SSCP Report Revision History

Date	Revision	Affected Section	Description of Change	Validation by the Notified Body
22 September 2021	01	All	Initial Release	N/A
9 January 2023	A	All	Content and format updates made throughout, bringing in more current information.	15 November 2022

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1. Device Identification, Intended Use & Device Description

Product or Trade Name	AcQMap 3D Imaging and Mapping Catheter SentiCath 3D Imaging and Mapping Catheter Note: The Acutus AcQMap 3D Imaging and Mapping Catheter is available as Biotronik-branded devices under the brand name of SentiCath 3D Imaging and Mapping Catheter.
Legal Manufacturer	Acutus Medical, Inc. 2210 Faraday Ave, Suite 100 Carlsbad, CA 92008 USA
SRN	US-MF-000019413
Basic UDI-DI	0857042007ACQMAPCATHNW
CND Code(s)[1]	C020105: Three dimensional electrocatheters, non-agreed mapping (contact and non-contact)
Class	Class III
Classification Rule	MDD Annex IX Rule 7.2 MDR Annex VIII Rule 7.2
Year When First CE Certificate Issued	MDD 93/42/EEC: May 02, 2016 MDR 2017/745: Certificate is Pending

[1] Medical Device Nomenclature per article 26 of MDR

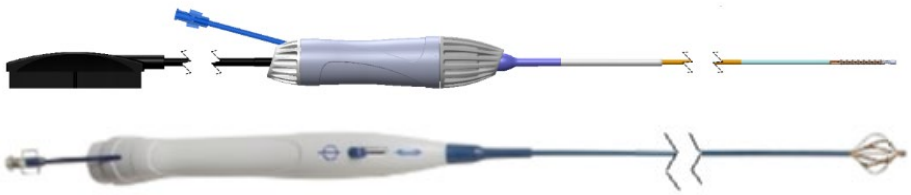
Authorized Representative	Medical Device Safety Service GmbH Schiffgraben 41 Hanover 30175 Germany SRN: DE-AR-000005430
Notified Body	DQS Medizinprodukte GmbH #0297
Intended Purpose[2]	The AcQMap 3D Imaging and Mapping Catheter is intended to be used to collect imaging and electrical mapping data from the right and left atria. The AcQMap Catheter is intended to be used in patients being treated for arrhythmias (abnormal heartbeats) in the right and left atria of the heart.
Indications[3]	The AcQMap 3D Imaging and Mapping Catheter is intended to be used to collect imaging and electrical mapping data from the right and left atria. The AcQMap Catheter is intended to be used in patients being treated for arrhythmias (abnormal heartbeats) in the right and left atria of the heart.
Intended Patient Population[4]	The AcQMap Catheter is intended to be used in patients with arrhythmias (abnormal heartbeats) in the atria of the heart. Supraventricular tachycardia (SVT) includes arrhythmias such as: atrial flutter, atrial fibrillation, AV nodal reentrant tachycardia (AVNRT), and atrial tachycardia.
Contraindications[5]	Use of the AcQMap Catheter is contraindicated in patients with: • implanted prosthetic, artificial, or repaired cardiac valves in the chamber being mapped and/or interatrial baffle or patch for transseptal approach • permanent pacemaker or ICD leads in the chamber being mapped. • hypercoagulopathy 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 which require catheter insertion from the femoral approach.

[2] Intended purpose means the use for which a device is intended according to the data supplied by the manufacturer on the label in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation (MDR, Article 2(12))

[3] This includes the stages and/or severities of the pathologies, the specific medical conditions, and the specific anatomical locations or confirmation that no anatomical locations are contraindicated, as applicable.

[4] The target population(s) shall be specified, for example if the device is intended for adults and/or children and/or infants/neonates

[5] Any contraindications or restrictions for use or limitations of the device shall be included

General Description of the Device[6]	AcQMap 3D Imaging and Mapping Catheter has: • High quality 3D ultrasound anatomy reconstruction with 48 dedicated piezoelectric sensors • Non-contact mapping with 48 dedicated engineered sensors • J-tip guidewire compatibility  Figure 1: AcQMap Catheter Model 900003 (top) and Model 900009/459229 (bottom)  Figure 2: AcQMap Catheter distal array The AcQMap Catheter is intended for use with the AcQMap System. The AcQMap System consists of the AcQMap Console and Workstation with associated accessories (Figure 1 and Figure 2) and the AcQMap Catheter (Figure 3 and 4). The AcQMap System collects data that enables the creation of 3D anatomical maps that display chamber-wide electrical activation. The AcQMap Catheter is the only invasive component of the AcQMap System.

[6] Refer to guidance in Section 3.1 of MDCG 2019-9

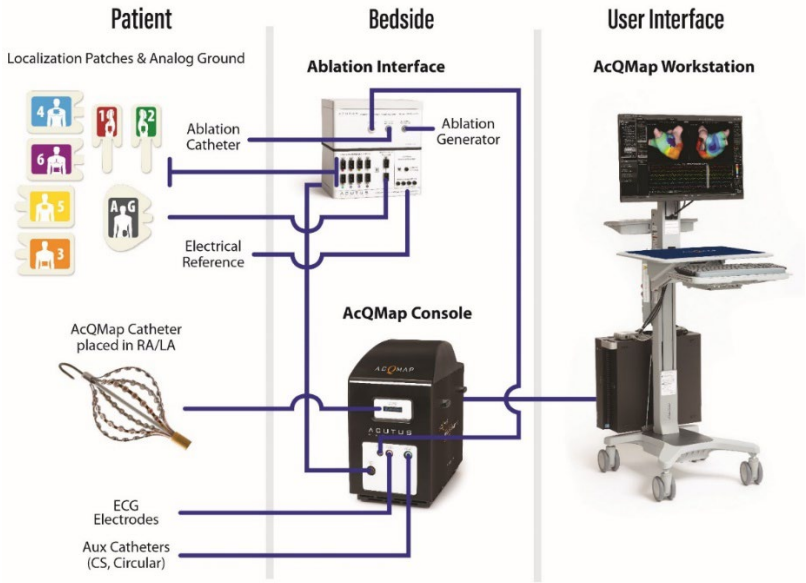


Figure 31: Assembled AcQMap System Model Number 900000

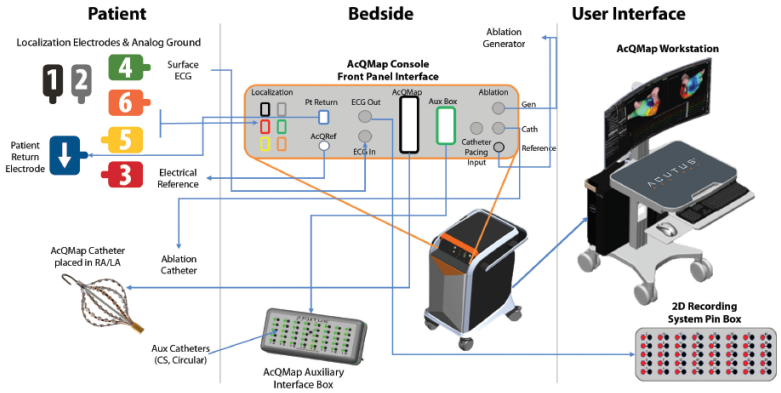


Figure 42: Assembled AcQMap System Model Number 900100

List and Description of Any Previous Generation(s) or Variants and a Description of the Differences	There are two generations of the AcQMap Catheter, models 900003 and 900009. The 900009 is different from the generation 1 catheter as follows: • Handle design and slider mechanism • Separate, reusable interface cable • Guidewire Compatibility changed to a 0.032” wire • Change of sterilization method from Radiation to EtO • Added an optional visual aid to an additional way to verify whether the basket is inside or outside the sheath • Updates made for ease of manufacturing and yield

<table>
<tr><td>List of Any Accessories Covered by this Plan</td><td>

The AcQMap Catheter model 900009 and SentiCath Catheter model 459229. have a separate, reusable cable (800530 or 459608) (Class Is)
<table>
<tr><th>Part Number</th><th>Title</th><th>Description of Purpose</th></tr>
<tr><td>459608</td><td>SentiCath Catheter Interface Cable</td><td>Enable communication between the AcQMap System and AcQMap Catheter model 900009 or SentiCath Catheter model 459229.</td></tr>
<tr><td>800530</td><td>AcQMap Catheter Interface Cable</td><td>Enable communication between the AcQMap System and AcQMap Catheter model 900009 or SentiCath Catheter model 459229.</td></tr>
</table>
</td></tr>
<tr><td>List of Any Other Devices and Products Intended to be Used in Combination with the Device</td><td>The AcQMap Catheter also requires the following components:
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: 0.035” [0.89 mm])
Three-way Stopcock
Syringe
Other supplies and catheters as needed to complete the established laboratory practice</td></tr>
</table>

