

RT300-S™ system

User Guide



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.

Restorative Therapies Inc
2363 Boston St
Baltimore, MD 21224
USA
Telephone: 1-800-609-9166
Fax: 1-410-534-6263

www.restorative-therapies.com

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Contents

Introduction	5
About this Guide	5
What You Need to Know Before You Start	5
Indications for Use	5
Contraindication.....	5
Warnings, Precautions and Safety Measures.....	6
Warnings	6
Precautions	6
Adverse Reactions.....	7
Safety Measures.....	8
Electrical Safety	8
Environment.....	8
Parts and Operation	8
Electrostatic Discharge.....	9
Electromagnetic Interference	9
RTI Technical Support	11
Terms used in this guide	11
RT300-S System	12
What is the RT300-S System used for?	12
Parts of the RT300-S System	12
Surface Electrodes	13
Setting Up the Equipment	14
RT300-S System Overview	14
RT300-S System Overview	15
Standard RT300-S Equipment	15
Optional RT300-S Equipment	16
RT300-SP Ergometer for Pediatrics	16
Assembling the RT300-S	17
Checking the Parts.....	17
Fitting the safety handle mount and extension	17
Fitting the safety handle.....	18
Fitting the controller / stimulator	19
Adjusting the pedal crank radius	20
Adjusting pediatric pedals.....	21
Base of support.....	24
Fitting the wheelchair restraints.....	24
Connecting the Power	24
Fitting the equipment	26
Using Surface Electrodes	26
Surface Electrode Placement Precautions.....	26
Caring for Surface Electrodes	26
Fitting the Surface Electrodes.....	27
Where to Place Surface Electrodes.....	28
Connecting the surface electrodes to the ergometer	29
Stimulation Cable Set.....	29
Connecting the Surface Electrodes	30
Using the RT300-S System.....	31
Initial setup	31
Calibrate the touch screen	31
Set the time and date	32
Positioning on the Ergometer	33
Setting the distance	33
Using the Calf Rests and Footrests	33
Using the wheelchair restraints	34

Using the Controller 35

Therapy Sessions..... 37

 How the therapy session progresses 37

 Inbuilt Safety Measures..... 37

 Handling Muscle Spasm..... 38

 Starting and Stopping a Therapy Session 38

 Data display graph..... 40

 Adjusting stimulation parameters..... 41

Troubleshooting 44

 Resetting the Controller 44

Care of the RT300-S System 45

 Cleaning and Maintenance 45

 Storing the RT300-S..... 45

 Moving the RT300-S System 45

Shipping Instructions 46

Symbols 46

Technical Specifications 47

RT300-S Ergometer Limited Warranty (USA) 48

 Limited Warranty, Terms and Conditions 48

 A. Introduction 48

 B. Enquiries and Warranty Service 48

 C. Your Warranties and Rights 48

 D. Warranty limitations 49

 E. Restrictions on product use..... 49

 F. Keywords 49

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).

Warnings, Precautions and Safety Measures

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

i 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

i 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;
-

- 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:

- Ø know how to recognize the signs of autonomic dysreflexia
- Ø 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:

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

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

i **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.

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.

- 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 Compatibility

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

Effective Radiated Power

The RT300-S has been shown to have the following Effective Isotropically Radiated Power:

Transmission Frequency	Average EIRP (dBm)	Peak EIRP (dBm)
2402 MHz	-1.65	-1.15
2441 MHz	-1.65	-1.15
2480 MHz	-1.98	-1.45

FCC Compliance

Changes or modifications to the RT300-S not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device and its antenna's must not be co-located or operating in conjunction with any other antenna or transmitter.

RESTORATIVE THERAPIES, INC.

FCC ID: TE8RT300-S

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Additional notes on electromagnetic compatibility

- To reduce the risk of electromagnetic interference space RT300-S systems at least 5' apart from each other.
- The RT300-S has been tested in a number of typical electromagnetic environmental situations however it is not possible to test for every potential situation. If you will be operating the RT300-S in an environment with the potential for significant electromagnetic interference please contact RTI or an electromagnetic compatibility expert for advise prior to use.
- The BlueTooth searching function of 3rd party devices such as PDA's may become slow in an environment where several RT300-S systems are operating.

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

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

i 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

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.

