Sigmedics, Inc.

The Parastep® System

User's Manual

0594.1

Dear User:

Congratulations on your purchase of a Parastep® System (herein after referred to as the "Parastep"), a patented microcomputer-controlled functional neuromuscular stimulation (FNS) system to stand and to attain limited ambulation and/or take steps, with assistance if required. We at Sigmedics, Inc. are very proud of this product and sincerely believe that by using the system regularly, you will become more proficient with it, and it will enhance your life-style.

The Parastep was developed by Daniel Graupe, Ph.D., Professor of Electrical Engineering and Computer Science, and Professor of Biomedical Engineering at the University of Illinois at Chicago. The system is the result of many years of laboratory study at the University of Illinois and clinical trials at Humana-Michael Reese Hospital and Medical Center, Chicago.

Sigmedics, Inc., was incorporated in 1988 to design, manufacture, and market rehabilitation products for the spinal cord injured. The organization is committed to producing high-quality products to meet your needs, providing you with up-to-date user information, and offering you the finest in customer service and support.

The Parastep was designed to emphasize safety and simplicity of use. In our efforts to further enhance and refine it, we welcome your input. If, as you become more proficient with the Parastep, you have questions or suggestions, please share them with us in writing or by calling:

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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, burns, 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 burn 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 Parastep® 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 osteoporosis 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).

I. Background

The Parastep is a patented microcomputer-controlled functional electrical stimulation system that enables unbraced standing and short-distance walking by upper-motor-neuron-injured paraplegics and some incomplete quadriplegics. It has the capability of directing up to 6 channels of electrical stimulation, and with the aid of a specially adapted control and stability walker, it enables the user to stand from a sitting position, walk short distances, and resume a sitting position.

Functional Neuromuscular Stimulation (FNS)

FNS 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. FNS has the potential to provide 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 FNS 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 FNS by means of electrical stimulation applied to peripheral nerves below the level of injury.

FNS systems generally include a stimulator that generates and varies electrical pulses and electrodes that can be attached to the skin surface.

How the Parastep® 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 the walker.

The system is designed to provide up to 6 channels of stimulation (i.e., stimulate up to 3 muscle groups on each leg). However, some individuals may require only 4 channels of stimulation to stand and ambulate.

When 4 channels are used, electrical stimulation is directed to 4 electrodes on each lower extremity. Stimulation of the quadriceps muscles results in knee extension, enabling the user to stand. Stimulation of nerves in the lower extremity initiates a 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 weight bearing.

When 6 channels of stimulation are used, electrical stimulation is directed to the previously mentioned sites and to two additional electrodes on each hip. 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.

II. Training to Use the Parastep® System

Evaluation

Learning to use the Parastep safely and effectively requires the coordinated effort of many people:

- The user;
- The physician who prescribes the system;
- The Parastep Clinical Program staff, including administration, physician, and physical therapist; and
- The staff of Sigmedics Inc., including clinical, technical, and user support personnel.

The most important member of the team is the user, whose physical condition, motivation, and commitment to the program ultimately will determine the activities of the entire team.

In most instances, the process begins with the patient's primary care physician. After discussing the Parastep program with their physician, potential users shall decide if the System could be of benefit to them. Potential candidates for the Parastep System include people with spinal cord injuries from C6 to T12.

If the user decides to pursue the program, the physician will refer him or her to a Parastep Clinical Program for evaluation by a physician and physical therapist experienced in rehabilitation medicine. The clinical evaluation includes examination of:

- Musculoskeletal integrity
- Range of motion
- Muscle contractile response to FNS
- Sensory perception of electrical stimulation to be sure that it will allow a sufficient level of stimulation to contract muscles
- Cardiorespiratory capacities
- Spasticity
- Learning capability to operate the system
- Motivation

Candidates also must demonstrate the following functional abilities:

- Sufficient muscle force production at the hip and knee for functional movement under FNS
- Adequate cardiopulmonary reserve
- The ability to transfer independently
- Adequate standing tolerance
- Balance and trunk control
- Hand/finger dexterity to manipulate system controls

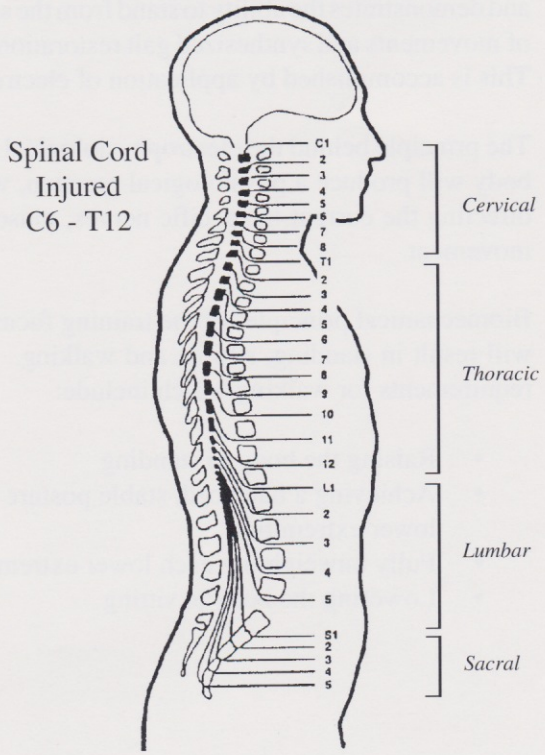

Figure 1

Once accepted into the Parastep Clinical Program, candidates receive 32 sessions of physical therapy training from a physical therapist, who will review and instruct the user in the operation of the system and gait techniques.

Muscle Reconditioning

Muscle reconditioning is required in preparation for gait training with the Parastep. Among the effects of paralysis and the inactivity secondary to spinal cord injury are muscle atrophy and reduced efficiency of other body systems, such as the cardiovascular and respiratory systems. Before potential Parastep users can attempt to learn to walk with the system, they must improve physiological functions to acceptable levels.

Through a therapist-prescribed program of therapeutic exercise, users will gradually improve these physiological functions. For example, early in the reconditioning program, users may find they become easily fatigued because of their diminished cardiovascular efficiencies. By following the physical therapist-prescribed exercises, users will develop endurance. The time frame for this progress will differ between individuals. The therapeutic exercise is an integral component of successful use of the system and overall well-being.

Gait Training

Once the physical therapist has determined that the user has regained sufficient strength and endurance, and demonstrates the ability to stand from the seated position, the training sessions will progress to control of movements and synthesized gait restoration. At this point, users will learn to walk under FNS control. This is accomplished by application of electrophysiological and biomechanical principles.

The principle behind the electrophysiological approach is that an electrical current applied to the human body will produce a physiological reaction, which can result in a series of muscular contractions. By directing the current to specific nerves, muscle activity can be coordinated for synergistic multi-joint movement.

Biomechanical principles of the training focus on learning the specific coordination of movements that will result in standing, sitting, and walking. Each user will successfully demonstrate the preliminary requirements for walking which include:

- Raising the body to standing
- Achieving a balanced, stable posture with 90% or more of the body's weight supported by the lower extremities
- Fully unweighting each lower extremity
- Lowering the body to sitting

The fundamental requirements of reciprocal gait that will be covered in the training include:

- Preventing collapse or toppling of the body
- Initiating forward momentum
- Controlling movement during forward progression
- Shortening the limb for swing-through during step-taking
- Advancing the swing leg
- Advancing the trunk over the stance leg

By working closely with the physical therapist, the user will determine how to achieve the most effective electrical stimulation level and technique for standing and short-distance walking. With training and practice, the user will master the biomechanical aspects of using the Parastep.

Functional Achievements

Upon successful completion of the Parastep Clinical Program, the user will be able to use the Parastep safely for standing, step-taking, and short-distance walking. These results may contribute to enhancing activities in daily living (ADL) ability. However, it is important to realize that the achievements of each user depend primarily upon his or her commitment to physical reconditioning and practicing with the Parastep.

III. Components of the Parastep® System

The Parastep comprises seven primary components. Carrying cases for the system components and the walker are provided with the system. An optional waist pouch for holding the stimulator/control unit and battery pack together while using the system, the Parapack™, is available through Sigmedics, Inc.

Stimulator/Control Unit

Photo #1a

The stimulator/control unit contains the microcomputer, software (firmware) and associated electronics that generate the electrical impulses, control the intensity of the stimulation, and activate all functions. Keys on the keypad *(Photo #1a)* allow the user to increase and decrease levels of stimulation to the muscles of the lower extremities for standing and step-taking. The stimulation intensity level is displayed by a 10-bar light emitting diode (LED) panel on the side of the unit *(Photo #1b)*.

Photo #1b

Battery Pack

Photo #2a

A rechargeable battery pack that powers the system contains 8 AA nickel cadmium batteries and is connected to the stimulator/control unit with a power cable *(Photo #2a)*. A built-in low battery alarm indicates when recharging is necessary by sounding an intermittent beep. A normal charge allows approximately 2 hours of use with a 4-channel system and approximately 1 hour of use with a 6-channel system. A green ON indicator and red CHARGE indicator are located on the top face of the unit *(Photo #2b)*.

