

Parastep™ Update

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

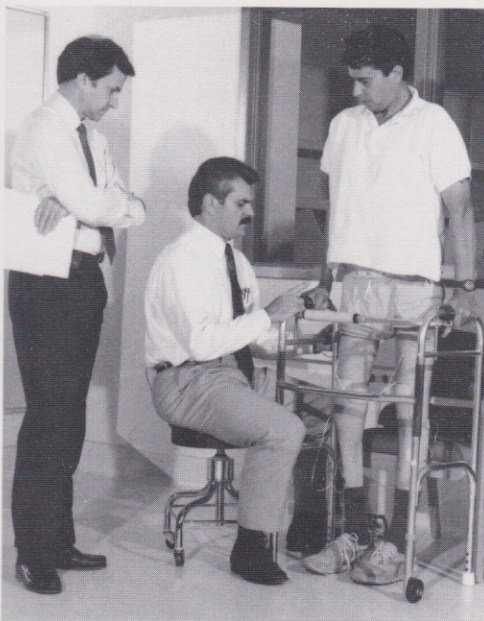
Issue 1

Introducing The Parastep™ System

Independent ambulation for the spinal cord injured

Physicians caring for the spinal cord injured can now offer their patients a new technology which provides unprecedented mobility and an enhanced potential to perform activities of daily living.

The Parastep System, designed, manufactured and marketed by Sigmedics, Inc., is the only product that enables independent, unbraced standing and short distance walking for members of the spinal cord injured population.



At Scripps Memorial Hospitals Rehabilitation Center, Craig Jackinsky stands using The Parastep System under the direction of Edward Chaplin, MD (left) and Robert A. Habasevich, VP Physical Therapy, Sigmedics.

"Although the Parastep System is still in the developmental stages, we are pleased with what we've seen so far with our patients who are learning how to use it," said Edward R. Chaplin, M.D., Medical Director at Scripps Memorial Hospitals Rehabilitation Center, Encinitas, California, one of several Parastep Clinics being established across the country.

Continued on page 2

Parastep™ offers functional improvement, new mobility for many spinal cord injured

Parastep user profile: Craig Prudian

"The best way to describe the Parastep," says Craig Prudian, "is that it is elegant in its simplicity."

"I was intrigued by the Parastep because of the opportunity to use my own leg muscles again," said Craig, an electrical engineer who is a Project Manager at General Motors Electro Motive Division, LaGrange, Illinois.

Before using the Parastep, Craig completed a program using long leg braces which was difficult for him because of his 6' 5" height. His desire was to begin using his leg muscles again.

"I look at the muscle mass in my legs since using the Parastep," says Craig, "and it doesn't appear much different than before I was injured in 1984."

The Parastep...helps me make my life as functional as possible now, with a great deal of hope for the future

Craig, age 34, whose injury is T-7 complete, describes his experience with the Parastep as "invigorating." He said it has helped him "maintain the whole me." He adds that his function has improved in other areas because of using the Parastep and being more mobile. He obtained insurance reimbursement for the acquisition of a Parastep System in 1990.

What Craig particularly likes about the Parastep System is that he can do his set-up preparation in a matter of minutes and be prepared to stand and walk short distances independently.

"The unit is no bigger than a Walkman," Craig said. "You clip it on your belt, attach your electrodes, and you're ready to go."

While the Parastep isn't necessarily for everyone with a spinal cord injury, Craig believes that the system represents a vision of more things to come in support of the spinal cord injured population.



Craig Prudian (T-7 complete) walks using The Parastep System as Robert A. Habasevich, VP Physical Therapy, Sigmedics, looks on.

"The Parastep won't be a substitute for all the activities I did before my injury," said Craig, "but it does give me a new sense of self...it helps me make my life as functional as possible now, with a great deal of hope for the future."

"With the proper commitment, an individual can become quite mobile with the Parastep," he continued. "The more motivated you are, the more benefit you'll derive from the Parastep on a daily basis." ■

Inside...

- *Perspectives on launching Sigmedics, Inc. and The Parastep System*
- *The Parastep System at a glance*
- *See the Parastep at major annual conferences in 1991*

Perspectives on the challenges of launching Sigmedics, Inc. and introducing The Parastep™ System to the health care industry

Interview with Paul F. Lavallee

The following is an interview with Paul F. Lavallee, President and Chief Executive Officer, Sigmedics, Inc. Lavallee joined the firm in 1988, bringing over 20 years of experience in the health care industry. He has played a key role in the formation of the company and is currently leading the management team that is introducing The Parastep System, a functional electrical stimulation system for unbraced standing and independent, short distance walking, to the physical medicine and rehabilitation community.

