

Parastep® Update

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

Issue 4

The Parastep® I System approved for U.S. marketplace

The first neuromuscular stimulator device enabling standing and walking by many people paralyzed with spinal cord injuries was approved for marketing recently by the Food and Drug Administration.

The microcomputer controlled functional neuromuscular stimulation device is called The Parastep System. It comes from the medical engineering sciences known as neuroprosthetics. The Parastep is manufactured and will be marketed by Sigmedics, Inc., a Northfield, IL based firm specializing in rehabilitation technology for the neurologically impaired.

The Parastep will be available only by physician prescription at Sigmedics, Inc. approved rehabilitation hospitals where individuals who meet pre-screening criteria are required to complete a physical therapy training program. While undergoing review, the system was available on an investigational basis at over 25 U.S. rehabilitation hospitals.

It is estimated there are about 250,000 people with spinal cord injuries in the U.S. today with about 10,000 new cases occurring annually. Between 30 and 40 percent of

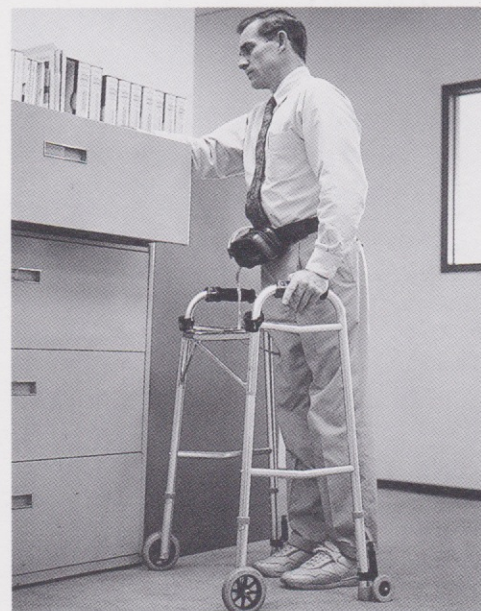
"One primary advantage of Parastep is that it is the only non-invasive product available that enables the spinal cord injured to activate their own muscles for standing and walking."

those people currently with spinal cord injuries could benefit from the Parastep, according to Paul F. Lavalley, Chairman, President and CEO, Sigmedics, Inc.

"One primary advantage of Parastep is that it is the only non-invasive product available that enables the spinal cord injured to activate their own muscles for standing and walking" Lavalley said, adding that "the system is not designed to replace the wheelchair."

The Parastep System consists of a microcomputer controlled neuromuscular stimulator, a battery pack with recharger, surface applied electrodes, power and

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Patrick W. Maher, Director, User Support Services, Sigmedics, Inc. walks with The Parastep System, the first neuromuscular stimulator device approved for marketing by the Food and Drug Administration enabling standing and walking by people paralyzed with spinal cord injuries. A Parastep pioneer, Patrick was among the original participants in the first FNS research clinic established in 1981 at Michael Reese Hospital and Medical Center, Chicago, IL. (See related feature story on page 4).

Parastep steps-up international presence

The Parastep System has been embraced by clinicians and consumers throughout Europe and parts of the Middle East in a manner similar to its reception in the United States. Parastep Programs have been established in Spain, France, Italy, Belgium, and Israel with interest in introducing the technology in Germany and the Netherlands.

In Spain, 45 physicians and 15 physical therapists representing 10 hospitals participated in two separate Parastep training programs each held over a three-day period. The Parastep is being made available throughout the country by E.O. Prim, S.A., a subsidiary of Prim, S.A., a major European medical distribution firm.

In France, a distributor agreement has been signed with Medimex, to make the

Parastep available throughout the country. Four Parastep Programs have been established in France, including one at Hospital Henry Gabrielle/Hospital de Lyon and another at Centre Hospitalier Regional et Universitaire de Rennes. In addition, programs have been started at Center Propara in Montpellier and L'Espoir Centre de Rééducation et Réadaptation Fonctionnelles Spécialisées. A Parastep Program has been started at Casa di Cura Privata Villa Margherita, SRL, in Vicenza, Italy and also at the Center for Traumatic Rehabilitation in Brussels, Belgium.

The program in Israel is being managed by a medical distribution firm, Bacchus Ltd. in conjunction with several hospitals throughout the country. ■

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- User profile: Edward Londono
- Clinical Users Symposium
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Parastep approved . . .

