# RT300

## Patient Assessment

Restorative Therapies

THE LEADER IN FES POWERED SYSTEMS

## Statement of intended use

RT300 is intended to be used for the following.

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

RT300 is a powered muscle stimulator and should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

RT300 is appropriate for children and adults.

US Patent pending 15/804,441

**Caution for RT300 users in the USA:** 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 or she practices to use or order the use of the device.

**Warning:** Modification of this equipment will void your warranty.

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Before initiating RT300 FES therapy with a patient, please review the health and safety considerations in Section 1 including absolute contraindications, warnings regarding use of RT300, and precautions and conditions requiring special consideration. Section 2 provides specific patient assessments for range of motion and pre-treatment screening. Finally, Section 3 reviews technical safety including electrical, environmental, and operational safety when conducting RT300 FES therapy.

# 1 HEALTH AND SAFETY

## 1.1 Absolute contraindications (when you must NOT use RT300)

Certain conditions contraindicate the use of RT300.

1. A patient must NOT use RT300 at all if any of the following is true.
    a. He/she has a cardiac demand pacemaker.
    b. She is pregnant - insufficient evidence is available regarding the safety of FES to an unborn child.

2. In addition, a patient must **NOT** use RT300 for **lower extremities** if he/she has unhealed fractures in the lower extremities.

3. Finally, a patient must **NOT** use RT300 for **upper extremities** if any of the following is true.
    a. He/she has a grade three or greater tear of either rotator cuff.
    b. He/she has shoulder subluxation that cannot be corrected with electrically evoked contractions or other means such as wearing a sling or taping the extremity.
    c. He/she has unhealed fractures in the upper extremities, shoulder girdle, or upper ribs.

## 1.2 Warnings

1. RT300 generates currents that could cause electrocution if used improperly.
2. Safety of a pulse width greater than 1000 usec has not be established in patients less than 22 years of age.
3. RT300 is a medical device prescribed by a physician. RT300 should only be used by the patient(s) for whom it is prescribed as it could cause harm otherwise.
4. If directed by a clinician, blood pressure and heart rate should be monitored during the therapy session.

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During therapy, if your patient's blood pressure or heart rate reaches a level that is unsafe or if the patient feels faint, light-headed or nauseous, stop the therapy session immediately. If these symptoms do not return to normal, take appropriate medical action.

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5. Stimulation should not be applied:
    - on the side of the neck at the angle of the jaw (where you typically measure your pulse over the carotid arteries) - it could cause a carotid sinus reflex, a rapid drop in blood pressure and heart rate;
    - over the neck or mouth - severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to impede airflow or even block it completely;
    - across the chest (trans-thoracically) - artificial electrical current flow near the heart may cause cardiac arrhythmia;
    - to the head (trans-cerebrally) - artificial electrical current flow near the brain could have unpredictable and dangerous effects;

- directly on the eyes;
- over swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc; and finally,
- over, or in proximity to, cancerous lesions.

6. Electrode placement and stimulation settings should be in accordance with the guidelines of the prescribing clinician.
7. Simultaneous connection of a patient to high-frequency surgical medical electrical equipment and RT300 with its SAGE Smart Therapy Controller may result in burns to the patient and possible damage to the stimulator.
8. Operation of RT300 and its SAGE Smart Therapy Controller within approximately three feet (one meter) of shortwave or microwave therapy medical electrical equipment may produce instability in the controller output.
9. RT300 and its SAGE Smart Therapy Controller should be kept out of the reach of children, pets, and pests. Children should only use RT300 under adult supervision. Never leave RT300 unattended when children are present.
10. RT300 and its SAGE Smart Therapy Controller should be used only with leads and electrodes that are provided by Restorative Therapies Inc and are in good condition.
11. Using electrodes that have current densities exceeding 2mA/cm$^2$ may require special attention by the operator.
12. The long-term effects of chronic electrical stimulation are unknown.
13. Some medical conditions can be aggravated by physical activity. If the patient's condition worsens during or after a therapy session, appropriate medical attention may be required.
14. Interconnection of this equipment to other equipment not described in the instructions for use could be unsafe.
15. Use of accessories, detachable parts, and materials not described in the instructions for use could be unsafe.
16. The patient should always wear shoes, preferably rubber-soled athletic-type shoes, and long socks to protect feet and ankles. Secure shoes and shoelaces with the Velcro straps when using RT300 leg system.
17. **When using RT300 for arm therapy**, **continuous assistance must always be available** because it may not be possible for the patient to stop the therapy if it is necessary to do so.

