SESSION #1

TITLE: Introduction to the Parastep® I System - Part I

PRESENTER:

TIME:

OBJECTIVES:

Upon completion of this session, the clinician will be able to:

1. Identify all system components.
2. Operate the system with thorough knowledge of all functions.
3. Demonstrate system operation:
   A. Electrode application
   B. System operation

SESSION #1

TITLE: Introduction to the Parastep® I System - Part I

PRESENTER:

I. IDENTIFY SYSTEM COMPONENTS

A. Stimulator Units - 6-channel/4-channel/"T" unit/"E" unit (Photos #1a, 1b & 4b)

1. Front panel control keypad
2. Stimulation level display (LED)
3. Power cable port
4. Electrode cable port
5. Walker cable port
6. Beeper audio port

B. Battery Pack (Photos #2a & 2b)

1. Battery end panel
   - On/off switch - on light, off/charge light
   - Power cable port
2. Battery audio port

C. Battery Pack Recharger (Photo #3)

D. Power Cables (Photo #6)

1. Short and long
2. Connection battery pack and stimulator

I. PARASTEP® I SYSTEM COMPONENTS (cont'd)

E. Electrode Cables (Photo #4a)

1. Standard 4 lead cable
2. Hip channel cable - red right, black left
3. Test unit 2 lead cable

F. Electrodes (Photo #5)

1. Square
2. Rectangular
3. Surface applied, self adhesive
4. Care of electrodes
5. Electrode failure modes
   - Impedance
   - Improper care
   - Lead failure

G. Control and Stability Device (Walker) (Photos #7a & 7b)

1. Switch modules
   - Identify all 6 switches
2. Cable connection to stimulator unit
3. Walker styles
   - Standard non-reciprocating
   - Wide non-reciprocating
   - Reciprocating
4. Other features
   - Height adjustability
   - Wheel choice
   - Standard legs

H. Paratester (Photos #8, 11, 12, 13, 14 & 15)

1. Tests integrity of system components
2. Test prior to system use

II. PARASTEP OPERATION

A. Stimulator Unit/Battery Pack

1. Review
   - Keypad functions
   - Display bar - function
   - Cable connections
   - Battery pack cable connection
   - On/off switch
2. Connect stimulator unit/battery pack
   - Switch on - display - audible beep
   - Stand key - observe LED
   - Increase L Quad/Decrease L Quad - observe LED
   - Increase L Step/Decrease L Step - observe LED
   - Increase L Hip/Decrease L Hip - observe LED
3. Connect walker to stimulator
   - Review switch modules on walker
   - Depress stand on walker switch
   - Increase R Quad/Decrease R Quad
   - Increase R Step/Decrease R Step
   - Increase R Hip/Decrease R Hip
   - Sit key
     - Note beep - 3 second delay - 1 second ramp down
     - Note - Cancel command - any switch

III. PARASTEP DEMONSTRATION

A. Electrode Application

B. Cable and System Application

III. PARASTEP® DEMONSTRATION (Cont'd)

C. System Activation

- Power-on
- Intensity level adjustment
- Activate stand function - 3 second ramp up
- Walk
- Activate sit function - 3 second delay - 1 second ramp down

SESSION #2

TITLE: Introduction to the Parastep System - Part II

PRESENTER:

TIME:

OBJECTIVES:

Upon completion of this session, the clinician will be able to:

1. Describe and locate electrode positions for FES testing, standing and walking.

2. Identify and operate the Parastep "T" unit.

3. Identify and operate the Parastep "E" unit.

4. Identify and describe stimulation profiles for Parastep stimulators.

5. Set up, operate and experience the Parastep® System.

SESSION #2

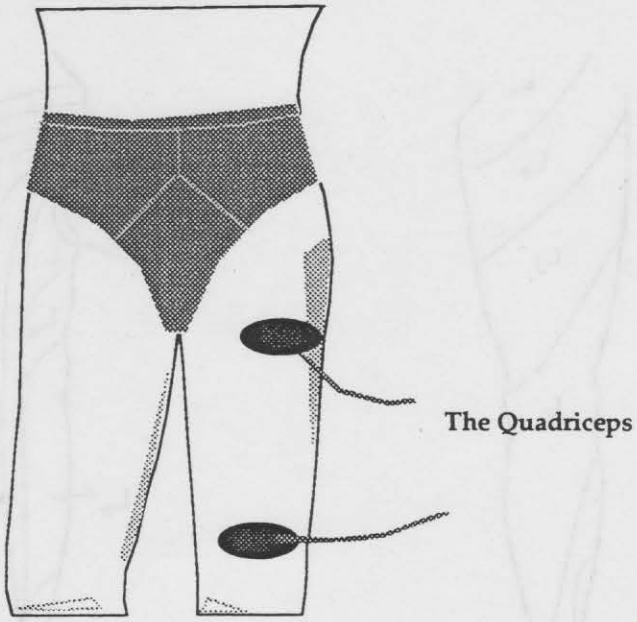
TITLE: Introduction to the Parastep System - Part II

PRESENTER:

I. COMMON ELECTRODE PLACEMENT SITES FOR FES STANDING AND WALKING

A. Electrode Positioning

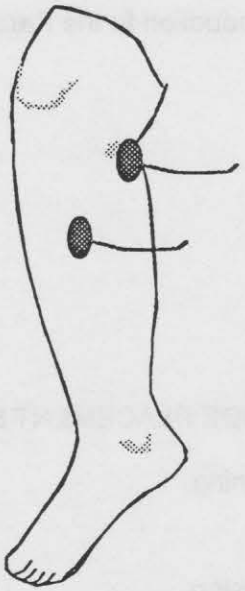
1. Knee Extension



2. Flexion Withdrawal

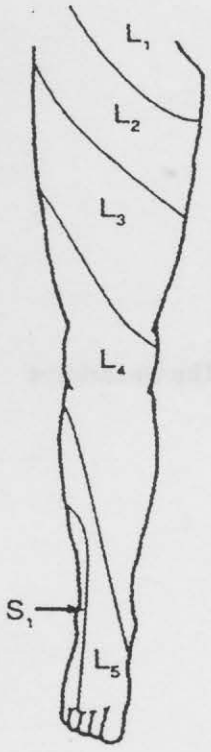
a. Motor response, innervation levels for muscles of flexion withdrawal
Iliopsoas - L_2, L_3, L_4
Biceps Femoris - L_5, S_1
Ant. Tibialis - L_4, L_5

b. Common Peroneal Nerve - L_4, L_5, S_1, S_2
Post. Femoral Cutaneous- L_2, L_3, L_4, L_5, S_1, S_2

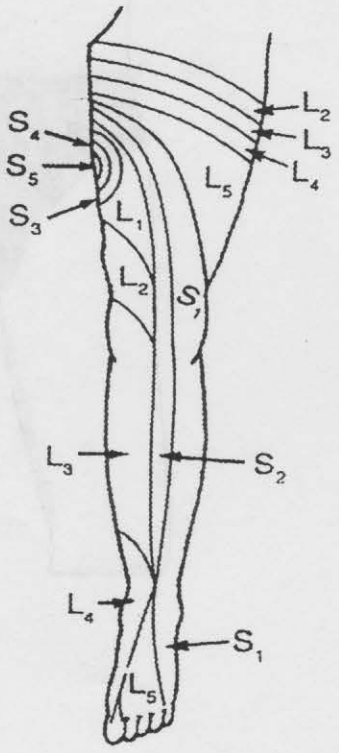


The Tibialis Anterior and Peroneal N.

c. Segmental Dermatome

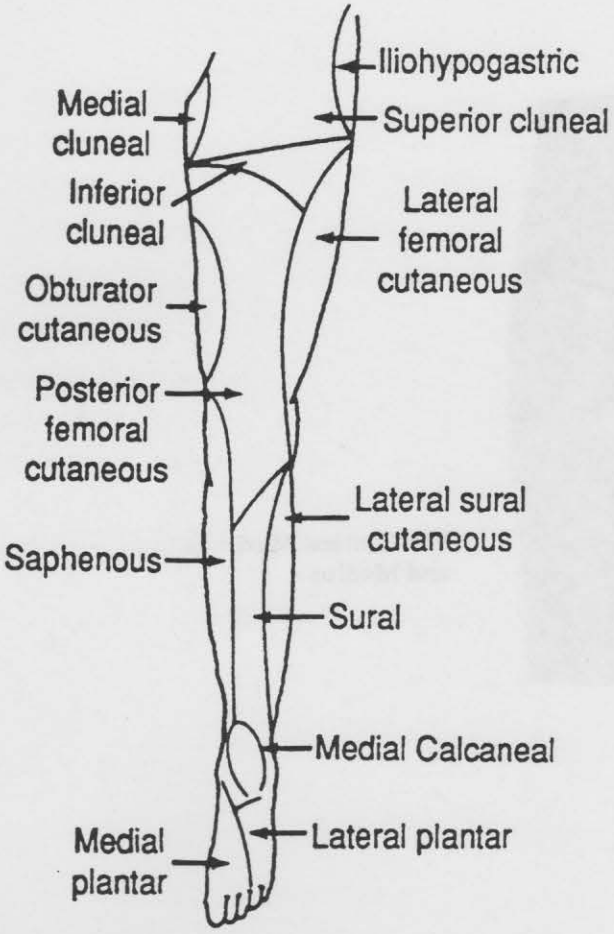


Anterior View

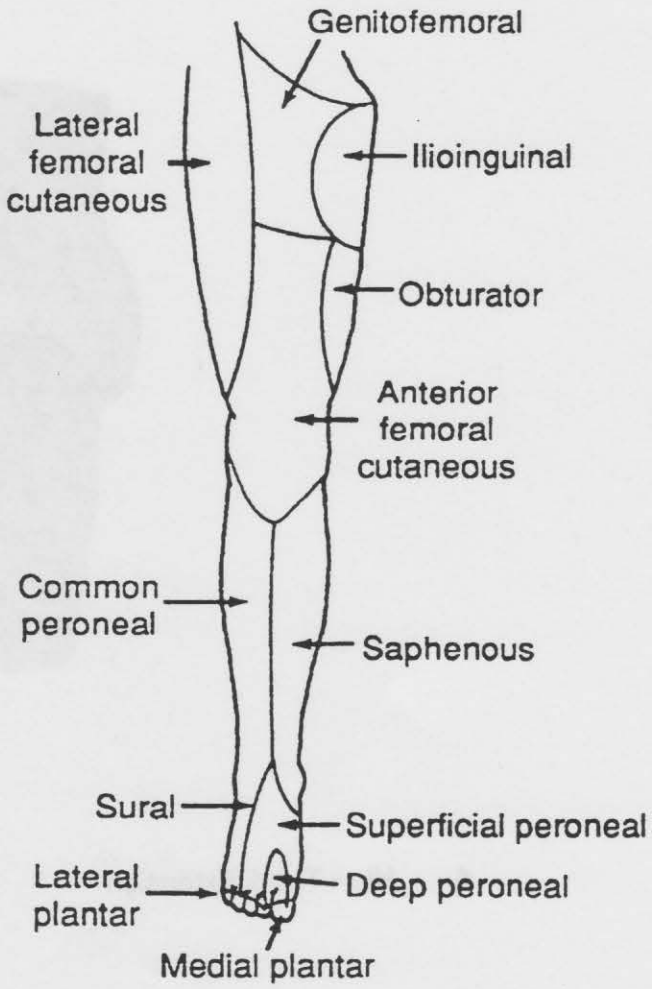


Posterior View

d. Peripheral Nerve Sensory Distribution

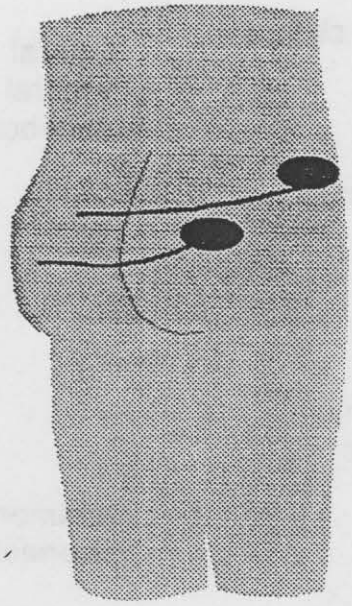


Posterior View



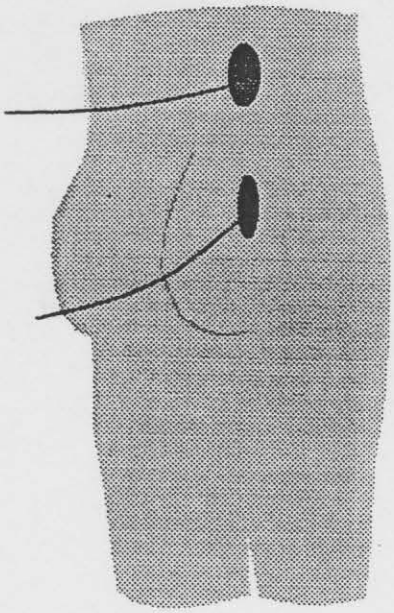
Anterior View

3. Hip Extension/Abduction



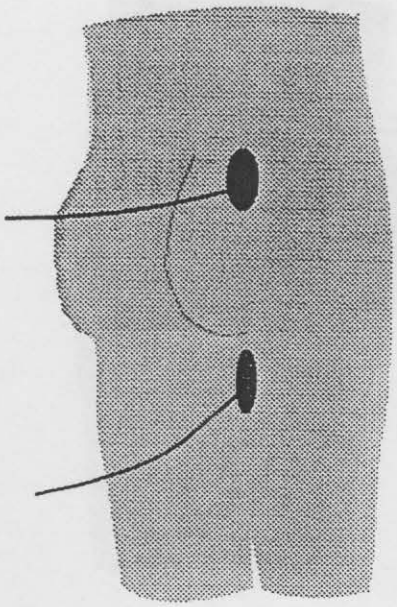
The Gluteus Maximus and Medius

4. Hip - Trunk Extension

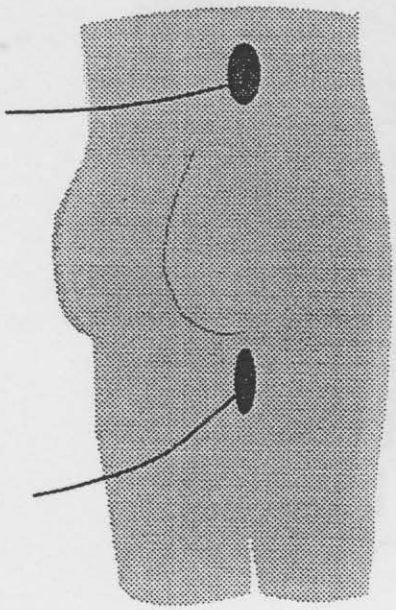


Alternatives for hip extension

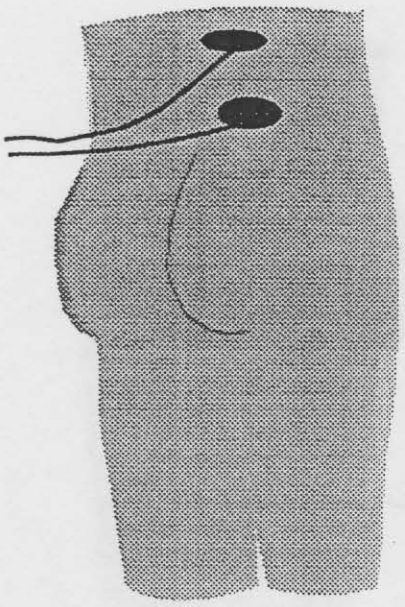
5. Alternatives for Hip Extension



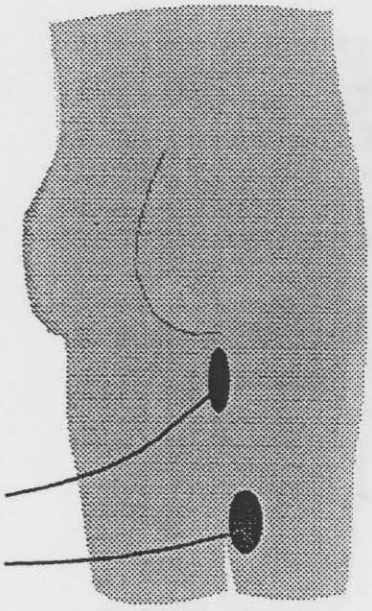
6. Alternatives for hip extension



7. Trunk Extension



8. Knee Flexion



II. CLINICAL FES STRENGTH TESTING UNIT SPECIFICATIONS

Wave Form:	Asymmetrical Biphasic
Frequency:	24 pps
Pulse width:	150 µs
Nominal current output range:	0 to 250 mA
Adjustable in 10 increments.	
Average current increase per increment:	21 mA
Nominal starting current:	50 mA
Level can be adjusted down to 0 mA.	
Nominal maximum current:	250 mA
Active output channel:	Right Quadriceps only
Active keys:	RQ Increase
	RQ Decrease
	Sit/Stand

System's features:

Stimulation output only ramps-up to set level.

No boost of stimulation level on sit down.

Beeper will sound when last Red LED bar is reached.

Beeper will sound if stimulation level is decreased below 1st green LED bar, and on subsequent level decreases.

Level can be adjusted down to 0 mA.

Immediate ramp-down on activation of sit command.

III. "E" UNIT

PARASTEP® I SYSTEM
4-CHANNEL FNS "E" UNIT OPERATING INSTRUCTIONS

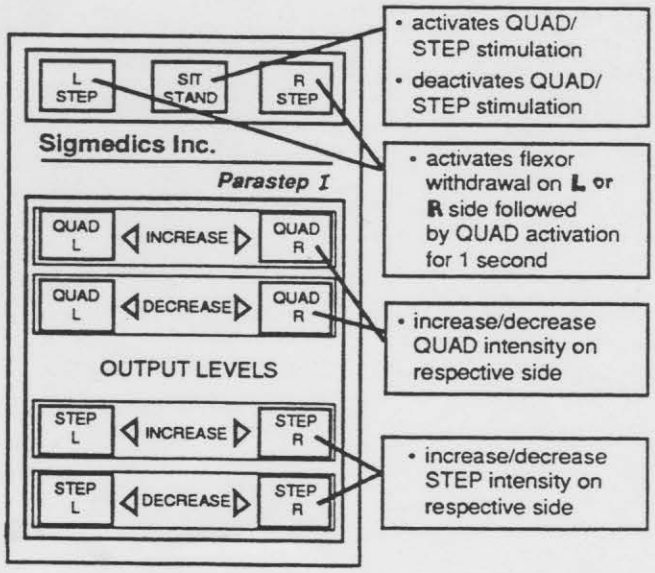
The "E" unit was designed to exercise lower extremity muscles in preparation for ambulation. The "E" unit operates in two separate modes:

1. QUADS - By positioning the toggle switch located on the back panel to "QUADS", the quadriceps muscles can be activated. In this mode the step function is disabled. **(NOTE: It is not possible to take steps while standing with this unit.)**
2. STEPS - By positioning the switch to "STEPS", the flexor withdrawal reflex can be activated for one second followed by one second of quadriceps stimulation. Quadriceps stimulation then shuts off after one second.

