SCI. The fact that many of these pathological system changes are reversible permits better understanding of the roles played by central innervation and physical activity on organ system function in persons with intact neuraxes. As levels of injury, types of injury and the extent of organ system dysfunction vary among persons with SCI, careful attention must be paid to accurate classification of individuals before entry into clinical treatment or study. The use of homogeneous subject populations based on similar levels, types and durations of injury is especially important if conclusions concerning deconditioning and reconditioning in these persons are to be reached.

Despite these special needs and warnings, many persons with SCI benefit from sustained therapeutic and recreational exercise. Individuals with higher levels of cord injury may require electrical stimulation to perform exercise, which poses special restrictions on use and unique risks from participation. Qualified individuals safely improved cardiovascular and musculoskeletal functions. Positive benefits of training on bone density, regulation of orthostatic tolerance and affect have been reported in studies with limited numbers of subjects and require well controlled investigations for confirmation. Individuals with spared motor control of the upper extremity can perform arm or wheelchair exercises and participate in recreational sports. Greater emphasis needs to be placed on strengthening of the upper extremity to preserve shoulder and arm functions for performance of daily living as these individuals age with their paralysis. Risks of injury or illnesses associat-

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ed with imprudent exercise must be managed to ensure that the desirable benefits of physical activity can be sustained. If carefully prescribed, exercise has the demonstrated ability to enhance the activity, life satisfaction and health of those with disability from SCI.

Acknowledgements

The preparation of this manuscript was made possible by funding from the Miami Project to Cure Paralysis, University of Miami, Florida, USA, and the Rehabilitation Research and Development Service, Department of Veterans Affairs, USA. The authors have no conflicts of interest directly relevant to the content of this review.

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E-mail: pjacobs@miami.edu

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Appendix H Software Design Description

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(b)(4) Software Design, Specification and Verification Documents

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5. APPENDIX A ERGOMETER CALIBRATION DATA

5.1 Ergometer Speed

Note:

1. The RPM command sent to the ergometer is 1.33 times the actual RPM desired.

RPM commanded	RPM expected	RPM measured	RPM reported by ergometer
5	3.75	3	3
10	7.5	6.7	6.5
15	11.25	10.7	11
20	15	15	15
25	18.75	19	19
30	22.5	22.7	23
35	26.25	26.5	26.5
40	30	31	31
45	33.75	34.5	34.5
50	37.5	38.5	38.5
55	41.25	42	42
60	45	46	46
65	48.75	50	50
70	52.5	54	54
75	56.25	58	58
80	60	60	60

Table 1 Ergometer speed verification

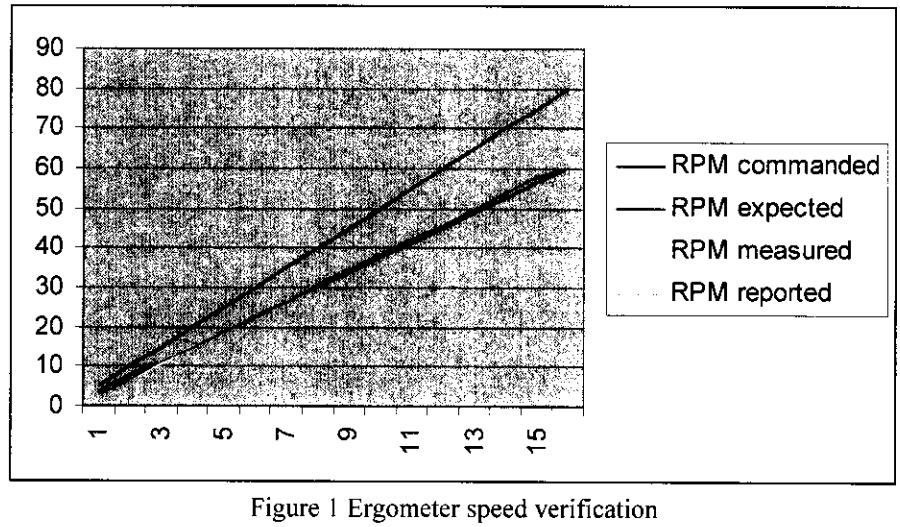

Figure 1 Ergometer speed verification

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5.2 Ergometer Drive Torque

Notes:

1. Multiply the drive torque command by 0.15 to get expected torque
2. Multiply the reported torque by 0.375 to get real reported torque

Torque commanded	Torque expected (Nm)	Torque measured (Nm)	Torque reported by ergometer
0	0	0.2	0
10	1.5	1.1	4
20	3	2.6	8
30	4.5	3.9	12
40	6	5.5	17
50	7.5	7	20
60	9	8.7	24
70	10.5	10.2	28
80	12	11.4	32
90	13.5	13.3	36
100	15	15.1	41
110	16.5	17	45
120	18	18.2	50
130	19.5	20	53
140	21	21.7	57
150	22.5	23	60

Table 2 Ergometer torque verification

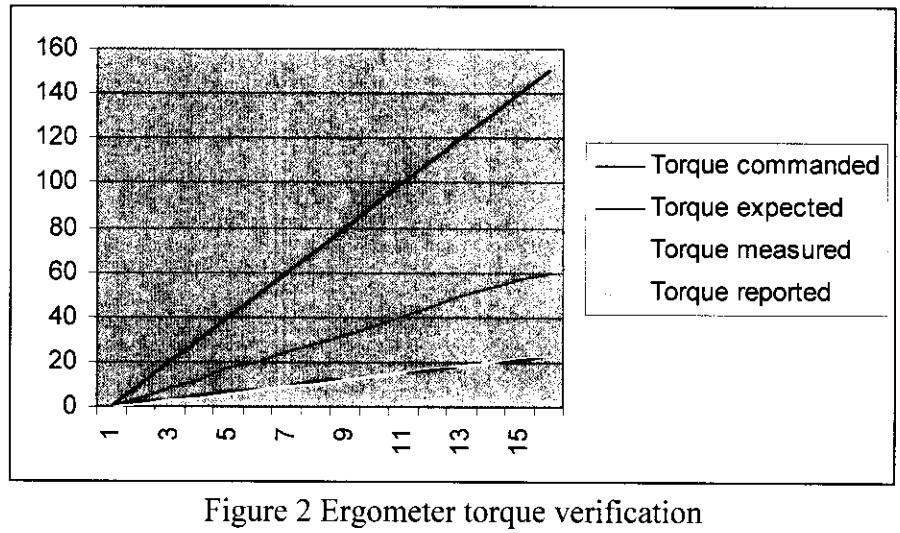

Figure 2 Ergometer torque verification

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5.3 Ergometer Resistance

Notes:

1. Multiply the resistance commanded by 0.14 and add 1 Nm offset to get the effective resistance set
2. Multiply the resistance reported with 0.375 to get the effective resistance reported

Resistance commanded	Resistance expected	Resistance measured	Resistance reported by ergometer
0	1	1.1	0
10	2.4	2.5	3
20	3.8	3.9	6
30	5.2	5.4	10
40	6.6	6.9	14
50	8	8	17
60	9.4	9.3	21
70	10.8	10.6	24
80	12.2	12.4	29
90	13.6	13.2	31
100	15	14.9	35
110	16.4	16.4	39
120	17.8	17.7	43
130	19.2	19	46
140	20.6	20.4	50
150	22	22	55