## 1.3 Precautions

Certain conditions or factors may increase the risk or discomfort associated with RT300 use or decrease its effectiveness. However, the benefits may outweigh the potential drawbacks.

All of the following temporary or chronic considerations may require therapy modifications and/or careful monitoring during therapy.

In all cases, guidelines for undertaking kinetic exercise should be considered[1].

### *1.3.1 Nervous system/neurological considerations*

Many cardiovascular parameters are regulated by the autonomic nervous system. While some of the considerations below may appear to be cardiovascular, the underlying cause is a temporary or chronic dysfunction of the autonomic nervous system. As such, they are included in this section on nervous system considerations. Autonomic dysfunction is not uncommon in patients with spinal cord injury (SCI).

[1] American College of Sports Medicine, Guidelines for Graded Exercise Testing and Exercise Prescription, 4th Edition. Lea & Febriger, 1991

#### *1.3.1.1 Autonomic dysreflexia*

Autonomic dysreflexia is a **potentially dangerous** complication sometimes associated with SCI at or above the T6 level. It is characterized by a sudden increase in blood pressure above safe levels.

Symptoms can vary among individuals. Common signs of autonomic dysreflexia include severe headache, a feeling of anxiety, profuse sweating above the level of injury, goose bumps (piloerection) below the level of injury, dry and pale skin below the level of injury, blurred vision, nasal congestion and abnormalities in cardiac rhythm.

Autonomic dysreflexia is typically triggered by noxious or unpleasant stimuli. The most common trigger is irritation of the bladder or colon. It can also be triggered by electrical stimulation.

The likelihood of autonomic dysreflexia is reduced if the patient empties bladder and bowels before beginning an RT300 therapy session. RT300 should **NOT** be used on a patient with a bladder infection or fever.

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Pay careful attention for any symptoms of autonomic dysreflexia that occur during a therapy program session. Autonomic dysreflexia can occur at any time even if the patient has not experienced it before or recently.

The vital signs display and the alarms from the pulse oximeter are not a substitute for careful monitoring for any signs of autonomic dysreflexia or other health related issues.

Common signs of autonomic dysreflexia in children include headache, dizziness, blurred vision, redness of the face, neck, ears, feeling hot, and sometimes goose bumps, an upset stomach, or tingling feelings.

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#### *1.3.1.2 Orthostatic hypotension*

Orthostatic hypotension is a form of low blood pressure that occurs when a person stands up from a sitting or lying position. Many people occasionally experience it, feeling dizzy for a few seconds to a few minutes.

#### *1.3.1.3 Thermal Dysregulation*

Patients with SCI may experience dysfunction of body temperature regulation (thermal dysregulation). The impact of thermal dysregulation or overheating can be reduced by:

- exercising in an environment where temperature and humidity are controlled,
- staying hydrated, and
- limiting the duration and intensity of exercise in hot or cold environments.

#### *1.3.1.4 Spasticity*

Spasticity is generally not prohibitive to RT300 use. If a patient experiences spasticity, he/she may benefit from a stretching program prior to therapy. Therapy program settings may require modification to reduce the probability of spasm.

In the long-term, FES therapy often reduces spasticity despite increasing muscle strength.

#### *1.3.1.5 Dysesthetic pain syndrome*

Dysesthetic pain syndrome in SCI is characterized by a burning, aching and/or tingling sensation below the level of injury. Electrical stimulation may aggravate symptoms of dysesthetic pain.

#### *1.3.1.6 Epilepsy*

If a patient has suspected or diagnosed epilepsy, careful monitoring is required. Depending on the severity, the patient may require a modified therapy or therapy may be prohibited.

#### *1.3.1.7 Denervated muscles*

Denervated muscles may not contract in response to stimulation.

### *1.3.2 Skeletal system*

#### *1.3.2.1 Heterotopic ossification/limited range of motion*

Heterotopic ossification (the presence of bone in soft tissue where bone does not normally exist) is not uncommon in SCI, musculoskeletal trauma or central nervous system injury. Associated limited range of motion may be accommodated with appropriate positioning in the seated position.

a. At least100 degrees of hip and knee flexion is recommended for leg therapy without the need for special positioning.
b. At least 90 degrees of shoulder flexion and 125 degree of elbow flexion is recommended for upper extremity therapy without the need for special positioning.

