



## **Acutus Medical® Receives FDA Clearance for Advanced Cardiac Mapping Technology for Complex Arrhythmias**

October 24, 2017

*FDA clearance of the AcQMap® High Resolution Imaging and Mapping System and AcQMap® 3D Imaging and Mapping Catheter is a major milestone for Acutus Medical*

*Clearance allows the AcQMap System to be used with commercially available cardiac ablation platforms*

**CARLSBAD, CA — October 24, 2017**– Acutus Medical® today announced that the U.S. Food and Drug Administration has cleared the AcQMap® High Resolution Imaging and Mapping System and the AcQMap® 3D Imaging and Mapping Catheter for use in patients for whom electrophysiology procedures have been prescribed. The Company plans to introduce initial commercial systems to U.S. customers in early 2018.

"This clearance will allow electrophysiologists (EP's) in the United States access to a new technology that uses ultrasound to visualize cardiac anatomy and dipole density to map the pathway of every heartbeat. The System can also be used with existing commercially available cardiac ablation platforms," said Steven McQuillan, Senior Vice President, Regulatory and Clinical Affairs, for Acutus Medical. "The AcQMap System was designed in close collaboration with some of the most respected names in the field to provide practitioners with a suite of tools that enables them to rapidly map and re-map to visualize changes throughout the ablation procedure. We firmly believe that by working together with EP practitioners and scientists, we will continue to uncover breakthrough innovations to improve and advance cardiac care."

### **European Experience**

The AcQMap System has been used in Europe over the past two years in a number of clinical trials and commercial settings. Clinical safety results from the DDRAMATIC-SVT trial were used to support the company's 510(k) clearance.

"We are extremely excited to have participated in the early clinical work and are now using the technology as part of a patient-specific strategy to assess and treat complex arrhythmias," said Dr. Tom Wong, from the Royal Brompton Hospital in London, England. "The AcQMap System is able to provide global dipole density mapping of irregular and chaotic activation in the atrial chambers, whereas conventional sequential mapping may struggle to provide us with the information that is required. In the cases we have performed thus far, real-time mapping of complex arrhythmias has allowed us to focus on areas of interest and terminate the arrhythmia using ablation therapy. We can now offer individualized, tailored therapy, and are one step closer to identifying the mechanisms of complex arrhythmias."

### **About the AcQMap High Resolution Imaging and Mapping System**

The AcQMap High Resolution Imaging and Mapping System detects and displays both standard voltage-based and higher resolution dipole density (charge-source) maps. The AcQMap System uniquely combines ultrasound anatomy construction with an ability to map the electrical-conduction of each heartbeat to identify complex arrhythmias across the entire atrial chamber. Following each ablation treatment, the heart can be re-mapped in seconds to continually visualize any changes from the prior mapping.

"Our company is dedicated to developing advanced intracardiac mapping tools that we hope will enable more precise diagnoses and less invasive and more targeted therapies, particularly in patients suffering from complex arrhythmias. The AcQMap System clearance represents a major step not seen since the inception of 3D mapping systems 20 years ago," said Graydon Beatty PhD, Chief Technology Officer, for Acutus Medical. "Despite decades of procedural and technical advancement in the electrophysiology field, only about 50% of patients with persistent complex atrial arrhythmias treated with ablation therapy can expect to remain arrhythmia free at 12 months. At Acutus, we think better mapping and the ability to re-map during the initial therapeutic procedure has the potential to lead to better outcomes and quality of life."

### **About Acutus Medical**

Acutus Medical is a global heart rhythm technology company transforming the way electrophysiologists diagnose and treat cardiac arrhythmias. Acutus Medical is a privately held company located in Carlsbad, CA. To learn more, visit <https://www.acutusmedical.com>.

### **Forward Looking Statements**

This press release contains forward-looking statements that are subject to many risks and uncertainties. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned product development, and clinical and regulatory milestones. We may use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained herein, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this press release. As a result of these factors, we cannot assure you that the forward-looking statements in this press release will prove to be accurate. Acutus Medical expressly disclaims any intent or obligation to update these forward-looking statements, except as required by law.

### **Media Contact**

Amy Covino  
201-774-3111  
[Amy.covino@tmstrat.com](mailto:Amy.covino@tmstrat.com)