Table 3 Ergometer resistance verification

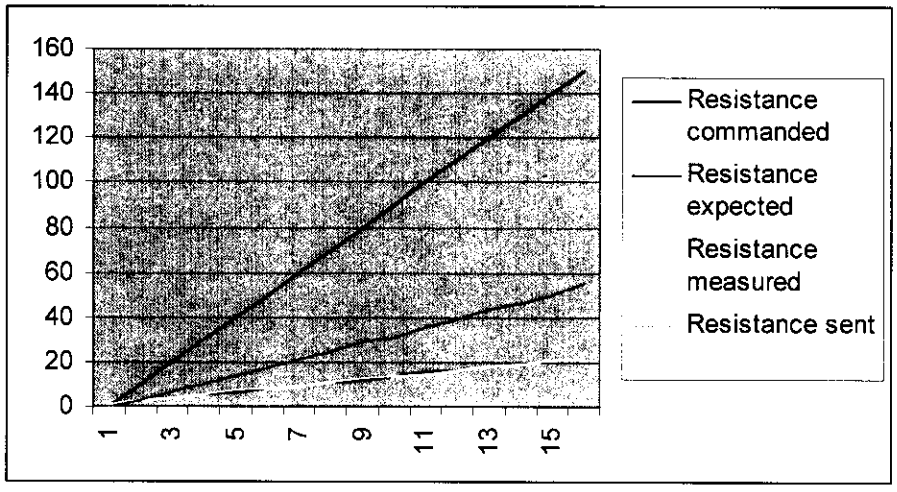

Figure 3 Ergometer resistance verification

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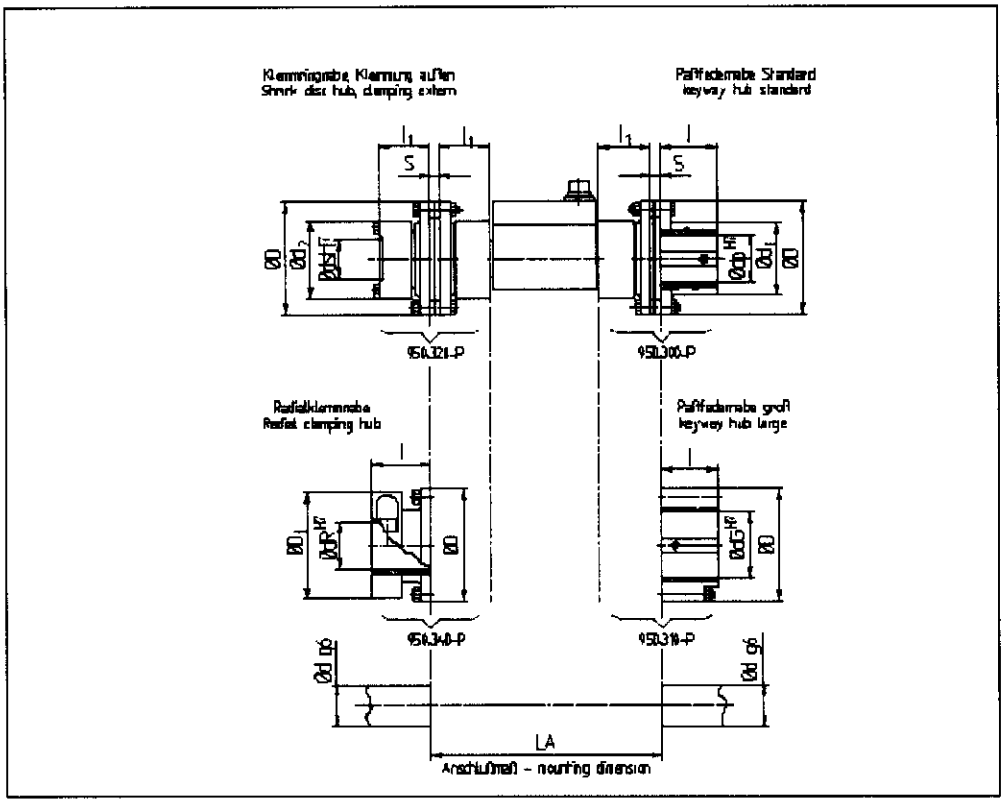
LORENZ MESSTECHNIK GmbH Obere Schloßstr 131 73553 Alfdorf ☎ 07172/93730-0 Fax 07172/93730-22

Drehmomentsensor Typ DR-20 mit Kupplung 950.3_0-P
torque sensor Typ DR-20 with coupling 950.3_0-P



TECHNISCHE DATEN - ***specifications*** **Typ 95...**

Grosse *size*	Maximal-moment-max *torque* $T_{A\,max}$ [Nm]	Maximal Drehzahl max *speed* N_{max} [min^{-1}]
16	160	13600
25	250	11800
64	640	8500
100	1000	7300

Alle Teile der Kupplung werden allseitig bearbeitet und liegen somit bei mittleren Drehzahlen im Bereich Q 6.3 gemäss VDI-Richtlinien 2060.
All elements of the coupling are machined all over and are there for in the range Q 6.3 according to VDI characteristics 2060 with medium speed

