InnerVision Medical Technologies Develops Ultrasound Device to Image Morbidly Obese

The Associated Press

InnerVision Medical Technologies, Inc., a developmental-stage company engaged in research and development of high-resolution ultrasound systems, today announced completion of its prototype ultrasound device and early evaluation results for imaging morbidly obese patients. The ultrasound system offers encouraging results, as the ultrasound signals are able to penetrate the abdomen deep enough to provide improved diagnostic quality images for patients with a body mass index (BMI) well above 50. (For reference, a 6-foot-5-inch, 450-pound person has a BMI of 53.4.)

InnerVision's announcement comes soon after the American Medical Association's (AMA) official classification of obesity as a disease, requiring a range of medical interventions to advance obesity treatment and prevention.

According to leading industry analyst Harvey Klein, Ph.D., president of Klein Biomedical Consultants, "This new technology shows promise in allowing for a greater number of obese patients to be scanned by ultrasound, thus avoiding the more costly computed tomography (CT) or magnetic resonance imaging (MRI) procedures for this patient population."

The Centers for Disease Control and Prevention (CDC) estimates that 36 percent of American adults are obese, and the World Health Organization (WHO) estimates that 10-30 percent of adults in the European Union are obese.

"We are thrilled with the early results from our clinical evaluations, specifically within the morbidly obese population," said Bhaskar Ramamurthy, Ph.D., chief technical officer of InnerVision. "Ultrasound is one of the least invasive and most cost-effective diagnostic tools available to health care professionals; however, conventional ultrasound lacks the ability to penetrate at an adequate depth to provide useful diagnostic images for obese patients, a condition that affects roughly one in three Americans. In fact, a large number of abdominal ultrasound exams are sub-optimal for this patient population due to body habitus."

Klein Biomedical Consultants reports just over 22 million abdominal ultrasound exams were performed in 2012. Through an independent, ad hoc survey of physicians, it is estimated that up to 10 percent of abdominal ultrasound exams are non-diagnostic due to obesity.

"For our early clinical evaluations, comparative ultrasound exams were performed on subjects with BMIs ranging from 50 to 66 using our system and an industry-leading system," continued Dr. Ramamurthy. "Initial results show that the InnerVision Medical system consistently delivered a more uniform image with better

resolution at depth, providing definitive, diagnostic information on deep structures, such as the liver and kidney. For one subject (BMI 57.5), a physician commented specifically that the industry-leading system's images of the subject's liver and kidney were non-diagnostic; however, the InnerVision Medical images were clearly diagnostic."

Obesity increases the risk of a number of health conditions including hypertension (high blood pressure), type 2 diabetes, gallstones, high cholesterol, coronary artery disease (CAD), sleep apnea and cancer. Obese individuals have a 50-100 percent increased risk of premature death, and it's estimated that obesity may be the cause of 300,000 deaths per year according to the U.S. Department of Health and Human Services. According to the WHO, class I obesity is defined by a BMI of 30 or greater; class II obesity is defined by a BMI of 35 or greater, and class III obesity is defined by a BMI of 40 or greater. An individual is considered morbidly obese if he or she has a BMI of 40 or greater.

InnerVision Medical's proprietary system architecture is derived from deep geologic seismic image processing techniques, which have been refined and conformed to medical ultrasound by the company's team of engineers. When the system is paired with custom transducers, the technology is especially adept at deep tissue diagnostic imaging for obese patients. InnerVision believes its innovative technology has the capability to improve image quality for all patient body types.

The initial study of the InnerVision Medical prototype system is being conducted in accordance with the U.S. Food & Drug Administration's (FDA) Investigational Device Exemption (IDE) under the approval of a local Investigational Review Board (IRB).