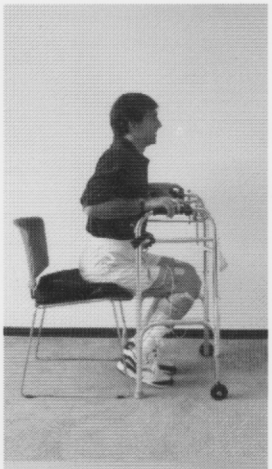
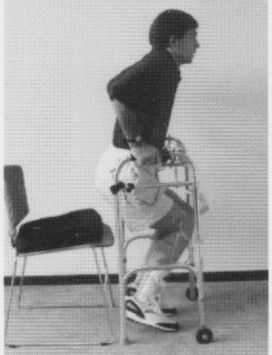
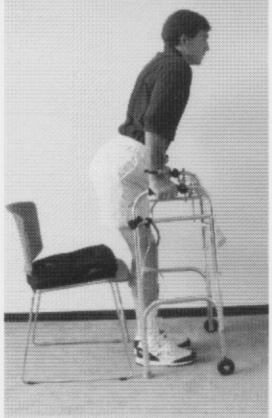
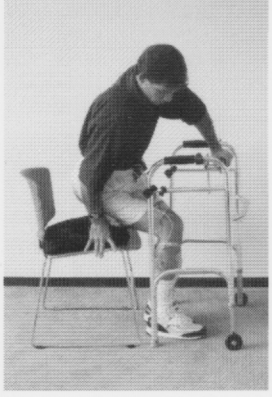
SIGMEDICS, INC.

Rehabilitation Technology for the Spinal Cord Injured









The Parastep® I System

Neuromuscular Electrical Stimulation (NMES)

NMES is a rehabilitation technology that uses low-voltage electrical impulses to evoke a peripheral nerve action potential, which in turn causes a skeletal muscle response. NMES has the potential to provide the spinal cord injured with the ability to stand and ambulate.

The excitability of nerve and muscle tissue provides the basis for the therapeutic use of NMES in spinal cord injury. When the neural pathway between the brain and individual muscles is disrupted or damaged, partial or total loss of voluntary muscle control results. However, a muscle, even when atrophied, may be reactivated and controlled through NMES by means of electrical stimulation applied to peripheral nerves below the level of injury.

How the Parastep I System Works

The Parastep works by delivering microcomputer-controlled electrical pulses through surface (skin)-applied electrodes to nerves and muscles, causing muscle contractions. The computer is programmed to control the sequence of muscle contractions in the lower extremities that enable the functions of sit-to-stand, right and left step, and stand-to-sit. Users are taught to initiate functions by activating commands through switch modules mounted on either side of the walker handle bars.

The system is designed to provide up to 6 channels of stimulation (i.e., stimulate up to 3 muscle groups on each leg). When 6 channels are used, electrical stimulation is directed to 6 electrodes on each lower extremity. Two electrodes are used per muscle group. Stimulation of the quadriceps muscles result in knee extension, enabling the user to stand. Stimulation of nerves in the lower extremity initiates a triple reflex response, resulting in contraction of muscles to flex the hip, knee, and ankle, which lifts the foot off the floor. Subsequent quadriceps stimulation extends the knee in preparation for heel strike and weight bearing. Stimulation of gluteal muscles extends the hips, contributing to stability while standing and taking steps.

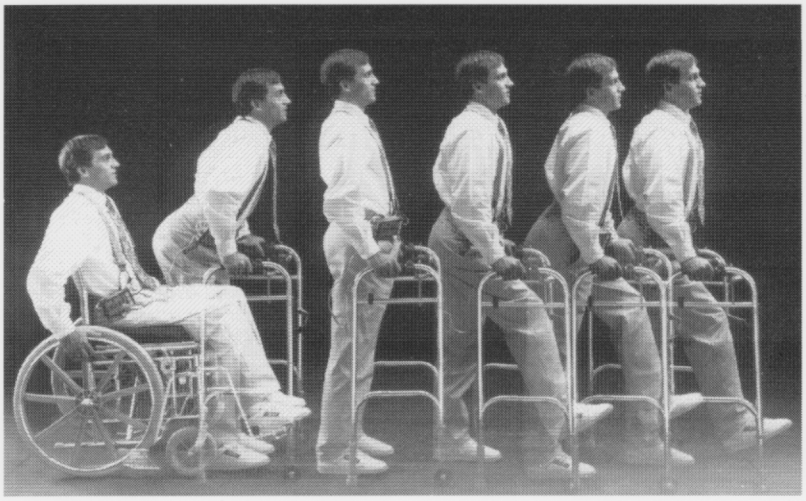
The user initiates and controls the intensity of stimulation to the muscles and nerves through the keypad on the stimulator/control unit or through switch modules mounted on the walker. The walker provides balance and stability during standing and walking.