Messbereich nominal *torque* [Nm]	Typ 95 Größe *size*	Abmessungen – *dimensions [mm]*															
				ds		dP		dR		dG		d1	d2	l	l1	s	LA
		D	D1	min	max	min	max	min	max	min	max						
50,100	16	77	73	14	26	16	32	25	35	30	45	50	53	40	35	7.1	164.2
200	25	89	84	20	36	20	40	30	40	35	55	60	64	45	40	7.2	194.4
500	64	123	115	30	45	30	55	35	55	55	75	80	84	65	50	9.6	219.2

Bei Bestellung bitte immer den gewünschten Ø d angeben
Please specify requested diameter Ø d at order

Email: info@lorenz-messtechnik.de
Homepage: www.lorenz-messtechnik.de

Technische Änderungen vorbehalten 080416a_dr-20_m ku typ-950.doc
Technical modification to reserve

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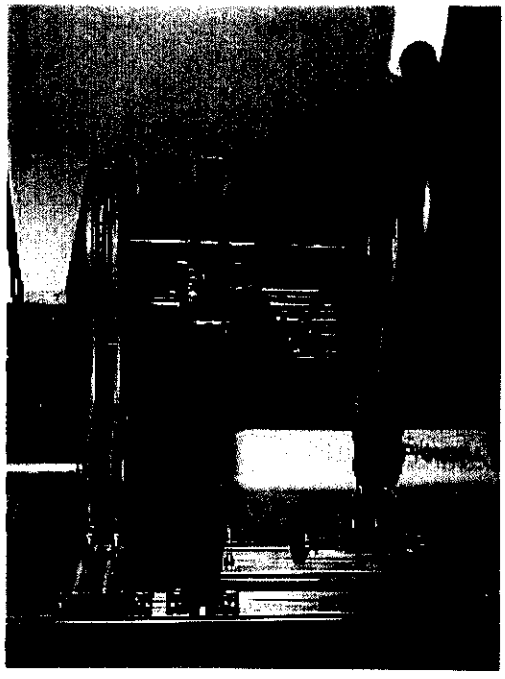