#### *1.3.2.2 Fractures, dislocations and surgery*

Fractures, dislocations, and surgery including but not limited to the following should be considered before beginning RT300 therapy:

- acute hip replacement,
- hip fracture,
- upper or lower limb stress fractures or
- hip or knee dislocation or subluxation.

#### *1.3.2.3 Mechanical implants*

Plates, pins, screws, and other hardware must have been implanted at least three months prior to RT300 use involving the effected limbs or joints.

#### *1.3.2.4 Osteoporosis*

Severe osteoporosis with increased risk of fractures requires a clinician's modifications to therapy.

#### *1.3.2.5 Spondylolisthesis*

Spondylolisthesis (the forward movement of a vertebra out of position and onto the bone below it) most often occurs with age but is also present in some cases of osteoporosis, arthritis or bone disease and is not uncommon with SCI injuries. Depending on the severity, the patient may require a modified therapy or therapy may be prohibited.

### *1.3.3 Wounds, infections, or fever*

Pressure sores or open wounds in the area of treatment should heal before using RT300. Compromised skin integrity of any type or an infection in the area of electrode placement can be affected by electrodes/stimulation.

In addition, a urinary tract infection or high fever could increase the probability of autonomic dysreflexia.

### 1.3.4 Implanted devices or recent surgical procedures

Implanted stimulators such as vagus nerve, phrenic, cardiac, cochlear or diaphragmatic stimulators **may interfere with or be affected by upper extremity FES**.

**ANY** other type of implanted device could also interfere with or be affected by RT300 use.

Any recent surgical procedure whose healing process could be disrupted by muscle contraction should be evaluated.

### 1.3.5 Cardiovascular and respiratory considerations

The following circulatory or cardiovascular conditions should be evaluated by a clinician before a patient begins RT300 therapy:

- suspected or diagnosed heart problems,
- high blood pressure or high heart rate, or
- tendency to hemorrhage following acute trauma or fracture.

Respiratory complications should be evaluated.

### 1.3.6 Cancer

If the patient has cancer, please consult the attending oncologist prior to RT300 use.

### 1.3.7 Menstruation

Caution should be used when applying electrical stimulation to the menstruating uterus.

### 1.3.8 Skin sensitivity to electrical stimulation

It is not uncommon to have some redness in the area of electrode placement during and/or after therapy.

You can minimize the sensation of irritation or burning by not using electrodes more often than recommended by their manufacturer and by not using an electrode or adhesive gel that has expired or is visibly altered in condition.

Having ensured that the electrodes and adhesive gel are in good condition, if your patient still feels an irritation at the site of the electrode, you can move it to a new location or try using a sensitive-skin electrode.

If symptoms persist, therapy may be contraindicated.

### 1.3.9 Prolonged period of RT300 disuse

If a patient has not used RT300 for a prolonged period (e.g. a few months), please re-evaluate therapy goals and therapy programs relative to the patient's current condition.

### 1.3.10 Prolonged exposure

If the patient experiences contact injuries such as skin irritation from applied parts or accessories due to prolonged exposure, stop using RT300 and re-evaluate therapy programs.

## 1.4 Upper extremity therapy for children

**Torus fractures**, also known as buckle fractures or incomplete fractures, are common in children. They occur when a child's bone, which is softer than an adult's, buckles or bends back upon itself without breaking the other side of the bone. Torus fractures have been reported in children during

upper extremity therapy. To reduce the chance of wrist injury of this kind during RT300 arm therapy, ensure that:

- the child's wrists are well supported;
- the child always uses the hand, wrist and arm adaptations recommended by the attending clinician; and
- the child remains seated facing straight ahead toward the SAGE tablet and avoids any twisting motion in his/her forearm and wrist.

If the child complains of wrist pain or if you notice any swelling in the wrist during or after upper extremity therapy, discontinue therapy immediately and re-evaluate therapy programs.

# 2 RT300 PATIENT ASSESSMENT FOR SUITABILITY

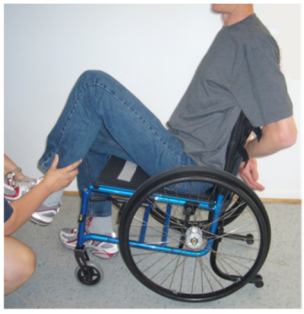
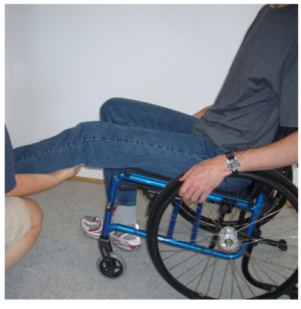
## 2.1 General considerations

In addition to careful consideration of the previously delineated contraindications, warnings, and precautions, the following should be true for your patient to receive RT300 FES therapy.