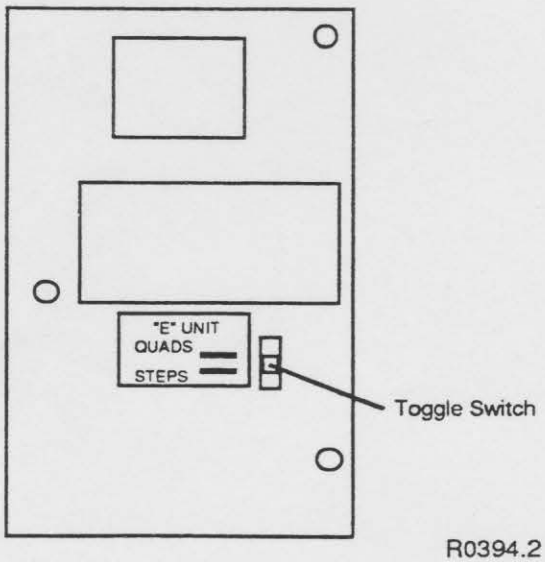
SET UP PROCEDURE:

1. Apply the quadriceps and the peroneal (steps) electrodes as instructed by your physical therapist.
2. Connect the electrode cables to the sockets marked R and L on the "E" unit.
3. Connect the leads to the electrodes.
4. Connect the battery pack to the "E" unit with the power cable.
5. Select "QUADS" or "STEPS" via the toggle switch located on the back panel of the "E" unit. **(NOTE: You must select the correct mode prior to turning on the battery pack.)**
6. Turn on the battery pack.
7. Proceed with setting the appropriate intensity levels and initiating the desired response by depressing and releasing the appropriate keys on the front panel of the unit.
8. To change to the alternate mode, turn off the battery pack. Position the toggle switch to the desired mode. Turn on the battery to repower the stimulator.
9. The "E" unit has been modified to prevent standing and taking steps. It is intended to be used only under supervision of a qualified physical therapist.

FRONT PANEL



BACK PANEL



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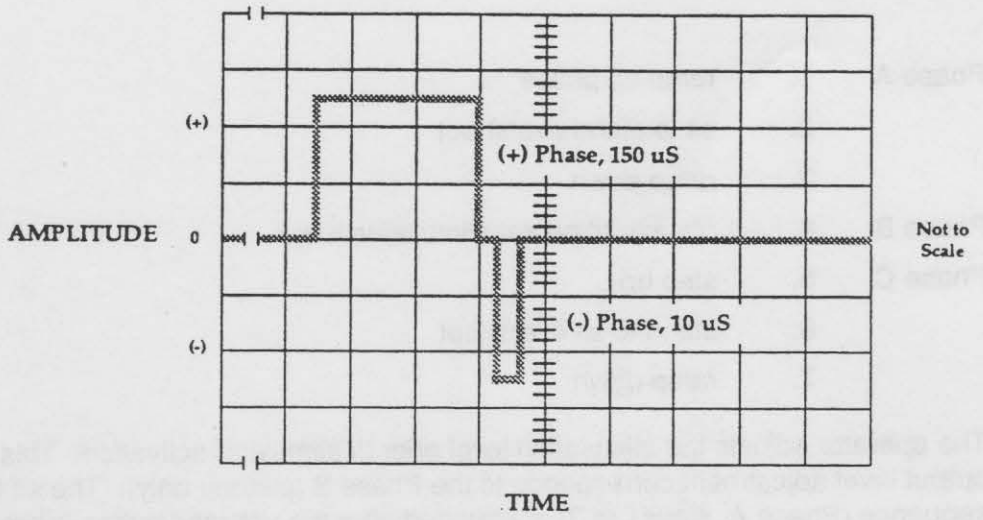
IV. Sigmedics Stimulation Profile

A. The Sigmedics stimulators have a specific output profile for the quadriceps muscle stimulation. This profile involves:

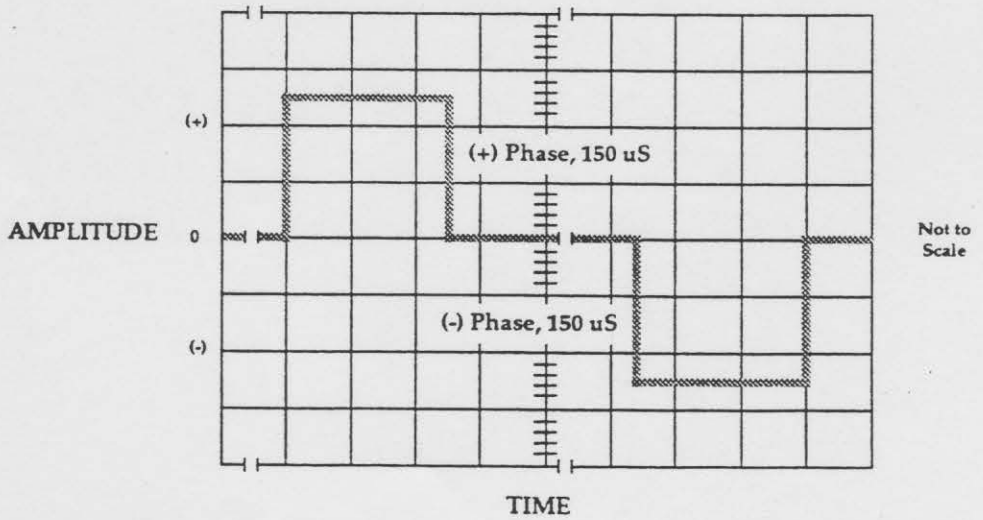
Phase A	1.	ramp up phase
	2.	sit to stand overshoot
	3.	ramp down
Phase B	4.	plateau at preset stimulation level
Phase C	5.	step up
	6.	stand to sit overshoot
	7.	ramp down

The operator adjusts the stimulation level prior to stimulator activation. This stimulator output level adjustment corresponds to the Phase B (plateau only). The sit to stand sequence (Phase A, steps1 to 3) is activated after the sit/stand button is pressed. The initial sit to stand overshoot level are not controlled by the operator. This is under software control. The duration of this sequence is approximately 3 seconds. The stand to sit sequence is activated upon release of the sit/stand switch after this switch has been depressed for 1.2 seconds or longer. The stand to sit overshoot levels are not under operator control. This overshoot is under software control. The duration of the stand to sit sequence is about 3 seconds.

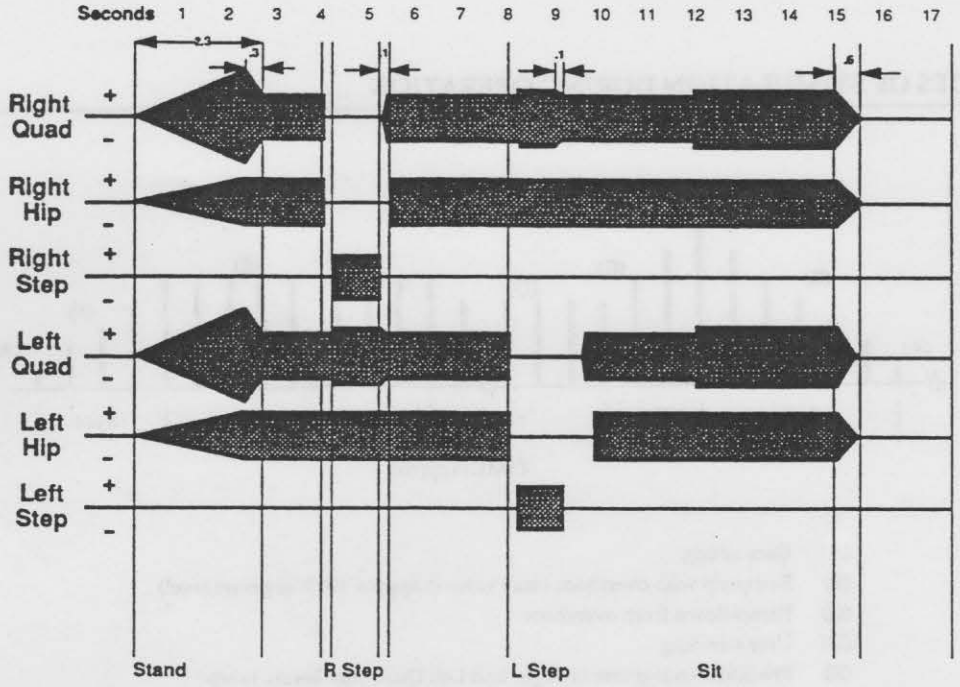
STIMULATOR OUTPUT WAVEFORM (BIPHASIC, ASYMMETRICAL)



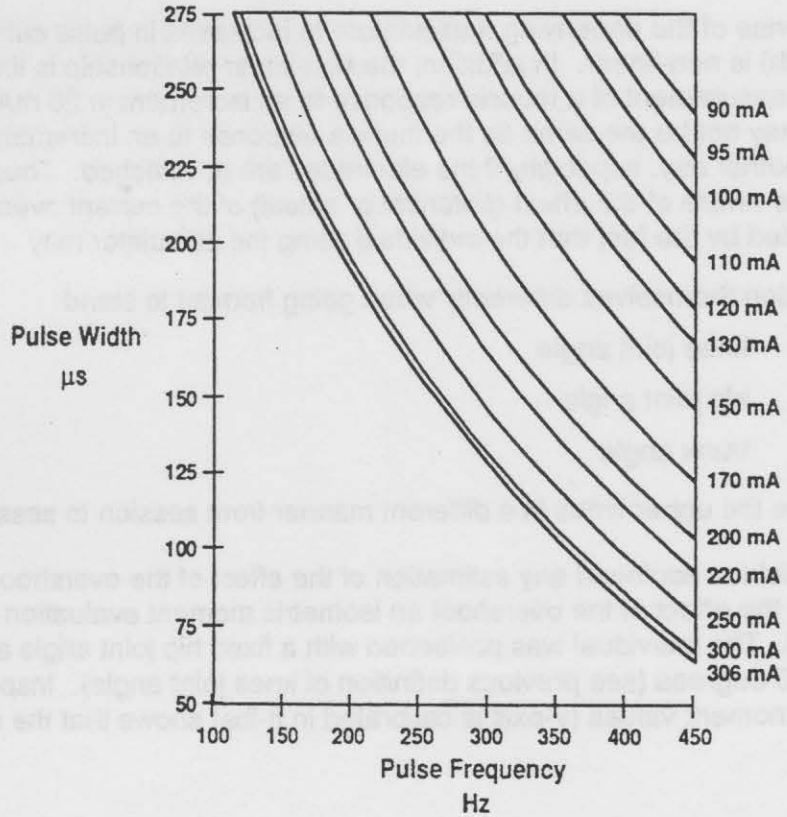
STIMULATOR OUTPUT WAVEFORM (ALTERNATING, SYMMETRICAL)



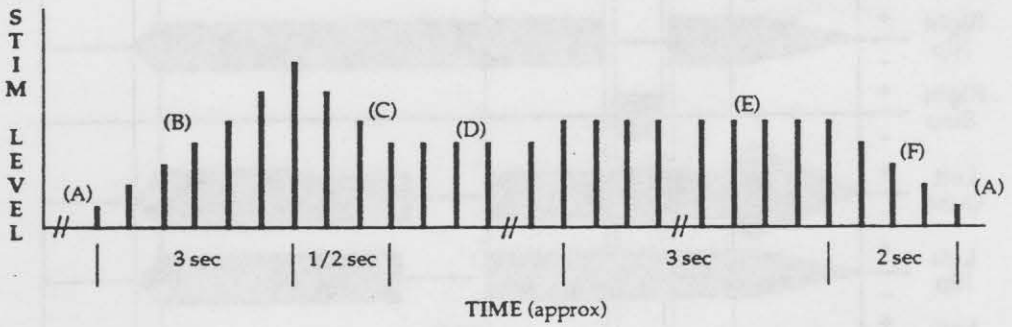
Stimulation Profile- Six Channel Stimulator



Pulse Charge Thresholds for Biological Tissue Damage



MODES OF STIMULATION DURING OPERATION



(A) User sitting
(B) Ramp-up with overshoot (max value is approx 100% of preset level)
(C) Ramp-down from overshoot
(D) User standing
(E) Pre-Sitdown increase of Right and Left Quad stim before ramp-down (max increase is approx 20% of preset level)
(F) Standing to sitting ramp-down

Discussion of the Overshoot

The response of the underlying musculature to increases in pulse current (with fixed pulse width) is non-linear. In addition, the non-linear relationship is time varying such that the measurement of a muscle response to an increment in 20 mA (150 to 170) one day may not be the same as the muscle response to an increment in 20 mA (150 to 170) another day, especially if the electrodes are re-attached. Thus, the operator may not be aware of the effect (potential or actual) of the current overshoot. This is compounded by the fact that the individual using the stimulator may

1. position themselves differently when going from sit to stand
   a. knee joint angle
   b. hip joint angle
   c. trunk angle
2. utilize the upper limbs in a different manner from session to session

These variables confound any estimation of the effect of the overshoot. In order to determine the effect of the overshoot an isometric moment evaluation should be performed. The individual was positioned with a fixed hip joint angle and the knee joint angle at 45 degrees (see previous definition of knee joint angle). Inspection of the isometric moment values (y-axis is calibrated in ft-lbs) shows that the moment profile

reflects the stimulation profile. However, on a separate occasion (two weeks earlier) the same individual was assessed with the same body position and a reasonable repositioning of the electrodes. What is important to note is that, although the shape of moment profile is consistent with the stimulation profile, the relationship between the peak moment and the magnitude of the moment during the plateau phase is different from day to day.

The operator of the stimulator is certainly aware of the effect of the response of the quadriceps muscle to the preset level of stimulation. This is true since this level is maintained for an extended period of time allowing the operator to get a feel for the strength of muscle contraction. In fully extended position, the force output of the quadriceps muscle group is near minimum since the muscle is positioned at the shortest length in force-length relationship. The initial overshoot from sit to stand is so brief that the operator (and the user without sensation) are incapable of judging the magnitude of the muscle response. Certainly, when the user goes from a sitting position to a standing position without the aid of the upper limbs, the joint moments about the hip, knee and ankle are maximal during the initial period of elevation. This fact may be the rationale behind the overshoot, however, this does consider the contribution of the upper limbs to the elevation from sit to stand. Indeed, many other sit to stand stimulators do not have such an overshoot. As such these rely more on a combination of lower limb and upper limb for the elevation phase.

Consideration should be made for instances where the individual using the stimulator varies the contribution of the upper limbs to the elevation phase. If the contribution is minimized, the moment required about the knee increases to the maximum allowed by the stimulation level. In this situation the speed of elevation decreases and approaches the isometric situation where the force produced by the muscle is potentially greater than the force produced under concentric contractions. In addition, during the initial stage of elevation from sit to stand, the knee joint angle is between 75 and 90 degrees flexed placing the quadriceps musculature in the mid-range of the force-length relationship allowing near maximal force output from the muscle.

In conclusion, the force output of the quadriceps muscle group can vary considerably even when the same stimulation levels are applied during repeated sit to stand sequences due a number of variables. The operator will be able to gauge the muscle contraction to the preset level of stimulation but will be unable to predict the muscle response to the initial stimulation overshoot with all the possible variations in the sit to stand sequence.

The patient is instructed in proper levels of stimulation to insure appropriate levels of FES muscle force while avoiding over stimulation. Muscle fatigue presents a limiting factor to functional ability. Early detection of fatigue is taught by awareness of proprioceptive information transmitted through the hands and shoulders. As quadriceps fatigue and the knees begin to flex increased weight is transferred to the hands and shoulders. Patients must develop an acute sense of change in these parameters to become independent.

SESSION # 4

TITLE: Parastep Candidate Selection & Evaluation

PRESENTER:

TIME:

OBJECTIVES:

Upon completion of this session, the participant will be able to:

1. Identify the therapeutic and functional use of FES in management of SCI.

2. Identify the indications for use of the Parastep® System.

3. Anticipate the clinical, social, psychological and physiological factors which may compromise a subject's successful completion of the Parastep program.

4. Evaluate a patient and determine his/her candidacy for the Parastep program.

SESSION #4

TITLE: Parastep Candidate Selection & Evaluation

PRESENTER:

I. THE ROLE OF FES IN THE REHABILITATION MANAGEMENT OF SCI

A. Multiple Perspectives

Engineer Neuroprosthetic System designed to restore control to paralyzed muscles in attempt to synthesize purposeful human movement.

Clinician Therapeutic Tool capable of improving function and optimizing the beneficial effects of exercise.

SCI User A current means to overcome the incapacity resulting from spinal cord injury.

B. Importance to SCI

- Provides a means to investigate the potential benefits of neurostimulation for restoration of human function
- Provides a means to evaluate the benefits of exercise in reducing the secondary consequences of Spinal Cord Injury
- Provides a means to evaluate and train candidates for consideration of implanted technologies
- Provides a means to enable spinal cord injured persons to gain control of paralyzed muscles to achieve individual functional objectives

C. What it is not

Cure for Spinal Cord Injury

Replacement for the Wheelchair

II. APPROVED USE INDICATIONS

The Parastep® System is indicated for enabling appropriately selected, skeletally mature persons with spinal cord injury (C6 - T12) to stand and attain limited ambulation and/or take steps, with assistance if required, following a prescribed program of Physical Therapy performed in conjunction with rehabilitation management of spinal cord injury.

