Parastep® *Update*

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

Issue 2

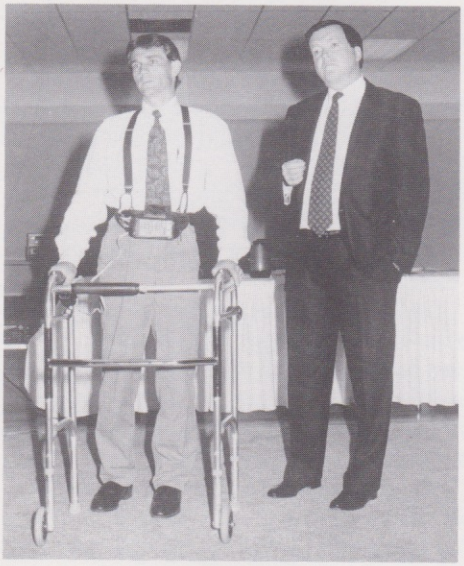
Parastep® System now available in Canada

The Parastep System, which enables independent, unbraced standing and short distance walking for appropriately selected spinal cord injured individuals, has been approved for use in Canada.

The Parastep has met the provisions of the Medical Devices Regulations of the Health and Welfare Bureau of Canada, Health Protection Branch. The U.S. Department of Health and Human Services, Food and Drug Administration, has also approved export of the device to Canada.

Availability of The Parastep System in Canada was announced by Paul F. Lavallee, President and C.E.O. of Sigmedics, Inc., at the annual meeting of the British Columbia Chapter of the Canadian Paraplegic Association, where a demonstration of the Parastep was given to the membership.

"Thirty-two sessions of physical therapy are typically required for use of the Parastep," said Lavallee. "We expect to have clinical programs in place by year-end at rehabilitation hospitals in major metropolitan areas of Canada. These institutions will provide physical therapy and training on system use to spinal cord injured individuals."



Patrick W. Maher (T-7 paraplegic) demonstrated The Parastep System with Paul F. Lavallee at the annual meeting of the B.C. Chapter, Canadian Paraplegic Assoc.

Steps in the right direction

Reprinted with permission from Craig Hospital, Englewood, CO

In a typical spinal cord injury, the injured person's brain isn't damaged and neither are the muscles the brain controls. Only the link between the brain and muscle has been broken. Using tiny electrical charges, commands issued by the brain can be simulated. The muscles of a person with a spinal cord injury – those cut off from their control center – can be stimulated into doing work like pedaling a specially designed stationary bicycling machine.

Such functional electrical stimulation (FES) strengthens weakened muscles during a patient's recovery, and can stop or reverse disuse atrophy of the muscles a paralyzed person can't control. In one form or another, electrical stimulation has been used on paralyzed muscles since the 1940's.

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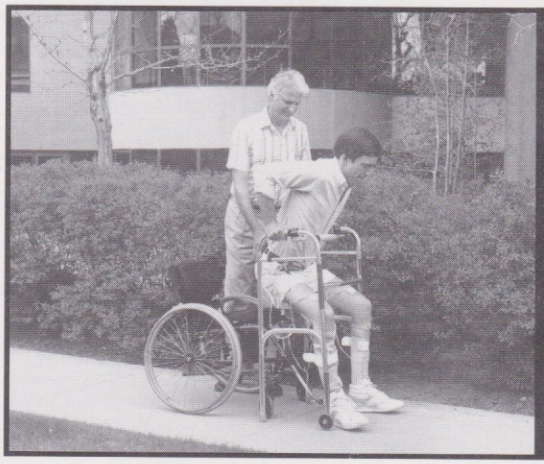
Below: John Medart works with Craig Hospital physical therapy director, Bill O'Daniel, while standing and walking short distances with The Parastep System. (Photo sequence continues on page 2.)

Photos courtesy of Craig Hospital.



Last January, Craig Hospital's physical therapy department began researching a use for a new application of FES – helping patients with permanent loss of control over their leg muscles to "walk." They are testing a new FES system called The Parastep System, to help spinal cord injured patients stand and walk short distances. Director of physical therapy, Bill O'Daniel, emphasizes that the program is in its infancy. "We're in the research stage only," he cautions. "The long-term practicality for ambulation still needs to be determined, based on both the exertion required of the patient and the price."