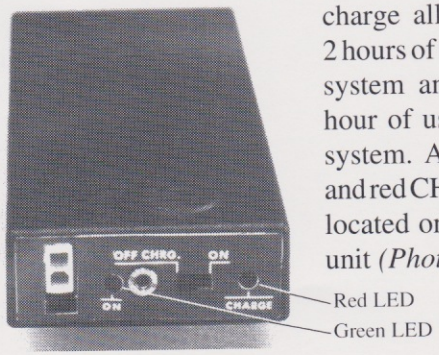

Photo #2b

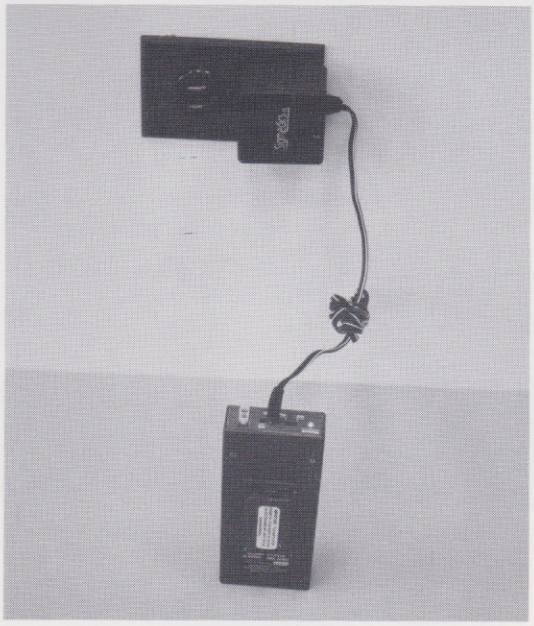

Photo #3

Battery Charger

This unit works like other battery chargers. Connect the recharger firmly into the jack on the battery pack and plug the other end into any household outlet *(Photo #3)*. The red CHARGE indicator on the battery pack will remain lit during charging. The battery pack should be charged initially for at least 12 hours and then every evening for the next day's use. The on/off switch should be on the "OFF CHRG" position when the battery pack is being charged.

CAUTION: Never charge the battery pack when it is connected to the stimulator/control unit or when the system is being operated. Do not leave the charger plugged into the wall outlet when not re-charging the battery pack.

Electrode Leads and Electrodes

Electrode leads connect the stimulator to electrodes. Each lead is color coded for the right and left leg and will connect to four electrodes on each extremity. One lead with four equal lengths will connect to electrodes on the hips for 6-channel use *(Photo #4a)*.

- The electrode lead with the BLACK protective hood is plugged into the jack on the stimulator/control unit marked LEFT.
- The electrode lead with the RED protective hood is plugged into the jack on the stimulator/control unit marked RIGHT.
- The electrode lead with the BLUE protective hood to the hip electrodes is plugged into the raised input jack on the stimulator/control unit *(Photo #4b)*.

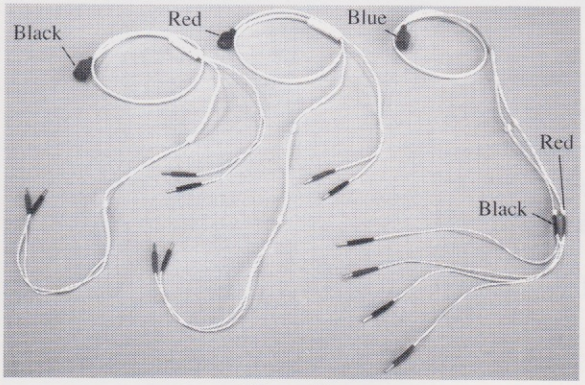

Photo #4a

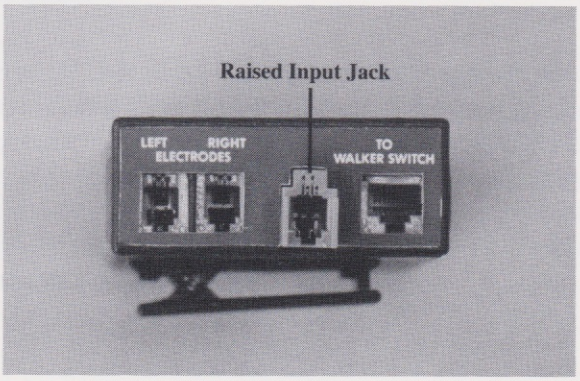

Photo #4b

Self-adhesive, reusable skin electrodes also are included *(Photo #5)*. Two electrodes are placed on each quadriceps muscle above the knee of each leg and two are placed on each lower leg for 4-channel use. Two additional electrodes are placed on each hip's musculature for 6-channel use.

CAUTION: Always be sure the Parastep is turned off before connecting electrode leads to electrodes.

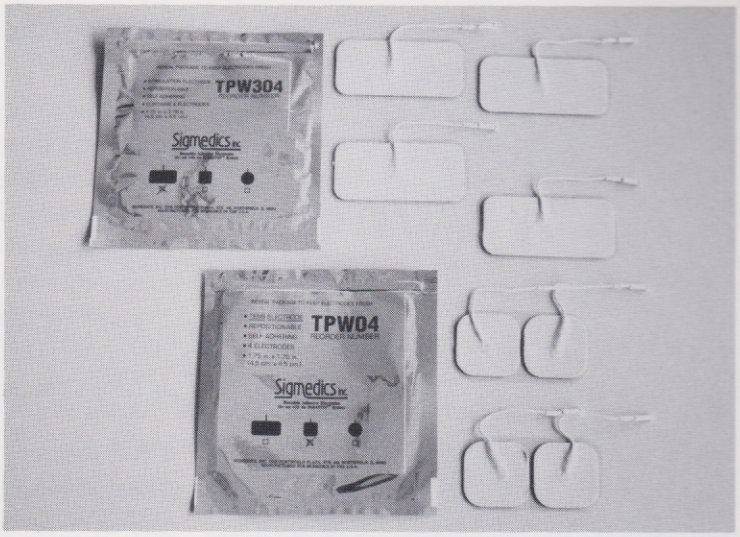

Photo #5

Power Cable

The power cable has two identical pronged plugs to connect the stimulator/control unit to the battery pack. A shorter power cable is available for use when carrying the stimulator/control unit and the battery pack in the Parapack™ *(Photo # 6)*.

CAUTION: Always be sure the battery pack is turned off before connecting the stimulator/control unit to the battery pack.

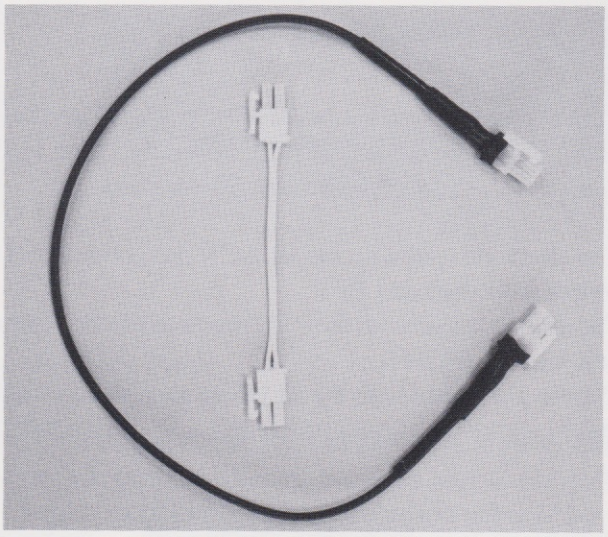

Photo #6

Control and Stability Walker

A specially electronically adapted folding walker allows the user to stand and to ambulate for short distances *(Photo #7a)*. It is connected to the stimulator/control unit via a flat cable that is part of the walker and is plugged into the jack in the stimulator/control unit labeled TO WALKER SWITCH. Hand-controlled switch modules are located immediately in front of the handlebar grips on the left and right sides of the walker *(Photo #7b)*. The buttons on these switch modules operate in a similar manner as the keys on the keypad of the stimulator/control unit, to activate sit/stand, stand/sit, cancel sit, right step, and left step functions. Stimulus intensity is also controlled through the buttons on these remote hand switch modules.

CAUTION: Always be sure the battery pack is turned off before connecting the walker to the stimulator/control unit.

