

The MedTech STRATEGIST

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CONNECTED HEALTH

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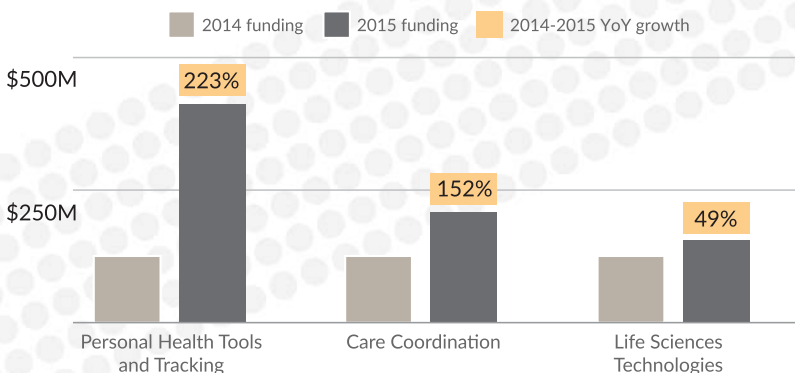
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MARKET TRACK

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Fastest Growing Categories in Connected Health



A Digital Biomarker

Helps Hospitals Treat Post-Op Patients

GI LOGIC LLC



Pasadena, CA

Sector: Postsurgical Care and Gastroenterology

Founded: 2013

Contact: James D. Beeton, Co-Founder/CEO, jbeeton@gi-logic.com

Business Founders: Jim Beeton, co-founder and managing

partner of Affinity Partners LLC (provided patient compliance solutions to sleep centers); a former VP at CardioSom LLC (respiratory and therapeutic sleep devices), Cardiac Rhythm management at Medtronic; and Gary Sterling, CEO of EP Dynamics Inc. (Cardiac EP space)

Scientific Founders: Brennan Spiegel, MD, MSHS; Director of Health Services Research, Cedars-Sinai Health System, Director, Cedars-Sinai Center for Outcomes Research and Education (CS-CORE) Cedars-

Sinai Site Leader, Clinical and Translational Science Institute(CTSI); and William J. Kaiser, PhD, Professor, Electrical Engineering Department, Co-Director, UCLA Wireless Health Institute, who is a physicist and an expert on sensors

Funding to date: \$1.8 million from individual investors; seeking investment in an \$8 million Series A round

How the company gets paid: Bundled into existing DRG codes for particular surgeries

Wearable biosensors provide the opportunity for the noninvasive and continuous collection of physiologic signals from patients to the degree that patterns of injury and disease can now be seen in ways that were never before possible when diagnosis and monitoring relied on episodic measurements made in clinical settings. New markers of disease are beginning to emerge; what Rock Health calls “digital biomarkers,” signatures of disease states created through the power of data capture and analytics. These digital biomarkers have some advantages over conventional blood biomarkers, since they can often be obtained in a noninvasive manner, combined with other relevant information, and shared digitally.

Many things can be tracked unobtrusively as patients go about their lives: heart rate, levels of activity, temperature, seizures, sleep patterns, the

list appears endless. But the full value of continuous tracking and data collection is only realized when it results in insights that can influence clinical decision-making, patient behavior, health, and economic outcomes. That’s simply not the case with many trackers on the market today.

And, there is one other important requirement for the success of medical wearable technology. Jim Beeton, Co-CEO of **GI Logic LLC**, says he and his Co-CEO Gary J. Sterling are experienced at looking at new medical technologies. Beeton began his career in the cardiac rhythm division of Medtronic in sales and sales management and moved on to work in the sleep testing industry, most recently as managing partner of Affinity Partners LLC. Sterling also began his career at Medtronic and is the former CEO of EP Dynamics Inc., the developer of a cardiology product designed to make transseptal access

safer. Beeton says, “My partner and I have looked at a lot of these wearable companies, but our first question is always, “how is this company going to monetize this technology?”

GI Logic, which is developing a patient-worn biosensor that reveals the functional status of the gastrointestinal system, believes it solves both the clinical and business requirements. The company will launch its first product into the hospital surgery market, where it will give clinicians objective information they’ve never had before to determine when to feed patients postoperatively. The new monitor, called *AbStats*, has the potential to avoid postoperative complications, speed healing, and shorten length of stay.

Beeton says he and Sterling were working on a wearable device of their own with the help of William Kaiser, PhD, a physicist and an expert in sen-

sors who is the co-director of the UCLA Wireless Health Institute in Los Angeles. In the course of that work, the two became acquainted with another project Kaiser was working on with gastroenterologist Brennan Spiegel, MD, then associate professor of medicine in the division of digestive diseases at the UCLA School of Medicine. Spiegel had asked “Why are gastroenterologists the only clinicians that can’t get a relevant vital sign on which to base treatment for their patients?” Other specialties can rely on ECGs, blood pressure cuffs, or pulse oximeters, but gastroenterologists only have the 200-year old stethoscope and their subjective judgments on what they can hear and feel from the surface of the belly.

