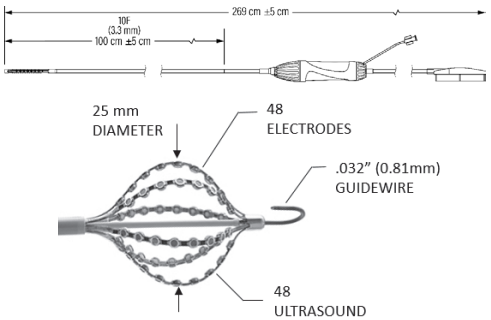
ACUTUS®
MEDICAL

900003 AcQMap®
3D Imaging and Mapping Catheter



Instructions for Use

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

System Description
The AcQMap 3D Imaging and Mapping Catheter only works in conjunction with the AcQMap High Resolution Imaging and Mapping System Model 900000.

The AcQMap System is an advanced imaging, navigation and mapping system capable of displaying:

- 3-D cardiac chamber reconstructions
- Cardiac electrical activity as waveform traces
- Dynamic, three-dimensional, Dipole Density Maps overlaid on the cardiac chamber reconstruction to show chamber-wide electrical activation.
- Remapping of the chamber at any time during the procedure
- Three-dimensional position of the AcQMap 3D Imaging and Mapping Catheter(s) and conventional electrophysiology catheters

Note: Use of the AcQMap High Resolution Imaging and Mapping System is described in the AcQMap System Operator Manual.

AcQMap Catheter Description
The AcQMap 3D Imaging and Mapping Catheter (AcQMap Catheter) has six (6) parylene coated Nitinol bracelets at the distal end that support an arrangement of 48 electrodes and 48 ultrasound transducers. The AcQMap Catheter is placed within the desired chamber and the distal end is deployed. There is no requirement for the electrodes or transducers to be in contact with the heart wall. The AcQMap Catheter is capable of endovascular delivery and contains a flexible distal segment that allows it to be directed via a sheath to various locations of interest within the heart's chamber(s).

The AcQMap Catheter is a diagnostic, single-use device that has a polymeric torque shaft and an integral handle. The AcQMap Catheter is capable of percutaneous, endovascular delivery over a super/extra stiff 0.032" (0.81 mm) J-tip guidewire. Use only the12 F AcQGuide Steerable Sheath with the AcQMap Catheter. The Device is provided sterile and non-pyrogenic. For dimensional information, refer to the product label.

Intended Use
The AcQMap 3D Imaging and Mapping Catheter is intended to be used in the right and left atrial chambers to collect ultrasound data for visualizing the selected chamber and recording electrical impulses in patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone.

Contraindications
Use of the AcQMap Catheter is contraindicated in patients with:

- implanted prosthetic, artificial, or repaired cardiac valves in the chamber being mapped and/or interatria baffle or patch for transseptal approach
- permanent pacemaker or ICD leads in the chamber being mapped.
- Hypercoagulopathy, visual presence of thrombus, or an inability to tolerate anticoagulation therapy during an electrophysiology procedure.
- a contraindication to an invasive electrophysiology procedure.
- active systemic infection.
- any other condition where catheter manipulation may not be safe.
- inferior vena cava embolic protection filter devices who require catheter insertion from the femoral approach.

Because the long-term effects of exposure to ionizing radation are unknown, careful consideration should therefore be given to pregnant women and pre-pubescent children.

Warnings and Precautions

Air entrapment - It is recommended that the distal end be captured and inserted into the sheath while it is submerged in order to help reduce the possibility of air becoming entrapped around the distal end during capture and catheter insertion.

Advancement / Withdrawal within the Vasculature - Do not advance or withdraw the AcQMap Catheter within the vasculature unless the distal end is completely contained within a sheath, guiding catheter, or introducer, as it may result in damage to cardiac and vascular structures.

Anticoagulation - Before insertion of the AcQMap Catheter, administer appropriate anticoagulation therapy to attain an activated clotting time (ACT) of >300 seconds for right atrial procedures and >350 seconds for left atrial procedures. To minimize the risk of thromboembolic events, ACT monitoring should be performed during the procedure to maintain an ACT at or above the target clotting time.

