

Parastep® Update

Periodic news updates on The Parastep® System published by Sigmedics, Inc.
One Northfield Plaza, Northfield, Illinois 60093

Issue 3

Making great strides at Shepherd

Reprinted with permission from Shepherd Spinal Center, Atlanta, GA

"Shepherd Spinal Center decided to participate in clinical trials for The Parastep® System because it believed that the Parastep had the most potential of all of the FES products on the market," said Montez Howard, P.T., Director of Physical Therapy at Shepherd.

"When you look at FES as a mode for standing and walking, it is really still in its infancy," explained Howard. "However, Sigmedics has developed a product that really works. And, the Company is very responsive to input we've given them about the Parastep since the clinical trials began."

Shepherd Spinal Center is now in its second year of participation in clinical trials for Sigmedics. Since beginning the program in February of 1991, four patients have successfully completed the program. In January of 1992, three additional Shepherd alumni entered the program.

Our former patients have definitely experienced the physical and psychological benefits of using the Parastep

Shepherd has a database of former patients that are still active in its outpatient rehab program, and, of those, all with the appropriate level of injury were evaluated for participation in clinical trials of The Parastep System. Criteria for participation in the trials included: former patients injured at T-12 level or above, aged 18 to 50 years, with healthy skin, good range of motion and mild muscle spasms, and no history of cardiopulmonary disease, osteoporosis, or substance abuse. Each patient participates in approximately 32 physical therapy sessions.

"Our former patients have definitely experienced the physical and psychological benefits of using The Parastep System," said Donald Peck Leslie, M.D., lead physician on



At Shepherd Spinal Center, Atlanta, GA, Donald Peck Leslie, M.D., lead physician of the Parastep program, with Travis Williams, Parastep user, and Myrtice Atrice, lead physical therapist.

Photo courtesy of Shepherd Spinal Center.

the project. "Not only has it proven to be an excellent mode of exercise for both the upper and lower extremities, but all have commented on the psychological boost that comes from an improved body image."

Myrtice Atrice, P.T., lead therapist on the project, agrees with Dr. Leslie. "All of our patients have remarked on how much better their legs look. They enjoy having a more 'normal' musculature. And, the Parastep has allowed those who have a unit at home to more easily accomplish daily tasks by standing and walking."

Atrice reported that some of Shepherd's patients are now going beyond level surface walking in a clinical setting and actually tackling curbs and steps. "We're a long way

Continued on page 2

Professionals share insights at roundtable meeting

Physicians and physical therapists managing Parastep Programs at rehabilitation hospitals across the country received clinical updates and offered their perspectives on a variety of topics related to the Parastep at a roundtable meeting held recently in Denver, CO.

Among the benefits of involvement in the Parastep Program, as stated by attendees, were the ability to stay abreast of the latest technology and to develop an exciting new product line/service for the hospital.

Presentations were made by Sigmedics, Inc. staff members Robert A. Habasevich, V. P. Physical Therapy, Raymond D. Hedenberg, Physical Therapist, and Jeanne L. Ayers, V. P. Marketing. Bill O'Daniel, Physical Therapy Director, Craig Hospital, Englewood, CO, conducted a session on patient problem solving with the Parastep.

In addition to Craig Hospital, clinicians at the gathering represented the following facilities: Hines Veterans Administration Hospital, Hines, IL; The Miami Project to Cure Paralysis, University of Miami School of Medicine, Miami, FL; Scripps Memorial Hospitals Rehabilitation Center, Encinitas, CA; Shepherd Spinal Center, Atlanta, GA; and University of Washington, Seattle, WA.

A group discussion was led by Ms. Ayers, which gave clinicians the opportunity to share their observations on the institutional and clinical motivations for involvement with the Parastep, product features and benefits, patient attitudes and training/clinician educational requirements. ■

Inside...

■ *User profile: Richard Coulson*

■ *Sigmedics' profile: Clinical services department*

■ *Speakers bureau established*

Making great strides...

Continued from front

from perfecting stair climbing," said Atrice. "But we truly feel that we are breaking new ground with the system."

Shepherd's staff dedicates about 20 hours each week to the project, said Atrice. Shepherd was fortunate to receive a grant of \$17,000 from the Rich Foundation to initiate the project, and now a \$25,000 contribution from the Phoenix Society Debutantes to cover the staff expense of participating in the trials.

"Aside from watching the patients progress through the stages of the program, the most positive experience has been working with Sigmedics," said Atrice. "The Company is obviously committed and is open to input from all participating clinics. I hope to watch this product go through several evolutions as it becomes more and more functional. For instance, we expect to see more compact units, additional param-

eters such as a biofeedback loop and other improvements down the line."