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electrode cables, a control and stability walker with control switches and physical therapy training.

In addition to its availability in the U.S., the Parastep has received widespread international recognition with programs established at rehabilitation hospitals in Spain, France, Italy, Belgium and Israel and growing interest in the technology throughout Europe. ■

Parastep Plus Program introduced across the U.S.

Sigmedics, Inc. has launched The Parastep Plus Program to hospitals currently providing a Parastep program as well as to other institutions who qualify to start a clinic.

Parastep Plus has been established to introduce the Sigmedics integrated working relationship and support services provided to hospitals when they establish a Parastep Program, including the benefits and responsibilities of participation to the patient and hospital.

Parastep Plus Program members have access to comprehensive services at Sigmedics, including clinical resources, user support, communications materials, and reimbursement management.

"Our primary goal through the Plus Program is to enable the hospitals to assure access to The Parastep System among the greatest number of spinal cord injured people who could potentially benefit from the technology," said James A. Burkett, Vice President, Sales, Sigmedics, Inc.

"The Plus Program establishes the integrated working relationship of the healthcare team, consisting of the patient, hospital, Sigmedics, and insurer. The team will work in a collaborative manner throughout all phases of the Plus Program," Burkett added.

For additional information about The Parastep Plus Program, contact James A. Burkett, Sigmedics, Inc., (708) 501-3500. ■

The Parastep® Plus Program Features:

- Technological Advancement
- Clinical Resources
- Communications Program
- User Support
- Reimbursement Management
- Revenue Enhancement

The Parastep System's Historic Path to the Marketplace

- **Clinical Research Begins at Michael Reese Hospital and Medical Center—**December 1981
- **Sigmedics is Incorporated—**December 1988
- **The Parastep System is Introduced—**February 1990
- **FDA Application Submitted—**May 1990
- **Parastep Clinics Established at Leading Rehabilitation Hospitals—**November 1990-Present
- **FDA Advisory Panel Unanimous Approval Recommendation—**August 1993
- **FDA Approval for Sales and Marketing—**April 1994

Parastep a challenge in reaching "outer limits" of success

Parastep User Profile: Edward Londono

Edward Londono enjoys a challenge. The 26 year old resident of Miami, FL believes the Parastep gives him the opportunity to strive to attain the "outer limits" of his potential with the system.

"I want to know, 'What are my limitations with the system?'," said Edward, injured at the T-7 level. "How far can I go and what can I do with it?"

Edward believes that as a result of his commitment to the Parastep, he has realized a more independent life-style. He received his training at the Miami Project to Cure Paralysis—University of Miami Parastep Program in Spring of 1992.

"I want to know, 'What are my limitations with the system? How far can I go and what can I do with it?'"

"Before I got involved with the Parastep, I felt like the person other people had to take care of...but now I feel a lot more independent and self-sufficient," said Edward. "I'm stronger and my self-esteem is greater since I know I can walk. My wife Jacqueline feels the same way...she has encouraged me along the way and participated in all of my training sessions."

Edward's success with the Parastep has come because of a personal commitment to making some progress with the system on an almost daily basis. He credits his ability to walk up to one mile at a time to focusing on achieving balance.

He uses the system to help him perform tasks around the house and in other environ-



Edward Londono demonstrates the Parastep® System before Her Majesty the Queen Fabiola in Ghent, Belgium. They are joined by Professor Dr. G. G. Vanderstraeten, President of the European Federation of Physical Medicine and Rehabilitation (right) and Paul F. Lavalley, Chairman, President and CEO, Sigmedics, Inc. (left).

ments. These have included painting, hanging pictures at home as well as entering the lavatory on airplanes.

While it won't replace the wheelchair, the Parastep has an important place in Edward's daily activities.

He has gone back to school this past fall to study computer science. "I walk to my desk at school with the Parastep," he said. "It gives me great satisfaction that I can keep setting goals with the system and achieving them." ■

Symposium unites professionals in FNS clinical discussion

A symposium attended by over 25 clinicians representing 17 Parastep Programs in the U.S. and Europe was sponsored recently by Craig Rehabilitation Hospital and Sigmedics, Inc. in Denver, CO.

The second "Clinical Users Symposium" was a "unique opportunity to bring together Parastep clinicians from across the country and the world to discuss the issues that are important to enabling patients with spinal cord injuries to stand and walk," said Robert A. Habasevich, Vice President, Physical Therapy, Sigmedics, Inc.