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- *Sigmedics' profile: Daniel Graupe, Ph.D.*
- *Parastep users hold first meeting*

Steps...

Continued from front

Craig and other hospitals are using the Parastep which is made by Chicago-based Sigmedics, Inc. A pre-market approval application has been filed with the U.S. Food and Drug Administration, and until it is approved, the device is considered investigational.

This was the first time in nine years that I've seen my legs take a step, and that was really exciting!

To date, four patients have completed the 32 training sessions with the Parastep FES walking system. Four more individuals will participate in the program this year. Says O'Daniel, "So far, the results show that the equipment works and that it's safe, but it does require a lot of energy expenditure from the patient." He stresses that the paraplegics who are accepted for this program must be in good physical condition and have sufficient upper body strength.

One of the FES volunteers is John Medart, a T-10 paraplegic who lost the use of his legs nine years ago. He kept his leg muscles in shape and maintained his cardiovascular fitness by pedaling a stationary bicycling machine as part of Craig's FES bike program, which began in 1984. At the end of his 32 sessions with the Parastep, Medart was able to "walk" 350 feet at a time.

"The walking is more difficult than riding the bike," he says. "It takes much more upper-body strength. But this was the first time in nine years that I've seen my legs take a step, and that was really exciting!"

Medart says he's enjoyed being a part of the research program and thinks it has great potential. He does wish for a time when less equipment will be needed. "I think that right now the goal is to get you out of your chair," he says.

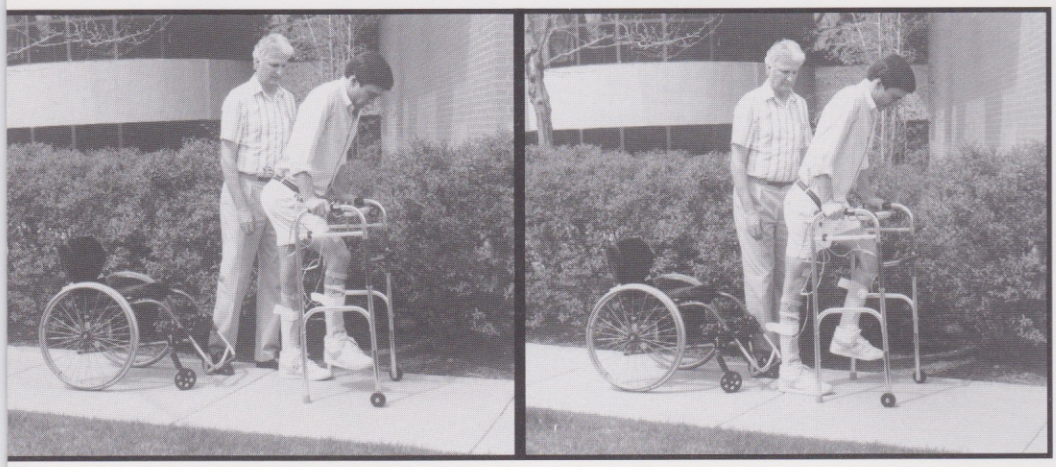
At the end of his 32 sessions with the Parastep, Medart was able to "walk" 350 feet at a time

Just being able to stand is important, says Medart. "I like the idea of being able to greet people face-to-face, or to be able to stand up at a wedding."

Kristi Wickiser, another volunteer who is little more than a year past her T-4 injury, agrees. "I have the standing unit at home. Being able to get into a cabinet to get a casserole dish is really nice."

"From a health standpoint," she adds, "getting those muscles fired up is important. It's good to know you're staying in shape."

Dr. Daniel P. Lammertse, Craig's medical director, says that while FES walking is good exercise, it's not intended to be a replacement for a wheelchair. "But the patients are very enthusiastic about it," he says. "It's an important evolution of the technology." ■



John Medart (above) comments on his use of The Parastep System: "I like the idea of being able to greet people face-to-face, or to be able to stand up at a wedding."

Top right: Carl Larson walks short distances with The Parastep System as Myrtice Atrice, P.T., looks on at the Shepherd Spinal Center, Atlanta, GA.