2. Risks and Warnings

2.1. Residual Risks and Undesirable Effects

Below are the Potential adverse effects for cardiac catheterization procedures where the AcQMap System is utilized. All device-related events reported within the clinical literature are

identified as potential risks or adverse events and are stated within the associated IFUs and Operators Manuals. Effects include, but are not limited to, the following

The AcQMap Catheter in use with the AcQMap System has the potential for the following Adverse Events and Residual Risks:	
• Acute Respiratory Distress Syndrome	• Myocardial infarction
• Air embolism	• Obstruction or perforation or damage to vascular system
• Allergic Reaction/Anaphylaxis	• Pericardial effusion
• Anemia	• Pericarditis
• Anesthesia reaction	• Phrenic nerve damage
• Arrhythmias	• Pleural effusion
• AV fistula	• Pneumonia
• Cardiac perforation/tamponade	• Pneumothorax
• Cardiac thromboembolism	• Pseudoaneurysm
• Catheter entrapment/entanglement	• Pulmonary edema
• Cerebrovascular accident (Stroke), hemorrhagic or thrombotic	• Pulmonary embolism
• Chest pain/discomfort	• Radiation injury
• Congestive heart failure	• Respiratory depression
• Coronary artery spasm	• Seizure
• Death	• Skin burns
• Endocarditis	• Temporary/complete heart block
• Expressive aphasia	• Thrombi
• Exacerbation of pre-existing atrial fibrillation	• Thromboembolism
• Heart Failure	• Transient ischemic attack (TIA)
• Hemothorax	• Unintended (in)complete sinus node, AV node, or other heart block or damage
• Hypotension	• Valvular damage/insufficiency
• Infections	• Vascular bleeding
• Laceration	• Vasovagal reactions
• Leakage of air or blood into the lungs or other organs due to perforation	• Ventricular tachycardia

The AcQMap Catheter in use with the AcQMap System has the potential for the following Adverse Events and Residual Risks:	
• Local hematomas/ecchymosis	• Worsening chronic obstructive pulmonary disease (COPD)

2.2. Warnings and Precautions

Topic	Warning/Precaution
Advancing the Slider Mechanism	Do not advance the AcQMap Catheter without the floppy end of a super/extra stiff 0.035" (0.89 mm) 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.
Advancement / Withdrawal within the Vasculature	Do not advance or withdraw the AcQMap Catheter within the vasculature unless the distal array is completely contained within a sheath, guiding catheter, or introducer, as it may result in damage to cardiac and vascular structures.
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.
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 prevent damage to the distal end of the catheter, ensure the capture device is used to aid in the insertion and withdrawal of the catheter.
Cardioversion (model 900000)	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.
Cardioversion (model 9001000)	Overlap of cardioversion patches and Localization Reference Electrode patches may result in patient skin burns. All signal inputs or outputs must be connected to the defibrillation-protected connectors of approved medical equipment only.
Catheter Placement	When in the proximity of the tricuspid valve, mitral valve, or other catheters, take care to reduce risk of catheter entrapment.
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 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 (model 900000)	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.

Topic	Warning/Precaution
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 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. It is recommended to 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 becomes 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.
Patient	Not intended for children, nursing women, and pregnant women.
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 felt or 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 a 0.032" J-tip guidewire in place.
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.

For warnings and precautions solely related to, for example, installation/preparation of a device or relating to special procedural steps, please refer to the AcQMap Catheter Instructions for Use provided on the Acutus Medical website: https://www.acutusmedical.com/int/product-safety-information/

2.3. Other Relevant Aspects of Safety, Including a Summary of any Field Safety Corrective Action (FSCA including FSN) if applicable

The serious and non-serious adverse events were reviewed for the reporting period. Four (4) serious adverse events were reported for the AcQMap System and are summarized in the table below.

There were no FSCA or FSN activities involving the AcQMap Catheters for this reporting period.

Adverse Event	Detail	Vigilance Report?
1	A Pericardial Effusion occurred on 20 August 2020, at John Radcliffe Hospital in Oxford, England. The 30-Day Medical Device Report for PC-000358 (Reference MDR 3012120746-2020-000004) was successfully submitted to the FDA on 11 September 2020.	No. A vigilance report was not required as a Pericardial Effusion is considered a labeled and known risk of the device and therefore is not reportable under MEDDEV 2.12-1 rev 8 Guidelines on medical devices vigilance system.
2	A Pericardial Effusions occurred on 22 December 2020, at John Radcliffe Hospital in Oxford, England. The 30-Day Medical Device Report for PC-000504 (Reference MDR 3012120746-2021-000001) was successfully submitted to the FDA on 19 January 2021.	
3	There was one (1) Cardiac Tamponade reported for the AcQMap Console model number 800500. The event is recorded in Product Complaint record PC-000378. The serious adverse event complaint rate is 0.08% (1 event/1324 cases). The Cardiac Tamponade occurred on 7 September 2020 at Skane Hospital in Lund, Sweden. The 30-Day Medical Device Report (Reference MDR 3012120746-2020-000005) was successfully submitted to the FDA on 2 October 2020.	No. A vigilance report was not required as a Cardiac Tamponade is considered a labeled and known risk of the device and therefore is not reportable under MEDDEV 2.12-1 rev 8 Guidelines on medical devices vigilance system.
4	A Cerebrovascular Accident (CVA or stroke) occurred on 7 March 2022 at Saint Alphonsus Regional Medical Center in Boise, Idaho, USA and was issued product complaint number PC-001083. The physician stated that she does not believe the CVA experienced by her patient is associated with the Acutus AcQMap Catheter or any other Acutus device. The Complaints department determined that there was no device failure or product malfunction, and it was determined that further vigilance reporting was not required	No. A vigilance report was not required as a cerebrovascular accident/stroke is considered a labeled and known risk of the device and therefore is not reportable under MEDDEV 2.12-1 rev 8 Guidelines on medical devices vigilance system

3. Summary of Clinical Evaluation and Post-market Clinical Follow-up (PMCF)

3.1. Summary of Clinical Data Related to Equivalent Device, if applicable

The AcQMap Catheter is not assessed and endorsed by the NB on the basis of equivalence. Therefore, this section is not applicable.

3.2. Summary of Clinical Data from Conducted Investigations of the Device Before the CE-Marking, if applicable

Clinical Study Name / Identifier	**DDRAMATIC**
Device Studied (Model)	AcQMap System (900000) and AcQMap Catheter (Model 900003)
If conducted under MDD or MDR, CIV ID or Reference if Study available in EUDAMED	Study Conducted under MDD 93/42 EEC and is not available in EUDAMED.
Reference to Clinical Trials Database or Publication where detailed data can be found	https://clinicaltrials.gov/ct2/show/NCT01872052 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6483005/ https://ichgcp.net/ru/clinical-trials-registry/NCT01872052
Countries where Clinical Study Conducted	Study conducted at two centers in Bruges, Belgium at AZ Sint-Jan and in Hamburg, Germany at the Universitätsklinikum Hamburg-Eppendorf.
Objective(s) of the Study	The primary objective of the study was to demonstrate the safety of the AcQMap High Resolution Imaging and Mapping System during Dipole Density endocardial data collection in subjects with type 1 atrial flutter (cavotricuspid isthmus-dependent).
Study Design	The study was a prospective, non-randomized, open-label study.
Duration of Follow-up	Patients were assessed for symptoms of recurrence and for potential adverse events through discharge. Further follow-up was performed at 7-10 days following the procedure.
Primary Endpoint(s)	The primary effectiveness endpoint was the collection of data adequate to construct offline pre- and post-treatment activation maps. The primary safety endpoint was the incidence of adverse device effects through 7 days post-procedure.
Secondary Endpoint(s)	N/A
Inclusion Criteria	1. Be aged 18 to 75 years