A. Who is it for?

- appropriately selected
- skeletally mature
- persons with spinal cord injury (C6 - T12)

1. Selection Criteria

- Stable ortho-neuro-metabolic systems following spinal cord injury
- Intact lower motor units L1 and below
- Motivation and commitment to participate in the program
- Effective muscle contractile response to stimulation
- Cognitive ability to successfully employ the system
- Sensory tolerance to electrical stimulus
- Independent in all transfers
- Standing tolerance greater than 3 minutes
- Balance and control skills to maintain an upright posture
- Hand and finger function to manipulate system controls
- Upper Extremity Strength sufficient to lift body weight out of a chair and into a standing walker
- Rehabilitation candidate for ambulation training

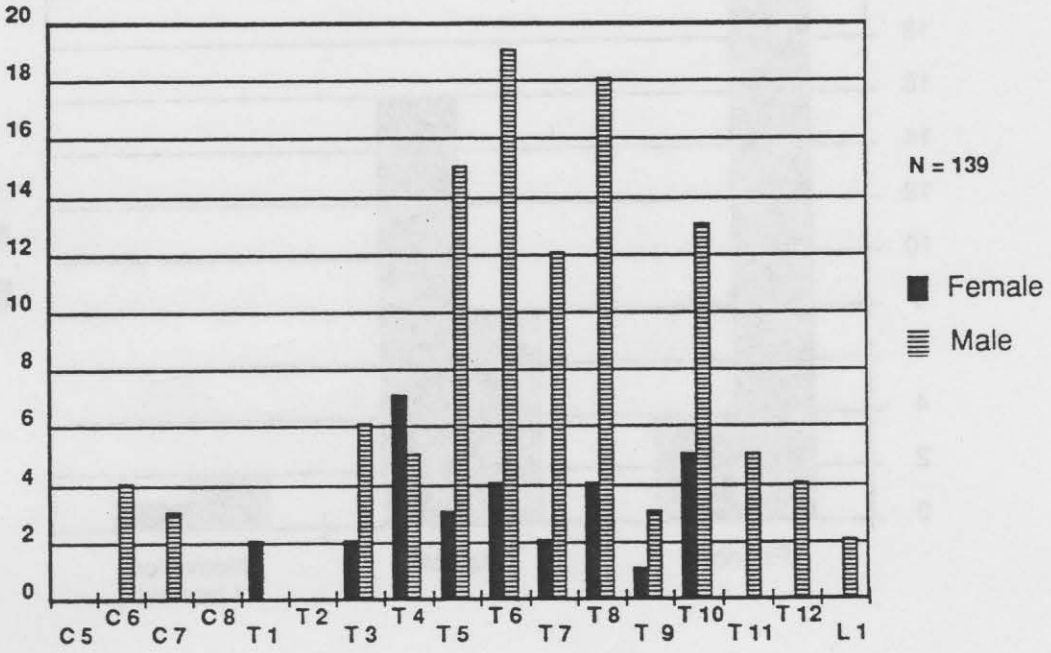
2. Skeletally Mature

- Epiphyseal closure
- Adult height attained (long bone growth complete)

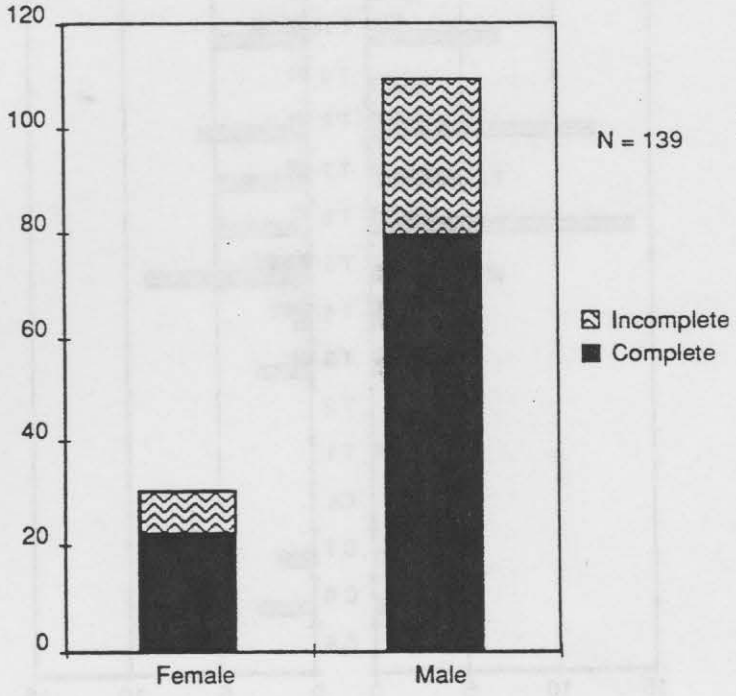
3. Spinal Cord Injured (C6 - T12)

- Trauma
- Tumor
- Ischemia
- Disease

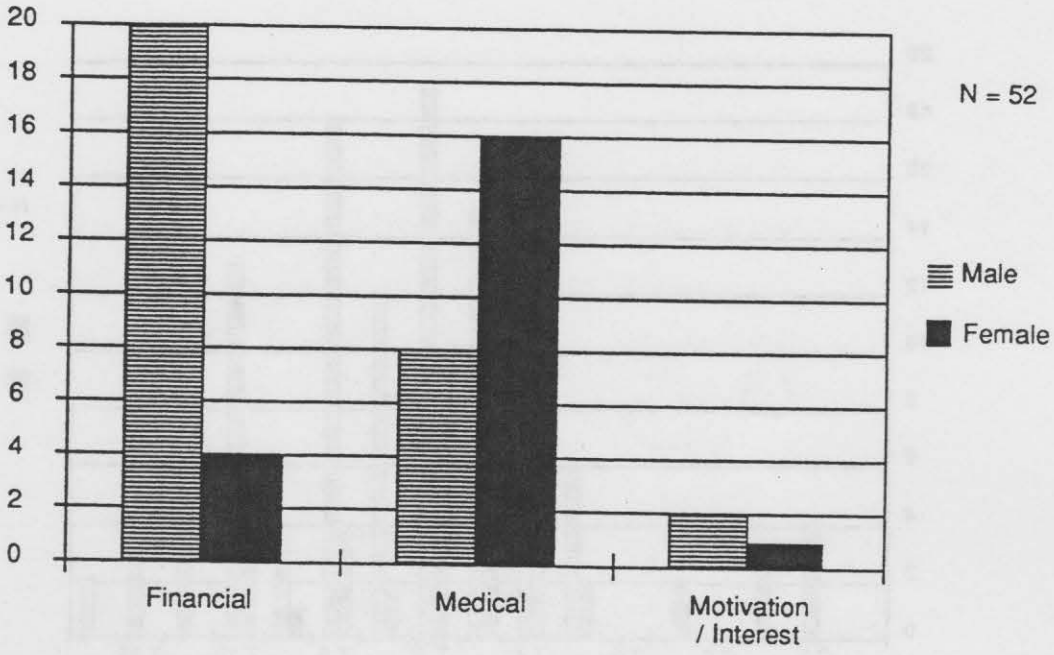
B. Subjects qualifying for training



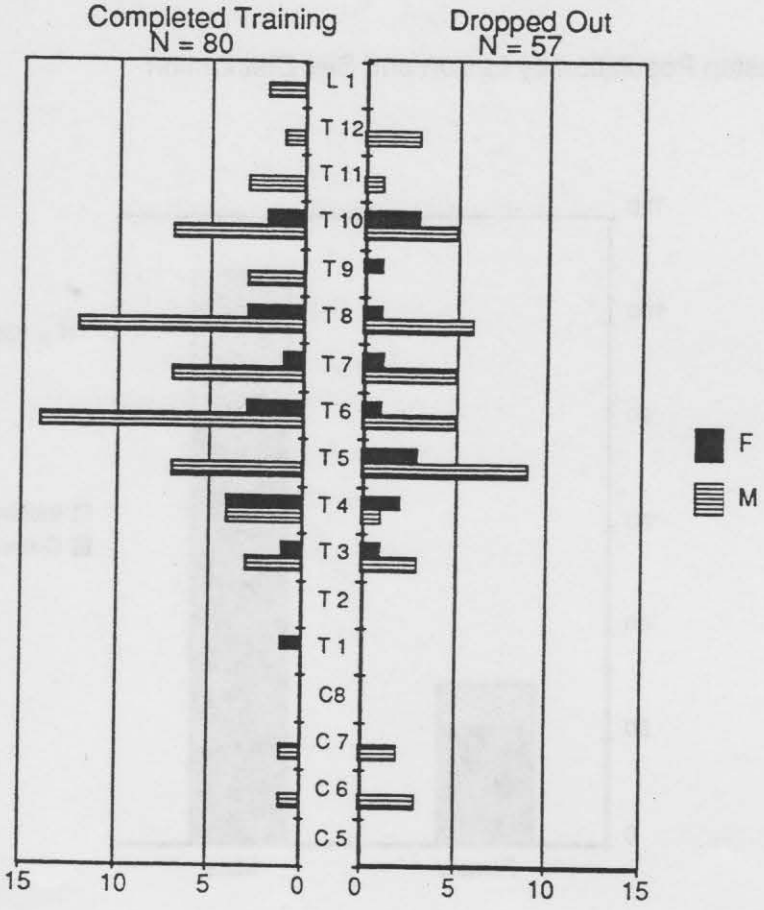
C. Parastep Population by Lesion and Sex Distribution



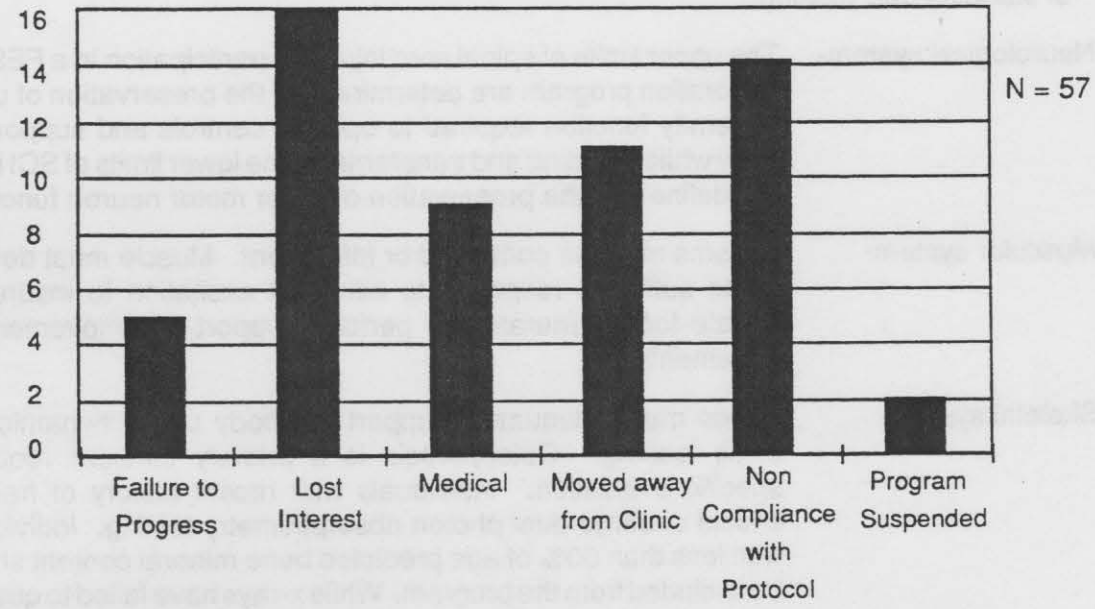
D. Classification of Reasons Cited for Disqualification



E. Compliance



F. Reasons for Drop Out



G. Medical Complications Leading to Discharge

Avascular Necrosis	1
Belching	1
Fatigue	1
Fracture	4
Ligament Laxity	1
Prostate Surgery	1
Total	9

H. Patient Selection

Patient selection of candidates for synthesized gait restoration programs must involve consideration of the functional ability of systems to adequately support the demands of standing and walking.

Neurological system- The upper limits of spinal cord injury for participation in a FES gait restoration program are determined by the preservation of upper extremity function required to operate controls and support the body while standing and transferring. The lower limits of SCI injury are defined by the preservation of lower motor neuron function.

Muscular system- Spasms must be controlled or infrequent. Muscle must demonstrate sufficient response to electrical excitation to insure adequate force generation to perform support and movement requirements.

Skeletal system- Bones must adequately support the body under dynamic and static loading. Osteoporosis is a primary concern requiring specific evaluation. Individuals with recent history of fracture should undergo dual photon absorptiometry testing. Individuals with less than 50% of age predicted bone mineral content should be excluded from the program. While x-rays have failed to quantify the degree of osteoporosis, cortical thickness as interpreted by radiological exam should be graded as moderate or better. Hip, knee, and ankle joints should demonstrate full articular excursion and be without significant degenerative joint disease.

Cardiovascular system- Patients with cardiovascular disease should undergo evaluation by a Cardiologist to determine risk status prior to exercise training. Uncontrolled hypertension is a contraindication to participation.

Respiratory system- Compromised ventilatory responses to exercise should be evaluated by pulmonary function analysis. C.O.P.D. should be evaluated by a Pulmonologist prior to program participation. Respiratory infection is a contraindication to exercise and program participation.

Urogenital system- Urologist coordination is required for patients with chronic renal disease. Exercise is contraindicated during periods of intercurrent urinary tract infections.

Cutaneous system- A Dermatologist should evaluate any acute skin disease prior to participation. Any cutaneous disorder at the site of electrode application is a contraindication to the continuation of electrical stimulation at that site.

Psychological system- Patients with a positive history of drug or alcohol abuse have proven unreliable or manipulative and should be considered relative contraindications. Patients who score high on the sociopathic index of the M.M.P.I. should be considered relative contraindications for program training.

III. MEDICAL EVALUATION

A. Medical:

1. Status six months post recovery from spinal cord injury and restorative surgery
2. Stable ortho-neuro-metabolic systems
3. Intact lower motor units (L1 and below)
4. Without history of lower extremity long bone stress fractures, hip or knee joint disease

B. Clinical:

1. Motivation
   Does the patient demonstrate and express appropriate motivation and commitment to the therapeutic program?
2. Musculoskeletal integrity
   Is muscle and joint stability available for weight bearing at upper and lower extremities?
3. Articular Excursions
   Is sufficient range of motion available at all extremity articulations?
4. Motor Excitability
   Does the patient demonstrate appropriate muscle contractile response to Functional Electrical Stimulation (FES)?
5. Controlled Spasticity
   Is motor hyper activity sufficiently controlled to allow safe independent upright stance?
6. Cognition
   Does the patient demonstrate adequate faculties and learning capability to successfully employ the Parastep System?
7. Sensation
   Does sensory perception of electrical stimulus allow sufficient level required for muscular contraction?

C. Functional Criteria:

1. Force Generation - Hip and Knee Torque
   Does the patient demonstrate sufficient muscular force with FES at the hip and knee required for function?
2. Cardiopulmonary Reserve
   Does the patient respond to upright positions and stepping with adequate hemodynamic and ventilatory responses?
3. Independent Transfers
   Is the patient independent in all transfers?
4. Standing Tolerance
   Does the patient demonstrate adequate standing tolerance to perform standing activities?
5. Balance and Trunk Control
   Does the patient demonstrate adequate balance and control skills to maintain an upright supported posture independently?
6. Grasp
   Does the patient demonstrate adequate hand and finger control to manipulate system controls?

D. Contraindications:

The Parastep system is not recommended for Patients presenting with the following conditions:

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

Medical Acceptance Evaluation Form

			yes	no
1.	Status six months post recovery spinal cord injury and restorative surgery (if any)		☐	☐
2.	Stable ortho-neuro-metabolic systems	2	☐	☐
3.	Intact lower motor units (L1 and below)	3	☐	☐
4.	Without history of long bone fractures, hip or knee degenerative joint disease	4	☐	☐
	Clinical Criteria:			
1.	Does the patient demonstrate and express appropriate motivation and commitment to the therapeutic program?	5	☐	☐
2.	Is muscle/joint stability available for weight bearing at upper and lower extremities?	6	☐	☐
3.	Is sufficient range of motion available at all extremity articulations?	7	☐	☐
4.	Does the patient demonstrate appropriate muscle contractile response to FES?	8	☐	☐
5.	Is motor hyper activity sufficiently controlled to allow safe independent upright stance?	9	☐	☐
6.	Does the patient demonstrate adequate learning ability to successfully employ the Parastep System?	10	☐	☐
7.	Does sensory perception of electrical stimulus allow sufficient intensity required for muscular contraction?	11	☐	☐
	Functional Criteria:			
1.	Is FES muscular force at the hip and knee sufficient for required function?	12	☐	☐
2.	Does the patient respond to upright positions and with adequate hemodynamic and ventilatory responses?	13	☐	☐
3.	Is the patient independent in all transfers?	14	☐	☐
4.	Does the patient demonstrate standing tolerance to perform biped activities?.	15	☐	☐
5.	Does the patient demonstrate adequate balance and control skills to maintain an upright supported posture independently ?	16	☐	☐
6.	Does the patient demonstrate adequate hand and finger control to manipulate system controls?	17	☐	☐
	Exclusionary Criteria:			
1.	Cardiac demand pacemaker	18	☐	☐
2.	Cancer in the area of electrode placement	19	☐	☐
3.	Severe scoliosis	20	☐	☐
4.	Fracture secondary to osteoporosis	21	☐	☐
5.	Skin disease at stimulation sites or over swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, thrombo phlebitis, varicose veins	22	☐	☐
6.	Irreversible contracture	23	☐	☐
7.	Autonomic Dysreflexia	24	☐	☐

IV PHYSICAL THERAPY FES EVALUATION

A. Pre Ambulation

A routine periodic clinical assessment should include evaluation of the following parameters to insure safety and successful use:

1. Musculo-Skeletal Evaluation

   Does the user demonstrate signs of joint instability at hip, knee or ankle which precludes standing or stepping?

   Does the user exhibit signs of soft tissue inflammation related to stress or over use?

2. Skin

   Does the user's skin show adverse signs related to stimulation?

3. Upper Extremity Strength

   Is strength adequate to enable a patient to lift his body weight out of a chair and into a standing walker?

   Is the patient able to stand using one arm for support?

4. Trunk Control and Balance

   Can the patient maintain upright stance with minimal upper extremity effort?

   Does the patient display protective extension reactions?

   Does the patient display protective equilibrium reactions?

   Does the patient demonstrate an adequate sense of balance?