■ What were the major challenges you faced upon joining Sigmedics, Inc.?

Probably one of the greatest challenges we faced as a company—and the one I addressed during my first few months on the job—is the varying attitudes, perceptions and opinions about functional electrical stimulation in the marketplace. I discovered early on that we needed to clearly differentiate our system from other FES products which are available for exercise, as well as experimental systems for standing and walking.

The Parastep is the only system that allows for independent, unbraced standing and short distance walking

Our system is totally different from others in the marketplace. The Parastep is the only system that allows for independent, unbraced standing and short distance walking for many spinal cord injured persons. People who use the Parastep usually have injuries at or above T12 with adequate trunk stability and balance to stand and take steps.

Introducing The Parastep™ System... *Continued from front*

"This technology creates the opportunity for the spinal cord injured patient to move about as never before possible," Dr. Chaplin added.

The Parastep utilizes pulse sequences to stimulate target peripheral nerves through easily attachable and removable surface electrodes. This stimulation, which is generated and directed by a microcomputer unit which is clipped onto the user's belt, results in muscle contraction and movement.

A reciprocating walker with surface mounted finger switches lets the user independently control the level of stimulation coming from the microcomputer unit and to



Paul F. Lavallee (right) conducts a status review with Frank E. Zeiss, VP Operations.

We've made great strides in getting our message across in the past several months. I'm confident of this because of the way the technology was embraced recently at the AAPM&R, American Congress of Rehabilitation Medicine as well as the Association of Rehabilitation Nurses annual conferences.

■ How are you introducing the Parastep to the professional community?

We're in the process of establishing Parastep Clinic programs through physicians and physical therapists at leading rehabilitation institutions across the country. We now have clinics established in Alabama, California, Colorado, Florida, Georgia, Illinois, New Jersey, and Ohio as well as in Canada, and we will be adding several more this year. I can announce at this point that Parastep Clinics are available at Michael Reese Hospital and Medical Center, Chicago; Scripps Memorial Hospitals Rehabilitation Center, Encinitas, CA; the University of Alabama at Birmingham and the University of Manitoba in Canada.

We believe our role is to serve as a support arm for the clinic's professionals and users

control the standing, stepping and sit-down commands (see *Parastep System at a glance*, back page flap).

The Parastep was designed and engineered by Daniel Graupe, Ph.D., Director of the Engineering Research Center on Signal and Image Processing and Its Medical Application, University of Illinois at Chicago. He has conducted research at Michael Reese Hospital and Medical Center, Chicago; the Israel Institute of Technology, Haifa, Israel; Colorado State University; the Illinois Institute of Technology, Chicago; and the Hines VA Hospital, Hines, Illinois. ■

wherever and whenever possible. Our management staff has developed a complete program of clinic support services, including clinical training, educational programs and on-going technical and service support.

Our goal is to help the institution operate its Parastep Clinic on an independent basis with the understanding that we have a participative relationship based on their need for our support.

■ Where does the Parastep System stand with respect to obtaining approval from the Food and Drug Administration?

We submitted our Premarket Approval Application (PMA) to the Food and Drug Administration in May, 1990. The approval process appears to be moving along as we expected. Until the Parastep is approved—which we anticipate in 1991—use of the system is still considered investigational by the FDA.

The Parastep System distinguishes itself in its innovation, specific application and claims

I think it's important to point out why Sigmedics is seeking a PMA, which typically involves a lengthier approval process than a simpler 510K "me too" approval. While the 510K oftentimes can provide a company with quick market entry, this kind of submission to the FDA is allowed when a company's technology is substantially equivalent to other devices that have already received 510K approval for marketing.

Clearly, The Parastep System distinguishes itself from any other product in its innovation, specific application and claims, and as such, a 510K approval would have been inappropriate.

The Parastep technology is being used by spinal cord injured persons in a totally unique manner—for independent, unbraced standing and short distance walking. No other company that we are aware of has submitted a PMA approval request for this kind of product application.

■ Tell us something about your background before joining Sigmedics?