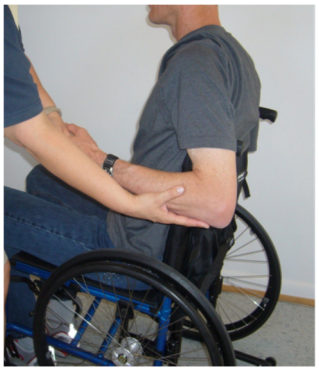
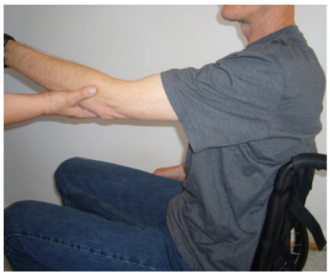
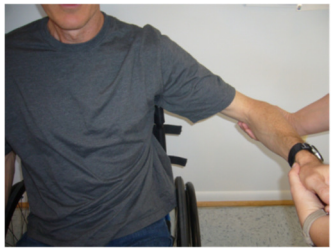
- Patients should be at least two weeks post injury and at least 1 week post-spine surgery.
- Patients should demonstrate blood pressure control, e.g. be capable of 20 minutes in a standing frame with no complications

## 2.2 RT300 range of motion (ROM) evaluation

### *2.2.1 Leg ROM*

| Photograph | Description | Pass/Fail |
|---|---|---|
|  | **Hip and knee flexion:**<br>Ensure there is appropriate hip and knee flexion by lifting the leg so that the thigh is raised and the hip and knee are flexed.<br>This should be done easily without significant force. | Left:_____<br>Right:_____ |
|  | **Knee extension:**<br>Ensure there is appropriate knee extension by lifting the foot and leg off the ground so that the knee extends. The thigh should remain on the chair.<br>This should be done easily without significant force. | Left:_____<br>Right:_____ |

### *2.2.2 Arm ROM*

| Photograph | Description | Pass/Fail |
|---|---|---|
|  | **Shoulder extension:**<br>Ensure there is appropriate shoulder extension by lifting the hand and forearm and moving the arm backwards.<br>This should be done easily without significant force. | Left:_____<br>Right:_____ |
|  | **Shoulder flexion and elbow extension:**<br>Ensure there is appropriate shoulder flexion and elbow extension by lifting the hand and forearm and raising the arm while bringing it forward.<br>This should be done easily without significant force. | Left:_____<br>Right:_____ |
|  | **Shoulder abduction:**<br>Ensure there is appropriate shoulder abduction (sideways) movement by lifting the hand and forearm and moving them sideways.<br>This should be done easily without significant force. | Left:_____<br>Right:_____ |

## 2.3 Pre-treatment screening

If a patient is not disqualified by the contraindications, paying careful attention to ABSOLUTE contraindications, and s/he demonstrates the required ROM, s/he should undergo a complete physical. In addition, the following are recommended, although not required, pre-treatment tests to verify her/his overall appropriateness for RT300 FES therapy. The clinician should exercise judgment in evaluating each individual patient's appropriateness.

**Table 1 Recommended pre-treatment screening procedures**

| Procedure | Completed |
|---|---|
| **General physical examination with reflex testing:**<br>Reflex testing: Intact reflexes indicate that the muscles will respond to electrical stimulation. If the absent reflex is due to a peripheral nerve injury or lower motor neuron disease, the individual is NOT a candidate for RT300. If there is any doubt as to the presence of an LMN lesion, an EMG should be considered. | |

| Procedure | Completed |
|---|---|
| **Physical and/or occupational therapy evaluation:** to assess joint range of motion, degree of spasticity, presence of spinal reflexes, residual sensory function, and residual motor function. | |
| **Complete X-rays of the lower extremities:** to assess evidence of heterotopic ossification or fracture, AP and lateral views of the femur, tibia/fibula, hips, knees, and ankle joints are recommended. | |
| **DEXA scan:** to assess osteoporosis in the lower extremities. | |
| **Sensory evaluation:** to assess comfort to stimulation if sensory return is present or anticipated. | |
| **Neurological evaluation:** if the patient has epilepsy. | |
| **Cardiac evaluation:** if the patient has known cardiovascular issues. | |
| **Additional screening tests for the upper extremities:**<br>a. Complete x-rays of the upper extremities: to assess evidence of heterotopic ossification or fracture, AP and lateral views of the ulna, radius, humerus, elbow, wrist and shoulder joints are recommended.<br>**b.** DEXA scan: to assess osteoporosis in the upper extremities. | |