	2. Have at least one documented occurrence of typical atrial flutter (cavotricuspid isthmus dependent) as verified by surface ECG within the past 6 months 3. Be able and willing to give informed consent
Exclusion Criteria	1. Have any contraindication to a non-emergent interventional electrophysiological procedure 2. Require treatment in the left atrium and/or a require a transseptal puncture to access the left atrium during the index procedure 3. Have had a myocardial infarction within the prior two months 4. Have had cardiac surgery within the prior three months 5. Have an intracardiac thrombus 6. Have permanent pacemaker or defibrillator leads in or through the right atrium 7. Have clinically significant tricuspid valve regurgitation or stenosis 8. Have had any cerebral ischemic event (including transient ischemic attacks) in the prior six months 9. Be pregnant 10. Be currently enrolled in any other clinical investigation 11. Have any other significant uncontrolled or unstable medical condition
Number of Subjects Enrolled (per treatment arm)	12 patients
Study Population	Patients were typical of those undergoing ablation for typical atrial flutter. Nine (9) men and three (3) women participated with a mean age of 59 years. All patients had a recent history of typical atrial flutter, with two (2) having undergone a previous ablation and nine (9) having undergone cardioversion within the past year. Frequency of symptoms ranged from daily to annually with the most common symptoms reported being palpitations and shortness of breath. One (1) patient was asymptomatic but was found to have typical atrial flutter following other procedures.
Summary of Study Methods	**Data Acquisition in the Right Atrium** **Preparation and Access** Femoral venous access was typically obtained with an 18 French (Fr) introducer using standard institutional procedure on one side and with institutional standard access on the opposite side. The 12Fr steerable sheath used with the AcQMap Catheter was maintained with a heparinized saline flush throughout the procedure and anticoagulation therapy was also administered throughout the procedure to maintain an ACT of >300 seconds. In some cases, the 12Fr steerable sheath was used directly without the 18Fr introducer. **The AcQMap Catheter Placement** In accordance with the AcQMap Catheter Instructions for Use, the AcQMap Catheter was advanced into the right atrium and passively deployed. The AcQMap Catheter was oriented to be in the inferior

	portion of the right atrium, generally centered in the chamber, without contacting the endocardial surface. **Pre-Ablation Mapping** Patients came into the procedure either in sinus rhythm or in atrial tachycardia. For patients in sinus rhythm, data was acquired while they were in this rhythm with atrial flutter induction at the discretion of the Investigator. Patients were paced from a septal location (typically via a coronary sinus catheter) and from a lateral location (typically via appropriately placed electrodes from a multipolar catheter). Dipole Density data were acquired in all unique rhythms for each patient. **Treatment** Using the institutional standard practice, an ablation line across the cavotricuspid isthmus was created. The AcQMap System was not used to guide treatment. Bidirectional conduction block across the ablation line was verified using standard post-ablation pacing.
Summary of Study Results	The AcQMap System was used in all 12 patients with a total of 14 AcQMap Catheters used. Pre-ablation data were collected during sinus rhythm in eight (8) patients and during atrial flutter in six (6) patients. All patients except for one (1) underwent pre-ablation pacing maneuvers during which data were collected as well. One (1) patient presented to laboratory in atrial tachycardia. Post-ablation data were collected in sinus rhythm in eight (8) patients and during pacing in nine (9) patients. While data were successfully collected in all patients, adequate maps were only able to be made in nine (9) patients. In patients 0201, 0202, and 0204, an insufficient number of viable signals were available for analysis due to damaged conductors within the catheter. Five (5) device experience reports (DERs) were reported in four (4) cases, none of which was associated with an adverse event. One report (patient 0201) was for the introduction of air into the sheath during withdrawal of the AcQMap Catheter at the end of the procedure. This did not occur in the other cases. The fact that this did not recur in the subsequent 11 cases suggests that it is not a design-related issue. Subsequent training at sites has emphasized the need for a saline drip on the sheath to ensure that air does not enter the sheath. The second report (patient 0202) was for noise in the recorded signals. There was a brief delay to the procedure as the cause of the noise was investigated. This included use of a second AcQMap Catheter but the noise source could not be directly determined during the procedure. However, the noise was diminished during subsequent procedures by changing the location of the analog ground reference from an external surface electrode (right leg) to an internal catheter electrode positioned in the IVC. It was later determined that the main source of noise was due to the large number of "open" signals in the AcQMap Catheter. These open signals acted as an antenna that recorded high noise levels. These opens were corrected with a minor design change to the AcQMap Catheter that

added redundant and/or re-routed circuitry to avoid this failure mechanism. No cases of excessive opens have been reported since the design change.

The third event (patient 0206) involved the observation of a thin strip of material attached to the AcQMap Catheter upon final withdrawal, which was the second insertion/withdrawal cycle for that the AcQMap Catheter. The piece of material was not retained. Inspection and analysis of the AcQMap Catheter used in the procedure demonstrated that the AcQMap Catheter met all specifications and specifically it did not have any sharp or rough edges that might cause internal sheath damage. No remarkable anatomical or patient characteristics were observed or identified that may have been associated with this event. Following this analysis, the sheath was also returned to the manufacturer for analysis but no root cause for the event could be determined for the sheath. Due to the inability to determine a root cause assigned to either the catheter or the sheath, additional testing of the AcQMap Catheter/sheath interaction was performed under simulated use conditions. The same model of sheath and catheters demonstrated that at least 10 insertion/withdrawal cycles were required to cause visible damage to the sheath, with no visible damage to the catheter. This is more than double the labeled limit of 4 insertion/withdrawal cycles. No corrective action(s) determined to be required due to this event. This event met the Serious Adverse Event (SAE) reporting criteria in Germany per MPSV §2 point 5 and was therefore reported to the German competent authority (BfArM), but it did not meet the SAE reporting criteria for MEDDEV 2.7/3. This type of event did not occur in any subsequent cases.

The fourth event (patient 0103) involved the observation of a small amount of biological material on the AcQMap Catheter when the catheter was withdrawn prior to ablation. The material was sent to pathology and was later identified as neutrophil granulocytes with interspersed fibrin. Activated clotting time (ACT) values varied widely despite diligent monitoring and heparin administration by the site. The table below shows that there were unusually large changes in ACT values in very short periods of time:

Time	ACT Value	Heparin	Catheter Times
11:45	---	8000	---
12:00	247	3000	---
12:12	354	---	---
12:35	321	---	Inserted
12:50	232	3000	---
13:00	352	---	---
13:15	268	3000	---
13:40	338	---	Withdrawn
14:00	372	---	---
14:30	259	2500	---

14:54	---	---	Inserted
15:00	352	---	Withdrawn

The AcQMap Catheter was returned to Acutus Medical and was found to meet all specifications (i.e., no defects, rough edges, etc.).

As explained by the Investigators at the site, the metabolism of heparin is very complex. Heparin binds to macrophage cells and is internalized and depolymerized by the macrophages. It also rapidly binds to endothelial cells, which precludes the binding to antithrombin that results in anticoagulant action. For higher doses of heparin, endothelial cell binding will be saturated, such that clearance of heparin from the bloodstream by the kidneys and liver is another means of metabolism. This might be an explanation as to why some patients metabolize heparin faster than other patients. There is also much patient-to-patient variation between heparin dose and extent of ACT, e.g. due to elevated body mass index, sex differences, etc. ACT variation is observed in clinical practice on a daily basis. Therefore, the conclusion for this event was that the biological material was a result of low ACT values caused by the patient's unusual response to and metabolism of heparin. In the opinion of the Investigators, this was a very low risk event.

The fifth event (patient 0103) involved leaking of the hemostasis valve in the 12Fr steerable sheath. According to the Investigator, this occurred after insertion of the dilator provided with the sheath. When used with the AcQMap Catheter, the performance of the hemostasis valve was acceptable but when used with an 8Fr ablation catheter after the AcQMap Catheter was removed from the sheath, leakage was unacceptable. An 8Fr sheath was inserted into the 12Fr steerable sheath for use with the 8Fr ablation catheter and this reduced the leakage to the point where the device performance was acceptable. Performance was also acceptable when the AcQMap Catheter was reinserted into the 12Fr sheath.

Importantly, the AcQMap Catheter was closely inspected by the Investigator each time it was withdrawn during every case and at the end of each procedure. In each observation other than the one reported above, the AcQMap Catheter was found to have no biological material adhered to any part of the AcQMap Catheter.