Capture Device - To avoid damage to the catheter, ensure the capture device is used to aid in the insertion and withdrawal of the catheter.

Cardioversion - To prevent system damage or patient injury,disconnect (1) all cables including the AcQMap Catheter from the front panel of the AcQMap Console and (2) the positive leads of the Localization Reference Electrodes from the Patient Interface Unit, prior to performing electrical cardioversion.

Catheter Entanglement/Entrapment - Do not allow the AcQMap Catheter to enter the ventricles as this may lead to catheter entanglement or entrapment. Ensure that the distal end of the deployed AcQMap Catheter remains in the atria at all times.

Catheter Placement - When in the proximity of the tricuspid valve, mitral valve, or other catheters, take care to reduce risk of catheter entrapment.

Catheter Withdrawal - To prevent damage to the AcQMap Catheter, always collapse the distal end of the catheter prior to withdrawing the catheter back into the sheath.

Connector - Keep the connector dry; wet connector pins may affect performance. Do not allow the connector end to be immersed in fluid.

Defibrillation - To prevent system damage or patient injury or death, prior to or immediately following the first defibrillation attempt, disconnect (1) all cables from the front panel of the AcQMap Console and (2) the positive leads of the Localization Reference Electrodes from the Patient Interface Unit.

Disposal - Dispose per local biohazard standards.

Electrical Isolation during Procedure - To prevent patient injury or death, use only IEC 60601-1 Type CF certified equipment, or equivalent. Do not touch non-medical equipment and the patient at the same time.

Fluoroscopy or System Guidance - The AcQMap Catheter should only be manipulated under fluoroscopic or AcQMap System observation. Manipulating the catheter without fluoroscopy or AcQMap System observation may result in damage to cardiac and vascular structures.

Guidewire Usage - Do not use the AcQMap Catheter without a super/extra stiff 0.032" J-tip guidewire in place, as it may result in damage to the catheter and/or guidewire lumen requiring catheter replacement or difficulty in manipulating the catheter.

Guiding Sheath Usage - Under fluoroscopy, ensure that the guiding introducer sheath's distal end is straight or, if necessary, only minimally curved prior to advancing or retracting the catheter through the sheath. To prevent damage to the catheter and guiding sheath, do not deploy the distal end of the catheter while it is inside the sheath.

Use only the 12 F AcQGuide™ Steerable Sheath with the AcQMap Catheter. Compatibility with other sheaths has not been established.

Handling - The AcQMap Catheter should be handled with care. Prior to use and during the procedure, inspect the packaging and AcQMap Catheter for bends, kinks, or other damage. Discontinue use if the AcQMap Catheter or its packaging is damaged.

Inspection - Do not use the AcQMap Catheter if the package is open and/or the sterile barrier is broken.

Magnetic Resonance Imaging - The AcQMap Catheter is not compatible with MRI.

Organic Solvents - Do not expose to organic solvents.

Qualified Users - Only physicians thoroughly trained in electrophysiology procedures should use the AcQMap Catheter.

Resistance - Do not advance or rotate the AcQMap Catheter if significant resistance is encountered as it may result in damage to cardiac and vascular structures.If significant resistance is felt, stop and evaluate device location under fluoroscopy.

Single Use - The AcQMap Catheter is intended for single-procedure use only. Do not attempt to reuse or re-sterilize as this may increase the risk of compromised device performance, cross-contamination or patient injury.

Storage - The AcQMap Catheter should be stored in a cool and dry place.

Turning the Control Knob - Do not turn the control knob of the AcQMap Catheter without the floppy end of a super/extra stiff 0.032" J-tip guidewire extended beyond the distal tip, as it may result in damage to the catheter and/or guidewire lumen requiring catheter replacement or difficulty in manipulating the catheter.

Use By Date - Use prior to the "Use-by date".

X-ray and Fluoroscopic Exposure - Minimize x-ray and fluoroscopic exposure. Due to the intensity of the x-ray beam and the duration of the fluoroscopic imaging during catheter procedures, patients and laboratory staff may be subjected to acute radiation injury and increased risk for somatic and genetic effects. Take all appropriate measures to minimize x-ray exposure to both patients and clinical staff. The long-term effects of protracted fluoroscopy have not been established.