Kaiser devised precise vibratory sensors and algorithms to categorize intestinal movements, and Beeton and Sterling gained an exclusive worldwide license to the technology from UCLA. They founded GI Logic in 2013 with \$1.8 million in funding from individual investors to further develop and commercialize *AbStats*, the first noninvasive monitor for diagnosing functional disorders of the alimentary tract.

AbStats gained FDA 510(k) clearance in December 2015. Its predicate device was the electronic stethoscope, but *AbStats* is much more capable. “While a clinician using a stethoscope listens for 10-15 seconds and moves the stethoscope around, we put vibratory sensors on the patient’s belly where they take in a broad range of vibrations created by both muscular and food movements—and not just the sounds that you can hear—on a continuous basis.” The system also gives back to clinicians a value by which to guide therapeutic intervention. The company is conducting studies on known disease states within the gut such as gastroparesis and pancreatitis, and says Beeton, “We are able to absolutely classify what these vibrations mean and to give back useful information.”

To Feed or Not to Feed

In the post-op setting, that information will guide clinicians as to when to safely feed patients to set them on a course of healing and get them out of the hospital. As a result of surgery and anesthesia, in most patients, the digestive tract is stunned for a period following surgery and is unable to move food along. Patients are not released from the hospital until it’s clear that their gastrointestinal motility has returned and they can tolerate food.

Doctors don’t have objective noninvasive tools to determine whether or not a patient has postoperative ileus (the term for prolonged paralysis of the gastrointestinal tract causing intolerance of oral intake). They often rely on the stethoscope, patient’s reports of pain levels and whether or not they’ve had a bowel movement, and clinical examination. The gold standard for measuring intestinal motility, antroduodenal manometry, requires the insertion of a nasogastric tube (it goes in through the patient’s nose and down the throat), to measure the GI tract’s muscle movement by measuring pressure waves. That procedure is not well tolerated by patients; not feasible in many cases, since patients need to discontinue certain drugs; and is time consuming and expensive, as are other invasive assessment tools.

Since the 1990s, many hospitals have implemented a protocol called ERAS (Enhanced Recovery After Surgery) a postoperative care plan designed to decrease complications, hasten recovery, and shorten hospital stay, one directive of which is to feed patients as early as possible. However, says Beeton, in 25% of cases, patients are fed before they’re ready, food festers in the stomach, and several negative consequences can happen. Patients may feel discomfort or vomit. What’s worse, aspirated food can lead to pneumonia, additional surgeries, early readmission, and even death.

According to some studies, postoperative ileus (POI) prolongs hospital length of stay by 30% and, in the US, is responsible for excess costs of more than \$1.46 billion annually. There is no definitive set of codified risk factors to guide surgeons or bedside caregivers as to which patients may or may not develop POI. *AbStats* will give physicians objective information about intestinal motility so they can determine what and when to feed patients.

AbStats consists of a pair of disposable biosensors that detect intestinal vibration signals. It is placed on a patient’s abdomen and connects to a small bedside computer with a monitor that measures intestinal event rates and displays a graph, which is a trend analysis over time, as well as a numeric value per hour of these intestinal events. “In studies conducted using the system, these rates correlated to physiologic digestive status. These event rates thus can now allow clinicians to make informed decisions on when and how to advance patient feeding,” says Beeton.

For the postoperative ileus indication, the company first validated its new measurement (in a study led by Brennan Spiegel, MD) in eight healthy controls, seven postoperative patients tolerating the fast-track feed protocol, and 25 patients with evidence of postoperative ileus. *AbStats* measurements showed high motility rates in patients tolerating fast-track feeding versus those with postoperative ileus.

In a second peer-reviewed study (by Kaneshiro et al and published September 25, 2015 in the *Journal of Gastrointestinal Surgery*) the investigators developed an automated prediction rule about the probability of a patient developing postoperative ileus, but clinicians were blinded to the values. The study recruited 28 patients undergoing colorectal surgery, and nurses and surgeons delivered care as they normally would, without the benefit of *AbStats*

guidance. Nine of the 28 patients developed postoperative ileus. The study found that *AbStats* could prospectively identify early warning signs of evolving POI and that it could rule out POI with a high degree of certainty. “It was remarkable. There were cases where the patient was clearly in an event range indicative of POI, but feeding was started and the patient got sicker.”