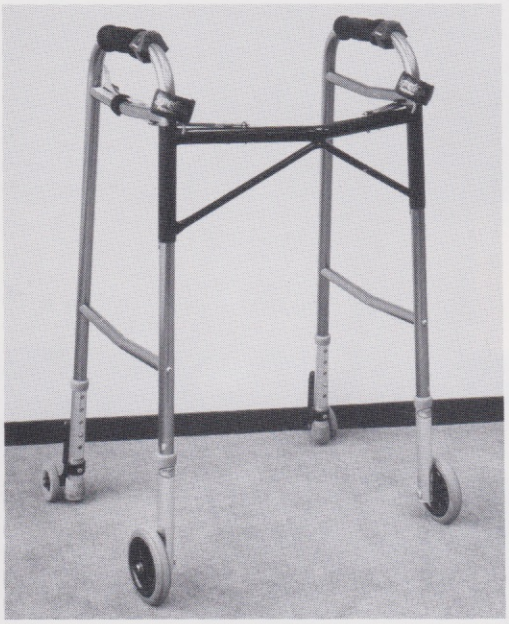

Photo #7a

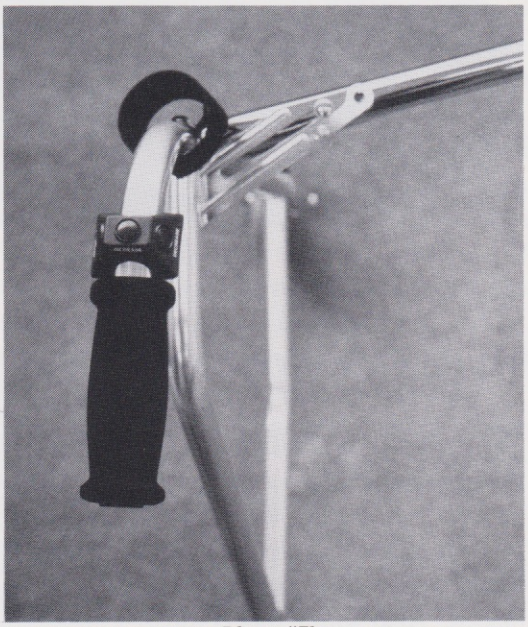

Photo #7b

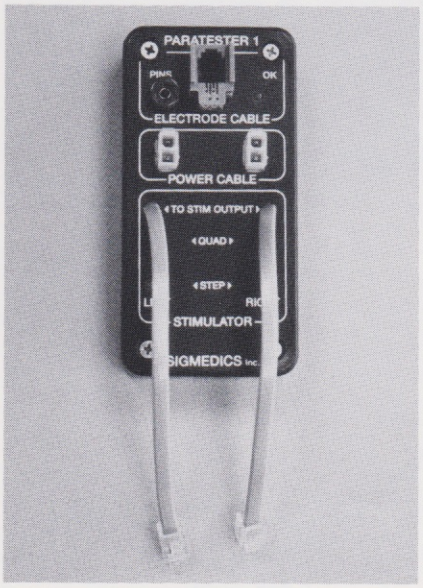

Photo #8

The Paratester™

The Paratester is a self-contained, battery-operated diagnostic tool to test electronic components of the stimulator/control unit, proper operation of the switch control modules, and the continuity and integrity of leads and cables *(Photo #8)*. It should be used once daily before using the system or as a diagnostic tool if the system is not functioning properly. Specific directions on use of the Paratester are included in the next section of this manual.

Carrying Cases

A small, rectangular, lightweight carrying case has compartments for each of the hand-held components of the Parastep, cables, electrode leads and electrodes *(Photo #9a)*. A separate lightweight case is provided to hold the folding walker when not in use *(Photo #9b)*.

Photo #9a

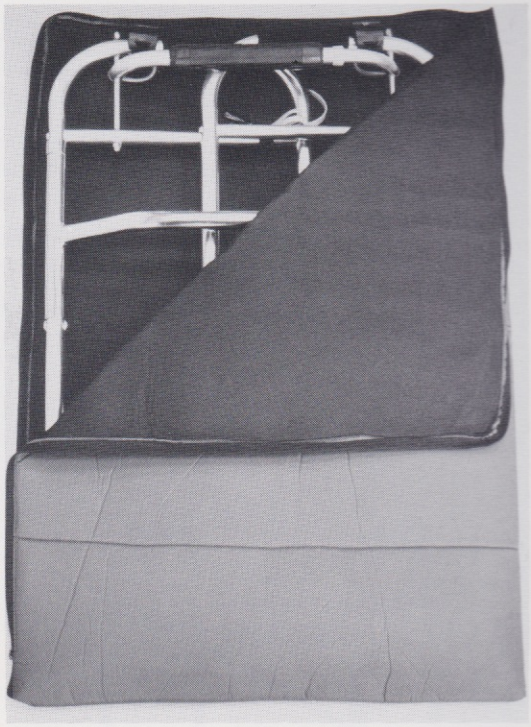

Photo #9b

The Parapack™ (Optional)

The Parapack is available for carrying the stimulator/control unit and battery pack during use *(Photo # 10)*. It has one compartment in which the stimulator/control unit is placed. Also within that compartment are elastic straps. The battery pack is held securely by these straps. The **shorter power cable** should be used to connect the stimulator/control unit to the battery pack when using the Parapack.

Photo #10

IV. Verifying Parastep® System Functioning

Using the Paratester™

The Paratester will verify the output of the stimulator/control unit, proper operation of the walker switch modules, and the integrity of the system's leads and cables. It should be used each time prior to system use to be sure the system components are functioning properly. Additionally, if the system is not working correctly, the Paratester will help to identify the problem.

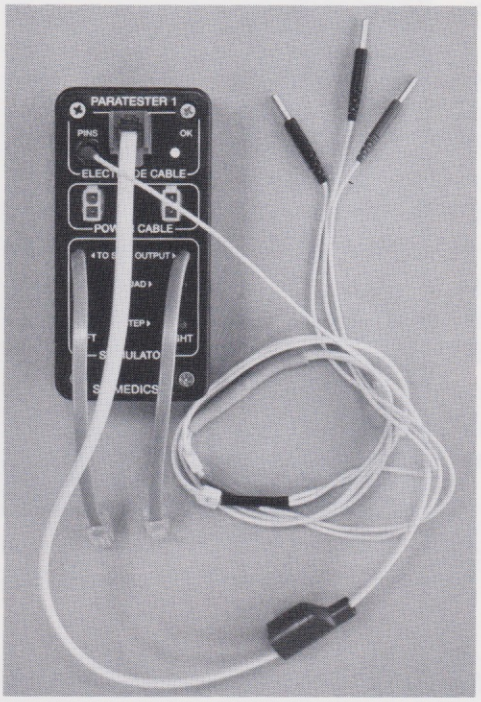

Photo #11

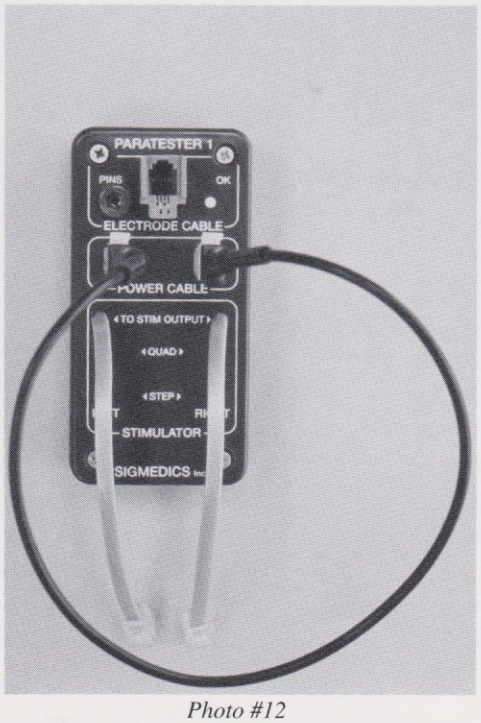

Photo #12

A. **Electrode leads:** Test each electrode lead separately in the upper section of the Paratester *(Photo #11)*:

- Insert the end of the lead with the protective hood into the gray jack and one of the four lead pins into the red jack marked PINS. The green LED marked OK will light. **If it does not, the electrode lead will need to be replaced.**
- Gently hold the rubber jacket of the inserted pin and move it left and right of center with enough force to bend the jacket slightly. This will determine whether the wires are intact. **If the LED blinks or turns off, do not use the electrode lead; it may be defective.**
- **Repeat this procedure for the other pins and for the remaining electrode leads.**
- If any of the leads are found defective, please contact the Sigmedics, Inc. Customer Service Department for new electrode leads.

B. **Power cable:** Test the power cable in the middle section of the Paratester *(Photo #12)*:

- Insert either end into the RIGHT jack and lock it in place. The green LED marked OK **should not** light up. If the green LED marked OK lights, there may be a short in the cable or the cable may be otherwise defective; do no use the cable.
- If the green LED does not light, insert the other end of the cable into the LEFT jack and lock it in place. The green LED marked OK should light now. If it does not, the cable does not conduct electricity and will need to be replaced.
- Gently move the cable from side to side several times. If the LED blinks or turns off, do not use the cable; it may be defective.
- Contact the Sigmedics, Inc. Customer Service Department for a new cable.

C. Stimulator/control unit: Before testing the stimulator/control unit, connect it to the battery pack. **CAUTION: Turn off the battery pack before making any connections.** Test the stimulator/control unit in the lower section of the Paratester *(Photo #13)*:

- Plug the cables from the Paratester labeled TO STIM OUTPUT into the RIGHT and LEFT channels, respectively, at the bottom side of the stimulator/control unit.
- Turn on the battery pack.
- Press and release the SIT/STAND key on the keypad of the stimulator/control unit. Both red LEDs on the Paratester marked QUAD should glow (flicker rapidly on-off).
- Press and release the L STEP key on the keypad. The red LED on the LEFT side of the Paratester should be interrupted momentarily while the LEFT STEP green LED should glow continuously for 1/2 to 1 second, depending on step duration. The RIGHT QUAD red LED should remain glowing.
- Repeat this procedure to test the R STEP key on the keypad. The RIGHT QUAD red LED should be interrupted momentarily while the RIGHT STEP green LED glows continuously for 1/2 to 1 second, depending on step duration. The LEFT QUAD red LED should remain glowing. **If any of the LEDs fails to respond properly, do not use the stimulator/control unit; it may be defective**.
- Contact the Sigmedics, Inc. Customer Service Department if the stimulator/control unit tests defective to arrange for service.

