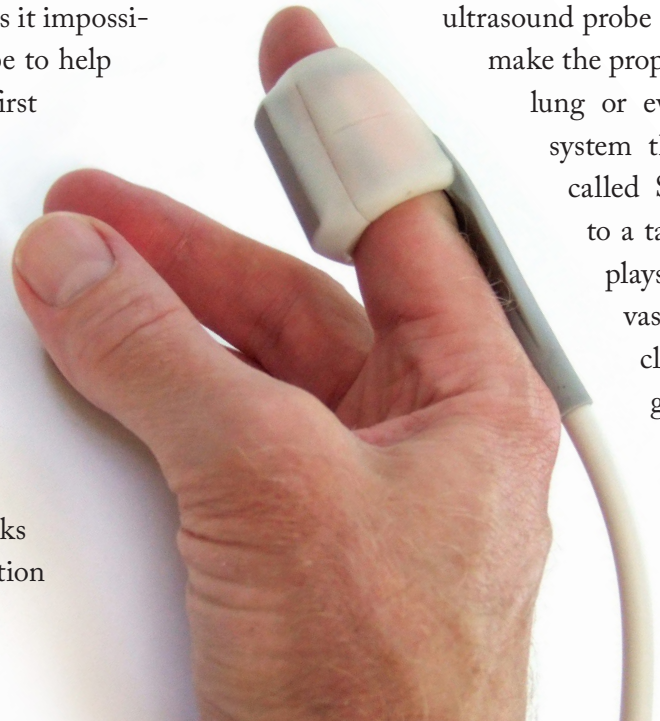
Just a TOUCH

A Fingertip Ultrasound System Developed for Field Medics Looks to the Commerical Market

A medic in Afghanistan is treating a warfighter who may have a collapsed lung. Confirming the diagnosis is crucial, but the noise and chaos of the battlefield makes it impossible. The medic could insert a tube to help the patient with respiration but first he needs to confirm the diagnosis. If he's wrong and inserts the tube anyway, other complications might arise. Should he proceed, even with the risks? Or should he wait and hope the patient will survive transport to a field hospital?

In the near future, thanks to the Small Business Innovation Research (SBIR) program and a company named Sonivate Medical, this dilemma is not as likely to occur. Instead, a field medic who is equipped with an ultrasound probe on the end of his finger can make the proper assessment of a collapsed lung or even internal bleeding. The system that makes this possible is called SonicEye® and it connects to a tablet or cell phone that displays ultrasound images of the vascular system, organs, muscles, and tendons as the finger moves over them. An interface guides the user through a field examination and saves the images. The system is small,



wearable, rugged, intuitive, and simple, a "Swiss Army knife" ultrasound, as described by its inventor, cardiologist and Sonivate Medical founder Ronald Schutz, MD. It was also just what the U.S. Army was looking for when it awarded a Phase I SBIR contract to Sonivate in 2009.

Schutz described the development of the SonicEye probe over the next few years: "We wanted it to feel like your finger. It should not be something that you notice. After a while it should seem as if the probe itself disappears while retaining a unique sense of touch to facilitate positioning, even in the dark. In order to do that, we had to rethink how things were being built."

That rethinking culminated in an innovative device with a dual array of ultrasound transducers in two frequencies—a miniature ultrasound instrument that, when a finger is inserted, leaves one hand completely free as well as fingers and the thumb of the other. The high-frequency linear array (located underneath the fingertip) can detect pneumothorax, (15 percent of conventional war injuries), and musculoskeletal issues and peripheral blood vessels; the low-frequency phased array (at the tip of the finger) does deep body scans to detect internal bleeding, foreign bodies, and assess deep organs.

The SonicEye probe was developed with the warfighter and medic in mind. However, with the coming commercialization of its product, Sonivate is anticipating a much broader market throughout the medical community.