   Is spatial orientation adequate?

   Is awareness of posture accurate?

5. Lower Extremity FES Force Production

   Is FES muscle power sufficient to maintain locked knees while full weight bearing in standing double support? (FES manual muscle test grade of Fair+)

   Can the patient detect quadriceps fatigue and properly adjust stimulus intensity?

6. Circulatory Adjustment

   Do heart rate and blood pressure respond appropriately to upright stance?

7. Posture

   Is standing posture erect with less than 20% of body weight born by the upper extremities?

8. Fatigue/Recovery

   Can the patient stand for a minimum of three minutes?

   Does fatigue occur rapidly?

   Does the patient recover standing capability reasonably soon after fatigue?

Physical Therapy Assessment Form

		yes	no
Musculo-Skeletal Evaluation			
Is the user without signs of joint instability at hip, knee or ankle which precludes standing or stepping?	1	☐	☐
Is the user without signs of soft tissue inflammation related to stress or over use?	2	☐	☐
Skin			
Does the user's skin tolerate stimulation?	3	☐	☐
Upper Extremity Strength			
Is strength adequate to enable a patient to lift his body weight out of a chair and into a standing walker?	4	☐	☐
Is the patient able to stand using one arm for support?	5	☐	☐
Trunk Control and Balance			
Can the patient maintain upright stance with minimal upper extremity effort?	6	☐	☐
Does the patient display protective extension reactions?	7	☐	☐
Does the patient display protective equilibrium reactions?	8	☐	☐
Does the patient demonstrate an adequate sense of balance?	9	☐	☐
Is spatial orientation adequate?	10	☐	☐
Is awareness of posture accurate?	11	☐	☐
Lower Extremity FES Force Production			
Is FES muscle power sufficient to maintain locked knees while full weight bearing in standing double support? (A grade of fair+ with FES MMT)	12	☐	☐
Can the patient detect quadriceps fatigue and properly adjust stimulus intensity?	13	☐	☐
Circulatory Adjustment			
Do heart rate and blood pressure respond appropriately to upright stance?	14	☐	☐
Do heart rate and blood pressure return to resting levels within 5 min after standing?	15	☐	☐
Posture			
Is standing posture erect with less than 20% of body weight born by the upper extremities?	16	☐	☐
Fatigue/Recovery			
Can the patient stand for a minimum of three minutes?	17	☐	☐
Does the patient recover standing capability reasonably soon (5-10 min) after fatigue?	18	☐	☐

SESSION #5

TITLE: Principles of FES Gait Restoration

PRESENTER:

TIME:

OBJECTIVES:

Upon completion of this session, the clinician will be able to:

1. Identify the biomechanical prerequisites for safe and effective FES ambulation.

2. Analyze the biomechanical requirements of FES users to ambulate with 4- and 6-channel stimulators.

3. Exercise professional judgement in determining safe and effective use of FES ambulation systems.

4. Discuss the effective use and limitations of FES technology for ambulating.

5. Conduct the Parastep Functional Ability evaluation with FES.

6. Conduct the Parastep Gait & Ambulation evaluation with FES.

SESSION #5

TITLE: Principles of FES Gait Restoration

PRESENTER:

I. INTRODUCTION

Following medical evaluation and clearance to begin a FES gait program, a physical therapy evaluation must be performed to assure candidates possess sufficient motor power to perform the functions of standing and stepping. While the concept of muscle testing paralyzed limbs to determine their functional strength remains a novel academic pursuit, a practical means of clinically testing FES strength has been developed to demonstrate force development changes associated with the FES ambulation program. Changes in maximum strength and stimulus to strength ratios are key indicators of physiological improvement and should be routinely monitored. Gait training begins when patients demonstrate adequate motor power to achieve and maintain stance from the seated position.

II. PRELIMINARY BIOMECHANICAL REQUIREMENTS FOR WALKING

A. Raise the body to standing-

The goal of training patients to stand, is to safely and effectively rise from a seated position using the upper extremities to guide the head and trunk. Quadriceps function should be sufficient to lift the body with minimal lifting contributed by the upper extremities.

B. Optimize postural alignment for standing-

The goal addressed in standing, is to achieve a balanced stable posture such that 90% of the body's weight is supported by the lower extremities.

C. Uniped support-

Lateral weight shifting is required for effective stepping to occur. Individuals must demonstrate the ability to fully unweight each lower extremity.

D. Unweight the upper extremities-

Full weight acceptance upon the lower extremities is required to advance the walker.

E. Lower the body to sitting-

Activation of the sit command to ramp down extensor stimulation necessitates a series of maneuvers be successfully performed to safely return to the seated position. Independence is attained only when the patient demonstrates these acquired skills to the satisfaction of the physical therapist.

Functional Ability Assessment

Session ☐

SCORING:	
0	CANNOT PERFORM
1	PERFORMS WITH ASSISTANCE (PHYSICAL) OF ANOTHER
2	PERFORMS WITH STAND-BY ASSIST (VERBAL)
3	PERFORMS INDEPENDENTLY

FUNCTION:

POWERED SIT-STAND-SIT	☐
STANDING LATERAL WEIGHT SHIFT	☐
ONE LEG STANCE	☐
WALKER ADVANCE	☐
STEPPING & FOOT PLACEMENT	☐
STANDING WEIGHT SHIFT (FORWARD-BACK)	☐
ALTERNATING GAIT	☐
DAILY FUNCTIONAL USE	☐

COMMENT:

III. FUNCTION TESTING

A. The goal of functional evaluation is to determine the individual's ability to perform the required elements of Parastep® System use to achieve independence. The professional judgement of the physical therapist is required to apply the following criteria:

B. Grading:

0 CAN NOT PERFORM

1 PERFORMS WITH ASSISTANCE (PHYSICAL) OF ANOTHER

2 PERFORMS WITH STAND-BY ASSIST (VERBAL)

3 PERFORMS INDEPENDENTLY

C. Criteria

1. POWERED SIT-STAND-SIT

Raise the body to standing- The goal of training patients to stand, is to safely and effectively rise from a seated position using the upper extremities to guide the head and trunk. Quadriceps function should be sufficient to lift the body with minimal lifting contributed by the upper extremities.

Optimize postural alignment for standing- The goal addressed in standing, is to achieve a balanced stable posture such that 90% of the body's weight is supported by the lower extremities.

Lower the body to sitting- Activation of the sit command to ramp down stimulation performed so as to safely return to the seated position. Independence is attained only when the patient demonstrates these acquired skills to the satisfaction of the physical therapist.

2. STANDING LATERAL WEIGHT SHIFT

Lateral weight shifting is required for effective stepping to occur. Individuals must demonstrate the ability to fully unweight each lower extremity.

3. ONE LEG STANCE

Uniped support must be demonstrated by the ability to support the body on one leg while opposite leg swing occurs.

4. WALKER ADVANCE

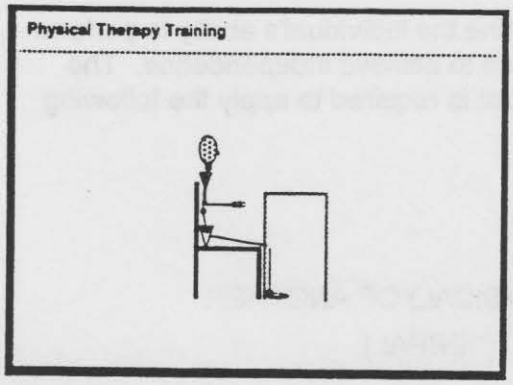
Unweighting the upper extremities is required with full weight acceptance upon the lower extremities to accomplish walker advance maneuvers.

5. STEPPING & FOOT PLACEMENT

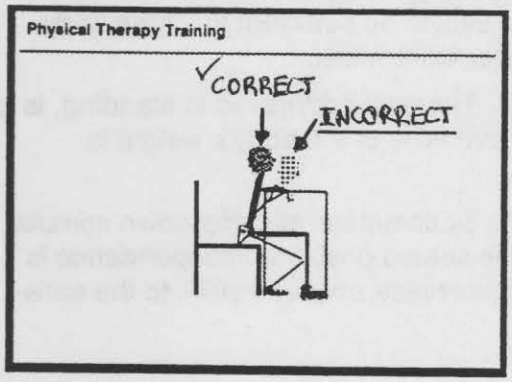
Stride length and foot position will vary for each individual and skill level attained. Therapist judgement must focus on the safe and effective performance of the movement required for forward locomotion.

6. STANDING WEIGHT SHIFT (FORWARD-BACK)

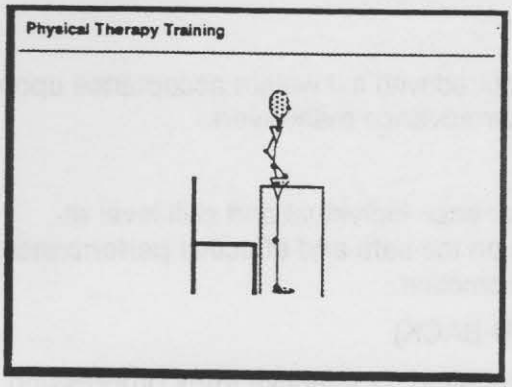
Anterior and posterior weight shifting is required for effective trunk progression and weight acceptance during gait. Individuals must demonstrate the ability to



Raise the body to standing- The goal is to stand safely and effectively rise from a seated position.



Using the upper extremities to guide the head and trunk. Quadriceps function should be sufficient to lift the body with minimal lifting contributed by the upper extremities.



Optimize postural alignment for standing- The goal addressed in standing is to achieve a balanced stable posture such that 90% of the body's weight is supported by the lower extremities.

transfer weight from back to front positioned extremity, and effectively position the trunk for effective locomotion.

7. ALTERNATING GAIT

   The user must demonstrate ability to repeat a left-right stepping sequence.

8. DAILY FUNCTIONAL USE

   The user must demonstrate ability to use the Parastep® System as part of his/her daily routine.

IV. BIOMECHANICAL REQUIREMENTS OF RECIPROCAL GAIT

A. Goal of gait training is to achieve safe and effective independent locomotion which is cosmetically acceptable and within user acceptable energy costs. Normal gait requires the coordinated functioning of over one hundred trunk and lower extremity muscles. It is conceded that synthesized gait restoration which utilizes a minimum of surface electrodes and channels of stimulation will only effectively control a fraction of that number, therefore, the pursuit of normal gait should not be confused as our purpose. Gait evaluation is performed with respect to the biomechanical requirements of biped locomotion as identified in the gait cycle, however, parameters of evaluation are restricted to the clinical judgement of qualified professionals utilizing the criteria of "safe" and "effective" in performance of these components.

B. Fundamental requirements for reciprocal gait

1. Prevent collapse or toppling of the body-

   Control of multi segment support is achieved by direct electrical stimulation of knee and hip extensors. Head and trunk control is achieved through use of a walker.

2. Injection of propulsive forces-

   The initiation of forward momentum is achieved by advancing the walker, flexing the trunk to position the head and shoulders over the walker and extending the arms and shoulders to pull the hips forward.

3. Control of forces providing propulsion and stability-

   The forward movement is controlled by volitional effort of the arm and shoulder girdle musculature to accelerate and decelerate the body's center of mass.

4. Shortening the limb for swing through-

   Reflex stimulation of mass flexion withdrawal is produced in response to nociceptive stimuli applied cutaneously to the lower leg. Ankle position is maintained through the use of a standard AFO assisting in toe clearance.

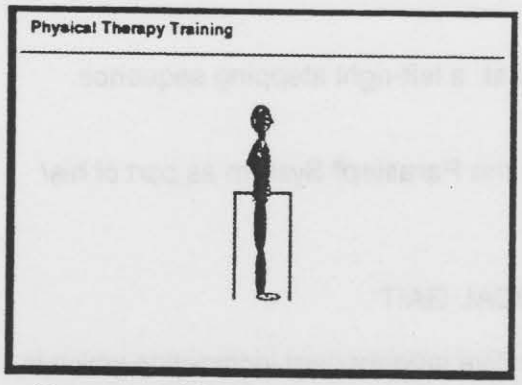
5. Advancing the swing leg-

   Within the latency afforded by flexion withdrawal, activation of the quadriceps through direct stimulation achieves both knee extension and heel strike as the reflex decays.

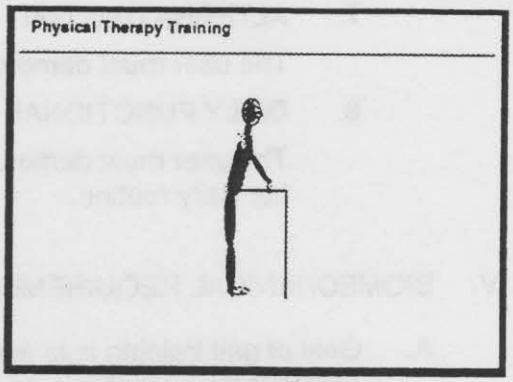
6. Advancing the trunk over the stance leg-

   Progression to mid stance is achieved by upper extremity extension and shoulder girdle depression movements.

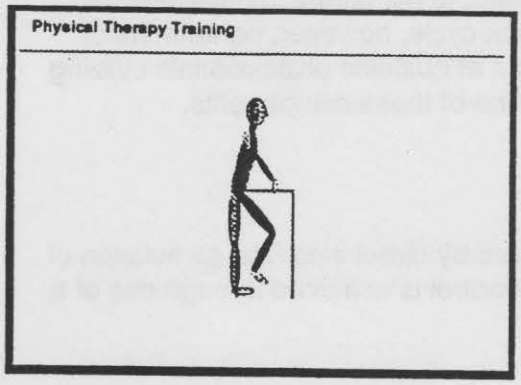
Parastep Gait Cycle



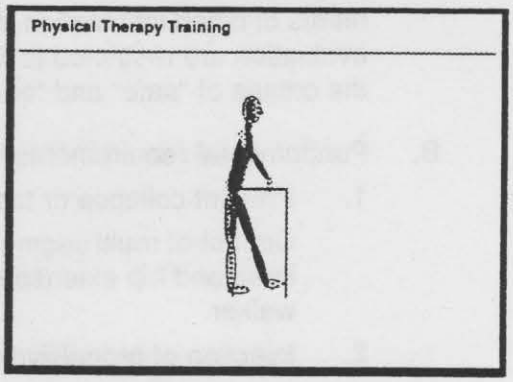
Supported Balanced Posture



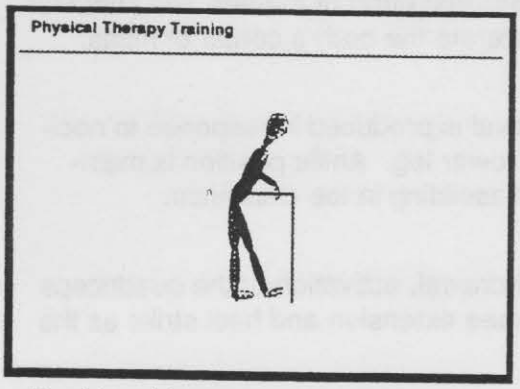
Advance Walker



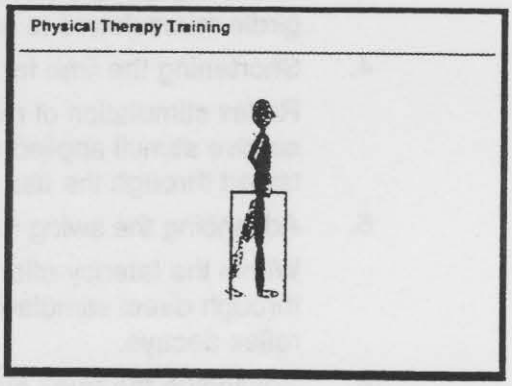
Trigger Flexion Response
for Right Step



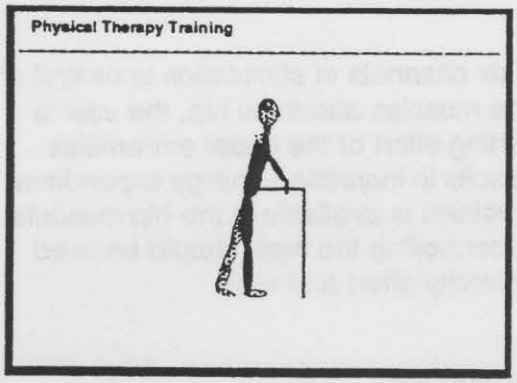
Right Heel Strike



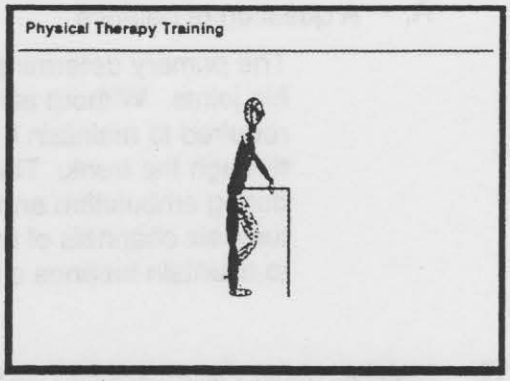
Position Head and Shoulders
over Advanced Foot



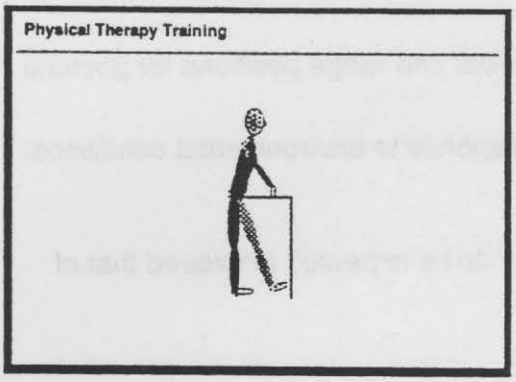
Depress Shoulder Girdle
Extend Elbows and
Pull Hips over Right Foot



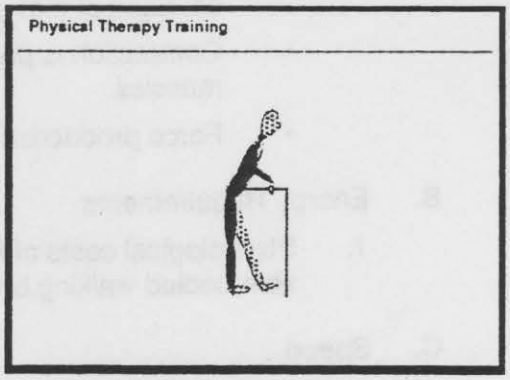
Advance Walker



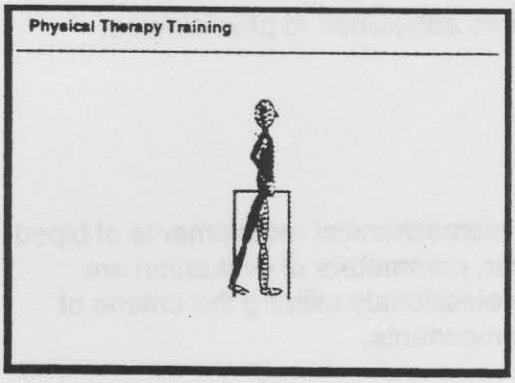
Trigger Flexion Response
for Left Step



Left Heel Strike



Position Head and Shoulders
over Advanced Foot



Depress Shoulder Girdle
Extend Elbows and
Pull Hips over Left Foot

V. 4 AND 6 CHANNEL INDICATIONS

A. A question of balance

The primary determinant in using four or six channels of stimulation is control of hip joints. Without active stimulation of the muscles about the hip, the user is required to maintain hip alignment by exerting effort of the upper extremities through the trunk. The additional effort results in increased energy expenditure during ambulation and standing. Unless volition is available in the hip musculature, six channels of stimulation, with two controlling the hips, should be used to maintain balance and reduce upper extremity effort and work.