Atrice and Leslie participated in a Sigmedics forum held for all hospitals participating in clinical trials in Denver last December. Additionally, Atrice presented two demonstrations of The Parastep System last year. Former patient Carl Larson accompanied Atrice to Boston to perform a demonstration for the American Physical Therapy Association annual meeting, and Atrice also presented at a conference of physical therapy and occupational therapy supervisors from all Model Spinal Cord Injury Systems.

How do the users feel about Parastep? "It's an exhilarating feeling to stand and be at eye level with everyone for a change," said Darryl Francis, a 27-year-old data processing associate from Marietta, GA. Darryl sustained a spinal cord injury in a motorcycle

accident three years ago.

As for taking steps, Darryl said, "It is a little awkward, but it is walking. Although I probably wouldn't replace my wheelchair with the Parastep, I think it's a great product for exercise and good health."

According to Darryl, health benefits include increased muscle mass, better circulation and decreased pressure sores. Darryl had the opportunity to provide this and other feedback to Sigmedics at a user's forum last fall. Among his recommendations for the Company were a waist pouch that would hold both the battery pack and the stimulation unit, cables that would stay connected better and a remote control for the walker (instead of the cable connector).

There is definitely a consensus at Shepherd – standing and walking short distances with The Parastep System is great exercise for the body and the mind! ■

Reaching a higher level of independence

Parastep user profile: Richard Coulson

Since his traumatic spinal cord injury in August 1990, Richard Coulson says he "refused to accept the standard dogma" that he would never walk again. A T-10 complete paraplegic as a result of an auto accident, Coulson embarked on an aggressive physical therapy and rehabilitation program immediately upon discharge as an inpatient at Memorial Rehabilitation Hospital, Long Beach, CA.

"I went right into therapy from the trauma center, and it has been an ongoing process for the past 1-1/2 years," said Coulson, age 36. "I also asked a lot of questions about my injury and pursued as many options as possible for standing and walking."

To this end, Coulson, a construction worker, created a standing frame he uses three to four hours daily. In addition, he tried other modalities for standing and weight bearing, but walking with them was too demanding, requiring him to rest after 20 to 30 feet.

Coulson learned of The Parastep System through his association with Memorial Rehabilitation Hospital and entered the Parastep pre-FDA investigational program in December 1991. "I saw the Parastep as a way to keep my momentum going, use my own muscles and gain some more independence," said Coulson.

He has found that the use of functional electrical stimulation increases the muscle mass in his legs. Standing in general reduces physical complications and



Richard Coulson (T-10 complete) walks short distances using The Parastep System as Robert A. Habasevich, V.P. Physical Therapy, Sigmedics, looks on. Coulson participates in the Parastep Program at Memorial Rehabilitation Hospital, Long Beach, CA.

Photo courtesy of Memorial Rehabilitation Hospital.

improves attitude. "I never thought I would be doing half of what I'm able to do with the Parastep."

Coulson is walking about 200 feet at a time with the Parastep, and he is getting more "fluid...becoming more natural" in his stepping function as the weeks pass. He also has been testing the Parastep with crutches.

He compares the use of the Parastep to learning how to ride a bicycle. "Once you're out there on your own, you develop your own technique." Coulson uses the Parastep E-Unit (4-channel) at home for standing and exercising his muscles. "The only days I don't use the E-Unit are when I go to Long Beach for my Parastep training sessions."

Throughout the years, Coulson has been a commercial diver at construction sites, helping to build docks, piers and bridges. A former navy aircraft mechanic, Coulson now dedicates a portion of his time to helping others in the spinal cord injury recovery process. He is working to establish a Los Angeles chapter of the American Paralysis Association.

"I want to help people see the bigger picture – to get out of their chairs and start climbing the rungs on the ladder to achieve greater independence," he said. "The Parastep represents one of those rungs, and those involved with the system today will be in a better position to benefit from new technologies in the years ahead." ■

Keeping in step with the needs of professionals and Parastep® System users

Physicians and physical therapists now have a unique opportunity to enhance their professional skills and practice of physical therapy using The Parastep System – a new technology in the rapidly evolving field of synthesized gait restoration.

"The role of the clinician is the ingredient that differentiates the Parastep from other functional electrical stimulation systems," said Robert A. Habasevich, Vice President Physical Therapy, Sigmedics, Inc. Habasevich, along with Raymond D. Hedenberg, Physical Therapist, heads Sigmedics' Clinical Services department, which serves as a professional liaison, training and educational resource to rehabilitation teams in hospitals having Parastep Programs across the U.S. and Canada.

"Ray and I are monitoring clinical use of the Parastep (at 19 hospitals to-date) as part of our FDA clinical trials program," said Habasevich. "Our colleagues' experiences with the technology and their patients' progress have given us the opportunity to develop clinical practice standards regarding use of the Parastep."