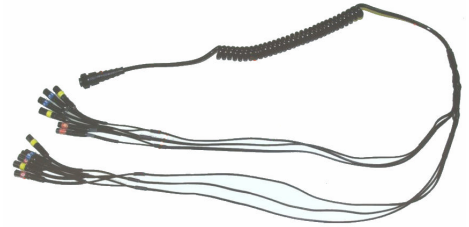
Setting Up the Equipment



Safety handle



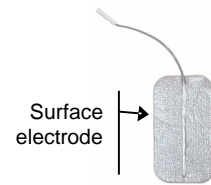
Controller / stimulator



Stimulation cable



Safety handle extension with cable



Surface electrode



Toolkit

Safety handle mount



Adult pedal (1 of 2)



or Pediatric pedal (1 of 2)



Wheelchair restraint (1 of 2)

Base unit



Power cord (USA)

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.

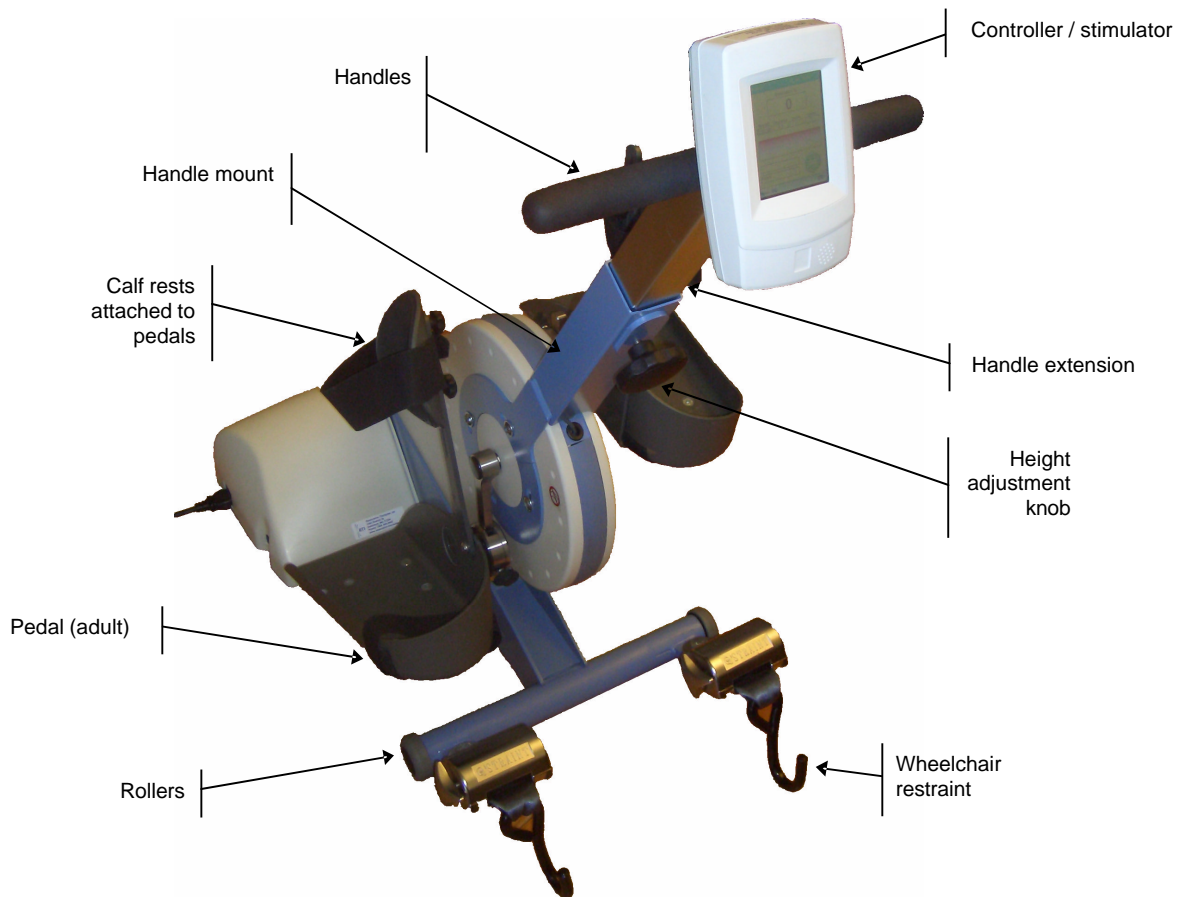


Figure 1: RT300-S system components

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.