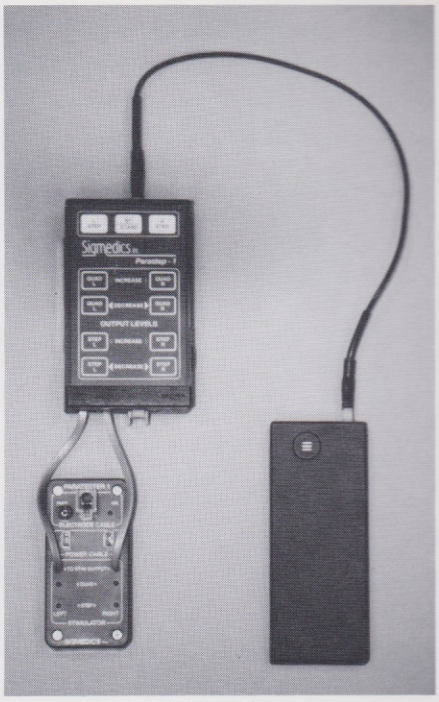

Photo #13

An additional test should be performed if 6 channels of stimulation are being used *(Photo #14)*:

- Connect the left cable from the Paratester marked TO STIM OUTPUT to the hip channel (protruding) jack on the bottom side of the stimulator/control unit. Leave the other cable from the Paratester unconnected.
- Turn on the battery pack.
- Press and release the SIT/STAND key on the keypad of the stimulator/control unit. Both red and green LEDs on the LEFT side of the Paratester should glow.
- Press and release the R STEP key. The LEFT QUAD red LED should stop glowing momentarily, while the LEFT STEP green LED should glow continuously.
- Repeat this procedure to test the L STEP key on the keypad. The LEFT STEP green LED should be interrupted momentarily while the LEFT QUAD red LED glows continuously. **If the two LEDs fail to respond properly, do not use the stimulator/control unit; it may be defective.**
- Contact the Sigmedics, Inc. Customer Service Department if the stimulator/control unit tests defective to arrange for service.

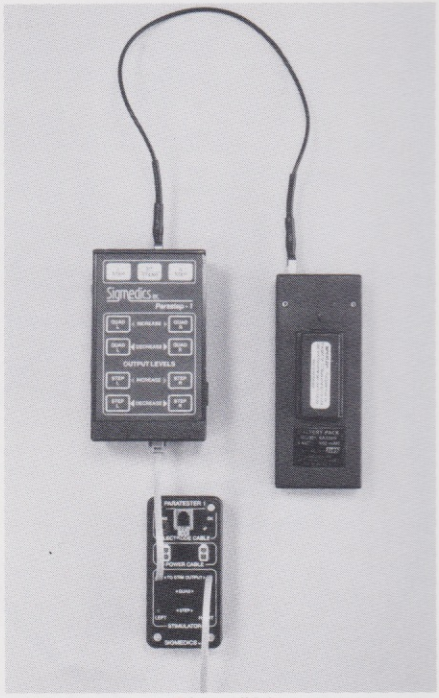

Photo #14

NOTE: Proper function of the walker (left and right) switch modules can be ascertained by following the same procedures described in Section C (previous page) with the exception of also connecting the walker cable into the stimulator/control unit jack marked TO WALKER SWITCH and initiating all commands from the walker switch modules (through button depression) rather than through the keys on the stimulator/control unit keypad. CAUTION: Before testing the proper function of the walker switch modules, please ensure that the procedures described in Section C (previous page) have been satisfactorily performed. This assures that the stimulator/control unit is properly functioning prior to the initiation of the walker switch modules test.

Testing the Paratester™

If it appears that the Paratester is not functioning:

- Remove the four screws at the corners of the face of the unit, open it up and replace the two AAA size internal batteries. Reinstall the cover, secure with the screws and repeat the test (see next section on "Replacing the Batteries"),
- If the test fails again, the Paratester is defective.
- Contact the Sigmedics, Inc. Customer Service Department to arrange for service.

Replacing the Batteries

Internal batteries for the Paratester should be replaced each year, before the light intensity of the green LED marked OK becomes too dim to be seen clearly:

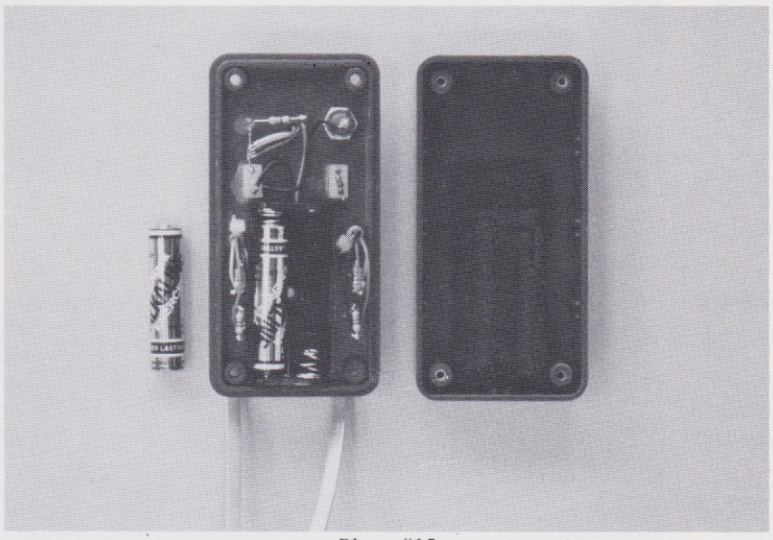

Photo #15

- Open the top panel of the Paratester by removing the four corner screws.
- Carefully remove and properly discard the two existing batteries and replace them with two new AAA alkaline cells. Be sure to observe proper polarity markings (+ and - signs) when inserting the cells into the battery holder.
- Reinstall the cover and secure the top panel with the four screws. *(Photo #15)*

CAUTION: Do not try to replace the batteries while using the Paratester.

V. Parastep® System Set-up

Before the Parastep can be used, electrodes must be placed in their proper positions and all components connected.

CAUTION: Do not turn the system on until all components are connected properly. Turn the system off before disconnecting any components or moving electrodes.

Placing the Electrodes

Electrode placement is critical for effective muscle and nerve stimulation. The physical therapist will determine the appropriate sites for each user's particular needs. Two quadriceps electrode sites and two lower leg electrodes sites will be determined for each leg when using a 4-channel system. When using a 6-channel system, two additional sites will be determined for hip stimulation. Electrode placement will vary from person to person and ultimately will affect the quality of the movement produced. The following guidelines provide a general idea of where the electrodes should be placed to provide stimulation for specific Parastep functions.

Knee extension: The quadriceps muscle extends the knee to enable the user to perform sit-to-stand and keeps the knee extended during standing. The quadriceps muscle also will flex the hip if the contraction is too intense. Optimal electrode placement ultimately is determined by the maximum force (knee extension) produced with the least amount of stimulation. Two electrodes are placed over the anterior thigh, far enough apart to cause the entire muscle to contract when stimulated *(Photo #16)*. Care must be taken to control placement so as to avoid stimulation of other muscles of the thigh, hips, or abdomen.

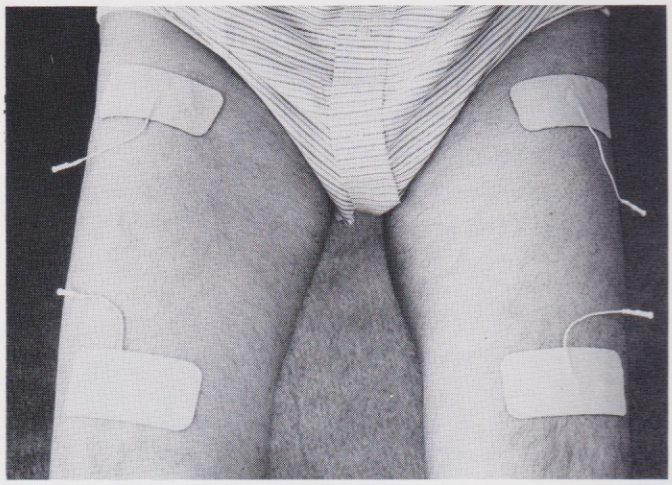

Photo #16

Stepping: Step-taking with the Parastep is a two-part process that involves shortening the limb and swinging the lower leg forward. Limb-shortening is achieved through a reflex contraction of the hip, knee, and ankle, causing each joint to flex. This is known as the flexion withdrawal reflex and is stimulated by a burst of electrical impulses to the sensory nerves of the lower extremity. Although the reflex occurs naturally in everyone, response to stimulation is unique to the individual. The physical therapist will determine where electrodes should be placed to maximize the reflex withdrawal response. Generally, stimulation of the pero-

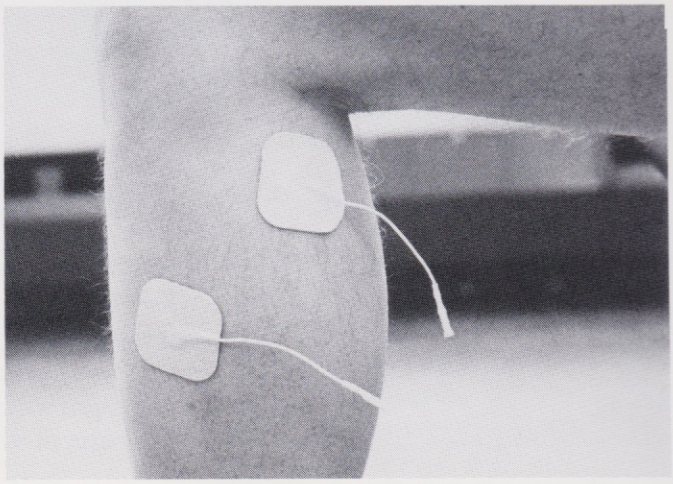

Photo #17

neal nerve behind the fibula head and the area over the anterior tibialis muscle are effective starting placements *(Photo #17)*. Once the leg has shortened reflexively, knee extension through the previously noted quadriceps stimulation sites will swing the lower leg forward in preparation for stepping on to the advanced foot.