Complications

No clinical adverse events were reported during the procedure. Five (5) adverse events were reported in four (4) patients post-procedure. Three (3) events were reported prior to patient discharge and two (2) were reported at the 7-day follow-up. One event was reported as being device-related. The table below summarizes the events reported for this study:

Event Type	*Timing*	*Event Summary*
Access Site Injury	7-day follow-up	Asymptomatic aneurysm spurium to be treated by catheter-based embolism. Not device-related.

	Prolonged Hospitalization	Prior to discharge	Presyncope following injection of Lopressor and nitroglycerin with onset of atrial fibrillation (AF) prior to an elective CT scan 3 days post-procedure. AF successfully treated with cardioversion but atrial tachycardia requiring a second cardioversion. Prolonged hospitalization classified this event as a serious adverse event per protocol definition. This event was neither procedure- nor device-related.
	Access Site Injury	Post-procedure	Minor groin bleed treated with compression. Not device-related.
	Access Site Injury	Post-procedure	Minor groin bleed treated with compression. Device-related.
	New-Onset Hypertension	7-day follow-up	Hypertension was identified and treated medically. Neither procedure- nor device-related. (*Note: Additional investigation showed the patient had high blood pressure prior to the procedure*).
Any Limitations of the Study	None.		
Any Device Deficiency and Replacements related to Safety and/or Performance during the Study	Due to the limited number of properly functioning catheter conductors, the data for three (3) patients were inadequate to create maps with full resolution. Changes to the design of the AcQMap Catheter to make the electronic circuitry more robust have since corrected the cause. Therefore, complete maps were created for the remaining nine (9) patients		

3.3. Summary of Clinical Data from Other Sources, if applicable

Articles from Literature Review

Comprehensive literature reviews have been conducted regarding current knowledge and SOTA clinical data relating to the AcQMap System and benchmark devices to identify and review technical and clinical data published in peer-reviewed journals that support the use of Acutus Medical AcQMap System. Independent literature searches were conducted on 21 May 2021 and on 25 July 2022 and included relevant peer reviewed literature published between March 2020 and June 2022. Twenty-nine (29) articles were determined to be relevant for this review period and their relevance is summarized in the table below.

Article	Conclusion	Relevance to Subject Device
Reddy 2020. Lattice-Tip Focal Ablation Catheter That Toggles Between Radiofrequency and Pulsed Field Energy to Treat Atrial Fibrillation: A First-in-Human Trial[i]	The authors concluded the following as it relates to the AcQMap High Resolution, Imaging, and Mapping System: 1) The study demonstrated the feasibility, procedural efficacy, and short-term safety of integrating high-resolution mapping into a single catheter that has the ability to toggle between high power radiofrequency or pulsed field ablation for the treatment of atrial fibrillation	The study was a first in man ablation system that used mapping technology. Performance results were related to the ablation catheter and safety results were related to the procedure. The clinical study was not designed to specifically evaluate a cardiac mapping system. However, safety events for any

			atrial ablation procedure would include adverse events inherent with manipulation of devices in the cardiac chamber. No adverse events were described other than those known to a mapping and ablation procedure.
	Reddy 2020. Pulsed Field Ablation in Patients With Persistent Atrial Fibrillation[ii]	The authors concluded the following: 1) Pulsed field ablation utilizing a "one-shot" catheter may effectively and safely treat patients diagnosed with persistent atrial fibrillation. The technique may achieve pulmonary vein isolation as well as left atrial posterior wall ablation. The lesions created showed durability. 2) The study demonstrated the potential role of PFA beyond paroxysmal to persistent forms of AF. (Pulsed Fields for Persistent Atrial Fibrillation [PersAFOne]; NCT04170621).	A mapping system was employed for follow-up assessments of patients in the study. However, the mapping system was not the device that was actually reviewed for safety and performance. The clinical study was not designed to specifically evaluate a cardiac mapping system. However, safety events for any atrial ablation procedure would include adverse events inherent with manipulation of devices in the cardiac chamber. No adverse events were described other than those known to a mapping and ablation procedure.
	Turagam 2020. Automated Noncontact Ultrasound Imaging and Ablation System for the Treatment of Atrial Fibrillation: Outcomes of the First-in-Human VALUE Trial[iii]	The authors concluded the following: In this first-in-human study, low- intensity collimated ultrasound-guided anatomic mapping and robotic ablation allowed PV isolation with good chronic safety; PV isolation improved with device enhancements. 1) The study demonstrated the feasibility of the novel Low-intensity Collimated Ultrasound System ablation system for atrial fibrillation ablation. 2) The LICU was a noncontact, semi-robotic, near-real-time anatomic rendering ablation system that had the ability to create accurate anatomic maps and to deliver consistent therapy that appeared to improve patient outcomes 3) Refinements of this technology will strive to improve safety and lesion durability.	The mapping strategy used in this study is similar to that of the AcQMap High Resolution, Imaging and Mapping System. It provided low-intensity ultrasound and non-contact mapping to reconstruct the chambers of the heart. The clinical study was designed to specifically evaluate a cardiac mapping system. Safety and effectiveness were demonstrated with respect to the utility of atrial mapping for AF ablation procedures. No new safety events were identified.
	Suehiro 2020. Circulating intermediate monocytes and toll-like receptor 4 correlate with low-voltage zones in atrial fibrillation[iv]	The authors concluded the following: The study demonstrated that a significant correlation existed between increased proportion of intermediate monocytes and the presence of low-voltages zones with the heart chamber. TLR4 expression in intermediate monocytes was higher in patients who demonstrated LVZs. The TLR4 expression level in intermediate monocytes was significantly associated with the total area of the LVZs	A mapping system was used to determine the three dimensional electroanatomy of the atria. The devices used were similar to the AcQMap High Resolution, Imaging and Mapping System. No new safety events were identified.
	Yao 2020. The value of extensive catheter linear ablation on persistent atrial fibrillation (the CLEAR-AF Study)[v]	The authors concluded the following: 1) Extensive linear ablation using contact force monitoring did not improve the long-term outcomes for persistent atrial fibrillation patients. 2) Repeat ablation procedures demonstrated a potentially higher chance of sinus rhythm restoration during follow-up.	The study used substrate characterization to identify ablation targets for persistent atrial fibrillation patients through use of a mapping system. Activation mapping and voltage mapping were carried-out to identify the mechanism of AT. The study focused on an

			ablation procedure and not on the mapping procedure. No new safety events were identified when mapping the atrial chambers.
	Hu 2021. Extra-pulmonary vein driver mapping and ablation for persistent atrial fibrillation in obese patients[vi]	The authors concluded the following: Obesity is associated with increased driver complexity measured as the average number and area of driver regions. Left atrial epicardial adipose tissue seemed to provide arrhythmic atrial substrate and to increase the probability of driver formation in obese patients. Driver ablation resulted in higher atrial fibrillation termination rate with improved long-term outcomes in obese patients diagnosed with persistent atrial fibrillation.	A mapping catheter was utilized in this study. No new safety events were identified when mapping atrial substrate.
	Vicera 2020. Identification of critical isthmus using coherent mapping in patients with scar-related atrial tachycardia[vii]	The authors concluded the following: Coherent mapping with conduction velocity vectors derived from adjacent mapping sites significantly improved the identification of critical isthmus (CI) sites, through identification of visually available display of non-conducting (SNO) zones, in scar-related ATs with isthmus-dependent re-entry as compared with conventional mapping. Catheter ablation targeting Cis was successful in eliminating scar-related atrial flutter of the left and right atria. Coherent mapping may be used in conjunction with conventional mapping strategies to facilitate recognition of slow conduction areas and critical sites that are important targets of ablation.	The article discussed mapping systems.
	Borlich 2019. Cardiac Mapping Systems: Rhythmia, Topera, EnSite Precision, and CARTO[viii]	The authors summarized the following: Modern 3-D mapping techniques and current catheter technology offer increasing accuracy and automation for electroanatomic reconstruction, annotation of intracardiac signals, and high quality lesion formation to promote an increase in ablation success and patient safety. These newer technologies reduce the need for fluoroscopy. This newer method has seen a rapid adoption into innovative strategies for care and has secured the treatment technologies as indispensable in the current cardiology practice.	The devices discussed mapping systems similar to the AcQMap High Resolution Imaging and Mapping System. Each system has unique features but all include a mapping device (catheter) for the cardiac chambers. No new safety events were discussed.
	Gabyi 2021. Novel SuperMap feature of dipole charge density mapping technique offers advantages for redo catheter ablation in highly symptomatic patients with inappropriate sinus tachycardia: A case series[ix]	This report suggests that the AcQMap system may offer advantages over traditional sequential mapping systems in the treatment of symptomatic IAST. It may be considered for redo after failure of initial procedure as well as for first line therapy. Further research is needed to demonstrate the advantages of this system	While this article was limited in that it was a case series of three patients, the article describes three successful redo IAST ablation procedures with the subject device used for cardiac mapping and accurate identification of ablation targets
	Liebregts 2022. Initial experience with AcQMap catheter for	This article highlights that the AcQMap system is able to provide fast high-	While the article describes the use of the AcQMap system in persistent AF and AFL