VI. LIMITATIONS OF FES SYNTHESIZED GAIT RESTORATION

A. Muscle performance-

1. With open loop control strategies:
   - Muscle is restricted to all or none contractile efforts at maximal physiological rates of motor unit discharge.
   - Contraction is primarily isometric at near end range positions for postural muscles.
   - Force production is non varying in response to environmental conditions.

B. Energy Requirements

1. Physiological costs of FES ambulation should be expected to exceed that of able bodied walking by five to ten times.

C. Speed

1. Skill and Endurance determine walking speed and each subject uniquely develops his or her comfort rate. This rate may not meet the user's expectation for effective ambulatory function.

D. Motivation Requirements

1. Physical demand of FES ambulation requires adherence to physiological training and user comment.

VII. GAIT EVALUATION

A. Gait evaluation is performed with respect to the biomechanical requirements of biped locomotion as identified in the gait cycle, however, parameters of evaluation are restricted to the clinical judgement of qualified professionals utilizing the criteria of "safe" and "effective" in performance of these components.

B. Criteria

1. Standing Posture

   Anterior-posterior alignment- A plumb line should fall through the ear-shoulder-hip-knee-ankle centers of rotation. Landmarks should not deviate from this line by more than 5cm when standing.

   Left-right alignment- A plumb line from the nose should divide the feet equally, deviation should be less than 3cm when standing.

2. Support

   Weight Bearing- Standing-85% of the body's weight should be born through the legs.

3. Dynamic Balance

   Standing- Patient is able to stand without toppling.

   Walking- Patient is able to take steps without toppling.

4. Gait Cycle

   Toe off- Patient's toe clears the floor when step is activated.

   Swing Through- Patient's foot clears the floor surface during swing.

   Heel Strike- Patient's heel contacts the floor in a straight line in front of toe off position.

   Stride Length- Toe off to heel strike is in excess of 15cm.

5. Weight Transfer

   A-P- Patient is capable of fully transferring body weight from back to advanced foot and position hips over the forward foot.

   Lateral- Patient is capable of fully transferring body weight to stance leg during step activation.

6. Walker Management

   Progression- Patient is capable of moving the walker forward and back while standing.

   Placement- Patient is capable of moving the walker side to side and turning the walker 45° to each side.

7. Turns

   Patient is able to circle 90° to the left and the right.

8. Locomotion

   Patient is able to ambulate 5 meters.

9. Time to walk 5 Meters

   Measured in seconds.

10. Ambulation Status

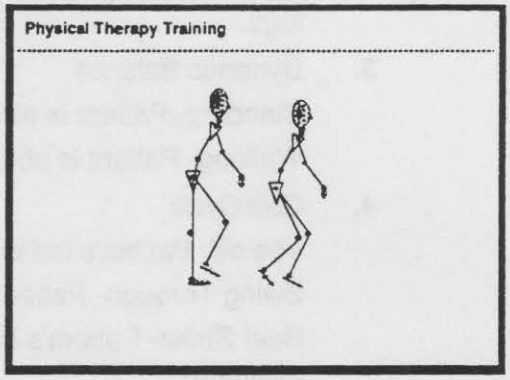
    Patient can perform above without the intervention of another person.

Independence is defined as the ability to put on and take off the system completely, perform sit to stand and stand to sit procedures, and ambulate over level surfaces without any assistance from another person.

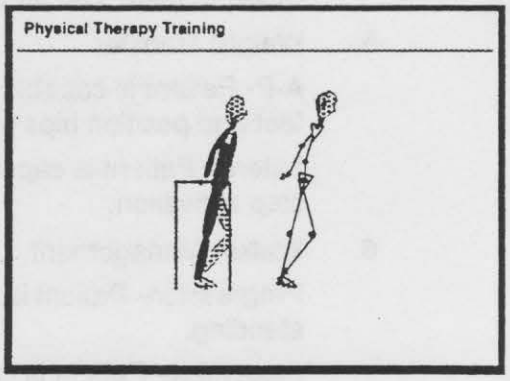
VIII. SITUATIONS OF INCREASED RISK

A. Three critical phases of gait require the therapist's vigilance to assure safety and prevent collapse:

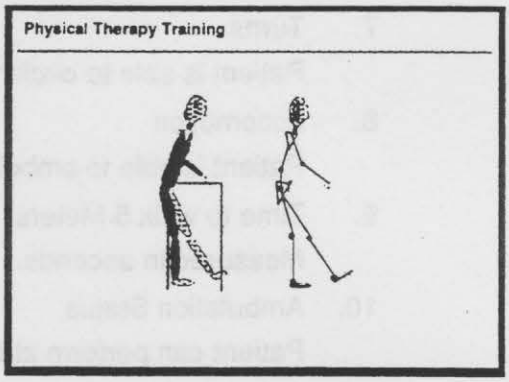
- Maintaining stability of the stance leg and hip during single leg support presents a situation where muscle stimulation and response is critical to prevent collapse. Here, the forces generated by gravity quickly accelerate when the fully loaded joints move into flexion and electrically stimulated antagonistic muscles cannot oppose with sufficient contractile force.



- Establishing clearance of the swing foot is critical to prevent tripping.



- Controlling step length and duration is essential to assure proper foot placement required to accept weight transfer.



B. Therapists must address these concerns with particular emphasis to insure safe and effective ambulation.

Gait and Ambulation Evaluation

Session ☐

Scoring
To receive a score of satisfactory the user must demonstrate component task performance both safely and effectively as determined by a physical therapist

	Satisfactory	Unsatisfactory	Criteria
STANDING POSTURE			
A-P ALIGNMENT	O	O	*< 5 cm deviation from the ear-shoulder-hip-knee-ankle joint-center line when standing*
L-R ALIGNMENT	O	O	*< 3cm deviation from the nose to feet centerline.*
SUPPORT			
LE WT BEARING	O	O	*Standing 85% of the body's weight is born through the legs.*
DYNAMIC BALANCE			
STANDING	O	O	*Subject is able to stand without toppling.*
WALKING	O	O	*Subject is able to take steps without toppling.*

GAIT CYCLE	LEFT		RIGHT		
	Satisfactory	Unsatisfactory	Satisfactory	Unsatisfactory	
TOE OFF	O	O	O	O	*Toe clears the floor when step is activated.*
SWING THROUGH	O	O	O	O	*Foot clears the floor surface during swing through.*
HEEL STRIKE	O	O	O	O	*Heel contacts the floor in a straight line in front of toe off.*
STRIDE LENGTH	O	O	O	O	*Toe off to heel strike is greater than 15 cm.*
STANCE	O	O	O	O	*Foot flat to toe off is stable and supports the body weight.*
WEIGHT TRANSFER					
A-P	O	O	O	O	*Fully transfer body weight and position hips over advanced foot.*
LAT	O	O	O	O	*Fully transfer body weight over stance foot.*

WALKER MANAGEMENT	Satisfactory	Unsatisfactory	
PROGRESSION	O	O	*Move the walker forward and back while standing.*
PLACEMENT	O	O	*Move walker side to side and rotate 45° to each side.*
TURNS	O	O	*Circle 90° to the left and right.*
LOCOMOTION	O	O	*Ambulate 10 feet over level surface.*

TIME TO WALK 10 feet _____ Seconds

AMBULATORY STATUS:

Independence is defined as the ability to put on and take off the system completely, perform sit to stand and stand to sit procedures, and ambulate over level surfaces without any assistance from another person.

NON AMBULATORY	O
REQUIRES VERBAL ASSISTANCE	O
REQUIRES PHYSICAL ASSISTANCE	O
INDEPENDENT	O

COMMENT:

SESSION #6

TITLE: Patient Screening & FES Ambulation (Lab)

PRESENTER:

TIME:

OBJECTIVES:

Upon completion of this session, the clinician will be able to:

1. Evaluate a S.C.I. candidate using the Medical Acceptance Evaluation and Physical Therapy Assessment forms.

2. Apply surface electrodes and instruct a S.C.I. subject in safe and effective use of the device.

3. Conduct and interpret results of the Parastep® Functional Ability Assessment.

PARASTEP® FES System

Medical Acceptance Evaluation

PATIENT NAME _____ ID # _____

DATE _____ INSTITUTION _____

		yes	no
Medical Criteria:			
1.	Status six months post recovery spinal cord injury and restorative surgery (if any)	1 ☐	☐
2.	Stable ortho-neuro-metabolic systems	2 ☐	☐
3.	Intact lower motor units (L1 and below)	3 ☐	☐
4.	Without history of long bone fractures, severe osteoporosis, hip or knee degenerative joint disease	4 ☐	☐
Clinical Criteria:			
1.	Does the patient demonstrate and express appropriate motivation and commitment to the therapeutic program?	5 ☐	☐
2.	Is muscle and joint stability available for weight bearing at upper and lower extremities?	6 ☐	☐
3.	Is sufficient range of motion available at all extremity articulations?	7 ☐	☐
4.	Does the patient demonstrate appropriate muscle contractile response to Functional Electrical Stimulation (FES)?	8 ☐	☐
5.	Is motor hyper activity sufficiently controlled to allow safe independent upright stance?	9 ☐	☐
6.	Does the patient demonstrate adequate learning ability to successfully employ the PARASTEP SYSTEM?	10 ☐	☐
7.	Does sensory perception of electrical stimulus allow sufficient level required for muscular contraction?	11 ☐	☐
Functional Criteria:			
1.	Is FES muscular force at the hip and knee sufficient for required function?	12 ☐	☐
2.	Does the patient respond to upright positions and with adequate hemodynamic and ventilatory responses?	13 ☐	☐
3.	Is the patient independent in all transfers?	14 ☐	☐
4.	Does the patient demonstrate adequate standing tolerance to perform biped activities?	15 ☐	☐
5.	Does the patient demonstrate adequate balance and control skills to maintain an upright supported posture independently ?	16 ☐	☐
6.	Does the patient demonstrate adequate hand and finger control to manipulate system controls?	17 ☐	☐
Exclusionary Criteria:			
1.	Cardiac demand pacemaker	18 ☐	☐
2.	Cancer in the area of electrode placement	19 ☐	☐
3.	Severe scoliosis	20 ☐	☐
4.	Fracture secondary to osteoporosis	21 ☐	☐
5.	Skin disease at stimulation sites or over swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, thrombo phlebitis, varicose veins	22 ☐	☐
6.	Irreversible contracture	23 ☐	☐
7.	Autonomic Dysreflexia	24 ☐	☐

I have evaluated the above individual and determined (him/her) to be a candidate for the Parastep functional electrical stimulation program to maximize (his/her) ambulatory potential. 28 ☐ ☐

_____ **MD**

Sigmedics 10/93

Submit this form to the medical monitor prior to the initiation of parastep training

PARASTEP® FES System

Physical Therapy Assessment

PATIENT NAME	ID #
DATE	INSTITUTION

Pre-training Assessment:

Musculo-Skeletal Evaluation

		yes	no
Is the user without signs of joint instability at hip, knee or ankle which precludes standing or stepping?	1	☐	☐
Is the user without signs of soft tissue inflammation related to stress or over use?	2	☐	☐

Skin

Does the user's skin tolerate stimulation?	3	☐	☐

Upper Extremity Strength

Is strength adequate to enable a patient to lift his body weight out of a chair and into a standing walker?	4	☐	☐
Is the patient able to stand using one arm for support?	5	☐	☐

Trunk Control and Balance

Can the patient maintain upright stance with minimal upper extremity effort?	6	☐	☐
Does the patient display protective extension reactions?	7	☐	☐
Does the patient display protective equilibrium reactions?	8	☐	☐
Does the patient demonstrate an adequate sense of balance?	9	☐	☐
Is spatial orientation adequate?	10	☐	☐
Is awareness of posture accurate?	11	☐	☐

Lower Extremity FES Force Production

Is FES muscle power sufficient to maintain locked knees while full weight bearing in standing double support? (A grade of fair+ with FES MMT)	12	☐	☐
Can the patient detect quadriceps fatigue and properly adjust stimulus intensity?	13	☐	☐

Circulatory Adjustment

Do heart rate and blood pressure respond appropriately to upright stance?	14	☐	☐
Do heart rate and blood pressure return to resting levels within 5 min after standing?	15	☐	☐

Posture

Is standing posture erect with less than 20% of body weight born by the upper extremities?	16	☐	☐

Fatigue/Recovery

Can the patient stand for a minimum of three minutes?	17	☐	☐
Does the patient recover standing capability reasonably soon (5-10 min) after fatigue?	18	☐	☐

I have evaluated the above individual and determined (him/her) to be a candidate for the Parastep functional electrical stimulation program to maximize (his/her) ambulatory potential.	19	☐	☐

PT

SIGNATURE

Submit this form to Sigmedics prior to the initiation of parastep training

PARASTEP® FES System

Functional Ability Assessment

PATIENT NAME	ID #
DATE	INSTITUTION

Session ☐

SCORING:

0	CANNOT PERFORM
1	PERFORMS WITH ASSISTANCE (PHYSICAL) OF ANOTHER
2	PERFORMS WITH STAND-BY ASSIST (VERBAL)
3	PERFORMS INDEPENDENTLY

FUNCTION:

POWERED SIT-STAND-SIT	☐
STANDING LATERAL WEIGHT SHIFT	☐
ONE LEG STANCE	☐
WALKER ADVANCE	☐
STEPPING & FOOT PLACEMENT	☐
STANDING WEIGHT SHIFT (FORWARD-BACK)	☐
ALTERNATING GAIT	☐
DAILY FUNCTIONAL USE	☐

COMMENT:

PT

SIGNATURE

SESSION #7

TITLE: Principles of FES Strength Training & Testing

PRESENTER:

TIME:

OBJECTIVES:

Upon completion of this session, the clinician will be able to:

1. Define muscular strength and endurance and state how these can be developed.

2. Describe principles of exercise training relating to muscle strength and endurance.
   - Overload
   - Specificity
   - Progressive resistance
   - Frequency

3. Describe muscle fatigue during electrical stimulation and the effect of the stimulation training program on:
   - Fiber cross-sectional area
   - Fiber type
   - Capillary density

4. Describe how to evaluate quadriceps muscle performance with FES in S.C.I. patients using free weight strength evaluation.

SESSION #7

TITLE: Principles of FES Strength Testing & Training

PRESENTER:

I. Exercise Training

- A. Muscle Strength
- B. Endurance
- C. Physiological Principles of Exercise Training
  1. Overload
  2. Specificity
  3. Progressive resistance
  4. Frequency

II. Electrically Induced Exercise

- A. Recruitment of fibers
- B. Frequency of stimulation
- C. Fatigue
- D. Muscle changes in response to stimulation with overload
- E. Muscle changes in response to stimulated endurance exercise training

III. Application to Parastep training

- A. Strength training - Methods
- B. Endurance training - Methods

IV. Free Weight Strength Evaluation

The free weight strength evaluation utilizes the following to estimate the Resultant Knee Joint Moment to elevate and then hold the limb in a fixed angular position with the addition of load to the ankle region. This is a description of the calculations required for this evaluation. The magnitude of the Resultant Knee Joint Moment is equal to the sum of the moment of weight of the shank and foot segments and the moment of the weight of the load.

For our purposes quadriceps strength is the estimate of the resultant knee joint moment achieved by electrical stimulation of the quadriceps during the designed test procedure. Our estimate ignores the weight of the limb and is calculated solely upon the load applied to the ankle.

The weight of the load can be measured directly. The distance from the knee joint axis of rotation to the lateral maleolus is measured (D). The location of the instantaneous knee joint axis of rotation is difficult to determine precisely. However, the error produced by any reasonable estimate of the knee joint axis of rotation is relatively small. When the lower limb is positioned such that the thigh segment is horizontal and when the stimulator is used to extend the lower leg about the knee to a horizontal position, the distance D is equal to the moment arm of the shank and foot weight and the load weight about the knee joint. When the leg segment deviates from the horizontal position the moment arm varies trigonometrically with the knee joint angle.

The standard unit of measure is Newtons for weight and meters for distance. The tendency of each force (weight) to produce rotation is called a moment. The unit of measure of a moment is the Newton-meter.

Force = mass (kg) X acceleration (m/s2)

Weight = mass (kg) X gravitational acceleration (m/s2) gravitational acceleration = -9.81 m/s2

1 N = 1 kg X 9.81 m/s2

1 kg = 2.2 lb

Our free weight assessment of quadriceps strength includes assessment of muscular endurance by calculating total work performed by estimate of the sum of all work performed during the test. Each contraction lifting the specified weight to complete knee extension raises that weight through an arc of motion to a vertical height approximately the length of the tibia. Therefore, work performed during each test contraction is estimated as the weight lifted multiplied by the length of the tibia (W=FxD).