During the past 20 years I've been involved in the formation and management of large organizations as well as entrepreneurial ventures, such as Sigmedics, in the health care industry. On four separate occasions in my career, I've worked with entrepreneurs/founders as chief executive or general

manager to organize and grow their companies.

I served as vice president of operations and then as president of the Hospital Division of Qualicare, Inc., where I managed the organization's growth to sixteen hospitals in ten states. I was also involved in developing and introducing new business lines and joint ventures in the management of overseas hospitals.

I've also worked with Medical Resources, Inc., a company that specialized in developing and managing outpatient diagnostic imaging centers. Throughout the years I've participated in health care policy making as a member of the Executive Committee at the Federation of American Health Systems.

The years I have spent on the provider side have already served me quite well at Sigmedics. I understand the pressures that hospital managers and staff are dealing with every day. There are growing competitive concerns, reimbursement issues, and staffing shortages that must be addressed in delivering patient care on a daily basis. And we're taking this into account in the way we manage our relationships.

■ *Who are the members of the management team at Sigmedics?*

One of the greatest challenges in building a company like Sigmedics is assembling a management staff that has the expertise to bring a breakthrough technology like the Parastep System to the marketplace.

Frank E. Zeiss has joined us as Vice President, Operations. Frank's depth of experience in the service and rehabilitation industries will support Sigmedics in a number of crucial areas including organizational and production management and research and development.

One of the greatest challenges... is assembling a management staff that has the expertise to bring a breakthrough technology like the Parastep System to the marketplace

Robert A. Habasevich, Vice President of Physical Therapy, has vast experience in the physical therapy industry. He has directed rehabilitation programs in a variety of institutional and free-standing settings, including Moss Rehabilitation Hospital in Philadelphia and Brigham and Women's Hospital in Boston. Bob is managing our clinical program while working very closely with physicians and physical therapists at Parastep Clinic sites across the country.

Parastep™ granted extensive news coverage by network affiliates

The Parastep System was the subject of prominent television coverage recently on both the ABC and NBC network affiliates in the Chicago area.

The clinically oriented news features described the Parastep as "a significant technological advancement designed to help improve the quality of life for many spinal cord injured persons." A segment was broadcast twice in November on the ABC affiliate, WLS-TV, Eyewitness News.

In addition, in December The Parastep System was the focus of a segment on Your Vital Signs, sponsored by the Chicago Metropolitan Health Care Council, on WMAQ-TV, an NBC affiliate.

During this 30-minute program, titled "Rehabilitation—Getting On With Life," The Parastep System appeared as one of five new technologies available for physical medicine and rehabilitation at Chicago area hospitals. ■

Patrick W. Maher, Director of Technical and Support Services, also serves as a resource to the Parastep Clinics. A paraplegic and avid user of the Parastep, Pat has intimate knowledge of our system and can provide a user's perspective to other Parastep candidates and clinicians. Pat has worked for several years in the medical products industry, in particular with durable medical equipment products for the disabled population.

Jeanne L. Ayers, Vice President of Marketing, is helping us develop our overall strategic marketing plan and brings outstanding analytical, organizational and management skills to the Sigmedics team. Jeanne has held marketing and planning positions at Baxter Healthcare Corporation, and her role will prove instrumental as we develop our post-FDA approval sales and customer support programs. She will serve as an excellent marketing resource for hospitals developing Parastep Clinic Programs.

Silvano A. Romeo, our Chief Engineer, is experienced in all aspects of design and development of microprocessor controlled instruments. He is responsible for engineering, software and new product development.

■ *Who is on the Board of Directors?*

We are fortunate to have assembled a Board of Directors from some of the nation's leading venture capital companies. They provide a great deal of insight and perspective as they have a lot of experience launching start-up companies like Sigmedics.

Robert G. McNeil, Ph.D., is a general partner of Sanderling Venture Partners II, a venture capital fund, with a 13-year history of specializing in medical and biotechnology investments.

Robert E. Larson, Ph.D., is a general partner of the Woodside Fund, a venture capital firm which invests in a wide variety of businesses, including the electronics and computer industries.

Board member Sona Wang is a partner in the Chicago based firm of Batterson, Johnson & Wang, which has been extensively involved in high technology companies.

In addition, both Daniel Graupe, Ph.D., who designed and engineered the Parastep System, and I serve on the Board as well. We have an excellent working team which meets on a six week basis to stay well informed on how the business is operating.