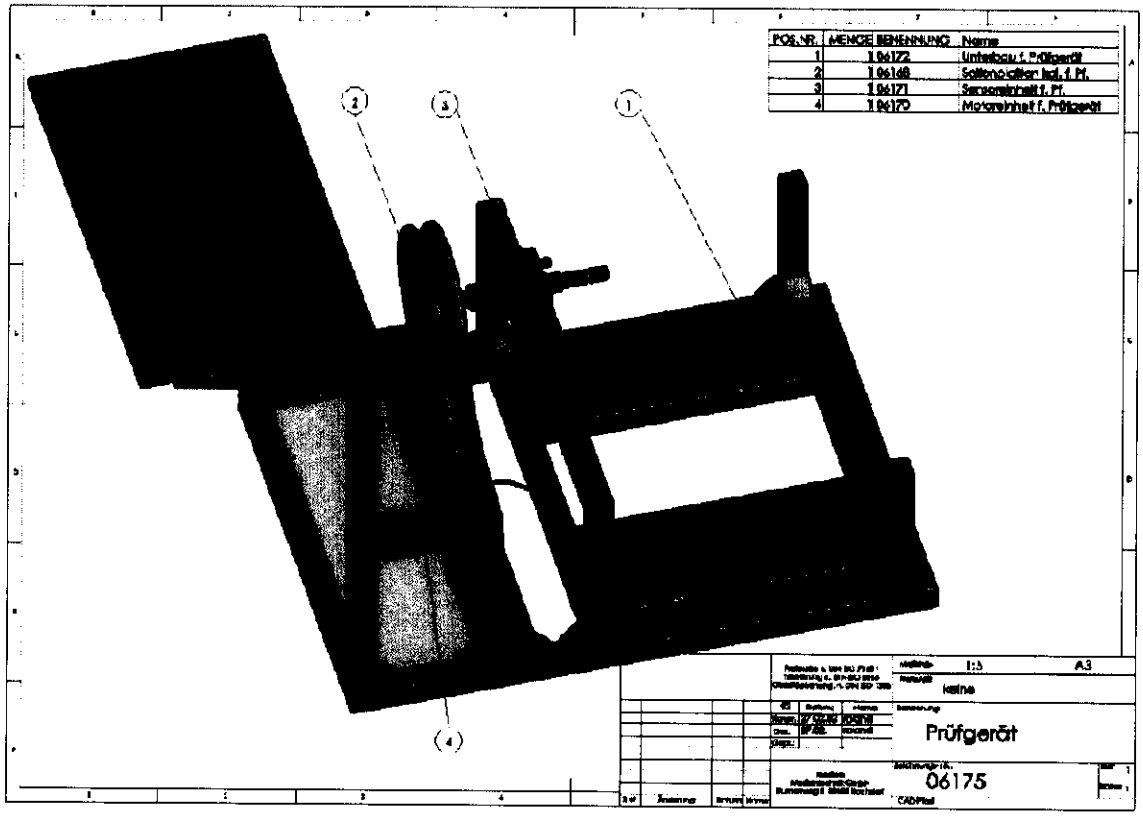

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Appendix K Traceability Matrix

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RT300 Requirements Traceability Report

This automatically generated report shows requirements tracing from the following source documents:

RT300 Software Requirements Description
RT300 Hazard Analysis
RT300 Software Design Description

Explaination of codes:

Code	Refers to
HA	Hazard analysis
LB	Product labeling
OT	Other
SDD	Software design description
SRS	Software requirement specification
SVP	Software verification protocol
UL	UL testing to IEC60601-1 and IEC60601-1-2

Trace report

Requirement	Satisfied / Verified
RT300:HA:001	RT300:SDD:025
RT300:HA:002	RT300:SDD:032, RT300:SRS:039, RT300:SVP:005
RT300:HA:003	RT300:SDD:027, RT300:SDD:030
RT300:HA:004	RT300:SDD:029, RT300:SRS:038, RT300:SVP:001
RT300:HA:005	RT300:LB:001
RT300:HA:006	RT300:LB:002
RT300:HA:007	RT300:UL:001
RT300:HA:008	RT300:SDD:031, RT300:SRS:034, RT300:SRS:036, RT300:SVP:037, RT300:SVP:039
RT300:HA:009	RT300:SDD:031
RT300:HA:010	RT300:SDD:035, RT300:SRS:035, RT300:SVP:038
RT300:HA:011	RT300:LB:003
RT300:HA:012	RT300:SDD:009, RT300:SRS:039, RT300:SVP:005
RT300:HA:013	RT300:SDD:033, RT300:SRS:014, RT300:SVP:016
RT300:HA:014	RT300:UL:002
RT300:HA:015	RT300:OT:001
RT300:HA:016	RT300:SDD:031, RT300:SRS:037, RT300:SVP:040
RT300:HA:017	RT300:SDD:001, RT300:SRS:020, RT300:SVP:023
RT300:HA:018	RT300:UL:001
RT300:HA:019	RT300:OT:002
RT300:SDD:001	RT300:SVP:015
RT300:SDD:002	RT300:SVP:023

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Requirement	Satisfied / Verified
RT300:SDD:003	RT300:SVP:014
RT300:SDD:004	RT300:SVP:025
RT300:SDD:005	RT300:SVP:030
RT300:SDD:006	RT300:SVP:029
RT300:SDD:007	RT300:SVP:042
RT300:SDD:008	RT300:SVP:002
RT300:SDD:009	RT300:SVP:005
RT300:SDD:010	RT300:SVP:003, RT300:SVP:004
RT300:SDD:011	RT300:SVP:017
RT300:SDD:012	RT300:SVP:007
RT300:SDD:013	RT300:SVP:034
RT300:SDD:014	RT300:SVP:031
RT300:SDD:015	RT300:SVP:032, RT300:SVP:033
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RT300:SDD:017	RT300:SVP:027
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RT300:SDD:020	RT300:SVP:028
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RT300:SDD:029	RT300:SVP:006
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RT300:SDD:032	RT300:SVP:011
RT300:SDD:033	RT300:SVP:017
RT300:SDD:034	RT300:SVP:008
RT300:SDD:035	RT300:SVP:038
RT300:SDD:036	RT300:SVP:009
RT300:SDD:037	RT300:SVP:016
RT300:SDD:038	RT300:SVP:019
RT300:SDD:039	RT300:SVP:001
RT300:SDD:040	RT300:SVP:006
RT300:SDD:041	RT300:SVP:026
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RT300:SRS:006	RT300:SDD:034, RT300:SVP:008