The sum of work performed during all test contractions is defined as the quadriceps work capacity (QWC). When divided by the subjects body weight for normalization an index of measurement is derived for comparing subject to subject.

$$\text{Quadriceps Work Capacity Index} = \frac{(W1+W2+...)}{\text{Body Weight} \times 100}$$

Measurement of strength or force generation in paralyzed muscle may seem a novel concept to some clinicians. However, clinical applications of functional neuromuscular stimulation requires qualification and analysis if FES applications are to be effective in the synthesis of human function. Isometric and isokinetic methodologies described elsewhere by Bajd, T. ('83), Scott , O.M. ('85), Knutsson, E. (85), Murry, M.P. (80), Marsolais, E.B. (83), have been used for this purpose. While these methods are accurate and reliable they may be unavailable for clinical use as they require specialized instrumentation not always available in the clinic setting. The following methodology was developed by Sigmedics, Inc. to assist clinicians to observe and quantify FES induced muscular force production with standard clinical equipment and physical therapy procedures. These methodologies are derived from the principles of maximal strength determinations using modified one repetition maximum techniques. Our purpose is to provide an easily applied methodology to estimate quadriceps strength under FES conditions and to standardize reporting such that test results may be compared over time or between subjects.

Preparation

a. Equipment:

Calibrated Sigmedics Test Unit

Ankle Weights, (2) 1 lb
(1) 3 lb
(1) 5 lb
(1) 10 lb

Tape Measure

Mat Table

Towel Roll

b. Instruction:

Explain to subject procedure and purpose

c. Set-up:

Position subject supine on a mat table, knees bent over the table edge, feet on floor, towel roll under knee to be tested to assure complete knee extension (tibia should be parallel to the floor upon extension). Non testing leg should be positioned with hip and knee flexed with foot flat on the mat table to flatten lumbar curve. Hips and pelvis should be stabilized during testing to prevent hip rotation or pelvic tilt.

Measure distance from knee axis to lateral malleolus and record.

Measure and record quadriceps girth 6" above suprapatellar border.

Apply quadriceps electrodes.

Attach quadriceps electrode cable to right channel of stimulator.

Testing

1. Protocol

Stabilize lower extremity to prevent hip rotation or pelvic tilting during testing.

Contraction 1 - Activate sit/stand to ramp up stimulation. Increase stimulation to complete ROM of knee with 0 lbs affixed to ankle. Activate sit/stand to ramp down stimulus.

Contraction 2- Repeat above with 1 lb affixed to the ankle.

Contraction 3- Repeat above with 2 lb affixed to the ankle.

Contraction 4- Repeat above with 3 lb affixed to the ankle.

Continue as above adding one pound with each contraction. Perform test without rest between contractions (not greater than 30 seconds between successive lifts). Increase stimulus sufficient to complete knee extension (do not stimulate in excess of current required to complete full extension). The test is terminated when increasing stimulus fails to achieve complete knee extension.

2. Record stimulus level after each contraction.

V. Physiological Cost Index (PCI)

1. Measure steady state heart rate (HR) and velocity (V).

1. $$\frac{HR_W - HR_R}{V} = \frac{\text{Beats}}{\text{Meter}}$$

FES Quadriceps Strength Assessment

Session ☐

RESPONSE TO ELECTRICAL STIMULATION

Testing Stimulator # _____

	LEFT	RIGHT
NO RESPONSE	☐	☐
BRIEF MUSCLE TWITCH	☐	☐
PALPABLE SUSTAINED CONTRACTION	☐	☐
SUSTAINED CONTRACTION PARTIAL LIMB MOVEMENT	☐	☐
STRONG CONTRACTION LIMB MOVEMENT THROUGH FULL RANGE	☐	☐

THIGH GIRTH (measured 15cm above suprapatellar border)	____ in	____ in
TIBIA LENGTH (measured from knee axis to lateral malleolus)	____ in	____ in
BODY WEIGHT	____ lbs	

QUADRICEPS STRENGTH / ENDURANCE TEST

LEFT			RIGHT		
CONTRACTION	(LBS)	STIMULUS INTENSITY	CONTRACTION	(LBS)	STIMULUS INTENSITY
1	0	_____	1	0	_____
2	1	_____	2	1	_____
3	2	_____	3	2	_____
4	3	_____	4	3	_____
5	4	_____	5	4	_____
6	5	_____	6	5	_____
7	6	_____	7	6	_____
8	7	_____	8	7	_____
9	8	_____	9	8	_____
10	9	_____	10	9	_____
11	10	_____	11	10	_____
12	11	_____	12	11	_____
13	12	_____	13	12	_____
14	13	_____	14	13	_____
15	14	_____	15	14	_____
16	15	_____	16	15	_____
17	16	_____	17	16	_____
18	17	_____	18	17	_____
19	18	_____	19	18	_____
20	19	_____	20	19	_____
21	20	_____	21	20	_____

Sigmedics FES Strength Testing Chart

(To be used with FES Strength Testing protocol)

Calculations below assume a tibial length of 12 inches and a body weight of 100 lbs.

Contraction	Weight (lbs.)	Work Wt x Tibia Length (ft-lbs)	Work Sum (W1+W2....)	Work Capacity Index $\frac{(W1+W2....)}{\text{Body Weight}} \times 100$
1	0	0.0	0	0.0
2	1	1.0	1	1.0
3	2	2.0	3	3.0
4	3	3.0	6	6.0
5	4	4.0	10	10.0
6	5	5.0	15	15.0
7	6	6.0	21	21.0
8	7	7.0	28	28.0
9	8	8.0	36	36.0
10	9	9.0	45	45.0
11	10	10.0	55	55.0
12	11	11.0	66	66.0
13	12	12.0	78	78.0
14	13	13.0	91	91.0
15	14	14.0	105	105.0
16	15	15.0	120	120.0
17	16	16.0	136	136.0
18	17	17.0	153	153.0
19	18	18.0	171	171.0
20	19	19.0	190	190.0
21	20	20.0	210	210.0
22	25	25.0	235	235.0
23	30	30.0	265	265.0
24	35	35.0	300	300.0
25	40	40.0	340	340.0
26	45	45.0	385	385.0
27	50	50.0	435	435.0
28	55	55.0	490	490.0
29	60	60.0	550	550.0
30	65	65.0	615	615.0
31	70	70.0	685	685.0
32	75	75.0	760	760.0
33	80	80.0	840	840.0
34	85	85.0	925	925.0

SESSION #8

TITLE: Strength Testing & Gait Evaluation (Lab)

PRESENTER:

TIME:

OBJECTIVES:

Upon completion of this session, the clinician will be able to:

1. Conduct and interpret results for the Parastep Strength Testing protocol.

2. Analyze the gait differences of FES users.

3. Develop appreciation for synthesized gait differences.

4. Develop appreciation for the contribution of posture and balance to successful walking.

5. Conduct and interpret results of the Parastep Gait Evaluation protocol.

FES Quadriceps Strength Assessment

Session ☐

RESPONSE TO ELECTRICAL STIMULATION

Testing Stimulator # _____

	LEFT	RIGHT
NO RESPONSE	☐	☐
BRIEF MUSCLE TWITCH	☐	☐
PALPABLE SUSTAINED CONTRACTION	☐	☐
SUSTAINED CONTRACTION PARTIAL LIMB MOVEMENT	☐	☐
STRONG CONTRACTION LIMB MOVEMENT THROUGH FULL RANGE	☐	☐

THIGH GIRTH (measured 15cm above suprapatellar border)	_____ in	_____ in
TIBIA LENGTH (measured from knee axis to lateral malleolus)	_____ in	_____ in
BODY WEIGHT	_____ lbs	

QUADRICEPS STRENGTH / ENDURANCE TEST

LEFT			RIGHT		
CONTRACTION	(LBS)	STIMULUS INTENSITY	CONTRACTION	(LBS)	STIMULUS INTENSITY
1	0	_____	1	0	_____
2	1	_____	2	1	_____
3	2	_____	3	2	_____
4	3	_____	4	3	_____
5	4	_____	5	4	_____
6	5	_____	6	5	_____
7	6	_____	7	6	_____
8	7	_____	8	7	_____
9	8	_____	9	8	_____
10	9	_____	10	9	_____
11	10	_____	11	10	_____
12	11	_____	12	11	_____
13	12	_____	13	12	_____
14	13	_____	14	13	_____
15	14	_____	15	14	_____
16	15	_____	16	15	_____
17	16	_____	17	16	_____
18	17	_____	18	17	_____
19	18	_____	19	18	_____
20	19	_____	20	19	_____
21	20	_____	21	20	_____

Gait/Ambulation Evaluation

Evaluate user's gait and ambulatory status. Demonstrate handling techniques which increase the safe and effective ambulatory skills for this user.

Analyze this user's gait: _____

_____

_____

_____

_____

_____

_____

_____

Identify the problems that are significant obstacles to "independent" ambulation for this user: _____

_____

_____

_____

_____

_____

_____

_____

Gait and Ambulation Evaluation

Session ☐

Scoring
To receive a score of satisfactory the user must demonstrate component task performance both safely and effectively as determined by a physical therapist

	Satisfactory	Unsatisfactory			Criteria
STANDING POSTURE					
A-P ALIGNMENT	O	O			*< 5 cm deviation from the ear-shoulder-hip-knee-ankle joint-center line when standing*
L-R ALIGNMENT	O	O			*< 3cm deviation from the nose to feet centerline.*
SUPPORT					
LE WT BEARING	O	O			*Standing 85% of the body's weight is born through the legs.*
DYNAMIC BALANCE					
STANDING	O	O			*Subject is able to stand without toppling.*
WALKING	O	O			*Subject is able to take steps without toppling.*
GAIT CYCLE	LEFT		RIGHT		
	Satisfactory	Unsatisfactory	Satisfactory	Unsatisfactory	
TOE OFF	O	O	O	O	*Toe clears the floor when step is activated.*
SWING THROUGH	O	O	O	O	*Foot clears the floor surface during swing through.*
HEEL STRIKE	O	O	O	O	*Heel contacts the floor in a straight line in front of toe off.*
STRIDE LENGTH	O	O	O	O	*Toe off to heel strike is greater than 15 cm.*
STANCE	O	O	O	O	*Foot flat to toe off is stable and supports the body weight.*
WEIGHT TRANSFER					
A-P	O	O	O	O	*Fully transfer body weight and position hips over advanced foot.*
LAT	O	O	O	O	*Fully transfer body weight over stance foot.*

WALKER MANAGEMENT

	Satisfactory	Unsatisfactory	
PROGRESSION	O	O	*Move the walker forward and back while standing.*
PLACEMENT	O	O	*Move walker side to side and rotate 45° to each side.*

TURNS O O *Circle 90° to the left and right.*

LOCOMOTION O O *Ambulate 10 feet over level surface.*

TIME TO WALK 10 feet _____ Seconds

AMBULATORY STATUS:

NON AMBULATORY	O	*Independence is defined as the ability to put on and take off the system completely, perform sit to stand and stand to sit procedures, and ambulate over level surfaces without any assistance from another person*
REQUIRES VERBAL ASSISTANCE	O	
REQUIRES PHYSICAL ASSISTANCE	O	
INDEPENDENT	O	

COMMENT:

Gait and Ambulation Evaluation

Session ☐

Scoring
To receive a score of satisfactory the user must demonstrate component task performance both safely and effectively as determined by a physical therapist

	Satisfactory	Unsatisfactory
STANDING POSTURE		
A-P ALIGNMENT	○	○
L-R ALIGNMENT	○	○
SUPPORT		
LOWER EXTREMITY WEIGHT BEARING	○	○
DYNAMIC BALANCE		
STANDING	○	○
WALKING	○	○

GAIT CYCLE	LEFT		RIGHT	
	Satisfactory	Unsatisfactory	Satisfactory	Unsatisfactory
TOE OFF	○	○	○	○
SWING THROUGH	○	○	○	○
HEEL STRIKE	○	○	○	○
STRIDE LENGTH	○	○	○	○
STANCE	○	○	○	○
WEIGHT TRANSFER				
A-P	○	○	○	○
LAT	○	○	○	○

WALKER MANAGEMENT	Satisfactory	Unsatisfactory
PROGRESSION	○	○
PLACEMENT	○	○

TURNS ○ ○

LOCOMOTION ○ ○

TIME TO WALK 5 meters _____ **Seconds**

AMBULATORY STATUS:

NON AMBULATORY ○

REQUIRES ASSISTANCE Verbal ○ Physical ○

INDEPENDENT ○

COMMENT:

SESSION #9

TITLE: Physical Therapy Training & Plan of Care

PRESENTER:

TIME:

OBJECTIVES:

Upon completion of this session, the clinician will be able to:

1. Understand how to apply appropriate training techniques for FES ambulation.
2. Develop an individualized plan of care to include:
   - Patient goals and objectives
   - Home exercise program
   - Appropriate progression of training
3. Identify and complete the required elements of patient training documentation for the Parastep® program.

SESSION # 9

TITLE: Physical Therapy Training & Plan of Care

PRESENTER:

I. PHYSICAL THERAPY TRAINING

Goals:

Training and physical therapy related to the Parastep system is directed at the clinical goals of independent transfer and upright stepping functions with the Parastep. Early in the training program the patient must demonstrate adequate cognitive faculties required for motor learning. Coordination of volitional and computer controlled movement patterns must be integrated into a new set of skills without reference to the normal developmental basis for ambulation.

While each patient and facility presents a unique set of circumstances requiring individual logistical solutions, the following training regime is suggested as one possible model to provide a baseline for measuring effectiveness.

Safety Objectives:

Patient Instruction - The user will demonstrate adequate understanding of system use, purpose and limitations.

Equipment Check and Maintenance - The user will understand and perform routine maintenance requirements of the system.

Falls - The user will understand and demonstrate successful techniques to minimizethe fall related risks.

Terrain and surfaces - The user will understand the requirements and demonstrate safe and effective negotiation of ambulating over varied surfaces and terrain.

Physiological Objectives :

Improve Strength

Improve Endurance

Improve Balance

Utility Objectives:

Powered Self Initiated Muscular Contraction

Powered Sit-Stand-Sit

Upright Weight Shift (Lateral)

One Leg Stance

Walker Advance

Stepping and Foot Placement

Upright Weight Shift (Forward)

Alternating Gait

Independent Use in ADL

III. EXAMPLE – PLAN OF CARE

It is intended to achieve the above goals within 32 sessions of physical therapy training. A session is defined as one outpatient visit to Physical Therapy on any given day. The session duration may vary dependent on patient progress and level of skill attained. A typical plan of care is outlined below which will serve as a model with the understanding that modification will be required to accommodate the individual requirements of each user.

Session	Physical Therapy Objective
1	FES Evaluation and Clinical History
	Perform Strength, Function, and Gait Evaluation
	Teach FES use and establish clinical expectation and training timetable
	Teach donning and doffing system
2	Instruct in stimulator use, electrode placement, quadriceps stimulation and intensity settings
	Instruct in home FES exercise for quadriceps
3	Instruct in powered sit to stand and stand to sit
4	Instruct in posture and balance skills
	Instruct in hand support, weight bearing, stimulation control for standing
	Teach fatigue detection techniques
5	Instruct in fall prevention
6	Perform Strength, Function, and Gait Evaluation
	Instruct in weight shifting (lateral) activities
	Instruct unilateral support techniques and one leg stance
	Reinforce safety procedures
7	Instruct in single step initiation
8	Instruct in foot placement and step length
9	Instruct in weight shifting (A-P)
10	Instruct in balance and posture
11	Stepping, balance and posture

12 Perform Strength, Function, and Gail Evaluation Stepping balance and posture

13 Stepping balance and posture

14 Stepping balance and posture

15 Instruct in walker use and management. Stepping balance and posture.

16 Gait and Ambulation Instruction

17 Gait and Ambulation Instruction

18 Perform Strength, Function, and Gait Evaluation Gait and Ambulation Instruction

19 Gait and Ambulation Instruction

20 Gait and Ambulation Instruction

21 Gait and Ambulation Instruction

22 Gait and Ambulation Instruction

23 Gait and Ambulation Instruction

24 Perform Strength, Function, and Gait Evaluation Gait and Ambulation Instruction

25 Gait and Ambulation Instruction

26 Gait and Ambulation Instruction

27 Gait and Ambulation Instruction

28 Gait and Ambulation Instruction

29 Gait and Ambulation Instruction

30 Gait and Ambulation Instruction

31 Gait and Ambulation Instruction

32 Final Evaluation

Perform Strength, Function, and Gait Evaluation Gait and Ambulation Instruction
Discharge with follow up.

Frequency:

Physical Therapy Training should be conducted 3 times per week or even more frequently dependent on the individual, his/her conditions and progress. Unsupervised training to improve strength and endurance should continue at home on a prescribed basis (usually daily) with an "E" type stimulator.

Duration:

Treatment sessions should be limited to user tolerance and progress accordingly. One to one and a half hour sessions, with rest stops in between, have been tolerated well by past and current users. It is expected that users will become independent in use of the Parastep System within 32 sessions of Physical Therapy over a ten to twelve week period. A typical treatment schedule is provided in the Patient Reporting Packet. Under an "accelerated" Physical Therapy program, a patient may be able to complete their training in a considerably shorter period of time.

Physical Therapy Treatment Record

Session ____

TRAINING PROVIDED THIS VISIT:

EVALUATIONS PERFORMED THIS VISIT:

KNEE STRENGTH ☐
FUNCTIONAL ABILITY ☐
GAIT & AMBULATION ☐
SYSTEM USED: ○ ❹ ❻ Channel
ELECTRODE PLACEMENT: _____

CLINIC NOTES:

Resting HR ____
Resting BP ____

STANDING:

	Time Seconds	HR End	BP End	Dyspnea	Max Stim Level
1					
2					
3					
4					

WALKING:

	Distance Feet	Steps	Time Seconds	HR End	BP End	Dyspnea	Max Stim Level
Walk 1							
Walk 2							
Walk 3							
Walk 4							
Walk 5							

Ambulatory Status: Non Ambulatory ( ) Physical Assist ( ) Verbal Assist ( ) Independent ( )

PROBLEMS IDENTIFIED/COMMENTS:

PLAN OF CARE:

HOME PROGRAM:

Case Conference Report

Summary of patient status

Problems Identified

Program Goals

Plan

MD

Weekly Home Exercise Log

SYSTEM USE:							
Date	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
STANDING:							
Time							
Number of Stands							
WALKING:							
Time							
Distance							
Max. Stim. Level							
EXERCISE:							
Quads: Sets							
Rep							
Wt.							
Steps: Sets							
Reps							
Sit to Stand: Sets							
Reps							
ACTIVITIES:							
PROBLEMS/COMMENTS:							

Discharge Summary

Frankel Score _____

Ashworth Score _____

Date of Discharge from the Parastep program _____

Reason for termination _____

Ambulatory Status at discharge _____

Does user intend to acquire a Parastep system? YES NO

Does user demonstrate the ability to be a home user? YES NO

Does user demonstrate the ability to be a community walker? YES NO

Disposition

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

SESSION #10

TITLE: Gait Analyses & Care Planning (Lab)

PRESENTER:

TIME:

OBJECTIVES:

Upon completion of this session, the clinician will be able to:

1. Perform and interpret results of clinical gait analyses techniques.
2. Analyze the gait differences of FES users.
3. Develop appreciation for synthesized gait limitations.
4. Make recommendations for gait improvement for FNS gait users.

