



SmartPill

Redefines "Noninvasive"

Measuring device for gastrointestinal disorders

Plumbing the mysteries of the digestive system has always posed difficulties for the practitioner. How does one test or image the insides of the esophagus, the stomach, the small and large intestines? In recent years, the standard approaches have been radioimaging or endoscopy, both with significant drawbacks for the patient and both with limited ability to probe the 30-foot length of the gastrointestinal (GI) tract. (A standard gastroscope is 3½ feet long; a colonoscope, 5½ feet.)

Now a Buffalo-born idea holds the promise of revolutionizing diagnosis and treatment of GI disorders by measuring key factors from inside every inch of the GI tract. The device, an ingestible diagnostic sensing capsule called the SmartPill pH.p Capsule, is simply swallowed by patients. As it travels through the digestive system, it continuously relays information on

temperature, pH, pressure and transit time to a monitoring device the size of a PalmPilot that patients wear on their belt (to the right), with no disruption to activities of daily living.

After one to three days, the capsule leaves the body through normal elimination, patients return the monitor to their doctor, and specialized software generates a detailed report on the SmartPill procedure and

how the GI system is functioning.

"It's a very elegant solution," says David L. Barthel, president and CEO of The SmartPill Corporation, the medical device company on the Buffalo Niagara Medical Campus that is developing the capsule. "Current methods of examining the GI tract have such negative implications that they put



people off. Patients don't want to go through the procedures, so they often suffer in silence."

The new device is intended to help diagnose GI motility disorders, such as gastroparesis, that inhibit the normal movement of food through the digestive tract.

Gastroparesis, the inability of the stomach to empty, is related to abnormalities of the nerves or muscles in the stomach that interfere with the normal mechanical action of contractions called "peristalsis."

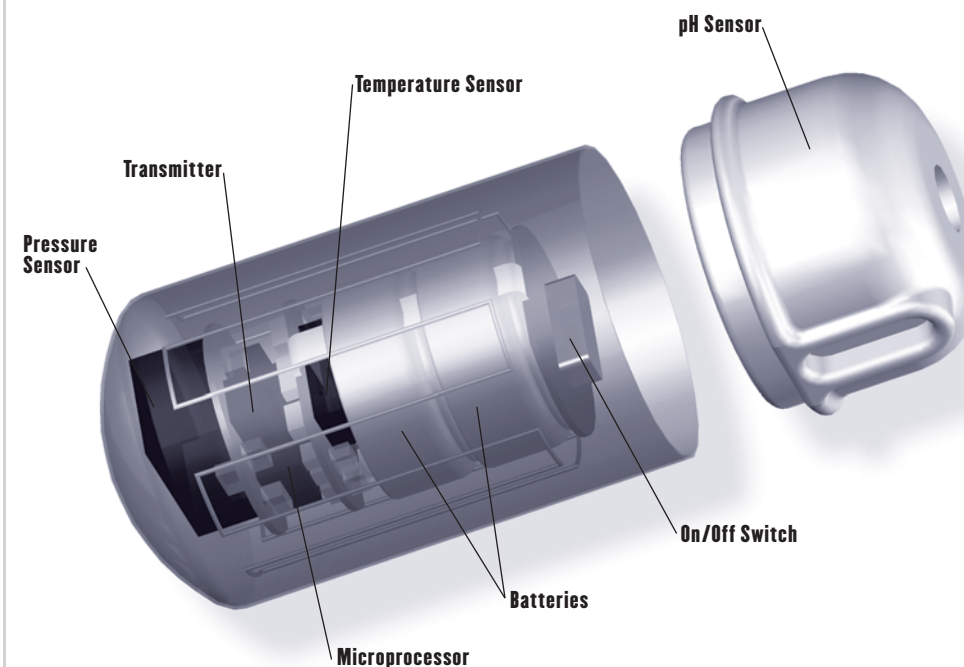
Common causes for the condition include diabetes and obesity; however, in up to 40 percent of cases, the cause remains unknown.

It's a market rife with opportunity: According to company figures, about three million Americans have gastroparesis severe enough to require hospitalization.

"We're hitting a very large market that just hasn't been addressed," says Barthel. "We're hoping to have FDA [Food and Drug Administration] approval and be on the market in the March/April 2006 time frame."

SmartPill completed physiological (proof-of-principle) testing in 2004.

In October 2005 it successfully completed a seven-site 510(k) clinical trial that involved 50 subjects with gastroparesis and about 80 control subjects. One of the seven test sites was the Veterans Affairs Western New York Health Care System in Buffalo, where the study was directed by Michael D. Sitrin, MD, professor of medicine at UB and chief of the Division of Gastroenterology, Hepatology, and Nutrition; and Jeffrey M. Lackner, PsyD, assistant professor of medicine, whose expertise is behavioral medicine with a



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By
SCOTT
THOMAS

specialization in functional disorders of the GI tract.

“One of the most immediate potential applications,” says Sitrin, “is that you can clearly see when the capsule leaves the stomach and enters the duodenum, because you get a sudden rise in pH. You can get a very good measure of when the capsule empties out of the stomach. There is a group of disorders associated with abnormal gastric emptying, so this will be useful.”

In the 510(k) clinical trial, subjects swallowed the SmartPill pH,p Capsule along with a radioisotope-tagged meal. Researchers then gathered information from the device and compared it with information from X-ray analysis of the digestive progress of the tagged meal. The goal was to see how closely the SmartPill data correlated to the X-ray data, considered the current gold standard of GI motility monitoring.