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

i 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.

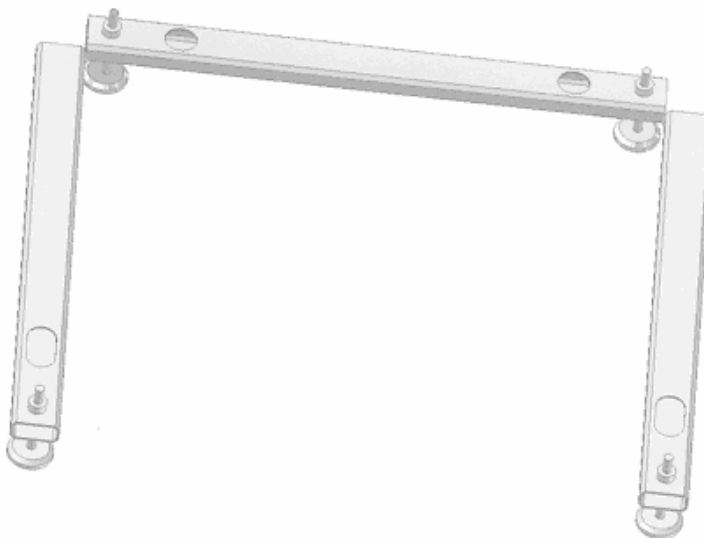


Figure 2 Ergometer platform with adjustable height legs, FA 100019

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.

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 12 for details on all parts.

i 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.

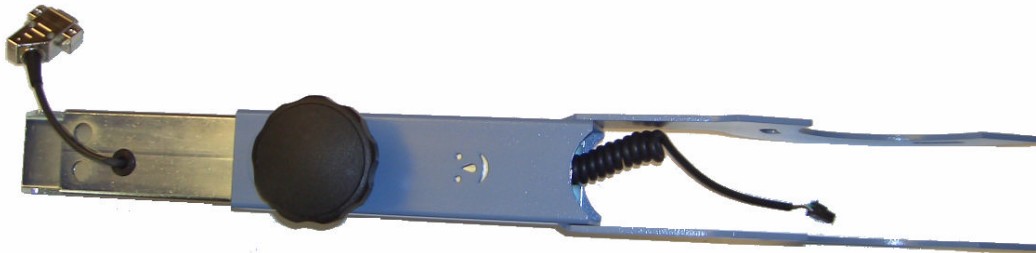


Figure 4 Slide the safety handle extension into the safety handle mount

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.

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

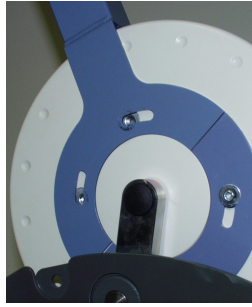


Figure 5: Bolt holes aligned

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



Figure 6 Allen (Hex) key

-
- i** It may be necessary to loosen the lower bolts and rotate the whole assembly.
-

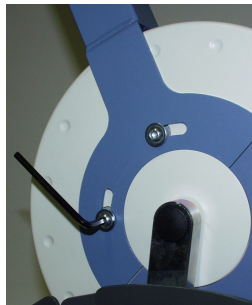


Figure 7: Tightening a bolt with the Allen (Hex) Key

Fitting the safety handle

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

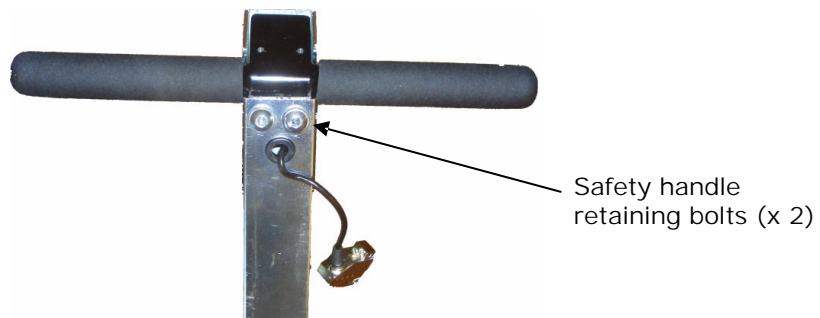


Figure 8: Fitting the safety handle

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.