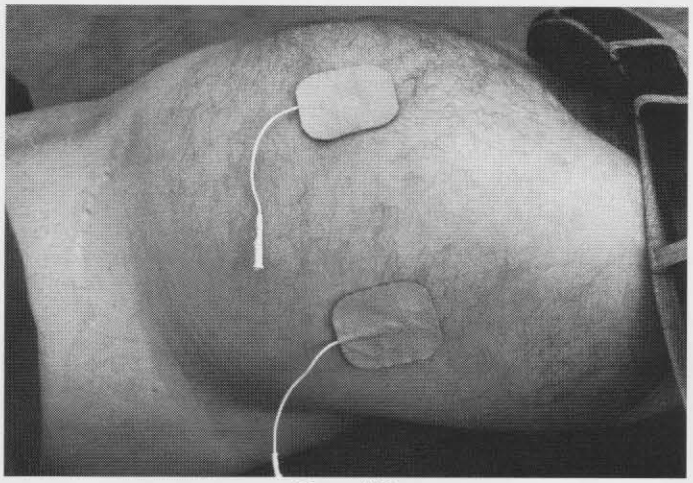

Photo #18

Hip control: Some users will require stimulation of the hip musculature to control hip and trunk position while standing and stepping. This is accomplished **only with a 6-channel system** through use of the two hip channels, which directly stimulate the muscles of the hips and lower back. Electrode placements will be specifically determined to balance the contribution of these muscles to the intended associated movements. Generally, two electrodes are placed on each hip over the gluteus medius and gluteus maximus muscles to keep the hips forward and level while standing and stepping *(Photo #18)*.

Connecting the Leads to the Electrodes

To avoid confusion, it is best to connect the leads to one leg at a time. **For 4-channel use**, start by connecting the top quadriceps electrode and move down to the shin electrode:

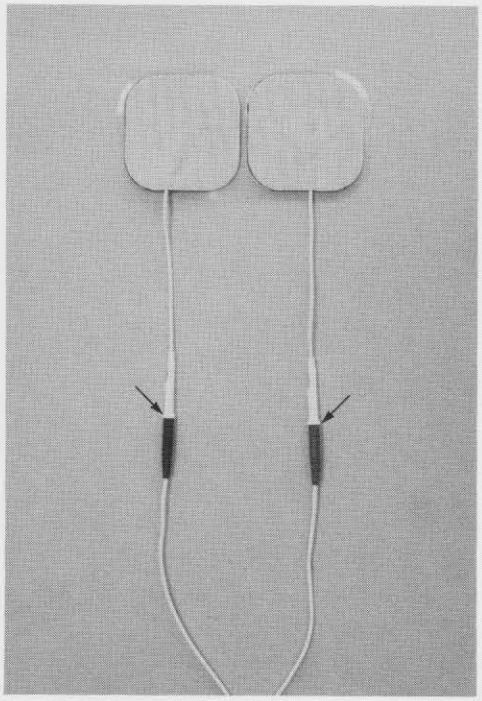

Photo #19

- Select the electrode lead with the BLACK protective hood for left leg connections.
- Connect the short lead with the black pin to the upper quadriceps electrode and the short lead with the red pin to the lower quadriceps electrode.
- Connect the long lead with the black pin to the peroneal electrode and the long lead with the red pin to the shin electrode.
- Repeat the same procedure on the right leg, using the electrode lead with the RED protective hood.

NOTE: Always verify that correctly colored leads are connected to the correct electrodes.

CAUTION: Be sure that all electrode lead pins are fully inserted and securely connected to the electrode connectors *(Photo #19)*.

For 6-channel use, start by connecting the top quadriceps electrode, move down to the shin electrode, then connect the hip leads. Choose the electrode lead with four equal lengths to connect to the hip electrodes:

- Connect the two leads with BLACK sleeve marker to the hip electrodes on the left side of the body.
- Connect the two leads with RED sleeve marker to the hip electrodes on the right side of the body.

NOTE: Always verify that the correctly colored lead sleeve markers are connected to the correct electrodes.

CAUTION: Be sure that all electrode lead pins are fully inserted and securely connected to the electrode wire connectors *(Photo # 19)*.

Connecting the Leads to the Stimulator/Control Unit

- Run the electrode cables from each leg (4-channel use) and from each leg and the hip (6-channel use) through the waistband of slacks or shorts.
- Retract the BLACK protective hood from the lead on the left leg and plug it into the jack on the bottom side of the stimulator/control unit marked LEFT ELECTRODES.
- Retract the RED protective hood from the lead on the right leg and plug it into the jack on the bottom side of the stimulator/control unit marked RIGHT ELECTRODES.
- Retract the BLUE protective hood from the lead on the hip and plug it into the unmarked protruding jack on the bottom side of the stimulator/control unit *(Photo #20)*.

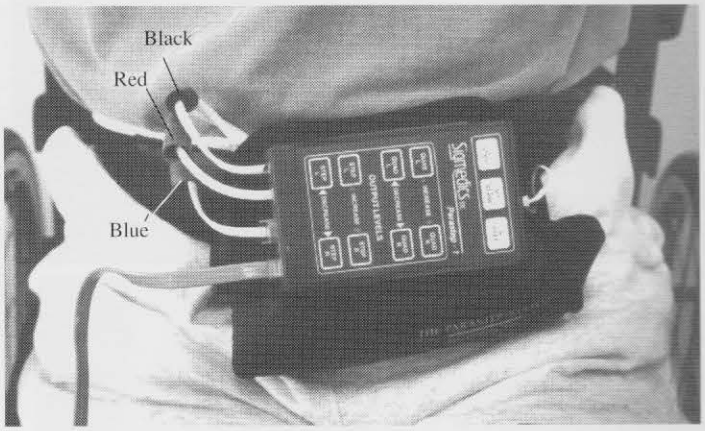

Photo #20

NOTE: Tug gently on each of the electrode leads to be sure that they are connected securely to the stimulator/control unit.

Connecting the Stimulator/Control Unit to the Battery Pack

- Grasp either plug of the power cable and insert it into the jack on the top of the stimulator/control unit so that it locks into place.
- Insert the other plug of the power cable into the matching jack on the battery pack *(Photo #21)*. The connection is secure when the plastic lock on the cable plug snaps into place. Remember to use the shorter power cable for connecting the stimulator/control unit to the battery pack if the Parapack will be used while operating the Parastep.

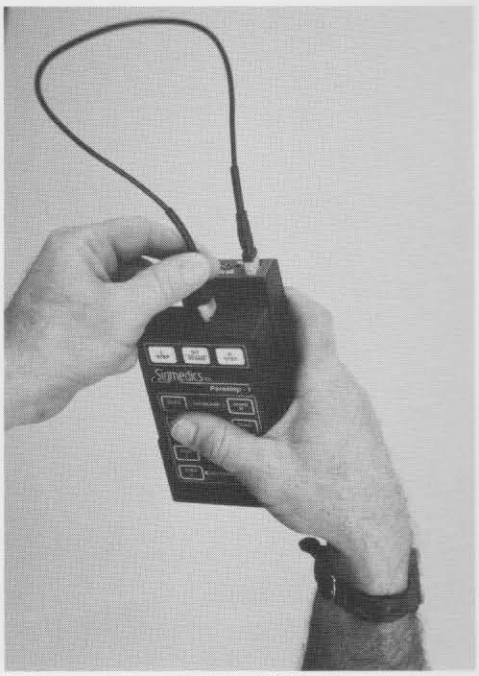
Photo #21

NOTE: Tug gently on the connecting cable to be sure the walker and the stimulator/control unit are connected securely.

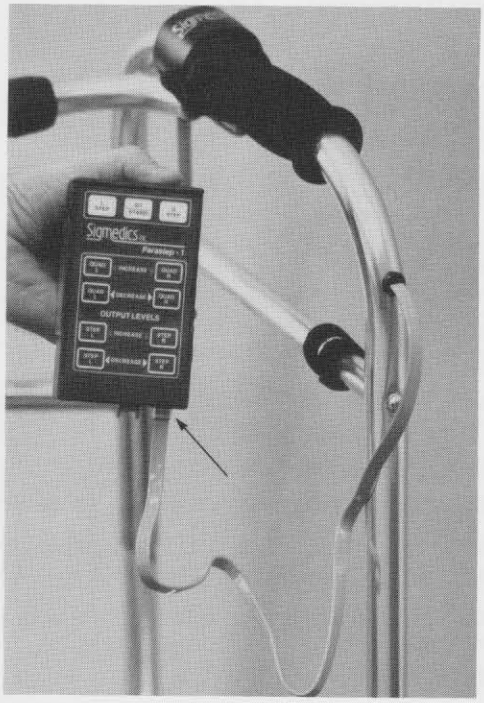

Photo #22

Connecting the Walker to the Stimulator/Control Unit

- Unfasten the strap that secures the connecting cable in place on the right side of the walker, remove the protective cover from the cable plug, and refasten the cover in place with the strap on the walker.
- Insert the walker plug into the jack on the bottom side of the stimulator/control unit marked TO WALKER SWITCH *(Photo #22).*

NOTE: Tug gently on the connecting cable to be sure the walker and the stimulator/control unit are connected securely.