Photo courtesy of Shepherd Spinal Center.

Parastep® represents a commitment to progress

Parastep user profile: Carl Larson

Carl Larson likes to compare his progress in using The Parastep System to playing a musical instrument. "The more you practice with it, the better you'll get," he says.

For Parastep users across the country, Carl's words could not have been better chosen. The former Delta airline pilot, age 50, has been committed to his use of the Parastep and believes he has benefited from his completion of the 32 sessions of physical therapy training he started in February 1991 at Shepherd Spinal Center, Atlanta, GA.

A resident of McDonough, GA, Carl, a T-9 paraplegic, was injured in 1989 when he fell from a tree he was pruning. He considers the Parastep a "tremendous breakthrough in technology," but he recognizes it's not a "cure all" for the paraplegic and wasn't intended to be.

"Progress in using the system depends a great deal on how much effort the individual is willing to put into it," says Carl. "I've used the Parastep for standing and walking around the house and for functional activities such as opening up the refrigerator door, getting a tray of ice cubes and having a drink of water."

In addition, Carl has used the Parastep to walk around his airplane and check the oil. He once walked from a parking lot into a shopping mall near his home. "I suppose with some more work there are other tasks I could do using the system, such as changing a light bulb or even painting portions of a room."

Carl used long leg braces in the year prior to his involvement with the Parastep. He feels that as a result of using the Parastep, his bones may be stronger from activating his leg muscles, and that he may be helping to reduce the risk of pressure sores.

"The Parastep has helped us get out of our wheelchairs to stand and walk ... and that's fantastic," said Carl. "People who are using the system will probably be in a better position to benefit from future technological developments, and that can mean even greater progress for the paraplegic." ■

After years of investigation, a step into the future with The Parastep® System

Sigmedics' profile:
Daniel Graupe, Ph.D.

From the start of his research work with paraplegics, Daniel Graupe, Ph.D., knew there was one primary goal: to see research participants step beyond the clinic to attain functional assistance with their activities of daily living through independent, unbraced standing and short distance walking.

Looking back on the past 22 years of clinical work with his colleagues, Dr. Graupe credits his background in applied mathematics and specialty in control theory and signal processing with helping him to invent and design The Parastep System.

His clinical results originated, in part, from his work as Professor of Electrical Engineering and Computer Science and Professor of Physical Medicine and Rehabilitation at the University of Illinois at Chicago and from his research in functional electrical stimulation (FES) conducted at Humana Hospital – Michael Reese, Chicago.

Earlier work in the field was conducted by Dr. Graupe at the Israel Institute of Technology, Haifa, Israel; at Colorado State University; at the Illinois Institute of Technology, Chicago; and at the Hines V.A. Hospital, Hines, IL.

I approached my research work in FES as a control and signal processing engineer

"I approached my research work in FES as a control and signal processing engineer," said Dr. Graupe. "I started working with amputees and developed a device to help them control the movement of their artificial limbs. Paraplegics share similar problems in achieving control of their limbs. I was able to apply much of what I learned from my work with amputees to FES and the paraplegic population."

In 1979, Dr. Graupe met Kate H. Kohn, M.D., Director of Physical Medicine and Rehabilitation at Humana Hospital – Michael Reese. Dr. Kohn had a particular interest in both paraplegics and amputees. Working together, Dr. Kohn and Dr. Graupe established the first FES clinic at Michael Reese in 1981. In conjunction with research conducted at the Illinois Institute of Technology, Dr. Graupe and Dr. Kohn recorded their first patient standing and walking in January of 1982.

Daniel Graupe, Ph.D., who invented and designed The Parastep System, with Kate Kohn, M.D., Chairman Emeritus, Department of Rehabilitation Medicine, Humana Hospital – Michael Reese. Dr. Kohn played a key role in the development of the Parastep.
Photo courtesy of Humana Hospital – Michael Reese.

"This achievement was only the beginning," said Dr. Graupe. "We were well aware that in 1981 Dr. Kralj of Yugoslavia demonstrated that steps could be taken by paraplegics through the application of functional electrical stimulation."