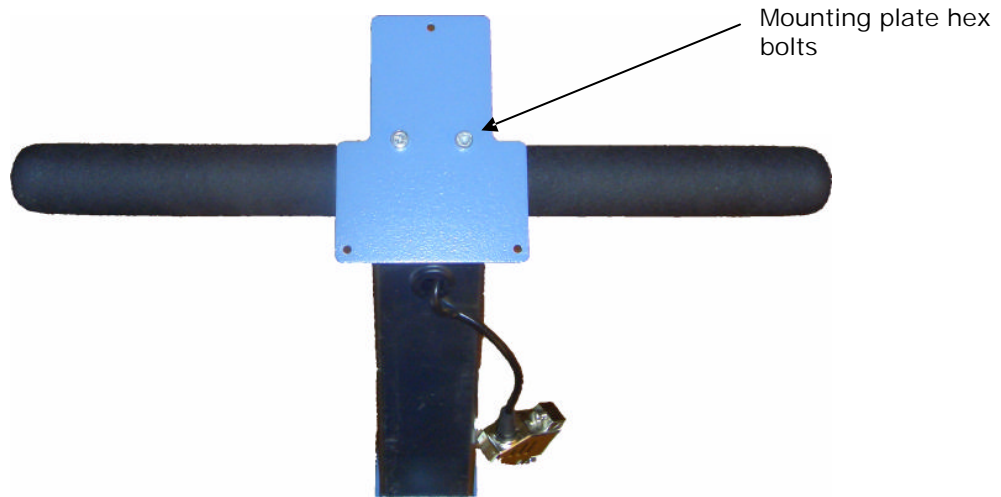


Figure 9 Controller Mounting Plate

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.

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

i 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 12 Pediatric pedal adjustment tools

The angle of the calf rest can be adjusted in three dimensions as shown in **Figure 13**.

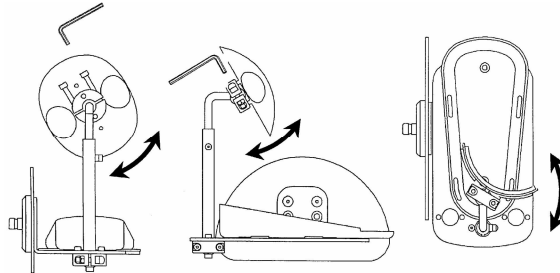


Figure 13 Calf support angle adjustment

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.

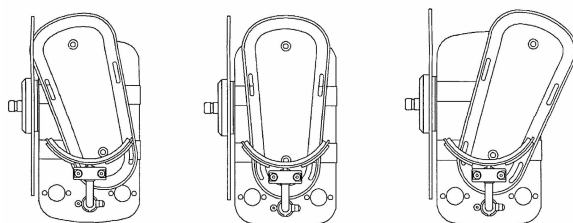


Figure 14 Foot plate angle adjustment

i 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).

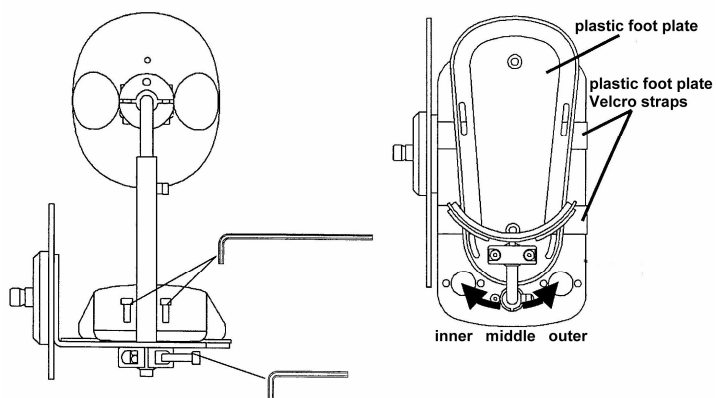


Figure 15 Calf rest position adjustment

The height of the calf rest can be adjusted as shown in Figure 16.

