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PAGE 1 OF 8

BodyMedia's SenseWear system shows better weight loss results

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BodyMedia (Pittsburgh, Pennsylvania) is touting study results for its metabolic assessment and behavioral therapy solution, SenseWear, which shows for the first time that the device can improve treatment outcomes when physicians incorporate it into weight loss intervention with their patients.

The results, published in the April 2007 issue of *Obesity*, provide data supporting the company's claim that the information gleaned from the SenseWear monitor, when used to report patients' metabolic activity, can "contribute to behavioral change and improve health."

"We found that right now, it really does help when these individuals download [the collected information] at their doctor's offices, and give them more information about what they're doing — such as their changes in behavior," Donna Wolf, PhD, clinical research manager for BodyMedia, told *Medical Device Daily*.

Physicians then can "really coach them, because we've found that the coaching aspect really does help the individual."

The SenseWear system consists of an armband monitor, which weighs less than 3 ounces, that records levels of activity through several sensor systems, including: skin temperature; galvanic skin response; heat flux; and 2-axis accelerometer.

The company also provides software that can be used at home to download information from the device.

Alternatively, the patient can take the system to a physician's office and download it there, which is where the coaching component enters. For the patients, the software translates the information into charts and graphs to more easily provide a translation of the numbers generated by the device.

The study results that the company has reported examined the effects of the SenseWear Body Monitoring System on 57 patients enrolled in a 12-week behavioral weight loss intervention program. According to the company, the results showed that weight loss was greater — about 5 pounds greater, Wolf said — among the patients who used SenseWear continuously during the program.

"I think the biggest thing is that people actually begin to learn about their bodies — they learn, they burn," Wolf said.

Wolf said that often people don't realize how many calories they're burning, or not burning, which allows weight to creep up slowly and largely unnoticed.

The SenseWear system is designed not only for those wanting to lose that extra 10 to 15 pounds, but also for those for whom weight control is critical to disease control and prevention — such as patients with obesity, cardiovascular disease and diabetes.

"Until now, physicians have not had an effective tool that encourages behavior modification in the millions of patients who are overweight or suffering from obesity in the U.S," Wolf said in a statement. "With the SenseWear Body Monitoring System, patients have a means to bridge the gap between clinicians' behavioral change recommendations and their ability to understand and adhere to them."

The device is meant as somewhat of a reality check, because people often have no awareness of the calories they may be taking in.

Often, Wolf said, "they are really shocked" by the data and the knowledge it provides, thus prompting heightened awareness and the incentive to make lifestyle/behavioral changes. Often this is a matter of taking just "little steps," she said.

In March at the **American College of Cardiology** (ACC; Washington) annual scientific meeting, where BodyMedia was

exhibiting, Chris Pacione, director of customer marketing, told *MDD* that diets simply don't work, and research has indicated that most dieters not only regain the weight they lost but add back even more (*MDD*, March 30, 2007).

The device is Class II exempt, meaning it does not require 510(k) clearance.

Currently, the SenseWear system must be purchased through the company, which has its own sales and marketing team, or through their physicians as an out-of-pocket expense.

"We are looking at different reimbursement strategies," Wolf told *MDD*. "Unfortunately, the biggest challenge with reimbursement is a lot of things that are preventative care for obesity or Type 2 diabetes are not reimbursable at this time."

BodyMedia also reported the results of 10 clinical studies using the SenseWear armband presented at the **American College of Sports Medicine** (ACSM; Indianapolis) annual meeting in New Orleans from May 30 to June 2. ■