Habasevich and Hedenberg travel around the country observing and consulting with physicians and physical therapists who have established Parastep Programs within their institutions. They serve as "traveling ombudsmen," collecting as much information on Parastep clinician and user experiences as they impart to their colleagues.

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Experience gathered at hospitals is shared with clinicians at other institutions to broaden their vision beyond their own four walls and to help them learn from nationwide experiences with the Parastep. Clinicians are encouraged to share their knowledge and experiences with the Parastep," said Habasevich. "We've found that individual perspectives have helped us to refine our clinical protocols and practices to the benefit of clinicians and users everywhere."

To this end, the Clinical Services department and other members of the Sigmedics staff recently hosted a "Clinical Users Forum" to enable physicians and physical therapists to share their experiences, insights and perspectives with The Parastep System.

Physicians and physical therapists from six U.S. hospitals attended the one-day



Raymond D. Hedenberg, Physical Therapist, with Patrick W. Maher, Parastep user and Director, User Support Services, Sigmedics, conduct a "Clinician Training Workshop" in Chicago attended last fall by physical therapists from rehabilitation hospitals in the U.S. and Canada.

gathering, which featured a series of roundtable discussions on issues related to patient education and training, user support and clinical research (see related story, front page).

In addition, the Clinical Services department provides education and training for physical therapists from newly established Parastep Programs. A two-day workshop entitled, "Synthesized Gait Restoration for the Spinal Cord Injured," is held bi-annually in Chicago and combines educational/lecture sessions with hands-on patient training.

"These continuing education programs, combined with our travels around the country, enable us to maximize the clinical outcomes of standing and walking short distances with the Parastep," said Habasevich.

In addition to the expertise of the Clinical Services department, Daniel Graupe, Ph.D., Professor of Electrical Engineering and Computer Science and Professor of Physical Medicine and Rehabilitation at the University of Illinois at Chicago, serves as a professional resource. Dr. Graupe is the inventor who designed and developed The Parastep System.

He, in conjunction with Kate Kohn, M.D., Chairman Emeritus, Department of Rehabilitation Medicine, Humana Hospital – Michael Reese, established the first Parastep Program. Dr. Kohn is one of several professionals who have increased the body of knowledge on the functional, physiological and psychological outcomes of Parastep use.

"The external control of excitable tissue for standing and walking short distances, using FES technology as represented by the Parastep, places us and our colleagues at the forefront of neurological rehabilitation for the 1990's," added Habasevich. "The

Parastep is a powerful clinical tool which enables selected SCI individuals to control the motor activity of the lower extremities for standing and ambulation." ■

Clinical staff profiles

Robert A. Habasevich, Vice President Physical Therapy, is a physical therapist with extensive experience as a rehabilitation operations manager in a variety of institutional and free-standing settings. Habasevich developed and managed rehabilitation contract services for Moss Rehab, Inc., Philadelphia, and served as Director, Programs in Physical Therapy at Moss Rehabilitation Hospital.

In addition, he served as Administrative Director, Rehabilitation Services, Brigham and Women's Hospital, Boston, MA, and Director, Rehabilitation, University of Connecticut Health Center, Farmington, CT. Habasevich has a B.A. degree from the Virginia Military Institute; a B.S. degree from the School of Allied Health, Medical College of Virginia; and an M.S. in Health Sciences, Boston University.

Raymond D. Hedenberg, Physical Therapist, served as Director of Physical Therapy at Allentown Rehabilitation Center, Allentown, PA. Previously, he was a Clinical Education Specialist for Loredan Biomedical, Inc., Davis, CA, as well as Facility Director, Director of Program Development of Northeastern Pennsylvania Region, Keystone Rehabilitation Systems, Indiana, PA.

For several years, Hedenberg was Vice President, Secretary and Principal of Valley Group Physical Therapists, an outpatient physical therapy center in Allentown, PA. Hedenberg has a B.S. degree in Health and Physical Education from East Stroudsburg University, East Stroudsburg, PA, and a certificate degree in physical therapy from the University of Pennsylvania, Philadelphia.

Sigmedics establishes speakers program

Sigmedics, Inc. staff members have been introducing The Parastep System to professional, consumer and insurance groups through its newly implemented speakers program. The program is designed to build awareness of technological advancements in rehabilitation, specifically standing and walking short distances for the spinal cord injured population.

A presentation titled, "FES Technology for Independent Ambulation," was made to the Medical Management conference sponsored by USAA Property and Casualty Insurance. The conference, held at USAA's headquarters in San Antonio, TX, was attended by over 50 case managers.

The presentation was made by Paul F. Lavalley, Chairman of the Board, President and CEO of Sigmedics, and Patrick W.

Maier, Director of User Support Services, who demonstrated and answered questions about The Parastep System. In addition, a similar presentation was made to the Rehabilitation Services Director and case managers at the home office of Wausau Insurance Companies.