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Requirement	Satisfied / Verified
RT300:SRS:007	RT300:SDD:036, RT300:SVP:009
RT300:SRS:008	RT300:SDD:018, RT300:SVP:010
RT300:SRS:009	RT300:SDD:032, RT300:SVP:011
RT300:SRS:010	RT300:SDD:022, RT300:SVP:012
RT300:SRS:011	RT300:SDD:019, RT300:SVP:013
RT300:SRS:012	RT300:SDD:003, RT300:SVP:014
RT300:SRS:013	RT300:SVP:015
RT300:SRS:014	RT300:SDD:033, RT300:SVP:016
RT300:SRS:015	RT300:SDD:011, RT300:SVP:017
RT300:SRS:016	RT300:SDD:037, RT300:SVP:019
RT300:SRS:017	., RT300:SVP:020
RT300:SRS:018	., RT300:SDD:001, RT300:SVP:021
RT300:SRS:019	RT300:SDD:024, RT300:SVP:022
RT300:SRS:020	RT300:SDD:001, RT300:SDD:002, RT300:SDD:016, RT300:SVP:023
RT300:SRS:021	RT300:SDD:023, RT300:SVP:024
RT300:SRS:022	RT300:SDD:004, RT300:SVP:025
RT300:SRS:023	RT300:SVP:026
RT300:SRS:024	RT300:SDD:017, RT300:SVP:027
RT300:SRS:025	RT300:SDD:020, RT300:SVP:028
RT300:SRS:026	RT300:SDD:006, RT300:SVP:029
RT300:SRS:027	RT300:SDD:005, RT300:SVP:030
RT300:SRS:028	RT300:SDD:014, RT300:SVP:031
RT300:SRS:029	RT300:SDD:015, RT300:SVP:032
RT300:SRS:030	RT300:SDD:015, RT300:SVP:033
RT300:SRS:031	RT300:SDD:013, RT300:SVP:034
RT300:SRS:032	RT300:SDD:026, RT300:SVP:035
RT300:SRS:033	RT300:SDD:028, RT300:SVP:036
RT300:SRS:034	RT300:SDD:031, RT300:SVP:037
RT300:SRS:035	RT300:SDD:031, RT300:SVP:038
RT300:SRS:036	RT300:SDD:031, RT300:SVP:039
RT300:SRS:037	RT300:SDD:031, RT300:SVP:040
RT300:SRS:038	RT300:SVP:001
RT300:SRS:039	RT300:SDD:009, RT300:SVP:005
RT300:SRS:040	RT300:SDD:021, RT300:SVP:041
RT300:SRS:041	RT300:SDD:007, RT300:SVP:042

Conclusion

No untraced or untested requirements are shown.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-5377; Released by CDRH on 12-8-2015

Appendix L RT300-S Brochure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RTI
Restorative Therapies Inc.
Baltimore, MD USA
Ph: (800) 609-9166
www.restorative-therapies.com

Restorative Therapies Inc
RT300-S
motorized FES ergometer

Photo to be replaced with one showing actual RT300-S device

Restorative Therapies Inc
2363 Boston St
Baltimore, MD 21224

Phone: 800 609-9166
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www.restorative-therapies.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Activity is key...

Nervous system damage from diseases or accidents almost always reduces activity levels. Over time this loss of activity can impair your general health, decrease your quality of life and increase demands on medical and social services.

Increasing your activity level can improve cardiovascular fitness and range of motion. It can raise energy levels, manage spasticity, and decrease muscle atrophy allowing you to better perform activities of daily living.

Predictably better health can bring other rewards: economic rewards of more gainful employment days; psychological rewards of greater self-esteem and confidence.

At Restorative Therapies we understand your need for effective, time-efficient therapy compatible with your rehabilitation goals and your environment.