treatment of persistent atrial fibrillation and atypical atrial flutter[x]	resolution activation maps of persistent AF and atypical atrial flutter	procedures, the study had a small population and is not sufficiently designed to provide conclusions with regard to safety and efficacy.
Liu 2022. Atrial fibrillation mechanisms before and after pulmonary vein isolation characterized by noncontact charge density mapping[xi]	Activation patterns were identified by using AcQMap and further classified. PerAF was different from PAF in demonstrating a higher region number and higher prevalence of D-Patterns but a lower region number and lower prevalence of O-Patterns and F-Patterns. Transitional activity was predominantly observed in the PerAF segment. Further studies are needed to investigate the impact of ablation on these areas.	This article aimed to classify the AF activation patterns using features of the subject device to perhaps help design future ablation strategies. There was no additional information aside from acute AF termination results regarding the safety or clinical outcome performance of the system when used for cardiac ablation.
Pope 2022. Global Substrate Mapping and Targeted Ablation with Novel Gold-tip Catheter in De Novo Persistent AF[xii]	AcQMap is a non-contact charge density electrophysiological mapping system for the assessment of atrial arrhythmias that uses ultrasound reconstruction of atrial anatomy. This is coupled with a RF ablation delivery system based around a gold tip contact-force sensing ablation catheter. Visualization of whole chamber activation and localized patterns of complex conduction during AF allows delivery of an individualized approach to catheter ablation incorporating non-pulmonary vein mechanisms of AF propagation. A parallel algorithm for the synchronous non-contact mapping of ATs facilitates accurate and rapid high-density evaluation of complex AT mechanisms.	This article provides detailed overview of the technology of the AcQMap system and AcQBlate catheters, as well as clinical application and insights into future benefits of the technology.
Pope 2021. Spatial and temporal variability of rotational, focal, and irregular activity: Practical implications for mapping of atrial fibrillation[xiii]	Charge density mapping facilitates identification of complex patterns of wavefront propagation during atrial fibrillation. A minimum duration of 20 s is required to identify regions of repetitive but transient rotational activation whilst shorter segments will accurately reveal regions with high frequency irregular and focal activation.	While this study utilized AcQMap during mapping procedures for AF, the study was not to determine ablation strategy or effectiveness. Instead, the study aimed to evaluate duration of mapping required to identify different types of activation, to perhaps help design future ablation strategies.
Pope 2022. Impact of Adenosine on Wavefront Propagation in Persistent Atrial Fibrillation: Insights From Global Noncontact Charge Density Mapping of the Left Atrium[xiv]	The results of this study suggest that rotational activation, in contrast with focal firing, and much less so LIA, is influenced by adenosine. The degree of rotational activation may serve as a surrogate measure of individual atrial functional properties, with little evidence that rotational activation seen with adenosine represents promising targets for ablation aimed at arrhythmogenic sources of AF perpetuation within the left atrium. Caution should be exercised when interpreting maps obtained after adenosine administration to guide nonpulmonary vein ablation.	This study utilized features of the subject device to analyze the effect of adenosine on propagation and how this may potentially guide ablation targets. No additional information was provided regarding the safety of the device, however it performed as expected to obtain the results of this study.
Ramak 2021. Novel noncontact charge density map in the setting of post-atrial fibrillation atrial tachycardias: first experience with the	This experience led to successful identification and ablation of the arrhythmic substrate in the setting of regular atrial tachycardias following index AF ablation.	This study describes a feature of the subject device that appears to be useful for the ablation of atrial tachycardias.

Acutus SuperMap Algorithm[xv]		
Hang 2021. Study on the Curative Effect and Safety of Radiofrequency Catheter Ablation of Paroxysmal Atrial Fibrillation via Zero-Fluoroscopy Transseptal Puncture under the Dual Guidance of Electroanatomical Mapping and Intracardiac Echocardiography[xvi]	This study suggests that it is safe and effective to perform the EAM-ICE procedure for catheter ablation of atrial fibrillation.	The electroanatomical mapping system used in this study (CARTO) is similar to the subject device. The study reported no procedural complications in any of the 110 subjects, indicating the relative safety of the device when used to navigate and perform a TS puncture.
Tahin 2021. Implementation of a zero fluoroscopic workflow using a simplified intracardiac echocardiography guided method for catheter ablation of atrial fibrillation, including repeat procedures[xvii]	These results suggest a ZF workflow of AF ablation can be successfully implemented into the routine practice of an electrophysiology laboratory, without compromising safety and effectivity.	While this study may be useful to those who perform ablation procedures and are interested in strategies to reduce fluoroscopy exposure, this was not relevant to the subject device as it did not describe or provide any additional information regarding the electroanatomical mapping portion of the ablation procedure.
Chierchia 2021. Substrate mapping of the left atrium in persistent atrial fibrillation: spatial correlation of localized complex conduction patterns in global charge-density maps to low-voltage areas in 3D contact bipolar voltage maps[xviii]	Due to wave front direction dependency, LVAs mapped with BVM in SR and during CS pacing only partially overlap in patients with PsAF. LCC-cores mapped during PsAF partially co-localize with LVAs.	This study compared the mapping of CARTO with AcQMap as the subject device. Data presented is in regards to developing future mapping and ablation strategies using the features of the subject device.
Pope 2022. Clinical utility of non-contact charge density 'SuperMap' algorithm for the mapping and ablation of organized atrial arrhythmias[xix]	This study demonstrated that SuperMap non-contact charge density mapping is a rapid and reliable approach to guide the ablation of complex ATs.	This study aimed to compare features of the subject device to another electroanatomic mapping system for mapping atrial tachycardias. Results were positive in that the subject device reliably showed similar findings.
Hsu 2022. Performance and acute procedural outcomes of the EnSite Precision™ cardiac mapping system for electrophysiology mapping and ablation procedures: results from the EnSite Precision™ observational study[xx]	This study demonstrates that the use of the Ensite system results in high procedural stability, short mapping times, high point density with the use of Auto/Turbo map requiring infrequent editing, low fluoroscopy time, and high prevalence of acute procedural success.	The Ensite system is similar to the subject device. The success in this study may support similar outcomes in the use of the subject device.
Hwang 2021. Ablation of persistent atrial fibrillation based on high density voltage mapping and complex fractionated atrial electrograms: a randomized controlled trial[xxi]	Persistent AF ablation targeting CFAE areas only within the low voltage zones in addition to the PVI using a high-density mapping technology with a multielectrode catheter and the CARTO standardized CFAE mapping system had a higher AF free survival as compared to a PVI only.	This study evaluates the benefit to adding ablation of CFAEs to PVI procedures than simply PVI alone when using a similar device to the subject device. This is relevant to the subject device in that it may be used in a similar fashion in mapping and ablation of CFAEs for possibly better patient outcomes.