Gait/Ambulation Evaluation

User #

Analyze this user's gait: _____

_____

_____

_____

_____

_____

_____

_____

Identify the problems that are significant obstacles to "independent" ambulation for this user: _____

_____

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Recommendations: _____

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Parastep®

Physical Therapy Protocol

NOTE: This The Parastep Physical Therapy Protocol incorporates the collective knowledge of Physical Therapy Procedures and clinical experiences our Professional staff have used or reviewed. It is intended to serve as a standard to demonstrate safety and effectiveness of the Parastep system.

TABLE OF CONTENTS

INTRODUCTION

Electrical stimulation applied to paralyzed muscles has demonstrated its therapeutic value since the early 1960's. Functional Electrical Stimulation (FES) has been described as "electrical stimulation of muscle deprived of nervous control with a view of providing muscular contraction and producing a functionally useful movement." (Graconin et.al., '67). FES of peripheral nerves producing muscular contractions is currently used in the treatment of spinal cord injured to maintain muscle viability and promote cardiovascular health. Most recently, FES has demonstrated its usefulness in enabling selected paralyzed individuals to stand and initiate biped gait.

This Physical Therapy protocol for the Parastep system has been developed for clinical use based upon accepted rehabilitation medicine and therapeutic practices for Functional Electrical Stimulation (FES) application. Clinical experience gained over the past nine years with use of the Parastep has guided the development of this protocol. It should be used by clinicians to assist with introduction of the system for use in clinical settings. It is understood that each institution reserves the right to impose policy and procedure regarding patient care and clinical practice. This protocol is intended to provide the foundation for safety and utility of the Parastep.

The Physical Therapy program described herein is intended to assure the successful clinical outcome of the Parastep system when used for appropriate spinal cord injured individuals. This outcome includes standing and taking steps with a walker to enhance the physiological and psychological well being and daily function of the user. It is anticipated this protocol may undergo future revisions as further experience with the system is gained.

We expect the Parastep system will prove to be a useful adjunct to standing ambulation and activities of daily living for the SCI and will provide an important alternative in the management of the spinal cord injured patient.

SYSTEM DESCRIPTION

The Parastep system is a comprehensive approach to enable standing and short distance walking. The system consists of professional physical therapy training/support services and product components.

Physical Therapy Training

Physical therapy is a key element of the Parastep system. Thirty-two sessions of physical therapy, including instruction on system use and gait training, are provided with the system.

The physical therapy sessions are provided by physical therapists at approved rehabilitation institutions across the country. Sigmedics has established a comprehensive training and education program for rehabilitation professionals (physiatrists, neurologists and physical therapists), including protocols for patient selection, patient education and training, and patient follow-up.

Product Components

The Parastep system consists of a microcomputer controlled neuromuscular stimulator, a battery pack with recharger, surface applied electrodes, power and electrode cables, a control and stability walker with surface mounted control switches, and the Paratester™, a diagnostic unit for testing system components.

The neuromuscular stimulator generates sequences of electrical impulses. These impulses are passed to the target peripheral nerves through surface applied skin electrodes, placed on the quadriceps muscles and over the peroneal nerves on the lower legs. Stimulation of the quadriceps muscles causes contraction which results in knee extension, allowing the user to stand. Stimulation of the peroneal nerve in the lower leg initiates a reflex contraction of the hip muscle to flex the hip, which allows the knee to bend, producing a step and allowing the user to walk.

Neuromuscular Electrical Stimulator

The stimulator unit houses the microcomputer and associated electronics which generate the electrical impulses that stimulate the user's legs. It provides a maximum of six stimulation channels: two for the hip musculature, two for the quadriceps muscles and two for the lower leg. The unit is lightweight (7.6 oz.) and is usually worn clipped to the user's belt. Users set levels of stimulation, increase or decrease levels of stimulation and activate commands for standing and stepping through a user-friendly key pad on the front of

the stimulator unit or through switches mounted on the walker. The stimulation level is displayed by a 10-segment LED (light emitting diode) display located on the side of the stimulator unit.

Battery Pack

The stimulator is powered by a rechargeable battery pack which contains eight AA nickel cadmium batteries. The battery pack is attached to the stimulator unit with a power cable and then is usually placed in the user's pocket. A low battery level indicator is built in, to warn users when recharging is necessary. A normal charge provides for approximately 2 1/2 hours of continuous use.

Electrodes and Lead Cables

Stimulation signals generated by the stimulator unit are sent by three cables to twelve self-adhering, surface skin electrodes that are applied to the user's legs. One cable connects to four electrodes on the right leg, and one cable connects to four electrodes on the left leg. The third cable provides stimulation to the hip musculature.

The Paratester™

The Paratester™ is a diagnostic tool for pretesting system components. The unit checks and alerts the user of possible malfunctions in the stimulator, and electrode and power cables.

Control and Stability Walker

A specially designed walker is utilized to compensate for the user's lack of balance. It provides support and stability while standing and walking. After presetting the initial levels of stimulation to be applied to the legs on the face panel (keypad) of the stimulator and attaching the walker cable to the stimulator unit, the user can operate all commands (stand, step, sit, increase/decrease levels of stimulus) through finger switches mounted on the handle bars of the walker.

PATIENT SELECTION

Patient selection of candidates for synthesized gait restoration programs must involve consideration of the functional ability of systems to adequately support the demands of standing and walking.

Neurological system- The upper limits of spinal cord injury for participation in a FES gait restoration program are determined by the preservation of upper extremity function required to operate controls and support the body while standing and transferring. The lower limits of SCI injury are defined by the preservation of lower motor neuron function.

Muscular system- Spasms must be controlled or infrequent. Muscle must demonstrate sufficient response to electrical excitation to insure adequate force generation to perform support and movement requirements.

Skeletal system- Bones must adequately support the body under dynamic and static loading. Osteoporosis is a primary concern requiring specific evaluation. Individuals with recent history of fracture should undergo dual photon absorptiometry testing. Individuals with less than 50% of age predicted bone mineral content should be excluded from the program. While x-ray have failed to quantify the degree of osteoporosis, cortical thickness as interpreted by radiological exam should be graded as moderate or better. Hip, knee, and ankle joints should demonstrate full articular excursion and be without significant degenerative joint disease.

Cardiovascular system- Patients with cardiovascular disease should undergo evaluation by a Cardiologist to determine risk status prior to exercise training. Uncontrolled hypertension is a contraindication to participation.

Respiratory system- Compromised ventilatory responses to exercise should be evaluated by pulmonary function analysis. C.O.P.D. should be evaluated by a Pulmonologist prior to program participation. Respiratory infection is a contraindication to exercise and program participation.

Urogenital system- Urologist coordination is required for patients with chronic renal disease. Exercise is contraindicated during periods of intercurrent urinary tract infections.

Cutaneous system- A Dermatologist should evaluate any acute skin disease prior to participation. Any cutaneous disorder at the site of electrode application in a contraindication to the continuation of electrical

stimulation at that site.

Psychological system- Patients with a positive history of drug or alcohol abuse have proven unreliable or manipulative and should be considered relative contraindications. Patients who score high on the sociopathic index of the M.M.P.I. should be considered relative contraindications for program training.

The following criteria are recommended for evaluating patient candidacy for a Parastep clinical trial:

Medical Criteria:

1. Status six months post recovery spinal cord injury and restorative surgery (if any)
2. Stable ortho-neuro-metabolic systems
3. Intact lower motor units (L1 and below)
4. No history of long bone stress fractures, osteoporosis, hip or knee joint disease

Clinical Criteria:

1. Motivation

   Does the patient demonstrate and express appropriate motivation and commitment to the therapeutic program?

2. Musculoskeletal integrity

   Is muscle and joint stability available for weight bearing at upper and lower extremities?

3. Articular Excursions

   Is sufficient range of motion available at all extremity articulations?

4. Motor Excitability

   Does the patient demonstrate appropriate muscle contractile response to

   Functional Electrical Stimulation (FES)?

5. Controlled Spasticity

   Is motor hyper activity sufficiently controlled to allow safe independent upright stance?

   ASHWORTH SCALE

   0 Hypotonic
   1 No increase in muscle tone
   2 Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder of the ROM
   3 More marked increase in muscle tone through motion, but affected parts are easily moved
   4 Considerable increase in tone-passive movement difficult
   5 Affected part rigid in flexion or extension

6. Cognition

   Does the patient demonstrate adequate faculties and learning capability to successfully employ the Parastep SYSTEM?

7. Sensation

   Does sensory perception of electrical stimulus allow sufficient level required for muscular contraction?

Functional Criteria:

1. Force Generation - Hip and Knee Torque

   Does the patient demonstrate sufficient muscular force with FES at the hip and knee required for function?

2. Cardiopulmonary Reserve

   Does the patient respond to upright positions and stepping with adequate hemodynamic and ventilatory responses?

3. Independent Transfers

   Is the patient independent in all transfers?

4. Standing Tolerance

   Does the patient demonstrate adequate standing tolerance to perform standing activities?

5. Balance and Trunk Control

   Does the patient demonstrate adequate balance and control skills to maintain an upright supported posture independently ?

6. Grasp

   Does the patient demonstrate adequate hand and finger control to manipulate system controls?

Contraindications

Patients presenting with the following conditions are not recommended for clinical trial of the Parastep system:

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, thrombophlebitis, varicose veins
6. Irreversible contracture
7. Autonomic dysreflexia

PHYSICAL THERAPY ASSESSMENT GUIDELINES

Following medical evaluation and clearance to begin a FES gait program a physical therapy evaluation must be performed to assure candidates possess sufficient motor power to perform the functions of standing and stepping. While the concept of muscle testing paralyzed limbs to determine their functional strength remains a novel academic pursuit, a practical means of clinically testing FES strength has been developed to demonstrate force development changes associated with the FES ambulation program. Changes in maximum strength and stimulus to strength ratios are key indicators of physiological improvement and should be routinely monitored. Gait training begins when patients demonstrate adequate motor power to achieve and maintain stance from the seated position.

Preliminary requirements for walking

Raise the body to standing- The goal of training patients to stand is to safely and effectively rise from a seated position using the upper extremities to guide the head and trunk. Quadriceps function should be sufficient to lift the body with minimal lifting contributed by the upper extremities.

Optimize postural alignment for standing- The goal addressed in standing to achieve a balanced stable posture such that 90% of the body's weight is supported by the lower extremities.

Uniped support- Lateral weight shifting is required for effective stepping to occur. Individuals must demonstrate the ability to fully unweight each lower extremity.

Unweight the upper extremities- Full weight acceptance upon the lower extremities is taught to accomplish walker advance maneuvers.

Lower the body to sitting- Activation of the sit command to ramp down extensor stimulation necessitates a series of maneuvers be successfully performed to safely return to the seated position. Independence is attained only when the patient demonstrates these acquired skills to the satisfaction of the physical therapist.

A routine periodic clinical assessment should include evaluation of the following parameters to insure safety and successful use:

Pretreatment Assessment:

1. Musculo-Skeletal Evaluation

   Does the user demonstrate signs of joint instability at hip, knee or ankle which precludes standing or stepping?

   Does the user exhibit signs of soft tissue inflammation related to stress or over use?

2. Skin

   Does the user's skin show adverse signs related to stimulation?

Pre-standing Assessment:

1. Upper Extremity Strength

   Is strength adequate to enable a patient to lift his body weight out of a chair and into a standing walker?

   Is the patient able to stand using one arm for support?

2. Trunk Control and Balance

   Can the patient maintain upright stance with minimal upper extremity effort?

   Does the patient display protective extension reactions?

   Does the patient display protective equilibrium reactions?

   Does the patient demonstrate an adequate sense of balance?

   Is spatial orientation adequate?

   Is awareness of posture accurate?

3. Lower Extremity FES Force Production

   Is FES muscle power sufficient to maintain locked knees while full weight bearing in standing double support? (FES manual muscle test grade of Fair +)

   Can the patient detect quadriceps fatigue and properly adjust stimulus intensity?

4. Circulatory Adjustment

   Do heart rate and blood pressure respond appropriately to upright stance?

4. Posture

   Is standing posture erect with less than 20% of body weight born by the upper extremities?

5. Fatigue/Recovery

   Can the patient stand for a minimum of three minutes?

   Does fatigue occur rapidly?

   Does the patient recover standing capability reasonably soon after fatigue?

Functional Ability

1. Don and Doff System

   Is the user able to apply and remove the system properly?

2. Powered Sit to Stand

   Is the user able to rise from a chair to standing and return?

3. Standing Weight Shift

   Does the patient perform lateral weight shift in the walker during stance?

4. One Leg Stance

   Is strength adequate to stand in the walker with full weight on one foot?

5. Walker management

   Does the patient unweight and advance the walker?

6. Flexion Withdrawal Reflex

   Is strength sufficient to flex hip and knee adequately during stimulated stepping?

   Is foot placement and heel strike appropriate for forward progression and stability?

7. Weight Transfer

   Can the patient fully transfer weight to advanced limb?

8. Reciprocation

   Can the patient alternate left and right stepping?

9. Progress and Rate of Progress

   Are functional achievements realized within expected time frames?

Ambulatory Ability

1. One Leg Stance

   Is strength adequate to stand in the walker with full weight on one foot?

2. Balance Trunk Control, Weight Shift

   Does the patient perform lateral weight shift in the walker during stepping?

3. Upper Extremity Endurance

   Is upper extremity power sufficient to sustain stepping activities?

4. Cardiovascular Response and Endurance

   Is Cardiopulmonary reserve sufficient to perform stepping activities?

   Is the user excessively short of breath?

Is hemodynamic response to exercise appropriate?

5. Fatigue/Recovery

   Does fatigue occur rapidly?

   Does the patient recover stepping capability reasonably soon after fatigue?

6. Gait Cycle

   Are the components of gait performed within acceptable parameters for purposeful ambulation?

7. Locomotion

   Are mechanics effective and efficient for point to point transfer.

   Can the user negotiate turns with the walker?

8. Progress and Rate of Progress

   Are functional achievements realized within expected time frames?

9. Ambulatory Status

   Is the user independent in standing and stepping activities?

PHYSICAL THERAPY TRAINING

Goals:

Training and physical therapy related to the Parastep system is directed at the clinical goals of independent transfer and upright stepping functions with the Parastep. Early in the training program the patient must demonstrate adequate cognitive faculties required for motor learning. Coordination of volitional and computer controlled movement patterns must be integrated into a new set of skills without the normal developmental basis.

While each patient and facility presents a unique set of circumstances requiring individual logistical solutions, the following training regime is suggested as one possible model to provide a base line for measuring effectiveness.

Goals of training include the following:

Safety:

1. Patient Instruction

   The user will demonstrate adequate understanding of system use, purpose and limitations.

2. Equipment Check and Maintenance

   The user will understand and perform routine maintenance requirements of the system.

3. Falls

   The user will understand and demonstrate successful techniques to minimize the fall related risks.

4. Terrain and surfaces

   The user will understand the requirements and demonstrate safe and effective negotiation of ambulating over varied surfaces and terrain.

Physiological:

1. Improve Strength
2. Improve Endurance

3. Improve Balance

Utility:

1. Powered Self Initiated Muscular Contraction
2. Powered Sit-Stand-Sit
3. Upright Weight Shift (Lateral)
4. One Leg Stance
5. Walker Advance
6. Stepping and Foot Placement
7. Upright Weight Shift (Forward)
8. Alternating Gait
9. Independent use in ADL

Goal of gait training is to achieve safe and effective independent locomotion which is cosmetically acceptable and within user acceptable energy costs. Normal gait requires the coordinated functioning of over one hundred trunk and lower extremity muscles. It is conceded that synthesized gait restoration which utilizes a minimum of surface electrodes and channels of stimulation will only effectively control a fraction of that number, therefore, the pursuit of normal gait should not be confused as our purpose. Gait evaluation is

performed with respect to the biomechanical requirements of biped locomotion as identified in the gait cycle, however, parameters of evaluation are restricted to the clinical judgement of qualified professionals utilizing the criteria of safe and effective performance of these components.

FUNDAMENTAL REQUIREMENTS FOR RECIPROCAL GAIT

Prevent collapse or toppling of the body- Control of multi segment support is achieved by direct electrical stimulation of knee and hip extensors. Head and trunk control is achieved through use of a walker.

Injection of propulsive forces- the initiation of forward momentum is achieved by advancing the walker, flexing the trunk to position the head and shoulders over the walker and extending the arms and shoulders to pull the hips forward.

Control of forces providing propulsion and stability- the forward movement is controlled by volitional effort of the arm and shoulder girdle musculature to accelerate and decelerate the body's center of mass.

Shortening the limb for swing through- reflex stimulation of mass flexion withdrawal is produced in response to nociceptive stimuli applied cutaneously to the lower leg. Ankle position is maintained through the use of a standard AFO assisting in toe clearance.

Advancing the swing leg- within the latency afforded by flexion withdrawal, activation of the quadriceps through direct stimulation achieves both knee extension and heel strike as the reflex decays.

Advancing the trunk over the stance leg- progression to mid stance is achieved by upper extremity extension and shoulder girdle depression movements.

The patient is instructed to adjust stimulation to insure sufficient levels of FES muscle force production while avoiding over stimulation. Muscle fatigue presents the primary limiting factor to functional ability. Early detection of fatigue is taught by awareness of proprioceptive information transmitted through the hands and shoulders. As quadriceps fatigue and the knees begin to flex increased weight is transferred to the hands and shoulders. Patients must develop an acute sense of change in these parameters to become independent.

