



signostics

**Signostics Receives FDA Clearance for Uscan™ – The
World’s First Smart Mobile-Connected Visualization Device
Specialized for Urologic Care**

*Uscan provides urologic visualization for efficient and more
confident point-of-care clinical decision-making*



Signostics received FDA clearance for Uscan™, the world's first smart mobile-connected ultrasound visualization device specialized for urologic care. Photo credit: Signostics.

May 06, 2016 09:00 AM Eastern Daylight Time

KIRKLAND, Wash.--(BUSINESS WIRE)--Signostics, the global innovator in smart, high reliability ultrasound devices for urology, announced today that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for Uscan™, the first smart mobile-connected ultrasound visualization device targeted at urologic care.

Using algorithms from the science of computer vision, Uscan actively recognizes the 3D contours of the bladder, for far more accurate volume measurements than the industry standard* even on obese and other hard-to-scan patients. It acquires up to 256 bladder slices – 32 times more than conventional bladder scanners – resulting in industry-leading accuracy. It also provides real-time ultrasound imaging of the kidneys, pelvic floor, prostate, gallbladder, bladder stones, and catheter emplacement, for quick and easy visual tracking and observation.

“Uscan doesn’t just scan; it sees – providing intelligent urologic visualization by leveraging science from current-day computer vision algorithms aimed at more efficient and confident point-of-care clinical decision-making,” said Kevin Goodwin, CEO. “Uscan will exceed historical industry standards for bladder volume measurement accuracy yet will also enable use for other urologic imaging needs, reducing the delays and expense of engaging specialized ultrasound equipment or sonographers.”

Uscan also offers integrated middleware not found in any comparably priced systems; and can be used in a range of clinical settings beyond urology, including the emergency department, maternity, pediatrics, oncology, rehabilitation, aged care and home nursing. The system’s removable probe, high-resolution touch screen tablet and handheld displays make it ideally suited for on-the-go clinical care.

It is compatible with Android operating systems, and has built-in WiFi and Bluetooth connectivity that enables fast and reliable image management and interoperability with electronic health record (EHR) systems.

Uscan also offers the industry's lowest cost of ownership in this market space, coming with a designed-in 5-year product warranty, with a "no fine print" pledge and requires no annual calibration. It is simple to learn and use, and provides real-time user guidance, eliminating the need for extensive training.

Signostics will introduce Uscan to U.S. healthcare providers attending the American Urological Association's 2016 Annual Meeting (AUA 2016) May 6-10, 2016 in San Diego, California.

Uscan is anticipated to be commercially available in the U.S. by June 2016.

About Signostics

Signostics Inc. is a wholly-owned subsidiary of Signostics Limited, a global medical device manufacturer. A KKR portfolio company, Signostics is pioneering smart ultrasound devices to enhance imaging and clinical decision making in urologic care. The company's products include Uscan, SignosRT ultrasound systems and the SignosRT Bladder Scanner – ultra-portable, affordable devices designed to assist with the diagnosis of common medical presentations at the bedside. The company has regulatory approvals in the U.S., Australia, Canada, Europe, Singapore and Japan, and exports to countries around the world. For more information, visit www.signosticsmedical.com.

Signostics and Uscan are Trademarks of Signostics Limited.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

*Based on comparative measurements of a phantom of known volume.

Contacts

Edelman

Jessica Donnelly, 323-202-1051

Jessica.Donnelly@edelman.com