RT200 Patient Assessment

510(k) Number: K103370

Device Name: RT200 functional electrical stimulation elliptical ergometer

Indications For Use:

The RT200 is 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 RT200 is intended for use with a surface electrical stimulation garment for population ages 12 and above.

Prescription Use __X__
(Part 21 CFR 801 Subpart D)

ABSOLUTE CONTRAINDICATIONS

There are three contraindications which absolutely exclude a patient from utilizing the RT200.

1. Powered muscle stimulators, including the RT200, should not be used on patients with cardiac demand pacemakers.

2. Fractures - The presence of unhealed fractures in the lower extremities restricts the patient from using the RT200 until the fracture is stable.

3. Pregnancy should be considered a temporary absolute contraindication, as the safety of the fetus has not been established when using electrical stimulation.

ADDITIONAL ABSOLUTE CONTRAINDICATIONS FOR THE UPPER EXTREMITIES

1. Grade 3 tear of either rotator cuff.

2. Inability to keep humeral head into glenohumeral joint including utilizing electrically evoked contraction of the shoulder.

3. Fractures - The presence of unhealed fractures in the upper extremities, shoulder girdle or upper ribs restricts the patient from using the RT200 until the fracture is stable.

RELATIVE CONTRAINDICATIONS

1. Denervated muscle in lower extremities- muscle contractions will not be evoked by the RT200's stimulation.

2. Severe Spasticity - In most cases, spasticity will not disqualify an individual from using the RT200. A vigorous stretching program may be necessary prior to therapy along with modified therapy settings to reduce the probability of spasm.

3. Heterotopic Ossification/Limited Range of Motion - The patient can be positioned in their chair to accommodate for minor limitations in joint ranges; however, a minimum of 100 degrees of hip and knee flexion is recommended.

4. Severe Osteoporosis - Mild to moderate osteoporosis is prevalent in the majority of the SCI population and in itself does not represent an immediate exclusion from the therapy. If the osteoporosis has progressed so that there is an increased risk of fractures, the therapy should be adjusted to account for the degree of osteoporosis.

5. Dysaesthetic Pain Syndrome - In some cases the pain syndrome may worsen making the stimulation and the therapy may be too uncomfortable to continue.

6. Presence of pressure sores or open wounds in area of treatment.

7. Recently (< 3month) implanted plates, pins, screws and other hardware.

ADDITIONAL RELATIVE CONTRAINDICATIONS FOR THE UPPER EXTREMETIES

a. Implanted stimulators such as vegus nerve, phrenic, cardiac, cochlear, diaphragmatic stimulators.

b. Malignancy.

c. Heterotopic Ossification/Limited Range of Motion - The patient can be positioned in their chair to accommodate for minor limitations in joint ranges; however, a minimum of 90 degrees of shoulder flexion and 100 degree of elbow flexion is recommended.

Additional Cautions for Upper Extremity Ergometry with Children:

Torus fractures, or buckle fractures, are extremely common injuries seen in children.

Because children have softer bones, one side of the bone may buckle upon itself without disrupting the other side; this is also known as an incomplete fracture. Torus fractures have been reported in children during upper extremity ergometry.

To reduce the chance of wrist injury:

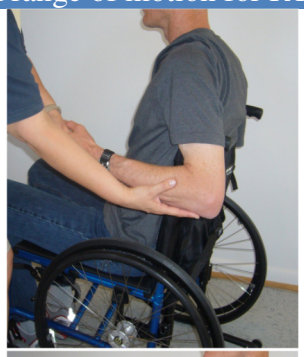
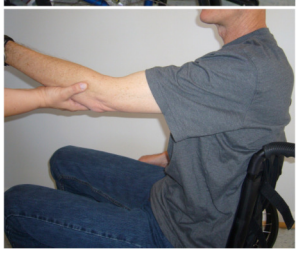
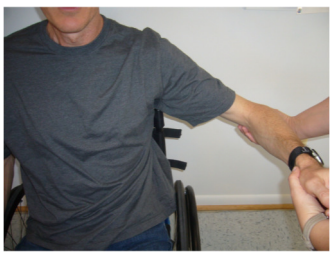
1. Ensure that the wrist is well supported during upper extremity ergometry.

2. Ensure that the hand, wrist and arm adaptations recommended by your clinician are always used.

3. Ensure that the child remains seated straight on towards the ergometer and avoid twisting motion of the forearm and wrist.

If a child complains of wrist pain or if notice any swelling of a wrist during or after upper extremity ergometry consult a clinician immediately.