"Our goal was to expand upon those first studies by introducing the elements of comprehensive control and integrated signal design that are essential for independent use." While early studies indicated that FES could enable some spinal cord injured persons to walk, Dr. Graupe's concern was that early systems required the presence of a professional to activate the system and to adjust it during standing and walking. In some cases, a harness and counter balanced weights were used to promote balance and stability.

"None of the early systems were designed for independent home/work place use by the patient. We wanted to develop a system for unbraced standing and short distance walking that was safe and which the user could control and operate by himself," said Dr. Graupe.

"We learned from rehabilitation specialists that physical therapy training, when combined with a reliable and controllable system, would achieve the stated clinical goals," said Dr. Graupe. "Participants in the Parastep Clinic have accomplished unbraced standing and short distance walking while independently controlling each step themselves."

Furthermore, users of the system, while in complete control of their own mobility, can concentrate on critical matters such as posture and balance.

As a result of years of careful control design and signal processing analysis, the Parastep now has a compact stimulator containing a single pulse transformer and one microcomputer chip which assumes the work formerly done by four or more such circuits.

Housed in one compact and lightweight unit that clips to the user's belt, the microcomputer is self-activated and processes all user commands while providing complex and sophisticated control for safe, independent ambulation.

A reciprocating walker with finger switches lets the user send signals to the microcomputer to control standing and stepping and the sit-down commands. The present system is powered by eight double-A batteries and weighs just over one pound.

"The computer control allows the user to learn to operate the system in minutes. Total time from initial electrode placement to the user's standing up, on his own feet, is under 10 minutes. Total time to fully disconnect the system is about two minutes," said Dr. Graupe.

The Parastep System is totally non-invasive. Each user must participate in 32 sessions of physical therapy training to learn system operation and to achieve proper posture and gait.

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What's next for The Parastep System? First and foremost, Dr. Graupe would like to see as many spinal cord injured persons as possible introduced to the Parastep.

"Many hospitals now have established Parastep Clinics which afford them the opportunity to train patients on the system," he said. "We want to see the Parastep help as many people with spinal cord injuries as possible. We want to help them stand up and get out of their wheelchairs so they can improve their quality of life, at home and at work, and maximize their own physical and psychological well being." ■

Parastep® User Group holds first meeting

Parastep users now have the opportunity to share their knowledge and experiences, as well as obtain information to enhance system use, through participation in Parastep User Groups being established in conjunction with hospitals across the country.

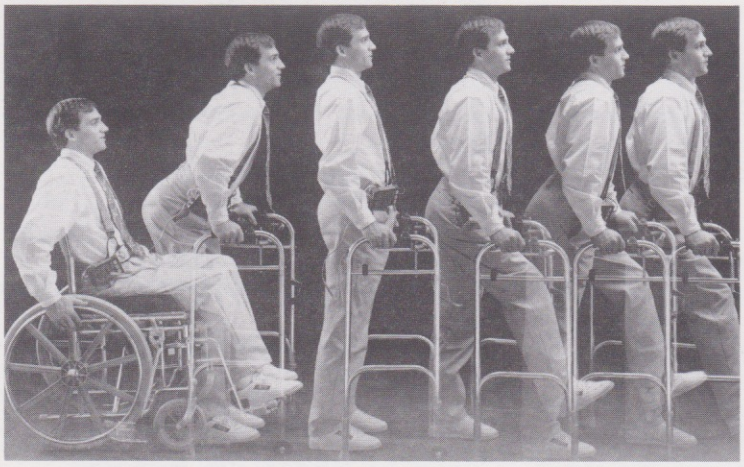
The first meeting of Parastep users in the Chicago area was held recently and included a discussion led by Robert A. Habasevich, VP, Physical Therapy, and Patrick W. Maher, Director, Marketing and User Support Services, both of Sigmedics, Inc.

"This group will give you the opportunity to learn more about life issues related to spinal cord injury, and the importance and benefits of standing and walking short distances," Habasevich told the members. "We will work together to serve as a support resource for achieving your individual goals in the use of The Parastep System."

Patrick W. Maher, Sigmedics, Inc., leads the opening discussion at the first meeting of the Chicago Parastep Users' Group.