Potential Adverse Effects
Potential adverse effects include, but are not limited to, the following:

- Adult Respiratory Distress Syndrome (ARDS)
- Air embolism
- Allergic reaction
- Anemia
- Anesthesia reaction
- Arrhythmias
- AV fistula
- Cardiac perforation/tamponade
- Cardiac thromboembolism
- Catheter entrapment/entanglement
- Cerebrovascular accident
- Chest pain/discomfort
- Congestive heart failure
- Coronary artery spasm
- Death
- Endocarditis
- Exacerbation of pre-existing atrial fibrillation
- Expressive aphasia
- Heart Failure
- Hemothorax
- Hypotension
- Increased phosphokinase level
- Infections
- Laceration
- Leakage of air or blood into the lungs or other organs due to perforation
- Local hematomas/ecchymosis
- Myocardial infarction
- Obstruction or perforation or damage to vascular system
- Pericardial effusion
- Pericarditis
- Phrenic nerve damage
- Pleural effusion
- Pneumonia
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary embolism
- Radiation injury
- Respiratory depression
- Seizure
- Skin burns
- Temporary complete heart block
- Thrombi
- Thromboembolism
- Transient ischemic attack
- Unintended (in)complete sinus node, AV node, or other heart block or damage
- Valvular damage/insufficiency
- Vascular bleeding
- Vasovagal reactions
- Ventricular tachycardia
- Worsening Chronic Obstructive Pulmonary Disease (COPD)

Accessories
The following supplies are not provided with the devices and need to be available and prepped per laboratory standard operating procedures prior to use of the AcQMap 3D Imaging and Mapping Catheter:

- The AcQMap High Resolution Imaging and Mapping System and accessories
- AcQGuide 12F Steerable Sheath
- Introducer Sheaths
- Guiding sheath
- Angiographic imaging supplies (i.e. radiopaque contrast, manifold, tubing, etc.)
- Heparinized normal saline
- Guidewire for sheath insertion (Maximum Diameter: 0.035" [0.89 mm])
- Super/extra stiff J-tip guidewire for AcQMap insertion (Maximum Diameter: 0.032" [0.81 mm])
- Three-way Stopcock
- Syringe
- Other supplies and catheters as needed to complete the established laboratory practice

Product Preparation
Warning: Do not use the AcQMap Catheter without a super/extra stiff 0.032" J-tip guidewire in place.
Warning: Use prior to the "Use-by date".

Warning: Do not use the AcQMap Catheter if the package is open or visibly damaged and/or the sterile barrier is broken.

1. Remove the AcQMap Catheter from the sterile packaging.
2. Ensure heparinized saline has been applied to all device surfaces.
3. Flush the guidewire lumen with heparinized saline.
4. Load the super/extra stiff 0.032" J-tip guidewire, leaving the J-tip extended beyond the distal end of the AcQMap Catheter.
5. With the distal end fully collapsed, submerge the distal end in a heparinized saline bath and advance the capture device so that it completely covers the catheter's distal end.

Product Operation

Warning: Do not advance or withdraw the AcQMap Catheter within the vasculature unless the distal end is completely contained within a sheath, guiding catheter, or introducer, as it may result in damage to cardiac and vascular structures.

Right Atrial Access

1. Using institutional standard practice (e.g. Seldinger technique), obtain femoral venous access.
2. Advance a guidewire into the superior vena cava (SVC) approximately 5 cm past the right atrium.
3. Over the guidewire, advance a 12 F sheath to the SVC-right atrial junction per manufacturer's instructions.

Left Atrial Access

1. Using institutional standard practice (e.g. Seldinger technique), obtain femoral venous access.
2. Using standard practice, obtain left atrial access via transseptal puncture.
3. Remove the transseptal sheath and dilator, leaving the guidewire in place.
4. Advance a 12 F sheath over the guidewire into the left atrium per manufacturer's instructions.

AcQMap Catheter Deployment

Warning: Do not advance or rotate the AcQMap Catheter if significant resistance is felt encountered as it may result in damage to cardiac and vascular structures. If significant resistance is felt, stop and evaluate device location under fluoroscopy.

