RT600 Patient Assessment

510(k) Number: K103366

Device Name: RT600 functional electrical stimulation stepper ergometer

Indications For Use:

The RT600 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 RT600 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 four contraindications which absolutely exclude a patient from utilizing the RT600.

1. Powered muscle stimulators, including the RT600, 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 RT600 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.

4. Partial body weight support is contraindicated when
- when loading of the hip, pelvic, abdominal and chest regions is prohibited
- in the presence of large disc bulge or rupture; groin infection or skin graft in the groin region

RELATIVE CONTRAINDICATIONS

1. Denervated muscle in extremities to be stimulated - muscle contractions will not be evoked by the RT600's stimulation.

2. Severe Spasticity - In most cases, spasticity will not disqualify an individual from using the RT600. 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.

RANGE OF MOTION CHECK

Assessment	Result	
Patient is able to achieve full left hip extension	YES	NO
Patient is able to achieve full right hip extension	YES	NO
Patient is able to achieve full left knee extension	YES	NO
Patient is able to achieve full right knee extension	YES	NO
Available range of left ankle dorsiflexion	__ Degrees	__ Degrees
Available range of right ankle dorsiflexion	__ Degrees	__ Degrees
Available range of left ankle plantarflexion	__ Degrees	__ Degrees
Available range of right ankle plantarflexion	__ Degrees	__ Degrees

CAUTIONS

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

1. Patients with ANY implanted medical device.

2. Patients who exhibit orthostatic hypotension

3. Patients with a history of uncontrolled orthostatic hypotension or autonomic dysreflexia

4. Patients with suspected or diagnosed heart problems

5. Patients with suspected or diagnosed epilepsy

6. Patients with high fever, high blood pressure, or high heart

7. Patients with respiratory complications

8. Patients with a cancerous lesion, noting especially that stimulation should not be applied over, or in proximity to, cancerous lesions

9. Patients with an infection in the area of electrode placement

10. Patients with a urinary tract infection as this may increase the probability of autonomic dysreflexia during a therapy session

11. Patients with gastrointestinal tubes as they may prevent use or require padding

12. Patients with a colostomy as it may prevent use or require padding

13. Patients with an acute hip replacement as it may prevent use or require unbuckling of the groin strap on the affected side

14. Patients with a hip fractures as it may prevent use or require unbuckling of the groin strap on the affected side

15. Patients with Spondylolisthesis as it may prevent use or require modification of harness application

16. Caution should be used in the presence of the following:
    a. history of hip or knee dislocation/subluxation
    b. history of lower limb stress fractures
    c. history of severe spasticity or spastic response to application of electrical stimulation
    d. history of compromised skin integrity

e. when there is a tendency to hemorrhage following acute trauma or fracture; and
f. following recent surgical procedures when muscle contraction may disrupt the healing process

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

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 RT600.

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 RT600. 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.

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

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.

TIME POST INJURY

1. Patient should be cleared by physician for partial body weight supported activity.

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