Masuda 2022. Low-Voltage-Area Ablation in Paroxysmal Atrial Fibrillation - Extended Follow-up Results of the VOLCANO Trial[xxii]	This article concludes that patients with LVAs demonstrated poor long-term rhythm outcomes irrespective of LVA ablation. ATs were frequently observed in patients with LVAs, and LVA ablation might exacerbate the incidence of iatrogenic AT.	Similar devices to the subject device were used in the mapping and ablation procedures (Rhythmia, CARTO). These results may translate to the use of the subject device in similar approaches.
Bergonti 2021. Long-Term Outcomes of Near-Zero Radiation Ablation of Paroxysmal Supraventricular Tachycardia: A Comparison With Fluoroscopy-Guided Approach[xxiii]	This study reinforces the concept that a minimally fluoroscopic approach is feasible and safe for ablation of supraventricular arrhythmias (AVNRT and AVRT), allowing a reduction of ionizing radiation exposure, with similar acute results to the conventional fluoroscopy-guided technique. The use of electroanatomic mapping systems also allows reduction of recurrences of arrhythmias and long-term complications.	Similar devices (NavX and CARTO) to the subject device were used in the MFA arm of the study. The outcomes of this study may translate similarly to the use of the subject device in a similar approach.
Gagyi 2021. New Possibilities in the Treatment of Brief Episodes of Highly Symptomatic Atrial Tachycardia: The Usefulness of Single-Position Single-Beat Charge Density Mapping[xxiv]	This study found that brief episodes of highly symptomatic AT can be mapped using single-position single-beat charge density mapping (AcQMap) and ablated successfully with high acute and long-term success rate. In addition, AT can be eliminated in a shorter period of time when patients are scheduled directly for AcQMap-guided procedures.	This study was performed using the subject device for a previously-unstudied group of patients with short-lasting arrhythmias. While the study population is small, the results appear to provide positive benefits.
Miyazaki 2022. Mapping and ablation of left atrial roof-dependent tachycardias using an ultra-high resolution mapping system[xxv]	The ultra-high resolution mapping system is useful to identify the critical isthmus of the tachycardia and to eliminate LA roof-dependent ATs. The "Lumipoint" module shows an area of potential interest in the ATs. The arrhythmia mechanisms are distinct in the individual patients, and elimination of all concomitant ATs is required for a better clinical outcome.	The device used in this study is similar to the subject device. The methods used in this study may be used in a comparable manner with the subject device in a similar subject population.
Vlachos 2021. Use of high-density activation and voltage mapping in combination with entrainment to delineate gap-related atrial tachycardias post atrial fibrillation ablation[xxvi]	This study concludes that high-resolution activation mapping combined with high-density voltage and entrainment mapping is the ideal strategy for ablation delineating the critical part of the circuit in endocardial gap-related reentrant AT after AF ablation. Using multipolar catheters with small inter-electrode spacing improves the accuracy in delineating ULVA critical for the re-entry circuit.	This study included three similar devices to the subject device (Rhytmia, CARTO, Ensite) and showed the benefit to using high density mapping when targeting ATs. The subject device may be used in similar fashion with comparable results.
Cuellar-Silva 2022. Rhythmia zero-fluoroscopy workflow with high-power, short-duration ablation: retrospective analysis of procedural data[xxvii]	This workflow combining ICE and EAM using the RHYTHMIA mapping system enables the use of zero fluoroscopy for AF ablation. This approach for AF ablation can eliminate the radiation exposure to patients and medical staff and reduce the physical burden associated with wearing protective lead aprons. Further study is needed to evaluate the long-term clinical outcomes.	This article describes a feature of a similar device for procedure-related reduction of radiation exposure. The subject device may also be used in a similar workflow to reduce fluoroscopy time for operator and patient.
Gunawardene 2022. Pulsed-field ablation combined with ultrahigh-density mapping in patients undergoing catheter ablation for atrial fibrillation:	This study concludes that, as illustrated by UHDx mapping, PFA creates wide antral circumferential PVI lesions and homogenous LAPW isolation with depression of tissue voltage to a minimum. PFA, therefore, seems to be a promising new technology for catheter	This was the first report of PFA-catheter visualization into UHDx electroanatomic mapping system with a similar device in a patient series. This may relate to the subject device, but more information is needed regarding

	Practical and electrophysiological considerations[xxviii]	ablation of atrial fibrillation. However, early PV reconnection can still occur with a low rate after PFA.	the features of the subject device and it's potential usage in PFA procedures.
	Mori 2021. Ultrahigh density atrio-ventricular dual-chamber mapping as a next generation tool for ablation of accessory pathways[xxix]	The dual-chamber mapping was useful for achieving an effective ablation while reducing radiation exposure. Mapping the atrium and ventricle all at once was useful for understanding the detailed connections of APs.	The dual-mapping feature of the similar device has shown to be useful in this study. Similar features of the subject device, especially those that may reduce fluoroscopy exposure and decrease procedure times may be comparable to the results of this study.

Clinical Data obtained from PMCF and PMS Plans

Completed Post-Market Clinical Studies:

UNCOVER AF: As the first post-market clinical study, Acutus Medical conducted the Utilizing Novel charge density Capabilities to Objectively Visualize the Etiology of Rhythms in Atrial Fibrillation ("UNCOVER-AF") pre- and post-market study. The study was initiated as a multi-center post-market study in Europe which enrolled a total of one hundred and twenty-five (125) subjects and completed follow-up in 2018. An additional small pre-market study in Canada enrolled four (4) additional subjects. The UNCOVER-AF study was conducted in compliance with ISO 14155:2011, Good Clinical Practice, and followed all national and local regulatory requirements for the applicable geographies. The results of this study were peer reviewed and accepted for publication by the journal editors at Circulation: Arrhythmia and Electrophysiology.

UNCOVER AF was a prospective, non-randomized, trial conducted at 13 centers across Europe and Canada. Patients with persistent atrial fibrillation (PersAF), classified as greater than 7 days and less than one year duration, aged 18-80 years, and scheduled for de novo catheter ablation were eligible to participate. Prior to pulmonary vein (PV) isolation, AF was mapped and then iteratively re-mapped to guide each subsequent ablation of charge density (CD)-identified targets. AF recurrence was evaluated at 3, 6, 9 and 12-months using continuous 24-hr ECG monitors.

The primary effectiveness outcome was freedom from AF greater than 30 seconds duration at 12 months for a single procedure. The secondary outcome was acute procedural efficacy. The primary safety outcome was freedom from device/procedure related major adverse events.

Between October 2016 and April 2017 129 patients were enrolled and 127 underwent mapping and catheter ablation. Acute procedural efficacy was demonstrated in 125 patients (98%). At 12-months, single procedure freedom from AF on or off anti-arrhythmic drugs was 72.5% (95% CI 63.9%-80.3%). Following one or two procedures, freedom from AF was 93.2% (95% CI 87.1%-97.0%). A total of 29 (23%) retreatments due to arrhythmia recurrence were performed with the average time from index procedure to first retreatment being seven months. The primary safety outcome was 98% with no device-related major adverse events reported.

Conclusions: The authors concluded that this novel ultrasound imaging and CD mapping system safely guided ablation of non-PV targets in PersAF patients with 73% single procedure and 93% second procedure freedom-from-AF at 12 months.

RECOVER AF: Acutus Medical completed a prospective, nonrandomized study at 14 sites across Europe, the UK and Canada between April 2018 and August 2019. Patients aged 18 to 80 years, scheduled for a first or second ablation retreatment for recurrent atrial fibrillation (AF) were eligible. Pulmonary veins (PV) were assessed for reconnection and re-isolated as needed. Single position, charge density maps of spontaneous or induced AF were created and used to guide non-PV ablation. Patients

were monitored with a 24-hour continuous atrial monitor at 3, 6 and 12-months following the initial AcQMap guided retreatment procedure.

One hundred twenty-eight (128) patients were enrolled, and 106 underwent catheter ablation. Seventy-nine (79) patients were returning for a first retreatment and 27 patients for a second retreatment. Non-PV targets were predominantly classified as localized irregular activation (75%) and were equally distributed across the anterior (51%) and posterior (49%) surfaces. Freedom from AF at 12-months on or off anti-arrhythmic drugs following a single AcQMap guided retreatment procedure was 71%. Freedom from AF was also calculated for first and second retreatment (75% and 60%), isolated veins and reconnected veins (60% and 75%) and No non-PV targets and PV-targets (76% and 70%). No major adverse events were reported.

Conclusions: The study concluded the AcQMap System can be used to safely guide ablation of non-PV targets in Persistent AF patients returning for a first or second retreatment demonstrating 71% freedom from AF at 12 months. Freedom from AF outcomes remained consistent irrespective of PV status, number of failed prior ablations and the presence or not of non-PV targets.