Warning: Before insertion of the AcQMap Catheter, administer appropriate anticoagulation therapy to attain an activated clotting time (ACT) of >300 seconds for right atrial procedures and >350 seconds for left atrial procedures. To minimize the risk of thromboembolic events, ACT monitoring should be performed during the procedure to maintain an ACT at or above the target clotting time.

1. To ensure a constant flow through the sheath, connect a heparinized saline drip to the sideport of the sheath through the use of a pressure bag or an IV pump.
2. Remove any guidewire and/or dilator used during sheath placement.
3. Aspirate and flush the sheath with heparinized saline via a three-way stopcock connected to the side port.
4. Ensure that the distal end of the AcQMap Catheter is covered with the capture device leaving approximately 1 mm of the distal tip of the AcQMap Catheter protruding from the capture device.

Warning: It is recommended that the distal end be captured and inserted into the sheath while it is submerged in order to help reduce the possibility of air becoming entrapped around the distal end during capture and catheter insertion.

5. Retract the J-tip of the guidewire into the Catheter before advancing the captured distal end into the hemostasis valve of the sheath.
6. Holding the proximal portion of the capture device, advance the capture device through the hemostasis valve until resistance is met (~1/3 of the capture device will be within the handle of the sheath)
7. Advance the AcQMap Catheter through the capture device into the sheath.
8. Retract the capture device from the hemostasis valve to the proximal section of the shaft of the AcQMap Catheter.
9. Advance the distal end of the AcQMap Catheter to the distal end of the sheath.
10. Under fluoroscopic guidance, advance the J-tip guidewire into the SVC for right-sided procedures or the left superior pulmonary vein for left-sided procedures.
11. After positioning the J-tip guidewire, advance the AcQMap Catheter out of the sheath to the approximate center of the atrium.
12. Once the AcQMap Catheter is positioned retract the guidewire leaving the J-tip fully visible.
13. Turn the control knob to the left (counter-clockwise) to deploy the distal end.

System Data Collection

Note: Mapping and recording data do not require contact with the endocardial surface of the heart.

1. Attach the AcQMap Catheter to the AcQMap Console.
2. Follow the AcQMap System Operators Manual to set up the AcQMap System for recording data.
3. Using fluoroscopic guidance, direct the AcQMap Catheter to different areas of the atrium to gather ultrasound data points. Gradually advance, retract, and rotate the AcQMap Catheter (approximately ± 60 °) using the sheath as needed. Contact with the endocardial surface is not required to collect data points.
4. When the ultrasound data has been gathered, reposition the AcQMap Catheter in the approximate center of the chamber to record biopotentials.
5. If additional ultrasound data is needed, the AcQMap Catheter may be moved within the chamber until adequate data has been gathered.

AcQMap Catheter Withdrawal

Warning: To prevent damage to the AcQMap Catheter, always collapse the distal end of the catheter prior to withdrawing the catheter back into the sheath.

Warning: Do not advance or withdraw the AcQMap Catheter within the vasculature unless the distal end is completely contained within a sheath, guiding catheter, or introducer, as it may result in damage to cardiac and vascular structures.

1. Disconnect the AcQMap Catheter from the AcQMap Console.
2. Rotate the AcQMap Catheter handle to the right (clockwise) to collapse the distal end completely.
3. Straighten the distal end of the sheath (as much as possible) prior to withdrawing the catheter (confirm uner fluoroscopy as required)
4. To remove the AcQMap Catheter ***and*** guidewire, under fluoroscopic guidance, slowly withdraw the AcQMap Catheter together with the guidewire, until the distal end is completely within the distal end of the sheath.
5. Insert the capture device through the hemostasis valve of the sheath until resistance is met.
6. Continue to ***slowly*** withdraw the AcQMap Catheter and guidewire until they are both contained within the capture device.
7. Withdraw the capture device from the hemostasis valve until the capture device, AcQMap Catheter and quidewire are completely out of the sheath.
8. Aspirate and flush the sheath with heparinized saline through the three-way stopcock.