# 3 TECHNICAL SAFETY

## 3.1 Electrical Safety

1. Only connect RT300 to a power outlet that uses the voltage shown on the product label.
2. Always touch a metal part of RT300 before you touch the controller or fit any parts – this will dissipate any **electrostatic build-up** that could otherwise damage electrical parts of the system or the software in the controller.
3. Never use the equipment in the vicinity of a flammable anesthetic mixture containing air, oxygen or nitrous oxide.
4. Connect the system parts only as described in this guide.
5. Do not connect or disconnect any parts while the system is turned on.
6. Do not use the system with any equipment not supplied by Restorative Therapies Inc. as doing so could change RT300's operation unpredictably, affecting the electrical safety and electromagnetic compatibility (EMC) of the system.
7. While electromagnetic interference (EMI) is uncommon, transmitters such as television, radio or cellular phone towers, microwave ovens and hand-held radios such as citizens band (CB) and ham could change RT300's operation unpredictably. To reduce the risk of EMI:
   - do not operate handheld transceivers such as CB radios while operating RT300,
   - place RT300 at least 20 feet (6.5 meters) away from microwave ovens and
   - be aware of nearby transmitters such as nearby radio or TV stations, and
   - there may be significant risks of reciprocal interference post by ME equipment during specific investigations or treatments.

8. RT300 contains complex electronic parts that must be serviced by qualified service personnel. Do not open the casings yourself or allow another person to open the casings as you, or they, may be seriously injured. Please contact Restorative Therapies Technical Support (see Section 4).

## 3.2 Environmental safety

1. Never use RT300 in wet or damp areas.
2. Position RT300 on an even, non-slip surface to ensure stability and immobility during use. You may wish to use an anti-slip device such as a rubber mat to prevent RT300 or the patient's chair/ wheelchair from moving backward during therapy.
3. Always place RT300 away from heat sources such as radiators, stoves, or space heaters.
4. Arrange the power cords so they will not be walked on, tripped over or damaged by objects resting on them.

## 3.3 Operational safety

1. The patient is an intended operator.
2. The patient should be dressed comfortably and be able to achieve the appropriate range of motion in legs and/or arms.
3. You can disconnect RT300 from the mains power supply either by unplugging it from the outlet or by disconnecting the power supply cord from RT300.
4. Position RT300 such that it is easy to disconnect its power cord.
5. Be careful of any cables or cords around the head and neck area, particularly those with excessive length, to prevent any situations that may lead to strangulation.
6. Avoid wearing anything that may catch or tangle in moving parts and secure your patient's shoe laces with the foot restraint Velcro straps so that they cannot tangle in the pedal crank.
7. Handle RT300 and its various parts carefully to reduce the risk of damage.
8. Carefully inspect each part of RT300 each time you use it and contact RTI Technical Support – and stop using RT300 – if you notice any damage such as cracks or breaks in the covering of a cable.
9. If any changes occur in how RT300 operates, stop using it and contact Restorative Therapies Technical Support (see Section 4).
10. If RT300 produces abnormal noises or smells, or appears damaged or faulty, stop therapy immediately, unplug the power cord, and contact Restorative Therapies Technical Support (see Section 4).
11. Repairs to RT300 must only be carried out by properly trained specialists.
12. Do not use the SAGE Smart Therapy Controller for any other purpose, e.g. to store documents or images, as this may alter controller function.
13. Let RT300 stand for about an hour before using for the first time or after it has been transported over a long distance.
14. Do not stand, or allow patients to stand, on the footrests or RT300's plastic motor covers.
15. Do not touch the pedals or hand attachments when RT300 is in operation. Keep all non-involved body parts clear of the crank's rotation when the machine is in operation.
16. Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

# 4 RTI SUPPORT

If you have questions regarding operation of
How to contact RTI technical support:

- Visit our website at **rt300.com** or restorative-therapies.com/technical_support.
- In the USA and Canada, call 1-800-609-9166 and select the option for support.
- In Australia, call 02 8006 0939.
- In the UK, contact Cyclone Mobility 0800 180 4850.
- In other countries, please utilize the International page on our website (restorative-therapies.com/international) to identify your local distributor.