These are small studies, and the company has more work to do. It will be sponsoring a registry called FASTER to see how physicians utilize the device on a broader scale, but says Beeton, “We can absolutely detect an early state of ileus.”

Digestive Disorders: A Healthcare Burden

In the postoperative setting, the company has access to a reimbursement and economic framework that makes its product attractive. “We don’t have to create a CPT code, we are coming in as something that is going to guide care and help the hospital reduce both

length of stay and overall resource utilization under the current code for each type of surgery.” Saving an average of one hospital day and the associated other care expenses for patients who develop problems related to feeding after surgery can easily justify the expense related to *AbStats*, according to Beeton.

But that’s simply the launch point for the company. *AbStats* enters a wide-open market in noninvasive telemetry and therapeutic guidance for gastrointestinal disorders. According to a survey of 2,000 US adults, conducted by **AbbVie** in 2013, 72% said they had experienced at least one of the following gastrointestinal symptoms a few times a month or more: diarrhea, gas, bloating, stomach pain, frequent bowel movements, unexplained weight-loss, and non-specific GI discomfort, and the majority of them experienced symptoms for more than six months. These vague complaints are responsible for more than 105 million office visits each year (see *Figure 5*). It’s an untapped market opportunity, and one other company, **G-Tech Medical Inc.**,

has just begun clinical trials with a product that addresses the same market. Its product measures the electrical signals that arise from muscular motor activity, to provide an “ECG of the gut,” according to the company.

GI Logic plans to make a smaller, wireless version of the biosensor that works with a smart phone for home use. In the postsurgical indication, surgeons are already requesting a home version, says Beeton. Once the patient gets home and complains of bloating, gas, and other symptoms, it’s difficult for the physician to know what that means. “If patients had this device at home, clinicians would have access to a hard number, and they would have the confidence to say, ‘Come on in,’ or ‘Stay home, you’re fine, it’s just gas,’ or ‘Stick with soft foods.’”

The patient wearable for the home market has the potential to lower admissions. “In 20 to 30 minutes we’ll be able to tell you if you have a small bowel obstruction, gastroparesis, or pancreatitis.” Indeed, many patients have suffered with surgical adhesions causing bowel obstruction and symptoms for years, and have exhausted thousands of dollars in inconclusive diagnostic work-ups. “We can capture these known signatures, put them into our algorithm and provide guidance. We want to detect specific GI disorders so the physicians will know what they’re up against, versus guessing, which is what they have to do now.”

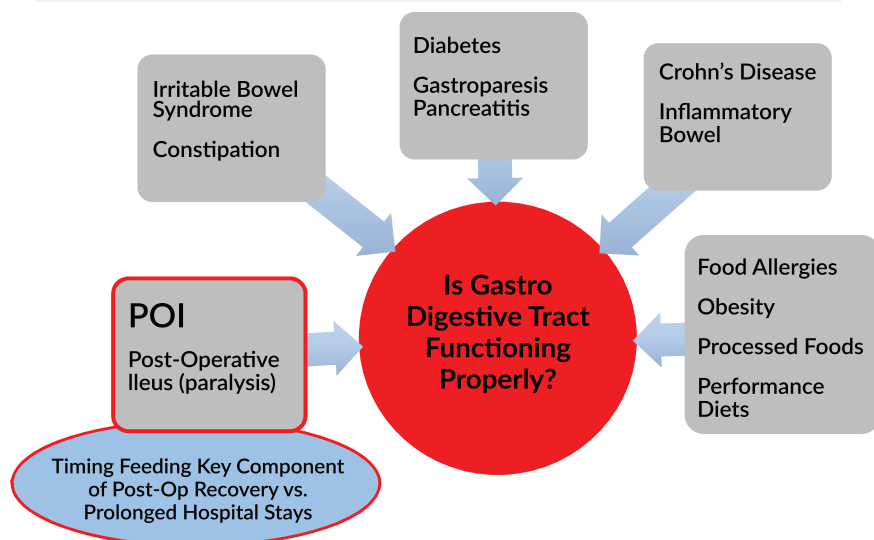
AbStats is like a thermometer, Beeton says. It will take some time and research to make sense of the information, but eventually it could become a ubiquitous tool for diagnosing all sorts of conditions. “We envision that *AbStats* is going to be the next vital sign and it will be applied to virtually every patient that checks into a hospital or clinic, just like blood pressure, heart rate, or pulse oximetry. We are the fifth vital sign.”

The company is seeking investors in an \$8 million venture round to help it build inventory and launch *AbStats* this coming May. 🟡

Figure 5

Digestive Disorders – A Healthcare Burden

•100M+ Americans •105M Office Visits •14.5M Hospital Admissions
\$98 Billion Direct Cost to Healthcare System



Source: GI Logic LLC