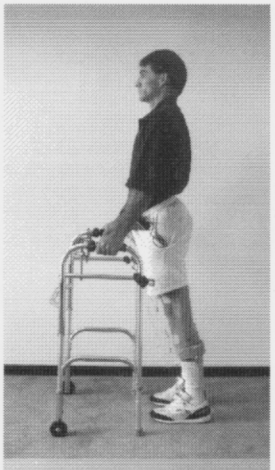
For your guidance, the Parastep I System has received U.S. FDA approval (#P900038) for commercial marketing following a Pre-Market Approval (PMA) submission and multi-center clinical trials. It is the only such device approved specifically for enabling appropriately selected and trained spinal cord injured individuals to stand and ambulate through the use of neuromuscular electrical stimulation.

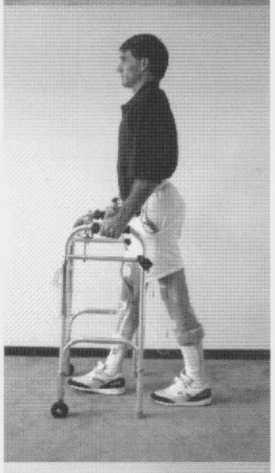
** Please note that the Centers for Medicare and Medicaid Services (CMS) as well as certain other major insurance carriers have announced that as of April 1, 2003 they will cover, under their respective policies, payment for the purchase of the Parastep I System and for the expenses relating to the required physical therapy training for qualifying beneficiaries and clients.*

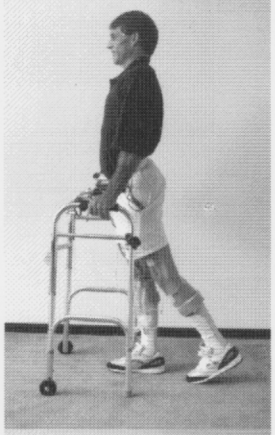
For further information please contact: info@sigmedics.com

www.sigmedics.com

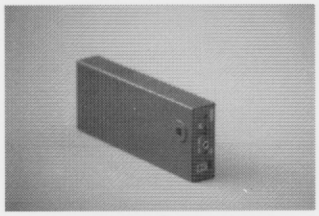


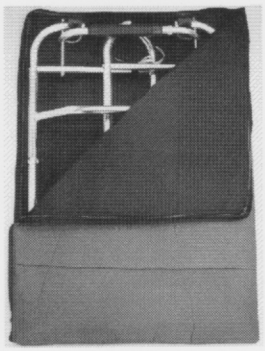






The Parastep® I System - Technical Specifications





Stimulator/Control Unit

Number of output channels: 4 or 6
Output current per channel: 0 to 300 milliamperes at peak of pulse, adjustable
Maximum output current: approximately 300 milliamperes at peak of pulse, internally limited
Maximum open circuit output voltage: 225 volts at peak of pulse, internally limited
Pulse rate (positive and negative phase): 24 pulses per second
Pulse width (each phase): 150 microseconds
Waveform: Alternating, symmetrical with zero net charge
Maximum charge per pulse: 45 microcoulombs at maximum setting
Average current per phase: 1 milliampere at maximum setting
Power Source: Eight (8), 1.2 volts, "AA" rechargeable Ni-Cad cells
Dimensions: 5" x 3" x 1-3/16"
Weight: approximately 8 ounces
All electrical specifications are +/- 10% into 470 Ohms load

Battery Pack

Number of cells: Eight (8), 1.2 volts, "AA" rechargeable Ni-Cad cells
Power pack capacity: 500-700 milliampere hours (nominal)
Time before recharge: approximately 1.3 hours at maximum current output
Recharge current: 50 milliamperes, internally limited
Dimensions: 5-11/16" x 2-5/16" x 3/4"
Weight: approximately 10 ounces

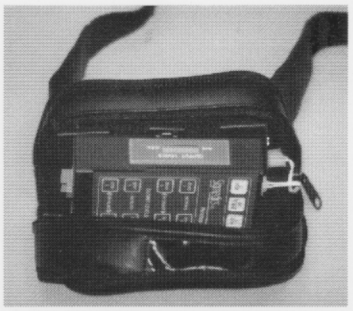
Battery Charger

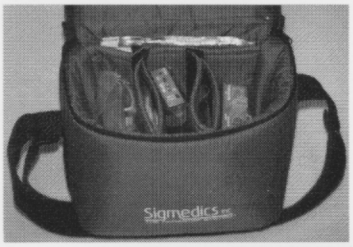
Recharger line voltage: 120 VAC, 60 Hz or 230 VAC, 50 Hz CE
Output: 18 VDC, 50 mA

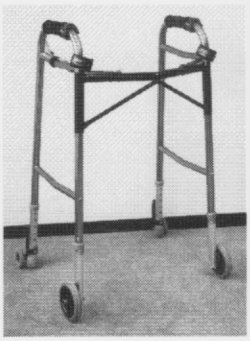
Control and Stability Walker

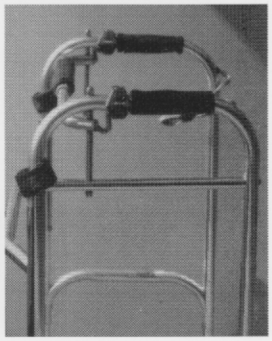
Non-reciprocating standard model:
Height: 32" to 36", adjustable in 1" increments
Base width: 23"
Base depth: Open 16"
Folded 3-3/4"
Inside Grip width: 16-3/4"
Weight: approximately 6.5 lbs.

