

## **SuperSonic Imagine Receives FDA Approval for Aixplorer Ultrasound System**

Innovative ShearWave Elastography and Impeccable Image Quality Bring New Levels of Diagnostic Capabilities to US Healthcare Market

AIX-EN-PROVENCE, France, Aug. 25 /PRNewswire/ -- SuperSonic Imagine today announced that it has received 510K Clearance from the FDA for its Aixplorer™ ultrasound system and will begin to market and deliver the device in the United States. Aixplorer is the only commercially available system of its kind with MultiWave™ Technology, which is based upon interaction between conventional longitudinal waves and shear waves in tissue. The system consists of an all software-based architecture which provides both impeccable B-mode images and, for the first time, displays tissue stiffness or elasticity information using shear waves. As stiffness is an additional parameter which characterizes tissue, Aixplorer brings clinicians significantly enhanced diagnostic information.

Aixplorer's SonicSoftware™, the power behind MultiWave Technology, has ingeniously benefited from a combination of the most advanced technology in the graphic games industry and the latest generation of multi-core processors to provide a complete ultrasound system with enhanced speed, accuracy and flexibility. The effect of this innovation is superior B-mode image clarity and an open door to new imaging modalities.

Speed, accuracy and flexibility play a large role in what many regard as Aixplorer's outstanding B-mode image quality. It brings fundamental improvements to traditional imaging by software that improves conspicuity, lateral and contrast resolution and delineation of structures to better characterize tissue. MultiWave imaging also supports TissueTuner, a unique tool that allows the user to adjust the system's parameters to accurately match the speed of sound in the tissue being imaged.

"Since we introduced Aixplorer there has been a great deal of anticipation for its FDA approval," said Jacques Souquet, PhD, President of the Aix-en-Provence, France based company. "Leading clinical investigators in the United States and globally report that the system provides exceptional clinical efficacy in better characterization of lesions. Based on their findings many regard Aixplorer's B-mode capabilities and ShearWave™ Elastography as the next level and future of ultrasound," he asserted.

Dr. David Cosgrove, Emeritus Professor of Clinical Ultrasound at Imperial College London and one of several clinical investigators across fifteen global sites using prospective formal protocols stated, "The B-mode quality on Aixplorer is superlative. We have had the opportunity to compare it with several reference systems for breast imaging. Time-and-again the Aixplorer images were more revealing, with cleaner, lower noise images and crisper margins to normal structures and lesions."

New imaging modalities have surfaced as Aixplorer presents its patented ShearWave Elastography. While shear waves naturally exist in the human body, SuperSonic Imagine's development of new MultiWave ultrasound technology produces images which leverage the interaction between longitudinal waves or B-Mode with shear waves. Aixplorer is the only system available which can generate, capture and compute shear wave velocity resulting in the bi-dimensional display of true tissue elasticity.

ShearWave Elastography is different from conventional or strain elastography which relies on manual compression for palpation and is therefore subjective and operator dependent. Instead, ShearWave Elastography is user-skill independent as it does not rely on compression but is based on the simultaneous use of both ultrasound waves and shear waves to assess tissue stiffness. ShearWave Elastography uses remote palpation to provide an objective assessment of tissue stiffness in real time using color-coded mapping. In addition, results are reproducible and lesions can be monitored over time.

Providing local tissue elasticity information in real time called for major technological breakthroughs in the ultrasound medical imaging field. Capturing shear waves in tissue requires acquisition rates of at least 5,000 Hz while conventional ultrasound acquisition speeds are approximately 100 Hz. With UltraFast™ Imaging,

Aixplorer can acquire data at speeds of up to 20,000 Hz which is 200 times faster than conventional ultrasound.

The significance of this technology was emphasized by Ellen Mendelson, MD, Professor of Radiology at the Feinberg School of Medicine, Northwestern University, who suggested that, "We expect Supersonic Imagine's ShearWave Elastography, which does not require manual compression, to augment the specificity of breast ultrasound examinations. This novel technology enables measurements of tissue stiffness to be obtained in seconds, easily and reproducibly using the same transducer to depict the B-mode BI-RADS® features of benign and malignant breast masses."

Aixplorer offers clinical performance and patient management advantages including:

- Improved lesion characterization through clarity, improved conspicuity, and better delineation of normal and abnormal structures
- Sharper borders and superior lateral and contrast resolution in different tissue densities from fatty to dense
- Simultaneous impeccable resolution while in B-mode, Color and Power Doppler
- Imaging in ShearWave Elastography displaying local tissue elasticity in real time
- Reproducible results that can be tracked over time
- User skill independence
- Time-saving easy upgrades of software
- Easy reporting with software-integrated BI-RADS
- Intuitive ergonomic design for comfort and ease of use

The market potential for Aixplorer in the United States and globally is significant according to Edward McClenny, Supersonic Imagine's General Manager for the Americas. "We've talked to hundreds of doctors and sonographers in many countries over the past months. I can't say how many times I've heard them comment that this is the best image quality they've ever seen. It is the combination of the spectacular image quality and the potential for ShearWave Elastography that is driving the excitement about this product."

The company received its CE mark in early 2009 and has been put to work in clinics throughout Europe and selected countries of Asia.

### **About SuperSonic Imagine**

SuperSonic Imagine, based in Aix-en-Provence, France, is a young, innovative, multicultural company with a commitment to providing advanced technology to improve medical diagnosis. Founded in 2005 by world-renowned ultrasound and medical imaging research scientists, SuperSonic Imagine has developed Aixplorer™, a complete ultrasound system with a revolutionary imaging technology. With offices in 4 continents, the company holds twenty-three international patents and submissions that are solely owned and solely used by SuperSonic Imagine. [www.supersonicimagine.com](http://www.supersonicimagine.com)

### **About Aixplorer®**

Aixplorer® is a next-generation ultrasound imaging system with unique technology that offers advantages in lesion detection and characterization. Using a method of imaging called ShearWave™ Elastography, Aixplorer can assess true tissue elasticity in real time providing user-skill independence and reproducible results. The Aixplorer ultrasound system also provides impeccable images and sophisticated features all packaged in an ergonomic design, to assist in the imaging diagnostic process. Aixplorer was named after its birthplace, Aix-en-Provence, in France.



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