Acoustic Output

Acoustic Output Reporting Table
Non-Auto Scanning Mode - 10 MHz Operating Mode: M-Mode
Applications:

Transducer Model	$I_{SPTA.3\ (mW/cm^2)}$	TI Type	TI Value	MI	$I_{PPA.3}$ @MI $_{max\ (W/cm^2)}$
900003	0.08	$TIS_{non\text{-}scan}$	3.62E-05	5.61E-02	1.03

SYMBOLS DESCRIPTION	
$I_{SPTA.3}$	Derated Spatial-Peak Temporal-Average Intensity (milliwatts per square centimeter).
$I_{PPA.3}$ @MI $_{max}$	The derated pulse-average intensity at the point of global maximum reported MI (watts per square centimeter).
MI	Mechanical Index.
TISnon-scan	The Soft Tissue Thermal Index in an auto-scanning mode.

Clinical Summary

The DDRAMATIC SVT study is a prospective, non-randomized, open-label study conducted at eight clinical sites outside the US. The objective of the study included demonstration of safety of the AcQMap High Resolution Imaging and Mapping System (AcQMap System). A total of 84 subjects at 8 sites outside the United States were enrolled in the trial.

Safety

In this study, patients being treated for a variety of SVT types, were enrolled. Patients with more than one arrhythmia were included in the study. After acquiring the pre-procedure map, patients typically underwent either RF or cryoablation. Investigational sites were instructed to report all procedure-related events regardless of etiology. Events were adjudicated by the site-specific investigator and further analyzed by the Sponsor medical reviewer. Table 3 summarizes the Primary Safety Endpoint Results.

Table 3. Primary Safety Endpoint Results

Serious Adverse Event	% (n/84)
• Freedom from a device (AcQMap Catheter or Console/Workstation/AIU, PIU) related SAE @ 7-days post procedure	84/84 (100%)
• Freedom from a device (AcQMap Sheath) related SAE @ 7-days post procedure	83/84 (98.8%)
• Freedom from a procedure-related SAE @ 7-days post procedure	82/84 (97.6%)

Table 4 shows the Distribution of All Serious Adverse Events.

Table 4. Distribution of All Serious Adverse Events

Event Type	Relationship to Device	Relationship to Procedure	Number of Events	Number (Percent) of Subjects with Events
Access Site Injury – AcQMap Site	Yes –Sheath	Probably	1	1/84 (1.2%)
Brian Tumor / Death	No	No	1	1/84 (1.2%)
Chest Infection	No	Probably	1	1/84 (1.2%)
Chronic Heart Failure / Death	No	No	1	1/84 (1.2%)
Chronic Mitral Valve Disease	No	No	1	1/84 (1.2%)
Renal Insufficiency Secondary to Sepsis	No	No	1	1/84 (1.2%)
Sudden Cardiac Arrest / Death	No	No	1	1/84 (1.2%)
Thyroid Dysfunction	No	No	1	1/84 (1.2%)
TOTAL			**8**	7/84 (8.3%)
TOTAL (Excluding Sheath-related Events)			**7**	7/84 (8.3%)

At 7 days, 100% of the treated subjects were free from any device-related adverse event. When evaluating procedure-related safety events, two subjects (2/84) had a procedure related SAE (97.6% subjects were free from a procedure SAE), and 21 subjects (21/84) had a procedure related AE (75% of subjects were free from a procedure-related AE).

LIMITED WARRANTY AND DISCLAIMER

Acutus Medical, Inc. warrants that reasonable care has been used in the design and manufacture of its products. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, and cleaning of a device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Acutus Medical's control directly affect the device and the results obtained from its use. Acutus Medical's obligation under this warranty is limited solely to the replacement of a device and Acutus Medical shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of the device. Acutus Medical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with a device. Acutus Medical assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, express or implied, including but nor limited to merchantability or fitness for a particular purpose, with respect to such devices.

Explanation of Symbols

Consult Instructions for Use

Do not re-sterilize

Do not re-use

Sterilized using irradiation

Catalogue Number

Batch code

Quantity of devices

Use-by date (YYYY-MM-DD)

Do not use if package damaged

Keep dry

Keep away from sunlight

Manufacturer

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Non-pyrogenic

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