Turning on the Battery Pack

After verifying that all leads and cables are properly and securely connected:

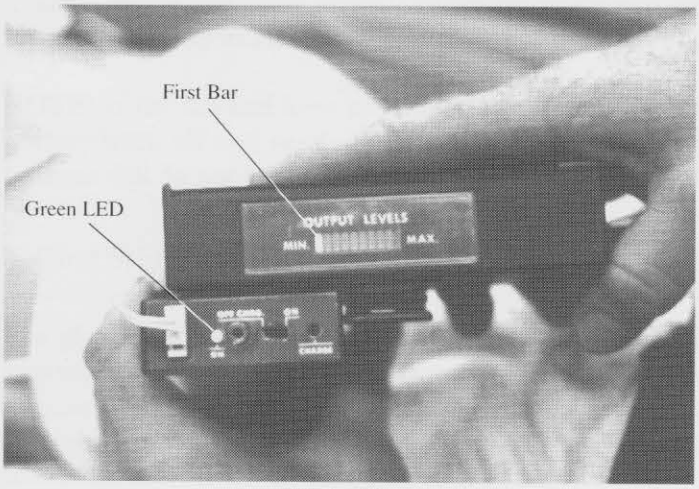

Photo #23

- Place the battery pack into a pocket or clip it to the pants' waistband. If placing it in the Parapack, remove the clip by inserting a pin (a straightened paper clip will also work) into the pinhole marked with the arrow above the clip and pressing down (instructions are provided by relief lettering on the back cover of battery pack). Place the battery pack with the serial number facing toward the body and the cable connector facing left.
- Turn on the battery pack. A green LED will light at the top face of the battery pack and the first bar of the LED panel on the side of the stimulator/ control unit will light briefly *(Photo # 23).*

NOTE: If either of the LEDs does not light, turn off the battery pack and recheck all lead and cable connections. Turn on the battery pack again. If either of the LEDs still does not light, turn off the battery pack and use the Paratester to check the electronic components of the stimulator/control unit and the continuity and integrity of the leads and cables.

Disconnecting the Parastep® System

After completing a session with the Parastep, disassemble the system by these steps:

- Turn off the battery pack.
- Disconnect the walker cable from the stimulator/control unit, attach the cover on the cable plug, and refasten the cable on the walker with the strap.
- Disconnect the power cable between the stimulator/control unit and the battery pack by depressing (unlocking) the angled catches over the prongs on the power cable connectors and gently pulling the power cable connectors out of the battery pack and stimulator/control jacks.
- Disconnect the electrode leads from the stimulator/control unit.
- Carefully replace the protective rubber hoods over the plugs of the electrode leads. The protective covers prevent accidental breakage of the plastic locking clips on the plugs.
- Carefully disconnect cable leads from electrodes so as not to bend the pins.
- Carefully remove electrodes from skin so that you do not damage the electrode wire lead or adhesive ("peel off" electrodes by gently lifting them from one corner).
- Place electrodes back on their plastic liners, reinsert in the foil pouch and reseal the pouch to help maintain good electrode condition.
- Carefully coil the electrode leads and the power cable and place them in their storage bags.
- Remove the stimulator/control unit and the battery pack from the waistband or Parapack.
- Replace all components of the system into their appropriate compartments in the components carrying case.

CAUTION: Never attempt to disconnect any part of the Parastep while the battery pack is turned on.

VI. Preparation for Using the Parastep® System

During the user's first few sessions with the Parastep, the physical therapist may hold and operate the stimulator/control unit, which will be connected to the electrode leads through a set of extension cables. When the therapist determines that the user can stand safely and understands how to use the controls on the keypad of the stimulator/control unit and the switch modules on the walker, he or she will instruct the user on how to use the system for walking.

With each use of the Parastep, it is important to verify that all components are properly and securely connected and to set individual initial stimulation levels. Following these steps will help to increase the user's proficiency in using the system.

Verifying Electrical Connections and Testing Keypad Keys and Walker Switch Module Buttons

Visually inspect all connections to be sure they are secure, including electrode leads to electrodes, electrode leads to stimulator/control unit, power cable from stimulator/control unit to battery pack, and cable from walker to stimulator/control unit.

While seated, test each key on the stimulator/control unit keypad and each button on the walker switch module to be sure they are functioning correctly and that all connections are secure. With the walker connected to the stimulator/control unit, it is possible to perform all commands from the switch module buttons on the walker. The user may test these functions prior to standing with the help of another person. While seated, activating the sit/stand command will cause quadriceps stimulation to cycle on and the knees to extend. **Before attempting this for the first time**, the user should solicit the help of another to control or assist the lower legs when the knees extend while remaining seated, **allowing unrestricted movement of the extremities**. Stimulus intensity and step functions may be activated from the switch modules while remaining seated. The person helping should support the lower legs throughout this process, **allowing unrestricted movement of the extremities**.

NOTE: If the keypad keys or walker switch module buttons do not function correctly, turn the battery pack off and verify that all connections are secure. If the keypad keys or switch module buttons still do not work, test the components with the Paratester™.

Setting Stimulation Levels

The physical therapist will have determined proper stimulation levels for each individual, but it is important to determine what levels are needed to achieve the necessary stimulation on a daily basis. Required stimulation levels can vary with increasing use of the system as the muscles become stronger. The goal is to determine the level of stimulation required to contract muscles and achieve knee extension so that the user can stand comfortably and safely.

Begin by reducing stimulation levels from the preset level:

- Turn on the battery pack.
- Reduce the stimulation for the left quadriceps electrodes by depressing and releasing the QUAD L DECREASE key on the keypad of the stimulator/control unit 15 times.
- Repeat this process for the right quadriceps electrodes using the QUAD R DECREASE key. This will reduce stimulation levels to near minimum.

If using 6 channels of stimulation, also reduce hip channel stimulation levels from the preset level:

- Reduce the stimulation for the left hip electrodes by depressing and holding the QUAD L DECREASE key for a duration of 3 blinks on the LED panel.
- Repeat this procedure 15 times.
- Repeat this entire process for the right hip electrodes using the QUAD R DECREASE key. This will reduce stimulation levels to near minimum.

To set new stimulation levels:

- Press and release the SIT/STAND key on the keypad. The LED panel on the side of the stimulator/control unit will light and the quad and hip channels will be activated.
- Increase stimulation to the left quadriceps one level at a time by pressing the QUAD L INCREASE key. The quadriceps muscle will contract *(Photo #24a)*. When the level of stimulation exceeds the preset levels, the LED panel will light progressively from green for minimum stimulation through orange for mid-range stimulation to red for maximum stimulation.
- Continue to increase stimulation until the knee is completely extended *(Photo #24b)*.
- Once the knee is extended, do not increase stimulation further. This will be the initial stimulation level for standing.
- Increase hip stimulation one level by holding the L QUAD INCREASE key for 3 blinks on the LED and releasing. Note the levels of stimulation as displayed on the LED panel. If this procedure has increased stimulation less than 15 clicks, make a mental note to determine the level of stimulation output below the preset levels. The therapist will help to determine the correct settings for each user.
- Press and hold the SIT/STAND key on the keypad until the LED panel on the side of the unit blinks. After releasing the key, stimulation to the quadriceps channels will increase by about 20% of set level and an audible beep will warn that the quad and hip channels will be deactivated in 3 seconds.

CAUTION: The therapist or an assistant should support the user's lower leg and foot and left hip when preparing to lower the legs to avoid jarring the feet on the floor. Although the stimulation will ramp down, as indicated on the LED panel, the setting for left quadriceps and left hip stimulation will remain at the established levels in the stimulator/control unit memory, but will not be displayed.

- To increase stimulation to the right quadriceps and right hip, repeat these procedures for the right quadriceps and right hip using the QUAD R INCREASE key.

CAUTION: Increase stimulation only one level at a time to avoid overstimulating the quadriceps muscle.

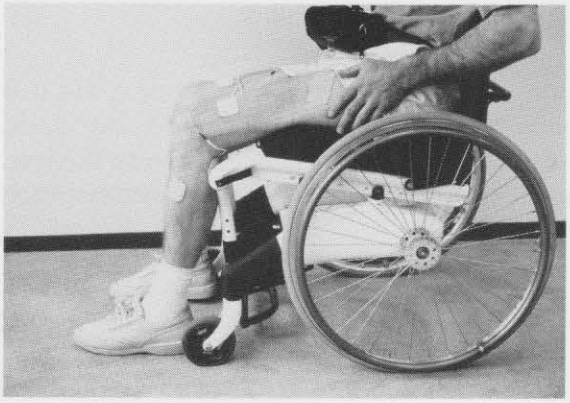

Photo #24a

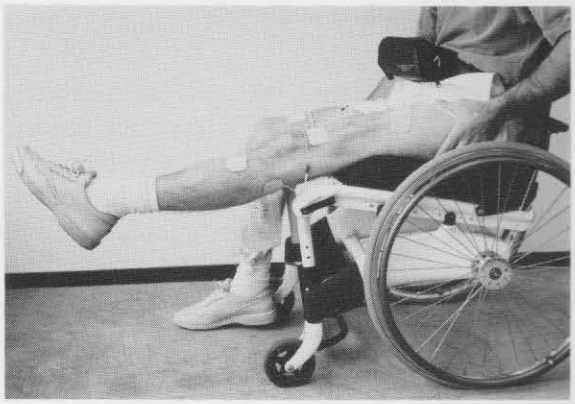

Photo #24b

NOTE: If the battery pack is turned off after manually setting stimulation levels in the stimulator/control unit, the process must be repeated to reset the levels. Once the battery pack is turned to the off position, the computer-preset baseline stimulation levels will be activated the next time the battery pack is turned on again.

