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Analogic Announces FDA Clearance for Breakthrough Sonic Window Handheld

First-of-a-Kind Ultrasound System Initially Targeted for Image-Guided Peripheral Intravenous Access (PIV); Fits in Clinicians' Pocket

PEABODY, Mass., April 9, 2014 (GLOBE NEWSWIRE) -- [Analogic Corporation](#) (Nasdaq:ALOG), enabling the world's medical imaging and aviation security technology, announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the handheld [Sonic Window™ ultrasound system](#), an imaging device for visualizing vasculature and guiding peripheral intravenous access (PIV). The new, ultra-compact ultrasound device provides direct visualization of structures beneath the skin in real time to effectively guide clinicians placing peripheral IVs.

"Improved visualization has been demonstrated to improve first attempt success in PIV insertion. The Sonic Window is an intuitive, handheld visualization tool that allows clinicians to quickly visualize a patient's vessel location, depth and size," said Jim Green, president and CEO of Analogic. "Intravenous access is often one of the first needs a patient has when medical or surgical intervention is necessary. First stick success has many potential benefits: complication and cost reduction, improved time-to-care and improved patient satisfaction. With the Sonic Window acting as a 'window through the skin and into the body,' clinicians are equipped with a portable imaging device that provides clear, easy-to-interpret images on a real-time display."

Unlike existing portable devices on the market today, the Sonic Window handheld is self-contained and does not have cables and wires connecting a transducer nor does it require a cart or stand to operate. The small, lightweight device, which is the size of a TV remote control, requires only one hand for operation. The system's controls may be manipulated during scanning without any interruption to the image on the screen. In addition, the handheld portable device has a rechargeable battery and does not need to be plugged in to operate.

Initial evaluation by clinicians reveals that the Sonic Window incorporates the benefits of breakthrough ultrasound imaging technology with portability, making it an efficient tool to use in a clinical setting for the successful establishment of PIV in the patient with challenging IV access.

"The Sonic Window provides clinicians with accurate depth measurement, allowing them to choose the appropriate catheter size and length. We are confident that the innovative Sonic Window handheld will offer clinicians a valuable tool for vascular access applications," continued Green. "The FDA clearance supports our previously announced plan to begin shipments later this summer. We also expect that the Sonic Window platform, which is based on our patented DSIQ technology and incorporates an advanced 2D ultrasound imaging array, will form the foundation of a family of products that will address procedure guidance and diagnostic needs in both acute care and physician offices."

About PIV

Care delays occur in approximately 25 percent of all patients regardless of care setting due to the inability to establish IV access according to Barton, AJ (1986), and the average number of attempts per patients using traditional techniques of sight and palpitation is 2.18. Estimates range from 300-500 million IV placements per year in the U.S., with one in three attempts resulting in failure in adults, and one in two attempts resulting in failure in pediatrics. According to Constantino, TG (2005), when traditional insertion methods are compared to image guided access, results show that success rates in the unguided group is 82 percent compared to the image guided group where success rates rise to 97 percent. In addition, the image-guided group attempts to completion drop to 1.7 attempts.

About Analogic

[Analogic](#) (Nasdaq:ALOG) provides leading-edge healthcare and security technology solutions to advance the practice of medicine and save lives. We are recognized around the world for advanced imaging systems and technology that enable computed tomography (CT), ultrasound, digital mammography, and magnetic resonance imaging (MRI), as well as automated threat detection for aviation security. Our CT, MRI, digital mammography, and ultrasound transducer products are sold to original equipment manufacturers (OEMs), providing state-of-the-art capability and enabling them to enter new markets and expand their existing market presence. Our market-leading BK Medical and Ultrasonix branded ultrasound systems, used in procedure-driven markets such as urology, surgery, and point-of-care, are sold to clinical end users through our direct sales

force. For over 40 years we've enabled customers to thrive, improving the health and enhancing the safety of people around the world. Analogic is headquartered just north of Boston, Massachusetts. For more information on the New Sonic Window, visit www.analogicultrasound.com/sonicwindow.

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