Physician Initiated Trials:

The AcQMap System is being used in a single-center, 35-subject study sponsored by Oxford University Hospitals NHS Trust. This study is not evaluating clinical outcomes of a procedure, but to correlate electrical signals obtained with propagation patterns identified using the AcQMap System and atrial properties identified on cardiac MRI. This study is currently ongoing and no data has been published. Further details can be found at www.clinicaltrials.gov with the NCT Number NCT04229472.

Current Post-Market Studies/Registries:

Acutus Medical currently is conducting data collection on two Registries for the AcQMap System. Enrollment is eligible to subjects who are completing an AcQMap arrhythmia mapping procedure where the System is used in a non-contact mode. This will include up to 500 subjects in the UK and EU (AcQMap Registry) and a mirrored study in the US (Discover US). Safety data is compiled through the Acutus Medical post market safety reporting process. Study outcome measures are related to performance of the AcQMap System and are being collected during 6-month, 12-month and 24-month follow-up visits. Safety data are collected within the current Acutus complaint reporting process.

AcQMap EU Registry: As of 30 June 2022, 332 European subjects have been enrolled and data collection is ongoing. The following is a brief summary of data collected on 201 patients at 10 sites. Of the 201 subjects enrolled, a total of 194 procedures have been completed.

Patient Demographics:

Characteristics	Results N (%) or M ± SD (range)
Age (years)	60.9 ± 11.8 (range: 18 – 86)
Gender (male)	138 (68.7%)
Left Atrial Diameter (mm)	40.3 ± 14.1 (range: 4 – 72)
Left Ventricular Ejection Fraction (LVEF)	54.4% ± 10.3% (range: 19% – 73%)
AF Arrhythmia History	

Time from First Diagnosis for AF (years)	3.99 ± 4.02 (range: 0 – 22.90)
Medical History	
Hypertension	77 (38.3%)
Coronary Artery Disease (CAD)	30 (14.9%)
Diabetes	17 (8.5%)
Prior Stroke/TIA	15 (7.5%)
Congestive Heart Failure	11 (5.5%)
CHADS-VASC Score	1.5 ± 1.3 (range: 0 – 7)

Preliminary outcome data were obtained for the first 100 subjects from the 194 cohort. The primary arrhythmia being treated that was reported at screening/baseline for these first 100 subjects are depicted in the following table.

Primary Arrhythmia Being Treated:

Characteristics	Results (N = 100)
Paroxysmal Atrial Fibrillation (PAF)	23%
Persistent Atrial Fibrillation (PersAF)	46%
Atrial Flutter (AFL)	7%
Long Standing Persistent Atrial Fibrillation (LSP)	6%
Atrial Tachycardia (AT)	16%
Other	2%

The average mapping times, ablation times and procedure times are captured in the following table.

Average Times by Treated Arrhytmia:

Time	AFL (N=7) M(SD)	LSP (N=6) M(SD)	PAF (N=23) M(SD)	PersAF (N=46) M(SD)	Overall (N=100) M(SD)
Average Mapping Time (minutes)	3.84 (1.93)	2.08 (1.68)	2.61 (1.22)	3.15 (1.10)	2.82 (1.38)
Average Ablation Time (minutes)	30.9 (21.5)	23.0 (17.4)	26.8 (14.3)	42.0 (62.9)	31.7 (45.2)
Average Procedure Time (hh:mm)	3:14 (1:26)	3:39 (0:35)	3:19 (0:51)	3:21 (0:42)	3:12 (0:51)

Of the first 100 subjects, 6-month and 12-month visits were completed by 98 and 74 subjects, respectively. Continuous ECG monitors as a secondary measure of outcomes were worn by subjects and subsequently analyzed, generating 87 six-month and 63 twelve-month reports. Predominant rhythms are reported in the following table.

Predominant Rhythm Reported at 6- and 12-months:

Predominant Rhythm	6-month N (%)	12-month N (%)
Sinus Rhythm (SR)	72 (73.5%)	56 (88.9%)
Atrial Fibrillation (AF)	7 (7.1%)	4 (6.3%)
Atrial Tachycardia (AT)	3 (3.1%)	0 (0%)
Atrial Flutter (AFL)	2 (2.0%)	1 (1.6%)
Other	3 (3.1%)	2 (3.2%)

Data collection activities are on-going.

Discover US Registry: As of 30 June 2022, 335 US subjects have been enrolled in the clinical registries and data collection is ongoing. The following is a brief summary of data collected on 103 patients at 19 sites.

Patient Demographics:

Characteristics	Results N (%) or M ± SD (range)
Age (years)	68.3 ± 9.4 (range: 25 – 84)
Gender (male)	66 (64.7%)
Left Atrial Diameter (mm)	44.1 ± 9.2 (range: 27.8 – 61)
Left Ventricular Ejection Fraction (LVEF)	56.2% ± 10.3% (range: 27.8 – 61)
AF Arrhythmia History	
Time from First Diagnosis for AF (years)	4.61 ± 6.09 (range: 0.01 – 34.23)
Number of Previous Ablations	1.5 ± 0.7 (range: 1 – 4)
Primary Arrhythmia Being Treated	
AFL	9 (8.82%)
AT	1 (0.98%)
AF	91 (89.22%)
Not Specified	1 (0.98%)
Medical History	
Hypertension	73 (71.6%)
Coronary Artery Disease (CAD)	28 (27.5%)
Diabetes	22 (21.6%)
Prior Stroke/TIA	11 (10.8%)
Congestive Heart Failure	21 (20.6%)
CHADS-VASC Score	2.8 ± 1.7 (range: 0 – 8)

Preliminary outcome data were obtained for the first 100 subjects. The primary arrhythmia being treated that was reported at screening/baseline for these first 100 subjects are depicted in the following table. There were 58% *de novo* ablation procedures and 28% retreatment ablation procedures where the AcQMap System was utilized.

Primary Arrhythmia Being Treated:

Characteristics	Results (N = 100)
Paroxysmal Atrial Fibrillation (PAF)	54%
Persistent Atrial Fibrillation (PersAF)	32%
Atrial Flutter (AFL)	9%
Long Standing Persistent Atrial Fibrillation (LSP)	4%
Atrial Tachycardia (AT)	1%

The average mapping times, ablation times and procedure times are captured in the following table.

Average Times by Treated Arrhythmia:

Time	AFL (N=9) M(SD)	LSP (N=4) M(SD)	PAF (N=54) M(SD)	PersAF (N=32) M(SD)	Overall (N=100) M(SD)
Average Mapping Time (minutes)	3.13 (2.29)	4.55 (7.90)	1.47 (1.95)	1.79 (1.55)	1.85 (1.81)

	Average Ablation Time (minutes): 27.13 (19.16); 42.40 (33.56); 36.08 (20.37); 32.50 (28.80); 34.00 (18.96) **Average Procedure Time (hh:mm)**: 2:54 (1:21); 2:10 (0:29); 3:03 (0:53); 2:57 (0:57); 3:04 (0:57) Of the first 100 subjects, 6-month visits were completed by 47 subjects. Of these, 38 continuous ECG monitors were worn by subjects and subsequently analyzed. Predominant rhythms at 6-months post-treatment are reported in the following table. Predominant Rhythm Reported at 6-months (Numbers do not add up to 100% as only dominant rhythms are reported): **Predominant Rhythm** / **6-month (%)** **Sinus Rhythm (SR)**: 81.6% **Atrial Fibrillation (AF)**: 1% **Atrial Tachycardia (AT)**: 1% **Atrial Flutter (AFL)**: 0% Data collection activities are on-going. **PMCF Conclusions:** The PMCF report analyzed the clinical data generated with the use of the AcQMap High Resolution Imaging and Mapping System. The data evaluation confirms the device is safe when used as intended. Complaint reporting has not identified any risks not previously discussed and mitigated in the device risk analysis. The current risk mitigations through device design, labeling and training on proper use appear adequate. No new contraindications have been identified. The performance of the device as evident in the European (AcQMap Registry) and US (Discover US) Registries supports the use of the device in ablation procedures where atrial substrate mapping is essential to arrhythmia management outcomes. Management of atrial arrhythmias when mapped with the AcQMap High Resolution Imaging and Mapping System may provide improved outcomes as evident in registry data and physician-initiated studies.
Clinical Data from Medical Device Registries	Acutus Medical currently is conducting data collection on two Post-Market Registries for the AcQMap System. Enrollment is eligible to subjects who are completing an AcQMap arrhythmia mapping procedure where the System is used in a non-contact mode. This will include up to 500 subjects in the UK and EU and a mirrored study in the US. Refer to the "Current Post-Market Studies/Registries" section in the row above.