“This is a very interesting thing,” notes Sitrin. “What we know about the motility of the GI tract has been coming from situations where it is very difficult to do research. You have patients sitting there for a short period of time with tubes

down them—a very artificial situation. This new method gives you a chance

to get some of these measurements in people who are in a much more natural situation. It really represents a new step forward.



“Eventually this may produce information on a whole group of disorders in which we think motility of the GI tract is an important issue, such as functional dyspepsia, IBS and chronic constipation, in which we have limited physical data on what’s actually going on with the patient.”

Lackner serves on The SmartPill Corporation’s scientific advisory board, which has contributed expertise in such areas as the design of the clinical trials. Commenting on that experience, he says: “Academic medicine and business are often odd bedfellows. But we have effectively

put together a group of young, innovative, forward-thinking academic researchers who are intrigued by this capsule methodology. You have people collaborating from a variety of high-quality medical institutions—UB, Harvard University, University of Michigan, Temple University, Wake Forest University, University of Kansas and University of Louisville—and those people are able to lend their expertise and methodology, so we can further the development of the device.”

Indeed, the FDA testing is only the latest chapter in the technology’s long history. The idea behind the SmartPill was developed by UB professor of pharmaceuticals Jerome J. Schentag, PharmD, in conjunction with another Buffalo-area scientist, David T. D’Andrea. (Schentag now serves on the scientific advisory board for The SmartPill Corporation, and D’Andrea is a member of the company’s engineering team.)

The device was conceived as a method of delivering medications directly to targeted areas of the digestive tract. It was chosen by *Popular Science* magazine as one of the top 100 inventions of 1992, but early efforts to develop the device for commercial application were not successful.

“We saw its tremendous immediate market potential as a medical device, not a drug delivery device,” recalls Barthel.

Today, The SmartPill Corporation employs 20 full-time people as it prepares for commercialization.

In addition to their work on the 510(k) clinical trial, Lackner, Sitrin and their SmartPill collaborators are currently conducting a series of trials aimed at maximizing the clinical utility of the device by linking the physiological data obtained by it with the symptoms of the patient.

These studies will continue through December 2006.

“I’m particularly interested in innovative assessments and outcomes research, so, for me, this is an opportunity to apply these interests to a novel device,” explains Lackner.

The clinical trials in Buffalo are supported by a \$500,000 grant from

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the New York State Office of Science, Technology and Academic Research (NYSTAR) under its Technology Transfer Incentive Program. NYSTAR funds high-tech projects with the potential for significant economic impact; its grant to UB for the SmartPill covered costs of personnel and the expenses of the clinical trial.

“The NYSTAR grant is a way of developing and cultivating entrepreneurial opportunities that link busi-

ness and the academic environment here at the University at Buffalo,” notes Lackner. “The clinical trials are largely being run here by people in the UB Division of Gastroenterology. Without that grant, we would not have been involved.”

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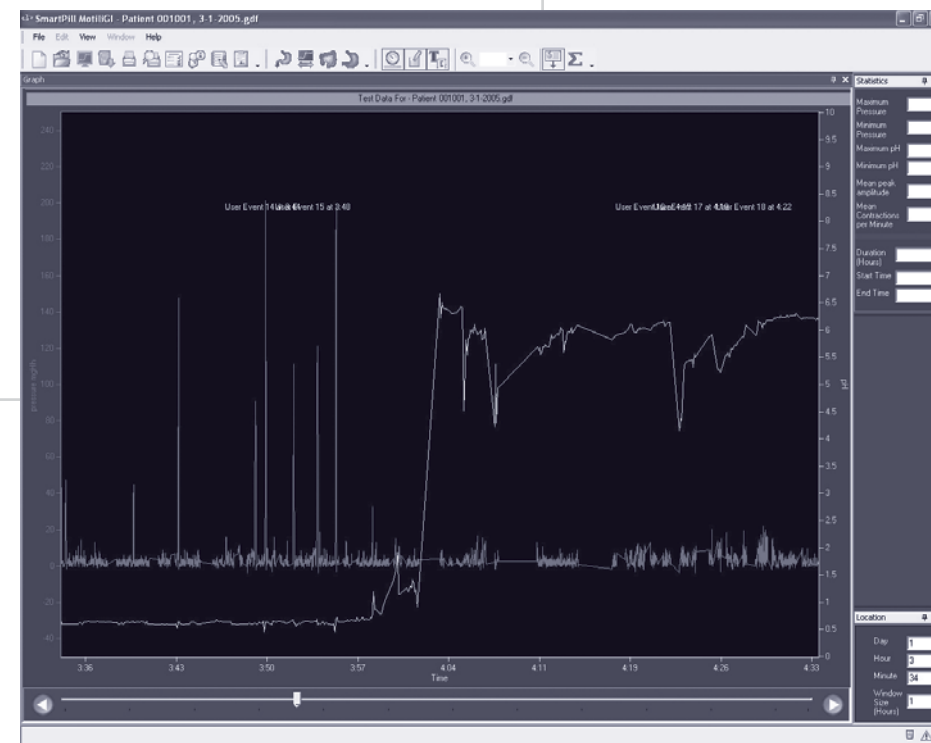
For example, he explains, sensors could search out signs of bacterial infection or detect biochemical markers that would indicate the presence of a tumor.

For those observers eager for the next Buffalo-born innovation to succeed in the marketplace, the SmartPill and its developers are a ray of economic hope in Western New York.

“They’ve been extremely conscientious and hard-working,” says Lackner. “They took this capsule from when it was just an idea and really plugged along. They’ve made believers out of a lot of us.” **BP**



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