

Acutus Medical's New Contact Mapping Software Receives CE Mark

FDA Clears Robust Second Generation AcQMap Platform

CARLSBAD, Calif. and MANNHEIM, Germany, April 26, 2019 – [Acutus Medical](#) today announced CE mark approval for AcQMap contact mapping software, offering expanded functionality that provides physicians with more options to inform individualized patient therapy. The company also announced FDA clearance of its second generation AcQMap platform. All AcQMap systems retain the unique ability to quickly reconstruct atrial anatomy using ultrasound and map electrical patterns using non-contact, charge density technology, creating ultra-high-resolution 3D images in real time.

"The contact mapping speed with the new Acutus system was extremely fast, which made it very easy to use," said Dr. Christian Meyer, University Medical Center Hamburg-Eppendorf, Hamburg, Germany. "Clinically, having this capability available on one system that also does non-contact mapping allows me to do exactly what makes sense case-by-case. For routine cases, my treatment strategy can be confirmed using conventional mapping catheters. In more complex cases, such as atrial fibrillation, I can gather more comprehensive data about each patient's anatomy and arrhythmia in real time with the non-contact charge density catheter, making AcQMap the complete atrial mapping solution."

Cardiac ablation treatment can improve quality of life for patients with atrial arrhythmias such as atrial fibrillation (AF). AF affects more than 33 million people globally and increases the risk of stroke and heart failure.^{1,2} AcQMap enables physicians to uncover the electrical activation pattern of the heart with real-time visualization during electrophysiology procedures. With non-contact mapping, physicians see full-chamber, continuous beat-by-beat arrhythmia conduction and can locate arrhythmias outside the pulmonary veins to inform their treatment strategy, enabling an iterative map-ablate-remap approach.

"With the introduction of contact mapping software in Europe, AcQMap is unquestionably the most agile and comprehensive cardiac imaging and mapping system available, offering full spectrum arrhythmia visualization in under three minutes. No other technology offers the suite of solutions incorporated into AcQMap," said Acutus Medical CEO Vince Burgess. "Our second generation system is engineered to be the cornerstone platform for electrophysiology labs for many years to come. We worked alongside physician partners to understand complex challenges and simple needs to improve the efficiency and safety of electrophysiology procedures. This next-gen AcQMap system has the capability to exponentially improve the day-to-day clinical utility of cardiac mapping and deliver long-term value by offering health systems a comprehensive solution for electrophysiologists and their patients."

Acutus Medical's contact mapping software is compatible with both first and second generation AcQMap platforms and will be installed on all European systems in Q3. The second generation AcQMap system is built to support future software innovations and will be available in the U.S. in Q3.

About Acutus Medical

[Acutus Medical](#) is a dynamic arrhythmia care company focused on developing distinct, innovative technologies that provide physicians and patients with improved results. At

Press Release



Acutus, we know that seeing is better than believing. Diagnosing and treating patients with atrial arrhythmias requires eliminating the unknown. Acutus' advanced cardiac imaging and mapping system provides real-time arrhythmia visualization displaying the heart's true activation pattern, turning the chaos of an atrial arrhythmia into a clear vision for electrophysiologists. Founded in 2011, Acutus is based in Carlsbad, California.

References

¹ Staerk L, Sherer JA, Ko D, et al. Atrial Fibrillation. *Circ Res* 2017;120:1501-17. DOI: [10.1161/CIRCRESAHA.117.309732](https://doi.org/10.1161/CIRCRESAHA.117.309732).

² Chugh, S.S., Havmoeller, R., Narayanan, K. et al. Worldwide epidemiology of atrial fibrillation: a Global Burden of Disease 2010 Study. *Circ* Feb 25. 2014; 129: 837-847. DOI: [10.1161/CIRCULATIONAHA.113.005119](https://doi.org/10.1161/CIRCULATIONAHA.113.005119).

Indications for Use

In the U.S., the AcQMap System is intended for use in patients for whom electrophysiology procedures have been prescribed. When used with the AcQMap Catheters, the AcQMap System is intended to be used to reconstruct the selected chamber from ultrasound data for purposes of visualizing the chamber anatomy and displaying electrical impulses as either dipole density-based or voltage-based maps of complex arrhythmias that may be difficult to identify using conventional mapping systems alone. And, when used with the specified Patient Electrodes, the AcQMap System is intended to display the position of AcQMap Catheters and conventional electrophysiology (EP) catheters in the heart.

In the EU, the AcQMap System is intended for use in patients for whom electrophysiology procedures have been prescribed. When used with the AcQMap Catheters, the AcQMap System is intended to be used in the right and/or left atria to visualize the selected chamber and display atrial electrical impulses. And, when used with patient electrodes, the AcQMap System is intended to display the position of AcQMap Catheters and conventional electrophysiology (EP) catheters in the heart. Or, when used with conventional electrophysiology catheters, the AcQMap System provides information about electrical activity of the heart and about catheter location during the procedure.

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