VII. Parastep® System Functions

The keys on the keypad of the stimulator/control unit and the buttons on the switch modules of the walker allow the user to initiate commands and to control the intensity of stimulation to the nerves and muscles. These controls make it possible for the user to stand from a sitting position, take steps, walk for short distances, and sit from a standing position.

Photo #25

Photo #26

Activating Quadriceps Stimulation for Standing

Earlier on, this function should be performed only under the direct supervision of a physical therapist:

- Lean slightly over the walker and press the **inside** button on the **right** switch module of the walker labelled **STAND/SIT** once *(Photo #25)*. Quadriceps stimulation will ramp up (over approximately 3 seconds) to preset levels, go momentarily beyond that, and then return to the preset levels.
- The user should position his or her body over the feet to take advantage of the quadriceps contraction that will extend the knees and straighten the legs, using the shoulders and arms to guide him/herself into a standing position.
- Once standing, transfer weight to the lower extremities. If the knees begin to flex, increase stimulation to the quadriceps by pressing and releasing the **center** button on the **left** switch module of the walker labelled **INCREASE** for the left quadriceps and the **center** button on the **right** switch module labelled **INCREASE** for the right quadriceps *(Photo #26 - Right-side switch module shown **only**)*.
- Repeat as necessary to maintain knee extension.

NOTE: Early in training, muscles will fatigue more quickly and standing time may be limited to only a few seconds. If quadriceps fail to maintain knee extension with increasing output levels, return to seated position by activating STAND/SIT and rest for a few minutes to allow the quadriceps to recover. With repeated attempts and daily use, muscle performance will improve.

The therapist will instruct the user on when and **how to adjust the level of stimulation required for hip muscles when using 6 channels**:

- **To increase stimulation** to the hips, press and hold the **center** button on the **left** switch module of the walker for the left side labelled **INCREASE** and the **center** button on the **right** switch module for the right side labelled **INCREASE** until the red LED on the **right** switch module or the LED panel on the side of the stimulator/control unit blinks three times.
- Repeat as necessary to attain appropriate stimulation level(s).
- **To decrease stimulation** to **all** hip muscles, press and hold the **inside** button on the **left** switch module of the walker labelled **DECREASE** until the red LED on the **right** switch module or the LED panel on the side of the stimulator/control unit blinks three times.
- Repeat as necessary to attain optimal level(s).
- Wait approximately 4 seconds before pressing the appropriate button to increase or decrease stimulation further.

The LED panel on the side of the stimulator/control unit will display changes in stimulation levels *(Photo #27)*. After briefly displaying the level of the channel that is increased or decreased, the LED will display the highest level of stimulation in use among **all** stimulated sites.

NOTE: The LED panel progresses or regresses one display bar for every two adjustment clicks in stimulation, although the intensity of stimulation does increase or decrease each time the appropriate key or button is pressed.

Photo #27

NOTE: For safety reasons, maximum intensities of stimulation have been limited for each channel. An audible beep will sound if these limits are reached.

Activating Step-Taking

From a standing position, stepping is accomplished by transferring weight to one lower extremity and activating the step function for the opposite leg. This function should be performed only under the direct supervision of a physical therapist.

- Press and release the **outside** button on the **left** switch module of the walker labelled **LEFT STEP** to step forward with the left leg.
- Press and release the **outside** button on the **right** switch module of the walker labelled **RIGHT STEP** to step forward with the right leg. In each case, the leg will respond by taking a step.

Photo #28

*(Photo #28 - Left-side switch module shown **only**)*

Each user will be instructed by the therapist how to transfer weight over the advanced leg and position the body over that leg. The next step is to advance the walker forward and activate the step function for the opposite leg.

Early on, step-taking must occur only under the direct instruction and supervision of a physical therapist who has been trained in synthesized gait restoration techniques with the Parastep. Early attempts to walk may be fatiguing and, therefore, may require frequent rests. The therapist will determine the appropriate training regimen for each individual's specific requirements.

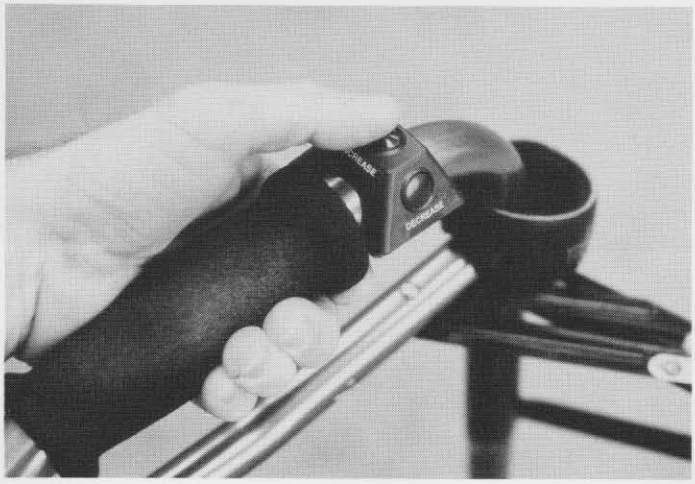

Photo #29

Photo #30

If it is necessary to increase the intensity of stimulation for step-taking:

- For the left step, press and hold the **center** button on the **left** switch module of the walker labelled **INCREASE** until the red LED on the **right** switch module or the LED panel on the stimulator/control unit blinks once.
- For the right step, press and hold the **center** button on the **right** switch module of the walker labelled **INCREASE** until the red LED on the **right** switch module or the LED panel on the stimulator/control unit blinks once.

*(Photo #29 - left switch module shown **only**).*

To decrease stimulation to both steps simultaneously:

- Press and hold the **inside** button on the **left** switch module of the walker labelled **DECREASE** until the red LED on the **right** switch module or the LED panel on the stimulator/control unit blinks once *(Photo #30)*.

Activating Sitting

The therapist will provide instruction on the proper techniques to be used in sitting down from a standing position. In general, the user should be positioned directly in front of a steady chair with the back of the knees touching the chair and the weight balanced equally on each leg.

Photo #31

- Press and hold the **inside** button on the **right** switch module of the walker labelled **STAND/SIT** *(Photo #31)* until the red LED on the **right** switch module or the LED panel on the stimulator/control unit blinks. This command may also be activated by pressing the SIT/STAND key on the stimulator/control unit and then following the aforementioned sequence.
- Release the key or button and the light will turn off. The system will emit one brief beep to indicate that quadriceps and hip (in the case a 6-channel system is being used) stimulation levels will begin to ramp down following a 3 second delay.
- One second before quadriceps stimulation begins the ramping down sequence, the red LED will relight. As the stimulation levels ramp down, the user should guide his or her hips securely onto the seating surface.

NOTE: There will be a brief increase in stimulation levels to both quadriceps in preparation for the stand-to-sit procedure.

Cancelling the Sit Command

To cancel the sit command:

- Press and release any button on the walker switch modules or any key on the keypad of the stimulator/control unit during the 2 second delay before the red LED relights. The system will emit a double beep to indicate that the sit function has been cancelled. Quadriceps stimulation will not be withdrawn if the sit function has been cancelled, and the user will remain standing.

VIII. Common Questions and Answers

For whom is the Parastep® System designed?

The Parastep is designed for use by spinal cord injured persons with paraplegia resulting from T1 to T12 spinal cord lesions. It may also provide benefit for some SCI persons with lower level incomplete quadriplegia. A medical evaluation and a physical therapy assessment are required to determine candidates for program participation.

How long does it take to learn to use the Parastep® System?

Thirty-two sessions of physical therapy at rehabilitation institutions across the country are provided to users who acquire the system. Physical therapy is scheduled two to three times per week. Completion of the training should provide the user with the instruction necessary to use the system safely.

Is it important that Parastep® physical therapy training be provided on a continuous and uninterrupted basis?

It is very important. Learning to walk with the Parastep requires conditioned muscles, lungs and heart. To skillfully use the Parastep requires practice. A patient can expect a lessening in his/her ability to ambulate with the Parastep if the training program is interrupted for several weeks and under such a circumstance the patient should return to the prescribing clinician for reevaluation or retraining prior to reuse.

How much energy is required to use the system?

At first, use of the Parastep will be very demanding for the deconditioned user. The physical therapist will challenge the user to continue practicing new training techniques without overtaxing the user's physiology. User commitment is required to achieve results. With time and training, walking ability, speed and biomechanical efficiency will improve, while energy costs will decrease.

How long can a user stand and how far can he/she walk with the system?

User performance with the Parastep is highly variable and depends upon each individual's physical condition and the level of skill developed. The physical therapist will set specific goals for each user regarding standing times and ambulatory distances.

How frequently should the Parastep® System be used to maintain and/or increase proficiency?

Users should use the Parastep daily to maintain and/or increase their Parastep-related abilities.

Why is regular use of the system recommended?

Regular standing and weight bearing is standard medical management for spinal cord injured persons. Frequent use of the Parastep is a convenient means for users to maximize the benefits associated with standing and stepping.

How do I use the Parastep® System if I only want to stand?

Place electrodes only on the quadriceps and hip muscles and connect electrode leads only to those electrodes. Follow the guidelines for setting stimulation levels, preparing to stand, standing, and sitting.

What maintenance do I need to do to keep up my system?

Maintenance and service recommendations are on pages 31.

How often should the electrodes be replaced?