The RT300-S

The RT300-S system empowers you to undertake rehabilitation sessions in your own home that will assist you by:

- **Relaxing muscle spasms**
- **Minimizing muscle atrophy**
- **Improving blood circulation**
- **Maintaining or increasing range of motion**

The RT300-S does this by utilizing a computer controlled motorized cycle ergometer with an integrated functional electrical stimulation system (FES). This enables you to cycle using your own muscles.

What is FES ?

Functional Electrical Stimulation is a rehabilitation technique where low-level electrical current is applied to an individual with a disability to enhance that person's health and ability to live independently.

In the case of the RT300-S, FES is used to stimulate patterned movement of the legs. This enables the muscles to perform cycling work even though the user has lost voluntary control of the muscles.

Passive & Active Therapy

Passive therapy is when your arms or legs are moved mechanically, e.g. by the motor of a cycle or by a physical therapist's manipulations.

Active therapy is when your muscles are doing the work to complete a movement under your own control or activated by FES.

What is a cycle ergometer ?

An ergometer is a device for measuring the amount of work done by a muscle or group of muscles. In the case of the RT300-S, the ergometer is the machine that allows the user to conduct both passive and active therapy.

How does the RT300-S motor help you ?

The RT300-S motor is an essential component of the system. The motor can provide both assistance and resistance depending upon the phase of a therapy session. When you first start using the RT300-S, your muscles will tire quickly.

The motor on the RT300-S will allow you to complete a full duration therapy session (one hour) in your home from day one in spite of this early muscle fatigue. As you progress with your therapy and your muscles strengthen the motor will provide resistance against which your muscles can work.

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Using the RT300-S

No transfer from your wheelchair is required. You sit in your wheelchair with your feet secured in the footrests and your legs supported by the leg guides.

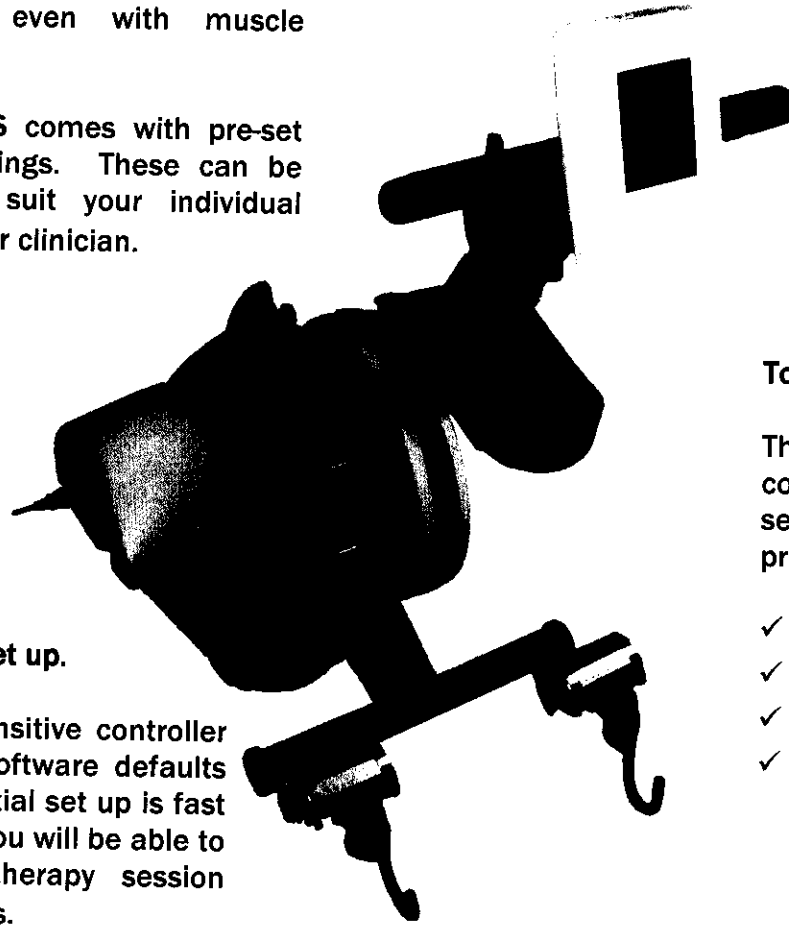
Surface electrodes placed on your skin over leg muscle groups are connected by a set of cables.