RT200 range of motion check

Leg range of motion for RT200		Yes / No
	Check that there is enough hip and knee flexion by lifting the leg so that the thigh is raised and the hip and knee are flexed. Make sure this can be done easily without needing to apply significant force. Check each leg.	Left: Right:
	Check that there is enough knee extension by lifting the foot and leg off the ground so that the knee extends. The thigh should remain on the chair. Make sure this can be done easily without needing to apply significant force. Check each leg.	Left: Right:
Arm range of motion for RT200		**Yes / No**
	Check that there is enough shoulder extension by lifting the hand and forearm and moving the arm backwards. Make sure this can be done easily without needing to apply significant force. Check each arm.	Left: Right:
	Check that there is enough shoulder flexion and elbow extension by lifting the hand and forearm and raising the arm while bringing it forward. Make sure this can be done easily without needing to apply significant force. Check each arm.	Left: Right:
	Check that there is enough shoulder abduction (sideways) movement by lifting the hand and forearm and moving them sideways. Make sure this can be done easily without needing to apply significant force. Check each arm.	Left: Right:

CAUTIONS

Caution should be exercised during the treatment of individuals with the following conditions:

1. Patients with any implanted medical device
2. Patients with suspected or diagnosed heart problems.
3. Patients with suspected or diagnosed epilepsy.
4. Patients with history of hip or knee dislocation/subluxation
5. Caution should be used in the presence of the following:

    a) a history of uncontrolled autonomic dysreflexia; Frequent and severe bouts of dysreflexia will disqualify the individual from using the RT200. Consider monitoring the patient's blood pressure and heart rate during initial therapy sessions;

    b) a history of lower limb stress fractures;

    c) a history of severe spasticity or spastic response to application of electrical stimulation;

    d) following recent surgical procedures when muscle contraction may disrupt the healing process.

ADDITIONAL CAUTIONS FOR THE UPPER EXTREMETIES

1. A history of upper limb stress fractures.
2. Uncontrolled hypertension

Special Considerations

Clinical judgment should be utilized to evaluate the potential relevance of the following special considerations:

1. Orthostatic hypotension
2. Ailments where high fever, high blood pressure, or high heart rate are present
3. Respiratory complications
4. A cancerous lesion - stimulation should not be applied over, or in proximity to, cancerous lesions
5. An infection in the area of electrode placement
6. A urinary tract infection – may increase the probability of autonomic dysreflexia during a therapy session

5. Guidelines for undertaking kinetic exercise should also be considered[1].

[1] American College of Sports Medicine, Guidelines for Graded Exercise Testing and Exercise Prescription, 3rd Edition. Lea & Febriger, 1986

PRE-TREATMENT SCREENING TESTS

Patients who are not disqualified by the contraindications should undergo a complete physical and a set of pre-treatment tests to verify their overall health and fitness for the RT200.

The following are recommended minimum pre-treatment tests. The clinician should exercise judgment in evaluating each individual patient:

1. General Physical Examination

2. Physical and/or Occupational Therapy Evaluation
A complete examination is recommended to assess joint range of motion, degree of spasticity, presence of spinal reflexes, residual sensory function, and residual motor function.

3. Sensory Evaluation
If sensory return is present or anticipated to cause discomfort, an optional evaluation may be needed to assess sensory comfort to stimulation.

4. Neurological Evaluation
If the patient has epilepsy a neurological consultation is recommended.

5. Cardiac Evaluation
If the patient has known cardiovascular issues, a cardiac consultation is recommended.

6. 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 the RT200. If there is any doubt as to the presence of a LMN lesion, an EMG should be considered.

7. SMAC 20
The SMAC 20 test is a comprehensive screen (measures 20 substances) used to assess whether blood values are in reference range. Any abnormal values should be reviewed by the patient's physician to determine if the therapy is still recommended.

8. Complete x-rays of the Lower Extremities
AP and lateral views of the femur, tibia/fibula, hips, knees, and ankle joints are recommended to provide evidence of heterotopic ossification or fracture.

9. DEXA scan to support clinical assessment of osteoporosis in the lower extremities.

ADDITIONAL SCREENING TESTS FOR THE UPPER EXTREMETIES

1. Complete x-rays of the Upper Extremities.
AP and lateral views of the ulna, radius, humerus, elbow, wrist and shoulder joints are recommended to provide evidence of heterotopic ossification or fracture

2. DEXA scan to support clinical assessment of osteoporosis in the upper extremities.

Time Post Injury

1. Patients should be at least two weeks post injury and at least 1 week post spine surgery.

2. Patients should demonstrate blood pressure control, e.g. 20 minutes in a standing frame.