The primary purpose of the symposium was to evaluate the progress made in the application of functional neuromuscular stimulation technology for paralyzed muscle control. In addition, the discussion extended into the application of FNS to disabilities such as multiple sclerosis, stroke and other upper motor lesions.

"A research group has been formed under the leadership of Patricia Winchester, Ph.D. of the University of Texas - Southwestern Medical Center," said Habasevich, "to promote the communication of Parastep related information and foster the development of manuscripts intended for publication."

Clinical articles will be developed and follow-up information disseminated by Sigmedics. Presentations were made by the following clinicians:

- "Parastep Clinical Trial Outcomes" by Robert A. Habasevich, M.S., P.T., Northfield, IL.
- "FES Muscle Testing and Training" by Patricia Winchester, Ph.D., P.T., University of Texas - Southwestern Medical Center at Dallas, TX.
- "Accelerated Parastep Training" by William O'Daniel, P.T., Craig Rehabilitation Hospital at Englewood, CO.
- "Case Study in FES Ambulation" by Tracy Sawyer, P.T. and Dawn Terry, P.T., Sunnyview Hospital and Rehabilitation Center at Schenectady, NY.
- "Volitional Movement Following Parastep Training" by Katherine Jones, P.T., Immanuel Medical Center at Omaha, NE.
- "Bone Mineral Density and Parastep Ambulation" by Rosalind Guest, P.T., The Miami Project at Miami, FL.
- "FES Muscle Performance Improvement Following Alupent Administration" by Rosalind Guest, P.T., The Miami Project, at Miami, FL.
- "Soft Tissue Injury and FES" by Leanne Robotta, P.T., Scripps Memorial



John Targowski, a Parastep user, demonstrates the system at a recent clinical training workshop, "Synthesized Gait Restoration for the Spinal Cord Injured".

Hospitals and Rehabilitation Center at Encinitas, CA.

- "FES Ambulation and SCI Management" by Kate Baxter, P.T., Woodrow Wilson Rehabilitation Center at Fishersville, VA.
- "Parastep Use in Multiple Sclerosis" by Dan Kelly, P.T., Cleveland Clinic at Cleveland, OH.
- "Observations On Improving Gait in M.S." by Daniel Graupe, Ph.D., University of Illinois at Chicago, IL.
- "Shepherd Spinal Center FES Clinical Update" by Myrtice Atrice, P.T., Shepherd Spinal Center at Atlanta, GA.
- "Towards Community Ambulation" by Linda Yasukawa, P.T. and Jennifer Ueberfluss, P.T., Rehabilitation Institute of Chicago at Chicago, IL.

In addition, other clinicians participating in the symposium included: Ellen Ney, P.T. and Dale Reckless, P.T., Harmarville Rehabilitation Center; Darlene Clemons, M.S.W., St. David's Rehabilitation Center; Mary Schmidt, M.S., P.T. and Margie Roos, P.T., Magee Rehabilitation Hospital; Christy Seay, P.T., Charlotte Institute of Rehabilitation; and Wendy Stasik, P.T., Woodrow Wilson Rehabilitation Center.

Representatives from Europe included: Regine Brissot, M.D., Centre Hospitalier Regional & Universitaire de Rennes; Jose Luis Osorio, Hospital Juan Canalejo; Marie Pierre Le Bot, M.D., Centre Hospitalier Regional & Universitaire de Rennes; and Sebastian de la Barrera, M.D., Hospital Juan Canalejo.

For additional information about the Clinical Users Symposium, please contact Robert A. Habasevich, Sigmedics, Inc., (708) 501-3500. ■

Seminars prepare clinicians for Parastep patient training

Nearly 35 clinicians representing 25 U.S. and international Parastep Programs have attended the last two Parastep Training Workshops sponsored by Sigmedics, Inc. in the Chicago area.

The program, "Synthesized Gait Restoration for the Spinal Cord Injured," is held several times throughout the year and combines didactic sessions with clinical laboratory training. Clinicians are required to complete the training program as part of their institution's requirements as a Parastep Clinic.

Guest faculty at the training seminars included: Patricia Winchester, Ph.D., P.T., Research Director for the Mobility and Assessment Lab and Assistant Professor, Department of Orthopaedic Surgery, University of Texas, Southwestern Medical Center, Dallas, TX; Emmanuel Rabischong, Ph.D., Laboratory of Clinical Neurophysiology, PROPARA Centre, Montpellier, France; and Rosalind Guest, P.T., The Miami Project, University of Miami, Miami FL. Parastep System users from various regions of the U.S. also participated in the programs.