Non-reciprocating x-wide model:
Height: 32" to 36", adjustable in 1" increments
Base width: 25-1/4"
Base depth: Open 19-1/2"
Folded 3-3/4"
Inside Grip width: 18-3/4"
Weight: approximately 6.5 lbs.









The Parastep® I System - Indications, Contraindications, Warnings, Precautions and Adverse Effects

INDICATIONS FOR USE

The Parastep® I System enables appropriately selected skeletally mature spinal cord injured persons (levels C6-T12) to stand and to attain limited ambulation and/or take steps, with assistance if required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of spinal cord injury. Effective use of the Parastep® I System requires the user to demonstrate (1) adequate trunk control and balance to maintain up right posture while standing and ambulating, and (2) intact flexion withdrawal reflexes in the lower extremities to shorten adequately the limb to initiate taking a step. For safe use of the Parastep® I System, a patient must be able to stand with the assistance of a walker and safely lower himself/herself to the ground without the system operating or have assistance available in the event of device failure. Physicians prescribing the Parastep® I System should be experienced in the rehabilitation management of spinal cord injured patients. In addition, the clinician training the patient is required to complete the Parastep® I System training provided by the manufacturer, Sigmedics, Inc. The effective use of the Parastep® I System to stand and take steps was found to be significantly improved for the 61% of the patients in the preapproval clinical trials who practiced standing and taking steps with the device at home during the period of time they were also enrolled in the physical therapy training sessions.

Caution: Federal law restricts this device to sale by or on the order of a licensed physician.

CONTRAINDICATIONS

1. Cardiac demand pacemaker
2. Cancer in the area of electrode placement
3. Severe scoliosis
4. Severe osteoporosis
5. Skin disease at stimulation sites or over swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, thrombo phlebitis. varicose veins
6. Irreversible contracture
7. Autonomic dysreflexia

WARNINGS

1. Adequate safety measures should be taken in the case of persons with suspected heart or pulmonary problems.
2. Persons known to have or suspected of having heart disease should not receive electrical stimulation without medical evaluation of cardiac status and appropriateness for functional neuromuscular stimulation (FNS).
3. Caution should be used in the transthoracic application of FNS devices, in that the introduction of electrical current into the heart may cause dysrhythmias.
4. Caution should be used in treating persons with suspected epilepsy.
5. Safety has not been established for the use of FNS devices during pregnancy.
6. Patients with sensation may find stimulation to be uncomfortable.
7. The use of electrodes or cables other than those obtained from Sigmedics, Inc. may cause unpleasant or even painful sensations, skin irritations, bums, or cause the device to be ineffective.
8. Do not carry the rechargeable battery in a pocket, purse or place where the battery terminals could be short circuited, or deliberately short circuit these terminals. as intense heat can be generated and fire or injury may result.
9. Do not attempt to recharge any battery other than the original Sigmedics, Inc. system or rechargeable battery that was obtained from Sigmedics, Inc., as alkaline or other non-rechargeable batteries may explode and/or bum when charging is attempted.
10. Never submerge the battery charger in water or any other liquid, or plug the charger into the wall outlet if it has been accidentally submerged or wet by water or other fluid. Allow the charger and system components to dry completely before using or plugging the charger back into the AC wall outlet.
11. Do not stimulate over the carotid sinus nerves, especially in patients with a known sensitivity to the carotid sinus reflex.
12. Do not position electrodes over neck or mouth as severe spasm of the laryngeal and pharyngeal muscles may occur. The contractions may be strong enough to close the airway or cause difficulty in breathing.
13. Do not apply stimulation to the head.
14. Keep the Parasteps® I System out of the reach of children.
15. Caution should be observed in treating patients with vision or hearing impairments which interfere with training.

PRECAUTIONS

1. Precaution should be observed in the presence of the following:
   a. Use in individuals with underlying bleeding diathesis.
   b. Use in individuals who have recently undergone surgical procedures when muscle contraction may disrupt the healing process.
   c. Placement of electrodes over the lower abdomen in women who are menstruating.
2. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced and/or prevented by proper preparation and daily cleaning of the skin at the electrode application site, use of an alternative conductive medium, or alternate electrode placement.
3. A user can expect a reduction of ambulatory ability if the use of the Parastep® I System is interrupted for several months. Under such circumstances, the user should return to the prescribing clinician for reevaluation and/or retraining prior to reuse.
4. The long-term effects of chronic electrical stimulation are unknown.
5. The long-term effects of use of the Parastep® I System on the growth and development of children are unknown.

ADVERSE EFFECTS

1. Skin irritation may occur at the electrode application site.
2. Improper use of electrodes may result in skin burns at the electrode application site.
3. Use of the Parastep® I System by persons with severe osteorporosis may result in fracture.
4. Use of the Parastep® I System by spinal cord injured persons may result in bruises sustained as a result of a fall(s).
5. Use of the Parastep® I System by persons with impaired sensation may result in soft tissue injury.
6. Use of the Parastep® I System may result in bone fracture(s).