With proper handling and regular system use, electrodes may last up to 15 days from initial use. As handling and use may vary, electrode life should be evaluated based upon individual habits and circumstances. Carefully review instructions for the application and removal as well as care and storage of electrodes provided on the back of each electrode package. Additional (replacement) electrodes may be ordered directly from the Sigmedics, Inc. Customer Service Department at 1-800-582-WALK.

Will I need to replace the batteries in the battery pack? If so, how do I do it?

If the battery pack does not charge correctly, it will require servicing. Contact the Sigmedics, Inc. Customer Service Department at 1-800-582-WALK for details and costs.

How do I get additional disposable supplies?

Contact the Sigmedics, Inc. Customer Service Department at 1-800-582-WALK.

What do I do if the system fails?

Turn off the system and verify that all connections have been made properly and are secure. If the system still does not work, test all electrode leads, the power cable, and the stimulator/control unit as well as walker switch modules with the Paratester™. If one of the components proves defective, contact Sigmedics, Inc. for a replacement. If none of the components proves defective, but the system still does not work, contact Sigmedics, Inc. at 1-800-582-WALK for further advice.

What do I do if one of the components breaks?

Contact Sigmedics, Inc. at 1-800-582-WALK for a replacement or for service to the component.

How long does it take to repair system parts?

Normal turnaround service is 48 to 72 hours from the date of receipt, but the user can request expedited service by prepaying for overnight shipping.

Is the system warranted?

The system is covered by a one-year warranty. Conditions of Sale, Repair and Replacement policy, and Limited Warranty are found on page 33 at the back of this manual.

IX. System Malfunction Troubleshooting Guide

Battery Pack		
Problem	Possible Cause(s)	Solution
Green LED does not light and/or initial beep does not sound when switch is moved to the ON position.	Battery pack is fully discharged.	Recharge battery pack overnight before use.
Red LED does not light during recharge, when switch is in the OFF CHRG position.	Charger is not plugged in. Charger or battery pack may be defective.	Plug in charger. Battery pack or charger may require servicing.
Intermittent beeping sounds when switch is moved to the ON position.	Battery pack requires recharging.	Recharge battery pack overnight before use.
Walker		
Problem	Possible Cause(s)	Solution
Stimulator/control unit does not respond to commands initiated from walker switch modules and/or red LED (located on right switch module) does not light (as outlined in user's manual).	Walker cable is not connected. Walker may be defective. Stimulator/control unit may be defective.	Connect walker cable to stimulator/control unit. Walker may require servicing. Test stimulator/control unit with Paratester. Initiate commands from walker switch module buttons.

	Stimulator/Control Unit	
Problem	Possible Cause(s)	Solution
First green bar on LED panel does not briefly light after battery pack is turned on.	Power cable is not connected.	Connect power cable securely.
	Power cable may be defective.	Test power cable with Paratester.
	Battery pack may be defective.	Test battery pack. See battery pack troubleshooting section.
	Stimulator/control unit may be defective.	Test stimulator/control unit output with Paratester.
No output out of stimulator/control unit, but first green bar on LED panel briefly lights after battery pack is turned on.	Stimulator/control unit may be defective.	Test stimulator/control unit output with Paratester.
	Electrode lead(s) may be defective.	Test electrode leads with Paratester and replace if necessary.
Stimulation is intermittent.	Electrode leads may be worn out or may be defective.	Test electrode leads with Paratester and replace if necessary.
	Electrode contact may be poor, or one or more electrodes may be worn out.	Reapply electrodes or replace suspect electrode(s).

X. Maintenance and Service

When not using the Parastep, store all components in a safe place to prevent damage.

Electrodes

- Electrodes, under normal use, are expected to provide 10 to 15 applications. The user should note the date when beginning to use each package of electrodes on the electrode package. The peroneal electrodes may have a shorter expected life than the shin, quadriceps, or hip electrodes because of their positioning.
- Follow use and storage instructions on the electrode package to extend the life and improve the performance of electrodes.

Electrode Leads and Power Cable

- Record the date of first use of electrode leads on the label located in the center junction of each lead.
- Visually inspect leads, cables, locking mechanisms, and connecting plugs before each session of use.
- Always plug electrode leads into electrodes carefully, while grasping both the electrode socket and the lead pin. Make sure the connection is snug, but do not use excessive force.
- If an electrode lead or the power cable is suspected to be a source of system failure, check its output with the Paratester. If it tests defective, immediately discard it and replace it with a new lead or cable.
- If an electrode lead or power cable plug connector begins to lose its ability to lock securely into the jack in the stimulator/control unit or the battery pack, or if the lock release pin breaks, immediately discontinue using it and replace it with a new lead or cable. This situation should not occur as long as you protect the lead and cable connectors with the protective covers when you are not using the system.

WARNING: DO NOT ATTEMPT TO MAKE ELECTRODE LEAD OR POWER CABLE REPAIRS BY YOURSELF AS SERIOUS PERSONAL INJURY COULD RESULT.

Walker

- Examine all joints of walker monthly, tighten as necessary, and lubricate with 3-in-one household oil.
- Check rubber boots and wheels of walker for wear. Replace as necessary.

XI. 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 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 volts AC, 60 Hz
Output: 18 volts DC at 50 milliamperes

Control and Stability Walker

Reciprocating model:
Reciprocating range: approximately 7-1/2"
Height: 32" to 36", adjustable in 1" increments
Base width: approximately 22"
Base depth: Open 15"
Folded 4"
Inside grip width: 21"
Weight: approximately 6 lbs.

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: 16-1/4"
Weight: approximately 6 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.

XII. Conditions of Sale, Repair and Replacement Policy, and Limited Warranty for the Parastep® System

This product is sold for use by, or on the order of a physician or other licensed practitioner authorized by law to use or prescribe the use of this device. Sigmedics, Inc., shall retain security interest in all delivered supplies, products, and components until payment in full has been received.

This product is warranted against failure or manufacturing defects for one (1) year from the date of purchase by the original purchaser. This warranty is not transferable. Within this period, Sigmedics, Inc., at its sole discretion, will repair or replace any defective product or component at no cost to the original purchaser with substantially similar new or rebuilt products or components.

The following components are covered by this warranty: stimulator/control unit, battery pack, battery charger, Paratester™, and control and stability walker.

This warranty is voided by any use of this product (or any of its components) for purposes other than those for which the product is intended and which do not follow instructions as outlined in the user's manual. This warranty does not cover defects or damage arising out of misuse, mishandling, accidents, storage, transportation, or repairs performed by anyone other than a Sigmedics, Inc., authorized and certified technician. **Unauthorized attempts at opening any of the cases of the components will result in voiding of warranty and may further cause or result in product malfunction and/or injury to the user.**

To obtain warranty service, the original purchaser should pack the defective component(s) carefully and forward freight prepaid* along with a brief explanation of the reason for returning the component(s) to:

Sigmedics, Inc.
One Northfield Plaza, Suite 410
Northfield, IL 60093
Attn: Service Department

Sigmedics, Inc., reserves the right to inspect all products returned and to advise the customer if it determines that such repair or replacement is not covered by this policy. In such event, with the customer's concurrence, all costs for repair, handling, and transportation shall be paid by the customer (owner of the equipment) at Sigmedics, Inc.'s prevailing rates.

This policy does not cover disposable items, such as electrodes and batteries. Power cables, electrode leads, and accessories (components carrying case, walker case, and Parapack™) are warranted for a period of thirty (30) days from their date of purchase against failure or manufacturing defects.

This policy does not cover damage arising out of owner's failure to provide, at recommended intervals, lubrication, cleaning, or any other preventive maintenance as deemed necessary and prescribed from time to time by Sigmedics, Inc.

This policy does not cover damage caused by rust, oxidation, or any other form of corrosion or damage or loss due to electrical storm, static electricity, flood, vandalism, and/or theft.

Except as expressly provided by this "Limited Warranty," Sigmedics, Inc., is not responsible for any direct, incidental, or consequential damage resulting from or caused by the failure of any of its products or components to function in a normal manner for whatever reason, whether the claim is based on warranty, contract, tort, or otherwise.

THE FOREGOING REPAIR AND REPLACEMENT POLICY IS OWNER'S SOLE AND EXCLUSIVE REMEDY IN THE EVENT OF A DEFECT IN THE PRODUCT, AND IS IN LIEU OF ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Please address any product service-related questions to the Service Department of Sigmedics, Inc. by calling 708-501-3500 or 1-800-582-WALK.

* Sigmedics, Inc., will assume the cost of the return shipping charges.

XIII. Glossary of Terms

- **Anterior tibialis muscle** — The upper two-thirds of the muscle that lies to the side of the tibia.
- **FNS (Functional Neuromuscular Stimulation)** — A rehabilitation technology that uses low-voltage electrical impulses to evoke a peripheral nerve action, which in turn causes a skeletal muscle response.
- **Fibula** — The outer and smaller of two bones of the leg between the knee and ankle.
- **Lateral** — To the side or away from the midline.
- **Parastep® System** — A patented microcomputer-controlled FNS system that enables independent standing and unbraced ambulation by paraplegics and some quadriplegics.
- **Paratester™** — A self-contained, battery-operated diagnostic tool to test electronic components of the Parastep® System and continuity and integrity of leads and cables.
- **Peroneal** — Of or relating to the fibula or outer portion of the leg.
- **Quadriceps** — The large muscles at the front of the thigh.
- **Ramping down or ramping up** — Gradual decrease or increase in electrical stimulation that can be viewed with the changing color bars in the LED display on the side of the stimulator/control unit.
- **Tibia** — The inner and larger of two bones of the leg between the knee and ankle.