

Relief for Acute and Chronic Pain

EACH year, over 50 million Americans are treated for pain resulting from wounds or surgery, joint and muscle injuries, or arthritis. As America's baby boomers age and begin to suffer from chronic illnesses, they will be seeking better ways to effectively manage pain.

One management method, ancient and well-established but not commonly used, is transcutaneous electrical nerve stimulation, or TENS. In this method, low-level electrical pulses are delivered through the skin to inhibit or interfere with the transmission of pain signals to the brain.

The problem with the method is that it has been too expensive and difficult to use. But that's about to change, because a team of Livermore, private-industry, and Russian scientists has developed a device that turns TENS into a viable treatment process. For their work, the team has been awarded an R&D 100 Award.

About TENS

In 1965, Canadian psychologist Ronald Melzack and British physiologist Patrick Wall performed an in-depth study of pain transmission and published a now-famous theory that spawned the development of TENS devices. Their study and those of others revealed that in 25 years of use, TENS had caused no serious side effects or injuries. In fact, these studies and the sustained sales of TENS devices during the study period validated TENS as an effective and safe pain-relieving alternative.

Traditionally, TENS devices have been prescribed for managing intense, intractable chronic pain. They are also routinely used in conjunction with other therapies during physical rehabilitation to maximize pain relief and increase patient tolerance for exercise and movement.

But standard TENS devices have been largely inappropriate for short-term, acute pain management because they have been large, complex, and expensive and have required operation by a licensed therapist or physician. If TENS were easier to use and less expensive, it could supplant narcotics and other common medical prescriptions for pain.

Wireless and Portable

That has now happened. Lawrence Livermore, Cyclotec Advanced Medical Technologies (Cyclotec), Inc., and the Biophysical Laboratory (Biofil) Ltd. of Sarov, Russia, working under the Department of Energy Initiatives for Proliferation Prevention Program, have formed a joint cooperative research agreement to develop an advanced, easy-to-use TENS technology, currently known as STIM-2002 TENS.

Jeffrey S. Mannheimer and Stephen A. Michaelson of Cyclotec developed the initial concept and clinical methodologies for the product based on commercial market needs. Livermore scientists Bill W. Colston, Jr., Kenneth J. Michlitsch, Luiz B. Da Silva, Alexander Rubenchik, Ted Saito, and John E. Marion partnered with Cyclotec and Biofil to develop and miniaturize a smart controller for the improved TENS device.

Some Livermore members of the team that developed STIM-2002 TENS. From left, Bill Colston (demonstrating one way of applying the STIM-2002 TENS device), Alexander Rubenchik, and John Marion. Not pictured are Kenneth Michlitsch, Luiz Da Silva, and Ted Saito.



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Russian scientists from Biofil, working with Cyclotec, completed the mechanical and electrical packaging and construction of the device.

The STIM-2002 TENS device consists of two miniature electronic modules. One is a remote-controlled, preprogrammed transmitter that can be kept in the user's pocket or worn like a pendant around the neck. The other is a stimulator-receiver that is positioned on top of a conductive adhesive electrode that attaches the device to the patient. The transmitter sends the stimulation paradigm to the receiver, which produces the pain-relieving pulses where the module has been applied. Because the receiver is integrated with and mounted on the electrode, lead wires—which encumber other commercial pulse stimulators—are unnecessary.

To use the device, a patient simply puts it on like a bandage. The electrodes can be easily reconfigured for different body applications (to the arm, wrist, knee, back, neck, or a small wound). Using the three buttons on the transmitter, a patient can select one of six stimulation treatment modes (depending on the pain and the desired therapy), different intensities of stimulation, and different cycling protocols (that is, cycling through selected stimulation modes for a desired treatment). The fingertip programming that the user performs is similar to changing the settings on a digital wristwatch and is much simpler than programming a VCR. In fact, the operation of this TENS is intuitive; it can be used safely and effectively without professional guidance.

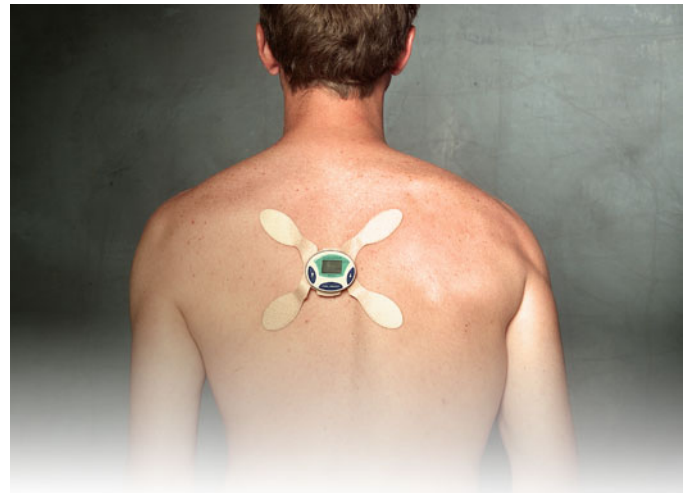
The device provides patients with feedback on operational status by continuously displaying current mode, elapsed time, and intensity. It also collects usage data that physicians can download if they so desire.

With its small size (as much as five times smaller than other TENS), wirelessness, ease of use, and cost effectiveness, the STIM-2002 TENS certainly gives patients greater flexibility, comfort, and rapid pain relief.

A Significant Breakthrough

Physicians, psychiatrists, and physical therapists believe STIM-2002 TENS to be a significant breakthrough because it allows TENS to be used outside the doctor's office. The U.S. National Institute on Drug Abuse, which supported the development of STIM-2002 TENS through grants to Cyclotec, recommends this TENS medical instrument because it offers pain sufferers with a "viable alternative to drugs for pain relief" and allows them to avoid drug side effects, abuse, or dependency.

In a range of uses—from treatment of minor cuts, burns, scratches, and wounds where regular bandages are applied, to alleviating the pain of minor surgical procedures such as suturing, to providing relief after arthroscopic surgery—TENS



The wireless STIM-2002 TENS receiver-stimulator can be applied to different parts of a patient's body. It is remote-controlled by a palm-sized transmitter.

offers faster, more precisely directed relief than oral and even some injected drugs. It has not caused any serious side effects and does not have anesthetic, narcotic, or addictive effects. Furthermore, TENS treatment can be stopped instantaneously, without waiting for the body to eliminate accumulated drugs.

The Next Improvements

In the future, the technology development team sees STIM-2002 TENS products configured as dynamic splints, braces, supports, and straps. They envision remote-controlled TENS transmitters in wristwatch form. They are completing an even smaller electronic "Band-Aid" that can protect open wounds, control pain, and enhance circulation to promote healing.

Clearly, the STIM-2002 TENS device will significantly improve the quality of life for millions of Americans. Users will have greater control and management of their pain so that their work and activities will not be affected or interrupted. And health professionals—including physical therapists, physical rehabilitation physicians, chiropractors, occupational therapists, and medical clinicians—will find that this device significantly augments and benefits their work.

—Sharon Emery

Key Words: electronic adhesive bandage, medical device, pain management, R&D 100 Award, transcutaneous electrical nerve stimulation (TENS).

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