Three critical phases of gait require the therapist's consideration to assure safety and prevent collapse. Maintaining stability of the stance leg and hip during single leg support presents the situation where muscle stimulation and response is critical to prevent collapse. Here the forces generated by gravity quickly accelerate when the fully loaded joints move into flexion and electrically stimulated antagonistic muscles can not oppose with sufficient contractile force. Second, establishing clearance of the swing foot is critical to

prevent tripping. And third, controlling step length and duration is essential to assure proper foot placement required for successful weight transfer. Therapists must address these biomechanical concerns with particular diligence to insure safe and effective ambulation.

PHYSICAL THERAPY PLAN OF CARE

It is intended to achieve the above goals within 32 hours of physical therapy training. A session is defined as a patient visit to physical therapy on any given day, A typical plan of care is outlined below which will serve as a model with the understanding that modification will be required to accommodate the individual requirements of each user.

Session	Physical Therapy Objective
1	FNS Evaluation and Clinical History Perform Strength, Function, and Gait Evaluation Teach FNS use and establish clinical expectation and training time table Teach donning and doffing system.
2	Instruct in stimulator use, electrode placement, quadriceps stimulation and intensity settings. Instruct in home FNS exercise for quadriceps.
3	Instruct in powered sit to stand and stand to sit.
4	Instruct in posture and balance skills. Instruct in hand support, weight bearing, stimulation control for standing. Teach fatigue detection techniques.
5	Instruct in fall prevention.
6	Perform Strength, Function, and Gait Evaluation Instruct in weight shifting (lateral) activities. Instruct unilateral support techniques and one leg stance. Reinforce safety procedures.
7	Instruct in single step initiation.
8	Instruct in foot placement and step length.
9	Instruct in weight shifting (A-P)
10	Instruct in balance and posture
11	Stepping, balance and posture
12	Perform Strength, Function, and Gait Evaluation Stepping balance and posture
13	Stepping balance and posture
14	Stepping balance and posture

15 Instruct in walker use and management. Stepping balance and posture

16 Gait and Ambulation Instruction

17 Gait and Ambulation Instruction

18 Perform Strength, Function, and Gait Evaluation Gait and Ambulation Instruction

19 Gait and Ambulation Instruction

20 Gait and Ambulation Instruction

21 Gait and Ambulation Instruction

22 Gait and Ambulation Instruction

23 Gait and Ambulation Instruction

24 Perform Strength, Function, and Gait Evaluation Gait and Ambulation Instruction

25 Gait and Ambulation Instruction

26 Gait and Ambulation Instruction

27 Gait and Ambulation Instruction

28 Gait and Ambulation Instruction

29 Gait and Ambulation Instruction

30 Gait and Ambulation Instruction

31 Gait and Ambulation Instruction

32 Final Evaluation
Perform Strength, Function, and Gait Evaluation Gait and Ambulation Instruction Discharge with follow up.

Frequency:

Physical Therapy training should be conducted 2-3 times per week. Unsupervised training to improve strength and endurance should continue at home on a prescribed basis (usually daily) .

Duration:

Treatment sessions should be limited to user tolerance and progress accordingly. One hour sessions have been tolerated well by past and current users. It is expected that users will become independent in use of the Parastep system with 32 hours of Physical Therapy over a twelve week to twenty four week period. A typical treatment schedule is provided in the Patient Reporting Packet.

Home Exercise Program

Patients enrolled in the Parastep program are encouraged to exercise at home while participating in physical therapy. The Parastep "E" unit has been developed to afford safe at home FNS practice. In clinical trials with the Parastep there was a statistically significant difference in ambulatory success for subjects who used the device for home training compared to those who did not. This result should be interpreted with caution since the prescription of home use/training was most likely predicated on progress of the patient. Thus, it is likely more reasonable to assert that subjects required home use/training to achieve the overall program success than to assert that home use did not have a significant effect.

The E unit is modified to deliver stimulation to four channels intended to stimulate the quadriceps with two channels of stimulation and stimulate the step reflex with two channels. A switch has been installed to prevent walking by limiting stimulation to either the quadriceps channels or the step channels separately, making it impossible to stand and take steps simultaneously.

In clinical trials with the parastep there was no statistically significant difference in ambulation success rates for subjects who used the device for home training compared to those who did not. This result, however, should be interpreted with caution since the prescription of home use/training was most likely predicated on progress of the patient. Thus, it is likely more reasonable to assert that the majority of subjects required home use/training to achieve the overall program success than to assert that home use did not have a significant effect. The major notable factor for home use is that subjects who received instructions for home practice of standing/stepping had a statistically significantly better success rate than those who did not receive such instruction.

There are several types of home use/training or conditioning prescribed for the subjects. Most subjects who used the stimulator at home receive quadriceps strengthening instruction. Subjects followed either an isotonic/resistive protocol or a combination of isotonic/resistive and isometric type exercises.

In general, an isotonic/resistive protocol for quadriceps strengthening consists of electrical stimulation applied to the quadriceps muscles initiating contraction during which the lower leg is allowed to extend through its range of motion at the knee. This motion may be resisted by gravity or weight may be added to limb for added resistance to the movement.

PARASTEP® I SYSTEM
4-CHANNEL FNS "E" UNIT OPERATING INSTRUCTIONS

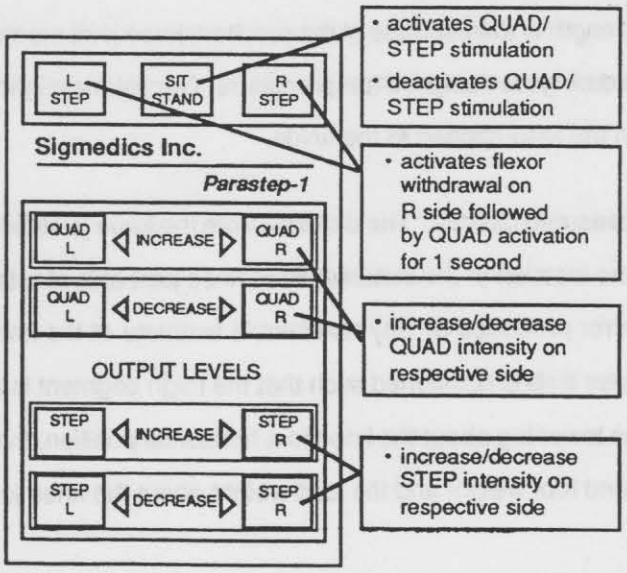
The "E" unit was designed to exercise lower extremity muscles in preparation for ambulation. The "E" unit operates in two separate modes:

1. QUADS - By positioning the toggle switch located on the back panel to "QUADS", the quadriceps muscles can be activated. In this mode the step function is disabled. **(NOTE: It is not possible to take steps while standing with this unit.)**
2. STEPS - By positioning the switch to "STEPS", the flexor withdrawal reflex can be activated for one second followed by one second of quadriceps stimulation. Quadriceps stimulation then shuts off after one second.

SET UP PROCEDURE:

1. Apply the quadriceps and the peroneal (steps) electrodes as instructed by your physical therapist.
2. Connect the electrode cables to the sockets marked R and L on the "E" unit.
3. Connect the leads to the electrodes.
4. Connect the battery pack to the "E" unit with the power cable.
5. Select "QUADS" or "STEPS" via the toggle switch located on the back panel of the "E" unit. **(NOTE: You must select the correct mode prior to turning on the battery pack.)**
6. Turn on the battery pack.
7. Proceed with setting the appropriate intensity levels and initiating the desired response by depressing and releasing the appropriate keys on the front panel of the unit.
8. To change to the alternate mode, turn off the battery pack. Position the toggle switch to the desired mode. Turn on the battery to repower the stimulator.
9. The "E" unit has been modified to prevent standing and taking steps. It is intended to be used only under supervision of a qualified physical therapist.

FRONT PANEL



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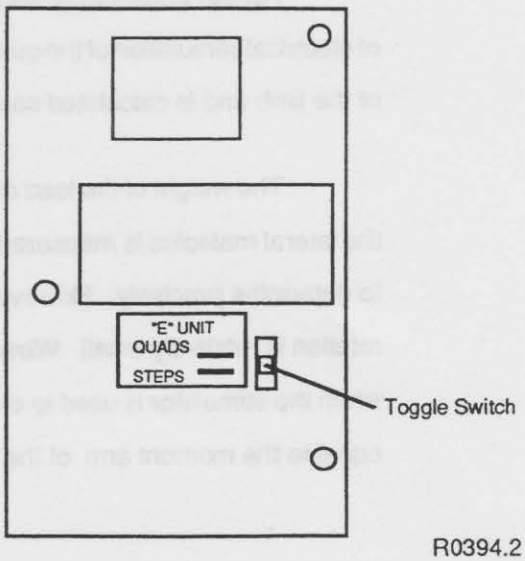

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FNS STRENGTH EVALUATION PROTOCOL

Introduction

The measurement of strength or force generation in paralyzed muscle may seem a novel concept to the uninformed clinician. However, clinical applications of functional neuromuscular stimulation requires qualification and analysis if FNS applications are to be effective in the synthesis of human function. Isometric and isokinetic methodologies described elsewhere by Bajd, T. ('83), Scott , O.M. ('85), Knutsson, E. (85), Murry, M.P. (80), Marsolais, E.B. (83), have been used for this purpose. While these methods are accurate and reliable they may be unavailable for clinical use as they require specialized instrumentation not always available in the clinic setting. The following methodology was developed by Sigmedics, Inc. to assist clinicians to observe and quantify FES induced muscular force production with standard clinical equipment and physical therapy procedures. These methodologies are derived from the principles of maximal strength determinations using modified one repetition maximum techniques. Our purpose is to provide an easily applied methodology to estimate quadriceps strength under FES conditions and to standardize reporting such that test results may be compared over time or between subjects.

Free Weight Strength Evaluation

The free weight strength evaluation utilizes the following to estimate the Resultant Knee Joint Moment to elevate and then hold the limb in a fixed angular position with the addition of load to the ankle region. This is a description of the calculations required for this evaluation. The magnitude of the Resultant Knee Joint Moment is equal to the sum of the moment of weight of the shank and foot segments and the moment of the weight of the load.

For our purposes quadriceps strength is the estimate of the resultant knee joint moment achieve by of electrical stimulation of the quadriceps during the designed test procedure. Our estimate ignores the weight of the limb and is calculated solely upon the load applied to the ankle.

The weight of the load can be measured directly. The distance from the knee joint axis of rotation to the lateral maleolus is measured (D). The location of the instantaneous knee joint axis of rotation is difficult to determine precisely. However, the error produced by any reasonable estimate of the knee joint axis of rotation is relatively small. When the lower limb is positioned such that the thigh segment is horizontal and when the stimulator is used to extend the lower leg about the knee to a horizontal position, the distance D is equal to the moment arm of the shank and foot weight and the load weight about the knee joint. When the

leg segment deviates from the horizontal position the moment arm varies trigonometrically with the knee joint angle.

The standard unit of measure is Newtons for weight and meters for distance. The tendency of each force (weight) to produce rotation is called a moment. The unit of measure of a moment is the Newton-meter.

Force = mass (kg) X acceleration (m/s2)
Weight = mass (kg) X gravitational acceleration (m/s2) gravitational acceleration = -9.81 m/s2
1 N = 1 kg X 9.81 m/s2
1 kg = 2.2 lb

Our free weight assessment of quadriceps strength includes assessment of muscular endurance by calculating total work performed by estimate of the sum of all work performed during the test. Each contraction lifting the specified weight to complete knee extension raises that weight through an arc of motion to a vertical height approximately the length of the tibia. Therefore, work performed during each test contraction is estimated as the weight times the length of the tibia (W=FxD).

The sum of work performed during all test contractions is defined as the quadriceps work capacity (QWC). When divided by the product of the subject's body weight and height for normalization an index of measurement is derived for comparing subject to subject.

$$\text{Quadriceps Work Capacity Index} = \frac{\Sigma(W1+W2+...)}{\text{Body Weight x Height}} \times 100$$

PREPARATION

1. Equipment:

   Calibrated Sigmedics Test Unit
   Ankle Weights, (2) 1 lb
   (1) 3 lb
   (1) 5 lb
   (1) 10 lb
   Tape Measure
   Mat Table
   Towel Roll

2. Instruction:

   Explain to subject procedure and purpose

3. Setup:

   Position subject supine on a mat table, knees bent over the table edge, feet on floor, towel roll under knee to be tested to assure complete knee extension (tibia should be parallel to the floor upon extension). Non testing leg should be positioned with hip and knee flexed with foot

flat on the mat table to flatten lumbar curve. Hips and pelvis should be stabilized during testing to prevent hip rotation or pelvic tilt.

Measure distance from knee axis to lateral malleolus and record.

Measure and record quadriceps girth 6" above suprapatellar border.

Apply quadriceps electrodes.

Attach quad electrode cable to right channel of stimulator.

TESTING

1. Protocol

Stabilize lower extremity to prevent hip rotation or pelvic tilting during testing.

Contraction 1- Activate sit/stand to ramp up stimulation. Increase stimulation to complete ROM of Knee with 0 lbs affixed to ankle. Activate sit/stand to ramp down stimulus.

Contraction 2- Repeat above with 1 lb affixed to the ankle.

Contraction 3- Repeat above with 2 lb affixed to the ankle.

Contraction 4- Repeat above with 3 lb affixed to the ankle.

Continue as above adding one pound with each contraction. Perform test without rest between contractions (not greater than 30 seconds between successive lifts). Increase stimulus sufficient to complete knee extension (do not stimulate in excess of current required to complete full extension). The test is terminated when increasing stimulus fails to achieve complete knee extension.

2. Record stimulus level after each contraction.

3. Repeat procedure for opposite knee.

CLINICAL FES STRENGTH TESTING UNIT SPECIFICATIONS

Wave Form:	Asymmetrical Biphasic
Frequency:	24 pps
Pulse width:	150 µs
Nominal current output range: Adjustable in 10 increments.	0 to 250 mA
Average current increase per increment:	21 mA
Nominal starting current: Level can be adjusted down to 0 mA.	50 mA
Nominal maximum current:	250 mA
Active output channel:	Right Quadriceps only
Active keys:	RQ Increase RQ Decrease Sit/Stand

System's features:

Stimulation output only ramps-up to set level.

No boost of stimulation level on sit down.

Beeper will sound when last Red LED bar is reached.

Beeper will sound if stimulation level is decreased below 1st green LED bar, and on subsequent level decreases.

Level can be adjusted down to 0 mA.

Immediate ramp-down on activation of sit command.

**The above values are approximate and may vary by ±10%

FUNCTION TESTING PROTOCOL

The goal of functional evaluation is to determine the individuals ability to perform the required elements of Parastep system use to achieve independence. The professional judgement of the physical therapist is required to apply the following criteria.

SCORING:

0	CAN NOT PERFORM
1	PERFORMS WITH ASSISTANCE (PHYSICAL) OF ANOTHER
2	PERFORMS WITH STANDBY ASSIST (VERBAL)
3	PERFORMS INDEPENDENTLY

FUNCTION:

POWERED SIT-STAND-SIT

Raise the body to standing- The goal of training patients to stand is to safely and effectively rise from a seated position using the upper extremities to guide the head and trunk. Quadriceps function should be sufficient to lift the body with minimal lifting contributed by the upper extremities.

Optimize postural alignment for standing- The goal addressed in standing to achieve a balanced stable posture such that 90% of the body's weight is supported by the lower extremities.

Lower the body to sitting- Activation of the sit command to ramp down extensor stimulation necessitates a series of maneuvers be successfully performed to safely return to the seated position. Independence is attained only when the patient demonstrates these acquired skills to the satisfaction of the physical therapist.

STANDING LATERAL WEIGHT SHIFT

Lateral weight shifting is required for effective stepping to occur. Individuals must demonstrate the ability to fully unweight each lower extremity.

ONE LEG STANCE

Uniped support must be demonstrated by the ability to support the body on one leg while opposite leg swing occurs.

WALKER ADVANCE

Unweighting the upper extremities required with full weight acceptance upon the lower extremities to accomplish walker advance maneuvers.

STEPPING & FOOT PLACEMENT

Stride length and foot position will vary for each individual and skill level attained. Therapist judgement must focus on the safe and effective performance of the movement required for forward locomotion.

STANDING WEIGHT SHIFT (FORWARD-BACK)

Anterior and posterior weight shifting is required for effective trunk progression and weight acceptance during gait. Individuals must demonstrate the ability to transfer weight from back to front positioned extremity and effectively position the trunk for effective locomotion

ALTERNATING GAIT

The user must demonstrate ability to repeat a left-right stepping sequence.

DAILY FUNCTIONAL USE

The user must demonstrate ability to use the Parastep system as part of his daily routine.

GAIT EVALUATION PROTOCOL

Gait evaluation is performed with respect to the biomechanical requirements of biped locomotion as identified in the gait cycle, however, parameters of evaluation are restricted to the clinical judgement of qualified professionals utilizing the criteria of safe and effective in performance of these components.

STANDING POSTURE

Anterior-posterior alignment-	A plumb line should fall through the ear-shoulder-hip-knee-ankle centers of rotation. Landmarks should not deviate from this line by more than 2" when standing.
Left-right alignment-	A plumb line from the nose should divide the feet equally, deviation should be less than 1" when standing.

SUPPORT

Weight Bearing-	Standing 85% of the body's weight should be born through the legs.

DYNAMIC BALANCE

Standing-	Patient is able to stand without toppling
Walking-	Patient is able to take steps without toppling

GAIT CYCLE

Toe off-	Patients toe clears the floor when step is activated
Swing Through-	Patients Foot clears the floor surface during swing
Heel Strike-	Patient's heel contacts the floor in a straight line in front of toe off position.
Stride Length-	Toe off to heel strike is in excess of 6".

WEIGHT TRANSFER

Anterior-posterior-	Patient is capable of fully transferring body weight from back to advanced foot and position hips over the forward foot.
Lateral-	Patient is capable of fully transferring body weight to stance leg during step activation.

WALKER MANAGEMENT

Progression-	Patient is capable of moving the walker forward and back while standing.
Placement-	Patient is capable of moving the walker side to side and turning the walker 45° to each side.
TURNS	Patient is able to circle 90° to the left and the right.
LOCOMOTION	Patient is able to ambulate 10'
TIME TO WALK 10 FEET	Measured in seconds
AMBULATION STATUS	Patient can perform above without the intervention of another person.