Early on, Schutz partnered with Scott Corbett, an acoustic physicist. They determined the probe would contain only the essentials—an ultrasound array, lens, and the necessary electronic circuitry. This would assure the probe stayed small and simple. Using 128 tiny microcircuits embedded in plastic combined with flex circuitry, Corbett developed a novel method to connect the wires from the fingertip to the top of the finger.

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In a Phase I SBIR, the company addressed the ergonomic problems of vascular access with traditional handheld probes. In addition to freeing up a hand for the procedure, SonicEye enabled a more natural method for guided needle access augmented by tactile feedback. This was the first innovation in image acquisition that leveraged an operator's innate capabilities for sense of touch and fine motor control unique to the fingertip, Schutz said. In Phase II the company conducted clinical trials and testing, refined the design, and began commercialization.

The company received FDA clearance for the original single linear array SonicEye probe in 2012. They initially partnered with a company to manufacture the complete system, but complications arose. Sonivate then had a probe but no complete system.

Advancements made through the SBIRs helped Sonivate secure a substantial contract with the Joint Warfighter Medical Research Program. The company eventually developed today's complete SonicEye Dual-Array Ultrasound System. The system consists of the SonicEye probe electronically connected to an image processor, then to a computer tablet or cell phone. A software user interface guides the medic, emergency worker, or other medical staff to conduct an eFAST (Focused Abdominal Sonography for Trauma

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and pneumothorax) exam.

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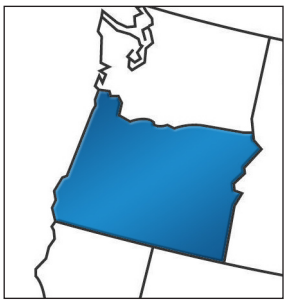
Hatlan credits the Madigan Army Medical Center (MAMC) at Joint Base Lewis McCord with ensuring Sonivate had military input and support while developing the system. "In less than a day's time we wanted to be able to train a medic to conduct the eFAST exam in about five minutes," he said.

Originally, the joint warfighter contract called for a wireless connection from the image processor to the cell phone. Sonivate found that ultra-wide band technology would have to be used so wireless signals could not be detected by others. However, ultra-wide band proved too slow, creating a lag from positioning of the probe to seeing the image. This, combined with research conducted at MAMC, resulted in a repositioning of the image processor to underneath the medic's phone and connected by USB cable.

Sonivate designed the current battery-powered system, where the compact, light-weight image processor can be easily clipped onto body armor in the field, or positioned on a nearby stand in a battalion aide station. "With Sonivate's user interface you rapidly see, record, save, and move on to the next view," Hatlan said. "You do ultrasound with one hand, and touch the screen or perform other tasks with the other."



Hatlan sees a vast potential market for an intuitively designed, easy to use, low-cost ultrasound system. "This is designed especially for the novice or the infrequent user," he said. "Whether it's a medic, a battalion aide station, an EMT, or an emerging clinic where doctors don't have a fulltime sonographer or don't regularly do ultrasound themselves. There are 15 million doctors worldwide, according to the World Health Organization, and most of them don't have ultrasound capability."

Hatlan and Schutz are a long way from Corbett's garage, where, in the early days, Schutz said, the inventors "cut off a perfectly good probe from the cable of an old ultrasound machine" and then connected and tested Schutz's theory for a miniature fingertip probe. "It looked like an electric chair for your finger," Schutz remembered. "All these wires were coming out it. But we spliced it on, wire by wire by wire, hooked it up to an old Hewlett Packard ultrasound machine, turned it on, and held our breaths. It was the craziest looking thing, but it worked!"

Like many innovations, today's elegant, intuitive probe had a humble beginning.

Sonivate Medical
Modernization Priority: General Warfighting Requirements (GWR)
Beaverton, OR • SBIR contract: W81XWH-10-C-0021 • Agency: Army • Topic: A09-102, Application of Finger-Mounted Ultrasound Array Probes