■ *What are the primary goals for Sigmedics and The Parastep System in 1991?*

Approval from the FDA to commercially market The Parastep System certainly would be at the top of the list. That's a goal we set from the very beginning and significant progress has been made in this area.

In 1991 we will expand upon our current studies on the applicability of the Parastep System for multiple sclerosis patients

In addition, we plan to increase the number of Parastep Clinics from its present number of 12 to 40 by year end in various regions of the country. During this year we will launch a user support network for Parastep users throughout the country, and we will develop a reimbursement program to provide the necessary reimbursement support to health care professionals and users.

In 1991 we will expand upon our current studies on the applicability of the Parastep System for multiple sclerosis patients. There are approximately 250,000 people with MS in the United States, half of whom have a moderate or severe gait disability. We're confident that many of these individuals may be helped by the Parastep.

Finally, we will increase research and development to make improvements and enhance the capabilities of our basic system, to explore new applications for the system, and to develop new products for the rehabilitation market. ■

1991 conference attendance schedule

- *American Academy of Neurology*
April 23-25, Boston, MA
Booth #1227

- *Abilities Expo*
May 17-19, Anaheim, CA
Booth #730

- *American Physical Therapy Association*
June 23-27, Boston, MA

- *Association of Rehabilitation Nurses*
October 23-27, Kansas City, MO
Booth # 630

- *American Academy of Physical Medicine and Rehabilitation and American Congress of Rehabilitation Medicine*
October 27-November 1, Washington, D.C.

Sigmedics, Inc. mission

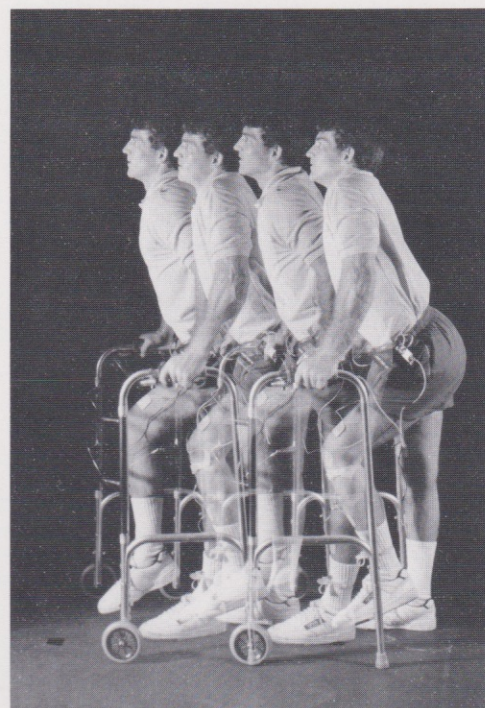
Rehabilitation technology for the spinal cord injured

Sigmedics, Inc. was founded to design, manufacture and market rehabilitation products which provide functional assistance in the activities of daily living for the spinal cord injured.

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Alan Blitz, Director, Marketing Communications and Editor, *Parastep™ Update* ■

Next issue...

- *Profile on Daniel Graupe, Ph.D., who engineered and designed The Parastep™ System*



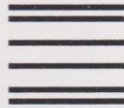
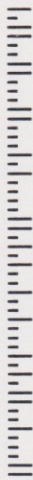
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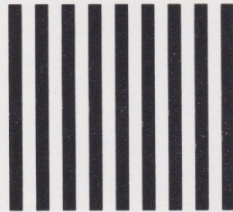
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**The Parastep™ System
at a glance**

*Independence and
control for the user*

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

- Microcomputer controlled neuromuscular electrical stimulator
- Paratester diagnostic unit for testing system components
- Battery activated power pack with recharger
- Power and electrode cables
- Reciprocating stability & control walker with finger switches
- Physical therapy training
- 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. ■

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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.

Name _____

Title _____

Institution _____

Address _____

City _____ State _____ Zip _____

Phone _____ Best time to call me _____

Parastep™ Clinic programs being implemented

Sigmedics, Inc. is in the process of establishing Parastep Clinic programs through physicians and physical therapists at leading rehabilitation institutions across the country.

Clinics have been implemented in Alabama, California, Colorado, Florida, Georgia, Illinois, New Jersey, Ohio as well as Canada, with several more clinics becoming available this year.

For additional information on the Parastep Clinic program, please contact:

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