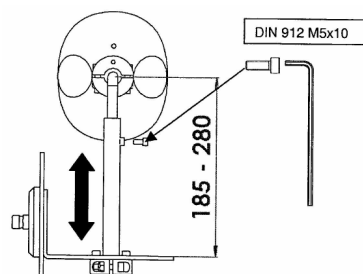


Figure 16 Calf rest height adjustment

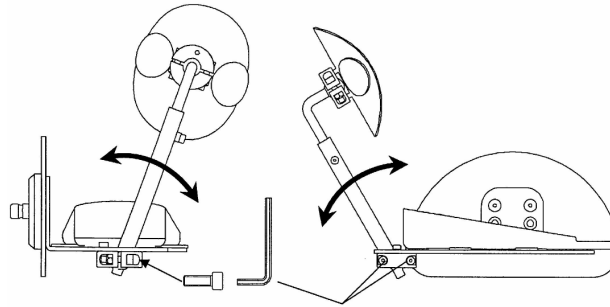


Figure 17 Calf rest angle adjustment

The height of the foot rest assembly can be adjusted as shown in Figure 18.

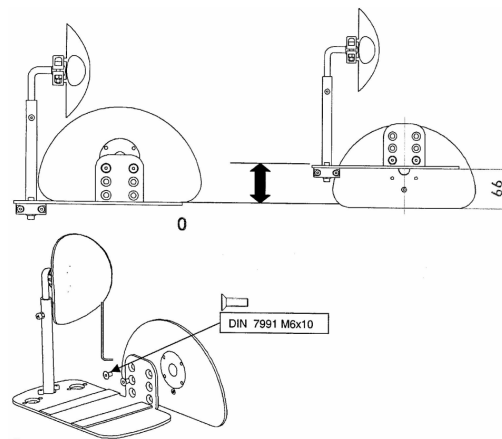


Figure 18 Foot plate assembly height adjustment

The feet must be strapped into place within the plastic foot rests using the Velcro straps shown in Figure 19.

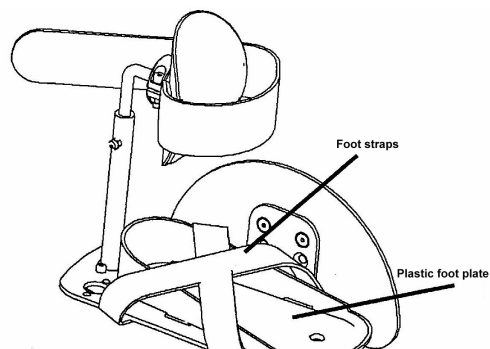


Figure 19 Foot straps

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.

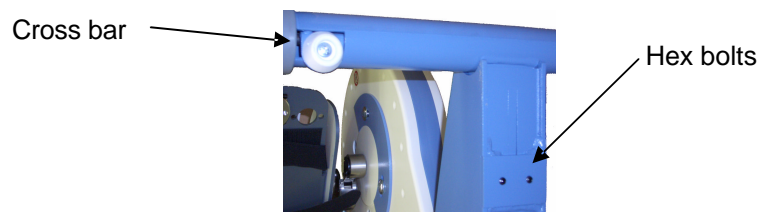


Figure 20 Hex bolts and cross bar for stability adjustment

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

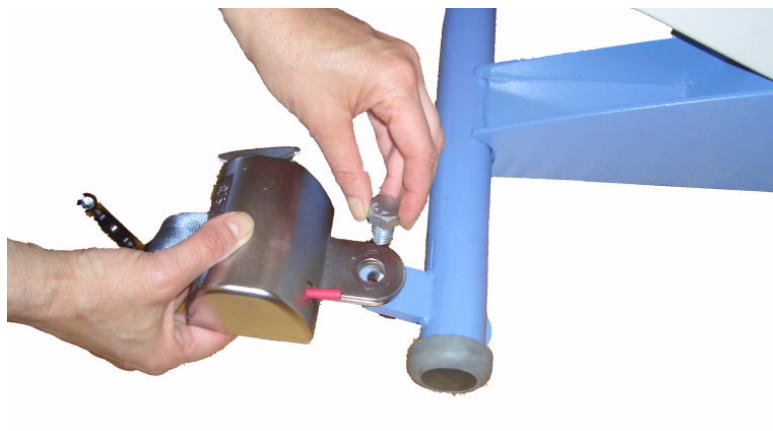


Figure 21 Fitting wheelchair restraint

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.



Figure 22: Power connection

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