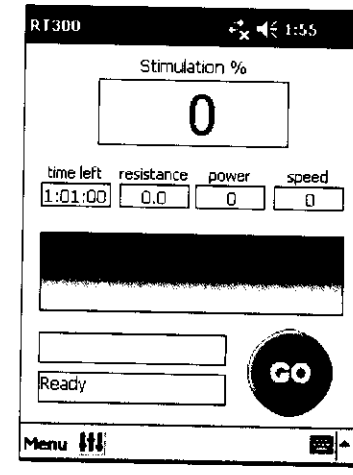
A computer controls the stimulation patterns sent to your legs producing a smooth pedaling motion. You then perform a therapy session.

Fully automatic therapies

The RT300-S is motorized to enable you to complete a full duration of therapy without assistance, even with muscle fatigue.

The RT300-S comes with pre-set therapy settings. These can be tailored to suit your individual needs by your clinician.





Touch-sensitive controller screen

The controller screen lets you control all aspects of your therapy session. Graphically view your progress:

- ✓ stimulation level
- ✓ speed
- ✓ time remaining
- ✓ resistance

Fast simple set up.

The touch sensitive controller screen and software defaults mean that initial set up is fast and simple. You will be able to begin your therapy session within minutes.

Portable & Compact

A strap in front and wheels on the back allow it to be easily moved across a room.

The RT300-S takes up very little floor space. The dimension of the base is less than 2 feet wide by 2 feet long (54 cm X 46 cm). The height of the handle is adjustable to fit the user. The RT300-S has a sleek, durable design intended for home use.

Inbuilt Safety Measures

- ✓ automatic speed control
- ✓ automatic stimulation control
- ✓ fatigue detection
- ✓ electrode monitoring system
- ✓ wheelchair restraints

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RT300-S
motorized FES ergometer

Is the RT300-S system right for me?

The RT300-S is **indicated** for

1. Relaxing muscle spasms
2. Minimizing muscle atrophy
3. Improving blood circulation
4. Maintaining or increasing range of motion

This device is contraindicated (inappropriate) if you have a cardiac demand pacemaker.

Consultation with your physician is ***required*** to determine if the RT300-S is suitable for you to use.

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

Is the RT300-S reimbursed?

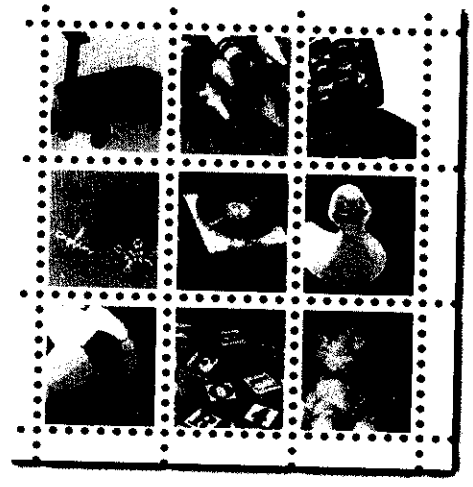
RTI works in collaboration with an insurance claims processing company to help maximize your reimbursement. Availability of insurance coverage for this therapy will depend upon several factors including the insurance that you hold. Please call RTI or see the web site for further details.

Is financing available?

RTI is able to refer you to medical finance providers who will assist you to finance the RT300-S on attractive terms. Please call RTI or see the web site for further details.

Pediatric version

The pediatric version, the RT300-SP, is intended for a population ages 4 to 12 years. It has a multi adjustable pedal system and reduced height handles.



Technical Specifications

6 channels of electrical stimulation

- 140mA (± 2mA) with 200V compliance

Motorized with virtual motor flywheel

- Torque 0 – 15Nm (± 1Nm)
- Speed 0 – 55rpm (± 2rpm)
- Noise Lpa ≤ 70dB (A)

Length 21.3" (54 cm)
Width 18.1" (46 cm)
Height 18.1" (46 cm) (without handles)
Weight 75 lbs (34 kg)

Description	Part Number
RT300-S Adult FES cycle ergometer	FA100052
RT300-SP Pediatric FES cycle ergometer	FA100053

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

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