In addition, presentations were made by Sigmedics, Inc. staff members, including Robert A. Habasevich, Vice President, Physical Therapy; Daniel Graupe, Ph.D., Chief Consulting Scientist; Frank E. Zeiss, Vice President, Operations and Administration; and Patrick W. Maher, Director, User Support Services.

For additional information about the clinical training seminar, contact Robert A. Habasevich, (708) 501-3500. ■

Parastep pioneer helps individuals meet challenges

Sigmedics Profile: Patrick W. Maher

For Pat Maher, the FDA approval granted to market the Parastep evokes a sense of great personal and professional accomplishment. A true Parastep pioneer, Pat is among the original participants in the first FNS research clinic, established in 1981 at Michael Reese Hospital and Medical Center, Chicago, IL.

As Director of User Support Services at Sigmedics, Pat counsels Parastep users and prospective candidates on maximizing the benefits of their involvement with the system. In tandem with Robert A. Habasevich, Vice President, Physical Therapy, he introduces the Parastep to clinicians and prospective users throughout the U.S. and Europe.

"I try to provide a life-style perspective for Parastep users and share my experiences that have compelled me to incorporate the system into my life," said Pat. "I help people see that the Parastep needs to be viewed as a tool in their life. It is important that goals and objectives be set for establishing the framework for success."

Pat, injured at the T-7 level, believes that use of the system is highly individualized and that progress is made with the Parastep in small increments. "Whatever the reason the system is used for—on a functional level or to attain greater physical and emotional well-being—the individual must be prepared to make an investment of time and energy."

"Frequently users will ask me, 'What is the end point?' I believe that success with the Parastep is a continual evolution, that your level of comfort will grow with dedication to using it on a regular basis."

As an example of the individual commitment necessary, Pat recently achieved his own personal best by becoming the first FNS system user without braces (AFOs only) to complete a consecutive one-mile walk using the Parastep.

While the Parastep has become a personal and professional challenge, Pat, who keeps a hectic work and personal schedule, realizes system use must be balanced with other demands in life.

"We're in the process of expanding upon our network of sharing practical information—experiences and training techniques with users across the country," Pat said.

Rehabilitation technology for the neurologically impaired

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Alan Blitz, Director, Communications, and Editor, Parastep® Update ■

"With the help of Parastep users, I'd like to keep building on the excitement that I and others have for this technology and help new Parastep users incorporate it into their life-style."

In the 10 years that have passed since Pat first walked using functional neuromuscular stimulation, he has concluded that all Parastep users are pioneers. "We're all working to bring about the evolution of this technology, and it will come more quickly with a growing base of committed users sharing their experiences and successes." ■

"I help people see that the Parastep needs to be viewed as a tool in their life. It is important that goals and objectives be set for establishing the framework for success."

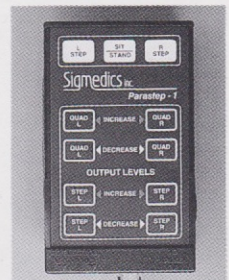
The Parastep System at a glance...

Independence and control for the user

The Parastep provides the user unprecedented control over all system functions, enabling the user to activate his/her own leg muscles for standing and walking. It is available only upon physician prescription for selected members of the spinal cord injured population and consists of:

- A microcomputer controlled functional neuromuscular 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 that controls all standing and stepping functions. The electromechanically modified walker provides balance and stability while standing and walking. It is a non-invasive system which uses easily attachable and removable surface electrodes. ■



The Parastep® I System enables appropriate spinal cord injured patients to stand and take steps. The Parastep I is not intended for all patients. Patients must generally be in good health and have the ability to demonstrate adequate trunk control and balance to maintain an upright posture. The Parastep I is contraindicated for individuals with severe scoliosis and osteoporosis as well as a variety of other conditions. A prescribed period of physical therapy training is necessary for the safe and effective use of the Parastep I. For complete information on the Parastep I, including indications, contraindications, warnings, precautions and adverse effects, contact Sigmedics, Inc., at One Northfield Plaza, Suite 410, Northfield, Illinois 60093-3016, (708) 501-3500.

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

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