Maier, along with Frank E. Zeiss, Vice President Operations and Administration who is spearheading Sigmedics' Case Management Department, also participated in a meeting attended by about 50 insurance company representatives at Younker Rehabilitation Center, Des Moines, IA. An overview of The Parastep System was presented by Physical Therapists Terri Casey and Marlene Gustafson, which included a discussion of system components, candidate selection, training proto-

cols, and a system demonstration by Maier and Rick Tovrea, a Parastep user at Younker.

Additional presentations were made to a spinal cord injured support group of over 100 attendees at Good Samaritan Hospital, Cincinnati, OH, as well as to about 50 members of the Ontario Chapter of the Canadian Paraplegic Association in Thunder Bay, Canada. Jeanne Ayers, Vice President Marketing, who gave the Canadian presentation, received a Certificate of Appreciation for Sigmedics' efforts on behalf of individuals with disabilities in the community.

Groups that would like to schedule a speaker through the Sigmedics, Inc. speakers program should contact Jeanne L. Ayers, V.P. Marketing, (708) 501-3500. ■

1992 conference attendance schedule

- *American Academy of Neurology*
San Diego, CA
Exhibits: May 5, 6 and 7
Booth # 123
See Dr. Edward Chaplin's Poster:
"Ambulation with FES for Individuals with SCI"
- *American Spinal Cord Injury Association*
Toronto, Canada
Exhibits: May 7, 8 and 9
Booth #9
- *American Physical Therapy Association*
Denver, CO
Exhibits: June 15, 16 and 17
Booth # 121
- *Medical Case Management Conference*
Nashville, TN
Exhibits: September 16, 17 and 18
Booth # 1015
- *Association of Rehabilitation Nurses*
Pittsburgh, PA
Exhibits: October 29 and 30
Booth #649
- *American Academy of Physical Medicine and Rehabilitation – American Congress of Rehabilitation Medicine*
San Francisco, CA
Exhibits: November 14, 15 and 16
Booth # not available
See program listing –
Ambulation and Spinal Cord Injury Disorders Workshop

Sigmedics, Inc. mission



Rehabilitation technology for the spinal cord injured

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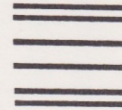
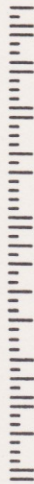
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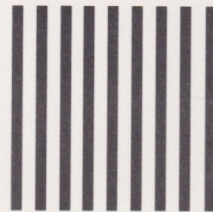
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The Parastep® System at a glance

Independence and control for the user

The Parastep System is available only upon physician prescription and has been designed for unbraced standing and short distance walking for many spinal cord injured persons. The system consists of:

- A microcomputer controlled neuromuscular electrical stimulator
- The Paratester, a diagnostic unit for testing system components
- A battery activated power pack with recharger
- Power and electrode cables; multi-use disposable electrodes
- A control and stability walker with finger switches
- Physical therapy training (32 sessions)
- Operator's manual; technical and service support

The user activates the microcomputer which controls all standing and stepping functions. The specially designed walker provides balance and stability while standing and walking. It is a non-invasive system which uses easily attachable and removable surface electrodes. ■



- I would like more information sent to me about The Parastep® System.
- Please call me. I would like to discuss The Parastep® System.
- I would like to see a demonstration of The Parastep® System. Call me when you are scheduled in my area.
- Please send me a copy of "Answers to Questions about The Parastep® System."

Name _____

Title _____

Institution _____

Address _____

City _____ State _____ Zip _____

Phone _____ Best time to call me _____

Parastep® programs being implemented

Sigmedics, Inc. is establishing pre-FDA, clinical investigational programs at leading rehabilitation institutions across the U.S. and Canada. Parastep programs have been established at these facilities:

Casa Colina Centers for Rehabilitation Pomona, CA	Rehabilitation Institute of Chicago Chicago, IL
Cleveland Clinic Foundation Cleveland, OH (Multiple Sclerosis Research)	Scripps Memorial Hospitals Rehabilitation Center Encinitas, CA
Craig Hospital Englewood, CO	Shepherd Spinal Center Atlanta, GA
Hines Veterans Administration Hospital Hines, IL	Spain Rehabilitation Center University of Alabama Birmingham, AL
Humana Hospital - Michael Reese Chicago, IL	University of Miami School of Medicine Miami, FL
Immanuel Medical Center Omaha, NE	University of Washington Hospital Seattle, WA
Kessler Institute for Rehabilitation West Orange, NJ	Woodrow Wilson Rehabilitation Center Fishersville, VA
The Magee Clinic North York, Ontario	Yunker Rehabilitation Hospital Des Moines, IA
Memorial Rehabilitation Hospital Long Beach, CA	

For additional information on the Parastep clinical investigation program, please contact:

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