

Acutus Medical Secures FDA Clearance, CE Mark for SuperMap™ and Announces First Procedures in U.S. and Initial Experience in EU

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Breakthrough Technology Enables Super-Fast Electrical Mapping and Re-Mapping of the Entire Heart Chamber – Leading to Rapid, Efficient and Individualized Ablation Strategies

Carlsbad, Calif., February 18, 2020 – Acutus Medical today announced FDA clearance and CE Mark of SuperMap – a revolutionary addition to its AcQMap 3D Imaging and Mapping System. SuperMap is a high-fidelity, high-resolution mapping algorithm for both stable and transient arrhythmias. SuperMap's user interface effortlessly guides electrophysiologists to quickly create exquisitely detailed whole-chamber maps of the left or right atrium using its unique non-contact roving "hover-map" approach. This allows electrophysiologists to diagnose and treat arrhythmia patients rapidly, consistently and potentially more effectively. Adding the SuperMap mode to the AcQMap system enables users to visualize any atrial rhythm in under three minutes. Rapidly mapping and re-mapping the whole heart chamber facilitates a new procedural workflow in EP ablation -- by making it practical to execute an iterative "map, ablate, re-map" approach to diagnosis and therapy.

With this groundbreaking addition, Acutus Medical delivers the only EP imaging and mapping system to offer three mapping modalities: contact mapping, non-contact mapping and non-contact hover mapping -- known as SuperMap.

Initial Experience EU*

"In less than three minutes, the AcQMap System can map the entire chamber to clearly identify re-entrant circuits, regions of slow conduction and focal origins. The Automatic Beat Grouping algorithm of SuperMap is helpful to map alternating or changing atrial tachycardias by categorizing and displaying multiple tachycardias occurring at the same time," said Dr. Tom Wong, Electrophysiologist, Royal Brompton & Harefield NHS Foundation Trust, London, England.

"Dynamic atrial substrate characterization is an emerging diagnostic strategy involving mapping of sinus and paced rhythms to identify clinically relevant areas of slow conduction, lines of block and critical zones of irregular activity. These areas may correlate with arrhythmia initiation or maintenance. SuperMap is the ideal tool for implementing this strategy. Within seconds, I can review the maps and identify zones of slow conduction," said Dr. Gian-Battista Chierchia, Electrophysiologist, Vrije Universiteit Brussel, Brussels, Belgium.

First Cases US

"It is critical to map repetitive rhythms in patients with irregular heartbeats. This approach is extremely helpful in identifying areas of low amplitude which may indicate scar. I am looking forward to integrating new technology into my workflow for the treatment of any arrhythmia," stated Gregory Feld, MD, Professor of Medicine at UC San Diego School of Medicine and director of the Cardiac Electrophysiology Program at UC San Diego Health.

"We recently completed an extraordinary case with the Acutus system and SuperMap. We captured three whole-chamber maps, targeted three ablation sites, and the patient left in sinus rhythm -- all in the span of one hour," said Arjun Gururaj, MD, Electrophysiologist, Nevada Heart & Vascular Center in Las Vegas, Nevada. "These are notoriously complex atrial tachycardias that the EP community knows about. SuperMap can show potential sources and likely mechanisms in those complex cases in minutes as opposed to hours with conventional systems -- because we are seeing things that we couldn't see before. Now we may be able to do something about it in far less time with better acute results. It has amazing potential."

Vince Burgess, President & CEO of Acutus Medical commented, "We have invested heavily in developing a unique, multifunctional mapping system that provides physicians with the visual information needed to effectively diagnose and treat patients. With three distinct and unique mapping modalities in one system, physicians can feel confident in tackling any atrial arrhythmia accurately and efficiently. We are committed to improving patient outcomes, expediting procedures times and further developing our full suite of products for the global electrophysiology community."

*The AcQMap System with SuperMap was CE Marked in October of 2019.

About Acutus Medical

Acutus Medical is an arrhythmia care company focused on developing a full suite of innovative technologies and products for the global electrophysiology community. We are committed to providing physicians and patients with tools that improve procedural efficiency and facilitate excellent outcomes. Acutus' lead product, the AcQMap, is an advanced cardiac imaging and mapping system that provides real-time arrhythmia visualization displaying the heart's true activation pattern, turning the chaos of a complex arrhythmia into a clear vision for electrophysiologists. At Acutus, we know that seeing is better than believing – and that diagnosing and treating patients with atrial arrhythmias requires eliminating the unknown. Founded in 2011, Acutus is based in Carlsbad, California.

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