3.4. Overall Summary of the Clinical Performance and Safety

As with similar 3D mapping systems, the Acutus Medical AcQMap Catheter is anticipated to have the potential benefits of providing data when mapping cardiac arrhythmias that can lead to more efficient and procedures with potentially better outcomes. This includes but is not limited to potentially any of the following:

- More precise identification of the cause of the patient's arrhythmia
- More precise identification of gaps in ablation lines

- Shorter procedure times
- Reduction in the patient's and operator's exposure to fluoroscopy (x-rays)
- Reduction in the number of ablation lesions required to treat the patient's arrhythmia
- Higher procedural success rates
- Lower complication rates (due to less overall catheter manipulation time)

Once the mapping portion of the arrhythmia is completed, the greatest risk is related to the therapeutic delivery of an energy modality to alter the endocardial substrate and eliminate the electrical pathway causing the arrhythmia. The Benefit/Risk profile for the AcQMap High Resolution, Imaging and Mapping System and AcQMap 3D Imaging and Mapping Catheter remains consistent with Acutus Medical, Inc.'s established Risk Management documentation and offer an acceptable Benefit-to-Risk ratio for the intended purpose of use in the collection of cardiac electrophysiological data and the creation of 3D representation of the endocardial surface.

All product literature, including the AcQMap High Resolution, Imaging and Mapping System and AcQMap 3D Imaging and Mapping Catheter's Instruction for Use documentation, is consistent and adequate with regard to current clinical data/knowledge, and appropriately covers all the hazards and other clinically relevant information that may have an impact on the use of the device.

3.5. Ongoing or Planned PMCF

There are several activities, either in process or are being developed, to continue to confirm the safety and performance of the AcQMap 3D Imaging and Mapping Catheter when used with the AcQMap Mapping System. The following table provides a summary of these activities, including specific methods/procedures to conduct, the aim of each activity described and the rationale for the appropriateness of the chosen specific methods, as well as the known limitations and timing of the planned activities.

Table 3.5-1: Summary of Specific Methods & Procedures to be Applied

Activity	Aim	Rationale & Known Limitations	Timeline
Post-Market Clinical Trials & Registries	Multiple ongoing global clinical trials/registries to evaluate the safety and effectiveness of the AcQMap System and Catheter. Data will be analyzed for safety and efficacy when patients have completed study follow-up visits.	With the increased use of the AcQMap System in the diagnostic evaluation of complex atrial arrhythmias, Acutus has continued to develop workflow algorithm that enhance the utility of the device. To date, these have been single-arm studies with a literature-based control for the comparator. No hypothesis is established therefore no statistical powering has been applied to derive a sample size.	Yearly
US FDA IDE Clinical Trials	A US/EU FDA IDE trial is proposed to evaluate an irrigated, contact force sensing RF ablation catheter when used to treat atrial	These studies are pre-market investigational device exemption studies (IDE) that follow the approval process by FDA. Clinical trial designs have been established and approved	Yearly

Activity	Aim	Rationale & Known Limitations	Timeline
	arrhythmias. The use of the AcQMap System and Catheter will be incorporated into an AF study. Safety and performance data collection for the approved devices will be included in the final data analysis. The clinical study will follow US IDE regulations and be in compliance with GCP and 21 CFR for safety reporting. Safety data will be independently adjudicated during the trial.	by FDA. Sample size determinations are based on a provided hypothesis and statistical powering. The study incorporating the use of the AcQMap has not been finalized but is anticipated to be approximately 350 subjects enrolled with a 12-month follow-up. The study will include a 3-member Data Safety Monitoring Board to adjudicate all safety events.	
Physician Initiated Trials	Physicians are encouraged to independently evaluate the real-world performance of the AcQMap System and Catheter.	Analysis and trending will be completed via screening of scientific literature and study data collection and reported through the Acutus complaint reporting process.	Yearly

4. Possible Diagnostic or Therapeutic Alternatives

Alternatives to using a non-contact cardiac catheter for cardiac mapping is using a contact catheter to gather data to a conventional electrophysiology system. A contact mapping catheter is intended to gather data by touching the heart wall. There are many different cardiac catheters with tip electrodes that can be used. These contact mapping catheter mapping techniques do require additional time to map the heart anatomy and gather data about the arrhythmia. The major limitation of a contact mapping catheter for electroanatomic mapping is that tachycardia must remain stable for the duration of data acquisition. Additionally, precise mapping of complex arrhythmias is challenging or even impossible by contact mapping. There may be a risk benefit to employing a non-contact catheter that is not intended to contact the heart wall.

The AcQMap System, including the AcQMap Catheter, is similar to other commercially available systems. It incorporates elements of an ultrasound system, a contact mapping catheter system, and a noncontact mapping system into one system but these combined functional elements are similar to the same elements found in commercially available devices. Comparison charts of the AcQMap Catheter and the AcQMap System to these devices are presented in the following tablebelow. The risk benefit is expected to be equal among non-contact catheters..

Device Name	*Acutus Medical AcQMap Catheter*	*Boston Scientific Constellation Catheter*	*St. Jude Medical EnSite Multi-Electrode Array*	*Siemens Acuson AcuNav Diagnostic Ultrasound Catheter*
Intended Use	Mapping of right and/or left atrial electrical impulses	For use in right atrial electrophysiology procedures to assist in the diagnosis of complex arrhythmias…may also be used for delivery of externally generated pacing stimuli	To record and map electrical potentials from the right atrium	For use directly within the vasculature and/or right heart for intravascular or intracardiac ultrasound imaging
Key Components	Expandable "basket" with 6 flexible splines each containing 8 ultrasound transducers and 8 embedded electrodes (48 total transducers and 48 total electrodes).	Expandable "basket" with 8 flexible splines each containing 4-8 platinum-iridium electrodes (32-64 total electrodes). A handle allows deployment and retraction of the basket	Expandable mesh "basket" with 64 total electrodes embedded within the wire mesh. A balloon is inflated within the mesh. A handle allows deployment and retraction of the basket as well as connection to an inflation device	Ultrasonic phased-array transducer. Handle allows steering of catheter
Method of Use	Percutaneous access and venous delivery to the right and/or left atrium. Handle is used to steer to specific anatomical areas. Ultrasound transducers send and receive ultrasound information for processing by the System. Electrodes emit and collect electrical voltage data for processing by the System.	Percutaneous access and venous delivery to right atrium. Handle is used to deploy basket. Electrodes collect electrical voltage data for processing by either a commercially available electrogram recording system or pacing generator.	Percutaneous access and venous delivery to right atrium. Handle is used to deploy basket and provide port for balloon inflation. Electrodes emit and collect electrical voltage data for processing by the EnSite System.	Percutaneous access and venous delivery to right atrium. Handle is used to steer catheter to various locations within the heart to obtain different views of cardiac structures.

5. Suggested Profile and Training for Users

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

6. Reference to Any Harmonized Standards and Common Specifications (CS) Applied

Currently there are no Common Specifications applicable for the AcQMap System devices. The following Table lists the relevant harmonized standards that apply to the AcQMap Catheter.

Standard / Revision	Document Title	Applied in Full?
EN ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	Yes
BS EN ISO 11135: 2014 + A1:2019	Sterilization of health care products-Ethylene oxide. Requirements for the development validation and routine control of a sterilization process for medical devices	Yes
BS EN ISO 17665-1: 2006	Sterilization of Health Care Products-Moist heat. Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	Yes
European Pharmacopoeia 9.3 (Section 2.6.14)	Bacterial Endotoxin Testing	Yes
IEC 60601-1: 2005 /A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Yes
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance	Yes
IEC 60601-2-37: 2015	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	Yes
IEC 62366-1: 2015	Medical devices – Application of usability engineering to medical devices	Yes
ISO 10555-1: 2013 + A1: 2017	Intravascular Catheters – Sterile and single-use Catheters – Part 1: General requirements	Yes
ISO 14971: 2019	Medical devices – Application of risk management to medical devices	Yes
ISO 15223-1: 2021	Medical Devices – Symbols to Be Used with Medical Device Labels, Labelling, and Information to Be Supplied – Part 1: General Requirements	Yes

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