Plans for additional Parastep User Groups are underway in cooperation with hospitals across the country where The Parastep System is available. A group has been launched recently at the Shepherd Spinal Center, Atlanta, GA.

Sigmedics, Inc. mission



Rehabilitation technology for the spinal cord injured

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Sigmedics' staff hosts clinical training seminar

Physical therapists from eight newly established Parastep Clinic programs at rehabilitation hospitals across the country attended a workshop in Chicago conducted by the Sigmedics' clinical staff on "Synthesized Gait Restoration Training for the Spinal Cord Injured."

The two-day workshop provided a combination of educational sessions with practical, hands-on experience. Among the subjects covered were an introduction to FES ambulation systems, evaluation of FES ambulation candidates, computer controlled FES systems – electronics and safety features, reimbursement considerations for FES ambulation systems, exercise training principles applicable to spinal cord injury, developing the care plan for FES synthesized gait training and clinical problem solving.

Attendees were greeted by Paul F. Lavallee, President and C.E.O., Sigmedics, Inc. The course instructors included Marilyn DeMont, P.T., Clinical Associate Professor, Boston University, and Sigmedics' staff members, including: Robert A. Habasevich, VP, Physical Therapy; Raymond Hedenberg, Physical Therapist; Patrick W. Maher, Director, Marketing and User Support Services; Frank E. Zeiss, VP, Operations; and Silvano A. Romeo, VP, Engineering.

Daniel Graupe, Ph.D., who invented and designed The Parastep System, gave a special presentation on "The Evolution of Parastep Technology."

For additional information about the next clinical training workshop, contact Robert A. Habasevich at (708) 501-3500.

1991 conference attendance schedule

REHABEX '91
Toronto, Canada
Exhibits: October 3, 4 and 5
Booth #359

Association of Rehabilitation Nurses
Kansas City, MO
Exhibits: October 23 and 24
Booth #630

American Academy of Physical Medicine and Rehabilitation – American Congress of Rehabilitation Medicine
Washington, DC
Exhibits: October 28 and 29
Booth #711

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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:

- 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.

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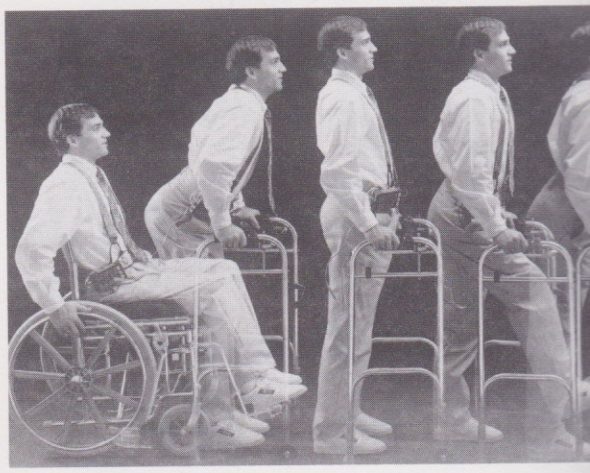

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☐ *I would like more information sent to me about The Parastep® System.*

☐ *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.*

☐ *Please send me a copy of "Technological Advancements in Rehabilitation: Independent Standing and Short Distance Walking for the Spinal Cord Injured."*

Name _____

Title _____

Institution _____

Address _____

City _____ State _____ Zip _____

Phone _____ Best time to call me _____

Parastep® Clinic programs being implemented

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

Casa Colina Centers for Rehabilitation
Pomona, CA

Cleveland Clinic Foundation
Cleveland, OH
(Multiple Sclerosis Research)

Craig Hospital
Englewood, CO

Hines Veterans Administration Hospital
Hines, IL

Humana Hospital – Michael Reese
Chicago, IL

Kessler Institute for Rehabilitation
West Orange, NJ

Memorial Rehabilitation Hospital
Long Beach, CA

Scripps Memorial Hospitals Rehabilitation Center
Encinitas, CA

Shepherd Spinal Center
Atlanta, GA

Spain Rehabilitation Center
University of Alabama
Birmingham, AL

University of Miami
School of Medicine
Miami, FL

University of Washington Hospital
Seattle, WA

Younker Rehabilitation Hospital
Des Moines, IA

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

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